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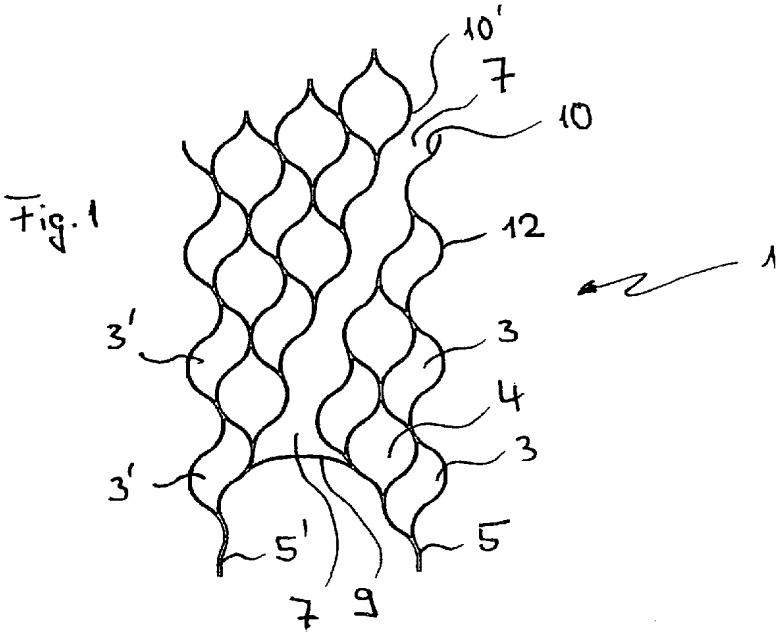


Fig. 1

(57) Abstract: The invention relates to a thrombectomy device having a substantially cylindrical stent structure (1). The stent structure comprises a plurality of meshes (3, 4) and also two connectors (5, 5') that are disposed at different meshes (3) at the proximal end of the stent structure (1). The device also has a guide wire (2), which comprises a coupling element (11) to which the connectors (5, 5') are coupled, and a slit (7), which extends helically over the lateral face (8) of the stent structure (1), and a tensioning clip (9) that spans the slit (7) at the proximal end.

(57) Zusammenfassung: Die Erfindung betrifft eine Thrombektomievorrichtung mit einer im Wesentlichen zylindrischen Stentstruktur (1), die eine Vielzahl von Maschen (3, 4) aufweist sowie zwei Verbinder (5, 5'), die an verschiedenen Maschen (3) am proximalen Ende der Stentstruktur (1) angeordnet sind und einem Führungsdraht (2), der ein Kopplungselement (11) aufweist, an das die Verbinder (5, 5') angekoppelt sind sowie einem Schlitz (7), der sich wendelförmig über die Mantelfläche (8) der Stentstruktur (1) erstreckt und einem Spannbügel (9) der am proximalen Ende den Schlitz (7) überspannt.

WO 2012/065748 A1

Thrombektomievorrichtung

Die Erfindung betrifft eine Thrombektomievorrichtung mit einer im Wesentlichen zylindrischen Stentstruktur, die eine Vielzahl von Maschen aufweist sowie zwei Verbinder, die an verschiedenen Maschen am proximalen Ende der Stentstruktur angeordnet sind und einem Führungsdraht, der ein Kopplungselement aufweist, an das die Verbinder angekoppelt sind. Die Thrombektomievorrichtung ist insbesondere dafür bestimmt, Thromben im zerebralen Bereich, wie sie häufig bei Schlaganfällen zu finden sind, für den Patienten schonend und zuverlässig zu entfernen.

Thromboembolische Erkrankungen wie Herzinfarkt, Lungenembolie, periphere Thrombose, Organembolien, etc. werden typischerweise durch einen Thromboembolus (im Folgenden kurz: Thrombus), also einem viskoelastischen Blutklumpen aus Blutplättchen, Fibrinogen, Gerinnungsfaktoren etc., ausgelöst, der sich in einem Blutgefäß festgesetzt hat und diese ganz oder teilweise verschließt. Der Verschluss von Organarterien führt dabei zu einer Unterbrechung der Versorgung des abhängigen Gewebes mit Sauerstoff und Nährstoffen. Der Störung des Funktionsstoffswechsels mit Funktionsverlust folgt innerhalb kurzer Zeit das Erliegen des Strukturstoffwechsels mit dem Untergang des betroffenen Gewebes (Infarkt). Die häufigsten hiervon beim Menschen betroffenen Organe sind das Herz und das Gehirn. Solche Veränderungen betreffen aber auch die Extremitätenarterien und die Lungenarterien. Venöse Thrombosen und thromboembolische Verschlüsse kommen auch gehäuft in den Bein- und Beckenvenen vor. Das Krankheitsbild eines thrombotischen Verschlusses eines intrakraniellen Sinus kann durch die Störung der venösen Drainage des Hirngewebes zu schweren Hirnblutungen führen.

Angesichts der Schwere der durch Thromboembolien ausgelösten Krankheitsbilder und der Häufigkeit dieser Erkrankungen sind verschiedene Techniken zur Auflösung oder Entfernung von Thromben bekannt.

So ist es bekannt, solche Patienten mit thrombolytischen Mitteln wie Streptokinase oder Urukinase oder mit Antikoagulantien zu behandeln, was der Thrombolyse oder der Eindämmung des Thrombenwachstums dient. Da diese Behandlungsmethoden meist zeitintensiv sind, werden sie oftmals mit Methoden kombiniert, die der medizinischen Zerkleinerung oder Entfernung des Thrombus bzw. Embolus dienen.

Neben offenen chirurgischen Eingriffen kommen im Stand der Technik zunehmend transluminale bzw. endovaskuläre Katheter-geführte interventionelle Therapieformen zum Einsatz, da diese weniger invasiv sind. So ist es bekannt, den Thrombus mittels Unterdruck erzeugenden Saugkathetern oder mechanisch mit Kathetern, welche mit Fangkörben, Wendeln, Haken oder dergleichen versehen sind, aus dem Körper des Patienten zu entfernen, siehe US 6,245,089 B1; US 5,171,233 A1, Thomas E. Meier et al., Stroke 2002 (9) 2232.

Der Nachteil thrombolytischer Behandlungsmethoden liegt darin, das sie nach Ablauf des Zeitfensters nur noch selten Erfolg haben. Auch die bekannten transluminalen Vorrichtungen können einen Thrombus häufig nicht vollständig entfernen, wobei auch die Gefahr besteht, dass der Thrombus oder Fragmente davon freikommen und im Blutstrom zu kleinlumigeren Gefäßen verfrachtet werden, wo sie schwerer zu erreichen und zu behandeln sind. Des Weiteren eignen sich die im Stand der Technik bekannten Vorrichtungen aufgrund ihrer Dimensionen und/oder geringen Flexibilitäten nur ungenügend zur Entfernung von Thromben aus besonders kleinlumigen oder stark gewundenen Gefäßen, wie denen des Gehirns.

Aus der WO 2004/008991 A1 ist ein medizinisches Implantat in Form eines offenen Stents bekannt, das zur Behandlung von Aneurysmen und anderen vaskulären Fehlbildungen bestimmt ist. Dieses Implantat wird mit Hilfe eines Führungsdrahts zum Einsatzort geführt und dort abgelöst. Es wurde vorgeschlagen, diese Kombination aus Implantat und Führungsdraht zur

Extraktion von Thromben einzusetzen, wobei naturgemäß die Ablösung des Implantatteils vom Führungsdraht unterbleibt. Nachteil dieser Konstruktion aus Implantat und Führungsdraht ist allerdings eine relativ geringe Spann- oder Federkraft. Das Konstrukt entfaltet eine nicht immer ausreichende Scherwirkung auf den in der Gefäßwandung sitzenden Thrombus, so dass Reste im Gefäß verbleiben. Die Anbindung an den Führungsdraht über eine sich verjüngende Struktur (Träne) führt insbesondere zu einer Verschlankung des proximalen Bereichs der Struktur unter Zug, die der Effizienz des Konstrukts entgegensteht.

Angesichts der mit dem Stand der Technik verbundenen Nachteile besteht die Aufgabe der Erfindung in der Bereitstellung einer Vorrichtung zur Entfernung von Fremdkörpern und Thromben aus Blutgefäßen, welche insbesondere die Entfernung von Thromben aus kleinlumigen Gefäßen erlaubt und dabei über eine gute Manövrierfähigkeit in stark gewundenen Gefäßen aufweist und über eine große Wirkfläche verfügt.

Diese Aufgabe wird erfindungsgemäß mit einer Vorrichtung der eingangs genannten Art gelöst, die über einen sich wendelförmig über die Mantelfläche der Stentstruktur erstreckenden Schlitz verfügt, für welchen am proximalen Ende der Stentstruktur von einem Spannbügel überspannt ist.

Die erfindungsgemäße Vorrichtung besteht aus einer zylinderischen Struktur, wie sie auch Stents aufweisen, mit einer Vielzahl von Maschen. Sie ist über zwei Verbinder mit einem Führungsdraht verbunden, der die präzise Platzierung erlaubt. Die Verbinder sind am proximalen Ende in einer Maschenstruktur angeordnet und enden in einem Kopplungselement, das seinerseits das distale Ende des Führungsdrahts darstellt.

Der hier gebrauchte Begriff „proximal" bezeichnet die zum behandelnden Arzt weisende Seite, „distal" dagegen die vom Arzt wegweisende Seite, beispielsweise der Stentstruktur oder des Führungsdrahts.

Die Maschenstruktur des Stents kann eine geflochtene Struktur sein, d. h. aus einzelnen Drähten bestehen, ist aber vorzugsweise eine geschnittene Struktur, bei der aus einem Rohr geeigneten Durchmessers mit Hilfe eines Lasers die

Maschenstruktur herausgeschnitten wird. Das Material ist in der Regel ein Metall, kann aber auch ein Kunststoff sein. Es muss über eine hinreichende Elastizität verfügen, die eine Kontraktion auf den Durchmesser eines üblichen Katheters erlaubt und andererseits bei der Freisetzung aus dem Katheter die Expansion auf den gewünschten und vorgegebenen Durchmesser.

Als Stentmaterialien kommen neben Eisenlegierungen (Edelstahl, Federstahl) und Kobalt-Chrom-Legierungen insbesondere Formgedächtnislegierungen in Frage, etwa binäre Nickel-Titan-Legierungen (Nitinol) und ternäre Nickel-Titan-Chrom-Legierungen (Chrom-dotierte Legierungen). Insbesondere Nitinol ist für die Anwendung in selbstexpandierenden Stentstrukturen im neurovaskulären Bereich bekannt.

Die erfindungsgemäße Vorrichtung ist im Prinzip eine flächige Struktur, die zu einem rohrförmigen Gebilde gerollt ist und einen Schlitz aufweist, der sich wendel- oder helixförmig über die Mantelfläche der Stentstruktur erstreckt. Dieser Schlitz kann dabei eine vollständige Wendel von 360° darstellen, aber auch eine nur partielle von beispielsweise etwa 180° oder 120°. Die Mantelfläche der Stentstruktur klafft im Bereich dieses Schlitzes auf, wobei die Breite des Schlitzes am Einsatzort jeweils auch vom Lumen des Gefäßes bestimmt wird, da sich die Stentstruktur nach der Freisetzung aus dem Katheter nur so weit entfalten kann, wie es das Gefäßlumen zulässt.

Um die Stentstruktur zum einen räumlich zu fixieren und andererseits mit einer gewissen Spannung zu versehen, erstreckt sich am proximalen Ende der Stentstruktur ein Spannbügel über den Schlitz. Der Spannbügel erhöht die Radialkraft der selbstexpandierenden Struktur, dient aber auch dazu, die einander gegenüberliegenden Kanten der Stentstruktur entlang des Schlitzes in ihrer Position zueinander festzuhalten.

Die erfindungsgemäße Thrombektomievorrichtung kann über dem proximalen Spannbügel hinaus weitere Spannbügel im zentralen und distalen Bereich aufweisen. Bei Verwendung von Formgedächtnismaterialien mit hinreichender Vorspannung kann aber auch auf jeglichen Spannbügel verzichtet werden.

Die erfindungsgemäße Thrombektomievorrichtung wird so eingesetzt, dass sie mittels eines Katheters an den Einsatzort verbracht wird und dort entweder im Thrombus selbst oder distal vom Thrombus freigesetzt wird. Die Vorrichtung expandiert im Gefäß und passt sich an das Gefäßlumen an. Entweder schon beim Aufspannen oder beim Zurückziehen verfängt sich das Thrombusmaterial in der Maschenstruktur und wird beim Zurückziehen der Vorrichtung in den Katheter mitgenommen. An der Gefäßwand anhaftende Teile des Thrombus werden durch die Scherwirkung der Maschen und der Kanten entlang des Schlitzes mitgenommen. Der Thrombus wird in den Katheter eingezogen und mit dem Katheter aus dem Körper entfernt.

Bei der Extraktion des Thrombus hat der wendelförmige Verlauf des Schlitzes über die Mantelfläche den besonderen Vorteil, dass die Kanten der Stentstruktur entlang des Schlitzes bei Zug tangential entlang des Umfanges der Gefäßwandung wandern. Dies verbessert die Scherwirkung. Gleichzeitig verbessert (vermindert) sich durch den wendelförmigen Verlauf die Biegesteifigkeit dergestalt, dass eine bessere Anpassung an kurvige Gefäße möglich ist. Dies erleichtert sowohl die Platzierung als auch die Extraktion von Thromben aus komplexen Gefäßstrukturen.

Der proximale Bügel verbessert den Radialkraftverlauf der Stentstruktur im proximalen Bereich. Insbesondere vermindert der Bügel eine Verschlankung der Stentstruktur und der Zugbelastung, wie sie beim Einziehen in den Katheter auftritt. Gleichzeitig wird eine zusätzliche Schälwirkung erreicht, wie sie auch von den Maschen und Kanten der Stentstruktur ausgeübt wird.

Von Bedeutung ist aber insbesondere die Verbesserung der Aufspannkraft im proximalen Bereich, die eine optimale Anpassung der Stentstruktur an das Gefäßlumen ermöglicht. Gleichzeitig werden die vom Schlitz voneinander getrennten Bereiche des Stents daran gehindert, sich gegeneinander zu verschieben.

Um ein problemloses Einziehen der Stentstruktur mit dem Bügel in den Katheter zu ermöglichen, weist der Spannbügel zum distalen Ende der Stentstruktur hin. Dies bedeutet, dass der Bogen des Bügels nach distal geschlossen ist, dagegen

nach proximal zusammen mit den Verbindern eine Schlaufe bildet, die im Kopplungselement zusammenläuft, ähnlich der Öffnung eines Fangkorbs.

Gemäß einer Variante kann die erfindungsgemäße Stentstruktur am distalen Ende durch eine Maschenstruktur verschlossen sein, so dass sich thrombotisches Material darin wie in einem Fangkorb sammelt

Wie schon festgestellt, wird die erfindungsgemäße Stentstruktur vorzugsweise aus einem zylindrischen Rohr mit Hilfe eines Lasers geschnitten. Dies erlaubt es, den einzelnen Maschen einen besonderen Querschnitt zu verleihen, beispielsweise quadratisch, rechteckig oder trapezförmig. Bei den rechteckigen und trapezförmigen Ausführungsformen kann zum einen die schmale Seite des Querschnitts an der Außenfläche liegen, zum anderen die lange Seite. Bevorzugt ist es, dass die schmale Seite sowohl des Rechtecks wie insbesondere des Trapezes zur Gefäßwand weist, was ein leichteres Eindringen des Thrombus in die Maschenstruktur ermöglicht und die gute Verdrängung des Thrombusmasse bei der Expansion der Stentstruktur erlaubt.

Die am proximalen Ende der Stentstruktur angeordneten Verbinder führen von an den Schlitz angrenzenden proximalen Waben zu einem Kopplungselement, in dem sie zusammengeführt sind. Sie sind Teile der Stentstruktur und bestehen deshalb aus dem gleichen Material.

Der Führungsdraht der erfindungsgemäßen Thrombektomievorrichtung ist ein üblicher Führungsdraht, wie er für endovaskuläre und insbesondere neuroradiologische Zwecke eingesetzt wird. Er endet distal in dem Kopplungselement, das seinerseits die proximalen Enden der Verbinder aufnimmt.

Das Kopplungselement selbst kann ein einfacher Schweißpunkt sein, in dem Führungsdraht und Verbinder zusammengeführt sind. Es kann weiterhin aber auch ein übliches Kopplungselement sein, das die Freisetzung der zylindrischen Stentstruktur erlaubt, die insbesondere dann geboten ist, wenn eine Rückholung aus medizinischen Gründen nicht angezeigt ist, beispielsweise weil sie zu Schäden beim Patienten führen würde. In diesem Fall kann die Stentstruktur als

Stent im Körper verbleiben und ihre Wirkung dadurch entfalten, dass sie im Thrombus einen Kanal ausbildet; der Thrombus wird durch die Maschenstruktur an die Gefäßwand gepresst.

Für letzteren Fall ist das Kopplungselement beispielsweise ein mechanisches Kopplungselement, das geeignet ist, bei Austritt aus dem Katheter die Verbinder freizusetzen. Zahlreiche solcher Systeme sind in der Fachliteratur beschrieben. Ebenfalls beschrieben sind hydraulische Ablösesysteme. Besonders geeignet sind elektrolytische Ablösungssysteme, bei denen ein elektrolytisch korrodierbares Teil durch Stromeinwirkung aufgelöst wird und die Verbindung zwischen Stentstruktur und Führungsdraht durchtrennt. Gemäß einer ersten Variante kann das Kopplungselement als solch ein elektrolytisch auflösbares Teil gestaltet sein, gemäß einer zweiten Variante sind die Verbinder mit einer solchen Ablösestelle bzw. einem separaten Ablöseelement versehen, das sich bei Stromeinwirkung auflöst. Geeignet als Ablöseelemente sind vorkorrodierte Edelstahlelemente, Magnesiumelemente oder Kobalt-Chrom-Legierungen. Solche Systeme sind in der Literatur beschrieben.

Bei der Gestaltung des proximalen Bereichs der zylindrischen Stentstruktur ist eine kurze Ausführung der Verbinder bevorzugt. Der Weg zwischen proximalem Ende der Maschenstruktur und Kopplungselement soll kurz gehalten werden. Dies verkürzt zum einen die ungenutzte Länge der Vorrichtung und erhöht andererseits die Spannung in der mit dem Spannbügel gebildeten Fangschlinge am proximalen Ende der Struktur.

Gemäß einer besonderen Ausführungsform kann der distale Bereich der zylindrischen Stentstruktur kegelförmig oder trompetenförmig aufgeweitet sein, um in diesem Bereich eine gute Anpassung an das Gefäßlumen zu ermöglichen. Bei der Extraktion von Thromben aus einem Gefäß kommt es auf einen möglichst großen Wirkbereich an, d. h. auf den Kontakt der Mantelfläche mit der Gefäßwand. Je größer die Kontaktfläche, desto größer die Chance, den Thrombus vollständig zu entfernen.

Führungsdraht und/oder Stentstruktur können in üblicher Weise mit Markern versehen sein, die röntgendicht sind, beispielsweise in Form von Spiralen oder Manschetten.

Die Erfindung wird durch die beiliegenden Abbildungen näher erläutert. Es zeigen:

Figur 1	in flächiger Darstellung eine erste Variante der erfindungsgemäßen Stentstruktur;
Figur 2	eine räumliche Darstellung der Stentstruktur von Figur 1;
Figur 3	eine flächige Darstellung einer zweiten Variante einer erfindungsgemäßen Stentstruktur;
Figur 4	eine räumliche Darstellung der Stentstruktur von Figur 3 mit angekoppeltem Führungsdraht;
Figur 5	eine perspektivische Darstellung einer erfindungsgemäßen Stentstruktur mit zwei Verbindern;
Figur 6	eine Darstellung der Stegquerschnitte der Stentstruktur und
Figur 7	eine schematische Darstellung der erfindungsgemäßen Thrombektomievorrichtung.

Figur 1 und 3 zeigen zwei Varianten einer erfindungsgemäßen zylindrischen Stentstruktur 1 mit den einzelnen Maschen 3 und 4 und den Verbindern 5 und 5'. Die Maschen 3 und 4 sind von zwei verschiedenen Typen, die einen (3) haben eine Wellenform, die anderen (4) eine bauchige Form mit zwei Spitzen. Im Zusammenwirken geben diese beiden Formen der Gesamtstruktur sowohl Stabilität als auch Flexibilität.

In der flächigen Darstellung der Abbildungen 1 und 3 verläuft durch die Stentstruktur ein Schlitz oder Kanal 7, der am proximalen Ende der Struktur von dem Spannbügel 9 überbrückt wird. Der Schlitz 7 wird begrenzt durch die Seitenflächen 10 und 10' der Maschenstruktur. Der Schlitz 7 verläuft nicht parallel zur Längsachse der Struktur sondern schräg zur Längsachse, was sich in der räumlichen Darstellung als wendelförmiger Verlauf entlang der Mantelfläche (siehe Figur 2/4) darstellt.

Die Darstellung in Figur 1 und 3 ist eine flächige Darstellung der aufgeschnittenen Stentstruktur 1; die räumlichen Darstellungen sind in Figur 2 und 4 wiedergegeben. In der flächigen Darstellung grenzen die Maschen 3 unmittelbar an die Maschen 3' dergestalt, dass sich ein insgesamt rohrförmiges Gebilde mit in etwa halb um die Mantelfläche 8 umlaufendem Schlitz oder Kanal 7 ergibt.

Die Varianten von Figur 1 und 3 unterscheiden sich in der Form der Verbinder 5 und 5', die im Falle von Figur 3 länger ausgebildet sind und in einem Kopplungselement 11 zusammengeführt sind (siehe Figur 4). Das Kopplungselement 11 kann beispielsweise ein elektrolytisch korrodierbares System sein, das es erlaubt, die Stentstruktur 1 vom Führungsdraht 12 abzulösen (siehe Figur 4). In der Variante gemäß Figur 2 können zwei Ablöseelemente 6, 6' zur elektrolytischen Ablösung vorgesehen sein.

Beiden Ausführungsformen ist gemein, dass der Schlitz 7 von dem Bügel 9 überbrückt wird. Der Bügel 9 selbst setzt an den Rändern 10, 10' des Maschenkonstrukts liegenden Waben an und weist mit seinem Bogen zur distalen Seite der Stentstruktur. Dies erlaubt das problemlose Einziehen der Stentstruktur in einen Katheter. Mit den angrenzenden Verbindern 5 und 5' bildet der Spannbogen 9 eine im Kopplungselement 11 (Figur 4) zusammenlaufende Fangschlaufe bzw. Öffnung eines Fangkorbs. Hierzu kann das distale Ende der Stentstruktur ebenfalls mit einer Maschenstruktur verschlossen sein.

In den Darstellungen von Figur 2 und 4, die die räumliche Wiedergabe der Stentstrukturen von Figur 1 und 3 sind, sind die auf der Rückseite liegenden

Stege der Stentstruktur hell dargestellt. Zu erkennen ist der am proximalen Ende der Struktur unter dem Spannbogen 9 durchlaufende Schlitz 7, der sich zur rechten Seite hin um die Mantelfläche 8 der Stentstruktur windet. Der Schlitz 7 endet distal auf der Unterseite der Stentstruktur 1 und beschreibt damit eine Drehung um etwa 180°.

Figur 5 zeigt die räumliche Darstellung einer erfindungsgemäßen Stentstruktur, wobei die Verbinder 5 und 5' mit einwärts gerichteten Haken versehen sind, die in eine entsprechende Aufnahme eines Kopplungselements 11 eines Führungsdrahts 12 eingreifen. Solange sich das Kopplungselement mit dem proximalen Ende der Verbinder 5 und 5' in einem Katheter befindet, ist die Stentstruktur 1 an den Führungsdraht gekoppelt. Bei Herausschieben aus dem Katheter erlischt die Verbindung zwischen den Verbindern 5, 5' und dem Kopplungselement 11 und die Struktur ist als Stent zum Verbleib im Gefäßsystem freigesetzt. Die Abkopplung wird aber nur in besonderen (Not)Fällen stattfinden, etwa wenn die Vorrichtung nicht ohne weiteres wieder in den Katheter zurückgezogen werden kann.

Deutlich zu erkennen in Figur 5 ist die Schlaufenstruktur aus Bogen 9 und Verbindern 5, 5' und der Verlauf der Stege 12 der Stentstruktur entlang der Mantelfläche 8, die mit ihrem Kanten dazu dienen, auf das zu entfernende Thrombusmaterial einzuwirken und dieses von der Gefäßwand abzuscheren.

Figur 6 zeigt die beiden bevorzugten Ausführungsformen von den Stegen 12 mit rechteckigem und trapezförmigem Querschnitt, wobei die schmale Seite jeweils zur Mantelfläche 8 der Stentstruktur 1 bzw. zur Gefäßwand 13 zeigt. Diese Ausführungsvarianten gewährleisten die notwendige Stabilität des Maschennetzes einerseits und eine gute Scher- und Verdrängungswirkung auf den Thrombus andererseits.

Figur 7 zeigt schematisch den Aufbau einer erfindungsgemäßem Thrombektomievorrichtung mit dem Führungsdraht 12, dem Kopplungselement 11, dem Bereich der proximalen Anbindung mit den Verbindern 5, 5', dem Wirkbereich mit der Mantelfläche 8 und dem distalen Bereich 13 mit einer trompetenförmigen Erweiterung.

In den Abbildungen stellen gleiche Bezugszeichen gleiche Sachverhalte dar.

Patentansprüche

1. Thrombektomievorrichtung mit

einer im Wesentlichen zylindrischen Stentstruktur (1), die eine Vielzahl von Maschen (3, 4) aufweist sowie zwei Verbinder (5, 5'), die an verschiedenen Maschen (3) am proximalen Ende der Stentstruktur (1) angeordnet sind und

einem Führungsdraht (2), der ein Kopplungselement (11) aufweist, an das die Verbinder (5, 5') angekoppelt sind,

gekennzeichnet durch einen Schlitz (7), der sich wendelförmig über die Mantelfläche (8) der Stentstruktur (1) erstreckt und einen Spannbügel (9), der am proximalen Ende der Stentstruktur (1) den Schlitz (7) überspannt.

2. Vorrichtung nach Anspruch 1, dadurch gekennzeichnet, dass sie aus einem Formgedächtnismaterial besteht, vorzugsweise aus Nitinol oder einer Nickel-Titan-Chrom-Legierung.

3. Vorrichtung nach Anspruch 1 oder 2, dadurch gekennzeichnet, dass der Spannbügel (9) mit seinem Bogen zum distalen Ende der Stentstruktur (1) weist.

4. Vorrichtung nach Anspruch 3, dadurch gekennzeichnet, dass der Spannbügel (9) und die Verbinder (5, 5') eine Schlaufe bilden, die im Kopplungselement (11) zusammenläuft.

5. Vorrichtung nach einem der vorstehenden Ansprüche, dadurch gekennzeichnet, dass sie einen oder mehrere weitere Bügel (9) im zentralen und/oder distalen Teil der Stentstruktur (1) aufweist.

6. Vorrichtung nach einem der vorstehenden Ansprüche, dadurch gekennzeichnet, dass die Stentstruktur (1) aus einem Rohr geschnitten ist und rechteckige oder trapezförmige Stegquerschnitte aufweist.

7. Vorrichtung nach Anspruch 6, dadurch gekennzeichnet, dass die Stegquerschnitte mit ihrer schmalen Seite die Mantelfläche (8) der Stentstruktur (1) bilden.

8. Vorrichtung nach einem der vorstehenden Ansprüche, dadurch gekennzeichnet, dass die Stentstruktur (1) mechanisch, hydraulisch oder elektrochemisch vom Führungsdraht (2) ablösbar ist.

9. Vorrichtung nach Anspruch 8, dadurch gekennzeichnet, dass das Kopplungselement (11) als Ablöseelement ausgebildet ist.

10. Vorrichtung nach Anspruch 8, gekennzeichnet durch zwei Ablösestellen, vorzugsweise mit elektrochemischer Ablösung.

11. Vorrichtung nach einem der vorstehenden Ansprüche, dadurch gekennzeichnet, dass das Kopplungselement (11) peripher angeordnet ist.

12. Vorrichtung nach einem der vorstehenden Ansprüche, dadurch gekennzeichnet, dass das distale Ende der Stentstruktur (1) kegelig oder trompetenförmig aufgeweitet ist.

13. Vorrichtung nach einem der vorstehenden Ansprüche, gekennzeichnet durch Markerelemente.

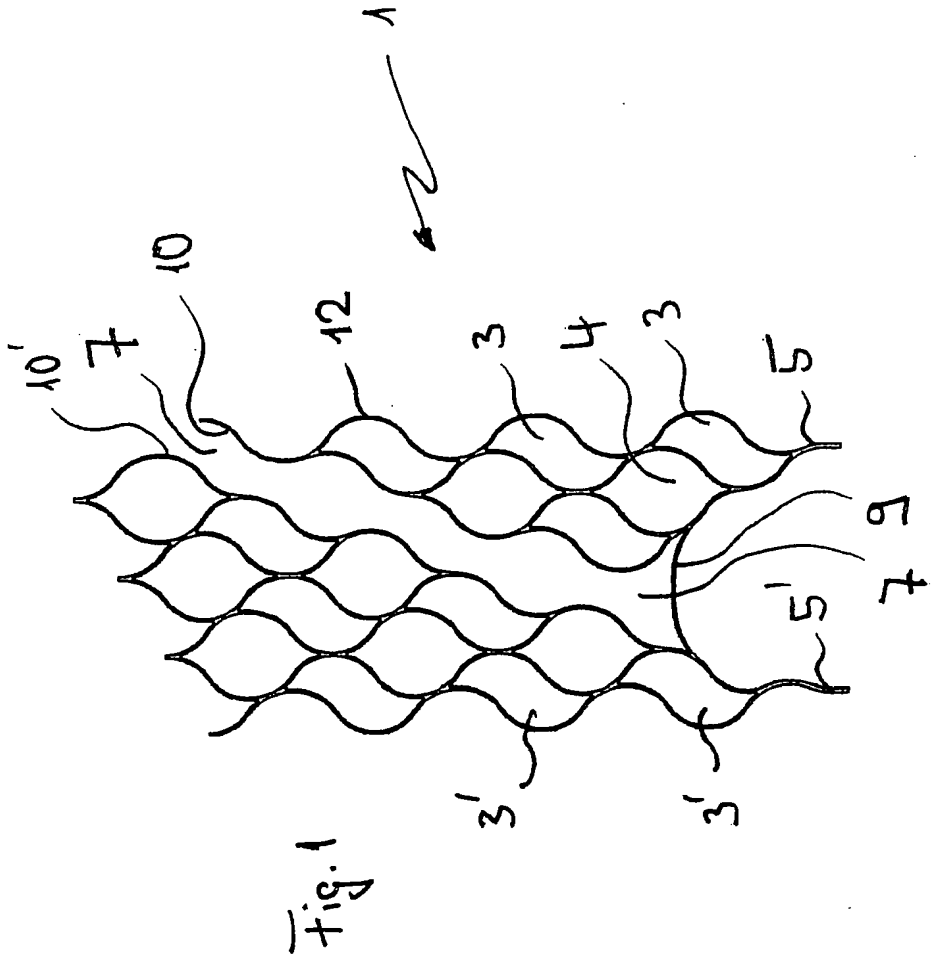


Fig. 1

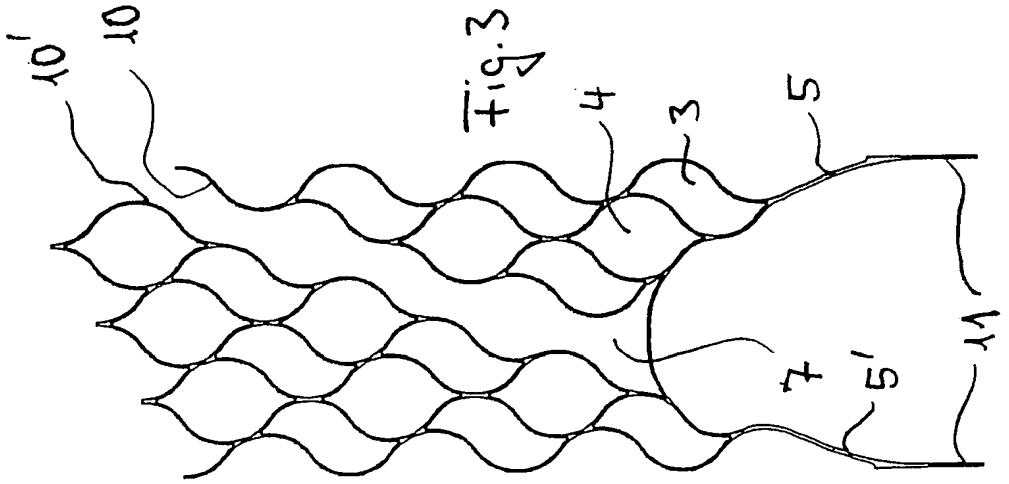


Fig. 3

Fig. 2

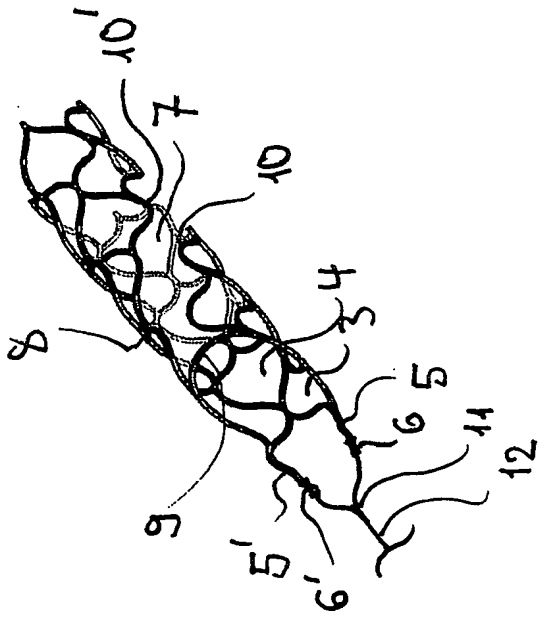


Fig. 4

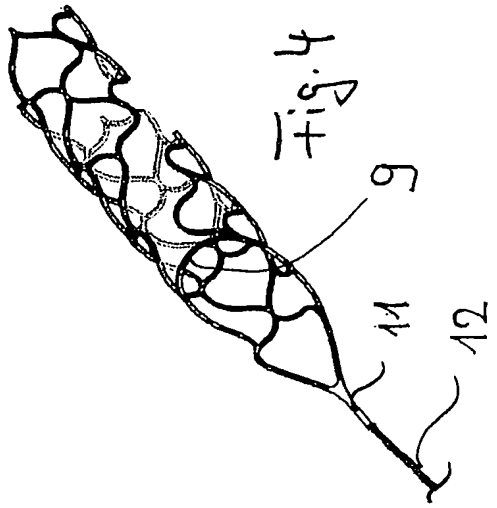
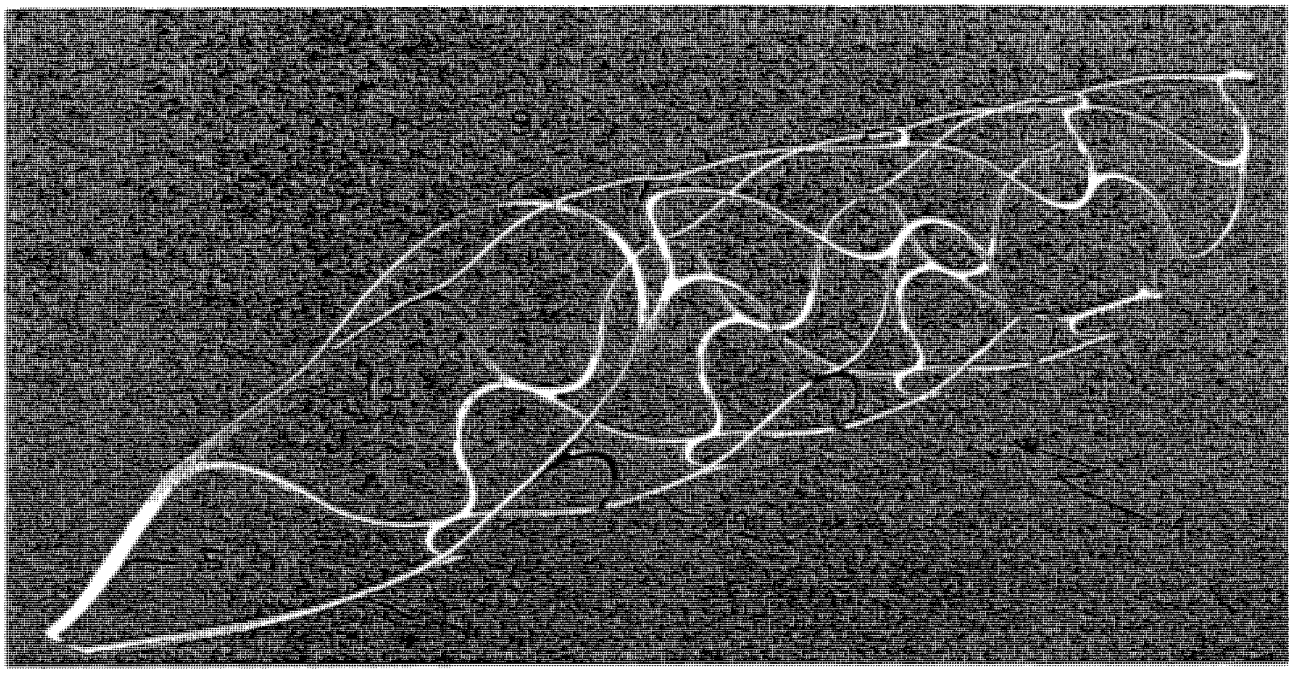


Fig. 5



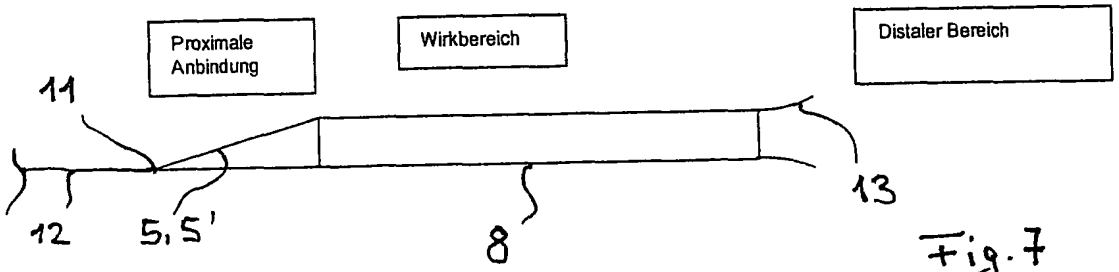


Fig. 7

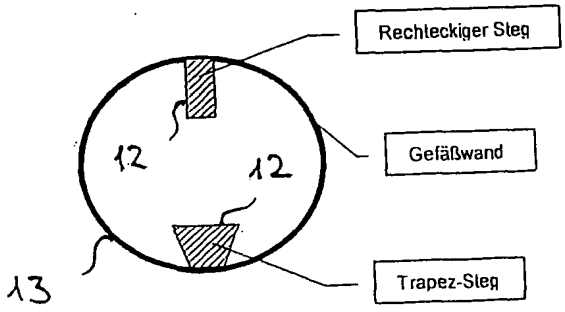


Fig. 6

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2011/005817

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/221 A61F2/90
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 2009/105710 A1 (MICRO THERAPEUTICS INC [US]; SLEE EARL HOWARD [US]; WILDER THOMAS III) 27 August 2009 (2009-08-27) page 10, line 6 - page 7, line 16; figures 1-13 page 9, line 3 - line 14 page 13, line 5 - page 14, line 25 -----	1-13
Y	US 5 618 299 A (KHOSRAVI FARHAD [US] ET AL) 8 April 1997 (1997-04-08) column 5, line 7 - line 28; figure 13 -----	1-13
A	WO 2007/089897 A2 (CLEVELAND CLINIC FOUNDATION [US]) 9 August 2007 (2007-08-09) page 16, line 5 - page 18, line 13; figures 8a-d -----	1
	-/--	

[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
23 February 2012	01/03/2012

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Moers, Roelof

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INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2011/005817

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 2005/094477 A2 (ANGIOSCORE INC [US]; KONSTANTINO EITAN [US]; FELD TANHUM [IL]; TZORI N) 13 October 2005 (2005-10-13) abstract; figures 1-24	1
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A	US 5 904 698 A (THOMAS THOMAS P [US] ET AL) 18 May 1999 (1999-05-18) column 5, line 41 - column 7, line 15; figures 1, 2	1,6

1

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/EP2011/005817

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INTERNATIONALER RECHERCHENBERICHT

Internationales Aktenzeichen
PCT/EP2011/005817

A. KLASSIFIZIERUNG DES ANMELDUNGSGEGENSTANDES
INV. A61B17/221 A61F2/90
ADD.

Nach der Internationalen Patentklassifikation (IPC) oder nach der nationalen Klassifikation und der IPC

B. RECHERCHIERTE GEBIETE

Recherchierter Mindestprüfstoff (Klassifikationssystem und Klassifikationssymbole)
A61B A61F

Recherchierte, aber nicht zum Mindestprüfstoff gehörende Veröffentlichungen, soweit diese unter die recherchierten Gebiete fallen

Während der internationalen Recherche konsultierte elektronische Datenbank (Name der Datenbank und evtl. verwendete Suchbegriffe)
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C. ALS WESENTLICH ANGESEHENE UNTERLAGEN

Kategorie*	Bezeichnung der Veröffentlichung, soweit erforderlich unter Angabe der in Betracht kommenden Teile	Betr. Anspruch Nr.
Y	WO 2009/105710 A1 (MICRO THERAPEUTICS INC [US]; SLEE EARL HOWARD [US]; WILDER THOMAS III) 27. August 2009 (2009-08-27) Seite 10, Zeile 6 - Seite 7, Zeile 16; Abbildungen 1-13 Seite 9, Zeile 3 - Zeile 14 Seite 13, Zeile 5 - Seite 14, Zeile 25	1-13
Y	US 5 618 299 A (KHOSRAVI FARHAD [US] ET AL) 8. April 1997 (1997-04-08) Spalte 5, Zeile 7 - Zeile 28; Abbildung 13	1-13
A	WO 2007/089897 A2 (CLEVELAND CLINIC FOUNDATION [US]) 9. August 2007 (2007-08-09) Seite 16, Zeile 5 - Seite 18, Zeile 13; Abbildungen 8a-d	1

-/--

[X] Weitere Veröffentlichungen sind der Fortsetzung von Feld C zu entnehmen [X] Siehe Anhang Patentfamilie

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Datum des Abschlusses der internationalen Recherche	Absendedatum des internationalen Recherchenberichts
23. Februar 2012	01/03/2012

Name und Postanschrift der Internationalen Recherchenbehörde	Bevollmächtigter Bediensteter
Europäisches Patentamt, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Moers, Roelof

1

C. (Fortsetzung) ALS WESENTLICH ANGESEHENE UNTERLAGEN

Kategorie*	Bezeichnung der Veröffentlichung, soweit erforderlich unter Angabe der in Betracht kommenden Teile	Betr. Anspruch Nr.
A	WO 2005/094477 A2 (ANGIOSCORE INC [US]; KONSTANTINO EITAN [US]; FELD TANHUM [IL]; TZORI N) 13. Oktober 2005 (2005-10-13) Zusammenfassung; Abbildungen 1-24	1
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A	US 5 980 552 A (PINCHASIK GREGORY [IL] ET AL) 9. November 1999 (1999-11-09) Spalte 3, Zeile 30 - Zeile 60; Abbildung 2c	1
A	US 5 904 698 A (THOMAS THOMAS P [US] ET AL) 18. Mai 1999 (1999-05-18) Spalte 5, Zeile 41 - Spalte 7, Zeile 15; Abbildungen 1, 2	1,6

1

INTERNATIONALER RECHERCHENBERICHT

Angaben zu Veröffentlichungen, die zur selben Patentfamilie gehören

Internationales Aktenzeichen
PCT/EP2011/005817

Im Recherchenbericht angeführtes Patentdokument	Datum der Veröffentlichung	Mitglied(er) der Patentfamilie	Datum der Veröffentlichung
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(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
30 April 2015 (30.04.2015)

WIPO | PCT

(10) International Publication Number
WO 2015/061365 A1

(51) **International Patent Classification**:
A61B 17/22 (2006.01) *A61M 25/01* (2006.01)

(21) **International Application Number**:
PCT/US2014/061645

(22) **International Filing Date**:
21 October 2014 (21.10.2014)

(25) **Filing Language**: English

(26) **Publication Language**: English

(30) **Priority Data**:

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61/949,953	7 March 2014 (07.03.2014)	US
14/299,997	9 June 2014 (09.06.2014)	US
14/299,933	9 June 2014 (09.06.2014)	US

(71) **Applicant**: **INCEPTUS MEDICAL, LLC** [US/US]; 8 Argonaut, Suite 100, Aliso Viejo, CA 92656 (US).

(72) **Inventors**: **COX, Brian, J.**; 3 Novilla, Laguna Niguel, CA 92677 (US). **LUBOCK, Paul**; 11 Santa Lucia, Monarch Beach, CA 92629 (US). **ROSENBLUTH, Robert**; 24161 Cherry Hills Place, Laguna Niguel, CA 92677 (US). **QUICK, Richard**; 22970 Bouquet Canyon, Mission Viejo, CA 92692 (US). **MARCHAND, Philippe**; 22276 Anthony Drive, Lake Forest, CA 92630 (US).

(74) **Agents**: **FOX, Mary, L.** et al.; Perkins Coie LLP, P.O. Box 1247, Seattle, WA 98111-1247 (US).

(81) **Designated States** *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

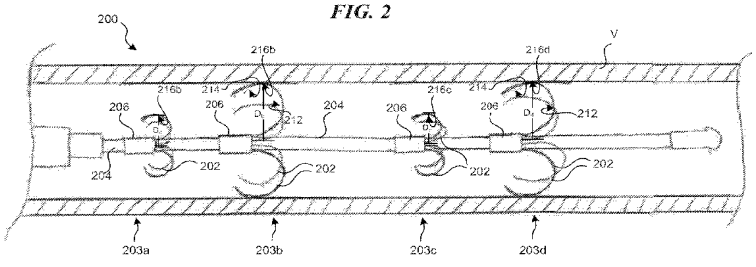
(84) **Designated States** *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report (Art. 21(3))*

(54) **Title**: METHODS AND APPARATUS FOR TREATING EMBOLISM

FIG. 2



(57) **Abstract**: A device and method for intravascular treatment of an embolism, and particularly a pulmonary embolism, is disclosed herein. One aspect of the present technology, for example, is directed toward a clot treatment device that includes a support member having a plurality of first clot engagement members and second clot engagement members positioned about the circumference of a distal portion of the support member. In an undeployed state, individual first clot engagement members can be linear and have a first length, and individual second clot engagement members can be linear and have a second length that is less than the first length. The clot engagement members can be configured to penetrate clot material along an arcuate path and hold clot material to the clot treatment device.

WO 2015/061365 A1

METHODS AND APPARATUS FOR TREATING EMBOLISM

CROSS-REFERENCE TO RELATED APPLICATION(S)

[0001] The present application claims the benefit of the following applications:

[0002] (a) U.S. Provisional Patent Application No. 61/893,859, filed October 21, 2013;

[0003] (c) U.S. Provisional Patent Application No. 61/949,953, filed March 7, 2014;

[0004] (d) U.S. Patent Application No. 14/299,933, filed June 9, 2014; and

[0005] (e) U.S. Patent Application No. 14/299,997, filed June 9, 2014.

[0006] All of the foregoing applications are incorporated herein by reference in their entireties. Further, components and features of embodiments disclosed in the applications incorporated by reference may be combined with various components and features disclosed and claimed in the present application.

TECHNICAL FIELD

[0007] The present technology relates generally to devices and methods for intravascular treatment of emboli within a blood vessel of a human patient.

BACKGROUND

[0008] Thromboembolism occurs when a thrombus or blood clot trapped within a blood vessel breaks loose and travels through the blood stream to another location in the circulatory system, resulting in a clot or obstruction at the new location. When a clot forms in the venous circulation , it often travels to the lungs via the heart and lodges within a pulmonary blood vessel PV causing a pulmonary embolism PE. A pulmonary embolism can decrease blood flow through the lungs , which in turn causes decreased oxygenation of the lungs , heart and rest of the body. Moreover, pulmonary embolisms can cause the right ventricle of the heart to pump harder to provide sufficient blood to the pulmonary blood vessels , which can cause right ventricle dysfunction (dilation), and heart failure in more extreme cases.

[0009] Conventional approaches to treating thromboembolism and/or pulmonary embolism include clot reduction and/or removal. For example, anticoagulants can be introduced to the affected vessel to prevent additional clots from forming, and thrombolytics can be introduced to the vessel to at least partially disintegrate the clot. However, such agents typically take a prolonged period of time (e.g., hours, days, etc.) before the treatment is effective and in some instances can cause hemorrhaging. Transcatheter clot removal devices also exist, however, such devices are typically highly complex, prone to cause trauma to the vessel, hard to navigate to the pulmonary embolism site, and/or expensive to manufacture. Conventional approaches also include surgical techniques that involve opening the chest cavity and dissecting the pulmonary vessel. Such surgical procedures, however, come with increased cost, procedure time, risk of infection, higher morbidity, higher mortality, and recovery time. Accordingly, there is a need for devices and methods that address one or more of these deficiencies.

BRIEF DESCRIPTION OF THE DRAWINGS

[0010] Many aspects of the present technology can be better understood with reference to the following drawings. The components in the drawings are not necessarily to scale. Instead, emphasis is placed on illustrating clearly the principles of the present disclosure.

[0011] Figure 1 is a side view of one embodiment of a clot treatment device in a low-profile or delivery state positioned in a blood vessel and configured in accordance with the present technology.

[0012] Figure 2 is a side view of the clot treatment device shown in Figure 1 in an unrestricted expanded or deployed state positioned in a blood vessel and configured in accordance with the present technology.

[0013] Figure 3 is a partial side view of the clot treatment device shown in Figure 2 showing an isolated, deployed clot engagement member within an embolism.

[0014] Figure 4 is a side view of a clot treatment device having distally-facing clot engagement members in a deployed state configured in accordance with another embodiment of the present technology.

[0015] Figure 5 is a side view of a clot treatment device having distally-facing clot engagement members in a deployed state configured in accordance with another embodiment of the present technology.

[0016] Figure 6 is a side perspective view of a clot treatment device in a deployed state configured in accordance with another embodiment of the present technology.

[0017] Figure 7 is a side perspective view of a clot treatment device in a deployed state configured in accordance with another embodiment of the present technology.

[0018] Figure 8 is a side perspective view of a portion of a clot treatment device in a deployed state having a plurality of ports configured in accordance with another embodiment of the present technology.

[0019] Figure 9A is a front view of a portion of a delivery system for a clot treatment device that includes an expandable member in a deployed state configured in accordance with an embodiment of the present technology.

[0020] Figure 9B is a front view of a portion of a delivery system for a clot treatment device that includes an expandable member in a deployed state configured in accordance with another embodiment of the present technology.

[0021] Figure 10A is a side view of an expandable member configured in accordance with the present technology.

[0022] Figure 10B is an end view of the expandable member shown in Figure 10A.

[0023] Figure 11A is a side cross-sectional view of a clot treatment device configured in accordance with the present technology.

[0024] Figure 11B is an expanded, isolated view of a portion of the clot treatment device shown in Figure 11A.

[0025] Figure 12 is a pressure-generating member configured in accordance with the present technology.

[0026] Figure 13 is a schematic representation of the venous system of a human leg.

[0027] Figure 14 is an enlarged schematic representation of a deep vein thrombosis.

DETAILED DESCRIPTION

[0028] Specific details of several embodiments of clot treatment devices, systems and associated methods in accordance with the present technology are described below with reference to Figures 1-14. Although many of the embodiments are described below with respect to devices, systems, and methods for treating an embolism, other applications and other embodiments in addition to those described herein are within the scope of the technology. Additionally, several other embodiments of the technology can have different states, components, or procedures than those described herein. Moreover, it will be appreciated that specific elements, substructures, advantages, uses, and/or other features of the embodiments described with reference to Figures 1-14 can be suitably interchanged, substituted or otherwise configured with one another in accordance with additional embodiments of the present technology. Furthermore, suitable elements of the embodiments described with reference to Figures 1-14 can be used as standalone and/or self-contained devices. A person of ordinary skill in the art, therefore, will accordingly understand that the technology can have other embodiments with additional elements, or the technology can have other embodiments without several of the features shown and described below with reference to Figures 1-14.

[0029] With regard to the terms "distal" and "proximal" within this description, unless otherwise specified, the terms can reference a relative position of the portions of a clot treatment device and/or an associated delivery device with reference to an operator and/or a location in the vasculature.

I. Selected Embodiments of Clot Treatment Devices

[0030] Figure 1 is a side view of one embodiment of a clot treatment device 200 ("the device 200") in a low-profile or delivery state positioned in a blood vessel V, and Figure 2 is a side view of the device 200 in an unrestricted expanded or deployed state that is well suited for removing clot material from a blood vessel (e.g., a pulmonary blood vessel). Referring to Figures 1 and 2 together, the device 200 can include a support member 204 and a plurality of treatment portions (referred to collectively as treatment portions 203, referred to individually as first-fourth treatment portions 203a-d, respectively) spaced apart along the support member 204. Each treatment portion 203 can include a hub 206 positioned around the support member 204 and a

plurality of clot engagement members 202 integral with and extending distally from the corresponding hub 206 to a distal free end 205. As such, individual treatment portions 203 can include a plurality of clot engagement members 202 positioned about the circumference of the support member 204. Although four treatment portions 203 are shown in Figures 1 and 2, in other embodiments the clot treatment device can include more or fewer than four treatment portions 203 (e.g., two treatment portions, three treatment portions, five treatment portions, etc.).

[0031] In the delivery state shown in Figure 1 the clot engagement members 202 can be generally linear and extend generally parallel to the support member 204. The distal ends 205 of the clot engagement members 202 are accordingly the distal-most portion of the clot engagement members 202 in the delivery state. In the expanded state, as shown in Figure 2, the clot engagement members 202 can project radially outwardly relative to the support member 204 in a curved shape. The clot engagement members 202 can have a proximally facing section 212 which defines a proximally facing concave portion, and, in some embodiments, the clot engagement members 202 can further include an end section 214 that curves radially inwardly from the proximally facing section 212. When deployed within a blood vessel adjacent to clot material, the clot engagement members 202 are configured to penetrate the clot material along an arcuate path and hold clot material to the device 200.

[0032] In some embodiments the treatment portions 203 can be fabricated from a single tube (e.g., a hypotube). A plurality of elongated slits may be cut or machined through the wall of the tube by various means known in the art (e.g., conventional machining, laser cutting, electrical discharge machining, photochemical machining, etc.) to form a plurality of clot engagement members 202 that are integral with the corresponding hub 206. In some embodiments, the tube can be cut such that individual clot engagement members 202 can have non-circular cross-sections. The cut tube may then be formed by heat treatment to move from the delivery state shown in Figure 1 to the deployed state shown in Figure 2 in which the arcuate clot engagement members 202 project radially outward. As is known in the art of heat setting, a fixture or mold may be used to hold the structure in its desired final configuration and subjected to an appropriate heat treatment such that the clot engagement members 202 assume or are otherwise shape-set to the desire arcuate shape. In some embodiments, the device or component may be held by a fixture and heated to about 475-525 ℃ for about 5-15 minutes to shape-set the structure. In some embodiments, the treatment

portions 203 can be formed from various metals or alloys such as Nitinol, platinum, cobalt-chrome alloys, 35N LT, Elgiloy, stainless steel, tungsten or titanium.

[0033] Referring still to Figures 1-2, the clot engagement members 202 of different treatment portions 203 can have different lengths (referred to collectively as L, referred to individually as first-fourth lengths L_a-L_b) in the delivery state (Figure 1) and thus can extend different distances D from the support member 204 in the deployed state (Figure 2). As such, deployment of the clot engagement members 202 self-centers the device within the blood vessel V and forces the stiffer, shorter clot engagement members 202 to be positioned radially farther from the vessel wall V. As used herein, "shorter clot engagement members" or "shorter treatment portions" refers to clot engagement members 202 and/or treatment portions 203 with lesser lengths L and/or distances D relative to the other clot engagement members 202 and/or treatment portions 203 of the same clot treatment device, and "longer clot engagement members" or "longer treatment portions" refers to clot engagement members 202 and/or treatment portions 203 with greater lengths L and/or distances D relative to the other clot engagement members 202 and/or treatment portions 203 of the same clot treatment device.

[0034] For example, as shown in Figure 1, in the delivery state, the first treatment portion 203a can have clot engagement members with a first length L_a, the second treatment portion 203b can have clot engagement members 202 with a second length L_b, the third treatment portion 203c can have clot engagement members 202 with a third length L_c, and the fourth treatment portion 203d can have clot engagement members 202 with a fourth length L_d. In Figure 1, the clot engagement member lengths L of adjacent treatment portions 203 alternate between shorter and longer clot engagement members (i.e., clot engagement members 202 of first and third treatment portions 203a, 203c alternate with clot engagement members 202 of the second and fourth treatment portions 203b, 203d along the support member 204). In other words, in the embodiment shown in Figure 1, the first length L_a is less than the second length L_b, the second length L_b is greater than the third length L_c, and the third length L_c is less than the fourth length L_d. In other embodiments, the clot treatment device 200 and/or treatment portions 203 can have other suitable configurations and/or arrangements. For example, the clot treatment device 200 can include any arrangement of treatment portions 203 having shorter clot engagement members 202 and treatment portions 203 having longer clot engagement members 202 relative to the shorter clot

engagement members 202. Moreover, the clot treatment device 200 can have any number of treatment portions 203 having shorter clot engagement members 202 and/or any number of treatment portions 203 having longer clot engagement members 202. Also, clot engagement members 202 having varying lengths need not be in separate treatment portions 203. For example, in some embodiments, one or more treatment portions 203 can include both shorter and longer clot engagement members 202 in the same treatment portion 203.

[0035] Referring to Figure 2, in the deployed state, the clot treatment device 200 can include a first treatment portion 203a having clot engagement members 202 with a radially furthest apex 216a that is a first distance D_a from the support member 204, a second treatment portion 203b having clot engagement members 202 with a radially furthest apex 216b that is a second distance D_b from the support member 204, a third treatment portion 203c having clot engagement members 202 with a radially furthest apex 216c that is a third distance D_c from the support member 204, and a fourth treatment portion 203d having clot engagement members 202 with a radially furthest apex 216d that is a fourth distance D_d from the support member 204. As shown in Figure 2, the distance D of the radially furthest apex of adjacent treatment portions 203 from the support member 204 can alternate between shorter (clot engagement members 202 of first and third treatment portions 203a, 203c) and longer (clot engagement members 202 of the second and fourth treatment portions 203b, 203d). In other words, in the embodiment shown in Figure 1, the first distance D_a is less than the second distance D_b, the second distance D_b is greater than the third length D_c, and the third distance D_c is less than the fourth distance D_d. In other embodiments, the clot treatment device 200 and/or treatment portions 203 can have other suitable configurations and/or arrangements. For example, the clot treatment device 200 can include any arrangement of treatment portions 203 having clot engagement members 202 with longer or shorter radially furthest apex distances D. Moreover, the clot treatment device 200 can have any number of treatment portions 203 having shorter clot engagement member radially furthest apex distances D and/or any number of treatment portions 203 having longer clot engagement members radially furthest apex distances D. Also, clot engagement members 202 having varying radially furthest apex distances D need not be in separate treatment portions 203. For example, in some embodiments, one or more treatment portions 203 can include engagement members 202 with both shorter radially furthest apex distances D and longer radially further apex distances D.

[0036] Advantageously, clot engagement members 202 having shorter radially furthest apex distances D and/or shorter lengths L can have a greater radial stiffness than clot engagement members 202 having longer radially furthest apex distances D and/or longer lengths L. As shown in the isolated side view of a clot engagement member of Figure 3, when deployed, the shorter, stiffer clot engagement members 202 can thus be spaced apart from the vessel wall V and grasp a more central portion of the clot material to provide mechanical resilience during withdrawal of the clot material CM while the apices of the longer, more flexible clot engagement members 202 (not shown in Figure 3) atraumatically engage and slide along the vessel wall V. In some embodiments, the stiffness of the shorter clot engagement members 202 may be from about 150% to about 400% greater than the stiffness of the longer clot engagement members 202. In some embodiments, the type of material, cross-sectional shape and/or area of the individual clot engagement members 202 can also be varied to affect the radial stiffness of the clot engagement members 202. For example, the relatively shorter clot engagement members 202 can be made from a first material and the relatively longer clot engagement members 202 can be made from a second material that is more ductile, elastic, and or flexible than the first material, and/or the shorter clot engagement members 202 can have a great cross-sectional thickness or area than the relatively longer clot engagement members 202.

[0037] The clot engagement members 202 can have a single or constant radius of curvature. In other embodiments, the clot engagement members 202 can have a plurality of radii of curvature, such as a first region with a first radius of curvature and a second region with a second radius of curvature. In some embodiments, the clot engagement members 202 can have a single radius of curvature that is the same for all of the clot engagement members 202. In other embodiments, the clot treatment device 200 can have a first group of clot engagement members 202 with a constant radius of curvature and a second group of clot engagement members 202 with a plurality of radii of curvature. Moreover, in additional embodiments the clot treatment device 200 can include a first group of clot engagement members 202 having a first radius of curvature and a second group of clot engagement members 202 having a second radius of curvature different than the first radius of curvature. In some embodiments, the radius of the clot engagement members 202 can be between about 1.5 mm and about 12 mm, and in some embodiments, between about 2 mm and about 12 mm.

[0038] Figure 4 is a side view of another embodiment of a clot treatment device 400 in a deployed state configured in accordance with the present technology. As shown in Figure 4, the clot treatment device 400 can include a support member 404 and a plurality of clot engagement members 402 positioned about the support member 404. The support member 404 can be an elongated tubular structure that includes a lumen configured to slidably receive a guidewire GW therethrough. As shown in Figure 4, in the deployed state, the clot engagement members 402 can extend radially outward from the support member 404 and curve distally such that individual clot engagement members 402 include a concave, distally-facing portion 411.

[0039] The clot engagement members 402 can be arranged in rows such that adjacent rows along the support member 404 alternate between long 407 and short 409 clot engagement members. Additionally, the short clot engagement members 409 can be circumferentially aligned with the long 407 clot engagement members 407 about the support member 404. In other embodiments, the clot engagement members 402 can have other suitable arrangements and/or configurations. For example, in some embodiments, one or more of the short clot engagement members 409 can be circumferentially offset from one or more of the long clot engagement members 409 about the support member 404, the long and short clot engagement members 407, 409 can be within the same rows, additionally or alternatively arranged in columns, and/or randomly positioned along or about the support member 404.

[0040] Figure 5 is a side view of another embodiment of a clot treatment device 500 in a deployed state configured in accordance with the present technology. As shown in Figure 5, the clot treatment device 500 can include an expandable mesh 505 and a plurality of arcuate clot engagement members 502 extending radially outwardly from the expandable mesh 505. Although only distally-facing clot engagement members 502 are shown in Figure 5, in other embodiments, the clot treatment device 500 can additionally or alternatively include proximally-facing clot engagement members (such as those shown in Figures 1-2 and Figure 3). In some embodiments, the clot engagement members 502 can be interwoven into the mesh structure 505. In other embodiments, the clot engagement members 502 can also be bonded, soldered, welded, tied or otherwise secured and/or mechanically interlocked to the mesh 505.

[0041] In certain procedures, it may be advantageous to move the clot treatment device along the vessel (fully or partially within the embolism) in both the upstream and downstream directions

to facilitate engagement and/or disruption of a clot or thrombus by the clot engagement members. During such procedures, it may be advantageous to include one or more distally-facing clot engagement members to enhance engagement and/or disruption of the clot material. Accordingly, the clot treatment devices of the present technology can include both proximally-facing clot engagement members and distally-facing clot engagement members. For example, Figures 6 is a perspective side view of a portion of a clot treatment device 600 having proximally-facing (e.g., concave proximally) treatment portions 603p (collectively referred to as treatment portions 603) comprised of proximally-facing 602p clot engagement members and distally-facing (e.g., concave distally) treatment portions 603d comprised of distally-facing 602d clot engagement members. As shown in Figure 6, the distally-facing clot engagement members 602d of the distally-facing treatment portions 603d extend radially outwardly from the corresponding hub 606, then curve distally to a distal free-end. Although the clot treatment device 600 shown in Figure 6 includes two distally-facing treatment portions 603d and two proximally-facing treatment portions 603p along the support member 604, the clot treatment device 600 can include any arrangement and/or configuration of treatment portions and/or clot engagement members. For example, as shown in the clot treatment device 700 of Figure 7, the adjacent treatment portions can alternate between those including proximally-facing clot engagement members 702p and distally-facing clot engagement members 703d.

[0042] Figure 8 is a side perspective view of a portion of another embodiment of a clot treatment device 800 configured in accordance with the present technology. As shown in Figure 8, the support member 804 of the clot treatment device 800 can include holes or ports 805 to allow the infusion of fluids (e.g., thrombolytics) along its length and between treatment portions (labeled 802a and 802b). The ports 805 can be positioned anywhere along the length of the support member 804 (e.g., proximal to the proximal-most treatment portion, distal to the distal-most treatment portion, in between treatment portions, etc.). The location of the ports 805 along the length of the support member 804 can enhance the direct infusion of the fluids into the clot and improve the biologic action and effectiveness of such drugs. Additionally, in some embodiments, the clot engagement members can be at least partially hollow and/or include ports or inlets along their lengths and/or at their free-ends.

II. Additional Embodiments of Clot Treatment Devices and Associated Devices, Systems and Methods

[0043] Figure 9 is a front view of a delivery system 900 for use with the clot treatment devices of the present technology. As shown in Figure 9, the delivery system 900 can include a guide-catheter 902 and an expandable member 904 (e.g., a balloon) coupled to a distal portion of the guide-catheter 902. In such embodiments, the expandable member 904 can be expanded to a diameter less than the vessel diameter, as shown in Figure 9. Use of the expandable member 904 coupled to the distal portion of the guide catheter 902 can divert flow in the vessel away from the distal portion of the guide catheter 902, thereby reducing or eliminating the possibility of clot material traveling proximal of the device during retraction of the clot treatment device 910 (and adherent clot) into the guide catheter 902 (shown in Figure 9B). Moreover, the use of an expandable member 904 with the guide catheter 902 can be advantageous as the expandable member 904 can form a funnel adjacent to the distal end of the guide catheter 904, thereby facilitating retraction of the clot material into the guide catheter 904. Additionally, expanding the expandable member 904 to a diameter that is less than the diameter allows some blood flow BF to occur through the vessel near the treatment site, thus reducing any risk associated with complete blockage of blood flow.

[0044] Figure 10A is a side view of a portion of a delivery system 1000 for use with the clot treatment devices of the present technology, and Figure 10B is a top view of the delivery system shown in Figure 10A. Referring to Figures 10A and 10B together, in those embodiments that include expandable members coupled to a distal portion of the guide catheter, the expandable member can center the guide catheter within the vessel, thereby enhancing and/or facilitating clot removal and/or aspiration. Since the clot treatment device is self-expanding, it will generally tend to self-center within the blood vessel in addition to the centering of the guide catheter enabled by the expandable members of the delivery system. Alignment of the guide catheter and clot treatment device will provide the best situation for guiding of clot to the distal end of the catheter with the least amount of shearing of clot by the distal end of the catheter. Thus, general alignment of the clot treatment device and the guide catheter may improve the efficiency and quality of clot extraction and/or clot aspiration and thereby reduce breakup of the clot and distal embolization. In some embodiments, a multi-lobed expandable member may be used to center the guide catheter within

the blood vessel while allowing some blood flow past the expandable members so as to not completely occlude the blood vessel during the procedure. Various multi-lobed expandable member configurations are known in the art including but not limited to a tri-lobed expandable member as shown in Figures 10A and 10B.

[0045] In any of the clot treatment device embodiments that comprise a central tube member, the inner tube or "tether tube" may be constructed so as to have spring properties. For example, as shown in Figures 11A and 11B, the tube may be a coil or spiral cut tube so that when tension is applied, it readily elongates. A spring inner tube member may provide improved self-expansion while still providing a lumen for a guidewire, catheter or the like to be inserted therethrough. Moreover, the inner tube or "tether tube" may be constructed with a first proximal tube that is attached to the clot treatment device proximal to the radially expanding segment and a second distal tube that is attached to the clot treatment device distal to the radially expanding segment. One tube may be larger in diameter than the other so that they may be over-lapped with a portion where the smaller tube is coaxial within the larger tube and thus "telescoped" as shown in Figures 11A and 11B. In this telescoped configuration, the tubes may slide freely relative to each other. Thus, with a telescoped inner tube configuration, a guidewire lumen is maintained while allowing a large elongation without plastic deformation.

[0046] Now referring to Figure 12, in some embodiments, parts of the system that retract and/or aspirate fluid and debris may be automated. For example, the movement of the pump (e.g. syringe) plunger may have a mechanism such as a linear actuator, drive screw or the like to effect movement under electronic control. Likewise, the linear movement of the device and delivery catheter for deployment and/or retraction may also be operated by a mechanism. In some embodiments, both the pump and the catheter and device movements may be mechanized and synchronized. In addition, sensors may be incorporated into the system on either the device and/or catheters such that the system will automatically turn mechanisms on/off as desired. This automation may be further controlled by a programmable controller, computer or electronics and software as is well-known in the art of automation. In some embodiments, the system may automatically shut off aspiration when a predetermined amount of device retraction has taken place. That way, the amount of blood that is aspirated is limited. In some embodiments, a continuously aspirating pump mechanism rather than the discrete pump (e.g. syringe) as described herein may be

used. The use of a foot petal, a hand switch or an automated or sensor actuated control to limit the duration of a continuous pump may allow smooth continuous aspiration during device retraction without excessive blood being removed from the patient. This may be accomplished by having the pump operate for a relatively short duration or pulses. In some embodiments, the pump may operate for less than about 15 seconds and in other embodiments less that about 5 seconds. A diagram of such a system with a continuous aspiration pump is shown in Figure F. In some embodiments, a method of synchronized device retraction and aspiration is described wherein less than about 500cc of blood and debris are removed from the patient. In other embodiments, the device may be retracted with aspiration of between about 50cc and 400cc, in some embodiments less than about 200cc and in some embodiments less than about 100cc of blood and debris.

III. Pertinent Anatomy and Physiology

[0047] Some embodiments described here may be particularly useful for the treatment of deep vein thrombosis. (See Figures 13 and 14). Deep vein thrombosis (DVT) is a medical condition that results from the formation of a blood clot, or thrombus, within a vein. Thrombi may develop in the veins of the calves, legs, arms, pelvis or abdomen, but they may occur in other locations as well. The clot is typically formed from a pooling of blood within the vein due to abnormally long periods of rest or inactivity, e.g. when an individual is bed ridden following surgery or suffering a debilitating illness or during extended airline flights. The propensity to form clots can be also be influenced by other factors including, coagulation disorders, the presence of cancer, dehydration, hormone replacement therapy, use of birth control pills, genetic deficiencies, autoimmune disorders, and endothelial cell injury and trauma, etc. Thrombi are likely to form at the location of a stenosis (e.g., an unnatural narrowing of an artery). Clots often form near the venous valves; one-way valves that prevent the back-flow of blood as it returns to the right heart (blood is squeezed up the leg against gravity and the valves prevent it from flowing back to our feet). Clinical sequelae of DVT are significant in both the acute and chronic settings. Initial consequences include acute lower-extremity symptoms, risk of pulmonary emboli (PE) and death. Long-term consequences include recurrent DVT, lower-extremity venous hypertension, claudication, pain, swelling and ulceration, which can result in significant post-thrombotic morbidity. Potentially thromboembolic DVT usually arises in one of the large deep veins of the lower limb (e.g. iliac and femoral veins). Patients with

iliofemoral DVT tend to have marked pain and swelling and up to 50% experience pulmonary embolism.

[0048] Percutaneous access for endovascular interventions is most often achieved in the vein distal to the occluded segment. For isolated iliac DVT, an ipsilateral common femoral puncture is most appropriate. Alternatively, a retrograde approach from either the jugular, iliac vein or the contralateral femoral vein may be used for isolated iliac and femoral vein DVT. More commonly, however, patients present with more extensive iliofemoral or iliofemoral popliteal thrombosis, in which case access is best obtained from the ipsilateral popliteal vein while the patient is positioned prone. Ultrasound guidance may be used for access of the popliteal or tibial veins and for any access obtained while the patient is fully anticoagulated. Further, a micropucture technique with a 22-gauge needle and 0.014-inch guidewire may minimize bleeding complications and vessel wall trauma. Following initial access, the thrombus is crossed with a guidewire to facilitate catheter or device positioning. For a lower puncture location (i.e., closer to the feet) such as the popliteal, a suitable (e.g., less than 10 F) catheter introducer sheath (such as a Flexor® manufactured by Cook, Inc. of Bloomington, Ind.) may be introduced into the vein over a guidewire. If alternate access is done for a retrograde approach to the thrombosis, a larger introducer (up to about 22F) may be used. If a downstream access is made and then a retrograde approach to the thrombus is done, an expandable tip catheter such as that shown in Figures 20 and 21 (PCT/US13/61470) may help prevent clot or debris that may be dislodged or embolized during the procedure from traveling toward the heart. Alternatively, if a lower or upstream access to the vein and then antegrade approach to the thrombus is made, an occlusion device such as a balloon or a filtration/capture device such a distal protection device may be place downstream of the thrombus. For example, a distal protection device may inserted into the iliac or IVC for a contralateral vein. An exemplary distal protection device is the SpiderFX™ Embolic Protection Device commercially available from Covidien (Plymouth, MN).

IV. Examples

[0049] The following examples are illustrative of several embodiments of the present technology:

1. A clot treatment device for treating an embolism within a blood vessel, the clot treatment device comprising:

a support member configured to extend through a delivery catheter, wherein the support member has a proximal portion and a distal portion;

a plurality of first clot engagement members positioned about the circumference of the distal portion of the support member, wherein, in the deployed state, individual first clot engagement members extend radially outwardly with respect to the support member and have a curved portion that includes a first radially furthest apex that extends a first radial distance from the support member;

a plurality of second clot engagement members positioned about the circumference of the distal portion of the support member, wherein, in the deployed state, individual second clot engagement members have a curved portion that includes a second radially furthest apex that extends a second radial distance from the support member, and wherein the first radial distance is greater than the second radial distance;

wherein, in the deployed state, individual curved portions of the first and second clot engagement members project radially outwardly relative to the support member in a curve that has a proximally extending section which defines a proximally facing concave portion, and wherein the curved portion of the first and second clot engagement members further includes an end section that curves radially inwardly from the proximally extending section; and

wherein the clot engagement members are configured to penetrate clot material along an arcuate path and hold clot material to the clot treatment device.

2. The clot treatment device of example 1, further comprising:

a first hub positioned around the support member at a first location; and

a second hub positioned around the support member at a second location spaced apart from the first location along the support member;

wherein—

individual first clot engagement members extend from the first hub, wherein a proximal portion of the first clot engagement members are integral with the first hub; and

individual second clot engagement members extend from the second hub, wherein a proximal portion of the second clot engagement members are integral with the second hub.

3. The clot treatment device of any of examples 1 or 2 wherein:

at least one of the first radially furthest apices of the individual first clot engagement members are configured to engage the vessel wall in a deployed state; and

none of the second radially furthest apices of the individual first clot engagement members are configured to engage the vessel wall in a deployed state.

4. The clot treatment device of any of examples 1-3 wherein the first clot engagement members have a first stiffness and the second clot engagement members have a second stiffness greater than the first stiffness.

5. The clot treatment device of any of examples 1-4 wherein:

the first clot engagement members are positioned about the support member at a first location along the length of the support member; and

the second clot engagement members are positioned about the support member at a second location along the length of the support member that is spaced longitudinally apart from the first location along the support member.

6. The clot treatment device of any of examples 1-5, further comprising:

a plurality of third clot engagement members positioned about the circumference of the distal portion of the support member, wherein, in the deployed state, individual third clot engagement members extend radially outwardly with respect to the support member and have a curved portion that includes a third radially furthest apex that extends a third radial distance from the support member; and

wherein the third radial distance is substantially the same as the first radial distance.

7. The clot treatment device of example 6, further comprising:

a plurality of fourth clot engagement members positioned about the circumference of the distal portion of the support member, wherein, in the deployed state, individual fourth clot engagement members extend radially outwardly with respect to the support member and have a curved portion that includes a fourth radially furthest apex that extends a fourth radial distance from the support member; and

wherein the fourth radial distance is substantially the same as the second radial distance.

8. The clot treatment device of example 7 wherein:

the first clot engagement members are positioned at a first location along the length of the support member;

the second clot engagement members are positioned at a second location along the length of the support member that is different than the first location;

the third clot engagement members are positioned at a third location along the length of the support member that is different than the first and second locations;

the fourth clot engagement members are positioned at a fourth location along the length of the support member that is different than the first, second, and third locations.

9. The clot treatment device of any of examples 1-5 and 7, further comprising:

a plurality of third clot engagement members positioned about the circumference of the distal portion of the support member, wherein, in the deployed state, individual third clot engagement members extend radially outwardly with respect to the support member and have a curved portion that includes a third radially furthest apex that extends a third radial distance from the support member; and

wherein the third radial distance is different than the second radial distance and the first radial distance.

10. The clot treatment device of any of examples 1-5 and 7, further comprising:

a plurality of third clot engagement members positioned about the circumference of the distal portion of the support member, wherein, in the deployed state, individual third clot engagement members extend radially outwardly with respect to the support

member and have a curved portion that includes a third radially furthest apex that extends a third radial distance from the support member; and

wherein, in the deployed state, individual curved portions of the third engagement members project radially outwardly relative to the support member in a curve that has a distally extending section which defines a distally facing concave portion, and wherein the curved portion of individual third engagement members further includes an end section that curves radially inwardly from the distally extending section.

11. A treatment device for treating an embolism within a blood vessel, the clot treatment device moveable between a low-profile undeployed state and a deployed state, the clot treatment device comprising:

a support member configured to extend through a delivery catheter, wherein the support member has a proximal portion and a distal portion;

a plurality of first clot engagement members positioned about the circumference of the distal portion of the support member, wherein, in the undeployed state, individual first clot engagement members are linear and have a first length;

a plurality of second clot engagement members positioned about the circumference of the distal portion of the support member, wherein, in the undeployed state, individual second clot engagement members are linear and have a second length that is less than the first length;

wherein, in the deployed state, the individual first and second clot engagement members project radially outwardly relative to the support member in a curve that has a proximally extending section which defines a proximally facing concave portion, and

wherein the clot engagement members are configured to penetrate clot material along an arcuate path and hold clot material to the clot treatment device.

12. The clot treatment device of example 11 wherein the curved portion further includes an end section that curves radially inwardly from the proximally extending section.

13. The clot treatment device of any of examples 11-12 wherein, in the undeployed state:

individual first clot engagement members are positioned parallel to the support member; and

individual second clot engagement members positioned parallel to the support member.

14. The clot treatment device of any of examples 11-13, further comprising:

a first hub positioned around the support member at a first location; and

a second hub positioned around the support member at a second location spaced apart from the first location along the support member;

wherein—

individual first clot engagement members extend distally from the first hub in the undeployed state, wherein a proximal portion of the first clot engagement members are integral with the first hub; and

individual second clot engagement members extend distally from the second hub in the undeployed state, wherein a proximal portion of the second clot engagement members are integral with the second hub.

VI. Conclusion

[0050] The above detailed descriptions of embodiments of the present technology are for purposes of illustration only and are not intended to be exhaustive or to limit the present technology to the precise form(s) disclosed above. Various equivalent modifications are possible within the scope of the present technology, as those skilled in the relevant art will recognize. For example, while steps may be presented in a given order, alternative embodiments may perform steps in a different order. The various embodiments described herein and elements thereof may also be combined to provide further embodiments. In some cases, well-known structures and functions have not been shown or described in detail to avoid unnecessarily obscuring the description of embodiments of the present technology.

[0051] From the foregoing, it will be appreciated that specific embodiments of the technology have been described herein for purposes of illustration, but well-known structures and functions have not been shown or described in detail to avoid unnecessarily obscuring the description of the embodiments of the technology. Where the context permits, singular or plural terms may also include the plural or singular term, respectively.

[0052] Certain aspects of the present technology may take the form of computer-executable instructions, including routines executed by a controller or other data processor. In some embodiments, a controller or other data processor is specifically programmed, configured, and/or constructed to perform one or more of these computer-executable instructions. Furthermore, some aspects of the present technology may take the form of data (e.g., non-transitory data) stored or distributed on computer-readable media, including magnetic or optically readable and/or removable computer discs as well as media distributed electronically over networks. Accordingly, data structures and transmissions of data particular to aspects of the present technology are encompassed within the scope of the present technology. The present technology also encompasses methods of both programming computer-readable media to perform particular steps and executing the steps.

[0053] Moreover, unless the word "or" is expressly limited to mean only a single item exclusive from the other items in reference to a list of two or more items, then the use of "or" in such a list is to be interpreted as including (a) any single item in the list, (b) all of the items in the list, or (c) any combination of the items in the list. Additionally, the term "comprising" is used throughout to mean including at least the recited feature(s) such that any greater number of the same feature and/or additional types of other features are not precluded. It will also be appreciated that specific embodiments have been described herein for purposes of illustration, but that various modifications may be made without deviating from the technology. Further, while advantages associated with certain embodiments of the technology have been described in the context of those embodiments, other embodiments may also exhibit such advantages, and not all embodiments need necessarily exhibit such advantages to fall within the scope of the technology. Accordingly, the disclosure and associated technology can encompass other embodiments not expressly shown or described herein.

CLAIMS

I/We claim:

1. A clot treatment device for treating an embolism within a blood vessel, the clot treatment device comprising:

a support member configured to extend through a delivery catheter, wherein the support member has a proximal portion and a distal portion;

a plurality of first clot engagement members positioned about the circumference of the distal portion of the support member, wherein, in the deployed state, individual first clot engagement members extend radially outwardly with respect to the support member and have a curved portion that includes a first radially furthest apex that extends a first radial distance from the support member;

a plurality of second clot engagement members positioned about the circumference of the distal portion of the support member, wherein, in the deployed state, individual second clot engagement members have a curved portion that includes a second radially furthest apex that extends a second radial distance from the support member, and wherein the first radial distance is greater than the second radial distance;

wherein, in the deployed state, individual curved portions of the first and second clot engagement members project radially outwardly relative to the support member in a curve that has a proximally extending section which defines a proximally facing concave portion, and wherein the curved portion of the first and second clot engagement members further includes an end section that curves radially inwardly from the proximally extending section; and

wherein the clot engagement members are configured to penetrate clot material along an arcuate path and hold clot material to the clot treatment device.

2. The clot treatment device of claim 1, further comprising:

a first hub positioned around the support member at a first location; and

a second hub positioned around the support member at a second location spaced apart from the first location along the support member;

wherein—

individual first clot engagement members extend from the first hub, wherein a proximal portion of the first clot engagement members are integral with the first hub; and

individual second clot engagement members extend from the second hub, wherein a proximal portion of the second clot engagement members are integral with the second hub.

3. The clot treatment device of claim 1 wherein:

at least one of the first radially furthest apices of the individual first clot engagement members are configured to engage the vessel wall in a deployed state; and

none of the second radially furthest apices of the individual first clot engagement members are configured to engage the vessel wall in a deployed state.

4. The clot treatment device of claim 1 wherein the first clot engagement members have a first stiffness and the second clot engagement members have a second stiffness greater than the first stiffness.

5. The clot treatment device of claim 1 wherein:

the first clot engagement members are positioned about the support member at a first location along the length of the support member; and

the second clot engagement members are positioned about the support member at a second location along the length of the support member that is spaced longitudinally apart from the first location along the support member.

6. The clot treatment device of claim 1, further comprising:

a plurality of third clot engagement members positioned about the circumference of the distal portion of the support member, wherein, in the deployed state, individual third

clot engagement members extend radially outwardly with respect to the support member and have a curved portion that includes a third radially furthest apex that extends a third radial distance from the support member; and

wherein the third radial distance is substantially the same as the first radial distance.

7. The clot treatment device of claim 6, further comprising:

a plurality of fourth clot engagement members positioned about the circumference of the distal portion of the support member, wherein, in the deployed state, individual fourth clot engagement members extend radially outwardly with respect to the support member and have a curved portion that includes a fourth radially furthest apex that extends a fourth radial distance from the support member; and

wherein the fourth radial distance is substantially the same as the second radial distance.

8. The clot treatment device of claim 7 wherein:

the first clot engagement members are positioned at a first location along the length of the support member;

the second clot engagement members are positioned at a second location along the length of the support member that is different than the first location;

the third clot engagement members are positioned at a third location along the length of the support member that is different than the first and second locations;

the fourth clot engagement members are positioned at a fourth location along the length of the support member that is different than the first, second, and third locations.

9. The clot treatment device of claim 1, further comprising:

a plurality of third clot engagement members positioned about the circumference of the distal portion of the support member, wherein, in the deployed state, individual third clot engagement members extend radially outwardly with respect to the support member and have a curved portion that includes a third radially furthest apex that extends a third radial distance from the support member; and

wherein the third radial distance is different than the second radial distance and the first radial distance.

10. The clot treatment device of claim 1, further comprising:

a plurality of third clot engagement members positioned about the circumference of the distal portion of the support member, wherein, in the deployed state, individual third clot engagement members extend radially outwardly with respect to the support member and have a curved portion that includes a third radially furthest apex that extends a third radial distance from the support member; and

wherein, in the deployed state, individual curved portions of the third engagement members project radially outwardly relative to the support member in a curve that has a distally extending section which defines a distally facing concave portion, and wherein the curved portion of individual third engagement members further includes an end section that curves radially inwardly from the distally extending section.

11. A treatment device for treating an embolism within a blood vessel, the clot treatment device moveable between a low-profile undeployed state and a deployed state, the clot treatment device comprising:

a support member configured to extend through a delivery catheter, wherein the support member has a proximal portion and a distal portion;

a plurality of first clot engagement members positioned about the circumference of the distal portion of the support member, wherein, in the undeployed state, individual first clot engagement members are linear and have a first length;

a plurality of second clot engagement members positioned about the circumference of the distal portion of the support member, wherein, in the undeployed state, individual second clot engagement members are linear and have a second length that is less than the first length;

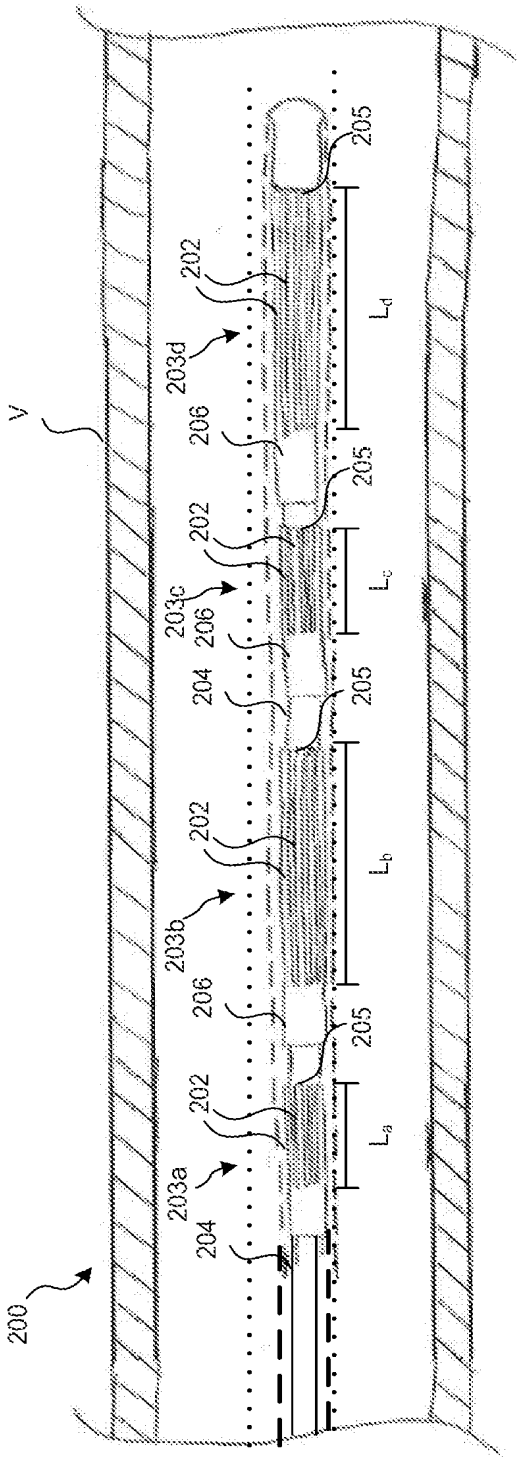
wherein, in the deployed state, the individual first and second clot engagement members project radially outwardly relative to the support member in a curve that has a proximally extending section which defines a proximally facing concave portion, and

wherein the clot engagement members are configured to penetrate clot material along an arcuate path and hold clot material to the clot treatment device.

12. The clot treatment device of claim 11 wherein the curved portion further includes an end section that curves radially inwardly from the proximally extending section.

13. The clot treatment device of claim 11 wherein, in the undeployed state:
individual first clot engagement members are positioned parallel to the support member; and
individual second clot engagement members positioned parallel to the support member.

14. The clot treatment device of claim 11, further comprising:
a first hub positioned around the support member at a first location; and
a second hub positioned around the support member at a second location spaced apart from the first location along the support member;
wherein—
individual first clot engagement members extend distally from the first hub in the undeployed state, wherein a proximal portion of the first clot engagement members are integral with the first hub; and
individual second clot engagement members extend distally from the second hub in the undeployed state, wherein a proximal portion of the second clot engagement members are integral with the second hub.


V
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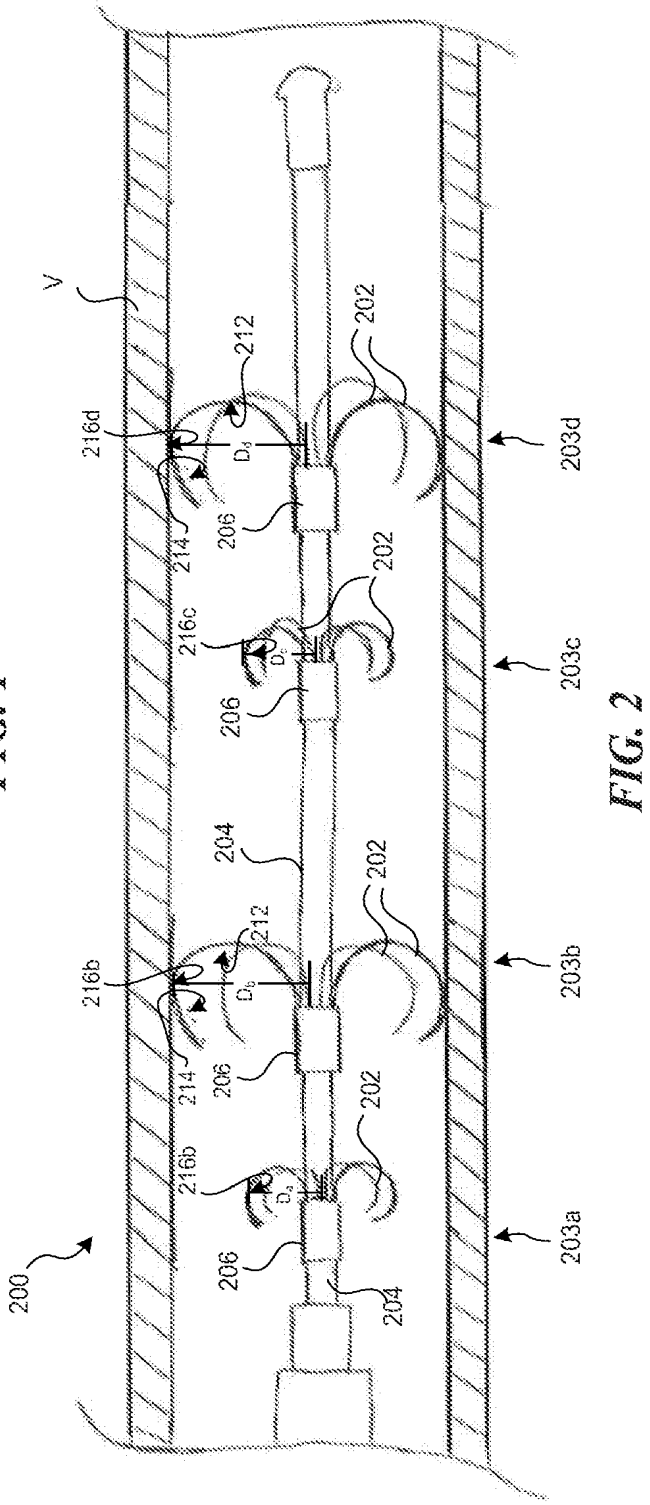
203b
203c
203d
202
204
205
206
L_a
L_b
L_c
L_d

FIG. 1


V
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202
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216c
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203b
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D_b
D_c
D_d

FIG. 2

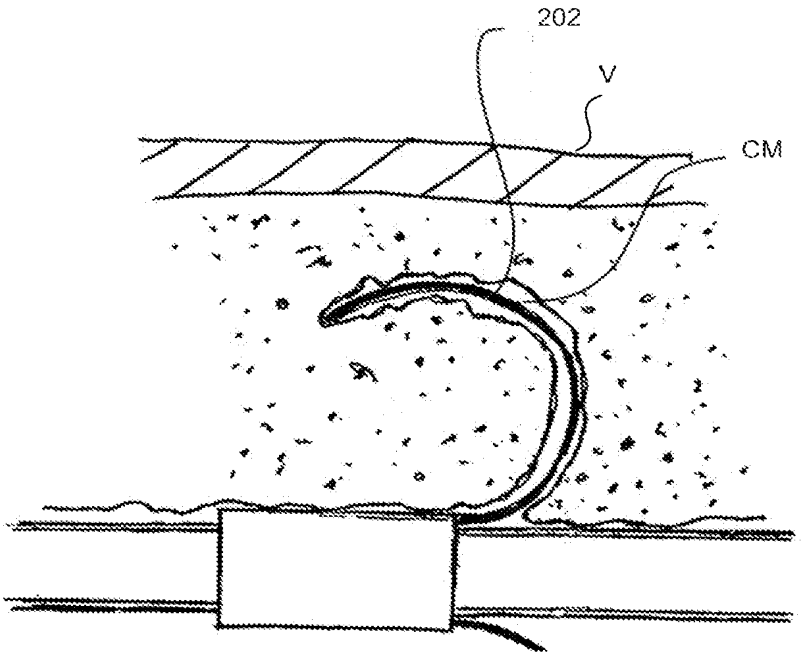

FIG. 3

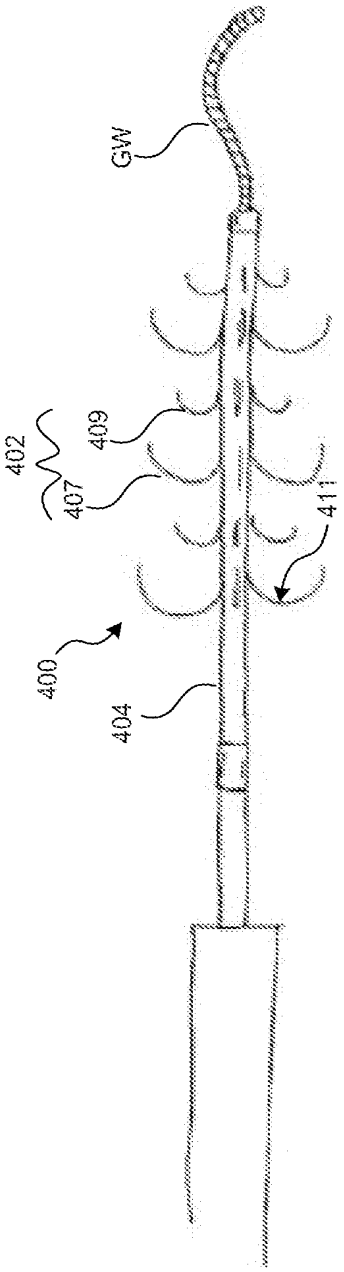

FIG. 4

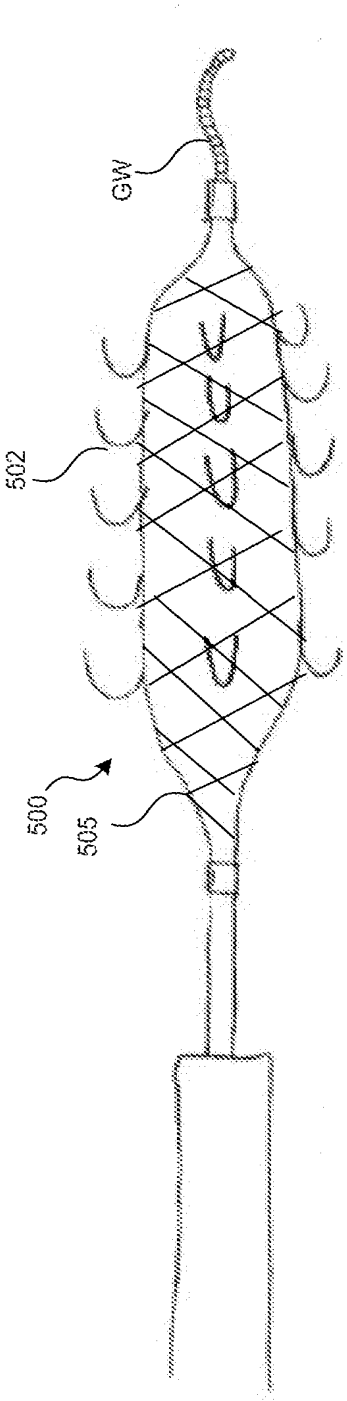

FIG. 5

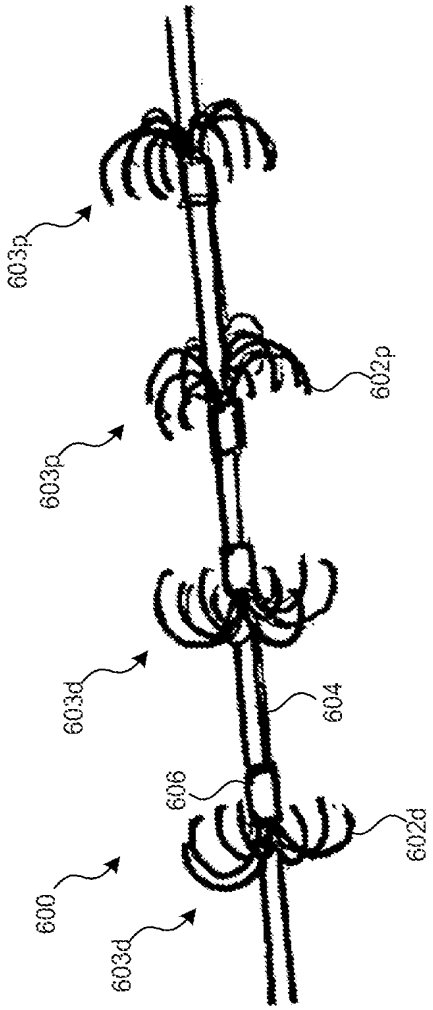
603p
602p
603p
603d
604
606
602d
600
603d

FIG. 6

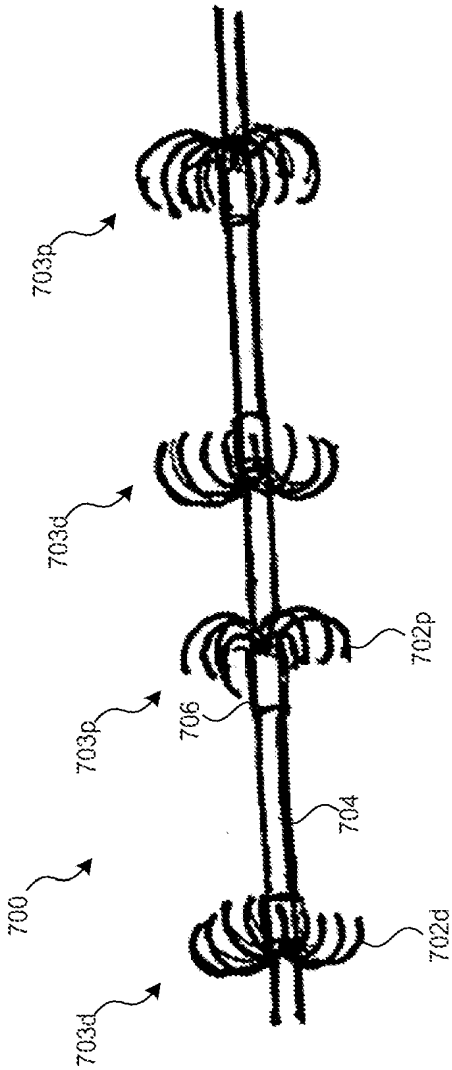
703p
703d
702p
703p
706
704
700
702d
703d

FIG. 7

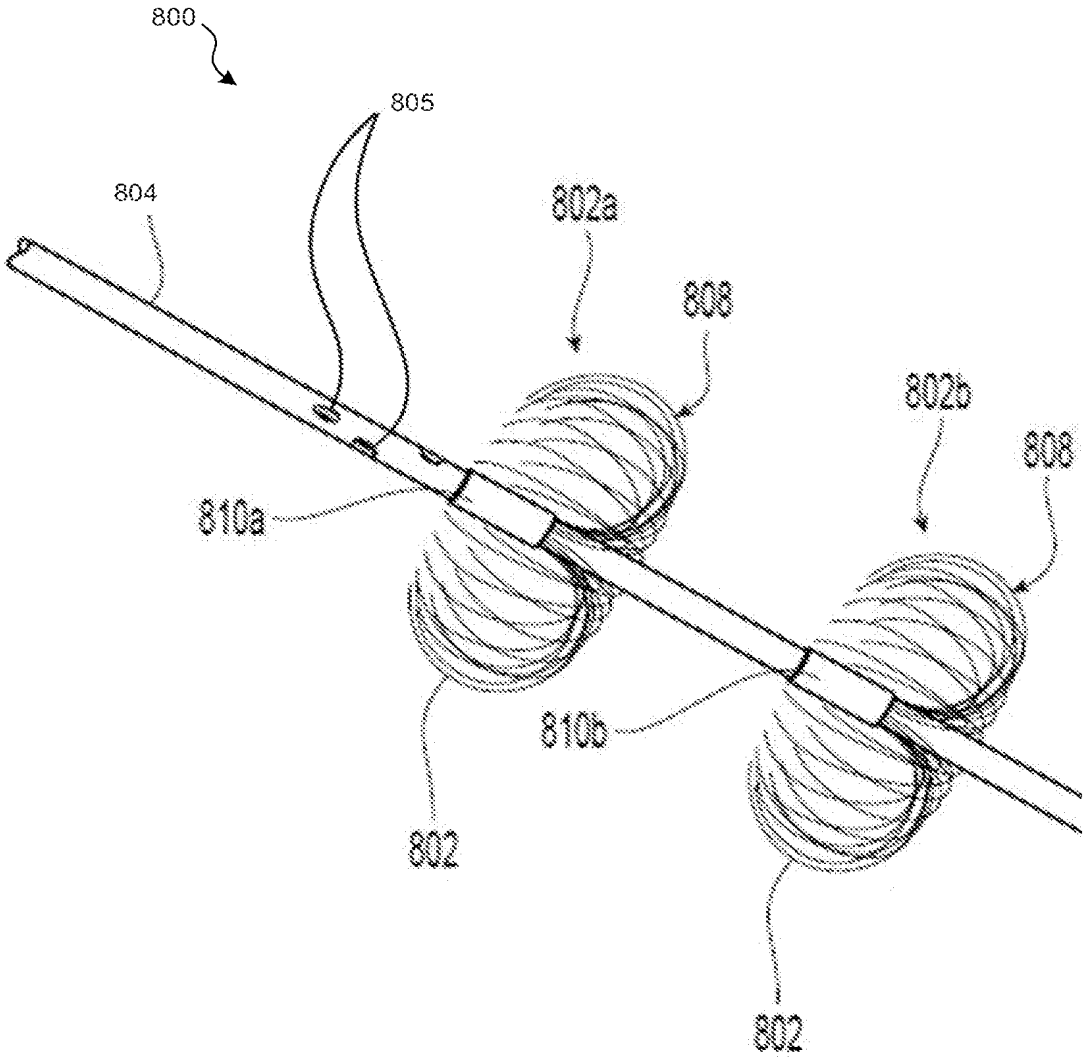

FIG. 8

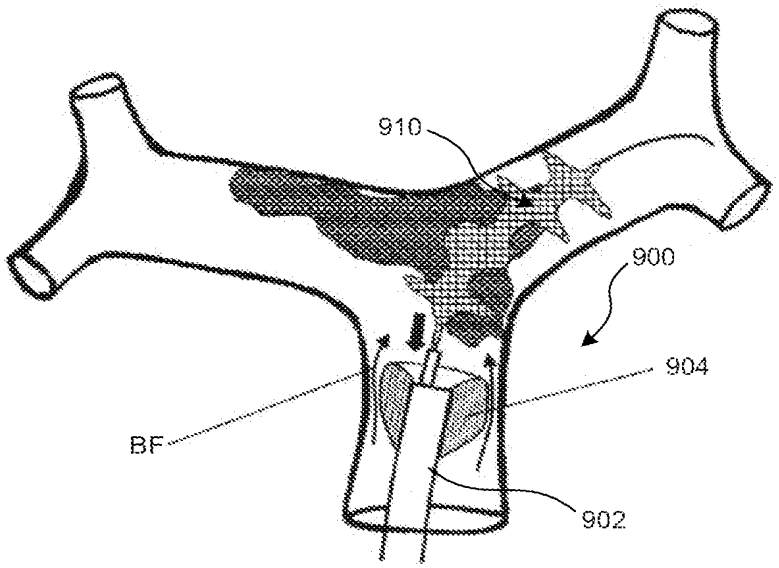

FIG. 9A

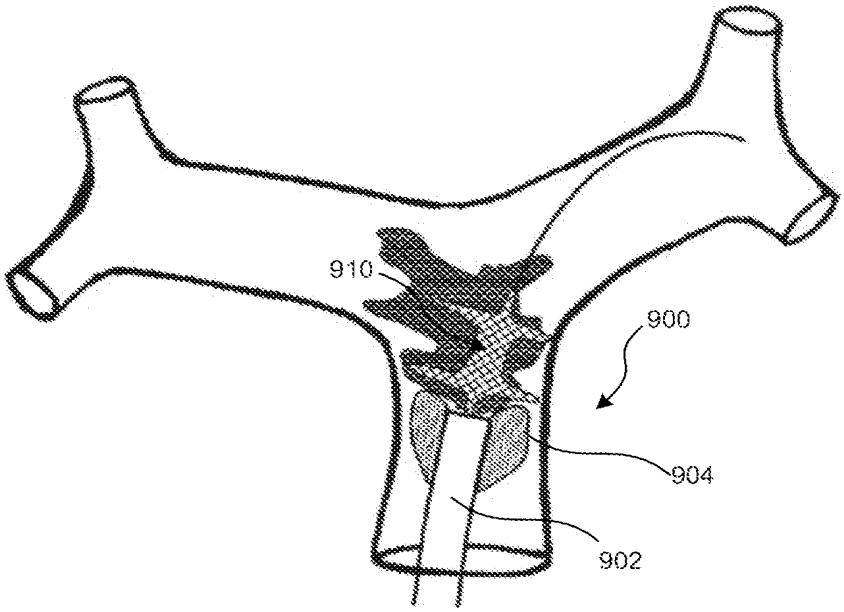

FIG. 9B

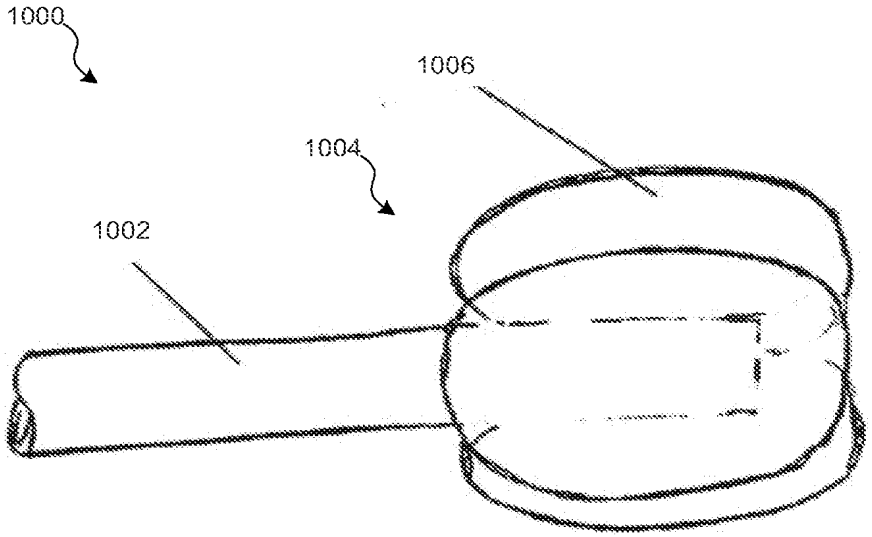

FIG. 10A

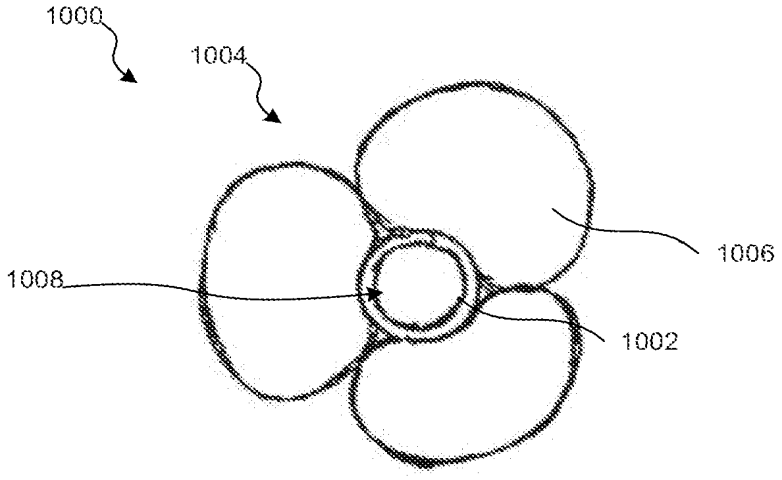

FIG. 10B

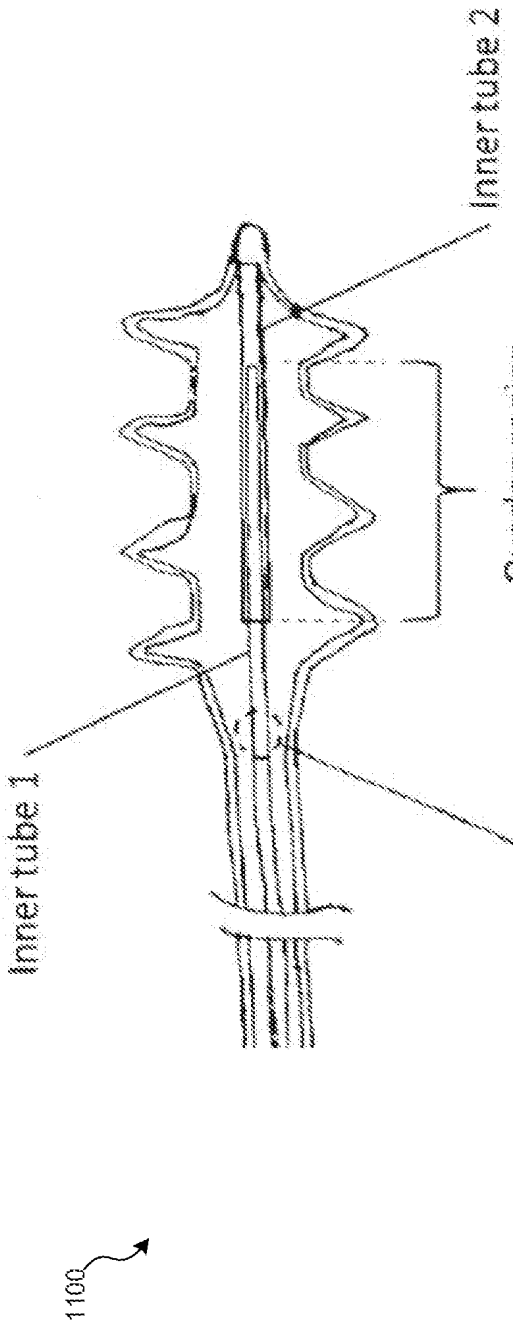

FIG. 11A

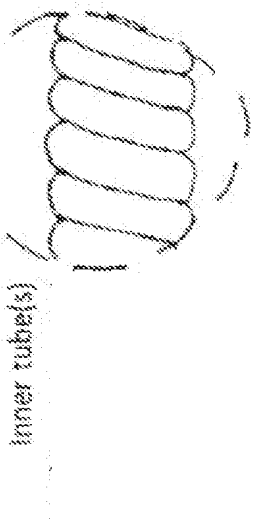

FIG. 11B

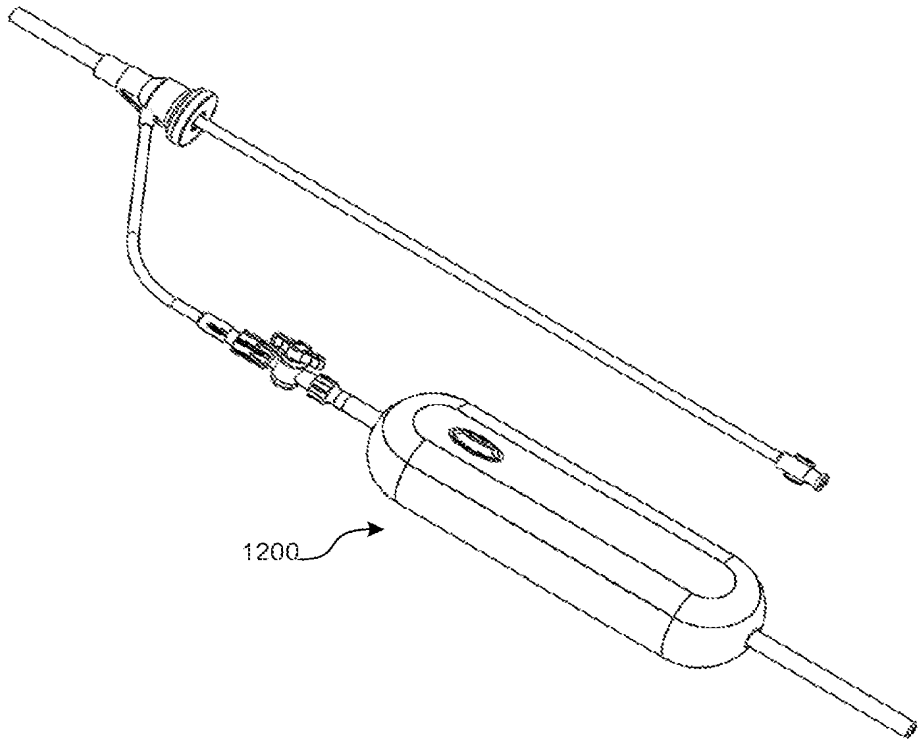

FIG. 12

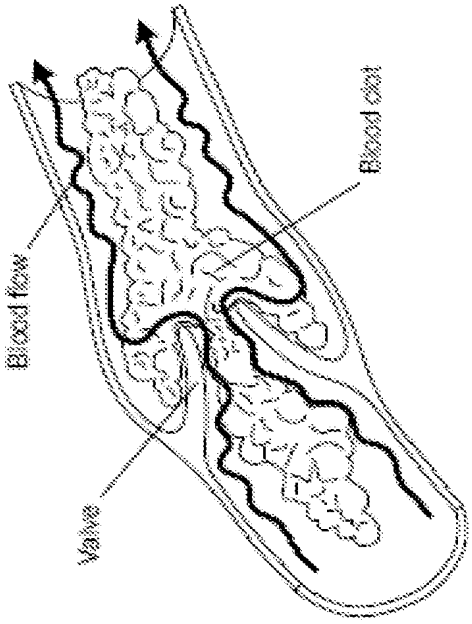
Blood flow
Blood clot
Valve

FIG. 14

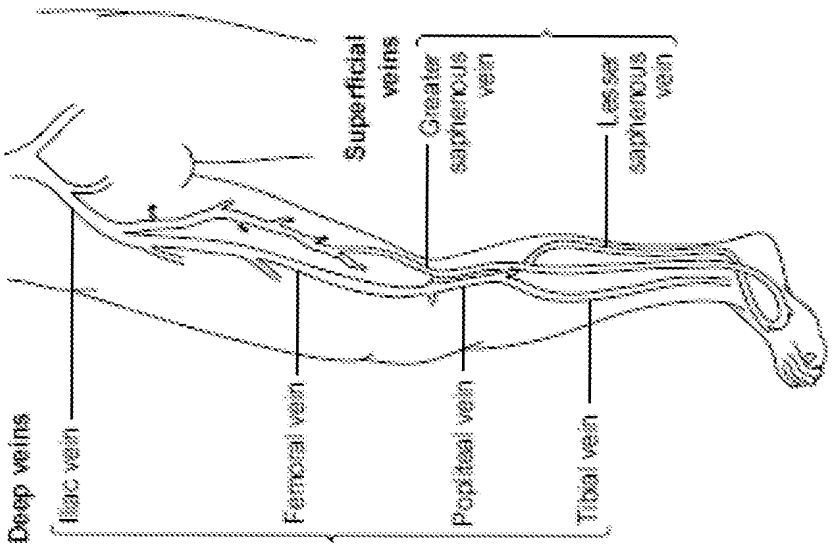
Deep veins
Iliac vein
Femoral vein
Popliteal vein
Tibial vein
Superficial veins
Greater saphenous vein
Lesser saphenous vein

FIG. 13

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2014/061645

A. CLASSIFICATION OF SUBJECT MATTER

A61B 17/22(2006.01)i, A61M 25/01(2006.01)i

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B 17/22; A61M 29/00; A61M 25/10; A61M 25/01

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
Korean utility models and applications for utility models
Japanese utility models and applications for utility models

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
eKOMPASS(KIPO internal) & Keywords: embolism, blood vessel, clot engagement member, curved portion, proximally extending section, end section, deployed state, undeployed state

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2011-0251629 A1 (GALDONIK et al.) 13 October 2011 See paragraphs [0050]-[0052], [0067]-[0068], [0072], [0075], [0076]; claims 1-3, 15, 16; and figures 1, 2.	1-14
Y	US 2008-0228209 A1 (DEMELLO et al.) 18 September 2008 See paragraphs [0069], [0070], [0072], [0073], [0075]-[0077]; and figures 7, 8.	1-14
A	US 6692504 B2 (KURZ et al.) 17 February 2004 See column 6, lines 36-62; column 7, lines 21-54; and figures 7, 8, 11-13.	1-14
A	US 2008-0167678 A1 (MORSI, HESHAM) 10 July 2008 See paragraphs [0026], [0027], [0031]-[0035], [0037], [0044]-[0047]; and figures 3, 6.	1-14
A	US 2006-0282111 A1 (MORSI, HESHAM) 14 December 2006 See paragraphs [0021]-[0025], [0031], [0035]-[0039]; and figures 1, 3.	1-14
A	US 2008-0015541 A1 (ROSENBLUTH et al.) 17 January 2008 See abstract; paragraphs [0204], [0205]; and figures 24C, 24D.	1-14

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents,such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
23 January 2015 (23.01.2015)	**23 January 2015 (23.01.2015)**

Name and mailing address of the ISA/KR
International Application Division
Korean Intellectual Property Office
189 Cheongsa-ro, Seo-gu, Daejeon Metropolitan City, 302-701, Republic of Korea
Facsimile No. ++82 42 472 3473

Authorized officer
CHANG, Bong Ho
Telephone No. +82-42-481-3353

Form PCT/ISA/210 (second sheet) (January 2015)

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
PCT/US2014/061645

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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		WO 99-56801 A3	06/04/2000

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	**FOR FURTHER ACTION**	see Form PCT/ISA/220 as well as, where applicable, item 5 below.
GWM-02-PCT6		
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/US2017/050933	11 September 2017 (11-09-2017)	12 September 2016 (12-09-2016)
Applicant		
STRYKER CORPORATION		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 5 sheets.

[X] It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

a. With regard to the **language,** the international search was carried out on the basis of:

[X] the international application in the language in which it was filed

[ ] a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))

b. [ ] This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6*bis*(a)).

c. [ ] With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. [X] **Certain claims were found unsearchable** (See Box No. II)

3. [ ] **Unity of invention is lacking** (see Box No III)

4. With regard to the **title,**

[X] the text is approved as submitted by the applicant

[ ] the text has been established by this Authority to read as follows:

5. With regard to the **abstract,**

[X] the text is approved as submitted by the applicant

[ ] the text has been established, according to Rule 38.2, by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority

6. With regard to the **drawings,**

a. the figure of the **drawings** to be published with the abstract is Figure No. 26A

[X] as suggested by the applicant

[ ] as selected by this Authority, because the applicant failed to suggest a figure

[ ] as selected by this Authority, because this figure better characterizes the invention

b. [ ] none of the figures is to be published with the abstract

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2017/050933

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 31-41
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2017/050933

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/22 A61B17/221
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	WO 2012/009675 A2 (LAZARUS EFFECT, INC.) 19 January 2012 (2012-01-19) paragraphs [0008], [0077], [0161], [0167] - [0170], [0172]; figures 10, 13B	1-14, 16-28,30 15,29
Y	US 2010/249815 A1 (JANTZEN ET AL.) 30 September 2010 (2010-09-30) paragraphs [0026], [0027], [0030]; figures 1,2	15,29
A	GB 2 498 349 A (COOK MEDICAL TECHNOLOGIES LLC) 17 July 2013 (2013-07-17) abstract; claims; figures page 8, line 12 - page 11, line 16	1,16,30

-/--

[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
26 October 2017	10/11/2017

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Giménez Burgos, R

1

Form PCT/ISA/210 (second sheet) (April 2005)

International application No
PCT/US2017/050933

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 2012/049652 A1 (ENDOGROWTH (PROPRIETARY) LTD) 19 April 2012 (2012-04-19) page 8, line 32 - page 15, line 26; figures 4-10	1,16,30
A	US 4 863 440 A (CHIN) 5 September 1989 (1989-09-05) abstract; figures	1,16,30

1

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2012009675 A2	19-01-2012	US 2014005712 A1	02-01-2014
		WO 2012009675 A2	19-01-2012
US 2010249815 A1	30-09-2010	NONE	
GB 2498349 A	17-07-2013	EP 2802275 A1	19-11-2014
		GB 2498349 A	17-07-2013
		US 2015005781 A1	01-01-2015
		WO 2013106146 A1	18-07-2013
WO 2012049652 A1	19-04-2012	US 2013226196 A1	29-08-2013
		WO 2012049652 A1	19-04-2012
		ZA 201302264 B	30-04-2014
US 4863440 A	05-09-1989	CA 1326198 C	18-01-1994
		DE 3686408 D1	17-09-1992
		DE 3686408 T2	21-01-1993
		EP 0227583 A2	01-07-1987
		JP 2529838 B2	04-09-1996
		JP S62170260 A	27-07-1987
		US 4863440 A	05-09-1989

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US2017/050933	11.09.2017	12.09.2016

International Patent Classification (IPC) or both national classification and IPC
INV. A61B17/22 A61B17/221

Applicant
STRYKER CORPORATION

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☒ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notifed the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

Name and mailing address of the ISA:	Date of completion of this opinion	Authorized Officer
European Patent Office P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Fax: +31 70 340 - 3016	see form PCT/ISA/210	Giménez Burgos, R Telephone No. +31 70 340-0

Form PCT/ISA/237 (Cover Sheet) (January 2015)

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of:

   ☑ the international application in the language in which it was filed.

   ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).

2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a))

3. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of a sequence listing:

   a. ☐ forming part of the international application as filed:

      ☐ in the form of an Annex C/ST.25 text file.

      ☐ on paper or in the form of an image file.

   b. ☐ furnished together with the international application under PCT Rule 13*ter*.1(a) for the purposes of international search only in the form of an Annex C/ST.25 text file.

   c. ☐ furnished subsequent to the international filing date for the purposes of international search only:

      ☐ in the form of an Annex C/ST.25 text file (Rule 13*ter*.1(a)).

      ☐ on paper or in the form of an image file (Rule 13*ter*.1(b) and Administrative Instructions, Section 713).

4. ☐ In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that forming part of the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of

☐ the entire international application

☒ claims Nos. 31-41

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international search *(specify)*:

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed *(specify)*:

☒ no international search report has been established for the whole application or for said claims Nos. 31-41

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

- ☐ furnish a sequence listing in the form of an Annex C/ST.25 text file, and such listing was not available to the International Searching Authority in the form and manner acceptable to it; or the sequence listing furnished did not comply with the standard provided for in Annex C of the Administrative Instructions.
- ☐ furnish a sequence listing on paper or in the form of an image file complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in the form and manner acceptable to it; or the sequence listing furnished did not comply with the standard provided for in Annex C of the Administrative Instructions.
- ☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rule 13*ter*.1(a) or (b).

☒ See Supplemental Box for further details

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	3-30
	No:	Claims	1, 2
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-30
Industrial applicability (IA)	Yes:	Claims	1-30
	No:	Claims	

2. Citations and explanations

see separate sheet

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The methods according to claims 31- 41 are methods of treatment of the living human or animal body by surgery.

The surgical methods of removing a clot from a blood vessel claimed, at least implies the surgical step of advancing a distal end of a self-rolling mechanical atherectomy apparatus through the blood vessel to the clot .

Therefore, no preliminary international examination is required to the subject matter of these method claims (see Article 34(4) and Rule 67.1 PCT).

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1 Reference is made to the following documents:

D1 WO 2012/009675 A2 (LAZARUS EFFECT, INC.)

D2 GB 2 498 349 A (COOK MEDICAL TECHNOLOGIES LLC)

D3 US 2010/249815 A1 (JANTZEN ET AL.)

D4 US 4 863 440 A (CHIN)

D5 WO 2012/049652 A1 (ENDOGROWTH (PROPRIETARY) LTD)

2 Independent claim 1, lack of novelty (Article 33(2) PCT).

The present application does not meet the criteria of Article 33(1) PCT, because the subject matter of claim 1 is not new in the sense of Article 33(2) PCT.

Document **D1** (Figs.: 13A, 13B, 13G; paragraphs [0008], [0161], [0167]-[0170] and [0172]) discloses a self-rolling mechanical atherectomy apparatus (350) for removing a clot from a vessel, comprising:

an outer tractor pusher (354) comprising a catheter having a distal end and a distal end opening (Figs.: 13B, 13G);

a tractor tube (370) comprising an outer tractor tube portion that extends distally in an un-inverted configuration and inverts into itself at a distal-facing region to form an inner tractor tube portion (Figs.: 13b, 13G),

wherein the tractor tube (370) is configured such that pulling the inner tractor tube portion proximally (paragraphs [0167]- [0170]):

compresses the outer tractor tube portion into a configuration having a column strength that resists collapsing (Figs.: 13B, 13G), and

causes a region of the outer tractor tube portion at the distal-facing region to roll over itself, unsupported, and invert into the inner tractor tube portion (Figs.: 13B, 13G) ; and

an inner tractor puller (352) coupled to the inner tractor tube portion and extending proximally within the outer tractor pusher (354).

The subject matter of claim 1 is therefore not new (Article 33(2) PCT).

3 Independent claim 16, lack of inventive step (Article 33(3) PCT).

The present application does not meet the criteria of Article 33(1) PCT, because the subject matter of claim 16 does not involve an inventive step in the sense of Article 33(3) PCT.

Document **D1** is regarded as being the prior art closest to the subject matter of claim 16, and discloses self-rolling mechanical atherectomy apparatus (350) for removing a clot from a vessels (see item 2 above), from which the subject matter of claim 16 differs in that the outer tractor is configured so that pulling the inner tractor tube portion proximally compresses into a configuration having a column strength that resists collapsing up to at least 500g of compression and extends inner tractor portion tube portion.

The present authority considers that the outer tractor portion column strength resistance claimed is merely one of several straightforward possibilities from which the skilled person would select, in accordance with circumstances, without the exercise of inventive skill, in order to prevent buckling when the catheter is pulled over the distal annulus (distal end opening).

Hence, no inventive step is present in the subject matter of claim 16.

4 Independent claim 30, lack of inventive step (Article 33(3) PCT).

The present application does not meet the criteria of Article 33(1) PCT, because the subject matter of claim 30 does not involve an inventive step in the sense of Article 33(3) PCT.

Document **D1** is regarded as being the prior art closest to the subject matter of claim 30, and discloses self-rolling mechanical atherectomy apparatus (350) for removing a clot from a vessels (see item 2 above) comprising a tractor tube formed by expandable braided wires, from which the subject matter of claim 30 differs in that the outer tractor tube portion has an expanded configuration with a distal-to-proximal facing braid angle for the expanded configuration of between about 80 and about 170 degrees; and wherein the outer tractor tube portion of the tractor tube is configured to expand to between about +/- 30% of an outer diameter of the outer tractor pusher.

The present authority considers that the outer tube portion expanded configuration claimed is merely one of several straightforward possibilities from which the skilled person would select, in accordance with circumstances, without the exercise of inventive skill, in order to be able to obtain a self-rolling (e.g., unsupported) tractor tube apparatus that will not kink or collapse or otherwise fail.

Hence, no inventive step is present in the subject matter of claim 30.

5 Dependent claims 2- 15 and 17- 29 appear to contain no features which in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect to novelty/ inventive step, since these features are also present in the atherectomy apparatus of documents **D1**- **D3** or are well known alternatives to the skilled man and here applied with no surprising effect.

Re Item VII

Certain defects in the international application

6 Independent claim 1 is not in the two-part form in accordance with Rule 6.3(b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art **D1** being placed in the preamble (Rule 6.3(b)(i) PCT) and the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).

7 The features of claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

8 Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in documents **D1**- **D3** is not mentioned in the description, nor are these documents identified therein.

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	**FOR FURTHER ACTION**	see Form PCT/ISA/220 as well as, where applicable, item 5 below.
GWM-02-PCT1		
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/US2017/029345	25 April 2017 (25-04-2017)	25 April 2016 (25-04-2016)
Applicant		
STRYKER CORPORATION		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 7 sheets.

[X] It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

a. With regard to the **language,** the international search was carried out on the basis of:

[X] the international application in the language in which it was filed

[ ] a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))

b. [ ] This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6*bis*(a)).

c. [ ] With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. [X] **Certain claims were found unsearchable** (See Box No. II)

3. [X] **Unity of invention is lacking** (see Box No III)

4. With regard to the **title,**

[X] the text is approved as submitted by the applicant

[ ] the text has been established by this Authority to read as follows:

5. With regard to the **abstract,**

[X] the text is approved as submitted by the applicant

[ ] the text has been established, according to Rule 38.2, by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority

6. With regard to the **drawings,**

a. the figure of the **drawings** to be published with the abstract is Figure No. 8a

[X] as suggested by the applicant

[ ] as selected by this Authority, because the applicant failed to suggest a figure

[ ] as selected by this Authority, because this figure better characterizes the invention

b. [ ] none of the figures is to be published with the abstract

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2017/029345

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 34-42
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [X] Claims Nos.: 34-42
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

see FURTHER INFORMATION sheet PCT/ISA/210

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [X] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1-33

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2017/029345

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/22 A61B17/221
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	GB 2 498 349 A (COOK MEDICAL TECHNOLOGIES LLC) 17 July 2013 (2013-07-17)	1-3,5, 7-16,19, 21, 23-26, 29-31, 33,62-73
A	abstract; claims; figures page 8, line 12 - page 11, line 16	43-45
Y	US 2010/249815 A1 (JANTZEN ET AL.) 30 September 2010 (2010-09-30)	1-3,5, 7-16,19, 21, 23-26, 29-31,33
	paragraphs [0026], [0027]; figures 1,2	

-/--

[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
12 January 2018	28/02/2018

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Giménez Burgos, R

3

Form PCT/ISA/210 (second sheet) (April 2005)

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 2012/049652 A1 (ENDOGROWTH (PROPRIETARY) LTD) 19 April 2012 (2012-04-19)	7-10
A	page 8, line 32 - page 15, line 26; figures 4-10	1,32,33
A	US 4 863 440 A (CHIN) 5 September 1989 (1989-09-05) abstract; figures	1
A	WO 2012/009675 A2 (LAZARUS EFFECT, INC.) 19 January 2012 (2012-01-19) paragraphs [0152], [0153], [0167] - [0172]; figures 10, 13B, 13G	1,62
Y	US 2007/149996 A1 (COUGHLIN) 28 June 2007 (2007-06-28) abstract; figures 6,7 paragraph [0032]	62-73
Y	US 2007/213765 A1 (ADAMS ET AL.) 13 September 2007 (2007-09-13) paragraphs [0050], [0083]; figures 1B, 13A,13B	66,73
Y	US 2015/190155 A1 (ULM, III) 9 July 2015 (2015-07-09) paragraph [0179]; figures 21-29	69
X,P	WO 2017/058280 A1 (GW MEDICAL LLC) 6 April 2017 (2017-04-06) the whole document	43-46, 48-51, 53-70,73

3

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2017/029345

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
GB 2498349 A	17-07-2013	EP 2802275 A1	19-11-2014
		GB 2498349 A	17-07-2013
		US 2015005781 A1	01-01-2015
		WO 2013106146 A1	18-07-2013
US 2010249815 A1	30-09-2010	NONE	
WO 2012049652 A1	19-04-2012	US 2013226196 A1	29-08-2013
		WO 2012049652 A1	19-04-2012
		ZA 201302264 B	30-04-2014
US 4863440 A	05-09-1989	CA 1326198 C	18-01-1994
		DE 3686408 D1	17-09-1992
		DE 3686408 T2	21-01-1993
		EP 0227583 A2	01-07-1987
		JP 2529838 B2	04-09-1996
		JP S62170260 A	27-07-1987
		US 4863440 A	05-09-1989
WO 2012009675 A2	19-01-2012	US 2014005712 A1	02-01-2014
		WO 2012009675 A2	19-01-2012
US 2007149996 A1	28-06-2007	NONE	
US 2007213765 A1	13-09-2007	AT 375131 T	15-10-2007
		AT 469614 T	15-06-2010
		AU 2003247676 A1	02-02-2004
		DE 60316814 T2	17-07-2008
		EP 1534178 A1	01-06-2005
		EP 1854428 A1	14-11-2007
		ES 2291689 T3	01-03-2008
		ES 2344610 T3	01-09-2010
		US 2004010280 A1	15-01-2004
		US 2007213765 A1	13-09-2007
		WO 2004006803 A1	22-01-2004
US 2015190155 A1	09-07-2015	US 2015190155 A1	09-07-2015
		US 2015190156 A1	09-07-2015
WO 2017058280 A1	06-04-2017	US 9463035 B1	11-10-2016
		US 2017086864 A1	30-03-2017
		WO 2017058280 A1	06-04-2017

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-33

Mechanical thrombectomy apparatus comprising: an elongate inversion support; a tractor; and a plurality of projections that extend from a portion of the tractor.

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2. claims: 43-61

Mechanical thrombectomy apparatus comprising: an elongate inversion support; a tractor comprising a flexible tube extending longitudinally, wherein the flexible tube comprises longitudinally alternating regions of higher and lower stiffness; and a puller coupled to a first end of the tractor.

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3. claims: 62-73

Mechanical thrombectomy apparatus comprising: an elongate inversion support; a tractor, wherein the tractor is biased to expand to have an inner diameter that is greater than the outer diameter of the elongate inversion support; in the inverted configuration and is biased to expand to have an inner diameter that is greater than the inner diameter of the elongate inversion support in the un-inverted configuration; and an elongate puller coupled to the first end of the tractor.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 34-42

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

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Continuation of Box II.2

Claims Nos.: 34-42

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guidelines C-IV, 7.2), should the problems which led to the Article 17(2) declaration be overcome.

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US2017/029345	25.04.2017	25.04.2016

International Patent Classification (IPC) or both national classification and IPC
INV. A61B17/22 A61B17/221

Applicant
STRYKER CORPORATION

1. This opinion contains indications relating to the following items:

- ☑ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☑ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☑ Box No. IV Lack of unity of invention
- ☑ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement
- ☒ Box No. VI Certain documents cited
- ☒ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notifed the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

Name and mailing address of the ISA:	Date of completion of this opinion	Authorized Officer
European Patent Office P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Fax: +31 70 340 - 3016	see form PCT/ISA/210	Giménez Burgos, R Telephone No. +31 70 340-0

Form PCT/ISA/237 (Cover Sheet) (January 2015)

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of:

   ☑ the international application in the language in which it was filed.

   ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).

2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a))

3. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of a sequence listing:

   a. ☐ forming part of the international application as filed:

      ☐ in the form of an Annex C/ST.25 text file.

      ☐ on paper or in the form of an image file.

   b. ☐ furnished together with the international application under PCT Rule 13*ter*.1(a) for the purposes of international search only in the form of an Annex C/ST.25 text file.

   c. ☐ furnished subsequent to the international filing date for the purposes of international search only:

      ☐ in the form of an Annex C/ST.25 text file (Rule 13*ter*.1(a)).

      ☐ on paper or in the form of an image file (Rule 13*ter*.1(b) and Administrative Instructions, Section 713).

4. ☐ In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that forming part of the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of

☐ the entire international application

☒ claims Nos. 34-42

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international search *(specify)*:

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed *(specify)*:

☒ no international search report has been established for the whole application or for said claims Nos. 34-42

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

- ☐ furnish a sequence listing in the form of an Annex C/ST.25 text file, and such listing was not available to the International Searching Authority in the form and manner acceptable to it; or the sequence listing furnished did not comply with the standard provided for in Annex C of the Administrative Instructions.
- ☐ furnish a sequence listing on paper or in the form of an image file complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in the form and manner acceptable to it; or the sequence listing furnished did not comply with the standard provided for in Annex C of the Administrative Instructions.
- ☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rule 13*ter*.1(a) or (b).

☒ See Supplemental Box for further details

Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees, the applicant has, within the applicable time limit:

   ☒ paid additional fees

   ☐ paid additional fees under protest and, where applicable, the protest fee

   ☐ paid additional fees under protest but the applicable protest fee was not paid

   ☐ not paid additional fees

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is

   ☐ complied with

   ☒ not complied with for the following reasons:

   see separate sheet

4. Consequently, this report has been established in respect of the following parts of the international application:

   ☐ all parts.

   ☒ the parts relating to claims Nos. 1-73

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-33, 43-73
	No:	Claims	
Inventive step (IS)	Yes:	Claims	4, 6, 17, 18, 20, 22, 27, 28, 32, 43-61
	No:	Claims	1-3, 5, 7-16, 19, 21, 23-26, 29-31, 33, 62-73
Industrial applicability (IA)	Yes:	Claims	1-33, 43-73
	No:	Claims	

2. Citations and explanations

see separate sheet

Box No. VI Certain documents cited

1. Certain published documents (Rules 43*bis*.1 and 70.10)

   and / or

2. Non-written disclosures (Rules 43*bis*.1 and 70.9)

   see form 210

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The methods according to claims 34- 42 are methods of treatment of the living human or animal body by surgery.

The surgical methods claimed, at least implies the surgical step of positioning a distal end of the thrombectomy apparatus adjacent to a clot within the vessel.

Therefore, no preliminary international examination is required to the subject matter of these method claims (see Article 34(4) and Rule 67.1 (iv) PCT).

Re Item IV

Lack of unity of invention

This Authority considers that the application does not meet the requirements of unity of invention and that there are three inventions covered by the claims indicated as follows:

claims: 1-33

Mechanical thrombectomy apparatus comprising: an elongate inversion support; a tractor; and a plurality of projections that extend from a portion of the tractor.

claims: 43-61

Mechanical thrombectomy apparatus comprising: an elongate inversion support; a tractor comprising a flexible tube extending longitudinally, wherein the flexible tube comprises longitudinally alternating regions of higher and lower stiffness; and a puller coupled to a first end of the tractor.

claims: 62-73

Mechanical thrombectomy apparatus comprising: an elongate inversion support; a tractor, wherein the tractor is biased to expand to have an inner diameter that is greater than the outer diameter of the elongate inversion support; in the inverted configuration and is biased to expand to have an inner diameter that is greater than the inner diameter of the elongate inversion support in the un-inverted configuration; and an elongate puller coupled to the first end of the tractor.

The common technical features of subjects 1- 3 is:

"A mechanical thrombectomy apparatus for removing a clot from a vessel, the apparatus comprising:

an elongate catheter having a proximal end and a distal end and a distal end opening;

a tractor comprising a flexible tube that extends distally in an un-inverted configuration within the catheter, inverts over the distal end opening of the catheter and extends proximally in an inverted configuration along the distal end of the catheter, wherein the tractor comprises a tubular wall, and wherein the tractor is configured to invert by rolling over the distal end opening of the catheter when a first end of the tractor is pulled proximally within the catheter".

These features are known from prior art document GB 2498349 A.

In particular, document GB 2498349 A (Figs.: 1- 3; page 8, line 12- page 11, line 5) discloses a mechanical thrombectomy apparatus for removing a clot from within a vessel, the apparatus comprising:

an elongate catheter (12) having a proximal end and a distal end and a distal end opening;

a tractor (14) comprising a flexible tube that extends distally in an un-inverted configuration within the catheter (12), inverts over the distal end opening of the catheter (12) and extends proximally in an inverted configuration along the distal end of the catheter (12), wherein the tractor (14) comprises a tubular wall, and wherein the tractor is configured to invert by rolling over the distal end opening of the catheter (12) when a first end (16) of the tractor (14) is pulled proximally within the catheter (12).

Therefore, the special technical features, in the sense of Rule 13.2 PCT, of the three subjects are:

for subject 1: that the mechanical thrombectomy apparatus further comprises a plurality of projections that extend from a portion of the tractor; in order to provide an improved clot grabbing and/or maceration.

for subject 2: that the mechanical thrombectomy apparatus tractor comprises a flexible tube extending longitudinally, wherein the flexible tube comprises longitudinally alternating regions of higher and lower stiffness; in order to enhance rolling of the tractor region (inverting) over the distal end

for subject 3: that the mechanical thrombectomy apparatus tractor is biased to expand to have an inner diameter that is greater than the outer diameter of the elongate inversion support; in the inverted configuration and is biased to expand to have an inner diameter that is greater than the inner diameter of the elongate inversion support in the un-inverted configuration; in order to prevent jamming and an increase resistance between the tractor and the outside of the catheter of the elongate inversion support.

It appears that between the different subjects mentioned, no same or corresponding special feature can be found apart from those already known from the prior art.

It is also submitted that the three different subjects clearly intend to solve problems of different nature.

In conclusion, there is not technical relationship between the subjects identified, and thus, the above mentioned set of claims is not so linked by a general inventive concept.

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1 Reference is made to the following documents:

D1 GB 2 498 349 A (COOK MEDICAL TECHNOLOGIES LLC)

D2 US 2010/249815 A1 (JANTZEN ET AL.)

D3 WO 2012/049652 A1 (ENDOGROWTH (PROPRIETARY) LTD)

D4 US 4 863 440 A (CHIN)

D5 WO 2012/009675 A2 (LAZARUS EFFECT, INC.)

D6 US 2007/149996 A1 (COUGHLIN)

D7 US 2007/213765 A1 (ADAMS ET AL.)

D8 US 2015/190155 A1 (ULM, III)

Subject 1: Claims 1- 33

2 Independent claim 1, lack of inventive step (Article 33(3) PCT).

The present application does not meet the criteria of Article 33(1) PCT, because the subject matter of claim 1 does not involve an inventive step in the sense of Article 33(3) PCT.

2.1 Document **D1** (Figs.: 1- 3; page 8, line 12- page 11, line 5) is regarded as being the prior art closest to the subject matter of claim 1, and discloses a mechanical thrombectomy apparatus for removing a clot from within a vessel, the apparatus comprising:

an elongate catheter (12) having a proximal end and a distal end and a distal end opening;

a tractor (14) comprising a flexible tube that extends distally in an un-inverted configuration within the catheter (12), inverts over the distal end opening of the catheter (12) and extends proximally in an inverted configuration along the distal end of the catheter (12), wherein the tractor (14) comprises a tubular wall, and wherein the tractor is configured to invert by rolling over the distal end opening of the catheter (12) when a first end (16) of the tractor (14) is pulled proximally within the catheter (12).

2.2 The subject-matter of claim 1 therefore differs from this known mechanical thrombectomy apparatus in that it further comprises: a plurality of projections that extend from a portion of the tractor that is inverted over the distal end opening of the catheter as the tractor rolls over the distal end opening of the catheter, wherein the plurality of projections do not extend from the tractor as it extends proximally in the inverted configuration along the distal end of the catheter.

2.3 The problem to be solved by the present invention may be regarded as the need for enhancing clot grabbing and/or maceration.

2.4 However, the outstanding differing features have already been employed for the same purpose in a similar mechanical thrombectomy apparatus for removing a clot from a vessel (see document **D2**: paragraphs [0026] and [0027]; and Figs.: 1 and 2).

In particular, document **D2** discloses a tractor comprising a scraping and thrombus capturing tube (20) of flexible material everted everted upon itself; and a plurality of projections (32, 34, 54) that extend from an internal portion of the eversible tractor (20).

2.5 It would be obvious to the person skilled in the art, namely when the same result is to be achieved, to include a plurality of projections extending from a portion of the tractor, as disclosed in document **D2**, with corresponding effect to the flexible tube tractor of document **D1**, thereby arriving at a mechanical thrombectomy apparatus for removing a clot from a vessel according to claim 1.

Therefore, the subject matter of claim 1 is not inventive (Article 33(3) PCT.

3 Independent claim 33, lack of inventive step (Article 33(3) PCT).

The additional technical feature included in claim 33, wherein the tractor is sufficiently soft such that without support from the catheter, the tractor collapses radially under an axial compression of less than 200g of force when inverting; is considered to come within the scope of the customary practice followed by persons skilled in the art, especially as the advantages thus achieved can readily be foreseen.

Therefore, the same reasoning applies, mutatis mutandis, to the subject-matter of the corresponding independent claim 33, which therefore is also considered not inventive.

4 Dependent claims 2, 3, 5, 7- 16, 19, 21, 23- 26, 29- 31 appear to contain no features which in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect to novelty/ inventive step, since these features are also present in the mechanical thrombectomy apparatuses of documents **D1**- **D3** or are well known alternatives to the skilled man and here applied with no surprising effect.

5 The combination of the features of claims 4, 6, 17, 18, 20, 22, 27, 28 and 32 is neither known from, nor rendered obvious by, the available prior art.

Subject 2: Claims 43-61

6 Independent claims 43, 44 and 45; positive opinion.

6.1 Document **D1** (Figs.: 1- 3; page 8, line 12- page 11, line 5) is regarded as being the prior art closest to the subject-matter of claims 43, 44 and 45, and discloses a mechanical thrombectomy apparatus for removing a clot from within a vessel, the apparatus comprising:

an elongate catheter (12) having a proximal end and a distal end and a distal end opening;

a tractor (14) comprising a flexible tube extending at least partially longitudinally within the catheter (12) to invert and extend over the distal end of the catheter; and

a puller (20) coupled to a first end of the tractor (14) and configured to pull the tractor (14) proximally to invert the tractor (14) over the distal end opening.

6.2 The subject matter of claims 43, 44 and 45 therefore differs from this known mechanical thrombectomy apparatus in that:

the tractor flexible tube comprises longitudinally alternating regions of higher and lower stiffness (3001, 3003, 3001, 3003,...), wherein the regions of higher stiffness (3001) have a stiffness that is greater than the regions of lower stiffness (3003).

6.3 The problem to be solved by the present invention may be regarded as the need for a thrombectomy apparatus that prevents jamming and also helps to grab the clots; due to the ratcheting action obtained by the variable stiffness alternating regions as they invert (roll) at the distal facing end of the elongate inversion support.

6.4 The solution to this problem proposed in claims 43, 44 and 45 of the present application are considered as involving an inventive step (Article 33(3) PCT) because the subject matter of claims 43, 44 or 45 is neither suggested in the relevant prior art, nor detailed hints towards the specific solution claimed can be seen to exist in the prior art.

7 Claims 46- 61 which are dependent claims 43, and/or 44, and/or 45 and likewise meet the requirements of the PCT with respect to novelty and inventive step.

Subject 3: Claims 62- 73

8 Independent claim 62, lack of inventive step (Article 33(3) PCT).

The present application does not meet the criteria of Article 33(1) PCT, because the subject matter of claim 1 does not involve an inventive step in the sense of Article 33(3) PCT.

8.1 Document **D1** (Figs.: 1- 3; page 8, line 12- page 11, line 5) is regarded as being the prior art closest to the subject matter of claim 1, and discloses a mechanical thrombectomy apparatus for removing a clot from within a vessel without jamming (Figs.: 1- 3), the apparatus comprising:

an elongate inversion support comprising a catheter (12) having a proximal end and a distal end and a distal end opening;

a tractor (14) comprising a flexible tube that extends distally in an un-inverted configuration (16) within the catheter (12), inverts over the distal end opening of the catheter (12) and extends proximally in an inverted configuration (18) along the distal end of the catheter (12), wherein the tractor (14) comprises a tubular wall, wherein the tractor is configured to invert by rolling over the distal end opening of the catheter (12) when a first end (16) of the tractor (14) is pulled proximally within the catheter (12) (page 10, lines 7- 11), wherein the tractor (14) is biased to expand greater than the outer diameter of the catheter (12) in the inverted configuration and biased to expand greater than the inner diameter of the catheter in the un-inverted configuration (Fig.: 2 and page 9, lines 19- 27); and

a puller (20) coupled to a first end of the tractor (14) and configured to pull the tractor proximally to invert the tractor (14) over the distal end opening page 8, line 26- page 9, line 5).

8.2 The subject matter of claim 1 therefore differs from this known mechanical thrombectomy apparatus in that the apparatus further includes a guidewire lumen extending through the elongate inversion support, puller and tractor that is configured to pass a guide wire; in order to allow the thrombectomy apparatus to more easily be positioned at the target site within the vasculature by tracking the device over a pre-inserted guidewire.

8.3 However, the outstanding differing features have already been employed for the same purpose in a similar mechanical thrombectomy apparatus for removing a clot from a vessel (see document **D6** (Figs.: 6 and 7; and paragraph [0032]) or **D5** (paragraphs [0172]; and Fig.: 13G).

8.3.1 In particular, document **D6** discloses a similar apparatus with an inversion support, puller and tractor that is configured to pass a guidewire.

In the embodiment disclosed in Fig.: 7, the elongate puller (703) has a guidewire lumen (709) such as a guidewire (708) can pass through the inversion support catheter, tractor and elongate puller (paragraph [0032]).

8.3.2 Also document **D5** discloses a similar apparatus with a puller and a tractor that is configured to pass a retrieval device (or suitably a guidewire).

In the embodiment disclosed in Fig.: 13G, the elongate puller (354) has a lumen (709) such as a retrieval device (200) can pass through the tractor and elongate puller (paragraph [0172]).

8.4 It would be obvious to the person skilled in the art, namely when the same result is to be achieved, to include an inversion support, puller and tractor that is configured to pass a guidewire, as disclosed in document **D6**, with corresponding effect to the puller and puller / tractor coupling of document **D1**, thereby arriving at a mechanical thrombectomy apparatus for removing a clot from a vessel according to claim 62.

Therefore, the subject matter of claim 62 is not inventive (Article 33(3) PCT.

9 Independent claim 63, lack of inventive step (Article 33(3) PCT).

The same reasoning applies, mutatis mutandis, to the subject matter of the corresponding independent claim 63, which therefore is also considered not inventive.

10 Dependent claims 64- 73 appear to contain no features which in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect to novelty/ inventive step, since these features are also present in the mechanical thrombectomy apparatuses of documents **D1** and **D6**- **D8** or are well known alternatives to the skilled man and here applied with no surprising effect.

Re Item VI

Certain documents cited

11 Certain published documents:

Application No Patent No	Publication date *(day/month/ year)*	Filing date *(day/month/ year)*	Priority date *(valid claim)* *(day/month/ year)*
WO 2017/058280	06/04/2017	15/02/2016	28/09/2016

Re Item VII

Certain defects in the international application

12 Independent claims 1, 32, 33, 43, 44 45 and 63 are not in the two part form in accordance with Rule 6.3(b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art being placed in the preamble (Rule 6.3(b)(i) PCT) and the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).

13 The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

14 Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in documents **D1**- **D8** is not mentioned in the description, nor are these documents identified therein.

Re Item VIII

Certain observations on the international application

15 Although the two groups of claims: 1, 32 and 33; and 43, 44, and 45 have been drafted as separate independent claims, they appear to relate effectively to the same subject matter and to differ from each other only with regard to the definition of the subject matter for which protection is sought and/or in respect of the terminology used for the features of that subject-matter.

The aforementioned groups of claims therefore lack conciseness and as such do not meet the requirements of Article 6 PCT.

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	**FOR FURTHER ACTION**	see Form PCT/ISA/220 as well as, where applicable, item 5 below.
GWM-04-PCT		
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/US2018/059607	7 November 2018 (07-11-2018)	9 November 2017 (09-11-2017)
Applicant		
STRYKER CORPORATION		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 8 sheets.

[X] It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

a. With regard to the **language,** the international search was carried out on the basis of:

[X] the international application in the language in which it was filed

[ ] a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))

b. [X] This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6*bis*(a)).

c. [ ] With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. [ ] **Certain claims were found unsearchable** (See Box No. II)

3. [X] **Unity of invention is lacking** (see Box No III)

4. With regard to the **title,**

[X] the text is approved as submitted by the applicant

[ ] the text has been established by this Authority to read as follows:

5. With regard to the **abstract,**

[X] the text is approved as submitted by the applicant

[ ] the text has been established, according to Rule 38.2, by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority

6. With regard to the **drawings,**

a. the figure of the **drawings** to be published with the abstract is Figure No. 9a

[X] as suggested by the applicant

[ ] as selected by this Authority, because the applicant failed to suggest a figure

[ ] as selected by this Authority, because this figure better characterizes the invention

b. [ ] none of the figures is to be published with the abstract

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2018/059607

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos :
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☒ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☒ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2018/059607

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/221 A61B17/34 A61M1/00
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2017/189550 A1 (STRYKER CORP [US]) 2 November 2017 (2017-11-02)	1-9, 11-15, 29-41
Y	abstract	19-28
A	paragraphs [0033], [0035] - [0036], [0049] - [0109]; figures 1-12	16-18

X	WO 2017/058280 A1 (GW MEDICAL LLC [US]) 6 April 2017 (2017-04-06)	1-18, 29-40
Y	abstract paragraphs [0014], [0015], [0043] - [0071], [0087], [0116] - [0171], [0190]; figures 1-38	19-28

	-/--	

[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
20 March 2019	28/03/2019

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Ioanovici, T

4

Form PCT/ISA/210 (second sheet) (April 2005)

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2017/303948 A1 (WALLACE MICHAEL P [US] ET AL) 26 October 2017 (2017-10-26)	1-15,41
A	abstract paragraphs [0058] - [0064], [0116] - [0148], [0159] - [0217]; figures 1-44	16-40
A	WO 2012/009675 A2 (LAZARUS EFFECT INC [US]; MARTIN BRIAN B [US]) 19 January 2012 (2012-01-19) abstract paragraphs [0167] - [0171]; figures 1-22	1-41
A	US 2005/085849 A1 (SEPETKA IVAN [US] ET AL) 21 April 2005 (2005-04-21) abstract paragraph [0083]; figures 5-46	1-41
X,P	WO 2017/210487 A1 (STRYKER CORP [US]) 7 December 2017 (2017-12-07) abstract paragraphs [0011] - [0017], [0020] - [0031], [0035] - [0088]; figures 1-10	1-4, 8-10, 13-15
X,P	WO 2018/049317 A1 (STRYKER CORP [US]) 15 March 2018 (2018-03-15) abstract paragraphs [0012], [0021] - [0036], [0054] - [0055], [0087] - [0134]; figures 1-28	1,3,4,8, 10,12, 13,15, 29-40
A	US 2011/160763 A1 (FERRERA DAVID A [US] ET AL) 30 June 2011 (2011-06-30) abstract paragraphs [0134], [0244] - [0246]; figures 2-60	1-41
A	US 2012/083868 A1 (SHRIVASTAVA SANJAY [US] ET AL) 5 April 2012 (2012-04-05) abstract paragraph [0052]; figures 1-10	1-41
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4

International application No
PCT/US2018/059607

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 2017/189591 A1 (STRYKER CORP [US]) 2 November 2017 (2017-11-02) abstract paragraph [0044]; figures 1-9	1-41

4

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2018/059607

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-15, 41

Inverting tube aparatus for removing a clot from a vessel comprising an inversion support catheter, a puller and a flexible inverting tube with a cuff at the second end

1.1. claim: 41

Inverting mechanical thrombectomy aparatus for removing a clot from a vessel comprising an inversion support catheter with a plurality of slots or cut-outs for enhancing flexibility, a puller and a flexible knitted inverting tube

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2. claims: 16, 18

Inverting tube aparatus for removing a clot from a vessel comprising an intermediate catheter, an inversion support catheter, a puller and a knitted inverting tube with filament knitted to form a plurality of interlocking loop stitched having a length between 0,5 and 10 mm

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3. claims: 17, 19-28

Inverting tube aparatus for removing a clot from a vessel comprising an inversion support catheter, a puller and a knitted inverting tube having a first and a second configuration, the knitted tube having an expanded outer diameter of 0,5-12 mm for the first region adjacent the first end in the first configuration, an inner diameter grater than 30% of an inner diameter of the inversion support catheter in the second configuration, and a second region of the knitted tube adjacent the second end has an expanded outer diameter less than the expanded outer diameter of the knitted tube region adjacent the first end and within 20% of an outer diameter of the inversion support catheter.

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4. claims: 29-40

Pre-loaded inverting mechanical thrombectomy aparatus for removing a clot from a vessel comprising an intermediate catheter, an inversion support catheter, a puller and a flexible inverting tube extending between the inversion support catheter and the intermediate catheter, wherein the puller and the inversion support catheter are releasabl held together.

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US2018/059607	07.11.2018	09.11.2017

International Patent Classification (IPC) or both national classification and IPC
INV. A61B17/221 A61B17/34 A61M1/00

Applicant
STRYKER CORPORATION

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement
- ☒ Box No. VI Certain documents cited
- ☒ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notifed the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

Name and mailing address of the ISA:	Date of completion of this opinion	Authorized Officer
European Patent Office P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Fax: +31 70 340 - 3016	see form PCT/ISA/210	Ioanovici, T Telephone No. +31 70 340-0

Form PCT/ISA/237 (Cover Sheet) (January 2015)

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of:

   ☑ the international application in the language in which it was filed.

   ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).

2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a))

3. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of a sequence listing:

   a. ☐ forming part of the international application as filed:

      ☐ in the form of an Annex C/ST.25 text file.

      ☐ on paper or in the form of an image file.

   b. ☐ furnished together with the international application under PCT Rule 13*ter*.1(a) for the purposes of international search only in the form of an Annex C/ST.25 text file.

   c. ☐ furnished subsequent to the international filing date for the purposes of international search only:

      ☐ in the form of an Annex C/ST.25 text file (Rule 13*ter*.1(a)).

      ☐ on paper or in the form of an image file (Rule 13*ter*.1(b) and Administrative Instructions, Section 713).

4. ☐ In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that forming part of the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

Box No. II Priority

1. ☒ The validity of the priority claim has not been considered because the International Searching Authority does not have in its possession a copy of the earlier application whose priority has been claimed or, where required, a translation of that earlier application. This opinion has nevertheless been established on the assumption that the relevant date (Rules 43*bis*.1 and 64.1) is the claimed priority date.

2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:

Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees, the applicant has, within the applicable time limit:

   ☒ paid additional fees

   ☐ paid additional fees under protest and, where applicable, the protest fee

   ☐ paid additional fees under protest but the applicable protest fee was not paid

   ☐ not paid additional fees

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is

   ☐ complied with

   ☒ not complied with for the following reasons:

   see separate sheet

4. Consequently, this report has been established in respect of the following parts of the international application:

   ☐ all parts.

   ☒ the parts relating to claims Nos. 1-41

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	2, 5, 7-9, 12, 15, 17-28, 30-33, 35-40
	No:	Claims	1, 3, 4, 6, 10, 11, 13, 14, 16, 29, 34, 41
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-41
Industrial applicability (IA)	Yes:	Claims	1-41
	No:	Claims	

2. Citations and explanations

see separate sheet

Box No. VI Certain documents cited

1. Certain published documents (Rules 43*bis*.1 and 70.10)

   and / or

2. Non-written disclosures (Rules 43*bis*.1 and 70.9)

   see form 210

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re Item IV

Lack of unity of invention

This Authority considers that the application does not meet the requirements of unity of invention and that there are 4 inventions covered by the claims indicated as follows:

The common matter linking together the independent claims (1,15,41), 16, 19 and (29,34) is the following: inverting apparatus for removing a clot from a vessel comprising: an inversion support catheter, a puller within the inversion support catheter and a flexible tube extending over the inversion support catheter.

This common matter does not comprise a single general inventive concept, based on same or corresponding technical features, because D3 (US2017/0303948) discloses an inverting apparatus for removing a clot from a vessel (abstract) comprising: an inversion support catheter (4113, fig.41), a puller (4105) within the inversion support catheter (fig.41) and a flexible tube (4103) extending over the inversion support catheter (fig.41).

Moreover independent claims (1,15,41), 16, 19 also have in common the fact that the flexible tube is configured to be pulled proximally by pulling the puller and the flexible tube inverts over the distal end and into the inversion support catheter, and this features are also disclosed in D3 (see para.[0208],fig.4,41)

Hence, the following separate inventions or groups of inventions are not so linked as to form a single general inventive concept:

Group 1. claims 1-15

Inverting tube apparatus for removing a clot from a vessel comprising an inversion support catheter, a puller and a flexible inverting tube with a cuff at the second end

Subgroup 1.1. claim 41

Inverting mechanical thrombectomy apparatus for removing a clot from a vessel comprising an inversion support catheter with a plurality of slots or cut-outs for enhancing flexibility, a puller and a flexible knitted inverting tube

Claim 41 has been grouped together with group 1 because the subject-matter of this claim is disclosed in D1.

Group 2. claims: 16, 18

Inverting tube apparatus for removing a clot from a vessel comprising an intermediate catheter, an inversion support catheter, a puller and a knitted inverting tube with filament knitted to form a plurality of interlocking loop stitched having a length between 0,5 and 10 mm

Group 3. claims: 17, 19-28

Inverting tube apparatus for removing a clot from a vessel comprising an inversion support catheter, a puller and a knitted inverting tube having a first and a second configuration, the knitted tube having an expanded outer diameter of 0,5-12 mm for the first region adjacent the first end in the first configuration, an inner diameter greater than 30% of an inner diameter of the inversion support catheter in the second configuration, and a second region of the knitted tube adjacent the second end has an expanded outer diameter less than the expanded outer diameter of the knitted tube region adjacent the first end and within 20% of an outer diameter of the inversion support catheter.

Claim 17 was grouped together with group 3 because it also refers to the knitted tube inner diameter relative to the inversion support catheter outer diameter.

Group 4. claims: 29-40

Pre-loaded inverting mechanical thrombectomy apparatus for removing a clot from a vessel comprising an intermediate catheter, an inversion support catheter, a puller and a flexible inverting tube extending between the inversion support catheter and the intermediate catheter, wherein the puller and the inversion support catheter are releasably held together.

Remaining technical features of group 1:

An inverting tube apparatus comprising: a flexible tube having a first end coupled at a distal end region of the puller and a second end comprising a cuff that is less flexible that a region of the flexible tube adjacent to the cuff. The cuff is tapered at the proximal facing end.

Problem: The remaining technical features of group 1 solve the problem of how to prevent the flexible tube from rolling completely inside the inversion support catheter

Remaining technical features of group 2:

An inverting tube apparatus comprising: an intermediate catheter; a knitted tube extending over the inversion support catheter, the knitted tube having a first end coupled at a distal end region of the puller and a second end that is free,wherein the knitted tube comprises a filament knitted to form a plurality of interlocking loop stitches, and wherein each loop stitch has a stitch length that is between 0.5mm and 10mm.

Problem: The remaining technical features of group 2 solve the problem of how to improve grabbing and removal of the clot.

Remaining technical features of group 3:

An inverting tube apparatus comprising: a knitted tube extending over the inversion support catheter in a first configuration, the knitted tube having a first end coupled to a distal end region of the puller, and a second end that is free to move relative to the inserting support catheter; wherein the knitted tube in the first configuration has an expanded outer diameter that is between 0.5 mm and 12 mm for a first region of the knitted tube that is adjacent to the first end, and the knitted tube in the second configuration has an inner diameter that is greater than 30% of an inner diameter of the inversion support catheter, and wherein a second region of the knitted tube adjacent to the second end has an expanded outer diameter that is less than the expanded outer diameter of the region of the knitted tube adjacent to the first end and within 20% of an outer diameter of the inversion support catheter.

Problem: The remaining technical features of group 3 solve the problem of how to snuggly fit the knitted tube over the inversion support catheter and provide expansion only at the distal region.

Remaining technical features of group 4:

A pre-loaded inverting mechanical thrombectomy apparatus configured to be delivered through a tortious anatomy, the apparatus comprising: an intermediate catheter having a distal end; an inversion support catheter extending distally from a lumen of the intermediate catheter, the inversion support catheter having a distal end and a distal end opening; a puller extending distally within the inversion support catheter; and a flexible tube extending proximally from a distal end region of the puller and between the intermediate catheter and the inversion support catheter,wherein the puller extends from the distal end of the intermediate catheter and the distal end opening of the inversion support catheter; and wherein the distal end opening of the inversion support is held within the lumen of the intermediate catheter, and wherein the flexible tube extends between the inversion support catheter and the intermediate catheter, and wherein the puller and inversion support catheter are releasably held together so that they move together while advancing distally within a vessel lumen.

Problem: The remaining technical features of group 4 solve the problem of how to prevent vessel wall damage from the flexible tube during tracking and prevent compressive force on the elongate inversion support.

Consequently, the remaining features of Group 1, Group 2, Group 3 and Group 4 are different. As the problems they solve are also different, these features are not corresponding either.

As the claims comprise neither the same, nor corresponding special technical features, the technical relationship between the subject matter of the claims required by Rule 13.1 PCT is lacking and the claims are not so linked as to form a single general inventive concept. The application does not fulfil the requirement for unity of invention in the sense of Rules 13.1 and 13.2 PCT.

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents:

D1 WO 2017/189550 A1 (STRYKER CORP [US]) 2 November 2017 (2017-11-02)

D2 WO 2017/058280 A1 (GW MEDICAL LLC [US]) 6 April 2017 (2017-04-06)

D3 US 2017/303948 A1 (WALLACE MICHAEL P [US] ET AL) 26 October 2017 (2017-10-26)

D4 WO 2012/009675 A2 (LAZARUS EFFECT INC [US]; MARTIN BRIAN B [US]) 19 January 2012 (2012-01-19)

D5 US 2005/085849 A1 (SEPETKA IVAN [US] ET AL) 21 April 2005 (2005-04-21)

D6 WO 2017/210487 A1 (STRYKER CORP [US]) 7 December 2017 (2017-12-07)

D7 WO 2018/049317 A1 (STRYKER CORP [US]) 15 March 2018 (2018-03-15)

D8 US 2011/160763 A1 (FERRERA DAVID A [US] ET AL) 30 June 2011 (2011-06-30)

D9 US 2012/083868 A1 (SHRIVASTAVA SANJAY [US] ET AL) 5 April 2012 (2012-04-05)

D10 WO 2012/049652 A1 (ENDOGROWTH PROPRIETARY LTD [ZA]; SMITH JAMES [ZA]) 19 April 2012 (2012-04-19)

D11 US 2014/155980 A1 (TURJMAN ALEXIS [US] ET AL) 5 June 2014 (2014-06-05)

D12 WO 2017/189591 A1 (STRYKER CORP [US]) 2 November 2017 (2017-11-02)

GROUP 1

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT.

D1 (abstract; paragraphs [0033], [0035] - [0036], [0049] - [0109]; figures 1-12) discloses:

An inverting tube apparatus for removing a clot from a vessel (abstract), the apparatus comprising:
an inversion support catheter (409,509,1011,4113, fig.4,10,41);
a puller (407,507,1003,4105) within a lumen of the inversion support catheter (fig. 4,10,41); and
a flexible tube (406,503,1007,4103) extending over a distal end of the inversion support catheter, the flexile tube having a first end coupled at a distal end region of the puller (fig.4,10,41) and a second end comprising a cuff (cuff 404,414,1006, fig. 4,10) that is less flexible (it is implicit that adding a cuff or a polymer material on the flexible tube will make that area less flexible) that a region of the flexible tube adjacent to the cuff (para.[0084.],[0097]), wherein the flexible tube is configure to be pulled proximally into the inversion support catheter by pulling the puller proximally so that the flexible tube rolls and inverts over a distal end of the inversion support catheter (para.[0049]).

Moreover claims 1 is also disclosed in D2 (see cuff in fig.2D,12,16,20A), D6 (intermediate document published on the 07.12.2017 and having the priority of 03.06.2016; see cuff in fig.4A,4B,10A,10B) and D7 (intermediate document published on the 15.03.2018 and having the priority of 12.09.2016; see cuff in fig.3A,8A,15B).

Furthermore D6 and D7 also disclose the subject-matter of claim 15 because both of these intermediate documents disclose a tapered cuff (D6: fig.7A and para.[0081], fig. 8B and para.[0086]; D7: fig.3A and para.[0087], fig.8A and para.[0107]-[0108], fig.15B and para.[0124]). Therefore also claim 15 lacks novelty.

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 41 is not new in the sense of Article 33(2) PCT.

D1 (abstract; paragraphs [0033], [0035] - [0036], [0049] - [0109]; figures 1-12) discloses:

An inverting mechanical thrombectomy apparatus for removing a clot from a vessel configured to be delivered through a tortious anatomy (abstract,para.[0061]), the apparatus comprising:
an inversion support catheter (409,509,700,1011,4113, fig.4,7,10,41) extending distally, the inversion support catheter having a distal end and a distal end opening (411, 707, fig.4,7,10,41), the inversion support catheter comprising a plurality of slots or cut-out regions along its length to enhance flexibility while maintaining column strength such that the inversion support catheter is able to withstand at least about 500g of compressive force (para.[0053]-[0054],[0079]-[0081],fig.7);
a puller (407,507,713,1003,4105) extending distally within the inversion support catheter (fig.4,7,10,41); and
a flexible tube (406,503,711,1007,4103) extending proximally from a distal end region of the puller (fig.4,7,10,41),
wherein the flexible tube comprises a knitted material that is held in compression along an outside region of the inversion support catheter and inverts over the distal end opening of the inversion support catheter and couples to the puller, and
wherein pulling the puller proximally causes the flexible tube to roll from the outside region of the inversion support catheter, over the distal end opening and invert into the inversion support catheter (para.[0049],[0061],[0065],fig.4,7,10,41).

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 15 does not involve an inventive step in the sense of Article 33(3) PCT.

As seen above in relation to claim 1, D1 discloses the inverting tube apparatus of claim 1, but fails to disclose the additional technical feature present in claim 15: the cuff tapered at the proximal facing end. The objective problem to be solved by a proximally tapered cuff could be defined as how to better assemble the different components of an inverting tube apparatus. Even though D1 does not disclose that the cuff may be tapered this modification is a normal design option for the skilled person in the art depending on the geometrical space requirements of the cuff, the cuff tapering proximally inwards facilitates assembly with an outer catheter, and the cuff tapering proximal outwards facilitates assembly with an inner catheter. Moreover stiffer proximal tapering of a flexible tractor tube is also disclosed in D2 (see para. [0146], fig.13) for permitting assembly with a pull wire and a guidewire. Therefore the skilled person would envisage such a tapered cuff for the D1 inverting apparatus without requiring any inventive skill.

Furthermore it is possible to start inventive step objections for claim 15 starting from any of the documents D1-D3, and at the same time also claim 1 lacks an inventive step starting from D3 which fails to disclose the cuff that is an obvious modification as it can be seen from D1 and D2.

Dependent claims 2-14 do not appear to contain any additional features which, in combination with the features of any claim to which it refers, meet the requirements of the PCT in respect of novelty and/or inventive step. The technical features of these claims are either disclosed in D1-D12 (D6 and D7 are only relevant for novelty because they are intermediate documents) or are minor constructional detail changes. Some examples of the disclosed features can be seen below:

Claim 3: D1 para.[0069].

Claim 5: D2 fig.13A.

Claim 6: D1 fig.10.

Claims 10-11: D1 para.[0101].

Claim 13: D1 para.[0049].

Claim 14: D1 para.[0097].

GROUP 2

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 16 is not new in the sense of Article 33(2) PCT.

D2 discloses:

An inverting tube apparatus for removing a clot from a vessel (para.[0014]), the apparatus comprising:
an intermediate catheter (outer catheter, para.[0043],[0055]);
an inversion support catheter (inner catheter, para.[0043],[0055]) within a lumen of the intermediate catheter;
a puller within a lumen of the inversion support catheter (para.[0056],[0057]); and
a knitted (para.[0059]) tube extending over the inversion support catheter (tractor, para.[0055]), the knitted tube having a first end coupled at a distal end region of the puller and a second end that is free (fig.12),
wherein the knitted tube is configured to be pulled proximally into the inversion support catheter by pulling the puller proximally so that the knitted tube rolls and inverts over a distal end of the inversion support catheter (para.[0056]),
wherein the knitted tube comprises a filament knitted to form a plurality of interlocking

loop stitches (para.[0048]), and
wherein each loop stitch has a stitch length that is between 0.5mm and 10mm (woven material pore size in the range of 0.05 and 1 mm, para.[0048]).

Furthermore the claimed value range not disclosed by D2 would still not be inventive in view of D8 (cell length of 2 mm, para.[0134],[0244]-[0246]), D9 (cell size of 3.5x2.5 mm, para.[0052]) or D11 (cell side of 1.8 mm, para.[0264]-[0265], fig.41) which all discloses similar cell sizes for enhancing gripping or macerating of blood clots.

Dependent claims 17-18 do not appear to contain any additional features which, in combination with the features of any claim to which it refers, meets the requirements of the PCT in respect of novelty and/or inventive step. The technical features of these claims are either disclosed in D1-D12 (D6 and D7 are only relevant for novelty because they are intermediate documents) or are minor constructional detail changes.

GROUP 3

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 19 does not involve an inventive step in the sense of Article 33(3) PCT.

D2 discloses:

An inverting tube apparatus for removing a clot from a vessel (para.[0014]), the apparatus comprising:
an inversion support catheter (inner catheter, para.[0043],[0055]);
a puller within a lumen of the inversion support catheter (para.[0056],[0057]); and
a knitted (para.[0059]) tube extending over the inversion support catheter in a first configuration (tractor, para.[0055]), the knitted tube having a first end coupled to a distal end region of the puller, and a second end that is free to move relative to the inserting support catheter (fig.12), wherein the knitted tube is configure to be pulled proximally into the inversion support catheter by pulling the puller proximally so that the knitted tube rolls and inverts over a distal end of the inversion support catheter into a second configuration within the inversion support catheter (para.[0056]);
further wherein the knitted tube in the first configuration has an expanded outer diameter that is between 0.5 mm and 12 mm (3-7mm, para.[0158]; for use in vessels having a 4-8 mm ID para.[0160]; woven tractor expands to an outer diameter 1.5 times greater than the catheter inner diameter when unconstrained, para.[0058]; expanded diameter between 1.3 and 10 times the catheter inner diameter, para. [0120]) for a first region of the knitted tube that is adjacent to the first end (the end coupled to the puller), and the knitted tube in the second configuration (rolled inside

the inversion support catheter) has an inner diameter that is greater than 30% of an inner diameter of the inversion support catheter (para.[0056])~~, and wherein a second region of the knitted tube adjacent to the second end has an expanded outer diameter that is less than the expanded outer diameter of the region of the knitted tube adjacent to the first end and within 20% of an outer diameter of the inversion support catheter.~~

The technical effect given by the missing technical features is that the second region reduced diameter prevents inversion of the knitted tube during placement of the apparatus before the puller is actuated.

The objective problem to be solved can be therefore formulated as how to increase safety for a clot removing inverting tube apparatus.

D1 from the same technical field discloses a proximal tractor end (414,1006) which is releasably adhered/locked to the outer diameter of the catheter (para.[00070], [00084]) for preventing the tractor from premature deploying and expanding (para. [00061],[00068]-[00072],[00084], fig.4B,10A-10C).

Considering that D1 solves the aforementioned problem it would be obvious for the skilled person in the art to combine the teachings of D1 with D2 and therefore obtaining the claimed apparatus.

Dependent claims 20-28 do not appear to contain any additional features which, in combination with the features of any claim to which it refers, meets the requirements of the PCT in respect of inventive step. The technical features of these claims are either disclosed in D1-D5 or D8-D12 or are minor constructional detail changes. Some examples of the disclosed features can be seen below:

Claim 20: D2 cuff in fig.2D,12,16,20A.

Claim 21: D2 fig.16-17.

Claim 25: D2 woven material pore size in the range of 0.05 and 1 mm, para.[0048].

GROUP 4

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 29 is not new in the sense of Article 33(2) PCT.

D2 discloses:

A pre-loaded (para.[0015],[0050],[0144],[0190]) inverting mechanical thrombectomy apparatus for removing a clot from a vessel (para.[0014]) configured to be delivered through a tortious anatomy (para.[0047]), the apparatus comprising:
an intermediate catheter having a distal end (outer catheter, para.[0043],[0055],[0134]

fig.6,12);
an inversion support catheter (inner catheter, para.[0043],[0055],[0134]) within a lumen of the intermediate catheter (fig.6,12), the inversion support catheter having a distal end and a distal end opening;
a puller (para.[0056],[0057]) extending within the inversion support catheter; and
a flexible tube (tractor, para.[0055]) extending proximally from a distal end region of the puller so that a distal-facing face of the puller extends distally beyond the flexible tube (fig.6),
wherein the puller extends from the distal end of the intermediate catheter and the distal end opening of the inversion support catheter (fig.6,12); and wherein the distal end opening of the inversion support is held within the lumen of the intermediate catheter (the inner catheter with the tractor tube are held within the outer catheter before deployment,para.[0055]), and wherein the flexible tube extends between the inversion support catheter and the intermediate catheter (fig.6-9,12).

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 34 is not new in the sense of Article 33(2) PCT.

The supplementary features (when compared to claim 29) of claim 34 are also disclosed in D2: puller and inversion support catheter are releasably held together during insertion of the apparatus before deployment (para.[0055],[0092],[0149]).

Moreover also D1 discloses a pre-loaded tractor (para.[00093],[000105]) comprising all the features of claims 29 and 34 (fig.8D,11, para.[00043],[00046]-[00047],[00079], [00099]-[000106]).

Dependent claims 30-33 and 35-40 do not appear to contain any additional features which, in combination with the features of any claim to which it refers, meets the requirements of the PCT in respect of novelty and/or inventive step. The technical features of these claims are either disclosed in D1-D12 (D6 and D7 are only relevant for novelty because they are intermediate documents) or are minor constructional detail changes. Some examples of the disclosed features can be seen below:

Claim 30,35: D1 para.[000107].

Claim 31,36: D2 para.[0059]; D1 para.[0036].

Claim 33: D2 para.[0055],[0092],[0149]; D1 fig.8D,11, para.[00043],[00046]-[00047], [00079],[00099]-[000106]

Re Item VI

Certain documents cited

Certain published documents

Application No Patent No	Publication date *(day/month/ year)*	Filing date *(day/month/ year)*	Priority date *(valid claim)* *(day/month/year)*
WO2017/210487	07/12/2017	01/06/2017	03/06/2016
WO2018/049317	15/03/2018	11/09/2017	12/09/2016

Re Item VII

Certain defects in the international application

Claim 36 send with the request under Article 91 seems to contain an obvious error in the dependency, as it should be dependent on claims 34 or 35 for not creating problems with added subject-matter (Article 19(2)/Article 34(2)(b) PCT).

Claim 37 send with the request under Article 91 seems to contain an obvious error in the dependency, it should be dependent on claim 34 for not creating problems with added subject-matter (Article 19(2)/Article 34(2)(b) PCT).

The present application does not meet the requirements of Rule 6.3(b) PCT regarding the use of the two-part form in claims, of Rule 6.2(b) PCT regarding reference signs, of Rule 10.1(d) PCT regarding internationally recognized units, nor those of Rule 5.1(a)(ii) PCT regarding mentioning relevant prior art in the description.

Re Item VIII

Certain observations on the international application

Although claims 1, 15 and 41 have been drafted as separate independent claims, they appear to relate effectively to the same subject-matter and to differ from each other only with regard to the definition of the subject-matter for which protection is sought and/or in respect of the terminology used for the features of that subject-matter. The aforementioned claims therefore lack conciseness and as such do not meet the requirements of Article 6 PCT.

Although claims 29 and 34 have been drafted as separate independent claims, they appear to relate effectively to the same subject-matter and to differ from each other only with regard to the definition of the subject-matter for which protection is sought and/or in respect of the terminology used for the features of that subject-matter. The aforementioned claims therefore lack conciseness and as such do not meet the requirements of Article 6 PCT.

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	FOR FURTHER ACTION	see Form PCT/ISA/220 as well as, where applicable, item 5 below.
International application No. PCT/US 16/17982	International filing date *(day/month/year)* 15 February 2016 (15.02.2016)	(Earliest) Priority Date *(day/month/year)* 28 September 2015 (28.09.2015)
Applicant GW MEDICAL LLC		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 3 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

a. With regard to the **language**, the international search was carried out on the basis of:

☒ the international application in the language in which it was filed.

☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

b. ☐ This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6*bis*(a)).

c. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☒ **Certain claims were found unsearchable** (see Box No. II).

3. ☐ **Unity of invention is lacking** (see Box No. III).

4. With regard to the **title**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2, by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the **drawings**,

a. the figure of the **drawings** to be published with the abstract is Figure No. 1

☐ as suggested by the applicant.

☒ as selected by this Authority, because the applicant failed to suggest a figure.

☐ as selected by this Authority, because this figure better characterizes the invention.

b. ☐ none of the figures is to be published with the abstract.

Form PCT/ISA/210 (first sheet) (January 2015)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 16/17982

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☒ Claims Nos.: 40-73, 78
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 16/17982

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61F 2/01 (2016.01)
CPC - A61B 17/221, A61F 2/01, A61B 2017/22038, A61B 2017/22079, A61B 2017/22081
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC(8) - A61F 2/01 (2016.01)
CPC - A61B 17/221, A61F 2/01, A61B 2017/22038, A61B 2017/22079, A61B 2017/22081

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
(CPC) 606/200, 159, 127; (CPC) A61B 2017/221*; A61F 2/013, 2002/01*
(Search term limited; see below)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PubWest (PGPB, USPT, EPAB, JPAB); Google; PatBase (All);
Search Terms: thrombectomy, embolectomy, remov*, captur*, thromb*, clot*, emboli*, plaque*, invert*, inversion, evert*, intussuscept*, mesh, net, basket, smooth*, round*, edge, tip, end, stiff*, reinforc*, snag*, expand*,

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X -- Y -- A	US 2015/0005781 A1 (LUND-CLAUSEN et al.) 01 January 2015 (01.01.2015) Entire document, especially Abstract, para[0003], para[0036]- para0042] and FIGS. 1-3.	1-2 5-20, 23-28, 30-34 --- 3-4, 21-22, 29, 35-39, 74-76, 79-80 --- 77
Y -- A	US 2010/0249815 A1 (JANTZEN et al.) 30 September 2010 (30.09.2010) Entire document, especially Abstract, para[0029] and FIGS. 1-4.	3-4, 21-22, 29, 35-39, 74-76, 79-80 --- 77
Y	US 2006/0293696 A1 (FAHEY et al.) 28 December 2006 (28.12.2006) Entire document, especially Abstract, para[0018], para[0125]- para[0126].	36, 75
A	US 2013/0317589 A1 (MARTIN et al.) 28 November 2013 (28.11.2013) Entire document.	1-39, 74-77, 79-80
A	US 2010/0030256 A1 (DUBRUL et al.) 04 February 2010 (04.02.2010) Entire document.	1-39, 74-77, 79-80
A	US 2003/0083693 A1 (DANIEL et al.) 01 May 2003 (01.05.2003) Entire document.	1-39, 74-77, 79-80
A	US 2007/0149996 A1 (COUGHLIN) 28 June 2007 (28.06.2007) Entire document.	1-39, 74-77, 79-80
A	US 2007/0112374 A1 (PAUL et al.) 17 May 2007 (17.05.2007) Entire document.	1-39, 74-77, 79-80

☐ Further documents are listed in the continuation of Box C. ☐

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
26 April 2016	06 MAY 2016
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Authorized officer: Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (January 2015)

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To: RICHARD D. SHOOP
SHAY GLENN LLP
2755 CAMPUS DRIVE, SUITE 210
SAN MATEO, CA 94403

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)*	06 MAY 2016
Applicant's or agent's file reference	FOR FURTHER ACTION See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US 16/17982	15 February 2016 (15.02.2016)	28 September 2015 (28.09.2015)

International Patent Classification (IPC) or both national classification and IPC
IPC(8) - A61F 2/01 (2016.01)
CPC - A61B 17/221, A61F 2/01, A61B 2017/22038, A61B 2017/22079, A61B 2017/22081

Applicant GW MEDICAL LLC

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule *43bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1 *bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

Name and mailing address of the ISA/US	Date of completion of this opinion	Authorized officer:
Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	26 April 2016	Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/237 (cover sheet) (January 2015)

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 16/17962

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of:

☒ the international application in the language in which it was filed.

☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a)).

3. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of a sequence listing:

a. ☐ forming part of the international application as filed:

☐ in the form of an Annex C/ST.25 text file.

☐ on paper or in the form of an image file.

b. ☐ furnished together with the international application under PCT Rule 13*ter*.1(a) for the purposes of international search only in the form of an Annex C/ST.25 text file.

c. ☐ furnished subsequent to the international filing date for the purposes of international search only:

☐ in the form of an Annex C/ST.25 text file (Rule 13*ter*.1(a))

☐ on paper or in the form of an image file (Rule 13*ter*.1(b) and Administrative Instructions, Section 713).

4. ☐ In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that forming part of the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 16/17982

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 40-73, 78

because:

☐ the said international application, or the said claims Nos. _____ relate to the following subject matter which does not require an international search *(specify)*:

☒ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. 40-73, 78 are so unclear that no meaningful opinion could be formed *(specify)*:

because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed *(specify)*:

☒ no international search report has been established for said claims Nos. 40-73, 78

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

☐ furnish a sequence listing in the form of an Annex C/ST.25 text file, and such listing was not available to the International Searching Authority in the form and manner acceptable to it; or the sequence listing furnished did not comply with the standard provided for in Annex C of the Administrative Instructions.

☐ furnish a sequence listing on paper or in the form of an image file complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in the form and manner acceptable to it; or the sequence listing furnished did not comply with the standard provided for in Annex C of the Administrative Instructions.

☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rule 13*ter*.1(a) or (b).

☐ See Supplemental Box for further details.

Form PCT/ISA/237 (Box No. III) (January 2015)

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 16/17982

Box No. V **Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	1-39, 74-77, 79-80	YES
	Claims	None	NO
Inventive step (IS)	Claims	77	YES
	Claims	1-39, 74-76, 79-80	NO
Industrial applicability (IA)	Claims	1-39, 74-77, 79-80	YES
	Claims	None	NO

2. Citations and explanations:

Claims 1-2, 5-20, 23-28, 30-34, lack an inventive step under PCT Article 33(3) as being obvious over US 2015/0005781 A1 to Lund-Clausen et al. (hereinafter: Lund-Clausen).

As per claim 1, Lund-Clausen describes a method of performing a mechanical thrombectomy to remove a clot from a blood vessel (Abstract, para[0003]), the method comprising:
advancing a distal end of a catheter (outer catheter 10, FIG. 1) through the blood vessel (vessel 22, FIG. 1) towards the clot (thrombus FIG. 1; para[0036]-[0037]);
exposing a distal tractor region of a [tube] that is within the catheter from the distal end of the catheter (20/14, FIG. 2; para[0041]), wherein the distal tractor region comprises an expandable first end region (18, FIGS. 1-3) and a less expandable second end region proximal to the expandable first end region (16, FIGS. 1-3; para[0038]: note 18 at least more expandable due to intermediate expandable region between ends 16/18);
allowing the expandable first end region to expand within the blood vessel (FIG. 2; para[0041]);
positioning the distal end of the catheter so that a distal end region of the catheter is between the less expandable second end region and the expandable first end region of the distal tractor region while the expandable first end region is doubled over the less expandable second end region (para[0044]; e.g. see analogous FIG. 2 for small thrombus); and
drawing the clot into the catheter by rolling the expandable first end region over the distal end of the catheter so that the expandable first end region inverts as the expandable first end region is pulled into the catheter (para[0044]; e.g. see analogous FIG. 2-3, para[0042] for small thrombus), but fails to describe specifically tube.
However, it would have been obvious to one skilled in the art to provide the wire as a tube, so as to provide increased flexibility for maneuvering.

As per claim 2, Lund-Clauson describes the method of claim 1, wherein positioning comprises distally advancing the distal end of the catheter so that the distal end region of the catheter is between the less expandable second end region and the expandable first end region of the distal tractor region (para[0044]; e.g. see analogous FIG. 2-3; para[0045]).

As per claim 3, Lund-Clausen describes the method of claim 1, but fails to describe wherein drawing the clot into the catheter comprises withdrawing the tube proximally. However, Lund-Clausen does describe this process for the smaller clots (FIGS. 2-3; para[0042]-[0043]). It would have been obvious to one skilled in the art to perform the capturing in either manner (as described for the smaller clot) so depending on the preference of the operator as one operation might be physically simpler.

As per claim 6, Lund-Clausen describes the method of claim 1, but fails to describe wherein drawing the clot into the catheter comprises withdrawing the tube proximally while advancing the catheter distally. However, Lund-Clausen does describe this process for the smaller clots (para[0046]). It would have been obvious to one skilled in the art to perform the capturing in such a manner (as described for the smaller clot) so as to reduce the push/pull range of motion.

As per claim 7, Lund-Clausen describes the method of claim 1, but fails to describe wherein drawing the clot into the catheter comprises withdrawing the tube proximally while advancing the catheter distally, wherein the tube is withdrawn at a different rate than the catheter is advanced.
However, Lund-Clausen does describe this push/pull process for the smaller clots (para[0046]). It would have been obvious to one skilled in the art to perform the capturing in such a manner (as described for the smaller clot) so as to reduce the push/pull range of motion, as well as poerforming said operation at different rates, because their push/pull forces would be different and making the rates the same would require extra effort.

As per claim 8, Lund-Clausen describes the method of claim 1, wherein allowing the expandable first end region to expand within the blood vessel comprises allowing a biasing element in the expandable first end region to expand so that the distal tractor region makes contact with an intima of the blood vessel (FIG. 2; para[0040]-[0041]: spring steel).

As per claim 9, Lund-Clausen describes the method of claim 1, but fails to describe wherein exposing the distal tractor region of the tube that is within the catheter from the distal end of the catheter comprises pushing the distal tractor region out of the distal end of the catheter.
However, Lund-Clausen describes where the pushing/pulling operations can be switched and/or combined for different aspects of the methods (para[0042]-[0046]). It would have been obvious to one skilled in the art to push the tube (while retracting the outer catheter) so as to reduce the push/pull range of motion.
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As per claim 10, Lund-Clausen describes the method of claim I, wherein exposing the distal tractor region of the tube that is within the catheter out of the distal end of the catheter comprises pulling the catheter proximally (para[0041]).

As per claim 11, Lund-Clausen describes the method of claim 1, wherein exposing the distal tractor region of the tube that is within the catheter from the distal end of the catheter comprises [pushing] the distal tractor region out of the distal end of the catheter to expose the expandable first end region already inverted over the less expandable second end region (para[0041]; FIGS. 1-2), but fails to describe pushing.
However, Lund-Clausen describes where the pushing/pulling operations can be switched and/or combined for different aspects of the methods (para[0042]-[0046]). It would have been obvious to one skilled in the art to push the tube (while retracting the outer catheter) so as to reduce the push/pull range of motion.

As per claim 12, Lund-Clausen describes the method of claim 1, but fails to describe wherein exposing the distal tractor region of the tube that is within the catheter from the distal end of the catheter comprises extending the expandable first end region out of the distal end of the catheter so that the expandable first end region inverts over the distal end of the catheter as the expandable first end region is extended.
However, Lund-Clausen describes where the pushing/pulling operations can be switched and/or combined for different aspects of the methods (para[0042]-[0046]) as well as describing that the device can alternatively open from it's shape memory characteristics (para[0048]) and that the device can be very long (para[0042]). It would have been obvious to one skilled in the art to push the tube (while retracting the outer catheter) so as to reduce the push/pull range of motion. Further, it is noted that such an inversion over the distal end of the catheter would happen for long length baskets in sufficiently large diameter vessels (between FIGS. 1-2).

As per claim 13, Lund-Clausen describes the method of claim 1, but fails to describe explicitly wherein exposing the distal tractor region of the tube comprises exposing at least 5 mm of the expandable first end region and at least 5 mm of the less expandable second end region.
However, Lund-Clausen describes that the device can be a range of sizes depending on the size of the thrombus (para[0042]). It would have been obvious to one skilled in the art to provide/expose any desired size, depending on the thrombus to be captured.

As per claim 14, Lund-Clausen describes the method of claim 1, but fails to describe wherein exposing the distal tractor region comprises exposing at least 1 cm of the expandable first end region inverted over at least 1 cm of the less expandable second end region.
However, Lund-Clausen describes that the device can be a range of sizes depending on the size of the thrombus (para[0042]). It would have been obvious to one skilled in the art to provide/expose any desired size, depending on the thrombus to be captured and the size of the vessel.

As per claim 15, Lund-Clausen describes the method of claim 1, wherein the expandable first end region comprises a mesh that is coupled adjacent to the less expandable second end region (para[0040]; FIGS. 1-3).

As per claim 16, Lund-Clausen describes the method of claim 1, wherein the expandable first end region comprises one or more of: a woven material, a mesh braided material, a knitted material, or a film material with multiple openings therethrough (para[0040; FIGS. 1-3).

As per claim 17, Lund-Clausen describes the method of claim 1, wherein advancing comprises advancing the distal end of the catheter through the blood vessel to position the distal end adjacent to the clot.

As per claim 18, Lund-Clausen describes a method of performing a mechanical thrombectomy to remove a clot from a blood vessel (Abstract, para[0003]), the method comprising:
advancing a distal end of a catheter (outer catheter 10, FIG. 1) through the blood vessel (vessel 22, FIG. 1) towards the clot (thrombus FIG. 1; para[0036]-[0037]);
exposing a distal tractor region of a [tube] that is within the catheter from the distal end of the catheter (20/14, FIG. 2; para[0041]), wherein the distal tractor region comprises an expandable first end region (16, FIGS. 1-3) and a less expandable second end region proximal to the expandable first end region (16, FIGS. 1-3; para[0038]: note 18 at least more expandable due to intermediate expandable region between ends 16/18) and configured so that the expandable first end region is inverted over the less expandable second end region (FIG. 1);
allowing the expandable first end region to expand within the blood vessel so that the distal end region of the catheter is between the less expandable second end region and the expandable first end region of the distal tractor region (para[0044]; e.g. see analogous FIG. 2 for small thrombus); and
drawing the clot into the catheter by advancing the catheter distally and [withdrawing the tube proximally] within the catheter so that the expandable first end region rolls over the distal end of the catheter and inverts as the expandable first end region is pulled into the catheter (para[0044], e.g. see analogous FIG. 2-3, para[0042] for small thrombus), but fails to describe specifically tube or withdrawing the tube proximally.
However, it would have been obvious to one skilled in the art to provide the wire as a tube, so as to provide increased flexibility for maneuvering. Finally, Lund-Clausen does describe this process of withdrawing the tube and extending the catheter for the smaller clots (para[0046]). It would have been obvious to one skilled in the art to perform the capturing in such a manner (as described for the smaller clot) so as to reduce the push/pull range of motion.

As per claim 19, Lund-Clausen describes the method of claim 18, wherein the expandable first end region is inverted over the less expandable second end region before exposing the distal tractor region (FIG. 1).

As per claim 20, Lund-Clausen describes the method of claim 18,wherein the exposing the distal tractor region comprises inverting the expandable distal end region over the less expandable second end region as the distal tractor region is exposed (para[0048],[0042]: note inherent for long length baskets in sufficiently large diameter vessels (between FIGS. 1-2).

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As per claim 23, Lund-Clausen describes the method of claim 18, but fails to describe wherein exposing the distal tractor region of the tube that is within the catheter from the distal end of the catheter comprises pushing the distal tractor region out of the distal end of the catheter. However, Lund-Clausen describes where the pushing/pulling operations can be switched and/or combined for different aspects of the methods (para[0042]-[0046]). It would have been obvious to one skilled in the art to push the tube (while retracting the outer catheter) so as to reduce the push/pull range of motion.

As per claim 24, Lund-Clausen describes the method of claim 18, wherein exposing the distal tractor region of the tube that is within the catheter out of the distal end of the catheter comprises pulling the catheter proximally (para[0041]).

As per claim 25, Lund-Clausen describes the method of claim 18, but fails to describe explicitly wherein exposing the distal tractor region of the tube comprises exposing at least 5 mm of the expandable first end region and at least 5 mm of the less expandable second end region.
However, Lund-Clausen describes that the device can be a range of sizes depending on the size of the thrombus (para[0042]). It would have been obvious to one skilled in the art to provide/expose any desired size, depending on the thrombus to be captured.

As per claim 26, Lund-Clausen describes the method of claim 18, wherein the expandable first end region of the distal tractor region comprises a mesh that is coupled adjacent to the less expandable second end region (para[0040]; FIGS. 1-3).

As per claim 27, Lund-Clausen describes the method of claim 18, wherein the expandable first end region comprises one or more of: a woven material, a mesh braided material, or a film material with multiple openings therethrough (para[0040; FIGS. 1-3).

As per claim 28, Lund-Clausen describes a method of performing a mechanical thrombectomy to remove a clot from a blood vessel (Abstract, para[0003]), the method comprising:
advancing a distal end of a catheter (outer catheter 10, FIG. 1) through the blood vessel (vessel 22, FIG. 1) towards the clot (thrombus FIG. 1; para[0036]-[0037]);
exposing a distal tractor region of a [tube] that is within the catheter from the distal end of the catheter (20/14, FIG. 2; para[0041]), wherein the distal tractor region comprises an expandable first end region (18, FIGS. 1-3) and a less expandable second end region proximal to the expandable first end region (16, FIGS. 1-3; para[0038]: note 16 at least more expandable due to intermediate expandable region between ends 16/18), wherein exposing comprises extending the expandable first end region out of the distal end of the catheter so that the expandable first end region inverts over the distal end of the catheter as the expandable first end region is extended (para[0048],[0042]: note inherent for long length baskets in sufficiently large diameter vessels (between FIGS. 1-2);
allowing the expandable first end region to expand within the blood vessel as it is extended out of the distal end of the catheter so that a distal end region of the catheter is between the less expandable second end region and the expandable first end region (para[0048],[0042]: note inherent for long length baskets in sufficiently large diameter vessels (between FIGS. 1-2); Also, para[0044]; e.g. see analogous FIG. 2 for small thrombus); and
drawing the clot into the catheter by withdrawing the tube proximally within the catheter so that the expandable distal end region rolls over the distal end of the catheter, collapses, and inverts as the expandable distal end region is pulled into the catheter (para[0044]; e.g. see analogous FIG. 2-3, para[0042] for small thrombus), but fails to describe specifically tube.
However, it would have been obvious to one skilled in the art to provide the wire as a tube, so as to provide increased flexibility for maneuvering.

As per claim 30, Lund-Clausen describes the method of claim 28, but fails to describe wherein exposing the distal tractor region of the tube that is within the catheter from the distal end of the catheter comprises pushing the distal tractor region out of the distal end of the catheter. However, Lund-Clausen describes where the pushing/pulling operations can be switched and/or combined for different aspects of the methods (para[0042]-[0046]). It would have been obvious to one skilled in the art to push the tube (while retracting the outer catheter) so as to reduce the push/pull range of motion.

As per claim 31, Lund-Clausen describes the method of claim 28, wherein exposing the distal tractor region of the tube that is within the catheter out of the distal end of the catheter comprises withdrawing the catheter proximally relative to the distal tractor region of the tube (para[0041]).

As per claim 32, Lund-Clausen describes the method of claim 28, but fails to describe wherein exposing the distal tractor region of the tube comprises exposing at least 5 mm of the expandable first end region and at least 5 mm of the less expandable second end region.
However, Lund-Clausen describes that the device can be a range of sizes depending on the size of the thrombus (para[0042]). It would have been obvious to one skilled in the art to provide/expose any desired size, depending on the thrombus to be captured.

As per claim 33, Lund-Clausen describes the method of claim 28, wherein the expandable first end region comprises a mesh that is coupled adjacent to the less expandable second end region (para[0040]; FIGS. 1-3).

As per claim 34, Lund-Clausen describes the method of claim 28, wherein the expandable first end region comprises one or more of: a woven material, a mesh braided material, or a film material with multiple openings therethrough (para[0040]; FIGS. 1-3).

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Claims 3-4, 21-22, 29, 35, 37-39, 74, 76, 79-80 lack an inventive step under PCT Article 33(3) as being obvious over Lund-Clausen in view of US 2010/0249815 A1 to Jantzen et al. (hereinafter: Jantzen).

As per claim 3, Lund-Clausen describes the method of claim 1, but fails to describe further comprising advancing a guidewire within the blood vessel to the clot, wherein advancing the distal end of the catheter comprises advancing the catheter over the guidewire through the blood vessel until the distal end of the catheter is proximate to the clot.
However, Jantzen describes an everting clot capturing device (Abstract, FIGS. 1-4) and further describes advancing a guidewire within the blood vessel to the clot, wherein advancing the distal end of the catheter comprises advancing the catheter over the guidewire through the blood vessel until the distal end of the catheter is proximate to the clot (para[0029]). It would have been obvious to one skilled in the art to utilize the guidewire for initial placement, as is well known in the art (Jantzen: para[0029]).

As per claim 4, Lund-Clausen describes the method of claim 1, but fails to describe further comprising advancing a guidewire within the blood vessel to the clot, wherein advancing the distal end of the catheter comprises advancing the catheter over the guidewire through the blood vessel until the distal end of the catheter is proximate to the clot, further wherein drawing the clot into the catheter comprises advancing the catheter towards the clot over the guidewire while rolling the expandable first end region over the distal end of thecatheter.
However, Jantzen describes an everting clot capturing device (Abstract, FIGS. 1-4) and further describes advancing a guidewire within the blood vessel to the clot, wherein advancing the distal end of the catheter comprises advancing the catheter over the guidewire through the blood vessel until the distal end of the catheter is proximate to the clot, further wherein drawing the clot into the catheter comprises advancing the catheter towards the clot over the guidewire while rolling the expandable first end region over the distal end of thecatheter (para[0029]: note wire removal optional). It would have been obvious to one skilled in the art to utilize the guidewire for initial placement, as is well known in the art (Jantzen: para[0029]).

As per claim 21, Lund-Clausen describes the method of claim 18, but fails to describe further comprising, before exposing the distal tractor region, advancing a guidewire within the blood vessel to the clot and advancing the catheter over the guidewire through the blood vessel until a distal end of the catheter is proximate to the clot.
However, Jantzen describes an everting clot capturing device (Abstract, FIGS. 1-4) and further describes before exposing the distal tractor region, advancing a guidewire within the blood vessel to the clot and advancing the catheter over the guidewire through the blood vessel until a distal end of the catheter is proximate to the clot (para[0029]). It would have been obvious to one skilled in the art to utilize the guidewire for initial placement, as is well known in the art (Jantzen: para[0029]).

As per claim 22, Lund-Clausen describes the method of claim 18, but fails to describe before exposing the distal tractor region, advancing a guidewire within the blood vessel to the clot and advancing the catheter over the guidewire through the blood vessel until a distal end of the catheter is proximate to the clot and leaving the guidewire in place while drawing the clot into the catheter.
However, Jantzen describes an everting clot capturing device (Abstract, FIGS. 1-4) and further describes before exposing the distal tractor region, advancing a guidewire within the blood vessel to the clot and advancing the catheter over the guidewire through the blood vessel until a distal end of the catheter is proximate to the clot and leaving the guidewire in place while drawing the clot into the catheter (para[0029]: note wire removal optional). It would have been obvious to one skilled in the art to utilize the guidewire for initial placement, as is well known in the art (Jantzen: para[0029]).

As per claim 29, Lund-Clausen describes the method of claim 28, but fails to describe further comprising advancing a guidewire within the blood vessel to the clot, wherein advancing the distal end of the catheter comprises advancing the catheter over the guidewire through the blood vessel until a distal end of the catheter is proximate to the clot.
However, Jantzen describes an everting clot capturing device (Abstract, FIGS. 1-4) and further describes advancing a guidewire within the blood vessel to the clot, wherein advancing the distal end of the catheter comprises advancing the catheter over the guidewire through the blood vessel until a distal end of the catheter is proximate to the clot (para[0029]). It would have been obvious to one skilled in the art to utilize the guidewire for initial placement, as is well known in the art (Jantzen: para[0029]).

As per claim 35, Lund-Clausen describes a mechanical thrombectomy apparatus for removing a clot from a vessel (Abstract, para[0003]), the apparatus comprising:
a catheter having a distal end and a distal end opening (12, FIGS. 1-3);
a flexible [tube] extending within the catheter and doubling back over the distal end of the catheter (20/14, FIG. 1), wherein the flexible tube is configured to slide and invert over the distal end opening when a first end of the flexible tube is pulled proximally within the catheter (FIG. 3; para[0042]); and
but fails to describe tube, or a guidewire lumen through the catheter and the flexible tube that is configured to pass a guidewire.
However, Jantzen describes an everting clot capturing device (Abstract, FIGS. 1-4) comprising a tube, and a guidewire lumen through the catheter and the flexible tube that is configured to pass a guidewire (para[0029]). It would have been obvious to one skilled in the art to utilize a hollow tube for the entire flexible tube portion, and utilize a guidewire for initial placement, as is well known in the art (Jantzen: para[0029]).

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INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 16/17982

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As per claim 37, Lund-Clausen describes a mechanical thrombectomy apparatus for removing a clot from a vessel (Abstract, para[0003]), the apparatus comprising:
an inner catheter having a distal end and a distal end opening (12, FIGS. 1-3);
a flexible [tube] extending though the catheter and doubling back over the distal end of the inner catheter (20/14, FIG. 1), wherein the flexible tube is configured to invert over the distal end opening when a first end of the flexible tube is pulled proximally within the inner catheter (FIG. 3; para[0042]);
an outer catheter extending over the inner catheter and flexible tube (10, FIG. 1);
but fails to describe a lubricious region of the flexible tube extending between a distal end of the outer catheter and the distal end opening of the inner catheter, wherein the majority of the flexible tube is not lubricious; and
a guidewire lumen through the catheter and the flexible tube configured to pass a guidewire.
However, Jantzen describes an everting clot capturing device (Abstract, FIGS. 1-4) comprising a tube, and a guidewire lumen through the catheter and the flexible tube that is configured to pass a guidewire (para[0029]). Jantzen further describes a proximal lubricious section (see smooth first/inner portion, FIG. 3) that is pulled in first, then and a distal non-lubricious region (outside with scraping device 30, FIG. 3) that is pulled in afterwards during eversion (para[0031],[0029]). It would have been obvious to one skilled in the art to utilize a hollow tube for the entire flexible tube portion, and utilize a guidewire for initial placement, as is well known in the art (Jantzen: para[0029]). It would have further been obvious to provide such lubricious and non-lubricious sections so as to provide scraping of the walls and extremities of the thrombus, but prevent snagging in the internal portion to ease the suction.

As per claim 38, Lund-Clausen describes a mechanical thrombectomy apparatus for removing a clot from a vessel (Abstract, para[0003]), the apparatus comprising:
an inner catheter having a distal end and a distal end opening (32, FIG. 4);
a flexible [tube] extending though the catheter and doubling back over the distal end of the inner catheter (40/34, FIG. 1), wherein the flexible tube is configured to invert over the distal end opening when a first end of the flexible tube is pulled proximally within the inner catheter (para[0047]-[0048]; e.g. see FIG. 3; para[0042]);
a releasable attachment between the flexible tube and an outer surface of the catheter (30, FIG. 4; para[0048]),
configured to release when the flexible tube is pulled with a predetermined force [that is greater than 0.01 N] (para[0048]); and
but fails to describe tube, that is greater than 0.01N, or a guidewire lumen through the catheter and the flexible tube configured to pass a guidewire.
However, it would have been obvious to one skilled int the art, through routine testing, to provide any desired release force, so as to provide a secure but simple release.
Finally, Jantzen describes an everting clot capturing device (Abstract, FIGS. 1-4) comprising a tube, and a guidewire lumen through the catheter and the flexible tube that is configured to pass a guidewire (para[0029]). It would have been obvious to one skilled in the art to utilize a hollow tube for the entire flexible tube portion, and utilize a guidewire for initial placement, as is well known in the art (Jantzen: para[0029]).

As per claim 39, Lund-Clausen describes a mechanical thrombectomy apparatus for removing a clot from a vessel (Abstract, para[0003]), the apparatus comprising:
a catheter having a distal end, a distal end opening and an inner diameter (12, FIGS. 1-3);
a flexible [tube] extending within the catheter and doubling back over the distal end of the catheter (20/14, FIG. 1), wherein the flexible tube is configured to slide and invert over the distal end opening when a first end of the flexible tube is pulled proximally within the catheter (FIG. 3; para[0042]), the
flexible tube having a [low Poisson's ratio], such that the flexible tube has a diameter of greater than half the inner diameter of the catheter when pulled proximally within the catheter with sufficient force to invert over the distal end opening (FIGS. 1-3; para[0042]); and
but fails to explicitly describe low Poisson's ratio or a guidewire lumen through the catheter and the flexible tube configured to pass a guidewire.
However, Lund-Clausen describes such an expansion (FIGS. 1-2). It would have been obvious to one skilled in the art to utilize a low Poisson's ratio material, so as to allow for the use of more types of materials for design flexibility and potential cost savings.
Finally, Jantzen describes an everting clot capturing device (Abstract, FIGS. 1-4) comprising a tube, and a guidewire lumen through the catheter and the flexible tube that is configured to pass a guidewire (para[0029]). It would have been obvious to one skilled in the art to utilize a hollow tube for the entire flexible tube portion, and utilize a guidewire for initial placement, as is well known in the art (Jantzen: para[0029]).

As per claim 74, Lund-Clausen describes a method of mechanically removing a thrombectomy (Abstract, para[0003]), the method comprising:
advancing a [guidewire] at least to the proximal end of a clot in a blood vessel (thrombus FIG. 1; para[0036]-[0037]);
advancing a thrombectomy apparatus distally [over the guidewire] (20/14, FIG. 2; para[0041]), wherein the thrombectomy apparatus comprises a catheter having a distal end and a distal end opening (12, FIG. 1) and a flexible tube extending along an outer diameter of the catheter and over the distal end of the catheter (14, FIG. 1), [so that the guidewire passes through a lumen of the catheter and the flexible tube];
pulling the flexible tube proximally from off of the outer diameter of the catheter and into the catheter lumen so that the flexible tube slides and inverts over the distal end opening (FIG. 2-3, para[0042]); and
drawing a clot into the inverted flexible tube as the flexible tube is drawn into the catheter (FIG. 2-3, para[0042]), but fails to describe guidewire, over a guidewire, so that the guidewire passes through a lumen of the catheter and the flexible tube.
However, Jantzen describes an everting clot capturing device (Abstract, FIGS. 1-4) and further describes advancing a guidewire within the blood vessel to the clot, advancing a thrombectomy apparatus distally over the guidewire, so that the guidewire passes through a lumen of the catheter and the flexible tube (para[0029]). It would have been obvious to one skilled in the art to utilize a hollow tube for the entire flexible tube portion, and utilize a guidewire for initial placement, as is well known in the art (Jantzen: para[0029]).

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As per claim 76, Lund-Clausen describes a method of mechanically removing a thrombectomy (Abstract, para[0003]), the method comprising:
advancing a [guidewire] adjacent a clot in a blood vessel (thrombus FIG. 1; para[0036]-[0037]);
advancing a thrombectomy apparatus distally [over the guidewire] (20/14, FIG. 2; para[0041]), wherein the thrombectomy apparatus comprises an inner catheter having a distal end and a distal end opening (12, FIG. 1) and a flexible tube extending along an outer diameter of the inner catheter and over the distal end of the catheter (14, FIG. 1), and an outer catheter (10, FIG. 1) securing a distal end region of the flexible tube against the outer diameter of the inner catheter (para[0040]-[0041]), [so that the guidewire passes through a lumen of the catheter and the flexible tube];
pulling the flexible tube proximally from off of the outer diameter of the catheter and into the catheter lumen so that a [lubricious] proximal leader region of the flexible tube slides and inverts over the distal end opening, until [a non-lubricious] distal region of the flexible tube is drawn into the inner catheter (FIG. 2-3, para[0042]); and
drawing a clot into the inverted flexible tube as the flexible tube is drawn into the catheter (FIG. 2-3, para[0042]), but fails to describe guidewire, over a guidewire, so that the guidewire passes through a lumen of the catheter and the flexible tube, lubricious and a non-lubricious.
However, Jantzen describes an everting clot capturing device (Abstract, FIGS. 1-4) and further describes advancing a guidewire within the blood vessel to the clot, advancing a thrombectomy apparatus distally over the guidewire, so that the guidewire passes through a lumen of the catheter and the flexible tube (para[0029]). Jantzen further describes a proximal lubricious section (see smooth first/inner portion, FIG. 3) that is pulled in first, then and a distal non-lubricious region (outside with scraping device 30, FIG. 3) that is pulled in afterwards during eversion (para[0031],[0029]). It would have been obvious to one skilled in the art to utilize a hollow tube for the entire flexible tube portion, and utilize a guidewire for initial placement, as is well known in the art (Jantzen: para[0029]). It would have further been obvious to provide such lubricious and non-lubricious sections so as to provide scraping of the walls and extremities of the thrombus, but prevent snagging in the internal portion to ease the suction.

As per claim 79, Lund-Clausen describes a mechanical thrombectomy device for removing a clot from a vessel (Abstract, para[0003]), the device comprising:
a catheter having a distal end and a distal end opening, wherein the catheter has an inner diameter and an outer diameter (outer catheter 10, FIG. 1; para[0036]);
a distal tractor region of a [tube] within the catheter (20/14, FIG. 2; para[0041]), wherein the distal tractor region (14, FIG. 2) comprises an expandable distal end region (18, FIGS. 1-3) and a less expandable distal end region proximal to the expandable distal end region (16, FIGS. 1-3; para[0038]: note 18 at least more expandable due to intermediate expandable region between ends 16/16), the distal tractor region configured so that the expandable distal end region is inverted over the less expandable distal end region (FIG. 1-2);
[a guidewire lumen through the catheter and the tube, including the distal tractor region, wherein the guidewire lumen is configured to pass a guidewire], and
[a proximal handle coupled to the tube and] configured to cause relative motion between the catheter and the tube such that the distal tractor region is released from within the inner diameter of the catheter so that the expandable distal end region may expand to a diameter that is greater than the outer diameter so that the catheter may be advanced between the expandable distal end region and the less expandable distal end region and the tube may be drawn proximally to pull the expandable distal end region over the distal end of the catheter so that the expandable distal end region rolls into the distal
end of the catheter, inverts, collapses and is drawn into the catheter (para[0044]; e.g. see analogous FIG. 2-3 for small thrombus; para[0045]),
but fails to describe tube, a guidewire lumen through the catheter and the tube, including the distal tractor region, wherein the guidewire lumen is configured to pass a guidewire, a proximal handle coupled to the tube.
However, though a handle is not described, it would have been obvious to one skilled in the art to provide a handle so as to more easily facilitate the pushing/pulling of the parts.
Finally, Jantzen describes an everting clot capturing device (Abstract, FIGS. 1-4) and further describes a guidewire lumen through the catheter and the tube, including the distal tractor region, wherein the guidewire lumen is configured to pass a guidewire (para[0029]). It would have been obvious to one skilled in the art to utilize a hollow tube for the entire flexible tube portion, and utilize a guidewire for initial placement, as is well known in the art (Jantzen: para[0029]).

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As per claim 80, Lund-Clausen describes a mechanical thrombectomy device for removing a clot from a vessel (Abstract, para[0003]), the device comprising:
a catheter having a distal end and a distal end opening, wherein the catheter has an inner diameter and an outer diameter (outer catheter 10, FIG. 1; para[0036]);
a tube having a distal tractor region within the catheter (20/14, FIG. 2; para[0041]), wherein the distal tractor region (14, FIG. 2) comprises an expandable distal end region (18, FIGS. 1-3) and a less expandable distal end region proximal to the expandable distal end region (16, FIGS. 1-3; para[0038]; note 18 at least more expandable due to intermediate expandable region between ends 16/18), further wherein the expandable distal end region is biased to invert over the less expandable distal end region as it is exposed from the distal end of the catheter (para[0042]-[0048]; note inherent for long length baskets in sufficiently large diameter vessels (between FIGS. 1-2));
[a guidewire lumen through the catheter and the tube, including the distal tractor region, wherein the guidewire lumen is configured to pass a guidewire]; and
[a proximal handle coupled to the tube and] configured to cause relative motion between the catheter and the tube such that the distal tractor region is released from within the inner diameter of the catheter so that the expandable distal end region may expand to a diameter that is greater than the outer diameter and the tube may be drawn proximally to pull the expandable distal end region over the distal end of the catheter so that the expandable distal end region rolls into the distal end of the catheter, inverts, collapses and is drawn into the catheter (para[0044]; e.g. see analogous FIG. 2-3 for small thrombus; para[0045]), but fails to describe tube, a guidewire lumen through the catheter and the tube, including the distal tractor region, wherein the guidewire lumen is configured to pass a guidewire, a proximal handle coupled to the tube.
However, though a handle is not described, it would have been obvious to one skilled in the art to provide a handle so as to more easily facilitate the pushing/pulling of the parts.
Finally, Jantzen describes an everting clot capturing device (Abstract, FIGS. 1-4) and further describes a guidewire lumen through the catheter and the tube, including the distal tractor region, wherein the guidewire lumen is configured to pass a guidewire (para[0029]). It would have been obvious to one skilled in the art to utilize a hollow tube for the entire flexible tube portion, and utilize a guidewire for initial placement, as is well known in the art (Jantzen: para[0029]).

Claims 36, 75 lack an inventive step under PCT Article 33(3) as being obvious over Lund-Clausen in view of Jantzen, in further view of US 2006/0293696 A1 to Fahey et al. (hereinafter: Fahey).

As per claim 36, A mechanical thrombectomy apparatus for removing a clot from a vessel (Abstract, para[0003]), the apparatus comprising:
a catheter having a distal end and a distal end opening (12, FIGS. 1-3), [wherein the distal end opening has a durometer that is greater than a durometer of a region immediately proximal to the distal end, further wherein the distal end opening has a rounded lip profile;]
a flexible [tube] extending within the catheter and doubling back over the distal end of the catheter (20/14, FIG. 1), wherein the flexible tube is configured to invert over the distal end opening when a first end of the flexible tube is pulled proximally within the catheter (FIG. 3; para[0042]); and
but fails to describe wherein the distal end opening has a durometer that is greater than a durometer of a region immediately proximal to the distal end, further wherein the distal end opening has a rounded lip profile or a guidewire lumen through the catheter and the flexible tube configured to pass a guidewire.
However, Jantzen describes an everting clot capturing device (Abstract, FIGS. 1-4) comprising a tube, and a guidewire lumen through the catheter and the flexible tube that is configured to pass a guidewire (para[0029]). It would have been obvious to one skilled in the art to utilize a hollow tube for the entire flexible tube portion, and utilize a guidewire for initial placement, as is well known in the art (Jantzen: para[0029]).
Finally, Fahey also describes the design of catheter tips designed to interact with and pull inside, such thrombus removal devices (Abstract, para[0125]), and describes designing the tips to be stiff relative to an adjacent region (para[0126], Abstract) as well as a rounded tip (para[0018]). It would have been obvious to one skilled in the art, through routine testing, to provide a stiffened tip with a rounded edges, so as to prevent snagging and collapse.

As per claim 75, Lund-Clausen describes a method of mechanically removing a thrombectomy, the method comprising:
advancing a [guidewire] adjacent a clot in a blood vessel (thrombus FIG. 1; para[0036]-[0037]);
advancing a thrombectomy apparatus distally [over the guidewire] (20/14, FIG. 2; para[0041]), wherein the thrombectomy apparatus comprises a catheter having a distal end and a distal end opening (12, FIG. 1) and a flexible tube extending along an outer diameter of the catheter and over the distal end of the
catheter (14, FIG. 1), [so that the guidewire passes through a lumen of the catheter and the flexible
tube];
pulling the flexible tube proximally from off of the outer diameter of the catheter and into the catheter lumen over [a rounded lip of] the distal end opening of the catheter so that the flexible tube slides and inverts over the distal end opening (FIG. 2-3, para[0042]), [wherein the distal end opening has a durometer that is greater than a durometer of a region immediately proximal to the distal end]; and
drawing a clot into the inverted flexible tube as the flexible tube is drawn into the catheter (FIG. 2-3, para[0042]), but fails to describe guidewire, over a guidewire, so that the guidewire passes through a lumen of the catheter and the flexible tube, a rounded lip of, wherein the distal end opening has a durometer that is greater than a durometer of a region immediately proximal to the distal end.
However, Jantzen describes an everting clot capturing device (Abstract, FIGS. 1-4) and further describes advancing a guidewire within the blood vessel to the clot, advancing a thrombectomy apparatus distally over the guidewire, so that the guidewire passes through a lumen of the catheter and the flexible tube (para[0029]). It would have been obvious to one skilled in the art to utilize a hollow tube for the entire flexible tube portion, and utilize a guidewire for initial placement, as is well known in the art (Jantzen: para[0029]).
Finally, Fahey also describes the design of catheter tips designed to interact with and pull inside, such thrombus removal devices (Abstract, para[0125]), and describes designing the tips to be stiff relative to an adjacent region (para[0126], Abstract) as well as a rounded tip (para[0018]). It would have been obvious to one skilled in the art, through routine testing, to provide a stiffened tip with a rounded edges, so as to prevent snagging and collapse.
----------Please See Continuation Sheet----------

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 16/17982

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of:
----------Supplemental Box:----------

Claim 77 meet the requirements under PCT Articles 33(2) and 33(3) because the prior art does not teach or fairly suggest the method as claimed by the applicant.

The prior art is exemplified by (1) Lund-Clausen and (2) Jantzen

As per claim 77, Lund-Clausen describes a method of mechanically removing a thrombectomy (Abstract, para[0003]), the method comprising:
advancing a [guidewire] adjacent a clot in a blood vessel (thrombus FIG. 1; para[0036]-[0037]);
advancing a thrombectomy apparatus distally [over the guidewire] (20/14, FIG. 2; para[0041]), wherein the thrombectomy apparatus comprises a catheter having a distal end and a distal end opening (12, FIG. 1) and a flexible tube extending along an outer diameter of the catheter and over the distal end of the catheter (14, FIG. 1), [so that the guidewire passes through a lumen of the catheter and the flexible tube];
pulling the flexible tube proximally from off of the outer diameter of the catheter and into the catheter lumen so that the flexible tube slides and inverts over the distal end opening (FIG. 2-3, para[0042]); and
[pulling or pushing the flexible tube distally out of the distal end of the catheter so that the flexible tube slides and inverts over the distal end opening and over the outer diameter of the catheter; and]
drawing a clot into the inverted flexible tube as the flexible tube is drawn into the catheter (FIG. 2-3, para[0042]).
but fails to describe guidewire, over a guidewire, so that the guidewire passes through a lumen of the catheter and the flexible tube, pulling or pushing the flexible tube distally out of the distal end of the catheter so that the flexible tube slides and inverts over the distal end opening and over the outer diameter of the catheter;
However, Jantzen describes an everting clot capturing device (Abstract, FIGS. 1-4) and further describes advancing a guidewire within the blood vessel to the clot, advancing a thrombectomy apparatus distally over the guidewire, so that the guidewire passes through a lumen of the catheter and the flexible tube (para[0029]). It would have been obvious to one skilled in the art to utilize a hollow tube for the entire flexible tube portion, and utilize a guidewire for initial placement, as is well known in the art (Jantzen: para[0029]).
Finally, Lund-Clausen describes an alternate embodiment that allows for the pushing the flexible tube distally out of the distal end of the catheter so that the flexible tube slides and inverts over the distal end opening and over the outer diameter of the catheter (para[0042]-[0046]), but as an alternative means for the expansion. No prior art fairly suggests providing an already everted basket, then straightening it, then again allowing it to every back before capturing the thrombus.

Claims 1-39, 74-77, 79-80 have industrial applicability as defined by PCT Article 33(4) because the subject matter can be made or used in industry.

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	**FOR FURTHER ACTION**	see Form PCT/ISA/220 as well as, where applicable, item 5 below.
100286WO0160246-70		
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/US2019/032601	16 May 2019 (16-05-2019)	1 June 2018 (01-06-2018)
Applicant		
CARRIER CORPORATION		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 4 sheets.

[X] It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

a. With regard to the **language,** the international search was carried out on the basis of:

[X] the international application in the language in which it was filed

[ ] a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))

b. [ ] This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6*bis*(a)).

c. [ ] With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. [ ] **Certain claims were found unsearchable** (See Box No. II)

3. [ ] **Unity of invention is lacking** (see Box No III)

4. With regard to the **title,**

[X] the text is approved as submitted by the applicant

[ ] the text has been established by this Authority to read as follows:

5. With regard to the **abstract,**

[X] the text is approved as submitted by the applicant

[ ] the text has been established, according to Rule 38.2, by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority

6. With regard to the **drawings,**

a. the figure of the **drawings** to be published with the abstract is Figure No. 2

[ ] as suggested by the applicant

[ ] as selected by this Authority, because the applicant failed to suggest a figure

[X] as selected by this Authority, because this figure better characterizes the invention

b. [ ] none of the figures is to be published with the abstract

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2019/032601

A. CLASSIFICATION OF SUBJECT MATTER
INV. G10K9/12
ADD. G08B3/10 G10K9/122

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
G10K G08B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2016/100252 A1 (PATTOK GREG R [US]) 7 April 2016 (2016-04-07) paragraph [0014] - paragraph [0030] figures 1-4	1-21
A	US 2011/187541 A1 (NOGUCHI TAKAHIRO [JP]) 4 August 2011 (2011-08-04) paragraphs [0002], [0007], [0021] figure 2	17
A	WO 2013/081773 A1 (UTC FIRE & SECURITY CORP [US]; GADONNIEX DENNIS MICHAEL [US] ET AL.) 6 June 2013 (2013-06-06) paragraphs [0009], [0016], [0017] figure 1	3-5,11, 12,18

-/--

[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
20 August 2019	02/09/2019

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Valenzuela, Miriam

1

Form PCT/ISA/210 (second sheet) (April 2005)

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 6 087 811 A (CRAWFORD IAN D [US] ET AL) 11 July 2000 (2000-07-11) column 1, line 5 - line 9 column 3, line 15 - line 17 column 6, line 22 - line 47; figures 2, 3A, 3B	3-5,11, 12,18
A	JP H09 114467 A (MITSUBISHI AUTO ENG; MITSUBISHI MOTORS CORP) 2 May 1997 (1997-05-02) paragraphs [0005], [0011] - paragraph [0015]; figures 1-3	1-21

1

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2019/032601

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2016100252 A1	07-04-2016	NONE	
US 2011187541 A1	04-08-2011	CA 2728828 A1	29-07-2011
		CN 102157145 A	17-08-2011
		EP 2362379 A1	31-08-2011
		US 2011187541 A1	04-08-2011
WO 2013081773 A1	06-06-2013	EP 2786358 A1	08-10-2014
		ES 2557123 T3	22-01-2016
		US 2013141245 A1	06-06-2013
		WO 2013081773 A1	06-06-2013
US 6087811 A	11-07-2000	NONE	
JP H09114467 A	02-05-1997	NONE	

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US2019/032601	16.05.2019	01.06.2018

International Patent Classification (IPC) or both national classification and IPC
INV. G10K9/12 ADD. G08B3/10 G10K9/122

Applicant
CARRIER CORPORATION

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notifed the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

Name and mailing address of the ISA:	Date of completion of this opinion	Authorized Officer
European Patent Office P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Fax: +31 70 340 - 3016	see form PCT/ISA/210	Valenzuela, Miriam Telephone No. +31 70 340-0

Form PCT/ISA/237 (Cover Sheet) (January 2015)

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of:

   ☑ the international application in the language in which it was filed.

   ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).

2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a))

3. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of a sequence listing:

   a. ☐ forming part of the international application as filed:

      ☐ in the form of an Annex C/ST.25 text file.

      ☐ on paper or in the form of an image file.

   b. ☐ furnished together with the international application under PCT Rule 13*ter*.1(a) for the purposes of international search only in the form of an Annex C/ST.25 text file.

   c. ☐ furnished subsequent to the international filing date for the purposes of international search only:

      ☐ in the form of an Annex C/ST.25 text file (Rule 13*ter*.1(a)).

      ☐ on paper or in the form of an image file (Rule 13*ter*.1(b) and Administrative Instructions, Section 713).

4. ☐ In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that forming part of the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	3-5, 8, 11, 12, 16-21
	No:	Claims	1, 2, 6, 7, 9, 10, 13-15
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-21
Industrial applicability (IA)	Yes:	Claims	1-21
	No:	Claims	

2. Citations and explanations

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

1 **Prior art**

Reference is made to the following documents:

D1 US 2016/100252 A1 (PATTOK GREG R [US]) 7 April 2016 (2016-04-07)

D2 US 2011/187541 A1 (NOGUCHI TAKAHIRO [JP]) 4 August 2011 (2011-08-04)

D3 WO 2013/081773 A1 (UTC FIRE & SECURITY CORP [US]; GADONNIEX DENNIS MICHAEL [US] ET AL.) 6 June 2013 (2013-06-06)

D4 US 6 087 811 A (CRAWFORD IAN D [US] ET AL) 11 July 2000 (2000-07-11)

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

2 **Independent claim 1**

The present application does not meet the criteria of Article 33(1) PCT because, with respect to document D1, the subject-matter of independent claim 1 is not new in the sense of Article 33(2) PCT.

2.1 Document D1 discloses (references in parenthesis applying to this document):

A method of powering a sounder (paragraph [15] "notification apparatus 10" and Fig.2 showing block diagram of control circuit 12 of the notification apparatus, i.e. sounder) comprising:

- providing a constant input current (Fig.2, item 14; paragraphs [16], [18], and [19]. The constant input current reads on the current draw of the speaker 14. D1 discloses that the notification apparatus 10 maintains the peak efficiency at the resonance frequency by monitoring and maintaining the current draw of the speaker 14, i.e. providing a constant input current.); and

- regulating an input voltage to a phase of a sound engine corresponding with an acoustic signal generated by a sound engine (Fig.2, items 18, 20 14; Fig.3, items 20, 14; Fig.4A to 4C; paragraphs [19], [21], [23], [29] and [30]. Regulating the input voltage reads on the controller 18 increasing or decreasing the driving frequency of the input voltage supplied to the speaker 14 to match the driving frequency of the input voltage when the speaker is operating at the resonance frequency as shown in Fig.4A. The phase of the sound engine corresponding with the acoustic signal generated by a sound engine reads on the speaker operating at the resonance frequency. D1 discloses that the controller 18 monitors the current draw of the speaker 14 to determine if the speaker is driven at the resonance frequency. The controller 18 increases or decreases the driving frequency supplied to the speaker 14 to ensure efficient operation at the resonance frequency.).

2.2 Hence, D1 discloses all the technical features of independent **claim 1**, which subject-matter is therefore not new (Article 33(2) PCT).

3 **Independent claim 9**

The present application does not meet the criteria of Article 33(1) PCT because, with respect to document D1, the subject-matter of independent claim 9 is not new in the sense of Article 33(2) PCT.

3.1 Document D1 discloses (references in parenthesis applying to this document):

A notification appliance (Fig.1, item 10 and paragraph [15] "notification apparatus 10") comprising:

- a sound engine generating a sound according to an acoustic pattern (Fig. 2, items 12 and 14; paragraph [17]. The notification apparatus comprises a control circuit 12 that controls the output of an audible tone from the speaker 14 at a peak level of efficiency by driving the speaker at the resonance frequency. The acoustic pattern reads on the resonance frequency of the speaker as shown in Fig.4A.); and
- a power control regulating input voltage to the sound engine that is matched to the acoustic pattern (Fig.2, items 18, 20 14; Fig.3, items 20, 14; Fig.4A to 4C; paragraphs [19], [21], [23], [29] and [30]. The power control reads on the controller 18. Regulating the input voltage reads on the controller 18 increasing or decreasing the driving frequency of the input voltage supplied to the speaker 14 to match the driving frequency of

the input voltage when the speaker is operating at the resonance frequency as shown in Fig.4A. Thus, when the speaker is operating at a frequency less or greater than the resonance frequency, shown in Fig.4B and 4C, the controller 18 regulates the driving frequency of the input voltage supplied to the speaker 14 to match the resonance frequency of the speaker and thus to ensure efficient operation.).

3.2 Hence, D1 discloses all the technical features of independent **claim 9**, which subject-matter is therefore not new (Article 33(2) PCT).

4 **Independent claim 17**

Independent claim 17 does not meet the criteria of Article 33(1) PCT, because, in view of D1 taken alone, the subject-matter of claim 17 does not involve an inventive step in the sense of Article 33(3) PCT.

4.1 Document D1 is considered to be the closest prior art to the subject-matter of claim 17. The same reasoning as for independent apparatus claim 9 applies, mutatis mutandis, to the features of the corresponding system claim 17 that have an overlap with the features specified in claim 9 (see section 3.1 above). D1 discloses these technical features, which subject-matter is therefore not new (Article 33(2) PCT).

4.2 The additional features of **claim 17** do not add anything of inventive significance. It is common general knowledge in the field of notification systems to connect a plurality of notification appliances by circuit wiring to provide electric power (see i.a. D2: Fig.2, item "to other audible alarm devices" and paragraph [21]. See i.a. D3: Fig.1, items 22 and paragraph [9]). Consequently, the subject-matter of independent claim 17 does not involve an inventive step in the sense of Article 33(2) PCT in view of document D1 taken alone.

5 **Dependent claims 2-8, 10-16, and 18-21**

Dependent claims 2-8, 10-16, and 18-21 do not contain any additional features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT regarding novelty (Article 33(2) PCT) or inventive step (Article 33(3) PCT).

5.1 **Article 33(2) PCT**

5.1.1 The features added by dependent claims 2, 6, 7, 10, 13-15, and 19-20 are known from D1 which discloses (references in parenthesis applying to this document):

- Claims 2, 13: (Implicit according to Fig.4A: Magnitude of the input voltage is constant, thus volume level of audible tone output from speaker 14 must be constant.)
- Claims 6, 7, 14, 15, 19, 20: (paragraphs [23] and [24]. Plurality of voltage levels to adjust the volume of the audible tone output from the speaker 14.)
- Claim 10: (Implicit according to Fig.4A: When voltage is input to the speaker, the audible tone is generated.)

5.1.2 Therefore, the subject-matter of **claims 2, 6, 7, 10, and 13-15** is not new within the meaning of Article 33(2) PCT, and the subject-matter of **claims 19-20** is not inventive within the meaning of Article 33(3) PCT.

5.2 **Article 33(3) PCT**

5.2.1 The additional features of dependent **claims 3-5, 11, 12, and 18** suggest minor implementation details which come within the scope of the customary practice followed by persons skilled in the art (see i.a. D3: Fig.1, item 22 "notification device" and item 26 "energy storage device"; paragraph [17]. See i.a. D4: Fig.2, item 220 "energy storage device"; column 6, lines 22-47), especially as the advantages thus achieved can be readily contemplated in advance. Therefore, the subject-matter of these claims does not add anything of inventive significance to the subject-matter of independent claim 1 or to any claim to which they refer (Article 33(3) PCT).

5.2.2 The additional features of **claims 8, 16, and 21** are considered obvious implementation details the skilled person would consider whenever appropriate without applying inventive skills. Therefore, the subject-matter of these claims cannot be considered to involve an inventive step (Article 33(3) PCT).

Re Item VIII

Certain observations on the international application

6 **Article 6 PCT**

The application does not meet the requirements of Article 6 PCT, because claims 1-6, 8, 9, 13, 14, 16, 19, and 21 are not clear, and claims lack 1, 9, and 17 essential features which are necessary to define the claimed invention, and claims 9 and 17 lack support.

6.1 **Claim 1** lacks essential features: Reading paragraph [46], it is evident that in order to provide a constant input current, as specified in claim 1, the current 15 flowing from the NAC has to be stored in the energy store 46 when the sound engine 28 is not generating sound. Only by buffering energy in the energy store 46, the input current can be kept constant. Consequently, storing input current in an energy store responsive to time intervals when the sound engine is not generating sound, is an essential feature necessary to define the claimed invention, which is missing in the independent claim 1, contrary to the requirements of Article 6 PCT.

6.2 In **claim 1**, the expression "regulating an input voltage to a phase of a sound engine corresponding with an acoustic signal generated by a sound engine" is not clear for the following reasons:

Which input voltage is regulated, the input voltage to the sounder or the input voltage to the sound engine? How does the sounder differ from the sound engine?

What is a phase of a sound engine, how is it defined? Does the expression "a phase of a sound engine corresponding with an acoustic signal generated by the sound engine" refer to the phase of the acoustic signal, or does it refer to a phase of the sound engine when the sound engine is generating sound versus a phase when the sound engine is not generating sound, i.e. a sound and no sound phase or an on-off phase of the sound engine (see paragraph [43] of the description)?

6.3 **Claim 2** does not meet the requirements of Article 6 PCT because the matter for which protection is sought is not clearly defined. The claim attempts to define the subject-matter in terms of the result to be achieved, which merely amounts to a statement of the underlying problem (regulating a sound output of the sound engine to a constant volume), without providing the technical features necessary for achieving this result. Which technical features are used to provide a constant sound output volume, is the regulation of the input voltage defined in claim 1 used or is some other means used?

6.4 In **claim 3**, the expression "the sound engine being between phases" is not clear. What phases are meant? And what is the status of the sound engine between phases? Does a phase of the sound engine refer to a time interval when the sound engine generates sound and the "between phases" a time interval when the sound engine does not generate sound? According to claim 4, it appears that the term "between phases" refers to a time interval when no sound is generated by the sound engine.

6.5 In **claims 2, 4, 5, and 6**, the terms "sound output", "sound", and "sound level" are not clear. Does the word sound in these terms refer to the acoustic signal specified in claim 1, which is generated by the sound engine? Is the word sound in claims 2, 4, and 5 used as synonym for the term "the acoustic signal" defined in claim 1? Or does it refer to another, additional sound signal? And does the term "sound level" in claim 6 refer to the sound level of the acoustic signal in claim 1 that is generated by the sound engine?

6.6 In **claim 8**, the expression "varying a ramp rate of a voltage to correspond with a sound pattern" is not clear for the following reasons:

Which voltage is meant? Is it the input voltage specified in claim 1?

Which sound pattern is meant? Is the sound pattern related to the acoustic signal generated by the sound engine?

6.7 In view of independent method claim 1 the corresponding independent apparatus **claim 9** lacks essential features: According to claim 1, it is evident that the applicant considers the "providing a constant current" as an essential feature necessary to define the claimed invention. These limitations are missing in claim 9, contrary to the requirements of Article 6 PCT.

Furthermore, as outlined for claim 1 in section 6.1 above, **claim 9** lacks a further essential feature, namely storing input current in an energy store responsive to time intervals when the sound engine is not generating sound. This feature is a further essential feature necessary to define the claimed invention, which is missing in the independent claim 9, contrary to the requirements of Article 6 PCT.

These objections for claim 9 may be overcome by including the features of claim 11.

The same objections of lack of essential features for claim 9 apply, mutatis mutandis, to the corresponding system **claim 17**. The objections for claim 17 may be overcome by including the features of claim 18.

6.8 **Claim 9** is not supported by the description as required by Article 6 PCT, as its scope is broader than justified by the description and drawings. Claim 9 specifies that the input voltage is regulated to match the acoustic pattern. The term "acoustic pattern" can be interpreted in many, very broad ways, such as e.g. a melodic pattern, a pitch pattern, a modulation pattern, etc. The description and drawings, however, specify only one type of acoustic pattern according to which the input voltage is regulated, namely a sound and no sound pattern (see paragraph [43] and Fig.3 and Fig.5). There is no basis in the description or drawings for any other type of acoustic pattern. Consequently, claim 9 lacks support.

The same objection applies, mutatis mutandis, to the corresponding system **claim 17**.

6.9 In **claim 13**, the expression " provide a constant volume" is not clear. Does the term "constant volume" refer to a constant volume of the sound generated by the sound engine according to the acoustic pattern, i.e. the sound and no sound pattern, or does it mean that the sound engine is regulated such that it generates continuously sound of constant volume without "no sound" phases?

6.10 In **claim 14**, the expression "adjust a sound level generated by the sound engine" is not clear. Does it refer to the sound level of the sound generated by the sound engine?

The same objection applies, mutatis mutandis, to the corresponding system **claim 19**.

6.11 In **claim 16**, the expression "adjust a voltage ramp rate to match an acoustic pattern" is not clear for the following reasons:

Which voltage is meant? Is it the input voltage specified in claim 9?

Does the term "an acoustic pattern" refer to the acoustic pattern mentioned in claim 9?

The same objection applies, mutatis mutandis, to the corresponding system **claim 21**.

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To: MATTHEW S. WILLIAMS
PERKINS COIE LLP
P.O. BOX 1247
SEATTLE, WA 98111-1247

RECEIVED
PATENT DOCKETING

JAN 25 2022

PERKINS COIE LLP

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT AND THE WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

Applicant's or agent's file reference 111552-8025WO00	Date of mailing *(day/month/year)* JAN 20 2022 **FOR FURTHER ACTION** See paragraphs 1 and 4 below
International application No. PCT/US 21/45072	International filing date *(day/month/year)* 06 August 2021 (06.08.2021)
Applicant INARI MEDICAL, INC.	

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

   Filing of amendments and statement under Article 19:
   The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

   When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

   How? Directly to the International Bureau preferably through ePCT, or on paper to:
   The International Bureau of WIPO, 34, chemin des Colombettes, 1211 Geneva 20, Switzerland

   For more detailed instructions, see the *PCT Applicant's Guide*, International Phase, paragraphs 9.004 – 9.011.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. ☐ **With regard to any protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:
   ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with any request to forward the texts of both the protest and the decision thereon to the designated Offices.
   ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Reminders**

   The applicant may **submit comments on an informal basis on the written opinion of the International Searching Authority** to the International Bureau. These comments will be made available to the public after international publication. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established.

   Shortly after the expiration of **18 months from the priority date, the international application will be published** by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau before the completion of the technical preparations for international publication (Rules 90*bis*.1 and 90*bis* 3).

   Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase **until 30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for **entry into the national phase** before those designated Offices. In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months. For details about the applicable time limits, Office by Office, see www.wipo.int/pct/en/texts/time_limits.html and the *PCT Applicant's Guide*, National Chapters.

   Within **22 months from the priority date, the applicant may request that a supplementary international search be carried out** by a different International Searching Authority that offers this service (Rule 45*bis*.1). The procedure for requesting supplementary international search is described in the *PCT Applicant's Guide*, International Phase, paragraphs 8.006-8.032.

Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Authorized officer Kari Rodriquez Telephone No. PCT Helpdesk: 571-272-4300

Form PCT/ISA/220 (revised January 2020)

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	FOR FURTHER ACTION
111552-8025WO00	see Form PCT/ISA/220 as well as, where applicable, item 5 below.

International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/US 21/45072	06 August 2021 (06.08.2021)	06 August 2020 (06.08.2020)

Applicant
INARI MEDICAL, INC.

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 4 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

a. With regard to the **language**, the international search was carried out on the basis of:

☒ the international application in the language in which it was filed.

☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

b. ☐ This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6*bis*(a)).

c. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☐ **Certain claims were found unsearchable** (see Box No. II).

3. ☒ **Unity of invention is lacking** (see Box No. III).

4. With regard to the **title**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2, by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the **drawings**,

a. the figure of the **drawings** to be published with the abstract is Figure No. 1B

☒ as suggested by the applicant.

☐ as selected by this Authority, because the applicant failed to suggest a figure.

☐ as selected by this Authority, because this figure better characterizes the invention.

b. ☐ none of the figures is to be published with the abstract.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 21/45072

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:
This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be searched, the appropriate additional search fees must be paid.

Group I: Claims 1-15 directed to an automatically-locking syringe.

Group II: Claims 16-20 directed to a clot treatment system.

Group III: Claims 21-28 directed to a syringe having a barrel and a vacuum indicator having a transparent tube and an indicator with a visual characteristic.

-*- See Supplemental Box -*-

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-15

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 21/45072

A. CLASSIFICATION OF SUBJECT MATTER

IPC - A61M 5/32; A61M 5/315 (2021.01)

CPC - A61M 5/32; A61M 5/502; A61M 5/3243; A61M 5/150641; A61M 5/3234; A61M 5/3232; A61M 5/5013; A61M 2005/5026; A61M 2005/3247; A61M 2005/3223; A61M 5/315

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
See Search History document

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
See Search History document

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
See Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2013/0126559 A1 (COWAN et al.) 23 May 2013 (23.05.2013); entire document, especially para [0028], and Fig. 1-2.	1-10
A	US 2004/0122359 A1 (WENZ et al.) 24 June 2004 (24.06.2004); entire document, especially para [0063]-[0066], and Fig. 7.	1-15
A	WO 2011/073176 A1 (NOVARTIS AG) 23 June 2011 (23.06.2011); especially pg 6 ln 33 to pg 7 ln 2, and Fig. 1-3.	10-15
A, P	WO 2021/067134 A1 (BECTON, DICKINSON AND COMPANY) 8 April 2021 (08.04.2021); entire document.	1-15
A	US 2004/0267272 A1 (HENNIGES et al.) 30 December 2004 (30.12.2004); entire document.	1-15

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"D" document cited by the applicant in the international application
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
2 December 2021	JAN 20 2022
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Authorized officer Kari Rodriquez Telephone No. PCT Helpdesk: 571-272-4300

Form PCT/ISA/210 (second sheet) (July 2019)

-*- Box III.0 - Explanations where unity of invention is lacking -*-

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

SPECIAL TECHNICAL FEATURES

The invention of Group I includes the special technical feature of a lock plate, not required by the claims of Groups II-III.

The invention of Group II includes the special technical feature of a catheter, not required by the claims of Groups I or III.

The invention of Group III includes the special technical feature of a transparent tube and an indicator movably positioned within the tube, not required by the claims of Groups I-II.

COMMON TECHNICAL FEATURES

Groups I and III share the common technical feature of a syringe having a barrel and a plunger movable through the barrel.
However, this shared technical feature does not represent a contribution over prior art as being anticipated by US 5,788,463 A (CHAN) (hereinafter Chan), which discloses a syringe (10; Fig. 1-10; col 4 ln 66 to col 5 ln 20) having a barrel (50; Fig. 1-10; col 5 ln 21-23) and a plunger movable through the barrel (60; Fig. 1-10; col 5 ln 21-23).

Groups II-III share the common technical feature of a vacuum indicator.
However, this shared technical feature does not represent a contribution over prior art as being anticipated by Chan, which discloses a vacuum indicator (15; Fig. 1-10; col 6 ln 36-50).

As the common technical features were known in the art at the time of the invention, these cannot be considered special technical features that would otherwise unify the groups.

Therefore, Groups I-III lack unity under PCT Rule 13 because they do not share a same or corresponding special technical feature.

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To: MATTHEW S. WILLIAMS
PERKINS COIE LLP
P.O. BOX 1247
SEATTLE, WA 98111-1247

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)*	JAN 20 2022
Applicant's or agent's file reference 111552-8025WO00	FOR FURTHER ACTION See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US 21/45072	06 August 2021 (06.08.2021)	06 August 2020 (06.08.2020)

International Patent Classification (IPC) or both national classification and IPC

IPC - A61M 5/32; A61M 5/315 (2021.01)

CPC - A61M 5/32; A61M 5/502; A61M 5/3243; A61M 5/150641; A61M 5/3234; A61M 5/3232; A61M 5/5013; A61M 2005/5026; A61M 2005/3247; A61M 2005/3223; A61M 5/315

Applicant INARI MEDICAL, INC.

1. This opinion contains indications relating to the following items:

- [x] Box No. I Basis of the opinion
- [ ] Box No. II Priority
- [ ] Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- [x] Box No. IV Lack of unity of invention
- [x] Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement
- [ ] Box No. VI Certain documents cited
- [ ] Box No. VII Certain defects in the international application
- [ ] Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

Name and mailing address of the ISA/US	Date of completion of this opinion	Authorized officer
Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	2 December 2021	Kari Rodriquez PCT Help Desk Telephone No. 571-272-4300

Form PCT/ISA/237 (cover sheet) (revised January 2019)

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 21/45072

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:

   ☒ the international application in the language in which it was filed.

   ☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(b)).

3. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of a sequence listing:

   a. ☐ forming part of the international application as filed:

      ☐ in the form of an Annex C/ST.25 text file.

      ☐ on paper or in the form of an image file.

   b. ☐ furnished together with the international application under PCT Rule 13*ter*.1(a) for the purposes of international search only in the form of an Annex C/ST.25 text file.

   c. ☐ furnished subsequent to the international filing date for the purposes of international search only:

      ☐ in the form of an Annex C/ST.25 text file (Rule 13*ter*.1(a)).

      ☐ on paper or in the form of an image file (Rule 13*ter*.1(b) and Administrative Instructions, Section 713).

4. ☐ In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that forming part of the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 21/45072

Box No. IV Lack of unity of invention

1. ☐ In response to the invitation (Form PCT/ISA/206) to pay additional fees the applicant has, within the applicable time limit:

   ☐ paid additional fees.

   ☐ paid additional fees under protest and, where applicable, the protest fee.

   ☐ paid additional fees under protest but the applicable protest fee was not paid.

   ☒ not paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is

   ☐ complied with.

   ☒ not complied with for the following reasons:

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be searched, the appropriate additional search fees must be paid.

Group I: Claims 1-15 directed to an automatically-locking syringe.

Group II: Claims 16-20 directed to a clot treatment system.

Group III: Claims 21-28 directed to a syringe having a barrel and a vacuum indicator having a transparent tube and an indicator with a visual characteristic.

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

SPECIAL TECHNICAL FEATURES

The invention of Group I includes the special technical feature of a lock plate, not required by the claims of Groups II-III.

The invention of Group II includes the special technical feature of a catheter, not required by the claims of Groups I or III.

The invention of Group III includes the special technical feature of a transparent tube and an indicator movably positioned within the tube, not required by the claims of Groups I-II.

COMMON TECHNICAL FEATURES

Groups I and III share the common technical feature of a syringe having a barrel and a plunger movable through the barrel.
However, this shared technical feature does not represent a contribution over prior art as being anticipated by US 5,788,463 A (CHAN) (hereinafter Chan), which discloses a syringe (10; Fig. 1-10; col 4 ln 66 to col 5 ln 20) having a barrel (50; Fig. 1-10; col 5 ln 21-23) and a plunger movable through the barrel (60; Fig. 1-10; col 5 ln 21-23).

Groups II-III share the common technical feature of a vacuum indicator.
However, this shared technical feature does not represent a contribution over prior art as being anticipated by Chan, which discloses a vacuum indicator (15; Fig. 1-10; col 8 ln 36-50).

As the common technical features were known in the art at the time of the invention, these cannot be considered special technical features that would otherwise unify the groups.

Therefore, Groups I-III lack unity under PCT Rule 13 because they do not share a same or corresponding special technical feature.

4. Consequently, this opinion has been established in respect of the following parts of the international application:

   ☐ all parts.

   ☒ the parts relating to claims Nos. 1-15

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 21/45072

Box No. V **Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	1-15	YES
	Claims	None	NO
Inventive step (IS)	Claims	1-15	YES
	Claims	None	NO
Industrial applicability (IA)	Claims	1-15	YES
	Claims	None	NO

2. Citations and explanations:
Claims 1-15 meet the criteria of PCT Article 33(2)-(3) because as will be shown, the prior art does not teach nor fairly suggest the claimed limitations.

The prior art is exemplified by (1) US 2013/0126559 A1 (COWAN et al.) (hereinafter Cowan); (2) US 2004/0122359 A1 (WENZ et al.) (hereinafter Wenz); and (3) WO 2011/073176 A1 (NOVARTIS AG) (hereinafter Novartis).

(1) Cowan teaches an automatically-locking syringe (8; Fig. 1-2; para [0028]), comprising:
a barrel (10; Fig. 1-2; para [0028]);
a plunger slidably positioned within the barrel (16; Fig. 1-2; para [0028]),
wherein the plunger is movable between a depressed position and a withdrawn position (depression and withdrawing action of 16 within 10; Fig. 1-2; para [0028]), and
wherein the plunger includes a lock feature (ratchet teeth upon 16; Fig. 1-2; para [0028]); and
a lock plate coupled to the barrel (18; Fig. 1-2; para [0028]),
wherein the lock plate includes a biasing member configured to bias the lock plate to a locking position (30; Fig. 1-2; para [0035]).

(2) Wenz teaches a syringe (Fig. 7; para [0063]-[0066]), comprising:
a barrel (unlabeled barrel through which 5 extends; Fig. 7; para [0064]),
a plunger (5; Fig. 7; para [0064]),
a lock plate (31, 32, 33, 34; Fig. 7; para [0064]-[0066]),
said lock plate having an opening extending therethrough (opening of 31, 32, 33, 34 through which 5 extends; Fig. 7),
wherein the plunger is slidably positioned in the opening (5 extending through opening of 31, 32, 33, 34; Fig. 7).

(3) Novartis teaches a syringe (2; Fig. 1-3; pg 6 ln 33 to pg 7 ln 2), comprising:
a first arm (22; Fig. 1-3; pg 7 ln 20-28),
a second arm (24; Fig. 1-3; pg 7 ln 20-28),
wherein the first arm is configured to be biased at least partially outwardly away from the longitudinal axis of the plunger to a locking position (outward bias of 22 away from 18; Fig. 1-3; pg 6 ln 25 to pg 9 ln 3).

-*- See Supplemental Box -*-

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of:
-*- Box V.2 - Citations and explanations -*-

As pertaining to claim 1, Cowan teaches an automatically-locking syringe (8; Fig. 1-2; para [0028]), comprising:
a barrel (10; Fig. 1-2; para [0028]);
a plunger slidably positioned within the barrel (16; Fig. 1-2; para [0028]),
wherein the plunger is movable between a depressed position and a withdrawn position (depression and withdrawing action of 16 within 10; Fig. 1-2; para [0028]), and
wherein the plunger includes a lock feature (ratchet teeth upon 16; Fig. 1-2; para [0028]); and
a lock plate coupled to the barrel (18; Fig. 1-2; para [0028]),
wherein the lock plate includes a biasing member configured to bias the lock plate to a locking position (30; Fig. 1-2; para [0035]);
but is silent wherein comprising:
said lock plate having an opening extending therethrough,
wherein the plunger is slidably positioned in the opening,
wherein-
when the plunger is moved from the depressed position to the withdrawn position, the lock feature is configured to engage the lock plate to drive the lock plate to a position away from the locking position to thereby permit the lock feature to pass through the opening, and
after the lock feature passes through the opening, the biasing member is configured to drive the lock plate to the locking position to inhibit movement of the plunger from the withdrawn position to the depressed position.
Further, Wenz teaches a syringe (Fig. 7; para [0063]-[0066]), comprising:
a barrel (unlabeled barrel through which 5 extends; Fig. 7; para [0064]),
a plunger (5; Fig. 7; para [0064]),
a lock plate (31, 32, 33, 34; Fig. 7; para [0064]-[0066]),
said lock plate having an opening extending therethrough (opening of 31, 32, 33, 34 through which 5 extends; Fig. 7),
wherein the plunger is slidably positioned in the opening (5 extending through opening of 31, 32, 33, 34; Fig. 7),
but the prior art does not teach nor fairly suggest:when the plunger is moved from the depressed position to the withdrawn position, the lock feature is configured to engage the lock plate to drive the lock plate to a position away from the locking position to thereby permit the lock feature to pass through the opening, and
after the lock feature passes through the opening, the biasing member is configured to drive the lock plate to the locking position to inhibit movement of the plunger from the withdrawn position to the depressed position.
The lock plate as claimed by the Applicant is driven away to prevent depression movement of the plunger through the barrel. There exists no motivation without benefit of hindsight for modification of the syringe of Cowan as modified by Wenz such the plunger is inhibited from depression movement as opposed to withdrawing movement, such that the claimed limitations are met.

As pertaining to claims 2-9, the prior art does not teach nor fairly suggest the claimed limitations, because claims 2-9 depend from claim 1.

As pertaining to claim 10, Wenz teaches an automatically-locking syringe (Fig. 7; para [0063]-[0066]), comprising:
a barrel (unlabeled barrel through which 5 extends; Fig. 7; para [0064]) including a flange (14; Fig. 7; para [0064]);
a plunger slidably positioned within the barrel (5; Fig. 7; para [0064]),
wherein the plunger is aligned along a longitudinal axis (longitudinal alignment of 5; Fig. 7), and
wherein the plunger is movable along the longitudinal axis between a depressed position and a withdrawn position (movement of 5 through unlabeled barrel; Fig. 7; para [0064]);
a lock member coupled to the plunger (31, 32, 33, 34; Fig. 7; para [0064]-[0066]),
wherein the lock member includes a body (body of 31; Fig. 7; para [0064]);
but is silent wherein:
the lock member includes a first arm hingedly coupled to the body,
wherein the first arm is configured to be biased at least partially outwardly away from the longitudinal axis of the plunger to a locking position; and
an actuator including a second arm,
wherein the actuator is movable between a first position and a second position, and
wherein the second arm is configured to engage the first arm in the second position to drive the first arm inwardly toward the longitudinal axis away from the locking position.
Further, Novartis teaches a syringe (2; Fig. 1-3; pg 6 ln 33 to pg 7 ln 2), comprising:
a first arm (22; Fig. 1-3; pg 7 ln 20-28),
a second arm (24; Fig. 1-3; pg 7 ln 20-28),
wherein the first arm is configured to be biased at least partially outwardly away from the longitudinal axis of the plunger to a locking position (outward bias of 22 away from 16; Fig. 1-3; pg 8 ln 25 to pg 9 ln 3),
but the prior art does not teach nor fairly suggest employment of the elements of Novartis upon the syringe of Wenz such that the claimed limitations are met.
There exists no motivation without benefit of hindsight for employment of the first arm and second arm of Novartis upon the syringe of Wenz, such that the second arm engages directly with the first arm in order to unlock the plunger for withdrawing.

As pertaining to claims 11-15, the prior art does not teach nor fairly suggest the claimed limitations, because claims 11-15 depend from claim 10.

Claims 1-15 have industrial applicability as defined by PCT Article 33(4) because the subject matter can be made or used by industry.

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	**FOR FURTHER ACTION**	see Form PCT/ISA/220 as well as, where applicable, item 5 below.
GWM-08-PCT		
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/US2019/050410	10 September 2019 (10-09-2019)	10 September 2018 (10-09-2018)
Applicant		
STRYKER CORPORATION		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 4 sheets.

[X] It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

a. With regard to the **language,** the international search was carried out on the basis of:

[X] the international application in the language in which it was filed

[ ] a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))

b. [ ] This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6*bis*(a)).

c. [ ] With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. [ ] **Certain claims were found unsearchable** (See Box No. II)

3. [ ] **Unity of invention is lacking** (see Box No III)

4. With regard to the **title,**

[X] the text is approved as submitted by the applicant

[ ] the text has been established by this Authority to read as follows:

5. With regard to the **abstract,**

[X] the text is approved as submitted by the applicant

[ ] the text has been established, according to Rule 38.2, by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority

6. With regard to the **drawings,**

a. the figure of the **drawings** to be published with the abstract is Figure No. 7

[X] as suggested by the applicant

[ ] as selected by this Authority, because the applicant failed to suggest a figure

[ ] as selected by this Authority, because this figure better characterizes the invention

b. [ ] none of the figures is to be published with the abstract

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2019/050410

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/22 A61B17/221 A61B17/3207
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2017/189535 A2 (STRYKER CORP [US]) 2 November 2017 (2017-11-02) abstract paragraphs [0022], [000154] - [000155], [000167] - [000195], [000219]; figures 2-42	1-28
X	WO 2018/049317 A1 (STRYKER CORP [US]) 15 March 2018 (2018-03-15) abstract paragraphs [0082], [000136] - [000149]; figures 1-28	1-28
X	WO 2017/189591 A1 (STRYKER CORP [US]) 2 November 2017 (2017-11-02) abstract paragraphs [00021] - [00024], [00036] - [00066]; figures 1-9	1-4,9-20

-/--

[X] Further documents are listed in the continuation of Box C. [X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
18 October 2019	25/10/2019

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Ioanovici, T

2

Form PCT/ISA/210 (second sheet) (April 2005)

International application No
PCT/US2019/050410

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 2009/086482 A1 (LAZARUS EFFECT INC [US]; MARTIN BRIAN B [US] ET AL.) 9 July 2009 (2009-07-09) abstract paragraphs [0159] - [0164]; figure 13	1-28

2

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2019/050410

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2017189535 A2	02-11-2017	CN 109890304 A	14-06-2019
		EP 3448280 A2	06-03-2019
		JP 2019519341 A	11-07-2019
		US 2017303948 A1	26-10-2017
		US 2019117244 A1	25-04-2019
		US 2019133622 A1	09-05-2019
		WO 2017189535 A2	02-11-2017
WO 2018049317 A1	15-03-2018	CN 109922744 A	21-06-2019
		EP 3509507 A1	17-07-2019
		JP 2019526381 A	19-09-2019
		US 2018070968 A1	15-03-2018
		WO 2018049317 A1	15-03-2018
WO 2017189591 A1	02-11-2017	CN 109414272 A	01-03-2019
		EP 3448278 A1	06-03-2019
		JP 2019514648 A	06-06-2019
		US 2017303939 A1	26-10-2017
		US 2018042624 A1	15-02-2018
		WO 2017189591 A1	02-11-2017
WO 2009086482 A1	09-07-2009	CN 102036611 A	27-04-2011
		EP 2231037 A1	29-09-2010
		JP 5385302 B2	08-01-2014
		JP 5914432 B2	11-05-2016
		JP 2011508635 A	17-03-2011
		JP 2013233454 A	21-11-2013
		JP 2016041275 A	31-03-2016
		US 2009299393 A1	03-12-2009
		US 2014005717 A1	02-01-2014
		US 2017325830 A1	16-11-2017
		WO 2009086482 A1	09-07-2009

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US2019/050410	10.09.2019	10.09.2018

International Patent Classification (IPC) or both national classification and IPC
INV. A61B17/22 A61B17/221 A61B17/3207

Applicant
STRYKER CORPORATION

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☒ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notifed the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

Name and mailing address of the ISA:	Date of completion of this opinion	Authorized Officer
European Patent Office P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Fax: +31 70 340 - 3016	see form PCT/ISA/210	Ioanovici, T Telephone No. +31 70 340-0

Form PCT/ISA/237 (Cover Sheet) (January 2015)

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of:

   ☑ the international application in the language in which it was filed.

   ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).

2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a))

3. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of a sequence listing:

   a. ☐ forming part of the international application as filed:

      ☐ in the form of an Annex C/ST.25 text file.

      ☐ on paper or in the form of an image file.

   b. ☐ furnished together with the international application under PCT Rule 13*ter*.1(a) for the purposes of international search only in the form of an Annex C/ST.25 text file.

   c. ☐ furnished subsequent to the international filing date for the purposes of international search only:

      ☐ in the form of an Annex C/ST.25 text file (Rule 13*ter*.1(a)).

      ☐ on paper or in the form of an image file (Rule 13*ter*.1(b) and Administrative Instructions, Section 713).

4. ☐ In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that forming part of the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	10-13, 16-20, 22, 23
	No:	Claims	1-9, 14, 15, 21, 24-28
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-28
Industrial applicability (IA)	Yes:	Claims	1-28
	No:	Claims	

2. Citations and explanations

see separate sheet

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents:

D1 WO 2017/189535 A2 (STRYKER CORP [US]) 2 November 2017 (2017-11-02)

D2 WO 2018/049317 A1 (STRYKER CORP [US]) 15 March 2018 (2018-03-15)

D3 WO 2017/189591 A1 (STRYKER CORP [US]) 2 November 2017 (2017-11-02)

D4 WO 2009/086482 A1 (LAZARUS EFFECT INC [US]; MARTIN BRIAN B [US] ET AL.) 9 July 2009 (2009-07-09)

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 1, 14 and 21 is not new in the sense of Article 33(2) PCT.

D1 (abstract; paragraphs [0022], [000154] - [000155], [000167] - [000195], [000219]; figures 2-42) discloses:

An atherectomy device for removing a plaque material from a blood vessel (abstract), the device comprising:
a catheter having a distal edge defining an opening that provides access to a lumen within the catheter (para.[000154]-[000155]); and
a tractor (144,201,311,405,601,1101,1401,1600) comprising a flexible tube that at least partially covers and extends along an outer surface of the catheter and inverts over the catheter distal edge, such that a first end of the flexible tube extends through the opening into the lumen of the catheter (fig.2-17,31-40),
wherein the flexible tube comprises a plurality of engagement features cut at an acute angle into an outer surface of the flexible tube to form a plurality of acute cutting edges (para.[00022],[000171],[000178]-[000182]), and
wherein the flexible tube is configured so that pulling the first end of the flexible tube proximally through the catheter lumen causes the flexible tube to roll and invert over the catheter distal edge, thereby exposing the acute cutting edges distally as the flexible tube rolls into the catheter lumen (para.[000181]-000182],fig.2-17,31-40).

Moreover D1 also discloses the supplementary features of claims 14 and 21, such as the different shapes engagement features (para.[000181]-[000184], fig.30-37), the activatable tractor (the term "activatable" is interpreted as being actuatable manually or by other driving means, para.[000219]), the spaced apart bands of engagement (knit

bands / circumferentially aligned hoops 1105 / interlocking keys 2601 / stiffer regions 2403/3001 in between flexible regions 2401/3003, para.[000181]-[000184], fig. 10,13, 17,18,20,26-37,40).

Furthermore D2 (abstract; paragraphs [0082], [000136] - [000149]; figures 1-28) and D3 (abstract; paragraphs [00021] - [00024], [00036] - [00066]; figures 1-9) also discloses all the features of claims 1 and 14, especially the engagement features (D2 para.[000144], [000150]; D3 para.[0038]).

Dependent claims 2-13, 15-20 and 22-28 do not appear to contain any additional features which, in combination with the features of any claim to which it refers, meet the requirements of the PCT in respect of novelty and/or inventive step. The technical features of these claims are either disclosed in D1-D4 or are minor constructional detail changes. Some examples of the disclosed features can be seen below:

Claims 2-3: D1 para.[000131],[000151],[000155],[000163],[000167],[000181]-[000184], fig.2C,13,17,25.

Claims 5-8, 22-27: D1 knit bands / circumferentially aligned hoops 1105 / interlocking keys 2601 / stiffer regions 2403/3001 in between flexible regions 2401/3003, para. [000181]-[000184], fig. 10,13, 17,18,20,26-37,40.

Claims 9-12, 15-18: D1 para.[000181]-[000184], fig.30-37.

Re Item VII

Certain defects in the international application

The present application does not meet the requirements of Rule 6.3(b) PCT regarding the use of the two-part form in claims, of Rule 6.2(b) PCT regarding reference signs, of Rule 10.1(d) PCT regarding internationally recognized units (see paragraphs [0059], [0064] for example), nor those of Rule 5.1(a)(ii) PCT regarding mentioning relevant prior art in the description.

Re Item VIII

Certain observations on the international application

Although claims 1, 14 and 21 have been drafted as separate independent claims, they appear to relate effectively to the same subject-matter and to differ from each other only with regard to the definition of the subject-matter for which protection is sought and/or in respect of the terminology used for the features of that subject-matter. The aforementioned claims therefore lack conciseness and as such do not meet the requirements of Article 6 PCT.

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To: MATTHEW S. WILLIAMS
PERKINS COIE LLP
P.O. BOX 1247
SEATTLE, WA 98111-1247

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT AND THE WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

Applicant's or agent's file reference 111552-8027WO00	Date of mailing *(day/month/year)* MAR 16 2022 **FOR FURTHER ACTION** See paragraphs 1 and 4 below
International application No. PCT/US 21/58793	International filing date *(day/month/year)* 10 November 2021 (10.11.2021)
Applicant INARI MEDICAL, INC.	

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

   Filing of amendments and statement under Article 19:
   The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

   When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

   How? Directly to the International Bureau preferably through ePCT, or on paper to:
   The International Bureau of WIPO, 34, chemin des Colombettes, 1211 Geneva 20, Switzerland

   For more detailed instructions, see the *PCT Applicant's Guide*, International Phase, paragraphs 9.004 – 9.011.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. ☐ **With regard to any protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:
   ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with any request to forward the texts of both the protest and the decision thereon to the designated Offices.
   ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Reminders**

   The applicant may **submit comments on an informal basis on the written opinion of the International Searching Authority** to the International Bureau. These comments will be made available to the public after international publication. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established.

   Shortly after the expiration of **18 months from the priority date, the international application will be published** by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau before the completion of the technical preparations for international publication (Rules 90*bis*.1 and 90*bis*.3).

   Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase **until 30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for **entry into the national phase** before those designated Offices. In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months. For details about the applicable time limits, Office by Office, see www.wipo.int/pct/en/texts/time_limits.html and the *PCT Applicant's Guide*, National Chapters.

   Within **22 months from the priority date, the applicant may request that a supplementary international search be carried out** by a different International Searching Authority that offers this service (Rule 45*bis*.1). The procedure for requesting supplementary international search is described in the *PCT Applicant's Guide*, International Phase, paragraphs 8.006-8.032.

Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Authorized officer Kari Rodriquez Telephone No. PCT Helpdesk: 571-272-4300

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference		FOR FURTHER ACTION
111552-8027WO00		see Form PCT/ISA/220 as well as, where applicable, item 5 below.
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/US 21/58793	10 November 2021 (10.11.2021)	10 November 2020 (10.11.2020)
Applicant INARI MEDICAL, INC.		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 3 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

a. With regard to the **language**, the international search was carried out on the basis of:

☒ the international application in the language in which it was filed.

☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

b. ☐ This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6*bis*(a)).

c. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☐ **Certain claims were found unsearchable** (see Box No. II).

3. ☒ **Unity of invention is lacking** (see Box No. III).

4. With regard to the **title**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2, by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the **drawings**,

a. the figure of the **drawings** to be published with the abstract is Figure No. 1C

☒ as suggested by the applicant.

☐ as selected by this Authority, because the applicant failed to suggest a figure.

☐ as selected by this Authority, because this figure better characterizes the invention.

b. ☐ none of the figures is to be published with the abstract.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 21/58793

A. CLASSIFICATION OF SUBJECT MATTER

IPC - A61B 17/03; A61B 17/04 (2022.01)

CPC - A61B 17/04; A61B 2017/0496; A61B 17/03; A61B 17/56; A61B 17/0467; A61B 17/8869; A61B 17/0482; A61B 17/0469

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
See Search History document

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
See Search History document

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
See Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X -- Y	US 5,376,101 A (GREEN et al.) 27 December 1994 (27.12.1994); entire document, especially col 6 ln 56 to col 7 ln 17, and Fig. 15-18.	1, 5-7 -- 2-4
Y	US 5,192,274 A (BIERMAN) 9 March 1993 (09.03.1993); especially col 2 ln 21-54, and Fig. 1-2.	2-3
Y	US 2013/0116708 A1 (ZINITI et al.) 9 May 2013 (09.05.2013); especially para [0090], and Fig. 18A-B.	4
A	US 2004/0260344 A1 (LYONS et al.) 23 December 2004 (23.12.2004); entire document.	1-7

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"D" document cited by the applicant in the international application
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
2 March 2022	MAR 16 2022
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Authorized officer Kari Rodriquez Telephone No. PCT Helpdesk: 571-272-4300

-*- Box III.0 - Explanations where unity of invention is lacking -*-

SPECIAL TECHNICAL FEATURES

The invention of Group I includes the special technical feature of when the first through-hole and the second through-hole receive the suture and the actuator is in the second position, the actuator and the housing cooperate to permit the suture to move relative to the housing, not required by the claims of Group II-III.

The invention of Group II includes the special technical feature of a biasing member operably coupled between the actuator and the housing, not required by the claims of Group I or II.

The invention of Group III includes the special technical feature of adjusting a tension of the suture to a desired tension, not required by the claims of Group I-II.

COMMON TECHNICAL FEATURES

Groups I-III share the common technical feature of a suture tensioning device.
However, this shared technical feature does not represent a contribution over prior art as being anticipated by US 8,888,791 B2 (JARAMILLO et al.) (hereinafter Jaramillo), which discloses a suture tensioning device (100; Fig. 1; col 5 ln 40-62).

Groups I-II share the common technical feature of a device for tensioning a suture, comprising:
a housing having a first through-hole; and
an actuator coupled to the housing and having a second through-hole,
wherein the actuator is movable relative to the housing from a first position to a second position.
However, this shared technical feature does not represent a contribution over prior art as being anticipated by Jaramillo, which discloses a device for tensioning a suture (Fig. 9; col 7 ln 41-51), comprising:
a housing (upper housing of 900; Fig. 9; col 7 ln 41-51) having a first through-hole (902; Fig. 9; col 7 ln 41-51); and
an actuator (903, unlabeled semicircular half adjacent 903; Fig. 9; col 7 ln 41-51) coupled to the housing and having a second through-hole (901; Fig. 9; col 7 ln 41-51),
wherein the actuator is movable relative to the housing from a first position (903 adjacent and flush with housing of 900; Fig. 9; col 7 ln 41-51) to a second position (position of Fig. 9 with 903 deployed rotated outward; Fig. 9; col 7 ln 41-51).

As the common technical features were known in the art at the time of the invention, these cannot be considered special technical features that would otherwise unify the groups.

Therefore, Groups I-III lack unity under PCT Rule 13 because they do not share a same or corresponding special technical feature.

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To: MATTHEW S. WILLIAMS
PERKINS COIE LLP
P.O. BOX 1247
SEATTLE, WA 98111-1247

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)*	MAR 16 2022
Applicant's or agent's file reference 111552-8027WO00	FOR FURTHER ACTION See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US 21/58793	10 November 2021 (10.11.2021)	10 November 2020 (10.11.2020)

International Patent Classification (IPC) or both national classification and IPC

IPC - A61B 17/03; A61B 17/04 (2022.01)

CPC - A61B 17/04; A61B 2017/0496; A61B 17/03; A61B 17/56; A61B 17/0467; A61B 17/8869; A61B 17/0482; A61B 17/0469

Applicant INARI MEDICAL, INC.

1. This opinion contains indications relating to the following items:

- [x] Box No. I Basis of the opinion
- [ ] Box No. II Priority
- [ ] Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- [x] Box No. IV Lack of unity of invention
- [x] Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement
- [ ] Box No. VI Certain documents cited
- [ ] Box No. VII Certain defects in the international application
- [ ] Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

Name and mailing address of the ISA/US	Date of completion of this opinion	Authorized officer
Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	2 March 2022	Kari Rodriquez PCT Help Desk Telephone No. 571-272-4300

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 21/58793

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:

☒ the international application in the language in which it was filed.

☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(b)).

3. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of a sequence listing:

a. ☐ forming part of the international application as filed:

☐ in the form of an Annex C/ST.25 text file.

☐ on paper or in the form of an image file.

b. ☐ furnished together with the international application under PCT Rule 13*ter*.1(a) for the purposes of international search only in the form of an Annex C/ST.25 text file.

c. ☐ furnished subsequent to the international filing date for the purposes of international search only:

☐ in the form of an Annex C/ST.25 text file (Rule 13*ter*.1(a)).

☐ on paper or in the form of an image file (Rule 13*ter*.1(b) and Administrative Instructions, Section 713).

4. ☐ In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that forming part of the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 21/58793

Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees the applicant has, within the applicable time limit:

   ☐ paid additional fees.

   ☐ paid additional fees under protest and, where applicable, the protest fee.

   ☐ paid additional fees under protest but the applicable protest fee was not paid.

   ☒ not paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is

   ☐ complied with.

   ☒ not complied with for the following reasons:

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be searched, the appropriate additional search fees must be paid.

Group I: Claims 1-7 directed to a device for tensioning a suture, having a housing with a first through-hole and an actuator with a second through-hole.

Group II: Claims 8-14 directed to a suture tensioning device, having a housing, an actutator, and a biasing member.

Group III: Claims 15-20 directed to a method of tensioning a suture.

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

SPECIAL TECHNICAL FEATURES

The invention of Group I includes the special technical feature of when the first through-hole and the second through-hole receive the suture and the actuator is in the second position, the actuator and the housing cooperate to permit the suture to move relative to the housing, not required by the claims of Group II-III.

The invention of Group II includes the special technical feature of a biasing member operably coupled between the actuator and the housing, not required by the claims of Group I or II.

The invention of Group III includes the special technical feature of adjusting a tension of the suture to a desired tension, not required by the claims of Group I-II.

COMMON TECHNICAL FEATURES

Groups I-III share the common technical feature of a suture tensioning device.
However, this shared technical feature does not represent a contribution over prior art as being anticipated by US 8,888,791 B2 (JARAMILLO et al.) (hereinafter Jaramillo), which discloses a suture tensioning device (100; Fig. 1; col 5 ln 40-62).

Groups I-II share the common technical feature of a device for tensioning a suture, comprising:
a housing having a first through-hole; and
an actuator coupled to the housing and having a second through-hole,
wherein the actuator is movable relative to the housing from a first position to a second position.
However, this shared technical feature does not represent a contribution over prior art as being anticipated by Jaramillo, which discloses a device for tensioning a suture (Fig. 9; col 7 ln 41-51), comprising:
a housing (upper housing of 900; Fig. 9; col 7 ln 41-51) having a first through-hole (902; Fig. 9; col 7 ln 41-51); and
an actuator (903, unlabeled semicircular half adjacent 903; Fig. 9; col 7 ln 41-51) coupled to the housing and having a second through-hole (901; Fig. 9; col 7 ln 41-51),
wherein the actuator is movable relative to the housing from a first position (903 adjacent and flush with housing of 900; Fig. 9; col 7 ln 41-51) to a second position (position of Fig. 9 with 903 deployed rotated outward; Fig. 9; col 7 ln 41-51).

-*- See Supplemental Box -*-

4. Consequently, this opinion has been established in respect of the following parts of the international application:

   ☐ all parts.

   ☒ the parts relating to claims Nos. 1-7

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 21/58793

Box No. V **Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	2-4	YES
	Claims	1, 5-7	NO
Inventive step (IS)	Claims	None	YES
	Claims	1-7	NO
Industrial applicability (IA)	Claims	1-7	YES
	Claims	None	NO

2. Citations and explanations:

Claims 1 and 5-7 lack novelty under PCT Article 33(2) as being anticipated by US 5,376,101 A (GREEN et al.) (hereinafter Green).

As pertaining to claim 1, Green teaches a device for tensioning a suture (Fig. 15-18; col 6 ln 56 to col 7 ln 17), comprising:
a housing (510; Fig. 15-18; col 6 ln 56-62) having a first through-hole (511; Fig. 15-18; col 6 ln 56-62); and
an actuator (520; Fig. 15-18; col 6 ln 56-62) coupled to the housing and having a second through-hole (passageway 526; Fig. 15-18; col 6 ln 63 to col 7 ln 13),
wherein the actuator is movable relative to the housing from a first position (position of 520 relative to 510 in Fig. 17; col 7 ln 4-12) to a second position (position of 520 relative to 510 in Fig. 16; col 6 ln 63 to col 7 ln 3),
wherein the first through-hole and the second through-hole are configured to receive a suture therethrough (10; Fig. 15-18; col 7 ln 1-3), and wherein-
when the first through-hole and the second through-hole receive the suture and the actuator is in the first position, the actuator and the housing cooperate to inhibit the suture from moving relative to the housing (receipt of 10 through 511, hole through 520, secured in Fig. 17; col 7 ln 4-17); and
when the first through-hole and the second through-hole receive the suture and the actuator is in the second position, the actuator and the housing cooperate to permit the suture to move relative to the housing (receipt of 10 through 511, hole through 520, adjustable in Fig. 16, col 6 ln 63 to col 7 ln 3).

As pertaining to claim 5, Green teaches the device of claim 1 wherein the first through-hole and the second through-hole are axially offset in the first position (position of 520 and 526 offset relative to 510 and 511 in Fig. 17; col 7 ln 4-12), and wherein the first through-hole and the second through-hole are axially aligned in the second position (position of 520 and 526 aligned relative to 510 and 511 in Fig. 16; col 6 ln 63 to col 7 ln 3).

As pertaining to claim 6, Green teaches the device of claim 5 wherein the housing and actuator engage the suture in the first position to clamp the suture relative to the housing (clamping of 10 with respect to 510 by 520 action; Fig. 16-17; col 6 ln 63 to col 7 ln 17).

As pertaining to claim 7, Green teaches the device of claim 1 wherein the first through-hole and the second through-hole are aligned along an axis in the second position (position of 520 and 526 aligned relative to 510 and 511 in Fig. 16; col 6 ln 63 to col 7 ln 3), and wherein the actuator is movable from the first position to the second position in a direction generally orthogonal to the axis (movement of 520 orthogonal to axis of 511; Fig. 16-17; col 6 ln 63 to col 7 ln 3).

Claims 2-3 lack an inventive step under PCT Article 33(3) as being obvious over Green in view of US 5,192,274 A to BIERMAN (hereinafter Bierman).

As pertaining to claim 2, Green teaches the device of claim 1, but is silent wherein further comprising a flexible pad coupled to the housing.
However, Bierman teaches a device (Fig. 1-2; col 2 ln 21-54), comprising:
a housing (12; Fig. 1-2; 2 ln 29-42); and
a flexible pad coupled to the housing (22; Fig. 1-2; col 2 ln 50-53, col 1 ln 22-24).
Accordingly, it would have been obvious to a person having ordinary skill in the art to have employed the pad of Bierman upon the device of Green, in order to safely and removably secure the device to a patient's skin.

As pertaining to claim 3, Green in view of Bierman teaches the device of claim 2 and Bierman further discloses wherein the flexible pad is configured to be placed against skin of a patient and to conform to the skin of the patient (flexible pad 22 applied upon skin of patient; Fig. 1-2; col 2 ln 50-53, col 1 ln 22-24).

-*- See Supplemental Box -*-

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 21/58793

Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**
Continuation of:
-*- Box IV.2 - Explanations where unity of invention is lacking -*-

As the common technical features were known in the art at the time of the invention, these cannot be considered special technical features that would otherwise unify the groups.

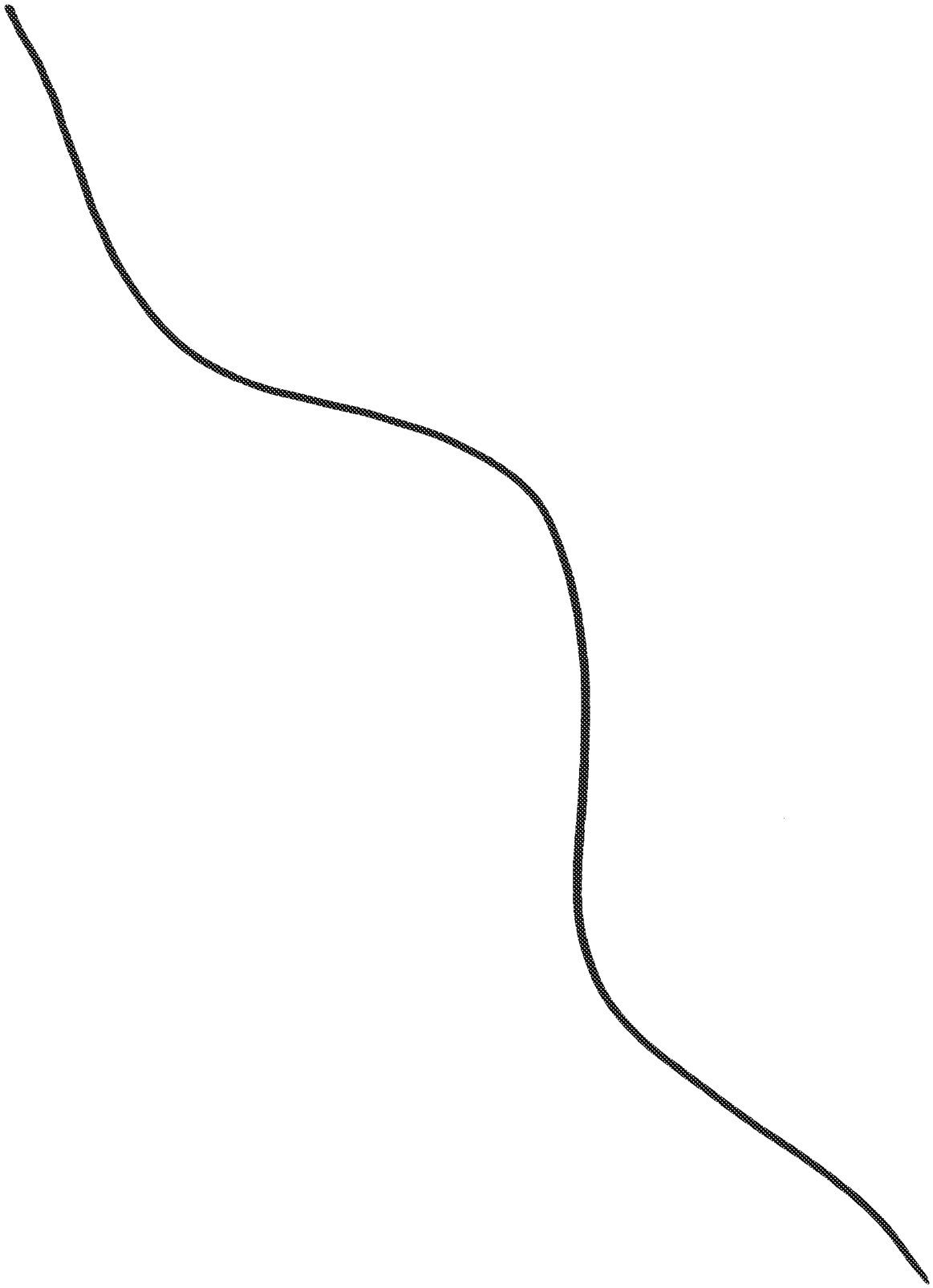
Therefore, Groups I-III lack unity under PCT Rule 13 because they do not share a same or corresponding special technical feature.

-*- Box V.2 - Citations and explanations -*-

Claim 4 lacks an inventive step under PCT Article 33(3) as being obvious over Green in view of US 2013/0116708 A1 to ZINITI et al. (hereinafter Ziniti).

As pertaining to claim 4, Green teaches the device of claim 1 but is silent wherein further comprising a biasing member operably coupled between the actuator and the housing, wherein the biasing member is configured to bias the actuator to the first position.
However, Ziniti further discloses a device (Fig. 18A-B; para [0090]), comprising:
a biasing member operably coupled between the actuator and the housing (spring 612; Fig. 18A-B; para [0093]),
wherein the biasing member is configured to bias the actuator to the first position (spring 612 capable of being disposed to bias actuator; Fig. 18A-B; para [0093]).
Accordingly, it would have been obvious to a person having ordinary skill in the art to have employed the biasing member of Ziniti upon the device of Green, in order to aid in user deployment of the device.

Claims 1-7 have industrial applicability as defined by PCT Article 33(4) because the subject matter can be made or used by industry.



Application Number	PCT/US 21/58793
Search Conducted By	SBF
Search Approved By	SCL

CPC/IPC Classifications Searched	IPC(8) A61B 17/03; A61B 17/04 (2022.01) CPC A61B 17/04; A61B 2017/0496; A61B 17/03; A61B 17/56; A61B 17/0467; A61B 17/8869; A61B 17/0482; A61B 17/0469
Date Conducted	25 February-2 March 2022 (25.02.-02.03.2022)

Documentation Searched	IPC(8) A61B 17/03; A61B 17/04 (2022.01) CPC A61B 17/04; A61B 2017/0496; A61B 17/03; A61B 17/56; A61B 17/0467; A61B 17/8869; A61B 17/0482; A61B 17/0469 (keyword limited; terms below)
Search Terms Used	Suture tensioner inari medical flowstasis retention large bore through holes lock retainer misalign tighten adjust gap aperture align line up slot friction clamp clutch thread cable cord increment ratchet button actuator spring load stop restrain
Date Conducted	25 February-2 March 2022 (25.02.-02.03.2022)

Electronic Database Searched	PatBase
Files Searched	Full-text: AU BE BR CA CH CN DE DK EP ES FI FR GB IN JP KR SE TH TW US WO Bibliographic: (European) AT BA BE BG CH CS CY CZ DD DK EE ES FI GE GR HR HU IE IS IT LT LU LV MC MD MT NL NO PL PT RO RS SE SI SK SM TR UA YU (Asia) EA GC HK ID IL IN KZ MN MY PH RU SG SU TH TJ TW UZ VN (North America) CA CR CU DO GT HN MX NI PA SV TT (South America) AR BR CL CO EC PE UY (Australasia) AU NZ (Africa) AP DZ EG KE MA MW OA ZA ZM ZW
Date Conducted	25 February-2 March 2022 (25.02.-02.03.2022)
Search Logic:	

25 February-
Search 1: pa=(inari medical*) (Results 12)
Search 2: inv=(macias jacqueline* or enright paige* or tu thomas*) (Results 16)
Search 3: 1 or 2 (Results 26)
Search 4: pn=(US8888791) (Results 1)
Search 5: 3 and ft=(suture* near tension*) (Results 0)
Search 6: ctf 4 or ctb 4 (Results 165)
Search 7: 6 and ft=(suture* near (tension* or tighten* or adjust*)) (Results 100)
Search 8: 7 not (4 or 3) (Results 99)
Search 9: cpc=(A61B2017/0496*) (Results 1269)
Search 10: 9 and ft=((hole* or gap* or aperture*) near (align* or (line up*))) (Results 176)
Search 11: 10 not (7 or 4 or 3) (Results 173)

28 February-
Search 12: pn=(US20040260344A1) (Results 1)
Search 13: ctf 12 or ctb 12 (Results 193)
Search 14: 13 and ft=(suture* near (tension* or tighten* or adjust*)) (Results 105)
Search 15: 14 not (12 or 10 or 7 or 4 or 3) (Results 99)
Search 16: pn=(jp2018000843) (Results 1)
Search 17: ctf 16 or ctb 16 (Results 4)
Search 18: cpc=(A61B17/8869*) (Results 409)
Search 19: 18 and ft=((hole* or gap* or aperture* or slot*) near (align* or (line up*) or misalign* or friction*)) (Results 89)
Search 20: 19 not (17 or 16 or 14 or 12 or 10 or 7 or 4 or 3) (Results 79)
Search 21: 13 and ft=((hole* or gap* or aperture*) near (align* or (line up*))) (Results 25)
Search 22: pn=(us5376101) (Results 1)
Search 23: ctf 22 or ctb 22 (Results 308)
Search 24: 23 and ft=((hole* or gap* or aperture* or slot*) near (align* or (line up*) or misalign* or friction*)) (Results 78)
Search 25: 24 not (22 or 21 or 19 or 17 or 16 or 14 or 12 or 10 or 7 or 4 or 3) (Results 57)

2 March-
Search 26: ic=(A61B17/03* OR A61B17/04*) (Results 44372)
Search 27: cpc=(A61B17/03* OR A61B17/04* OR A61B17/56* OR A61B17/0467* OR A61B17/8869* OR A61B17/0482* OR A61B17/0469* OR A61B2017/0496*) (Results 45941)
Search 28: 26 or 27 (Results 76570)
Search 29: 28 and ft=((hole* or gap* or aperture* or slot*) near (align* or (line up*) or misalign* or friction* or clamp* or clutch*)) (Results 9859)
Search 30: 29 and ft=((suture* or thread* or cable* or cord*) near (tension* or tighten* or increment* or ratchet*)) (Results 1998)
Search 31: 30 and ft=(button* or actuator* or (spring* near load*)) (Results 1019)
Search 32: 31 and ft=(spring*) (Results 873)
Search 33: 32 and ft=(suture* near (lock* or stop* or restrain*)) (Results 238)
Search 34: 33 not (24 or 22 or 21 or 19 or 17 or 16 or 14 or 12 or 10 or 7 or 4 or 3) (Results 156)
Search 35: ft=(suture* near (tension* or tighten*)) (Results 6198)
Search 36: 35 and ft=((hole* or gap* or aperture* or slot* or groove*) near (align* or (line up*) or misalign* or friction*)) (Results 1081)
Search 37: 36 and ft=(suture* near (lock* or stop* or restrain*)) (Results 452)
Search 38: 37 and ft=(spring*) (Results 317)
Search 39: 38 and ft=(spring* near (load* or actuat*)) (Results 154)
Search 40: 39 not (33 or 24 or 22 or 21 or 19 or 17 or 16 or 14 or 12 or 10 or 7 or 4 or 3) (Results 20)

Electronic Database Searched	Google
Files Searched	Google Patents
Date Conducted	25 February-2 March 2022 (25.02.-02.03.2022)
Search Logic:	

Suture tensioning through holes
About 12,200 results

Suture tensioning through holes ratchet
About 4,700 results

Suture tensioning through holes lock
About 12,000 results

Suture retainer lock hole misalign
About 6,350 results

Electronic Database Searched	Google
Files Searched	Google Web
Date Conducted	25 February-2 March 2022 (25.02.-02.03.2022)
Search Logic:	

Suture tensioner
About results

Suture tensioner inari medical
About results

Flowstasis suture retention
About results

Large bore suture retention

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To: MATTHEW S. WILLIAMS
PERKINS COIE LLP
P.O. BOX 1247
SEATTLE, WA 98111-1247

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT AND THE WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

Applicant's or agent's file reference: 111552-8029WO00	Date of mailing (day/month/year): MAR 22 2022
International application No.: PCT/US 21/59735	FOR FURTHER ACTION See paragraphs 1 and 4 below
Applicant: INARI MEDICAL, INC.	International filing date (day/month/year): 17 November 2021 (17.11.2021)

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

Filing of amendments and statement under Article 19:
The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46).

When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

How? Directly to the International Bureau preferably through ePCT, or on paper to:
The International Bureau of WIPO, 34, chemin des Colombettes, 1211 Geneva 20, Switzerland

For more detailed instructions, see the *PCT Applicant's Guide*, International Phase, paragraphs 9.004 – 9.011.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. ☐ **With regard to any protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:
   ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with any request to forward the texts of both the protest and the decision thereon to the designated Offices.
   ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Reminders**

The applicant may **submit comments on an informal basis on the written opinion of the International Searching Authority** to the International Bureau. These comments will be made available to the public after international publication. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established.

Shortly after the expiration of **18 months from the priority date, the international application will be published** by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau before the completion of the technical preparations for international publication (Rules 90*bis*.1 and 90*bis*.3).

Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later); otherwise, the applicant must, within **20 months** from the priority date, perform the prescribed acts for **entry into the national phase** before those designated Offices. In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months. For details about the applicable time limits, Office by Office, see www.wipo.int/pct/en/texts/time_limits.html and the *PCT Applicant's Guide*, National Chapters.

Within **22 months from the priority date, the applicant may request that a supplementary international search** be carried out by a different International Searching Authority that offers this service (Rule 45*bis*.1). The procedure for requesting supplementary international search is described in the *PCT Applicant's Guide*, International Phase, paragraphs 8.006–8.032.

Name and mailing address of the ISA/US: Mail Stop PCT, Attn: ISA/US, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Authorized officer: Kari Rodriquez Telephone No. PCT Helpdesk: 571-272-4300

Form PCT/ISA/220 (revised January 2020)

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference		FOR FURTHER ACTION
111552-8029WO00		see Form PCT/ISA/220 as well as, where applicable, item 5 below.
International application No	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/US 21/59735	17 November 2021 (17.11.2021)	18 November 2020 (18.11.2020)
Applicant INARI MEDICAL, INC.		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 4 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

a. With regard to the **language**, the international search was carried out on the basis of:

☒ the international application in the language in which it was filed.

☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

b. ☐ This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6*bis*(a)).

c. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☐ **Certain claims were found unsearchable** (see Box No. II).

3. ☒ **Unity of invention is lacking** (see Box No. III).

4. With regard to the **title**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2, by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the **drawings**,

a. the figure of the drawings to be published with the abstract is Figure No. 18

☒ as suggested by the applicant.

☐ as selected by this Authority, because the applicant failed to suggest a figure.

☐ as selected by this Authority, because this figure better characterizes the invention.

b. ☐ none of the figures is to be published with the abstract.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 21/58735

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:
This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I: Claims 1-7 directed to a proximal ring, a distal ring and a tube portion.

Group II: Claims 8-20 directed to a handle and an actuator.

Continued in Supplemental Box

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-7

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 21/60735

A. CLASSIFICATION OF SUBJECT MATTER
IPC - A61M 25/00 (2022.01)
CPC - A61M 25/0147; A61M 25/0138

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
See Search History document

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
See Search History document

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
See Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2019/246240 A1 (INTUITIVE SURGICAL OPERATIONS, INC.) 26 December 2019 (26.12.2019), entire document, especially Fig 4A, 4C; para [0071]-[0084]	1-3, 5-7
Y		4-5
Y	US2010/0016837 A1 (Howat) 21 January 2010 (21.01.2010), entire document, especially Fig 1-5; para [0034]-[0042]	4-5
A	US 2004/0138625 A1 (Saadat et al.) 15 July 2004 (15.07.2004), entire document	1-7
A	US 2020/0113413 A1 (AMBU A/S) 16 April 2020 (16.04.2020), entire document	1-7
A	US 2009/0192498 A1 (Ostrovsky et al.) 30 July 2009 (30.07.2009), entire document	1-7

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"D" document cited by the applicant in the international application
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
20 February 2022	MAR 29 2022
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Authorized officer Kari Rodriquez Telephone No. PCT Helpdesk: 571-272-4300

Form PCT/ISA/210 (second sheet) (July 2019)

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 21/59735

/* Box No. III - Observations where unity of invention is lacking */

The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

SPECIAL TECHNICAL FEATURES

The invention of Group I includes the special technical feature of a proximal ring; a distal ring configured to be fixedly attached to a pull wire; and a tube portion extending between the proximal and distal rings, wherein the tube portion includes a plurality of openings extending therethrough to define a plurality of ribs, and wherein the ribs are configured to flex away from each other when the pull wire is pulled proximally, not required by Group II.

The invention of Group II includes the special technical feature of a handle coupled to the proximal region of the aspiration catheter, wherein the handle includes an actuator; and pull wire extending between the actuator and the deflectable member, wherein actuation of the actuator is configured to pull the pull wire, not required by the claims of Group I.

COMMON TECHNICAL FEATURES

Groups I-II share the common technical features of an aspiration catheter including a proximal region and a distal region, wherein the distal region includes a deflectable member; and a pull wire configured to deflect the deflectable member to deflect the distal region of the aspiration catheter relative to the proximal region. However, this shared technical feature does not represent a contribution over prior art as being anticipated by US 2004/0138525 A1 to Saadat et al. (hereinafter "Saadat"), which discloses an aspiration catheter (30; Fig 21A-21B; para [0097]; see analogous Fig 41, para [0125] describing tool arm 30 used for aspiration, wherein the tool arm 30 is interpreted as an aspiration catheter) including a proximal region (proximal half of 30; Fig 21A-21B; para [0097]; the proximal half of 30 being the bottom-most half of the entire tool arm 30 in the orientation shown in Fig 21A) and a distal region (distal half of 30; Fig 21A-21B; para [0097]; the distal half of 30 being the top-most half of the entire tool arm 30 in the orientation shown in Fig 21A), wherein the distal region includes a deflectable member (portion of 30 from bottom slot 132 to the distal-most end of 30; Fig 21A-21B; para [0097]); and a pull wire configured to deflect the deflectable member to deflect the distal region of the aspiration catheter relative to the proximal region (96; Fig 21A-21B; para [0097]; pullwire 96 is shown to be attached to the portion of 30 extending distally from distal-most slot 132 via fixation point 104 wherein pulling the pullwire 96 causes the distal tip of tool arm 30 to deflect relative to the proximal region of tool arm 30).

As the common technical features were known in the art at the time of the invention, these cannot be considered special technical feature that would otherwise unify the groups.

Therefore, Groups I-II lack unity under PCT Rule 13 because they do not share a same or corresponding special technical feature.

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To: MATTHEW S. WILLIAMS
PERKINS COIE LLP
P.O. BOX 1247
SEATTLE, WA 98111-1247

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis* 1)

Date of mailing *(day/month/year)*	MAR 22 2022
Applicant's or agent's file reference: 111552-8029WO00	FOR FURTHER ACTION: See paragraph 2 below

International application No.	International filing date *(day month year)*	Priority date *(day month year)*
PCT/US 21/59735	17 November 2021 (17.11.2021)	18 November 2020 (18.11.2020)

International Patent Classification (IPC) or both national classification and IPC

IPC - A61M 25/00 (2022.01)

CPC - A61M 25/0147; A61M 25/0138

Applicant: INARI MEDICAL, INC.

1. This opinion contains indications relating to the following items.

- [X] Box No. I Basis of the opinion
- [ ] Box No. II Priority
- [ ] Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- [X] Box No. IV Lack of unity of invention
- [X] Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement
- [ ] Box No. VI Certain documents cited
- [ ] Box No. VII Certain defects in the international application
- [X] Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

Name and mailing address of the ISA/US	Date of completion of this opinion	Authorized officer
Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	20 February 2022	Kari Rodriquez PCT Help Desk Telephone No. 571-272-4300

Form PCT/ISA/237 (cover sheet) (revised January 2019)

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 21/59738

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of:

☒ the international application in the language in which it was filed.

☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. ☐ This opinion has been established taking into account the rectification of an obvious mistake authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(b)).

3. ☐ With regard to any nucleotide and/or amino acid sequence disclosed in the international application, this opinion has been established on the basis of a sequence listing:

a. ☐ forming part of the international application as filed:

☐ in the form of an Annex C/ST.25 text file.

☐ on paper or in the form of an image file.

b. ☐ furnished together with the international application under PCT Rule 13*ter*.1(a) for the purposes of international search only in the form of an Annex C/ST.25 text file.

c. ☐ furnished subsequent to the international filing date for the purposes of international search only:

☐ in the form of an Annex C/ST.25 text file (Rule 13*ter*.1(a)).

☐ on paper or in the form of an image file (Rule 13*ter*.1(b) and Administrative Instructions, Section 713).

4. ☐ In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that forming part of the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 21/59735

Box No. IV Lack of unity of invention

1. [X] In response to the invitation (Form PCT/ISA/206) to pay additional fees the applicant has, within the applicable time limit:
   - [ ] paid additional fees.
   - [ ] paid additional fees under protest and, where applicable, the protest fee.
   - [ ] paid additional fees under protest but the applicable protest fee was not paid.
   - [X] not paid additional fees.
2. [ ] This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is
   - [ ] complied with.
   - [X] not complied with for the following reasons:

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I: Claims 1-7 directed to a proximal ring; a distal ring and a tube portion.

Group II: Claims 8-20 directed to a handle and an actuator.

The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

SPECIAL TECHNICAL FEATURES

The invention of Group I includes the special technical feature of a proximal ring; a distal ring configured to be fixedly attached to a pull wire; and a tube portion extending between the proximal and distal rings, wherein the tube portion includes a plurality of openings extending therethrough to define a plurality of ribs, and wherein the ribs are configured to flex away from each other when the pull wire is pulled proximally, not required by Group II.

The invention of Group II includes the special technical feature of a handle coupled to the proximal region of the aspiration catheter, wherein the handle includes an actuator; and pull wire extending between the actuator and the deflectable member, wherein actuation of the actuator is configured to pull the pull wire, not required by the claims of Group I.

COMMON TECHNICAL FEATURES

Groups I-II share the common technical features of an aspiration catheter including a proximal region and a distal region, wherein the distal region includes a deflectable member; and a pull wire configured to deflect the deflectable member to deflect the distal region of the aspiration catheter relative to the proximal region. However, this shared technical feature does not represent a contribution over prior art as being anticipated by US 2004/0138525 A1 to Saadat et al. (hereinafter "Saadat"), which discloses an aspiration catheter (30; Fig 21A-21B; para [0097]; see analogous Fig 41, para [0128] describing tool arm 30 used for aspiration, wherein the tool arm 30 is interpreted as an aspiration catheter) including a proximal region (proximal half of 30; Fig 21A-21B; para [0097]; the proximal half of 30 being the bottom-most half of the entire tool arm 30 in the orientation shown in Fig 21A) and a distal region (distal half of 30; Fig 21A-21B; para [0097]; the distal half of 30 being the top-most half of the entire tool arm 30 in the orientation shown in Fig 21A), wherein the distal region includes a deflectable member (portion of 30 from bottom slot 132 to the distal-most end of 30; Fig 21A-21B; para [0097]); and a pull wire configured to deflect the deflectable member to deflect the distal region of the aspiration catheter relative to the proximal region (98; Fig 21A-21B; para [0097]; pullwire 98 is shown to be attached to the portion of 30 extending distally from distal-most slot 132 via fixation point 104 wherein pulling the pullwire 98 causes the distal tip of tool arm 30 to deflect relative to the proximal region of tool arm 30).

As the common technical features were known in the art at the time of the invention, these cannot be considered special technical feature that would otherwise unify the groups.

Therefore, Groups I-II lack unity under PCT Rule 13 because they do not share a same or corresponding special technical feature.

4. Consequently, this opinion has been established in respect of the following parts of the international application:
   - [ ] all parts.
   - [X] the parts relating to claims Nos. 1-7

Form PCT/ISA/237 (Box No. IV) (revised January 2015)

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 21/58735

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	3-6, 7	YES
	Claims	1-2, 8	NO
Inventive step (IS)	Claims	None	YES
	Claims	1-7	NO
Industrial applicability (IA)	Claims	1-7	YES
	Claims	None	NO

2. Citations and explanations:

Claims 1-2 and 8 lack novelty under PCT Article 33(2) as being anticipated by WO 2019/246240 A1 to INTUITIVE SURGICAL OPERATIONS, INC. (hereinafter "Intuitive").

As per claim 1, Intuitive teaches an aspiration catheter (Fig 4A, 4C; para [0071]-[0084]; the flexible elongate device 400 is taught to correspond to elongate device 202, which is taught in para [0064] to be used for suction - further, para [0072] teaches wherein flexible elongate device 400 comprises a main lumen 411, which receives medical tools and is considered to be capable of receiving a suction tool or having suction applied therethrough), comprising:
a proximal region (402; Fig 4A; para [0072]); and
a distal region (404, portion of 408 extending distally from 425 collectively; Fig 4A; para [0072]) including a deflectable member (422, 424, 425 collectively; Fig 4A, 4C; para [0072]-[0076]), wherein the deflectable member includes:
a proximal ring (425; Fig 4A; para [0078]);
a distal ring configured to be fixedly attached to a pull wire (422; Fig 4A; para [0073]; control elements 421, taught to be pull wires, are taught to attach to distal mount 422); and
a tube portion extending between between the proximal and distal rings (424; Fig 4A; para [0076]-[0076]; axial support structure 424 is shown to extend between stopper 425 and distal mount 422), wherein the tube portion includes a plurality of openings extending therethrough (openings extending through left portions of 424; Fig 4A; para [0076]-[0078]; the axial support structure 424 is shown to comprise openings extending through every other circular portion of 424 on the left side) to define a plurality of ribs (left sides of 424; Fig 4A; para [0076]-[0078]; the left half of axial support structure 424 includes portions extending between the left openings), and wherein the ribs are configured to flex away from each other when the pull wire is pulled proximally (Fig 4A; para [0076]-[0078]; Intuitive teaches wherein when unequal forces are applied to control elements, the distal section 404, with axial support structure 424, bends in the direction defined by the net actuation forces, such that inherently when a right control element 421 is pulled, the support structure 424 bends right, which causes the left portions of 424 extending between the left openings to flex away from each other).

As per claim 2, Intuitive teaches the aspiration catheter of claim 1 wherein the tube portion includes a spine extending in a direction between the proximal and distal rings (right-most edge of 424; Fig 4A; para [0076]-[0078]; the axial support structure comprises a right most edge extending between the distal mount 422 and stopper 425), wherein the ribs extend away from the spine (Fig 4A; para [0076]-[0078]; the left portions of 424 extend away from the right-most edge of 424), and wherein the spine is configured to extend generally parallel to and over the pull wire (Fig 4A, para [0076]-[0078]; the control elements 421 are taught to extend through control element lumens 412, wherein Fig 4C shows the edges of axial support 424 to extend over the control element lumens 412, wherein the right-most edge of the axial support inherently extends over the right control elements 421 within the control element lumens 412).

As per claim 8, Intuitive teaches the aspiration catheter of claim 1 wherein the tube portion extends along a longitudinal axis in a relaxed state (Fig 4A; para [0072]-[0078]; the control elements 421 are taught to be used to bend the distal section 404 when force is applied to control elements 421, para [0077], wherein Fig 4A is reasonably considered to be a relaxed state such that control elements 421 are not actuated, wherein the axial support structure 424 is shown to extend along the longitudinal axis of the flexible elongate device 400, shown to be the horizontal axis extending through the main lumen 411 in Fig 4A), and wherein the plurality of openings (Box VIII) extend circumferentially about the longitudinal axis and generally parallel to one another in the relaxed state (Fig 4A, para [0072]-[0076]; the left openings of axial support structure 424 are shown to extend circumferentially about the longitudinal axis of the flexible elongate device 400 and further shown to be substantially parallel to one another in Fig 4A).

Claims 3 and 7 lack an inventive step under PCT Article 33(3) as being obvious over Intuitive.

As per claim 3, Intuitive teaches the aspiration catheter of claim 1, wherein the proximal region and the distal region define a lumen [having a diameter of 20 French or greater] (411; Fig 4A, 4C; para [0072]) While Intuitive teaches a similar catheter used to be positioned within an esophagus of a patient (Fig 3A-3B; para [0068]; the medical instrument shown in Fig 3A-3B is shown to be relatively large and inserted into the esophagus of the patient), Intuitive is silent as to the diameter of the lumen. However, it is well known in the art that optimizing size, shape and angle is of the ordinary skill in the art. Accordingly, it would have been obvious to one of ordinary skill in the art to have optimized the size of the lumen to have arrived at the lumen having a diameter of 20 French or greater, in order to allow for the lumen to receive more instrument (para [0072]).

-*-Continued in Supplemental Box-*-

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 21/58735

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claim 8: The term "the openings" is confusing and lacks proper antecedent basis. The term "the openings" appears to be referring to the plurality of openings previously referred to. For purposes of this opinion, the term "the openings" has been interpreted to be "the plurality of openings."

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 21/60735

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of:
-*-Box V.2 - Citations and explanations-*-

As per claim 7, Intuitive teaches the aspiration catheter of claim 1. While Intuitive teaches wherein the proximal ring includes an annular lumen configured to slidably receive the pull wire therethrough (Fig 4A; para [0072]; the control element lumen 412, shown to be annular in Fig 4C, is shown to extend through stopper 425) and an annular member extending through the lumen (423; Fig 4A-4B; para [0073]-[0076]; coil pipe 423 is taught to extend through the control element lumens 412 and terminate at the transition section 406 proximal to the distal section 404); Intuitive does not specifically teach wherein the proximal ring includes an annular member configured to slidably receive the pull wire therethrough. However, it is well known that routine experimentation and various engineering design choices could have been made to have arrived at wherein the proximal ring includes an annular member configured to slidably receive the pull wire therethrough (Note: providing the coil pipe 423 to extend through the control element lumen 412 within stopper 425, allows for the coil pipe 423 to still terminate proximal to distal section 404, as taught in para [0073]). Accordingly, it would have been obvious to one of ordinary skill in the art to have arrived at wherein the proximal ring includes an annular member configured to slidably receive the pull wire therethrough, in order to improve the structural integrity of the lumen within the proximal ring.

Claims 4-5 lack an inventive step under PCT Article 33(3) as being obvious over Intuitive in view of US 2010/0016837 A1 to Howat.

As per claim 4, Intuitive teaches the aspiration catheter of claim 1, further comprising an intermediate region between the proximal and distal regions (portion of 408 extending proximally from 425; Fig 4A; para [0072]). While Intuitive teaches wherein select portions of the aspiration catheter can be stiffened (para [0105]), Intuitive does not specifically teach wherein the proximal region and the intermediate region include a braid of wires extending therethrough. However, Howat teaches a similar catheter (Fig 5-8; para [0034]-[0042]) wherein a proximal region and an intermediate region include a braid of wires extending therethrough (Fig 8; para [0034]-[0037]; Howat teaches wherein an introducer sheath 20 is assembled, in which a braided member 40 is shown to extend along the entire length of the inner tube of the introducer sheath such that the braided member 40 extends through a proximal and intermediate region of the introducer sheath 20). Accordingly, it would have been obvious to one of ordinary skill in the art to have employed the braid of wires taught by Howat with the aspiration catheter taught by Intuitive, in order to improve the structural integrity of the aspiration catheter.

As per claim 5, Intuitive in view of Howat teach the aspiration catheter of claim 4, and Howat further teaches wherein the intermediate region includes a wire coiled around the braid (Fig 7; para [0038]; a coiled member 50, wherein para [0022] further teaches wherein coiled member is a flat wire coil, wherein the coiled member 50 extends along the length of the inner tube 30, such that the coiled member 50 is considered to be included in the intermediate region with the modification as combined).

Claims 1-7 have industrial applicability as defined by PCT Article 33(4) because the subject matter can be made or used by industry.

UNITED STATES
PATENT AND TRADEMARK OFFICE

P.O. Box 1450
Alexandria, VA 22313 - 1450
www.uspto.gov

ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
17/865,266	**09/07/2022 01:39:51 PM ET**	**111552-8016.US04**

Title of Invention

HEMOSTASIS VALVES AND METHODS OF USE

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	6816	FILED BY	Christina Flores
PATENT CENTER #	60944768	FILING DATE	07/14/2022
CUSTOMER #	25096	FIRST NAMED INVENTOR	Benjamin E. Merritt
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	Matthew Williams

Documents

TOTAL DOCUMENTS: 7

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
NPL_EESR_191919257_Oct_8_2019.PDF	7	Non Patent Literature	651 KB
NPL_ISR_WO_PCTUS1950410_Oct_25_2019.PDF	9	Non Patent Literature	926 KB
NPL_ISR_WO_PCTUS2145072_Jan_20_2022_10pages.PDF	10	Non Patent Literature	1411 KB
NPL_ISR_WO_PCTUS2158793_Mar_16_2022_13pages.PDF	13	Non Patent Literature	1645 KB

NPL_ISR_WO_PCTUS2159718_Mar_22_2022_13pages.PDF	13	Non Patent Literature	5341 KB
NPL_ISR_WO_PCTUS2159735_Mar_22_2022_11pages.PDF	11	Non Patent Literature	3817 KB
NPL_ISR_WO_PCTUS2135965_Sep_28_2021_12pages.PDF	12	Non Patent Literature	517 KB

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
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NPL_ISR_WO_PCTUS2159735_Mar_22_2022_11pages.PDF	1DBA26CF3C307C9EB9812835717E85A5CC544D99C8B528EEF27239C5779BCDCF857E4FB26EA56ED6C05A5ABC7DE1B175E

	0C19048367992C66584F9ABD555436A
NPL_ISR_WO_PCTUS2135965_Sep_28_2021_12pages.PDF	F2E0B7E471F6EE167B0B4F8966804134066DE07C1D66821137AFF60A449A5C96527A2AAD2F817013A8E1F9B22BC1322E1D32C65B5657152184015FEE56AFD5BC

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To: MATTHEW S. WILLIAMS
PERKINS COIE LLP
P.O. BOX 1247
SEATTLE, WA 98111-1247

RECEIVED
PATENT DOCKETING
MAR 28 2022
PERKINS COIE LLP

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT AND THE WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

Applicant's or agent's file reference: 111552-8028WO00	Date of mailing (day/month/year): MAR 22 2022
International application No.: PCT/US 21/59718	FOR FURTHER ACTION: See paragraphs 1 and 4 below
Applicant: INARI MEDICAL, INC.	International filing date (day/month/year): 17 November 2021 (17.11.2021)

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

Filing of amendments and statement under Article 19:
The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46).

When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

How? Directly to the International Bureau preferably through ePCT, or on paper to: The International Bureau of WIPO, 34, chemin des Colombettes, 1211 Geneva 20, Switzerland.

For more detailed instructions, see the *PCT Applicant's Guide*, International Phase, paragraphs 9.004 – 9.011.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. ☐ **With regard to any protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:
   - ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with any request to forward the texts of both the protest and the decision thereon to the designated Offices.
   - ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Reminders**

The applicant may **submit comments on an informal basis on the written opinion of the International Searching Authority** to the International Bureau. These comments will be made available to the public after international publication. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established.

Shortly after the expiration of **18 months from the priority date, the international application will be published** by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau before the completion of the technical preparations for international publication (Rules 90*bis*.1 and 90*bis*.3).

Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase **until 30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for **entry into the national phase** before those designated Offices. In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months. For details about the applicable time limits, Office by Office, see www.wipo.int/pct/en/texts/time_limits.html and the *PCT Applicant's Guide*, National Chapters.

Within **22 months from the priority date, the applicant may request that a supplementary international search be carried out** by a different International Searching Authority that offers this service (Rule 45*bis*.1). The procedure for requesting supplementary international search is described in the *PCT Applicant's Guide*, International Phase, paragraphs 8.006-8.032.

Name and mailing address of the ISA/US: Mail Stop PCT, Attn: ISA/US, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450, Facsimile No. 571-273-8300	Authorized officer: Kari Rodriquez, Telephone No. PCT Helpdesk: 571-272-4300

Form PCT/ISA/220 (revised January 2020)

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	FOR FURTHER ACTION
111552-6028WO00	See Form PCT/ISA/220 as well as, where applicable, item 5 below.

International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/US 21/59718	17 November 2021 (17.11.2021)	18 November 2020 (18.11.2020)

Applicant
INARI MEDICAL, INC.

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 4 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1 **Basis of the report**

a. With regard to the **language**, the international search was carried out on the basis of:

☒ the international application in the language in which it was filed.

☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

b. ☐ This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6*bis*(a)).

c. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2 ☐ **Certain claims were found unsearchable** (see Box No. II).

3 ☒ **Unity of invention is lacking** (see Box No. III).

4 With regard to the **title**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5 With regard to the **abstract**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2, by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6 With regard to the **drawings**,

a. the figure of the **drawings** to be published with the abstract is Figure No. 7C

☒ as suggested by the applicant.

☐ as selected by this Authority, because the applicant failed to suggest a figure.

☐ as selected by this Authority, because this figure better characterizes the invention.

b. ☐ none of the figures is to be published with the abstract.

Form PCT/ISA/210 (first sheet) (July 2019)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 21/59718

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:
This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I: Claims 1-14 directed to an aspiration catheter.

Group II: Claims 15-20 directed to a method of removing clot material from a blood vessel.

-^Continued in Supplemental Box-^

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-14

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 21/59716

A. CLASSIFICATION OF SUBJECT MATTER
IPC - A61M 25/00; A61B 17/22 (2022.01)
CPC - A61M 25/0041; A61M 25/0045

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
See Search History document

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
See Search History document

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
See Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	CN 110652645 A (Shanghai Warbey Medical Technology Co Ltd) 07 January 2020 (07.01.2020), entire document, especially	1-14
Y	US 2006/0074401 A1 (Ross) 06 April 2006 (06.04.2006), entire document, especially	1-14
A	US 2016/0151605 A1 (GMEDIX, INC.) 02 June 2016 (02.06.2016), entire document	1-14
A	US 2013/0197454 A1 (Terumo Kabushiki Kaisha) 01 August 2013 (01.08.2013), entire document	1-14

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents
"A" document defining the general state of the art which is not considered to be of particular relevance
"D" document cited by the applicant in the international application
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
03 March 2022	MAR 22 2022
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Authorized officer Kari Rodriquez Telephone No. PCT Helpdesk: 571-272-4300

Form PCT/ISA/210 (second sheet) (July 2019)

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 21/50710

The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The invention of Group II includes the special technical feature of positioning a distal lip of the aspiration catheter proximate the clot material; activating a pressure source coupled to the aspiration catheter via a fluid control device, while the fluid control device is closed, to generate a vacuum in the pressure source; and opening the fluid control device to apply the vacuum to the aspiration catheter to thereby aspirate at least a portion of the clot material into the aspiration catheter, not required in Group I.

The inventions of Groups I-II share the technical features of an aspiration catheter, comprising: a distal portion and a proximal portion, wherein the distal portion is configured to deflect away from a longitudinal axis of the proximal portion. Specifically, Groups I and II are related as an apparatus (Group I) and methods for using the apparatus (Group II). The apparatus is known in prior art as shown in CN 110652645 A to Shanghai Wachey Medical Technology Co Ltd (hereinafter "Shanghai"). Therefore, Groups I and II lack unity since the shared technical features do not represent a contribution over Shanghai.

Shanghai discloses of an aspiration catheter (Fig 1A-1B; para [0093]-[0098]; para [0115] further teaches wherein the catheter can be used for aspiration), comprising: a distal portion (left half of 10; Fig 1A-1B; para [0093]) and a proximal portion (right half of 10; Fig 1A-1B; para [0093]), wherein the distal portion is configured to deflect away from a longitudinal axis of the proximal portion (Fig 1A-1B; para [0075]; Shanghai teaches wherein the distal region of the aspiration catheter has good flexibility wherein the flexibility of the distal end of the catheter allows for a distal end of the braid of wires within the distal end of the catheter taught by Shanghai to be flexible and deflectable with respect to the longitudinal axis of the proximal portion taught by Shanghai).

As the common features were known in the art at the time of the invention, they cannot be considered special technical features that would otherwise unify the groups.

Therefore, Groups I-II lack unity under PCT Rule 13 because they do not share a same or corresponding special technical feature.

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To: MATTHEW S. WILLIAMS
PERKINS COIE LLP
P.O. BOX 1247
SEATTLE, WA 98111-1247

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)*	MAR 22 2022
Applicant's or agent's file reference: 111552-8028WO00	FOR FURTHER ACTION: See paragraph 2 below

International application No.	International filing date *(day month year)*	Priority date *(day month year)*
PCT/US 21/59718	17 November 2021 (17.11.2021)	18 November 2020 (18.11.2020)

International Patent Classification (IPC) or both national classification and IPC
IPC - A61M 25/00; A61B 17/22 (2022.01)
CPC - A61M 25/0041; A61M 25/0045

Applicant: INARI MEDICAL, INC.

1. This opinion contains indications relating to the following items:

- [X] Box No. I Basis of the opinion
- [ ] Box No. II Priority
- [ ] Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- [X] Box No. IV Lack of unity of invention
- [X] Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement
- [ ] Box No. VI Certain documents cited
- [ ] Box No. VII Certain defects in the international application
- [X] Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

Name and mailing address of the ISA/US	Date of completion of this opinion	Authorized officer
Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	03 March 2022	Kari Rodriquez PCT Help Desk Telephone No. 571-272-4300

Form PCT/ISA/237 (cover sheet) (revised January 2019)

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No
PCT/US 21/59718

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:

☒ the international application in the language in which it was filed.

☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(b)).

3. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of a sequence listing:

a. ☐ forming part of the international application as filed:

☐ in the form of an Annex C/ST.25 text file.

☐ on paper or in the form of an image file.

b. ☐ furnished together with the international application under PCT Rule 13*ter*.1(a) for the purposes of international search only in the form of an Annex C/ST.25 text file.

c. ☐ furnished subsequent to the international filing date for the purposes of international search only:

☐ in the form of an Annex C/ST.25 text file (Rule 13*ter*.1(a)).

☐ on paper or in the form of an image file (Rule 13*ter*.1(b) and Administrative Instructions, Section 713).

4. ☐ In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that forming part of the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 21/59718

Box No. IV Lack of unity of invention

1. [X] In response to the invitation (Form PCT/ISA/206) to pay additional fees the applicant has, within the applicable time limit

- [ ] paid additional fees.
- [ ] paid additional fees under protest and, where applicable, the protest fee.
- [ ] paid additional fees under protest but the applicable protest fee was not paid.
- [X] not paid additional fees.

2. [ ] This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is

- [ ] complied with.
- [X] not complied with for the following reasons:

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I: Claims 1-14 directed to an aspiration catheter.

Group II: Claims 15-20 directed to a method of removing clot material from a blood vessel.

The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The invention of Group II includes the special technical feature of positioning a distal tip of the aspiration catheter proximate the clot material; activating a pressure source coupled to the aspiration catheter via a fluid control device, while the fluid control device is closed, to generate a vacuum in the pressure source; and opening the fluid control device to apply the vacuum to the aspiration catheter to thereby aspirate at least a portion of the clot material into the aspiration catheter, not required in Group I.

The inventions of Groups I-II share the technical features of an aspiration catheter, comprising: a distal portion and a proximal portion, wherein the distal portion is configured to deflect away from a longitudinal axis of the proximal portion. Specifically, Groups I and II are related as an apparatus (Group I) and methods for using the apparatus (Group II). The apparatus is known in prior art as shown in CN 110652645 A to Shanghai Wanbey Medical Technology Co Ltd (hereinafter "Shanghai"). Therefore, Groups I and II lack unity since the shared technical features do not represent a contribution over Shanghai.

Shanghai discloses of an aspiration catheter (Fig 1A-1B; para [0093]-[0099]; para [0115] further teaches wherein the catheter can be used for aspiration), comprising: a distal portion (left half of 10; Fig 1A-1B; para [0083]) and a proximal portion (right half of 10; Fig 1A-1B; para [0093]), wherein the distal portion is configured to deflect away from a longitudinal axis of the proximal portion (Fig 1A-1B, para [0076]; Shanghai teaches wherein the distal region of the aspiration catheter has good flexibility wherein the flexibility of the distal end of the catheter allows for a distal end of the braid of wires within the distal end of the catheter taught by Shanghai to be flexible and deflectable with respect to the longitudinal axis of the proximal portion taught by Shanghai).

As the common features were known in the art at the time of the invention, they cannot be considered special technical features that would otherwise unify the groups.

Therefore, Groups I-II lack unity under PCT Rule 13 because they do not share a same or corresponding special technical feature.

4. Consequently, this opinion has been established in respect of the following parts of the international application:

- [ ] all parts.
- [X] the parts relating to claims Nos. 1-14

Form PCT/ISA/237 (Box No. IV) (revised January 2019)

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No
PCT/US 21/59718

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement

1 Statement

Novelty (N)	Claims	1-14	YES
	Claims	None	NO
Inventive step (IS)	Claims	None	YES
	Claims	1-14	NO
Industrial applicability (IA)	Claims	1-14	YES
	Claims	None	NO

2 Citations and explanations:
Claims 1-7 lack an inventive step under PCT Article 33(3) as being obvious over CN 110650645 A to Shanghai Warbey Medical Technology Co Ltd (hereinafter "Shanghai") in view of US 2008/0074401 A1 to Ross.

As per claim 1, Shanghai teaches an aspiration catheter (Fig 1A-1B; para [0093]-[0099]; para [0115] further teaches wherein the catheter can be used for aspiration), comprising:
an inner liner (20; Fig 1A-1B; para [0093]) defining a lumen (21; Fig 1A-1B; para [0093]) and having a proximal region (right half of 28; Fig 1A-1B; para [0093]) and a distal region (left half of 28; Fig 1A-1B; para [0093]);
a braid of wires over the inner liner (40; Fig 1A-1B; para [0093]), [wherein a deflectable portion of the braid of wires (Box VIII) over at least a portion of the distal region of the inner liner is configured to deflect away from a longitudinal axis of the proximal region when the aspiration catheter is unconstrained];
a wire coiled over at least a portion of the distal region of the inner liner (30; Fig 1A-1B; para [0093], [0099]); and
an outer sheath over the braid of wires (Box VIII), the wire, and the inner liner (50; Fig 1A-1B; para [0093]).
While Shanghai teaches wherein the distal region of the aspiration catheter has good flexibility (Fig 1A-1B; para [0076]; the flexibility of the distal end of the catheter allows for a distal end of the braid of wires within the distal end of the catheter taught by Shanghai to be flexible and deflectable), Shanghai does not specifically teach wherein a deflectable portion of the braid of wires (Box VIII) over at least a portion of the distal region of the inner liner is configured to deflect away from a longitudinal axis of the proximal region when the aspiration catheter is unconstrained. However, Ross teaches a similar catheter (Fig 1-2; para [0024]-[0034]) comprising a braid of wires (2A, Fig 1-2; para [0027]; reinforcing material 24 is taught to be formed of a braid made of metallic filaments) over an inner liner (22; Fig 1-2; para [0027]) wherein a deflectable portion of the braid of wires (Box VIII) over at least a portion of the distal region of the inner liner is configured to deflect away from a longitudinal axis of the proximal region when the catheter is unconstrained (Fig 1-2; para [0025]-[0026], [0035]; Ross teaches wherein the elongate shaft 16, including the reinforcing material 24 can be bent depending on the desired application - see Fig 6 further showing a configuration of the catheter that is formed to a bent configuration at the distal tip of the catheter). Accordingly, it would have been obvious to one of ordinary skill in the art to have employed deflectable portion taught by Ross with the aspiration catheter taught by Shanghai, in order to allow for improved navigation of tortuous vessels (para [0006]-[0010]).

As per claim 2, Shanghai in view of Ross teach the aspiration catheter of claim 1, and Ross further teaches wherein the wires in the deflectable portion of the braid of wires (Box VIII) is pre-shaped to deflect away from the longitudinal axis (Fig 1-2; para [0032]-[0035]; the catheter is taught to be formed as shown in Fig 6 by constraining the catheter in a desired curvature of position and then heating the shaft to shrink the shrink tubing 28, such that the reinforcing material 24 is pre-shaped in the curved configuration).

As per claim 3, Shanghai in view of Ross teach the aspiration catheter of claim 1, and Ross further teaches wherein the deflectable portion of the braid of wires (Box VIII) is configured to deflect away from the longitudinal axis to have a bend angle of between about 165-195 degrees (Box VIII) when the aspiration catheter is unconstrained (Fig 1-2; para [0032]-[0035]; the catheter is taught to be formed as shown in Fig 6 by constraining the catheter in a desired curvature of position and then heating the shaft to shrink the shrink tubing 28, such that the reinforcing material 24 is pre-shaped in the curved configuration - Fig 6 further shows the bend angle to be almost exactly 180 degrees at the distal end, such that the bend angle is reasonably considered to be between 165-195 degrees).

As per claim 4, Shanghai in view of Ross teach the aspiration catheter of claim 1, and Ross further teaches wherein the deflectable portion of the braid of wires (Box VIII) is configured to deflect away from the longitudinal axis to have a bend angle [of about 270 degrees] when the aspiration catheter is unconstrained (Fig 1-2; para [0032]-[0035]; the catheter is taught to be formed as shown in Fig 6 by constraining the catheter in a desired curvature of position and then heating the shaft to shrink the shrink tubing 28, such that the reinforcing material 24 is pre-shaped in the curved configuration). While Ross teaches wherein the catheter can have a bent shape depending on the desired application (para [0025]), Ross does not specifically teach a bend angle of about 270 degrees. However, it is well known that optimizing size, shape and angle is of the ordinary skill in the art. Accordingly, it would have been obvious to one of ordinary skill in the art to have arrived at a bend angle of about 270 degrees, in order to allow for improved navigation of tortuous vessels.

-\-Continued in Supplemental Box-\-

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCTUS 21/59718

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claims 1-4 and 9-10: The term "the braid" is confusing and lacks proper antecedent basis. The term "the braid" appears to be referring to the braid of wires previously referred to. For purposes of this opinion, the term "the braid" has been interpreted as "the braid of wires."

Claim 3: The recitation "between about between about 165-195 degrees" appears to be a typographical error that is inconsistent with known grammatical standards and has been interpreted to be "between about 165-195 degrees."

Claim 4: The recitation "between about 270 degrees" appears to be a typographical error that is inconsistent with known grammatical standards and has been interpreted to be "about 270 degrees."

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of
-*-Box V.2 - Citations and explanations-*-

As per claim 6, Shanghai in view of Ross teach the aspiration catheter of claim 1. While Shanghai teaches wherein the aspiration catheter can be used as a neurovascular catheter (para [0007]-[0008]), Shanghai does not specifically teach wherein the lumen has a diameter of 20 French or greater. However, it is well known in the art that routine experimentation and various engineering design choices could have been made to have arrived at wherein the lumen has a diameter of 20 French or greater (Note: providing a larger diameter allows for aspiration of larger vessels, such as the aorta, which help provide oxygenated blood to the brain and spinal cord). Accordingly, it would have been obvious to one of ordinary skill in the art to have arrived at wherein the lumen has a diameter of 20 French or greater, in order to allow for use in larger blood vessels.

As per claim 6, Shanghai in view of Ross teach the aspiration catheter of claim 1. While Shanghai teaches wherein the aspiration catheter can be used as a neurovascular catheter (para [0007]-[0008]), Shanghai does not specifically teach wherein the lumen has a diameter of 24 French or greater. However, it is well known in the art that routine experimentation and various engineering design choices could have been made to have arrived at wherein the lumen has a diameter of 24 French or greater (Note: providing a larger diameter allows for aspiration of larger vessels, such as the aorta, which help provide oxygenated blood to the brain and spinal cord). Accordingly, it would have been obvious to one of ordinary skill in the art to have arrived at wherein the lumen has a diameter of 24 French or greater, in order to allow for use in larger blood vessels.

As per claim 7, Shanghai in view of Ross teach the aspiration catheter of claim 1 wherein the inner liner is formed from polytetrafluoroethylene material (Fig 1A-1B, para [0097]), and wherein the outer sheath is formed from a thermoplastic elastomer material (Fig 1A-1B, para [0110]; the outer layer 50 is taught to be made of Pebax).

Claims 1 and 8-14 lack an inventive step under PCT Article 33(3) as being obvious over Shanghai in view of Ross (second treatment)

As per claim 1, Shanghai teaches an aspiration catheter (Fig 1A-1B; para [0093]-[0098]; para [0115] further teaches wherein the catheter can be used for aspiration), comprising:
an inner liner (20; Fig 1A-1B, para [0093]) defining a lumen (21; Fig 1A-1B, para [0093]) and having a proximal region (right half of 20, Fig 1A-1B; para [0093]) and a distal region (left half of 20, Fig 1A-1B, para [0093]);
a braid of wires over the inner liner (40, Fig 1A-1B; para [0093]), [wherein a deflectable portion of the braid of wires (Box VIII) over at least a portion of the distal region of the inner liner is configured to deflect away from a longitudinal axis of the proximal region when the aspiration catheter is unconstrained];
a wire coiled over at least a portion of the distal region of the inner liner (30; Fig 1A-1B; para [0093], [0099]); and
an outer sheath over the braid of wires (Box VIII), the wire, and the inner liner (50; Fig 4; para [0111]; Shanghai teaches an outer layer 50, which can be reasonably considered to be used with the catheter 10 shown in Fig 1A-1B).
While Shanghai teaches wherein the distal region of the aspiration catheter has good flexibility (Fig 1A-1B; para [0076]; the flexibility of the distal end of the catheter allows for a distal end of the braid of wires within the distal end of the catheter taught by Shanghai to be flexible and deflectable), Shanghai does not specifically teach wherein a deflectable portion of the braid of wires (Box VIII) over at least a portion of the distal region of the inner liner is configured to deflect away from a longitudinal axis of the proximal region when the aspiration catheter is unconstrained. However, Ross teaches a similar catheter (Fig 1-2; para [0024]-[0034]) comprising a braid of wires (2A, Fig 1-2, para [0027]; reinforcing material 24 is taught to be formed of a braid made of metallic filaments) over an inner liner (22; Fig 1-2; para [0027]) wherein a deflectable portion of the braid of wires (Box VIII) over at least a portion of the distal region of the inner liner is configured to deflect away from a longitudinal axis of the proximal region when the catheter is unconstrained (Fig 1-2; para [0025]-[0026], [0035]; Ross teaches wherein the elongate shaft 16, including the reinforcing material 24 can be bent depending on the desired application - see Fig 6 further showing a configuration of the catheter that is formed to a bent configuration at the distal tip of the catheter). Accordingly, it would have been obvious to one of ordinary skill in the art to have employed deflectable portion taught by Ross with the aspiration catheter taught by Shanghai, in order to allow for improved navigation of tortuous vessels (para [0008]-[0010]).

As per claim 8, Shanghai in view of Ross teach the aspiration catheter of claim 1 wherein the outer sheath has a first hardness over the proximal region (Fig 4, para [0111]; the proximal region of outer layer 50 is taught to comprise a material with about a 75D shore hardness), and wherein the outer sheath has a second hardness over the distal region of the inner liner that is less than the first hardness (Fig 4, para [0111]; the distal part of the outer layer 50 is taught to comprise an ultra-low hardness material, which has a hardness of about 60A shore hardness).

-*-Continued in next Supplemental Box-*-

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 21/59718

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of:
-*-Box V.2 - Citations and explanations-*-

As per claim 9, Shanghai teaches an aspiration catheter (Fig 1A-1B, 4; para [0080]-[0088], [0111]-[0112]; para [0115] further teaches wherein the catheter can be used for aspiration), comprising:
a proximal region defining a longitudinal axis (region of 10 comprising proximal part of outer layer 50; Fig 1A-1B, 4; para [0093]-[0099], [0111]-[0112]; the outer layer 50 is taught to comprise three parts, including a proximal part, positioned at the proximal end of the catheter body 10);
an intermediate region extending from the proximal region (region of 10 comprising transition section of outer layer 50; Fig 1A-1B, 4; para [0093]-[0099], [0111]-[0112]; the outer layer 50 is taught to comprise three parts, including a transition section extending from the proximal part of the proximal end of the catheter body 10);
a distal region extending from the intermediate region (region of 10 comprising distal part of outer layer 50; Fig 1A-1B, 4; para [0093]-[0099], [0111]-[0112]; the outer layer 50 is taught to comprise three parts, including a distal part, positioned at the distal end of the catheter body 10);
an inner liner (20; Fig 1A-1B; para [0093]) defining a lumen (21; Fig 1A-1B; para [0083]) and extending through the proximal region, the intermediate region and the distal region (Fig 1A-1B; para [0093]-[0099]);
a braid of wires extending over the inner liner and through the proximal region, the intermediate region and the distal region (40; Fig 1A-1B; para [0093]), [wherein a deflectable portion of the braid of wires (Box VIII) over at least a portion of the distal region of the inner liner is configured to deflect away from a longitudinal axis of the proximal region when the aspiration catheter is unconstrained];
a wire coiled in the distal region (30; Fig 1A-1B; para [0093], [0098]); and
an outer sheath extending over the braid of wires (Box VIII), the wire, and the inner liner and through the proximal region, the intermediate region, and the distal region (50; Fig 4; para [0111]-[0112]; Shanghai teaches an outer layer 50, which can be reasonably considered to be used with the catheter 10 shown in Fig 1A-1B).
While Shanghai teaches wherein the distal region of the aspiration catheter has good flexibility (Fig 1A-1B, para [0078]; the flexibility of the distal end of the catheter allows for a distal end of the braid of wires within the distal end of the catheter taught by Shanghai to be flexible and deflectable), Shanghai does not specifically teach wherein a deflectable portion of the braid of wires (Box VIII) over at least a portion of the distal region of the inner liner is configured to deflect away from a longitudinal axis of the proximal region when the aspiration catheter is unconstrained. However, Ross teaches a similar catheter (Fig 1-2; para [0024]-[0034]) comprising a braid of wires (24; Fig 1-2; para [0027]; reinforcing material 24 is taught to be formed of a braid made of metallic filaments) over an inner liner (22; Fig 1-2; para [0027]) wherein a deflectable portion of the braid of wires (Box VIII) over at least a portion of the distal region of the inner liner is configured to deflect away from a longitudinal axis of the proximal region when the catheter is unconstrained (Fig 1-2; para [0025]-[0026], [0035]; Ross teaches wherein the elongate shaft 18, including the reinforcing material 24 can be bent depending on the desired application - see Fig 6 further showing a configuration of the catheter that is formed to a bent configuration at the distal tip of the catheter). Accordingly, it would have been obvious to one of ordinary skill in the art to have employed deflectable portion taught by Ross with the aspiration catheter taught by Shanghai, in order to allow for improved navigation of tortuous vessels (para [0006]-[0010]).

As per claim 10, Shanghai in view of Ross teach the aspiration catheter of claim 1, and Ross further teaches wherein the deflectable portion of the braid of wires (Box VIII) is configured to deflect away from the longitudinal axis to have a bend angle of between about 165-195 degrees (Box VIII) when the aspiration catheter is unconstrained (Fig 1-2; para [0032]-[0035]; the catheter is taught to be formed as shown in Fig 6 by constraining the catheter in a desired curvature of position and then heating the shaft to shrink the shrink tubing 28, such that the reinforcing material 24 is pre-shaped in the curved configuration - Fig 6 further shows the bend angle to be almost exactly 180 degrees at the distal end, such that the bend angle is reasonably considered to be between 165-195 degrees).

As per claim 11, Shanghai in view of Ross teach the aspiration catheter of claim 9 wherein the outer sheath has (a) a first hardness in the proximal region of between about 65D-75D (Fig 4; para [0111]; Shanghai teaches wherein the proximal part of outer layer 50 has a shore hardness of about 75D), (b) a second hardness in the intermediate region of between about 50D-60D (Fig 4; para [0111]; Shanghai teaches wherein the transition section has a shore hardness of between 30D-63D allowing for a shore hardness of 60D to make up the transition section), and (c) a third hardness in the distal region [of between about 30D-40D] (Fig 4; para [0111]; Shanghai teaches wherein the distal part has a shore hardness of about 60A). While Shanghai teaches wherein a third hardness is less than the first hardness and the second hardness (Fig 4; para [0111]), Shanghai does not specifically teach between about 30D-40D. However, it is well known in the art that routine experimentation and various engineering design choices could have been made to have arrived at between about 30D-40D. Accordingly, it would have been obvious to one of ordinary skill in the art to have arrived at between about 30D-40D, in order to provide improved structural integrity in the distal region of the aspiration catheter.

As per claim 12, Shanghai in view of Ross teach the aspiration catheter of claim 9 wherein the outer sheath (a) has a first hardness in the proximal region (Fig 4; para [0111]; Shanghai teaches wherein the proximal part of outer layer 50 has a shore hardness of about 75D), (b) a second hardness in the intermediate region less than the first hardness (Fig 4, para [0111]; Shanghai teaches wherein the transition section has a shore hardness of between 30D-63D), and (c) a third hardness in the distal region less than the second hardness (Fig 4, para [0111]; Shanghai teaches wherein the distal part has a shore hardness of about 60A).

As per claim 13, Shanghai in view of Ross teach the aspiration catheter of claim 12 wherein (a) the proximal region has a first length (Fig 4; para [0112]; the proximal part is taught to have a length of 1000-1200mm), (b) the intermediate region has a second length less than the first length (Fig 4; para [0112]; the transition section is taught to have a length of 10-30mm), and (c) the distal region has a third length greater than the second length and less than the first length (Fig 4; para [0112]; the distal part is taught to comprise a length of 100-200mm).

-*-Continued in next Supplemental Box-*-

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 21/59718

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of:
^-Box V.2 - Citations and explanations *-

As per claim 14, Shanghai in view of Ross teach the aspiration catheter of claim 13. While Shanghai teaches wherein the overall length of the catheter body can be easily modified to suit specific applications, Shanghai does not specifically teach wherein the first length is between about 20.0- 28.0 inches, the second length is between about 2.0-3.0 inches, and the third length is between about 11.00-15.00 inches. However, it is well known that optimizing size, shape and angle is of the ordinary skill in the art. Accordingly, it would have been obvious to one of ordinary skill in the art to have optimized the size of the first length, the second length and the third length to have arrived at wherein the first length is between about 20.0- 28.0 inches, the second length is between about 2.0-3.0 inches, and the third length is between about 11.00-15.00 inches. Accordingly, it would have been obvious to one of ordinary skill in the art to have arrived at wherein the first length is between about 20.0- 28.0 inches, the second length is between about 2.0-3.0 inches, and the third length is between about 11.00-15.00 inches, in order to improve navigation of the aspiration catheter within blood vessels.

Claims 1-14 have industrial applicability as defined by PCT Article 33(4) because the subject matter can be made or used by industry.

Form PCT/ISA/237 (Supplemental Box) (revised January 2019)

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To MATTHEW S. WILLIAMS
PERKINS COIE LLP
P.O. BOX 1247
SEATTLE, WA 98111-1247

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT AND THE WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

	Date of mailing *(day/month/year)* SEP 28 2021
Applicant's or agent's file reference 111552-8026WO00	**FOR FURTHER ACTION** See paragraphs 1 and 4 below
International application No. PCT/US 21/35965	International filing date *(day/month/year)* 04 June 2021 (04.06.2021)
Applicant INARI MEDICAL, INC.	

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith

Filing of amendments and statement under Article 19:
The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

How? Directly to the International Bureau preferably through ePCT, or on paper to:
The International Bureau of WIPO, 34, chemin des Colombettes, 1211 Geneva 20, Switzerland

For more detailed instructions, see the *PCT Applicant's Guide*, International Phase, paragraphs 9.004 – 9 011.

2 ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. ☐ **With regard to any protest** against payment of (an) additional fee(s) under Rule 40 2, the applicant is notified that:

☐ the protest together with the decision thereon has been transmitted to the International Bureau together with any request to forward the texts of both the protest and the decision thereon to the designated Offices.

☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Reminders**

The applicant may **submit comments on an informal basis on the written opinion of the International Searching Authority** to the International Bureau. These comments will be made available to the public after international publication. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established

Shortly after the expiration of **18 months from the priority date, the international application will be published** by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau before the completion of the technical preparations for international publication (Rules 90*bis*.1 and 90*bis*.3).

Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase **until 30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for **entry into the national phase** before those designated Offices. In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months For details about the applicable time limits, Office by Office, see www wipo.int/pct/en/texts/time_limits html and the *PCT Applicant's Guide*, National Chapters.

Within **22 months from the priority date, the applicant may request that a supplementary international search be carried out** by a different International Searching Authority that offers this service (Rule 45*bis*.1) The procedure for requesting supplementary international search is described in the *PCT Applicant's Guide*, International Phase, paragraphs 8.006-8.032

Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Authorized officer Kari Rodriquez Telephone No. PCT Helpdesk: 571-272-4300

Form PCT/ISA/220 (revised January 2020)

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference		FOR FURTHER ACTION
111552-8026WO00		see Form PCT/ISA/220 as well as, where applicable, item 5 below.
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/US 21/35965	04 June 2021 (04.06.2021)	05 June 2020 (05.06.2020)
Applicant		
INARI MEDICAL, INC.		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 2 sheets

☐ It is also accompanied by a copy of each prior art document cited in this report

1 **Basis of the report**

a. With regard to the **language**, the international search was carried out on the basis of:

☒ the international application in the language in which it was filed

☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))

b. ☐ This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6*bis*(a))

c ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No I.

2. ☐ **Certain claims were found unsearchable** (see Box No. II).

3. ☐ **Unity of invention is lacking** (see Box No III).

4. With regard to the **title**,

☒ the text is approved as submitted by the applicant

☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

☒ the text is approved as submitted by the applicant

☐ the text has been established, according to Rule 38.2, by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the **drawings**,

a the figure of the **drawings** to be published with the abstract is Figure No. 10C

☒ as suggested by the applicant

☐ as selected by this Authority, because the applicant failed to suggest a figure

☐ as selected by this Authority, because this figure better characterizes the invention.

b. ☐ none of the figures is to be published with the abstract.

Form PCT/ISA/210 (first sheet) (July 2019)

INTERNATIONAL SEARCH REPORT

International application No
PCT/US 21/35965

A. CLASSIFICATION OF SUBJECT MATTER

IPC - A61B 17/00, A61B 17/22, A61B 17/3207, A61M 25/10, A61M 1/00 (2021.01)

CPC - A61M 2025/1045, A61B 17/22, A61B 17/221, A61B 2217/005, A61M 2025/109

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
See Search History document

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
See Search History document

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
See Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X -- Y	US 5,011,488 A (Ginsburg) 30 Apnl 1991 (30.04.1991), entire document	1-10, 13-17, 19-20 --- 18
X	US 5,800,457 (Gelbfish) 1 Septemebr 1998 (01.09.1998), entire document	8, 11-12
Y	WO 2009/082513 A1 (Tex Medical) 2 July 2009 (02.07.2009), entire document	18
A	US 2002/0161392 A1 (Dubrul) 31 October 2002 (31.10.2002), entire document	1-20
A	WO 2018/148174 A1 (KP Medcure, Inc) 16 August 2018 (16.08.2018), entire document	1-20

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents
"A" document defining the general state of the art which is not considered to be of particular relevance
"D" document cited by the applicant in the international application
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance, the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
6 August 2021	SEP 28 2021
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No 571-273-8300	Authorized officer Kari Rodriquez Telephone No. PCT Helpdesk: 571-272-4300

Form PCT/ISA/210 (second sheet) (July 2019)

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To: MATTHEW S. WILLIAMS
PERKINS COIE LLP
P.O. BOX 1247
SEATTLE, WA 98111-1247

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)*	SEP 28 2021

Applicant's or agent's file reference	FOR FURTHER ACTION
111552-8026WO00	See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US 21/35965	04 June 2021 (04.06.2021)	05 June 2020 (05.06.2020)

International Patent Classification (IPC) or both national classification and IPC

IPC - A61B 17/00, A61B 17/22, A61B 17/3207, A61M 25/10, A61M 1/00 (2021.01)

CPC - A61M 2025/1045, A61B 17/22, A61B 17/221, A61B 2217/005, A61M 2025/109

Applicant

INARI MEDICAL, INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step and industrial applicability, citations and explanations supporting such statement
- ☐ Box No VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66 1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

Name and mailing address of the ISA/US	Date of completion of this opinion	Authorized officer
Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	6 August 2021	Kari Rodriquez PCT Help Desk Telephone No 571-272-4300

Form PCT/ISA/237 (cover sheet) (revised January 2019)

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No
PCT/US 21/35965

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:

☒ the international application in the language in which it was filed.

☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2 ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(b))

3. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of a sequence listing:

a. ☐ forming part of the international application as filed:

☐ in the form of an Annex C/ST.25 text file.

☐ on paper or in the form of an image file

b. ☐ furnished together with the international application under PCT Rule 13*ter* 1(a) for the purposes of international search only in the form of an Annex C/ST 25 text file.

c ☐ furnished subsequent to the international filing date for the purposes of international search only:

☐ in the form of an Annex C/ST.25 text file (Rule 13*ter*.1(a))

☐ on paper or in the form of an image file (Rule 13*ter* 1(b) and Administrative Instructions, Section 713).

4 ☐ In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that forming part of the application as filed or does not go beyond the application as filed, as appropriate, were furnished

5. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 21/35965

Box No. V **Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	11-12, 18	YES
	Claims	1-10, 13-17, 19-20	NO
Inventive step (IS)	Claims	None	YES
	Claims	1-20	NO
Industrial applicability (IA)	Claims	1-20	YES
	Claims	None	NO

2 Citations and explanations.
Claims 1-10, 13-17, 19-20 lack novelty under PCT Article 33(2) as being anticipated by US 5,011,488 A to Ginsburg.

As per claim 1, Ginsburg discloses a funnel catheter assembly, comprising:
an outer shaft defining a lumen (12, Fig. 1 - outer shaft with a lumen);
an inner shaft extending through the lumen and having a proximal portion and a distal portion (14 Fig. 1 - inner shaft extending through 12 lumen having a proximal and distal end);
an expandable funnel coupled to the distal portion of the inner shaft (30, Fig. 1 - expandable funnel 30 coupled to distal portion of inner shaft); and
a control assembly (22, 40, Fig. 1) configured to move the funnel between a first position and a second position, wherein in the first position, the funnel is constrained within the lumen of the outer shaft (Fig. 2A - funnel is constrained within lumen of the outer shaft), and in the second position, the funnel is positioned at least partially outside the lumen of the outer shaft such that the funnel can expand (Fig. 2C - funnel is outside the lumen of the outer shaft such funnel can expand).

As per claim 2, Ginsburg discloses the funnel catheter assembly of claim 1 wherein the control assembly (22, 40, Fig. 1) is coupled to the outer shaft and configured to move the outer shaft relative to the inner shaft (Fig. 1; Col 5, ln 44-46 - see how control assembly is coupled to outer shaft and is capable of being used to move outer shaft relative to inner shaft).

As per claim 3, Ginsburg discloses the funnel catheter assembly of claim 1 wherein the control assembly includes an actuator movable to move the funnel between the first and second positions (24, Fig. 1 - proximal housing movement).

As per claim 4, Ginsburg discloses the funnel catheter assembly of claim 3 wherein the actuator is a slider (Col 5, ln 44-46 - pressure applied to actuator 24 provides axial sliding motion of the outer tube and inner tube).

As per claim 5, Ginsburg discloses the funnel catheter assembly of claim 1 wherein the funnel (30, Fig. 1) includes a proximal portion and a distal portion (Fig. 1 - funnel end connected to inner shaft 14 is proximal and distal is opposite end), and wherein the proximal portion of the funnel is coupled to the distal portion of the inner shaft (Fig. 1 - proximal portion of funnel is coupled to distal portion of inner shaft).

As per claim 6, Ginsburg discloses the funnel catheter of claim 5 wherein the distal portion of the funnel is coupled to the outer shaft (Fig. 1, Fig. 2C - when funnel 30 is retracted, distal portion of funnel is coupled to outer shaft).

As per claim 7, Ginsburg discloses the funnel catheter assembly of claim 1, further comprising a sealable hub (46, Fig. 1 - sealing member used to seal the proximal end tube) and a side port (48, Fig. 1 - aspiration port), wherein the side port (48, Fig. 1 - aspiration port) is rotatably coupled (Col 4, ln 61-66 - inner and outer tube can rotate thus the side port is rotatably coupled) between the control assembly (22, 40 Fig. 1) and the sealable hub (46, Fig. 1 - sealing open proximal end of tube).

-*-Continued in Supplemental Box-*-

Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**
Continuation of:
-*-Box V.2 - Citations and Explanations-*-

As per claim 8, Ginsburg discloses a funnel catheter assembly, comprising:
an outer shaft defining an outer lumen (12, Fig. 1 - outer shaft with a lumen);
an inner shaft extending through the outer lumen and having a proximal portion and a distal portion (14 Fig. 1 - inner shaft extending through 12 lumen having a proximal and distal end);
an expandable funnel coupled to the distal portion of the inner shaft (30, Fig. 1 - expandable funnel 30 coupled to distal portion of inner shaft); and
a control assembly (22, 40, Fig. 1) operably coupled to the proximal portion of the outer shaft and configured to move the outer shaft between a first position and a second position (22, 40, Fig. 1 - both 22 and 40 are used to move the outer shaft between the first and second position) wherein in the first position, the outer shaft is positioned at least partially over the funnel to radially constrain the funnel (Fig. 2C - outer shaft is position to radially constrain the funnel), and
in the second position, the outer shaft is retracted proximally relative to the funnel such that the funnel can radially expand (Fig. 2A - outer shaft is retracted to allow the funnel to expand).

As per claim 9, Ginsburg discloses the funnel catheter assembly of claim 8 wherein the control assembly includes a housing (22, Fig. 1) and an actuation member (40, Fig. 1), wherein the actuation member is coupled to a proximal portion of the outer shaft (40, Fig. 1 - actuation member is couple to proximal portion of outer shaft), and wherein the actuation member is slidable along the housing to move the outer shaft between the first and second positions (Fig. 1 -

As per claim 10, Ginsburg discloses the funnel catheter assembly of claim 8 wherein the funnel is configured to self expand (Col 6, ln 13-30 - spring elements can be used to allow the funnel to self-expand).

As per claim 13, Ginsburg discloses the funnel catheter assembly of claim 8 wherein the inner shaft defines an inner lumen sized to receive a dilator (70, Fig. 5C - inflatable balloon to come into contact with inside wall of blood vessel).

As per claim 14, Ginsburg discloses a method of operating a funnel catheter assembly during an intravascular procedure on a patient, the method comprising:
at least partially inserting an inner shaft (14 Fig. 1), an outer shaft (12, Fig. 1), and a funnel (30, Fig. 1) of the funnel catheter assembly into the vasculature of the patient (Fig. 5A; Col 6, ln 39-40 - assembly is introduced into vasculature of patient);
advancing the inner shaft (14 Fig. 1), the outer shaft (12, Fig. 1), and the funnel (30, Fig. 1) together to a deployment position within the vasculature of the patient (Col 6, ln 48-50 - system is positioned so it lies just outside region of stenosis), wherein the funnel is sheathed within a lumen of the outer shaft during the advancement (Fig. 5A - funnel is sheathed within a lumen during advancement);
moving the outer shaft relative to the inner shaft to unsheathe the funnel and permit the funnel to expand to an expanded position (Col 6, ln 48-60 - outer shaft is moved relative to inner shaft to unsheathe funnel to allow funnel to expand);
maintaining the funnel in the expanded position during at least a portion of the intravascular procedure (Fig. 5C-5E - funnel is maintained in expanded position during a portion of the procedure);
moving the outer shaft relative to the inner shaft and/or moving the inner shaft relative to the outer shaft to sheath the funnel within the lumen of the outer shaft (Col 7, ln 4-12 - outer shaft is moved relative to inner to sheath the funnel); and
withdrawing the funnel catheter assembly from the patient (Col 7, ln 12-15 - assembly is removed from patient).

As per claim 15, Ginsburg discloses the method of claim 14 wherein the funnel is self-expandable (30, Fig. 1 - expandable funnel 30 coupled to distal portion of inner shaft), and wherein moving the outer shaft relative to the inner shaft to unsheathe the funnel includes permitting the funnel to self-expand to the expanded position (Col 6, ln 49-60 - outer shaft is moved relative to inner shaft to allow funnel to self-expand).

As per claim 16, Ginsburg discloses the method of claim 14 wherein moving the outer shaft relative to the inner shaft to unsheathe the funnel includes moving a slider of a control assembly of the funnel catheter assembly from a first position to a second position, and wherein the slider is coupled to a
proximal portion of the outer shaft (24, Fig. 1; Col 5, ln 44-46 -outer shaft is moved relative to inner shaft to unsheathe the funnel by moving a slider 24 which is coupled to proximal portion of outer shaft).

As per claim 17, Ginsburg discloses the method of claim 14 wherein moving the outer shaft relative to the inner shaft to unsheathe the funnel includes rotating a rotatable element of a control assembly of the funnel catheter assembly from a first position to a second position (Col 4, ln 61-68 - inner and outer shaft are free to rotate in respect to each other).

As per claim 19, Ginsburg discloses the method of claim 14 wherein,
inserting the inner shaft (14 Fig. 1), the outer shaft (12, Fig. 1), and the funnel (30, Fig. 1) into the vasculature of the patient further includes at least partially inserting a dilator positioned within the inner shaft into the vasculature of the patient (Fig. 5A; Col 6, ln 39-40 - assembly is introduced into vasculature of patient); and
advancing the inner shaft (14 Fig. 1), the outer shaft (12, Fig. 1), and the funnel (30, Fig. 1) further includes advancing the inner shaft (14 Fig. 1), the outer shaft (12, Fig. 1), and the funnel (30, Fig. 1), and the dilator (70, Fig. 5C - inflatable balloon to come into contact with inside wall of blood vessel) together to the deployment position (Col 6, ln 48-50 - system is positioned so it lies just outside region of stenosis).

-*-Continued in next Supplemental Box-*-

Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**
Continuation of
-*-Supplemental Box - Box V.2 - Citations and Explanations-*-

As per claim 20, Ginsburg discloses the method of claim 14 wherein moving the outer shaft relative to the inner shaft to unsheathe the funnel includes moving the outer shaft in a first direction (Col 6, ln 48-60 - outer shaft is moved relative to inner shaft to unsheathe funnel to allow funnel to expand), and wherein the method further comprises moving the outer shaft relative to the inner shaft to sheath the funnel by moving the outer shaft in a second direction opposite to the first direction (Col 7, ln 4-12 - outer shaft is moved relative to inner to sheath the funnel).

Claims 8, 11-12 lack novelty under PCT Article 33(2) as being anticipated by US 5,800,457 to Gelbfish.

As per claim 8, Gelbfish discloses a funnel catheter assembly, comprising:
an outer shaft defining an outer lumen (26, Fig. 2 - outer shaft with outer lumen);
an inner shaft extending through the outer lumen and having a proximal portion and a distal portion (12, Fig. 3D - inner shaft extending through outer lumen 26 and having a proximal and distal portion);
an expandable funnel coupled to the distal portion of the inner shaft (18, Fig. 3D - expandable funnel coupled to distal portion of inner shaft 12); and
a control assembly operably coupled to the proximal portion of the outer shaft (22, Fig. 2; Col 7, ln 11-15 - control unit 22 includes and is coupled to proximal portion of outer shaft 26) and configured to move the outer shaft between a first position and a second position (Col 7, ln 9-15 - outer member 26 is slide over inner shaft 12),
wherein
in the first position, the outer shaft is positioned at least partially over the funnel to radially constrain the funnel (Fig. 3A - outer shaft is positioned over the funnel to constrain the funnel), and
in the second position, the outer shaft is retracted proximally relative to the funnel such that the funnel can radially expand (Fig. 3B - outer shaft is retracted such the funnel can radially expand).

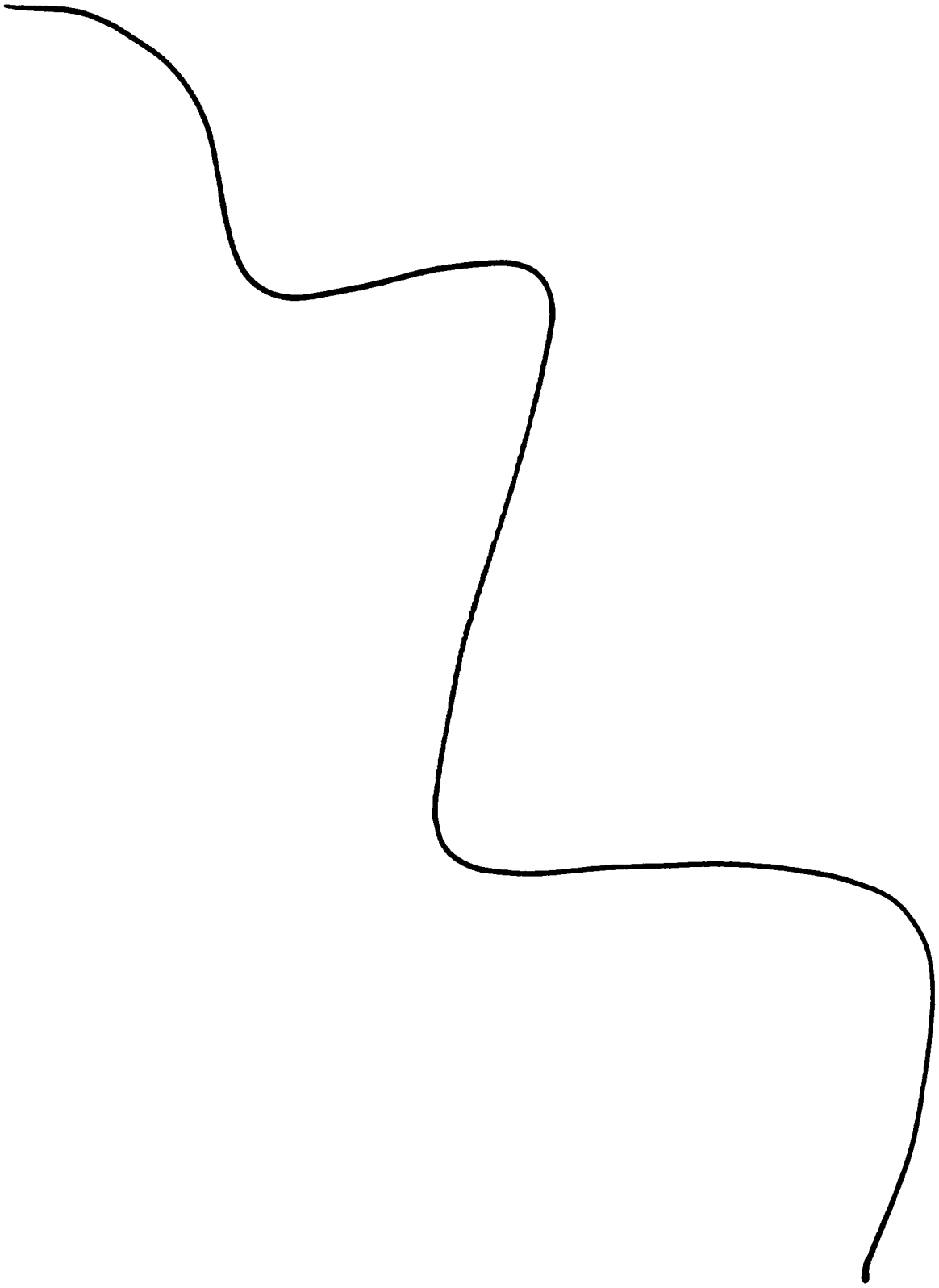
As per claim 11, Gelbfish discloses the funnel catheter assembly of claim 8 wherein the funnel is non-self expanding (Col 7, ln 25-30 - rod 30 is connected to shaft 12 to deploy the funnel), wherein the funnel is further coupled to a distal portion of the outer shaft (Fig. 3A - outer shaft 26 is coupled to funnel when unexpanded), and wherein movement of the outer shaft from the first position to the second position is configured to expand the funnel (Fig. 3B - outer shaft is move to second position to expand the funnel).

As per claim 12, Gelbfish discloses the funnel catheter assembly of claim 11 wherein a distal portion of the funnel is coupled to the distal portion of the outer shaft via one or more tethers (Fig. 3D; Col 8, ln 3-10 - distal portion of funnel is couple to distal portion of outer shaft through tether 42, 44 which traverses an aperture in the outer shaft).

Claims 18 lack an inventive step under PCT Article 33(3) as being obvious over Ginsburg in view of WO 2009/082513 A1 to Tex Medical (hereinafter 'Tex').

As per claim 18, Ginsburg discloses the method of claim 14 but is silent wherein the funnel is non-self-expanding, and wherein the method further comprises actuating the funnel to expand to the expanded position. Tex discloses the method of the funnel (20, Fig. 3A-B) wherein the funnel is coupled to a distal portion of the outer shaft (para [0042] - coupled at one end to distal end 11 of cannula 10) wherein the funnel is non-self expanding (para [0042] - in order to expand funnel 20 cannula 10 may include a balloon 33 position within cannula 10, in addition to an attachment mechanism such as string 34 connecting the balloon to the funnel, wherein when the balloon 33 is inflated it will pull on the string 34 thus deploying the funnel into an open position). Accordingly, it would have been obvious to a person of ordinary skill in the art to utilize Tex's non-self expanding funnel system with Ginsburg's funnel catheter assembly to allow for more control over the funnel deployment through controlled inflation of the balloon.

Claims 1-20 have industrial applicability as defined by PCT Article 33(4) because the subject matter can be made or used by industry.



SEARCH HISTORY

Application Number	PCT/US 21/35965
Search Conducted By	JEF
Search Approved By	SCL

CPC/IPC Classifications Searched	CPC - A61M 2025/1045, A61B 17/22, A61B 17/221, A61B 2217/005, A61M 2025/109 IPC(8) - A61B 17/00, A61B 17/22, A61B 17/3207, A61M 25/10, A61M 1/00 (2021.01)
Date Conducted	06 August 2021 (06.08.2021)

Documentation Searched	CPC - Y10S 55/35, B01D 53/261 IPC(8) - A42B 3/28, A62B 18/00, A62B 23/00, B01D 45/00, A62B 7/00, F24F 1/04 (2021.01)
Search Terms Used	Intra, Intravascular, Treat, Treatment, Funnel, Catheter, Thrombi, Thrombus, Thrombosis, ClotTriver, Invari Medical, Adjustable, Percutaneous, Shaft, Blood, Clot
Date Conducted	06 August 2021 (06.08.2021)

Electronic Database Searched	PatBase
Files Searched	Full-text: AU BE BR CA CH CN DE DK EP ES FI FR GB IN JP KR SE TH TW US WO Bibliographic: (Europe) AT BA BE BG CH CS CY CZ DD DK EE ES FI GE GR HR HU IE IS IT LT LU LV MC MD MT NL NO PL PT RO RS SE SI SK SM TR UA YU (Asia) EA GC HK ID IL IN KZ MN MY PH RU SG SU TH TJ TW UZ VN (North America) CA CR CU DO GT HN MX NI PA SV TT (South America) AR BR CL CO EC PE UY (Australasia) AU NZ (Africa) AP DZ EG KE MA MW OA ZA ZM ZW
Date Conducted	06 August 2021 (06.08.2021)

Search Logic:

Search 1: PN=(US5102415 or US10898212) (Results 2)
Search 2: IC=(A61B17/00 or A61B17/22 or A61B17/3207 or A61M25/10 or A61M1/00) (Results 152615)
Search 3: CPC=(A61M2025/1045 or A61B17/22 or A61B17/221 or A61B2217/005 or A61M2025/109) (Results 7069)
Search 4: 2 or 3 (Results 153968)
Search 5: 4 and ft=(funnel) (Results 3521)

Search 6:	5 and ft=(thromb*) (Results 674)
Search 7:	6 and ft=(inner near outer) (Results 400)
Search 8:	7 and ft=(blood) (Results 388)
Search 9:	8 and ft=(inner near shaft) (Results 127)
Search 10:	9 and ft=(expand) (Results 117)
Search 11:	10 and ft=(mov*) (Results 114)
Search 12:	11 and ft=(expand* near funnel) (Results 32)
Search 13:	12 and Ft=(non* near self near expand*) (Results 2)
Search 14:	PN=(WO2004093966) (Results 1)
Search 15:	CTA 14 (Results 1656)
Search 16:	Ft=(funnel near catheter) (Results 750)
Search 17:	16 and ft=(outer or inner) (Results 560)
Search 18:	17 and ft=(expand) (Results 213)
Search 19:	18 and ft=(tether) (Results 27)
Search 20:	18 and ft=(self) (Results 142)
Search 21:	20 and ft=(blood) (Results 124)
Search 22:	21 and ft=(vessel) (Results 106)

Electronic Database Searched	Google
Files Searched	Scholar (Articles excluding patents)
Date Conducted	06 August 2021 (06.08.2021)

Search Logic:

Intravascular Treatment Funnel Catheter
10,000,000

Funnel Catheter Assembly
11,400,000

Thrombi Extraction Catheter
8,820,000

Thrombus Aspiration Catheter
7,160,000

Thrombus Funnel Catheter
7,800,000

Thrombosis Catheter
12,700,000

Thrombosis Funnel Catheter
10,900,000

ClotTriver Inari Medical

5,170

Catheter with Funnel End
13,200,000

Catheter adjustable Funnel Inner Shaft
14,900,000

Catheter Adjustable Funnel Inner Shaft Blood Clot
11,600,000

Percutaneous Funnel Catheter
12,300,000

Electronic Database Searched	Google
Files Searched	Patents (US Patents/Published Applications, EPO publications, International, China, Germany, Canada)
Date Conducted	06 August 2021 (06.08.2021)

Search Logic:

Funnel Catheter Blood Clot
12,760

Percutaneous Funnel Catheter
11,569

Catheter Adjustable Funnel Inner Shaft Blood Clot
1,374

Thrombus Adjustable Funnel Catheter
3,652

Funnel Aspiration Catheters
7,210

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/865,266	07/14/2022	Benjamin E. Merritt	111552-8016.US04	6816

25096 7590 08/10/2022

PERKINS COIE LLP - SEA General
PATENT-SEA
P.O. BOX 1247
SEATTLE, WA 98111-1247

EXAMINER
CENTRAL, DOCKET

ART UNIT	PAPER NUMBER
3783	

NOTIFICATION DATE	DELIVERY MODE
08/10/2022	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentprocurement@perkinscoie.com

Decision Granting Request for Prioritized Examination (Track I)	**Application No.** 17/865,266	**Applicant(s)** Merritt et al.	
	Examiner CHERYL P GIBSON BAYLOR	**Art Unit** OPET	**AIA (FITF) Status** Yes

1. THE REQUEST FILED 14 July 2022 IS **GRANTED** .

The above-identified application has met the requirements for prioritized examination

A. ☑ for an original nonprovisional application (Track I).
B. ☐ for an application undergoing continued examination (RCE).

2. **The above-identified application will undergo prioritized examination**. The application will be accorded special status throughout its entire course of prosecution until one of the following occurs:

A. filing a **petition for extension of time** to extend the time period for filing a reply;

B. filing an **amendment to amend the application to contain more than four independent claims, more than thirty total claims** , or a multiple dependent claim;

C. filing a **request for continued examination** ;

D. filing a notice of appeal;

E. filing a request for suspension of action;

F. mailing of a notice of allowance;

G. mailing of a final Office action;

H. completion of examination as defined in 37 CFR 41.102; or

I. abandonment of the application.

Telephone inquiries with regard to this decision should be directed to CHERYL GIBSON BAYLOR at (571)272-3213. In his/her absence, calls may be directed to Petition Help Desk at (571) 272-3282.

/CHERYL GIBSON BAYLOR/ Paralegal Specialist, OPET	

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number: 17/865,266

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY FEE($)
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	320
SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	700
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	800
TOTAL CLAIMS (37 CFR 1.16(i))	9 minus 20 =	*			OR	x 100 =	0.00
INDEPENDENT CLAIMS (37 CFR 1.16(h))	1 minus 3 =	*				x 480 =	0.00
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).						0.00
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							0.00
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL			TOTAL	1820

APPLICATION AS AMENDED - PART II

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY ADDITIONAL FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE($)
AMENDMENT A	Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY ADDITIONAL FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE($)
AMENDMENT B	Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest found in the appropriate box in column 1.

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APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
17/865,266	07/14/2022		1820	111552-8016.US04	9	1

CONFIRMATION NO. 6816

25096
PERKINS COIE LLP - SEA General
PATENT-SEA
P.O. BOX 1247
SEATTLE, WA 98111-1247

FILING RECEIPT

OC000000135335295

Date Mailed: 07/25/2022

Receipt is acknowledged of this non-provisional utility patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF FIRST INVENTOR, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection.

Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please submit a written request for a corrected Filing Receipt, including a properly marked-up ADS showing the changes with strike-through for deletions and underlining for additions. If you received a "Notice to File Missing Parts" or other Notice requiring a response for this application, please submit any request for correction to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections provided that the request is grantable.

Inventor(s)

Benjamin E. Merritt, San Clemente, CA;
John C. Thress, Capistrano Beach, CA;
Paul Lubock, Monarch Beach, CA;

Applicant(s)

Inari Medical, Inc., Irvine, CA;

Power of Attorney: The patent practitioners associated with Customer Number 25096

Domestic Priority data as claimed by applicant

This application is a CON of 17/705,189 03/25/2022
which is a CON of 17/226,318 04/09/2021
which is a CON of 16/117,519 08/30/2018 PAT 11000682
which claims benefit of 62/554,931 09/06/2017

Foreign Applications for which priority is claimed (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see http://www.uspto.gov for more information.) - None.
Foreign application information must be provided in an Application Data Sheet in order to constitute a claim to foreign priority. See 37 CFR 1.55 and 1.76.

Permission to Access Application via Priority Document Exchange: Yes

Permission to Access Search Results: Yes

Applicant may provide or rescind an authorization for access using Form PTO/SB/39 or Form PTO/SB/69 as appropriate.

If Required, Foreign Filing License Granted: 07/21/2022
The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 17/865,266**
Projected Publication Date: 11/03/2022
Non-Publication Request: No
Early Publication Request: No
Title

HEMOSTASIS VALVES AND METHODS OF USE

Preliminary Class

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: No

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at http://www.uspto.gov/web/offices/pac/doc/general/index.html.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, http://www.stopfakes.gov. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4258).

LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

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The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign AssetsControl, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

Doc Code: TRACK1.REQ
Document Description: TrackOne Request

PTO/AIA/424 (04-14)

CERTIFICATION AND REQUEST FOR PRIORITIZED EXAMINATION UNDER 37 CFR 1.102(e) (Page 1 of 1)

First Named Inventor:	Benjamin E. Merritt	Nonprovisional Application Number (if known):	Not Yet Assigned
Title of Invention:	HEMOSTASIS VALVES AND METHODS OF USE		

APPLICANT HEREBY CERTIFIES THE FOLLOWING AND REQUESTS PRIORITIZED EXAMINATION FOR THE ABOVE-IDENTIFIED APPLICATION.

1. The processing fee set forth in 37 CFR 1.17(i)(1) and the prioritized examination fee set forth in 37 CFR 1.17(c) have been filed with the request. The publication fee requirement is met because that fee, set forth in 37 CFR 1.18(d), is currently $0. The basic filing fee, search fee, and examination fee are filed with the request or have been already been paid. I understand that any required excess claims fees or application size fee must be paid for the application.

2. I understand that the application may not contain, or be amended to contain, more than four independent claims, more than thirty total claims, or any multiple dependent claims, and that any request for an extension of time will cause an outstanding Track I request to be dismissed.

3. The applicable box is checked below:

I. ☑ Original Application (Track One) - Prioritized Examination under § 1.102(e)(1)

i. (a) The application is an original nonprovisional utility application filed under 35 U.S.C. 111(a). This certification and request is being filed with the utility application via EFS-Web.

---OR---

(b) The application is an original nonprovisional plant application filed under 35 U.S.C. 111(a). This certification and request is being filed with the plant application in paper.

ii. An executed inventor's oath or declaration under 37 CFR 1.63 or 37 CFR 1.64 for each inventor, **or** the application data sheet meeting the conditions specified in 37 CFR 1.53(f)(3)(i) is filed with the application.

II. ☐ Request for Continued Examination - Prioritized Examination under § 1.102(e)(2)

i. A request for continued examination has been filed with, or prior to, this form.
ii. If the application is a utility application, this certification and request is being filed via EFS-Web.
iii. The application is an original nonprovisional utility application filed under 35 U.S.C. 111(a), or is a national stage entry under 35 U.S.C. 371.
iv. This certification and request is being filed prior to the mailing of a first Office action responsive to the request for continued examination.
v. No prior request for continued examination has been granted prioritized examination status under 37 CFR 1.102(e)(2).

Signature /Paul T. Parker/	Date 2022-07-14
Name (Print/Typed) Paul T. Parker	Practitioner Registration Number 38,264

Note: *This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications. Submit multiple forms if more than one signature is required.**

☑ *Total of 1 forms are submitted.

Privacy Act Statement

The **Privacy Act of 1974 (P.L. 93-579)** requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

PTO/AIA/14 (11-15)
Approved for use through 04/30/2017. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	111552-8016.US04
	Application Number	
Title of Invention	HEMOSTASIS VALVES AND METHODS OF USE	

The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76.
This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application.

Secrecy Order 37 CFR 5.2:

☐ Portions or all of the application associated with this Application Data Sheet may fall under a Secrecy Order pursuant to 37 CFR 5.2 (Paper filers only. Applications that fall under Secrecy Order may not be filed electronically.)

Inventor Information:

Inventor 1 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Benjamin	E.	Merritt	

Residence Information (Select One) ● US Residency Non US Residency Active US Military Service

City	State/Province	Country of Residence
San Clemente	CA	US

Mailing Address of Inventor:

Address 1	c/o Inari Medical, Inc.
Address 2	6001 Oak Canyon, Suite #100
City	Irvine
State/Province	CA
Postal Code	92618
Country	US

Inventor 2 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	John	C.	Thress	

Residence Information (Select One) ◉ US Residency Non US Residency Active US Military Service

City	State/Province	Country of Residence
Capistrano Beach	CA	US

Mailing Address of Inventor:

Address 1	c/o Inari Medical, Inc.
Address 2	6001 Oak Canyon, Suite #100
City	Irvine
State/Province	CA
Postal Code	92618
Country	US

Inventor 3 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Paul		Lubock	

Residence Information (Select One) ◉ US Residency Non US Residency Active US Military Service

PTO/AIA/14 (11-15)
Approved for use through 04/30/2017. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	111552-8016.US04
	Application Number	
Title of Invention	HEMOSTASIS VALVES AND METHODS OF USE	

City	Monarch Beach	State/Province	CA	Country of Residence	US

Mailing Address of Inventor:

Address 1	c/o Inari Medical, Inc.
Address 2	6001 Oak Canyon, Suite #100

City	Irvine	State/Province	CA
Postal Code	92618	Country	US

All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the **Add** button. Add

Correspondence Information:

Enter either Customer Number or complete the Correspondence Information section below.
For further information see 37 CFR 1.33(a).

☐ **An Address is being provided for the correspondence Information of this application.**

Customer Number	25096		
Email Address	patentprocurement@perkinscoie.com	Add Email	Remove Email

Application Information:

Title of the Invention	HEMOSTASIS VALVES AND METHODS OF USE		
Attorney Docket Number	111552-8016.US04	Small Entity Status Claimed	☐
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)	10	Suggested Figure for Publication (if any)	2

Filing By Reference:

Only complete this section when filing an application by reference under 35 U.S.C. 111(c) and 37 CFR 1.57(a). Do not complete this section if application papers including a specification and any drawings are being filed. Any domestic benefit or foreign priority information must be provided in the appropriate section(s) below (i.e., "Domestic Benefit/National Stage Information" and "Foreign Priority Information").

For the purposes of a filing date under 37 CFR 1.53(b), the description and any drawings of the present application are replaced by this reference to the previously filed application, subject to conditions and requirements of 37 CFR 1.57(a).

Application number of the previously filed application	Filing date (YYYY-MM-DD)	Intellectual Property Authority or Country

Publication Information:

☐ Request Early Publication (Fee required at time of Request 37 CFR 1.219)

☐ **Request Not to Publish.** I hereby request that the attached application not be published under 35 U.S.C. 122(b) and certify that the invention disclosed in the attached application **has not and will not** be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing.

PTO/AIA/14 (11-15)
Approved for use through 04/30/2017. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	111552-8016.US04
	Application Number	
Title of Invention	HEMOSTASIS VALVES AND METHODS OF USE	

Representative Information:

Representative information should be provided for all practitioners having a power of attorney in the application. Providing this information in the Application Data Sheet does not constitute a power of attorney in the application (see 37 CFR 1.32).
Either enter Customer Number or complete the Representative Name section below. If both sections are completed the customer Number will be used for the Representative Information during processing.

Please Select One:	● Customer Number	US Patent Practitioner	○ Limited Recognition (37 CFR 11.9)
Customer Number	25096		

Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, 365(c), or 386(c) or indicate National Stage entry from a PCT application. Providing benefit claim information in the Application Data Sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78.
When referring to the current application, please leave the "Application Number" field blank.

Prior Application Status	Pending		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
	Continuation of	17/705189	2022-03-25
Prior Application Status	Pending		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
17/705189	Continuation of	17/226318	2021-04-09
Prior Application Status	Patented		Remove

Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
17/226318	Continuation of	16/117519	2018-08-30	11000682	2021-05-11

Prior Application Status	Expired		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
16/117519	Claims benefit of provisional	62/554931	2017-09-06

Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the **Add** button. Add

Foreign Priority Information:

PTO/AIA/14 (11-15)
Approved for use through 04/30/2017. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	111552-8016.US04
	Application Number	
Title of Invention	HEMOSTASIS VALVES AND METHODS OF USE	

This section allows for the applicant to claim priority to a foreign application. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55. When priority is claimed to a foreign application that is eligible for retrieval under the priority document exchange program (PDX)[i] the information will be used by the Office to automatically attempt retrieval pursuant to 37 CFR 1.55(i)(1) and (2). Under the PDX program, applicant bears the ultimate responsibility for ensuring that a copy of the foreign application is received by the Office from the participating foreign intellectual property office, or a certified copy of the foreign priority application is filed, within the time period specified in 37 CFR 1.55(g)(1).

Remove

Application Number	Country[i]	Filing Date (YYYY-MM-DD)	Access Code[i] (if applicable)

Additional Foreign Priority Data may be generated within this form by selecting the **Add** button. Add

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications

☐ This application (1) claims priority to or the benefit of an application filed before March 16, 2013 and (2) also contains, or contained at any time, a claim to a claimed invention that has an effective filing date on or after March 16, 2013.
NOTE: By providing this statement under 37 CFR 1.55 or 1.78, this application, with a filing date on or after March 16, 2013, will be examined under the first inventor to file provisions of the AIA.

PTO/AIA/14 (11-15)
Approved for use through 04/30/2017. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	111552-8016.US04
	Application Number	
Title of Invention	HEMOSTASIS VALVES AND METHODS OF USE	

Authorization or Opt-Out of Authorization to Permit Access:

When this Application Data Sheet is properly signed and filed with the application, applicant has provided written authority to permit a participating foreign intellectual property (IP) office access to the instant application-as-filed (see paragraph A in subsection 1 below) and the European Patent Office (EPO) access to any search results from the instant application (see paragraph B in subsection 1 below).

Should applicant choose not to provide an authorization identified in subsection 1 below, applicant **must opt-out** of the authorization by checking the corresponding box A or B or both in subsection 2 below.

NOTE: This section of the Application Data Sheet is **ONLY** reviewed and processed with the **INITIAL** filing of an application. After the initial filing of an application, an Application Data Sheet cannot be used to provide or rescind authorization for access by a foreign IP office(s). Instead, Form PTO/SB/39 or PTO/SB/69 must be used as appropriate.

1. Authorization to Permit Access by a Foreign Intellectual Property Office(s)

A. Priority Document Exchange (PDX) - Unless box A in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the European Patent Office (EPO), the Japan Patent Office (JPO), the Korean Intellectual Property Office (KIPO), the State Intellectual Property Office of the People's Republic of China (SIPO), the World Intellectual Property Organization (WIPO), and any other foreign intellectual property office participating with the USPTO in a bilateral or multilateral priority document exchange agreement in which a foreign application claiming priority to the instant patent application is filed, access to: (1) the instant patent application-as-filed and its related bibliographic data, (2) any foreign or domestic application to which priority or benefit is claimed by the instant application and its related bibliographic data, and (3) the date of filing of this Authorization. See 37 CFR 1.14(h)(1).

B. Search Results from U.S. Application to EPO - Unless box B in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the EPO access to the bibliographic data and search results from the instant patent application when a European patent application claiming priority to the instant patent application is filed. See 37 CFR 1.14(h)(2).

The applicant is reminded that the EPO's Rule 141(1) EPC (European Patent Convention) requires applicants to submit a copy of search results from the instant application without delay in a European patent application that claims priority to the instant application.

2. Opt-Out of Authorizations to Permit Access by a Foreign Intellectual Property Office(s)

☐ A. Applicant **DOES NOT** authorize the USPTO to permit a participating foreign IP office access to the instant application-as-filed. If this box is checked, the USPTO will not be providing a participating foreign IP office with any documents and information identified in subsection 1A above.

☐ B. Applicant **DOES NOT** authorize the USPTO to transmit to the EPO any search results from the instant patent application. If this box is checked, the USPTO will not be providing the EPO with search results from the instant application.

NOTE: Once the application has published or is otherwise publicly available, the USPTO may provide access to the application in accordance with 37 CFR 1.14.

PTO/AIA/14 (11-15)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	111552-8016.US04
	Application Number	
Title of Invention	HEMOSTASIS VALVES AND METHODS OF USE	

Applicant Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

Applicant 1 — Remove

If the applicant is the inventor (or the remaining joint inventor or inventors under 37 CFR 1.45), this section should not be completed. The information to be provided in this section is the name and address of the legal representative who is the applicant under 37 CFR 1.43; or the name and address of the assignee, person to whom the inventor is under an obligation to assign the invention, or person who otherwise shows sufficient proprietary interest in the matter who is the applicant under 37 CFR 1.46. If the applicant is an applicant under 37 CFR 1.46 (assignee, person to whom the inventor is obligated to assign, or person who otherwise shows sufficient proprietary interest) together with one or more joint inventors, then the joint inventor or inventors who are also the applicant should be identified in this section.

Clear

● Assignee	Legal Representative under 35 U.S.C. 117	Joint Inventor
Person to whom the inventor is obligated to assign.	Person who shows sufficient proprietary interest	

If applicant is the legal representative, indicate the authority to file the patent application, the inventor is:

Name of the Deceased or Legally Incapacitated Inventor:

If the Applicant is an Organization check here. ☒

Organization Name	Inari Medical, Inc.		
Mailing Address Information For Applicant:			
Address 1	6001 Oak Canyon, Suite #100		
Address 2			
City	Irvine	**State/Province**	CA
Country	US	Postal Code	92618
Phone Number		Fax Number	
Email Address			

Additional Applicant Data may be generated within this form by selecting the Add button. Add

Assignee Information including Non-Applicant Assignee Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

PTO/AIA/14 (11-15)
Approved for use through 04/30/2017. OMB 0651-0032
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	111552-8016.US04
	Application Number	
Title of Invention	HEMOSTASIS VALVES AND METHODS OF USE	

Assignee 1

Complete this section if assignee information, including non-applicant assignee information, is desired to be included on the patent application publication. An assignee-applicant identified in the "Applicant Information" section will appear on the patent application publication as an applicant. For an assignee-applicant, complete this section only if identification as an assignee is also desired on the patent application publication.

Remove

If the Assignee or Non-Applicant Assignee is an Organization check here. ☐

Prefix	**Given Name**	Middle Name	**Family Name**	Suffix

Mailing Address Information For Assignee including Non-Applicant Assignee:

Address 1			
Address 2			
City		**State/Province**	
Country i		Postal Code	
Phone Number		Fax Number	
Email Address			

Additional Assignee or Non-Applicant Assignee Data may be generated within this form by selecting the Add button. Add

Signature:

Remove

NOTE: This Application Data Sheet must be signed in accordance with 37 CFR 1.33(b). **However, if this Application Data Sheet is submitted with the INITIAL filing of the application and either box A or B is not checked in subsection 2 of the "Authorization or Opt-Out of Authorization to Permit Access" section, then this form must also be signed in accordance with 37 CFR 1.14(c).**

This Application Data Sheet **must** be signed by a patent practitioner if one or more of the applicants is a **juristic entity** (e.g., corporation or association). If the applicant is two or more joint inventors, this form must be signed by a patent practitioner, **all** joint inventors who are the applicant, or one or more joint inventor-applicants who have been given power of attorney (e.g., see USPTO Form PTO/AIA/81) on behalf of **all** joint inventor-applicants.

See 37 CFR 1.4(d) for the manner of making signatures and certifications.

Signature	/Paul T. Parker/			Date (YYYY-MM-DD)	2022-07-14
First Name	Paul T.	Last Name	Parker	Registration Number	38,264

Additional Signature may be generated within this form by selecting the Add button. Add

PTO/AIA/14 (11-15)
Approved for use through 04/30/2017. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	111552-8016.US04
	Application Number	
Title of Invention	HEMOSTASIS VALVES AND METHODS OF USE	

This collection of information is required by 37 CFR 1.76. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 23 minutes to complete, including gathering, preparing, and submitting the completed application data sheet form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

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The information provided by you in this form will be subject to the following routine uses:

1 The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3 A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent CooperationTreaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Doc Code: PA..
Document Description: Power of Attorney

PTO/AIA/82A (07-13)
Approved for use through 03/31/2021. OMB 0651-0035
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

TRANSMITTAL FOR POWER OF ATTORNEY TO ONE OR MORE REGISTERED PRACTITIONERS

NOTE: This form is to be submitted with the Power of Attorney by Applicant form (PTO/AIA/82B) to identify the application to which the Power of Attorney is directed, in accordance with 37 CFR 1.5, unless the application number and filing date are identified in the Power of Attorney by Applicant form. If neither form PTO/AIA/82A nor form PTO/AIA82B identifies the application to which the Power of Attorney is directed, the Power of Attorney will not be recognized in the application.

Application Number	Not Yet Assigned
Filing Date	Concurrently Herewith
First Named Inventor	Benjamin E. Merritt
Title	HEMOSTASIS VALVES AND METHODS OF USE
Art Unit	Not Yet Assigned
Examiner Name	Not Yet Assigned
Attorney Docket Number	111552-8016.US04

SIGNATURE of Applicant or Patent Practitioner

Signature	/Paul T. Parker/	Date (Optional)	2022-07-14
Name	Paul T. Parker	Registration Number	38,264
Title (if Applicant is a juristic entity)	Attorney for Applicant		
Applicant Name (if Applicant is a juristic entity)	Inari Medical, Inc.		

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications. If more than one applicant, use multiple forms.

☑ *Total of 1 forms are submitted.

This collection of information is required by 37 CFR 1.131, 1.32, and 1.33. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Doc Code: PA..
Document Description: Power of Attorney

PTO/AIA/82B (07-13)
Approved for use through 03/31/2021. OMB 0651-0035
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number

POWER OF ATTORNEY BY APPLICANT

I hereby revoke all previous powers of attorney given in the application identified in either the attached transmittal letter or the boxes below.

Application Number	Filing Date

(Note: The boxes above may be left blank if information is provided on form PTO/AIA/82A.)

☑ I hereby appoint the Patent Practitioner(s) associated with the following Customer Number as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the application referenced in the attached transmittal letter (form PTO/AIA/82A) or identified above: 25096

OR

☐ I hereby appoint Practitioner(s) named in the attached list (form PTO/AIA/82C) as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the patent application referenced in the attached transmittal letter (form PTO/AIA/82A) or identified above. (Note: Complete form PTO/AIA/82C.)

Please recognize or change the correspondence address for the application identified in the attached transmittal letter or the boxes above to:

☑ The address associated with the above-mentioned Customer Number

OR

☐ The address associated with Customer Number:

OR

☐ Firm or Individual Name					
Address					
City		State		Zip	
Country					
Telephone		Email			

I am the Applicant (if the Applicant is a juristic entity, list the Applicant name in the box):

Inari Medical, Inc.

☐ Inventor or Joint Inventor (title not required below)

☐ Legal Representative of a Deceased or Legally Incapacitated Inventor (title not required below)

☑ Assignee or Person to Whom the Inventor is Under an Obligation to Assign (provide signer's title if applicant is a juristic entity)

☐ Person Who Otherwise Shows Sufficient Proprietary Interest (e.g., a petition under 37 CFR 1.46(b)(2) was granted in the application or is concurrently being filed with this document) (provide signer's title if applicant is a juristic entity)

SIGNATURE of Applicant for Patent

The undersigned (whose title is supplied below) is authorized to act on behalf of the applicant (e.g., where the applicant is a juristic entity).

Signature		Date (Optional)	10 Dec 2021
Name	Brian Strauss		
Title	Vice President, Inari Medical, Inc.		

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Benjamin E. Merritt et al.

Application No.: Not Yet Assigned	Confirmation No.: NA
Filed: Concurrenlty Herewith	Art Unit: Not Yet Known
For: HEMOSTASIS VALVES AND METHODS OF USE	Examiner: Not Yet Known

AUTHORIZATION FOR: EXTENSIONS OF TIME UNDER 37 C.F.R. § 1.136(a)(3) AND PAYMENT OF FEES UNDER 37 C.F.R. § 1.17

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Commissioner:

With respect to the above-identified application, the Commissioner is authorized to treat any concurrent or future reply requiring a petition for an extension of time under 37 C.F.R. § 1.136(a)(3) for its timely submission as incorporating a petition therefor for the appropriate length of time.

The Commissioner is also authorized to charge any extension of time fees or other fees that may be required under 37 C.F.R. § 1.17 for any paper filed concurrently herewith or in the future, or credit any overpayment, to Deposit Account No. 50-0665.

Dated: July 14, 2022

Respectfully submitted,

By _/Paul T. Parker/____
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Attorney for Applicant

DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

Title of Invention	HEMOSTASIS VALVES AND METHODS OF USE

As the below named inventor, I hereby declare that:

This declaration is directed to:

[ ] The attached application, or

[x] United States application or PCT international application number 16/117,519

filed on August 30, 2018.

The above-identified application was made or authorized to be made by me.

I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

I hereby acknowledge that any wilful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

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LEGAL NAME OF INVENTOR

Inventor: Benjamin E. Merritt Date: 8/31/18

Signature: _____

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form. Use an additional PTO/AIA/01 form for each additional inventor.

DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

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LEGAL NAME OF INVENTOR

Inventor: John C. Thress Date: 8/31/18

Signature: _____

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LEGAL NAME OF INVENTOR

Inventor: Paul Lubock Date: September 14, 2018

Signature:

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form. Use an additional PTO/AIA/01 form for each additional inventor.

HEMOSTASIS VALVES AND METHODS OF USE

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is a U.S. Patent Application No. 17/705,189, filed on March 25, 2022, entitled "HEMOSTASIS VALVES AND METHODS OF USE," which is a continuation of U.S. Patent Application No. 17/226,318, filed on April 9, 2021, entitled "HEMOSTASIS VALVES AND METHODS OF USE," which is a continuation of U.S. Patent Application No. 16/117,519, filed on August 30, 2018, now issued as U.S. Patent No. 11,000,682, and entitled "HEMOSTASIS VALVES AND METHODS OF USE," which claims the benefit of U.S. Provisional Patent Application No. 62/554,931, filed on September 6, 2017, and entitled "HEMOSTASIS VALVES AND METHODS OF USE," each of which is herein incorporated by reference in its entirety.

BACKGROUND

[0002] During a surgical procedure, a portion of a patient's body (e.g., vasculature) is accessed to allow for performance of a desired intervention or treatment. During such surgical procedures, it is desired to minimize patient blood loss, prevent delivery of air into the vasculature, and to maintain the sterility of the accessed portions or sites of the patient's body so as to prevent issues such as infection. Further, the desire for improved patient outcomes has led to the development of hemostasis valves that facilitate minimally invasive surgery.

[0003] In minimally invasive surgery, small incisions are created through a blood vessel which one or several catheters are inserted. Each of these one or several catheters can define a lumen extending longitudinally through that catheter. These catheters are moved to a position proximate to tissue, nerves, or other body structures targeted by the surgery, and then tools for performing the procedure are inserted through the lumens of some or all of these catheters.

[0004] To minimize blood loss, prevent delivery of air into the vasculature, and to facilitate maintenance of sterility within the patient's body (e.g., blood vessel), these catheters are equipped with hemostasis valves. These valves seal or selectably seal the lumens of the catheters. In many instances, these valves can seal the lumen of the catheter when a tool extends through the catheter,

and specifically through the valve. Additionally the valves can seal the lumen when a tool is removed or does not extend through the catheter.

[0005] While such traditional hemostasis valves are greatly beneficial for intravascular access, they have some drawbacks. For example, some valves may not seal adequately for all interventional applications or tools, and/or the operation of some valves may be complicated for operator use. The drawbacks of such valve designs may in turn increase the complexity of any surgery performed therewith and/or reduce patient safety (e.g., bleeding, infection, and/or other detrimental complications). Accordingly, new and improved hemostasis valves and methods of use are desired.

SUMMARY

[0006] The following relates to valves, medical systems incorporating valves, and methods of using the same. The valve can include a tubular member that can be constricted, collapsed, and/or sealed by one or several tensioning mechanisms. The tensioning mechanism can include at least one filament that extends around at least a portion of the tubular member. The filament can interact with the tubular member to constrict, collapse, and/or seal the tubular member via manipulation of the tensioning mechanism(s). A tool can be inserted through the valve to gain access to a patient's body and specifically to gain access to a blood vessel. Through the use of the tensioning mechanism and filament to constrict, collapse, and/or seal the tubular member, the valve can seal around a wide range of tool sizes and shapes, as well as multiple tools of differing sizes simultaneously. Additionally, such a valve creates a robust seal that maintains its seal when a vacuum is applied such as occurs during aspiration.

[0007] Aspects of the present disclosure relate to a hemostatic valve for sealing a medical device. The hemostatic valve includes an elongate member having a first end, a second end, and a central lumen extending therebetween. In some embodiments, the elongate member is pliable. The hemostatic valve can include a reinforcement structure extending along at least a portion of the elongate member, such that the reinforcement structure is coupled to the elongate member. The hemostatic valve includes an active tensioning mechanism coupled to the elongate member. In some embodiments, the tensioning mechanism is moveable between a first configuration in which the central lumen is constricted and sealed and a second configuration in which the central lumen is

open. Optionally, the valve may be manually adjusted by the user to intermediate positions between fully open and fully closed. Additionally, an instrument (e.g. catheter) may provide an intermediate position where the valve creates hemostasis without user adjustment.

[0008] In some embodiments, the elongate member can be a compliant polymer tube. In some embodiments, the tensioning mechanism can include at least one filament extending at least partially around the elongate member. In some embodiments, the reinforcement structure is positioned between the at least one filament and the elongate member. In some embodiments, the reinforcement structure can be a braided mesh. In some embodiments, the reinforcement structure is coupled to the elongate member at a position proximate to the first end of the elongate member and at a position proximate to the second end of the elongate member. In some embodiments, the reinforcement structure is not coupled to the elongate member at a position between the first end of the elongate member and the second end of the elongate member. In some embodiments, the central portion of the compliant polymer tube that is constrained or collapsed by the tensioning mechanism, and at least one filament, is not coupled to the reinforcement structure.

[0009] In some embodiments, the tensioning mechanism can include an actuator coupled to the at least one filament. In some embodiments there are two tensioning mechanisms coupled to the at least one filament that operate in opposite directions. In some embodiments the two tensioning mechanisms are attached to the same filament. In some embodiments the two tensioning mechanisms are attached to opposing filaments. In some embodiments, the actuator can be moveable to control movement of the at least one filament from a first position in which the central lumen is constricted and sealed to a second position in which the central lumen is open. In some embodiments, the at least one filament is in the first position when the tensioning mechanism is in the first configuration. In some embodiments, the actuator is biased towards the first position. In some embodiments, the actuator is biased toward the second position. In some embodiments, the actuator can be a manual actuator.

[0010] In some embodiments, the at least one filament forms a loop around the elongate member. In some embodiments, the at least one filament forms a bight around a portion of the elongate member. In some embodiments, the at least one filament can include a first filament and a second filament. In some embodiments, each of the first filament and the second filament are coupled to the same actuator. In some embodiments, each of the first filament and the second

filament are coupled to different actuators. In some embodiments, the first filament and the second filament are moveable from the first position to the second position. In some embodiments, each of the first filament and the second filament form a loop around the elongate member. In some embodiments, the first filament forms a first bight around a first portion of the elongate member, and the second filament forms a second bight around a second portion of the elongate member. In some embodiments, the first bight extends through the second bight.

[0011] In some embodiments, the hemostatic valve can include a shell defining a first aperture and a second aperture. In some embodiments, the elongate member extends from the first aperture to the second aperture and fluidly couples the first aperture and the second aperture. In some embodiments, the tensioning mechanism is self-adjustable to seal around tools of different sizes extending through the hemostatic valve. In some embodiments, the central lumen can comprise a single lumen, and in some embodiments, the central lumen can comprise a plurality of lumens.

[0012] One aspect of the present disclosure relates to a delivery system for intravascular access of a blood vessel within a patient's body. The delivery system includes a catheter having a first end, a second end, and a catheter lumen extending therebetween and a hemostatic valve coupled to the first end of the catheter. The hemostatic valve includes a tubular member having a first end, a second end, and a central lumen extending therebetween. In some embodiments, the central lumen of the tubular member is fluidly coupled with the catheter lumen. The hemostatic valve includes an active tensioning mechanism coupled to the tubular member, the tensioning mechanism can be moveable between a first configuration in which the tensioning mechanism constricts on the central lumen and the central lumen is sealed and a second configuration in which the central lumen is open.

[0013] In some embodiments, the hemostatic valve further includes a reinforcement structure extending along at least a portion of the tubular member. In some embodiments, the reinforcement structure is located between the tensioning mechanism and the tubular member. In some embodiments, the reinforcement structure can be a braided mesh. In some embodiments, the reinforcement structure is coupled to the tubular member at a position proximate to the first end of the tubular member and at a position proximate to the second end of the tubular member. In some embodiments, the reinforcement structure is adhered to the tubular member at the first end of the

tubular member and at the second end of the tubular member. In some embodiments, the reinforcement structure is uncoupled to the tubular member between the first end of the tubular member and the second end of the tubular member.

[0014] In some embodiments, the tensioning mechanism can include at least one filament extending at least partially around the tubular member. In some embodiments, the tensioning mechanism can include an actuator coupled to the at least one filament. In some embodiments, moving the tensioning mechanism from the first configuration to the second configuration can include moving the actuator and the thereto coupled at least one filament from a first position to a second position. In some embodiments, the filament constricts and seals the central lumen of the tubular member when the filament is in the first position.

[0015] In some embodiments, the actuator can be a manual actuator. In some embodiments, the actuator can include a pair of opposing and depressable buttons, which buttons can be biased towards an undepressed position. In some embodiments, the central lumen is sealed when the buttons are in the undepressed position. In some embodiments, the filament can be a monofilament. In some embodiments, the filament can be at least one of: a polymer filament; or a metallic filament. In some embodiments, the catheter can include a thrombus extraction device.

[0016] One aspect of the present disclosure relates to a method of sealing a delivery device accessing a blood vessel of a patient. The method includes inserting the delivery device including a catheter and a hemostatic valve into the blood vessel of the patient. In some embodiments, the catheter can have a first end, a second end, and a catheter lumen extending therethrough. In some embodiments, the hemostatic valve can be coupled to the first end and can have a tubular member defining a central lumen fluidly coupled with the catheter lumen and a tensioning mechanism coupled with the tubular member. In some embodiments, the tensioning mechanism collapses and seals the central lumen in a first configuration and thereby seals access to the blood vessel. The method can include moving the tensioning mechanism of the hemostatic valve to a second configuration. In some embodiments, the central lumen is open and access to the blood vessel is unsealed when the tensioning mechanism is in the second configuration. The method can include advancing a shaft of a tool through the delivery device until a first end of the tool reaches a desired position within the blood vessel of the patient and a portion of the shaft is positioned within the central lumen of the tubular member. The method can include returning the tensioning mechanism

of the hemostatic valve to the first configuration such that the tubular member collapses on the shaft of the tool and seals around the shaft of the tool.

[0017] In some embodiments, the method includes retracting the shaft of the tool from the delivery device. In some embodiments, the tensioning mechanism is maintained in the first configuration during and after the retracting of the shaft of the tool from the delivery device. In some embodiments, the tensioning mechanism is moved to the second configuration during the retracting of the shaft of the tool from the delivery device, and the tensioning mechanism is returned to the first configuration after the shaft of the tool is retracted from the delivery device.

[0018] In some embodiments, the tensioning mechanism can include at least one filament extending at least partially around the tubular member. In some embodiments, the at least one filament collapses the tubular member when the tensioning mechanism is in the first configuration. In some embodiments, the at least one filament circumferentially constricts the tubular member to collapse the tubular member when the tensioning mechanism is in the first configuration. In some embodiments, the hemostatic valve can include a reinforcement structure located between the at least one filament and the tubular member.

[0019] In some embodiments, the at least one filament forms a loop around the elongate member, and moving the tensioning mechanism from the second configuration to the first configuration reduces a size of the loop to thereby constrict the tubular member within the loop. In some embodiments, the filament forms at least one bight around a portion of the elongate member. In some embodiments, the filament can include a first filament and a second filament. In some embodiments, the at least one bight can include a first bight oriented in a first direction and formed by the first filament and a second bight oriented in a second direction and formed by the second filament. In some embodiments, the first and second bights overlap to encircle a portion of the tubular member within a constricting area.

[0020] In some embodiments, moving the tensioning mechanism from the second configuration to the first configuration can include moving the first bight in the first direction and the second bight in the direction to reduce the size of the constricting area and collapse and seal the central lumen of the tubular member. In some embodiments, the tensioning mechanism can include an actuator. In some embodiments, moving the tensioning mechanism to the second configuration can include manipulating the actuator. In some embodiments, the method includes applying a

vacuum to the delivery device and/or delivery system to aspirate material through the catheter. In some embodiments, the central lumen remains sealed during the aspiration. In some embodiments, the tool can include a thrombus extraction device.

BRIEF DESCRIPTION OF THE DRAWINGS

[0021] Figure 1 is a perspective view of one embodiment of a delivery device.

[0022] Figure 2 is a side-section view of one embodiment of a hemostasis valve in a first configuration.

[0023] Figure 3 is a side-section view of one embodiment of the valve in a second configuration.

[0024] Figure 4 is a side-section view of one embodiment of the valve in the first configuration and with a tool extending through the valve.

[0025] Figure 5 is a side-section view of one embodiment of a single-button hemostasis valve in a first configuration.

[0026] Figure 6 is a perspective view of a filament of a valve forming a loop.

[0027] Figure 7 is a perspective view of two filaments of a valve, each of the filaments forming a loop.

[0028] Figure 8 is a perspective view of two overlapping and interlocked bights in an open configuration.

[0029] Figure 9 is a perspective view of two overlapping and interlocked bights in a closed configuration.

[0030] Figure 10 is a flowchart illustrating one embodiment of a method for sealing a valve and/or catheter.

[0031] Figure 11 is a side view of one embodiment of a thrombectomy system including the delivery device.

[0032] Figure 12 is a side-section view of another embodiment of a hemostasis valve having two-piece caps.

DETAILED DESCRIPTION

[0033] The present disclosure relates to a valve that can be used a hemostasis valve. This valve, also referred to herein as a garrote valve can seal with or without a tool extending through the valve. The garrote valve provides convenient, single-handed operation for a wide range of medical devices including catheters, wires, embolectomy systems, or the like. This single-handed operation of the garrote valve allows the user to easily and quickly swap different tools being used through the valve without compromising hemostasis and therefore simplifying the procedure. Combined with single-handed operation, the garrote valve provides robust sealing either with or without a tool extending through the valve. This robust sealing minimizes leakage in applications with a pressure differential on different sides of the valve. This pressure differential can arise, for example, during the application of vacuum aspiration in a procedure. Even under such conditions, as well as under other conditions, the garrote valve maintains seal integrity and prevents leakage in one or both directions.

[0034] The garrote valve includes a tubular member. The tubular member is a flexible member that defines a central lumen, which can, in some embodiments, define a single lumen, and in some embodiments, defines a plurality of lumens. In some embodiments, each of the plurality of lumens can comprise the same size and shape, and in some embodiments, some or all of the plurality of lumens can comprise different sizes and shapes. In some embodiments, for example, the plurality of lumens can comprise a lumen sized and/or shaped to receive a guide wire and a lumen sized and/or shaped to receive a tool. The tubular member extends at least partially through a constricting mechanism. The constricting mechanism can be moved from a first configuration to a second configuration, and the constricting mechanism can collapse and/or seal the central lumen of the tubular member when the constricting mechanism is in the first configuration. The constricting mechanism creates the above-discussed robust seal of the tubular member and thus of the valve.

[0035] With reference now to **Figure 1**, a perspective view of one embodiment of a delivery system 100, also referred to herein as a delivery device 100, is shown. The delivery system 100 can include a catheter 102 and a garrote valve 104, also referred to herein as valve 104. The catheter 102 can comprise a shaft 106, also referred to herein as an elongate sheath 106, having a proximal end 108, also referred to herein as a first end 108, that can connect to the valve 104 and a distal end

110, also referred to herein as a second end 110. The shaft 106 can define a catheter lumen 112 extending from the proximal end 108 of the shaft 106 to the distal end 110 of the shaft 106. The catheter 102 and specifically the shaft 106 can comprise a variety of shapes and sizes and can be made from a variety of materials. In some embodiments, the catheter 102 can be flexible and/or can be made from a biocompatible material. The elongate sheath 106 can have an outer diameter of at least 4 French, at least 6 French, at least 8 French, at least 10 French, at least 12 French, at least 14 French, at least 18 French, at least 20 French, at least 22 French, between 4 French and 30 French, between 8 French and 24 French, between 12 French and 20 French, and/or any other or intermediate size.

[0036] The valve 104 can include an outer shell 114. The outer shell 114 can comprise a variety of shapes and sizes and can be made from a variety of materials. In some embodiments, the outer shell 114 can be made from one or several polymers or composites. The outer shell 114 can include features that allow interaction with and/or control of the valve 104 to move the valve 104 between the first configuration and the second configuration.

[0037] The outer shell 114 can include a proximal cap 116 located at a proximal end 118 of the outer shell 114 and a distal cap 120 located at a distal end 122 of the shell 114. The proximal cap 116 can include and/or house a proximal aperture 124, also referred to herein as a proximal channel 124, a first channel 124, or a first aperture 124, that extends through the proximal cap 116, and the distal cap 120 can include and/or house a distal aperture 126, also referred to herein as a distal channel 126, a second channel 126, or second aperture 126, that extends through the distal cap 120. As seen in Figure 1, the distal cap 120 connects to the shaft 106 of the catheter 102 at the distal end 122 of the valve 104.

[0038] The proximal cap 116 and the distal cap 120 are connected via a housing 128. The housing 128 can be a one-piece housing 128 or a multi-piece housing 128. In the embodiment depicted in Figure 1, the housing comprises a two-piece housing 128. The housing 128 can be configured to receive and couple with each of the proximal cap 116 and the distal cap 120, and as seen in Figure 1, the housing 128 is coupled with each of the proximal cap 116 and the distal cap 120 to secure the relative position of the proximal cap 116 and the distal cap 120 with respect to each other.

[0039] The housing 128 can define an interior channel 130 through which an elongate member 132, also referred to herein as a tubular member 132, a septum 132, or a tubular septum 132, can extend and connect the proximal cap 116 and the distal cap 120. The elongate member 132 can comprise a variety of shapes and sizes and can be made from a variety of materials. In some embodiments, the elongate member 132 can comprise a compliant tubular structure that can be, for example, a thin-walled compliant tubular structure. The thin-walled structure of the elongate member 132 can facilitate the collapse, and specifically the uniform collapse of the elongate member 132 and the sealing of the elongate member 132. In some embodiments, the elongate member 132 is an elastic, resilient material that may comprise a polymer including either a natural or synthetic polymer. In some embodiments, the elongate member can comprise an elastic, resilient material that may comprise silicone, urethane, ethylene-vinyl acetate, natural or synthetic rubber or other elastomers known in the art. In some embodiments, the elongate member 132 can comprise a silicone tube.

[0040] The elongate member 132 can comprise a proximal end 134, also referred to herein as a first end 134, that can couple to the proximal cap 116, and a distal end 136, also referred to herein as a second end 136, that can couple to the distal cap 120. The elongate member 132 can define a central lumen 138 that can extend from the first end 134 to the second end 136 of the elongate member 132. The elongate member 132 can be coupled to the proximal cap 116 such that the central lumen 138 is fluidly coupled with the proximal aperture 124 of the proximal cap 116, and the elongate member 132 can be coupled to the distal cap 120 such that the central lumen 138, as seen in **Figure 2** and in **Figure 3**, is fluidly coupled with the distal aperture 126 of the distal cap 120.

[0041] The central lumen 138 of the elongate member 132 can be defined by a wall of the elongate member 132 that can have a thickness that is uniform along the length of the elongate member 132 between the first end 134 and the second end 136, or that is non-uniform along the length of the elongate member 132 between the first end 134 and the second end 136. In some embodiments, the wall can have a thickness that is approximately between 0.005 inches and 0.05 inches, and/or approximately between 0.010 inches and 0.030 inches. As used anywhere herein, "approximately" refers to a range of +/- 10% of the value and/or range of values for which "approximately" is used.

[0042] In some embodiments, the elongate member 132 can be cylindrically shaped, and specifically can be circular-cylindrically shaped. In some embodiments, the elongate member 132 can be dog-bone shaped to facilitate, for example, connection to each of the proximal cap 116 and the distal cap 120. In some embodiments, the elongate member 132 can include one or several outward-extending protuberances that engage with all or portions of a constricting mechanism 141, also referred to herein as a tensioning mechanism 141, of the valve 104 to secure a position of all or portions of the constricting mechanism 141 with respect to the elongate member 132. In some embodiments, the constricting mechanism 141 can be self-adjusting to seal around tools of different sizes extending through the valve 104.

[0043] The constricting mechanism 141 can, in some embodiments, collapse and seal the elongate member 132 via compression and/or constriction, and specifically via constriction with at least one filament 150. The constricting mechanism 141 can comprise: an actuator 142 which can be a manual actuator such as one or several buttons 144; and the at least one filament 150 that can extend at least partially around the elongate member 132. In some embodiments, the use of the constricting mechanism 141 can facilitate sealing of the valve around tools or instruments of a wide range of sizes and/or diameters, and particularly around tools or instruments that fit through the elongate member 132.

[0044] The housing 128 can further include one or several retention features 140. The one or several retention features 140 of the housing can engage with and retain all or portions of the constricting mechanism 141 of the valve 104. In some embodiments, the one or several retention features 140 of the housing 128 can retain the actuator 142 and/or can couple the actuator 142 to the housing 128. The actuator 142 can comprise any desired type of actuator including, for example, a manual actuator and/or an automated actuator such as, for example, an electromechanical actuator including a solenoid-based actuator. In some embodiments, the actuator can comprise one or several buttons 144, and specifically, as depicted in Figure 1, the actuator 142 can comprise a first button 144-A and a second button 144-B. Alternatively, and as depicted in **Figure 5**, the actuator 142 can comprise a single button 144. In such an embodiment, the filament 150 can be coupled to the single button 144 and to a portion of the housing 128 such as, for example, to grip portion 500 of the housing 128 such that the movement of the single button 144 causes the sealing and/or opening of the elongate member 132 and of the valve 104.

[0045] The actuator 142 can be biased towards a configuration such as, for example, biased towards the first configuration or biased towards the second configuration. As depicted in Figure 2, which shows the constricting mechanism 141 in the first configuration, the actuator 142 can be biased towards the first configuration wherein the elongate member 132 is collapsed and/or sealed by a bias feature 146. In this first configuration, the buttons 144 can be in a first position, also referred to herein as an undepressed position. This bias feature 146 can, as shown in Figure 2, include a first spring 148-A configured to bias the first button 144-A towards the first position corresponding to the first configuration of the constricting mechanism 141, and a second spring 148-B configured to bias the second button 144-B towards a first position corresponding to the first configuration of the constricting mechanism 141. One or both of the first spring 148-A and the second spring 148-B can comprise a tension spring, compression spring, a torsion spring, a coil spring, or any other desired type of spring.

[0046] In some embodiments, one or both of the first spring 148-A and the second spring 148-B can generate sufficient force so as to allow actuation of the actuator 142 with a single hand and so as to collapse and seal the elongate member 132 when the constricting mechanism 141 is in the first configuration. In some embodiments, one or both of the first spring 148-A and the second spring 148-B can generate a force of: at least 0.1 pounds, at least 0.2 pounds, at least 0.3 pounds, at least 0.4 pounds, at least 0.5 pounds, at least 0.6 pounds, at least 0.7 pounds, at least 0.8 pounds, at least 0.9 pounds, at least 1 pound, at least 1.5 pounds, at least 2 pounds, at least 3 pounds, at least 5 pounds, and/or at least 10 pounds and in some embodiments one or both of the first spring 148-A and the second spring 148-B can generate a force approximately between: 0.1 and 10 pounds, 0.1 and 5 pounds, 0.1 and 1.5 pounds, 0.2 and 1 pounds, and/or 0.4 and 0.8 pounds.

[0047] The constricting mechanism 141 can include at least one filament 150 that extends at least partially around the elongate member 132. In some embodiments, the at least one filament 150 can circumferentially constrict the elongate member 132 to collapse and seal the elongate member 132 when the constricting mechanism 141 is in the first configuration. The filament can be made from a variety of materials including, for example, a polymer, a synthetic, and/or a metal. In some embodiments, the filament 150 can be nylon, stainless steel, nitinol, silicone, or the like. In some embodiments, the filament can comprise a single strand such as, for example, a monofilament, and in some embodiments, the filament can comprise a plurality of strands that can be, for example,

twisted, woven, grouped, and/or fused to form the filament. In some embodiments, the filament 150 can comprise one or several threads, lines, cords, rope, ribbon, flat wire, sheet, or tape.

[0048] The filament 150 can be coupled to the actuator 142 such that the filament 150 selectively constricts, collapses, and/or seals the elongate member 132, and specifically the central lumen 138 of the elongate member 132 based on the movement and/or position of the actuator 142. In some embodiments, the filament 150 can be connected to one or both of the buttons 144-A, 144-B such that the filament 150 collapses, constricts, and/or seals the elongate member 132 and specifically the central lumen 138 of the elongate member 132 when the buttons 144-A, 144-B are in the first position, and the filament 150 can be connected to one or both of the buttons 144-A, 144-B such that the elongate member 132 and specifically the central lumen 138 of the elongate member 132 is open and uncollapsed when the buttons 144-A, 144-B are in the second position. In some embodiments in which the actuator 142 comprises a single button 144, as depicted in Figure 5, the filament 150 can be connected to the button 144 and to the housing 128 such that the filament 150 is tightened when the button 144 moves to the first position.

[0049] In some embodiments, the at least one filament 150 can extend along an axis 152 that can be perpendicular to a central axis 154 of the elongate member 132 and/or of the apertures 124, 126. In some embodiments, the axis 152 of the at least one filament 150 can intersect and be perpendicular to the central axis 154 of the elongate member 132 and/or of the apertures 124, 126. In some embodiments, the actuator 142, and specifically the buttons 144-A, 144-B can move along this axis 152 when moved from the first position to the second position.

[0050] In Figure 3, an embodiment of the valve 104 with the constricting mechanism 141 in the second configuration is shown. As specifically shown, both of the first and second buttons 144-A, 144-B are in the second position, depressed into the retention features 140 of the housing 128. In this second position, the filament 150 is loosened, thereby allowing the expansion of the elongate member 132 and the unsealing of the central lumen 138 of the elongate member 132.

[0051] As further seen in Figure 3, the proximal cap 116 has a proximal end 300 and a distal end 302. The proximal cap 116 can include a funnel portion 301 of the proximal aperture 124, which funnel portion 301 can facilitate insertion of a tool into the proximal aperture 124. The distal end 302 of the proximal cap 116 can partially extend into the interior channel 130 of the housing 128. The proximal cap 116 can include a mating feature 304 that can mate with the proximal end

134 of the elongate member 132. In some embodiments, the proximal end 134 of the elongate member 132 can fit over the mating feature 304 of the proximal cap 116. The proximal end 134 of the elongate member 132 can be compressed between the mating feature 304 of the elongate member 132 and a portion of the interior channel 130 of the housing 128 into which the mating feature 304 is inserted to thereby secure the proximal end 134 of the elongate member 132 on the mating feature 304. In some embodiments, the proximal end 134 of the elongate member 132 can be further secured on the mating feature 304 by a proximal O-ring 306 that can be compressed between the housing 128 and the mating feature 304 of the proximal cap 116 to sealingly couple the elongate member 132 to the proximal cap 116.

[0052] The distal cap 120 has a proximal end 308 and a distal end 310. The distal cap can include a mating feature 312 located on the proximal end 308 of the distal cap 120, which mating feature 312 can mate with the distal end 136 of the elongate member 132. In some embodiments, the distal end 136 of the elongate member 132 can fit over the mating feature 312 of the distal cap 123. The distal end 136 of the elongate member 132 can be compressed between the mating feature 312 of the elongate member 132 and a portion of the interior channel 130 of the housing 128 into which the mating feature 312 is inserted to thereby secure the distal end 136 of the elongate member 132 on the mating feature 312. In some embodiments, the distal end 136 of the elongate member 132 can be further secured on the mating feature 312 by a distal O-ring 314 that can be compressed between the housing 128 and the mating feature 312 of the proximal cap 116 to sealingly couple the elongate member 132 to the distal cap 120.

[0053] The distal cap 120 can, in some embodiments, further include a side port barb 314 that can extend laterally away from the distal cap 120 and specifically away from the distal aperture 126 of the distal cap 120. The side port barb 314 can define a side port channel 316 that can extend through the side port barb 314 and fluidly connect to the distal aperture 126. In some embodiments, the side port barb 314 can include a securement feature 318 such as a barb that can secure coupling of a hose or tube to the side port barb 314.

[0054] In some embodiments, the side barb 314 can be used to apply a vacuum to the portions of the delivery device 100, and particularly to portions of the delivery device 100 that are distal of the axis 152 along which the elongate member 132 seals. This vacuum can be applied to aspirate a material through the delivery device 100, and specifically through the catheter 102 of the delivery

device. This aspirated material can be a biological material including, for example, bodily fluids, multi-phase bodily materials that can include, for example, a fluidic portion and at least one solid portion, or the like.

[0055] In some embodiments, due to the narrowing shape of the elongate member 132 when the constricting mechanism 141 is in the first configuration, a vacuum applied to the portions of the delivery device 100 distal to the axis 152 draws the elongate member 132 towards the first configuration and can, in some embodiments, increase the strength, robustness, and/or strength of the seal of the valve 104. This attribute of the valve 104 can provide benefits over other valve designs in which a vacuum can compromise the seal of the valve, and thus the ability to draw a vacuum and aspirate can be limited.

[0056] In some embodiments, the valve 104 can further include a reinforcement structure 320 that can extend along all or portions of the elongate member 132. The reinforcement structure 320 can facilitate the uniform collapse of the elongate member 132, can prevent the at least one filament 150 from cutting through and/or tearing the elongate member 132, and can assist in guiding one or several tools through the elongate member 132. The reinforcement structure 320 can be tubular, can extend along and around the elongate member 132, and can be positioned so as to be between the elongate member 132 and the at least one filament 150.

[0057] The reinforcement structure 320 can include a proximal end 322 and a distal end 324. In some embodiments, the reinforcement structure 320 extends along and around the elongate member 132, and is positioned such that the proximal end 322 of the reinforcement structure 320 is proximate to the first end 134 of the elongate member 132 and the distal end 324 of the reinforcement structure 320 is proximate to the second end 136 of the elongate member 132.

[0058] The reinforcement structure 320 can be coupled to the elongate member 132. In some embodiments, the reinforcement structure 320 is coupled to the elongate member 132 along the length of the reinforcement structure 320, and in some embodiments, the reinforcement structure 320 is coupled to the elongate member 132 and distinct positions along the length of the elongate member 132 and/or the reinforcement structure 320. In one embodiment, for example, the reinforcement structure 320 can be coupled to the elongate member 132 at one or both of the proximal end 322 of the reinforcement structure 320 and the distal end 324 of the reinforcement structure 320 and/or at one or both of the first end 134 and the second end 136 of the elongate

member 132. In some embodiments, the reinforcement structure 320 can be coupled to the elongate member 132 via one or several other components of the valve 104. In some embodiments, the reinforcement structure 320 can be coupled to the elongate member 132 via the compression of the reinforcement structure 320 and the elongate member 132 between the housing 128 and one or both of the proximal 116 and the distal 120.

[0059] In some embodiments, the reinforcement structure 320 can be adhered to the elongate member 132 via, for example, an adhesive such as silicone adhesive. In some embodiments, the adhesive can be circumferentially applied to the reinforcement structure 320 and/or the elongate member 132 in an adhesive ring that can, for example, a have a length approximately between: 0.010 inches and 0.5 inches; 0.02 and 0.4 inches; 0.050 inches and 0.0250 inches, or any other or intermediate range.

[0060] In one embodiment, each of the proximal end 322 and the distal end 324 of the reinforcement structure 320 can be adhered via an adhesive to the elongate member 132. In such an embodiment, the reinforcement structure 320 may be uncoupled to the elongate member 132 at positions other than the coupling at one or both of the proximal end 322 and the distal end 324 of the reinforcement structure 320, and thus the reinforcement structure 320 is uncoupled to the elongate member 132 at a position between the first end 134 and the second end 136 of the elongate member 134 and/or between the proximal end 322 and the distal end 324 of the reinforcement structure 320.

[0061] The lack of coupling of the reinforcement structure 320 to the elongate member 132 can facilitate and improve the collapse of the elongate member 132 around a tool 400, also referred to herein as instrument 400 or device 400, inserted through the valve 104 as shown in **Figure 4**. The tool 400 can be any device inserted through the valve 104 including, for example, one or several additional catheters, lines, wires, grippers, punches, cutters, or the like. As seen in Figure 4, the tool 400 is inserted through the valve 104 and specifically through the elongate member 132 of the valve. As shown, the constricting mechanism 141 is in the first configuration and the elongate member 132 and the central lumen 138 of the elongate member 132 is collapsed around the tool 400, and specifically around a shaft 402 of the tool 400 to thereby seal the valve 104 around the tool 400 and specifically around the shaft 402 of the tool 400. The constricting mechanism 141 can seal

around tools 400 that fit through the elongate member 132, regardless of the size of the tool 400. Thus, the valve can be used with a wide variety of tools.

[0062] The reinforcement structure 320 can comprise a variety of designs, shapes, sizes, and materials. In some embodiments, the reinforcement structure 320 can be sized and shaped so as to receive elongate member 132 and to be positioned between the elongate member 132 and the at least one filament 150. In some embodiments, the reinforcement structure 320 can be made from a material sufficiently strong to prevent the cutting of the at least one filament 150 through the elongate member 132.

[0063] In some embodiments, the reinforcement structure can comprise a coil or a mesh sheath. The mesh sheath can, in some embodiments, comprise a braided mesh. The braided mesh can be made from any desired number of wires in any desired configuration. In some embodiments, the braided mesh can comprise a 4 wire braided mesh, an 8 wire braided mesh, a 12 wire braided mesh, a 16 wire braided mesh, a 20 wire braided mesh, a 24 wire braided mesh, a 32 wire braided mesh, a 48 wire braided mesh, a 64 wire braided mesh, a 72 wire braided mesh, an 80 wire braided mesh, a 96 wire braided mesh, or any other or intermediate braided mesh. In some embodiments, the braided mesh can comprise: a 1x1 configuration. In some embodiments, the wire in the braided mesh can be any desired material including, for example, a metal wire such as a nitinol wire or a stainless steel wire, a polymer wire, or a natural wire. In one embodiment, the braided mesh can comprise a 48 wire mesh in a 1x1 configuration made with a nitinol wire having a diameter of 0.003 inches.

[0064] With reference now to **Figures 6** through **9**, different embodiments and/or configurations of the filament 150 are shown. The filament 150 can comprise a single filament 150 having a first end 600 and a second end 602 as shown in Figure 6. The filament 150, and specifically which first and second ends 600, 602 can be coupled to the actuator 142 to move the filament 150 between the first and second configurations or positions and/or from the first configuration or position to the second configuration or position. In some embodiments, both of the first end 600 and the second end 602 can be coupled to a single button 144, in some embodiments, each of the first end 600 and the second end 602 can be coupled to different buttons 144, and in some embodiments, one of the first end 600 and the second end 602 can be coupled to a button 144

and the other of the first end 600 and the second end 602 can be coupled to the housing 128 or other portion of the valve 104.

[0065] In some embodiments, the filament 150 can comprise multiple filaments, and specifically, as shown in Figures 7 through 9, the filament 150 can comprise a first filament 150-A and a second filament 150-B. In embodiments in which the filament 150 comprises multiple filaments, each of the multiple filaments can have a first end 700 and a second end 702. The first and second filaments 150-A, 150-B can be coupled to the actuator 142. In such embodiments, the first and second ends 700, 702 can be coupled to the actuator 142 to move the filaments 150-A, 150-B between the first and second configurations and/or from the first configuration to the second configuration. In some embodiments, both of the first end 700 and the second end 702 of one or more of the multiple filaments 150 can be coupled to a single button 144, in some embodiments, each of the first end 700 and the second end 702 of one or more of the multiple filaments 150 can be coupled to different buttons 144, and in some embodiments, one of the first end 700 and the second end 702 of one or more of the multiple filaments 150 can be coupled to one button 144 and the other of the first end 700 and the second end 702 of those one or more filaments 150 can be coupled to the housing 128 or other portion of the valve 104.

[0066] The filament 150 can be arranged in a variety of configurations. In some embodiments, the filament 150 can be configured to form a single loop 604 that can extend around the elongate member 132 and/or through which the elongate member 132 can be received as shown in Figure 6, and in some embodiments, the filament 150 can be configured to form multiple loops, and specifically a first loop 704 and a second loop 706 as shown in Figure 7. The first and second loops 704, 706 can each receive the elongate member 132. In some embodiments, a diameter or size of the loop 604, or of the loops 704, 706 can decrease when the constricting mechanism 141 is moved from the second configuration to the first configuration.

[0067] In some embodiments, the filament 150 can be configured to form a bight 800, which bight 800 can be a single bight or multiple bights. As used herein, a "bight" refers to a U-shaped section between the two ends of the filament 150. As depicted in Figures 8 and 9, the bight 800 can comprise multiple bights, and specifically a first bight 800-A and a second bight 800-B. In some embodiments, the first bight 800-A can extend through the second bight 800-B such that the first and second bights 800-A, 800-B interlock, whereas in other embodiments, the first and second

bights 800-A, 800-B can be non-interlocking. Similarly, in embodiments containing the filament 150 having multiple loops, one or several of the multiple loops can be interlocking.

[0068] In some embodiments, the bight 800, and specifically one or both of the first bight 800-A and the second bight 800-B can be formed around a portion of the elongate member 132 and/or can extend around a portion of the elongate member 132. Each bight 800 can define a partially enclosed receiving area 808 wherein the elongate member 132 can be received. Thus, the first bight 800-A can define a first receiving area 808-A and the second bight 800-B can define a second receiving area 808-B.

[0069] As seen in Figures 8 and 9, multiple bights, and specifically the first and the second bights 800-A, 800-B can be positioned and oriented such that the first bight 800-A has a first orientation or first direction as indicated by arrow 810, and the second bight has a second orientation or second direction as indicated by the arrow 812. In some embodiments, the first orientation is different from the second orientation such that the first and second receiving areas 808-A, 808-B overlap and define an encircled area 814, also referred to herein as a constricting area 814. The elongate member 132 can be received within the encircled area 814. In embodiments in which bights 800-A, 800-B overlap to define the encircled area 814, the movement of the constricting mechanism 141 to the first configuration can result in and/or include the first bight 800-A moving in the direction indicated by the arrow 810 and/or the second bight 800-B moving in the direction indicated by the arrow 812, which movement of the bights 800-A, 800-B decreases the size of the encircled area 814 and constricts, collapses, and/or seals the elongate member 132 extending through the encircled area 814.

[0070] The filament(s) 150 forming the bights 800 can each apply an arcuate line or narrow longitudinal zone of pressure to the elongate member 132. If the filament(s) are circular in cross-section, the zone of pressure can be very small, and can, in some embodiments, be less than the diameter or thickness of the filament. In some embodiments, the filaments have a diameter or width less than about 2.5mm, less than about 2mm, less than about 1.5mm, less than about 1.25mm, less than about 1mm, less than about 0.75mm, less than about 0.5mm, and/or less than about 0.25mm. In some embodiments, the filaments can have a diameter or width of between about 0.01mm and 2.5mm, between about 0.05mm and 2mm, between about 0.1mm and 1mm, and/or between about 0.125mm and 0.70mm. In some embodiments, the arcuate line or zone of pressure may form two

opposing arcs and in other embodiments, the arcuate line of pressure may be a singular substantially circular line or zone that encircles the elongate member at least once. The longitudinal length of the of the line or zone of pressure may be very short compared to other valves known in the art. In some embodiments, the longitudinal length of the zone of pressure applied to the elongate member 132 by the filament(s) 150 may be less than about 2.0mm and in some embodiments less than about 0.5mm. In some embodiments, the filament(s) 150 can have any desired cross-sectional shape including, for example, a circular cross-section, a rectangular cross-section, an oval cross-section, a square cross-section, a polygonal cross-section, a triangular cross-section, or any other desired shape of cross-section.

[0071] With reference now to **Figure 10**, a flowchart illustrating one embodiment of a process 1000 for sealing a valve 104 and/or catheter 102 accessing a body of a patient is shown. The process 1000 can be performed using the valve 104 and/or the delivery system 100. The process 1000 begins at block 1002, wherein the delivery device 100, and specifically the catheter 102 of the delivery device 100 is inserted into the body of the patient. In some embodiments, this can include inserting the catheter 102 into a portion of the circulator system of the patient such as, for example, a blood vessel including an artery or a venous vessel. In some embodiments, the delivery device 100 can be inserted into the body of the patient directly through an aperture or incision in the patient, and in some embodiments, the delivery device 100 can be inserted into the body of the patient via another catheter or device. In some embodiments, the constricting mechanism 141 can be in the first configuration while the delivery device 100 and/or the catheter 102 is inserted into the patient's body.

[0072] After the delivery device 100 is inserted into the body of the patient, the process 1000 proceeds to block 1004, wherein the constricting mechanism 141 is moved from the first configuration to the second configuration. As described above, the central lumen 138 of the elongate member 132 is unsealed when the constricting mechanism 141 is in the second configuration. In some embodiments, the moving of the constricting mechanism 141 from the first configuration to the second configuration can include the manipulation of the actuator 142 and/or the control of the actuator 142, and specifically the depressing of the one or several buttons 144 to move the filament 150 from the first position to the second position to allow the expansion and opening of the central lumen 138 of the elongate member 132.

[0073] After the constricting mechanism 141 is moved from the first configuration to the second configuration, the process 1000 proceeds to block 1006, wherein the tool 400, and specifically the shaft 402 of the tool 400 is advanced through the delivery device 100 and specifically through the valve 104 until a first end of the tool reaches a desired position within the body of the patient. In some embodiments, a portion of the shaft 402 can be positioned within the central lumen 138 of the elongate member 132 after the advancing of the tool 400 through the delivery device 100. In some embodiments, after the tool 400 is advanced through the delivery device 100, the desired procedure can be performed with the tool.

[0074] After the tool 400 is advanced through the delivery device 100, or while the tool 400 is being advanced through the delivery device 100, the process 1000 proceeds to block 1008, wherein the constricting mechanism 141 is returned to the first configuration. In some embodiments, the returning of the constricting mechanism 141 to the first configuration can include the release of the one or several buttons 144 and/or the control of the actuator 142 to reconfigure the constricting mechanism 141 to the first configuration. In some embodiments, the return of the constricting mechanism 141 to the first configuration can result in the collapse and/or sealing of the elongate member 132 and specifically the central lumen 138 of the elongate member 132 around the tool 400 and specifically around the shaft 402 of the tool 400. The return of the constricting mechanism 141 to the first configuration, or the movement of the constricting mechanism 141 to the first configuration can include the decreasing of the size and/or diameter of one or several loops formed by the filament 150 and/or the movement of one or several bights 800 such as, for example, the movement of the first bight 800-A in the first direction indicated by arrow 810 and the movement of the second bight 800-B in the second direction indicated by arrow 812 to reduce the size of the constricting area 814. In some embodiments, after the constricting mechanism is returned to the first configuration, the desired procedure can be performed with the tool.

[0075] After the constricting mechanism is returned to the first configuration, the process 1000 proceeds to block 1010, wherein the tool 400, and specifically the shaft 402 of the tool 400 is retracted from the delivery device 100, and more specifically from the valve 104. In some embodiments, the valve 104 can remain sealed during the retracing of the tool 400 and/or the shaft 402 of the tool. In some embodiments, the valve 104 remains sealed during the retracting of the tool 400 and/or the retracting of the shaft 402 of the tool 400 as the constricting mechanism 141 can

remain in the first configuration during the retracing of the tool 400 and/or the shaft 402 of the tool 400.

[0076] In some embodiments, the constricting mechanism 141 can be moved to the second configuration to allow the retraction of the tool 400 and/or the shaft 402 of the tool 400 from the valve 104, and the constricting mechanism 141 can be returned to the first configuration when the tool 400 and/or the shaft 402 of the tool 400 is removed from the valve 104. In some embodiments, the retraction of the tool 400 and/or shaft 402 of the tool 400 from the valve 104 can be performed with the constricting mechanism 141 left in the first configuration. In some embodiments, the constricting mechanism 141 can be moved to the second configuration, and then returned to the first configuration via the manipulation and/or control of the actuator 142, which manipulation and/or control of the actuator 142 can include the depressing of the one or several buttons 144 to move the constricting mechanism 141 to the second configuration, and the release of the one or several buttons 144 to return the constricting mechanism 141 to the first configuration. In some embodiments, if the procedure is complete, the delivery device 100 can then be removed from the body of the patient, and any incision created for the procedure can be closed.

[0077] With reference now to Figure 11, a side view of one embodiment of a thrombectomy system 1100 including the delivery device 100 and a thrombus extraction device 1102 is shown. In some embodiments, the thrombectomy system 1100 can be used to access a blood vessel 1104 to treat and/or extract a thrombus 1106 from the blood vessel 1104. The thrombus extraction device 1102 can include a self-expanding coring element 206 and expandable cylindrical portion 208. In some embodiments, and as shown in Figure 11, the thrombus extraction device 1102 can be the tool 400 that can extend through the valve 104, and in some embodiments, the valve 104 can be a part of the thrombus extraction device 1102. Further details of thrombectomy systems, thrombus extraction devices, and methods of using the same are disclosed in: U.S. Application No. 15/268,296, filed September 16, 2016, and entitled "INTRAVASCULAR TREATMENT OF VASCULAR OCCLUSION AND ASSOCIATED DEVICES, SYSTEMS, AND METHODS"; U.S. Application No. 15/498,320, filed April 26, 2017, and entitled "DEVICES AND METHODS FOR TREATING VASCULAR OCCLUSION"; and U.S. Application No. 15/466,740, filed on March 22, 2017, and entitled "DEVICE AND METHOD FOR TREATING VASCULAR OCCLUSION", the entirety of each of which is hereby incorporated by reference herein.

[0078] With reference now to Figure 12, a side-section view of another embodiment of the hemostasis valve 104 having two piece caps 116, 120 is shown. The valve 104 can include a housing 128 defining an interior channel 130 through which the tubular member 132 can extend. The valve 104 can include the proximal cap 116 and the distal cap 120. In some embodiments, the proximal cap 116 can comprise a two piece cap and can include a proximal exterior member 1200 and a proximal channel member 1202. In some embodiments, the distal cap 120 can comprise a two-piece cap and can include a distal exterior member 1204 and a distal channel member 1206. In some embodiments, this coupling between the proximal exterior member 1200 and the proximal channel member 1202 and/or the coupling between the distal exterior member 1204 and the distal channel member 1206 can be a sealed coupling so as to prevent the leakage of material including fluid or gas between the respective ones of the proximal exterior member 1200 and the proximal channel member 1202 and/or the distal exterior member 1204 and the distal channel member 1206. In some embodiments, this sealing coupling can be achieved and/or maintained via a seal such as an O-ring 1208 that can be positioned between the proximal exterior member 1200 and the proximal channel member 1202 and/or between the distal exterior member 1204 and the distal channel member 1206.

[0079] In some embodiments, the proximal exterior member 1200 can be coupled, and in some embodiments, rotatingly coupled to the proximal channel member 1202 in a manner to allow the rotation of the proximal exterior member 1200 without rotating the proximal channel member 1202. Similarly, in some embodiments, the distal exterior member 1204 can be rotatingly coupled to the distal channel member 1206 in a manner to allow the rotation of the distal exterior member 1204 without the rotating of the distal channel member 1206. In some such embodiments, the channel members 1202, 1206 can be non-rotatable with respect to the housing 128 and/or the tubular member 132, and one or both of the exterior members 1200, 1204 can be rotatable with respect to the housing 128 and/or the tubular member 132. In such an embodiment, the maintaining of the rotational position of the channel members 1202, 1206 with respect to the housing 128 and/or the tubular member 132 can prevent the twisting of the tubular member 132 which can result in the sealing of the tubular member 132 regardless of the configuration of the constructing mechanism 141.

[0080] The exterior members 1200, 1204 can comprise a variety of shapes and sizes and can include a variety of features. In some embodiments, one or both of the exterior members 1200, 1204 can be coupled to, for example, a shaft similar to the shaft 106 shown in figure 1. In some embodiments, for example, the distal exterior member 1204 can be coupled to a shaft 106, including, for example, can be non-detachably coupled to the shaft 106. In some embodiments, one or both of the exterior members can include one or several features configured to facilitate coupling with the valve 104. These one or several features can include, for example, one or several male or female: connectors; couplers; attachment mechanisms; or the like. In some embodiments, these one or several features can facilitate use of the valve with other existing components, instruments, tools, or the like. In some embodiments, for example, one or both of the exterior members 1200, 1204 can comprise either a male or female luer fitting, and specifically as shown in Figure 12, the distal exterior member 1204 can comprise a male luer fitting 1210.

[0081] Several aspects of the present technology are set forth in the following examples.

1. A hemostatic valve for sealing a medical device, the hemostatic valve comprising:

an elongate member having a first end, a second end, and a central lumen extending therebetween, wherein the elongate member is pliable;

a reinforcement structure extending along at least a portion of the elongate member, wherein the reinforcement structure is coupled to the elongate member; and

an active tensioning mechanism coupled to the elongate member, wherein the tensioning mechanism is moveable between a first configuration wherein the central lumen is constricted and sealed and a second configuration wherein the central lumen is open.

2. The hemostatic valve of example 1, wherein the elongate member comprises a compliant polymer tube.

3. The hemostatic valve of example 1 or 2, wherein the tensioning mechanism comprises at least one filament extending at least partially around the elongate member.

4. The hemostatic valve of example 3, wherein the reinforcement structure is positioned between the at least one filament and the elongate member.

5. The hemostatic valve of example 4, wherein the reinforcement structure comprises a braided mesh.

6. The hemostatic valve of example 4 or 5, wherein the reinforcement structure is coupled to the elongate member at a position proximate to the first end of the elongate member and at a position proximate to the second end of the elongate member.

7. The hemostatic valve of example 6, wherein the reinforcement structure is not coupled to the elongate member at a position between the first end of the elongate member and the second end of the elongate member.

8. The hemostatic valve of any one of examples 3–7, wherein the tensioning mechanism comprises an actuator coupled to the at least one filament, wherein the actuator is moveable to control movement of the at least one filament from a first position wherein the central lumen is constricted and sealed to a second position wherein the central lumen is open, wherein the at least one filament is in the first position when the tensioning mechanism is in the first configuration.

9. The hemostatic valve of example 8, wherein the actuator is biased towards the first position.

10. The hemostatic valve of example 8 or 9, wherein the actuator is biased toward the second position.

11. The hemostatic valve of any one of examples 8–10, wherein the actuator comprises a manual actuator.

12. The hemostatic valve of any one of examples 8–11, wherein the at least one filament forms a loop around the elongate member.

13. The hemostatic valve of any one of examples 8–12, wherein the at least one filament forms a bight around a portion of the elongate member.

14. The hemostatic valve of any one of examples 8–13, wherein the at least one filament comprises a first filament and a second filament, wherein each of the first filament and the second filament are coupled to the actuator, and wherein the first filament and the second filament are moveable from the first position to the second position.

15. The hemostatic valve of example 14, wherein each of the first filament and the second filament form a loop around the elongate member.

16. The hemostatic valve of example 14 or 15, wherein the first filament forms a first bight around a first portion of the elongate member, and wherein the second filament forms a second bight around a second portion of the elongate member.

17. The hemostatic valve of example 16, wherein the first bight extends through the second bight.

18. The hemostatic valve of any one of examples 1–17, further comprising a shell defining a first aperture and a second aperture, wherein the elongate member extends from the first aperture to the second aperture and fluidly couples the first aperture and the second aperture.

19. The hemostatic valve of any one of examples 1–18, wherein the tensioning mechanism is self-adjustable to seal around tools of different sizes extending through the hemostatic valve.

20. The hemostatic valve of any one of examples 1–19, wherein the central lumen comprises a single lumen.

21. The hemostatic valve of any one of examples 1–20, wherein the central lumen comprises a plurality of lumens.

22. A delivery system for intravascular access of a blood vessel within a patient's body, the delivery system comprising:

a catheter having a first end, a second end, and a catheter lumen extending therebetween;

a hemostatic valve coupled to the first end of the catheter, the hemostatic valve comprising:

a tubular member having a first end, a second end, and a central lumen extending therebetween, wherein the central lumen of the tubular member is fluidly coupled with the catheter lumen; and

an active tensioning mechanism coupled to the tubular member, the tensioning mechanism moveable between a first configuration wherein the tensioning mechanism constricts on the central lumen and the central lumen is sealed and a second configuration wherein the central lumen is open.

23. The delivery system of example 22, wherein the hemostatic valve further comprises a reinforcement structure extending along at least a portion of the tubular member.

24. The delivery system of example 22 or 23, wherein the reinforcement structure is located between the tensioning mechanism and the tubular member.

25. The delivery system of example 24, wherein the reinforcement structure comprises a braided mesh.

26. The delivery system of example 24 or 25, wherein the reinforcement structure is coupled to the tubular member at a position proximate to the first end of the tubular member and at a position proximate to the second end of the tubular member.

27. The delivery system of example 26, wherein the reinforcement structure is adhered to the tubular member at the first end of the tubular member and at the second end of the tubular member.

28. The delivery system of example 27, wherein the reinforcement structure is uncoupled to the tubular member between the first end of the tubular member and the second end of the tubular member.

29. The delivery system of any one of examples 22–28, wherein the tensioning mechanism comprises at least one filament extending at least partially around the tubular member.

30. The delivery system of example 29, wherein the tensioning mechanism comprises an actuator coupled to the at least one filament, wherein moving the tensioning mechanism from the first configuration to the second configuration comprises moving the actuator and the thereto coupled at least one filament from a first position to a second position, wherein the filament constricts and seals the central lumen of the tubular member when the filament is in the first position.

31. The delivery system of example 30, wherein the actuator comprises a manual actuator.

32. The delivery system of example 31, wherein the actuator comprises a pair of opposing and depressable buttons, wherein the buttons are biased towards an undepressed position.

33. The delivery system of example 31 or 32, wherein the central lumen is sealed when the buttons are in the undepressed position.

34. The delivery system of any one of examples 30–33, wherein the filament comprises a monofilament.

35. The delivery system of any one of examples 30–34, wherein the filament comprises at least one of: a polymer filament; or a metallic filament.

36. The delivery system of any one of examples 22–35, wherein the catheter comprises a thrombus extraction device.

37. A method of sealing a delivery device accessing a blood vessel of a patient, the method comprising:

inserting the delivery device comprising a catheter and a hemostatic valve into the blood vessel of the patient, the catheter having a first end, a second end, and a catheter lumen extending therethrough, and the hemostatic valve coupled to the first end and having a tubular member defining a central lumen fluidly coupled with the catheter lumen and a tensioning mechanism coupled with the tubular member, wherein the tensioning mechanism collapses and seals the central lumen in a first configuration and thereby seals access to the blood vessel;

moving the tensioning mechanism of the hemostatic valve to a second configuration, wherein the central lumen is open and access to the blood vessel is unsealed when the tensioning mechanism is in the second configuration;

advancing a shaft of a tool through the delivery device until a first end of the tool reaches a desired position within the blood vessel of the patient and a portion of the shaft is positioned within the central lumen of the tubular member; and

returning the tensioning mechanism of the hemostatic valve to the first configuration such that the tubular member collapses on the shaft of the tool and seals around the shaft of the tool.

38. The method of example 37, further comprising retracting the shaft of the tool from the delivery device.

39. The method of example 38, wherein the tensioning mechanism is maintained in the first configuration during and after the retracting of the shaft of the tool from the delivery device.

40. The method of example 38 or 39, wherein the tensioning mechanism is moved to the second configuration during the retracting of the shaft of the tool from the delivery device, and wherein the tensioning mechanism is returned to the first configuration after the shaft of the tool is retracted from the delivery device.

41. The method of any one of examples 37–40, wherein the tensioning mechanism comprises at least one filament extending at least partially around the tubular member, wherein the at least one filament collapses the tubular member when the tensioning mechanism is in the first configuration.

42. The method of example 41, wherein the at least one filament circumferentially constricts the tubular member to collapse the tubular member when the tensioning mechanism is in the first configuration.

43. The method of example 41 or 42, wherein the hemostatic valve comprises a reinforcement structure located between the at least one filament and the tubular member.

44. The method of any one of examples 41–43, wherein the at least one filament forms a loop around the elongate member, and wherein moving the tensioning mechanism from the second configuration to the first configuration reduces a size of the loop to thereby constrict the tubular member within the loop.

45. The method of any one of examples 41–44, wherein the filament forms at least one bight around a portion of the elongate member.

46. The method of example 45, wherein the filament comprises a first filament and a second filament, and wherein the at least one bight comprises a first bight oriented in a first direction and formed by the first filament and a second bight oriented in a second direction and formed by the second filament, wherein the first and second bights overlap to encircle a portion of the tubular member within an constricting area.

47. The method of example 46, wherein moving the tensioning mechanism from the second configuration to the first configuration comprises moving the first bight in the first direction and the second bight in the direction to reduce the size of the constricting area and collapse and seal the central lumen of the tubular member.

48. The method of any one of examples 37–47, wherein the tensioning mechanism comprises an actuator, and wherein moving the tensioning mechanism to the second configuration comprises manipulating the actuator.

49. The method of any one of examples 37–48, further comprising applying a vacuum to the delivery device to aspirate material through the catheter, wherein the central lumen remains sealed during the aspiration.

50. The method of any one of examples 37–49, wherein the tool comprises a thrombus extraction device.

51. A hemostatic valve for sealing a medical device, the hemostatic valve comprising:

an elongate member having a first end, a second end, and a central lumen comprising a plurality of lumens extending therebetween, wherein the elongate member is pliable; and

an active tensioning mechanism coupled to the elongate member, wherein the tensioning mechanism is moveable between a first configuration wherein the central lumen is constricted and sealed and a second configuration wherein the central lumen is open.

[0082] Other variations are within the spirit of the present invention. Thus, while the invention is susceptible to various modifications and alternative constructions, certain illustrated embodiments thereof are shown in the drawings and have been described above in detail. It should be understood, however, that there is no intention to limit the invention to the specific form or forms disclosed, but on the contrary, the intention is to cover all modifications, alternative constructions, and equivalents falling within the spirit and scope of the invention, as defined in the appended claims.

[0083] In the previous description, various embodiments of the present invention are described. For purposes of explanation, specific configurations and details are set forth in order to provide a thorough understanding of the embodiments. However, it will also be apparent to one skilled in the art that the present invention may be practiced without the specific details. Furthermore, well-known features may be omitted or simplified in order not to obscure the embodiment being described.

[0084] The use of the terms "a" and "an" and "the" and similar referents in the context of describing the invention (especially in the context of the following claims) are to be construed to cover both the singular and the plural, unless otherwise indicated herein or clearly contradicted by context. The terms "comprising," "having," "including," and "containing" are to be construed as open-ended terms (i.e., meaning "including, but not limited to,") unless otherwise noted. The term "connected" is to be construed as partly or wholly contained within, attached to, or joined together, even if there is something intervening. Recitation of ranges of values herein are merely intended to serve as a shorthand method of referring individually to each separate value falling within the range, unless otherwise indicated herein, and each separate value is incorporated into the specification as if it were individually recited herein. All methods described herein can be performed in any suitable order unless otherwise indicated herein or otherwise clearly contradicted by context. The use of any and all examples, or exemplary language (e.g., "such as") provided herein, is intended merely to better illuminate embodiments of the invention and does not pose a limitation on the scope of the invention unless otherwise claimed. No language in the specification should be construed as indicating any non-claimed element as essential to the practice of the invention.

[0085] Preferred embodiments of this invention are described herein, including the best mode known to the inventors for carrying out the invention. Variations of those preferred embodiments may become apparent to those of ordinary skill in the art upon reading the foregoing description. The inventors expect skilled artisans to employ such variations as appropriate, and the inventors intend for the invention to be practiced otherwise than as specifically described herein. Accordingly, this invention includes all modifications and equivalents of the subject matter recited in the claims appended hereto as permitted by applicable law. Moreover, any combination of the above-described elements in all possible variations thereof is encompassed by the invention unless otherwise indicated herein or otherwise clearly contradicted by context.

[0086] All references, including publications, patent applications, and patents, cited herein are hereby incorporated by reference to the same extent as if each reference were individually and specifically indicated to be incorporated by reference and were set forth in its entirety herein.

CLAIMS

1. An aspiration catheter, comprising:

an elongate, flexible tubular body, having a proximal end, a distal end and a central lumen;

a hemostasis valve on the proximal end of the catheter, the hemostasis valve comprising -

(a) a collapsible tubular sidewall defining a valve lumen in communication with the central lumen; and

(b) a constricting mechanism having at least a first actuator, a first filament formed into a loop around the collapsible tubular sidewall, the filament having at least a first end portion extending away from the loop and connected to the first actuator, and a first spring configured to move the first actuator in a direction that pulls the first end portion such that the diameter of the valve lumen decreases in response to reducing a diameter of the loop.

2. The aspiration catheter of claim 1 wherein:

the collapsible tubular sidewall comprises a tubular member defining the valve lumen configured to slidably receive the elongate, flexible tubular body;

the constricting mechanism further comprises a second actuator and a second spring coupled to the second actuator; and

the filament further comprises a second end portion extending away from the loop in a different direction than the first end portion and connected to the second actuator, and wherein the first actuator and the second actuator are moveable between (a) a first position wherein the filament circumferentially constricts the valve lumen to create a seal about the elongate, flexible tubular body and (b) a second position wherein the filament is moved to open the valve lumen at least partially.

3. The aspiration catheter of claim 2 wherein the tubular member is pliable.

4. The aspiration catheter of claim 2 wherein the first actuator comprises a first button and the second actuator comprises a second button, wherein the first button and the second button

are undepressed in the first position, and wherein the first button and the second button are depressed in the second position.

5. The aspiration catheter of claim 2 wherein, when the first actuator and the second actuator are in the first position, the valve lumen of the tubular member is configured to remain constricted and sealed when a pressure differential exists between (a) a first volume outside the valve lumen and adjacent to a first end of the tubular member and (b) a second volume outside the central lumen and adjacent to a second end of the tubular member.

6. The aspiration catheter of claim 2 wherein, when the first actuator and the second actuator are in the first position, the valve lumen of the tubular member is configured to remain constricted and sealed when vacuum pressure is applied to a volume outside the valve lumen and adjacent to either a first end or a second end of the tubular member.

7. The aspiration catheter of claim 2 wherein the valve lumen of the tubular member extends a long a first longitudinal axis, wherein the first actuator and the second actuator are movable between the first and second positions along a second longitudinal axis, and wherein the first longitudinal axis is orthogonal to the second longitudinal axis.

8. The aspiration catheter of claim 2 wherein the first spring comprises a first compression spring coupled to the first member and the second spring comprises a second compression spring coupled to the second member.

9. The aspiration catheter of claim 2 wherein, in the first position, the first actuator and the second actuator pull the filament to circumferentially constrict the collapsible tubular member such that the valve lumen is constricted and sealed.

ABSTRACT OF THE DISCLOSURE

Devices, systems, and methods for sealing medical devices, particularly during intravascular access, are disclosed herein. Some aspects relate to a hemostatic valve for sealing a wide range of medical devices, such as catheters, wires, embolectomy systems. The valve can include an elongate member having a first end, a second end, and a central lumen extending therebetween. A reinforcement structure extends along at least a portion of the elongate member and is coupled to the elongate member. A shell defining a first aperture and a second aperture may be included, which first and second apertures can be fluidly coupled by the elongate member. A tensioning mechanism is coupled to the shell and to the elongate member, the tensioning mechanism can be moveable between a first configuration wherein the tensioning mechanism is collapsed and the central lumen is sealed and a second configuration wherein the central lumen is open.

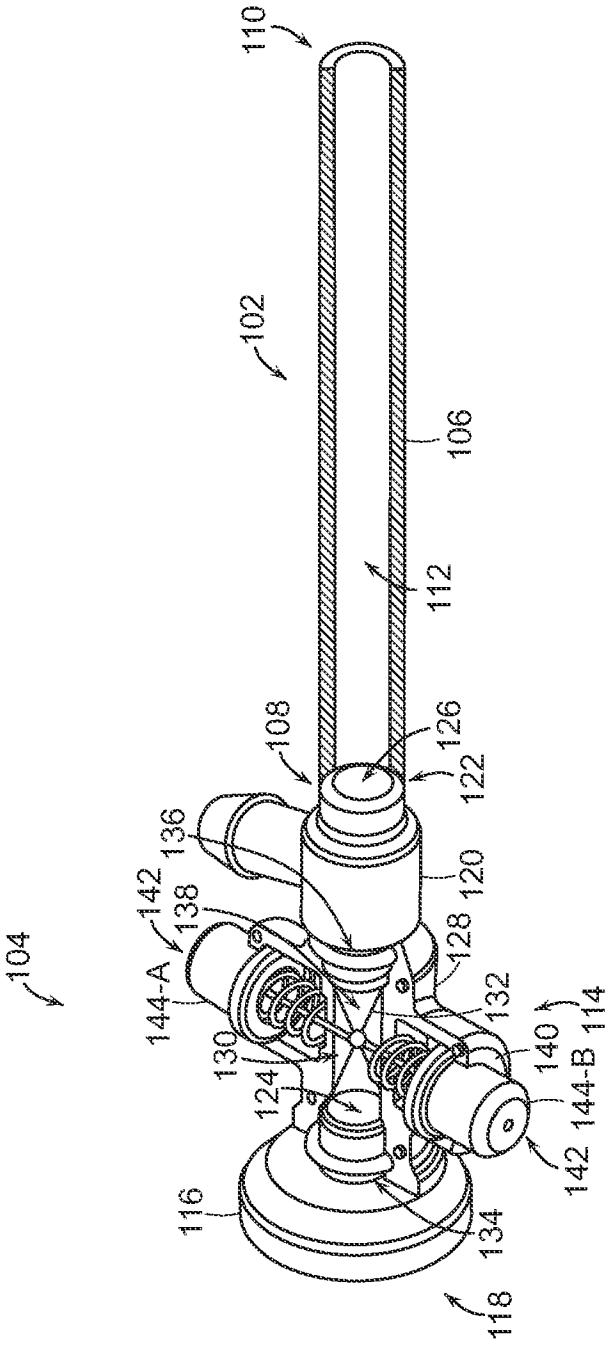
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FIG. 1

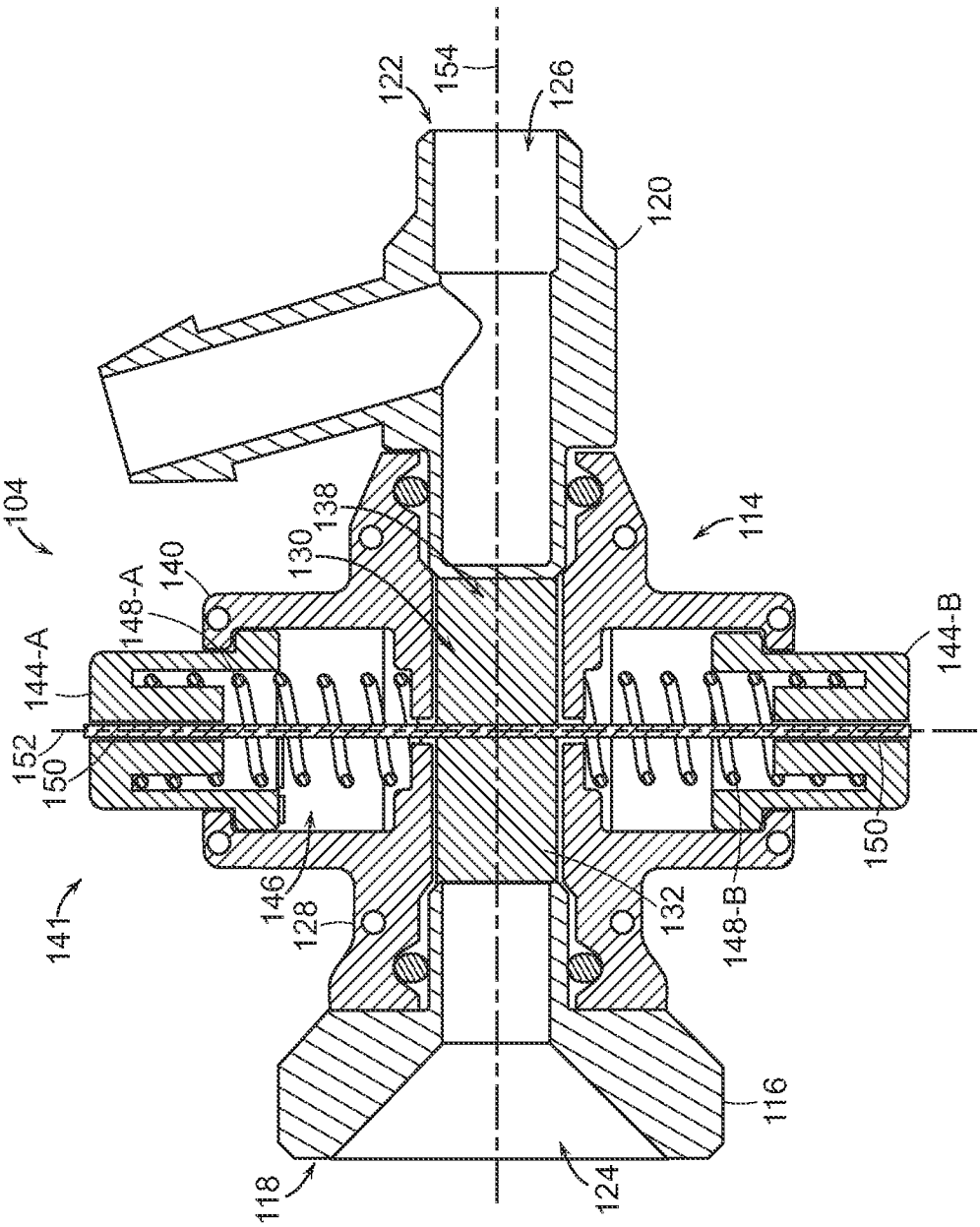
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FIG. 2

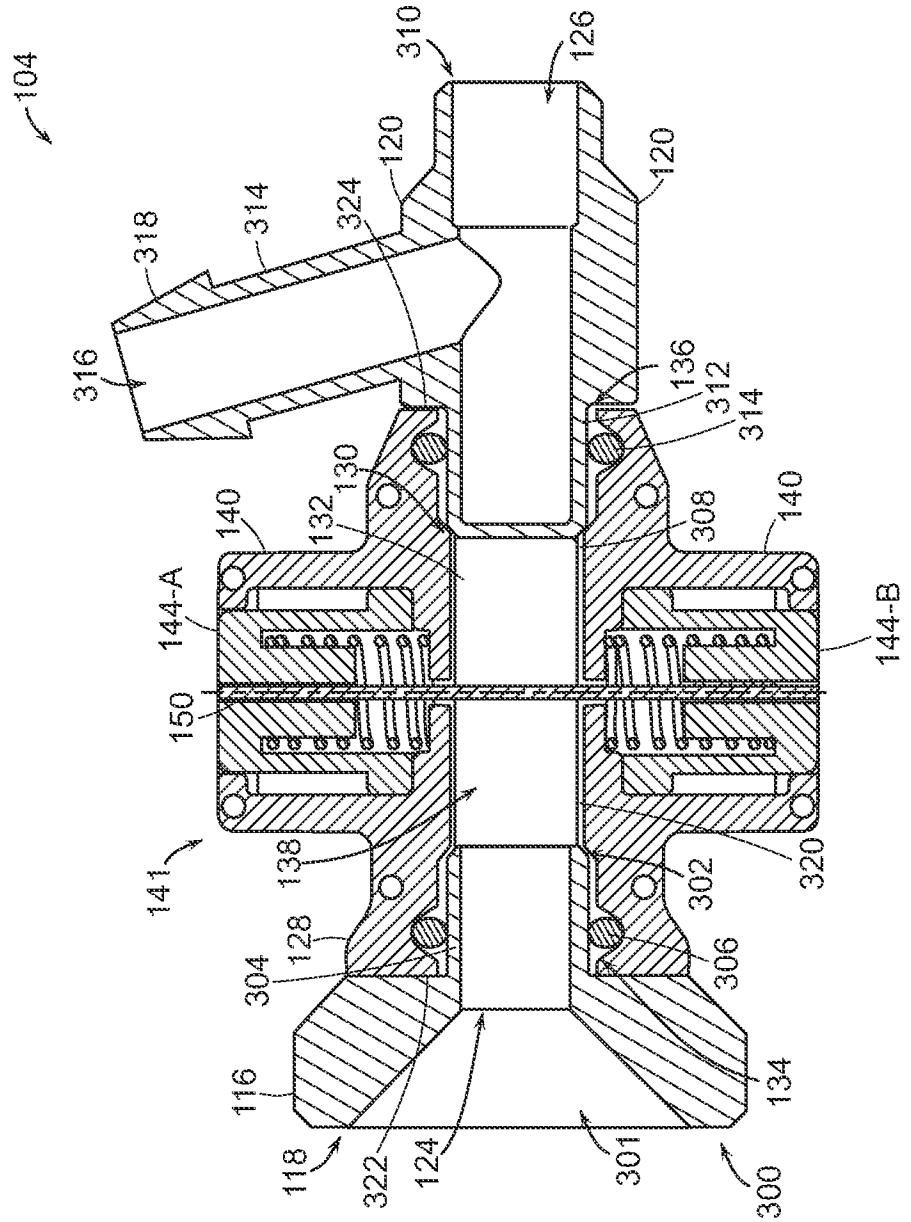
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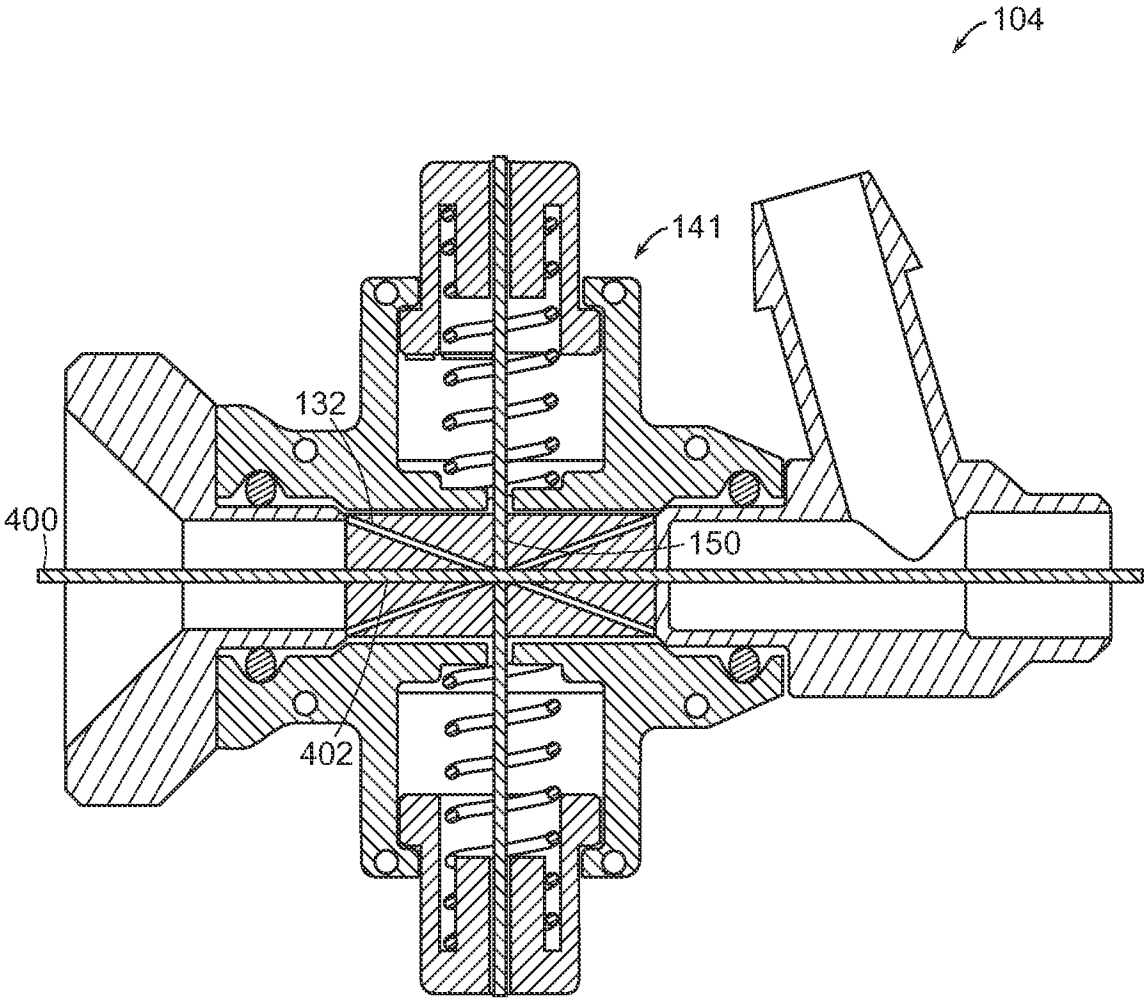
FIG. 3



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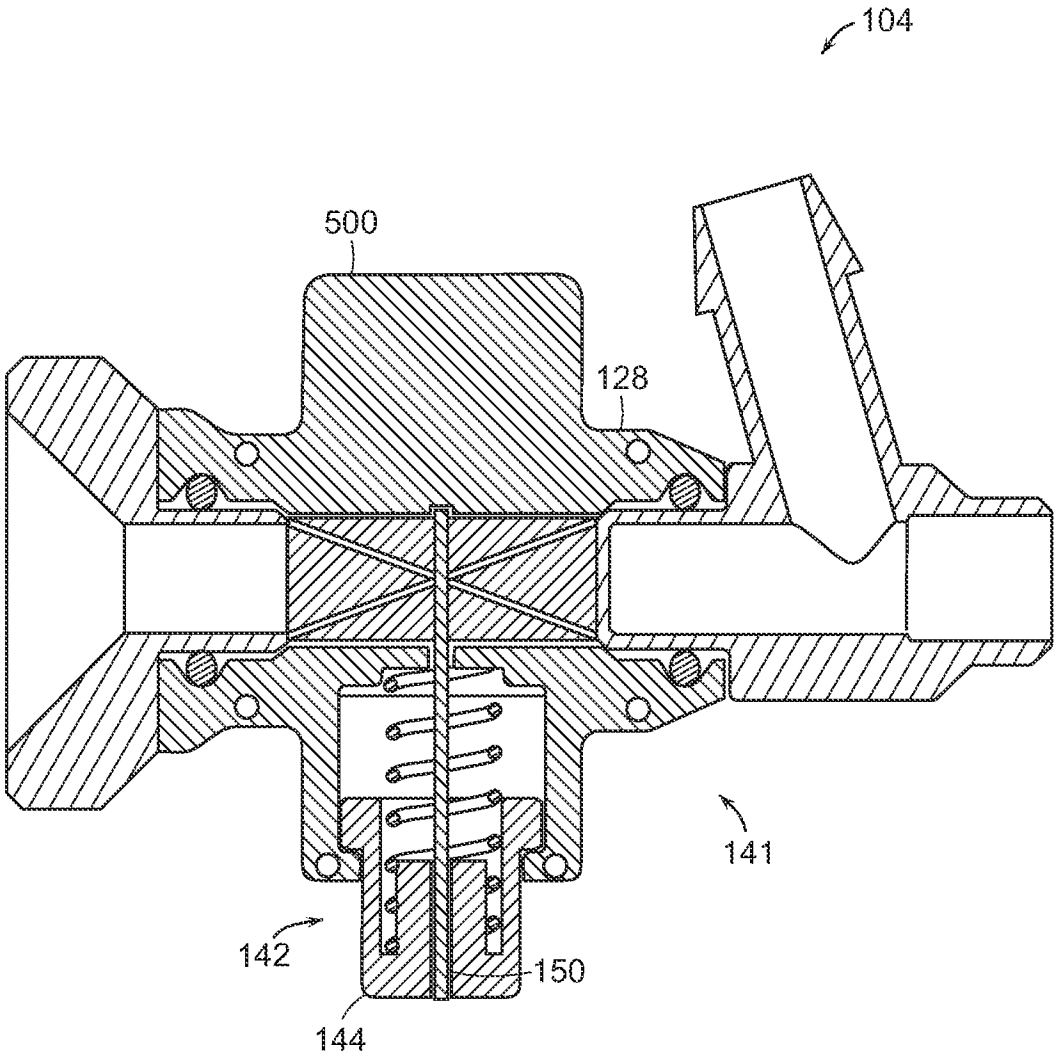


FIG. 5

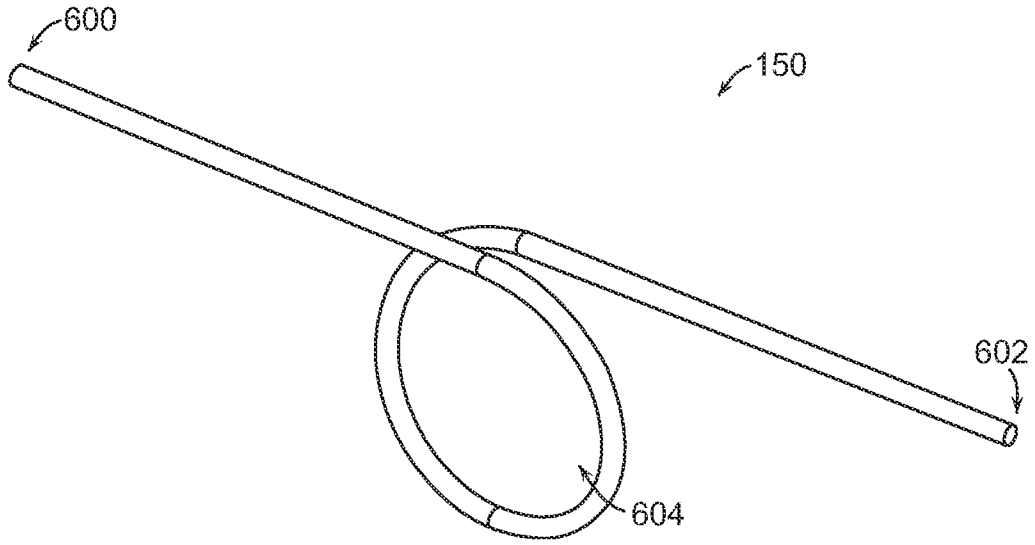


FIG. 6

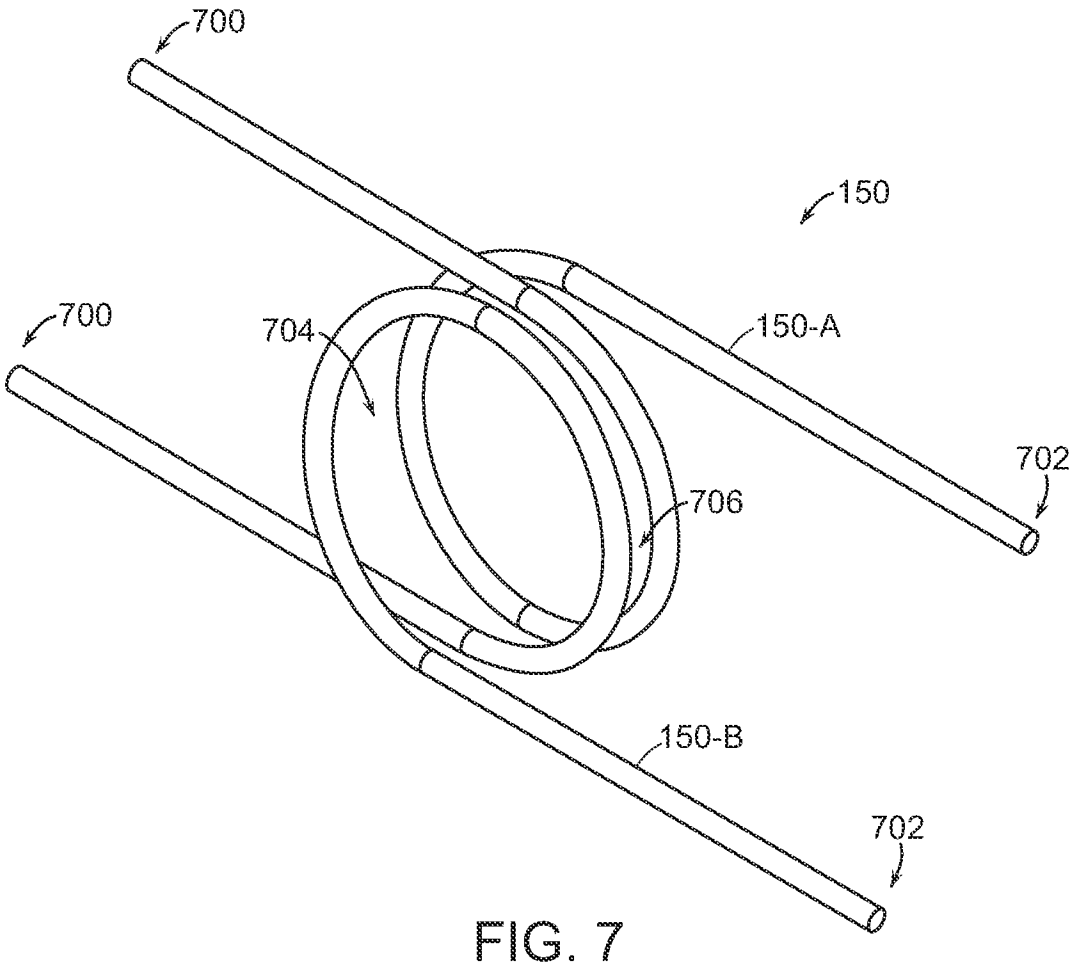
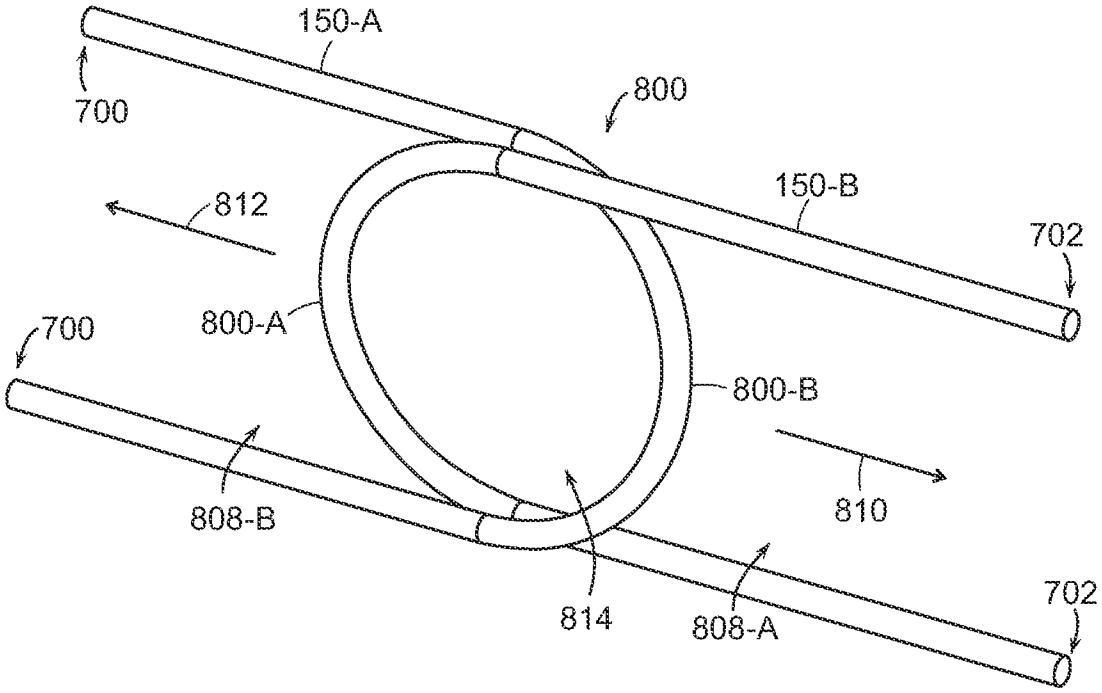


FIG. 7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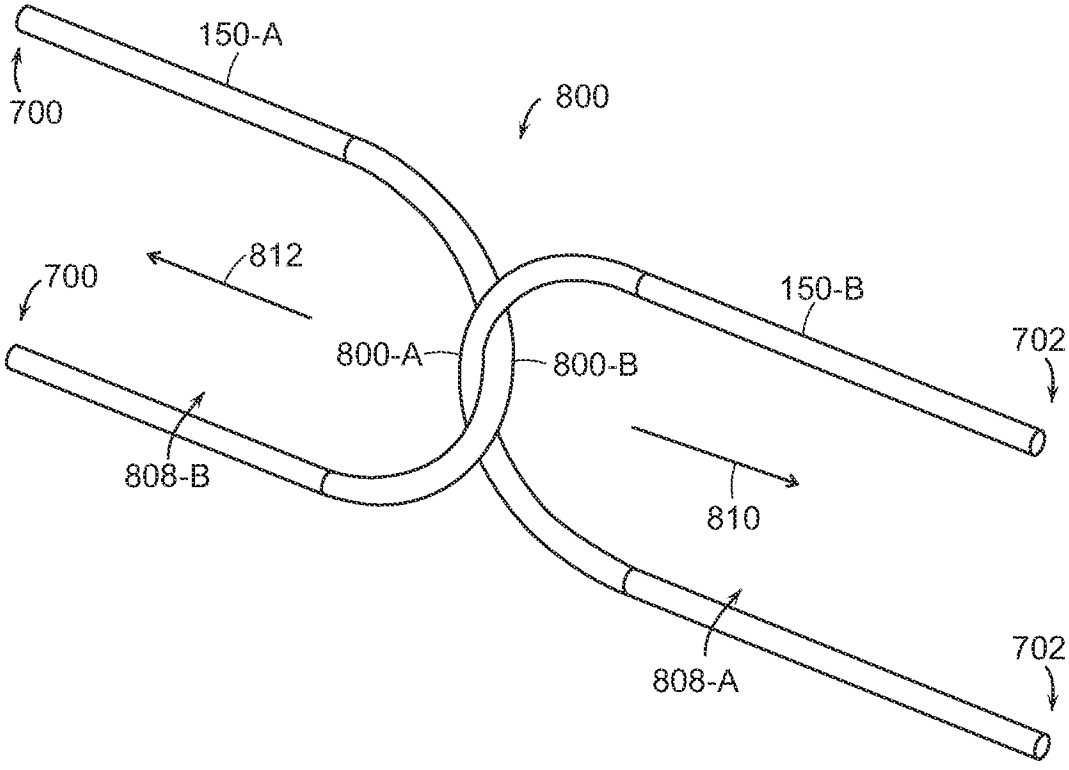
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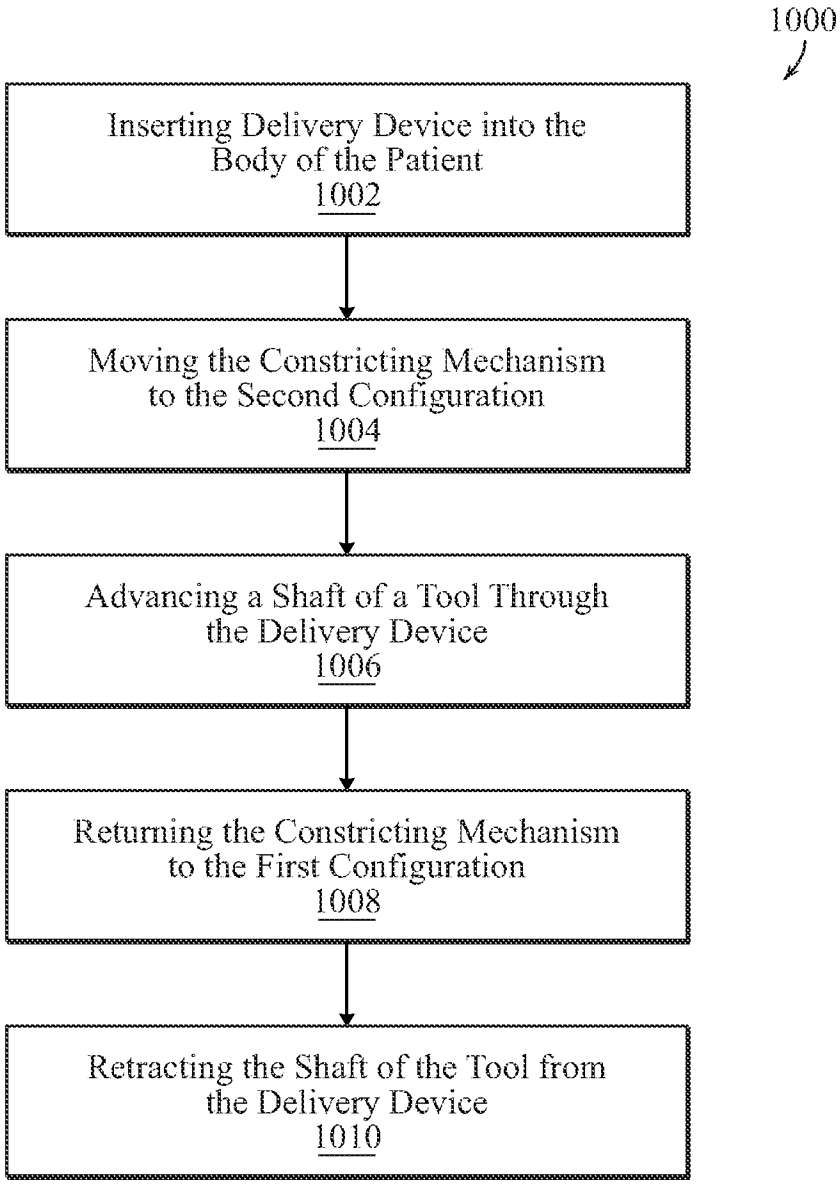
FIG. 9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Inserting Delivery Device into the Body of the Patient
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Moving the Constricting Mechanism to the Second Configuration
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Advancing a Shaft of a Tool Through the Delivery Device
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Returning the Constricting Mechanism to the First Configuration
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Retracting the Shaft of the Tool from the Delivery Device
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FIG. 10

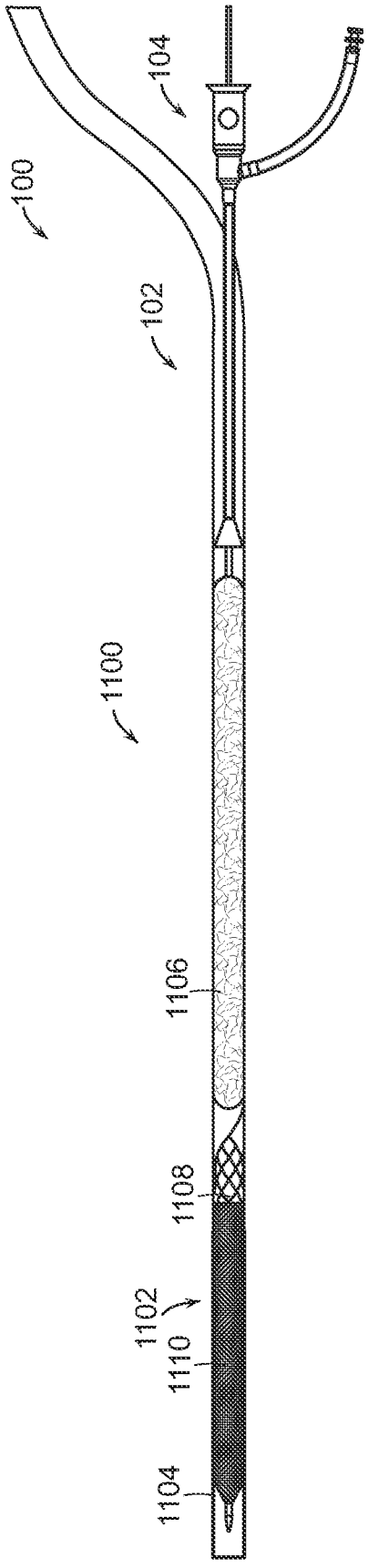

FIG. 11

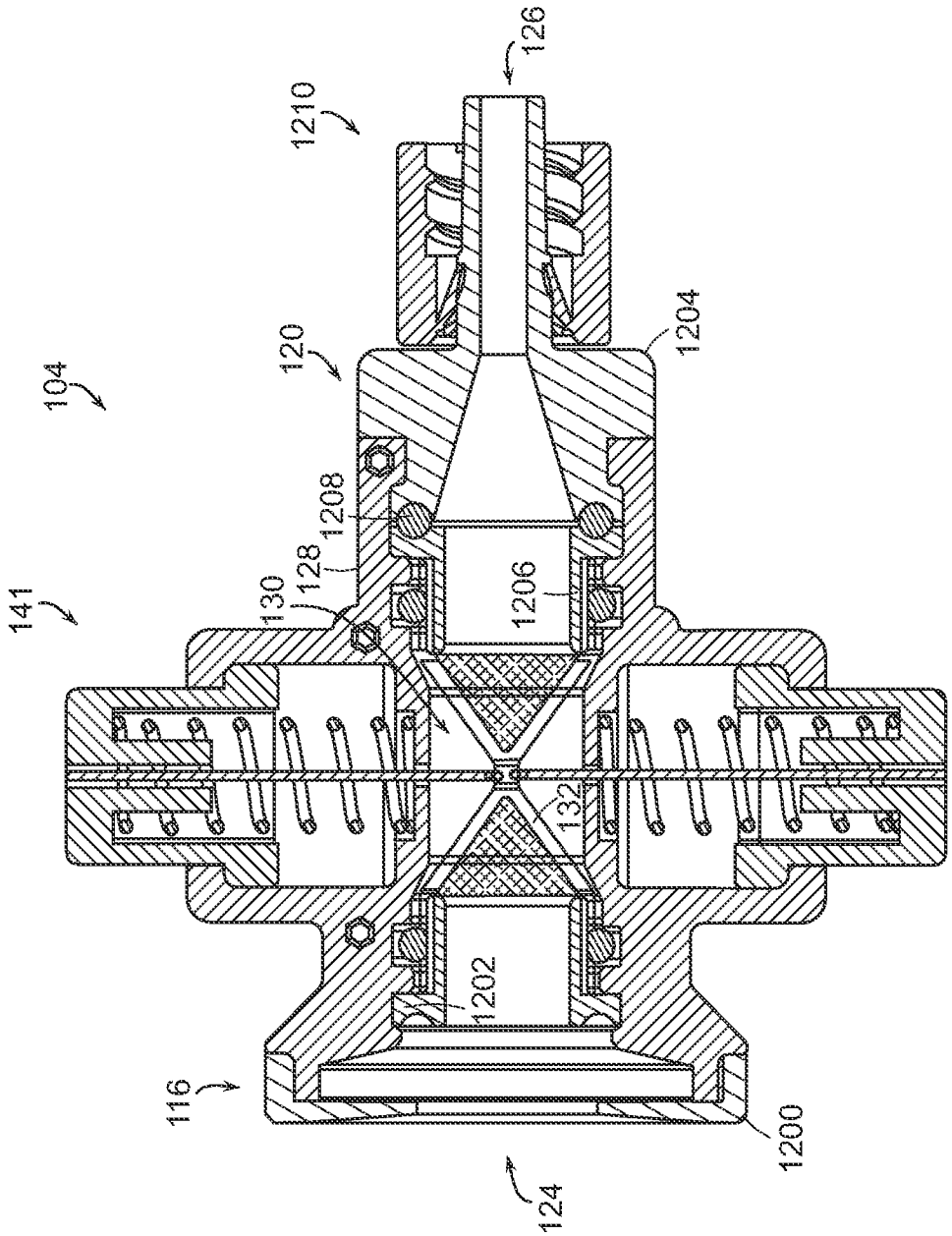
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FIG. 12

Electronic Patent Application Fee Transmittal

Application Number:	
Filing Date:	
Title of Invention:	HEMOSTASIS VALVES AND METHODS OF USE
First Named Inventor/Applicant Name:	Benjamin E. Merritt
Filer:	Paul T Parker/JiYoung Anderson
Attorney Docket Number:	111552-8016.US04

Filed as Large Entity

Filing Fees for Track I Prioritized Examination - Nonprovisional Application under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
UTILITY APPLICATION FILING	1011	1	320	320
UTILITY SEARCH FEE	1111	1	700	700
UTILITY EXAMINATION FEE	1311	1	800	800
REQUEST FOR PRIORITIZED EXAMINATION	1817	1	4200	4200
Pages:				
Claims:				
Miscellaneous-Filing:				
PROCESSING FEE, EXCEPT PROV. APPLS.	1830	1	140	140

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
		Total in USD ($)		**6160**

Electronic Acknowledgement Receipt

EFS ID:	46195517
Application Number:	17865266
International Application Number:	
Confirmation Number:	6816
Title of Invention:	HEMOSTASIS VALVES AND METHODS OF USE
First Named Inventor/Applicant Name:	Benjamin E. Merritt
Customer Number:	25096
Filer:	Paul T Parker/JiYoung Anderson
Filer Authorized By:	Paul T Parker
Attorney Docket Number:	111552-8016.US04
Receipt Date:	14-JUL-2022
Filing Date:	
Time Stamp:	19:45:09
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$6160
RAM confirmation Number	E20227DJ45343348
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Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Track One Request	Track-One-Request-111552-8016US4.PDF	877332 8ad983c854081704f213fc988880f9e3681888cc	no	2
Warnings:					
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2	Application Data Sheet	ADS-111552-8016US4.PDF	1823487 a534be8acb6350a6cb8b029b334905052029130c	no	9
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	Claims	34	35
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National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.