

US011697012B2

(12) United States Patent Merritt et al.

(45) Date of Patent: Ju

US 11,697,012 B2 Jul. 11, 2023

(54) HEMOSTASIS VALVES AND METHODS OF

(71) Applicant: Inari Medical, Inc., Irvine, CA (US)

(72) Inventors: **Benjamin E. Merritt**, San Clemente, CA (US); **John C. Thress**, Capistrano

Beach, CA (US); **Paul Lubock**, Monarch Beach, CA (US)

(73) Assignee: Inari Medical, Inc., Irvine, CA (US)

(*) Notice: Subject to any disclaimer, the term of this

patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: 17/865,266

(22) Filed: Jul. 14, 2022

(65) **Prior Publication Data**

US 2022/0347455 A1 Nov. 3, 2022

Related U.S. Application Data

- (63) Continuation of application No. 17/705,189, filed on Mar. 25, 2022, which is a continuation of application (Continued)
- (51) **Int. Cl. A61M 39/06** (2006.01) **A61B 17/3207** (2006.01)
- (52) **U.S. Cl.**CPC *A61M 39/0613* (2013.01); *A61B 17/3207* (2013.01); *A61M 2039/062* (2013.01); *A61M 2039/0673* (2013.01)
- (58) Field of Classification Search
 CPC A61M 2039/0673; A61M 39/0613; A61M
 2039/062; A61M 2039/0626
 See application file for complete search history.

(56) References Cited

(10) **Patent No.:**

U.S. PATENT DOCUMENTS

2,846,179 A 8/1958 Monckton 2,955,592 A 8/1960 Maclean (Continued)

FOREIGN PATENT DOCUMENTS

AU 2015210338 8/2015 CN 102186427 9/2011 (Continued)

OTHER PUBLICATIONS

European Patent Application No. 13838945.7, Extended European Search Report, 9 pages, dated Apr. 15, 2016.

(Continued)

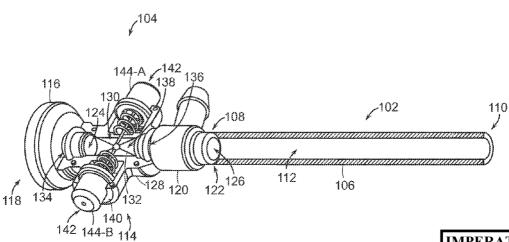
Primary Examiner — Quynh-Nhu H. Vu (74) Attorney, Agent, or Firm — Perkins Coie LLP

(57) ABSTRACT

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.

9 Claims, 10 Drawing Sheets

100



IMPERATIVE Ex. 1001 IPR Petition - US 11,697,012

	Relate	d U.S. A	application Data	5,746,758 A		Nordgren et al.
	No. 17/2263	18 filed	on Apr. 9, 2021, which is a	5,749,858 A 5,769,816 A		Cramer Barbut et al.
			ation No. 16/117,519, filed on	5,782,817 A		Franzel et al.
			Pat. No. 11,000,682.	5,800,457 A		Gelbfish
	1108. 50, 201	0, 110 1		5,827,229 A		Auth et al.
(60)	Provisional at	plication	n No. 62/554,931, filed on Sep.	5,846,251 A	12/1998	Hart Lafontaine et al.
(00)	6, 2017.	F		5,860,938 A 5,873,866 A		Kondo et al.
	,			5,873,882 A	2/1999	Straub et al.
(56)		Referen	ces Cited	5,876,414 A	3/1999	
	110.1		DOCUMENTS	5,895,406 A 5,908,435 A		Gray et al. Samuels
	U.S. 1	PALENT	DOCUMENTS	5,911,710 A		Barry et al.
	3,088,363 A	5/1963	Sparks	5,911,733 A	6/1999	
	3,197,173 A	7/1965	Taubenheim	5,911,754 A 5,941,869 A		Kanesaka et al. Patterson et al.
	3,435,826 A		Fogarty	5,947,985 A	9/1999	
	3,515,137 A 3,675,657 A *		Santomieri Gauthier A61B 17/132	5,954,737 A	9/1999	Lee
	5,075,057 11	111512	606/203	5,971,938 A		Hart et al.
	3,892,161 A	7/1975		5,972,019 A 5,974,938 A	11/1999	Engelson et al.
	3,923,065 A		Nozick et al.	5,989,233 A	11/1999	
	4,030,503 A 4,034,642 A		Clark, III Iannucci et al.	5,993,483 A	11/1999	
	4,222,380 A		Terayama	6,030,397 A 6,059,814 A	2/2000 5/2000	Moneti et al.
	4,243,040 A		Beecher	6,066,158 A		Engelson et al.
	4,287,808 A 4,324,262 A	9/1981 4/1982	Leonard et al.	6,068,645 A	5/2000	Tu
	4,393,872 A		Reznik et al.	6,126,635 A		Simpson et al.
	4,469,100 A	9/1984	Hardwick	6,142,987 A 6,146,396 A	11/2000	Konya et al.
	4,523,738 A		Raftis et al.	6,146,403 A		St. Germain
	4,551,862 A *	11/1985	Haber A61F 2/0036 600/491	6,152,946 A		Broome et al.
	4,604,094 A	8/1986		6,156,055 A		Ravenscroft
	4,611,594 A	9/1986	Grayhack et al.	6,159,230 A 6,165,196 A		Samuels Stack et al.
	4,643,184 A		Mobin-Uddin	6,168,579 B1		Tsugita
	4,646,736 A 4,650,466 A	3/1987	Auth et al.	6,179,859 B1		Bates et al.
	4,776,337 A	10/1988		6,221,006 B1 6,228,060 B1	4/2001 5/2001	Dubrul et al.
	4,790,812 A		Hawkins, Jr. et al.	6,238,412 B1		Dubrul et al.
	4,863,440 A 4,870,953 A		Chin et al. DonMichael et al.	6,245,078 B1	6/2001	Ouchi
	4,883,458 A	11/1989		6,245,089 B1	6/2001 7/2001	Daniel et al.
	4,886,062 A	12/1989	Wiktor	6,254,571 B1 6,258,115 B1	7/2001	
	4,890,611 A		Monfort et al.	6,264,663 B1	7/2001	Cano
	4,898,575 A 4,946,440 A	8/1990	Fischell et al.	6,306,163 B1	10/2001	
	4,960,259 A		Sunnanvader et al.	6,322,572 B1 6,350,271 B1	11/2001	Lee Kurz et al.
	4,978,341 A		Niederhauser	6,361,545 B1		Macoviak et al.
	5,059,178 A 5,100,423 A	10/1991	Ya Fearnot	6,364,895 B1	4/2002	Greenhalgh
	5,127,626 A		Hilal et al.	6,368,339 B1 6,383,205 B1		Amplatz Samson et al.
	5,129,910 A		Phan et al.	6,402,771 B1		Palmer et al.
	5,135,484 A		Wright	6,413,235 B1	7/2002	Parodi
	5,154,724 A 5,158,533 A		Andrews Strauss et al.	6,423,032 B2	7/2002	
	5,158,564 A	10/1992	Schnepp-Pesch et al.	6,432,122 B1 6,451,036 B1		Gilson et al. Heitzmann et al.
	5,192,274 A		Bierman	6,458,103 B1		Albert et al.
	5,192,286 A 5,192,290 A	3/1993	Phan et al. Hilal	6,475,236 B1		Roubin et al.
	5,197,485 A		Grooters	6,485,502 B2 6,508,782 B1		Don Michael Evans et al.
	5,329,923 A		Lundquist	6,511,492 B1		Rosenbluth et al.
	5,360,417 A 5,364,345 A		Gravener et al. Lowery et al.	6,514,273 B1		Voss et al.
	5,376,101 A		Green et al.	6,530,923 B1		Dubrul et al.
	5,383,887 A	1/1995	Nadal	6,530,935 B2 6,544,276 B1	4/2003	Wensel et al. Azizi
	5,389,100 A		Bacich et al.	6,544,278 B1		Vrba et al.
	5,419,774 A 5,421,824 A		Willard et al. Clement et al.	6,544,279 B1		Hopkins et al.
	5,443,443 A	8/1995		6,551,342 B1	4/2003 5/2003	Shen et al.
	5,456,667 A		Ham et al.	6,564,828 B1 6,569,181 B1	5/2003	
	5,476,450 A 5,490,859 A	12/1995	Ruggio Mische et al.	6,575,995 B1		Huter et al.
	5,490,839 A 5,496,365 A	3/1996		6,589,263 B1	7/2003	Hopkins et al.
	5,527,326 A	6/1996	Hermann et al.	6,596,011 B2		Johnson et al.
	5,549,626 A		Miller et al.	6,602,271 B2 6,605,074 B2		Adams et al. Zadno-Azizi et al.
	5,591,137 A 5,653,684 A		Stevens Laptewicz et al.	6,605,102 B1		Mazzocchi et al.
	5,662,703 A		Yurek et al.	6,610,077 B1		Hancock et al.

(56)	References Cited			8,092,486			Berrada et al.		
	I	IS P	ATENT	DOCUMENTS	8,100,935 8,109,962		1/2012 2/2012	Rosenbluth et al.	
).b. I	ALLINI	DOCUMENTS	8,118,829			Carrison et al.	
	6,620,148 H	В1	9/2003	Tsugita	8,197,493			Ferrera et al.	
	6,620,179 I			Brook et al.	8,246,641			Osborne et al. Marchand et al.	
	6,620,182 H		9/2003 9/2003	Khosravi et al.	8,261,648 8,267,897		9/2012		
	6,623,460 H 6,635,068 H			Dubrul et al.	8,298,257			Sepetka et al.	
	6,645,222 H			Parodi et al.	8,317,748	B2	11/2012	Fiorella et al.	
	6,660,013 H	B2		Rabiner et al.	8,337,450		12/2012		
	6,660,014 H			Demarais et al.	RE43,902 8,357,178			Hopkins et al. Grandfield et al.	
	6,663,650 H 6,692,504 H			Sepetka et al. Kurz et al.	8,361,104			Jones et al.	
	6,699,260 E			Dubrul et al.	8,409,215	B2	4/2013	Sepetka et al.	
	6,702,830 H	В1		Demarais et al.	8,486,105			Demond et al.	
	6,719,717 H			Johnson et al.	8,491,539 8,512,352		7/2013 8/2013		
	6,755,847 H 6,767,353 H	B2 R1	6/2004 7/2004		8,535,283			Heaton et al.	
	6,790,204 E			Zadno-Azizi et al.	8,535,334	B2	9/2013		
	6,800,080 H		10/2004		8,545,526			Martin et al.	
	6,818,006 H			Douk et al.	8,568,432 8,574,262		10/2013	Straub Ferrera et al.	
	6,824,545 H 6,824,550 H			Sepetka et al. Noriega et al.	8,579,915			French et al.	
	6,824,553 H			Gene et al.	8,585,713			Ferrera et al.	
	6,830,561 H			Jansen et al.	8,608,754			Wensel et al.	
	6,846,029 I			Ragner et al.	8,657,867			Dorn et al. Fiorella et al.	
	6,902,540 H			Dorros et al. Kleshinski	8,696,622 8,715,314			Janardhan et al.	
	6,939,361 H 6,942,682 H			Vrba et al.	8,721,714		5/2014		
	6,945,977 E			Demarais et al.	8,753,322			Hu et al.	
	6,960,189 H			Bates et al.	8,771,289			Mohiuddin et al.	
	6,960,222 H		11/2005		8,777,893 8,784,441			Malewicz Rosenbluth et al.	
	7,004,931 H 7,004,954 H			Hogendijk Voss et al.	8,784,442			Jones et al.	
	7,036,707 E			Aota et al.	8,795,305		8/2014	Martin et al.	
	7,041,084 H	B2	5/2006	Fotjik	8,795,345			Grandfield et al.	
	7,052,500 H			Bashiri et al.	8,801,748 8,808,259		8/2014	Martin Walton et al.	
	7,056,328 H 7,063,707 H		6/2006	Arnott Bose et al.	8,814,927			Shin et al.	
	7,069,835 E			Nishri et al.	8,820,207	B2	9/2014	Marchand et al.	
	7,094,249 H	В1	8/2006	Thomas et al.	8,826,791			Thompson et al.	
	7,179,273 H			Palmer et al.	8,828,044 8,833,224			Aggerholm et al. Thompson et al.	
	7,223,253 H 7,232,432 H			Hogendijk Fulton, III et al.	8,845,621		9/2014		
	7,232,432 E		7/2007		8,852,226	B2	10/2014	Gilson et al.	
	7,285,126 H	B2		Sepetka et al.	8,939,991			Krolik et al.	
	7,300,458 H			Henkes et al.	8,945,143 8,945,172			Ferrera et al. Ferrera et al.	
	7,306,618 H 7,320,698 H		1/2007	Demond et al.	8,956,384			Berrada et al.	
	7,323,002 H			Johnson et al.	8,992,504	B2		Castella et al.	
	7,331,980 H	B2	2/2008	Dubrul et al.	9,005,172		4/2015	Chung	
	7,534,234 H		5/2009		9,028,401 9,078,682			Bacich et al. Lenker et al.	
	7,578,830 H 7,621,870 H			Kusleika et al. Berrada et al.	9,101,382			Krolik et al.	
	7,674,247 E		3/2010		9,125,683	B2	9/2015	Farhangnia et al.	
	7,691,121 H		4/2010	Rosenbluth et al.	9,126,016		9/2015		
	7,695,458 H			Belley et al.	9,149,609 9,155,552			Ansel et al. Ulm, III	
	7,763,010 H 7,766,934 H			Evans et al. Pal et al.	9,161,766			Slee et al.	
	7,775,501 E		8/2010		9,173,668		11/2015	Ulm, III	
	7,780,696 H		8/2010	Daniel et al.	9,186,487			Dubrul et al.	
	7,905,877 H			Oscar et al.	9,204,887 9,216,277			Cully et al. Myers	A61M 30/0613
	7,905,896 H 7,938,809 H		3/2011	Straub Lampropoulos et al.	9,358,037			Farhangnia et al.	A01W1 35/0013
	7,938,809 E			Webster et al.	9,259,237	B2		Quick et al.	
	7,967,790 H	B2		Whiting et al.	9,283,066			Hopkins et al.	
	7,976,511 H		7/2011		9,351,747 9,439,664		5/2016 9/2016	Kugler et al.	
	7,993,302 H 7,993,363 H			Hebert et al. Demond et al.	9,439,004			White et al.	
	7,993,363 E 8,043,313 E			Krolik et al.	9,456,834		10/2016		
	8,052,640 H	B2		Fiorella et al.	9,463,035	B1	10/2016	Greenhalgh et al.	
	8,057,496 H			Fischer, Jr.	9,463,036			Brady et al.	
	8,057,497 H			Raju et al.	9,526,864		12/2016		
	8,066,757 E 8,070,769 E		11/2011 12/2011	Ferrera et al.	9,526,865 9,566,424		12/2016 2/2017		
	8,070,769 E 8,070,791 E			Ferrera et al.	9,500,424			Nguyen et al.	
	8,075,510 H			Aklog et al.	9,616,213	B2	4/2017	Furnish et al.	
	8,088,140 H	B2	1/2012	Ferrera et al.	9,636,206	B2	5/2017	Nguyen et al.	

(56)	Referen	nces Cited	2003/0116731	A1*	6/2003	Hartley	
IIS	PATENT	DOCUMENTS	2003/0125663	A1	7/2003	Coleman et al.	251/297
0.6.	171111111	BOCCIMENTS	2003/0135230			Massey et al.	
9,643,035 B2	5/2017	Mastenbroek	2003/0135258	$\mathbf{A}1$		Andreas et al.	
9,700,332 B2		Marchand et al.	2003/0153873			Luther et al.	
9,717,514 B2		Martin et al.	2003/0153973			Soun et al.	
9,717,519 B2		Rosenbluth et al.	2003/0168068 2003/0176884			Poole et al. Berrada et al.	
9,744,024 B2 9,757,137 B2		Nguyen et al. Krolik et al.	2003/01/0884			Weldon et al.	
9,827,084 B2		Bonnette et al.	2003/0208224			Broome	
9,844,386 B2		Nguyen et al.	2003/0216774	A1	11/2003	Larson	
9,844,387 B2	12/2017	Marchand et al.	2004/0039412			Isshiki et al.	
9,848,975 B2	12/2017		2004/0068288		4/2004	Palmer et al.	
9,849,014 B2		Kusleika	2004/0073243 2004/0098033		4/2004 5/2004	Sepetka et al. Leeflang et al.	
9,962,178 B2 9,980,813 B2*		Greenhalgh et al. Eller F16K 7/06	2004/0098033			Kusleika et al.	
9,999,493 B2		Nguyen et al.	2004/0122359			Wenz et al.	
10,004,531 B2	6/2018	Rosenbluth et al.	2004/0127936	$\mathbf{A}1$	7/2004	Salahieh et al.	
10,010,335 B2		Greenhalgh et al.	2004/0133232			Rosenbluth et al.	
10,016,266 B2		Hauser	2004/0138525			Saadat et al.	
10,028,759 B2		Wallace et al.	2004/0138692 2004/0167567			Phung et al. Cano et al.	
10,045,790 B2 10,098,651 B2		Cox et al. Marchand et al.	2004/0199201			Kellett et al.	
10,130,385 B2		Farhangnia et al.	2004/0199202			Dubrul et al.	
10,226,263 B2		Look et al.	2004/0260344			Lyons et al.	
10,238,406 B2		Cox et al.	2004/0267272			Henniges et al.	
10,271,864 B2		Greenhalgh et al.	2005/0033172 2005/0038468			Dubrul et al. Panetta et al.	
10,327,883 B2 10,335,186 B2		Yachia Rosenbluth et al.	2005/0054995			Barzell et al.	
10,342,571 B2		Marchand et al.	2005/0055047			Greenhalgh	
10,349,960 B2		Quick	2005/0085769			MacMahon et al.	
10,383,644 B2		Molaei et al.	2005/0085826			Nair et al.	
10,478,535 B2	11/2019		2005/0085846 2005/0085849			Carrison et al. Sepetka et al.	
10,524,811 B2 10,588,655 B2		Marchand et al. Rosenbluth et al.	2005/0089849		6/2005	Teague et al.	
10,695,159 B2		Hauser	2005/0177132			Lentz et al.	
10,709,471 B2		Rosenbluth et al.	2005/0187570			Nguyen et al.	
10,799,331 B2	10/2020		2005/0283165			Gadberry	
10,912,577 B2		Marchand et al.	2005/0283166 2005/0283186			Greenhalgh et al. Berrada et al.	
11,000,682 B2 11,013,523 B2		Merritt et al. Arad Hadar	2006/0020286			Niermann	
11,058,445 B2		Cox et al.	2006/0042786		3/2006		
11,058,451 B2		Marchand et al.	2006/0047286		3/2006		
11,147,571 B2		Cox et al.	2006/0074401 2006/0089533		4/2006	Ziegler et al.	
11,154,314 B2 11,259,821 B2	10/2021 3/2022	Buck et al.	2006/0100662			Daniel et al.	
11,406,801 B2		Fojtik et al.	2006/0155305	A1	7/2006	Freudenthal et al.	
11,433,218 B2		Quick et al.	2006/0173525			Behl et al.	
11,439,799 B2		Buck et al.	2006/0195137 2006/0200221			Sepetka et al. Malewicz	
11,457,936 B2 11,529,158 B2	10/2022	Buck et al.	2006/0200221			Hattier et al.	
11,529,138 B2 11,554,005 B2		Merritt et al.	2006/0224177		10/2006		
11,559,382 B2		Merritt et al.	2006/0229645		10/2006	Bonnette et al.	
2001/0004699 A1		Gittings et al.	2006/0247500		11/2006	Voegele et al.	
2001/0031981 A1		Evans et al.	2006/0253145 2006/0276874		11/2006	Wilson et al.	
2001/0041909 A1 2001/0049486 A1		Tsugita et al. Evans et al.	2006/02/03/4		12/2006		
2001/0049480 A1 2001/0051810 A1		Dubrul et al.	2006/0293696		12/2006	Fahey et al.	
2002/0022858 A1		Demond et al.	2007/0010787			Hackett et al.	
2002/0022859 A1		Hogendijk	2007/0038225			Osborne Elmaleh	
2002/0026211 A1		Khosravi et al.	2007/0093744 2007/0112374			Paul, Jr. et al.	
2002/0032455 A1		Boock et al.	2007/0118165			DeMello et al.	
2002/0049452 A1		Kurz et al.	2007/0149996			Coughlin	
2002/0095161 A1 2002/0095171 A1	7/2002	Dhindsa Belef	2007/0161963			Smalling	
2002/0111648 A1		Kusleika et al.	2007/0179513 2007/0191866			Deutsch Palmer et al.	
2002/0120277 A1		Hauschild et al.	2007/01918028			Miloslavski et al.	
2002/0147458 A1		Hiblar et al.	2007/0208361	A1	9/2007	Okushi et al.	
2002/0151918 A1		Lafontaine et al.	2007/0208367			Fiorella et al.	
2002/0156457 A1	10/2002		2007/0213753		9/2007		
2002/0161392 A1 2002/0169474 A1	10/2002	Dubrul Kusleika	2007/0213765 2007/0255252		9/2007	Adams et al.	
2002/01694/4 A1 2002/0173819 A1		Leeflang et al.	2007/0255252 2007/0288054			Tanaka et al.	
2002/01/3819 A1 2002/0188276 A1		Evans et al.	2008/0015541			Rosenbluth et al.	
2003/0083693 A1	5/2003	Daniel et al.	2008/0088055		4/2008		
2003/0100919 A1		Hopkins et al.	2008/0157017			Macatangay et al.	
2003/0114875 A1	6/2003	Sjostrom	2008/0167678	A1	7/2008	Morsi	

(56)	Referer	ices Cited	2012/0310166		12/2012	
T	I C DATENIT	DOCUMENTS	2013/0030460 2013/0035628			Marks et al. Garrison et al.
C	J.S. PATENT	DOCUMENTS	2013/0046332			Jones et al.
2008/0183136	A1 7/2008	Lenker et al.	2013/0066348			Fiorella et al.
2008/0228209		DeMello et al.	2013/0092012		4/2013	Marchand et al.
2008/0234715		Pesce et al.	2013/0096571		4/2013 4/2013	
2008/0234722		Bonnette et al.	2013/0102996 2013/0116708			Ziniti et al.
2008/0262528 A 2008/0269798 A		Ramzipoor et al.	2013/0116721			Takagi et al.
2008/0300466		Gresham	2013/0126559		5/2013	Cowan et al.
2009/0018566		Escudero et al.	2013/0144326			Brady et al.
2009/0054918		Henson	2013/0165871 2013/0184703		7/2013	Fiorella et al. Shireman et al.
2009/0062841 A 2009/0069828 A		Amplatz et al. Martin et al.	2013/0197454			Shibata et al.
2009/0009828 2			2013/0197567		8/2013	Brady et al.
2009/0160112	A1 6/2009	Ostrovsky	2013/0226196		8/2013	
2009/0163846		Aklog et al.	2013/0281788 2013/0289608		10/2013	Garrison Tanaka et al.
2009/0182362 A 2009/0192495 A		Thompson et al. Ostrovsky et al.	2013/0285608			Martin et al.
2009/0192493		Harding et al.	2013/0345739			Brady et al.
2009/0292307		Razack	2014/0005712		1/2014	
2009/0299393		Martin et al.	2014/0005713 2014/0005715			Bowman Castella et al.
2010/0016837		Howat Dubrul et al.	2014/0005717			Martin et al.
2010/0030256 A 2010/0042136 A		Berrada et al.	2014/0025048		1/2014	
2010/0087844		Fischer, Jr.	2014/0031856			Martin
2010/0087850		Razack	2014/0046133			Nakamura et al.
2010/0114113		Dubrul et al.	2014/0046243 2014/0052161			Ray et al. Cully et al.
2010/0121312 A 2010/0137846 A		Gielenz et al. Desai et al.	2014/0074144			Shrivastava et al.
2010/0197840 2		Van Wordragen et al.	2014/0121672		5/2014	Folk
2010/0204712		Mallaby	2014/0155830			Bonnette et al.
2010/0217276		Garrison et al.	2014/0155980 2014/0180397			Turjman Gerberding et al.
2010/0249815 A 2010/0268264 A		Jantzen et al. Bonnette et al.	2014/0155908		7/2014	
2010/0208204 2		Rapaport et al.	2014/0188127			Dubrul et al.
2011/0034986		Chou et al.	2014/0188143			Martin et al.
2011/0034987		Kennedy	2014/0236219 2014/0243882		8/2014 8/2014	Dubrul et al.
2011/0054405 A 2011/0060212 A		Whiting et al. Slee et al.	2014/0243882			Jemison
2011/0000212 2		Gunderson et al.	2014/0257363			Lippert
2011/0125181		Brady et al.	2014/0276403			Follmer et al.
2011/0144592	A1* 6/2011	Wong A61M 39/0613	2014/0296868			Garrison et al. Bonnette et al.
2011/01/2022	.1 6/2011	604/175	2014/0303658 2014/0318354			Thompson et al.
2011/0152823 A 2011/0152993 A		Mohiuddin et al. Marchand et al.	2014/0324091			Rosenbluth
2011/0160742		Ferrera et al.	2014/0330286			Wallace et al.
2011/0160763		Ferrera et al.	2014/0336691 2014/0343593			Jones et al. Chin et al.
2011/0190806		Wittens	2014/0364896			Consigny
2011/0196309 A 2011/0196414 A		Porter et al.	2014/0371779	A1	12/2014	Vale et al.
2011/0213290		Chin et al.	2015/0005781			Lund-Clausen et al.
2011/0213403		Aboytes	2015/0005792 2015/0018859		1/2015 1/2015	
2011/0224707		Miloslavski et al.	2015/0018860		1/2015	
2011/0245807 A 2011/0251629 A		Sakata et al. Galdonik et al.	2015/0018929			Martin et al.
2011/0264133		Hanlon et al.	2015/0025555		1/2015	
2011/0265681		Allen et al.	2015/0032144 2015/0059908			Holloway Mollen
2011/0288529 A 2011/0288572 A		Fulton Martin	2015/0088190			Jensen
2011/0288372 7		Ferrera et al.	2015/0127035			Trapp et al.
2012/0059309	A1 3/2012	di Palma et al.	2015/0133990 2015/0150672			Davidson
2012/0059356		di Palma et al.	2015/0164523		6/2015	Brady et al.
2012/0083824 A 2012/0083868 A		Berrada et al. Shrivastava	2015/0164666			Johnson et al.
2012/0089808 2		Rapaport et al.	2015/0173782			Garrison et al.
2012/0101480		Ingle et al.	2015/0190155			Ulm, III
2012/0101510		Lenker et al.	2015/0190156 2015/0196380			Ulm, III Berrada et al.
2012/0138832 A 2012/0143239 A		Townsend Aklog et al.	2015/0196744			Aboytes
2012/0143239 2		Cox et al.	2015/0209058			Ferrera et al.
2012/0172918	A1 7/2012	Fifer et al.	2015/0209165	$\mathbf{A}1$	7/2015	Grandfield et al.
2012/0179181		Straub et al.	2015/0238207			Cox et al.
2012/0197277		Stinis Lorrison et al.	2015/0250578 2015/0265299			Cook et al. Cooper et al.
2012/0232655 A 2012/0271105 A		Nakamura et al.	2015/0205299			Rosenbluth
2012/0271231		Agrawal	2015/0305859		10/2015	
2012/0277788		Cattaneo	2015/0352325		12/2015	

(56)	Reference	es Cited	2019/01: 2019/023			5/2019 8/2019	Cox et al. Quick
U.S.	PATENT D	OCUMENTS	2019/023			8/2019	Brady et al.
			2019/032				Marchand et al.
2015/0360001 A1	12/2015 Q		2019/033 2019/033				Torrie et al. Greenhalgh et al.
2015/0374391 A1 2016/0022293 A1	12/2015 Q	Quick Dubrul et al.	2020/004				Merritt et al.
2016/0058540 A1		Oon Michael	2020/01			4/2020	
2016/0074627 A1	3/2016 C		2021/002 2021/01			1/2021 4/2021	
2016/0106448 A1 2016/0106449 A1		Brady et al. Brady et al.	2021/013				Sonnette et al.
2016/0113663 A1		Brady et al.	2021/018			6/2021	Thress
2016/0113664 A1		Brady et al.	2021/023 2021/029				Marchand et al. Merritt et al.
2016/0113665 A1 2016/0113666 A1	4/2016 B 4/2016 Q	Brady et al.	2021/023				Buck et al.
2016/0143721 A1		Rosenbluth	2021/033	30344	A1		Rosenbluth et al.
2016/0151605 A1		Velch et al.	2021/037 2022/000			12/2021 1/2022	Thress et al.
2016/0206344 A1 2016/0008014 A1		Bruzzi et al. Rosenbluth	2022/000			1/2022	
2016/0220741 A1		Garrison et al.	2022/000	00507	A1	1/2022	Hauser
2016/0228134 A1	8/2016 N	Aartin et al.	2022/003				Marchand et al.
2016/0262774 A1	9/2016 H	Ionda Rosenbluth et al.	2022/002 2022/003				Cox et al. Thress et al.
2016/0262790 A1 2016/0287276 A1	10/2016 K		2022/012			4/2022	
2016/0367285 A1	12/2016 S	Sos	2022/014				Enright et al. Dolendo et al.
2017/0014560 A1		Ainskoff et al.	2022/015 2022/015				Dolendo et al.
2017/0037548 A1 2017/0042571 A1	2/2017 L 2/2017 L		2022/016			5/2022	
2017/0049942 A1	2/2017 C	Conlan et al.	2022/016			5/2022	
2017/0056032 A1	3/2017 L		2022/016 2022/02			5/2022 7/2022	Cox et al.
2017/0058623 A1 2017/0079672 A1	3/2017 Ja 3/2017 Q	affrey et al. Duick	2022/02				Merritt et al.
2017/0086864 A1		reenhalgh et al.	2022/024			8/2022	
2017/0100142 A1	4/2017 L		2022/034 2022/034				Merritt et al. Merritt et al.
2017/0105743 A1 2017/0105745 A1	4/2017 V 4/2017 R	ale et al. Rosenbluth et al.	2022/03-			11/2022	
2017/0112514 A1		Marchand et al.	2022/034			11/2022	`
2017/0112513 A1		Marchand et al.	2022/036 2023/004			11/2022 2/2023	Quick et al.
2017/0189041 A1 2017/0196576 A1	7/2017 C 7/2017 L		2023/002			3/2023	Quick Merritt et al.
2017/0233908 A1		Kroczynski et al.	2023/003				Cox et al.
2017/0252057 A1		Bonnette et al.					
2017/0265878 A1 2017/0303939 A1		Marchand et al. Greenhalgh et al.		FO:	REIG	N PATEI	NT DOCUMENTS
2017/0303942 A1		reenhalgh et al.	CN	1	103764	1040	4/2014
2017/0303947 A1		reenhalgh et al.	CN		03932		7/2014
2017/0303948 A1 2017/0319221 A1	10/2017 W 11/2017 C	Vallace et al.	CN		04068		10/2014
2017/0325839 A1		Rosenbluth et al.	CN CN		108348 110652		7/2018 1/2020
2017/0340867 A1		Accisano, II	CN		111281		6/2020
2017/0348014 A1 2018/0042623 A1	12/2017 W 2/2018 B	Vallace et al.	DE	1020	17004		7/2018
2018/0042624 A1		Greenhalgh et al.	EP EP		1254 1867		11/2002 2/2013
2018/0042626 A1		reenhalgh et al.	GB			3072	4/1981
2018/0064453 A1 2018/0064454 A1		farrison et al. Josordo et al.	GB		2498		7/2013
2018/0070968 A1		Vallace et al.	JP JP		H6190	3049 3090 A	7/1994 12/1995
2018/0092652 A1		Marchand et al.	JР		01522		5/1999
2018/0104404 A1 2018/0105963 A1	4/2018 N 4/2018 Q		JP		04097		4/2004
2018/0125512 A1		lguyen et al.	JP JP		05-095)05230		6/2005 9/2005
2018/0184912 A1	7/2018 A		JP		05323		11/2005
2018/0193043 A1 2018/0236205 A1		Aarchand et al. Crautkremer et al.	JР		06094		4/2006
2018/0256177 A1		Cooper et al.	JP WO	WO19)11526)97013		1/2010 5/1997
2018/0256178 A1	9/2018 C		WO		O9833		8/1998
2018/0296240 A1 2018/0344339 A1	10/2018 R 12/2018 C	Rosenbluth et al.	WO		O9838		9/1998
2018/0361116 A1	12/2018 Q	Quick et al.	WO WO		O9839 O9851		9/1998 11/1998
2019/0000492 A1		Casey et al.	WO	wois			9/1999
2019/0046219 A1 2019/0070401 A1		Aarchand et al. Aerritt et al.	WO		O0032		6/2000
2019/0117244 A1		Vallace et al.	WO WO	WO20	00053 O0202		9/2000 1/2002
2019/0133622 A1		Vallace et al.	WO		00202		2/2003
2019/0133623 A1 2019/0133624 A1		Vallace et al. Vallace et al.	WO	WO20			3/2004
2019/0133624 A1 2019/0133625 A1		Vallace et al.	WO WO	W020)04093)05046		11/2004 5/2005
2019/0133626 A1	5/2019 W	Vallace et al.	WO	WO20	06110)186	10/2006
2019/0133627 A1	5/2019 W	Vallace et al.	WO	WO20	006124	1307	11/2006

(56)	References Cited					
	FOREIGN PATI	ENT DOCUMENTS				
WO	WO2007092820	8/2007				
WO	WO2009082513	7/2009				
WO	WO2009086482	7/2009				
WO	WO2009155571	12/2009				
WO	WO2010002549	1/2010				
WO	WO2010010545	1/2010				
WO	WO2010023671	3/2010				
WO	WO2010049121	5/2010				
WO	WO2010102307	9/2010				
WO	WO2011032712	3/2011				
WO	WO2011054531	5/2011				
WO	WO2011073176	6/2011				
WO	W02012011097	1/2012				
WO	WO2012009675	1/2012				
WO	WO2012049652	4/2012				
WO	WO2012065748	5/2012				
WO WO	WO2012120490 WO2012162437	9/2012 11/2012				
WO	WO2012162437 WO2014047650	3/2014				
WO	WO2014047630 WO2014081892	5/2014				
WO	WO2014001892 WO2015006782	1/2015				
wo	WO2015060762 WO2015061365	4/2015				
WO	WO2015001505 WO2015121424	8/2015				
WO	W02015121121 W02015191646	12/2015				
WO	WO2015189354	12/2015				
WO	W02017024258	2/2017				
WO	W02017070702	4/2017				
WO	WO2017058280	4/2017				
WO	WO2017106877	6/2017				
WO	WO2017189535	11/2017				
WO	WO2017189550	11/2017				
WO	WO2017189591	11/2017				
WO WO	WO2017189615	11/2017 12/2017				
WO	WO2017210487 WO2018049317	3/2018				
WO	W02018049317 W02018080590	5/2018				
WO	WO2018080390 WO2018148174	8/2018				
WO	WO2019010318	1/2019				
WO	W02019050765	3/2019				
WO	W02019075444	4/2019				
WO	WO2019094456	5/2019				
WO	WO2019222117	11/2019				
WO	WO2019246240	12/2019				
WO	WO2020036809	2/2020				
WO	WO2021067134	4/2021				
WO	WO2021076954	4/2021				
WO	WO2021127202	6/2021				
WO	WO2021248042	12/2021				
WO	WO2022032173	2/2022				
WO	WO2022103848	5/2022				
WO	WO2022109021 WO2022109034	5/2022				
WO	W O 2022 109034	5/2022				

OTHER PUBLICATIONS

Gibbs, et al., "Temporary Stent as a bail-out device during percutaneous transluminal coronary angioplasty: preliminary clinical experience," British Heart Journal, 1994, 71:372-377, Oct. 12, 1993, 6 pgs.

Gupta, S. et al., "Acute Pulmonary Embolism Advances in Treatment", JAPI, Association of Physicians India, Mar. 2008, vol. 56, 185-101

International Search Report and Written Opinion for International App. No. PCT/US13/61470, dated Jan. 17, 2014, 7 pages. International Search Report and Written Opinion for International App. No. PCT/US2014/046567, dated Nov. 3, 2014, 13 pages. International Search Report and Written Opinion for International App. No. PCT/US2014/061645, dated Jan. 23, 2015, 15 pages.

International Search Report for International App. No. PCT/US13/71101, dated Mar. 31, 2014, 4 pages.

Konstantinides, S. et al., "Pulmonary embolism hotline 2012—Recent and expected trials", Thrombosis and Haemostasis, Jan. 9, 2013:33; 43-50.

Konstantinides, S. et al., "Pulmonary embolism: risk assessment and management", European Society of Cardiology; European Heart Journal, Sep. 7, 2012:33, 3014-3022.

Kucher, N. et al., "Percutaneous Catheter Thrombectomy Device for Acute Pulmonary Embolism: In Vitro and in Vivo Testing", Circulation, Sep. 2005:112:e28-e32.

Kucher, N., "Catheter Interventions in Massive Pulmonary Embolism", Cardiology Rounds, Mar. 2006 vol. 10, Issue 3, 6 pages. Kucher, N. et al., "Management of Massive Pulmonary Embolism", Radiology, Sep. 2005:236:3 852-858.

Kucher, N. et al., "Randomized, Controlled Trial of Ultrasound-Assisted Catheter-Directed Thrombolysis for Acute Intermediate-Risk Pulmonary Embolism." Circulation, 2014, 129, pages 9 pages. Kuo, W. et al., "Catheter-directed Therapy for the Treatment of Massive Pulmonary Embolism: Systematic Review and Meta-analysis of Modern Techniques", Journal of Vascular and Interventional Radiology, Nov. 2009:20:1431-1440.

Kuo, W. et al., "Catheter-Directed Embolectomy, Fragmentation, and Thrombolysis for the Treatment of Massive Pulmonary Embolism After Failure of Systemic Thrombolysis", American College of CHEST Physicians 2008: 134:250-254.

Kuo, W. Md, "Endovascular Therapy for Acute Pulmonary Embolism", Continuing Medical Education Society of Interventional Radiology ("CME"); Journal of Vascular and Interventional Radiology, Feb. 2012: 23:167-179.

Lee, L. et al, "Massive pulmonary embolism: review of management strategies with a focus on catheter-based techniques", Expert Rev. Cardiovasc. Ther. 8(6), 863-873 (2010).

Liu, S. et al, "Massive Pulmonary Embolism: Treatment with the Rotarex Thrombectomy System", Cardiovascular Interventional Radiology; 2011: 34:106-113.

Muller-Hulsbeck, S. et al. "Mechanical Thrombectomy of Major and Massive Pulmonary Embolism with Use of the Amplatz Thrombectomy Device", Investigative Radiology, Jun. 2001:36:6:317-322

Reekers, J. et al., "Mechanical Thrombectomy for Early Treatment of Massive Pulmonary Embolism", CardioVascular and Interventional Radiology, 2003: 26:246-250.

Schmitz-Rode et al., "New Mesh Basket for Percutaneous Removal of Wall-Adherent Thrombi in Dialysis Shunts," Cardiovasc Intervent Radiol 16:7-10 1993 4 pgs.

Schmitz-Rode et al., "Temporary Pulmonary Stent Placement as Emergency Treatment of Pulmonary Embolism," Journal of the American College of Cardiology, vol. 48, No. 4, 2006 (5 pgs.).

Schmitz-Rode, T. et al., "Massive Pulmonary Embolism: Percutaneous Emergency Treatment by Pigtail Rotation Catheter", JACC Journal of the American College of Cardiology, Aug. 2000:36:2:375-380.

Spiotta, A et al., "Evolution of thrombectomy approaches and devices for acute stroke: a technical review." J NeuroIntervent Surg 2015, 7, pages 7 pages.

Svilaas, T. et al., "Thrombus Aspiration During Primary Percutaneous Coronary Intervention." The New England Journal of Medicine, 2008, vol. 358, No. 6, 11 pages.

Tapson, V., "Acute Pulmonary Embolism", The New England Journal of Medicine, Mar. 6, 2008:358:2037-52.

The Penumbra Pivotal Stroke Trial Investigators, "The Penumbra Pivotal Stroke Trial: Safety and Effectiveness of a New Generation of Mechanical Devices for Clot Removal in Intracranial Large Vessel Occlusive Disease." Stroke, 2009, 40: page 9 pages.

Truong et al., "Mechanical Thrombectomy of Iliocaval Thrombosis Using a Protective Expandable Sheath," Cardiovasc Intervent Radiol27-254-258, 2004, 5 pgs.

Turk et al., "Adapt Fast study: a direct aspiration first pass technique for acute stroke thrombectomy." J NeuroIntervent Surg, vol. 6, 2014, 6 pages.

Uflacker, R., "Interventional Therapy for Pulmonary Embolism", Journal of Vascular and Interventional Radiology, Feb. 2001: 12:147-164.

Verma, R., Md et al. "Evaluation of a Newly Developed Percutaneous Thrombectomy Basket Device in Sheep With Central Pulmonary Embolisms", *Investigative Radiology*, Oct. 2006, 41, 729-734.

(56) References Cited

OTHER PUBLICATIONS

International Search Report and Written Opinion for International App. No. PCT/US2015/034987 filed Jun. 9, 2015, Applicant: Inceptus Medical, LLC, dated Sep. 17, 2015, 12 pages.

English translation of Japanese Office Action received for JP Application No. 2016-564210, Applicant: Inceptus Medical, LLC, dated Sep. 4, 2017, 4 pages.

Australian Exam Report received for AU Application No. 2015274704, Applicant: Inceptus Medical, LLC, dated Sep. 7, 2017, 3 pages. European Search Report received for EP Application No. 15805810. 7, Applicant: Inceptus Medical, LLC, dated Sep. 4, 2017, 6 pages. International Search Report and Written Opinion for International App. No. PCT/US2016/067628 filed Dec. 19, 2016, Applicant: Inari Medical, Inc., dated Apr. 10, 2017, 11 pages.

Goldhaber, S. et al. "Percutaneous Mechanical Thrombectomy for Acute Pulmonary Embolism—A Double-Edged Sword," American College of CHEST Physicians, Aug. 2007, 132:2, 363-372.

Goldhaber, S., "Advanced treatment strategies for acute pulmonary embolism, including thrombolysis and embolectomy," Journal of Thrombosis and Haemostasis, 2009: 7 (Suppl. 1): 322-327.

International Search Report and Written Opinion for International App. No. PCT/US2017/029696, Date of Filing: Apr. 26, 2017, Applicant: Inari Medical, Inc., dated Sep. 15, 2017, 19 pages.

International Search Report and Written Opinion for International App. No. PCT/US2016/058536, Date of Filing: Oct. 24, 2016, Applicant: Inari Medical, Inc., dated Mar. 13, 2017, 14 pages.

European First Office Action received for EP Application No. 13838945.7, Applicant: Inari Medical, Inc., dated Oct. 26, 2018, 7 pages.

International Search Report and Written Opinion for International App. No. PCT/US2018/048786, Date of Filing: Aug. 30, 2018, Applicant: Inari Medical, Inc., dated Dec. 13, 2018, 12 pages. International Search Report and Written Opinion for International App. No. PCT/US2018/055780, Date of Filing: Oct. 13, 2018, Applicant: Inceptus Medical LLC., dated Jan. 22, 2019, 8 pages. European Search Report for European Application No. 16876941.2, Date of Filing: Dec. 19, 2016, Applicant: Inari Medical, Inc., dated Jul. 18, 2019, 7 pages.

Extended European Search Report for European Application No. 16858462.1, Date of Filing: Oct. 24, 2016, Applicant: Inari Medical, Inc., dated Jun. 3, 2019, 10 pages.

International Search Report and Written Opinion for International App. No. PCT/US2019/045794, Date of Filing: Aug. 8, 2019, Applicant: Inari Medical, Inc., dated Nov. 1, 2019, 17 pages.

Partial Supplementary European Search Report for European Application No. 17864818.4, Date of Filing: May 21, 2019, Applicant: Inari Medical, Inc., dated Apr. 24, 2020, 11 pages.

International Search Report and Written Opinion for International App. No. PCT/US2020/056067, Date of Filing: Oct. 16, 2020; Applicant: Inari Medical, Inc., dated Jan. 22, 2021, 8 pages.

Extended European Search Report for European Application No. 20191581.6, Applicant: Inari Medical, Inc., dated Mar. 31, 2021, 11 pages.

International Search Report and Written Opinion for International App. No. PCT/US2020/055645, Date of Filing: Dec. 17, 2020; Applicant: Inari Medical, Inc., dated Apr. 14, 2021, 12 pages.

Extended European Search Report for European Application No. 18853465.5, Applicant: Inari Medical, Inc., Date of Mailing: May 7, 2021, 2021, 7 pages.

Vorwerk, D. Md, et al., "Use of a Temporary Caval Filter to Assist Percutaneous Iliocaval Thrombectomy: Experimental Results." SCVIR, 1995, 4 pages.

PCT International Search Report and Written Opinion for International Appln. No. PCT/US2020/014854, dated Oct. 5, 2020 (13 pages).

PCT International Search Report and Written Opinion for International Appln. No. PCT/US2020/018655, dated Dec. 16, 2020 (22 pages).

PCT International Search Report and Written Opinion for International Appln. No. PCT/US2020/017684, dated Nov. 30, 2020 (19 pages).

Extended European Search Report for EP Patent Appln. No. 20185092.2 dated Sep. 11, 2020, 6 pages.

EP Examination Report for EP Patent Appln. No. 18745794.0 dated Jul. 20, 2020, 4 pages.

Wikipedia; Embolectomy; retrieved from the internet: https://en.wikipedia.org/wiki/Embolectomy; 4 pgs.; retrieved/printed: Mar. 24, 2016.

O'Sullivan; Thrombolysis versus thrombectomy in acute deep vein thrombosis; Interventional Cardiology 3(5); pp. 589-596; Oct. 2011. Capture Vascular Systems; (company website); retrieved from the internet: http://www.capturevascular.com; 3 pgs.; retrieved/printed: Mar. 24, 2016.

Edwards Lifesciences; Fogarty® Occlusion Catheters (product brochure); retrieved from the internet: http://web.archive.org/web/20150228193218/http://www.edwards.com/products/vascular/atraumaticocclusion/pages/occlusioncatheter.aspx; ©2011; 2 pgs.; retrieved/printed: Mar. 24, 2011.

Boston Scientific; Fetch(TM) 2 Aspiration Catheter (product information); retrieved from the internet: http://www.bostonscientific.com/en-US/products/thrombectomy-systems/fetch2-aspiration-catheter. html; 2 pgs.; retrieved/printed: Mar. 24, 2016.

Penumbra, Inc.; Indigo® System (product information); retrieved from the internet: http://www.penumbrainc.com/peripherallpercutaneous-thromboembolectomy/indigo-system; 7 pgs.; retrieved/printed: Mar. 24, 2016.

Youtube; Merci Retrieval System X Series Animation; uploaded Mar. 16, 2009 (product information); posted on May 7, 2009 by SSMDePAUL, time 1:09, retrieved from the internet: https://www.youtube.com/watch?v=MGX7deuFkhc; 3 pgs.; retrieved/printed: Mar. 24, 2016.

COVIDIEN; Solitaire(TM) AS Neurovascular Remodeling Device (product information); retrieved from the internet: http://www.ev3.net/neuro/intl/remodeling-devices/solitaire-ab.htm; © 2015; 2 pgs.; retrieved/printed: Mar. 24, 2016.

PCT International Search Report and Written Opinion for International Patent Appln. No. PCT/US2019/050467, Applicant Stryker Corporation, dated Dec. 18, 2019 (17 pages).

PCT International Search Report and Written Opinion for International Appln. No. PCT/US2017/029440, Applicant Stryker Corporation, dated Jul. 7, 2017.

PCT International Search Report and Written Opinion for International Appln. No. PCT/US2017/029472, Applicant Stryker Corporation, dated Jul. 7, 2017.

PCT International Search Report and Written Opinion for International Appln. No. PCT/US2017/035543, Applicant Stryker Corporation, dated Aug. 14, 2017.

PCT International Search Report and Written Opinion for International Appln. No. PCT/US2017/029366, Applicant Stryker Corporation, dated Aug. 29, 2017.

PCT International Search Report and Written Opinion for International Appln. No. PCT/US2017/050933, Applicant Stryker Corporation, forms PCT/ISA/210, 220, and 237, dated Nov. 10, 2017 (16 pages).

International search report and written opinion dated Feb. 28, 2018 for PCT/US2017/029345, Applicant Stryker Corporation 26 pages. Extended European Search Report dated Aug. 22, 2018 for European patent appln No. 16852212.6, 6 pages.

Extended European Search Report dated Oct. 5, 2018 for European patent appln No. 18174891.4, 6 pages.

International search report and written opinion dated Nov. 14, 2018 for PCT/US2018/040937, Applicant Stryker Corporation 16 pages. International Search Report and Written Opinion dated Mar. 28, 2019 for International Appln. No. PCT/US2018/059607.

International Search Report and Written Opinion dated May 6, 2016 for PCT/US2016/017982.

PCT International Search Report and Written Opinion for International Patent Appln. No. PCT/US2019/032601, Applicant Stryker Corporation, dated Jul. 23, 2019 (12 pages).

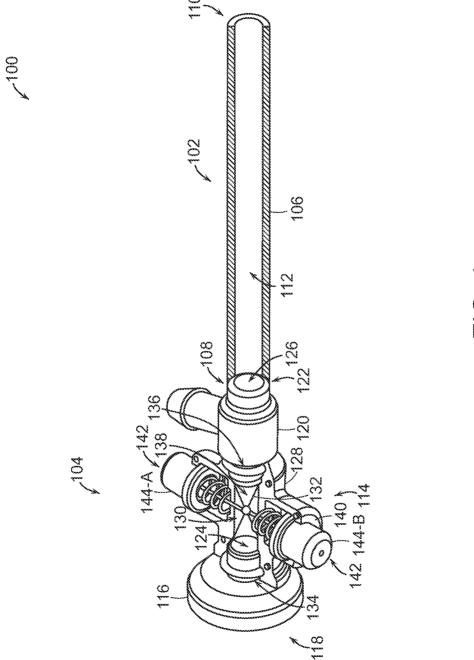
Extended European Search Report dated Oct. 8, 2019 for European Patent Application No. 19191925.7.

(56) References Cited

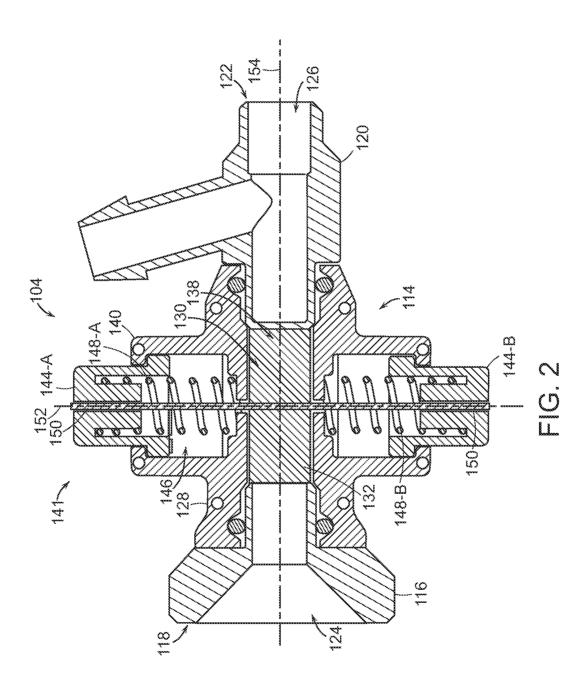
OTHER PUBLICATIONS

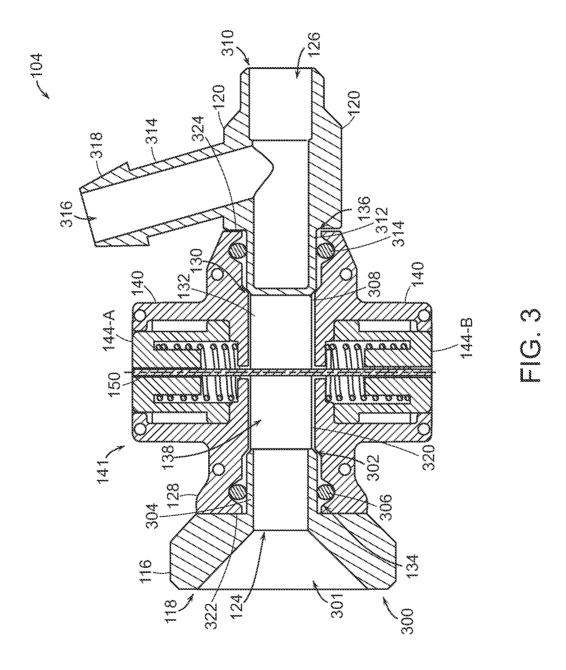
International Search Report and Written Opinion for International Patent Appln. No. PCT/US2019/050410 dated Oct. 25, 2019. International Search Report and Written Opinion for International App. No. PCT/US21/35965, Date of Filing: Jun. 4, 2021, Applicant: Inari Medical, Inc., dated Sep. 28, 2021, 12 pages. International Search Report and Written Opinion for International App. No. PCT/US21/45072 Date of Filing: Aug. 6, 2021, Applicant: Inari Medical, Inc., dated Jan. 20, 2022, 10 pages. International Search Report and Written Opinion for International App. No. PCT/US21/58793; Date of Filing: Nov. 10, 2021, Applicant: Inari Medical, Inc., dated Mar. 16, 2022, 13 pages. International Search Report and Written Opinion for International App. No. PCT/US21/59718; Date of Filing: Nov. 17, 2021, Applicant: Inari Medical, Inc., dated Mar. 22, 2022, 13 pages. International Search Report and Written Opinion for International App. No. PCT/US21/59735; Date of Filing: Nov. 17, 2021, Applicant: Inari Medical, Inc., Date of Mailing: Mar. 22, 2022, 11 pages.

^{*} cited by examiner



<u>С</u>





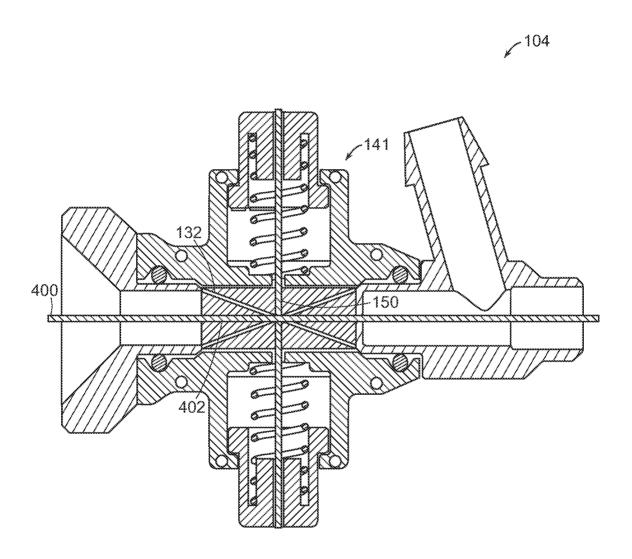


FIG. 4

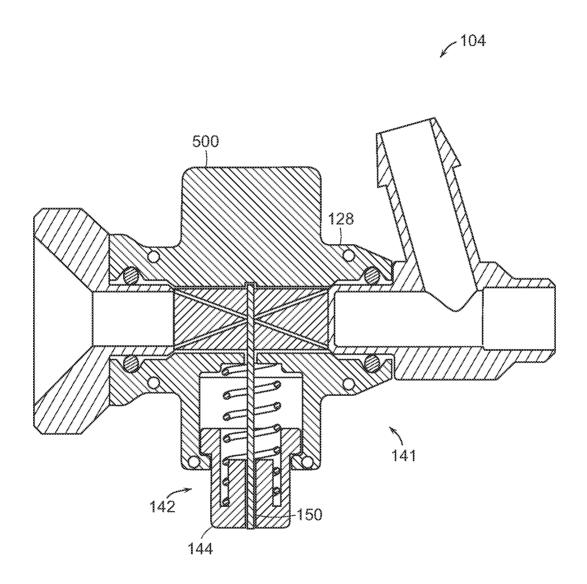


FIG. 5

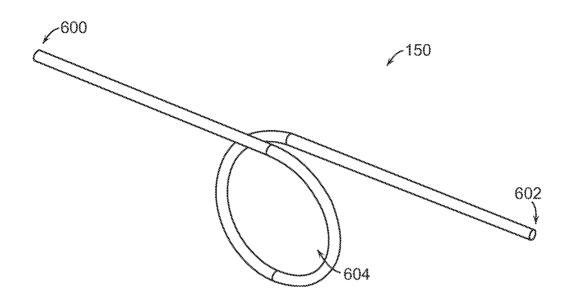
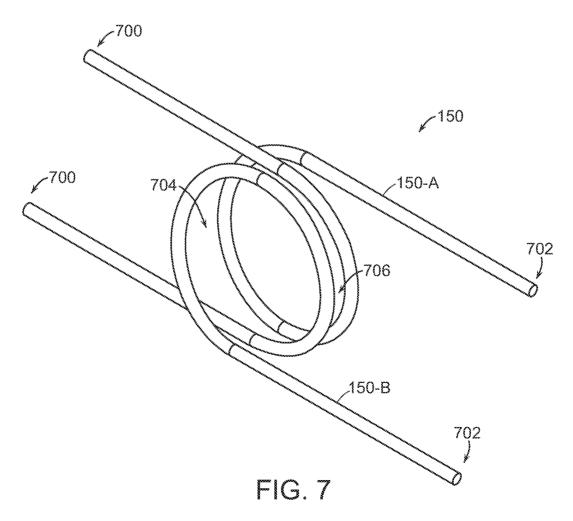


FIG. 6



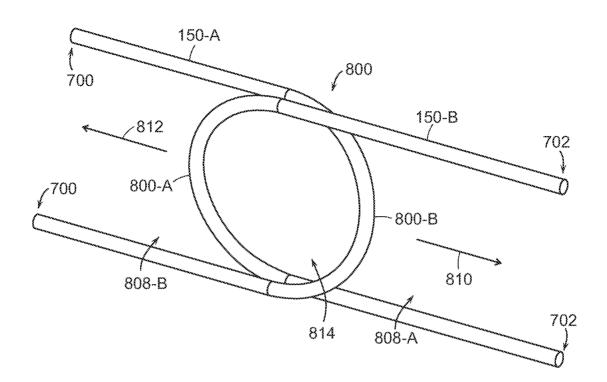


FIG. 8

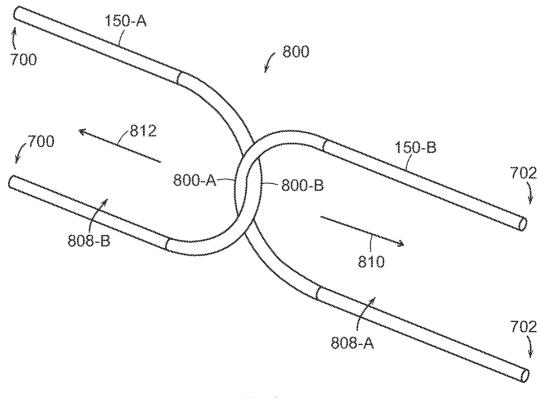


FIG. 9

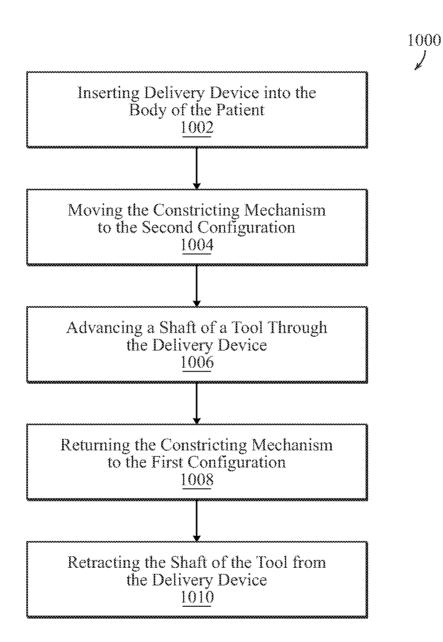
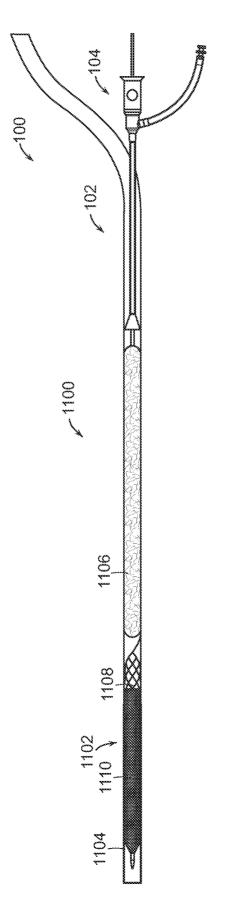
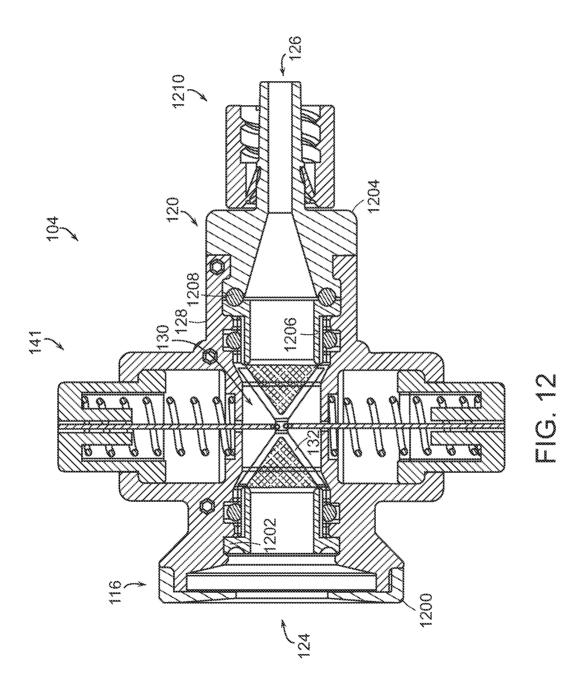


FIG. 10





HEMOSTASIS VALVES AND METHODS OF

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. patent application Ser. No. 17/705,189, filed on Mar. 25, 2022, entitled "HEMOSTASIS VALVES AND METHODS OF USE," which is a continuation of U.S. patent application Ser. No. 17/226,318, filed on Apr. 9, 2021, entitled "HEMOSTASIS VALVES AND METHODS OF USE," which is a continuation of U.S. patent application Ser. No. 16/117,519, filed on Aug. 30, 2018, now issued as U.S. Pat. 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 Sep. 6, 2017, and entitled "HEMOSTASIS VALVES AND METHODS OF USE," each of which is herein incorporated by reference in its entirety.

BACKGROUND

During a surgical procedure, a portion of a patient's body (e.g., vasculature) is accessed to allow for performance of a 25 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 30 for improved patient outcomes has led to the development of hemostasis valves that facilitate minimally invasive surgery.

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 35 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.

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 45 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.

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 55 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

The following relates to valves, medical systems incorporating valves, and methods of using the same. The valve 65 can include a tubular member that can be constricted, collapsed, and/or sealed by one or several tensioning mecha-

2

nisms. 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.

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 hemo-20 static 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.

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 40 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 fila-50 ment, is not coupled to the reinforcement structure.

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 60 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.

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. 5 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 15 forms a second bight around a second portion of the elongate member. In some embodiments, the first bight extends through the second bight.

In some embodiments, the hemostatic valve can include a shell defining a first aperture and a second aperture. In some 20 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 25 some embodiments, the central lumen can comprise a single lumen, and in some embodiments, the central lumen can comprise a plurality of lumens.

One aspect of the present disclosure relates to a delivery system for intravascular access of a blood vessel within a 30 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 35 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 40 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.

In some embodiments, the hemostatic valve further 45 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 50 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 55 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.

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 65 tensioning mechanism from the first configuration to the second configuration can include moving the actuator and

4

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.

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.

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.

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.

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.

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.

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

FIG. 1 is a perspective view of one embodiment of a delivery device.

FIG. 2 is a side-section view of one embodiment of a hemostasis valve in a first configuration.

FIG. 3 is a side-section view of one embodiment of the valve in a second configuration.

FIG. 4 is a side-section view of one embodiment of the valve in the first configuration and with a tool extending through the valve.

FIG. 5 is a side-section view of one embodiment of a single-button hemostasis valve in a first configuration.

FIG. 6 is a perspective view of a filament of a valve forming a loop.

FIG. 7 is a perspective view of two filaments of a valve, 40 each of the filaments forming a loop.

FIG. 8 is a perspective view of two overlapping and interlocked bights in an open configuration.

FIG. **9** is a perspective view of two overlapping and interlocked bights in a closed configuration.

FIG. 10 is a flowchart illustrating one embodiment of a method for sealing a valve and/or catheter.

FIG. 11 is a side view of one embodiment of a thrombectomy system including the delivery device.

FIG. 12 is a side-section view of another embodiment of 50 a hemostasis valve having two-piece caps.

DETAILED DESCRIPTION

The present disclosure relates to a valve that can be used 55 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 60 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 65 robust sealing either with or without a tool extending through the valve. This robust sealing minimizes leakage in

6

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.

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.

With reference now to FIG. 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 45 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.

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.

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 FIG. 1, the distal cap 120 connects to the shaft 106 of the catheter 102 at the distal end 122 of the valve 104.

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 FIG. 1, the housing comprises a two-piece housing 128. The housing 128 can be configured to receive 5 and couple with each of the proximal cap 116 and the distal cap 120, and as seen in FIG. 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.

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 15 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 20 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 25 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 30 silicone tube.

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 35 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 40 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 FIG. 2 and in FIG. 3, is fluidly coupled with the distal aperture 126 of the distal cap 120.

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 50 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 55 a range of +/-10% of the value and/or range of values for which "approximately" is used.

In some embodiments, the elongate member 132 can be cylindrically shaped, and specifically can be circular-cylindrically shaped. In some embodiments, the elongate member 60 132 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, 65 also referred to herein as a tensioning mechanism 141, of the valve 104 to secure a position of all or portions of the

8

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.

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.

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 FIG. 1, the actuator 142 can comprise a first button 144-A and a second button 144-B. Alternatively, and as depicted in FIG. 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.

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 FIG. 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 FIG. 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.

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 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 5 0.8 pounds.

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 10 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, 15 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 20 310. The distal cap can include a mating feature 312 located filament. In some embodiments, the filament 150 can comprise one or several threads, lines, cords, rope, ribbon, flat wire, sheet, or tape.

The filament 150 can be coupled to the actuator 142 such that the filament 150 selectively constricts, collapses, and/or 25 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 35 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 FIG. 5, the filament 150 can be 40 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.

In some embodiments, the at least one filament 150 can extend along an axis 152 that can be perpendicular to a 45 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 50 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.

In FIG. 3, an embodiment of the valve 104 with the constricting mechanism 141 in the second configuration is 55 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 60 unsealing of the central lumen 138 of the elongate member

As further seen in FIG. 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.

The distal cap 120 has a proximal end 308 and a distal end 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.

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.

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.

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.

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 5 150 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 10 between the elongate member 132 and the at least one filament 150.

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 15 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 20 132

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 25 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 30 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 35 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 40 132 between the housing 128 and one or both of the proximal 116 and the distal 120.

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 50 or intermediate range.

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 55 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 60 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.

The lack of coupling of the reinforcement structure 320 to the elongate member 132 can facilitate and improve the 65 collapse of the elongate member 132 around a tool 400, also referred to herein as instrument 400 or device 400, inserted

12

through the valve 104 as shown in FIG. 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 FIG. 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.

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.

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 1×1 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 1×1 configuration made with a nitinol wire having a diameter of 0.003 inches.

With reference now to FIGS. 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 FIG. 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.

In some embodiments, the filament 150 can comprise multiple filaments, and specifically, as shown in FIGS. 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 5 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 10 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

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 20 member 132 can be received as shown in FIG. 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 FIG. 7. The first and second loops 704, 706 can each receive the elongate member 132. 25 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.

more filaments 150 can be coupled to the housing 128 or 15

other portion of the valve 104.

In some embodiments, the filament 150 can be configured 30 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 FIGS. 8 and 9, the bight 800 can comprise multiple bights, and specifically a first bight 800-A and a 35 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 40 containing the filament 150 having multiple loops, one or several of the multiple loops can be interlocking.

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 45 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 50 receiving area 808-B.

As seen in FIGS. 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 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 60 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 65 include the first bight 800-A moving in the direction indicated by the arrow 810 and/or the second bight 800-B

14

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.

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 2.5 mm, less than about 2 mm, less than about 1.5 mm, less than about 1.25 mm, less than about 1 mm, less than about 0.75 mm. less than about 0.5 mm, and/or less than about 0.25 mm. In some embodiments, the filaments can have a diameter or width of between about 0.01 mm and 2.5 mm, between about 0.05 mm and 2 mm, between about 0.1 mm and 1 mm, and/or between about 0.125 mm and 0.70 mm. 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 2.0 mm and in some embodiments less than about 0.5 mm. In some embodiments, the filament(s) 150 can have any desired crosssectional shape including, for example, a circular crosssection, 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.

With reference now to FIG. 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.

After the delivery device 100 is inserted into the body of orientation or first direction as indicated by arrow 810, and 55 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.

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 5 104 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 10 embodiments, after the tool 400 is advanced through the delivery device 100, the desired procedure can be performed with the tool.

After the tool 400 is advanced through the delivery device 100, or while the tool 400 is being advanced through the 15 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 20 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 25 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 30 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 35 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.

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 retracting of the tool 45 400 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 retracting of the tool 400 and/or the 50 shaft 402 of the tool 400.

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 55 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 60 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.

16

With reference now to FIG. 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 selfexpanding coring element 206 and expandable cylindrical portion 208. In some embodiments, and as shown in FIG. 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 Ser. No. 15/268,296, filed Sep. 16, 2016, and entitled "INTRAVASCULAR TREAT-MENT OF VASCULAR OCCLUSION AND ASSOCI-ATED DEVICES, SYSTEMS, AND METHODS"; U.S. application Ser. No. 15/498,320, filed Apr. 26, 2017, and entitled "DEVICES AND METHODS FOR TREATING VASCULAR OCCLUSION"; and U.S. application Ser. No. 15/466,740, filed on Mar. 22, 2017, and entitled "DEVICE AND METHOD FOR TREATING VASCULAR OCCLU-SION", the entirety of each of which is hereby incorporated by reference herein.

With reference now to FIG. 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

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.

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 FIG. 1. In some embodiments, for 15 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 20 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 25 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 FIG. 12, the distal exterior member 1204 can comprise a male luer fitting 1210.

Several aspects of the present technology are set forth in 30 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 35 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 40 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 elon- 45 gate 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 rein- 50 ingreforcement structure is positioned between the at least one a 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 55 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 65 coupled to the at least one filament, wherein the actuator is moveable to control movement of the at least one filament

18

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, $_{20}$ 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 25 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 30 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 35 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 45 filament; or a metallic filament.
- 36. The delivery system of any one of examples 22-35, wherein the catheter comprises a thrombus extraction devices
- 37. A method of sealing a delivery device accessing a 50 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 60 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 65 the tensioning mechanism is in the second configuration; 20

- 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 15 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 5 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.

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 15 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 20 the invention, as defined in the appended claims.

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. 25 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.

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 con- 35 text. 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, 40 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 45 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 50 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 nonclaimed element as essential to the practice of the invention. 55

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 60 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 65 appended hereto as permitted by applicable law. Moreover, any combination of the above-described elements in all

22

possible variations thereof is encompassed by the invention unless otherwise indicated herein or otherwise clearly contradicted by context.

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.

The invention claimed is:

- 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 a 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 5 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 10 filament to circumferentially constrict the collapsible tubular member such that the valve lumen is constricted and sealed.

* * * * *