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(54) **CATHETER SYSTEM AND METHODS OF USING SAME**

(75) Inventors: **Stefan Schreck**, Fallbrook, CA (US); **Elbert Tzeng**, Irvine, CA (US); **Todd Abraham**, Mission Viejo, CA (US); **Jonathan Phan**, Garden Grove, CA (US); **Joshua Benjamin**, Aliso Viejo, CA (US); **Jacqueline Macias**, South Gate, CA (US); **Kevin Chu**, Tustin, CA (US); **William L. Gould**, Fallbrook, CA (US)

(73) Assignee: **Endologix, Inc.**, Irvine, CA (US)

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See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

2,127,903 A 8/1938 Bowen  
2,437,542 A 5/1944 Krippendorf  
2,845,959 A 8/1958 Sidebotham  
2,990,605 A 7/1961 Demsyk

(Continued)

FOREIGN PATENT DOCUMENTS

CA 2220141 11/1996  
DE 295 21 548 U1 2/1995

(Continued)

OTHER PUBLICATIONS

International Search Report and Written Opinion, re PCT/US2012/027151, mailed Jun. 26, 2012.

(Continued)

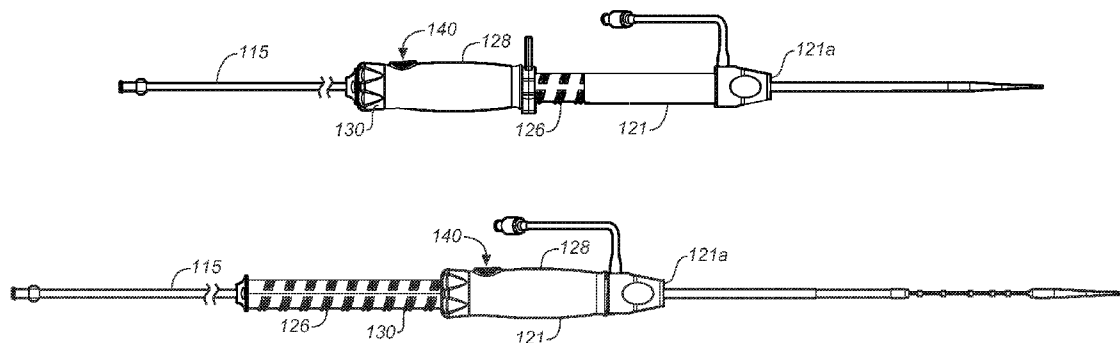
*Primary Examiner* — Jonathan W Miles

(74) *Attorney, Agent, or Firm* — Knobbe Martens Olson & Bear LLP

(57) **ABSTRACT**

A modular catheter system including a sheath projecting distally from a delivery catheter having a main body module. An inner core module carrying a stent thereon, the inner core being axially movable through the main body of the delivery catheter and the delivery catheter sheath, a handle member supported by the main body of the delivery catheter, the handle member being selectively axially engageable with the inner core such that the handle member and the inner core move together in an axial direction when the handle member is engaged with the inner core; and an adjustment member supported by the main body, the adjustment member being configured such that rotation of the adjustment member causes the adjustment member to move axially along the main body by either axially sliding the handle member relative to the main body or by rotating the adjustment member.

**23 Claims, 32 Drawing Sheets**



*Imperative Care v. Inari Medical*  
US Patent 12,109,384  
**Imperative Care Ex. 1043**

(56)

References Cited

U.S. PATENT DOCUMENTS

3,029,819 A	4/1962	Starks	5,484,444 A	1/1996	Braunschweiler et al.
3,096,560 A	7/1963	Liebig	5,489,295 A	2/1996	Piplani et al.
3,805,301 A	4/1974	Liebig	5,496,365 A	3/1996	Sgro
4,362,156 A	12/1982	Feller, Jr. et al.	5,507,727 A	4/1996	Crainich
4,473,067 A	9/1984	Schiff	5,507,767 A	4/1996	Maeda et al.
4,497,074 A	2/1985	Ray et al.	5,507,769 A	4/1996	Marin et al.
4,501,263 A	2/1985	Harbuck	5,507,771 A	4/1996	Gianturco
4,503,568 A	3/1985	Madras	5,522,880 A	6/1996	Barone et al.
4,525,157 A	6/1985	Vaillancourt	5,522,881 A	6/1996	Lentz
4,562,596 A	1/1986	Kornberg	5,522,883 A	6/1996	Slater et al.
4,580,568 A	4/1986	Gianturco	5,545,211 A	8/1996	An et al.
4,592,754 A	6/1986	Gupte et al.	5,554,118 A	9/1996	Jang
4,617,932 A	10/1986	Kornberg	5,554,181 A	9/1996	Das
4,723,550 A *	2/1988	Bales et al. .... 606/108	5,562,697 A	10/1996	Christiansen
4,723,938 A	2/1988	Goodin et al.	5,562,726 A	10/1996	Chuter
4,756,307 A	7/1988	Crownshield	5,562,728 A	10/1996	Lazarus et al.
4,768,507 A	9/1988	Fischell et al.	5,571,173 A	11/1996	Parodi
4,800,882 A	1/1989	Gianturco	5,575,816 A	11/1996	Rudnick et al.
4,816,028 A	3/1989	Kapadia et al.	5,575,818 A	11/1996	Pinchuk
4,840,940 A	6/1989	Sottiturai	5,578,071 A	11/1996	Parodi
4,856,516 A	8/1989	Hillstead	5,578,072 A	11/1996	Barone et al.
4,878,906 A	11/1989	Lindemann et al.	5,591,197 A	1/1997	Orth et al.
4,907,336 A	3/1990	Gianturco	5,591,198 A	1/1997	Boyle et al.
4,922,905 A	5/1990	Strecker	5,591,229 A	1/1997	Parodi
4,981,478 A	1/1991	Evard et al.	5,591,230 A	1/1997	Horn et al.
4,981,947 A	1/1991	Tomagou et al.	5,593,417 A	1/1997	Rhodes
4,994,069 A	2/1991	Ritchrt et al.	5,604,435 A	2/1997	Foo et al.
4,994,071 A	2/1991	MacGregor	5,607,445 A	3/1997	Summers
5,019,090 A	5/1991	Pinchuk	5,609,625 A	3/1997	Piplani et al.
5,035,706 A	7/1991	Giantureo et al.	5,609,627 A	3/1997	Goicoechea et al.
5,064,435 A	11/1991	Porter	5,609,628 A	3/1997	Keranan
5,078,726 A	1/1992	Kreamer	5,628,755 A	5/1997	Heller et al.
5,084,010 A *	1/1992	Plaia et al. .... 604/22	5,628,783 A	5/1997	Quiachon et al.
5,104,399 A	4/1992	Lazarus	5,628,786 A	5/1997	Banas et al.
5,108,424 A	4/1992	Hoffman, Jr. et al.	5,628,788 A	5/1997	Pinchuk
5,116,349 A	5/1992	Aranyi	5,630,829 A	5/1997	Lauterjung
5,123,917 A	6/1992	Lee	5,630,830 A	5/1997	Verbeek
5,133,732 A	7/1992	Wiktor	5,632,763 A	5/1997	Glastra
5,135,535 A	8/1992	Kramer	5,632,772 A	5/1997	Alcime et al.
5,135,536 A	8/1992	Hillstead	5,639,278 A	6/1997	Dereume et al.
5,156,619 A	10/1992	Ehrenfeld	5,641,373 A	6/1997	Shannon et al.
5,178,634 A	1/1993	Martinez	5,643,171 A	7/1997	Bradshaw et al.
5,197,976 A	3/1993	Herweck et al.	5,643,278 A	7/1997	Wijay
5,201,757 A	4/1993	Heyn et al.	5,647,857 A	7/1997	Anderson et al.
5,211,658 A	5/1993	Clouse	5,649,952 A	7/1997	Lam
5,222,969 A	6/1993	Gillis	5,651,174 A	7/1997	Schwartz et al.
5,256,141 A	10/1993	Gancheff et al.	5,653,727 A	8/1997	Wiktor
5,275,622 A	1/1994	Lazarus et al.	5,653,743 A	8/1997	Martin
5,282,824 A	2/1994	Gianturco	5,653,746 A	8/1997	Schmitt
5,282,860 A	2/1994	Matsuno et al.	5,653,747 A	8/1997	Dereume
5,304,200 A	4/1994	Spaulding	5,662,580 A	9/1997	Bradshaw et al.
5,314,444 A	5/1994	Gianturco	5,662,614 A	9/1997	Edoga
5,314,472 A	5/1994	Fontaine	5,662,675 A	9/1997	Polanskyj Stockert et al.
5,316,023 A	5/1994	Palmaz et al.	5,662,700 A	9/1997	Lazarus
5,320,602 A	6/1994	Karpiel	5,662,701 A	9/1997	Plaia et al.
5,324,306 A *	6/1994	Makower et al. .... 606/213	5,662,702 A	9/1997	Keranan
5,330,500 A	7/1994	Song	5,662,703 A	9/1997	Yurek et al.
5,342,387 A	8/1994	Summers	5,665,115 A	9/1997	Cragg
5,350,397 A	9/1994	Palermo et al.	5,665,117 A	9/1997	Rhodes
5,354,308 A	10/1994	Simon et al.	5,669,880 A	9/1997	Solar
5,360,443 A	11/1994	Barone et al.	5,669,924 A	9/1997	Shaknovich
5,366,504 A	11/1994	Andersen et al.	5,669,934 A	9/1997	Sawyer
5,370,683 A	12/1994	Fontaine	5,674,241 A	10/1997	Bley et al.
5,387,235 A	2/1995	Chuter	5,674,276 A	10/1997	Andersen et al.
5,397,355 A	3/1995	Marin et al.	5,676,671 A	10/1997	Inoue
5,405,377 A	4/1995	Cragg	5,676,685 A	10/1997	Razaivi
5,415,664 A	5/1995	Pinchuk	5,676,696 A	10/1997	Marcade
5,423,886 A	6/1995	Arru et al.	5,676,697 A	10/1997	McDonald
5,425,765 A	6/1995	Tiefenbrun et al.	5,679,400 A	10/1997	Tuch
5,443,477 A	8/1995	Marin et al.	5,681,345 A	10/1997	Tuteneuer
5,443,498 A	8/1995	Fontaine	5,681,346 A	10/1997	Orth et al.
5,443,500 A	8/1995	Sigwart	5,683,448 A	11/1997	Cragg
5,458,615 A	10/1995	Klemm et al.	5,683,449 A	11/1997	Marcade
5,462,530 A	10/1995	Jang	5,683,450 A	11/1997	Goicoechea et al.
5,464,450 A	11/1995	Buscemi et al.	5,683,451 A	11/1997	Lenker et al.
			5,683,452 A	11/1997	Barone et al.
			5,683,453 A	11/1997	Palmaz
			5,690,642 A	11/1997	Osborne et al.
			5,690,643 A	11/1997	Wijay

(56)

## References Cited

## U.S. PATENT DOCUMENTS

5,690,644 A	11/1997	Yurek et al.	5,961,546 A	10/1999	Robinson et al.
5,693,066 A	12/1997	Rupp et al.	5,961,548 A	10/1999	Shmulewitz
5,693,084 A	12/1997	Chuter	5,976,153 A *	11/1999	Fischell et al. .... 623/1.11
5,693,086 A	12/1997	Goicoechea et al.	5,976,155 A	11/1999	Foreman et al.
5,693,087 A	12/1997	Parodi	6,004,347 A	12/1999	McNamara et al.
5,693,088 A	12/1997	Lazarus	6,004,348 A	12/1999	Banas et al.
5,695,516 A	12/1997	Fischell et al.	6,017,363 A	1/2000	Hojeibane
5,695,517 A	12/1997	Marin et al.	6,027,779 A	2/2000	Campbell et al.
5,697,948 A *	12/1997	Marin et al. .... 606/198	6,027,811 A	2/2000	Campbell et al.
5,700,269 A *	12/1997	Pinchuk et al. .... 606/108	6,030,415 A	2/2000	Chuter
5,713,917 A	2/1998	Leonhardt	6,039,749 A	3/2000	Marin et al.
5,716,365 A	2/1998	Goicoechea et al.	6,039,755 A	3/2000	Edwin et al.
5,716,393 A	2/1998	Lindenberg et al.	6,039,758 A	3/2000	Quiachon et al.
5,718,724 A	2/1998	Goicoechea et al.	6,045,557 A	4/2000	White et al.
5,718,973 A	2/1998	Lewis et al.	6,051,020 A	4/2000	Goicoechea et al.
5,720,735 A	2/1998	Dorros	6,053,940 A	4/2000	Wijay
5,720,776 A	2/1998	Chuter et al.	6,068,635 A	5/2000	Gianotti
5,723,004 A	3/1998	Dereume et al.	6,070,589 A	6/2000	Keith et al.
5,725,519 A	3/1998	Penner et al.	6,074,398 A	6/2000	Leschinsky
5,733,325 A	3/1998	Robinson et al.	6,077,295 A	6/2000	Limon et al.
5,738,674 A	4/1998	Williams et al.	6,077,296 A	6/2000	Shokoohi et al.
5,746,776 A	5/1998	Smith et al.	6,077,297 A	6/2000	Robinson et al.
5,749,880 A	5/1998	Banas et al.	6,086,611 A	7/2000	Duffy et al.
5,749,921 A	5/1998	Lenker et al.	6,090,128 A	7/2000	Douglas
5,755,770 A	5/1998	Ravenscroft	6,096,027 A	8/2000	Layne
5,755,771 A	5/1998	Penn et al.	6,106,548 A	8/2000	Reubin et al.
5,755,777 A	5/1998	Chuter	6,110,180 A	8/2000	Foreman et al.
5,769,885 A	6/1998	Quiachon et al.	6,117,142 A	9/2000	Goodson et al.
5,769,887 A	6/1998	Brown et al.	6,117,167 A	9/2000	Goicoechea et al.
5,776,142 A	7/1998	Gunderson	6,123,722 A	9/2000	Fogarty et al.
5,782,855 A	7/1998	Lau et al.	6,123,723 A	9/2000	Konya et al.
5,792,144 A *	8/1998	Fischell et al. .... 606/108	6,126,685 A	10/2000	Lenker et al.
5,797,952 A	8/1998	Klein	6,129,756 A	10/2000	Kugler et al.
5,800,456 A	9/1998	Maeda et al.	6,132,458 A	10/2000	Stachle et al.
5,800,508 A	9/1998	Goicoechea et al.	6,146,415 A	11/2000	Fitz
5,800,526 A	9/1998	Anderson et al.	6,149,680 A	11/2000	Shelso et al.
5,810,836 A	9/1998	Hussein et al.	6,152,944 A	11/2000	Holman et al.
5,810,873 A	9/1998	Morales	6,168,610 B1	1/2001	Marin et al.
5,817,100 A	10/1998	Igaki	6,171,281 B1	1/2001	Zhang
5,824,037 A	10/1998	Fogarty et al.	6,183,481 B1	2/2001	Lee et al.
5,824,039 A *	10/1998	Piplani et al. .... 623/1.11	6,183,509 B1	2/2001	Dibie
5,824,041 A	10/1998	Lenker et al.	6,187,036 B1	2/2001	Shaolian
5,824,053 A	10/1998	Khosravi et al.	6,192,944 B1	2/2001	Greenhalgh
5,843,092 A	12/1998	Heller et al.	6,197,049 B1	3/2001	Shaolian et al.
5,843,160 A	12/1998	Rhodes	6,203,735 B1	3/2001	Edwin et al.
5,843,162 A	12/1998	Inoue	6,254,609 B1	7/2001	Vrba et al.
5,843,164 A	12/1998	Frantzen et al.	6,258,099 B1	7/2001	Mareiro et al.
5,843,167 A	12/1998	Dwyer et al.	6,261,316 B1	7/2001	Shaolian et al.
5,851,228 A	12/1998	Pinheiro	6,273,909 B1	8/2001	Kugler et al.
5,855,599 A	1/1999	Wan	6,280,466 B1	8/2001	Kugler et al.
5,860,998 A	1/1999	Robinson et al.	6,280,467 B1	8/2001	Leonhardt
5,867,432 A	2/1999	Toda	6,283,991 B1	9/2001	Cox et al.
5,868,783 A	2/1999	Tower	6,302,893 B1	10/2001	Limon et al.
5,871,536 A	2/1999	Lazarus	6,348,066 B1	2/2002	Pinchuk et al.
5,879,321 A	3/1999	Hill	6,350,278 B1	2/2002	Lenker et al.
5,879,366 A	3/1999	Shaw et al.	6,352,553 B1	3/2002	Van der Burg et al.
5,891,193 A	4/1999	Robinson et al.	6,352,561 B1	3/2002	Leopold et al.
5,893,887 A	4/1999	Jayaraman	6,355,060 B1	3/2002	Lenker et al.
5,902,334 A	5/1999	Dwyer et al.	6,361,557 B1	3/2002	Gittings et al.
5,906,619 A *	5/1999	Olson et al. .... 606/108	6,361,637 B2	3/2002	Martin et al.
5,906,640 A	5/1999	Penn et al.	6,379,365 B1 *	4/2002	Diaz .... 606/108
5,906,641 A	5/1999	Thompson et al.	6,395,017 B1	5/2002	Dwyer et al.
5,910,145 A *	6/1999	Fischell et al. .... 606/108	6,395,018 B1	5/2002	Castaneda
5,911,752 A	6/1999	Dustrude et al.	6,395,019 B2	5/2002	Chobotov
5,916,263 A	6/1999	Goicoechea et al.	6,398,807 B1	6/2002	Chouinard et al.
5,919,225 A	7/1999	Lau et al.	6,409,750 B1	6/2002	Hyodoh et al.
5,925,075 A	7/1999	Myers et al.	6,409,757 B1	6/2002	Trout, III et al.
5,925,076 A *	7/1999	Inoue .... 606/198	6,416,474 B1	7/2002	Penner et al.
5,928,279 A	7/1999	Shannon et al.	6,416,542 B1	7/2002	Marcade et al.
5,935,135 A	8/1999	Bramfitt et al.	6,432,131 B1	8/2002	Ravenscroft
5,935,161 A	8/1999	Robinson et al.	6,432,134 B1	8/2002	Anson et al.
5,938,696 A	8/1999	Goicoechea et al.	6,464,721 B1	10/2002	Marcade et al.
5,948,018 A	9/1999	Dereume et al.	6,468,298 B1	10/2002	Pelton
5,954,729 A	9/1999	Bachmann et al.	6,475,166 B1	11/2002	Escano
5,957,973 A	9/1999	Quiachon et al.	6,475,170 B1	11/2002	Doron et al.
			6,491,719 B1	12/2002	Fogarty et al.
			6,500,202 B1	12/2002	Shaolian et al.
			6,508,790 B1	1/2003	Lawrence
			6,508,833 B2	1/2003	Pavcnick et al.

(56)

References Cited

U.S. PATENT DOCUMENTS

6,508,835 B1	1/2003	Shaolian et al.	7,105,016 B2 *	9/2006	Shiu et al. ....	623/1.12
6,511,325 B1	1/2003	Lalka et al.	7,122,051 B1	10/2006	Dallara et al.	
6,514,281 B1	2/2003	Blaeser et al.	7,122,052 B2	10/2006	Greenhalgh	
6,517,572 B2	2/2003	Kugler et al.	7,125,464 B2	10/2006	Chobotov et al.	
6,517,573 B1	2/2003	Pollock et al.	7,127,789 B2	10/2006	Stinson	
6,520,988 B1	2/2003	Colombo et al.	7,137,993 B2	11/2006	Acosta et al.	
6,524,335 B1	2/2003	Hartley et al.	7,160,318 B2	1/2007	Greenberg et al.	
6,533,811 B1	3/2003	Ryan et al.	7,163,715 B1	1/2007	Kramer	
6,551,350 B1	4/2003	Thornton et al.	7,175,652 B2	2/2007	Cook et al.	
6,554,848 B2	4/2003	Boylan et al.	7,175,657 B2	2/2007	Khan et al.	
6,558,396 B1	5/2003	Inoue	7,189,256 B2	3/2007	Smith	
6,562,063 B1	5/2003	Euteneuer et al.	7,201,770 B2	4/2007	Johnson et al.	
6,565,596 B1	5/2003	White et al.	7,235,095 B2	6/2007	Haverkost et al.	
6,565,597 B1	5/2003	Fearnot et al.	7,241,308 B2	7/2007	Andreas et al.	
6,569,192 B1	5/2003	Foreman et al.	7,244,444 B2	7/2007	Bates	
RE38,146 E	6/2003	Palmaz et al.	7,261,733 B1	8/2007	Brown et al.	
6,572,643 B1	6/2003	Gharibadeh	7,264,631 B2	9/2007	DiCarlo	
6,572,645 B2	6/2003	Leonhardt	7,264,632 B2	9/2007	Wright et al.	
6,576,006 B2	6/2003	Limon et al.	7,267,685 B2	9/2007	Butaric et al.	
6,576,009 B2	6/2003	Ryan et al.	7,270,675 B2	9/2007	Chun et al.	
6,582,459 B1 *	6/2003	Lau et al. ....	7,297,156 B2	11/2007	Nelson	
6,582,460 B1	6/2003	Cryer	7,300,454 B2 *	11/2007	Park et al. ....	623/1.11
6,585,758 B1	7/2003	Chouinard et al.	7,314,483 B2	1/2008	Landau et al.	
6,589,251 B2	7/2003	Yee et al.	7,316,708 B2	1/2008	Gordon et al.	
6,592,614 B2	7/2003	Lenker et al.	7,320,703 B2	1/2008	DiMatteo et al.	
6,592,615 B1	7/2003	Marcade et al.	7,381,216 B2	6/2008	Buzzard et al.	
6,607,551 B1	8/2003	Sullivan et al.	7,402,168 B2	7/2008	Acosta et al.	
6,613,073 B1	9/2003	White et al.	7,419,501 B2	9/2008	Chiu et al.	
6,613,075 B1	9/2003	Healy et al.	7,435,253 B1	10/2008	Hartley et al.	
6,616,675 B1	9/2003	Evvard et al.	7,473,271 B2	1/2009	Gunderson	
6,620,191 B1	9/2003	Svensson	7,476,244 B2	1/2009	Buzzard et al.	
6,652,579 B1	11/2003	Cox et al.	7,491,230 B2	2/2009	Holman et al.	
6,669,716 B1 *	12/2003	Gilson et al. ....	7,520,895 B2	4/2009	Douglas et al.	
6,669,718 B2	12/2003	Besselink	7,553,324 B2	6/2009	Andreas et al.	
6,673,102 B1	1/2004	Vonesh et al.	7,572,289 B2	8/2009	Sisken et al.	
6,676,667 B2	1/2004	Mareiro et al.	7,578,838 B2	8/2009	Melsheimer	
6,699,274 B2	3/2004	Stinson	7,635,382 B2	12/2009	Pryor	
6,702,845 B1	3/2004	Cully et al.	7,637,932 B2	12/2009	Bolduc et al.	
6,733,523 B2	5/2004	Shaolian et al.	7,651,519 B2	1/2010	Dittman	
6,743,210 B2	6/2004	Hart et al.	7,666,219 B2	2/2010	Rasmussen et al.	
6,749,627 B2	6/2004	Thompson et al.	7,674,284 B2	3/2010	Melsheimer	
6,752,819 B1	6/2004	Brady et al.	7,691,135 B2	4/2010	Shaolian et al.	
6,761,733 B2	7/2004	Chobotov et al.	7,717,923 B2	5/2010	Kennedy, II et al.	
6,767,359 B2	7/2004	Weadock	7,722,657 B2	5/2010	Hartley	
6,818,014 B2	11/2004	Brown et al.	7,736,383 B2	6/2010	Bressler et al.	
6,821,292 B2	11/2004	Pazienza et al.	7,736,384 B2	6/2010	Bressler et al.	
6,866,669 B2	3/2005	Buzzard et al.	7,758,625 B2	7/2010	Wu et al.	
6,887,256 B2	5/2005	Gilson et al.	7,763,063 B2 *	7/2010	Arbefeuille et al. ....	623/1.11
6,899,728 B1	5/2005	Phillips et al.	7,766,952 B2	8/2010	Horan et al.	
6,911,039 B2 *	6/2005	Shiu et al. ....	7,771,463 B2	8/2010	Ton et al.	
6,923,829 B2	8/2005	Boyle et al.	7,785,361 B2	8/2010	Nikolchev et al.	
6,926,732 B2	8/2005	Derus et al.	7,799,266 B2	9/2010	Parker et al.	
6,929,661 B2	8/2005	Bolduc et al.	7,833,259 B2	11/2010	Boatman	
6,932,837 B2	8/2005	Amplatz et al.	7,837,724 B2	11/2010	Keeble et al.	
6,939,352 B2	9/2005	Buzzard et al.	7,842,066 B2	11/2010	Gilson et al.	
6,939,371 B2	9/2005	Kugler et al.	7,867,267 B2	1/2011	Sullivan et al.	
6,939,377 B2	9/2005	Jayaraman et al.	7,879,081 B2	2/2011	DiMatteo et al.	
6,942,692 B2	9/2005	Landau et al.	7,883,537 B2	2/2011	Grayzel et al.	
6,942,693 B2	9/2005	Chouinard et al.	7,935,140 B2	5/2011	Griffin	
6,953,475 B2	10/2005	Shaolian et al.	8,002,814 B2	8/2011	Kennedy, II et al.	
6,960,217 B2	11/2005	Bolduc	8,021,420 B2	9/2011	Dolan	
6,981,982 B2	1/2006	Armstrong et al.	8,062,344 B2	11/2011	Dorn et al.	
6,984,244 B2	1/2006	Perez et al.	8,075,607 B2	12/2011	Melsheimer	
6,994,722 B2	2/2006	DiCarlo	8,075,608 B2	12/2011	Gordon et al.	
7,004,964 B2	2/2006	Thompson et al.	8,092,508 B2	1/2012	Leynov et al.	
7,004,967 B2	2/2006	Chouinard et al.	8,167,892 B2	5/2012	Feller, III et al.	
7,014,653 B2	3/2006	Ouriel et al.	8,182,522 B2	5/2012	Sarac et al.	
7,022,133 B2	4/2006	Yee et al.	2002/0049412 A1	4/2002	Madrid et al.	
7,025,773 B2	4/2006	Gittings et al.	2002/0120322 A1 *	8/2002	Thompson et al. ....	623/1.11
7,025,779 B2	4/2006	Elliott	2002/0193806 A1 *	12/2002	Moening et al. ....	606/108
7,029,496 B2	4/2006	Rakos et al.	2003/0004560 A1	1/2003	Chobotov et al.	
7,052,511 B2	5/2006	Weldon et al.	2003/0065386 A1	4/2003	Weadock	
7,056,323 B2	6/2006	Mareiro et al.	2003/0074043 A1	4/2003	Thompson	
7,074,236 B2	7/2006	Rabkin et al.	2003/0083730 A1	5/2003	Stinson	
7,101,390 B2	9/2006	Nelson	2003/0097169 A1	5/2003	Brucker et al.	
			2003/0125751 A1 *	7/2003	Griffin et al. ....	606/108
			2003/0167060 A1 *	9/2003	Buzzard et al. ....	606/108
			2003/0225445 A1	12/2003	Derus et al.	
			2004/0006380 A1	1/2004	Buck et al.	

(56)

References Cited

U.S. PATENT DOCUMENTS

2004/0039400 A1\* 2/2004 Schmieding et al. .... 606/108  
 2004/0111095 A1\* 6/2004 Gordon et al. .... 606/108  
 2004/0167618 A1 8/2004 Shaolian et al.  
 2004/0176832 A1 9/2004 Hartley et al.  
 2004/0193180 A1\* 9/2004 Buzzard et al. .... 606/108  
 2005/0021123 A1 1/2005 Dorn et al.  
 2005/0027305 A1\* 2/2005 Shiu et al. .... 606/108  
 2005/0027345 A1 2/2005 Horan et al.  
 2005/0038494 A1 2/2005 Eidenschink  
 2005/0049607 A1\* 3/2005 Hart et al. .... 606/108  
 2005/0058327 A1 3/2005 Pieper  
 2005/0059994 A1 3/2005 Walak et al.  
 2005/0060025 A1 3/2005 Mackiewicz et al.  
 2005/0080476 A1 4/2005 Gunderson et al.  
 2005/0113693 A1 5/2005 Smith et al.  
 2005/0113905 A1 5/2005 Greenberg et al.  
 2005/0119731 A1 6/2005 Brucker et al.  
 2005/0121120 A1 6/2005 Van Dijk et al.  
 2005/0125002 A1\* 6/2005 Baran et al. .... 606/108  
 2005/0159803 A1 7/2005 Lad et al.  
 2005/0165480 A1 7/2005 Jordan et al.  
 2005/0171598 A1 8/2005 Schaeffer  
 2005/0171599 A1 8/2005 White  
 2005/0240153 A1 10/2005 Opie  
 2005/0240258 A1 10/2005 Bolduc et al.  
 2005/0240260 A1 10/2005 Bolduc  
 2006/0129223 A1 6/2006 Jabbour et al.  
 2006/0200223 A1 9/2006 Andreas et al.  
 2006/0212107 A1 9/2006 Case et al.  
 2006/0233990 A1 10/2006 Humphrey et al.  
 2006/0233991 A1 10/2006 Humphrey et al.  
 2006/0265045 A1\* 11/2006 Shiu et al. .... 623/1.11  
 2006/0276872 A1 12/2006 Arbefeulle et al.  
 2007/0010867 A1 1/2007 Carter et al.  
 2007/0043421 A1 2/2007 Mangiardi et al.  
 2007/0043430 A1 2/2007 Stinson  
 2007/0055339 A1 3/2007 George et al.  
 2007/0118207 A1 5/2007 Amplatz et al.  
 2007/0156224 A1 7/2007 Cioanta et al.  
 2007/0168014 A1\* 7/2007 Jimenez et al. .... 623/1.12  
 2007/0203571 A1 8/2007 Kaplan et al.  
 2007/0213805 A1 9/2007 Schaeffer et al.  
 2007/0260301 A1 11/2007 Chuter et al.  
 2008/0082154 A1 4/2008 Tseng et al.  
 2008/0125849 A1 5/2008 Burpee et al.  
 2008/0294230 A1 11/2008 Parker  
 2009/0030495 A1 1/2009 Koch  
 2009/0099638 A1 4/2009 Grewe  
 2009/0105798 A1 4/2009 Koch  
 2009/0138065 A1 5/2009 Zhang et al.  
 2009/0192586 A1 7/2009 Tabor et al.  
 2009/0254165 A1\* 10/2009 Tabor et al. .... 623/1.11  
 2009/0276028 A1 11/2009 Bailey et al.  
 2010/0030318 A1 2/2010 Berra  
 2010/0094393 A1 4/2010 Cordeiro et al.  
 2010/0114290 A1 5/2010 Rasmussen et al.  
 2010/0168834 A1 7/2010 Ryan et al.  
 2010/0179635 A1 7/2010 Dittman  
 2010/0274270 A1\* 10/2010 Patel et al. .... 606/159  
 2010/0274340 A1 10/2010 Hartley et al.  
 2011/0009945 A1 1/2011 Parker et al.  
 2011/0046712 A1\* 2/2011 Melsheimer et al. .... 623/1.11  
 2011/0218607 A1\* 9/2011 Arbefeulle et al. .... 623/1.11  
 2011/0251664 A1\* 10/2011 Acosta De Acevedo .... 623/1.11  
 2011/0257718 A1\* 10/2011 Argentine .... 623/1.11

2011/0270371 A1\* 11/2011 Argentine ..... 623/1.11  
 2011/0282425 A1\* 11/2011 Dwork ..... 623/1.11  
 2011/0313503 A1\* 12/2011 Berra et al. .... 623/1.11  
 2012/0109279 A1\* 5/2012 Mayberry et al. .... 623/1.11  
 2012/0123517 A1\* 5/2012 Ouellette et al. .... 623/1.12

FOREIGN PATENT DOCUMENTS

DE 295 21 776 U1 2/1995  
 EP 0 177 330 B1 6/1991  
 EP 0 596 145 A1 5/1994  
 EP 0 621 015 B1 10/1994  
 EP 0 659 389 A1 6/1995  
 EP 0 688 545 B1 12/1995  
 EP 0 689 806 A1 1/1996  
 EP 0 712 614 A1 5/1996  
 EP 0 732 088 A2 9/1996  
 EP 0 732 088 A3 9/1996  
 EP 0 740 928 A1 11/1996  
 EP 0 740 928 B1 11/1996  
 EP 0 747 020 A2 12/1996  
 EP 0 775 470 A1 5/1997  
 EP 0 783 873 A2 7/1997  
 EP 0 783 873 B1 7/1997  
 EP 0 783 874 A2 7/1997  
 EP 0 783 874 B1 7/1997  
 EP 0 880 948 A1 12/1998  
 EP 0 904 745 A2 3/1999  
 EP 0 974 314 A2 1/2000  
 EP 0 732 088 B1 4/2000  
 EP 1 358 903 A2 11/2003  
 EP 2 680 915 1/2014  
 ES 1 038 606 7/1998  
 JP 04-25755 1/1992  
 JP 08-336597 12/1996  
 JP 9-511160 11/1997  
 JP 2000-500047 1/2000  
 WO 93/13825 7/1993  
 WO 94/24961 11/1994  
 WO 95/21592 8/1995  
 WO 96/34580 11/1996  
 WO 96/39999 12/1996  
 WO 96/41589 12/1996  
 WO 97/10757 3/1997  
 WO 97/10777 3/1997  
 WO 97/14375 4/1997  
 WO 97/17911 5/1997  
 WO 97/19652 6/1997  
 WO 97/26936 7/1997  
 WO 97/33532 9/1997  
 WO 97/45072 12/1997  
 WO 98/02100 1/1998  
 WO 98/53761 12/1998  
 WO 99/29262 6/1999  
 WO 99/44536 9/1999  
 WO 99/47077 9/1999  
 WO 99/58084 11/1999  
 WO 2005/037076 4/2005  
 WO 2005/067819 7/2005  
 WO 2012/118901 9/2012

OTHER PUBLICATIONS

International Preliminary Report on Patentability, re PCT/US2012/027151, mailed Sep. 12, 2013, in 8 pages.  
 US 6,413,270, 07/2002, Thornton et al. (withdrawn)

\* cited by examiner

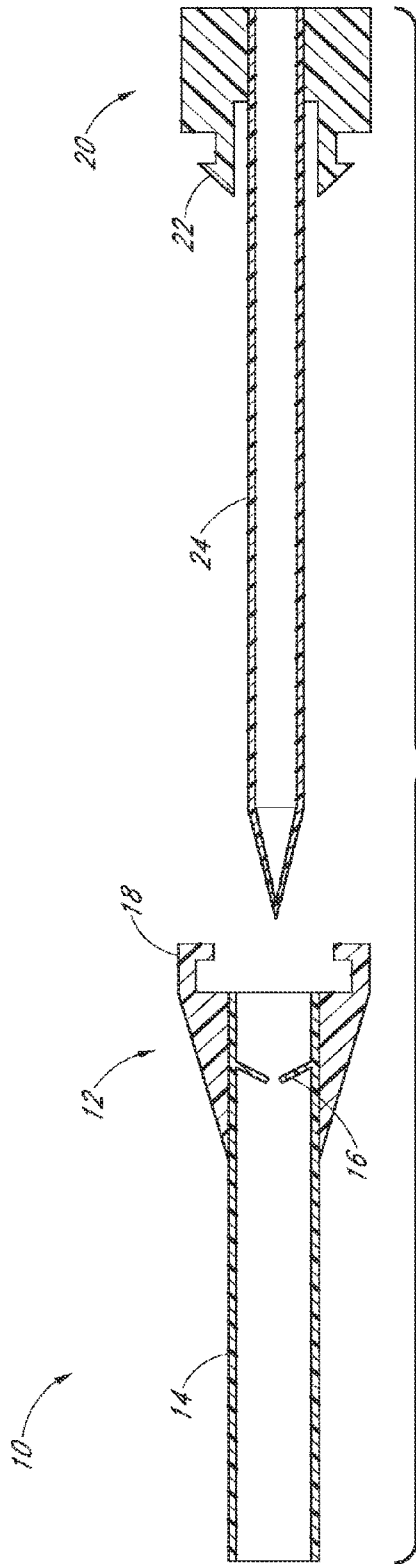


FIG. 1A

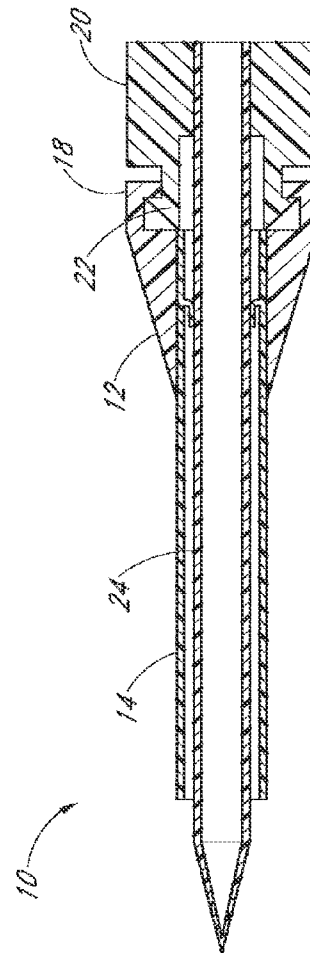


FIG. 1B

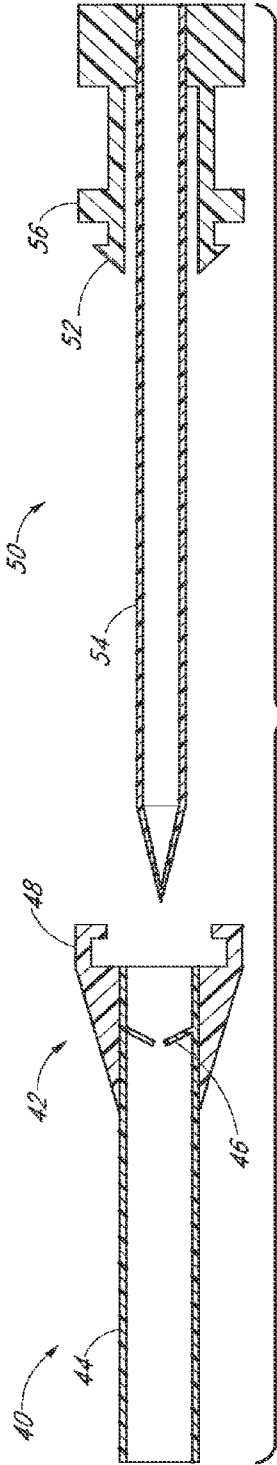


FIG. 2A

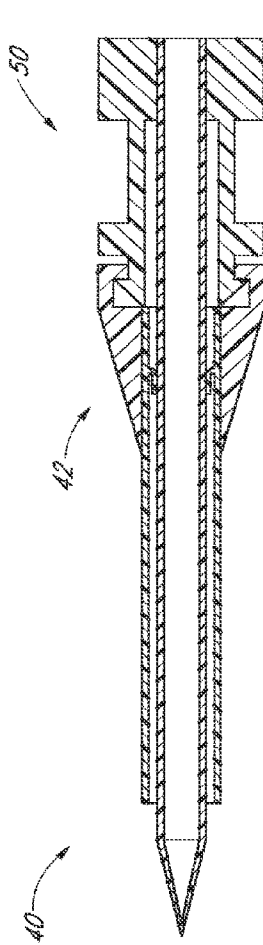


FIG. 2B

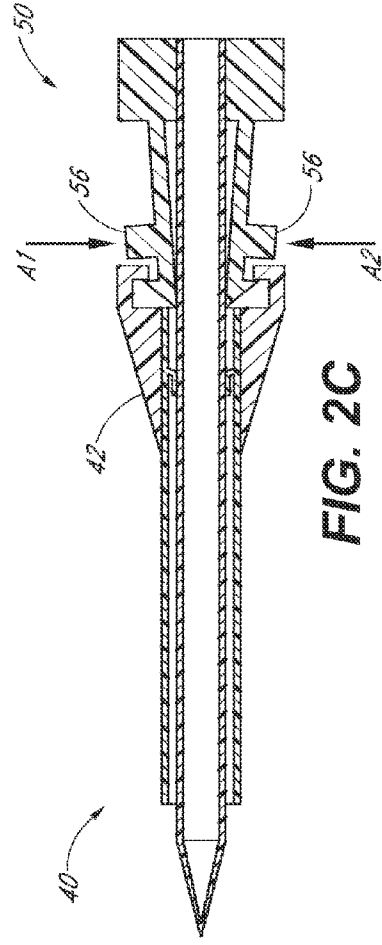


FIG. 2C

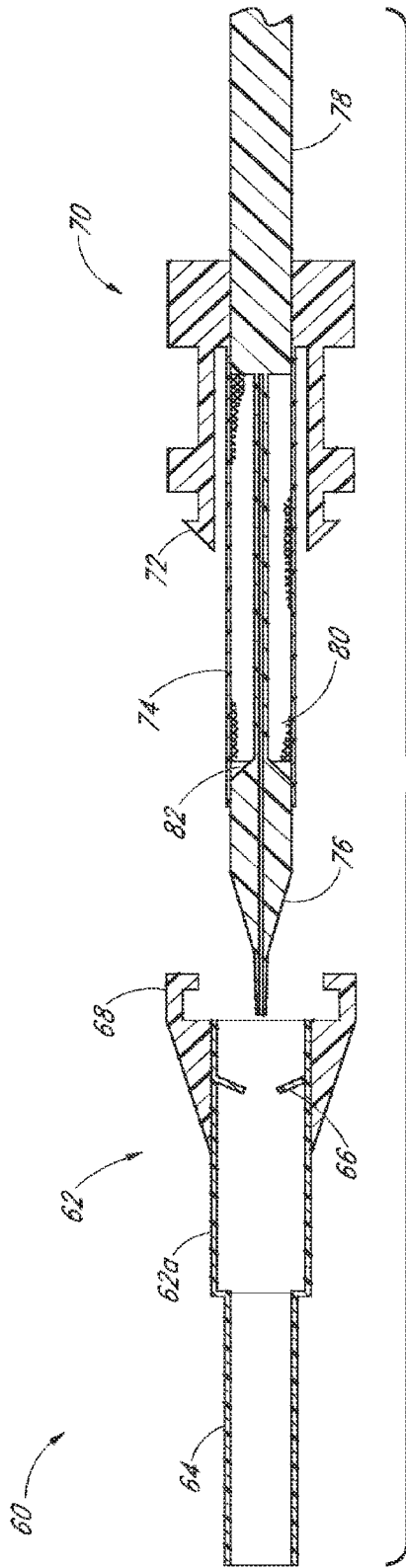


FIG. 3A

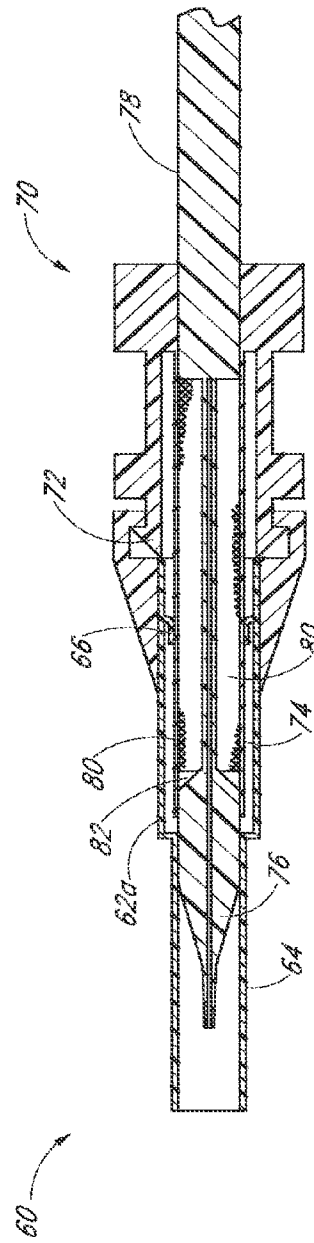


FIG. 3B

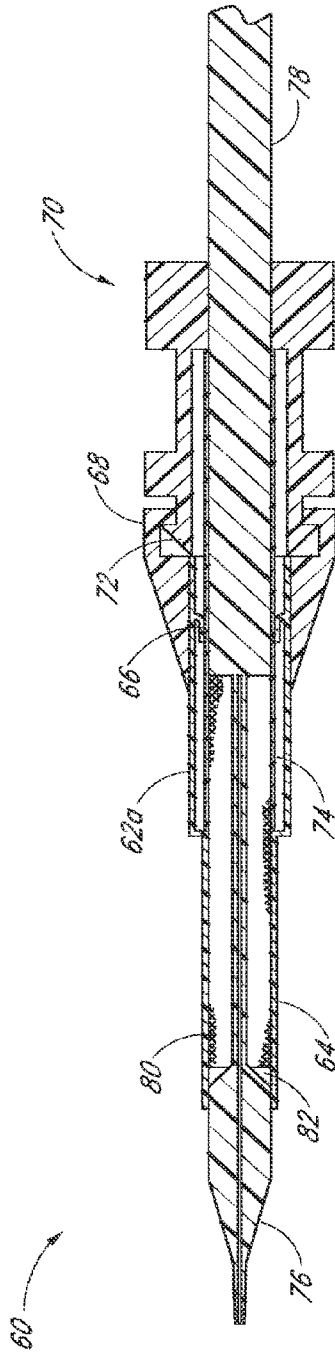


FIG. 3C

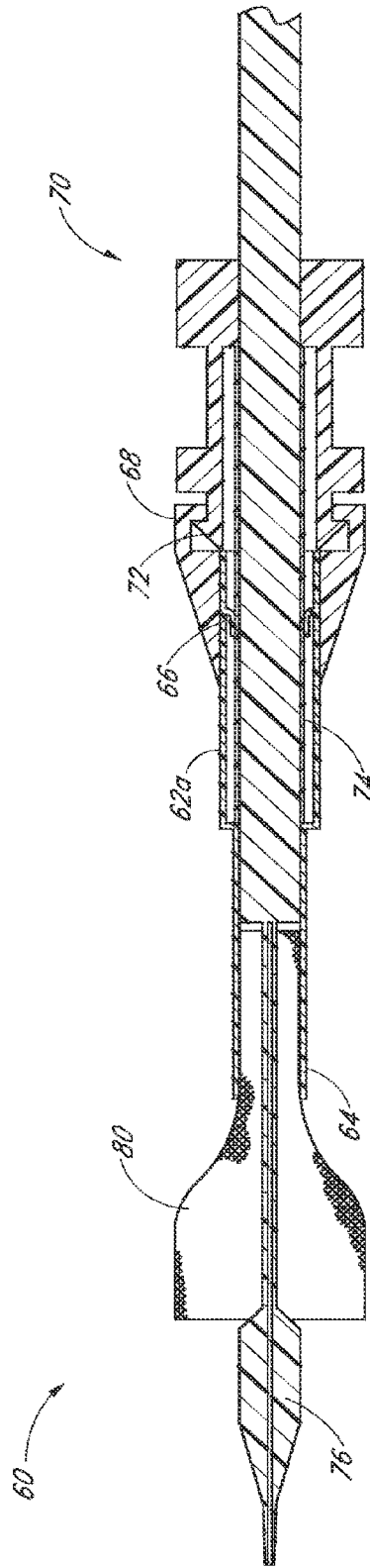


FIG. 3D

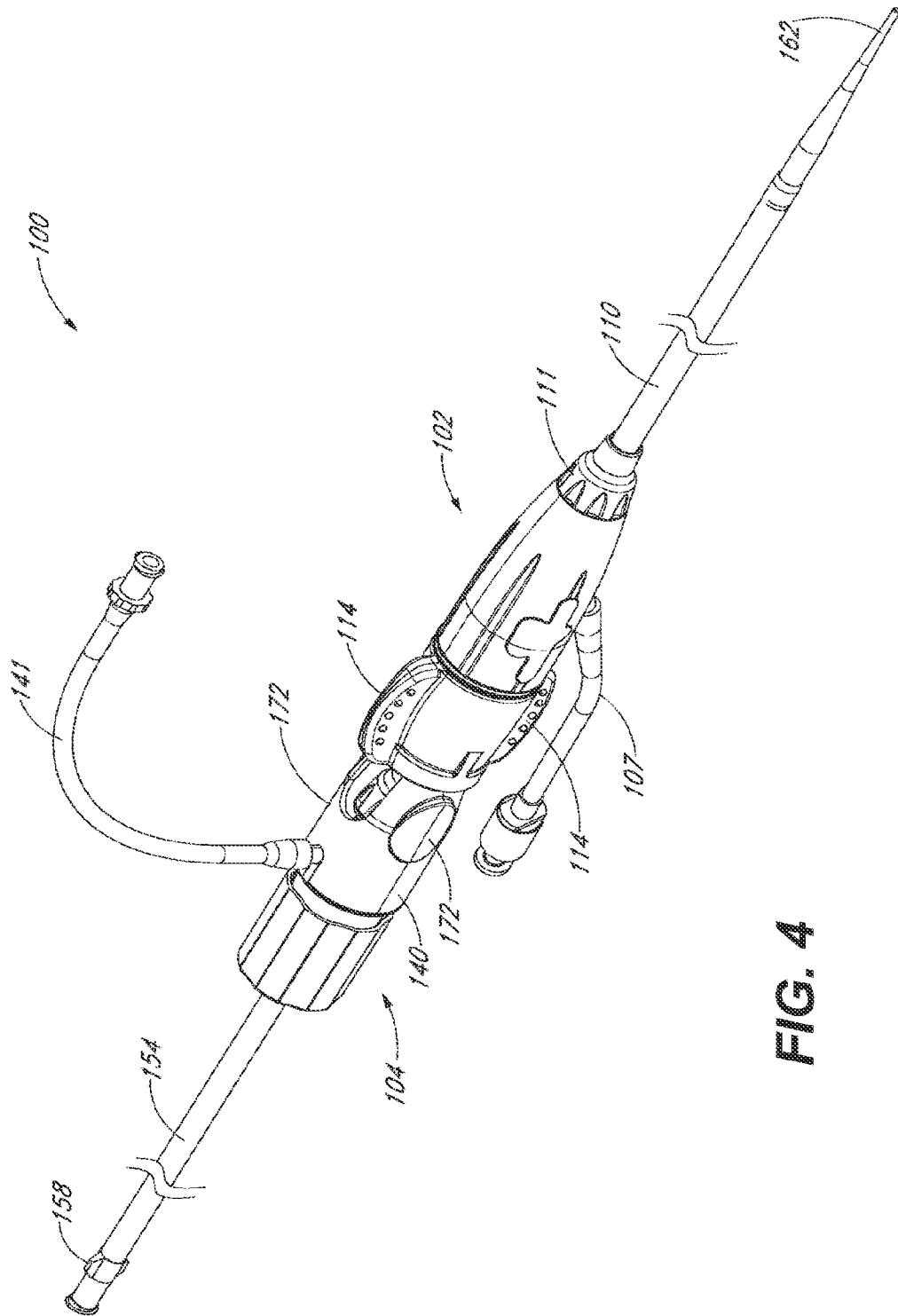
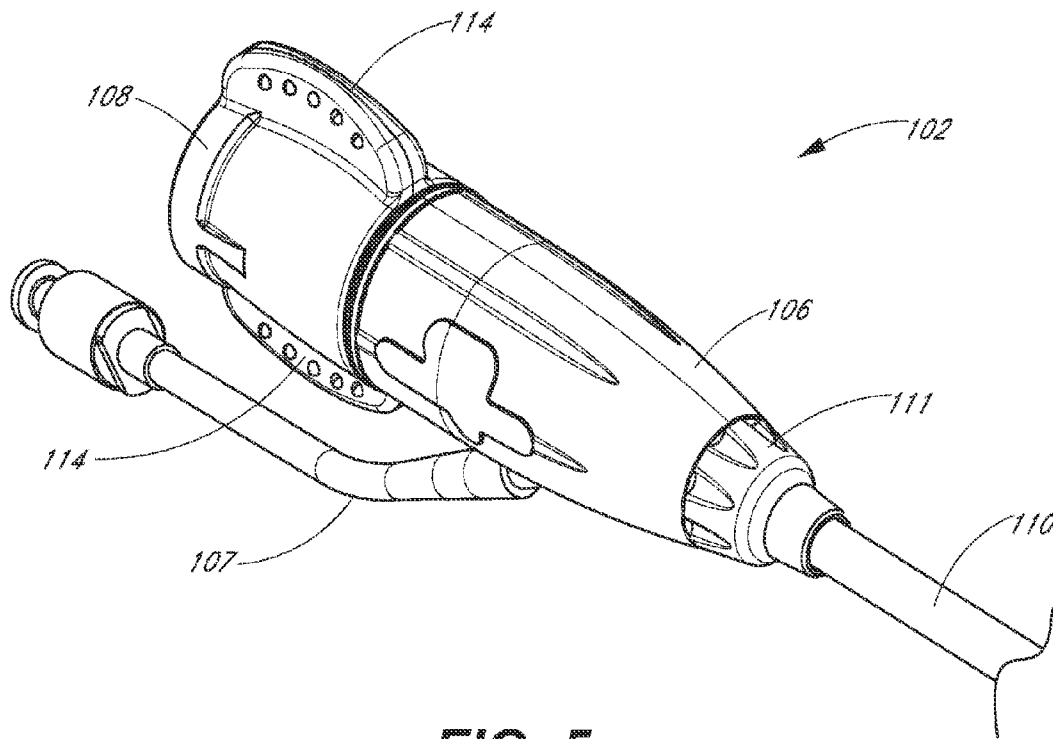


FIG. 4



**FIG. 5**

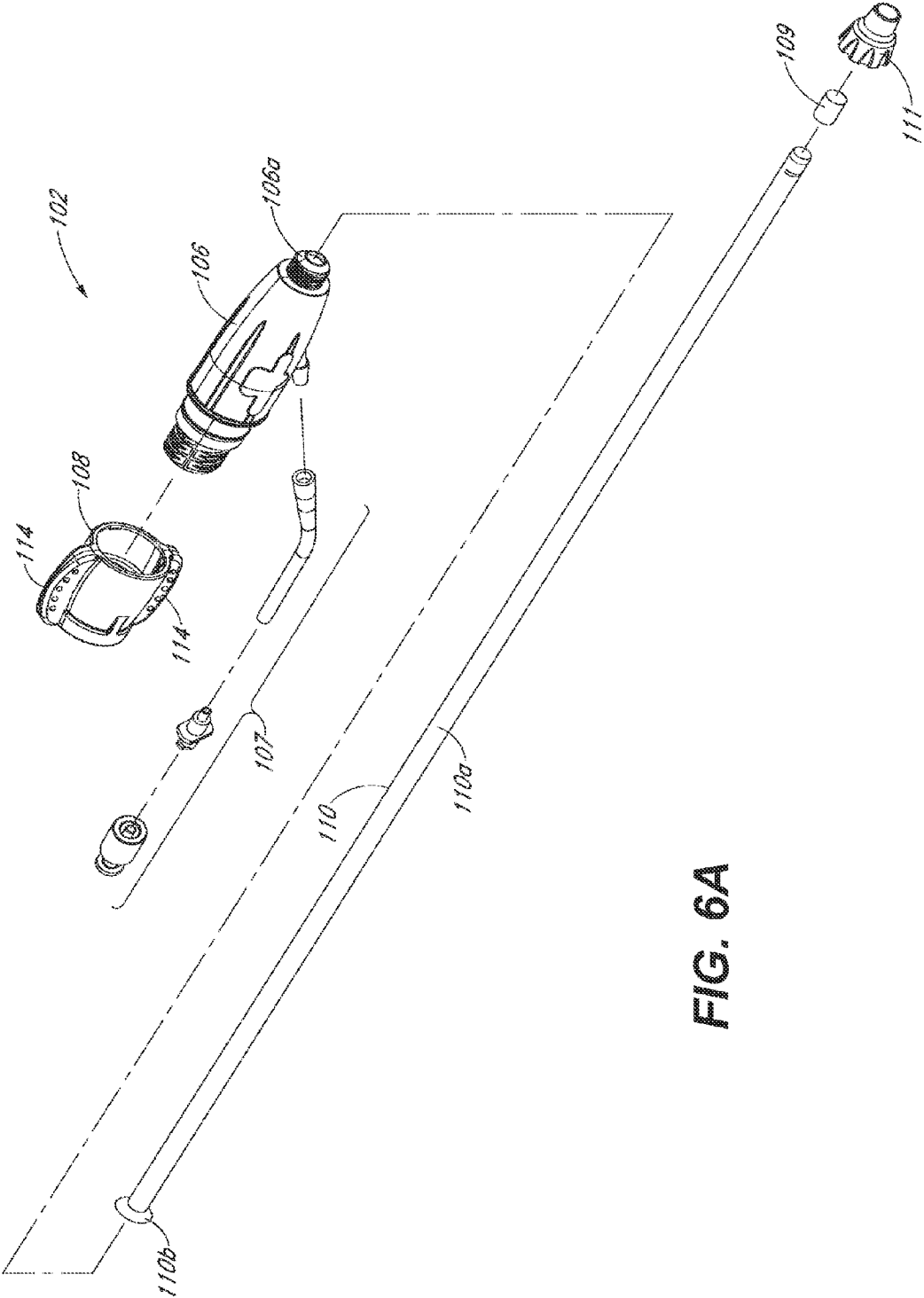


FIG. 6A

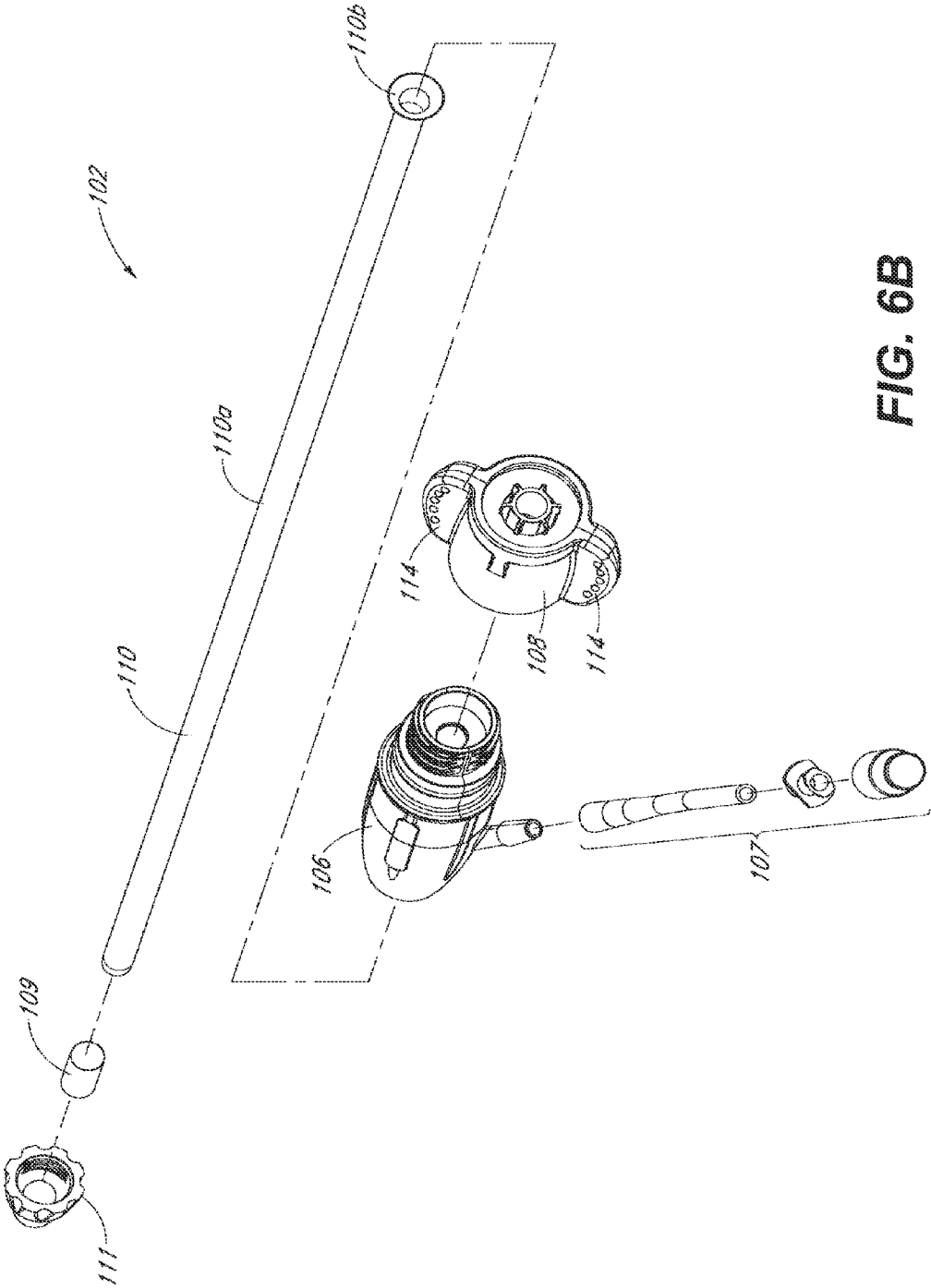


FIG. 6B

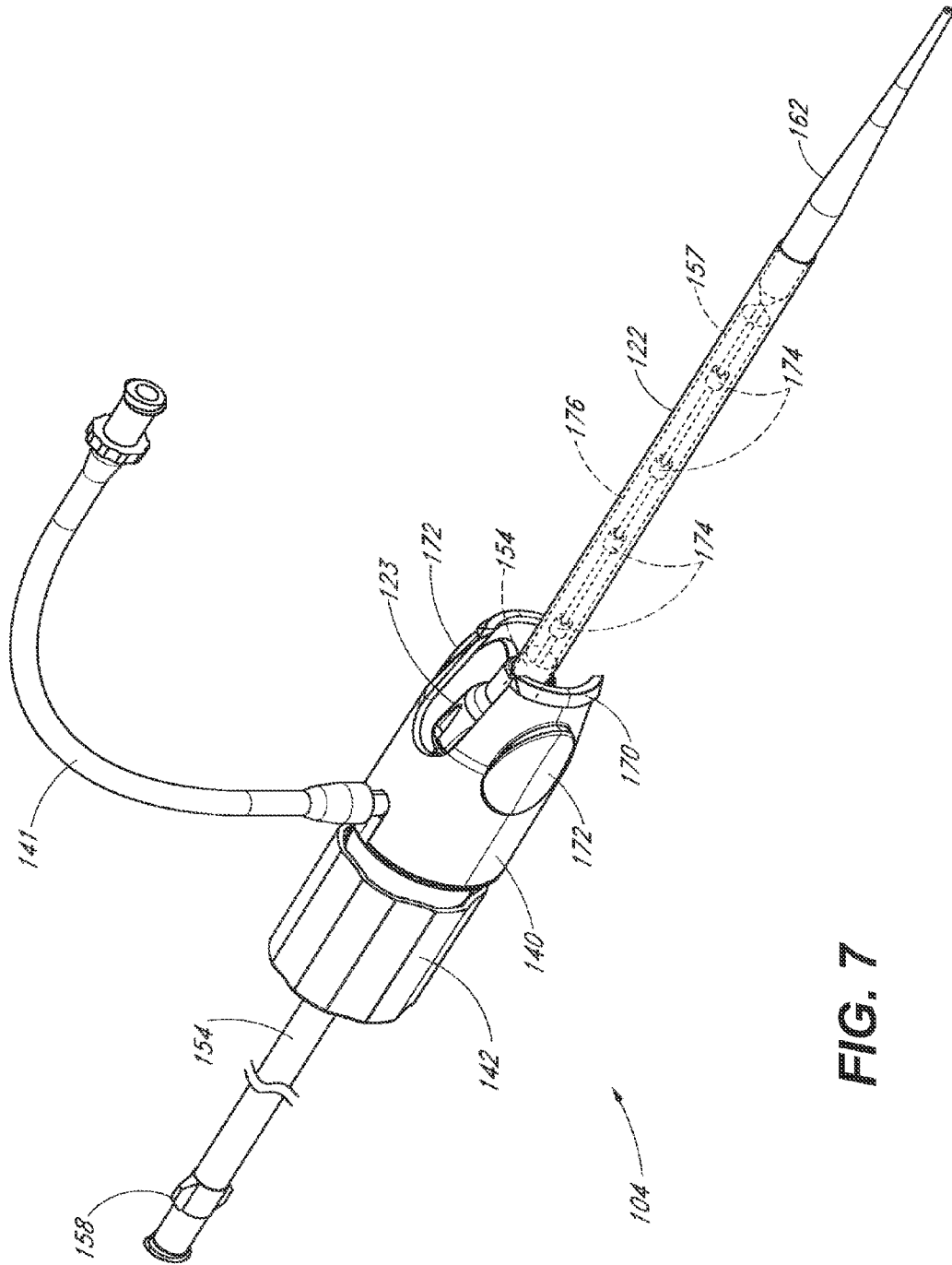


FIG. 7

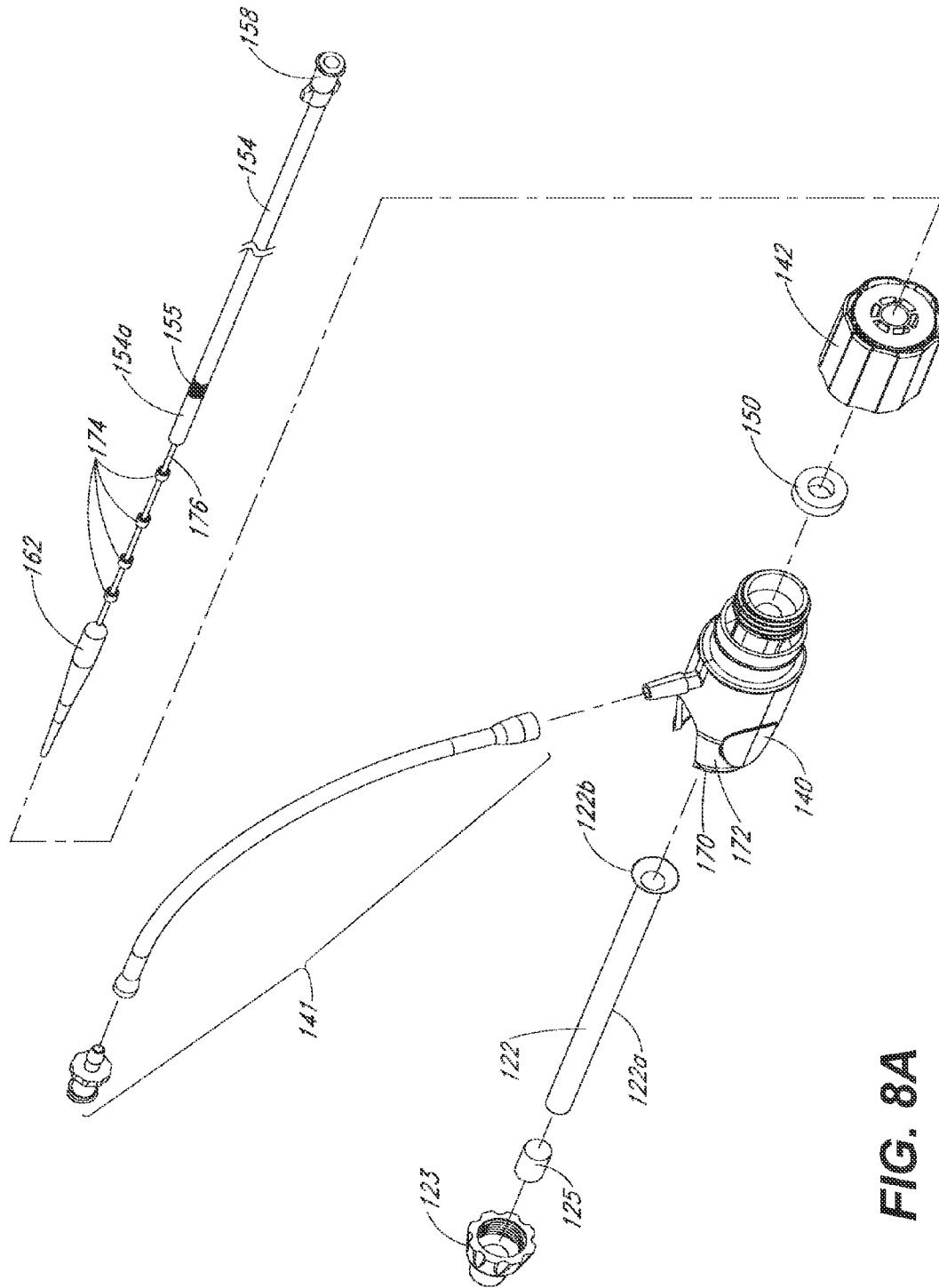


FIG. 8A



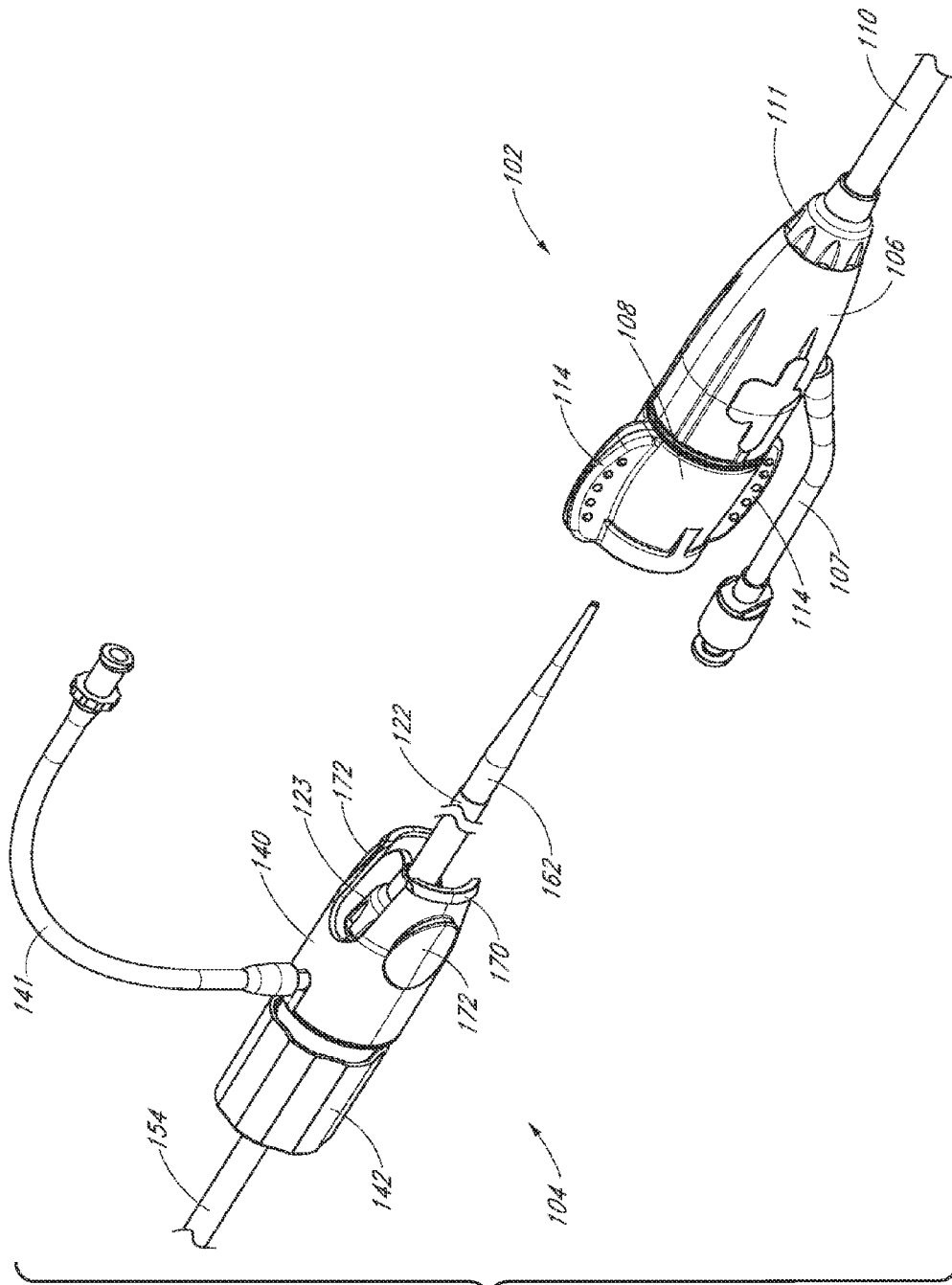


FIG. 9

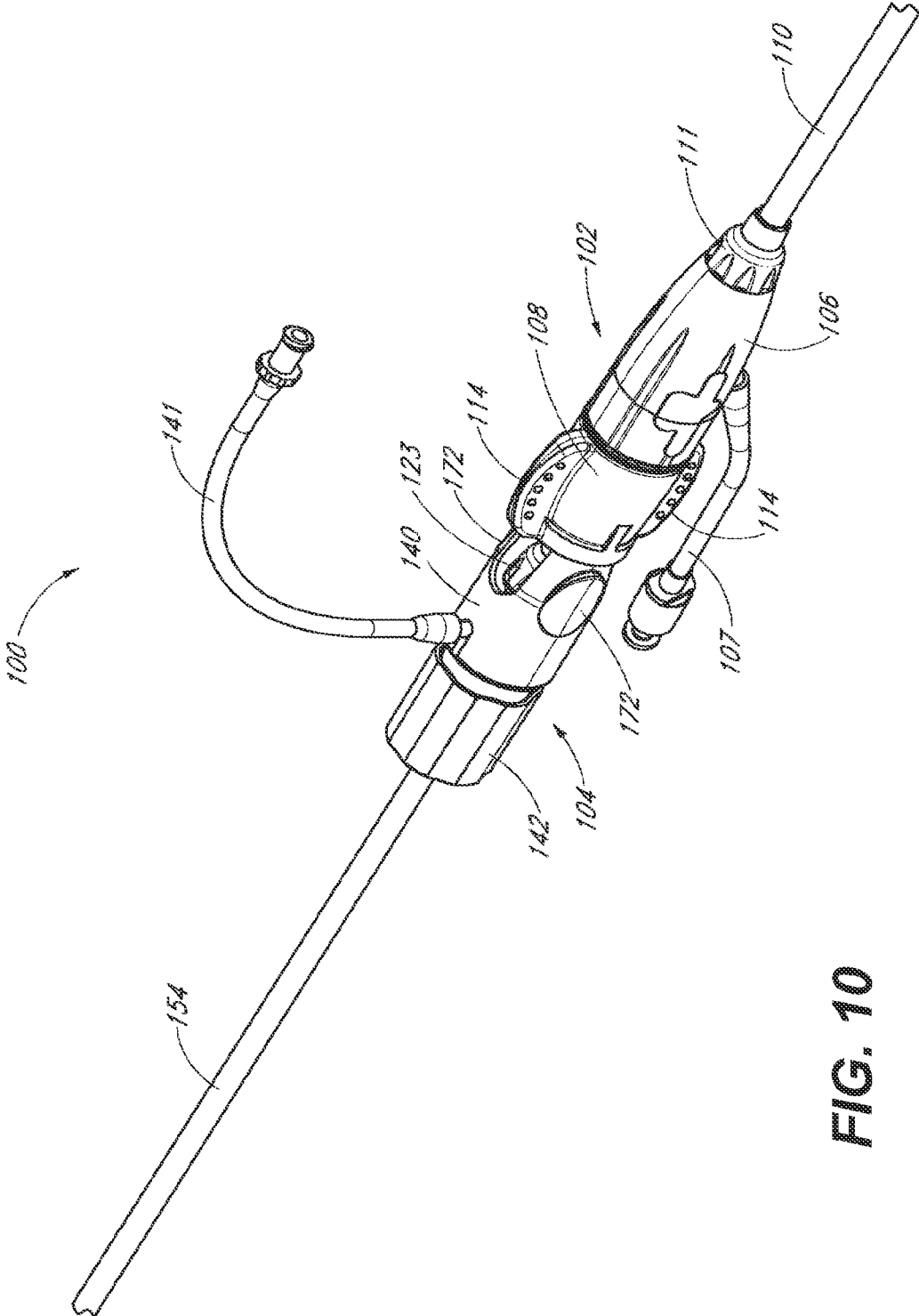
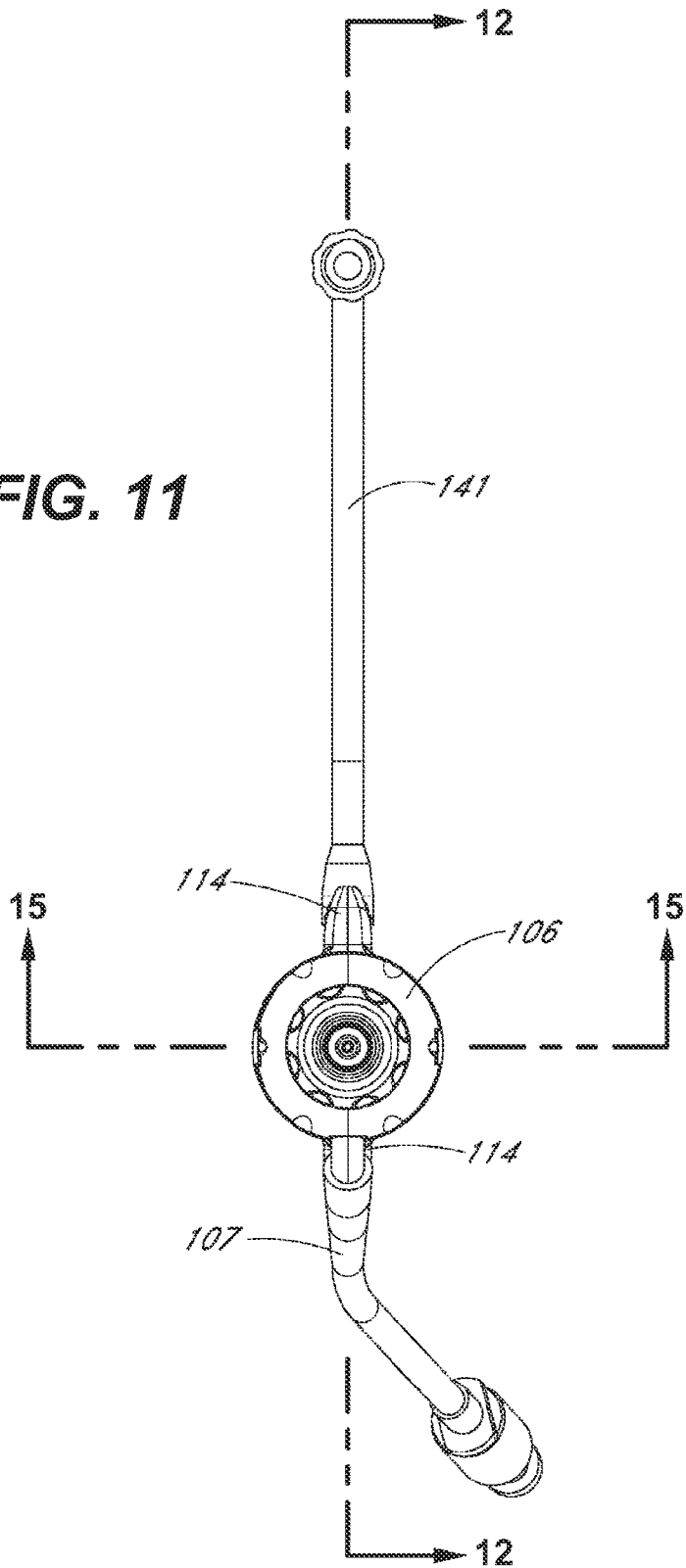
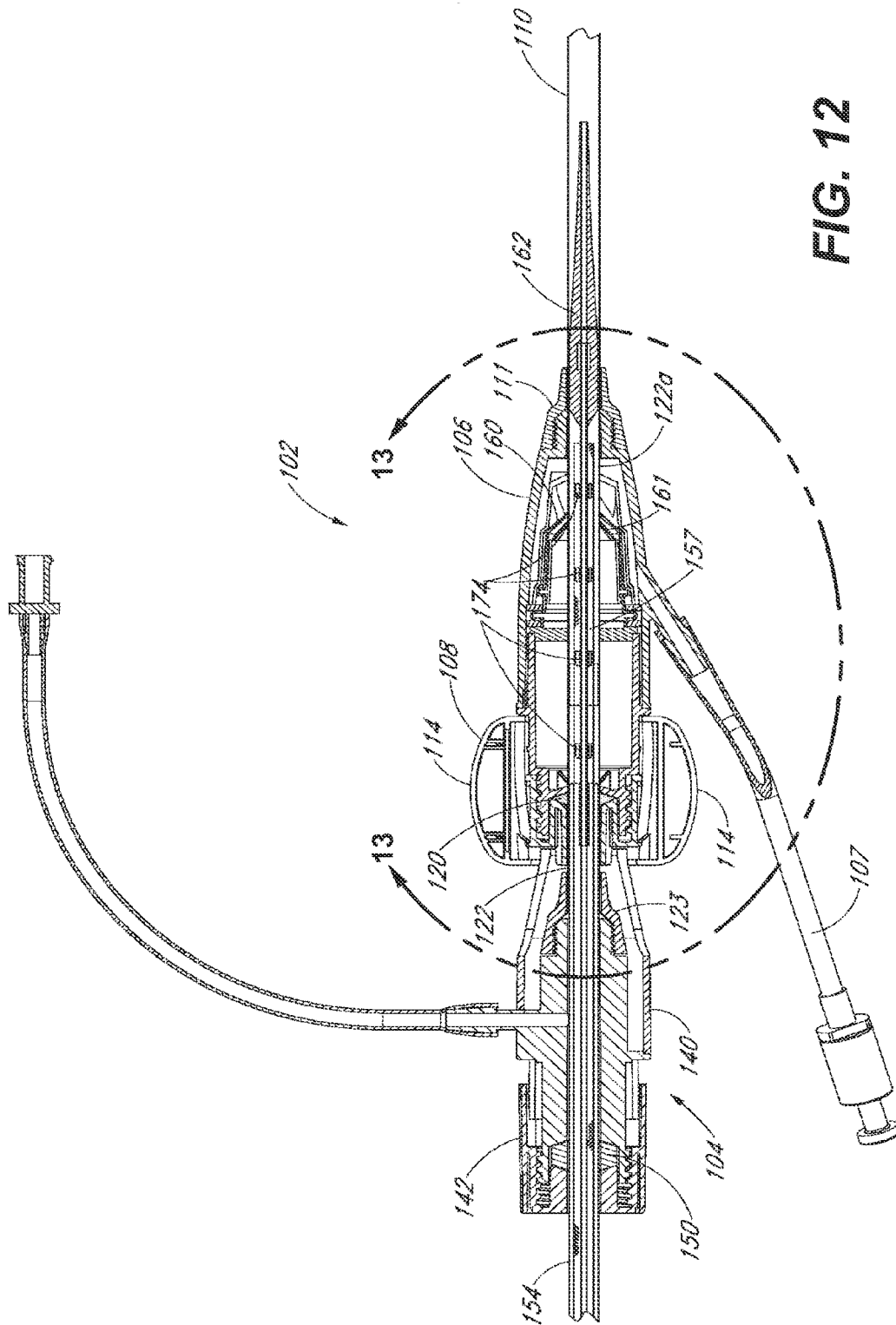


FIG. 10

**FIG. 11**





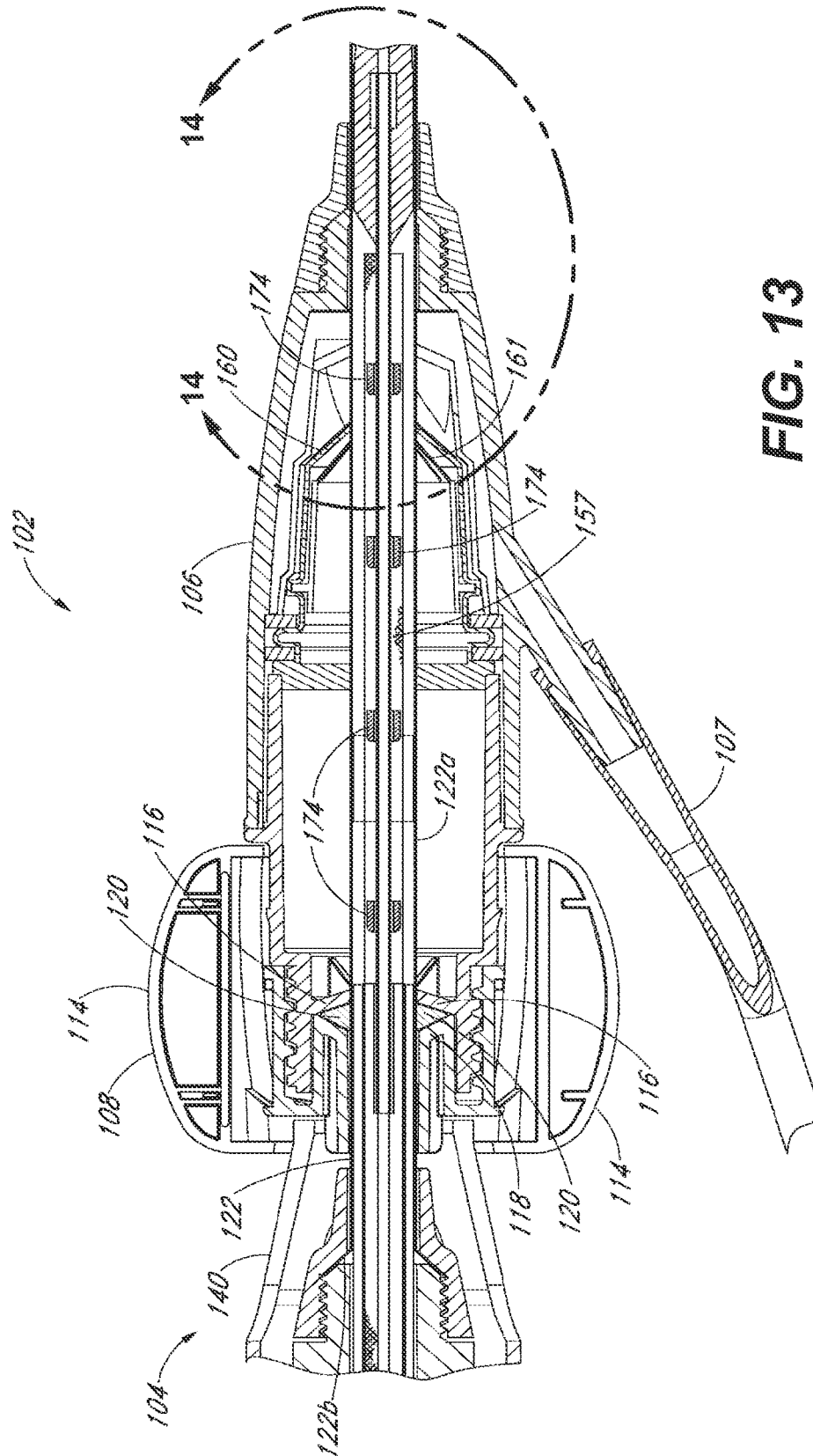


FIG. 13

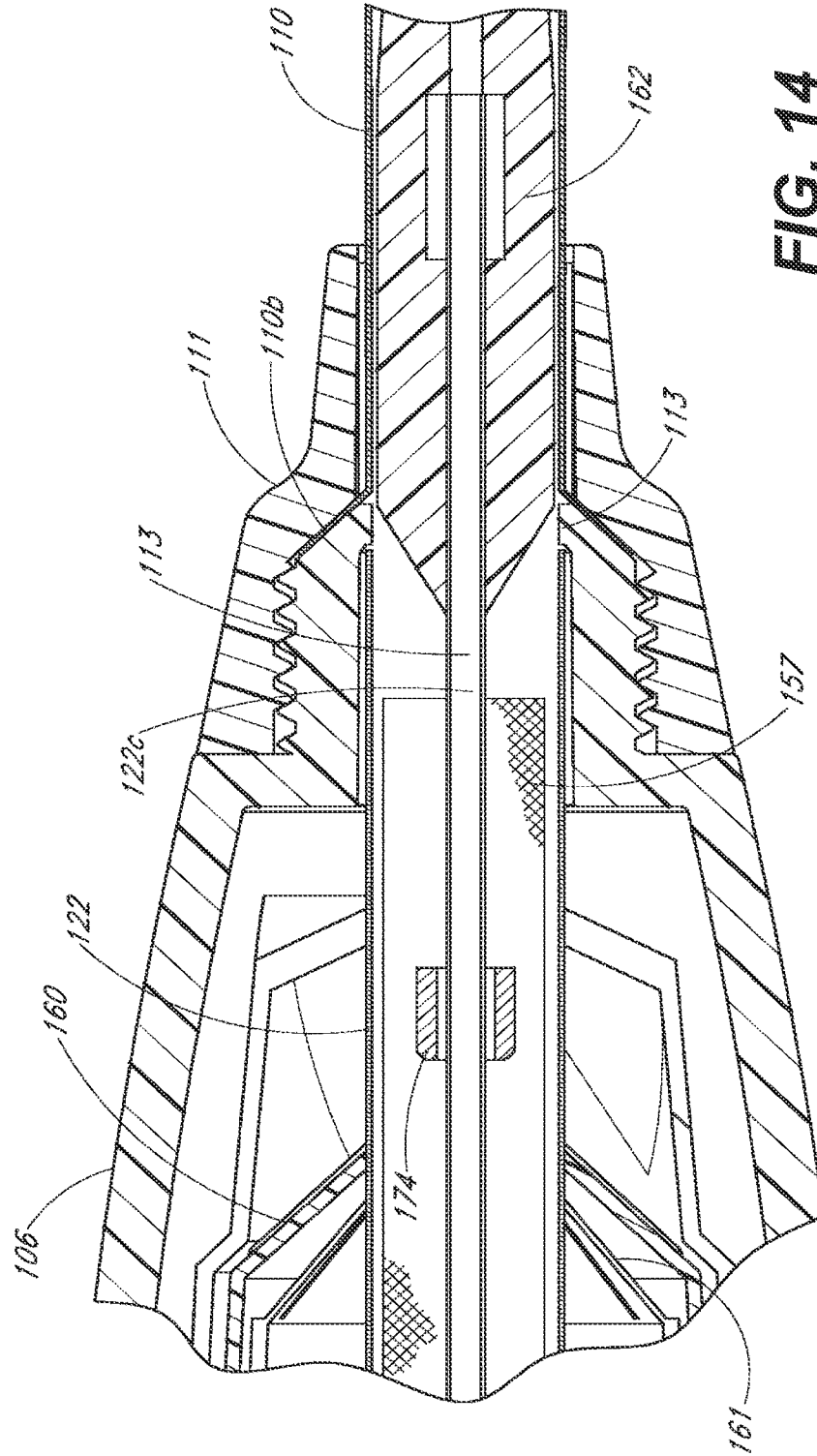


FIG. 14

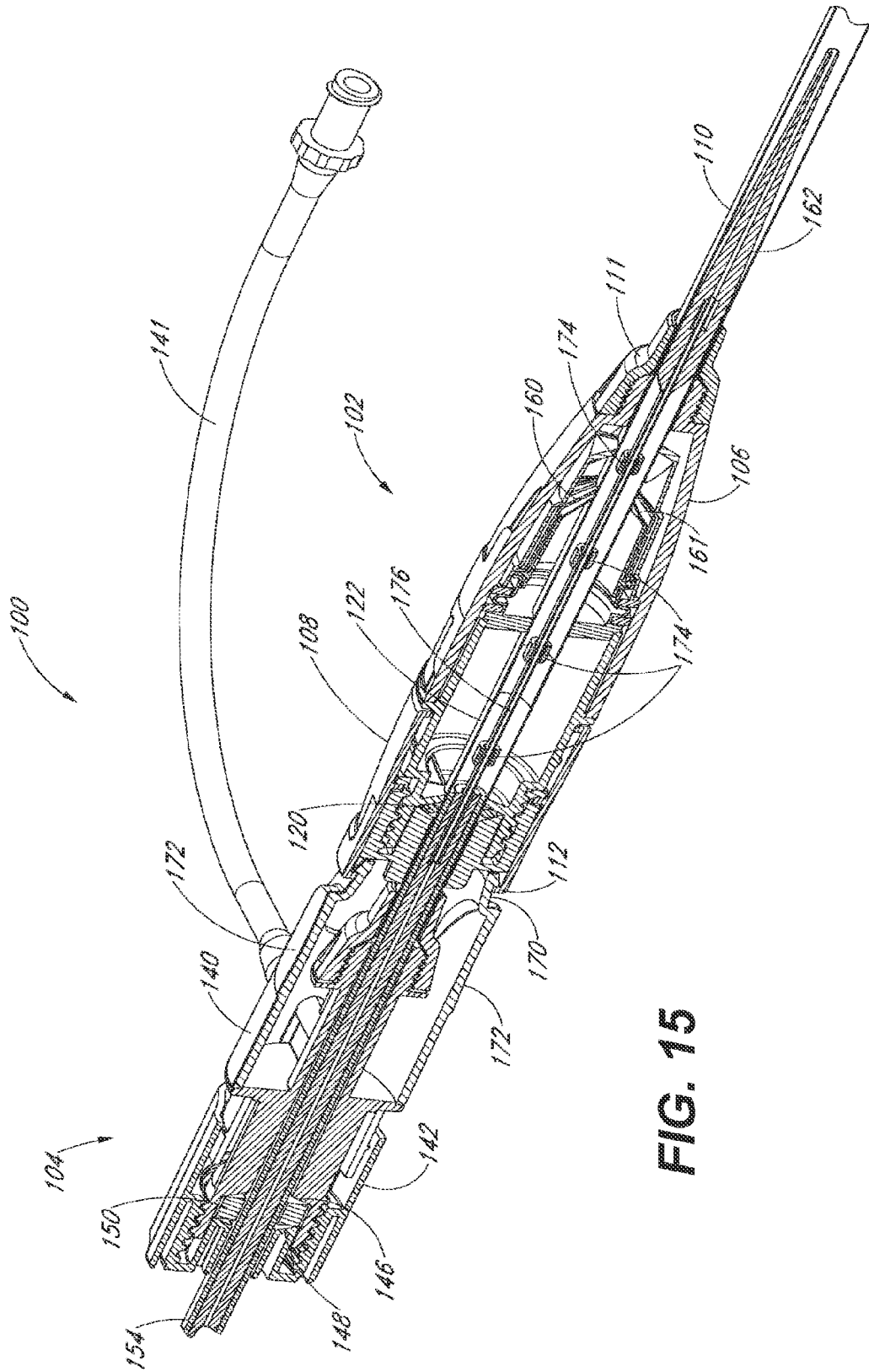


FIG. 15

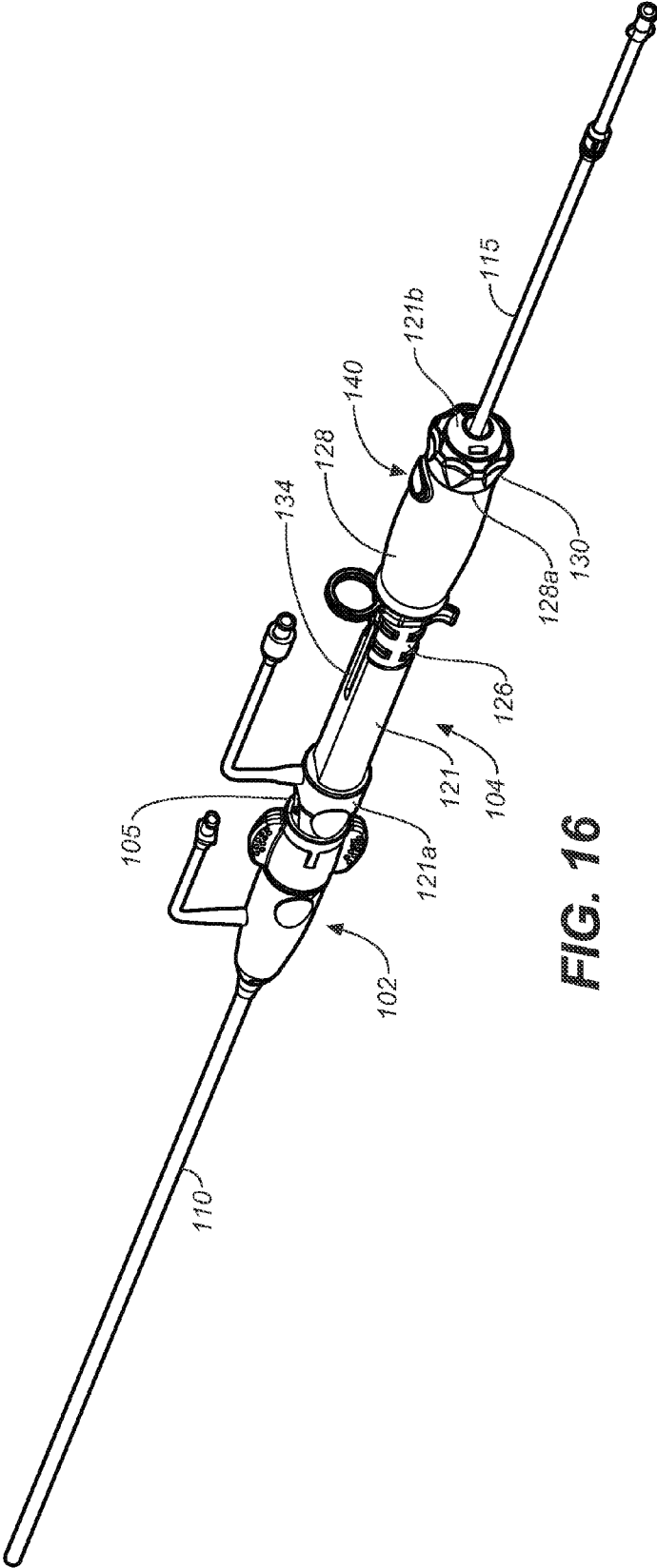


FIG. 16

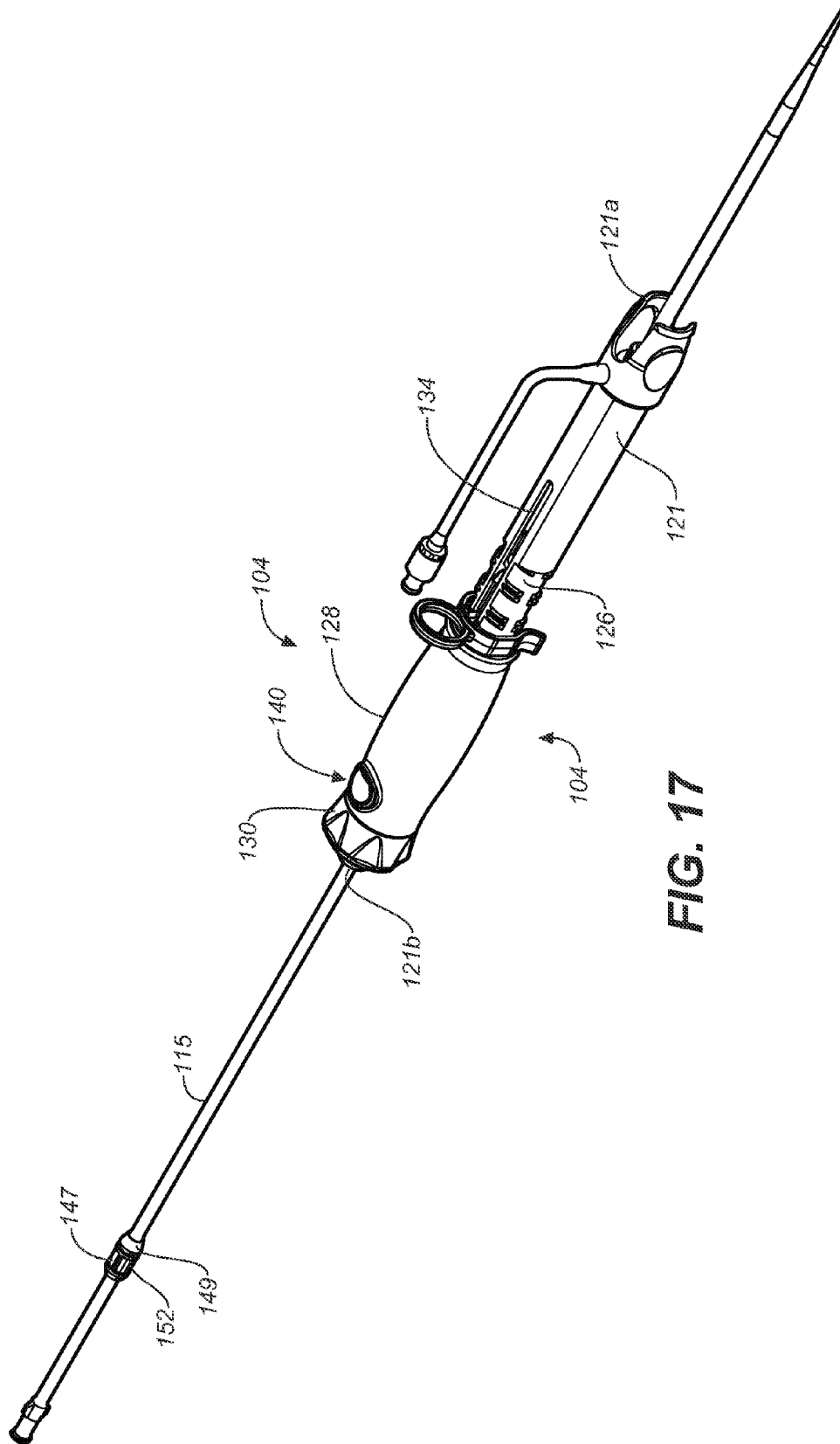


FIG. 17

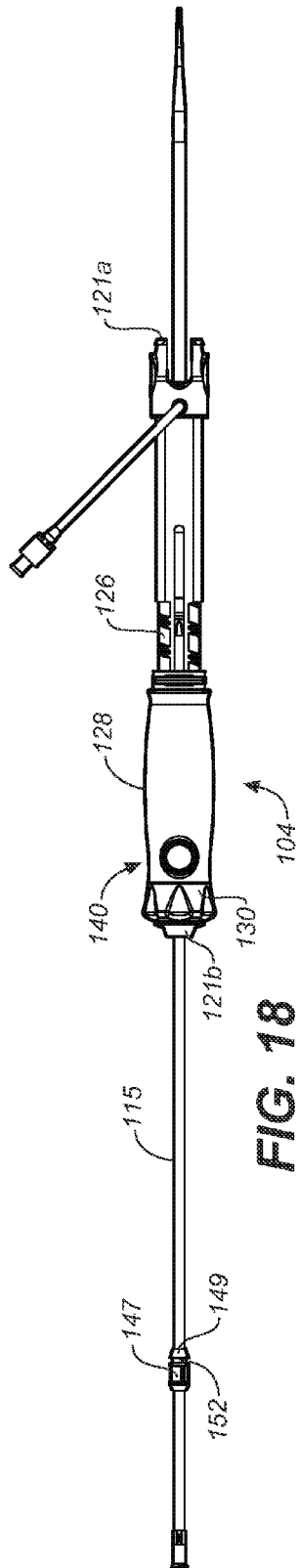


FIG. 18

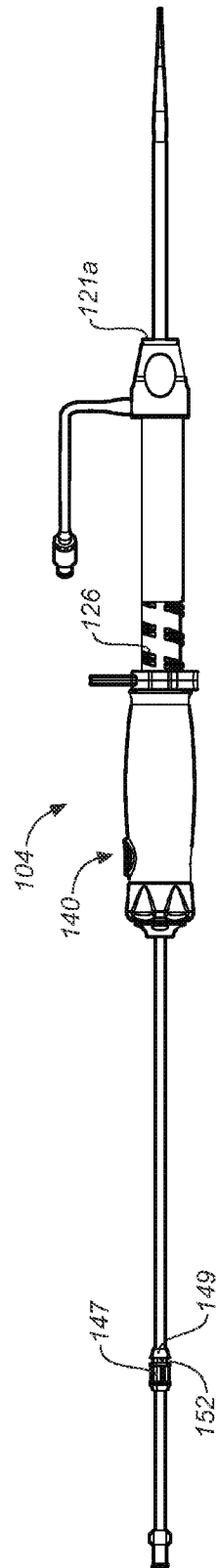


FIG. 19

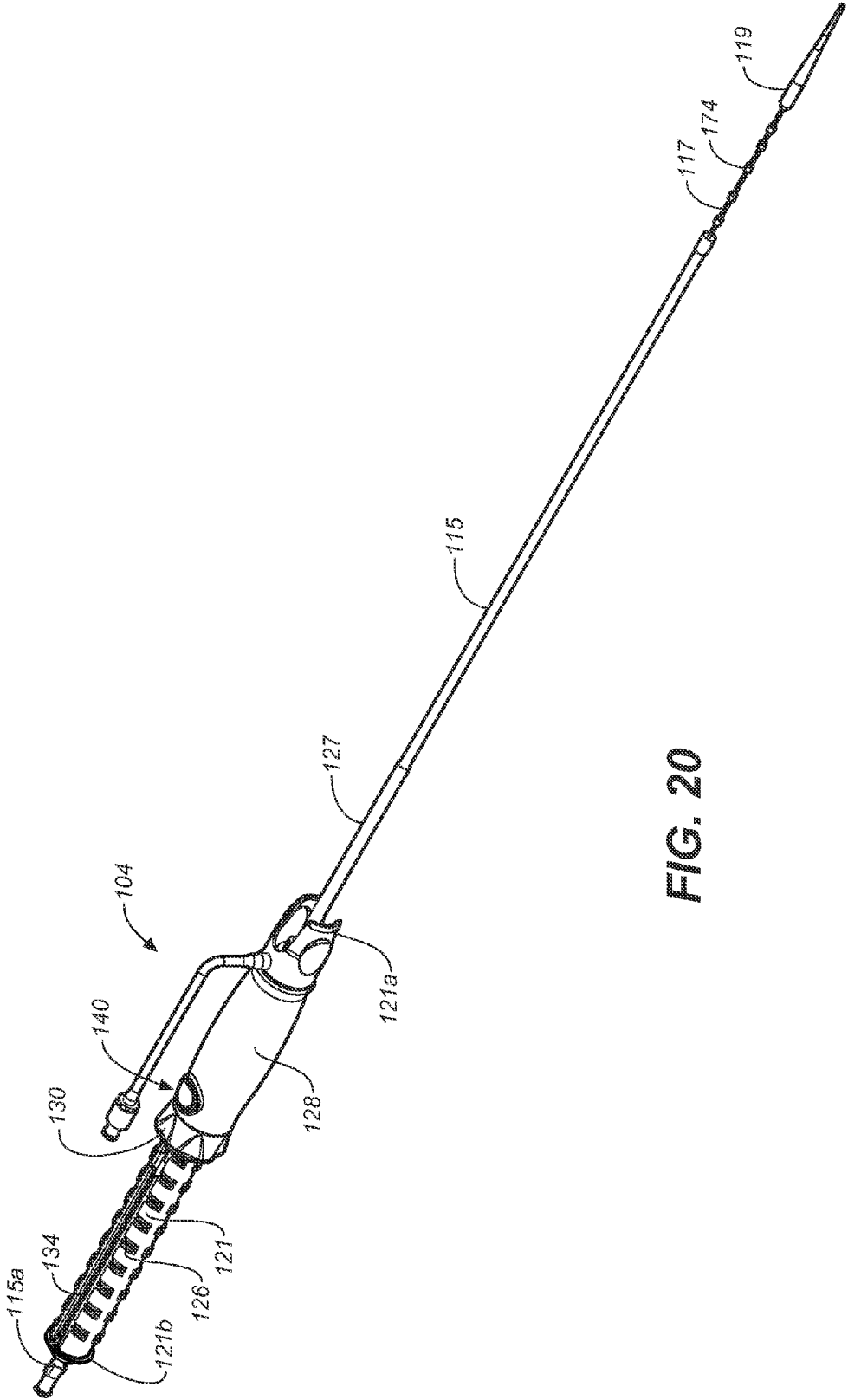
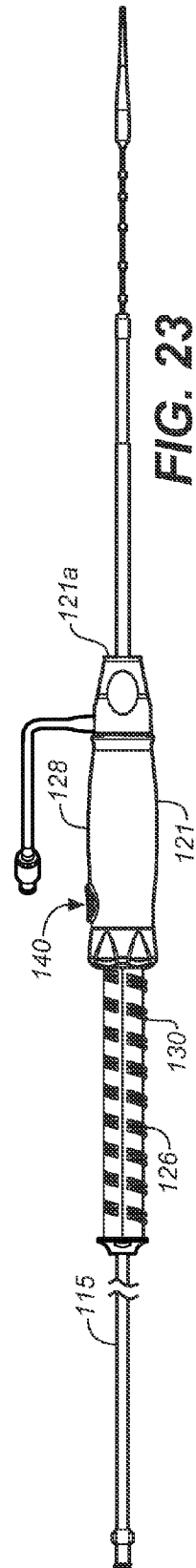
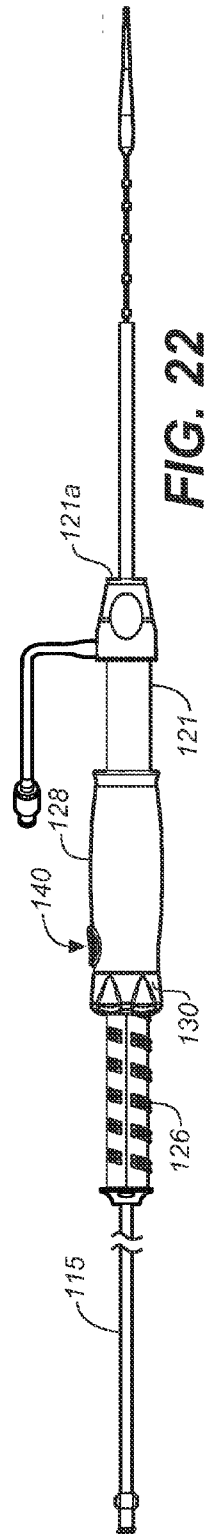
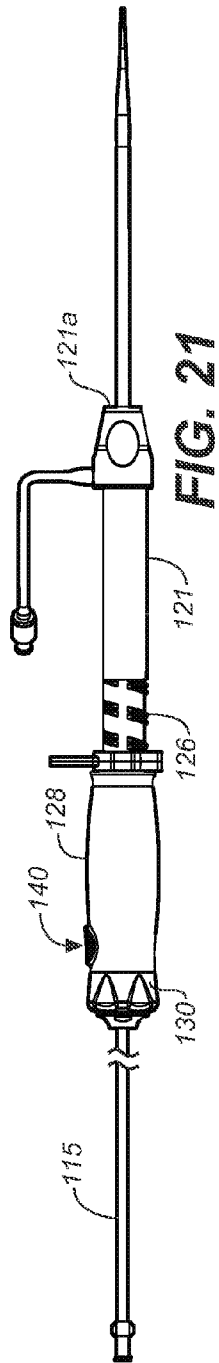
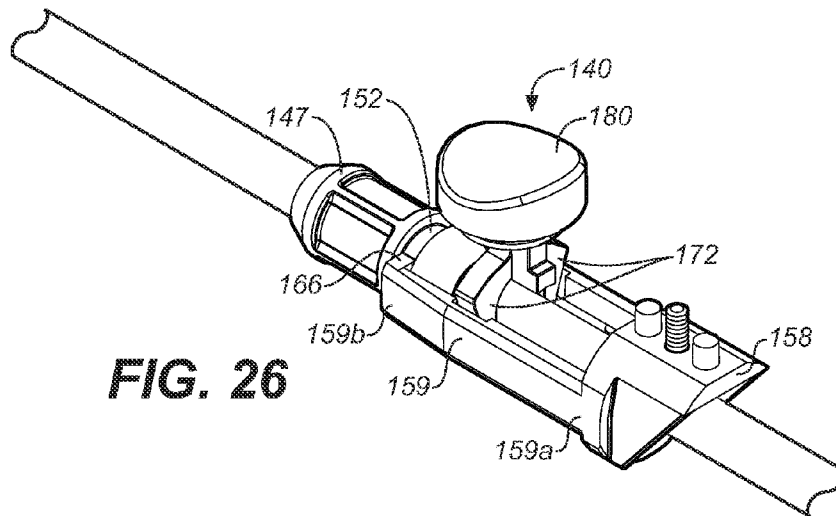
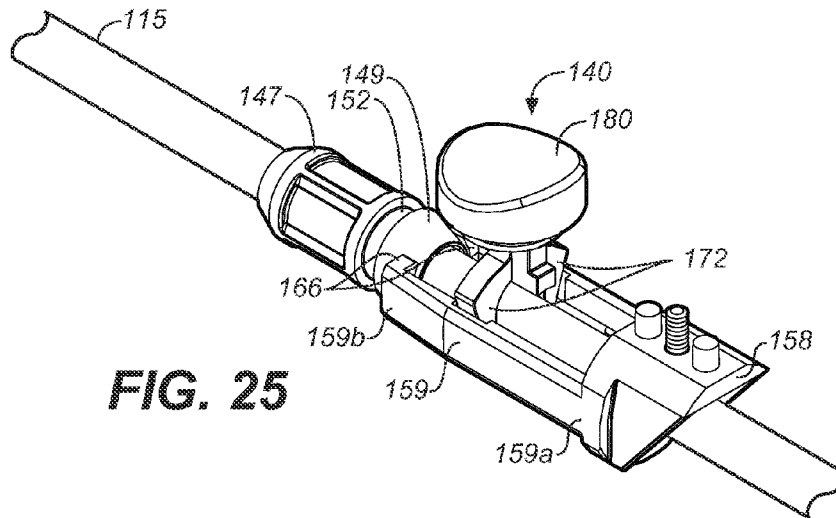
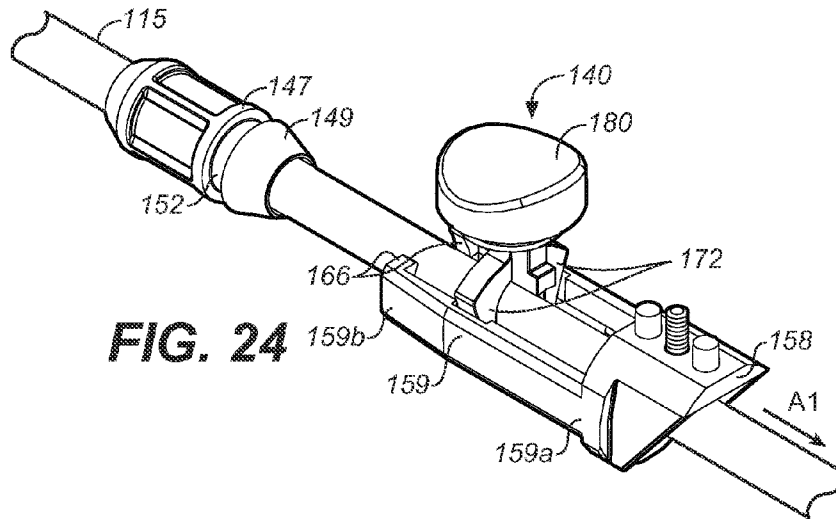
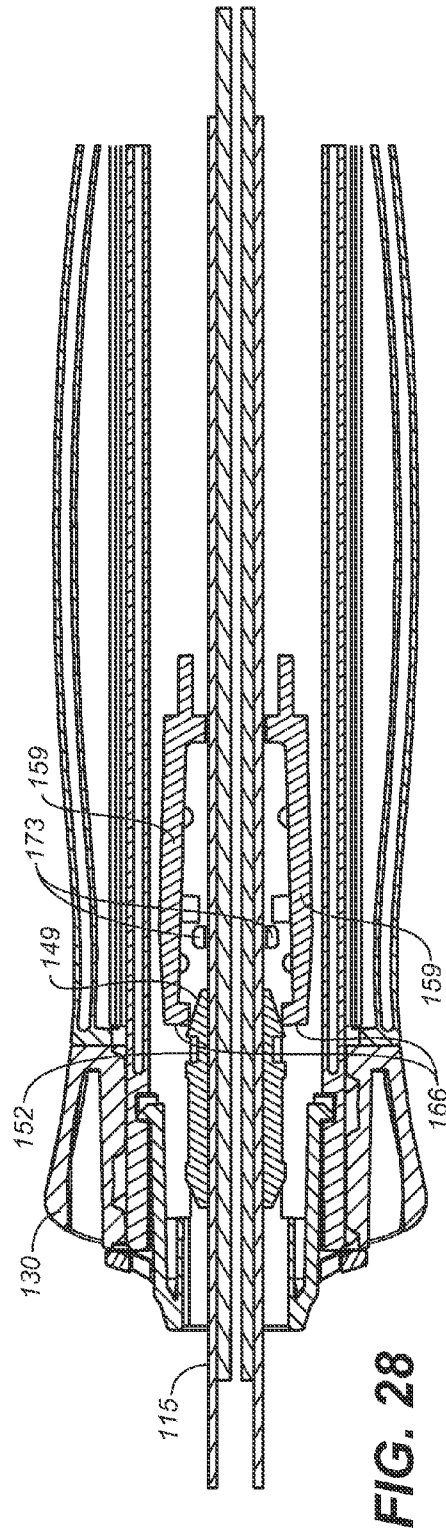
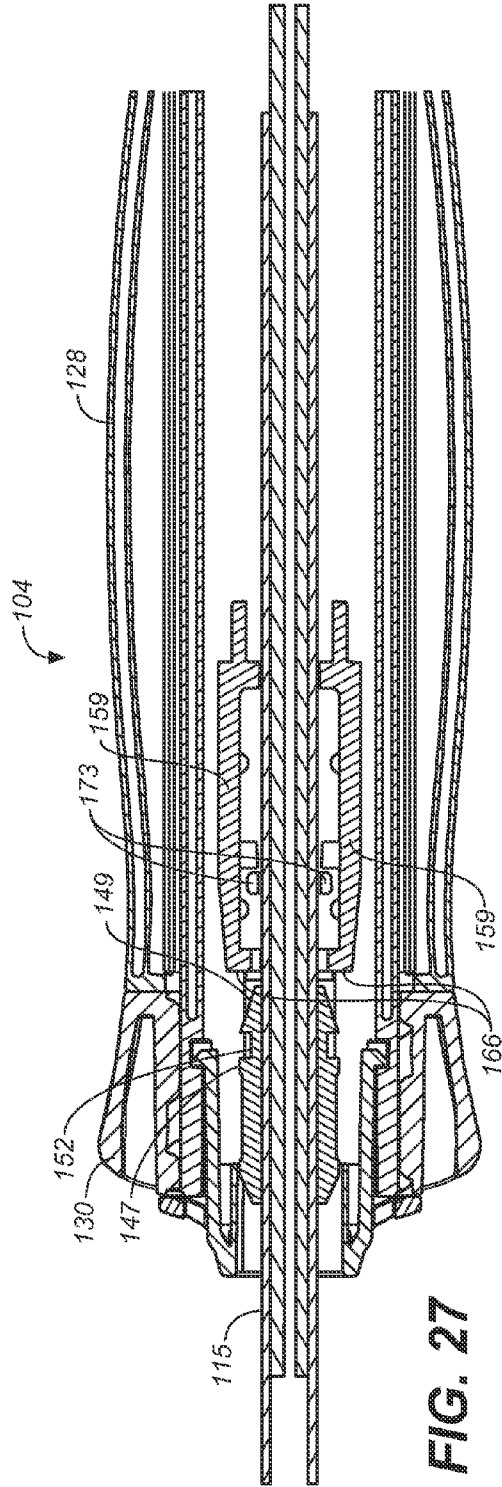


FIG. 20







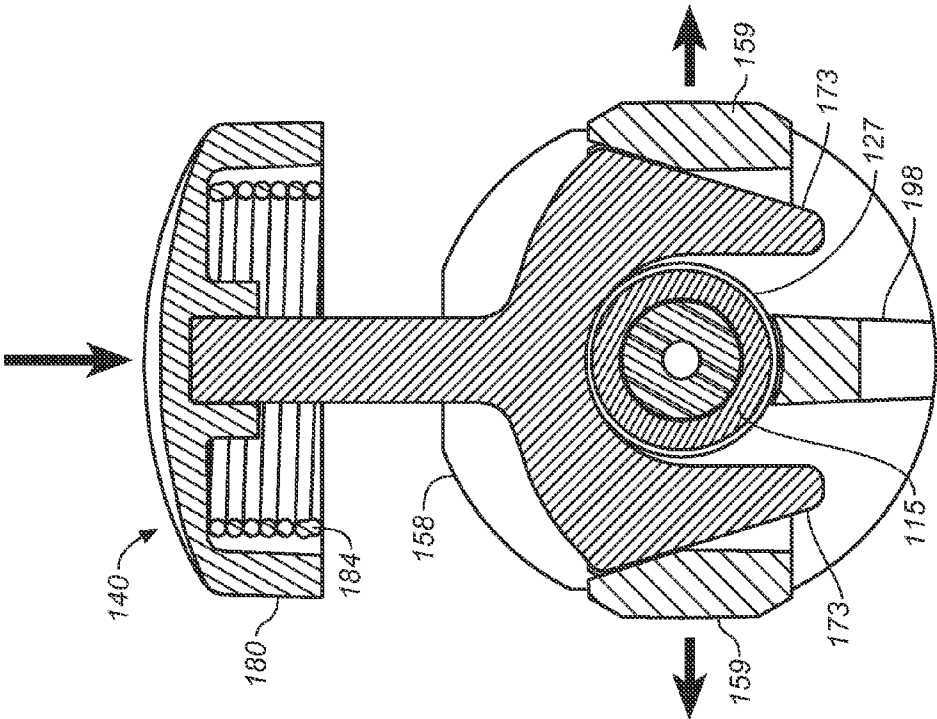


FIG. 27B

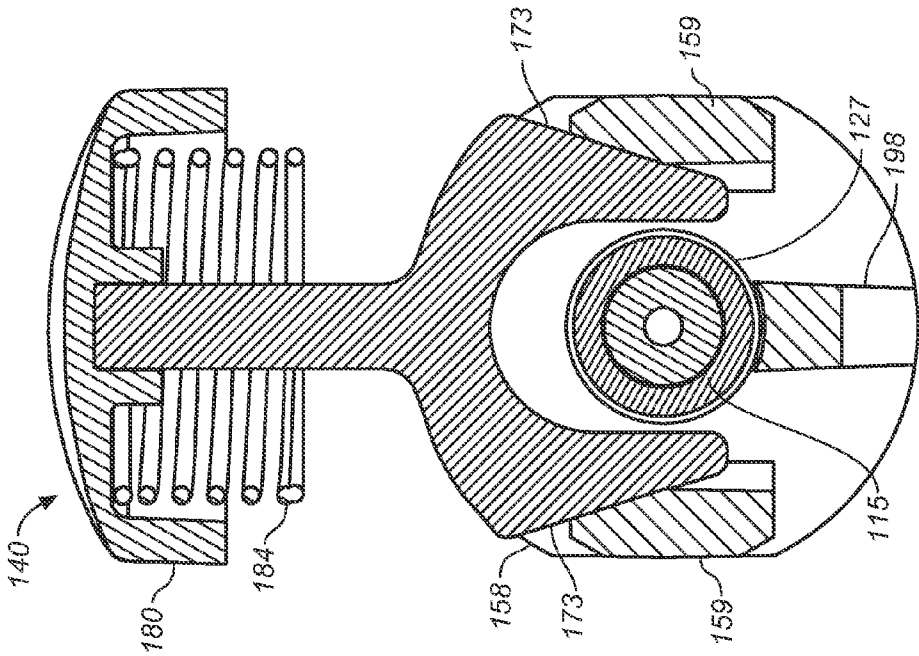
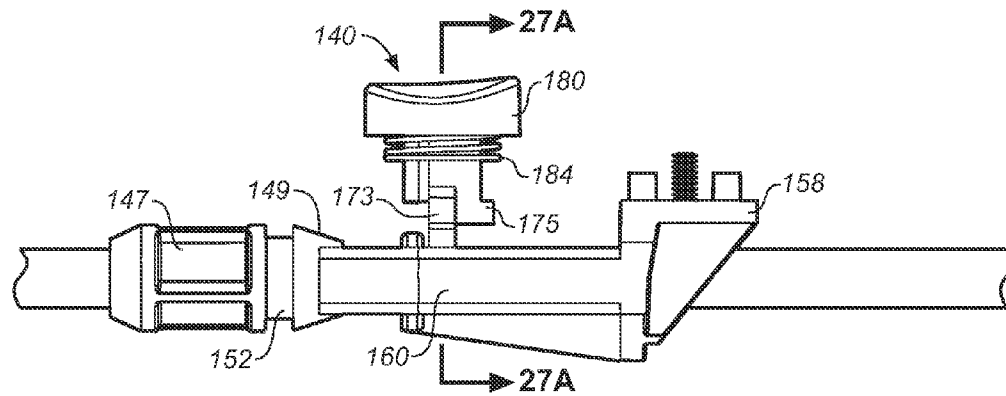
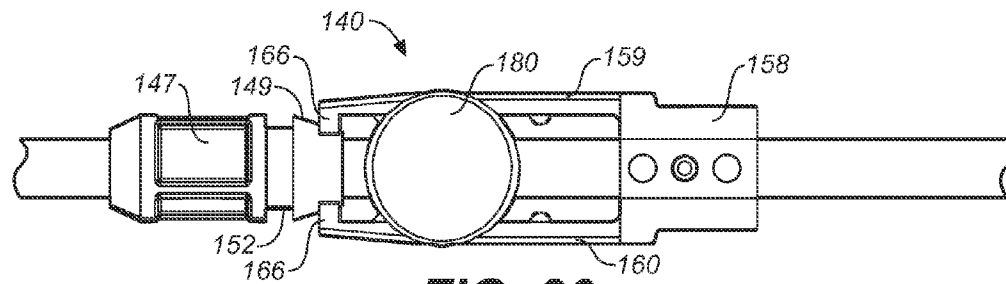


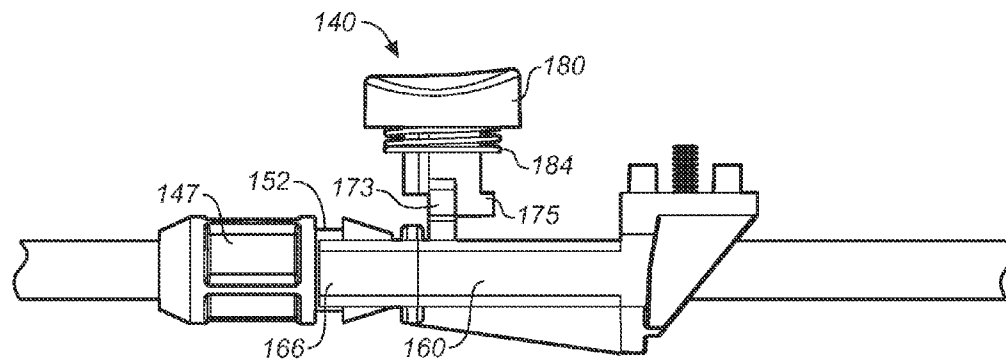
FIG. 27A



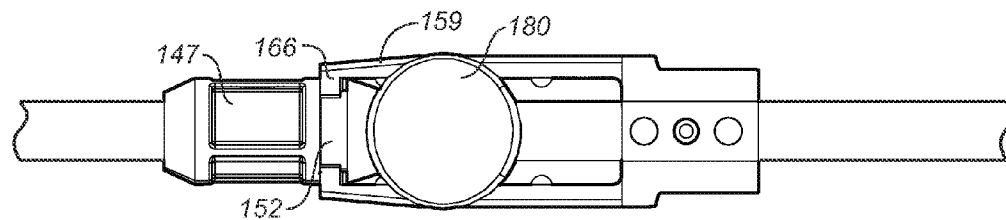
**FIG. 29**



**FIG. 30**



**FIG. 31**



**FIG. 32**

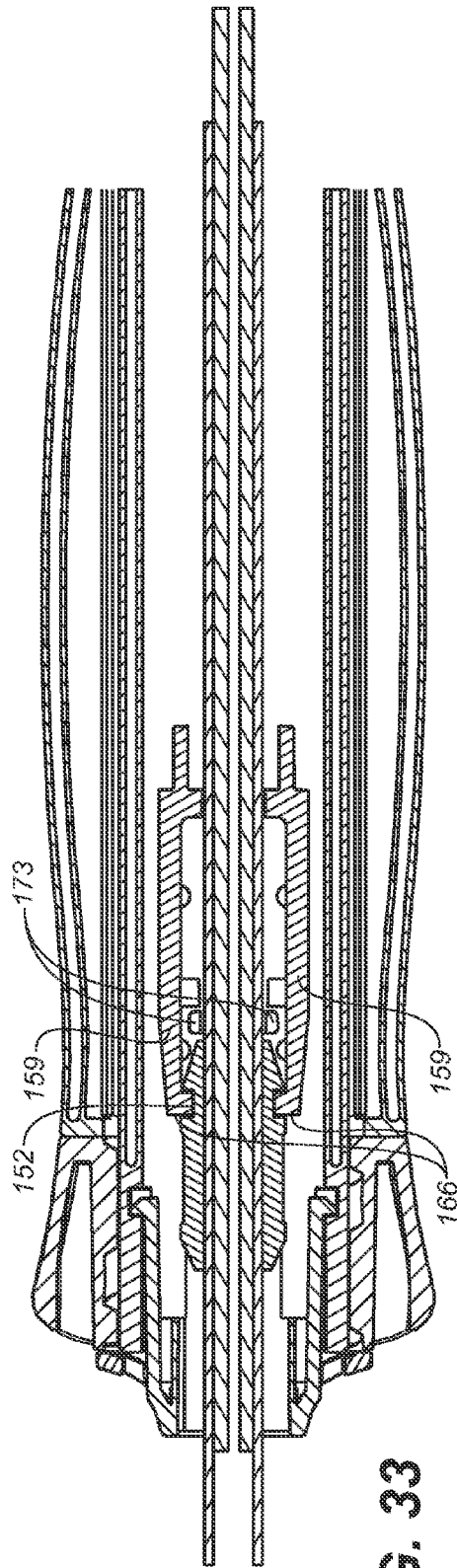


FIG. 33

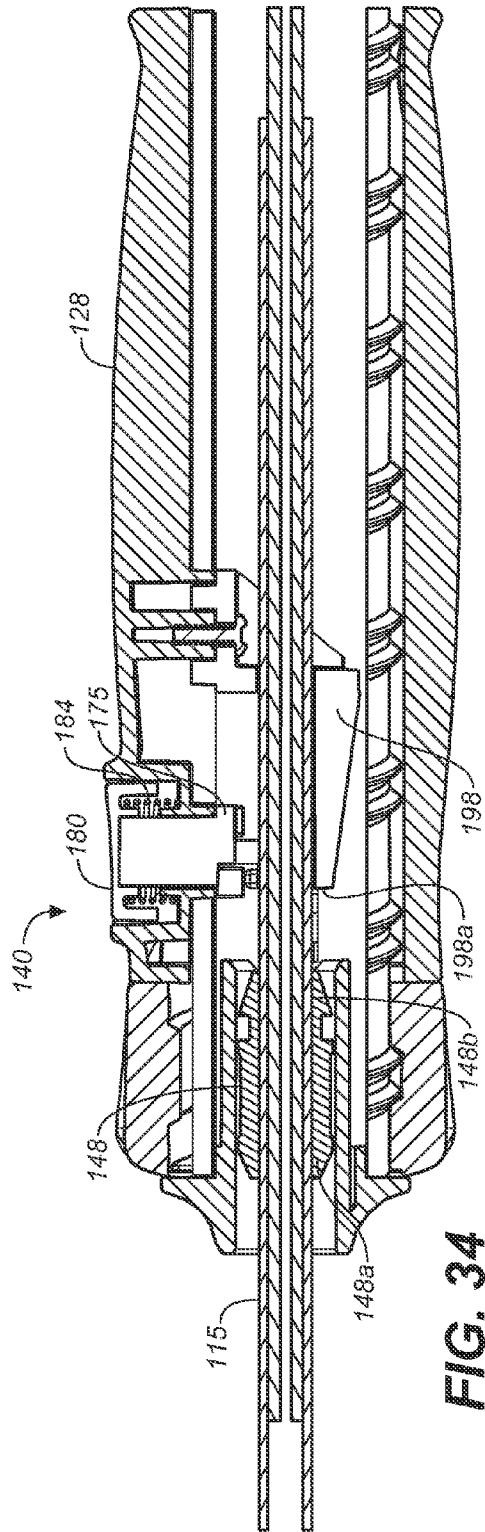


FIG. 34

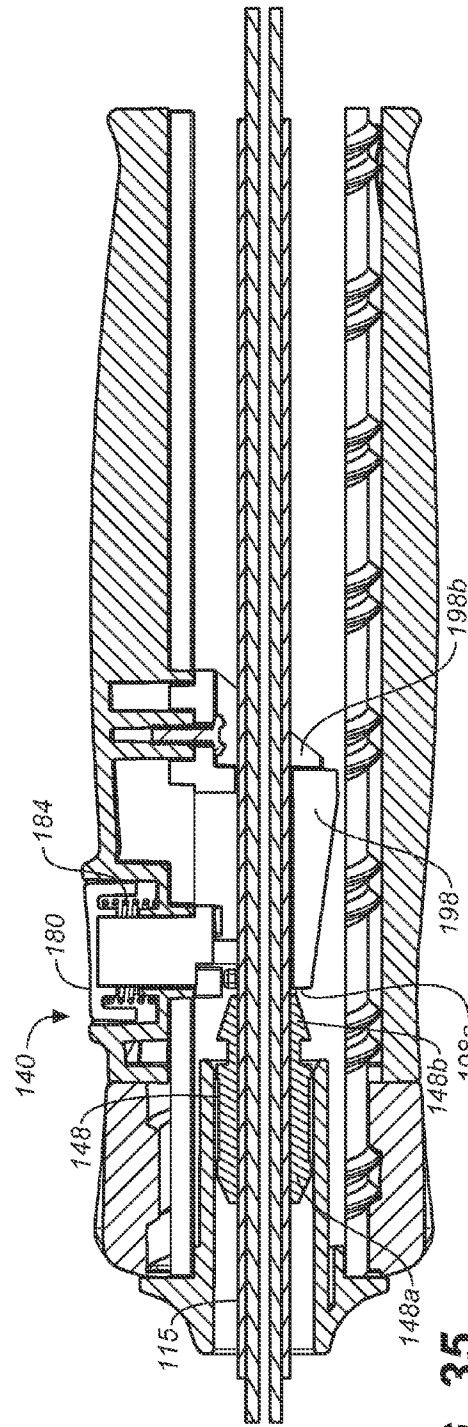
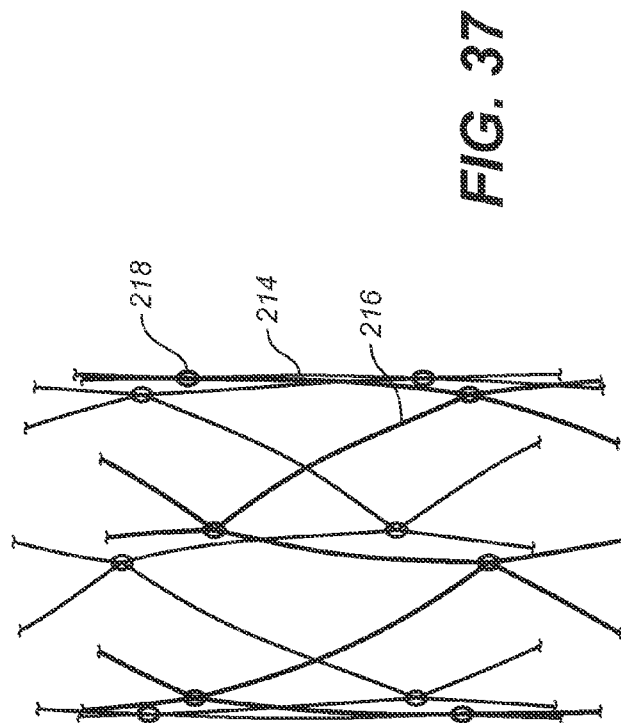
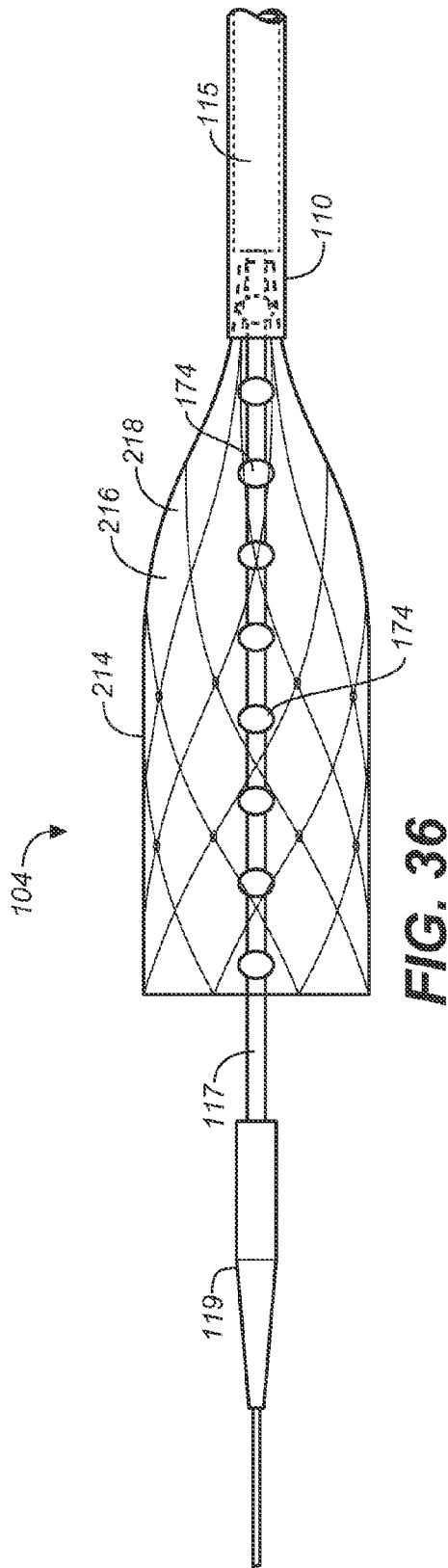


FIG. 35



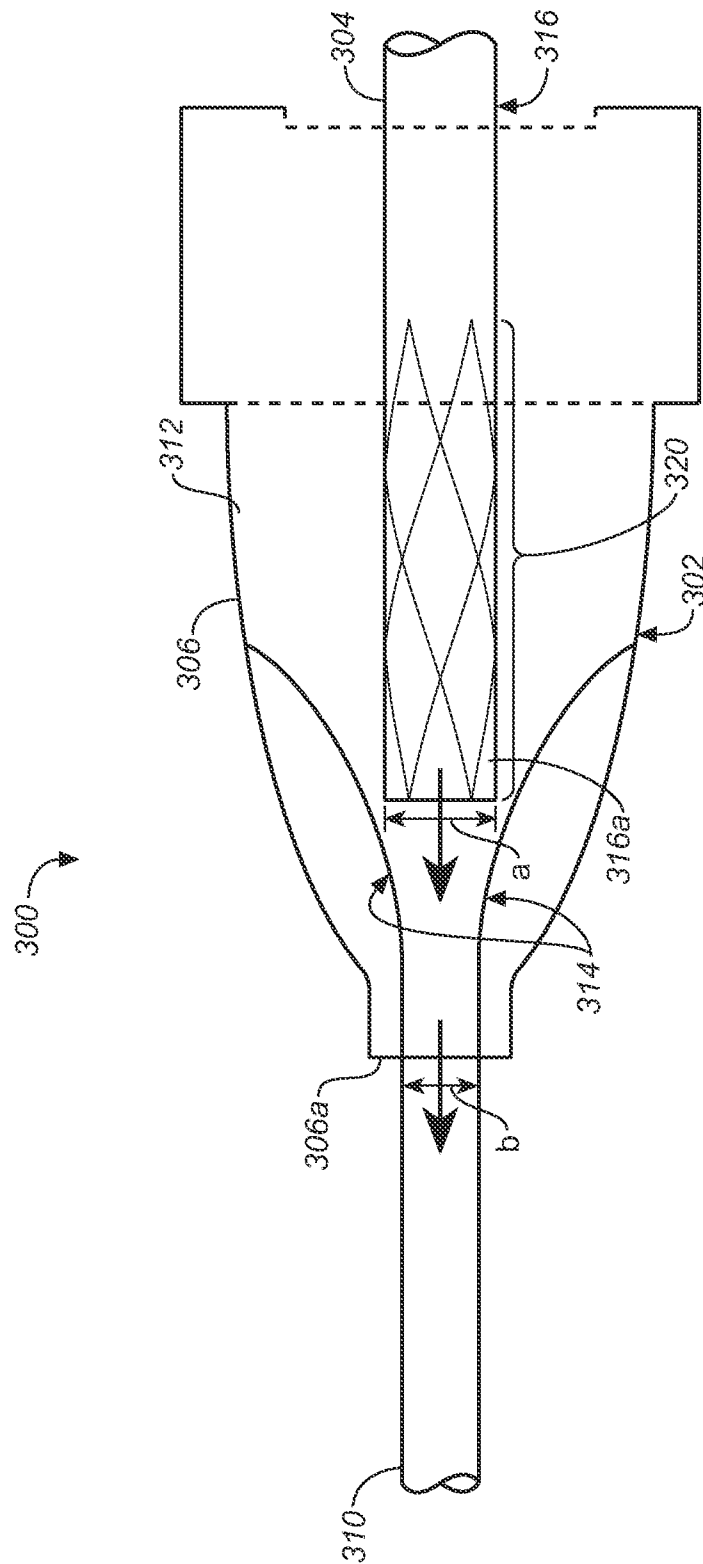
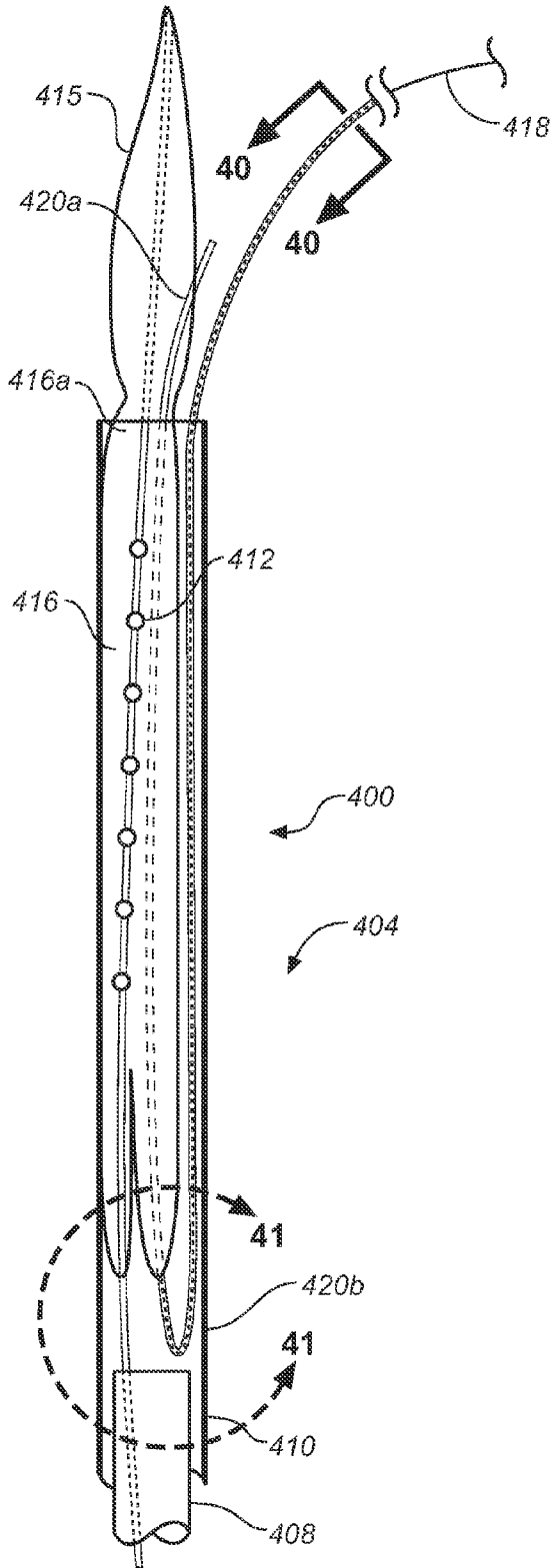
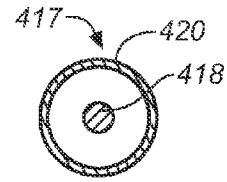


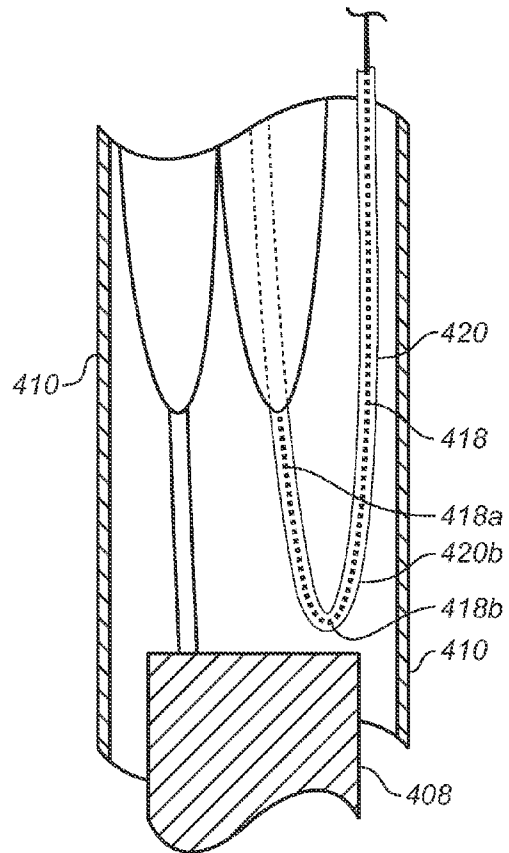
FIG. 38



**FIG. 39**



**FIG. 40**



**FIG. 41**

## CATHETER SYSTEM AND METHODS OF USING SAME

### PRIORITY CLAIM

The present application claims priority from U.S. Patent Application No. 61/448,154, filed Mar. 1, 2011, the content of which is incorporated by reference herein in its entirety. The benefit of priority is claimed under the appropriate legal basis including, without limitation, under 35 U.S.C. §119(e).

### INCORPORATION BY REFERENCE

U.S. application Ser. No. 11/623,022, filed Jan. 12, 2007, entitled "DUAL CONCENTRIC GUIDEWIRE AND METHODS OF BIFURCATED GRAFT DEPLOYMENT," U.S. application Ser. No. 12/101,863, filed Apr. 11, 2008, entitled "BIFURCATED GRAFT DEPLOYMENT SYSTEMS AND METHODS," U.S. application Ser. No. 12/496,446, filed Jul. 1, 2009, entitled "CATHETER SYSTEM AND METHODS OF USING SAME," U.S. application Ser. No. 12/769,506, filed Apr. 28, 2010, entitled "APPARATUS AND METHOD OF PLACEMENT OF A GRAFT OR GRAFT SYSTEM," and U.S. Pat. No. 6,077,296, entitled "ENDOLUMINAL VASCULAR PROSTHESIS," are hereby incorporated by reference as if fully set forth herein.

### TECHNICAL FIELD

The present disclosure relates to catheter systems, in particular, catheter systems for delivering a medical prosthesis.

### BACKGROUND

Introducer catheters or introducer sheaths can be used for minimal invasive placement of catheters into blood vessels. Introducer catheter sheaths typically comprise tubing that is inserted into the blood vessel and a seal or valve at the proximal end of the tubing which is positioned outside of the body. The seal can provide a hemostatic seal against blood loss. Stents or other medical prostheses are typically passed through the introducer sheath into the blood vessel or body passageway. The introducer sheath thus provides continuous access for the delivery of stents or other medical prostheses, protects the inner wall of the blood vessel or body passageway against damage when the stent or other prostheses is advanced through the body passageway, and provides a hemostasis seal against blood loss.

There are situations in which the catheters require substantial maneuvering within the blood vessel. For example, placement of a stent or stent graft may require the delivery catheter to be positioned precisely axially as well as rotationally at a specific location within the blood vessel. In addition deployment of the stent may require precise operation of the delivery system within the introducer. In these situations, the operator has to carefully control both the position of the introducer and the delivery system. A need exists for a delivery system that permits a user or medical practitioner to precisely control the axial position of the stent or prosthesis during deployment.

### SUMMARY

Embodiments disclosed herein pertain to a catheter system for the insertion and positioning of diagnostic or therapeutic devices into blood vessels. The system comprises an introducer or an introducer sheath (also referred to herein as an outer sheath) and at least one delivery catheter. The introducer

catheter can be introduced through a percutaneous puncture site into the blood stream. A docking mechanism can engage the proximal end of the introducer catheter assembly with a distal end portion of a delivery catheter and can prevent axial movement between the introducer catheter assembly and the delivery catheter assembly.

The catheter system can include an introducer catheter and a delivery catheter, where the introducer catheter includes an outer sheath and a seal that has an adjustable hemostasis valve connected to the proximal portion of the outer sheath. The introducer catheter and the delivery catheter can be configured such that the delivery catheter can removably engage with the introducer catheter such that, when the delivery catheter is engaged with the introducer catheter, the delivery catheter can be axially fixed to the introducer catheter so as to prevent substantial axial movement between the introducer catheter and the delivery catheter and to enable the catheters to be manipulated in an axial direction as a single unit.

Alternatively, the delivery catheter and introducer catheter can be configured such that, when the delivery catheter is engaged with the introducer catheter, an inner core of the delivery catheter can be rotated relative to the introducer catheter and the introducer sheath (also referred to herein as an outer sheath). Alternatively, the delivery catheter can be configured such that the inner core thereof can be locked or substantially prevented from rotational movement relative to the outer sheath of the introducer catheter and/or relative to the introducer catheter. Also disclosed is a method of placement of a stent or medical prosthesis into a blood vessel, wherein the stent or medical prosthesis is passed through an introducer sheath and the proximal end of the introducer catheter physically engages with or is removably docked with a distal end portion of the delivery catheter to prevent substantial axial motion between the introducer sheath and the delivery catheter.

Some endoprotheses, including stents, grafts, stent grafts, and dissection treatment devices, (all such endoprotheses are collectively referred to herein as a stent or stents) may require precise placement in both axial and rotational direction. For example, stents or stent grafts with fenestrations require accurate placement of those fenestrations relative to the branch vessels. The catheter systems disclosed herein can be configured to allow for the rotation of the delivery catheter and, hence, the stent, relative to the introducer sheath. In some embodiments, the friction that can otherwise impede the rotational freedom of the delivery catheter can be further reduced by lining the inner surface of the introducer sheath and/or the tubular sheath of the deployment catheter with a low-friction coating such as polytetrafluoroethylene, silicone, hydrophobic silicone, or other lubricating substance, or by applying a hydrophilic coating to the outer surface of the inner core or restraining sheaths of the delivery catheter. The lubrication can be swabbed onto the target surface.

Thus, the introducer sheath can remain rotationally static or fixed while the delivery catheter is rotated within the introducer sheath. This can protect the delivery catheter and stent from being damaged, torqued, or stressed during the rotational manipulation of the delivery catheter and stent, and also prevent any damage or stress on the vessel wall from the rotation of the delivery catheter or stent.

Additionally, the delivery catheter can be configured to permit a user or medical practitioner to selectively control or prevent the rotational movement of the delivery catheter and stent relative to the introducer catheter, or the inner core of the delivery catheter and stent relative to the outer sheath of the delivery catheter. For example, the delivery catheter can comprise a threaded hub supported at the proximal end portion of

the delivery catheter configured to selectively constrict or tighten against an outer wall of the inner core of the delivery catheter. By constricting the hub against the inner core, the inner core can be prevented or inhibited from rotating relative to the introducer catheter. By loosening the hub relative to the inner core, the rotational freedom of the inner core or delivery catheter relative to the introducer sheath can be restored.

#### BRIEF DESCRIPTION OF THE DRAWINGS

These and other features, aspects and advantages will now be described in connection with certain embodiments, in reference to the accompanying drawings. The illustrated embodiments, however, are merely examples and are not intended to be limiting. The following are brief descriptions of the drawings.

FIG. 1A is a schematic representation of a catheter system comprising a docking arrangement to physically engage a catheter with an introducer sheath.

FIG. 1B is a schematic representation of the catheter system shown in FIG. 1A, showing the catheter engaged with the introducer sheath.

FIG. 2A is a schematic representation of another catheter system comprising a docking arrangement to physically engage a catheter with an introducer sheath.

FIG. 2B is a schematic representation of the catheter system shown in FIG. 2A, showing the catheter engaged with the introducer sheath.

FIG. 2C is a schematic representation of the catheter system shown in FIG. 2A, showing a mechanism for disengaging the catheter from the introducer sheath.

FIG. 3A is a schematic representation of another catheter system comprising a docking arrangement to physically engage a catheter with an introducer sheath, the catheter system being configured to deliver a stent or stent graft into a blood vessel.

FIG. 3B is a schematic representation of the catheter system shown in FIG. 3A, showing the catheter engaged with the introducer sheath.

FIG. 3C is a schematic representation of the catheter system shown in FIG. 3A, illustrating the axial insertion of a stent into the tubular sheath of the introducer sheath shown in FIG. 3A.

FIG. 3D is a schematic representation of the catheter system shown in FIG. 3A, illustrating the stent being deployed after the tubular sheath of the introducer sheath shown in FIG. 3A has been retracted from the stent.

FIG. 4 is an oblique view of a catheter system comprising an introducer and a delivery catheter.

FIG. 5 is an oblique view of the introducer shown in FIG. 4.

FIG. 6A is a first exploded assembly view of the introducer shown in FIG. 5.

FIG. 6B is a second exploded assembly view of the introducer shown in FIG. 5.

FIG. 7 is an oblique view of the delivery catheter shown in FIG. 4.

FIG. 8A is a first exploded assembly view of the delivery catheter shown in FIG. 7.

FIG. 8B is a second exploded assembly view of the delivery catheter shown in FIG. 7.

FIG. 9 is an oblique view of the catheter system shown in FIG. 4, showing the delivery catheter before the docking mechanism of the delivery catheter has been engaged with the docking mechanism of the introducer.

FIG. 10 is an oblique view of the catheter system shown in FIG. 4, showing the delivery catheter after the docking

mechanism of the delivery catheter has been engaged with the docking mechanism of the introducer.

FIG. 11 is an end view of the catheter system shown in FIG. 4.

FIG. 12 is a cross-sectional view of the catheter system shown in FIG. 4, taken at line 12-12 of FIG. 11.

FIG. 13 is an enlarged cross-sectional view of the catheter system shown in FIG. 4, showing a close up of 13-13 of FIG. 12.

FIG. 14 is an enlarged section view of the catheter system shown in FIG. 4, showing a close up of 14-14 of FIG. 13.

FIG. 15 is a cross-sectional view of the catheter system shown in FIG. 4, taken at line 15-15 of FIG. 11.

FIG. 16 is an oblique view of a catheter system, having a delivery catheter assembly docked to an introducer catheter assembly.

FIG. 17 is an oblique view of the delivery catheter assembly of FIG. 16.

FIG. 18 is a top view of the delivery catheter assembly of FIG. 16.

FIG. 19 is a side view of the delivery catheter assembly of FIG. 16.

FIG. 20 is an oblique view of the delivery catheter assembly of FIG. 16, illustrating the sheath in a fully retracted position relative to the inner core member.

FIG. 21 is a side view of the delivery catheter of FIG. 16, showing the handle member and the inner core in a pre-deployment first position relative to the housing shaft of the delivery catheter.

FIG. 22 is a side view of the delivery catheter of FIG. 16, showing the handle member and the inner core in a second, partial deployment position relative to the housing shaft of the delivery catheter.

FIG. 23 is a side view of the delivery catheter of FIG. 16, showing the handle member and the inner core in a third, fully advanced position on the housing shaft of the delivery catheter.

FIG. 24 is an oblique view of the inner core engagement assembly and the inner core, showing the inner core in a first, disengaged position relative to the inner core engagement assembly, other components of the delivery catheter being removed from this view for clarity.

FIG. 25 is a cross-sectional view of a portion of the delivery catheter through the axial centerline of the delivery catheter, showing the inner core in the first, disengaged position relative to the inner core engagement assembly.

FIG. 26 is an oblique view of the inner core engagement assembly and the inner core as in FIG. 24, showing the inner core in a second, partially engaged position relative to the inner core engagement assembly.

FIG. 27 is a side view of the inner core engagement assembly and the inner core as in FIG. 26, showing the inner core in the second, partially engaged position relative to the inner core engagement assembly.

FIG. 27A is a cross-sectional view of a portion of the delivery catheter taken through the line 27A-27A of FIG. 29, showing one or more components of the delivery catheter in a first position.

FIG. 27B is a cross-sectional view of a portion of the delivery catheter taken through the line 27A-27A of FIG. 29, showing one or more components of the delivery catheter in a second position.

FIG. 28 is a top view of the inner core engagement assembly and the inner core as in FIG. 26, showing the inner core in the second, partially engaged position relative to the inner core engagement assembly.

5

FIG. 29 is a cross-sectional view of a portion of the delivery catheter through the axial centerline of the delivery catheter, showing the inner core in a second, partially engaged position relative to the inner core engagement assembly.

FIG. 30 is an oblique view of the inner core engagement assembly and the inner core as in FIG. 24, showing the inner core in a third, engaged position relative to the inner core engagement assembly.

FIG. 31 is a side view of the inner core engagement assembly and the inner core as in FIG. 30, showing the inner core in the third, engaged position relative to the inner core engagement assembly.

FIG. 32 is a top view of the inner core engagement assembly and the inner core as in FIG. 30, showing the inner core in the third, engaged position relative to the inner core engagement assembly.

FIG. 33 is a cross-sectional view of a portion of the delivery catheter through the axial centerline of the delivery catheter, showing the inner core in the third, engaged position relative to the inner core engagement assembly.

FIG. 34 is a cross-sectional view of a portion of the delivery catheter through the axial centerline of the delivery catheter, showing the inner core in the disengaged position relative to the inner core engagement assembly.

FIG. 35 is a cross-sectional view of a portion of the delivery catheter through the axial centerline of the delivery catheter, showing the inner core in the engaged position relative to the inner core engagement assembly.

FIG. 36 is an illustration of a prosthesis partially deployed by the delivery catheter.

FIG. 37 is a side view of an exemplifying stent that can be deployed with the delivery catheter illustrated in FIG. 36.

FIG. 38 is a schematic side view of a catheter system having an introducer catheter assembly showing a stent being loaded into an outer sheath of the introducer catheter.

FIG. 39 is a schematic side view of a catheter system having a deployment catheter assembly showing a stent supported therein, and a branch vessel wire assembly loaded in the delivery catheter.

FIG. 40 is a cross-sectional view of the branch vessel wire assembly taken at line 40-40 of FIG. 39.

FIG. 41 is an enlarged schematic view of a portion 41-41 of the branch vessel wire assembly of FIG. 39.

#### DETAILED DESCRIPTION

The following detailed description is now directed to certain specific embodiments. In this description, reference is made to the figures wherein like parts are designated with like numerals throughout the description and the drawings. Described below are various embodiments of a catheter system that can comprise an introducer sheath and a docking arrangement. The catheter systems disclosed herein can be used in diagnostic or therapeutic procedures such as, but not limited to, endoluminal vascular prosthesis deployment procedures.

FIG. 1A is a schematic representation of a catheter system 10 comprising a docking arrangement configured to physically engage a catheter 20 with an introducer 12. FIG. 1B is a schematic representation of the catheter system 10 shown in FIG. 1A, showing the catheter 20 engaged with the introducer 12. The catheter 20 or any catheter disclosed herein can be a diagnostic or therapeutic catheter, or any other suitable catheter. The introducer 12 can comprise a tubular sheath 14, a seal 16, and a female docking mechanism 18. The first seal 16 can be a rubber seal, an interference or close tolerance fit

6

between adjacent components, an adjustable hemostasis valve, or any other suitable sealing component or feature.

The catheter 20 catheter has a shaft 24 and a male docking mechanism 22. As illustrated in FIG. 1B, the catheter 20 is inserted into the introducer 12 and the female docking mechanism 18 is engaged with the male docking mechanism 22. The docking mechanism prevents the introducer 12 and the catheter 20 from moving axially with respect to each other when the docking mechanism is engaged. Additionally, the catheter system 10 is configured so that the catheter 20 can rotate within the introducer 12, even when the catheter 20 is docked with the introducer 12.

The introducer 12 comprises a tubular introducer sheath 14 and a seal 16 (which, again, can be a rubber seal, an interference or close tolerance fit, an adjustable hemostasis valve, or any other suitable sealing component or feature) connected to the proximal end of the introducer sheath 14. The overall design of the sheath 14 and seal 16 may be similar to the design of commercially available introducers, or any other introducers presently known or later developed. The catheter 20 has an outside dimensional profile (crossing profile) that is sized and/or configured to pass through the introducer sheath 14. The proximal end of the catheter 20 and the proximal end of the introducer sheath 14 are configured to permanently or removably engage with each other, and to allow for the rotation of the catheter 20 within the introducer sheath 14 while substantially limiting the axial movement of the catheter 20 with respect to the introducer sheath 14.

With respect to the sizing of the introducer lumen versus the size of the outer sheath (containing the stent graft), in one configuration they are the same size and the introducer acts as a sheath, as the stent graft is pushed from its initial position within the outer sheath through to the lumen of the introducer. In a second configuration, the introducer lumen is larger than the outside diameter of the outer sheath and the two easily rotate relative to one another as needed for rotational alignment. Further, the introducer material can be softer or more flexible material than the outer sheath, so while the stent graft could be initially loaded into a strong high-strength sheath material, it could be extruded through to the lower strength more highly flexible introducer material for the short time needed to deliver the stent grafts to its treatment site. The materials that might be used to provide this feature, include any kind of soft polymer extrusion including Nylon, PEBAX, and PE.

After engagement of the catheter and introducer, the combined system is operable by a single operator. The catheter system 10 is configured so that the catheter 20 can substantially freely rotate within the introducer sheath 14, which can allow for precise rotational positioning of the catheter within the introducer. After completion of the procedure, the catheter 20 is disengaged from the introducer 12 so that the catheter 20 can be removed from the patient's body. Additionally, the introducer 12 can be repositioned for a second intervention and a second catheter can be inserted and engaged with the introducer 12 for additional procedures.

FIG. 2A is a schematic representation of a catheter system 40 comprising a docking arrangement to physically engage a catheter 50 with an introducer 42. FIG. 2B is a schematic representation of the catheter system 40, showing the catheter 50 engaged with the introducer 42. FIG. 2C is a schematic representation of the catheter system 40 shown in FIG. 2A, showing a mechanism for disengaging the catheter 50 from the introducer 42.

In particular, FIG. 2C schematically illustrate that the catheter 50 can be disengaged from the male docking mechanism 52 and the introducer 42 by compressing the levers or tabs 56.

Accordingly, as illustrated the male docking mechanism **52** can be elongated and can comprise levers **56**.

FIG. **3A** is a schematic representation of a catheter system **60** comprising a docking arrangement to physically engage a catheter **70** with an introducer **62**, the catheter system **60** being configured to deliver a stent or stent graft **80** into a blood vessel.

FIG. **3B** is a schematic representation of the catheter system **60** shown in FIG. **3A**, showing the catheter **70** engaged with the introducer **62**. FIG. **3C** is a schematic representation of the catheter system **60** shown in FIG. **3A**, illustrating the axial insertion of a stent or stent graft **80** into the tubular sheath **64** of the introducer **62** shown in FIG. **3A**. FIG. **3D** is a schematic representation of the catheter system **60** shown in FIG. **3A**, illustrating the stent **80** being deployed after the tubular sheath **64** of the introducer **62** shown in FIG. **3A** has been retracted from the stent **80**.

Self-expanding stent or stents grafts are typically retained in a deployment sheath within the delivery catheter. The deployment sheath can protect the stent or stent graft and the vessel wall from damage during insertion and can retain the stent or stent graft in a collapsed low-profile configuration during delivery. The stent or stent graft can be deployed in the desired position of the blood vessel by removing the deployment sheath and allowing the stent or stent graft to radially expand against the wall of the blood vessel. To pass such a delivery catheter into the desired blood vessel, the catheter system can be configured so that the inner diameter of the introducer sheath is larger than the outer diameter of the deployment sheath. Clinicians prefer a low profile of the introducer sheath to minimize damage to the blood vessel and allowing for access into small blood vessels.

Cartridge systems have been developed, in which the stent or stent graft can be transferred from delivery sheath into the introducer sheath and the stent or stent graft can be passed through the introducer sheath to the target location. In such cartridge systems, the introducer sheath effectively acts as a deployment sheath. The transfer eliminates the need for a second sheath and minimizes the profile of the system in the blood vessel. The docking arrangement provides a secure engagement of the delivery catheter and the introducer sheath prior to transfer of the stent or stent graft into the introducer sheath. This prevents potential user errors in the transfer and further converts the delivery catheter and introducer sheath into a single-user system.

As illustrated in FIGS. **3A-3D**, the catheter system **60** is used to transfer and deploy a stent or stent graft **80** into a blood vessel (blood vessel not shown). As illustrated therein, the introducer **62** comprises a tubular sheath **64** that is inserted into the body of the patient. The proximal end **62a** of the introducer **62** can be sized and/or configured to accommodate the deployment sheath **74** of the catheter **70**. The introducer sheath can also have a seal **66** (referred to herein as a first seal) and a female docking mechanism **68**, similar to any of the embodiments of the seal, hemostasis valve, and/or docking mechanisms described above. The seal **66** can be an annular rubber seal (as illustrated), an interference or close tolerance fit between adjacent components, an adjustable hemostasis valve, or any other suitable sealing component or feature. The stent delivery catheter **70** can comprise an inner core **78**, a pocket **82** that can house the collapsed stent **80**, a deployment sheath **74** that can retain the collapsed stent **80**, and a catheter tip **76**.

As illustrated in FIG. **3B**, the catheter **70** can be inserted into the introducer **62** when the docking mechanisms **68** and **72** are engaged. In some embodiments (not illustrated), the deployment sheath **74** of the delivery catheter **70** can be sized

and configured to be received within the larger diameter proximal end **62a** of the introducer sheath and to extend into the distal tubular sheath **64** of the introducer **62**. Alternatively, the deployment sheath **74** of the delivery catheter **70** can be sized and configured to be received within the larger diameter proximal end **62a** of the introducer sheath but not the distal tubular sheath **64** of the introducer **62**. In some embodiments, as illustrated in FIGS. **3C** and **3D**, the deployment sheath **74** and the tubular sheath **64** can be sized and configured such that, when the deployment sheath **74** has advanced through the proximal end **62a** of the introducer sheath, the similar size or shape of the distal tubular sheath **64** can prevent the deployment sheath **74** from advancing through the distal tubular sheath **64**. The inner and/or outer diameters of the deployment sheath **74** and the tubular sheath **64** can be substantially the same.

As illustrated in FIG. **3C**, The inner core **78** of the catheter **70** can be pushed distally, thereby transferring the stent **80** from the deployment sheath **74** into the tubular sheath **64** of the introducer **62**. The stent **80** can be advanced until the catheter tip **76** reaches the distal end of the tubular sheath **64**. In this configuration, the catheter/introducer system effectively becomes a single-unit deployment catheter. Thus, the tubular sheath **64** can function as a deployment sheath. The stent **80** can be advanced in a collapsed configuration within the protective introducer **62** to the target location in the blood vessel without increasing the profile of the delivery system. If the delivery catheter were passed through a traditional introducer sheath, the sheath of the introducer would have to be of a larger diameter than the deployment sheath of the delivery catheter to accommodate the stent and the deployment sheath. 2) other advantages which were mentioned:

In the configuration described the device can be rotated after it has been introduced to the introducer, but before it is deployed, further the device can be accurately position as a result of the low friction between the introducer and the outer sheath. When devices having an expanded diameter of 25 and 28 mm diameter devices are to be used, the same (one size) introducer sheath can be used for either and both devices delivery. Only when a larger 34 mm diameter device, having a larger compressed crossing profile, is to be delivered, is it necessary to use a larger introducer. The fact that the introducer and delivery catheter mechanically engage and create a single unitary structure which can be held by one hand, allows a single user to manipulate the whole system with two hands) one hand holding the core stationary and the second hand manipulating the sheath retraction mechanism.

As is known in the art, delivery catheters with loaded stent grafts typically have less trackability and pushability than an introducer sheath supported by a dilator. This is due to the fact that the stent grafts alter the local stiffness of the catheters. This can lead to kinking of the delivery catheter during insertion. By placing the introducer sheath with a dilator first, a conduit for placing the stent graft is established. Kinking of the delivery system pacing through the sheath is very unlikely.

FIG. **4** is an oblique view of another catheter system **100** comprising an introducer catheter **102** (also referred to as an introducer) and a delivery catheter **104**. The delivery catheter **104** can be configured for the delivery of an endoluminal prosthesis, or for any other suitable use. Therefore, the embodiments of the catheters and introducers disclosed herein can be configured for any suitable purpose, and the embodiments of the introducers disclosed herein can be configured to receive any suitable catheter design.

FIG. **5** is an oblique view of the introducer **102** of the catheter system **100** shown in FIG. **4**. FIGS. **6A** and **6B** are a

first and a second exploded assembly view of the introducer **102** shown in FIG. **5**. With reference to FIGS. **4-6**, the introducer **102** can have a main body **106**, a threadably engageable hub portion **108**, an introducer sheath **110**, and a threaded cap **111** configured to threadably engage with a threaded end portion of the main body **106**.

In some embodiments, a first tube **107** can be supported by the main body **106** so as to provide an orifice or access port into the main body **106**. The first tube **107** can be used to flush the introducer **102** with saline or other suitable substances at any stage, such as but not limited to prior to the advancement of an endoluminal prosthesis through the introducer **102**, or prior to other procedures for which an introducer may be used. The first tube **107** can support any suitable medical connector and/or valve on the distal end thereof.

The introducer sheath **110** can have an elongate portion **110a** extending to any predetermined or desired length. As will be discussed in greater detail below, similar to the introducer **12** of the catheter system **10** described above, the introducer sheath **110** can be configured such that an endoluminal prosthesis that is advanced into the introducer sheath **110** can be constrained or restrained by the introducer sheath **110**. In this arrangement, the inside and/or outside diameter of the introducer sheath **110** can be approximately the same as or similar to the inside and/or outside diameter of the outer sheath of a delivery catheter that is engaged with the introducer **102**. The elongate portion **110a** can be circular in cross-section (as illustrated), or can define any suitable cross-sectional shape such as without limitation triangular, square, hexagonal, octagonal, or polygonal.

Further, as shown most clearly in FIG. **6A**, the introducer sheath **110** can have a flared end portion **110b** that can be configured to abut against a fore surface **106a** of the main body **106**. With reference to FIG. **6A**, the elongate portion **110a** of the introducer sheath **110** can pass through an opening formed in the cap **111** so that the flared portion **110b** of the introducer sheath **110** can be engaged with and/or overlap an inside surface of the cap **111**. In this configuration, the cap **111** supporting the introducer sheath **110** can be threadably engaged with the main body **106** so that the introducer sheath **110** can be supported by the main body **106**.

Additionally, with reference to FIGS. **6A** and **6B**, a tubular support or spacer **109** can be inserted over the elongate portion **110a** of the introducer sheath **110** and positioned approximately adjacent to the flared portion **110b**. The tubular spacer **109** can improve the fit and, hence, the seal between the outside surface of the introducer sheath **110** and the cap **111**. The tubular spacer **109** can also provide additional support to the introducer sheath **110**.

FIG. **7** is an oblique view of the delivery catheter **104** of the embodiment of the catheter system **100** shown in FIG. **4**.

FIGS. **8A** and **8B** are a first and second exploded assembly view of the delivery catheter **104** shown in FIG. **7**.

FIG. **9** is an oblique view of the catheter system **100** shown in FIG. **4**, showing the delivery catheter **104** before the docking mechanism of the delivery catheter **104** has been engaged with the docking mechanism of introducer **102**.

FIG. **10** is an oblique view of the catheter system **100** shown in FIG. **4**, showing the delivery catheter **104** after the docking mechanism of the delivery catheter **104** has been engaged with the docking mechanism of the introducer **102**.

FIG. **11** is an end view of the catheter system shown in FIG. **4**, with the delivery catheter **104** engaged with the introducer **102**. FIG. **12** is a section view of the embodiment of the catheter system **100** shown in FIG. **4**, taken at line **12-12** of FIG. **11**. FIG. **13** is an enlarged section view of the catheter system **100** shown in FIG. **4**, defined by curve **13-13** of FIG.

**12**. FIG. **14** is an enlarged section view of the embodiment of the catheter system shown in FIG. **4**, defined by curve **14-14** of FIG. **13**. Finally, FIG. **15** is a section view of the catheter system shown in FIG. **4**, taken at line **15-15** of FIG. **11**.

As shown most clearly in FIGS. **12** and **15**, the hub portion **108** of the introducer **102** can have a docking mechanism or flange **112** or can be configured to removably receive or engage with the delivery catheter **104**. In some embodiments, as in the illustrated embodiment, the docking mechanism **112** of the introducer **102** can be configured to be a female receiver, configured to receive a male docking member of the catheter **104**, as will be described below. The hub portion **108** can comprise one or more tabs **114** configured to improve a user's grip on the hub portion **108**, and ability to rotate the hub portion **108** relative to the main body **106**.

With reference to FIGS. **12**, **13**, and **15**, some embodiments of the seal portion of the introducer **102** will be described. As mentioned above, the hub portion **108** can be configured to be threadably engageable with the main body **106**. The main body **108** can define an inner annular surface **116** that can be angled (so as to not be perpendicular to the axial centerline of the catheter system **100**). The surface **116** can be angled approximately 75 degrees relative to the axial centerline of the catheter system **100**, or from approximately 65 degrees or less to approximately 80 degrees or more relative to the axial centerline of the catheter system **100**. The surface **116** can be approximately perpendicular to the axial centerline of the catheter system **100**.

Similarly, the hub portion **108** can define an inner annular surface **118** that can be angled so as to not be perpendicular to the axial centerline of the catheter system **100**. The surface **118** of the hub portion **108** can be angled approximately 75 degrees relative to the axial centerline of the catheter system **100**, or from approximately 65 degrees or less to approximately 80 degrees or more and relative to the axial centerline of the catheter system **100** in a direction that is opposite to the direction of the angle defined by the surface **116** of the main body **106**. In some embodiments, as in the illustrated embodiment, the shape and angular orientation of the surface **118** of the hub portion **108** can be approximately minor the shape and angular orientation of the surface **116** of the main body **106**. The surface **118** can be approximately perpendicular to the axial centerline of the catheter system **100**.

An annular seal member **120** can be supported by the introducer **102** and positioned between the surface **116** of the main body **106** and the surface **118** of the hub portion **108**. The seal member **120** can be formed from a resilient material, such as silicone, rubber or any other suitable material. The seal member **120** can be configured such that, when the hub portion **108** is threaded onto the main body **106**, the surface **118** of the hub portion **108** can be moved axially toward the surface **116** of the main body **106**, thereby compressing or squeezing the seal member **120**. The relative angles of the surface **116** of the main body **106** and the surface **118** of the hub portion **108** can cause the seal member **120** to be forced against an outer sheath **122** of the delivery catheter **104** or other component of the delivery catheter **104** that is engaged with the introducer **102**, thereby creating an adjustable seal between the outer sheath **122** of the delivery catheter **104**, which can project distally from an end portion of the delivery catheter **104**, and the introducer **102**. The level of seal can be adjusted by tightening or loosening the hub portion **108** of the introducer **102** relative to the main body **106** of the introducer **102**. The introducer **102** can be configured to provide a seal against devices with a profile ranging from 1 Fr to 20 Fr.

Alternatively, in some embodiments, any of the seals or seal portions described herein can be an interference or close

tolerance fit between adjacent components such as, the outer sheath **122** and one or more inside surfaces of the main body **106** or the hub portion **108** of the introducer **102**. In some embodiments, any of the seals or seal portions described herein can be an interference or close tolerance fit between the inner core **154** and one or more inside surfaces of the main body **140** or the hub portion **142** of the catheter **104**.

As shown in FIGS. 7, 8A, and 8B, some embodiments of the delivery catheter **104** can comprise a main body **140** and a hub portion **142** threadably engageable with the main body **140**. Some embodiments of the delivery catheter **104** can also have an outer sheath **122** supported by the main body **140**. In particular, the outer sheath **122** can be removably supported by the main body **140** using a cap **123** threadably supported by the main body **140**. Further, the outer sheath **122** can have an elongate portion **122a** extending to any predetermined or desired length.

As mentioned above, the inside and/or outside diameter of the outer sheath **122** of a delivery catheter **104** can be approximately the same as or similar to the inside and/or outside diameter of the introducer sheath **110**. The elongate portion **122a** can be circular in cross-section (as illustrated), or can define any suitable cross-sectional shape such as without limitation triangular, square, hexagonal, octagonal, or polygonal.

The outer sheath **122** can have a flared end portion **122b** that can be configured to abut against a fore surface **140a** of the main body **140**. With reference to FIG. 8A, the elongate portion **122a** of the outer sheath **122** can pass through an opening formed in the cap **123** so that the flared portion **122b** of the outer sheath **122** can be engaged with and/or overlap an inside surface of the cap **123**. In this configuration, the cap **123** supporting the outer sheath **122** can be threadably engaged with the main body **140** as mentioned above so that the outer sheath **122** is supported by the main body **140**.

Additionally, with reference to FIGS. 8A and 8B, a tubular support or spacer **125** can be inserted over the elongate portion **122a** of the outer sheath **122** and positioned approximately adjacent to the flared portion **122b** of the outer sheath **122**. The tubular spacer **125** can improve the fit and, hence, the seal between the outside surface of the outer sheath **122** and the cap **123**. The tubular spacer **125** can also provide additional support to the outer sheath **122**.

Similar to the hub portion **108** of the introducer **102**, the hub portion **142** of the delivery catheter **104** can be configured to be threadably engageable with the main body **140** of the delivery catheter **104**. The main body **140** can define an inner annular surface **146** that can be angled so as to not be perpendicular to the axial centerline of the catheter system **100**. The surface **146** can be angled approximately 75 degrees relative to the axial centerline of the catheter system **100**, or from approximately 80 degrees or more to approximately 65 degrees or less relative to the axial centerline of the catheter system **100**. The surface **146** can be approximately perpendicular to the axial centerline of the catheter system **100**.

In some embodiments, a second tube **141** can be supported by the main body **140** so as to provide an orifice or access port into the main body **140**. The second tube **141** can be used to flush the delivery catheter **104** with saline or other suitable substances at any stage, such as but not limited to prior to the advancement of an endoluminal prosthesis through the delivery catheter **104** and/or introducer **102**, or prior to other procedures for which an delivery catheter may be used. The second tube **141** can support any suitable medical connector and/or valve on the distal end thereof.

Similarly, the hub portion **142** can define an inner annular surface **148** that can be angled so as to not be perpendicular to

the axial centerline of the catheter system **100**. The surface **148** of the hub portion **142** can be angled approximately 75 degrees relative to the axial centerline of the catheter system **100**, or from approximately 65 degrees or less to approximately 80 degrees or more relative to the axial centerline of the catheter system **100** in a direction that is opposite to the direction of the angle defined by the surface **146** of the main body **140**. The surface **148** can be approximately perpendicular to the axial centerline of the catheter system **100**.

Similar to that of the introducer, in some embodiments, a seal or seal portion comprising an annular seal member **150** can be supported by the delivery catheter **104** and positioned between the surface **146** of the main body **140** and the surface **148** of the hub portion **142**. The seal member **150** can be formed from a resilient material, such as silicone, rubber or any other suitable material. The seal member **150** can be configured such that, when the hub portion **142** is threaded onto the main body **140**, the surface **148** of the hub portion **142** can be moved axially toward the surface **146** of the main body **140**, thereby compressing or squeezing the seal member **150**. The relative angles of the surface **146** of the main body **140** and the surface **148** of the hub portion **142** can cause the seal member **150** to be forced against the inner core **154** of the delivery catheter **104**, thereby creating an adjustable seal between the inner core **154** the outer sheath **122** of the delivery catheter **104**.

The level of seal can be adjusted by tightening or loosening the hub portion **142** of the delivery catheter **104** relative to the main body **140** of the delivery catheter **104**. Additionally, The rotational freedom of inner core **154** of the delivery catheter **104** can be inhibited or prevented by tightening the seal member **150** as described above. Thus, the force exerted by the seal member **150** on the inner core **154** can be adjusted to permit the inner core **154** and/or other components to rotate relative to the main body **140** and hub portion **142** of the delivery catheter **104**. As illustrated in FIG. 4, an end portion or cap **158** can be supported at the proximal end of the inner core **154** to facilitate a user's ability to axially slide and/or rotate that inner core **154** relative to the main body **140** and hub portion **142** of the delivery catheter **104**. The cap **158** can have wings or tabs formed thereon to increase the torque or rotational force that can be exerted on the inner core **154**. Alternatively, The seal or seal portion within the catheter **104** can be formed from an interference or close tolerance fit between adjacent components such as, without limitation, the inner core **154** and one or more inside surfaces of the main body **140** or the hub portion **142** of the catheter **104**.

The inner core **154** can have a band or other marking **155** near a distal end thereof. The marking **155** can be sized, positioned, and configured to provide a visual indication to the medical practitioner as to the location of the end portion **154a** of the inner core **154** and/or the location of a catheter tip **162** as the inner core **154** is being advanced into or withdrawn from the introducer **102**.

In some embodiments, as illustrated most clearly in FIGS. 12 and 13, an additional seal member **160** can be supported by the main body **106** of the introducer **102** to provide an additional seal between the outer sheath **122** of the delivery catheter **104** and the introducer **102**. The seal **160** can be a flap type seal formed from a conically shaped piece of resilient material such as, but not limited to, rubber having one or more slits therein to allow the distal tip **162** and the outer sheath **122** to pass therethrough. In some embodiments, a supported flange **161** can be supported within the main body **106** and positioned behind the seal **160** to support the seal **160** and maintain the position of the seal **160** so that the seal **160** does not become inverted when the delivery catheter **104** is

13

removed from the introducer 102. The distal tip 162 can be formed from a soft material such as rubber and can be configured to be atraumatic so as to prevent any damage to a patient's vasculature as the catheter 104 is being advanced through the patient's vasculature.

As mentioned above, in some embodiments, as in the illustrated embodiment, the docking mechanism 112 of the introducer 102 can be configured to receive a male docking member or portion of the catheter 104. In particular, with reference to FIGS. 7, 8A and 8B, one or more deflectable tabs 170 can be supported by the main body 140 of the catheter 104. The tabs 170 can be deflected by pressing or exerting a radial inward force against pads 172, causing the ends of the tabs 170 to move radially inward toward the axial centerline of the main body 104. By deflecting the tabs 170 inwardly, the main body 140 of the catheter 104 can be moved axially into engagement with the hub portion 108 of the introducer 102. The tabs 170 can be automatically deflected inwardly when the main body 140 of the catheter 104 is moved axially into engagement with the hub portion 108 of the introducer 102. Once the main body 140 of the catheter 104 is moved axially into engagement with the hub portion 108 of the introducer 102 so as to abut against the hub portion 108 of the introducer, the tabs 170 can be released, thereby removably locking the main body 140 of the catheter 104 to the hub portion 108 of the introducer 102.

In this configuration, the catheter 104 can be axially engaged with or locked to the introducer 102 so that a user can axially manipulate the introducer 102 and the catheter 104 simultaneously. Additionally, in some embodiments, in this configuration, as discussed above, the catheter system 100 can be configured such that at least the inner core 154 of the catheter 104 can be rotated relative to the main body 140 of the catheter 104 and the introducer 102.

In some embodiments, as shown in FIGS. 7, 8A, and 8B, the inner core 154 has a central tube or wire 176 configured to support a stent, such as stent 157 illustrated in FIGS. 7 and 12-14. Additionally, one or more beads or tabs 174 can be formed on or supported by the central tube or wire 176. The tabs 174 can be configured to increase the axial support or connection between the inner core 154 and an endoluminal prosthesis supported by the central tube 176 when the prosthesis is supported in a collapsed configuration by the central tube 176. The catheter 104 can be configured such that an opening passes through the distal tip 162, the central tube 176, and the inner core 154. The opening can be configured so that at least the distal tip 162, the central tube 176, and the inner core 154 can be advanced over a guidewire positioned within a patient's vasculature, such as is described in U.S. patent application Ser. No. 12/101,863 filed on Apr. 11, 2008 (titled: BIFURCATED GRAFT DEPLOYMENT SYSTEMS AND METHODS), which application is hereby incorporated by reference in its entirety as if fully set forth herein.

Additionally, in some embodiments (not illustrated), the tabs 174 can be sized, spaced, and otherwise configured to provide axially support to multiple individual stent segments. For example, without limitation, multiple independent or tethered stent segments can be positioned within a tubular or bifurcated graft, and the stent graft can be positioned relative to the tabs 174 such that the tabs 174 are positioned between the stent segments. This arrangement can reduce the overall diameter of the outer sheath 122, the introducer sheath 110, and other components comprising the catheter system, can enhance the axial support provided by the tabs 174 to the endoluminal prosthesis, and can allow for a more uniform distribution of support forces between the tabs 174 and the endoluminal prosthesis. The tabs 174 can be sized, spaced,

14

and otherwise configured so as to be positioned adjacent to the links, bends, loops, and/or other connectors formed in a tubular or bifurcated stent, such as the links, bends, loops, and/or other connectors comprising the embodiments of the stents disclosed in U.S. Pat. No. 6,077,296 titled ENDOLUMINAL VASCULAR PROSTHESIS, which patent is hereby incorporated by reference as if fully set forth herein.

With reference to FIGS. 13-15, the outer sheath 122 of the deployment catheter 104 can be advanced into an axial opening within the introducer 102 when the deployment catheter 104 is engaged with the introducer 102. The outer sheath 122 can be sized and configured such that the distal end portion 122c of the outer sheath 122 can terminate within the introducer 102 prior or proximal to the proximal end or flared portion 110b of the introducer sheath 110. Although not required, the introducer 102 can have a constricted portion 113 formed in the main body 106 of the introducer. In some embodiments, as shown most clearly in FIG. 14, the catheter system 100 can be configured such that the distal end 122c of the outer sheath 122 terminates prior to or approximately adjacent to a constricted portion 113 of the main body 106 of the introducer 102.

In some embodiments (not illustrated), the distal end portion 122c of the outer sheath 122 can be positioned near to or approximately adjacent to the proximal end portion or the flared portion 110b of the introducer sheath 110, regardless of whether the catheter 104 has a constricted portion 113. The inner diameter of the constricted portion 113 can be approximately the same as the inner diameter of the outer sheath 122 and/or the inner diameter of the introducer sheath 110.

Therefore, The outer sheath 122 of the catheter 104 and the introducer sheath 110 can be configured to provide a lumen having a generally uniform cross-sectional size through the catheter system through which the endoluminal prosthesis can be advanced. The lumen through the catheter system 100 through which the endoluminal prosthesis can be advanced can be substantially continuous, so that the endoluminal prosthesis can be advanced through the catheter system 100 without the prosthesis being obstructed by or snagging on any components or features of the catheter system 100 as it is being advanced. The lumen can be substantially continuous but have short gaps on the order of approximately 1 mm to approximately 3 mm in the lumen such as, without limitation, adjacent to the distal end of the outer sheath 122 of the catheter 104 and/or adjacent to the proximal or flared end 110b of the introducer sheath 110. For example, in some embodiments, short gaps can be formed adjacent to the distal end of the outer sheath 122 of the catheter 104 and/or adjacent to the proximal or flared end 110b of the introducer sheath 110 as some components comprising the catheter system 100 are threadedly engaged with other components comprising the catheter system 100. Further, in some embodiments, one or more surfaces of other components comprising the catheter 104 or the introducer 102 in addition to the outer sheath 122 and the introducer sheath 110, such as without limitation the constricted portion 113 of the main body 106 of the introducer 102 as discussed above, can form portions of the lumen through the catheter system 100.

The outer sheath 122 can constrain or restrain an endoluminal prosthesis supported by the central tube 176 as described above. In this configuration, as the catheter tip 162, central core 154, and an endoluminal prosthesis (such as, but not limited to, stent 157 illustrated in FIGS. 7 and 12-14) are advanced through the outer sheath 122, the outer sheath 122 can restrain the endoluminal prosthesis and prevent the endoluminal prosthesis from expanding before reaching the target position within the patient's vasculature. Additionally,

the catheter system **100** can be configured such that, as the catheter tip **162**, central core **154**, and endoluminal prosthesis are advanced past the distal end **122c** of the outer sheath **122**, the constricted portion **113** and, subsequently, the introducer sheath **110** can radially restrain the endoluminal prosthesis as the endoluminal prosthesis is advanced through the introducer sheath **110**.

The endoluminal prosthesis or the stent **157** can be a tubular stent, a bifurcated stent, or any other desirable stent, graft, stent graft, or endoluminal prosthesis (collectively referred to herein as stent or stents), including without limitation any of the stents or grafts disclosed in U.S. patent application Ser. No. 12/101,863 referenced above and incorporated herein by reference as if fully set forth herein. Accordingly, the catheter system **100** or catheter **104** can be configured to deploy any suitable or desirable stent or stents.

Thus, in this configuration, the endoluminal prosthesis can be transferred from the outer sheath **122** to the introducer sheath **110**. In this arrangement, using the introducer sheath **110** as the restraint can allow the outside diameter of the introducer sheath **110** to be reduced, which can minimize trauma to the patient's vasculature and assist in the deployment of the endoluminal prosthesis.

Many embodiments of the docking mechanism and catheter system have been described in connection with FIGS. **1-15**. It will be apparent to one of ordinary skill in the art that there are many potential embodiments of a permanent or removable docking mechanism that may be suitable for medical use and which are contemplated herein. For example, in some embodiments, a nut-screw combination could be used to connect the introducer sheath and the catheter. As another example, a bayonet style locking mechanism, such as is used for camera lenses, can also be used. In some embodiments, any of the components or features of some embodiments of the catheters disclosed herein or other catheters available in the field can be combined to form additional embodiments, all of which are contemplated herein.

The catheter system disclosed in FIG. **16** has an introducer catheter assembly, also referred to herein as an introducer catheter, and a delivery catheter assembly, also referred to herein as a delivery catheter.

The catheter systems disclosed herein can be used for diagnostic or therapeutic procedures such as, but not limited to, endoluminal vascular prosthesis deployment procedures. It should be apparent to one skilled in the art that the catheter system embodiments disclosed herein can be used for delivering prostheses for supporting body tissue in general as well as various blood vessels and aneurysms. Examples of such blood vessels that can be treated with the catheter system embodiments disclosed herein include the aorta, aortic aneurysms such as abdominal aortic aneurysms, saphenous vein grafts, the vena cava, the renal arteries, the iliac arteries, the femoral arteries, the popliteal artery, the carotid artery, the cranial arteries, pulmonary arteries, etc. Other organs or body tissue that can be treated with some catheter system embodiments disclosed herein include the prostate, the biliary tract, the esophagus, the trachea, the fallopian tubes, the vas deferens, the ureters, the tear ducts, the salivary ducts.

The catheter systems disclosed herein can be configured for deployment of a wide range of endoluminal prostheses, including mechanically expandable stents, self-expanding stents, drug eluting stents, grafts, bifurcated and non-bifurcated stent grafts, fenestrated stent grafts, suprarenal stent extensions, stent segments, dissection treatment devices, medical prostheses deployable in any suitable region of the body, and any of the stents or prostheses disclosed in U.S. application Ser. No. 12/101,863, filed Apr. 11, 2008, U.S.

application Ser. No. 12/496,446, filed Jul. 1, 2009, U.S. application Ser. No. 12/769,506, filed Apr. 28, 2010, and U.S. Pat. No. 6,077,296, which are hereby incorporated by reference as if fully set forth herein.

The stent can have an oversized graft have a mid portion that is not sutured or otherwise attached to the stent frame. In this configuration, the mid portion can be permitted to expand against an inside wall of the vessel or passageway to further improve the seal between the graft and the vessel wall. Additionally, the stent can have an oversized graft of highly collapsible, flexible material (e.g., expanded polytetrafluoroethylene) such that, when the stent is expanded, the graft can form tight folds in the seal zone to reduce cross-sectional area of leak zones between the stent and the vessel wall.

For simplicity, all such foregoing stents or prostheses are collectively referred to herein as a stent or stents unless otherwise defined. Therefore, while illustrations and the disclosure that follows may describe stents and may show deployment in a particular passageway or in a region of the body, it is contemplated that any of the embodiments disclosed herein can be used, with or without modifications within the capabilities of one of ordinary skill in the art, for deployment of any desired prosthesis in any suitable portion of the body.

FIG. **16** is an oblique view of a catheter system **100**, having a delivery catheter assembly **104** docked to an introducer catheter assembly **102**. FIGS. **17-19** are oblique, top, and side views, respectively, of the delivery catheter assembly **104** of FIG. **1**. With reference to FIGS. **16-17**, the catheter system **100** has a docking arrangement wherein a proximal end portion of an introducer catheter assembly **102** can receive and dock with a distal end portion **121a** of the main body **121** (also referred to herein as housing member or housing shaft) of a delivery catheter assembly **104**. The introducer catheter **102** can have an outer sheath **110** (also referred to herein as an introducer sheath) supported by and extending from a distal end portion of the introducer catheter **102**. Similarly, the delivery catheter assembly **104** has a tubular sheath **127** (also referred to herein as a delivery catheter sheath) extending from a distal end portion **121a** of the housing shaft **121**. The sheath **127** can be made from polyether ether ketone (PEEK), or any other suitable material.

Additional details regarding the features and components of such a docking arrangement and other details regarding the catheter system are disclosed in U.S. application Ser. No. 12/101,863, filed Apr. 11, 2008, entitled "BIFURCATED GRAFT DEPLOYMENT SYSTEMS AND METHODS" and U.S. application Ser. No. 12/496,446, filed Jul. 1, 2009, entitled "CATHETER SYSTEM AND METHODS OF USING SAME," both incorporated by reference as if fully set forth herein. Any of the embodiments of the catheter systems, the delivery catheters, and the introducer catheters disclosed herein can have any of the components, features, materials, or other details of any of the embodiments of the catheters disclosed in the foregoing applications, which combinations are made part of this disclosure.

One or more stents can be loaded in, supported by, and delivered by the catheter system **100** embodiments disclosed herein. A stent or stents can be loaded into the delivery catheter assembly **104** during assembly of the delivery catheter assembly **104** or just before the surgical procedure by compressing the stent around an outer surface of an inner core member **115** of the delivery catheter assembly **104**.

A removable restraint and/or an outer sheath of the introducer catheter and/or delivery catheter can hold the stent in a compressed state. In the compressed state, the stent can be held in a generally fixed axial position relative to the inner core such that axial or rotational movement of the inner core

will result in axial and rotationally movement of the stent. As will be discussed, the inner core can have features, such as fins, beads, tabs, or other projections, to improve the traction or grip between the compressed stent and the inner core or inner core wire. the inner core with the stent compressed around the outer surface thereof will be advanced through a constriction element in or adjacent to the introducer catheter to compress the stent to the approximate inner diameter of the outer sheath projecting from the introducer catheter.

the inner core member 115 can have a core wire 117 forming a portion of the inner core member 115. An atraumatic distal tip 119 can be supported at a distal end portion of the core wire 117. The inner core member 115, core wire 117, and the distal tip 119 can comprise a continuous lumen there-through, being configured to receive a guide wire therein such that the inner core member 115, the core wire 117, and the distal tip 119 can be advanced over the guide wire. the stent can be collapsed or compressed about at least a portion of the inner core wire 117 in the stent loaded condition.

As mentioned, the catheter system can be configured such that the inner core member 115 is axially slidable relative to the outer sheath 110. In this configuration, the stent can be deployed in the target region of the patient's vasculature by retracting the outer sheath 110 relative to the inner core member 115, thereby exposing the stent. In some embodiments where the outer sheath 110 provides radial constraint to the stent, exposing the stent will permit a self-expanding stent to self-expand against the vessel wall as the outer sheath 110 is being retracted.

As will be described in greater detail, some embodiments of the catheter system 100 disclosed herein are configured such that, when a user or surgeon manipulates the delivery catheter assembly 104 slowly and with mechanical advantage in a first manner, the delivery catheter can be used to slowly and controllably deploy a stent or a portion of a stent from the delivery catheter assembly 104. Some embodiments of the catheter system disclosed herein are further configured such that, when a user or surgeon manipulates the delivery catheter assembly 104 quickly by directly pulling the adjustment member in a second manner, the delivery catheter assembly 104 is used to more rapidly deploy the stent or a portion of the stent from the delivery catheter assembly 104.

The catheter systems disclosed herein can be configured to accommodate any combination of the manners of deployment described above. For example, the user or surgeon can initially manipulate the delivery catheter in the first manner to slowly deploy the stent from the delivery catheter assembly 104 and then, once the proper positioning of the partially deployed stent is confirmed, the surgeon can then manipulate the delivery catheter assembly 104 in the second manner to rapidly deploy the remainder of the stent.

With reference to FIG. 16, a distal end portion 121a of the housing shaft 121 of the delivery catheter assembly 104 is removably and axially supported by a female receiving portion 105 supported at a proximal end portion of the introducer catheter 102. The introducer catheter 102 supports an outer sheath 110 at a distal end thereof, the outer sheath 110 defining a lumen therethrough that is configured to slidably receive an inner core member 115 therein. The inner core member 115 can be slidably advanced through an opening or lumen in the delivery catheter assembly 104, through an opening or lumen in the introducer catheter 102, and through a lumen in the outer sheath 110.

The delivery catheter assembly 104 has a main body or housing shaft 121 having a distal end portion 121a and a proximal end portion 121b. The housing shaft 121 pounds a generally tubular cross-sectional shape, and has external

threads 126 along a portion of the housing shaft 121 (referred to as the threaded portion 126).

The housing shaft 121 supports a slidable handle member 128 that can be configured to slide axially along the housing shaft 121 between the distal end portion 121a of the housing shaft 121 and an rotatable adjustment member 130 supported by the housing shaft 121. As will be described, the delivery catheter assembly 104 is configured such that the handle member 128 is selectively engageable with the inner core member 115. When in the engaged configuration, movement of the handle member 128 results in simultaneous and equal movement of the inner core member 115. the delivery catheter assembly 104 can be configured such that the handle member 128 is prevented from rotating relative to the housing shaft 121 and, consequently, the introducer catheter 102 and outer sheath 110, to prevent any inadvertent rotation of the inner core member 115 when the handle member 128 is engaged with the inner core member 115.

The threaded portion 126 extends along approximately 60% of the length of the housing shaft 121. The threaded portion 126 can extend along approximately 40% to approximately 70% of the length of the housing shaft 121. The threaded portion 126 can be positioned adjacent to the proximal end portion 121b of the housing shaft 121. The length of the threaded portion 126 can be from approximately 20% to approximately 200% of the length of the stent to be deployed by the catheter. For example, if only the proximal end portion of the stent is to be deployed by rotation of the adjustment member 130, the length of the threaded portion can be approximately from 20% to approximately 50% of the length of the stent. As used throughout this disclosure, the term approximately can mean plus or minus 15% of the stated value.

Preventing the rotational movement of the handle member 128 can be achieved in any number of ways. For example, the handle member 128 has a tab, protrusion, or similar feature or features that can project into one or more channels or slots formed in the housing shaft 121. As illustrated in FIG. 16, the housing shaft 121 can have a single slot 134 extending in a linear fashion along a portion of the length of the housing shaft 121, the slot 134 configured to slidably receive therein a tab, protrusion, or other similar feature supported by the handle member 128.

The handle member 128 pounds an inner core engagement assembly 139 supported by the handle member 128. As mentioned, the delivery catheter assembly 104 is configured such that, when the inner core member 115 is axially engaged with the handle member 128, any axial movement of the handle member 128 will result in simultaneous axial movement of the inner core member 115 relative to the introducer catheter 102 and the outer sheath 110. Depressing the inner core engagement assembly 139 can release the inner core member 115 from the handle member 128 so that the inner core member 115 can be axially moved relative to the handle member 128. In some configurations, the inner core member 115 can be rotated relative to the handle member 128 even when the inner core member 115 is axially engaged with the handle member 128.

As mentioned, the rotatable adjustment member 130 is supported by the housing shaft 121. The rotatable adjustment member 130 is threadedly engaged with the outer threads on the threaded portion 126 of the handle member 128. In this configuration, rotating or turning the rotatable adjustment member 130 in one direction causes the rotatable adjustment member 130 to advance along the threads and move in an axial direction toward the distal end portion 121a of the housing shaft 121. Rotating or turning the rotatable adjust-

ment member 130 in a second, opposite direction causes the rotatable adjustment member 130 to move in an axial direction away from the distal end portion 121a of the housing shaft 121 of the delivery catheter assembly 104. As a result of the threaded engagement between the rotatable adjustment member 130 and the housing shaft 121, the rotatable adjustment member 130 can be prevented from axially sliding relative to the housing shaft 121. Accordingly, the handle member 128 can axially slide but be prevented from rotating relative to the housing shaft 121, and the rotatable adjustment member 130 can rotate but be prevented from axially sliding relative to the housing shaft 121.

In use, a surgeon may grasp the handle member 128 with one hand (for example, the left hand) and the rotatable adjustment member 130 (which is initially axially positioned adjacent the proximal 130a of the housing shaft) with the other hand. The surgeon moves the inner core member 115 to engage with the handle member 128. To retract the outer sheath 110 of the introducer catheter 102 relative to the inner core member 115, the surgeon holds the handle member 128 in a fixed position while axially withdrawing the housing shaft 121 of the delivery catheter assembly 104, which is axially fixed to the introducer catheter 102 and to outer sheath 110. Holding the handle member 128 in a fixed position, with the inner core engagement (and release) assembly 139 engaged with the inner core member 115, holds the inner core member 115 fixed as the outer sheath 110 is axially retracted relatively inner core member 115 fixed to the housing shaft 121. Retracting the housing shaft 121 portion of the delivery catheter assembly 104 can be done by grasping and rotating the rotatable adjustment member 130 or directly by applying a pull force to retracting the rotatable adjustment member 130 relative to the handle member 128. This step causes withdrawal of the outer sheath 110 relative to the inner core member 115 is desired.

The slower incremental withdrawal of the outer sheath 110 relative to the inner core member 115 is accomplished as the rotatable adjustment member 130 axially abuts a proximal end 128a of the handle member 128. Rotating the rotatable adjustment member 130 in a first direction while holding the handle member 128 in a fixed axial position will slowly and incrementally and controllably retract or withdraw the housing shaft 121 of the delivery catheter assembly 104 and, consequently, the outer sheath 110. This controlled withdrawal of the outer sheath 110 is usually performed during the initial deployment phase of exposing and deploying a stent, to allow the surgeon greater control and accuracy in positioning the stent in the target location.

In sum, in this configuration, with the handle member 128 initially positioned on a proximal portion of the housing shaft 121, a surgeon can controllably retract the outer sheath 110 to expose the stent by holding the handle member 128 in a fixed position relative to the patient in one hand, while using his or her other hand to turn the rotatable adjustment member 130 in a first direction to retract the housing shaft 121 and outer sheath 110 relative to the handle member 128 and inner core member 115. Once the surgeon is confident that the stent is in the desired position, the surgeon can then more rapidly retract the outer sheath 110 relative to the inner core member 115 by grabbing and axially retracting the housing shaft 121 relative to the handle member 128.

As illustrated in FIGS. 17-19, the delivery catheter assembly 104 can have a selectively engageable locking feature positioned on the inner core member 115, such as the lock engagement ring 147. As will be described in greater detail below, the engagement ring 147 can be configured to removably engage with the inner core engagement assembly 139.

As discussed above, when the inner core member 115 is engaged with the engagement assembly 139, the inner core member 115 is axially locked to the engagement assembly 139 such that axial movement of the handle member 128 results in simultaneous axial movement of the inner core member 115. the inner core member 115 can be free to rotate relative to the engagement assembly 139 and the handle member 128 even when in the locked or engaged position. The engagement ring 147 can be adhered to, integrally formed with, or otherwise permanently fixed to an outer surface of the inner core member 115.

With reference to FIGS. 17-19, some embodiments of the engagement ring 147 can have a tapered surface 149 and an annular channel 152. The tapered surface 149 can improve the ease with which the engagement ring 147 can be advanced into the engagement assembly 139. Additional details regarding these components will be described below.

FIG. 20 is an oblique view of the delivery catheter assembly 104 of FIG. 16, illustrating the inner core member 115 in a fully or approximately fully advanced position relative to the delivery catheter assembly 104. In this position, the inner core member 115, the inner core wire 117, and the distal tip 119 are all advanced past the end of the sheath 127 of the delivery catheter assembly 104. When the delivery catheter assembly 104 is engaged with the introducer catheter 102, the inner core member 115, the inner core wire 117, and the distal tip 119 are also be advanced relative to the end of the outer sheath 110 such that a stent supported by the inner core member 115 would be at least partially, and in some cases fully, exposed.

FIGS. 21-23 are side views of the delivery catheter of FIG. 16, showing the sheath in a first, pre-deployment position, a second, partial deployment position, and a third, fully retracted position, respectively, and the positions of the housing shaft 121, handle member 128, and the inner core member 115 of the delivery catheter assembly 104. The delivery catheter assembly 104 is configured such that the handle member 128 slides along the housing shaft 121 between the first position, as illustrated in FIG. 21, and at least a third position, as illustrated in FIG. 23. Therefore, in this configuration, the handle member 128 is held stationary while the user or surgeon can retract the housing shaft 121 by sliding it relative to the handle member 128. Accordingly, when the handle member 128 is engaged with the inner core member 115, a surgeon can very rapidly advance the inner core member 115 relative to the distal end portion 121a of the housing shaft 121 of the delivery catheter assembly 104 by sliding the handle member 128 toward the distal end portion 121a of the housing shaft 121. Similarly, if the surgeon desires to hold the inner core member 115 and prosthesis in a fixed position within the patient's vasculature, the surgeon or user can hold the handle member 128 in a fixed position and axially slide or retract the delivery catheter assembly 104 away from the patient's body so as to retract the outer sheath 110 of the introducer catheter 102 relative to the inner core member 115 and prosthesis, thereby exposing the prosthesis.

The rotatable adjustment member 130 is separable from the handle member 128 so that the adjustment member 130 and housing shaft 121 can move independently of the handle member 128. The adjustment member 130 includes inside threads that engage with the external threads on the threaded portion 126 of the housing shaft 121. Rotating the adjustment member 130 in a first direction axially retracts the housing shaft 121 and sheath as the adjustment member 130 maintains contact with the handle member 128 as the adjustment member rotates. Rotation of the adjustment member 130 is used to control the speed of slow retraction of the housing shaft 121

or an axial force applied to the adjustment member provides the option of a quick retraction.

The handle member 128 is selectively engageable with the inner core member 115. FIG. 24 is an oblique view of the inner core engagement assembly 139 and the inner core member 115, showing the inner core member 115 in a first, disengaged position relative to the inner core engagement assembly 139, other components of the delivery catheter being removed from this view for clarity. FIG. 25 is a cross-sectional view of a portion of the delivery catheter assembly 104 through the axial centerline of the delivery catheter assembly 104, showing the inner core member 115 in a first, disengaged position relative to the inner core engagement assembly 139. FIG. 26 is an oblique view of the inner core engagement assembly 139 and the inner core member 115 as in FIG. 24, showing the inner core in a second, partially engaged position relative to the inner core engagement assembly.

With reference to FIGS. 24-26, in some embodiments of the delivery catheter assembly 104, an engagement ring 147 is supported by the inner core member 115. The engagement ring 147 has a tapered fore surface 149 and a channel or depression 152 formed around an outside surface of the engagement ring 147. The fore surface 149 can have a generally frustoconical shape, and the channel 152 can be formed all around the engagement ring 147 forming a ring groove. The engagement ring 147 is adhered to, formed integrally with, or otherwise fastened to or supported by the inner core member 115 at any desired position along the length of the inner core member 115.

With reference to FIGS. 24-26, a body member 155 of the engagement assembly 139 supports one or more tabs or arms 159 configured to engage with the engagement ring 147. The one or more arms 159 can have inward facing tabs or projections 166 supported at the proximal end 159b of the one or more arms 159. The arms 159 are supported by the body member 155 in a cantilevered configuration so that the base portion 159a of the one or more arms 159 is fixed to the body member 155 and such that the proximal end portion 159b of the one or more arms 159 is unsupported. The arms 159 are supported by the body member 155.

The engagement ring 147 is configured to be received by the inner core engagement assembly 139 by sliding the inner core member 115 in a first (distal) direction (represented by arrow A1 in FIG. 24) until the engagement ring 147 is engaged with the engagement assembly 139. As illustrated in FIG. 26, as the inner core member 115 and engagement ring 147 are moved toward the engagement assembly 139, a tapered fore surface 149 of the engagement ring 147 causes the tabs or arms 163 spread apart as the engagement ring 147 is advanced into the engagement assembly 139, as illustrated in FIGS. 26-28. With further advancement of the inner core member 115 relative to the handle member 128, when the protruding portions 166 of the arms 159 are in axial alignment with the channel 152, the protruding portions 166 of the arms 159 can compress and shrink (spring) toward each other and into the channel 152 due to the bias of the one or more arms 159. As illustrated in FIGS. 30-32, the inner core member 115 is axially engaged with the handle member 128 until the user disengages the engagement assembly 139 from the engagement ring 147. the inner core member 115 can be freely rotated relative to the handle member 128 even when axially engaged with the handle member 128.

The engagement assembly 139 is further configured so that moving the one or more arms 159 in a radial direction (spreading them, as shown in FIG. 27B) will cause the protruding portions 166 of the arms 159 to be lifted away from the channel 152 of the engagement ring 147. The one or more

spread tabs 173 supported by a body portion 175 or configured to exert the necessary radial force (spreading) on the arms 159 to lift the protruding portions 166 away from the engagement ring 147. The spread tabs 173 can have a tapering shape such that, moving the spread tabs 173 in a downward direction relative to the one or more arms 159 deflects the arms 159 outward. Depressing button 180 forces the spread tabs 173 downward, thereby deflecting the arms 159 outward so that the engagement ring 147 is axially released and axially moved away from the engagement assembly 139.

FIG. 34 is a cross-sectional view of a portion of the delivery catheter through the axial centerline of the delivery catheter, showing the inner core member 115 in a disengaged position relative to the inner core engagement assembly 139.

FIG. 35 is a cross-sectional view of a portion of the delivery catheter assembly 104 through the axial centerline of the delivery catheter assembly 104, showing the inner core member 115 in an engaged position relative to the inner core engagement assembly 139. As illustrated therein, a biasing mechanism or spring member 184 is supported by the handle member 128 and is configured to bias the button 180 and, consequently, the spread tabs 175, in a first direction away from the inner core member 115.

Further, with reference to FIGS. 34-35, the handle member 128 has a stop member 198 configured to limit the range of motion of the engagement ring 147 and inner core member 115 relative to the handle member 128. For example, the first end portion 198a of the stop member 198 is configured to abut against a fore surface 149 of the engagement ring 147 when the engagement ring 147 is advanced into the handle member 128.

The stent can be preloaded in the introducer catheter assembly or introducer sheath such that the stent need not be transferred into the catheter assembly or introducer sheath during the surgical operation. The delivery catheter system can have an introducer sheath, inner core, and some or all of the other features of the delivery catheter disclosed herein in one apparatus. In of this inclusive apparatus, the inner core can be permanently joined to the handle member 128 such that there would be no need to configure the delivery catheter to be selectively engageable with the inner core, thereby simplifying the assembly and potentially simplifying the surgical procedures. Therefore, some embodiments of this inclusive delivery catheter assembly, the delivery catheter assembly can have all of the components, features, details, or configurations of the embodiments of the catheter system 100 described above, wherein the inner core engagement assembly 139 and the lock engagement ring 147 of the inner core member 115 can be replaced with a non-selectable coupling or other connection between the inner core member 115 and the handle member 128.

FIG. 36 is an illustration of a prosthesis partially deployed by the delivery catheter assembly 104. FIG. 37 is a partial side view exemplifying a stent that can be deployed with the delivery catheter assembly 104. The deployment catheter illustrated in FIG. 36 can be adapted for deployment of any suitable prosthesis and is not limited to deployment of the stent illustrated in FIG. 37. With reference to FIGS. 20, 36, and 37, one or more beads or tabs 174 can be formed on or supported by the core wire 117. The tabs 174 can be configured to increase the axial support or connection between the inner core wire 117 and a stent 214 supported by the core wire 117 when the stent is supported in a compressed on the core wire 117. Additionally, the tabs 174 can be sized, spaced, and otherwise configured to provide axial support to multiple individual stent segments (not illustrated). For example, multiple independent or tethered stent segments can be posi-

tioned within a tubular or bifurcated graft or otherwise, and the stent can be positioned relative to the tabs 174 such that the tabs 174 are positioned between the stent segments 216 or between the apices, knuckles, or connection points 218 interconnecting the struts.

In the configuration shown, the beads or tabs 174 supported by the core wire 117 can engage the struts 216 or connection points 218 of the stent 214 to help prevent the stent from axially slipping relative to the inner core wire 117 for portions of the stent 214 that remain compressed within the outer sheath 110. This arrangement provides greater control over the stent 214 during the final stages of deployment of the stent 214, for example, when only an end portion of the stent 214 remains compressed within the outer sheath 110, as illustrated in FIG. 36.

Additionally, positioning the tabs 174 between the struts 216 or connection points 218 can reduce the compressed diameter or crossing profile of the compressed prosthesis, the outer sheath 110, and other components comprising the catheter system. This arrangement can also allow for a more uniform distribution of support forces between the tabs 174, the inner core wire 117, and the stent 214. The tabs 174 can be sized, spaced, and otherwise configured so as to be positioned adjacent to the links, bends, loops, and/or other connectors formed in a tubular or bifurcated stent, such as the links, bends, loops, and/or other connectors comprising the embodiments of the stents disclosed in U.S. Pat. No. 6,077,296, entitled ENDOLUMINAL VASCULAR PROSTHESES, which patent is hereby incorporated by reference as if fully set forth herein.

In any of the catheter system embodiments disclosed herein, the catheter system can be configured as described herein such that the stent can be compressed from a first diameter or size to a second diameter or size as the stent is being loaded into the introducer or introducer sheath. The first diameter or size can be the fully relaxed or expanded diameter of the stent, or the first diameter or size can be a partially compressed diameter. For example, for some of the embodiments disclosed herein, the stent can be compressed from a first diameter, as defined or controlled by the sheath of the delivery catheter or by an assembly apparatus surrounding the stent, to a second diameter, as defined or controlled by the introducer sheath. The reduction ratios of the stent when advanced into the introducer can be from approximately 50% to approximately 95%, meaning that the second diameter can be from approximately 50% to approximately 95% of the first diameter.

FIG. 38 is a side view of a catheter system 300 having an introducer catheter assembly 302, showing a stent being loaded into an outer sheath of the introducer catheter assembly 302. Only a portion of the delivery catheter 304 is illustrated and certain features of the introducer catheter assembly 302 have been omitted for clarity. The catheter system 300 and/or the introducer catheter assembly 302 can have any of the components, features, materials, or other details of any of the embodiments of the catheter systems or introducer catheter assemblies disclosed or incorporated by reference herein, including U.S. application Ser. No. 12/496,446, filed Jul. 1, 2009, entitled "CATHETER SYSTEM AND METHODS OF USING SAME." Further, the embodiments of the introducer catheter assembly 302 can be configured to work with any of the delivery catheter assembly embodiments disclosed or incorporated by reference herein.

With reference to FIG. 38, the introducer catheter assembly 302 can have a main body portion 306 and an outer sheath 310 supported at a distal end 306a of the main body portion 306. An inner aperture or opening 312 on the inside of the intro-

ducer catheter assembly 302 can be coaxial with the opening formed through the outer sheath 310. the introducer catheter assembly 302 can have tapered or curved wall portions 314 that are configured to compress the stent 320 from a first diameter "a" to a second diameter "b" that is equal to an inside diameter of the (introducer) outer sheath 310 as the stent 320 is being advanced through the introducer catheter assembly 302.

The introducer catheter assembly 302 and the delivery catheter can be configured such that the distal end 316a of the sheath 316 terminates prior to or approximately adjacent to the constricted portion of the main body portion 306. In this configuration, the stent can be loaded into the delivery catheter in a relaxed or mostly relaxed (i.e., expanded) state having diameter "a", and be compressed by the tapered wall portions 314 of the introducer catheter assembly 302 to a final, compressed diameter "b", thereby reducing the stresses applied to the stent prior to loading the stent in the introducer catheter assembly 302.

The sheaths supported by the delivery catheter, for example sheath 316 or the sheath 127 discussed above, can overlap or be advanceable into at least the proximal portion of the introducer or outer sheath 310, 110, or so that the sheath 316 or the sheath 127 discussed above can be advanceable through the entire length of the introducer or outer sheath 310, 110. A distal portion of the sheath supported by the delivery catheter can be tapered. In this configuration, the stent can be further compressed or compressed as it is being passed through the distal portion of the delivery catheter sheath into the introducer or introducer sheath.

The introducer catheter assembly 302 can be configured to receive and deploy any of a variety of prostheses, including non-bifurcated and bifurcated stents and stent grafts, stent segments, fenestrated stents, and other similar stents or stent grafts disclosed herein or otherwise. the introducer catheter assembly 302 or any other introducer catheter assembly embodiment disclosed herein can be configured to receive and removably couple with any of a variety of delivery catheters, including accessory stent catheters, suprarenal stents or stent extension catheters, or bifurcated stent delivery catheters.

The outer sheath 310 or any other outer sheath embodiment disclosed herein has an inner diameter of approximately 0.237 in. and an outer diameter of approximately 0.253 in. When used for the delivery of a bifurcated stent, the sheath 316 has an inner diameter of approximately 0.251 in. and an outer diameter of approximately 0.263 in. When used for the delivery of an accessory stent or non-bifurcated stent, the sheath 316 has an inner diameter of approximately 0.241 in. and an outer diameter of approximately 0.263 in.

When used for the delivery of a bifurcated stent, the inner core (not illustrated in FIG. 38) the catheter system has an outer diameter of approximately 0.212 in. When used for the delivery of a non-bifurcated stent, the inner core of any catheter system has an outer diameter of approximately 0.213 in.

FIG. 39 is a schematic side view of a catheter system 400 having a deployment catheter assembly 404 comprising an inner core 408, an outer sheath 410, a plurality of tabs 412 supported by a core wire 414 axially attached to the inner core 408, and a distal tip 415 axially attached to the core wire 414. A stent 416 is supported by the delivery catheter 404 and is surrounded by the outer sheath 410. The stent 416 is a self-expanding bifurcated stent, as herein illustrated, or can be any other stent or medical prosthesis disclosed or incorporated by reference herein or otherwise. The delivery catheter 404 can further comprise a branch vessel wire assembly 417 loaded in the delivery catheter 404.

FIG. 40 is a cross-sectional view of the branch vessel wire assembly 417 taken at line 40-40 of FIG. 39, and FIG. 41 is an enlarged schematic view of a portion of the branch vessel wire assembly 417 defined by curve 41-41 of FIG. 39. The branch vessel wire assembly 417 includes an inner wire 418 positioned at least partially within a hollow tube or guidewire 420. The branch vessel wire assembly 417, the inner wire 418, or the hollow tube 420 can have any of the sizes, features, materials, or other details of the dual concentric guidewire disclosed in U.S. application Ser. No. 11/623,022, filed Jan. 12, 2007, which is incorporated by reference as if fully set forth herein.

The hollow tube 420 can project through an inside lumen of the stent 416 such that a distal end 420a of the hollow tube 420 projects past an end portion 416a of the stent 416. Additionally, the hollow tube 420 has a curved or kinked portion 420b proximal to the end of the stent 416. The outer sheath 410 holds the curved portion 420b of the hollow tube 420 in the curved position or orientation (the first state) so as to mechanically link or lock the inner wire 418 axially to the hollow tube 420 until the curve or bend in the curved portion 420b is relaxed. As will be discussed, the curve or bend in the curved portion 420b can be relaxed by retracting or withdrawing the outer sheath 410 past the curved portion 420b of the hollow tube 420, thereby allowing the hollow tube 420 and inner wire 418 to relax and straighten. Therefore, when the hollow tube 420 is in the first state, the inner wire 418 will be axially fixed to the hollow tube 420 such that the inner wire 418 is axially retracted without becoming disengaged from the hollow tube 420. When the outer sheath 410 is retracted past the curved portion 420b of the hollow tube 420, the hollow tube 420 relaxes so that the curved portion 420b is no longer be axially locked to the inner wire 418. In this second, relaxed state, the inner wire 418 can be axially advanced or retracted into and out of the hollow tube 420.

In this arrangement, the inner wire 418 can be advanced through a first puncture site in a first branch vessel or passageway (such as the ipsilateral iliac artery) and then withdrawn through a second branch vessel or passageway (such as the contralateral iliac artery), using any suitable cross-over techniques. For example, the inner wire can be advanced through the ipsilateral iliac artery in a slitted lumen formed in a dual lumen dilator. The dilator can be withdrawn and set aside, allowing the inner wire 418 to pass through the slit in the lumen of the dual lumen dilator, thereby leaving a proximal end of the inner wire 418 positioned within the abdominal aorta. In this position, the inner wire 418 can be snared and retracted through the contralateral iliac artery and through a second puncture site.

Many embodiments of the catheter system have been described in connection with the accompanying figures. It will be apparent to one of ordinary skill in the art that there are many potential embodiments of the catheter system that may be suitable for medical use and which are contemplated herein. For example, any of the components or features of some embodiments of the catheters disclosed herein or other catheters available in the field can be combined to form additional embodiments, all of which are contemplated herein.

While the above description has shown, described, and pointed out features as applied to various embodiments, it will be understood that various omissions, substitutions, and changes in the form and details of the device or process illustrated may be made without departing from the spirit of the disclosure. Additionally, the various features and processes described above may be used independently of one another, or may be combined in various ways. All possible combinations and subcombinations are intended to fall within

the scope of this disclosure. Further, as will be recognized, certain embodiments described herein may be embodied within a form that does not provide all of the features and benefits set forth herein, as some features may be used or practiced separately from others.

What is claimed is:

1. A catheter system comprising:

a delivery catheter comprising:

a main body having a proximal end portion and a distal end portion;

a delivery catheter sheath projecting distally from a distal end portion of the main body;

an inner core configured to a support a stent thereon, the inner core being axially advanceable through the main body of the delivery catheter and the delivery catheter sheath;

a handle member supported by the main body of the delivery catheter, the delivery catheter being configured such that the handle member and the inner core move together in an axial direction when the handle member is connected to the inner core; and

an adjustment member supported by the main body, the adjustment member being configured such that rotation of the adjustment member causes the adjustment member to move axially along the main body;

wherein the handle member is axially moveable along the main body of the delivery catheter between the distal end portion of the main body and the adjustment member by either axially sliding the handle member relative to the main body or by rotating the adjustment member relative to the main body when the adjustment member is rotated to provide an axial contact force with the handle member.

2. The catheter system of claim 1, wherein the inner core is non-selectably coupled to the handle member.

3. The catheter system of claim 1, wherein the inner core is selectively engageable by the handle member, and the catheter system is configured such that the handle member and the inner core move together in an axial direction when the handle member is engaged with the inner core.

4. The catheter system of claim 1, wherein the inner core comprises a core wire supporting a plurality of tabs spaced axially along at least a portion of the inner core, the tabs being positioned on the core wire such that the stent overlaps one or more of the tabs in a stent loaded state.

5. The catheter system of claim 4, wherein the inner core comprises a core wire and the plurality of tabs are spaced axially along at least a portion of the core wire.

6. The catheter system of claim 4, wherein the plurality of tabs are configured to engage the endoskeleton of the stent in a stent loaded state.

7. The catheter system of claim 1, further comprising an introducer catheter comprising a main body and a tubular introducer sheath projecting from a distal end portion of the main body, the introducer catheter being configured to selectively engageably receive the delivery catheter.

8. The catheter system of claim 7, wherein the introducer sheath is configured to axially receive at least the inner core therethrough.

9. The catheter system of claim 7, wherein the stent diameter can be reduced by between 5% and 50% when the stent is advanced into the introducer sheath by passing the stent through a tapered passageway within the introducer catheter.

10. The catheter system of claim 7, wherein at least a portion of an inside surface of the introducer sheath is covered

27

with a low-friction coating comprising at least one of polytetrafluoroethylene, silicone, hydrophobic silicone, and another lubricating substance.

11. The catheter system of claim 7, wherein the introducer catheter is selectively engageable with the delivery catheter so that, when the delivery catheter is engaged with the introducer catheter, the axial movement of either of the introducer catheter and the delivery catheter will cause the simultaneous and equal axial movement of the other of the introducer catheter and the delivery catheter.

12. The catheter system of claim 7, wherein the catheter system is configured such that, when the introducer catheter and the delivery catheter are engaged, the delivery catheter can rotate relative to the introducer catheter.

13. The catheter system of claim 7, wherein the catheter system is configured such that, when the delivery catheter is engaged with the introducer catheter, the delivery catheter sheath and the introducer sheath do not overlap.

14. The catheter system of claim 7, wherein the catheter system is configured such that, when the delivery catheter is engaged with the introducer catheter, at least a distal portion of the delivery catheter sheath overlaps at least a proximal portion of the introducer sheath or a proximal portion of the introducer sheath overlaps at least a distal portion of the delivery catheter sheath.

15. The catheter system of claim 7, wherein the catheter system is configured such that, when the delivery catheter is engaged with the introducer catheter, a tapered distal portion of the delivery catheter sheath advances into a proximal portion of the introducer sheath.

16. The catheter system of claim 7, wherein an inner diameter of the delivery catheter sheath is larger than an inner diameter of the introducer sheath.

17. The catheter system of claim 1, wherein the inner core comprises a core wire supporting a plurality of tabs spaced axially along at least a portion of the inner core, the tabs being positioned on the core wire such that the stent overlaps one or more of the tabs in a stent loaded state.

18. The catheter system of claim 1, wherein the stent comprises a graft that is attached to the stent in at least the distal end portions of the graft, but not the mid-section of the graft.

28

19. A delivery catheter system comprising:

a main body having a proximal end portion and a distal end portion;

an outer sheath projecting from the distal end portion of the main body;

an inner core configured to support a stent thereon, the inner core being axially advanceable through the main body of the delivery catheter and the outer sheath;

a handle member supported by the main body of the delivery catheter, the handle member being axially coupled with the inner core such that the handle member and the inner core move together in an axial direction; and

an adjustment member supported by the main body of the delivery catheter, the adjustment member being configured such that rotation of the adjustment member provides a mechanical advantage that causes the adjustment member to move axially along the main body;

wherein the handle member can be moved axially relative to the main body of the delivery catheter between the distal end portion of the main body and the adjustment member by either axially sliding the handle member relative to the main body or by rotating the adjustment member relative to the main body when the adjustment member is in contact with the handle member, thereby axially moving the inner core relative to the outer sheath.

20. The catheter system of claim 19, wherein the inner core is non-reversably coupled to the handle member.

21. The catheter system of claim 19, wherein the inner core comprises a core wire supporting a plurality of tabs spaced axially along at least a portion of the inner core, the tabs being positioned on the core wire such that the stent overlaps one or more of the tabs in a stent loaded state.

22. The catheter system of claim 21, wherein the inner core comprises a core wire and the plurality of tabs are spaced axially along at least a portion of the core wire.

23. The catheter system of claim 21, wherein the plurality of tabs are configured to engage the endoskeleton of the stent in a stent loaded state.

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