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L90	354	A61B2017/56.cpc. AND (reservoir container collect\$4) WITH (debris thromb\$5 embol\$5) AND filter SAME valve	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/09/06 12:53 PM
L91	67	("3224434" "3342175" "3526219" "3727602" "3785380" "3889657" "4243048" "4249541" "4393879" "4655226" "4680029" "4794928" "4815477" "4838855" "4857045" "5011490" "5030201" "5073168" "5087265").pn. OR ("5197485").urpn. AND (PGPB USPT USOC).dbnm.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2022/09/06 01:34 PM
L92	42	("3623607" "3785380" "3863624" "3889657" "3890712" "4068664" "4400168" "4417874" "4468217" "4701164" "4813926" "4878900" "4886492" "5013300" "5078605" "5098416" "5123840" "5197485" "5244458" "D365146"	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2022/09/06 01:41 PM

		"5520668" "5597385" "5630939" "5741134" "5766134" "5779649" "5807353" "6083175").pn. OR ("6908455").urpn. AND (PGPB USPT USOC).dbnm.					
L93	7822	A61B10/04.cpc.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/09/06 01:49 PM
L94	3	A61B10/04.cpc. AND (debris thromb\$5 embol\$5) SAME filter SAME valve	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/09/06 01:49 PM
L95	3	A61B10/04.cpc. AND (debris thromb\$5 embol\$5) SAME filter AND filter SAME valve	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/09/06 01:50 PM
L96	1	A61B10/04.cpc. AND (debris thromb\$5 embol\$5) SAME filter AND check near3 valve	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/09/06 01:50 PM
L97	7	("5827229" "8057497" "20050137498" "20060129091" "20090036871" "20130317529" "20140081075").pn. OR ("10456152").urpn. AND (PGPB USPT USOC).dbnm.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2022/09/06 02:09 PM
L98	43	606/159.ccls. AND (debris thromb\$5 embol\$5) SAME filter AND filter SAME valve	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/06 02:12 PM
L99	4	("20150352325" "20150173782" "20130035628" "5197485").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/06 04:11 PM
L100	21	606/159.ccls. AND (debris thromb\$5 embol\$5) SAME filter AND filter SAME (housing chamber) AND (housing chamber) SAME valve	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/06 04:39 PM
L101	22	606/159.ccls. AND (debris thromb\$5 embol\$5) SAME filter AND filter SAME (housing chamber container) AND (housing chamber	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/06 04:52 PM

		container cartridge magazine) SAME valve					
L102	1970	A61B17/\$6.cpc. AND check near3 valve AND catheter	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/07 01:03 PM
L103	155	A61B17/\$6.cpc. AND check near3 valve AND catheter AND valve SAME connector SAME cap	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/07 01:04 PM
L104	380	A61B17/\$6.cpc. AND check near3 valve AND catheter AND valve SAME cap	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/07 01:14 PM
L105	484	A61M2039/027.cpc.	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/07 01:23 PM
L106	564	A61B17/\$6.cpc. AND one near3 way near4 valve AND catheter AND valve SAME cap	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/07 01:41 PM
L107	448	A61M39/0613.cpc.	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/07 01:50 PM
L108	27	("4946133" "5125915" "5167637" "5205831" "5205834" "5259842" "5478331" "5507732" "5556387" "5810869" "5895376" "5957901" "6024729" "6197016" "6287280" "6299132" "6344031" "6609696" "7226433" "20030066978" "20030094429" "20040172008" "20060229564" "20070073242" "20080255651" "20080289181").pn. OR ("8951229").urpn. AND (PGPB USPT USOC).dbnm.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2022/09/07 02:11 PM
L109	1	("5,349,984").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/07 02:13 PM
L110	111	("2960998" "3025874" "4665943" "4681132" "4805664" "4953589" "5098405").pn. OR ("5349984").urpn. AND (PGPB USPT USOC).dbnm.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2022/09/07 02:14 PM
L111	67	("3224434" "3342175" "3526219" "3727602" "3785380" "3889657" "4243048" "4249541"	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2022/09/08 10:34 AM

		"4393879" "4655226" "4680029" "4794928" "4815477" "4838855" "4857045" "5011490" "5030201" "5073168" "5087265").pn. OR ("5197485").urpn. AND (PGPB USPT USOC).dbnm.					
L112	320	stopcock near2 valve SAME (suction vacuum aspirat\$4) AND A61B17/\$6.cpc.	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/08 02:50 PM
L113	362	stopcock near2 valve SAME (suction vacuum aspirat\$4) AND A61B2017/\$6.cpc.	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/08 02:57 PM
L114	4	("20150352325" "6564828" "5197485" "20130035628").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2022/12/05 09:12 AM
L115	5	("20150352325" "6564828" "5197485" "20130035628" "20220346813").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2022/12/05 09:14 AM
L116	38	(Artificial Intelligence) More like doc: US-5197485-A Text: (US-8657840-B2 OR US-8475482-B2 OR US-20120215245-A1 OR AU-2003255187-A1 OR JP-2021527479-A OR US-3889657-A OR US-20060270974-A1 OR AU-6501800-A OR EP-1885430-A2 OR WO-2006124307-A2 OR CA-2609138-A1 OR US-5522826-A OR EP- 1206220-B1 OR US- 5827229-A OR AU- 2003252147-A1 OR WO-2004011058-A2 OR EP-1539275-A2 OR AU-2003252147-B9 OR AU-2003252147-B2 OR US-4393879-A).did.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/12/05 09:34 AM
L118	11	(tuan WITH v WITH nguyen).xp. AND skin SAME abras\$4	(US-PGPUB; USPAT)	OR	ON	ON	2023/01/06 09:40 AM
L119	66	("2701559" "2712823" "2867214" "2881763" "2921585" "4378804" "4646482" "4957747"	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/01/06 09:43 AM

		"5012797" "5035089" "5037431" "5037432" "5100412" "5121388" "5207234" "5697920" "5800446" "5810842" "5971999" "6042552" "6241739" "6423078" "6500183" "6641591" "6695583" "7070488" "7153311" "7276072" "7837695" "20040010268" "20040122447" "20040143274").pn. OR ("8277287").urpn. AND (PGPB USPT USOC).dbnm.					
L120	15	51/\$6.ccls. AND valve SAME filter AND (vacuum\$4 suction\$4 aspirat\$)	(US-PGPUB; USPAT)	OR	ON	ON	2023/01/06 09:48 AM
L121	45	("10478535" "11259821" " "11433218" "1143979 9" "11457936" "115291 58" "20010049486" "20 040127936" "20060217 664" "20070010787" "2 0080234715" "2010021 7276" "20110034986" " 20110196309" "201302 81788" "20140257363" "20140296868" "20150 173782" "20160220741 " "20170056032" "2017 0196576" "2017025205 7" "20170319221" "201 70340867" "201801044 04" "20190239910" "20 190336142" "20210022 843" "20210315598" "2 0220211400" "2022034 6800" "20220346801" "2 0220346814" "202203 47455" "20220362512" "3675657" "5158564" "6 451036" "6719717" "69 60189" "7004931" "722 3253" "8057497" "9216 277" "9980813").PN.	(US-PGPUB; USPAT)	OR	ON	ON	2023/01/06 10:07 AM
L122	197	("3965896" "3985133" "4518497" "4898572" "4921478" "5055198" "5114400" "5135492" "5215519" "5374401" "5407425" "5549569" "5743886" "5759160" "5833650" "5876611"	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/01/06 10:14 AM

		"5954695" "5961472" "5971948" "6059745" "6161547" "6251291" "6423032" "6447473" "20010049486").pn. OR ("7223253").urpn. AND (PGPB USPT USOC).dbnm.					
L123	8583	A61M1/60.0001.0003.c pc.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN), FPRS, EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/01/06 04:18 PM
L124	709	L123 AND filter	(US-PGPUB; USPAT)	OR	ON	ON	2023/01/06 04:18 PM
L125	465	L123 AND filter AND valve	(US-PGPUB; USPAT)	OR	ON	ON	2023/01/06 04:31 PM
L126	45	("10478535" "11259821" "11433218" "1143979 9" "11457936" "115291 58" "20010049486" "20 040127936" "20060217 664" "20070010787" "2 0080234715" "2010021 7276" "20110034986" " 20110196309" "201302 81788" "20140257363" " 20140296868" "20150 173782" "20160220741 " "20170056032" "2017 0196576" "2017025205 7" "20170319221" "201 70340867" "201801044 04" "20190239910" "20 190336142" "20210022 843" "20210315598" "2 0220211400" "2022034 6800" "20220346801" " 20220346814" "202203 47455" "20220362512" " 3675657" "5158564" "6 451036" "6719717" "69 60189" "7004931" "722 3253" "8057497" "9216 277" "9980813").PN.	(US-PGPUB; USPAT)	OR	ON	ON	2023/01/07 11:13 AM

L127	4	("6719717" "5197485" "20150352325" "6564828").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/01/07 12:21 PM
L128	5	("6719717" "5197485" "20150352325" "6564828" "8057497").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/01/07 03:37 PM
L129	6	("6719717" "5197485" "20150352325" "6564828" "8057497" "11154314").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/01/24 03:45 PM
L130	336	A61B17/\$6.cpc. AND ((one near3 way near4 valve) (check near3 valve)) SAME filter AND catheter	(US-PGPUB; USPAT)	OR	ON	ON	2023/01/25 08:28 AM
L131	378	A61B2017/\$6.cpc. AND ((one near3 way near4 valve) (check near3 valve)) SAME filter AND catheter	(US-PGPUB; USPAT)	OR	ON	ON	2023/01/25 08:28 AM
L132	630	A61B17/\$6.cpc. AND ((one near3 way near4 valve) (check near3 valve)) SAME filter AND catheter	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/01/25 08:28 AM
L133	661	A61B2017/\$6.cpc. AND ((one near3 way near4 valve) (check near3 valve)) SAME filter AND catheter	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/01/25 08:28 AM
L134	92	("2795390" "3552712" "4268005" "4406656" "4451252" "4516398"	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/01/25 09:01 AM

		"4705501" "4894057" "4923462" "4955375" "5112301" "5161773" "5180364" "5197192" "5290263" "5295956" "5305982" "5314406" "5374244" "5376100" "5441482" "5464398" "5527292" "5549626" "5584803" "5669876" "5827243" "5833650" "5935100" "6066149" "6179816" "6251121" "6450987" "6468291" "6540712" "6551268" "6595967" "6660014" "6855136" "6908474" "7223253" "20020103472" "20020151918" "20040019310" "20050020973" "20050085761").pn. OR ("8002725").urpn. AND (PGPB USPT USOC).dbnm.					
L135	461	("3631848" "4771777" "4840690" "4865581" "4921478" "4921479" "4946440" "5135484" "5250060" "5312356" "RE34633" "5324262" "5328471" "5338300" "5380284" "5385562" "5429605" "5437632" "5443454" "5454795" "5476450" "5484407" "5484412" "5484418" "5492530" "5496294" "5522836" "5527292" "5542937" "5558635" "5573520" "5599326" "5628754" "5658264" "5658309" "5667499" "5695483" "5702373" "5707376" "5730734" "5749849" "5749858" "5776141" "5794629" "5795341" "5810869" "5827229" "5833650" "5836926" "5846251" "5851210" "5853400" "5876367" "5876386" "5882334" "5895399" "5908407" "5913848" "5916208" "5921952" "5928192" "5935122" "5938645"	(US-PGPUB, USPAT, USOCR)	OR	ON	ON	2023/01/25 09:17 AM

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		"5997523"	"6004310"				
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		"6030369"	"6033388"				
		"6044845"	"6053903"				
		"6053904"	"6071263"				
		"6074357"	"6074398"				
		"6090072"	"6110139"				
		"6139524"	"6146370"				
		"6146373"	"6146415"				
		"6152909"	"6152912"				
		"6159230"	"6161547"				
		"6165199"	"6176844"				
		"6197016"	"6206868"				
		"6210370"	"6234971"				
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		"6277139"	"6287319"				
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		"6306106"	"6306163"				
		"6364900"	"6368316"				
		"6368344"	"6379325"				
		"6383172"	"6413235"				
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		"6428531"	"6435189"				
		"6436087"	"6454741"				
		"6458151"	"6464864"				
		"6481439"	"6482172"				
		"6482217"	"6508824"				
		"6517520"	"6527746"				
		"6533800"	"6540712"				
		"6544276"	"6549800"				
		"6551268"	"6555057"				
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		"6582448"	"6595953"				
		"6595980"	"6605074"				
		"6612999"	"6623471"				
		"6623491"	"6623518"				
		"6626886"	"6632236"				
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		"6638245"	"6641573"				
		"6645160"	"6645222"				
		"6652480"	"6656152"				
		"6663650"	"6663652"				
		"6676637"	"6679893"				
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		"6755803"	"6755847"				
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		"6790204"	"6824545"				
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		"6960189"	"6972030"				
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		"7033325"	"7033336"				
		"7033344"	"7048758"				
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		"7104979"	"7108677"				
		"7144386"	"7150712"				
		"7152605"	"7166088"				
		"7169165"	"7172621"				
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		"7458980"	"7497844"				
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		"8066757"	"8142413"				
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		"8181324"	"8221348"				
		"8231600"	"8251978"				
		"8252010"	"8292850"				
		"8343089"	"8414516"				
		"8425549"	"8465456"				
		"8523801"	"8545552"				
		"8574245"	"8708954"				
		"8870805"					
		"RE45380"	"8961549"				
		"8996095"	"9034007"				
		"9126018"	"9144662"				
		"RE45760"					
		"RE45776"					
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		"20010049486"					
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L136	18	A61B2017/\$6.cpc. AND ((one near3 way near4 valve) (check near3 valve)) SAME filter SAME hous\$4 AND catheter	(US-PGPUB; USPAT)	OR	ON	ON	2023/01/25 09:55 AM
L139	2	blood SAME filter AND ((one near3 way near4 valve) (check near3 valve)) SAME filter SAME convenien\$4 AND catheter	(US-PGPUB; USPAT)	OR	ON	ON	2023/01/25 10:16 AM
L140	193	blood SAME filter AND ((one near3 way near4 valve) (check near3 valve)) SAME filter SAME in WITH one AND catheter	(US-PGPUB; USPAT)	OR	ON	ON	2023/01/25 10:19 AM
L141	1968	((one near3 way near4 valve) (check near3 valve)) SAME filter AND catheter	(US-PGPUB; USPAT)	OR	ON	ON	2023/01/25 10:34 AM
L142	605	((one near3 way near4 valve) (check near3 valve)) SAME filter AND catheter AND blood WITH filter	(US-PGPUB; USPAT)	OR	ON	ON	2023/01/25 10:34 AM
L143	66	("2006/0111667").urpn. AND (PGPB USPT USOC).dbnm.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/01/25 10:43 AM
L144	3961	one near3 way near4 valve WITH filter	(US-PGPUB; USPAT)	OR	ON	ON	2023/01/25 10:48 AM
L145	1114	one near3 way near4 valve WITH filter AND blood	(US-PGPUB; USPAT)	OR	ON	ON	2023/01/25 10:48 AM

L146	76	("2992701" "3275145" "3545438" "3568977" "3930096" "4111228" "4141379" "4167482" "4222407" "4239041" "4311587").pn. OR ("4488961").urpn. AND (PGPB USPT USOC).dbnm.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/01/25 10:50 AM
L147	37	("2008/0011667").urpn. AND (PGPB USPT USOC).dbnm.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/01/25 11:15 AM
L150	10	("20150352325" "20130035628" "5197485" "8057497" "20100297577" "20080011667" "20180042623" "20060206028" "11154314" "20050020973").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/01/25 03:05 PM
L151	11	("20150352325" "20130035628" "5197485" "8057497" "20100297577" "20080011667" "20180042623" "20060206028" "11154314" "20050020973" "6719717").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/01/26 08:41 AM
L152	37	(Artificial Intelligence) More like doc: US-20100297577-A1 Text: (EP-2432417-A1 OR WO-2010135005-A1 OR CA-2799300-A1 OR US-9693843-B2 OR WO-2022011143-A1 OR US-5630939-A OR US-4083706-A OR US-20220008178-A1 OR US-5741134-A OR CA-2161165-C OR US-20080257815-A1 OR US-6299763-B1 OR EP-0779799-A1 OR WO-9639986-A1 OR US-3890712-A OR US-8393898-B2 OR US-20050239016-A1 OR WO-2006049878-A2 OR US-20060093990-A1 OR CA-2161165-A1).did.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/01/26 09:15 AM

L153	21	("2010/0297577").urpn. AND (PGPB USPT USOC).dbnm.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/01/26 09:19 AM
L154	45	("10478535" "11259821 "11433218" "1143979 9" "11457936" "115291 58" "20010049486" "20 040127936" "20060217 664" "20070010787" "2 0080234715" "2010021 7276" "20110034986" " 20110196309" "201300 35628" "20130281788" " 20140257363" "20140 296868" "20160220741 "20170056032" "2017 0196576" "2017025205 7" "20170319221" "201 70340867" "201801044 04" "20190239910" "20 190336142" "20210022 843" "20210315598" "2 0220211400" "2022034 6800" "20220346801" "2 0220346813" "202203 47455" "20220362512" " 3675657" "5158564" "6 451036" "6564828" "67 19717" "6960189" "700 4931" "7223253" "9216 277" "9980813").PN.	(US-PGPUB; USPAT)	OR	ON	ON	2023/05/09 04:43 PM
L155	23	("11013523" "11406801 "11554005" "1155938 2" "20030116731" "200 50054995" "201201729 18" "20140052161" "20 160262774" "20180042 623" "20180184912" "2 0180256177" "2021013 7667" "20220142638" "2 0220151647" "202201 52355" "4611594" "542 1824" "5653684" "5908 435" "6818006" "90786 82" "9827084").PN.	(US-PGPUB; USPAT)	OR	ON	ON	2023/05/09 04:44 PM
L156	13	("20010031981" "20040 102807" "20140074144 "20140188127" "2021 0236148" "2023004677 5" "20230062809" "202 30070120" "5158533" "6 059814" "8535283" "8 753322" "8808259").PN.	(US-PGPUB; USPAT)	OR	ON	ON	2023/05/09 04:44 PM
L157	45	(Artificial Intelligence) Similar to: 17/865,307 with 0 CPC	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY,	OR	ON	ON	2023/05/09 05:21 PM

		<p>Selections and 0 Text Selections Text: (US-20190231373-A1 OR US-11154314-B2 OR US-20220240959- A1 OR US- 20220346814-A1 OR US-20220346813-A1 OR US-20230046775- A1 OR CA-2939315-C OR AU-2015274704-A1 OR WO-2015191646- A1 OR EP-3094363-A1 OR US-9526864-B2 OR WO-2021025440-A2 OR CN-106470728-A OR JP-2017518093-A OR WO-2023279009- A2 OR AU- 2015274704-B2 OR CA-2939315-A1 OR US-10426498-B1 OR WO-2021016213-A1 OR EP-3998966-A1 OR KR-20220038096-A OR US-20150360001-A1 OR WO-2021194789- A1 OR EP-4164727-A1 OR JP-2022540692-A OR US-20220125450- A1 OR JP-6438495-B2 OR WO-2010093521- A1 OR US- 20100204672-A1 OR US-20200121336-A1 OR JP-2020062317-A OR CN-112890914-A OR EP-3713507-A1 OR CN-114502086-A OR US-11589880-B2 OR US-20230062809-A1 OR JP-2021023827-A OR US-20220346801- A1 OR US-11554005- B2 OR US-11490911- B2 OR WO- 2011142994-A2 OR US-20220346800-A1 OR US-20220218369- A1 OR KR- 20210018115-A OR EP-4144307-A1 OR KR-20210110003-A OR KR-102371974-B1 OR US-20160135826-A1 OR US-20210137540- A1 OR CN-108024820-</p>	<p>CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN))</p>				
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L158	0	A).did. (vacuum SAME aspiration AND housing SAME chamber AND cap SAME aspirat\$4 AND flow WITH path SAME cap AND catheter SAME flexible SAME port SAME housing AND flow WITH regulator AND first WITH operator SAME actuation WITH mechanism AND second WITH operator AND filter SAME housing SAME flow WITH path).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2023/05/22 10:28 AM
L159	35	("11013523" "11406801" "11554005" "11559382" "20010031981" "20030116731" "20040102807" "20050054995" "20120172918" "20140052161" "20140074144" "20140188127" "20160262774" "20180042623" "20180184912" "20180256177" "20210137667" "20220142638" "20220151647" "20220152355" "20230046775" "20230062809" "20230070120" "4611594" "5158533" "5421824" "5653684" "5908435" "6059814" "6818006" "8535283" "8753322" "8808259" "9078682" "9827084").PN	(US-PGPUB; USPAT)	OR	ON	ON	2023/05/22 04:06 PM
L160	46	(Artificial Intelligence) Similar to: 17/865,297 with 0 CPC Selections and 0 Text Selections Text: (US-20190231373-A1 OR US-11154314-B2 OR US-20220240959-A1 OR US-20220346814-A1 OR US-20220346813-A1 OR US-20230046775-A1 OR AU-2015274704-A1 OR EP-3094363-A1 OR CA-2939315-C OR WO-2015191646-A1	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN))	OR	ON	ON	2023/05/22 04:09 PM

		OR JP-2017518093-A OR WO-2023279009-A2 OR AU-2015274704-B2 OR CA-2939315-A1 OR US-20150360001-A1 OR US-20150352325-A1 OR US-9526865-B2 OR US-20230062809-A1 OR JP-2021023827-A OR US-11554005-B2 OR US-20220346800-A1 OR US-11490911-B2 OR US-20220346801-A1 OR EP-3772357-A1 OR US-20220218369-A1 OR KR-20210018115-A OR KR-20210110003-A OR KR-102371974-B1 OR US-20160135826-A1 OR US-20210137540-A1 OR CN-108024820-A OR CN-111938750-A OR CN-112336414-A OR CN-112842461-A OR US-20220330960-A1 OR US-11553935-B2 OR WO-2023009703-A1 OR US-20230043096-A1 OR CA-3114285-A1 OR AU-2019321256-A1 OR WO-2020036809-A1 OR EP-3836855-A1 OR CN-108024804-A OR US-20200046368-A1 OR CN-113729856-B OR US-20230026412-A1 OR US-11559382-B2 OR JP-2021534851-A OR WO-2022104374-A1 OR US-11241243-B2).did.					
L161	1	("20210177262").PN.	(US-PGPUB; USPAT)	OR	ON	ON	2023/06/12 10:28 PM
L162	2	("20210177262" "20220346638").PN.	(US-PGPUB; USPAT)	OR	ON	ON	2023/06/13 08:28 AM
L163	44	(Artificial Intelligence) Similar to: 17/763,810 with 0 CPC Selections and 0 Text Selections Text: (CN-114746033-A OR US-20220346638-A1	(US-PGPUB; USPAT; USOCR, FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV,	OR	ON	ON	2023/06/13 10:00 AM

		OR WO-2021076356-A1 OR EP-4044942-A1 OR JP-2022553223-A OR EP-3166512-B1 OR JP-2020114426-A OR EP-3781021-B1 OR US-11147583-B2 OR US-20200069327-A1 OR JP-2022078035-A OR JP-2017519599-A OR US-20210059713-A1 OR US-20220039828-A1 OR WO-2016007652-A1 OR EP-3166512-A1 OR CA-2955242-A1 OR US-20180146978-A1 OR US-10357277-B2 OR JP-6728128-B2 OR WO-2022192102-A1 OR JP-2021521916-A OR WO-2019204797-A1 OR EP-3781021-A1 OR JP-7021278-B2 OR CN-107106190-B OR CN-107106190-A OR CN-112312828-A OR CN-108882948-A OR US-20210076949-A1 OR US-11399863-B2 OR US-20230157718-A1 OR US-20190029714-A1 OR JP-2019513446-A OR WO-2017173370-A1 OR EP-3435892-A1 OR JP-6959255-B2 OR US-11382653-B2 OR US-10660510-B2 OR US-20170215914-A1 OR US-20200060718-A1 OR US-20220273337-A1 OR WO-2012145133-A2 OR JP-2011229956-A OR US-20120046679-A1 OR CA-2803992-A1 OR WO-2012003430-A2 OR EP-2588012-A2 OR JP-2013531542-A OR EP-2588012-B1).did	MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN))				
L164	8777	A61M1/60,0001,0003.c pc.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS,	OR	ON	ON	2023/06/13 10:55 AM

			IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)				
L165	466	A61M39/0613.cpc.	(US-PGPUB; USPAT)	OR	ON	ON	2023/06/13 10:55 AM
L166	2	("20150352325" "20070038225" "2015002555").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/06/13 06:46 PM
L167	3	("20150352325" "20070038225" "2015002555").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/06/13 06:46 PM
L169	18	A61B17/\$6.cpc. AND pre near3 charg\$4 WITH vacuum WITH (source syringe) AND catheter SAME (clot thromb\$4)	(US-PGPUB; USPAT)	OR	ON	ON	2023/06/14 10:17 AM
L170	18	A61B2017/\$6.cpc. AND pre near3 charg\$4 WITH vacuum WITH (source syringe) AND catheter SAME (clot thromb\$4)	(US-PGPUB; USPAT)	OR	ON	ON	2023/06/14 10:20 AM
L171	29	A61B2017/\$6.cpc. AND pre near3 charg\$4 WITH vacuum WITH (source syringe) AND catheter SAME (clot thromb\$4)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/14 10:21 AM
L172	37	A61B2017/\$6.cpc. AND pre near3 charg\$4 WITH vacuum AND catheter SAME (clot thromb\$4)	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE,	OR	ON	ON	2023/06/14 10:21 AM

			SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)				
L173	681	A61B2017/\$6.cpc. AND (aspirat\$6 vacuum) WITH open\$4 WITH valve AND catheter SAME (clot thromb\$4)	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/14 10:26 AM
L174	837	A61B2017/\$6.cpc. AND (aspirat\$6 vacuum suction\$4) WITH open\$4 WITH valve AND catheter SAME (clot thromb\$4)	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/14 10:26 AM
L175	116	A61B2017/\$6.cpc. AND (aspirat\$6 suction\$4) WITH open\$4 WITH valve WITH (vacuum WITH source) AND catheter SAME (clot thromb\$4) SAME (aspirat\$6 suction\$6)	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/14 10:31 AM
L176	3	("20150352325" "20070038225" "2015002555" "20220240959").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/06/14 05:48 PM

L177	4	("20150352325" "20070038225" "20150025555" "20220240959").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/06/14 05:49 PM
L178	5	("20150352325" "20070038225" "20150025555" "20220240959" "5911710").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/06/16 01:16 PM
L179	408	("4430081" "4580573" "4626245" "4857062" "4895346" "4929235" "4978341" "4978344" "5000745" "5006114" "5041095" "5051109" "5092845" "5092846" "5098406" "5102395" "5106054" "5114408" "5125903" "5127626" "5154701" "5167637" "5176652" "5195980" "5205829" "5207649" "5215527" "5215528" "5256150" "5267966" "5269997" "5273546" "5290245" "5290249" "5300033" "5304142" "5304143" "5304156" "5312362" "5312363" "5330436" "5334160" "5336192" "5350362" "5350363" "5356390" "5366446" "5403292" "5458640" "5584808" "5591137" "5599305").pn. OR ("5911710").urpn. AND (PGPB USPT USOC).dbnm.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/16 01:17 PM
L180	19	("4112932" "4535773" "5112321" "5217441" "5224930").pn. OR ("5330436").urpn. AND (PGPB USPT USOC).dbnm.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/16 01:42 PM
L181	1	("5256150").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/06/17 10:27 AM
L182	284	("2844351" "4311138" "4401433" "4540411" "4580573" "4601713" "4738666" "4857062" "5015239" "5066285").pn. OR ("5256150").urpn. AND (PGPB USPT USOC).dbnm.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/17 10:28 AM

PE2E SEARCH - Search History (Interference)

There are no Interference searches to show.

Doc code: IDS

PTO/SB/08a (01-10)

Doc description: Information Disclosure Statement (IDS) Filed

Approved for use through 07/31/2012. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	17/498,642- Conf# 1040
	Filing Date	October 11, 2021
	First Named Inventor	Richard Quick
	Art Unit	Not Yet Assigned
	Examiner Name	Not Yet Assigned
	Attorney Docket Number	111552-8023.US02

U.S. PATENTS					
Examiner Initial*	Cite No	Patent Number	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
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	24.	4890611	01-02-1990	Monfort et al.	
	25.	4946440	08-07-1990	Hall	
	26.	4960259	10-02-1990	Sunnanvader et al.	
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	28.	5059178	10-22-1991	Ya	
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50.	5876414	03-02-1999	Straub	
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54.	5972019	10-26-1999	Engelson et al.	
55.	5974938	11-02-1999	Lloyd	
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62.	6168579	01-02-2001	Tsugita	
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70.	6350271	02-26-2002	Kurz et al.	
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64.	International Search Report and Written Opinion for International App. No. PCT/US21/59718; Date of Filing: November 17, 2021, Applicant: Inari Medical, Inc., Date of Mailing: March 22, 2022, 13 pages.
65.	International Search Report and Written Opinion for International App. No. PCT/US21/59735; Date of Filing: November 17, 2021, Applicant: Inari Medical, Inc., Date of Mailing: March 22, 2022, 11 pages.
66.	
67.	
68.	

EXAMINER SIGNATURE

Examiner Signature	/TUAN V NGUYEN/	Date Considered	06/14/2023
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Doc code: IDS

Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-10)

Approved for use through 07/31/2012. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	17/498,642- Conf# 1040
	Filing Date	October 11, 2021
	First Named Inventor	Richard Quick
	Art Unit	Not Yet Assigned
	Examiner Name	Not Yet Assigned
	Attorney Docket Number	111552-8023.US02

¹ See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. ² Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). ³ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ Applicant is to place a check mark here if English language translation is attached.

CERTIFICATION STATEMENT

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Those documents which are marked with a double asterisk (**) next to the Cite No. in the attached form PTO/SB/08 are not supplied because they were previously cited by or submitted to the Office in prior application number **16/258,344** and filed on **January 25, 2019** and relied upon in this application for an earlier filing date under 35 U.S.C. § 120.

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	Attorney Docket Number	111552-8023.US02

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Signature	/Matthew S. Williams/	Date (YYYY-MM-DD)	2022-09-06
Name/Print	Matthew S. Williams	Registration Number	77,516

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	Attorney Docket Number	111552-8023.US02

U.S. PATENTS AND PUBLICATIONS					
Examiner Initial*	Cite No	Patent Number	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	1.	6564828	05-20-2003	Ishida	
	2.	5197485	03-30-1993	Grooters	
	3.	20130035628	02-07-2013	Garrison et al.	
	4.	8057497	11-15-2011	Raju et al.	
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	7.	20170196576	07-13-2017	Long et al.	
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	10.	20110196309	08-11-2011	Wells	
	11.	20140296868	10-02-2014	Garrison et al.	
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	18.	6719717	04-13-2004	Johnson et al.	
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	20.	6960189	11-01-2005	Bates et al.	
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	23.	20220211400	07-07-2022	Cox et al.	
	24.	11433218	09-06-2022	Quick et al.	
	25.	20040127936	07-01-2004	Salahieh et al.	
	26.	20210022843	01-28-2021	Hauser	
	27.	5158564	10-27-1992	Schnepp-Pesch et al.	
	28.	20220347455	11-03-2022	Merritt et al.	
	29.	20220346800	11-03-2022	Merritt et al.	
	30.	20220346813	11-03-2022	Quick	

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	Examiner Name	Not Yet Assigned
	Attorney Docket Number	111552-8023.US02

31.	20220346814	11-03-2022	Quick	
32.	20220346801	11-03-2022	Merritt et al.	
33.	3675657	07-11-1972	Gauthier	
34.	9216277	12-22-2015	Myers	
35.	9980813	05-29-2018	Eller	
36.	6451036	09-17-2002	Heitzmann et al.	
37.	20080234715	09-25-2008	Pesce et al.	
38.	20110034986	02-10-2011	Chou et al.	
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41.	20060217664	09-28-2006	Hattler et al.	
42.	20170252057	09-07-2017	Bonnette et al.	
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44.	11457936	10-04-2022	Buck et al.	
45.	11259821	03-01-2022	Buck et al.	
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48.	11529158	12-20-2022	Hauser	
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53.	5653684	08-05-1997	Laptewicz et al.	
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58.	20180256177	09-13-2018	Cooper et al.	
59.	11013523	05-25-2021	Arad Hadar	
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FOREIGN PATENT DOCUMENTS						
Examiner Initial*	Cite No	Foreign Document Number ³	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁵
	1.					
	2.					
	3.					
	4.					

NON-PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁵
	1.		
	2.		
	3.		
	4.		
	5.		

EXAMINER SIGNATURE			
Examiner Signature	/TUAN V NGUYEN/	Date Considered	06/14/2023
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☐ See attached certification statement.

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☒ None

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SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Matthew S. Williams/	Date (YYYY-MM-DD)	2023-01-05
Name/Print	Matthew S. Williams	Registration Number	77,516

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	Attorney Docket Number	111552-8023.US02

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	First Named Inventor	Richard Quick
	Art Unit	3771
	Examiner Name	Tuan Van Nguyen
	Attorney Docket Number	111552-8023.US02

U.S. PATENTS AND PUBLICATIONS					
Examiner Initial*	Cite No	Patent Number	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	1.	11406801	08-09-2022	Fojtik et al.	
	2.	11554005	01-17-2023	Merritt et al.	
	3.	11559382	01-24-2023	Merritt et al.	
	4.	6818006	11-16-2004	Douk et al.	
	5.	9078682	07-14-2015	Lenker et al.	
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	8.	20180184912	07-05-2018	Al-Ali	
	9.	20160262774	09-15-2016	HONDA	
	10.	20120172918	07-05-2012	Fifer et al.	
	11.	20050054995	03-10-2005	Barzell et al.	
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	14.	5158533	10-27-1992	Strauss et al.	
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	16.	20140188127	07-03-2014	Dubruil et al.	
	17.	20140074144	03-13-2014	Shrivastava et al.	
	18.	8535283	09-17-2013	Heaton et al.	
	19.	8753322	06-17-2014	Hu et al.	
	20.	8808259	08-19-2014	Walton et al.	
	21.	20230062809	03-02-2023	Merritt et al.	
	22.	20230070120	03-09-2023	Cox et al.	
	23.	20010031981	10-18-2001	Evans et al.	
	24.	20040102807	05-27-2004	Kusleika et al.	
	25.	6059814	05-09-2000	Ladd	

FOREIGN PATENT DOCUMENTS						
Examiner Initial*	Cite No	Foreign Document Number ³	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁵
	1.	WO2006124307	11-23-2006	KERBEROS PROXIMAL SOLUTIONS, INC.		

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Doc description: Information Disclosure Statement (IDS) Filed

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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.

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ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #
17/498,642

RECEIPT DATE / TIME
04/04/2023 02:03:48 PM ET

ATTORNEY DOCKET #
111552-8023.US02

Title of Invention

SINGLE INSERTION DELIVERY SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED SYSTEMS AND METHODS

Application Information

APPLICATION TYPE Utility - Nonprovisional Application
under 35 USC 111(a)

PATENT # -

CONFIRMATION # 1040

FILED BY Michelle Burge

PATENT CENTER # 61864582

FILING DATE 10/11/2021

CUSTOMER # 25096

FIRST NAMED
INVENTOR Richard Quick

CORRESPONDENCE
ADDRESS -

AUTHORIZED BY Matthew Williams

Documents

TOTAL DOCUMENTS: 2

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
2023-04-04_IDS_SB08_1115528023US02.pdf	3	Information Disclosure Statement (IDS) Form (SB08)	135 KB

Warning: This is not a USPTO supplied IDS fillable form. Data in the form cannot be automatically loaded to other USPTO systems.

FOR_WO2006124307.pdf	19	Foreign Reference	1338 KB
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Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
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2023-04-04_IDS_SB08_1115528023US02.pdf	CB8274268C62BAC3057B00C50507496A93D752C37D60F75ADF3F1A98C99EEF1C59362A9172CA91DC65E5A3D650414E9CF47F2F4FFE45E862C774CF3C48D21806
FOR_WO2006124307.pdf	4D4E16192D85DA1B42279B3E92B4AB2F1F7B9A9641A8B8FF321626546D06794936F60072ECF52BE8F6C74B7C7787E787B70CFB9C8D49DC455ED07082B58E5572

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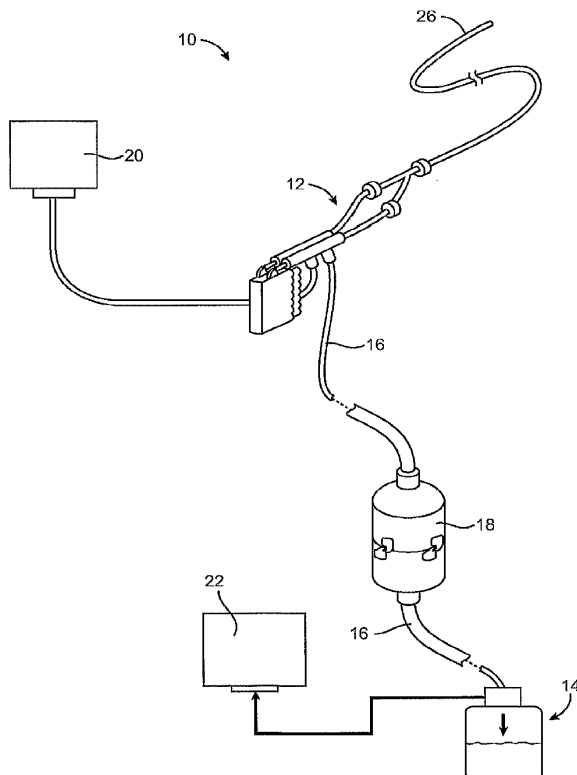
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(54) Title: METHODS AND SYSTEMS FOR FILTERING ASPIRATED MATERIALS



(57) Abstract: Solid materials are separated from hollow body structure aspirates using a filter assembly disposed between an aspiration catheter and an aspirate receptacle. Filter elements having different pore or mesh sizes may be used to size classify the separated solid materials. Multiple filter assemblies may be disposed in parallel or series between the aspiration catheter and aspirate receptacle to provide for different levels of size classification.

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METHODS AND SYSTEMS FOR FILTERING ASPIRATED MATERIALS

BACKGROUND OF THE INVENTION

5 [0001] 1. Field of the Invention. The present invention relates generally to medical apparatus and methods. More particularly, the present invention relates to a method and system for separating and optionally classifying solids removed from a patient in a fluid aspirate.

[0002] Aspiration is a part of many surgical procedures performed in various body
10 structures and lumens. Blood and/or other natural body fluids may be aspirated from various hollow body structures, such as blood vessels, cysts, pseudocysts, abscesses, blood vessel grafts, lung passages, bile ducts, ureters, urethras, fallopian tubes, ear canals, the gastrointestinal tract, and the like. In some instances, aspiration is performed on a natural
body fluid(s) only, while in many other instances, a liquid irrigant will be introduced which
15 will form at least part of the aspirated fluid. Such irrigants may comprise saline or other biologically inert fluids. Alternatively, such irrigants may comprise biologically active agents, such as thrombolytic agents introduced to occluded blood vessels, antiseptic or antibiotic agents introduced to infected body locations, or the like.

[0003] Of particular interest to the present invention, fluids aspirated from any of these
20 hollow body structures will often contain solid materials, such as cellular debris, damaged tissue, thrombus, or the like, which is aspirated together with the fluid. In many instances, such removed solid materials will have diagnostic or other value to a treating physician. For example, during aspiration, it may be desirable to monitor the solid materials which are being removed in order to decide when to terminate or alter or adjust the aspiration protocol.
25 Additionally, the identification of the aspirated material may serve as a diagnostic tool to direct further intervention or other therapies.

[0004] While the collected materials may be observed in the aspirate collection bags which are commonly employed in such procedures, it will usually be difficult to remove the materials while additional aspirate is entering the collection bags and the solids will
30 frequently remain suspended and difficult to separate from the collected materials.

[0005] For these reasons, it would be desirable to provide improved and additional systems and protocols for separating solid materials from liquid and fluid aspirates removed from a hollow body structure. It would be particularly desirable if the methods and protocols permitted direct observation and/or removal of the separated solid materials while an aspiration protocol was continuing. It would be further desirable if the separated solid materials were collected in a form substantially separated from a liquid fraction of the materials removed from the hollow body structure and further that the separated solid materials be in a convenient structure or assembly to permit easy removal and observation. In some instances, it would also be desirable to provide for classification of the solid materials, i.e. separation based on size, while the aspiration protocol was being performed. At least some of these objectives will be met by the inventions described and claimed hereinbelow.

[0006] 2. Description of the Background Art. Patient irrigation and aspiration systems which may employ the separation technology of the present application are described in commonly assigned U.S. Patent Nos. 6,827,701 and 6,878,128, the full disclosures of which are incorporated herein by reference.

BRIEF SUMMARY OF THE INVENTION

[0007] In a first aspect of the present invention, methods are provided for separating materials in fluid aspirates removed from a hollow body structure. The fluid is aspirated from the hollow body structure, where the fluid carries entrained solid materials in the aspirate. The solid materials are filtered from the fluid to produce both a filtrate and a fluid stream. The fluid stream is collected separately from the filtrate. In this way, the filtrate may be easily observed and optionally removed from the aspiration circuit even while the aspiration protocol continues.

[0008] The fluid may be aspirated from a variety of hollow body organs and other structures, including blood vessels, cysts, pseudocysts, abscesses, blood vessel grafts, lung passages, bile ducts, ureters, urethras, fallopian tubes, ear canals, joint capsules, the gastrointestinal tract, and the like. Thus, natural body fluids which may be aspirated according to the present invention include blood, bile, urine, synovial fluid, and the like. In addition to such natural body fluids, the hollow body structures may optionally be irrigated prior to and/or during aspiration. The introduction of irrigation fluid may improve debris capture through the aspiration channel by creating localized mixing / turbulence and possibly

decreasing the viscosity of the aspirant. Thus, the aspirated fluids may comprise or consist of a variety of irrigant fluids introduced to the hollow body structure. Suitable irrigant fluids include saline, lactated ringers, and the like. The irrigant fluids may further comprise active agents intended for therapeutic or diagnostic purposes. For example, in the case of occluded blood vessels, thrombolytic agents may be introduced as part of an irrigant stream. Alternatively, in the case of infected hollow body structures, the irrigant may include antibiotics, antiseptics, or the like.

[0009] Most typically, aspiration will be performed by introducing an aspiration catheter, cannula, or other tubular or needle-like device into the hollow body structure. By applying a vacuum to a proximal end of the aspiration device, the fluid may be withdrawn through a port or ports at or near the distal end of the device which has been placed within an interior region of the hollow body structure. For convenience, as used hereinafter and in the claims, the aspiration structure will be referred to as a "catheter," but it will be appreciated that this term is intended to be broad enough to encompass needles, cannulas, tubular structures, conduits, and other aspiration structures known in the medical art.

[0010] The aspirated fluids will usually be collected in an aspirate receptacle, such as a conventional fluid collection bag. A syringe, vacuum connection, or other conventional vacuum source may be connected at or through the catheter and/or the aspiration receptacle in order to aspirate the fluid from the hollow body structure, through the aspiration catheter, and into the aspirate receptacle. The filter(s) may be positioned before or after the aspiration source.

[0011] In a preferred aspect of the present invention, at least one filter assembly including a filter housing and a removable (and replaceable) filter element is placed between the aspiration catheter and the aspirate receptacle in order to remove solid materials from the aspirate before the remaining liquid phase of the aspirate flows to the aspirate receptacle. The filter element may be any conventional filter element, such as a paper, polymer, a woven filter membrane, a screen, other porous member, or the like. The filter element may have any one of a variety of geometries including cup-shaped, conical and the filter could be inclined or slanted in the filter-housing to spread the filtrate over the filter to permit differentiation of the filtrate material. Additionally, the filter element could be coated or otherwise combined with a chemical, biological, or other indication or marker to facilitate identification of different analytes or markers present in the filtrate, typically using colormetric indicating

systems. Preferably, the filter element will allow the separated solid materials to collect on an exposed surface so that the solid materials will be easily removed and/or absorbed. The filter element will have a pore size or screen size selected to separate solid particles at a desired particle size cutoff. For example, suitable filter membranes may have a pore size in the range from 1 μm to 1000 μm , usually from 5 μm to 240 μm , and preferably from 20 μm to 120 μm . For separation of larger particles, screens having mesh sizes in the range from 0.1mm to 5mm, and preferably from 0.2mm to 1mm may be used.

[0012] In a specific aspect of the methods of the present invention, at least two filter assemblies may be provided between the aspiration catheter and the aspirate receptacle. The two or more filter assemblies may be disposed in parallel, in series, or in a combination of parallel and series arrangements. Typically, valving will be provided so that the multiple filter assemblies may be isolated from the flowing stream of aspirate so that the filter elements may be removed and the collected solids observed even while the aspiration protocol continues. In some cases, an unfiltered bypass path will be provided with valving so that a single filter assembly or group of filter assemblies may be isolated while the aspirate is directed or shunted to the aspirate receptacle without any filtration.

[0013] In a further specific aspect of the methods of the present invention, two or more filter elements may be employed in series or in parallel in order to size classify the materials being removed. Most simply, two, three, or more filter elements having progressively smaller pore or mesh sizes may be provided in series in a single filter housing. Alternatively, such a series of progressively smaller filtering elements could be provided in separate filter assemblies which are disposed in series between the aspiration catheter and the aspirate receptacle. Alternatively, separate filter assemblies having filter elements with differing particle size cutoffs could be provided in parallel or in a series-parallel arrangement in order to separately collect and classify particles having different sizes. In any of these ways, the solid materials may be filtered and separated into at least two size groups, often at least three size groups, and into virtually any number of different sized collection groups desired.

[0014] In a second aspect of the present invention, systems for aspirating a hollow body structure comprise an aspiration catheter, an aspirate receptacle connectable to receive aspirate from the aspiration catheter, and at least one filter assembly disposed between the aspiration catheter and the aspirate receptacle. Typically, the aspirate receptacle will be a fluid collection bag, although any other conventional medical receptacle would be suitable.

The aspirate receptacle will typically be connected by a flexible tube between the aspiration catheter and the aspirate receptacle. Usually, a syringe, vacuum connector, or other conventional vacuum source will be provided in order to effect the system aspiration.

[0015] The filter assembly usually comprises at least one filter housing having at least one
5 filter element removably disposed in an interior thereof. The filter element, as described
above, may comprise a filter membrane, a mesh, link, or the like, having a pore or mesh size
selected to collect and separate solids having a target threshold size or sizes. The filter
housing and optionally filter element may be at least partially transparent to permit
10 observation of the solid materials as they collect. In an exemplary embodiment, the filter
housing has an upper shell and a lower shell which may be taken apart to permit introduction,
removal, and replacement of the filter element in the interior of the housing. The housing
will further have conventional connectors to permit connection at an upper end to the
aspiration catheter and at a lower end to the aspirate receptacle.

[0016] The system may further comprise at least a second filter assembly, a third filter
15 assembly, or even greater number of filter assemblies which may be disposed in parallel or
series to the first filter assembly. Additionally, at least one unfiltered flow path may be
provided in parallel to the filter assembly(ies), and valving will be provided to permit
selective flow through any one or more of the filter assemblies as well as through the
unfiltered flow path. The different filter assemblies may each have a filter element with a
20 different pore or mesh size. Alternatively, two or more filter elements may be provided
within a single filter assembly, where the individual filter elements within the individual
assembly may optionally have different pore or mesh sizes.

BRIEF DESCRIPTION OF THE DRAWINGS

[0017] Fig. 1 illustrates an exemplary system including an irrigant source, an aspiration and
25 irrigation catheter, a filter assembly, an aspirate receptacle, and a vacuum source, constructed
in accordance with the principles of the present invention.

[0018] Fig. 2 illustrates an exemplary filter housing constructed in accordance with the
principles of the present invention.

[0019] Figs. 3 and 4 illustrate two exemplary filter assembly connection patterns which
30 may be employed in the apparatus and methods of the present invention.

[0020] Fig. 5 illustrates use of filter elements having different pore or mesh sizes disposed in series for classifying solid materials in accordance with the principles of the present invention.

[0021] Fig. 6 illustrates the use of filter elements having different pore or mesh sizes
5 disposed in parallel for classifying solid material sizes in accordance with the principles of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

[0022] The present invention provides systems and methods for separating solid materials, typically particulate materials, from aspirated body fluids, including both natural body fluids
10 and introduced fluids. As shown in Fig. 1, an exemplary system 10 comprises catheter 12 (move the arrow for 12 distal to the 2-line section) which is connected to an aspirate receptacle 14 by tubing 16. The catheter 12 is illustrated as an irrigation/aspiration catheter which is connectable to a source of irrigant fluid 20. Exemplary irrigation/aspiration catheters are described in commonly assigned U.S. Patent Nos. 6,827,701 and 6,878,128,
15 both of which have been previously incorporated herein by reference. It will be appreciated, however, that the present invention does not require that the catheters 12 provide for irrigation, but rather only that they provide for aspiration and the ability to discharge a fluid aspirate stream to an aspirate collection receptacle.

[0023] The irrigation/aspiration catheter 12 illustrated in Fig. 1 and described in the
20 copending U.S. patents incorporated above, provides for a pair of syringe elements for both introducing the irrigant fluid from the irrigant source 20 and discharging the aspirate stream to the aspirate receptacle 14. In other cases and for other aspiration catheters, it may be desirable to provide a separate vacuum source 22 which may be connected to or through the catheter 12 and/or aspirate receptacle 14 in order to draw the aspirate stream through the
25 tubing 16 or other discharge connections. The present invention, of course, does not depend on what particular mechanism is provided for generating the aspirate stream or the location of the said mechanism with respect to the filter(s).

[0024] The catheter 12 has a distal end or portion 26 which is introducible into a target hollow body structure in order to withdraw fluid therefrom to produce the aspirate stream. In
30 the preferred example of the irrigation aspiration catheter, described in the previously incorporated commonly owned U.S. patents, the catheter 12 will be intended for introduction

to a blood vessel for introducing a thrombolytic agent in order to disrupt clot. In this exemplary use, the solid material aspirated by the catheter will frequently comprise disrupted clot, thrombus, and/or plaque, which is then discharged through the aspirate line 16 to the aspirate receptacle. It will be appreciated, however, that the present invention is not limited
5 to vascular use, clot disruption, or any other particular treatment protocol, and may instead extend to the different hollow body structures and body fluids described above.

[0025] In the simplest embodiment of the present invention, a single filter housing 18 is disposed between the aspiration catheter 12 and the aspirate receptacle 14, as illustrated in Fig. 1. As shown in Fig. 2, the filter assembly 18 typically comprises an upper shell 30, a
10 lower shell 32, and a filter element 34 which may be disposed within the interior of the shells. The upper shell 30 is removable from the lower shell 32, typically including mating connectors 36 disposed about the open peripheries of each shell. All or a portion of the shells 30 and 32, as well as optionally the filter element 34, may be composed of transparent materials in order to permit observation of the collection of solids within the filter element 34
15 as the aspiration progresses. While the particular structure of filter assembly 18 shown in Fig. 2) is suitable and presently preferred, a variety of other specific filter assembly constructions could also be used.

[0026] The filter elements 34 may comprise any one of a variety of conventional filtering materials, as generally described above in the Summary of the Invention. The geometries in
20 which the filter elements 34 are arranged will depend in large part on the construction of the remainder of the filter assembly. In the embodiment of Fig. 18, the filter element 34 is constructed so that it nests within the lower shell 32 of the filter assembly. A wide variety of other geometries would also be suitable.

[0027] In many instances, it will be desirable to provide two or more filter assemblies 18
25 between the aspiration catheter 12 and the aspirate receptacle 14. As illustrated in Fig. 3, a pair of filter assemblies 18 are disposed in parallel to receive the aspirate through an upper portion of tubing 16 and discharge the aspirate through a lower portion of tubing 16. Isolation valves 40 are provided so that either of the filter assemblies 18 may be taken off-line to permit access even while the aspiration continues. Optionally, as shown in broken
30 line, a third filter assembly 18 may also be provided in parallel. It is clear that any number of such filter assemblies may be provided in parallel, although the valving may have to be

modified in order to permit any single one of the assemblies to be isolated while all others remain on line.

[0028] The filter assembly arrangement of Fig. 4 illustrates another arrangement within the scope of the present invention. A first filter assembly 18 may be provided and isolated by valves 40 in parallel with an unfiltered flow path 50 having a valve 52 therein. With this embodiment, all flow could be directed through the filter assembly 18 with valve 52 being closed. Should it be desired to gain access to filter 18, the isolation valves 40 could be closed and the flow path valve 52 open.

[0029] As a still further option, as shown in broken line in Fig. 4, additional filter assemblies 18 could be provided, with individual assemblies 18 being disposed in series, where the two series assemblies may be together placed in parallel with first filter assembly 18. It will be appreciated that a wide variety of different parallel and/or series arrangements of filter assemblies and unfiltered flow paths may be provided within the scope of the present invention.

[0030] Referring now to Figs. 5 and 6, it should also be appreciated that filter elements having different pore or mesh sizes may also be provided in series and/or in parallel in order to permit separation and classification of the particulate solid materials which are being separated from the flowing aspirate. For example, as shown in Fig. 5, three filter elements 70, 72, and 74 may be placed in series, with progressively smaller pore or mesh sizes in the direction of flow. Thus, all particles having a size greater than a first threshold would collect on top of the first filter element 70, while intermediate particle sizes having a smaller threshold size would collect on the second filter element 72. Still smaller particles would collect on the third filter element having the smallest pore or mesh sizes, while still smaller particles would pass into the aspirate receptacle without separation. The three filter elements 70, 72, and 74 could be arranged within a single filter housing or alternately within a series of three filter housings.

[0031] The filter elements 70, 72, and 74 could also be arranged in parallel, as shown in Fig. 6. Each of the screens would collect particles having a size greater than the threshold pore or mesh size of the filter element. Such a parallel arrangement of the different sized filter elements, however, would not result in true size classification, since each of the filters would collect the larger elements and would only allow smaller elements to selectively pass. This configuration would allow the use of indicator media which would be placed in the

filter(s). This indicator(s) could detect the presence of a certain biological or chemical components in the aspirant or filtered solids for the diagnostic purposes.

[0032] The collected elements could be used for a variety of therapeutic purposes. For example, when collecting aspirated thrombus in thrombolytic procedures,

- 5 [0033] The collected material could be used to diagnose certain disease states or conditions. These diagnostic findings could then be used to direct further interventions and/or treatments.

[0034] While the above is a complete description of the preferred embodiments of the invention, various alternatives, modifications, and equivalents may be used. Therefore, the above description should not be taken as limiting the scope of the invention which is defined
10 by the appended claims.

WHAT IS CLAIMED IS:

- 1 1. A method for separating materials removed from a hollow body
2 structure, said method comprising:
3 aspirating a fluid from the hollow body structure, wherein solid materials from
4 the hollow body structure are entrained in the aspirate;
5 filtering solids from the aspirate to produce a filtrate and a fluid stream; and
6 collecting the fluid stream separately from the filtrate.
- 1 2. A method as in claim 1, wherein aspirating the fluid comprises
2 introducing an aspiration catheter in the hollow body structure.
- 1 3. A method as in claim 1, wherein filtering comprises interposing at least
2 one filter assembly including a filter housing and a removable filter element between the
3 aspiration catheter and an aspirate receptacle.
- 1 4. A method as in claim 3, further comprising removing the filter element
2 from the housing to permit inspection of solids collect by the filter element.
- 1 5. A method as in claim 4, wherein the filter element is removed while
2 aspirate continues to flow from the aspiration catheter to the aspirate receptacle.
- 1 6. A method as in claim 5, wherein the aspirate flow is directed past the
2 filter assembly while the filter element is removed.
- 1 7. A method as in claim 6, wherein the aspirate is directed past the filter
2 assembly through at least a second filter assembly disposed in parallel to the first filter
3 assembly.
- 1 8. A method as in claim 6, wherein the aspirate is directed past the filter
2 assembly through an unfiltered flow path disposed in parallel to the filter assembly.
- 1 9. A method as in claim 1, wherein filtering comprises separating the
2 solids into at least two size groups.
- 1 10. A method as in claim 1, wherein filtering comprises separating the
2 solids into at least three size groups.

- 1 11. A method as in claim 1, wherein filtering comprises passing the fluid
2 through at least two filter elements, wherein said filter elements have different pore sizes.
- 1 12. A method as in claim 11, wherein the at least two filter elements are
2 arranged in series.
- 1 13. A method as in claim 11, wherein the at least two filter elements are
2 arranged in parallel.
- 1 14. A method as in claim 1, wherein the hollow body structure is selected
2 from the group consisting of blood vessels, cysts, pseudocysts, abscesses, blood vessel grafts,
3 lung passages, bile ducts, ureters, urethras, fallopian tubes, ear canals, and gastrointestinal
4 tracts.
- 1 15. A method as in claim 14, wherein the hollow body structure is an
2 artery.
- 1 16. A method as in claim 15, wherein the artery is a coronary artery, a
2 peripheral artery, or a cerebral artery.
- 1 17. A method as in claim 14, wherein the hollow body structure is a vein.
- 1 18. A method as in claim 17, wherein the vein is a peripheral vein.
- 1 19. A method as in claim 1, further comprising introducing an irrigation
2 fluid to the hollow body structure, wherein at least a portion of the aspirated fluid comprises
3 the irrigation fluid.
- 1 20. A method as in claim 19, wherein aspirating and introducing the
2 irrigation fluid are performed with an irrigation and aspiration catheter positioned in the
3 hollow body structure.
- 1 21. A method as in claim 19, wherein the irrigation fluid comprises saline.
- 1 22. A method as in claim 1, wherein the irrigation fluid comprises a
2 biologically active agent.

- 1 23. A method as in claim 22, wherein the biologically active agent
2 comprises a thrombolytic agent.
- 1 24. A system for aspirating a hollow body structure, said system
2 comprising:
3 an aspiration catheter;
4 an aspirate receptacle connectable to receive aspirate from the aspiration
5 catheter;
6 at least one filter assembly disposed between the aspiration catheter and the
7 aspirate receptacle.
- 1 25. A system as in claim 24, wherein the aspirate receptacle is a fluid
2 collection bag.
- 1 26. A system as in claim 24, further comprising a flexible tube connecting
2 the aspiration catheter to the aspirate receptacle, wherein the filter housing is connected to the
3 flexible tube between the catheter and the receptacle.
- 1 27. A system as in claim 24, wherein the filter assembly comprises:
2 at least one filter housing; and
3 at least one filter element removably disposed in the filter housing to separate
4 solids from aspirate flowing from the irrigation and aspiration catheter to the aspirate
5 receptacle.
- 1 28. A system as in claim 26, wherein the filter housing is at least partly
2 transparent to allow observation of the filter contents.
- 1 29. A system as in claim 26, wherein the filter housing comprises an upper
2 shell and a lower shell, wherein the upper shell and lower shell are separable to provide
3 access to the filter element in an interior of the filter housing.
- 1 30. A system as in claim 27, further comprising at least a second filter
2 assembly disposed in parallel and/or series to the first filter assembly between the irrigation
3 and aspiration catheter and the aspirate receptacle, and valving to permit selective diversion
4 of aspirate flow through either filter assembly.

1 31. A system as in claim 30, wherein the second filter assembly has a filter
2 element with a pore size different from that of the first filter assembly.

1 32. A system as in claim 27, wherein the filter assembly includes at least
2 two filter elements, wherein at least one of said filter elements has a different pore size than
3 that of another filter element.

1 33. A system as in claim 27, further comprising at least one flow path in
2 parallel to the filter assembly, and valving to permit selective bypass of the filter assembly.

1 34. A system as in claim 24, wherein the aspiration catheter comprises a
2 catheter shaft having at least one irrigation lumen, at least one aspiration lumen, at least one
3 irrigation port near a distal end of the shaft, and at least one aspiration port near said distal
4 end.

1 35. A system as in claim 34, wherein the distal end of the shaft is free from
2 isolation balloons.

1 36. A system as in claim 35, wherein the distal end of the shaft includes at
2 least one isolation balloon disposed proximally of the irrigation and aspiration ports.

1 37. A system as in claim 34, wherein the distal end of the shaft includes at
2 least a second isolation balloon disposed proximally of the irrigation and aspiration ports.

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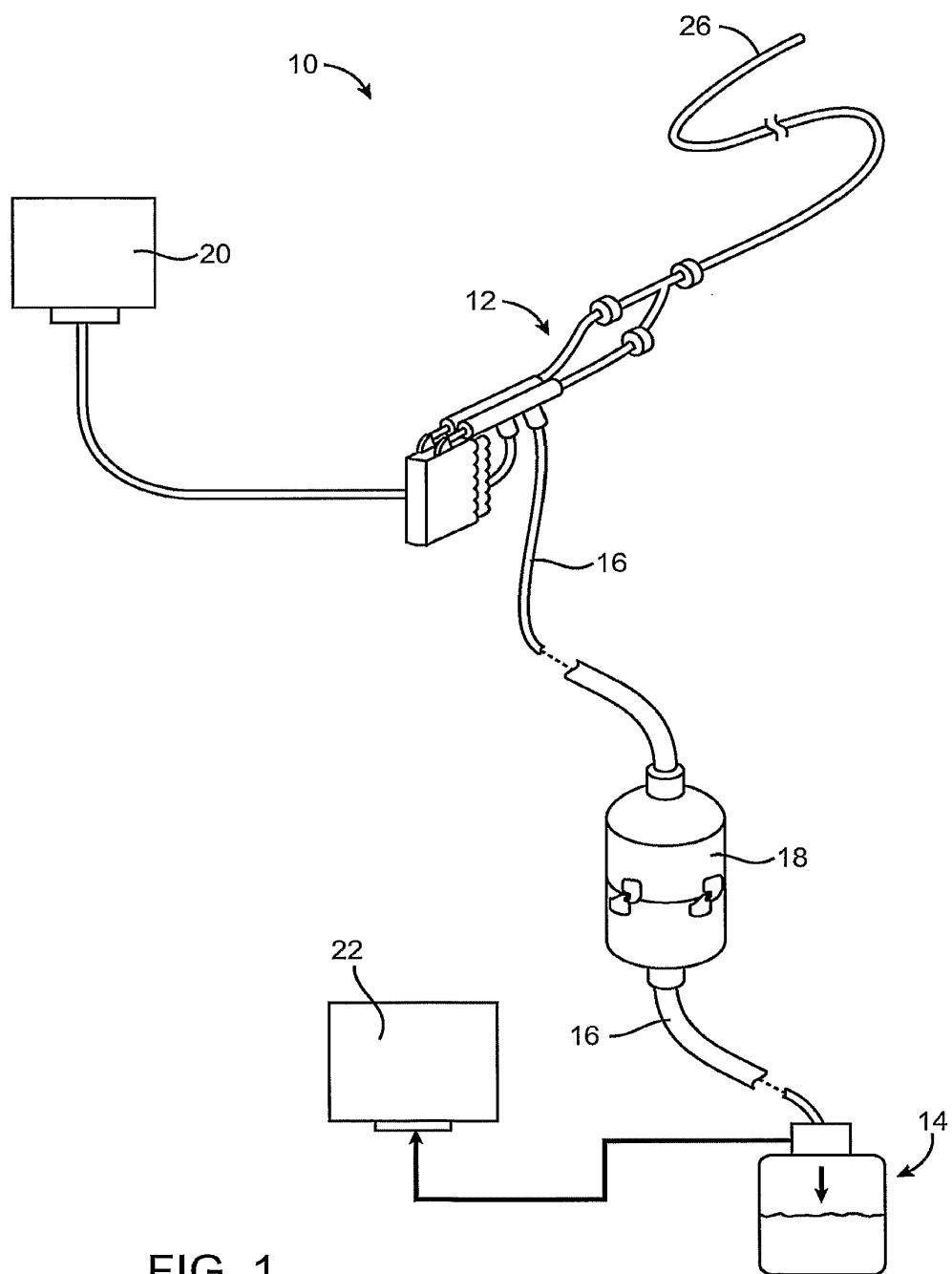
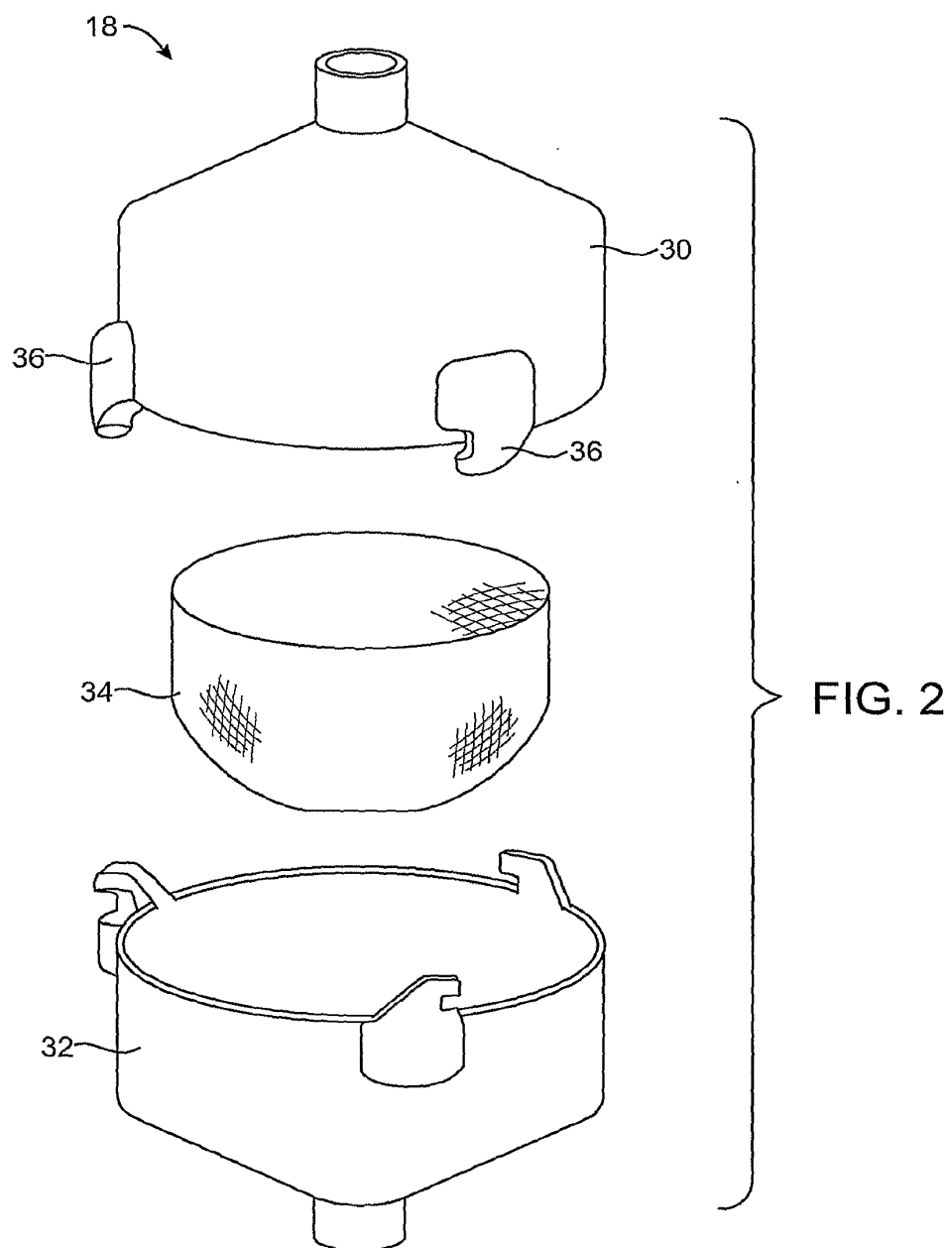


FIG. 1

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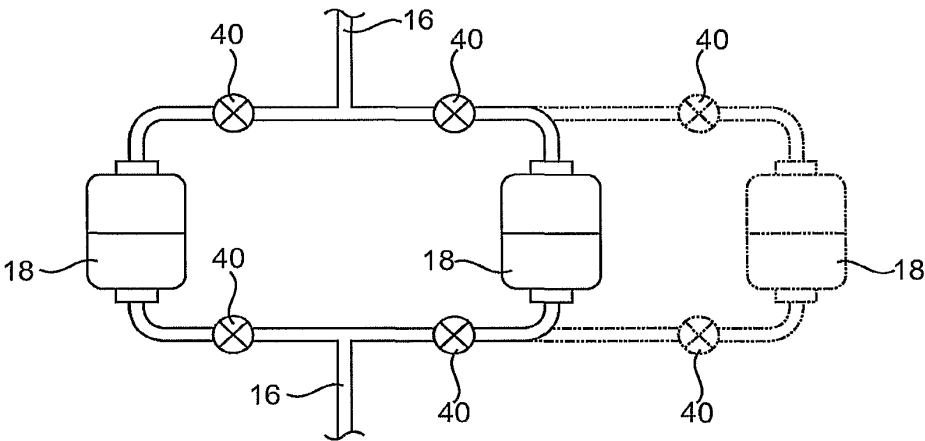


FIG. 3

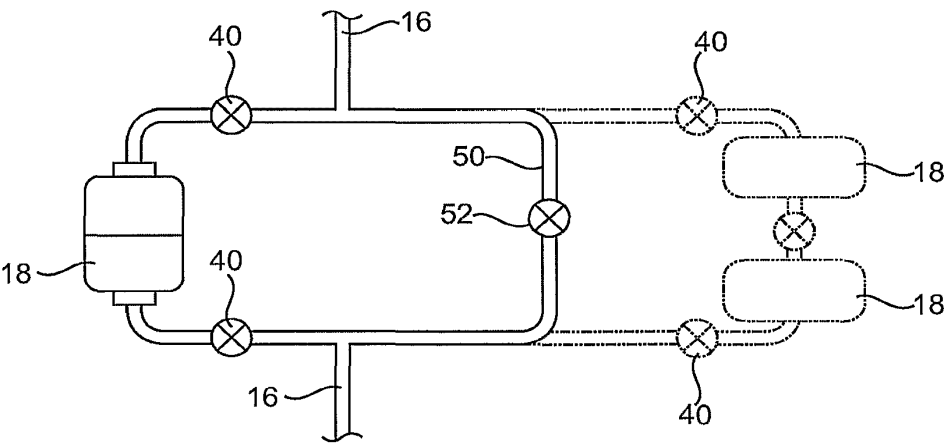
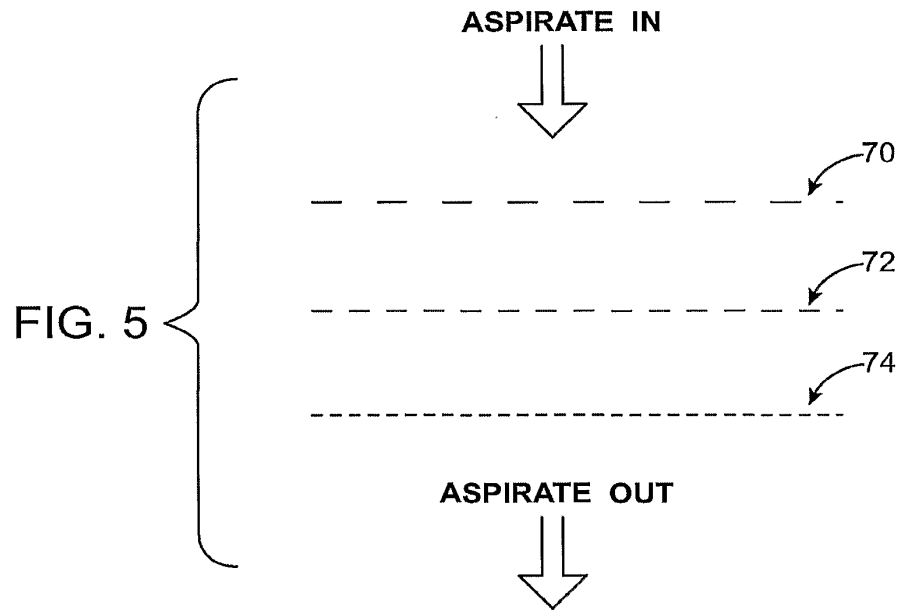
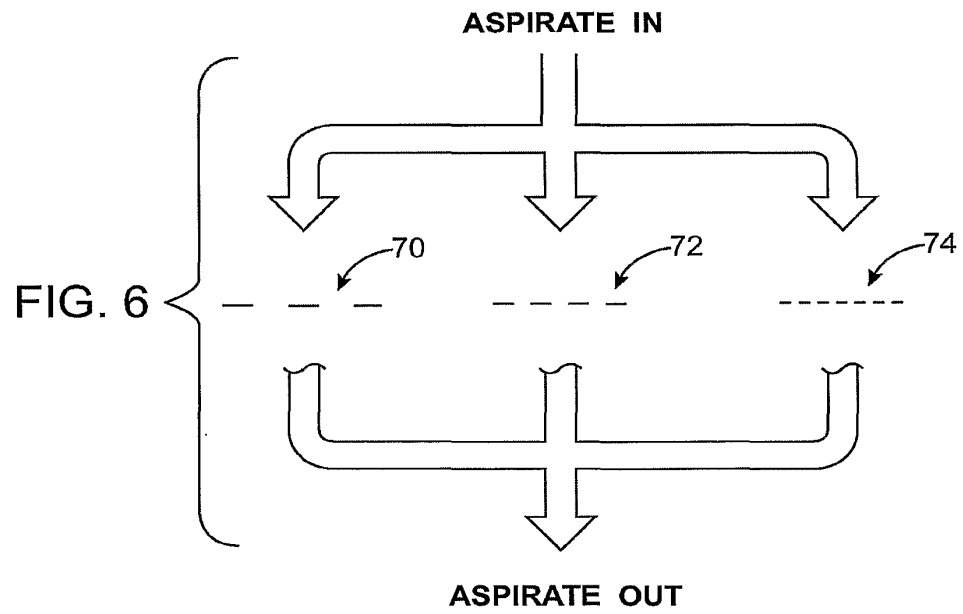


FIG. 4

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	17/498,642- Conf# 1040
	Filing Date	October 11, 2021
	First Named Inventor	Richard Quick
	Art Unit	Not Yet Assigned
	Examiner Name	Not Yet Assigned
	Attorney Docket Number	111552-8023.US02

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Examiner Initial*	Cite No	Foreign Document Number ³	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁵
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	2.					
	3.					
	4.					

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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁵
	1.		
	2.		
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	5.		

EXAMINER SIGNATURE			
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.			
¹ See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. ² Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). ³ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.			
⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ Applicant is to place a check mark here if English language translation is attached.			

CERTIFICATION STATEMENT
Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

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☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e) (1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e) (2).

☐ See attached certification statement.

☐ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ None

It is submitted that the Information Disclosure Statement is in compliance with 37 C.F.R. § 1.98 and the Examiner is respectfully requested to consider the listed references. This Information Disclosure Statement is not to be construed as a representation that: (i) a search has been made; (ii) additional information that may be material to the examination of this application does not exist; (iii) the information, protocols, results and the like reported by third parties are accurate or enabling; or (iv) the cited information is, or is considered to be, material to patentability. In addition, Applicant does not admit that any enclosed item of information constitutes prior art to the subject invention and specifically reserves the right to demonstrate that any such reference is not prior art.

COPIES OF REFERENCES

In accordance with 37 C.F.R. § 1.98(a)(2)(ii), Applicant has not submitted copies of U.S. patents and U.S. patent applications. Applicant submits herewith copies of foreign patents and non-patent literature in accordance with 37 C.F.R. § 1.98(a)(2).

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Matthew S. Williams/	Date (YYYY-MM-DD)	2023-01-05
Name/Print	Matthew S. Williams	Registration Number	77,516

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief

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APPLICATION #
17/498,642

RECEIPT DATE / TIME
01/05/2023 12:11:45 PM ET

ATTORNEY DOCKET #
111552-8023.US02

Title of Invention

SINGLE INSERTION DELIVERY SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED SYSTEMS AND METHODS

Application Information

APPLICATION TYPE Utility - Nonprovisional Application
under 35 USC 111(a)

PATENT # -

CONFIRMATION # 1040

FILED BY JiYoung Anderson

PATENT CENTER # 61391468

FILING DATE 10/11/2021

CUSTOMER # 25096

FIRST NAMED
INVENTOR Richard Quick

CORRESPONDENCE
ADDRESS -

AUTHORIZED BY Matthew Williams

Documents

TOTAL DOCUMENTS: 1

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
2023-1-5-IDS-SB08-111552-8023US2.PDF	5	Information Disclosure Statement (IDS) Form (SB08)	141 KB

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DOCUMENT	MESSAGE DIGEST(SHA-512)
2023-1-5-IDS-SB08-111552-8023US2.PDF	99ED0A2DA40308A530D6AEF67879287B8A69A8FE2C5A85319 03B4C0C949837EFF43C49244F891F633DA73729947D2EA4456

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New Applications Under 35 U.S.C. 111

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National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

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EXAMINER SIGNATURE

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CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e) (1).

OR

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☐ See attached certification statement.

☐ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ None

It is submitted that the Information Disclosure Statement is in compliance with 37 C.F.R. § 1.98 and the Examiner is respectfully requested to consider the listed references. This Information Disclosure Statement is not to be construed as a representation that: (i) a search has been made; (ii) additional information that may be material to the examination of this application does not exist; (iii) the information, protocols, results and the like reported by third parties are accurate or enabling; or (iv) the cited information is, or is considered to be, material to patentability. In addition, Applicant does not admit that any enclosed item of information constitutes prior art to the subject invention and specifically reserves the right to demonstrate that any such reference is not prior art.

COPIES OF REFERENCES

In accordance with 37 C.F.R. § 1.98(a)(2)(ii), Applicant has not submitted copies of U.S. patents and U.S. patent applications. Applicant submits herewith copies of foreign patents and non-patent literature in accordance with 37 C.F.R. § 1.98(a)(2).

Those documents which are marked with a double asterisk (**) next to the Cite No. in the attached form PTO/SB/08 are not supplied because they were previously cited by or submitted to the Office in prior application number **16/258,344** and filed on **January 25, 2019** and relied upon in this application for an earlier filing date under 35 U.S.C. § 120.

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SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Matthew S. Williams/	Date (YYYY-MM-DD)	2022-09-06
Name/Print	Matthew S. Williams	Registration Number	77,516

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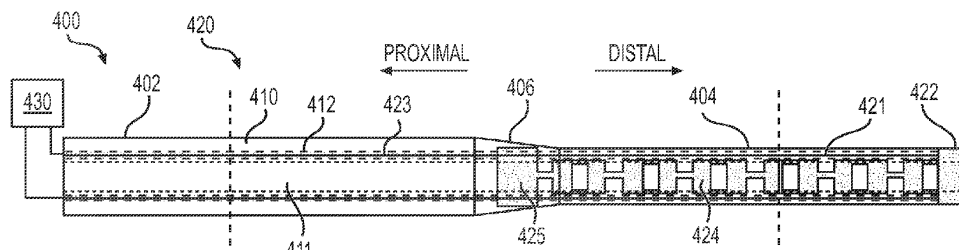


FIG. 4A

(57) Abstract: Disclosed herein are a range of stiffening mechanisms or systems that assist or enable holding a pose or shape of a flexible body (1010, 216, 410, 420, 801). These stiffening mechanisms may be part of the steering mechanism (500, 800), may be separately actuated and/or may themselves also enable steering of the flexible elongate device (400). Further, the stiffening mechanisms may use information from sensor (826) systems, such as a shape sensor (222, 314, 426) in the form of an optical fiber, a plurality of EM sensors (426, 826) distributed along the length of a flexible device, and/or navigation systems, such as a sensor system (108) that computes the approximate location of medical instruments (such as a flexible body) within the anatomy of the patient and/or medical tools that are delivered through a main lumen (411, 811) of the flexible body (1010, 216, 410, 420, 801), to inform a control system (112, 116) which then controls formation and holding of a shape of the flexible body (1010, 216, 410, 420, 801).

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INARI_018391

SYSTEMS AND METHODS FOR HOLDING A FLEXIBLE ELONGATE DEVICE IN A POSE

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of U.S. Provisional Patent Application Serial No. 62/687,120 filed June 19, 2018, the disclosure of which is expressly incorporated herein by reference.

TECHNICAL FIELD

[0002] The present disclosure is directed to teleoperated systems and in particular teleoperated systems involving use of flexible elongate devices.

BACKGROUND

[0003] Flexible elongate devices can be employed in range of fields needing access to restricted openings such as for the exploration of pipes or in medical procedures, especially minimally invasive medical techniques.

[0004] Minimally invasive medical techniques are intended to reduce the amount of tissue that is damaged during medical procedures, thereby reducing patient recovery time, discomfort, and harmful side effects. Such minimally invasive techniques may be performed through natural orifices in a patient anatomy or through one or more surgical incisions. Through these natural orifices or incisions physician may insert minimally invasive medical instruments (including surgical, diagnostic, therapeutic, or biopsy instruments) to reach a target tissue location.

[0005] One such minimally invasive technique is to use a flexible and/or steerable elongate device, such as a flexible catheter, that can be inserted into anatomic passageways and navigated toward a region of interest within the patient anatomy. In some applications, the flexible and/or steerable elongate device needs to be held in a particular shape to enable or improve the safety of a procedure. It would be advantageous to provide improvements to systems and methods for holding a flexible elongate device in a desired pose.

SUMMARY OF THE INVENTION

[0006] Disclosed herein are a range of stiffening mechanisms or systems that assist or enable holding a pose or shape of a flexible body. These stiffening mechanisms may be part of the steering mechanism, may be separately actuated and/or may themselves also enable steering of the flexible elongate device. Further, the stiffening mechanisms may use information from sensor systems, such as a shape sensor in the form of an optical fiber, a plurality of EM sensors distributed

along the length of a flexible device, and/or navigation systems, such as a sensor system that computes the approximate location of medical instruments (such as a flexible body) within the anatomy of the patient and/or medical tools that are delivered through a main lumen of the flexible body, to inform a control system which then controls formation and holding of a shape of the flexible body.

[0007] One embodiment includes a flexible elongate device having a flexible body, a support structure, and a stiffening mechanism. The flexible body has a proximal end, a distal end, and at least one lumen extending between the proximal and distal ends. The flexible body has sufficient flexibility to form a pose. The support structure is coupled with the flexible body. The support structure includes a plurality of sub-elements arranged in series. At least a portion of the sub elements are configured to spread apart when the flexible body flexes into the pose. The stiffening mechanism has at least one stiffening element extending along at least a portion of the flexible body and is configured for actuation independent of the support structure. Actuation of the at least one stiffening element stiffens the support structure to hold at least a portion of the pose of the flexible body. The stiffening element includes a compression feature configured to engage the support structure.

[0008] The support structure includes a coil and the sub-elements include windings of the coil in another embodiment. The support structure includes a spine in another embodiment.

[0009] In various embodiments, the stiffening mechanism includes an inflatable system wherein the inflatable system includes a balloon configured to engage the support structure. The balloon can be configured to extend in between the sub-elements. For example, the balloon can be configured to extend between the sub-elements due to application of a vacuum pressure causing the balloon to collapse into an exterior of the support structure and in between the sub-elements. In yet another embodiment, the balloon is configured to extend in between the sub-elements due to the application of an inflation pressure causing the balloon to expand into an interior defined within the support structure and in between the sub-elements.

[0010] The balloon system, in other embodiments, includes a plurality of balloon portions. For example, the balloon portions can be selectively inflatable to hold the at least the portion of the pose. The balloon portions can be positioned between the sub elements. Further, the balloon portions can spiral between the sub elements.

[0011] In yet another embodiment, the stiffening mechanism can comprise a plurality of control elements extending along the flexible body and configured to exert tension on the flexible body in conjunction with selective inflation of the balloon portions to further hold the at least the portion of the pose.

[0012] Other embodiments can include a shape sensor configured to determine the pose of the flexible body and a controller. The controller can be connected in communication with the shape sensor and the controller is configured to activate the stiffening mechanism to hold at least the portion of the pose of the flexible body.

[0013] In another embodiment, the medical system includes a flexible body, a shape sensor, a stiffening mechanism and a controller. The flexible body has a proximal end, a distal end, and at least one lumen extending between the proximal and distal ends, wherein the flexible body includes a plurality of sub-portions. The shape sensor extends along at least a portion of the flexible body. The stiffening mechanism has a plurality of stiffening elements, each of the stiffening elements positioned within one of the plurality of sub-portions, wherein the sub-portions extend along the flexible body. The controller is connected in communication with the shape sensor, configured to selectively activate the stiffening elements based in part on data received from the shape sensor.

[0014] In another embodiment, the controller is further configured to selectively activate the stiffening elements based in part on a type of instrument for insertion through the flexible body. For example, the controller can be configured to energize selected ones of the stiffening elements to reduce curvature of the flexible body to match a stiff type of instrument.

[0015] In another embodiment, the controller is further configured to selectively activate the stiffening elements based in part on anatomical information. The anatomical information can also information identifying a target area of anatomy and wherein the controller is further configured to actuate selected ones of the stiffening elements to protect the target area of anatomy.

[0016] In another embodiment, the shape sensor includes at least one of a shape sensing fiber extending along the flexible body or a plurality of EM sensors extending along the flexible body.

[0017] In other embodiments, the stiffening mechanism includes a longitudinal balloon array having a plurality of balloon portions and wherein each of the stiffening elements is one of the plurality of balloon portions.

[0018] In another embodiment, the flexible body includes a coil with a plurality of adjacent windings and wherein each of the balloon portions are configured to extend between the adjacent windings with the application of pressure. Further, controller may be configured to selectively apply pressure to each of the balloon portions to urge apart adjacent windings to shape the flexible body.

[0019] Other embodiments further comprise a steering mechanism configured to control the distal end portion of the flexible body. For example, the steering mechanism can include a plurality of pull wires and wherein the controller is further configured to adjust tension in the pull

wires along with selective activation of the stiffening elements to hold the portion of the flexible body in the pose.

[0020] In other embodiments, the plurality of stiffening elements includes a plurality of nitinol actuators. For example, the flexible body can include a wall structure and the plurality of nitinol actuators are embedded in the wall structure. The plurality of nitinol actuators can be distributed circumferentially within the wall structure.

[0021] Other embodiments include a method of holding at least a portion of a pose of a flexible body. The method can include engaging a stiffening element of a stiffening mechanism within a spacing between at least a pair of the plurality of sub-elements, wherein the plurality of sub-elements extend along the flexible body.

[0022] In another embodiment, engaging stiffening element includes urging a portion of the stiffening element into the spacing between the at least the pair of the plurality of sub-elements.

[0023] In another embodiment, urging the portion of the stiffening element includes one of inflating or deflating the stiffening element.

[0024] In another embodiment, actuating a plurality of pull wires extending within a wall structure of the flexible body including adjusting tension in the plurality of pull wires while selectively activating the stiffening elements to hold the pose of the flexible body.

[0025] Other embodiments include a method of holding a pose of a flexible body using a controller. The method includes measuring a current configuration of a flexible body based at least in part on a sensor coupled to the flexible body, determining a desired configuration of the flexible body, and selectively activating a stiffening mechanism to position the flexible body from the current configuration to the desired configuration, wherein the stiffening mechanism includes a plurality of stiffening elements distributed down the length of the flexible body.

[0026] In another embodiment, positioning the flexible body in the desired configuration includes activating each of the plurality of stiffening elements independently.

[0027] In another embodiment, the current configuration includes a measured shape of the flexible body.

[0028] In another embodiment, the method can comprise identifying a small radius in the measured shape, wherein selectively activating the stiffening mechanism includes activating select ones of the plurality of the stiffening elements to increase a bend radius of the flexible body at the identified small radius in the measured shape.

[0029] In another embodiment, the method can comprise receiving information describing stiffness of an instrument to be delivered by the flexible body, wherein the identifying of the small radius in the measured shape includes determining a minimum bend radius corresponding to the

stiffness of the instrument.

[0030] In another embodiment, determining the desired configuration comprises receiving information identifying a target area of anatomy and setting the desired configuration to activate select ones of the plurality of the stiffening elements at the identified target area of anatomy. The information received identifying the target area of anatomy may be based on live imaging.

[0031] In another embodiment, determining the desired configuration comprises receiving a preoperatively recorded surgical image, registering the flexible body to the preoperatively recorded surgical image using sensor data from the sensor coupled to the flexible body, and identifying a portion of the flexible body positioned within the identified target area of anatomy based on the registration. The information received identifying the target area of anatomy is based on the preoperatively recorded surgical image

[0032] In other embodiments, the plurality of the stiffening elements includes a plurality of nitinol actuators extending within a wall structure of the flexible body, and wherein the selectively activating the stiffening mechanism includes energizing at least one of the plurality of nitinol actuators.

[0033] In yet other embodiments, the plurality of the stiffening elements includes a plurality of balloons, and wherein the selectively activating the stiffening mechanisms includes inflating or deflating at least one of the plurality of balloons.

[0034] Embodiments of the present invention have a range of advantages. For example, in the environment of articulating devices that navigate the tortuosity of human anatomy, it is advantageous to securely hold the contorted position of said device while instruments are being delivered through the device. Frequently, devices that pass through an articulating device will exert forces that have a tendency to straighten a contorted and articulated portion of the device. Embodiments of the invention provides various apparatus and methods to hold the pose of a catheter in a contorted position for stable delivery of instruments

BRIEF DESCRIPTIONS OF THE DRAWINGS

[0035] FIG. 1 is a simplified diagram of a teleoperated medical system according to some embodiments.

[0036] FIG. 2A is a simplified diagram of a medical instrument system according to some embodiments.

[0037] FIG. 2B is a simplified diagram of a medical instrument with an extended medical tool according to some embodiments.

[0038] FIGS. 3A and 3B are simplified diagrams of side views of a patient coordinate space

including a medical instrument mounted on an insertion assembly according to some embodiments.

[0039] FIGS. 4A-4C are simplified diagrams of a flexible elongate device according to some embodiments.

[0040] FIG. 5 is a simplified cross-sectional view of a control element conduit according to some embodiments.

[0041] FIGS. 6A-6D are simplified diagrams of a stiffening mechanism or system according to some embodiments.

[0042] FIGS. 7A-7D are simplified diagrams of a stiffening mechanism or system according to some embodiments.

[0043] FIGS. 8A-8E are simplified diagrams of a stiffening mechanism or system according to some embodiments.

[0044] FIGS. 9A-9B are simplified diagrams of methods of using a flexible elongate device with a stiffening mechanism of other embodiments.

[0045] FIGS. 10A-10B are simplified diagrams of a stiffening mechanism or system according to some embodiments.

[0046] FIG. 11 is a simplified flow diagram of a method for identifying target areas of anatomy and activating a stiffening mechanism according to some embodiments.

[0047] FIG. 12 is a simplified flow diagram of a method for identifying an external force and activating a stiffening mechanism according to some embodiments.

DETAILED DESCRIPTION

[0048] In the following description, specific details are set forth describing some embodiments consistent with the present disclosure. Numerous specific details are set forth in order to provide a thorough understanding of the embodiments. It will be apparent, however, to one skilled in the art that some embodiments may be practiced without some or all of these specific details. The specific embodiments disclosed herein are meant to be illustrative but not limiting. One skilled in the art may realize other elements that, although not specifically described here, are within the scope and the spirit of this disclosure. In addition, to avoid unnecessary repetition, one or more features shown and described in association with one embodiment may be incorporated into other embodiments unless specifically described otherwise or if the one or more features would make an embodiment non-functional.

[0049] In some instances well known methods, procedures, components, and circuits have not been described in detail so as not to unnecessarily obscure aspects of the embodiments.

[0050] This disclosure describes various instruments and portions of instruments in terms of their state in three-dimensional space. As used herein, the term “position” refers to the location of an object or a portion of an object in a three-dimensional space (e.g., three degrees of translational freedom along Cartesian x-, y-, and z-coordinates). As used herein, the term “orientation” refers to the rotational placement of an object or a portion of an object (three degrees of rotational freedom – e.g., roll, pitch, and yaw). As used herein, the term “pose” refers to the position of an object or a portion of an object in at least one degree of translational freedom and to the orientation of that object or portion of the object in at least one degree of rotational freedom (up to six total degrees of freedom). As used herein, the term “shape” refers to a set of poses, positions, or orientations measured along an object.

[0051] FIG. 1 is a simplified diagram of a teleoperated medical system 100 according to some embodiments. In some embodiments, teleoperated medical system 100 may be suitable for use in, for example, surgical, diagnostic, therapeutic, or biopsy procedures. While some embodiments are provided herein with respect to such procedures, any reference to medical or surgical instruments and medical or surgical methods is non-limiting. The systems, instruments, and methods described herein may be used for animals, human cadavers, animal cadavers, portions of human or animal anatomy, non-surgical diagnosis, as well as for industrial systems and general robotic or teleoperational systems.

[0052] As shown in FIG. 1, medical system 100 generally includes a manipulator assembly 102 for operating a medical instrument 104 in performing various procedures on a patient P. The manipulator assembly 102 may be teleoperated, non-teleoperated, or a hybrid teleoperated and non-teleoperated assembly with select degrees of freedom of motion that may be motorized and/or teleoperated and select degrees of freedom of motion that may be non-motorized and/or non-teleoperated. Manipulator assembly 102 is mounted to or near an operating table T. A master assembly 106 allows an operator (e.g., a surgeon, a clinician, or a physician as illustrated in FIG. 1) to view the interventional site and to control manipulator assembly 102. Master assembly 106 generally includes one or more control devices for controlling manipulator assembly 102.

[0053] Manipulator assembly 102 supports medical instrument 104 and may optionally include a plurality of actuators or motors that drive inputs on medical instrument 104 in response to commands from the control system (e.g., a control system 112). The actuators may optionally include drive systems that when coupled to medical instrument 104 may advance medical instrument 104 into a naturally or surgically created anatomic orifice. Other drive systems may move the distal end of medical instrument 104 in multiple degrees of freedom, which may include three degrees of linear motion (e.g., linear motion along the X, Y, Z Cartesian axes) and in three

degrees of rotational motion (e.g., rotation about the X, Y, Z Cartesian axes). Additionally, the actuators can be used to actuate an articulable end effector of medical instrument 104 for grasping tissue in the jaws of a biopsy device and/or the like. Actuator position sensors such as resolvers, encoders, potentiometers, and other mechanisms may provide sensor data to medical system 100 describing the rotation and orientation of the motor shafts. This position sensor data may be used to determine motion of the objects manipulated by the actuators.

[0054] Teleoperated medical system 100 may include a sensor system 108 with one or more sub-systems for receiving information about the instruments of manipulator assembly 102. Such sub-systems may include a position/location sensor system (e.g., an electromagnetic (EM) sensor system); a shape sensor system for determining the position, orientation, speed, velocity, pose, and/or shape of a distal end and/or of one or more segments along a flexible body that may make up medical instrument 104; and/or a visualization system for capturing images from the distal end of medical instrument 104.

[0055] Teleoperated medical system 100 also includes a display system 110 for displaying an image or representation of the surgical site and medical instrument 104 generated by sub-systems of sensor system 108. Display system 110 and master assembly 106 may be oriented so operator O can control medical instrument 104 and master assembly 106 with the perception of telepresence. Display system 110 may present images of a surgical site recorded pre-operatively or intra-operatively using image data from imaging technology such as, computed tomography (CT), magnetic resonance imaging (MRI), fluoroscopy, thermography, ultrasound, optical coherence tomography (OCT), thermal imaging, impedance imaging, laser imaging, nanotube X-ray imaging, and/or the like. The pre-operative or intra-operative image data may be presented as two-dimensional, three-dimensional, or four-dimensional (including e.g., time based or velocity-based information) images and/or as images from models created from the pre-operative or intra-operative image data sets. In some embodiments, often for purposes of imaged guided surgical procedures, display system 110 may display a virtual navigational image in which the actual location of medical instrument 104 is registered (i.e., dynamically referenced) with the preoperative or concurrent images/model.

[0056] In some embodiments, display system 110 may display a virtual navigational image in which the actual location of medical instrument 104 is registered with preoperative or concurrent images to present the operator O with a virtual image of medical instrument 104 within the surgical site from an external viewpoint. An image of a portion of medical instrument 104 or other graphical or alphanumeric indicators may be superimposed on the virtual image to assist operator O in the control of medical instrument 104. As described herein, visual representations of data

points may be rendered to display system 110. For example, measured data points, moved data points, registered data points, and other data points described herein may be displayed on display system 110 in a visual representation.

[0057] Teleoperated medical system 100 may also include control system 112. Control system 112 includes at least one memory and at least one computer processor (not shown) for effecting control between medical instrument 104, master assembly 106, sensor system 108, and display system 110. Control system 112 also includes programmed instructions (e.g., a non-transitory machine-readable medium storing the instructions) to implement some or all of the methods described in accordance with aspects disclosed herein, including instructions for providing information to display system 110. While control system 112 is shown as a single block in the simplified schematic of FIG. 1, the system may include two or more data processing circuits with one portion of the processing optionally being performed on or adjacent to manipulator assembly 102, another portion of the processing being performed at master assembly 106, and/or the like. The processors of control system 112 may execute instructions comprising instruction corresponding to processes disclosed herein and described in more detail below. Any of a wide variety of centralized or distributed data processing architectures may be employed. Similarly, the programmed instructions may be implemented as a number of separate programs or subroutines, or they may be integrated into a number of other aspects of the teleoperational systems described herein. In one embodiment, control system 112 supports wireless communication protocols such as Bluetooth, IrDA, HomeRF, IEEE 802.11, DECT, and Wireless Telemetry.

[0058] In some embodiments, control system 112 may receive force and/or torque feedback from medical instrument 104. Responsive to the feedback, control system 112 may transmit signals to master assembly 106. In some examples, control system 112 may transmit signals instructing one or more actuators of manipulator assembly 102 to move medical instrument 104. Control system 112 may optionally further include a virtual visualization system to provide navigation assistance to operator O when controlling medical instrument 104 during an image-guided surgical procedure.

[0059] During a virtual navigation procedure, sensor system 108 may be used to compute an approximate location of medical instrument 104 with respect to the anatomy of patient P. The location can be used to produce both macro-level (external) tracking images of the anatomy of patient P and virtual internal images of the anatomy of patient P. The system may implement one or more electromagnetic (EM) sensor, fiber optic sensors, and/or other sensors to register and display a medical implement together with preoperatively recorded surgical images, such as those from a virtual visualization system. For example, PCT Publication WO 2016/191298 (published

December 1, 2016) (disclosing “Systems and Methods of Registration for Image Guided Surgery”), which is incorporated by reference herein in its entirety, discloses such one system.

[0060] FIG. 2A is a simplified diagram of a medical instrument system 200 according to some embodiments. Medical instrument system 200 includes elongate device 202, such as a flexible catheter, coupled to a drive unit 204. Elongate device 202 includes a flexible body 216 having proximal end 217 and distal end or tip portion 218.

[0061] Medical instrument system 200 further includes a tracking system 230 for determining the position, orientation, speed, velocity, pose, and/or shape of distal end 218 and/or of one or more segments 224 along flexible body 216 using one or more sensors and/or imaging devices as described in further detail below. The entire length of flexible body 216, between distal end 218 and proximal end 217, may be effectively divided into segments 224. Tracking system 230 may optionally be implemented as hardware, firmware, software or a combination thereof which interact with or are otherwise executed by one or more computer processors, which may include the processors of control system 112 in FIG. 1.

[0062] Tracking system 230 may optionally track distal end 218 and/or one or more of the segments 224 using a shape sensor 222. Shape sensor 222 may optionally include an optical fiber aligned with flexible body 216 (e.g., provided within an interior channel (not shown) or mounted externally). In one embodiment, the optical fiber has a diameter of approximately 200 μm . In other embodiments, the dimensions may be larger or smaller. The optical fiber of shape sensor 222 forms a fiber optic bend sensor for determining the shape of flexible body 216. In one alternative, optical fibers including Fiber Bragg Gratings (FBGs) are used to provide strain measurements in structures in one or more dimensions. Various systems and methods for monitoring the shape and relative position of an optical fiber in three dimensions are described in U.S. Patent Application No. 11/180,389 (filed July 13, 2005) (disclosing “Fiber optic position and shape sensing device and method relating thereto”); U.S. Patent Application No. 12/047,056 (filed on Jul. 16, 2004) (disclosing “Fiber-optic shape and relative position sensing”); and U.S. Patent No. 6,389,187 (filed on Jun. 17, 1998) (disclosing “Optical Fibre Bend Sensor”), which are all incorporated by reference herein in their entireties.

[0063] In some embodiments, tracking system 230 may optionally and/or additionally track distal end 218 using a position sensor system 220. Position sensor system 220 may be a component of an EM sensor system with position sensor system 220 including one or more conductive coils that may be subjected to an externally generated electromagnetic field. Each coil of the EM sensor system then produces an induced electrical signal having characteristics that depend on the position and orientation of the coil relative to the externally generated electromagnetic field. In some

embodiments, position sensor system 220 may be configured and positioned to measure six degrees of freedom, e.g., three position coordinates X, Y, Z and three orientation angles indicating pitch, yaw, and roll of a base point or five degrees of freedom, e.g., three position coordinates X, Y, Z and two orientation angles indicating pitch and yaw of a base point. Further description of a position sensor system is provided in U.S. Patent No. 6,380,732 (filed August 11, 1999) (disclosing “Six-Degree of Freedom Tracking System Having a Passive Transponder on the Object Being Tracked”), which is incorporated by reference herein in its entirety. In some examples, a series of positional sensors (not shown), such as electromagnetic (EM) sensors similar to the sensors in position sensor 220 may be positioned along flexible body 216 and then used for shape sensing. Flexible body 216 includes a channel 221 sized and shaped to receive a medical instrument 226.

[0064] FIG. 2B is a simplified diagram of flexible body 216 with medical instrument 226 extended according to some embodiments. In some embodiments, medical instrument 226 may be used for procedures such as surgery, biopsy, ablation, illumination, irrigation, or suction.

[0065] Medical instrument 226 may additionally house cables, linkages, or other actuation controls (not shown) that extend between its proximal and distal ends to controllably bend the distal end of medical instrument 226. Steerable instruments are described in detail in U.S. Patent No. 7,316,681 (filed on Oct. 4, 2005) (disclosing “Articulated Surgical Instrument for Performing Minimally Invasive Surgery with Enhanced Dexterity and Sensitivity”) and U.S. Patent Application No. 12/286,644 (filed Sept. 30, 2008) (disclosing “Passive Preload and Capstan Drive for Surgical Instruments”), which are incorporated by reference herein in their entireties.

[0066] Flexible body 216 may also house cables, linkages, or other steering controls (not shown) that extend between drive unit 204 and distal end 218 to controllably bend distal end 218 as shown, for example, by broken dashed line depictions 219 of distal end 218. Steerable elongate devices are described in detail in U.S. Patent Application No. 13/274,208 (filed Oct. 14, 2011) (disclosing “Catheter with Removable Vision Probe”), which is incorporated by reference herein in its entirety. In embodiments in which medical instrument system 200 is actuated by a teleoperational assembly, drive unit 204 may include drive inputs that removably couple to and receive power from drive elements, such as actuators, of the teleoperational assembly. In some embodiments, medical instrument system 200 may include gripping features, manual actuators, or other components for manually controlling the motion of medical instrument system 200. Elongate device 202 may be steerable or, alternatively, the system may be non-steerable with no integrated mechanism for operator control of the bending of distal end 218. In some examples, one or more lumens, through which medical instruments can be deployed and used at a target surgical location, are defined in the walls of flexible body 216.

[0067] The information from tracking system 230 may be sent to a navigation system 232 where it is combined with information from visualization system 231 and/or the preoperatively obtained models (e.g., anatomic models of the patient anatomy) to provide the physician or other operator with real-time position information. In some examples, the real-time position information may be displayed on display system 110 of FIG. 1 for use in the control of medical instrument system 200. In some examples, control system 116 of FIG. 1 may utilize the position information as feedback for positioning medical instrument system 200. Various systems for using fiber optic sensors to register and display a surgical instrument with surgical images are provided in U.S. Patent Application No. 13/107,562, filed May 13, 2011, disclosing, “Medical System Providing Dynamic Registration of a Model of an Anatomic Structure for Image-Guided Surgery,” which is incorporated by reference herein in its entirety.

[0068] In some examples, medical instrument system 200 may be teleoperated within medical system 100 of FIG. 1. In some embodiments, manipulator assembly 102 of FIG. 1 may be replaced by direct operator control. In some examples, the direct operator control may include various handles and operator interfaces for hand-held operation of the instrument.

[0069] FIGS. 3A and 3B are simplified diagrams of side views of a patient coordinate space including a medical instrument mounted on an insertion assembly according to some embodiments. As shown in FIGS. 3A and 3B, a surgical environment 300 includes a patient P is positioned on the table T of FIG. 1. Instrument carriage 306 or insertion stage 308 may include actuators, such as servomotors, (not shown) that control motion of instrument carriage 306 along insertion stage 308. Elongate device 310 is coupled to an instrument body 312. Instrument body 312 is coupled and fixed relative to instrument carriage 306. In some embodiments, an optical fiber shape sensor 314 is fixed at a proximal point 316 on instrument body 312. Shape sensor 314 measures a shape from proximal point 316 to another point such as distal end 318 of elongate device 310. Point gathering instrument 304 may be substantially similar to medical instrument system 200. A position measuring device 320 provides information about the position of instrument body 312 as it moves on insertion stage 308 along an insertion axis A. Position measuring device 320 may include resolvers, encoders, potentiometers, and/or other sensors that determine the rotation and/or orientation of the actuators controlling the motion of instrument carriage 306 and consequently the motion of instrument body 312. In some embodiments, insertion stage 308 is linear. In some embodiments, insertion stage 308 may be curved or have a combination of curved and linear sections.

[0070] FIG. 3A shows instrument body 312 and instrument carriage 306 in a retracted position along insertion stage 308. In FIG. 3B, instrument body 312 and instrument carriage 306 have

advanced along the linear track of insertion stage 308 and distal end 318 of elongate device 310 has advanced into patient P.

[0071] FIGS. 4A-4C are simplified diagrams of a flexible elongate device 400 according to some embodiments. According to some embodiments consistent with FIGS. 1-3, flexible elongate device 400 may correspond to elongate device 202 of medical instrument system 200. As depicted in FIG. 4A, flexible elongate device 400 can include a proximal section 402, a distal section 404 and a transition section 406 therebetween.

[0072] Flexible elongate device 400 can include a flexible body 410 with a flexible wall having a thickness extending from an inner surface to an outer surface of the flexible body 410. A main lumen 411 can extend within the flexible body 410, through the proximal section 402, the transition section 406, and the distal section 404. The main lumen 411 can provide a delivery channel for a medical tool, such as an endoscope, biopsy needle, ultrasound (EBUS or IVUS) probe, ablation tool, chemical delivery tool, and/or the like, to be inserted through flexible body 410. According to some embodiments, a plurality of control element lumens 412 extend through the flexible wall of the flexible body 410 arranged circumferentially in the flexible wall around the main lumen 411. According to some embodiments, a sensor lumen 419 extends through the flexible wall of the flexible body 410. The sensor lumen 419 can extend from the proximal end of the flexible elongate device 400, through the proximal section 402, transition section 406, terminating at a distal portion of the distal section 404. In some examples, flexible body 410 may include various other types of lumens for electrical wires, fibers, sensors, small medical instruments, chemical delivery, and/or the like. In alternative embodiments, flexible body 410 may include an all-purpose lumen that can be used for a variety of purposes, including accommodating multiple concurrently inserted instruments, control elements, sensors, and/or the like.

[0073] As depicted in FIGS. 4A-4C, within each of the control element lumens 412, a coil pipe or conduit 423 can extend through the proximal section 402 of the flexible body 410, providing channels through which a plurality of control elements 421 extends. In some examples, control elements 421 can include pull wires, tendons, push rods and/or the like. The conduits 423 terminate at the transition section 406, proximal to the distal section 404. The control elements 421 extend out of the conduits 423 at the transition section 406, entering the distal section 404 through control element lumens 412, and attach to a distal mount 422. The one or more control elements 421 can be used to actuate distal section 404 of flexible elongate device 400. As depicted in FIGS. 4B and 4C, four control elements 421 can be disposed within control element lumens 412 and evenly spaced around the circumference of flexible elongate device 400.

[0074] In the illustrative example provided in FIG. 4B, a pair of lumens that includes sensor lumen 419 and one of control element lumens 412 is approximately centered along a side of the rounded square formed by main lumen 411. Consequently, neither sensor lumen 419 nor control element lumens 412 are individually centered along the side of the rounded square. Moreover, because control elements 421 are equally spaced around the perimeter of the rounded square, none of the control element lumens 412 are centered relative to the rounded square. As a result, the square formed by control elements 421 and the rounded square formed by main lumen 411 are offset by approximately 30 degrees. However, it is to be understood that different numbers and/or arrangements of control elements 421 are possible. For example, control elements 421 may be unevenly spaced around the circumference of flexible elongate device 400 and/or centered relative to the sides of main lumen 411.

[0075] Distal section 404 is actuated by applying actuation forces to control elements 421 (e.g., pulling and/or pushing on control elements 421 in an unequal manner). Applying actuation forces causes distal section 404 to bend in the direction defined by the net actuation forces. In some examples, the actuation forces may be applied manually, robotically, and/or the like. For example, the actuation forces may be applied using an actuator 430 positioned at the proximal end of flexible elongate device 400. Conduits 423 transfer the actuation forces applied to control elements 421 from the proximal end to the distal end of proximal section 402 at transition section 406. Consequently, even when unequal actuation forces are applied to control elements 421, little actuation force appears within proximal section 402. In some examples, conduits 423 may be flexible to retain the flexibility of proximal section 402. Further examples of conduits are provided in P.C.T. Patent Application PCT/US14/62188 entitled “Flexible Instrument with Embedded Actuation Conduits,” filed October 24, 2014, which is hereby incorporated by reference in its entirety.

[0076] Any bend along the length of the proximal section 402 of the flexible elongate device 400 results in a change of length of control element lumens 412. For example, with reference to FIG. 4A, if the flexible body bends in a downward motion, the control element lumens 412 on the lower portion of flexible body 410 will decrease in length while the control element lumens 412 on the upper portion of flexible body will increase in length. Thus, it can be necessary for the conduits 423 to axially slide within the control element lumens 412. In some examples, the conduits can be constrained (e.g., fixed and/or prevented from sliding proximally along a conduit longitudinal axis) at a proximal end of the flexible elongate device within the actuator 430 and can terminate at the transition section 406. The conduits may be constrained (e.g., fixed and/or prevented from sliding distally along a conduit longitudinal axis) at the transition section 406. In

this example, within transition section 406, a stopper 425 is coupled between conduits 423 on the stopper proximal side and an axial support structure 424 on the distal stopper side. Stopper 425 prevents conduits 423 from shifting distally along flexible elongate device 400. In alternative examples, the conduits may be fixed to stopper 425.

[0077] Within distal section 404, axial support structure 424 is configured to bend in response to actuation forces applied to control elements 421. Consequently, when unequal actuation forces are applied to control elements 421, distal section 404 bends in the direction defined by the net actuation forces. Axial support structure 424 supports distal section 404 against axial loads generated by the actuation forces applied to control elements 421. In particular, axial support structure 424 may prevent or reduce distortion, compression and/or collapse of distal section 404 under axial loads. Further examples of axial support structures are provided in U.S. Provisional Patent Application 62/378,943 entitled “Axial Support Structure for a Flexible Elongate Device,” which is hereby incorporated by reference in its entirety.

[0078] Although axial support structure 424 is depicted as having a spine-like structure in FIG. 4A, other structures are possible. In some examples, axial support structure 424 may be formed as a single large coil that encloses main lumen 411. Additionally, while FIG. 4C illustrates control elements 421 within control element lumens 412, in a similar configuration as shown in FIG. 4B for proximal section 402, axial support structure 424 may include conduits similar to conduits 423. In some embodiments, conduits 423 may continue to run through both proximal and distal sections of flexible body 420. In alternative embodiments, separate conduits 423 may run in the proximal section and distal section. Whereas the conduits of conduits 423 are arranged concentrically around control elements 421 to counteract the actuation forces applied to control elements 421, the conduits of axial support structure 424 may be offset from control elements 421 (e.g., located at different positions around the circumference of flexible body 410) to allow axial support structure 424 to bend in response to actuation forces. Alternately or additionally, the conduits of axial support structure 424 may be more flexible (e.g., smaller diameter and/or constructed using smaller gauge wire) than the conduits of conduits 423.

[0079] In some examples, one or more of lumens 411, 412, 419, and/or sections thereof, may be keyed. That is, a lumen and/or a portion of a lumen may have a non-circular cross-sectional shape that prevents or constrains the rotation of a tool (e.g., a medical instrument, sensor, fiber, electrical wire, actuation element, and/or the like) with a matching non-circular cross-sectional shape when inserted through the lumen. As depicted in FIG. 4B, main lumen 411 of proximal section 402 is keyed. In particular, the main lumen 411 has a rounded square cross-sectional shape that supports four keyed orientations.

[0080] In some examples, a localization sensor 426, such as an optical fiber of shape sensor 222, extends through sensor lumen 419. Like conduits 423, localization sensor may be constrained (e.g., fixedly attached and/or prevented from sliding axially) at each end of flexible elongate device 400. In one example, the localization sensor is fixedly attached to distal mount 422, free-floating within sensor lumen 419, and fixedly attached at actuator 430. In some examples, a service loop can be provided within actuator 430 between a fixed localization attachment and a proximal end of flexible elongate device 400 to accommodate the varying length of sensor lumen 419 due to bending. In alternative examples, the service loop can be provided between actuator 430 and the distal end of flexible elongate device 400 or within the flexible elongate device.

[0081] In some examples, the cross-sectional shape of lumens 411-419 may change between proximal section 402 and distal section 404. For example, main lumen 411 may be keyed within proximal section 402 and unkeyed within distal section 404. As depicted in FIG. 4C, main lumen 411 of distal section 404 is unkeyed, having a circular cross-sectional shape that does not constrain the rotation of a medical instrument inserted therein. Examples of keyed lumens are discussed in greater detail below with reference to FIG. 10.

[0082] In some examples, the diameter of lumens 411-419 may change between proximal section 402 and distal section 404. Accordingly, lumens 411-419 may be tapered within transition section 406 to provide a gradual transition between the different cross-sectional shapes, e.g., a keyed lumen on the proximal side and an unkeyed lumen on the distal side.

[0083] In some examples, the flexible wall of the flexible body 410 may vary between the proximal section 402 and distal section 404. In some examples, a required bending flexibility and/or compressive strength may vary along the length of the catheter based on potential positioning within patient anatomy. Thus, the flexible wall may include a plurality of layers which can vary within a proximal section flexible wall and within a distal section flexible wall.

[0084] Despite the advantages of the above-described construction of the flexible elongate device 400 being able to actuate distal section 404 of flexible elongate device 400 by, for example, operation of the control elements 421 within conduits 423, in certain situations, once the flexible elongated device 400 is positioned in a desired pose, attempting to hold the shape of the flexible body in a desired configuration can be difficult. In addition, instances occur in which it would be advantageous to adapt the shape of the flexible body 410 based on known information about the surrounding anatomy and/or the instruments to be inserted through the main lumen 411, or other lumens. To this end, a range of stiffening mechanisms or systems are described that assist or enable holding a pose or shape of the flexible body 410. These stiffening mechanisms may be part of the steering mechanism, may be separately actuated and/or may themselves also enable steering

of the flexible elongate device 400. Further, the stiffening mechanisms may use information from sensor systems, such as shape sensor 426 in the form of an optical fiber, a plurality of EM sensors distributed along the length of a flexible device, a plurality of force sensors distributed along the length of a flexible device, and/or navigation systems, such as sensor system 108 that computes the approximate location of medical instruments (such as the flexible body 410) within the anatomy of the patient and/or medical tools that are delivered through main lumen 411, to inform the control system 112 which then controls formation and holding of a shape of the flexible body 410.

[0085] In some embodiments, stiffening mechanisms, especially stiffening mechanisms with sub-elements, exhibit behaviors that can be used to stiffen the shape of the flexible body 410. In one embodiment, as shown in FIGS. 6A-6D, for example, a stiffening system or mechanism 500 uses the characteristics of the coil pipe 423 within the control element lumen 412 to stiffen the pose of the flexible body 410.

[0086] FIG. 5 is an enlarged schematic showing an example of the conduit or coil pipe 423 within control element lumen 412 extending around the control element 421, such as a pull wire. Notably, in this example, the coil pipe 423 includes a plurality of windings 504. In this configuration, the windings 504 of the coil pipe 423 extend linearly in a stacked array with very little (or no) distance between them. The windings 504 are shown as rings but the coil pipe 423 can be a helical structure that extends helically along a central axis of the control element lumen 412. The control element lumen 412 and the control element 421 are shown in a straight, or unbent, configuration.

[0087] The stiffening mechanism 500 shown in FIGS. 6A – 6D, includes a restricting balloon 502 sleeved over the coil pipe 423. During actuation and steering of the flexible elongate device 400, the restricting balloon is in a passive or natural state. Once the flexible elongate device has been positioned at a desired target location, vacuum can be applied using a pump (not shown), deflating balloon 502 to interdigitate within the spaces between a plurality of windings 504 of the coil pipe. This interdigitation stiffens to hold the shape of the coil pipe 423 subsequently holding the shape and pose of the flexible elongate body 400 and providing a more stable platform for delivery of instruments through the flexible body 410.

[0088] FIG. 6A shows a cross-sectional view of the control element lumen 412, and the stiffening mechanism 500 including the balloon 502. The external circle denotes the outline of the control element lumen 412 within which is a balloon layer or internal wall 506a. The balloon wall extends around (e.g., is sleeved over) the coil pipe 423. In the illustrated embodiment of FIGS. 6A-6D, the balloon 502 can be formed as a tubular structure with an open center lumen such that

the balloon 502 can extend between the coil pipe 423 and an inner surface of the control element lumen 412. FIG. 6B shows a cross-sectional view taken along the longitudinal axis of a portion of the flexible body 410.

[0089] FIG. 6C shows a cross-sectional view of the control element lumen 412 bending under tension from the control element 421 (or other forces and manners of application thereof) into a curved pose along with the surrounding wall structure of the flexible body 410. In this bent pose, the windings 504 of the coil pipe 423 spread apart on the outer curvature due to tracing a longer path and compress more together on the inner curvature as they are tracing a shorter path. The balloon 502, not yet under an inflation pressure or deflation vacuum pressure, passively bends along with the control element lumen 412 and the coil pipe 423.

[0090] In FIG. 6D, the stiffening mechanism is activated by using the pump to apply a suction pressure or vacuum within the lumen of the balloon 502. The suction pressure draws the compliant balloon wall 506a inward into conforming contact with the windings 504 of the coil pipe 423. Generally, on an outside curvature where the windings are spread apart, the balloon wall 506a fills the gap between adjacent pairs of the windings. Even on an inner curvature formed in the coil pipe 423, the balloon wall 506a could achieve some interdigitation between the windings 504. In this embodiment, the adherence of the balloon wall 506a tightens the relationship between it and the windings 504 causing friction which interferes with the coil pipe 423 thus holding it in its current configuration or pose. The presence of the balloon wall 506a in between the windings 504 may wedge the adjacent pairs of windings 504 into the spread apart relationship.

[0091] FIGS. 7A-7D show another embodiment using a balloon 502 that is similar to the embodiment of FIGS. 6A-6D, except the balloon 502 is positioned within the coil pipe 423 such that an external balloon wall 506b is positioned along an inner surface of the coil pipe 423. In the illustrated embodiment of FIGS. 7A-7D, the balloon 502 can be formed as a tubular structure with an open center lumen such that the balloon 502 can extend between the control element 421 and the coil pipe 423, as shown in FIG. 7A. In an alternative embodiment, a pull wire is not used to control actuation of the elongate flexible device 400, so the balloon 502 can be positioned within a lumen of the coil pipe 423, filling the entire coil pipe lumen when inflated. In either configuration, the balloon is inflated (FIG. 7C to FIG. 7D) to adhere against and interdigitate between the windings 504 of the coil pipe 423. This embodiment could be combined with, or substituted for, the embodiment of FIGS. 6A-6D (or used with other embodiments within the scope of this disclosure) depending on the desired level of friction or mechanical blocking and strength of the hold.

[0092] While a single coil pipe 423 is shown for FIGS. 6A-6D and 7A-7D, it should be understood that multiple coil pipes may be distributed within a single elongated flexible device 400. For example, as shown in the embodiments above of FIGS. 4A-4C, there are four control element lumens 412 and each of these could include one or more balloons 502 extending over the coil pipes 23 within the lumens 412. Alternatively or additionally, in another example without pull wires, as shown in FIG 10A, a single coil pipe 1023 could surround a lumen 1011 of an elongated flexible device 1000 including flexible body 1010. Regardless, multiple coil pipes 423 with multiple balloons 502 or balloon portions could be used for one, several, or all the control elements 421 used in the flexible elongate device 400. Each of these balloons 502 could be selectively drawn inward with a vacuum to engage the respective windings 504 of the coils or expanded outward with pressure to engage respective windings 504 of the coils, depending on the shape or pose of the flexible body 410. Additionally, separate balloons or balloon portions could be distributed down the length of each coil pipe, such that stiffening or holding of coil pipe positions could vary down the length of the coil pipe. Thus, by controlling the amount and distribution of the applied vacuum and pressure to different balloons or balloon portions, an entire length of a flexible body can be actively controlled depending upon where and how stiff and what shape is required by the particular anatomy or particular medical procedure.

[0093] As noted above, the axial support structure 424 of the flexible body 410 may include a single large coil that encloses the main lumen 411. The structure of this larger coil, like the coil pipe 423, can be used to stiffen the flexible body 410 in a pose or shape in other embodiments. FIGS. 10A-10B show a cross-section of an embodiment including a coil pipe 1023 surrounding a lumen 1011 of an elongated flexible device 1000 including flexible body 1010. In one embodiment, a single balloon 1002 can spiral along between windings of the coil pipe 1023. As shown in FIG. 10A, the balloon is in a deflated configuration showing a cross-section which bows inward. In this embodiment, the balloon can be inflated (not shown) to force the windings of the coil pipe 1023 to expand against adjacent windings, causing the flexible body 1010 to stiffen or hold a current pose. In an alternative embodiment, a set of separate balloons or a single balloon may be partitioned into balloon portions 1002a-1002d, each positioned within different windings of the coil pipe 1023. As illustrated in FIG. 10B, each balloon portion 1002a-1002d are selectively inflated or deflated to stiffen the flexible body 1010 in a bent configuration. In this example, selected inflation of balloon portions 1002a and 1002c, can cause hold an angle between adjacent segments of the coil support structure 1023 and, along with it, the shape of the flexible body 410. On an inner bend of the flexible body 1010, balloon portions 1002b and 1002d, are deflated to allow for compression of adjacent segments along the inner bend.

[0094] The actuator 430 may include actuation for both control of the pump for inflating or drawing vacuum in the balloons and mechanisms for varying the amount of tension in the control elements 421. Thus, the actuator 430 may vary inflation and or vacuum in the balloons and tension of the control elements 421 in a coordinated relationship to achieve the desired amount of stiffness of the shape or pose of the flexible body 410. The control system 112's actuation of the balloons 502 (or other stiffening elements) and control elements 421 can be based on feedback from various sensors (such as localization sensor 426) to accomplish other objectives, such as adapting to instruments or avoiding injury to sensitive anatomy or withstanding different loading profiles. In this case, the shaping function of the control elements 421 can be facilitated by the stiffening mechanism 500, rather than the stiffening mechanism just being used to stiffen and hold a current pose or shape of the flexible body 410.

[0095] The balloon 502 can be generally constructed of similar materials as balloons for other medical applications, such as for deployment of various medical devices, such as cardiovascular devices. Such balloons can have varied beginning and end shapes depending upon the processes and molds employed in their creation. For example, balloons with large inflated diameters can be compressed down to compact configurations due to careful folding or forming. Generally, however, the balloons used in the embodiments of FIGS. 6A-6D and 7A-7D benefit from sufficient toughness to withstand multiple uses and the friction of interaction with the support structure – such as being able to be trapped or pinched between the windings 504 of the coil pipe 423. At the same time, the balloons benefit from sufficient flexibility to conform to the coil pipe 423 where spread apart to achieve a sufficient amount of friction or blocking for higher stiffnesses of holding the pose under a range of loading conditions.

[0096] The stiffening mechanism 500 could also employ other stiffening elements for holding the shape of the flexible body 410. For example, a foam could be expanded between the coil pipe 423 and the control element lumen 412 or MEMS technology employed to drive wedges or blockers between the spread apart windings 504. The balloons 502 could also be deployed in arrays of multiple balloons and the balloons themselves could be shaped to have features – such as wedge shapes configured for urging between the spread apart coils if inflated or vacuumed into contact with the coil pipe 423. Although the illustrated use of a coil pipe 423 works particularly well because of the nature of the windings 504 forming stacked, adjacent elements that spread apart during bending. Balloons could also be employed with other support structures than the coil pipe. For example, an interconnected linkage may be used in association with (or as) the control elements 421 wherein the linkages have a shape or articulation relative to each other that is stiffened upon being adhered to or wedged between by a balloon. The spacing and shape of the

sub-elements could also be configured to work well with the shape and features of the stiffening elements of the stiffening mechanism. For example, wedge-shaped spaces between sub-elements of the support structure could be locked by insertion of conforming wedge-shaped stiffening elements.

[0097] It should be noted that some embodiments of the invention work well with any type of flexible elongate device 400 with the flexible body 410, wherein the flexible body has some changing structural characteristic that can be trapped, blocked, adhered to or otherwise intervened in with the operative elements of the stiffening mechanism 500 to stiffen the pose or shape of the flexible body. In previously described embodiments, the structural characteristics are within coil pipes. However, in alternative or additional examples, a support structure such as axial support structure 424 may be used in conjunction with one or more balloons surrounding the support structure or positioned within a lumen of the support structure. Particularly useful is a support structure that uses a plurality of sub-elements arranged in series, where the sub-elements exhibit differential characteristics (such as spreading apart) when adjusted into various shapes by flexing or shaping of the flexible body 410 in which they are embedded.

[0098] FIGS. 8A-8E show another embodiment of a stiffening mechanism 800 for a flexible elongate device with a flexible body 801 defining a lumen 811 and divided into a plurality of portions or segments 812. In this embodiment, the stiffening mechanism includes a plurality of nitinol wires 810 distributed circumferentially around each of the plurality of segments 812. Generally, selective activation or energizing of the nitinol wires 810 causes them to engage – by changing their length – the portion of the flexible body to hold or change its pose. The controller of the stiffening mechanism 800 can then modulate its energizing of the nitinol wires 810 based on feedback from various sensors, such as the sensor 826, to hold the pose in varying conditions. In another aspect, the nitinol wires 810 could be employed to just hold the pose of the portion of the flexible body 801 rather than be involved in shaping or steering the flexible body 410.

[0099] FIG. 8A shows the nitinol wires 810, in one aspect, can be embedded in a wall structure of the flexible body 801. For example, four of the nitinol wires 810 are distributed circumferentially with about 90 degrees between them. Also, FIG. 8A shows a sensor lumen such as sensor lumen 819, defined within the wall structure of the flexible body 801 about equidistant between two of the nitinol wires 810. This distribution of the nitinol wires 810 and positioning of the sensor lumen 819, with the sensors 826, such as a fiber-based shape sensor, extending therein, facilitates 360-degree bending control of the flexible body 801 by selectively controlling the amount of energization of the four nitinol wires 810 based on feedback from the shape sensor. The sensors 826 within the sensor lumen 819 may include one or more additional sensors instead of or

in addition to the optical fiber shape sensor. For example, the sensors 826 may include a plurality of EM sensors distributed along the length of the flexible body 801, a plurality of force sensors distributed along the length of the flexible body 801, and/or navigation systems, such as sensor system 108 that computes the approximate location of medical instruments (such as the flexible body 801) within the anatomy of the patient and/or medical tools that are delivered through main lumen 811, to inform the control system 112 which then controls formation and holding of a shape of the flexible body 801. Fewer or more embedded nitinol wires 810 are possible with different relative distributions within the wall structure depending on the desired amount and distribution of actuation and holding forces from the stiffening mechanism 800.

[0100] FIGS. 8B-8E show how the flexible body 801 can be formed of a plurality of portions or segments 812. Each of the segments is a short cylindrical portion of the whole flexible body 801. In this embodiment, the nitinol wires 810 are short lengths beginning and ending in the segment. The actuator 430 may be coupled to each of these lengths of nitinol wires 810 and able to energize those wires to be able to hold or adjust the pose of the segment. FIGS. 8D and 8E show how the segments 812 can be arranged end-to-end to form a longitudinal array 814 and a larger portion (or the entire) flexible body 801. In addition, FIG. 8E shows how the cumulative change in pose of each of the segments 812 results in a change in, and/or holding of shape of, the flexible body 801.

[0101] The nitinol wires are comprised of a shape memory material in the form of a nickel-titanium alloy with a transition temperature. The actuator 430 can selectively change the length of the nitinol wires by heating them, such as with electrical power, through the transition temperature to change between shapes. For example, the memorized shape of the nitinol wires may be a shorter length than the starting length. Thus, heating the nitinol wire causes it to shorten and then change the pose of the segment by compressing the segment 812. Memorized shapes could also be various curves or other configurations to help with shaping. Notably, embodiments of the present invention may also include shape memory materials other than nitinol or mechanical devices that are able to expand, retract and/or change shape to cause and hold pose changes.

[0102] In the previously described balloon and nitinol wire embodiments, the flexible body can be driven to a target location with balloon portions or nitinol wires deactivated or otherwise in a natural configuration, using pull wires or other control elements 421 for steering. Once in position, the current shape of the flexible body 410 or 801 can be measured using a shape sensing system such as tracking system 230. Then, the balloon portions 508 or nitinol wires 810 can be selectively inflated, deflated, or actuated in varying amounts to help maintain the measured shape.

[0103] In the case of nitinol wires, using the data from the optical fiber or other shape sensor, the controller system 112 can be configured to energize the appropriate nitinol wires 810 of the longer composite tube (with multiple segments) to hold its shape. Also, using shape data from the optical fiber sensor, such as sensing deviations from a desired pose or shape, forces could be applied in appropriate regions to maintain a measured shape. Additionally, the nitinol wires 810 can be used to apply greater force to increase bending moments when a stiff instrument is inserted through the device.

[0104] In another example, the balloon portions 508 can be inflated/deflated or nitinol wires can be activated, and pull wires can be additionally controllably altered in tension to maintain the measured shape. Both examples include automatic maintenance of a measured shape or the automatic hold of a pose using pull wires to further stiffen the flexible body 410.

[0105] In other embodiments, the flexible body 410/801 can be navigated within tortuous anatomy 516 in a flexible state, parked within anatomy to position a distal end of the flexible body 410/801 at a target location, then select portions of the flexible body may be stiffened or rigidized depending on different conditions. For example, during a pre-procedure planning stage, a user can identify target areas of the anatomy on a pre-operative model or map, about which one or more proximate portions of the flexible body 410/801 may be selectively rigidize. For example, target areas of the anatomy may include anatomy which are particularly sensitive (e.g., a lung airway is near the pleura, or in a different application, the path of a flexible body 410/801 is near an organ). Alternatively or additionally, imaging techniques can be used to automatically identify target areas of the anatomy. Using registration of a flexible elongate device 400 and real time tracking previously described in reference to FIGS. 2A and 2B, and by identifying the target areas of the anatomy, the flexible body 410/801 can be parked at a target, then portions of the flexible body 410/801 which are proximate the target areas of the anatomy (e.g. various discrete portions along the length of flexible body 410/801) can be selectively discretely rigidized, using stiffening mechanisms such as stiffening mechanism 500/800, to provide protection for the target area of the anatomy (e.g., sensitive anatomy) during delivery of devices through the catheter.

[0106] In another embodiment, the flexible body 410/801 is positioned in tortuous anatomy 516 forcing it adapt to and form tight bends, as shown in FIG. 9A. Thus, delivering a stiff device through a working lumen of the flexible body is challenging. Using selective stiffening control of the embodiments above, a tight bend 518 could be identified as a target area of the anatomy manually by a user, automatically by the control system analyzing the pre-operative model using imaging techniques, and/or by the control system 112 using shape sensing data and a threshold setting for a minimum bend radius. Along the length of the catheter positioned around the tight

bend 518, the control system 112 can command the actuator 430 and stiffening mechanism 500/800 to reconfigure the shape of the flexible body 410 into a larger radius to allow for delivery of the stiff device, as shown in FIG. 9B.

[0107] More generally, in some embodiments, the control system 112 measures a current configuration of the flexible body 410/801 and determines a desired configuration of the flexible body 410/801. The current configuration of the flexible body 410/801 may include a current pose, for example, measuring the current configuration includes measuring a shape of the current pose, such as a radius of a curve along the flexible body 410/801. As discussed above, the current pose may be determined using shape sensing data from an optical fiber sensor or other shape sensor (e.g. a plurality of EM or strain sensors) along the length of the flexible body 410/801. Alternatively, shape may be determined using kinematic data describing the flexible body 410/801 and actuator 430 such as which actuators are activated, a tension in actuators, or pressure applied by actuators.

[0108] The control system 112 may determine deviations from the current configuration to a desired configuration of the flexible body 410/801. Responsive to the determined deviations, the control system 112 can command the actuator 430 to selectively stiffen one or more stiffening mechanisms 500/800 along the length of the flexible body 410/801 to apply forces in appropriate regions to position the flexible body from the current configuration to the desired configuration. For example, the stiffening mechanisms may include a plurality of the balloon portions 508/1002 and/or nitinol wires 810 distributed down the length of the flexible body 410/801 to stiffen discrete portions of the flexible body 410/801 down the length of the flexible body 410/801. Each of the stiffening mechanisms (e.g. each of the balloon portions 508/1002 and/ or each of the nitinol wires 810) may be independently activated by the actuator 430.

[0109] Following the examples above, the control system 112 may determine deviations from the measured radius of a curve at a location along the flexible body 410/801 (e.g., current configuration) and the minimum bend radius (e.g., desired configuration). The minimum bend radius may be determined by the control system 112 based on receiving information describing stiffness of an instrument to be delivered by the flexible body 410/801. Accordingly, the control system 112 can command the actuator 430 to selectively stiffen ones of the stiffening mechanisms along the length of the flexible body 410/801 to apply forces in appropriate regions to position the flexible body to increase a bend radius of the curve at the location along the flexible body 410/801.

[0110] Again following the examples above, the control system 112 may determine the desired configuration by identifying target areas of the anatomy. FIG. 11 is a simplified flow diagram of a method 1100 performed by the control system 112 for identifying target areas of the anatomy

and activating a stiffening mechanism according to some embodiments. For example, the target areas of the anatomy may be identified based on the control system 112 receiving live images or preoperatively recorded surgical images and identifying portions of the flexible body 410/801 that are proximate to the target areas of the anatomy. For example, at 1102, live images or pre-operative images are received by the control system 112. The images may be received from imaging technology such as, computed tomography (CT), magnetic resonance imaging (MRI), fluoroscopy, thermography, ultrasound, optical coherence tomography (OCT), thermal imaging, impedance imaging, laser imaging, nanotube X-ray imaging, and/or the like. In one embodiment, a pre-operative model may be generated from pre-operative images.

[0111] At 1104, target areas of the anatomy may be identified within the pre-operative model, by a user, or automatically using imaging techniques. In another embodiment, target areas of the anatomy can be identified (by users or automatically using imaging techniques) within captured live images. The identified target areas of the anatomy include sensitive anatomy or anatomy with tight bends within anatomical passageways (e.g. small radius bends where the radius is less than the minimum bend radius), for example.

[0112] At 1106, the control system 112 may be used to register the flexible body 410/801 to the live images or to the pre-operative model using sensor data from one or more sensors 426 (or 826) positioned along the flexible body 410/801, while the flexible body is being navigated within anatomy. The registration of the flexible body 410/801 to the pre-operative model/live image is based on the relative known positions between position/shape sensors (e.g. fiber optic shape sensors, EM sensors, etc.) and stiffening mechanism components 502/1002/810. Various systems for using fiber optic sensors to register and display a surgical instrument with surgical images are provided in U.S. Patent Application No. 13/107,562, filed May 13, 2011, disclosing, “Medical System Providing Dynamic Registration of a Model of an Anatomic Structure for Image-Guided Surgery,” which is incorporated by reference herein in its entirety. Systems for registering live imaging devices to a pre-operative image or imaging system are provided in PCT application PCT/US2017/017433, filed February 2, 2017, disclosing, “Systems and Methods for Using Registered Fluoroscopic Images in Image-Guided Surgery” and PCT application PCT/US17/17391, filed February 2, 2017, disclosing, “Systems and Methods of Pose Estimation and Calibration of Perspective Imaging System in Image Guided Surgery”, which are each incorporated by reference herein in their entirety.

[0113] Information from tracking system 230 may be sent to a navigation system 232 where it is combined with information from visualization system 231 and/or the pre-operatively obtained models (e.g., anatomic models of the patient anatomy) to provide the physician or other operator

with real-time position information. At 1108, the real-time position information, including the current configuration of the flexible body 410/801 is received by the control system 112. At 1110, based on the real time position information of the flexible body 410/801, and the identified target areas of the anatomy, the control system 112 can identify portions of the flexible body 410/801 that are positioned at the target areas of the anatomy. At 1112, the control system 112 can command actuators 430, to selectively stiffen one or more stiffening mechanisms 500/800 along the length of the flexible body 410/801 proximate the target areas of the anatomy (the determined portion/s of the flexible body 410/801) to provide protection for sensitive anatomy or to reconfigure the specific length of the flexible body to form a larger radius bend that is greater than or equal to the minimum bend radius.

[0114] In some examples, the real-time position information may be displayed on display system 110 of FIG. 1 for use in the control of medical instrument system 200. In some examples, a virtual image of the flexible body may be overlaid or integrated into the pre-operative model and the identified target areas of the, such as sensitive anatomy and/or tight bends may be displayed. The virtual image of the flexible body may be updated based on the real-time position information obtained from tracking system 230.

[0115] In another embodiment, the flexible body 410/801 is positioned in anatomy which may apply an external force against the flexible body 410/801. For example, anatomy may apply an external force as part of respiration, circulation, or excretion. Using selective discrete stiffening control of the embodiments above, upon detecting an external force at a location at a distal end or along the length of the flexible body 410/801, the control system 112 can command the actuator 430 to selectively stiffen discrete portions along the length of the flexible body 410/801 at the location of the external force.

[0116] FIG. 12 is a simplified flow diagram of a method 1200 performed by the control system 112 for identifying an external force and activating a stiffening mechanism according to some embodiments. At 1202, the control system 112 receives sensor data from one or more sensors 426 (or 826) positioned along the flexible body 410/801 for detecting application of an external force. At 1204, the control system 112 determines whether any of the received sensor data is out of a predetermined threshold for identifying application of an external force to the flexible body 410/801.

[0117] For example, the external force may be detected based on detecting a change in the shape of the flexible body 410/801 as determined by the shape sensor. In some examples, the external force is detected based on a change in shape determined by the shape sensor or a change in shape viewed by live imaging that is not a result of control of the actuator 430 or movement of

a medical instrument through the main lumen 411/811. In other words, the external force is detected based on a change in shape determined by the shape sensor that is independent of operation of the actuator 430 or movement of a medical instrument through the main lumen 411/811. In another example, a fiber optic shape sensor can be configured to calculate both shape and force along the length of the flexible body 410/810.

[0118] In another example, the external force may be detected based on readings from one or more force sensors positioned along the length of the flexible body 410/801. The force sensors may include one or more of a strain gauge, a load cell, a force sensing resistor, or any other suitable force sensor. Each of the force sensors may correspond to a particular location, region, or segment of the flexible body 410/801.

[0119] At 1208, the control system 112 identifies a corresponding location, region, or segment of the flexible body 410/801 where the sensor data is out of threshold. For example, the control system 112 identifies a corresponding location, region, or segment of the flexible body 410/801 where an external force is being applied to the flexible body 410/801. At 1210, upon one of the force sensors detecting where the external force is being applied to the flexible body 410/801, the control system 112 can command the actuator 430 to selectively stiffen the flexible body 410/801 at the corresponding location of the external force. In some examples, the external force detected based on the force sensors is independent of operation of the actuator 430 or movement of a medical instrument through the main lumen 411/811.

[0120] In one embodiment as described above, the flexible body 410/801 is fully positioned in anatomy such that a distal end of the flexible body 410/801 is positioned at or near an anatomical target to be used as a working channel for delivery of therapeutic and/or diagnostic tools. In order to protect anatomy, the controller may selectively stiffen discrete portions of the flexible body. Shape sensing and or external force measurements can be used to determine a portion (or plurality of portions) of the flexible body 410/801 is/are currently configured in a tight radius bend or experiencing external force. Additionally or alternatively, shape sensing can be used in conjunction with a registered pre-operative model where target areas of anatomy have been previously identified, to determine whether a portion (or plurality of portions) of the flexible body 410/801 is/are currently configured in a tight radius bend (e.g., a radius less than the minimum bend radius) or experiencing external force due to the current positioning of the flexible body 410/801 in anatomy. The controller can then selectively activate discrete stiffening elements 502/1002/810 to selectively stiffen portions of the flexible body 410/801 located at the determined portions of the flexible body 410/810.

[0121] In an alternative embodiment, the flexible body is navigated through anatomy and as a portion of the flexible body is actively inserted through a portion of anatomy that has been identified as a target area of the anatomy (e.g. tight bend, sensitive anatomy, etc.), the controller selectively activates the portion situated within the target area of anatomy. In one example, shape sensing can be used in conjunction with a registered pre-operative model by the controller to determine which portion of the flexible body is currently positioned within a target area of the anatomy. In another example, the controller can use shape sensing and/or force sensing to instantly determine which portion or plurality of portions of the flexible body is/are positioned within a tight bend or experience an excessive external force beyond a threshold. The controller can then selectively active discrete stiffening elements 502/1002/810 to selectively stiffen portions of the flexible body 410/801 located at the determined portions of the flexible body which are positioned within a target area of the anatomy, experience a tight bend, and/or experience excessive external force. The controller can propagate the selective stiffness down the length of the flexible device as the flexible device is inserted in anatomy. Accordingly, the flexible body may be stiffened in a controlled manner into a desired pose that protects anatomy from damage the flexible body as it is inserted into anatomy. For example, as a most distal section of the flexible body is positioned near to a target area of the anatomy, the controller selectively stiffens the most distal section only. Then as the flexible body is further inserted in anatomy, the most distal section is relaxed and a section just proximal the most distal section is selectively stiffened. Thus, as the flexible body is being inserted within anatomy, the flexible body can be positioned in a known and controlled pose to protect anatomy instead of allowing a fully flexible device to potentially rub or press against anatomical walls.

[0122] Embodiments above disclose embodiments of stiffening mechanism 500 that provide for selective stiffening of portions of the elongate body along its length and actuation of discrete balloon, nitinol wire or other stiffening elements for selective stiffening to hold a pose or shape. In other embodiments, selective inflation and deflation of balloon portions 1002a-1002d can be used to additionally or alternatively actuate and control steering of the elongated flexible device 1000 in addition to holding pose of the flexible body 1010 of the elongated flexible device 1000. This same ability to steer the flexible body 410 can be employed to hold the pose or shape of the flexible body 410. For example, feedback from the shape sensor 426 could be used to selectively adjust to pressure in the balloons to hold the pose or shape of the flexible body 410.

ADDITIONAL EXAMPLES

[0123]

1. A method of holding a pose of a flexible body using a controller, the method comprising:
measuring a current configuration of a flexible body based at least in part on a sensor coupled to the flexible body;
determining a desired configuration of the flexible body; and
selectively activating a stiffening mechanism to position the flexible body from the current configuration to the desired configuration, wherein the stiffening mechanism includes a plurality of stiffening elements distributed down the length of the flexible body.
2. The method of example 1, wherein positioning the flexible body in the desired configuration includes activating each of the plurality of stiffening elements independently.
3. The method of examples 1 or 2, wherein the current configuration includes a measured shape of the flexible body.
4. The method of example 3 further comprising identifying a small radius in the measured shape, wherein selectively activating the stiffening mechanism includes activating select ones of the plurality of the stiffening elements to increase a bend radius of the flexible body at the identified small radius in the measured shape.
5. The method of example 4 further comprising receiving information describing stiffness of an instrument to be delivered by the flexible body, wherein the identifying of the small radius in the measured shape includes determining a minimum bend radius corresponding to the stiffness of the instrument.
6. The method of any of examples 1-5, wherein determining the desired configuration comprises:
receiving information identifying a target area of anatomy; and
setting the desired configuration to activate select ones of the plurality of the stiffening elements at the identified target area of anatomy.

7. The method of any of examples 1-5, wherein determining the desired configuration comprises:
 - receiving information identifying anatomical passageways including small radius bends;
 - and
 - setting the desired configuration to activate select ones of the plurality of the stiffening elements at the small bends.
8. The method of example 6 or 7, wherein the information received is based on live imaging.
9. The method of example 6 or 7, wherein determining the desired configuration further comprises:
 - receiving a preoperatively recorded surgical image;
 - registering the flexible body to the preoperatively recorded surgical image using sensor data from the sensor coupled to the flexible body;
 - identifying a portion of the flexible body positioned within the identified target area of anatomy or the small bends based on the registration.
10. The method of example 6 or 7, wherein the information received is based on the preoperatively recorded surgical image.
11. The method of any of examples 1-10, wherein the current configuration includes an external force applied to the flexible body.
12. The method of any of examples 1-11, wherein the plurality of the stiffening elements includes a plurality of nitinol actuators extending within a wall structure of the flexible body, and wherein the selectively activating the stiffening mechanism includes energizing at least one of the plurality of nitinol actuators.
13. The method of any of examples 1-11, wherein the plurality of the stiffening elements includes a plurality of balloons, and wherein the selectively activating the stiffening mechanisms includes inflating or deflating at least one of the plurality of balloons.

CLAIMS

What is claimed is:

1. A medical system comprising:
a flexible elongate device including:
a flexible body with a proximal end, a distal end, and at least one lumen extending between the proximal and distal ends, wherein the flexible body includes a plurality of sub-portions;
a shape sensor extending along at least a portion of the flexible body; and
a stiffening mechanism having a plurality of stiffening elements, each of the stiffening elements positioned within one of the plurality of sub-portions, wherein the sub-portions extend along the flexible body; and
a controller connected in communication with the shape sensor, configured to selectively activate the stiffening elements based in part on data received from the shape sensor.
2. The medical system of claim 1, wherein the controller is further configured to selectively activate the stiffening elements based in part on a type of instrument for insertion through the flexible body.
3. The medical system of claim 2, wherein the controller is configured to energize selected ones of the stiffening elements to reduce curvature of the flexible body to match a stiff type of instrument .
4. The medical system of claim 1, wherein the controller is further configured to selectively activate the stiffening elements based in part on anatomical information.
5. The medical system of claim 4, wherein the anatomical information includes information identifying a target area of anatomy and wherein the controller is further configured to actuate selected ones of the stiffening elements to protect the target area of anatomy.
6. The medical system of claim 4, wherein the anatomical information includes identifying a small radius bend within the anatomy and wherein the controller is further configured to actuate selected ones of the stiffening elements to reduce the curvature of the flexible body around the small radius bend.

7. The medical system of any of claims 1-6, wherein the shape sensor includes at least one of a shape sensing fiber extending along the flexible body or a plurality of EM sensors extending along the flexible body.

8. The medical system of any one of claims 1-6, wherein the stiffening mechanism includes a longitudinal balloon array having a plurality of balloon portions and wherein each of the stiffening elements is one of the plurality of balloon portions.

9. The medical system of claim 8, wherein the flexible body includes a coil with a plurality of adjacent windings and wherein each of the balloon portions are configured to extend between the adjacent windings with the application of pressure.

10. The medical system of claim 9, wherein the controller is further configured to selectively apply pressure to each of the balloon portions to urge apart adjacent windings to shape the flexible body.

11. The medical system of any one of claims 1-6, further comprising a steering mechanism configured to control the distal end portion of the flexible body, wherein the steering mechanism includes a plurality of pull wires and wherein the controller is further configured to adjust tension in the pull wires along with selective activation of the stiffening elements to hold the portion of the flexible body in a pose determined from the shape sensor data.

12. The medical system of any one of claims 1-6, wherein the plurality of stiffening elements includes a plurality of nitinol actuators, the flexible body includes a wall structure, and the plurality of nitinol actuators are embedded in the wall structure.

13. The medical system of claim 12, wherein the plurality of nitinol actuators are distributed circumferentially within the wall structure.

14. A flexible elongate device comprising:
- a flexible body with a proximal end, a distal end, and at least one lumen extending between the proximal and distal ends, the flexible body having sufficient flexibility to form a pose;
 - a support structure coupled with the flexible body, the support structure including a plurality of sub-elements arranged in series, wherein at least a portion of the sub-elements are configured to spread apart when the flexible body flexes into the pose; and
 - a stiffening mechanism having at least one stiffening element extending along at least a portion of the flexible body and configured for actuation independent of the support structure, wherein actuation of the at least one stiffening element stiffens the support structure to hold at least a portion of the pose of the flexible body;
- wherein the at least one stiffening element includes a compression feature configured to engage the support structure.
15. The flexible elongate device of claim 14, wherein the support structure includes a coil and the sub-elements include windings of the coil.
16. The flexible elongate device of claim 14, wherein the support structure includes a spine.
17. The flexible elongate device of any one of claims 14-16, wherein the stiffening mechanism includes an inflatable system.
18. The flexible elongate device of claim 17, wherein the inflatable system includes a balloon configured to extend in between the sub-elements.
19. The flexible elongate device of claim 18, wherein the balloon is configured to extend in between the sub-elements due to the application of a vacuum pressure causing the balloon to collapse into an exterior of the support structure and in between the sub-elements.

20. The flexible elongate device of claim 18, wherein the balloon is configured to extend in between the sub-elements due to the application of an inflation pressure causing the balloon to expand into an interior defined within the support structure and in between the sub-elements.

21. The flexible elongate device of claim 17, wherein the inflatable system includes a plurality of balloon portions.

22. The flexible elongate device of claim 21, wherein the plurality of balloon portions are selectively inflatable to hold the at least the portion of the pose.

23. The flexible elongate device of claim 21, wherein the plurality of balloon portions are positioned between the sub elements.

24. The flexible elongate device of claim 21, wherein the plurality of balloon portions spiral between the sub elements.

25. The flexible elongate device of claim 21, further comprising a plurality of control elements extending along the flexible body and configured to exert tension on the flexible body in conjunction with selective inflation of the balloon portions to further hold the at least the portion of the pose.

26. The flexible elongate device of any one of claims 14-16, further comprising:
a shape sensor configured to determine the pose of the flexible body; and
a controller, wherein the controller is connected in communication with the shape sensor and wherein the controller is configured to activate the stiffening mechanism to hold at least the portion of the pose of the flexible body.

27. A method of holding at least a portion of a pose of a flexible body, the method comprising engaging a stiffening element of a stiffening mechanism within a spacing between at least a pair of a plurality of sub-elements, wherein the plurality of sub-elements extend along the flexible body.

28. The method of claim 27, further comprising wherein engaging the stiffening element includes urging a portion of the stiffening element into the spacing between the at least the pair of the plurality of sub-elements.

29. The method of claim 28, wherein the urging of the portion of the stiffening element includes one of inflating or deflating the stiffening element.

30. The method of claim 27-29, further comprising actuating a plurality of pull wires extending within a wall structure of the flexible body including adjusting tension in the plurality of pull wires while selectively activating the stiffening elements to hold the pose of the flexible body.

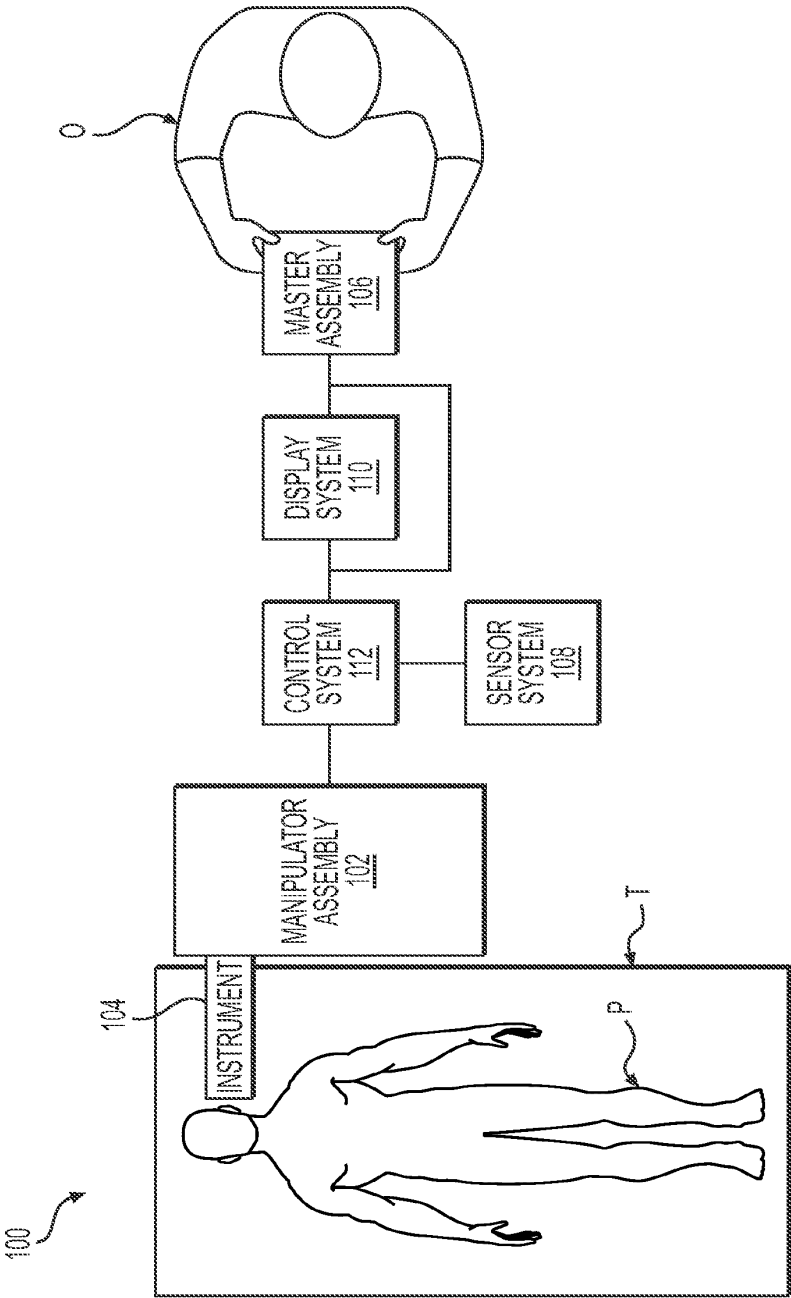
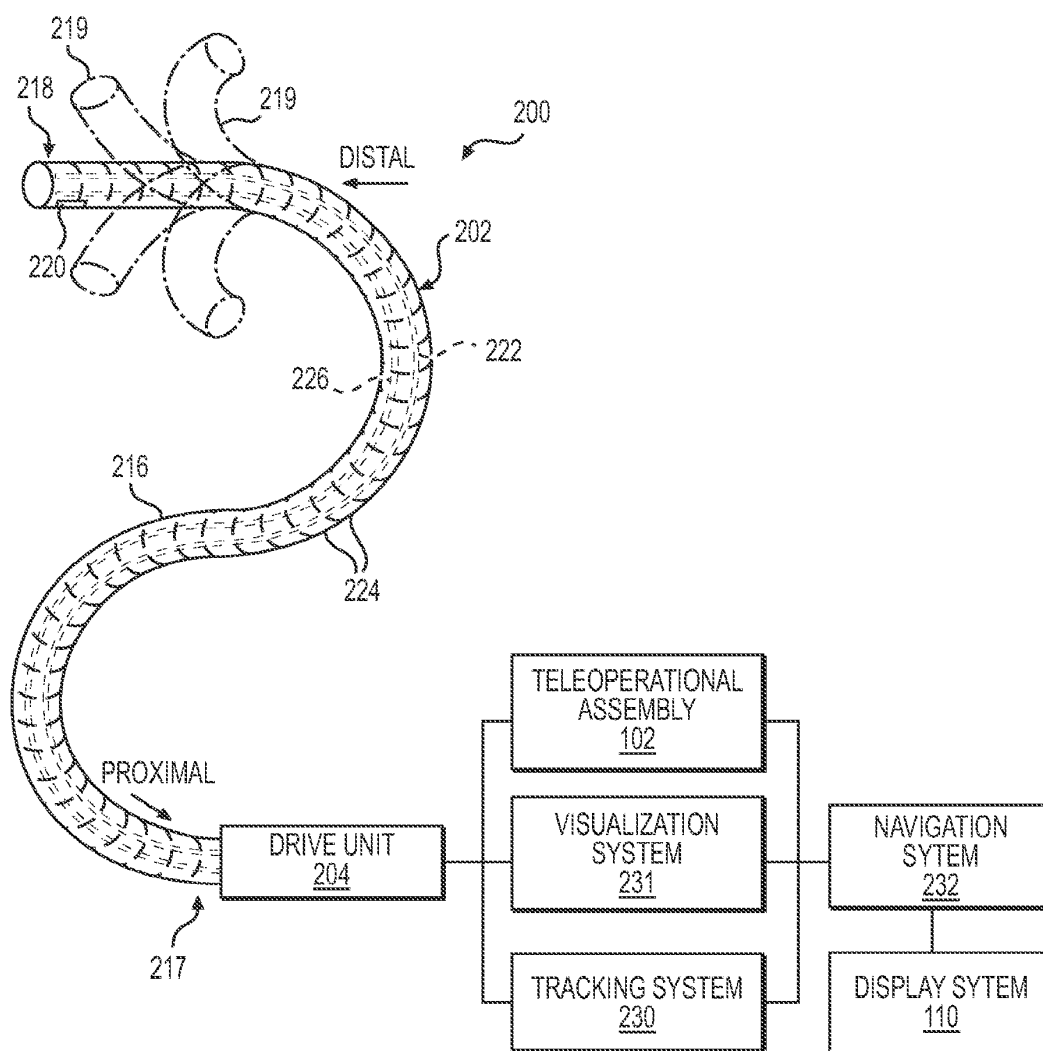
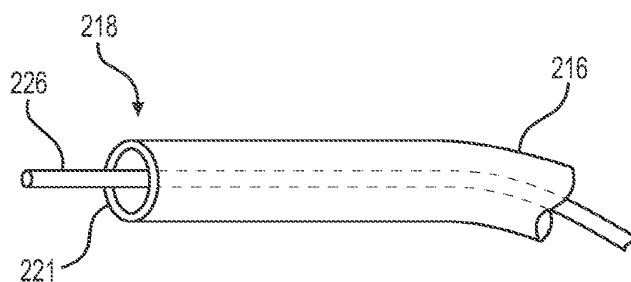


FIG. 1

**FIG. 2A****FIG. 2B**

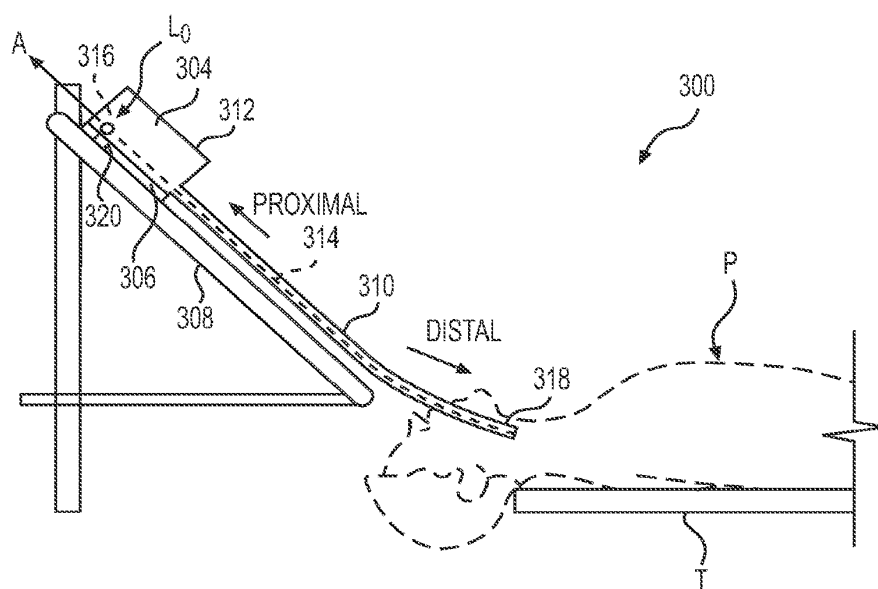


FIG. 3A

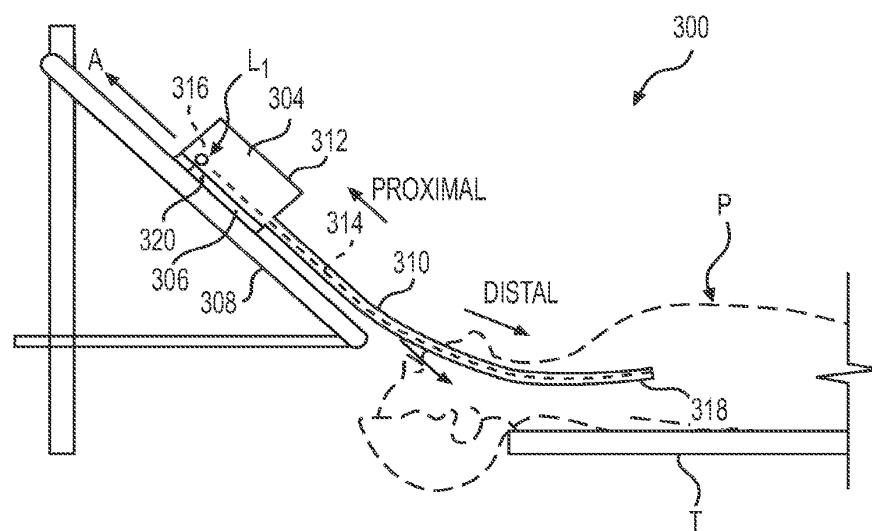


FIG. 3B

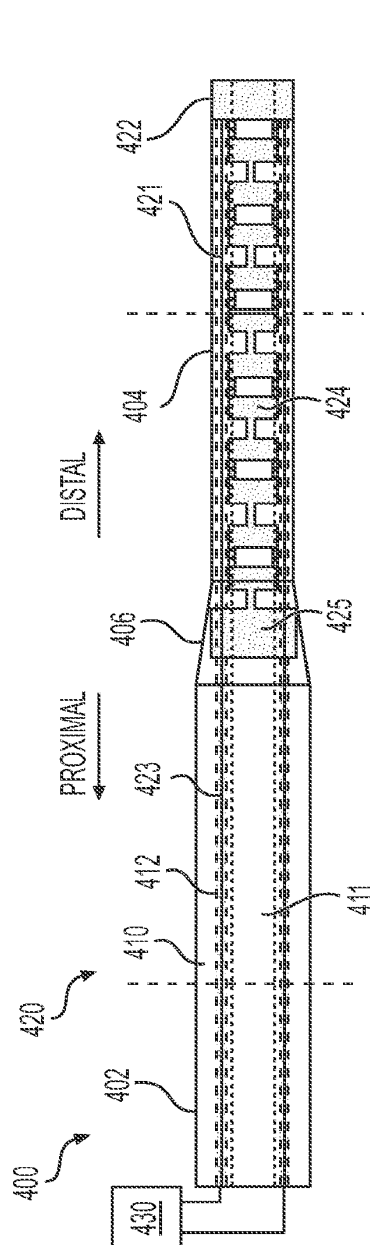


FIG. 4A

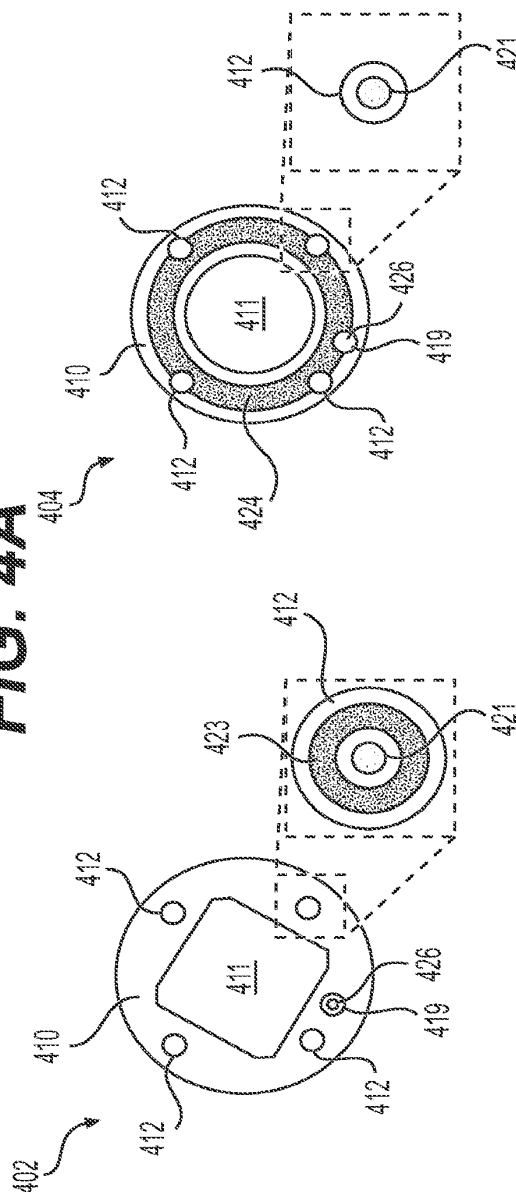
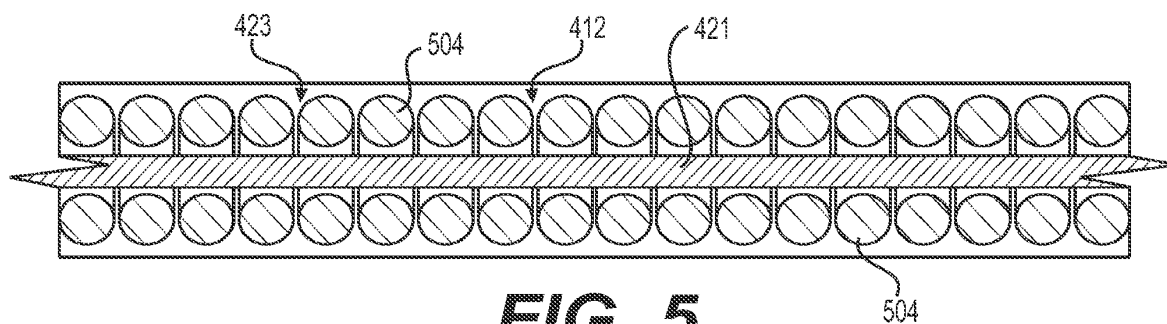
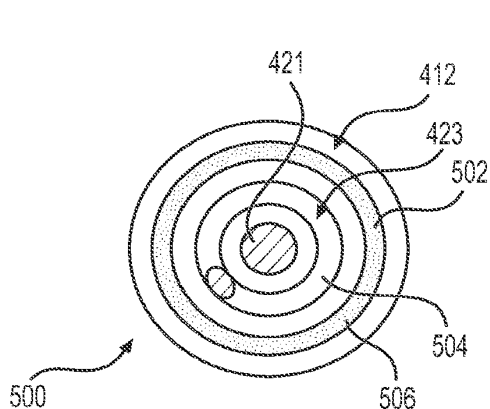
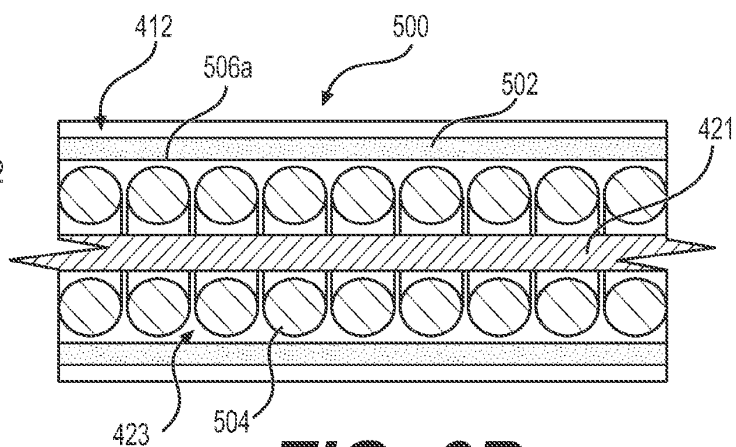
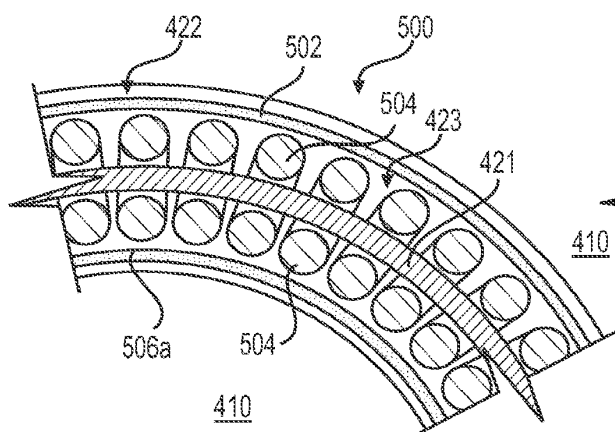
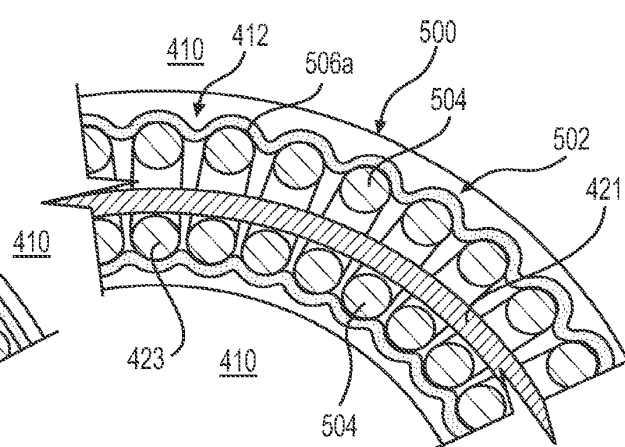


FIG. 4C

FIG. 4B

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**FIG. 5****FIG. 6A****FIG. 6B****FIG. 6C****FIG. 6D**

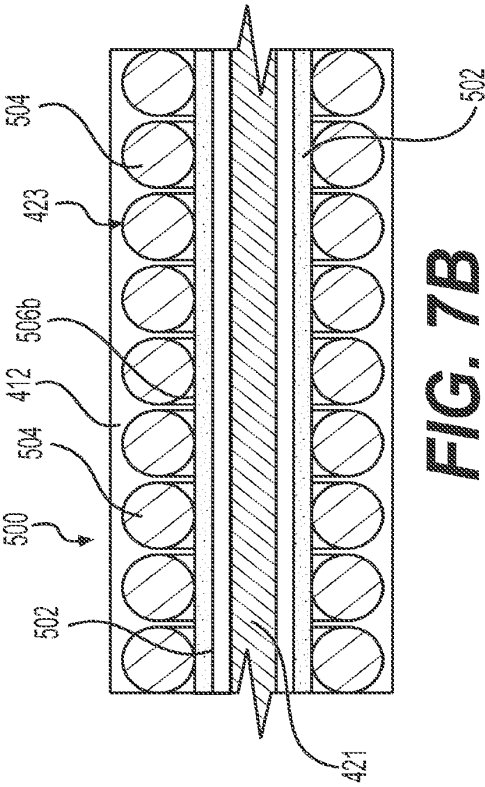


FIG. 7A

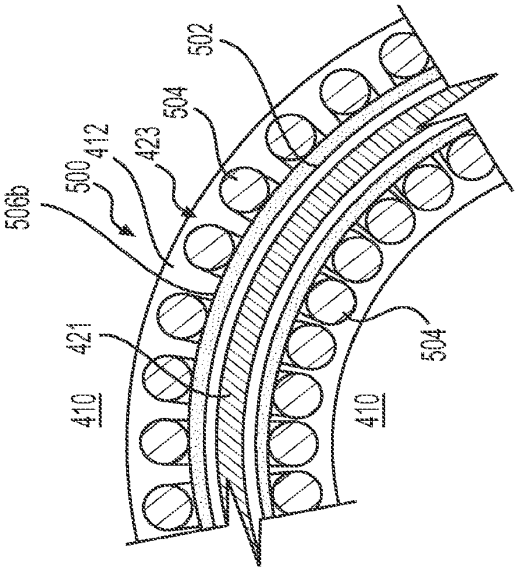


FIG. 7B

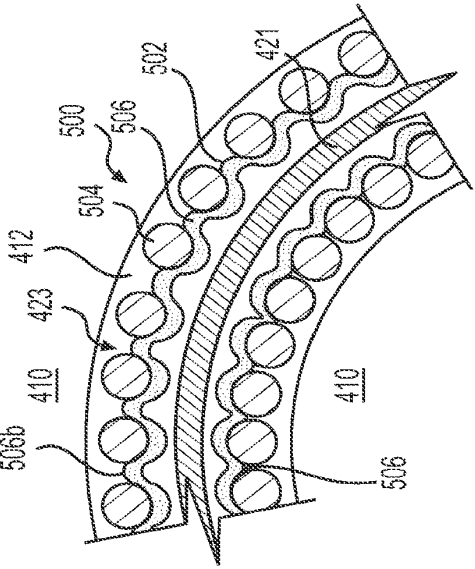


FIG. 7C

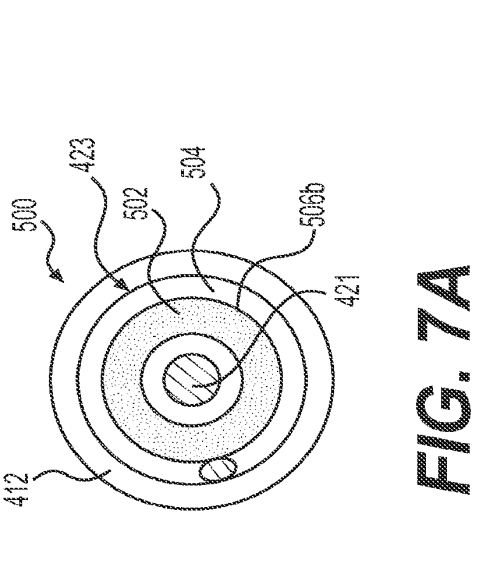
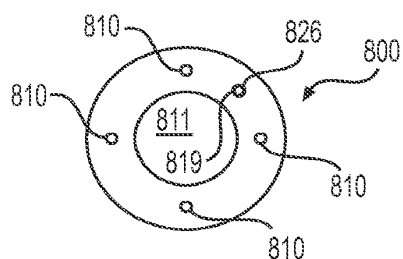
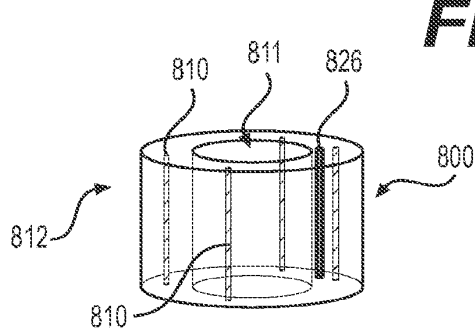
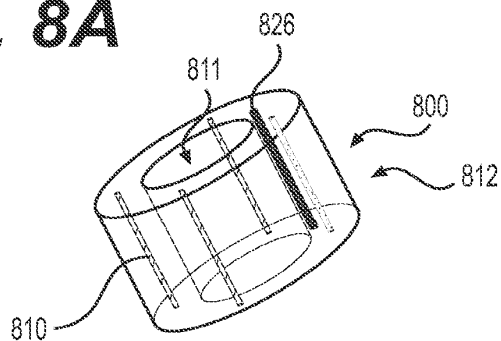
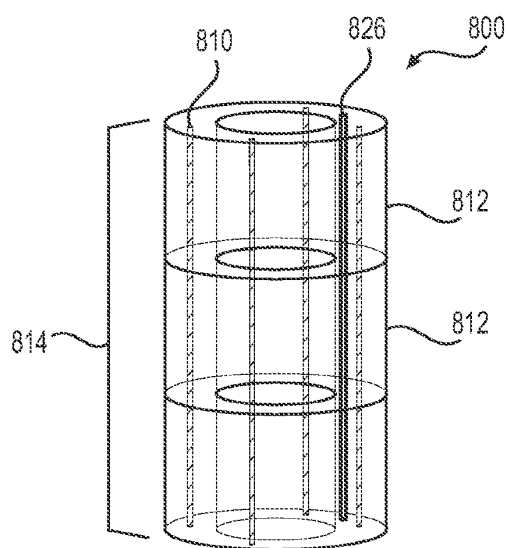
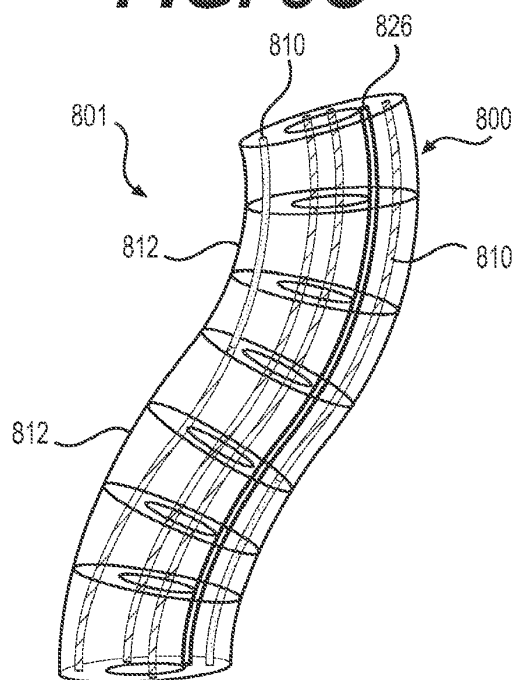
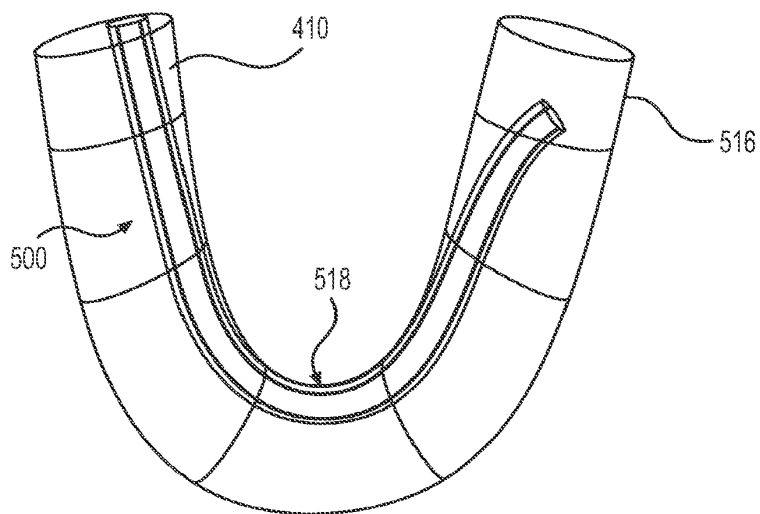
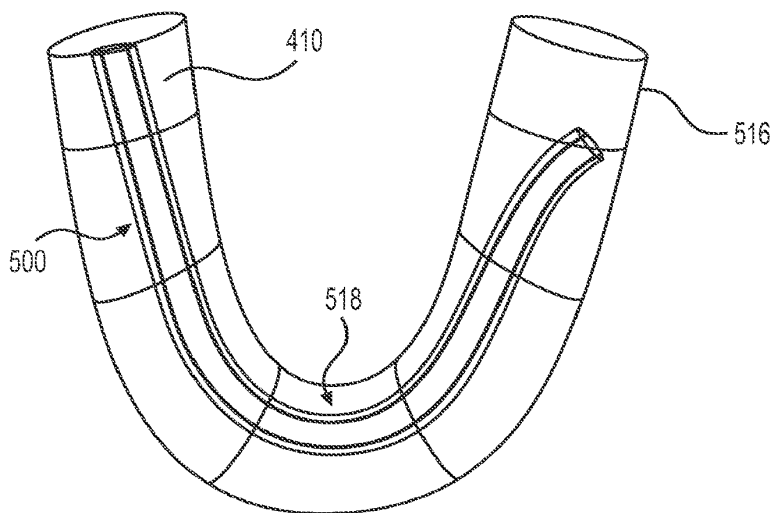


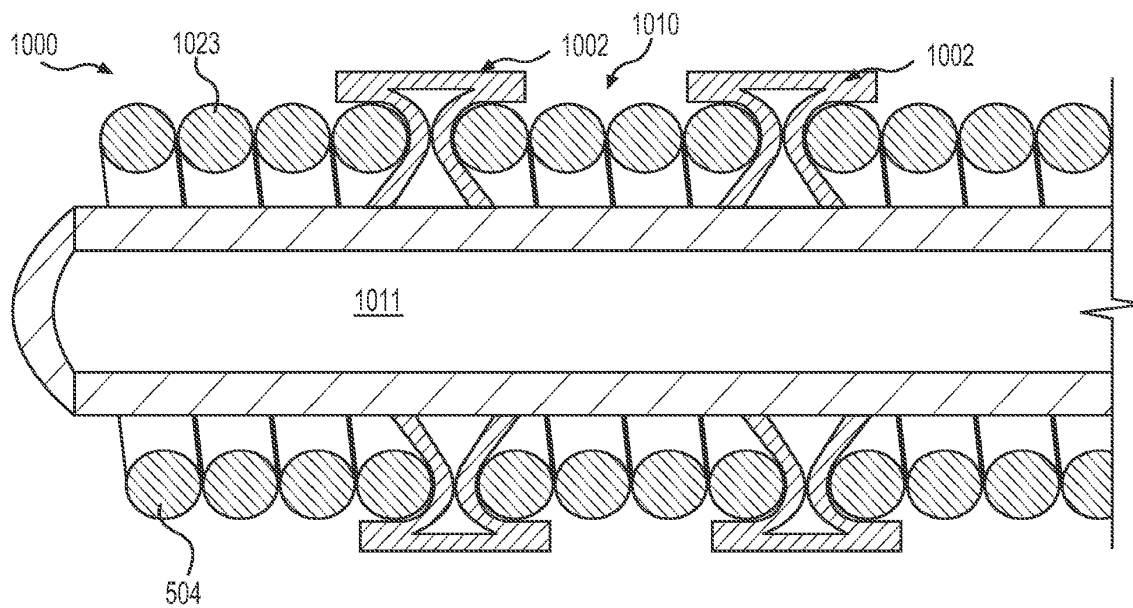
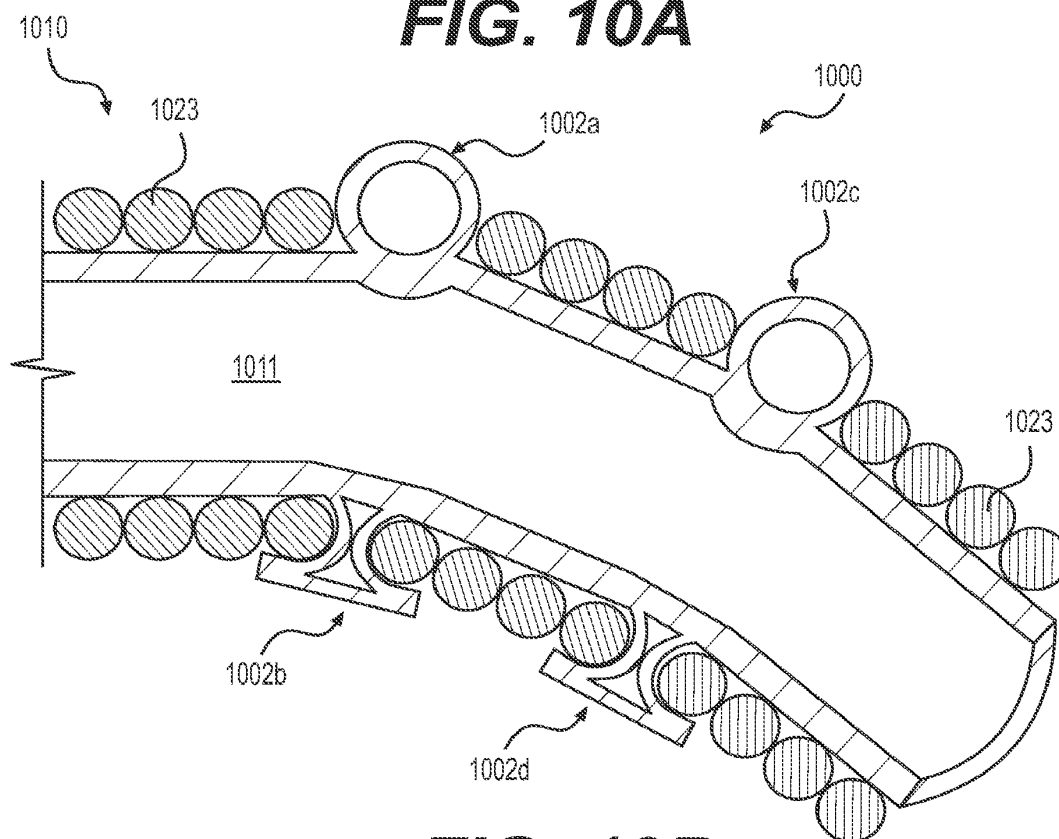
FIG. 7D

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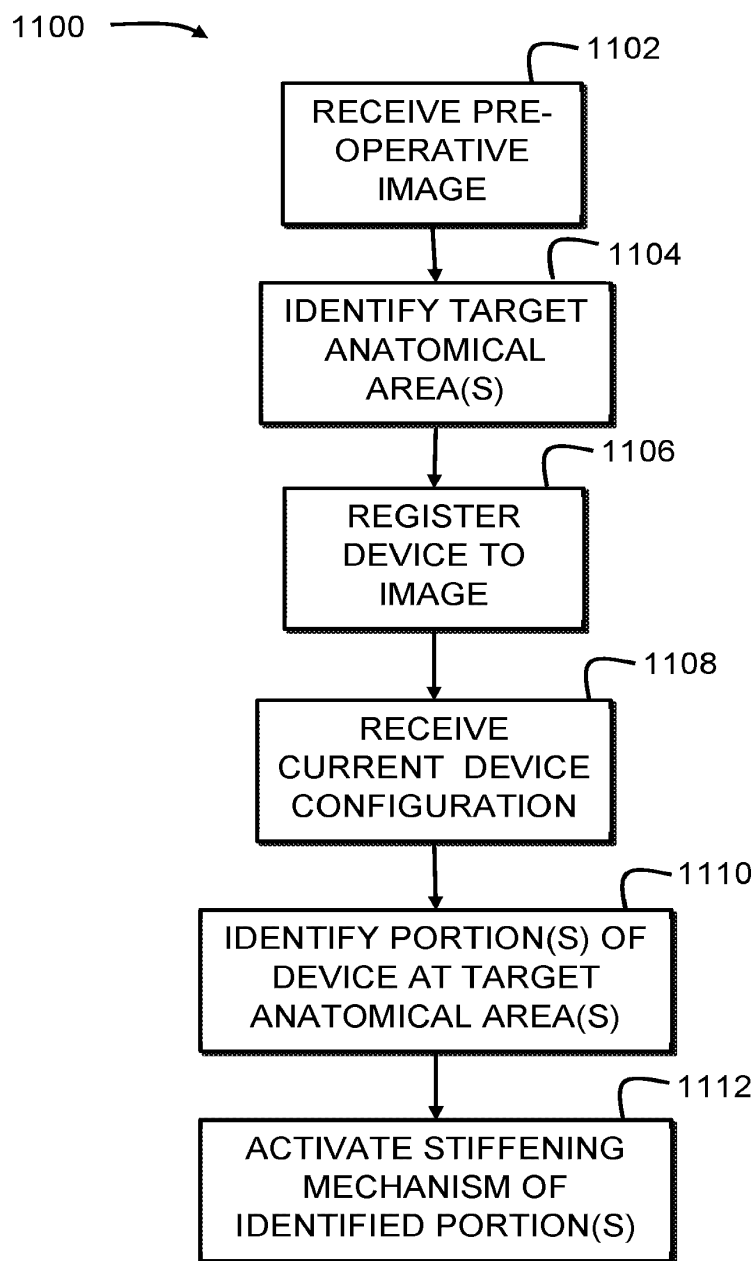
**FIG. 8A****FIG. 8B****FIG. 8C****FIG. 8D****FIG. 8E**

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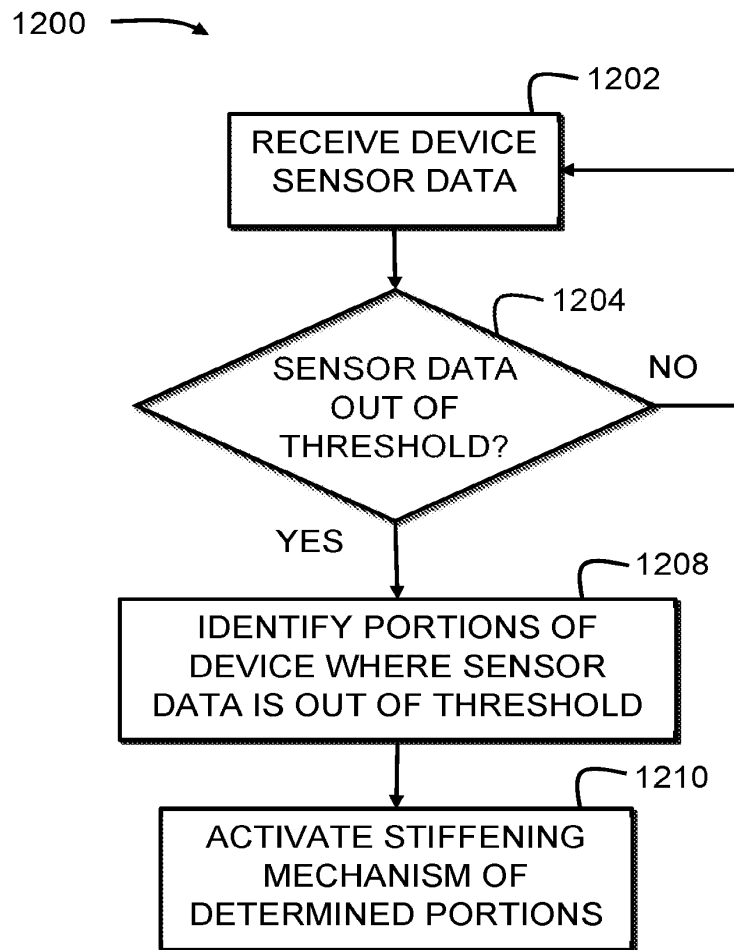
**FIG. 9A****FIG. 9B**

**FIG. 10A****FIG. 10B**

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**FIG. 11**

11/11

**FIG. 12**

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2019/037954

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61B1/00 A61B1/005 A61B1/018 A61B1/267 A61M25/01
ADD. A61B17/00 A61B34/20 G02B23/24

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

B. FIELDS SEARCHED

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A61B G02B A61M

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C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2016/160586 A1 (BARRISH MARK D [US]) 6 October 2016 (2016-10-06) paragraphs [0003], [0007], [0025], [0053], [0055], [0081], [0180], [0185] paragraphs [0194], [0195], [0307] figures 1, 1-1, 3, 4A, 4B -----	1,7-30
X	US 2013/096385 A1 (FENECH CAROLYN M [US] ET AL) 18 April 2013 (2013-04-18) paragraphs [0024], [0025], [0033], [0036], [0039] figures 1, 3A -----	1-5,7
X	WO 2018/005928 A1 (INTUITIVE SURGICAL OPERATIONS [US]) 4 January 2018 (2018-01-04) paragraphs [0044], [0063] - [0065], [0078] -----	1,4,6



Further documents are listed in the continuation of Box C.



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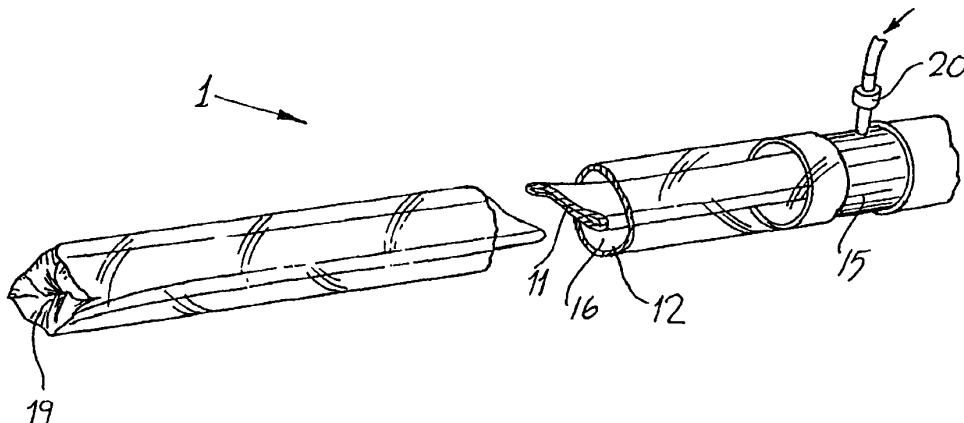
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		US 2019231449 A1	01-08-2019
		WO 2018005928 A1	04-01-2018



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(21) International Application Number: PCT/IE99/00124 (22) International Filing Date: 1 December 1999 (01.12.99) (30) Priority Data: 981000 1 December 1998 (01.12.98) IE 990109 15 February 1999 (15.02.99) IE 990110 15 February 1999 (15.02.99) IE (71) Applicant (for all designated States except US): ATROPOS LIMITED [IE/IE]; 1 Earlsfort Centre, Hatch Street, Dublin 2 (IE). (72) Inventors; and (75) Inventors/Applicants (for US only): BONADIO, Frank [US/IE]; 2 Martello Terrace, Bray, Co. Wicklow (IE). YOUNG, Derek, William [IE/IE]; 3 Cloister Way, Carysfort Avenue, Blackrock, County Dublin (IE). REID, Alan [IE/IE]; 7 Kincora Drive, Clontarf, Dublin 3 (IE). (74) Agents: O'BRIEN, John, A. et al.; John A O'Brien & Associates, 3rd floor, Duncairn House, 14 Carysfort Avenue, Blackrock, County Dublin (IE).		(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i>
(54) Title: A MEDICAL DEVICE COMPRISING AN EVERTABLE SLEEVE  (57) Abstract <p>A medical device may comprise an introducer (1) for introducing an object such as an instrument through a body opening such as the throat. The device (1) comprises a tubular sleeve (10) of pliable plastics material which is turned axially back on itself to define inner and outer sleeves sections (11, 12). The inner sleeve section (11) defines an inner lumen (19) and the sleeve may be twisted to centralise the lumen. The sleeve is pre-shaped to define a desired non-linear shape. A chamber (16) between the inner and outer sleeve section (11, 12) is inflatable. The device may also be deployed remotely for example, for balloon angioplasty.</p>		

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A MEDICAL DEVICE COMPRISING AN EVERTABLE SLEEVE

Introduction

5 The invention relates to a medical device, particularly for use in minimally
invasive and endoluminal surgical and medical techniques. In particular the
invention relates to an introducer for introducing an instrument into the body
through an opening. More specifically, the invention relates to a device to assist
10 in the introduction of endoscopic devices into the lumen of a natural bodily
orifice, in particular the rectum and colon.

The introduction of an instrument or the like through a body opening such as the
throat or rectum is traumatic for the patient and difficult for the medical
practitioner as such openings lead into a complex passageway(s) through which
15 the instruments must be passed. Therefore great skill and experience is required.

Background of the Invention.

20 The practise of gastroenterology has been much improved due to the development
of the fibre-optic endoscope. Modern endoscopes consist of a control section
attached to a long flexible shaft with a steerable tip. The flexible shaft carries
several tubes for light, air, water and suction. In some cases a biopsy channel with
a larger bore to allow therapeutic procedures to be performed is included. Light is
transmitted through non-coherent fibre-optic bundles. Older scopes used coherent
25 fibre-optic bundles for transmission of the image but these are largely obsolete
now and video-endoscopes are the norm. These use fibre-optic bundles for light
transmission only and use a CCD TV camera for image acquisition. The camera
output is then transmitted through wire pairs.

30 Endoscopes use a torque control mechanism that allows the endoscope to be
steered through the passage of interest using control wheels on the handle at the
proximal end. Steering is achieved by turning control knobs on the control section

of the endoscope. There are usually two knobs, one for lateral control and another for vertical control. These control wheels are attached to guide wires that run up through the endoscope and are attached to the tip.

5 An endoscope is typically 100-150 centimetres long and may be inserted into either end of the digestive system. Generally the devices have specific design features adapted to the bodily opening through which the endoscope is inserted. The endoscope is pushed from the bottom and guided through tortuous passages using external manipulation.

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In the upper gastrointestinal tract the insertion of the device presents relatively little difficulty. This is due to the short length of the upper GI tract and the relatively straight anatomy. Difficulty is encountered when attempting to advance into the proximal end of the small intestine for example to examine the pancreato-
15 duodenal junction.

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In the lower GI tract the picture is quite different. The lower GI tract is made up of the rectum and the large intestine or colon. The colon, in a textbook arrangement of its anatomy, extends upwards from the lower right quadrant, traverses the width of the body just below the diaphragm, extends downwards
20 along the left side of the abdomen and then loops in a retrograde manner before linking up with the rectum and the anus. Even with this textbook arrangement, the large intestine is difficult to cannulate with a flexible endoscope due to the flexible nature of the endoscope shaft and the floppy nature of the colon. It is even
25 more difficult with the more realistic lumen anatomies. In some people the sigmoid colon can be very long and is unfixed, except by its mesentery, and so can be extremely difficult to cannulate due to its predisposition to form loops when an endoscope is pushed through it. Some anatomical landmarks, such as the recto-sigmoidal junction, the splenic flexure and the hepatic flexure, are difficult to pass
30 through simply because of their tortuous nature. Problems traversing these areas are exacerbated by looping of the endoscope in the sigmoid colon.

Endoscopy is a difficult technique that can only be mastered after performing many hundreds of examinations. The ability to speedily cannulate the bowel and traverse the entire colon all the way to the caecum is a skill that is only enjoyed by a minority of endoscopists. Published research on the subject of difficulty encountered in endoscopy shows that the procedure fails in up to 15% of cases where failure is defined as inability to reach or visualise the caecum. Up to 35% of cases are considered to be difficult as defined by extended duration of the procedure and experience of pain by the patient. Other research shows that up to 29% of cases are considered to be technically difficult.

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Several devices have been described in the prior art to assist in the practise of lower GI endoscopy.

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US-A-3805770 describes an endoscope guide and lubricating means comprising a cylindrical spongy member to guide and lubricate the endoscope as it enters the anus. This device however does not address the problems associated with looping of the scope in the sigmoid colon and resulting problems crossing the splenic and hepatic flexures.

20

US-A-4207872 describes a sleeve device for positioning on the end of an endoscope to assist it in advancing through a body passage. The device has protrusions extending perpendicularly from the sleeve that may be expanded and retracted using fluid pressure. Upon repetitious expansion and retraction of the protrusions using pulsing pressure within the device, the device assists in advancing the scope along the body passage. There is likely to be considerable internal friction between the device and the inner wall of the body passage.

25

US-A-4321915 describes a device consisting of an everting tube which includes a pressure and evacuation valve to allow eversion and retraction of the tube. The tube is slidably attached to a fibre-optic bundle for vision. Whilst this device allows a means of vision to be advanced up the confines of a body passage it cannot be used with existing endoscopes because of its size. It is proposed for use

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in small narrow bore tubes such as the urethra. There is a similar problem with the device disclosed in US-A-4615331. This device consists of an everting tube which has a plurality of folds which telescope open as the everting tube advances.

5 US-A-4676228 describes a device that is removably attached to the front end of an endoscope to assist in pulling the scope through the colon. It consists of two inflatable cuff sections that are alternatively inflated and deflated whilst being moved towards and away from each other. In this way the endoscope is dragged up through the colon in short steps. This procedure is lengthy and complex. In
10 addition, there is considerable friction between the colon and the scope.

US-A-4971033 describes a flexible endoscope with a working channel designed to cause the tube to stiffen when fluid pressure is applied to the channel. The channel takes up space in the endoscope that is more appropriately used for either vision,
15 suction, insufflation or tissue sampling. In addition, an endoscope is stiffened along a particular section or along its entire length which exacerbates the difficulty of passing the endoscope through the floppy sigmoid colon.

US-A-5045070 describes an everting tube for entering body cavities and
20 depoloying a tube for administration of drugs or therapy through the tube. The device is designed for introducing a channel attached to the tube and is not designed for introducing a removable endoscope or the like.

WO-A-97/32515 describes a semi-toroidal tube for introducing an endoscope into
25 a body cavity for examination and therapeutic purposes. The device is a tubular endless body that everts at its distal end and inverts at its proximal end when advanced through a duct such as the human colon. WO-A-99/01171 describes a similar device with the addition of corrugations designed to assist in the passage of the endless tube around the anatomy of the colon.

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US-A-5941815 describes a sigmoid splint device for use in endoscopy. The device is intended to be used to keep the sigmoid colon from looping while the operator is attempting to cross more difficult junctions.

5 In general, such known devices are either difficult to use, cause discomfort to the patient, can only be advanced incrementally, do not cater for complex nature and shape of tortuous body passageways.

10 There is a need for an improved medical device which will address at least some of these problems and which may be especially used as an introducer to navigate the lower gastrointestinal tract with minimum discomfort to the patient.

Statements of Invention

15 According to the invention there is provided a medical device for insertion in a body opening or an incision comprising:

a sleeve of pliable material, the sleeve having a twisted sleeve section to define a reduced lumen section;

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the sleeve having an outer sleeve section and an inner sleeve section;

a chamber for pressurised fluid defined between the inner and outer sleeve sections;

25

the inner sleeve section defining a lumen to receive an object;

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the pressurised sleeve being evertable on engagement of an object in the lumen and axial movement of an object relative thereto so that the twisted inner sleeve section is rolled over outwardly to become an outer untwisted sleeve section and the untwisted outer sleeve section is correspondingly rolled over inwardly to become a twisted inner sleeve section.

Preferably the sleeve is turned axially back on itself to define an outer sleeve section and a twisted inner sleeve section.

5 In one embodiment the device the sleeve sections define a continuous endless track which may be advanced by engaging an object in the lumen.

In one embodiment the device includes a guide collar for locating relative to a datum, a sleeve section being movable relative to the collar on engaging an object
10 into the lumen and/or on passage of an object through the lumen. In a preferred arrangement the free ends of the sleeve are joined to the collar.

The device preferably includes an inflation port for inflation of the enclosed chamber between the sleeve sections.

15 In a preferred arrangement the device includes adjustment means for adjusting the twist in the sleeve.

In one embodiment of the invention at least portion of the sleeve has a non linear shape. Usually, the non linearity corresponds to a desired predetermined shape.
20 The non linearity may be in at least two, and typically in three dimensions

In one embodiment the sleeve is biased into the non linear shape.

25 The sleeve may be sculpted or formed into the non linear shape.

In one embodiment the device includes guide means through which the sleeve and/or an object is advanced. Typically, the guide means includes a ring means for placing in a body opening or incision through which the sleeve and/or an
30 object is advanced.

In another embodiment of the invention the device includes a delivery means for delivery of the device to a remote location. In one case, the delivery means is a tube such as a catheter or cannula.

5 In one aspect the device defines a transporter for delivery or retrieval of an object to or from a desired location.

In another aspect the device defines an introducer for introducing an object such as an instrument to a desired location.

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In a further aspect the device is an expandable element. The expandable element may be a balloon for angioplasty.

Brief Description of Drawings

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The invention will be more clearly understood from the following description thereof given by way of example only, in which :-

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Fig. 1 is a perspective view from a proximal end of an introducer according to the invention.

Fig. 2 is a perspective view from a distal end of the introducer of Fig. 1;

Fig. 3 is a cross sectional view of the introducer in one position of use;

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Fig. 4 is a cross sectional view of the introducer in another position;

Fig. 5 is an end view of the introducer;

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Figs 6 and 7 are diagrammatic view illustrating one method for manufacturing the introducer;

Figs 8 and 9 are side partially cross sectional view of other introducers;

Figs 10 to 14 are cross sectional views illustrating the operation of an expandable medical device according to the invention;

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Fig. 15 is side, partially cross section view of the device of Figs 10 to 14, in use; and

Fig. 16 is an enlarged view of a detail of Fig. 15.

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Figs 17 to 25 are diagrams illustrating the principles of operation of the invention.

Fig. 27 is a perspective view of an introducer device in an untwisted configuration;

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Fig. 28 is a plan view of the device of Fig. 27;

Fig. 29 is a cross sectional view of the line A-A in Fig. 28;

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Fig. 30 is a perspective view of the introducer device of Fig. 27 in a twisted configuration;

Fig. 31 is a plan view of the device of Fig. 30; and

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Fig. 32 is a cross sectional view on the line B-B in Fig. 31.

Detailed Description

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Referring initially to Figs 1 to 7 there is illustrated a medical device according to the invention which in this case is configured as an introducer 1 for introducing an object such as an instrument through a body opening such as the throat or rectum.

5 The device 1 comprises an elongate tubular sleeve 10 of pliable material, especially a suitable biocompatible gas impermeable plastics material which is turned axially back on itself to define an inner sleeve section 11 and an outer sleeve section 12. The sleeve sections 11, 12 are joined in this case via a collar 15, to define an enclosed inflatable chamber 16 therebetween. The inner sleeve
10 section 11 defines an inner lumen 19 and the sleeve is twisted to centralise the lumen 19. An inflation port 20 is provided for inflating the chamber 16 between the inner and outer sleeve sections.

15 It will be particularly apparent that the device of the invention may be readily advanced through a complex passageway such as the bowel or the like. It may therefore be used for cannulating such a passageway.

Figs 6 and 7 illustrate the twisting of the sleeve 10. The free ends of the sleeve 10 are rotated relative to one another prior to or after final assembly to the collar 15.
20 The twist will be apparent with reference to the points marked X. Such a twist may be provided when the device is in situ and is adjustable in situ.

The present invention provides a device that permits an endoscope or similar instrument to pass easily through the body's natural canals for purposes of
25 performing an endoscopic examination of those canals. The introducer allows the user to easily pass beyond junctions such as the sigmoid colon, splenic and hepatic flexures and other convolutions of the body's inner canals in the upper or lower gastrointestinal tracts. In addition, the device allows pain free cannulation of the body's canals by substantially eliminating friction and rubbing contact between
30 the endoscope and the walls of the canal under examination. Further the device is easy to manufacture and is convenient and simple to use.

Referring to Figs 8 and 9 there are illustrated other devices 50, 51 according to the invention which may be twisted or not. The devices are pre-shaped for a particular use. The devices may be biased to form a desired non linear shape on eversion. In this case the device has sculpted sections 52, 53 to confirm, an
5 eversion to a desired shape. It will be noted that the sculpted section 53 is initially part of the inner sleeve section. On eversion, it become unparalleled into a section of desired shape. The devices may be formed by moulding and/or sculpting to define the desired shape dependent to the passageway to be navigated.

10 The devices address two significant problems in lower GI endoscopy: the problem of friction between the endoscope and the colon and the problem caused difficulty in navigating bends and convolutions in the colon. Such a device would place itself between the colon and the endoscope such that the scope passed through the lumen of the colon without touching the side walls of the colon. Some
15 conventional introducers can address this problem, especially in a straight section of colon, but will have difficulties when the colon is in any way convoluted or has a tight junction or bend. In reality all colons have such a twisted layout. In the case of conventional devices the device may fail to turn at the bend and will simply push up against the side wall of the colon causing pain and possibly
20 damage to the mesentry. In serious cases the wall of the colon may be perforated.

The devices of the invention are predisposed to bend at certain points or gradually slope in a certain direction. In this way the device, for example, can be inserted into the rectum and will be disposed towards following the bend of the sigmoid
25 colon or turn at the splenic flexure as it moves through the colon. The device may be predisposed to bend at more than one point. For example, it could be constructed in such a manner that it would gradually curve through the sigmoid colon and then straighten out to traverse the descending colon. A further turn could be constructed into the device so that it would turn at the splenic flexure.
30 By preshaping the everting tube in this manner it would be possible to plan all the bends and convolutions in a passageway to be navigated.

The device may be used as a transporter for delivery or retrieval of an object. It has the effect of providing a substantially frictionless tunneling action. The device may be used endoluminally. The device may be used for example to provide a soft tissue dissector or an envaginator and may be delivered through a delivery device such as a tubular sleeve, catheter or the like. The device itself may be used in medical procedures such as in the form of a balloon which may be linear or non linear.

Referring to Figs 10 to 16 there is illustrated a device 60 similar to that of Figs 1 to 7 which is deliverable through a tube 6 such as a cannula. A pressure is applied to push the device 61 out through an end opening of the tube 61 as illustrated in Figs 10 to 12. To retract the device a suction force is applied to draw the device 60 back into the tube 61 as illustrated in Figs 13 and 14.

Referring in particular to Figs 15 and 16 there is illustrated one mechanism which may be used to deliver the device 60 through the tube 61 and to remotely control the operation of the device 60. Air is delivered through an air delivery tube 65 extending through the outer tube 61. The air delivery tube 65 has a central outlet 66 for driving the device 60 and one or more entry ports 67 for delivery of inflation air into the air chamber 69 defined by the device 60. In this way the inflation of the device 60 can be readily remotely controlled. The device 60 may

be used, for example for tissue dissection or for delivery/deployment of a balloon angioplasty, stent or the like.

The Twisted Tube

Consider the hollow cylindrical tube shown in Fig. 17. The wall of the cylinder defines a lumen through its centre. Consider a linear element A-B. if the upper edge of the tube is rotated through some angle point A will move to the position

shown in the middle sketch. The element A-B will still define a straight line. The tube will distort into a nominally hour glass shape with a reduced lumen at mid height. The diameter of the lumen at the neck of the tube is dependant on the angle of twist. When the upper edge is rotated through 180° the lumen will close down to zero diameter. At any horizontal plane through a twisted tube the material must be wrinkled and hence under compressive hoop stress. If the height of the tube remains unaltered then the element A-B in a twisted tube, being longer than in a plain tube, must be under tensile axial stress. If the tube is free of axial constraint the overall length of the tube will reduce.

Lumen Diameter vs. Angle of Twist

Fig. 18 a shows the lumen diameter (D2) as a proportion of the tube diameter (D1) for angles of twist (E) from 0 to 180 degrees. The lumen diameter is calculated as:

$$D2 = D1 \cos(E/2).$$

As can be seen the lumen diameter is independent of the tube length

Elongate object passed through twisted tube

As can be clearly seen from Figs 18a and 18b the angle of twist necessary to collapse the lumen of a tube to the diameter of an elongate object passed therethrough is dependant on the ratio of the tube diameter and the diameter of the elongate object. The angle of twist can be calculated from:

$$\cos^{-1}(E/2) = D2/D1$$

Where E = angle of twist

$D1$ = tube diameter

$D2$ = diameter of elongate object

- 5 Although depicted as of circular profile, a tube of sufficiently compliant material will conform to any non recursive profile. For such a profile $D2$ is taken as the smallest diameter which can be inscribed within the profile.

Twin walled pressure vessels under internal pressure

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- Consider a thin walled tube as shown in Fig. 19a. One end of the tube is folded back on itself as shown in Fig. 19b and the free ends conjoined. What is defined is essentially a twin walled tube (or two coaxial tubes conjoined at their ends) with an enclosed volume between the two walls. The introduction of a pressurised fluid into the enclosed volume will cause the outer tube to behave like a pressurised aircraft fuselage, that is it will be subject to tensile axial and hoop stresses. The inner tube will be subject to tensile axial stress and compressive hoop stress. As a result the lumen will collapse in to a nominally duck bill configuration but constrained by the outer tube.

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- Greater control of the lumen can be obtained by the introduction of a twist into the tube. The tube shown in Fig. 20a is twisted as shown in Fig. 20b. One end of the tube is folded back on itself, as shown in Fig. 20c, and the free ends conjoined. As in the previous example this configuration defines two coaxial conical vessels conjoined at their bases and at the apex. However the common apex is not constrained to remain in this configuration. In reality in the inner and outer tubes are free to behave as individual tubes each with half of the original twist and as such the composite tube can better be defined as two coaxial hour glass tubes as shown in Fig. 20d, each containing half the original total twist. As both the inner and outer tubes are necked they each are subject to compressive hoop stresses. The introduction of a pressurised fluid into the enclosed volume produces what is believed to be a novel response.

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Firstly, consider the outer tube. It is a necked hour glass tube with compressive hoop stresses. The introduction of the pressurised fluid induces tensile hoop stresses, negating the compressive hoop stresses induced by the twist. Since, to remain in its twisted configuration, the tube must have compressive hoop stresses and since the pressurised fluid overcomes these compressive stresses the tube must untwist and take on a nominally cylindrical configuration, see Fig. 20e. Since the inner and outer tubes are conjoined, as the outer tube untwists the inner tube twists more in response. Since the outer tube now has no twist the inner tube must have all the twist. If the original total twist were 180° then the lumen would close totally. Additionally, the material defining the inner tube will be central within the diameter of the outer tube. This configuration will for brevity be called a Cyclops.

Translation of an elongate object through a Cyclops

Consider the arrangement depicted in Fig. 21a. A shaft is passed through a Cyclops with the lumen in mutual contact with the shaft. The outside diameter of the Cyclops is resting in mutual contact with a fixed surface. Consider points of contact A, between the Cyclops and the fixed surface, and B, between the shaft and the lumen of the Cyclops. As the shaft is translated, as shown in Fig. 21b, Point A remains fixed whilst the leading end of the lumen rolls out. Since the Cyclops does not change in overall length the trailing end of outside diameter rolls in as depicted. It will be apparent that the shaft translates to the right twice as far as the Cyclops. This, of course, is exactly the motion of a caterpillar track. From this point of view a Cyclops could be considered as a three dimensional caterpillar track. Since points A and B on the Cyclops do not move relative to their corresponding positions on the shaft and the fixed surface there is no frictional resistance to the translation of the shaft. In Fig. 21c the Cyclops has translated to the right by approximately its own length. The material which had originally formed the inner tube has rolled out to become the outer tube and vice versa. In other words the Cyclops has turned inside out. Since the inner tube of the

Cyclops is in a twisted configuration and since the point B remains in contact with the same point on the shaft the shaft rotates about its axis as depicted by arrow C (in this instance approx. 120°). In order to obtain this translation the resistance required to be overcome is that generated as the leading and trailing ends of the Cyclops deform as they roll out and roll in respectively.

Effects of an introduced member

Assume that the Cyclops in Fig. 22 has a 180° twist and is filled with a fluid under pressure. The lumen is closed by the action of the twist. As the shaft enters the Cyclops the pliable nature of the material of the Cyclops allows it to envelop the leading edge of the shaft as shown in Fig. 22b. As can be seen the effective volume of the Cyclops decreases. There will be a resulting increase of the fluid pressure causing the lumen to exert a greater pressure on the shaft. As the shaft proceeds through the Cyclops, see Fig. 22c, the pressure increases to its maximum. ($P_1V_1=P_2V_2$). If it is not desirable that there be such a pressure increase then the supply of fluid could be controlled by a pressure regulator.

Forces acting on the Lumen due to axial component of pressure

Fig. 23a depicts a Cyclops subject to internal pressure P. A force (F_{axial}) is induced in the Cyclops. Since the cross sectional area of the Cyclops is uniform the system is in force balance. A proportion of this force is taken by the outside cylinder and the remainder is taken by the material which constitutes the lumen. If a shaft, or similar, is pressed against one end of the Cyclops an imbalance is introduced. Consider the material of the inner tube in isolation. Fig. 23b, F represents the proportion of the axial force taken by the inner tube. As with the Cyclops as a whole this is in force balance. When an imposed force (F_{imp}) is applied to one end of the inner tube the net force acting at the left end of the tube is now less than that acting on the right hand end. The system is in an unbalanced situation. The inner tube must therefore translate to the right hand side.

Cyclops as an axial force limiter

Fig. 24a depicts a Cyclops with two independent shafts inserted, one in each end.

5 Shaft B is in contact with a fixed surface. The fluid pressure within the Cyclops causes the lumen material to be maintained in tension. A force F is applied to shaft A, Fig. 24b. This force is transferred to shaft B via the lumen material and is reacted by the fixed surface. Force F exerts a compressive axial force on the lumen material. As force F increases the applied compressive force begins to negate the axial tensile force induced by the pressurised fluid. When force F becomes greater than the initial tensile force the lumen material goes into axial compression. This will cause the lumen material to buckle. The maximum axial force that the inner tube of a Cyclops can transmit is equal to the tensile force induced into the inner sleeve by the pressurised fluid.

Effects of the tube preform shape

20 Consider the tube preform shown in Fig. 25a. The lower portion defines a circular elbow with an upper section configured as a plain cylinder. If the cylindrical section is inverted as indicated, with or without a twist, and the free ends of the preform conjoined a basic Cyclops is formed. The elbow section must wrinkle up in order to lie within the plain cylinder as shown in Fig. 25b. As previously, the introduction of a pressurised fluid into the enclosed cavity formed will cause the elbow section to collapse forming a closed lumen and the cylindrical section to inflate, see Fig. 25c. The plain cylinder, being on the outside of the structure, will determine the shape of the inflated Cyclops. The Cyclops will be in force balance. If a force is applied to the lower end of the lumen the net force on the lumen will cause the Cyclops to translate. The upper portion of the lumen will roll out and the lower end of the cylindrical wall will roll in, Fig. 25d.

Since the outside wall of the Cyclops is now made up of part of the original plain cylinder and part of the elbow section the inflation pressure will cause the Cyclops to take on the form of this composite profile, the Cyclops will appear to bend as it translates. Figs 25d shows the Cyclops completely inverted. All of the elbow section forms the outer wall and all of the plain cylindrical section forms the inner tube. As such the Cyclops has take on the form of the elbow section. It will be noted that lumen material follows the shortest line between the ends of the Cyclops. For simplicity of illustration the Cyclops has been represented as translating in two space. It will be apparent that if the preform were "sculpted" or moulded such that its axis were three dimensional then as the Cyclops translated the path of translation would follow a three dimensional path. It will also be appreciated that the preform need not be of a regular cross section. Variations in tube diameter along it's length is possible.

Referring to Figs. 26(a) to 26(d) there is illustrated the roll-out or eversion of a pre-shaped device, in this case an introducer device 100. The device 100 is in this case pre-shaped or sculpted to roll-out in a non-linear shape corresponding to a desired predetermined shape. The non linearity may be in two, and in this case three dimensions. The introducer 100 is initially in the shape of a tubular sleeve. On eversion the introducer first turns in one direction (Fig. 26(b)), then in another direction (Fig. 26(c)) and, finally in a still further direction illustrated in Fig. 26(d). Such an arrangement greatly facilitates the navigation of the device along torturous routes.

Referring to Figs. 27 to 32 there is illustrated another introducer device 100 according to the invention which is similar to the devices described above and like parts are identified by the same reference numerals. In particular, the device 100 is similar to and operates in a similar manner to the introducer described above with reference to Figs. 1 to 7. In this case the introducer is adjustable to vary the degree of twist in the elongate tubular sleeve 10 from an untwisted configuration illustrated in Figs. 27 to 29 to a twisted configuration illustrated in Figs. 30 to 32.

The sleeve 10 is attached at one end 101 to a first shaft section 102 and is attached on the other end 103 to a second shaft section 104. The shaft sections 102, 104 have a respective male projection 105 and a complementary female recess 106 which interengage to facilitate relative rotation therebetween. The shaft sections 102, 104 have respective handles formed by knobs 107, 108 to facilitate manipulation to vary the degree of twist. In use, the shaft section 104 may be turned by the knob 108 to any desired extent, for example from the untwisted configuration of Fig. 27 to the twisted configuration of Fig. 30. The variation in the twist may be effected prior to insertion of the device and/or when the device is in situ.

Reference is also made to appropriate alternatives and modifications which are outlined in our parallel applications referenced ATRO1/C, ATRO12/C, ATRO15/C, ATRO16/C, ATRO17/C, the entire contents of which are incorporated herein by reference.

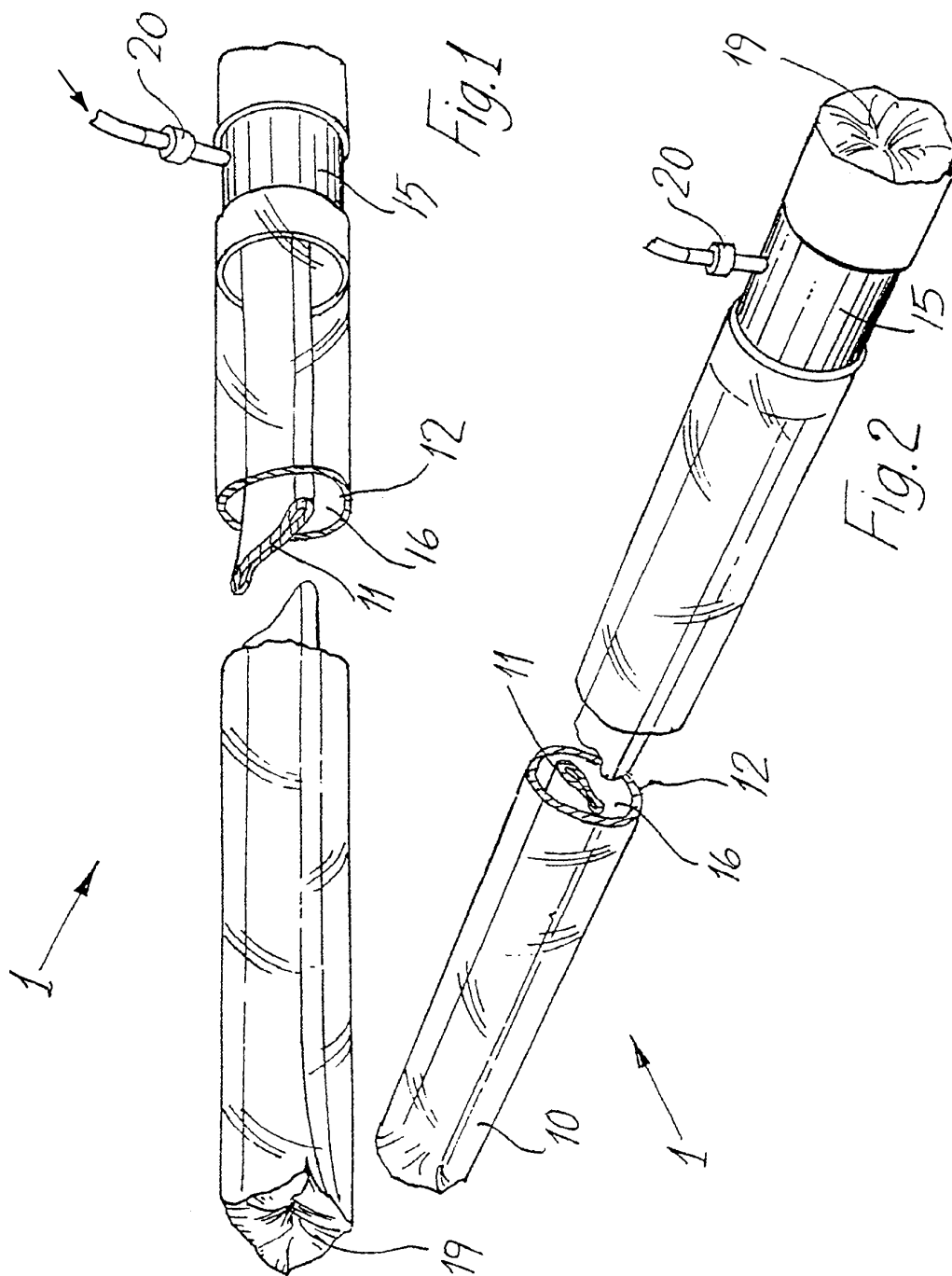
The invention is not limited to the embodiments hereinbefore described which may be varied in detail.

Claims

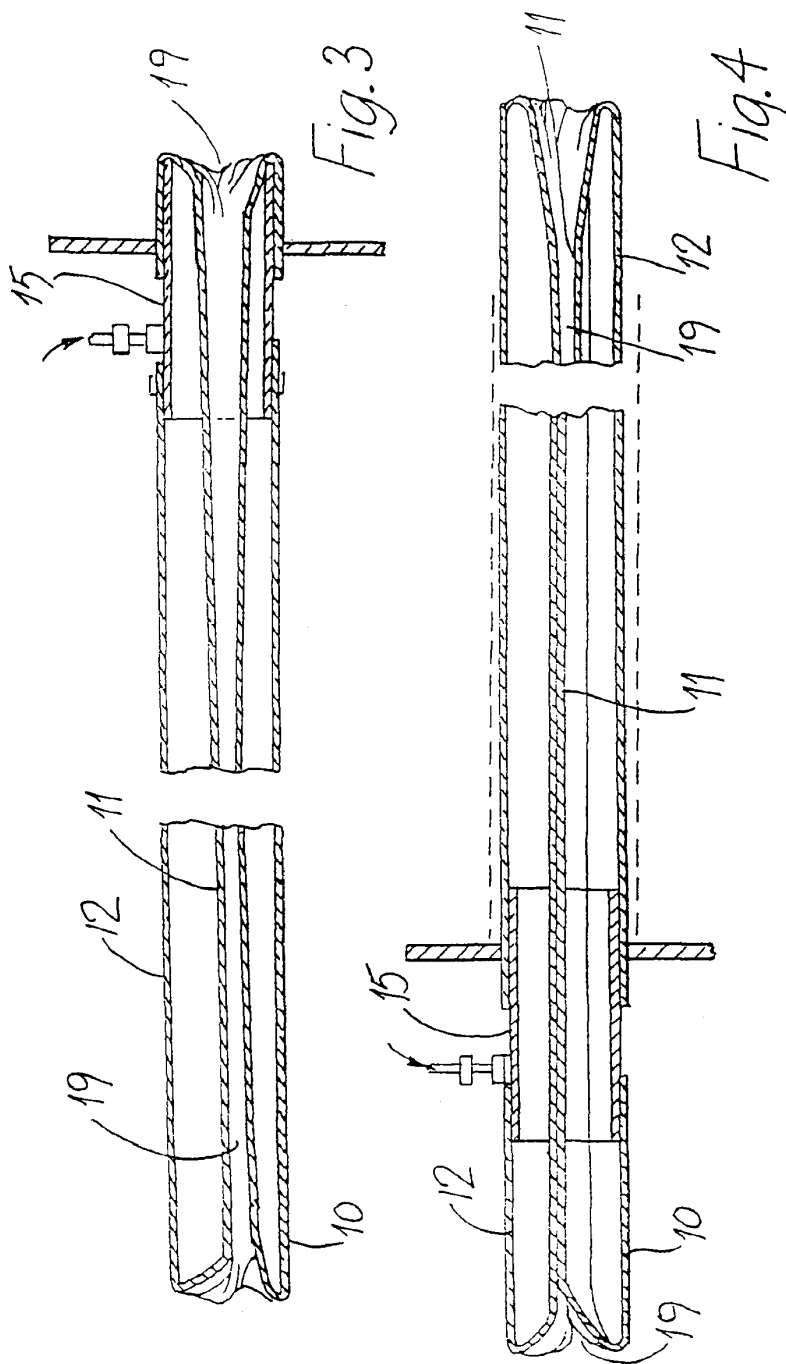
1. A medical device for insertion in a body opening or an incision
5 comprising:
- a sleeve of pliable material, the sleeve having a twisted sleeve
section to define a reduced lumen section;
- 10 the sleeve having an outer sleeve section and an inner sleeve
section;
- a chamber for pressurised fluid defined between the inner and outer
sleeve sections;
- 15 the inner sleeve section defining a lumen to receive an object;
- the pressurised sleeve being evertable on engagement of an object in
the lumen and axial movement of an object relative thereto so that
20 the twisted inner sleeve section is rolled over outwardly to become
an outer untwisted sleeve section and the untwisted outer sleeve
section is correspondingly rolled over inwardly to become a twisted
inner sleeve section.
- 25 2. A device as claimed in claim 1 wherein the sleeve is turned axially back on
itself to define an outer sleeve section and a twisted inner sleeve section.
3. A device as claimed in claim 1 or 2 wherein the sleeve sections define a
continuous endless track which may be advanced by engaging an object in
30 the lumen.

4. A device as claimed in any preceding claim including a guide collar for locating relative to a datum, a sleeve section being movable relative to the collar on engaging an object into the lumen and/or on passage of an object through the lumen.
- 5
5. A device as claimed in claim 4 wherein the free ends of the sleeve are joined to the collar.
6. A device as claimed in any preceding claim including an inflation port for inflation of the enclosed chamber between the sleeve sections.
- 10
7. A device as claimed in any preceding claim including adjustment means for adjusting the twist in the sleeve.
8. A device as claimed in any preceding claim wherein at least portion of the sleeve has a non linear shape.
- 15
9. A device as claimed in claim 8 wherein the non linearity corresponds to a desired predetermined shape.
- 20
10. A device as claimed in claim 8 or 9 wherein the non linearity is on at least two dimensions.
11. A device as claimed in any of claims 8 to 9 wherein the non linearity is in three dimensions.
- 25
12. A device as claimed in any of claims 8 to 11 wherein the sleeve is biased into the non linear shape.
13. A device as claimed in any of claims 8 to 12 wherein the sleeve is sculpted or formed into the non linear shape.
- 30

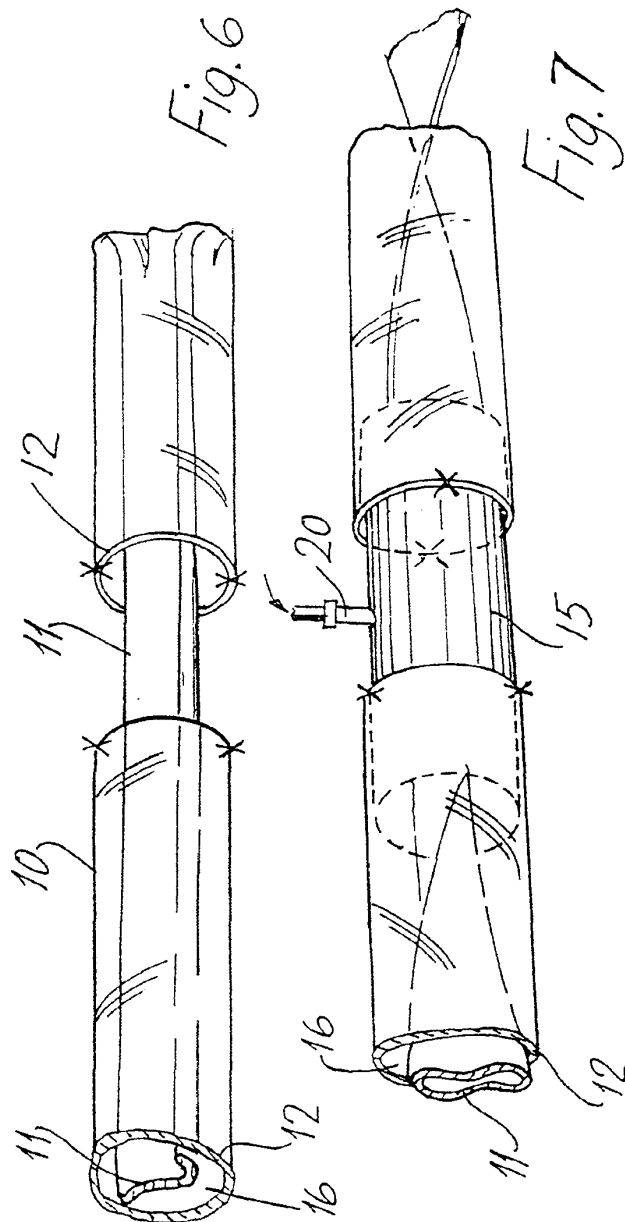
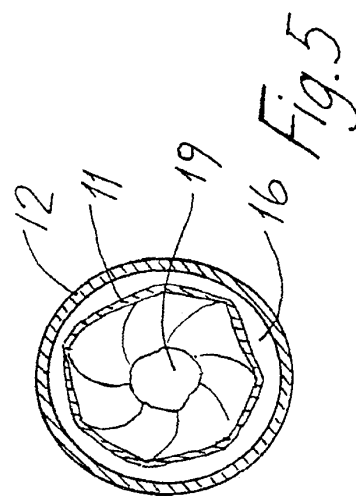
14. A device as claimed in any preceding claim including guide means through which the sleeve and/or an object is advanced.
- 5 15. A device as claimed in claim 14 wherein the guide means includes a ring means for placing in a body opening or incision through which the sleeve and/or an object is advanced.
- 10 16. A device as claimed in any preceding claim including a delivery means for delivery of the device to a remote location.
- 15 17. A device as claimed in claim 16 wherein the delivery means is a tube.
18. A device as claimed in claim 15 or 16 wherein the delivery means is a catheter.
19. A device as claimed in any preceding claim wherein the device defines a transporter for delivery or retrieval of an object to or from a desired location.
- 20 20. A device as claimed in any preceding claim wherein the device defines an introducer for introducing an object such as an instrument to a desired location.
- 25 21. A device as claimed in any of claims 1 to 18 wherein the device is an expandable element.
22. A device as claimed in claim 21 wherein the expandable element is a balloon for angioplasty.
- 30 23. A medical device substantially as hereinbefore described with reference to the accompanying drawings.



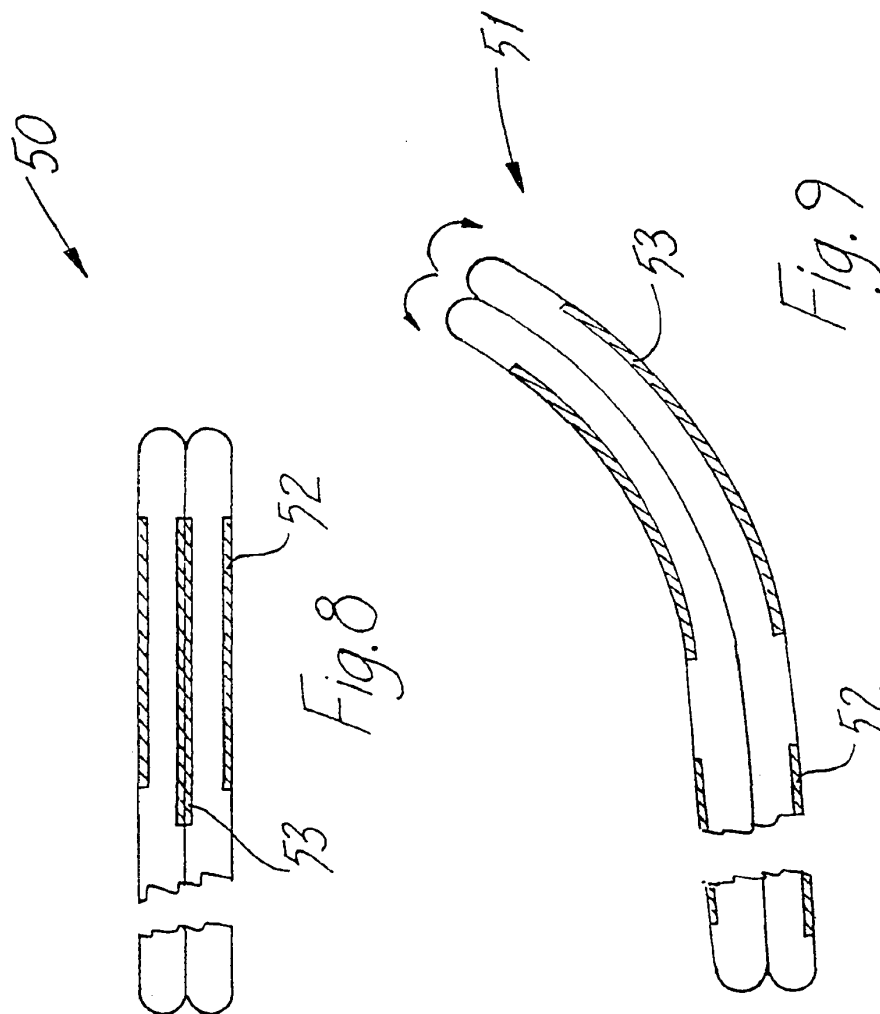
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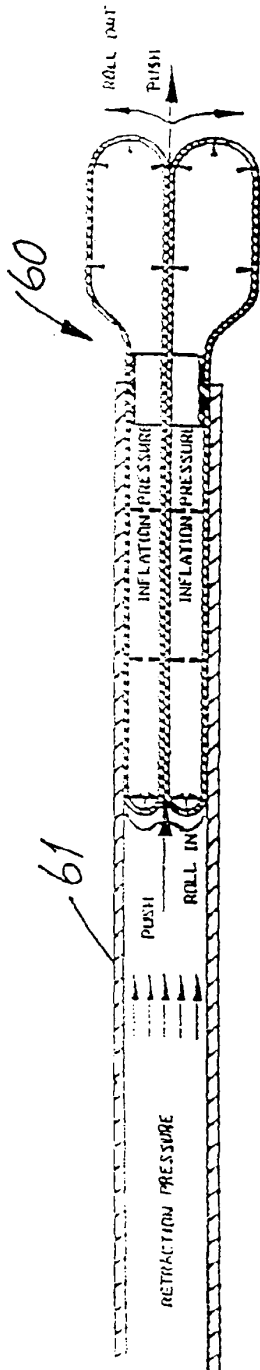


Fig. 10

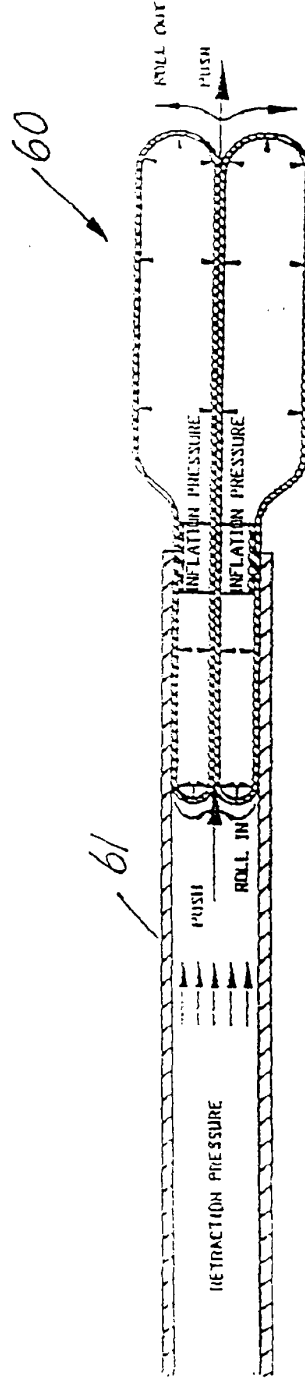


Fig. 11

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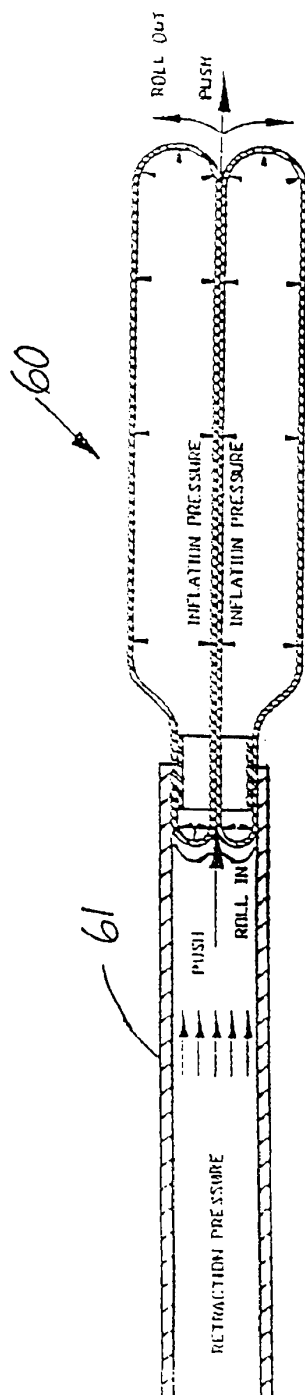


Fig. 12

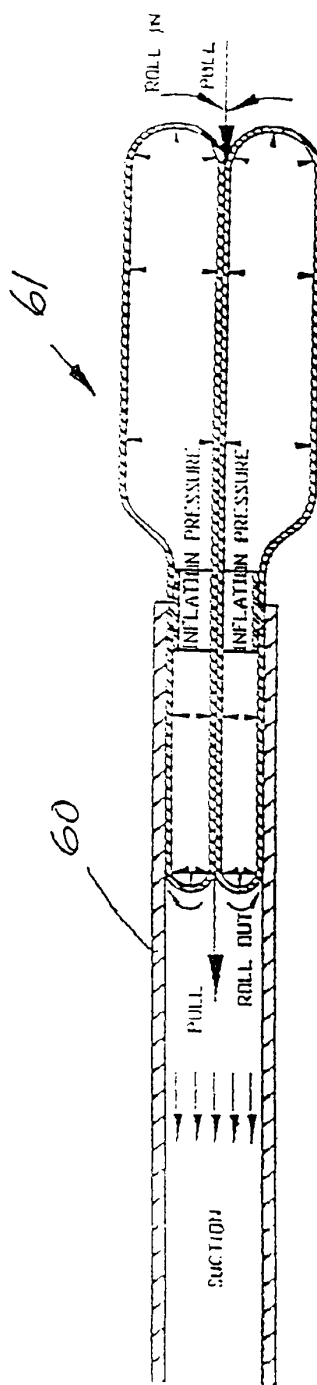


Fig. 13

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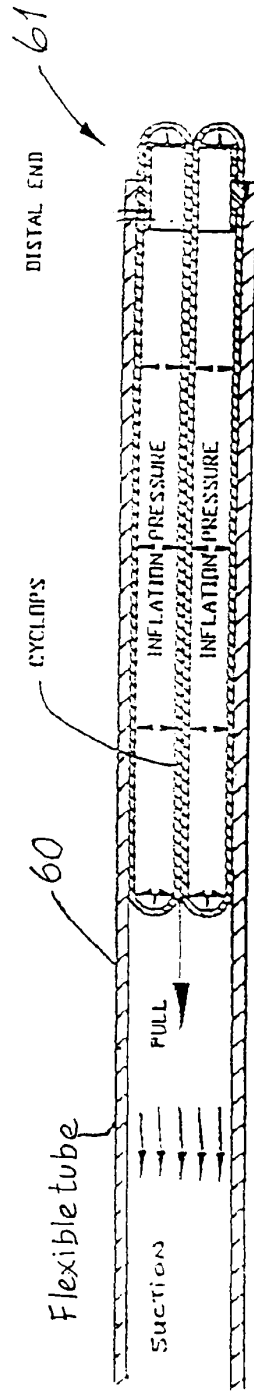


Fig. 14

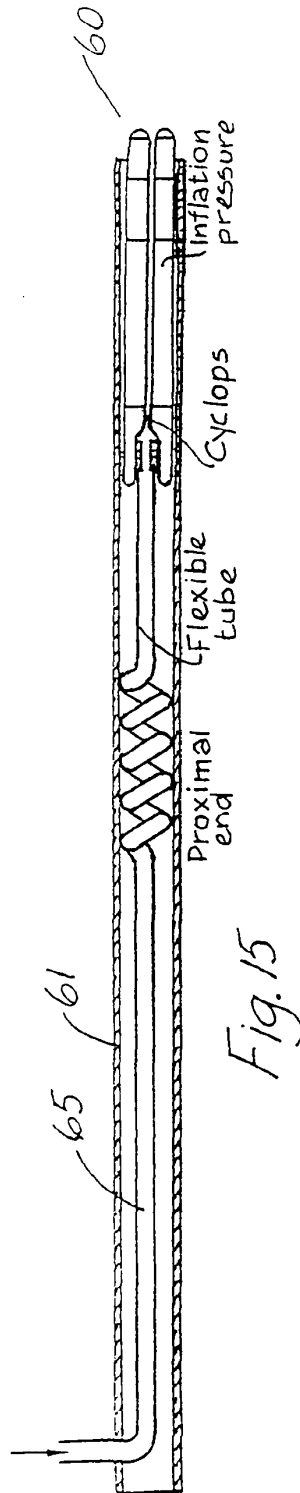


Fig. 15

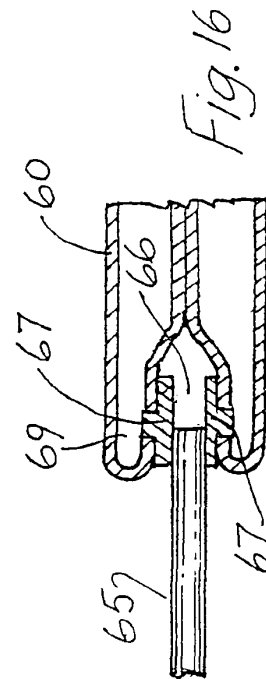


Fig. 16

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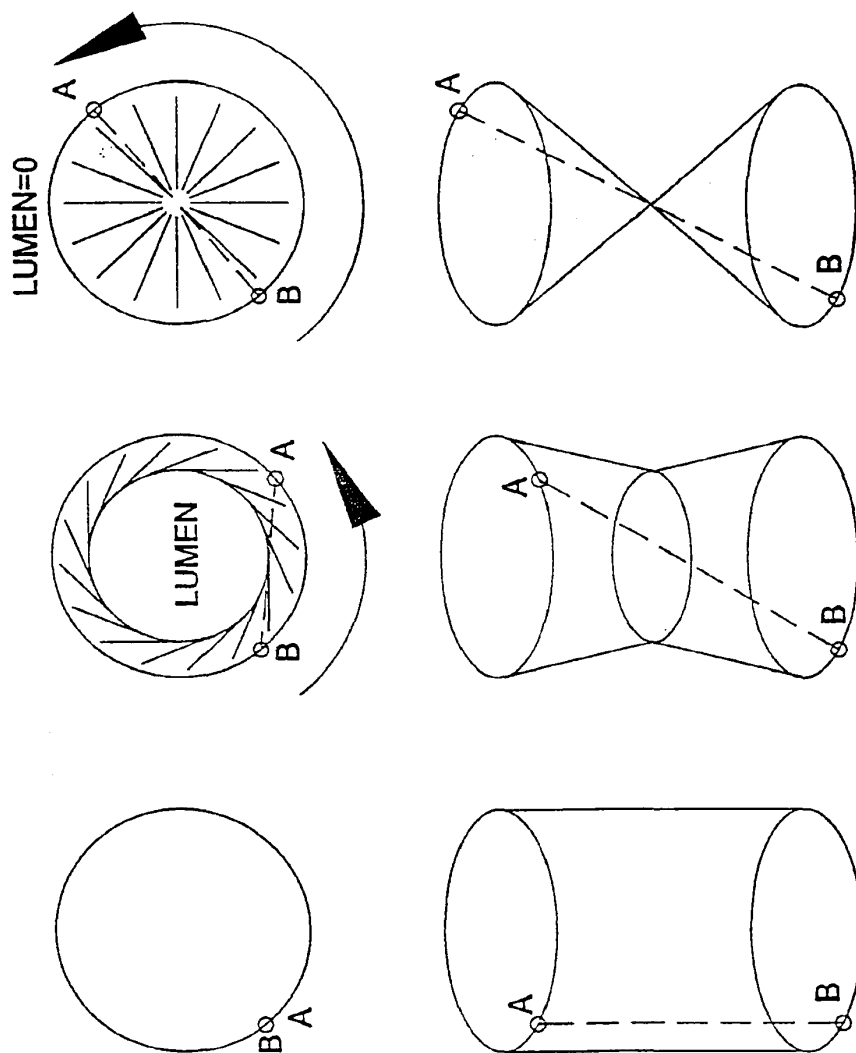


Fig. 17 The Twisted Tube

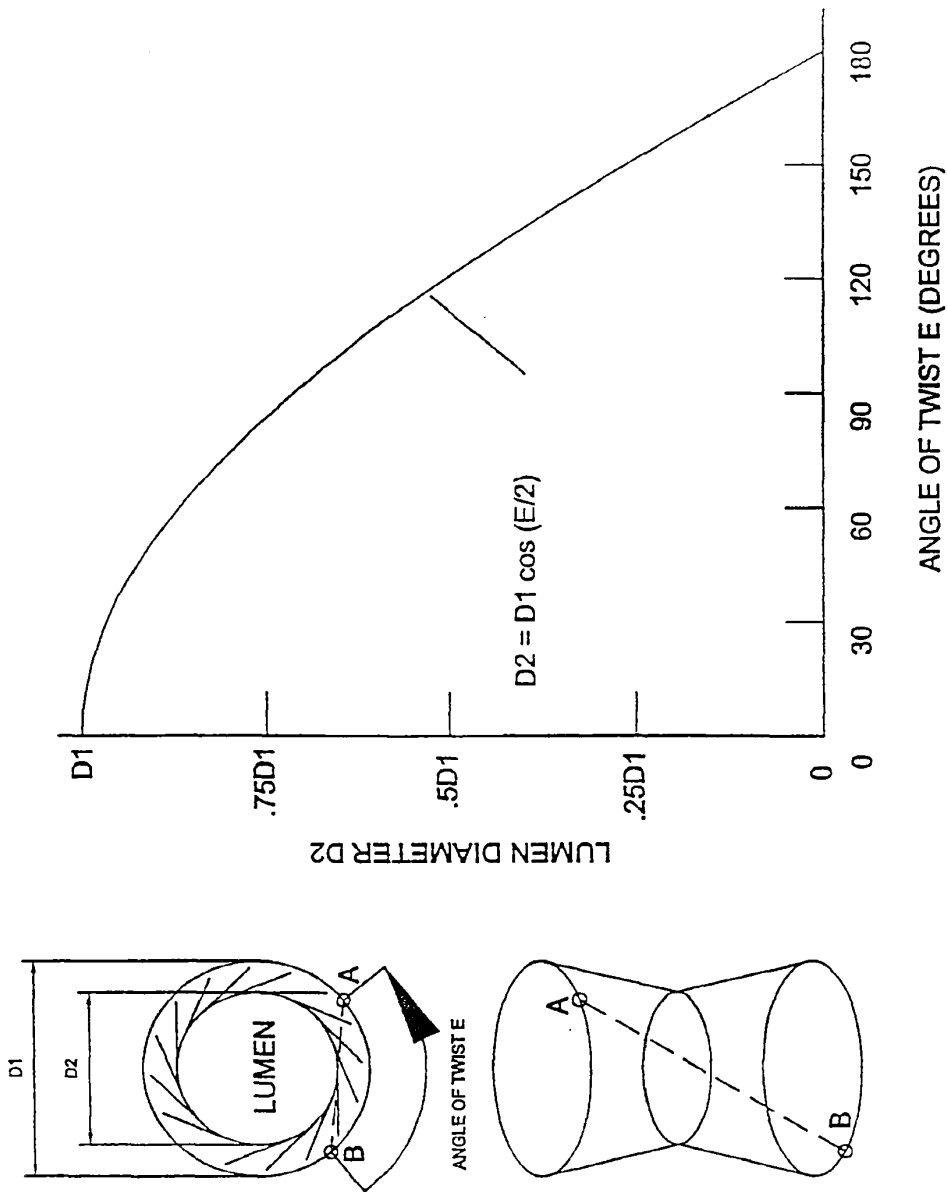


Fig.18a Angle of twist vs lumen

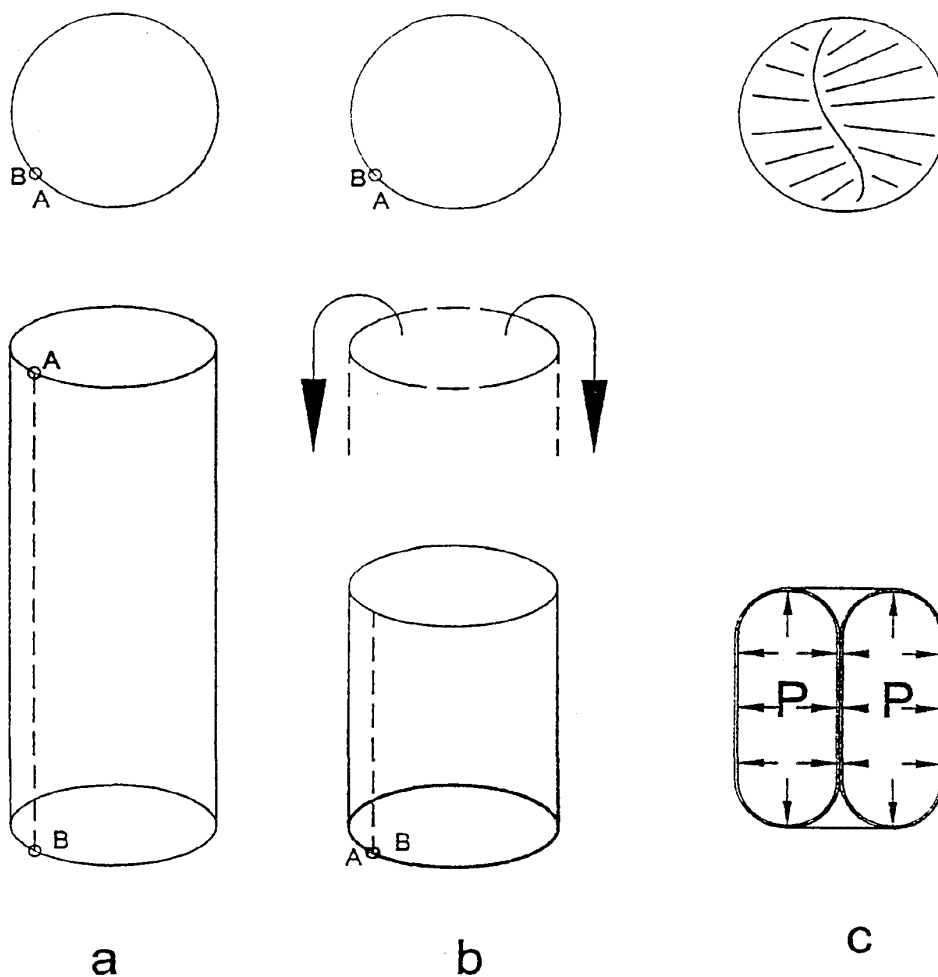


Fig.19 Twin Walled vessel under internal pressure

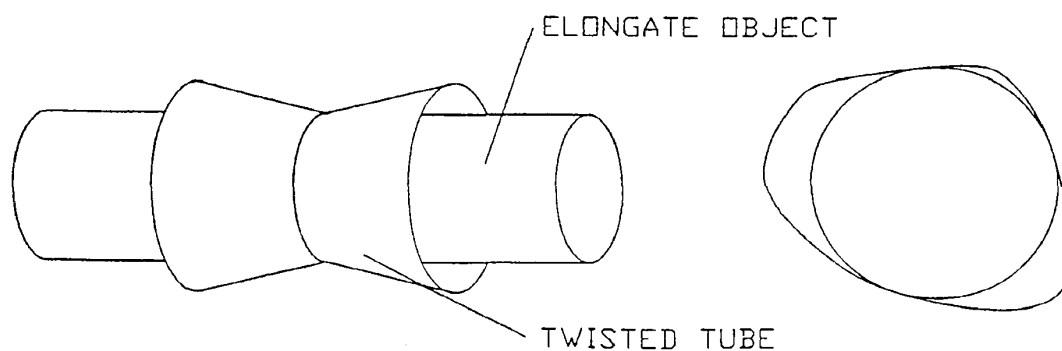


Fig.18b Twisted tube with elongate object passing therethrough

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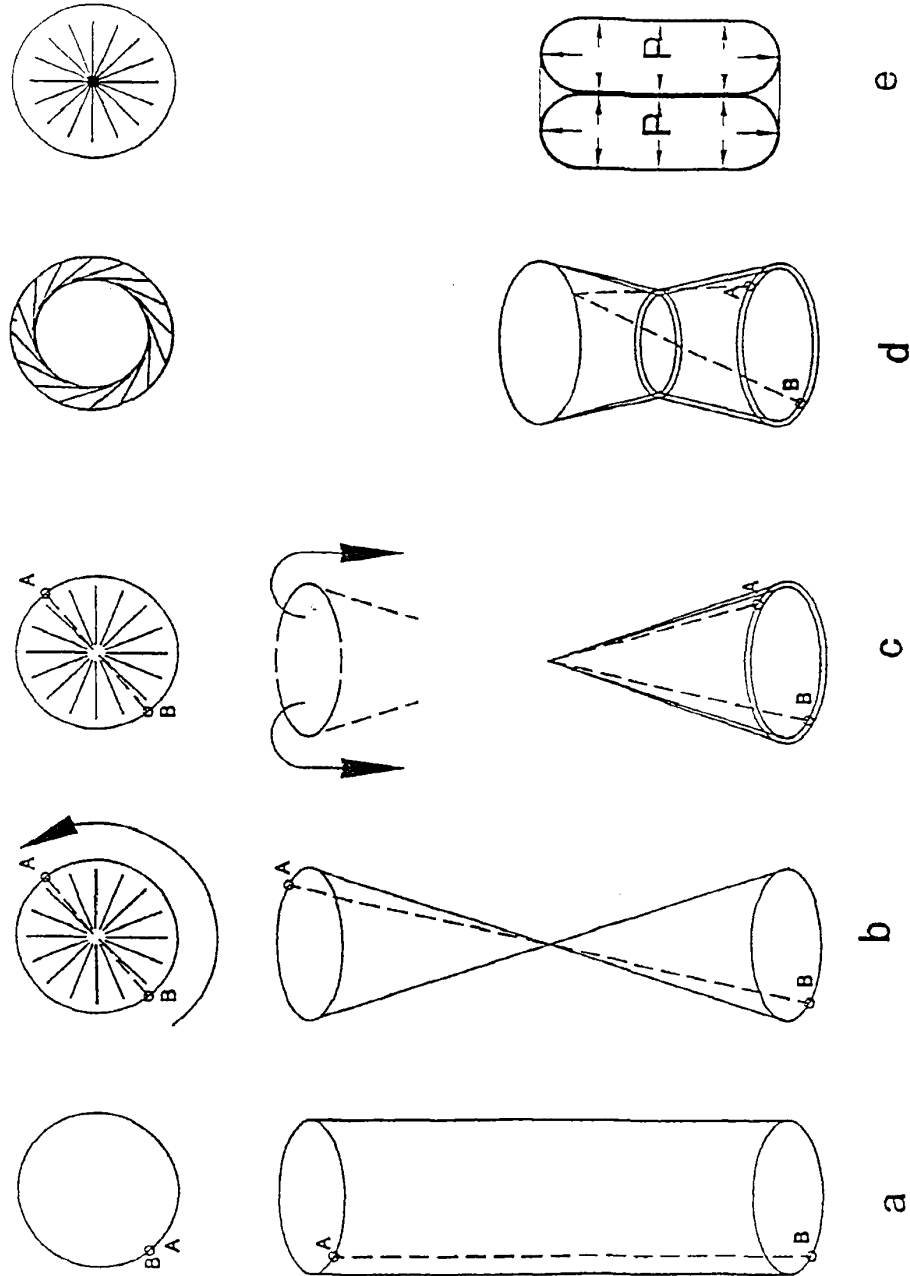


Fig.20 Twin walled tube with twist subject to internal pressure

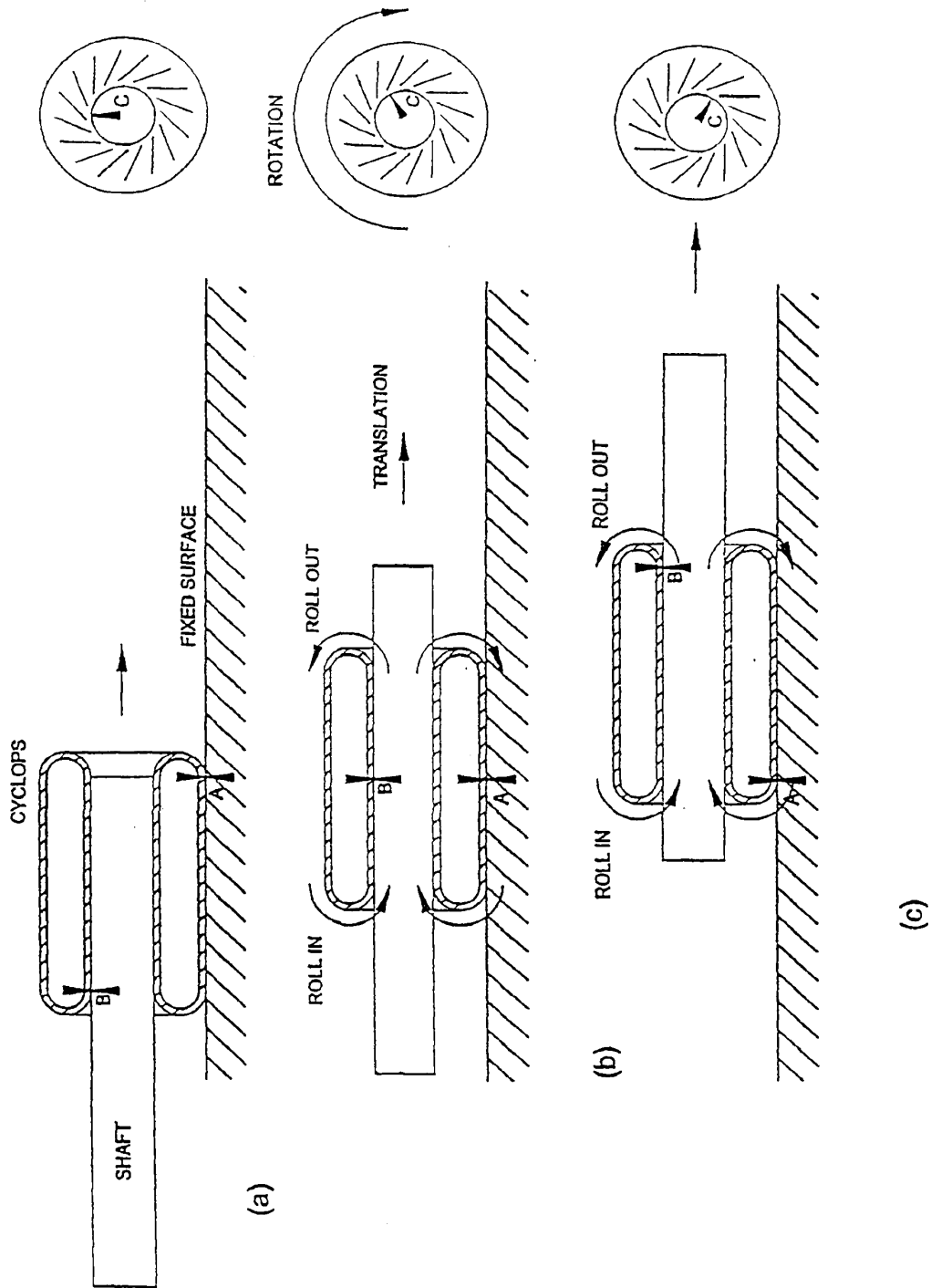


Fig.21 Translation of a shaft within a Cyclops

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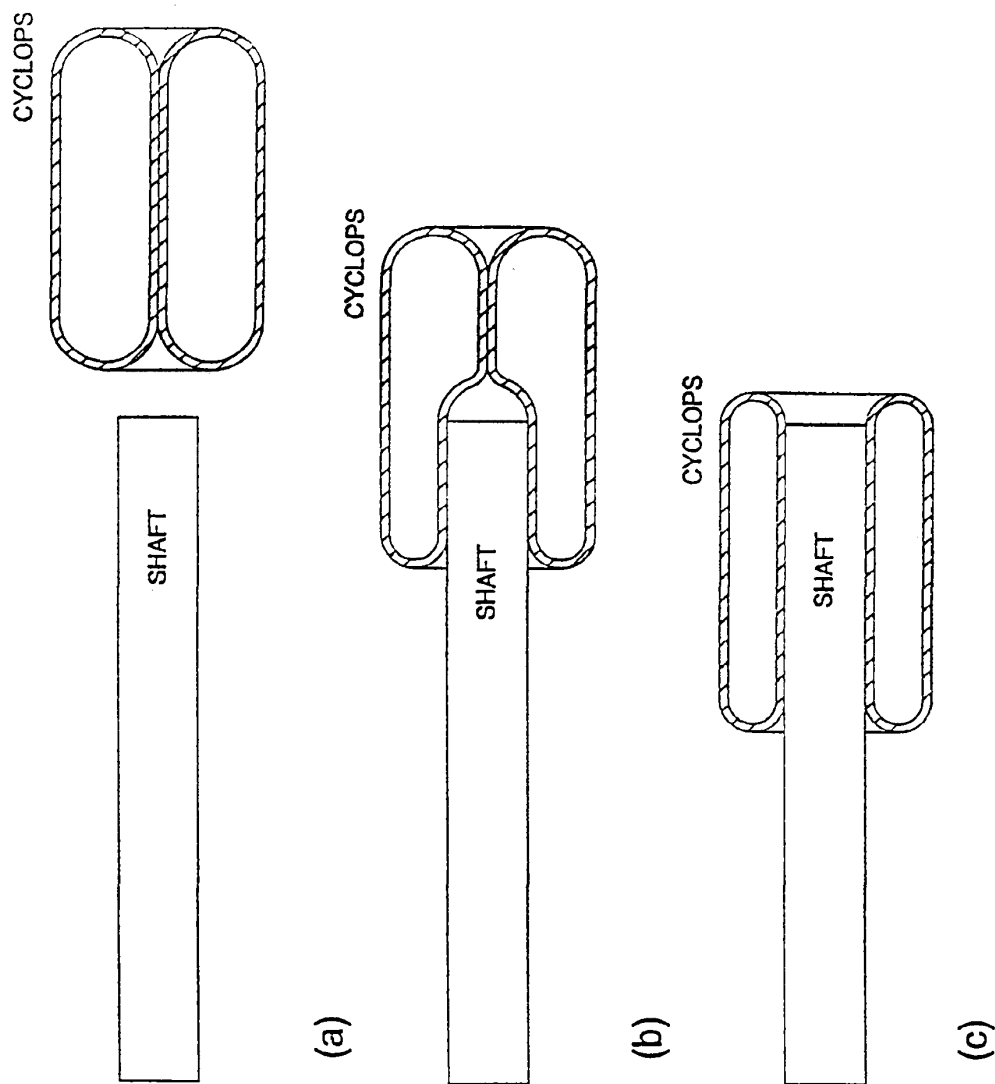


Fig.22 The deformation of a Cyclops as a shaft enters and translates

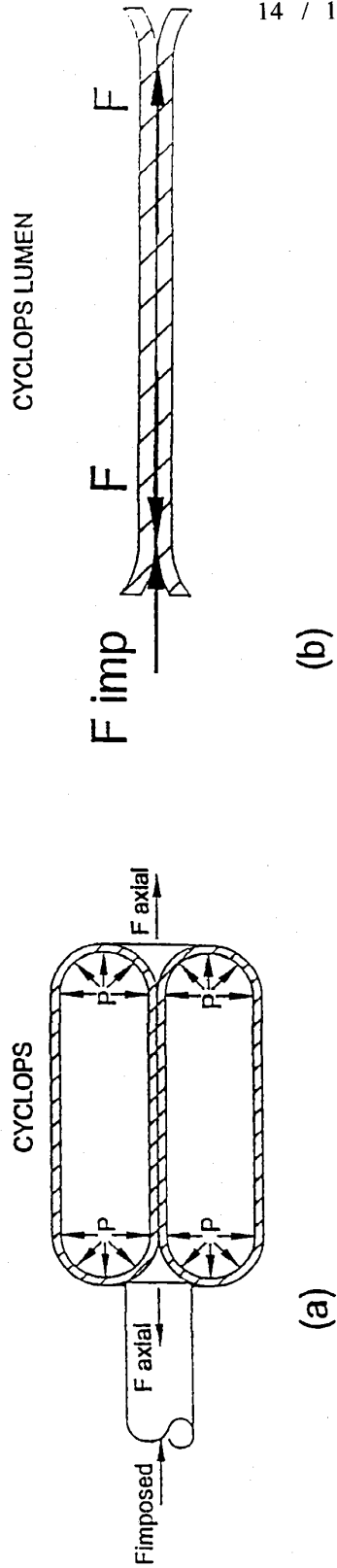
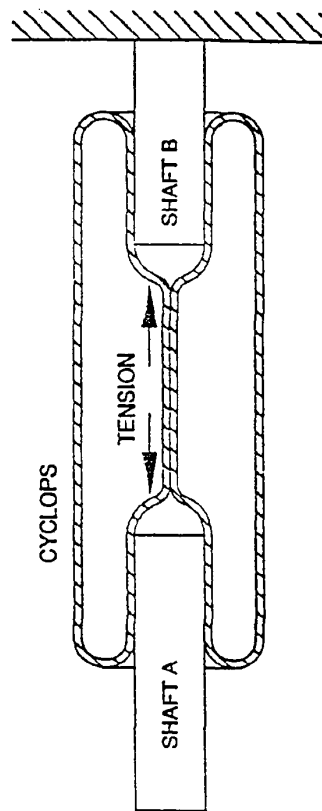
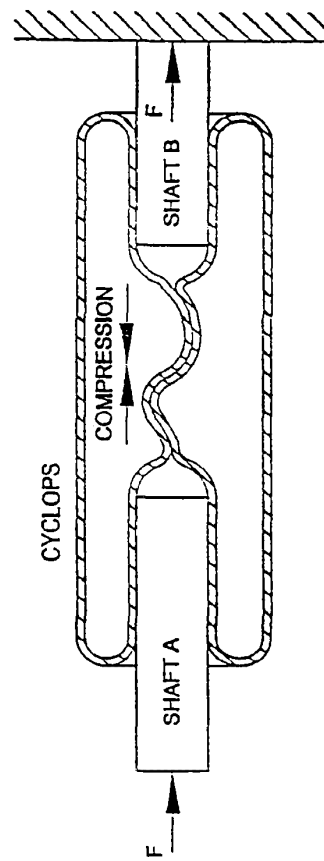


Fig 23 Forces acting on Cyclops lumen due to axial component of pressure

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(a)



(b)

Fig.24 Stiffness of Cyclops lumen

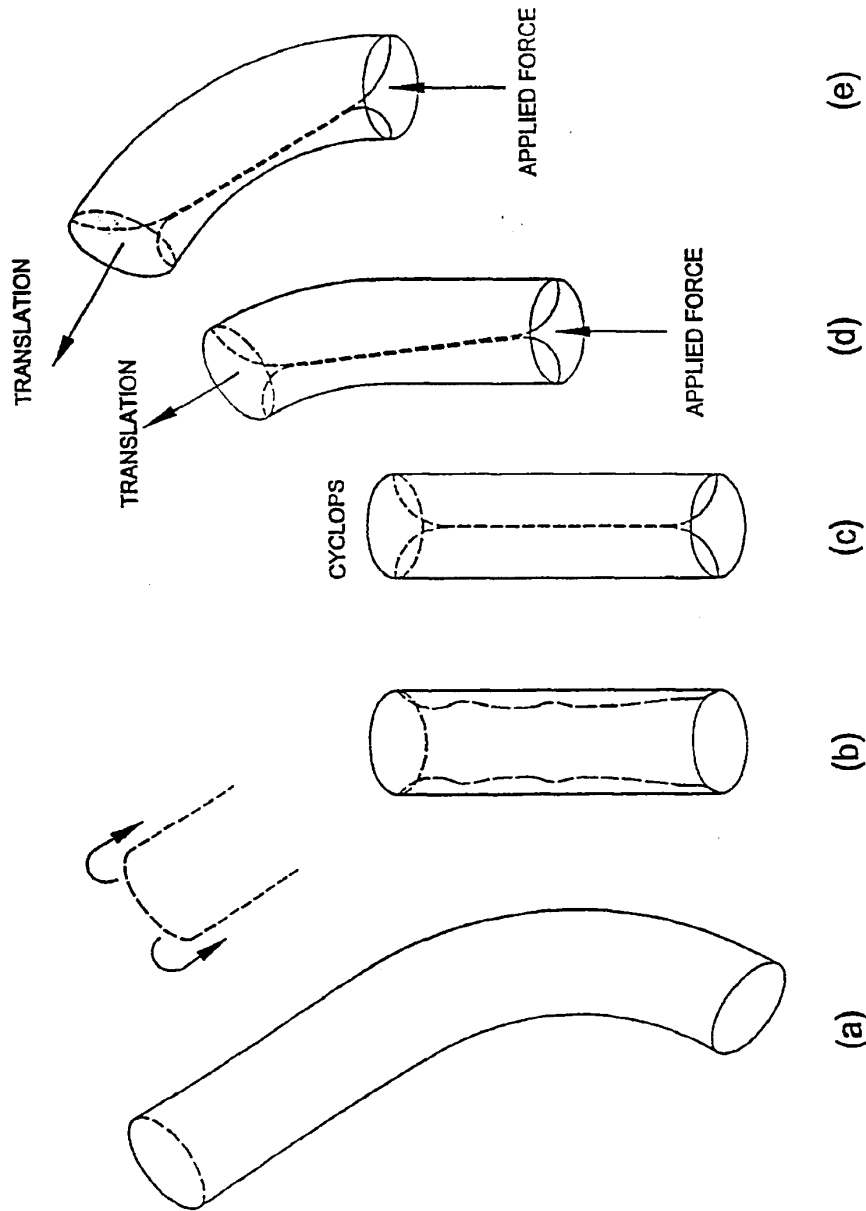
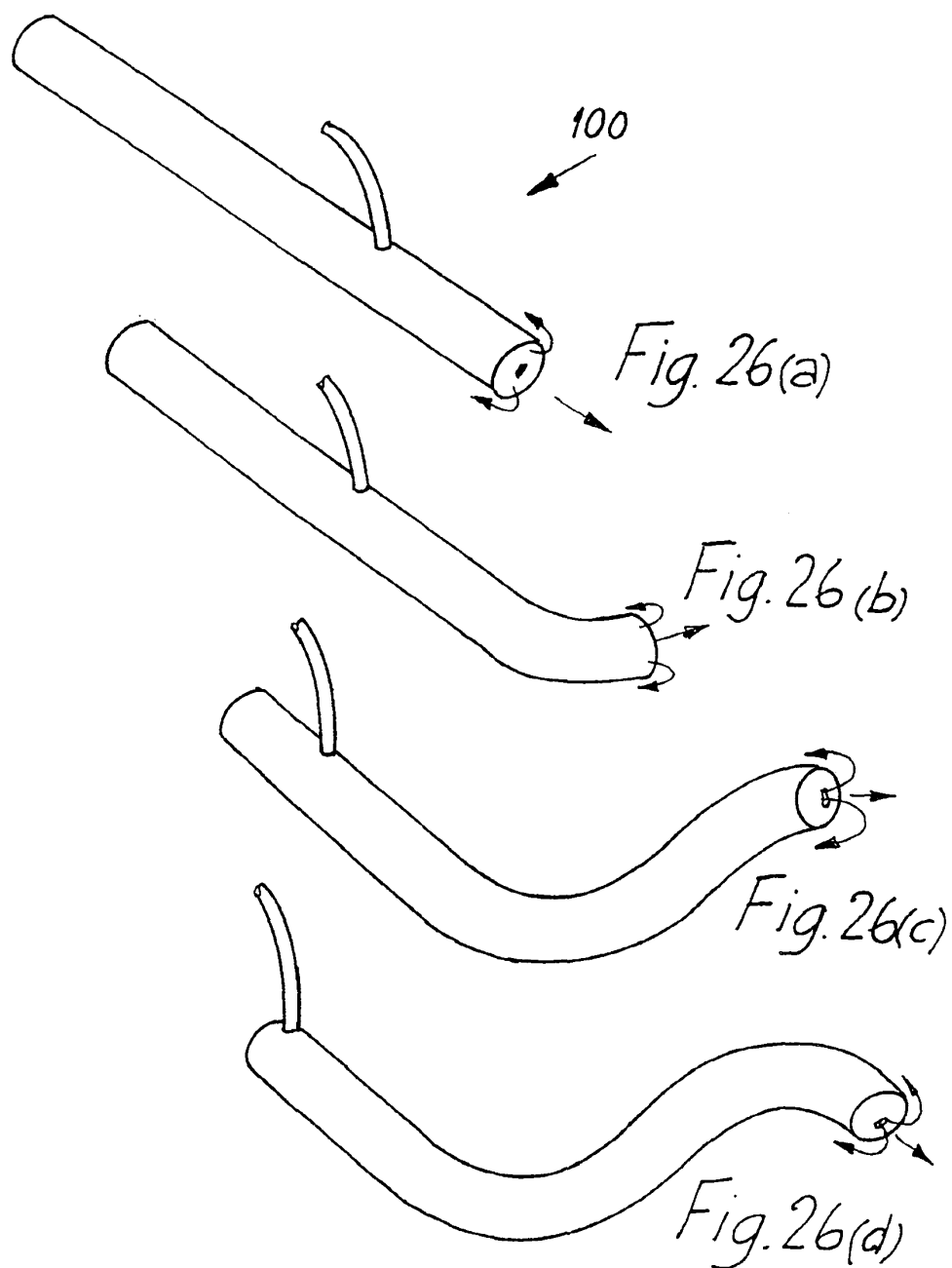


Fig.25 Effects of tube preform shape



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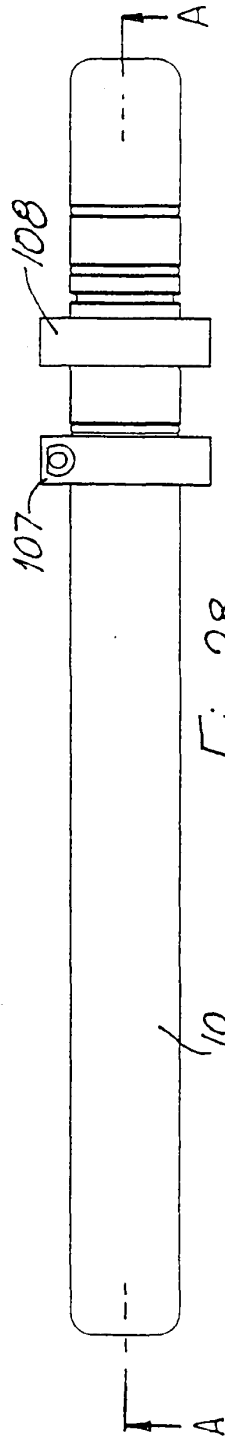


Fig. 28

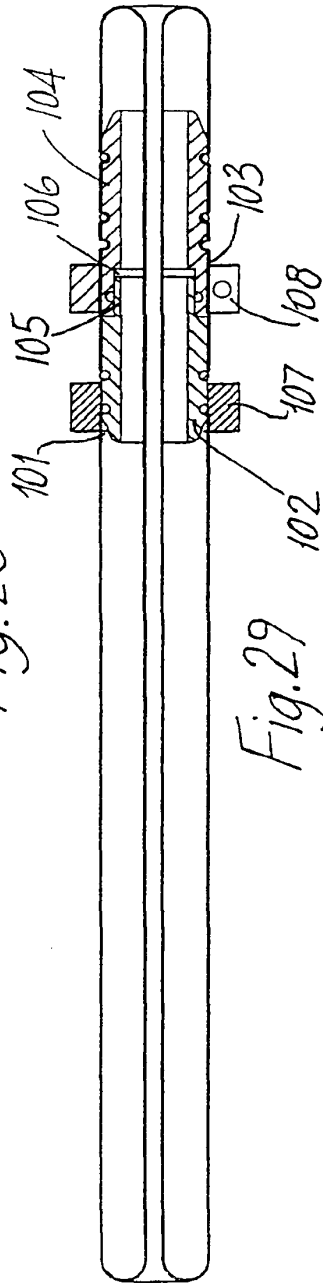


Fig. 29

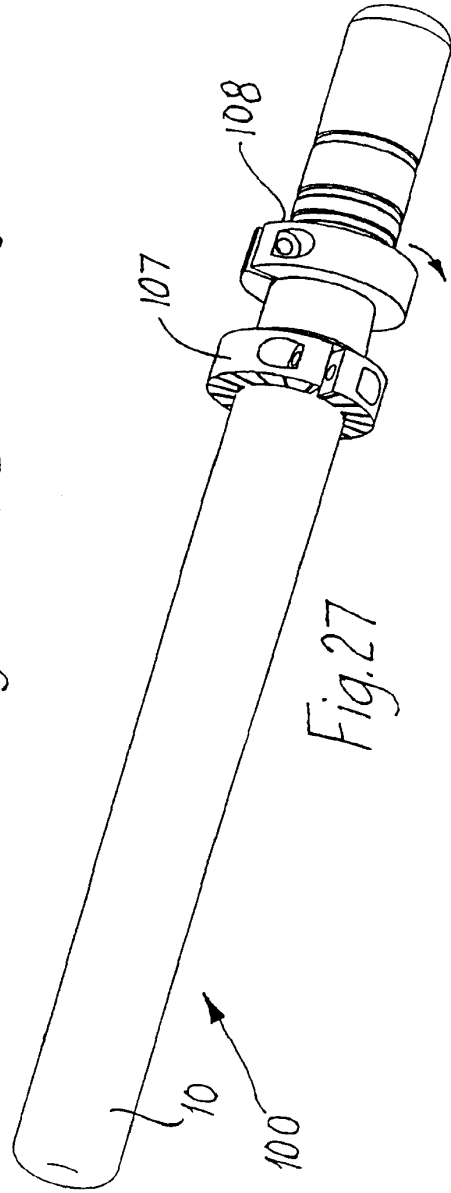
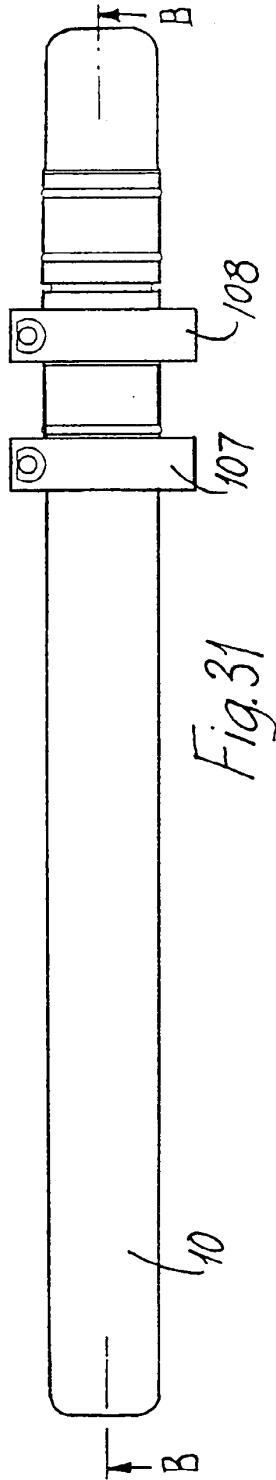
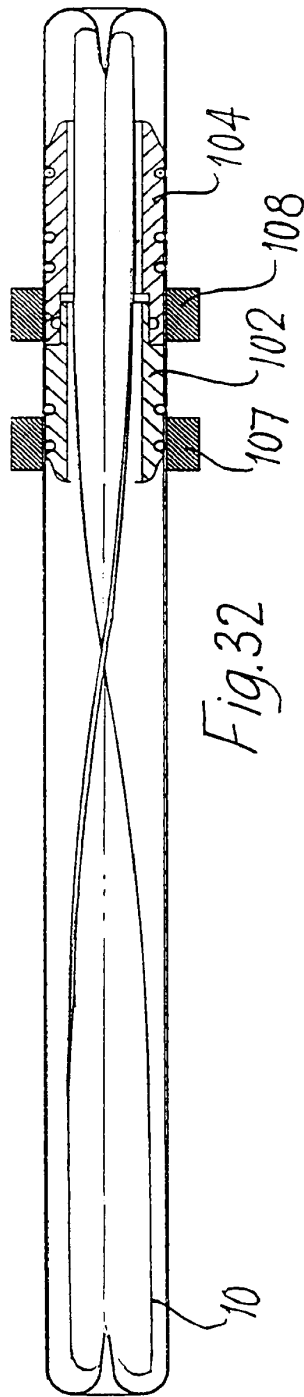
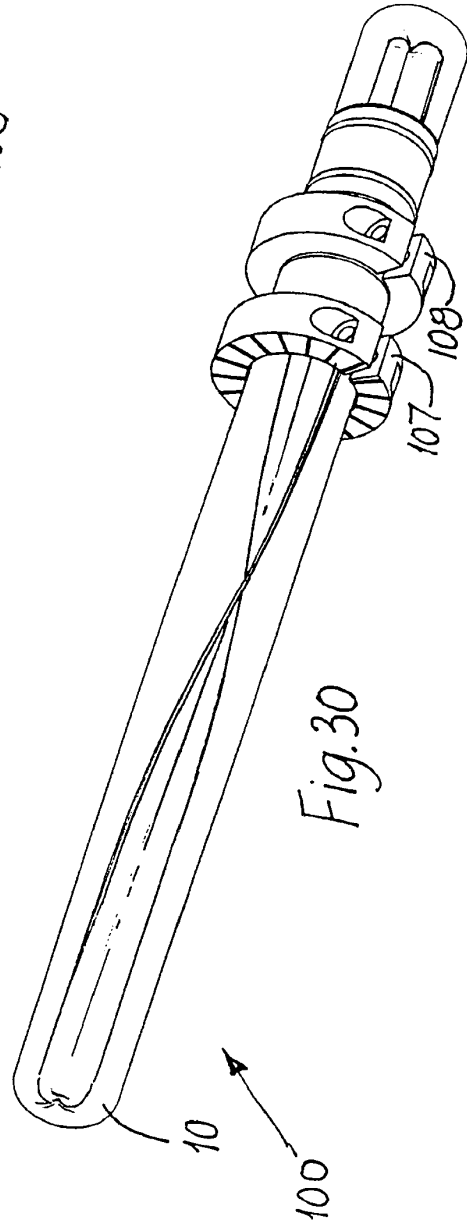


Fig. 27

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INTERNATIONAL SEARCH REPORT

International Application No
PCT/IE 99/00124

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B17/34 A61M25/01

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B A61M

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 634 937 A (MOLLENAUER KENNETH H ET AL) 3 June 1997 (1997-06-03) column 10, line 16 - line 50	1
A	US 5 636 645 A (OU HONZEN) 10 June 1997 (1997-06-10) cited in the application column 6, line 34 - line 54	1
A	WO 98 48724 A (CARROLL MAUREEN E ; NIEMANN ALLISON C (US); STAMM EDWARD I JR (US);) 5 November 1998 (1998-11-05) cited in the application figure 6B & US 5 906 577 A	1

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents:

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

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

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

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

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

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

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

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Date of the actual completion of the international search

29 February 2000

Date of mailing of the international search report

07/03/2000

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Fax: (+31-70) 340-3016

Authorized officer

Gérard, B

INTERNATIONAL SEARCH REPORT

International Application No

PCT/IE 99/00124

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	DE 37 39 532 C (ZERBST EKKEHARD) 8 December 1988 (1988-12-08) column 3, line 14 - line 21 <u> </u>	1

INTERNATIONAL SEARCH REPORT

International application No.

PCT/IE 99/00124

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☒ Claims Nos.: 23
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

SEE RULE 6.2(a) PCT
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

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

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/IE 99/00124

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
US 5634937	A	03-06-1997	WO 9636283 A		21-11-1996
			US 5964781 A		12-10-1999
US 5636645	A	10-06-1997	NONE		
WO 9848724	A	05-11-1998	US 5906577 A		25-05-1999
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DE 3739532	C	08-12-1988	NONE		

Form PCT/ISA/210 (patent family annex) (July 1992)

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代理人 张兰英

(51) Int. Cl.

A61B 17/22 (2006.01)

A61M 25/00 (2006.01)

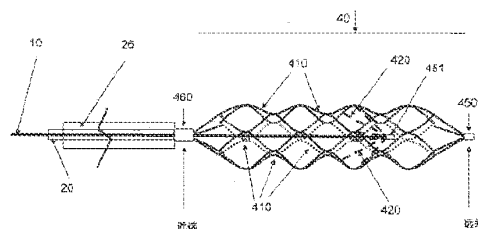
权利要求书4页 说明书29页 附图58页

(54) 发明名称

血管内血栓切除装置及其使用方法

(57) 摘要

提供一种用于加大或恢复腔内流量的装置和方法。该装置和方法可通过从血管内去除凝块和/或重新打开血管来治疗像中风的病症。该装置可具有可扩张隔壁，该可扩张隔壁包括可重构元件和支承元件。支承元件可调节可重构元件的径向力和构造，由此允许从血管有效地去除凝块和/或重新打开血管，而对血管的损伤最少或没有损伤。或者，该装置可具有接合隔壁，该接合隔壁包括远侧接合元件和近侧接合元件。血管内的凝块可接合到远侧接合元件和近侧接合元件内和/或之间。可调节接合元件中的一个或两个的位置以及接合元件之间的间距以确保与凝块或闭塞物的接合。



1. 一种用于体腔的装置,所述装置包括:
推送管件和可扩张隔室;
其中,所述可扩张隔室包括:
控制元件,所述控制元件包括近端和远端;
可重构元件,所述可重构元件与支承元件和所述控制元件相关联;以及
支承元件,所述支承元件与所述控制元件和所述可重构元件相关联,其中,所述支承元件构造成调节所述可重构元件的径向力和构造。
2. 如权利要求1所述的装置,其特征在于,所述控制元件包括线材、线缆或编织物。
3. 如权利要求1所述的装置,其特征在于,所述可重构元件和/或所述支承元件包括多个线材。
4. 如权利要求3所述的装置,其特征在于,所述可重构元件能自扩张到松弛的可扩张状态,以形成隔室或筐状物。
5. 如权利要求4所述的装置,其特征在于,所述可重构元件包括多个单元,且单元的尺寸和形成所述单元的线条的厚度在所述可重构元件内变化。
6. 如权利要求1所述的装置,其特征在于,所述支承元件呈支杆的形式,所述支杆由与所述可重构元件相同的材料制成,并且自动连接到所述可重构元件。
7. 如权利要求1所述的装置,其特征在于,所述支承元件呈丝网或编织物的形式。
8. 如权利要求1所述的装置,其特征在于,所述推送管件连接到所述可扩张隔室。
9. 如权利要求1所述的装置,其特征在于,所述控制元件被所述推送管件围绕,并能在所述推送管件内自由运动。
10. 如权利要求1所述的装置,其特征在于,所述支承元件包括第一构造和第二构造,所述支承元件和所述控制元件之间的角度在所述第一构造下比在所述第二构造下小。
11. 如权利要求1所述的装置,其特征在于,所述支承元件包括第一构造和第二构造,所述第一构造具有比所述第二构造的外直径小的外直径。
12. 如权利要求10和11所述的装置,其特征在于,所述控制元件向远侧方向突出使所述支承元件过渡到所述第一构造,因而,所述可重构元件的径向力减小。
13. 如权利要求10和11所述的装置,其特征在于,所述控制元件向近侧方向突出使所述支承元件过渡到所述第二构造,因而,所述可重构元件的径向力增大。
14. 如权利要求1所述的装置,其特征在于,所述装置构造成去除阻塞血管的闭塞物/凝块、打开血管的阻塞部段和/或增大血管内的流量。
15. 如权利要求1所述的装置,其特征在于,所述可重构元件的远端连结从而形成端部闭合的可重构元件,或者不连结从而形成端部敞开的可重构元件。
16. 如权利要求1所述的装置,其特征在于,所述可重构元件的各侧连结从而形成各侧闭合的可重构元件,或者不连结从而形成各侧敞开的可重构元件。
17. 如权利要求1所述的装置,其特征在于,所述支承元件包括多个线材,且所述线材能在所述近端和远端之间延伸,并且基本上被所述可重构元件围绕。
18. 如权利要求1所述的装置,其特征在于,所述可重构元件和所述支承元件呈丝网的形式,所述丝网能在所述近端和远端之间延伸,且所述支承元件基本上被所述可重构元件围绕,由此形成双层的可重构元件或可扩张隔室。

19. 如权利要求 1 所述的装置,其特征在于,所述可重构元件包括大致平行对准的多个直线形线材和呈大致圆形的多个线材,且所述支承元件包括与所述可重构元件和所述控制元件相关联的至少两个线材,由此形成伞形的可扩张隔室。

20. 如权利要求 1 所述的装置,其特征在于,所述可重构元件的远端和所述支承元件的远端不连接,并且独立运动。

21. 如权利要求 1 所述的装置,其特征在于,非创伤性柔性线圈附连到所述可重构元件的所述远侧末端。

22. 如权利要求 1 所述的装置,其特征在于,所述装置包括远侧可扩张结构和近侧可扩张结构。

23. 如权利要求 22 所述的装置,其特征在于,所述第一可扩张结构包括可重构元件、控制元件以及可选地支承元件。

24. 如权利要求 22 所述的装置,其特征在于,所述第二可扩张结构包括可重构元件和可选地封闭元件。

25. 如权利要求 22 所述的装置,其特征在于,所述远侧可扩张结构和所述近侧可扩张结构之间的间距可调。

26. 一种去除存在于血管的第一位置的闭塞物 / 凝块的方法,所述方法包括:
将如权利要求 1 所述的装置引入所述血管;
将所述装置定位在所述血管的所述第一位置;
通过调节所述装置的可重构元件的径向力和 / 或构造而与所述闭塞物 / 凝块接合;以及
从所述第一位置去除所述闭塞物 / 凝块。

27. 如权利要求 26 所述的方法,其特征在于,去除所述闭塞物 / 凝块还包括选自如下组中的一个或多个:

使所述闭塞物 / 凝块至少部分地与所述装置接合;
将所述闭塞物 / 凝块拆解成小尺寸碎屑,并收集所述碎屑中的至少一部分;以及
使所述血管的区域扩张。

28. 如权利要求 26 所述的方法,其特征在于,所述方法构造成应用于治疗中风。

29. 一种增大血管内流量的方法,所述方法包括:

将如权利要求 1 所述的装置引入所述血管;
将所述装置定位在大约所述血管的需要增大流量的第一位置;以及
调节所述装置的可重构元件的径向力和 / 或构造以使所述第一位置的区域扩张。

30. 一种去除存在于血管的第一位置的闭塞物 / 凝块的方法,所述方法包括:

将如权利要求 1 所述的装置引入所述血管;
将所述装置定位在大约所述血管的所述第一位置;
通过所述控制元件的近侧运动使与所述可重构元件相关联的支承元件延伸来支持所述可重构元件的扩张状态;

通过所述控制元件的近侧运动使与所述可重构元件相关联的支承元件延伸来进一步支持所述可重构元件的更扩张状态;

用于处于扩张状态的所述可重构元件 / 可扩张隔室来抓取所述闭塞物 / 凝块;

通过使所述控制元件向远侧运动来使所述可重构元件的构造向更松弛状态变化；以及从所述第一位置去除所述闭塞物/凝块。

31. 一种去除存在于血管的第一位置的闭塞物/凝块的方法，所述方法包括：

将如权利要求 22 所述的装置引入所述血管；

将所述装置定位在所述血管的位置远侧；

向近侧拉动推送管件，以抓取处于扩张状态的两个可扩张结构之间的闭塞物/凝块；

通过所述控制元件的近侧运动使与所述可重构元件相关联的支承元件延伸来支持所述可重构元件的扩张状态；

用近侧可扩张结构来抓取所述闭塞物/凝块；

用远侧可扩张结构来捕获闭塞物/凝块碎屑；

在拉动所述控制元件时可选地收回所述装置以增大所述可扩张结构的径向力，并进一步支持所述可扩张结构的扩张状态；以及

从所述第一位置去除所述闭塞物/凝块。

32. 一种用于体腔的装置，所述装置包括：

微型导管，所述微型导管包括近端和远端；

管件隔室；

中心线；以及

接合隔室，

其中，所述接合隔室包括：

近侧接合元件；以及

远侧接合元件，

其中，所述远侧接合元件是与所述中心线相关联的可扩张元件，且所述近侧接合元件和所述远侧接合元件之间的间距可调。

33. 如权利要求 32 所述的装置，其特征在于，所述远侧接合元件包括形成支架的多个线材或支杆。

34. 如权利要求 32 所述的装置，其特征在于，所述远侧接合元件与延伸到所述装置的近端的中心线固定，由此，所述远侧接合元件在体腔内的位置由所述中心线的运动来控制。

35. 如权利要求 32 所述的装置，其特征在于，所述近侧接合元件是包括多个线材或支杆的可扩张元件，并能扩张成漏斗状或锥形结构。

36. 如权利要求 32 所述的装置，其特征在于，所述近侧接合元件与所述中心线相关联，并沿所述中心线运动。

37. 如权利要求 36 所述的装置，其特征在于，所述近侧接合元件与延伸到所述装置的近端的管件隔室固定，由此，所述近侧接合元件在体腔内的位置由所述管件隔室的运动来控制。

38. 如权利要求 36 所述的装置，其特征在于，所述近侧接合元件不与所述管件隔室固定，并构造成沿所述中心线自由运动。

39. 如权利要求 32 所述的装置，其特征在于，所述近侧接合元件位于所述微型导管的远端处。

40. 如权利要求 39 所述的装置，其特征在于，所述近侧接合元件不是所述微型导管的

一体部分,而是固定在所述微型导管的所述远端处。

41. 如权利要求 39 所述的装置,其特征在于,所述近侧接合元件是可膨胀或接合元件。

42. 如权利要求 39 所述的装置,其特征在于,所述近侧接合元件是微型导管的一体部分。

43. 如权利要求 42 所述的装置,其特征在于,所述近侧接合元件包括所述微型导管的所述远端的构造成根据施加于所述微型导管的所述远端的压力来改变形状的部分。

44. 如权利要求 42 所述的装置,其特征在于,所述近侧接合元件包括所述微型导管的所述远端的包括微型导管末端的部分和覆盖所述微型导管末端的薄管件层,其中,所述近侧接合元件的至少一部分构造成在移除所述薄管件层时改变形状。

45. 如权利要求 32 所述的装置,其特征在于,所述管件隔室包括推送管件和连接管件。

46. 如权利要求 32 所述的装置,其特征在于,所述管件隔室由一件具有可变刚度的管件制成,因而,所述管件隔室的远端是软的和柔性的,因此,所述装置能通过曲折的解剖体,同时所述管件隔室的近端刚硬到加强所述装置的可推送性。

47. 如权利要求 32 所述的装置,其特征在于,所述中心线包括线材、线缆或编织物。

48. 如权利要求 32 所述的装置,其特征在于,所述近侧接合元件和所述远侧接合元件之间的间距约在 0 到 50 毫米的范围内可调。

49. 如权利要求 32 所述的装置,其特征在于,所述近侧接合元件包括面向所述远侧接合元件的远端,所述近侧接合元件的所述远端被弯曲、倒圆或弄成圆滑。

50. 如权利要求 32 所述的装置,其特征在于,所述近侧接合元件包括面向所述远侧接合元件的远端,所述近侧接合元件的所述远端构造成不与所述体腔的表面直接接触。

51. 一种从体腔内的第一位置去除闭塞物的至少一部分的方法,所述方法包括:

将如权利要求 32 所述的装置引入所述体腔内;

将所述装置定位在大约所述第一位置;

使所述闭塞物的至少一部分与所述接合元件接合;以及

从所述第一位置去除接合的闭塞物。

52. 如权利要求 51 所述的方法,其特征在于,所述接合包括:

调节所述近侧接合元件和所述远侧接合元件中的一个或两个的位置以使所述闭塞物的至少一部分与所述近侧接合元件和/或所述远侧接合元件接合。

53. 如权利要求 51 所述的方法,其特征在于,所述接合包括:

调节所述近侧接合元件和所述远侧接合元件之间的间距以使所述闭塞物的至少一部分接合到所述近侧接合元件和所述远侧接合元件之间。

54. 如权利要求 51 所述的方法,其特征在于,所述方法还包括:

在接合之后,锁定所述近侧接合元件和所述远侧接合元件中的一个或两个的位置。

55. 如权利要求 51 所述的方法,其特征在于,在所述接合时,所述闭塞物的至少一部分与选自如下组的任何部件接合:所述体腔的表面、所述微型导管、所述管件隔室、所述近侧接合元件、所述远侧接合元件及其任何组合。

血管内血栓切除装置及其使用方法

[0001] 发明背景

技术领域

[0002] 本发明总地涉及用于诸如人体血管之类的体腔内的装置及其使用方法。

[0003] 相关技术的说明

[0004] 会至少部分地由于血管的阻塞或闭塞或凝块而造成多种病症。这种病症的熟知示例包括但不限于是中风。其它这种病症包括心肌梗塞、下肢缺血、血管移植物和旁路的闭塞或凝块以及静脉血栓。

[0005] 中风经常被称为“脑部侵袭”。这由于脑部供血紊乱经常会造成脑部功能的快速和明显丧失。由此,运动无力、语言的使用、视觉和许多其它生物功能会暂时地或不可逆地受到影响。中风是出血性的(由于出血)或者缺血性的(由于供血不足)。大部分中风是缺血性的。估计每年在美国发生约 700000 起缺血性中风。缺血性中风的大多数起因包括在供给脑部的血管中形成血栓(结块)或者从诸如心脏的另一源至供给脑部的血管的栓塞物。有时,在脑部中有预先存在的血管狭窄之处形成血栓,通常形成动脉粥样硬化疾病。

[0006] 急性缺血性中风的治疗集中于尽可能快地重新建立至脑部的血流。治疗包括使用诸如组织纤溶酶原激活剂(tPA)、血栓溶解剂(降凝块药)之类的药物。最近,食品与药品管理局已许可诸如 Merci 血栓切除装置(加利福尼亚州山景城的集中医药公司(Concentric Medical))以及 Penumbra 吸入血栓切除导管(加利福尼亚州阿拉米达的派母巴公司(Penumbra, Inc.))以及 Solitaire 血栓切除装置(加利福尼亚州欧文的 cv3 神经血管公司(Neurovascular))的装置用于急性中风的血栓切除。这些装置不总是能实现完全再通。有时,它们根本不能打开血管或者仅可部分地打开血管。它们工作起来还耗时,在重新打开血管之前需要装置多次进入颅内循环。此外,它们会弄碎凝块,并使得凝块的某些部分会在脑循环中运动到更远侧。需要具有以更快速方式执行的具有高完全再通率以及完全或部分凝块捕获功能的装置。

发明内容

[0007] 根据本发明的一方面,提供用于体腔内的装置。该装置可包括推送管件和可扩张隔室。根据一些实施例,可扩张隔室可包括包含近端和远端的控制元件、可重构元件和支承元件,该可重构元件可与支承元件和控制元件相关联,支承元件可与控制元件和可重构元件相关联。根据一些其它实施例,支承元件可构造或调节可重构元件的径向力和构造。

[0008] 在前述装置中,控制元件在至少一些实施例中可包括线材、线缆、或编织物。在一些其它实施例中,可重构元件和/或所述支承元件可包括多个线材。在又一些其它实施例中,可重构元件能自扩张到松弛的可扩张状态,以形成隔室或筐状物。在另一些其它实施例中,可重构元件包括多个单元,且单元的尺寸和形成所述单元的线材或支杆的尺寸可在可重构元件内变化。

[0009] 在一些实施例中,前述装置的支承元件呈支杆的形式,该支杆由与可重构元件相

同的材料制成,并且自动连接到可重构元件。在一些其它实施例下,支承元件可以呈丝网或编织物的形式。在一些替代实施例中,推送管件可连接到可扩张隔室。在又一些其它实施例下,控制元件可被推送管件围绕,并能在推送管件内自由运动。

[0010] 在一些其它实施例中,前述装置的支承元件可包括第一构造和第二构造,支承元件和控制元件之间的角度在所述第一构造比在第二构造下小。在某些实施例中,支承元件可包括第一构造和第二构造,所述第一构造的外直径比第二构造的外直径小。

[0011] 根据又一些其它实施例,控制元件向远侧方向突出使支承元件过渡到第一构造,因而,可重构元件的径向力或构造可减小。在一些替代实施例中,控制元件向近侧方向突出可使支承元件过渡到第二构造,因而,可重构元件的径向力或构造可增大。在某些方面,该装置可构造成去除阻塞血管的闭塞物/凝块,打开血管的阻塞部位和/或增大血管内的流量。

[0012] 根据某些方面,可重构元件的远端可连结从而形成端部闭合的可重构元件,或者不连结从而形成端部敞开的可重构元件。在一些实施例中,可重构元件的各侧可连结从而形成各侧闭合的可重构元件,或者不连结从而形成各侧敞开的可重构元件。在某些实施例中,支承元件包括多个线材,且这些线材能在所述近端和远端之间延伸,并且基本上被可重构元件围绕。

[0013] 在一些其它方面,前述装置的可重构元件和支承元件呈丝网的形式,该丝网能在近端和远端之间延伸,且支承元件基本上被可重构元件围绕,由此形成双层的可重构元件或可扩张隔室。在一些实施例中,可重构元件可包括大致平行对准的多个直线形线材和呈大致圆形的多个线材,且支承元件包括与可重构元件和控制元件相关联的至少两个线材,由此形成伞形的可扩张隔室。

[0014] 根据又一些其它方面,可重构元件的远端和支承元件的远端不连接,并且能独立运动。在某些实施例中,非创伤性线圈可附连到可重构元件的远侧末端。

[0015] 根据又一些其它方面,该装置包括远侧可扩张结构和近侧可扩张结构。在一些实施例中,第一可扩张结构包括可重构元件、控制元件和可选地支承元件。在一些其它实施例中,第二可扩张结构包括可重构元件和可选地封闭元件。在某些实施例中,远侧和近侧可扩张结构之间的间距可调。

[0016] 根据又一些其它方面,提供了一种在血管的第一位置去除闭塞物/凝块的方法。该方法可包括将根据至少一些实施例的前述装置引入血管内,将装置定位在血管的第一位置,通过调节装置的可重构元件的径向力和/或构造而与闭塞物/凝块接合;以及从第一位置去除闭塞物/凝块。在一些实施例中,去除闭塞物/凝块还包括选择如下的一个或多个:使闭塞物/凝块至少部分地与装置接合,将闭塞物/凝块拆解成小尺寸碎屑,并收集碎屑中的至少一部分;以及使血管的区域扩张。在一些其它实施例中,该方法可构造成应用于治疗中风。

[0017] 根据又一些其它方面,提供一种增大血管内流量的方法。该方法可包括将根据至少一些实施例的前述装置引入血管内,将装置定位在血管的需要增大流量的第一位置附近;以及调节装置的可重构元件的径向力和/或构造以使第一位置的区域扩张。

[0018] 根据又一些其它方面,提供了一种在血管的第一位置去除闭塞物/凝块的方法。该方法可包括将根据至少一些实施例的前述装置引入血管内,将装置定位在血管的第一

置附近,通过控制元件的近侧运动使与可重构元件相关联的支承元件延伸来支持可重构元件的扩张状态,通过控制元件的近侧运动使与可重构元件相关联的支承元件延伸来进一步支持可重构元件的更扩张状态,用处于扩张状态的可重构元件/可扩张隔室来抓取闭塞物/凝块,通过使控制元件向远侧运动来使可重构元件的构造向松弛状态变化,以及从第一位置去除闭塞物/凝块。

[0019] 根据又一些其它方面,提供了一种在血管的第一位置去除闭塞物/凝块的方法。该方法可包括将根据至少一些实施例的前述装置引入血管内,将装置定位在血管的位置远侧;向近侧拉动推送管件,以抓取处于扩张状态的两个可扩张结构之间的闭塞物/凝块,通过控制元件的近侧运动使与可重构元件相关联的支承元件延伸来支持可重构元件的扩张状态,用近侧可扩张结构来抓取闭塞物/凝块,用远侧可扩张结构来捕获闭塞物/凝块碎屑;在拉动控制元件时可选地收回装置以增大可扩张结构的径向力,并进一步支持可扩张结构的扩张状态,以及从第一位置去除闭塞物/凝块。

[0020] 根据本发明的又一方面,提供用于体腔内的装置。该装置可包括微型导管,该微型导管包括近端和远端、管件隔室、中心线以及接合隔室。接合隔室可包括近侧接合元件和远侧接合元件。远侧接合元件是与中心线相关联的可扩张元件,且近侧接合元件和远侧接合元件之间的间距可调。

[0021] 在一些实施例中,前述装置的远侧接合元件可包括形成支架的多个线材或支杆。远侧接合元件可相对于延伸到装置近端的中心线固定,由此,远侧接合元件在体腔内的位置由中心线的运动来控制。

[0022] 在一些其它实施例中,前述装置的近侧接合元件可以是包括多个线材或支杆的可扩张元件,并能扩张成漏斗状或锥形结构。近侧接合元件可与中心线相关联,并沿中心线运动。在一些替代实施例中,近侧接合元件相对于延伸到装置近端的管件隔室固定,由此,近侧接合元件在体腔内的位置由管件隔室的运动来控制。在又一些替代实施例中,近侧接合元件可以相对于管件隔室不固定,并构造成沿中心线自由运动。

[0023] 在又一些替代实施例中,近侧接合元件可位于微型导管的远端处。在某些实施例中,近侧接合元件不是微型导管的一体部分,而是固定在微型导管的远端处。

[0024] 在又一些其它实施例中,近侧接合元件可以是可膨胀或接合元件。在某些实施例中,近侧接合元件可以是微型导管的一体部分。

[0025] 在又一些其它实施例中,前述装置的近侧接合元件可包括微型导管的远端的构造成根据施加于微型导管远端的压力来改变形状的部分。在某些实施例中,近侧接合元件包括微型导管的远端的包括微型导管末端的部分和覆盖微型导管末端的薄管件层,其中,近侧接合元件的至少一部分构造成在移除薄管件层时改变形状。

[0026] 在又一些其它实施例中,任何前述装置的管件隔室可包括推送管件和连接管件。

[0027] 在又一些其它实施例中,装置的管件隔室可由一件具有可变刚度的管件制成,因而,管件隔室的远端是软和柔性的,因此,装置能通过曲折的解剖体,同时管件隔室的近端刚硬到加强装置的可推送性。

[0028] 在又一些其它实施例中,任何装置的中心线可包括线材、线缆或编织物。近侧接合元件和远侧接合元件之间的间距在约 0 到 50 毫米的范围内可调。

[0029] 在又一些其它实施例中,近侧接合元件可包括面向所述远侧接合元件的远端,近

侧接合元件的所述远端被弯曲、倒圆或弄成圆滑。在替代实施例中,装置的近侧接合元件包括面向远侧接合元件的远端,近侧接合元件的远端构造不与体腔的表面直接接触。

[0030] 根据本发明的另一方面,提供一种从体腔内的第一位置去除闭塞物的至少一部分的方法。该方法可包括将前述装置引入体腔内,将装置定位在第一位置附近,使闭塞物的至少一部分与接合元件接合;以及从第一位置去除接合的闭塞物。

[0031] 在一些实施例中,该方法的接合步骤可包括调节近侧接合元件和所述远侧接合元件中的一个或两个的位置,以使闭塞物的至少一部分与近侧接合元件和/或远侧接合元件接合。在一些其它实施例中,该方法的接合步骤可包括调节近侧接合元件和远侧接合元件中的一个或两个的位置,以使闭塞物的至少一部分接合到近侧接合元件和远侧接合元件之间。

[0032] 在一些其它实施例中,该方法还可包括在接合之后锁定近侧接合元件和远侧接合元件中的一个或两个的位置。在某些实施例中,在前述方法的接合步骤中,闭塞物的至少一部分与选择如下组的任何部件接合:体腔的表面、微型导管、管件隔室、近侧接合元件、远侧接合元件及其任何组合。

附图说明

[0033] 图 1 示出根据本发明的一些实施例的装置的非限制性说明性示例。

[0034] 图 2A-F 示出根据本发明的一些实施例的装置的特别是当该装置位于体腔内时的另一非限制性说明性示例,并示出根据本发明的一些实施例的用于从血管去除闭塞物/凝块和/或使血管扩张的机构的一些非限制性示例。

[0035] 图 3A-D 示出根据本发明的一些实施例的装置的又一非限制性说明性示例。

[0036] 图 4A-C 示出根据本发明的一些实施例的装置的另一非限制性说明性示例。

[0037] 图 5A-C 示出根据本发明的一些实施例的又一非限制性说明性装置。

[0038] 图 6A-C 示出根据本发明的一些实施例的装置的另一非限制性说明性示例。

[0039] 图 7A-D 示出根据本发明的一些实施例的装置的又一非限制性说明性示例。

[0040] 图 8A-D 示出根据本发明的一些实施例的装置的又一非限制性说明性示例。

[0041] 图 9A-E 示出根据本发明的一些实施例的装置的又一非限制性说明性示例。

[0042] 图 10A-D 示出根据本发明的一些实施例的装置的又一非限制性说明性示例。

[0043] 图 11 示出根据本发明的一些实施例的装置的另一非限制性说明性示例。

[0044] 图 12A-D 示出根据本发明的一些实施例的装置的又一非限制性说明性示例。

[0045] 图 13 示出根据本发明的一些实施例的装置的另一非限制性说明性示例。

[0046] 图 14A-D 示出根据本发明的一些实施例的制成装置的过程的非限制性说明性示例。

[0047] 图 15 示出根据本发明的一些实施例的包括装置的设备非限制性说明性示例。

[0048] 图 16 示出根据本发明的一些实施例的装置的另一非限制性说明性示例。

[0049] 图 17A-B 示出根据本发明的一些实施例的装置的另一非限制性说明性示例。

[0050] 图 18 示出根据本发明的一些实施例的包括装置的设备非限制性说明性示例。

[0051] 图 19A-H 示出根据本发明的一些实施例的去除血闭塞物/血凝块或者使血管扩张的方式的一些非限制性说明性示例。

[0052] 图 20A, A', B 和 C 示出根据本发明的装置的非限制性说明性示例。图 20A 示出装置的打开状态, 图 20B 示出装置的闭合状态(远侧接合元件和近侧接合元件之间), 而图 20C 示出具有远侧接合元件的端部闭合的远侧末端的装置。图 20A' 示出近侧接合元件由管件构成的实施例。

[0053] 图 21A-C 示出根据本发明的用于从体腔去除闭塞物或一部分闭塞物的方法的非限制性说明性示例。

[0054] 图 22A-D 示出根据本发明的用于从体腔去除闭塞物或一部分闭塞物的方法的又一非限制性说明性示例。

[0055] 图 23A-F 示出根据本发明的用于从体腔去除闭塞物的方法的一些其它非限制性说明性实施例。

[0056] 图 24 示出根据本发明的系统的非限制性说明性实施例。

[0057] 图 25 示出根据本发明的系统的又一非限制性说明性实施例。

[0058] 图 26A-B 示出根据本发明的装置的另一非限制性说明性实施例。图 26A 示出装置的打开状态, 而图 26B 示出装置的闭合状态。

[0059] 图 27A-C 示出根据本发明的用于从体腔去除闭塞物或一部分闭塞物的方法的非限制性说明性示例。

[0060] 图 28 示出根据本发明的系统的另一非限制性说明性实施例。

[0061] 图 29 示出根据本发明的系统的另一非限制性说明性实施例。

[0062] 图 30A-B 示出根据本发明的装置的又一非限制性说明性实施例。图 30A 示出装置的打开状态, 而图 30B 示出装置的闭合状态。

[0063] 图 31A-C 示出根据本发明的用于从体腔去除闭塞物的方法的又一非限制性说明性实施例。

[0064] 图 32A-B 示出根据本发明的装置的又一非限制性说明性实施例。图 32A 示出装置的打开状态, 而图 32B 示出装置的闭合状态, 在该闭合状态下, 闭塞物与装置接合。

[0065] 图 33A-B 示出根据本发明的装置的又一非限制性说明性实施例。图 33A 示出装置的打开状态, 而图 33B 示出装置的闭合状态, 在该闭合状态下, 闭塞物与装置接合。

[0066] 图 34A-B 示出根据本发明的装置的又一非限制性说明性实施例。图 34A 示出装置的打开状态, 而图 34B 示出装置的闭合状态, 在该闭合状态下, 闭塞物与装置接合。

[0067] 图 35 示出根据本发明的装置的又一非限制性说明性实施例。特别是, 附图示出装置的近侧部的替代实施例。

[0068] 图 36A-C 示出根据本发明的装置的又一非限制性说明性实施例。特别是, 附图示出微型导管包括可转变成不同形状的末端的实施例。

[0069] 图 37A-D 示出根据本发明的特别是使用图 36 中所示的装置从体腔去除闭塞物的方法的非限制性说明性实施例。

[0070] 图 38A-D 示出根据本发明的装置的又一非限制性说明性实施例, 在该实施例中, 微型导管在其大约远端处包括可转变末端。

[0071] 图 39A-B 示出根据本发明的装置的另一非限制性说明性实施例, 在该实施例中, 微型导管在其大约远端处包括可转变末端。

[0072] 图 40A-B 示出根据本发明的装置的另一非限制性说明性实施例, 在该实施例中,

微型导管在其大约远端处包括可转变末端。

[0073] 图 41A-C 示出根据本发明的装置的又一非限制性说明性实施例,在该实施例中,微型导管在其大约远端处包括可转变末端。

[0074] 图 42A-B 示出根据本发明的装置的又一非限制性说明性实施例,在该实施例中,微型导管在其大约远端处包括可转变末端。

[0075] 图 43A-B 示出根据本发明的装置的又一非限制性说明性实施例,在该实施例中,微型导管在其大约远端处包括可转变末端。

[0076] 图 44A-B 示出根据本发明的装置的又一非限制性说明性实施例,在该实施例中,微型导管在其大约远端处包括可转变末端。

[0077] 图 45A-B 示出根据本发明的装置的又一非限制性说明性实施例,在该实施例中,微型导管在其大约远端处包括可转变末端。

[0078] < 用于在附图中标示主要部件的附图标记 >

[0079] 1: 体腔表面

[0080] 5: 引导线

[0081] 10: 控制元件 / 中心线

[0082] 20: 推送管件

[0083] 21: 内推送管件

[0084] 22: 中间推送管件

[0085] 23: 外推送管件

[0086] 24: 远侧推送管件

[0087] 25: 近侧推送管件

[0088] 26: 引导器套管

[0089] 30: 微型导管

[0090] 31: 连接管件

[0091] 35: 微型导管毂

[0092] 40: 可扩张隔室

[0093] 41: 近侧元件连接件

[0094] 42: 近侧元件连结介质

[0095] 43: 外部近侧元件连接件

[0096] 50: 腔体表面

[0097] 60: 闭塞物 / 凝块

[0098] 65: 近侧接合元件

[0099] 70: 近侧元件标记

[0100] 80: 远侧元件连接件

[0101] 81: 远侧元件连结介质

[0102] 82: 外部远侧元件连接件

[0103] 90: 远侧接合元件

[0104] 100: 远侧元件标记

[0105] 120: 远侧部件控制手柄

- [0106] 130: 接头
- [0107] 140: 近侧部件的远侧连接件
- [0108] 150: 近侧部件的连接线
- [0109] 160: 近侧部件的段连接件
- [0110] 170: 可膨胀或可扩张元件
- [0111] 180: 注射通道
- [0112] 190: 注射器
- [0113] 195: 注射液体
- [0114] 200: 可转变的微型导管远侧末端
- [0115] 210: 外套管
- [0116] 220: 线材
- [0117] 230: 通道
- [0118] 410: 可重构元件
- [0119] 420: 支承元件
- [0120] 425: 封闭元件
- [0121] 430: 连接件
- [0122] 431: 外部连接件
- [0123] 432: 内部连接件
- [0124] 440: 标记
- [0125] 450: 远端连接件
- [0126] 451: 支承元件远侧连接件
- [0127] 452: 支承元件外部远侧连接件
- [0128] 453: 支承元件内部远侧连接件
- [0129] 455: 近侧可扩张结构的连接件
- [0130] 460: 近端连接件
- [0131] 461: 外部近端连接件
- [0132] 462: 内部近端连接件
- [0133] 463: 连接件连结介质(粘合剂、焊料等)
- [0134] 470: 调节管
- [0135] 471: 滑动管
- [0136] 475: 长内管
- [0137] 480: 高峰位置
- [0138] 490: 控制元件手柄管件
- [0139] 520: 连接线 / 抗拉伸线
- [0140] 540: 线圈
- [0141] 550: 远侧可扩张结构 / 远侧结构
- [0142] 560: 近侧可扩张结构 / 近侧结构
- [0143] 570: 连结介质
- [0144] 580: 推送管件连接点

[0145] 495: 远侧柔性线圈

具体实施方式

[0146] 本发明总地涉及用于诸如血管的体腔内的装置及其使用方法。在一些实施例中, 装置可定位在体腔内, 以使内腔扩张和 / 或从内腔去除闭塞物 / 凝块。尽管装置位于体腔需要治疗的部分内, 但操作者可操纵该装置以使内腔扩张和 / 或与闭塞物 / 凝块接合。

[0147] 本发明的一些方面提供构造成治疗血管内病症、包括但不限于是中风的装置和方法。在一些实施例中, 装置和方法构造成通过从血管去除闭塞物 / 凝块和 / 或使具有一定潜在狭窄的血管重新打开以在血管内恢复血流来治疗与缺血性中风相关的病症。

[0148] 血管的非限制性示例可包括动脉、静脉和起到循环系统的部件作用的手术植入的移植物和旁路。

[0149] 术语“闭塞物”或“凝块”一般包括部分或完全阻碍血管内腔的任何物质。闭塞物 / 凝块减缓或阻碍了流经内腔的流动(例如, 血流或任何其它生物流体)。闭塞物 / 凝块的示例可包括存在于血管以及脂肪或外来物体内的血闭塞物 / 血凝块和动脉粥样硬化斑块。

[0150] 术语“中风”一般包括部分地由于扰乱对脑部供血而引起的病症。扰乱可由血液的阻塞(例如, 缺血性中风)和 / 或出血(例如, 出血性中风)引起。特别是, 缺血性中风会由于血管的部分或基本上闭塞 / 结块而引起。缺血性病症的治疗可应用于在脑部以及诸如心脏的其它组织内存在的血管。由此, 本申请中公开的装置和方法不限于用于任何特定器官, 而是可应用于需要使内腔扩张或去除闭塞物 / 凝块以恢复血流的任何人体血管。此外, 根据本发明的装置和方法可用于治疗会造成除了局部缺血外的其它病症的静脉闭塞物 / 凝块。

[0151] 通过导管将该装置引入血管内。“导管”一般包括能插入体腔内的管状结构, 由此允许将装置和 / 或化学物质给送到需要进行治疗的人体区域。术语“微型导管”可指构造在诸如血管的相对较小的体腔内给送的导管。

[0152] 术语“管件”一般是指可包括用于保持和 / 或传导被包含的物体的中空空间(例如, 圆筒形)的诸如导管的管状物体。管件可由各种材料制成, 诸如金属、塑料、玻璃或其任何组合。

[0153] 术语“线材”一般是指拉成柔性细线或细杆的金属或非金属物体。线材的长度和厚度可从纳米级大幅变化到米级。

[0154] 术语“支架”一般是指暂时或永久地放置于例如血管、通道或管道的体腔内以治愈或解除障碍物的管状支承件。支架可由一个或多个线材构成。在一些情况下, 支架可以呈支杆的形式, 支杆一般是指形成框架的一部分并设计成抗压缩的杆或条。在一些其它情况下, 支架可以呈线网或丝网的形式。

[0155] 此外, 可以在不影响本发明范围的情况下进行对于本领域技术人员来说显然的许多不同变化和改型, 以适当地用于特定治疗病症。因此, 不仅在本申请中公开的示例、而且这种显然的变化和改型也应包含在本发明的范围内。

[0156] 本发明的一个方面与用于血管的装置有关, 该装置包括可重构元件、支承元件、控制元件、推送管件等。控制元件、可重构元件和支承元件形成可扩张隔室。

[0157] 血管的尺寸可从较小动脉和静脉中的约 0.03 英寸(约 1 毫米)的直径大幅变化到主动脉中的约 1.0 英寸(约 25 毫米)的直径。由此, 在一些实施例中, 装置的直径可从塌陷

状态下的约 0.01 英寸(约 0.25 毫米)到扩张状态下的 1.0 英寸(约 25 毫米)。

[0158] 在一些实施例中,控制元件可包括线材、编织物或线缆,并构造成控制可扩张隔室的构造。各种材料可用于制造控制元件,控制元件包括金属和非金属材料。用于控制元件的金属材料的一些非限制性示例可包括镍、钛、不锈钢、钴、铬和前述的任何合金,诸如是镍钛诺(NiTi)、不锈钢或钴铬合金。此外,具有控制元件的期望特性的任何聚合物或塑料可用于生产该控制元件。聚合物包括但不限于聚酰亚胺、PEEK(聚醚醚酮)、尼龙、PTFE(聚四氟乙烯)、PET(聚对苯二甲酸乙二醇酯)、聚丙烯等。包括但不限于 PTFE 涂覆的不锈钢或 PTFE 涂覆的 NiTi 的聚合物涂覆的金属也可用作控制元件;控制元件还可由复合材料制成,诸如, NiTi 或不锈钢上的 PTFE 或 FEP(氟化乙烯丙烯)管件等。

[0159] 控制元件的直径可从约 0.001 英寸到约 0.10 英寸。

[0160] 术语“可扩张隔室”一般包括能插入体腔内的结构,以通过打开血管或去除闭塞物/凝块使阻塞的血管再通或者消除局部流动收缩。可重构元件是形成可扩张隔室的一个部件。在一些实施例中,可重构元件可包括由管件或板材构成的支杆(参见图 3 中示例)。在一些其它实施例中,可重构元件可包括能形成网的多个线材(参见图 4 中示例)。在一些其它实施例中,可重构元件的多个线材可对准在一起并形成管状形状(参见图 11 中示例)。可重构元件可由金属材料制成。用于可重构元件的这种金属材料的一些非限制性示例包括镍钛(NiTi)合金、不锈钢、钛及其合金、以及钴铬(CoCr)合金等。或者,具有可重构元件的期望特性的任何聚合物或塑料可用作生产该可重构元件的材料。在其它替代示例中,可使用两种或更多种不同材料来构造可重构元件。

[0161] 在一些实施例中,用于可重构元件的支杆的直径可从约 0.0005 英寸变化到 0.1 英寸(12.5 μm 到 2500 μm)。在一些其它实施例中,用于可重构元件的线材的直径可从约 0.0005 英寸变化到 0.1 英寸(12.5 μm 到 2500 μm)。可重构元件大致柔性并具有弹性或超弹性特性。因此,可重构元件的构造可重构。可重构元件通常包括至少三种不同的构造,它们被称为“塌缩(即,轴向延伸、折叠或闭合)”构造、“松弛(即,未折叠或打开)”构造以及“扩张(即,径向延伸或径向扩张)”构造。可重构元件的完全塌缩构造一般表示可重构元件的外半径变为最小而其轴向长度最大的状态。当装置位于其引导器套管或微型导管内时,可重构元件处于其塌缩构造。当将可重构元件从微型导管或引导器套管推出时,并且如果没有压缩力,即没有任何约束,可重构元件处于其松弛状态。可重构元件的扩张构造一般表示可重构元件的外半径进一步扩张的状态。可重构元件的构造可通过控制元件或支承元件控制从其塌缩状态或松弛状态到扩张状态。外直径可随可重构元件的构造变化而变化,并且在塌缩构造下可从约 0.01 英寸变化到 0.5 英寸(0.25mm 到 12.5mm)。扩张构造直径的范围从约 0.04 英寸到 1.0 英寸(1.0mm 到 25mm)。可重构元件的轴向长度还可随其构造变化而变化。在某些实施例中,可重构元件的轴向长度可在其变得塌缩时增大。相反,可重构元件的轴向长度可在其变得扩张时缩短。可重构元件的轴向长度的范围可从约 0.1 英寸到 3 英寸(2.5mm 到 75mm)。

[0162] 根据本发明的一些实施例,支承元件包括多个线材或支杆。支承元件的多个线材或支杆可呈大致直线形状或大致非直线形状。在某些实施例中,支承元件呈丝网形式。在其它实施例中,支承元件呈编织物形式。在其它实施例中,支承元件呈通过激光切割由管制成的有孔管状形式。在其它实施例中,支承元件连同可重构元件呈通过激光切割或光蚀刻

工艺制成的有孔板形式。支承元件一般构造成调节可重构元件的构造,由此提供对可重构元件的径向扩张程度的精密控制。装置的这种精密控制机构在许多方面是有益的。在将装置递送并释放到选定的治疗部位之后,看起来似乎自扩张可重构元件的半径和/或径向力可小于对于该应用所期望的半径和/或径向力。在这种情况下,支承元件可向内腔进一步提供径向力/压力。可期望有时增加或减少装置施加于周围组织或闭塞物/凝块的径向力大小。在这种情况下,可动态控制可重构元件的构造,以提供根据本发明的装置的较大范围的径向力。该装置还可在递送、移除和/或操作该装置的同时减少对血管造成不必要的冲击或损伤或将其减到最少。在一些实施例中,当递送该装置时,在装置在血管内释放并可扩张到大于内腔直径时,它会向内腔提供不期望的压力和/或冲击。在这种情况下,可通过在必要时控制元件和支承元件的运动来减小可重构元件的直径和径向力。在其它情况下,当移除装置时,径向力会太大,并且在拉回通过血管时可能会引起损伤。相似地,可通过控制元件和支承元件的运动来减小可重构元件的直径和径向力。

[0163] 本发明的又一方面与用于血管的装置有关,该装置包括微型导管、中心线、管件部件和接合部件/隔室。接合部件/隔室可包括近侧接合元件和远侧接合元件。在一些实施例中,远侧接合元件可与中心线相关联。近侧和远侧接合元件中的一个或两个可以是接合元件。在某些实施例中,远侧和近侧接合元件之间的间距可调。远侧和近侧接合元件之间的间距可在至少一些实施例中约从 0mm 调节到 50mm。在某些实施例中,远侧和近侧接合元件之间的间距可调节为约 0mm, 5mm, 10mm, 15mm, 20mm, 25mm, 30mm, 35mm, 40mm, 45mm 和 50mm 以及它们之间的任何范围。在替代实施例中,远侧和近侧接合元件之间的间距可调节到大于 50 毫米。

[0164] 在一些实施例中,可将装置引入血管。血管的尺寸可从较小的动脉和静脉中的约 0.03 英寸(约 1 毫米)的直径大幅变化到较大动脉中的约 1.0 英寸(约 25 毫米)。由此,在一些实施例中,装置的直径可从约 0.01 英寸(约 0.25 毫米)到 1.0 英寸(约 25 毫米)。同样,当接合隔室打开(或扩张)或闭合(或塌缩)时,在操作过程中单个装置的直径可以改变。

[0165] 在一些实施例中,装置还包括中心线。中心线可穿过管件部件,并自由地运动通过管件部件。在某些实施例中,中心线与接合隔室相关联。更具体地,中心线可与远侧接合元件和近侧接合元件相关联。相关联一般是指两个物体之间的任何类型的连接。相关联包括固定,因此,当两个物体相关联时,一个物体的运动将受到另一物体的阻碍。换言之,一旦两个物体以固定方式相关联,则两个物体的运动将同步。然而,相关联不一定表示一个物体固定到另一个。由此,当两个物体相关联但不在固定状态下时,一个物体相对于另一物体的运动不受到阻碍。因此,在至少一些实施例中,均与中心线相关联的远侧接合元件和近侧接合元件可沿中心线自由运动。

[0166] 根据某些实施例,中心线与远侧接合元件固定或连结。在一些情况下,远侧接合元件的近端可连结到中心线的远端。中心线和远侧接合元件之间的关联(即,连接)可通过诸如焊接、胶粘或夹住之类的各种方式完成。在一些实施例中,中心线和远侧接合元件之间的接头被远侧元件连接件所覆盖。或者,将不提供覆盖物来围绕连接的控制线和远侧接合元件。

[0167] 在一些实施例中,中心线可包括线材、编织物或绳缆或呈线材、编织物或绳缆的形式。各种材料可用于制造中心线,这些材料包括金属和非金属材料。用于中心线的金属材料

料的一些非限制性示例可包括镍、钛、不锈钢、钴、铬以及前述任何合金,诸如镍钛诺(NiTi)或钴铬合金。此外,具有呈中心线的期望特性的任何聚合物或塑料可用于生产中心线。聚合物包括但不限于是聚酰亚胺、PEEK(聚醚醚酮)、尼龙、PTFE(聚四氟乙烯)、PET(聚对苯二甲酸乙二酯)、聚丙烯等。包括但不限于 PTFE 涂覆的不锈钢或 PTFE 涂覆的 NiTi 的聚合物涂覆的金属也可用作中心线。还可施加亲水涂层。可部分地施加这种涂层,以减小中心线和管件隔室之间的摩擦。中心线也可由复合材料制成,诸如 NiTi 线上的 PTFE 或 FEP(氟化乙烯丙烯)管件或者不锈钢上的 PTFE 或 FEP 管件等。中心线的直径范围可从约 0.001 英寸到 0.25 英寸。在某些实施例中,中心线的直径可以约为 0.001, 0.002, 0.003, 0.004, 0.005, 0.006, 0.007, 0.008, 0.009, 0.011, 0.012, 0.013, 0.014, 0.015, 0.016, 0.017, 0.018, 0.019, 0.020, 0.021, 0.022, 0.023, 0.024 和 0.025 英寸。或者,中心线的直径可大于 0.025 英寸。

[0168] 术语“接合隔室”一般包括这样的结构,即,该结构可压缩成小直径并插入体腔内,并且在释放压缩时扩张到较大直径,以通过打开血管或去除闭塞物的至少一部分来使阻塞的血管再通或者消除局部流动收缩。接合隔室可包括远侧接合元件和近侧接合元件。远侧接合元件和近侧接合元件在至少一些实施例中可以是编织结构。它们还可通过激光切割的海波管或者光蚀刻的板材来制成。会需要热处理使它们处于期望形状,例如锥形或圆柱形形状。

[0169] 在一些实施例中,接合元件可包括由管件或板材制成的支架。在一些其它实施例中,接合元件可包括能形成网的多个线材。在一些情形下,远侧接合元件的远端可如图 20C 中可见那样是闭合的。或者,远侧接合元件的远端可保持打开,如图 20A 中可见那样。

[0170] 远侧接合元件可由金属材料制成。用于远侧接合元件的这种金属材料的一些非限制性示例包括镍钛(NiTi)合金、不锈钢、钛及其合金以及钴铬(CoCr)合金。或者,可使用具有针对远侧接合元件的期望特性的任何聚合物或塑料。在一些实施例中,远侧接合元件由柔性材料制成。在其它替代示例中,远侧接合元件能使用诸如聚合物涂覆的金属材料的两种或更多种不同材料来制成。

[0171] 在一些实施例中,远侧接合元件的直径可从约 1 毫米变化到其扩张状态下的约 8 毫米。在某些实施例中,处于其扩张状态的远侧接合元件的直径可以约为 1mm, 2mm, 3mm, 4mm, 5mm, 6mm, 7mm 和 8mm 或它们之间任何范围。在一些其它实施例中,远侧接合元件的长度可从约 10mm 变化到 40mm。在某些实施例中,远侧接合元件的长度可约为 10mm, 15mm, 20mm, 25mm, 30mm, 35mm 和 40mm 或者任何它们之间的范围。此外,在替代实施例中,远侧接合元件的长度可大于 40mm。

[0172] 远侧接合元件一般是柔性的,并且具有弹性或超弹性特性。由此,远侧接合元件的形状可变化。远侧接合元件通常包括至少两种不同的构造,这些构造被称为“塌缩(即,折叠或闭合)”构造以及“松弛(即,未折叠或打开)”构造。远侧接合元件的塌缩构造一般表示远侧接合元件的外半径变为最小的状态。当远侧接合元件位于微型导管内时,远侧接合元件处于其塌缩构造。当将远侧接合元件推出微型导管时且如果没有约束远侧接合元件的压缩力,远侧接合元件处于其松弛状态。在一些实施例中,远侧接合元件可包括可自扩张的支架。由此,一旦将支架推出微型导管或者撤回微型导管从而使支架留在微型导管远侧,则支架不受约束,并且它将自行扩张。由于远侧接合元件的柔性特性,可通过向微型导管轻轻拉

动或者推动远侧接合元件而将远侧接合元件容易地放置于微型导管内。

[0173] 根据本发明的一些实施例,近侧接合元件可包括由管件或板材制成的一个或多个线材。在一些其它实施例中,近侧接合元件可包括能如图 20 中所示形成为筐状形状的一个或多个线材。或者,近侧接合元件能制造成许多形状或形式。例如,近侧接合元件的可面向体腔表面的远端可进行修改,以减少对体腔表面的任何损伤。由此,使近侧接合元件的远端基本上平滑,以使得即使与近侧接合元件直接接触,体腔也保持很大程度上不受损。同样,近侧接合元件的远端将例如如图 30 中所示那样弯曲,因而,尖锐的端部将不与体表面直接接触。此外,近侧接合元件的形状或形式可在操作过程中变化。因此,在某些实施例中,近侧接合元件的远端、更具体来说是远侧末端可构造成在操作过程中移除。例如,如图 32-34 中所示,近侧接合元件的远侧末端直接(例如,图 33 和 34)或间接地(例如经由如图 32 中所示的连接线)连接到连接件。借助这些构造,近侧接合元件的远侧末端将通过连接件的运动而移动离开体腔。更具体来说,当远侧元件的近侧连接件连同凝块向近侧运动时,它可向近侧拉动近侧接合元件的远侧末端,并将近侧元件折叠成期望的筐形,其中末端为圆形或非创伤性的。因此,至少在一些实施例中,由于与体腔表面(例如,血管)直接接触而产生的损伤体腔的风险将大幅降低。这些末端特征还在需要时在内腔中向前推动近侧接合元件,并且不损伤体腔表面。

[0174] 在一些实施例中,近侧接合元件构造成大幅改善凝块接合和收回效率。例如,如图 3 中所示那样,当使用根据一些实施例的装置时,闭塞物可设置在近侧和远侧接合元件之间。该设计具有通过用两个独立的接合元件保持闭塞物或凝块来牢固接合闭塞物或凝块的改善的能力。

[0175] 近侧接合元件可由金属材料制成。用于近侧接合元件的这种金属材料的一些非限制性示例包括镍钛(NiTi)合金、不锈钢、钛及其合金以及钴铬(CoCr)合金。或者,可使用具有针对近侧接合元件的期望特性的任何聚合物或塑料。在一些实施例中,近侧接合元件由柔性材料制成。在其它替代示例中,近侧接合元件能使用两种或更多种不同材料来制成,如图 34 中所示。

[0176] 在一些实施例中,近侧接合元件的直径可从约 1 毫米变化到其扩张状态下的约 8 毫米。在某些实施例中,处于其扩张状态的近侧接合元件的直径可以约为 1mm, 2mm, 3mm, 4mm, 5mm, 6mm, 7mm 和 8mm 或任何它们之间的范围。在一些其它实施例中,近侧接合元件的长度可从约 2mm 变化到 40mm。在某些实施例中,近侧接合元件的长度可约为 2mm, 5mm, 7mm, 10mm, 12mm, 15mm, 17mm, 20mm, 22mm, 25mm, 27mm, 30mm, 32mm, 35mm, 37mm, 40mm 或任何它们之间的范围。此外,在替代实施例中,近侧接合元件的长度可大于 40mm。

[0177] 近侧接合元件一般是柔性的,并且具有弹性或超弹性特性。由此,近侧接合元件的形状可变化。近侧接合元件通常包括至少两种不同的构造,这些构造被称为“塌缩(即,折叠或闭合)”构造以及“松弛(即,未折叠或打开)”构造。近侧接合元件的塌缩构造一般表示近侧接合元件的外半径变为最小的状态。当近侧接合元件位于微型导管内时,近侧接合元件处于其塌缩构造。

[0178] 当近侧接合元件不在微型导管内并且不受约束时,近侧接合元件处于其松弛构造。

[0179] 在一些实施例中,近侧接合元件由弹性或超弹性材料制成,并由此自扩张。由于其

柔性特性,可通过向微型导管轻轻拉动会推动近侧接合元件而将近侧接合元件容易地放置于微型导管内。在其它替代实施例中,近侧接合元件可具有多于两种的不同状态。例如,如图 32-34 中所示那样,近侧接合元可构造成在操作过程中改变其形状,并且由此将呈完全塌缩和完全松弛状态之间的许多不同状态。

[0180] 在一些实施例中,可将一种或多种标记加到装置。这种标记可包括不透辐射材料,这些材料有助于监测装置在体内的位置和/或运动。不透辐射标记的一些非限制性示例可包括金、金合金、CoCr 合金、铂或铂合金。标记也可呈不透辐射涂层的形式。标记可加到装置中的任何位置。在一些实施例中,可将一种或多种标记加到远侧接合元件处,因此,将确定远侧接合元件在体内的位置。在一些其它实施例中,可将一种或多种标记加到近侧接合元件处,因而将确定近侧接合元件在体内的位置。在又一些其它实施例中,远侧和近侧接合元件均包含标记。远侧和近侧接合元件中的每个内的标记可以是相同或不同材料。或者,可将一种或多种标记加到中心线和/或管件隔室。在一些实施例中,标记可以约为 0.10 到 4mm 长,而直径约为 0.001 到 0.030 英寸。然而,任何尺度(例如,长度、直径、尺寸和质量)和标记的形状方面的任何变型是合适的。

[0181] 在一些实施例中,装置可包括管件隔室。管件隔室可包括多个管件元件。这种管件元件可包括推送管件和连接管件。推送管件还可在至少一些实施例中包括内推送管件、中间推送管件、外推送管件。同样在替代实施例中,推送管件可包括远侧推送管件和近侧推送管件。各种材料可用于制造管件元件,它们包括金属和非金属材料。在一些实施例中,远侧推送管件和/或外推送管件可由诸如 PTFE 或 PET 的光滑和柔性聚合物制成。中间和近侧推送管件可由镍钛诺超弹性材料、不锈钢、CoCr 合金、钛合金或聚合物(诸如,聚酰亚胺、PEEL 等)制成。管件元件中的一个或多个也可涂覆有诸如 PTFE 涂层、亲水涂层等的润滑材料。管件元件也可由复合材料制成,诸如镍钛诺线材上的 PTFE 或 FEP(氟化乙烯丙烯)管件或者不锈钢上的 PTFE 或 FEP 管件等。

[0182] 中心线可呈线材、编织物或管件的形式。用于中心线的金属材料的一些非限制性示例可包括镍、钛、不锈钢、钴、铬以及前述任何合金,诸如镍钛诺(NiTi)或钴铬合金。此外,具有呈中心线的期望特性的任何聚合物或塑料可用于生产中心线。聚合物包括但不限于是聚酰亚胺、PEEK(聚醚醚酮)、尼龙、PTFE(聚四氟乙烯)、PET(聚对苯二甲酸乙二酯)、聚丙烯等。包括但不限于 PTFE 涂覆的不锈钢或 PTFE 涂覆的 NiTi 的聚合物涂覆的金属也可用作中心线。还可施加亲水涂层。

[0183] 在一些实施例中,推送管件和连接管件的直径可约为 0.001 到 0.050 英寸。在其它实施例中,推送管件和连接管件的直径可小于 0.001 英寸或者超过 0.050 英寸。在又一些其他实施例中,装置可包括推送管件,而没有连接管件。

[0184] 为了说明的目的,在以下附图中提供根据本发明的装置的一些非限制性和说明性示例。尽管为了说明的目的文中仅描述了少数示例性应用,但也可进行对于本领域普通技术人员来说显然的许多不同改型和修改,而不影响本发明的范围。因此,不仅在本申请中公开的示例、而且明显的改型和修改也应包含在本发明的范围内。

[0185] 参见图 1,示出包括可重构元件(410)、支承元件(420)、控制元件(10)和推送管件(20)的装置。可扩张隔室(40)可存在于引导器套管(26)内。

[0186] 在临床手术过程中,可将该装置经由引导器套管(26)推入微型导管(30)内,并且

进一步推到损伤部位,如图2中所示。可重构元件(410)可连接到推送管件(20),在此情况下是中空薄管。支承元件可与控制元件相关联。控制元件(10)的至少一部分可由推送管件(20)围绕,并且控制元件(10)可自由地滑动通过推送管件(20)。由此,控制元件(10)和推送管件(20)的运动可不受彼此的限制,并且分别可沿装置的轴向轴线自由滑动,如图3B和4B中所示。可借助引导线将微型导管放置于闭塞物/凝块位置处。推送管件可用于将装置推入微型导管。然后,在治疗过程中可将该装置的可扩张隔室推出微型导管。可通过向近侧或远侧拉动或推动控制元件来调节可重构元件的径向力和直径。

[0187] 图2示出从血管去除闭塞物/凝块所需步骤。由此,内腔表面(50)可代表血管壁。在一些实施例中,可将该装置递送到存在有闭塞物/凝块(60)的内腔区域(50)。在递送过程中,借助引导线(5),微型导管的远侧末端可行进到阻塞部位,并穿过闭塞物/凝块(60),如图2A中所示。血管造影导引可用于确定微型导管相对于血管和闭塞物/凝块的位置。

[0188] 在移除引导线(5)之后,可将收回装置引入微型导管(30)内。可将可扩张隔室(40)推过微型导管(30)直到可扩张隔室(40)的远端到达微型导管的远端为止(图2B)。如图2C中所示,当推送管件(20)保持稳定时,可通过向近侧拉动微型导管(30)来略撤回微型导管(30)。可扩张隔室(40)暴露于闭塞物/凝块(60),并部分地打开,如图2D中所示。操作者可调节可重构元件(410)的构造,即可重构元件的径向力、直径和轴向长度,以允许可重构元件(410)使闭塞物/凝块(60)裂开或与闭塞物/凝块(60)接合、破坏闭塞物/凝块(60)的至少一部分和/或使血管内腔扩张。可重构元件构造的这种调节可至少通过向远侧或近侧拉动或推动控制元件(10)来实现,如图2E中所示。在闭塞物/凝块(60)与可扩张隔室(40)接合之后,可从血管收回装置连同微型导管(30),如图2F中所示。

[0189] 或者,可先将微型导管放置到超出闭塞物/凝块,可扩张部件可在闭塞物/凝块远侧打开。在操纵并调节可重构元件的直径和径向力之后,可向近侧拉动该装置,而闭塞物/凝块可被可扩张隔室捕获并被拉出血管。

[0190] 尽管图2的实施例示出从内腔的阻塞部位基本上去除闭塞物/凝块,但可使用诸如破坏闭塞物/凝块的至少一部分的替代治疗。闭塞物/凝块经常是基本上软的,并且能以相对微小的冲击来使其断开。在这种情况下,可重构元件可将闭塞物/凝块部分地分裂成更小的部分。用装置收集并从主体去除各片阻塞材料。如果在可重构元件在血管内径向扩张时可重构元件的线材或支杆切过闭塞物/凝块(例如,血凝块),则当它扩张到血管的全直径时,闭塞物/凝块的各部分变得包含到可扩张隔室内或与可扩张隔室接合。通过将可重构元件部分地拉到微型导管末端内来使可重构元件略塌缩,可重构元件各单元的线材/支杆之间的开口将变得更小。这会将闭塞物/凝块保持在可扩张隔室内。支承元件还可有助于将闭塞物/凝块保持在可扩张隔室内。然后,可从血管拉出包含闭塞物/凝块的各部分的整个装置。在其它替代实施例中,该装置可使内腔扩开/扩张成在内腔的阻塞部位处重新形成流动。闭塞物/凝块也可以不用软到足以允许装置与闭塞物/凝块基本上接合。在这种情况下,可重构元件的构造可控制成与闭塞物/凝块的至少一部分接合,并使其运动。当可重构元件的直径进一步打开时,它的线材或支杆将推抵于闭塞物/凝块。当向近侧拉动时,可重构元件和闭塞物/凝块之间的摩擦会引起闭塞物/凝块从血管壁脱开并被去除。

[0191] 图3和4示出根据本发明的一些实施例的装置。该装置包括推送管件(20),该推送管件(20)与可重构元件(410)的近端连接件(460)连接。推送管件以及控制元件基本上

是长的。在一些实施例中,推送管件以及控制元件可长到足以使操作者经由推送管件以及控制元件从体外控制收回装置。在一些实施例中,推送管件以及控制元件可延伸约 100cm, 110cm, 120cm, 130cm, 140cm, 150cm, 160cm, 170cm, 175cm, 180cm, 185cm, 190cm 或 200cm。如果必要,这些线材可延伸超过 200 厘米。

[0192] 可重构元件(410)可包括至少两个端部,即远端和近端。可重构元件(410)的远端一般是指在近端之前进入人体的端部。可重构元件(410)的近端一般是指使可重构元件(410)与推送管件(20)相关联的端部。

[0193] 在一些实施例中,可重构元件(410)的远端闭合,这意味着可重构元件的线材或支杆(410)的远端借助例如熔化焊接、焊料焊接或胶粘、在使用或不使用连接件(430 或 450)的情况下保持在一起。在一些实施例中,控制元件(10)的远端和支承元件(420)的远端可借助例如熔化焊接、焊料焊接或胶粘等、在使用或不使用连接件(451)的情况下保持在一起。或者,远端连接件(451)可用于联接控制元件(10)的远端和支承元件(420)的远端。在可重构元件(410)的近端处有外侧近端连接件(461)和内侧近端连接件(462),这两个近端连接件都是如图 3B-8B 中所示的管状结构。可重构元件(410)的近侧线材或支杆端部可置于外侧近端连接件(461)和内侧近端连接件(462)之间,并且通过上述手段固定在位。控制元件(10)可通过内侧近端连接件(462)的内腔,以使它能在内侧近端连接件(462)内自由滑动。

[0194] 该装置还包括支承元件(420),该支承元件(420)可与可重构元件的线材/支杆(410)以及控制元件(10)相关联。支承元件(420)可经由连接件(430 和 / 或 451)与控制元件(10)相关联,例如如图 7 中所示。在一些实施例中,支承元件(420)以基本上固定不动的方式与控制元件(10)的远端相关联。由此,当向近侧拉动控制元件(10)时,可向近侧拉动支承元件(420)的远端。支承元件(420)可如图 3 和 4 中所示附连到可重构元件(410)。在该实施例中,附连到可重构元件(410)的支承元件端部可向外运动,从而使可重构元件(410)扩大(如图 3C 和 4C 中所示)。这将增大可重构元件的径向力。在其它实施例中,支承元件(420)由与如图 3 和 14 中所示的可重构元件(410)相同的材料制成。由此,无须连结这两个部件。在此实施例中,向近侧拉动控制元件(10)将使支承元件(420)与控制元件(10)之间的角度 α (图 3C)扩大,从而使可重构元件(410)变大(如图 3D 中所示)。这将增大可重构元件的径向力。

[0195] 如图 3B 和 4B 中所示,控制元件(10)可存在于近侧内连接件(462)的内腔内,并自由地滑动通过连接件(460)。在一些实施例中,可将标记(440)加到装置,例如,支承元件(420)在标记处与线材/支杆(410)相关联。这种标记可包括不透辐射材料,该材料有助于看到/监测装置在人体内的位置和/或运动。不透辐射标记的一些非限制性示例可包括金和/或铂。如果期望,可在支承元件(420)和可重构元件(410)的线材/支杆、控制元件或支承元件(420)的任何部分之间的一些附连点处加入标记。例如,可将标记施加于可重构元件的大约远端和/或近端处,或者涂覆到线材和/或连接件的任何部分上。还可通过使用 CoCr 合金作为可重构元件、控制元件和/或支承元件来实现装置的不透辐射特性。

[0196] 能以多种方式来构造支承元件。图 3、13 和 14 中所示的具体示例是内在结构,即,支承元件和可重构元件由管件或平板的一件材料制成。由此,不需要它们之间的附加连结/粘合。

[0197] 图 4 包括呈大致线性线材形式的多个支承元件。用于制造支承元件的材料是金属或非金属材料。用于支承元件的一些非限制性材料包括但不限于是镍、钛、NiTi、不锈钢、钴铬和前述任何合金。通过控制元件和支承元件的运动可控制可重构元件的构造。在使微型导管穿过闭塞物 / 凝块之后, 可将该装置递送到微型导管内。当该装置从微型导管脱开时 (参见例如图 2), 它可露出并与闭塞物 / 凝块接合。

[0198] 在一些实施例中, 可重构元件一旦离开微型导管, 则可以自扩张, 并且可通过向远侧或近侧拉动或推动控制元件还可进一步改变可重构元件的构造。通过控制元件和支承元件可进一步控制可重构元件的径向力。如果自扩张隔壁构造造成扩张到大于血管直径, 该自扩张过程会向壁施加过大的力。这会造成对血管伤害, 从而造成撕裂或穿孔。由此, 有益的是能以精密的方式控制可重构元件的构造 (包括可重构元件的径向力、尺寸和形状) 以实现安全和有效的治疗。此外, 在可重构元件实现其标称自扩张直径之后, 可重构元件需要进一步扩张, 或可重构元件的径向力需要进一步增大。例如, 会需要加强可重构元件的径向力以与闭塞物 / 凝块基本上接合、切过闭塞物 / 凝块和 / 或移动闭塞物 / 凝块。因此, 所期待的是, 需要在治疗过程中动态改变可重构元件的构造。根据本发明的至少一些实施例的装置设计成提供可重构元件的这种动态控制。

[0199] 或者, 可重构元件可以不是自扩张的, 并由此需要控制可重构元件的完全打开和闭合。在这种情况下, 当可扩张隔壁从微型导管脱开以治疗内腔中的病症时, 可以向近侧略拉动控制元件, 以使可重构元件可轴向扩张。类似于自扩张的可重构元件, 该非自扩张的可重构元件的进一步扩张或塌缩将通过附连到支承元件的控制元件的运动来控制。

[0200] 在一些实施例中, 装置包括至少两个机构来控制可重构元件的构造。首先, 由支承元件提供控制。支承元件一般由控制元件控制。在控制元件进行远侧运动时, 支承元件也变得沿轴向轴线延伸。当控制元件向近侧缩回时, 支承元件将径向扩张, 这将向可重构元件提供进一步支承压力。当控制元件更向近侧运动时, 支承元件将变得更扩张, 由此控制元件和支承元件之间的角度 (图 3 和 4 中的 α) 将增大。角度 α 的范围可以在约 0 度到 90 度之间。此外, 将通过控制元件的运动来控制可重构元件的构造 (例如, 可重构元件的总体形状、轴向长度和外直径)。控制元件的向远侧运动将使可重构元件转换到其塌缩状态, 即可重构元件轴向延伸且其外直径缩小, 同时轴向长度增加。控制元件的向近侧运动将使可重构元件的构造向其扩张状态转换, 即可重构元件变得径向扩张。由此, 可重构元件的轴向长度可缩小, 而外直径增加。可重构元件向其扩张状态的这种转换将加强可重构元件的径向力。

[0201] 连接件可以是诸如不锈钢 (SS)、铂、金、镍钛诺管件的金属海波管件, 诸如聚酰亚胺管件的塑料管件, 或者可以由不锈钢、铂合金、金或 CoCr 合金线材等构成的一段线圈。当使用诸如金、铂等的透辐射材料时, 连接件也可用作标记。

[0202] 在一些实施例中, 将在血管内控制可重构元件的构造, 以从内腔去除闭塞物 / 凝块和 / 或使内腔扩张。一旦闭塞物 / 凝块与可重构元件接合, 则该装置从内腔撤回并最终从人体撤出。当从内腔撤回装置时, 与闭塞物 / 凝块接合的可扩张隔壁可部分地撤回微型导管内或留在微型导管远侧。具有闭塞物 / 凝块的可扩张隔壁和微型导管可同时拉回到具有较大内直径的引导导管内。可使用荧光检查法来确定微型导管、引导导管和可扩张隔壁之间的相对位置。

[0203] 图 5 和 6 中提供该装置的替代实施例。在该特定实施例中, 支承元件(420)包括如图 5 中所示的多个线材或如图 6 中所示的编织结构。支承元件(420)从可重构元件或线材/支杆(410)的近端延伸, 并止于可重构元件(410)的远端(在图 5-7 中标记为“*”)之前, 由此形成双层可扩张隔室。支承元件(420)的远端可与控制元件(10)的远侧末端固定。

[0204] 如图 5B 和 6B 中所示, 可通过近侧连接件(460)来使可重构元件(410)与支承元件(420)相关联。近侧连接件可包括至少两个隔室, 即, 外近侧连接件(461)和内近侧连接件(462)。可重构元件线材的近端和支承元件的近端用粘合剂、熔化焊接、焊料焊接来固定(463), 或通过近侧外部连接件和内部连接件之间的机械连接来固定。在一些其它实施例中, 这些内近侧连接件和外近侧连接件可以是管状或线圈结构, 并且控制元件可自由地滑动通过内部连接件。

[0205] 在上述装置中, 当控制元件(10)向近侧撤回时, 它会引起支承元件(420)扩张, 从而向可重构元件线材/支杆提供支承, 这导致可重构元件(410)的直径的扩大和径向力的扩大。

[0206] 图 7 中提供该装置的又一替代实施例。在该特定示例中, 支承元件(420)构造成包括两个高峰(plateau)位置(480), 在这两个位置, 支承元件(420)可向可重构元件线材/支杆(410)提供最大的支承强度。支承元件(420)可形成如图 7 中可见的正弦形状。支承元件的远端固定到控制元件(10)。可重构元件和支承元件的近端都如图 7B 中所示固定到近侧连接件。如图 7C 中所示, 支承元件的中间(薄)部段经由中间外部和内部管件连接件连接, 而控制元件在近侧和中间连接件(430)内自由运动。

[0207] 在支承元件内具有两个或更多个高峰的一个优点是能在较佳位置选择性地加强径向力。如图 7 中容易可见, 可重构元件(410)在两个高峰位置(480)处从支承元件(420)获得最大的支承强度, 并且当它远离高峰时支承强度将减小。由此, 如果期望, 装置可向内腔区域提供较大范围的径向力。此外, 支承元件的数目也可从两个变化到更多个, 这些支承元件可周向分布在控制元件(10)周围, 以使装置的径向力和/或外部形状和密度变化。

[0208] 图 8 中提供该装置的又一替代实施例。在该特定示例中, 控制元件(10)延伸通过支承元件(420)的远端, 并到达可重构元件(410)的远端。如图 8C 中可见, 支承元件的远端可沿控制元件自由地滑动。支承元件(420)可在支承元件(420)的远端处例如经由连接件(451)与控制元件(10)相关联。连接件 450 由支承性远侧内部连接件(453)和支承性远侧外部连接件(452)构成, 从而在它们之间连结支承元件的远端。控制元件(10)可在内部连接件的内腔中滑动。当向近侧拉动控制元件(10)时, 可重构元件的连接件(450)和支承元件的远端(451)之间的距离变短。当两个连接件彼此接触时, 支承元件将扩张, 从而压抵于可重构元件, 并且产生附加的径向力, 如图 8D 中可见那样。图 8 的该特定实施例的一个益处是支承元件的远端(451)和可重构元件的远端(450)轴向对准, 从而在向近侧拉动控制元件时避免支承元件末端倾斜。当该装置缩回到微型导管内时, 还可避免对可重构元件(410)和支承元件(420)之间的线材轴向长度的限制。

[0209] 图 9 中提供该装置的又一替代实施例。在该特定示例中, 支承元件(420)包括至少两个高峰位置(480)。此外, 支承元件(420)的远端可以不是在装置的远端附近基本上固定不动的。因此, 支承元件(420)可在支承元件的远端处例如经由连接件(430)与控制元件(10)相关联。这些连接件(430)可构造成沿控制元件自由滑动。连接件(430)的结构还由

内部连接件和外部连接件构成,以确保控制元件能自由地运动通过连接件。由此,当向近侧拉动控制元件时,可重构元件的远端连接件(450)可运动到更靠近于支承元件的远端。当两个连接件彼此接触时,支承元件将扩张,并且将推抵于可重构元件(410),从而如图9E中可见那样产生附加的径向力。

[0210] 图9的该特定装置可提供至少三个益处。支承元件包括多于一个高峰位置,高峰位置可允许在较佳位置处选择性地加强径向力。由此,如果期望,装置可向内腔区域提供较大范围的径向力。此外,类似于图8的装置,支承元件的远端和支承元件的远端通过控制元件轴向对准,从而在向近侧拉动控制元件时避免末端倾斜。当装置缩回到微型导管内时,还可避免对可重构元件(410)和支承元件(420)之间的线材轴向长度的约束。

[0211] 根据本发明的一些实施例,可将调节管用于所有所述设计中的装置。如图10中可见,调节管(470)可在支承元件的近端和远端之间放置于控制元件上。调节管可选择性地沿控制元件自由滑动。当在装置中存在调节管时,调节管可防止连接件(451或430)太接近于可扩张隔室的近端。由此,具有调节管(470)的装置可防止可重构元件的过度轴向扩张。当将装置拉回到引导器套管或微型导管内时,管件还可防止或减少控制元件与支承元件的支杆/线材之间的摩擦。

[0212] 图11中提供该装置的又一替代实施例。在该特定伞形装置中,可重构元件(410)可包括多个线材,并如图中可见那样形成管状结构。也可包括多个线材的支承元件可用于改变可重构元件的构造。支承元件(420)可与控制元件(10)以及可重构元件(410)相关联,且关联位置中的至少一些可联接有标记(440)。支承元件(420)以及可重构元件(410)能以基本上固定不动的方式与控制元件(10)相关联。支承元件(420)的所有线材可经由连接件(430)与控制元件(10)相关联。连接件(430)固定到控制元件。因此,向近侧拉动控制元件(10)或向远侧推动控制元件(10)还可相应地作用于其它线材(即,可重构元件和支承元件)。

[0213] 图12中示出前述装置的一些非限制性和说明性改型。在图12A和12B中所示的装置中,可重构元件(410)包括沿装置的轴向轴线对准的八个大致直线形线材。该装置还包括分布在装置的近端和远端之间的两组支承元件(420)。每组支承元件(420)可包括四个线材以操纵装置的径向力。或者,图12C的装置包括可重构元件(410)和支承元件(420),可重构元件(410)包括轴向对准的六个大致直线形线材,而支承元件(420)包括在同一组内的三个线材。此外,诸如使用一组或两组支承元件以及使用多于三组支承元件的任何进一步和其它改型可应用于该装置。此外,如果期望,可重构元件和支承元件可呈类似于图7中可见的丝网(编织物)的形式。

[0214] 在图13中示出根据本发明的另一实施例。在该特定示例中,可重构元件单元的尺寸和支杆的尺寸或线材的直径可在单个装置内变化。从可重构元件的近端到远端,该单元可从大尺寸变为小尺寸,或者反之,且支杆尺寸可从厚支杆变成薄支杆,或反之。在该图中所示的装置中,可重构元件(410)在区域A中比在区域B中具有一般更大的单元,或者反之。此外,支杆尺寸或线材直径可在区域A中比区域B更厚,或者反之。这些实施例的优点可包括如下中的至少一个或多个:

[0215] 1) 较大近侧单元尺寸可具有较小的线材密度,这在增加径向力时会增加每个支杆施加的力和压力。这会使可重构元件(线材或支杆)能更容易地切过闭塞物/凝块或使其裂

开。闭塞物/凝块也可由于较宽的开口更容易地落入可扩张隔室内。小尺寸的远侧单元用于捕获和保持从可扩张隔室的近端裂开的闭塞物/凝块碎屑,因此碎屑将不会从装置逸出而行进到下游。

[0216] 2) 可重构元件的支杆尺寸也可从近端变化到远端,其中,近端处的支杆较宽/厚,而远端处支杆较薄。大又牢固的近端支杆将具有较大刚度,并可更容易地切割闭塞物/凝块。由于远端处加大数目的单元,远端处的支杆尺寸需要薄,以使装置能在其压缩状态下保持较小轮廓,从而能装入微型导管内。

[0217] 由此,应用中所示的示例不应认为限制本发明的范围,而是可以在不影响本发明范围的情况下进行对于本领域技术人员来说显然的许多不同修改和改型。因此,不仅在本申请中公开的示例、而且明显的修改和变型也应包含在本发明的范围内。

[0218] 可通过本领域中已知的多种技术来制造根据本发明的一些实施例的装置。例如,可重构元件和支承元件可由某件材料通过激光切割海波管制成。通过激光器切割之后的海波管可热固成可重构元件和支承元件的期望的形状和尺寸,这些可重构元件和支承元件能如图 13 中所示进一步组装到装置内。

[0219] 或者,可重构元件/支杆和支承元件/支杆可由相同薄型板通过激光切割或光蚀刻制成,如图 14A 中可见。该部件可热固成可重构部件和支承部件的期望形状和尺寸。这些部件可进一步组装到装置内。可重构元件的各侧可使用粘合剂、熔化焊接、焊料焊接和机械连结等方式来连结以形成各侧闭合的可扩张隔室(参见图 14B)或者简单地敞开作为各侧敞开的可扩张隔室(图 14C)。

[0220] 可重构元件的远端可以是闭合端部(线材或支杆端部连结,图 14B 和 14C 中所示)或者可以是开口端部(即,线材或支杆端部未连结,如图 14D 中所示)。

[0221] 海波管和金属板可由选自以下的一种或多种制成:镍钛(NiTi)合金、不锈钢、钛(及其合金)和钴铬(CoCr)合金等。

[0222] 加工海波管或薄板的上述技术的许多实施例的一个优点是可避免多个线材(例如,可重构元件和支承元件之间)的相关联(或连结),因此,装置轮廓(尺寸)可较小。这些实施例与编织线材结构相比有利,因为可重构元件的支杆均连接到每个单元或窗的角部处。在不增加装置的轮廓的情况下,可通过单元形状和结构设计来控制径向力。

[0223] 本发明的一些实施例涉及设计成将可扩张隔室放置于对象的血管结构内的装置。对象可以是需要治疗、诸如去除血液堵塞物/血凝块和/或恢复体内的血流的患者。在图 15 和 18 中示出装置的示例性非限制性实施例。根据一些方面,在推送管件(20)和可扩张隔室(40)之间有线圈部段(540)。该线圈部段可被认为是推送管件的一部分。线圈(540)的功能可使装置的远侧部段柔性,因此,装置可通过曲折的血管。为了进一步改善装置的可推送性,可将诸如 PTFE、PET 等的塑料管件加到线圈周围,或者在推送管件的远端处简单地替换线圈作为柔性推送部件。如果使用线圈,一个或多个的薄线材(520)可用于连接推送管件(20)和可扩张隔室(40)的连接件,以防止线圈(540)伸展。根据另一些方面,推送管件(20)可连接到线圈(540)。此外,控制元件(10)可在推送管件(20)的内腔以及可重构元件的近侧连接件(460)和线圈或柔性管部段内自由滑动。根据又一些其它方面,在装置的近端处,控制元件手柄管件(490)可加到并固定到控制元件(10)的近端。借助该特征,操作者可容易地抓取控制元件手柄管件(490),以控制可重构元件的打开或闭合。部件之间的

所有连接可通过胶粘(粘合剂)、熔化焊接、焊料焊接等连结。参见图 15, 柔性线圈(495)可加到可扩张隔室的远端, 以使装置末端为非创伤性, 从而避免戳到管腔。

[0224] 在图 16 和图 17 中示出其它替代实施例。在这些实施例中, 该装置可包括两个结构, 即远侧可扩张结构(550)和近侧可扩张结构(560)。对于图 16 中所示的装置, 两个可扩张结构之间的距离可改变/调节, 即, 例如通过推动或拉动控制元件(10), 远侧结构可向近侧结构拉动/滑动或者远离近侧结构推动/滑动。

[0225] 参照图 16, 远侧结构(550)呈包括可重构元件(410)、支承元件(420)和控制元件在内的筐状物或可扩张隔室的形式。控制元件(10)的远侧末端可连接到支承元件(420), 并可在滑动管(471)和推送管件(20)内自由移动。通过经由控制元件来调节支承元件, 可调节远侧结构的半径和径向力。如本申请中其它地方所示, 支承元件的调节可通过推动或拉动中心元件来实现。在一些其它实施例中, 滑动管(471)的近端可固定到推送管件的远端。远侧结构(550)的远端可通过连接件(460)固定到滑动管的中间点。近侧结构可以是伞形部件(560)。近侧结构的近端可与包括外部连接件和内部连接件在内的连接件(455)相关联。连接件的内直径一般大于滑动管的外直径, 以使滑动管能在连接件内自由地滑动。在闭塞物/凝块收回过程中, 当使微型导管脱离时, 近侧结构由于摩擦而由微型导管的末端保持。近侧结构可与远侧结构分开。当拉动推送管件时, 远侧结构向近侧结构运动。可接合/抓取两个结构之间的闭塞物/凝块(图 19 中将进一步示出装置如何捕获闭塞物/凝块的详细机构)。如果向近侧拉动控制元件, 则远侧结构可进一步扩张。滑动管(在连接件 460 和滑动管的末端之间)的段具有与图 10 中的调节管(470)相同的功能, 即, 阻止远侧结构如之前部分中所述那样过度扩张。标记(440)也可如需要地加到远侧和近侧结构的远侧末端。

[0226] 参见图 17A, 近侧结构(560)是可扩张隔室, 它由可重构元件(410)、支承元件(420)和控制元件(10)构成。该结构的近端可连接到外管(460)和内管(475)之间。控制元件(10)的远侧末端能连接到支承元件(450), 并在近侧结构的远端处在内管(475)内以及在推送管件(20)内自由运动。通过经由控制元件来调节支承元件, 可调节近侧结构的构造和径向力。远侧结构(550)呈包括可重构元件(410)和封闭元件(425)在内的筐状物或可扩张隔室的形式。在远侧结构的中间, 封闭元件的末端可通过连接件(451)来连结, 以形成闭合的隔室/结构。封闭元件的结构可以与前述支承元件的一样, 但其功能仅仅是使隔室闭合。由于封闭元件的末端不连接到控制元件, 所以不能调节结构(550)的构造和径向力。或者, 也可在没有封闭元件的情况下形成远侧结构。远端可通过如图 17B 中所示使可重构元件(410)的远侧线材/支杆连结来闭合(451)。远侧结构(550)的近端可固定到控制元件的远侧末端。在收回过程中, 远侧结构可捕获不能由近侧结构保持/包含的闭塞物/凝块碎屑。两个结构之间的空间还可用作在收回过程中包含闭塞物/凝块或闭塞物/凝块碎屑的室。

[0227] 从推送管件末端/近侧连接件延伸到近侧结构(560)的中间部分内的内管件(475)具有与图 10 中的调节管 470 相同的功能, 即, 如之前部分中所述那样防止远侧可扩张结构的过度扩张。

[0228] 在包括两个隔室的实施例中, 可如申请中其它地方公开那样通过激光切割、光蚀刻或线材编织形成远侧部件和近侧部件。其它地方所述的各种材料可用于形成可重构元

件。在这种实施例中,近侧结构的强度/刚度或线材/支杆尺寸可与远侧结构不同。此外,远侧结构的尺寸(当它完全扩张时)可与近侧结构不同。

[0229] 在图 18 中示出使用图 16 中所示设计作为示例的构造应用包括两个可扩张结构的实施例的装置。在此特定实施例中,在装置中采用远侧结构(550)和近侧结构(560)。在图 19 中示出使用根据图 18 的装置来收回闭塞物/凝块。图 19 中所示的机构仅仅示出各种应用,并表示为某些实施例的说明。如申请中其它地方所述,根据本申请的装置可用于收回或去除例如血管内的闭塞物/凝块。此外,装置可用于使内腔区域扩张和/或恢复血流,这可以需要或不需要收回闭塞物/凝块。

[0230] 在闭塞物/凝块(60)如图 19A 可见定位在血管(50)内的假设条件下,包括收回装置的微型导管(30)可行进和定位在闭塞物/凝块近侧或远侧附近。然后,使微型导管(30)脱开,以使收回装置暴露于闭塞物/凝块。在图 19 中所示的一些实施例中,闭塞物/凝块可通过如下机构接合和收回:

[0231] 闭塞物/凝块(60)可保持在近侧结构(560)与微型导管(30)的末端之间,并从原位置被去除(图 19B)。

[0232] 闭塞物/凝块(60)可保持在近侧结构(560)与远侧结构(550)之间,并从原位置被去除(图 19C)。

[0233] 闭塞物/凝块(60)可由近侧结构(560)保持/接合,并从原位置被去除(图 19D)。在一些情况下,闭塞物/凝块可接合到近侧结构和动脉壁之间,并借助闭塞物/凝块与装置之间的摩擦去除。

[0234] 闭塞物/凝块(60)可由远侧结构(550)保持/接合,并从原位置被去除(图 19E)。在一些情况下,闭塞物/凝块可接合到远侧结构和动脉壁之间,并借助摩擦去除。

[0235] 闭塞物/凝块(60)可由于近侧结构而裂开成碎屑。碎屑会落入远侧结构(550)或被远侧结构(550)捕获和/或留在近侧结构(560)和远侧结构(550)之间(图 19F),并从原位置被去除。

[0236] 闭塞物/凝块(60)可接合在各种位置/位点,并通过任何上述机构(图 19G)的组合去除,并且从原位置被去除。

[0237] 根据一些实施例,在闭塞物/凝块接合和/或收回过程中,能在任何时间拉回控制元件(10),以操纵收回装置的径向力和半径(即,尺寸),以确保闭塞物/凝块与装置接合,并且不滑离装置(图 19H)。

[0238] 图 20 示出根据本发明的一方面的装置。该装置可包括管件部件和接合隔室。管件部件可包括诸如推送管件(20)和连接管件(31)的多个管件元件。接合隔室可包括远侧接合元件(90)和近侧接合元件(65)。该装置还可包括中心线(10)。

[0239] 如图 20 中可见,在某些实施例中,远侧接合元件(90)和近侧接合元件 65 与中心线(10)相关联。在某些实施例中,远侧接合元件 90 可连接到(或固定到)中心线(10),且近侧接合元件(65)可连接到连接管件(31),该连接管件还可连接到推送管件(20)。中心线(10)可放置于连接管件 31 和推送管件(20)内,并自由运动通过连接管件以及推送管件。在一些实施例中,中心线(10)和推送管件(20)可延伸到装置的近端。

[0240] 在一些实施例中,可独立操纵中心线(10)和连接管件(31),由此允许单独控制远侧接合元件和近侧接合元件。更具体来说,远侧接合元件将通过连接到远侧接合元件的中

心线的运动来控制；而近侧接合元件将通过与近侧接合元件连接的连接管件或推送管件的运动来控制。在诸如图 20 中可见那样的某些实施例中，推送管件和连接管件彼此连接，由此，推送管件的运动可最终控制近侧接合元件。

[0241] 在某些实施例中，远侧接合元件可在其远端处具有开口端部（例如，参见图 20A）。或者，在某些其它实施例中，远侧元件可在其远端处具有闭合端部（例如，参见图 20C）。远侧接合元件（90）可连接到中心线（10）。远侧接合元件可通过例如焊接、胶粘或夹紧的各种手段在其大约近端处连接到中心线。

[0242] 在某些实施例中，中心线（10）和远侧接合元件（90）之间的连接置于远侧元件连接件（80）内。远侧元件连接件可呈较短管或线圈的形式，并放置于中心线（10）上。在一些实施例中，远侧元件连接件可包括外部远侧元件连接件（82）和 / 或远侧元件连结介质（81）。在这种实施例中，远侧接合元件的近端可放置于外部连接件和中心线之间。在一些情况下，远侧接合元件、连接件和中心线可通过诸如夹子、扣钩或紧固件之类的连结介质来连接，这些连结介质将远侧接合元件和中心线紧固或保持在一起。

[0243] 根据一些实施例，近侧接合元件可包括多个线材。或者，近侧接合元件可由管件例如通过激光切割技术来制成。因此，在某些实施例中，在近端处省去了一小段管件，并且在远端处切割或形成支承件，如图 20A' 中可见。在这种实施例中，是近侧接合元件的一体部分的位于近端处的管件段可用作近侧元件连接件。在替代实施例中，可将单独的近侧元件连接件加到装置，如图 20A 中可见。在一些实施例中，近侧元件连接件（41）可包括诸如连结介质（42）和外部近侧元件连接件（43）的多个元件。在这种实施例中，近侧接合元件的近端可置于内部近侧元件连接件处、外部近侧元件连接件处或外部近侧元件连接件和连接管件的末端之间。在一些实施例中，将近侧接合元件的近端置于内部近侧元件连接件内。在一些情况下，近侧接合元件的近端与连接件可使用诸如夹子、扣钩或紧固件之类的连结介质来连结，这些连结介质紧固或保持远侧接合元件，更具体是其近端。或者，近侧元件连接件可包括其内放置有近侧接合隔室的单层管件。

[0244] 当存在单独的近侧元件连接件（例如，图 20）时，近侧接合元件到近侧连接件的连接可通过诸如焊接或胶粘的各种手段来进行。或者，如上讨论的那样，近侧连接件可包括能紧固或保持近侧接合元件的连结介质。在任何情况下，近侧元件连接件围绕中心线，并且允许中心线在近侧元件连接件内作自由运动。

[0245] 在某些实施例中，装置包含连接到近侧接合元件的连接管件。在一些实施例中，连接管件可进一步连接到推送管件，例如如图 20 中所示。借助该构造，近侧接合元件永久地连接到推送管件。然而，或者，将近侧接合元件固定到推送管件是暂时的或者可逆的，因此，如果期望，则近侧接合元件、可选地连同近侧连接件能从推送管件脱开。作为另一替代方式，近侧接合元件和与其相关联的近侧元件连接件可以不固定到管件隔室处（参见，例如图 26）。替代地，它们能沿中心线自由滑动。

[0246] 根据本发明的一方面，远侧接合元件的位置可通过控制中心线来确定。例如，在图 20 中所示的实施例中，远侧接合元件与中心线连接。操作者能控制中心线的运动（例如，推入和推出），以将远侧接合元件定位在期望的位置。在某些实施例中，近侧接合元件可通过例如推送管件、连接管件或两者的管件元件的运动来定位。如图 20 中所示，在一些实施例中，近侧接合元件固定到管件元件的远端附近。由此，操作者可通过控制管件元件、即推送

管件和连接管件将近侧接合元件定位在期望位置。借助这些构造,能独立操纵两个接合元件。此外,这允许使两个接合元件之间的间距能变化。当用该装置来治疗患者时,装置的两个接合元件之间的间距能变化的这方面是有益的。该设计能通过将闭塞物或凝块保持在两个独立的接合元件之间来牢固地接合闭塞物或凝块。此外,通过调节每个接合元件的位置以及两者之间的距离,它可使保持的效率和精度最大化。

[0247] 在图 20B 中,示出图 20A 中所示的装置的不同状态。在该闭合位置,向近侧拉动中心线,由此向近侧接合元件拉动远侧接合元件,从而缩短两个接合元件之间的距离。

[0248] 图 21 示出从体腔(例如,血管)去除凝块或闭塞物的示例性实施例。在某些实施例中,装置可如下所述用于与凝块或闭塞物接合并从体腔去除凝块或闭塞物:

[0249] (A) 首先借助引导线的引导将微型导管(30)设置到在体腔内发生闭塞的区域。根据凝块或闭塞物的硬度、长度、位置和形状,微型导管可部分地穿过凝块(或闭塞物)或者到达凝块远侧。之后,管件隔室和接合部件可通过微型导管递送到闭塞物。在该技术中,近侧可扩张元件与远侧可扩张元件分离。当放置于装置内时,将近侧接合元件的末端放置于凝块或闭塞物后面/近侧。

[0250] (B) 将微型导管拉回以使接合部件和管件隔室的一部分脱开。理想地,近侧接合元件位于凝块近侧,而远侧接合元件位于凝块远侧,或者如果凝块相当长的话,位于凝块的近侧部的远侧。在一些实施例中,如图 21B 中可见那样,在此阶段,凝块将至少部分地由远侧接合元件保持或与其接合。

[0251] (C) 如果期望,操作者还可调节接合元件中的一个或两个的位置。例如,在保持推送管件以固定近侧接合元件时,操作者可向近侧拉动与远侧接合元件连接的中心线。然后,由于远侧接合元件与凝块之间的摩擦,凝块将向近侧运动。当这发生时,两个接合元件之间的距离缩短了,而凝块被抓取或接合在两个接合元件内和/或之间。如果操作者在拉动中心线和远侧接合元件时感觉到阻力,这表示凝块被接合在两个接合元件内和/或之间。然后,他或她能锁定远侧和近侧接合元件的位置,并从体腔(例如,动脉)拉出装置和被接合的凝块连同微型导管。在一些实施例中,通过置于装置上的标记(70)和/或(100)来识别装置的位置。

[0252] 在图 22 中,示出从体腔去除凝块或闭塞物的技术的替代实施例。该装置可如下所述用于与凝块或闭塞物接合并从体腔去除凝块或闭塞物:

[0253] (A) 微型导管(30)行进到在体腔内发生闭塞的区域。微型导管可在凝块或闭塞物的远端上前进。根据凝块或闭塞物的硬度、长度、位置和形状,微型导管可穿过凝块(或闭塞物)或者在基本上不干扰凝块的情况下经过凝块。在一些实施例中,一旦微型导管位于闭塞区域附近的位置,就将管件隔室和接合元件引入到微型导管内。在某些情况下,操作者可将微型导管和可扩张隔室放置于一旦脱开近侧接合元件就位于凝块近端的远侧的位置。如申请中其它地方阐释的,例如能使用装置中存在的标记来监测装置的位置。

[0254] (B) 使微型导管脱开,且接合隔室和管件隔室的一部分露出。

[0255] (C) 操作者还可进一步调节接合元件中的一个或两个的位置。例如,当保持中心线以及因此保持远侧接合元件稳定时,拉回近侧接合元件直至其远端刚经过凝块的近端。这可通过观察近侧接合元件的远端内的标记(70)来指示。近侧接合元件的远端在此位置打开。或者,如果期望,在保持近侧接合元件时,可调节远侧接合元件。此外,如果期望,可一

起调节近侧和远侧接合元件以确保与凝块的接合。

[0256] (D) 当通过固定推送管件来保持近侧接合元件稳定时, 操作者可拉动连接到远侧接合元件的中心线。然后, 由于远侧接合元件与凝块之间的摩擦, 凝块可向近侧运动。两个接合元件之间的距离缩短了, 且凝块被抓取或接合在两个接合元件内和 / 或之间。如果操作者在拉动中心线和远侧接合元件时感觉到阻力, 这表示凝块被接合在两个部件内和 / 或之间。然后, 他或她能锁定远侧和近侧接合元件的位置, 并从体腔 (例如, 动脉) 拉出装置和接合的凝块连同微型导管。在一些实施例中, 通过置于装置上的标记 (70) 和 / 或 (100) 来识别装置和微型导管的位置。

[0257] 图 22 中所示的实施例的一些优点包括近侧接合元件能在脱开之后定位到凝块近侧, 以在相对于凝块或闭塞物放置接合部件时确保相对较高的精度。由于可将近侧接合元件直接放置于凝块或闭塞物后面, 当拉动远侧接合元件以使凝块向近侧运动时, 凝块在接合到两个接合元件之间之前仅须行进非常短的距离。因此, 与图 21 中所示的技术相比, 凝块丢失的可能性降低。

[0258] 在图 23 中, 表示出使用装置接合凝块的一些附加机构。如图 23 中所示, 凝块可接合到管件元件和体腔表面 (例如, 动脉壁) 之间 (23A)、微型导管和近侧接合元件之间 (23B)、近侧接合元件和动脉壁之间 (23C)、远侧接合元件和动脉壁之间 (23D)、近侧和远侧接合元件之间 (23E) 以及近侧接合元件和导管末端之间并且同时在两个接合元件之间 (23F)。因此, 显然可以在不脱离本发明的范围和精神的情况下对本申请中公开的装置和方法进行各种修改和应用。由此, 当然本发明的范围包含这种变型和修改中的任一种。

[0259] 图 24 示出包括前述装置的系统的说明性实施例。在一些实施例中, 中心线 (10) 可延伸到装置的近端, 并连接到远侧部件手柄 (120)。系统从远端到近端的长度可以约为 100 到 200 厘米。在一些实施例中, 系统从远端到近端的长度可约为 100cm, 110cm, 120cm, 130cm, 140cm, 150cm, 160cm, 170cm, 180cm, 190cm 和 200cm。在一些其它实施例中, 系统从远端到近端的长度可比 100 厘米短或者比 200 厘米长。在一些实施例中, 系统可包括多个推送管件, 诸如近侧推送管件 (25)、中间推送管件 (22) 和远侧推送管件 (24)。在一些其它实施例中, 连接管件可连接到中间和近侧推送管件。可在系统的远端处, 即如图 24 中所示借助远侧部件控制手柄和近侧推送管件由操作者来操作远侧和近侧接合元件。

[0260] 图 25 示出存在有远侧推送管件和近侧推送管件的系统的替代实施例。在连接管件顶上有远侧推送管件。在一些实施例中, 推送管件中的至少一些部分是柔性的以确保装置能行进通过曲折路径。在其它实施例中, 远侧推送管件中的至少一些部分可以是光滑和柔性的, 因此, 它还加强装置的可推送性。在某些实施例中, 推送管件的近端可由刚硬 / 牢固的管件制成, 以加强装置的可推送性。

[0261] 在装置需要拉回到微型导管内的情况下, 每个接合元件可独立操作。例如, 可先将近侧接合元件拉回到微型导管内, 然后可通过拉动中心线将远侧部件拉入微型导管内, 以避免两个元件 (及其支杆) 交叠。这将避免两个可扩张元件彼此交叠以及不能拉到微型导管内。在某些实施例中, 一旦凝块被接合, 两个接合元件的位置可锁定。在这种实施例中, 两个接合元件的运动将同步, 且将它们相继引入微型导管内。

[0262] 图 26 示出装置的替代实施例。特别是, 近侧接合元件可以不与管件隔壁连接。而是, 与近侧元件连接件 (41) 相关联的近侧接合元件 (65) 可如图 26A 中可见那样沿中心线

10 自由滑动。在一些实施例中,近侧元件连接件(41)的内直径大于中心线(10)的外直径,因此,与近侧元件连接件(41)相关联的近侧接合元件(65)可在中心线(10)上自由滑动。此外,在至少一些实施例中连接管件是不需要的。图 26B 示出图 26A 中所示的实施例的闭合状态,其中,向近侧拉动中心线(10),由此,远侧接合元件 90 向近侧接合元件(65)运动。这将缩短两个接合元件之间的空间(或距离)。该特征将装使装置能如下图中所示与凝块接合。

[0263] 图 27 示出特别是使用图 26 中所示的装置从体腔(例如,血管)去除凝块或闭塞物的示例性实施例。在某些实施例中,装置可如下所述用于与凝块或闭塞物接合并从体腔去除凝块或闭塞物:

[0264] (A) 先借助引导线的引导使微型导管(30)行进到在体腔内发生闭塞的区域。微型导管可定位到在凝块或闭塞物近端的远侧。根据凝块或闭塞物的硬度、尺寸、位置和形状,微型导管可穿过凝块(或闭塞物)或者在基本上不干扰凝块的情况下经过凝块。之后,管件隔室和接合隔室可通过微型导管递送到闭塞物。近侧可扩张元件与远侧可扩张元件分开。当放置装置时,近侧接合元件的末端放置于凝块或闭塞物的近侧。

[0265] (B) 使微型导管脱开,且接合隔室和管件隔室的一部分露出。操作者可将装置调节成使近侧接合元件可位于凝块近侧,而远侧接合元件可位于凝块远侧,或者如果凝块相当长,则至少经过凝块的一部分。在一些实施例中,如图中可见,在此阶段,凝块将至少部分地由远侧接合元件保持。

[0266] (C) 操作者可进一步调节远侧接合元件的位置。例如,操作者可向近侧拉动与远侧接合元件连接的中心线。然后,由于远侧接合元件与凝块之间的摩擦,凝块将向近侧运动。两个接合元件之间的间距缩短。当凝块与近侧接合元件接触时,凝块可被抓取或接合到两个接合元件内和/或之间。同时,接合隔室和凝块进一步拉动到微型导管末端附近。为了确保接合,操作者可锁定远侧接合元件的位置并拉动装置。

[0267] 在某些实施例中,图 27 中所示的过程可如下进行:当进行图 26 中所示过程时,当装置脱开时,在微型导管内腔和近侧接合元件之间会有摩擦,并且近侧接合元件被拉离远侧接合元件。一旦两个元件离开微型导管,两个接合元件之间的间距可最大化或者基本上延长。操作者无须在展开之后调节两个接合元件的位置。操作者可通过与中心线连接的推送管件向近侧拉动远侧接合元件。因此,两个部件之间的距离将缩短以与凝块接合。在某些情形下,微型导管的末端可用于防止近侧接合元件向后运动。当操作者在向近侧拉动推送管件/中心线时感到阻力时,这可表示凝块被接合到两个接合元件内和/或之间,且近侧接合元件还被微型导管的末端止挡。此时,可锁定该装置并将其从体腔移除。因此,能容易地并以高效率去除凝块或闭塞物。

[0268] 图 28 示出包括图 26 中所示装置的系统的又一示例性实施例。或者,图 20 中所示的装置可用于图 28 的该系统中。在一些实施例中,近侧接合元件(65)位于中心线(10)周围,由此,它能在远侧接合元件 90 和推送管件(140)的远侧末端之间自由地滑动。此外,远侧接合元件 90 可连接到中心线(10)。中心线(10)可向近侧延伸。中心线 10 可与推送管件(例如,近侧推送管件 25、中间推送管件 22、内推送管件 21 和外推送管件 23)中的至少一个连结。因此,与图 24 中所示的实施例不同,中心线 10 不必延伸到装置的近端。而是,它可与管件元件中的任一个连接,并且与连接的管件一起被控制。在一些实施例中,外推送管

件(23)可以是柔性的且光滑的,并放置到接近于系统的远端,因而,它可允许装置通过体腔内的曲折路径。此外,在一些其它实施例中,薄内推送管件(21)可存在于系统中,而该内推送管件(21)可以是柔性的,但又能增加系统的可推送性。在又一些其它实施例中,具有一定柔性的中间推送管件(22)可存在于系统中。在又一些其它实施例中,相对刚硬的远侧推送管件(24)和/或近侧推送管件(25)可存在于该系统内,以使该系统的可推送性进一步提高。一个或多个推送管件可用粘合剂彼此连接,并还可与包括中心线(10)在内的其它部件连接。在又一些其它实施例中,具有可变刚度的单个推送管件可用于该装置中,以替代多个推送管件和连结部。该管件可通过将管件磨成不同壁厚或通过螺旋形切割来形成,以确保远端更柔性,而近端更刚硬。

[0269] 图 29 示出存在远侧推送管件和近侧推送管件的系统的替代实施例。在该实施例中,中心线(10)可以不延伸到系统的近端。类似于图 28 中所示的示例,中心线连接到管件元件中的一个或多个,并且通过连接的管件元件来控制。在连接管件项上有远侧推送管件。在一些实施例中,远侧推送管件中的至少一些部分是柔性的,以确保装置能行进通过曲折路径。在其它实施例中,远侧推送管件中的至少一些部分可以是光滑和柔性的,因此,它还加强装置的可推送性。在某些实施例中,推送管件的近端可由刚硬/牢固的管件制成,以加强装置的可推送性。

[0270] 图 30A 示出装置的替代实施例。与图 20 中所示的实施例不同,该装置包括可推动和可拉动的近侧接合元件。然而,在该设计中修改了近侧接合元件的远侧末端。近侧接合元件的远端可如图 30 中所示向内弯曲或弄成圆滑,这可进一步确保末端对于动脉的内壁是无创伤性的。由此,可在动脉内腔中拉动和推动近侧接合元件,而损伤动脉壁的风险低得多。图 30B 示出图 30A 中所示的装置的靠拢状态,其中,近侧和远侧接合元件之间的距离最小化。

[0271] 图 31 示出特别是使用图 30 中所示的装置从体腔(例如,血管)去除凝块或闭塞物的示例性实施例。该图中所示的凝块收回机构很大程度上类似于图 21 和 22 中的收回机构。

[0272] 根据本发明的一些实施例的装置具有明显优点。例如,在操作过程中,如果凝块不位于两个接合元件内和/或之间,或者一个或两个接合元件位于凝块太远侧或太近侧,操作者可将近侧接合元件中的一个或两个定位成确保接合。特别是,在图 31 中所示的实施例中,通过经由连接管件拉动或推动来将近侧接合元件调节到期望位置。由于近侧元件具有非创伤性圆形末端且能被向前推动以使凝块与远侧元件接合,该手术/技术可避免需要仅用远侧接合元件来拉动凝块一段距离,这可进一步降低在手术过程中丢失凝块的可能性。因此,这种装置可使用两个接合元件与凝块接合,并稳定凝块直至从体腔去除凝块。两个接合元件的这种独立控制允许在手术过程中非常精细地调节装置,因此,特别是在治疗中的精确定位是必要的情形下(例如,脑内中风治疗)十分有用。

[0273] 图 32A 示出装置的替代实施例。在该特定实施例中,近侧接合元件具有筐状特征。在该近侧接合元件(65)上没有相对尖锐的端部,因为近侧接合元件的远端通过近侧接合元件的连接线(150)连接到近侧接合元件的远侧连接件(140)。因此,当近侧接合元件被压缩时,其远端将向后运动并形成如图 32B 中所示的光滑远端。该光滑端部对于动脉内腔是无创伤性的。在至少一些实施例中,该近侧接合元件可在体腔内拉动和推动。在某些实施例中,近侧接合元件的远端比近侧接合元件的其它部分薄。因此,当凝块在两个接合元件内和

/ 或之间被拉动或推动时,近侧接合元件的远侧部会弯折或者翻转,如图 32B 中所示,因而,凝块被近侧接合元件接合将不会被近侧接合元件 65 和近侧接合元件的远侧连接件(140)之间的附加关联所阻碍。

[0274] 图 33A 示出装置的另一替代实施例。在该特定实施例中,近侧接合元件具有筐状特征。然而,与图 32 中所示的实施例不同,近侧接合元件 65 的远端与近侧部件的远侧连接件(140)直接连结。该装置还在近侧接合元件上具有不尖锐的端部,且由此还减少损伤体腔的任何风险。在该设计中,用于近侧接合元件的近侧部的材料可以与近侧接合元件的其它部分的材料相同或者不同。在某些实施例中,近侧接合元件的远侧部可由比近侧接合元件的其它部分相对柔性的元件构成。由此,当凝块抵靠于近侧接合元件被拉动时,近侧接合元件的远侧部会弯折或翻转,以使近侧接合元件可如图 33B 中所示与凝块更好接合。

[0275] 图 34A 示出装置的另一替代实施例。该装置还包括用于进一步确定装置的安全性的附加特征。该设计可包括具有筐状特征的近侧接合元件。将近侧元件的远侧部通过软的/柔性连接件(例如,段连接件 160)连结到近侧元件的近侧部,这些软的/柔性连接件允许弯折,而远侧部向后压缩。可例如通过控制与近侧接合元件相关联的管件隔室而拉动或推动近侧接合元件。在近侧接合元件中没有尖锐端部,因此,它对于动脉壁来说无创伤性。此外,在该设计中,近侧接合元件可由多于一种材料制成,材料中的一种比另一种软。因此,在与凝块接合时易于使近侧接合元件的至少远侧部弯折或翻转(参见图 34B)。

[0276] 图 35 示出装置的近侧部的又一替代实施例。该装置还包括用于进一步确定装置的安全性的附加特征。该设计包括具有圆形远侧端部的近侧接合元件,以形成对于血管更无创伤的末端。因此,可例如通过控制与近侧接合元件相关联的管件隔室而拉动或推动近侧接合元件。

[0277] 下图 36-45 提供用于接合(和去除)凝块的近侧元件位于微型导管的远侧末端或端部处的进一步的替代实施例。在一些实施例中,该接合元件可附连到微型导管的远侧末端处。在一些其它实施例中,微型导管本身的远侧末端或端部成形为并构造起起到近侧接合元件的作用。换言之,近侧接合元件是微型导管的一体部分。

[0278] 在一些实施例中,可单独地附连到微型导管或者是微型导管的一体部分的近侧接合元件可在收回过程中或需要时改变形状和/或尺寸。例如,在收回装置放置于期望位置,即完全或部分经过凝块之后,可将收回装置插入微型导管内。然后,可向近侧拉动微型导管以使装置脱开。当微型导管的远侧末端到达凝块的大约近端处时,将微型导管的远侧末端操纵成改变成打开/漏斗形状。当保持微型导管稳定时,收回装置可连同与收回装置的接合元件部分接合的凝块一起拉回,直至凝块基本上或完全接合(或捕获)在微型导管的远侧末端(即,近侧接合元件)与收回装置的接合元件(即,远侧接合元件)之间。通过将收回装置和微型导管锁定到装置的近端处,可从例如动脉的内腔拉出装置和微型导管连同被接合的凝块。

[0279] 在微型导管的远侧末端提供近侧接合元件的某些实施例中,它可简化收回装置的设计以及由此其制造过程。代替两个单独的接合元件,例如如图 20 的实施例中所示,收回装置可仅需一个接合元件,即远侧接合元件,而起到近侧接合元件作用的另一元件可由微型导管来提供。

[0280] 图 36 示出诸如囊体的可膨胀或接合元件附连到微型导管的远端/远侧末端处的

装置的实施例。可扩张或接合元件(170)的形状和尺寸可通过其膨胀和收缩来控制。根据一些实施例,可扩张或接合元件(170)可例如通过用注射器 190 将液体(195)(例如,盐水溶液)注入可扩张或接合元件(170)内来膨胀,以形成期望的形状。在某些实施例中,将注入的液体通过注射通道 180 传递到可扩张或接合元件(170)。可扩张或接合元件(170)在膨胀后的形状和尺寸可变化。例如,当将预形成的囊体附连到微型导管的远侧末端时,它在膨胀时可成形为任何预形成的形状,例如漏斗状形状,如图 36B 中可见那样。或者,如图 36C 中可见,当膨胀时可仅增加可扩张或接合元件(170)的表面面积。由微型导管提供的可变形的近侧接合元件可单独地或者与其它元件(例如,体腔表面、微型导管、管件隔室、近侧接合元件、远侧接合元件及其任何组合)组合并以高效率与凝块接合(例如,参见图 33 和 37)。

[0281] 图 37 示出使用图 36 的装置来接合和去除凝块的机构。在收回过程中,操作者可将微型导管(30)插入体腔(例如,动脉)内直至远侧末端进入或通过凝块(60)。收回装置可与微型导管一起或者一旦微型导管在位则通过微型导管递送到阻塞物位置。在某些实施例中,可推动收回装置直至其接合元件 90 可如图 37A 中可见那样通过凝块的至少一部分。当保持收回装置稳定时,操作者可向后(即,向近侧)拉动微型导管,直至微型导管的远侧末端位于凝块的大约近端处,并且使收回装置的接合元件 90 露出,并扩张到其松弛或打开状态(图 37B)。因此,凝块可位于远侧接合元件 90 和微型导管的远侧末端(即,近侧接合元件 170)之间。然后,操作者可使微型导管 170 的可变形的远侧末端扩张,以将末端在凝块的近端处变形为漏斗形状(图 37C)。当保持微型导管稳定时,操作者可向后拉动远侧接合元件 90,因而,凝块可向后运动,并且接合到远侧接合元件 90 与微型导管的远侧末端(170)之间。然后,操作者可固定微型导管和收回装置,并且将它们拉出动脉,这使得能去除凝块。

[0282] 图 38 示出微型导管的远侧末端形成接合元件、更具体是近侧接合元件的装置的另一实施例。在该特定实施例中,例如通过激光切割来切割微型导管(200)的远侧末端,因而,在收回过程中,它能在被凝块(60)和/或远侧接合元件 90 压缩时转变成漏斗形状。在某些实施例中,在到达微型导管远侧末端的到底端之前结束切割过程,因而,微型导管的远侧末端仍是闭合的。

[0283] 图 39 示出微型导管的远侧末端(200)经受螺旋形切割的实施例的又一替代方案。类似于图 38 的装置,在收回过程中,当被压缩时,微型导管的远侧末端将成形为例如漏斗形状(图 39B)。在某些实施例中,在到达微型导管远侧末端的到底端之前结束切割过程,因而,微型导管的远侧末端仍是闭合的。

[0284] 图 40 示出微型导管的远侧末端形成成为编织结构的又一实施例。或者,如申请中其它地方所述,单独的编织结构可附连到微型导管的远侧末端处。附连到微型导管处或形成于微型导管内的编织结构(200)可以是具有或不具有塑料涂层的金属编织物。在与远侧接合元件 90 一起与凝块接合时,编织结构(200)将被压缩和成形为例如漏斗形状,因而,凝块保持在远侧接合元件 90 和编织结构(200)之间。

[0285] 图 41 示出微型导管的远侧末端切割到底端的又一实施例。因此,如图中可见,微型导管的远侧末端的该到底端并不闭合。在用远侧接合部件 90 向后拉动凝块时,微型导管的末端压缩成例如漏斗形状(沙嘴),并且凝块保持在收回装置的远侧接合部件 90 和微型导管(200)的远侧末端之间。图 41B 和 C 示出微型导管的开口末端的两个不同形状。

[0286] 在某些实施例中,近侧接合元件可包括微型导管的远端的包括微型导管末端的一

部分和覆盖微型导管末端的一层薄管件。在一些实施例中,近侧接合元件的至少一部分构成在移除一层薄管件时改变形状。在图 42 中示出这种实施例的示例。图 42 示出一装置,在该装置中,外套管层施加于微型导管。在某些实施例中,用作接合元件的微型导管的远侧末端可包括预成形结构或形状记忆结构。外套管(210)可保持微型导管的远侧末端(200),因此,它能在接合之前通过凝块。当将微型导管向近侧拉到凝块时,通过向近侧拉动外套管而使末端打开到其预成形,例如漏斗形状。或者,形状记忆材料可用于微型导管的远侧末端(200),因而,它能在从外套管露出时形成一定形状。

[0287] 图 43 示出线材用于在微型导管的远侧末端处提供一定形状的装置的又一实施例。图 43B 中所示的该设计示出具有嵌入到末端内的例如弹性线材的线材(220)的微型导管的远侧末端(200),以确保末端将在被拉出外套管(210)之后扩张到其预设定的形状。

[0288] 图 44 示出装置的另一实施例。在该特定实施例中,预成形漏斗末端结构(切片的)放置于微型导管的末端处,且微型导管的末端通过线材(220)保持,这些线材延伸通过微型导管壁的内通道(230)内的内腔。线材可保持微型导管的末端平直或未折叠,直到在接合之前该末端通过凝块。当通过向近侧拉动线材而将微型导管向近侧拉到凝块时,末端打开到其预成形、例如漏斗形状。

[0289] 图 45 示出编织结构和外套管被一起采用的装置的又一实施例。将预成形编织结构放置于微型导管的远侧末端,一层外套管保持末端平直,因此,能在接合之前循环前进到达或通过凝块。当通过向近侧拉动外套管而将微型导管定位到凝块近侧时,编织物末端打开到其预成形、例如漏斗形状。

[0290] 尽管文中描述了各种方面和实施例,但其它方面和实施例将对于本领域技术人员来说是显然的。文中公开的各种方面和实施例是出于说明的目的,并且不意在限制,由下述权利要求书表示实际范围和精神。

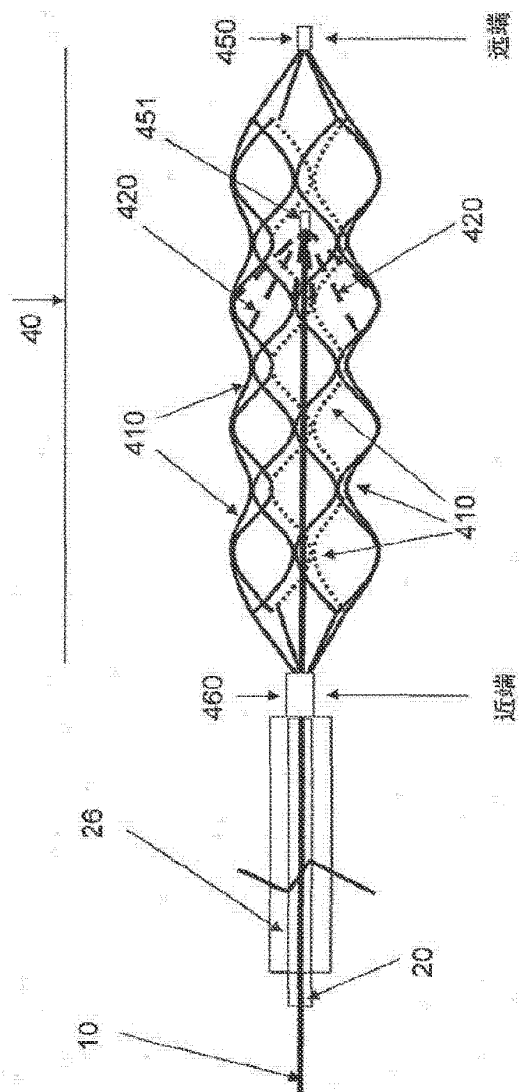


图 1

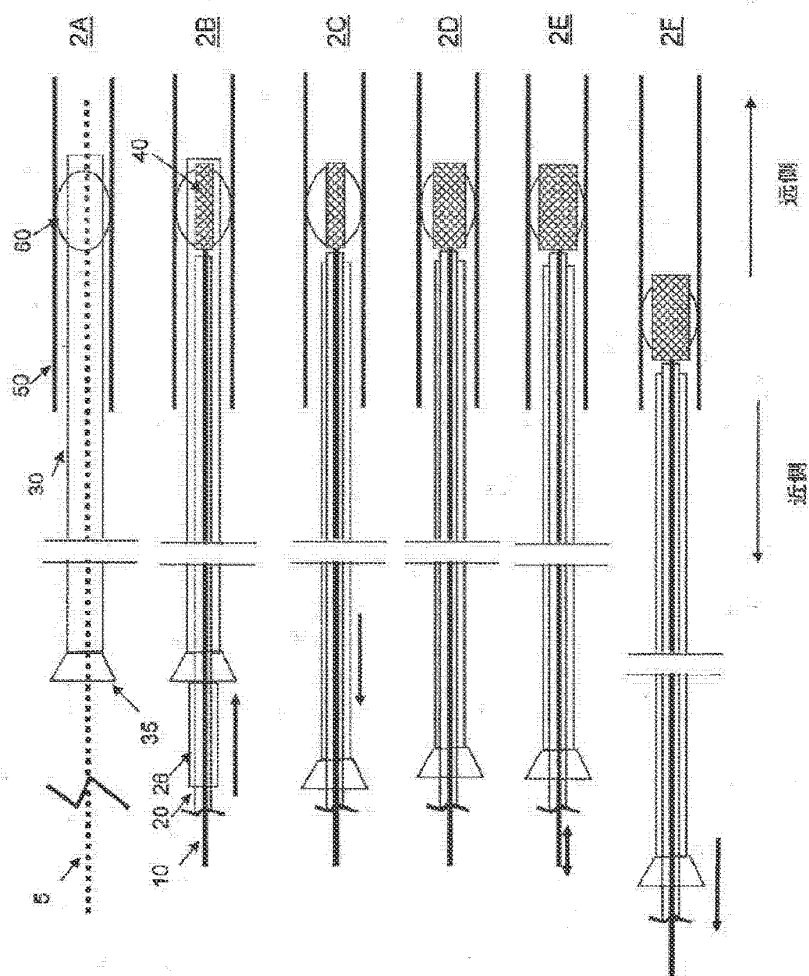


图 2A--F

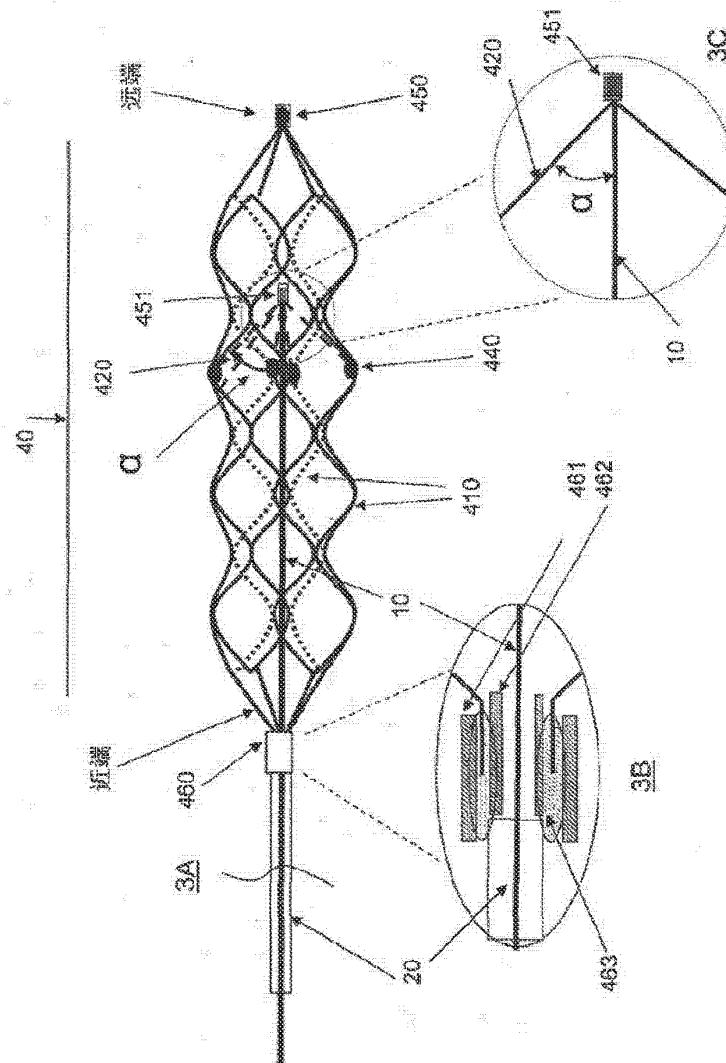


图 3A-C

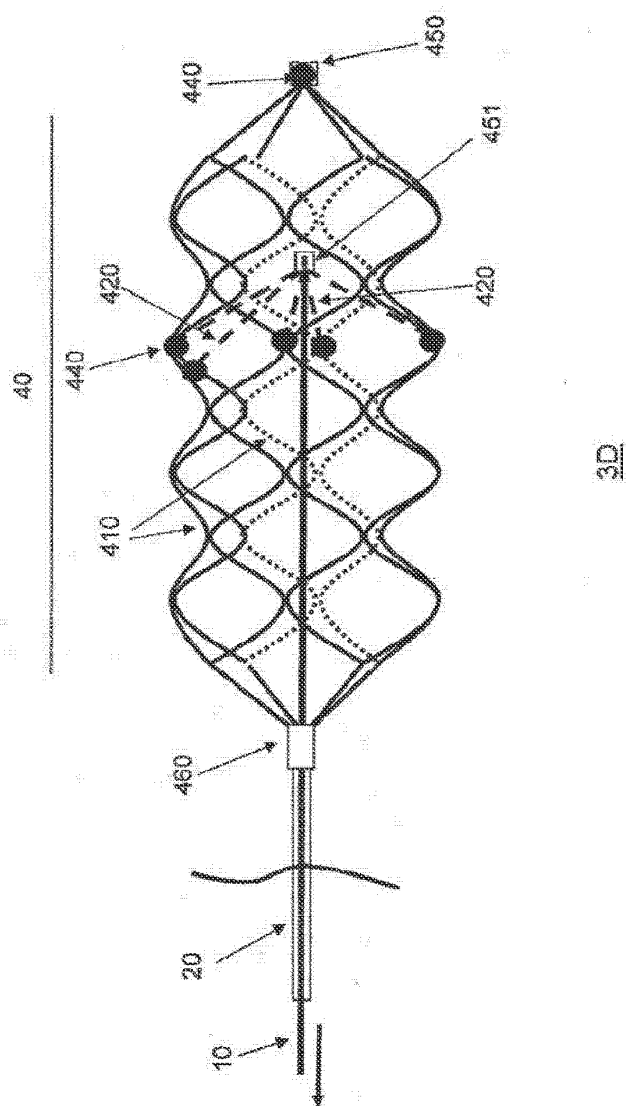


图 3D

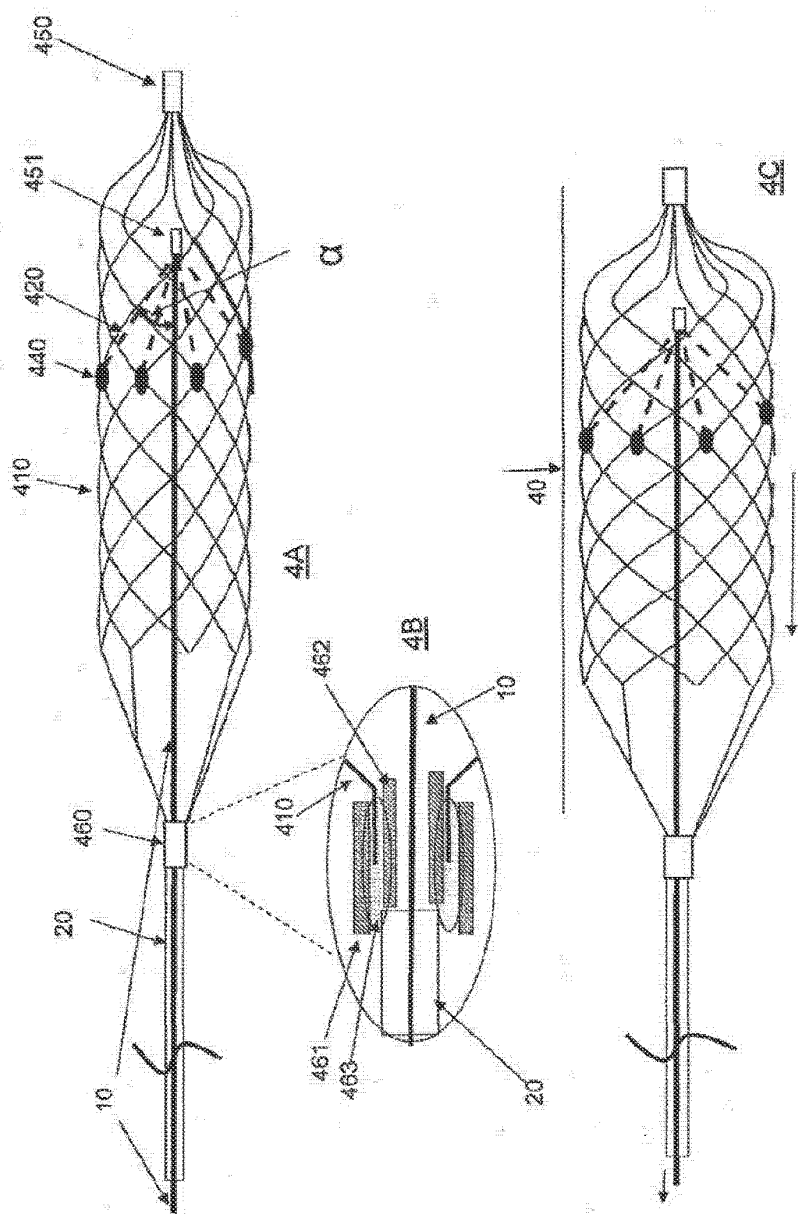


图 4A-C

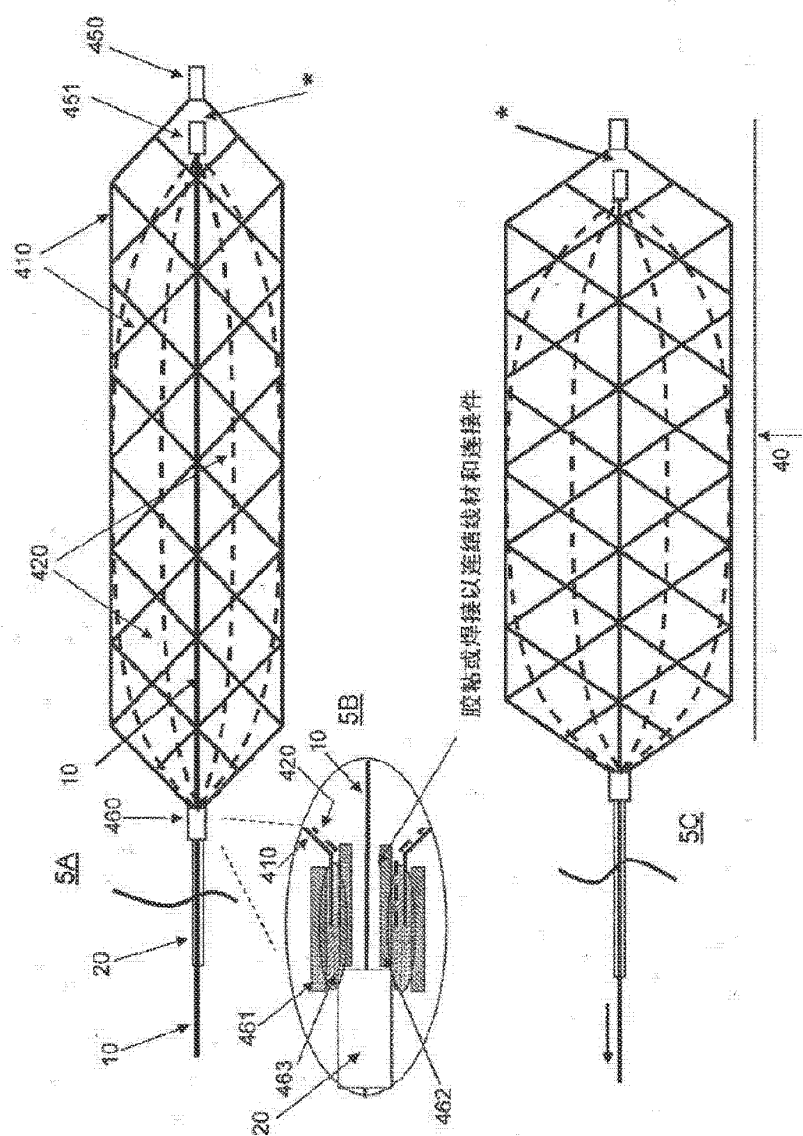


图 5A-C

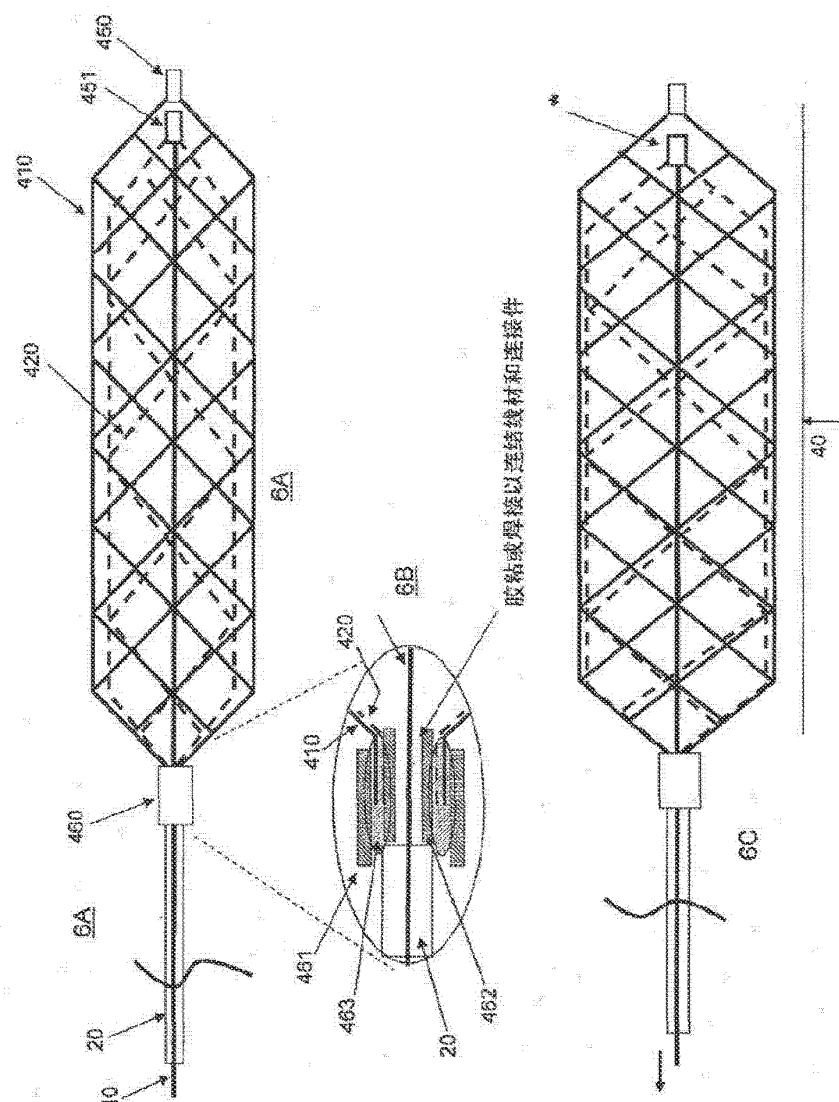


图 6A-C

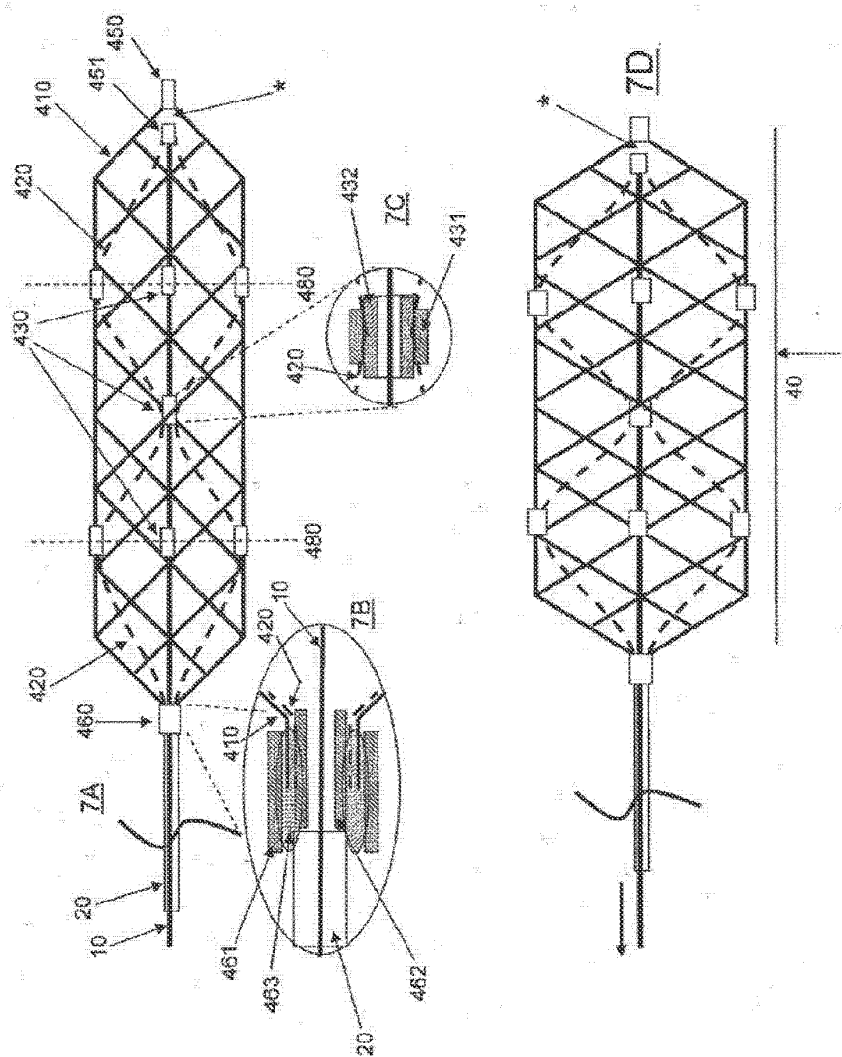


图 7A-D

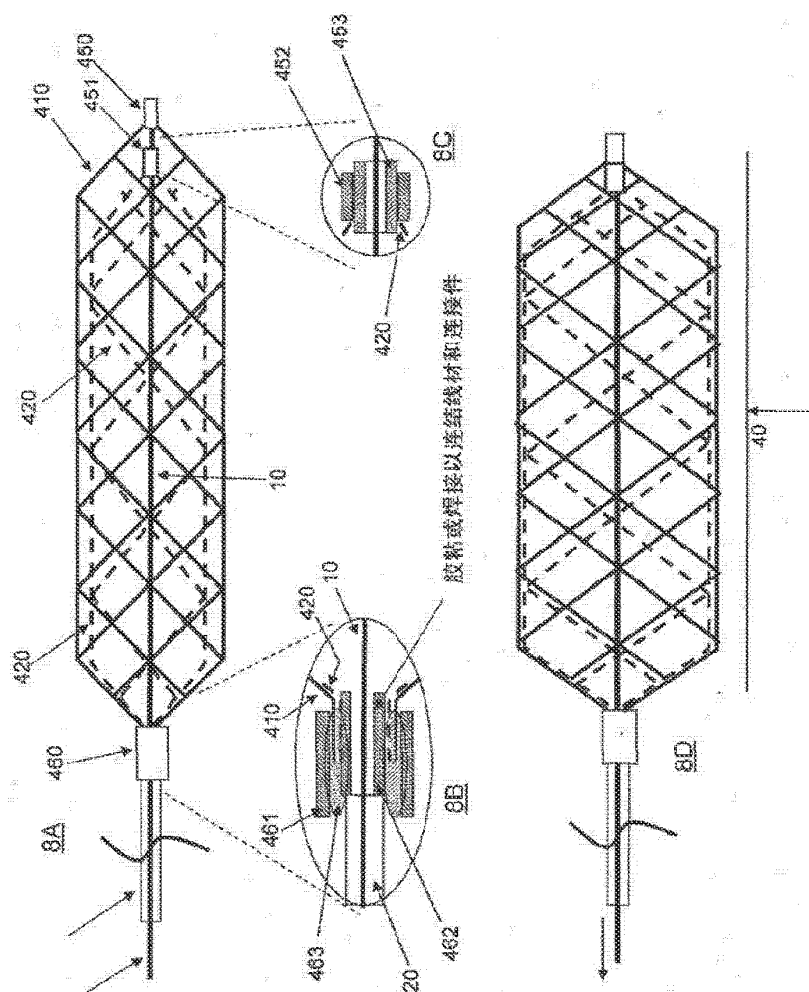


图 8A-D

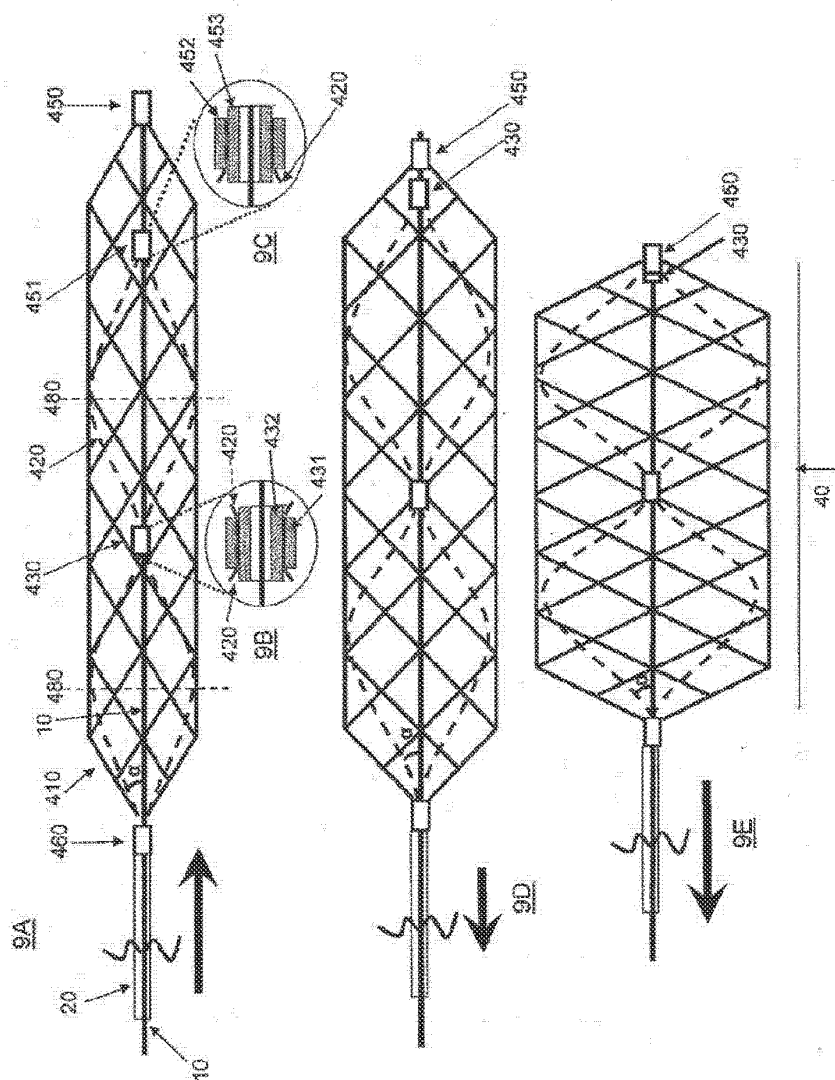


图 9A-E

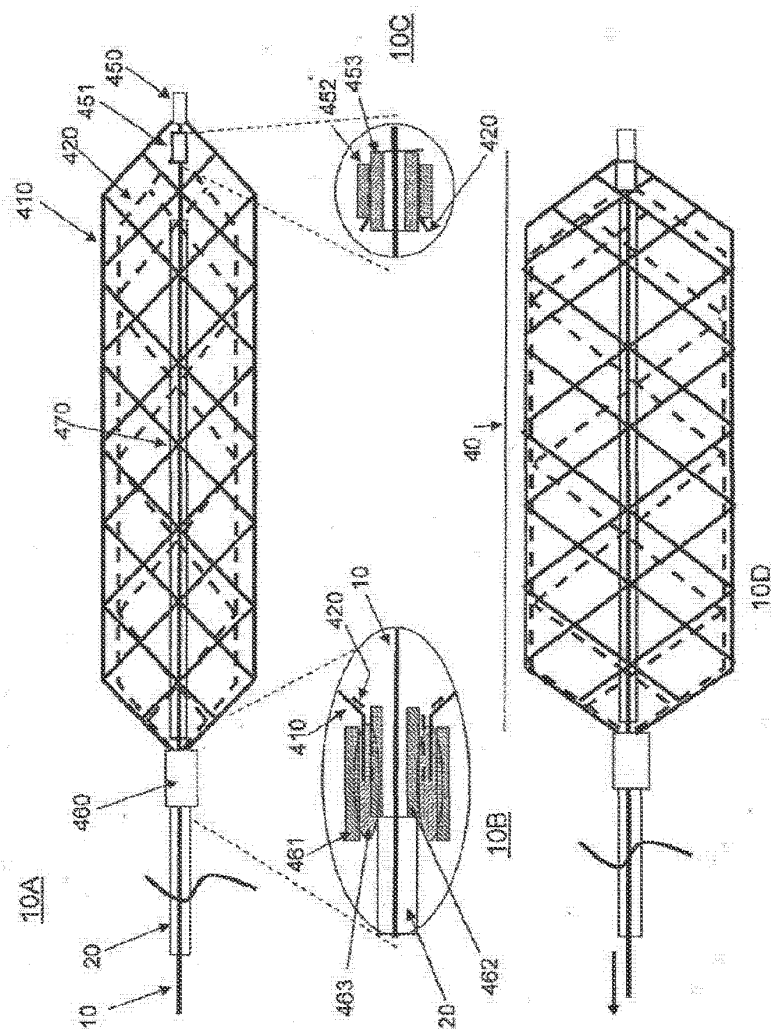


图 10A-D

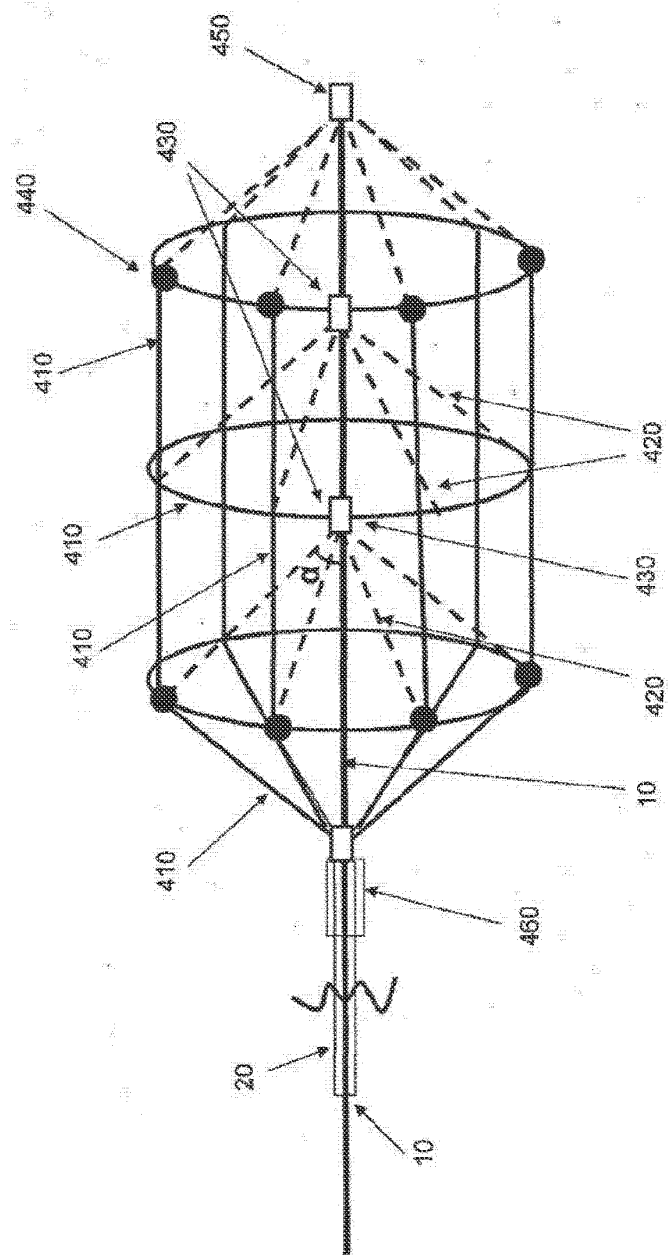
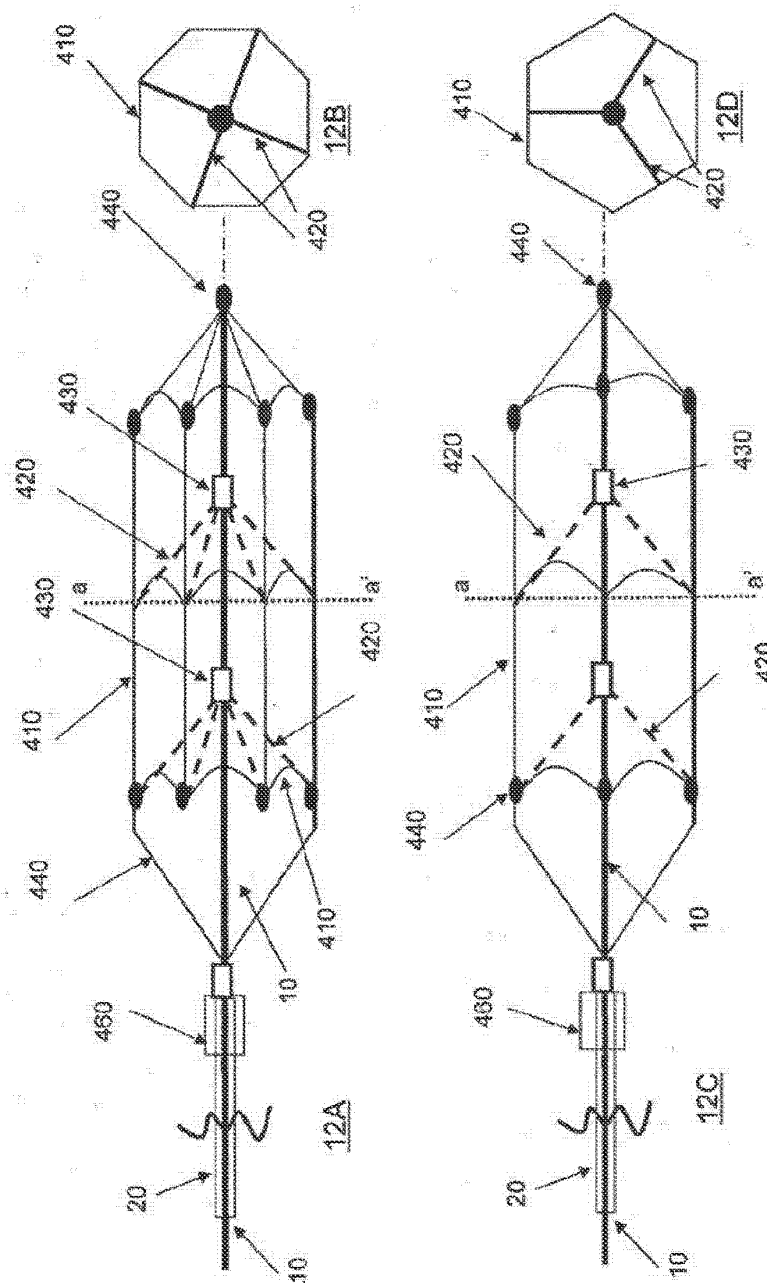


图 11



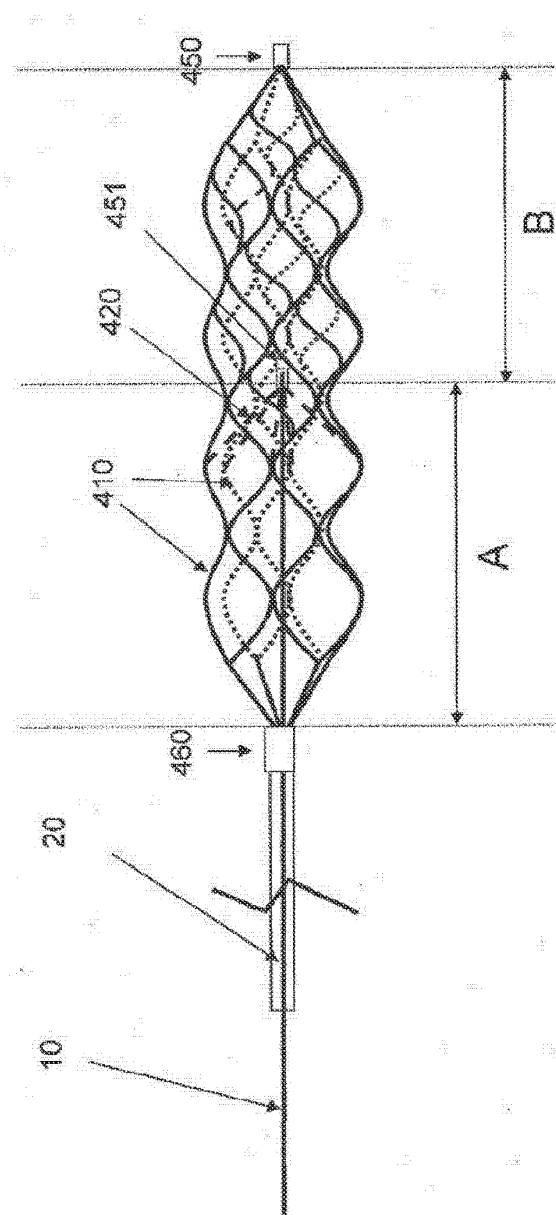


图 13

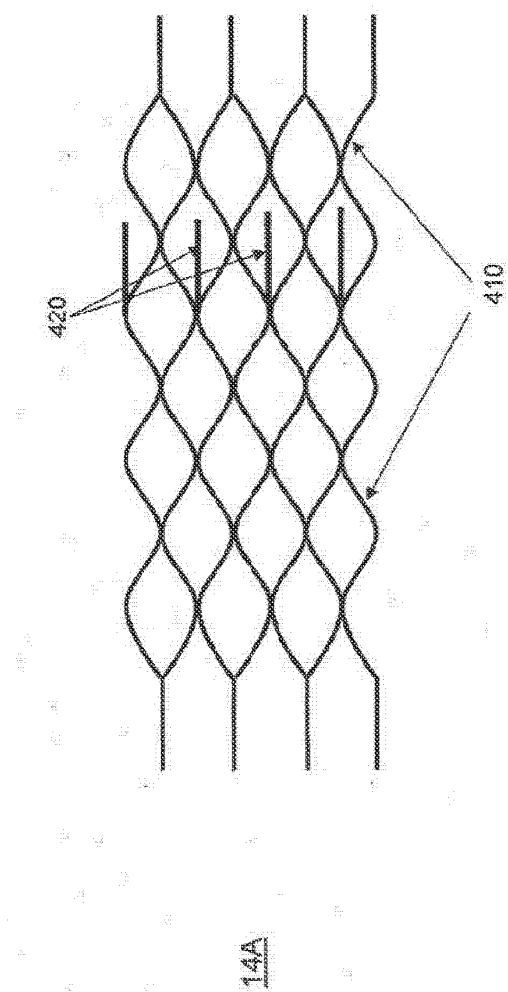


图 14A

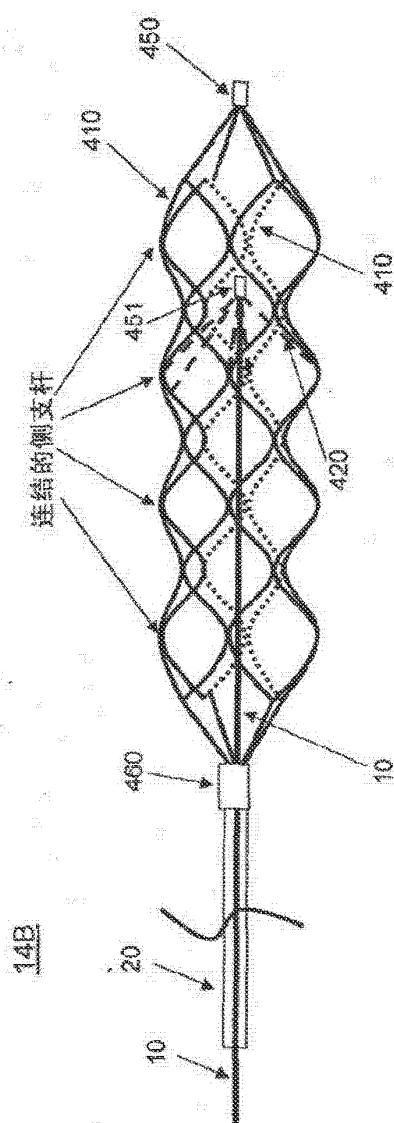


图 14B

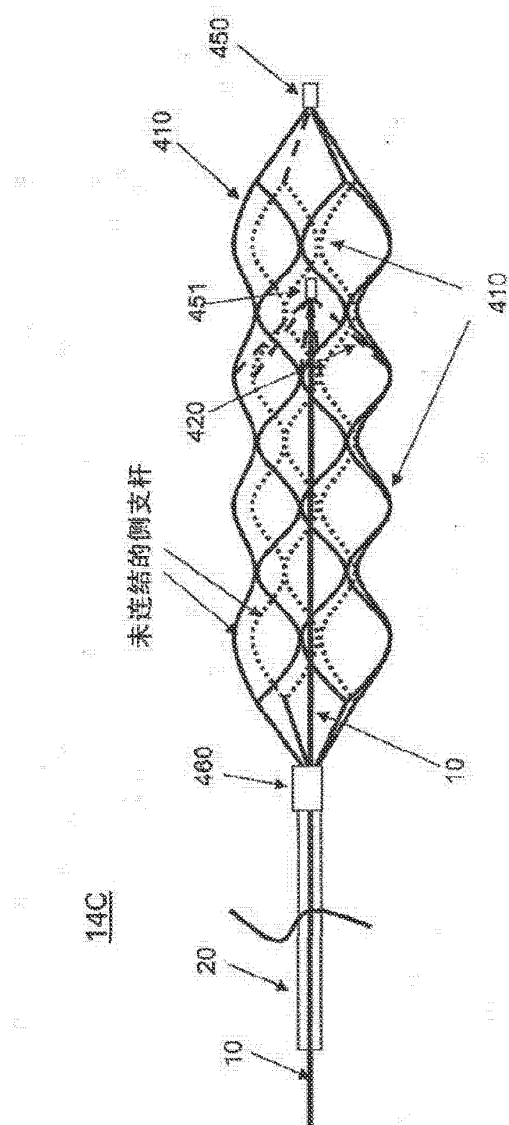


图 14C

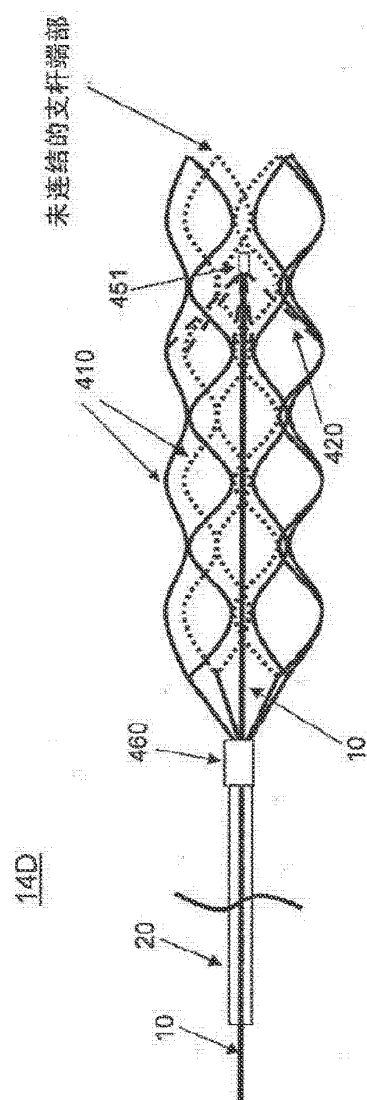


图 14D

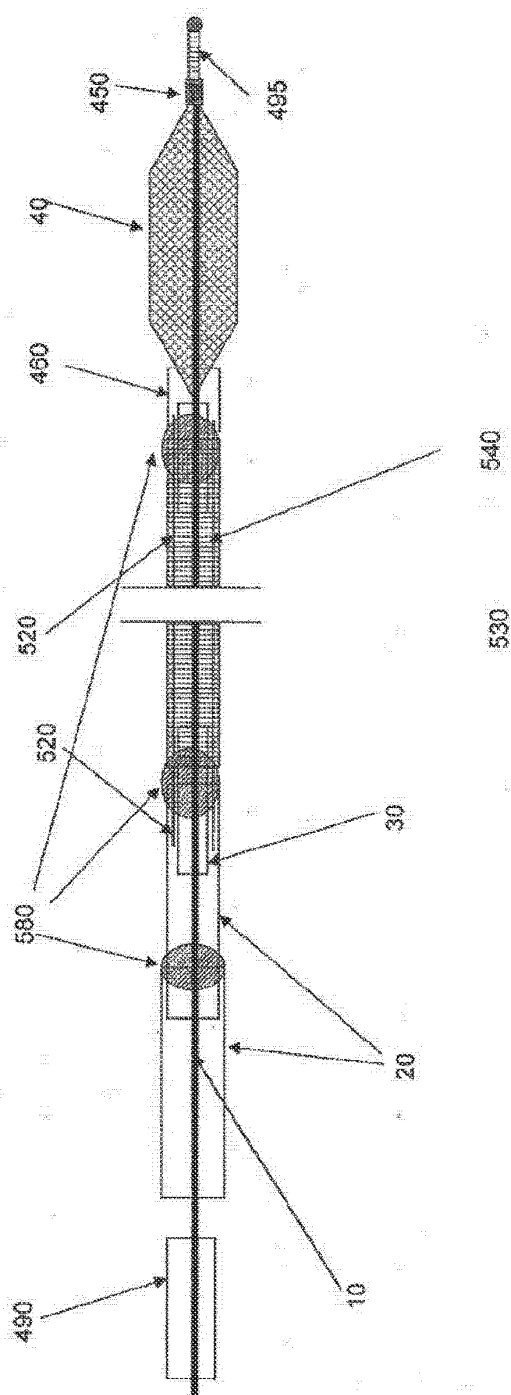


图 15

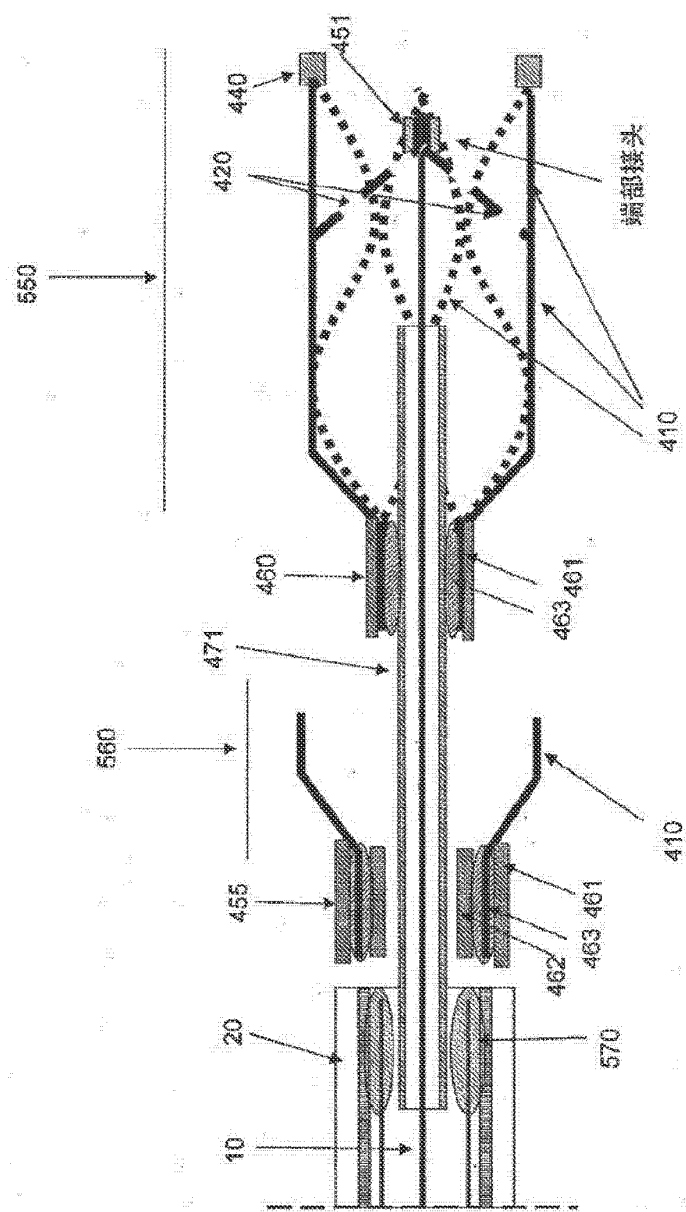


图 16

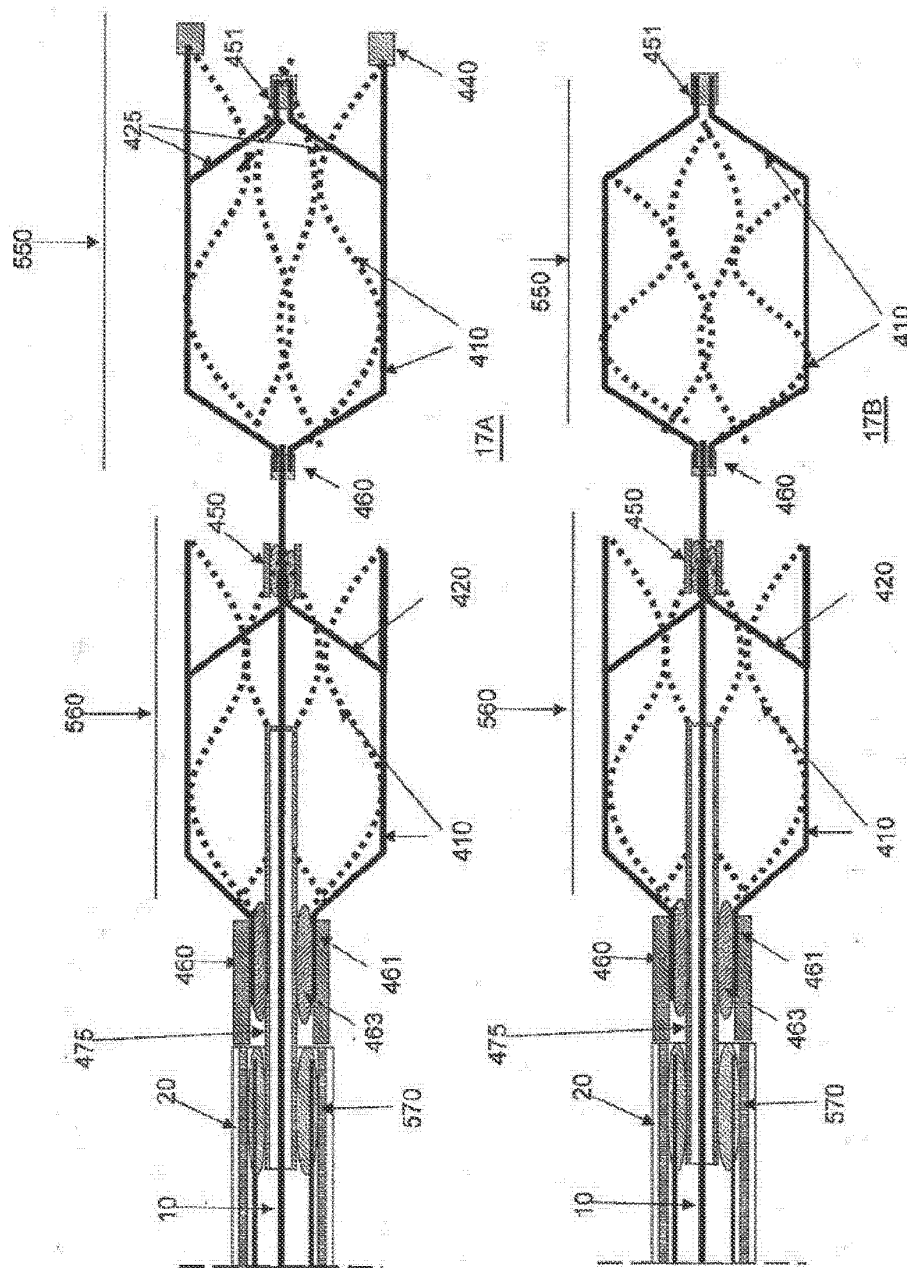


图 17A-B

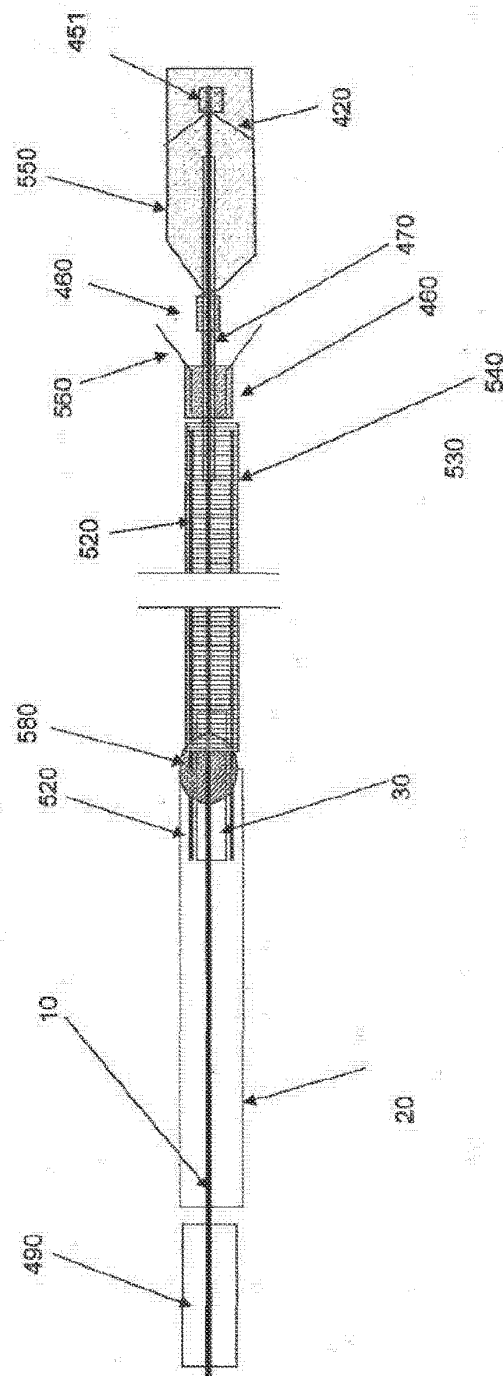


图 18

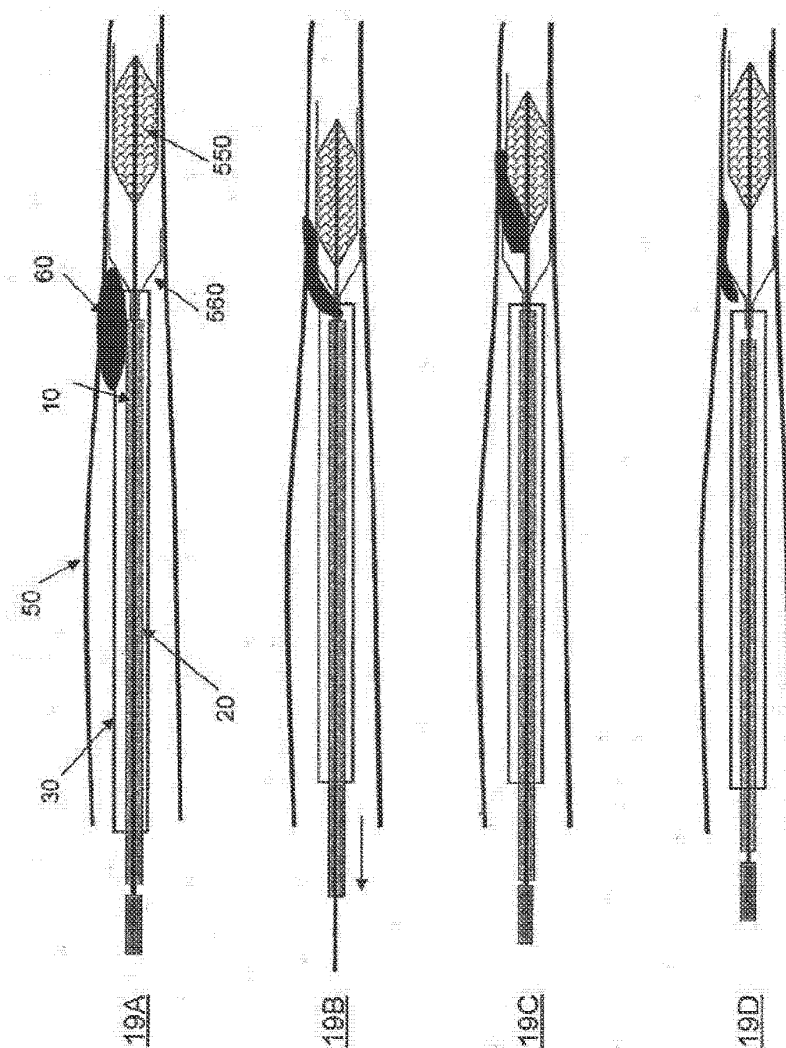


图 19A-D

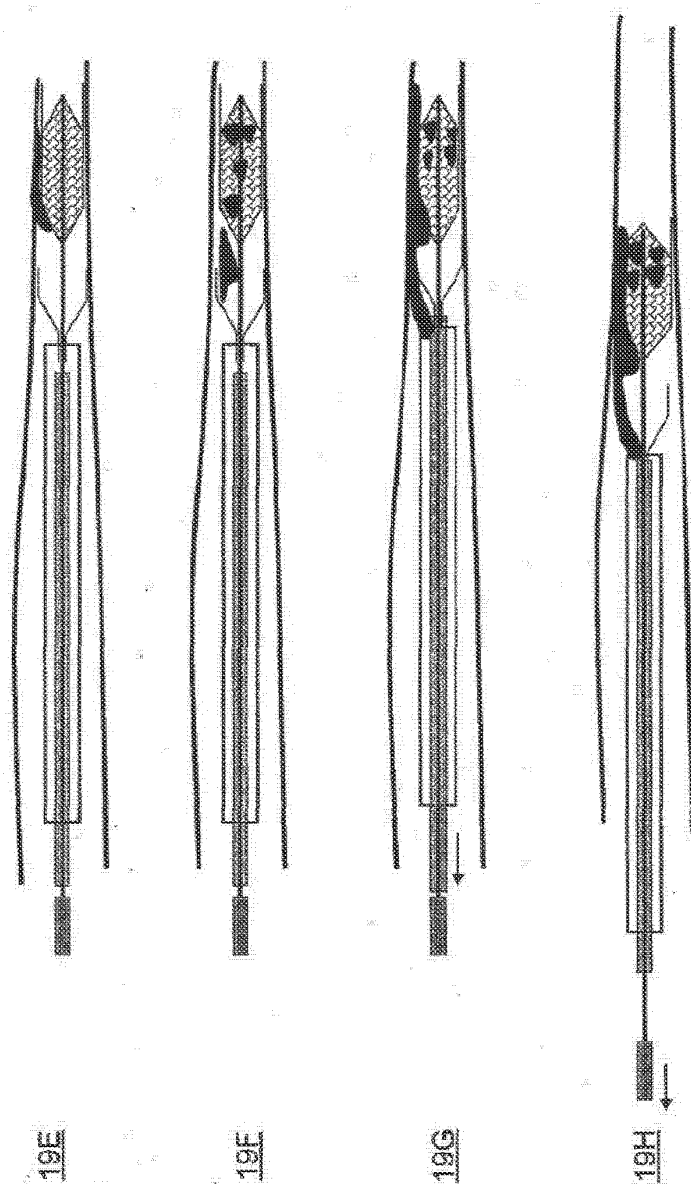


图 19E-H

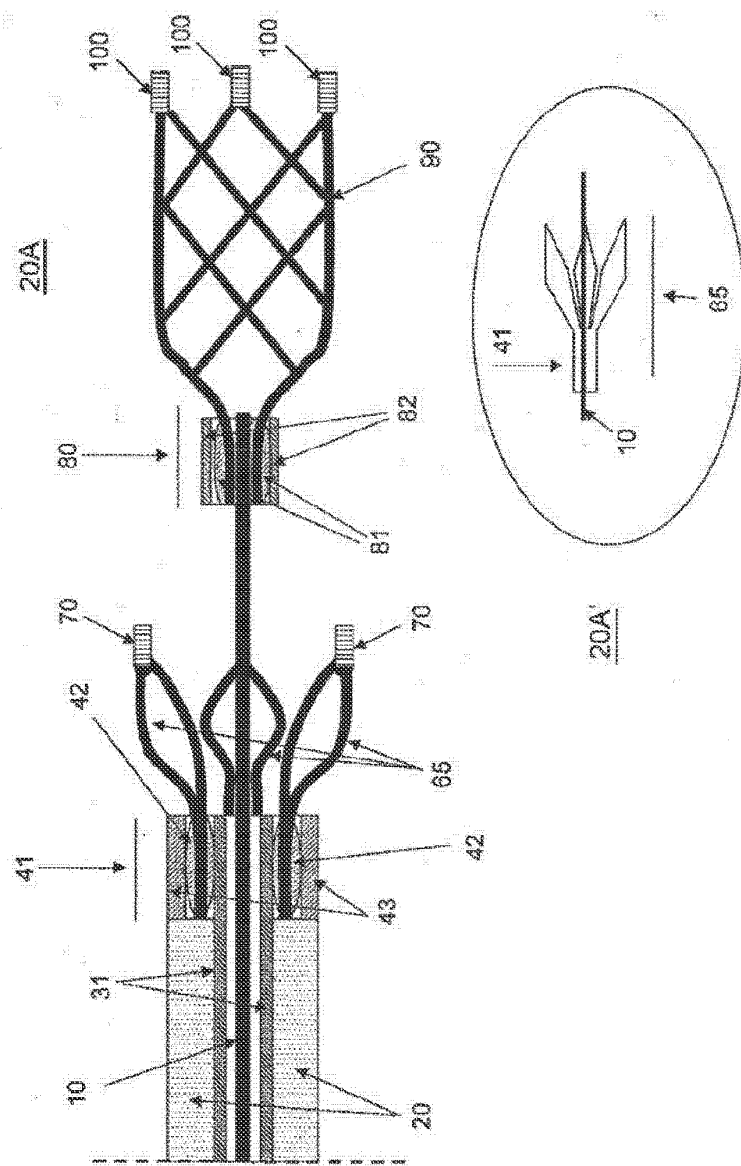


图 20A-A'

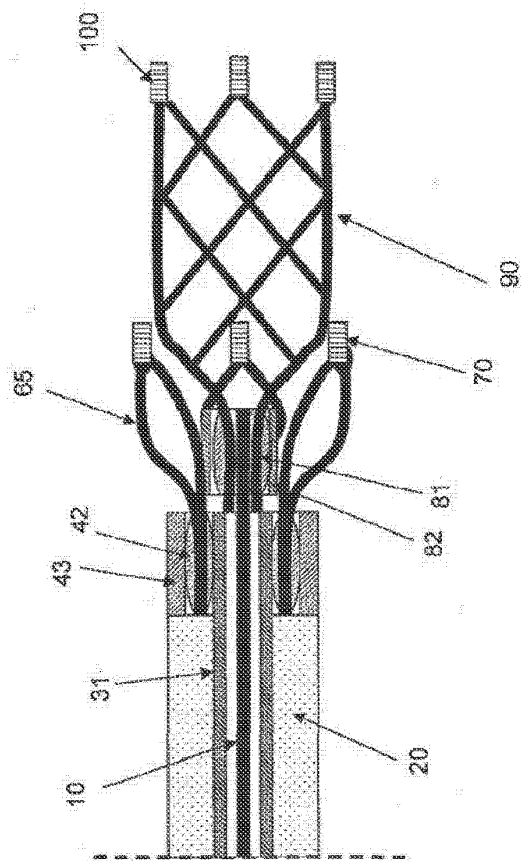


图 20B

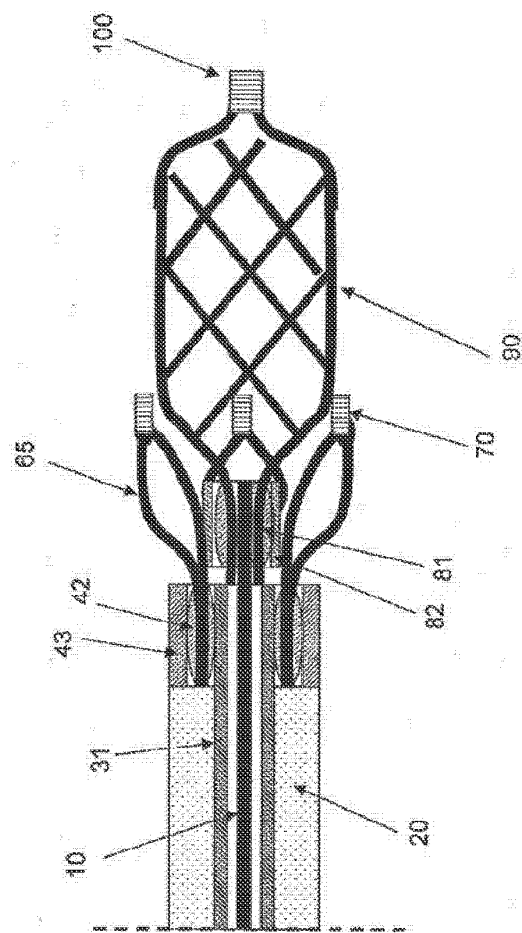


图 20C

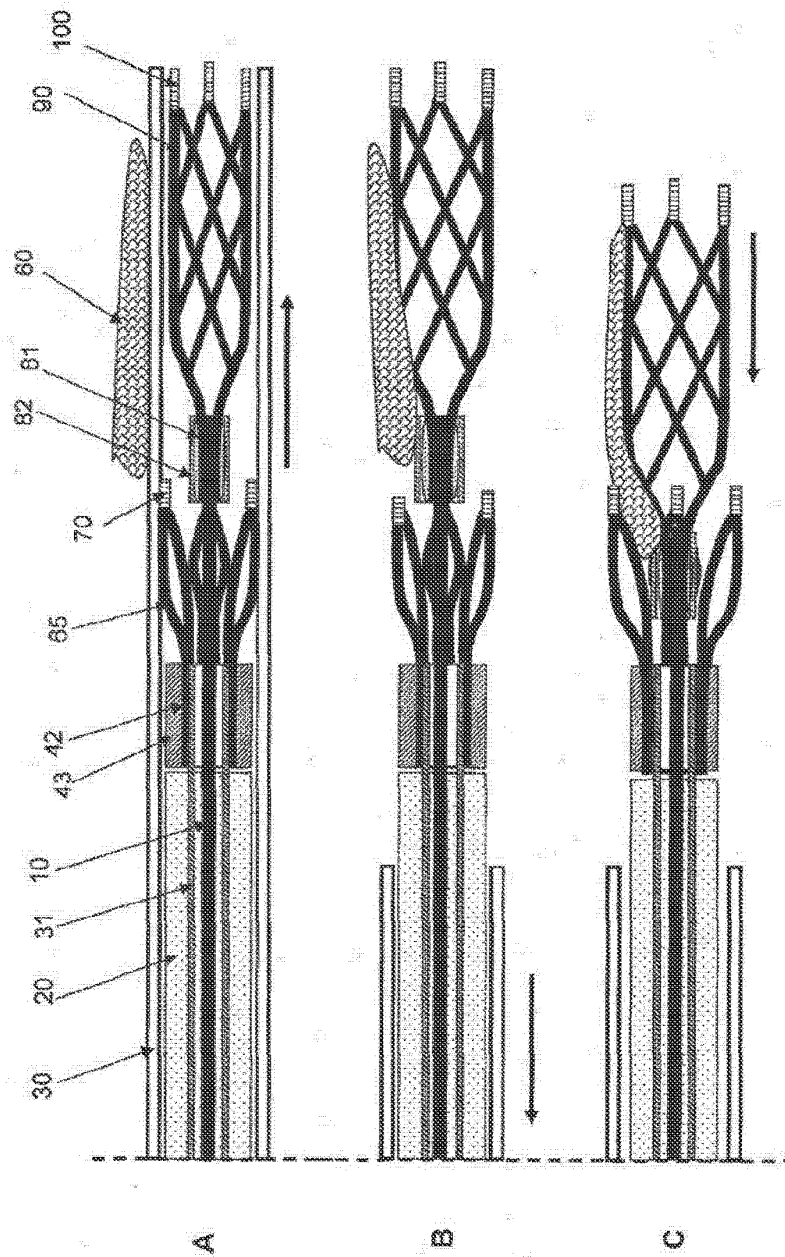


图 21A-C

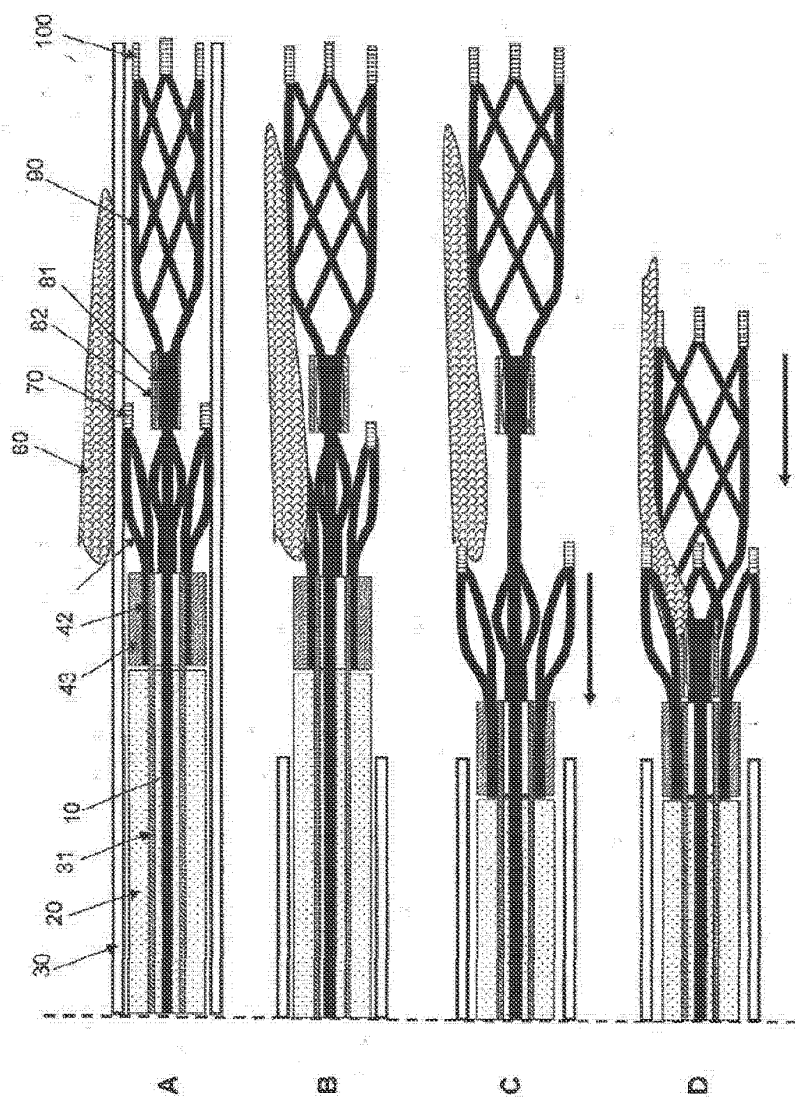


图 22A-D

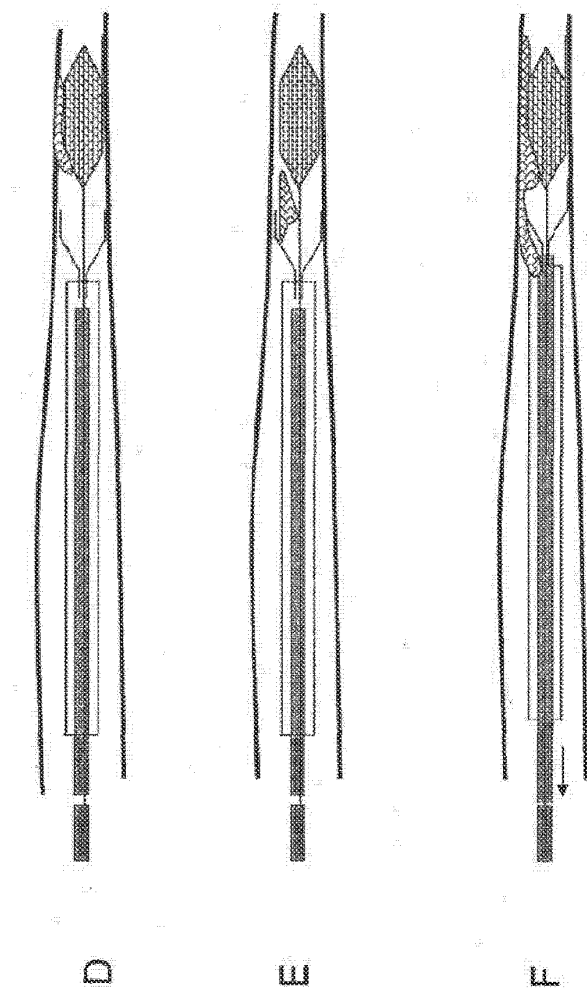


图 23D-F

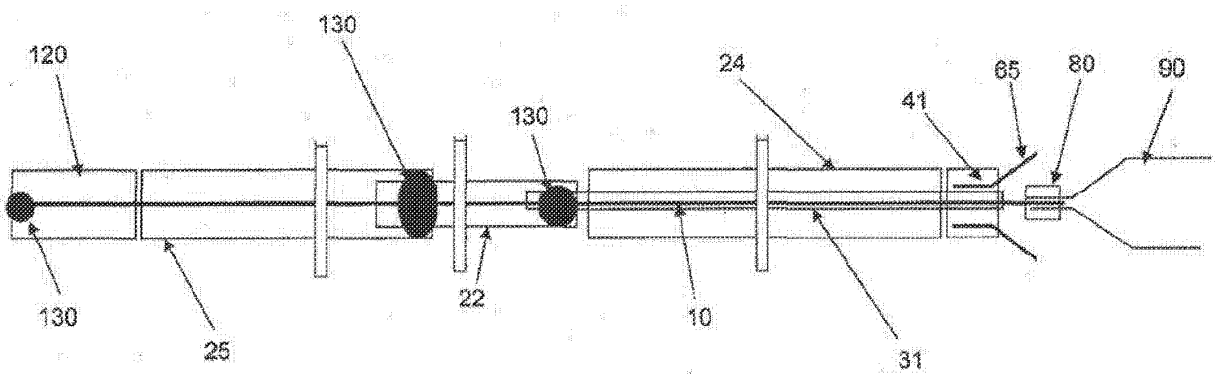


图 24

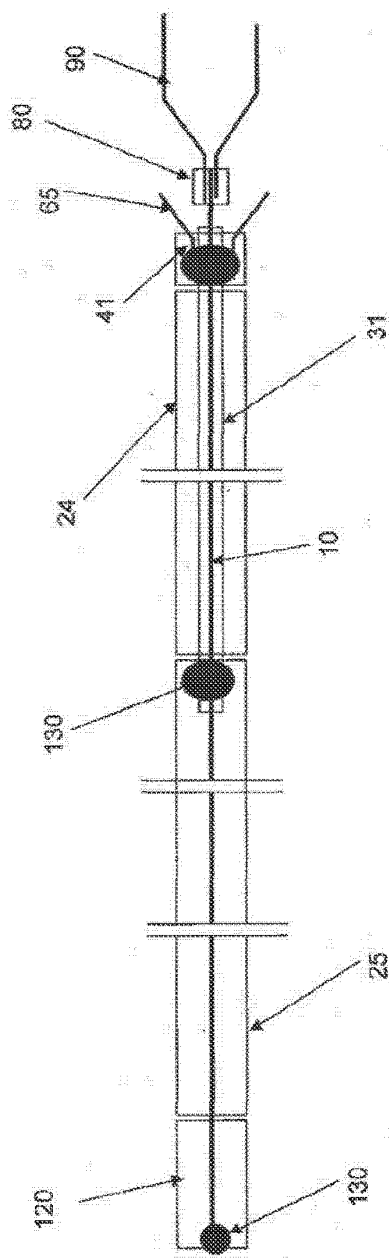


图 25

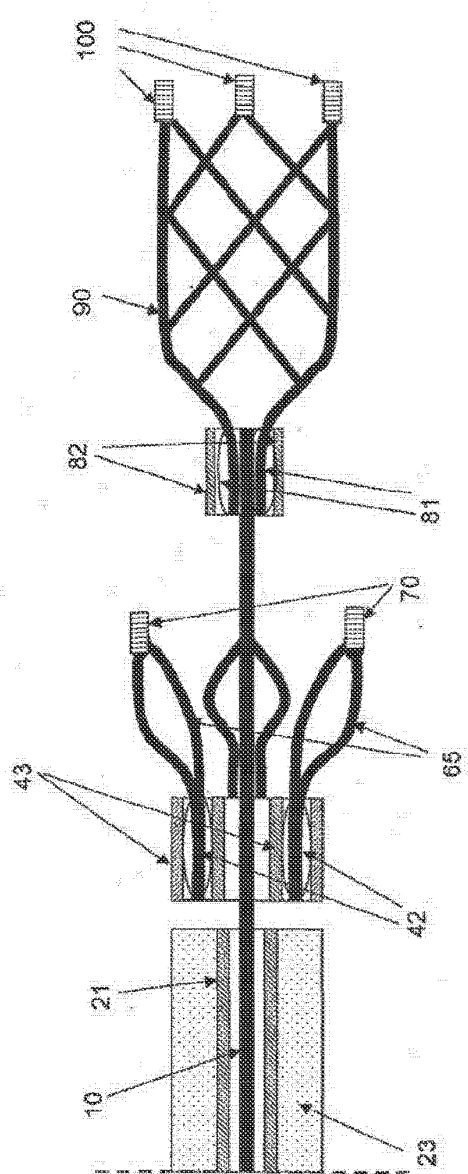


图 26A

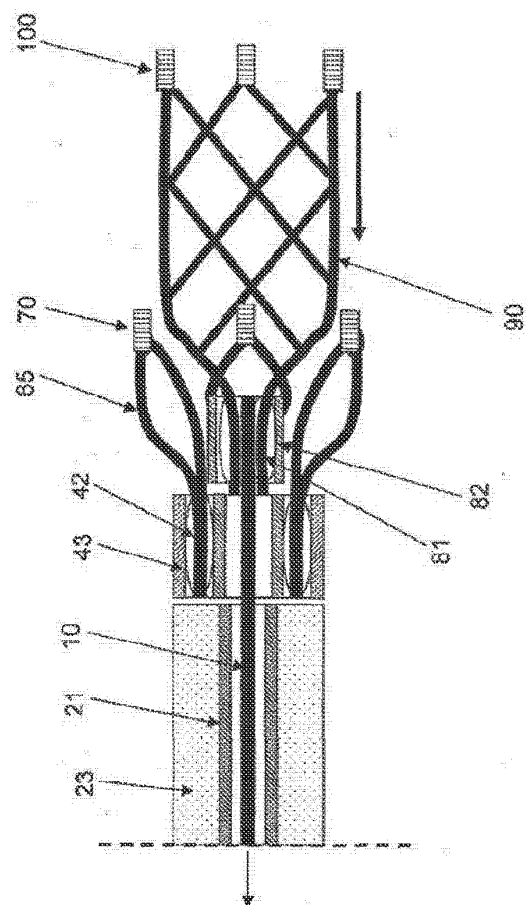


图 26B

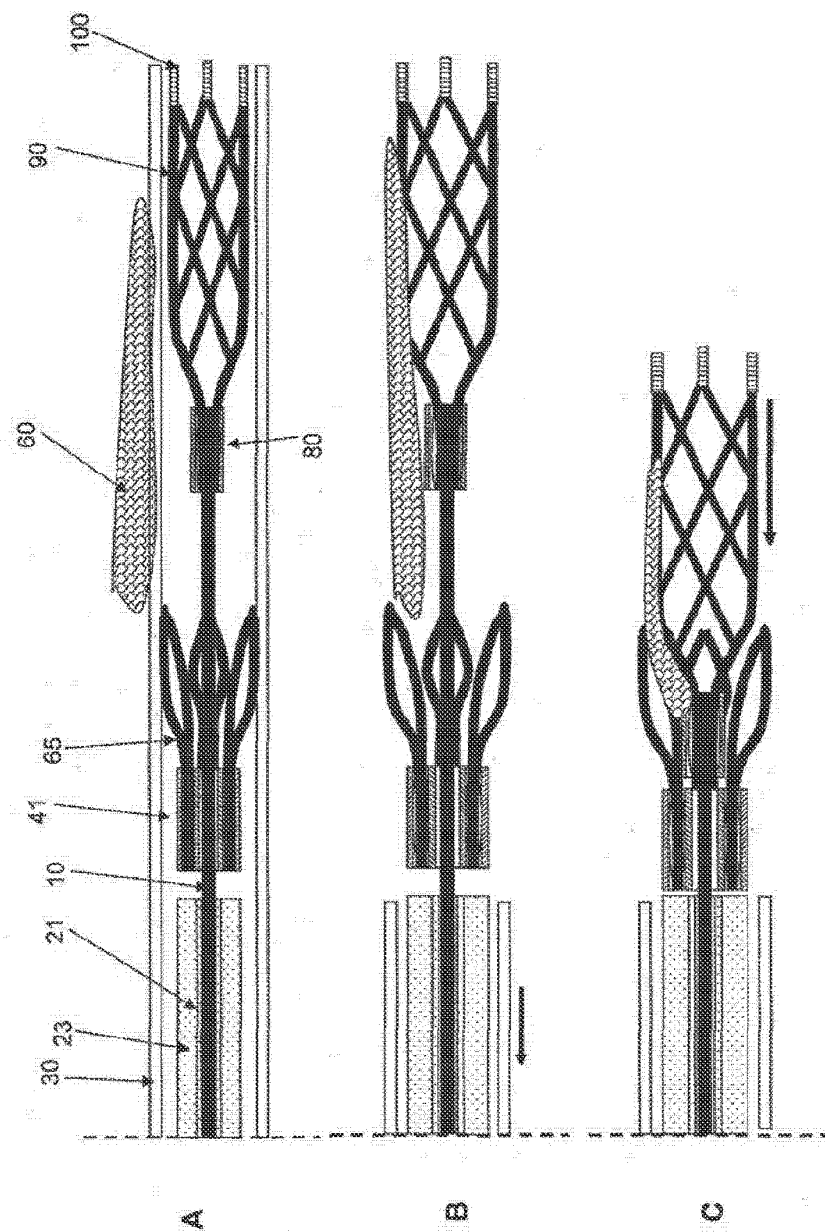


图 27A-C

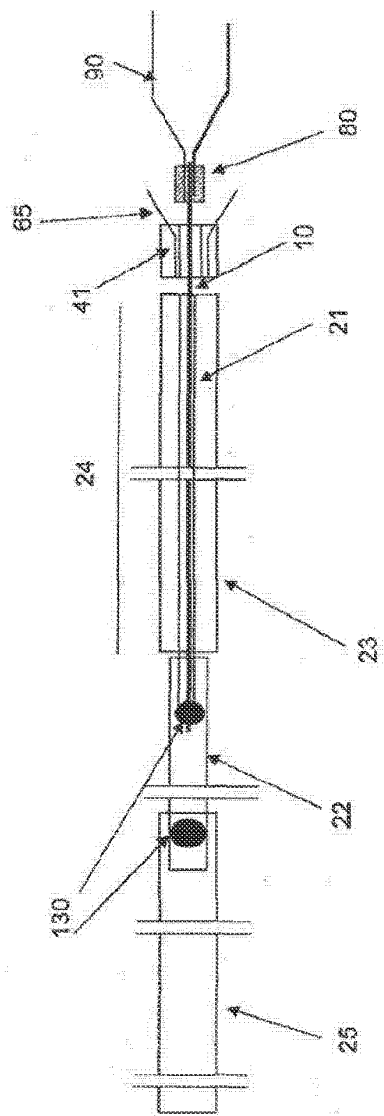


图 28

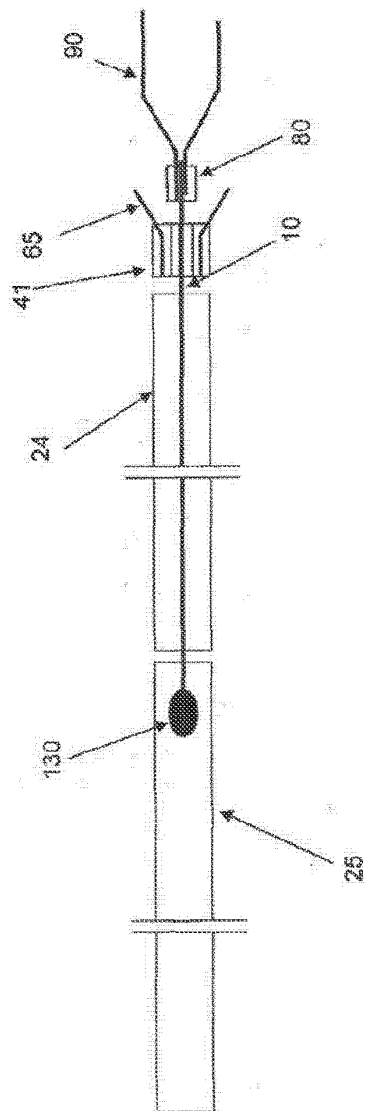


图 29

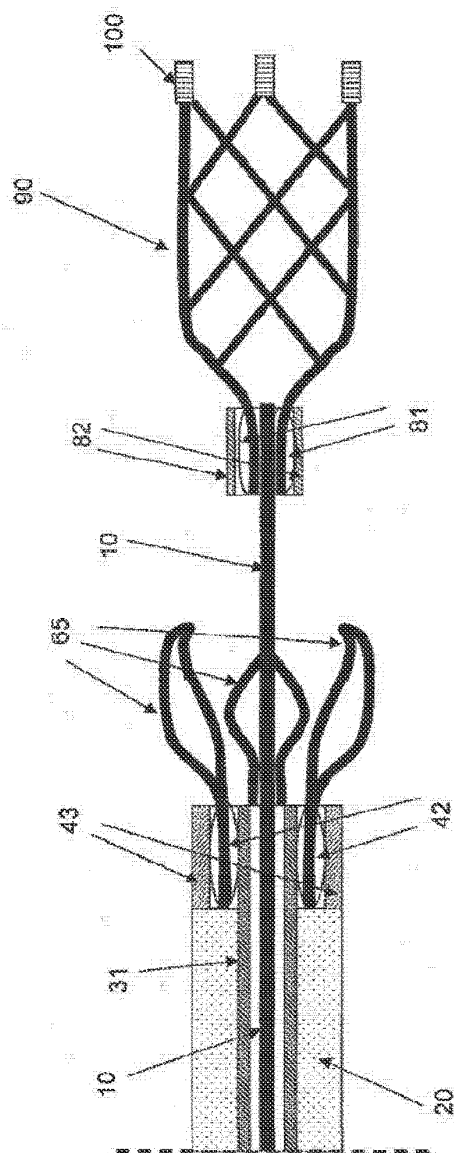


图 30A

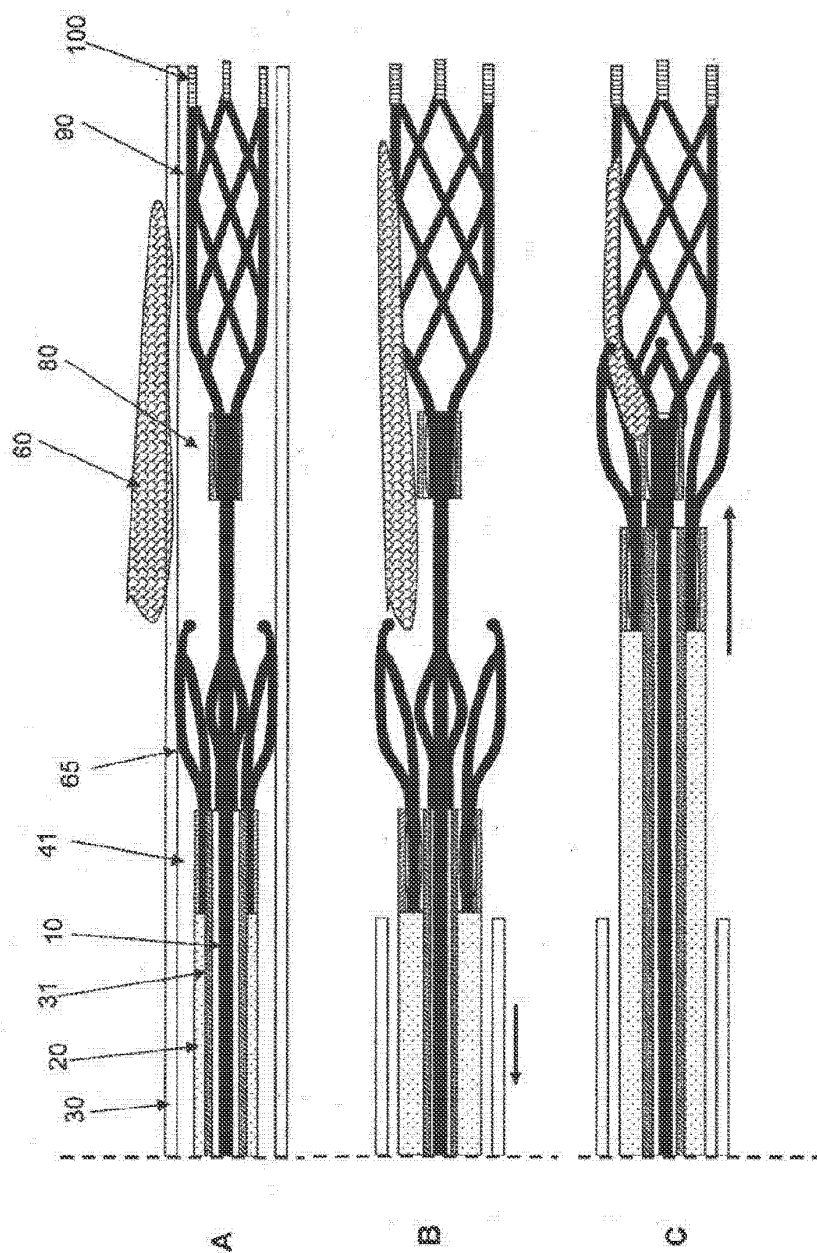


图 31A-C

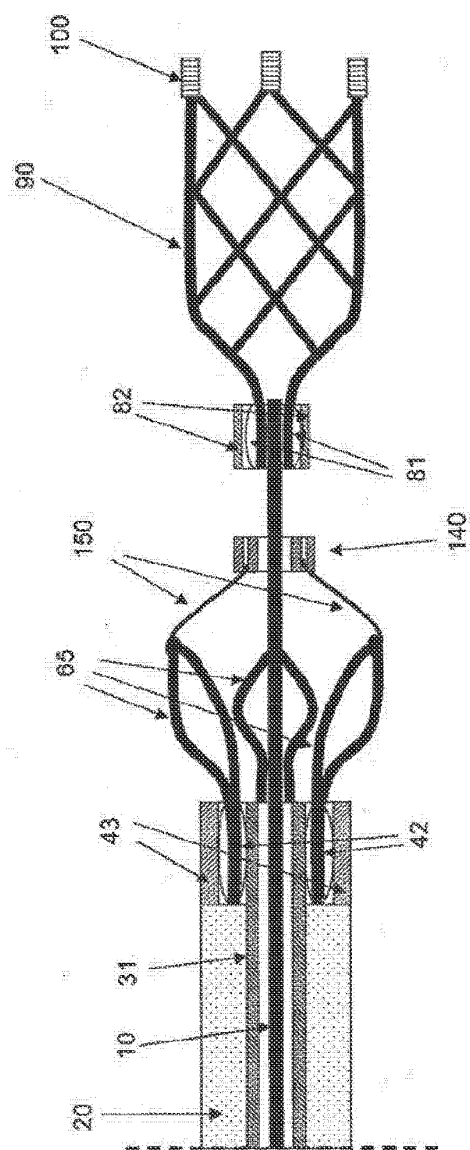


图 32A

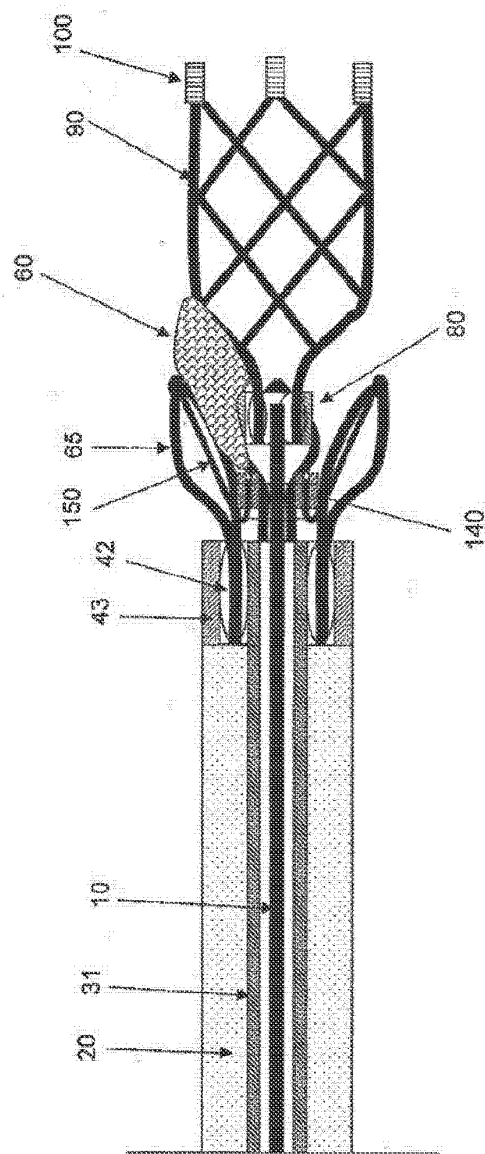


图 32B

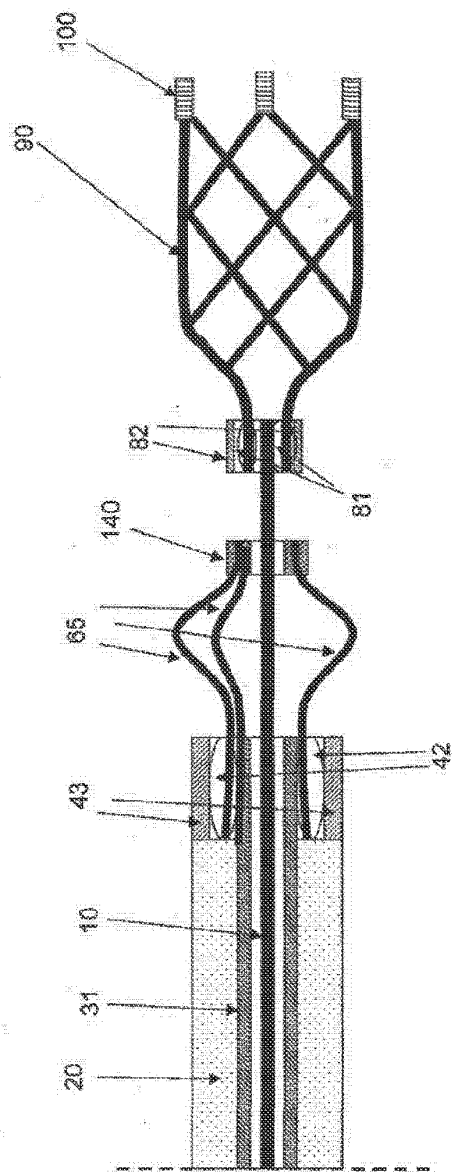


图 33A

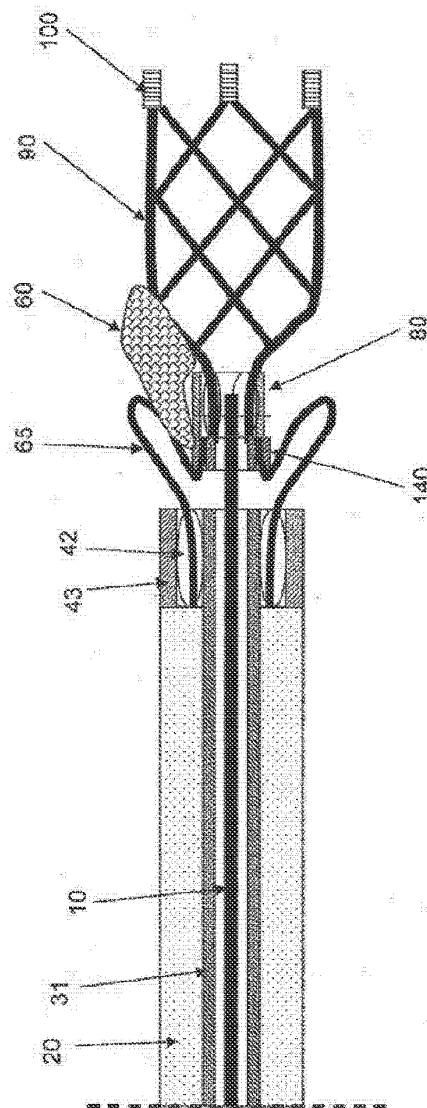


图 33B

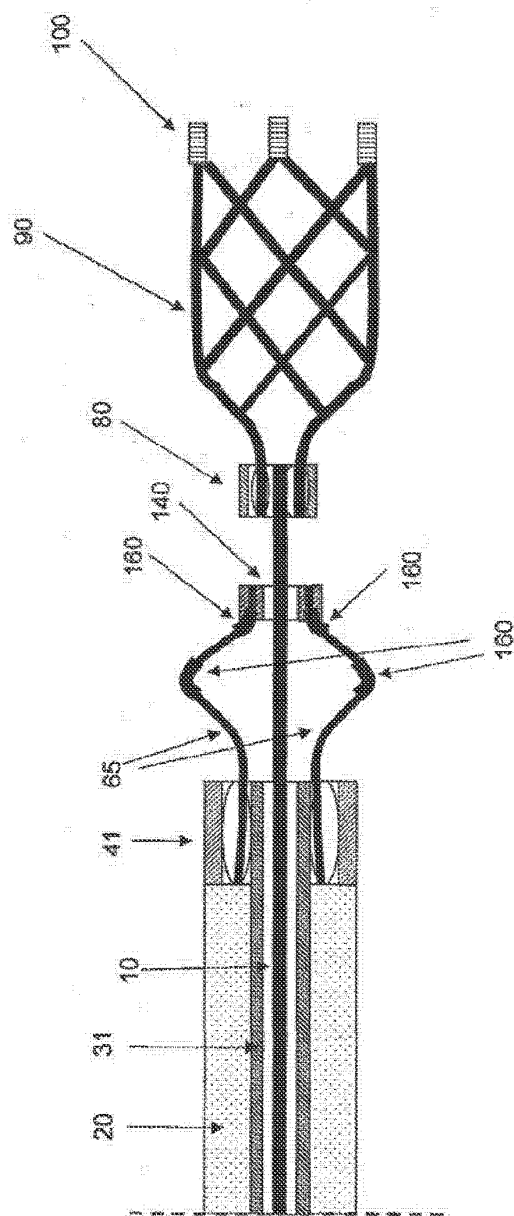


图 34A

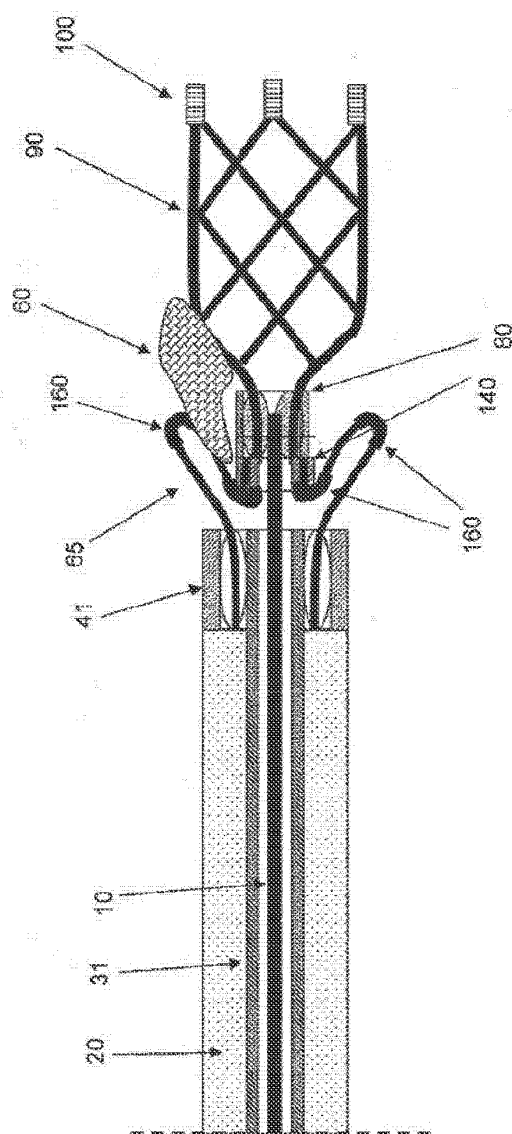


图 34B

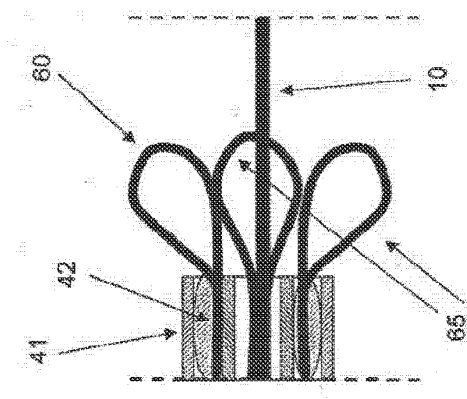


图 35

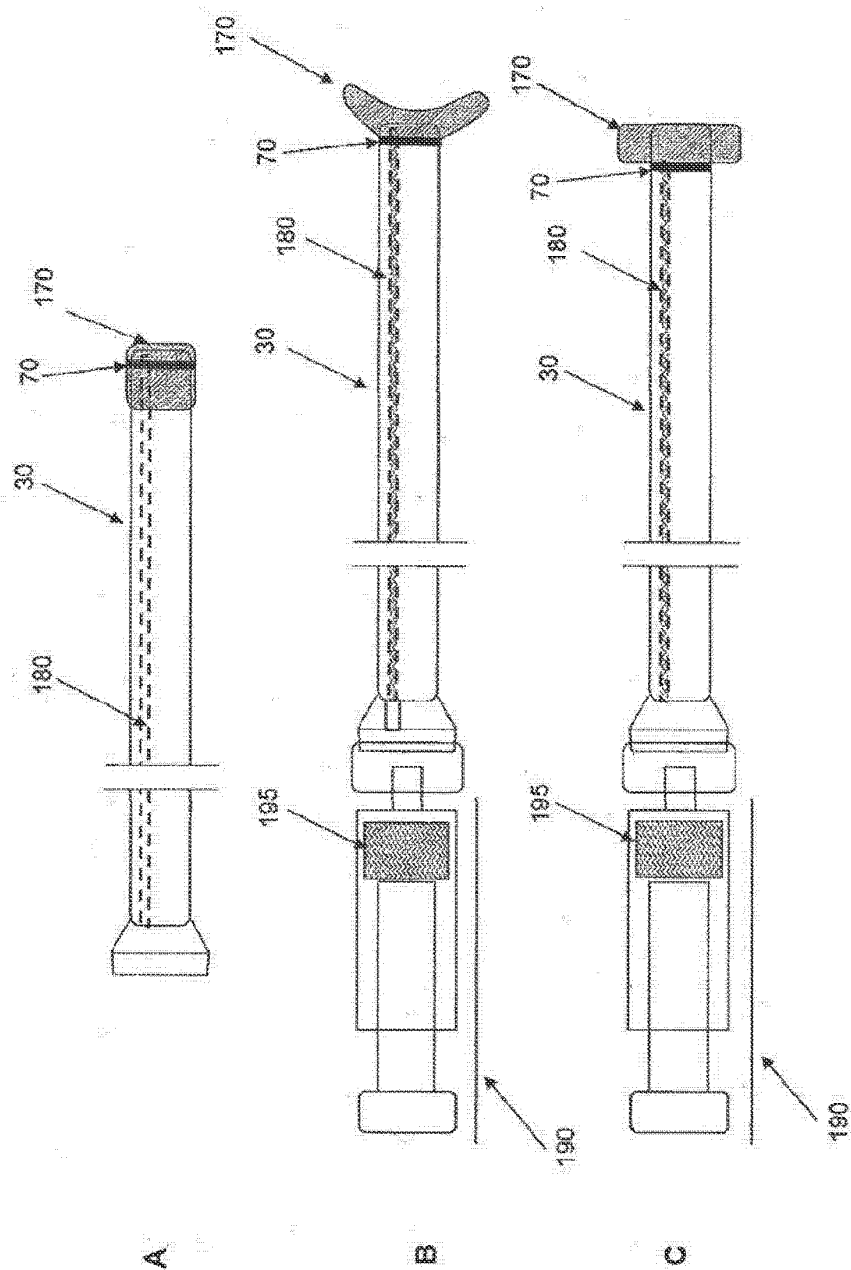


图 36A-C

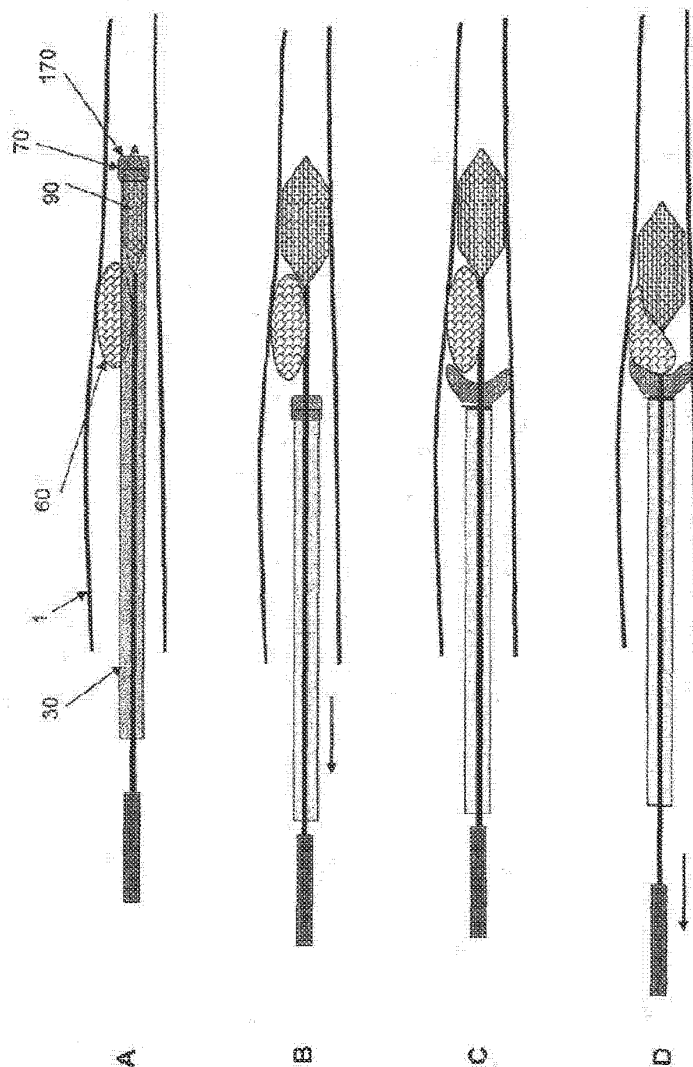


图 37A-D

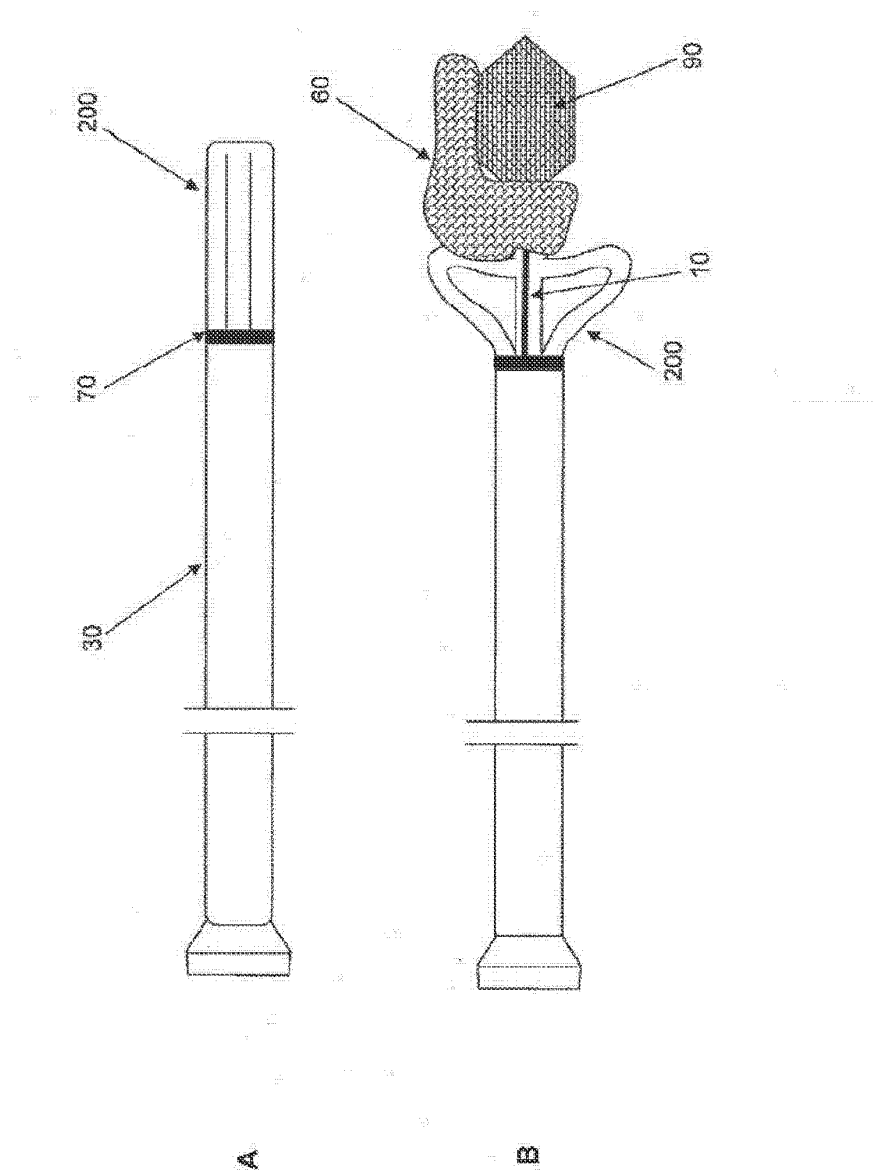


图 38A-B

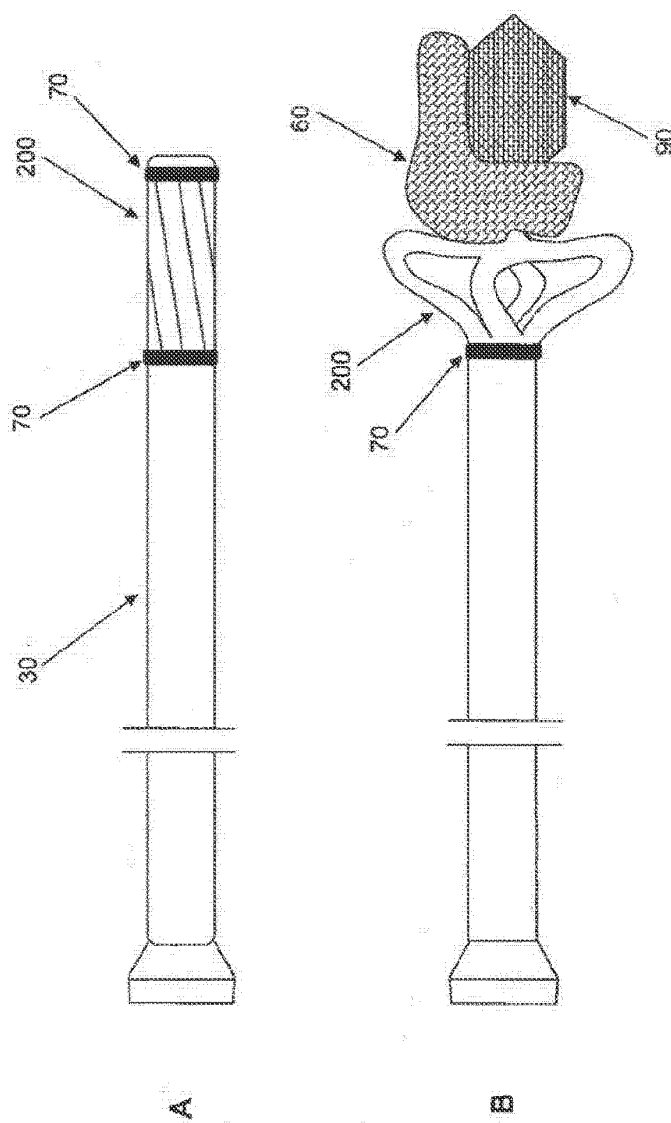


图 39A-B

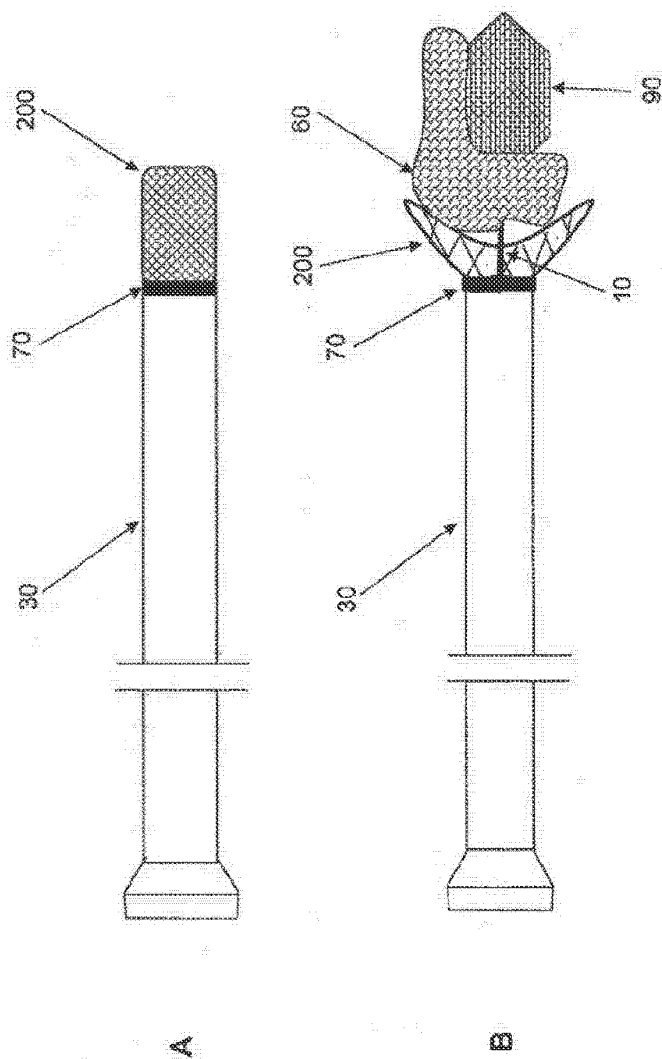


图 40A-B

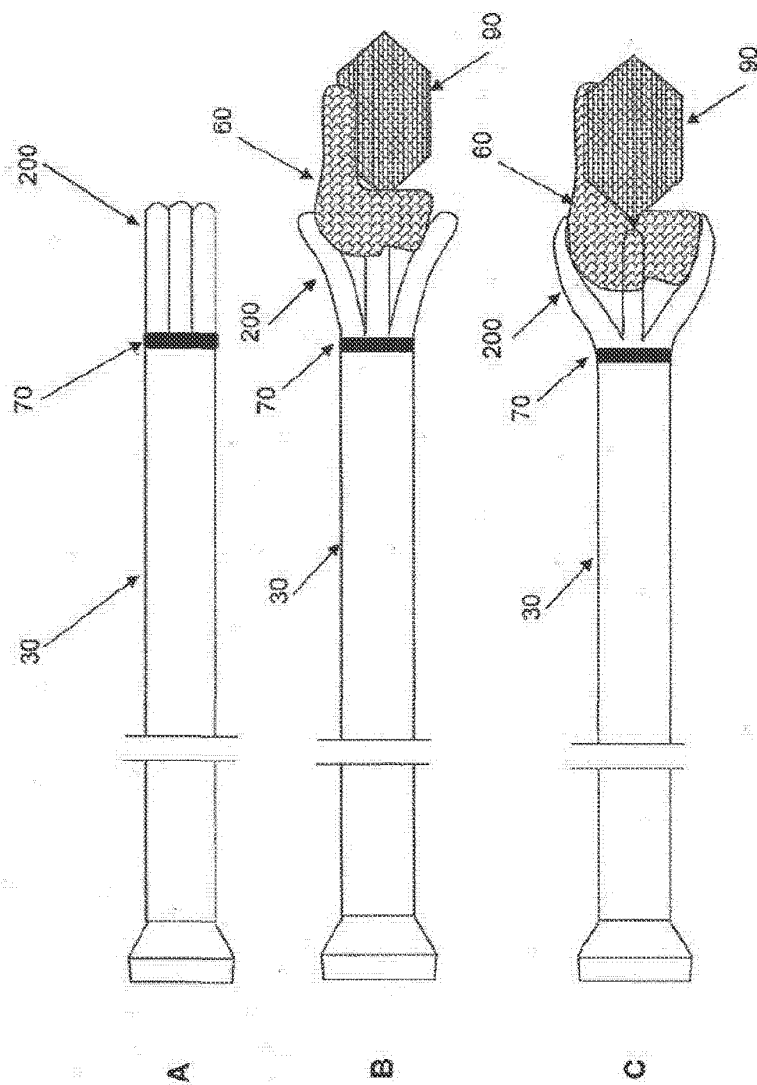


图 41A-C

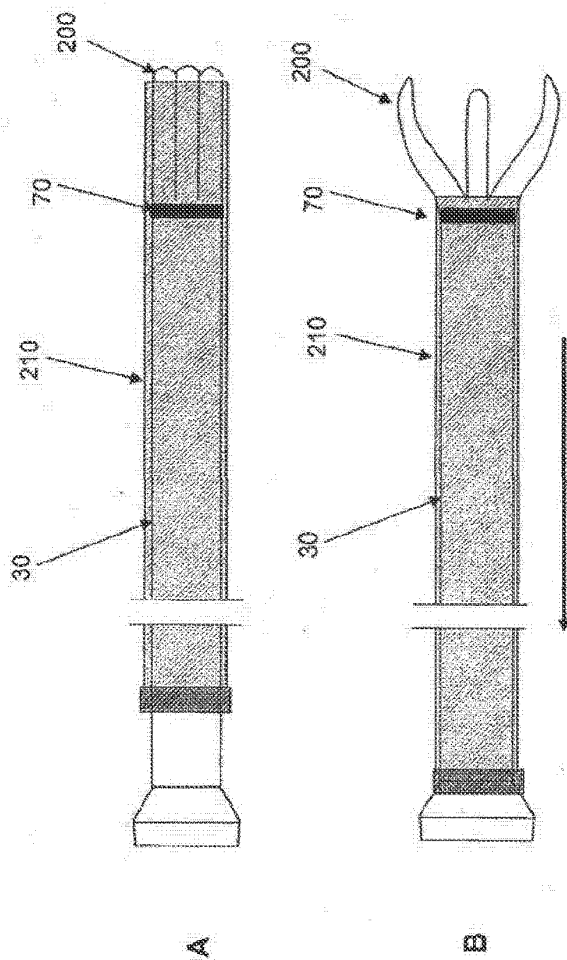


图 42A-B

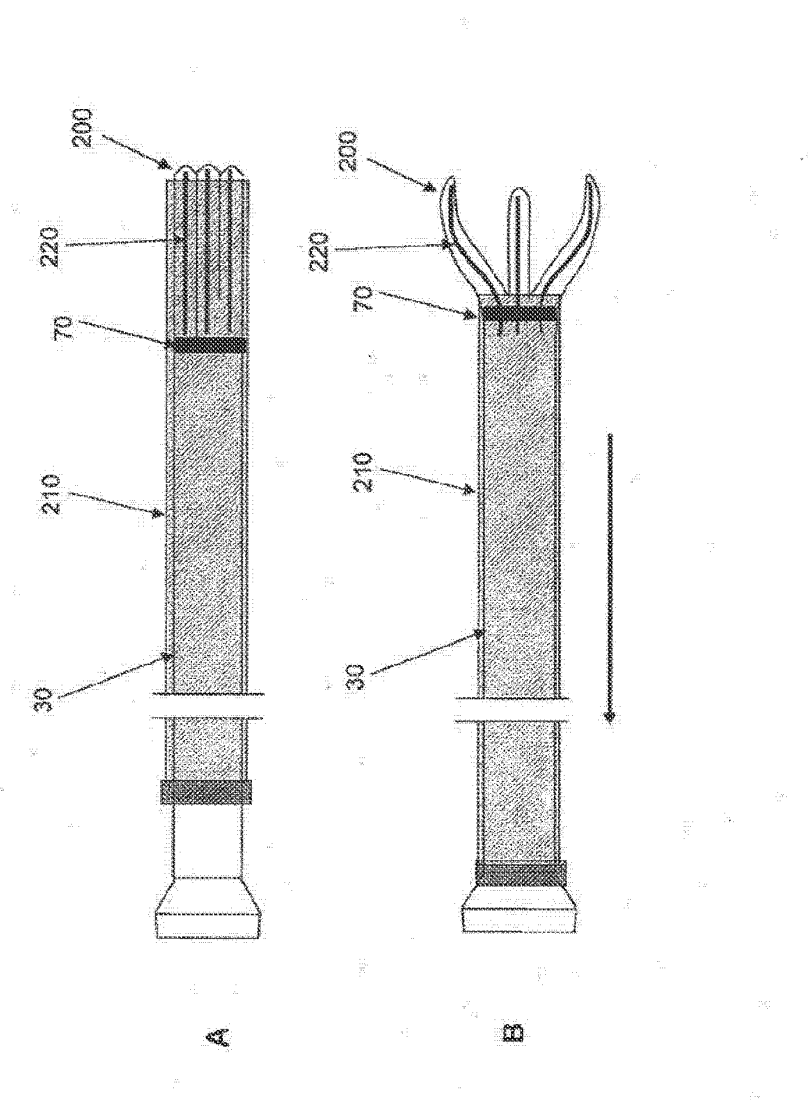


图 43A-B

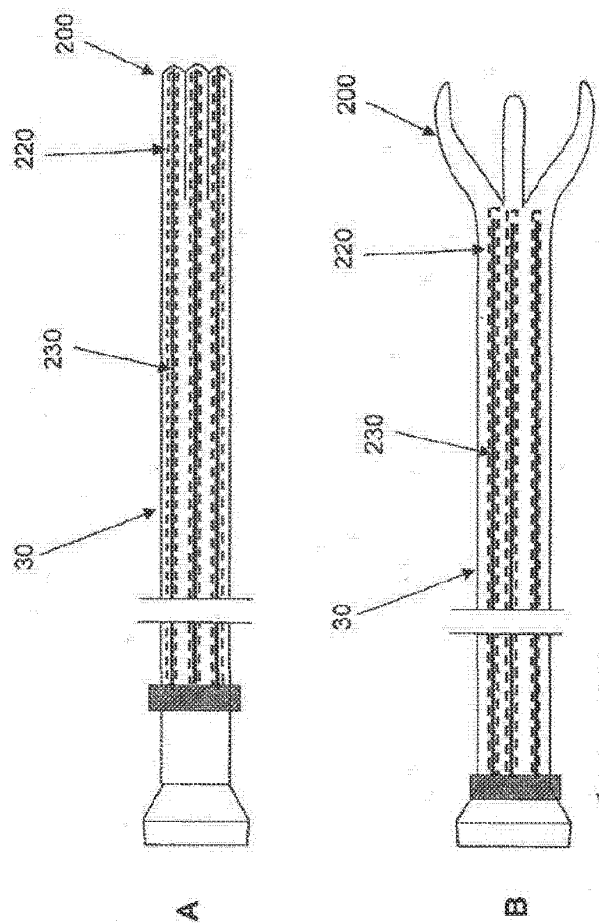


图 44A-B

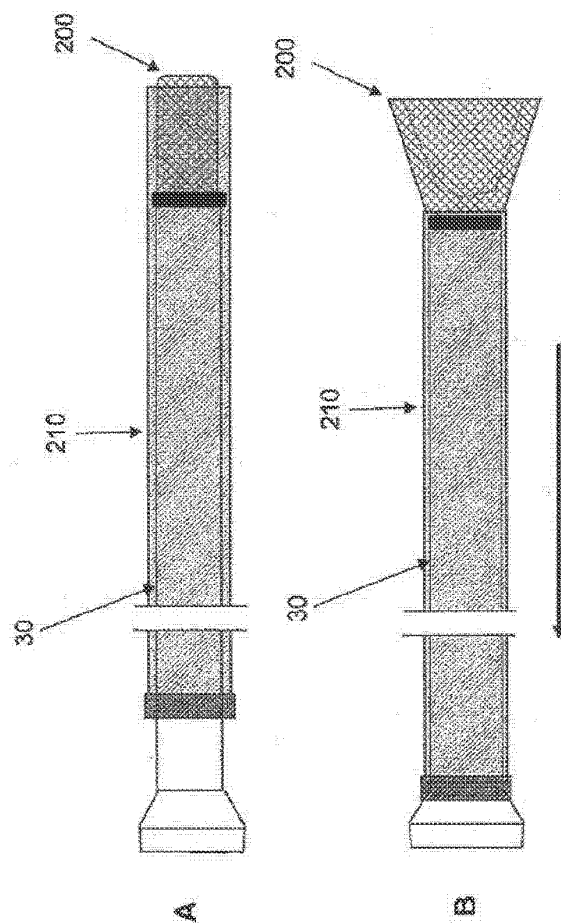


图 45A-B



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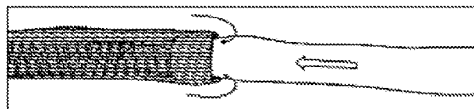


FIG. 8A

(57) Abstract: Mechanical thrombectomy apparatuses that may be config-
ured to prevent or reduce jamming (e.g., "anti-j amming" thrombectomy de-
vices), grab clot, and/or macerate the thrombus, e.g., clot, being removed.
These mechanical thrombectomy apparatuses may include a tractor compris-
ing a flexible tube of material that inverts as it rolls over itself while be-
ing drawn into a catheter in a conveyor-like motion. In particular, described
herein are mechanical thrombectomy apparatuses having tractors selectably
extendable projections that may aid in grabbing and/or macerating a clot.
Also described herein are seesawing tractors for mechanical thrombectomy
apparatuses.

ANTI-JAMMING AND MACERATING THROMBECTOMY APPARATUSES AND METHODS

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This patent application claims priority to U.S. provisional patent application no. 62/327,024, filed on April 25, 2016 and titled “DOZER THROMBECTOMY SYSTEM”; U.S. provisional patent application no. 62/345,152, filed on June 3, 2016, and titled “DOZER THROMBECTOMY SYSTEM 2”; and U.S. provisional patent application no. 62/393,460, filed on September 12, 2016, and titled “DOZER II THROMBECTOMY SYSTEM PROV”.

[0002] This patent application may be related to U.S. patent application no 15/291,015, filed on October 11, 2016, titled “MECHANICAL THROMBECTOMY APPARATUSES AND METHODS”, which is a continuation of U.S. Patent Application No. 15/043,996, filed February 15, 2016, now U.S. 9,463,035, which claims priority to each of the following provisional patent applications: U.S. Provisional Patent Application No. 62/284,300, filed September 28, 2015; U.S. Provisional Patent Application No. 62/284,752, filed October 8, 2015; and U.S. Provisional Patent Application No. 62/245,560, filed October 23, 2015.

[0003] Each of these patents and patent applications is herein incorporated by reference in its entirety.

INCORPORATION BY REFERENCE

[0004] All publications and patent applications mentioned in this specification are herein incorporated by reference in their entirety to the same extent as if each individual publication or patent application was specifically and individually indicated to be incorporated by reference.

FIELD

[0005] The apparatuses and methods described herein relate to mechanical removal of objects from within a body. In particular, described herein are mechanical thrombectomy apparatuses and methods.

BACKGROUND

[0006] It is often desirable to remove tissue from the body in a minimally invasive manner as possible, so as not to damage other tissues. For example, removal of tissue from within a vasculature, such as blood clots, may improve patient conditions and quality of life.

[0007] Many vascular system problems stem from insufficient blood flow through blood vessels. One causes of insufficient or irregular blood flow is a blockage within a blood vessel referred to as a blood clot, or thrombus. Thrombi can occur for many reasons, including after a trauma such as surgery, or due to other causes. For example, a large percentage of the more than 1.2 million heart attacks in the United States are caused by blood clots (thrombi) which form within a coronary artery.

[0008] When a thrombus forms, it may effectively stop the flow of blood through the zone of formation. If the thrombus extends across the interior diameter of an artery, it may cut off the flow of blood through the artery. If one of the coronary arteries is 100% thrombosed, the flow of blood is stopped in that artery, resulting in a shortage of oxygen carrying red blood cells, e.g., to supply the muscle (myocardium) of the heart wall. Such a thrombosis is unnecessary to prevent loss of blood but can be undesirably triggered within an artery by damage to the arterial wall from atherosclerotic disease. Thus, the underlying disease of atherosclerosis may not cause acute oxygen deficiency (ischemia) but can trigger acute ischemia via induced thrombosis. Similarly, thrombosis of one of the carotid arteries can lead to stroke because of insufficient oxygen supply to vital nerve centers in the cranium. Oxygen deficiency reduces or prohibits muscular activity, can cause chest pain (angina pectoris), and can lead to death of myocardium which permanently disables the heart to some extent. If the myocardial cell death is extensive, the heart will be unable to pump sufficient blood to supply the body's life sustaining needs. The extent of ischemia is affected by many factors, including the existence of collateral blood vessels and flow which can provide the necessary oxygen.

[0009] Clinical data indicates that clot removal may be beneficial or even necessary to improve outcomes. For example, in the peripheral vasculature, inventions and procedures can reduce the need for an amputation by 80 percent. The ultimate goal of any modality to treat these conditions of the arterial or venous system is to remove the blockage or restore patency, quickly, safely, and cost effectively. This may be achieved by thrombus dissolution, fragmentation, thrombus aspiration or a combination of these methods.

[00010] Mechanical thrombectomy devices may be particularly advantageous. Depending on the size, location and extent of a clot, it may also be particularly advantageous to

mechanical retrieve and break apart the clot in a manner that is both safe and effective. There is a definite need for a thrombectomy device, and particularly a mechanical thrombectomy device that can be more effective in removing tissue such as clots from within a body. Described herein are apparatuses (devices, systems and kit) and methods of using them that may address the needs and problems discussed above.

SUMMARY OF THE DISCLOSURE

[00011] Described herein are mechanical thrombectomy apparatuses (devices, systems, etc.) and methods of using and making them. These apparatuses may be configured to prevent or reduce jamming and enhance grabbing and/or macerating a thrombus, e.g., clot, being removed. Typically, the mechanical thrombectomy apparatuses described herein are inverting tractor thrombectomy apparatuses that includes a tractor (e.g., tractor region, tractor portion, etc.) comprising a flexible tube of material that inverts over itself as it rolls over a distal end opening of an elongate inversion support. The elongate inversion support typically comprises a catheter having a distal end opening into which the tractor inverts. The flexible tractor inverts and rolls back into itself and may be drawn into the elongate inversion support in a conveyor-like motion; the outward-facing region rolls around to become an inward-facing region, e.g., within the lumen of the elongate inversion support. The rolling motion may thus draw a clot or other object within a vessel into the elongate inversion support.

[00012] Implementation of a rolling tractor that is sufficiently flexible to easily roll at the distal end (e.g., over a catheter) but sufficiently stiff to prevent jamming at the distal end of the elongate inversion support has proven challenging.

[00013] The elongate inversion support portion of the apparatus described herein may be or may include (particularly at its distal end) any appropriate catheter, e.g., a flexible tube that can be inserted into a body vessel (e.g., blood vessel) into which the more flexible tractor portion can be withdrawn by pulling against the elongate inversion support. The elongate inversion support may, in some variations, also be referred to as outer catheters (e.g., when the puller for the tractor is referred to as an inner catheter) and/or inversion catheters and/or support catheter, as it may support the inversion of the tractor. The elongate inversion support, including a catheter forming the elongate inversion support, may include a braided or woven portion, a spiral or coiled portion, etc. (e.g., having a braided shaft), may have a single layer or multiple layers, and may be formed of biocompatible materials, including polymers, metals, etc. (e.g., PTFE). Examples of vascular catheters that may form the elongate inversion support include micro catheters.

[00014] The mechanical thrombectomy apparatuses described herein include a tractor region and/or elongate inversion support that are configured to prevent jamming, while still able to efficiently “grab” a clot from within a vessel. For example, described herein are mechanical thrombectomy apparatuses that may be configured to grab or grasp and/or macerate a clot as it is mechanically drawn into the apparatus for removal. Although suction may be used in addition to the mechanical grabbing of the clot, in some variations suction is not used.

[00015] The tractor regions described herein may include projections that extend from the tractor region, particularly or exclusively as it bends around during inverting (e.g., at the distal end of the device). These projections may remain flat or non-extending when the tractor is held in parallel with the elongate inversion support. Alternatively, the projections may extend at all times. In general, the tractor may be formed of a woven materials, knitted material, or laser-cut sheet of material. The knitted and/or woven materials may be fibrous materials (including natural fibers, synthetic fibers, etc.), polymeric materials, or the like. For example, the material (e.g., strands) forming the woven or knitted material may be one or more of: monofilament polymer, multifilament polymer, NiTi filament, NiTi tube with radiopaque metallic center, Cobalt chromium alloy filament, Cobalt chromium alloy tube with radiopaque metallic center, Nylon, Polyester, Polyethylene terephthalate, and Polypropylene. The sheets of material (e.g. a solid sheet of material) formed into the tractor region may be one or more of: polymeric material (e.g., PTFE), silicone materials, polyurethanes, shape memory alloys, stainless steels, etc. The sheets may be extruded, glued, or the like. The sheets may be cut to form pores and/or projections. For example, the sheets may include one or more laser-cut projections. Any of these apparatuses may be coated with a hydrophilic and/or hydrophobic coating, and/or may include pores. The tractor may have a porosity of greater than >60% (greater than 70%, greater than 75%, greater than 80%, greater than 85%, etc., between 60-95, 65-95, 70-95%, etc.).

[00016] For example, described herein are clot-grabbing mechanical thrombectomy apparatuses that include a tractor region. The tractor region may include a plurality of clot-grabbing projections extending from one face of the tractor. In some variations, the clot-grabbing projections may be configured so that they move to extend (e.g., out of the plane of the tractor) when the tractor region bends around, e.g., around the distal end of the catheter of the elongate inversion support, to invert.

[00017] In general, a mechanical thrombectomy apparatus for removing a clot from a vessel may include: a elongate inversion support comprising a catheter having a distal end

and a distal end opening; a tractor comprising a flexible tube extending longitudinally within the catheter and doubling back over the distal end of the catheter to extend along the distal end of the catheter, an inner puller coupled to a distal end of the tractor; and a guidewire lumen extending through the catheter, tractor and the inner puller and configured to pass a guidewire. The proximal end of the tractor may be loose (e.g., may be free to slide over the catheter). The tractor may also be configured so that it is biased to hold itself against outer diameter of the catheter, and simultaneously biased to expand when inverted within the catheter; in this configuration, the inverting distal-facing end of the tractor may be flared outward slightly so that the diameter of the tractor expands slightly near the distal-facing inverting end of the apparatus. This configuration may also maintain the portion of the tractor within the catheter so that it is close to the inner diameter of the catheter; e.g., the inner diameter of the portion of the tractor within the catheter may be greater than 50 % of the inner diameter of the catheter, greater than 55% of the inner diameter of the catheter, greater than 60% of the inner diameter of the catheter, greater than 65% of the inner diameter of the catheter, greater than 70% of the inner diameter of the catheter, greater than 75% of the inner diameter of the catheter, etc.

[00018] For example, a mechanical thrombectomy apparatus for removing a clot from a vessel may include: an elongate inversion support comprising a catheter having a distal end and a distal end opening; a tractor comprising a flexible tube that extends distally in a first configuration within the catheter, inverts over the distal end opening of the catheter and extends proximally in a second configuration (that is inverted relative to the first configuration) along the distal end of the catheter, wherein the tractor comprises a tubular wall, further wherein the tractor is configured to invert by rolling over the distal end opening of the catheter when a first end of the tractor is pulled proximally within the catheter; and a plurality of projections that extend from a portion of the tractor that is inverted over the distal end opening of the catheter as the tractor rolls over the distal end opening of the catheter, wherein the plurality of projections do not extend from the tractor as it extends proximally in the inverted configuration along the distal end of the catheter.

[00019] As mentioned, in general, the mechanical thrombectomy apparatuses described herein may include a clot-grabbing projection. For example, a mechanical thrombectomy apparatus for removing a clot from a vessel may include: an elongate inversion support comprising a catheter having a distal end and a distal end opening; a tractor comprising a flexible tube extending within the catheter and doubling back over the distal end of the catheter to extend along the distal end of the catheter, the flexible tube comprising a tube

wall, wherein the tractor is configured to invert over the distal end opening when a first end of the tractor is pulled proximally within the catheter, further wherein the tractor comprises a plurality of projections configured so that the plurality of projections extend out of a plane of the tube wall as the tube wall inverts over the distal end opening, further wherein the plurality of projections remain in the plane of the tube wall as the tube wall extends along the distal end of the catheter; and a guidewire lumen extending through the catheter and the tractor and configured to pass a guidewire.

[00020] In particular, the tractor may be a tube of woven ribbons, further wherein the plurality of projections is formed from edges of the ribbons. The ribbons may comprise flattened strips or strands of material having at least one (through typically four) elongate edges. For example, the ribbons may have a rectangular cross-section. In some variations the ribbons may have square or triangular or other cross-sections having one or more edges. Ribbons having edges may be woven, e.g., so that they are arranged in a helical pattern as they extend over the distal end of the elongate inversion support. Thus, the edge(s) of the ribbon may extend outward, out of the plane of the tractor, when the tractor inverts. These extending edges may bend up, forming scooping, cutting and/or grabbing projections over the bending region of the tractor. The ribbons may be formed of any appropriate material, including those discussed above, such as a metallic or polymeric material.

[00021] The projections from the tractor regions described herein may be formed by cut-out regions in the tractor material. For example, a sheet or tube of material may be used to form the tractor, such as a tube of steel (e.g., stainless steel), polyester, nylon, expanded Polytetrafluoroethylene (ePTFE), Nitinol, or a fabric, and projections may be formed, e.g., by cutting, from the tube or sheet. For example, the projections may be cut from the tube wall. In some variations the projections may be cut in addition to openings, slits, slots, or gaps (e.g., forming pores). For example, a tractor may have at least one porous section having a pore pattern having a longitudinal separation between pores of less than about 0.005 inches in width. In some variations, the projections may be cut from the tube wall at an angle of less than 90° tangent to the tube wall. For example, each of the plurality of projections may have a width in a direction transverse to the flexible tube and a length in a direction along a long axis of the flexible tube; the ratio of length to width may be between, e.g., 2 and 100 (e.g., 5 and 100, 10 and 100, 5 and 90, 5 and 80, 5 and 70, 5 and 50, 10 and 90, 10 and 80, 10 and 70, 10 and 60, etc.).

[00022] The projections may be shaped to grab and/or macerate the clot. For example, all or some of the plurality of projections may have one or more of: a paddle shape, a scoop

shape, and spike shape. The projections may extend proud of the plane of the tractor (e.g., at 90° or perpendicular to the tractor surface from which the projection extends, or between about 45-135° from the plane of the tractor surface, etc.). The projections may be sharp (e.g., may have sharp ends). The projections may extend between 0.01 mm to 5mm from the tractor surface (e.g., between 0.01 mm and 2 mm, between 0.05 mm and 1 mm, etc.). The size of the projections may be scaled to the size of the tractor and/or the size of the vessel into which the apparatus is intended to be inserted into.

[00023] In any of the apparatuses described herein, the elongate inversion support (e.g., catheter) may be adapted to enhance rolling of the tractor region (inverting) over the distal end. For example, in any of the apparatuses described herein, the catheter may be configured so that the material hardness of the catheter decreases over the distal end of the catheter until the distal end opening, wherein the distal end opening has a material hardness that is greater than a material hardness of a region immediately proximal to the distal end, further wherein the distal end opening has a rounded lip profile. The catheter distal end may be stiffer because it is thicker (e.g., it may be formed by inverting the distal end of the catheter back over itself, and/or it may be formed of a stiffer material than the adjacent more proximal region (including by including a reinforcing material).

[00024] The projections configured to help grab clot may be distributed over the entire length of the tractor, or only over a region of the tractor (e.g., the distal end region, e.g., the distal 5 mm, 7mm, 10 mm, 15 mm, 20 mm, etc. or less). In some variations, the distribution of projections may be non-uniform distributed, e.g., the tractor may include a non-uniform density of projections along the length of the tractor. The projections may be oriented relative to the tractor so that the projections extend in the distal direction when the tractor is on the outer diameter of the catheter, which may help them grab clot.

[00025] The projections may be configured (e.g., by laser cutting the tube forming the tractor) as a plurality of slots or openings through the tractor.

[00026] In any of the apparatuses described herein, the tractor may include one or more coatings from the group of: a lubricious coating, a metal coating, a heparin coating, an adhesive coating, and a drug coating. In particular the tractor may include a uniform or non-uniform lubricious (e.g., hydrophilic) coating. Such coatings may assist in making the tractor slide more easily to invert (e.g., over the distal end of the catheter), but may make it particularly hard to grab clot. The projections described herein may address this issue.

[00027] Any of the apparatuses described herein may include a releasable attachment between the tractor and an outer surface of the elongate inversion support (e.g., catheter),

configured to release when the tractor is pulled with a force that is greater than a predetermined force threshold. This may prevent premature deployment of the apparatus. The releasable attachment may be a breakable (e.g., frangible) region, e.g., of an adhesive, etc. or a releasable tie, etc. The releasable attachment may be formed by regions of different hydrophobicity/hydrophilicity. Any of these apparatuses may be configured so that the force required to deploy the apparatus is greater than a predetermined threshold, e.g., the releasable force threshold may be greater than 50 g, 100 g, 200 g, 300 g, 400 g, 500 g, 600 g, 700 g, 800 g, 900 g, 1000 g, etc. of force (e.g., greater than 200 g of force). In addition, any of these apparatuses may include a cover, an outer elongate inversion support comprising a catheter, sleeve, sheath, etc., holding the proximal end of the tractor against the catheter until it is ready to be deployed. Deployment may mean releasing the end (e.g., the end on the outer surface of the catheter) from a releasable attachment; once deployed, the force required to pull the tractor proximally in the catheter, including drawing the tractor from along the outer diameter of the catheter, inverting the tractor and pulling the tractor into the catheter distal end opening (without a clot or other material in the tractor) may be substantially less than the initial deployment force. For example, the force required to pull the tractor into the catheter proximally may be 1 gram (g) of force or less (or 2 g, 3 g, 4 g, 5 g, 6 g, 7 g, 8 g, 9 g, 10 g, 20 g, 30 g, 40 g, 50 g, etc., of force or less). Alternatively or additionally, any of these apparatuses may include a material between the tractor and the catheter (e.g., a sleeve, coating, etc.) to reduce the amount of force required to invert the catheter over the distal end of the catheter, and/or to prevent jamming of the tractor in the catheter.

[00028] As mentioned, any of these apparatuses may include a puller, e.g., an elongate puller coupled to a distal end of the tractor. Any of these apparatuses may include an elongate puller within the catheter coupled to a distal end of the tractor. The elongate puller may comprise a hypotube having an inner lumen that is continuous with the guidewire lumen through the flexible tube.

[00029] In general, the tractor may be any appropriate length. For example, the tractor may be between 3 to 100 cm long (e.g., between 3 and 50 cm, between 3 and 40 cm, between 3 and 30 cm, between 3 and 20 cm, between 10 and 100 cm, between 10 and 50 cm, between 20 and 100 cm, between 20 and 50 cm, etc.).

[00030] In any of these apparatuses, the apparatus may be configured so that the tractor may be retracted into the catheter by applying less than 300 grams of force (e.g., less than 400 g of force, less than 300 g of force, less than 200 g of force, less than 100 g of force, less than 90 g of force, less 80 g of force, less than 70 g of force, less than 60 g of force, less than

50 g of force, less than 10 g of force, etc.) to a distal end of the flexible tube. For example, as mentioned above, the apparatus may include a hydrophilic coating, a lubricant on the catheter and/or tractor, a sleeve between the tractor and catheter, etc. This force required to retract the tractor into the catheter typically refers to the force required to roll the tractor over the distal end of the tractor; an initial deployment force (e.g., to release the end of the tractor outside of the catheter) may be greater than the force required to retract the catheter (e.g., greater than 100 g of force, 200 g of force, 300 g of force, 400 g of force, 500 g of force, 600 g of force, 700 g of force, 800 g of force, 900 g of force, 1000 g of force, 1500 g of force, 2000 g of force, etc.).

[00031] For example, a mechanical thrombectomy apparatus for removing a clot from a vessel may include: an elongate inversion support comprising a catheter having a distal end and a distal end opening; a tractor comprising a flexible tube that extends distally in a first (e.g., “un-inverted”) configuration within the catheter, inverts over the distal end opening of the catheter into a second configuration (that is inverted relative to the first configuration) and extends proximally in an inverted configuration along the distal end of the catheter, the flexible tube comprising a plurality of ribbons having a square or rectangular cross-section woven together, wherein the tractor is configured to invert by rolling over the distal end opening of the catheter when a first end of the tractor is pulled proximally within the catheter, wherein a plurality of edges of the plurality of ribbons extend from a portion of the tractor that is inverted over the distal end opening of the catheter as the tractor rolls over the distal end opening of the catheter, further wherein the projecting edges are not extended from the tractor in a portion of the tractor that extends over the distal end of the catheter; and a guidewire lumen extending through the catheter and the tractor and configured to pass a guidewire.

[00032] A mechanical thrombectomy apparatus for removing a clot from a vessel may include: an elongate inversion support comprising an elongate inversion support comprising a catheter having a distal end and a distal end opening; a tractor comprising a flexible tube extending within the catheter and doubling back over the distal end of the catheter to extend along the distal end of the catheter, the flexible tube comprising a tube wall formed from a plurality of woven ribbons having a square or rectangular cross-section, wherein the tractor is configured to invert over the distal end opening when a first end of the tractor is pulled proximally within the catheter, further wherein the tractor comprises a plurality of projections configured so that the plurality of projections extend out of a plane of the tube wall as the tube wall inverts over the distal end opening, further wherein the plurality of projections are

formed from edges of the ribbons and the projections remain in the plane of the tube wall as the tube wall extends along the distal end of the catheter; and a guidewire lumen extending through the catheter and the tractor and configured to pass a guidewire.

[00033] A mechanical thrombectomy apparatus for removing a clot from a vessel may include: an elongate inversion support comprising a catheter having a distal end and a distal end opening; a tractor comprising a flexible tube extending within the catheter and doubling back over the distal end of the catheter, the flexible tube comprising a tube wall, wherein the tractor is configured to invert over the distal end opening when a first end of the tractor is pulled proximally within the catheter, further wherein the tractor comprises a plurality of projections formed in the tube wall and configured so that the plurality of projections extend proud of the tractor when the tractor inverts over the distal end opening and otherwise remain in a plane of the tube wall; wherein each of the plurality of projections have a width in a direction transverse to the flexible tube and a length in a direction along a long axis of the flexible tube, further wherein the ratio of length to width is between 10 and 100; and a guidewire lumen through the catheter and the tractor configured to pass a guidewire.

[00034] Any of the apparatuses described herein may be configured so that the tractor is highly soft, and therefore rolls around the distal end of the catheter forming the elongate inversion support easily without jamming and/or requiring a large force to roll the tractor over the distal end opening of the catheter. In particular, tractors having a low axial compression strength, that would, but for the elongate inversion support, typically buckle, have been found to prevent jamming of the elongate inversion support as the tractor inverts. In particular, unsupported tractors (e.g., tractor that are not rolling over a catheter supported annular opening) that are configured to collapse radially under an axial compression of less than about 500g of force (e.g., less than: about 500g force, about 400g force, about 300g force, about 200g force, about 150 g force, about 100 g force, about 50 g force, etc.) may be particularly helpful in preventing jamming. For most knitted, woven, and braided tractors, including those described herein, when the tractor is configured to withstand greater than this amount of axial compression force, the tractor may jam, and/or may require excessive force to invert. Thus, in any of the apparatuses and methods described herein, the tractor may be sufficiently soft such that without support from the catheter, the tractor collapses radially under an axial compression of less than 200g of force when inverting (and may instead buckle).

[00035] Further, in any of the apparatuses described herein, the tractor may be biased to expand to greater than the outer diameter of the catheter in a second configuration (that is

inverted relative to the first configuration) where the tractor is extending over the outer diameter of the catheter. The same tractor may be biased to expand to greater than the inner diameter of the catheter of the elongate inversion support in the first (e.g., un-inverted), configuration where the tractor is within the catheter of the elongate inversion support. Thus, in relaxed configuration, prior to assembling with the elongate inversion support, the tractor may be oversized compared to the catheter of the elongate inversion support; the portion of the tractor that extends within the catheter of the elongate inversion support, referred to as “un-inverted,” may have an inner diameter that is greater than the inner diameter of the catheter, which may tend to drive the tractor toward the walls of the inner diameter of the catheter without collapsing down into the catheter. Further, the inner diameter of the tractor in the “inverted” configuration, e.g., the configuration of the portion that is doubled back over and along the catheter of the elongate inversion support, may be greater than the outer diameter of the catheter of the elongate inversion support. This arrangement may prevent jamming and an increased resistance between the tractor and the outside of the catheter of the elongate inversion support. The catheter may be biased to expand in both the inverted and un-inverted configurations by, e.g., heat setting. The tractor may be inverted to transition between the first and second configurations by rolling over the distal end of the catheter; the terms “inverted” and “un-inverted” are therefore relative terms.

[00036] Also described herein are methods of removing a clot using a mechanical thrombectomy apparatus. For example, a method of removing a clot using a mechanical thrombectomy apparatus may include: positioning a distal end of the mechanical thrombectomy apparatus adjacent to a clot within a vessel, wherein the mechanical thrombectomy apparatus includes a tractor region that extends along a distal region of an elongate inversion support having a catheter and inverts over a distal end of the catheter so that a distal end of the tractor extends proximally within the catheter; pulling the distal end of the tractor proximally within the catheter to invert the tractor over the distal end of the catheter to extend a plurality of projections from the tractor and grab the clot; and drawing the clot into the catheter.

[00037] Any of these methods may include macerating the clot with the plurality of projections.

[00038] For example, a method of removing a clot using a mechanical thrombectomy apparatus may include: positioning a distal end of the mechanical thrombectomy apparatus adjacent to a clot within a vessel, wherein the mechanical thrombectomy apparatus includes a tractor region that extends along a distal region of a catheter and inverts over a distal end of

the catheter so that a first end of the tractor extends proximally within the catheter; pulling the first end of the tractor proximally within the catheter to roll the tractor over the distal end of the catheter so that the tractor inverts over the distal end of the catheter and extends a plurality of projections from the tractor; grabbing the clot with the plurality of projections; and drawing the clot into the catheter.

[00039] As mentioned above, the tractor may comprises a plurality of woven ribbons having a square or rectangular cross-section, further wherein pulling the distal end of the tractor proximally within the catheter to invert the tractor over the distal end of the catheter to extend a plurality of projections from the tractor comprises extending a plurality of edges of the woven ribbons from out of a plane of the tractor as the tractor is inverted over the distal end of the catheter to grab the clot with the extended edges.

[00040] Alternatively or additionally, the tractor may comprise a plurality of cut-out regions formed in the tractor, further wherein pulling the distal end of the tractor proximally within the catheter to invert the tractor over the distal end of the catheter extends the cut-out regions forming the plurality of projections from the tractor to grab the clot. Any of these methods may include sliding a loose proximal end of the tractor over the catheter as the distal end of the tractor is pulled proximally.

[00041] Any of these methods may include using a guidewire. For example, positioning the distal end of the mechanical thrombectomy apparatus may comprise sliding the mechanical thrombectomy apparatus over a guidewire.

[00042] Similarly, any of these methods may include releasing a releasable attachment between the tractor and an outer surface of the catheter.

[00043] Pulling the distal end of the tractor proximally may comprises maintaining an inner diameter of the tractor within the catheter at greater than 60 % of an inner diameter of the catheter to prevent the tractor from locking over the distal end of the catheter.

[00044] Also described herein are apparatuses having tractor regions with variable stiffness along the length of the tractor. These apparatuses may invert (roll) at their distal-facing end of the tractor with a ratcheting motion. These apparatuses, and methods of using them, may provide a movement that prevents jamming, and may also help grab clot.

[00045] For example, described herein are mechanical thrombectomy apparatuses for removing a clot from a vessel that may include: a catheter having a distal end and a distal end opening; a tractor comprising a flexible tube extending longitudinally within the catheter and doubling back over the distal end of the catheter to extend along the distal end of the catheter, wherein the flexible tube comprises longitudinally alternating regions of higher and lower

stiffness, wherein the regions of higher stiffness have a stiffness that is greater than the regions of lower stiffness; an inner puller coupled to a distal end of the tractor; and a guidewire lumen extending through the catheter, tractor and the inner puller and configured to pass a guidewire.

[00046] A mechanical thrombectomy apparatus for removing a clot from a vessel may include: a catheter having a distal end and a distal end opening; a tractor comprising a flexible tube extending longitudinally within the catheter and doubling back over the distal end of the catheter to extend along the distal end of the catheter, wherein the flexible tube comprises longitudinally alternating regions of higher and lower stiffness, wherein the regions of higher stiffness have a stiffness that is greater than the regions of lower stiffness, further wherein a diameter of the distal-facing end of the tractor oscillates as the tractor is pulled proximally within the catheter to invert the tractor over the distal end of the catheter; an inner puller coupled to a distal end of the tractor; and a guidewire lumen extending through the catheter, tractor and the inner puller and configured to pass a guidewire.

[00047] A mechanical thrombectomy apparatus for removing a clot from a vessel may include: a catheter having a distal end and a distal end opening having a radius; a tractor comprising a flexible tube extending longitudinally within the catheter and doubling back over the distal end of the catheter to extend along the distal end of the catheter, wherein the flexible tube comprises longitudinally alternating regions of higher and lower stiffness helically arranged around the flexible tube, wherein the regions of higher stiffness have a first length and a stiffness that is greater than the regions of lower stiffness, wherein the first length is between about 0.1 and 1.1 times the radius of the catheter; an inner puller coupled to a distal end of the tractor; and a guidewire lumen extending through the catheter, tractor and the inner puller and configured to pass a guidewire.

[00048] Thus, the regions of higher stiffness may have a longitudinal length along the flexible tube that is between about 0.05 and 1.2 (e.g. between 0.1 and 1.1 between 0.2 and 1 between 0.3 and 1 between 0.5 and 1, between 0.5 and 1.1, etc.) times the radius of the catheter. The the regions of higher and lower stiffness may be helically arranged around the flexible tube. In any of these apparatuses, the ratcheting motion may be seen by an oscillation of the diameter of the distal end-facing end of the tractor as it rolls over the catheter. For example, the diameter of the distal-facing end of the tractor may oscillate as the tractor is pulled proximally within the catheter to invert the tractor over the distal end of the catheter.

[00049] As mentioned, the tractor may be formed of a woven and/or knitted material. For example tractor may comprise a knitted material comprising one or more of: steel, polyester, nylon, expanded Polytetrafluoroethylene (ePTFE), and Nitinol. The tractor may comprise a sheet of one or more of: steel, polyester, nylon, expanded Polytetrafluoroethylene (ePTFE), Nitinol, or a fabric. The sheet may comprise a plurality of cut-out regions modifying the stiffness.

[00050] Methods of operating any of the apparatuses described herein (including the apparatuses including a ratcheting or see-saw tractors) are also described herein.

[00051] As mentioned above, any of the apparatuses described herein may be configured to prevent jamming by pre-biasing the tractor region so that it has an inner diameter in a first configuration within the lumen of the catheter (referred to for convenience herein as the “un-inverted” configuration, relative to the configuration of the portion of the tractor that has rolled over the distal end opening of the catheter) has a greater outer diameter than the inner diameter of the catheter. Further, any of the apparatuses described herein may also have an inner diameter in a second configuration over the catheter (referred to herein as the “inverted” configuration, relative to the first configuration) that is greater than the outer diameter of the catheter.

[00052] For example, described herein are mechanical thrombectomy apparatus for removing a clot from a vessel without jamming comprising: an elongate inversion support comprising a catheter having a distal end and a distal end opening; a tractor comprising a flexible tube that extends distally in a first configuration (e.g., an “un-inverted” configuration) within the catheter, inverts over the distal end opening of the catheter and extends proximally in a second (e.g., “inverted”) configuration along the distal end of the catheter, wherein the tractor comprises a tubular wall, further wherein the tractor is configured to invert by rolling over the distal end opening of the catheter when a first end of the tractor is pulled proximally within the catheter, wherein the tractor is biased to expand to have an inner diameter that is greater than the outer diameter of the catheter in the inverted configuration and is biased to expand to have an inner diameter that is greater than the inner diameter of the catheter in the un-inverted configuration; and an elongate puller coupled to the first end of the tractor.

[00053] A mechanical thrombectomy apparatus for removing a clot from a vessel without jamming may include: an elongate inversion support comprising a catheter having a distal end and a distal end opening; a tractor comprising a flexible tube that extends distally in a first (an “un-inverted”) configuration within the catheter, inverts over the distal end opening

of the catheter and extends proximally in a second (an “inverted”) configuration along the distal end of the catheter, wherein the tractor comprises a tubular wall, further wherein the tractor is configured to invert by rolling over the distal end opening of the catheter when a first end of the tractor is pulled proximally within the catheter, wherein the tractor is biased to expand to greater than the outer diameter of the catheter in the inverted configuration and is biased to expand to greater than the inner diameter of the catheter in the un-inverted configuration; an elongate puller coupled to a first end of the tractor and configured to pull the tractor proximally to invert the tractor over the distal end opening; and a guidewire lumen extending through the elongate inversion support, puller, and tractor that is configured to pass a guidewire. The tractor may be any of the tractors described herein, e.g., a woven tube, a braided tube, a knitted material, etc.

[00054] Any of the apparatuses described herein may be used with or may include an outer catheter within which the elongate inversion support extends distally; this outer catheter may be referred to as a sleeve or sheath, or in some variations an “intermediate” catheter, as it may be positioned, e.g., using a guidewire or by itself, first within the vasculature and then the elongate inversion support and tractor may be inserted within it to guide them to the clot to be removed, including after removing the guidewire, or leaving the guidewire in position. Any of these devices may be used with a vacuum to help capture and pull clot. For example, if an outer catheter is used, the outer catheter (within which the elongate inversion support can extend distally) may be proximally coupled to a vacuum source. The elongate inversion support may be configured as described herein to permit drawing the vacuum to the end of the elongate inversion support and/or outer catheter. For example, the elongate inversion support may have a diameter that is leaves sufficient clearance. In particular, the apparatus may be configured so that there is at least about 0.002 inches or greater (e.g., 0.003 inches or greater, 0.004 inches or greater, 0.005 inches or greater, 0.006 inches or greater, etc.) between the outer diameter of the catheter and the inner diameter of the outer catheter. The elongate inversion support may have a catheter with the distal end opening about which the tractor inverts that extends only part ways from the distal end towards the proximal end of the elongate inversion support. For example, the full catheter portion of the elongate inversion support may extend less 0.5 cm or less, 1 cm or less, 2 cm or less, 3 cm or less, 4 cm or less, 5 cm or less, etc. In some variations the elongate inversion support comprises a catheter that is skived at the proximal end. The catheter, and particularly the distal end region of the elongate inversion support, may include one or more openings, slots, holes, windows, cut-out

regions, etc. for allowing vacuum to pass from the outer sleeve and preventing choking of the flow of vacuum from the distal end of the apparatus.

[00055] As mentioned, in any of the variations described herein, the tractor may be configured to collapse radially under an axial compression of less than 200g of force. Thus, the tractor may be sufficiently soft and easy to roll (and invert) over the distal end aperture (distal end opening, e.g. of a catheter of the elongate inversion support). Similarly, the elongate inversion support may be configured to withstand buckling of an axial compression of greater than 500 g of force, sufficient to allow pulling of the tractor over the distal end opening (e.g. aperture) of the elongate inversion support without collapsing, kinking or displacing the elongate inversion support. In some variations, and particularly peripheral vascular variations, the elongate inversion support is configured to withstand buckling of an axial compression of greater than 1500 g of force.

[00056] Any of the apparatuses described herein may include a tractor having one or more coatings from the group of: a lubricious coating, a metal coating, a heparin coating, an adhesive coating, and a drug coating.

[00057]

BRIEF DESCRIPTION OF THE DRAWINGS

[00058] The novel features of the invention are set forth with particularity in the claims that follow. A better understanding of the features and advantages of the present invention will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the invention are utilized, and the accompanying drawings of which:

[00059] FIGS. 1A-1H illustrate an example of an apparatus for mechanically removing an object such as a clot from a body region. FIG. 1A shows an example of an elongate inversion support portion of an apparatus, configured as a catheter portion. For example, at least the distal end of the elongate inversion support may be configured as a catheter. FIG. 1B shows an enlarged view of a distal end (opening) of the catheter of the elongate inversion support of FIG. 1A, showing the aperture formed by the distal end opening; FIG. 1C shows an example of a distal tractor region of a flexible tube (tractor tube) extending from a puller (the puller in this example is configured as a catheter. The tractor is shown in a first (e.g., un-inverted) configuration) and may be biased open, e.g., by heat setting, to have an outer diameter that is greater than the inner diameter of the catheter of the elongate inversion support, as shown in FIG. 1D. FIG. 1D shows the same distal tractor region of FIG. 1C with

the expandable first end region expanded. This first configuration may be compressed down into the elongate inversion support and the distal end inverted over the catheter portion of the elongate inversion support, as shown in FIG. 1E. In FIG. 1E, the assembled mechanical thrombectomy apparatus with the elongate inversion support and the flexible tube forming the tractor is shown. The tractor extends through the catheter of the elongate inversion support and doubles back over the distal end opening of the catheter and extends over the outer diameter of the catheter. The outer portion of the tractor (extending along the outer diameter of the catheter) may be held in a collapsed configuration (as shown in FIG. 1E), or it may be expanded, as shown in FIG. 1F. Thus, the tractor may be biased so that in the second configuration (inverted over the distal end of the catheter), the tractor has a 'relaxed' outer diameter that is greater than the outer diameter of the catheter of the elongate inversion support. FIGS. 1G and 1H illustrate the use of the apparatus of FIGS. 1E and 1F to remove a clot by drawing the flexible tube proximally and/or advancing the catheter distally towards the clot so that the expandable first end region inverts as it is drawn into the distal end of the catheter, pulling the clot into the catheter.

[00060] FIG. 1I illustrates an alternative variation of a tractor and puller. In FIG. 1I, the tractor is shown attached to the distal end of a tapered or narrow puller; the distal end region is tapered, and includes a radiopaque marker at or near the attachment site to the tractor; the tractor may be knitted, braided, woven, etc. Thus, in some variations the distal end region of the puller may have a greater flexibility than the proximal end of the puller. The puller may be hollow (e.g., a catheter or hypotube) or solid (e.g., like a wire).

[00061] FIGS. 2A and 2B illustrate jamming of a mechanical thrombectomy apparatus. In FIG. 2A the mechanical thrombectomy apparatus includes a tractor region that collapses within the inner diameter (lumen) of the catheter portion of the elongate inversion support, jamming so that the tractor region cannot roll, without applying excessive force, or at all, around the open end of the catheter. Similarly, in FIG. 2B, the tractor region is loose, and also jams on the distal open end of the catheter as it inverts.

[00062] FIG. 2C illustrates an example of an anti-jamming configuration, in which the distal-facing, inverting portion of the tractor is flared outwards at an angle, so that the portion of the tractor on either side of the catheter end approaches at an angle of less than 45 degrees relative to a length of the tractor (e.g., 0.5 mm, 1 mm, 2mm) on either side of the opening. In this example, the portion of the tractor that is around the outer diameter is biased to contract down onto the outer diameter of the catheter, and after inverting the bias is to expand outward slightly, resulting in the trumpet-shaped inverting region. Even in this configuration, the

tractor may be set (e.g., biased) so that the outer diameter of the first configuration (within the catheter of the elongate inversion support) has a greater outer diameter than the inner diameter of the catheter in the relaxed state (e.g., when not compressed and constrained in the catheter inner diameter), and the outer diameter of the tractor in the second configuration (inverted over the outer diameter of the catheter of the elongate inversion support) is greater than the outer diameter of the catheter. In some variations the unconstrained first configuration has a greater OD than the unconstrained OD of the second configuration. Alternatively, the unconstrained OD of the first configuration may be less than the OD of the unconstrained OD of the second configuration.

[00063] FIGS. 3A-3C illustrate the operation of a mechanical thrombectomy apparatus having a tractor region such as that shown in FIG. 2C capturing a clot. In FIG. 3A the apparatus is positioned adjacent to the clot. FIG. 3B shows an alternative variation in which a guidewire is used to position the apparatus; the guidewire may remain in place during capture of the clot, or it may be removed. FIG. 3C shows the apparatus capturing the clot by rolling the tractor portion of the apparatus over the end of the catheter of the elongate inversion support as the tractor portion is drawn proximally; the apparatus may be advanced distally within the lumen of the vessel.

[00064] FIGS. 4A and 4B illustrate another example of a mechanical thrombectomy apparatus having a tractor in which an anti-jamming sleeve portion is included between the catheter outer diameter and the tractor. In FIG. 4A the tractor portion is configured to include a central guidewire lumen and a hypotube (inner catheter) is used to pull the proximal end of the tractor; in FIG. 4B the tractor is configured to collapse down to a puller wire.

[00065] FIGS. 5A-5B illustrate formation of catheter tip having a stiffer distal end adapted to prevent jamming and/or collapse of the catheter distal opening when inverting a tractor over the distal end. In FIG 5A the tip is shown with a slightly proximally-offset from the distal end marker band; in FIG. 5B the tip of the catheter has been folded back over itself, increasing both the diameter of the catheter at the distal end and the stiffness of the distal end.

[00066] FIGS. 6A-6B is an example of a distal tip or end region of a catheter such as that shown in FIG. 5B, over which a tractor is inverting. FIG. 6A is an example of a side perspective view and FIG. 6B shows the distal end face of the apparatus.

[00067] FIGS. 7A-7E illustrate examples of heat set 0.085" ID PET (FIGS. 7A-7C) tractors and nickel titanium heat-set 0.085" ID tractors.

[00068] FIGS. 8A-8D illustrate operation of mechanical thrombectomy apparatus pulling in a clot. FIGS. 8E-8F illustrate reversal of the apparatus of FIGS. 8A-8D, ejecting the clot.

- [00069] FIGS. 9A-9C illustrate operation of an apparatus having a 48-end PET (0.002" monofilament) tractor. FIG. 9D illustrates reversing the apparatus of FIGS. 9A-9C.
- [00070] FIGS. 9E-9G illustrate operation of an apparatus having a 72-end PET (0.002" 4x0.0008" filament) tractor drawing in a clot.
- [00071] FIGS. 10A-10E illustrate examples of knitted tractors.
- [00072] FIGS. 11A-11D illustrate patterns that may be used to form a tractor for a mechanical thrombectomy apparatus.
- [00073] FIGS. 12A-12I show examples of microstructures that may be included in any of the mechanical thrombectomy apparatuses described herein.
- [00074] FIGS. 13A and 13B show side and cross-sectional views, respectively, illustrate an example of a tractor having selectively deployable projections that may extend from the inverting region of the tractor to assist in grabbing and/or macerating a clot.
- [00075] FIG. 14 illustrates an example of an apparatus including a plurality of projections extending from the tractor region that may aid in grabbing and/or macerating a clot.
- [00076] FIG. 15A shows an example of a distal end of a mechanical thrombectomy apparatus having a tractor formed from a plurality of filaments having a round cross-sectional profile; the tractor of FIG. 15A does not include any projections extending therefrom. FIG. 15B illustrates the outer profile of a filament of the device of FIG. 15A as it inverts over a distal catheter opening of the elongate inversion support. FIG. 15C illustrates the rounded profile of the filaments forming the tractor of FIG. 15A.
- [00077] FIG. 15D is a section through a rectangular filament (e.g., ribbon filament) having four edges. FIG. 15E illustrates the projection of a ribbon filament as it inverts over a catheter filament; because it approaches from an angle relative to the catheter opening (and because it is constrained by the adjacent filaments) the edge of the ribbon forming the inverting region may project up and out of the plane of the tractor.
- [00078] FIGS. 16A and 16D illustrate an example of a tractor having a plurality of projections formed by rectangular filaments (e.g., ribbon filaments) as schematically illustrated in FIGS. 15D-15E. FIG. 16A shows a top perspective view and FIG. 16B is a side view.
- [00079] FIGS. 17A-17D illustrate exemplary tractors formed by cutting (e.g., laser cutting) a tubular material.
- [00080] FIGS. 18A-18C illustrate different slotted patterns that may be cut into a tube (or sheet) to form a tractor region.
- [00081] FIG. 19 is another example of a pattern that may be use to form a tractor region.

[00082] FIGS. 20A-20B show an example of a pattern that may be use to form a tractor region. FIG. 20B is an enlarged view of the pattern of FIG. 20A.

[00083] FIGS. 21A-21B show an example of a pattern that may be use to form a tractor region. FIG. 21B is an enlarged view of the pattern of FIG. 21A.

[00084] FIGS. 22A-22B show an example of a pattern that may be use to form a tractor region. FIG. 22B is an enlarged view of the pattern of FIG. 22A.

[00085] FIGS. 23A-23B show an example of a pattern that may be use to form a tractor region. FIG. 23B is an enlarged view of the pattern of FIG. 23A.

[00086] FIGS. 24A-24B show an example of a pattern that may be use to form a tractor region. FIG. 24B is an enlarged view of the pattern of FIG. 24A.

[00087] FIGS. 25A-25C illustrate tractor regions having different patterns of slots and openings.

[00088] FIG. 26A illustrates bending of a typical small bore catheter distal tip.

[00089] FIGS. 26B-26C show examples of a catheter comprising a keyed slotted tube extending along the entire length of the catheter.

[00090] FIG. 27 shows an example of a catheter design formed as a slotted tube.

[00091] FIGS. 28A-28B is an example of a catheter design.

[00092] FIGS. 29A-29B is an example of a catheter design.

[00093] FIG. 30A schematically illustrates a portion of a tractor having alternating stiff/less stiff regions. FIGS. 30B-30D illustrate the seesawing motion of a tractor having alternating stiff/less stiff regions.

[00094] FIG., 31A is an example of a knitted tractor having alternating more stiff/less stiff regions extending in a corkscrewing/helical pattern along the length of the tractor.

[00095] FIGS. 31B-31C show side and end views, respectively of an apparatus having a knitted tractor, similar to that shown in FIG. 31A.

[00096] FIGS. 31D and 31E show side and end views, respectively of an apparatus having a knitted tractor.

[00097] FIGS. 32A-32B illustrate jamming in an apparatus having a seesawing tractor region that has alternating stiff regions that are too long for the diameter of the catheter over which it is inverting.

[00098] FIGS. 32C-32D illustrate jamming in an apparatus having a seesawing tractor region that has alternating stiff regions that are too small for the catheter over which it is inverting.

[00099] FIGS. 33A and 33B illustrate another example of an apparatus having a knitted tractor.

[00100] FIG. 34 is a schematic of a knitted tractor.

[00101] FIGS. 35A-35C illustrate movement of the loops of a knitted tractor having loops of a nickel titanium filament forming alternating stiff/less stiff regions (arranged down the long axis of the tractor).

[00102] FIGS. 36A-36B illustrate end perspective and side perspective views, respectively, of an apparatus having a knitted tractor.

[00103] FIGS. 37A-37C illustrate seesawing operation of the apparatus of FIGS. 36A-36B.

[00104] FIGS. 38A-38B show an example of an apparatus having a motor-driven tractor.

[00105] FIGS. 39A-39C illustrate operation of the apparatus of FIGS. 38A-38B.

[00106] FIGS. 40A-40C illustrate apparatuses as described herein including patterned coatings (e.g., hydrophilic and/or hydrophobic coatings).

[00107] FIG. 41A illustrates a method for removing clot using an intermediate catheter (e.g., sleeve) and a vacuum, in which a mechanical thrombectomy apparatus is extended from a distal end of the intermediate catheter to remove a clot.

[00108] FIG. 41B illustrates a method for removing clot using an intermediate catheter (e.g., sleeve) and a vacuum, in which a mechanical thrombectomy apparatus removes a clot that has been drawn into the distal end of the intermediate catheter.

[00109] FIGS. 42A-42B illustrate a variation of a catheter of an elongate inversion support having both different diameters (e.g., a larger-diameter distal catheter connected to a smaller-diameter proximal region extending longitudinally in the proximal-to-distal axis), and a plurality of openings (e.g., cut-out regions, holes, etc.).

[00110] FIGS. 42C-42D illustrate another variation of a catheter of an elongate inversion support having a plurality of opening formed therethrough.

[00111] FIGS. 42E-42F illustrate another variation of a catheter of an elongate inversion support having a distal catheter region and an elongate support member formed by skive cutting the catheter.

[00112] FIGS. 42G-42H illustrate another variation of an elongate inversion support having a distal catheter region and an elongate support member extending from the catheter region.

[00113] FIGS. 42I-42J illustrate another variation of an elongate inversion support having a plurality of openings along the distal-to-proximal length.

[000114] FIGS. 42K-42L illustrate another variation of an elongate inversion support having a minimal catheter region at the distal end forming a distal end opening that is connected to an elongate support (e.g., wire, tube, bar, rod, etc.).

[000115] FIG. 43A is another variation of an elongate inversion support having a minimal catheter region at the distal end. FIGS. 43B-43D illustrate an elongate inversion support such as the one shown in FIG. 43A having additional supports (FIG. 43B) and used as part of a mechanical thrombectomy apparatus (FIG. 43C and 43D).

[000116] FIGS. 44A-44C illustrates an example of the operation of a mechanical thrombectomy apparatus with an expandable distal end region.

DETAILED DESCRIPTION

[000117] In general, described herein are mechanical thrombectomy apparatuses having an inverting tractor that is configured to prevent jamming and grab a blood clot. These apparatuses may include an elongate elongate inversion support support that supports an annulus over which the tractor inverts at the distal end. The tractor may comprise a flexible tube that doubles back over (e.g., inverts) over the distal end of the elongate inverting support (e.g., a catheter) so that it extends into the annulus opening of the elongate inverting support and an inner puller coupled to the inner end of the tractor that the tractor can be pulled proximally to pull and invert the tractor over the annulus at the distal end of the elongate inverting support to roll and capture a clot. The apparatus may include a guidewire lumen extending through the elongate inverting support, and/or tractor puller that is configured to pass a guidewire.

[000118] Any of the apparatuses described herein may be adapted to prevent jamming, e.g., by including a coating (e.g., hydrophilic, lubricious coating, etc.) or the like to enhance the sliding and inverting of the tractor over the distal end. Further, any of these apparatuses may include one or more projections that are configured to enhance grabbing and/or maceration of a clot. Grabbing of a clot may be particularly, but not exclusively, helpful when the tractor is lubricious. Although lubricious tractors may resist jamming and require less force to operate, e.g., inverting over the distal end of the catheter, it may be more difficult to initially grab or grasp clot when the tractor is more lubricious. It may also be particularly helpful to include projections that are retracted along the length of the tractor adjacent to the outer diameter of the elongate inverting support (e.g., catheter), for example, when positioning the

apparatus within a vessel, but extend the projections outward from the tractor when rolling and inverting to grab a clot.

[000119] In general, a mechanical thrombectomy apparatus for removing a clot from a vessel may be a system, assembly or device including an elongate inversion support having a distal end and a distal annulus, and a flexible tractor assembly at least partially inverted and configured to roll and invert over the distal annulus of the elongate inverting support.

[000120] In many of the examples described herein, the elongate inversion support is a catheter (or a portion of a catheter at the distal end) and the annulus is formed by the distal end opening of the catheter; the tractor extends within the catheter and doubles back over the distal end of the catheter to extend over the outer diameter of the catheter at the distal end of the catheter, although it may extend proximal for any appropriate distance (including between 1-30 cm, between 2-20 cm, greater than 1 cm, 2 cm, 3 cm, 4 cm, 5 cm, 6 cm, 7 cm, 8 cm, 9 cm, 10 cm, 11 cm, 12 cm, 15 cm, 20 cm, etc.). The end of the tractor within the catheter may be coupled to a puller (e.g., at a proximate puller region connected to the distal or inner end of the tractor). The tubular tractor may include an elongate lumen that is configured to allow passage of a guidewire. The tubular tractor may also be configured to slide along the long axis within the catheter lumen and invert over the distal end opening of the catheter when the proximal end region is pulled proximally. The tractor may be referred to herein as a tractor assembly, tractor portion, tractor tube, or simply a tractor, and is typically positioned and longitudinally slideable within the catheter, and arranged so a portion of the tractor (sometimes referred to as the “distal tractor region” or “distal-facing” tractor region) doubles back over itself.

[000121] For example, FIG. 1A shows one variation of a catheter of an elongate inversion support that may form part of the apparatuses described herein. In this example, the elongate inversion support includes a catheter 100 having a distal end region 103 that includes a distal end opening 105. The distal end region may have an increasing softness (measured by durometer, e.g., shore durometer) except that the very distal-most end region (distal end 105, including the distal end opening) may be substantially less soft than the region immediately proximate to it. Thus, although the distal tip region of the catheter (e.g., the distal most x linear dimensions, where x is 10 cm, 7 cm, 5 cm, 4 cm, 3 cm, 2 cm, 1 cm, 9 mm, 8 mm, 7 mm, 6 mm, 5 mm, 4 mm, 3 mm) has an increasing softness/decreasing hardness extending from the proximal to distal ends, the very distal end region 107 (e.g., measured as distal most z linear dimensions, where z is 1 cm, 9 mm, 8 mm, 7mm, 6 mm, 5 mm, 4 mm, 3 mm, 2 mm, 1 mm, 0.8 mm, 0.5mm, 0.3 mm, 0.2mm, etc., and z is always at least three times less than x)

has a hardness that is greater than the hardness of the region immediately proximal to it, and may be as hard or harder than the proximal-most region of the distal tip region.

[000122] In FIG. 1A, the elongate inversion support is an elongate hollow catheter having a column strength that is sufficient to prevent buckling when the catheter is pulled over the distal annulus (distal end opening). Thus, the elongate inversion support may be configured so that it does not collapse (e.g., buckle) when 500 g or less of compressive force is applied (e.g., at least about 700 g, 600 g, 500 g, 400 g, 300 g, etc. of compressive force) for neurovascular applications. For peripheral vascular applications the elongate inversion support may be selected or configured to withstand at least 1500 g of compressive force (e.g., at least about 2000 g, 1900 g, 1800 g, 1700 g, 1600 g, 1500 g, 1400 g, etc. of compressive force). In general, any of the apparatuses described herein may include a elongate inversion support that is not a full-length catheter, but may include a portion of a catheter, typically at the distal end, connected to a rod, wire, hypotube, or the like (as will be described in greater detail below in reference to FIGS. 42A-43D) or may be skived. Thus, any of the apparatuses and methods described herein may be adapted for use with an elongate inversion support that is not limited to catheters, including elongate inversion supports that include a portion of a catheter, or that include a ring or other structure forming the annulus at the distal end. In FIG. 1A the catheter 100 of the elongate inversion support may be any appropriate type of catheter or portion of a catheter, including microcatheters appropriate for neurovascular use.

[000123] In some variations the distal end 105 of the elongate inversion support is adapted so that the tractor may slide or roll and invert over the distal end of the catheter without being caught (binding, jamming) or without substantial friction. For example, in some variations the distal tip (end) may be curved or radiused 109 as shown in FIG. 1B, particularly on the outer surface (e.g., the transition from outer diameter to inner diameter).

[000124] FIG. 1C shows an example of a flexible tractor 144 coupled to a puller 146. In this example to form a pullable tractor assembly 140, the tractor is shown integrated with the puller, forming the assembly. In FIG. 1C, the tractor is a tube of material (e.g., wove, knitted, braided, etc.) that is flexible and elongate. The tractor is shown extended from the puller in a first configuration. It may be particularly beneficial if the relaxed outer diameter of the flexible tractor in this first configuration has a greater outer diameter than the outer diameter of the catheter of the elongate inversion support into which the tractor will be positioned prior to inverting. The flexible and tubular tractor 144 may be sufficiently soft and flexible (e.g., having a low collapse strength) so as to easily roll and fold over the distal aperture of the elongate inversion support. The puller 146 may typically be a less-expandable (or non-

expandable) structure (tube, puller, etc.). In the example shown in FIG. 1C, the tractor 144 is configured, e.g., by shape-setting (heat setting, etc.), to expand in the relaxed first configuration to a radial diameter that is between 1.1 and 10 times the diameter of the inner diameter of the catheter of the elongate inversion support when unconstrained, as shown in FIG. 1D. In FIG. 1D, the tractor of FIG. 1C is shown in an expanded, relaxed, configuration. Thus the expandable tractor may be biased to expand open. The tractor may be formed of a mesh, braided, woven, knitted, or sheet of material and is generally adapted to grasp the object to be removed (e.g., blood clot).

[000125] In FIGS. 1C and 1D the tractor and puller have two portions, a tractor 144 and a less expandable (or non-expandable) proximal portion comprising the puller 146. The puller may be a separate region, such as a wire, catheter or hypotube, which is connected to an end region of the tractor (e.g., a flexible mesh, woven, braided, etc.), e.g., the distal end or near the distal end. The inverting region of the tractor, where it rolls and inverts over the distal end opening of the catheter may be referred to as the distal-facing region of the tractor, which may actively grab clot when rolling.

[000126] In FIG. 1E, the flexible tractor of FIG. 1C is shown with the tractor doubled back over itself an over the the distal end of the catheter of the elongate inversion support 101. The distal end region is collapsed down, e.g., onto the puller and the elongate inversion support, and may be held collapsed. In this example a tractor hold 188 may be used to hold the tractor collapsed down onto the outer diameter of the elongate inversion support. However, in an unconstrained or deployed configuration, as shown in FIG. 1F, the tractor in this second configuration (e.g., the portion that is inverted over the distal end of the catheter) has an outer diameter that is greater than the outer diameter of the catheter of the elongate inversion support. Thus, the tractor 144 may be biased so that it has a relaxed expanded configuration in the first configuration (as shown in FIG. 1C) that is greater than the inner diameter (ID) of the catheter of the elongate inversion support portion of the apparatus and the relaxed expanded configuration of the second configuration (shown in FIG. 1F) inverted over the catheter has an OD that is greater than the OD of the catheter. The tractor is expandable and may be coupled to the puller. In some variations the flexible tractor and the puller may comprise the same material but the tractor may be more flexible and/or expandable, or may be connected to a push/pull wire or catheter.

[000127] FIGS. 1G and 1H illustrate the removal of a clot using an apparatus such as the apparatus assembled from the components of FIGS. 1A and 1E. In this example the apparatus is configured as a thrombectomy apparatus including a catheter of an elongate

inversion support 101 and a flexible tractor that extends over the distal end region of the catheter and doubles-over itself at the distal end of the catheter to invert so that the external tractor end region is continuous with an inner less-expandable (in this example, less-expandable includes non-expandable) second distal end region 146 (puller) that extends proximally within the catheter and forms an inner lumen that may pass a guidewire. The pusher/puller member that may be a rod or other member that is continuous with the distal end region of the tractor. In FIG. 1G the apparatus is shown positioned and deployed within the vessel 160 near a clot 155. The clot may be drawn into the catheter by pulling the tractor 140 proximally into the catheter 101, as indicated by the arrow 180 showing pulling of the inner portion of the flexible tractor (e.g., using a handle, not shown) resulting in rolling the tractor over the end opening of the catheter and into the catheter distal end and inverting the expandable distal end region so that it is pulled into the catheter, shown by arrows 182. The end of the tractor outside of the catheter may be “loose” relative to the outer wall of the catheter. FIG. 1I illustrates another example of a tractor assembly 154 including a tractor 144 that is coupled to a puller 156. The puller in this example is tapered (having tapering region 161) and may therefore have a different flexibility of the distal end region than the proximal end region. For example the proximal end region may be less flexible than the narrower-diameter distal end region 195 to which the tractor is coupled. The assembly includes a radiopaque marker 165. The tractor may be attached to the puller by any appropriate means. For example, the tractor may be crimped, glued, fused, or otherwise attached to the puller, typically permanently.

[000128] In general the mechanical thrombectomy apparatuses described herein may be highly flexible, both before actuating and during operation. For example, the flexible tractor may not increase the stiffness/flexibility of the catheter of the elongate inversion support, and particularly the distal end region of the catheter too much, to avoid impacting maneuverability, particularly within tortuous vessels of the neurovasculature. Described herein are flexible tractor tube portions that increase the stiffness of the last y cm (e.g., distal most 20 cm, 18 cm, 15 cm, 12 cm, 10 cm, 9 cm, 8 cm, 7 cm, 6 cm, 5 cm, 4 cm, 3 cm, 2 cm, 1 cm, etc.) of the catheter less than a predetermined percentage (e.g., less than 10%, 12%, 15%, 18%, 20%, 25%, 30%, etc.). For example, described herein are flexible tractor tube portions that pass through the catheter and double back over the distal end of the catheter but increase the stiffness of a distal 5 cm of the catheter by less than 15% of the stiffness of the distal 5 cm of the catheter without the flexible tube extending therethrough and doubling back over the distal end of the catheter.

[000129] Jamming may occur if the tractor cannot easily invert over the distal end of the catheter, as shown in FIGS. 2A and 2B. In FIG. 2A, pulling the tractor 201 proximally from within the catheter 207 of the elongate inversion support, e.g., by pulling 204 on the inner puller catheter 205, would normally cause the tractor to roll 211 over the distal end of the catheter tip. If the force required to pull the tractor so that it inverts and rolls into the catheter is too great, such as 200 g of force (e.g., greater than 10 g force, greater than 20 g force, greater than 30 g force, greater than 40 g force, greater than 50 g force, greater than 60 g force, greater than 70 g force, greater than 80 g force, greater than 90 g force, greater than 100 g force, etc.), exclusive of any initial deployment force to release the tractor, described herein, then the device is jammed. Typically the tractor may be pulled and inverted over the distal end opening with significantly less force than this jamming force. Jamming may lead to collapse of the elongate inversion support, and device failure. Jamming may occur when, for example, the tractor gets caught on the distal end opening of the catheter of the elongate inversion support. In FIG. 2A, one failure mode leading to jamming results when the portion of the tractor within the catheter 213 collapses inward, as shown. The inventors have found that it is desirable, and may prevent jamming, if the portion of the tractor within the catheter collapses only so that it has a diameter (e.g., inner diameter) of 40% or more of the inner diameter of the catheter (e.g., 45% or more, 50% or more, 55% or more, 60% or more, 65% or more, 70% or more, 75% or more, etc. of the inner diameter of the catheter).

[000130] Similarly, FIG. 2B illustrates another example of an apparatus in which jamming has occurred, as indicated by the "X" through the arrows showing the proximal movement of the tractor within the catheter 204' and rolling 211' of the distal-facing inverting portion of the tractor. In FIG. 2B, the tractor bends sharply around the distal end of the catheter. This sharp bend may result in jamming over the distal end of the catheter, as shown.

[000131] Various features that may be used alone or in any combination to prevent jamming of the tractor on the catheter are described herein. For example, in FIG. 2C, a the tractor may be biased so that the portion of the tractor within the catheter in the first configuration 223 (e.g., extending from the puller in an un-inverted configuration in FIG. 2C) would have a relaxed outer diameter (OD) that is approximately equal to or greater than the ID of the catheter (e.g., the relaxed OD of the tractor is between 0.8x to 3x the ID of the catheter), and the OD of the tractor in a second configuration (inverted relative to the first configuration) 221 is typically greater than or approximately equal to the OD of the catheter (e.g., the relaxed OD of the tractor in the second configuration is between about 0.9x and 5x the OD of the catheter, e.g., >1x the OD of the catheter, etc.). It should be noted that the

tractor may be configured so that the relaxed OD of the first configuration of the tractor is greater than the relaxed OD of the tractor in the second (inverted) configuration, or vice versa. This combination of biasing may result in a distal-facing inverting region that is slightly trumpet-shaped 227, as shown. This trumpet shape may result in an angle of approach between the surface of the tractor and the open end of the catheter that is more close to perpendicular relative to the open end, as can be seen by comparing FIG. 2C with FIGS. 2A and 2B. The outwardly-flaring distal-facing tractor region may therefore prevent jamming. FIGS. 3A-3C illustrate the operation of an apparatus including a tractor region that flares outward at the distal-facing rolling/inverting region as it rolls over the distal end of the catheter. In FIG. 3A, the apparatus 305 is driven down the vessel 160 into proximity with the clot 155. A guidewire 309 may be used to aid in positioning, as shown in the alternative view of FIG. 2B. For example, a guidewire may be first guided to the clot, and the apparatus may then be slid over the guidewire to position adjacent to the clot. The guidewire may be left in place or removed before actuating the apparatus as shown in FIG. 3C to remove the clot. In FIG. 3C, the apparatus is actuated by drawing proximally 309 on the inner portion of the tractor 311 so that it rolls and inverts 182 over the distal end of the catheter, as shown. The inverting tractor grabs and pulls the clot into the catheter, compressing and/or distorting it as it pulls it inside. The apparatus may be advanced distally as the tractor is pulled proximally. In some variations the tractor may be expanded longitudinally (distally-proximally) within the catheter as it is drawn proximally within the catheter, because it may be a woven, knitted or elastic material. This may allow the clot to be drawn in quickly and may secure it within the catheter.

[000132] The tractors may be woven, braided and/or knitted materials. For woven and braided materials, which may include a plurality of fibers that are woven or braided to form the inverting tube, these structures may be tuned to prevent jamming and/or to reduce the force necessary to pull the tractor and invert over the catheter tip. For example, the mechanical atherectomy apparatus may include a braid-type tractor that can roll freely around the tip of catheter even in a tortuous anatomy and when grabbing clot by tuning one or more of the braid structure; minimizing the braid angle; including a hydrophilic coating on the distal aspect of the catheter outer diameter (OD) or the inner diameter (ID) of the braid (e.g., tractor); including a radiused wall on the catheter; and/or increasing the stiffness of the distal tip region relative to adjacent proximal regions.

[000133] As mentioned, the tractor (e.g., braided, woven, knitted, etc.) may be configured to collapse down into the inner diameter (ID) of the catheter as little as possible. For example

the tractor may collapse to an ID that is greater than, equal to, or within 90%, 85%, 75%, 70%, 65%, 60%, or 50% of the catheter inner diameter (ID)/Catheter Tip OD, since, when the tractor is being pulled around catheter tip it may create axial tension on the tractor (e.g., braid, knit, etc.) that can inadvertently cause the tractor to jam on the catheter tip. When tractor is pulled around catheter tip, the tractor is being pulled in the axial orientation creating axial tension on tractor structure as the tractor is being pulled through the catheter ID. By having the tractor elements jam at an ID greater than or equal to 90%, 85%, 75%, 70%, 65%, 60%, or 50% of the catheter ID (or in some variations, OD), when being axially tensioned, the tractor is less likely to grab/synch down onto the catheter tip, helping the braid roll around the catheter tip with less axial force applied by the user. If less axial force is required by the user to pull the tractor structure around the tip then the catheter tip is less likely to buckle or deflect when retracting the tractor. It may be advantageous to minimize the chance the catheter tip will buckle. The tractor can be tuned to "jam" at a specific ID by controlling any of the following variables and in any combination: selecting a specific number of braid ends, selecting the size/diameter of the braid ends; selecting the braid material (e.g., multifilament or monofilament); heat setting the bias on the braid (e.g., braid diameter); and selecting a braid pattern, e.g., 1x2, 1x1 or any other pattern.

[000134] The braid angle may be minimized to prevent locking up of the rolling of the tractor over the catheter end opening. Typically, the lower the braid angle (e.g., 45 degrees or less, 40 degrees or less, 35 degrees or less, 30 degrees or less, 25 degrees or less, 20 degrees or less, etc.) the less likely it is to have the braid cross over points catch on the catheter tip.

[000135] In any of the variations described herein, the catheter and/or a surface of the tractor may be coated to enhance rolling over the distal end region of the catheter. It may be helpful to have a hydrophilic coating on the distal aspect of the catheter OD or the ID of the tractor so the tractor can more easily slide over the catheters distal end and around the tip of the catheter when pulled through the inside of the catheter.

[000136] The radius wall of the catheter tip may be chosen/set to within a range that allows sliding. For example, it may be helpful for the tip of the catheter to have the largest radius possible but at least 0.0025" radius wall on the catheter, ideally approximately 0.005" radius wall.

[000137] The stiffness of the distal of the catheter may be sufficiently stiff to prevent collapse as the tractor is pulled; it may also be lubricious (e.g., by a coating or material property). The distal most section of the catheter tip (e.g., the last 5mm) may be fabricated of

a material which is stiff enough and lubricious enough so the distal tip of the catheter does not collapse or buckle inward ward when the braid structure is rolling around the catheter tip. Thus, the distal tip may have a stiffness that is greater than the more proximal region at the distal end of the catheter.

[000138] As will be described in greater detail below, it may be helpful or desirable to have pores in the tractor. A lack of gaps or small pore size may limit the ability of the braid to grab clot. Alternatively or additionally, it may be desirable to form a braid structure with texture. One example is to braid 2 or more different diameter braid ends into the same structure: the difference in braid end diameters will help form a texture to the braid structures outer surface, aiding the grabbing of the clot when rolling the braid-dozer around the catheter tip.

[000139] As an alternative (or in addition) the tractor may be configured to lock so it does not compress in diameter during axial load by adding a coating, laminate or adhesive to the braid at a desired diameter. Adding a thin coating, laminate or adhesive can inhibit the braid elements from sliding with respect to each other, thereby locking the braid to a specific diameter. The coating can be applied while leaving the majority of the pores and pore area substantially open. Examples of thin coatings include urethanes and silicones with and without hydrophilic coatings and hydrophilic coatings with no tie layer.

[000140] Reducing the sliding friction of tractor to outer catheter wall, improving tractor to tip rolling, and/or enhancing tractor to inner catheter sliding may also be achieved by including a sliding skin or sleeve. For example, a thin (e.g., ultrathin) sleeve may be used. The sleeve would be made from low friction polymer (PET, PE, PP, PTFE, ePTFE, Pebax, urethanes) by braiding, knitting, weaving, extrusion, melt blown, melt spinning, etc. The sleeve could be made from laser slotted tubing, chemical etching, micro machining. The sleeve could be also coated with a lubricious coating such as a hydrophilic coating. Lubricious coatings can be located on the outside and/or inside surfaces. The sleeve may be placed between the dozer element and the catheter wall and attached to the puller element. The sleeve may be less than 0.002" thick, ideally, less than 0.001" wall thickness. The sleeve may decouple the tractor clot grabbing system from the catheter wall, tip rolling and inner catheter dragging friction. The sleeve could be totally free from the tractor, connected to the tractor in discrete locations or connected fully to the tractor. This may allow the tractor to be designed to grab clot (larger wires: 0.001" to 0.002" for neuro, and 0.002" to 0.007" for other applications) and the skin to be minimized in thickness and structure to reduce friction and skin bending stiffness.

[000141] FIG. 4A shows one example of a sleeve that may be used. In this example, the sleeve 403, such as those described above, may be positioned between the catheter 401 outer diameter and the tractor 405. The sleeve (or “skin”) may be inverted with the tractor, or it may be held on the outer diameter and the tractor moved over it. FIG. 4B is another example in which the tractor is pulled by a pull wire 409; in FIG. 4A the tractor is pulled by a puller catheter 408 within the outer device catheter 401.

[000142] In some variations, the tractor region may be formed of with a mixed or hybrid structure, combining one or more of interwoven or knitted braid polymer filaments with metallic filaments. The mixed structure (hybrid structure) may leverage both metallic elements interwoven with low friction polymer elements. The metallic filaments may create stiffness elements that may grip/grab a clot. The polymer filaments may aid in grabbing clot but may provide surface friction reduction to the outer catheter wall, the catheter tip and the inner catheter wall once around the tip.

[000143] Any of the apparatuses described herein may include a tractor having a hydrophilic/lubricous coating on the inside surface, e.g., for braided/knitted tractors, on the inside surface (contacting the outer and inner diameter of the catheter) of the braid/knit, which is in contact with the outside of the catheter. Examples of lubricous coatings include hydrophilic coatings (e.g., hydrogels) and hydrophobic coatings (e.g., fluorine coating such as PTFE & FEP, parylene, silicone, siloxane (silicone additive) added to various polymers including pebax to make any material more lubricious, Polyethylene, polypropylene, FEP)

[000144] As mentioned above, any of these apparatuses may include a distal tip that is less rigid (e.g., “softer”) than the more proximal regions of the distal tip. This may be achieved by having a structural supporting member reinforcing the distal tip, or by modifying the material forming the distal tip. In some variations, the distal tip of the catheter may be stiffened (made more rigid) by inverting over the catheter end. See, e.g., FIGS. 5A-5B showing an inverted soft tip of a catheter. In this example, a 72-end PET braid was used to invert the tip 501 of the 0.071 catheter back over itself 505 as shown in FIG. 5B. Inverting the distal section of the catheter tip, which may include a hydrophilic coating, inside of the catheter and (in this example, though not a necessity) a radiopaque marker band 507. This may crease a larger radius tip which is relatively stiffer than the tip and has a hydrophilic coating around the outer diameter and inner diameter all the way on the last 2-5 mm of the catheter. Optionally, the catheter may be delivered with a tip similar to that show in FIG. 5A, but when the tractor is pulled initially into the catheter, the distal end of the catheter may invert to form the tip as shown in FIG. 5B.

[000145] FIGS. 6A and 6B show another example of an inverted soft-tip catheter over which a tractor 601 (in this example, a PET braid having 72 ends and a 4 x 0.0008" material). The tractor in FIG. 6A is rolled over the hydrophilic coated tip 603 showing a large collapsed radius (e.g., it does not collapse down on itself). The coating of hydrophilic material enhanced the rolling of the material over the catheter. The catheter was loaded with the tractor having a small (2 mm) ID tube, which is very close to the catheter OD. In this example, 23 cm of tractor was pulled easily into the catheter having a rolled tip as shown in FIG. 5B. In this example, the tip did not collapse, however other tractor materials (e.g., metallic, such as Nitinol materials) may collapse the tip, even when inverted as shown.

[000146] FIGS. 7A-7F illustrate examples of braided tractors that may be used. In these examples, FIGS. 7A-7C show PET braids that are heat-set to 0.085" IDs (at 395°F for 10 min). For example, FIG. 7A is a 0.001 inch PET, having 36 ends and a 77° braid angle at 9 mm, and 0.008 OD filaments. This example was highly porous, but was the least stable of all of the examples shown in FIGS. 7A-7F. FIG. 7B is a 72-end 0.001 polyester strand braid of 8 mm, 90° braid angle, with 4 filaments in each strand. FIG. 7C is a 48-end braid tractor of 0.002" polyester, 90° angle over 9 mm mandrel. The braid shown in FIG. 7A collapses 50% of the diameter, while the braided tractor shown in FIG. 7B collapsed less than 5% of the diameter, and the braided tractor of FIG. 7C collapsed less than 25% of the diameter. FIGS. 7D and 7E show Nitinol braided tractors heat-set to 0.085" ID (at 510 °C for 8 min). These braided tractors were constrained to 0.070 inches to show the pore size when pulling into a 0.071 catheter. Other examples of braided tractors had between 96 or 144 ends of 0.0005"-0.0015" PET mono or 0.0005" - 0.001" filaments with a <35° braid angle.

[000147] FIGS. 8A-8D illustrate the operation of a 72-end 0.001" NiTi tractor capturing clot in a model vessel. In this example showing pulling the clot into the catheter, the ID of the vessel is nearly the same as the OD of the catheter tip. Drawing the tractor into the vessel shows that the tractor region does not collapse down with inverted into the vessel, preventing locking of the end, and leaving space for drawing the clot, as shown. FIGS. 8E and 8F illustrate reversing the rolling movement of the device to eject the clot from the apparatus.

[000148] Similarly, FIGS. 9A-9C illustrate using a 48-end 0.002" PET monofilament braided tractor capturing a clot in a vessel. FIG. 9D shows reversing of the same apparatus to eject the clot. FIGS. 9E-9G show another example of a braided tractor, comprising a 72-end 0.001" PET (4x 0.0008" fil) material drawing clot into the device by rolling the tractor region into the catheter, as shown.

[000149] As discussed above, tractors may also be formed of a knitted material. A knitted material typically includes materials in which the same filament (or a series of filaments connected in tandem) is knitted to itself to form the tractor. It may be particularly advantageous to use a knit to form a tractor as described herein. For example, FIGS. 10A-10F illustrate an example of a 0.002" knitted tractor 26 needle (SN5923) material, which is a circular weft knit of 0.002" PET monofilament 26 needle head Greige (from Secant Medical). In FIGS. 10A-10C, the knit material is not heat set; the tractor regions shown in FIG. 10E is heat set, knot post-heat treated (at 395°F, 10 min on 0.085" mandrel).

[000150] Any of the apparatuses described herein may include a tractor region that is configured to grab a clot. In particular, described herein are apparatuses that may include a tractor region that has a plurality of projections extending from the tractor, particularly when the tractor rolls around the distal end of the catheter and inverts; these projections may help grab and/or macerate the clot.

[000151] For example, described herein are apparatuses including a plurality of projections that are formed as part of the tractor region. For example, any of these apparatuses may be configured to include projections that are formed by cutting (e.g., laser cutting) or forming from the tractor. Cutting and may be used to form projections or protrusions from a tube of material (or a sheet formed into a tube during processing) such as a sheet or tube of NiTi, thin-film NiTi, cobalt chromium, stainless steel, etc. Projections may be formed from a laser cut NiTi hypotube, a NiTi laser cut sheet, or the like. Projections may also be formed on any of these devices by welding. For example, projections may be formed by welding to a thin-film NiTi tube or sheet. The cut or formed tractor regions may be configured to have virtually any pattern or shape. For example a tractor region having projections that extend from an inverting/rolling tractor region may be formed of a metallic or polymeric material that can include any cut or shaped pattern so that the pattern lays flat (e.g., in the plane of the tractor) on outside of catheter and extend from the tractor (e.g., out of the plane of the tractor) as it rolls around the catheter. The projections may comprise portions of the tractor region pattern that extend and may grab and/or cut, e.g., macerate, the clot as they stick into the clot. These same regions of the tractor may then lie relatively flat against the ID of the catheter when fully inverted and pulled into the catheter.

[000152] In general, cut may be made in the tubes or sheets (e.g., sheets to be formed into tubes) in order to enhance flexibility, porosity and/or to add projections that may extend from the tractor as it is rolled over the distal end opening of a flexible tube (e.g., catheter). A

tractor may therefore be formed into any appropriate pattern, so long as it is sufficiently flexible.

[000153] For example, FIGS. 11A-11D illustrate examples of patterns that may be used for a flexible tractor region. These two dimensional (2D) patterns (e.g., textured surfaces) may provide flexibility of the tractor region in rolling and inverting over the catheter distal end; in some variations, such patterns may help grab a clot when the tractor is rolled and pulled into catheter. These patterns or textures could be formed by laser cutting, molding of plastics or thin film metal (e.g., NiTi Technology), stamping, etching, or the like. The patterns shown in FIGS. 11A-11D generally form closed-cell shapes having angled arms forming the cell walls. The angles may allow deformation in one or more directions. The pattern may mimic the patterns of woven, braided and/or knitted materials, or may be different.

[000154] In any of the apparatuses described herein, the tractor region may also include surface micropatterns that may be added or formed onto the tractor. These micropatterns may help with grabbing a clot. For example, FIGS. 12A-12I illustrate micropatterns protrusions, projections, knobs, bumps, spikes, etc. that may extend from the surface of the tractor. In some variations, e.g., in FIGS. 12A-12C, 12E and 12F, the micropatterns may extend from the tractor region at all times, not just when rolling over the end of the catheter. Another example of an apparatus including a tractor having projections that extend from the tractor including the portion of the tractor that is over the catheter is shown in the apparatus of FIG. 14. In FIG. 15, the tractor 1401 includes a plurality of projections 1403 that extend from the tractor at all times, including the portion of the tractor that is rolling over the distal end opening of the catheter (the distal-facing tractor portion) as well as the portion that is over the outer diameter of the catheter, and within the inner diameter of the catheter. Other variations (e.g., FIG. 12D-12I, FIGS. 13A-13B, and 16A-16B) may project only from the portion of the tractor that is rolling over the distal end opening of the catheter.

[000155] For example, FIGS. 13A and 13B illustrate an example of a tractor region having a plurality of projections that extend from the portion of the surface of the tractor only when that portion of the tractor is inverting and rolling. FIG. 13B illustrates the extension of the projections 1105 from the tractor as the tractor is rolling over the distal catheter opening 1109 to invert. In this example, the tractor is a tubular structure 1101 having longitudinally arranged lengths of tractor material 1103 forming a backbone. Spanning between these flat, elongate regions 1103 are regions that extend between adjacent elongate regions first distally in the long axis, then back proximally. As the tractor rolls over the end of the catheter opening, e.g., as shown in cross-section in FIG. 13B, the loops of material 1105 extend out of

the tractor (out of the plane of the tractor that is defined by the long axis of the tractor), and form projections 1105 that, as the tractor rolls over itself (inverting), extend outward, as shown in FIG. 11B. These projections may help grab a clot.

[000156] Projections formed in the tractor may be formed by cutting (e.g., laser cutting, press cutting, etc.), etching, etc., or they may be woven, braided or knitted into the tractor. For example when the tractor is formed of tube or sheet of material, the projections may be formed from the plane of the tractor material by removing material to leave a projection that may extend up and out of the material. When the tractor is not bending (e.g., inverting), the projections may have a low profile that does not substantially impact tracking of the tractor region when positioning the apparatus, e.g., moving it through a vessel in a patient's anatomy, while still enabling and enhancing rolling around the tip of the catheter. A projection that may help grab a clot may extend distally (e.g., towards the distal tip of the catheter when positioned on the outer catheter surface), so that as the tractor is rolled into the catheter, they extend distally (e.g., shown in FIG. 11B). Thus, the projections may create a grabbing effect. In some variations the projections may also cut into the clot and may macerate it. The projections may also help with catheter removal.

[000157] In some variations the tractor is a woven, braided or knitted tractor that may be formed of one or more strands that have one or more (e.g., 2, 3, 4, etc.) edges that may project from the plane of the tractor as it rolls over the distal end of the catheter. When the strand(s) forming the tractor have a rounded profile (see, e.g. FIG. 15C), as the tractor inverts over the catheter, the face of the inverting distal-facing tractor region remains smooth, as shown in FIG. 15A. FIG. 15B shows a single strand inverting over the distal end opening of a catheter.

[000158] If the strand forming the braided or woven tractor region is instead formed of a material having an edge (e.g., a ribbon, such as a ribbon having a rectangular profile, as shown in FIG. 15D), when the tractor rolls over the distal end opening of the catheter, particularly where the strand (e.g., ribbon) is at an angle relative to the distal end opening (and the distal-facing inverting portion of the tractor), as shown in FIG. 15E, the edge of the strand projects upwards and away from the tractor, out of the plane of the tractor. This is schematically shown in FIG. 15E, showing a rectangular strand or ribbon that may be woven, e.g., in a helical weave, and the edge 1505 of the woven strand twists up and out of the plane of the tractor as it inverts over the catheter to form a projection 1507 as shown in FIG. 15E. This projection may act as a scoop or shovel-like element that may help grab the clot, even if the tractor is lubricated and/or lubricious.

[000159] FIGS. 16A-16B illustrate an example of a tractor formed from a plurality of strands having an edge; shown here as strands that are ribbons having an edge (forming a rectangular profile).

[000160] In FIG. 16A and 16B, the apparatus includes a catheter having a distal end and a distal end opening (not visible beneath the distal end-face of the tractor shown), and a tractor 1600 that includes a flexible tube that extends within the catheter, inverts over the distal end opening of the catheter and extends over the distal end of the catheter. The tractor forms a tubular wall and is configured to invert by rolling over the distal end opening of the catheter, as shown in FIG. 16A, when a first end of the tractor is pulled proximally within the catheter. The tractor includes a plurality of projections 1603 (in this example, formed by the edges of the ribbon-shaped strands, that extend from the distal-facing portion of the tractor as it is inverted over the distal end opening of the catheter. As the tractor rolls over the distal end opening of the catheter, the ribbon-shaped strands twist up and out 1603 of the tractor. These twisting edges form projections that can help grab a clot. Thus, FIG. 16A shows a distal end-face of the tractor inverting region as it rolls over the distal end opening of the catheter from the outer diameter to the inner diameter of the catheter. The plurality of projection regions 1603 are formed as the strands (ribbons) twist so that the edges of the strands extend up out of the plane of the tractor. As shown in FIG. 16B, when the tractor is over the outer diameter of the catheter, including the catheter distal end and more proximal regions, these strands do not project out of the tractor, but remain flush against the outer diameter, even when the catheter, and therefore the tractor, are bent and positioned in a tortuous vessel; only when inverting do they project outward. Thus, the projections are not extended from the tractor in the portion of the tractor that extends over the distal end of the catheter. The center of this apparatus forms a guidewire lumen extending through the catheter and the tractor and may pass a guidewire. When the tractor is extended along the outer diameter of the catheter proximal to the inverting region, the strands, which are helically woven to form the tractor, remain flat, in the flat cylindrical surface (“plane”) of the tractor.

[000161] As will be described in greater detail below, in some variations, including knitted tractor variations, the cells of the tractor may extend up and out of the inverting distal-facing region as it rolls around the catheter. These projections may also act as scoops, shovels, etc. and may help grab onto a clot.

[000162] Some variations of the tractors described herein may be formed of a non-woven, non-braided and non-knitted material. The tractor may be formed of a sheet and/or tube of material that may be directly fabricated (e.g., extrusion, etc.). This tractor may be cut,

including laser cut, to form slots. In some variations these cuts may form projections. For example, the tractor may be formed of a solid (including porous) material into which a pattern is formed (e.g., slots, cut-out regions, etc.) including patterns that produce projections as described above. A tractor region may be formed of a tube of material into which slots or cut-out regions are formed. Such apparatuses may include a tractor formed from a tube of material such as ePTFE (which may be relatively soft, strong in tension and radial compression), NiTi (a super elastic and/or thermally settable material), a fabric (which may be a soft, thin walled material having a reasonably high radial/axial strength), or the like. The tractor may have material frictional properties and material surface hardness that are appropriate to grabbing a clot. In general, materials that are softer may be easier to track the apparatus in the anatomy. As mentioned, the tractor may have pores and may therefore have a tube porosity. The pores may be formed by removing material (or shaping into the openings) and may be oriented to aid in flexibility, rolling and/or tissue grabbing. A tube forming a tractor may be laser cut at an angle relative to axial length, or it may be laser cut (e.g., perpendicular versus angled relative to the tube thickness). Angled cuts may create a cutting surface to mince or macerate a clot, whereas perpendicular or rounded cuts through the thickness of the tractor may enhance grabbing of clot. Any of the tractors described herein may have a final shaped cross-section that is heat-set and/or formed on a mandrel (e.g., formed shape as set on heat treatment mandrel). The tractor regions described herein may be self-expanding. For example, in particular, the tractor may be set (e.g., as a shape-memory material) to expand outwards when inverted (e.g., within the catheter) and may therefore collapse inward slightly when inverted over the outside of the catheter. As discussed above in reference to FIGS. 2C and 3A-3C, this may aid in forming a trumpet shaped distal-facing region of the tractor, where the tractor is inverted over itself. Some variations of tractors may not be self-expanding. As mentioned, the tractor may be formed of a polymeric material (e.g., ePTFE, PET, PP, Nylon), metals (including alloys) or combinations of these. The tractor may have a low profile (e.g., minimum thickness), may be highly flexible and able to navigate through tortuous vessels, may be able to invert around the catheter tip, may have clot grabbing properties (including projections and/or surface roughness) and may provide a column strength in compression (e.g., strut stiffness), and may be partially or completely radiopaque. The tractors described herein may scale from 1mm OD fully formed to 15mm. Any of these tractors may include a lubricious surface on one or both sides (particularly the side that faces outwards when extending over the outer diameter).

[000163] Examples of slotted laser cut tubes forming a tractor are provided herein, including those shown in FIGS. 17A-25B. The starting tubes may be flexible or rigid. For example, a soft flexible tube, strip, or roll of material such as ePTFE or a dense fabric (e.g., knit or weave or braid) may be used. Flexible tubes may provide tractors and/or combinations of tractors and catheters that allow tracking of the apparatus to the treatment site even in tortuous vessels. Tracking allows pushing of the apparatus through tortuous vessels of small caliber over long distances from their introduction site to the human body, over length that can exceed 1 meter in some uses. A flexible tube (pre-laser cutting to form the tractor) may have a softness resulting in a low radial crush force, such as a micro-porous, polymer based tube. The tube may be processed (e.g., by cutting or any of the other techniques mentioned herein) to provide flexibility (e.g., the ability to pull the tractor into catheter, invert, and expand over catheter outer diameter) and/or to create a textured/porous surface that may aid in grabbing a clot (e.g., emboli) and may provide free spaces (voids) that may help store and/or masticate emboli, making them easier to store within the apparatus and transport. Prior to forming into the tractors the sheets or tubes (e.g., films, rolls, etc.) may have a smooth surface. Patterns may be formed into the sheet or tube to form the tractor. For example, laser slot patterns may be formed in the material to increase macro-surface roughness. Holes, slots, edges, divots, and bumps may be formed on the material. In addition to helping grab and hold emboli, such holes or slots may create free space in the tube wall to cut the clot and/or carry it away. The patterns used to form any of the tractors described herein may have a shorter strut length to strut width ratios. Short, wider struts may create tractors that are stiffer and may grab clot better. In combination with strut length to width, in some variations, thicker walls may be preferred. Thicker slotted walls may create stiffer struts and more aggressive surface texture to grab clots. Furthermore, thicker walls may enhance clot storage capacity within the slot gaps.

[000164] In some variations, it may be beneficial to provide slot designs which do not foreshorten. For example, if the slotted tube design is pulled axial (e.g., down its length), the tube diameter may not decrease. A decreasing diameter slotted tube may grab the outside of the catheter and cleat, increasing drag force when the tube is pulled.

[000165] In variations in which the initial tube or sheet of material used to form the tractor tube is relatively rigid (e.g., formed of a material such as Steel, Nitinol, Polyester, PTFE, Nylon, etc.), the initial tube stiffness/hardness may enhance the clot-grabbing ability when the tractor is slotted properly, to allow both increased flexibility, expansion and rolling. For example, a rigid tube may include slot designs that focuses in catheter tracking and creates a

flexibly bending tractor with minimal foreshortening, that is able to be pulled into a catheter (inverting) structure. As with the more flexible starting tubes discussed above, tractors formed of more rigid starting materials may grab and transfer a clot, and the number of slots and/or voids may be increased to increase clot grabbing and/or carrying capacity. A slotted tube forming a tractor may include surface grabbing features, such as channels/corrugations (e.g. any of the microstructures such as those shown in FIGS. 12A-12I above. More rigid tubes may create harder or stiffer slotted tractors. For example, when struts are formed into the tractor (e.g., by cutting, etc.), the slot strut length to strut width may be greater than with less rigid starting materials, and may be a function of the rigid tubes elastic modulus. Higher elasticity materials (e.g., Niti, PET, PTFE) may have strut length to width ratios from 10 to 100. Stiffer materials (e.g., steel, MP35N) may have a length to width ratio greater than 50. The wall thickness to strut width for elastic materials may be, for example, between 0.5 to 10; for stiffer materials it may be between 0.25 to 5.

[000166] As mentioned, any of the apparatuses described herein may include a tractor region that is non-foreshortening. The foreshortening of the tractor may depend at least in part on the slot designs for non-woven, non-braided, non-knitted designs (e.g., tractors that are not formed of a strand or strands of material). FIGS. 17A-17D illustrate an example of non-foreshortening design. Also, for both flexible and rigid starting tubes forming a non-woven tractor, the tube inner diameter can be slightly bigger than catheter tube outer diameter pre-slotting. Slotted tube designs which foreshorten may reach their smallest diameter limit when tensioned axially. If the tube is sized to be slightly larger than the catheter outer diameter, then it may jam (preventing any foreshortening) before it cleats to the catheter outer diameter. Tractor regions formed of an initially rigid material may grab clot more efficiently than tractors having an equivalent thickness but formed of a more flexible material. More flexible materials may deform as a function of stiffness.

[000167] FIGS. 17A-17D illustrate an example of tractors that are formed by cutting slots and/or windows into tubes of material. In FIGS. 17A-17D, an initially soft material (e.g., ePTFE) was formed by a subtractive manufacturing technique to form, slots, pores and textures in the soft flexible tube. In FIGS. 17A-17D, a 3mm ID ePTFE tube (configured to be used with a 2.9mm OD catheter) was made to be highly flexible and have some level of column stiffness and radial/hoop stiffness by laser-cutting slot patterns into the tube wall to create textures and bend zones which impart clot grabbing and rolling. The ePTFE itself is highly lubricous. Addition of a lubricant (e.g., hydrophilic coating) may improve tracking and rolling. Lubricant can be applied to ID and OD or to either separately. FIG. 17A shows

a first pattern 1701, having minimal cuts to create a smooth rolling of the tractor around the catheter 1703 portion of the apparatus.

[000168] A second exemplary pattern is shown in FIG. 17B. In this example, the apparatus slightly larger cut-out regions 1709 (removed by laser cutting in this example), which may create better clot grabbing properties and more clot holding capacity. In FIG. 17B, the ePTFE tube forming the tractor region is slotted on the outside of the catheter. Note that the porosity (14 holes around the circumference) may help grab and hold clot. In both FIG. 17A and 17B, the laser pattern may foreshorten, but may jam before it grips/cleats the catheter outer surface.

[000169] Another example of a tractor was made from a 2.9 mm OD ePTFE tube (configured for use with a 3 mm ID catheter). This example was made to be highly flexible and have some level of column stiffness and radial/hoop stiffness by laser-cutting slot patterns into the tube wall in a pattern to create textures and configured to include bend zones which impart clot grabbing and rolling. Similarly, a tractor may be made of, e.g., a 2.9mm OD PET woven fabric tube (for use with a 3mm ID catheter). The tractor may be formed of 30 Denier PET multi-filaments, 0.003" thickness. The resulting tractor may be configured to be soft and have some level of column stiffness and radial/hoop stiffness by laser cutting slot patterns into the tube wall in a patterns providing texture and bend zones which may impart clot grabbing and rolling. As with ePTFE, the PET material may itself be lubricous although additional lubricant may be added to improve tracking and rolling. Lubricant can be applied to ID and OD or to either separately.

[000170] An example of a tractor made from a somewhat rigid starting material was formed from a nickel titanium (NiTi) tube having a 3mm OD (which may be used with, e.g., a 2.9 mm ID catheter). The wall thickness in these examples was between 0.001" and 0.002". Laser slot patterns were cut into the tube wall in various patterns to create textures and purpose-designed bend zones which may help impart clot grabbing and rolling. A lubricant may be applied, e.g., as a coating, to the ID and OD or to either separately. A first pattern similar to that shown in FIG. 17A was made by minimal laser cutting to create a smooth rolling tractor. The strut length to width ratio was between 25-50. A second pattern having larger slots/openings (similar to that shown in FIG. 17B) was formed by laser cutting. These patterns may foreshorten, but typically minimize or stop foreshortening before the tractor grips/cleats the catheter outer surface (which may result in jamming). The Niti design has the additional benefits of radiopacity, thermal shaping and super elasticity.

[000171] Any of these designs or patterns may for projections that may extend from the rolling distal-facing and inverting portion of the tractor, as discussed above. Such projection may be cut out as “teeth” or elongate members. The regions forming the projections may be sharp, e.g., pointy and/or cutting. Sharp projections may be chew and cut a mature clot. These projections regions may be short or long, may extend in one or more directions (e.g., forward or backward or bidirectional), and may be scoop-shaped (e.g., paddle-shaped). The number of projections may be selected based on the desired coarseness, e.g., the number of projections, the size (length/width/thickness), etc. The projections may change density down their length. For example, the laser pattern can be designed to allow tractor rolling (e.g., long struts) more easily initially, then have grabbing teeth at higher density; alternatively the tractor may be configured for greater initially grabbing, having a pattern with more and/or larger projections initially (distally) then transitioning to more slits (and flexibility) toward the proximal end, which may make it easier to pull. Further, the distribution of projections can be uniform around the tube perimeter and/or non-uniform (e.g., forming a spiral pattern, distributed in patches, having open areas, etc.).

[000172] Any of the tractors described herein may include a marker or markers (e.g., radiopaque markers, such as gold, Pt, etc.). When forming the tractor from a tube or sheet, the tubes may be cut, then shaped to have any profile, such as straight, rolled over the tip, flaring at the proximal end, etc. Any of the microstructure described herein may be included or formed, as mentioned above, e.g., wells on the struts may help carry and grab clot. Tractors formed of tubes from which material was removed (or sheets formed into tubes) may be configured to have less cleating of the tractor onto the outer diameter of the clot, preventing jamming, particularly compared to woven or braided or knitted materials. However any of the slotted tube tractor configurations described herein may be used with, e.g., in combination with, a braid or knit or polymer sleeve, including either in parallel or in series. In general, any of these tractors may be formed as multi-layers, particular these slotted tube tractors.

[000173] For example, a tractor portion of an apparatus may be formed by removing material from a Niti tube that is slightly smaller than the inner diameter of the catheter that it will be used with, or it may be made from a tube that is slightly larger than the outer diameter of the catheters. The tube may be cut with a pattern that increase the coarseness of the outer surface (e.g., to include projections such as struts/scoops/teeth). For example a 0.001" tube wall thickness or smaller may be used.

[000174] FIGS. 17C and 17D illustrate an example of a tractor region cut from paper. In FIG. 17C a rigid paper tube was cut to include slots and the distal end expanded, as shown. It may be inverted over itself and used as a tractor region. This paper prototype was prepared to illustrate the effectiveness of this pattern. Similarly, FIG. 17D is an example of a prototype tractor region.

[000175] FIGS. 18A-18C illustrate examples of patterns that may be formed into a flat sheet or tubular member to form a tractor (e.g., slotted tractor). Similar to those shown in FIGS. 17A-17D. In FIG. 18A, the pattern may be cut to form the tractor. White regions 1801 may represent or form struts, while the lines indicate slots 1803 from which material is removed. This pattern is one of many resulting in a flexible tube having stout struts. FIG. 18B shows a similar example having a higher density of slots forming thinner struts and potentially higher porosity, which may result in a larger clot-carrying capacity. FIG. 18C illustrates an example of a pattern having curves that may produce a slightly more bendable (flexible in bending stiffness) slotted tractor. In FIGS. 18A-18C, the pattern is oriented so that the distal direction of the tractor formed by the pattern is at the right or left of the pattern shown (e.g., the tube is oriented right and left, relative to the figures, so that the tube is formed by rolling up from the bottom of the figure).

[000176] FIG. 19 is an example of a pattern that may be formed into a tube as part of a tractor having a plurality of both slots 1903 and cut-out regions 1901 (holes). Another example of a pattern having a plurality of cut-out holes 2001 formed into it is shown in FIGS. 20A and 20B. FIG. 20B shows an enlarged view.

[000177] An example of a pattern having a plurality of projections is shown in FIGS. 21A-24B. For example in FIGS. 21A and 21B, the pattern includes a plurality of slots 2101 and cut-out regions that leave a projecting strut or tooth 2105 behind. In these examples, the tooth 2105 is pointed and oriented to the left of the page, which may be the distal end direction of the tractor. (e.g., the left side of the image may correspond to the distal end of the tractor); thus when the pattern is formed into a tubular body to form the tractor, and the tractor is inverted over itself (e.g., rolling over the distal end opening of a catheter) the plurality of pointed projections 2105 may extend out of the tractor, and may help grab and draw clot into the catheter.

[000178] Similarly, the pattern shown in FIGS. 22A-22B illustrate another example include a slot 2201, a projection 2203 and a cut-out portion 2205. As in FIGS. 21A and 21B, the projection may extend out of the plane of the tubular tractor (shown here as the plane of the paper, even when rolled up to form the tractor region). FIG. 23A, and enlarged view of FIG.

24B, shows another example of a pattern for a tractor that is similar to that shown in FIG. 21A-21B, but with smaller projecting regions. In this example, the projections 2305 are sharp, and open into an opening 2303 connected to a slot 2301. The pattern shown in FIGS. 24A-24B is similar to that shown in FIG. 23A-23B but with additional openings (cut out regions 2407) which may increase the carrying capacity (e.g., clot carrying capacity) of the tractor region.

[000179] FIGS. 25A-25C are examples of laser-cut tube prototypes of tractor regions. In FIGS. 25B and 25C the tractor region is inverted over the distal end opening of the catheter.

[000180] In any of the tractor regions described herein, the tractor may have sufficient coarseness to grab the clot, yet still roll easily around catheter tip. Coarseness may relate to the thickness profile of the tractor region. For example, knitted tractors may be more coarse than braided tractors, due to the macro structure (e.g., cells, wire cross overs, shape of cells). The ability of the tractor to capture and transfer (like a conveyor) clot material through the catheter may be aided by coarser macro structures. In addition, as mentioned above, projections may both increase the coarseness and may help aid in grabbing clot. However, projections that extend only when inverting the tractor may be desirable; e.g., the tractor may feel smooth to the touch unless the dozer is rolled around a corner. The act of rolling the tractor may expose or activate the passive grabbing elements (projections). As mentioned, any of these apparatuses may include pores. For example, any of these apparatuses may include pores having a size that is greater than 1/50th of the catheter circumference. For example, the pore size may be 200 μm or greater (e.g., 300 μm or greater, 400 μm or greater, 500 μm or greater, etc.). In some variations the number pores (openings) per circumference may be between 5-20, 5-10, 10-15, 15-20, etc. pores on per catheter circumference on the tractor. As mentioned, the projections may be sharp, or dull, or may have an enlarged surface area (e.g., paddle-shaped). Sharp strut edges may grab and/or cut clots, while projections may also help grab clot. For example, a tractor may have a texture/roughness of at 0.0005" or greater (e.g., 0.0001"-0.0010"). The tractor may be formed of an inherently lubricious material, and/or may be lubricated through the use of hydrophilic coating on the tractor and/or OD of aspiration catheter or construction of lubricious hydrophobic materials such as Polyethylene, Polypropylene, fluoropolymers, FEP, PTFE.

TRACTORS HAVING ALTERNATING STIFFNESS

[000181] Also described herein are tractors having alternating stiffness along their length. For example, a mechanical thrombectomy apparatus for removing a clot from a vessel may

include a elongate inversion support including a catheter and having a distal end and a distal end opening and a tractor that is configured as a flexible tube that extends longitudinally within the catheter and doubles back over the distal end of the catheter to extend over the distal end of the catheter. The tractor may be formed of longitudinally alternating regions of higher and lower stiffness, wherein the regions of higher stiffness have a stiffness that is greater than the regions of lower stiffness. In some variations this may allow the lower stiffness regions to act as hinge-regions relative to the stiffer regions, when the tractor is pulled into the catheter. These variations may result in a seesawing motion at the distal end opening of the catheter, as the tractor is inverted and pulled into the catheter. This is illustrated schematically in FIGS. 30A-30D. For example, a portion of a length of tractor may include more stiff regions 3001 and less stiff regions 3003 that are alternating along the long axis of the tractor, as shown schematically in FIG. 30A. As the tractor region is inverted over the distal opening of the catheter (shown in FIG. 30B, in which a portion of the catheter wall is shown 3009), pulling the tractor over the wall 3009 causes the more flexible portions to bend over the wall, while the less flexible regions 3001 bend less or not at all. FIGS. 30B-30D illustrate progression of a tractor portion over the distal end opening, showing the bending of the less stiff/more flexible regions 3003 over the wall, while the more stiff/less flexible regions 3001 do not bend. The result is that, as shown by the arrows on the bottom, the diameter of the distal-facing region changes, and oscillates, as the tractor is pulled into the catheter.

[000182] Thus, the tractor may be configured so that it rolls around the catheter tip opening and inverts in a ratcheting fashion, in which parts of the tractor that are stiffer than other sections alternate with more stiff regions. These differently-stiff sections may cause the tractor rolling around the catheter tip to move in a semi-rigid manor and/or a pivoting/seesawing motion around the distal face of the catheter opening and the regions adjacent to the distal opening.

[000183] Tractors having alternating stiff/less stiff regions down the length of the catheter (including arranged in a helical manner spiraling down the length) may be formed in a variety of different manners, including constructing braids, laser cut tubes, knits, weaves, and laminates. For example, FIGS. 31A-31D illustrate an example of a knitted tractor region having this configuration. As the the variable stiffness tractor rolls around the catheter, sections of the tractor may temporarily dive to towards the center of the catheter ID, which may also aid in grabbing clot or a foreign body to pull into the catheter. The apparatus may be configured so that the tractor includes sections that sea-saw around the catheter tip so the

dozer protrudes into the catheter ID by a distal equivalent to 5%, 10%, 15%, 20%, 25%, 30%, 40%, 50%, 70%, 80%, 90% of the catheter's inner radius length, or any range of the numbers.

[000184] The tractor shown in FIG. 31A is a knit construct which has sections that are stiffer alternating with others sections that are less stiff. A first region 2401 of FIG. 31A, is stiffer than the adjacent second region 2403, which is also adjacent to another stiffer region 2401'; the stiffer/less stiff regions alternate and spiral in a helix along the length of the tractor. As the knit tractor shown in FIG. 31A rolls around the catheter, the less stiff section 2403 of the knit shown may temporarily bend, diving the stiffer region 2401 towards the center of the catheter inner diameter in a seesawing motion. FIG. 21B shows a side view of an apparatus including a knit tractor such as shown in FIG. 31A, having alternating stiff/less stiff regions extending down the length of the tractor. FIG. 31C illustrates the distal-facing and inverting tractor that is rolling (in a seesawing manner) over the distal end opening in the catheter. FIGS. 31D and 31E show alternative side and end views, respectively, of a mechanical thrombectomy apparatus including a tractor region such as is shown in FIG. 31A.

[000185] In this example, when the tractor rolls over the distal end opening of the catheter, the alternating stiff/less stiff construction causes the stiffer region to moves towards the center of the catheter, which may aid in grabbing clot or a foreign body to pull into the catheter. The tractor may therefore seesaw around the catheter tip opening so that the tractor protrudes into the catheter ID by a distal equivalent to 5%, 10%, 15%, 20%, 25%, 30%, 40%, 50%, etc. of the catheter's inner radius length, before withdrawing, and then repeating the cycle.

[000186] The alternating stiff and less stiff regions may have a distance (e.g., axial distance, along the long axis of the tractor) that is related to the inner diameter of the catheter. In particular, if the stiff regions are too large relative to the catheter inner diameter, then the tractor may jam in the catheter, as illustrated in FIGS. 32A and 32B. In FIGS. 32A and 32B, for example, the stiff regions are greater than half the diameter of the inner diameter of the catheter. As shown in FIG. 32B, pulling the tractor into the catheter results in locking or jamming the tractor in the end of the catheter. In some variations the stiff region may be slightly larger than half the diameter without jamming, for example, if the adjacent stiff and less stiff regions wind around the tractor at a sufficiently large angle (e.g., greater than 10 degrees, 15 degrees, 20 degrees, etc.) so that only a subset of the stiff regions moving into the inner diameter of the catheter at the same time. Thus, the length of the stiffer regions may be 0.7 times the diameter of the catheter ID or less (e.g., 0.65 times, 0.6 times, 0.55 times, 0.5

time, 0.45 times, 0.4 times, etc., the diameter of the catheter ID or less). This may also be expressed the length of the stiff region being 1.3 times the radius of the catheter ID or less (e.g., 1.2 times, 1.1 times, 1.0 times, 0.9 times, 0.8 times, etc. the radius of the catheter ID or less).

[000187] Similarly, if the length of the stiff regions is too small, it will not see-saw in any appreciable amount and may, in some variations, jam onto the end of the catheter, as illustrated in FIGS. 32C and 32D. In FIGS. 32C and 32D, the length of the stiffer alternating regions is not substantially larger than the thickness of the catheter (e.g., the distance between the ID and OD of the catheter), so that no seesawing motion will occur. For example, the length of the stiff region may be 1.1 times or more than the thickness of the catheter (e.g., 1.2 times, 1.3 times, 1.4 times, 1.5 times, 1.6 times, 1.7 times, 1.8 times, 1.9 times, 2 times, etc. or more than the thickness of the catheter). Alternatively the length of the stiff regions may be 0.1 times the radius of the catheter or greater (e.g., 0.2 times the radius of the catheter, 0.3 times the radius of the catheter, etc.).

[000188] In FIG. 32A-32B, the tractors formed of knit materials having different sizes post-heat treatment (e.g., 0.002" knit 26 needle (SN5923) heat treated on a 0.085" mandrel) than those shown in FIG. 32C and 32D. In FIGS. 32A-32B, the knit material locked on and could not be rolled over the catheter. Relative to the size of the knit, the ID of the catheter (0.045" ID/0.055" OD) was too small. In contrast, in FIGS. 32C and 32D, the catheter dimensions were too large for the knit (e.g., 0.085" ID 72D Pebax, 0.95" OD); the knit material could not pull around and invert on the tubing of this size.

[000189] FIGS. 33A and 33B illustrate another example of a seesawing tractor formed from a knitted material. FIG. 34 shows an enlarged view of a portion of knitted material forming a tractor. The knitted tractor is formed from a filament (a monofilament or group of fibers collected into a filament) that is knitted to itself. The knit may be a tubular knitted material formed from a filament (monofilament or group of filaments) forming interlocking loops as shown in FIG. 34. In this example, the regions of overlap 3401 between the loops form the stiffer region, while the non-overlapping regions form the less stiff regions 3403. In any of the variations described herein, the loops formed by the knit may also act as protrusions as discussed above, and may aid in drawing the clot into the catheter and/or macerating the clot. For example, the sequence of illustrations in FIGS. 35A-35C show a portion of a knitted tractor having loops of nickel titanium forming alternating stiff/less stiff regions (arranged down the long axis of the tractor) as they roll in a seesawing manner over the distal end opening of the catheter. In this example, a single loop 3501 has been indicated showing it's

progression from flush against the wall of the outer diameter of the catheter as the tractor is pulled into the catheter, until, as it approaches the distal opening of the catheter, it inverts by swinging the loop portion 3501 out of the plane of the tractor and up, where it may help grab clot material, as shown in FIGS. 35B-35C. The seesawing motion of a knitted tractor may also be seen in FIGS. 36A-36B and 37A-37C. An example of a mechanical thrombectomy apparatus is shown in FIGS. 36A-36B from end and side perspective views. FIGS. 37A-37C illustrate a method (e.g., that may be used for grabbing and removing a clot from a vessel) including pulling the distal end of the tractor (in this example, a knitted, seesawing tractor) proximally into the catheter. As shown in FIG. 37A the tractor may initially pull a stiff region 3703 towards the catheter opening. Because it is sufficiently stiff that it does not bend over the edge of the catheter, but is 'hinged to an adjacent stiff region, as the tractor is pulled proximally, the stiff region eventually tilts over the edge (in a seesawing motion), so that one end flips up away from the opening, as shown in FIG. 37B (stiff segment 3703 is indicated); finally it slides forward into the inner diameter of the catheter, as shown in FIG. 37C.

[000190] As discussed above, it may be desirable to have a tractor region that is sufficiently and/or selectively coarse so that it may grab a clot. In some variations a rougher tractor may grab clot despite the lubriciousness of the tractor. Knits may be generally more coarse than braids due to their macro structure (e.g., cells, wire cross overs, shape of cells). Knits may also have the desired porosity discussed above (e.g., having a porosity that permits the tractor to grab and store clot/clot carrying capacity). The size of the pores may be, e.g., between 5-20, 5-10, 10-15 or 15-20 pores on the tractor per circumference. The knit may be formed of any appropriate material, including, e.g., Nickle titanium (Niti) wire. For example, a knit may be formed of a PET monofilament, a PTFE monofilament, etc. A knitted tractor may also have a surface lubricity based on either material properties (e.g., metal, polymer, etc.) or added lubricant (inside, outside, both), and may be radiopaque (e.g., including an inter weave in Pt., DFT, over braid wires with Pt., etc.)

Patterned Tractors

[000191] Also described herein are tractors having a pattern of lubricious and/or non-lubricious regions on their outward-facing surfaces. These patterned regions may be coatings and/or surface modification, they may be formed by the material properties of the tractor, and/or they may be due to the application of a lubricious material (e.g., lubricant) in the pattern. A pattern of lubrication and/or non-lubricous material may assist in reducing friction while enhancing clot grabbing. A uniform lubricant (e.g., hydrophilic surface) on the outer-

facing surface of the tractor has been found to reduce the ability of the tractor to grab a clot, particularly in the absence of other clot-grabbing features, such as the protrusions and edges discussed and illustrated above. Thus, described herein are patterns of lubricious and/or non-lubricious (including less lubricious, and tacky or adhesive) materials that may be included on the outward-facing surface of the tractor that may enhance pulling the tractor proximally into the device (e.g., the catheter of the elongate inversion support) and inverting the tractor, while still permitting or even enhancing clot grabbing.

[000192] For example, any of the methods and apparatuses described herein may also include a pattern of non-uniform hydrophilic and/or hydrophobic coating (e.g., a patterned lubricious coating) that may assist with the positioning of the apparatus within the tortuous vessels before or during grabbing a clot. Even a partial hydrophilic coating (e.g., lubricious coating) on the outer-facing surface of the tractor element may reduce friction within the vessel ID. These lubricious regions (e.g., coatings) may be arranged in a pattern such as alternating regions (e.g., bands, stripes, checkerboard pattern, grid, spots, etc.). For example, it may be preferred to partially coat the tractor (e.g., braid) with a hydrophilic material such as using, e.g., a 5 mm coated length of braid followed by a 5 mm non-coated section. This coating may be in other patterns, as mentioned, including strips (longitudinal strips), a spiral pattern coating, a random pattern coating, etc. FIGS. 40A-40C illustrate examples of hydrophilic coating options.

[000193] For example, FIG. 40A shows an example of an apparatus including a tractor region and 4001 a catheter of an elongate inversion support 4005 into which the tractor is inverted and drawn proximally at the distal end of the tractor. The tractor 4001 may be attached to a puller 4009 (e.g., pull wire or pull catheter) to pull, or in any of these variations, push and pull, the tractor within the catheter from the distal end of the tractor. The proximal end of the tractor is attached over the outer surface (OD) of the outer catheter 4005. In FIGS. 40A-40C the tractor is shown as a braided tractor, but any of the tractor types (braided, woven, knitted, solid/cut-out, etc.) described herein may be configured to include a pattern of more/less lubricious regions.

[000194] The tractor shown in FIG. 40A includes a pattern of lubricious regions arranged in bands along the distal-to-proximal elongate length of the tractor. For example, regions coated with a lubricious material 4011 and uncoated (less lubricious or even sticky) regions 4013 alternate down the length of the tractor. Alternatively, the pattern may be formed of a grid or checkered pattern, a spiral/helical pattern along the length of the tractor, etc. As the tractor is drawn into the catheter and inverted 4017, the alternating lubricious/non-lubricious

regions may help grab clot, which is particularly or only important when initially pulling the clot material into the inverting tractor and therefore the catheter.

[000195] FIG. 40B illustrates another example of a tractor 4001 in which elongate (in the long axis of the tractor) lengths of lubricious 4021 and non-lubricious 4023 regions alternate to form a stripe pattern down the length of the tractor. These “stripes” may be varying in size (e.g., diameter) and may be curved, zig-zag, wavy, etc.

[000196] In some variations, lubricious regions may be separated by non-lubricious regions by a minimum and/or maximum distance. For example the lubricious regions may be alternated with non-lubricious regions (including less lubricious and/or sticky/adhesive regions) by between 0.05mm and 15 mm (e.g., by greater than at least: 0.005 mm, 0.01 mm, 0.02 mm, 0.03 mm, 0.04 mm, 0.05 mm, 0.06 mm, 0.07 mm, 0.08 mm, 0.09 mm, 0.1 mm, 0.2 mm, 0.3 mm, 0.4 mm, 0.5 mm, 0.6 mm, 0.7 mm, 0.8 mm, 0.9 mm, 1mm, 2 mm, 3 mm, 4 mm, 5 mm, etc.). Similarly the maximum separation between lubricious regions may be less than about: 20 mm, 15 mm, 10 mm, 9 mm, 8 mm, 7 mm, 6 mm, 5 mm, etc.). The minimum and maximum distance may be determined based on the size of the tractor (e.g., diameter), and/or the rate at which the tractor is to be pulled. The minimum distance may also or alternatively be based on the lubriciousness of the coating. More highly lubricious materials may be separated by a greater minimum distance.

[000197] In some variations only a portion of the tractor is coated, either completely or in a pattern, and the proximal end portion (e.g., the last portion be drawn into the catheter) is not lubricious (e.g., uncoated or coated in a tacky/sticky material); the region distal to that (e.g., the region near the initial distal-facing inverting portion of the tractor) is lubricious.

Alternatively, the proximal end portion is lubricious (e.g., coated with a lubricious material) but the region distal to that (e.g., the region near the initial distal-facing inverting portion of the tractor) is uncoated or is tacky/sticky to help initially grab the clot.

[000198] For example, FIG. 40C shows an example of an apparatus including a sleeve 4035 or cover over the most proximal end of the tractor 4001. This sleeve may itself be lubricious on the outer-facing surface, and may protect or hold the tractor in position until it is drawn distally over the catheter, exposed, and inverted to grab/pull clot 4017. The proximal end of the tractor under the sleeve may be lubricious and/or non-lubricious (e.g., patterned) 4033. The region proximal to the inverting portion, and distal to the sleeve, 4037 may be lubricious or (preferably) non-lubricious and/or a pattern of non-lubricious and lubricious regions.

ELONGATE INVERSION SUPPORTS

[000199] In general, the elongate inversion supports described herein may be or may include catheters that are operated with the tractor and are configured so that the tractor may invert over the distal end opening (aperture) of the elongate inversion support. Any appropriate elongate inversion support may be used and may be configured as a catheter (or micro catheter). Since the tractor region is pulled against the catheter to invert it, the catheter may be configured to have high compression resistance while maintaining superior tip bending (e.g., flexible tip) which may allow it to reach distal vessel segments within the human vasculature.

[000200] Small bore catheters including those for use herein may have braid reinforced segments combined with coil reinforcement. A braid may be used on the proximal end of the catheter to provide column stiffness and medium shaft flexibility, and coils are typically used distally to enhance flexibility while sacrificing column strength. The apparatuses described herein may use a catheter having a slotted tube distal segment element that, when activated, can create a significant axial column compression through the entire catheter shaft. Typically, this column compression may result in some catheter foreshortening and catheter bending (e.g., cork screwing). Described herein are catheters that may reduce this foreshortening and corkscrewing by leveraging slotted tube elements into the catheter distal segment (e.g., the last 8cm or less).

[000201] FIGS. 26A illustrates bending of a typical small bore catheter distal tip. As seen in FIG. 21A, the catheter may bend around a small radius (as compared to the reference dime). The distal segment of this catheter may include a coil, and a low-durometer thin-walled polymer that is relatively soft, flexible and stretchy.

[000202] FIGS. 26B-26C illustrate, for comparison, a catheter comprising a keyed slotted tube extending along the entire length of the catheter. In this variation, the interlocking key segment 2601 of the design provides a axial stiffness when the structure sees compressive loads in the axial direction through the interlocking segments stacking or contacting a one or more point about its circumference. This structure still allows for adequate conformability around a tight radius allowing it to be push-able through a tortuous anatomy (ie neuro tortuous vessel). In order to increase bending flexibility and therefore the ability to make tighter turns, the keys may be shorter or longer and/or nested.

[000203] In general, the bending stiffness of the catheter is a function of the material, material composite structure, wall thickness, strut length, strut width, cell angle, strut shape,

and cell length. FIG. 27 shows an example of a catheter design formed as a slotted tube. The tube includes cut-out regions that provide flexibility while leaving column strength.

[000204] Another example of a catheter configured to have a high column strength and stiffness along its entire length is shown in FIGS. 28A-28B. In FIG. 28A, a hybrid laser-formed coil (spiral) has compaction-resistant features, along the entire continuous length of the catheter. The coil bending stiffness in this design is a function of the material, wall thickness, coil width, helix angle, hinge shape, hinge height, hinge location (e.g., linear axial or out of phase/helix), shape of coil surface and the catheter material stiffness.

[000205] The catheter configuration shown in FIGS. 29A-28B illustrate variations in which individual hoop/ring segments are linked by a polymer wall of the catheter only. The ring bending stiffness is a function of the material, wall thickness, ring width, hinge shape, hinge height, hinge location (linear axial or out of phase/helix), shape of ring surface and the catheter material stiffness.

[000206] Any of the apparatuses described herein may include a catheters having a hard distal tip (e.g., formed of a PTFE, PEEK, stainless steel, etc.) and may be radiused to enhance rolling. The tip opening may be radiused from a middle of catheter wall, without an outer radius. Any of these catheters may include a lubricious coating. Finally, any of these catheters may also be configured to permit aspiration (e.g., drawing suction) through them, which may be helpful.

[000207] FIGS. 42A-43D, described in greater detail below, including examples of elongate inversion supports that may be used in any of the apparatuses described.

[000208] For example, any of the apparatuses described herein may include or be configure for use with a vacuum. The vacuum may aid in initially gasping or grabbing the thrombus. The vacuum may be applied from the distal end of the apparatus and/or of an intermediate or outer catheter or sleeve that is used with the apparatuses (e.g., elongate inversion support and inverting tractor) described herein. Also described herein are apparatuses that are adapted for use with a vacuum, including for use with an intermediate or outer catheter through which the apparatus may be delivered to the clot. The apparatus may grab clot from within the outer catheter, or it may be extended distally out of the intermediate or outer catheter.

[000209] FIG. 41A shows an example of a configuration in which an outer/intermediate catheter or sleeve that is highly flexible may be maneuvered, for example with a guidewire, to a distal end of the device. Thus, the intermediate catheter may be maneuvered near, or adjacent to, the thrombus. As in any of these methods of use described herein, imaging (such as fluoroscopy, contrast imaging, etc.) may be used. Once in positioned, the guidewire may

be removed or left in place, and the apparatus including the elongate inversion support and inverting tractor may be extended within the intermediate catheter/sleeve. In FIG. 41A, the intermediate catheter 4104 is shown positioned within the vessel 4109 distally. As with any of the illustrations here, in the vessel may be highly tortuous and branching, although for convenience it is shown as straight in the figures. The apparatus 4100 is extended distally through the intermediate catheter, and extends out of the distal opening of the intermediate catheter to grab the clot 4111, as shown. The puller 4105 may thus be drawn proximally (to the left in the figure) to pull the tractor 4103 from over the catheter portion of the elongate inversion support 4113, so that it inverts and rolls into the lumen of the elongate inversion support, capturing and drawing the clot in with it. The clot may be compressed.

[000210] Thus, this configuration may be referred to as a vessel cleaner. In addition to the rolling of the tractor to grab and pull the clot, the clot may be pulled by a vacuum applied from one or both of the intermediate catheter 4121 and/or the elongate inversion support 4123. Vacuum may be applied, e.g., within the intermediate catheter, before the apparatus is positioned distally (or even within the intermediate catheter at all) or after it has been extended distally from the intermediate catheter. This configuration shown in FIG. 41A may introduce the tractor through outer catheter to the face of clot. As mentioned, the mechanical thrombectomy apparatus may be extended distally from the intermediate catheter either by pushing it out distally and/or by pulling back the intermediate catheter to deploy all or part of the tractor into vessel, as shown. If vacuum is applied through the catheter, the catheter forming the elongate inversion support may be jacketed or sealed to allow aspiration through this catheter.

[000211] Optionally pull vacuum through outer and/or inner and/or puller. As mentioned, thereafter the tractor may be pulled proximally relative to the the elongate inversion support to pull the clot. The intermediate catheter may then be advanced distally and/or the mechanical thrombectomy apparatus may be withdrawn proximally to remove the apparatus once the clot has been removed. Thereafter an angiogram may be taken to confirm that the clot has been removed.

[000212] Alternatively, in FIG. 41B, a clot may be removed using the intermediate catheter to draw a vacuum with the mechanical thrombectomy apparatus within the lumen (e.g., near the distal end, but not extending fully from the distal end) of the intermediate catheter. As described for FIG. 41A, in FIG. 41B the intermediate catheter may be inserted into the vessel (e.g., using a guidewire) so that the distal end is positioned near the clot. Suction may be

used to draw the clot into the intermediate catheter either before the mechanical thrombectomy device is inserted or after it has been inserted.

[000213] In FIG. 41B, the elongate inversion support 4113' is particularly well suited for use with a vacuum applied through the intermediate catheter 4104 surrounding the apparatus. For example, in FIG. 41B, the elongate inversion support 4113' include a distal catheter region 4125 that extends just a few cm from the distal end opening in which the clot is drawn. The elongate inversion support then tapers down to an elongate support, which may be formed by a wire, hypotube or skived region. This configuration may prevent the catheter from blocking the lumen of the intermediate catheter and and therefore increasing the resistance of the vacuum before it can reach the open distal end and apply suction to drawn the clot. Alternatively or additionally, the outer diameter of the catheter portion of the elongate inversion support may be sized to allow more of the vacuum to pass. For example, the apparatus may be sized such that there is at least about 0.002 inches or greater (e.g., 0.003, 0.004, 0.005, 0.006, etc., inches) between the outer diameter of the catheter and the inner diameter of the intermediate catheter ("outer catheter"). This may also permit unimpeded rolling of the tractor over the distal end opening of the elongate inversion support.

[000214] In operation, the method of removing clot such as shown in FIG. 41B may include pulling at least the tip of a clot into the intermediate catheter through the use of a vacuum 4121. Typically the clot may clog within the intermediate catheter; the mechanical thrombectomy apparatuses described herein may be used to remove the clot from within the intermediate catheter. For example, while maintaining vacuum, the mechanical thrombectomy apparatus may be inserted (or it may be preloaded in intermediate catheter as mentioned) and the tractor puller 4105 may be pulled to pull the clot out of the intermediate catheter and the vessel, compress and/or macerate it and pull it into the apparatus and therefore the intermediate catheter, where it can be withdrawn proximally, e.g., by removing the mechanical thrombectomy apparatus. As mentioned, an angiogram may be taken through intermediate catheter (e.g., leaving it in place in case the mechanical thrombectomy apparatus needs to be re-inserted and used to remove more clot) to confirm clot has been removed.

[000215] As mentioned, a full catheter such as shown in FIG. 41A may block or prevent the vacuum from reaching the distal end of the intermediate vessel. Therefore it may be beneficial to adapt the mechanical thrombectomy apparatus so that it can be used with vacuum within an intermediate catheter or sleeve, as shown in FIG. 41B. This may be achieved as mentioned above, by minimizing the larger-diameter catheter portion of the elongate inversion support forming the distal end opening over which the tractor inverts. In

FIG. 42A for example, the elongate inversion support 700 has a distal catheter portion 701 having a larger diameter than the more proximal region 703, and also includes a plurality of openings, holes, gaps, cut-out regions, slots, etc. 709 that may allow the flow of vacuum through the elongate inversion support more easily. The elongate inversion support shown also includes a distal end 707 into which a tractor 711 inverts, as shown in FIG. 42B. IN FIG. 42B, the elongate inversion support is shown transparent so that the puller 713 and tractor within the elongate inversion support is visible.

[000216] Similarly, in FIGS. 42B and 42C, the entire length of the elongate inversion support includes a plurality of cut-out regions 713 which may increase the ability to allow the flow of a vacuum or other fluid within the apparatus, but may still allow the elongate inversion support to provide column strength to resist collapsing up to at least 500 g of compressive longitudinal force applied by, e.g., pulling on the tractor. Similarly, the elongate inversion support of FIGS. 42E and 42F show a skived catheter that also includes openings 709 along its length. The puller and tractor 412 are shown within the elongate inversion support in FIG. 42F. FIGS. 42G and 42H illustrate an example in which rather than a skived portion of the catheter, the distal catheter region of the elongate inversion support is formed by a wire, bar, tube, 721 etc., that is attached to the catheter at the distal end. The catheter may also optionally include openings 709. The elongate inversion support of FIGS. 42I and 42J includes openings 709' along all or much of its length (particularly near the distal end region) as shown.

[000217] Finally, the variation of the elongate inversion support shown in FIG. 42K includes a minimal catheter portion 732 that is connected to a wire, bar, tube, hypotube, skived region, etc.

[000218] FIGS. 43A-43D illustrate the operation of a similar minimal elongate inversion support 800. In this example, the apparatus includes a distal aperture 743 bonded securely to a wire, bar, tube, hypotube, skived region, etc. 746 forming an elongate support. The elongate support may be hollow (e.g., may include a lumen for a guidewire) or solid. The elongate support may also include one or more additional support guides 750 as shown in FIG. 43B. These supports may help contain the puller and/or tractor within the elongate inversion support. Any of the elongate inversion supports described herein may include additional support guides. The elongate inversion support of FIG. 8B is shown with a tractor 711 and puller 712 in FIG. 43C. As mentioned, this variation may be particularly well suited for use with an intermediate (e.g., "outer") catheter, sleeve, or the like 809, as shown in FIG. 43D.

POWER DRIVEN TRACTORS

[000219] Also described herein are mechanical thrombectomy apparatuses in which the tractor is power driven. Any of the tractors described herein may also be driven by a motor, instead of or in addition to the manual driven tractor described. For example, a power-driven tractor may be shown in FIGS. 38A-38B and 39A-39C. In FIG. 38A the tractor is a continuous tractor. FIG. 38B illustrates the catheter and tractor region, without the motor shown in FIG. 38A. The tractor comprises a plurality of belts, chains, lengths, etc. that run longitudinally and may act like a conveyor to pull clot into the apparatus. The loops of material may therefore be run as a power-driven tractor. FIGS. 39A-39C illustrate the operation of the apparatus of FIGS. 38A-38B, shown grabbing a clot.

[000220] Any of the methods (including user interfaces) described herein may be implemented as software, hardware or firmware, and may be described as a non-transitory computer-readable storage medium storing a set of instructions capable of being executed by a processor (e.g., computer, tablet, smartphone, etc.), that when executed by the processor causes the processor to control perform any of the steps, including but not limited to: displaying, communicating with the user, analyzing, modifying parameters (including timing, frequency, intensity, etc.), determining, alerting, or the like.

EXPANDABLE DISTAL ENDS

[000221] Any of the mechanical thrombectomy apparatuses described herein may include an elongate inversion support having a distal end that is expandable from a smaller diameter aperture (e.g., distal end opening) to a larger-diameter aperture. This expansion may be performed by pulling the clot within the catheter. For example, FIGS. 44A-44C illustrates the operation of an example of an elongate inversion support configured as a catheter having an expandable distal end. In this variation the catheter distal end 4401 may include slots or slits 4403 formed or cut, e.g., by laser-cutting, in the distal end of the catheter of the elongate inversion support. The apparatus may be operated as described above, positioning near (e.g., against or adjacent to) a clot, and pulling proximally on the puller to draw the tractor 4405 into the catheter, as shown in FIG. 44B. Although the apparatuses described herein may generally compress a clot greatly, compression may be made easier and/or more efficient by providing a more gradual decrease in radial diameter. As shown in FIG. 44B, when the tractor is rolled over the distal end opening and inverted, the clot may be drawn in along with the tractor. As the large clot 4413 is brought into the distal end opening, the distal end

opening may expand and open along the slots or slits 4403, as shown in FIG. 44C, so that the distal end opening flares out. In some variations an elastic sleeve, gasket, ring or cover (not shown in FIG. 44A-44C) may be included at least partially covering the distal end to prevent the edge from catching the tractor. For example, an elastic or stretchable layer may cover the cut distal end so that the distal end may be opened to form an outward flare. In FIG. 44C the outward-flared distal end is shown forming a funnel-shape into which the clot may be pulled. This funnel-shaped opening may help compress the clot so that it may be drawn into the mechanical thrombectomy apparatus.

[000222] In some variations the elongate inversion support may be configured to have, or to assume, a funnel-shape at the distal-facing end. The distal-facing end may always have a funnel-shaped mouth at the distal end opening, or the distal end opening may be configured to assume a funnel shape, as shown in FIGS. 44A-44C. In some variations the distal end of the elongate inversion support is configured to be elastic in a radial direction, but maintain stiffness along the proximal-to-distal axis (in compressive load). For example, the distal end of the elongate inversion support may be configured with strands or rods extending in the proximal-to-distal axis that have a high compressive load strength, but which may separate from each other to enlarge the distal end opening; for example they may be connected by rings in which more distal rings are more elastic/stretchable than more proximal rings.

[000223] When a feature or element is herein referred to as being "on" another feature or element, it can be directly on the other feature or element or intervening features and/or elements may also be present. In contrast, when a feature or element is referred to as being "directly on" another feature or element, there are no intervening features or elements present. It will also be understood that, when a feature or element is referred to as being "connected", "attached" or "coupled" to another feature or element, it can be directly connected, attached or coupled to the other feature or element or intervening features or elements may be present. In contrast, when a feature or element is referred to as being "directly connected", "directly attached" or "directly coupled" to another feature or element, there are no intervening features or elements present. Although described or shown with respect to one embodiment, the features and elements so described or shown can apply to other embodiments. It will also be appreciated by those of skill in the art that references to a structure or feature that is disposed "adjacent" another feature may have portions that overlap or underlie the adjacent feature.

[000224] Terminology used herein is for the purpose of describing particular embodiments only and is not intended to be limiting of the invention. For example, as used herein, the singular forms "a", "an" and "the" are intended to include the plural forms as well, unless the

context clearly indicates otherwise. It will be further understood that the terms "comprises" and/or "comprising," when used in this specification, specify the presence of stated features, steps, operations, elements, and/or components, but do not preclude the presence or addition of one or more other features, steps, operations, elements, components, and/or groups thereof. As used herein, the term "and/or" includes any and all combinations of one or more of the associated listed items and may be abbreviated as "/".

[000225] Spatially relative terms, such as "under", "below", "lower", "over", "upper" and the like, may be used herein for ease of description to describe one element or feature's relationship to another element(s) or feature(s) as illustrated in the figures. It will be understood that the spatially relative terms are intended to encompass different orientations of the device in use or operation in addition to the orientation depicted in the figures. For example, if a device in the figures is inverted, elements described as "under" or "beneath" other elements or features would then be oriented "over" the other elements or features. Thus, the exemplary term "under" can encompass both an orientation of over and under. The device may be otherwise oriented (rotated 90 degrees or at other orientations) and the spatially relative descriptors used herein interpreted accordingly. Similarly, the terms "upwardly", "downwardly", "vertical", "horizontal" and the like are used herein for the purpose of explanation only unless specifically indicated otherwise.

[000226] Although the terms "first" and "second" may be used herein to describe various features/elements (including steps), these features/elements should not be limited by these terms, unless the context indicates otherwise. These terms may be used to distinguish one feature/element from another feature/element. Thus, a first feature/element discussed below could be termed a second feature/element, and similarly, a second feature/element discussed below could be termed a first feature/element without departing from the teachings of the present invention.

[000227] Throughout this specification and the claims which follow, unless the context requires otherwise, the word "comprise", and variations such as "comprises" and "comprising" means various components can be co-jointly employed in the methods and articles (e.g., compositions and apparatuses including device and methods). For example, the term "comprising" will be understood to imply the inclusion of any stated elements or steps but not the exclusion of any other elements or steps.

[000228] In general, any of the apparatuses and methods described herein should be understood to be inclusive, but all or a sub-set of the components and/or steps may

alternatively be exclusive, and may be expressed as “consisting of” or alternatively “consisting essentially of” the various components, steps, sub-components or sub-steps.

[000229] As used herein in the specification and claims, including as used in the examples and unless otherwise expressly specified, all numbers may be read as if prefaced by the word “about” or “approximately,” even if the term does not expressly appear. The phrase “about” or “approximately” may be used when describing magnitude and/or position to indicate that the value and/or position described is within a reasonable expected range of values and/or positions. For example, a numeric value may have a value that is +/- 0.1% of the stated value (or range of values), +/- 1% of the stated value (or range of values), +/- 2% of the stated value (or range of values), +/- 5% of the stated value (or range of values), +/- 10% of the stated value (or range of values), etc. Any numerical values given herein should also be understood to include about or approximately that value, unless the context indicates otherwise. For example, if the value “10” is disclosed, then “about 10” is also disclosed. Any numerical range recited herein is intended to include all sub-ranges subsumed therein. It is also understood that when a value is disclosed that “less than or equal to” the value, “greater than or equal to the value” and possible ranges between values are also disclosed, as appropriately understood by the skilled artisan. For example, if the value “X” is disclosed the “less than or equal to X” as well as “greater than or equal to X” (e.g., where X is a numerical value) is also disclosed. It is also understood that the throughout the application, data is provided in a number of different formats, and that this data, represents endpoints and starting points, and ranges for any combination of the data points. For example, if a particular data point “10” and a particular data point “15” are disclosed, it is understood that greater than, greater than or equal to, less than, less than or equal to, and equal to 10 and 15 are considered disclosed as well as between 10 and 15. It is also understood that each unit between two particular units are also disclosed. For example, if 10 and 15 are disclosed, then 11, 12, 13, and 14 are also disclosed.

[000230] Although various illustrative embodiments are described above, any of a number of changes may be made to various embodiments without departing from the scope of the invention as described by the claims. For example, the order in which various described method steps are performed may often be changed in alternative embodiments, and in other alternative embodiments one or more method steps may be skipped altogether. Optional features of various device and system embodiments may be included in some embodiments and not in others. Therefore, the foregoing description is provided primarily for exemplary

purposes and should not be interpreted to limit the scope of the invention as it is set forth in the claims.

[000231] The examples and illustrations included herein show, by way of illustration and not of limitation, specific embodiments in which the subject matter may be practiced. As mentioned, other embodiments may be utilized and derived there from, such that structural and logical substitutions and changes may be made without departing from the scope of this disclosure. Such embodiments of the inventive subject matter may be referred to herein individually or collectively by the term “invention” merely for convenience and without intending to voluntarily limit the scope of this application to any single invention or inventive concept, if more than one is, in fact, disclosed. Thus, although specific embodiments have been illustrated and described herein, any arrangement calculated to achieve the same purpose may be substituted for the specific embodiments shown. This disclosure is intended to cover any and all adaptations or variations of various embodiments. Combinations of the above embodiments, and other embodiments not specifically described herein, will be apparent to those of skill in the art upon reviewing the above description.

CLAIMS

What is claimed is:

1. A mechanical thrombectomy apparatus for removing a clot from a vessel, the apparatus comprising:
 - an elongate inversion support comprising a catheter having a distal end and a distal end opening;
 - a tractor comprising a flexible tube that extends distally in an un-inverted configuration within the catheter, inverts over the distal end opening of the catheter and extends proximally in an inverted configuration along the distal end of the catheter, wherein the tractor comprises a tubular wall, further wherein the tractor is configured to invert by rolling over the distal end opening of the catheter when a first end of the tractor is pulled proximally within the catheter; and
 - a plurality of projections that extend from a portion of the tractor that is inverted over the distal end opening of the catheter as the tractor rolls over the distal end opening of the catheter, wherein the plurality of projections do not extend from the tractor as it extends proximally in the inverted configuration along the distal end of the catheter.
2. The apparatus of claim 1, wherein the tractor is sufficiently soft such that without support from the catheter, it collapses radially under an axial compression of less than 200g of force when inverting.
3. The apparatus of claim 1, wherein the tractor is biased to expand to greater than the outer diameter of the catheter in the inverted configuration and is biased to expand to greater than the inner diameter of the catheter in the un-inverted configuration.
4. The apparatus of claim 1, further comprising a guidewire lumen extending through the elongate inversion support and the tractor and configured to pass a guidewire.
5. The apparatus of claim 1, wherein the proximal end of the elongate inversion support comprises a skived proximal end of the catheter.
6. The apparatus of claim 1, wherein the catheter comprises a plurality of lateral openings along the distal end.

7. The apparatus of claim 1, wherein the tractor comprises a plurality of woven ribbons forming the tubular wall, further wherein the plurality of projections comprises edges of the ribbons.
8. The apparatus of claim 7, wherein the ribbons have a rectangular cross-section.
9. The apparatus of claim 7, wherein the ribbons are arranged in a woven helical pattern.
10. The apparatus of claim 7, wherein the ribbons are formed of a metallic or polymeric material.
11. The apparatus of claim 1, wherein the tractor comprises a knitted material.
12. The apparatus of claim 1, wherein the tubular wall of the tractor comprises steel, polyester, nylon, expanded Polytetrafluoroethylene (ePTFE), Nitinol, or a fabric.
13. The apparatus of claim 1, wherein the projections are cut from the tubular wall.
14. The apparatus of claim 1, wherein each of the plurality of projections have a width in a direction transverse to a long axis of the tractor and a length in a direction along the long axis of the tractor, further wherein the ratio of length to width is between 10 and 100.
15. The apparatus of claim 1, wherein each of the plurality of projections has one or more of: a paddle shape, a scoop shape, and spike shape.
16. The apparatus of claim 1, wherein the plurality of projections comprise sharp ends.
17. The apparatus of claim 1, wherein the material hardness of catheter decreases over the distal end of the catheter until the distal end opening, wherein the distal end opening has a material hardness that is greater than a material hardness of a region immediately proximal to the distal end, further wherein the distal end opening has a rounded lip profile.
18. The apparatus of claim 1, wherein there is a non-uniform density of projections along the length of the tractor.

19. The apparatus of claim 1, wherein the projections are oriented relative to the tractor so that the projections extend in the distal direction when the tractor is on the outer diameter of the catheter.
20. The apparatus of claim 1, wherein the projections further comprising a plurality of slots or openings through the tubular wall of the tractor.
21. The apparatus of claim 1, wherein the tractor comprises one or more coatings from the group of: a lubricious coating, a metal coating, a heparin coating, an adhesive coating, and a drug coating.
22. The apparatus of claim 1, wherein the tubular wall of the tractor has a pore pattern having a longitudinal separation between pores of less than about 0.005 inches.
23. The apparatus of claim 1, further comprising a releasable attachment between the tractor and an outer surface of the catheter, wherein the releasable attachment is configured to release when the tractor is pulled with a force that is greater than a predetermined force threshold.
24. The apparatus of claim 19, wherein the releasable force threshold is 0.01 N.
25. The apparatus of claim 1, further comprising a sleeve extending over the catheter and tractor.
26. The apparatus of claim 1, further comprising an elongate puller extending proximally from the first end of the tractor, wherein the puller is coupled to the first end of the tractor.
27. The apparatus of claim 26, wherein the elongate puller comprises a hypotube having an inner lumen that is continuous with a lumen through the tractor.
28. The apparatus of claim 1, wherein the tractor a lumen within the catheter having an inner diameter that is 80 % or greater than an inner diameter of the catheter, so that the tractor does not collapse closed within the catheter.
29. The apparatus of claim 1, wherein the tractor is 3 cm to 50 cm long.

30. The apparatus of claim 1, wherein the apparatus is configured so that the tractor is retractable into the catheter by applying 300 g of force or less to a distal end of the tractor.
31. The apparatus of claim 1, wherein the proximal end of the tractor is loose so that it may be pulled along an outer diameter of the catheter as the tractor is pulled proximally within the catheter.
32. A mechanical thrombectomy apparatus for removing a clot from a vessel, the apparatus comprising:
- an elongate inversion support comprising a catheter having a distal end and a distal end opening;
 - a tractor comprising a flexible tube that extends distally in an un-inverted configuration within the catheter, inverts over the distal end opening of the catheter and extends proximally in an inverted configuration along the distal end of the catheter, the flexible tube comprising a plurality of ribbons having a square or rectangular cross-section woven together, wherein the tractor is configured to invert by rolling over the distal end opening of the catheter when a first end of the tractor is pulled proximally within the catheter, wherein a plurality of edges of the plurality of ribbons extend from a portion of the tractor that is inverted over the distal end opening of the catheter as the tractor rolls over the distal end opening of the catheter, further wherein the projecting edges are not extended from the tractor in a portion of the tractor that extends over the distal end of the catheter; and
 - a guidewire lumen extending through the catheter and the tractor and configured to pass a guidewire.
33. A mechanical thrombectomy apparatus for removing a clot from a vessel, the apparatus comprising:
- an elongate inversion support comprising a catheter having a distal end and a distal end opening; and
 - a tractor comprising a flexible tube that extends distally in an un-inverted configuration within the catheter, inverts over the distal end opening of the catheter and extends proximally in an inverted configuration along the distal end of the catheter, the tractor comprising a tubular wall, wherein the tractor

is configured to invert by rolling over the distal end opening of the catheter when a first end of the tractor is pulled proximally within the catheter, further wherein the tractor comprises a plurality of projections formed from the tube wall that extend from a portion of the tractor that is inverted over the distal end opening of the catheter as the tractor rolls over the distal end opening of the catheter, wherein the plurality of projections are not extended from the tractor in a portion of the tractor that extends proximally in the inverted configuration along the distal end of the catheter; wherein the tractor is sufficiently soft such that without support from the catheter, the tractor collapses radially under an axial compression of less than 200g of force when inverting.

34. A method of removing a clot using a mechanical thrombectomy apparatus, the method comprising:

positioning a distal end of the mechanical thrombectomy apparatus adjacent to a clot within a vessel, wherein the mechanical thrombectomy apparatus includes a tractor region that extends along a distal region of a catheter and inverts over a distal end of the catheter so that a first end of the tractor extends proximally within the catheter;

pulling the first end of the tractor proximally within the catheter to roll the tractor over the distal end of the catheter so that the tractor inverts over the distal end of the catheter and extends a plurality of projections from the tractor;

grabbing the clot with the plurality of projections; and

drawing the clot into the catheter.

35. A method of removing a clot using a mechanical thrombectomy apparatus, the method comprising:

positioning a distal end of the mechanical thrombectomy apparatus adjacent to a clot within a vessel, wherein the mechanical thrombectomy apparatus includes a soft tractor region that extends along a distal region of a catheter and inverts over a distal end of the catheter so that a first end of the tractor extends proximally within the catheter, wherein the tractor is sufficiently soft such that without support from the catheter, the tractor collapses

- radially under an axial compression of less than 200g of force when inverting;
- pulling the first end of the tractor proximally within the catheter to roll the tractor over the distal end of the catheter so that the tractor inverts over the distal end of the catheter and extends a plurality of projections from the tractor;
- grabbing the clot with the plurality of projections; and
- drawing the clot into the catheter.
36. The method of claim 34 or 35, further comprising macerating the clot with the plurality of projections.
37. The method of claim 34 or 35, wherein the tractor comprises a plurality of ribbons having a square or rectangular cross-section, further wherein pulling the distal end of the tractor proximally within the catheter to roll the tractor over the distal end of the catheter comprises extending a plurality of edges of the ribbons from an inverting portion of the tractor as the tractor is rolled over the distal end of the catheter.
38. The method of claim 34 or 35, wherein the tractor comprises a plurality of cut-out regions formed in the tractor, wherein pulling the first end of the tractor proximally within the catheter to roll the tractor over the distal end of the catheter extends the cut-out regions from an inverting portion of the tractor as the tractor is rolled over the distal end of the catheter.
39. The method of claim 34 or 35, further comprising sliding a loose second end of the tractor over the catheter as the first end of the tractor is pulled proximally.
40. The method of claim 34 or 35, wherein positioning the distal end of the mechanical thrombectomy apparatus comprises sliding the mechanical thrombectomy apparatus over a guidewire.
41. The method of claim 34 or 35, further comprising releasing a releasable attachment between the tractor and an outer surface of the catheter.
42. The method of claim 34 or 35, wherein pulling the first end of the tractor proximally comprises maintaining an inner diameter of the tractor within the catheter at greater

than 60 % of an inner diameter of the catheter to prevent the tractor from locking over the distal end of the catheter.

43. A mechanical thrombectomy apparatus for removing a clot from a vessel, the apparatus comprising:
- an elongate inversion support comprising a catheter having a distal end and a distal end opening;
 - a tractor comprising a flexible tube extending longitudinally within the catheter and doubling back over the distal end of the catheter to invert and extend over the distal end of the catheter, wherein the flexible tube comprises longitudinally alternating regions of higher and lower stiffness, wherein the regions of higher stiffness have a stiffness that is greater than the regions of lower stiffness; and
 - a puller coupled to a first end of the tractor and configured to pull the tractor proximally to invert the tractor over the distal end opening.
44. A mechanical thrombectomy apparatus for removing a clot from a vessel, the apparatus comprising:
- an elongate inversion support comprising a catheter having a distal end and a distal end opening;
 - a tractor comprising a flexible tube extending longitudinally within the catheter, doubling back over the distal end of the catheter, and extending over the distal end of the catheter, wherein the flexible tube comprises longitudinally alternating regions of higher and lower stiffness, wherein the regions of higher stiffness have a stiffness that is greater than the regions of lower stiffness, further wherein a diameter of a distal-facing doubled-back region of the tractor oscillates as the tractor is pulled proximally within the catheter to invert the tractor over the distal end of the catheter;
 - a puller coupled to a first end of the tractor and configured to pull the tractor proximally to invert the tractor over the distal end opening.
45. A mechanical thrombectomy apparatus for removing a clot from a vessel, the apparatus comprising:

an elongate inversion support comprising a catheter having a distal end and a distal end opening having a radius and a catheter wall thickness at the distal end opening;

a tractor comprising a flexible tube extending longitudinally within the catheter and doubling back over the distal end of the catheter to extend over the distal end of the catheter, wherein the flexible tube comprises longitudinally alternating regions of higher and lower stiffness helically arranged around the flexible tube, wherein the regions of higher stiffness have a first length and a stiffness that is greater than the regions of lower stiffness, wherein the first length is between 1.1 times the catheter wall thickness at the distal end opening and 1.1 times the radius of the catheter; and

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

46. The apparatus of claim 43 or 44, wherein the regions of higher stiffness have a longitudinal length along the flexible tube that is 1.1 times the radius of the catheter or less.
47. The apparatus of claim 43 or 44, wherein the regions of higher and lower stiffness are helically arranged around the flexible tube.
48. The apparatus of claim 43 or 45, wherein a diameter of the distal-facing end of the tractor oscillates as the tractor is pulled proximally within the catheter to invert the tractor over the distal end of the catheter.
49. The apparatus of claim 43, 44 or 45, wherein the tractor comprises a knitted material.
50. The apparatus of claim 43, 44 or 45, wherein the tractor comprises a knitted material comprising one or more of: steel, polyester, nylon, expanded Polytetrafluoroethylene (ePTFE), and Nitinol.
51. The apparatus of claim 43, 44 or 45, wherein the tractor comprises a sheet of one or more of: steel, polyester, nylon, expanded Polytetrafluoroethylene (ePTFE), Nitinol, or a fabric.
52. The apparatus of claim 51, wherein the sheet comprises a plurality of cut-out regions modifying the stiffness.

53. The apparatus of claim 43, 44 or 45, wherein the tractor comprises one or more coatings from the group of: a lubricious coating, a metal coating, a heparin coating, an adhesive coating, and a drug coating.
54. The apparatus of claim 43, 44 or 45, wherein the tractor has at least one porous section having a pore pattern having a longitudinal separation between pores of less than about 0.005 inches in width.
55. The apparatus of claim 43, 44 or 45, further comprising a releasable attachment between the tractor and an outer surface of the catheter, configured to release when the tractor is pulled with a force that is greater than a predetermined force threshold.
56. The apparatus of claim 55, wherein the releasable force threshold is 0.01 N.
57. The apparatus of claim 43, 44 or 45, further comprising an outer catheter or sleeve extending over the catheter and flexible tube.
58. The apparatus of claim 44 or 45, further wherein the puller comprises a hypotube having an inner lumen that is continuous with a guidewire lumen through the flexible tube.
59. The apparatus of claim 43, 44 or 45, wherein an inner diameter of the portion of the tractor within the catheter is greater than 80 % of an inner diameter of the catheter so that the tractor does not collapse closed within the catheter.
60. The apparatus of claim 43, 44 or 45, wherein the tractor is 3 to 50 cm long.
61. The apparatus of claim 43, 44 or 45, wherein the apparatus is configured so that the tractor may be retracted into the catheter by applying less than 300 grams of force to a distal end of the flexible tube.
62. A mechanical thrombectomy apparatus for removing a clot from a vessel without jamming, the apparatus comprising:
- an elongate inversion support comprising a catheter having a distal end and a distal end opening;
 - a tractor comprising a flexible tube that extends distally in an un-inverted configuration within the catheter, inverts over the distal end opening of the

- catheter and extends proximally in an inverted configuration along the distal end of the catheter, wherein the tractor comprises a tubular wall, further wherein the tractor is configured to invert by rolling over the distal end opening of the catheter when a first end of the tractor is pulled proximally within the catheter,
- wherein the tractor is biased to expand to have an inner diameter that is greater than the outer diameter of the catheter in the inverted configuration and is biased to expand to have an inner diameter that is greater than the inner diameter of the catheter in the un-inverted configuration; and
- an elongate puller coupled to the first end of the tractor.
63. A mechanical thrombectomy apparatus for removing a clot from a vessel without jamming, the apparatus comprising:
- an elongate inversion support comprising a catheter having a distal end and a distal end opening;
 - a tractor comprising a flexible tube that extends distally in an un-inverted configuration within the catheter, inverts over the distal end opening of the catheter and extends proximally in an inverted configuration along the distal end of the catheter, wherein the tractor comprises a tubular wall, further wherein the tractor is configured to invert by rolling over the distal end opening of the catheter when a first end of the tractor is pulled proximally within the catheter,
 - wherein the tractor is biased to expand to greater than the outer diameter of the catheter in the inverted configuration and is biased to expand to greater than the inner diameter of the catheter in the un-inverted configuration;
 - an elongate puller coupled to a first end of the tractor and configured to pull the tractor proximally to invert the tractor over the distal end opening; and
 - a guidewire lumen extending through the elongate inversion support, puller, and tractor that is configured to pass a guidewire.
64. The apparatus of claim 62 or 63, wherein the tractor comprises a woven tube.
65. The apparatus of claim 62 or 63, wherein the tractor comprises a braided tube.
66. The apparatus of claim 62 or 63, wherein the tractor comprises a knitted material.

67. The apparatus of claim 62 or 63, further comprising an outer catheter within which the elongate inversion support extends distally.
68. The apparatus of claim 62 or 63, further comprising outer catheter within which the elongate inversion support extends distally and a vacuum source coupled to a proximal end of the outer catheter.
69. The apparatus of claim 62 or 63, further comprising outer catheter within which the elongate inversion support extends distally, and a vacuum source coupled to a proximal end of the outer catheter, wherein there is at least about 0.002 inches or greater between the outer diameter of the catheter and the inner diameter of the outer catheter.
70. The apparatus of claim 62 or 63, wherein the tractor is sufficiently soft such that without support from the catheter, it collapses radially under an axial compression of less than 200g of force when inverting.
71. The apparatus of claim 62 or 63, wherein the elongate inversion support is configured to withstand buckling of an axial compression of greater than 500 g of force.
72. The apparatus of claim 62 or 63, wherein the elongate inversion support is configured to withstand buckling of an axial compression of greater than 1500 g of force.
73. The apparatus of claim 62 or 63, wherein the tractor comprises one or more coatings from the group of: a lubricious coating, a metal coating, a heparin coating, an adhesive coating, and a drug coating.

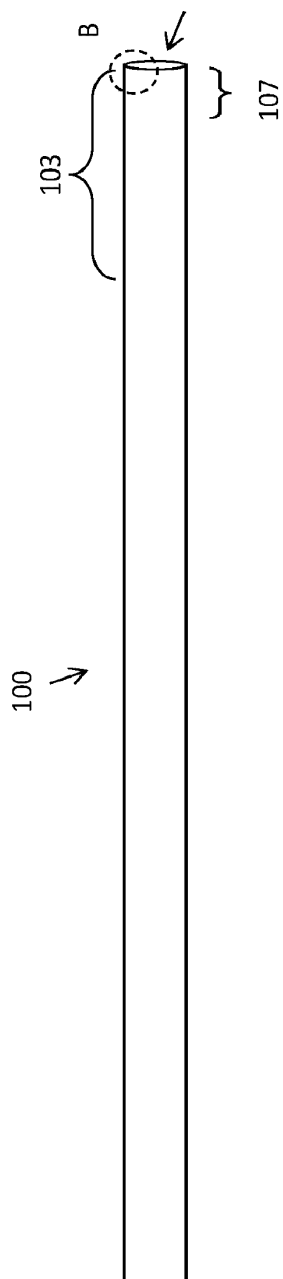


FIG. 1A

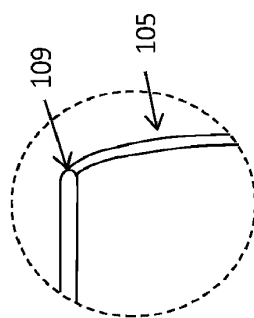


FIG. 1B

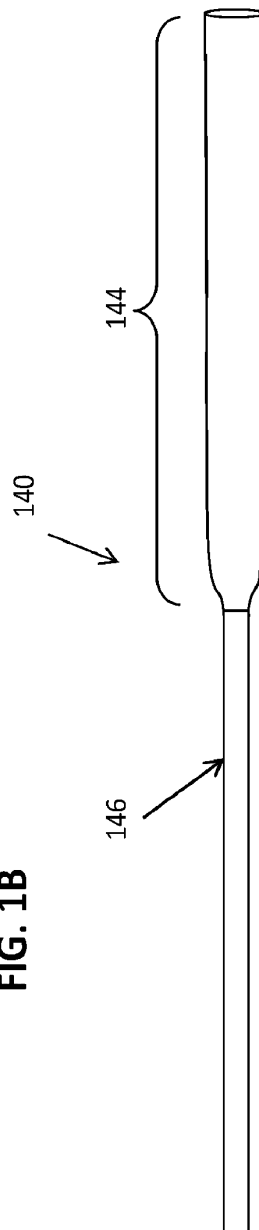


FIG. 1C

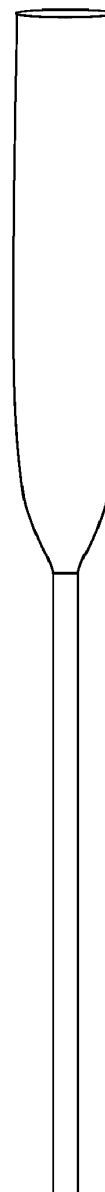


FIG. 1D

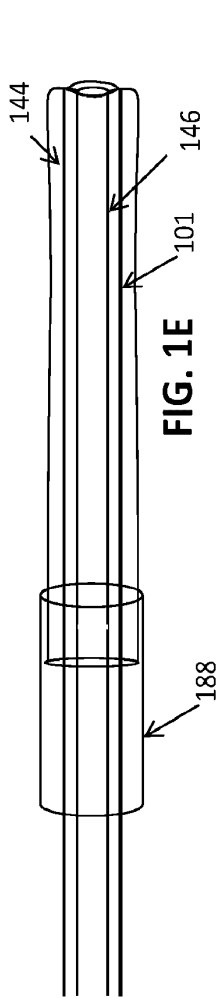


FIG. 1E

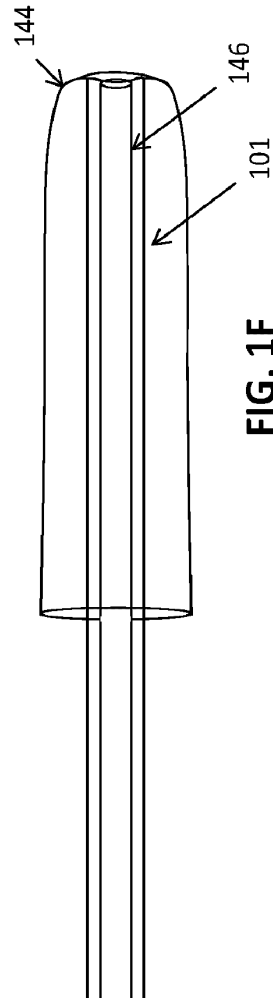


FIG. 1F

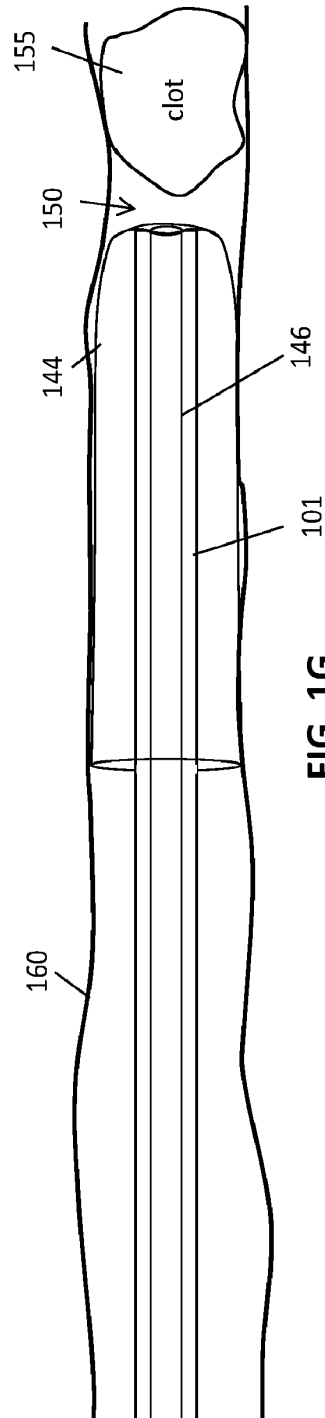


FIG. 1G

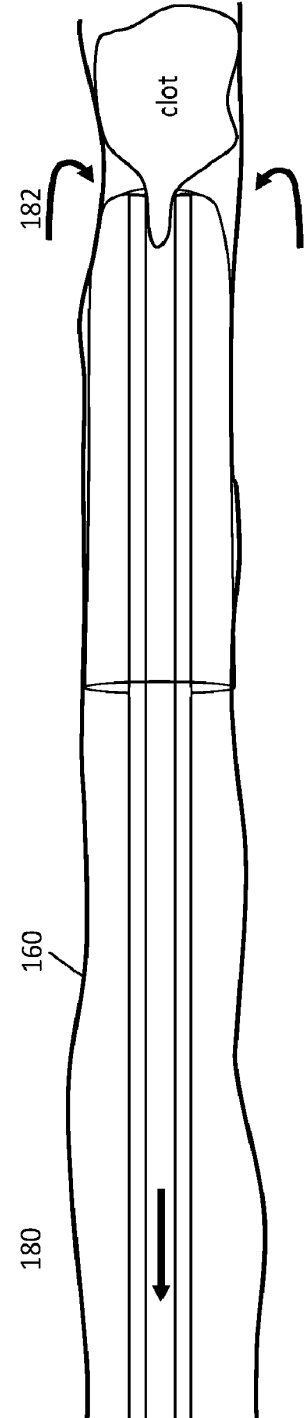


FIG. 1H

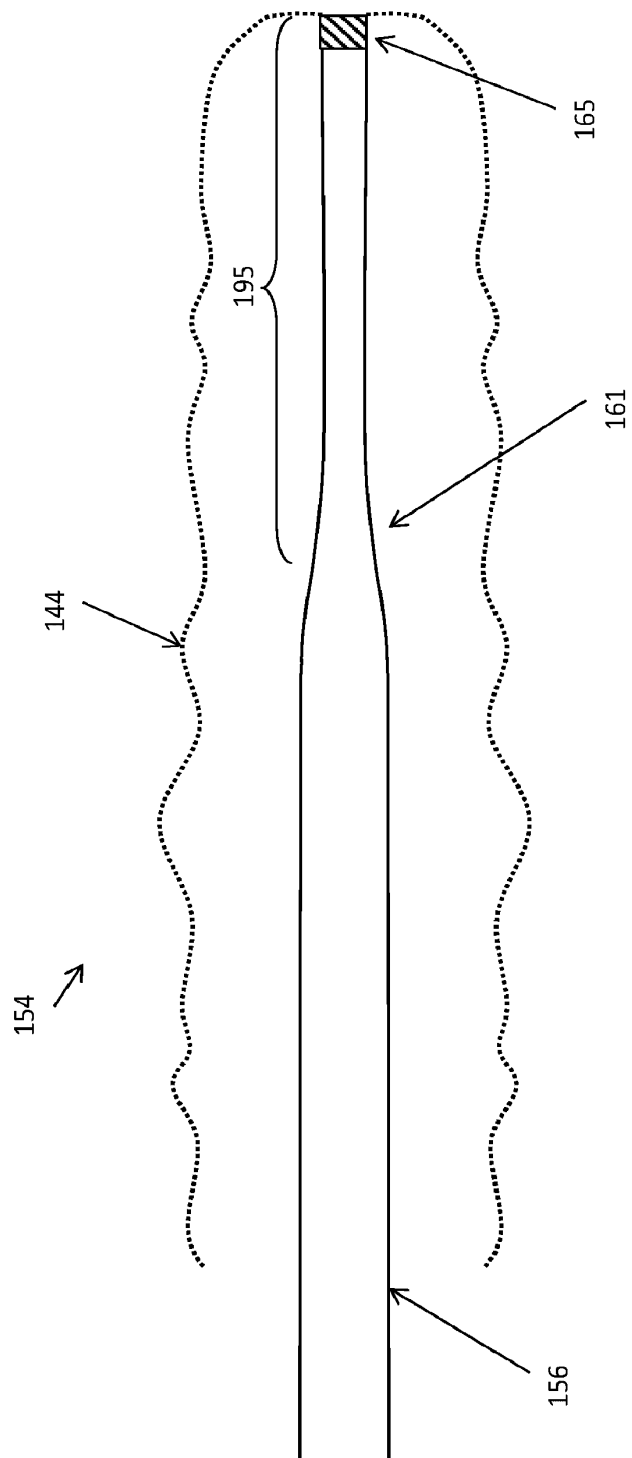
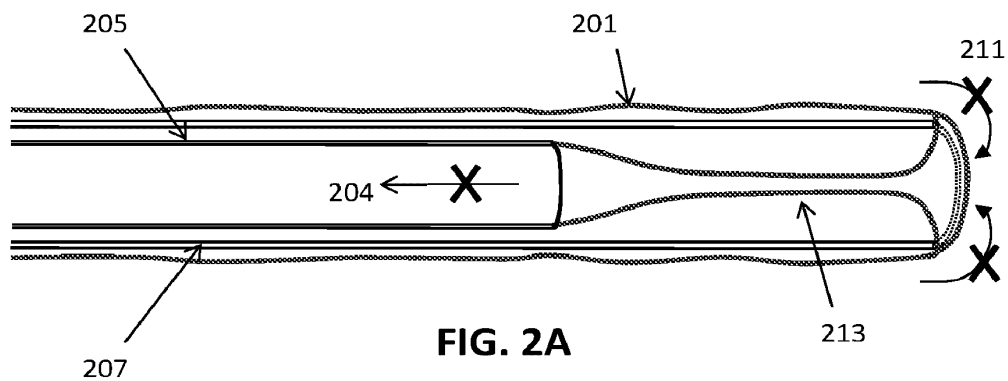
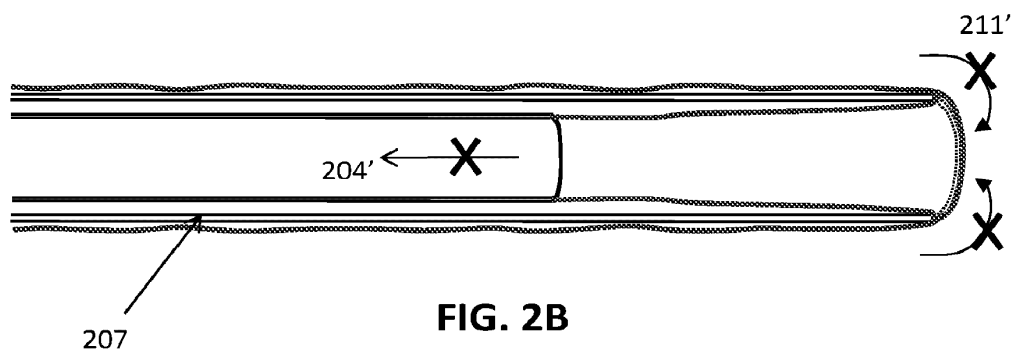
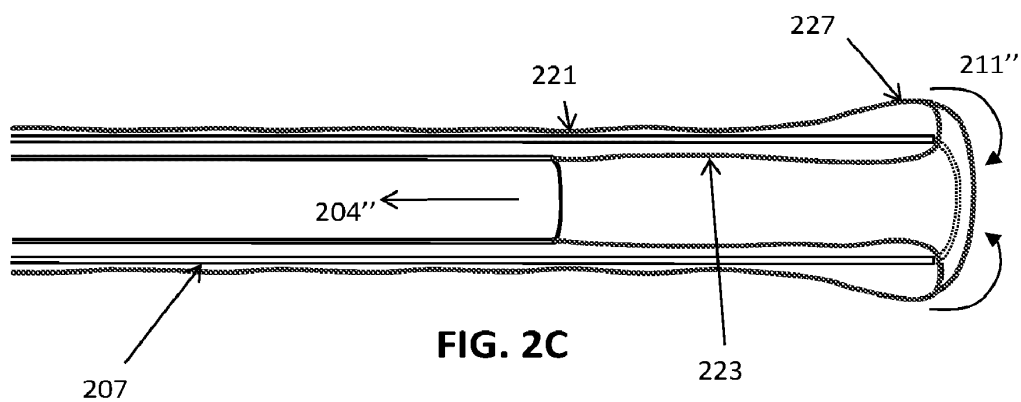


FIG. 1I



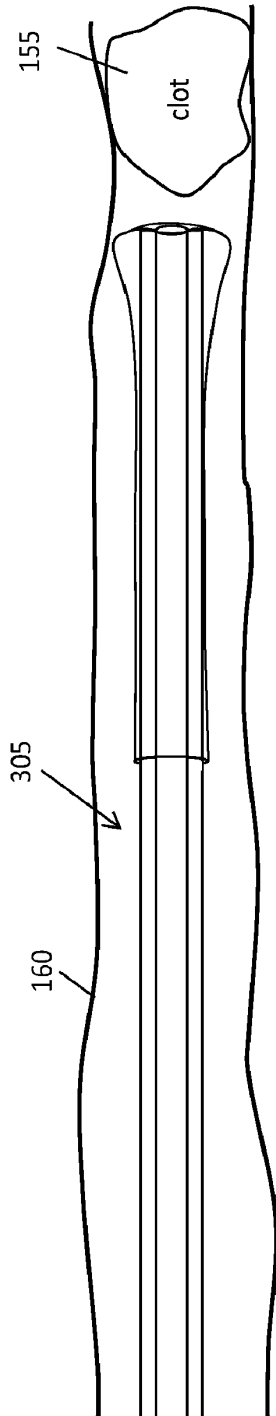


FIG. 3A

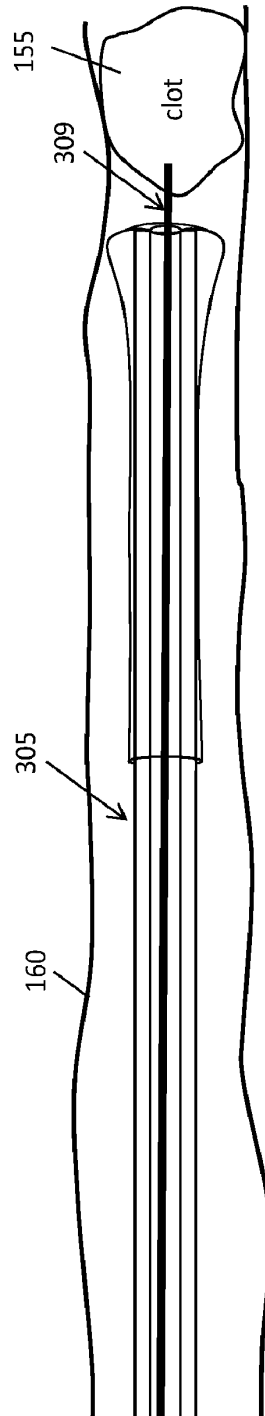


FIG. 3B

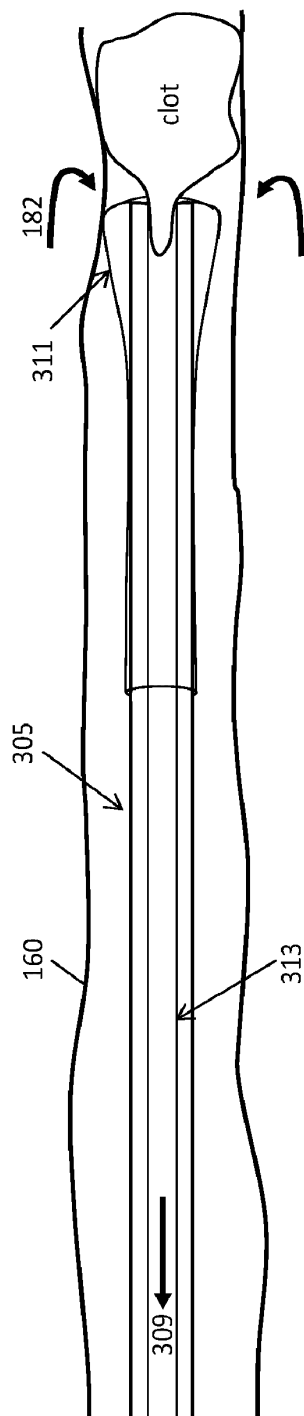


FIG. 3C

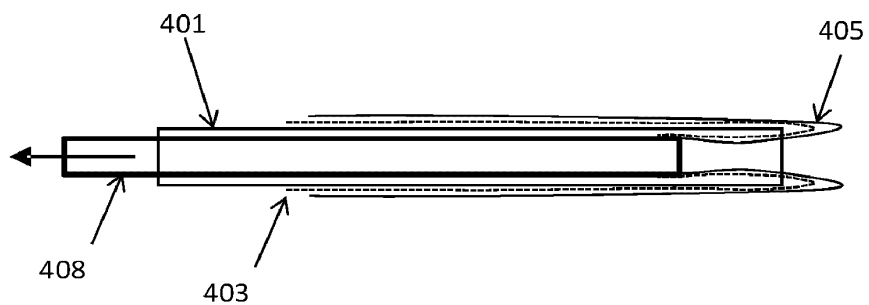


FIG. 4A

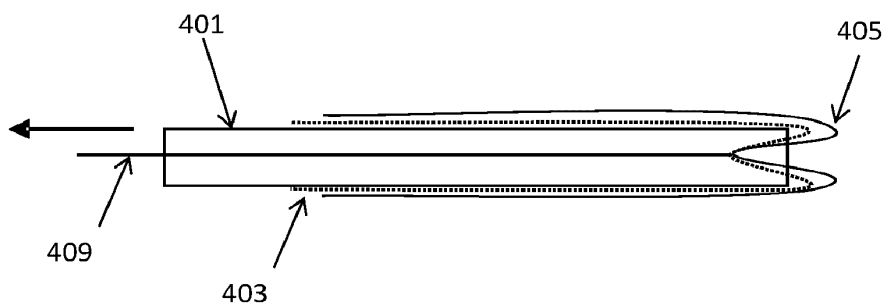


FIG. 4B

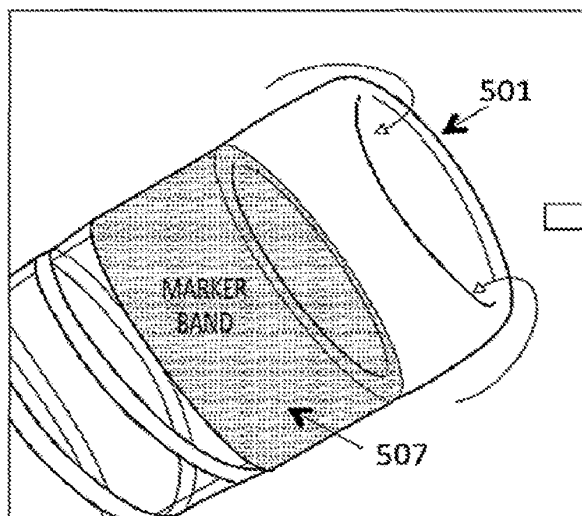


FIG. 5A

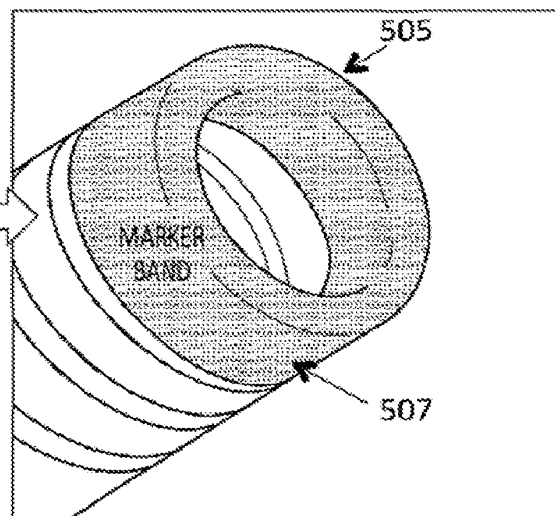


FIG. 5B

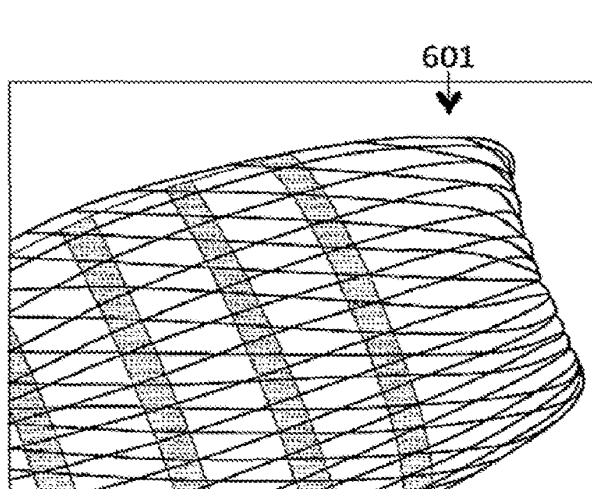


FIG. 6A

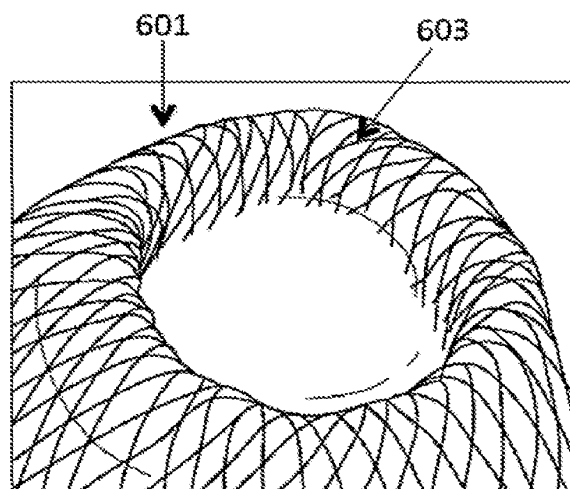
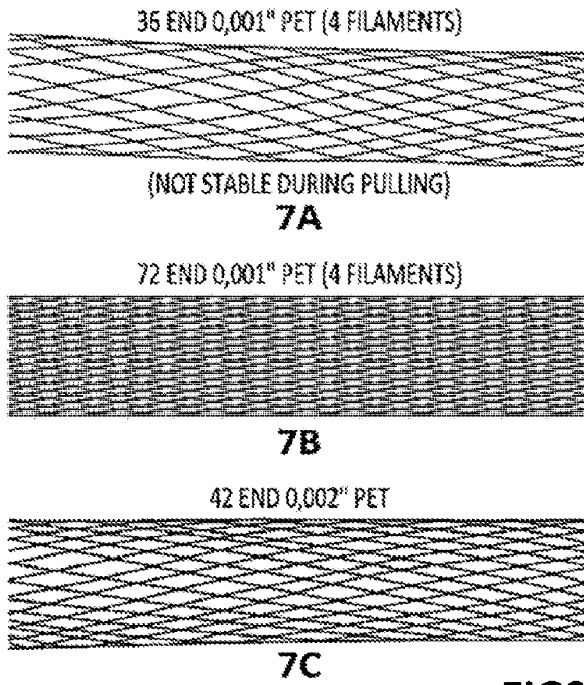
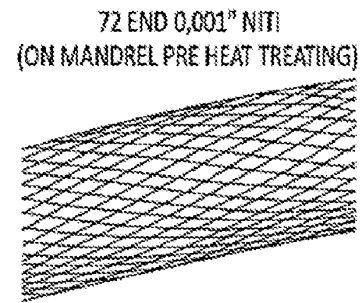
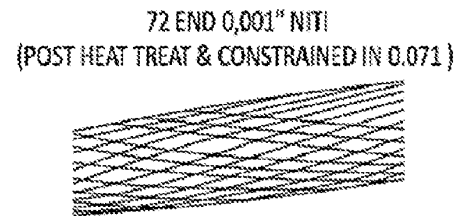


FIG. 6B



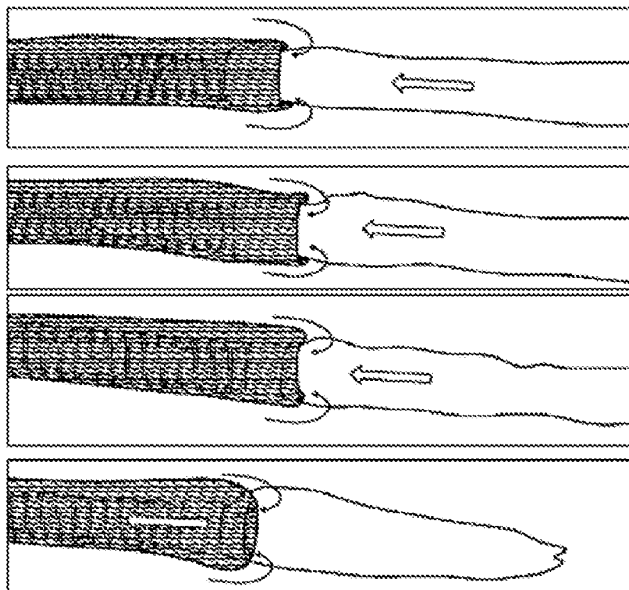
7D



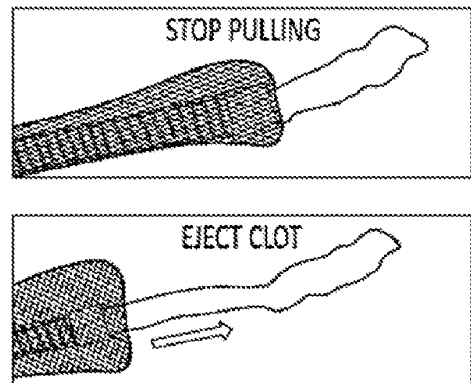
7E

FIGS. 7A-7E

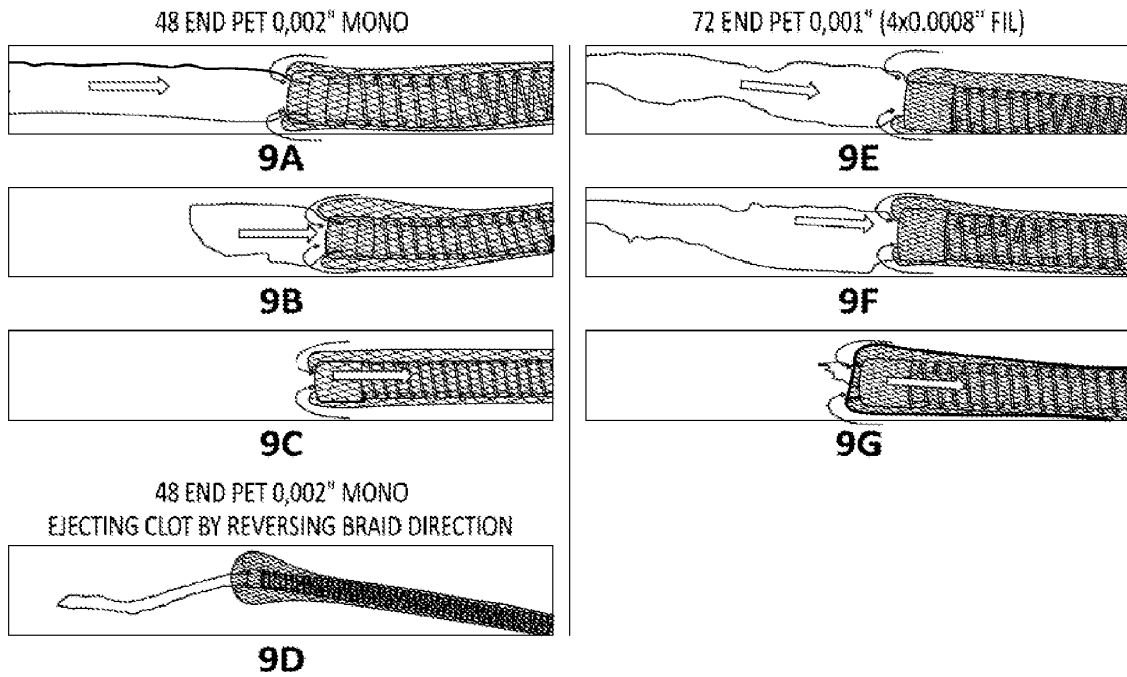
PULLING CLOT IN: VESSEL ID ~ SAME AS CATHETER TIP



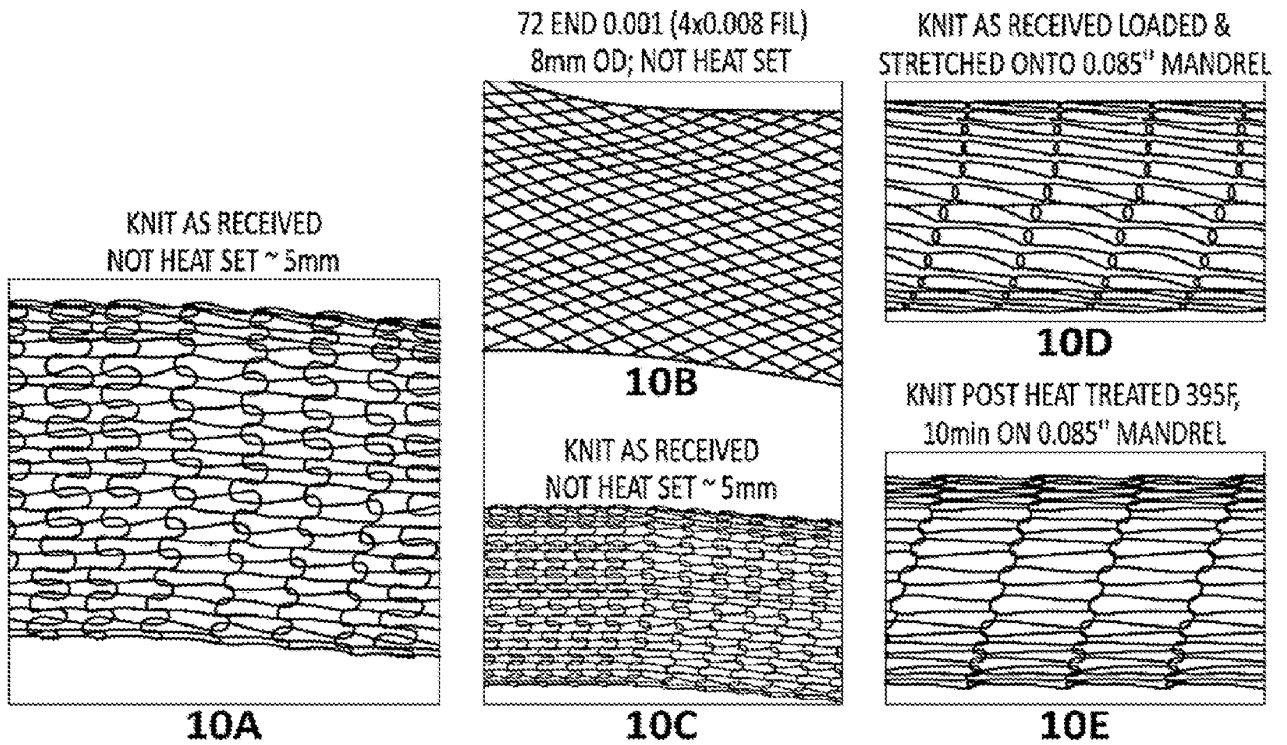
BRAID IN REVERSE: EJECTING CLOT
(DIFFERENT PIECE OF CLOT)



FIGS. 8A-8F



FIGS. 9A-9F



FIGS. 10A-10E

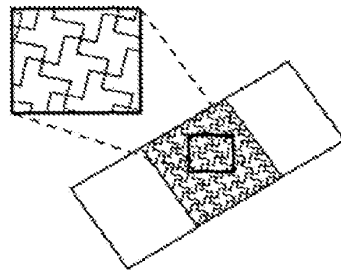


FIG. 11A

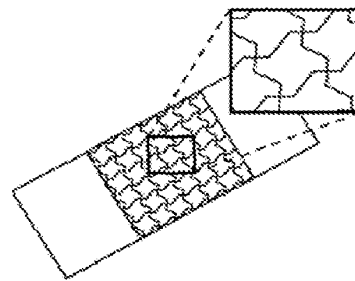


FIG. 11B

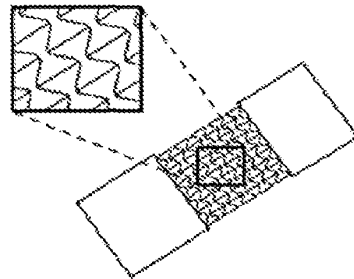


FIG. 11C

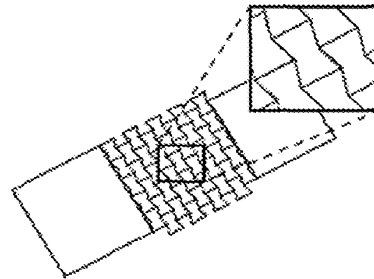


FIG. 11D

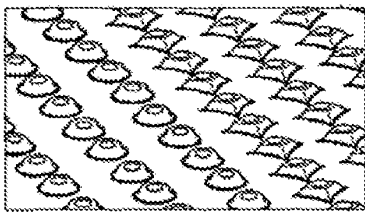


FIG. 12A

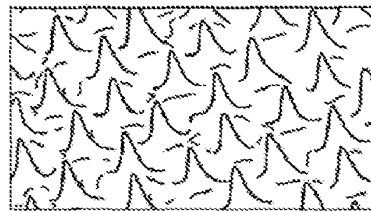


FIG. 12B

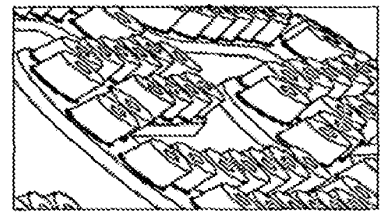


FIG. 12C

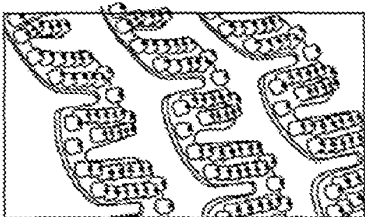


FIG. 12D

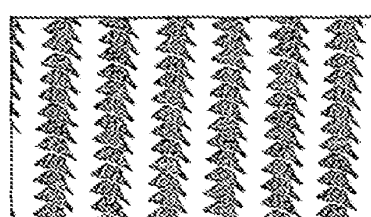


FIG. 12E

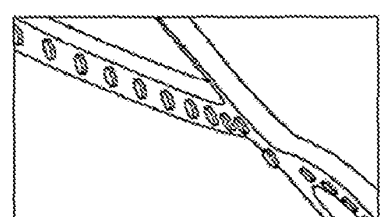


FIG. 12F

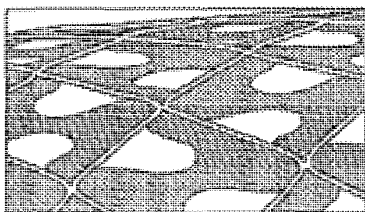


FIG. 12G

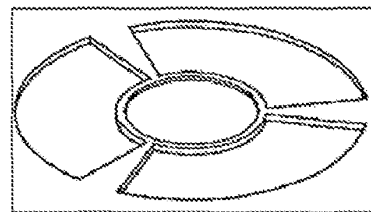


FIG. 12H



FIG. 12I

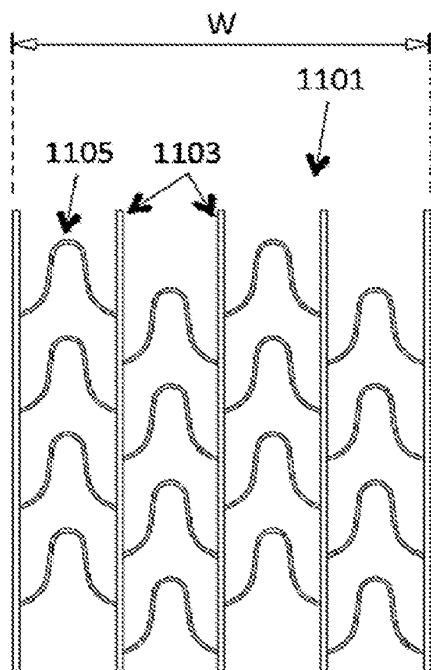


FIG. 13A

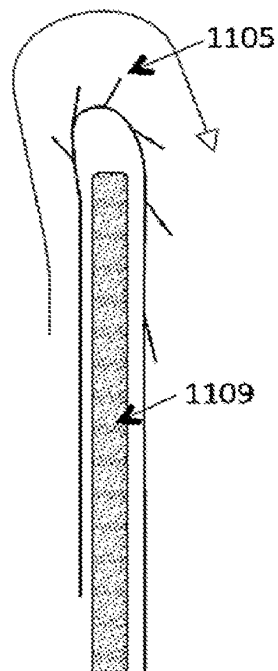


FIG. 13B

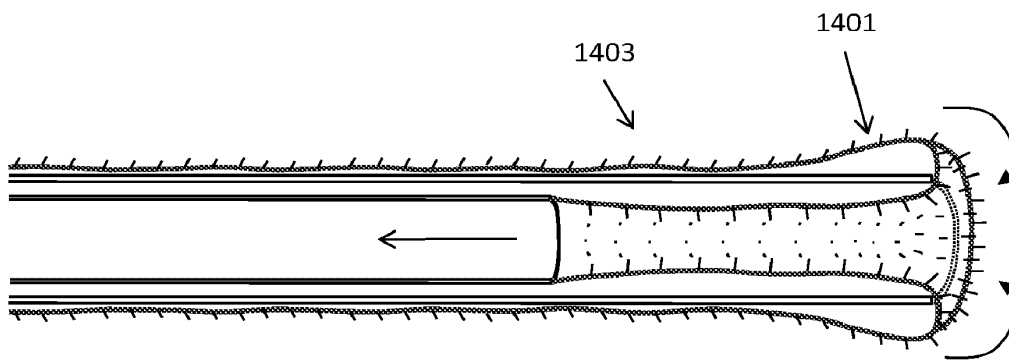


FIG. 14

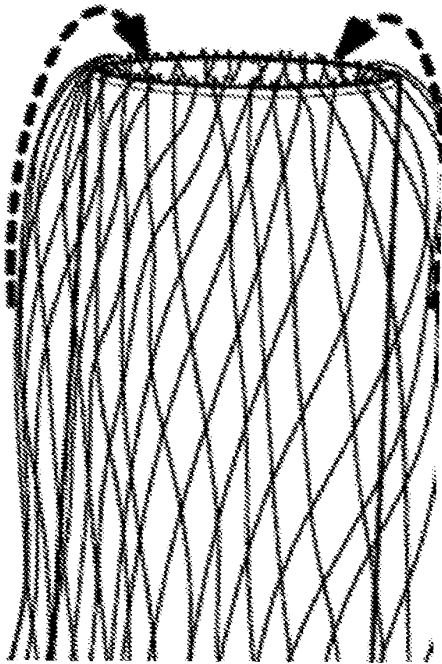


FIG. 15A

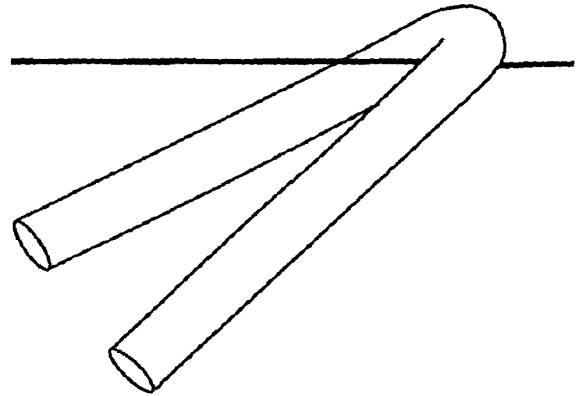


FIG. 15B



FIG. 15C



FIG. 15D

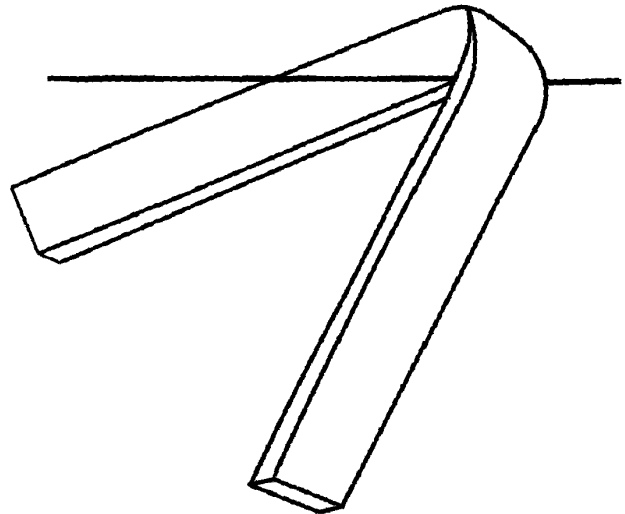
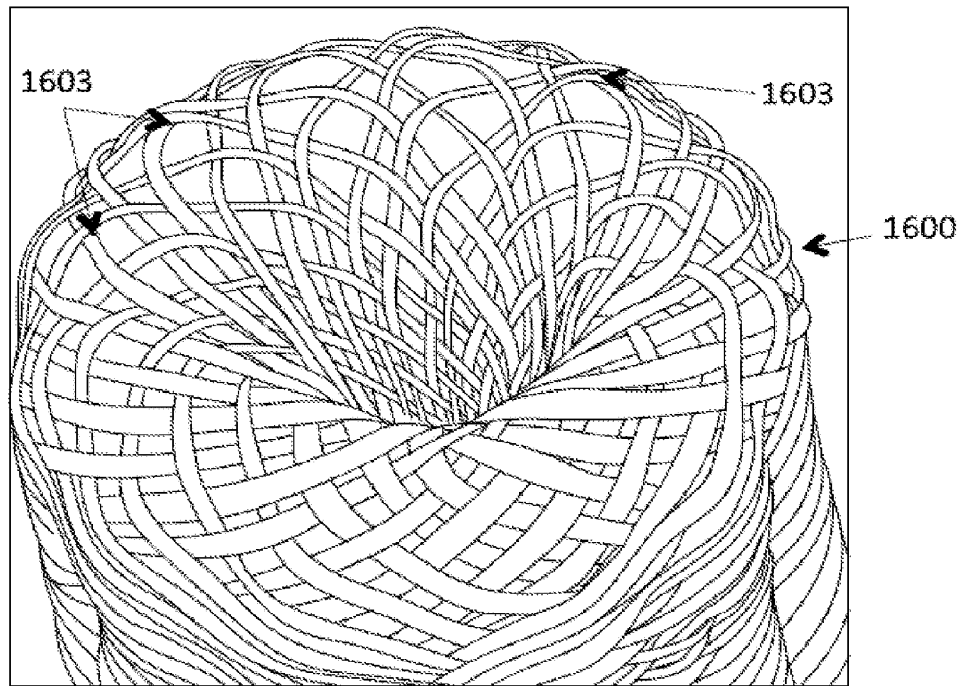
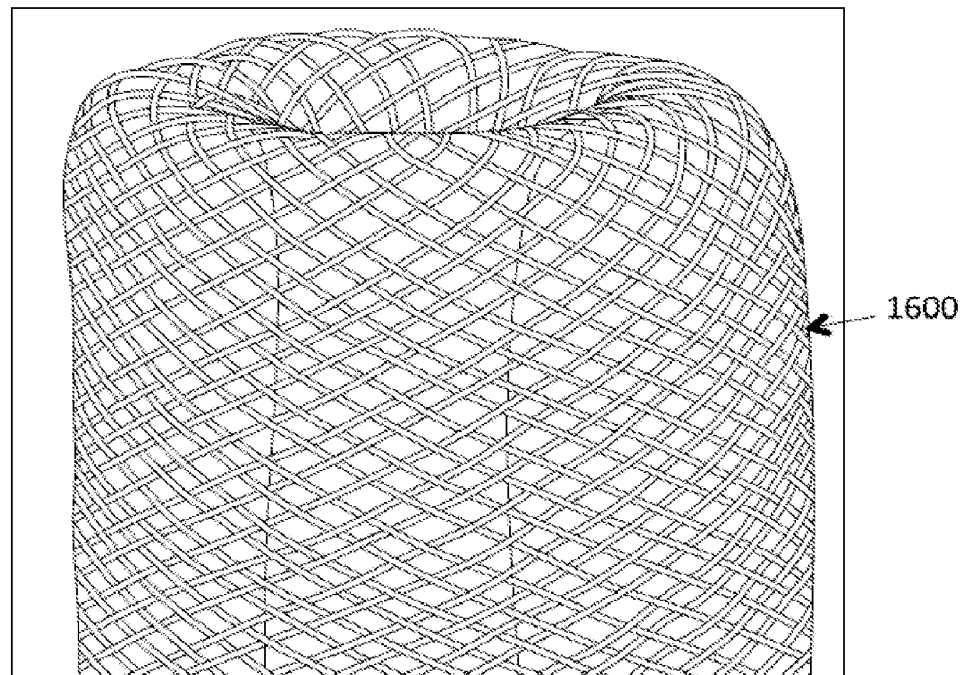


FIG. 15E

**FIG. 16A****FIG. 16A**

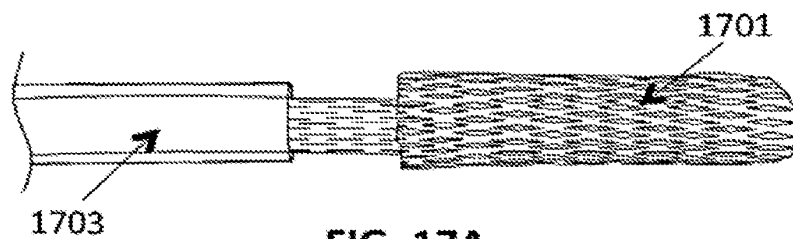


FIG. 17A

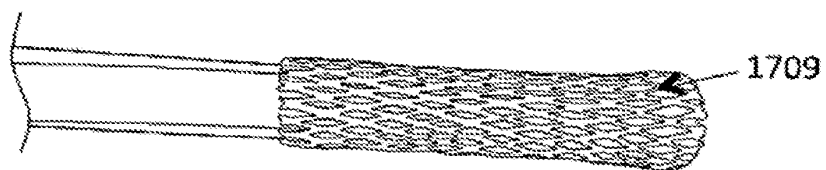


FIG. 17B

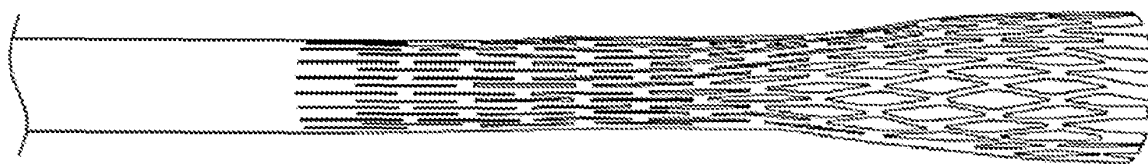


FIG. 17C

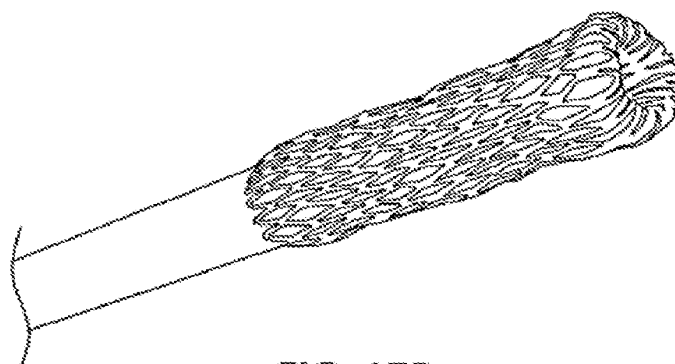


FIG. 17D

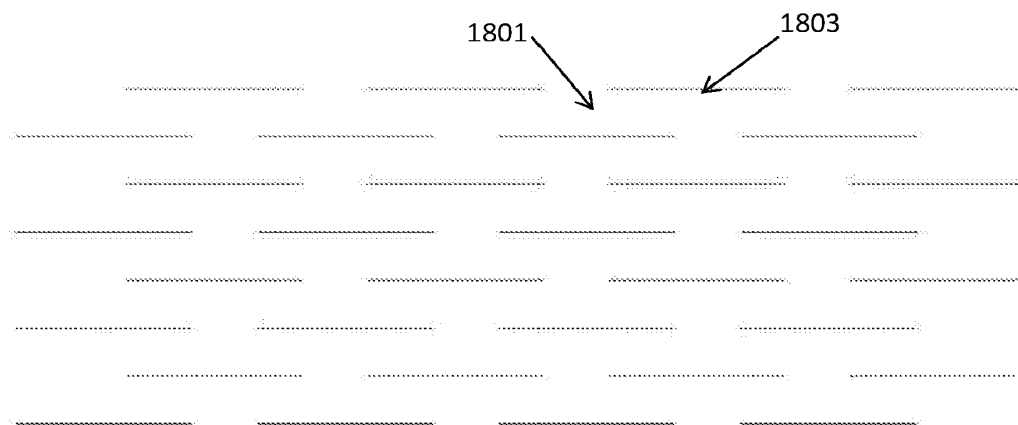


FIG. 18A

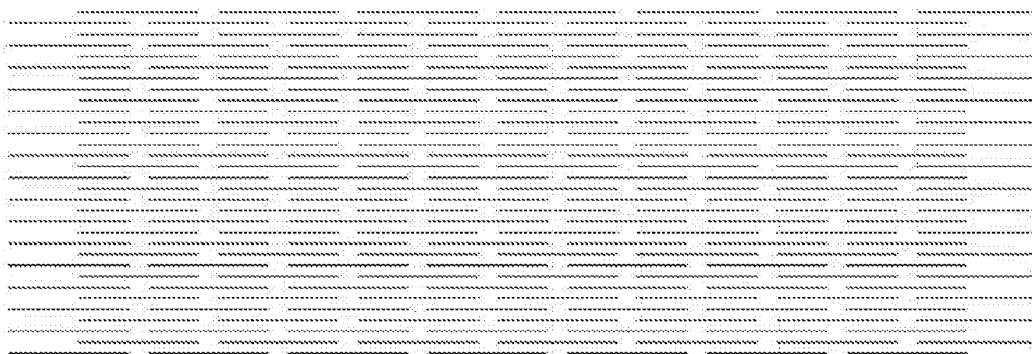


FIG. 18B

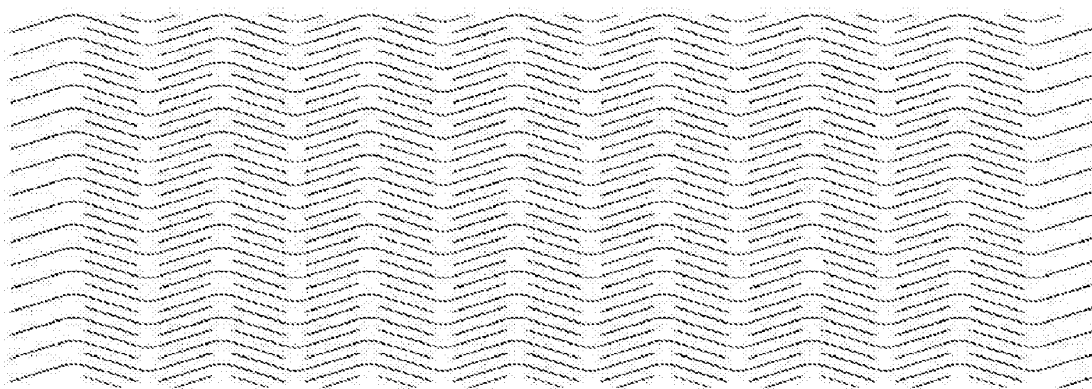


FIG. 18C

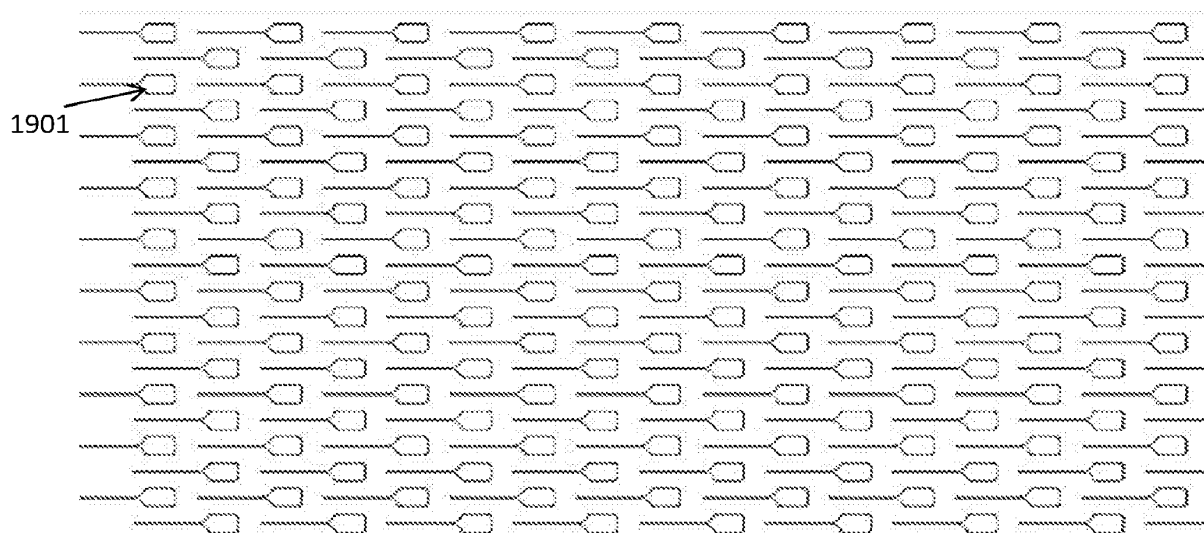


FIG. 19

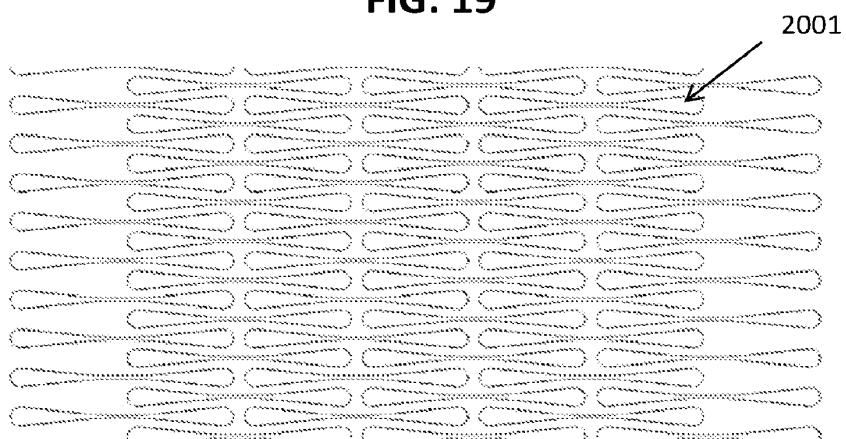


FIG. 20A

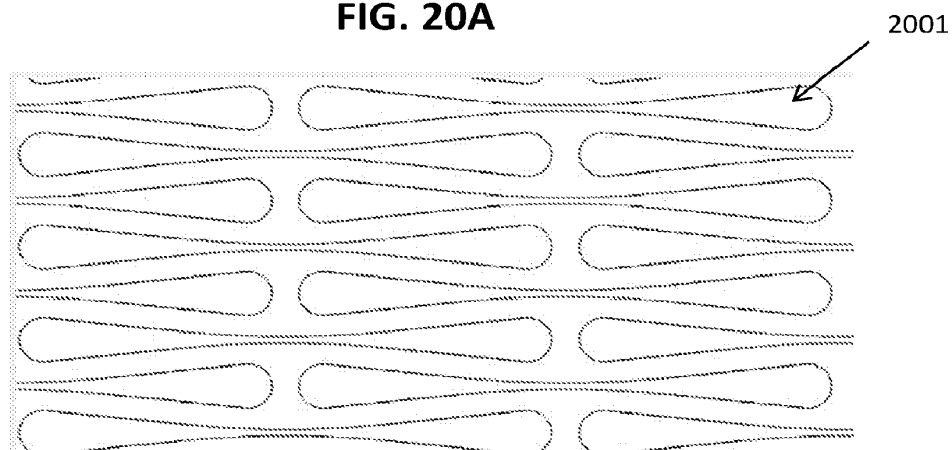


FIG. 20B

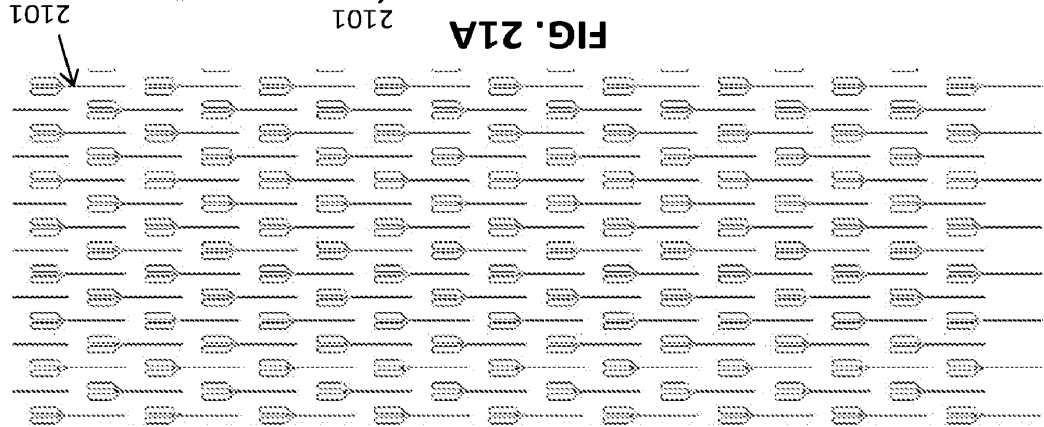


FIG. 21A

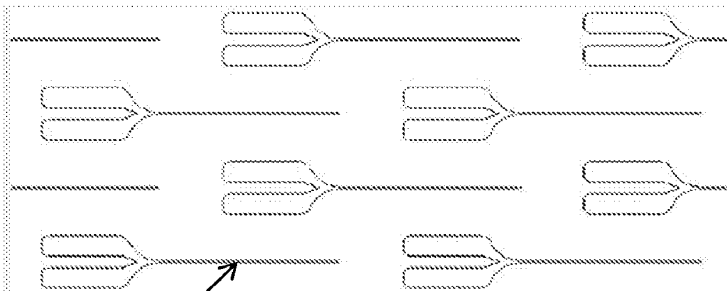


FIG. 21B

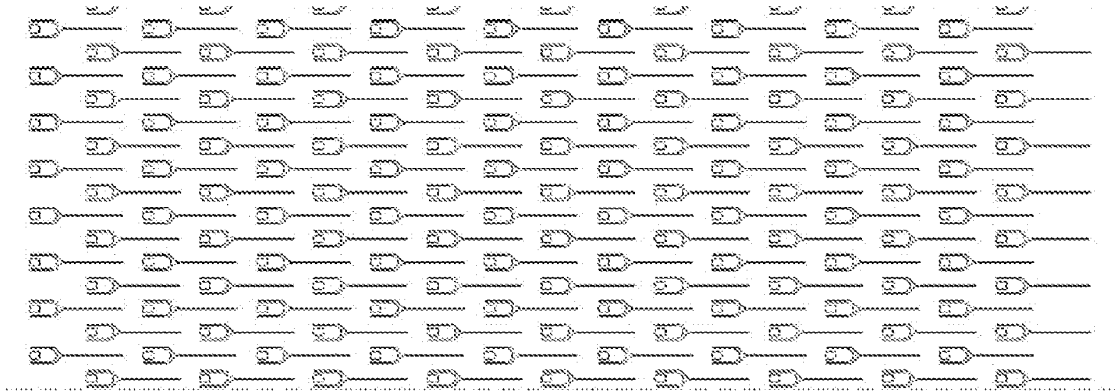


FIG. 22A

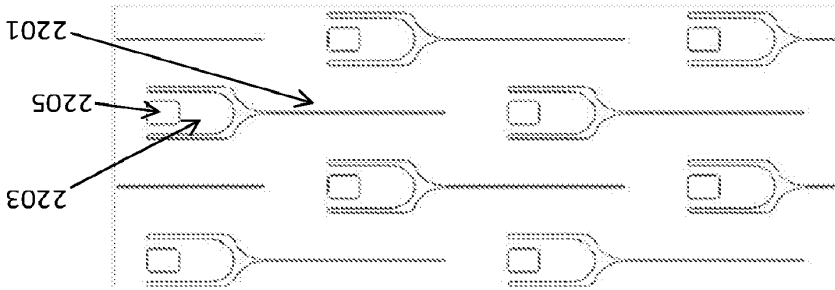
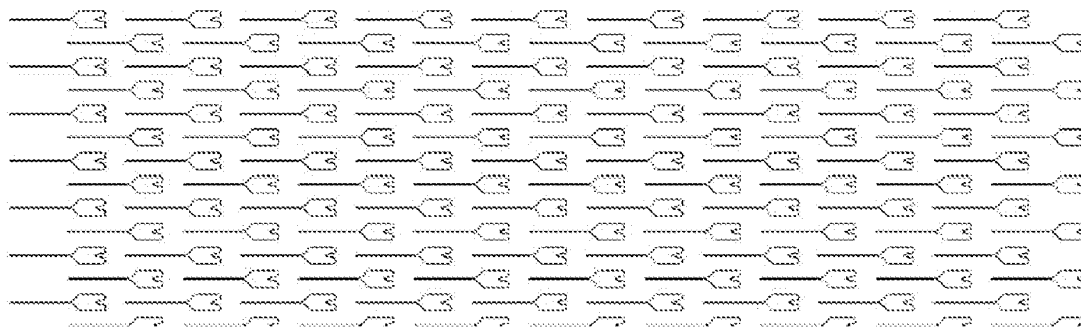
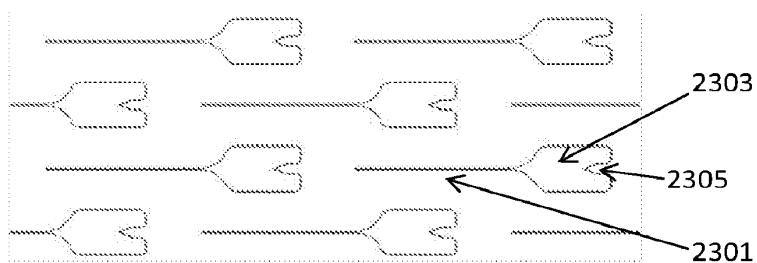
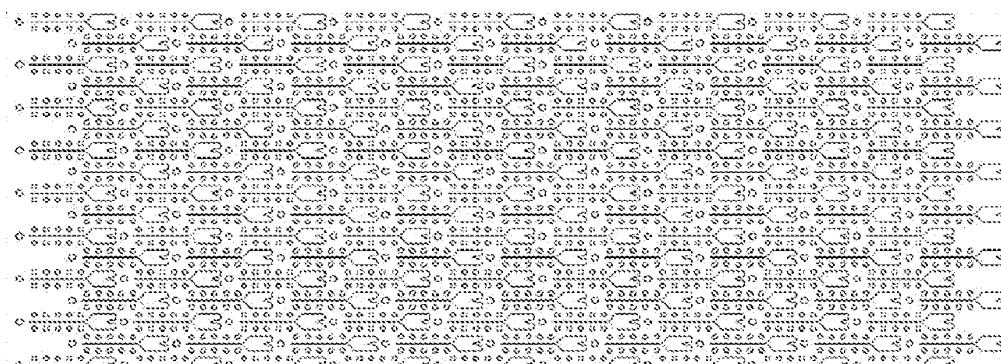
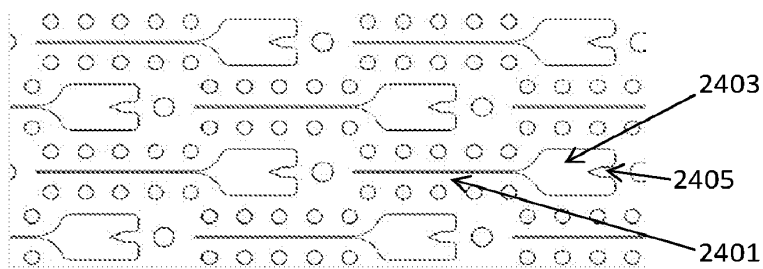


FIG. 22B

**FIG. 23A****FIG. 23B****FIG. 24A****FIG. 24B**

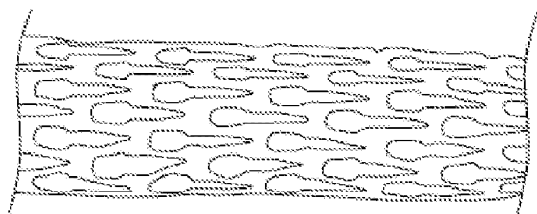


FIG. 25A

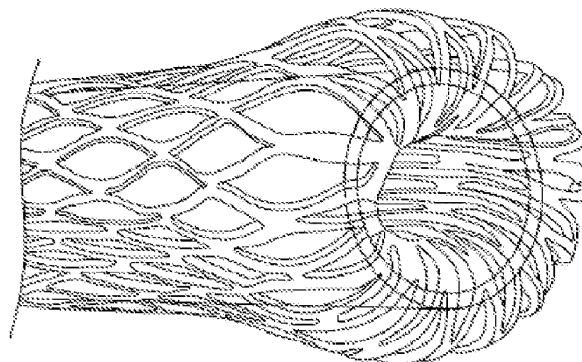


FIG. 25C

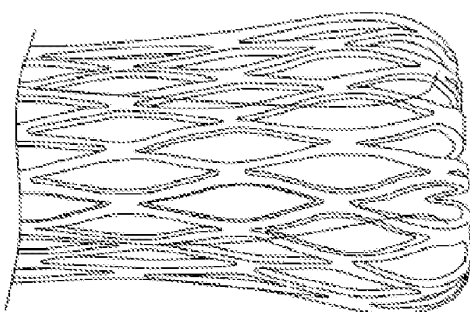


FIG. 25B

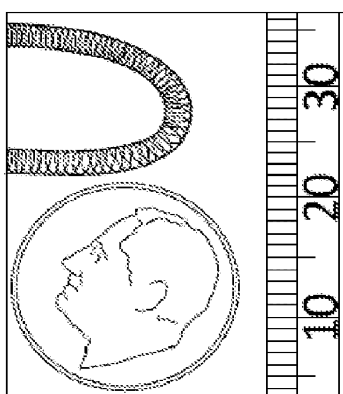


FIG. 26A

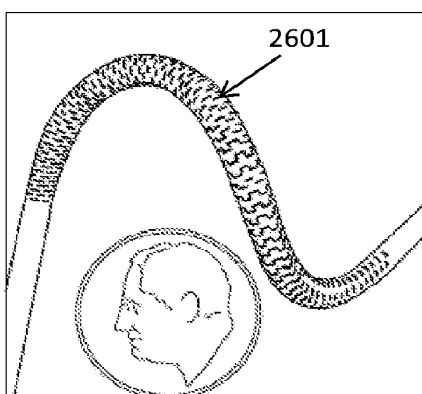


FIG. 26B

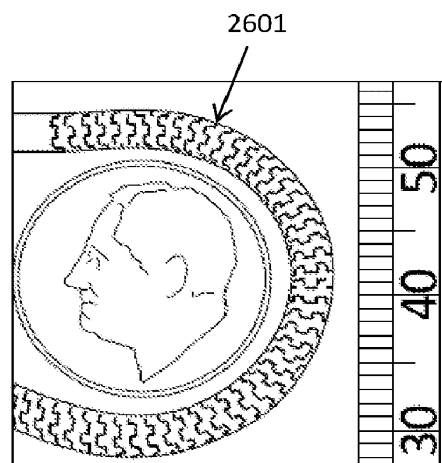


FIG. 26C

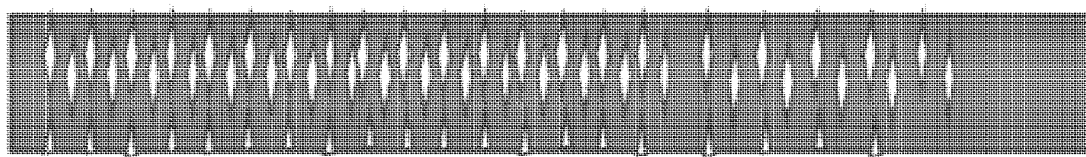


FIG. 27

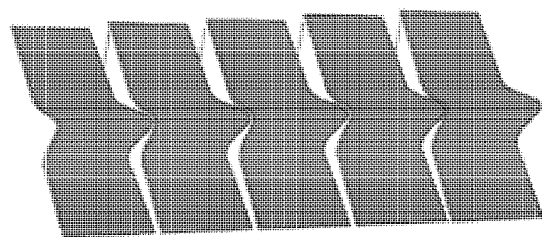


FIG. 28A

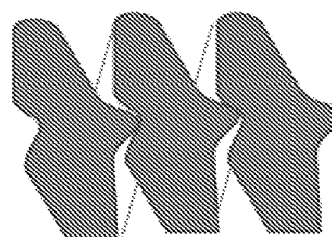


FIG. 28B

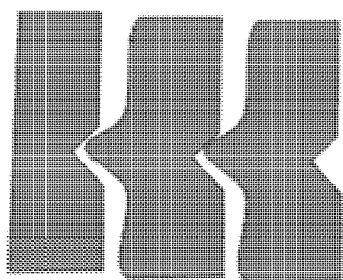


FIG. 29A

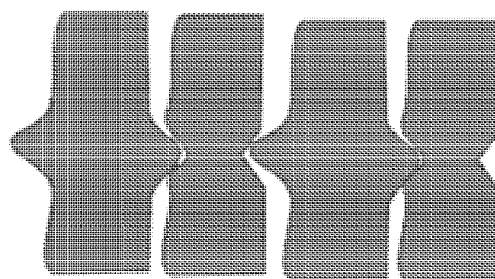
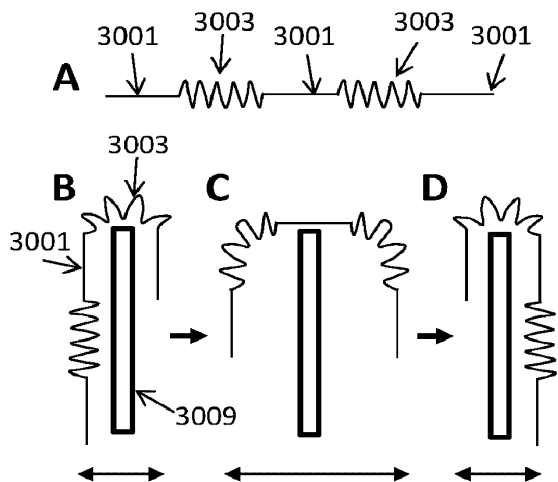


FIG. 29B



FIGS. 30A-30D

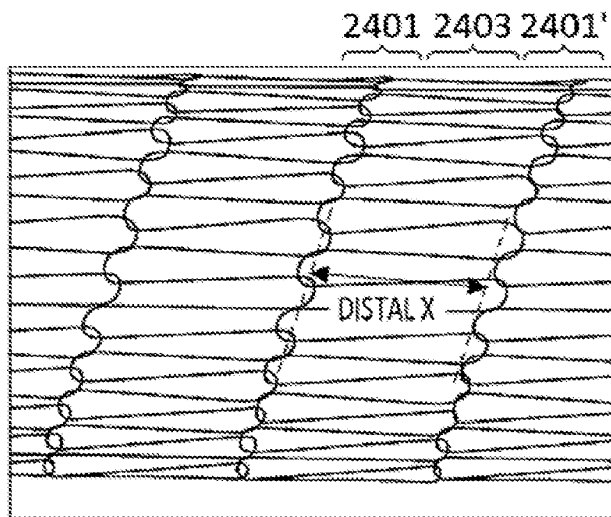
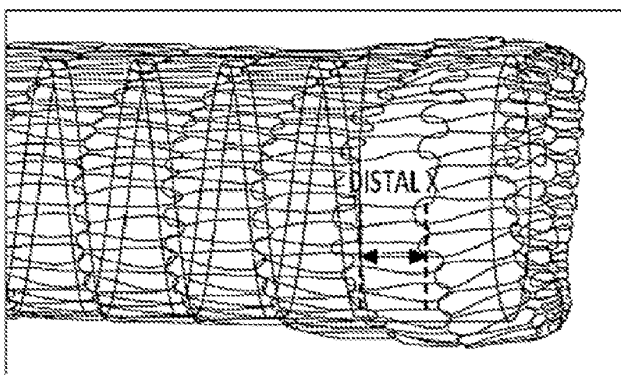
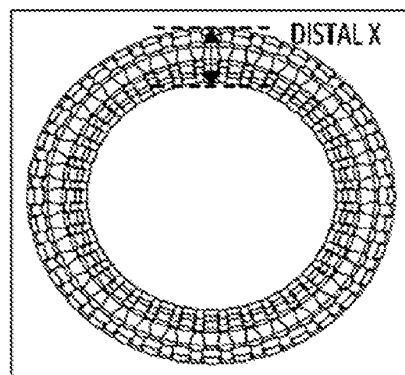


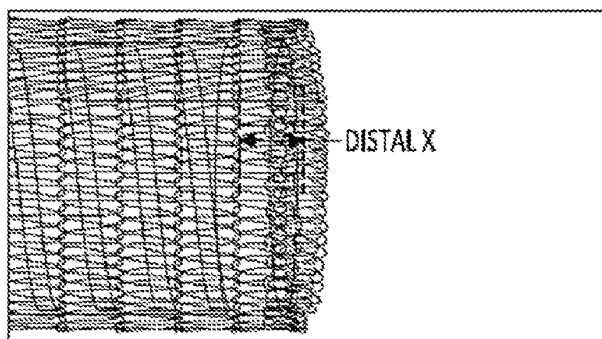
FIG. 31A



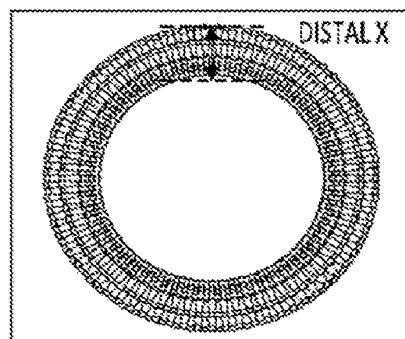
31B



31C



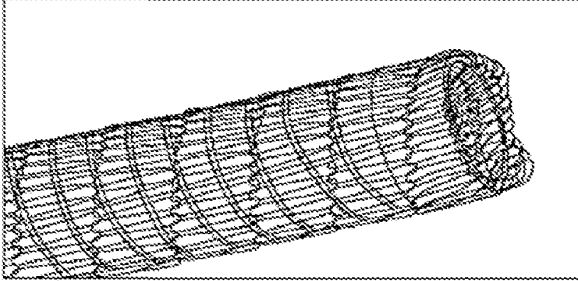
31D



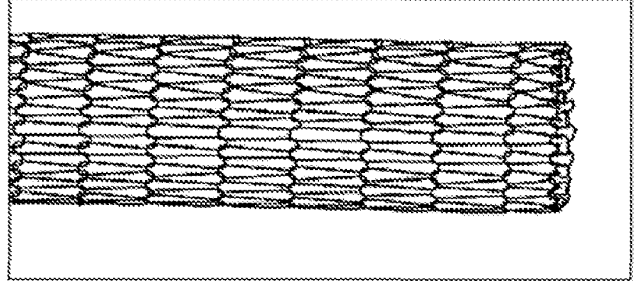
31E

FIGS. 31B-31E

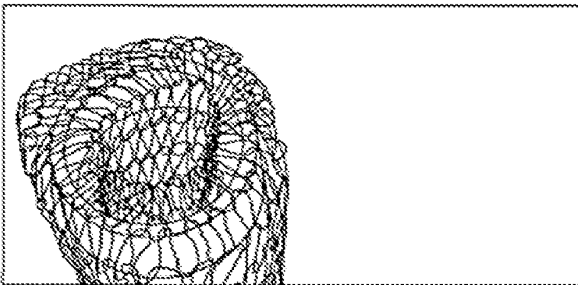
32A 0.045" ID CATHETER, 0.055 OD
(TOO SMALL)



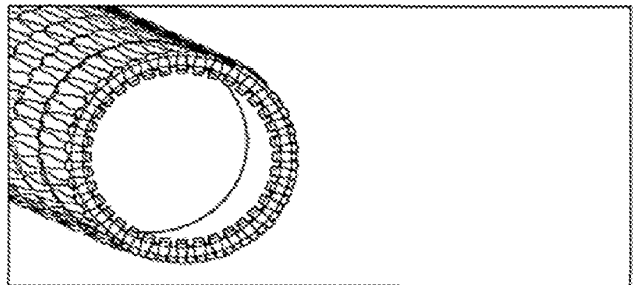
32C 0.085" ID 72D PEBAX, 0.95" OD
(TOO BIG)



32B



32D



FIGS. 32A-32D

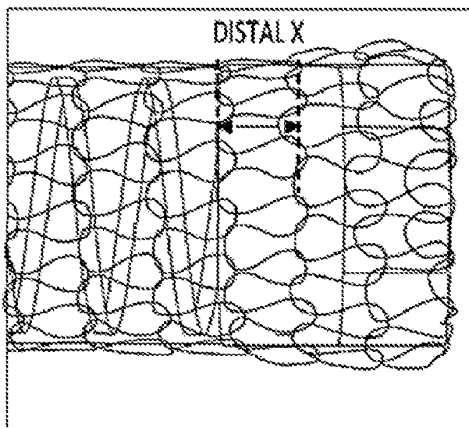


FIG. 33A

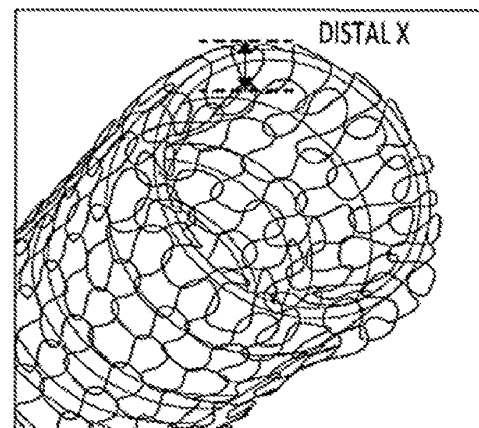


FIG. 33B

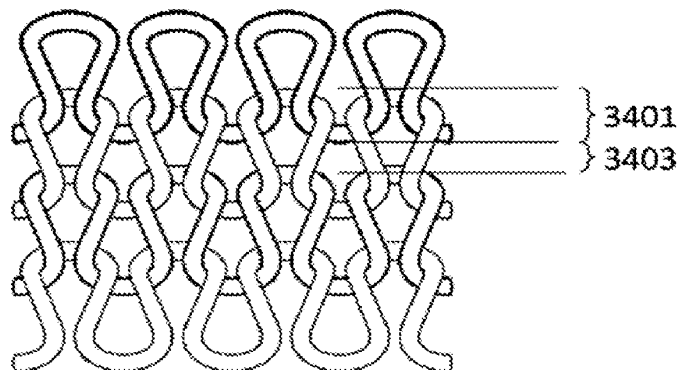


FIG. 34

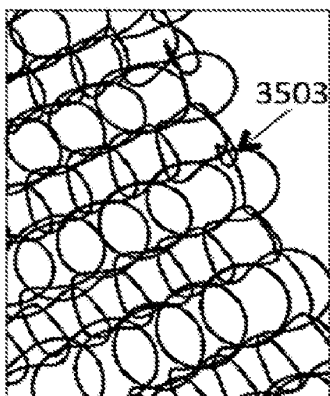


FIG. 35A

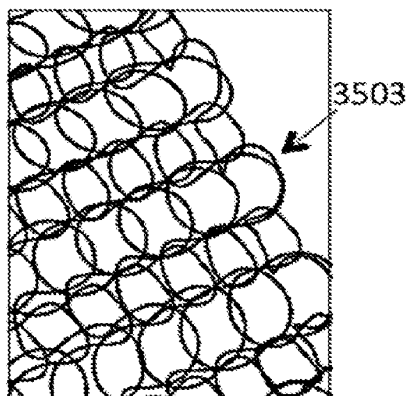


FIG. 35B

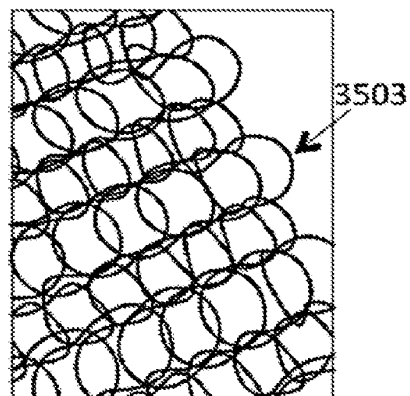


FIG. 35C

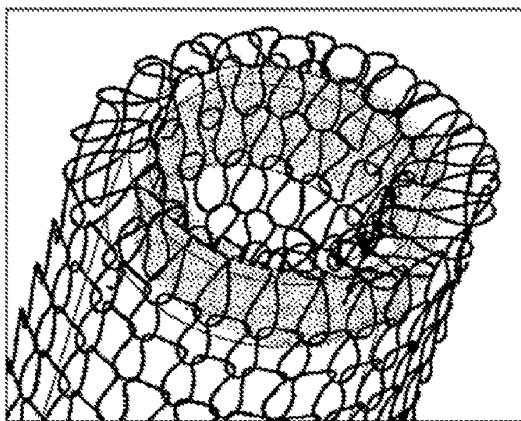


FIG. 36A

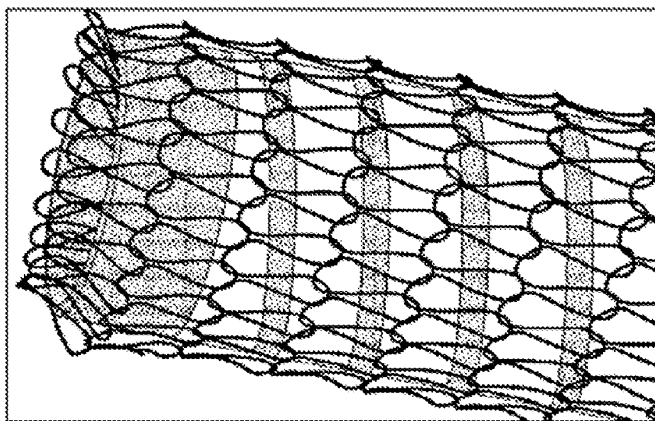


FIG. 36B

FIG. 37A

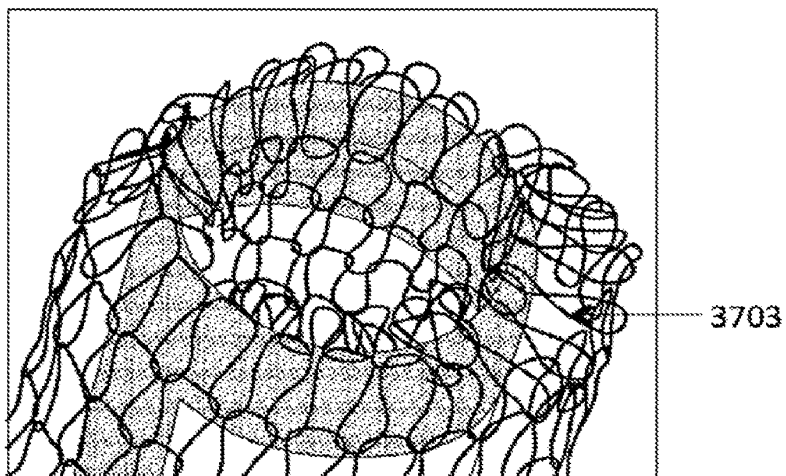


FIG. 37B

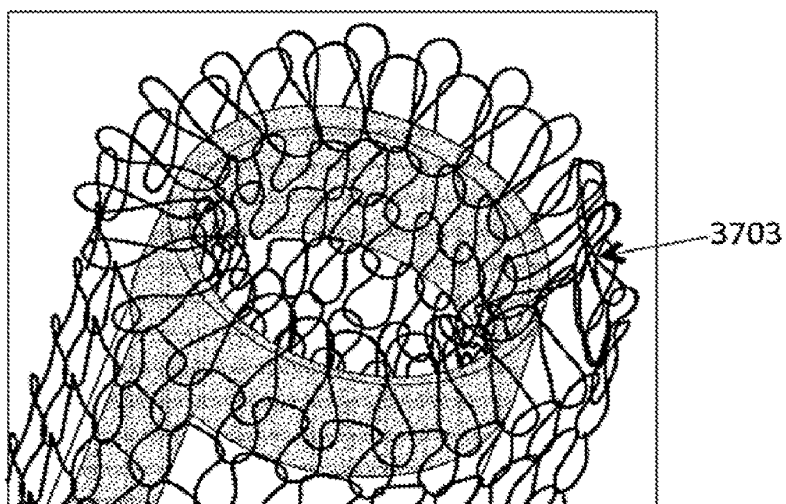
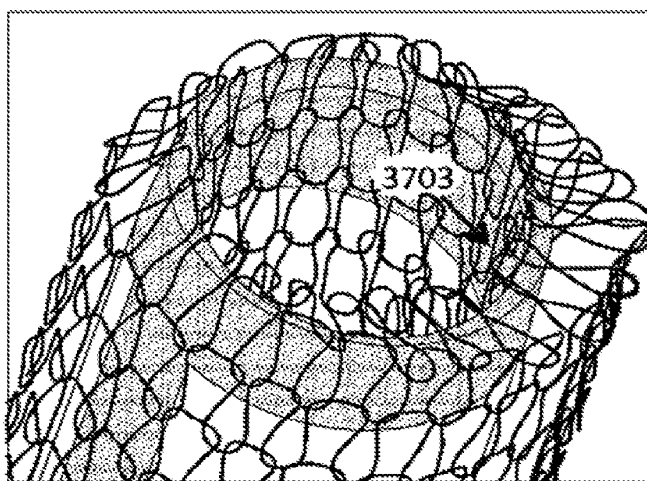
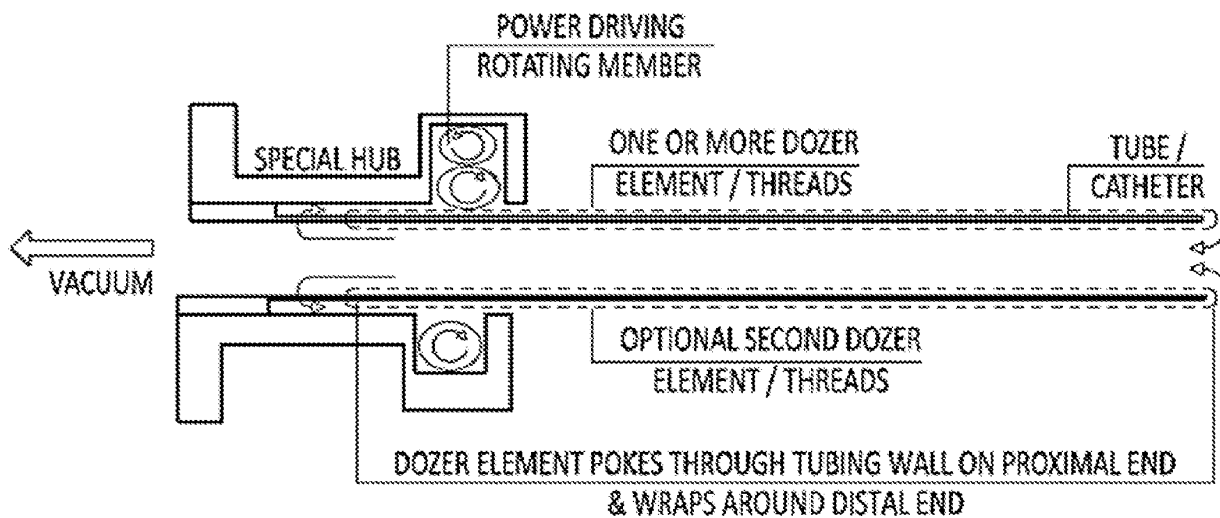
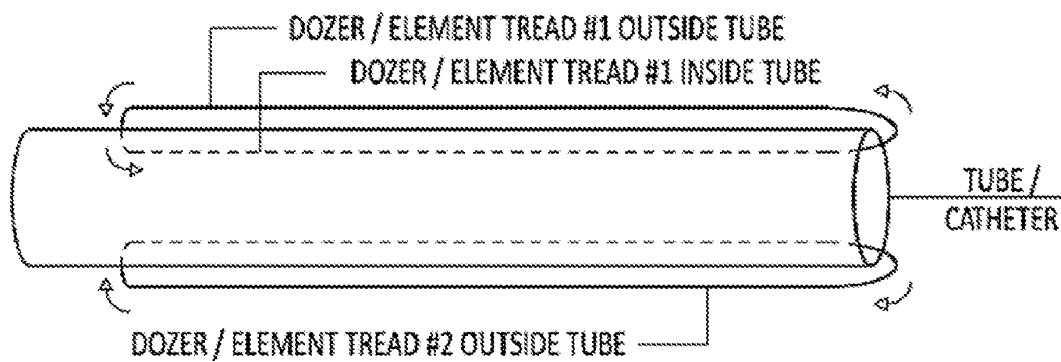


FIG. 37C



**FIG. 38A****FIG. 38B**

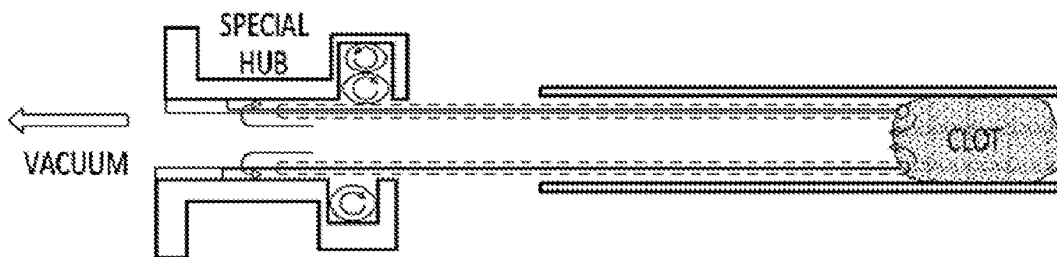


FIG. 39A

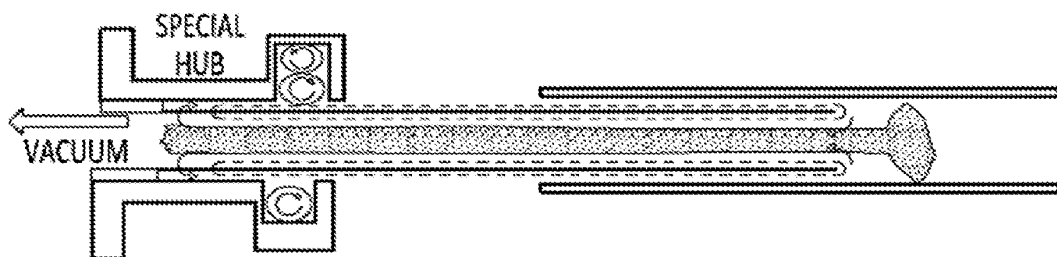


FIG. 39B

POWER DRIVEN CONTINUOUS TRACTOR OPTIONALLY LOADED INTO
LARGER ID CATHETER, WHICH MAY BE DELIVERED FIRST TO FACE OF SLOT

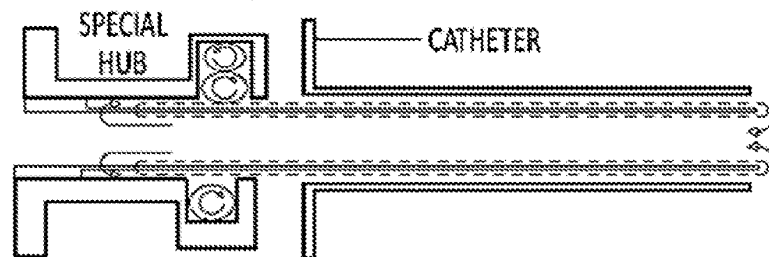


FIG. 39C

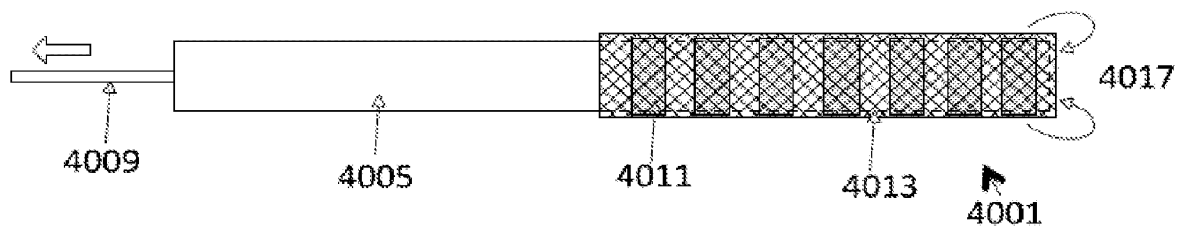


FIG. 40A

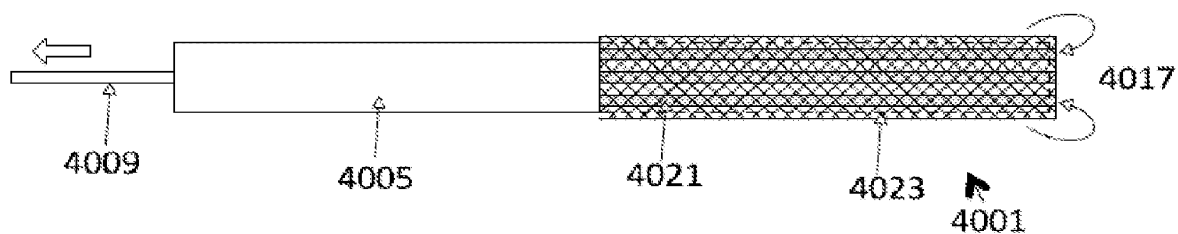


FIG. 40B

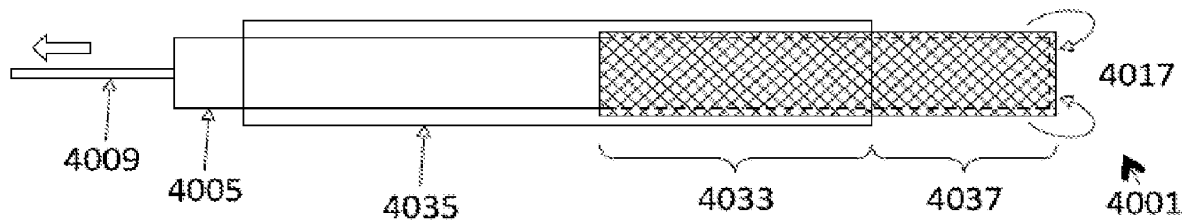


FIG. 40C

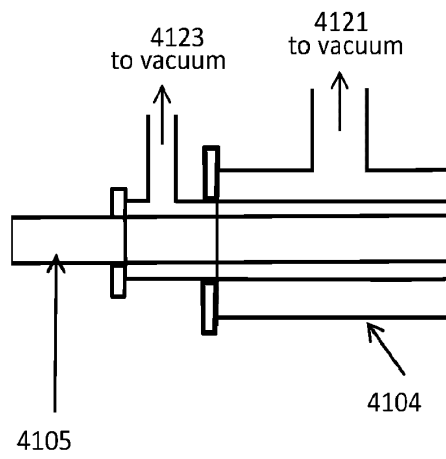
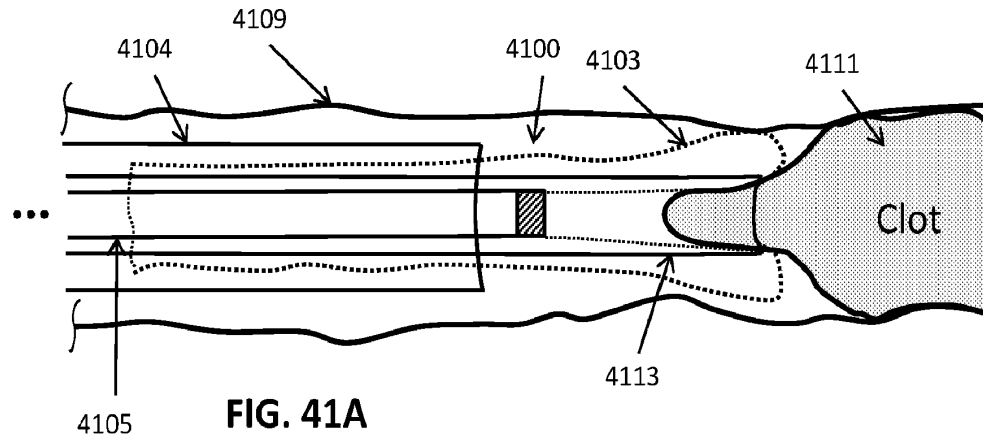


FIG. 41A

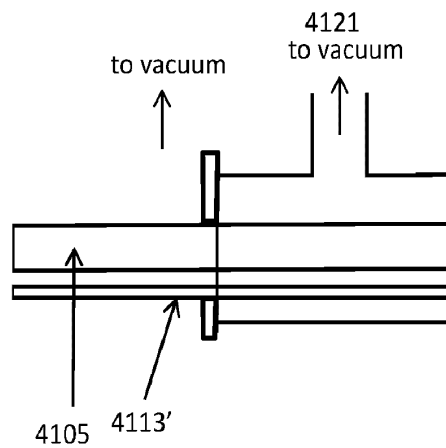
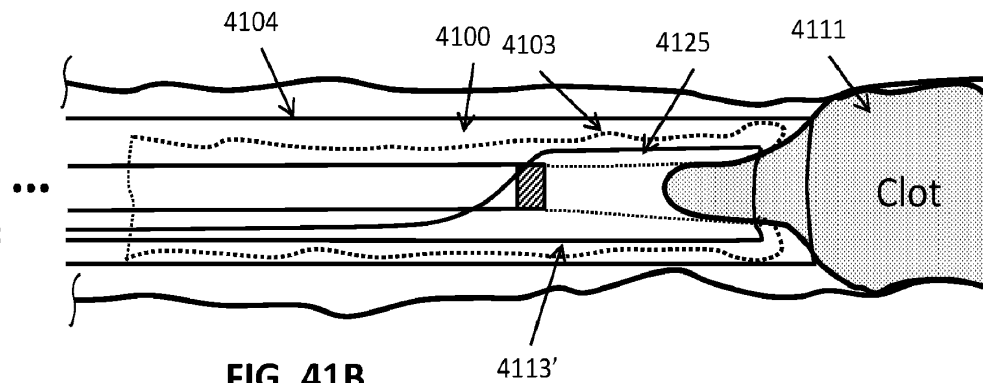
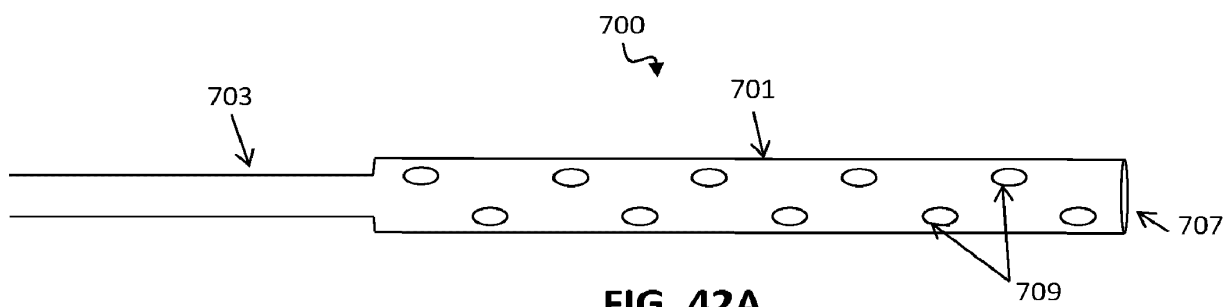
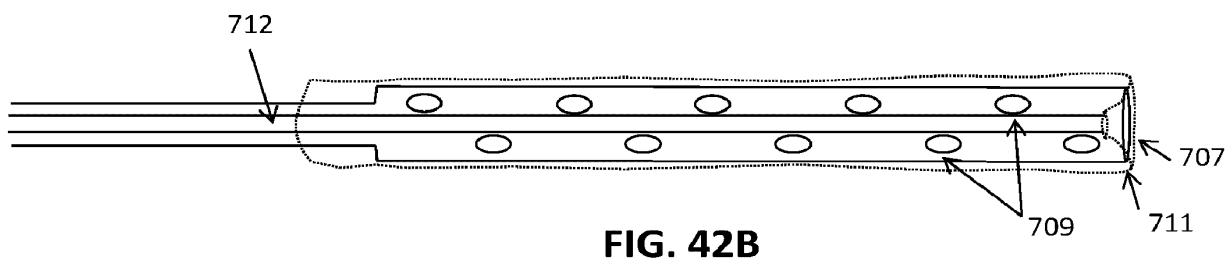
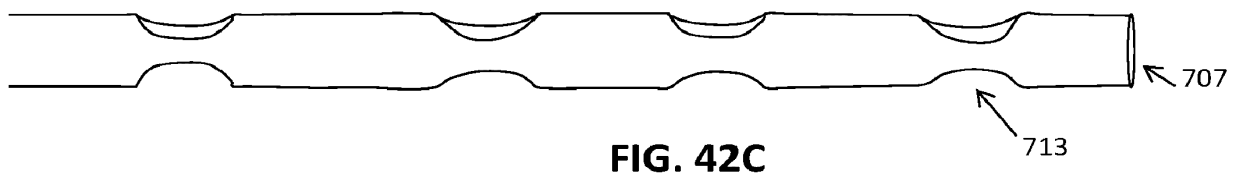
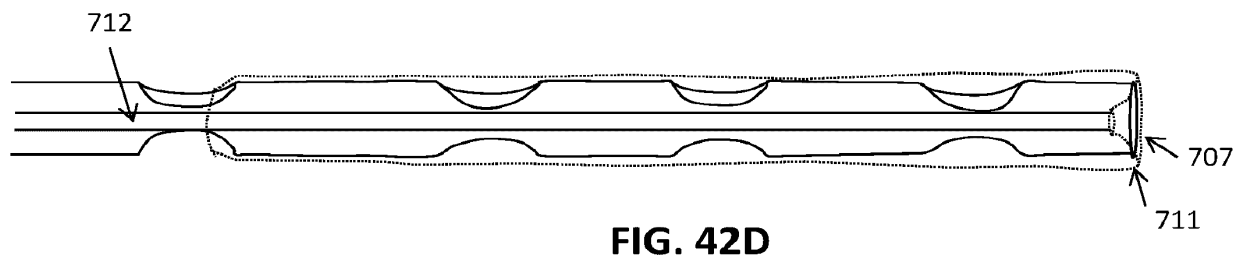


FIG. 41B



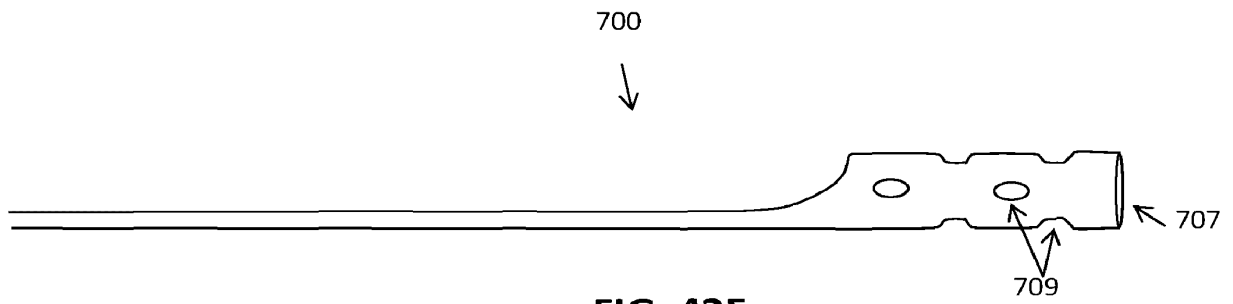


FIG. 42E

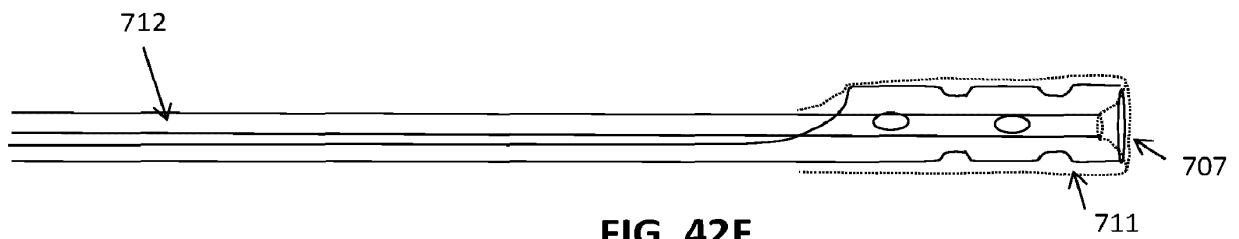


FIG. 42F

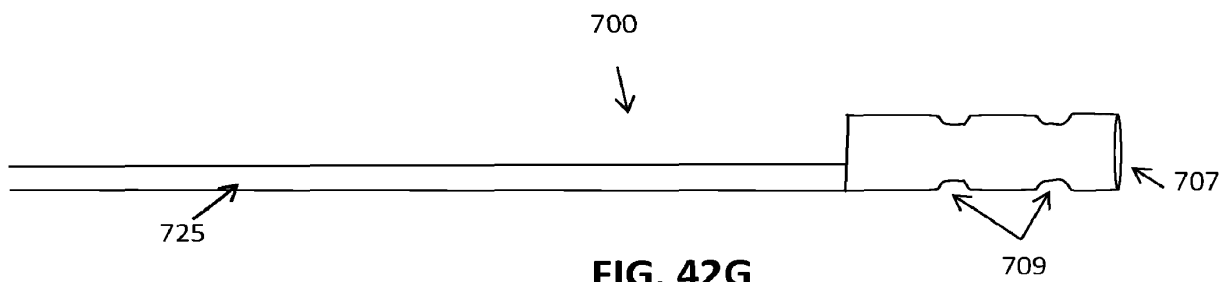


FIG. 42G

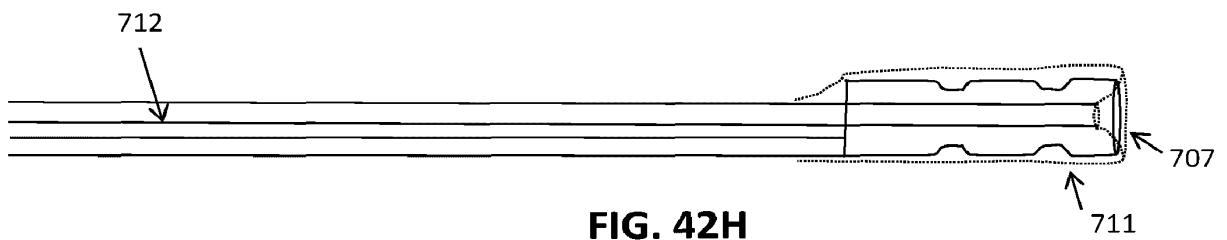
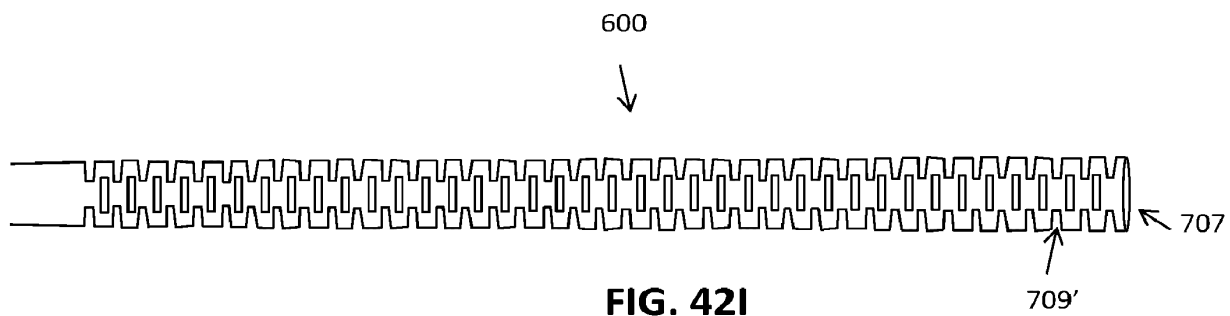
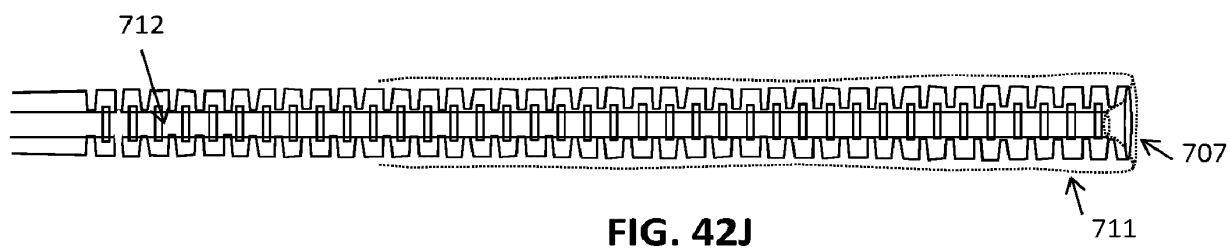
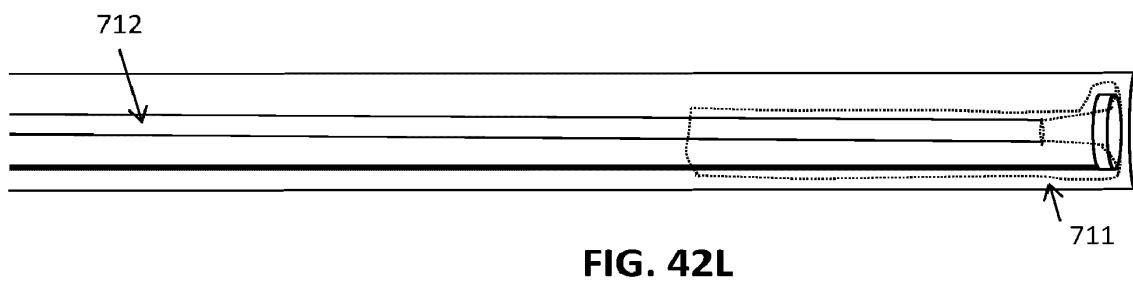


FIG. 42H



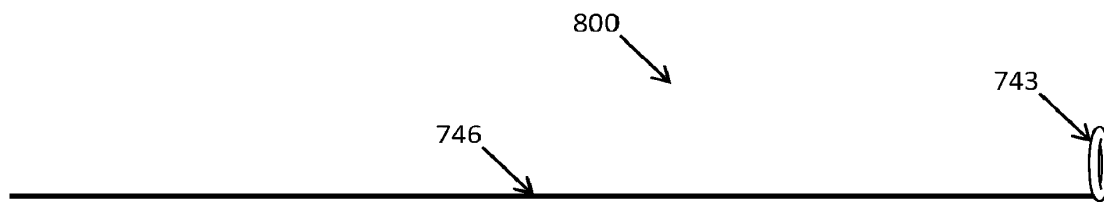


FIG. 43A

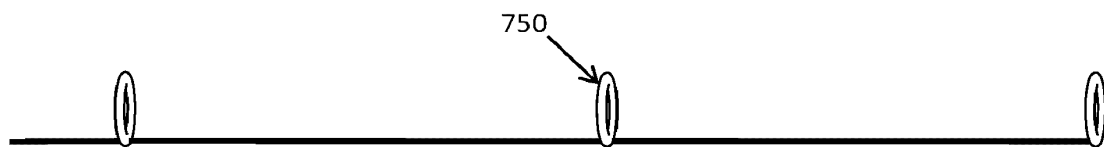


FIG. 43B

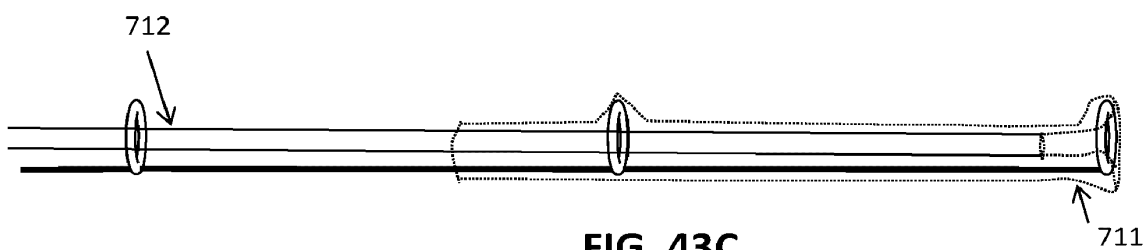


FIG. 43C

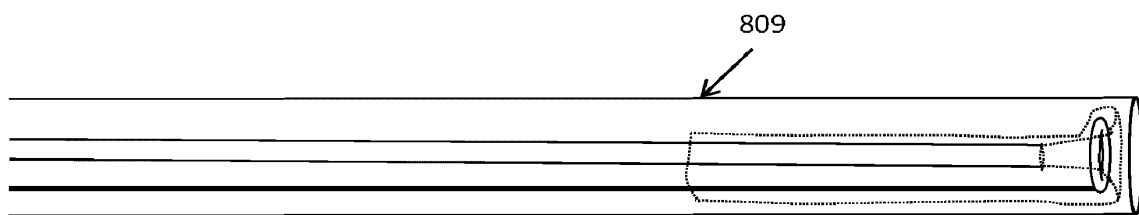
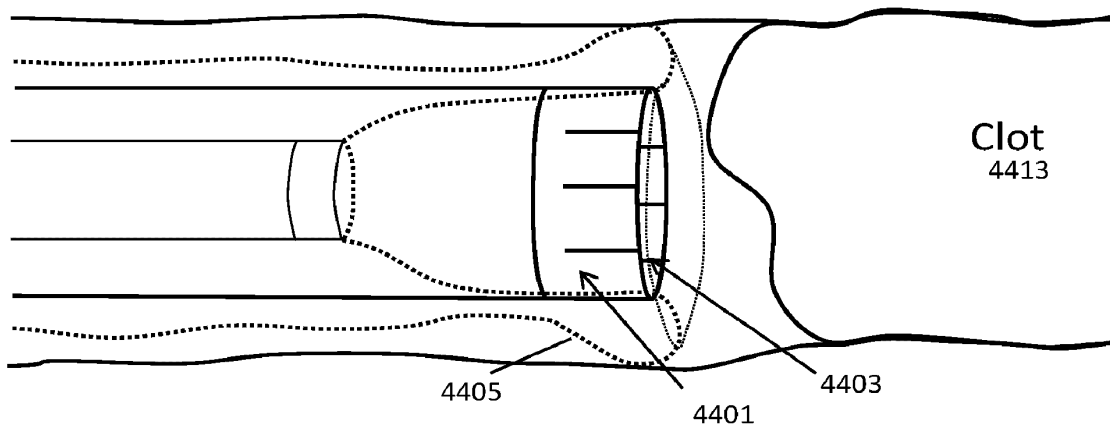
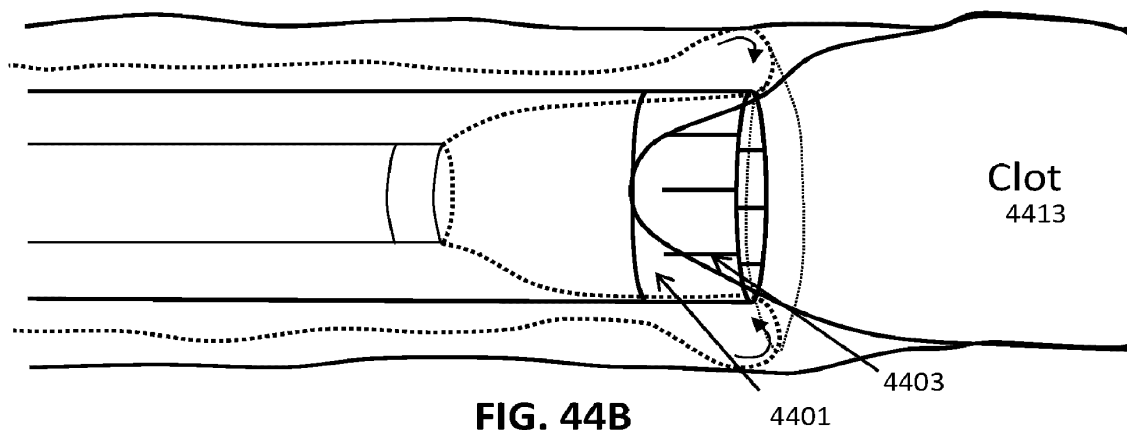
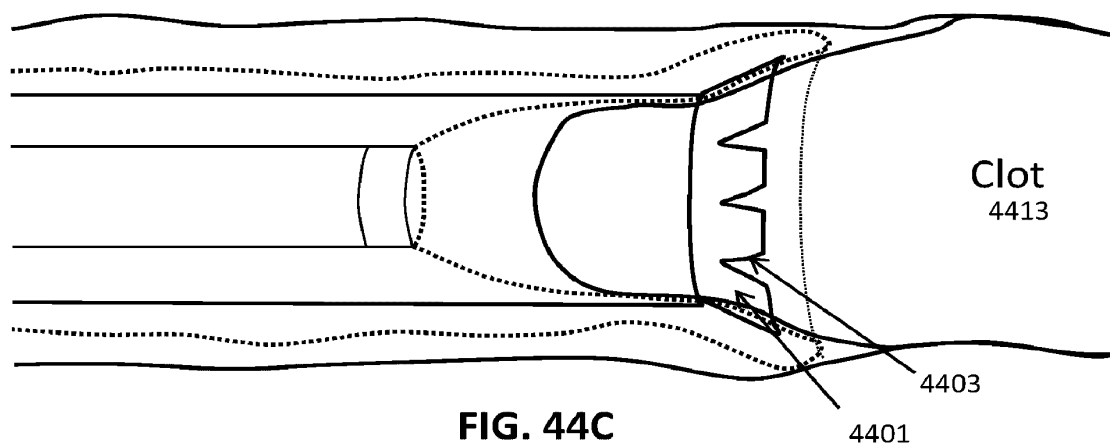


FIG. 43D



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DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN,
HR, HU, ID, IL, IN, IR, IS, JO, JP, KE, KG, KH, KN, KP,
KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME,
MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ,
OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA,
SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN,
TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) **Designated States** (*unless otherwise indicated, for every
kind of regional protection available*): ARIPO (BW, GH,
GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ,
UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ,
TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK,
EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV,
MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM,
TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW,
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kind of national protection available*): AE, AG, AL, AM,
AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ,
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(54) **Title:** SELF-ROLLING THROMBECTOMY APPARATUSES AND METHODS

(57) **Abstract:** Self-rolling mechanical atherectomy aka thrombectomy appara-
tuses for removing a clot from a vessel include a tractor tube portion that rolls
and inverts over itself in a continuous motion, tractor-like, to draw material into
the tractor tube, wherein the tractor tube rolls over itself without requiring any
additional internal support at the distal-facing region of the tractor tube.

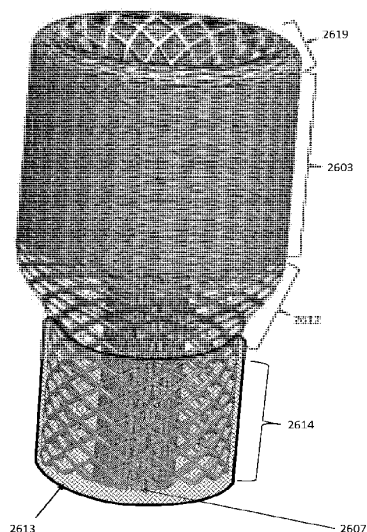


FIG. 26A

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SELF-ROLLING THROMBECTOMY APPARATUSES AND METHODS

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This patent application claims the benefit of priority to U.S. Provisional Patent Application No. 62/393,460, filed September 12, 2016.

5 [0002] The subject matter of this patent application is related to the subject matter disclosed and described in each of U.S. Patent Application No 15/291,015, filed October 11, 2016; U.S. Patent Application No. 15/043,996, filed February 15, 2016, now U.S. 9,463,035, U.S. Patent Application No. 15/496,570, filed April 25, 2017; U.S. Patent Application No. 15/496,668, filed April 25, 2017; U.S. Patent Application No. 15/496,786, filed April 25, 10 2017; U.S. Patent Application No. 15/497,092, filed April 25, 2017; and U.S. Patent Application No. 15/611,546, filed June 1, 2017. Each of the foregoing patents and patent applications is incorporated by reference herein in its entirety.

INCORPORATION BY REFERENCE

15 [0003] All publications and patent applications mentioned in this specification are herein incorporated by reference in their entirety to the same extent as if each individual publication or patent application was specifically and individually indicated to be incorporated by reference.

FIELD

20 [0004] The apparatuses and methods described herein relate to mechanical removal of objects from within a body. In particular, described herein are mechanical thrombectomy apparatuses and methods.

BACKGROUND

25 [0005] It is often desirable to remove tissue from the body in as minimally invasive a manner as possible, so as not to damage other tissues. For example, removal of tissue from within a patient's vasculature, such as removal of blood clots from veins and arteries, may improve patient conditions and quality of life.

[0006] Many vascular problems stem from insufficient blood flow through blood vessels. One cause of insufficient or irregular blood flow is a blockage within a blood vessel referred to as a blood clot, or thrombus. Thrombi can occur for many reasons, including after a trauma 30 such as surgery. For example, a large percentage of the more than 1.2 million heart attacks in the United States are caused by blood clots (thrombi) which form within a coronary artery.

[0007] When a thrombus forms, it may effectively stop the flow of blood through the zone of formation. If the thrombus extends across the interior diameter of an artery, it may cut off the flow of blood through the artery. If a coronary artery is 100% thrombosed, the flow of blood is stopped in that artery, resulting in a shortage of oxygen carrying red blood cells, e.g., to supply the muscle (myocardium) of the heart wall. Such a thrombosis can be triggered within an artery by damage to the arterial wall from atherosclerotic disease. Thus, the underlying disease of atherosclerosis may not cause acute oxygen deficiency (ischemia) but can trigger acute ischemia via induced thrombosis. Similarly, thrombosis of one of the carotid arteries can lead to stroke because of insufficient oxygen supply to the brain. Oxygen deficiency reduces or prohibits muscular activity, can cause chest pain (angina pectoris), and can lead to death of myocardium which permanently disables the heart. If myocardial cell death is extensive, the heart will be unable to pump sufficient blood to supply the body's needs.

[0008] Clinical data indicates that clot removal may be beneficial or even necessary to improve outcomes in such cases. For example, in the peripheral vasculature, interventions and procedures can reduce the need for an amputation by 80 percent. The ultimate goal of any modality to treat these conditions of the arterial or venous system is to remove the blockage or restore patency, quickly, safely, and cost effectively. This may be achieved by thrombus dissolution, fragmentation, thrombus aspiration or a combination of these methods.

[0009] Mechanical thrombectomy devices may be particularly advantageous. Depending on the size, location and extent of a clot, it may also be particularly advantageous to mechanically retrieve and break apart the clot in a manner that is both safe and effective. There is a definite need for a thrombectomy device, and particularly a mechanical thrombectomy device that can be more effective in removing tissue such as clots from within a body. Described herein are systems and apparatuses, and methods of using such systems and apparatuses, that address the needs and problems discussed above.

SUMMARY OF THE DISCLOSURE

[00010] Described herein are mechanical thrombectomy apparatuses (devices, systems, etc.) and methods of using and making them.

[00011] In general, described herein are self-rolling mechanical atherectomy apparatuses for removing a clot from a vessel. These atherectomy apparatuses, which may also be referred to as thrombectomy apparatuses, typically include a tractor tube portion that rolls and inverts over itself in a continuous motion, tractor-like, to draw material into the tractor tube.

The apparatuses described herein may be similar to the mechanical atherectomy apparatuses, systems and methods disclosed and described in the above-list of related U.S. patents and applications, which have been incorporated by reference herein in their entirety. However, the self-rolling mechanical atherectomy apparatuses described herein are configured such that the tractor tube (also referred to as a tractor region) rolls and inverts over itself unsupported at the distal-facing end when the inner tractor tube portion is pulled proximally. Specifically, the apparatuses described herein are configured so that the tractor tube rolls and inverts over itself, unsupported, without the need for an internal catheter extending within the inverting tractor tube providing a support or distal end opening to roll over.

5 [00012] Thus, the tractor tube is inverted over itself to form a distal-facing region at the distal end of the self-rolling mechanical atherectomy apparatus where, in a deployed configuration, the outer tractor tube portion rolls over and into itself, unsupported to become the inner tractor tube portion as the proximal end of the inner tractor tube portion is pulled proximally. At least the distal-most region of the tractor tube (e.g., the region at or near the distal-facing, inverting region of the tractor tube) is unsupported over at least the distal-most 1 or more cm of the apparatus. The tractor tube may be actuated to roll over itself by pulling proximally on the inner tractor tube portion (or an inner tractor puller coupled to the inner tractor tube portion) and/or by pushing distally on a proximal end of the outer tractor tube portion that is braced against an outer tractor pusher. In general, in an expanded configuration, the proximal end of the outer tractor tube portion is braced against a tapered portion of the tractor tube proximal to the outer tractor tube portion.

15 [00013] The tractor tube may be adapted to allow unsupported rolling over itself having a column strength of the outer tractor tube portion that resists buckling and/or collapse when compressed by pulling proximally on the inner tractor tube portion. As described in greater detail herein, this may be accomplished by one or more of forming the tractor tube from a braided material having a compressed braid angle relative to the proximal-to-distal axis that is greater than 80 degrees (e.g., greater than 85 degrees, greater than 90 degrees, greater than 95 degrees, greater than 100 degrees, between 80-170 degrees, between 90-170 degrees, between 95-170 degrees, etc.); the braid angle of the inner tractor tube portion under tension in the proximal-to-distal axis is typically much less than the compressed braid angle of the outer tractor tube portion in compression, and may be, e.g., less than 90 degrees (e.g., less than 85 degrees, less than 80 degrees, less than 75 degrees, less than 70 degrees, less than 65 degrees, less than 60 degrees, less than 50 degrees, less than 45 degrees, less than 40 degrees, between 90-5 degrees, between 80-5 degrees, between 70-5 degrees, between 65-5 degrees,

between 60-5 degrees, etc.). The compressed outer tractor tube braid angle refers to the braid angle of the outer tractor tube in the deployed (e.g., radially expanded) configuration; pulling the inner tractor tube portion proximally, e.g., by pulling the inner tractor puller, results in a compressive load on the outer tractor tube portion that is continuous but inverted relative to the inner tractor tube portion.

[00014] For example, described herein are self-rolling mechanical atherectomy apparatuses that include: an outer tractor pusher comprising a catheter having a distal end and a distal end opening; a tractor tube comprising an outer tractor tube portion that extends distally in an un-inverted configuration and inverts into itself at a distal-facing region to form an inner tractor tube portion, wherein the tractor tube is configured so that pulling the inner tractor tube portion proximally compresses the outer tractor tube portion so that it has a column strength that resists collapsing, further wherein pulling the inner tractor tube proximally causes a region of the outer tractor tube portion at the distal-facing region to roll over itself, unsupported, and invert into the inner tractor tube portion; and an inner tractor puller coupled to the inner tractor tube portion and extending proximally within the outer tractor pusher.

[00015] In general, the outer tractor pusher may be a catheter, tube, cannula, or the like. During delivery or positioning of the apparatus, the tractor tube, and an inner tractor puller, if included, may be held within the outer tractor pusher in an un-deployed configuration. Prior to clot removal, the tractor tube may be deployed out of the outer tractor pusher portion and the outer tractor pusher portion may be expanded into a deployed configuration that has an outer radial diameter that is greater than the inner radial diameter of the outer tractor pusher. The outer tractor pusher may then be positioned to support or brace the outer tractor tube portion to allow it to roll over and into itself distally when the inner tractor puller is pulled proximally. Alternatively, a separate distal access catheter may be included, and the outer tractor pusher may be held within the distal access catheter along with the tractor tube prior to deployment within the blood vessel.

[00016] In any of these apparatuses, the outer tractor pusher may be coupled to a proximal end of the outer tractor tube portion of the tractor tube. Alternatively, the proximal end of the outer tractor tube portion may be unconnected to the outer tractor pusher.

[00017] As mentioned, the apparatus may include a distal access catheter. The outer tractor pusher, the tractor tube and inner tractor puller may be held within the distal access catheter in an un-deployed configuration, further wherein the tractor tube may be configured to be pushed distally out of the distal access catheter so that the outer tractor tube portion may

expand to a diameter that is greater than an outer diameter of the distal access catheter in a deployed configuration. Alternatively, the outer tractor pusher may be configured as a distal access catheter wherein the tractor tube and inner tractor puller may be held within the outer tractor pusher in an un-deployed configuration, further wherein the tractor tube may be configured to be deployed by being pushed distally out of the outer tractor pusher so that the outer tractor tube portion expands to an outer diameter that is greater than an outer diameter of the outer tractor pusher.

[00018] In any of the self-rolling mechanical atherectomy apparatuses described herein, the tractor tube may be configured so that pulling the inner tractor tube proximally compresses the outer tractor tube portion and the column strength of the outer tractor tube portion resists collapsing up to at least 300g of compression (e.g., at least about 350 g of compression, at least about 400 g of compression, at least about 450 g of compression, at least about 500 g of compression, at least about 550 g of compression, at least about 600 g of compression, at least about 650 g of compression, at least about 700g of compression, etc.).

[00019] In general, the tractor tube comprises a braided or woven material. For example, the tractor tube may be a woven or braided tube, e.g., formed of one or a plurality of filament. The filaments may be monofilaments or bundles of filaments, and may be a polymeric material, a metal material, a natural fiber material, etc. For example, the tractor tube may be formed of between 24-48 filaments. The tractor tube may be formed of a plurality of filaments having a diameter of greater than about 0.003 inches (e.g., greater than 0.0020 inches, greater than 0.0025 inches, greater than 0.0035 inches, greater than 0.0040 inches, greater than 0.0045 inches, greater than 0.0050 inches, etc.).

[00020] In particular, the tractor tube may be configured to resist buckling when rolling over itself based in part on the arrangement of the filaments. For example, the outer tractor tube portion may have a braid angle in a proximal to distal axis (in a compressed configuration) that is between 80 and 170 degrees, and the inner tractor tube portion may have a braid angle in the proximal to distal axis (e.g., under tension) of less than 80 degrees.

[00021] In any of the apparatuses described herein, the proximal end of the outer tractor tube portion may be configured to have a tapered shape when the outer tractor tube portion is expanded radially outward. This tapered region may be shape set into the tractor tube (e.g., when the tractor tube is formed of a shape-settable material, for example, such as a nickel titanium alloy) and/or it may be formed by attaching a retaining structure to the proximal end of the outer tractor tube portion, such as a retaining band, retaining ring, etc., or by attachment to the outer tractor pusher.

[00022] As mentioned, the distal-facing region of the tractor tube may be unsupported, including unsupported over at least 1 cm proximally from the distal-facing region of the tractor tube (e.g., at least 1.5 cm, at least 2 cm, at least 2.5 cm, etc.). Thus, the tractor tube does not roll over a support (such as a catheter) at the distal-facing tractor portion at the distal

5 end of the device.

[00023] In general, the tractor tube may be porous. For example, the tractor tube may have a porosity of 50% or greater (e.g., 55% or greater, 60% or greater, 65% or greater, 70% or greater, 75% or greater, etc.).

[00024] Any of the apparatuses described herein may be used with a guidewire, for placing the apparatus. For example, the inner tractor puller may include an inner lumen configured to pass a guidewire out of a distal end of the apparatus. In general a guidewire may be included as part of the apparatus.

[00025] Any of these apparatuses may include a vacuum source coupled to the tractor tube and configured to apply a vacuum (e.g., aspiration) therethrough. The vacuum source may include a pump.

[00026] For example, a self-rolling mechanical atherectomy apparatus for removing a clot from a vessel may include: an outer tractor pusher comprising a catheter having a distal end and a distal end opening; a tractor tube comprising an outer tractor tube portion that extends distally in an un-inverted configuration and inverts into itself at a distal-facing region to form an inner tractor tube portion, wherein the tractor tube is configured so that pulling the inner tractor tube portion proximally compresses the outer tractor tube portion so that it has a column strength that resists collapsing up to at least 500g of compression and extends inner tractor tube portion, further wherein pulling the inner tractor tube proximally causes a region of the outer tractor tube portion at the distal-facing region to roll over itself, unsupported, and invert into the inner tractor tube portion; and an inner tractor puller coupled to the inner tractor tube portion and extending proximally within the outer tractor pusher.

[00027] Also described herein are methods of removing a clot from a blood vessel using any of the apparatuses described herein. Generally, these methods may include actuating a self-rolling mechanical atherectomy apparatus so that the distal-facing region of the tractor tube is unsupported as the outer tractor tube portion rolls over and into itself and inverts, pulling in any clot or other target material into the tractor tube. The tractor tube is typically configured to roll over itself without support (e.g., be “self-rolling”) from any other structure, e.g., by having a sufficient column strength in the outer tractor tube portion in compression to resist or prevent buckling, bending or collapse, yet be sufficiently flexible that it may bend

and navigate through the often tortious anatomy of the vasculature (and particularly the neurovasculature), and to roll over itself. Various configurations are described herein to achieve this combination of flexibility and column strength, including forming the apparatus with a braided (or woven) tractor tube having a large braid angle in the outer tractor tube portion (under compression) and a relatively smaller braid angle in the inner tractor tube portion (e.g., under tension).

[00028] For example, a method of removing a clot from a blood vessel may include: advancing a distal end of a self-rolling mechanical atherectomy apparatus through the blood vessel to the clot, wherein the self-rolling mechanical atherectomy apparatus comprises a tractor tube, an outer tractor pusher, and an inner tractor puller; pulling an inner tractor puller of the tractor tube proximally to compresses an outer tractor tube portion of the tractor tube, wherein pulling the inner tractor puller proximally causes the outer tractor tube portion at a distal-facing region of the tractor tube to roll over itself, unsupported, and invert into the inner tractor tube portion; and engaging the clot with the tractor tube as it rolls over itself so that the clot is pulled into the tractor tube.

[00029] Any of these methods may include deploying the tractor tube of the self-rolling mechanical atherectomy apparatus so that the outer tractor tube portion of the tractor tube expands to have an outer diameter that is greater than an outer diameter of the outer tractor pusher. Pulling the inner tractor puller may include bracing a distal-facing end of the outer tractor pusher against a tapered face of the tractor tube that is proximal to the outer tractor tube portion. Thus, the tapered face or region of the tractor tube may be pushed against the outer tractor pusher when the tractor tube is attached or un-attached to the outer tractor pusher. When attached to the outer tractor pusher, the tapered face region of the tractor tube may still be driven against the opening of the outer tractor pusher.

[00030] Any of the methods described herein may include advancing a guidewire within the blood vessel to the clot, wherein advancing the self-rolling mechanical atherectomy apparatus comprises advancing the self-rolling mechanical atherectomy apparatus over the guidewire through the blood vessel until the self-rolling mechanical atherectomy apparatus is proximate to the clot.

[00031] Engaging (or “grabbing”) the clot may include advancing the outer tractor pusher distally while pulling the inner tractor puller proximally. Alternatively or additionally, engaging the clot may include advancing the outer tractor pusher distally at a first rate while pulling the inner tractor puller proximally at a second rate that is different (e.g., faster) than the first rate.

[00032] In general, advancing may include advancing the self-rolling mechanical atherectomy apparatus distally with the tractor tube and inner tractor puller within the outer tractor pusher, wherein the tractor tube is in an un-deployed configuration. Once near (e.g., adjacent) the clot or other target, the tractor tube may be deployed from the inner tractor puller and/or distal access catheter.

[00033] Any of these methods may include applying aspiration through the tractor tube.

[00034] Advancing the self-rolling mechanical atherectomy apparatus may include advancing a distal access catheter enclosing the tractor tube, outer tractor pusher and inner tractor puller, wherein the outer tractor tube portion is inverted over the inner tractor puller in an un-deployed configuration within the distal access catheter.

[00035] Pulling the inner tractor puller may include applying up to 500 g of compressive force on the outer tractor tube portion without collapsing the outer tractor tube portion.

[00036] For example, a method of removing a clot from a blood vessel may include: advancing a distal end of a self-rolling mechanical atherectomy apparatus through the blood vessel to the clot, wherein the self-rolling mechanical atherectomy apparatus comprises a tractor tube, an outer tractor pusher, and an inner tractor puller; deploying the tractor tube of the self-rolling mechanical atherectomy apparatus so that an outer tractor tube portion of the tractor tube expands to have an outer diameter that is greater than an outer diameter of the outer tractor pusher, wherein a distal-facing end of the outer is braced against a tapered face of the tractor tube proximal to the outer tractor tube portion, and wherein the outer tractor tube portion inverts over itself at a distal-facing region of the tractor tube and extends proximally within the outer tractor tube portion as an inner tractor tube portion that is coupled to the inner tractor puller; pulling the inner tractor puller proximally to compresses the outer tractor tube portion of the tractor tube, and to cause the outer tractor tube portion of the tractor tube to roll over itself, unsupported, at the distal-facing region and to invert into the inner tractor tube portion; engaging the clot with the tractor tube as it rolls over itself so that the clot is pulled into the tractor tube; and withdrawing the self-rolling mechanical atherectomy holding the clot from the blood vessel.

BRIEF DESCRIPTION OF THE DRAWINGS

[00037] The novel features of the invention are set forth with particularity in the claims that follow. A better understanding of the features and advantages of the present invention will be obtained by reference to the following detailed description that sets forth illustrative

embodiments, in which the principles of the invention are utilized, and the accompanying drawings of which:

[00038] FIGS. 1A-1C illustrate an example of an apparatus for mechanically removing an object such as a clot from a body region that include an inverted tube (e.g., “tractor” tube) of material that rolls and inverts over the distal end of an inner catheter. FIG. 1A shows the device, including the tractor tube portion connected to a puller that is within the catheter. The tractor tube may be deployed in a vessel near a clot, as shown in FIG. 1B. To activate this type of mechanical thrombectomy device the end of the tractor tube in the catheter, which is shown connected to a puller also within the catheter, is pulled proximally away from the clot, rolling the tractor tube over the distal end of the catheter and inverting it, as shown in FIG. 1C. The clot may then be drawn into the catheter by the rolling and inverting action of the tractor tube.

[00039] FIG. 2A illustrates one example of a self-rolling mechanical atherectomy apparatus that is configured so that the distal-facing portion of the tractor tube inverts over itself, unsupported, when the internal tube portion of the tractor tube is pulled proximally. In FIG. 2A, the apparatus includes an outer tractor pusher (e.g., catheter, cannula, tube, etc.), a tractor tube that is inverted over itself at a distal-facing portion of the apparatus, and an inner tractor puller (e.g., rod, catheter, cannula, tube, etc.) connected to an inner tractor tube portion of the tractor tube that is inverted relative to the outer tractor tube portion and extends inside of the outer tractor tube portion.

[00040] FIG. 2B shows the apparatus of FIG. 2A within a delivery catheter (e.g., a distal access catheter).

[00041] FIG. 2C is another example of a self-rolling mechanical atherectomy apparatus similar to the one shown in FIG. 2A, in which the end of the outer tractor tube portion of the tractor tube that is on the outside of the inverted tractor tube is attached to the outer tractor pusher.

[00042] FIG. 2D is another example of a self-rolling mechanical atherectomy apparatus similar to the apparatus shown in FIG. 2D, in which the end of the outer tractor tube portion of the tractor tube that is on the outside of the inverted tractor tube is attached to an outer tractor pusher that is internal to an outer (e.g., distal access) catheter, and may be used to push or pull the tractor tube from the proximal end. The outer catheter may be slid distally to protect the tractor portion, or it may be held proximally relative to the outer tractor pusher to help support the proximal end of the outer tractor tube portion of the tractor tube.

[00043] FIGS. 3A and 3B show examples of self-rolling mechanical atherectomy apparatuses. In FIG. 3A, the tractor tube is formed of as a woven structure that is configured to compress with a large braid angle under tension, e.g., when pushing the outer tractor tube portion distally and/or pulling the inner tractor tube portion proximally, and is further configured to have a small braid angle in the inner tractor tube portion. Thus, the tractor tube supports itself so that it may roll over itself and invert at a distal-facing region when either the inner tractor tube portion of the tractor tube is pulled proximally (and the outer tractor tube portion of the tractor tube is held in position or pushed distally), or when the outer tractor tube portion of the tractor tube is pushed distally (and when the inner tractor tube portion is pulled proximally or held in position). The tractor tube rolls over itself at the distal-facing region of the tractor tube and this rolling action may draw material into the inner tractor tube portion. FIG. 3B is similar to FIG. 3A, except that one end of the tractor tube (the region adjacent to the outer tractor tube portion) is constrained within the outer tractor pusher, and the outer tractor pusher pushes or braces against the tapered surface between the constrained region and the outer tractor tube portion.

[00044] FIGS. 4A-4D illustrates the operation of a self-rolling mechanical atherectomy apparatus such as those shown in FIGS. 2A-3. In FIG. 4A, the self-rolling mechanical atherectomy apparatus has a tractor tube is inverted over itself at a distal-facing region, and includes an inner tractor tube portion that is connected to an inner tractor puller. The inner tractor puller shown may be a rod, catheter, or cannula (e.g., hypotube). In this example, the end of the outer tractor tube portion of the tractor tube is connected to an outer tractor pusher (catheter). FIG. 4B illustrates the self-rolling mechanical atherectomy apparatus being actuated to roll and invert the tractor tube over itself, unsupported, at its distal-facing region. In FIG. 4B, the outer tractor tube region has sufficient column strength to prevent buckling, or collapse of the tractor tube under the applied tension. The apparatus is actuated in FIG. 4B by pushing the outer tractor pusher distally (to the right) while holding the inner tractor puller fixed relative to the patient's body (e.g., the vessel). FIG. 4C shows actuation of the self-rolling mechanical atherectomy apparatus of FIG. 4A so that the tractor tube rolls and inverts from the outer tractor tube portion to the inner tractor tube portion at the distal-facing region by holding the outer tractor pusher and pulling proximally on the inner tractor puller. FIG. 4D illustrates actuation of the self-rolling mechanical atherectomy apparatus of FIG. 4A by both pulling the inner tractor tube portion proximally (e.g., by pulling the inner tractor puller proximally) and by pushing the outer tractor tube portion distally (e.g., by pushing the outer tractor pusher distally).

[00045] FIGS. 5A-5D illustrate the use of a self-rolling mechanical atherectomy apparatus such as those shown schematically above, to remove a clot (thrombus) from within a vessel. In FIG. 5A, the apparatus includes an outer catheter (e.g., distal access catheter), a tractor tube having an outer tractor tube portion that inverts at a distal-facing region into an inner tractor tube portion, an inner tractor puller connected at the proximal end of the inner tractor tube portion of the tractor tube, and an outer tractor pusher connected at the proximal end of the outer tractor tube portion of the tractor tube. The apparatus is in a vessel and is maneuvered so that the distal-facing end region of the tractor tube is adjacent to the clot. Once positioned, the outer catheter may be withdrawn, and tension may be applied (e.g., by pushing distally on the outer tractor pusher), expanding the tractor tube within the vessel, as shown in FIG. 5B. The tractor tube may be positioned at or against the clot. Thereafter, the tractor tube may be rolled on itself, unsupported by any internal catheter at the distal-facing end region, as shown in FIG. 5C, by pulling the inner tractor puller proximally and/or pushing the outer tractor pusher distally, drawing the clot into the inner tractor tube portion. This process may be continued until the entire clot is pulled into the inner tractor tube portion, as shown in FIG. 5D. Thereafter the tractor tube, outer tractor pusher and inner tractor puller may be withdrawn back into the distal access catheter and withdrawn from the vessel.

[00046] FIGS. 6A-6D illustrate a method of removing of a clot using a self-rolling mechanical atherectomy apparatus. In FIG. 6A, the apparatus includes a tractor tube having an outer tractor tube portion, distal-facing region where the outer tractor tube portion inverts into an inner tractor tube portion, and an inner tractor puller that is connected to the inner tractor tube portion. The tractor tube and the inner tractor puller are held within a distal access catheter, and the outer tractor tube portion is unattached. The self-rolling mechanical atherectomy apparatus is positioned within a vessel near a clot. In FIG. 6B the outer distal access catheter is withdrawn proximally and/or the inner tractor puller is advanced distally, so that the tractor tube is partially extended from the distal end of the outer distal access catheter and adjacent to the clot. The outer tractor tube portion is placed under tension, e.g., by pulling the inner tractor puller proximally, as shown in FIG. 6B, expanding the outer tractor tube portion so that it is jammed against the distal opening of the outer distal access catheter. As the inner tractor puller is pulled proximally, the tractor tube rolls and inverts at the distal-facing region, drawing the inner tractor tube portion proximally and engaging the clot, as shown in FIG. 6C. The inner tractor tube portion is withdrawn proximally by pulling the

inner tractor puller until the clot is engulfed, as shown in FIG. 6D. The self-rolling mechanical atherectomy apparatus, holding the clot, may then be withdrawn.

[00047] FIG. 7A-7B illustrate possible failure modes for the operation of a self-rolling mechanical atherectomy apparatus. In FIG. 7A, the tractor tube (e.g., the outer tractor tube portion) is shown collapsed when applying tension by pulling the inner tractor puller proximally. In FIG. 7B, the tractor tube (e.g., the outer tractor tube portion) is shown collapsed when applying tension by pushing the outer tractor pusher (e.g., an outer catheter) distally. The configuration of the tractor tube may be configured to avoid this failure mode, including adjusting the braid angle of the outer and/or inner tractor tube portions, the amount of expansion of the tractor in the outer tractor tube portion, the number of strands (or strand equivalents) forming the tractor tube, the minimum length of expanded tractor tube, the material used for the tractor tube, the thickness of the strands or strand equivalents of the tractor tube, the porosity of mesh forming the tractor tube, or combinations of these.

[00048] FIGS. 8A and 8B illustrate another example of a possible failure mode of a self-rolling mechanical atherectomy apparatus. FIG. 8A shows an example of a self-rolling mechanical atherectomy apparatus. FIG. 8B show the apparatus of FIG. 8A when the outer tractor tube portion is placed under tension by advancing the outer catheter (e.g., outer tractor pusher) relative to the inner tractor puller, collapsing the proximal end of the outer tractor pusher portion

[00049] FIG. 9 schematically illustrates a self-rolling mechanical atherectomy apparatus showing examples of internal and external braid angles for the outer tractor tube portion and the inner tractor tube portion, respectively.

[00050] FIG. 10 is an example of the distal-facing region of a self-rolling mechanical atherectomy apparatus.

[00051] FIG. 11 is an example of a self-rolling mechanical atherectomy apparatus including a tractor tube that is inverted over itself, and an inner tractor puller.

[00052] FIG. 12 shows an example of the attachment of an outer tractor tube portion of a tractor tube connected to an outer tractor pusher, showing the braid angle of the outer tractor tube portion.

[00053] FIG. 13 is another example of a distal-facing region of a self-rolling mechanical atherectomy apparatus, similar to that shown in FIG. 10.

[00054] FIGS. 14A-14D show examples of a method of using a self-rolling mechanical atherectomy apparatus having a pre-shaped tractor tube. In FIG. 14A the self-rolling mechanical atherectomy apparatus, which is held within a distal access catheter, is positioned

adjacent to a clot within a blood vessel. Once positioned, distal access catheter is withdrawn, allowing the outer tractor tube portion of the tractor tube to expand, as shown in FIG. 14B. The proximal end of the outer tractor tube portion is tapered, as shown, and may present a face that the distal access catheter, acting as an outer tractor pusher, may push against, as shown in FIG. 14C. The proximal end may be shape-set into this tapered shape, or it may be formed in this shape. Thereafter, the proximal end of the inner tractor tube portion may be pulled proximally to roll the outer tractor tube portion over itself (unsupported) so that it inverts into the inner tractor tube portion, capturing and drawing the clot with it, as shown in FIG. 14D. The inner tractor tube may be pulled fully back into the outer tractor pusher (in this example, the distal access catheter) and withdrawn from the body.

[00055] FIG. 15A illustrates an example of a tractor tube including an outer tractor tube portion that is tapered forming a face that may be braced against an outer tractor pusher. The distal end of an exemplary outer tractor pusher is shown for reference. FIG. 15B is an example of another example of an outer tractor tube portion including a collar (shown as a ring) that forms a tapered shape at the proximal end of the outer tractor tube portion or a tractor tube.

[00056] FIGS. 16A-16C illustrate another example of a self-rolling mechanical atherectomy apparatus in which the proximal end of the outer tractor tube portion of the tractor tube of the apparatus is releasably attached to an outer tractor pusher, e.g., by bonding with a frangible material, mechanical connection, dissolvable connection, etc. In contrast, the proximal end of the inner tractor tube portion of the tractor tube may be permanently bonded to an inner tractor puller, as shown in FIG. 16A. FIG. 16B illustrates the use of the self-rolling mechanical atherectomy apparatus of FIG. 16A to grab and withdraw a clot from a vessel by pulling the inner tractor tube portion of the tractor tube proximally, so that the outer tractor tube portion rolls over itself, unsupported, at the distal-facing region of the tractor tube, and inverts to become more inner tractor tube portion. FIG. 16C illustrates the fully withdrawing the tractor tube into the outer tractor pusher, releasing the end of the tractor tube that is attached to the outer tractor pusher and allowing the entire (now inverted) tractor tube to be withdrawn into the apparatus.

[00057] FIGS. 17A-17D illustrate exemplary tractor tubes formed by cutting (e.g., laser cutting) a tubular material.

[00058] FIGS. 18A-18C illustrate different slotted patterns that may be cut into a tube (or sheet) to form a tractor tube or portion of a tractor tube.

[00059] FIG. 19 is another example of a pattern that may be used to form a tractor tube.

[00060] FIGS. 20A-20B show an example of a pattern that may be use to form a tractor tube. FIG. 20B is an enlarged view of the pattern of FIG. 20A.

[00061] FIGS. 21A-21B show an example of a pattern that may be use to form a tractor tube. FIG. 21B is an enlarged view of the pattern of FIG. 21A.

[00062] FIGS. 22A-22B show an example of a pattern that may be use to form a tractor tube. FIG. 22B is an enlarged view of the pattern of FIG. 22A.

[00063] FIGS. 23A-23B show an example of a pattern that may be use to form a tractor tube. FIG. 23B is an enlarged view of the pattern of FIG. 23A.

[00064] FIGS. 24A-24B show an example of a pattern that may be use to form a tractor tube. FIG. 24B is an enlarged view of the pattern of FIG. 24A.

[00065] FIGS. 25A-25B illustrate tractor regions having different patterns of slots and openings.

[00066] FIG. 26A illustrates another example of a tractor portion of a self-rolling mechanical atherectomy apparatus, showing properties of different regions (“zones”) of the tractor tube in different configurations, including an inner tractor tube portion that stretches in tension, a distal-facing region between the inner tractor tube portion and the outer tractor tube portion, a high column strength outer tractor tube portion, a constrained region at the proximal end of the outer tractor tube portion, and a transition zone between the high column strength outer tractor tube portion and the constrained region.

[00067] FIGS. 26B and 26C illustrate the functional operation of the different regions (“zones”) of the self-rolling mechanical atherectomy apparatus shown in FIG. 26A. Pulling on the inner tractor tube portion (e.g., by pulling on the inner tractor tube portion itself or on an inner tractor puller to which it is attached) causes the outer tractor tube portion closest to the distal-facing region of the tractor tube to roll over itself and invert into the inner tractor tube portion; at least in part because of the high column strength of the outer tractor tube portion and the strength of the transition zone preventing the tractor tube from collapsing (as shown in FIGS. 7A-7B and 8B). FIG. 26B shows a side perspective view, while FIG. 26C shows a sectional view through the self-rolling mechanical atherectomy apparatus of FIG. 26B during operation of the apparatus.

[00068] FIG. 27A shows a top view looking proximally on the distal-facing region of the tractor puller of FIGS. 26A-26C, showing the change in the braid angle from the high column strength (large braid angle) outer tractor tube portion in compression, to the elongated (small braid angle) inner tractor tube portion in extension, when pulling the inner tractor tube portion proximally.

[00069] FIG. 27B shows a bottom view looking distally from the constrained region at the proximal end of the outer tractor tube portion, showing the inside of the distal-facing region of the tractor tube.

[00070] FIG. 28 illustrates a shape outline of a tractor tube of a self-rolling mechanical atherectomy apparatus, showing a funnel shape that may be formed as the tractor tube is rolled over itself, unsupported, at the distal-facing region. The tractor tube may be configured to form this funnel shape; the tractor tube may be a braided, woven, knit, solid, or some combination of these.

DETAILED DESCRIPTION

[00071] In general, described herein are self-rolling mechanical thrombectomy apparatuses having an inverting tractor tube that is configured to roll over and into itself at an unsupported distal-facing region that is at the very distal end of the apparatus, which may be used to capture and remove a blood clot from a blood vessel. These apparatuses may include a tractor tube that comprises a flexible tube that doubles back over (e.g., inverts) over itself so that an outer portion (e.g., an outer tractor tube portion) rolls and inverts, becoming an inner portion (e.g., an inner tractor tube portion) as this inner portion is pulled proximally. The apparatus typically includes an outer tractor pusher that supports and/or pushes the tractor tube just proximal to the proximal end of the outer tractor tube portion. The tractor tube may taper from the outer tractor tube diameter (which is typically larger than the diameter of the outer tractor pusher) to a diameter that is smaller than the inner diameter of the outer tractor pusher. The end of the tractor tube may be attached to the outer tractor pusher or it may be unattached to the outer tractor pusher. Any of these apparatuses may also include an inner tractor puller that is coupled to the other end of the tractor tube (e.g., the end that become the proximal end of the inner tractor tube portion when operating as described herein). Thus, the apparatus may be actuated to cause the tractor tube to roll and invert over itself, unsupported at the distal-most end, by pulling directly on the inner tractor tube portion or by pulling on an inner tractor puller that is coupled to the proximal end of the inner tractor tube portion.

[00072] Thus, in general, the inner tractor tube portion may therefore be pulled proximally to roll and invert the tractor tube over itself, without the need to roll over an annulus at the distal end of an elongate inverting support, since the apparatus may be configured to have a sufficient column strength on the outer portion of the tractor tube (the radially-expanded and longitudinally compressed outer tractor tube portion) to prevent buckling, bending or failure of the tractor tube when compression force (e.g., up to 300 g or more, 350 g or more, 400 g or

more, 500 g, etc.) is applied to the outer tractor tube region by pulling the inner tractor tube region proximally. This is an improvement compared to other mechanical atherectomy apparatuses, including those described and shown in FIGS. 1A-1C, which typically include an elongate support that includes an annulus over which the tractor inverts at the distal end.

5 The support (e.g., catheter) is typically positioned in the distal end region (e.g., the distal-facing tractor tube region) of the apparatus and the tractor tube inverts over it, rather than over itself; such embodiments may therefore require that the support be maneuvered with the tractor, any outer catheter and any inner puller.

[00073] For example, FIGS. 1A-1C shows an example of a mechanical thrombectomy apparatus that is not self-rolling. In this variation, an elongate inversion support is included (shown here as catheter 101) as a part of the mechanical thrombectomy apparatus. In this example, the elongate inversion support catheter 101 has a distal end region 103 that includes a distal end opening. The distal end region may have an increasing softness (measured by durometer, e.g., shore durometer) except that the very distal-most end region may be
15 substantially less soft than the region immediately proximate to it.

[00074] In FIG. 1A, the elongate inversion support (e.g., catheter 101) is an elongate hollow catheter having a column strength that is sufficient to prevent buckling when the catheter is pulled over the distal annulus (distal end opening). Thus, the elongate inversion support may be configured so that it does not collapse (e.g., buckle) when 500 g or more of
20 compressive force is applied (e.g., at least about 700 g, 600 g, 500 g, 400 g, 300 g, etc. of compressive force), for neurovascular applications. For peripheral vascular applications the elongate inversion support may be selected or configured to withstand a higher force (e.g., at least 1500 g of compressive force, at least about 2000 g, 1900 g, 1800 g, 1700 g, 1600 g, 1500 g, 1400 g, etc. of compressive force). The elongate inversion support may not be a full-
25 length catheter, but may include a portion of a catheter, typically at the distal end, connected to a rod, wire, hypotube, or the like or may be skived. However, in each of these example, the support extends to the distal end region of the apparatus to provide a supporting surface over which the tractor tube can roll.

[00075] In FIG. 1A the support catheter 101 of the elongate inversion support may be any
30 appropriate type of catheter or portion of a catheter, including microcatheters appropriate for neurovascular use.

[00076] FIG. 1B shows an example of a flexible tractor 144 coupled to a puller 146. In this example to form a pullable tractor assembly 140, the tractor is shown integrated with the puller, forming the assembly, however the support catheter 101 extends between the outer

tractor tube portion and the inner tractor tube portion all the way to the distal-facing tractor portion at the distal-most end of the apparatus. In FIG. 1C, the tractor is a tube of material (e.g., wove, knitted, braided, etc.) that is flexible and elongate. In general, it may be particularly beneficial if the relaxed outer diameter of the flexible tractor in this first configuration has a greater outer diameter than the outer diameter of the catheter of the elongate inversion support into which the tractor will be positioned prior to inverting. The flexible and tubular tractor 144 may be sufficiently soft and flexible (e.g., having a low collapse strength) so as to easily roll and fold over the distal aperture of the elongate inversion support. The puller 146 may typically be a less-expandable (or non-expandable) structure (tube, puller, etc.). In the example shown in FIG. 1C, the tractor 144 is configured, e.g., by shape-setting (heat setting, etc.), to expand in the relaxed first configuration to a radial diameter that is between 1.1 and 10 times the diameter of the inner diameter of the catheter of the elongate inversion support when unconstrained, as shown in FIG. 1C. In FIG. 1C, the tractor of FIG. 1C is shown in an expanded, relaxed, configuration. Thus the expandable tractor may be biased to expand open. The tractor may be formed of a mesh, braided, woven, knitted, or sheet of material and is generally adapted to grasp the object to be removed (e.g., blood clot).

[00077] In FIG. 1C, the flexible tractor of FIG. 1B is shown with the tractor doubled back over itself and over the distal end of the catheter of the elongate inversion support 101. The distal end region is collapsed down, e.g., onto the puller and the elongate inversion support, and may be held collapsed. In this example a tractor hold 188 may be used to hold the tractor collapsed down onto the outer diameter of the elongate inversion support. However, in an unconstrained or deployed configuration the tractor (e.g., the portion that is inverted over the distal end of the catheter) has an outer diameter that is greater than the outer diameter of the catheter of the elongate inversion support. Thus, the tractor 144 may be biased so that it has a relaxed expanded configuration in the first configuration (as shown in FIG. 1C) that is greater than the inner diameter (ID) of the catheter of the elongate inversion support portion of the apparatus and the relaxed expanded configuration of the second configuration inverted over the catheter has an OD that is greater than the OD of the catheter. The tractor is expandable and may be coupled to the puller. In some variations the flexible tractor and the puller may comprise the same material but the tractor may be more flexible and/or expandable, or may be connected to a push/pull wire or catheter.

[00078] FIG. 1C illustrates the removal of a clot using this supported tractor apparatus shown in FIGS. 1A and 1B. In this example the apparatus is configured as a thrombectomy

apparatus including a catheter of an elongate inversion support 101 and a flexible tractor that extends over the distal end region of the catheter and doubles-over itself at the distal end of the catheter to invert so that the external tractor end region is continuous with an inner less-expandable (in this example, less-expandable includes non-expandable) second distal end
5 region 146 (puller) that extends proximally within the catheter and forms an inner lumen that may pass a guidewire. The pusher/puller member that may be a rod or other member that is continuous with the distal end region of the tractor.

[00079] However, described herein are self-rolling atherectomy (thrombectomy) apparatuses that do not need to roll over a support such as an elongate inversion support
10 catheter. Instead, these apparatuses are configured to roll over just themselves, unsupported at their distal end. FIGS. 2A-2D illustrate examples of self-rolling thrombectomy apparatuses 200. Any of these apparatuses may include a tractor tube 206 (e.g., having, in a deployed configuration, an outer tractor tube portion 204, an inner tractor tube portion 208, and a distal-facing region 206 at which they invert) that may be configured to prevent collapse
15 when under compression. In FIG. 2A, the apparatus also includes an inner tractor puller 205 coupled to the proximal end of the inner tractor tube portion 208, and an outer tractor pusher 207 which is shown (in this example) unconnected to the tractor tube.

[00080] FIGS. 2B-2D illustrate other variations of the self-rolling atherectomy apparatuses. In FIG. 2B, the apparatus of FIG. 2A is shown in a separate distal access
20 catheter 211. The tractor tube is in an un-deployed configuration, within the distal access catheter; once deployed, the outer tractor tube portion may expand as shown in FIG. 2A. The self-rolling atherectomy apparatus shown in FIG. 2C is similar to that shown in FIG. 2A, however the proximal end of the outer tractor tube 204 is attached 213 to the outer tractor pusher 207. In FIG. 2D, the apparatus of FIG. 2C is shown including both an outer tractor
25 pusher 207 as well as a distal access catheter 211.

[00081] Any of these apparatuses may include a guidewire lumen extending through the tractor tube and/or inner tractor puller that is configured to pass a guidewire.

[00082] Any of these apparatuses may include one or more projections that are configured to enhance engaging and/or maceration of a clot. Engaging the clot may be particularly, but
30 not exclusively, helpful when the tractor is lubricious. It may also be particularly helpful to include projections that are retracted along the length of the tractor adjacent to the outer diameter of the elongate inverting support (e.g., catheter), for example, when positioning the apparatus within a vessel, but extend the projections outward from the tractor when rolling and inverting to grab a clot.

[00083] In many of the examples described herein, the tractor tube and/or inner tractor puller may extend for any appropriate distance (including between 1-100 cm, between 2-100 cm, greater than 1 cm, 2 cm, 3 cm, 4 cm, 5 cm, 6 cm, 7 cm, 8 cm, 9 cm, 10 cm, 11 cm, 12 cm, 15 cm, 20 cm, etc.). Similarly, the outer tractor pusher may extend to the same length or longer. The tractor tube may form an elongate lumen that is configured to allow passage of a guidewire, as mentioned. The tractor tube may also be configured to slide along the long axis within a distal access catheter (and/or an outer tractor pusher) lumen, e.g., during initial placement in the vessel. The tractor tube may therefore be longitudinally slideable within the distal access catheter, and may be arranged so a portion of the tractor tube (the distal –facing tractor region) doubles back over itself within the distal access catheter/outer tractor pusher or after being deployed from the distal access catheter or outer tractor pusher.

[00084] In general the self-rolling mechanical thrombectomy apparatuses described herein may be highly flexible, both before actuating and during operation.

[00085] The self-rolling mechanical thrombectomy apparatuses described herein typically create a rolling cylinder (tractor or tractor tube) that may be used to entrap or ensnare foreign objects from the human body.

[00086] The structure of the tractor tube may be formed from wires, threads, filaments, laser slotted tubing, or the like. The tractor tube may be braided, or may have a braided appearance. See, e.g., FIG. 3. When activated to roll and invert over itself, the tractor tube may produce a center-grabbing effect, similar to conveyor belt. The self-rolling mechanical thrombectomy apparatus may be delivered via a catheter (e.g., distal access catheter and/or outer tractor pusher) to a site of interest (peripheral vessel, neuro vascular, MIS surgical procedure, etc.). When the apparatus is in place, the device may be pushed and/or pulled, as described and illustrated below to activate the tractor tube so that it acts like a grabbing conveyor belt.

[00087] For example, FIG. 3A illustrates an apparatus including a tractor tube 303, outer tractor pusher 305 and inner tractor puller 307. The tractor tube is shown in a deployed configuration. In this example, the tractor tube 303 includes an outer tractor tube portion 309 that is shown in a compressed configuration having a large braid angle (e.g., greater than 150 degrees in this example). The tractor tube 303 also includes an inner tractor tube portion 311 that has a much smaller braid angle (e.g., less than 45 degrees in this example). The portion of the tractor tube proximal to the outer tractor tube portion 309 is a constrained region 313 that may be held (e.g., by shape setting, by a mechanical or structural constraint, such as a ring or catheter, etc.) in an intermediate configuration that is not as radially expanded as the

outer tractor tube portion 309. A tapered region 315 is formed between the constrained region 313 of the tractor tube and the outer tractor tube portion 309 and may act as a bracing surface for an outer tractor pusher 305' (as shown in FIG. 3B). In FIG. 3A, the outer tractor pusher is shown pushing against 317 the end of the constrained region 313 of the tractor tube 303.

5 [00088] In FIG. 3A and 3B, the tractor tube includes a distal-facing region 319 where the tractor tube rolls and inverts over itself. As will be illustrated below (e.g., in FIGS. 26A-26C), when the outer tractor pusher pushes against the end of the tractor tube closest to the outer tractor tube portion and the inner tractor tube portion is pulled proximally, the resulting compressive force compresses the outer tractor tube region 309, resulting in a column
10 strength that prevents buckling and failure of the tractor tube while driving rolling of the outer portion of the tractor tube over and into itself at the distal-facing region 319 of the tractor tube.

[00089] Thus, any of these apparatuses may include a patterned (e.g., braided) tractor tube that may be shape set (e.g., heat set). The inner tractor tube region may be configured to have
15 a lower column strength that allows it to expand to adjust to the clot diameter as it is drawn into the tractor tube.

[00090] FIGS. 4A-4D illustrate examples actuating a self-rolling mechanical atherectomy apparatus. For example, in FIG. 4A, similar to that shown in FIG. 2A-2D, the self-rolling mechanical atherectomy apparatus includes a tractor region (having an expanded/deployed
20 outer tractor region 404 that is continuous with an inner tractor region 408 after rolling and inverting over itself at the distal-facing region. In FIG. 4D the apparatus is shown deployed, with the outer tractor tube portion 404 expanded radially, having an outer diameter that is greater than the inner diameter of the outer tractor pusher 405. The outer tractor pusher is braced against the tapered region 415 proximal to the outer tractor tube region.

25 [00091] FIGS. 4B-4D illustrate alternative methods of actuating the tractor tube so that it rolls over itself and inverts, unsupported, only at the distal end. For example, in FIG. 4B, the outer tractor pusher 405 is pushed distally while the inner tractor puller is held, causing the outer tractor tube portion to roll over itself 431 and invert into the inner tractor tube portion, as shown. Similarly, in FIG. 4C, the tractor tube is actuated by pulling proximally on the
30 inner tractor tube portion while holding the outer tractor pusher in place. FIG. 4D illustrates a combined method including both pushing the outer tractor pusher distally while pulling the inner tractor puller proximally; the two may be operated at different rates or distances. For example, the inner tractor puller may be pulled more proximally than the outer tractor pusher is pushed. In some variations, the entire apparatus may be advanced distally by

pushing the outer tractor pusher distally, while still pulling the inner tractor puller proximally to roll the tractor tube into itself, as shown.

[00092] FIGS. 5A-5D illustrate removal of a clot using a self-rolling mechanical atherectomy apparatus as described herein. In this example, the self-rolling mechanical atherectomy apparatus is a co-axial system including both a distal access catheter 509 and an outer tractor pusher 511, as well as an inner tractor puller 513. The apparatus is deployed in a blood vessel 503. In FIG. 5A, the self-rolling mechanical atherectomy apparatus is shown in an un-deployed configuration in which the tractor tube 505, which is connected at one end 523 to the outer tractor pusher, and at the other (inner) end to the inner tractor puller 513, is in a collapsed configuration within the lumen of the distal access catheter 509. The apparatus is initially positioned adjacent to the clot 519 (FIG. 5A). The distal-facing end 516 of the tractor tube is shown initially inside the distal end of the distal access catheter 509. The tractor tube 505 can either be preloaded in the distal access catheter 509 during access or delivered through the distal access catheter after the distal access catheter is positioned adjacent to the clot. The inner tractor puller can be cannulated (like a catheter) to allow delivery of a guidewire through its self to aid in delivery of the system to the clot. In FIG. 5A, the distal-facing region 516 of the tractor tube is the distal-most end of the assembly. Alternatively the distal-facing region 516 of the tractor tube can be inverted on itself (not shown) prior to delivering the system up to the clot.

[00093] The tractor tube may be made of a braid structure as described above. In this example, when constrained, it may have low braid angles (e.g., between 5 - 90 degrees, between 5-45 degrees, between 5-30 degrees, etc.). After it is released from the distal access catheter and deployed, the braid angle would may be much larger; once compression is applied to the outer tractor tube portion, e.g., by pulling on the inner tractor puller, the braid angle will be much larger (e.g., between 80-170 degrees), while the braid angle in the portion under tension (e.g., the inner tractor tube portion) may be much lower (e.g., less than 90 degrees, less than 80 degrees, less than 70 degrees, etc.). In this context, the braid angle referred to herein may refer to the braid angle relative to the proximal-to-distal axis, and the angle formed between intersecting strands of the mesh forming the tractor tube. This is illustrated below, in FIG. 9.

[00094] In FIG. 5B, the apparatus is shown deployed from the distal access catheter by pulling back on the distal access catheter to release the tractor tube, allowing it to expand radially to an outer diameter that is larger than the inner diameter of both the distal access catheter and the outer tractor pusher. Alternatively or additionally, the tractor tube can be

driven forward out of the distal access catheter, (e.g. and into or towards the clot) rather than pulling back the distal access catheter.

[00095] In FIG. 5C, the inner tractor puller 513 is retracted proximally to cause the tractor tube to invert over and into itself, unsupported at the distal-facing region of the tractor tube, so that it can grab clot and pull the clot into the tractor tube, as shown. The distal facing region of the of tractor tube forms a conical shape as it inverts on its self. By continuing to pull the inner tractor puller or fix the inner tractor puller and push the outer tractor pusher (or some combination of both movements), the conical shape formed on the tractor tube behaves like a conveyor, engaging (i.e., “grabbing”) the clot 519 and pulling it into the tractor tube, engulfing the clot and capturing it, as shown in FIG.5D.

[00096] Pushing the outer tractor pusher and/or pulling the inner tractor puller may be continued until the clot is fully captured. The clot can be removed from the vessel by either withdrawing the entire system, or by pulling the tractor tube into the distal access catheter and then pulling out the tractor tube while leaving the distal access catheter in place. The distal access catheter and or other components (e.g., the inner tractor puller and/or tractor tube) can have vacuum applied during, before and/or after clot engagement by the tractor tube. Alternatively, while pulling the inner tractor puller and pushing the outer tractor pusher, the tractor tube may be withdrawn inside the distal end of the outer tractor pusher with the clot.

[00097] FIGS.6A-6D illustrate the operation of an alternative variation of a self-rolling mechanical atherectomy apparatus, in which the same catheter acts as both the distal access catheter (e.g., delivering the apparatus to the clot) and the outer tractor pusher, e.g., pushing or bracing the tractor tube from the proximal end to allow it to rollover itself distally.

[00098] In FIG. 6A, the apparatus includes a tractor tube 605 that is connected at one end to an inner tractor puller 613; both the tractor tube and the inner tractor puller are held within the outer tractor pusher 611 (acting as a distal access catheter). This configuration may be referred to as a single axial system. The tractor tube is not attached 623 to the outer tractor pusher in this example. In FIG. 6B, the tractor tube may be deployed by pulling back the outer tractor tube (distal access catheter) 611 and allowing the outer tractor tube portion of the tractor tube to expand radially, as shown. The tractor tube 605 can be fully deployed into vessel or the proximal end of the tractor tube can remain in the outer tractor pusher, as shown. The outer tractor pusher braces against the tractor tube at a tapered end before (e.g., just proximal to) the outer tractor tube portion. Alternatively, the tractor tube can be driven

forward into the clot and out of the outer tractor pusher rather than pulled back to deploy the tractor tube in the vessel.

[00099] In FIG. 6C, the inner tractor tube portion is retracted proximally so as to invert the tractor tube over and into itself, thereby engaging the clot 619. The distal-facing region of the tractor tube forms a conical shape as it inverts on itself when pulling the inner tractor puller and/or pushing the outer tractor pusher. By continuing to pull inner tractor puller or holding the inner tractor puller fixed and pushing the outer tractor pusher (or some combination of both movements), the conical shape formed on the tractor tube may act like a conveyor, engaging and pulling the clot into tractor tube (i.e., engulfing and capturing the clot). As shown in FIG. 6D, the clot may be engaged/grabbed and enclosed at least partially, within the tractor tube and removed from patient.

[000100] The self-rolling mechanical atherectomy apparatuses described herein may provide improved clot engagement with lower grabbing forces, and without jamming. As will be described in greater detail below, these apparatuses may be tuned to provide sufficient column strength so that they do not fail during operation, and the forces required to invert the tractor tube are relatively small. The high column stiffness of the expanded tractor tube acts like a catheter-tube, enabling it to be easily advanced forward in a vessel. Finally, these apparatuses can be used with or without aspiration.

[000101] As mentioned above, the self-rolling mechanical atherectomy apparatuses described herein are specifically configured so that the tractor tube portion rolls over itself, unsupported, at its distal end when pulling the inner tractor tube portion proximally and/or pushing the outer tractor tube portion distally. Generally, when pushing and/or pulling a flexible tube that is woven, braided, knitted, or even solid, the tractor tube will bend, buckle or collapse. This is particularly true of flexible tractor tubes that inverted over themselves and biased to expand radially outward in either or both the outer tractor tube configuration and the inner tractor tube configuration). Buckling and collapsing are therefore failure modes for such tractor tube which must be avoided if operating a self-rolling mechanical atherectomy apparatus.

[000102] FIGS. 7A-7B and 8A-8B illustrate these common failure modes. In FIG. 7A, self-rolling mechanical atherectomy apparatus 701 similar to those shown in FIGS. 2A-2D, 3A-3D, 4A-4D, 5A-5D, and 6A-6D are shown buckling or collapsing when either or both the inner tractor tube portion is pulled proximally (e.g., by pulling an inner tractor puller) or the outer tractor tube portion is pushed proximally (e.g., by pushing an outer tractor pusher). In FIG. 7A, a distal access catheter 709 is configured as an outer tractor pusher because a

tapered portion 712 of the tractor tube that is proximal to the outer tractor tube portion 703 of the tractor tube 705 is pushed against the distal opening face 710 of the distal access catheter when the outer tractor pusher (distal access catheter 709) is pushed distally while holding the inner tractor puller 711 fixed relative to the vessel wall as indicated (or alternatively pulling it
5 proximally). In this example, although the outer tractor tube portion 703 may be rolling over itself, unsupported, at its distal end (distal facing end 719), the outer tractor tube portion 803 in the expanded configuration (e.g., not constrained within the distal access catheter) does not have sufficient column strength to prevent the outer tractor tube portion from compressing and buckling. One or more outer tractor tube regions buckle 721, 721',
10 collapsing under the compressive force on the outer tractor tube portion. In some variations, the tractor tube will roll slightly, as shown in FIG. 7A; alternatively, the tractor tube will not roll at all, but will immediately collapse or buckle.

[000103] In FIG. 7A, the force required to roll and invert at the distal end is greater than the force that will cause the expanded outer tractor tube region to buckle; as a result, the outer
15 tractor tube buckles. Once the tractor tube 705 begins to buckle or collapse, it will no longer roll over the distal end region, may lead to further collapse. In addition, the force required to advance the increasingly collapsed tractor tube distally by pushing the outer tractor pusher/distal access catheter may increase substantially.

[000104] A similar failure may occur when pulling the inner tractor tube region proximally,
20 as illustrated in FIG. 7B. In FIG. 7B, a distal access catheter 709 is braced against the distal opening face of the distal access catheter and the inner tractor tube portion 707 is pulled proximally, by pulling on the inner tractor puller 711. The outer tractor tube portion 703 is in the expanded configuration (e.g., not constrained within the distal access catheter). Because the tractor tube 705 is unsupported at the distal-facing end 719, pulling on the inner tractor
25 tube portion 707 compresses the outer tractor portion 705. In this case, as in FIG. 7A, the compressive force is greater than column strength of the outer tractor tube portion. Typically, the force applied to actuate the devices described herein may be up to a maximum of about 400 g of force, (e.g., 300 g of force, 350 g of force, 400 g of force, 450 g of force, 500 g of force, 550 g of force, 600 g of force, etc.), particularly in neurovascular applications. When
30 the applied actuating force, which becomes the applied compressive force, is greater than the column strength of the outer tractor tube portion, the outer tractor tube portion buckles 731, 731' as shown in FIG. 7B.

[000105] Thus, in general, for any of the apparatuses described herein to operate, they must be configured so that the column strength of the expended outer tractor tube portion, which

may be a braided or woven material, is greater than at least the maximum force in the range of forces used to actuate the apparatus so that the tractor tube rolls and inverts over itself, unsupported, at its distal-facing end region. For example, the apparatuses described herein may be configured so that the outer tractor tube portion has a column strength that is

5 sufficient to resist buckling or collapse under a compressive force of least about 500 g.

[000106] In addition to the column strength of the outer tractor tube under compression, which may lead to buckling or collapse around the longitudinal length of the apparatus, as shown in FIGS. 7A-7B, FIGS. 8A-8B illustrate another failure mode causing collapse at the proximal end of the outer tractor tube portion, which may occur when the proximal tapered

10 portion of the expanded tractor tube buckles against the outer tractor pusher/distal access catheter.

[000107] For example, in FIG. 8A, a self-rolling mechanical atherectomy apparatus 801 is shown in an expanded or deployed configuration. The tractor tube 805 includes an outer tractor tube region 803 that is expanded out of the distal end of the distal access catheter. The tractor tube includes a proximal tapered region 812 that is braced against the distal end opening 810 of the distal access catheter 809. The apparatus also includes an inner tractor puller 811 that is connected to an end of the tractor tube 805; when the tractor tube rolls and inverts over itself at the distal-facing end 819, the inner tractor puller 811 will be attached to the proximal end of the inner tractor tube region. FIG. 8A shows the apparatus prior to

20 actuating by either or both pulling the inner tractor puller and/or pushing the outer tractor pusher (in this configuration, the distal access catheter).

[000108] In FIG. 8B, upon actuating the apparatus, e.g., by either or both pulling or pushing, the tapered region 812 at the proximal end of the outer tractor tube portion 803, against which the distal end opening 810 of the outer tractor pusher 809 pushes or braces

25 collapses, folding the proximal end of the outer tractor tube portion over the distal access catheter. In this example, the relative weakness of the proximal tapered region between the expanded outer tractor tube portion and the distal end opening of the outer tractor pusher/distal access catheter causes this tapered region to fail, so that the tractor tube rolls over 841 the open end 810 of the distal access catheter (and therefore over itself proximally),

30 rather than rolling over itself distally at the distal-facing opening 819.

[000109] As illustrated by FIGS. 7A-7B and 8B-8B, the apparatus, and particularly the tractor tube, should preferably be configured so that the column strength of the expanded outer tractor tube portion is greater than the maximum applied compressive force (e.g.,

actuating force), and the strength of the tapered region should resist the force applied by the outer tractor pusher.

[000110] Thus, a functional self-rolling mechanical atherectomy apparatus for removing a clot from a vessel should be configured to avoid at least these failure modes. Specifically a self-rolling mechanical atherectomy apparatus should have a tractor tube with a sufficient column strength in an expanded outer tractor tube portion so as to resist a compressive force of greater than at least some minimum threshold (e.g., 400 g of force, 500 g of force, 600 g of force, etc.). Alternatively or additionally, the tractor tube should have a tapered region proximal to the expanded outer tractor tube portion that is configured to resist the distally directed force applied by the outer tractor pusher.

[000111] Described herein are configurations and parameters for forming a tractor tube meeting these criterion. For example, the tractor tube may be formed of a material (and particularly a mesh, e.g., braided or woven material) having a braid angle in the expanded tractor tube, when compressed by pushing and/or pulling, in a proximal-to-distal axis that is between about 80 and about 170 degrees. The inner tractor tube portion may have a braid angle in the proximal to distal axis under tension of less than 80 degrees (e.g., less than 75 degrees, less than 70 degrees, less than 65 degrees, less than 60 degrees, less than 50 degrees, less than 45 degrees, less than 40 degrees, less than 35 degrees, etc.). In addition, the amount of expansion of the outer tractor tube portion may be between +/- about 30% of the outer diameter of the outer tractor pusher. In addition, for woven or braided configurations, the number of strands (or strand equivalents) may be at least 12 (e.g., 12 or more, 16 or more, 18 or more, 24 or more, 36 or more, 40 or more, 50 or more, 60 or more, 72 or more, etc.). The expanded tractor tube may also be configured to have a minimum length (e.g., of 0.7 cm or greater, e.g., 0.8 cm or greater, 0.9 cm or greater, 1 cm or greater, 1.2 cm or greater, etc.). For example, the unsupported tractor tube length may be ≥ 1 cm. When the tractor tube is formed of a woven or braided material, the material used for the tractor tube may be a monofilament or a collection of filaments. The tractor tube may also include a number of pores (e.g., cells) formed by the strands; the porosity of the mesh may be, for example, 70% or less (e.g., 65% or less, 60% or less, 55% or less, 50% or less, 45% or less, etc.) and in particular, 60% or less.

[000112] In general, the applicants have found that, for braided or woven tractor tubes having the following ranges of parameters, a self-rolling (e.g., unsupported) tractor tube apparatus will not kink or collapse or otherwise fail as described in FIGS. 7A and 7B and 8A-8B: the tractor tube may be formed of a least 10 strands and have a distal-to-proximal facing

braid angle for the expanded configuration of the outer tractor tube portion of between about 80 and about 170 degrees, a distal-to-proximal facing braid angle of the tensioned inner tractor tube portion that is always less than the braid angle of the expanded outer tractor tube portion and is about 80 degrees or less, further wherein the outer tractor tube portion of the tractor tube is configured to expand to between about +/- 30% of the outer diameter of the outer tractor pusher. Such tractor tubes may have sufficient column strength to resist collapsing when actuated (e.g., with at least 500 g of force) and under compression so as to roll over the distal-facing end of the tractor tube, unsupported.

[000113] For example, it may be preferable that, for braided or woven tractor tubes, the tractor tube is formed of a least 10 strands of materials (more preferably at least 12 strands of material, still more preferably at least 16 strands of material), where the strands have a thickness of about 0.003 inches or greater. The fibers forming the tractor tube may have a distal-to-proximal facing braid angle of between about 80 and about 170 degrees in the expanded outer tractor tube portion under compression and a braid angle in a distal-to-proximal direction of the tensioned inner tractor tube portion that is less than the braid angle of the expanded outer tractor tube portion and is 80 degrees or less. The outer tractor tube portion of the tractor tube may be configured to expand to within +/- about 30% of the outer diameter of the outer tractor pusher. The length of the tractor tube may be at least 1 cm or more.

[000114] Thus, in any of the apparatuses described herein, the tractor tube may be flexible enough to be pushed through a catheter located in the tortuous neuro vasculature anatomy. The tractor may be delivered partially inverted (e.g., rolled on itself) to the clot face through a catheter. The distal-facing end of the tractor tube is generally unsupported (e.g., the tractor tube does not roll over and against the distal opening of a catheter or other support). The unsupported outer tubular length of the tractor tube may be of adequate length when in its axial compressed form to grab typical clot lengths seen in stroke patients (e.g., 1 cm or greater) in a single pass/pull. Typically, the outer tractor tube portion rolls around the distal-facing end of the tractor tube when the distal-facing end of the tractor tube is adjacent and may be in contact (e.g., jammed up against) a clot. The user may then drive the outer tube distally by (or while) pulling the inner tractor puller, and therefore the inner tractor tube portion, proximally, and either supporting or pushing the outer tractor pusher distally. The axial pushing forces on the tractor tube generate an axial compressive load on the expanded outer tractor tube portion and, as long as the column strength is greater than the compressive load, and as long as the strength of the tapered region against the outer tractor pusher is

sufficient, the tractor tube will roll over itself, unsupported, without kinking, collapsing or otherwise failing. Thus, the flexible tractor tubes described herein are configured to have sufficient axially columnar stiffness that when axially compressive forces are applied, the outer tractor tube portion rolls and inverts rather than bunch, buckle, accordion or collapse.

- 5 [000115] In general, the outer tractor tube portion may be configured so that the maximum expansion relative to the outer diameter of the outer tractor pusher that it is supported against is sized appropriately so device doesn't jam in vessel when pushed & axially compressed, or collapse as shown in FIG. 8B. If the expanded outer diameter (OD) of the outer tractor tube portion is too big, the tractor tube may lock in the vessel when being pushed, rather than
10 advancing in the vessel or driving the rolling/inverting action. Similarly, if the tractor tube OD is too small, the tractor tube may not be large enough to grab the clot sufficiently (e.g., it may core out center of clot only, leaving some of the clot behind or requiring additional removal steps. Thus, in general, the tractor tube may be configured so that it does not over-expand, e.g., due to compressive forces are applied by user to the tractor tube.
- 15 [000116] In any of the apparatuses described herein, the tractor tube may have sufficient coarseness at its rolling tip to engage and grab a clot. For example, when the tractor tube rolls over the distal end of the apparatus, the inner tractor tube portion may maintain an adequate inner diameter (ID) to leave room for clot. Thus, the inner tractor tube portion may also be configured to expand radially outwards somewhat, rather than collapse onto itself when
20 pulled and tensioned proximally. For example, the inner tractor tube portion may be biased radially outwards to have an inner diameter that is 30% or more of the inner diameter of the expanded outer tractor tube portion (e.g., 35% or more, 45% or more, 50% or more, 55% or more, 60% or more, etc.). The tractor tube may generally be porous, which may provide additional coarseness. For example, it may be beneficial to have a porous structure that has
25 relatively small pores (e.g., small enough to capture all the clot when inverting/rolling), and a sufficient number of pores (e.g., less than 70%, less than 65%, less than 60%, less than 55%, less than 50%, etc. porosity).

- [000117] Any of the apparatuses described herein can be used in combination with vacuum/aspiration. For example a vacuum may be applied through the inner tractor puller
30 and/or the tractor tube. Further, any of the apparatuses described herein may be configured so that they are visible under fluoroscopy; in particular, the tractor tube or a portion of the tractor tube may be configured so that it is visible under fluoroscopy.

[000118] FIG. 9 shows one example of a self-rolling thrombectomy apparatus with a braided tractor tube that is configured to provide sufficient column strength in the outer

tractor tube portion when compressed to as to prevent failure by kinking, bending, collapsing or otherwise failing. In FIG. 9, the apparatus includes a distal access catheter 909, an outer tractor pusher 913, and a braided tractor tube 905. The braided tractor tube has an expanded, outer tractor tube portion 903, a tapered portion 912 proximal to the outer tractor tube portion, and an inner tractor tube portion 907 that is connected to an inner tractor puller 911. The tractor tube 905 inverts over itself so that the outer tractor tube portion rolls and inverts to become the inner tractor tube portion at the distal-facing end region 919.

[000119] In FIG. 9, an exemplary distal-to-proximal facing braid angle 909 (Φ_1) for the outer tractor tube portion is illustrated. This Φ_1 angle may be between 80 degrees and 170 degrees, but is more preferably > 90 degrees. In the example shown in FIG. 9, it is between 110 degrees and 160 degrees. FIG. 10 shows an example of a distal-facing end region 1019 of a prototype tractor tube that is configured as described above, including having a distal-to-proximal facing angle (Φ_1) 1015 of between 80 degrees and 70 degrees; in this example, the Φ_1 angle is approximately 130 degrees. Returning to FIG. 9, the outer tractor tube portion in the expanded state has a high braid angle, jammed braid state, and max diameter that provide a high resistance to axial compressive force (e.g., column strength in compression), which makes it easy to advance/push braid structure forward, as well as resisting kinking and failure of the tractor tube. In FIG. 9, the distal-to-proximal braid angle of the inverted, inner tractor tube region 911 (shown as Φ_2) is typically much smaller than Φ_1 , and may be, e.g., less than 90 degrees (e.g., less than 80 degrees, less than 70 degrees, less than 60 degrees, etc.). In FIG. 10, the distal-to-proximal facing braid angle of the inner tractor tube portion 1007 (Φ_2) is also shown, and in this example is about 35 degrees. The low braid angle of the inner tube region is formed as the braid collapses to a small diameter when the tractor tube rolls around distal-facing end, and inverts inside the larger outer tractor tube portion. In FIG. 10, the braided tractor tube is formed of 24 strands ("24 end") of 0.0005" x 0.0010" NiTi ribbon that is braided to have a maximum OD (when axially compressed of 2.5mm.

[000120] FIGS. 11, 12 and 13 illustrate other examples of tractor tubes that may be used as part of a rolling mechanical atherectomy apparatus as described. In FIG. 11, the tractor tube 1105 is shown inverted over itself. The outer tractor tube portion is expanded to a large braid angle. As described and shown above, the braid angle is the distal-to-proximal facing angle formed between intersecting strands of the braid. In FIG. 11 and FIG. 12, the braid angle is greater than 120 degrees for the fully expanded outer tractor tube portion 1103. The inner tractor tube portion is not easily visible in FIG. 11. The proximal end of the outer tractor tube portion is tapered, and has a smaller braid angle as it tapers down (e.g., the tapering braid

angle goes from the expanded outer tractor tube portion braid angle of >120 degrees to approximately 90 degrees where it is attached to the outer surface of the outer tractor pusher 1113. The tractor tube in FIG. 11 is formed of a braided Nickel titanium (NiTi) material. In FIG. 12 a similar tractor tube is shown, including a braid angle (distal-to-proximal facing) of the expanded outer tractor tube portion 1203 that is approximately 150 degrees. The tapered region 1212 proximal to the outer tractor tube portion transitions to a smaller braid angle (e.g., between about 100 and 70 degrees), where it is attached to the outer tractor pusher 1213. FIG. 13 shows a distal-facing end of a tractor tube of a self-rolling apparatus that is unsupported. The distal-facing end 1319 of the tractor tube shown illustrates the inverted, rolling end of the tractor tube. The tractor tube does not enclose or surround a support element (e.g., catheter, loop, etc.) at or near the distal-facing end that is rolling.

[000121] FIGS. 14A-14D illustrate an alternative to the “clot grabbing” tractor tube in which the region of the tractor tube that is proximal to the expanded outer tractor tube portion is shape set into a taper in the relaxed, otherwise expanded, configuration. For example, in FIG. 14A, the apparatus is configured as a single-axis system within a vessel 1402. In operation, the apparatus is delivered within the vessel 1402 through a distal access catheter 1409. A guidewire may also be used to position the apparatus. In FIG. 14A, the apparatus is compressed within the distal access catheter and slid or otherwise driven through the vessel to the clot 1455. The tractor tube 1405 is compressed, but is pre-rolled around itself with a distal-facing end region at the distal end of the device that may be positioned in proximity to the clot 1455 in the vessel. The inner tractor tube portion is attached to an inner tractor puller 1411. In this single axial system shown, the distal access catheter 1409 also acts as the outer tractor pusher once the tractor is pushed out of the catheter and expanded, as shown in FIG. 14B.

[000122] In FIG. 14B, the distal access catheter may be withdrawn proximally and/or the rest of the apparatus may be pushed distally, allowing the distal access catheter to release and deploy the apparatus so that the outer tractor tube portion 1403 can expand to a diameter that is within +/- 30% of the outer diameter of the distal access catheter/outer tractor pusher 1409. In this example, the distal access catheter is withdrawn proximally past the outer, proximal end of the tractor tube portion, showing that this end of the tractor tube is pre-set to a tapered shape 1412. Thus, in FIG. 13C, the distal access catheter (outer tractor pusher) may be advanced distally back over this tapered region, to either drive the outer tractor tube portion distally or to brace against the tapered portion and hold the outer tractor tube portion in position while pulling the inner tractor tube portion proximally, as shown. Thus, in FIG. 14C,

the distal-facing region of the tractor tube forms a conical shape as it inverts on itself when the inner tractor puller is pulled proximally and/or the outer tractor pusher (distal access catheter) is pushed distally. By continuing to pull inner tractor puller and/or hold the inner tractor puller and push the outer tractor pusher (or some combination of both movements), the conical shape formed on the tractor tube behaves like a conveyor, thereby “grabbing” the clot and pulling the clot into tractor tube (e.g., engulfing the clot/capturing the clot). Once the tractor tube is inverted, it (along with the captured clot) can be pulled into the distal access catheter, as shown in FIG. 14D. In FIG. 14D, the inner tractor puller can be fully retracted and the tractor tube can be removed from the patient out of the distal access catheter.

5 [000123] FIGS. 15A and 15B illustrate variations for forming the pre-set tapered regions of the tractor tube proximal to the expanded outer tractor tube portions. In FIG. 15A, the tapered proximal region 1512 is shown with a rolled distal-facing end region 1532. In this example, the maximum outer diameter is within a predefined range of the outer diameter of the outer tractor pusher catheter 1513 is within a predefined percentage (e.g., between about +/- 5%, 10%, 15%, 20%, 25%, 30%, 35%, 40%, 45%, 50%, etc. of the outer diameter of the distal access catheter 1513). The tapered distal region 1512 may be formed by shape setting to the tapered shape. Alternatively, as shown in FIG. 15B, the apparatus may include a limiter, such as a ring, neck, band, etc. 1552 that limits the expansion of the tractor tube portion.

10 [000124] For example, in FIG. 15B, the proximal end of the tractor tube 1505 on the outside of the tractor tube includes a polymer and/or metal ring 1552 or bulking agent to increase the effective wall thickness of the proximal end of the tractor tube, making it easier for the distal end opening of the distal access catheter to engage with this proximal end of the tractor tube, and may also support and allow for easier pushing of the construct, and/or prevent the failure mode shown in FIG. 8B, above. This can be achieved by bonding, fusing or integrating a separate element into the proximal end of the tractor tube (e.g., stent, O ring, beading of glue/adhesive, fusing or melting a polymer ring or by inverting the braid so the braid is doubled up on the proximal end, making the wall thickness thicker). Alternatively or additionally, the ends of the braid at this proximal end may be left open and even purposely frayed to provide filaments that would easily catch on the distal end of the distal access catheter when trying to push the tractor tube distally.

25 [000125] In general, the self-rolling apparatuses described herein may have a jammed braid angle on the outside of the tractor tube (e.g., a maximum diameter of the braid). The braid's maximum diameter during axially compression may be slightly smaller and/or larger than the vessel ID (e.g., it may have the same OD, > 5% bigger, >10% bigger, <5 % smaller, <10%

smaller, < 20% smaller, < 30% smaller, etc.). This may facilitate the structure advancing when pushed forward. Examples of high braid angles range from 80-170deg, or by an increment within that range by 10 deg or more. For example, a tractor tube for an M1 vessel (e.g., 2-2.5mmID) may have 36 braid ends of 0.001" NiTi wire formed onto a 2mm mandrel at max braid angle. This tractor tube may be annealed to this shape on the 2mm mandrel. In another example, a tractor tube may be formed for an M1 vessel (e.g., 2-2.5mmID), from 48 braid ends of 0.0005" by 0.001" of flat wire onto a 2.5 mm mandrel, at max angle. In another example, a tractor tube for an M1 vessel (e.g., 2-2.5mmID) may have a braid of 48 ends of 0.0005" by 0.001" flat NiTi wire onto a 2.5 mm mandrel, near max angle, that is removed from mandrel, and slid over a larger mandrel of 2.75mm (e.g., to increase braid angle to a jammed braid angle). In another example, for a larger vessel (e.g., 3-3.5 mm ID), a braid having 72 ends of 0.0005" by 0.001" of flat NiTi wire may be formed onto a 3 mm mandrel, near max angle, removed from the mandrel, and slid over a larger mandrel of 3.5 mm (to increase braid angle to a jammed braid angle). For much larger vessels (e.g., 5 -8mm) a 72 ends 0.002"-0.003" NiTi wire, having a max braid angle on 5-8 mm mandrel may be formed.

[000126] In general, the tractor tube may be formed of flat wires; this may help create a grabbing edge when the braid rolls. In addition, radiopaque wires can be mixed into the pattern for visibility under flouro (e.g., platinum, platinum iridium, DFT wire, gold, marker bands or beads, etc.). Any of these apparatuses can be delivered pre-loaded inside the distal access catheter and/or separately (e.g., using a secondary catheter after the distal access catheter is in position) delivered.

[000127] Any of the tractor tubes may be coated with a flexible material like urethane, silicone or other elastic element. A coating can be throughout the entire tractor tube length and/or thickness or partially on the length, e.g., just on one surface (such as inside or outside of the structure). In one embodiment, the tractor tube surface that touches ID of the distal access catheter wall when rolled around the catheter tip may not have a coating (as this surface touches the clot), while the other surfaces may have a coating or lamination. These coatings may cover all the interstices of the structure so aspiration/vacuum could be applied through the inner tractor puller and/or the distal access catheter to get a vacuum force to the clot. The coating could also include a hydrophilic coating to help make the CGS more lubricous for rolling on itself.

[000128] In any of the apparatuses described herein, the proximal end of tractor tube may be temporarily attached to the distal end of the outer tractor pusher (in some variations, the distal access catheter). For example, a temporary bond or connection between the end of the

tractor tube and the outer tractor pusher may allow the tractor tube to push and maybe pull the tractor tube distally and proximally; however, when the tractor tube is fully inverted, the tractor tube may be released from the distal end of the outer tractor pusher, allowing the user to pull out both elements separately (e.g., the outer tractor pusher and the tractor tube). FIGS.

5 16A-16C illustrate one example of this. In FIG. 16A, the apparatus includes a distal access catheter 1609 that has been withdrawn over a separate outer tractor pusher 1613 within the blood vessel 1602. The outer tractor pusher is temporarily attached 1633 (e.g., by a frangible bond or connection that is fused, adhesive and/or a mechanical connection) to an end of the tractor tube 1605, and particularly the end that is proximal to the outer tractor tube portion, which is shown expanded in this example. The opposite end of the tractor tube is permanently attached 1631 to the distal end of an inner tractor puller 1611. The apparatus is shown deployed within the vessel adjacent to a clot 1619.

[000129] In FIG. 16B, the inner tractor puller may be withdrawn proximally as described above to grab the clot and withdraw it into the tractor tube as it is rolled from the outer tractor tube portion into the inner tractor tube portion. Once the entire outer tractor tube portion has been rolled and inverted into itself, the connection to the outer tractor pusher may be broken, as shown in FIG. 16C, so that the entire tractor tube may be withdrawn into the outer tractor pusher and distal access catheter, as shown.

[000130] FIGS. 26A-26C and 27A-27B illustrate examples tractor tubes that are formed from slotted tubes (e.g. tubes formed with slot or openings cut through them). The same general properties described above for woven/braided tractor tubes may be applied to rolled/cut or otherwise formed tractor tubes. For example, in FIG. 26A, the tractor tube may be formed of a tube of material into which slots and pores (windows) through the tube have been laser cut. The material may initially be a sheet of solid (e.g., nickel titanium) material. In FIG. 26A, the tractor tube includes a distal-facing region 2619 is the rolling zone of the tractor tube, the region where the outer tractor tube portion 2603 rolls and inverts to become the inner tractor tube portion 2607. The cuts in the sheet of material form quadrilaterals arranged with a "braid angle" (in this variation, a cut angle) that converts from the very large braid angle in the compressed outer tractor tube portion 2603 to a much smaller braid angle in the inner tractor tube region.

[000131] The expanded outer tractor tube region 2603 shows that the angles of the pores (the braid angle) arranged in the proximal-to-distal axis have an angle of between 80-170 degrees, as described above. In This example, the angle is approximately 165 degrees. The cut-out pores are approximately diamond shapes and the entire circumference is cut with

these shapes, forming a larger diameter, flexible cylindrical column structure that has a very high column strength. Just proximal to the expanded outer tractor tube region 2603 is a tapered region 2612 that is a transition zone between a smaller diameter region that is constrained to have a smaller diameter (e.g., by the outer tractor pusher and/or the distal access catheter). The length (along the distal-to-proximal axis) of this tapering transition region 2612 may be approximately 0.25x to 2x the diameter (outer diameter) of the outer tractor tube region 2603.

[000132] As mentioned, the constrained region 2614 may be constrained so that it cannot expand radially (unlike the expanded outer tractor tube region), and may also be held to the outer tractor pusher by a releasable bond, as described above in FIGS. 16A-16D. This region may be held within the outer tractor pusher 2613.

[000133] FIG. 26B illustrates the rolling movement of the variation shown in FIG. 26A when the inner tractor tube portion 2607 is pulled proximally 2651. In this example, pulling the inner tractor tube portion proximally results in the elongation and tension on the inner tractor tube portion, putting compression (by the forced pulling down 2653 from the inner tractor tube portion, and the opposing force 2655 from the outer tractor pusher 2613) on the outer tractor tube portion 2603. The compressive force as well as the biasing force from the tractor tube maintains the expansion 2657 of the outer tractor tube portion. Pulling the inner tractor tube proximally and holding the outer tractor pusher (or pushing it distally) results in rolling 2659 of the distal-facing region of the tractor tube, causing it to collapse and fold back onto itself, as shown. The outer diameter of the outer tractor tube portion is therefore compressed to a minimum axial (distal-to-proximal) length, and a jammed maximum diameter, as shown. The constrained region 2614 is held within the outer tractor pusher 2613 by the constraining force 2661 against the inner diameter of the outer tractor pusher. The outer tractor pusher also applies a force 2665 against the tapered region 2612.

[000134] The sectional view of FIG. 26C provides additional detail, showing the transition between the outer tractor tube portion 2603 and the inner tractor tube portion 2607. As shown, the outer regions of the tractor tube (e.g., the constrained region, the tapered region and the outer tractor tube portion 2603) are all in compression while the inner regions (e.g., the inverting region and the inner tractor tube portion 2607) are in tension, causing rolling of the tractor tube.

[000135] FIGS. 27A-27B show views looking down the long axis of the tractor tube from the distal end and the proximal ends, respectively. In FIG., 26C, the transition in the cut angles ("braid angles") between the outer tractor tube portion and the inner tractor tube

portion at the distal-facing region of the tractor is apparent. FIG. 28 is a transparent view of a tractor tube showing the regions discussed above. In FIG. 28, the tractor tube includes the distal-facing region 2819 which forms a funnel-shape 2841 as it transitions from the expanded outer tractor tube portion 2803 to the inner tractor tube portion 2807. The inner
5 funnel region could be formed/shaped and/or laser cut to be more similar in diameter to the ID of the outer tube, as described above. Thus, the inner tractor tube diameter could be biased to expand to a particular diameter (e.g., a fraction of the constrained tractor tube region, such as 30%, 40%, 45%, 50%, 60%, 65%, 70%, 80%, etc., or a fraction of the unconstrained outer tractor tube portion, etc.). In FIG. 28, the shape outline also shows the constrained region
10 2814, and a tapered region 2812 that is proximal to the expanded outer tractor tube region 2803. As already mentioned above, the tractor tubes may be formed from braid, knit, fabric tube, polymer extrusion, etc.

[000136] For example, any of the tractor tubes described herein may be formed from a laser-cut tube material. Examples of slotted laser cut tubes forming a tractor are provided
15 herein, including those shown in FIGS. 17A-25B. The starting tubes may be flexible or rigid. For example, a soft flexible tube, strip, or roll of material such as ePTFE or a dense fabric (e.g., knit or weave or braid) may be used. Flexible tubes may provide tractors and/or combinations of tractors and catheters that allow tracking of the apparatus to the treatment site even in tortuous vessels. Tracking allows pushing of the apparatus through tortuous
20 vessels of small caliber over long distances from their introduction site to the human body, over length that can exceed 1 meter in some uses. A flexible tube (pre-laser cutting to form the tractor) may have a softness resulting in a low radial crush force, such as a micro-porous, polymer based tube. The tube may be processed (e.g., by cutting or any of the other techniques mentioned herein) to provide flexibility (e.g., the ability to pull the tractor into
25 catheter, invert, and expand over catheter outer diameter) and/or to create a textured/porous surface that may aid in engaging/grabbing a clot (e.g., emboli) and may provide free spaces (voids) that may help store and/or masticate emboli, making them easier to store within the apparatus and transport. Prior to forming into the tractors the sheets or tubes (e.g., films, rolls, etc.) may have a smooth surface. Patterns may be formed into the sheet or tube to form the
30 tractor. For example, laser slot patterns may be formed in the material to increase macro-surface roughness. Holes, slots, edges, divots, and bumps may be formed on the material. In addition to helping grab and hold emboli, such holes or slots may create free space in the tube wall to cut the clot and/or carry it away. The patterns used to form any of the tractors described herein may have a shorter strut length to strut width ratios. Short, wider struts may

create tractors that are stiffer and may grab clot better. In combination with strut length to width, in some variations, thicker walls may be preferred. Thicker slotted walls may create stiffer struts and more aggressive surface texture to grab clots. Furthermore, thicker walls may enhance clot storage capacity within the slot gaps.

- 5 [000137] In some variations, it may be beneficial to provide slot designs which do not foreshorten. For example, if the slotted tube design is pulled axial (e.g., down its length), the tube diameter may not decrease. A decreasing diameter slotted tube may grab the outside of the catheter and cleat, increasing drag force when the tube is pulled.

- [000138] In variations in which the initial tube or sheet of material used to form the tractor tube is relatively rigid (e.g., formed of a material such as Steel, Nitinol, Polyester, PTFE, Nylon, etc.), the initial tube stiffness/hardness may enhance the clot-grabbing ability when the tractor is slotted properly, to allow both increased flexibility, expansion and rolling. For example, a rigid tube may include slot designs that focuses in catheter tracking and creates a flexibly bending tractor with minimal foreshortening, that is able to be pulled into a catheter (inverting) structure. As with the more flexible starting tubes discussed above, tractors formed of more rigid starting materials may grab and transfer a clot, and the number of slots and/or voids may be increased to increase clot grabbing and/or carrying capacity. A slotted tube forming a tractor may include surface grabbing features, such as channels/corrugations (e.g. any of the microstructures such as those shown in FIGS. 12A-12I above. More rigid tubes may create harder or stiffer slotted tractors. For example, when struts are formed into the tractor (e.g., by cutting, etc.), the slot strut length to strut width may be greater than with less rigid starting materials, and may be a function of the rigid tubes elastic modulus. Higher elasticity materials (e.g., Niti, PET, PTFE) may have strut length to width ratios from 10 to 100. Stiffer materials (e.g., steel, MP35N) may have a length to width ratio greater than 50.
- 20 The wall thickness to strut width ratio for elastic materials may be, for example, between 0.5 to 10. For stiffer materials, the wall thickness to strut width ratio may be, for example, between 0.25 to 5.

- [000139] As mentioned, any of the apparatuses described herein may include a tractor region that is non-foreshortening. The foreshortening of the tractor may depend at least in part on the slot designs for non-woven, non-braided, non-knitted designs (e.g., tractors that are not formed of a strand or strands of material). FIGS. 17A-17D illustrate an example of non-foreshortening design. Also, for both flexible and rigid starting tubes forming a non-woven tractor, the tube inner diameter can be slightly bigger than catheter tube outer diameter pre-slotting. Slotted tube designs which foreshorten may reach their smallest diameter limit
- 30

when tensioned axially. If the tube is sized to be slightly larger than the catheter outer diameter, then it may jam (preventing any foreshortening) before it cleats to the catheter outer diameter. Tractor regions formed of an initially rigid material may grab clot more efficiently than tractors having an equivalent thickness but formed of a more flexible material, although more flexible materials may deform as a function of stiffness.

[000140] FIGS. 17A-17D illustrate an example of tractors that are formed by cutting slots and/or windows into tubes of material. In FIGS. 17A-17D, an initially soft material (e.g., ePTFE) was formed by a subtractive manufacturing technique to form, slots, pores and textures in the soft flexible tube. In FIGS. 17A-17D, a 3mm ID ePTFE tube (configured to be used with a 2.9mm OD catheter) was made to be highly flexible and have some level of column stiffness and radial/hoop stiffness by laser-cutting slot patterns into the tube wall to create textures and bend zones which impart clot grabbing and rolling. The ePTFE itself is highly lubricous. Addition of a lubricant (e.g., hydrophilic coating) may improve tracking and rolling. Lubricant can be applied to ID and OD or to either separately. FIG. 17A shows a first pattern 1701, having minimal cuts to create a smooth rolling of the tractor around the catheter 1703 portion of the apparatus.

[000141] A second exemplary pattern is shown in FIG. 17B. In this example, the apparatus slightly larger cut-out regions 1709 (removed by laser cutting in this example), which may create better clot grabbing properties and more clot holding capacity. In FIG. 17B, the ePTFE tube forming the tractor region is slotted on the outside of the catheter. Note that the porosity (14 holes around the circumference) may help grab and hold clot. In both FIG. 17A and 17B, the laser pattern may foreshorten, but may jam before it grips/cleats the catheter outer surface.

[000142] Another example of a tractor was made from a 2.9 mm OD ePTFE tube (configured for use with a 3 mm ID catheter). This example was made to be highly flexible and have some level of column stiffness and radial/hoop stiffness by laser-cutting slot patterns into the tube wall in a pattern to create textures and configured to include bend zones which impart clot grabbing and rolling. Similarly, a tractor may be made of, e.g., a 2.9mm OD PET woven fabric tube (for use with a 3mm ID catheter). The tractor may be formed of 30 Denier PET multi-filaments, 0.003" thickness. The resulting tractor may be configured to be soft and have some level of column stiffness and radial/hoop stiffness by laser cutting slot patterns into the tube wall in a patterns providing texture and bend zones which may impart clot grabbing and rolling. As with ePTFE, the PET material may itself be lubricous although

additional lubricant may be added to improve tracking and rolling. Lubricant can be applied to ID and OD or to either separately.

- [000143]** An example of a tractor made from a somewhat rigid starting material was formed from a nickel titanium (NiTi) tube having a 3mm OD (which may be used with, e.g., a 2.9 mm ID catheter). The wall thickness in these examples was between 0.001" and 0.002". Laser slot patterns were cut into the tube wall in various patterns to create textures and purpose-designed bend zones which may help impart clot grabbing and rolling. A lubricant may be applied, e.g., as a coating, to the ID and OD or to either separately. A first pattern similar to that shown in FIG. 17A was made by minimal laser cutting to create a smooth rolling tractor, with a strut length to width ratio between 25-50. A second pattern having larger slots/openings (similar to that shown in FIG. 17B) was formed by laser cutting. These patterns may foreshorten, but typically minimize or stop foreshortening before the tractor grips/cleats the catheter outer surface (which may result in jamming). The Niti design has the additional benefits of radiopacity, thermal shaping and super elasticity.
- [000144]** Any of these designs or patterns may for projections that may extend from the rolling distal-facing and inverting portion of the tractor, as discussed above. Such projection may be cut out as "teeth" or elongate members. The regions forming the projections may be sharp, e.g., pointy and/or cutting. Sharp projections may be chew and cut a mature clot. These projections regions may be short or long, may extend in one or more directions (e.g., forward or backward or bidirectional), and may be scoop-shaped (e.g., paddle-shaped). The number of projections may be selected based on the desired coarseness, e.g., the number of projections, the size (length/width/thickness), etc. The projections may change density down their length. For example, the laser pattern can be designed to allow tractor rolling (e.g., long struts) more easily initially, then have grabbing teeth at higher density; alternatively the tractor may be configured for greater initially grabbing, having a pattern with more and/or larger projections initially (distally) then transitioning to more slits (and flexibility) toward the proximal end, which may make it easier to pull. Further, the distribution of projections can be uniform around the tube perimeter and/or non-uniform (e.g., forming a spiral pattern, distributed in patches, having open areas, etc.).
- [000145]** Any of the tractors described herein may include a marker or makers (e.g., radiopaque markers, such as gold, Pt, etc.). When forming the tractor from a tube or sheet, the tubes may be cut, then shaped to have any profile, such as straight, rolled over the tip, flaring at the proximal end, etc. Any of the microstructure described herein may be included or formed, as mentioned above, e.g., wells on the struts may help carry and grab clot.

Tractors formed of tubes from which material was removed (or sheets formed into tubes) may be configured to have less cleating of the tractor onto the outer diameter of the clot, preventing jamming, particularly compared to woven or braided or knitted materials. However any of the slotted tube tractor configurations described herein may be used with, e.g., in combination with, a braid or knit or polymer sleeve, including either in parallel or in series. In general, any of these tractors may be formed as multi-layers, particular these slotted tube tractors.

[000146] For example, a tractor portion of an apparatus may be formed by removing material from a Niti tube that is slightly smaller than the inner diameter of the catheter that it will be used with, or it may be made from a tube that is slightly larger than the outer diameter of the catheters. The tube may be cut with a pattern that increase the coarseness of the outer surface (e.g., to include projections such as struts/scoops/teeth). For example a 0.001" tube wall thickness or smaller may be used.

[000147] FIGS. 17C and 17D illustrate an example of a tractor region cut from paper. In FIG. 17C a rigid paper tube was cut to include slots and the distal end expanded, a shown. It may be inverted over itself and used as a tractor region. This paper prototype was prepared to illustrate the effectiveness of this pattern. Similarly, FIG. 17D is an example of a prototype tractor region.

[000148] FIGS. 18A-18C illustrate examples of patterns that may be formed into a flat sheet or tubular member to form a tractor (e.g., slotted tractor). Similar to those shown in FIGS. 17A-17D. In FIG. 18A, the pattern may be cut to form the tractor. White regions 1801 may represent or form struts, while the lines indicate slots 1803 from which material is removed. This pattern is one of many resulting in a flexible tube having stout struts. FIG. 18B shows a similar example having a higher density of slots forming thinner struts and potentially higher porosity, which may result in a larger clot-carrying capacity. FIG. 18C illustrates an example of a pattern having curves that may produce a slightly more bendable (flexible in bending stiffness) slotted tractor. In FIGS. 18A-18C, the pattern is oriented so that the distal direction of the tractor formed by the pattern is at the right or left of the pattern shown (e.g., the tube is oriented right and left, relative to the figures, so that the tube is formed by rolling up from the bottom of the figure).

[000149] FIG. 19 is an example of a pattern that may be formed into a tube as part of a tractor having a plurality of both slots 1903 and cut-out regions 1901 (holes). Another example of a pattern having a plurality of cut-out holes 2001 formed into it is shown in FIGS. 20A and 20B. FIG. 20B shows an enlarged view.

- [000150] An example of a pattern having a plurality of projections is shown in FIGS. 21A-24B. For example in FIGS. 21A and 21B, the pattern includes a plurality of slots 2101 and cut-out regions that leave a projecting strut or tooth 2105 behind. In these examples, the tooth 2105 is pointed and oriented to the left of the page, which may be the distal end direction of the tractor. (e.g., the left side of the image may correspond to the distal end of the tractor); thus when the pattern is formed into a tubular body to form the tractor, and the tractor is inverted over itself (e.g., rolling over the distal end opening of a catheter) the plurality of pointed projections 2105 may extend out of the tractor, and may help grab and draw clot into the catheter.
- 10 [000151] Similarly, the pattern shown in FIGS. 22A-22B illustrate another example include a slot 2201, a projection 2203 and a cut-out portion 2205. As in FIGS. 21A and 21B, the projection may extend out of the plane of the tubular tractor (shown here as the plane of the paper, even when rolled up to form the tractor region). FIG. 23A, and enlarged view of FIG. 24B, shows another example of a pattern for a tractor that is similar to that shown in FIG. 21A-21B, but with smaller projecting regions. In this example, the projections 2305 are sharp, and open into an opening 2303 connected to a slot 2301. The pattern shown in FIGS. 24A-24B is similar to that shown in FIG. 23A-23B but with additional openings (cut out regions 2407) which may increase the carrying capacity (e.g., clot carrying capacity) of the tractor region.
- 20 [000152] FIGS. 25A-25B are examples of laser-cut tube prototypes of tractor regions. In FIG. 25B the tractor region is inverted over the distal end opening of the catheter.
- [000153] When a feature or element is herein referred to as being "on" another feature or element, it can be directly on the other feature or element or intervening features and/or elements may also be present. In contrast, when a feature or element is referred to as being "directly on" another feature or element, there are no intervening features or elements present. It will also be understood that, when a feature or element is referred to as being "connected", "attached" or "coupled" to another feature or element, it can be directly connected, attached or coupled to the other feature or element or intervening features or elements may be present. In contrast, when a feature or element is referred to as being "directly connected", "directly attached" or "directly coupled" to another feature or element, there are no intervening features or elements present. Although described or shown with respect to one embodiment, the features and elements so described or shown can apply to other embodiments. It will also be appreciated by those of skill in the art that references to a structure or feature that is disposed "adjacent" another feature may have portions that overlap or underlie the adjacent feature.
- 30

[000154] Terminology used herein is for the purpose of describing particular embodiments only and is not intended to be limiting of the invention. For example, as used herein, the singular forms "a", "an" and "the" are intended to include the plural forms as well, unless the context clearly indicates otherwise. It will be further understood that the terms "comprises" and/or "comprising," when used in this specification, specify the presence of stated features, steps, operations, elements, and/or components, but do not preclude the presence or addition of one or more other features, steps, operations, elements, components, and/or groups thereof. As used herein, the term "and/or" includes any and all combinations of one or more of the associated listed items and may be abbreviated as "/".

[000155] Spatially relative terms, such as "under", "below", "lower", "over", "upper" and the like, may be used herein for ease of description to describe one element or feature's relationship to another element(s) or feature(s) as illustrated in the figures. It will be understood that the spatially relative terms are intended to encompass different orientations of the device in use or operation in addition to the orientation depicted in the figures. For example, if a device in the figures is inverted, elements described as "under" or "beneath" other elements or features would then be oriented "over" the other elements or features. Thus, the exemplary term "under" can encompass both an orientation of over and under. The device may be otherwise oriented (rotated 90 degrees or at other orientations) and the spatially relative descriptors used herein interpreted accordingly. Similarly, the terms "upwardly", "downwardly", "vertical", "horizontal" and the like are used herein for the purpose of explanation only unless specifically indicated otherwise.

[000156] Although the terms "first" and "second" may be used herein to describe various features/elements (including steps), these features/elements should not be limited by these terms, unless the context indicates otherwise. These terms may be used to distinguish one feature/element from another feature/element. Thus, a first feature/element discussed below could be termed a second feature/element, and similarly, a second feature/element discussed below could be termed a first feature/element without departing from the teachings of the present invention.

[000157] Throughout this specification and the claims which follow, unless the context requires otherwise, the word "comprise", and variations such as "comprises" and "comprising" means various components can be co-jointly employed in the methods and articles (e.g., compositions and apparatuses including device and methods). For example, the term "comprising" will be understood to imply the inclusion of any stated elements or steps but not the exclusion of any other elements or steps.

[000158] In general, any of the apparatuses and methods described herein should be understood to be inclusive, but all or a sub-set of the components and/or steps may alternatively be exclusive, and may be expressed as “consisting of” or alternatively “consisting essentially of” the various components, steps, sub-components or sub-steps.

5 [000159] As used herein in the specification and claims, including as used in the examples and unless otherwise expressly specified, all numbers may be read as if prefaced by the word "about" or "approximately," even if the term does not expressly appear. The phrase "about" or "approximately" may be used when describing magnitude and/or position to indicate that the value and/or position described is within a reasonable expected range of values and/or
10 positions. For example, a numeric value may have a value that is +/- 0.1% of the stated value (or range of values), +/- 1% of the stated value (or range of values), +/- 2% of the stated value (or range of values), +/- 5% of the stated value (or range of values), +/- 10% of the stated value (or range of values), etc. Any numerical values given herein should also be understood to include about or approximately that value, unless the context indicates otherwise. For
15 example, if the value "10" is disclosed, then "about 10" is also disclosed. Any numerical range recited herein is intended to include all sub-ranges subsumed therein. It is also understood that when a value is disclosed that "less than or equal to" the value, "greater than or equal to the value" and possible ranges between values are also disclosed, as appropriately understood by the skilled artisan. For example, if the value "X" is disclosed the "less than or
20 equal to X" as well as "greater than or equal to X" (e.g., where X is a numerical value) is also disclosed. It is also understood that the throughout the application, data is provided in a number of different formats, and that this data, represents endpoints and starting points, and ranges for any combination of the data points. For example, if a particular data point "10" and a particular data point "15" are disclosed, it is understood that greater than, greater than or
25 equal to, less than, less than or equal to, and equal to 10 and 15 are considered disclosed as well as between 10 and 15. It is also understood that each unit between two particular units are also disclosed. For example, if 10 and 15 are disclosed, then 11, 12, 13, and 14 are also disclosed.

[000160] Although various illustrative embodiments are described above, any of a number
30 of changes may be made to various embodiments without departing from the scope of the invention as described by the claims. For example, the order in which various described method steps are performed may often be changed in alternative embodiments, and in other alternative embodiments one or more method steps may be skipped altogether. Optional features of various device and system embodiments may be included in some embodiments

and not in others. Therefore, the foregoing description is provided primarily for exemplary purposes and should not be interpreted to limit the scope of the invention as it is set forth in the claims.

[000161] The examples and illustrations included herein show, by way of illustration and not of limitation, specific embodiments in which the subject matter may be practiced. As mentioned, other embodiments may be utilized and derived there from, such that structural and logical substitutions and changes may be made without departing from the scope of this disclosure. Such embodiments of the inventive subject matter may be referred to herein individually or collectively by the term “invention” merely for convenience and without intending to voluntarily limit the scope of this application to any single invention or inventive concept, if more than one is, in fact, disclosed. Thus, although specific embodiments have been illustrated and described herein, any arrangement calculated to achieve the same purpose may be substituted for the specific embodiments shown. This disclosure is intended to cover any and all adaptations or variations of various embodiments. Combinations of the above embodiments, and other embodiments not specifically described herein, will be apparent to those of skill in the art upon reviewing the above description.

CLAIMS

1. A self-rolling mechanical atherectomy apparatus for removing a clot from a vessel, comprising:

5 an outer tractor pusher comprising a catheter having a distal end and a distal end opening;

 a tractor tube comprising an outer tractor tube portion that extends distally in an un-inverted configuration and inverts into itself at a distal-facing region to form an inner tractor tube portion, wherein the tractor tube is configured such that pulling the inner tractor tube portion proximally (i) compresses the outer tractor tube portion into a configuration having a column strength that resists collapsing, and (ii) causes a region of the outer tractor tube portion at the distal-facing region to roll over itself, unsupported, and invert into the inner tractor tube portion; and

15 an inner tractor puller coupled to the inner tractor tube portion and extending proximally within the outer tractor pusher.

2. The apparatus of claim 1, wherein the outer tractor pusher is coupled to a proximal end of the outer tractor tube portion of the tractor tube.

20 3. The apparatus of claim 1, further comprising a distal access catheter, wherein the outer tractor pusher, the tractor tube, and inner tractor puller are held within the distal access catheter in an un-deployed configuration, and wherein the tractor tube is configured to be deployed by being pushed distally out of the distal access catheter so that the outer tractor tube portion expands to a diameter that is greater than an outer diameter of the distal access catheter in a deployed configuration.

25 4. The apparatus of claim 1, wherein the outer tractor pusher is configured as a distal access catheter in which the tractor tube and inner tractor puller are held within the outer tractor pusher in an un-deployed configuration, and wherein the tractor tube is configured to be deployed by being pushed distally out of the outer tractor pusher so that the outer tractor tube portion expands to an outer diameter that is greater than an outer diameter of the outer tractor pusher.

5. The apparatus of claim 1, wherein the tractor tube is configured so that pulling the inner tractor tube proximally compresses the outer tractor tube portion into a configuration in which the column strength of the outer tractor tube portion resists collapsing up to at least 500g of compression.

5

6. The apparatus of claim 1, wherein the outer tractor tube portion of the tractor tube is configured to expand to between about +/- 30% of an outer diameter of the outer tractor pusher.

10

7. The apparatus of claim 1, wherein the tractor tube comprises a braided material.

8. The apparatus of claim 7, wherein the outer tractor tube portion has a braid angle in a proximal to distal axis in a compressed configuration that is between 80 and 170 degrees, and the inner tractor tube portion has a braid angle in the proximal to distal axis under tension of less than 80 degrees.

15

9. The apparatus of claim 1, wherein the tractor tube is formed of between 24-48 filaments.

20

10. The apparatus of claim 1, wherein the tractor tube is formed of a plurality of filaments, each having a diameter of greater than 0.003 inches.

11. The apparatus of claim 1, wherein the proximal end of the outer tractor tube portion is configured to have a tapered shape when the outer tractor tube portion is expanded radially outward.

25

12. The apparatus of claim 1, wherein the distal-facing region of the tractor tube is unsupported over at least 1 cm proximally from the distal-facing region of the tractor tube.

30

13. The apparatus of claim 1, wherein the tractor tube has a porosity of 60% or greater.

14. The apparatus of claim 1, wherein the inner tractor puller comprises an inner lumen configured to pass a guidewire out of a distal end of the apparatus.

15. The apparatus of claim 1, further comprising a vacuum source coupled to the tractor tube and configured to apply a vacuum therethrough.

5 16. A self-rolling mechanical atherectomy apparatus for removing a clot from a vessel, comprising:

 an outer tractor pusher comprising a catheter having a distal end and a distal end opening;

 a tractor tube comprising an outer tractor tube portion that extends distally in an un-
10 inverted configuration and inverts into itself at a distal-facing region to form an inner tractor tube portion, wherein the tractor tube is configured so that pulling the inner tractor tube portion proximally (i) compresses the outer tractor tube portion into a configuration having a column strength that resists collapsing up to at least 500g of compression and extends inner tractor tube portion, and (ii) causes a region of the outer tractor tube portion at the distal-
15 facing region to roll over itself, unsupported, and invert into the inner tractor tube portion; and

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

20 17. The apparatus of claim 16, wherein the outer tractor pusher is coupled to a proximal end of the outer tractor tube portion of the tractor tube.

 18. The apparatus of claim 16, further comprising a distal access catheter, wherein the outer tractor pusher, the tractor tube, and inner tractor puller are held within the distal access
25 catheter in an un-deployed configuration, and wherein the tractor tube is configured to be deployed by being pushed distally out of the distal access catheter so that the outer tractor tube portion expands to a diameter that is greater than an outer diameter of the distal access catheter in a deployed configuration.

30 19. The apparatus of claim 16, wherein the outer tractor pusher is configured as a distal access catheter in which the tractor tube and inner tractor puller are held within the outer tractor pusher in an un-deployed configuration, and wherein the tractor tube is configured to be deployed by being pushed distally out of the outer tractor pusher so that the

outer tractor tube portion expands to an outer diameter that is greater than an outer diameter of the outer tractor pusher.

20. The apparatus of claim 16, wherein the tractor tube comprises a braided material.

5

21. The apparatus of claim 20, wherein the outer tractor tube portion has a braid angle in a proximal to distal axis in a compressed configuration that is between 80 and 170 degrees, and the inner tractor tube portion has a braid angle in the proximal to distal axis under tension of less than 80 degrees.

10

22. The apparatus of claim 16, wherein the outer tractor tube portion of the tractor tube is configured to expand to between about +/- 30% of an outer diameter of the outer tractor pusher.

15

23. The apparatus of claim 16, wherein the tractor tube is formed of between 24-48 filaments.

24. The apparatus of claim 16, wherein the tractor tube is formed of a plurality of filaments, each having a diameter of greater than 0.003 inches.

20

25. The apparatus of claim 16, wherein the proximal end of the outer tractor tube portion is configured to have a tapered shape when the outer tractor tube portion is expanded radially outward.

25

26. The apparatus of claim 16, wherein the distal-facing region of the tractor tube is unsupported over at least 1 cm proximally from the distal-facing region of the tractor tube.

27. The apparatus of claim 16, wherein the tractor tube has a porosity of 60% or greater.

30

28. The apparatus of claim 16, wherein the inner tractor puller comprises an inner lumen configured to pass a guidewire out of a distal end of the apparatus.

29. The apparatus of claim 16, further comprising a vacuum source coupled to the tractor tube and configured to apply a vacuum therethrough.

30. A self-rolling mechanical atherectomy apparatus for removing a clot from a vessel, comprising:

an outer tractor pusher comprising a catheter having a distal end and a distal end opening;

a tractor tube formed from 10 or more strands, the tractor tube comprising an outer tractor tube portion that extends distally in an un-inverted configuration and inverts into itself at a distal-facing region to form an inner tractor tube portion, wherein the tractor tube is configured such that pulling the inner tractor tube portion proximally (i) compresses the outer tractor tube portion into a configuration having a column strength that resists collapsing, and (ii) causes a region of the outer tractor tube portion at the distal-facing region to roll over itself, unsupported, and invert into the inner tractor tube portion,

wherein the outer tractor tube portion has an expanded configuration with a distal-to-proximal facing braid angle for the expanded configuration of between about 80 and about 170 degrees; and wherein the outer tractor tube portion of the tractor tube is configured to expand to between about +/- 30% of an outer diameter of the outer tractor pusher; and

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

31. A method of removing a clot from a blood vessel, comprising:

advancing a distal end of a self-rolling mechanical atherectomy apparatus through the blood vessel to the clot, wherein the self-rolling mechanical atherectomy apparatus comprises a tractor tube, an outer tractor pusher, and an inner tractor puller;

pulling an inner tractor puller of the tractor tube proximally to compresses an outer tractor tube portion of the tractor tube, wherein pulling the inner tractor puller proximally causes the outer tractor tube portion at a distal-facing region of the tractor tube to roll over itself, unsupported, and invert into the inner tractor tube portion; and

engaging the clot with the tractor tube as it rolls over itself so that the clot is pulled into the tractor tube.

32. The method of claim 31, further comprising deploying the tractor tube of the self-rolling mechanical atherectomy apparatus so that the outer tractor tube portion of the tractor

tube expands to have an outer diameter that is greater than an outer diameter of the outer tractor pusher.

33. The method of claim 31, wherein pulling the inner tractor puller comprises
5 bracing a distal-facing end of the outer tractor pusher against a tapered face of the tractor tube that is proximal to the outer tractor tube portion.

34. The method of claim 31, further comprising advancing a guidewire within the
blood vessel to the clot, wherein advancing the self-rolling mechanical atherectomy apparatus
10 comprises advancing the self-rolling mechanical atherectomy apparatus over the guidewire through the blood vessel until the self-rolling mechanical atherectomy apparatus is proximate to the clot.

35. The method of claim 31, wherein engaging the clot comprises advancing the outer
15 tractor pusher distally while pulling the inner tractor puller proximally.

36. The method of claim 31, wherein engaging the clot comprises advancing the outer
tractor pusher distally at a first rate while pulling the inner tractor puller proximally at a
second rate that is faster than the first rate.

20

37. The method of claim 31, wherein advancing the distal end of the self-rolling
mechanical atherectomy apparatus comprises advancing the self-rolling mechanical
atherectomy apparatus distally with the tractor tube and inner tractor puller within the outer
tractor pusher, wherein the tractor tube is in an un-deployed configuration.

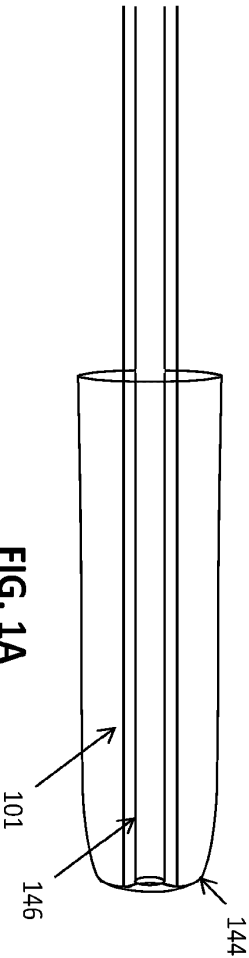
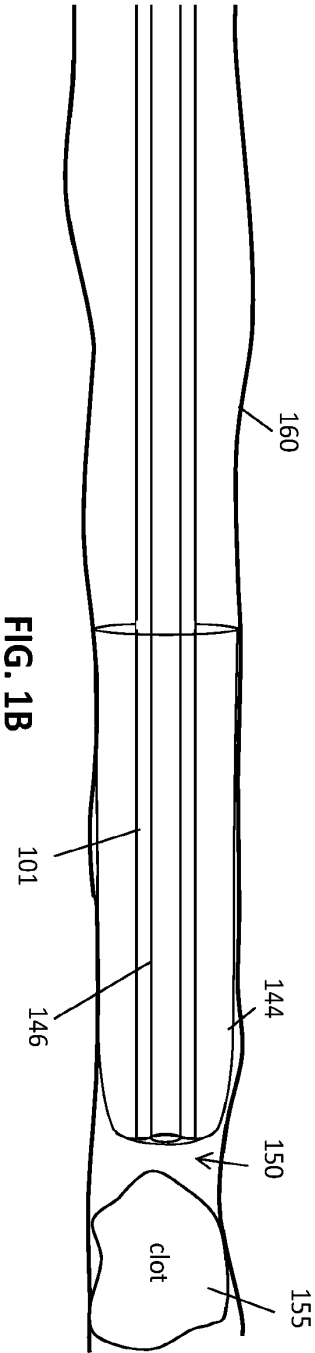
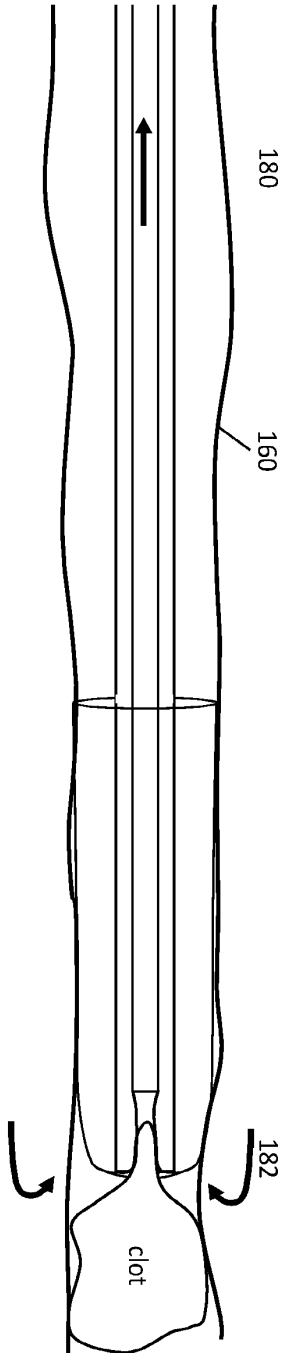
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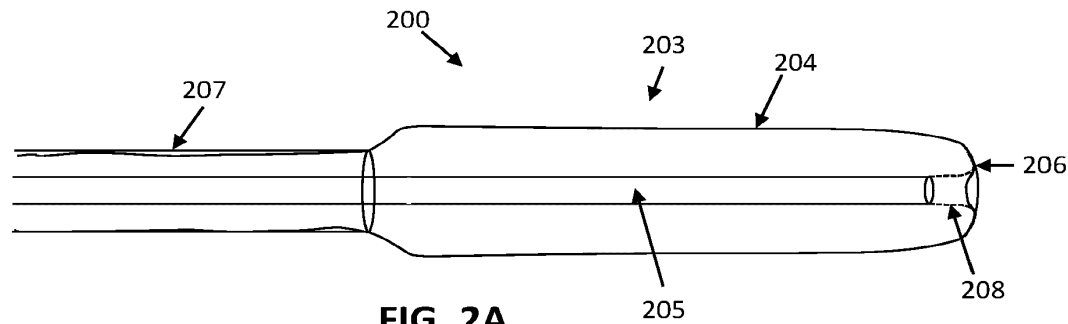
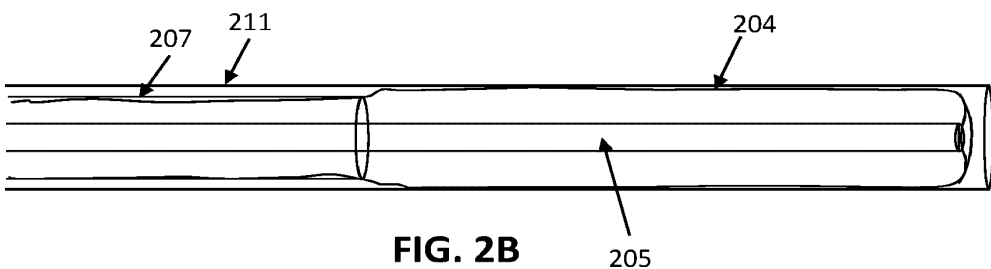
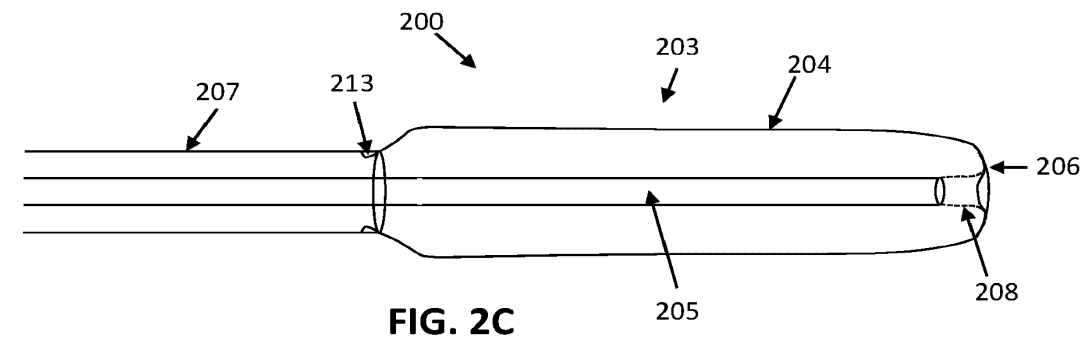
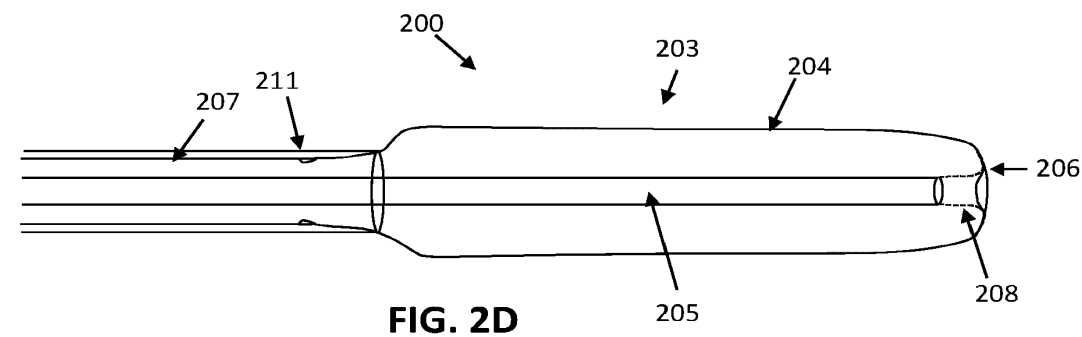
38. The method of claim 31, further comprising applying aspiration through the
tractor tube.

39. The method of claim 31, further wherein advancing the distal end of the self-
30 rolling mechanical atherectomy apparatus comprises advancing a distal access catheter enclosing the tractor tube, outer tractor pusher and inner tractor puller, wherein the outer tractor tube portion is inverted over the inner tractor puller in an un-deployed configuration within the distal access catheter.

40. The method of claim 31, wherein pulling the inner tractor puller comprises applying up to 500 g of compressive force on the outer tractor tube portion without collapsing the outer tractor tube portion.

- 5 41. A method of removing a clot from a blood vessel, comprising:
- advancing a distal end of a self-rolling mechanical atherectomy apparatus through the blood vessel to the clot, wherein the self-rolling mechanical atherectomy apparatus comprises a tractor tube, an outer tractor pusher, and an inner tractor puller;
- deploying the tractor tube of the self-rolling mechanical atherectomy apparatus so that
- 10 an outer tractor tube portion of the tractor tube expands to have an outer diameter that is greater than an outer diameter of the outer tractor pusher, wherein a distal-facing end of the outer is braced against a tapered face of the tractor tube proximal to the outer tractor tube portion, and wherein the outer tractor tube portion inverts over itself at a distal-facing region of the tractor tube and extends proximally within the outer tractor tube portion as an inner
- 15 tractor tube portion that is coupled to the inner tractor puller;
- pulling the inner tractor puller proximally to compresses the outer tractor tube portion of the tractor tube, and to cause the outer tractor tube portion of the tractor tube to roll over itself, unsupported, at the distal-facing region and to invert into the inner tractor tube portion;
- engaging the clot with the tractor tube as it rolls over itself so that the clot is pulled
- 20 into the tractor tube; and
- withdrawing the self-rolling mechanical atherectomy holding the clot from the blood vessel.





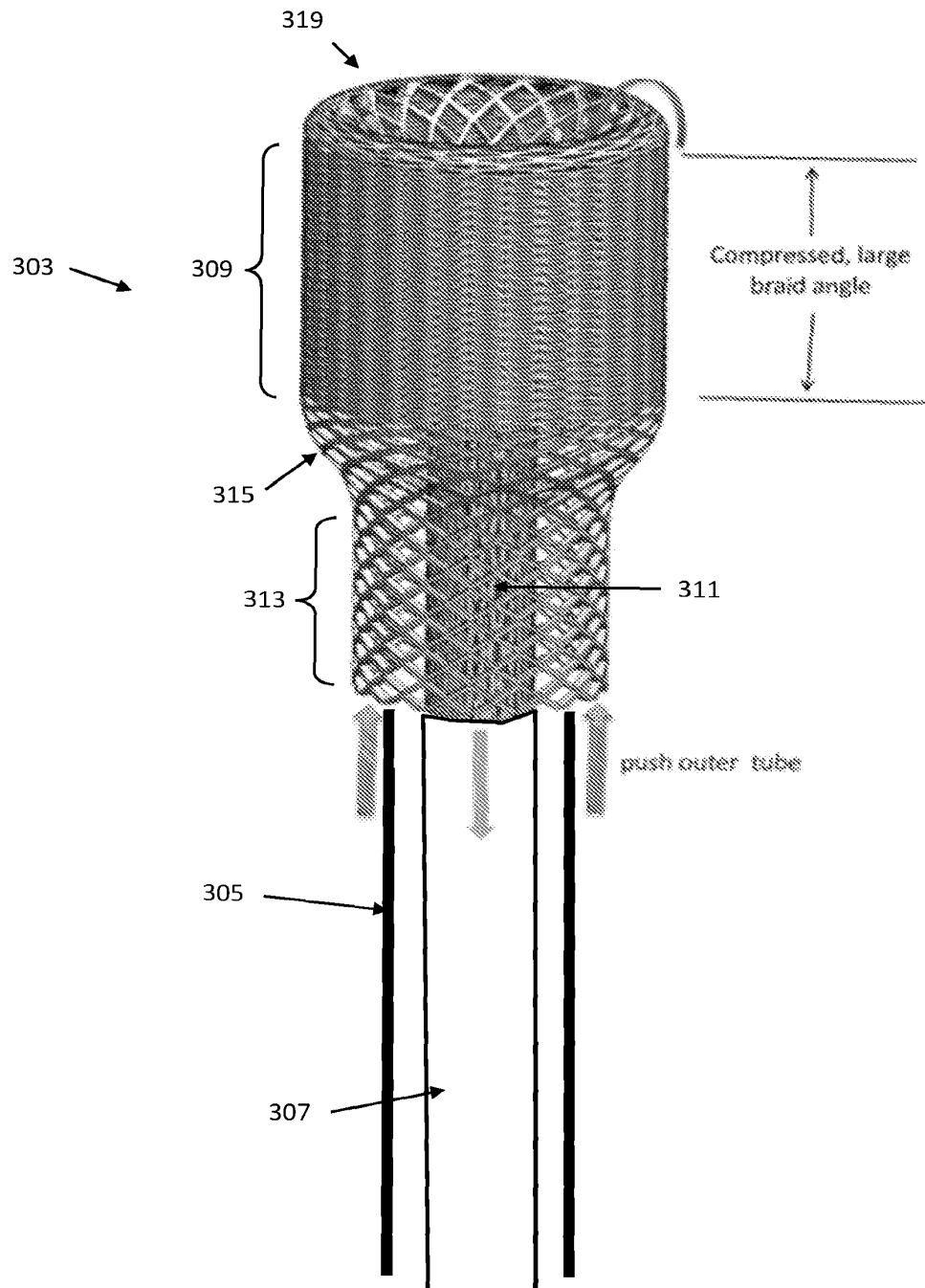


FIG. 3A

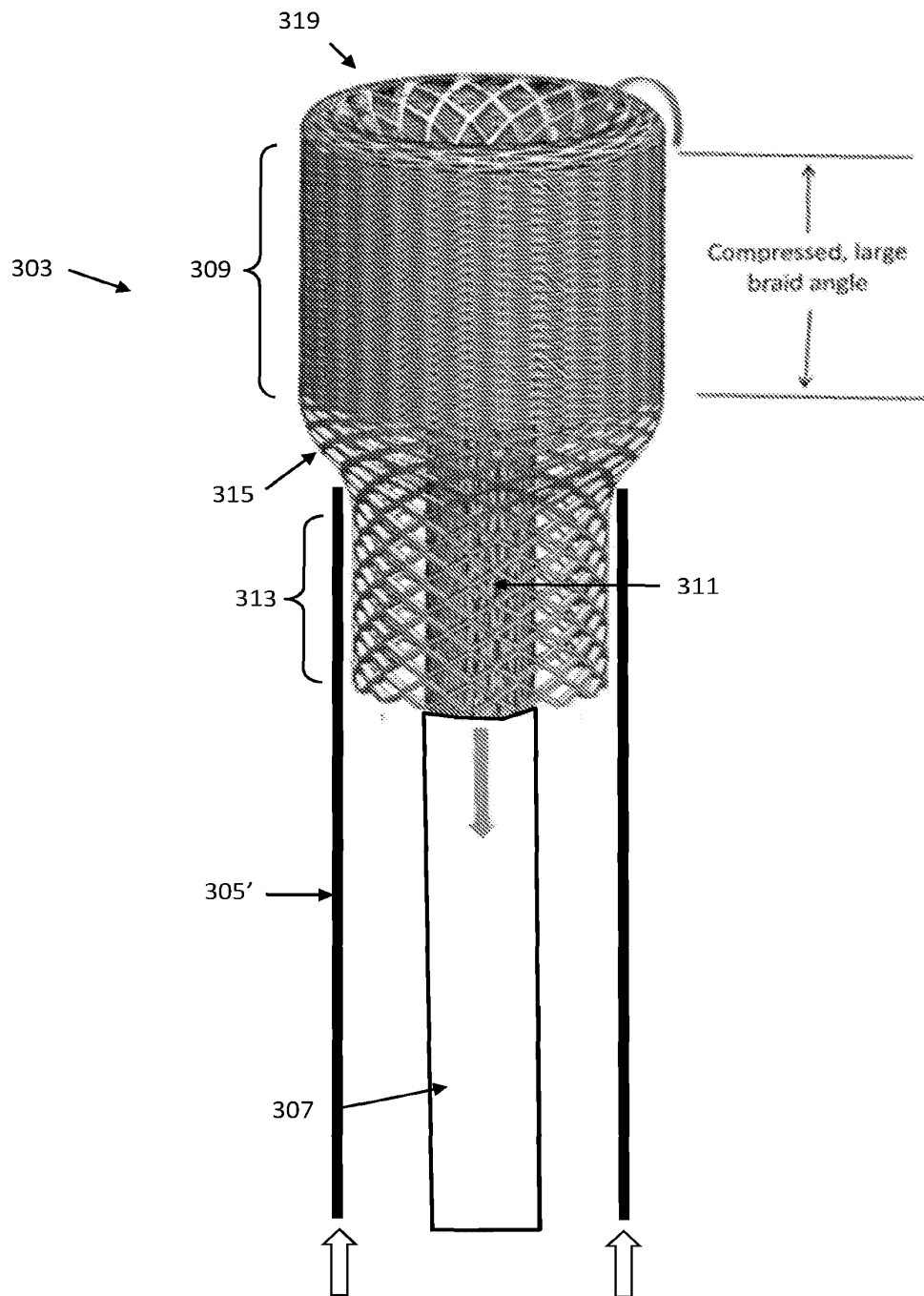


FIG. 3B

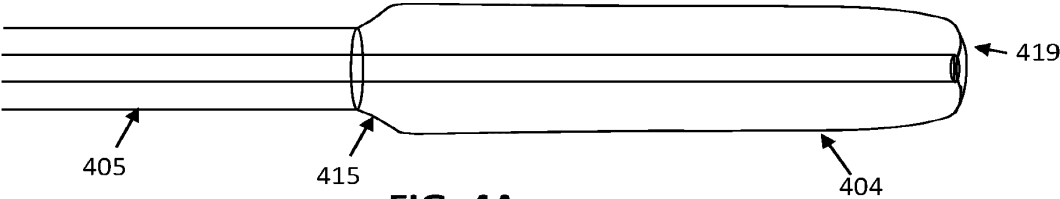


FIG. 4A



FIG. 4B

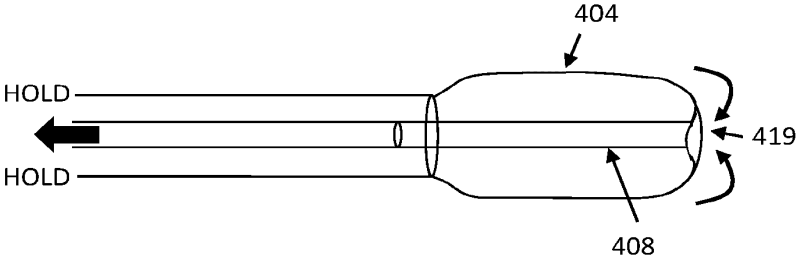


FIG. 4C

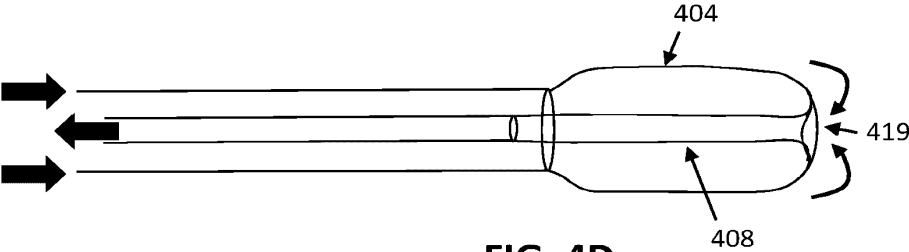


FIG. 4D

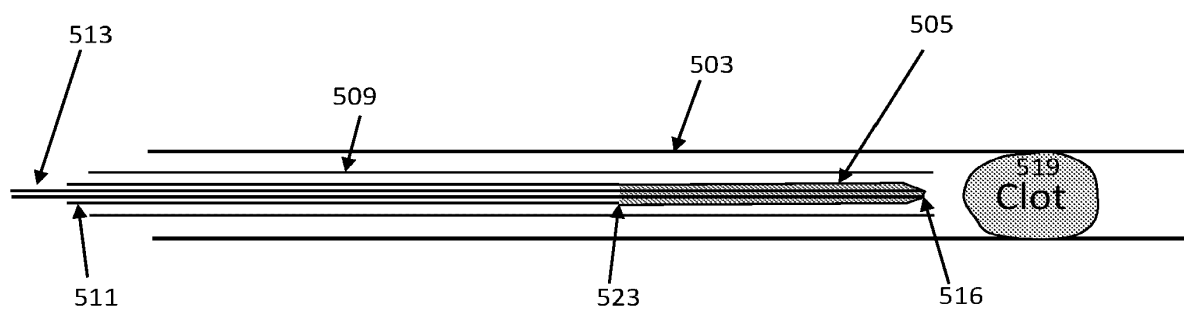


FIG. 5A



FIG. 5B

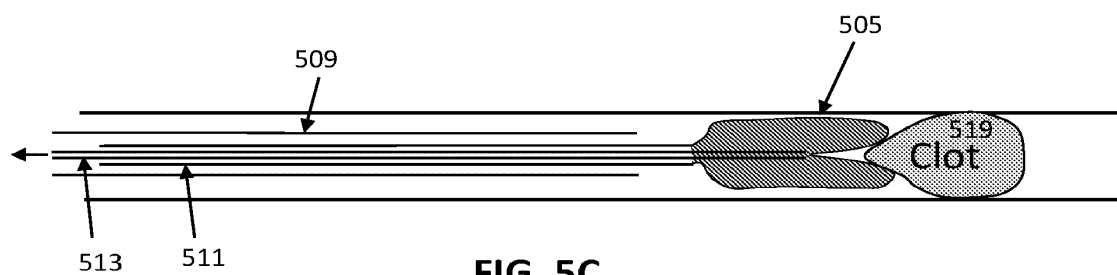


FIG. 5C



FIG. 5D

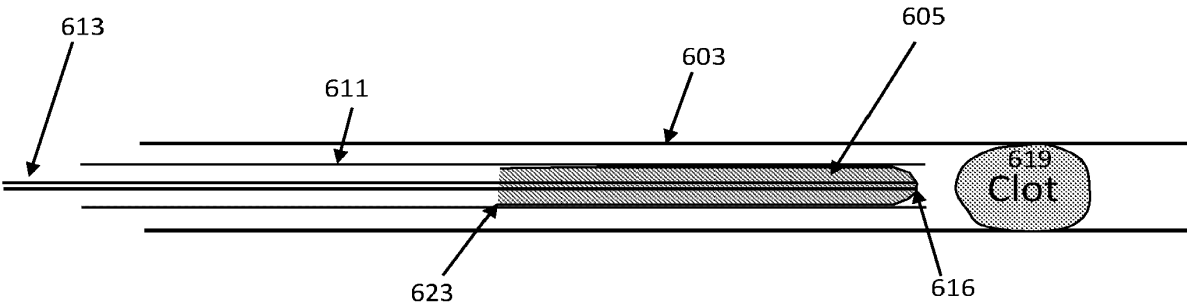


FIG. 6A

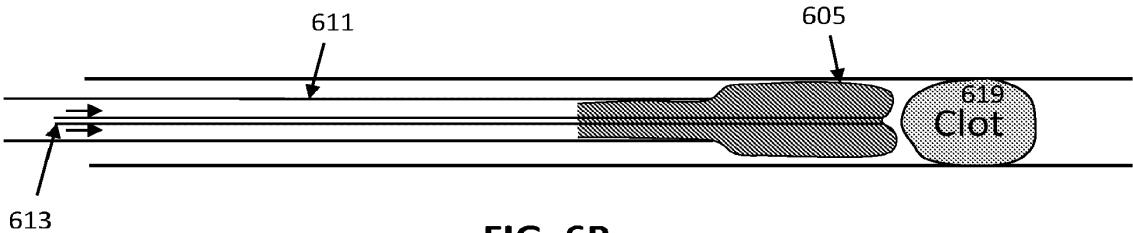


FIG. 6B

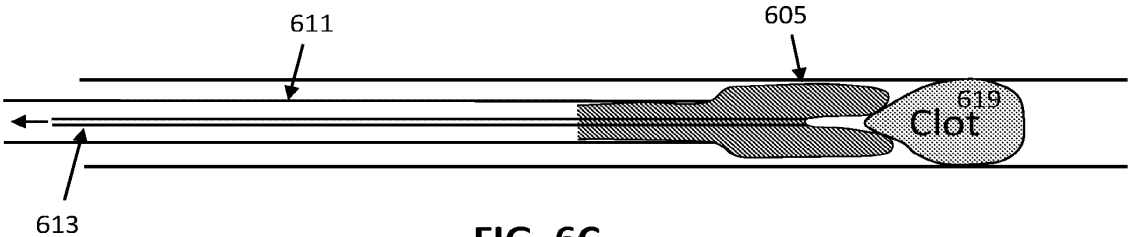


FIG. 6C

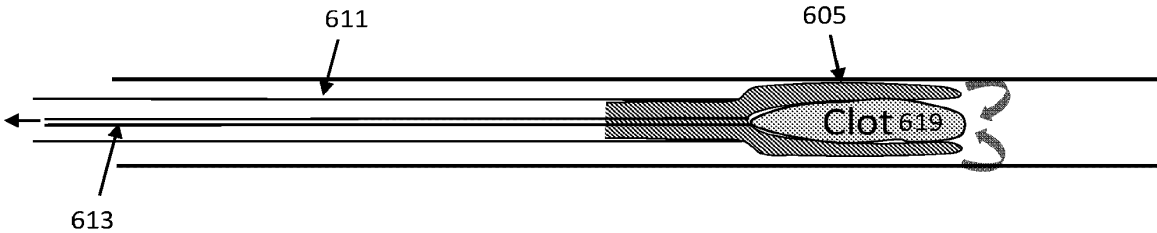


FIG. 6D

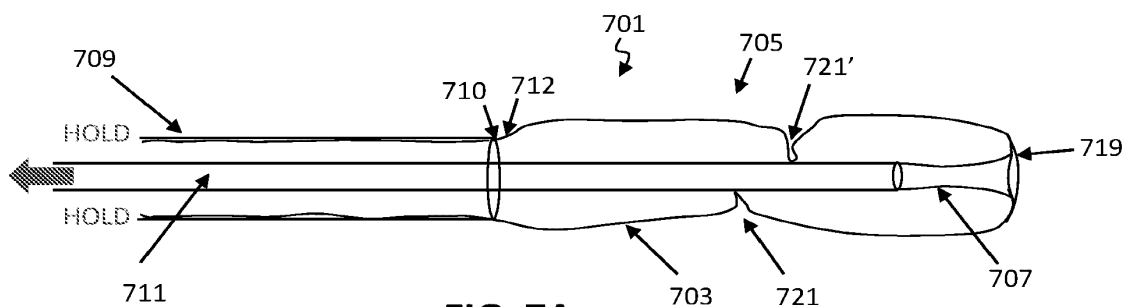


FIG. 7A

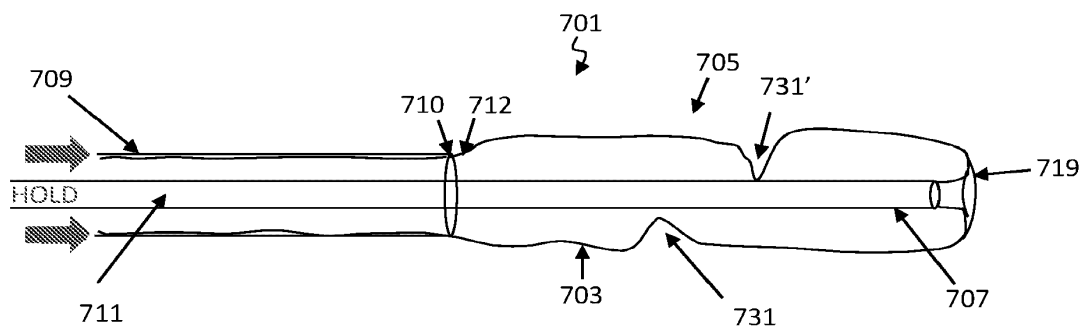


FIG. 7B

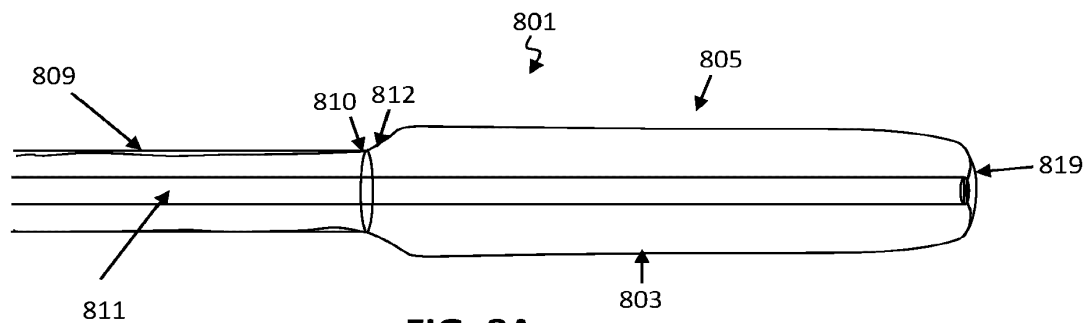


FIG. 8A

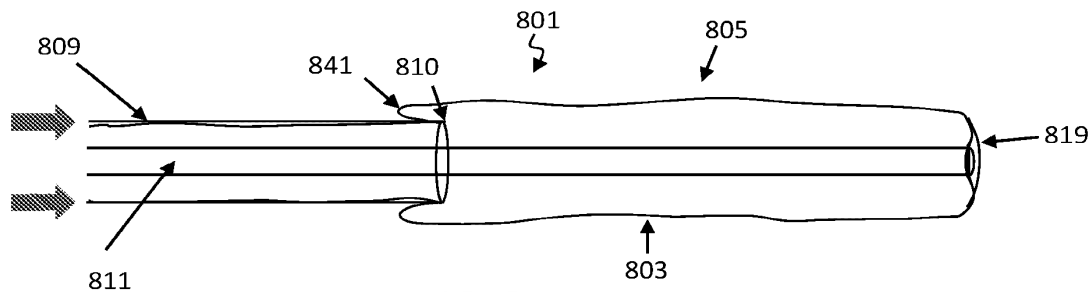


FIG. 8B

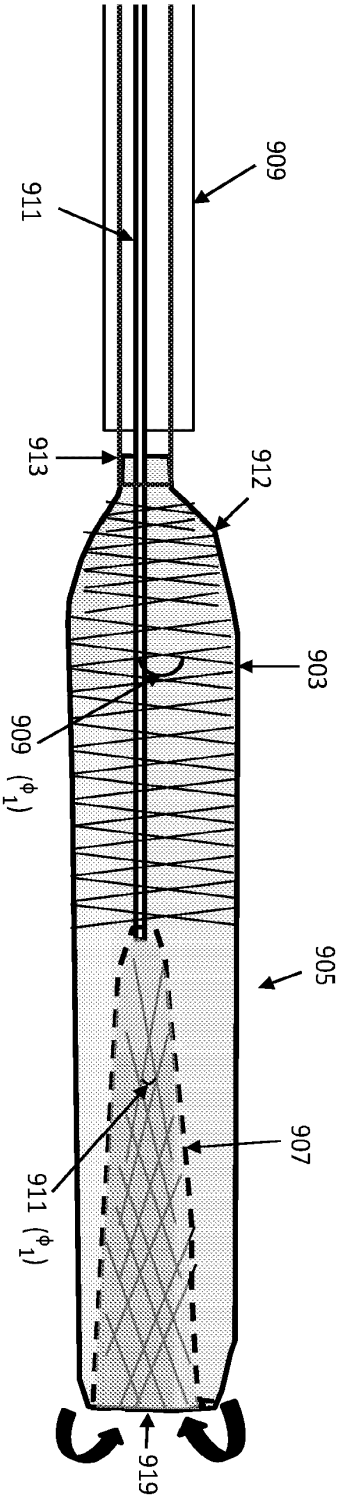


FIG. 9

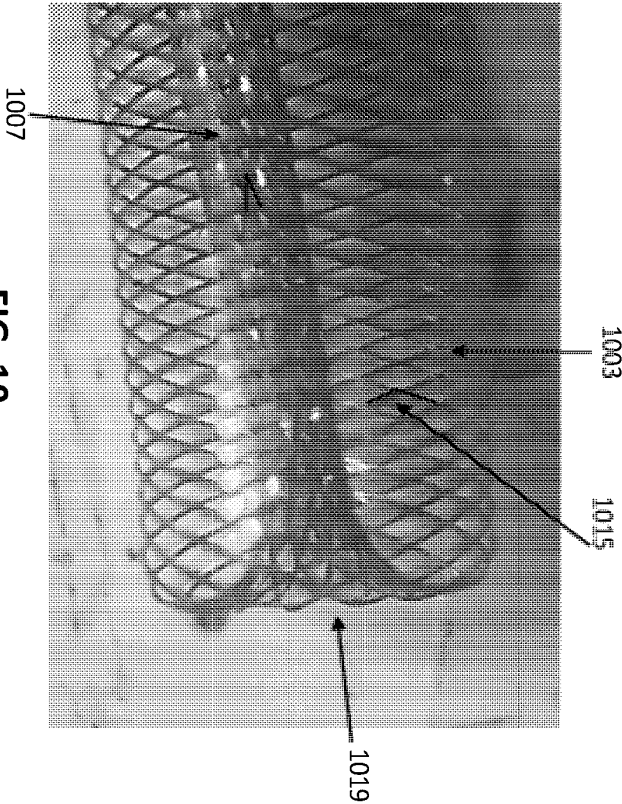
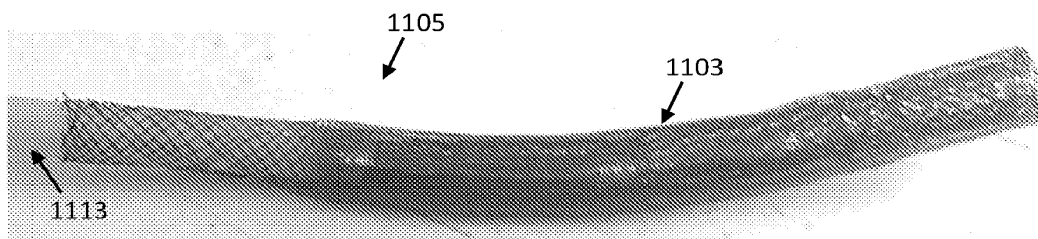
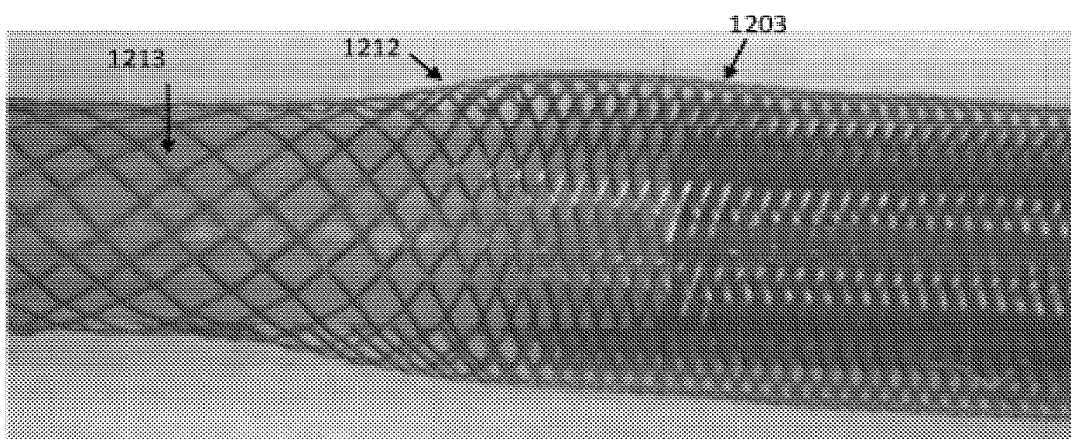
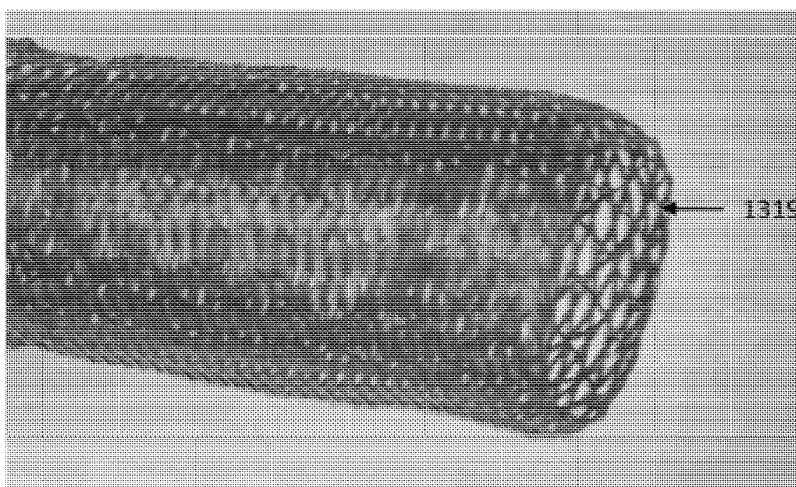
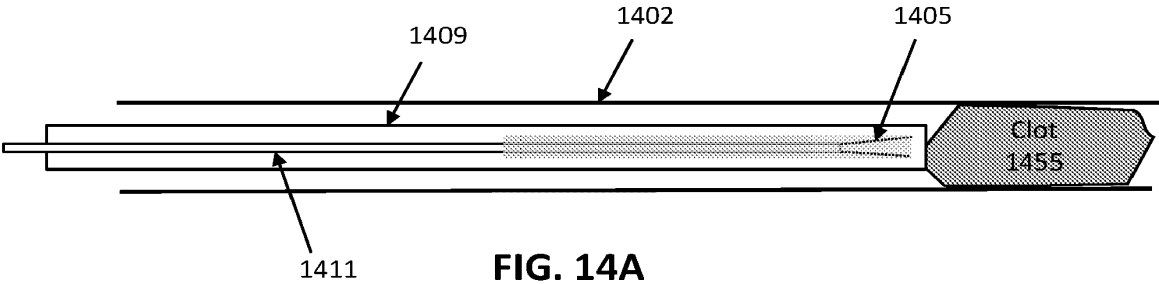
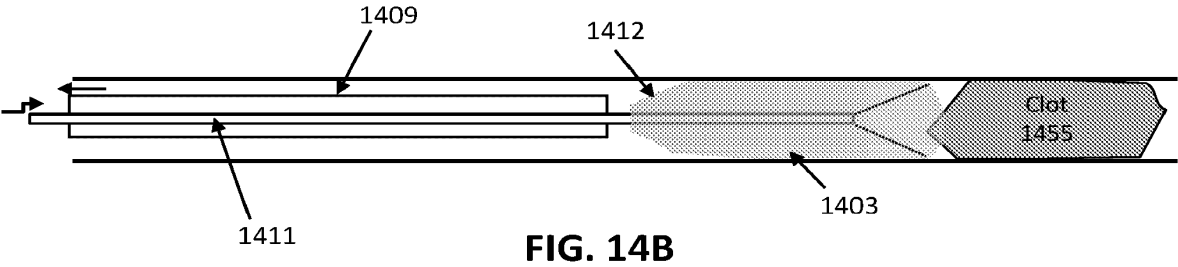
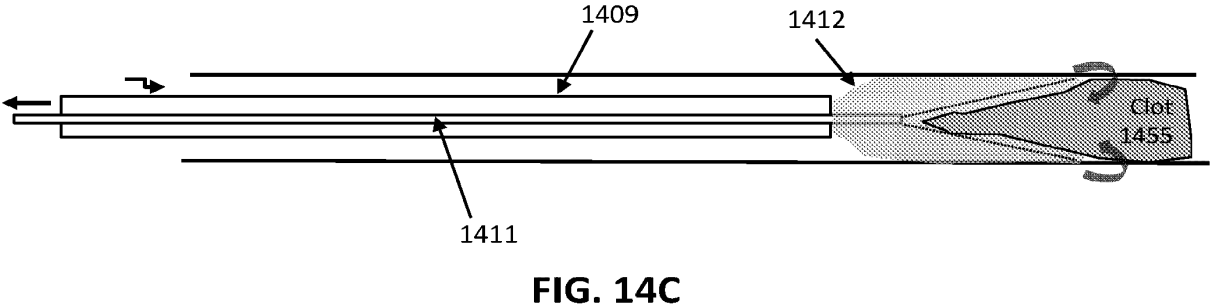
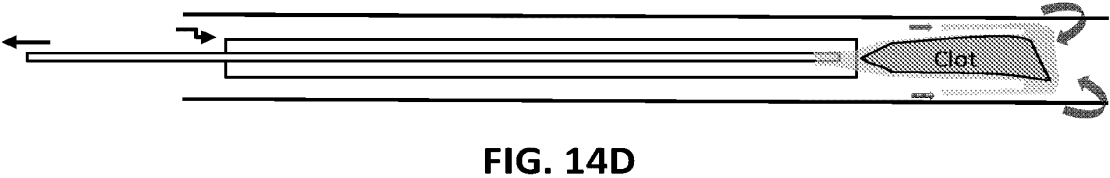


FIG. 10

**FIG. 11****FIG. 12****FIG. 13**



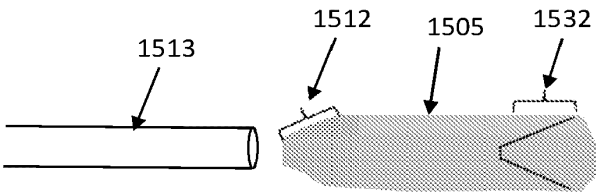


FIG. 15A

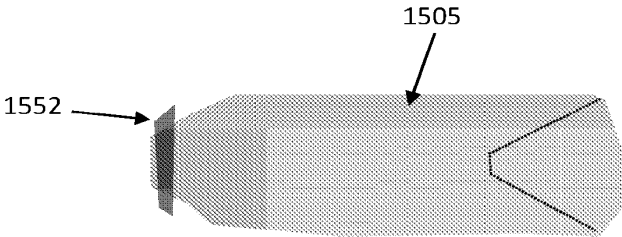


FIG. 15B

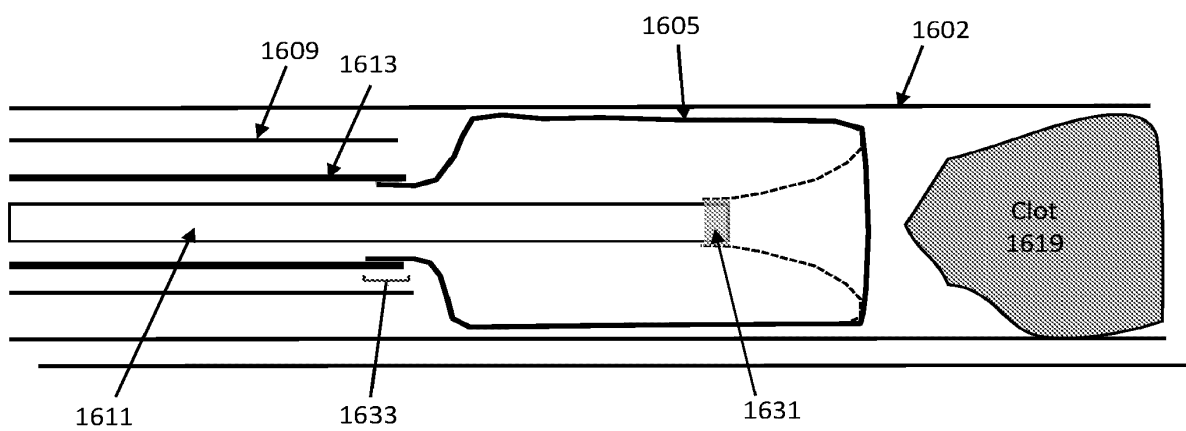


FIG. 16A

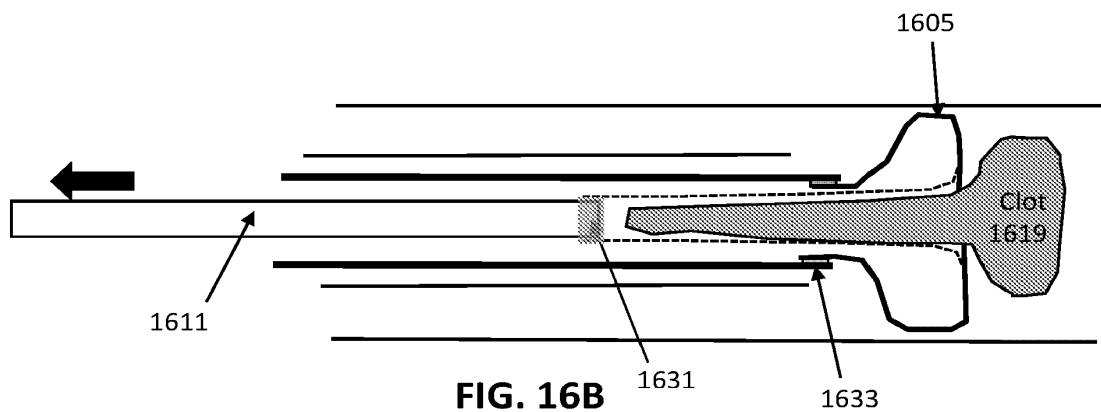


FIG. 16B

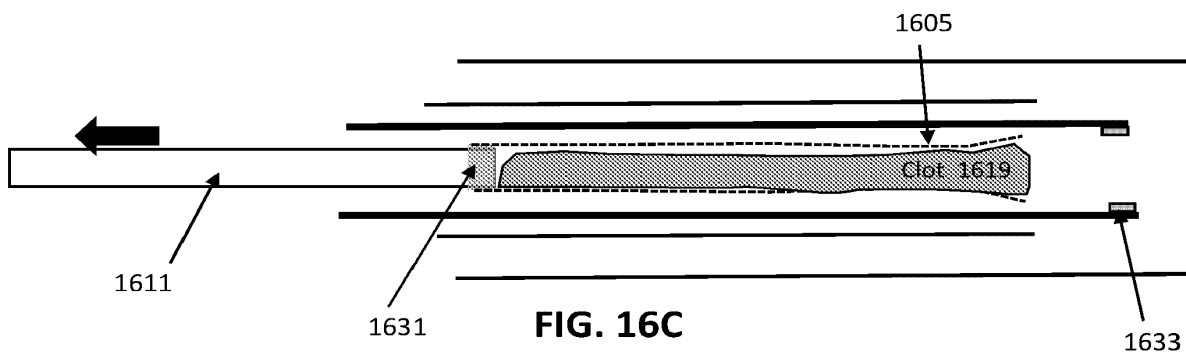


FIG. 16C

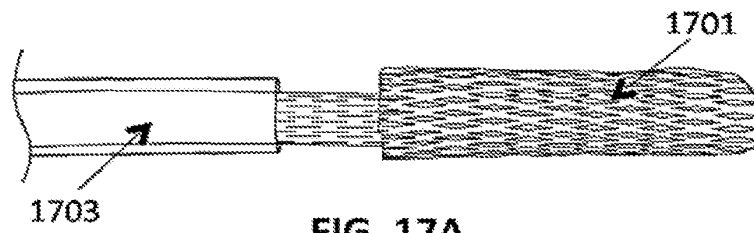


FIG. 17A

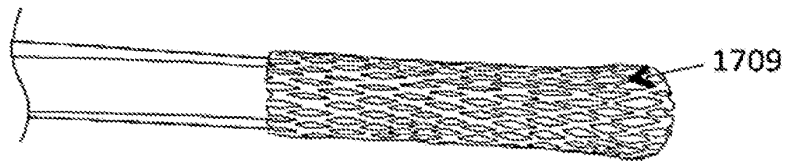


FIG. 17B

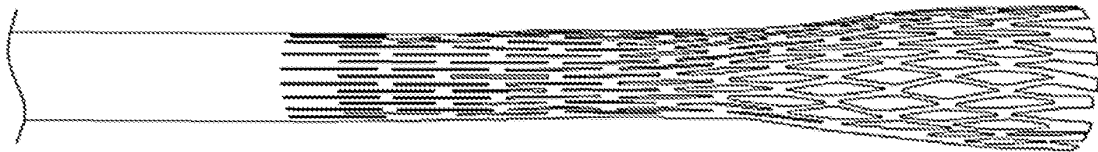


FIG. 17C

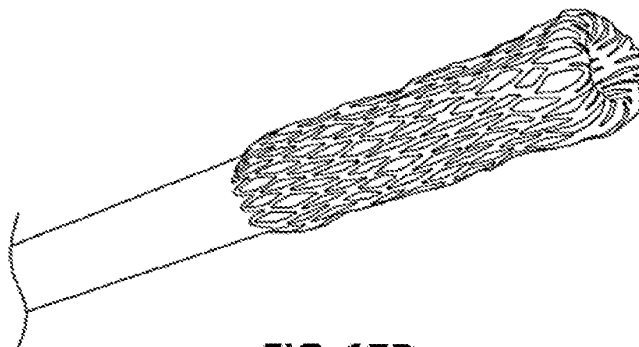


FIG. 17D

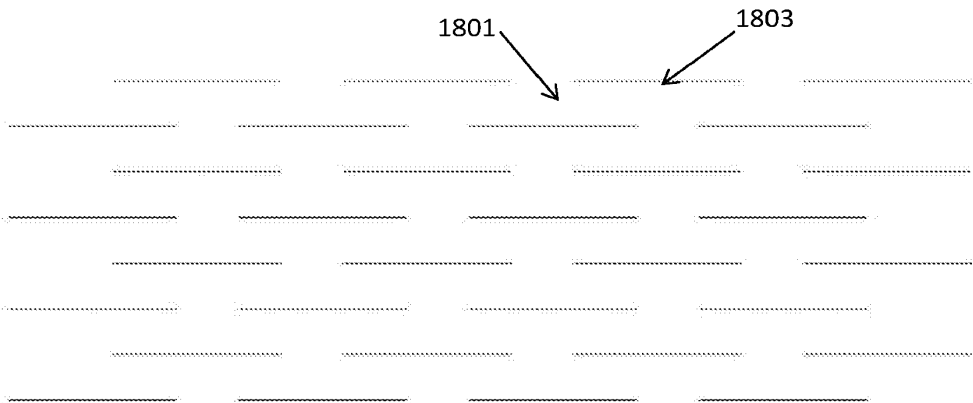


FIG. 18A

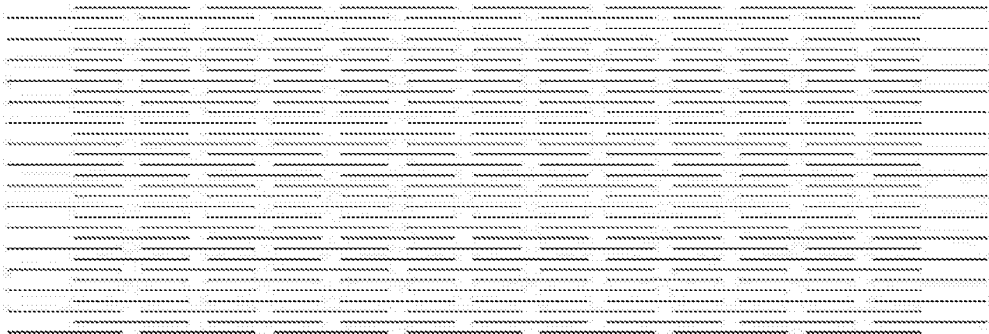


FIG. 18B

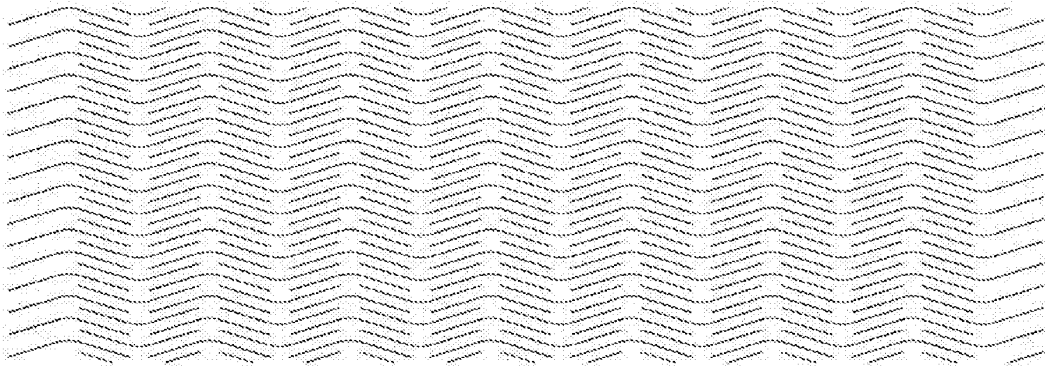


FIG. 18C

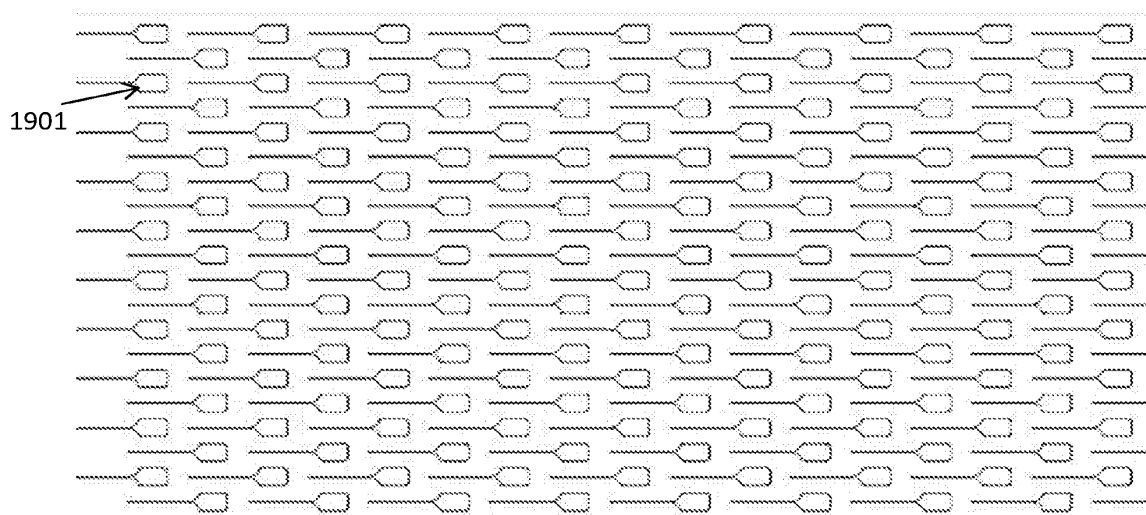


FIG. 19

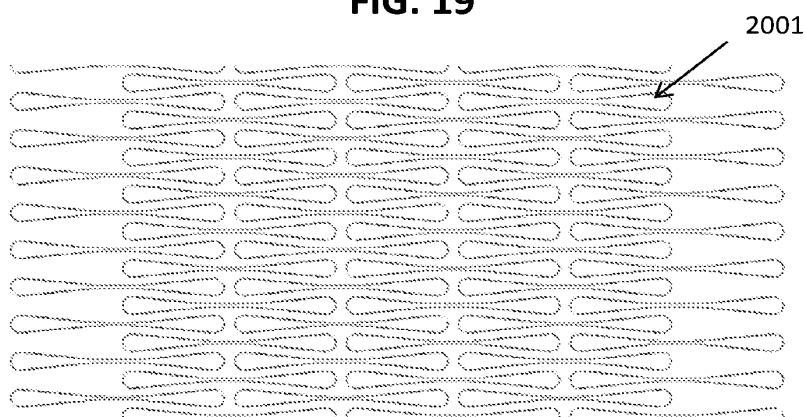


FIG. 20A

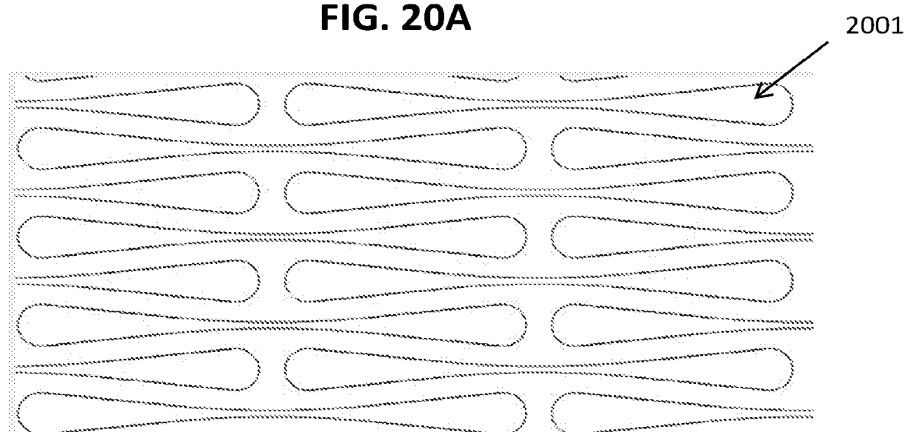


FIG. 20B

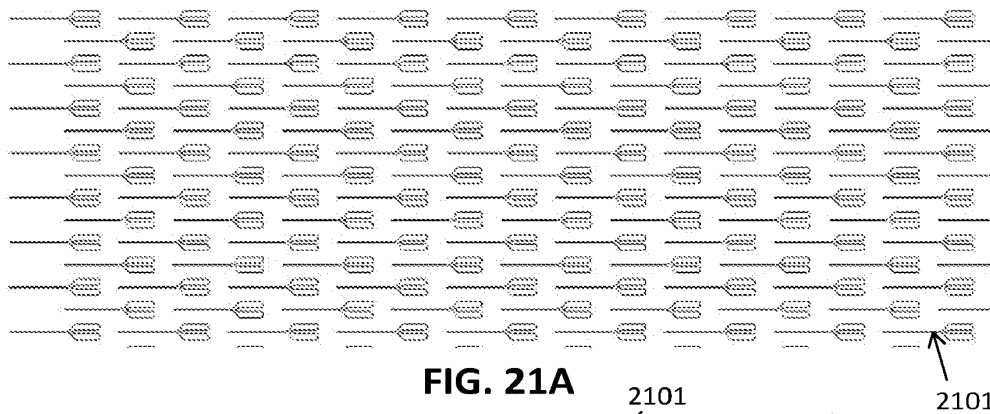
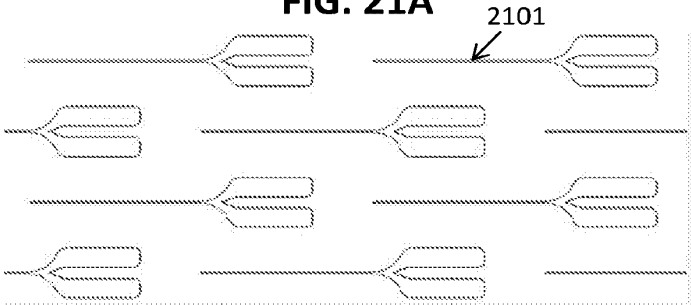


FIG. 21B

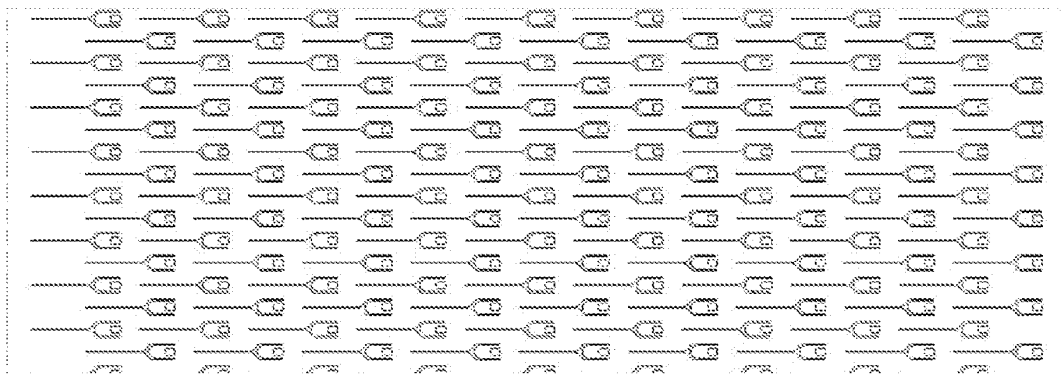


FIG. 22A

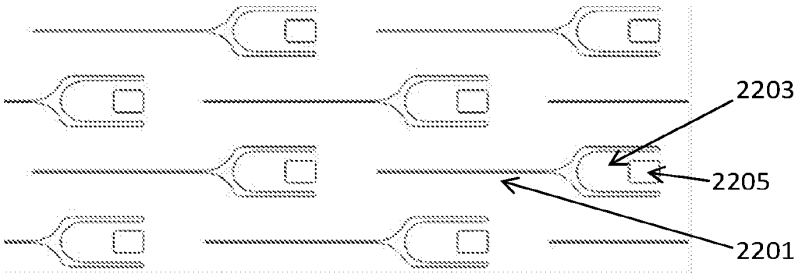


FIG. 22B

FIG. 24B

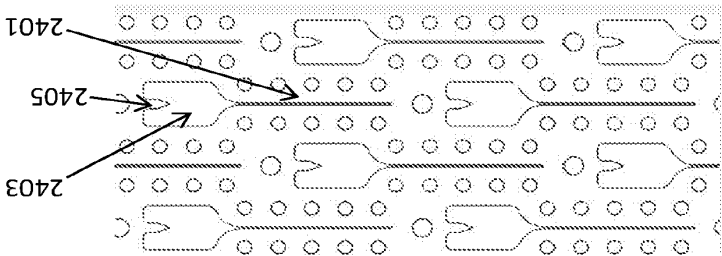


FIG. 24A

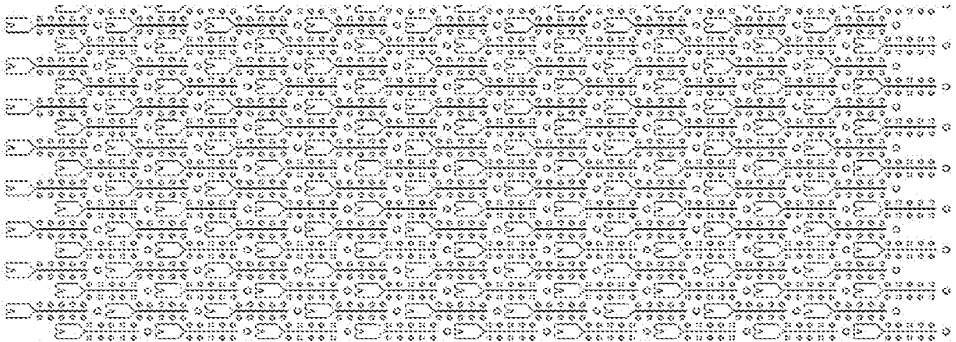


FIG. 23B

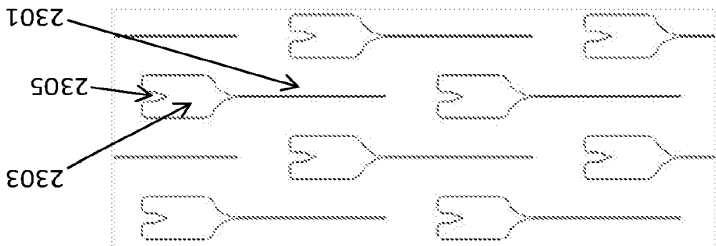
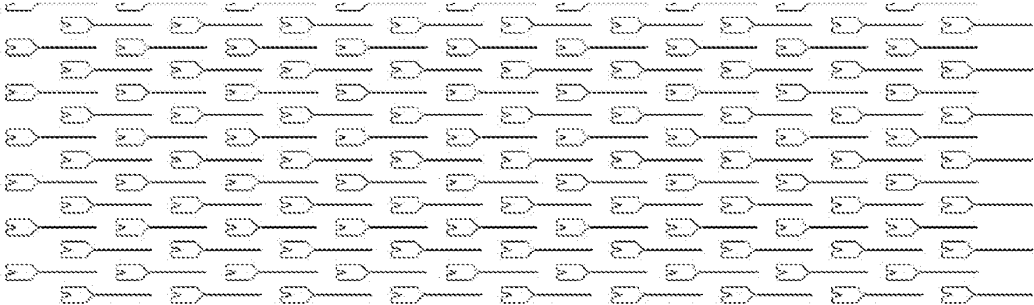


FIG. 23A



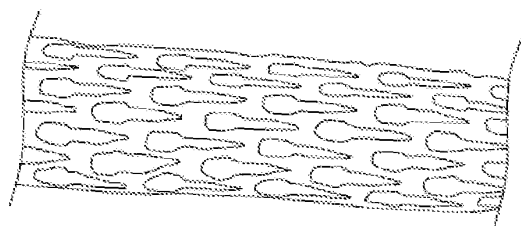


FIG. 25A

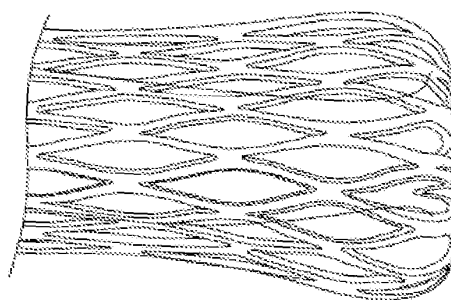


FIG. 25B

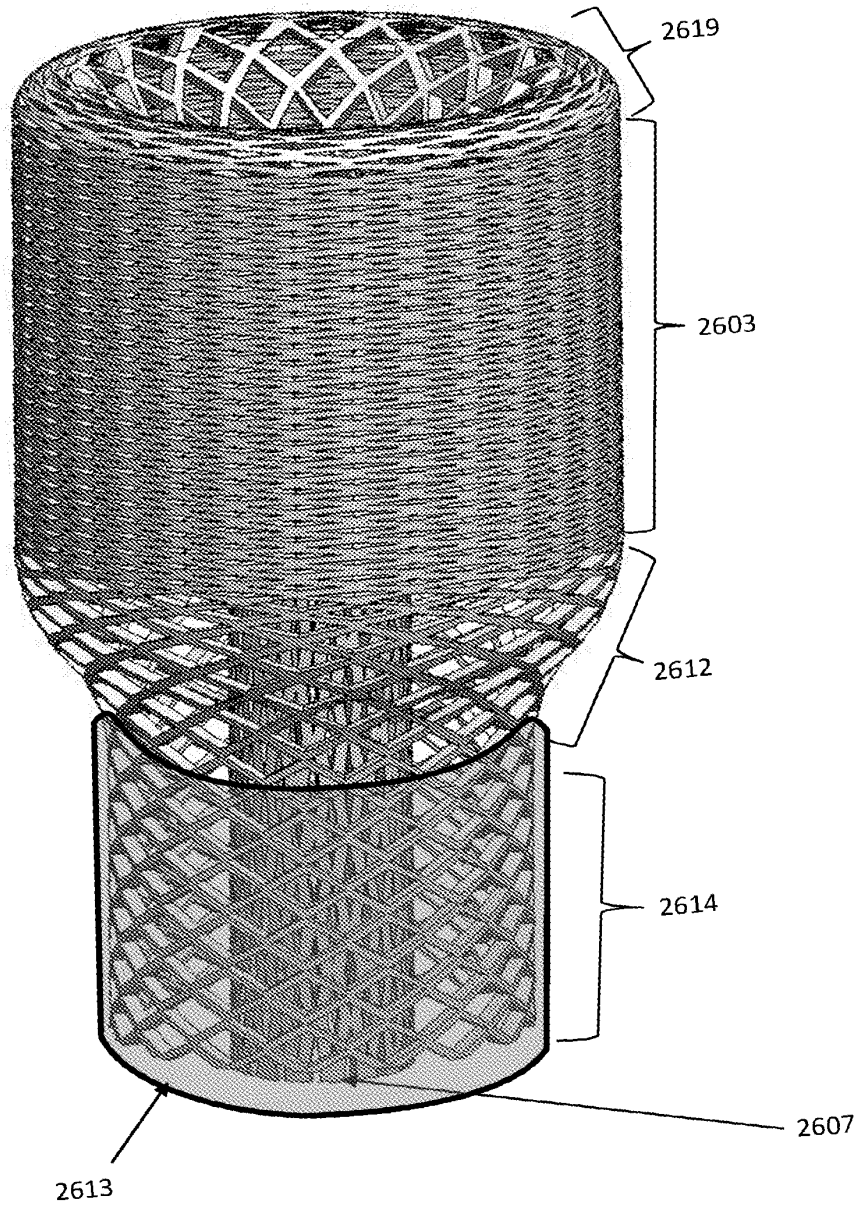


FIG. 26A

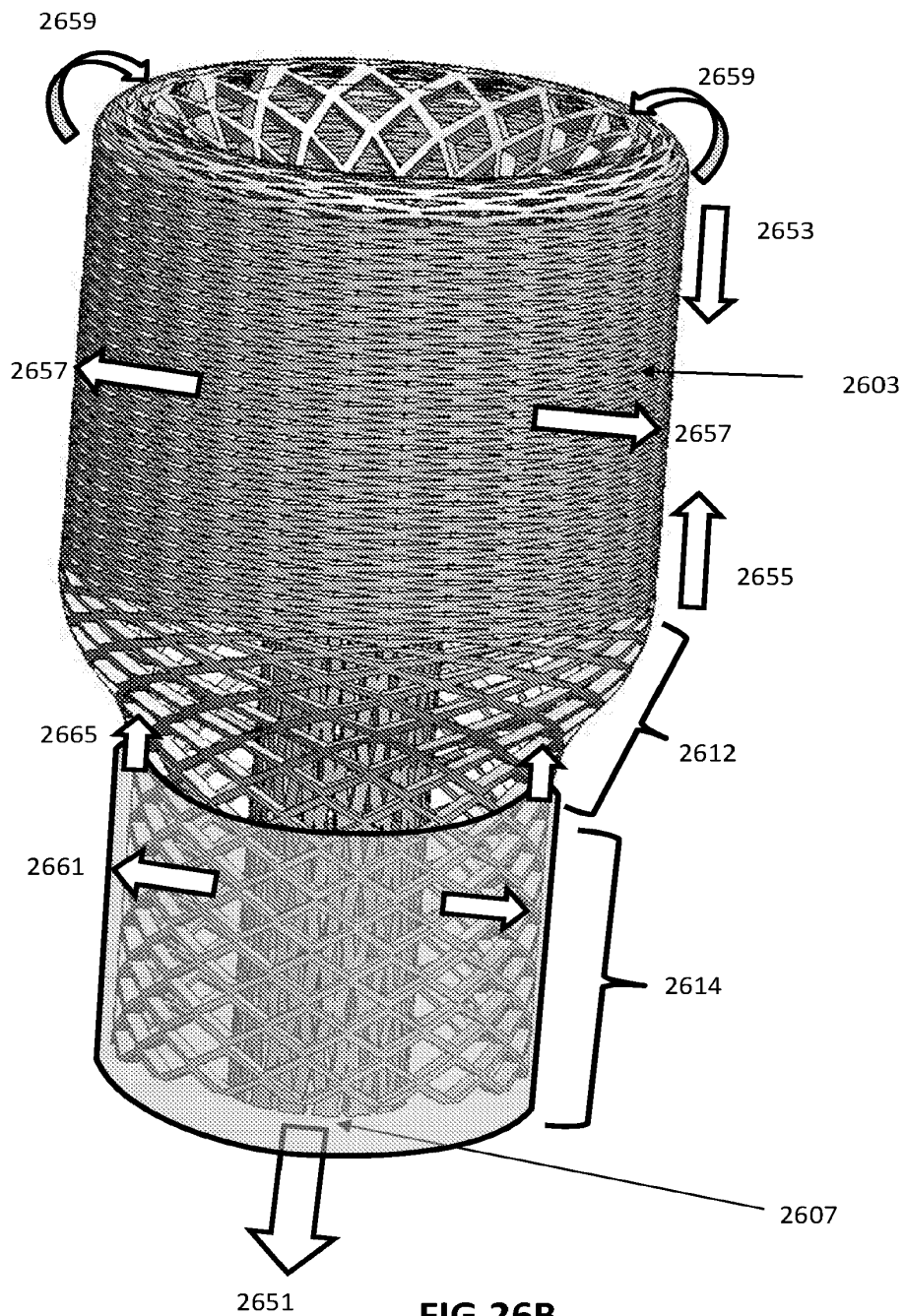


FIG. 26B

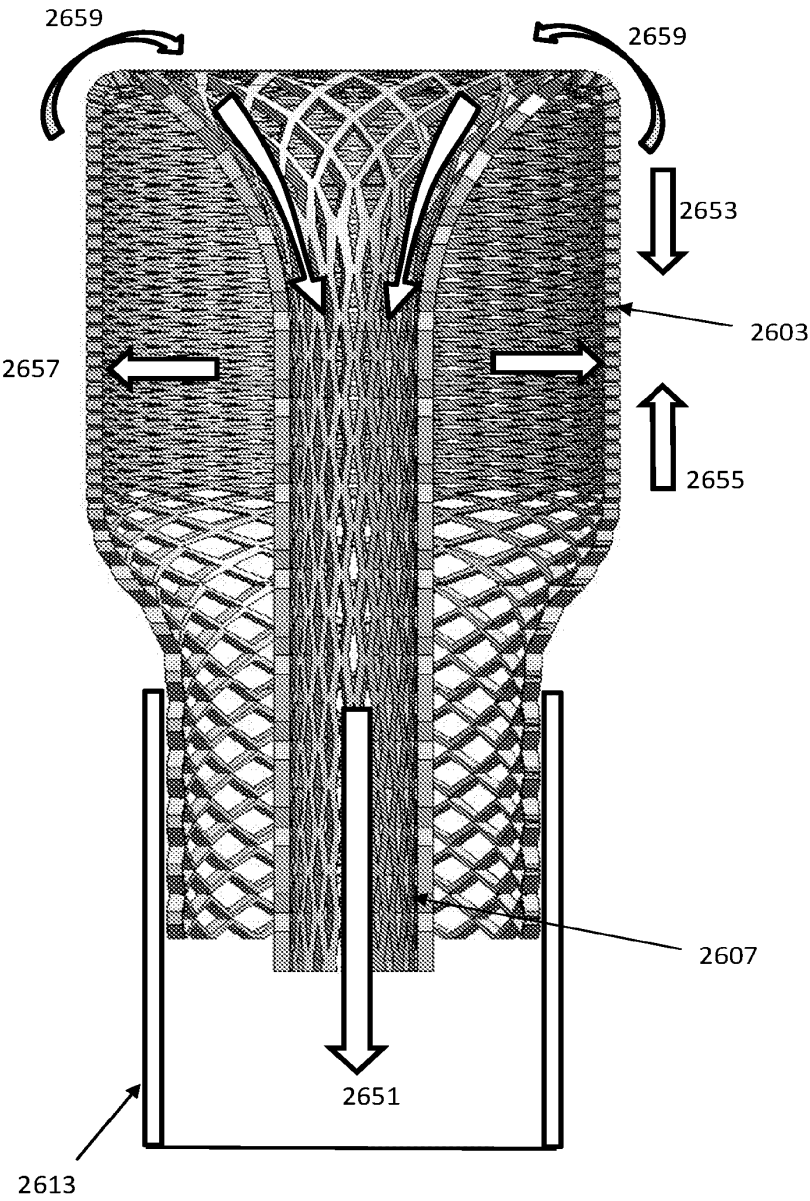


FIG.26C

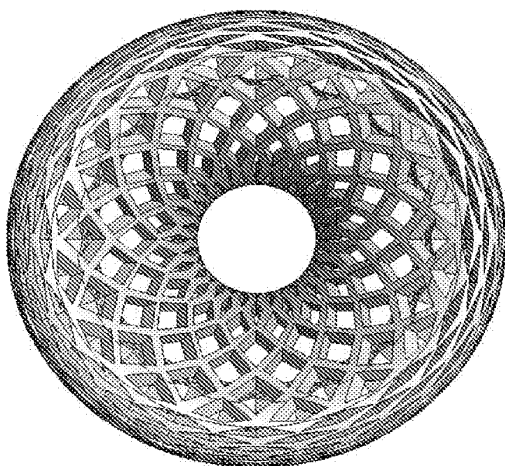


FIG. 27A

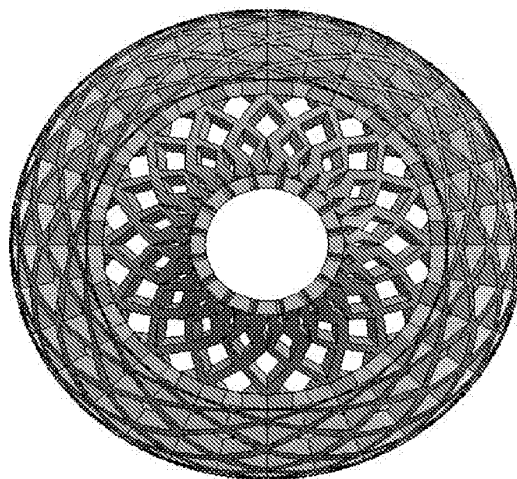


FIG. 27B

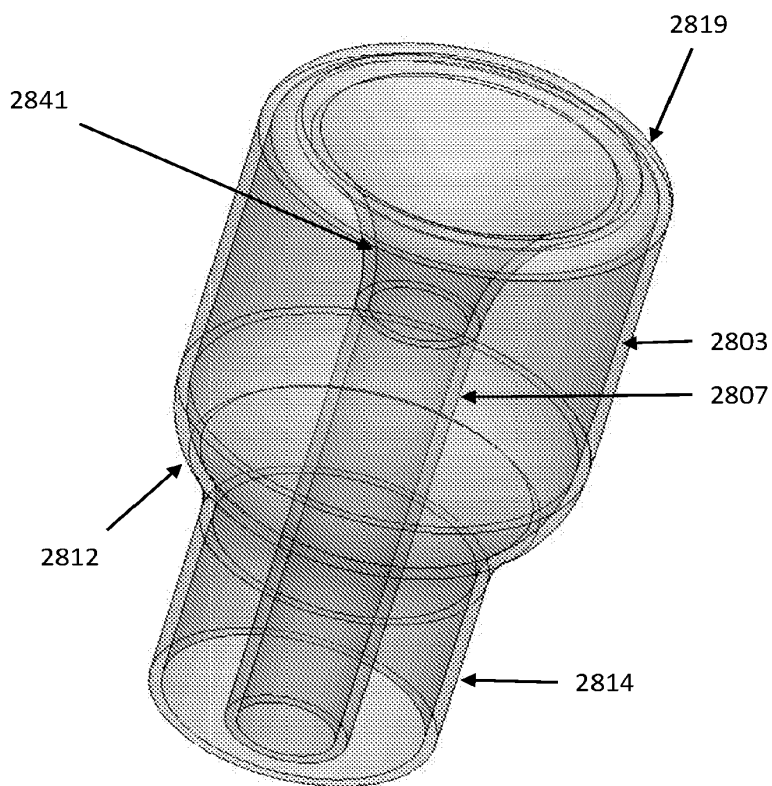


FIG. 28

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2017/050933

A. CLASSIFICATION OF SUBJECT MATTER INV. A61B17/22 A61B17/221 ADD.		
According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) A61B		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) EPO-Internal		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2012/009675 A2 (LAZARUS EFFECT, INC.) 19 January 2012 (2012-01-19)	1-14, 16-28,30
Y	paragraphs [0008], [0077], [0161], [0167] - [0170], [0172]; figures 10, 13B -----	15,29
Y	US 2010/249815 A1 (JANTZEN ET AL.) 30 September 2010 (2010-09-30)	15,29
	paragraphs [0026], [0027], [0030]; figures 1,2 -----	
A	GB 2 498 349 A (COOK MEDICAL TECHNOLOGIES LLC) 17 July 2013 (2013-07-17) abstract; claims; figures page 8, line 12 - page 11, line 16 ----- -/--	1,16,30
☒ Further documents are listed in the continuation of Box C. ☒ See patent family annex.		
* Special categories of cited documents : "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier application or patent but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family		
Date of the actual completion of the international search		Date of mailing of the international search report
26 October 2017		10/11/2017
Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016		Authorized officer Giménez Burgos, R

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

INARI_018756

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2017/050933

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

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

INARI_018757

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2017/050933

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

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

1. ☒ Claims Nos.: 31-41
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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

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

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2017/050933

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

Form PCT/ISA/210 (patent family annex) (April 2005)

INARI_018759



(51) International Patent Classification:
A61B 17/03 (2006.01) A61B 17/04 (2006.01)

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PCT/US2021/058793

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10 November 2021 (10.11.2021)

(25) Filing Language: English

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(30) Priority Data:
63/111,774 10 November 2020 (10.11.2020) US

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(72) Inventor; and

(71) Applicant: MACIAS, Jacqueline [US/US]; 9 Parker, Suite #100, Irvine, California 92618 (US).

(72) Inventors: ENRIGHT, Paige Elizabeth; 9 Parker, Suite #100, Irvine, California 92618 (US). TU, Thomas M.; 9 Parker, Suite #100, Irvine, California 92618 (US).

(74) Agent: WILLIAMS, Matthew S. et al.; Perkins Coie LLP, P.O. Box 1247, Seattle, Washington 98111-1247 (US).

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

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

(54) Title: DEVICES FOR ADJUSTABLY TENSIONING SUTURES, AND ASSOCIATED SYSTEMS AND METHODS

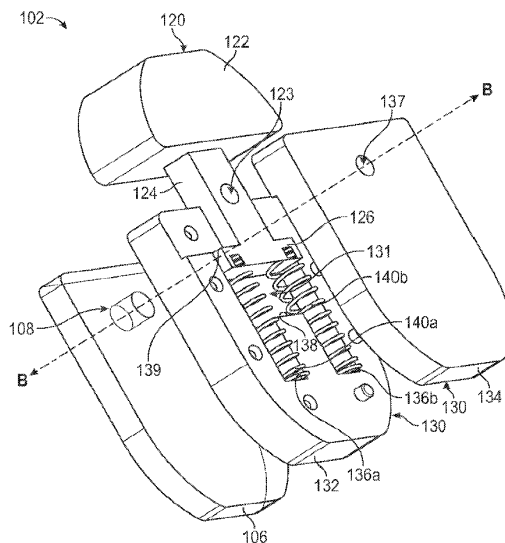


FIG. 1C

(57) Abstract: Disclosed herein are devices, systems, and methods for adjustably tensioning sutures, such as sutures used to close a catheter access site of a human patient. In some embodiments, a suture tensioning device includes a housing and an actuation member slidably coupled to the housing. The housing can include a first through-hole and a second through-hole at least partially aligned along an axis. The actuation member can include a third-through-hole. The suture tensioning device can further include a biasing member operably coupled between the actuation member and the housing. The biasing member can bias the actuation member to a first position in which the third through-hole is offset from the axis. The actuation member is movable to a second position in which the third through-hole is at least partially aligned with the first and second through-holes along the axis.

Published:

- *with international search report (Art. 21(3))*
- *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*

DEVICES FOR ADJUSTABLY TENSIONING SUTURES, AND
ASSOCIATED SYSTEMS AND METHODS

CROSS-REFERENCE TO RELATED APPLICATION

[0001] This application claims the benefit of U.S. Provisional Patent Application No. 63/111,774, filed November 10, 2020, and titled "DEVICES FOR ADJUSTABLY TENSIONING SUTURES, AND ASSOCIATED SYSTEMS AND METHODS," which is incorporated herein by reference in its entirety.

TECHNICAL FIELD

[0002] The present technology generally relates to systems, methods, and devices for adjustably tensioning sutures, such as sutures used to close a percutaneous catheter access site of a human patient.

BACKGROUND

[0003] Percutaneous medical procedures involve accessing the inner organs, tissue, and/or vasculature of a patient via a puncture in the skin of the patient. A percutaneous approach is commonly used in intravascular procedures such as angioplasty, stenting, clot removal, and so on. More specifically, many intravascular procedures include inserting a catheter and/or medical device into a blood vessel of a patient through an access site, such as a popliteal access site, an internal jugular access site, a femoral access site, or another venous or arterial access site. For example, an introducer assembly can be positioned in the blood vessel through the access site, and one or more medical instruments can be advanced through the introducer assembly for carrying out the intravascular procedure.

[0004] After such procedures, the access site must be closed to maintain hemostasis as the patient recovers. Common techniques for closing the access site include manual compression and suturing. However, it may be difficult to successfully close the access site and achieve hemostasis when the access site is large, such as for intravascular procedures utilizing large bore catheters. Additionally, the access site closure may be uncomfortable to the patient during recovery.

BRIEF DESCRIPTION OF THE DRAWINGS

[0005] Many aspects of the present technology can be better understood with reference to the following drawings. The components in the drawings are not necessarily to scale. Instead, emphasis is placed on illustrating clearly the principles of the present disclosure.

[0006] Figures 1A and 1B are an isometric view and a partially-exploded isometric view, respectively, of a suture tensioning device in accordance with embodiments of the present technology.

[0007] Figures 1C and 1D are exploded top and bottom isometric views, respectively, of the tensioning assembly 102 in accordance with embodiments of the present technology.

[0008] Figure 1E is an exploded isometric view of a dressing assembly of the suture tensioning device in accordance with embodiments of the present technology.

[0009] Figure 2 is an isometric view of a threading tool for use with the suture tensioning device in accordance with embodiments of the present technology.

[0010] Figure 3 is a flow diagram of a process or method for operating the suture tensioning device in accordance with embodiments of the present technology.

[0011] Figures 4A and 4B are isometric views of the suture tensioning device illustrating threading of a suture therethrough in accordance with embodiments of the present technology.

[0012] Figure 5 is an enlarged side cross-sectional view of a suture positioned within the tensioning assembly of the suture tensioning device in accordance with embodiments of the present technology.

[0013] Figure 6 is an exploded isometric view of a tensioning assembly in accordance with additional embodiments of the present technology.

[0014] Figures 7A and 7B are an exploded isometric view and an isometric view, respectively, of a suture tensioning device in accordance with additional embodiments of the present technology.

[0015] Figure 8 is an exploded isometric view of a tensioning assembly in accordance with additional embodiments of the present technology.

[0016] Figure 9 is an exploded isometric view of a suture tensioning device in accordance with additional embodiments of the present technology.

[0017] Figures 10A and 10B are isometric views of a tensioning assembly in a first position and a second position, respectively, in accordance with additional embodiments of the present technology.

[0018] Figure 11 is an isometric view of a tensioning assembly in accordance with additional embodiments of the present technology.

[0019] Figure 12 is an exploded isometric view of a tensioning assembly in accordance with additional embodiments of the present technology.

[0020] Figures 13A and 13B are isometric views of a tensioning assembly in a first position and a second position, respectively, in accordance with additional embodiments of the present technology.

DETAILED DESCRIPTION

[0021] The present technology is generally directed to devices for adjustably tensioning sutures, such as sutures used to close a catheter access site of a human patient, and associated systems and methods. In some embodiments, a suture tensioning device includes a housing and an actuation member slidably coupled to the housing. The housing can include a first through-hole and a second through-hole at least partially aligned with one another along an axis. The actuation member can include a third-through-hole. The suture tensioning device can further include a biasing member operably coupled between the actuation member and the housing. The biasing member can exert a biasing force against the actuation member that holds the actuation member in a first position in which the third through-hole is offset from the axis and therefore not aligned with the first and second through-holes of the housing. The actuation member can be movable against the biasing force of the biasing member to a second position in which the third through-hole is at least partially aligned with the first and second through-holes along the axis.

[0022] In operation, a user can thread a suture through the first, second, and third through-holes when the actuation member is in the second position. The suture can be used to close a puncture in the patient, such as a catheter access site. After adjusting the tension in the suture to a desired tension, the user can release the actuation member to permit the biasing member to drive the actuation member to the first position. In the first position, the actuation member and/or the housing engage the suture to inhibit the suture from moving through the first, second, and third through-holes. Accordingly, the suture tensioning device can maintain the desired tension

in the suture. To adjust the tension in the suture, the user can actuate (e.g., depress) the actuation member against the biasing force of the biasing member to move the actuation member to the second position. The user can then adjust the tension in the suture to another desired tension, and then release the actuation member to lock the suture in position at the selected tension. Accordingly, in one aspect of the present technology the suture tensioning device allows the tension in the suture to be easily adjusted. For example, the user can increase the tension to better close the puncture and maintain hemostasis and/or decrease the tension to accommodate patient comfort.

[0023] Certain details are set forth in the following description and in Figures 1–13B to provide a thorough understanding of various embodiments of the present technology. In other instances, well-known structures, materials, operations, and/or systems often associated with intravascular procedures, percutaneous access sites, etc., are not shown or described in detail in the following disclosure to avoid unnecessarily obscuring the description of the various embodiments of the technology. Those of ordinary skill in the art will recognize, however, that the present technology can be practiced without one or more of the details set forth herein, and/or with other structures, methods, components, and so forth.

[0024] The terminology used below is to be interpreted in its broadest reasonable manner, even though it is being used in conjunction with a detailed description of certain examples of embodiments of the technology. Indeed, certain terms may even be emphasized below; however, any terminology intended to be interpreted in any restricted manner will be overtly and specifically defined as such in this Detailed Description section.

[0025] The accompanying Figures depict embodiments of the present technology and are not intended to be limiting of its scope unless expressly indicated. The sizes of various depicted elements are not necessarily drawn to scale, and these various elements may be enlarged to improve legibility. Component details may be abstracted in the Figures to exclude details such as position of components and certain precise connections between such components when such details are unnecessary for a complete understanding of how to make and use the present technology. Many of the details, dimensions, angles and other features shown in the Figures are merely illustrative of particular embodiments of the disclosure. Accordingly, other embodiments can have other details, dimensions, angles and features without departing from the present technology. In addition, those of ordinary skill in the art will appreciate that further

embodiments of the present technology can be practiced without several of the details described below.

[0026] With regard to the terms "distal" and "proximal" within this description, unless otherwise specified, the terms can reference a relative position of the portions of a catheter subsystem with reference to an operator and/or a location in the vasculature. Also, as used herein, the designations "rearward," "forward," "upward," "downward," etc., are not meant to limit the referenced component to a specific orientation. It will be appreciated that such designations refer to the orientation of the referenced component as illustrated in the Figures; the systems of the present technology can be used in any orientation suitable to the user.

[0027] Figures 1A and 1B are an isometric view and a partially-exploded isometric view, respectively, of a suture tensioning device 100 in accordance with embodiments of the present technology. Referring to Figures 1A and 1B together, the suture tensioning device 100 can include a tensioning assembly 102 (shown exploded in Figure 1B) configured to be coupled to a dressing assembly 104 via a pad 106. The dressing assembly 104 is configured to be positioned over an incision or puncture in a patient (e.g., a human patient), such as a percutaneous access site, and can be adhered to the patient (e.g., the skin of the patient) around the puncture. The tensioning assembly 102 is configured to receive and tension one or more sutures used to close the puncture. Figures 1C and 1D are exploded top and bottom isometric views, respectively, of the tensioning assembly 102 in accordance with embodiments of the present technology. The pad 106 is shown as partially transparent in Figures 1A–1D for clarity. Figure 1E is an exploded isometric view of the dressing assembly 104 in accordance with embodiments of the present technology.

[0028] Referring first to Figure 1E, in some embodiments the dressing assembly 104 includes a contact layer 110 and an adhesive portion 112 over and/or integrated with the contact layer 110. The contact layer 110 and the adhesive portion 112 are shown as partially transparent in Figure 1E for the sake of clarity. In the illustrated embodiment, the dressing assembly 104 has a generally elongate, oval-like shape while, in other embodiments, the dressing assembly 104 can have other shapes (e.g., rectangular, circular, rectilinear, polygonal, irregular). In some embodiments, the contact layer 110 includes and/or comprises an adhesive material (e.g., an acrylic and/or acrylate material) on its underside for releasably securing the dressing assembly 104 to a patient. In some embodiments, the contact layer 110 (e.g., an upper surface of the contact layer 110) can include a medical tape including, for example, a polyethylene material.

The adhesive portion 112 can comprise an acrylic, acrylate, or other suitable adhesive material. In the illustrated embodiment, the dressing assembly 104 includes a first removable protection layer 114a and a second removable protection layer 114b (collectively "protection layer 114") coupled to the contact layer 110 (e.g., a lower surface of the contact layer 110). The protection layer 114 can cover, seal, and/or protect the contact layer 110 and its adhesive before the dressing assembly 104 is used, and can be removed before placing the dressing assembly 104 on the patient. In some embodiments, the first removable protection layer 114a and the second removable protection layer 114b can be folded to facilitate their removal from the contact layer 110. In other embodiments, the dressing assembly 104 can include more or fewer layers and/or can include different materials. For example, the dressing assembly 104 can include multiple different layers laminated together.

[0029] In the illustrated embodiment, (i) the protection layer 114 includes/defines a first opening 111 (e.g., a through-hole or aperture formed between the first removable protection layer 114a and the second removable protection layer 114b), (ii) the contact layer 110 includes a second opening 113, and (iii) the adhesive portion 112 includes a third opening 115 (collectively "openings 111–115"). Referring to Figures 1A, 1B, and 1E together, the openings 111–115 are at least partially aligned to define a through-hole 118 extending entirely through the dressing assembly 104 between a first surface 117a (e.g., a lower surface) and a second surface 117b (e.g., an upper surface) thereof. The tensioning assembly 102 is configured to be secured to the adhesive portion 114 of the dressing assembly 104 over the through-hole 118. As described in greater detail below with reference to Figures 3–4B, one or more sutures can be threaded (e.g., routed, inserted) through the through-hole 118 to the tensioning assembly 102.

[0030] In operation of the suture tensioning device 100, the dressing assembly 104 can be placed against the skin of a patient with the protection layer 114 in place. After positioning the openings 111–115 over/at a desired location, such as an incision in the patient, an operator can peel back and remove the first removable protection layer 114a and the second removable protection layer 114a and then adhere the contact layer 110 to the patient.

[0031] Referring to Figures 1A–1D together, the tensioning assembly 102 can include an actuation member 120 movably (e.g., slidably) coupled to/within a housing 130 having a lower housing portion 132 and an upper housing portion 134. In the illustrated embodiment, the lower housing portion 132 and/or the upper housing portion 134 (e.g., either together or individually) define a channel 131 including a first biasing member mount 136a, a second biasing member

mount 136b, a first stop surface 138, and a second stop surface 139. The actuation member 120 can include (i) a press portion 122 extending at least partially outside the housing 130, (ii) an elongate portion 124 extending from the press portion 122 into the housing 130 past the second stop surface 139, and (iii) a flange or mount portion 126 extending from the elongate portion 124 and at least partially through the channel 131. A first biasing member 140a can be operably coupled between the first biasing member mount 136a and the mount portion 126 of the actuation member 120. Likewise, a second biasing member 140b can be operably coupled between the second biasing member mount 136b and the mount portion 126 of the actuation member 120.

[0032] The biasing members 140 are configured (e.g., shaped, sized, and/or positioned) to drive the actuation member 120 outward away from the first stop surface 138 in a direction indicated by arrow A in Figure 1A (e.g., in a horizontal or lateral direction). In some embodiments, the biasing members 140 are compression springs that extend through the channel 131 and that are directly attached to the biasing member mounts 136 and the mount portion 126 via an adhesive, fasteners (e.g., screws), welding, or another suitable attachment mechanism. In other embodiments, the tensioning assembly 102 can include more or fewer of the biasing members 140 (e.g., one, three, four or more) operably coupling the actuation member 120 to the housing 130. In some embodiments, the biasing members 140 can have a spring constant of between about 10–25 pounds per inch (e.g., between about 12–22 pounds per inch, between about 16–18 pounds per inch, about 17 pounds per inch, and so on).

[0033] In the illustrated embodiment, the lower housing portion 132 includes/defines a first through-hole 133 (Figure 1D), the elongate portion 124 of the actuation member 120 includes a second through-hole 123 (Figure 1C), and the upper housing portion 134 includes a third through-hole 137. The first through-hole 133 and the third through-hole 137 are at least partially aligned with one another (e.g., superimposed over one another) along an axis B shown in Figures 1C and 1D (e.g., a vertical axis).

[0034] The tensioning assembly 102 is in a first position (e.g., a lock position) in Figures 1A–1D in which the biasing members 140 bias the actuation member 120 outward in the direction of arrow A such that the mount portion 126 engages/contacts the second stop surface 139 of the lower housing portion 132. In the first position, the second through-hole 123 through the elongate portion 124 of the actuation member 120 is not aligned with the first and third through-holes 133, 137 of the housing 130. More specifically, the second through-hole 123 is positioned axially away from the axis B such that the second through-hole 123 is not

superimposed with the first and third through-holes 133, 137. In operation, the actuation member 120 can be actuated to move the tensioning assembly 102 from the first position to a second position (e.g., a release position; shown in Figure 4B) in which the second through-hole is aligned with the first and third through-holes 133, 137. More specifically, a user (e.g., a physician, nurse) can press the press portion 122 of the actuation member 120 to drive the actuation member 120 inward in the direction of arrow C shown in Figure 1B—against the biasing force of the biasing members 140—until the mount portion 126 engages the first stop surface 138 of the lower housing portion 132. In the second position, the second through-hole 123 is at least partially aligned with the first and third through-holes 133, 137 along the axis B. In some embodiments, the movement of the actuation member 120 in the direction of arrow C is generally orthogonal to the axis B.

[0035] Referring to Figures 1A–1E together, in some embodiments the pad 106 can be coupled to/between the lower housing portion 132 and the adhesive portion 114 of the dressing assembly 104 via an adhesive, fasteners, a snap-fit arrangement, and/or the like. In some embodiments, the pad 106 can be flexible and configured to conform to the skin of a patient during use of the suture tensioning device 100. For example, the pad 106 can be formed from a thermoplastic elastomer (TPE), rubber, silicone, and/or another flexible material. In some embodiments, the adhesive portion 114 of the dressing assembly 104, the pad 106, and the lower housing portion 132 of the housing 130 all have the same generally curved-rectangular planform shape. In other embodiments, the adhesive portion 114, the pad 106, and the lower housing portion 132 can have different shapes (e.g., rectangular, circular, rectilinear, polygonal, irregular) and/or different shapes than one another. In some embodiments, the pad 106 can be omitted and the lower housing portion 132 can be directly attached to the adhesive portion 114 of the dressing assembly 104.

[0036] In the illustrated embodiment, the pad 106 includes/defines a through-hole 108 that is aligned along the axis B with (i) the first and third through-holes 133, 137 of the tensioning assembly 102 and (ii) the through-hole 118 of the dressing assembly 104. Accordingly, when the tensioning assembly 102 is in the second position with the actuation member 120 pressed inward toward the housing 130, each of the through-holes 108, 118, 123, 133, and 137 are at least partially aligned to define a continuous path through the suture tensioning device 100 for receiving one or more sutures.

[0037] Figure 2 is an isometric view of a threading tool 250 for use with the suture tensioning device 100 in accordance with embodiments of the present technology. The threading tool 250 can include an elongate portion 252 and a loop portion 254 enclosing/defining an opening 256. In some embodiments, the elongate portion 252 and the loop portion 254 can be formed from a flexible material, such as a nylon monofilament. In some embodiments, the elongate portion 252 can be more rigid than the loop portion 254. For example, the elongate portion 252 can be formed of a different, more rigid material than the loop portion 254 and/or can be made thicker than the loop portion 254. As described in detail below with reference to Figures 4A and 4B, the threading tool 250 can be inserted and pulled through the tensioning assembly 102 when the tensioning assembly 102 is in the second position to pull/thread one or more sutures positioned in the opening 256 through the tensioning assembly 102.

[0038] Figure 3 is a flow diagram of a process or method 360 for operating the suture tensioning device 100 in accordance with embodiments of the present technology. Although some features of the method 360 are described in the context of the embodiments shown in Figures 1A–2 for the sake of illustration, one skilled in the art will readily understand that the method 360 can be carried out using other suitable systems and/or devices described herein—for example, using any of the suture tensioning devices described below with reference to Figures 6–13B.

[0039] At block 361, the method 360 includes threading one or more sutures through the suture tensioning device 100. The sutures can be used to close a puncture in a patient. Figures 4A and 4B, for example, are isometric views of the suture tensioning device 100 illustrating threading of a suture 470 therethrough before the dressing assembly 104 has been attached to the skin in accordance with embodiments of the present technology. In some embodiments, the sutures 470 have a U.S.P. size of between about #4-0 to #2. Referring first to Figure 4A, a user can insert/loop the suture 470 (e.g., end portions 472 of the suture 470) through the opening 256 of the threading tool 250. With the tensioning assembly 102 in the second position, the user can then insert the elongate portion 252 of the threading tool 250 through the through-holes in the dressing assembly 104, the pad 106, and the tensioning assembly 102. For example, the user can depress the actuation member 120 to maintain the tensioning assembly 102 in the second position. Then, referring to Figure 4B, the user can pull the threading tool 250 entirely through the through-holes in the suture tensioning device 100 to pull the suture 470 therethrough. In other embodiments, the user can thread the suture 470 through the suture tensioning device 100 without using the threading tool 250.

[0040] In some embodiments, the suture 470 can be threaded/tied in a figure eight around the puncture. In some embodiments, the suture 470 is not knotted (e.g., in a surgeon's knot) before being threaded through the suture tensioning device 100. The puncture can be an access site into the body of the patient used to carry out a percutaneous medical procedure, such as an intravascular procedure that includes inserting a catheter or medical device into a blood vessel of the patient through the access site. The access site can be a popliteal access site, an internal jugular access site, a femoral access site, or another venous or arterial access site. In some embodiments, the access site can be relatively large, such as those needed to facilitate intravascular procedures utilizing large bore catheters. In some embodiments, the access site can be used to facilitate any of the clot removal procedures described in detail in (i) U.S. Patent No. 9,700,332, filed September 16, 2016, and titled "INTRAVASCULAR TREATMENT OF VASCULAR OCCLUSION AND ASSOCIATED DEVICES, SYSTEMS, AND METHODS," (ii) U.S. Patent No. 10,098,651, filed April 26, 2017, and titled "DEVICES AND METHODS FOR TREATING VASCULAR OCCLUSION," and/or (iii) U.S. Patent Application No. 16/536,185, titled "SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS," filed August 8, 2019, each of which is incorporated herein by reference in its entirety.

[0041] At block 362, the method 360 includes coupling the suture tensioning device 100 to the patient. For example, the user can remove the protection layer 116 from the dressing assembly 104 and press the lower layer 110 of the dressing assembly 104 against the skin of the patient around the puncture to adhere the dressing assembly 104 to the patient over/around the puncture. In some embodiments, the dressing assembly 104 can be coupled to the patient before the suture 470 is threaded through the tensioning assembly 102 and/or before the tensioning assembly 102 is coupled to the dressing assembly 104.

[0042] At block 363, the method 360 includes adjusting the suture 470 to have a desired/selected tension. For example, the user can continue depressing the actuation member 120 to move the tensioning assembly 102 to the second position, and then pull the suture 470 until a desired tension is achieved. The tension can be sufficient to close the puncture in the patient and maintain hemostasis at the puncture.

[0043] At block 364, the method 360 includes locking the suture 470 in the suture tensioning device 100 to maintain the desired tension in the suture 470. For example, after pulling the suture 470 to have the desired tension, the user can simply release the actuation

member 120 to allow the actuation member 120 to return to the first position from the second position, thereby preventing the suture 470 from moving within the tensioning assembly 102. More specifically, Figure 5 is an enlarged side cross-sectional view of the suture 470 positioned within the tensioning assembly 102 with the actuation member 120 in the first position in accordance with embodiments of the present technology.

[0044] Referring to Figures 1A–D and 5 together, releasing the actuation member 120 allows the biasing members 140 to drive the actuation member 120 away from the first stop surface 138 toward and/or into engagement with the second stop surface 139, thereby moving the second through-hole 123 out of alignment with the first and third through-holes 133, 137. As the actuation member 120 moves to the first position, a perimeter or edge 527 of the second through-hole 123 engages the suture 470 and pulls the suture 470 through the channel 131 within the housing 130 in the direction of the arrow A (Figure 1A). Thus, as shown in Figure 5, the suture 470 traverses through the tensioning assembly 102 along a serpentine path, and the friction/engagement between the suture 470 and the actuation member 120 and the housing 130 can lock/clamp the suture 470 in position—inhibiting or even preventing movement of the suture 470 through the housing 130. That is, the tensioning assembly 102 cinches the suture 470 in the first position to inhibit movement of the suture 470 therethrough.

[0045] At block 365, the method 360 optionally includes adjusting the tension of the suture 470. To adjust the tension, the user can depress the actuation member 120 to move the actuation member 120 against the biasing force of the biasing members 140 to the second position, and then advance or retract the suture 470 through the tensioning assembly 102 to decrease or increase the tension, respectively. For example, the user may wish to increase the tension of the suture 470 to increase the constriction force on the puncture to facilitate hemostasis. Conversely, the user may wish to decrease the tension of the suture 470 to accommodate the comfort of the patient. Accordingly, in one aspect of the present technology the suture tensioning device 100 permits the tension in the suture 470 to be simply adjusted by depressing/releasing the actuation member 120 and without disturbing the dressing assembly 104. In contrast, conventional techniques for closing punctures include knotting a suture used to close the puncture to maintain tension in the suture. However, knots prevent the tension in the suture from being easily adjusted—as the knot must be undone and then retied to adjust the tension.

[0046] At block 366, the method 360 includes removing the suture 470 from the suture tensioning device 100 and removing the suture tensioning device 100 from the patient. For

example, the user can depress the actuation member 120 to move the actuation member 120 to the second position, and then pull the tensioning assembly 102 and/or the dressing assembly 104 away from the patient to remove the suture 470 therefrom. In some embodiments, the tensioning assembly 102 can be decoupled from the dressing assembly 104 and removed from over the suture 470 while the dressing assembly 104 remains on the patient.

[0047] Figures 6–13B illustrate additional embodiments of suture tensioning devices and tensioning assemblies in accordance with the present technology. The suture tensioning devices described with reference to Figures 6–13B can include several features generally similar or identical to the features of one another and/or the features of the suture tensioning device 100 described in detail with reference to Figures 1A–5, and can be operated in and function in a generally similar or identical manner. Accordingly, the description of Figures 6–13B emphasizes the unique features of the various embodiments. However, one skilled in the art will appreciate that the various embodiments can be combined and/or modified. For example, each of the tensioning assemblies described with reference to Figures 6–13B can be coupled to a dressing assembly (e.g., the dressing assembly 104) and/or a flexible pad (e.g., the pad 106), even if not expressly shown.

[0048] Figure 6 is an exploded isometric view of a tensioning assembly 602 in accordance with additional embodiments of the present technology. In the illustrated embodiment, the tensioning assembly 602 includes an actuation member 620 operably coupled to a housing or base 630 via a first biasing member 640a and a second biasing member 640b. More specifically, the first biasing member 640a can be coupled in/between a first biasing member mount 629a on the actuation member 620 and a first channel 636a formed in the base 630. Similarly, the second biasing member 640b can be coupled in/between a second biasing member mount 629b on the actuation member 620 and a second channel 636b formed in the base 630. The base 630 can include a channel 631 configured to slidably receive an elongate portion 624 of the actuation member 620. The base 630 can further include a first through-hole 633 and a second through-hole 637 extending at least partially therethrough and providing access to the channel 631. The first and second through-holes 633, 637 can be at least partially aligned with one another (e.g., along an axis extending therethrough). The elongate portion 624 of the actuation member 620 can include a third through-hole 623.

[0049] The biasing members 640 are configured to bias the actuation member 620 away from the base 630 to a first position in which the third through-hole is not aligned with (e.g., is

offset from) the first and second through-holes 633, 637. A user can depress the actuation member 620 toward the base 630 against the biasing force of the biasing members 640 to drive the elongate portion 624 of the actuation member 620 through the channel 631 such that the third through-hole 623 is aligned with the first and second through-holes 633, 637. Accordingly, in operation the user can insert one or more sutures through the through-holes 623, 633, 637 when the tensioning assembly 602 is in the second position, and can then release the actuation member 620 to allow the tensioning assembly 602 to return to the first position. In the first position, the actuation member 620 and the base 630 can cinch the sutures (e.g., in the manner described with respect to Figure 5) to inhibit movement of the sutures through the tensioning assembly 602.

[0050] Figures 7A and 7B are an exploded isometric view and an isometric view, respectively, of a suture tensioning device 700 in accordance with additional embodiments of the present technology. Referring to Figures 7A and 7B together, the suture tensioning device 700 can include a tensioning assembly 702, a dressing assembly 704, and a pad 706 (e.g., a flexible pad). The pad 706 defines a through-hole 708 and is configured (e.g., sized and shaped) to be positioned in an aperture 719 in the dressing assembly 704. For example, the pad 706 can be directly coupled to the skin of a patient through the aperture 719.

[0051] In the illustrated embodiment, the tensioning assembly 702 includes a base portion 780 including/defining a channel 781 and configured to be positioned in the through-hole 708 of the pad 706. In other embodiments, the base portion 780 can be coupled to the pad 706 over the through-hole 708. The tensioning assembly 702 further includes a body portion 782 coupled to the base portion 780. The body portion 782 defines a channel 783 that is accessible via a pair of first through-holes 784 (a lower one of the first through-holes 784 is obscured in Figures 7A and 7B). The tensioning assembly 702 can further include an actuation member 786 having an elongate portion 785 rotatably positioned within the channel 783. The elongate portion 785 includes a second through-hole 787. The channel 781 of the base portion 780 and the first through-holes 784 of the body portion 782 are at least partially aligned along an axis extending therethrough. The actuation member 786 is rotatable to rotate the second through-hole 787 of the elongate portion 785 into and out of alignment with the first through-holes 784 and the channel 781.

[0052] In operation, a user can rotate the actuation member 786 such that the second through-hole 787 is aligned with the channel 781 and the first through-holes 784, and then thread one or more sutures through the channel 781, the lower one of the first through-holes 784, the

second through-hole 787, and the upper one of the first through-holes 784. Once the one or more sutures are threaded through the tensioning assembly 702, the actuation member 786 can be rotated to cinch the sutures to inhibit movement of the sutures through the tensioning assembly 702. In some embodiments, the sutures can be wound around the elongate portion 785 of the actuation member 786 to cinch the sutures via the friction between the sutures and the outer surface of the elongate portion 785. In some embodiments, the actuation member 786 can be rotated in a first direction (e.g., clockwise) to increase the tension in the sutures, and in a second direction (e.g., counterclockwise) to decrease the tension in the sutures. Accordingly, in one aspect of the technology the tensioning assembly 702 is actuatable to increase/decrease the tension in the sutures without requiring a user to manually pull/release the sutures through the tensioning assembly 702.

[0053] Figure 8 is an exploded isometric view of a tensioning assembly 802 in accordance with additional embodiments of the present technology. In the illustrated embodiment, the tensioning assembly 802 includes an actuation member 890 (e.g., a lever arm) rotatably coupled to a housing 892. More specifically, the housing 892 can include a base 893 and a sidewall 894 projecting from the base 893, and the actuation member 890 can be an elongate member extending through and supported by the sidewall 894 (e.g., extending through a pair of openings therein). The base 893 can include/define a first through-hole 895, and the actuation member 890 can include a second through-hole 896. In some embodiments, the tensioning assembly 802 can further include a cap 898 having a third through-hole 899 and configured to be coupled to the housing 892 opposite the base 893. When the cap 898 is coupled to the housing 892, the first and third through-holes 895, 899 can be at least partially aligned with one another. The actuation member 890 is rotatable to rotate the second through-hole 896 into and out of alignment with the first and third through-holes 895, 899.

[0054] In operation, a user can rotate the actuation member 890 such that the second through-hole 896 is aligned with the first and third through-holes 895, 899, and then thread one or more sutures through each of the through-holes. Once the one or more sutures are threaded through the tensioning assembly 802, the actuation member 890 can be rotated to wind the sutures around the actuation member 890 to cinch the sutures via the friction between the sutures and the outer surface of the actuation member 890. In some embodiments, the actuation member 890 can be rotated in a first direction (e.g., clockwise) to increase the tension in the sutures, and in a second direction (e.g., counterclockwise) to decrease the tension in the sutures. Accordingly, in one aspect of the technology the tensioning assembly 802 is actuatable to increase/decrease

the tension in the sutures without requiring a user to manually pull/release the sutures through the tensioning assembly 802.

[0055] Figure 9 is an exploded isometric view of a suture tensioning device 900 in accordance with additional embodiments of the present technology. In the illustrated embodiment, the suture tensioning device 900 includes a tensioning assembly 902 configured to be coupled to a dressing assembly 904. The dressing assembly 904 defines a through-hole 918 and can be applied to a patient over and/or proximate to a puncture in the skin of the patient. The tensioning assembly 902 includes a base portion 980 and a cap or lid portion 982 configured to releasably mate with and engage the base portion 980. More specifically, the base portion 980 can include/define an annular groove 983 configured (e.g., shaped, sized, and/or positioned) to receive a flange portion 986 of the lid portion 982. The lid portion 982 can be rotated by a user to rotate the flange portion 986 through the groove 983. In some embodiments, the lid portion 982 further includes a projection 987 extending radially outward from the flange portion 986 and configured to be positioned in a track 988 formed in the base portion 980 (e.g., in a sidewall of the base portion 980). Rotation of the lid portion 982 can bring the projection 987 into contact with end portions of the track 988, thereby limiting the rotation of the lid portion 982. That is, the track 988 can extend only partially around the base portion 980 such that the lid portion 982 is rotatable through an angle less than 360 degrees. In the illustrated embodiment, the base portion 980 includes a first through-hole 990 and the lid portion 982 includes a second through-hole 992 that can be rotated into and out of alignment with the first through-hole 990.

[0056] In operation, a user can rotate the lid portion 982 such that the second through-hole 992 is aligned with the first through-hole 990, and then thread one or more sutures through the through-hole 918 in the dressing assembly 904 and the first and second through-holes 992, 994. Once the one or more sutures are threaded through the tensioning assembly 902, the lid portion 982 can be rotated to cinch the sutures in the groove 983 between the flange portion 986 and the base portion 980 to inhibit movement of the sutures through the tensioning assembly 902. In some embodiments, the lid portion 982 can be rotated in a first direction (e.g., clockwise) to increase the tension in the sutures, and in a second direction (e.g., counterclockwise) to decrease the tension in the sutures. Accordingly, in one aspect of the technology the tensioning assembly 902 is actuatable to increase/decrease the tension in the sutures without requiring a user to manually pull/release the sutures through the tensioning assembly 902.

[0057] Figures 10A and 10B are isometric views of a tensioning assembly 1002 in a first position and a second position, respectively, in accordance with additional embodiments of the present technology. Referring to Figures 10A and 10B together, the tensioning assembly 1002 includes (i) a base 1080 defining a recess 1081 and (ii) a compressible member 1082 configured (e.g., shaped and sized) to be inserted into the recess 1081. In some embodiments, the compressible member 1082 can be formed from a material having a softer durometer than the base 1080. Accordingly, the compressible member 1082 can be pushed into the recess 1081 and snugly secured therein via a friction-fit or snap-fit arrangement. In the illustrated embodiment, the base 1080 defines a first through-hole 1084 and the compressible member 1082 defines a second through-hole 1086. In the first position, when the compressible member 1082 is positioned outside of the recess 1081, the second through-hole 1086 can have a first diameter D_1 . In the second position, when the compressible member 1082 is compressed inside of the recess 1081, the second through-hole 1086 can have a second diameter D_2 that is smaller than the first diameter D_1 . Moreover, the first and second through-holes 1084, 1086 can be at least generally aligned over one another in the second position.

[0058] In operation, a user can thread one or more sutures through the first and second through-holes 1084, 1086 when the tensioning assembly 1002 is in the first position. The user can then manually adjust the tension in the sutures before positioning (e.g., snapping) the compressible member 1082 into the recess 1081. The diameter D_2 of the second through-hole 1086 can be small enough that the compressible member 1082 cinches/grips the sutures in the second position to inhibit movement of the sutures through the tensioning assembly 1002. To adjust the tension in the sutures, the user can remove the compressible member 1082 from the recess 1081 and manually adjust the tension.

[0059] Figure 11 is an isometric view of a tensioning assembly 1102 in accordance with additional embodiments of the present technology. In the illustrated embodiment, the tensioning assembly 1102 includes a flexible tube 1180 and a clamp 1182 positioned around the flexible tube 1180. The flexible tube 1180 includes a first end portion 1183a, a second end portion 1183b, and a middle portion 1183c extending therebetween. The flexible tube 1180 can define a lumen 1185 extending between the first and second end portions 1183a, b. In some embodiments, a diameter of the lumen 1185 can vary. For example, in the illustrated embodiment the flexible tube 1180 is flared at the first and second end portions 1183a, b such that the diameter of the lumen 1185 is greater at and near the first and second end portions 1183a, b than at the middle portion 1183c. The clamp 1184 can include a first arm 1186a and a second

arm 1186b that are pivotally coupled together via, for example, a pin 1188. The clamp 1182 is in a first position in Figure 11 in which the arms 1186 are pivoted apart from each other. The arms 1186 can each include one or more mating/engagement features (not shown) such that the arms 1186 can be pivoted toward each other and coupled together in a second position (e.g., via a snap-fit arrangement). In the second position, the arms 1186 compress the flexible tube 1180. In the illustrated embodiment, the clamp 1182 is positioned around the middle portion 1183c of the flexible tube 1180. In some embodiments, the diameter of the flexible tube 1180 at the first and second end portions 1183a, b can be greater than a diameter of the clamp 1182 in the first position such that the clamp 1182 does not easily slide off the flexible tube 1180.

[0060] In operation, a user can thread one or more sutures through the lumen 1185 when the clamp 1182 is in the first position. The user can then manually adjust the tension in the sutures before moving the arms 1186 of the clamp 1182 to the second position to compress the flexible tube 1180 against/onto the sutures to cinch/grip the sutures to inhibit movement of the sutures through the tensioning assembly 1102. To adjust the tension in the sutures, the user can move the clamp 1182 to the first position illustrated in Figure 11 and manually adjust the tension.

[0061] Figure 12 is an exploded isometric view of a tensioning assembly 1202 in accordance with additional embodiments of the present technology. In the illustrated embodiment, the tensioning assembly 1202 includes a lower portion 1280, an upper portion 1282 coupled to the lower portion 1280 and defining a lumen 1283, and a flexible membrane 1284 positioned in the lumen 1283. The lower portion 1280 can include a first through-hole 1286, the flexible membrane 1284 can include a second through-hole 1288, and the upper portion 1282 can include a third through-hole (obscured in Figure 12). Each of the through-holes can be at least partially aligned with another. The upper portion 1282 can further include a port 1285 configured to operably/fluidly couple the flexible membrane 1284 with an external pressure source (e.g., a vacuum source such as a syringe). Applying negative pressure to the port 1285 can at least partially collapse the flexible membrane 1284.

[0062] Accordingly, in operation, a user can thread one or more sutures through the first through-hole 1286 in the lower portion 1280, the second through-hole 1288 in the flexible membrane 1284, and the third through-hole in the upper portion 1282 without applying negative pressure to the port 1285. The user can then manually adjust the tension in the sutures before applying negative pressure to the port 1285 to collapse the flexible membrane 1284 around the sutures to cinch/grip the sutures to inhibit movement of the sutures through the tensioning

assembly 1202. To adjust the tension in the sutures, the user can remove the negative pressure source and manually adjust the tension in the sutures.

[0063] Figures 13A and 13B are isometric views of a tensioning assembly 1302 in a first position and a second position, respectively, in accordance with additional embodiments of the present technology. Referring to Figures 13A and 13B together, the tensioning assembly 1302 includes an elongate flexible strap 1380 and a base 1390. In the illustrated embodiment, the base 1390 includes a first opening 1392 and a second opening 1394 extending therethrough between a first surface 1391 and a second surface 1393. The strap 1380 can include a tab portion 1382 and a ratchet surface 1384 including a plurality of ridges or ratchet portions 1386. In the illustrated embodiment, the strap 1380 is threaded through the first and second openings 1392, 1394 such that the ratchet surface 1384 faces radially-inward and the tab portion 1382 is positioned near and/or in the second opening 1394 and is accessible at the first surface 1391. In the first position shown in Figure 13A, the tab portion 1382 is separated from (e.g., disengaged from, decoupled from) the ratchet surface 1384. In the second position shown in Figure 13B, the tab portion 1382 engages the ratchet surface 1384.

[0064] In operation, with the tensioning assembly 1302 in the first position, a user can thread one or more sutures along the ratchet surface 1384 of the strap 1380 and through the first opening 1392 (e.g., in a direction from the first surface 1391 toward the second surface 1393). The user can then move the tensioning assembly 1302 to the second position by pressing the tab portion 1382 of the strap 1380 against the ratchet surface 1384 and the suture to secure the suture to the strap 1380 (e.g., against one or more of the ratchet portions 1386). In some embodiments, the user can then adjust the tensioning in the strap by pulling/pushing the strap 1380 through the base 1390, like a zip-tie, until a desired suture tension is reached. To remove the suture, the tensioning assembly 1302 can be returned to the first position and the suture removed from the first opening 1392.

[0065] In some embodiments, the tensioning assemblies described in detail herein can have other features and/or the features of the various embodiments can be combined. For example, any of the tensioning assemblies including a rotatable actuation member (e.g., the tensioning assembly 702, the tensioning assembly 802, the tensioning assembly 902, and so on) can utilize a slot rather than a hole for securing the suture to the actuation member. Specifically, for example, the elongate portion 785 of the actuation member 786 of the tensioning assembly 702 described in detail with respect to Figures 7A and 7B can include a slot extending at least

partially therethrough instead of the second through-hole 787. The slot can receive and secure the suture without requiring that the slot be fully aligned with the channel 781 of the base portion 780 or the first through-hole 784. Similarly, the second through-hole 896 of the actuation member 890 of the tensioning assembly 802 described in detail with respect to Figure 8 can be replaced with a slot, and so on. In some embodiments, the tensioning assemblies described in detail herein can have one or more locking features for inhibiting movement of the actuation members to, for example, maintain tension in a suture secured thereto/therein.

[0066] Several aspects of the present technology are set forth in the following examples:

1. A device for tensioning a suture, comprising:
a housing having a first through-hole; and
an actuator coupled to the housing and having a second through-hole, wherein the actuator is movable relative to the housing from a first position to a second position, wherein the first through-hole and the second through-hole are configured to receive a suture therethrough, and wherein—
when the first through-hole and the second through-hole receive the suture and the actuator is in the first position, the actuator and the housing cooperate to inhibit the suture from moving relative to the housing; and
when the first through-hole and the second through-hole receive the suture and the actuator is in the second position, the actuator and the housing cooperate to permit the suture to move relative to the housing.
2. The device of example 1, further comprising a flexible pad coupled to the housing.
3. The device of example 2 wherein the flexible pad is configured to be placed against skin of a patient and to conform to the skin of the patient.
4. The device of any one of examples 1–3 further comprising a biasing member operably coupled between the actuator and the housing, wherein the biasing member is configured to bias the actuator to the first position.

5. The device of any one of examples 1–4 wherein the first through-hole and the second through-hole are axially offset in the first position, and wherein the first through-hole and the second through-hole are axially aligned in the second position.

6. The device of example 5 wherein the housing and actuator engage the suture in the first position to clamp the suture relative to the housing.

7. The device of any one of examples 1–6 wherein the first through-hole and the second through-hole are aligned along an axis in the second position, and wherein the actuator is movable from the first position to the second position in a direction generally orthogonal to the axis.

8. A suture tensioning device, comprising:
a housing having a first through-hole and a second through-hole, wherein the first and second through-holes are at least partially aligned along an axis;
an actuator slidably coupled to the housing, wherein the actuator includes a third through-hole; and
a biasing member operably coupled between the actuator and the housing, wherein the biasing member is configured to bias the actuator toward a first position in which the third through-hole is offset from the axis, and wherein the actuator is movable to a second position in which the third through-hole is at least partially aligned with the first and second through-holes along the axis.

9. The suture tensioning device of example 8 wherein the first, second, and third through-holes are configured to receive a suture therethrough, and wherein the actuator and the housing engage the suture when the actuator is in the first position to inhibit the suture from moving through the first, second, and third through-holes.

10. The suture tensioning device of example 8 or example 9 wherein the first, second, and third through-holes are configured to receive a suture therethrough, and wherein the actuator and the housing engage the suture when the actuator is in the first position to maintain a tension of the suture.

11. The suture tensioning device of any one of examples 8–10 wherein the biasing member is a first biasing member, wherein the suture tensioning device further comprises a second biasing member operably coupled between the actuator and the housing, and wherein the first and second biasing members are configured to bias the actuator to the first position.

12. The suture tensioning device of any one of examples 8–11, further comprising a flexible pad coupled to a lower portion of the housing, wherein the flexible pad includes a fourth through-hole aligned with the first and second through-holes along the axis, and wherein the flexible pad is configured to be placed against skin of a patient and to conform to the skin of the patient.

13. The suture tensioning device of any one of examples 8–12, further comprising a dressing assembly configured to be attached to skin of a patient around a puncture in the skin, wherein the housing is configured to be releasably coupled to the dressing assembly.

14. The suture tensioning device of any one of examples 8–14 wherein the actuator is movable from the first position to the second position in a direction generally orthogonal to the axis.

15. A method of tensioning a suture used to close a puncture in skin of a patient, the method comprising:

- threading the suture through a suture tensioning device;
- adjusting a tension of the suture to a desired tension; and
- actuating the suture tensioning device to lock the suture in the suture tensioning device to maintain the desired tension.

16. The method of example 15 wherein actuating the suture tensioning device to lock the suture includes releasing an actuator of the suture tensioning device.

17. The method of example 16 wherein adjusting the tension of the suture includes pulling the suture while depressing the actuator.

18. The method of example 16 or example 17 wherein the method further comprises, after releasing the actuator to lock the suture, pulling the suture while depressing the actuator to adjust the tension in the suture from the desired tension to another desired tension.

19. The method of any one of examples 15–18 wherein the method further comprises adjusting the tension in the suture from the desired tension to another desired tension, wherein adjusting the tension in the suture to the other desired tension includes actuating the suture tensioning device to unlock the suture from the suture tensioning device.

20. The method of any one of examples 15–19 wherein the method further comprises positioning a flexible pad of the suture tensioning device against the skin of the patient.

[0067] The above detailed descriptions of embodiments of the technology are not intended to be exhaustive or to limit the technology to the precise form disclosed above. Although specific embodiments of, and examples for, the technology are described above for illustrative purposes, various equivalent modifications are possible within the scope of the technology as those skilled in the relevant art will recognize. For example, although steps are presented in a given order, alternative embodiments may perform steps in a different order. The various embodiments described herein may also be combined to provide further embodiments.

[0068] From the foregoing, it will be appreciated that specific embodiments of the technology have been described herein for purposes of illustration, but well-known structures and functions have not been shown or described in detail to avoid unnecessarily obscuring the description of the embodiments of the technology. Where the context permits, singular or plural terms may also include the plural or singular term, respectively.

[0069] Moreover, unless the word "or" is expressly limited to mean only a single item exclusive from the other items in reference to a list of two or more items, then the use of "or" in such a list is to be interpreted as including (a) any single item in the list, (b) all of the items in the list, or (c) any combination of the items in the list. Additionally, the term "comprising" is used throughout to mean including at least the recited feature(s) such that any greater number of the same feature and/or additional types of other features are not precluded. It will also be appreciated that specific embodiments have been described herein for purposes of illustration, but that various modifications may be made without deviating from the technology. Further, while advantages associated with some embodiments of the technology have been described in

the context of those embodiments, other embodiments may also exhibit such advantages, and not all embodiments need necessarily exhibit such advantages to fall within the scope of the technology. Accordingly, the disclosure and associated technology can encompass other embodiments not expressly shown or described herein.

CLAIMS

I/We claim:

1. A device for tensioning a suture, comprising:
a housing having a first through-hole; and
an actuator coupled to the housing and having a second through-hole, wherein the actuator is movable relative to the housing from a first position to a second position, wherein the first through-hole and the second through-hole are configured to receive a suture therethrough, and wherein—
when the first through-hole and the second through-hole receive the suture and the actuator is in the first position, the actuator and the housing cooperate to inhibit the suture from moving relative to the housing; and
when the first through-hole and the second through-hole receive the suture and the actuator is in the second position, the actuator and the housing cooperate to permit the suture to move relative to the housing.
2. The device of claim 1, further comprising a flexible pad coupled to the housing.
3. The device of claim 2 wherein the flexible pad is configured to be placed against skin of a patient and to conform to the skin of the patient.
4. The device of claim 1 further comprising a biasing member operably coupled between the actuator and the housing, wherein the biasing member is configured to bias the actuator to the first position.
5. The device of claim 1 wherein the first through-hole and the second through-hole are axially offset in the first position, and wherein the first through-hole and the second through-hole are axially aligned in the second position.
6. The device of claim 5 wherein the housing and actuator engage the suture in the first position to clamp the suture relative to the housing.

7. The device of claim 1 wherein the first through-hole and the second through-hole are aligned along an axis in the second position, and wherein the actuator is movable from the first position to the second position in a direction generally orthogonal to the axis.

8. A suture tensioning device, comprising:
a housing having a first through-hole and a second through-hole, wherein the first and second through-holes are at least partially aligned along an axis;
an actuator slidably coupled to the housing, wherein the actuator includes a third through-hole; and
a biasing member operably coupled between the actuator and the housing, wherein the biasing member is configured to bias the actuator toward a first position in which the third through-hole is offset from the axis, and wherein the actuator is movable to a second position in which the third through-hole is at least partially aligned with the first and second through-holes along the axis.

9. The suture tensioning device of claim 8 wherein the first, second, and third through-holes are configured to receive a suture therethrough, and wherein the actuator and the housing engage the suture when the actuator is in the first position to inhibit the suture from moving through the first, second, and third through-holes.

10. The suture tensioning device of claim 8 wherein the first, second, and third through-holes are configured to receive a suture therethrough, and wherein the actuator and the housing engage the suture when the actuator is in the first position to maintain a tension of the suture.

11. The suture tensioning device of claim 8 wherein the biasing member is a first biasing member, wherein the suture tensioning device further comprises a second biasing member operably coupled between the actuator and the housing, and wherein the first and second biasing members are configured to bias the actuator to the first position.

12. The suture tensioning device of claim 8, further comprising a flexible pad coupled to a lower portion of the housing, wherein the flexible pad includes a fourth through-hole aligned

with the first and second through-holes along the axis, and wherein the flexible pad is configured to be placed against skin of a patient and to conform to the skin of the patient.

13. The suture tensioning device of claim 8, further comprising a dressing assembly configured to be attached to skin of a patient around a puncture in the skin, wherein the housing is configured to be releasably coupled to the dressing assembly.

14. The suture tensioning device of claim 8 wherein the actuator is movable from the first position to the second position in a direction generally orthogonal to the axis.

15. A method of tensioning a suture used to close a puncture in skin of a patient, the method comprising:

threading the suture through a suture tensioning device;
adjusting a tension of the suture to a desired tension; and
actuating the suture tensioning device to lock the suture in the suture tensioning device to maintain the desired tension.

16. The method of claim 15 wherein actuating the suture tensioning device to lock the suture includes releasing an actuator of the suture tensioning device.

17. The method of claim 16 wherein adjusting the tension of the suture includes pulling the suture while depressing the actuator.

18. The method of claim 16 wherein the method further comprises, after releasing the actuator to lock the suture, pulling the suture while depressing the actuator to adjust the tension in the suture from the desired tension to another desired tension.

19. The method of claim 15 wherein the method further comprises adjusting the tension in the suture from the desired tension to another desired tension, wherein adjusting the tension in the suture to the other desired tension includes actuating the suture tensioning device to unlock the suture from the suture tensioning device.

20. The method of claim 15 wherein the method further comprises positioning a flexible pad of the suture tensioning device against the skin of the patient.

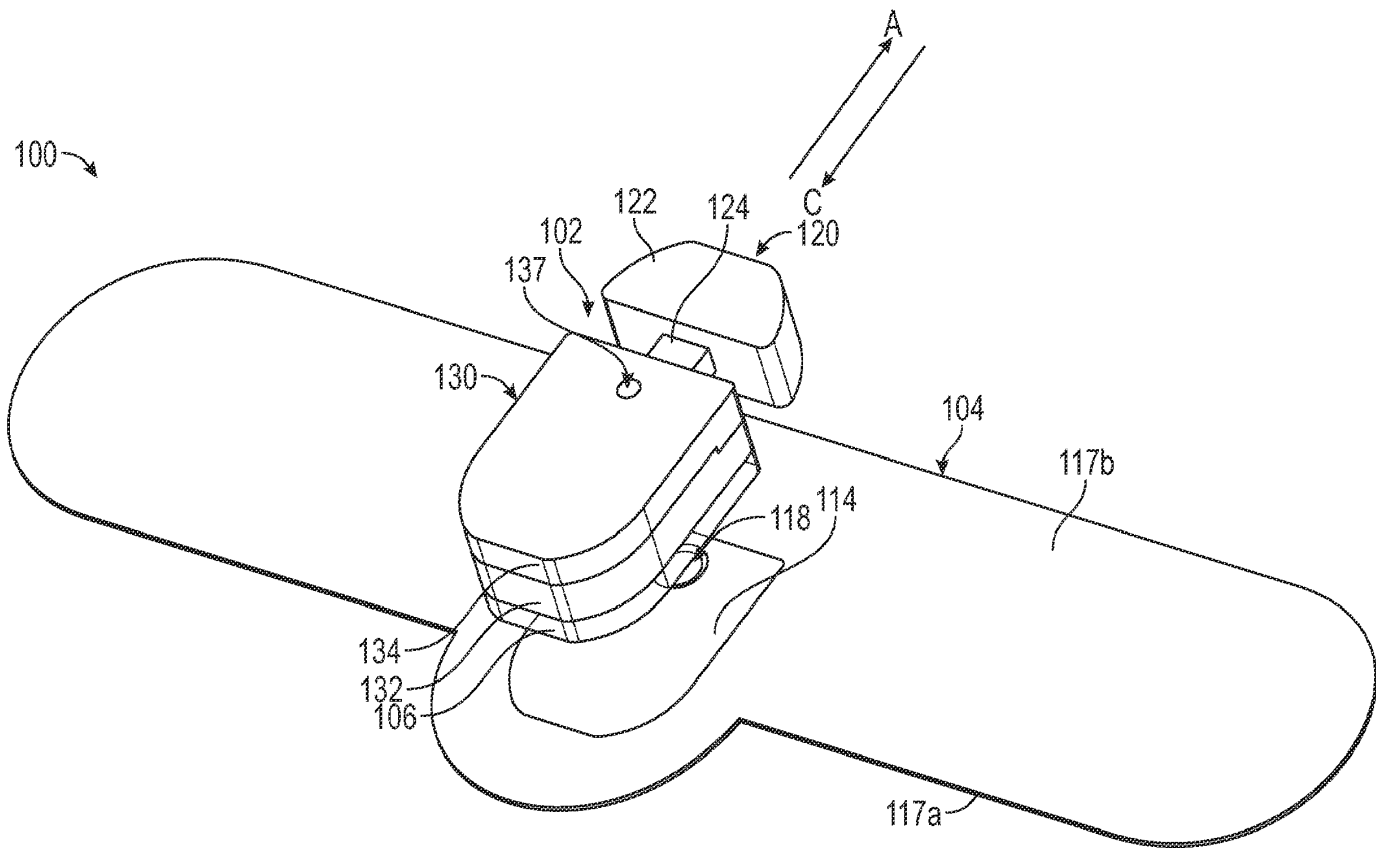


FIG. 1A

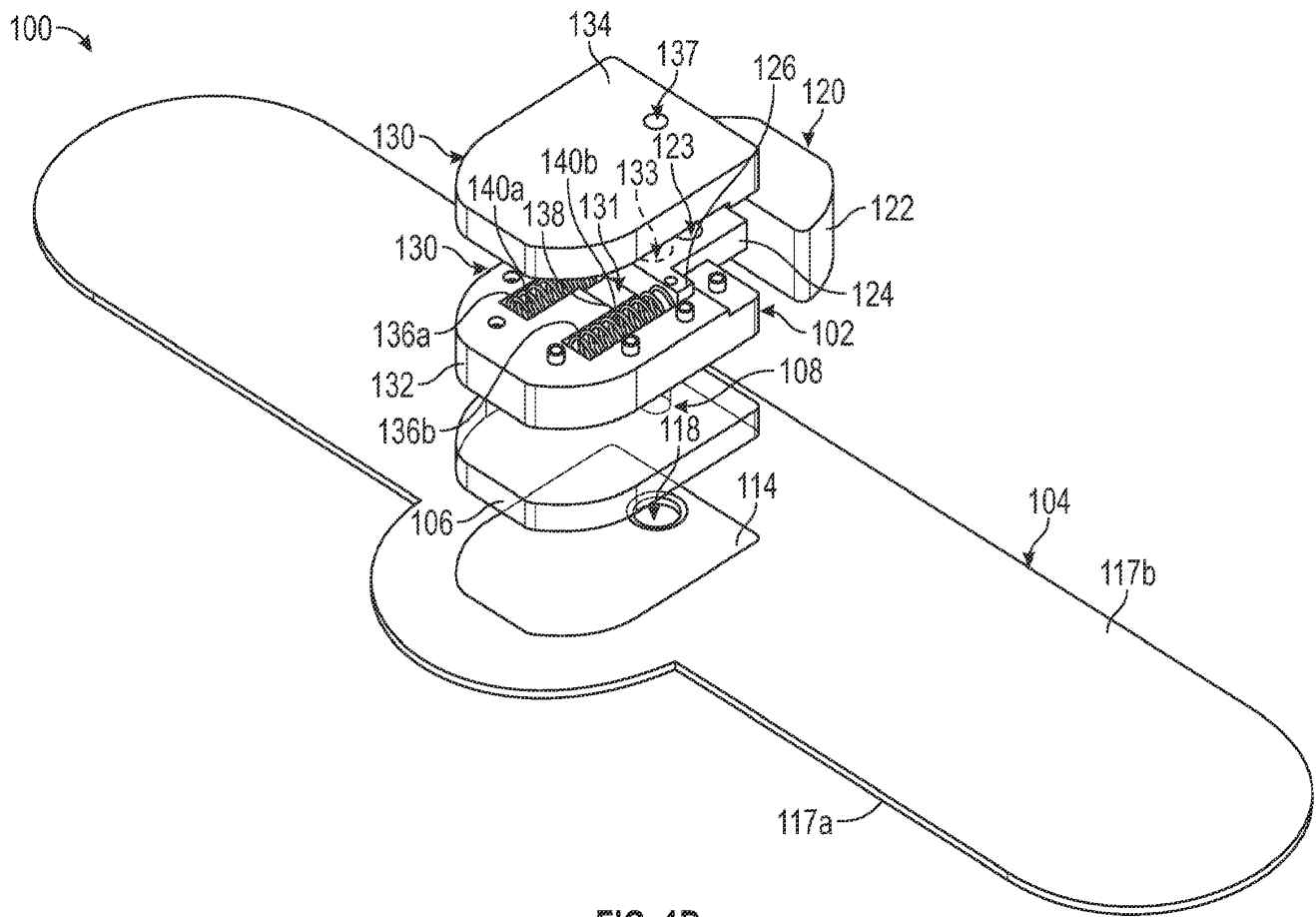


FIG. 1B

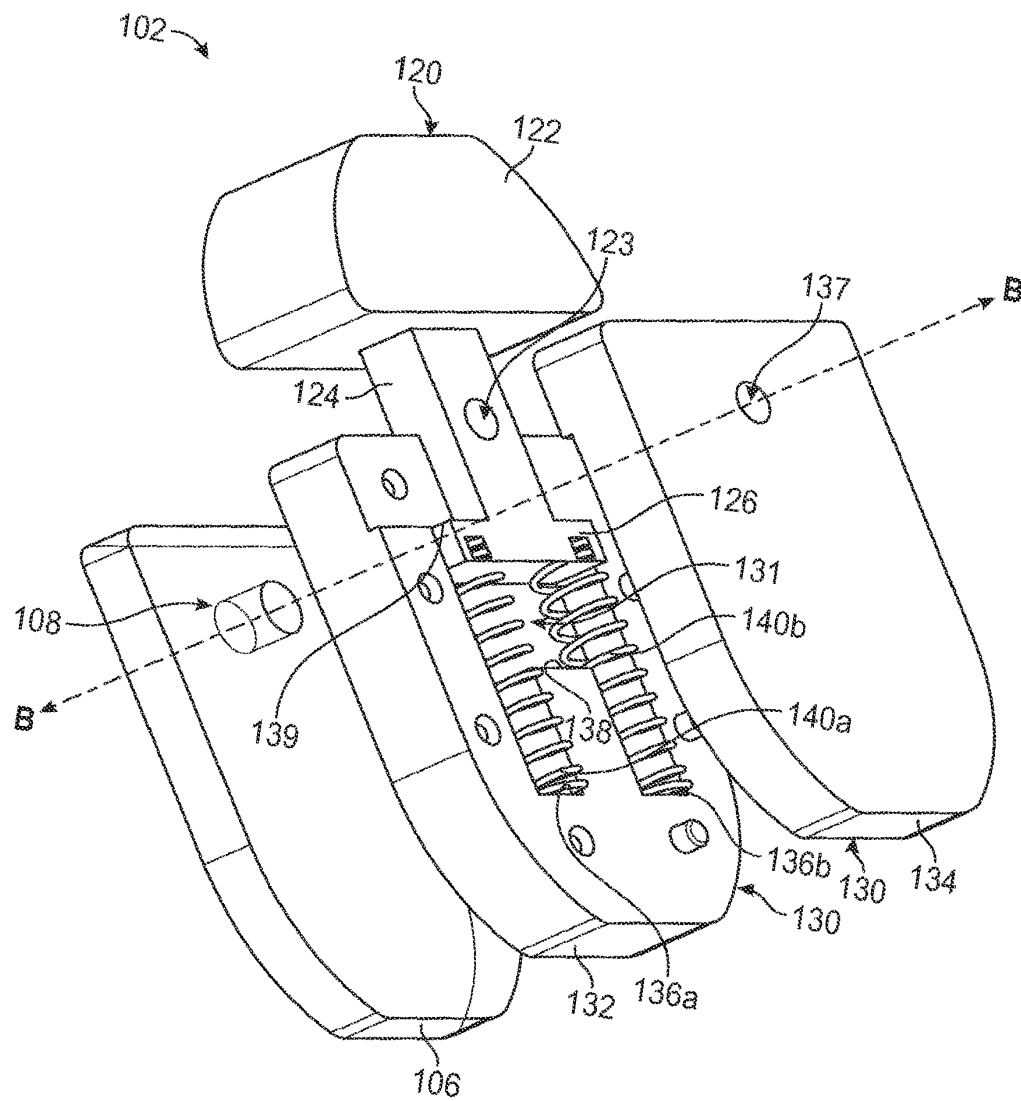


FIG. 1C

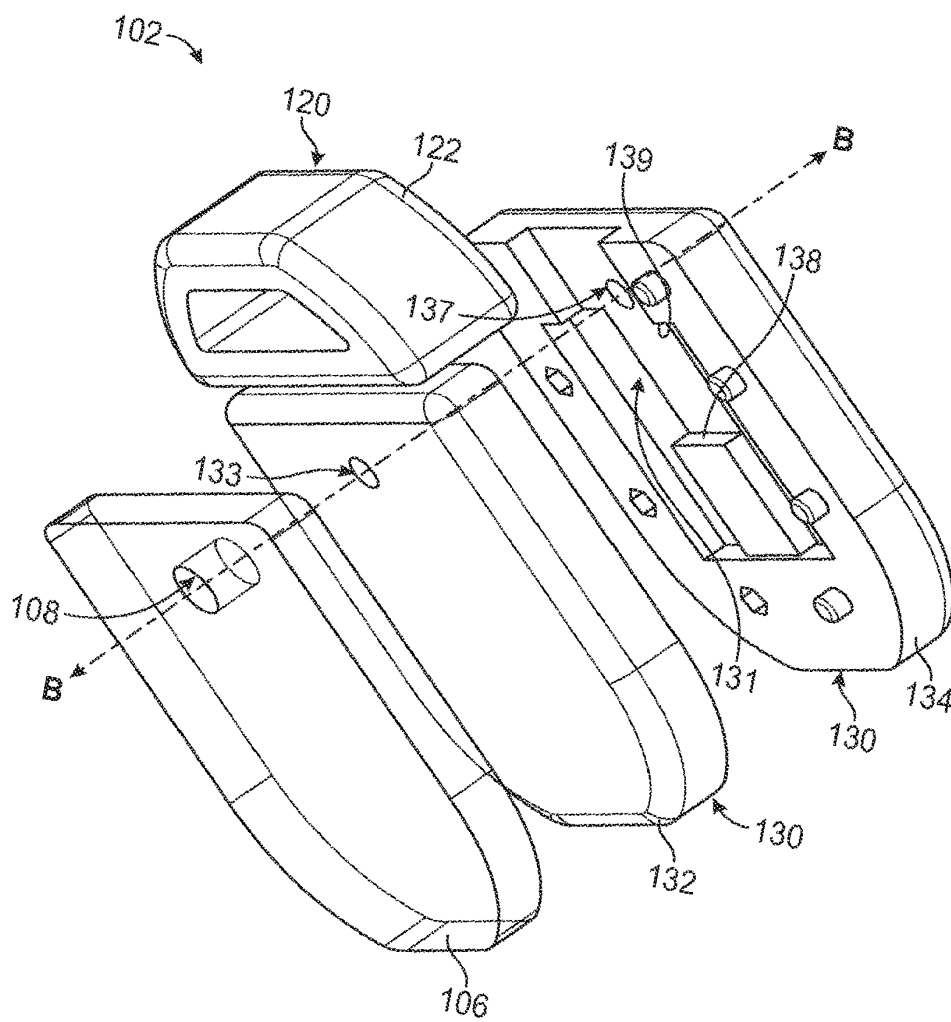


FIG. 1D

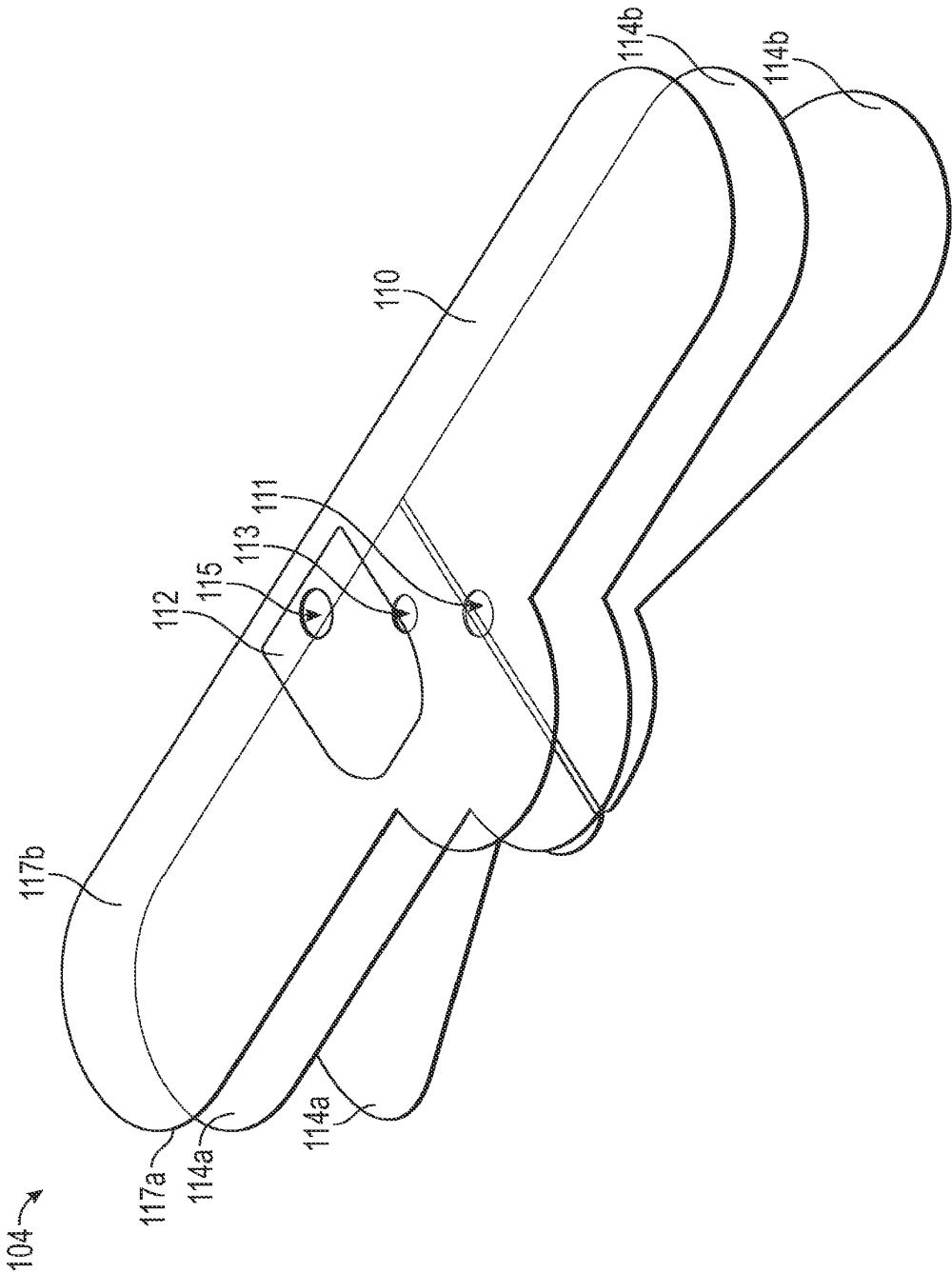


FIG. 1E

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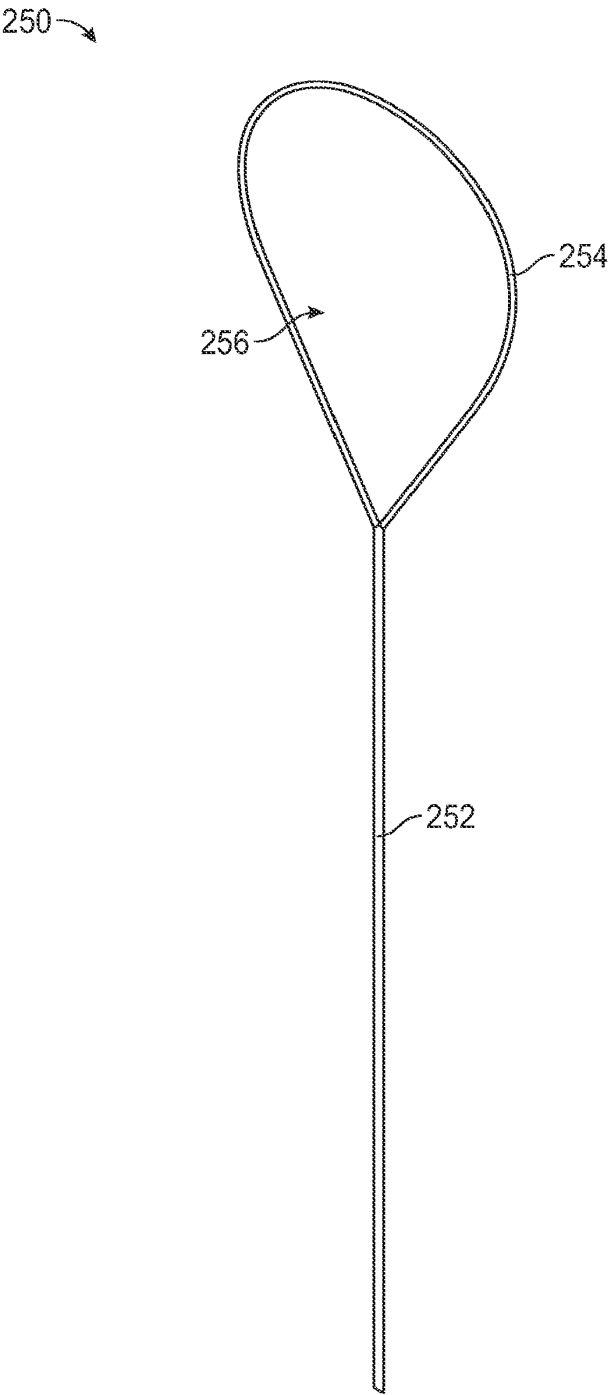


FIG. 2

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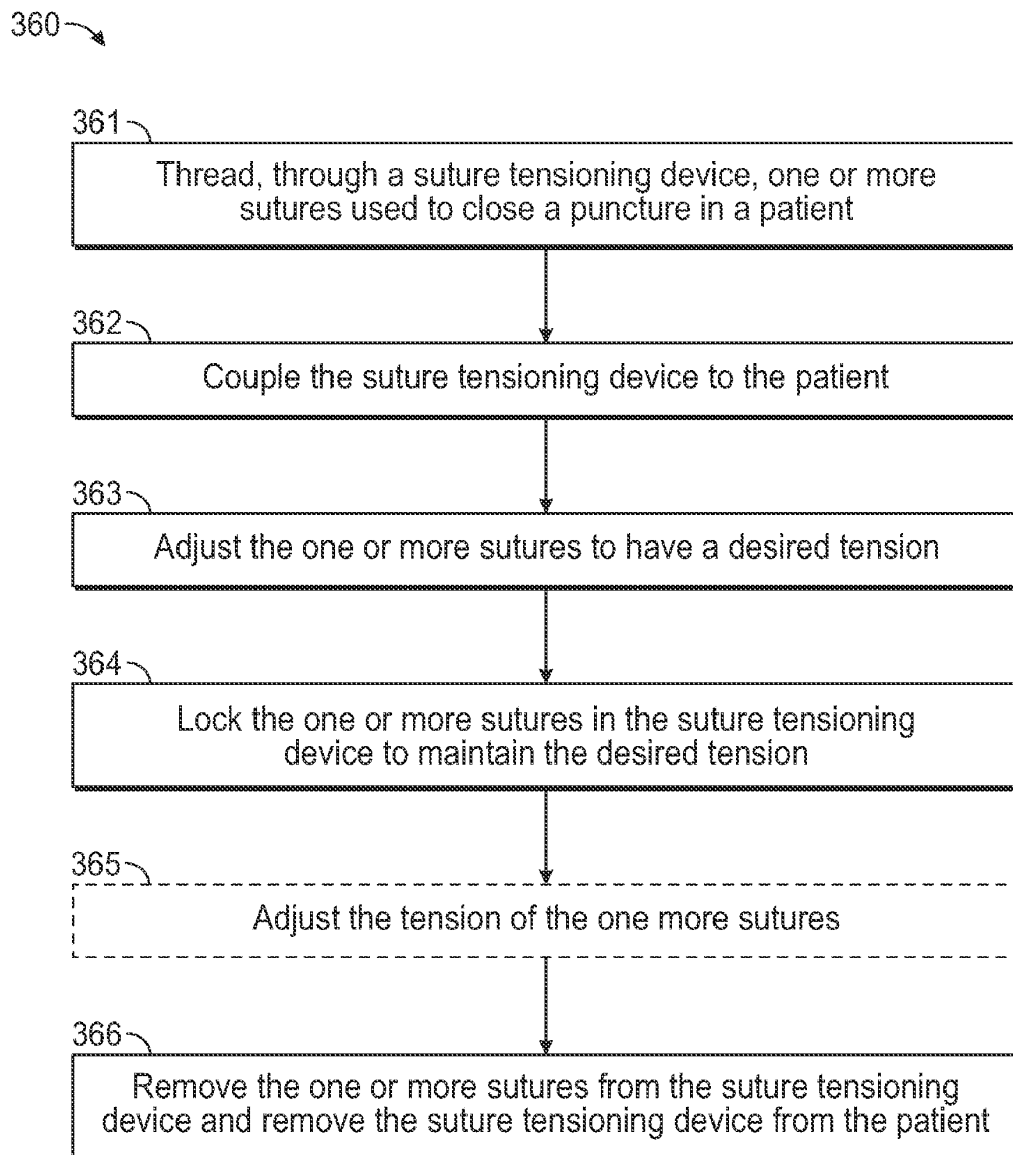


FIG. 3

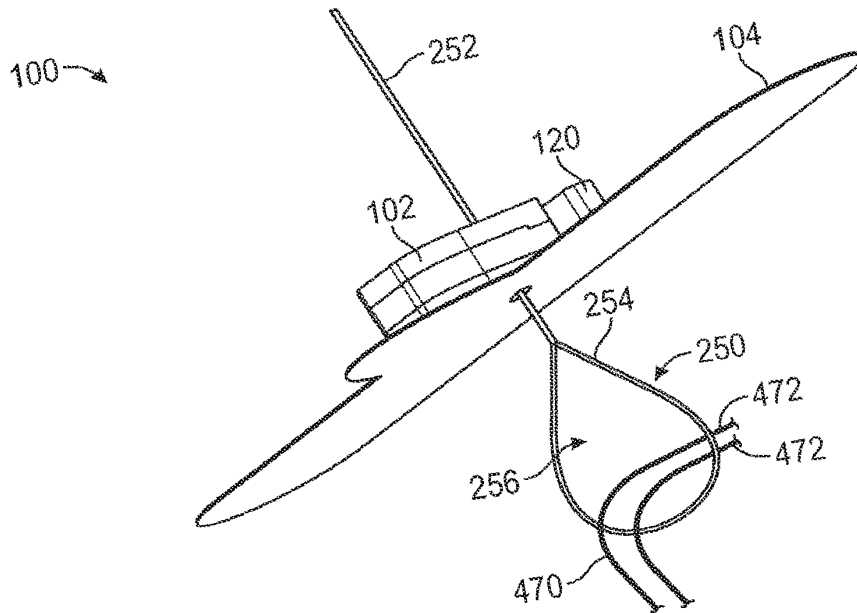


FIG. 4A

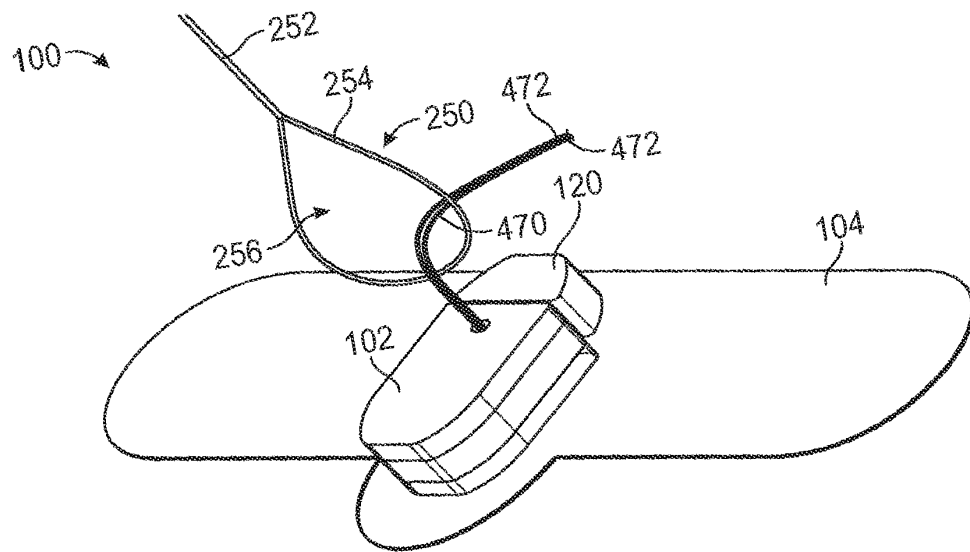


FIG. 4B

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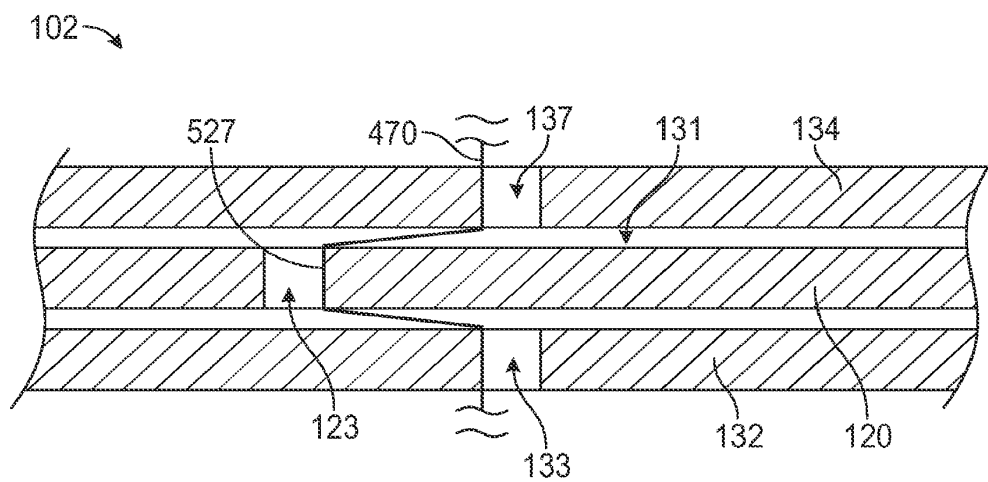


FIG. 5

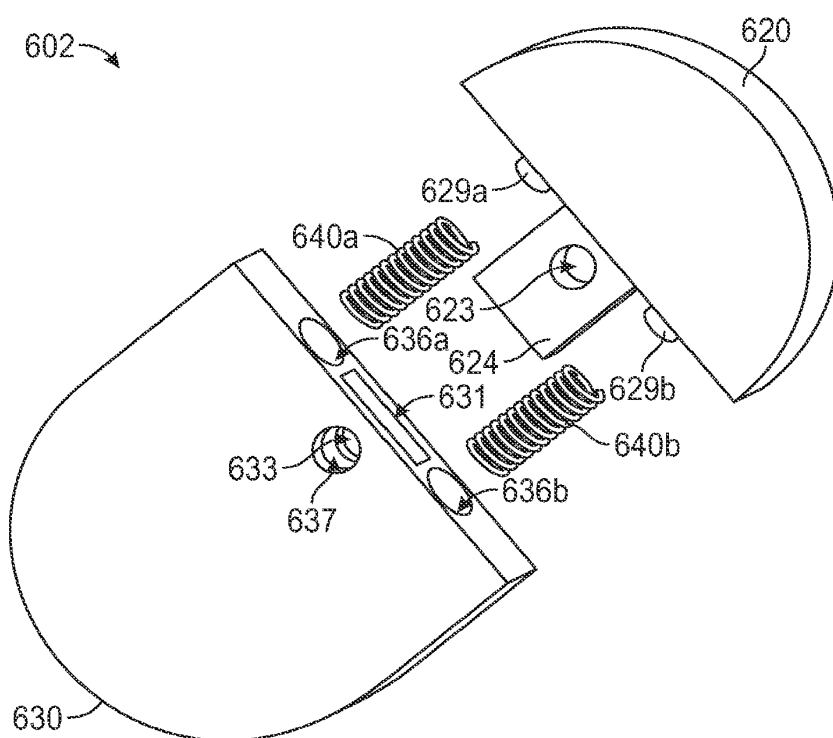


FIG. 6

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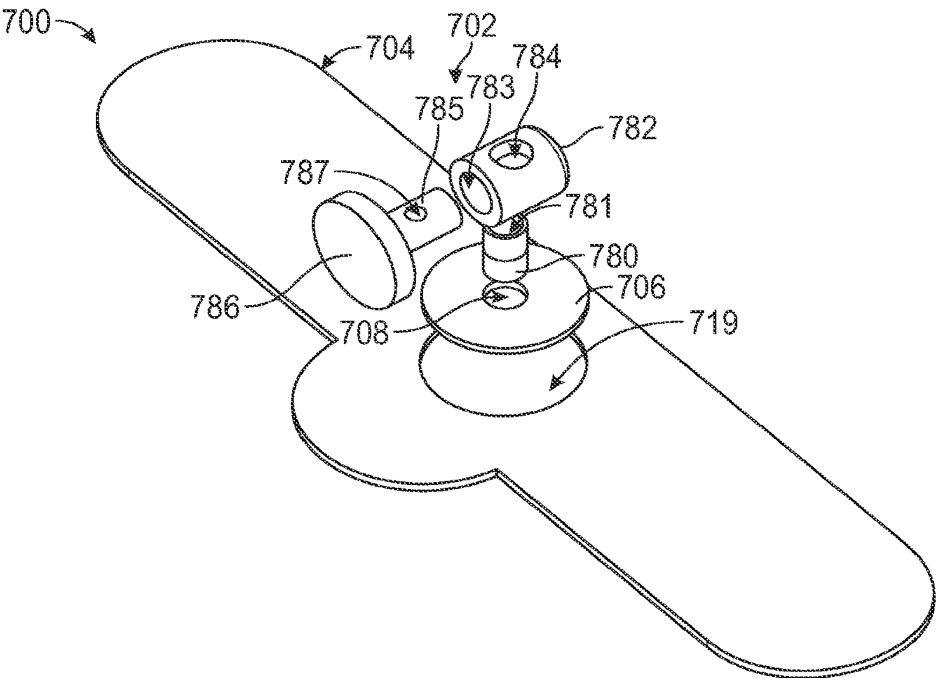


FIG. 7A

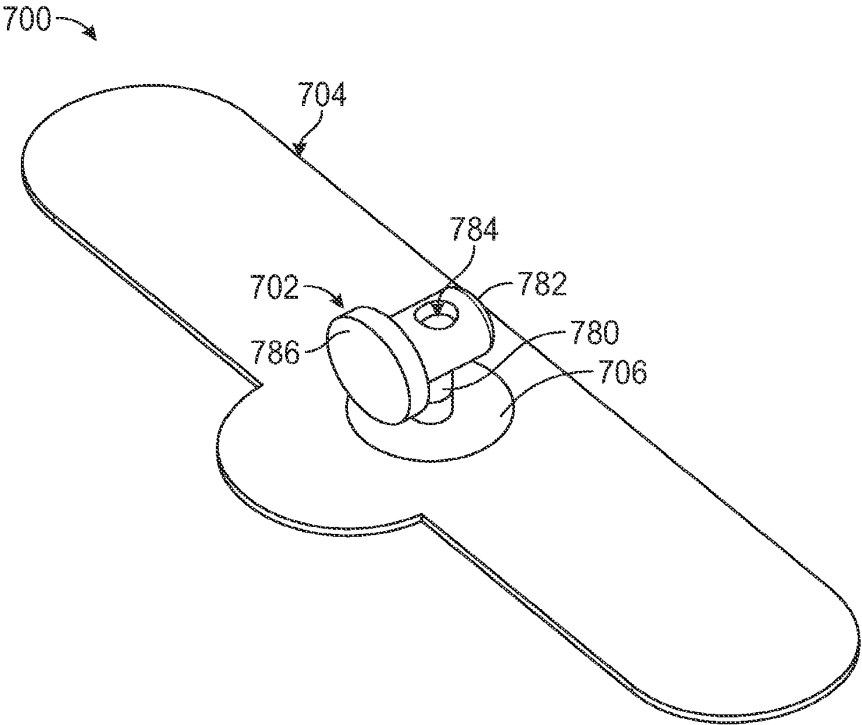


FIG. 7B

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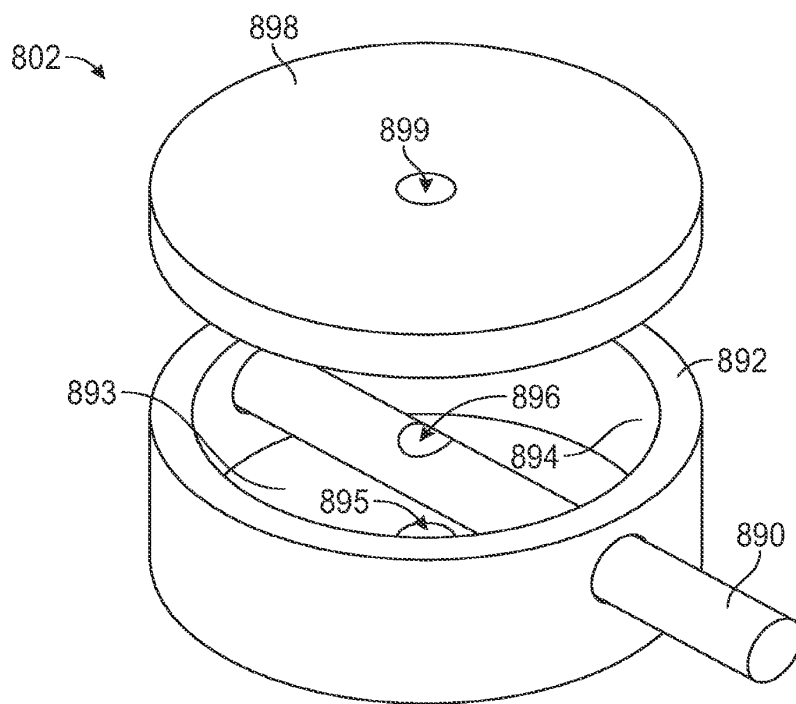


FIG. 8

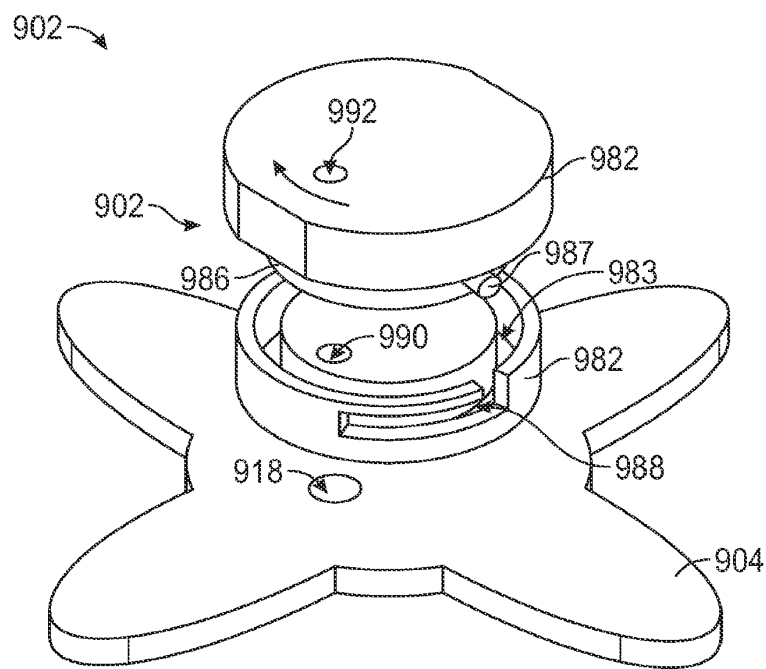


FIG. 9

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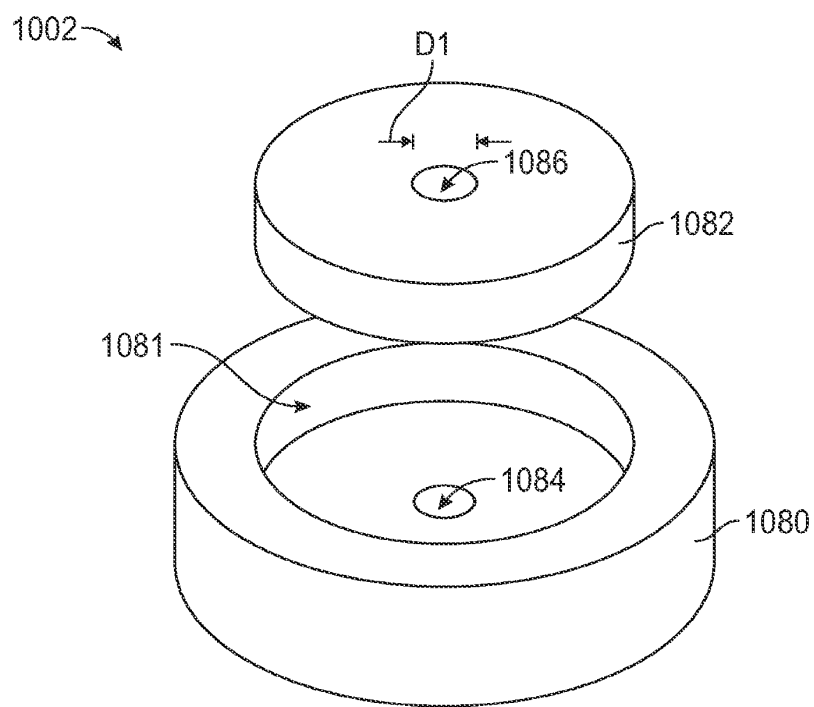


FIG. 10A

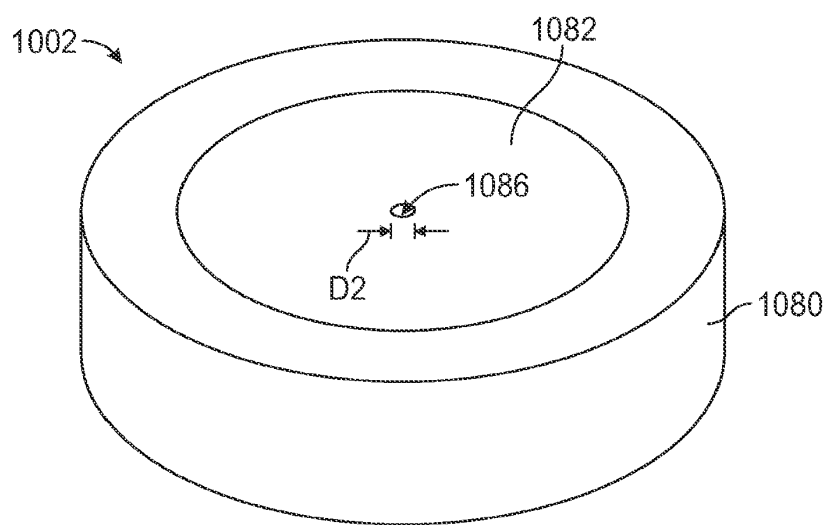


FIG. 10B

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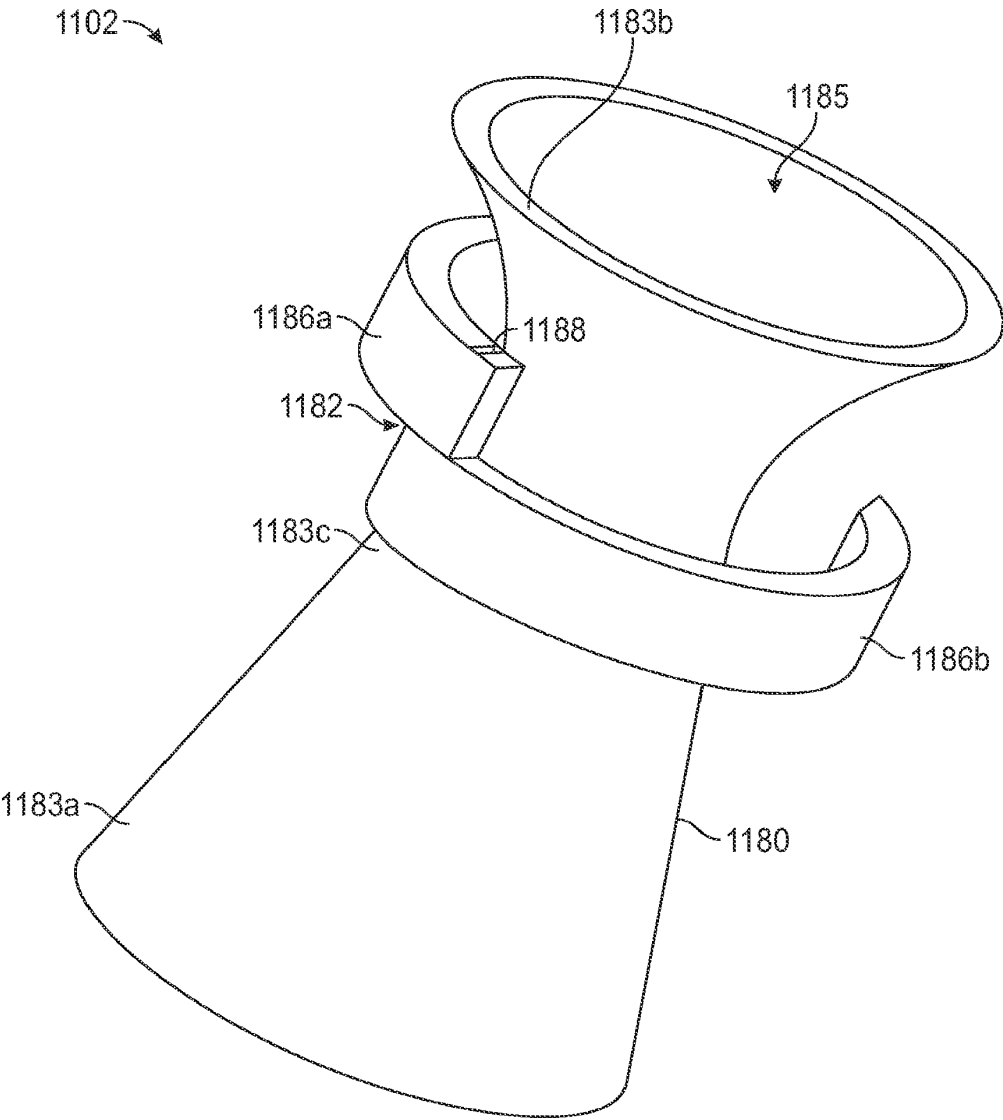


FIG. 11

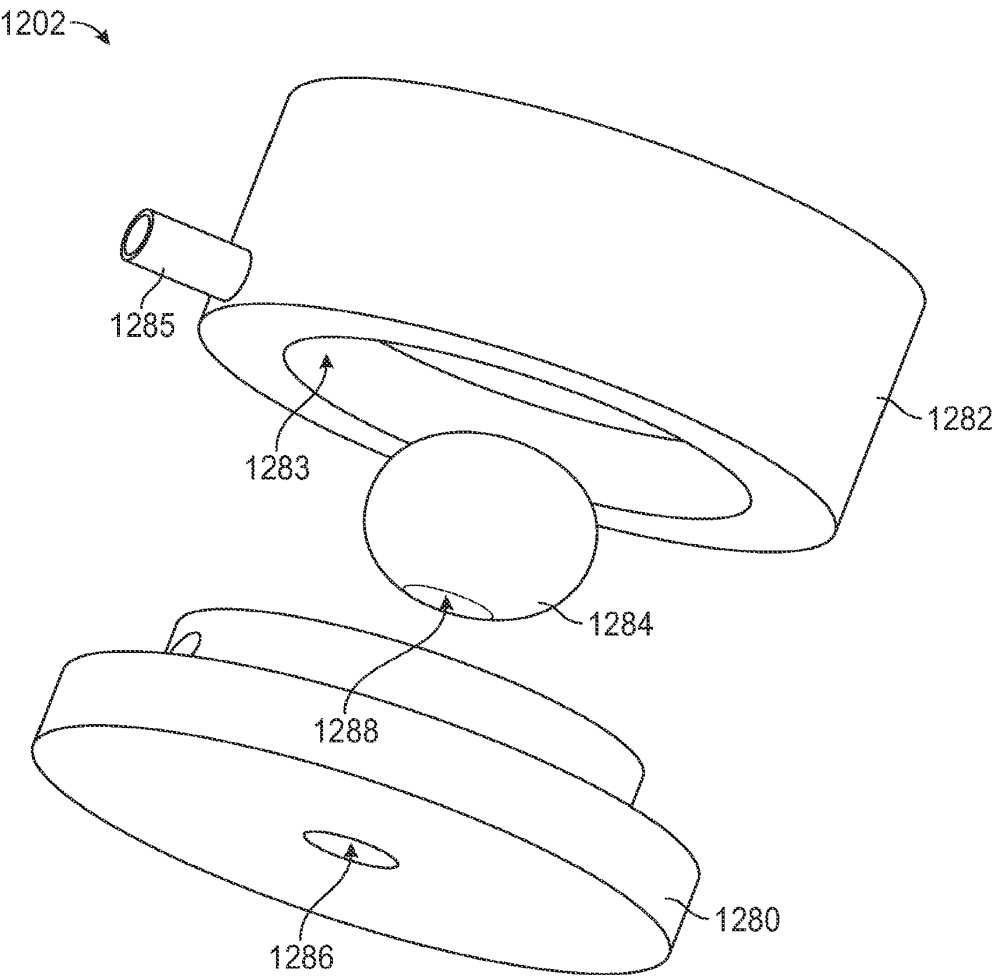
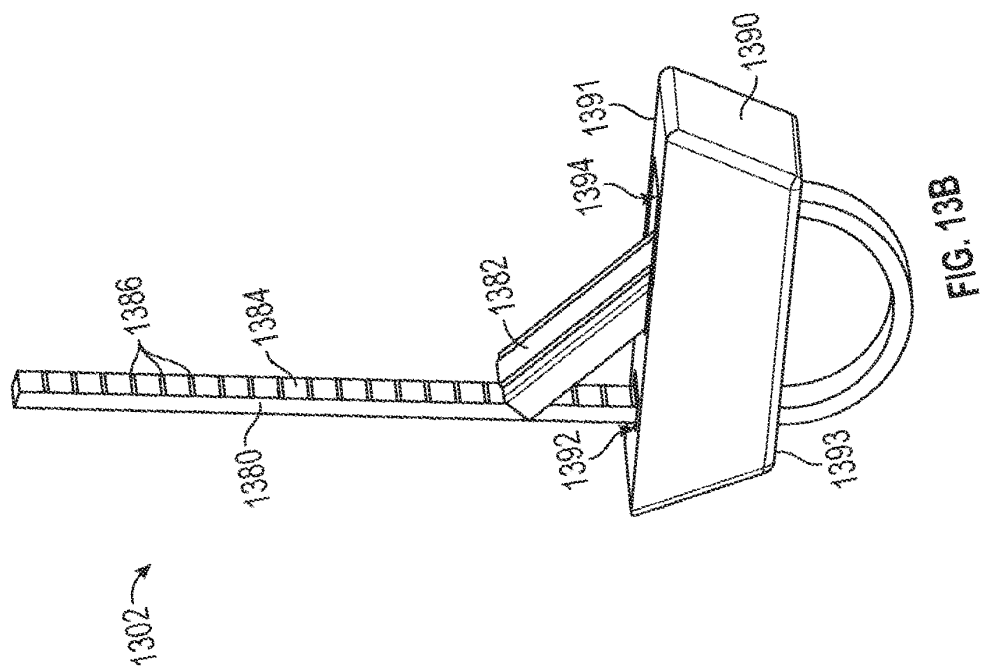
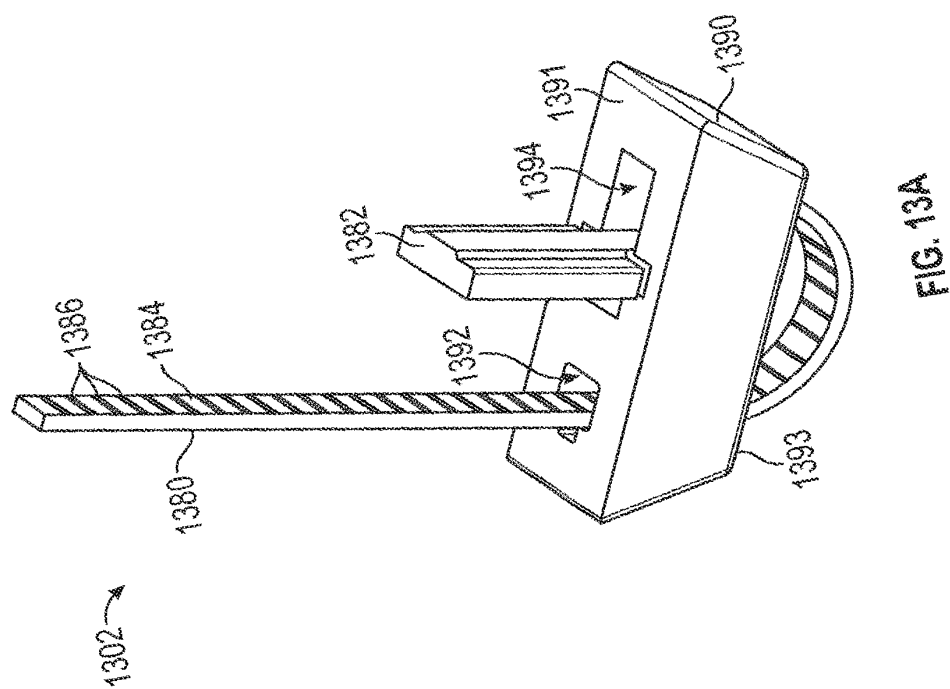


FIG. 12



INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 21/58793

A. CLASSIFICATION OF SUBJECT MATTER

IPC - A61B 17/03; A61B 17/04 (2022.01)

CPC - A61B 17/04; A61B 2017/0496; A61B 17/03; A61B 17/56; A61B 17/0467; A61B 17/8869; A61B 17/0482; A61B 17/0469

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

See Search History document

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

See Search History document

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

See Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X -- Y	US 5,376,101 A (GREEN et al.) 27 December 1994 (27.12.1994); entire document, especially col 6 in 56 to col 7 in 17, and Fig. 15-18.	1, 5-7 -- 2-4
Y	US 5,192,274 A (BIERMAN) 9 March 1993 (09.03.1993); especially col 2 in 21-54, and Fig. 1-2.	2-3
Y	US 2013/0116708 A1 (ZINITI et al.) 9 May 2013 (09.05.2013); especially para [0090], and Fig. 18A-B.	4
A	US 2004/0260344 A1 (LYONS et al.) 23 December 2004 (23.12.2004); entire document.	1-7

☐ Further documents are listed in the continuation of Box C.☐ See patent family annex.

* Special categories of cited documents:

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

"D" document cited by the applicant in the international application

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

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search

2 March 2022

Date of mailing of the international search report

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Kari Rodriguez

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Form PCT/ISA/210 (second sheet) (July 2019)

INARI_018804

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.

PCT/US 21/58793

-*- Box III.0 - Explanations where unity of invention is lacking -*-

SPECIAL TECHNICAL FEATURES

The invention of Group I includes the special technical feature of when the first through-hole and the second through-hole receive the suture and the actuator is in the second position, the actuator and the housing cooperate to permit the suture to move relative to the housing, not required by the claims of Group II-III.

The invention of Group II includes the special technical feature of a biasing member operably coupled between the actuator and the housing, not required by the claims of Group I or II.

The invention of Group III includes the special technical feature of adjusting a tension of the suture to a desired tension, not required by the claims of Group I-II.

COMMON TECHNICAL FEATURES

Groups I-III share the common technical feature of a suture tensioning device.

However, this shared technical feature does not represent a contribution over prior art as being anticipated by US 8,888,791 B2 (JARAMILLO et al.) (hereinafter Jaramillo), which discloses a suture tensioning device (100; Fig. 1; col 5 In 40-62).

Groups I-II share the common technical feature of a device for tensioning a suture, comprising:

a housing having a first through-hole; and

an actuator coupled to the housing and having a second through-hole,

wherein the actuator is movable relative to the housing from a first position to a second position.

However, this shared technical feature does not represent a contribution over prior art as being anticipated by Jaramillo, which discloses a device for tensioning a suture (Fig. 9; col 7 In 41-51), comprising:

a housing (upper housing of 900; Fig. 9; col 7 In 41-51) having a first through-hole (902; Fig. 9; col 7 In 41-51); and

an actuator (903, unlabeled semicircular half adjacent 903; Fig. 9; col 7 In 41-51) coupled to the housing and having a second through-hole (901; Fig. 9; col 7 In 41-51),

wherein the actuator is movable relative to the housing from a first position (903 adjacent and flush with housing of 900; Fig. 9; col 7 In 41-51) to a second position (position of Fig. 9 with 903 deployed rotated outward; Fig. 9; col 7 In 41-51).

As the common technical features were known in the art at the time of the invention, these cannot be considered special technical features that would otherwise unify the groups.

Therefore, Groups I-III lack unity under PCT Rule 13 because they do not share a same or corresponding special technical feature.



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(74)专利代理机构 北京康信知识产权代理有限

责任公司 11240

代理人 刘凤迪

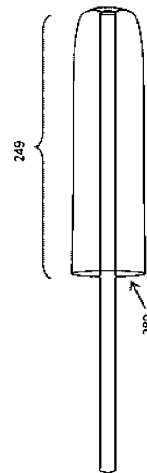
权利要求书2页 说明书31页 附图83页

(54)发明名称

机械取栓装置

(57)摘要

一种用于从血管去除凝块而没有堵塞的机械取栓装置,包括:导管,具有远侧端部区域和远侧端部开口,其中,远侧端部区域的在远侧端部开口处的硬度大于远侧端部区域的紧邻远侧端部开口的区域的硬度,进一步其中,远侧端部开口具有圆形唇缘轮廓;柔性管,在导管内延伸并且在导管的远侧端部上翻折回来,其中,柔性管被配置成当在导管内向近侧拉动柔性管的第一端部时在远侧端部开口上滑动并翻转;以及穿过导管和柔性管的导丝腔,被配置成使导丝通过。



1. 一种用于从血管去除凝块而不堵塞的机械取栓装置,所述装置包括:

导管,具有远侧端部区域和远侧端部开口,其中,所述远侧端部区域的在所述远侧端部开口处的硬度大于所述远侧端部区域的紧邻所述远侧端部开口的硬度,进一步其中,所述远侧端部开口具有圆形唇缘轮廓;

柔性管,在所述导管内延伸并且在所述导管的所述远侧端部上翻折回来,其中,所述柔性管被配置成当在所述导管内向近侧拉动所述柔性管的第一端部时在所述远侧端部开口上滑动并翻转;以及

穿过所述导管和所述柔性管的导丝腔,被配置成使导丝通过。

2. 根据权利要求1所述的装置,其中,所述柔性管具有大于5cm的长度,并且所述柔性管被配置成使得通过向所述柔性管的远侧端部施加小于1000克的力,能将所述柔性管收回到所述导管中。

3. 根据权利要求1所述的装置,其中,所述柔性管包括编织管。

4. 根据权利要求1所述的装置,其中,所述柔性管的在所述导管的所述远侧端部上翻折回来的区域形成唇缘,所述唇缘相对于所述导管的长轴线具有 5° 至 60° 之间的滚动角度(Φ)。

5. 根据权利要求1所述的装置,其中,延伸穿过所述导管并且在所述导管的所述远侧端部上翻折回来的所述柔性管使所述导管的远侧5cm的刚度增加小于所述导管的所述远侧5cm的所述刚度的15%,而不使所述柔性管延伸穿过所述导管和在所述导管的所述远侧端部上翻折回来。

6. 根据权利要求1所述的装置,还包括位于所述柔性管上的可释放附件,所述可释放附件被配置成当以大于0.01N的预定力阈值的力拉动所述柔性管时释放。

7. 根据权利要求1所述的装置,其中,所述柔性管被配置成当所述柔性管在所述导管中被轴向地且向近侧拉动时径向地压缩5%至20%之间。

8. 根据权利要求1所述的装置,还包括在所述导管和所述柔性管上延伸的外导管。

9. 根据权利要求1所述的装置,其中,所述柔性管被配置成当在所述导管内向近侧拉动所述柔性管的第一端部时在所述远侧端部开口上翻转,其中,所述柔性管具有低泊松比,使得网状的所述柔性管当被用足够的力在所述导管内向近侧拉动时的直径大于所述导管的内径的一半,以在所述远侧端部开口上翻转。

10. 根据权利要求1所述的装置,还包括在所述导管内并耦接到所述柔性管的远侧端部的细长拉动器,其中,所述细长拉动器包括具有内腔的海波管,所述内腔与穿过所述柔性管的所述导丝腔连续。

11. 根据权利要求1所述的装置,还包括围绕所述柔性管的远侧端部区域的保持环,所述保持环被配置成将所述柔性管保持抵靠在所述导管上。

12. 根据权利要求1所述的装置,还包括真空连接件,所述真空连接件用于将所述导丝腔耦接到真空以通过所述导丝腔施加真空。

13. 根据权利要求1所述的装置,还包括外导管真空泵,所述外导管真空泵耦接到所述导管与所述柔性管之间的空间并且被配置成在所述导管的位于所述导管的内壁与所述柔性管之间的腔内施加真空。

14. 根据权利要求1所述的装置,还包括:拉动器,其中,所述柔性管的远侧端部耦接到

所述拉动器的远侧端部;以及外导管,所述外导管布置在所述导管上且邻近于所述柔性管的近侧端部,所述装置还包括具有控制器的手柄,所述控制器被配置成协调推进所述外导管以向远侧推动所述柔性管的所述近侧端部和向近侧拉动所述拉动器以将所述柔性管的所述近侧端部拉入所述导管。

15.根据权利要求1所述的装置,所述柔性管被能释放地保持,并且所述柔性管被配置成当用大于0.01N的预定力阈值的力拉动所述柔性管时释放。

机械取栓装置

[0001] 本申请是申请日为2016年2月15日、申请号为201680056752.7的中国发明专利申请“机械取栓装置和方法”的分案申请。

[0002] 相关申请的交叉引用

[0003] 本专利申请要求以下临时专利申请中的每一个的优先权，其中的每一个的全部内容通过引证结合于本文：2015年9月28日提交的美国临时专利申请第62/284,300号；2015年10月8日提交的美国临时专利申请第62/284,752号；以及2015年10月23日提交的美国临时专利申请第62/245,560号。

[0004] 本说明书中提到的所有公开和专利申请的全部内容都通过引用结合于本文，其程度如同每个单独的公开或专利申请被特定地和单独地指示通过引用结合。

技术领域

[0005] 本文所描述的装置和方法涉及从身体内机械去除物体。具体地，本文描述了机械取栓装置和方法。

背景技术

[0006] 通常希望尽可能以微创方式从身体中去除组织，以免损伤其他组织。例如，从脉管系统去除组织（例如，血凝块）可改善患者状况和生活质量。

[0007] 许多脉管系统问题源于流过血管的血液不足。造成血液流量不足或不规则的一个原因是血管内的阻塞，这被称为血凝块或血栓。出现血栓的原因很多，包括诸如手术的创伤之后或由于其他原因。例如，在美国超过120万的心脏病发作中很大一部分是由冠状动脉内形成的血凝块（血栓）引起的。

[0008] 当形成血栓时，它可以有效地阻止血液流过形成区域。如果血栓横过脉的内径延伸，则其可以切断通过动脉的血液流动。如果冠状动脉中的一个100%形成血栓，则血液流动在该动脉中停止，导致携带红血球的氧气短缺，例如用于供应心脏壁的肌肉（心肌）。此类血栓形成对于防止血液损失是不必要的，但是可能由于动脉粥样硬化疾病对动脉壁的损伤而在动脉内被不期望地引发。因此，动脉粥样硬化的潜在疾病可能不会引起急性缺氧（缺血），但可经由诱导血栓形成引发急性缺血。类似地，颈动脉中的一个血栓形成可导致中风，这是因为颅内重要神经中枢的供氧不足。缺氧会降低或禁止肌肉活动，会引起胸痛（心绞痛），并可导致心肌死亡，这在某种程度上会永久地使心脏失去活力。如果心肌细胞死亡很广泛，则心脏将不能泵送足够的血液以供应人体的生命维持需求。局部缺血的程度受许多因素影响，包括可以提供必要氧气的侧支血管和血流的存在。

[0009] 临床数据表明，去除凝块对于改善预后可能是有益的，甚至是必要的。例如，在外周脉管系统中，发明和程序可以减少80%的截肢需求。治疗这些动脉或静脉系统状况的任何方式的最终目标是快速、安全且经济有效地去除堵塞或恢复通畅。这可以通过血栓溶解、碎裂、血栓抽吸或这些方法的组合来实现。

[0010] 导管导向取栓术和溶栓治疗通常被认为创伤小，不太可能降低与常规手术技术

相关的发病率和死亡率。近年来,将化学溶解剂直接给予冠状动脉已经显示出对具有血栓形成冠状动脉的患者有益处。在此过程中,将导管立即置于堵塞物的前方,并将链激酶滴定位成在血栓的上游侧定向。链激酶是一种能够及时溶解纤维蛋白分子的酶。该程序可能需要几个小时,并不总是成功地打破血栓。此外,其可能导致下游血栓碎片(栓子),这可能导致小直径分支的堵塞。美国专利第4,646,736号公开了一种取栓设备,其可以快速去除阻塞性血栓。然而,该装置的特征在于小的导管尖端尺寸,并因此不能对凝块施加显著的总力。而且,在旋转线材的“火线”中,未处于在血管壁上取得的良好位置的凝块不会被纤维切除。对于血流中游离的凝块尤其如此,这是因为在不存在诸如手指的限制的情况下,在这些凝块内旋转几乎是不可能的。

[0011] 该取栓设备的其它缺点包括当在旋转期间线材侧向移动时难以在所有旋转角度期间将凝块保持在线材上方的空间中,这对于扫动动脉腔有时是需要的。实际上,除了最小的动脉(即直径小于1.5mm)之外,几乎不可能用旋转线材扫出整个动脉腔。附加的严重的可能的缺点是凝块的碎片可能在下游成为栓塞。

[0012] 美国专利申请2015/0005781中描述了用于捕获栓子的另一种方法。该申请描述了具有从远侧端部延伸的篮状件的导管。可以向近侧拉动诸如杆或线缆的致动器以将篮状件收回到导管中。不幸的是,篮状件阻塞腔的内部,阻止与定位和/或支撑导丝同时使用,并且篮状件必须保持在导管的远侧端部中或在其附近。取决于被去除的材料(例如凝块)的硬度,篮状件的取回通常会使导管的远侧端部收缩,阻止其使用,并且篮状件可能难以拉入导管中,特别是当保持凝块时。这可能会导致使凝块偏向。最后,在插入血管中之前,篮状件必须被预加载到导管的远侧端部中,并且预加载可能既困难又耗时,并且可能在展开之前破坏设备。

[0013] 因此,确实需要一种可以更有效地从身体内去除诸如凝块的组织的取栓设备,特别是机械取栓设备。本文所描述的是可以解决上面论述的需要和问题的装置(设备、系统和套件)以及使用它们的方法。

发明内容

[0014] 通常,本文描述了医疗装置,包括医疗设备和包括这些医疗设备的系统,以及操作这些医疗设备以用于收集对象的方法,所述对象包括但不限于血凝块(血栓)、组织(活组织检查、小肿瘤、息肉、钙化物、肾结石等)。本文所描述的装置通常包括细长导管,其具有腔和远侧端部并具有通向腔中的远侧端部开口。导管可以是具有任何适当直径(例如<1Fr、1Fr至6Fr、1Fr至9Fr等)的低轮廓神经管导管(例如微导管、插入导管等)。柔性牵引器组件或部分(例如,在本文中可被称为柔性牵引器管或简单地柔性管)通常定位在导管内并且可在导管内纵向滑动,并且布置成使得远侧端部区域(“远侧牵引器区域”)在导管的远侧端部上翻折回来。柔性管(“牵引器管”)通常是细长和中空的,并且被配置成当在导管内向近侧拉动柔性管的第一端部时在远侧端部开口上滑动和翻转。形成远侧牵引器区域的远侧端部可以是管状的或不是管状的(例如,它可以由材料条等形成)。组合式导管和柔性牵引器组件还形成穿过导管和柔性管的导丝腔,该导丝腔被配置成使导丝穿过。

[0015] 在使用中,导丝可以被配置成滑动穿过该装置(并且可以形成装置的一部分)以允许定位并且在一些变型中支撑,通常在不干扰牵引器管的操作的情况下将诸如血凝块

的物体拉入导管的主体。

[0016] 除了具有布置在导管内并且在导管的远侧端部上翻转或翻折的柔性牵引器管的导管之外,本文所描述的装置还可以包括一个或多个特征或元件,其允许这些设备在脉管系统内操作而不收缩,特别是在其远侧端部处,尽管在优选地相当柔软的远侧端部的远侧边缘/开口上施加拉力矩。进一步地,这些装置可以适用于最小化将远侧牵引器区域取回到导管中并在导管的远侧端部开口上翻转而不损坏或减弱远侧牵引器区域所需的力,从而防止装置内的柔性牵引器管在其本身上或与导管一起破裂、束缚、堵塞或缠结。例如,如下面将更详细描述,这些装置中的任一个可以包括在导管的远侧端部处或附近的选择性润滑区域。导管端部可以被成形为允许管的远侧端部的柔性牵引器区域的翻转。另外,导管的端部轮廓(例如,最远侧5mm、4mm、3mm、2mm、1mm等)可以具有防止导管的收缩/屈曲的刚度(例如硬度)的布置。可替代地或附加地,柔性牵引器管可以适于在导管周围“扫动”血管的尽可能大部分以从血管内收集物体,同时仍然允许相对较低的力收回到导管中并且在导管的远侧端部上翻转。柔性管的牵引器部分(可指代管的在导管内的远侧部分)通常可包括邻近于第二可较少扩张(或不可扩张)的端部区域的远侧可扩张(第一)端区,其要么紧邻要么由间隔区域分开。第二端部区域靠近于第一端部区域(当第一端部区域和第二端部区域两者都被拉入导管时)。柔性牵引器管可以一直延伸穿过导管到达近侧端部和/或近侧手柄,或者其可以在导管的近侧端部之前终止并且连接到拉动器。拉动器可以是另一个可能较少柔性管,或者线材、杆、绳等。柔性牵引器管通常被配置成具有穿过其的腔(例如,中心腔或径向偏移的腔),导丝可以穿过该腔通过,穿过包括导管和柔性牵引器管的装置。当导丝位于该腔内时,通常可以操作柔性牵引器管(例如,向近侧拉动并且在一些变型中向远侧推动)。

[0017] 装置可预先加载以用于远侧牵引器区域的展开以及物体在脉管内的捕获,或者在一些变型中,装置可以在将导丝和/或导管定位在血管内之后或期间在体内加载。例如,在一些变型中,通过保持远侧牵引器区域收回到导管中直到导管位于脉管内,并且优选地在待去除的物体附近,该装置可以适于体内使用。一旦定位,柔性管的在导管内的远侧牵引器区域可以从导管向远侧延伸,扩张以形成捕获形状,其可以在向远侧推进导管或不向远侧推进导管的情况下被拉入并且在导管的远侧端部上翻转。因此,远侧牵引器部分可以被安全且可靠地输送至腔内的必要部位,而没有损坏装置或身体的风险。

[0018] 例如,执行机械取栓以从血管去除凝块的方法可以包括:将导管的远侧端部朝向凝块推进通过血管;将管的位于导管内的远侧牵引器区域从导管的远侧端部暴露,其中,远侧牵引器区域包括可扩张的第一端部区域以及靠近于可扩张的第一端部区域的可较少扩张的第二端部区域;允许可扩张的第一端部区域在血管内扩张;将导管的远侧端部定位成使得导管的远侧端部区域位于远侧牵引器区域的可较少扩张的第二端部区域和可扩张的第一端部区域之间,同时可扩张的第一端部区域在可较少扩张的第二端部区域上翻折;以及通过将可扩张的第一端部区域在导管的远侧端部上滚动使得可扩张的第一端部区域在可扩张的第一端部区域被拉动到导管中时翻转,将凝块拉入导管。

[0019] 如上所述,将导管的远侧端部朝向凝块推进通过血管的步骤可以包括在导丝上推进。导管可以在导丝上向远侧滑动或者与导丝一起向远侧延伸(或向近侧收回)。内(牵引器)管可以被保持在导管内(例如,在远侧端部附近、中间区域或者在近侧端部附近),或

者在一些变型中,可以在将导管定位在脉管内之后插入。导管的远侧端部可以定位在待去除的物体(例如,凝块)处、附近或邻近,或者它可以分开预定的距离,例如以允许通过将远侧牵引器区域延伸出导管的远侧端部之外并且扩张以准备将物体取回到导管中来设定用于装置的空间。

[0020] 因此,一旦定位,就可以通过暴露远侧牵引器区域并且定位导管的远侧端部以及在变型中的导丝来展开该装置,以允许物体被捕获并被拉入导管。通过向近侧拉动导管,同时保持包括远侧牵引器区域的柔性管静止(例如相对于血管)和/或通过向远侧延伸柔性管,可以暴露远侧牵引器区域。

[0021] 如上所述,柔性管可以包括远侧牵引器区域,该远侧牵引器区域包括可扩张的第一端部区域。该端部区域通常是多孔的(例如,由网状物、针织物、机织物或其他材料形成,包括具有穿设有多个开口的固体材料)并且适于抓取待去除的物体(例如血块)。该第一端部区域通常可扩张至导管的内径的约1.3倍至约10倍之间(例如,在约1.5倍至约7倍之间、约1.5倍至约5倍之间、约1.5倍至约4倍之间、约1.5倍至约3倍等)。形成牵引器部分的该第一远侧端部区域通常邻近于可较少扩张(或基本上不可扩张的)的第二端部区域。第二区域可以使导管向近侧一直向下延伸,或者使导管部分向下延伸。通常,牵引器部分的第一端部区域暴露于导管之外并用于捕获凝块或其他物体;第二端部区域可在定位期间暴露,但在操作期间可保持在导管内。

[0022] 因此,将管的位于导管内的远侧牵引器区域从导管的远侧端部暴露可以包括将远侧牵引器区域延伸或推出导管的远侧端部之外。在一些变型中,远侧牵引器区域被预先形成为使得第一可扩张的远侧端部区域在第二远侧端部区域上翻折;在其他变型中,第一远侧端部区域与可较少扩张的第二远侧端部区域在同一直线上且远离。然后可以向远侧移动导管,使得导管的远侧端部区域(包括远侧端部)在远侧牵引器区域的扩张的可扩张的第一端部区域与可较少扩张的第二端部区域之间的径向间隙中延伸。

[0023] 在远侧牵引器区域被推出导管的远侧端部之外的任何变型中,例如在该初始体内设置阶段期间,柔性管(特别是远侧牵引器区域)可以被配置成或以其他方式适于允许推出导管之外而不束缚。如果可扩张的第一端部区域特别地被捕获在导管的内壁上,则可能发生可扩张的管的导管内的束缚,从而阻止展开。在一些变型中,可扩张的第一端部区域被配置成具有细丝(例如镍钛诺、聚合物等)的网状管状构件,该网状管状构件在具有约24至144个股线,股线在直径上的厚度为0.0005英寸至0.005英寸,其中,网状管状构件在纵向轴线上延伸,进一步其中,网状管状构件的长度大于5cm,当围绕导管的远侧端部被拉动和翻转时,在纵向轴线的方向上的交叉股线之间形成35度的编织角度,并且当不受约束时在导管的外部扩张到大于导管的内径的1.5倍的直径。在该配置下,管状构件被发现是可推动的。

[0024] 在其他变型中,当可扩张的第一远侧端部区域被推出或延伸出导管的远侧端部之外时,其可以被配置(例如,预成形、形状设定等)成在导管的远侧端部上翻转并扩张。导管可以向远侧移动,帮助将远侧牵引器区域的该可扩张的第一端部区域相对于导管的外侧向近侧推动。

[0025] 在这些方法中的任一种中,远侧牵引器区域可以包括可扩张的第一端部区域以及靠近于可扩张的第一端部区域的可较少扩张的第二端部区域,并且可扩张的第一端部

区域被允许在血管内扩张。

[0026] 因此,在展开阶段即将结束之际,导管的远侧端部通常被定位成使得导管的远侧端部区域径向地位于远侧牵引器区域的可较少扩张的第二端部区域和可扩张的第一端部区域之间,同时可扩张的第一端部区域在可较少扩张的第二端部区域上翻折。

[0027] 此后,可以通过将可扩张的第一端部区域在导管的远侧端部上滚动来将物体(例如凝块)拉入导管,使得当可扩张的第一端部区域被拉入导管中时,可扩张的第一端部区域翻转。

[0028] 如上所述,定位可以包括向远侧推进导管的远侧端部,使得导管的远侧端部区域位于远侧牵引器区域的可较少扩张的第二端部区域和可扩张的第一端部区域之间。

[0029] 导丝可以与本文所描述的任何方法一起使用。对于本文所描述的任何方法而言,可以包括将血管内的导丝推进至凝块,其中,推进导管的远侧端部包括在导丝上推进导管通过血管,直到导管的远侧端部靠近于凝块。导丝可以插入或穿过凝块,或者其可以刚好位于凝块之前。导丝可以在凝块去除期间被留下,或者其首先可以部分或完全取回。例如,这些方法中的任一种可以包括将血管内的导丝推进至凝块,其中,推进导管的远侧端部包括在导丝上推进导管穿过血管,直到导管的远侧端部靠近于凝块。进一步其中,将凝块拉入导管包括在将可扩张的第一端部区域在导管的远侧端部上滚动的同时在导丝上朝向凝块推进导管。

[0030] 将凝块拉入导管通常包括将远侧牵引器区域(例如,可扩张的第一端部区域)在导管的远侧端部上滚动。该装置也可以在远侧牵引器区域的致动期间向远侧移动。例如,将血块拉入导管可以包括向近侧取回管(以将远侧牵引器区域在远侧端部上滚动)和/或在向远侧推进导管的同时向近侧取回管。

[0031] 在这些方法中的任一种中,将凝块拉入导管可包括在向远侧推进导管的同时向近侧取回管,其中,以与推进导管不同的速率取回该管。在一些配置中,比向近侧拉管(远侧牵引器区域)更迅速地向远侧推进导管可能是有益的。在一些变型中,可以比向近侧取回管(远侧牵引器区域)更慢地推进导管。可替代地,它们以相同的速率移动。通过观察导管内的近侧运动(例如,第二端部区域的近侧运动)可以确定柔性管的运动速率。

[0032] 通常,远侧牵引器区域的可扩张的第一端部区域是可扩张的并且可以形成可以与诸如凝块的物体接合的面向远侧的嘴部或唇缘。可扩张的牵引器区域的唇缘的嘴部可相对于导管外径(OD)的长轴线形成5度至60度、并且优选地至少为10度(例如10°至60°、10°至50°、10°至45°等)范围内的切向角度或滚动角度(如下面参考图18A至图18C和图21D更详细描述)。只要滚动角度至少为10度并且管收回到导管中,则管应该不会束缚或阻塞导管尖端。网状管可以通过改变刚度以确保滚动角度大于10度而构造。可替代地或与保持最小滚动角度组合,可能期望在导管的最远侧尖端处保持导管材料ID和导管的OD之间的物理空间或间隙(如下面在图18A至图18C中更详细描述)。该间隙可能需要大于例如0.1 mm、0.2 mm、0.3 mm、0.4 mm、0.5 mm、0.7 mm、0.8 mm、0.9 mm、1.0 mm等,以确保当管被收回时管围绕导管的远侧端部滚动。扩张材料(例如网状材料、机织材料、编织材料、针织材料、穿孔材料等)可以允许其本身在血管内扩张。因此可扩张的第一区域可以是可自扩张的。远侧牵引器区域的可扩张的第一端部区域可以被预先偏置以扩张。在一些变型中,使用形

状记忆材料(例如,形状记忆合金)。在一些变型中,偏置元件被包括在可扩张的第一端部区域中或与可扩张的第一端部区域成一体以扩张使得远侧牵引器区域。可扩张的第一端部区域可以扩张至接触血管的内膜。在一些变型中,装置可以被配置(例如,设定尺寸,包括确定可扩张的第一端部区域的尺寸),使得远侧牵引器区域的最远侧端部与血管腔接触。因此,本文所描述的变型中的任一个可以附加地或可替代地包括偏置元件,诸如圈、环、支架等以推动可扩张的远侧端部区域,使得其可以通过施加增加的径向力将其扩张开来而与脉管接触。在一些变型中,该开口偏置(圈、螺旋、环等)位于远侧牵引器区域的可扩张的第一端部区域的远侧端部处或附近。

[0033] 本文所描述的变型中的任一个可以包括可扩张的导管尖端。例如,在一些变型中,导管尖端的硬度可以足够柔软以当远侧牵引器区域被向近侧拉入导管时向近侧压缩;轴向压缩远侧端部尖端可使其在远侧端部处略微扩张(例如,使得其可扩张)。

[0034] 如上所述,将管的位于导管内的远侧牵引器区域从导管的远侧端部暴露可以包括将远侧牵引器区域推出导管的远侧端部之外。可替代地或附加地,将管的位于导管内的远侧牵引器区域暴露于导管的远侧端部之外可以包括向近侧拉动导管。例如,将管的导管内的远侧牵引器区域从导管的远侧端部暴露可以包括将远侧牵引器区域推出导管的远侧端部之外以暴露已经在可较少扩张的第二端部区域上翻转的可扩张的第一端部区域。

[0035] 在一些变型中,将管的位于导管内的远侧牵引器区域从导管的远侧端部暴露包括将可扩张的第一端部区域延伸出导管的远侧端部之外,使得当可扩张的第一端部区域延伸时,可扩张的第一端部区域在导管的远侧端部上翻转。

[0036] 远侧牵引器区域的可扩张的第一端部区域可以是任何适当的长度,并且该长度的任何部分(全部、90%、80%、70%、60%、50%、40%等)可能在该设定时段期间暴露。例如,在一些变型中,暴露管的远侧牵引器区域可以包括暴露至少5mm的可扩张的第一端部。可扩张的第一端部区域可以是例如5mm或更大(例如,在约5mm至500mm之间的6mm、7mm、8mm、9mm、10mm、11mm、12mm、13mm、14mm、15mm、16mm、17mm、18mm、19mm、20mm、25mm、30mm、35mm、40mm、45mm、50mm、55mm、60mm、70mm、80mm、90mm、100mm、110mm、120mm、130mm、140mm、150mm、200mm、300mm、400mm、500mm等,在约5mm、6mm、7mm、8mm、9mm、10mm、11mm、12mm、13mm、14mm、15mm、16mm、17mm、18mm、19mm、20mm、25mm、30mm、35mm、40mm、45mm、50mm、55mm、60mm、70mm、80mm、90mm、100mm、110mm、120mm、130mm、140mm、150mm、200mm的任何较小值与10mm、11mm、12mm、13mm、14mm、15mm、16mm、17mm、18mm、19mm、20mm、25mm、30mm、35mm、40mm、45mm、50mm、55mm、60mm、70mm、80mm、90mm、100mm、110mm、120mm、130mm、140mm、150mm、200mm、300mm、400mm、500mm的任何较大值之间,其中较小值总是小于较大值)。在这些变型中的任一个中,当暴露远侧牵引器区域时,仅可扩张的第一远侧端部区域可以暴露出导管之外(例如,当将可扩张的远侧端部区域向远侧推出并且允许其在导管的远侧端部上翻转),或者可扩张的第一远侧端部区域和可较少扩张的第二远侧端部区域两者都可以全部或部分暴露。例如,暴露至少1cm的可扩张的第一端部区域和至少1cm的可较少扩张的第二端部区域。可扩张的第一端部区域可以在可较少扩张的第二端部区域上翻转(翻折回来)。

[0037] 如上所述,可扩张的第一端部区域可以包括既可扩张又能够抓取物体(例如凝块)的任何适当材料。例如,远侧牵引器区域的可扩张的第一端部区域可以包括邻近于可

较少扩张的第二端部区域耦接的网状物。例如，可扩张的第一端部区域可以是以下中的一种或多种：机织材料、网状编织材料、针织材料或穿设有多个开口的膜材料。可较少扩张的第二端部区域可以由相同的材料制成，或者其可以由不同的材料制成。可较少扩张的第二端部区域可以具有相同的结构（例如机织等）或者其可以具有不同的结构，包括可扩张的第一端部区域的结构的可较少扩张变型。例如，可较少扩张的第二端部区域可以是非多孔的（例如非机织的、非针织的等，或固体材料）或较少多孔的（例如，紧密机织的小空隙针织孔、紧密编织物）。在一些变型中，可较少扩张的第二端部区域可包括位于可扩张的第一端部区域（例如，具有中间可扩张性）与第二端部区域的不可扩张部分之间的过渡区域。通常，远侧牵引器区域的可较少扩张的第二端部包括不可扩张的结构和材料。

[0038] 执行机械取栓以从血管去除凝块的方法可以包括：将导管的远侧端部朝向凝块推进通过血管；将管的位于导管内的远侧牵引器区域从导管的远侧端部暴露，其中，远侧牵引器区域包括可扩张的第一端部区域和靠近于可扩张的第一端部区域的可较少扩张的第二端部区域，并且被配置成使得可扩张的第一端部区域在可较少扩张的第二端部区域上翻转；允许可扩张的第一端部区域在血管内扩张，使得导管的远侧端部区域位于远侧牵引器区域的可较少扩张的第二端部区域与可扩张的第一端部区域之间；以及通过向远侧端部推进导管并在导管内向近侧取回导管使得可扩张的第一端部区域在导管的远侧端部上滚动并在可扩张的第一端部区域被拉动到导管中时翻转，将凝块拉入导管。

[0039] 如上所述，在暴露远侧牵引器区域之前，可扩张的第一端部区域可以在可较少扩张的第二端部区域上翻转。可替代地，暴露远侧牵引器区域可以包括当暴露远侧牵引器区域时使可扩张的远侧端部区域在可较少扩张的第二端部区域上翻转。通常，将管的位于导管内的远侧牵引器区域从导管的远侧端部暴露可以包括将远侧牵引器区域推出导管的远侧端部之外。将管的位于导管内的远侧牵引器区域暴露在导管的远侧端部之外可包括向近侧牵拉导管。

[0040] 执行机械取栓以从血管去除凝块的方法可包括：将导管的远侧端部朝向凝块推进通过血管；将管的位于导管内的远侧牵引器区域暴露于导管的远侧端部之外，其中，远侧牵引器区域包括可扩张的第一端部区域和可较少扩张的第二端部区域，其中，暴露包括将可扩张的第一端部区域延伸导管的远侧端部之外，使得当可扩张的第一端部区域延伸时，可扩张的第一端部区域在导管的远侧端部上翻转；允许可扩张的第一端部区域当延伸出导管的远侧端部之外时在血管内扩张，使得导管的远侧端部区域位于可较少扩张的第二端部区域与可扩张的第一端部区域之间；以及通过在导管内向近侧取回管使得当可扩张的远侧端部区域被拉入导管中时可扩张的远侧端部区域在导管的远侧端部上滚动、收缩和翻转，将凝块拉动到导管中。将管的位于导管内的远侧牵引器区域从导管的远侧端部暴露可以包括将远侧牵引器区域推出导管的远侧端部之外。可替代地或附加地，将管的位于导管内的远侧牵引器区域暴露于导管的远侧端部之外可以包括相对于管的远侧牵引器区域向近侧取回导管。

[0041] 本文还描述了用于从血管去除凝块的机械取栓设备，该设备包括：导管，其具有远侧端部和远侧端部开口，其中导管具有内径和外径；管的位于导管内的远侧牵引器区域，其中，远侧牵引器区域包括可扩张的远侧端部区域以及靠近于可扩张的远侧端部区域的可较少扩张的远侧端部区域，远侧牵引器区域被配置成使得可扩张的远侧端部区域在

可较少扩张的远侧端部区域上翻转;穿过导管和管的导丝腔,该导丝腔包括远侧牵引器区域,其中,导丝腔被配置成使导丝通过;以及近侧手柄,其耦接至管并且被配置成引起导管与管之间的相对运动,使得从导管的内径内释放远侧牵引器区域,使得可扩张的远侧端部区域可以扩张至大于外径的直径,使得可以在可扩张的远侧端部区域与可较少扩张的远侧端部区域之间推进导管,并且可以向近侧拉该管以在导管的远侧端部上拉动可扩张的远侧端部区域,使得可扩张的远侧端部区域滚动到导管的远侧端部中、翻转、收缩并被拉入导管。

[0042] 例如,用于从脉管去除凝块的机械取栓设备可以包括:导管,其具有远侧端部和远侧端部开口,其中,导管具有内径和外径;管,其具有位于导管内的远侧牵引器区域,其中,远侧牵引器区域包括可扩张的远侧端部区域和靠近于可扩张的远侧端部区域的可较少扩张的远侧端部区域,进一步其中,可扩张的远侧端部区域被偏置成当其从导管的远侧端部暴露时在可较少扩张的远侧端部区域上翻转;穿过导管和管的导丝腔,该导丝腔包括远侧牵引器区域,其中,导丝腔被配置成使导丝通过;以及近侧手柄,其耦接至管并且被配置成引起导管与管之间的相对运动,使得从导管的内径内释放远侧牵引器区域,使得可扩张的远侧端部区域可以扩张至大于外径的直径,并且可以向近侧拉该管以在导管的远侧端部上拉动可扩张的远侧端部区域,使得可扩张的远侧端部区域滚动到导管的远侧端部中、翻转、收缩并被拉入导管中。

[0043] 本文还概括描述了机械取栓装置。例如,本文描述了用于从脉管去除凝块的机械取栓装置,包括:导管,其具有远侧端部和远侧端部开口;柔性管,其在导管内延伸并且在导管的远侧端部上翻折回来,其中,柔性管被配置成当在导管内向近侧拉动柔性管的第一端部时在远侧端部开口上滑动并翻转;以及穿过导管和柔性管的导丝腔,被配置成使导丝通过。

[0044] 用于从脉管中去除凝块的机械血栓装置可包括:导管,其具有远侧端部和远侧端部开口,其中远侧开口的硬度大于紧邻远侧端部的区域的硬度,进一步其中远侧端部开口具有圆形唇缘轮廓;柔性管,其在导管内延伸并且在导管的远侧端部上翻折回来,其中柔性管被配置以当柔性管的第一端部在导管内向近侧被拉动时在远侧端部开口上翻转;以及导丝腔,其穿过导管以及被配置以通过导丝的柔性管。导管远侧端部硬度可以大于60A肖氏硬度或大于40D肖氏硬度。

[0045] 用于从脉管去除凝块的机械取栓装置,其包括:内导管,其具有远侧端部和远侧端部开口;柔性管,其延伸穿过导管并且在内导管的远侧端部上翻折回来,其中,柔性管被配置成当在内导管内向近侧拉动柔性管的第一端部时在远侧端部开口上翻转;外导管,其在内导管和柔性管上延伸;柔性管的在外导管的远侧端部与内导管的远侧端部开口之间延伸的润滑区域,其中,大部分柔性管是未润滑的;以及穿过导管和柔性管的导丝腔,其被配置成使导丝通过。

[0046] 用于从脉管去除凝块的机械取栓装置可以包括:内导管,其具有远侧端部和远侧端部开口;柔性管,其延伸穿过导管并且在内导管的远侧端部上翻折回来,其中,柔性管被配置成当在内导管内向近侧拉动柔性管的第一端部时在远侧端部开口上翻转;可释放附件,其位于柔性管和导管的外表面之间,被配置成当以预定力(例如,大于0.01N)拉动柔性管时释放;以及穿过导管和柔性管的导丝腔,其被配置成使导丝通过。

[0047] 用于从脉管去除凝块的机械取栓装置可包括：导管，其具有远侧端部、远侧端部开口和内径；柔性管，其延伸穿过导管并且在导管的远侧端部上翻折回来，其中，柔性管被配置成当在导管内向近侧拉动柔性管的第一端部时在远侧端部开口上翻转，柔性管具有低泊松比，使得柔性管当被用足够的力在导管内向近侧拉动时的直径大于导管的内径的一半，以在远侧端部开口上翻转；以及穿过导管和柔性管的导丝腔，被配置成使导丝通过。具有低泊松比的柔性管可以小于0.5或者在0.05至0.5或0.1至0.3的范围内。

[0048] 如上清楚所述，柔性管通常包括远侧牵引器区域，远侧牵引器区域具有可扩张的第一端部区域以及邻近于第一端部区域的可较少(或不可)扩张的第二端部区域。因此，柔性管可以包括网状管。

[0049] 通常，形成本文所描述的装置的一部分的导管是高度灵活的，如适用于所采取的侵害路径，例如，通过神经脉管导管。在一些变型中，组装装置(具有缠绕在远侧端部上并准备好操作的柔性管)的总体刚度在不具有柔性管的导管的原始刚度的预定百分比内(例如，在10%内、在12%内、在15%内、在16%内、在17%内、在18%内、在19%内、在20%内、在25%内、在30%内等)。例如，延伸穿过导管并且在导管的远侧端部上翻折回来的柔性管可以将导管的远侧5cm的刚度增加小于导管的远侧5cm的刚度的预定百分比(例如15%)，而不使柔性管延伸穿过其中和在导管的远侧端部上翻折回来。

[0050] 在本文所描述的变型中的任一个中，柔性管的远侧牵引器区域适于抓取物体，例如凝块。特别地，柔性管可以是多孔的或者具有至少一个多孔区段，所述多孔区段具有孔隙图案，所述孔隙图案在宽度小于预定距离(例如，约0.005英寸)的孔隙之间具有纵向间隔。如在该示例中所使用的，“孔隙”包括网状物(机织物等)的股线之间的窗口、开口、间隙等以及穿过固体片形成的孔隙。通常，对于机织(并且特别是编织)的可扩张的第一端部区域材料，较小的细丝在抓取时可能更好，并且因此较小的孔隙尺寸可能是优选的。最佳尺寸可以取决于材料，包括细丝尺寸、孔隙百分比、孔隙间距的尺寸、孔径等。例如，在一些变型中，孔隙率大于>60% (大于70%、大于75%、大于80%、大于85%等，在60%至95%、65%至95%、70%至95%等之间)以及纤维直径(对于机织材料)为<0.005是有利的。确保凝块或异物被抓取所需的柔性管状构件的有效孔径可以在50微米至1000微米(μm)的范围内，或者在100 μm 至200 μm 、100 μm 至300 μm 、100 μm 至500 μm 或500 μm 至1000 μm 的范围内。柔性管状构件可沿其长度具有各种孔径。

[0051] 通常，如本文所用，机织材料包括通过以交织图案(例如，交织股线、细丝、材料长度等)编织多股材料而形成的任何材料。网状物是一种机织材料。取决于形成织物的材料的弹性，机织材料通常在某些方向上(在偏置方向上)更可伸展/可扩张。机织材料通常以平行或几乎平行的路径行进。针织材料可以更柔性并且通常指的是曲折的单个路径或路线，从而形成可以对称布置和互锁的环路。机织材料可以非常可拉伸/柔性的。针织结构区域可较少拉伸，但仍然非常柔性。

[0052] 在本文所描述的装置中的任一个中，并且特别是预加载或预成形的版本中，该装置可以包括位于柔性管与导管的外表面之间的可释放附件，其被配置成当用大于预定力阈值的力拉动柔性管时释放。例如，可释放力阈值可以大于约0.001N、大于约0.005N、大于约0.01N、大于约0.03N、大于约0.05N、大于约0.08N、大于约0.1N、大于约0.3N、大于约0.5N等)。

[0053] 在本文所描述的装置中的任一个中,柔性管可以包括多个柔性材料条,其中,条被布置成与柔性管的长轴平行。可替代地或附加地,在这些变型中的任一个中,远侧端部开口可以包括多个凹口或通道,当柔性管在远侧端部开口上翻转时,形成柔性管的纤维或条被拉入该凹口或通道。

[0054] 在本文所描述的装置中的任一个中,柔性管可以包括具有穿设有多个孔的聚合物管。例如,柔性管可以包括远侧端部、近侧端部以及在远侧端部与近侧端部之间的主体区域,其中,主体区域从较柔性的远侧端部过渡到较刚性的近侧端部。

[0055] 如上所述,在本文所描述的变型中的任一个中,导管的远侧端部(例如,远侧端部开口区域)可以适于防止当在导管开口上翻转时收缩但仍然足够柔软以为神经管应用提供合适的使用。例如,本文所述的装置中的任一个在远侧端部(例如,在远侧端部开口/边缘处)处的硬度可大于紧邻远侧端部的区域的硬度。这些远侧端部开口中的任一个都可以具有圆形唇缘轮廓。通常,尽管远侧端部区域的硬度可能降低(变得“较软”),但是非常最远侧端部(开口)的硬度可能较高。这与圆形端部形状一起可以减小在将远侧牵引器区域(例如,可扩张的第一端部区域)拉入导管时使其翻转所需的力,同时防止导管的远侧端部区域收缩。

[0056] 本文所描述的装置中的任一个还可以包括适于相对于导管向近侧拉入柔性管的手柄。手柄可以附接到或可附接到导管和/或柔性管,并且可以包括用于独立地或者更优选地以协调的方式(或者在这两个模式之间切换)而致动的单独的控制装置。例如,这些装置中的任一个可以包括耦接到导管的近侧端部区域的驱动手柄,其中,驱动手柄包括控制器,该控制器被配置成在被致动时协调在向近侧收回柔性管的同时向远侧推进导管。

[0057] 这些装置中的任一个还可以包括在导管和柔性管上延伸的外导管。外导管可以在导管和柔性管上延伸,并且可以保持远侧牵引器区域(导管外部)的外部部分收缩,直到其已经被输送。这些装置中的任一个都可以包括在外导管的远侧端部和远侧端部开口之间延伸的柔性管的润滑区域,其中,大部分柔性管是未润滑的。该润滑区域可以减小致动该装置所需的初始力。

[0058] 在本文所描述的装置中的任一个中,柔性管可被配置成当在导管内向近侧拉动柔性管的第一端部时在远侧端部开口上翻转,并且柔性管可具有低泊松比,使得柔性管(其可以是网状管)当被用足够的力在导管内向近侧拉动时的直径大于导管的内径的一半,以在远侧端部开口上翻转。

[0059] 这些装置中的任一个可以包括位于导管内的拉动器(例如细长拉动器)并且耦接到柔性管的远侧端部。拉动器通常被配置成向近侧拉入柔性管,但是在一些变型中它可以向远侧移动柔性管。例如,这些装置中的任一个还可包括位于导管内并耦接到柔性管的远侧端部的细长拉动器,其中,细长拉动器包括具有内腔的海波管,该内腔与穿过柔性管的导丝腔连续。

[0060] 如上所述,在一些变型中,柔性管包括可推动的柔软外部网状物。例如,远侧牵引器区域(并且特别是可扩张的第一端部区域)可以由24至144个股线形成,股线在直径上具有0.0020英寸或更小的厚度,其中,网状管状构件在纵向轴线上延伸,进一步其中,网状物管状构件的长度大于5cm,网状管状构件当围绕导管的远侧端部被拉动和翻转时在纵向轴线的方向上的交叉股线之间形成约35度或更小的编织角度,并且当不受约束时在导管的

外部扩张到大于导管的内径的1.5倍的直径。

[0061] 当柔性管由股线(例如机织、编织等)形成时,股线可以由以下中的任一者形成:单丝聚合物、复丝聚合物、镍钛(NiTi)丝、具有不透射线金属中心的镍钛管、钴铬合金丝、具有不透射线金属中心的钴铬合金管、尼龙、聚酯、聚对苯二甲酸乙二醇酯和聚丙烯。

[0062] 如上所述,这些装置中的任一个都可以被配置成使得柔性管(例如可扩张的远侧端部区域)可释放地保持在导管上。例如,这些装置中的任一个可以包括围绕柔性管的远侧端部区域的保持环,该保持环被配置成将柔性管可释放地保持抵靠在导管上。

[0063] 在这些变型中的任一个中,柔性管的形状可以被设定成当在导管内被向近侧拉入导管之后时具有不同的直径。通常,柔性管可以包括多个机织丝或一个(或多个)针织丝。在一些变型中,整个(或大部分)柔性管由机织或针织细丝形成,并且柔性管的近侧端部可形成与形成拉线的细丝或细丝束相反的渐缩开口。可替代地或附加地,柔性管可以由具有小于0.020英寸的厚度的聚合物套筒形成,其中,套筒包括穿孔图案,其中,穿孔延伸穿过聚合物。穿孔图案可以包括具有由以下一个或多个构成的形状的穿孔:圆形孔、矩形孔和锯齿形状。

[0064] 这些装置中的任一个可以包括耦接到柔性管的近侧端部的一侧的拉线,该拉线被配置成被向近侧拉以将柔性管拉动到导管内。

[0065] 通常,柔性管可以是任何适当的长度。例如,柔性管可以在3cm至200cm之间(例如,3cm至150cm、3cm至100cm、3cm至50cm等)。

[0066] 在本文所描述的装置中的任一个中,装置的柔性管可被配置成使得可通过向柔性管的远侧端部施加小于预定量的力(例如500克的力、450克的力、400克的力、350克的力、300克的力、250克的力、200克的力、150克的力等)将柔性管收回到导管中。

[0067] 在这些变型中的任一个中,柔性管可以包括位于柔性管的第一端部与第二端部之间的渐缩部。在一些变型中,柔性管可以在导管的整个长度内延伸,使得柔性管的近侧端部被配置成远离导管的近侧端部向近侧被拉动以使柔性管在远侧端部开口上滑动并翻转。

[0068] 本文所描述的装置中的任一个还可以包括真空源。例如,这些装置中的任一个可以包括导丝真空泵,该导丝真空泵耦接到导丝腔的近侧端部并且被配置成通过其施加真空。例如,这些装置中的任一个可以包括外导管真空泵,该外导管真空泵耦接到导管与柔性管之间的空间并且被配置成在导管的位于导管的内壁与柔性管之间的腔内施加真空。

[0069] 如上所述,该装置可以包括拉动器,其中,柔性管的远侧端部耦接到拉动器的远侧端部。外导管可以布置在导管上且邻近于柔性管的近侧端部。这些装置中的任一个还可以包括具有控制器的手柄,该控制器被配置成协调推进外导管以向远侧推动柔性管的近侧端部和向近侧拉动拉动器以将柔性管的近侧端部拉入导管。例如,如本文所描述的装置可以包括:拉动器,其中,柔性管的远侧端部耦接到拉动器的远侧端部;外导管,其可滑动地布置在耦接到柔性管的近侧端部的导管上;以及手柄,其具有控制器,该控制器被配置成协调在向近侧拉动拉动器以将柔性管的近侧端部拉入导管的同时向远侧推进外导管以向远侧推动柔性管的近侧端部,或者在向远侧推动拉动器以将柔性管的近侧端部推出导管之外的同时向近侧拉动外导管以向近侧拉动柔性管的近侧端部。

[0070] 本文还描述了机械地去除血栓的方法,包括:将导丝至少推进到血管中的凝块的

近侧端部;在导丝上向远侧推进取栓(例如凝块去除)装置,其中,取栓装置包括具有远侧端部和远侧端部开口的导管以及沿着导管的外径且在导管的远侧端部上延伸的柔性管,使得导丝穿过导管的腔以及柔性管;从离开导管的外径向近侧拉动柔性管并将柔性管拉动到导管腔中,使得柔性管在远侧端部开口上滑动并翻转;以及当柔性管被拉入导管时将凝块拉入翻转的柔性管。

[0071] 机械地去除取栓的方法可以包括:推进导丝邻近血管中的凝块;在导丝上向远侧推进取栓装置,其中,取栓装置包括具有远侧端部和远侧端部开口的导管以及沿着导管的外径且在导管的远侧端部上延伸的柔性管,使得导丝穿过导管的腔以及柔性管;从离开导管的外径向近侧拉动柔性管并在导管的远侧端部开口的圆形唇缘上将柔性管拉动到导管腔中,使得柔性管在远侧端部开口上滑动并翻转,其中,远侧端部开口的硬度大于紧邻远侧端部的区域的硬度;以及当柔性管被拉入导管时将凝块拉入翻转的柔性管。

[0072] 机械地去除取栓术的方法可以包括:推进导丝邻近血管中的凝块;在导丝上向远侧推进取栓装置,其中,取栓装置包括具有远侧端部和远侧端部开口的内导管、沿着内导管的外径且在导管的远侧端部上延伸的柔性管,以及将柔性管的远侧端部区域固定抵靠在内导管的外径上的外导管,使得导丝穿过导管的腔和柔性管;从离开导管的外径向近侧拉动柔性管并将柔性管拉动到导管腔中,使得柔性管的润滑近侧引导区域在远侧端开口上滑动并翻转,直到柔性管的未润滑远侧区域被拉入内导管;以及当柔性管被拉入导管时将凝块拉入翻转的柔性管。

[0073] 机械地去除取栓术的方法可以包括:推进导丝邻近血管中的凝块;在导丝上向远侧推进取栓装置,其中,取栓装置包括具有远侧端部和远侧端部开口的导管以及沿着导管的外径且在导管的远侧端部上延伸的柔性管,使得导丝穿过导管的腔和柔性管;从离开导管的外径向近侧拉动柔性管并将柔性管拉动到导管腔中,使得柔性管在远侧端部开口上滑动并翻转;将柔性管向远侧拉出或推出导管的远侧端部,使得柔性管在远侧端开口上滑动并翻转;以及当柔性管被拉入导管时将凝块拉入翻转的柔性管。

[0074] 在本文所描述的方法中的任一个中,导丝可以至少部分地定位在血管中的凝块内。

附图说明

[0075] 在所附权利要求中特别阐述了本发明的新颖特征。通过参考以下详细描述来获得对本发明的特征和优点的更好理解,所述详细描述阐述了利用本发明原理的说明性实施例以及附图,附图中:

[0076] 图1A至图1H示出了用于机械地去除诸如形成身体区域的凝块的物体的装置的一个变型。图1A示出了该装置的导管部分;图1B示出了导管的远侧端部(开口)的放大视图;图1C示出了柔性管(牵引器管)的远侧牵引器区域的示例,其示出了处于收缩(未扩张)配置的柔性管的可扩张的第一端部区域,而图1D示出了具有可扩张的第一端部区域的相同的远侧牵引器区域。图1E示出了组装的机械取栓装置,其中柔性管延伸穿过导管并且在导管的远侧端部上翻折回来,使得柔性管的可扩张的第一端部区域(形成远侧牵引器区域的一部分)至少部分地位于导管外侧并处于非扩张状态。图1F示出了图1E的装置,其中可扩张的第一端部区域扩张。图1G和图1H示出了图1E和图1F的装置的使用以通过向近侧拉柔

性管和/或向远侧朝向凝块推进导管而去除凝块,使得可扩张的第一端部区域当其被拉入导管的远侧端部中时翻转,将凝块拉动到导管中。

[0077] 图2A至图2D示出了可以是本文所描述的装置的一部分的柔性管(牵引器管)的变型。图2A示出了包括远侧牵引器区域的柔性管的远侧端部,远侧牵引器区域在远侧端部处包括可扩张的第一端部区域,其邻近于可较少扩张的第二端部区域。在图2B中,可扩张的第一端部区域由多个机织纤维形成。在图2C中,可扩张的第一端部区域由整个具有多个小孔的材料片形成。在图2D中,可扩张的第一端部区域在可较少扩张的第二端部区域上翻折(doubled over,对折)。

[0078] 图3A至图3F示出了机械取栓装置的一个示例的体内展开和操作。在该示例中,在将导管定位在凝块附近之后,远侧牵引器区域被推动穿过导管,直到远侧牵引器区域从凝块的远侧端部暴露(图3A至图3D),使得可扩张的第一端部区域扩张至血管的内膜;然后在可扩张的第一端部区域与可较少扩张的第二端部区域之间推进导管(图3D至图3E),并且可扩张的第一端部区域被拉入导管中,使得其翻转并将凝块拉入导管中(图3E至图3F)。

[0079] 图4A至图4F示出了机械取栓装置的另一个示例的体内展开和操作。在该示例中,柔性(牵引器)管的可扩张的第一端部区域在通过将可扩张的第一端部区域延伸出导管的远侧端部而定位导管部分(图4A至图4B)之后被展开,使得可扩张的第一端部区域在导管的远侧端部区域上翻折回来(图4C至图4D)。一旦暴露和展开,可扩张的第一端部区域可以在向远侧推进导管或不向远侧推进导管的情况下被拉回到导管中以将凝块拉动到导管中(图4F)。

[0080] 图5A至图5E示出了机械取栓装置的另一个示例的体内展开和操作,其中可扩张的第一端部区域在定位在凝块附近的血管内之后向远侧延伸出导管的端部(图5A至图5C)。一旦可扩张的第一端部区域已经延伸并允许在脉管内扩张,则可以向远侧推进导管和导管内的柔性管的其余部分(图5D),使得可扩张的第一端部区域在远侧端部上翻折,如图所示。此后,在向远侧推进导管或不向远侧推进导管的情况下,可扩张的第一端部区域可以被拉回到导管中,以将凝块拉动到导管中(图5E)。

[0081] 图6A和图6B示出了一种机械取栓装置,其包括导管以及延伸穿过导管并在导管的远侧端部(形成远侧牵引器区域)上翻折回来的柔性管(牵引器管),以及在远侧牵引器区域上的外导管或释放保护器导管。图6A示出了定位在凝块附近的装置;图6B示出了与导丝一起使用的装置,该导丝穿过装置的导丝腔以用于定位和操作该装置。

[0082] 图7A至图7D示出了如图6A至图6B所示的取栓装置的操作,其示出了邻近凝块定位远侧端部/远侧牵引器区域(图7A),然后将凝块拉动到导管中(图7B至图7C)并且最终去除凝块和柔性牵引器管(图7D)。

[0083] 图8示出了包括可选真空源的取栓装置。

[0084] 图9A至图9D示出了本文所描述的取栓装置与导丝结合的操作。导丝可以完全或部分地经过凝块,并且该装置可以在导丝上被致动,从而提供增强的稳定性和功效。

[0085] 图10A示出了用于致动诸如本文所描述的取栓装置的装置的手柄(近侧)手柄的一个变型。手柄可以被耦接并且可以单独地或以协调的方式致动导管和柔性(牵引器)管(包括远端侧牵引器区域)的运动。

[0086] 图10B示出了用于如本文所描述的装置的近侧手柄的另一示例,其包括用于控制

(单独或一起)导管和/或内柔性牵引器管的致动的控制器。

[0087] 图11A示出了用于包括如本文所描述的取栓装置的装置的近侧手柄 的另一示例。

[0088] 图11B是示出用于如本文所描述的装置的手柄的操作的机械示意图。

[0089] 图12A和图12B示出了变型,其中装置的柔性牵引器管的可扩张的 第一端部区域可释放地固定到导管的外表面;在装置的致动使得远侧牵引 器区域可以被拉入导管的远侧端部中之前,可以分离可释放附件。在图 12A中,外管(例如,远侧牵引器区域上的外导管或释放保护器导管)至 少覆盖可扩张的远侧端部区域的端部。在图12B中,远侧牵引器区域 的可 扩张的第一端部区域可包括可释放地将可扩张的第一端部区域固定到导 管的外径的带、粘合剂、焊接件(例如,脆的粘合剂或其他附件)、卡扣 配合件、抓持件等。

[0090] 图13A和图13B示出了本文所描述的装置的柔性(例如牵引器)管 的近侧端部区域(牵引器区域)的示例。图13A示出了其中牵引器管的近 侧端部形成与管的腔径向偏离的拉线的示例;如图所示,导丝仍然可以经 过管(和导管)的腔以用于该装置的操作。图13B示出了其中拉线(或杆、构件等)由与柔性牵引器管的其余部分不同的材料形成的示例。

[0091] 图14示出了远侧牵引器区域,其包括远侧牵引器区域的可扩张的第 一端部区域的近侧端部区域附近的有限润滑区域;可扩张的第一端部区域 的其他部分可能不是润滑的,远侧牵引器区域的其余部分也可能不是润滑 的。

[0092] 图15A至图15D示出了具有成形的可扩张的第一端部区域的柔性(牵 引器)管。特别地,这些不同的可扩张的第一端部区域可以被预先设定为 不同的直径,这可以帮助拉入和/或破坏导管内的凝块。图15A示出了第 一示例,其中可扩张的第一端部区域通过多个拉线耦接到拉动器部分。在 这些示例中,可扩张的第一端部区域被示出未在柔性管状构件 (牵引器管) 的较近侧部分上翻转。图15B示出了由不可径向扩张的多个拉线连接的多 个可扩张的端部区域。图15C示出了具有多个预先设定直径的可扩张的第 一端部区域。图15D示出了通过形成可扩张的第一端部区域的两束或多束 细丝耦接到牵引器管的较近侧拉动器部分的可扩张的第一端部区域。

[0093] 图16示出了可扩张的第一端部区域的另一示例,其包括到导管的外 径的多个可释放附件;这些可释放附件(其可以是脆的、弹性的等)可以 通过施加足够的力而被释放,以允许将远侧牵引器区域拉动到导管中以用 于致动该装置。

[0094] 图17示出了其中可扩张的第一端部区域在导管的远侧端部区域的外 径上被加载(例如弹簧加载,压缩等)并且被可释放地锁定或以其他方式(例如,通过可靠的附件)保持 在位(in place,在适当位置)的示例;该 可释放附件可以防止装置在致动之前的展开,并且可扩张的第一端部区域 的加载可以使得远侧牵引器区域更容易在导管的远侧端部上翻 转以将凝 块拉入装置中。

[0095] 图18A至图18C示出了具有不同刚度的可扩张的第一端部区域的示 例。

[0096] 图19A和图19B示出了用于组装如本文所述的装置的组装方法。

[0097] 图20A和图20B示出了可用作本文所描述的装置的远侧牵引器区域 的一部分的可扩张的第一端部区域的示例性轮廓。

[0098] 图21A至图21D示出了用于去除凝块的装置的示例。图21A示出了 在耦接到导管之前的可扩张的第一端部区域的示例。图21B示出了通过拉 动柔性(牵引器)管的近侧端部而将血管(玻璃管)内的可扩张的第一端 区域拉入导管中。图21C示出了装置的远侧端部区

域,其包括在导管的远侧端部区域上翻折的可扩张的第一端部区域。图21D示出了将凝块拉入导管中的图21C的装置。

[0099] 图22示出了图21D的可扩张的第一端部区域,其在将其向近侧拉出导管之后具有所捕获的凝块。

[0100] 图23A至图23D示出了如本文所描述的机械取栓装置,其捕获血凝块并将其拉入装置中。

[0101] 图23E示出了柔性牵引器管已经从导管去除(例如近侧)之后保持在柔性牵引器管内的凝块。

[0102] 图24是包括柔性牵引器构件的装置的另一个示例,其中,远侧牵引器区域由多个细丝形成,多个细丝布置成非机织或编织材料的条(纵向平行)。这些条(strip)可以是细丝或管等。

[0103] 图25A至图25F示出了柔性牵引器组件的远侧牵引器区域的另一变型,其中,可扩张的第一端部区域(例如,远侧牵引器区域的远侧端部区域)由多个细丝或条形成,类似于在图24中所示的;导管的远侧端部包括通道,如图25A至图25D所示;这些条可以装配在这些通道内,如图25C至图25D所示。图25E和图25F示出了穿过图25C和图25D的截面图。

[0104] 图26A和图26B示出了具有外套筒(例如,外导管或释放保护器导管或其他外套筒/保护器)的图25A至图25F的装置的变型

[0105] 图27A和图27B示出了穿过图26A至图26B的装置的截面图。

[0106] 图28是包括柔性牵引器组件的远侧牵引器区域的装置,该柔性牵引器组件具有多个纵向平行的(非机织/编织的)细丝或条,其中细丝或条的远侧端部通过远侧连接彼此连接。

[0107] 图29示出了装置中的柔性牵引器组件的远侧牵引器区域,其中纵向平行的(非机织/编织的)细丝或条包括抓取元件。

[0108] 图30A至图30C示出了具有抓取元件的细丝/条的示例。抓取元件(和/或包括它们的细丝)可以用作本文所描述的变型中的任一个的一部分,包括机织或编织的远侧牵引器区域。

[0109] 图31示出了一种变型,其中远侧牵引器区域适于往复运动(例如,推动和拉动)使得可扩张的第一端部区域可被拉入导管中并从导管翻转出。

[0110] 图32示出了如本文所述的装置的另一示例,其中可扩张的第一端部区域的最远侧端部固定到导管的远侧端部的一部分;可扩张的第一端部区域的其余部分具有足够的弹性/柔性以被拉入导管中(用其拉动凝块)。然后柔性牵引器组件可以被收回并且整个装置被拉出。该示例可能包括可选的真空。

[0111] 图33是装置的另一示例,其中柔性牵引器组件的拉动器部分由与远侧牵引器区域相同的材料形成,但可以被层压或以其他方式被增强以具有比远侧牵引器区域更小的柔性/可拉伸性。

[0112] 图34示出了其中远侧牵引器区域适于在被拉入导管中时压缩凝块的另一示例。

[0113] 图35A至图35C示出了如图34所示的装置的操作,其中通过将远侧牵引器区域的可扩张的第一端部区域拉回到压缩凝块(图35A至图35B)的导管中(例如,在牵引器组件的

拉动器区域上拉动) 而将凝块拉入导管; 释放牵引器组件和/或向远侧推动牵引器组件可以进一步破碎凝块并将其从远侧牵引器区域释放, 使得其可以利用手动或动力真空源向近侧抽吸 (图35C)。

[0114] 图36示出了一种使用装置和方法的示例, 其中向近侧拉入柔性牵引器组件可以使装置向远侧行进通过导丝上的主体 (例如血管), 该导丝可以被处理以接合远侧牵引器区域。

[0115] 图37A至图37C示出了一种使用装置和方法, 其中向近侧拉柔性牵引器组件可以使装置向远侧行进。

[0116] 图38A和图38B示出了装置和使用该装置从血管中去除材料的方法的另一变型, 其中该装置是“无限”牵引机构, 其中大量的牵引器材料 (例如, 网状物) 储存在一个外保持区域中, 其被卷起但在扩充使用上不是必须的。

具体实施方式

[0117] 通常, 本文描述了用于从身体机械地去除物体的方法和装置。虽然这些方法和装置可以适用于从身体的各种区域去除各种物体, 但它们可能特别适合于从血管的腔内去除血凝块。因此本文所描述的是机械取栓装置 (例如设备和系统)。

[0118] 本文所描述的装置 (例如, 用于从血管去除凝块的机械取栓装置) 可以是包括具有远侧端部和远侧端部开口的细长导管的组件以及至少部分位于导管内的柔性牵引器组件, 其中, 牵引器组件的远侧端部区域被配置为远侧牵引器区域, 远侧牵引器区域至少部分地在导管内延伸并且在导管的远侧端部上翻折回来。牵引器组件可以包括连接到远侧牵引器区域的近侧推动器区域。柔性牵引器组件包括配置成允许导丝通过的细长腔。柔性牵引器组件还被配置成在近侧端部区域被向近侧拉动时沿着导管腔内的长轴线滑动并且在导管的远侧端部开口上翻转。牵引器组件在本文可被称为柔性牵引器组件、柔性牵引器部分、柔性牵引器管或简单的柔性管, 并且典型地定位在导管内并且可在导管内纵向可滑动, 并且布置成使得远侧端部区域 (“远侧牵引器区域”) 在导管的远侧端部上翻折回来。

[0119] 例如, 图1A示出了可形成本文所描述的装置的一部分的导管的一种变型。在该示例中, 导管100包括远侧端部区域103, 远侧端部区域包括远侧端部105。除了非常远侧尖端 (远侧端部105) 可以实质上比紧邻其的区域较不柔软之外, 远侧端部区域可以具有增加的柔软度 (通过硬度计测量, 例如肖氏硬度计)。因此, 虽然远侧尖端区域 (例如, 最远侧的x线性尺寸, 其中x为10cm、7cm、5cm、4cm、3cm、2cm、1cm、9mm、8mm、7mm、6mm、5mm、4mm、3mm) 具有从近侧端部到远侧端部延伸的增加的柔软度/减小的硬度, 非常远侧端部区域107 (例如, 测量为最远侧的z线性尺寸, 其中z为1cm、9mm、8mm、7mm、6mm、5mm、4mm、3mm、2mm、1mm、0.8mm、0.5mm、0.3mm、0.2mm等, 并且z总是比x小至少三倍) 的硬度大于紧邻其的区域的硬度, 并且可以与远侧尖端区域的最近侧区域一样硬或比其更硬。

[0120] 导管100也可以被称为内导管或牵引器导管。可以使用任何适当类型的导管, 包括适用于神经血管使用的微导管。

[0121] 在一些变型中, 导管的远侧端部105适于使得远侧牵引器区域可以在导管的远侧端部上滑动并翻转而不被捕获 (束缚) 或没有实质摩擦。例如, 在一些变型中, 远侧尖端 (端部) 可以是弯曲的或倒圆的109, 如图1B所示。特别是在外表面上 (例如从外径到内径的过

渡)。在一些变型中,远侧尖端包括一个或多个通道,如图25A至图28所示和所述的,包括围绕面向远侧的边缘的通道,以引导远侧牵引器区域的滑动。

[0122] 图1C示出了柔性牵引器管140的示例。在图1C中,管是柔性的并且细长(具有通常比导管101大的长度),并且包括远侧牵引器区域142,该远侧牵引器区域包括配置成紧邻近侧区域146上折叠的最远侧可扩张的第一端部区域144,其可以是可较少扩张的第二端部区域。通常,可扩张的远侧端部区域被配置成在不受约束时扩张至介于导管的内径的直径的1.3倍至10倍之间的径向直径。图1D示出了处于扩张配置的图1C的可扩张的远侧端部区域。因此可扩张的远侧端部区域可以被偏置以扩张打开。可扩张的远侧端部区域可以形成网状物、机织物或材料片,并且通常适于抓取待去除的物体(例如血凝块)。

[0123] 图1C中一般性示出的柔性牵引器管被示出为图1E中的可扩张的远侧端部区域在其本身上(例如在更近侧的可较少扩张的第二端部区域上)翻折回来。在图1E中,可扩张的远侧端部区域收缩,而在图1F中,可扩张的远侧端部区域扩张。通常,可扩张的远侧端部区域可以与近侧的可较少扩张的第二端部区域区分开,然而在一些变型中,整个柔性牵引器管可以包括在导管内被推动和/或拉动且不包括近侧的可较少扩张的远侧端部区域的可扩张的材料(例如,网状物、机织物等)。

[0124] 图1G和图1H示出了使用诸如由图1A和图1E的部件组装的装置的装置去除凝块。在该示例中,该装置被配置为包括导管101和柔性牵引器管的取栓装置,该柔性牵引器管包括可扩张的远侧端部区域144,该可扩张的远侧端部区域在导管的远侧端部区域上延伸并且在导管的远侧端部上翻折,使得可扩张的远侧端部区域与内近侧的可较少扩张的(在该示例中,可较少扩张的包括不可扩张的)第二远侧端部区域146连续,该第二远侧端部区域在导管内向近侧延伸并形成可使导丝通过的内腔。柔性牵引器管(未示出)的近侧端部可以包括推动器/拉动物构件,该推动器/拉动物构件可以是与远侧端部区域(远侧牵引器区域140)连续的杆或其它构件。在图1G中,装置被示出在凝块155附近的血管160内定位并展开。通过将远侧牵引器区域140取回到导管101中,可以将凝块拉入导管中,如箭头180所示,其示出了柔性牵引器管的内部部分的拉动(例如,使用手柄,未示出),从而导致将可扩张的远侧端部区域拉动到导管远侧端部中并翻转可扩张的远侧端部区域,使得其被拉动到导管中,如箭头182所示。可扩张的远侧端部区域的远侧端部可相对于导管的外壁“松动”,或者其可被去除附接或在一些变型中永久附接。

[0125] 通常,定位这些装置并致动它们可能是具有挑战性的,这是因为它们在致动之前和操作期间都必须是高度柔性的。例如,一般来说,柔性牵引器管必须不能增加导管的刚度/柔性,并且特别是导管的远侧端部区域过多,或者对于操纵来说过于困难和/或危险,特别是在神经血管系统的侵蚀血管内。本文所描述的是柔性牵引器管部分,其增加了小于预定百分比(例如,小于10%、12%、15%、18%、20%、25%、30%等)的导管的最后y cm(例如,最远侧的20cm、18cm、15cm、12cm、10cm、9cm、8cm、7cm、6cm、5cm、4cm、3cm、2cm、1cm等)的刚度。例如,本文所描述的是柔性牵引器管部分,其穿过导管并且在导管的远侧端部上翻折回来,但是在没有柔性管延伸穿过其中并且在导管的远侧端部上翻折回来的情况下,将导管的远侧5cm的刚度增加小于导管的远侧5cm的刚度的15%。

[0126] 例如,图2A示出了柔性牵引器管201。在该示例中,柔性牵引器管包括在近侧推动器区域201的远侧的远侧牵引器区域242,该远侧牵引器区域具有可扩张的第一端部区域

244以及可较少扩张的第二端部区域 246。整个柔性牵引器管是中空的并且可以使导丝通过(未示出)。柔性牵引器管的各个区域可以由相同的材料(例如,机织的、编织的等细丝(filament)或多个细丝)制成,或者它们可以由不同的材料制成。

[0127] 图2B示出了具有远侧牵引器区域的柔性牵引器管,或者至少由多个机织纤维形成的可扩张的第一端部区域244'。可替代地,可扩张的第一端部区域可由一个(或多个)针织纤维或机织和针织纤维的组合形成。可扩张的第一端部区域可以通过纤维或机织/针织图案的形状设定特性或通过包含一个或多个偏置构件(例如,环、弹簧、带、细丝等)而被偏置地打开(如图所示),其倾向于至少将可扩张的第一端部区域的远侧端部区域偏置打开。

[0128] 图2C示出了由包括多个开口(例如,孔、穿孔、通道、窗口等)的材料片形成的可扩张的第一端部区域的另一变型。这些开口可以是任何尺寸,包括不均匀尺寸(例如尺寸的范围)或均匀尺寸。穿过片的这些开口的尺寸可取决于所使用的材料,例如聚合物材料(PTFE)、硅树脂材料、聚氨酯、形状记忆合金等。在一些变型中,片的孔隙率大于>60%(大于70%、大于75%、大于80%、大于85%等、在60%至95%之间、在65%至95%之间、在70%至95%之间等)是有益的。

[0129] 在这些变型中的任一个中,远侧牵引器区域被配置成使得其可以在其本身上被翻转(例如,翻折),如图2D所示。在一些变型中,该装置可被执行为使得可扩张的第一端部区域在其本身上和/或在导管的远侧端部区域上翻转,或者其可以被配置成使得其可以在体内(例如在血管内)在导管的远侧端部展开和翻转。通常,在装置可被致动之前,导管可以插入可扩张的第一端部区域与柔性牵引器管上的可扩张的第一端部区域的近侧的区域之间,在一些变型中,其可以是可较少扩张的第二远侧端部区域。该空间289可以通过在可扩张的第一端部区域的远侧端部处或附近的偏置构件而保持打开。如所提到的,该可扩张的第一端部区域开口偏置构件可以是环、带、弹簧、线圈等,并且可以由偏置元件(例如,形状设定材料,诸如形状记忆合金)、橡胶或其他聚合物材料等制成。

[0130] 尽管存在相关的挑战,但是本文所描述的装置的体内展开可以为操作装置的用户提供许多优点。图3A至图3F示出了配置用于体内展开的取栓装置的一个示例。在该示例中,该装置包括导管301,该导管可以使用导丝313定位(如同本文所描述的变型中的任一个)。导丝可以延伸到或进入(或穿过)待去除的物体,其示出为在血管360内的图3A中的凝块355。装置的导管可以与导丝一起插入或在导丝之后插入,并且在有或没有柔性牵引器管在导管的远侧端部处或附近的情况下,可以将导管定位在凝块附近(例如,邻近或紧邻)。在图3A中,在导丝已经定位之后,定位导管,并且如图3B所示,从血管中取出导管。导丝可以是线材,较小的导管或可以定位(例如,操纵)到凝块和/或穿过凝块的装置的组合。在定位导管之后,包括远侧牵引器区域342的内柔性牵引器管340被推动穿过导管至导管的远侧端部区域,如图3C所示。在该示例中,形成远侧牵引器区域的柔性牵引器管的远侧端部包括示出为网状物344的可扩张的第一端部区域,该网状物在近侧端部处(推动器区域305)连接到与柔性牵引器管的其余部分连续的近侧的不可扩张的第二端部区域。可扩张的第一端部区域的机织网状物344在收缩(非扩张)配置中在管状第二端部区域/推动器区域的外侧上预先翻转,并且可以滑动穿过导管的腔,并且(当导丝留在适当的位置或用于调节该位置时)在导丝(未示出)上滑动。如图3D所示,柔性牵引器管的远侧牵引器区域

然后通过延伸(在该示例中,向远侧推动柔性牵引器管和/或向近侧拉动导管)而暴露于导管的外侧,从而允许远侧牵引器区域(示为网状物)344的可扩张的第一端部区域沿着第一端部区域的长度扩张。在图3D中,这显示为可以完全扩张至血管的内膜的支架状结构,在可扩张的第一端部区域与可较少扩张的(在此情况下是不可扩张的)第二端区域346之间形成分离。特别地,第一端部区域的扩张可以大于导管的内腔的直径的1.3倍(例如,大于1.5倍、大于2倍、大于2.2倍、大于2.5倍、大于3倍、大于3.5倍、大于4倍、大于5倍、大于6倍、大于7倍、大于8倍、大于9倍、大于10倍等)。

[0131] 在图3D中,导管在远侧牵引器区域的第一端部区域与第二端部区域之间向远侧滑动。然后通过向近侧拉动柔性牵引器管(例如,近侧牵引器区域)和/或向远侧推进导管中的一者或两者,而可以通过将可扩张的第一端部区域向近侧取回到导管中来移除凝块。在一些变型中,既推进该装置(特别是导管),同时又取回可扩张的第一端部区域并将其翻转到导管中可能是有益的。可以比取回柔性牵引器管更快地推进导管。

[0132] 如图3F所示,凝块355可以被拉入到具有可扩张的第一端部区域的导管中。

[0133] 体内展开方法和装置的另一种变型示于图4A至图4F中。在该示例中,柔性牵引器管的自扩张的第一端部区域被配置成当其被推出导管时在导管的端部上自扩张,使得它将在导管的远侧端部上滑动。如以上对于图3A至图3B所描述,可以使用导丝413等来定位该装置。在图4A中,将导管401定位在邻近待去除的凝块455的导丝413上。在图4B中,导丝可以(可选地)被去除,或者(优选地)保留在位。包括远侧牵引器区域的柔性牵引器管434然后可以在导管内向远侧移动并且以可扩张的第一端部区域444延伸出远侧端部,使得其在远侧端部上翻转466并且在远侧端部区域上向近侧滑动,如图4C所示。该过程可以通过在脉管的腔内向远侧推动装置来辅助,因为第一端部区域444的扩张可以帮助将其抵靠血管的壁固定,如图4D至图4E所示。一旦暴露,通过向近侧拉动柔性牵引器管434和/或向远侧端部推进组件(或至少导管),可扩张的第一端部区域可以取回到装置中,如图4F所示。凝块455然后可以被拉入装置中。

[0134] 图5A至图5E示出了使用机械取栓装置的体内展开和取栓(凝块去除)方法的另一变型。在图5A中,包括导管501和内柔性牵引器管534的装置500(例如,在导丝上,未示出)被推进至凝块555附近。在该示例中(其可以与本文所描述的方法中的任一个相关),该装置与柔性牵引器构件一起定位,该柔性牵引器构件具有未展开的远侧牵引器区域,该远侧牵引器区域已经在远侧定位在装置的远侧端部区域附近。如图5B所示,处于图5A中导管501内的收缩配置的可扩张的第一端部区域544被推出导管的远侧端部并扩张至腔的壁,如图5B和图5C所示。一旦推出并扩张,可向远侧推进导管和导管内的柔性牵引器管的部分,如图5D所示,导致可扩张的第一端部区域544翻转,在导管501的远侧端部区域上翻折。通过图5E,装置已经在凝块555附近展开并且可以如已经描述的那样被致动以去除凝块,但是将远侧牵引器区域的可扩张的第一端部区域拉动到导管中,使得它翻转并将凝块拉入导管中。导管可以可选地同时被推进。注意,上述体内展开的方法也可以用于加载用于插入体内的装置,以便将导管径向地定位在柔性牵引器管的可扩张的第一端部区域与较近侧部分之间。

[0135] 图6A示出了具有柔性牵引器管634的取栓装置的另一变型的示例,该柔性牵引器管634具有形成于编织(例如机织)或针织材料的该示例中的柔性第一(远侧)端部区域

644,其中,柔性第一端部区域(牵引器区域)在导管601的远侧端部上翻转并且附接到柔性牵引器管634的近侧端部区域。如在本文所描述的装置中的任一个中,柔性牵引器管的该近侧端部区域可以是海波管、导管或者在导管内可推动/可拉动并且在其远侧端部附接到柔性牵引器区域(例如,远侧牵引器区域)(包括在一些变型中的可扩张的第一端部区域)的层压机织物/网状物或机织材料。注意,在一些变型中,远侧牵引器区域(第一端部区域)可以是不可扩张的,但是可以只是柔性的。

[0136] 在图6A中,附接到柔性牵引器管的远侧牵引器区域的第一端部区域被外导管或套筒(保护器)677覆盖。在该示例中,该装置还包括在内导管601与保护器导管或套筒677之间的中间导管679。在一些变型中,柔性第一端部区域644可以附接到该中间导管,包括可拆卸地附接使得向近侧拉动柔性牵引器管634将使其脱离并允许网状物(柔性第一端部区域644)在血管中展开。在图6A所示的变型中,柔性第一端部区域644未附接至中间导管679。

[0137] 本文所描述的装置中的任一个,包括图6A中所示的装置,可以与如图6B所示的导丝633一起使用(并且可以包括导丝)。图7A至7D示出了图6A至图6B中所示的设备的操作以去除凝块755。在该装置中,柔性牵引器管734的近侧端部可以耦接到真空源(未示出),该真空源当向近侧取回牵引器管734以在导管的端部上翻转远侧牵引器区域时可以被致动。在图7A中,装置位于凝块755附近。在图7B中,通过如箭头所示拉动柔性牵引器管734而翻转远侧牵引器区域并将其拉动到导管中。在该示例中,远侧牵引器区域不被扩张,这是因为它仍然被外套筒777覆盖,如图7B和图7C所示。可以通过推动或通过向近侧拉动远侧牵引器端部区域(在该示例中示为网状物744)的动作以使其在导管的远侧端部上翻转中的一者或两者,向远侧朝向凝块或者在凝块上推进该装置。一旦凝块被去除,装置可以被取回并从血管中被拉出,如图7D所示。

[0138] 如上所述,这些变型中的任一个可以包括一个或多个真空源。图8示出了包括真空源的一个示例,其示出了耦接到柔性牵引器管834的腔的近侧端部处的第一可选真空源。例如,与真空和牵引器管834耦接的可以是旋转止血阀(RHV),如图所示。在图8中,在(可选)外导管877和内导管801或(可选)中间导管878之间形成第二(可选)真空连接。可以在该方法的任何适当部分处施加真空,包括在柔性牵引器管834的收回期间去除凝块。

[0139] 如上所述,本文所描述的装置中的任一个可以包括导丝并且可以在手术期间将导丝留在适当的位置。图9A至9D示出了当导丝913留在适当的位置时去除物体(例如凝块)的方法。在该示例中,该装置类似于图6A至图6B中所示的装置,并且可以包括可选的真空源。在图9A中,包括远侧牵引器区域944的柔性第一端部区域944的翻转部分的导管的远侧端部定位成邻近凝块,并且通过向近侧拉动而被致动以将凝块拉入导管中,如图9B所示。在该示例中,凝块已经被导丝913穿透,因此具有翻转的牵引器区域的导管尖端可以通过推动导管927和/或通过向近侧拉动牵引器管919而在导丝上被向前推进。这可以继续直到整个凝块在导管内,如图9C所示。

[0140] 在本文所描述的变型中的任一个中,该装置可以包括一个或多个标记,或者可以被配置成与一种或多种对比剂一起使用以帮助使所描述的方法可视化。进一步地,这些方法中的任一种都可以包括可视化。可视化可以是间接的(例如,使用荧光镜检查或等效技术),或者可以是直接的,例如使用一个光纤用于直接使该装置可视化(例如,通过装置的

腔)。

[0141] 在图9D中,具有捕获物体(例如凝块)的牵引器管可以从装置的近侧去除并且可以检查所去除的材料(例如,通过组织学/细胞学检查)。随后或同时去除导管。如上所述,当去除物体(例如凝块)时,可能期望在柔性牵引器管向近侧拉回(未示出)的同时(向近侧)拉回导丝。在一些变型中,远侧牵引器区域(例如,编织/机织或针织区域)可以抓取导管内的导丝并且还可以帮助在凝块上或朝向凝块向远侧推进该装置,如下面在图36以及图37A至图37C中更详细地描述的。

[0142] 通常,抓取器(远侧牵引器区域)的滚动效果通过导管相对于远侧牵引器区域的运动而被致动。如果远侧牵引器区域向近侧固定并且导管被推进,则远侧牵引器区域可以具有1:1的抓取比。如果远侧牵引器区域被拉动通过导管,则抓取效果可能被放大。例如,当远侧牵引器区域被拉回(通过拉动牵引器管)并且当内导管被向远侧推动1个单元时翻转进入内导管中在导管内的近侧的1个单元,抓取效果大约是2倍。如果当内导管向远侧推进一个单元时,远侧牵引器区域被取回到导管中向近侧两个单元,则抓取效果可以是大约3倍。远侧牵引器区域和导管的同时运动可以通过手柄来协调。

[0143] 通常,本文所描述的装置中的任一个可以包括手柄。手柄可以与柔性牵引器管和/或导管(例如内导管)和/或任何外导管(例如保护器、套筒等)耦接。手柄可被配置成允许柔性牵引器管和/或导管的选择性的分开致动和/或这些部件的协调运动。图10A和图10B示出了可以使用的手柄的示例。在图10A中,手柄包括驱动机构以拉回牵引器管,并且因此在导管的远侧端部上翻转远侧牵引器区域和/或相对于远侧牵引器区域推进导管。在图10A中,手柄包括可旋转手柄1001,该可旋转手柄与导管驱动器1003耦接。手柄连接到导管1005和具有远侧牵引器区域1011的内部柔性牵引器管1009两者。手柄可以被配置成使得导管的推进(向远侧)与牵引器管的拉动(向近侧)的比率可以被选择和/或可以取决于导管驱动螺纹的螺距或其他机械机构。

[0144] 手柄的另一个变型在图10B中示出。在该示例中,手柄可以附接到牵引器管以拉动(或推动)牵引器管1017,并且因此在导管的远侧端部上翻转远侧牵引器区域,并且手柄的另一部分可以耦接到导管以推动/拉动导管1015。

[0145] 图11A示出了手柄机构1107的另一个变型,该手柄机构被配置成通过在附件部位1105处耦接到牵引器管的近侧端部来拉动本文所述的装置中的任一个的抓取器(远侧牵引器区域),和/或通过耦接到导管的近侧端部来推进导管。手柄机构的另一个示例在图11B中示意性地示出,其示出了杠杆机构1109和与可以固定或可调节的内牵引器管耦接的耦接件。

[0146] 在本文所描述的装置中的任一个(例如,机械取栓装置)中,远侧牵引器区域可以被预加载在导管中/上,使得它可以通过向近侧拉动耦接到远侧牵引器区域的牵引器管和/或向远侧推进导管而被致动。在其中远侧牵引器区域包括在导管的远侧端部上翻折的柔性和/或可扩张的第一端部区域(例如,由网状物和/或机织物材料形成)的预加载变型中,装置可以是适于防止第一端部区域在已经被定位在凝块处或凝块附近之前无意地移位和/或扩张。

[0147] 图12A和图12B示出了附接到导管外侧的远侧牵引器区域的可释放附件的示例。通过施加应用于柔性牵引器管的近侧端部的适当量的力(例如拉力)可以释放这些附件中

的任一个。例如,如图12A所示,远侧牵引器区域(示为网状物1204)的外远侧端部被从外导管或管1203延伸的肩部或衬垫覆盖)。类似地,在图12B中,远侧牵引器区域(示为网状物1204)的外远侧端部被单独的带、环或衬垫1209覆盖。通过添加细丝(例如在编织或机织变型中,附加编织细丝)、通过添加涂层、通过热定形至较大直径,和/或通过添加轴向编织间拉线,当张紧(例如在牵引器管上向近侧拉动)时,可以防止远侧牵引器区域收缩或直径减小。

[0148] 本文所描述的变型中的任一个可包括作为柔性牵引器管的一部分的近侧拉杆或拉线。进一步地,牵引器管的近侧端部区域可能比远侧端部(远侧牵引器区域)柔性更小。图13A和图13B示出了柔性牵引器管的示例。在图13A中,管包括近侧锥形区域,其中,远侧牵引器区域1305由向近侧1307渐缩(tapered, 锥化)到拉线的材料(例如,网状物/机织材料)形成,为导丝1309留出空间并允许远侧牵引器区域在导管上翻转。近侧拉线部分可由形成远侧牵引器区域的细丝形成,例如,在其中机织或编织远侧牵引器区域的变型中。这些细丝可以通过例如其他材料(诸如有助于使其更硬或更柔顺的聚合物)来增强。图13B示出了另一个示例,其中,柔性牵引器管的近侧端部由拉线1315形成,该拉线可以是单独的材料或附接到拉线的远侧端部并形成远侧牵引器区域1317的编织线束的延伸部。

[0149] 本文所描述的装置中的任一个可以被处理或适应为减少在导管端部上翻转远侧牵引器区域所需的力。例如,在一些变型中,远侧端部可以被处理为润滑的,或者远侧牵引器区域的全部或一部分可以被处理以提高摩擦力。例如,在一些变型中,仅远侧牵引器区域的一部分(例如最初在导管的远侧端部上相互作用/翻转的部分)被处理;远侧牵引器区域的其余部分不被处理。图14示出了此类装置的一个示例。在图14中,可扩张和/或柔性第一端部区域(其定位于导管外侧)的最近侧端部1405用润滑涂层处理或由润滑材料形成。第一端部区域的剩余部分(未按比例示出)不是润滑的1403。由于较近侧区域1405暴露于血管和导管的远侧端部,所以它可以更有效地追踪目标或者允许装置追踪目标以及更有效地开始在远侧端部上翻转。该区域可以以任何适当的方式制成润滑的,包括但不限于涂层,诸如疏水/亲水涂层,并且形成或包括更润滑的聚合物材料(例如PTFE)。

[0150] 通常,本文所描述的远侧牵引器区域中的任一个可以适于包括不同的轮廓,包括预先设定以具有(例如,形状设定)可以更容易地在远侧端部上滑动/移动和/或抓取凝块或其他目标物体以用于去除的轮廓。例如,图15A至图15D示出了具有形成不同远侧牵引器区域的不同远侧端部轮廓的牵引器管。例如,在图15A中,远侧牵引器区域包括由通过多个拉线连接到牵引器管的近侧端部的由编织/网状或机织材料形成的最远侧可扩张和/或柔性第一端部区域1505。这些拉线1517可以由形成编织/网状或机织的远侧端部区域的相同线材或细丝形成。图15B示出了另一种变型,其中,多个离散的编织/网状或机织的远侧端部区域通过拉线1515连接;这些拉线区域1515可以是比编织/网状或机织区域1516更少可扩张的和/或柔性的。在图15C中,远侧端部区域被编织/网状或机织,但预先设定为具有不同的直径。因此这些区域沿其长度可以具有不同的形状;当这些形状被拉入导管中时,这些形状可被热定形以更好地抓取或破碎凝块。图15D示出了编织或支架状第一端部区域1521的示例,其通过形成编织/网状或机织的远侧牵引器的相同细丝的相同细丝或束连接到牵引器管1520的海波管或其他更近侧端部区域1523。

[0151] 本文所描述的装置中的任一个还可以或可替代地包括附接到导管的外表面上的

多个可释放附件,从而将远侧牵引器区域(并且特别是远侧端部部分)固定到外表面。在图16中,示出了形成可释放附件的三个环1603、16.3'、1603",其将远侧牵引器区域1644的远侧端部固定到导管1601的外侧。在该示例中,聚合物涂层/膜与编织物附接或成一体,形成远侧牵引器区域以帮助防止其过早地滑出或滑离导管(例如,直到由使用者拉动)。该装置可以包括沿着导管的长度径向定位的多个附件,如图所示,以帮助其保持固定到导管输送系统的外径。在一些变型中,这些可释放附件是弹性构件(例如聚氨酯环),但可以是脆的,并且允许破坏以释放远侧牵引器区域。

[0152] 图17示出了另一种变型,其中,可释放附件定位成使得远侧牵引器区域的一部分被弹簧加载(偏置)以驱动它在导管远侧端部上滚动并进入导管腔中。在图17中,远侧牵引器区域1704的远侧端部可被固定(固定、附接或松动但受约束),并且在导管的远侧端部附近的较近侧端部区域可被可释放地固定到导管1707。例如,聚合物涂层或膜可以附接到远侧牵引器区域(在图17中示出为编织物1744)并且被耦接以使远侧牵引器区域1705的在远侧端部1704与可释放附接部位1707之间的一部分保持张紧(例如,压缩)。然后释放可释放附件1707可以施加驱动围绕导管远侧端部的远侧牵引器区域的力,以帮助将凝块拉入装置中,并减小翻转远侧牵引器区域所需的力。

[0153] 如上所述,形成远侧牵引器区域(并且特别是最远侧柔性和/或可扩张的第一端部区域)的材料可以由任何适当的材料形成。例如,该材料可以包括织物、机织物、针织物、编织物、缝合物、管和/或平片。该材料可以具有任何合适的厚度,例如在0.0005"至0.015"的壁厚之间,并且可以具有从低至高孔隙率的任何合适间隔/尺寸(孔隙率)的孔。远侧牵引器区域的全部或一部分可以是不透射线的或无线电透明的。在机织、针织、编织或缝制的变型中,材料可以由多丝或单丝形成。不同尺寸的细丝可以混合在一起(例如,大和/或小)以通过增加或减少织物表面纹理来改变抓取效果。在一些变型中,材料(包括形成材料的细丝)可以是基于聚合物的(例如PET、尼龙、聚丙烯、PTFE、ePTFE)、弹性和非弹性的(例如PU、硅酮、橡胶、莱卡)、金属细丝(例如镍钛、包括DFT的拉伸充填的镍钛,即带Pt内芯的镍钛、钢、不锈钢、钴铬合金等)以及金属和聚合物细丝的混合物。织物的端部可以是激光切割/焊接或自由切割。在一些变型中,远侧牵引器区域的全部或部分包括膜或片。该膜可以在0.0005"至0.008"厚度之间。该膜可以通过管挤出或片形成并且卷成管。在一些变型中,膜是纱线增强的。膜可以是开槽的(例如,可以包括被切割的孔和/或狭缝以改进抓持或滑入导管)。在一些变型中,膜具有纹理化表面(例如,翻转时暴露的纹理化内表面)。膜可形成具有沿长度具有脊和/或环(径向环)和/或线和/或具有锯齿形图案的管。纹理化内表面可以包括大丝和小丝的混合物,和/或可以由更多孔的较密度的织物形成。

[0154] 在一些变型中,抓取器元件的可视性是期望的,但并非始终需要。例如,如上所述,标记可以位于设备上。在一些变型中,可能期望看到结构的整个结构或近侧端部和远侧端部。例如,材料可以是镍钛诺或在铂材料(DFT)上拉制的镍钛诺以增强可视性。

[0155] 变型中的任一个可以包括位于编织结构中的任一个的内侧的旋转螺旋钻元件以协助将凝块拉回到鞘。如上所述,这些装置中的任一个都可以包括真空源。向系统添加真空可能有助于远侧牵引器区域将凝块/栓塞拉入导管中的能力。所施加的真空可以是稳定的/恒定的、倾斜的或脉动的。

[0156] 在一些变型中,使用它们的装置和方法可以包括阻流近侧球囊(例如,定位在凝

块附近),其可以在手术期间减少凝块上的压力。

[0157] 本文所描述的装置和方法可以用于捕获活检样品(例如,来自乳房或任何其他器官)。例如,当执行腹腔镜手术时,可以使用这些装置去除较大的组织段(例如,癌症、胆囊等)。

[0158] 当形成远侧牵引器区域的材料是机织/编织材料时,所得到的网状结构可具有范围从1cm到100cm长以围绕导管的外径(OD)的编织物长度,优选地长度为在约3cm至30cm之间。

[0159] 在这些变型中的任一种中,牵引器管和/或导管(包括远侧牵引器区域)可以被构造使得可以拉动远侧牵引器区域,使得远侧牵引器区域以最小的力在导管远侧端部的 外径周围被拉入(翻转),使得导管尖端不会在血管中弯曲或显著变形(例如,蛇形扭动),其中,拉力小于约:50克、100克、300克、500克、800克、1000克、2千克、3千克、5千克、8千克、10千克、15千克、20千克等。

[0160] 在其中抓取器(远侧牵引器区域)至少在远侧端部(例如,可扩张的和/或柔性第一端部区域)上构造为机织(例如编织)结构的变型中,形成机织结构的细丝的示例可以包括:镍钛、镍钛-PT DFT线材(Pt内部的镍钛管)、PET、PP、尼龙、Algiloy、SS、混合材料。当使用时,镍钛可能被蚀刻以使其非常平滑。细丝端部的数量可以是约:16、24、36、48、77、96、144或这些整数之间的任何数量。任何编织结构都可以使用。例如,示例性编织结构可以包括1×1(1×1)、1×2、2×2等。在一些变型中,形成机织和/或针织材料的细丝包括单丝,例如所具有的外径(O.D.)尺寸约为:0.0005”、0.00075”、0.001”、0.0015”、0.002”、0.003”或在本文列出的整数之间的尺寸或直径尺寸的组合。如上所述,这些装置可以适用于使用的神经脉管系统,例如假设2mm至3mm脉管内径(ID)。例如,如本文所描述的适于神经脉管应用的装置可以包括韧炼至3mm至7mm OD的0.001”至0.002”聚合物编织物的36个至72个端部。在一些变型中,远侧牵引器区域包括24个编织线材,其具有以45度角度编织的在2mm心轴上韧炼的0.0005”至0.0015”或0.002”的扁平镍钛线材。可替代地,在一个变型中,远侧牵引器区域包括编织材料,该编织材料由以45度角度编织的在2mm心轴上韧炼的0.002”厚度的镍钛线材的24个线材形成。在一个示例中,远侧牵引器区域包括编织材料,该编织材料包括以45度角度编织的在2mm心轴上韧炼的0.002”DFT镍钛线材的24个线材。在一个示例中,远侧牵引器区域包括机织材料,该机织材料包括与在2mm心轴上的0.002”镍钛线材的8个附加端部混合的0.003”线材的8个端部。在一个示例中,远侧牵引器区域包括编织材料,该编织材料包括在2mm心轴上韧炼的0.002”铂铱线材的16个端部。在一个示例中,远侧牵引器区域包括编织材料,该编织材料包括具有0.002”直径的外径的PP单丝的24个端部。在一个示例中,远侧牵引器区域包括编织材料,该编织材料包括0.003”PP单丝的12个端部。在一个示例中,远侧牵引器区域包括编织材料,该编织材料包括0.003”PP单丝的16个端部。在一个示例中,远侧牵引器区域包括编织材料,该编织材料包括1x1、90度编织角度、8mm心轴的0.001”PET或PP的72个端部。在一个示例中,远侧牵引器区域包括编织材料,该编织材料包括1x1、75度编织角度、6mm心轴的0.001”PET或PP的36个端部。在一个示例中,远侧牵引器区域包括编织材料,该编织材料包括1x1、90度编织角度、8mm心轴的0.002”PET或PP的48个端部。在一个示例中,远侧牵引器区域包括编织材料,该编织材料包括1x1、70度编织角度、6mm心轴的0.002”PET或PP的48个端部。

[0161] 在其中远侧牵引器区域包括网状物的变型中,管状网状物可由针织或替代结构形成,该针织或替代结构被构造成使得当网状牵引器被轴向拉动并且围绕导管尖端的外侧并进入导管ID中时,径向压缩(管状网状物内径ID的变化)经受直径减小5%至20%。这种5%至20%网状物直径的减小可以有助于在将网状物拉动到导管中时抓取凝块或异物,而不会产生很大的径向压缩力使得在拉动时管状网状物结合在导管尖端上并且不容易围绕导管尖端滚动。相反,当向近侧拉入时,机织的网状物可在导管内收缩20%至60%之间,这可提供其他所去除材料的凝块的大量压缩。

[0162] 在其中该装置被配置用于外围血管(例如,具有4mm至8mm血管ID)的变型中,远侧牵引器区域可以被配置用于该应用。例如,远侧牵引器区域可以包括具有形成在4mm心轴上并被韧炼的0.009"PP单丝的24个端部的编织材料。远侧牵引器区域可以包括具有4mm心轴韧炼的0.008"PP单丝的编织材料。远侧牵引器区域可以包括具有4mm心轴韧炼的0.006"PP单丝的72个端部的编织材料。远侧牵引器区域可以包括具有4mm心轴韧炼的36个端部的编织材料。远侧牵引器区域可以包括具有心轴韧炼的0.004"DFT镍钛的48个端部的编织材料。

[0163] 在其中装置被配置为活检装置(例如,具有4mm至12mm样本大小)的变型中,该装置可以是机织材料,其包括在10mm心轴上形成的PP 0.007"单丝的72个端部。在一些变型中,装置(例如,远侧牵引器区域)可以包括在1mm心轴上形成的0.004"镍钛的48个端部。在一些变型中,装置(例如,远侧牵引器区域)可以包括在12mm心轴上的PP 0.008"单丝的48个端部。

[0164] 在本文所描述的变型中的任一个中,所述装置可以被配置成具有相对低的摩擦。特别地,远侧牵引器区域可以具有低摩擦力以允许在收回凝块时更容易和/或可靠地拉动穿过导管。如上所述,这些变型中的任一个可以包括润滑材料和/或涂层,包括在抓取器(远侧牵引器区域)上使用或涂覆一种或多种以下材料:PET、PP、PTFE、ePTFE。当形成装置的材料是小直径细丝金属结构时,细丝的直径可以在0.0005"至0.003"之间。材料可以是镍钛、不锈钢、MP35n、Ti、铂、铂铱、钴铬合金等。

[0165] 在远侧牵引器区域是网状物(例如,机织和/或针织材料)的变型中,远侧牵引器区域相对于导管直径的直径可以取决于机织/针织结构。例如,当编织时,比率可以在2至1之间或更大;当经编时,比率在1.5至1之间或更大。当形成为激光管时,比例在1.1至1之间或更大。类似地,对于编织管或带结构,导管内部的编织角度应该在导管内侧在编织角度的0度至45度之间,并且在导管外侧在编织角度的约20度至90度之间。在远侧牵引器区域包括针织编织(例如,经编)管的变型中,该装置可以包括每英寸12个至16个端部。对于具有0.0035"ID导管的装置:可以使用20至40D PET复丝的12个至16个端部,或者可以使用0.0007"至0.003" PET或聚丙烯(Polypro)或PTFE单丝的12个至16个端部,或者可以使用0.0007"至0.002"镍钛、不锈钢、MP35n等的12个至16个端部。

[0166] 如上所述,在一些变型中,远侧牵引器区域由ePTFE形成为片(例如,形成为管或带)。这种材料可以是薄壁的(例如厚度在0.0005"至0.003"之间),被认为是有壁厚的(在0.0005"至0.002"之间),并且可以在导管尖端上折叠/起作用。该材料可能包括0.001"至0.004",带有支架状的激光图案。

[0167] 包括不同形状的远侧牵引器区域的装置的设计的其他示例可以是导管ID的功

能。例如,在一些变型中,装置可以选择导管ID、细丝的数量、细丝的直径/长度、弯曲/滚动刚度的刚度、泊松比、抓取器的内表面的摩擦(和/或纹理)等。较小直径的导管比较大直径的导管可能需要更少的网状物细丝或者更小的ePTFE管IDS。例如,在编织远侧牵引器区域的一些变型中,该装置可以包括具有远侧牵引器区域的0.072" ID导管,该远侧牵引器区域具有以90度编织角度编织在6mm心轴上的0.0008"至0.002" 镍钛线材的24个至72个端部。在一些变型中,远侧牵引器区域由以90度编织角度编织在6mm心轴上的0.0008"至0.002PP单丝的24个至72个端部形成。在一些变型中,远侧牵引器区域由针织编织物(假定0.072" 导管)形成,并且可以包括在3mm心轴上韧炼的16个端部或40D PET 复丝自由经编针织物。在一些变型中,远侧牵引器区域由在3mm心轴上韧炼的经编针织的0.002" PP单丝的16个端部形成。在具有由ePTFE管形成的远侧牵引器区域(同样,假设0.072" 导管)的变型中,远侧牵引器区域可以是0.002"厚的3mm的管。可替代地,远侧牵引器区域可以是0.002"厚的3mm的管激光器,其被开槽以收缩和抓取凝块。

[0168] 如所提及的,在一些变型中,该装置被配置成在远侧牵引器区域中包括抓持内网状表面。例如,该装置可以包括具有较大直径编织细丝和/或混合直径细丝的激光开槽ePTFE管。在一些变型中,抓持内网状表面可以用作为经编针织成型管的针织编织物形成。此类结构可以具有自然的宏观结构以允许网状物滚动和抓持凝块,因为细丝不会平行于导管进入导管ID,而是它们相对于导管长轴线是垂直或环状的。对于其中远侧牵引器区域由ePTFE激光开槽材料(材料片)形成的示例,该结构可以包括切割成允许泊松比影响管直径同时产生抓持纹理以抓取凝块的狭缝。

[0169] 通常,通过使用自扩张的和/或较硬的远侧牵引器区域(例如,远侧牵引器区域的自扩张的和/或柔性第一端部区域),可以增强远侧牵引器区域在抓取凝块中的有效性)。当远侧牵引器区域的第一端部区域由编织物形成时,较硬的细丝(例如,由较大直径的细丝、较硬的材料、较大数量的纤维等形成)可导致远侧牵引器的更扩张的第一端部区域,如图18A至图18C所示。在图18A中,较柔软的远侧牵引器区域不会扩张超出导管的OD相当大的距离。图18B示出了远侧牵引器区域的略微更硬/更可扩张的第一端部区域。图18C示出了最可扩张的远侧牵引器区域1801,其可以最佳地扩张至血管1803的内膜。

[0170] 如图18A至图18C所示,可扩张的牵引器区域的唇缘的嘴部可相对于导管OD的长轴线形成切向角度或滚动角度(ϕ)。该角度可以在大约5°至60°的范围内(例如,10°至60°、10°至50°、10°至45°、10°至40°等,并且优选地至少为10度)。本发明人惊奇地发现,在一些变型中,当牵引器区域被收回到导管中时与管具有至少约10度(例如10°至60°、10°至50°、10°至45°、10°至40°)的滚动角度可防止导管尖端上的束缚或堵塞。网状管可以被修改(例如,在远侧尖端或端部区域处),包括通过修改远侧尖端的刚度和/或形状,以确保滚动角度大于10度。可替代地或与保持最小滚动角度的组合,可能期望在导管最远侧尖端处保持管材料ID与导管的OD之间的物理空间或间隙(参见例如图18A至图18C)。间隙可能需要大于0.1mm、0.2mm、0.3mm、0.4mm、0.5mm、0.7mm、0.8mm或1.0mm,以确保当管收回时,管围绕导管的远侧端部滚动。

[0171] 在这些变型中的任一个中,如上所述,远侧牵引器区域可以是润滑的(例如,亲水涂层、硅树脂涂层、薄氨基甲酸酯或其他薄弹性体涂层)。可以包括一个或多个聚合物编织物端部以增强润滑性(例如,聚丙烯、尼龙等)。进一步地,编织角可保持较小(例如,小于70

度、50度、45度 等)以允许更好的拉动。当远侧牵引器区域在导管的尖端周围/上方滚动时,可以测量该角度。增加机织物的端部的数量也可以防止第一端部区域在导管内的锁定,使得编织元件之间的间隙/空间更小并且当远侧牵引器区域在导管的端部上滚动时不太可能阻碍导管尖端。当形成为编织元件时,这些装置中的任一个还可以包括轴向元件,该轴向元件在拉动时不太可能收缩或直径减小,并且因此当在尖端上滚动时不太可能挂在导管开口上。当使用镍钛(例如 $>0.0001''$ 直径)时使用稍大的编织细丝也是有利的;直径越大,编织物可变形以锁定到导管尖端的可能性就越小。如上所述,在一些变型中,远侧牵引器区域可被热定形以在向远侧推进时在导管的远侧端部上自动滚动。

[0172] 图19A和图19B示出了用于形成远侧牵引器区域的翻折回来配置的替代方法。在图19A中,管状远侧牵引器区域1903可以耦接到拉动器/推动器1901,然后如上所述在导管尖端上翻转。在图19B中,管状编织物1905穿过编织物向远侧附接到线材/拉动器1901并被拉动以在导管的远侧端部上使其翻转。

[0173] 通常,远侧牵引器区域的第一端部区域可具有任何适当的形状(参见图15A至图15D)。图20A和图20B示出了可以形成远侧牵引器区域的渐缩机织物的示例。在图20A中,编织物具有锥形侧面轮廓,其可以附接到拉动器(柔性牵引器管的近侧端部)并且翻转。本文所述的编织物中的任何一种可以包括标记线材(例如,DFT、金、铂、铂铱等)以帮助可视化(例如,荧光镜)。在图20B中,网状物比图20A中更突然地渐缩。

[0174] 如上所述,通常,本文所描述的导管中的任一个可适用于这些装置。例如,合适的导管可以是高度柔性的,并具有良好的柱刚度(例如,当向远侧推进时其长度不会缩短)。导管可以具有高角度编织物加强元件。例如,导管可以具有穿过近侧端部至远侧端部的高角度编织物(70度至85度,小线材镍钛、不锈钢、钴铬、MP35N、扁平或圆形线材),以及针对导管的远侧1cm至5cm的较小编织角度。这将允许当施加轴向压缩时和/或在内扩张力(例如血块)下导管的内径扩张。

[0175] 通常,这些导管中的任一个都可以包括改变的刚度/顺应性。例如,近侧三分之一(1/3)可能较硬;中间部分可能不太硬,而远侧20%(1/5)可能是最不硬的。进一步地,导管的远侧尖端可以具有如图1A和图1B中所描述的适当的半径(曲线)。通常,半径应该是平滑且圆形的,而不是方形的。另外,导管的远侧尖端可以由足够硬的材料(约72D或更硬)制成,以允许编织物滚动而不抓取尖端。例如,导管尖端可以具有硬质金属结构以减少摩擦(例如,不锈钢、Pt等)。当拉动远侧牵引器区域时导管尖端压缩/弯曲越少越好。在一些变型中,导管包括附加加强件,诸如编织增强件而不是线圈加强件,以防止导管最后5cm至10cm的编织物屈曲。因此,如本文所描述的,在一些变型中,导管的尖端可由润滑和/或硬质材料制成,以当编织物围绕导管尖端被拉动或被推动时帮助减少编织物与导管尖端的摩擦。润滑材料可以包括诸如PTFE、FEP和/或亲水涂层的粉状聚合物。如尼龙之类的硬质材料或不锈钢之类的金属材料、铂和PT铱合金可用于该尖端,并且向近侧熔合/附接到较柔软材料。如果硬质尖端被放置在导管尖端的远侧端部上,则其长度可能是短的(例如 $<5\text{mm}$ 并且优选地 $<3\text{mm}$),因此它不会不利地影响导管追踪。

[0176] 图21A至图21D示出了用于去除凝块的装置的示例。在该示例中,远侧牵引器区域由拉下到 $0.071''$ 的导管上的10mm(扩张)直径的大约72个端部的细旦尼尔PET网状物形成,如图21A和图21B所示。图21A示出了在耦接到导管之前的可扩张的第一端部区域的示例。

图21B示出了通过拉动柔性(牵引器)管的近侧端部将血管(玻璃管)内的可扩张的第一端区域拉入导管中。图21C示出了装置的远侧端部区域,其包括在导管的远侧端部区域上翻折的可扩张的第一端部区域。图21D示出了将凝块拉入导管中的图21C的装置。

[0177] 另一个示例检查了由具有72个端部和0.001”直径细丝的6mm编织物形成的远侧牵引器区域,该细丝滚动进入0.071”ID导管并且在0.071”ID导管上翻折。成功去除20cm长的“中等硬度”5mm凝块。图22示出了在将其向近侧拉出导管之后具有所捕获的凝块的图21D的可扩张的第一端部区域。

[0178] 图23A至图23D示出了如本文所述的机械取栓装置,其捕获血凝块并将其拉入装置中。图23E示出了在柔性牵引器管已经从导管去除(例如向近侧)之后保持在柔性牵引器管内的凝块。

[0179] 在本文所描述的一些变型中,远侧牵引器区域不是由机织或针织材料形成,而是由纵向布置(例如,平行或近似平行布置)的条或束构成。例如,图24是包括柔性牵引器构件的装置的另一个示例,其中,远侧牵引器区域由多个细丝形成,该多个细丝布置在未机织或编织的材料条(纵向平行)。这些条可以是细丝或管等。

[0180] 图25A至图25F示出了柔性牵引器组件的远侧牵引器区域的另一变型,其中,可扩张的第一端部区域(例如,远侧牵引器区域的远侧端部区域)由多个细丝或条形成,类似于图24中所示的;如图25A至图25D所示,导管的远侧端部包括通道;这些条可以装配在这些通道内,如图25C至图25D所示。图25E和图25F示出了穿过图25C和图25D的截面图。图25A、图25C和图25E示出了侧视图并且图25B、图25D和图25F示出了轴向视图。在该示例中,导管尖端包括细丝/条2503在其中行进的通道2502。形成远侧牵引器区域的条附接到柔性牵引器管2505的更近侧的拉动器区域,如图25E所示。

[0181] 图26A和图26B示出了具有外套筒(例如,外导管或释放保护器导管或其他外套筒/保护器)的图25A至图25F的装置的变型。

[0182] 图27A至图27B示出了穿过图26A至图26B的装置的截面图。

[0183] 图28是包括柔性牵引器组件的远侧牵引器区域的装置,柔性牵引器组件具有多个纵向平行的(非机织/编织)细丝或条,其中,细丝或条的远侧端部通过远侧连接件彼此连接。

[0184] 图29示出了装置中的柔性牵引器组件的远侧牵引器区域,其中,纵向平行的(非机织/编织)细丝或条包括抓取元件。

[0185] 图30A至图30C示出了具有抓取元件的细丝/条的示例。抓取元件(和/或包括它们的细丝)可以用作本文所描述的变型中的任一个的一部分,包括机织或编织的远侧牵引器区域。带有抓取元件的对于细丝/条的其他选择可以包括编织条、网状物/机织条和微线圈。

[0186] 在本文所描述的这些配置中的任一种中,该装置可以适于允许远侧牵引器区域的往复运动,从导管的远侧端部的外侧至内侧并回到外侧而循环。例如,图31示出了其中远侧牵引器区域适于往复运动(例如,推动和拉动)使得可扩张的第一端部区域可被拉入导管中并且从导管翻转出的变型。在该示例中,牵引器管(拉动器)3105附接到远侧牵引器区域3144,该远侧牵引器区域可以附接(并且在一些变型中不附接)到内导管3101上的第二导管3109。中间导管3109可以耦接到拉动器3105,并且两者一起往复运动,使得编织物

在导管3101的内侧来回往复运动。这可以帮助破碎凝块,这可能特别是在与抽吸一起使用时。

[0187] 图32示出了如本文所述的装置的另一示例,其中,远侧牵引器区域的柔性第一端部区域的最远侧端部3205不可释放地固定到导管3201的外侧的远侧端部;可扩张的第一端部区域3209的其余部分具有足够的弹性/柔性以被拉入导管中(用其拉动凝块3255)。然后柔性牵引器组件可以被收回并且整个装置被取回。该示例可能包括可选的真空3260。

[0188] 图33是装置的另一个示例,其中,柔性牵引器组件的拉动器部分3305由与远侧牵引器区域3344相同的材料形成,但可以层压或以其他方式加强以具有比远侧牵引器区域更小的柔性/可拉伸性。

[0189] 图34示出了另一个示例,其中,远侧牵引器区域3444适于当拉入导管3401中时压缩凝块3455。图35A至图35C示出了如图34所示的装置的操作,其中,凝块3455通过将远侧牵引器区域的可扩张的第一端部区域取回到压缩凝块的导管中(例如在牵引器组件的牵引器区域3505上拉动)而被拉入导管中(图35A至图35B);释放牵引器组件和/或向远侧推动牵引器组件可以进一步破碎凝块并且将其从远侧牵引器区域释放,使得它可以向近侧分段(图35C)。

[0190] 图36示出了一种装置和使用方法的示例,其中,向近侧拉柔性牵引器组件可以向远侧推进装置穿过导丝上的主体(例如血管),该导丝可以被处理以接合远侧牵引器区域。在该示例中,该装置可以被配置成拉动具有形成远侧牵引器区域3644的网状物的内牵引器管(导管3605),该远侧牵引器区域附接到其远侧端部并且在导管3601的远侧端部上翻转。拉动柔性牵引器管3605使编织物在导管3601的开口上滚动。形成远侧牵引器区域(例如,远侧牵引器区域的第一端部区域)的网状物/编织物被构造成当拉伸负载施加到该结构上并且锁定/抓取内线材(导丝3677)时在直径上收缩。该内导丝可能具有抓取线材的粘性、粗糙或多变的表面辅助网状物/编织物。当网状物/编织物抓取在导丝上时,牵引器管由于反作用力而将在脉管中被向前驱动。可替代地,用户将能够在拉回牵引管的同时能够容易地将外导管3601向前推进穿过血管。

[0191] 图37A至图37C示出了另一种装置和使用方法,其中,向近侧拉柔性牵引器组件可以向远侧推进该装置。在图37A中,远侧牵引器区域3744附接至中间导管3703(可包括可选的外导管3705),并且远侧牵引器区域3744的相对端部结合至在该导管的内径内的内导管3701的远侧端部。在图37B中,向远侧推进内导管,从而使远侧牵引器区域在侧向和前方扩张。如图37C所示,然后可以向远侧推动外导管和内导管,以使装置向远侧移动。

[0192] 在一些变型中,远侧柔性牵引器区域可以被保持预先加载在导管的外侧,例如以卷或束的形式被保持预先加载在导管的远侧端部区域上,使得其可以被逐渐拉出外存储区域并且在导管的远侧端部上滚动和翻转。一个此类变型的示例示出在图38A和图38B中,该示例性装置可用于从血管内去除材料,如图38B所示,并且可以称为“无限(infinite)”牵引器机构,因为大量(例如,大于50cm、大于60cm、大于70cm、大于80cm、大于90cm、大于100cm、大于150cm、200cm、大于300cm、大于400cm、大于500cm等)的牵引器材料(例如,网状物)可存储在外保持区域中,其被卷起但在扩大使用上不是必要的。

[0193] 在图38A中,该装置可以包括导管(内导管)3811并且远侧牵引器区域3806由在导管的远侧端部附近的壳体区域3813中卷起的网状物3803形成。通过在导管内向近侧拉动

远侧牵引器区域,凝块3805可被拉入导管中。由于大量远侧牵引器区域可能存储在近侧并且向近侧被取回,因此 这种变化对于非常长的手术或者需要去除大量材料的情况可能是有用的。

[0194] 这种变型可以允许使用者展开较长长度的网状物,这对于更刚度的工具(诸如在手术期间的刚度海波管)可能是有利的,例如,在吸脂手术中 去除脂肪、去除脑内出血或更大的外周血管凝块中的凝块。

[0195] 如上所述,在本文所描述的变型中的任一个中,远侧牵引器构件可以是机织(例如针织)或编织的网状材料。网状物可以是针织材料,包括例如纬编针织物、圆形针织物、经编针织物和/或编织针织物。

[0196] 当特征或元件在本文中被称为“在”另一特征或元件“上”时,其可以直接在另一特征或元件上,或者也可以存在中间特征和/或元件。相反,当特征或元件被称为“直接在”另一特征或元件“上”时,不存在中间特征或元件。还将理解,当特征或元件被称为“连接”、“附接”或“耦接”到另一特征或元件时,其可直接连接、附接或耦接到另一特征或元件,或者可能不存在中间特征或元件。相反,当特征或元件被称为“直接连接”、“直接附接”或“直接耦接”到另一特征或元件时,不存在中间特征或元件。虽然相对于一个实施例进行了描述或示出,但是所描述或示出的特征和元件可以应用于其他实施例。本领域的技术人员还将认识到,对“邻近”另一个特征设置的结构或特征的提及可以具有与邻近特征重叠或位于其下面的部分。

[0197] 本文所使用的术语仅用于描述特定实施例的目的,而不意图限制本发明。例如,如本文所使用的,除非上下文另外明确指出,否则单数形式“一”,“一个”和“该”也旨在包括复数形式。将进一步理解,当在本说明书中使用时,术语“包括”和/或“包含”指定所述特征、步骤、操作、元件和/或部件的存在,但不排除一个或多个其他特征、步骤、操作、元件、部件和/或其组合的存在或添加。如本文所使用的,术语“和/或”包括相关所列项目中的一个或多个的任何和所有组合,并且可以缩写为“/”。

[0198] 为便于描述,本文可以使用诸如“在...之下”、“在...下方”、“下”、“在...上”、“上”等的空间相对术语以描述一个元件或特征与另一个元件或特征的关系,如图所示。将理解,空间相对术语旨在包括除了附图中所描绘的方位之外的装置在使用或操作中的不同方位。例如,如果附图中的设备是翻转的,则被描述为在其他元件或特征“之下”或“下方”的元件将被定向为“在”其他元件或特征“上”。因此,示例性术语“在...下面”可以包括上方和下方两种方向。设备可以以其他方式定向(旋转90度或以其他方位)并且相应地解释在本文所使用的空间相对描述符。类似地,除非另外特别指出,否则术语“向上”、“向下”、“竖直”、“水平”等仅用于解释的目的。

[0199] 虽然术语“第一”和“第二”在本文中可以用于描述各种特征/元件(包括步骤),但除非上下文另有指示,否则这些特征/元件不应受这些术语限制。这些术语可以用于区分一个特征/元件与另一个特征/元件。因此,下面论述的第一特征/元件可以被称为第二特征/元件,并且类似地,在不脱离本发明的教导的情况下,下面所论述的第二特征/元件可以被称为第一特征/元件。

[0200] 在整个说明书和所附的权利要求书中,除非上下文另有要求,否则词语“包含”以及诸如“包含了”和“其包含”的变型意味着各种部件可以在方法和物品中共同采用(例如,

包括设备和方法的组合物和装置)。例如,术语“其包含”将被理解为暗示包含任何陈述的元件或步骤,但不排除任何其他元件或步骤。

[0201] 如在本说明书和权利要求书中所使用的,包括在示例中所使用的并且除非另有明确说明,即使术语没有明确出现,所有的数字也可以读作像“约”或“大约”这样的词语开头。当描述幅度和/或位置以指示所描述的值和/或位置在值和/或位置的合理预期范围内时,可以使用短语“约”或“大约”。例如,数值可以具有所述值(或值的范围)的 $\pm 0.1\%$ 的值、所述值(或值的范围)的 $\pm 1\%$ 的值、所述值(或值的范围)的 $\pm 2\%$ 的值、所述值(或值的范围)的 $\pm 5\%$ 的值、所述值(或值的范围)的 $\pm 10\%$ 的值等。本文给出的任何数值也应被理解为包括约或大约该值,除非上下文另有指示。例如,如果公开了值“10”,则“约10”也被公开。本文列举的任何数值范围旨在包括其中所包含的所有子范围。还应理解,当公开值时,“小于或等于”该值、“大于或等于该值”以及值之间的可能范围也被公开,如本领域技术人员所适当理解的。例如,如果公开了值“X”,则还公开了“小于或等于X”以及“大于或等于X”(例如,其中X是数值)。还应该理解,在整个申请中,数据以多种不同的格式提供,并且该数据表示端点和起点以及数据点的任何组合的范围。例如,如果公开了特定的数据点“10”和特定的数据点“15”,则可以理解,大于、大于或等于、小于、小于或等于并且等于10和15被认为是公开的以及在10和15之间。还应该理解,还公开了两个特定单元之间的每个单元。例如,如果公开了10和15,则还公开了11、12、13和14。

[0202] 尽管以上描述了各种说明性实施例,但是在不脱离如权利要求所描述的本发明的范围的情况下可以对各种实施例进行多种改变中的任何一种。例如,其中执行各种所描述的方法步骤的顺序通常可以在替代实施例中改变,并且在其他替代实施例中,可以完全跳过一个或多个方法步骤。各种设备和系统实施例的可选特征可以包括在一些实施例中而不包括在其他实施例中。因此,前面的描述主要是为了示例性的目的而提供的,并且不应该被解释为限制如在权利要求中所阐述的本发明的范围。

[0203] 本文包括的示例和说明通过说明而非限制的方式示出了其中可以实践主题的特定实施例。如上所述,其他实施例可以被利用并从中导出,使得可以在不脱离本公开的范围的情况下进行结构和逻辑替换和改变。本发明主题的此类实施例在本文中可以单独地或共同地由术语“发明”引用,仅仅是为了方便,并且无意将本申请的范围自愿地限制到任何单个发明或发明构思,如果事实上公开了不止一个的话。因此,尽管本文已经说明和描述了具体实施例,但是为了实现相同目的而计算出的任何布置都可以替代所示的具体实施例。本公开旨在覆盖各种实施例的任何和所有修改或变型。上述实施例的组合以及本文中未具体描述的其它实施例对于本领域技术人员在查看以上描述时将是显而易见的。

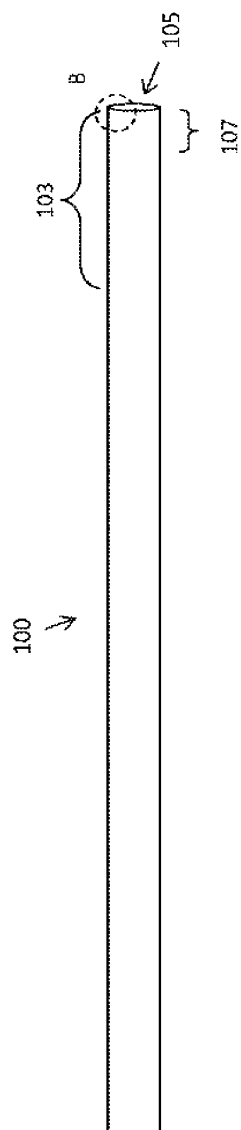


图1A

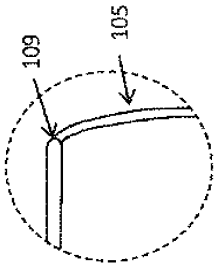


图1B

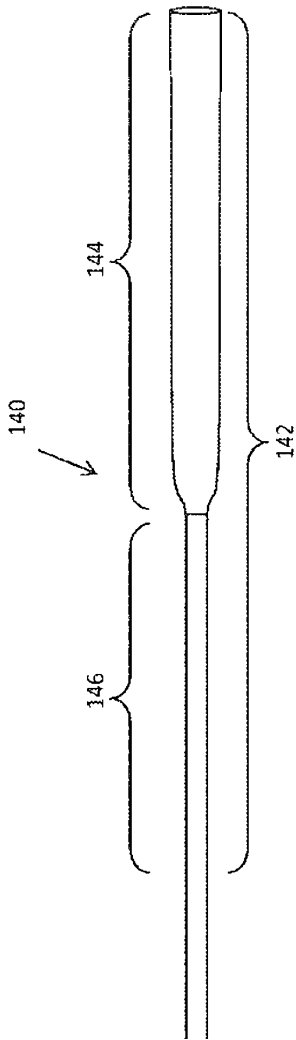


图1C

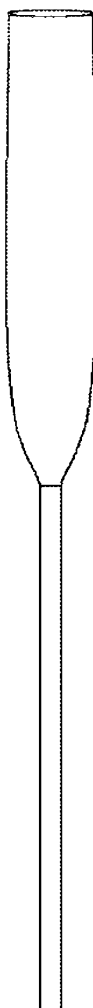


图1D

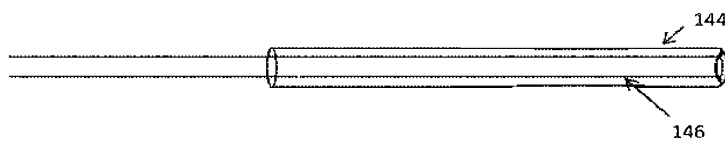


图1E

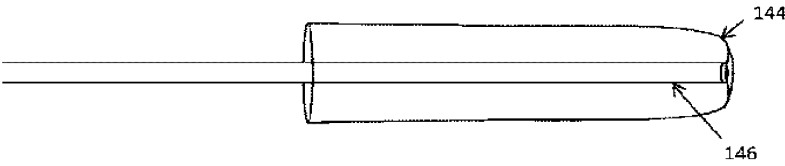


图1F

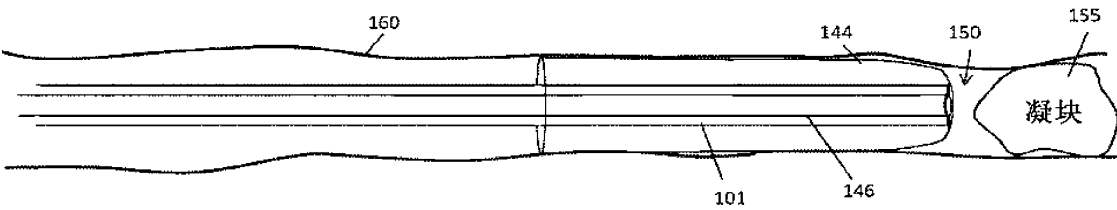


图1G

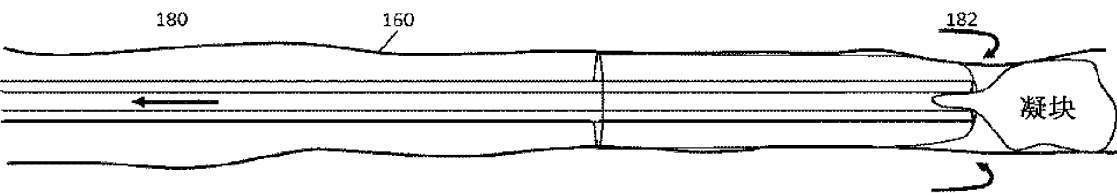


图1H

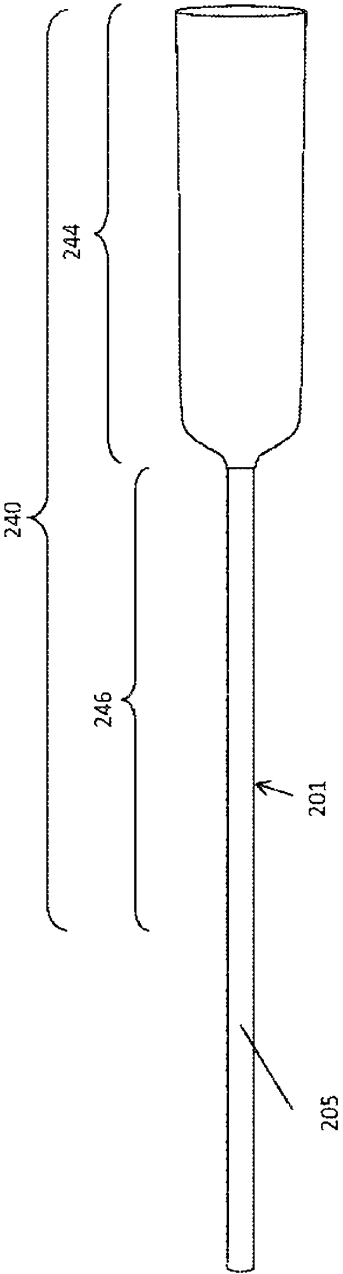


图2A

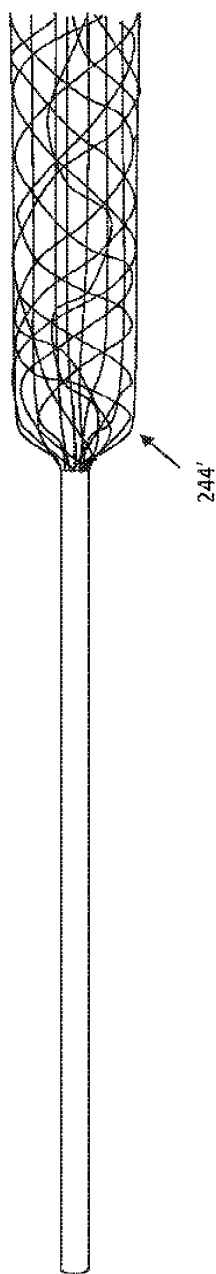


图2B

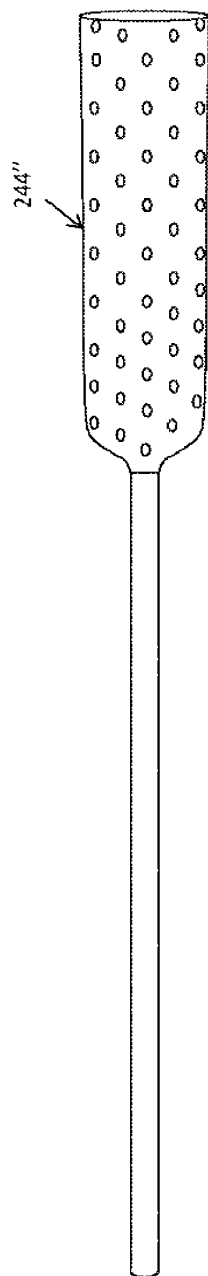


图2C

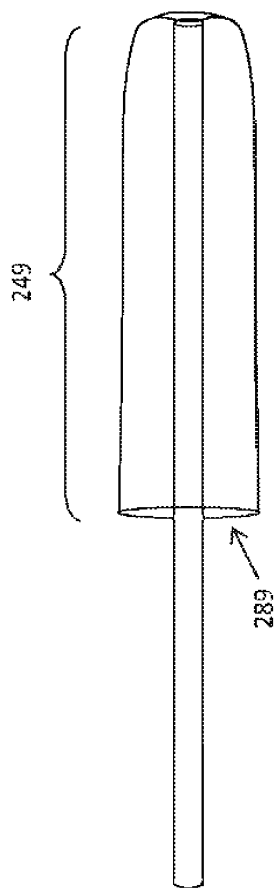


图2D

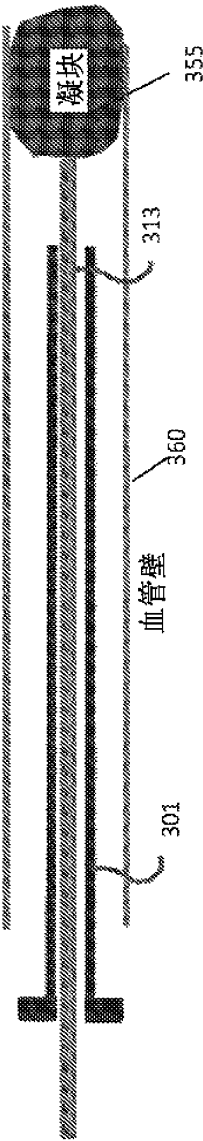


图3A

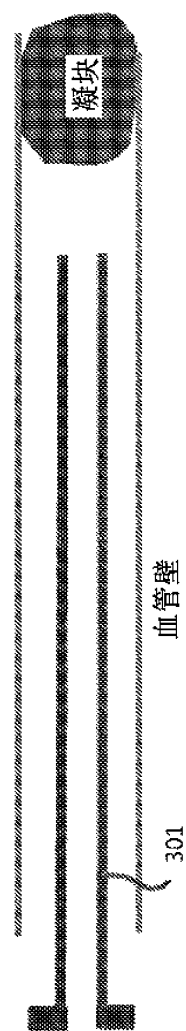


图3B

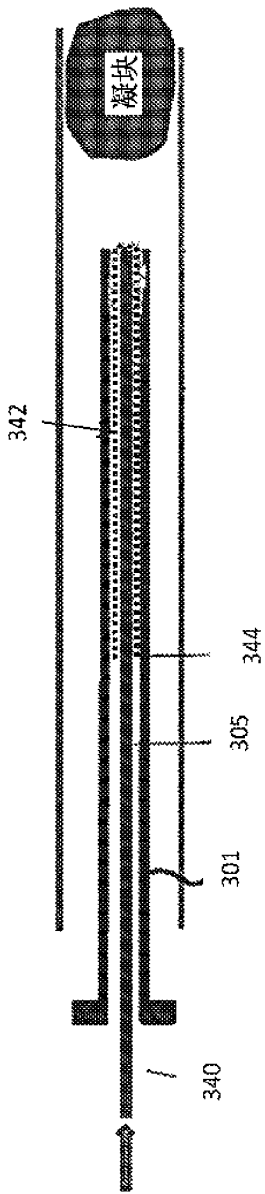


图3C

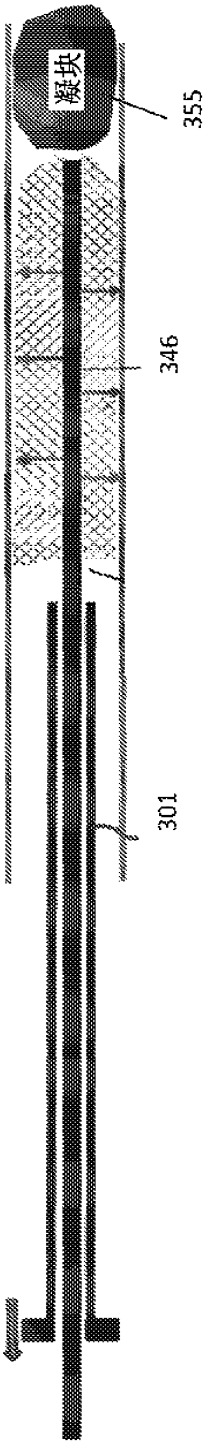


图3D

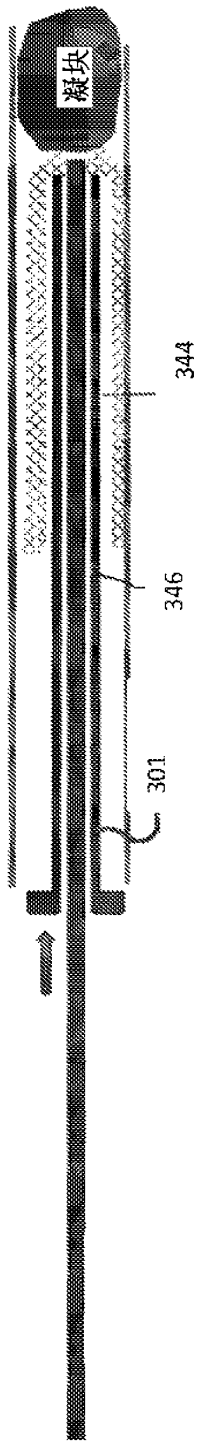


图3E

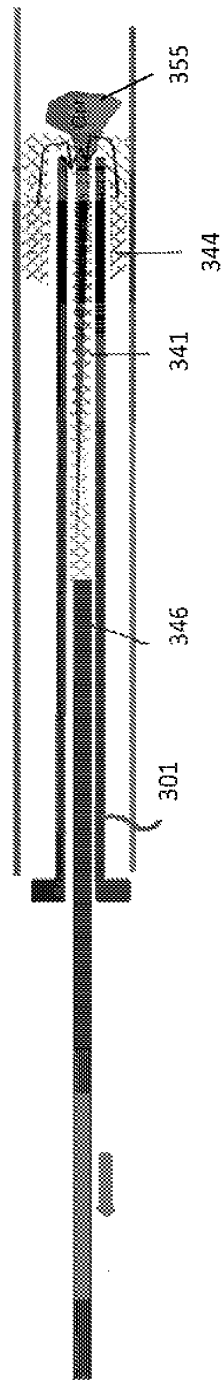


图3F

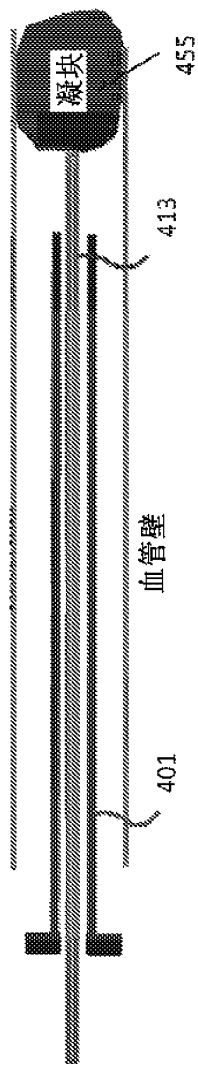


图4A

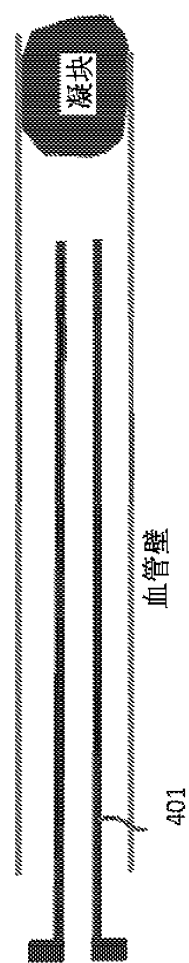


图4B

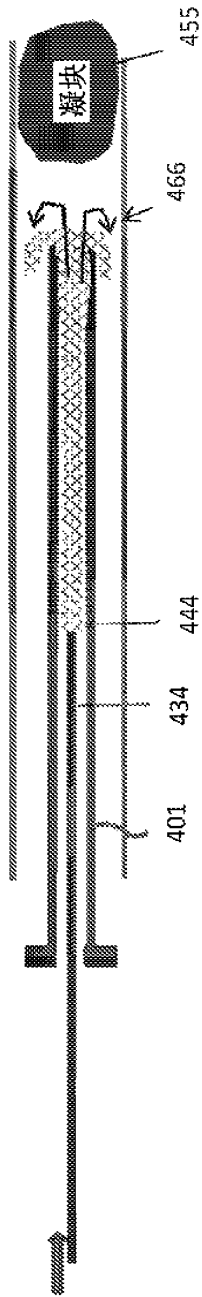


图4C

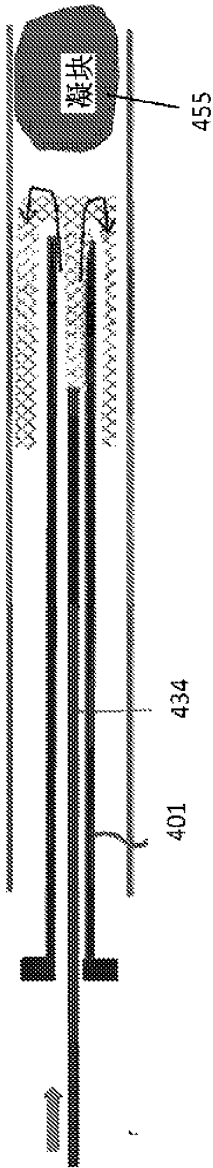


图4D

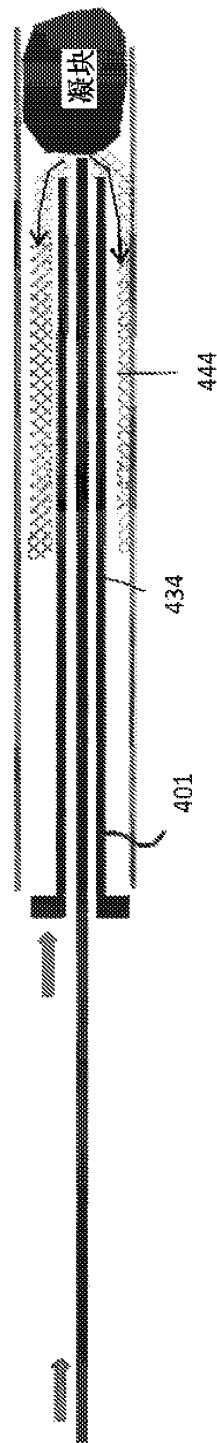


图4E

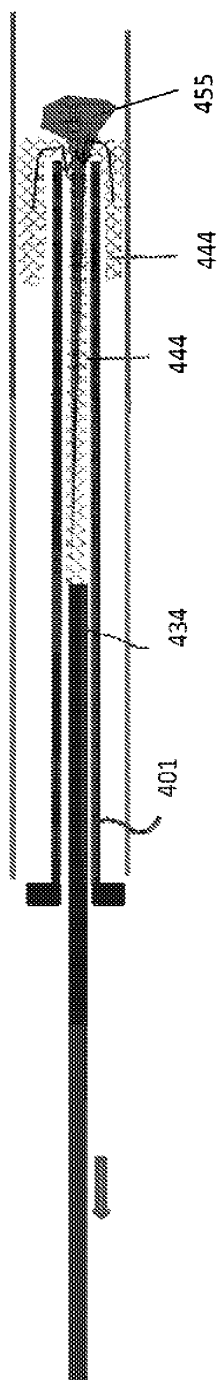


图4F

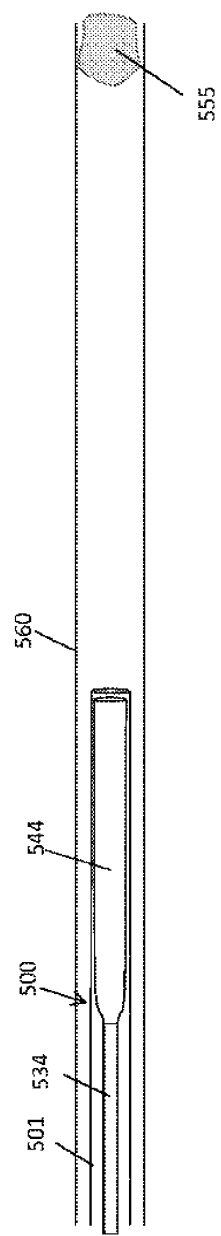


图5A

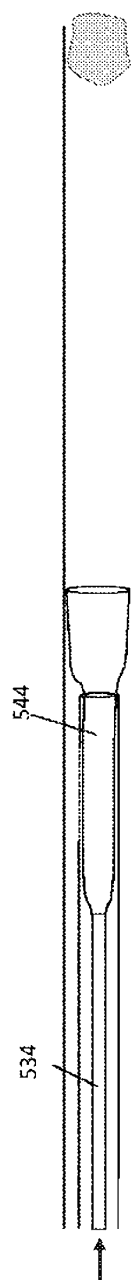


图5B

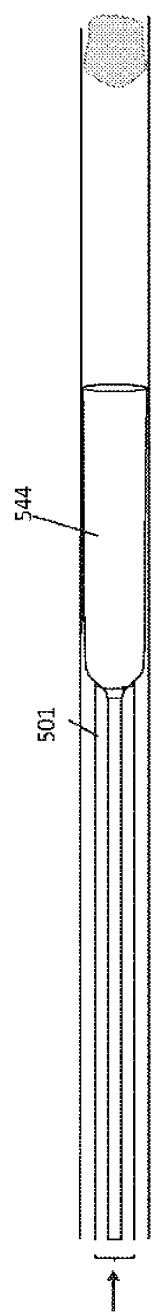


图5C

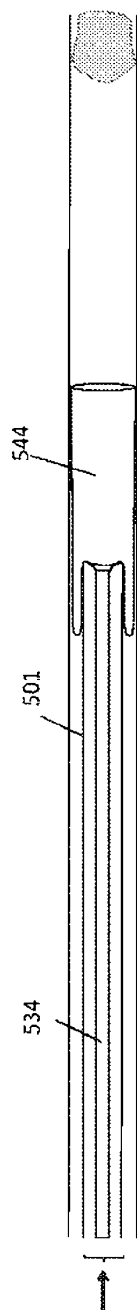


图5D

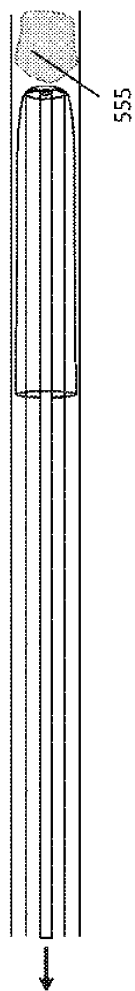


图5E

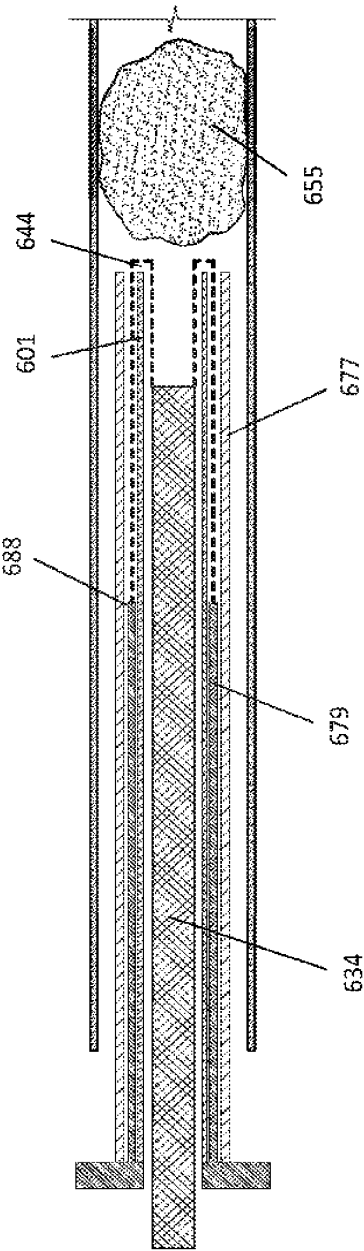


图6A

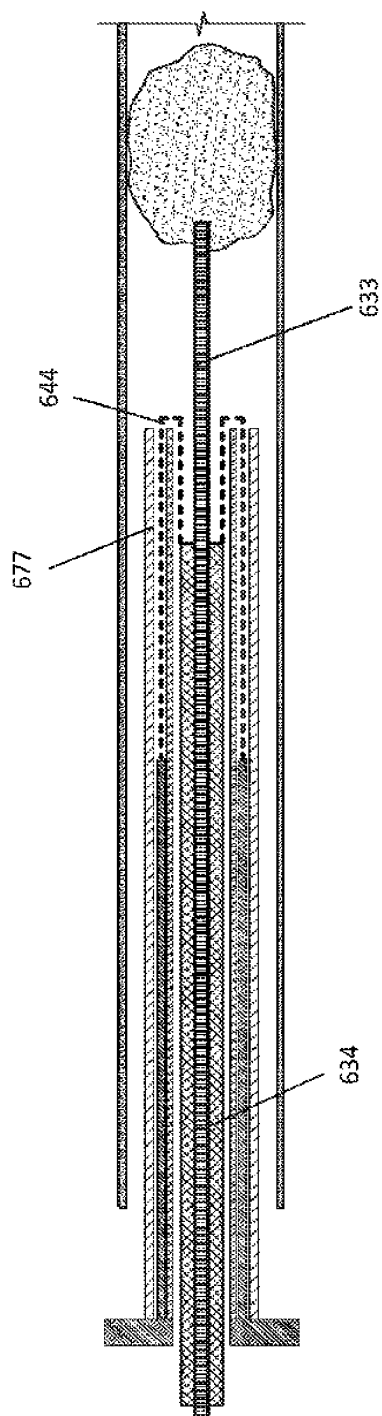
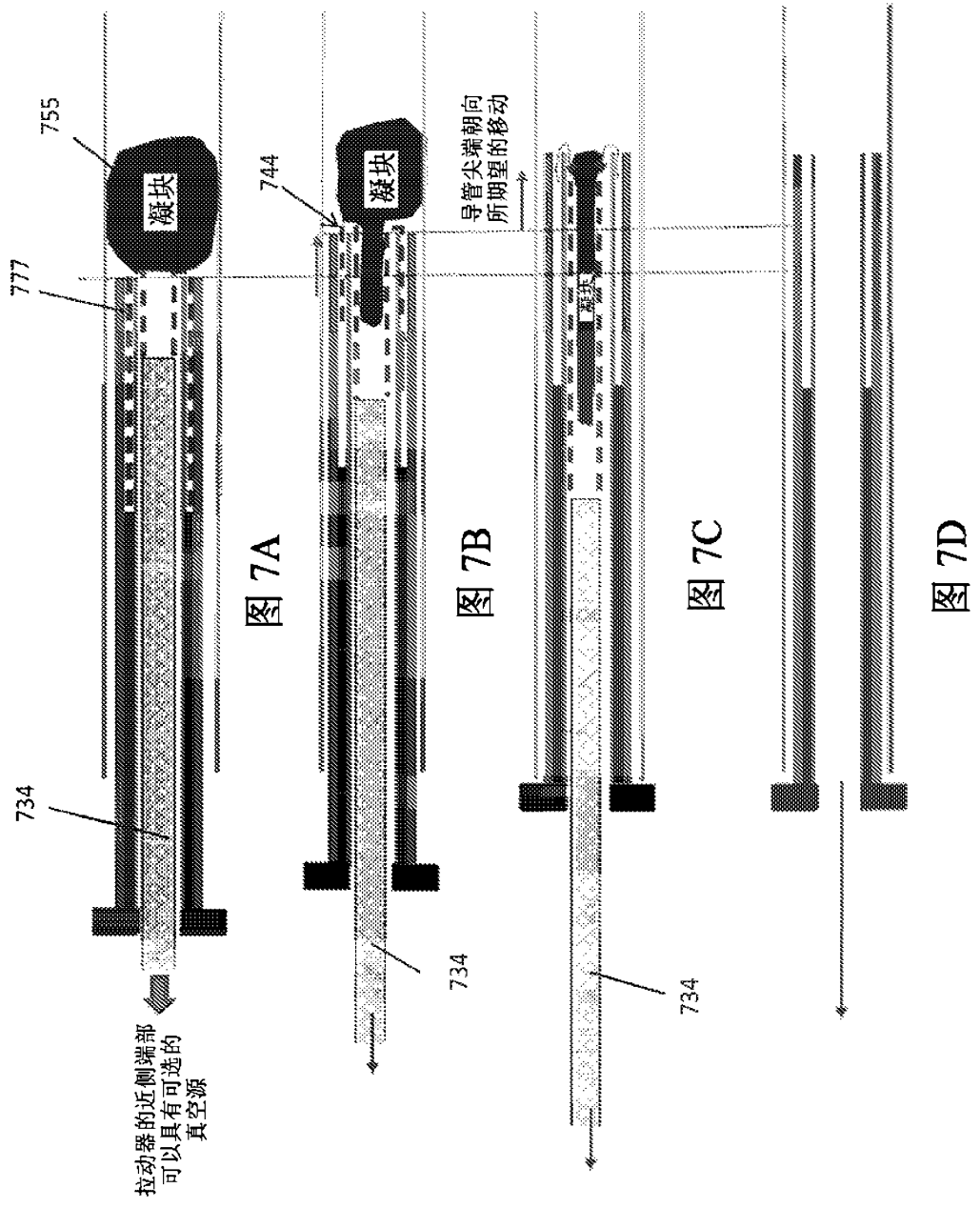


图6B

61



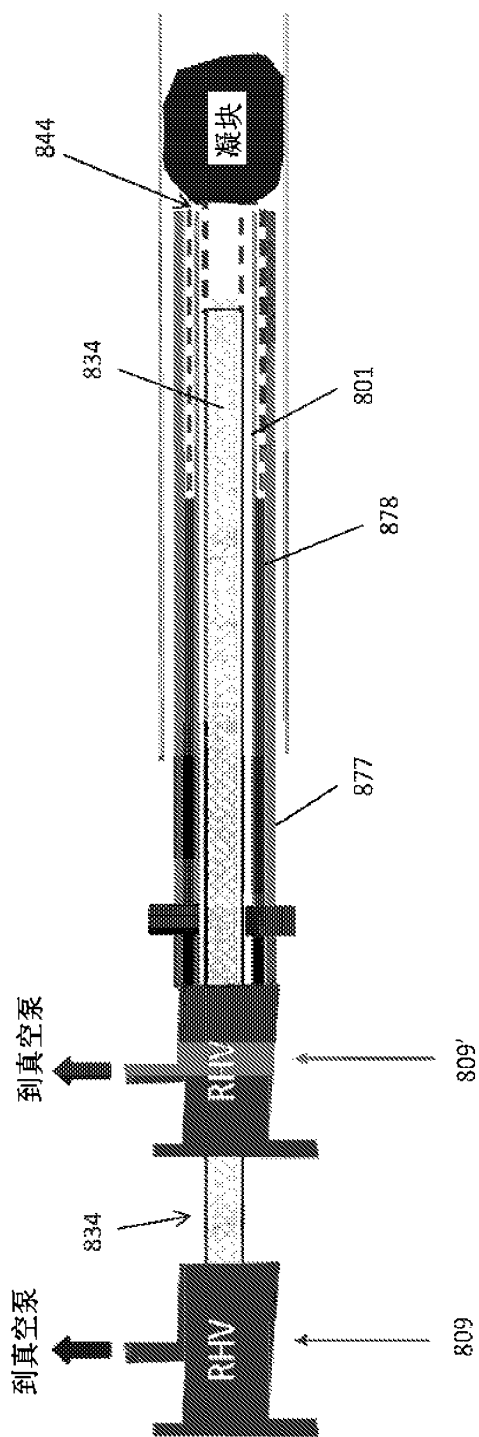


图8

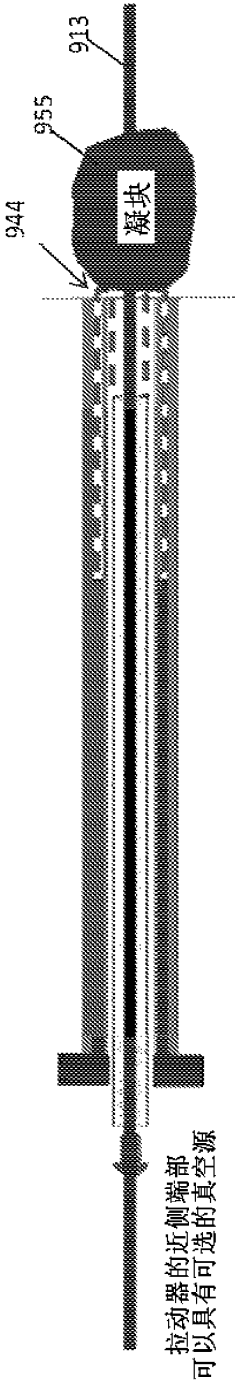
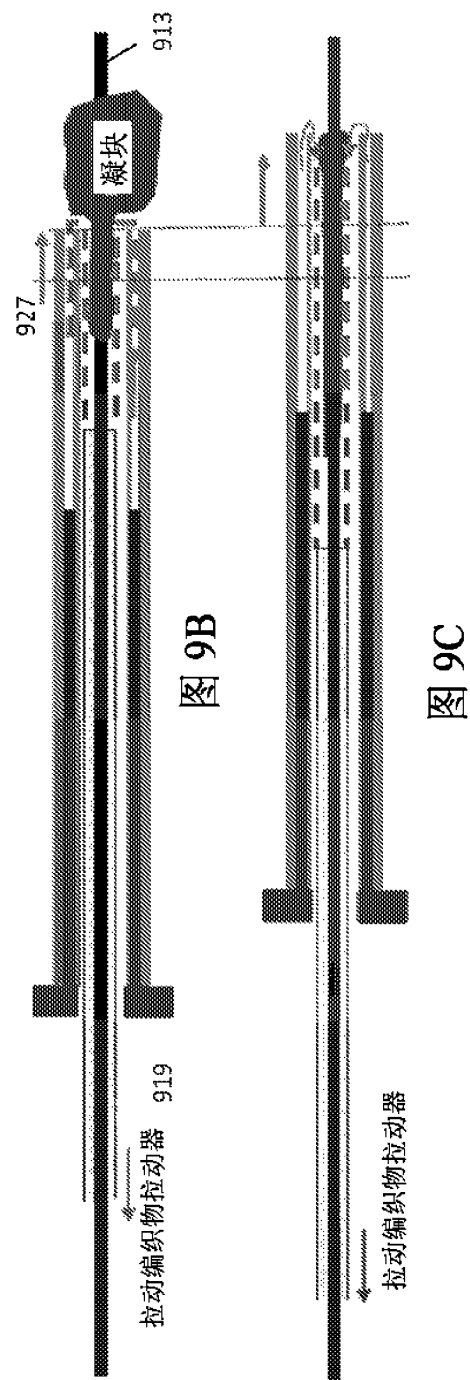


图9A



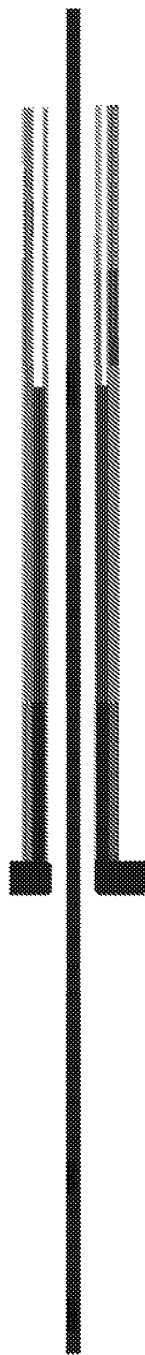


图9D

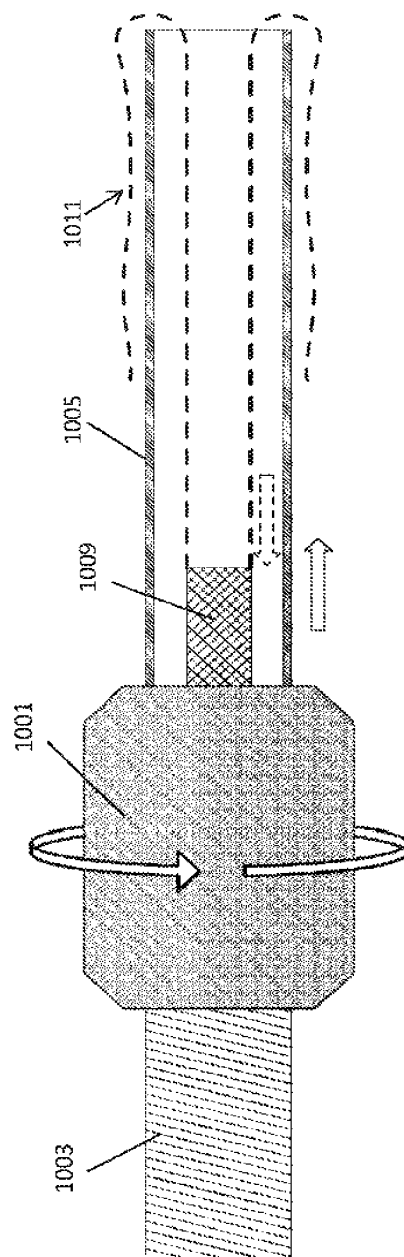


图10A

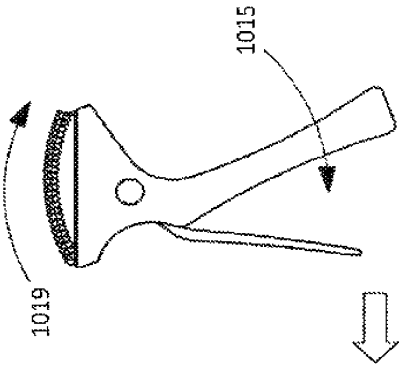


图10B

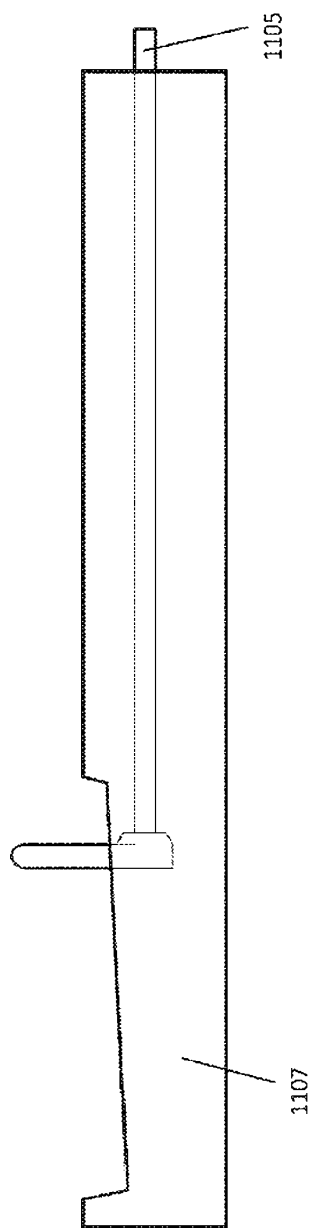


图11A

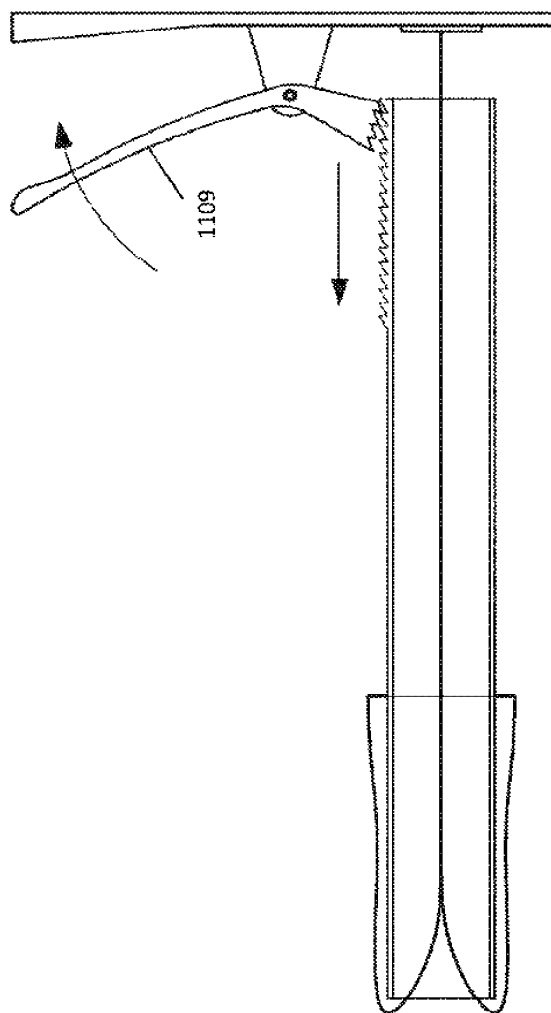


图11B

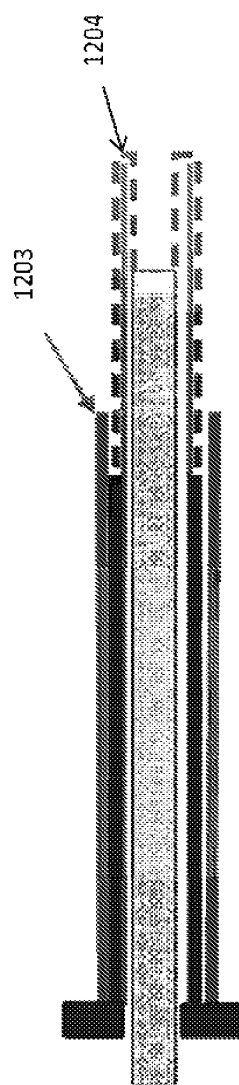


图12A

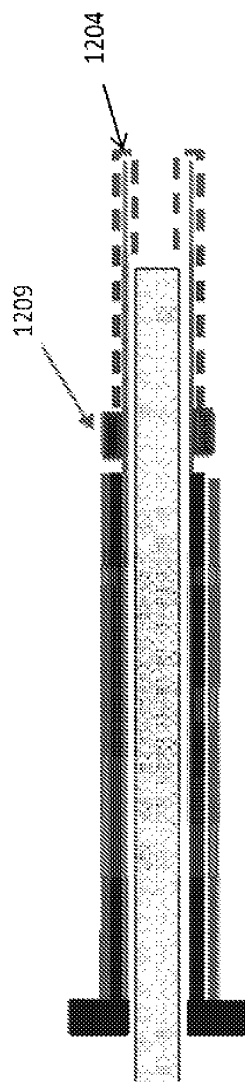


图12B

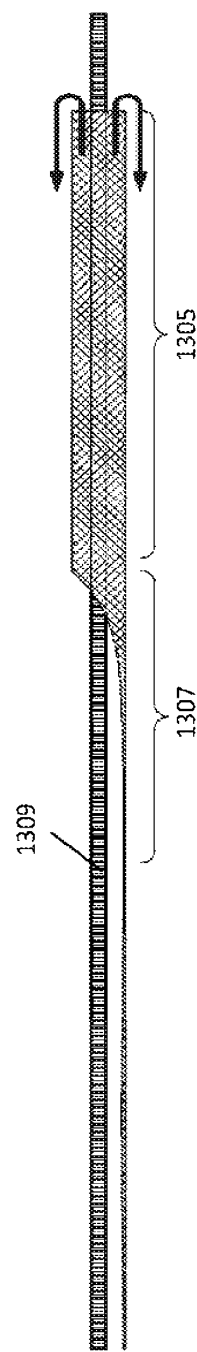


图13A

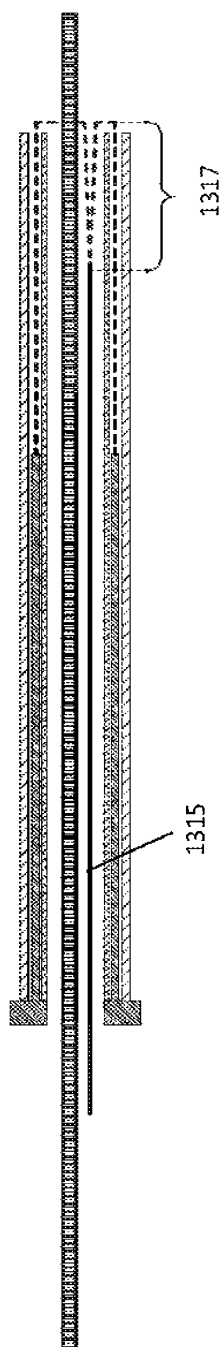


图13B

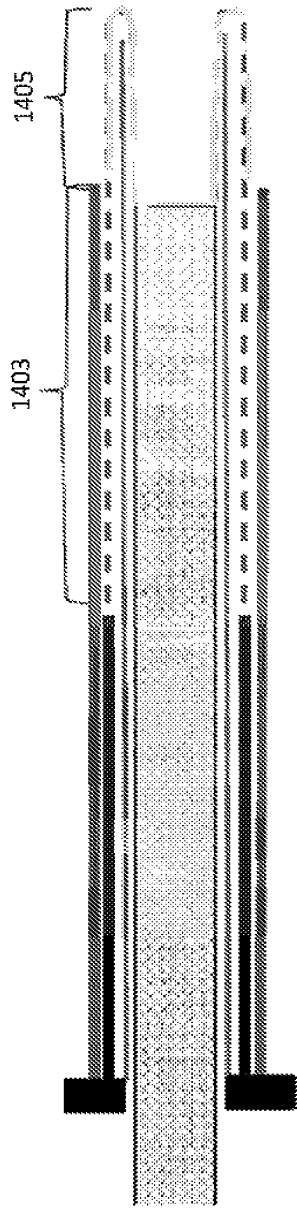


图14

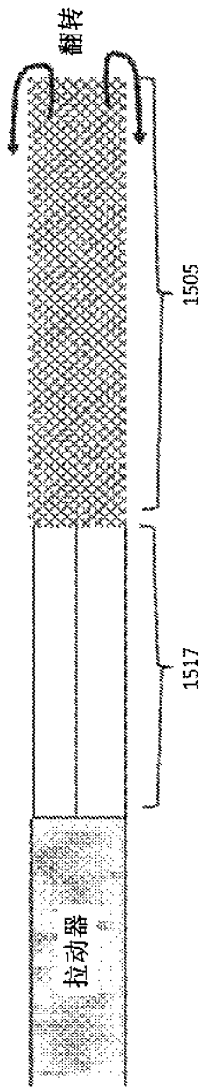


图15A

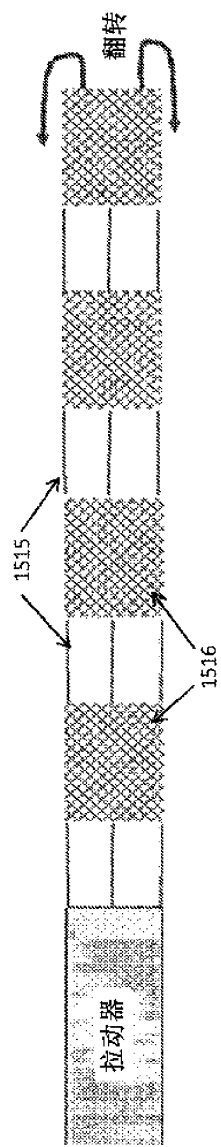


图15B

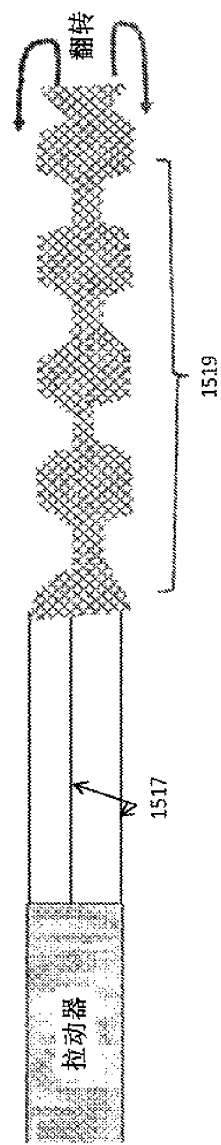


图15C

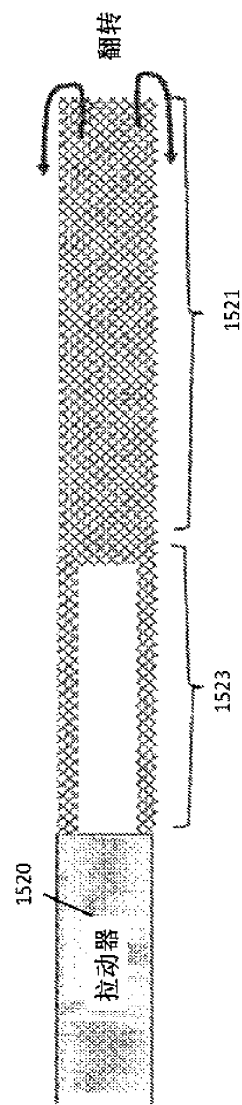


图15D

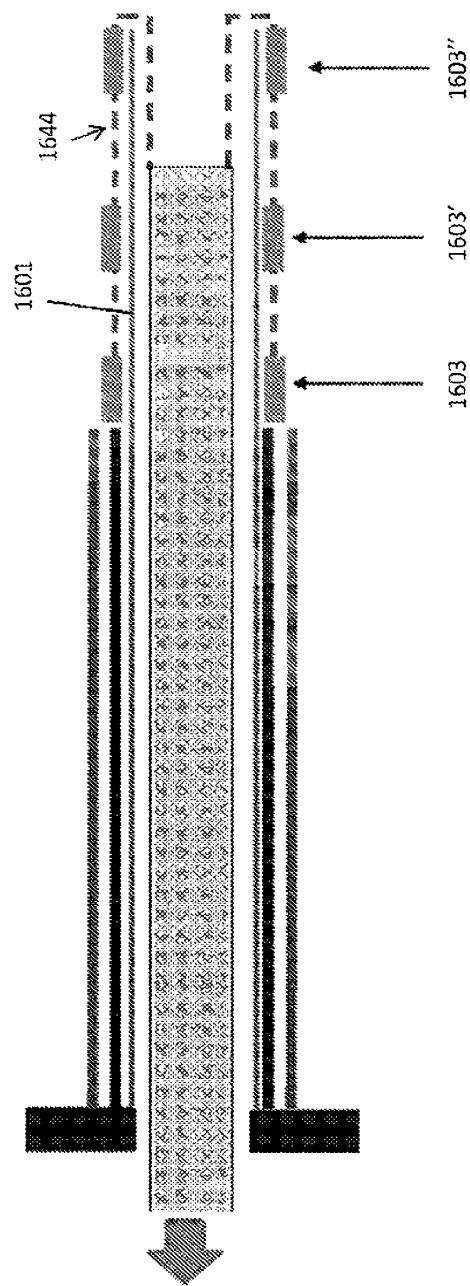


图16

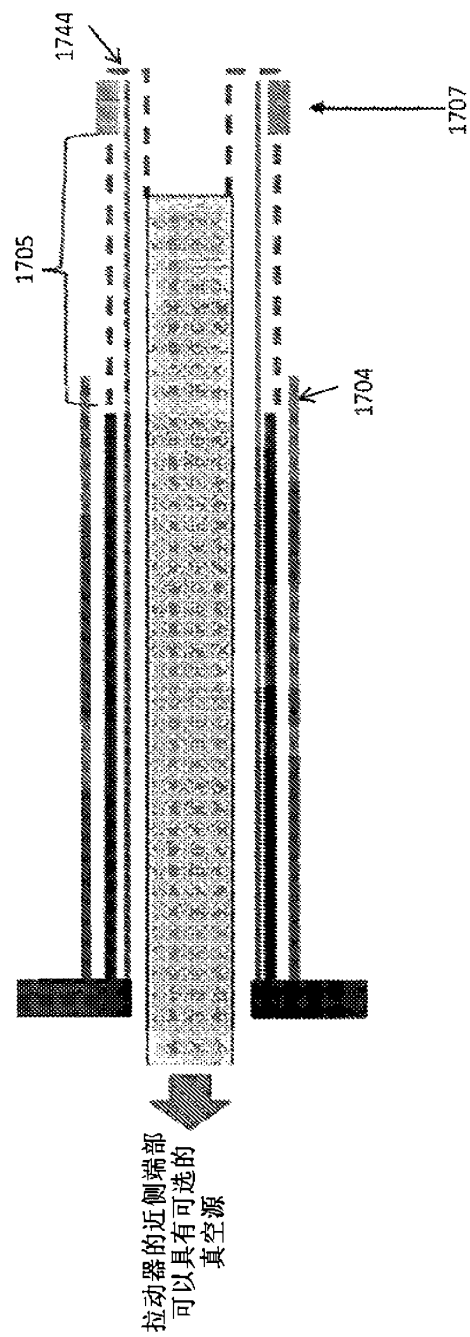


图17

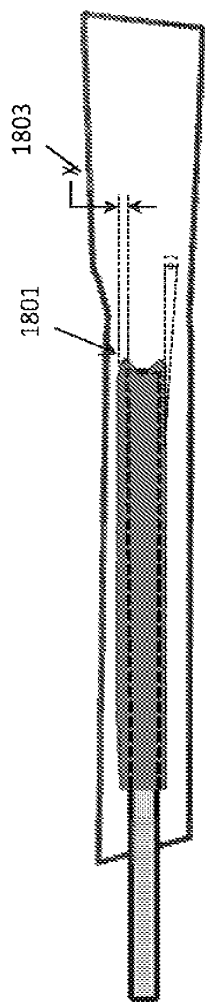


图18A

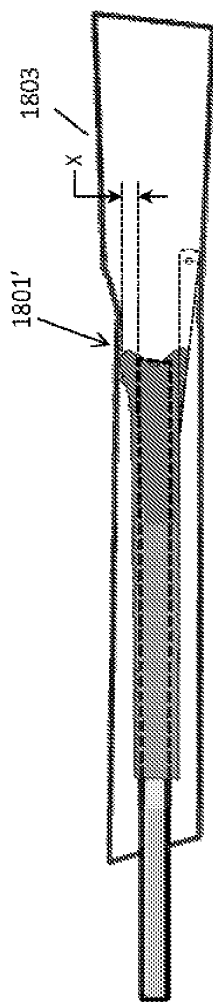


图18B

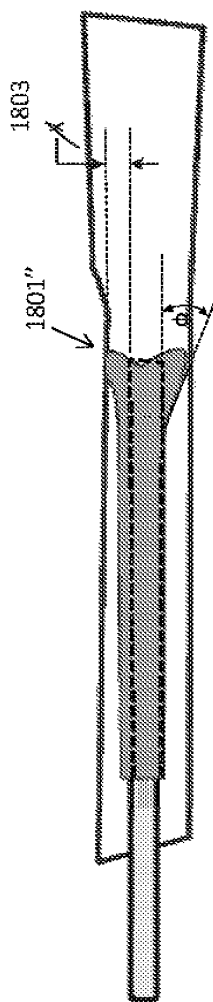


图18C

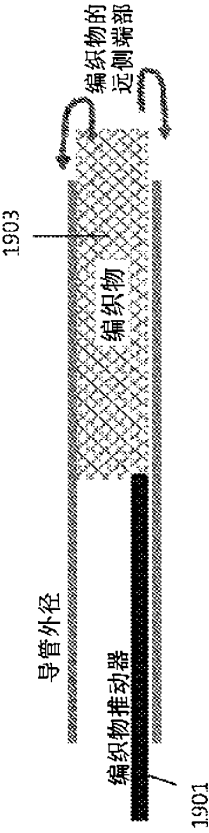


图 19A

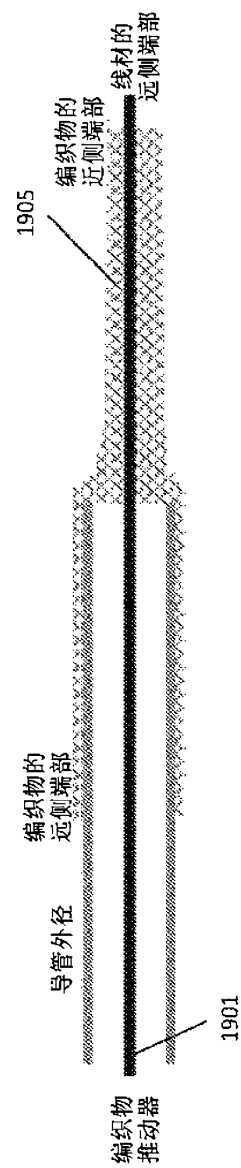


图19B

示例形状 1 (侧轮廓): 将任一方向加载到导管上并翻转



图 20A



图20B

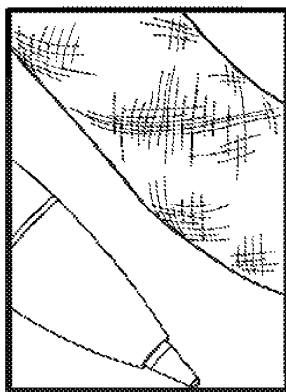


图21A

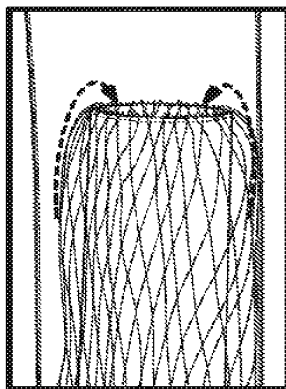


图21B

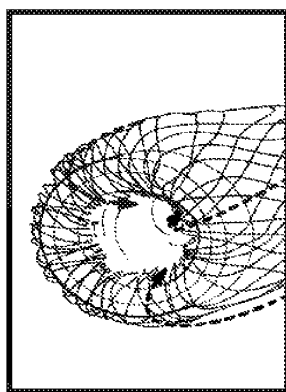


图21C

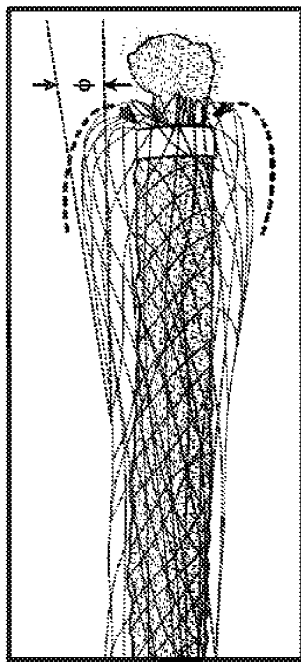


图21D

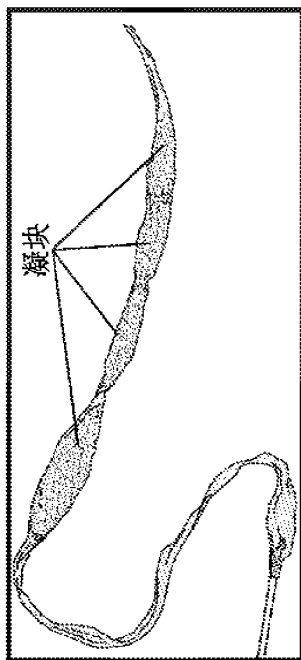


图22

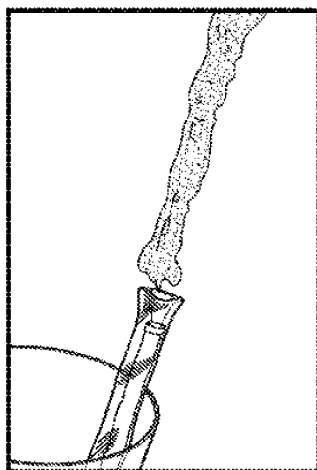


图23A

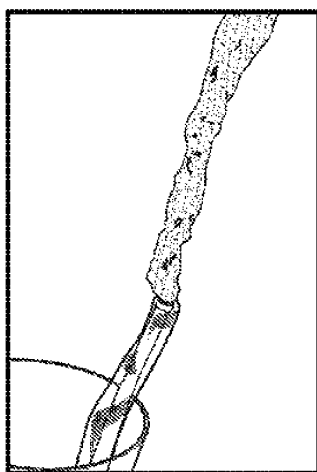


图23B

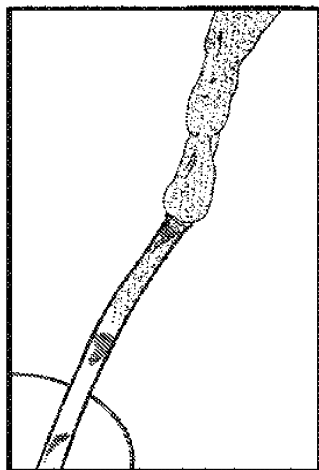


图23C

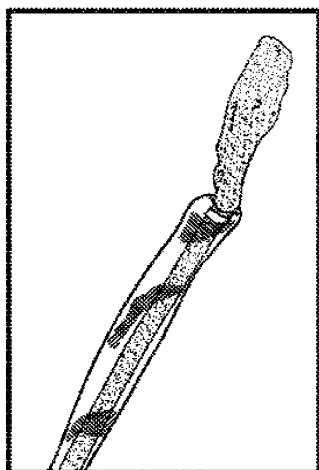


图23D

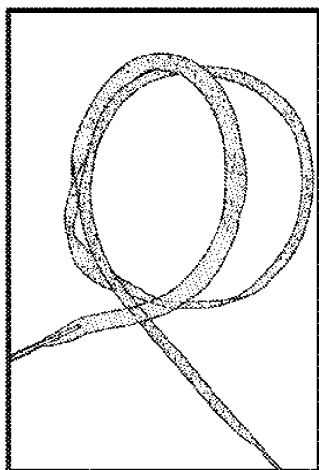


图23E

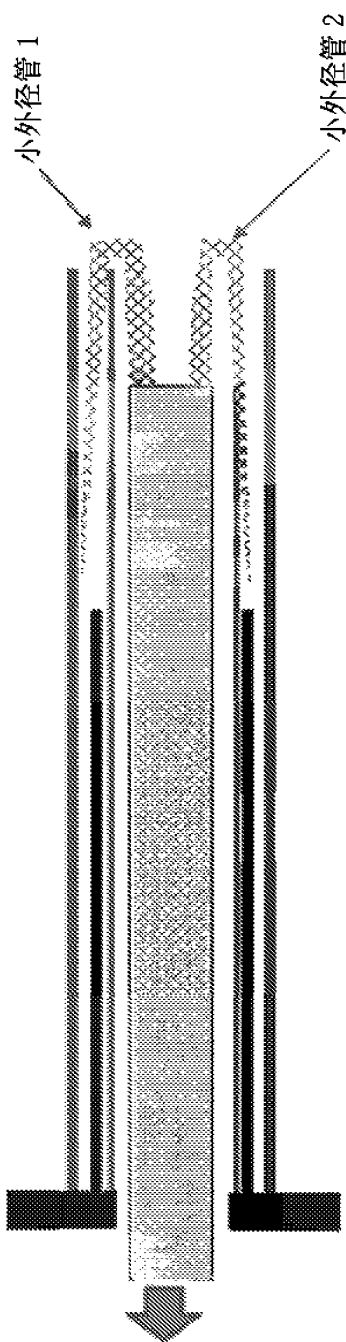


图 24

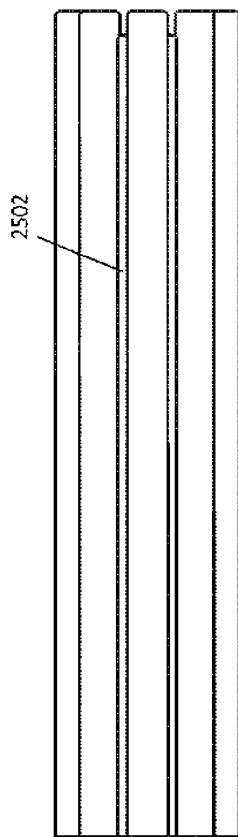


图25A

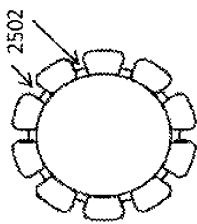


图25B

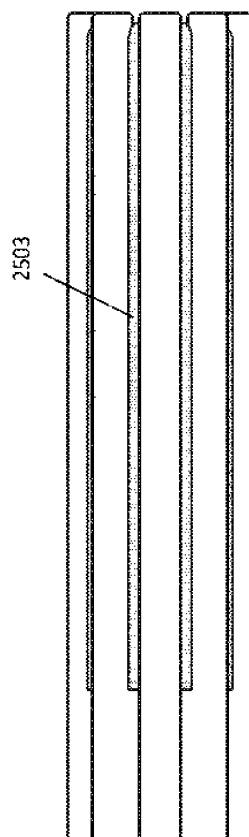


图25C

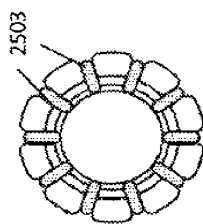


图25D

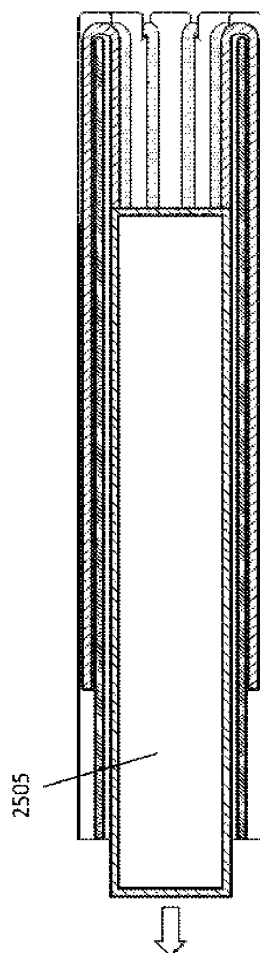


图25E



图25F

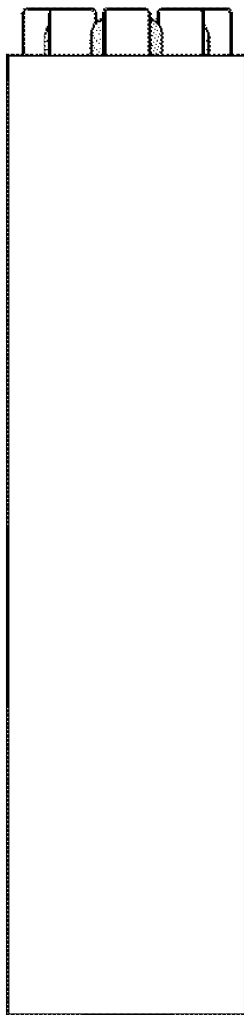


图26A

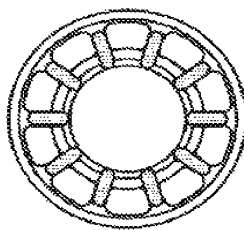


图26B

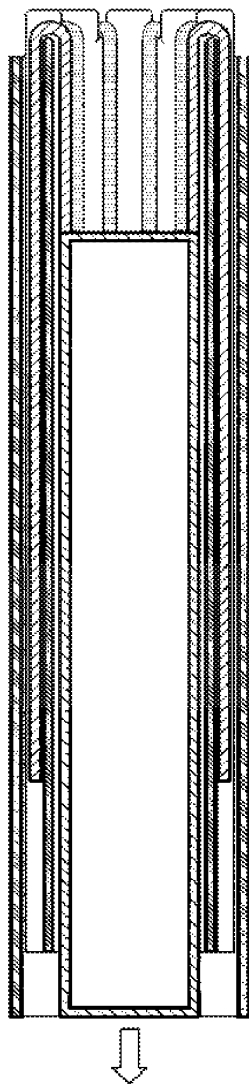


图27A



图27B

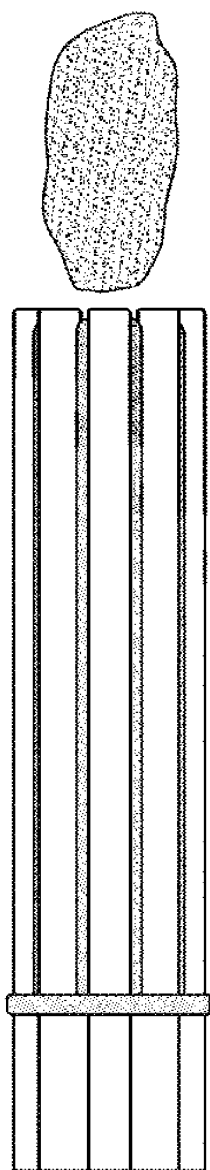


图28

100

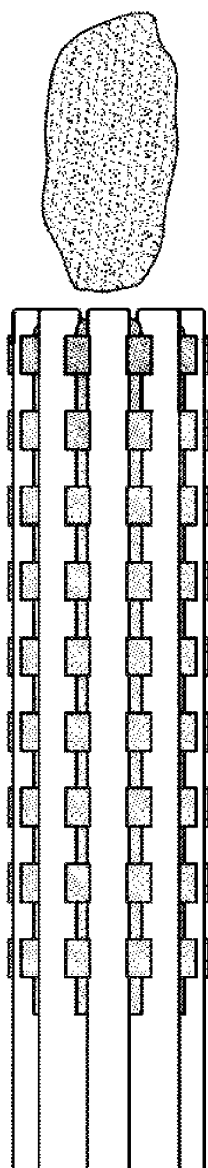


图29



图30A



图30B



图30C

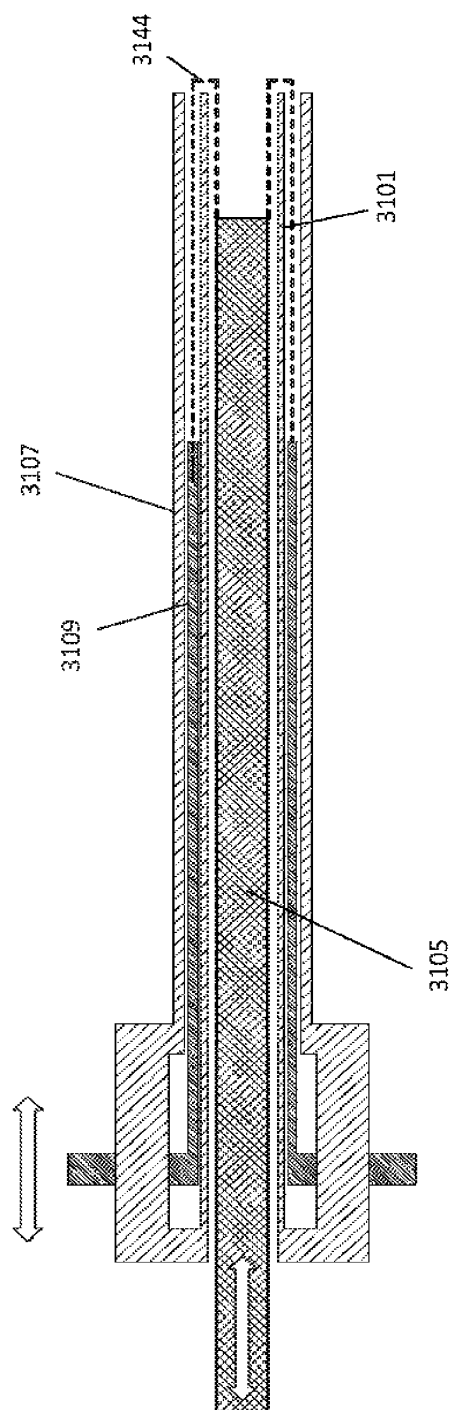


图31

105

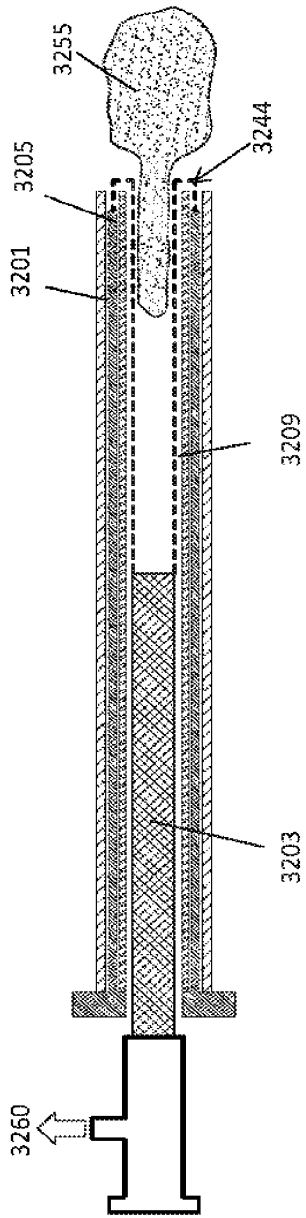


图32

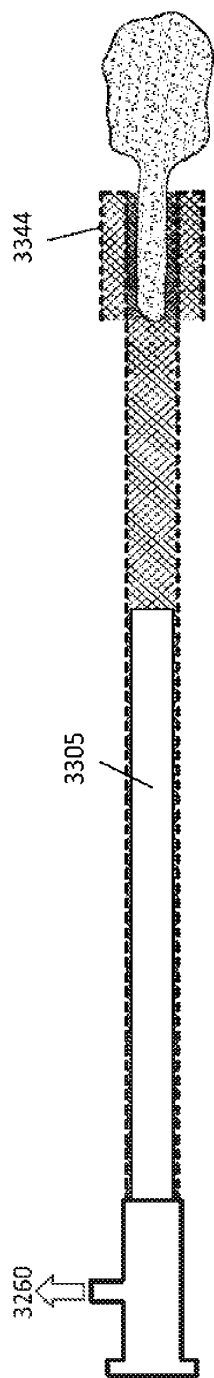


图33

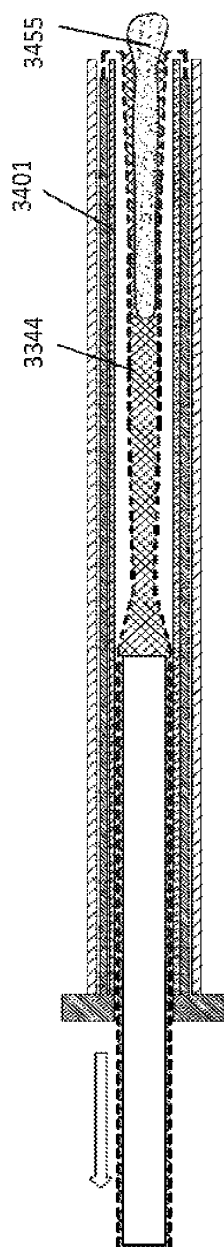


图34

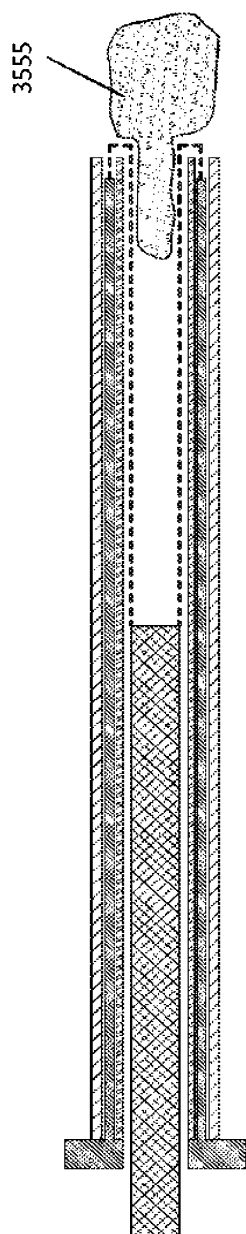


图35A

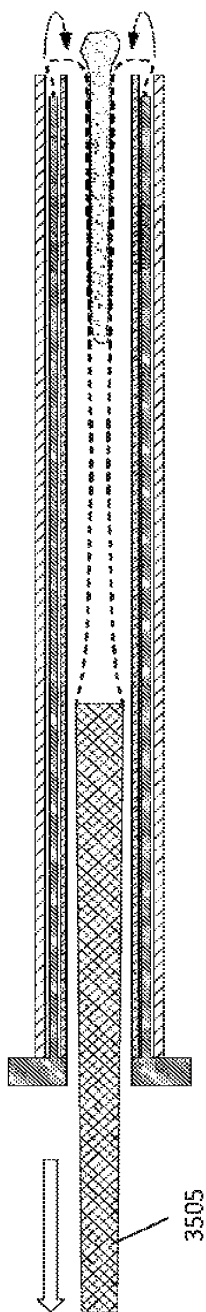


图35B

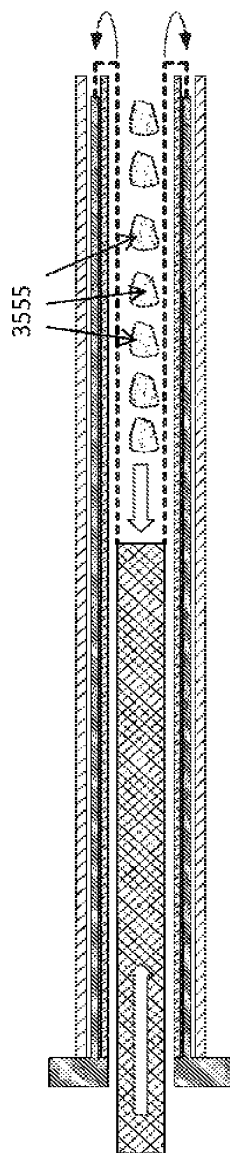


图35C

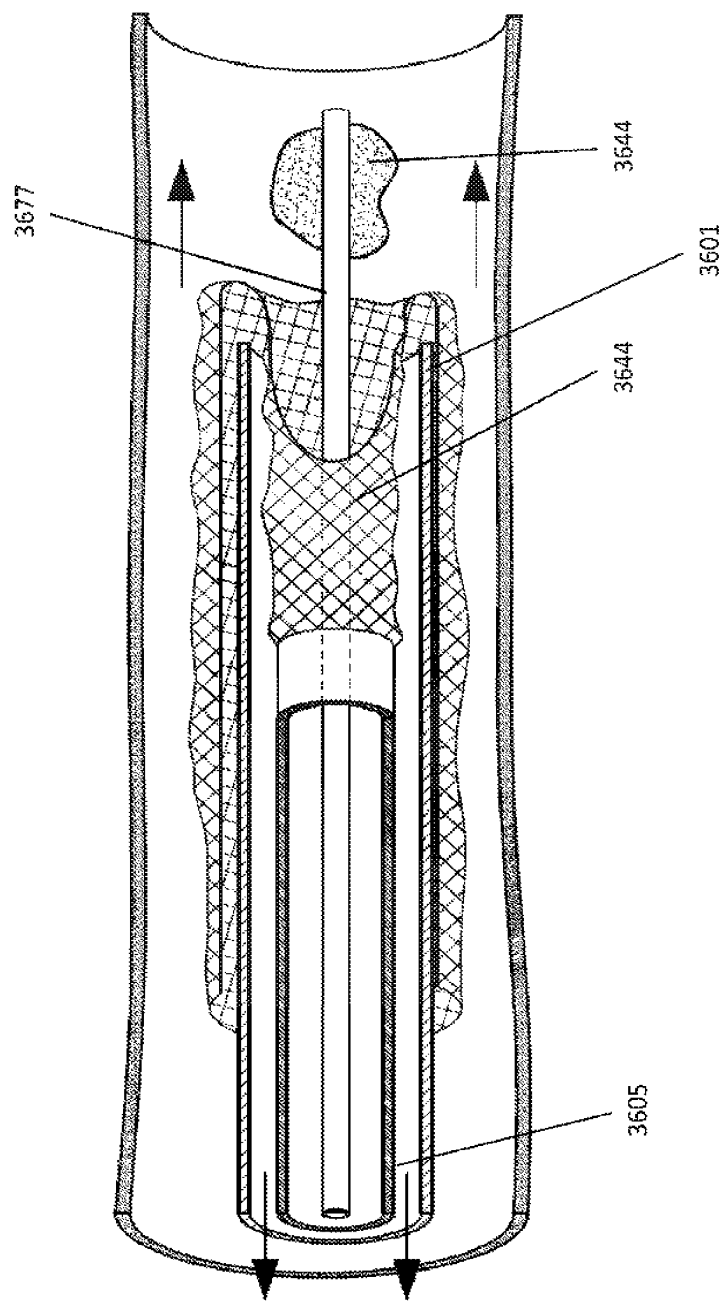


图36

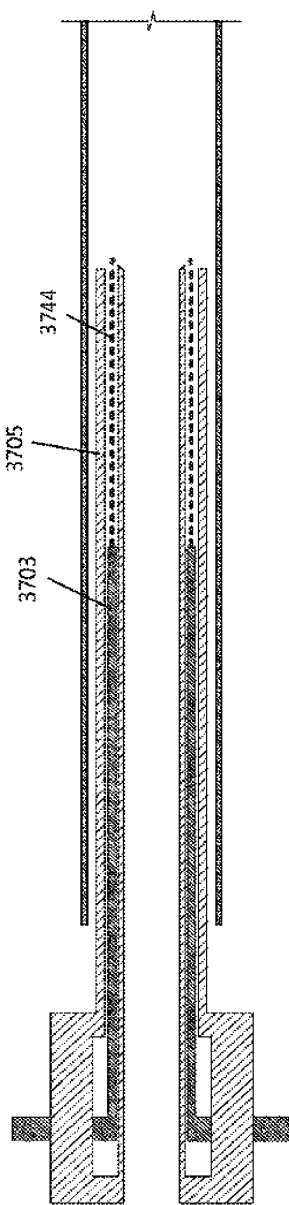


图37A

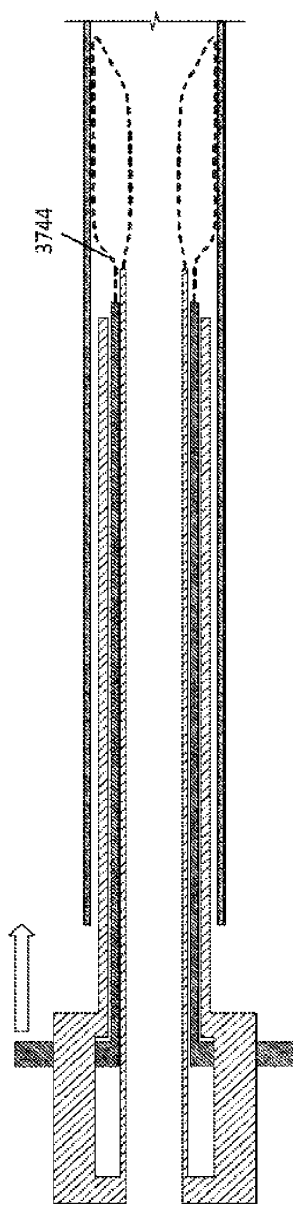


图37B

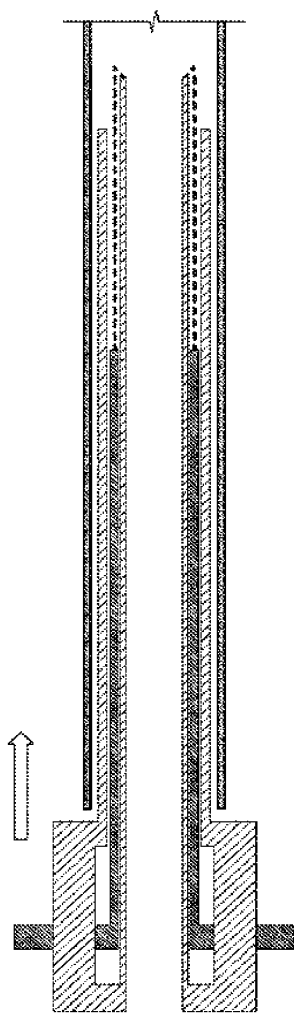


图37C

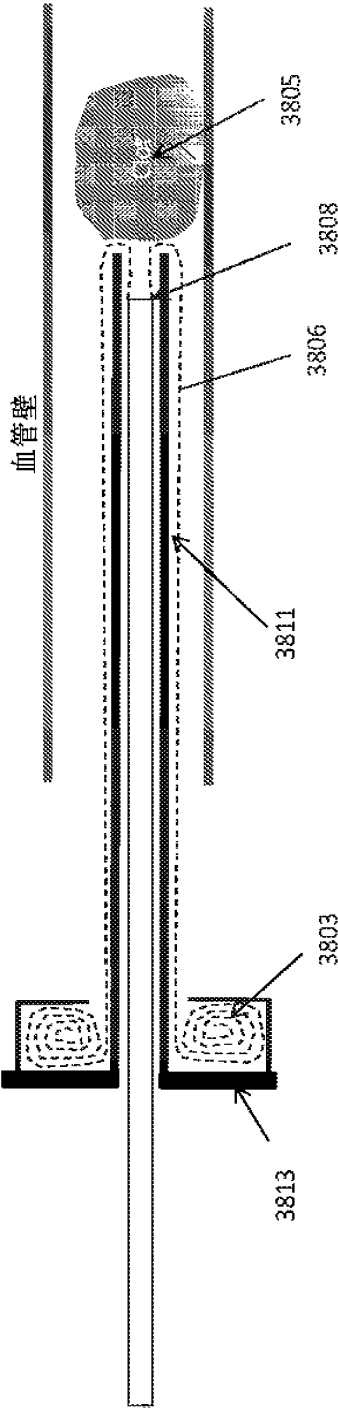


图38A

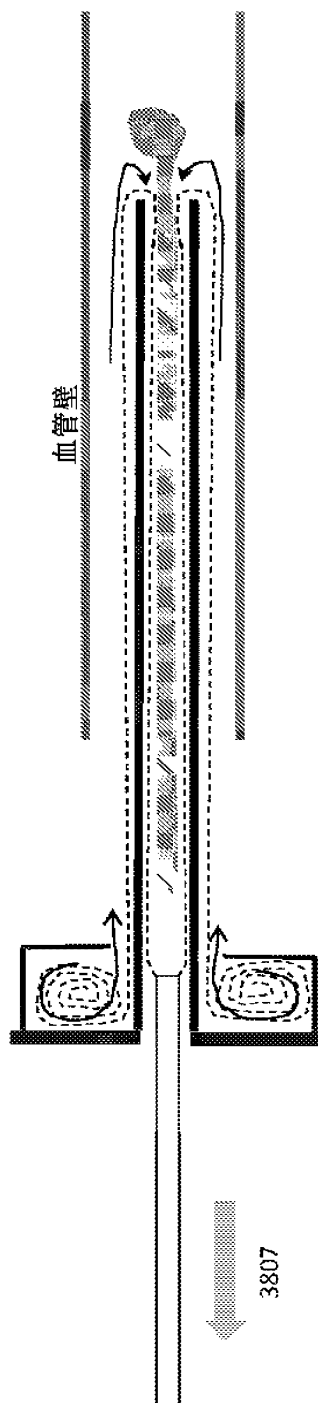


图38B

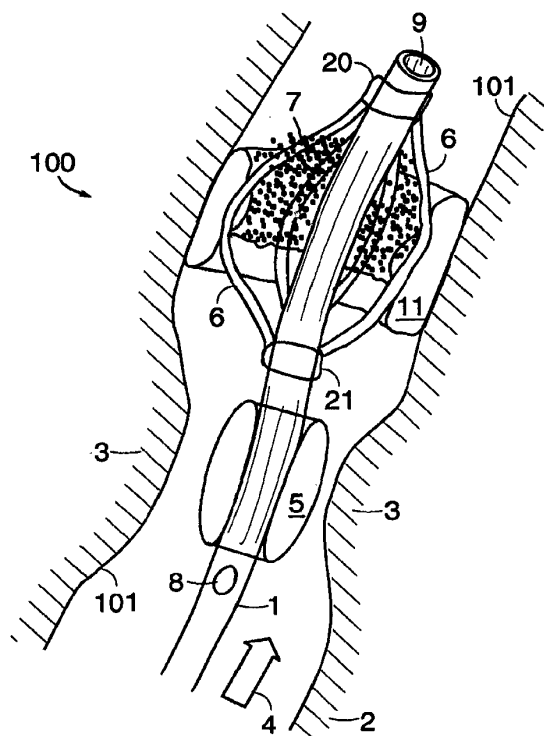


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(54) Title: CATHETER-FILTER SET HAVING A COMPLIANT SEAL**(57) Abstract**

A catheter-filter set in an embodiment may be used in a vas through which a biological fluid may flow. This embodiment includes a tubular member, having a lumen disposed along its length and an insertion end for insertion into the vas. The lumen defines a longitudinal axis and a radial direction perpendicular thereto. The embodiment also has a filter, coupled to the tubular member and having a circumference, for trapping undesired particles. Finally, the embodiment includes a resilient member, having compliance in the radial direction, disposed circumferentially about the filter and, when deployed in the vas, forms a seal against the interior wall of the vas. Other embodiments are also provided.



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CATHETER-FILTER SET HAVING A COMPLIANT SEAL

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Technical Field

The present invention relates to catheter-filter sets, including those for use in angioplasty and other procedures.

Background Art

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A large number of medical procedures utilize catheters. A catheter is defined herein and within the appended claims as a tubular, flexible instrument for insertion into a body cavity. Catheters may facilitate the withdrawal or introduction of fluids or other substances and may, in combination with other coupled components, perform a variety of other useful functions.

20

Catheters coupled with inflatable balloons provide the means to facilitate the unblocking of and the relief of constriction within various body passageways and vessels. Such angioplasty procedures can replace other more invasive surgical procedures and provide acceptable solutions to correct life threatening conditions. However, these procedures carry a risk of serious secondary

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problems associated with the transmission of unwanted material downstream of the operative site. Any material, such as plaque built up in arterial vessels, which does not adhere to the interior vas wall or is in another way removed from the vessel following treatment becomes a likely source of downstream blockage.

30

In arterial angioplasty, embolic ischemic damage distal to the angioplasty site is a major complication of the procedure. Mobile arterial plaque is a major factor linked with ischemic stroke or end organ/limb infarction. In particular, carotid

- 2 -

artery angioplasty is not a favored practice at present due to the risk of emboli and resulting stroke.

Some catheters coupled with downstream filtering capability have been previously disclosed. Several utilize wire mesh filters which are generally not
5 compliant and do not accommodate localized changes in vessel diameter and shape which may be caused by on-going fluid flow restoration and pulsatility. Other designs contain deployment structures which may make insertion prior to and retraction after completion of a procedure problematic or unduly risky.

Typical prior art catheter arrangements are disclosed in United States
10 patents 4,723,549; 4,794,928; 5,662,671; and 5,695,519. These documents are hereby incorporated herein by reference.

Summary of the Invention

Various embodiments of the present invention solve problems of the prior art by providing radial compliance to accommodate localized changes in vessel
15 diameter and shape which may be caused by on-going fluid flow restoration and pulsatility. Furthermore, some embodiments of the invention provide a device that is biased to return to its lowest profile condition in the absence of active operator input to facilitate making arterial angioplasty, particularly in the cerebral and coronary beds, more fail-safe. Various embodiments of the invention
20 avoid asperities or protrusions which can traumatize or otherwise damage or irritate interior vas walls. Similarly various embodiments provide for cushioning of the filter element against the vas wall when it is deployed. This cushioning effect is balanced with the requirement of effective sealing of the vas to prevent any unwanted downstream flow of matter.

25 Accordingly, in a first embodiment of the invention there is provided a catheter-filter set for use in a vas through which a biological fluid may flow. This embodiment includes a tubular member, having a lumen disposed along its length and an insertion end for insertion into the vas. The lumen defines a longitudinal axis and a radial direction perpendicular thereto. The embodiment
30 also has a filter, coupled to the tubular member and having a circumference, for trapping undesired particles. (Unless the context otherwise requires, the term

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"particles" as used in this description and the accompanying claims refers to substances to be removed from a vas, and may include thrombotic material.) Finally, the embodiment includes a resilient member, having compliance in the radial direction, disposed circumferentially about the filter and, when deployed in the vas, forming a seal against the interior wall of the vas. In further embodiments, the resilient member may be inflatable, such as a balloon, or alternatively may be an O-ring or sleeve. The outer surface of the resilient member may form the seal with the interior wall or may otherwise effectuate the seal. In a related embodiment the resilient member is a balloon having an anterior for receiving an inflation fluid and a shape so that when the balloon is inflated there is provided a passageway permitting fluid flow through the filter. In accordance with another related embodiment, the balloon is toroidal in shape and may have anisotropic elasticity so that during inflation its interior cross-section expands relatively less than its radial extent. Alternatively or in addition, the catheter-filter set may include an elastic member coupled to the balloon and the tubular member for causing the balloon to be radially confined when not deployed. In yet another variation, regardless whether a balloon is utilized, the filter has a stowed position where the filter is radially confined and disposed in the lumen so that the catheter-filter set may be inserted into and removed from the vas, and a deployed position, where the filter is radially expanded.

Various embodiments of the present invention have a range of potential applications. The application of embodiments to angioplasty procedures will be apparent to those skilled in the art. In addition, through either standard open technique or laparoscopic technique, retrieval of common duct stones in the biliary tree is facilitated by catheter passage utilizing embodiments herein. Similarly, through either standard open technique or cystographic technique, retrieval of ureteral and bladder duct stones is, also, facilitated by catheter passage via endoscopic or surgical methods. A catheter coupled with an inflatable balloon may also be utilized to effect balloon sphincteroplasty and stone retrieval. Embodiments herein provide improved devices to effectively retrieve such stones and to avoid their further passage or migration downstream.

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Embodiments herein may also employable as a temporary filtering device for the vena cava. In the process of lytic treatment for deep venous thrombosis, there is a risk of clot (thrombus) breaking loose and causing pulmonary embolism, a potentially fatal event. Although filters exist for vena
5 cava use, these are permanent structures with attendant long term morbidity. Having an effective and retractable filter which is in place only for the time of significant risk, *i.e.*, during deep venous clot lysis, would allow protection from pulmonary embolism and avoidance of the long term sequelae of a permanent filter insertion.

10 Discussion of medical procedures and associated devices in this description may focus, for example, upon arterial (blood circulation), biliary, and ureteral systems. This focus in no way limits the applicability of embodiments herein to any and all other uses for catheters with filtration capability known to those skilled in the art.

15 In another embodiment, there is provided a catheter-filter set having a tubular member, which has a first lumen disposed along its length, an insertion end for insertion into and a retraction end for retraction out of the vas. The lumen defines a longitudinal axis and a radial direction perpendicular thereto. The embodiment also has a filter, coupled to the tubular member proximal to the
20 insertion end, wherein the filter has a stowed position and a deployed position, and a non-inflatable actuator, coupled to the filter, for causing the filter to move from the stowed position to the deployed position, wherein, absent operation of the actuator, the filter is biased to be in the stowed position. In a related embodiment, the set also includes a vas conditions-modifying element located
25 upstream from the filter; this element may be an angioplasty balloon. In yet another related embodiment, the tubular member has a second lumen having an inlet upstream from the vas conditions-modifying element and an outlet downstream from the filter, permitting unimpeded, downstream fluid flow to
30 bypass the filter. In further embodiment, the set has a plurality of resilient ribs, each rib having a first end coupled to the tubular member, each rib also coupled to the filter, the ribs having a stowed condition in which they are parallel to the

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longitudinal axis and a deployed condition in which at least a portion of each rib is disposed radially outward from the tubular member. Each rib may have a second end slidably mounted on the tubular member and coupled to the actuator. The catheter-filter set may further include a resilient member, having
5 compliance in the radial direction, disposed circumferentially about the filter and, when deployed in the vas, forming a seal against the interior wall of the vas.

In another embodiment in accordance with the present invention, there is provided a catheter-filter set having:

- 10 a. a tubular member, having a lumen disposed along its length, an insertion end for insertion into and a retraction end for retraction out of the vas, the lumen defining a longitudinal axis and a radial direction perpendicular thereto; and
- b. a filter, coupled to the tubular member proximal to the insertion
end, wherein the filter has a stowed position wherein the filter is radially
15 confined and disposed in the lumen so that the catheter-filter set may be inserted into and removed from the vas, and a deployed position, wherein the filter is radially expanded.

Brief Description of the Drawings

20 Figs. 1A and 1B are longitudinal views of a catheter-filter set, in the deployed and the stowed conditions, respectively, used in a vas as part of an angioplasty device and using a toroidal balloon according to an embodiment of the invention.

Figs. 2A and 2B are longitudinal views of a portion of a catheter-filter set,
25 in the stowed and the deployed conditions, respectively, illustrating generally filter deployment according to an embodiment of the invention utilizing ribs for structuring the filter.

Figs. 3A and 3B are longitudinal views of a catheter-filter set, in
accordance with a tether deployment embodiment of the invention, showing
30 stowed and deployed conditions, respectively.

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Figs. 4A and 4B are longitudinal views of a catheter-filter set, in accordance with a balloon deployment embodiment of the invention, showing stowed and deployed conditions, respectively.

Fig. 5 is a longitudinal view of a catheter-filter set in accordance with an embodiment using balloon deployment wherein elastic bands bias the set in a stowed condition.

Figs. 6A and 6B are stowed and deployed conditions respectively of an embodiment similar to that of Figs. 4A and 4B, but wherein the ribs are normally twisted in a stowed condition, in which the embodiment is biased.

Fig. 7A is a cross-sectional view of a catheter-filter set in the deployed condition illustrating a balloon deployment design according to an embodiment of the invention in which the balloon has a passageway to permit fluid flow therethrough. Figs. 7B and 7C are longitudinal views of the same embodiment in the stowed and the deployed conditions, respectively.

Fig. 8A is a cross-sectional view of a catheter-filter set according to an embodiment of the invention, using for deployment a balloon 11 that is asymmetrically disposed with respect to the tubular member. Fig. 8B is a longitudinal view of the same embodiment in the deployed condition. Fig. 8C shows detail of the catheter-balloon interface.

Fig. 9 is a view of a catheter-filter set according to an embodiment of the invention utilizing a retractable O-ring.

Fig. 10 is a perspective view of a catheter-filter set according to an embodiment of the invention that is similar to the embodiment of Fig. 9, but utilizing a sleeve in lieu of the O-ring.

Fig. 11A is a perspective view of a catheter-filter set according to an embodiment of the invention utilizing a tethered O-ring, shown in the deployed condition. Fig. 11B is a longitudinal view of the same embodiment in the stowed condition.

Detailed Description of Specific Embodiments

Various embodiments of the catheter-filter set described herein address a number of shortcomings inherent in previous designs. Some desirable features

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for the filter portion of the set are that it be easily confined in a radial direction for ease of set insertion and removal, that it be capable of capturing and safely removing all particles flowing downstream in a vas, and additionally, it should be designed so as to minimize the risk of accidental deployment and to collapse
5 into position for removal in the event of failure. It should be atraumatic to the native vas wall and should accommodate changes in vas diameter.

Figs. 1A and 1B are longitudinal views of a catheter-filter set, in the deployed and the stowed conditions, respectively, used in a vas as part of an angioplasty device and using a toroidal balloon according to an embodiment of
10 the invention. Fig. 1A shows a catheter 1 inserted into a vas 2. The vas may be constricted or otherwise blocked at a location 3. Downstream fluid flow is indicated by arrow 4. An angioplasty balloon 5 affixed to the catheter and inflatable (by means well known in the art) is positioned proximate to location 3. During and after the angioplasty balloon 5 inflation process, unwanted particles
15 may flow downstream from location 3. A plurality of resilient ribs 6 (four are shown in this view) are coupled to the catheter 1 by two collars, one collar 20 at a downstream end and the other collar 21 at an opposing, upstream end of the catheter. In this embodiment, one of collars 20 and 21 is fixed relative to the catheter 1 and the other of the collars is free to slide along the catheter 1. The ribs
20 6 and both collars 20 and 21 are positioned at a location downstream from location 3 and the angioplasty balloon 5. A filter 7 is shown attached to the ribs 6 and to the catheter 1. A toroidal balloon 11, which is distinct from the angioplasty balloon 5, is attached to the ribs 6. In this embodiment, the toroidal balloon 11 is mounted approximately midway along the length of the ribs 6 and positioned
25 radially outward from the catheter 1. (The filter 7 is represented in this figure and figures below by a dot or hash pattern; for clarity of representation, the dot or hash pattern is not shown to occupy the entire region occupied by the filter. It will be understood, however, that when deployed the filter, together with any accompanying structure, such as the balloon 11, will occupy the entire cross
30 section of the vas so as to operate in an effective manner known in the art.)

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Fig. 1B shows that, in accordance with the embodiment in the stowed condition, the ribs parallel to the longitudinal axis of the catheter 1 facilitating set 100 insertion into and retraction out of the vas 2 minimizing trauma to the vas wall 101. During insertion and retraction of set 100 and catheter 1 into and out of the vas 2, the uninflated toroidal balloon 11 is collapsed and radially confined against the ribs 6 and the uninflated angioplasty balloon 5 is collapsed against the catheter 1. As illustrated in Fig. 1A, when the toroidal balloon 11 is inflated (in accordance with means well known in the art), one of collars 20 and 21 slides toward the other collar causing at least a portion of each of the ribs 6 and the filter 7 to be disposed radially outward from the catheter 1. The toroidal balloon 11 effectively spans any radial distance between, on the one hand, the vas wall 101, and on the other hand, the ribs 6 with the expanded filter 7. The toroidal balloon 11 thus forms a compliant seal between the set 100 and the vas wall 101.

After this compliant seal has been established, the angioplasty balloon 5 may then be inflated to unblock the vas 2 at location 3. The deployed filter 7 may then capture unwanted particles flowing downstream during and after operation and subsequent deflation of the angioplasty balloon 5. After the procedure, the toroidal balloon 11 is deflated, and the set 100 returns to the position shown in Fig. 1B for retraction from the vas 2. Unwanted particles are trapped within the filter 7 and are safely removed from the vas 2 upon retraction of the set 100. Additionally, biasing components (for example, as discussed below in connection with later figures) may be used in connection with the set 100 to insure the return to the position shown in Fig. 1B after deflation of the toroidal balloon 11. These components may include, and are not limited to, elastic bands coupled to one or more elements of the ribs 6, the filter 7, and collars 20 and 21.

Also shown in Fig. 1A, an inlet port 8 is provided by the catheter 1 at a location upstream from the angioplasty balloon 5 and an outlet port 9 is provided downstream from the filter 7. The ports are in communication with a lumen of the catheter; the lumen may be the same as the lumen used for other purposes or may be a separate dedicated lumen. The result of this structure is an auto-perfusion pathway from inlet port 8 through a catheter lumen to the outlet port 9

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to permit the unimpeded flow of a quantity of fluid during the time in which the medical procedure is being performed. The feature is advantageous when deleterious results may occur from even short intervals of downstream fluid starvation or depletion. Hypoperfusion during angioplasty balloon inflation is primarily relevant to the cerebral and coronary beds. Carotid artery angioplasty, in which the brain is immediately downstream from the location 3, is a prime example of a procedure benefiting from an auto-perfusion pathway. In many arterial applications, given the normal magnitude of blood pressures, there may be provided a lumen having an internal diameter of 1 to 2 mm. Even when blood flow is not as high as normal, the reduced rate of flow may nevertheless significantly reduce the risk of tissue damage caused by a complete interruption of flow in the cerebral and coronary beds.

Figs. 2A and 2B are longitudinal views of a portion of a catheter-filter set, in the stowed and the deployed conditions, respectively, illustrating generally filter deployment according to an embodiment of the invention utilizing ribs 6 for structuring the filter 7. Fig. 2A shows the ribs 6 and the filter 7 coupled to and juxtaposed with the catheter 1 in conjunction with the downstream collar 20. In Fig. 2B the ribs 6, which are resilient, are expanded radially from the catheter 1 to form a convex shape. The expanded ribs 6 support the filter 7 as shown.

Preferably, the ribs 6 are free from asperities. The ribs 6 may be made of any resilient material with sufficient rigidity to support and to enable deployment of the filter 7. The number of ribs 6 may be selected to be sufficiently large to facilitate a seal of the filter 7 with the interior wall of the vas 2 but not so numerous as to significantly obstruct fluid flow or convenient operation of the set. In the embodiment of Figs. 2A and 2B, the ribs 6 are disposed radially outward from the filter 7. In other embodiments of the invention, the ribs 6 may be disposed radially inward from the filter 7, so that, when stowed, the resilient ribs 6 lie immediately adjacent to the catheter 1. Such other embodiments may deploy in a fashion analogous to opening of an umbrella. The ribs 6 may have one free end as in Figs. 2A and 2B, or be coupled to the catheter 1 at both ends and bow in the middle for deployment as for example in Figs 1A and 1B. The

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filter 7 may beneficially be made of a porous, compliant material in a manner known in the art. Suitable materials may include, but are not limited to, woven nylon, plastic resins such as PTFE sold under the Teflon trademark by Dupont of Wilmington, Delaware, other woven polymer, porous silicone rubber and latex
5 rubber. Suitable materials are sufficiently porous to permit a small downstream flow of fluid yet capable of collecting any dangerous particles. For example, calculations suggest that, for an arterial application, a woven material with a fiber porosity of 90% and a spacing of 200 microns may pose little impediment to normal blood flow while trapping undesirable particles..

10 Figs. 3A and 3B are longitudinal views of a catheter-filter set, in accordance with a tether deployment embodiment of the invention, showing stowed and deployed conditions, respectively. As shown in Fig. 3B, the ribs 6 of this embodiment are attached to the catheter 1 at both ends by collars 20 and 21. The upstream end collar 21 is free to slide along the catheter 1 while the
15 downstream end collar 20 is fixed. Collar 21 is tethered with line 30 so that an operator can, by applying an upstream force to line 30 slide collar 21 downstream toward collar 20. This action urges the ribs 6 to form a convex shape and to expand radially from the catheter 1. As Figs. 3A and 3B show, tethering may be accomplished by attaching one end of line 30 to collar 21, feeding the line 30
20 through a port 31 provided by the catheter 1 at a position downstream from collar 21. The line passes into a lumen of the catheter and exits the catheter 1 upstream at its retraction end. The ribs 6 may expand to the full radial extent of the vas 2. Other material, as discussed in connection with other figures, may be coupled to the ribs 6 proximate to their approximate midpoint in length to
25 provide better sealing action and cushioning at the interface with the vas wall 101. (For example, the toroidal balloon of Figs. 1A and 1B may be employed; alternatively, any suitable resilient sleeve or O-ring may be utilized.) The ribs 6 will return to the stowed position of Fig. 3A, in accordance with the embodiment of the invention, with the elimination of the applied upstream force on line 30.
30 This provides a set 100 which is biased to remain in and revert to the stowed position. Such bias provides for assured collapsibility upon retraction and offers

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a high degree of fail-safe operation by minimizing the chance of accidental deployment.

Another embodiment according to the invention provides a filter deployment technique using an inflatable toroidal balloon **11** with ribs **6** which have their upstream end uncoupled to the catheter **1**. The stowed position is shown in Fig. 4A; the deployed position in Fig. 4B. Operation of this embodiment is similar to that of Figs. 1A and 1B with respect to the use of a toroidal balloon and to that of Figs. 2A and 2B with respect to the ribs **6**. A tube **40** is provided for inflation fluid communication between a lumen disposed within the catheter **1** and the toroidal balloon **11**. The opposing ends of tube **40** are, respectively, inserted and remain within ports **41**, provided by the catheter **1**, and **42**, provided by the toroidal balloon **11**. The ends of tube **40** may be secured in the ports **41** and **42** with adhesives or using other methods in a manner known in the art. The uninflated toroidal balloon **11**, as shown in Fig. 4A is coupled to the upstream ends of the ribs **6** and juxtaposed with the catheter **1**. As shown in Fig. 4B, with inflation of the toroidal balloon **11**, the resilient ribs **6** expand radially from the catheter **1** to form a convex shape supporting the filter **7**. At its most radially outward extent, the inflated toroidal balloon **11** effects a compliant seal between the set **100** and the vas wall **101**. The toroidal balloon **11** may be made by wrapping fiber around it so that its expansion will be constrained in such a way that the diameter of its inflatable cross-section increases to a lesser degree than its radial (perpendicular to the catheter axis) dimension. In fact, this mode of inflation can be produced by any material that is anisotropic having a high stiffness (or Young's modulus) in the direction of the fiber wrapping and a low stiffness in the direction perpendicular to the wrapping. The inflation of the toroidal balloon provides the necessary structural rigidity needed to withstand the forces associated with downstream fluid flow (in particular, arterial blood flow) while the set **100** is in the deployed condition.

Fig. 5 is a longitudinal view of a catheter-filter set in accordance with an embodiment using balloon deployment wherein elastic bands **50** are employed to bias the set in a stowed condition. The bands **50** are coupled to an upstream collar

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51 and a second downstream collar 52. Both collars 51 and 52 are coupled to the catheter 1; the second downstream collar 52 is positioned at a distance farther downstream along the catheter 1 than collar 20 to which optional ribs 6 may be coupled. This embodiment provides a set 100 which is biased to revert to the
5 stowed condition. On deflation of the toroidal balloon 11, the bands 50 act to force the balloon 11, the ribs 6, and the filter 7, with any entrapped particles within, to revert to the stowed condition for safe retraction.

Figs. 6A and 6B are stowed and deployed conditions respectively of an embodiment similar to that of Figs. 4A and 4B, but wherein the ribs are normally
10 twisted in a stowed condition, in which the embodiment is biased. The ribs 6 (which are here differently shaded to permit differentiation in the figure), when in a relaxed, unstressed configuration, fit snugly about the catheter 1 bore in a helical arrangement, as shown in Fig. 6A. The filter 7 is gathered together inside the ribs while the cushioning balloon 11 lies outside the ribs 6 but deflated into a
15 collapsed configuration. The ribs 6 in this embodiment are attached at both the upstream and downstream ends to collars 21 and 20 respectively. The collars 21 and 20 are constrained so as to prevent movement in the longitudinal direction, but the downstream collar 20 can be rotated by rotation of a stiff line 60 threaded through a lumen 61 of the catheter 1. Rotation of the downstream collar 20
20 causes the ribs 6 to bow outward into the deployed position illustrated in Fig. 6B. Once deployed, the balloon 11 can be inflated to provide a resilient seal against the interior wall of the vas 101 while maintaining an open space between the balloon 11 and catheter 1 for fluid flow. Bowing of the ribs deploys the filter 7 attached to the inner surface of the balloon 11 so that it can function as a trap for
25 debris released from an upstream site. Retraction of the ribs 6 occurs when the stiff line 60 is allowed to rotate back to its original position and the balloon 11 is deflated. The filter set is therefore biased closed in that when pressure is relieved from the balloon 11 and the torque exerted on the stiff line 60 is released, the ribs 6 and filter 7 revert to their stowed position.

30 Fig. 7A is a cross-sectional view of a catheter-filter set in the deployed condition illustrating a balloon deployment design according to an embodiment

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of the invention in which the balloon has a passageway to permit fluid flow therethrough. Figs. 7B and 7C are longitudinal views of the same embodiment in the stowed and the deployed conditions, respectively. In this embodiment, the inflation balloon **11** takes on the shape of two "Ds" back-to-back. The advantage
5 of this embodiment is that the catheter **1** passes directly through the inflatable portion of the balloon **11**, avoiding the need for a separate inflation line that might be prone to rupture because of its small diameter. Fig. 7A shows the balloon in a view along the axis of the vas **2** looking in the downstream direction. The catheter **1** can be seen passing through at the center, and is sealed to the
10 balloon at the points where it passes through the balloon membrane. The catheter has a port inside the balloon **11** that is used for balloon inflation. The filter **7** is seen in Fig. 7A through the openings in the balloon **11** through which the fluid is free to flow. Fig. 7B shows the balloon **11** in the retracted or stowed position. Elastic bands **50** hold the deflated balloon **11**, so that it is radially
15 confined, tight against the catheter **1**. The filter **7** is gathered together and held against the catheter **1** in part by the elastic bands **50**. Deployment is accomplished by inflation of the balloon **11**, a process that forces the balloon **11** into its double-D shape shown in longitudinal view in Fig. 7C. The inflated balloon **11** of Fig. 7C forms a flexible seal against the vas wall **101** and deploys
20 the filter **7**. The filter in this embodiment is firmly tethered to the catheter at its downstream end to aid in gathering the filter **7** to the catheter on balloon deflation. The balloon **11** is made from a flexible but relatively inextensible polymer so that on inflation, it takes the shape shown.

Fig. 8A is a cross-sectional view of a catheter-filter set according to an
25 embodiment of the invention, using for deployment a balloon **11** that is asymmetrically disposed with respect to the tubular member. Fig. 8B is a longitudinal view of the same embodiment in the deployed condition. Fig. 8C shows detail of the catheter-balloon interface. This embodiment increases the area available for flow through the "doughnut hole" of the balloon **11** and, like
30 the embodiment of Figs. 7A through 7C, avoids the need for a separate inflation tube connecting the balloon **11** with the catheter **1**. In this embodiment, the

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catheter 1 passes through the toroidal balloon 11 at location 80 on its circumference; a seal is provided between the balloon 11 and the catheter so that the balloon can be inflated through a port as in the embodiment of Figure 7. In the stowed position, shown in Figure 8A, an elastic band 50 attached to the

5 balloon 11 at a point diametrically opposite to the inflation site 80 draws the balloon 11 in the upstream direction. When and as the balloon 11 is deflated, it and filter 7 are collapsed radially against the catheter 1 bore under the force of the elastic band 50. Additional elastic bands may be optionally used on the downstream side to help gather together the filter 7 on deflation. The filter is

10 deployed by inflation of balloon 11 through the port at location 80 as illustrated in Figure 8B. Balloon inflation also seals the balloon 11 in a flexible manner against the wall of the vas. In the process of balloon inflation, the catheter 1 is displaced off center toward the wall of the vas so as to increase the area available for flow. All flow still passes through the filter 7.

15 Fig. 9 is a perspective view of a catheter-filter set according to an embodiment of the invention utilizing a retractable O-ring. The downstream end of the catheter 1 is pictured at a location downstream of a suitable vas-modifying element. The filter 7 is fastened to an O-ring 90 which in turn, is coupled to a set of resilient ribs 6 (four of which are shown). When in the deployed position

20 (shown) the ribs 6 are pushed out of the downstream end of the catheter 1. The resilience of the O-ring 90 (optionally, in combination with shape memory of the ribs 6) causes the ribs 6 to separate as the O-ring 90 deploys into its natural circular shape, producing a seal against the wall of the vas. In so doing, the O-ring 90 expands the filter 7 so that it can trap debris released from an upstream

25 location. The filter 7 is returned to its original undeployed position by retracting the ribs 6 into the catheter 1, exerting a radially-inward force on the O-ring 90, causing it to buckle into a

multi-lobed pattern with outside radial dimension much smaller than in the deployed position. The ribs 6 can be drawn into the catheter 1 by means of a stiff

30 tether line 91 attached to the ribs 6 at their upstream end 92 within the catheter lumen. The tether line 91 must be sufficiently rigid that it can exert the force

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needed to deploy the filter 7 and the O-ring 90. For ease of retrieval, the filter 7 can be sheathed by a second catheter that slides on the outer bore of the catheter 1, slipping over the buckled O-ring 90 and filter 7.

Fig. 10 is a perspective view of a catheter-filter set according to an embodiment of the invention that is similar to the embodiment of Fig. 9, but utilizing a cylindrical sleeve 93 in lieu of the O-ring 90. An advantage of the sleeve is that the filter 7 can be entirely contained within the sleeve 93 when the ribs and filter are in the retracted position, thus eliminating the necessity for a second catheter.

Fig. 11A is a perspective view of a catheter-filter set according to an embodiment of the invention utilizing a tethered O-ring, shown in the deployed condition. Fig. 11B is a longitudinal view of the same embodiment in the stowed condition. This embodiment shows that an O-ring 191 may be employed in situations in which the filter 7 is attached upstream of the end of the catheter 1. Deployment, in this embodiment, is accomplished when the operator relaxes the force applied by the line 121 which passes through the wall of the catheter 1 at point 122. The line 121 is attached to a collar 21 that can slide freely along the bore of the catheter 1. When force is relaxed, the resilience of the O-ring 191 that exerts a tension in a plurality of tether lines 200 (two are shown) pulls the collar 21 in the downstream direction. The O-ring 191, selected to be of an outer diameter when fully extended slightly larger than the normal diameter of the vas, provides a flexible seal against the wall of the vas when the tension force in tethers 200 is reduced. A filter 7 is attached around the circumference of the O-ring 191 and is deployed when the O-ring is allowed to expand to fill the vas. The O-ring 191 is also attached to a plurality of additional tethers 201 (two are shown) that are rigidly fixed to the downstream collar 20. All tether lines 200 and 201 are inextensible and, in this embodiment, are attached at points distributed roughly equidistant around the circumference of the O-ring 191. To retract and stow the filter, the operator pulls on the line 121 and the O-ring buckles into the configuration shown in Figure 11B due to the alternating

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attachments of the tether lines **200** and **201**. The buckling of the O-ring **191** also helps to gather together the filter **7**.

Although the invention has been described with reference to several preferred embodiments, it will be understood by one of ordinary skill in the art
5 that various modifications can be made without departing from the spirit and the scope of the invention, as set forth in the claims hereinbelow.

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What is claimed is:

1. A catheter-filter set for use in a vas through which a biological fluid may flow, the vas having an interior wall, the fluid flow defining downstream and upstream directions, there being a risk of the presence of undesired particles in
5 the fluid, the catheter-filter set comprising:
 - a. a tubular member, having a lumen disposed along its length and an insertion end for insertion into the vas, the lumen defining a longitudinal axis and a radial direction perpendicular thereto;
 - b. a filter, coupled to the tubular member and having a circumference,
10 for trapping undesired particles; and
 - c. a resilient member, having compliance in the radial direction, disposed circumferentially about the filter and, when deployed in the vas, forming a seal against the interior wall.
2. A catheter-filter set according to claim 1, wherein the resilient member is
15 an O-ring.
3. A catheter-filter set according to claim 1, wherein the resilient member is a sleeve.
4. A catheter-filter set according to claim 1, wherein the resilient member is a
balloon having an interior for receiving an inflation fluid and a shape so that
20 when the balloon is inflated there is provided a passageway permitting fluid flow through the filter.
5. A catheter-filter set according to claim 4, further comprising an elastic member coupled to the balloon and the tubular member for causing the balloon to be radially confined when not deployed.
- 25 6. A catheter-filter set according to claim 4, wherein the balloon is toroidal and its interior has a cross-section.
7. A catheter-filter set according to claim 6, wherein the resilient balloon has anisotropic elasticity so that during inflation its interior cross-section expands relatively less than its radial extent.
- 30 8. A catheter filter set according to claim 1, such that the filter has a stowed position where the filter is radially confined and disposed in the lumen so that

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the catheter-filter set may be inserted into and removed from the vas, and a deployed position, where the filter is radially expanded.

9. A catheter-filter set for use in a vas through which a biological fluid may flow, the vas having an interior wall, the fluid flow defining downstream and upstream directions, there being a risk of the presence of undesired particles in the fluid, the catheter-filter set comprising:
- a. a tubular member, having a first lumen disposed along its length, an insertion end for insertion into and a retraction end for retraction out of the vas, the lumen defining a longitudinal axis and a radial direction perpendicular thereto;
 - b. a filter, coupled to the tubular member proximal to the insertion end, wherein the filter has a stowed position wherein the filter is radially confined so that the catheter-filter set may be inserted into and removed from the vas, and a deployed position, wherein the filter is radially expanded; and
 - c. a non-inflatable actuator, coupled to the filter, for causing the filter to move from the stowed position to the deployed position; wherein, absent operation of the actuator, the filter is biased to be in the stowed position.
10. A catheter-filter set according to claim 9, further comprising:
- d. a vas conditions-modifying element, associated with the tubular member and located upstream from the filter.
11. A catheter-filter set according to claim 9 wherein element (d) is an angioplasty balloon.
12. A catheter-filter set according to claim 9, wherein the tubular member has a second lumen, the second lumen having an inlet upstream from the vas conditions-modifying element and an outlet downstream from the filter, permitting unimpeded, downstream fluid flow to bypass the filter.
13. A catheter-filter set according to claim 12, wherein the second lumen has a diameter of from approximately 1 mm to approximately 2 mm.
14. A catheter-filter set according to claim 9, further comprising:

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- d. a plurality of resilient ribs, each rib having a first end coupled to the tubular member, each rib also coupled to the filter, the ribs having a stowed condition in which they are parallel to the longitudinal axis and having a deployed condition in which at least a portion of each
- 5 rib is disposed radially outward from the tubular member.
- 15. A catheter-filter set according to claim 14, wherein the filter, in the deployed position, has a maximum radial extent and each rib, in the deployed condition, radially extends a distance less than the maximum radial extent of the filter.
- 10 16. A catheter-filter set according to claim 14, wherein each rib has a second end slidably mounted on the tubular member and coupled to the actuator.
- 17. A catheter-filter set according to claim 16, wherein each rib is coupled to a collar slidably mounted on the tubular member.
- 18. A catheter-filter set according to claim 14, further comprising:
- 15 e. a vas conditions-modifying element, associated with the tubular member and located upstream from the filter.
- 19. A catheter-filter set according to claim 18 wherein element (e) is an angioplasty balloon.
- 20. A catheter-filter set according to claim 18, wherein the tubular member has
- 20 a second lumen, the second lumen having an inlet upstream from the vas conditions-modifying element and an outlet downstream from the filter, permitting unimpeded, downstream fluid flow to bypass the filter.
- 21. A catheter-filter set according to claim 20, wherein the second lumen has a diameter of from approximately 1 mm to approximately 2 mm.
- 25 22. A catheter-filter set according to claim 9, further comprising:
 - d. a resilient member, having compliance in the radial direction, disposed circumferentially about the filter and, when deployed in
- the vas, forming a seal against the interior wall.
- 23. A catheter-filter set according to claim 22, further comprising:
- 30 e. a plurality of resilient ribs, each rib having a first end coupled to the tubular member, each rib also coupled to the filter, the ribs having a

- 20 -

stowed condition in which they are parallel to the longitudinal axis and having a deployed condition in which at least a portion of each rib is disposed radially outward from the tubular member.

24. A catheter-filter set according to claim 23, wherein the filter, in the
5 deployed position, has a maximum radial extent and each rib, in the deployed condition, radially extends a distance less than the maximum radial extent of the filter.
25. A catheter-filter set according to claim 23, wherein each rib has a second end slidably mounted on the tubular member and coupled to the actuator.
- 10 26. A catheter-filter set according to claim 25, wherein each rib is coupled to a collar slidably mounted on the tubular member.
27. A catheter-filter set according to claim 23, further comprising:
f. a vas conditions-modifying element, associated with the tubular member and located upstream from the filter.
- 15 28. A catheter-filter set according to claim 27 wherein element (f) is an angioplasty balloon.
29. A catheter-filter set according to claim 23, wherein the tubular member has a second lumen, the second lumen having an inlet upstream from the vas conditions-modifying element and an outlet downstream from the filter,
20 permitting unimpeded, downstream fluid flow to bypass the filter.
30. A catheter-filter set according to claim 29, wherein the second lumen has a diameter of from approximately 1 mm to approximately 2 mm.
31. A catheter-filter set according to claim 22, wherein the resilient member is an O-ring.
- 25 32. A catheter-filter set according to claim 22, wherein the resilient member is a sleeve.
33. A catheter-filter set according to claim 22, wherein the resilient member is a resilient balloon having an interior for receiving an inflation fluid and a shape so that when the resilient balloon is inflated there is provided a passageway
30 permitting fluid flow through the filter.

- 21 -

34. A catheter-filter set according to claim 33, wherein the resilient balloon is toroidal and its interior has a cross-section.

35. A catheter-filter set according to claim 34, wherein the resilient balloon has anisotropic elasticity so that during inflation its interior cross-section expands
5 relatively less than its radial extent.

36. A catheter-filter set for use in a vas through which a biological fluid may flow, the vas having an interior wall, the fluid flow defining downstream and upstream directions, there being a risk of the presence of undesired particles in the fluid, the catheter-filter set comprising:

- 10 a. a tubular member, having a lumen disposed along its length, an insertion end for insertion into and a retraction end for retraction out of the vas, the lumen defining a longitudinal axis and a radial direction perpendicular thereto; and
- b. a filter, coupled to the tubular member proximal to the insertion
15 end, wherein the filter has a stowed position wherein the filter is radially confined and disposed in the lumen so that the catheter-filter set may be inserted into and removed from the vas, and a deployed position, wherein the filter is radially expanded.

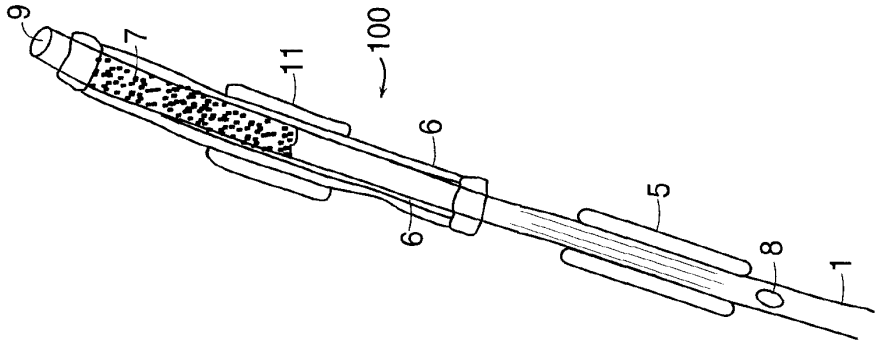


FIG. 1B

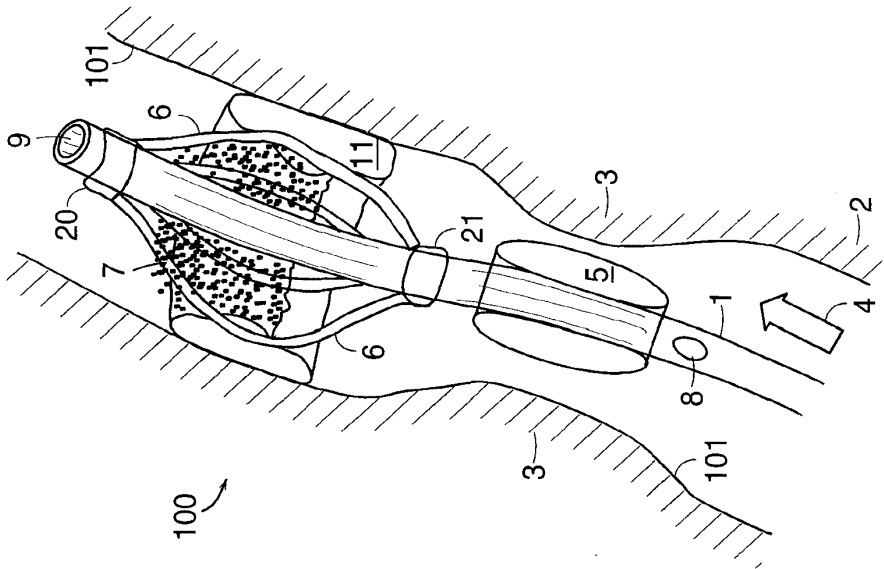


FIG. 1A

SUBSTITUTE SHEET (RULE 26)

2/9

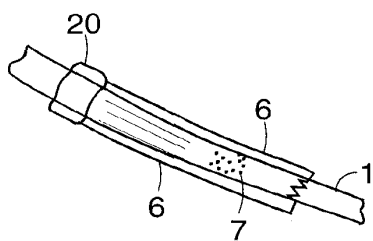


FIG. 2A

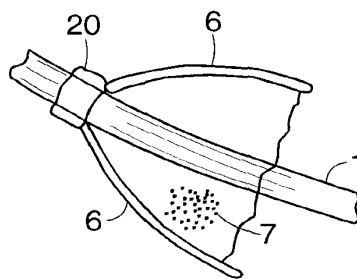


FIG. 2B

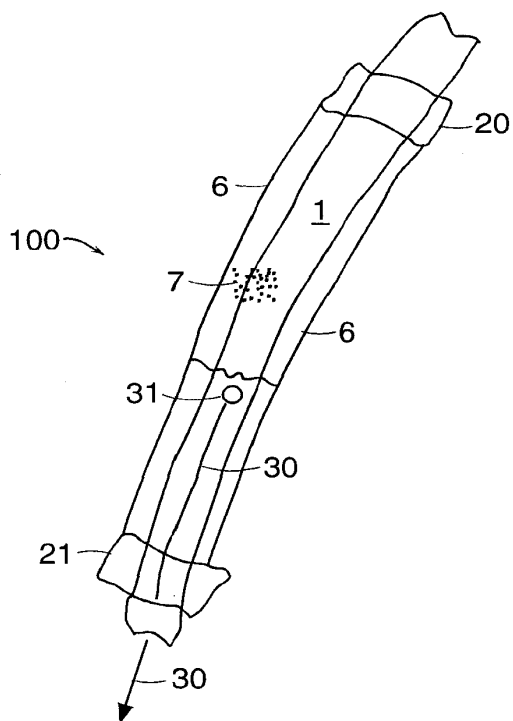


FIG. 3A

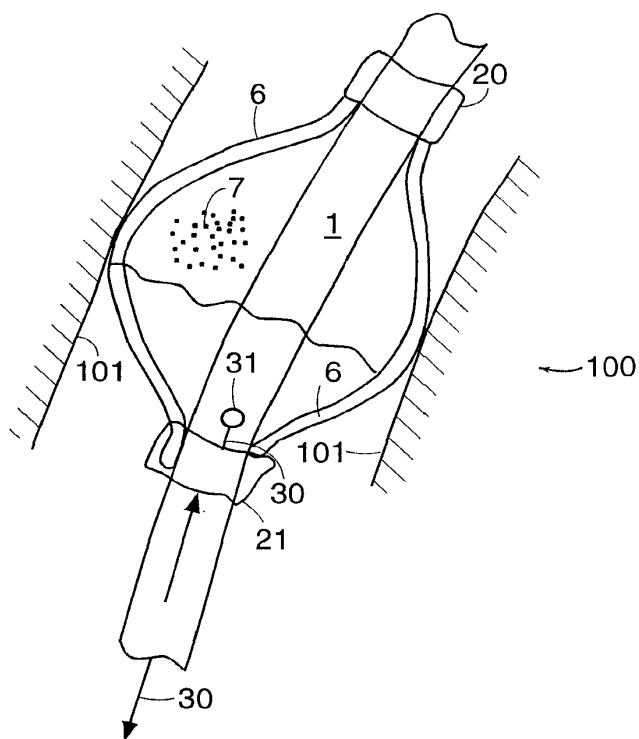


FIG. 3B

SUBSTITUTE SHEET (RULE 26)

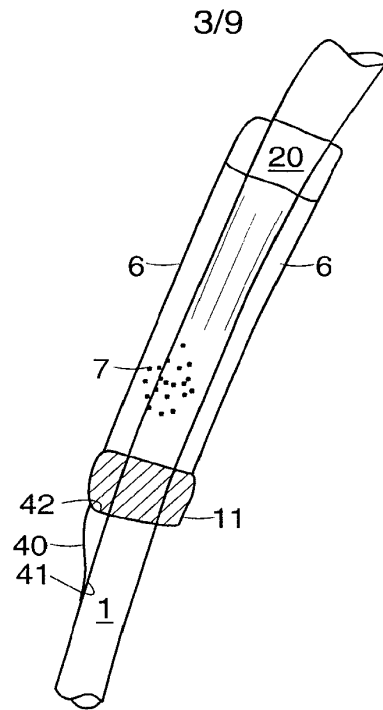


FIG. 4A

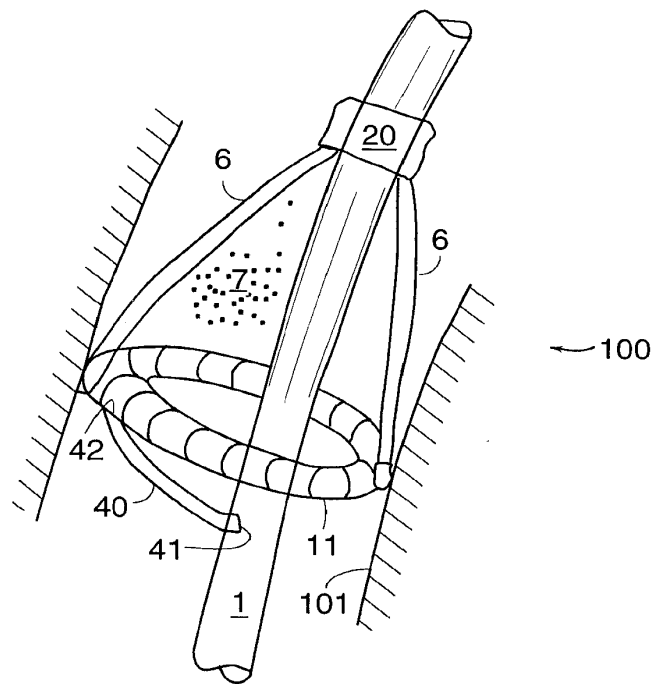


FIG. 4B

SUBSTITUTE SHEET (RULE 26)

4/9

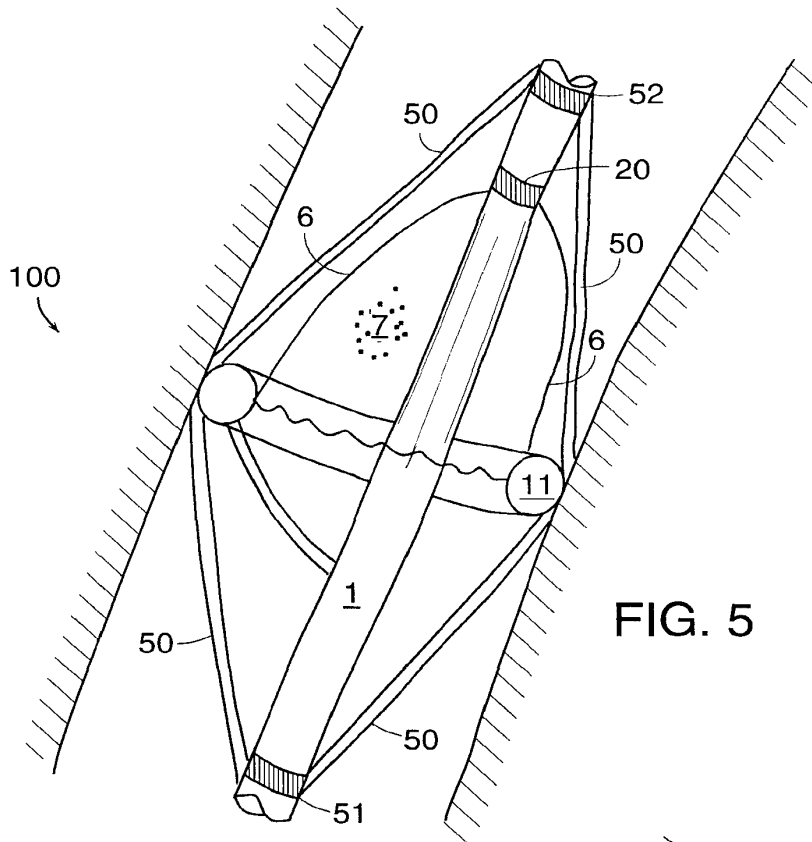


FIG. 5

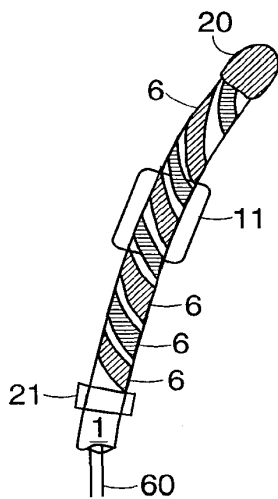


FIG. 6A

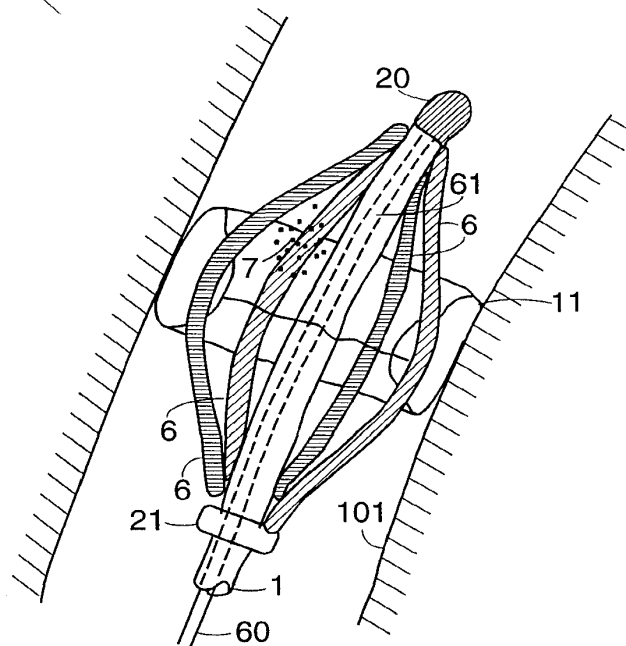


FIG. 6B

SUBSTITUTE SHEET (RULE 26)

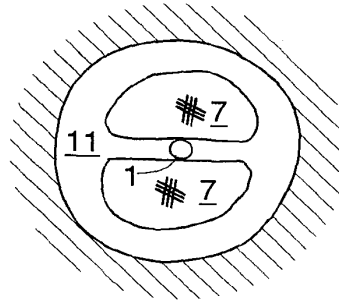


FIG. 7A

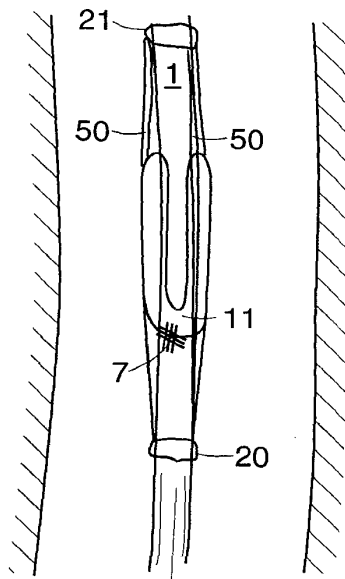


FIG. 7B

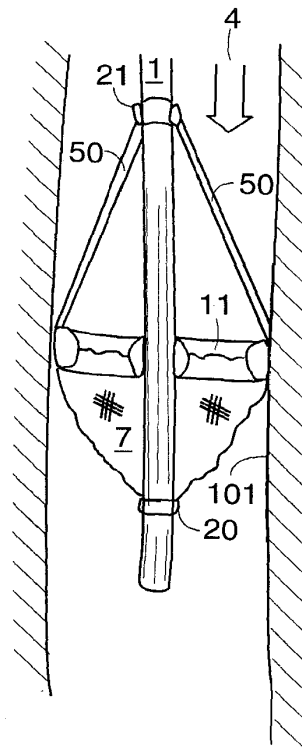


FIG. 7C

SUBSTITUTE SHEET (RULE 26)

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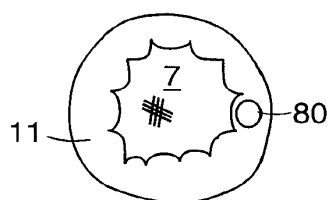


FIG. 8A

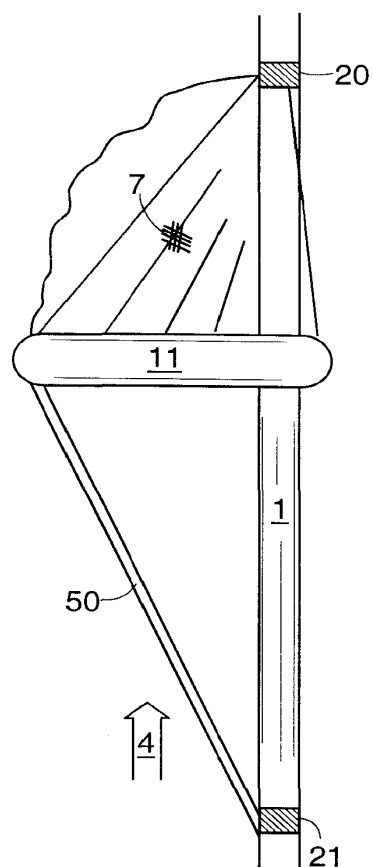


FIG. 8B

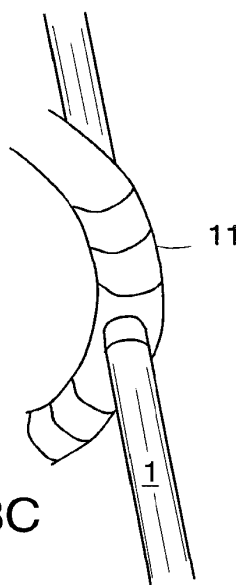


FIG. 8C

SUBSTITUTE SHEET (RULE 26)

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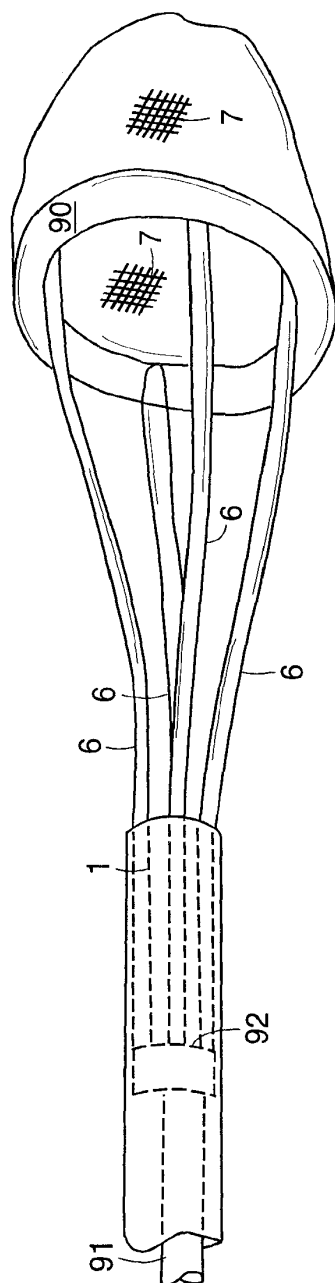


FIG. 9

SUBSTITUTE SHEET (RULE 26)

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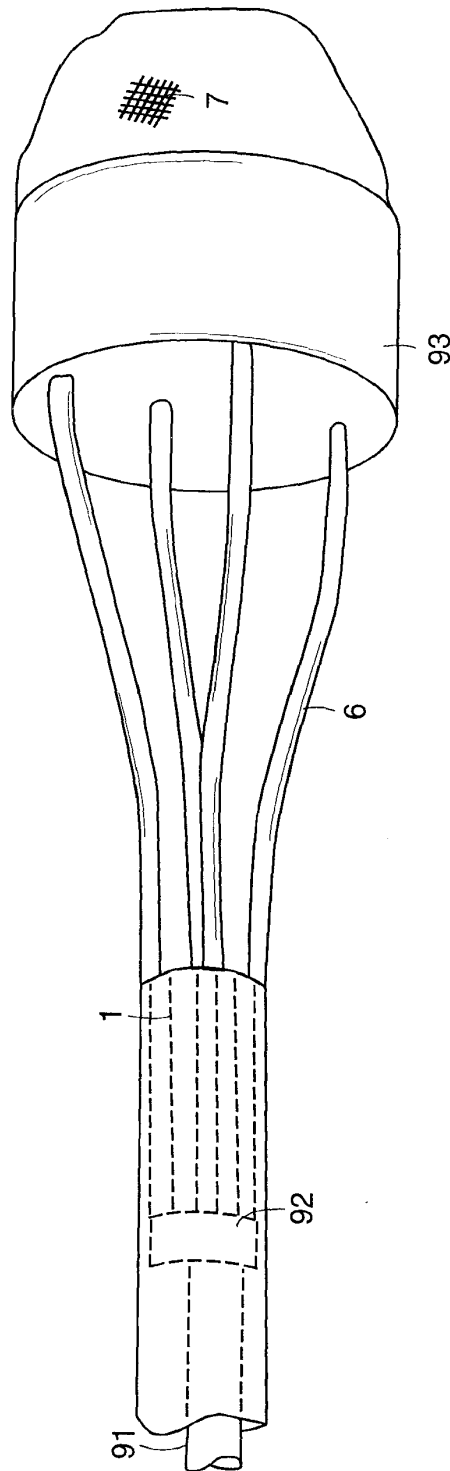


FIG. 10

SUBSTITUTE SHEET (RULE 26)

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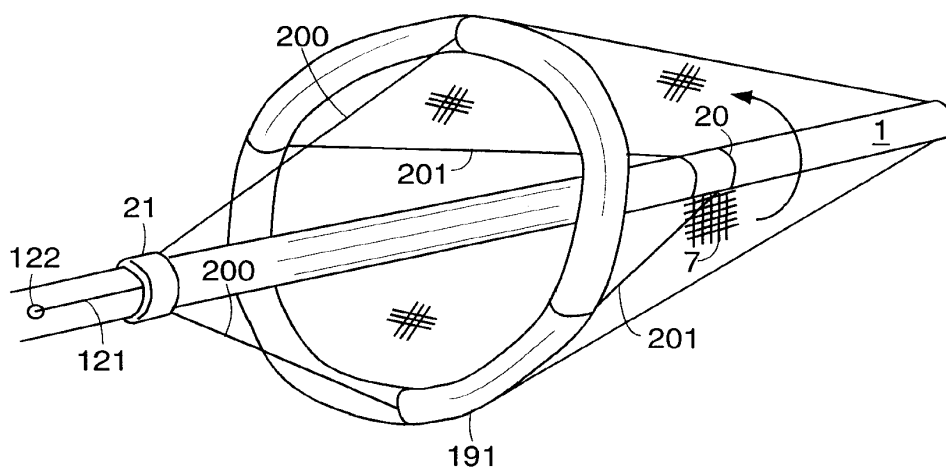


FIG. 11A

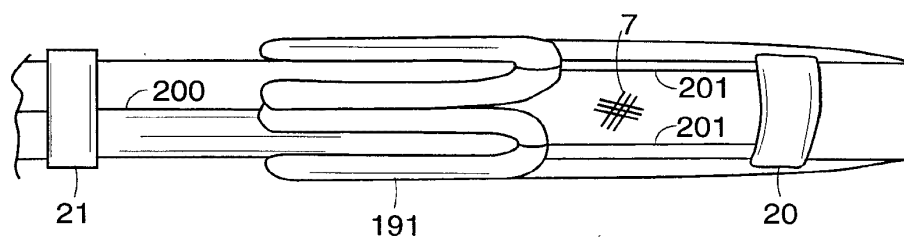


FIG. 11B

SUBSTITUTE SHEET (RULE 26)

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 98/10220

A. CLASSIFICATION OF SUBJECT MATTER IPC 6 A61F2/01 A61M29/02		
According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) IPC 6 A61F A61B		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
Electronic data base consulted during the international search (name of data base and, where practical, search terms used)		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 95 05209 A (TECH. DEV. CENTER) 23 February 1995	1-4, 6-8, 36
Y	see page 13, line 29 - page 15, line 11 see page 7, line 6 - line 10; figures 1, 13-15	5, 9-35
Y	US 4 723 549 A (WHOLEY ET AL.) 9 February 1988 cited in the application see column 3, line 2 - line 66; figures 1-6	5, 9-35
-/--		
☒ Further documents are listed in the continuation of box C. ☒ Patent family members are listed in annex.		
Special categories of cited documents : "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier document but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art. "&" document member of the same patent family		
Date of the actual completion of the international search 21 August 1998		Date of mailing of the international search report 02/09/1998
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016		Authorized officer Moers, R

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 98/10220

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	<p>DATABASE WPI Week 8122 8 July 1981 Derwent Publications Ltd., London, GB; AN 78-70163A XP002075206 & SU 764 684 A (CHELY MED. INST.) see abstract; figures 1-5 ---</p>	1-3, 9, 36
X A	<p>US 5 053 008 A (BAJAJ) 1 October 1991 see column 7, line 55 - column 8, line 47; figures 1-4 ---</p>	1, 36 3, 7, 32, 35
A	<p>US 5 470 314 A (WALINSKY PAUL) 28 November 1995 see column 7, line 13 - line 18 -----</p>	7, 35

1

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 98/10220

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9505209 A	23-02-1995	AU 7567394 A	14-03-1995
US 4723549 A	09-02-1988	NONE	
US 5053008 A	01-10-1991	NONE	
US 5470314 A	28-11-1995	NONE	

Form PCT/ISA/210 (patent family annex) (July 1992)

INARI_018957

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

To: MATTHEW S. WILLIAMS PERKINS COIE LLP P.O. BOX 1247 SEATTLE, WA 98111-1247
RECEIVED PATENT DOCKETING JAN 25 2022 PERKINS COIE LLP

NOTIFICATION OF TRANSMITTAL OF
 THE INTERNATIONAL SEARCH REPORT AND
 THE WRITTEN OPINION OF THE INTERNATIONAL
 SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

Applicant's or agent's file reference 111552-8025WO00	Date of mailing <i>(day/month/year)</i> JAN 20 2022
International application No. PCT/US 21/45072	International filing date <i>(day/month/year)</i> 06 August 2021 (06.08.2021)
Applicant INARI MEDICAL, INC.	

1. ☒	<p>The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.</p> <p>Filing of amendments and statement under Article 19: The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):</p> <p>When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.</p> <p>How? Directly to the International Bureau preferably through ePCT, or on paper to: The International Bureau of WIPO, 34, chemin des Colombettes, 1211 Geneva 20, Switzerland</p> <p>For more detailed instructions, see the <i>PCT Applicant's Guide</i>, International Phase, paragraphs 9.004 - 9.011.</p>
2. ☐	<p>The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.</p>
3. ☐	<p>With regard to any protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:</p> <p>☐ the protest together with the decision thereon has been transmitted to the International Bureau together with any request to forward the texts of both the protest and the decision thereon to the designated Offices.</p> <p>☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.</p>
<p>4. Reminders</p> <p>The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. These comments will be made available to the public after international publication. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established.</p> <p>Shortly after the expiration of 18 months from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau before the completion of the technical preparations for international publication (Rules 90bis.1 and 90bis.3).</p> <p>Within 19 months from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later); otherwise, the applicant must, within 20 months from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices. In respect of other designated Offices, the time limit of 30 months (or later) will apply even if no demand is filed within 19 months. For details about the applicable time limits, Office by Office, see www.wipo.int/pct/en/texts/time_limits.html and the <i>PCT Applicant's Guide</i>, National Chapters.</p> <p>Within 22 months from the priority date, the applicant may request that a supplementary international search be carried out by a different International Searching Authority that offers this service (Rule 45bis.1). The procedure for requesting supplementary international search is described in the <i>PCT Applicant's Guide</i>, International Phase, paragraphs 8.006-8.032.</p>	

Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Authorized officer <p style="text-align: center;">Kari Rodriguez</p> Telephone No. PCT Helpdesk: 571-272-4300
---	---

Form PCT/ISA/220 (revised January 2020)

INARI_018958

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 111552-8025WO00		FOR FURTHER ACTION see Form PCT/ISA/220 as well as, where applicable, item 5 below.	
International application No. PCT/US 21/45072	International filing date (<i>day/month/year</i>) 06 August 2021 (06.08.2021)	(Earliest) Priority Date (<i>day/month/year</i>) 06 August 2020 (06.08.2020)	
Applicant INARI MEDICAL, INC.			

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

This international search report consists of a total of 4 sheets.

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

1. Basis of the report

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

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

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

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

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

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

4. With regard to the title,

- ☒ the text is approved as submitted by the applicant.
☐ the text has been established by this Authority to read as follows:

5. With regard to the abstract,

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

6. With regard to the drawings,

- a. the figure of the drawings to be published with the abstract is Figure No. 1B
☒ as suggested by the applicant.
☐ as selected by this Authority, because the applicant failed to suggest a figure.
☐ as selected by this Authority, because this figure better characterizes the invention.
b. ☐ none of the figures is to be published with the abstract.

Form PCT/ISA/210 (first sheet) (July 2019)

INARI_018959

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 21/45072

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

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

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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

This International Searching Authority found multiple inventions in this international application, as follows:
This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be searched, the appropriate additional search fees must be paid.

Group I: Claims 1-15 directed to an automatically-locking syringe.

Group II: Claims 16-20 directed to a clot treatment system.

Group III: Claims 21-28 directed to a syringe having a barrel and a vacuum indicator having a transparent tube and an indicator with a visual characteristic.

*- See Supplemental Box *-

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-15

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

Form PCT/ISA/210 (continuation of first sheet (2)) (July 2019)

INARI_018960

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 21/45072

A. CLASSIFICATION OF SUBJECT MATTER

IPC - A61M 5/32; A61M 5/315 (2021.01)

CPC - A61M 5/32; A61M 5/502; A61M 5/3243; A61M 5/150641; A61M 5/3234; A61M 5/3232; A61M 5/5013; A61M 2005/5026; A61M 2005/3247; A61M 2005/3223; A61M 5/315

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

See Search History document

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

See Search History document

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

See Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2013/0126559 A1 (COWAN et al.) 23 May 2013 (23.05.2013); entire document, especially para [0028], and Fig. 1-2.	1-10
A	US 2004/0122359 A1 (WENZ et al.) 24 June 2004 (24.06.2004); entire document, especially para [0063]-[0066], and Fig. 7.	1-15
A	WO 2011/073176 A1 (NOVARTIS AG) 23 June 2011 (23.06.2011); especially pg 6 in 33 to pg 7 in 2, and Fig. 1-3.	10-15
A, P	WO 2021/067134 A1 (BECTON, DICKINSON AND COMPANY) 8 April 2021 (08.04.2021); entire document.	1-15
A	US 2004/0267272 A1 (HENNIGES et al.) 30 December 2004 (30.12.2004); entire document.	1-15



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents:

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

"D" document cited by the applicant in the international application

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

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search

2 December 2021

Date of mailing of the international search report

JAN 20 2022

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US, Commissioner for Patents
P.O. Box 1450, Alexandria, Virginia 22313-1450

Facsimile No. 571-273-8300

Authorized officer

Kari Rodriguez

Telephone No. PCT Helpdesk: 571-272-4300

Form PCT/ISA/210 (second sheet) (July 2019)

INARI_018961

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.

PCT/US 21/45072

Box III.0 - Explanations where unity of invention is lacking -*

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

SPECIAL TECHNICAL FEATURES

The invention of Group I includes the special technical feature of a lock plate, not required by the claims of Groups II-III.

The invention of Group II includes the special technical feature of a catheter, not required by the claims of Groups I or III.

The invention of Group III includes the special technical feature of a transparent tube and an indicator movably positioned within the tube, not required by the claims of Groups I-II.

COMMON TECHNICAL FEATURES

Groups I and III share the common technical feature of a syringe having a barrel and a plunger movable through the barrel. However, this shared technical feature does not represent a contribution over prior art as being anticipated by US 5,788,463 A (CHAN) (hereinafter Chan), which discloses a syringe (10; Fig. 1-10; col 4 in 66 to col 5 in 20) having a barrel (50; Fig. 1-10; col 5 in 21-23) and a plunger movable through the barrel (60; Fig. 1-10; col 5 in 21-23).

Groups II-III share the common technical feature of a vacuum indicator. However, this shared technical feature does not represent a contribution over prior art as being anticipated by Chan, which discloses a vacuum indicator (15; Fig. 1-10; col 8 in 36-50).

As the common technical features were known in the art at the time of the invention, these cannot be considered special technical features that would otherwise unify the groups.

Therefore, Groups I-III lack unity under PCT Rule 13 because they do not share a same or corresponding special technical feature.

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To: MATTHEW S. WILLIAMS PERKINS COIE LLP P.O. BOX 1247 SEATTLE, WA 98111-1247
RECEIVED PATENT DOCKETING JAN 25 2022 PERKINS COIE LLP

Date of mailing (day/month/year)	JAN 20 2022
FOR FURTHER ACTION See paragraph 2 below	
Applicant's or agent's file reference 111552-8025WO00	
International application No. PCT/US 21/45072	International filing date (day/month/year) 06 August 2021 (06.08.2021)
Priority date (day/month/year) 06 August 2020 (06.08.2020)	
International Patent Classification (IPC) or both national classification and IPC IPC - A61M 5/32; A61M 5/315 (2021.01) CPC - A61M 5/32; A61M 5/502; A61M 5/3243; A61M 5/150641; A61M 5/3234; A61M 5/3232; A61M 5/5013; A61M 2005/5026; A61M 2005/3247; A61M 2005/3223; A61M 5/315	
Applicant INARI MEDICAL, INC.	

1. This opinion contains indications relating to the following items:	
☒	Box No. I Basis of the opinion
☐	Box No. II Priority
☐	Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☒	Box No. IV Lack of unity of invention
☒	Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement
☐	Box No. VI Certain documents cited
☐	Box No. VII Certain defects in the international application
☐	Box No. VIII Certain observations on the international application
2. FURTHER ACTION	
If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.	
If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.	
For further options, see Form PCT/ISA/220.	

Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Date of completion of this opinion 2 December 2021	Authorized officer Kari Rodriguez PCT Help Desk Telephone No. 571-272-4300
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Form PCT/ISA/237 (cover sheet) (revised January 2019)

INARI_018963

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US 21/45072

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of:
 - ☒ the international application in the language in which it was filed.
 - ☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).
2. ☐ This opinion has been established taking into account the rectification of an obvious mistake authorized by or notified to this Authority under Rule 91 (Rule 43bis.1(b)).
3. ☐ With regard to any nucleotide and/or amino acid sequence disclosed in the international application, this opinion has been established on the basis of a sequence listing:
 - a. ☐ forming part of the international application as filed:
 - ☐ in the form of an Annex C/ST.25 text file.
 - ☐ on paper or in the form of an image file.
 - b. ☐ furnished together with the international application under PCT Rule 13ter.1(a) for the purposes of international search only in the form of an Annex C/ST.25 text file.
 - c. ☐ furnished subsequent to the international filing date for the purposes of international search only:
 - ☐ in the form of an Annex C/ST.25 text file (Rule 13ter.1(a)).
 - ☐ on paper or in the form of an image file (Rule 13ter.1(b) and Administrative Instructions, Section 713).
4. ☐ In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that forming part of the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
5. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US 21/45072

Box No. IV Lack of unity of invention

1. ☐ In response to the invitation (Form PCT/ISA/206) to pay additional fees the applicant has, within the applicable time limit:
- ☐ paid additional fees.
 - ☐ paid additional fees under protest and, where applicable, the protest fee.
 - ☐ paid additional fees under protest but the applicable protest fee was not paid.
 - ☒ not paid additional fees.

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

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

- ☐ complied with.
- ☒ not complied with for the following reasons:

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be searched, the appropriate additional search fees must be paid.

Group I: Claims 1-15 directed to an automatically-locking syringe.

Group II: Claims 16-20 directed to a clot treatment system.

Group III: Claims 21-28 directed to a syringe having a barrel and a vacuum indicator having a transparent tube and an indicator with a visual characteristic.

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

SPECIAL TECHNICAL FEATURES

The invention of Group I includes the special technical feature of a lock plate, not required by the claims of Groups II-III.

The invention of Group II includes the special technical feature of a catheter, not required by the claims of Groups I or III.

The invention of Group III includes the special technical feature of a transparent tube and an indicator movably positioned within the tube, not required by the claims of Groups I-II.

COMMON TECHNICAL FEATURES

Groups I and III share the common technical feature of a syringe having a barrel and a plunger movable through the barrel. However, this shared technical feature does not represent a contribution over prior art as being anticipated by US 5,788,463 A (CHAN) (hereinafter Chan), which discloses a syringe (10; Fig. 1-10; col 4 ln 66 to col 5 ln 20) having a barrel (50; Fig. 1-10; col 5 ln 21-23) and a plunger movable through the barrel (60; Fig. 1-10; col 5 ln 21-23).

Groups II-III share the common technical feature of a vacuum indicator. However, this shared technical feature does not represent a contribution over prior art as being anticipated by Chan, which discloses a vacuum indicator (15; Fig. 1-10; col 8 ln 36-50).

As the common technical features were known in the art at the time of the invention, these cannot be considered special technical features that would otherwise unify the groups.

Therefore, Groups I-III lack unity under PCT Rule 13 because they do not share a same or corresponding special technical feature.

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

- ☐ all parts.
- ☒ the parts relating to claims Nos. 1-15

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/US 21/45072

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

1. Statement

Novelty (N)	Claims	1-15	YES
	Claims	None	NO
Inventive step (IS)	Claims	1-15	YES
	Claims	None	NO
Industrial applicability (IA)	Claims	1-15	YES
	Claims	None	NO

2. Citations and explanations:

Claims 1-15 meet the criteria of PCT Article 33(2)-(3) because as will be shown, the prior art does not teach nor fairly suggest the claimed limitations.

The prior art is exemplified by (1) US 2013/0126559 A1 (COWAN et al.) (hereinafter Cowan); (2) US 2004/0122359 A1 (WENZ et al.) (hereinafter Wenz); and (3) WO 2011/073176 A1 (NOVARTIS AG) (hereinafter Novartis).

(1) Cowan teaches an automatically-locking syringe (8; Fig. 1-2; para [0028]), comprising:
a barrel (10; Fig. 1-2; para [0028]);
a plunger slidably positioned within the barrel (16; Fig. 1-2; para [0028]),
wherein the plunger is movable between a depressed position and a withdrawn position (depression and withdrawing action of 16 within 10; Fig. 1-2; para [0028]), and
wherein the plunger includes a lock feature (ratchet teeth upon 16; Fig. 1-2; para [0028]); and
a lock plate coupled to the barrel (18; Fig. 1-2; para [0028]),
wherein the lock plate includes a biasing member configured to bias the lock plate to a locking position (30; Fig. 1-2; para [0035]).

(2) Wenz teaches a syringe (Fig. 7; para [0063]-[0066]), comprising:
a barrel (unlabeled barrel through which 5 extends; Fig. 7; para [0064]),
a plunger (5; Fig. 7; para [0064]),
a lock plate (31, 32, 33, 34; Fig. 7; para [0064]-[0066]),
said lock plate having an opening extending therethrough (opening of 31, 32, 33, 34 through which 5 extends; Fig. 7),
wherein the plunger is slidably positioned in the opening (5 extending through opening of 31, 32, 33, 34; Fig. 7).

(3) Novartis teaches a syringe (2; Fig. 1-3; pg 6 in 33 to pg 7 in 2), comprising:
a first arm (22; Fig. 1-3; pg 7 in 20-28),
a second arm (24; Fig. 1-3; pg 7 in 20-28),
wherein the first arm is configured to be biased at least partially outwardly away from the longitudinal axis of the plunger to a locking position (outward bias of 22 away from 18; Fig. 1-3; pg 6 in 25 to pg 9 in 3).

.* See Supplemental Box .*

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US 21/45072

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

- Box V.2 - Citations and explanations -.

As pertaining to claim 1, Cowan teaches an automatically-locking syringe (8; Fig. 1-2; para [0028]), comprising:
a barrel (10; Fig. 1-2; para [0028]);
a plunger slidably positioned within the barrel (16; Fig. 1-2; para [0028]),
wherein the plunger is movable between a depressed position and a withdrawn position (depression and withdrawing action of 16 within 10; Fig. 1-2; para [0028]), and
wherein the plunger includes a lock feature (ratchet teeth upon 16; Fig. 1-2; para [0028]); and
a lock plate coupled to the barrel (18; Fig. 1-2; para [0028]),
wherein the lock plate includes a biasing member configured to bias the lock plate to a locking position (30; Fig. 1-2; para [0035]);
but is silent wherein comprising:
said lock plate having an opening extending therethrough,
wherein the plunger is slidably positioned in the opening,
wherein-
when the plunger is moved from the depressed position to the withdrawn position, the lock feature is configured to engage the lock plate to drive the lock plate to a position away from the locking position to thereby permit the lock feature to pass through the opening, and
after the lock feature passes through the opening, the biasing member is configured to drive the lock plate to the locking position to inhibit movement of the plunger from the withdrawn position to the depressed position.
Further, Wenz teaches a syringe (Fig. 7; para [0063]-[0066]), comprising:
a barrel (unlabeled barrel through which 5 extends; Fig. 7; para [0064]),
a plunger (5; Fig. 7; para [0064]),
a lock plate (31, 32, 33, 34; Fig. 7; para [0064]-[0066]),
said lock plate having an opening extending therethrough (opening of 31, 32, 33, 34 through which 5 extends; Fig. 7),
wherein the plunger is slidably positioned in the opening (5 extending through opening of 31, 32, 33, 34; Fig. 7),
but the prior art does not teach nor fairly suggest: when the plunger is moved from the depressed position to the withdrawn position, the lock feature is configured to engage the lock plate to drive the lock plate to a position away from the locking position to thereby permit the lock feature to pass through the opening, and
after the lock feature passes through the opening, the biasing member is configured to drive the lock plate to the locking position to inhibit movement of the plunger from the withdrawn position to the depressed position.
The lock plate as claimed by the Applicant is driven away to prevent depression movement of the plunger through the barrel. There exists no motivation without benefit of hindsight for modification of the syringe of Cowan as modified by Wenz such the plunger is inhibited from depression movement as opposed to withdrawing movement, such that the claimed limitations are met.

As pertaining to claims 2-9, the prior art does not teach nor fairly suggest the claimed limitations, because claims 2-9 depend from claim 1.

As pertaining to claim 10, Wenz teaches an automatically-locking syringe (Fig. 7; para [0063]-[0066]), comprising:
a barrel (unlabeled barrel through which 5 extends; Fig. 7; para [0064]) including a flange (14; Fig. 7; para [0064]);
a plunger slidably positioned within the barrel (5; Fig. 7; para [0064]),
wherein the plunger is aligned along a longitudinal axis (longitudinal alignment of 5; Fig. 7), and
wherein the plunger is movable along the longitudinal axis between a depressed position and a withdrawn position (movement of 5 through unlabeled barrel; Fig. 7; para [0064]);
a lock member coupled to the plunger (31, 32, 33, 34; Fig. 7; para [0064]-[0066]),
wherein the lock member includes a body (body of 31; Fig. 7; para [0064]);
but is silent wherein:
the lock member includes a first arm hingedly coupled to the body,
wherein the first arm is configured to be biased at least partially outwardly away from the longitudinal axis of the plunger to a locking position; and
an actuator including a second arm,
wherein the actuator is movable between a first position and a second position, and
wherein the second arm is configured to engage the first arm in the second position to drive the first arm inwardly toward the longitudinal axis away from the locking position.
Further, Novartis teaches a syringe (2; Fig. 1-3; pg 6 in 33 to pg 7 in 2), comprising:
a first arm (22; Fig. 1-3; pg 7 in 20-28),
a second arm (24; Fig. 1-3; pg 7 in 20-28),
wherein the first arm is configured to be biased at least partially outwardly away from the longitudinal axis of the plunger to a locking position (outward bias of 22 away from 18; Fig. 1-3; pg 8 in 25 to pg 9 in 3),
but the prior art does not teach nor fairly suggest employment of the elements of Novartis upon the syringe of Wenz such that the claimed limitations are met.
There exists no motivation without benefit of hindsight for employment of the first arm and second arm of Novartis upon the syringe of Wenz, such that the second arm engages directly with the first arm in order to unlock the plunger for withdrawing.

As pertaining to claims 11-15, the prior art does not teach nor fairly suggest the claimed limitations, because claims 11-15 depend from claim 10.

Claims 1-15 have industrial applicability as defined by PCT Article 33(4) because the subject matter can be made or used by industry.

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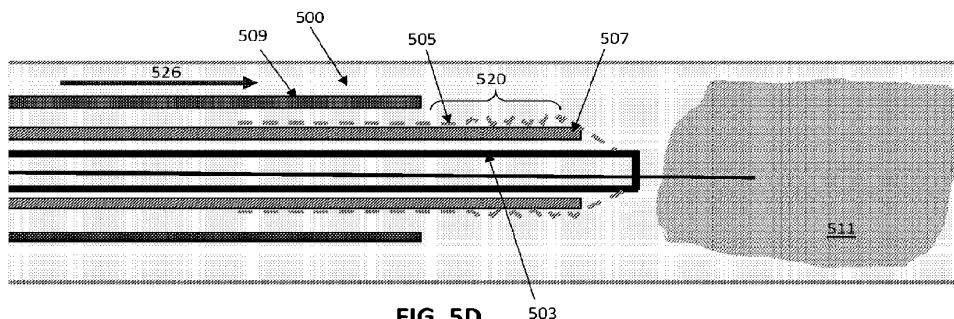


FIG. 5D

(57) Abstract: Inverting tube thrombectomy apparatus for removing clot that are configured to prevent compression of the apparatus that may separate the distal end of the apparatus from the clot and may make it difficult to advance the apparatus to engage with the clot, particularly in a tortuous vessel. The apparatuses and methods of using them described herein may be adapted to prevent tension in the flexible tube that is rolling and inverting over the distal end of the inversion support catheter when capturing a clot. Also described herein are inverting tube thrombectomy apparatus that are configured to reload either automatically or manually within the vessel to capture additional clot material.

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INARI_018968

INVERTING THROMBECTOMY APPARATUSES AND METHODS OF USE

FIELD

[0001] The apparatuses and methods described herein relate to mechanical removal of objects from within a body. In particular, described herein are mechanical thrombectomy apparatuses and methods.

BACKGROUND

[0002] Many vascular problems stem from insufficient blood flow through blood vessels. One causes of insufficient or irregular blood flow is a blockage within a blood vessel referred to as a blood clot, or thrombus. Thrombi can occur for many reasons, including after a trauma such as surgery, or due to other causes. For example, a large percentage of the more than 1.2 million heart attacks in the United States are caused by blood clots (thrombi) which form within a coronary artery. It is often desirable to remove tissue from the body in a minimally invasive manner as possible, so as not to damage other tissues. For example, removal of tissue, such as blood clots, from within a patient's vasculature may improve patient conditions and quality of life.

[0003] Mechanical thrombectomy devices may be particularly advantageous. There is a definite need for thrombectomy devices, and particularly a mechanical thrombectomy devices that can be easily and accurately delivered through the often tortious anatomy in the peripheral and central vasculature, then reliably deployed to remove clot material. Further, there is a need for devices that are easy and intuitive to operate. Described herein are apparatuses (devices, systems and kit) and methods of using them that may address the needs and problems discussed above.

SUMMARY OF THE DISCLOSURE

[0004] Described herein are mechanical thrombectomy apparatuses (devices, systems, etc.) and methods of using and making them. These apparatuses may also be referred to as inverting mechanical thrombectomy apparatuses and/or inverting tube thrombectomy apparatuses.

[0005] In particular, described herein are inverting tube thrombectomy apparatuses that may be deployed within even the most tortious vessels of the anatomy and may maintain their proximity to the clot during operation. Generally, the inverting tube thrombectomy

apparatuses described herein may include an inner puller (which may be configured as a puller catheter), an inverting flexible tube attached at a distal end region of the puller, and an outer inversion support catheter; the flexible tube may initially extend over an external region at the distal end of the inversion support catheter. All or a portion of the inversion support catheter, flexible tube and puller may be housed within an intermediate (e.g., delivery) catheter. In operation, the puller may be pulled to roll and invert the flexible tube over the open distal end of the inversion support catheter. This rolling and inversion of the flexible tube may capture a material, such as a clot, and pull it into the inner lumen of the inversion support catheter as the flexible tube is rolled and inverted.

[0006] Specifically, the inverting tube thrombectomy apparatuses and methods of operating them may prevent or reduce compression of the distal end of the inversion support catheter that may otherwise separate the end of the apparatus from the clot (e.g., kick back) and make further tracking of the apparatus within a tortious vessel difficult. Thus, in some variations of inverting tube thrombectomy apparatuses, pulling on the inverting tube (e.g., woven/braided/etc. tractor) compresses the distal end of the inversion support catheter (particularly in tortious anatomy), and causes it to separate from the clot and make additional tracking difficult within the tortious vessel.

[0007] Thus, any of the apparatuses described herein may be configured to prevent tension in the external portion of the flexible tube that is on the outer surface of the inversion support catheter before and/or during rolling and inverting the flexible tube over the distal end of the inversion support catheter.

[0008] Also described herein are methods for removing a clot (or multiple portions of a clot, or multiple clots) from a vessel. For example, a method of removing a clot from a vessel may include: advancing an inverting tube thrombectomy apparatus through a vessel until a distal end of the inverting tube thrombectomy apparatus is proximate to the clot, wherein the inverting tube thrombectomy apparatus comprises an inversion support catheter, a puller catheter slideable within a lumen of the inversion support catheter, and a flexible tube having a first end coupled at a distal end region of the puller catheter and a second end coupled to the inversion support catheter; applying aspiration through a lumen in the puller catheter to hold the clot on a distal end of the puller catheter; pushing the inversion support catheter distally to form slack in the flexible tube; and pulling the puller catheter proximally relative to the inversion support catheter to roll and invert the inversion support catheter over the distal end of the inversion support catheter and pull the clot into the inversion support

catheter. This process may be repeated multiple times without removing the apparatus from the vessel.

[0009] For example, described herein are methods of removing a clot from a vessel, the method comprising: advancing an inverting tube thrombectomy apparatus through a vessel until a distal end of the inverting tube thrombectomy apparatus is proximate to the clot, wherein the inverting tube thrombectomy apparatus comprises an inversion support catheter, a puller catheter slideable within a lumen of the inversion support catheter, and a flexible tube having a first end coupled at a distal end region of the puller catheter and a second end coupled to the inversion support catheter; applying aspiration through a lumen of the puller catheter to hold the clot on a distal end of the puller catheter; pushing the inversion support catheter distally to expand the flexible tube radially outward; pulling the puller catheter proximally while advancing the inversion support catheter distally to roll and invert the inversion support catheter over the distal end of the inversion support catheter and pull the clot into the inversion support catheter; and pulling the clot proximally through the lumen of the puller catheter.

[00010] Thus, pushing the inversion support catheter distally to form slack in the flexible tube may include expanding the flexible tube radially outward from the puller catheter.

[00011] Any of these methods may include pulling the clot proximally through the lumen of the puller catheter. For example, pulling the clot proximally through the lumen of the puller catheter may comprise aspirating the clot through the puller catheter, and/or using a wire to draw the clot proximally through the lumen of the puller catheter.

[00012] Any of these methods may include reloading the inverting tube thrombectomy apparatus while still in the vessel so that additional clot may be removed with the same device. Thus, any of these methods may include removing a second clot with the inverting tube thrombectomy apparatus. Reloading the inverting tube thrombectomy apparatus may comprise advancing the puller catheter distally relative to the inversion support catheter. Reloading may be done automatically or manually. For example, advancing the puller catheter distally may releasing the puller catheter so that a bias advances the puller catheter distally (e.g., automatically or semi-automatically).

[00013] In any of these methods, pulling the puller catheter proximally may comprise applying vacuum through the lumen of the puller catheter. Vacuum may be applied through the entire procedure (e.g., continuously) or through just a portion of the procedure, e.g., when drawing the clot proximally through the lumen of the puller catheter.

[00014] Any of these methods may include the use of an inverting tube thrombectomy apparatus that includes an intermediate catheter; the inversion support catheter and the puller catheter may be held (slidably held) within the intermediate catheter for delivery and may be extended from the intermediate catheter when the distal end is near the clot.

[00015] For example, in some variations, the apparatus and/or method of using it may be configured to form slack in an external portion of the flexible tube on the outer surface of the inversion support catheter. Slack may be formed by driving the second end of the flexible tube (that may not be attached to anything, including the intermediate catheter or the inversion support catheter) distally over the inversion support catheter. In some variations the second end of the flexible tube may be held between the inversion support catheter outer surface and the intermediate catheter. For example, in an un-deployed state, the inverting tube thrombectomy apparatus may be tracked through the vasculature with most of the flexible tube, inversion support catheter and puller housed within the intermediate catheter. This assembly may be tracked through the vasculature over a guidewire, for example, in some variations, the puller and the attached first end of the flexible tube may be extended slightly out of the distal end of the intermediate catheter. Once deployed at the clot, the intermediate catheter may be withdrawn proximally (or the pusher, flexible tube and/or inversion support catheter extended distally out of the intermediate catheter) but leaving a portion of the second end of the flexible tractor between the intermediate catheter and the inversion support catheter; advancing the intermediate catheter distally may then bunch up (form slack) the flexible tube. The pusher may be held fixed, advanced distally or (in the variation described below, pulled proximally). Alternatively, in some variations the intermediate catheter may be fully removed from over the flexible tube and advancing it distally may push on the end of the flexible tube (which may include a cuff), to drive the flexible tube distally. The second end of the flexible tube may be adapted so that it may be pushed by the intermediate catheter. As mentioned, the second end of the flexible tube may include a cuff, which may be a region of relative stiffness compared to the adjacent region of the flexible tube.

[00016] In some variations, apparatus and method are configured to both push on the second end of the flexible tube distally, and pull on the first end by pulling the puller (e.g., puller catheter) proximally. This may limit or reduce tension on the outside portion of the tractor. Thus, in any of these methods, the intermediate catheter may be pushed distally at the same time the puller is pulled proximally (at the same, or different rates) to reduce tension on the outside portion of the flexible tube, thereby reducing the compressive force applied to the distal end of the inversion support catheter.

[00017] For example, described herein are method of removing a clot from a vessel that may include: advancing an inverting tube thrombectomy apparatus through a vessel until a distal end of the inverting tube thrombectomy apparatus is proximate to the clot, wherein the inverting tube thrombectomy apparatus comprises an intermediate catheter, an inversion support catheter within a lumen of the intermediate catheter, a puller within a lumen of the inversion support catheter, and a flexible tube having a first end coupled at a distal end region of the puller, wherein flexible tube inverts over a distal end of the inversion support catheter and an external portion of the flexible tube extends proximally over the inversion support catheter; positioning the puller and inversion support catheter adjacent to the clot; and pushing a proximal end region of the external portion of the flexible tube distally over the inversion support catheter during one or both of: before or while pulling the puller proximally so that the external portion of the flexible tube rolls and inverts over the distal end of the inversion support catheter.

[00018] Pushing the proximal end region of the external portion of the flexible tube may include pushing the proximal end region of the external portion of the flexible tube by advancing the intermediate catheter distally. Alternatively or additionally, the proximal end region of the external portion of the flexible tube (which may be referred to as the second end of the flexible tube) may be pushed by a different member, such as a push wire or rod.

[00019] In some variations, pushing the proximal end region of the external portion of the flexible tube comprises pushing the proximal end region of the external portion of the flexible tube before pulling the puller proximally to form slack in the external portion of the flexible tube. Slack may refer to a region in which the flexible tube is not under tension, and may be loose; in some variations the slack region may be bunched up on itself. In some variations the slack region may be compressed, so that it expands (e.g., when pulled from the first end) easily.

[00020] In some variations, pushing the proximal end region of the external portion of the flexible tube comprises pushing the intermediate catheter distally to push the proximal end region of the external portion of the flexible tube distally while pulling the puller proximally, wherein the flexible tube is not attached to the intermediate catheter.

[00021] In any of the apparatuses and methods described herein, the flexible tube may be unattached to the intermediate catheter. For example, the second end of the flexible tube may be loose.

[00022] In any of the methods and apparatuses described herein, a vacuum may be applied through the puller. Thus, the apparatus, and particularly the puller, may be adapted to include

a lumen or passage for applying suction. This suction may be used to pull the clot out from the flexible tube once it has been all or partially engulfed, e.g., by the flexible tube.

[00023] In general, any of the methods described herein may include capturing the clot within the flexible tube as the puller is pulled proximally.

[00024] For example, a method of removing a clot from a vessel may include: advancing an inverting tube thrombectomy apparatus through a vessel until a distal end of the inverting tube thrombectomy apparatus is proximate to the clot, wherein the inverting tube thrombectomy apparatus comprises an intermediate catheter, an inversion support catheter within a lumen of the intermediate catheter, a puller within a lumen of the inversion support catheter, and a flexible tube having a first end coupled at a distal end region of the puller, wherein flexible tube inverts over a distal end of the inversion support catheter and an external portion of the flexible tube extends proximally over the inversion support catheter; positioning the puller and inversion support catheter adjacent to the clot; forming slack in the external portion of the flexible tube; and pulling the puller proximally so that the external portion of the flexible tube rolls and inverts over the distal end of the inversion support catheter so that the slack in the external portion of the flexible tube is withdrawn into the inversion support catheter.

[00025] In any of these methods pulling the puller proximally may comprise withdrawing all or a majority of the slack into the inversion support catheter before a second end of the flexible tube is moved distally over the inversion support catheter. For example, pulling the puller proximally may comprise withdrawing the slack into the inversion support catheter while applying 1 pound or less of force (e.g., applying 0.75 or less pounds of force, applying 0.5 pounds or less of force, applying 0.4 pounds or less of force, applying 0.3 pounds or less of force, applying 0.25 pounds or less of force, applying 0.2 pounds or less of force, applying 0.1 pound or less of force, etc.) proximally against the distal end of the inversion support catheter.

[00026] In any of the methods described herein, pulling the puller proximally may comprise withdrawing the slack into the inversion support catheter without causing the distal end of the inversion support catheter to withdraw from the clot within the vessel. Thus, the methods described herein may prevent the kickback (e.g., separation from the clot) described above.

[00027] Forming slack may comprise advancing the intermediate tube distally to push at least part of the external portion of the flexible tube distally to form slack in the external portion of the flexible tube over the inversion support catheter. For example, forming slack

may comprise axially compressing the external portion of the flexible tube on the inversion support catheter by driving the second end of the flexible tube distally. Forming slack may include driving a second end of the flexible tube distally without moving the puller proximally.

[00028] For example, a method of removing a clot from a vessel may include: advancing an inverting tube thrombectomy apparatus through a vessel until a distal end of the inverting tube thrombectomy apparatus is proximate to the clot, wherein the inverting tube thrombectomy apparatus comprises an intermediate catheter, an inversion support catheter within a lumen of the intermediate catheter, a puller within a lumen of the inversion support catheter, and a flexible tube having a first end coupled at a distal end region of the puller, wherein flexible tube inverts over a distal end of the inversion support catheter and an external portion of the flexible tube extends proximally over the inversion support catheter; positioning the puller and inversion support catheter adjacent to the clot; advancing the intermediate tube distally relative to the pusher to push at least part of the external portion of the flexible tube distally to form slack in the external portion of the flexible tube over the inversion support catheter; pulling the puller proximally so that the external portion of the flexible tube rolls and inverts over the distal end of the inversion support catheter so that the slack in the external portion of the flexible tube is withdrawn into the inversion support catheter; and capturing the clot with the rolling flexible tube to draw the clot into the inversion support catheter.

[00029] Any of the methods described herein may include reducing the tension on the flexible tube (and particularly the portion of the flexible tube that rolls and inverts over the distal end of the inversion support catheter). For example, a method of removing a clot from a vessel may include: advancing an inverting tube thrombectomy apparatus through a vessel until a distal end of the inverting tube thrombectomy apparatus is proximate to the clot, wherein the inverting tube thrombectomy apparatus comprises an intermediate catheter, an inversion support catheter within a lumen of the intermediate catheter, a puller within a lumen of the inversion support catheter, and a flexible tube having a first end coupled at a distal end region of the puller, wherein flexible tube inverts over a distal end of the inversion support catheter and an external portion of the flexible tube extends proximally over the inversion support catheter; and positioning the puller and inversion support catheter adjacent to the clot; and pushing a proximal end region of the external portion of the flexible tube distally over the inversion support catheter while pulling the puller proximally so that the

external portion of the flexible tube rolls and inverts over the distal end of the inversion support catheter.

[00030] In some variations, pushing the proximal end region of the external portion may comprise pushing the intermediate catheter distally to drive the proximal end region of the external portion distally.

[00031] Also described herein are apparatuses, including in systems, for removing a clot. For example the apparatus comprising: an intermediate catheter; an inversion support catheter within a lumen of the intermediate catheter; a puller within a lumen of the inversion support catheter; a flexible tube having a first end coupled at a distal end region of the puller, wherein flexible tube inverts over a distal end of the inversion support catheter and an external portion of the flexible tube extends proximally over the inversion support catheter; and a handle coupled to the intermediate catheter and the puller, wherein the handle is configured to, when activated by a control on the handle, automatically advance the intermediate catheter while one or more of: holding the puller fixed or withdrawing the puller proximally as the intermediate catheter is advanced.

[00032] The methods and apparatuses described herein may alternatively or additionally include automatic reloading. For example, described herein are apparatuses and methods of using them that automatically reload the flexible tube after it has been inverted and rolled into the inversion support catheter, so that additional (or a different) clot may be captured. Clot that has already been captured within the inverted flexible tube may be removed proximally through the puller (e.g., puller catheter), using a vacuum and/or a wire within the puller. This may allow the device to be repeatedly used to remove clot without requiring the device to be removed from the body. Thus, the apparatus may repeatedly peck or bite at a clot by repeatedly rolling and inverting the flexible tube into the inversion support catheter, clearing the portion of the clot captured from the flexible tube into the puller, then automatically and/or manually everting the flexible tube back over the distal end and out of the inversion support catheter. In some variations the inversion support catheter may include a narrower inner diameter region near the distal end than more proximal regions, so that the flexible tube within the inversion support catheter may expand outwards slightly more proximally within the inversion support catheter, which may help release the compressed clot from the flexible tube. In some variations, the flexible tube may be lubricious (e.g., coated, etc.) within the inverted configuration (e.g., within the inversion support catheter). The suction through the puller be applied continuously or intermittently. The suction pressure may be monitored to confirm removal of the clot from the flexible tube before re-setting.

[00033] For example, described herein are methods of removing clot from a vessel, the method comprising: advancing an inverting tube thrombectomy apparatus through a vessel until a distal end of the inverting tube thrombectomy apparatus is proximate to the clot, wherein the inverting tube thrombectomy apparatus comprises an intermediate catheter, an inversion support catheter within a lumen of the intermediate catheter, a puller within a lumen of the inversion support catheter, and a flexible tube having a first end coupled at a distal end region of the puller, wherein flexible tube inverts over a distal end of the inversion support catheter and an external portion of the flexible tube extends proximally over the inversion support catheter; and positioning the puller and inversion support catheter adjacent to the clot; pulling the puller proximally to roll the external portion of the flexible tube over a distal end of the inversion support catheter so that it inverts and is drawn into the inversion support catheter, capturing clot and pulling clot material into the inversion support catheter; applying a vacuum through the puller to suction the clot proximally through the puller; and pulling a second end of the flexible tube proximally to roll and evert the external portion of the flexible tube over the distal end of the inversion support catheter so that it extends proximally over the inversion support catheter.

[00034] In some variations, the method may repeat the step to remove additional clot. For example, the method may include repeating (e.g., cycling) one or more times, the steps of pulling the puller, applying the vacuum and pulling the second end of the flexible tube to remove additional clot material.

[00035] In any of these methods, applying the vacuum may comprise turning the vacuum on while or after the puller is pulled proximally. Pulling the second end of the flexible tube may comprise releasing the puller to allow a bias force to pull the second end of the flexible tube proximally.

BRIEF DESCRIPTION OF THE DRAWINGS

[00036] The novel features of the invention are set forth with particularity in the claims that follow. A better understanding of the features and advantages of the present invention will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the invention are utilized, and the accompanying drawings of which:

[00037] FIG. 1A illustrates one example of an intermediate catheter (“delivery catheter” or I.C.) that may be used with a mechanical thrombectomy apparatus as described herein.

[00038] FIGS. 1B-1C2 illustrate components of a mechanical thrombectomy apparatus (also referred to herein as an inverting tube thrombectomy apparatus); FIG. 1B shows an example of an elongate inversion support catheter that is configured to include a plurality of slots (shown here as transverse slots) arranged along the catheter in order to enhance flexibility of the elongate inversion support catheter while providing sufficient column strength to resist buckling as the tractor tube is drawn proximally to invert. The slot pattern of FIG. 1B is intended as a single example only. Other slot/cut-out patterns may be used. FIGS. 1C1 and 1C2 show a flexible tubes attached to a puller (e.g., puller catheter in FIG. 1C1, or puller wire in FIG. 1C2). The flexible tubes are shown attached at a first end to a distal end region of the puller; in FIG. 1C1 the puller is a puller catheter (PMC) while in FIG. 1C2 the puller is a guidewire. The flexible tube is shown schematically and may be a knitted, woven, or braided material.

[00039] FIGS. 2A-2C illustrate the operation of an inverting tractor mechanical thrombectomy apparatus (e.g., inverting tube thrombectomy apparatus) as described above. FIG. 2A shows the assembled apparatus in which the flexible tube is coupled to the puller and within the elongate inversion support catheter with the flexible tube inverting over the distal end of the elongate inversion support catheter. FIG. 2B shows the apparatus of FIG. 2A delivered within a vessel near a clot. FIG. 2C shows the operation of the apparatus to withdraw the clot by pulling proximally on the flexible tube from within the elongate inversion support catheter so that the flexible tube is pulled to roll over and evert from the inverted configuration on the outside of the distal end of the elongate inversion support catheter into the un-inverted configuration within the elongate inversion support catheter, pulling the clot with it.

[00040] FIG. 3A is an example of a preloaded assembly of an inverting tube thrombectomy apparatus including an intermediate catheter that may be used as described in order to the apparatus through a tortuous vessel to a clot location. In this example, all of the other components of the inverting tube thrombectomy apparatus (elongate inversion support catheter) may be held within the intermediate catheter (and may be locked in this position) until deployed, while the pusher (e.g., PMC) and flexible tube are partially extending distally. A guidewire may also be used.

[00041] FIG. 3B shows the inverting tube thrombectomy apparatus of FIG. 3A with the inversion support catheter advanced distally.

[00042] FIGS. 4A-4B illustrate one example of an inverting tube thrombectomy apparatus within a tortuous anatomy that may pull away from the clot when deploying the flexible tube

(e.g., when rolling the flexible tube over the distal end and into the inversion support catheter. In FIG. 4A, the inverting tube thrombectomy apparatus is positioned adjacent to the clot. In FIG. 4, in the tortuous anatomy, once the puller is pulled proximally to invert the flexible tube (also referred to herein as the tractor tube) over the distal end of the inversion support catheter, the inverting tube thrombectomy apparatus, and particularly the inversion support catheter, may compress, causing the distal face of the flexible tube and the elongate support catheter to pull away from the clot. In a tortuous anatomy, such as shown in FIGS. 4A-4B, it may be particularly difficult to advance the apparatus back to the clot (and forward), particularly while the puller pulling the flexible tube over the distal end of the inversion support catheter applies a proximal force against the inversion support catheter.

[00043] FIGS. 4C and 4D illustrate another example of the 'kickback' that may occur in an inverting tube thrombectomy apparatus which may be difficult to correct for in a tortuous vessel. In FIG. 4C the inverting tube thrombectomy apparatus (e.g., the distal face of the puller, attached flexible tube and/or inversion support catheter) is positioned adjacent to the clot. In FIG. 4D the puller is withdrawn proximally, rolling the flexible tube over the distal end of the inversion support catheter and into the lumen of the inversion support catheter. In this example, pulling the flexible tube over the distal end moves the distal end away from the clot.

[00044] FIGS. 5A-5L illustrate one example of a method of operating an inverting tube thrombectomy apparatus to remove a clot that alleviates the tension (compressive force) applied by pulling the flexible tube over the distal end opening of the inversion support catheter, preventing the separation of the inverting tube thrombectomy apparatus from the clot. In this example, the method includes forming slack in an external portion of the flexible tube prior to pulling the puller proximally to roll the flexible tube and invert it over the distal end face of the inversion support catheter.

[00045] FIGS. 6A-6C illustrate an example of a method for removing a clot using an inverting tube thrombectomy apparatus that prevents pull back of the end of the inverting tube thrombectomy apparatus from the clot. In this example, the method includes reducing tension in flexible tube as it is rolled and inverted over the distal end of the inversion support catheter by introducing slack (in this example, compressing the flexible tube) prior to rolling and inverting the flexible tube over the distal end face of the inversion support catheter.

[00046] FIGS. 7A-7B illustrate an example of a method of removing a clot using an inverting tube thrombectomy apparatus that prevents pull back of the end of the inverting tube thrombectomy apparatus from the clot. In this example, the method includes

coordinating pushing the second (unattached) end of the flexible tube distally (e.g., by pushing on the intermediate catheter) and pulling the puller proximally.

[00047] FIG. 8 is an example of an inverting tube thrombectomy apparatus that is configured to automatically reload to remove multiple ‘bites’ of clot without needing to be removed from within the vessel. In FIG. 8, the inverting tube thrombectomy apparatus includes the flexible tube (e.g., a woven tube) a puller, and an inversion support catheter; a return bias (e.g., in this example, a coil spring) is attached to the second end of the flexible tube to reset the flexible tube on the outside of the inversion support catheter after it is rolled and inverted into the inversion support catheter and released.

[00048] FIGS. 9A-9D illustrate a method of removing a clot including automatically reloading the flexible tube without having to remove it from the vessel.

[00049] FIGS. 10A-10B show another example of an inverting tube thrombectomy apparatus that is configured to automatically reload to remove multiple ‘bites’ of clot without needing to be removed from within the vessel. FIG. 10A schematically illustrates an example of an inverting tube thrombectomy apparatus that includes a self-biased flexible tube that is coupled to an outer region of the inversion support catheter. FIG. 10B shows an example of an embodiment of the inverting tube thrombectomy apparatus including a self-biased flexible tube configured as a stacked braid.

[00050] FIGS. 11A-11F illustrate an example of a method of removing clot and automatically reloading the flexible tube without having to remove it from the vessel.

[00051] FIG. 12 is a schematic illustration (not to scale) of one variation of an apparatus for removing one or more clot(s) from a vessel. This apparatus may be configured to remove multiple clots by repeatedly withdrawing clot and resetting to an initial position; clot material may be withdrawn through the lumen of the puller catheter (e.g., inner catheter).

DETAILED DESCRIPTION

[00052] In general, described herein are inverting tube thrombectomy apparatus having a flexible tube, configured as an inverting flexible tube or an inverting tractor tube (“tractor tube”) that may be pulled proximally to invert over and into the distal end of an elongate inversion support catheter. An end of the tractor tube may be coupled to a puller (e.g., pull wire, pull catheter, etc.) to provide the proximal pulling force. In particular, described herein are apparatuses and methods of using them that improve or enhance the ease of use, including tracking of the apparatus within a tortuous vessel to remove a clot by rolling the flexible tube into the elongate inversion support catheter and grabbing the clot.

[00053] In general, the apparatus described herein may be configured to prevent compression of the apparatus (e.g., the inversion support catheter) when pulling the puller to roll and invert the flexible tube into the inversion support catheter, which may separate the distal end of the apparatus from the clot and may make it difficult to advance the apparatus to engage with the clot, particularly in a tortuous vessel. Any of the apparatuses described herein (and methods of using them) may be adapted to prevent tension in the flexible tube in the region of the flexible tube that is rolling and inverting over the distal end of the inversion support catheter. For example, tension may be reduced in the region of the flexible tube (the external portion of the flexible tube) by pushing from the second, usually loose or unattached, end of the flexible tube on the outside of the inversion support catheter. The flexible tube may be pushed by a member, including a dedicated wire, rod, etc., or by an outer or intermediate catheter. In some variations, the method may include pushing the end (e.g., the second end, opposite from the first end attached to the puller) of the flexible tube distally to form a slack region.

[00054] FIGS. 1A-C2 and 2A-2C illustrate examples of inverting tube thrombectomy apparatus and methods of operating them to remove a clot, respectively.

[00055] An inverting tube thrombectomy apparatus for removing a clot from a vessel may be a system, assembly or device including an inversion support catheter having a distal end and a distal annulus (distal end opening), and a flexible tube assembly (which may be referred to as a tractor tube or tractor tube assembly) including a flexible tube coupled to an elongate puller that is positioned within the elongate inversion support catheter. The flexible tube is configured to roll and invert over the distal end opening of the elongate inversion support catheter when pulled proximally by the puller. Knitted tractor tubes are of particular interest and described herein, although it should be understood that other tractor tubes, e.g., woven, braided, etc., may be used.

[00056] Tracking of any of the inverting tractor mechanical thrombectomy apparatus described herein may include an intermediate catheter (I.C.) as a delivery catheter along with a guidewire. For example, FIG. 1A illustrates an example of a typical intermediate catheter 101. Note that in some variations an intermediate catheter is not needed or used and the inverting tractor mechanical thrombectomy apparatus may be delivered to the deployment site near the clot to be removed without the need for an intermediate catheter.

[00057] FIG. 1B illustrates one example of an inversion support catheter. In this example, the elongated inversion support catheter 103 is formed of a normally high column-strength material (such as a metal, e.g. Nitinol) having a number openings (e.g., cut-out regions) or

slots along the length to provide enhanced flexibility. The distal end of the elongate inversion support catheter is open 105. Either the entire length or a portion of the length may be cut/slotted as described. The elongate inversion support catheter includes a catheter body having a distal end region that includes a distal end opening 105. The distal end region may have an increasing softness (measured by durometer, e.g., shore durometer) except that the very distal-most end region (distal end 105, including the distal end opening) may be substantially less soft than the region immediately proximate to it. Thus, although the distal tip region of the catheter (e.g., the distal most x linear dimensions, where x is 10 cm, 7 cm, 5 cm, 4 cm, 3 cm, 2 cm, 1 cm, 9 mm, 8 mm, 7 mm, 6 mm, 5 mm, 4 mm, 3 mm) has an increasing softness/decreasing hardness extending from the proximal to distal ends, the very distal end region 107 (e.g., measured as distal most z linear dimensions, where z is 1 cm, 9 mm, 8 mm, 7 mm, 6 mm, 5 mm, 4 mm, 3 mm, 2 mm, 1 mm, 0.8 mm, 0.5 mm, 0.3 mm, 0.2 mm, etc., and z is always at least three times less than x) has a hardness that is greater than the hardness of the region immediately proximal to it, and may be as hard or harder than the proximal-most region of the distal tip region.

[00058] In FIG. 1B, the elongate inversion support catheter is an elongate hollow catheter having a column strength that is sufficient to prevent buckling when the catheter is pulled over the distal annulus (distal end opening). Thus, the elongate inversion support may be configured so that it does not collapse (e.g., buckle) when 500 g or less of compressive force is applied (e.g., able to withstand at least about 500g, at least about 700 g, at least about 600 g, at least about 500 g, at least about 400 g, at least about 300 g, etc. of compressive force) for neurovascular applications. For peripheral vascular applications the elongate inversion support may be selected or configured to withstand at least 1500 g of compressive force (e.g., at least about 2000 g, 1900 g, 1800 g, 1700 g, 1600 g, 1500 g, 1400 g, etc. of compressive force). In general, any of the apparatuses described herein may include an elongate inversion support catheter that is not a full-length catheter, but may include a portion of a catheter, typically at the distal end, connected to a rod, wire, hypotube, or the like. In FIG. 1B the catheter 103 of the elongate inversion support catheter may be any appropriate type of catheter or portion of a catheter, including microcatheters appropriate for neurovascular use.

[00059] The inversion support catheter may be solid (e.g., may not include the cuts/slots shown in FIG. 1B).

[00060] In some variations the distal end 105 of the elongate inversion support catheter is adapted so that the tractor may slide or roll and invert over the distal end of the catheter without being caught (binding, jamming) or without substantial friction. For example, in

some variations the distal tip (end) may be curved or radiused, particularly on the outer surface (e.g., the transition from outer diameter to inner diameter).

[00061] FIG. 1C1 shows an example of a flexible tube 111 coupled to a puller 113, forming a pullable tractor assembly 140. In this example, the tractor tube 111 is shown integrated with the puller 113 and extending back over the puller. The puller in this example is a catheter (e.g. a micro catheter, also referred to herein as a PMC or pull micro catheter). In this example, the opposite end of the flexible tractor tube 111 is open and free (e.g., not connected to the puller or catheter, e.g. elongate inversion support catheter, intermediate catheter, etc.). This open, free, end may be adapted to be expanded and held open, e.g., by shape setting back on itself and/or by including an annular bias, to enhance deployment and positioning of the catheter between the flexible tractor tube and the puller. In FIGS. 1C1 and 1C2, the tractor tube is formed of material (e.g., wove, knitted, braided, etc.) that is flexible and elongate. The flexible tube 111 is shown extended from the puller in a first configuration. The relaxed outer diameter of the flexible tractor in this first configuration may have a greater outer diameter than the outer diameter of the catheter of the elongate inversion support into which the tractor will be positioned prior to inverting, or it may be approximately the same. The flexible and tubular tractor 111 may be sufficiently soft and flexible (e.g., having a low collapse strength) so as to easily roll and fold over the distal aperture of the elongate inversion support. The tractor 111 may be configured, e.g., by shape-setting (heat setting, etc.), to expand in the relaxed first configuration to a radial diameter that is between 1.1 and 10 times (e.g., between 1.1x and 5x, between 1.1x and 4x, etc.) the diameter of the inner diameter of the catheter of the elongate inversion support when unconstrained. In FIG. 1C2, the tractor tube 111 is shown coupled to a guidewire (non-hollow structure) 115. The tractor may be formed of a mesh, braided, woven, knitted, or sheet of material and is generally adapted to grasp the object to be removed (e.g., blood clot).

[00062] The flexible tubes (e.g., tractor tubes) described herein generally comprises a flexible tube of material that inverts over itself as it rolls over a distal end opening of an elongate inversion support. The flexible tube may be formed of a knitted material, and may be configured (e.g., sized, oriented, etc.) to roll smoothly over the distal end opening of the elongate inversion support catheter. The flexible tube may be configured so that it is doubly biased, in order to prevent jamming and to grab and compress relatively large clots as it rolls and inverts into the elongate inversion support catheter at the distal end opening of the elongate inversion support catheter; the flexible tube may be biased so that it has an expanded (e.g., relaxed) un-inverted configuration having an outer diameter that is approximately the

same or slightly larger than the inner diameter of the elongate inversion support catheter, which may be referred to as a second configuration of the flexible tube. The flexible tube may also be further biased so that it has an expanded (e.g., relaxed) inverted configuration (which may be referred to as a first configuration) having an inner and outer diameter that is larger than the outer diameter of the elongate inversion support catheter. The inner diameter in this first configuration may be greater than 1.2x (e.g., between 1.2x and 10x, between 1.2x and 8x, between 1.2x and 6x, between 1.2x and 5x, between 1.2x and 3x, etc.) the outer diameter of the inversion support catheter. Thus, when the flexible tube is placed in and over the distal end of the inversion support catheter, a first (inner) portion of the tractor tube is within the distal end of the elongate inversion support catheter in the un-inverted configuration and it is biased to expand towards (and in some configuration against) the inner diameter of the inversion support catheter; the region of the flexible tube that is inverted over the distal end opening of the inversion support catheter and extends proximally down the outside of the inversion support catheter is in an inverted configuration in which the inner diameter of the flexible tube is biased to be larger than the outer diameter of the inversion support catheter. This double-biased configuration may be a result of the weave pattern (e.g., knitting), and/or a shape setting of the material forming the tractor tube, which may be a shape memory material. As a result, the inverting portion of the flexible tube, where it rolls and inverts over itself at the distal end of the inversion support catheter may be prevented from collapsing on itself as the tractor tube is rolled and pulled into the inversion support catheter. In some variations this configuration may also result in a somewhat flattened (e.g., and in some cases “trumpet shaped”) distal end face that is rolling over the distal end opening of the elongate inversion support catheter. The trumpet-shaped distal end may have a teardrop-shaped cross-section. In some variations, the distal end face of the flexible tube may be T-shaped.

[00063] Also described herein are variations in which the first configuration of the flexible tube on the outside of the inversion support catheter (which may be referred to herein as an elongate inversion support catheter) may be flush or nearly flush with the outer diameter of the inversion support catheter, e.g., within 50%, 40%, 30%, 20%, etc. of the outer diameter of the inversion support catheter.

[00064] The flexible tube may be coupled to a puller that is within the lumen of the inversion support. The puller may be a wire, filament, rod or more preferably a catheter or tube (and may be referred to herein as a pull micro catheter or “PMC” for convenience). A

guidewire may be passed through the flexible tube, and therefore through the inversion support and the tractor tube. As will be described herein, this may be used for positioning.

[00065] The inversion support catheter may be configured as a catheter having a distal end opening into which the tractor inverts. The flexible tube may invert and rolls back into itself and may be drawn into the inversion support in a conveyor-like motion; the outward-facing region rolls around to become an inward-facing region, e.g., within the lumen of the inversion support catheter. The rolling motion may thus draw a clot or other object within a vessel into the inversion support. The inversion support catheter may be shaped or configured to have a sufficient column strength to withstand the compressive pulling force of the flexible tube as it is drawn (and rolled, inverting) into the distal end of the inversion support catheter. The inversion support catheter may be slotted (e.g., may include a plurality of slots or openings) to provide increased flexibility as well as column strength. However, as will be described herein, many inversion support catheters may become less flexible (e.g., more rigid) when a compressive force is applied to the flexible tube, either as a result of pulling the flexible tube proximally, either from within the inversion support catheter, or from the outside of the inversion support catheter as the flexible tube brushes against the vessel and/or a delivery catheter when being driven distally towards a clot.

[00066] The methods and apparatuses described herein may be used with any of the apparatuses and methods described, for example, in U.S. app. no. 15/291,015, filed on 10/11/2016 (“Mechanical Thrombectomy Apparatuses and Methods”) and U.S. app. no. 15/496570, filed on 4/25/2017 (“Anti-Jamming and Macerating Thrombectomy Apparatuses and methods”), previously incorporated by reference in their entirety.

[00067] The inverting tube thrombectomy apparatus (e.g., a mechanical thrombectomy apparatus) may be inserted through a vessel such as a blood vessel, artery, etc., until a distal end, or a distal-most end, of the inverting tube thrombectomy apparatus is proximate to a clot. The clot may be immediately adjacent to the end of the apparatus, or it may be within a few cm (e.g., within 1 cm, within 2 cm, within 3 cm, within 4 cm, etc.). This may be detected by visualization, such as fluoroscopy. Thus the apparatuses described herein may include one or more markers for visualization. Contrast may be used to visualize the clot and/or may be released from the apparatus. The apparatus may be deployed in a pre-loaded/pre-assembled configuration, as will be described in more detail below.

[00068] In any of these methods described herein, the flexible tube may be knitted and/or the apparatus may be configured with the opening into the vacuum lumen (e.g., through the puller catheter) at the distal-most end of the device, so that the flexible tube extends behind

(proximal) the distal-facing end of the puller catheter. For example, the method of removing a clot from a vessel may include: advancing an inverting tube thrombectomy apparatus through a vessel until a distal end of the inverting tube thrombectomy apparatus is proximate to a clot, wherein the inverting tube thrombectomy apparatus comprises an intermediate catheter, an inversion support catheter within a lumen of the intermediate catheter, a puller catheter within a lumen of the elongate support catheter, and a knitted tube having a first end coupled at a distal end region of the puller catheter, wherein knitted tube inverts over a distal end of the inversion support catheter and extends proximally between the intermediate catheter and the inversion support catheter, further wherein the knitted tube comprises a filament that is knitted to form a plurality of interlocking loop stitches; advancing the puller catheter distally so that a distal face of puller catheter extends distally from the inverting tube thrombectomy apparatus further than the knitted tube; applying a vacuum through the puller catheter to engage the clot with the distal face of the puller catheter; and pulling the puller catheter proximally to roll the knitted tube over a distal end of the inversion support catheter so that the knitted tube inverts over the distal end of the inversion support catheter, captures the clot, and pulls the clot proximally into the inversion support catheter.

[00069] The second end of the flexible tube may comprise a cuff that is less flexible than a region of the tube adjacent to the cuff. As will be described in more detail below, the cuff may be formed as a material attached to or applied onto/over the end of the flexible tube. For example, the second end of the flexible tube may comprise a cuff formed of a polymeric material applied onto/over the knitted tube. The cuff may be slit or cut (e.g., all or partially along its length) to provide some flexibility when pulling over or around the end of the tube. For example, the cuff may include longitudinal slits along its length. The cuff may have a durometer that is greater than the durometer of the flexible tube (e.g., knitted tube). The cuff, in some variations, is thicker than the flexible tube. In any of the variations described herein, the cuff may be radiopaque (e.g., by including a radiopaque material, such as platinum) on or within the cuff.

[00070] FIG. 2A illustrates an example of a deployed inverting tube thrombectomy apparatus 200. In FIG. 2B the inverting tractor mechanical thrombectomy apparatus is shown deployed near a clot 209 within a vessel. In the deployed configuration the puller 201 (shown here as a puller micro catheter) is held within the elongate inversion support catheter so that the flexible tube 203 extends from the end of the puller and expands toward the inner radius of the elongate inversion support catheter 207; at the distal end opening of the elongate inversion support catheter the flexible tube inverts over itself and extends proximally in an

inverted configuration over the distal end of the elongate inversion support catheter. As shown in FIG. 2C, by pulling the puller proximally, the flexible tube may roll and invert over the distal end opening of the elongate inversion support catheter, drawing the adjacent clot into the elongate inversion support catheter, as shown.

[00071] FIG. 2A the inversion support catheter is positioned between the flexible tube and the puller so that the flexible tube can be pulled proximally by pulling on the puller and rolling the flexible tube into the elongate inversion support catheter so that it inverts. The portion of the flexible tube that is inverted over the distal end of the elongate inversion support catheter has an outer diameter that is greater than the outer diameter of the elongate inversion support catheter. In some variations the diameter (e.g., inner diameter) of the external portion of the flexible tube outside of the inversion support catheter may be approximately the same diameter (e.g., within 1.01x and 1.3x) of the outer diameter of the inversion support catheter. In some variations, the flexible tube may be biased so that it has a relaxed expanded configuration with a diameter that is greater than the outer diameter (OD) of the elongate inversion support catheter; in addition, the flexible tube may also be configured (e.g., by heat setting, etc.) so that when the flexible tube is inverted and rolled over the distal end opening into the elongate inversion support catheter, the inverted flexible tube within the elongate inversion support catheter has an outer diameter that is greater than the inner diameter of the elongate inversion support catheter (e.g., greater than 0.1x, 0.5x, 0.6x, 0.7x, 0.75x, 0.8x, 0.9x, 1x, etc. the inner diameter, ID, of the elongate inversion support catheter. This combination of an un-inverted diameter of the flexible tube of greater than the diameter of the OD of the elongate inversion support catheter and an inverted diameter of the flexible tube of greater than about 0.7x the ID of the elongate inversion support catheter is surprisingly helpful for preventing jamming of the apparatus, both when deploying the apparatus and when rolling the flexible tube over the distal end opening of the elongate inversion support catheter to grab a clot. The flexible tube may be expandable and may be coupled to the puller as shown. In some variations the flexible tube and the puller may comprise the same material but the flexible tube may be more flexible and/or expandable, or may be connected to elongate puller (e.g., a push/pull wire or catheter).

[00072] In FIG. 2C the clot may be drawn into the elongate inversion support catheter by pulling the flexible tube proximally into the distal end of the elongate inversion support catheter, as indicated by the arrows 211, 211' showing pulling of the inner portion of the flexible tube, resulting in rolling the flexible tube over the end opening of the catheter and into the catheter distal end and inverting the expandable distal end region so that it is pulled

into the catheter, shown by arrows. The end (e.g., the second end) of the flexible tube outside of the catheter may be “loose” relative to the outer wall of the catheter.

[00073] In general the inverting tube thrombectomy apparatuses described herein may be highly flexible, both before actuating and during operation. For example, the flexible tube may not increase the stiffness/flexibility of the catheter of the elongate inversion support, and particularly the distal end region of the catheter too much, to avoid impacting maneuverability, particularly within tortuous vessels of the neurovasculature. Described herein are flexible tubes portions that increase the stiffness of the last y cm (e.g., distal most 20 cm, 18 cm, 15 cm, 12 cm, 10 cm, 9 cm, 8 cm, 7 cm, 6 cm, 5 cm, 4 cm, 3 cm, 2 cm, 1 cm, etc.) of the catheter less than a predetermined percentage (e.g., less than 10%, 12%, 15%, 18%, 20%, 25%, 30%, etc.). For example, described herein are flexible tube portions that pass through the catheter and double back over the distal end of the catheter but increase the stiffness of a distal 5 cm of the catheter by less than 15% of the stiffness of the distal 5 cm of the catheter without the flexible tube extending therethrough and doubling back over the distal end of the catheter.

[00074] As mentioned, the flexible tubes may be woven, braided and/or knitted materials. For woven and braided materials, which may include a plurality of fibers that are woven or braided to form the inverting tube, these structures may be tuned to prevent jamming and/or to reduce the force necessary to pull the flexible tube and invert over the catheter tip. For example, the mechanical atherectomy apparatus may include a braid-type flexible tube that can roll freely around the tip of catheter even in a tortuous anatomy and when grabbing clot by tuning one or more of the braid structure; minimizing the braid angle; including a hydrophilic coating on the distal aspect of the catheter outer diameter (OD) or the inner diameter (ID) of the braid (e.g., flexible tube); including a radiused wall on the catheter; and/or increasing the stiffness of the distal tip region relative to adjacent proximal regions. Alternatively it may be advantages to have a hydrophilic coating on 1, 3, 5, 10, or 15 cm of the distal ID or the entire catheter ID. This may even enhance aspiration of the clot without a tracking element.

[00075] As mentioned, the flexible tube (e.g., braided, woven, knitted, etc.) may be configured to collapse down into the inner diameter (ID) of the catheter as little as possible. For example the flexible tube may collapse to an ID that is greater than, equal to, or within 90%, 85%, 75%, 70%, 65%, 60%, or 50% of the catheter inner diameter (ID)/Catheter Tip OD, since, when the flexible tube is being pulled around catheter tip it may create axial tension on the flexible tube (e.g., braid, knit, etc.) that can inadvertently cause the flexible

tube to jam on the catheter tip. When flexible tube is pulled around catheter tip, the flexible tube is being pulled in the axial orientation creating axial tension on flexible tube structure as the flexible tube is being pulled through the catheter ID. By having the flexible tube elements jam at an ID greater than or equal to 90%, 85%, 75%, 70%, 65%, 60%, or 50% of the catheter ID (or in some variations, OD), when being axially tensioned, the flexible tube is less likely to grab/synch down onto the catheter tip, helping the braid roll around the catheter tip with less axial force applied by the user. If less axial force is required by the user to pull the flexible tube structure around the tip then the catheter tip is less likely to buckle or deflect when retracting the flexible tube. It may be advantageous to minimize the chance the catheter tip will buckle. The flexible tube can be tuned to "jam" at a specific ID by controlling any of the following variables and in any combination: selecting a specific number of braid ends, selecting the size/diameter of the braid ends; selecting the braid material (e.g., multifilament or monofilament); heat setting the bias on the braid (e.g., braid diameter); and selecting a braid pattern, e.g., 1x2, 1x1 or any other pattern.

[00076] The braid angle may be minimized to prevent locking up of the rolling of the flexible tube over the catheter end opening. Typically, the lower the braid angle (e.g., 45 degrees or less, 40 degrees or less, 35 degrees or less, 30 degrees or less, 25 degrees or less, 20 degrees or less, etc.) the less likely it is to have the braid cross over points catch on the catheter tip.

[00077] In any of the variations described herein, the catheter and/or a surface of the flexible tube may be coated to enhance rolling over the distal end region of the catheter. It may be helpful to have a hydrophilic coating on the distal aspect of the catheter OD or the ID of the flexible tube so the flexible tube can more easily slide over the catheter's distal end and around the tip of the catheter when pulled through the inside of the catheter.

[00078] The radius wall of the catheter tip may be chosen/set to within a range that allows sliding. For example, it may be helpful for the tip of the catheter to have the largest radius possible but at least 0.0025" radius wall on the catheter, ideally approximately 0.005" radius wall.

[00079] The stiffness of the distal of the elongate inversion support catheter may be sufficiently stiff to prevent collapse as the flexible tube is pulled; it may also be lubricious (e.g., by a coating or material property). The distal most section of the elongate inversion support catheter tip (e.g., the last 5mm) may be fabricated of a material which is stiff enough and lubricious enough so the distal tip of the catheter does not collapse or buckle inwardward.

when the braid structure is rolling around the catheter tip. Thus, the distal tip may have a stiffness that is greater than the more proximal region at the distal end of the catheter.

[00080] It may be helpful or desirable to have pores in the flexible tube. A lack of gaps or small pore size may limit the ability of the braid to grab clot. Alternatively or additionally, it may be desirable to form a braid structure with texture. One example is to braid two or more different diameter braid ends into the same structure: the difference in braid end diameters will help form a texture to the braid structures outer surface, aiding the grabbing of the clot when rolling the braid-dozer around the catheter tip.

[00081] As an alternative (or in addition) the flexible tube may be configured to lock so it does not compress in diameter during axial load by adding a coating, laminate or adhesive to the braid at a desired diameter. Adding a thin coating, laminate or adhesive can inhibit the braid elements from sliding with respect to each other, thereby locking the braid to a specific diameter. The coating can be applied while leaving the majority of the pores and pore area substantially open. Examples of thin coatings include urethanes and silicones with and without hydrophilic coatings and hydrophilic coatings with no tie layer.

[00082] FIG. 3A shows one example of a pre-loaded inverting tube thrombectomy apparatus for removing a clot from a vessel that may be delivered through a tortuous anatomy. In this example, the apparatus may include an intermediate catheter 303 having a distal end 305. The intermediate catheter (I.C.) may be considered part of the inverting mechanical thrombectomy apparatus, although in other variations it may be considered a separate component that is used with the inverting mechanical thrombectomy apparatus. The apparatus also includes an elongate inversion support catheter 307 within the lumen of the intermediate catheter. The elongate inversion support catheter 307 has a distal end 311 and a distal end opening. The apparatus also includes a puller 319 extending distally within the elongate inversion support catheter and a flexible tube 315 extending proximally from a distal end region of the puller. The puller extends from the distal end of the intermediate catheter and the distal end opening of the elongate inversion support catheter.

[00083] In the configuration shown in FIG. 3A, the elongate inversion support catheter is held within the lumen of the intermediate catheter so that the distal end opening of the elongate inversion support catheter is proximal to the distal end opening of the intermediate catheter by a first distance 325. This distance may be between about 1mm and about 10 cm (e.g., between about 2 mm and about 10 mm, between about 2 mm and about 20 mm, between about 2mm and about 30 mm, etc.). The elongate inversion support catheter may be fixed in position relative to the intermediate catheter, so that as the two move together, until

released. For example, the proximal ends of the intermediate catheter and the elongate inversion support catheter may be removably coupled.

[00084] The flexible tube in the pre-assembled apparatus of FIG. 3 extends between the elongate inversion support catheter and the intermediate catheter for some second distance along the length 323 of the elongate inversion support catheter. Securing the end of the flexible tube between the I.C. and the distal end of the elongate inversion support catheter may help both hold it in place, so that the flexible tube may be pushed formed (e.g., in compression). For example, the second length 323 may be between about 1 mm and about 50 cm (e.g., between about 5 cm and about 10 cm, between about 1 cm and about 20 cm, between about 1 cm and about 10 cm, between about 2 cm and about 20 cm, between about 2 cm and about 10 cm, etc.).

[00085] The portion of the flexible tube 315 and puller 319 (e.g., pull micro catheter, or pmc) in this pre-loaded example may extend distally and ride over the guidewire 317. The flexible tube and puller may also be longitudinally fixed relative to the intermediate catheter 303 (e.g., by releasably locking, e.g., at the distal end region) or they may be somewhat longitudinally slideable (and, in some variations, prevented from exceeding a range of, e.g., between about 1 mm and 20 cm from the distal end opening 305 of the intermediate catheter.

[00086] In this example, the portion 327 of the flexible tube 315 that extends outside of the intermediate catheter 303 may be between about 1 mm and about 20 cm (e.g., between about 1 cm and about 7cm, between about 1 cm and about 10 cm, between about 1 cm and about 15 cm, between about 2 cm and about 10 cm, between about 2 cm and about 7 cm, etc.). As mentioned, this distance may be fixed (e.g., by fixing the puller with respect to the push catheter and/or I.C.), or variable. In any of these variations, the puller may extend some distance 329 beyond the distal attachment site for the flexible tube, or the flexible tube may be attached at the distal end of the puller. The distance from the attachment site of the flexible tube and the distal end of the puller may be between about 0 mm and about 10 cm, for example (e.g., between about 1 mm and about 10 cm, between about 1 mm and about 5 cm, etc.).

[00087] FIG. 3B shows the apparatus of FIG. 3A, but with the inversion support catheter 307 advanced distally. In this example, the distal opening 311 of the inversion support catheter 307 has been pushed distally toward the attachment site of the flexible tube, and any clot. Once in position, the puller may be pulled proximally to invert the flexible tube into the inversion support catheter.

FLEXIBLE TUBES HAVING SLACK

[00088] FIGS. 4A-4B and 4C-4D illustrate kickback when using an inverting tube thrombectomy apparatus. For example, in FIG. 4A, a model of a tortuous vessel 403 (e.g., a neurovascular region) is shown; the vessel is transparent to show a clot 411 and an inverting tube thrombectomy apparatus 400 that has been positioned with the distal end 401 adjacent to the clot. This example of an inverting tube thrombectomy apparatus includes a puller with a flexible tube attached near the distal end, and an inversion support catheter. The puller extends within the lumen of the inversion support catheter and the flexible tube extends from within the lumen of the inversion support catheter, out of the distal end of the inversion support catheter where it everts over itself to extend proximally along the outside from the distal end of the inversion support catheter. The second end of the flexible tube may be held between the outer surface of the inversion support catheter and an inner surface of an intermediate catheter, or it may be fully released from intermediate catheter. When positioned next to the clot 411 in FIG. 4A, the distal end of the catheter and therefore the inverting face of the flexible tube, may be positioned next to the clot. Pulling the puller proximally will roll and invert the flexible tube (the outer portion of the flexible tube) over the distal end of the inversion support catheter. However, as shown in FIG. 4B, the force applied by the flexible tube pulling proximally against the inversion support catheter (even a high column-strength inversion support catheter as shown in FIG. 1B) may compresses the distal end of the inversion support catheter slightly, and/or may causes it to separate from the clot. In FIG. 4B, the same device after pulling the puller proximally is shown with the distal end separated slightly from the clot (space 422). This compressive force may also make additional distal tracking of the deployed device difficult within the tortuous vessel.

[00089] FIGS. 4C and 4D illustrate another example of this. In FIG. 4C the distal end 401 of the inverting tube thrombectomy apparatus 400 is adjacent to the clot 411. Pulling the puller proximally to roll and invert the flexible tube into the inversion support catheter may pull the distal end of the inverting tube thrombectomy apparatus 400 away from the clot 411, as shown in FIG. 4D, introducing a gap 422.

[00090] In order to prevent this kickback, the tension on the flexible tube may be reduced or eliminated. For example, FIGS. 5A-5L illustrate one example of a method of removing a clot that reduces or eliminates the tension on the portion of the flexible tube that is rolling and inverting over the distal end of the apparatus. In FIG. 5A, a sectional view through an inverting tube thrombectomy apparatus is shown. The inverting tube thrombectomy

apparatus includes a puller 503 (shown as a puller catheter) with a flexible tube 505 (e.g., a woven tube, knitted tube, etc.) attached near the distal end, and an inversion support catheter 507. The puller extends within the lumen of the inversion support catheter and the flexible tube extend from within the lumen of the inversion support catheter, out of the distal end of the inversion support catheter where it everts over itself to extend proximally along the outside from the distal end of the inversion support catheter. The second end of the flexible tube may be held between the outer surface of the inversion support catheter and an inner surface of an intermediate catheter 509, as shown. In FIG. 5A, the apparatus may be tracked over a guidewire 513 to be positioned adjacent to a clot 511. Thus, the apparatus may be pre-loaded with an intermediate catheter to the face of a clot. In FIG. 5B, the inversion support catheter 507 may be advanced distally towards the clot, as shown by arrow 521. The intermediate catheter 509 may then be pulled back, as shown by the arrow 524 in FIG. 5C to completely or partially unsheath the flexible tube 505, exposing the outer portion of the flexible tube over the inversion support catheter 507. For example, in some variations the intermediate catheter may be pulled back is 30-95% of the length of the flexible tube 505.

[00091] To prevent kickback when inverting the flexible tube, slack 520 may be added to the outer portion of the flexible tube, as shown in FIG. 5D. In this example, slack 520 (shown as a bunching up of the flexible tube on the outside of the inversion support catheter before the distal end) may be added to the flexible tube by pushing the intermediate catheter distally 526 (e.g., approximately 50% of the exposed length of the flexible tube, e.g., the outer flexible tube region). In woven flexible tubes, this may compress the weave. Thereafter, the device may be operated, e.g., by pulling the puller, to roll and invert the flexible tube and grab clot. For example in FIG. 5E, the guidewire is first removed, and aspiration (e.g., vacuum) may be applied through the lumen of the puller (and/or the inversion support catheter) to connect to the clot. The apparatus may also be additionally tracked distally slightly, to capture the clot 511 as shown in FIG. 5F. For example, when aspiration is being applied, the apparatus 500 may be advanced 527 (the intermediate catheter, inversion support catheter and/or puller, all or some of which may be locked together proximally) distally until flow through the puller stops, indicating that the clot is on the puller (e.g., “corked”), as shown in FIG. 5F.

[00092] Once positioned, the puller may be pulled proximally 532 while advancing the inversion support catheter and intermediate catheter (together), as shown in FIGS. 5G-5J, to capture clot. Additional slack may be added during this process by, for example, advancing the intermediate catheter independently of the rest of the device; alternatively or additionally,

the flexible tube may be released from between the intermediate catheter and the inversion support catheter, as shown in FIG. 5I. As shown in FIGS. 5K and 5L, the clot may be removed fully into the inversion support catheter and/or the intermediate catheter (as shown in FIG. 5L) by withdrawing first the puller and then the rest of the apparatus proximally, while applying aspiration (e.g., suction) through the intermediate catheter.

[00093] FIGS. 6A-6C illustrate another example of a method of removing a clot while preventing kickback by releasing tension on the flexible tube. In FIG. 6A, an example of an apparatus 600 (similar to that shown in FIG. 5A, above) is positioned adjacent to a clot 603. As described above, before pulling the puller to roll and invert the flexible tube into the inversion support catheter, the outside region of the flexible tube may be compressed to form slack, for example, by advancing the intermediate catheter distally, after partially or completely removing from over the flexible tube, to push the flexible tube distally. Thereafter, in FIG. 6B, the puller may be pulled proximally while advancing the intermediate catheter to capture clot. In FIG. 6C, the intermediate catheter may be fully unsheathed from over the flexible tube, and more of the clot may be ingested by the rolling, inverting flexible tube.

[00094] FIGS. 7A-7B illustrate an alternative variation in which the tension on the flexible tube may be reduced or eliminated when rolling and inverting the outer portion of the flexible tube by coordinating the application of both a distal pushing force on the second end of the flexible and a pulling force on the first end of the flexible tube when pulling the puller proximally. In FIG. 7A, the apparatus 700 includes a puller 703 to which the flexible tube 705 is attached near the distal end of the puller. An inversion support catheter 707 is between the puller and the flexible tube, and an intermediate catheter 709 extends over the majority of the length of the apparatus. In FIG. 7A, the apparatus is shown deployed, but prior to rolling/inverting the flexible tube 705. In FIG. 7B, tension that may otherwise apply a compressive force on the distal end of the inversion support catheter may be reduced or eliminated by applying a distal force (e.g., by advancing the intermediate catheter distally 721 in this example) before or while pulling 723 the puller proximally to roll and invert the flexible tube over the distal end. The puller may be pulled slightly faster than the rate at which the intermediate catheter is advanced distally, as the flexible tube may extend slightly within the inversion support catheter.

AUTOMATIC RELAOADING

[00095] FIGS. 8-11F illustrate apparatuses and methods that automatically reload the flexible tube after grabbing all or a portion of clot. For example, in FIG. 8, the apparatus includes a bias (an external bias) for pulling the flexible tube from within the inversion support catheter back outside of the inversion support catheter (rolling and everting). In FIG. 8, the apparatus 800 includes a puller 803 and a flexible tube (e.g., woven, knitted, etc.). A first end of the flexible tube 805 is attached near the distal end region of the puller. The puller is within the lumen of an inversion support catheter 807, and the flexible tube extends over the outer surface of the inversion support catheter. A region 806 of the flexible tube extends on the outside of the inversion support catheter. The second end (or a region at the second end) of the flexible tube is connected to a bias 811, shown here as a spring element. The spring may be heat set in a compressed configuration, as shown. A distal end of the bias 815 is attached to the second end of the flexible tube (or a cuff, not shown, on the flexible tube). Another, e.g., a proximal end 817, of the spring may be attached to the inversion support catheter 807, as shown.

[00096] FIGS. 9A-9D illustrate the operation of an apparatus such as that shown in FIG. 8, which is biased to return the flexible tube to the outside of the inversion support catheter. The amount of bias may be set so that the force applied is relatively low (e.g., pushing the puller distally may allow the flexible tube to reset (e.g., evert and roll back) the flexible tube to the outside of the inversion support catheter; alternatively the bias may be higher, so that the bias resets the flexible tube after just releasing the puller.

[00097] In FIG. 9A, the apparatus 900 may be approximated near the clot and aspiration (e.g., suction) applied through the lumen of the puller 903, as shown, until the clot is attached to the puller ("corked"). The puller 903 may then be pulled proximally, as shown in FIG. 9B, to roll 933 the flexible tube 905 and invert it into the inversion support catheter 907, capturing the clot. Pulling the puller proximally also pulls against the bias 911. The puller may be pulled until it reaches a stop, which may be set by the bias (spring 911) or by a mechanical stop, or both. Once The clot or portion of the clot within the inversion support catheter that has been engulfed by the flexible tube may then be aspirated proximally down the puller, as shown in FIG. 9C. Once cleared from the flexible tube, which may be detected by monitoring the suction through the puller (e.g., showing a drop in suction pressure when the clot is removed proximally from the flexible tube), the flexible tube may be reset outside of the inversion support catheter as shown in FIG. 9D, by applying a small force driving the

puller distally, allowing the spring (bias) to evert and roll the flexible tube back out of the inversion support catheter and over the outside surface, as shown. This processes may be repeated 915 as many times as desired; large clots may be removed by taking multiple bites in this manner, or multiple different clots may be removed with the same apparatus. The apparatus shown in FIGS. 8 and 9A-9D may include an intermediate catheter (not shown).

[00098] The flexible tube, as described above, may be any appropriate flexible tube. For example, the flexible tube may be a braid (e.g., braid structure). In some variations the flexible tube may be a braid of a flat or round wire that is braided and heat set (as described above, it may be heat set to have an inner diameter in tension that is greater than the outer diameter of the inversion support catheter). For example the flexible tube may be formed as a braid of 144 strands of 0.001" NiTi filaments that are braided at large braid angle (e.g., having a very smooth surface). In some variations, the braid may include a low durometer polymer laminate or covering, on all or braid part of braid length. In some variations, the braid may be configured as a knit structure. The knit may be formed of a round or flat wire having a circular knit structure. The apparatus may be heat set so that the ID of the flexible tube when tensioned is greater than the outer diameter of the inversion support catheter. A knit may include a low durometer polymer laminate or covering, on all or braid part of braid length.

[00099] Any appropriate bias may be used. For example, the bias may be a spring such as a metallic or polymeric spring. The spring may be heat set in a closed pitch form. For example, the spring may be a metal or metallic material such as NiTi, Cobalt Cr, stainless steel, etc. The spring may be, e.g., a polymeric tubing spring, such as a spring formed of a silicone, urethane, latex or other elastic material.

[000100] In some variations, an additional element, such as a wire, may be used to assist the clot in removing/releasing from the flexible tube. For example, a wire have a bent or bendable distal end may be used to help pull the clot out of the distal end of the puller.

[000101] FIGS. 10A-11F illustrate another example of an apparatus including a bias to restore the flexible tube to the outside of the apparatus. In this variations, the flexible tube is biased to return to the outside of the inversion support catheter. For example, in FIG. 10A, the apparatus 1000 includes a puller 1003 to which a flexible tube 1005 is attached at a first end to the distal end region of the puller. The puller has a relatively large outer diameter (in both this example and the example shown above in FIG. 8), but is slidably held within the inner lumen of the inversion support catheter 1007. In addition, the flexible tube 1005 is attached at the second end to the outside of the inversion support catheter at an attachment

region 1009. In FIG. 10A, the flexible tube is biased to spring back to this configuration (e.g., a loading or insertion configuration), in which the flexible tube is outside of the inversion support catheter. In this example the flexible tube is attached proximal to the distal end of the puller; any appropriate distance from the distal end of the puller may be used (e.g., more than 0.1 mm, 0.2 mm, 0.3 mm, 0.5 mm, 1 mm, 2 mm, 3 mm, etc. and/or less than about 0.1 mm, 0.2 mm, 0.3 mm, 0.5 mm, 1 mm, 2 mm, 3 mm, 4 mm, 5 mm, 6 mm, 7 mm, 8 mm, 9 mm, 10 mm, etc.). Alternatively the flexible tube may be attached to the distal end of the puller (e.g., flush with the distal end).

[000102] In some variations, the flexible tube is configured as a braid that has a stacked configuration when attached to the outside of the inversion support catheter with the puller distal end aligned with the end of the inversion support catheter. In FIG. 10B, for example, a flexible tube shown as a weave formed of a Nitinol material having a stacked braid configuration is illustrated.

[000103] FIGS. 11A-11F illustrate the operation of an apparatus such as the one shown in FIG. 10A. In FIG. 11A, the apparatus is deployed near the clot 1109 with the puller 1103 extended distally ahead of the rest of the apparatus. In FIG. 11B, aspiration may be used to attach the clot 1109 to the puller (shown with the clot “corked” on the distal end of the puller). Thereafter, the inversion support catheter 1107 may be advanced 1131 distally to compress 1133 the weave of the flexible tube 1105, causing it to stack up as shown in FIG. 11C into a stacked configuration. This configuration is equivalent to forming slack in the flexible tube as described above. While (optionally, but preferably) still applying aspiration through the puller, the inversion support catheter 1107 may be advanced distally 1137 (as shown in FIG. 11D), against the clot, and at least partially over it. The inversion support catheter (e.g., the outer catheter) may be advanced distally so that the distal end of the inversion support catheter extends to or past the end of the puller, which may advance the flexible tube over the clot. The inversion support catheter may then be advanced distally while pulling the puller proximally, to roll and invert the flexible tube, as shown in FIG. 11E, to further ingest the clot, as shown. Alternatively the inversion support catheter may be held still while pulling the puller proximally; in some variations the inversion support catheter and puller are moved in a coordinated manner, either together simultaneously or incrementally and alternately.

[000104] The clot within the puller may be removed proximally (e.g., by aspiration and/or mechanically, such as using a wire), as shown in FIG. 11F. In addition, the puller may be advanced distally to evert and roll the flexible tube back out of the inversion support catheter.

This process may then be repeated (shown by dashed arrow 1139) to remove additional clot material. In any of these variations, the clot may be cut after a certain amount of it has entered into the device, e.g., by a separate or integrated cutter (such as a wire, etc.). This may allow repeated bites of clot to be removed using the same device.

[000105] Although not shown explicitly in FIG. 11C, the apparatus shown may also include an intermediate catheter, e.g., within which the inversion support catheter (outer catheter) and the puller (pull catheter, inner pull catheter or inner catheter) may move into and/or out of, as shown in FIGS. 5K-5L, above).

[000106] FIG. 12 illustrates one example of an apparatus (e.g., a system) for removing a clot, a series of clots and/or multiple clots, as described herein. The schematic shown in FIG. 12 is not to scale. For example, in FIG. 12, the apparatus includes an inversion support catheter 1211 and a puller catheter 1215 within a lumen of the inversion support catheter 1211. The puller catheter, as described above, may have a large inner diameter to allow removal of clot through the puller catheter inner lumen. For example, the inner diameter of the puller catheter may be about 75% (or about 80% or about 85% or about 90% or about 95%) or more than the inner diameter of the inversion support catheter. In some variations the outer diameter of the puller catheter is within 15% or less of the inner diameter of the inversion support catheter (e.g., within 12%, within 10%, within 8%, within 7%, within 5%, etc.). Thus the puller catheter may slide within the inversion support catheter, but may maximize the inner diameter of the inversion support catheter in order to pass clot through the puller catheter.

[000107] A flexible tube 1217 is connected to the distal end region of the puller catheter and to an outer surface of the distal end region (or distal end) of the inversion support catheter, as shown. Thus, the flexible tube has a first end coupled at a distal end region of the puller catheter, and a second end coupled at an outer surface of a distal end region of the inversion support catheter. As mentioned above, the flexible tube may be any appropriate material for grabbing clot, such as a woven, knitted or braided material, including metallic woven, knitted and/or braided materials. The flexible tube may be biased or may include a biasing element that is pre-biased to drive the flexible tube to the initial (delivery) configuration, such as shown in FIG. 10A. For example, in some variation the flexible tube includes a shape memory material, such as Nitinol, that is biased to return to the predetermined shape.

[000108] In FIG. 12, an intermediate catheter is not shown, but may be included and the inversion support catheter, puller catheter and flexible tube may be passed through the intermediate catheter.

[000109] The apparatus shown in FIG. 12 also includes a handle 1205 coupled to the inversion support catheter and the puller catheter. The handle is shown schematically in FIG. 12, but may be shaped for held-held use; alternatively the handle may be part of a base unit that is not hand-held. As shown, the handle includes a vacuum port 1219 that couples to a vacuum 1225, and may couple the vacuum line to a lumen of the puller catheter.

[000110] The handle may include one or more controls 1203, 1207, 1209 that may control the operation of the apparatus and particular the relative movement of the puller catheter and the inversion support catheter. The proximal end regions of the puller catheter and the inversion support catheters may be coupled to one or more actuators within the handle (not visible) to drive axial movement (distal/proximal movement) of these members. For example the handle may be configured to, when activated by one or more controls on the handle, advance the inversion support catheter distally before concurrently advancing the inversion support catheter distally while withdrawing the puller catheter proximally, as described in the methods illustrated in FIGS. 11A-11F (and particularly FIG. 11C and FIG. 11D-11E described above). In any of these variations, the handle may be configured to reset the inversion support catheter proximally and the puller catheter distally, e.g., to reset the puller catheter and the inversion support catheter to the delivery configuration. For example, the apparatus may include a control 1209 that may release the inner and/or outer catheters (e.g., the puller catheter and/or inversion control catheter) to allow the device to return to the delivery catheter; alternatively the control may actively move the inner and outer catheters to the delivery configuration.

[000111] The handle may be further configured to apply vacuum through the puller catheter while advancing the inversion support catheter distally before concurrently advancing the inversion support catheter distally while withdrawing the puller catheter proximally. For example, the handle may include control logic that applies the negative pressure (e.g., vacuum from the vacuum device 1225) when the actuators within the handle move the inversion support catheter distally while moving the puller catheter proximally. The control logic within the handle may be software, hardware or firmware, and may coordinate operation of the handle. For example the handle may be configured to separately and/or jointly move the inner catheter (puller catheter) and the outer catheter (inversion support

catheter), as mentioned above, and/or to coordinate the application of suction (e.g., vacuum) through the puller catheter.

[000112] Separate controls on the handle may control the movements involved in the different stages of the operation. For example, the handle may include a first control to advance the inversion support catheter distally and a second control to advance the inversion support catheter distally while withdrawing the puller catheter proximally. Alternatively or additionally, the first control may advance the inversion support catheter distally and may separately advance the inversion support catheter distally while withdrawing the puller catheter proximally. In some variations, the handle is configured to advance the inversion support catheter distally to a predetermined distance (e.g., 1 mm, 2 mm, 3 mm, 4 mm, 5 mm, 1 cm, 1.5 cm, 2 cm, 3 cm, etc.) before advancing the inversion support catheter distally while withdrawing the puller catheter proximally to a variable distance and/or to a second predetermined distance (e.g., 1 mm, 2 mm, 3 mm, 4 mm, 5 mm, 1 cm, 1.5 cm, 2 cm, 3 cm, 4 cm, 5 cm, 6 cm, 7 cm, 8 cm, 9 cm, etc.).

[000113] When a feature or element is herein referred to as being "on" another feature or element, it can be directly on the other feature or element or intervening features and/or elements may also be present. In contrast, when a feature or element is referred to as being "directly on" another feature or element, there are no intervening features or elements present. It will also be understood that, when a feature or element is referred to as being "connected", "attached" or "coupled" to another feature or element, it can be directly connected, attached or coupled to the other feature or element or intervening features or elements may be present. In contrast, when a feature or element is referred to as being "directly connected", "directly attached" or "directly coupled" to another feature or element, there are no intervening features or elements present. Although described or shown with respect to one embodiment, the features and elements so described or shown can apply to other embodiments. It will also be appreciated by those of skill in the art that references to a structure or feature that is disposed "adjacent" another feature may have portions that overlap or underlie the adjacent feature.

[000114] Terminology used herein is for the purpose of describing particular embodiments only and is not intended to be limiting of the invention. For example, as used herein, the singular forms "a", "an" and "the" are intended to include the plural forms as well, unless the context clearly indicates otherwise. It will be further understood that the terms "comprises" and/or "comprising," when used in this specification, specify the presence of stated features, steps, operations, elements, and/or components, but do not preclude the presence or addition of one or more other features, steps, operations, elements, components, and/or groups thereof.

As used herein, the term "and/or" includes any and all combinations of one or more of the associated listed items and may be abbreviated as "/".

[000115] Spatially relative terms, such as "under", "below", "lower", "over", "upper" and the like, may be used herein for ease of description to describe one element or feature's relationship to another element(s) or feature(s) as illustrated in the figures. It will be understood that the spatially relative terms are intended to encompass different orientations of the device in use or operation in addition to the orientation depicted in the figures. For example, if a device in the figures is inverted, elements described as "under" or "beneath" other elements or features would then be oriented "over" the other elements or features. Thus, the exemplary term "under" can encompass both an orientation of over and under. The device may be otherwise oriented (rotated 90 degrees or at other orientations) and the spatially relative descriptors used herein interpreted accordingly. Similarly, the terms "upwardly", "downwardly", "vertical", "horizontal" and the like are used herein for the purpose of explanation only unless specifically indicated otherwise.

[000116] Although the terms "first" and "second" may be used herein to describe various features/elements (including steps), these features/elements should not be limited by these terms, unless the context indicates otherwise. These terms may be used to distinguish one feature/element from another feature/element. Thus, a first feature/element discussed below could be termed a second feature/element, and similarly, a second feature/element discussed below could be termed a first feature/element without departing from the teachings of the present invention.

[000117] Throughout this specification and the claims which follow, unless the context requires otherwise, the word "comprise", and variations such as "comprises" and "comprising" means various components can be co-jointly employed in the methods and articles (e.g., compositions and apparatuses including device and methods). For example, the term "comprising" will be understood to imply the inclusion of any stated elements or steps but not the exclusion of any other elements or steps.

[000118] In general, any of the apparatuses and methods described herein should be understood to be inclusive, but all or a sub-set of the components and/or steps may alternatively be exclusive, and may be expressed as "consisting of" or alternatively "consisting essentially of" the various components, steps, sub-components or sub-steps.

[000119] As used herein in the specification and claims, including as used in the examples and unless otherwise expressly specified, all numbers may be read as if prefaced by the word "about" or "approximately," even if the term does not expressly appear. The phrase "about"

or “approximately” may be used when describing magnitude and/or position to indicate that the value and/or position described is within a reasonable expected range of values and/or positions. For example, a numeric value may have a value that is +/- 0.1% of the stated value (or range of values), +/- 1% of the stated value (or range of values), +/- 2% of the stated value (or range of values), +/- 5% of the stated value (or range of values), +/- 10% of the stated value (or range of values), etc. Any numerical values given herein should also be understood to include about or approximately that value, unless the context indicates otherwise. For example, if the value “10” is disclosed, then “about 10” is also disclosed. Any numerical range recited herein is intended to include all sub-ranges subsumed therein. It is also understood that when a value is disclosed that “less than or equal to” the value, “greater than or equal to the value” and possible ranges between values are also disclosed, as appropriately understood by the skilled artisan. For example, if the value “X” is disclosed the “less than or equal to X” as well as “greater than or equal to X” (e.g., where X is a numerical value) is also disclosed. It is also understood that the throughout the application, data is provided in a number of different formats, and that this data, represents endpoints and starting points, and ranges for any combination of the data points. For example, if a particular data point “10” and a particular data point “15” are disclosed, it is understood that greater than, greater than or equal to, less than, less than or equal to, and equal to 10 and 15 are considered disclosed as well as between 10 and 15. It is also understood that each unit between two particular units are also disclosed. For example, if 10 and 15 are disclosed, then 11, 12, 13, and 14 are also disclosed.

[000120] Although various illustrative embodiments are described above, any of a number of changes may be made to various embodiments without departing from the scope of the invention as described by the claims. For example, the order in which various described method steps are performed may often be changed in alternative embodiments, and in other alternative embodiments one or more method steps may be skipped altogether. Optional features of various device and system embodiments may be included in some embodiments and not in others. Therefore, the foregoing description is provided primarily for exemplary purposes and should not be interpreted to limit the scope of the invention as it is set forth in the claims.

[000121] The examples and illustrations included herein show, by way of illustration and not of limitation, specific embodiments in which the subject matter may be practiced. As mentioned, other embodiments may be utilized and derived there from, such that structural and logical substitutions and changes may be made without departing from the scope of this

disclosure. Such embodiments of the inventive subject matter may be referred to herein individually or collectively by the term “invention” merely for convenience and without intending to voluntarily limit the scope of this application to any single invention or inventive concept, if more than one is, in fact, disclosed. Thus, although specific embodiments have been illustrated and described herein, any arrangement calculated to achieve the same purpose may be substituted for the specific embodiments shown. This disclosure is intended to cover any and all adaptations or variations of various embodiments. Combinations of the above embodiments, and other embodiments not specifically described herein, will be apparent to those of skill in the art upon reviewing the above description.

CLAIMS

1. A system for removing a clot, the system comprising:

an inversion support catheter;

a puller catheter within a lumen of the inversion support catheter;

a flexible tube having a first end coupled at a distal end region of the puller catheter, and a second end coupled at an outer surface of a distal end region of the inversion support catheter; and

a handle coupled to the inversion support catheter and the puller catheter, the handle comprising a vacuum port configured to couple a lumen of the puller catheter to a vacuum, further wherein the handle is configured to, when activated by one or more controls on the handle, advance the inversion support catheter distally before concurrently advancing the inversion support catheter distally while withdrawing the puller catheter proximally.

2. The apparatus of claim 1, wherein the first end of the flexible tube is coupled proximal to the distal end of the puller catheter by greater than 0.5 mm.

3. The apparatus of claim 1 or 2, wherein the handle is further configured to reset the inversion support catheter proximally and the puller catheter distally.

4. The apparatus of any of claims 1-3, further wherein the flexible tube further comprises a bias configured to extend the puller catheter distally relative to the inversion support catheter.

5. The apparatus of any of claims 1-4, wherein the flexible tube comprises a woven or knitted material.

6. The apparatus of any of claims 1-4, wherein the flexible tube comprises a braided material.

7. The apparatus of any of claims 1-6, wherein the handle is further configured to apply vacuum through the puller catheter while advancing the inversion support catheter distally before concurrently advancing the inversion support catheter distally while withdrawing the puller catheter proximally.

8. The apparatus of any of claims 1-7, wherein the handle comprises a first control to advance the inversion support catheter distally and a second control to advance the inversion support catheter distally while withdrawing the puller catheter proximally.

9. The apparatus of any of claims 1-7, wherein the handle comprises a first control to advance the inversion support catheter distally and to separately advance the inversion support catheter distally while withdrawing the puller catheter proximally.

10. The apparatus of any of claims 1-7, wherein the handle is configured to advance the inversion support catheter distally to a predetermined distance before advancing the inversion support catheter distally while withdrawing the puller catheter proximally.

11. The apparatus of any of claims 1-10, wherein the outer diameter of the puller catheter is within about 10% of the inner diameter of the inversion support catheter.

12. A system for removing a clot, the system comprising:

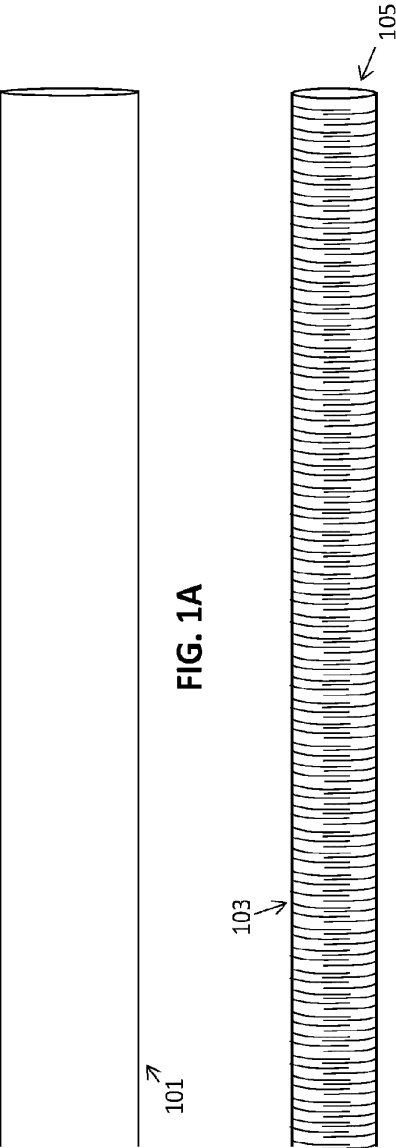
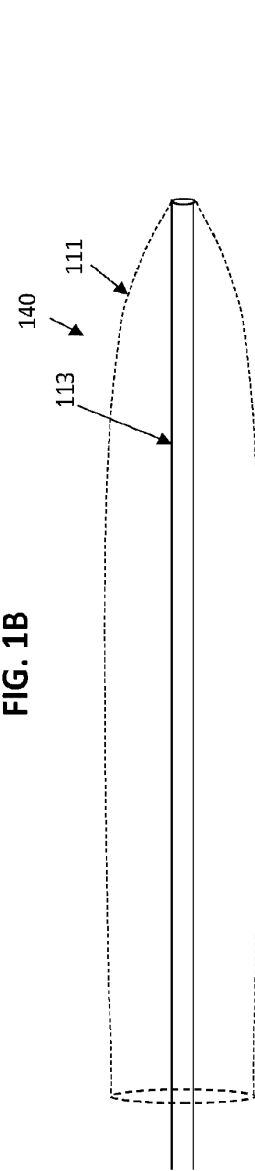
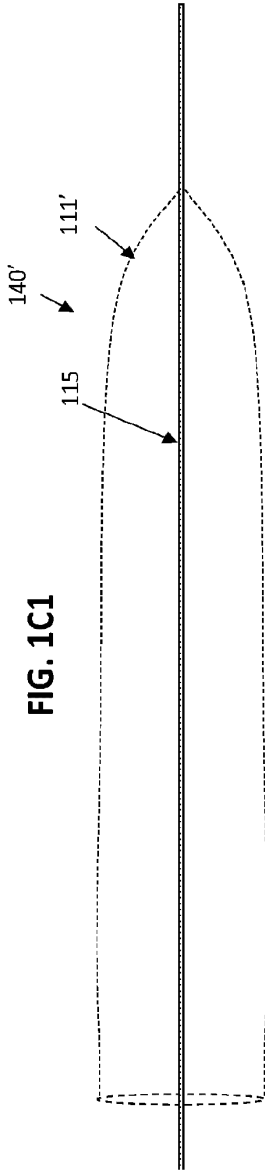
an intermediate catheter;

an inversion support catheter within a lumen of the intermediate catheter;

a puller within a lumen of the inversion support catheter;

a flexible tube having a first end coupled at a distal end region of the puller, wherein flexible tube inverts over a distal end of the inversion support catheter and an external portion of the flexible tube extends proximally over the inversion support catheter; and

a handle coupled to the intermediate catheter and the puller, wherein the handle is configured to, when activated by a control on the handle, automatically advance the intermediate catheter while one or more of: holding the puller fixed or withdrawing the puller proximally as the intermediate catheter is advanced.



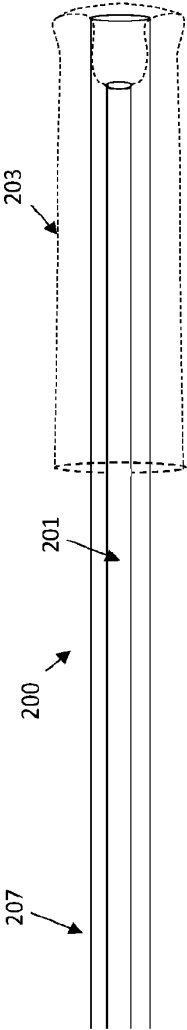


FIG. 2A

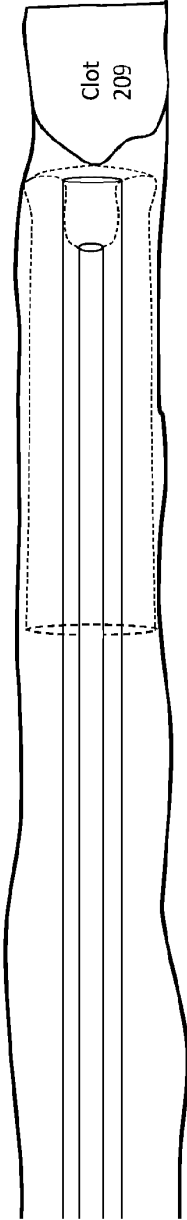


FIG. 2B

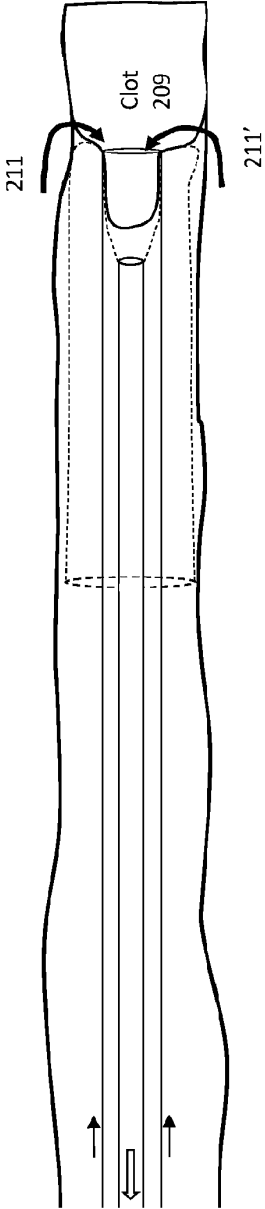


FIG. 2C

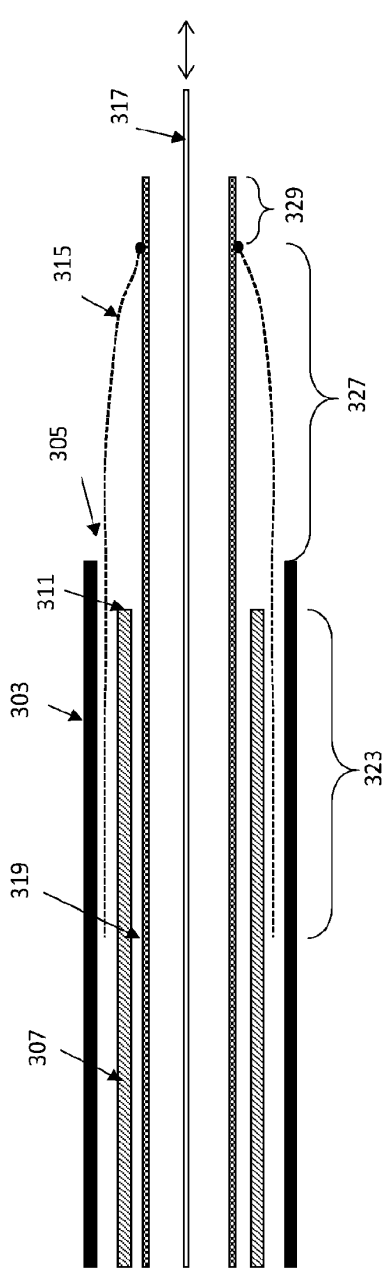


FIG. 3A

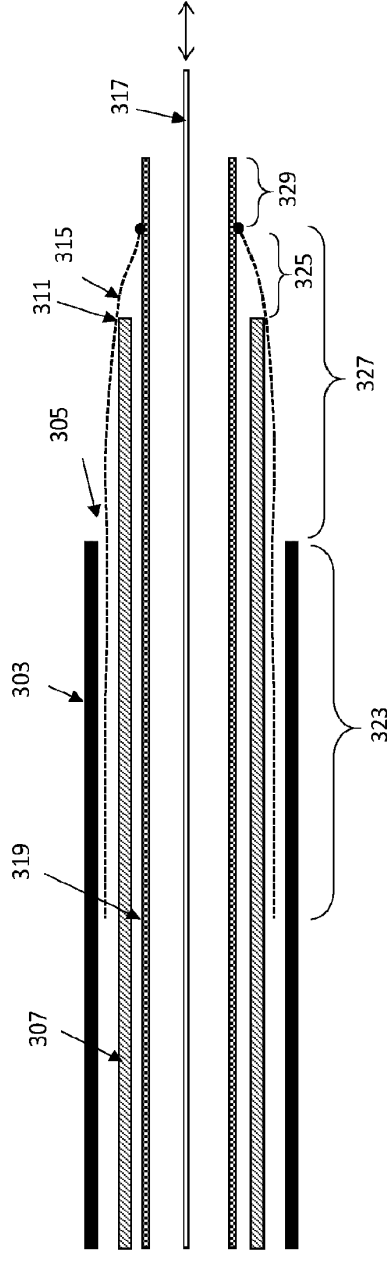


FIG. 3B

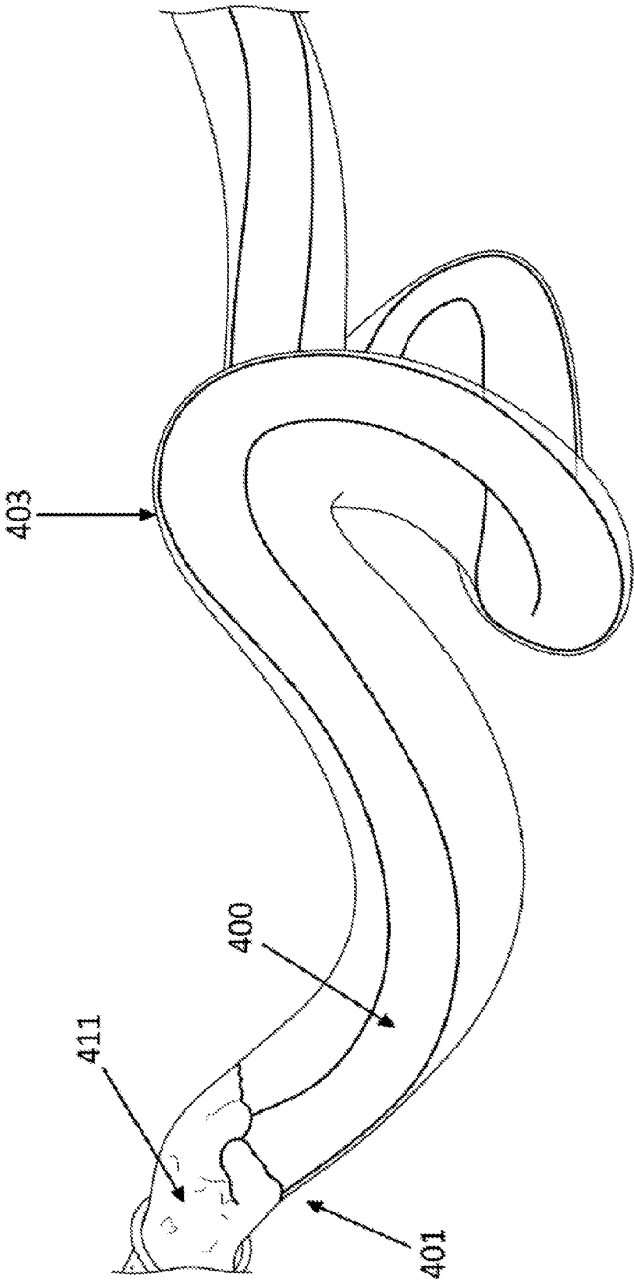


FIG. 4A

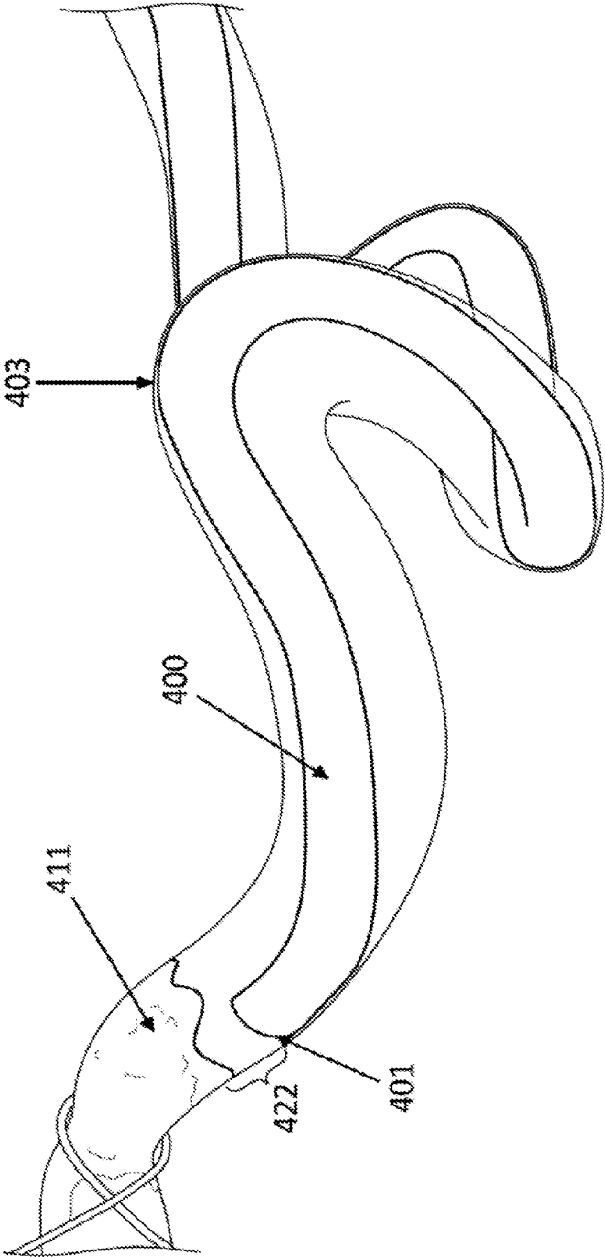


FIG. 4B

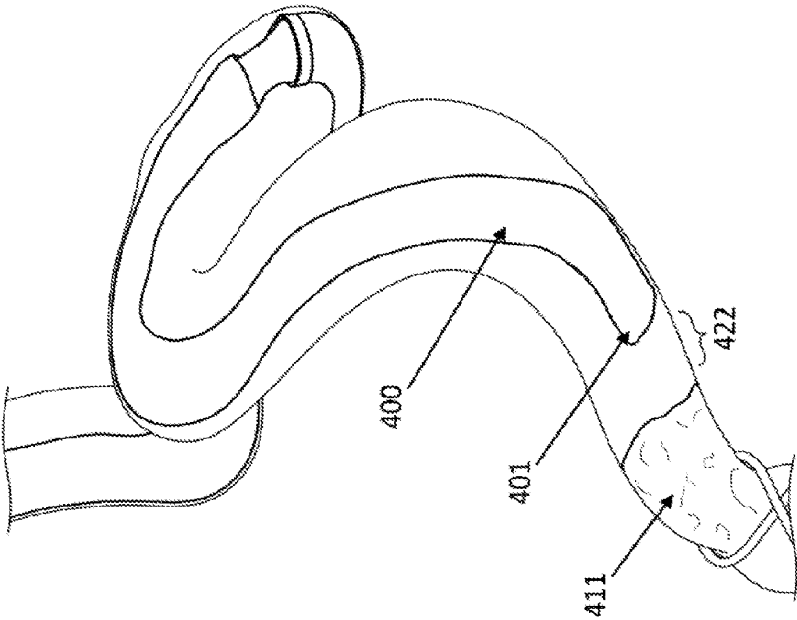


FIG. 4D

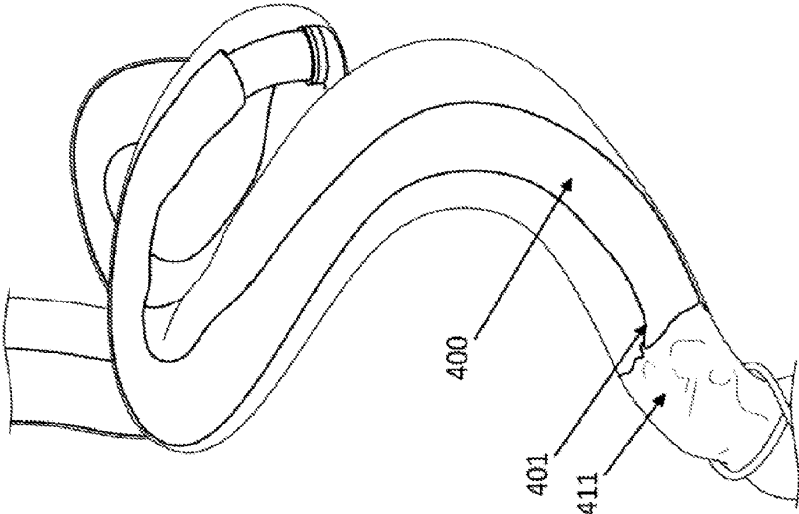


FIG. 4C

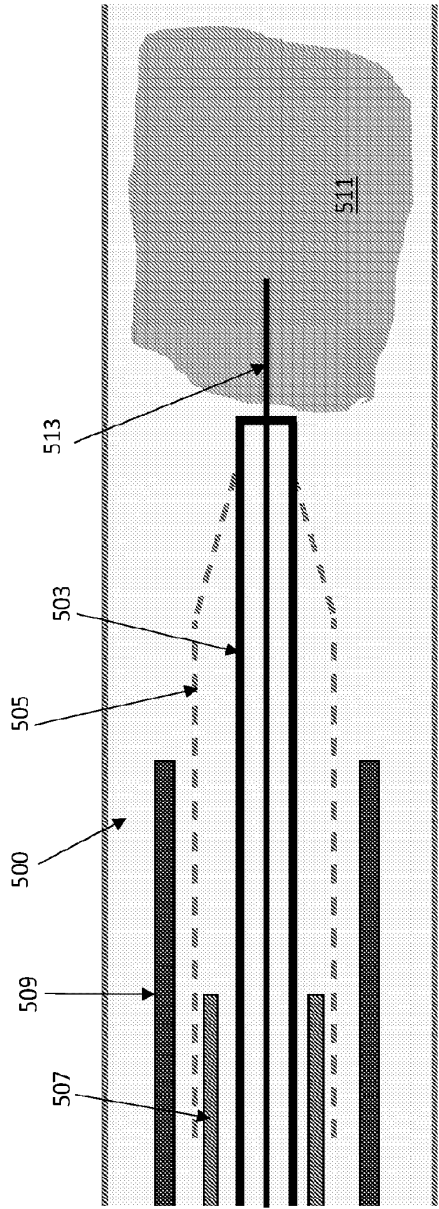


FIG. 5A

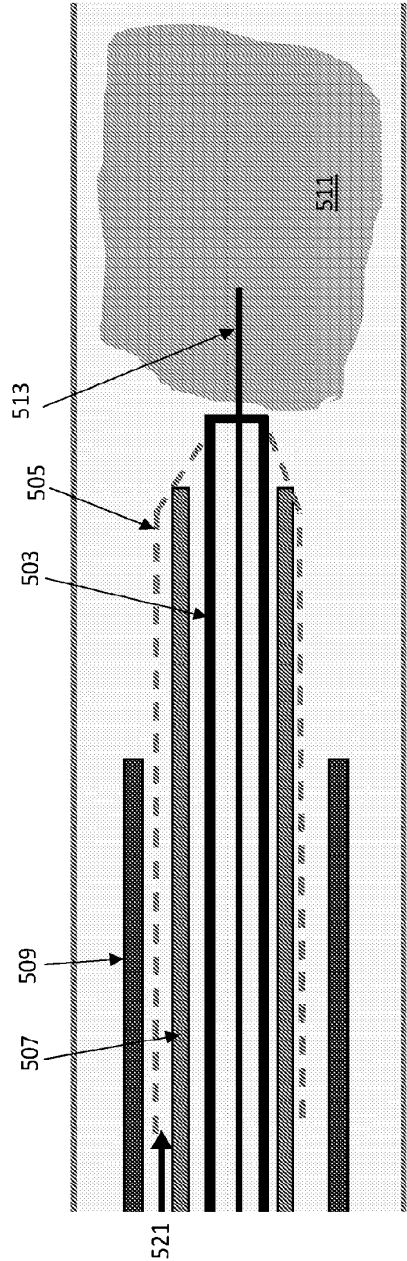


FIG. 5B

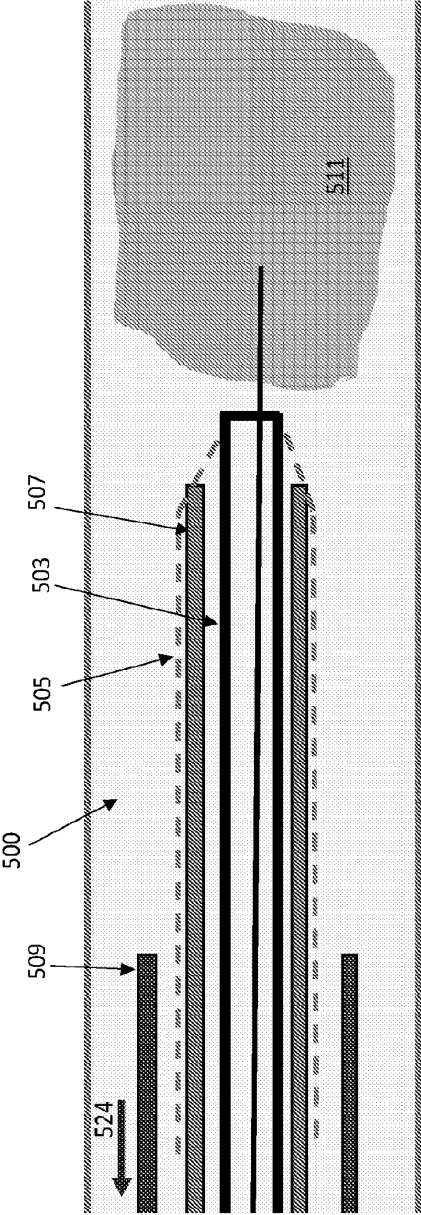


FIG. 5C

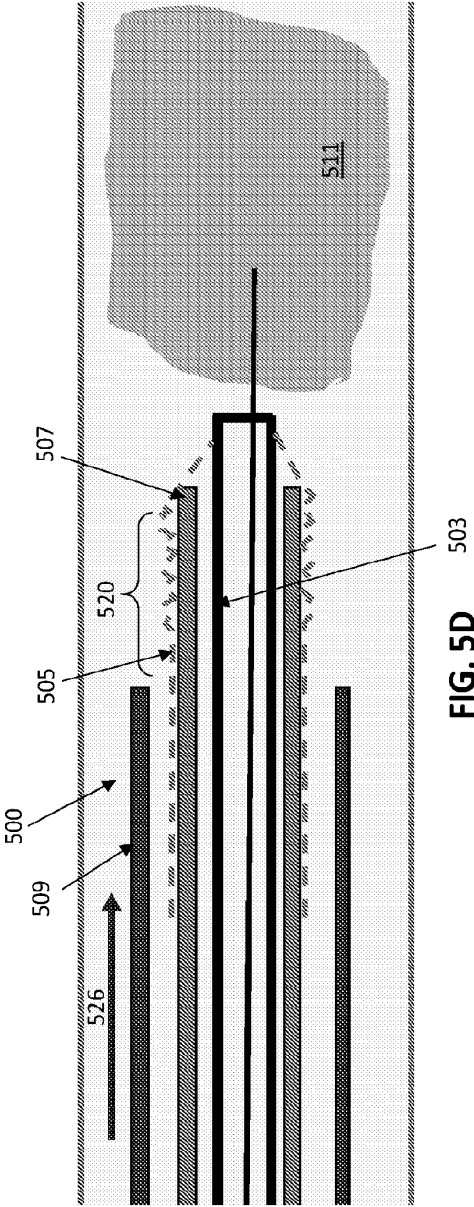


FIG. 5D

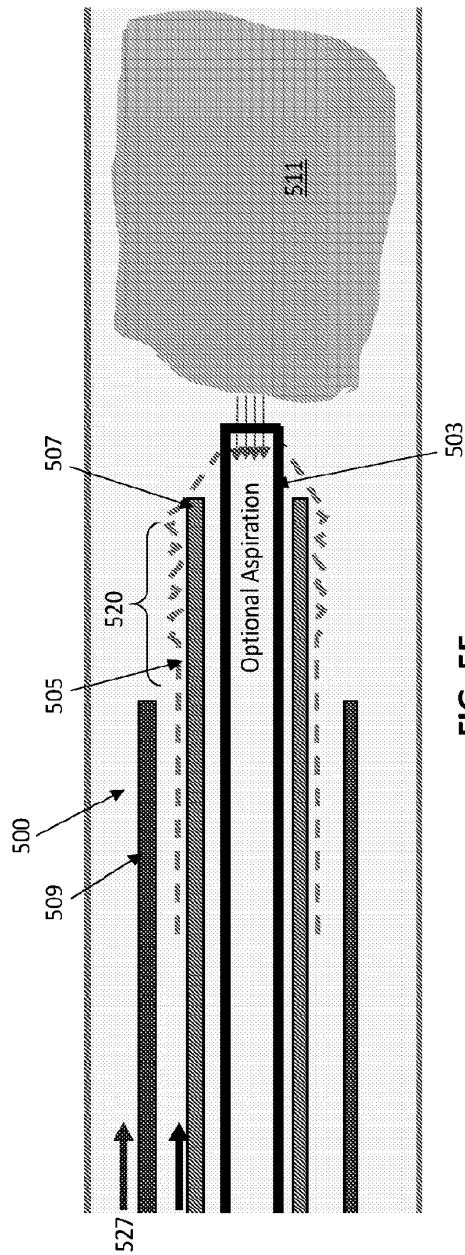


FIG. 5E

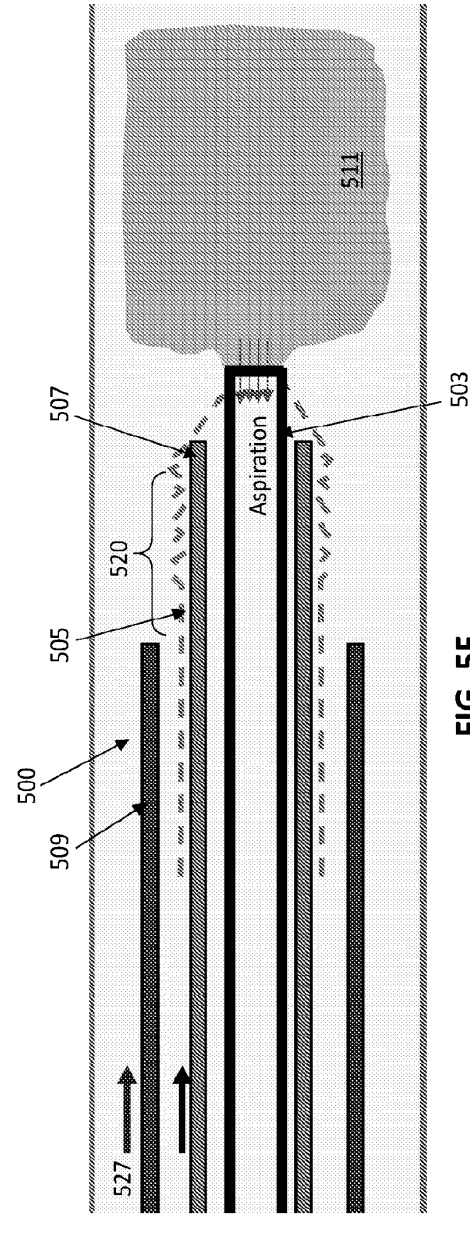


FIG. 5F

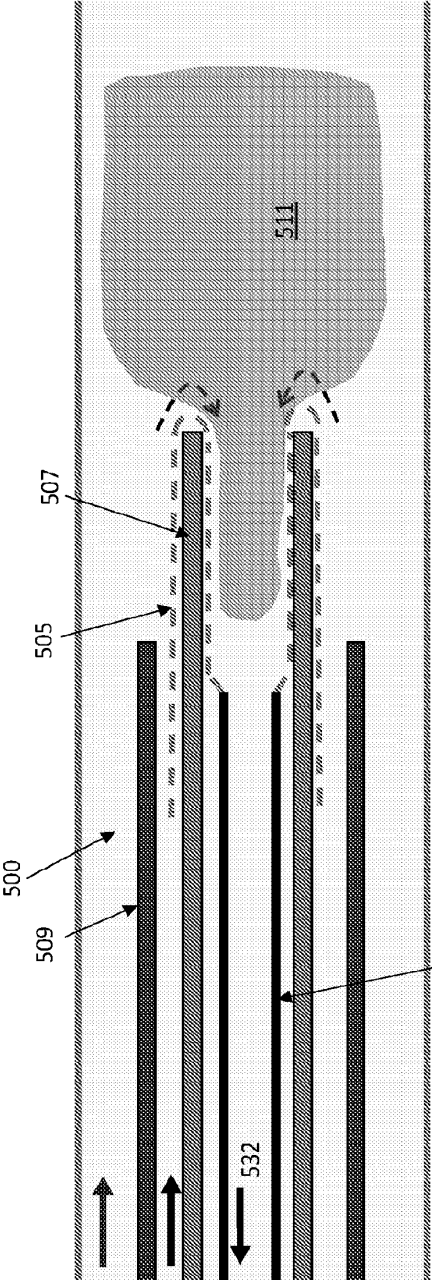


FIG. 5G

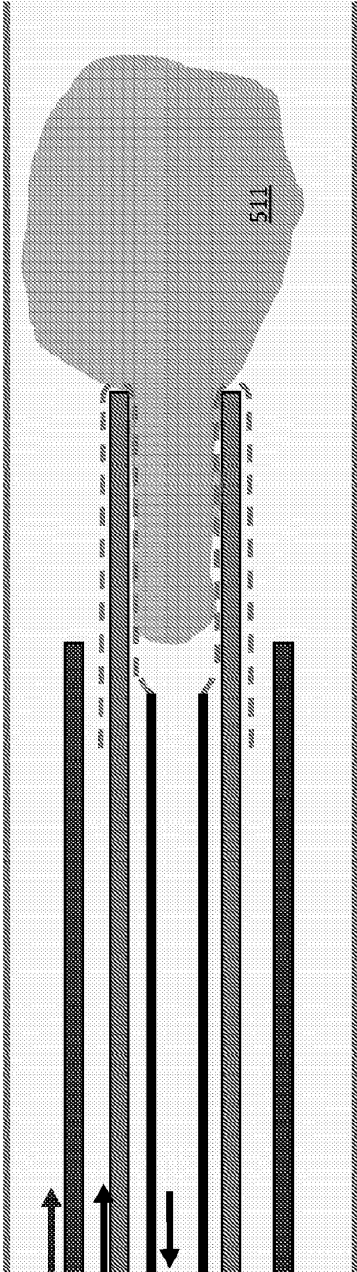
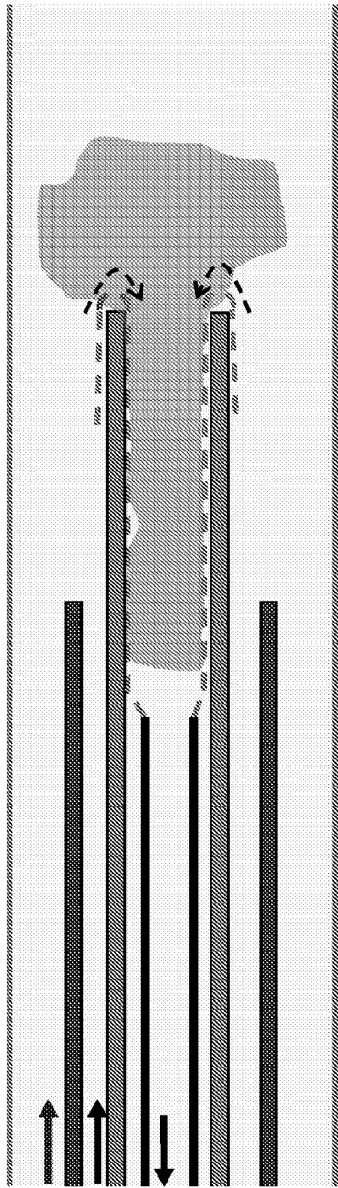
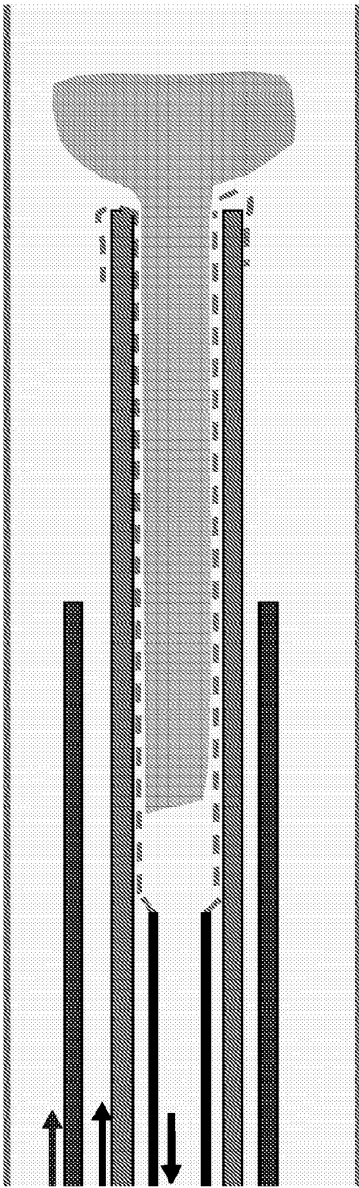


FIG. 5H



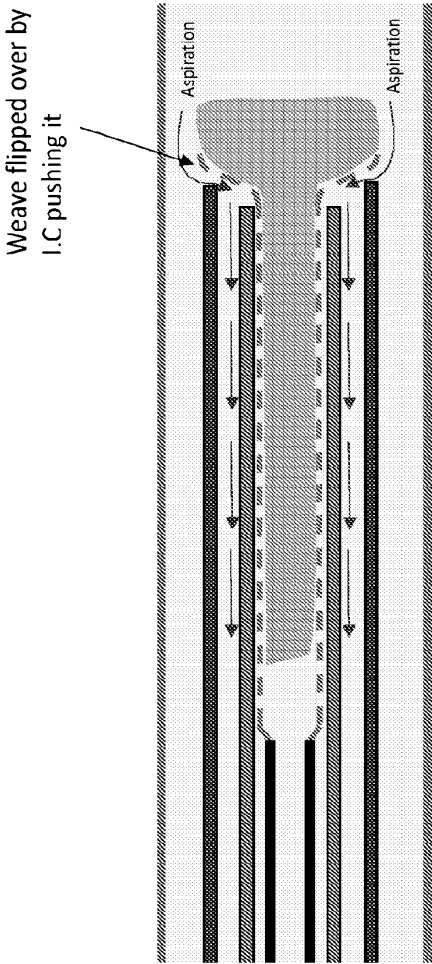


FIG. 5K

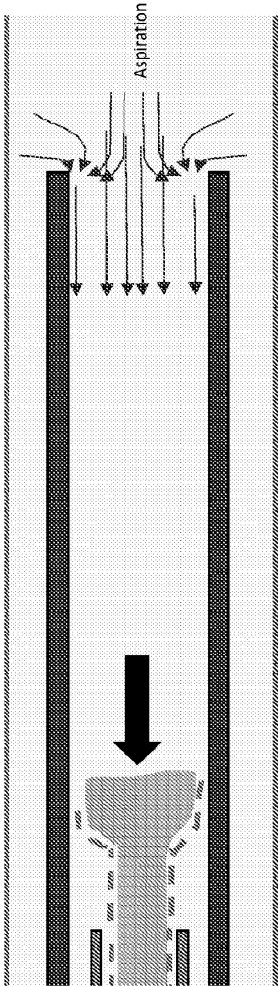


FIG. 5L

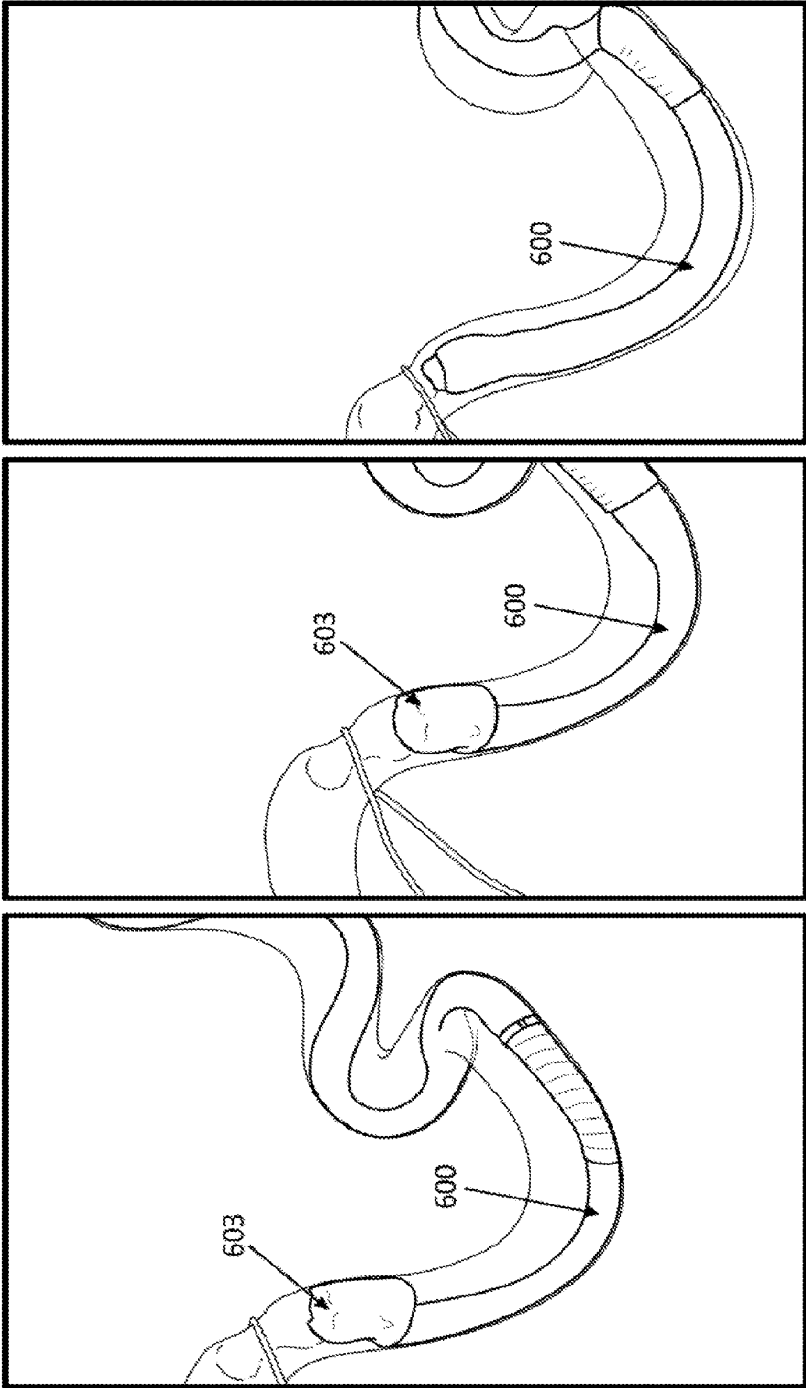


FIG. 6C

FIG. 6B

FIG. 6A

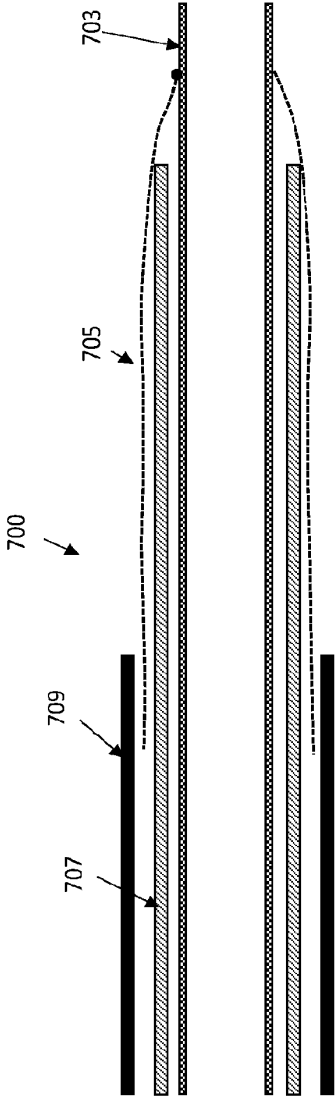


FIG. 7A

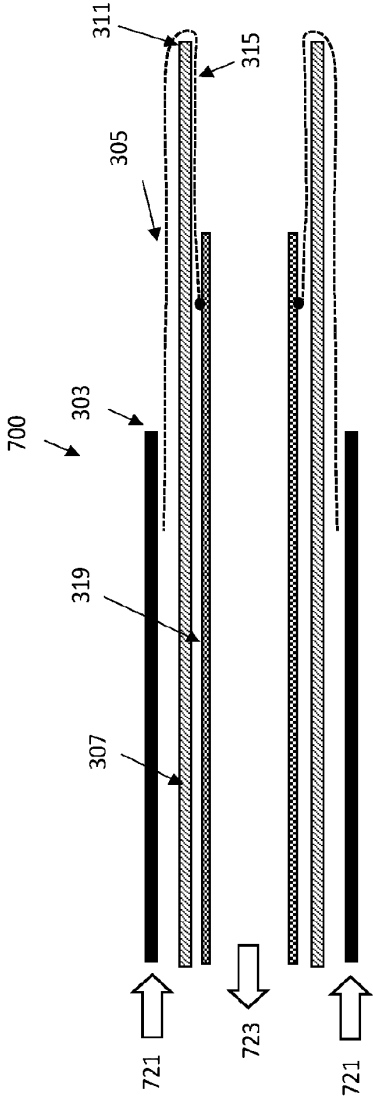


FIG. 7B

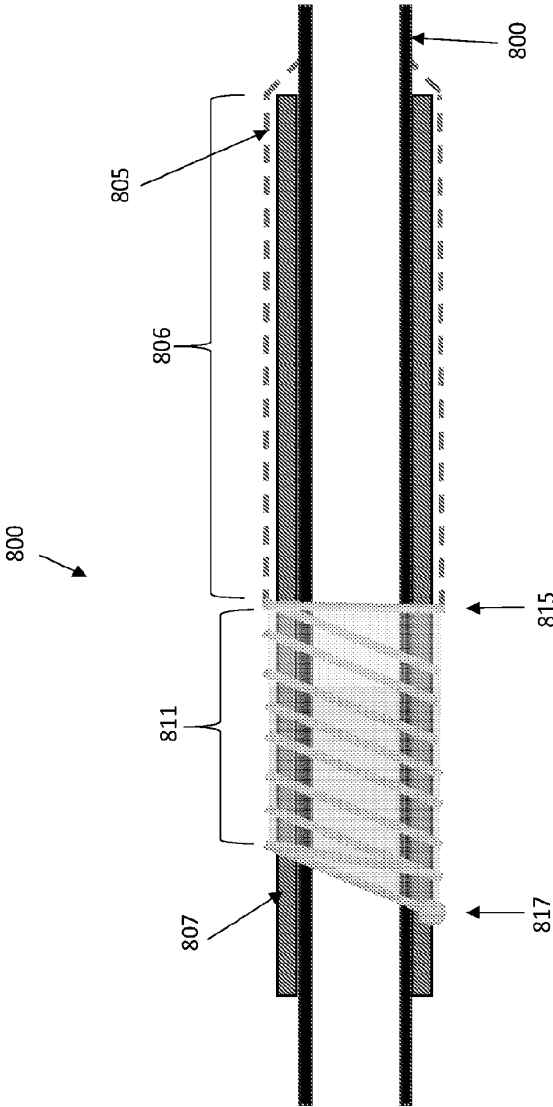
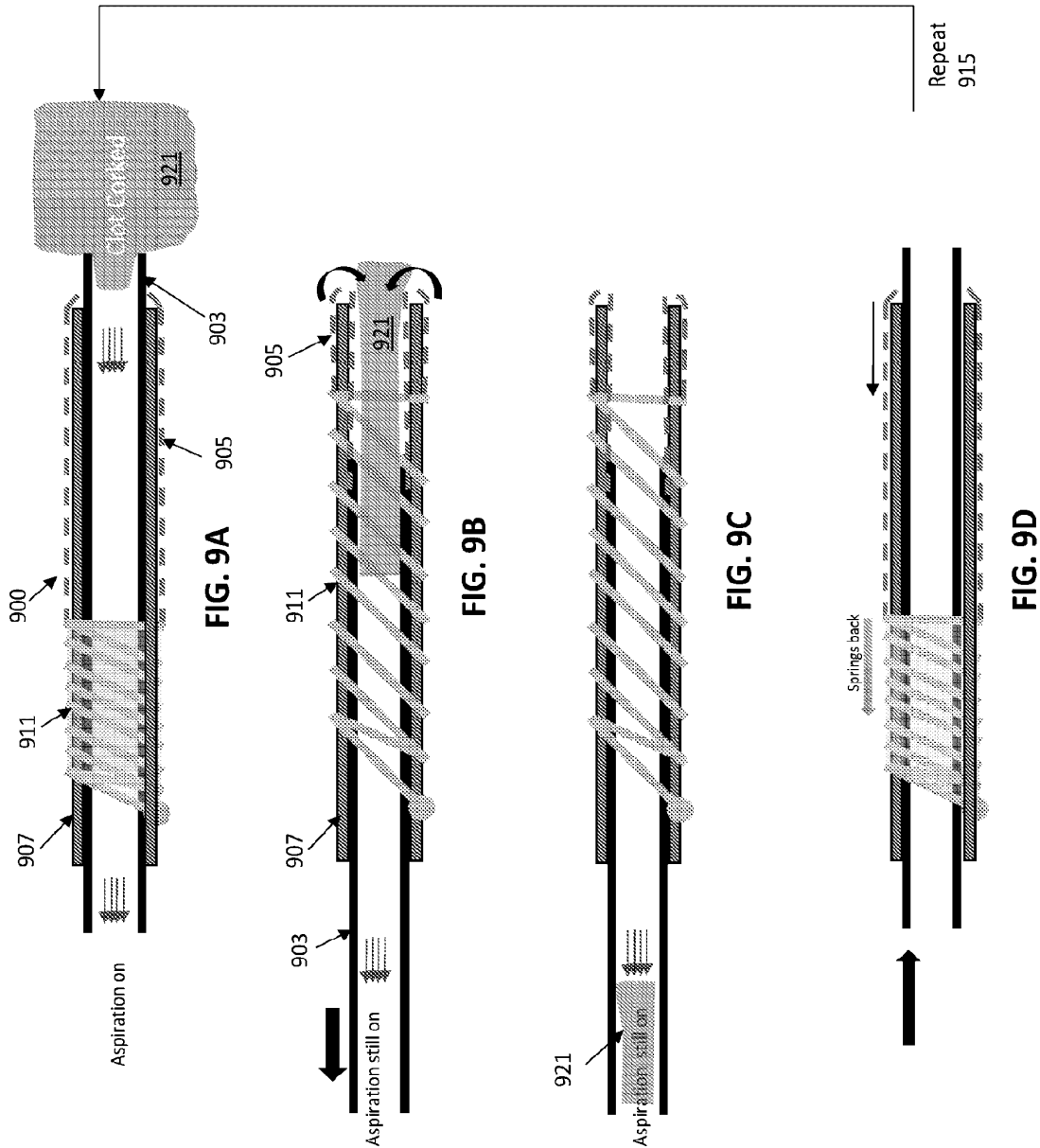


FIG. 8



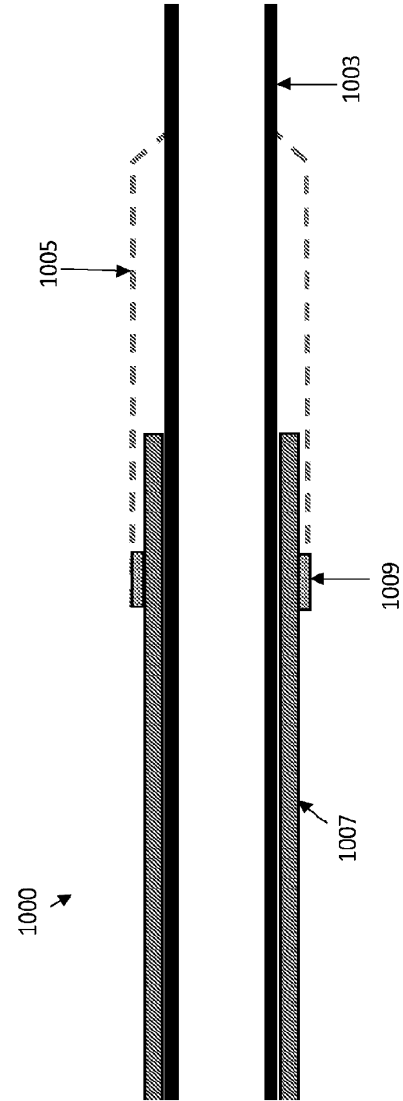


FIG. 10A

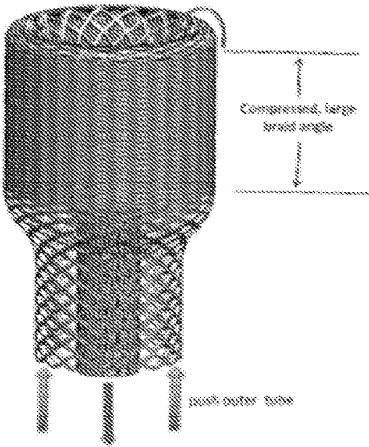
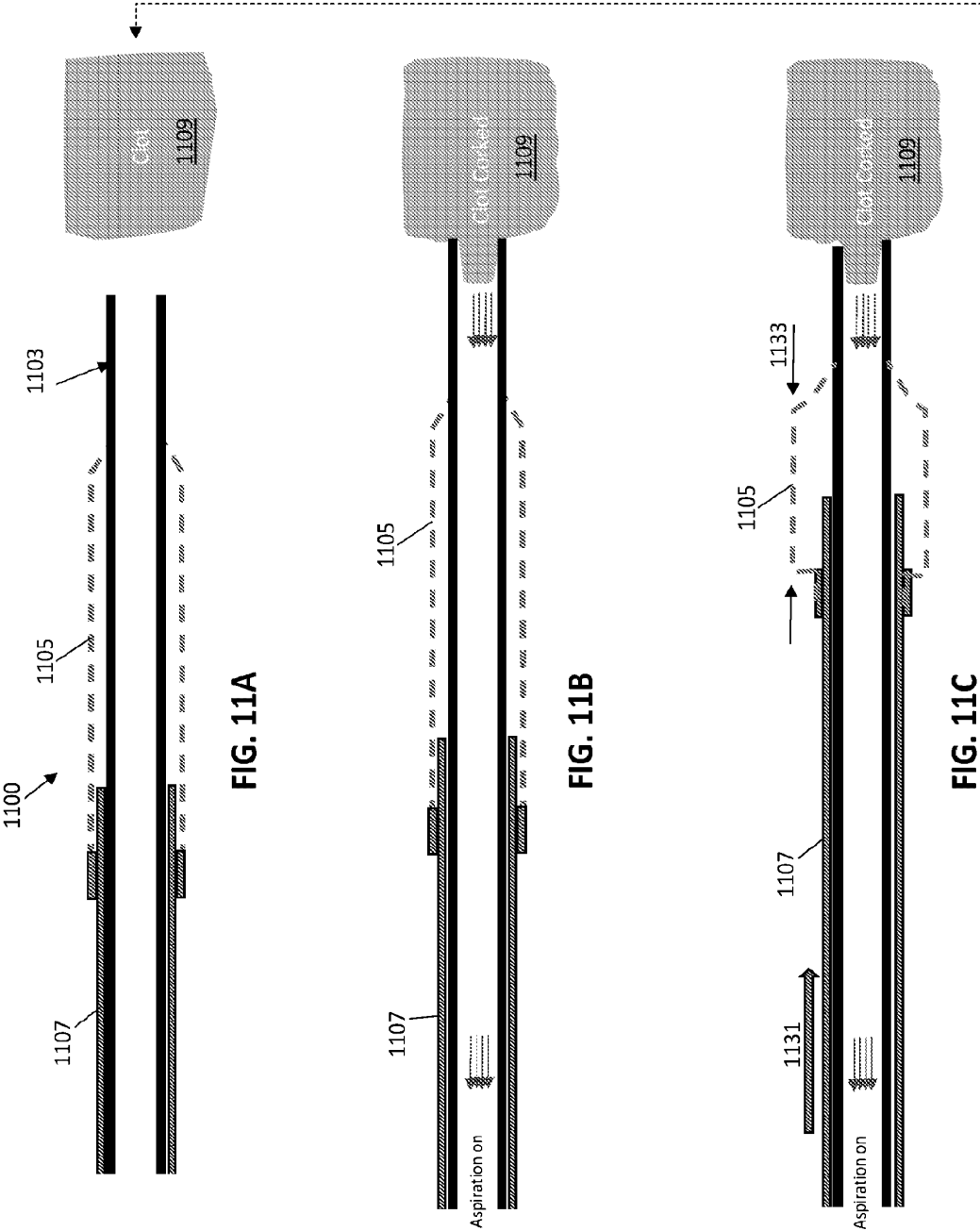


FIG. 10B



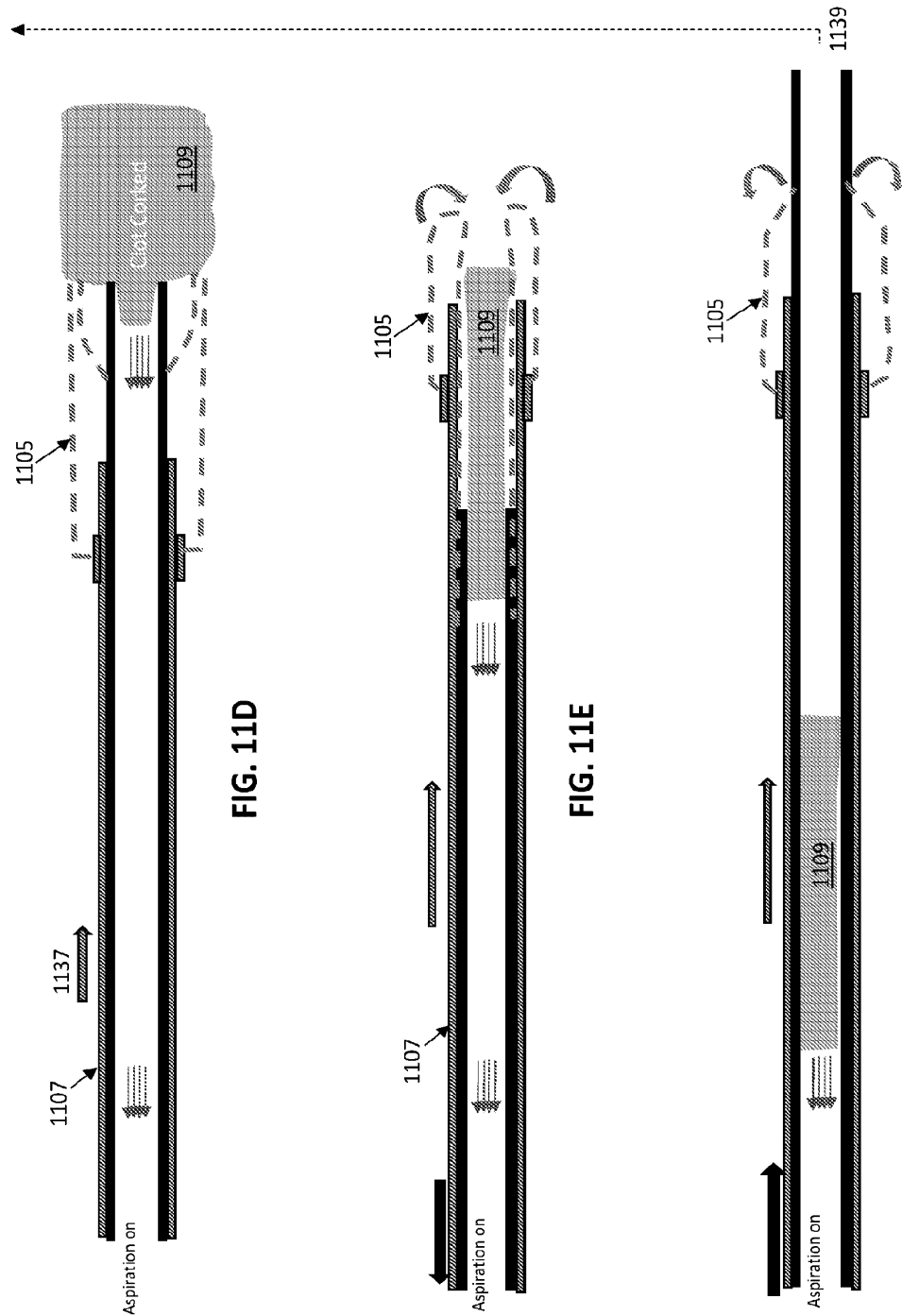


FIG. 11D

FIG. 11E

FIG. 11F

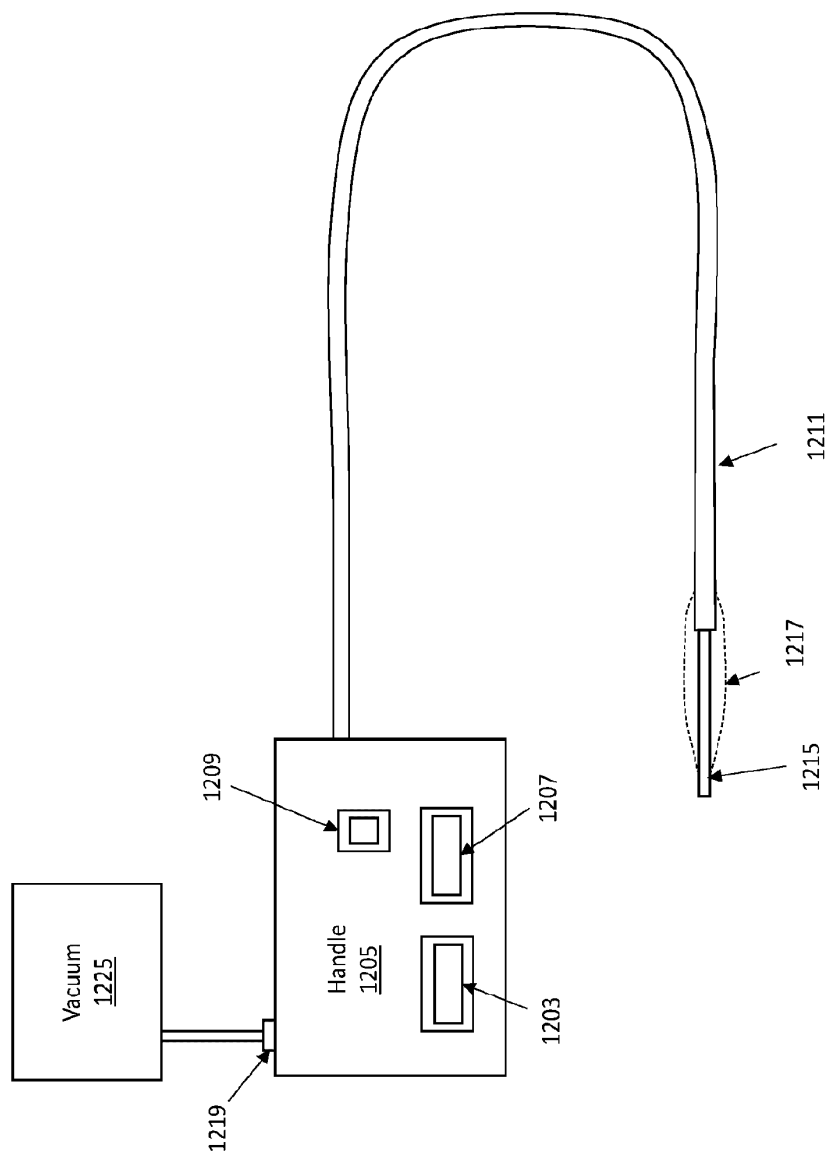


FIG. 12
(not to scale)

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2019/032061

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61B17/22 A61B17/221 A61B17/34
ADD.

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

B. FIELDS SEARCHED

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

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

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

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	<p>US 2017/086864 A1 (GREENHALGH E SKOTT [US] ET AL) 30 March 2017 (2017-03-30) cited in the application figure 6A figure 8 figure 10A figure 36 paragraph [0134] - paragraph [0136] paragraph [0141] - paragraph [0142] paragraph [0158] paragraph [0188] paragraph [0193]</p> <p style="text-align: center;">----- -/--</p>	1-12

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

☒ See patent family annex.

* Special categories of cited documents :

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

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search

10 July 2019

Date of mailing of the international search report

23/07/2019

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2
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Authorized officer

Biegler, Marcel

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2019/032061

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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A	US 5 389 100 A (BACICH STEVEN R [US] ET AL) 14 February 1995 (1995-02-14) figure 2 column 1, line 15 - line 68 -----	1
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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2019/032061

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(12) STANDARD PATENT
(19) AUSTRALIAN PATENT OFFICE

(11) Application No. **AU 2015210338 B2**

(54) Title
STEERABLE MEDICAL DELIVERY DEVICES AND METHODS OF USE

(51) International Patent Classification(s)
A61M 25/01 (2006.01) **A61M 25/16** (2006.01)
A61M 25/09 (2006.01)

(21) Application No: **2015210338** (22) Date of Filing: **2015.08.04**

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(74) Agent / Attorney
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US 7402151 B2

ABSTRACT

A steerable medical device, comprising a steerable portion; a first tubular member comprising a first flexible polymeric tubular member; and a second tubular member comprising a second flexible polymeric tubular member, wherein the first tubular member is disposed within the second tubular member and permanently axially fixed to the second tubular member at a fixation location distal to the steerable portion; and an external controller that is adapted to be actuated to put one of the first tubular member and the second tubular member in tension and the other of the first tubular member and the second tubular member in compression, and wherein the first and second tubular members are adapted such that the steerable portion is steered in a first direction when the external controller is actuated.

STEERABLE MEDICAL DELIVERY DEVICES AND METHODS OF USE**CROSS-REFERENCE**

[0001] This application claims the benefit of U.S. Provisional Application No. 61/220,160, filed June 24, 2009; U.S. Provisional Application No. 61/220,163, filed June 24, 2009; and U.S. Provisional Application No. 61/232,362, filed August 7, 2009, all of which are incorporated by reference herein.

BACKGROUND OF THE INVENTION

[0002] Delivery devices are used to deliver, or guide, medical devices or instruments to a target location within a subject. The delivery devices provide access to target locations within the body where, for example, diagnostic, therapeutic, and interventional procedures are required. Access via these devices is generally minimally invasive, and can be either percutaneous, or through natural body orifices. The access can require providing a guiding path through a body lumen, such as, for example without limitation, a blood vessel, an esophagus, a trachea and adjoining bronchia, ducts, any portion of the gastro intestinal tract, and the lymphatics. Once the delivery device has provided access to the target location, the delivery device is then used to guide the medical device or instrument to perform the diagnostic, therapeutic, or interventional procedure. An example of such a delivery device is a guide catheter, which may be delivered by steering it to its required destination, tracking it along a previously delivered guide wire, or both. The list of components being delivered for use percutaneously is large and rapidly growing.

[0003] Minimal outer dimensions of these delivery devices are important for minimizing the injury associated with delivery. Minimizing the wall thickness of the delivery device provides additional space for the medical device to be guided, while minimizing the injury associated with entry into the subject and the closure needed. Flexibility of the delivery device is important in allowing the guiding device to track or be steered to its target destination along tortuous paths while minimizing injury to the intervening tissues. The delivery device also needs to have compressive and tensile properties sufficient to support its delivery to the target site. When tracking around bends in the body, any kinks created in the guiding device can create an obstruction to the delivery of the medical device. When used as a steerable device, the distal end of the delivery device is preferably deflectable over a range of bend radii and responsive to the steering controls. The delivery device also should support torque transmitted from the handle to the distal region.

[0004] Once the delivery device is in place the delivery device preferably also supports torque around a distal bend such that the medical device may be rotated into position while sustaining some contact loads. Additionally, once in place the guiding device preferably is sufficiently stiff to support and guide the medical device to its target destination. The guiding device should also remain stable and not shift from one state of equilibrium to another either spontaneously or under the influence of forces being imparted to it from the delivery of the medical device or its own control mechanisms. As the delivery

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device often travels down fluid-filled lumens such as, for example without limitation, blood vessels, it should additionally incorporate a seal against fluids impinging upon its periphery and another at its distal end which interfaces with the medical device to maintain a seal around the delivery device.

[0005] There exists a need for improved steerable delivery devices and guiding medical devices.

SUMMARY OF THE INVENTION

[0006] One aspect of the disclosure is a steerable medical delivery device. The device includes a steerable portion comprising a first tubular member and a second tubular member, wherein one of the first and second tubular members is disposed within the other, wherein the first and second tubular elements are axially fixed relative to one another at a fixation location distal to the steerable portion, and wherein the first and second tubular members are axially movable relative to one another along the steerable portion to steer the steerable portion in a first direction, and wherein the first tubular member is adapted to preferentially bend in a first direction.

[0007] In some embodiments the second tubular member is substantially uniform and is not adapted to preferentially bend.

[0008] In some embodiments the first tubular member comprises at least one slot therein to define a first spine. The second tubular member can also include at least one slot therein to define a second spine.

[0009] In some embodiments the first tubular member comprises a braided material.

[0010] In some embodiments the first tubular member is disposed within the second elongate tubular member.

[0011] In some embodiments the first tubular member is adapted to be moved axially relative to the second tubular member to apply one of a compressive force and a tensile force to the first tubular member and the other of the compressive force and the tensile force to the second tubular member to steer the steerable portion in a first direction.

[0012] In some embodiments the second tubular member is adapted to preferentially bend in a second direction, which can be substantially opposite the first direction.

[0013] In some embodiments the second elongate tubular element is a floating tubular member.

[0014] One aspect of the disclosure is a steerable medical delivery device. The device includes a steerable portion comprising an outer tubular member and an inner tubular member, wherein the inner tubular member is disposed radially within the outer tubular member, wherein the outer tubular member includes at least one outer slot therein to define an outer spine, wherein the inner tubular member includes at least one inner slot therein to define an inner spine, the inner and outer spines being offset relative to one another, and wherein the outer tubular member and the inner tubular member are axially movable relative to one another along the steerable portion and are axially fixed relative to one another at a location distal to the steerable portion.

[0015] In some embodiments the outer tubular member comprises a plurality of discontinuous slots to define the outer spine.

[0016] In some embodiments the inner tubular member comprises a plurality of discontinuous slots to define the inner spine.

[0017] In some embodiments the inner and outer spines are offset substantially 180 degrees from one another.

[0018] In some embodiments the inner and outer spines are adapted to receive one of a compressive force and a tensile force to steer the steerable portion of the delivery device. The inner spine can be adapted to receive a compressive force thereto and the outer spine can be adapted to receive a tensile force thereto to steer the steerable portion of the delivery device in a first direction. Alternatively, the inner spine is adapted to receive a tensile force thereto and the inner spine is adapted to receive a compressive force thereto to steer the steerable portion of the delivery device in a first direction.

[0019] In some embodiments the inner and outer slots are in substantial alignment relative to a longitudinal axis of the steerable portion when the steerable portion is in a straightened configuration. The inner and outer slots can be substantially perpendicular to the longitudinal axis of the steerable portion when the steerable portion is in a straightened configuration.

[0020] In some embodiments the inner and outer slots are not in alignment relative to a longitudinal axis of the steerable portion when the steerable portion is in a straightened configuration.

[0021] In some embodiments at least one of the outer slot and the inner slot includes a first interlocking element and a second interlocking element each adapted to allow relative movement therebetween when in a first configuration and each further adapted to prevent movement therebetween when in a second configuration.

[0022] In some embodiments the delivery device further comprises a fixation element distal to the steerable portion adapted to prevent axial movement between the outer tubular element and the inner tubular element.

[0023] In some embodiments the inner tubular member has an inner surface, and wherein the inner surface is sized to allow a medical device to be advanced therethrough.

[0024] One aspect of the disclosure is a method of steering a medical delivery device. The method includes a steerable medical delivery device comprising a steerable portion with an outer tubular member and an inner tubular member, wherein the outer tubular member includes at least one outer slot therein to define an outer spine, and wherein the inner tubular members includes at least one inner slot therein to define an inner spine, the inner and outer spines being offset relative to one another. The method includes applying a compressive force to one of the inner and outer spines and a tensile force to the other of the inner and outer spines to steer the steerable portion from a first configuration to a second configuration. The method also includes preventing relative axial movement of the inner tubular member and outer tubular member at a location distal to the steerable portion while the steerable portion is being steered.

[0025] In some embodiments the applying step comprises applying the compressive force to the inner spine, and wherein applying the compressive force to the inner spine causes the tensile force to be applied to the outer spine to steer the steerable portion. Applying the compressive force to inner spine can include moving the inner tubular member distally relative to the outer tubular member.

[0026] In some embodiments the applying step comprises applying the tensile force to the inner spine, and wherein applying the tensile force to the inner spine causes the compressive force to be applied

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to the outer spine to steer the steerable portion. Applying the tensile force to the inner spine can include moving the inner tubular member proximally relative to the outer tubular member.

[0027] In some embodiments the applying step comprises applying the compressive force to the outer spine, and wherein applying the compressive force to the outer spine causes the tensile force to be applied to the inner spine to steer the steerable portion. Applying the compressive force to the outer spine can include moving the outer spine distally relative to the inner tubular member.

[0028] In some embodiments the applying step comprises applying the tensile force to the outer spine, and wherein applying the tensile force to the outer spine causes the compressive force to be applied to the inner spine to steer the steerable portion. Applying the tensile force to the outer spine can include moving the outer tubular element proximally relative to the inner tubular member.

[0029] One aspect of the disclosure is a steerable medical delivery device. The medical device includes an elongate member comprising a steerable portion adapted to be steered in a first direction, and a floating element disposed within the steerable portion, wherein the floating element is axially fixed relative to the elongate member at a location proximal to the steerable portion, and is not axially fixed relative to the elongate member along the steerable portion.

[0030] In some embodiments the elongate member is a catheter.

[0031] In some embodiments the elongate member comprises an inner tubular member with an inner slot therein to define a first spine, and an outer tubular member with an outer slot therein to define an outer spine, wherein the spines are offset from one another.

INCORPORATION BY REFERENCE

[0032] All publications and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication or patent application was specifically and individually indicated to be incorporated by reference.

BRIEF DESCRIPTION OF THE DRAWINGS

[0033] The novel features of the invention are set forth with particularity in the disclosure herein. A better understanding of the features and advantages of the present invention will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the disclosure are utilized, and the accompanying drawings of which:

[0034] FIG. 1 is a perspective view of a steerable portion of a steerable medical delivery device.

[0035] FIGS. 2a, 2b, and 2c illustrate steering of exemplary steerable portions of steerable medical delivery devices

[0036] FIG. 3 illustrates a flattened view showing an exemplary slot pattern for use in a steerable portion of a delivery device.

[0037] FIG. 4 illustrates a flattened view showing an exemplary slot pattern for use in a steerable portion of a delivery device.

[0038] FIG. 5 illustrates a flattened view showing an exemplary slot pattern for use in a steerable portion of a delivery device.

- [0039] FIG. 6 illustrates a flattened view showing an exemplary slot pattern for use in a steerable portion of a delivery device.
- [0040] FIGS. 7a and 7b illustrate flattened views showing exemplary slot patterns for use in a steerable portion of a delivery device.
- [0041] FIG. 8 illustrates an exemplary steerable portion including an outer slotted tubular member and an inner slotted tubular member, with an intermediate tubular element therebetween.
- [0042] FIG. 9 illustrates an exemplary steerable portion including an outer slotted tubular member and an inner non-slotted tubular member.
- [0043] FIG. 10 illustrates an exemplary steerable portion including an inner slotted tubular member and outer non-slotted tubular member.
- [0044] FIG. 11a is a representation of a pattern for use in a steerable portion capable of being cut from a tube or created by winding a ribbon into a tube.
- [0045] FIG. 11b illustrates a section of a ribbon for use in the tube of FIG. 11a.
- [0046] FIGS. 12a and 12b are different views of a groove pattern for use in a steerable portion.
- [0047] FIGS. 13a, 13b, and 13c are various views of a cut pattern for use in a guide catheter
- [0048] FIG. 14 illustrates an outer guide member and a delivery device therein.
- [0049] FIG. 15 illustrates a discontinuous cut pattern for use on a tubular member that is most steerable in compression.
- [0050] FIGS. 16a and 16b illustrate a portion of a tubular member formed with the cut pattern from FIG. 15, while FIG. 16c illustrates compressive and tensile forces acting thereon.
- [0051] FIG. 17 is a graph illustrating Force v. Displacement behavior associated with the application of loads or displacements at various points around the tubular member shown in FIGS. 15-16c.
- [0052] FIG. 18 illustrates a continuous cut pattern for use on a tubular member that is most steerable in tension.
- [0053] FIG. 19 illustrates a discontinuous cut pattern for use on a tubular member most steerable in tension.
- [0054] FIG. 20 illustrates a continuous cut pattern for use on a tubular member most deflectable in tension.
- [0055] FIG. 21 illustrates a discontinuous cut pattern for use on a tubular member with a substantially straight, continuous spine.
- [0056] FIG. 22 illustrates a discontinuous cut pattern for use on a tubular member with a helical, continuous spine.
- [0057] FIG. 23 is a flattened view of an exemplary tubular member with more than one spines.
- [0058] FIG. 24 is a flattened view of an exemplary member with a single substantially straight spine.
- [0059] FIG. 25 illustrates a flattened portion of an exemplary tubular member. The slots create a relatively neutral pattern.
- [0060] FIG. 26 illustrates a flattened portion of an exemplary tubular member including interlocking features with complimentary curved surfaces that are adapted to support rotation of the tubular member.

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- [0061] FIG. 27 illustrates an exemplary steerable delivery device including a floating tubular member disposed therein.
- [0062] FIG. 28 illustrates an exemplary steerable medical delivery system.
- [0063] FIGS. 29A and 29B illustrate an exemplary embodiment of a lockable portion of a guiding device.
- [0064] FIGS. 30A-30H illustrate exemplary beads that can be used in a lockable guiding device.

DETAILED DESCRIPTION OF THE INVENTION

[0065] The disclosure relates generally to steerable delivery devices, which may be considered steerable guide devices, and their methods of use. The steerable delivery devices can be used to deliver, or guide, any type of suitable medical device or instrument therethrough to a location within a patient's body. For example, the steerable delivery devices can be used to deliver, or guide, a medical device into bodily lumens such as, for example without limitation, a blood vessel, an esophagus, a trachea and possibly adjoining bronchia, any portion of the gastrointestinal tract, an abdominal cavity, a thoracic cavity, various other ducts within the body, and the lymphatics. Once the steerable delivery device has gained access to a target location within the subject, the medical device or instrument is delivered, or guided, to the target location to carry out the medical intervention. Steerable delivery devices described herein can be tracked along a previously delivered guide wire.

[0066] Figure 1 is a perspective view of a distal portion of an exemplary steerable delivery device. Steerable device 10 includes steerable portion 12 and has distal end 15. Steerable portion 12 includes an outer tubular member 14 and inner tubular member 16. Outer tubular member 14 has an inner surface defining a lumen therein, and inner tubular member 14 is sized to be disposed within the inner lumen of outer tubular member 14. Outer tubular member 14 and inner tubular member 16 are axially fixed relative to one another at fixation location 18 along the length of steerable device 10. That is, at fixation location 18, the inner and outer tubular members are not adapted to move distally or proximally relative to one another. Fixation location 18 is located distal to steerable portion 12. At locations proximal to fixation location 18, inner tubular member 16 and outer tubular member 14 are axially movable relative to one another. That is, along steerable portion 12, inner tubular member 16 and outer tubular member 14 are adapted to move axially relative to another. Outer tubular member 14 has slots 22 formed therein to define spine 20. Spine 20 extends along a length of steerable portion 12. Slots 22 are shown substantially perpendicular to the longitudinal axis "L" of steerable portion 12, when steerable portion 12 is in a straightened configuration as shown in Figure 1. Inner tubular member 16 also has slots formed therein (not shown) in the steerable portion to define a spine (not shown).

[0067] Figures 2a and 2b illustrate an exemplary embodiment of a steerable delivery device. Steerable device 30 has a distal end 37 and includes outer tubular element 34 and inner tubular element 36 which are axially immovable relative to one another at fixation location 38, but are axially movable proximal to fixation location 38. Outer tubular element 34 includes a plurality of slots 42 formed therein to define spine 40. Inner tubular element 36 also includes a plurality of slots formed therein (not shown) to define a spine (not shown). In Figures 2a and 2b, the spines are disposed substantially 180 degrees

apart from one another. Figure 2a illustrates steerable portion 32 deflected, or steered, into a first bent configuration, while Figure 2b illustrates steerable portion 32 steered into a second bent configuration different than the first bent configuration. To steer the steerable portion into the configuration shown in Figure 2a, a proximal portion of outer tubular member 34 is moved axially, and specifically proximally, relative to inner tubular member 36, while the tubular elements 34 and 36 are axially fixed relative to one another at fixation location 38. This can be accomplished by pulling outer tubular member 23 in a proximal "P" direction while maintaining the position of inner tubular member 36, by pushing inner tubular member 36 in a distal "D" direction while maintaining the position of outer tubular member, or by a combination thereof. The relative axial movement of the inner and outer tubular members as shown in Figure 2a applies substantially opposing compressive and tensile forces to the spines of the tubular members, thus deflecting, or steering, the device in the direction of spine 40 of outer tubular member 34, as is shown in Figure 2a. Figure 2b illustrates a step of steering device 30 in the substantially opposite direction from that shown in Figure 2a. To steer device 30 into the configuration shown in Figure 2b, inner tubular member is moved proximally relative to outer tubular member 34. This can be performed by moving the outer tubular member distally, moving the inner tubular member proximally, or a combination thereof. This relative axial movement applies substantially opposing compressive and tensile forces to the spines in steerable portion 32 of device 30, thereby deflecting the device in a direction substantially opposite that of spine 40 of outer tubular member 34.

[0068] Figure 2c shows a sectional view of the steerable portion from Figure 2b, including optional floating tubular member 505 disposed within inner tubular member 504. Steerable portion 500 includes inner tubular member 504 and outer tubular member 502. Inner tubular member 504 has interrupted slots 512 formed therein to define spine 506. Outer tubular member 502 has interrupted slots 510 formed therein to define spine 508. The steerable portion is bent along the axis of spine 506. Spine 508 and spine 506 are substantially 180 degrees apart from one another (i.e., they are on substantially opposite sides of steerable portion 500).

[0069] To steer steerable portion 500 into the configuration shown in Figure 2c (also shown in Figure 2b), inner tubular member 504 is pulled in the proximal direction relative to outer tubular member 502, as is illustrated in Figure 2b. Pulling on the inner member 504 applies a tensile force to inner spine 506. Because inner and outer tubular members 504 and 502 are axially fixed relative to one another at a location distal to the steerable portion, pulling on inner member 504 relative to outer tubular member 502 results in a compressive force applied to the distal end of the steerable portion of outer tubular member 502. The compressive force begins to compress slots 510 on outer tubular member 502. Compression of outer slots 510 causes outer tubular member to bend in the direction shown in Figure 2c, and the bending stops when inner slots 510 are closed. Thus, outer slots 510 limit the degree of the bend of steerable portion 500. The same type of bending that is shown in Figures 2b and 2c would occur if outer tubular element 502 were pushed distally relative to inner tubular member 504.

[0070] If outer tubular member 502 were pulled proximally relative to inner tubular member 504 (or if inner tubular member 504 were pushed distally relative to outer tubular member 502), steerable portion

500 would bend in the manner shown in Figure 2a. The degree of the bend would be limited by inner slots 512.

[0071] Figure 2c illustrates an embodiment of a medical device including a floating tubular member, which may be referred to herein as a floating liner. In general, a floating liner is disposed within an outer structure. In the exemplary embodiment in Figure 2c, the outer structure includes the inner and outer tubular members. The outer structure generally provides structural and mechanical properties for the delivery device, and the floating liner provides lubricity for a medical device or instrument to be advanced therethrough. A floating liner is generally impermeable as well. A floating liner “floats” with a portion of the outer structure. That is, the floating liner is not fixed to a portion of the outer structure in which it floats. In the exemplary embodiment in Figures 2c, the floating liner floats within the steerable portion (i.e., is not attached to the steerable portion). In general, a floating liner is attached to the outer structure at a location proximal to the steerable or bendable portion of the device. For example, in the embodiment in Figure 2C, the floating liner is attached to the outer structure at a location proximal to the steerable portion. A floating liner doesn’t impede the ability of the outer structure to move as it is steered, bent, actuated, receives forces applied thereto, etc.

[0072] In some embodiments the floating liner is a lubricious polymer tube. In some embodiments the floating liner includes wire windings and/or axially laid wires.

[0073] The outer structure in which the floating liner floats can be any suitable tubular member. For example, the outer structure can be a catheter, guiding device, a steerable device, etc. In some embodiments the outer structure has a neutral bending preference but is not intended to be steered. In this embodiment the outer structure provides axial and radial stiffness thereby limiting the likelihood of kinks while the floating liner provides lubricity and is additionally restrained from kinking by the outer structure.

[0074] Figures 2a and 2b also show proximal portion 35 of device 30, which is proximal to steerable portion 32, having a substantially neutral portion designed to have no preferential bending axis while at the same time transmitting axial force and torque applied at a proximal end of the device (not shown).

[0075] In some embodiments, the inner and outer tubular members are adapted to have opposing compressive and tensile loads applied thereto to steer the steerable portion. In some embodiments at least one of the tubular members has a neutral bending axis. A neutral bending axis, as used herein, generally refers to an axis of the tubular member along which there is substantially no axial displacement in response to a compressive and/or tensile force applied thereto. Axial displacement along the neutral bending axis, in response to a compressive and/or tensile force applied thereto, is less than axial displacement of structures elsewhere in the tubular member. In particular, axial displacement along the neutral bending axis is minimal relative to axial displacement of structures elsewhere in the tubular member. Examples of a neutral bending axis include spine 382 in Figure 21 and spines 412 and 414 in Figure 23.

[0076] In some embodiments at least one of the tubular members is adapted to offset the neutral bending axis relative to the opposite tubular member. The neutral bending axes of the tubular members

can be offset to be approximately tangent to opposite sides of the opposing members, making the neutral bending axis offset equal to the diameter of the device, thus providing the highest possible bending leverage ratio for a given device diameter.

[0077] The tubular members described herein may exhibit preferential or neutral bending behavior. Neutral bending behavior implies that the displacement for a given radially applied load (from the edge of the tubular member through the longitudinal axis of the tubular member) will be independent of the radial angle from which the load was applied. In contrast, in a non-neutral structure the displacement associated with a radial load will change as a function of the radial angle. An exemplary tubular member tending towards neutral bending behavior is shown in Figure 25 or the uninterrupted spiral pattern of Figure 25 which is essentially a spring.

[0078] In some embodiments the inner and outer tubular elements are adapted to be rotated relative to one another to enhance the steerability of the steerable portion. The tubular elements can rotate relative to one another yet remain axially fixed relative to one another at a location distal to the steerable portion. In these embodiments, in addition to axial forces being applied to one or more tubes, one or more tubular members are also rotated with respect to each other to steer the steerable portion.

[0079] In some embodiments only one of the inner and outer tubular members has at least one slot defining a spine along the steerable portion, while the other does not have any slots along the steerable portion. For example, in Figures 2a and 2b, outer tubular member 34 can have a slot and a spine while inner tubular member 36 does not have a slot formed therein. Alternatively, inner tubular member 36 can have at least one slot and a spine while outer tubular member 34 does not have a slot formed therein. The steerable portion can be steered as described herein if at least one of the inner and outer tubular members is adapted to preferentially bend in a first direction.

[0080] In the embodiment in Figures 1 and 2 the slots in both tubular members are substantially perpendicular to the longitudinal axis of the steerable portion. The slots in one or both of the tubular members can be, however, at an angle relative to the longitudinal axis that is other than substantially 90 degrees.

[0081] In some embodiments the steerable device also includes a tubular element disposed between the inner and outer tubular members. The intermediate member can be, for example without limitation, a flexible polymeric material. The intermediate member can be encasing one or both of the tubular members, or comprising one or both of the members. The intermediate member can be adapted to provide a fluid barrier and/or a low friction surface.

[0082] Slots as described herein can be formed in a tubular member by laser machining or other machining processes. Forming the slots creates at least one spine in a tubular member. A spine as used herein can be considered a region of the steerable portion that imparts axial stiffness in compression or tension, or both, and may additionally include features that provide torsional stiffness. When a single spine is created in a tubular member, the neutral bending axis of the tubular member is moved to the spine of the tubular member.

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[0083] In some embodiments, a tubular member includes at least two spines, the combination of which moves the neutral bending axis of the tubular member to an axis parallel to, or tangent to when bent, the longitudinal axis of the tubular device and passing through the spines.

[0084] In some embodiments a liner, such as a flexible polymer liner, is bonded on the inner surface of the inner tubular member. In some embodiments a flexible polymer is bonded or otherwise disposed over the outer surface of the outer tubular member. A liner can also be disposed such that it is encasing the inner tubular member.

[0085] In some embodiments the steerable portion is comprised of a first tubular member that is adapted to bend preferentially in a first direction and a second tubular member that is not adapted to bend preferentially in one direction. In some instances of these embodiments, the second tubular member is a flexible polymer material with or without a braided or wire support. In some instances, a wire or other structural support is included in the first tubular member in the deflectable area to increase compressive and tensile stiffness along one side of the tubular member, thus moving the neutral bending axis from the longitudinal axis of the tubular member to the side of the tubular member that includes the structural support. In some instances wires are laid longitudinally and distributed evenly to increase axial stiffness in tension without creating a preferential bending.

[0086] In some embodiments the device includes three tubular members, having three offset neutral bending axes approximately 120 degrees radially spaced apart, thus providing the steerable device with universal steering in any direction.

[0087] Figure 3 illustrates, for ease of description, a flattened, or unrolled, portion of exemplary tubular member 50, which can be an inner or an outer tubular member. Tubular member 50 includes fixation region 52, steerable portion 54, and a proximal neutral portion 58. Steerable portion 54 includes a plurality of slots 56 formed therein to define spine 55 extending along the steerable portion. Slots 56 are sinuous-shaped slots, and spine 55 has a generally straight configuration along the length of steerable portion 54. That is, spine 55 is substantially parallel with the longitudinal axis of the tubular member. Fixation region 52 includes a plurality of holes 57 to facilitate bonding to provide for axial fixation relative to a second tubular member (not shown). Proximal portion 58 includes a plurality of multiple overlapping slots 60 to provide the desired flexibility, axial force transmission, and torque transmission characteristics.

[0088] Figure 4 illustrates a flattened, or unrolled, portion of exemplary tubular member 61, which can be an inner or an outer tubular member of a steerable portion. Tubular member 61 includes fixation region 62, steerable portion 64, and proximal neutral bending portion 68. Neutral bending portion 68 will exhibit minimal bending preference upon a compressive or tensile force applied thereto. Tubular member 61 is similar to tubular member 50 shown in Figure 3, but includes linking elements 72, which can be flexible. Each linking element extends from one side of a slot to the other side. Each linking element includes two arm portions extending from one side of the slot to the other side of the slot. The two arms meet at the point at which they are connected to one side of the slot. The linking elements extend along steerable portion 64 on substantially the opposite side as spine 65. Linking elements 72 enhance and/or

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control torque response and bending of steerable portion 64. As steerable portion 64 is bent about spine 65, linking elements 72 bend and stretch under tension. As steerable portion 64 is twisted, or put in torque, linking elements 72 are put in compression. In torque, the gap between a given linking element and the section of the tubular member proximally adjacent to the given linking element collapses, effectively increasing the torsional stiffness of steerable portion 64.

[0089] Figure 5 illustrates a flattened portion of exemplary tubular member 80, including fixation portion 82, steerable portion 84, and proximal neutral portion 86. The embodiment in Figure 5 is similar to the outer tubular member as shown in Figures 2a and 2b. Steerable portion 84 includes substantially straight slots 90 that are substantially perpendicular to the longitudinal axis of tubular member 80. Spine 88 is substantially straight in configuration, extending along the length of steerable portion 84 substantially parallel to the longitudinal axis of the tubular member 80. Fixation portion 82 includes holes 92 therethrough (four shown) to facilitate bonding. Proximal portion 86 has multiple overlapping slots 94 to give the desired flexibility, axial force and torque transmission.

[0090] Figure 6 illustrates a flattened portion of exemplary tubular member 96, including fixation portion 98, steerable portion 100, and proximal neutral portion 102. Steerable portion 100 includes substantially straight slots 108 that are substantially perpendicular to the longitudinal axis of tubular member 96, but each is offset relative to the adjacent slot so that spine 106 has a sinuous shape extending along the length of steerable portion 100. Fixation portion 98 includes holes 104 therethrough (four shown) to facilitate bonding. Proximal portion 102 includes multiple overlapping slots 110 to give the desired flexibility, axial force and torque transmission characteristics.

[0091] Figures 7a and 7b illustrate exemplary portions of flattened first and second tubular members 112 and 128. First tubular member 112 can be an inner tubular member and second tubular member 128 can be an outer tubular member, or first tubular member 112 can be an outer tubular member and second tubular member 128 can be an inner tubular member. Tubular members 112 and 128 can be assembled as part of a steerable delivery device. That is, one of the first and second tubular members can be disposed within the other. First tubular member 112 includes fixation portion 114, steerable portion 116, and proximal neutral portion 118. Fixation portion 114 includes holes 120. Steerable portion 116 has slots 124 formed therein to define spine 122. Spine 122 has a generally sinuous shape. Proximal portion 118 includes a plurality of overlapping slots 126. Second tubular member 128 includes fixation portion 130, steerable portion 132, and proximal neutral portion 134. Fixation portion 130 includes holes 136. Steerable portion 132 has slots 140 formed therein to define spine 138. Spine 138 has a generally sinuous shape. Proximal portion 134 includes a plurality of overlapping slots 142.

[0092] In Figures 7a and 7b, the slots in each of tubular members 112 and 128 are offset relative to the adjacent slot, interrupted, and have a general helical configuration. Spines 122 and 138 have generally sinuous configurations. The slots in the tubular members are at the same angle relative to the longitudinal axis of the tubular member, but are formed in opposite helical patterns. A advantage of having inner and outer tubular members with slots that are not in alignment (as opposed to inner and outer tubular members that have slots perpendicular to the longitudinal axis of the tubular member) is that the

slots are less likely to get caught up on one another as the steerable portion is steered. The angled slots shown in Figures 7a and 7b also provide for an increased torque response based on a torque applied at the proximal end of the device.

[0093] Figure 8 illustrates a portion of an exemplary steerable delivery device. Steerable device 150 includes outer tubular member 152, inner tubular member 154, and intermediate tubular member 156. A portion of outer tubular member 152 and intermediate member 156 are cut away to show inner tubular member 154. Intermediate tubular member 156 can be a flexible polymeric tube. Inner and outer tubes 152 and 154 have slots 160, 164 formed therein to define spines 158 and 162. The spines are substantially 180 degrees apart, as shown. The slots formed in the respective tubular members are at an angle relative to the longitudinal axis of the steerable portion and are formed in opposite helical patterns.

[0094] Figure 9 illustrates a portion of an exemplary steerable delivery device. Steerable device 166 includes outer tubular member 168 and inner tubular member 170. Inner tubular member 170 can be a flexible polymeric tubular element. Outer tubular member 168 has a plurality of slots 174 formed therein to define spine 172. Inner tubular member 170 has no preferential bending axis. Inner tubular member 170 could alternatively have a modified bending axis offset by having, for example, a stiffening element incorporated into the wall of inner tubular member 170 approximately 180 degrees from spine 172. In some embodiments inner tubular member 170 may incorporate wire braids and or axially-laid wires which reduce kinkability and increase axial stiffness as is common in braided catheters or other similar known tubular medical devices.

[0095] Figure 10 illustrates a portion of an exemplary steerable delivery device. Steerable delivery device 178 includes outer tubular member 180 and inner tubular member 182. Outer tubular member 180 can be, for example, a flexible polymeric tubular member. Inner tubular member 182 has a plurality of slots 186 formed therein to define spine 184, which is substantially parallel to the longitudinal axis of the steerable portion. Outer tubular member 180 has no preferential bending axis. Alternatively, outer tubular member 180 can have a preferential bending axis. For example, a structural support element can be incorporated into the wall of outer tubular member 180 approximately 180 degrees from spine 184. Outer tubular member 180 can be substantially the same as inner tubular element 170 in Figure 9, but for any lubricity enhancing feature. In some embodiments inner tubular member 170 may incorporate wire braids and or axially laid wires which reduce kinkability and increase axial stiffness as is common in braided catheter or other similar known tubular medical device.

[0096] In an alternative embodiment, the device includes inner and outer slotted tubes, and additionally includes an outermost tubular member similar to 180 shown in Figure 10. The outermost tubular member can be, for example without limitation, a polymeric tubular member.

[0097] Figure 11a illustrates a portion of an exemplary embodiment of a first tubular member that can be included in a steerable delivery device. Tubular member 190 is a tubular member formed from a ribbon wire. Tubular member 190 has spine 192 formed by coiling a ribbon shaped with interlocking elements 194 and 196, which together form an interlocking feature along spine 192. Interlocking elements 194 and 196 may be press-fit to interlock the two. The interlocking elements can be encased

with a tubular member, such as a polymer tubular member, to secure them in place. The interlocking elements can also, or alternatively, have a polymer tubular member disposed therein to help secure them in place. In addition to the interlocking features, the ribbon wire has sections of decreased width 198 which once wound into a tubular structure create the steerable portion for flexibility. A second tubular member of the steerable delivery device can be created in a similar manner to the tubular member in Figure 11a. Figure 11b illustrates an embodiment of the ribbon with interlocking elements 196 and decreased width regions 200 between elements 196. The angle of interlocking elements 196 relative to the longitudinal axis of the tubular element can be varied based on the pitch of the coil. Such a pattern can additionally be fabricated by laser machining.

[0098] Figures 12a and 12b illustrate an exemplary embodiment of a tubular member. Tubular member 210 comprises a tube 214 with grooves 212 formed therein on the outer surface of tube 214. Grooves 212 do not extend all the way through tube 214. Tubular member can be, for example, a stiff polymeric tubular member. Figure 12a shows a sectional view of a portion of tubular 210 showing the depth of grooves 212 in the steerable portion. Figure 12b illustrates a flattened view of tubular member 210 showing grooves 212 formed in tube 214. Grooves 212 define a single substantially straight spine 216. Grooves 212 cut into tube 214 increase flexibility of the steerable portion to allow the steerable portion to be steered. Spine 216 provides for the application of compressive and tensile forces to steer the device. Because the cut does not go all the way through the wall of the tube, it inherently creates a fluid tight barrier and a lubricious liner. In some embodiments tubular member 210 can an inner or outer tubular member of a steerable device, and the other of the inner and outer tubular elements can also includes a tubular element with grooves formed thereon. In some embodiments the steerable device can also have a polymeric sleeve to encapsulate the outer tube to create a smooth outer surface.

[0099] Figure 13a illustrates a portion of an exemplary introducer sheath reinforcement member 220. Member 220 is formed by laser cutting a tubular member to slots or gaps therein. A helical slot 222 defines interlocking T-shaped patterns 224 formed in reinforcement member 220. The helical path is shown generally in helical path 226. Flexibility slots 228 are formed in member 220 to provide flexibility to member 220. Member 220 also includes bonding slots 230 formed therein to allow for bonding to one or more components of the device. Figure 13b illustrates member 220 from Figure 13a in a flattened pattern showing the interlocking T-shaped pattern along helical path 226, flexibility slots 228, and bonding slots 230. Figure 13c shows a close-up of the section shown in Figure 13b.

[00100] In some embodiments a guide catheter includes a relatively rigid metal or polymer reinforcement member (an example of which is shown in Figure 13a-13c) layered between an inner and an outer flexible polymer tube. The rigid reinforcement member can be laser machined or otherwise cut in a pattern in order to enhance flexibility along the longitudinal axis of the tube, to allow some limited radial compliance, and to allow bonding of the inner and outer flexible polymers. The slot pattern can include an interlocking T-shaped pattern arranged helically around the tube for flexibility and radial compliance, a slot pattern where the slots are substantially perpendicular to the tube longitudinal axis, and are patterned along the tube longitudinal axis to further enhance flexibility and bonding of said layers.

[00101] Figure 14 illustrates an exemplary embodiment of a guide system adapted to guide and deliver a therapeutic, diagnostic, interventional, or any other type of medical device 260 intraluminally to a target location within a body. Guide system 250 includes outer guide member 252 and steerable delivery device 256, a portion of which is disposed within outer guide member 250. Steerable delivery device 256 can be, for example, any of the steerable delivery devices described herein. Outer guide member 252 has a preset bend 254 that can be formed by, for example, heat setting. Steerable delivery device 256 includes steerable portion 258, which can be formed as, for example, any of the steerable portions described herein. For example, steerable delivery device can include outer and inner tubular members, wherein at least one of the tubular members is adapted to preferentially bend in a first direction. In the embodiment shown in Figure 14, steerable portion 258 is comprised of a single steerable tubular member steered into the configuration shown in Figure 14 by actuating pull wire 264. Alternatively, steerable delivery device 256 can be comprised of the embodiment described in Figure 2, and steered by relative axial movement of inner and outer tubular members, as described herein.

[00102] Alternatively, outer guide member 252 can be adapted to be bent using optional pull wire 262, shown in Figure 14. In such an embodiment bend 254 may or may not be preset. Guide member 250 comprises a tubular member incorporating a pattern of slots as described for steering portions herein. When located in position pull wire 262 is tensioned and the axial and torsional stiffness of bend 254 is thereby increased. A steerable outer guide member 252 in its delivery configuration (non-bent) is generally loose and compliant, but is tensioned or compressed to reconfigure it into a pre-set shape. Its stiffness in the bent configuration is a function of the amount of tension or compression applied and the particular slot pattern chosen.

[00103] Bend 254 in outer guide member 252 is compliant enough to be straightened for delivery, for example advanced on a guide wire, but rigid enough to be able to guide steerable delivery device 256 around bend 254. Steerable delivery device 256 is steerable and transmits torque.

[00104] The structural properties of the inner and outer tubular members of the steerable delivery device will determine the manner in which they respond to force applied thereon. The structural properties of the inner and/or outer tubes will depend on the tubing material and the design, or characteristics, of the slots created in the tubular members (unless one of the inner and outer tubular members does not have any slots therein). The design of the slot pattern is therefore a function of the required structural properties of the tubular member. For example, structural properties of the tubular member that can be modified by changing the design of the slots or slot patterns include flexural stiffness, torque transmission, steerability, radius of curvature, and allowable wall thickness of the steerable assembly.

[00105] Figure 15 is a flattened view and illustrates a portion of an exemplary steerable portion of a tubular member. Tubular member 290 can be an inner or an outer tubular member as described herein. Steerable portion 290 is typically a laser-cut tubular member, but may in fact be fabricated by any technique capable of creating the appropriate widths of cuts required (e.g., water jet, wire EDM, etc.) wherein first cut, or slot, 292 is made, defined by first surface 294 and second surface 296. Slot 292

extends almost all the way around tubular member 290, and defines spine 308. Slots 282 are thickest, along the tubular longitudinal axis, along compression axis C which allows tubular member to be compressed along compression axis C, which changes the configuration of tubular member 290. Tubular member 290 also includes interlocking features 298 (only one of which is labeled), which include first interlocking element 300 and second interlocking element 302. Slot 292 includes slot portion 304, which is defined by the first and second interlocking elements 300 and 302 and allows for movement between the two interlocking elements 300 and 302 in the axial direction. Tubular member 290 also includes stress relief slots 306, which extend across spine 308 and provide stress relief for spine 308. Stress relief slots 306 can be considered to be axially in-between slots 292. Slots 292 are not connected with slots 306. Slots 306 are substantially thinner than slots 292. As will be described in detail below, tubular member 290 is adapted to be compressed along compression axis C, which is substantially 180 degree from spine 308.

[00106] Figures 16a and 16b illustrate a portion of tubular member 290 shown in Figure 15. Figure 16b illustrates tubular member 290 with slot 292, with a greatest thickness along compression axis C. Slot 292 includes slot 304, which is defined by interlocking elements 300 and 303. Slot 292 and slot 304 allow for compression of tubular member 290, shown in Figure 16a. When a compressive force A is applied along compressive axis C surfaces 294 and 296 are brought closer towards another, as are surfaces 300 and 302. Slots 292 and 304 therefore allow for axial compression of tubular member 290, until surfaces 294 and 296 engage one another, or until surfaces 300 and 302 engage one another, whichever happens first. Slots 292 and 304 can be designed such that the slots close at the same time. Once the surfaces engage, they behave substantially like a solid tube and can no longer be compressed along the engagement points. Upon a compressive force to tubular member 290, tubular member will therefore be steered into the configuration shown in Figure 16a. Similarly, when a tensile force is applied to tubular member 290 shown in Figure 16a, tubular member 290 will straighten to the configuration shown in Figure 16b. Particularly, tubular member 290 will straighten until the interlocking features engage one another and prevent further movement. Figure 16c illustrates the tubular member from Figures 16a and 16b and indicates points of load application including those illustrated in Figures 16b and 16c. Torsional force T indicates a torsional force acting on tubular member 290 upon the application of torque at a proximal end of the device. Tensile and compressive forces are listed as “a” or “b” depending on the behavior exhibited by the tubular member as described below.

[00107] Figure 17 is a graph illustrating Force v. Displacement behavior associated with the application of loads or displacements at various points around tubular member 290 shown in Figures 15-16c. The Force/Displacement behavior of tubular member 290 for loads applied in planes passing through the longitudinal axis of the tubular member, ranges between the lines A and B in Figure 17. Curve A illustrates the behavior along a compliant axis on the surface of the tubular member and parallel to the longitudinal axis of the tubular member where the slots are widest, while curve B illustrates the behavior where the slots are vary narrow. As the tubular member is bent about spine 308 in a fashion which closes slots 292, the forces required to bend the tubular member are low and the

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Force/Displacement curve has a small slope. The tubular member is compliant in this region. When the width of the slots decreases to zero the structure becomes much stiffer as indicated by the second much higher slope region of curve A. The amount of displacement associated with closing the slots is essentially indicated by point D where the slope of the Force/Displacement curve changes. Curve A indicates the behavior expected from forces applied at a point along compressive axis C, illustrating that a large amount of axial displacement follows from minimal compressive force on tubular member 290. Upon closing slots, the compressive axis becomes stiff (indicated by the large increase in Force at point D in the curve). Curve B in the graph indicates compression along the axis running through spine 308. Due to stress relief slots 306, a small amount of compressive displacement occurs before spine 308 stiffens and begins to act substantially like a solid tube, as indicated by point E in the graph. The structure will exhibit the behavior of curve B for tensional loads applied to the top of the structure on the compressive axis C as the gaps closed under this loading are very narrow. Curve B also represents the behavior of the structure to torsional loads, as the gaps impacted most by these loads are narrow.

[00108] Figure 18 illustrates a flattened view of exemplary tubular member 320. Slot 330, or cut, formed therein has a spiral (also referred to herein as helical) pattern and is un-interrupted. Tubular member 320 is shown in an as-cut compressed configuration, and is adapted to be expanded the greatest amount along expansion axis EA upon the application of a tensile force thereto. Tubular member 320 includes interlocking features 332, which include surfaces 322 and 324, and surfaces 326 and 328. Slot 330 includes the slot defined by surfaces 326 and 328, and by surfaces 322 and 324. In this embodiment the slot, or gap, defined by surfaces 326 and 328 is larger than the gap defined by surfaces 322 and 324. That is, the gap that is closer to expansion axis EA is larger than the gap that is further from expansion axis EA. Tubular member 334 also includes spine 334, which is interrupted by small slots 336. As illustrated in Figure 16c, tubular member 320, upon the application of axial loads applied thereto, will exhibit Force/Displacement curves as follows: a compressive force (downwards) applied at EA will exhibit curve B, while a tensile load at EA (upwards) will exhibit curve A. A torsional load will exhibit curve B.

[00109] Figure 19 is a flattened view and illustrates a portion of a tubular member. Tubular member 270 can be an inner or an outer tubular member as described herein. Steerable portion 270 is a laser-cut tubular member wherein first cut, or slot, 274 is made to define spine 276. Cut 274 is made almost all the way around tubular member 270. Cut 274 also defines interlocking features 278 (only one of them is labeled), which are comprised of a first interlocking element 280 and a second interlocking element 282. Cut 274 includes cut 284, which creates the interlocking features and allows for movement between the two interlocking elements. Tubular member 270 also includes stress relief 272, which extend across spine 276 and provide stress relief for spine 276. Stress relief slots 272 can be considered to be axially in-between slots 274. Slots 274 are not connected with slots 272. Tubular member 270 is adapted to be expanded along expansion axis EA, and is adapted to be minimally compressible upon the application of compressive forces thereto. Spine 276 is substantially static. Upon the application of tensile forces to

tubular member 270 along expansion axis EA, tubular member 270 will deflect from a straightened configuration into a bent configuration.

[00110] Figure 20 illustrates an embodiment similar to that shown in Figure 18 and only differences in the structure between the two will be described. All other features can be considered the same. Tubular member 350 includes interlocking features including interlocking elements 354 and 356. Slot 360 created in tubular member 350 includes the gap defined by surfaces of interlocking elements 354 and 356.

[00111] Figure 21 illustrates a flattened portion of an exemplary tubular member 380 including interrupted cuts 390 that define spine 382. Tubular member 380 includes interlocking features 384, which include interlocking elements 386 and 388. Interlocking features 384 allow for expansion along expansion axis EA upon the application of a tensile force thereto. Tubular member 380, like all tubular members described herein unless specifically stated otherwise, can be incorporated into a steerable portion as an inner or an outer tubular member.

[00112] Figure 22 illustrates a flattened portion of an exemplary tubular member 400. Interrupted slots 404 define spine 402, which has a spiral shape. Tubular member 400 does not have static axis.

[00113] Figure 23 illustrates a flattened portion of an exemplary tubular member 410. Tubular member 410 includes interrupted helical slots 418, which define spines 412 and 414. Tubular member 410 has two spines, 180 degrees around the periphery of the device from one other. The helical cut pattern repeats itself every 180 degrees to define substantially straight spines. Tubular member 410 also includes a plurality of interlocking features 420 which provide torsional stiffness. The maximal expansion/compression is at axis 416.

[00114] Figure 24 illustrates a flattened portion of an exemplary tubular member 430, which is similar to the embodiment in Figure 23 but rather than repeating every 180 degrees, the cut pattern repeats every 360 degrees. Slots 434 have an interrupted helical design, and tubular member 430 has a single spine 432. Feature 436 provides additional torsional stiffness. Tubular member 430 exhibits maximal expansion/compression along axis 438.

[00115] Figure 25 illustrates a flattened portion of an exemplary tubular member 440. Tubular member 440 includes slots 448, which repeat every 190 degrees to define spines 442 and 446. The slots have an interrupted helical pattern, and create a relatively neutral pattern.

[00116] Figure 26 illustrates a flattened portion of an exemplary tubular member 450. Tubular member 450 has uninterrupted slot 456 formed therein, which repeats every 360 degrees. Tubular member 450 also includes interlocking features 454 comprised of at least two interlocking elements as described herein. In this embodiment, the interlocking elements have complimentary curved surfaces and are adapted to support rotation. Slot 456 defines spines 452, while slot 456 allows compression and/or expansion along axes A.

[00117] Figure 27 illustrates an exemplary steerable delivery device including steerable portion 520. Steerable delivery device includes outer tubular member 522, inner tubular member 524, and floating inner member 534. Inner tubular member 524 is disposed within and coaxial to outer tubular member

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522, and floating inner member 534 is disposed within and coaxial with inner tubular member 524.

Floating inner member 534 is axially fixed relative to inner tubular member 524 at a location proximal to steerable portion 520. The device shown in Figure 27 can also include a liner member disposed between the outer and inner tubular members.

[00118] Figure 28 illustrates an exemplary steerable delivery system 600. System 600 includes control device 602 that is adapted to steer steerable portion 610 of a steerable delivery device. The steerable delivery device includes outer tubular member 606 and inner tubular member 608 disposed within outer tubular member 606. Control device 602 includes housing 612 with a slot therein adapted to allow for movement of actuator 604. Actuator 604 is coupled to inner tubular member 608, and is adapted to be moved axially, either distally D or proximally P to control the axial movement of inner tubular member 608. Any other suitable type of actuator can also be used including actuators incorporating mechanical advantage. Actuation of actuator 604 causes inner tubular member 608 to move axially relative to outer tubular member, which causes steerable portion 610 to bend. The control device is therefore adapted to steer steerable portion 610 inside of a subject. System 600 also includes a floating liner member 616 and hemostatic valve 614.

[00119] One aspect of the disclosure is a guide device that is adapted to be maintained, or locked, in a specific configuration to provide access for a medical device or instrument to be passed therethrough, but may or may not be steerable. In Figures 2A-2C, steerable portion 32 is adapted to be steered or deflected into any configuration between those shown in Figures 2A and 2B. Steerable portion is adapted to be steered to, for example, navigate bends or turns within a bodily lumen. In that specific embodiment, compressive and/or tensile forces are applied to the inner and/or outer tubular members to steer the steerable portion. In some embodiments, once steerable portion 32 is steered into a curved configuration, the forces applied thereto (e.g., compressive, tensile, torsional) can be released, and yet a medical device or instrument can be passed through the tubular members. In some embodiments, however, the bent configuration of the steerable portion can be maintained by maintaining the application of the forces thereto. For example, in Figures 2A-2C, steerable portion 32 can be maintained, or locked, in the bent configurations shown by maintaining the application of the compressive and/or tensile forces. By maintaining the application of the forces to the steerable portion or locking the relative displacements of the inner and outer tubes, the inner and outer tubes are substantially axially fixed relative to one another along the length of the steerable portion.

[00120] In an exemplary method of use, multiple bend portions may be incorporated and adapted to have a locked configuration that closely mimics, or resembles, a portion of the subject's anatomy. The bend portion can be advanced through the subject (e.g., over a guide wire) to a desired location, and can then be actuated into a curved configuration, such as by the application of compressive and/or tensile forces thereto. The curved configuration can be adapted to resemble the path of the anatomical lumen in which the device is positioned. Application of the actuation force maintains, or stiffens, the bend portions in the desired curved configuration. A medical device or instrument can then be advanced through the curved portion to a target location within the subject.

[00121] The device shown in Figure 14 can alternatively be configured to be operated in this manner. For example, steerable delivery device 256 in Figure 14 can be actuated to have a first bend or curved region 254 and a second bend or curved region 258. The curves, or bends, form a general S-shaped portion of the device. The delivery device 256 can be maintained, or locked, in the general S-shape to guide a medical device or instrument therethrough. The S-shape of the delivery device 256 can be used if it resembles a portion of the anatomy into which it is placed, but any other type of preformed configuration can be used, depending on the anatomical requirements. In the alternative to Figure 14, the delivery device can be actuated into the configuration shown by the application of compressive and/or tensile forces to inner and outer tubular members, as is described herein.

[00122] Figures 29A and 29B illustrate an exemplary embodiment of a portion of a lockable device adapted to be locked, or maintained, in a specific configuration that mimics that of a portion of the subject's anatomy. In the unlocked form the structure is compliant and easily guidable whereas in the locked form the device is rigid in its predetermined form. The device can then be used to provide access for a medical device or instrument to be passed therethrough to a target location within the subject. Bend portion 700 of the device includes a plurality of beads, 702, 704, and 706. Bead 702 is the distal-most bead, bead 706 is the proximal-most bead and beads 704 are disposed between the two end beads 702 and 706. The beads are separate and distinct structural features, not mechanically coupled to one another. Each bead has two bores 715 therethrough, each adapted to receive one of the two control wires 708. Control wires 708 are secured only to distal bead 702, using any suitable technique (e.g., adhesive). Wires 708 therefore are adapted to be axially moveable relative to beads 704 and 706. Proximal bead 706 has a substantially constant height H around the periphery of the bead, while beads 702 and 704 do not have a constant height. Specifically, the height of the beads 702 and 704 decreases around a portion of each of the beads. The gap between adjacent beads is therefore relatively large between bead 702 and 704, and between beads 704, while the gap between bead 706 and the adjacent bead 704 is relatively small compared to the other gaps.

[00123] To adjust the lockable portion into its predetermined form, an axially directed (i.e., distally directed) compressive force C is applied to proximal bead 706 while maintaining wires 208 in position. Maintaining wires 208 in position can occur based on a proximally directed tensile force applied to wires 208, or wires 208 may be secured to a portion of the delivery system that is not actuated. This causes the distance between surfaces 711 and 713 to decrease, until they engage one another as shown in Figure 29B. The actuation force is continued until all of the beads' adjacent surfaces are engaged, as shown in the configuration in Figure 29B. In Figure 29B, lockable portion 700 is in a bent configuration adapted to mimic a portion of the patient's anatomy in which it is to be positioned. Figure 29B also shows a section portion of one side of the beads through which one of wires 708 passes. Lockable portion is maintained in the locked configuration in Figure 29B by maintaining the distally directed compressive force to proximal bead 706 or the relative displacements between distal bead 702 and proximal bead 706. Lockable portion 208 can also be bent into the configuration shown in Figure 29B upon the application of a proximally directed tensile force applied to wires 708, while applying a distally directed compressive

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force to proximal bead 706. While six beads are shown in Figures 29A and 29B, the lockable portion can have two or more beads.

[00124] Figures 30A-30H show exemplary beads that can be incorporated into a lockable portion as described herein. Figure 30A illustrates bead 716 with wire bores 717 therethrough. The height H of bead 716 is substantially constant. When the height is substantially constant, the planes through the proximal and distal ends of the beads are substantially parallel. When the height is not constant, the planes are not parallel. Bead 716 is the same as proximal bead 706 in Figure 29A. In an embodiment with a lockable portion comprised entirely of beads that have a constant height, the lockable portion would have a straight configuration under compression. Figure 30B shows bead 718 with bores therethrough, wherein the height at portion 720 is less than at portion 721. Bead 718 has the same general shape as beads 702 and 704 in Figure 29A. The height of portion 720 can be adjusted to modify the curvature of the lockable portion. Generally, as height 720 decreases, the degree of the bend increases (i.e., the radius of curvature decreases). Similarly, the height of portion 721 can be modified to modify the curvature. Figure 30C illustrates bead 722 that can be injection molded. Bead 722 includes two outer wire features 724 and two inner wire features 726 formed in bead 722. Each outer wire feature has a portion that overlaps with a portion the corresponding inner wire feature to define an opening through which a control wire can pass. Molding the bead with the wire features to create the wire bore can be easier than forming a hole the entire way through the bead. Bead 722 is formed to have 2 control wires pass therethrough. Figure 30D illustrates bead 730 that can be injection molded. Bead 730 includes two indentations 732 and two indentations 734. The indentations in bead 730 allow for the height of wire bore 736 to be less than it would be without the indentations. The indentations can make the wire bores easier to mold. Figure 30E illustrates bead 740 including tabs 742 stamped therein. The tabs are stamped in the body of bead 740 to form wire openings 744, through which a control wire is passed. Bead 740 can be, for example, a hypotube, sheet metal rolled into an annular shape, etc. Figure 30F is similar to Figure 30E and includes interlocking features including interlocking elements 754 (male) and 756 (female). The interlocking features generally enhance torque transmission. The interlocking feature could be comprised of any interlocking elements described herein or any other suitable interlocking elements. Figure 30G illustrates bead 760 including an inner corrugated member 764 and outer member 762. The spaces between inner member 764 and outer member 762 define control wire bores 768, which are adapted to receive control wires therethrough. In Figure 30G, twelve control wires can be passed through bead 760. Figure 30H shows a plurality of beads 760 (from Figure 30G) and 770, each with inner member 764 and outer member 762. In adjacent beads 760 and 770, the control wire bores are defined by peaks and valleys formed in the inner members on adjacent beads.

[00125] While the embodiments have been shown with control wires being secured relative to a single bead, all of the control wires in a lockable portion need not be secured to the same bead. For example, a control wire can be secured to any bead in the lockable portion.

[00126] The locked configuration of the lockable portion can be modified by modifying characteristics of the beads. For example, the number of beads in the lockable portion can be modified to

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change the radius of curvature. The height of portion of the beads can be modified, as shown in the comparison between Figure 30A and 30B. The lockable portion additionally need not include beads of the same type. For example, a lockable portion could alternate the beads shown in Figures 30A and 30B, creating a curve with a degree of bend less than that shown in Figure 29A. Beads of similar design can be rotationally offset from one another along the length of the lockable portion. For example, in the embodiment in Figure 29A, every other bead could be rotated 90 degrees in the same direction relative to the adjacent beads. Additionally, the relative angle between the control wire bore axis and the plane of a bead end can be adjusted. For example, in Figure 30B, the axes of control wire bores 719 can be substantially 90 degrees relative to the plane of the distal end of bead 718. The axes of bores 719, can, however, be offset such that they are not substantially 90 degrees relative to the plane of the distal end of bead 718.

[00127] The beads as described herein can have almost any length. In some embodiments a bead is a section of straight tubing. Any bead can also incorporate any of the slotted cut patterns described herein

[00128] While the lockable portions have been shown to include curved, or bent sections, the lockable device can have a locked configuration in which the device is substantially straight. For example, if the lockable device included 2 or more beads as shown in Figure 30A, the lockable device would have a substantially straight locked configuration.

[00129] In some embodiments the lockable device could have a floating liner (as described herein) disposed therein. The floating liner could, in some embodiments, be secured to the distal-most bead. The lockable device could alternatively or additionally have an outer liner disposed on the outside of the lockable device. The outer liner could also be secured to the distal-most bead or the outer liner could be affixed to the inner liner and the beads left to float inside.

[00130] In some embodiments the lockable device (e.g., the device shown in Figures 29A and 29B) is adapted to be advanced over a steerable device within the subject. For example, a traditional guidewire or the steerable device shown in Figures 2A-2C can be steered to a desired location within the subject. A lockable device, such as a beaded lockable device described herein, can then be tracked over the steered device. The lockable device comprising at least two beads is flexible to allow it to follow the curvature of the steered device. Once the lockable device has been advanced over the steered device to the desired position, the beads of the lockable device are locked in place as described herein, and the lockable device assumes its preset configuration.

[00131] In alternative embodiments, the lockable portion (e.g., the beaded structure in Figures 29A and 29B) includes a floating liner therein.

[00132] In an exemplary embodiment of use, a guiding element (e.g., a guidewire) is advanced to a desired location within the subject. The device comprising the lockable portion is then tracked over the guiding element until it reaches a desired position. The lockable portion is then actuated to change the configuration of the lockable portion to the desired configuration. The lockable portion is then maintained, or locked, in the desired configuration. A medical device, medical instrument, or other device is then advanced therethrough to a target location within the subject.

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[00133] While preferred embodiments of the present disclosure have been shown and described herein, it will be obvious to those skilled in the art that such embodiments are provided by way of example only. Numerous variations, changes, and substitutions will now occur to those skilled in the art without departing from the disclosure. It should be understood that various alternatives to the embodiments of the disclosure described herein may be employed in practicing the disclosure. The following claims define the scope of the disclosure and that methods and structures within the scope of these claims and their equivalents are covered thereby.

Claims

1. A steerable medical device, comprising:
 - a steerable portion;
 - a first tubular member comprising a first flexible polymeric tubular member; and
 - a second tubular member comprising a second flexible polymeric tubular member, wherein the first tubular member is disposed within the second tubular member and permanently axially fixed to the second tubular member at a fixation location distal to the steerable portion; and
 - an external controller that is adapted to be actuated to put one of the first tubular member and the second tubular member in tension and the other of the first tubular member and the second tubular member in compression, and wherein the first and second tubular members are adapted such that the steerable portion is steered in a first direction when the external controller is actuated.
2. The steerable medical delivery device of claim 1 wherein the first and second flexible polymeric tubular members each comprise a wall of solid material along the steerable portion.
3. The steerable medical delivery device of claim 2 wherein the first and second tubular members each further comprise a structural support embedded in the respective first and second flexible polymeric tubular members.
4. The steerable medical delivery device of claim 2 wherein the first and second flexible polymeric tubular members each comprise a variable structure in the steerable portion, and the variable structures impart the respective preferential bending.
5. The steerable medical delivery device of claim 4 wherein the variable structures for each is a variable thickness in the steerable portion, and the variable thicknesses impart the preferential bending in the respective first and second tubular members.
6. The steerable medical device of claim 1 wherein the first and second tubular members are configured to preferentially bend in opposite directions.
7. The steerable medical device of claim 1 wherein the external controller is adapted so that when the actuator is actuated, the first tubular member and the second tubular member are axially moved relative to one another within the external controller.

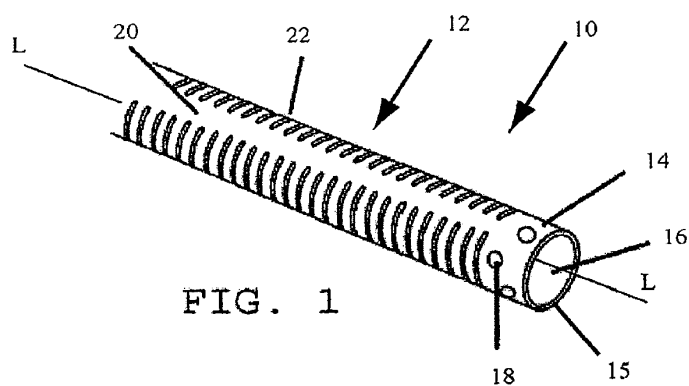


FIG. 1

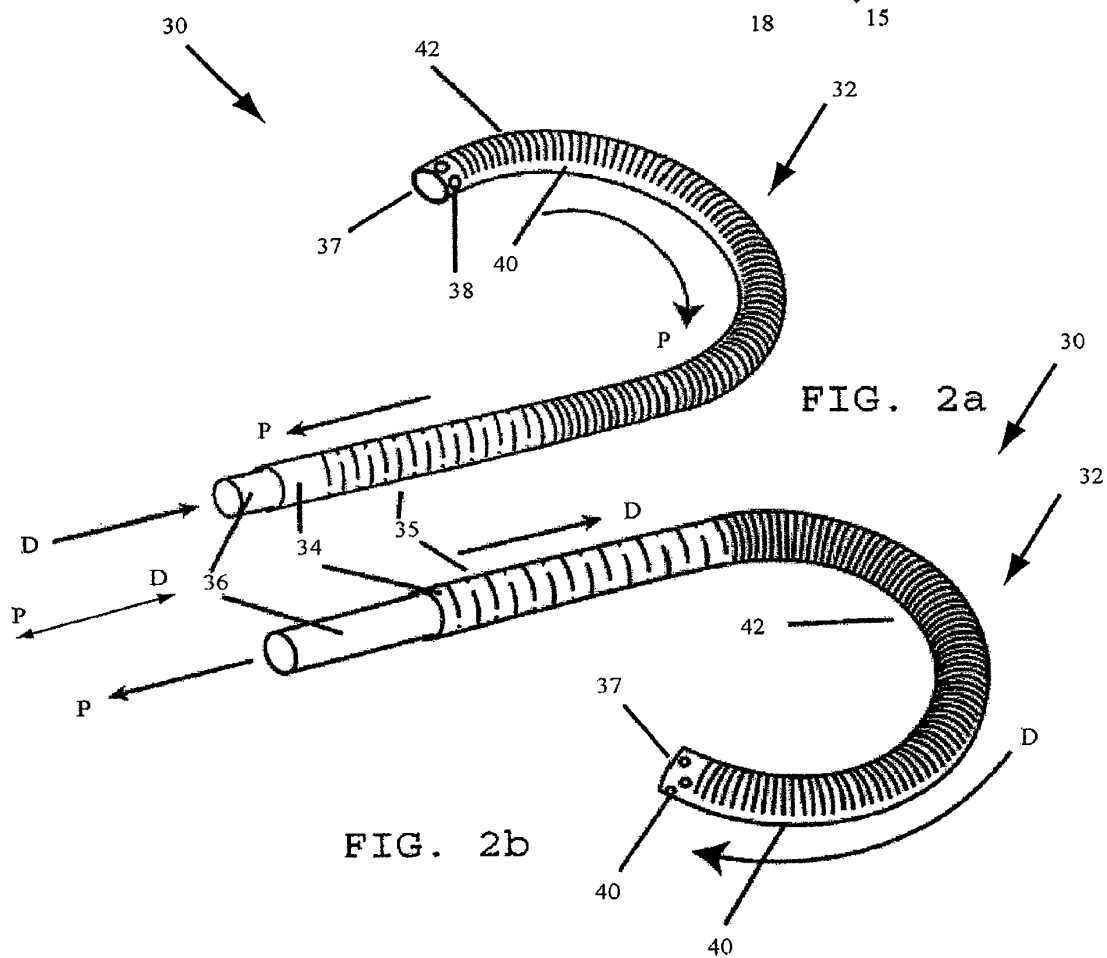


FIG. 2b

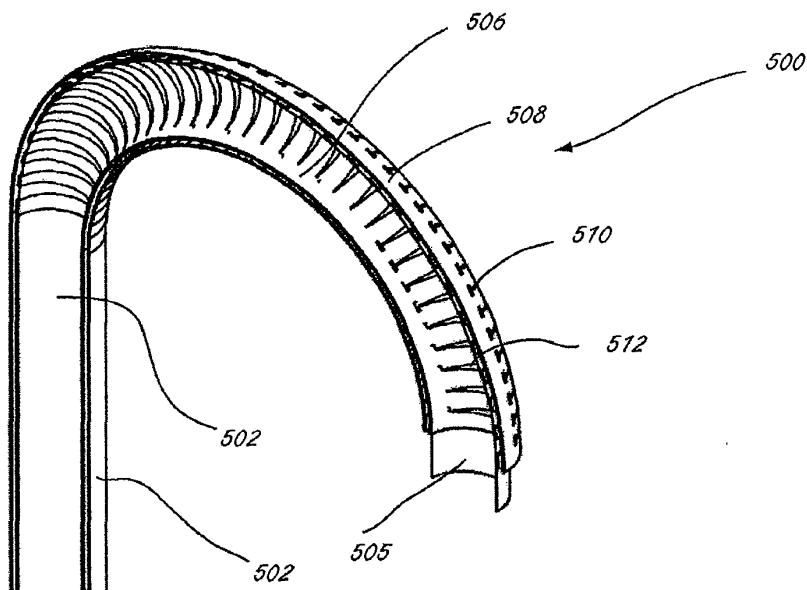


Fig 2c

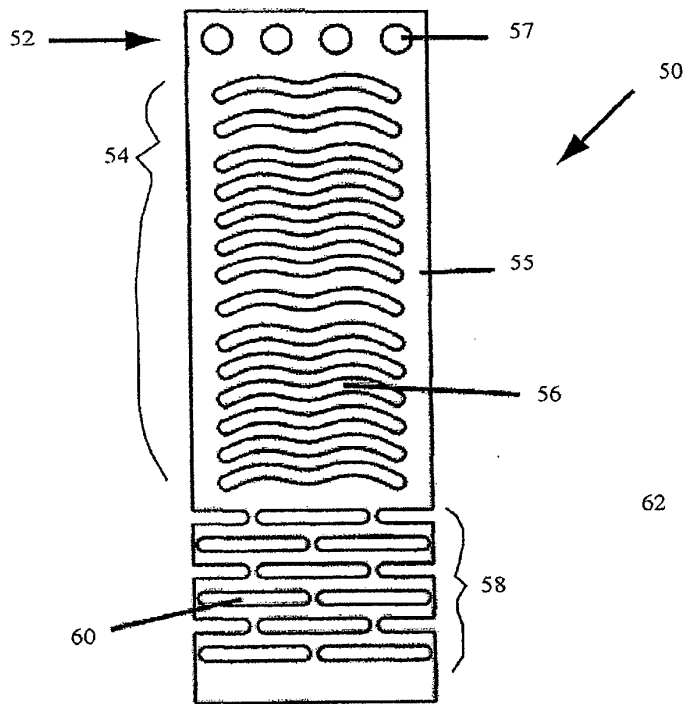


FIG. 3

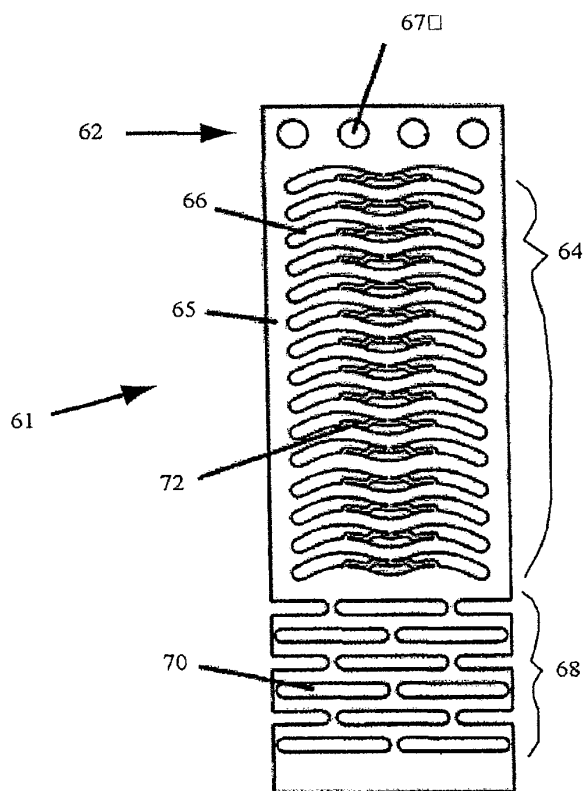


FIG. 4

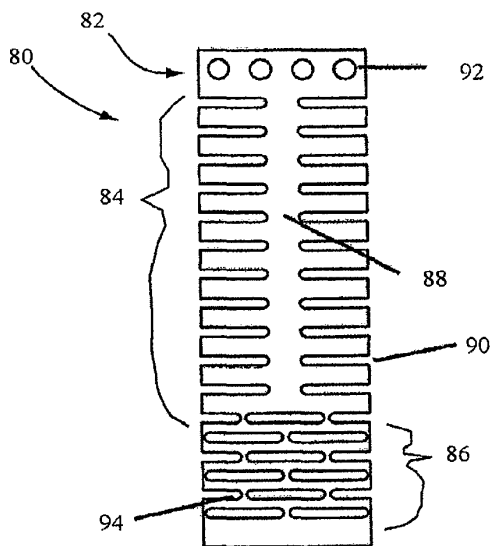


FIG. 5

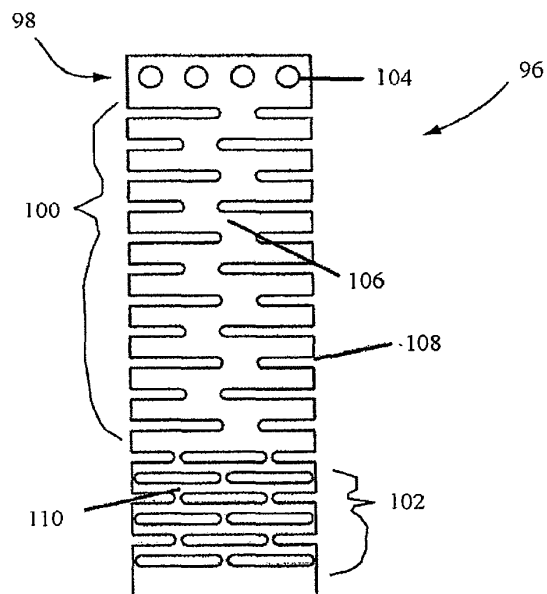


FIG. 6

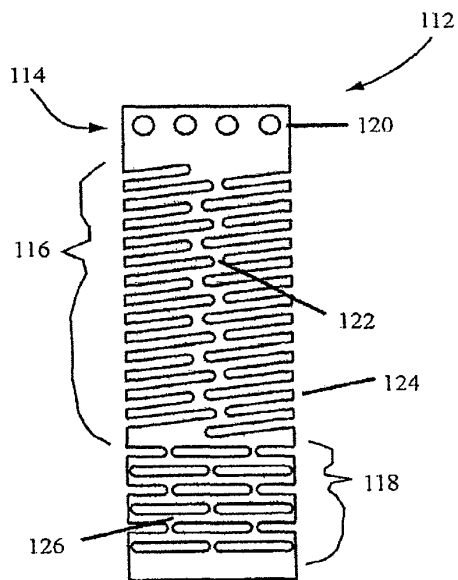


FIG. 7a

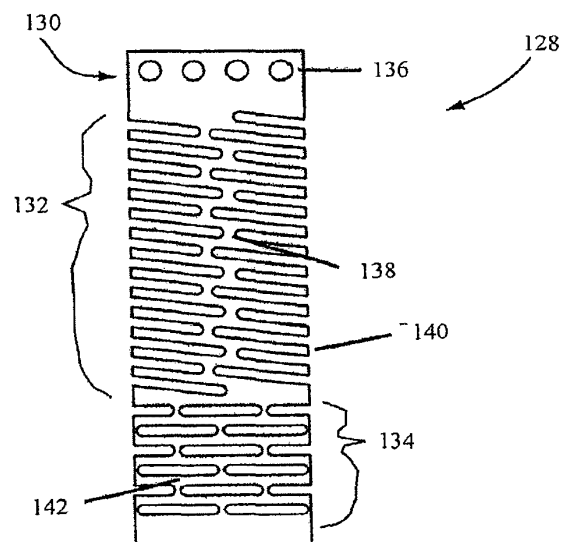


FIG. 7b

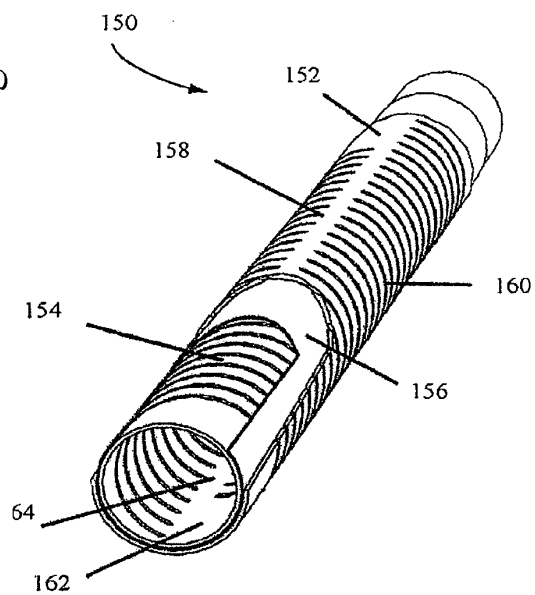


FIG. 8

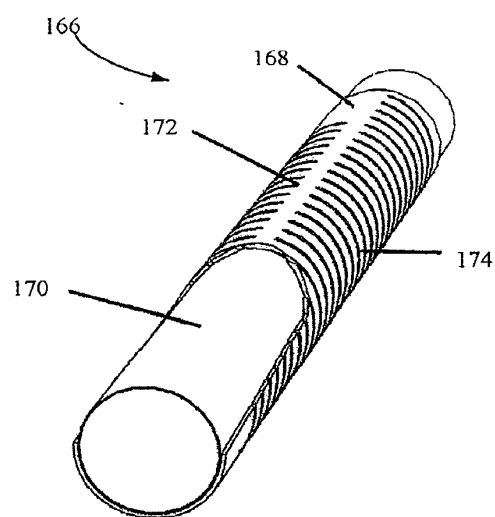


FIG. 9

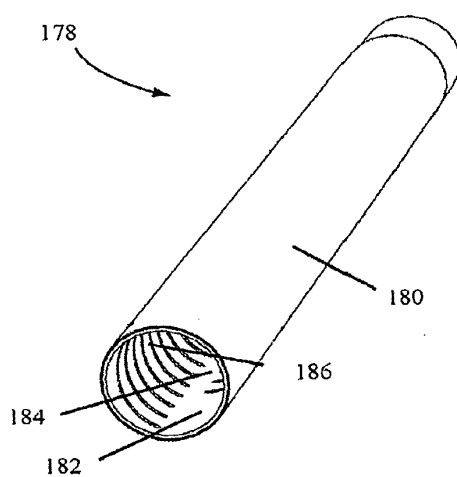
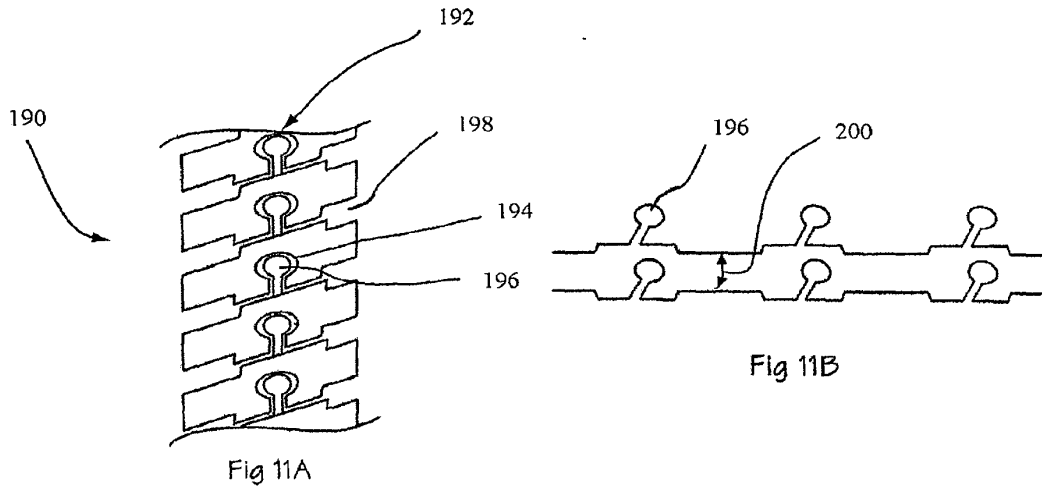
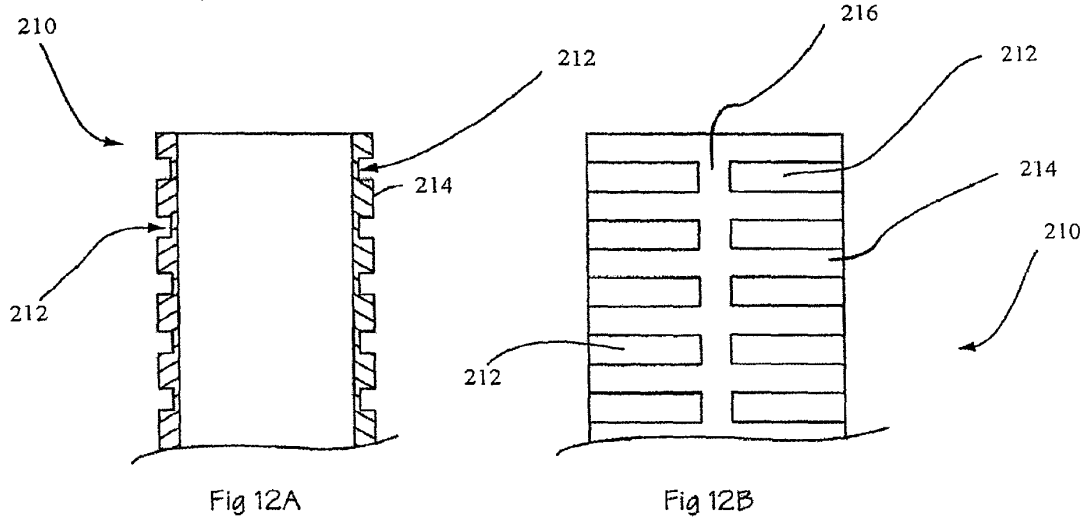


FIG. 10



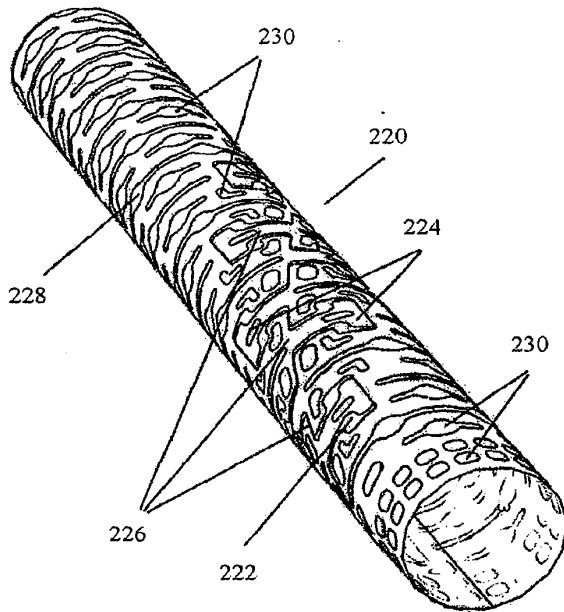


Fig 13a

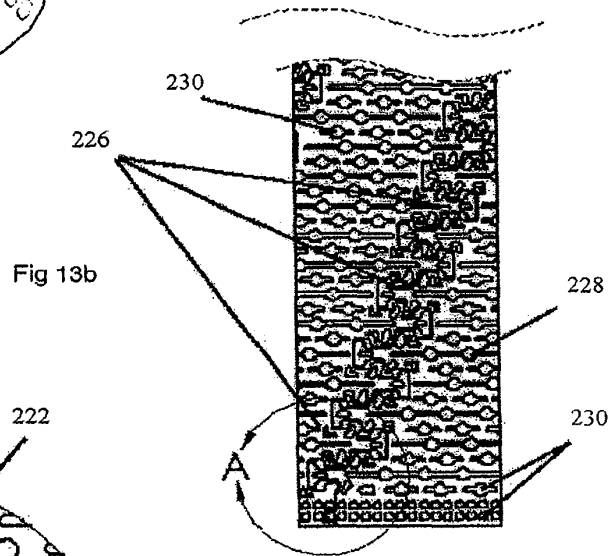


Fig 13b

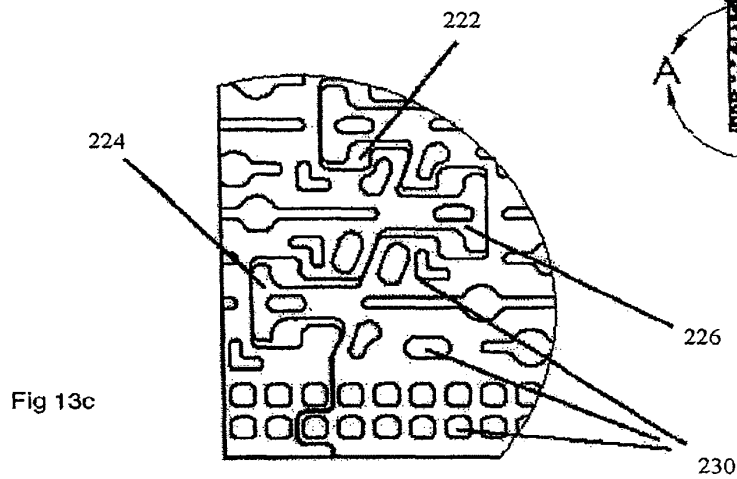


Fig 13c

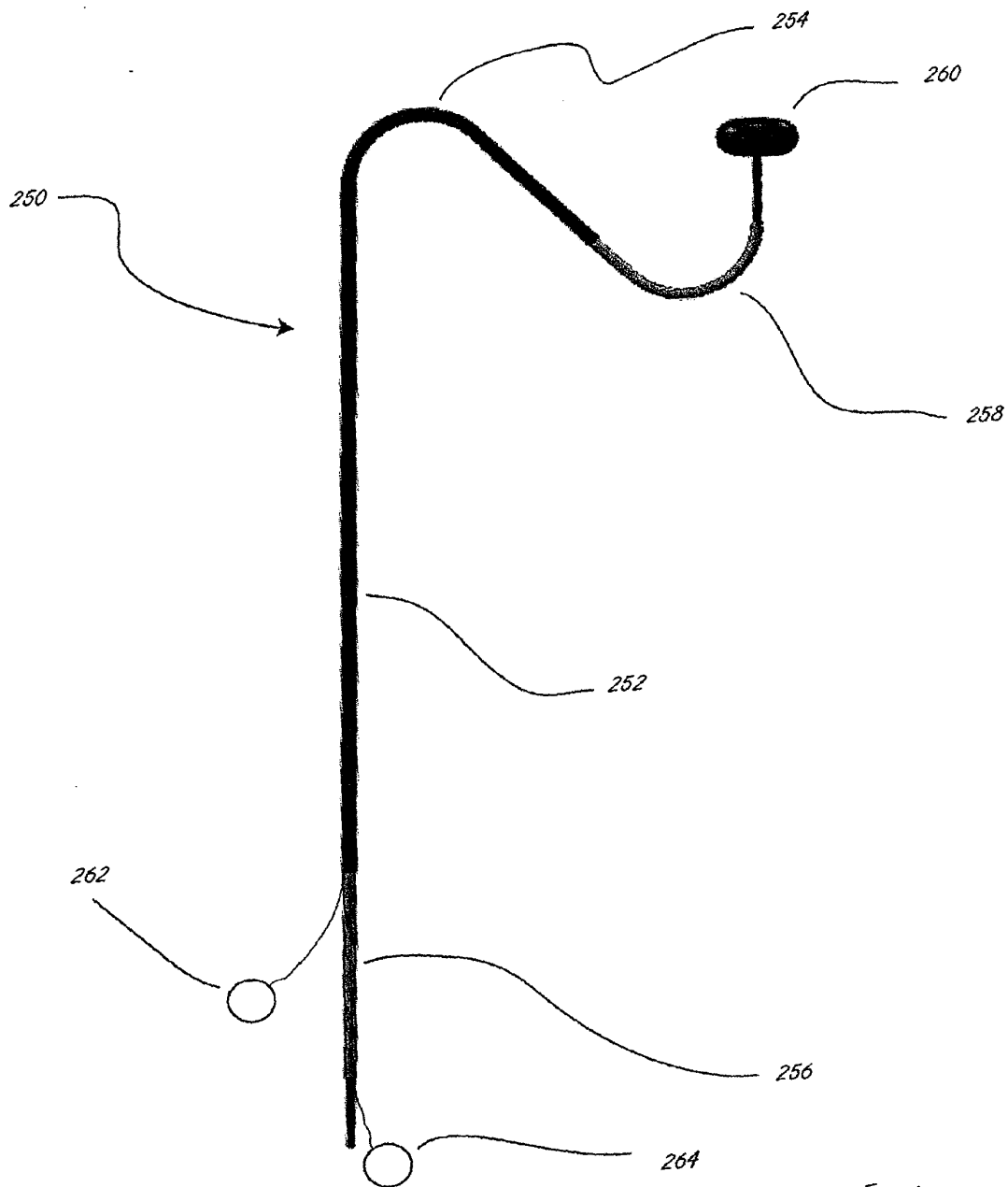


Fig. 14

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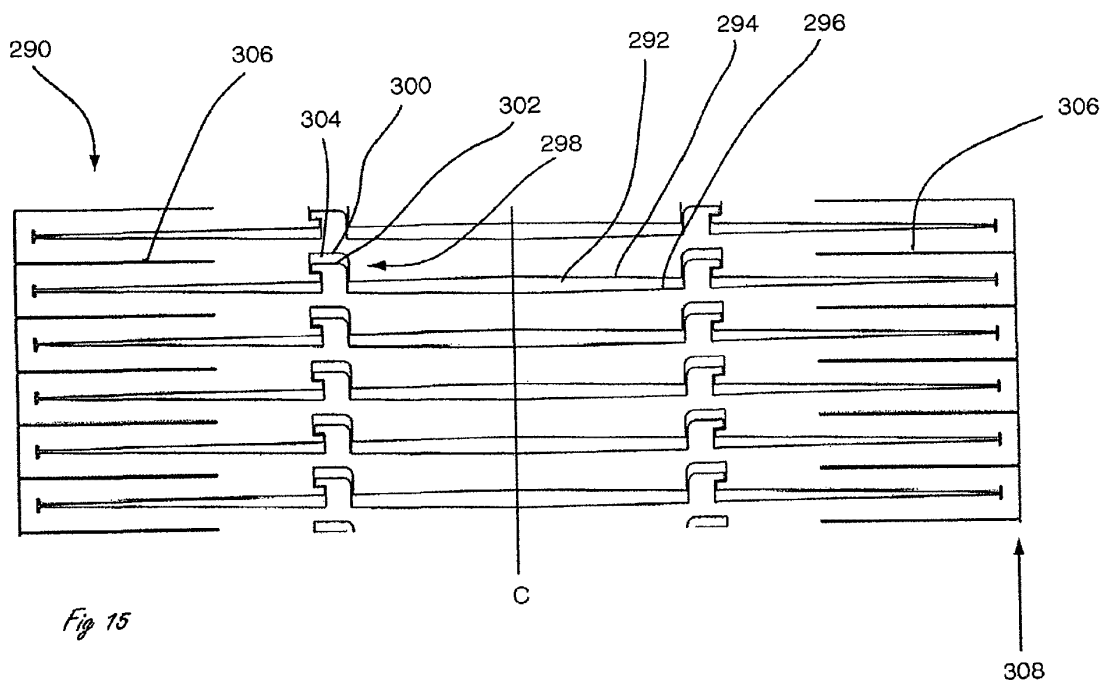


Fig 15

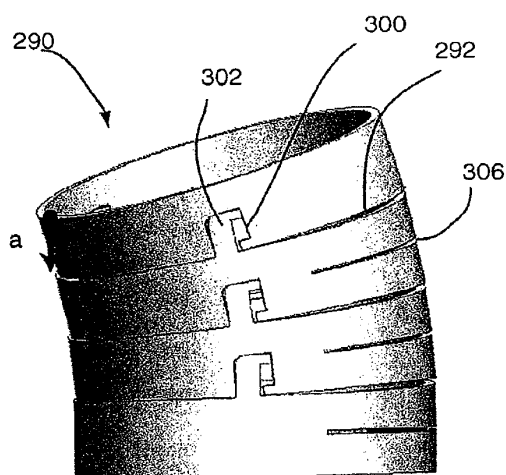


Fig 16a

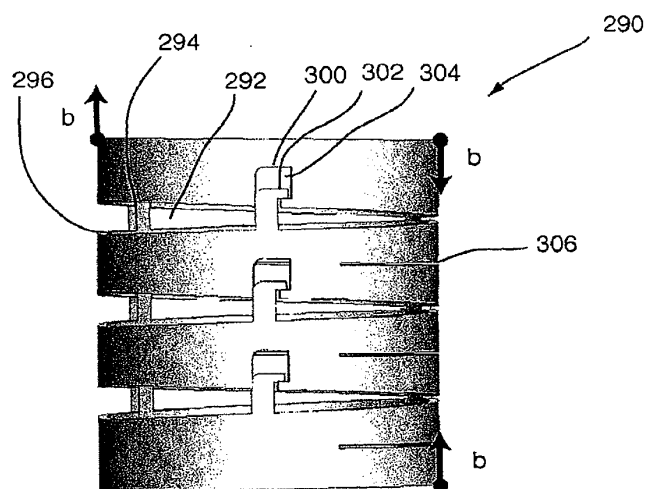


Fig 16b

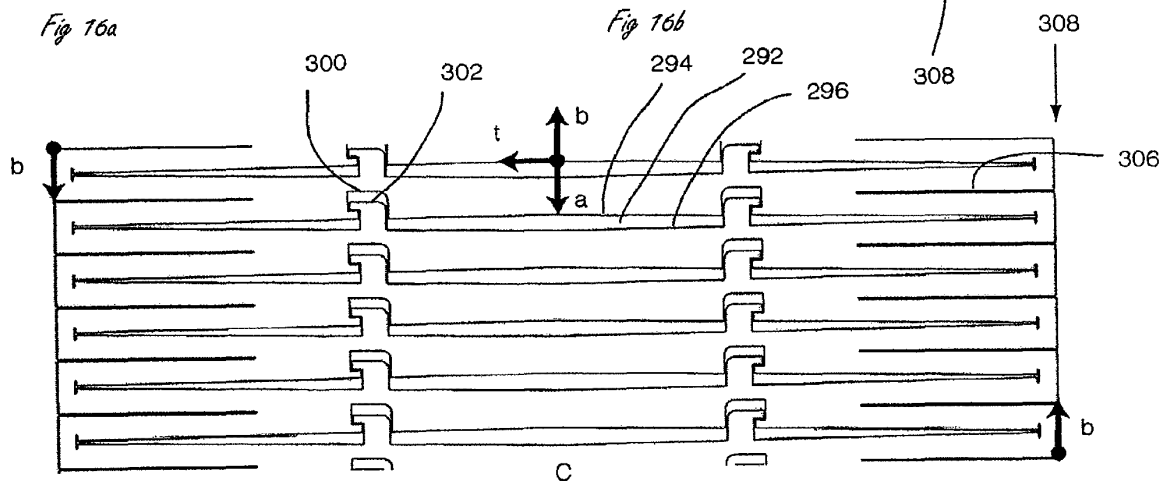


Fig 16c

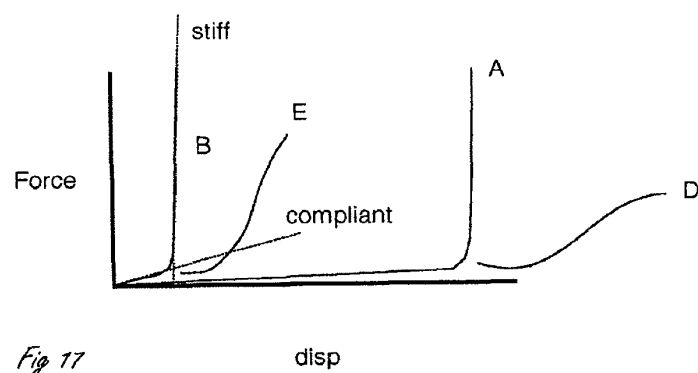
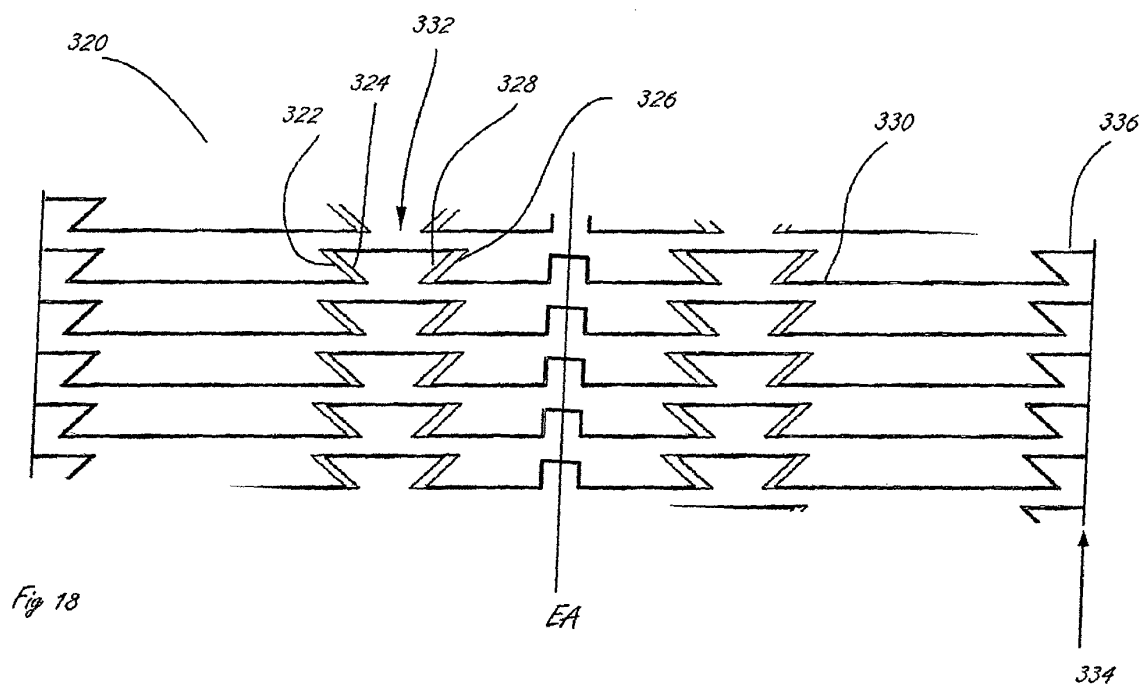
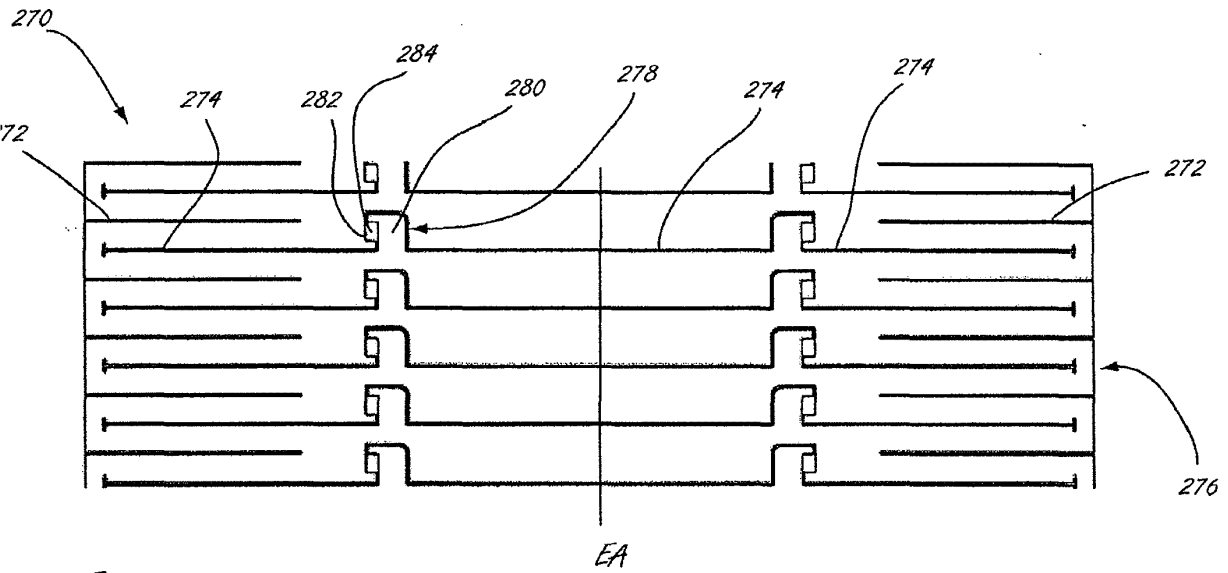
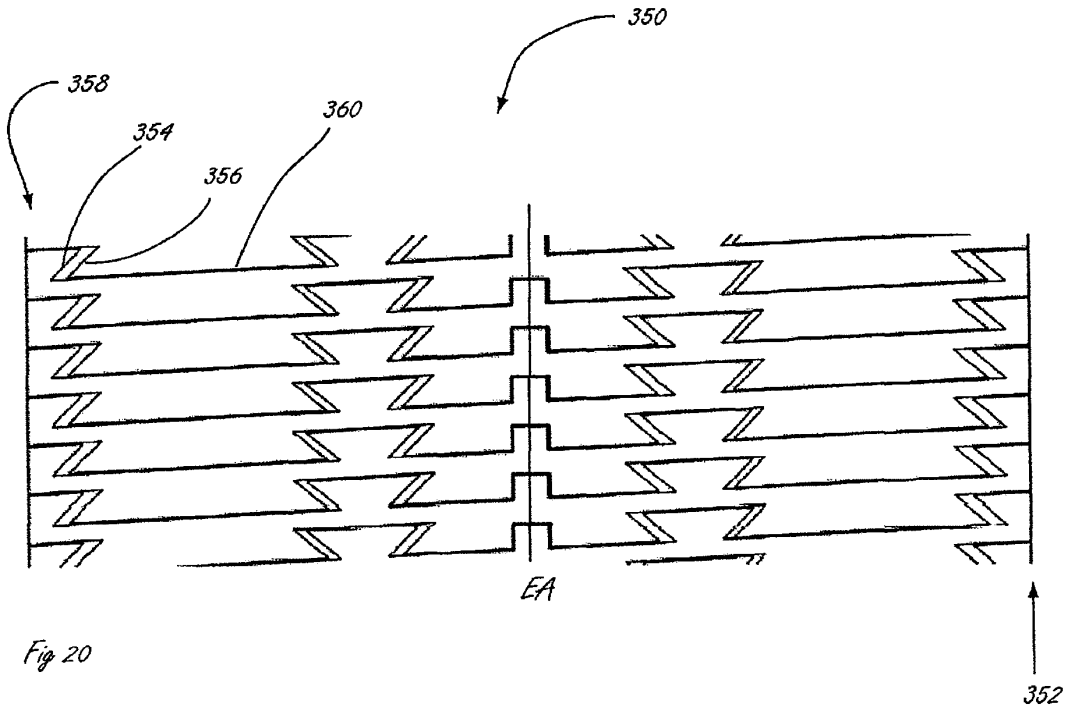


Fig 17

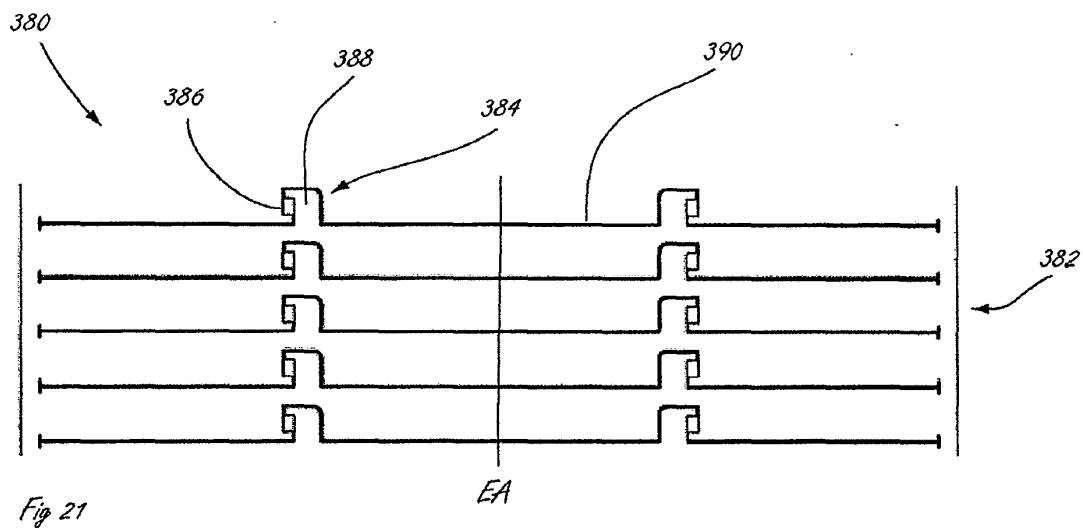
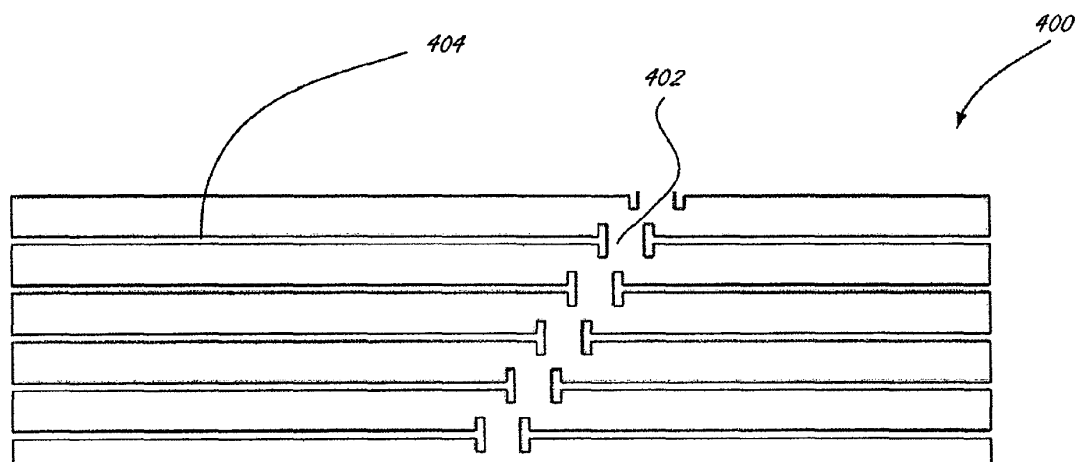
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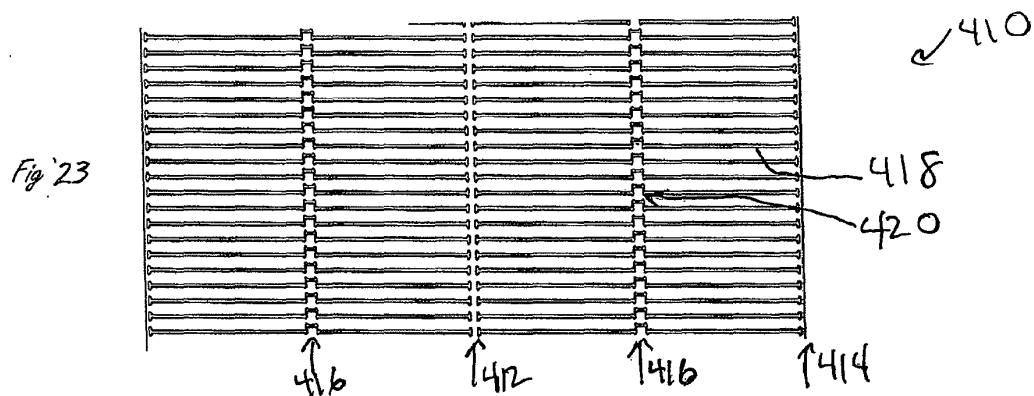
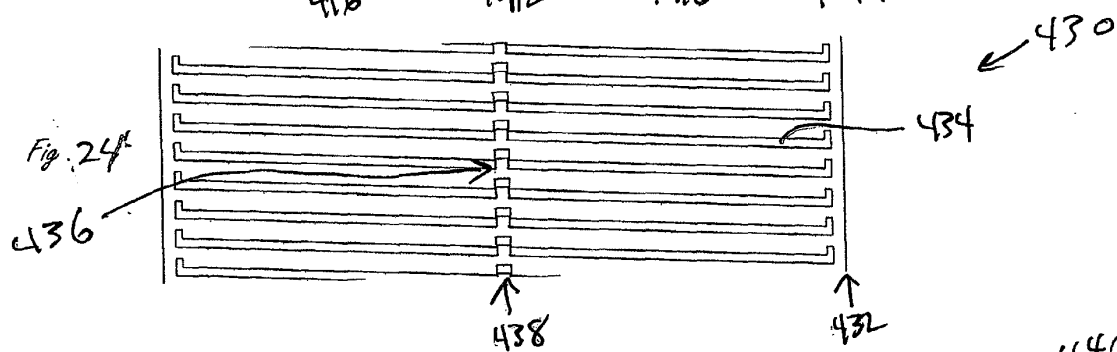
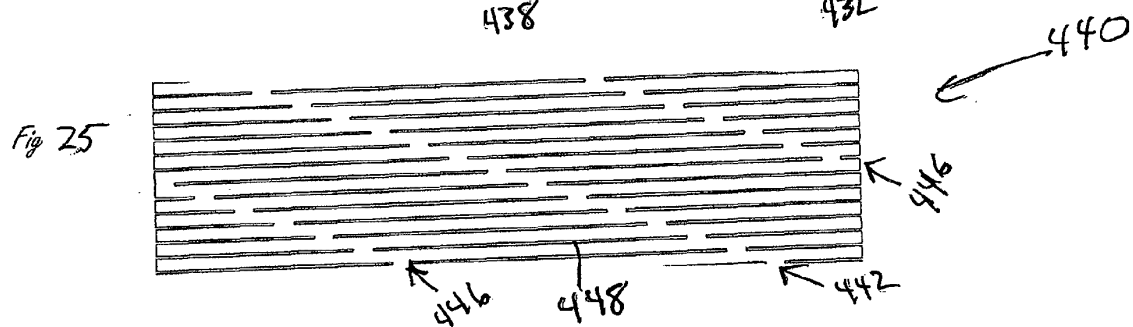
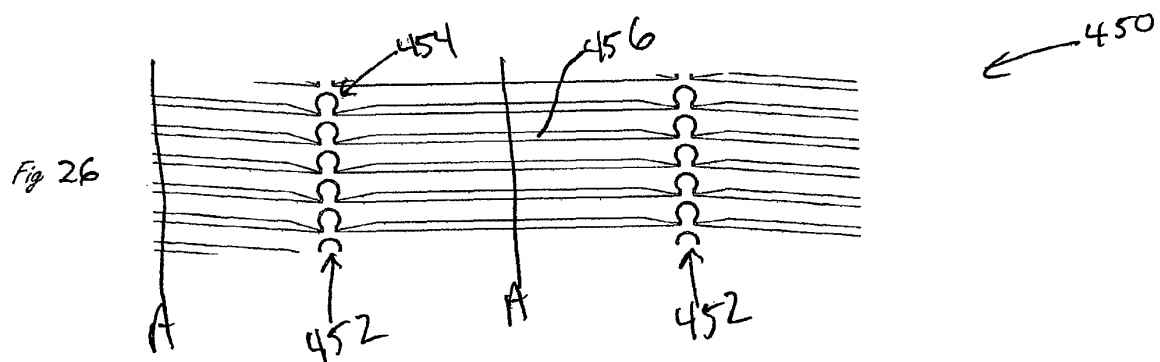


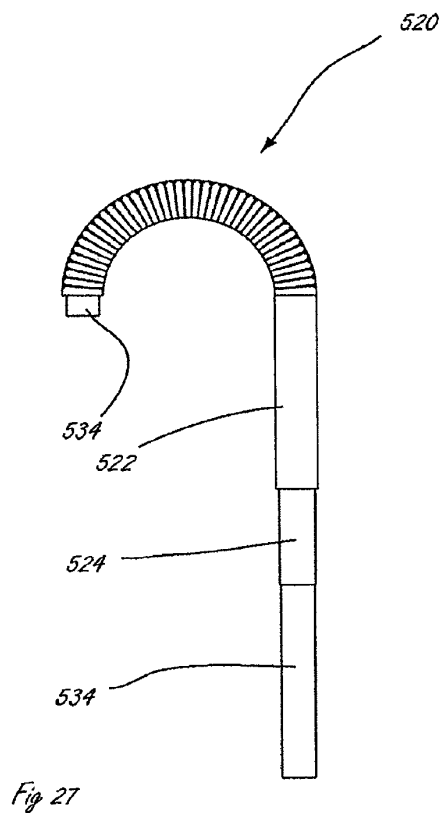
2015210338 04 Aug 2015



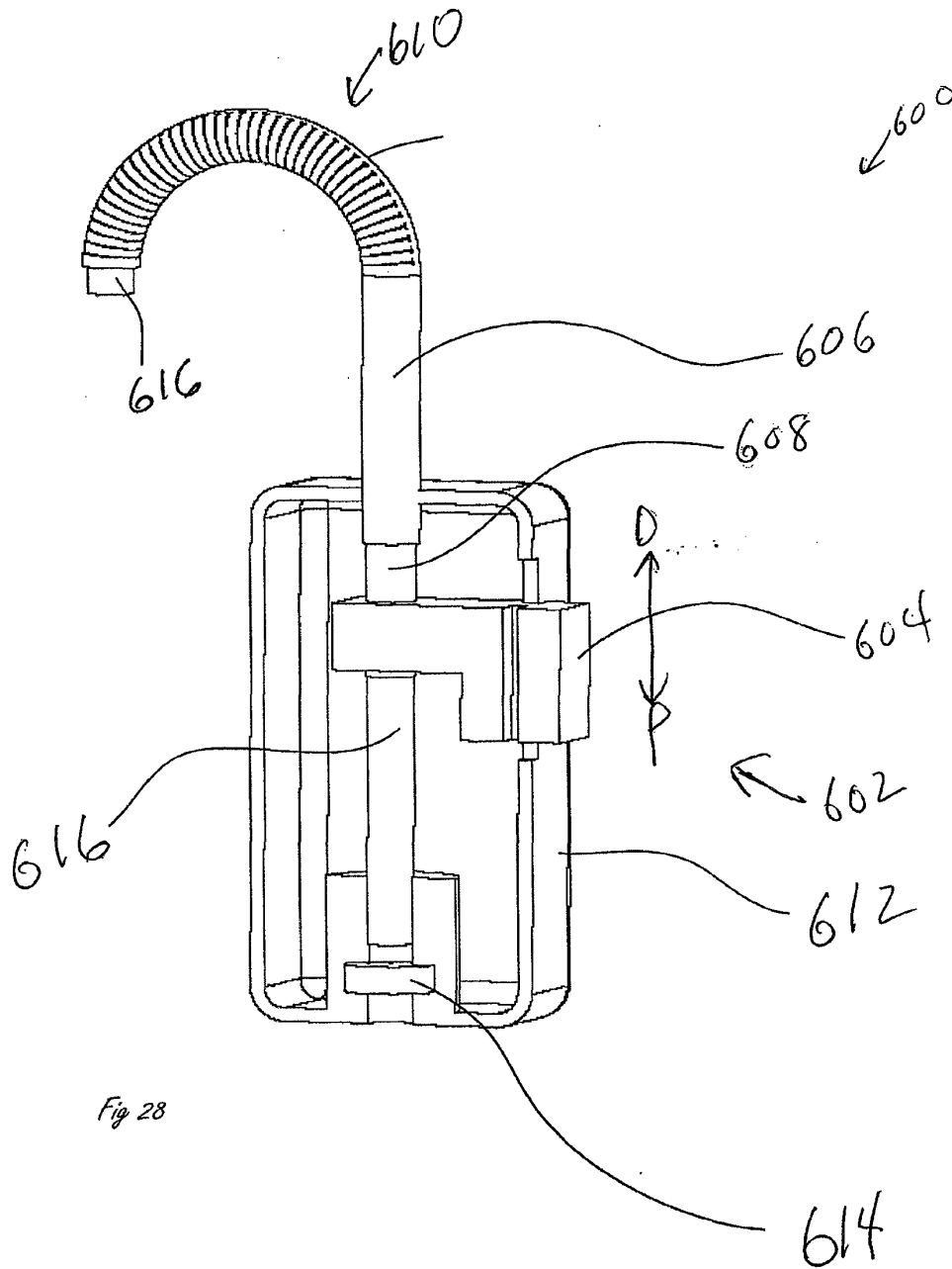
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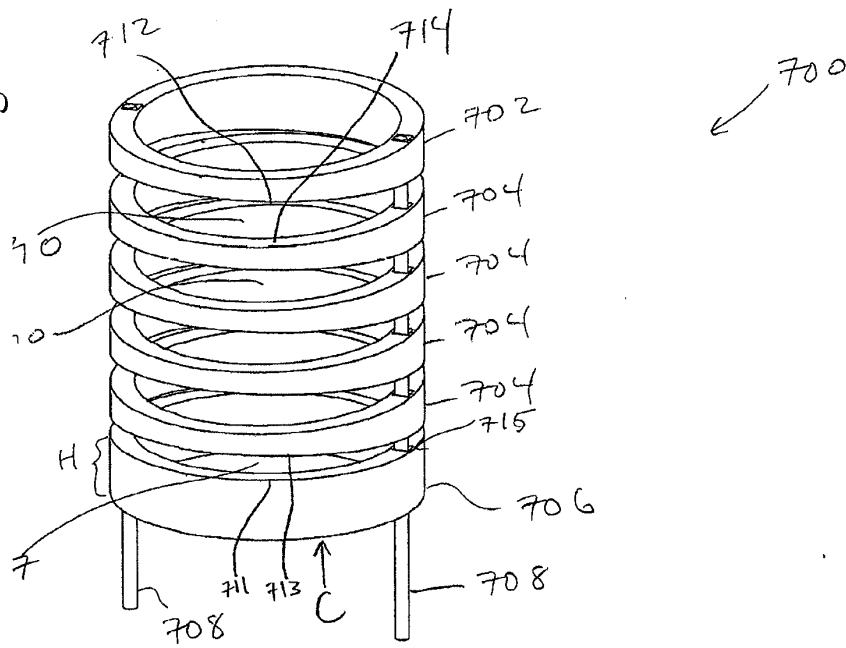


FIG. 29A

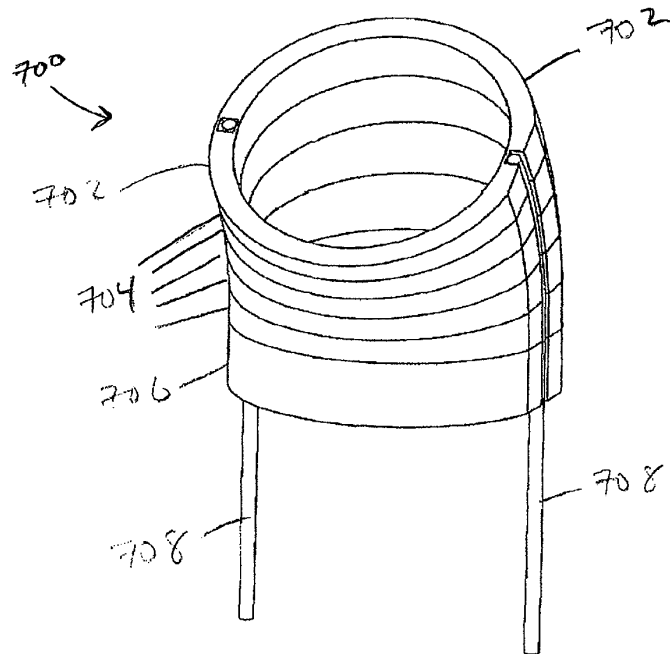
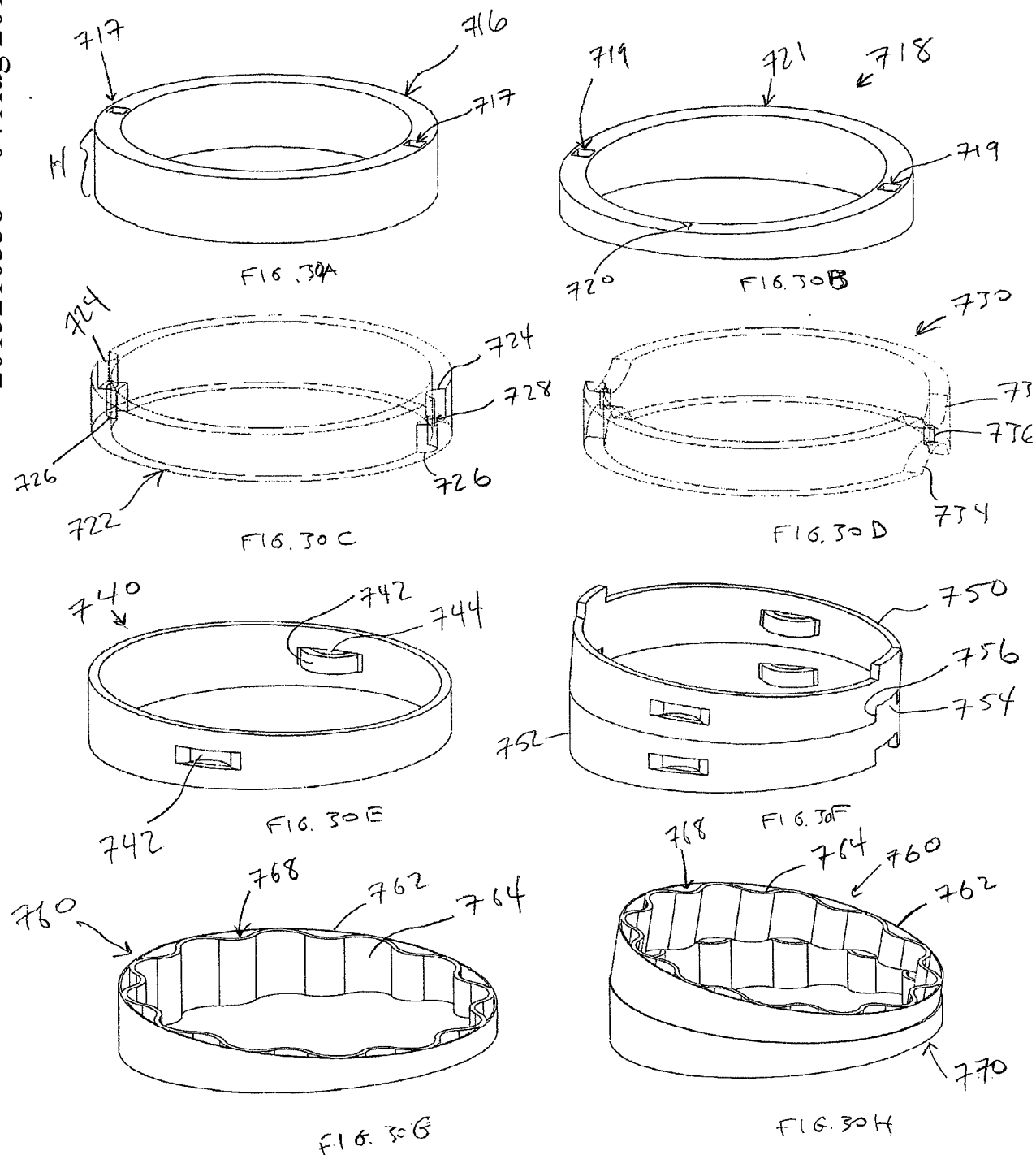


FIG. 29B



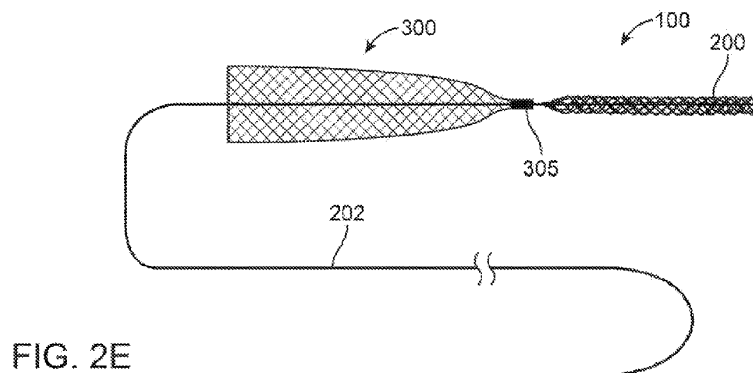


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- Declarations under Rule 4.17:**
- as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))
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(54) Title: RETRIEVAL SYSTEMS AND METHODS FOR USE THEREOF



(57) Abstract: The devices and methods described herein relate to improved structures for removing obstructions from body lumens. Such devices have applicability in through-out the body, including clearing of blockages within the vasculature, by addressing the frictional resistance on the obstruction prior to attempting to translate and/or mobilize the obstruction within the body lumen.

RETRIEVAL SYSTEMS AND METHODS FOR USE THEREOF

RELATED APPLICATIONS

- [0001] This application is a non-provisional of U.S. Provisional Application Nos. 61/489,183 filed May 23, 2012 entitled RETRIEVAL SYSTEMS AND METHODS FOR USE THEROF, and 61/489,254 filed May 24, 2012 entitled STENT RETRIEVER WITH INTEGRATED PROTECTION the entirety of each of which is incorporated by reference.

FIELD OF THE INVENTION

- [0002] The devices described herein are intended to retrieve obstructions from the body. Such devices have applicability throughout the body, including clearing of blockages within body lumens and providing passive protection of such, such as the vasculature, by providing a capturing portion that can translate and/or mobilize the obstruction within the body lumen.

BACKGROUND OF THE INVENTION

- [0003] A large number of medical procedures require the use of medical device(s) to remove an obstruction from a body lumen, vessel, or other organ. An inherent risk in such procedures is that mobilizing or otherwise disturbing the obstruction can potentially create further harm if the obstruction or a fragment thereof dislodges from the retrieval device. If a particle or the obstruction breaks free from the device and flows downstream, it is highly likely that the particle or obstruction will become trapped in smaller and more tortuous anatomy. In many cases, the physician will no longer be able to use the same retrieval device to again remove the obstruction because the size of the device may prevent advancing the device to the site of the new obstruction.
- [0004] Even in successful procedures, a physician must proceed with caution to prevent the walls of the vessel or body lumen from imparting undesired forces to shear or dislodge the obstruction as it is translated through the body during removal. These forces have the potential of breaking portions or fragments of the obstruction away. In some cases, the obstruction can simply break free from the retrieval device and can lodge in a new area causing more concern than the original blockage.
- [0005] Procedures for restoring flow within the cerebral vasculature as a result of ischemic stroke are one example of where these issues present a concern. The brain relies on its arteries and veins to supply oxygenated blood from the heart and lungs and to remove carbon dioxide

and cellular waste from brain tissue. Blockages that interfere with this supply eventually cause the brain tissue to stop functioning. If the disruption in supply occurs for a sufficient amount of time, the continued lack of nutrients and oxygen causes irreversible cell death (infarction). Accordingly, immediate medical treatment of an ischemic stroke is critical for the recovery of a patient. To access the cerebral vasculature a physician typically advances a catheter from a remote part of the body (typically a leg) through the vasculature and into the cerebral region of the vasculature. Once within the cerebral region, the physician deploys a device for retrieval of the obstruction causing the blockage. Concerns about dislodged obstructions or the migration of dislodged fragments increases the duration of the procedure at time when restoration of blood flow is paramount. Furthermore, a physician might be unaware of one or more fragments that dislodge from the initial obstruction and cause blockage of smaller more distal vessels.

[0006] Many physicians currently use stents to perform thrombectomy (i.e. clot removal) to resolve ischemic stroke. Typically, the physician deploys the stent into the clot, in an attempt to push the clot to the side of the vessel and re-establish blood to flow. Tissue plasminogen activator ("Tpa") is often injected into the bloodstream through an intravenous line. The TPA must travel in the blood stream until it reaches the clot that is causing the blockage. Once the Tpa contacts the clot, it begins to break up the clot with the hope of restoring blood flow to the affected areas. Tpa is also often administered to supplement the effectiveness of the stent. Yet, if attempts at clot dissolution are ineffective or incomplete, the physician can attempt to remove the stent while it is expanded against or enmeshed within the clot. In doing so, the physician must effectively drag the clot from the vessel, in a proximal direction, into a guide catheter located within vessels in the patients neck (typically the carotid artery). While this procedure has been shown to be effective in the clinic and easy for the physician to perform, there remain some distinct disadvantages using this approach.

[0007] The stent may not sufficiently hold onto the clot as it drags the clot to the catheter. In such a case, the clot might not move from the vessel. Another risk is that use of the stent might mobilize the clot might from the original blockage site, but the clot might not adhere to the stent during translation toward the catheter. This is a particular risk when translating through bifurcations and tortuous anatomy. Furthermore, blood flow can migrate the clot (or fragments of the clot) into a branching vessel at a bifurcation. If the clot is successfully brought to the guide catheter in the carotid artery, yet another risk is that the clot may be "stripped" or "sheared" from the stent as the stent enters the guide catheter. Regardless, simply dragging an expanded stent (either fully or partially expanded) can result in undesired

trauma to the vessel. In most cases, the stent is oversized compared to the vessel. Dragging a fixed metallic (or other) structure can pull the arteries and/or strip the cellular lining from the vessel, causing further trauma such as a hemorrhagic stroke (leakage of blood from a cerebral vessel). Also, the stent can become lodged on plaque on the vessel walls resulting in further vascular damage.

[0008] In view of the above, there remains a need for improved devices and methods that can remove occlusions from body lumens and/or vessels. While the discussion focuses on applications in the cerebral vasculature, the improved devices and methods described below have applications outside of the area of ischemic stroke.

SUMMARY OF THE INVENTION

[0009] The examples discussed herein show the inventive device in a form that is suitable to retrieve obstructions or clots within the vasculature. The term obstructions may include blood clot, plaque, cholesterol, thrombus, naturally occurring foreign bodies (i.e., a part of the body that is lodged within the lumen), a non-naturally occurring foreign body (i.e., a portion of a medical device or other non-naturally occurring substance lodged within the lumen.) However, the devices are not limited to such applications and can apply to any number of medical applications where elimination or reduction of the number of connection points is desired.

[0010] The devices discussed herein include interventional medical devices for retrieving and securing an obstruction within a vessel lumen. In one example the device comprises a shaft having a flexibility to navigate through tortuous anatomy, the shaft a distal portion and a proximal portion; a capturing structure located at a distal portion of the shaft comprising a plurality of struts, the capturing structure having a reduced profile for positioning in or adjacent to the obstruction and an expanded profile, such that when expanded into the obstruction, the struts at least partially enmesh with the obstruction such that subsequent movement of the capturing structure permits dislocation of at least a portion of the obstruction from the lumen; an eversible cover having a fixed section affixed relative to a proximal end of the capturing structure, a free section extending in a proximal direction from the distal section and a cover wall extending from the fixed section to the free section, where the eversible cover is expandable such that at least a portion of the eversible cover has a diameter equal to or greater than the capturing structure, the eversible cover being axially compliant such that when the shaft is moved proximally within the lumen, in some cases friction between the cover wall and the lumen resists proximal movement of the cover wall to cause the eversible

cover to evert over the capturing structure allowing for the free section of the cover to be distal to the fixed end of the capturing portion. Evert or eversible generally includes movement of the device within the cover causing the cover to turn inside out as it protects and covers the retrieval device. The covers disclosed herein can be expandable through self-expanding configurations, or via actuated expansion (e.g., a shape memory alloy, spring expansion, or other actuation).

- [0011] In one example, the device includes a configuration where the eversible cover, capturing structure, and shaft are a unitary structure. The device can also be configured so that each wire located at an end of the free section loops back to the cover causing the wires at the end of the free section to be continuous.
- [0012] In another variation at least a portion of the cover wall adjacent to the distal end has a set shape that is everted upon expansion. The device can also optionally include a catheter body, where in a delivery configuration, the shaft, capturing structure and eversible cover are located within the catheter body and where the capturing structure is advanceable in and out of a distal end of the catheter body.
- [0013] The device can also be configured so that the fixed section of the eversible cover comprises a pre-set shape to reduce a force required to evert the evertable cover.
- [0014] The retrieval devices can comprise any number of capturing or retrieval device such as a filter, an artherectomy device, a rotational cutter, an aspiration device, stent based retrievers and retrieval baskets.
- [0015] The methods described herein can include methods of securing an obstruction within a vessel. In one example, the method can comprise: positioning a catheter within a vessel; advancing a shaft having a retrieval device affixed thereto out of the catheter; advancing an eversible cover out of the catheter such that a fixed end of the eversible cover is affixed adjacent to a proximal end of the retrieval device and a free end of the eversible cover is moveable relative to the shaft and retrieval device; expanding a at least a portion of the eversible cover against a portion of a wall of the vessel; manipulating the retrieval device to become at least partially enmeshed with the obstruction; and proximally translating the shaft and retrieval device with at least a portion of the obstruction affixed thereto such that resistance of the eversible cover against the vessel resists movement of the eversible cover causing the free section of the eversible cover to evert over the proximally translated retrieval device.
- [0016] In another variation, the methods can include further withdrawing the shaft from the vessel such that during withdrawal the eversible cover forms a protective barrier over the

obstruction to lessen shearing forces caused by the vessel and reduce dislodging portions of the obstruction from the retrieval device.

[0017] Another variation of a method includes a method of preparing a retrieval device comprising: providing a retrieval device having been previously removed from a body of a patient where the retrieval device includes a protective cover where a fixed end of the protective cover is affixed adjacent to a proximal end of the retrieval device and where a free end is located distally to the fixed end covering the retrieval device and is moveable relative to the second end; reversing the protective cover by moving the free end proximally of the fixed while the fixed end remains affixed adjacent to the proximal end of the retrieval device; inserting the retrieval device and cover into a catheter where the free end of the cover is proximal to the fixed end of the cover and retrieval device such that upon deployment from the catheter, the free end of the cover deploys proximally to the fixed end of the cover.

[0018] In another example, the devices described herein can include medical device retrieval systems for securing an obstruction within a vessel lumen and for use with a catheter configured to be navigated through the vasculature. In one variation, the device comprises an elongated stent comprising a plurality of struts, the stent being collapsible for positioning in the catheter during delivery and having an expanded profile such that when expanded the struts are configured to engage the obstruction; a shaft fixedly attached to the elongated stent and having a flexibility to navigate through tortuous anatomy; a fluid permeable cover having a distal end coupled to a proximal end of the elongated stent a cover wall defining a cavity and extending along the shaft, and a proximal end being moveable relative to the shaft, where the fluid permeable cover is collapsible for positioning in the catheter during delivery and is expandable upon deployment from the catheter such that at least a portion of the fluid permeable cover is expandable; where the fluid permeable cover is axially pliable such that when the device is deployed in the vessel the frictional forces between the vessel and the fluid permeable cover permit proximal movement of the shaft and elongated stent to cause inversion of the fluid permeable cover wall such that the fluid permeable cover wall everts over the elongated stent.

[0019] Another variation of a device includes an interventional medical device for use with a catheter configured for delivery through vasculature for securing an obstruction within a vessel lumen. For example, the device can comprise a shaft having a flexibility to navigate through tortuous anatomy, the shaft having a distal portion and a proximal portion; a capturing device comprising a sidewall, the capturing device fixedly located at a distal portion of the shaft and having a reduced profile for positioning in the catheter and an expanded

profile, such that upon deployment from the catheter, the capturing device expands to force a portion of the sidewall into the obstruction to at least partially attach to the obstruction; a cover having a distal end coupled adjacent to a proximal end of the capturing structure, a proximal end and a cover wall extending therebetween, where the proximal end of the cover is slidable relative to the distal end, where the cover is expandable such that when located in the catheter the cover is in a reduced delivery state and upon advancement from the catheter the cover expands with the proximal end located proximally of the distal end, where the cover wall is compliant such that when deployed from the catheter and the shaft is pulled in a proximal direction frictional forces between the vessel and the cover wall or proximal end cause the cover to invert as the cover wall inverts over the capturing device to surround the capturing device.

[0020] Another variation of the device include an interventional medical device for securing a retrieval device having one or more obstructions located therein for removal from a body. In one such example the medical device includes a sheath having a flexibility to navigate through tortuous anatomy, the sheath a distal portion and a proximal portion and a lumen extending therethrough; an eversible cover having a fixed section affixed to the distal portion of the sheath, a free section extending in a proximal direction from the fixed section and a cover wall extending from the fixed section to the free section, where the eversible cover is expandable, the eversible cover being axially compliant such that when the retrieval device is positioned through the sheath lumen moved in a proximal direction against the eversible cover, the eversible cover everts over the retrieval device allowing for the free section of the cover to be distal to the retrieval device.

[0021] Another variation of the method includes advancing a shaft having a retrieval device affixed thereto to the obstruction; advancing a protective device over the shaft, the protective device comprising a sheath having an eversible cover, where a fixed end of the eversible cover is affixed to a distal portion of the sheath and a free end of the eversible cover is located proximal to the fixed end; positioning the fixed end of the eversible cover adjacent to the retrieval device and expanding at least a portion of the eversible cover against a portion of a wall of the vessel; proximally translating the shaft and retrieval device with at least a portion of the obstruction affixed thereto such that resistance of the eversible cover against the vessel resists movement of the eversible cover causing the free section of the eversible cover to evert over the proximally translated retrieval device.

[0022] The capturing portions described herein can include a stent retrieval device for expanding against one or more occlusive bodies in a vasculature. In one example, the stent

retrieval device includes an elongate shaft having a flexibility to navigate through tortuous anatomy, the elongate shaft having a distal portion and a proximal portion; a plurality of filaments that diverge from the distal portion of the elongate shaft to form an expandable elongated stent body having a open distal end and a fluid permeable closed proximal end and a cavity therebetween, where divergence of the filaments at the distal portion of the elongate shaft forms the fluid permeable closed proximal end; where the plurality of filaments extending along the shaft are free of any connection joints in the distal portion to permit increased flexibility of the distal portion as it navigates through tortuous anatomy; and one or more connection joints proximal to the distal portion where the connection joints secure the plurality of filaments to the shaft.

[0023] The stent retrieval can also include at least one of the plurality of filaments that comprise at least two wires twisted together, the elongated stent body further comprising at least one intersection of filaments, where the wires of each filament are interwoven to provide increased outward radial strength of the elongated stent body and such that the wires slide relative to each other as the elongated stent body expands or compresses in diameter to reduce a force required to linearize the elongated stent body.

[0024] The stent retrieval device can have an exterior surface of the elongated stent body that comprises an irregular surface formed by intersection of filaments.

[0025] The stent retrieval device can also have intersection of filaments comprising a barb or knuckle and where a plurality of barbs or knuckles are radially spaced about the elongated stent body. The stent retrieval device can also have an intersection of filaments that comprises a barb or knuckle and where a plurality of barbs or knuckles are aligned with an axis of the elongated stent body.

[0026] In one variation of the devices described herein, the device comprises a main bundle or group of wires that diverge to form a device having various shapes but few or no connections points or joints (where fabrication of such a construction is referred to as "jointless"). Clearly, the inventive devices described herein are not limited to such a jointless construction. Additional variation includes one or more leading wires that are attached to a capturing portion as described below.

[0027] Devices of the present invention can incorporate any number of wires of different characteristics including, but not limited to, materials, shapes, sizes and/or diameters. Clearly, the number of permutations of device configurations is significant. Providing devices with such a composite construction allows for the manipulation of the device's properties to suite the intended application.

[0028] As noted herein, the joint-less construction improves the flexibility and strength of the device by eliminating joints, connection points, or other attachment points. In addition, the joint-less construction improves the ability of the device to be delivered through a small microcatheter. As a result, the device and microcatheter are able to access remote regions of the vasculature.

[0029] The devices may be fabricated to be self-expanding upon deployment from a catheter. Alternatively, the devices can be constructed from shape-memory alloys such that they automatically deploy upon reaching a pre-determined transition temperature.

[0030] It should be noted that in some variations of the invention, all or some of the device can be designed to increase their ability to adhere to the obstruction. For example, the wires may be coupled to an energy source (e.g., RF, ultrasonic, or thermal energy) to “weld” to the obstruction. Application of energy to the device can allow the surrounding portion to deform into the obstruction and “embed” within the obstruction. Alternatively, the device can impart a positive charge to the obstruction to partially liquefy the obstruction sufficiently to allow for easier removal. In another variation, a negative charge could be applied to further build thrombus and nest the device for better pulling force. The wires can be made stickier by use of a hydrophilic substance(s), or by chemicals that would generate a chemical bond to the surface of the obstruction. Alternatively, the filaments may reduce the temperature of the obstruction to congeal or adhere to the obstruction.

[0031] Additional devices and methods for treating ischemic stroke are discussed in commonly assigned U.S. Patent application nos.: 11/671,450 filed February 5, 2007; 11/684,521 filed March 9, 2007; 11/684,535 filed March 9, 2007; 11/684,541 filed March 9, 2007; 11/684,546 filed March 9, 2007; 11/684,982 filed March 12, 2007, 11/736,526 filed April 17, 2007, 11/736,537 filed April 17, 2007, 11/825,975 filed September 10, 2007; 12/344,378 filed 12/26/2008, 13/012,727 filed 1/24/2011, and 13/226,222 filed 9/6/2011; the entirety of each of which is incorporated by reference. The principles of the invention as discussed herein may be applied to the above referenced cases to produce devices useful in treating ischemic stroke. In other words, the wire-shaped construction of devices according to present invention may assume the shapes disclosed in the above-referenced cases when such a combination is not inconsistent with the features described herein.

BRIEF DESCRIPTION OF THE DRAWINGS

- [0032] Each of the following figures diagrammatically illustrates aspects of the invention. Variation of the invention from the aspects shown in the figures is contemplated.
- [0033] Fig. 1 illustrates an example of a device according to the present invention when used in a system for removing obstructions from body lumens.
- [0034] Figs. 2A to 2C illustrate working ends of various coverable retrieval devices.
- [0035] Figs. 2D and 2E show variations of retrieval devices.
- [0036] Fig. 2F shows an independent eversible cover on a delivery sheath.
- [0037] Figs. 3A to 3C illustrates an example of a coverable retrieval device where the cover everts about the retrieval structure.
- [0038] Fig. 4A to 4I illustrates an example where an improved retrieval device with passive protection retrieves a clot from tortuous anatomy.
- [0039] Figs. 4J and 4K illustrate examples of an obstruction or other material captured within a retrieval device with a cover further protecting the loaded retrieval device.
- [0040] Fig. 5A illustrates a retrieval device having a retrieval structure adjacent to a double layer cover.
- [0041] Fig. 5B shows a funnel with a free end that tapers down about the delivery wire.
- [0042] Figs. 5C and 5D show a fixed end of a cover that is pre-shaped to reduce the force required to evert the cover wall.
- [0043] Fig. 5E shows alternate variation of a passive cover integrated into a retrieval device.
- [0044] Fig. 5F illustrates a cover having a pre-set flattened cover wall at a fixed end of the retrieval structure.
- [0045] Figs. 5G to 5I illustrate various layered covers.
- [0046] Fig. 5J shows a cover that is constructed directly onto the retrieval structure rather than the delivery shaft.
- [0047] Figs. 5K and 5L show a variation of a cover and retrieval device where the cover is first mounted in a distal direction and then inverted in a proximal direction.
- [0048] Figs. 6A to 6L illustrate a variation of covers for use as describe herein.
- [0049] Figs. 7A to 7C show additional variations of covers.
- [0050] Fig. 8 illustrates a variation of a proximal and distal end of an additional retrieval device.
- [0051] Figs. 9A to 9C illustrate wires of different constructions within a delivery wire or shaft.

- [0052] Figs. 10A to 10E illustrate additional variations of covers for use as described above.
- [0053] Figs. 11A to 11C illustrate additional variations of covers for use with the devices and methods described herein.
- [0054] Figs. 12A to 12E illustrate various stent designs for increasing the ability of a stent to adhere to an occlusion within a vessel.
- [0055] Fig. 12G illustrates a proximal end of the stent structure.

DETAILED DESCRIPTION

- [0056] It is understood that the examples below discuss uses in the cerebral vasculature (namely the arteries). However, unless specifically noted, variations of the device and method are not limited to use in the cerebral vasculature. Instead, the invention may have applicability in various parts of the body. Moreover, the invention may be used in various procedures where the benefits of the method and/or device are desired.
- [0057] Fig. 1 illustrates a system **10** for removing obstructions from body lumens as described herein. In the illustrated example, this variation of the system **10** is suited for removal of an obstruction in the cerebral vasculature. As stated herein, the present devices and methods are useful in other regions of the body including the vasculature and other body lumens or organs. For exemplary purposes, the discussion shall focus on uses of these devices and method in the vasculature.
- [0058] It is noted that any number of catheters or microcatheters may be used to locate the catheter/microcatheter **12** carrying the obstruction removal device **200** at the desired target site. Such techniques are well understood standard interventional catheterization techniques. Furthermore, the catheter **12** may be coupled to auxiliary or support components **14**, **16** (e.g., energy controllers, power supplies, actuators for movement of the device(s), vacuum sources, inflation sources, sources for therapeutic substances, pressure monitoring, flow monitoring, various bio-chemical sensors, bio-chemical substance, etc.) Again, such components are within the scope of the system **10** described herein.
- [0059] In addition, devices of the present invention may be packaged in kits including the components discussed above along with guiding catheters, various devices that assist in the stabilization or removal of the obstruction (e.g., proximal-assist devices that holds the proximal end of the obstruction in place preventing it from straying during removal or assisting in the removal of the obstruction), balloon-tipped guide catheters, dilators, etc.

[0060] Fig. 2A illustrates a working end of a coverable retrieval device **100**. Typically, the device includes a capturing or retrieval structure **200**. In the illustrated example, the retrieval structure **200** comprises an elongated stent structure. However, unless specifically noted, the capturing structure can comprise any number of devices, including but not limited to a filter, an artherectomy device, a rotational cutter, an aspiration catheter.

[0061] The retrieval structure **200** is located at a distal end of a delivery wire **202**. In one variation, the retrieval structure **200** can be permanently affixed to the delivery wire **200** by such methods including, but not limited to adhesive bonding, soldering, welding, polymer joining, or any other conventional method. In some variations, the retrieval device **200** can be formed from one or more wires forming the delivery wire **202** or shaft **202**. The delivery wire **202** can have sufficient column strength such that it can axially advance and retract the device **100** within the vasculature as the physician manipulates a non-working end of the delivery wire **202** outside of the body. Accordingly, the delivery wire **202** should have a length that is sufficient to extend from the target area, e.g., the cerebral vasculature, to the entry point on the body. Alternatively, additional variations of the device **100** can allow for the use of a support member or catheter that positions the retrieval structure **200** as needed. Additional features of the retrieval structure **200** can be found in the commonly assigned patents and applications cited herein and incorporated by reference.

[0062] The coverable retrieval device **100** further includes a cover **300** (also referred to as a funnel or sheath) affixed relative to a proximal end **206** of the retrieval structure **200**. By being affixed relative to a proximal end **206**, a distal end **204** of the retrieval structure **200** can move relative to the cover **300** so that the cover **300** everts over the proximal end **206** of the structure **200** when the cover **300** is expanded within a vessel and as the structure **200** is withdrawn into the distal end **302** of the cover **300**. This mechanism is discussed in detail below.

[0063] Figs. 2B and 2C illustrate alternative variations of a coverable retrieval device **100**. As shown in Fig. 2B and 2C, the distal end **302** of the cover **300** can be spaced from the proximal end **206** of the retrieval structure **200**. Alternatively, the distal end **302** of the cover **300** can extend over a portion of the retrieval structure **200**. In some variations, at least a section of the cover **300** expands to a greater diameter than a diameter of the retrieval structure **200**. This allows the cover **300** to expand to a vessel wall where the vessel holds the cover stationary while the device is pulled proximally through the cover to evert the cover. In alternate variations, the cover **300** expands to the same or lesser diameter than the retrieval structure **200** or other device.

- [0064] Fig. 2D shows a retrieval device **100** with a catheter **112** (usually a microcatheter). The retrieval device **100** can comprise a single unitary device of a cover **300** and retrieval structure **200** (in this case the retrieval structure is an elongated stent structure). One benefit of a unitary device is that additional devices complicates the procedure and can increase the duration of what is ordinarily a time sensitive procedure. The retrieval device **100** can be positioned through the catheter **112** that includes a hub **114**. As a result, the physician only needs to manipulate the unitary retrieval device **100** and the catheter/microcatheter **112**. The retrieval device **100** is loaded into the catheter **112** for placement at the target site. In addition, the retrieval device can be reloaded if the procedure must be repeated. The cover **300** and retrieval structure **200** described herein can comprise any construction described herein or as known by those skilled in the art.
- [0065] Fig. 2E shows a retrieval device **100** with a cover **300** and retrieval device **200** with a radiopaque marker **305** therebetween. As shown, variations of the device **100** do not require a catheter or microcatheter.
- [0066] Fig. 2F illustrates an eversible cover **300** located on a sheath **330** having a lumen **332** extending therethrough. A separable retrieval device **200** can be coupled to the cover **300** and sheath **330** by inserting the wire **202** of the cover retrieval device **200** through the lumen **332** of the sheath **330**. In this variation, the eversible cover **300** can be used with any number of different interventional tools. The separate devices can be assembled prior to delivery into the patient. Alternatively, the devices can be positioned within the body and subsequently joined once the retrieval device **200** engages the target area.
- [0067] Fig. 3A illustrates an example of a coverable retrieval device **100** where the cover **300** is in the process of everting about the retrieval structure **200**. As shown, arrow **50** illustrates a force applied on the wire **202** in a proximal direction. Arrows **52** illustrate a resistance force applied by the friction of the expanded cover **300** against a vessel or similar wall. This friction force **52** prevents or resists proximal movement of the free end **304** of the cover **300** while the fixed end **302** moves in a proximal direction with the proximal end **206** of the retrieval structure **200**. This action causes a wall **306** of the cover **300** to evert over the retrieval structure **200**. Ultimately, and as shown in Fig. 3B, the free end **304** of the cover **300** ends up distally over the fixed end **302**. As shown, the wall of the everted cover **300** provides a safety type cover for the retrieval device **200**. In additional variations, the fixed end **302** of the cover can actually be slidable or moveable along the delivery wire **202**. However, the similar principle as discussed above shall apply to cause everting of the cover **300** over the retrieval structure **200**.

[0068] Fig. 3C illustrates another variation of a coverable retrieval device **100** after the cover **300** is everted about the retrieval structure **200**. In this variation, the free end **304** of the cover **300** ends up distally of the fixed end **302** and tapers or collapses towards the free end **304**. The cover **300** can be shape set so that prior to eversion the cover is as shown above where the forces acting on the cover wall **306** expand outwards, but after eversion the forces on the cover wall **306** cause the tapering or collapsing as shown in Fig. 3C.

[0069] In accordance with the illustrations discussed above, the cover **300** can be made so that the cover wall **306** is atraumatic when dragged across a lumen wall. The cover can be manufactured from any number of materials including a fabric, a reinforced fabric, a braid, weave, or any such material that allows for expansion against a wall of the body lumen or vessel as well as to allow everting of a wall **306** of the cover over the retrieval device **200**. The cover wall **306** can also comprise combinations of these materials such as braids of polymer material with metal fibers, soft braids with coil reinforcements or various other combinations.

[0070] The cover wall can comprise a mesh that can include any medically acceptable materials such as a Nitinol braid. Furthermore, the mesh allows for flow through the vessel or lumen while expanded. However, additional variations of the device can include a solid layer of material substituted for the mesh. Moreover the cover can comprise any number of configurations. For example, the cover can comprise a single layer wall or a multi layer wall, the open end of the cover could be made to have terminated ends such as by using continuous wire loops formed during the braiding process. Alternatively, the ends can be cut and then terminated by encasing in polymer, laser welds, or by folding inward for a discreet length and then terminating

[0071] In one example, the cover **300** comprises a continuous wire construction as described in earlier commonly assigned patent applications incorporated by reference. In one variation the cover **300** comprises a finely braided wire, such as 48-96 wires of .0005" to 0.002" diameter fine Nitinol wire or similar. Additionally, the wire can comprise cobalt chromium, stainless steel, or similar, or drawn filled tube (dft) with platinum core. In additional variations, a flat wire or oval wire can be used. The wire does not need to be uniform. Instead, a number of different types of wires can be used. Some of the individual wires could be platinum alloys for added radiopacity.

[0072] Fig. 4A to 4I illustrates an example where an improved retrieval device **100** with passive protection retrieves a clot **2** from tortuous anatomy. Fig. 4A illustrates a clot **2** that obstructs blood flow in a vessel **6**. As noted herein, the vessel **6** can comprise any vessel in

cerebral vasculature, coronary or peripheral vasculature. Alternatively, the device and methods for use are not limited to use in the vasculature. Variations of the principles, concepts, method and devices described herein can be applicable wherever a retrieval device can be used. Fig. 4A also illustrates a guide sheath or access catheter **108** that is advanced within the vessel. During a procedure, the physician will advance the access catheter **108** as far distally as possible. However, due to the size of the access catheter **108**, a physician typically positions it a distance away from the obstruction **2**. As shown, there can be any number of bifurcations **8** in the vessel **6** located between the access catheter **108** and the obstruction **2**. As discussed herein, in some variations, the access catheter **108** can be used to remove the obstruction **2** from the body once the obstruction is captured by a retrieval device. However, the greater the distance between the initial location of the obstruction **2** and the location of the access catheter **108**, the greater the risk that the obstruction **2** can break free from the retrieval device or become dislodged due to anatomic or environmental features, including but not limited to bifurcations, the wall of the lumen, the tortuosity of the anatomy, vessel wall plaque, etc.

[0073] Fig. 4B illustrates an optional catheter **112** that advances from the access catheter **108** to the site of the obstruction **2**. Once at the site, the catheter **112** can deploy a retrieval device (not shown in Fig. 4B) so that the retrieval device can engage the clot **2**. Alternatively, the catheter **112** can traverse the obstruction **2** as shown in Fig. 4C and deploy a portion of the retrieval device **100** distally to the obstruction **2**. The physician then manipulates the retrieval device **100** to secure the obstruction **2**. For example, the physician can deploy the retrieval structure **200** distally to the obstruction **6** and withdraw the retrieval structure **200** proximally to secure the obstruction **2**. In another variation, the physician can position the retrieval structure **200** within the catheter **2** while the catheter **112** is through or adjacent to the obstruction **2**. Then, the physician can withdraw the catheter **112** to expose the retrieval structure **200** so that it secures to the obstruction **2** after expansion. In the illustrated example, the retrieval structure **200** comprises an elongated stent type structure that expands (or is expanded) to enmesh or secure to the obstruction. Although not illustrated, the system can include a distal capture filter or basket as described in any of the commonly assigned applications incorporated by reference herein.

[0074] Next, as shown in Fig. 4E, the physician can further withdraw the catheter **112** to expose a cover **300** as described above. In many cases, the physician exposes the cove **300** once the retrieval structure **200** is engaged with the obstruction **2**. This sequential process allows for easier repositioning of the retrieval structure **200** if necessary. Alternatively, the

cover 300 can be deployed prior to engaging the retrieval structure 200 with the obstruction 2. If necessary, the physician can apply a proximal force on the delivery wire 202 while withdrawing the catheter 112 to prevent inadvertent movement of the obstruction 2 and retrieval device 200.

[0075] Fig. 4F illustrates the stage with a fully exposed the cover 300 and a catheter 112 moved closer towards the access sheath 108. As shown, the free end 304 of the cover 300 is proximal to fixed end 306 of the cover 300. As also noted above, the cover 300 can be a shape memory alloy that expands against the walls of the vessel 6 upon reaching body temperature. Alternatively, the cover 300 can be self expanding upon deployment into the vessel 6. In some variations, the cover wall 306 comprises a porous material or construction that allows blood to continue to flow through the cover 300.

[0076] In addition, some variations of the retrieval device 100 include a cover 300 that has at least a section that expands to a greater diameter or dimension than the retrieval structure 200. This allows for expansion of the cover 300 against the wall of the vessel 6. In most variation, expansion of the cover 300 provides sufficient friction against the walls of the vessel to overcome column strength of the cover walls 306 allowing for everting of the cover walls 306 over the retrieval structure 200 and obstruction 2 as discussed herein. As noted above, in alternate variations the cover 300 can expand a diameter or dimension that is equal to or less than the retrieval structure 200.

[0077] Figs. 4G illustrates proximal movement of the delivery wire 202, which causes proximal translation of the obstruction 2 and retrieval structure 200. Because the cover 300 is expanded against the walls of the vessel 6 the free end 304 of the cover 300 does not move or moves less than the fixed end 306 of the cover 300. The fixed end 306 moves with the obstruction 2 and retrieval structure 200 in a proximal direction causing the cover walls 306 to evert over the obstruction 2 and retrieval structure 200. Unlike a conventional funnel, the everting cover functions similar to a conveyor belt type movement as the obstruction and retrieval structure move together. This action allows for a passive type of protection since cover 300 does not need to be actuated over the obstruction 2 and retrieval structure 200 and can be performed in a quick manner by simply withdrawing the deployed retrieval device 100.

[0078] Fig. 4H illustrates a stage where the fixed end 306 of the cover 300 is now proximal to the free end 304. As shown, the everted cover 300 forms a protective sheath or cover over the obstruction 2 and the retrieval structure 200. Fig. 4H also illustrates how the cover 300 protects the obstruction 2 and retrieval structure 200 as they are pulled along the vessel and navigate the tortuous anatomy, walls of the vessel, as well as bifurcations 8. The cover 300

and cover wall 306 also protects the vasculature from the surface of the retrieval structure 200 and obstruction 2.

[0079] Fig. 4I shows the obstruction 2 and retrieval structure 200 protected by the cover 300 as the retrieval device 100 is positioned against or within the access catheter 108 in preparation for removal from the body. The retrieval device 100 can remain outside of the access catheter 108 as the physician removes both devices from the body. Alternatively, the cover 300 can assist in pulling the retrieval device 100 and obstruction 2 into the access catheter 108 by compressing the obstruction 2 as it is pulled into the access catheter 108.

[0080] Figs. 4J and 4K illustrate examples of an obstruction or other material 2 captured within a retrieval device 2 with a cover 300 further protecting the loaded retrieval device 200.

[0081] Figs. 5A to 5K show a variety of cover configurations. Fig. 5A illustrates a retrieval device 100 having a retrieval structure 200 adjacent to a double layer cover 300 with an exterior wall 306 and an interior wall 308.

[0082] Fig. 5B shows a cover 300 with a free end 304 that tapers down about the delivery wire 202 where the cover 300 will eventually form a double wall configuration when the cover 300 everts over the retrieval structure 200. The tapered free end 304 limits the cover 304 from moving once the retrieval structure 200 reaches the free end 304 thereby forming double wall protection over the retrieval structure 200.

[0083] Figs. 5C and 5D show how a fixed end 302 of a cover 300 can be pre-shaped to reduce the force required to evert the cover wall 306 or to lower the threshold to trigger passive covering of the retrieval structure by the cover.

[0084] Fig. 5E shows alternate variation of a passive cover 300 integrated into a retrieval device 100. In this variation, the retrieval device 100 includes a control shaft or wire 202 to manipulate the working end of the retrieval device 100. The cover 300 floats along the shaft 202 between two fixed anchors or nodes 220, 222. The cover 300 can float or slide between the fixed nodes 220, 222. The nodes 220, 222 can comprise radiopaque marker bands, glue joints, or any other mechanical obstructions capable of stopping the translation of cover 300. When the device 100 advances through a microcatheter, the rear or proximal node 220 limits rearward movement of the cover 300. When positioned appropriately, the microcatheter can be withdrawn to expose the retrieval device 200 and cover 300 as described herein. When the retrieval structure 200 engages the obstruction (not shown) the retrieval device 100 can be withdrawn by pulling on the delivery shaft 202. While this occurs, the cover 300, being expanded against the vessel remains stationary (or moves at a slower rate than the obstruction and retrieval structure 200 due to the friction against the vessel wall). The retrieval structure

200 and clot enter the cover 300, causing the distal node 222 to make contact with the near end 320 of the cover 300. This contact causes the retrieval structure 200 and cover 300 to translate as an integrated unit. It should be appreciated that the cover could be a single layer or double layer cover, and could have any of the wire design variables and termination variables described herein.

[0085] Fig. 5F illustrates a cover having a pre-set flattened cover wall 304 at a fixed end 302 that is spaced from a proximal end of the retrieval structure 200. Figs. 5G to 5I illustrate various layered covers 300. The layered covers allow for shortening the axial length of the cover and therefore shortens the required translation length. Layering of the cover wall 306 allows for a shortened deployed length of the cover 300 when deployed in the vessel or body structure. As the cover 300 everts over the retrieval structure 200 the layered wall 306 extends. As a result, shortening the length reduces the length that the cover 300 extends into the proximal vessels and reduces the length of that the retrieval structure 200 must travel to become protected by the cover 300. This also helps shorten the distance required to move the device 100 to complete eversion of the cover 300.

[0086] Fig. 5J shows a cover 300 that is constructed directly onto the retrieval structure 200 rather than the delivery shaft 202. This construction also assists in reducing the distance necessary to complete passive protection of the retrieval structure by the cover.

[0087] Fig. 5K show a variation of a cover 300 that is mounted in a distal direction over the retrieval device 200 and then everted in a proximal direction over the wires or shaft 202 as shown by arrows 230. Once everted, as shown by Fig. 5L, the device 100 is ready for deployment as discussed herein.

[0088] Figs. 6A to 6B illustrate a variation of a cover 350 for use as describe herein. Additionally, the cover 350 can be used with any obstruction retrieval device not limited to the retrieval baskets and stents described herein. The covers 350 disclosed herein can be used where the physician desires to shield the obstruction being removed from the frictional effects of the arteries or from the local anatomy (e.g., branching vessels, tortuous anatomy, or other substances on the vessel walls). In use, the covers can be sized for use with guide catheters, micro-catheters, and/or distal access catheters. The covers can include any number of radiopaque marker bands to allow non-invasive imaging of the device (see marker 390 affixed between cover 350 and shaft 212 in Fig. 7B as one example). In any case, once the retrieval device captures a clot or obstruction, as described above, the device and clot are protected by the cover so that the cover eliminates or reduces direct contact between the interior of the wall of the vessel and the clot.

[0089] Figs. 6A to 6C show a variation in which a cover is created from one or more mesh tubes 372. Fig. 6B illustrates inversion of the tube 372 so that a first end 374 is drawn over the tube 372 towards a second end 376. As shown in Fig. 6C, this creates a double walled cover having an exterior wall 378 separated from an interior wall 380. In one example, such a spacing or gap could range between 0.001 inches to 0.100 inches. However, any range is contemplated within alternative variations of the device. In some variations the inverted cover 350 is heat set to maintain a separation between layers or walls 378 380 of the cover 350. Typically, if the cover 350 is not created from a radiopaque material, a marker band will be placed on the proximal end 376 and adjacent to a shaft or catheter to which the cover 350 is attached. In some variations the construction of the mesh material is compliant to allow for movement of a first part of the mesh relative to a second part of the mesh through compression and expansion of the mesh material. In such a case, the individual strands forming the mesh are moveable relative to one another to cause the mesh to be naturally compliant. Accordingly, this construction permits the inner wall 380 to move or deflect with the retrieval device and/or obstruction as the device is withdrawn into the cover 350. In some variations, both ends of the mesh 374 and 376 are affixed to the catheter, shaft or wire.

[0090] In many variations, the cover mesh is selected to minimize friction when the interior layer 380 moves against the exterior layer 378. For example, the braid pattern, wire, wire diameter, angle of the braid and or other features can be selected to reduce friction between the outer layer 378 and inner layer 380. This permits the inner layer 380 to move proximally with a retrieval device while the outer layer remains stationary. Again, as discussed above, the construction of the mesh permits compression and expansion of the mesh layer to permit movement of the inner layer while the outer layer remains affixed when engaged against the vessel wall. In certain variations, the cover is heat set so that the inner layer has cushioning and the ability to deflect to assist in movement of the inner layer. Fig. 5C also illustrates a cover 350 having a tapered design.

[0091] Figs. 6D to 6L illustrate additional variations of cover construction to produce covers having more than two walls. For example, a mesh tube 372 is everted or drawn over a second end 376 in the direction 420. As shown in Fig. 6E this produces a dual layer cover having an open ends 422 and 424 and a folded end 426. The dual layer tube is then folded over again in the direction 420. This creates a cover construction with an exterior layer 378 and an interior layer 380 as well as a first intermediate layer 381 and a second intermediate layer 383. As shown in Fig. 6F, the cover can be set to assume the tapered shape having an opening at the

first end 374 that is flared with the ends of the mesh at the second end 372, which are ultimately affixed to a shaft, wire or other catheter device as described herein.

[0092] Fig. 6G illustrates another example of a cover construction. As shown, a first mesh tube 372 is placed coaxially with a second tube 372. The concentric tubes are then everted in direction 420 to produce a four layer cover. As shown in Fig. 6H, the cover can comprise an interior mesh layer 380, and exterior mesh layer 378 as well as any number of intermediate layers 381, 383 depending on the number of tubes that are initially used. The second end 372 of the cover 350 includes four unconnected ends of the mesh tubes that can be affixed to a shaft or tube as discussed herein, while the first end 374 of the cover 350 can be shape set to taper from the opening.

[0093] Figs. 6I to 6L illustrate another example of the construction of a multi-wall cover. As shown in Fig. 6I, a first end 374 of a mesh tube 372 is everted over and beyond a second end 376 in direction 420 to produce the configuration of Fig. 6J. Next, the first end 374 is everted or folded back in direction 420 to produce the configuration of Fig. 6K. Finally, the first end 374 is folded again in direction 420 so that the ends 374 and 376 are even to produce the cover configuration shown in Fig. 6K. Again, one end of the cover 350 can be set to form the tapered shape while the other respective end can be affixed to a catheter or shaft.

[0094] Although the covers of the present disclosure are presented without additional structures, it should be noted that these covers are coupled with a shaft or other member so that the cover can be advanced within the target anatomy to assist in removal of a device, structure, or debris from the site.

[0095] Figs. 7A to 7C show additional variations of covers 350. Fig. 7A illustrates a cover in which the cover wall as defined by the inner layer 380 and outer layer 378 is set in a shape that varies along a length of the cover. For example, the end adjacent to the cover opening 382 can be set to a bulbous shape. Such a configuration assists in maintaining separation of layers 378 and 380, which aids in re-entry of the retrieval device. Additional configurations of cover walls that vary in thickness are within the scope of this disclosure.

[0096] One of the benefits of using a cover 350 as described herein is that the cover reduces flow through the vessel when deployed so that the retrieval device can remove the obstruction without the full force of the flow of blood opposing the obstruction. Typically, conventional devices relied upon the use of an inflated balloon to obstruct flow. However, use of a cover eliminates the need for total occlusion of blood flow. Fig. 7B illustrates a further improvement on a cover 350 that aids in flow reduction. As shown, the cover 350 includes a dense region 386 and a relatively less dense region 384. This configuration permits greater

blood flow through the region 385 while region 386 reduces or prevents blood flow. Furthermore, the distal section of the cover is more flexible and conformable. Additional mesh layers can be added to any of the cover designs to alter flow characteristics or even provide reinforcement to the cover. Alternatively, or in combination, the braid density can be altered to adjust the porosity of the braid at different sections. Furthermore, additional braid layers can also be used to affect porosity of portions of the cover or even the entire cover. Deployment of a cover can reduce blood flow by 30% to 40%. Adding additional layers or coatings can additionally reduce flow.

[0097] Fig. 7C shows another variation of a cover 350 in which the mesh partially or totally is obscured using a polymeric coating 388 that reduces the permeability of the mesh design. Furthermore, drugs or other substances can be placed within the cover wall of any of the covers or can be deposited on the cover using the polymeric coatings. In some examples, the covers described herein can range from a length of 10 mm up to 50 mm. The OD at the opening of the cover can range from 7 mm and could range between 4 mm to 10 mm. Again, any range of dimensions is contemplated within the disclosure.

[0098] The covers described herein can further be stacked on a device. For example, two or more covers can be placed on a device to provide added protection.

[0099] The cover/reentry devices described herein can be constructed of any material currently used in vascular applications, including those discussed above. Furthermore, fabrication of the cover from a DFT material can provide additional benefits as the entire cover remains radiopaque and can be imaged non-invasively. Furthermore, the covers can be provided with any type of medicament or bioactive substance either in a polymer that coats the mesh or in a delivery agent within the mesh or between layers. Such substances include tpa, urokinase, IIb/IIIa inhibitors, and other clot disruptors or inhibitors.

[0100] Fig. 8 illustrates another variation of a retrieval device 400 including a distal capture portion 426 coupled to one or more leading wires in the form of a main bundle 402. The main bundle extends through a sheath 106 that includes a proximal capture portion 460. The configuration of the retrieval device 400 can incorporate the proximal and distal capture portions discussed herein as well as various other configurations discussed in the commonly assigned patent applications noted above.

[0101] An end 464 of the proximal capture portion 460 is affixed to a distal end of the sheath 106. However, as noted above, other variations are within the scope of the disclosure. The main bundle 402 can optionally terminate at a handle 442. As noted above, in certain variations, the main bundle is joined to a stiffer wire or stiffer bundle of wires. This allows

the device **400** to have a very flexible distal section with a relatively stiffer proximal section. The device **400** can have a proximal bundle **403** that comprises either the exposed wires or a covering/tube over the wires. In certain variations, the bundle or wire **402**, **403** can be encapsulated with a coating. The device also includes a cover **300** adjacent to the retrieval device.

[0102] The proximal end of the sheath **106** includes a sheath handle **444**. As discussed herein, axial movement of the bundle **402** or proximal bundle **403** (typically at the handle **442**) results in movement **126**, or translation of the bundle within the sheath **106**. This action moves the distal capture portion **426** (as shown by arrows **126**). In certain variations, the device **400** is loaded into a microcatheter (not shown but discussed above) that is delivered to the site of the obstruction and crosses the obstruction.

[0103] In some variations, the sheath hub **444** includes one or more locking hubs **446**. Where actuation (either axial or rotational) of the locking hub **446** locks the main bundle **402** relative to the sheath handle **444** and sheath **106**. It follows that such locking action also locks the distal capture portion **426** relative to the proximal capture portion **460**. A variety of methods can be employed to increase a frictional interference between the locking hub **446** and the proximal bundle **403**. As a result, when a physician determines a length of an obstruction, the physician can set a spacing between the capturing portions **426** **460** by locking the proximal bundle **403** relative to the sheath hub **444**. Accordingly, the proximal bundle **403** can include any type of incremental markings to allow the physician to readily determine a spacing of the capturing portions. As illustrated, the sheath hub **444** can include additional injection ports to deliver fluid or other substances through the sheath **106**.

[0104] As noted above, the device **400** can be used with a micro-catheter. In those variations it is important that the device **400** is loaded without damaging the distal bundle **402**, capture portions **426** **460**, and/or sheath **106**. As a result, the device **400** can include an optional cover **486** that reduces the proximal capture portion **460** (and /or the distal capture portion **426**) for loading within the microcatheter and/or sheath **106**.

[0105] Another variation of the device **400** includes an insertion tool **480** slidably affixed to the sheath **480**. Because variations of the device **400** can be extremely flexible, the insertion tool **480** can be used to provide column strength to the sheath **106**, bundle **402** or other components as the device **400** is pushed into the microcatheter. The insertion tool comprises a rigid section **482** and a frictional coupler **484**. The rigid section **282** has a column strength that supports the device **400** to prevent buckling. The frictional coupler **484** can be a flexible material that allows an operator to squeeze or grip the coupler **484** to create a temporary

frictional interface between the loading tool 480 and the device 400 (typically the sheath 106). Such an action allows axial advancement of the device 400 as the loading tool 480 is advanced into the microcatheter. Once the rigid section 482 is fully inserted into the microcatheter, the operator releases the frictional coupler 484 and can withdraw the loading tool 480 from the catheter without withdrawing the device 400. The insertion tool 480 can also include an optional loading tube 486 slidably coupled to the rigid section 482. When used, the cover 486 can withdraw the proximal and distal capturing portion 226 260 within the loading tube 486. The loading tube 486 then couples to a microcatheter allowing the capturing portions to advance therein as the rigid section 482 and frictional coupler 484 advance the device 400 relative to the loading tube 486.

[0106] Figs. 9A to 9C show cross sectional views taken along the line 9A-9A in Fig. 2A. As shown, the wire form construction described herein allows for a number of configurations depending on the particular application. For example, the individual wires 254 (as discussed herein) may themselves comprise a bundle of smaller wires or filaments. In addition, the wires can be selected from materials such as stainless steel, titanium, platinum, gold, iridium, tantalum, Nitinol, alloys, and/or polymeric strands. In addition, the wires used in a device may comprise a heterogeneous structure by using combinations of wires of different materials to produce a device having the particular desired properties. For example, one or more wires in the device may comprise a shape memory or superelastic alloy to impart predetermined shapes or resiliency to the device. In some variations, the mechanical properties of select wires can be altered. In such a case, the select wires can be treated to alter properties including: brittleness, ductility, elasticity, hardness, malleability, plasticity, strength, and toughness.

[0107] The device may include a number of radiopaque wires, such as gold and platinum for improved visibility under fluoroscopic imaging. In other words, any combination of materials may be incorporated into the device. In addition to the materials, the size of the wires may vary as needed. For example, the diameters of the wires may be the same or may vary as needed.

[0108] In addition, the individual wires may have cross-sectional shapes ranging from circular, oval, d-shaped, rectangular shape, etc. Fig. 9A illustrates one possible variation in which a number of circular wires 254 are included around another larger wire 256. Moreover, the device is not limited to having wires having the same cross-sectional shape or size. Instead, the device can have wires having different cross-sectional shapes. For example, as shown in Fig. 9B, one or more wires 256 can have a different cross-sectional shape or size

than a reminder of the wires 254. Clearly, any number of variations is within the scope of this disclosure. This construction can apply to the retrieval portion, capturing portion and/or the covering portion of the device.

[0109] To illustrate one such example, a device can have 8-12 wires made of .003" round superelastic material (e.g., Nitinol). The device may additionally have 2-4 wires made from .002" platinum for fluoroscopy. Of the 8-12 Nitinol wires, 1-4 of these wires can be made of a larger diameter or different cross-section to increase the overall strength of the device. Finally, a couple of polymer fibers can be added where the fibers have a desired surface property for clot adherence, etc. Such a combination of wires provides a composite device with properties not conventionally possible in view of other formation means (such as laser cutting or etching the shape from a tube or joining materials with welds, etc.). Clearly, any number of permutations is possible given the principles of the invention.

[0110] In another example, the device may be fabricated from wires formed from a polymeric material or composite blend of polymeric materials. The polymeric composite can be selected such that it is very floppy until it is exposed to either the body fluids and or some other delivered activator that causes the polymer to further polymerize or stiffen for strength. Various coatings could protect the polymer from further polymerizing before the device is properly placed. The coatings could provide a specific duration for placement (e.g., 5 minutes) after which the covering degrades or is activated with an agent (that doesn't affect the surrounding tissues) allowing the device to increase in stiffness so that it doesn't stretch as the thrombus is pulled out. For example, shape memory polymers would allow the device to increase in stiffness.

[0111] In another variation, one or more of the wires used in the device may comprise a Drawn Filled Tube (DFT) such as those provided by Fort Wayne Metals, Fort Wayne, Indiana. As shown in Fig. 9C, such a DFT wire 252 comprises a first material or shell 258 over a second material 260 having properties different from the outer shell. While a variety of materials can be used, one variation under the present devices includes a DFT wire having a superelastic (e.g., Nitinol) outer tube with a radiopaque material within the super-elastic outer shell. For example, the radiopaque material can include any commercially used radiopaque material, including but not limited to platinum, iridium, gold, tantalum, or similar alloy. One benefit of making a capturing portion from the DFT wire noted above, is that rather than having one or more markers over the capturing portion, the entire capturing portion can be fabricated from a super-elastic material while, at the same time, the super-elastic capturing portion is made radiopaque given the core of radiopaque material within the super-elastic

shell. Clearly, any composite DFT wire 252 can be incorporated into the system and capturing portions described herein.

[0112] Another aspect applicable to all variations of the devices is to configure the devices or portions thereof that engage the obstruction to improve adherence to the obstruction. One such mode includes the use of coatings that bond to certain clots (or other materials causing the obstruction.) For example, the wires may be coated with a hydrogel or adhesive that bonds to a thrombus. Accordingly, as the device secures about a clot, the combination of the additive and the mechanical structure of the device may improve the effectiveness of the device in removing the obstruction. Coatings may also be combined with the capturing portions or catheter to improve the ability of the device to encapsulate and remove the obstruction (e.g., a hydrophilic coating).

[0113] Such improvements may also be mechanical or structural. Any portion of the capturing portion can have hooks, fibers, or barbs that grip into the obstruction as the device surrounds the obstruction. The hooks, fibers, or barbs 370 can be incorporated into any portion of the device. However, it will be important that such features do not hinder the ability of the practitioner to remove the device from the body.

[0114] In addition to additives, the device can be coupled to an RF or other power source (such as 14 or 16 in Fig. 1), to allow current, ultrasound or RF energy to transmit through the device and induce clotting or cause additional coagulation of a clot or other the obstruction.

[0115] Figs. 10A to 10E illustrate additional variations of covers 300 for use as described above. For example, as show in Fig. 10A, a cover 300 can comprise a single wire, coil, or laser cut tube 350. Alternatively, as shown in Fig. 10B, the cover 300 can comprises two or more 350, 352 wires or coils. Fig. 10C shows a cover 300 comprising a coil 350 inside a mesh structure 354. A variation of the device shown in Fig. 10C can include a compliant atraumatic mesh 354 that is radially supported by the coil (whether interior or exterior to the mesh). The coil 350 provides the outward force against the vessel. Fig. 10D illustrates a polymeric film or membrane 356 coupled to a coil 350. The polymeric film 356 can be permeable to fluid flow or impermeable. Fig. 10E illustrates a dual layer braid construction having an inner braid 358 and an outer braid 360. The braids can be constructed to have unique properties. For example, the inner braid 358 can be composed of fewer wires or larger diameter wires, such that it provides an expansion force against the vessel wall. The outer braid 360 can comprise a softer construction and increased compliance. Accordingly, it can be comprised of a number of smaller diameter wires having a denser pattern to provide increased surface area to protect the obstruction as it is removed from the body. Alternatively,

these two constructional elements (e.g., braids of varying diameters) can be combined into a single layer or even multiple layers for the cover.

[0116] Fig. 11A illustrates yet another variation of a device 100 having a retrieval structure 200 and cover 300 where the cover is simply fabricated from the same material as the retrieval structure so long as it functions as described herein. The variation can optionally include one or more barbs 370 to increase resistance against a vessel wall.

[0117] Fig. 11B and 11C illustrate a variation where the cover 300 comprises a balloon material. Fig. 11B illustrates the balloon cover 370 prior to deployment. Fig. 11C illustrates the balloon cover 370 once deployed.

[0118] The retrieval devices described herein can optionally comprise elongated stents 400 as shown in Figs. 12A to 12E. These stents 400 can include any number of features to better assist the stent 400 in becoming enmeshed into the obstruction. For example, Fig. 12A illustrates a variation of a stent 400 affixed to a shaft 412. As noted herein, the shaft 412 can include a lumen extending therethrough. Alternatively, the shaft 412 can include a solid member with the stent 400 affixed to a distal end thereof. The variation shown in Fig. 12A includes a stent where a distal end 414 that is "closed off" by intersecting elements or wires 402 403. Accordingly, any of the variations of the stents disclosed herein can include an open lumen type stent or a closed lumen type stent as shown in Fig. 12A. As noted herein, the wires forming the stent 400 can comprise a single wire that is wound from a first direction (e.g., from proximal to distal) and then wound back in a second direction (e.g., from distal to proximal).

[0119] Fig. 12A also illustrates a stent 400 comprised of twisted wires 402 or elements. For example, Fig. 12B shows a magnified view of the section 12B in Fig. 12A. As illustrated, the elements 402 403 are twisted to increase the surface area at the exterior perimeter of the stent 400. The twisting or spiraling of the elements 402 403 creates additional surface area to increase the ability of the stent 400 to capture debris, thrombus, foreign body, etc. as the stent is expanded against the debris. The twisting elements 402 403 can twist along the entire length of the stent 400 or along one or more portions of the stent. In certain variations, the twisting of the elements 402 403 is sufficiently loose such that as the stent expands into a clot or obstruction, the twisted pairs slightly separate to allow material to become trapped between the elements making up the pairs. The construction shown in Figs. 12A and 12B also provide an additional benefit to a retrieval stent. In the illustrated variation, the twisted or spiraling elements interlock with crossing elements to form intersections 405 that provided added radial expansive force. As shown, a first twisted element 407 passes in between elements 402 403 of

an intersecting element 409. When in an expanded state, the element on the interior of the intersection 405 (in this case element 403) provides an added outward radial force against the intersection 405. However, since the elements are not affixed but instead are slidable at the intersection 405, the force required to linearize and compress the stent 400 is reduced due to the fact that the intersections are not affixed but slidable over the adjacent elements. This reduced linearization force allows the stent to be compressed to a small diameter for positioning within a microcatheter but allow for a significant radial expansive force once removed from the microcatheter. This design allows for a reduction in radial force of the stent against the vessel wall when the stent is pulled and removed from the vessel. However, this design also provides a high degree of radial force due to the interweaving of elements when the stent is deployed in the vessel prior to withdrawal of the stent.

[0120] Figs. 12C to 12F illustrate another variation of types of stents 400 that have an irregular surface at an exterior of the stent 400 that is formed by an intersection of elements 402 403. The intersection or crossing of the elements forms a type of barb or knuckle 416 that creates an irregular surface on the exterior of the stent 400. Fig. 12C illustrates a variation of a stent 400 having a plurality of knuckles 52 that are radially spaced about an axis 390 of the stent 400. Fig. 12E shows another variation of a stent 400 with knuckles 416 aligned with an axis 390 of the stent 400 as shown in Fig. 12D. Although the figures show the axial and radial aligned knuckles 416 on separate devices, both types of knuckles 416 can be incorporated into a single stent structure. Varying the alignment of knuckles can permit increased radial force as the stent expands into the obstruction or increased flexibility as the stent navigates through tortuous anatomy.

[0121] Fig. 12G illustrates a proximal end of the stent structure 400 as shown, a plurality of elements 402 and 403 extend along the shaft 412 and diverge to form the fluid permeable closed proximal end of the stent structure 400. The elements 402 and 403 that extend along the shaft 412 can be covered by a sheath, tube, spiral cut tube, or any structure 418 that prevents separation of the elements 402 403. A variation of the stent structure 402 includes a construction where the elements 402 403 are not glued, welded, or have any similar type of joint in the distal portion 420 of the shaft 412. Instead, the joint 411 is located proximal to the distal section of the shaft 412 in an intermediate section 422. Because joints or other similar features reduce flexibility of the joined structure, positioning the joints 411 in a proximal area allows the the distal portion 420 of the shaft to remain flexible.

[0122] The methods described herein may also include treating the obstruction prior to attempting to remove the obstruction. Such a treatment can include applying a chemical or

pharmaceutical agent with the goal of making the occlusion shrink or to make it more rigid for easier removal. Such agents include, but are not limited to chemotherapy drugs, or solutions, a mild formalin, or aldehyde solution.

[0123] As for other details of the present invention, materials and manufacturing techniques may be employed as within the level of those with skill in the relevant art. The same may hold true with respect to method-based aspects of the invention in terms of additional acts that are commonly or logically employed. In addition, though the invention has been described in reference to several examples, optionally incorporating various features, the invention is not to be limited to that which is described or indicated as contemplated with respect to each variation of the invention.

[0124] Various changes may be made to the invention described and equivalents (whether recited herein or not included for the sake of some brevity) may be substituted without departing from the true spirit and scope of the invention. Also, any optional feature of the inventive variations may be set forth and claimed independently, or in combination with any one or more of the features described herein. Accordingly, the invention contemplates combinations of various aspects of the embodiments or combinations of the embodiments themselves, where possible. Reference to a singular item, includes the possibility that there are plural of the same items present. More specifically, as used herein and in the appended claims, the singular forms “a,” “and,” “said,” and “the” include plural references unless the context clearly dictates otherwise.

[0125] It is important to note that where possible, aspects of the various described embodiments, or the embodiments themselves can be combined. Where such combinations are intended to be within the scope of this disclosure.

CLAIMS

We claim

1. An interventional medical device for retrieving and securing an obstruction within a vessel lumen, the device comprising:
 - a shaft having a flexibility to navigate through tortuous anatomy, the shaft a distal portion and a proximal portion;
 - a capturing structure located at a distal portion of the shaft comprising a plurality of struts, the capturing structure having a reduced profile for positioning in or adjacent to the obstruction and an expanded profile, such that when expanded into the obstruction, the struts at least partially enmesh with the obstruction such that subsequent movement of the capturing structure permits dislocation of at least a portion of the obstruction from the lumen;
 - an eversible cover having a fixed section affixed relative to a proximal end of the capturing structure, a free section extending in a proximal direction from the fixed section and a cover wall extending from the fixed section to the free section, where the eversible cover is expandable, the eversible cover being axially compliant such that when the shaft is moved proximally within the lumen, the eversible cover everts over the capturing structure allowing for the free section of the cover to be distal to the fixed end of the capturing portion.
2. The medical device of claim 1, where the eversible cover, capturing structure, and shaft are a unitary structure.
3. The medical device of claim 1, where each wire located at an end of the free section loops back to the cover causing the wires at the end of the free section to be continuous.
4. The medical device of claim 1, where at least a portion of the cover wall adjacent to the distal end has a set shape that is everted upon expansion.
5. The medical device of claim 1, further comprising a catheter body, where in a delivery configuration, the shaft, capturing structure and eversible cover are located within the catheter body and where the capturing structure is advanceable in and out of a distal end of the catheter body.

6. The medical device of claim 1, where the eversible cover comprises a plurality of layers forming the cover wall.
7. The medical device of claim 1, where the free section of the eversible cover partially restricts about the shaft without being attached to the shaft.
8. The medical device of claim 1, where a portion of the cover wall extends distally beyond the fixed section when the eversible cover is expanded.
9. The medical device of claim 1, where the fixed section of the eversible cover comprises a pre-set shape to reduce a force required to evert the evertable cover.
10. The medical device of claim 1, where the cover wall is layered in an undulating pattern upon deployment.
11. The medical device of claim 1, where the capturing structure comprises an elongated stent structure.
12. The medical device of claim 1, where the capturing structure comprises a device selected from a group consisting of a filter, an artherectomy device, a rotational cutter, an aspiration device, stent based retrievers and retrieval baskets.
13. The medical device of claim 1, where the cover is self expanding.
14. The medical device of claim 1, where a portion of the cover at or adjacent to the distal opening comprises a bulbous shape.
15. The medical device of claim 1, where the cover comprises a first porous section having a first porosity and at least a second porous section having a second porosity, where the first and second porosity are different such that the ability of fluid to flow through the first porous section and second porous section differs.
16. The medical device of claim 15, where the first porous section comprises a first braid density and the second porous section comprises a second braid density.
17. The medical device of claim 15, where the first porous section comprises an additional braid layer.

18. The medical device of claim 15, where the first porous section prevents fluid from flowing therethrough.
19. The medical device of claim 15, where the first porous section is distal to the second porous section and where the first porosity is greater than the second porosity.
20. The medical device of claim 15, where the first porous section comprises a circumferential area of the cover.
21. The medical device of claim 1, further comprising at least one polymeric layer on or adjacent to a region of the cover.
22. The medical device of claim 21, further comprising at least one medicament on or in the polymeric layer.
23. The medical device of claim 1, further comprising at least one radiopaque marker on a distal end of the shaft.
24. The medical device of claim 1, where the cover comprises a mesh material
25. The medical device of claim 24, where the mesh material comprises a single continuous wire.
26. The medical device of claim 24, where at least a portion of the mesh material is fabricated from a drawn filled tube material.
27. The medical device of claim 24, where at least a portion of the mesh material is fabricated from a radiopaque material.
28. The medical device of claim 1, where the eversible cover comprises at least one wire coiled such that turns of the coil form the cover wall.
29. The medical device of claim 28, where the cover further comprises a braid adjacent to the coil.
30. The medical device of claim 28, where the cover further comprises a film coupled to the coil.

31. The medical device of claim 1, where the eversible cover comprises at least one barb or knuckle at an exterior surface of the cover wall.
32. The medical device of claim 1, where the eversible cover comprises an inner braided layer and an outer braided layer, where the outer braided layer is relatively more compliant than the inner braided layer.
33. A method of securing an obstruction within a vessel, the method comprising:
positioning a catheter within a vessel;
advancing a shaft having a retrieval device affixed thereto out of the catheter;
advancing an eversible cover out of the catheter such that a fixed end of the eversible cover is adjacent to a proximal end of the retrieval device and a free end of the eversible cover is moveable relative to the shaft and retrieval device;
expanding at least a portion of the eversible cover against a portion of a wall of the vessel;
manipulating the retrieval device to become at least partially enmeshed with the obstruction; and
proximally translating the shaft and retrieval device with at least a portion of the obstruction affixed thereto such that resistance of the eversible cover against the vessel resists movement of the eversible cover causing the free section of the eversible cover to evert over the proximally translated retrieval device.
34. The method of claim 33, further comprising further withdrawing the shaft from the vessel such that during withdrawal the eversible cover forms a protective barrier over the obstruction to lessen shearing forces caused by the vessel and reduce dislodging portions of the obstruction from the retrieval device.
35. A method of preparing a retrieval device comprising:
providing a retrieval device *having been previously removed from a body of a patient* where the retrieval device includes a protective cover where a fixed end of the protective cover is affixed adjacent to a proximal end of the retrieval device and where a free end is located distally to the fixed end covering the retrieval device and is moveable relative to the second end;
reversing the protective cover by moving the free end proximally of the fixed while the fixed end remains affixed adjacent to the proximal end of the retrieval device;

inserting the retrieval device and cover into a catheter where the free end of the cover is proximal to the fixed end of the cover and retrieval device such that upon deployment from the catheter, the free end of the cover deploys proximally to the fixed end of the cover.

36. A method of securing an obstruction within a vessel, the method comprising:
- advancing a shaft having a retrieval device affixed thereto to the obstruction;
 - advancing a protective device over the shaft, the protective device comprising a sheath having an eversible cover, where a fixed end of the eversible cover is affixed to a distal portion of the sheath and a free end of the eversible cover is located proximal to the fixed end;
 - positioning the fixed end of the eversible cover adjacent to the retrieval device and expanding at least a portion of the eversible cover against a portion of a wall of the vessel;
 - proximally translating the shaft and retrieval device with at least a portion of the obstruction affixed thereto such that resistance of the eversible cover against the vessel resists movement of the eversible cover causing the free section of the eversible cover to evert over the proximally translated retrieval device.
37. A medical device retrieval system for securing an obstruction within a vessel lumen and for use with a catheter configured to be navigated through the vasculature, the device comprising:
- an elongated stent comprising a plurality of struts, the stent being collapsible for positioning in the catheter during delivery and having an expanded profile such that when expanded the struts are configured to engage the obstruction;
 - a shaft fixedly attached to the elongated stent and having a flexibility to navigate through tortuous anatomy;
 - a fluid permeable cover having a distal end coupled to a proximal end of the elongated stent a cover wall defining a cavity and extending along the shaft, and a proximal end being moveable relative to the shaft, where the fluid permeable cover is collapsible for positioning in the catheter during delivery and is expandable upon deployment from the catheter such that a portion of the fluid permeable cover is expandable;
 - where the fluid permeable cover is axially pliable such that when the device is deployed in the vessel and frictional forces are applied against the fluid permeable cover, proximal movement of the shaft and elongated stent cause inversion of the fluid

permeable cover wall such that the fluid permeable cover wall everts over the elongated stent.

38. An interventional medical device for use with a catheter configured for delivery through vasculature and for securing an obstruction within a vessel lumen, the device comprising:

a shaft having a flexibility to navigate through tortuous anatomy, the shaft having a distal portion and a proximal portion;

a capturing device comprising a sidewall, the capturing device fixedly located at a distal portion of the shaft and having a reduced profile for positioning in the catheter and an expanded profile, such that upon deployment from the catheter, the capturing device expands to force a portion of the sidewall into the obstruction to at least partially attach to the obstruction;

a cover having a distal end coupled adjacent to a proximal end of the capturing structure, a proximal end and a cover wall extending therebetween, where the proximal end of the cover is slidable relative to the distal end, where the cover is expandable such that when located in the catheter the cover is in a reduced delivery state and upon advancement from the catheter the cover expands with the proximal end located proximally of the distal end, where the cover wall is compliant such that when deployed from the catheter and the shaft is pulled in a proximal direction frictional forces between the vessel and the cover wall or proximal end cause the cover to invert as the cover wall inverts over the capturing device to surround the capturing device.

39. An interventional medical device for securing a retrieval device having one or more obstructions located therein for removal from a body, the medical device comprising:

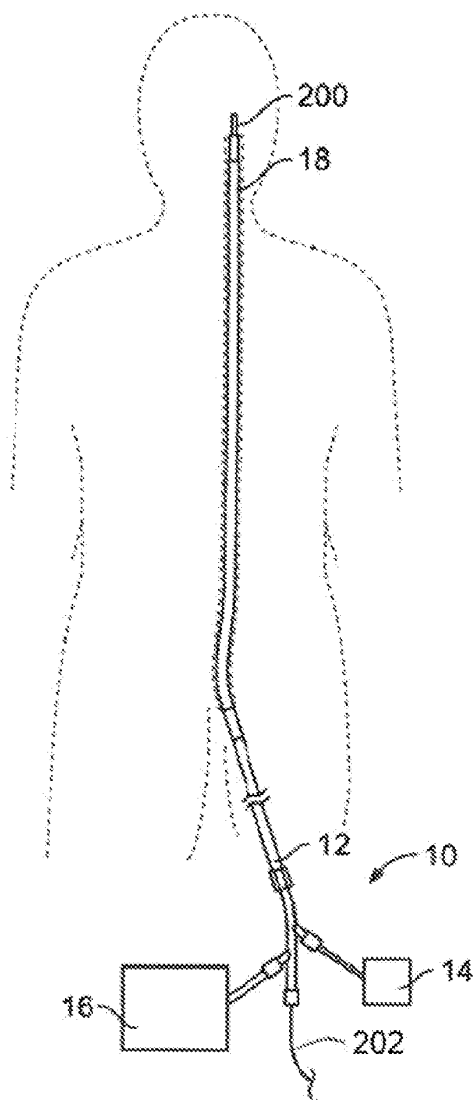
a sheath having a flexibility to navigate through tortuous anatomy, the sheath a distal portion and a proximal portion and a lumen extending therethrough;

an eversible cover having a fixed section affixed to the distal portion of the sheath, a free section extending in a proximal direction from the fixed section and a cover wall extending from the fixed section to the free section, where the eversible cover is expandable, the eversible cover being axially compliant such that when the retrieval device is positioned through the sheath lumen and moved in a proximal direction against the eversible cover, the eversible cover everts over the retrieval device allowing for the free section of the cover to be distal to the retrieval device.

40. A stent retrieval device for expanding against one or more occlusive bodies in a vasculature, the stent retrieval device comprising:
- an elongate shaft having a flexibility to navigate through tortuous anatomy, the elongate shaft having a distal portion and a proximal portion;
 - a plurality of filaments that diverge from the distal portion of the elongate shaft to form an expandable elongated stent body having an open distal end and a fluid permeable closed proximal end and a cavity therebetween, where divergence of the filaments at the distal portion of the elongate shaft forms the fluid permeable closed proximal end;
 - where the plurality of filaments extending along the shaft are free of any connection joints in the distal portion to permit increased flexibility of the distal portion as it navigates through tortuous anatomy; and
 - one or more connection joints proximal to the distal portion where the connection joints secure the plurality of filaments to the shaft.
41. The stent retrieval device of claim 40, wherein at least one of the plurality of filaments comprise at least two wires twisted together, the elongated stent body further comprising at least one intersection of filaments, where the wires of each filament are interwoven to provide increased outward radial strength of the elongated stent body and such that the wires slide relative to each other as the elongated stent body expands or compresses in diameter to reduce a force required to linearize the elongated stent body.
42. The stent retrieval device of claim 40, where the exterior surface of the elongated stent body comprises an irregular surface formed by intersection of filaments.
43. The stent retrieval device of claim 42, where the intersection of filaments comprises a barb or knuckle and where a plurality of barbs or knuckles are radially spaced about the elongated stent body.
44. The stent retrieval device of claim 42, where the intersection of filaments comprises a barb or knuckle and where a plurality of barbs or knuckles are aligned with an axis of the elongated stent body.
45. The stent retrieval device of claim 42, where the elongated stent body comprises a plurality of barbs or knuckles radially spaced about the elongated stent body and a plurality of barbs or knuckles axially aligned with an axis of the elongated stent body.

46. The stent retrieval device of claim 40, where at least one filament comprises a drawn filled tube material.
47. The stent retrieval device of claim 40, where at least one filament comprises at least one wire comprised of a first material and at least a second wire comprised of at least a second material different from the first material.
48. The stent retrieval device of claim 40, where at least one filament comprises at least one wire comprised of a first material and at least a second filament having at least one wire comprised of at least a second material different from the first material.

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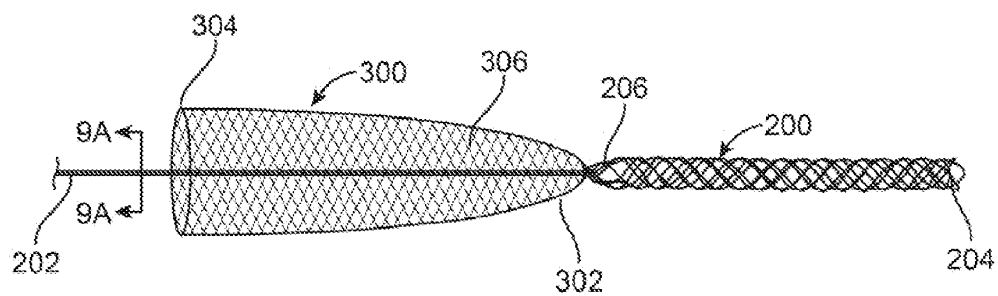


FIG. 2A

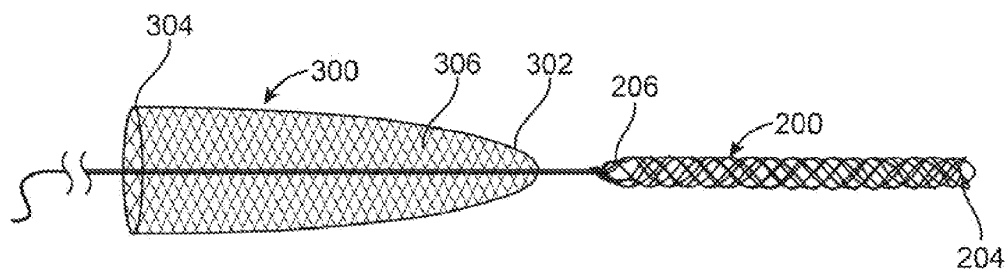


FIG. 2B

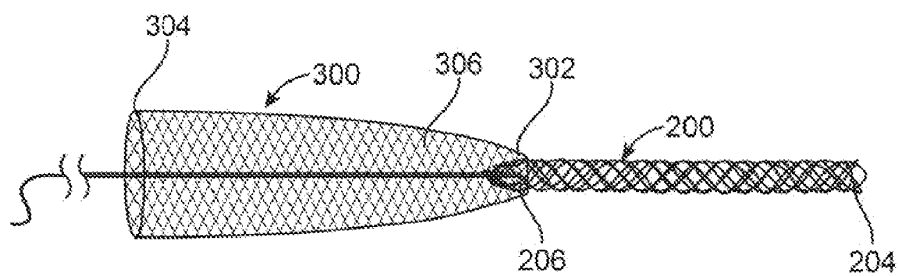


FIG. 2C

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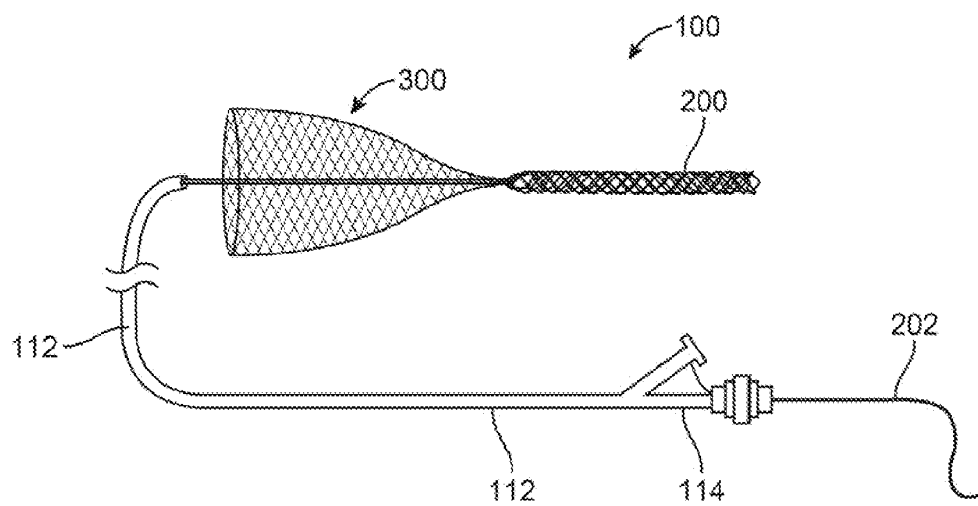


FIG. 2D

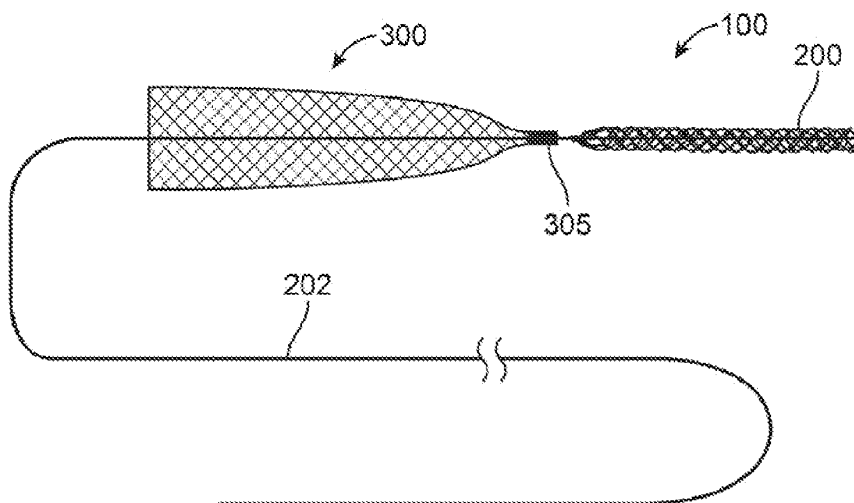


FIG. 2E

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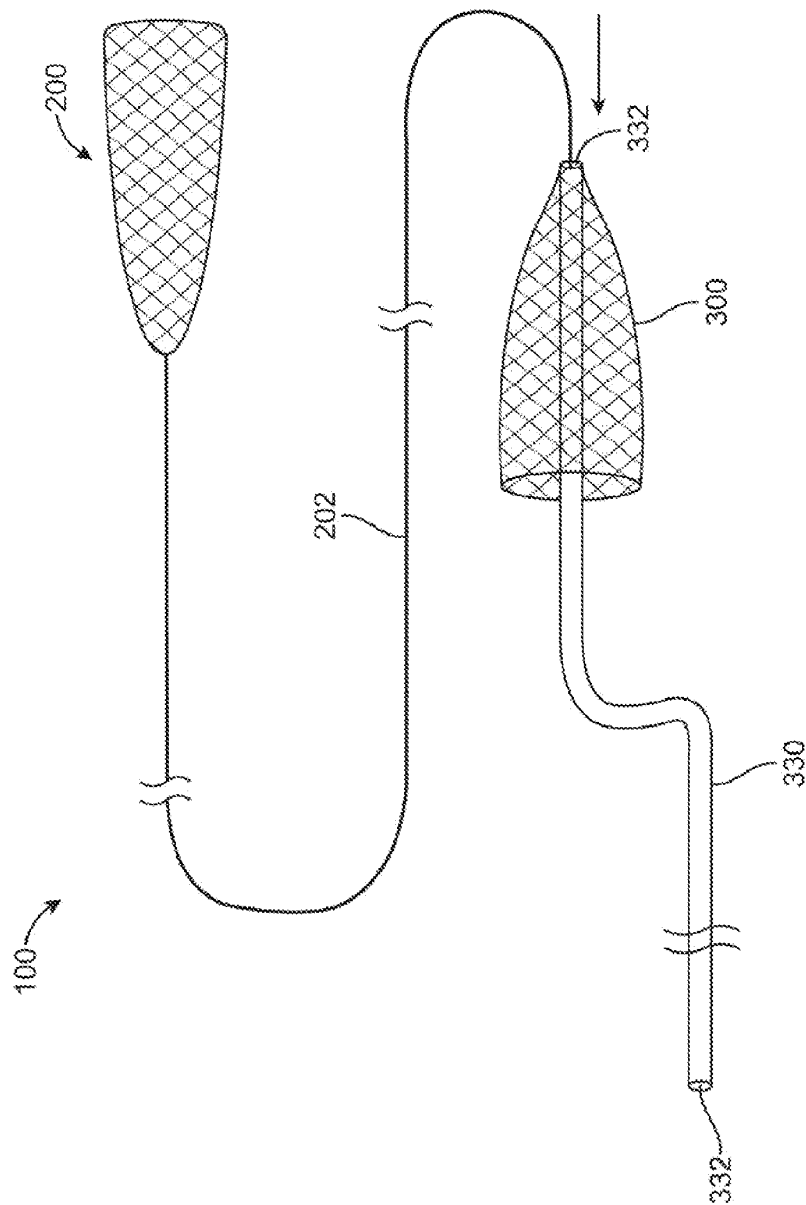


FIG. 2F

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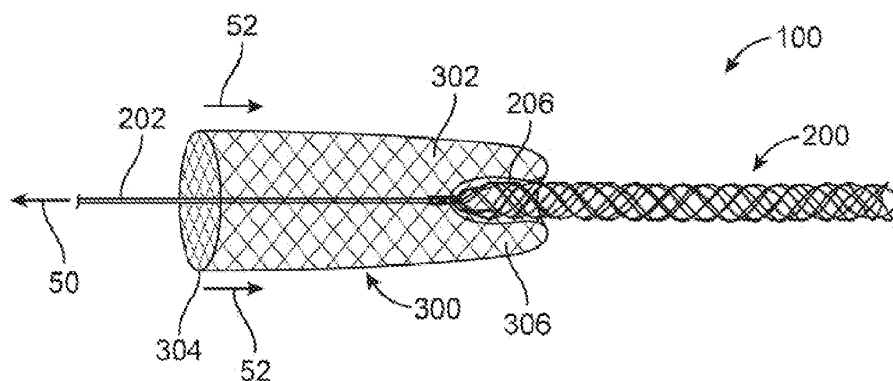


FIG. 3A

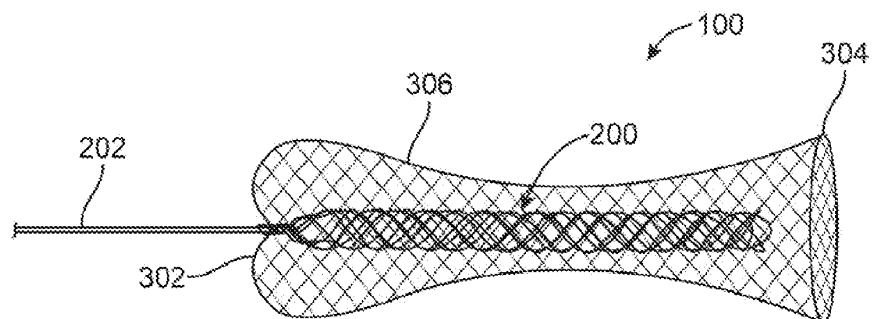


FIG. 3B

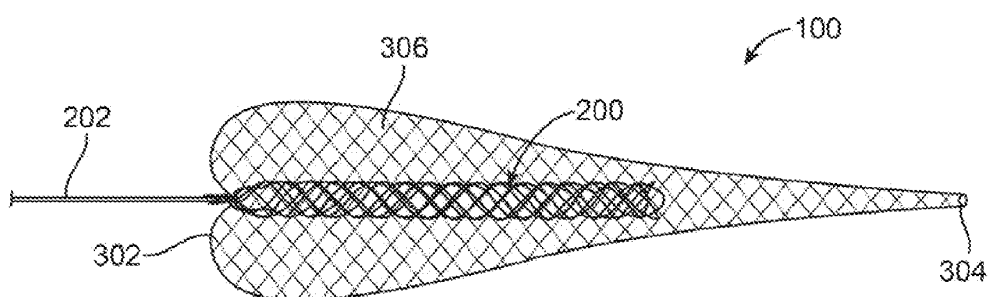


FIG. 3C

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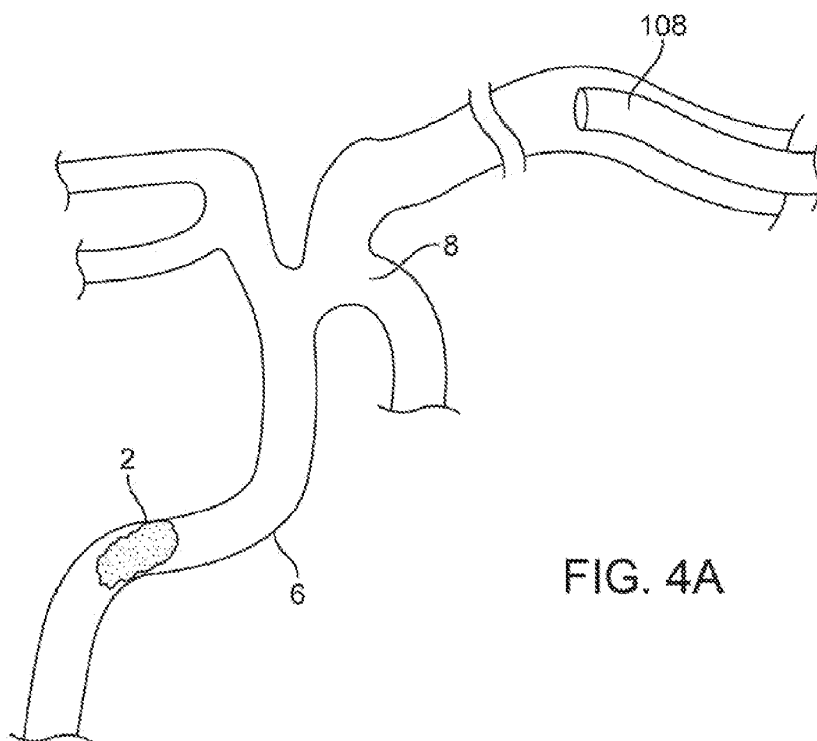


FIG. 4A

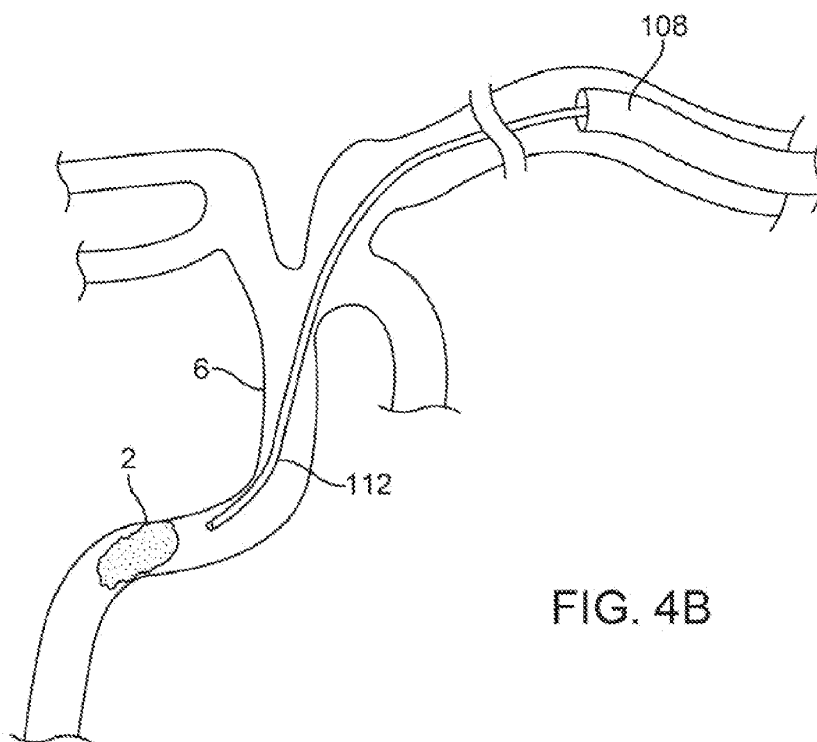
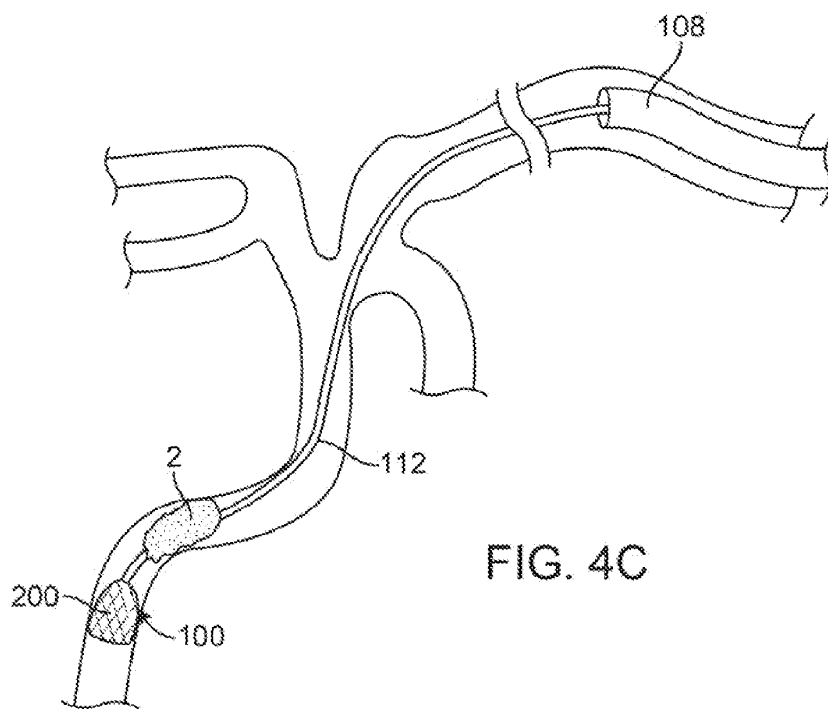
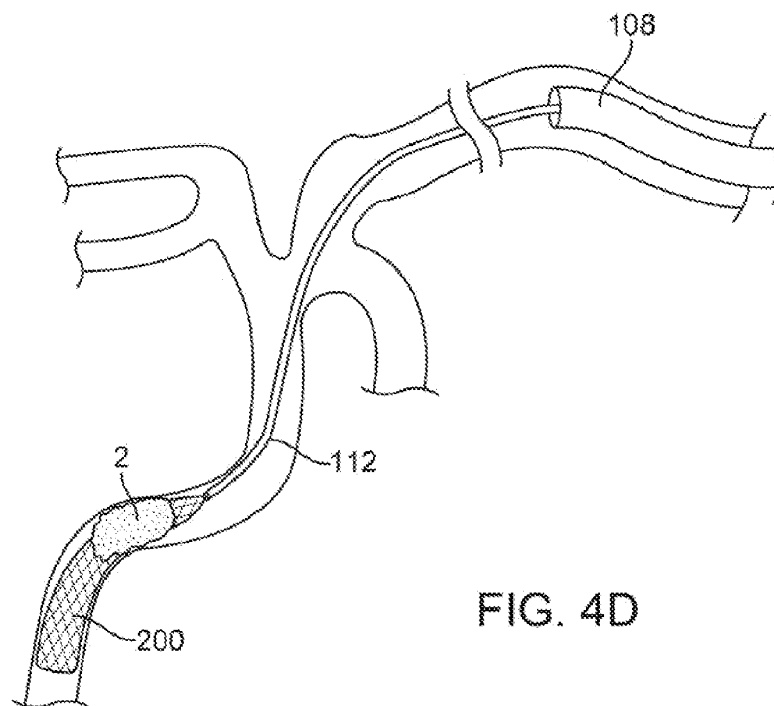


FIG. 4B

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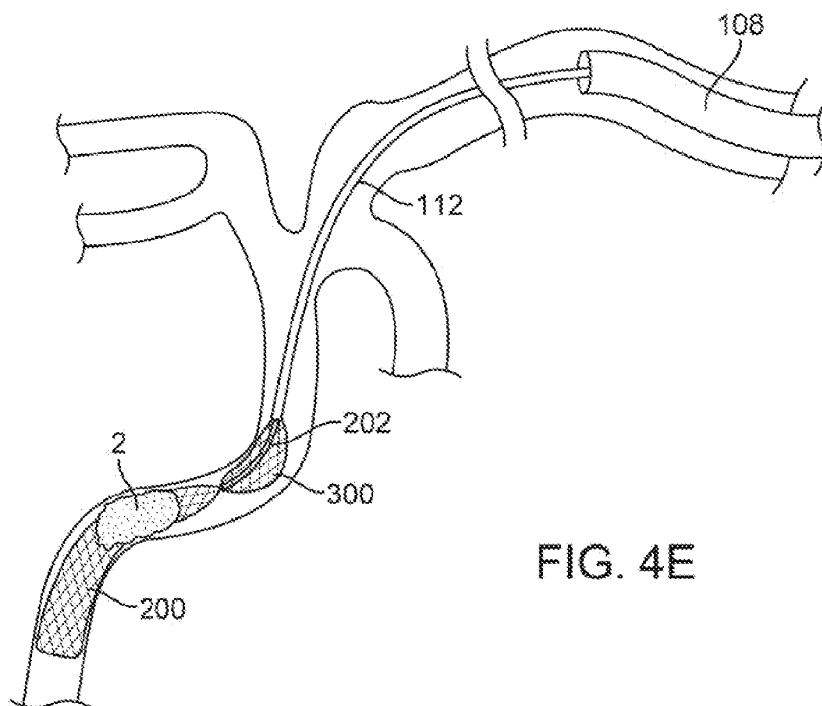


FIG. 4E

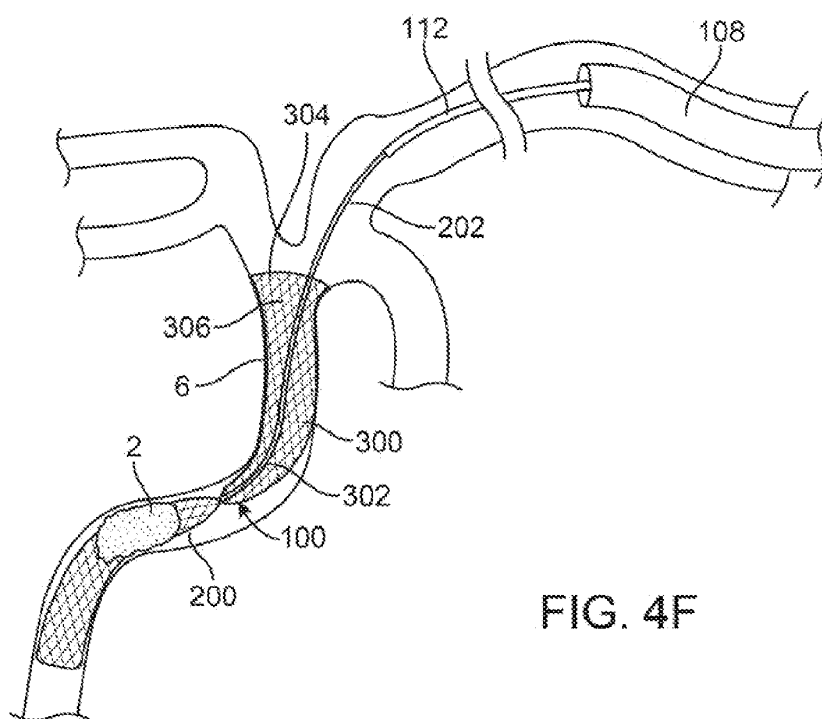


FIG. 4F

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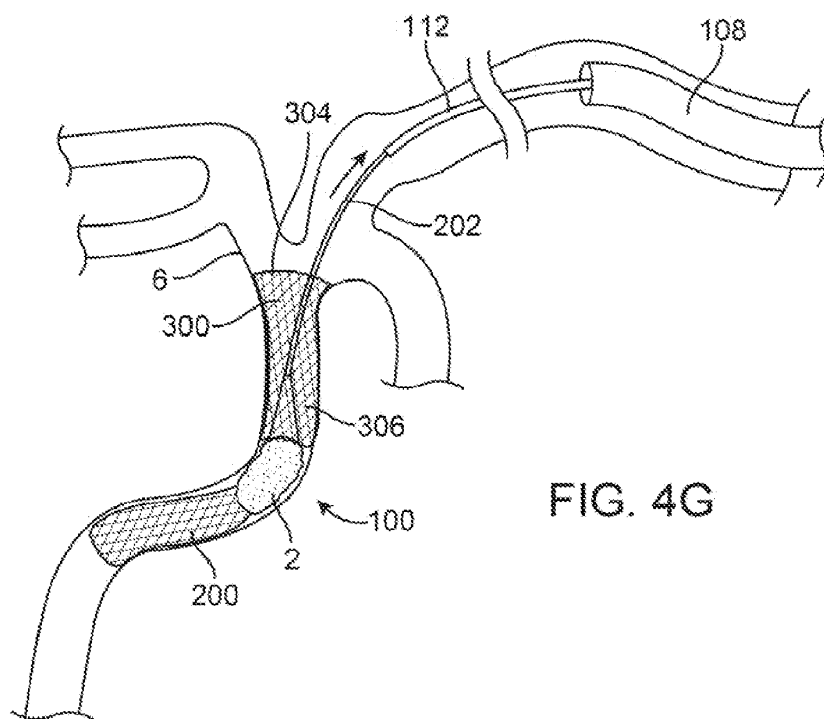


FIG. 4G

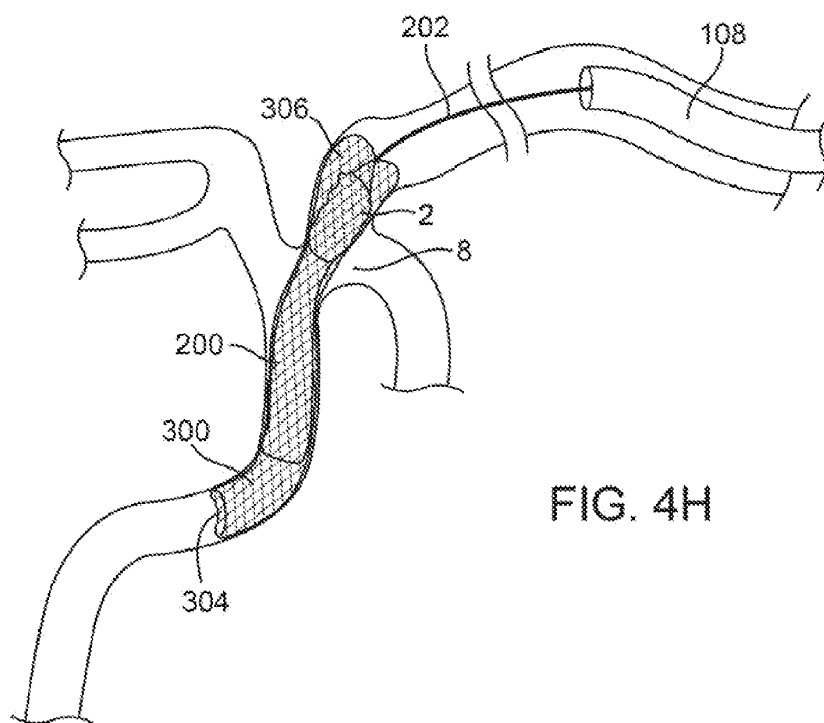


FIG. 4H

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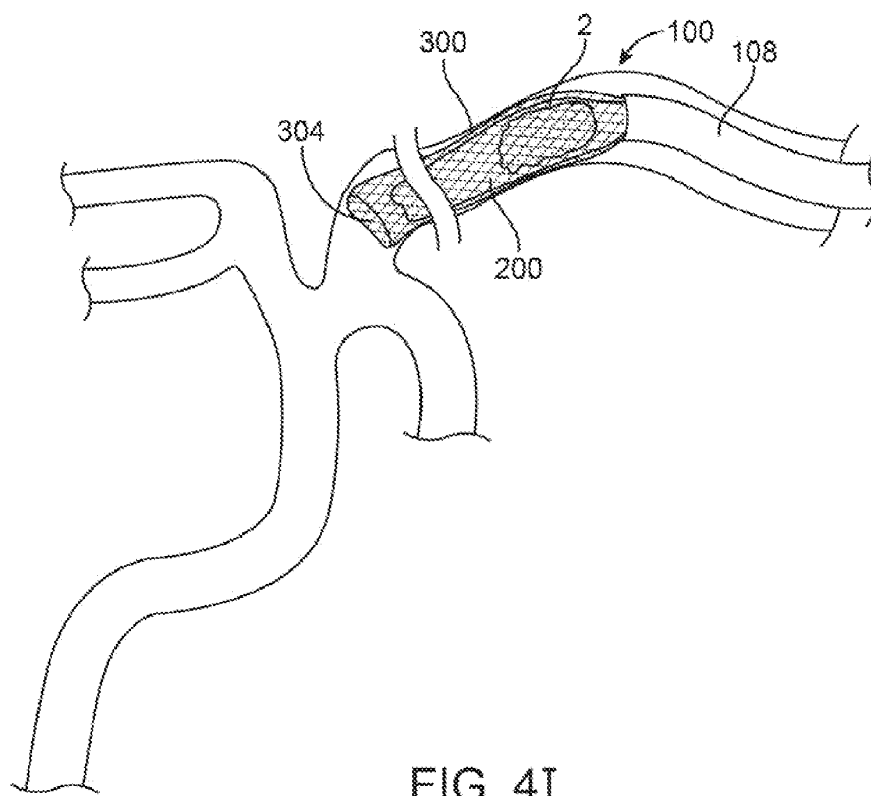


FIG. 4I

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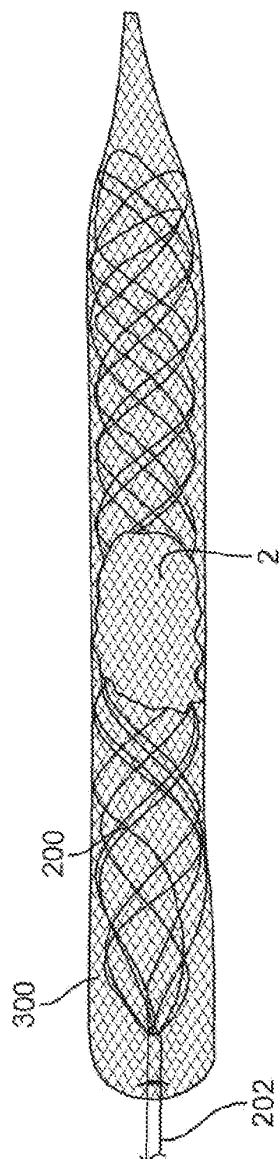


FIG. 4J

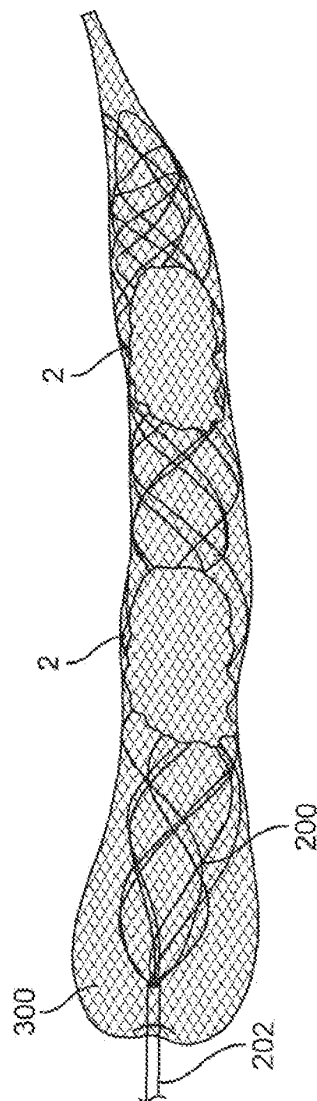


FIG. 4K

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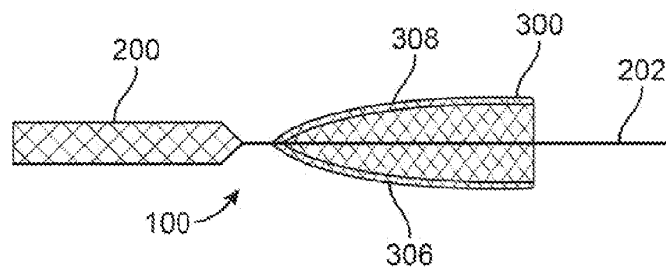


FIG. 5A

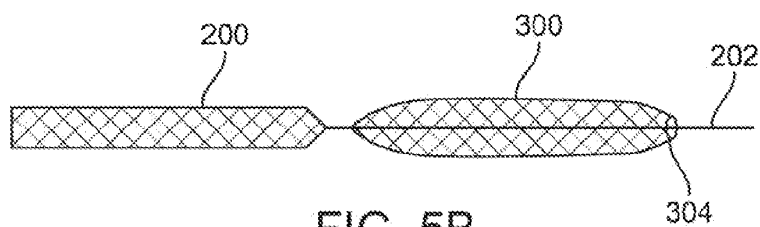


FIG. 5B

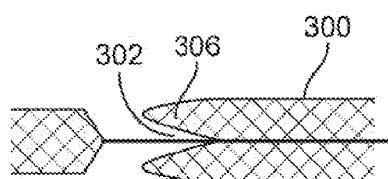


FIG. 5C

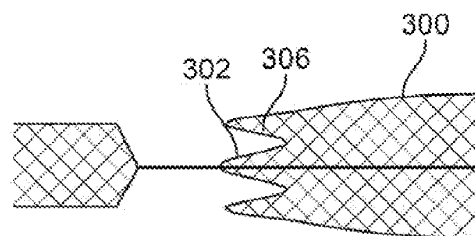


FIG. 5D

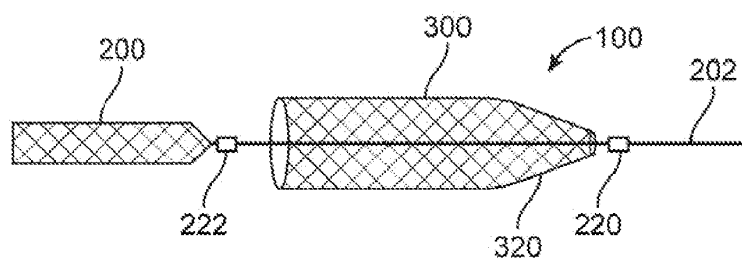


FIG. 5E

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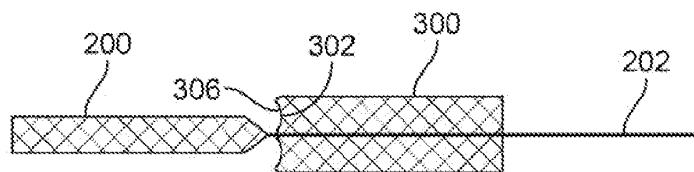


FIG. 5F

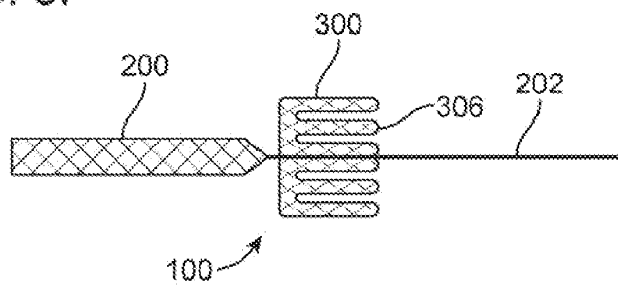


FIG. 5G

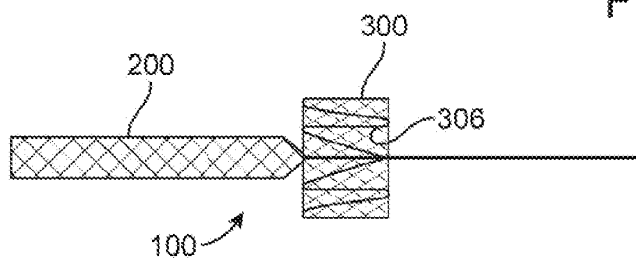


FIG. 5H

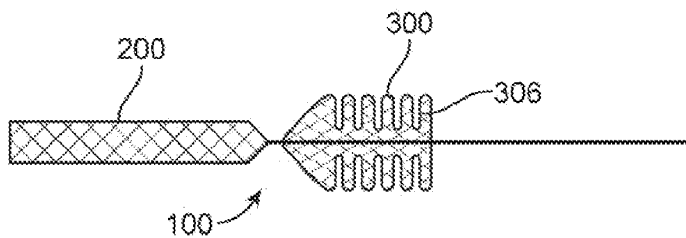


FIG. 5I

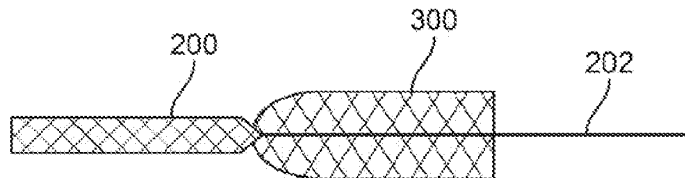


FIG. 5J

SUBSTITUTE SHEET (RULE 26)

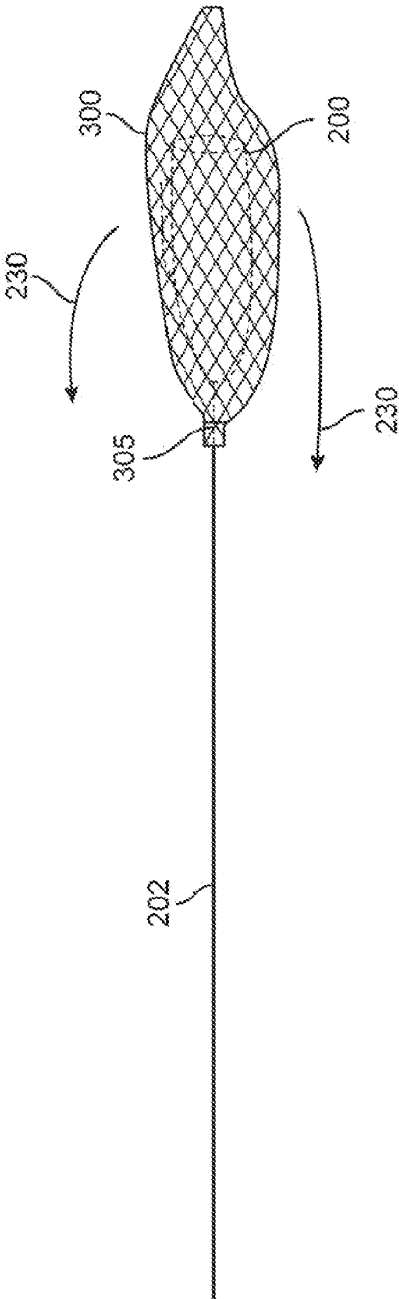


FIG. 5K

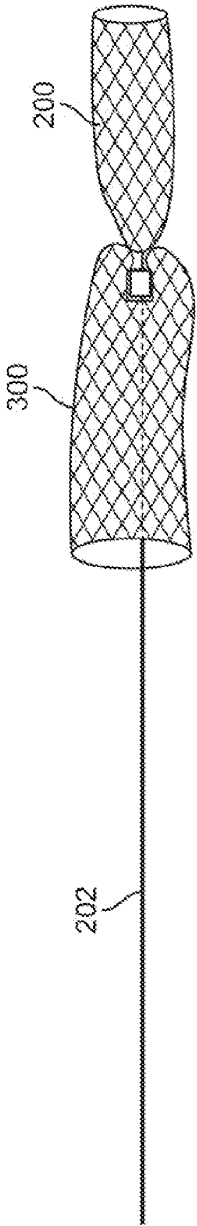


FIG. 5L

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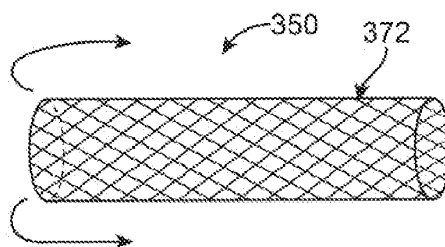


FIG. 6A

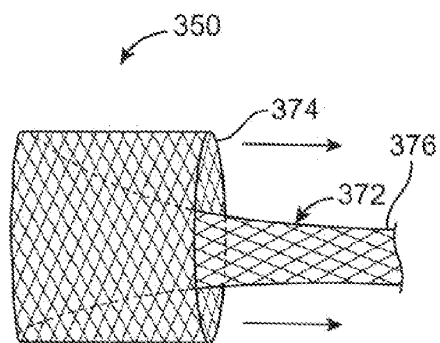


FIG. 6B

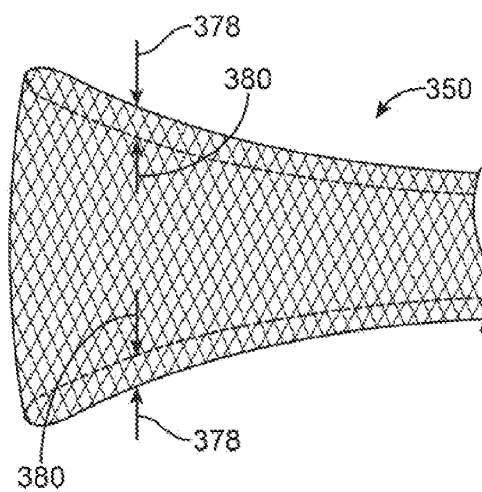
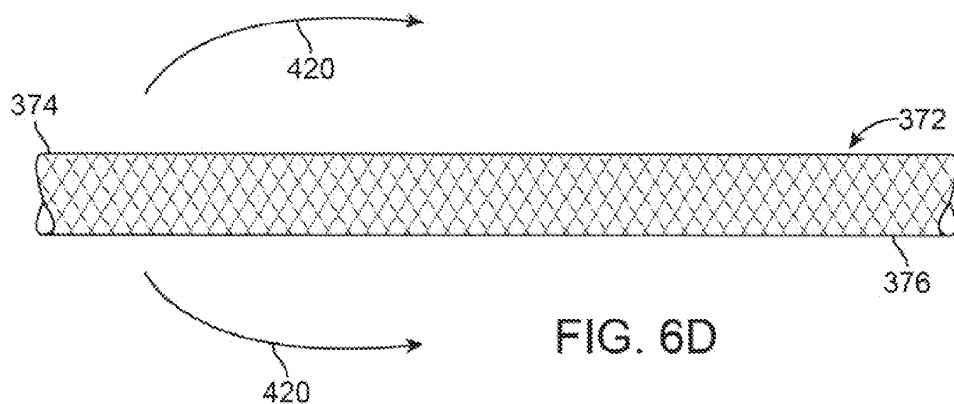
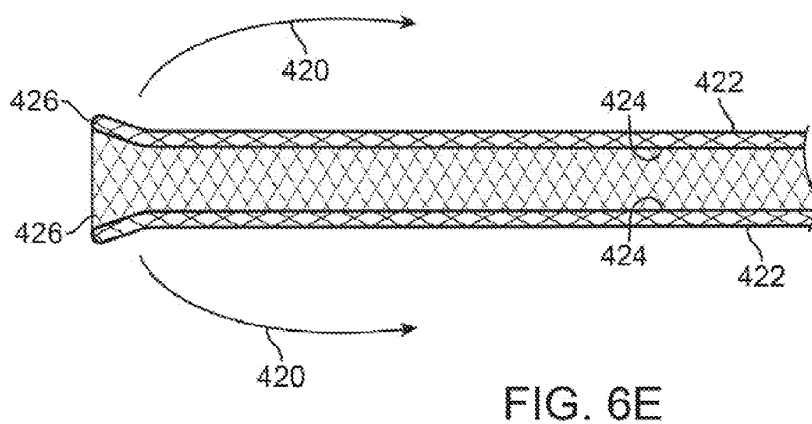
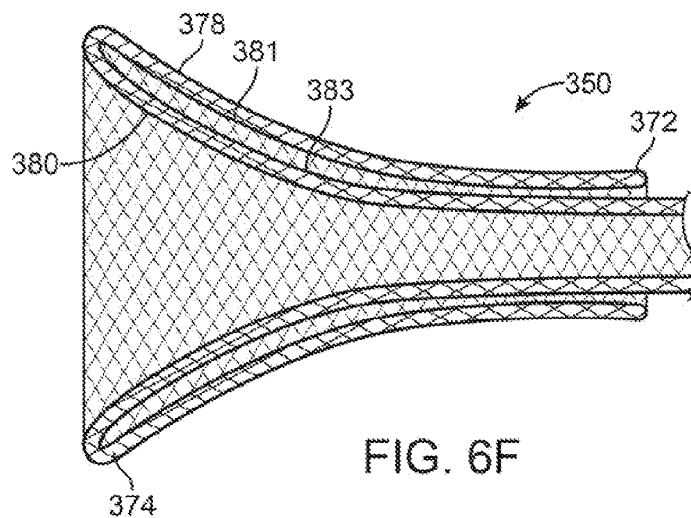


FIG. 6C

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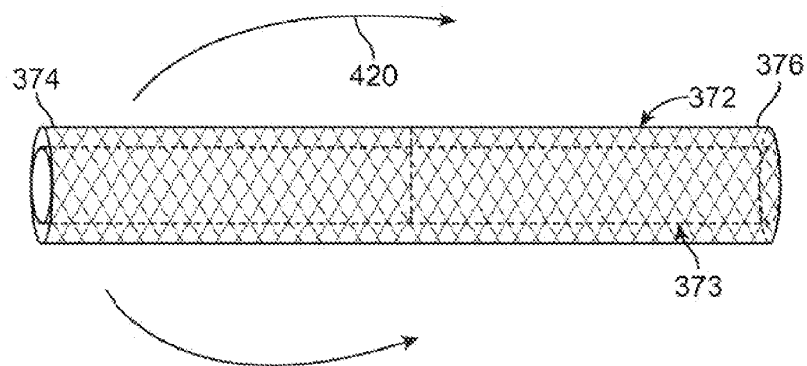


FIG. 6G

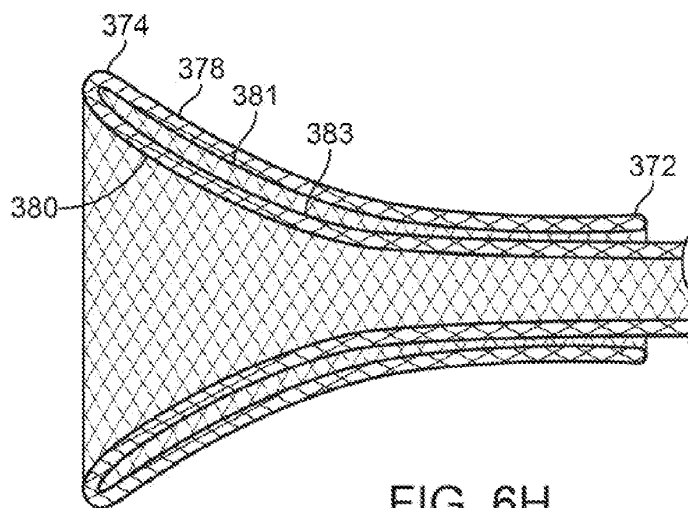


FIG. 6H

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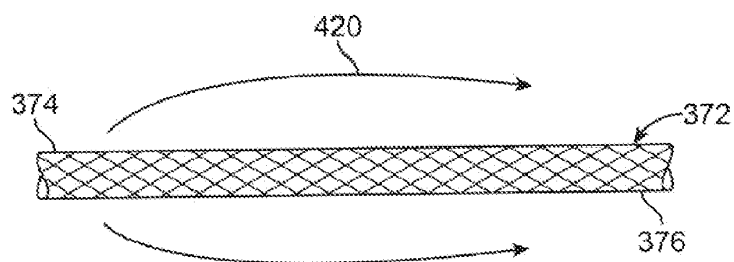


FIG. 6I

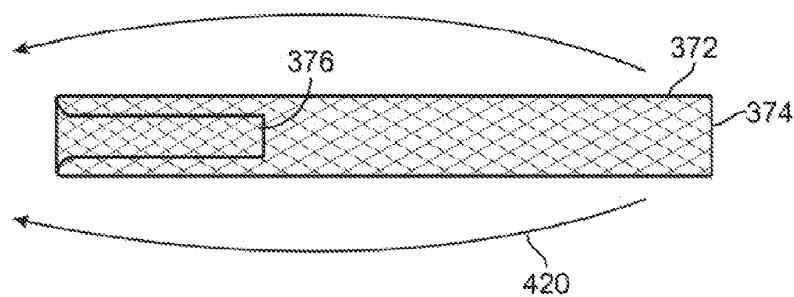


FIG. 6J

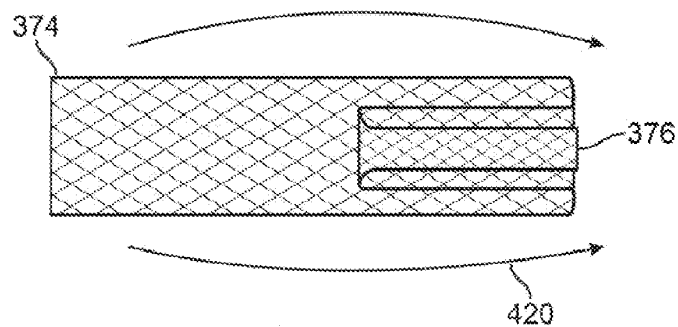


FIG. 6K

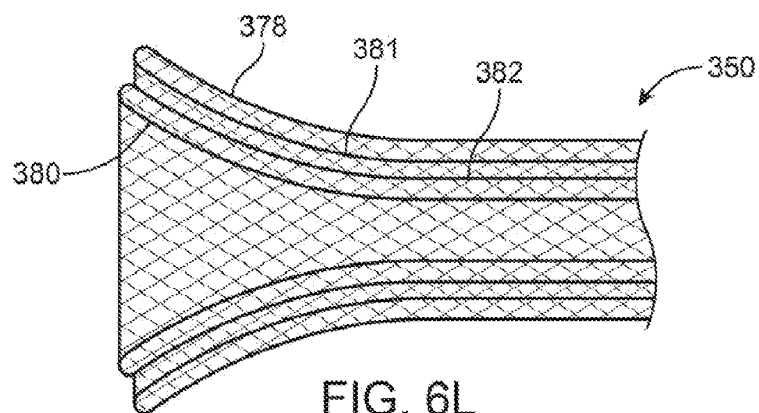


FIG. 6L

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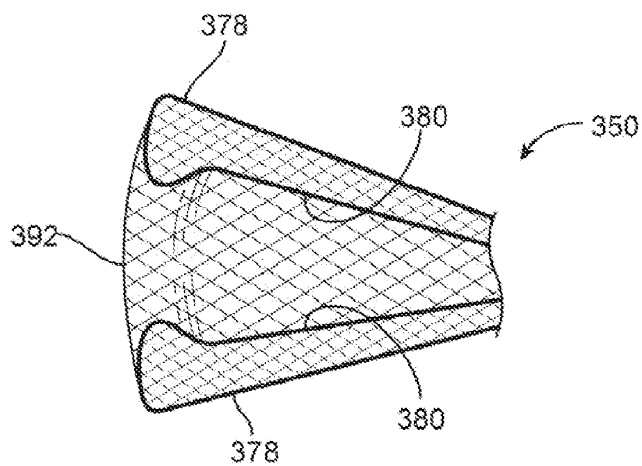


FIG. 7A

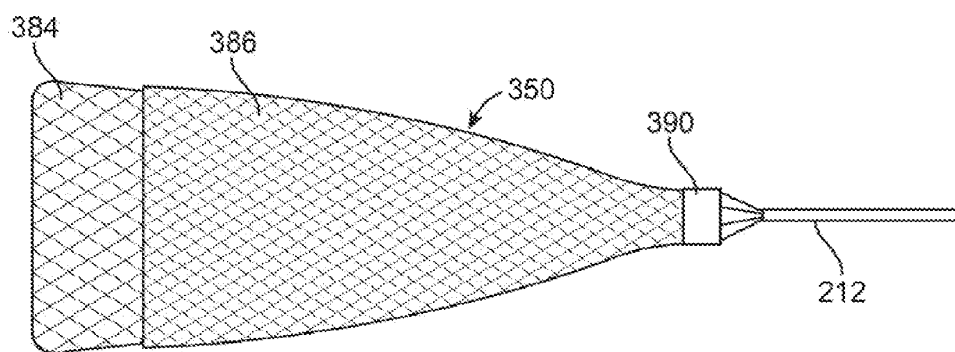


FIG. 7B

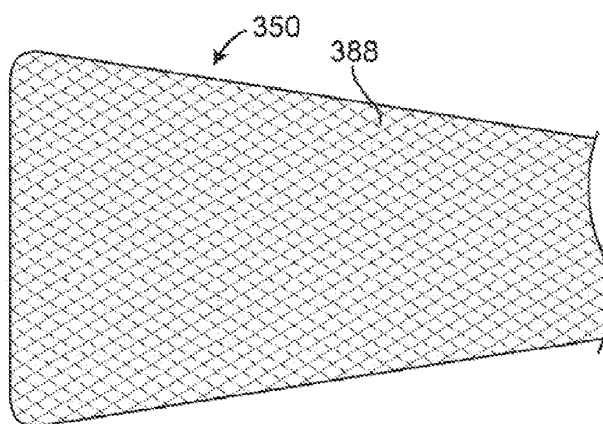


FIG. 7C

SUBSTITUTE SHEET (RULE 26)

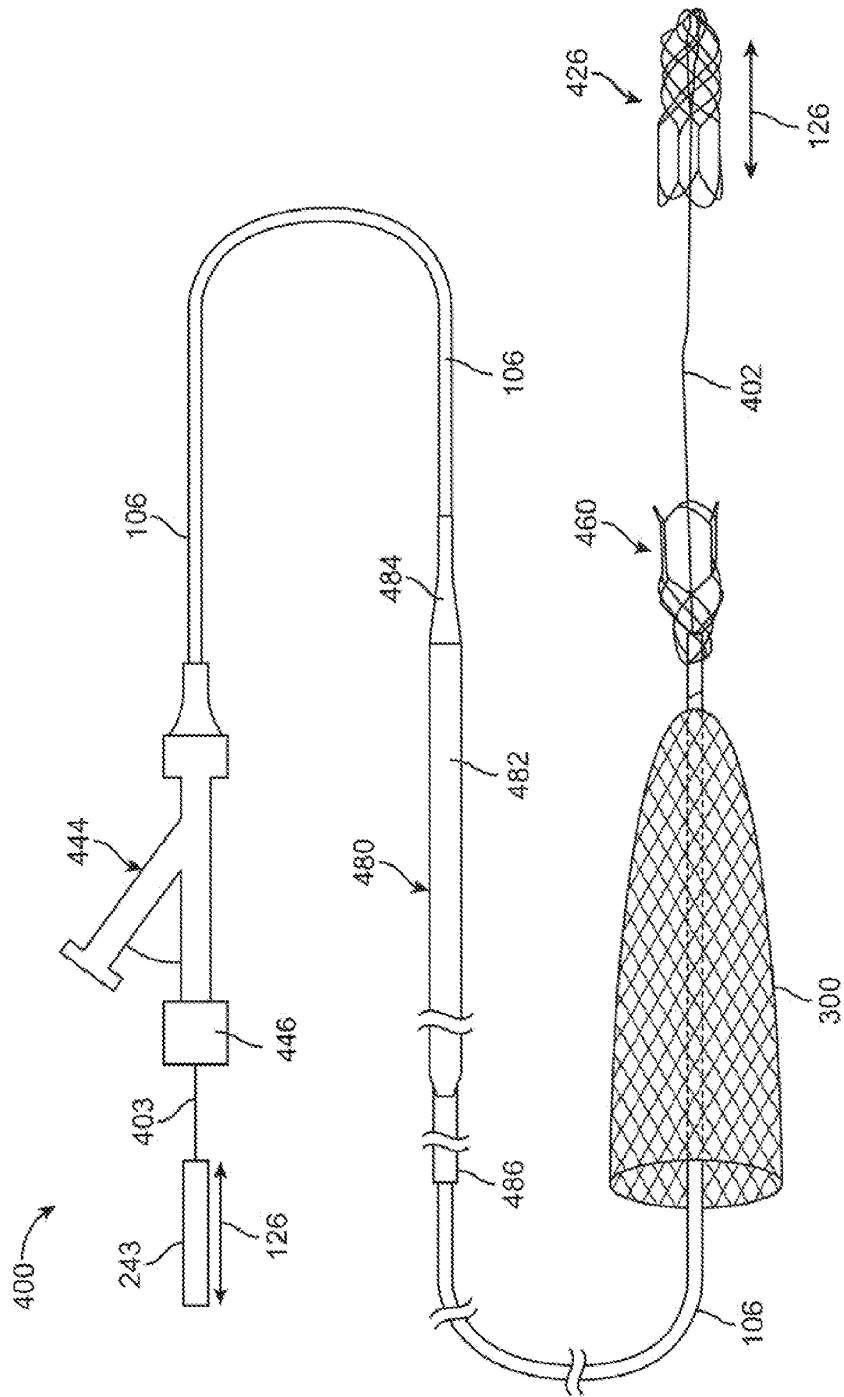


FIG. 8

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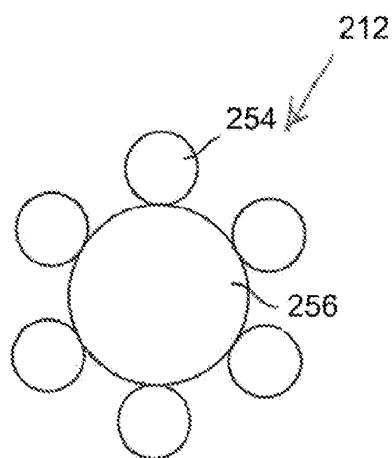


FIG. 9A

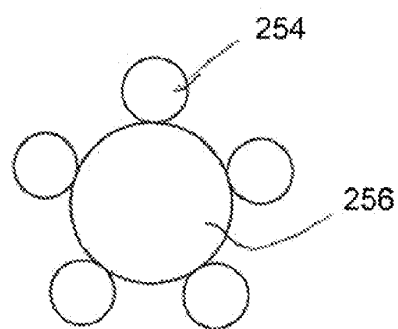


FIG. 9B

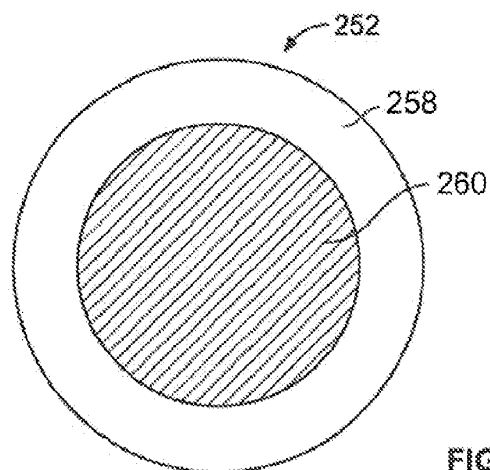


FIG. 9C

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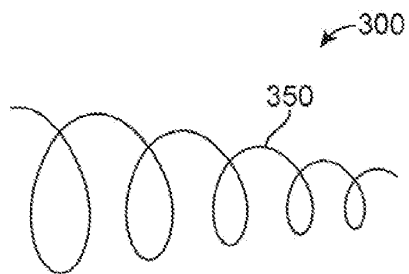


FIG. 10A

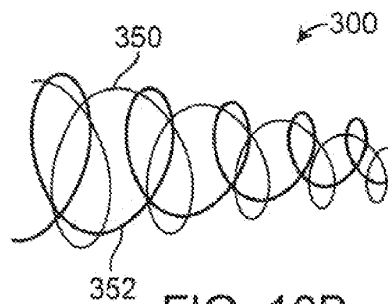


FIG. 10B

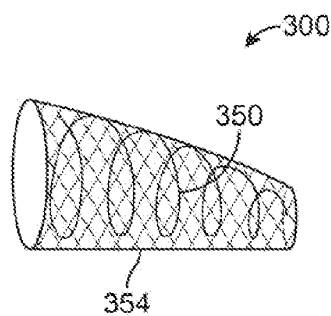


FIG. 10C

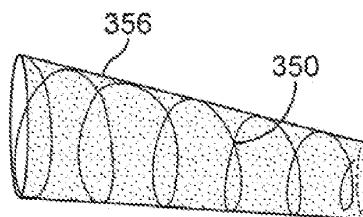


FIG. 10D

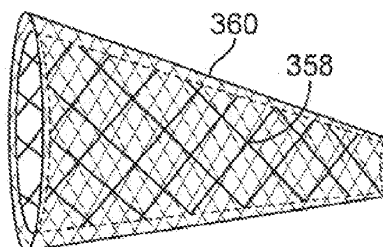


FIG. 10E

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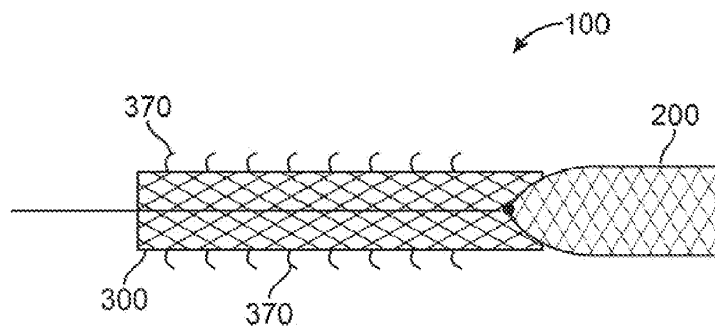


FIG. 11A

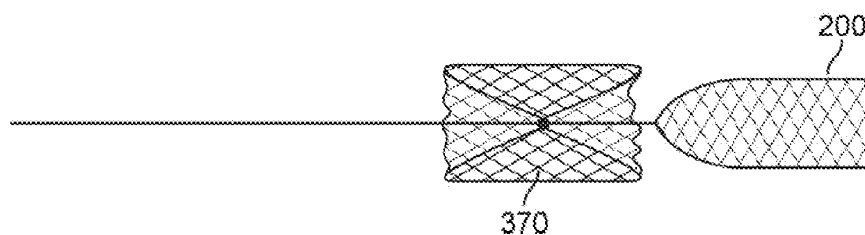


FIG. 11B

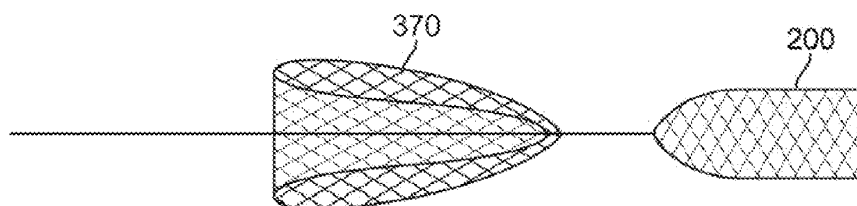


FIG. 11C

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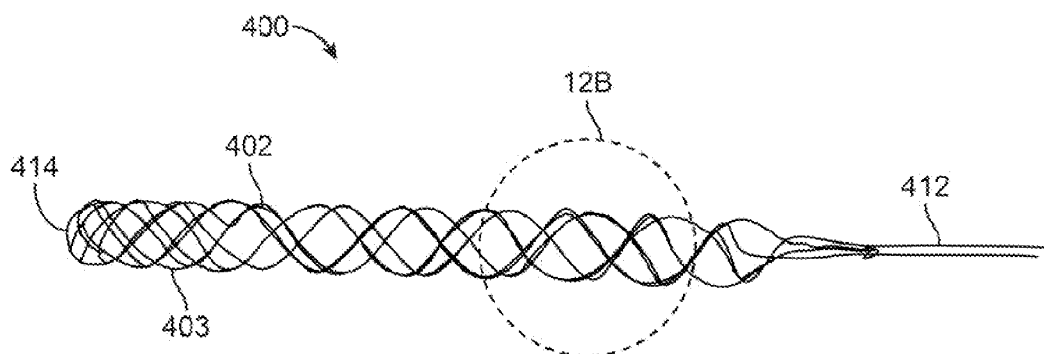


FIG. 12A

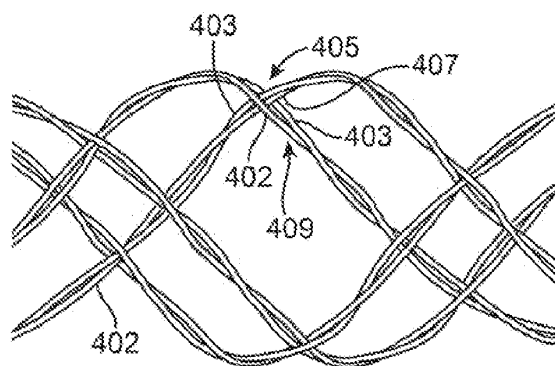


FIG. 12B

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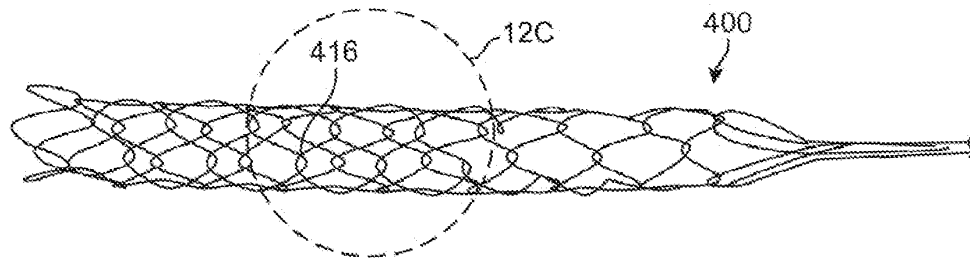


FIG. 12C

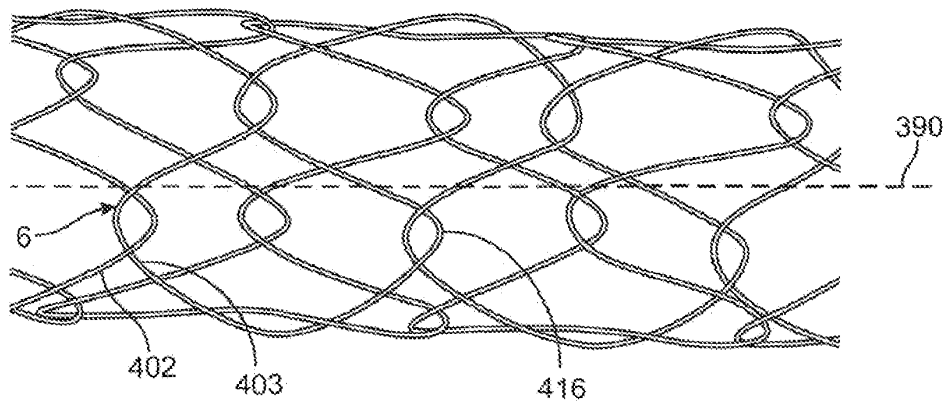


FIG. 12D

SUBSTITUTE SHEET (RULE 26)

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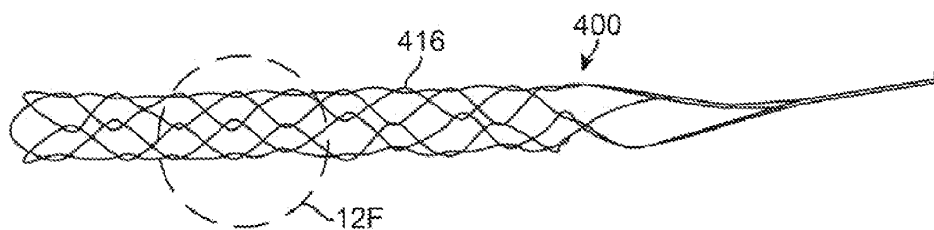


FIG. 12E

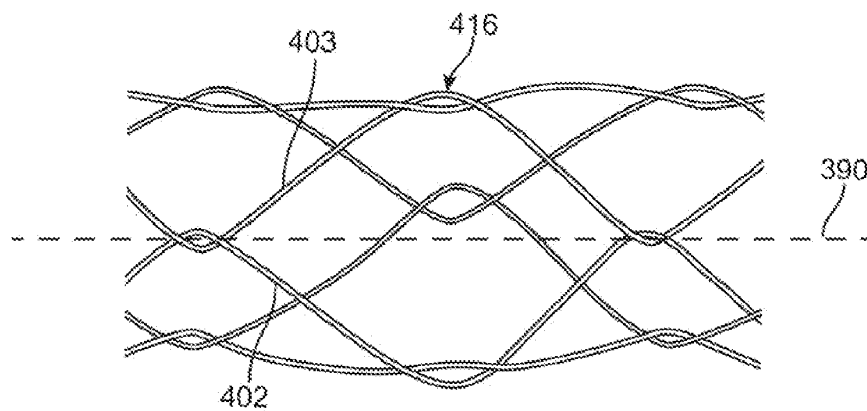


FIG. 12F

SUBSTITUTE SHEET (RULE 26)

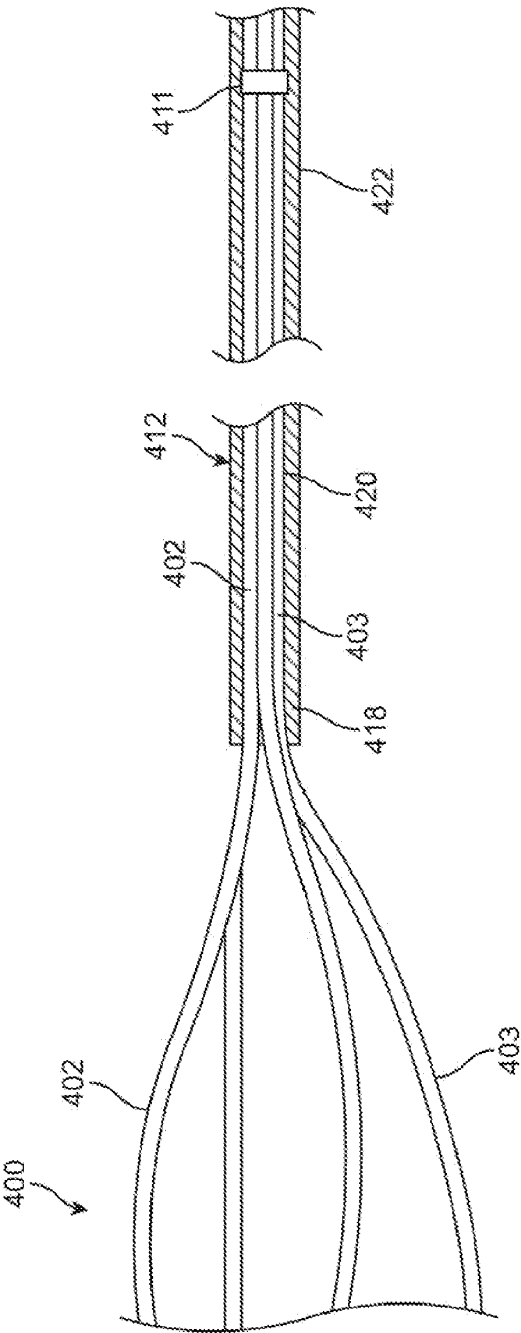


FIG. 12G

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 12/39216

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61B 17/22 (2012.01)

USPC - 606/159

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
USPC: 606/159

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
USPC: 606/170, 1, 180, 200 (keyword limited; terms below)

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

PubWEST(PGPB, USPT, EPAB, JPAB); Google

Search Terms Used: drug, medication, medicament, film, coat\$3, layer, inner, outer, braid\$3, polymer\$2, inver\$4, ever\$4, sheath, sleeve, cover, stent, strut, remov\$3, retriev\$3, radiopaque, plaque, obstruction, clot, thromb\$2, reus\$4, basket, reposition\$3, net\$4, web\$4

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X ----- Y	US 2009/0299393 A1 (MARTIN et al) 03 December 2009 (03.12.2009) fig 3H, 5B, para [0017], [0072]-[0073], [0108]-[0109], [0141]	40-48 ----- 3, 11-12, 25-26, 31, 33-34, 36-38
X	US 2005/0085826 A1 (NAIR et al.) 21 April 2005 (21.04.2005) Entire document, especially para[0034]- para[0039] and figs. 1, 4-9.	39
X ----- Y	US 2010/0076452 A1 (SEPETKA et al) 25 March 2010 (25.03.2010) fig 13, 14, 15, 16, 17, 18, 22, 26, 52, para [0089]-[0091], [0095], [0100], [0116]	1-2, 4-5, 7-8, 14, 23-24 ----- 3, 6, 9-13, 15-22, 25-34, 36-38
Y	US 2005/0283186 A1 (BERRADA et al) 22 December 2005 (22.12.2005) fig 3A, 3B, 20A, para [0081], [0128], [0142], [0149]	6, 9-10, 13, 15-22, 27-30, 32
Y	US 2005/0234505 A1 (DIAZ et al) 20 October 2005 (20.10.2005) para [0054]	35
Y	US 2009/0287291 A1 (BECKING et al) 21 April 2009 (21.04.2009) para [0095]	17, 32
Y	US 2010/0185210 A1 (HAUSER et al) 22 July 2010 (22.07.2010) para [0053]	22

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


* Special categories of cited documents:

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

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

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search

06 August 2012 (06.08.2012)

Date of mailing of the international search report

06 SEP 2012

Name and mailing address of the ISA/US

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Lee W. Young

PCT Helpdesk: 571-272-4300
PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (July 2009)

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(45) Date of publication and mention
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23.07.2003 Bulletin 2003/30

(51) Int Cl.7: **A61B 17/00**

(21) Application number: **01850081.9**

(22) Date of filing: **03.05.2001**

(54) **Guiding tool for wound closure element**

Führungswerkzeug für Wundverschluss

Outil de guidage pour fermeture de plaie

(84) Designated Contracting States:
**AT BE CH CY DE DK ES FI FR GB GR IE IT LI LU
MC NL PT SE TR**

(43) Date of publication of application:
06.11.2002 Bulletin 2002/45

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751 43 Uppsala (SE)**

(56) References cited:
**WO-A-01/13800 US-A- 5 620 461
US-A- 5 649 950 US-A- 5 725 519**

Note: Within nine months from the publication of the mention of the grant of the European patent, any person may give notice to the European Patent Office of opposition to the European patent granted. Notice of opposition shall be filed in a written reasoned statement. It shall not be deemed to have been filed until the opposition fee has been paid. (Art. 99(1) European Patent Convention).

Description

[0001] The present invention relates generally to sealing of a percutaneous incision or puncture in the wall of a vessel, duct, lumen or hollow organ in the body of a living being, by positioning a sealing device in said incision or puncture, where the incision or puncture is smaller than said sealing device. In particular the invention relates to a guiding tool for enabling the correct positioning of such a sealing device, ensuring a leak-proof sealing.

Background of the invention

[0002] In recent years a number of devices and apparatuses have been developed enabling the closure or occlusion of e.g. punctures in the femoral artery following catheterization. Instead of applying a pressure to the puncture site for a period of time sufficient for blood clot formation to occur, the new methods are e.g. based on providing a plug, commonly referred to as an "artery plug", in the puncture. The plug is made of a resorbable material, such that it can be left in place until the tissue has recovered properly and the wound or puncture is healed. The plug can be made of collagen, and applied to the outside of a vessel against a counteracting element, also made of a resorbable material, introduced into the interior of the vessel. A locking means secures the collagen plug in place. A device of this kind is disclosed in US-5,935,147 (Kensey et al). The sealing action is thus performed by the externally applied collagen plug. However, a certain percentage of applied plugs will not be leak-proof and often further compression by other devices or manually must be applied.

[0003] Alternatively, a plug can be made of two members such that a first member is positioned within a vessel and acts as the occluding member, and a second member is positioned outside the vessel and locked to the first member by a locking means. In order to ensure leak-proof action, the first member is larger than the puncture in all directions, i.e. it will cover a surface larger than the area of the puncture. In order to make this possible, the first member is foldable. A device of this kind is disclosed in our own EP-application EP-00850184.3 (corresponding to US patent application serial No. 09/704,726).

[0004] US-A-5 649 950 discloses a loading device for a collapsible occluder. This device has a conical lumen. US-A-5 649 950 corresponds to the preamble of claim 1.

[0005] The problem facing all systems wherein a folding or deformation of an element is needed in order to introduce the element into a vessel or through any tissue wherein the hole is smaller than the element itself, is that it can be difficult to achieve a reproducible unfolding, that accurately seals the hole from the inside. Also, in many cases the closure element is provided inside an introducer member such as a tube, in a folded state, already at the time of manufacture of the kit comprising

all components. If the kit is stored for extended periods of time, and even for shorter times, the folded closure element most likely does not unfold properly at the time of use. To avoid the risk of permanent deformation, the closure element could be inserted into the introducer device by the physician, but this would require an extra manipulation, and it might be very difficult to maintain the sterility of the devices in such a case.

Summary of the invention

[0006] Thus, in view of the problem with the prior art devices, it is the object of the present invention to improve the rate of successful sealing operations using wound closure devices, when foldable or deformable closure elements are introduced into a vessel through a hole, smaller than the element itself, and to enable the folding and unfolding operation to take place during the sealing operation, and to avoid manipulation of the closure element by the physician at the time of performing the sealing operation.

[0007] This object is achieved by the provision of a guiding tool which in a controlled manner deforms or folds a wound closure element such that it after having been introduced through a puncture, unfolds and regains its original shape in a reproducible and controllable manner, and thereby provides adequate sealing at an excellent rate of success, this procedure taking place at the time of performing the sealing operation. The guiding tool according to the invention is defined in claim 1.

Brief Description of the Drawings

[0008]

Fig. 1 a-c is a schematic illustration of a system for wound closure during operation thereof;

Fig. 2a illustrates an embodiment of the guiding tool not belonging to the invention in cross section;

Fig. 2b is a view in longitudinal cross section of a second embodiment of the inventive guiding tool;

Fig. 2c illustrates cross sections at A-E in Fig. 2b;

Fig. 2d is a perspective cut view in two different directions of a third preferred embodiment of the inventive guiding tool;

Fig. 3a is a cross section view of a closure element; and

Fig. 3b is a top view of a closure element.

Detailed Description of the invention

[0009] Fig. 1a-c illustrates the procedure of inserting a wound closure (occlusion) element 2 in a blood vessel 4 and clamping it by means of a locking member 6. Thereby, an incision 8 is made in the blood vessel 4 in question, and an introducer tube 10 is inserted into the vessel 4, see Fig. 1a. Then, a folded, or in some other manner deformed closure element 2 is passed through said introducer tube 10 and into the vessel 4. The closure element 2 is secured to e.g. a suture 12, and some rigid elongated element 14 such as a steel pin or pusher rod (not shown) can be used to guide the closure element 2 through the tube 10 and into the vessel 4, where it unfolds. Once the closure element 2 has unfolded inside the vessel 4, the pusher rod and the introducer tube 10 are withdrawn from the vessel but maintained close to the exterior of the vessel 4. Then, the closure element 2 is pulled back using the suture 12, so as to be located in a position where it is held against the interior vessel wall 16, Fig. 1b. An essentially disk shaped locking element 18, having a central hole, is provided on the suture 12, the suture running through said hole, such that the locking member can be moved along the suture 12 to be brought into contact with the exterior vessel wall 20. By the provision of suitable friction enhancing means 19 on the very distal end of the suture, the locking element can be pushed against the wall of the vessel while engaging the portion of the suture having higher friction, and thereby cause a locking of the closure element, Fig. 1c. This principle is used in e.g. US-5,916,236.

[0010] It is important that the closure element unfolds in a reproducible way, such that it will contact the inner vessel wall around the circumference of the incision. If the closure element is delivered to the user in a folded state, in position inside the introducer, as a "kit" ready for use by a physician, and the kit has been stored on a shelf for some time, it may happen that the closure element has become permanently deformed, and will not assume the desired shape (which may be to regain its original shape) inside the vessel. Such an event would of course dramatically increase the risk that the closure element will not fulfill its function, and cause a leakage.

[0011] Therefore, in accordance with the present invention, there is provided a guiding tool that is connectable to an introducer of the type discussed above, the closure element being provided in said guiding tool in an unfolded state. Thereby the actual deformation or folding of the closure element, necessary to enable insertion through the incision (which is smaller than the closure element) and into the blood vessel, is not performed until the time of performing the operation of inserting the closure element. In this way, the closure element will not be subjected to a prolonged deformation during storage.

[0012] An embodiment not falling under the invention is illustrated in Fig. 2a. It comprises a body in the shown embodiment in the form of an elongated tube like mem-

ber 20 (although cylindrical outer symmetry is no requirement), having an inner lumen 22 that has a first diameter in the proximal end portion 24 and over a fraction of its length (up to the dotted line X), forming a space 26 in which an closure element (not shown) can be housed without being deformed. Over a second fraction of the length, from the dotted line X and up to the distal end 26 portion, the lumen becomes narrower, rendering the 22 lumen cone shaped over this portion. Finally there is a connection portion 28, connectable to an introducer tube (such as the tube 10 in Fig. 1a). The exit diameter is equal to or slightly smaller than the inner diameter of the introducer tube, i.e. small enough to enable passing the closure element into the blood vessel.

[0013] In Fig. 2b a second embodiment of the guiding tool according to the present invention is illustrated. It is adapted for a closure element 30 having the general shape shown in Figs. 3a and 3b. The closure element suitable for use with the illustrated embodiment of the guiding tool, has a thick mid portion 32, that is generally elongated, and has peripheral wings 34 or edges, which are substantially thinner, and thus more flexible than the mid portion 32. The peripheral shape is like a slightly distorted ellipse, but could in principle be circular, the wings 34 thereby forming rather a collar or a brim surrounding the mid portion. Other shapes are also possible. A suitable kind of closure element is disclosed and claimed in our copending EP-00850184.3. In view of its flexibility, the wings 34 or brim are foldable such that the entire element will have a smallest dimension in a folded state that fits well within an incision or puncture in a blood vessel, thereby enabling insertion into said vessel.

[0014] Thus, the embodiment of the guiding tool according to the present invention shown in Fig. 2b, comprises an essentially tubular element 42 having a proximal end 44 and a distal end 46 and a lumen 48 extending between said distal 46 end and said proximal end 44. There is further a wound closure element introduction opening 50 in the proximal end 44, and a wound closure element exit opening 52 in the distal end 46. The distal end is shaped so as to be connectable to an introducer tube, like the one described above in connection with Fig. 1.

[0015] The lumen 48 has inner walls 54 provided with wound closure element deformation surfaces 56, adapted to deform a wound closure element during passage thereof, past said surfaces 56, through the guiding tool, from an essentially undeformed or unfolded state to a deformed or folded state. The effect of this deformation/folding should be such that the overall dimension of the wound closure element is changed to render it capable of passing through the puncture in the blood vessel. Also, after passage through said incision or puncture it must regain a shape that is capable of providing a sealing action against the inner wall of the vessel.

[0016] In Fig. 2b there is also shown a pusher rod 51, having a fork like configuration, that is used to push the

closure element 30 through the introducer and into the blood vessel. This pusher rod is retracted once the element is properly located inside the vessel.

[0017] In the embodiment shown in Fig. 2b the deformation surfaces 56 have a specific design, illustrated by a sequence in Fig. 2c, which are cross section views through the lumen at the positions indicated with corresponding letters A, B, C, D, E in Fig. 2b. Thus, there is one guiding surface 56 for each wing on the closure element 30, and a guiding recess 60 in which the thicker mid portion 32 of the closure element 30 will run during its passage through the guiding tool. The guiding surfaces will initially have an orientation such that the wings 34 of the unfolded or undeformed closure element 30, when inserted into the guiding tool in the introduction opening, will rest thereon in a position and orientation causing no deformation (referred to as a "horizontal" orientation; position A in Fig. 2c). Thereby the nominal shape of the closure element 30 is preserved also during extended storage. In a direction towards the exit opening, the guiding surfaces will gradually become elevated (A-B-C-D-E in Fig 2c) from the initial, essentially horizontal orientation, and also curved such that they form what could be referred to as a "quasi-conical" lumen inside the tool. At the end of the lumen, near the exit opening, the guiding surfaces will have reached a state where the cross section of the lumen is essentially circular, and where the diameter corresponds to the inner diameter of the introducer tube.

[0018] Preferably, there are guiding rails 62 provided above the guiding surfaces 56, such that the wings or brims 34 of the closure element 30 will be kept down during the process of pushing it with the pusher rod through the guiding tool, thereby preventing inadvertent tilting or incorrect behavior of the closure element during the movement through said guiding tool. The rails are preferably integrated in the "roof" of the lumen. However, they can also be provided as an insert and attached by suitable means inside the lumen.

[0019] In a further variation of the above described embodiment, the interior lumen of the guiding tool essentially has a cross section that exactly corresponds to the cross section of the closure element. This lumen would then form a guiding slot inside the tool, whereby the slot would be shaped so as to gradually change from a cross section corresponding to the above mentioned "horizontal orientation" to an essentially circular cross section, the diameter of which would be smaller than the incision through which the closure element is to be inserted. There must however be a space above the closure element for the access by the pushing rod needed for advancing the closure element through the tool and the introducer.

[0020] The sequence A-E in Fig. 2c illustrates the folding process, and it is clearly seen that the closure element reaches a folded state where it conforms to the circular cross section of the introducer tube, which is connected to the guiding tool at the exit end thereof.

[0021] Another embodiment of the guiding tool is shown in Fig. 2d, showing perspective cuts through the device at two orientations perpendicular to each other. Like reference numerals are used for like elements in Figs. 2c and 2d. Like in the above described embodiment, this embodiment of the guiding tool comprises an essentially tubular element 42 having a proximal end 44 and a distal end 46 and a lumen 48 extending between said distal 46 end and said proximal end 44. There is further a wound closure element introduction opening 50 in the proximal end 44, and a wound closure element exit opening 52 in the distal end 46. The distal end is shaped so as to be connectable to an introducer tube.

[0022] Also in this embodiment, the lumen 48 has inner walls 54 also provided with wound closure element deformation surfaces 56, adapted to deform a wound closure element during passage thereof, past said surfaces 56, through the guiding tool, from an essentially undeformed state to a deformed state.

[0023] However, the deformation surfaces have a different design in this embodiment. Namely, one wall of the inner lumen is flat such that the closure element can be placed essentially flat thereon, in an unfolded state, e.g. during shelf storage, corresponding to the "horizontal orientation" discussed above in connection with Fig. 2b, but with the thicker mid portion facing upwards. Towards the exit opening the lumen is shaped as cone, much like in the first embodiment of Fig. 2a, whereby the final diameter of the inner lumen corresponds to a diameter smaller than the diameter of the opening in the blood vessel through which the closure element is to be introduced. About half-way along the conical portion of the lumen, there are provided a pair of deflection surfaces 64, having a "steeper" angle than the over-all cone angle of the lumen. These surfaces will engage the peripheral brim or collar portions of the closure element, such that they are deflected or bent downwards from the essentially flat initial position. Also, the pusher rod discussed above will cause the closure element not to lie completely flat, but slightly angled with the trailing edge at a slightly elevated position compared to the leading edge. Furthermore, said pusher rod will assist in keeping the leading edge forced against the flat surface.

[0024] In order to facilitate correct positioning of the closure element during insertion, also in this case there may be provided guiding rails like those described above.

[0025] The invention having been described with reference to preferred embodiments thereof can be subject to alterations and modifications by the man skilled in the art, and the scope of the invention is limited only by the appended claims.

55 Claims

1. A guiding tool for controllable and reversible folding or deformation of a wound closure element (2) be-

fore insertion of said wound closure element into a percutaneous incision or puncture in the wall (4) of a vessel, duct, lumen or hollow organ in the body of a living being, said incision or puncture being smaller than said wound closure element in an unfolded or undeformed state, said tool comprising a body (20) having a distal end (26) and a proximal end (24) and a lumen (22) extending between said distal end and said proximal end; a wound closure element introduction opening (50) in the proximal end, and a wound closure element exit opening (52) in the distal end;

characterized in that

said lumen has inner walls (54) provided with wound closure element guiding surfaces (56, 64) in the form of separate deflection elements protruding from the inner wall of said lumen, for reversibly reducing the spatial extension of a wound closure element during its passage through the guiding tool, by engaging a peripheral brim or collar portions of the closure element, such that they are deflected or bent downwards from an essentially flat initial position, whereby said wound closure element is capable of passing through said incision or puncture, and whereby it after passage through said incision or puncture assumes a shape that is capable of providing a sealing action against said incision or puncture.

2. The tool as claimed in claim 1, wherein said guiding surfaces (56) in the proximal end of said tool are essentially flat, and in a direction towards the distal end, gradually becomes elevated and also curved such that they form a quasi-conical lumen inside the tool, and wherein the guiding surfaces, at the distal end of the lumen, near the exit opening, will have reached a state where the cross section of the lumen is essentially circular.

3. The tool as claimed in claim 1 or 2, wherein there are guiding rails (62) provided above the guiding surfaces (56), such that wings or rims (34) of a closure element (30) will be kept down during the process of pushing through the guiding tool, said guiding rails (62) being arranged to prevent the closure element from inadvertent tilting or other incorrect behavior during its movement through the guiding tool.

4. The tool as claimed in claim 1, wherein said introduction opening is larger than said exit opening, and optionally is provided with a sealing plug (53) to prevent leakage of body fluid.

5. The tool as claimed in claim 1, wherein said guiding surfaces (56) gradually change from the proximal end, where they do not affect the nominal shape of the wound closure element (30), towards the distal end where they force the wound closure element

(30) to assume a shape that conforms to the inner lumen of an introducer tube, connectable to the distal end of said guiding tool.

6. The tool as claimed in claim 1, wherein said lumen is cone shaped at least in the distal region of said guiding tool, and has a large enough diameter in the proximal region of the guiding tool, that the nominal shape of the wound closure element (30) is not affected, and a small enough diameter in the distal end that the wound closure element conforms to the inner lumen of an introducer tube, connectable to the distal end of said guiding tool.

7. The tool as claimed in claim 1, wherein the proximal region of the tool is essentially cylindrical, forming a storage compartment for said closure element (30), in which the nominal shape of the wound closure element is not affected.

8. A system for the introduction and securing of a wound closure element into a percutaneous incision or puncture in the wall of a vessel, duct, lumen or hollow organ in the body of a living being, said incision or puncture being smaller than said wound closure element in an unfolded or undeformed state, said system comprising

a wound closure element (30);

an introducer tube (10) for introducing said wound closure element into said incision;

a pusher device for enabling the passage of said wound closure element through said introducer; and

a tool as claimed in claim 1, connectable to said introducer.

Patentansprüche

1. Führungswerkzeug zum gesteuerten und reversiblen Falten oder Verformen eines Wundverschlusselements (2) vor der Einführung dieses Wundverschlusselements in einen perkutanen Schnitt oder eine perkutane Punktur in der Wand (4) eines Gefäßes, eines Kanals, eines Lumens oder eines hohlen Organs im Körper eines Lebewesens, wobei der Schnitt oder die Punktur kleiner ist als das Wundverschlusselement in einem ungefalteten oder nichtverformten Zustand, wobei das Werkzeug einen Körper (20) mit einem distalen Ende (26) und einem proximalen Ende (24) sowie einem Lumen (22) aufweist, das sich zwischen dem distalen und dem proximalen Ende erstreckt, eine Einführöffnung (50) für das Wundverschlusselement in dem proximalen Ende und eine Ausgangsöffnung (52) für das Wundverschlusselement in dem distalen Ende;

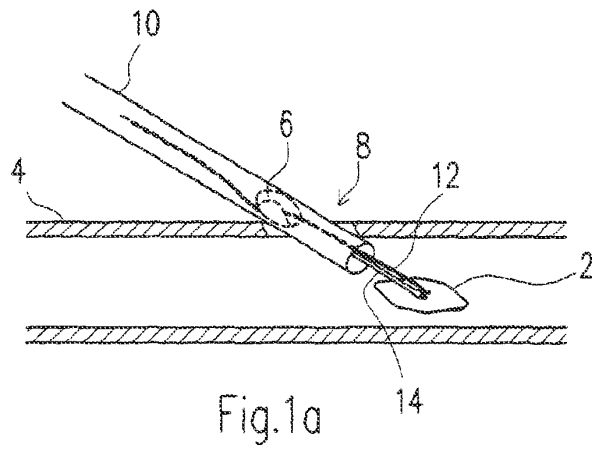
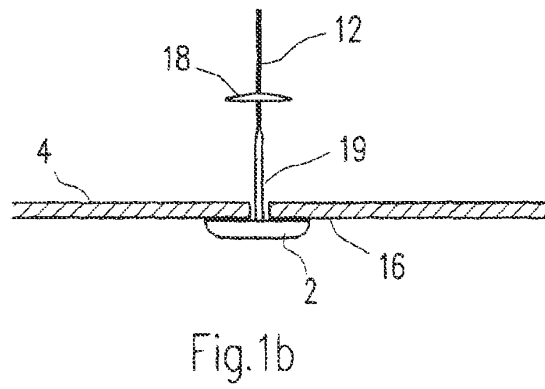
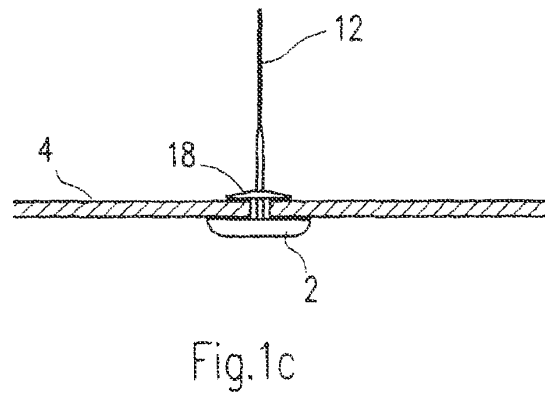
dadurch gekennzeichnet, dass

- das Lumen Innenwände (54) hat, die mit Führungsflächen (56, 64) für das Wundverschlusselement in Form von separaten Ablenkelementen versehen sind, die von der Innenwand des Lumens hervorstehen, um die räumliche Ausdehnung eines Wundverschlusselements während seines Durchgangs durch das Führungswerkzeug durch Ineingriffbringen eines Außenrands oder Kragenbereichs des Verschlusselements reversibel zu reduzieren, so dass diese aus einer im Wesentlichen flachen anfänglichen Position abgelenkt oder nach unten gebogen werden, wobei das Wundverschlusselement durch den Schnitt oder die Punktur hindurchtreten kann und wobei es nach dem Durchtritt durch den Schnitt oder die Punktur eine Gestalt annimmt, die eine Dichtungswirkung gegen den Schnitt oder die Punktur bieten kann.
2. Werkzeug nach Anspruch 1, wobei die Führungsflächen (56) am proximalen Ende des Werkzeugs im Wesentlichen flach sind und in Richtung des distalen Endes nach und nach erhaben und auch gekrümmt werden, so dass sie ein quasi konisches Lumen innerhalb des Werkzeugs bilden, und wobei die Führungsflächen am distalen Ende des Lumens in der Nähe der Ausgangsöffnung einen Zustand erreicht haben werden, wo der Querschnitt des Lumens im Wesentlichen kreisförmig ist.
3. Werkzeug nach Anspruch 1 oder 2, wobei Führungsschienen (62) oberhalb der Führungsflächen (56) vorgesehen sind, so dass Flügel oder Kanten (34) eines Verschlusselements (30) während des Vorgangs des Hindurchdrückens durch das Führungswerkzeug unten gehalten werden, wobei die Führungsschienen (62) so angeordnet sind, dass ein unbeabsichtigtes Kippen oder anderweitiges unkorrektes Verhalten des Verschlusselements während seiner Bewegung durch das Führungswerkzeug hindurch verhindert wird.
4. Werkzeug nach Anspruch 1, wobei die Einführöffnung größer ist als die Ausgangsöffnung und optional mit einem Dichtungsverschluss (53) versehen ist, um ein Auslaufen von Körperflüssigkeit zu verhindern.
5. Werkzeug nach Anspruch 1, wobei die Führungsflächen (56) sich von dem proximalen Ende, wo sie die Nenngestalt des Wundverschlusselements (30) nicht beeinflussen, in Richtung des distalen Endes, wo sie das Wundverschlusselement (30) dazu zwingen, eine Gestalt einzunehmen, die sich dem inneren Lumen einer Einführöhre anpasst, verbindbar mit dem distalen Ende des Führungswerkzeugs, nach und nach verändern.
6. Werkzeug nach Anspruch 1, wobei das Lumen zu
- mindest im distalen Bereich des Führungswerkzeugs kegelförmig ist und im proximalen Bereich des Führungswerkzeugs einen Durchmesser hat, der groß genug ist, um die Nenngestalt des Wundverschlusselements (30) nicht zu beeinflussen, und im distalen Ende einen Durchmesser hat, der klein genug ist, damit sich das Wundverschlusselement an das innere Lumen einer Einführöhre, verbindbar mit dem distalen Ende des Führungswerkzeugs, anpasst.
7. Werkzeug nach Anspruch 1, wobei der proximale Bereich des Werkzeugs im Wesentlichen zylindrisch ist und ein Aufbewahrungsabteil für das Verschlusselement (30) bildet, wobei die Nenngestalt des Wundverschlusselements nicht beeinträchtigt wird.
8. System zum Einführen und Sichern eines Wundverschlusselements in einen perkutanen Schnitt oder eine perkutane Punktur in der Wand eines Gefäßes, eines Kanals, eines Lumens oder eines hohlen Organs im Körper eines Lebewesens, wobei der Schnitt oder die Punktur kleiner ist als das Wundverschlusselement in einem ungefalteten oder nicht-deformierten Zustand, wobei das System Folgendes aufweist:
- ein Wundverschlusselement (30) ;
 - eine Einführöhre (10) zum Einführen des Wundverschlusselements in den Schnitt;
 - eine Druckeinrichtung zum Ermöglichen des Durchgangs des Wundverschlusselements durch die Einführöhre hindurch; und
 - ein Werkzeug nach Anspruch 1, das mit der Einführöhre verbindbar ist.

Revendications

1. Outil de guidage pour le repliement ou la déformation contrôlables et réversibles d'un élément de fermeture de plaie (2) avant l'insertion dudit élément de fermeture de plaie dans une incision percutanée ou un orifice dans la paroi (4) d'un vaisseau, d'un canal, d'une ouverture ou d'un organe creux dans le corps d'un être vivant, où ladite incision ou ledit orifice est plus petit que ledit élément de fermeture de plaie à l'état non replié ou non déformé, ledit outil comprenant un corps (20) avec une extrémité distale (26) et une extrémité proximale (24) et une ouverture (22) entre lesdites extrémités distale et proximale, une ouverture d'introduction (50) de l'élément de fermeture de plaie à l'extrémité proximale et une ouverture de sortie (52) de l'élément de

- fermeture de plaie à l'extrémité distale, **caractérisé en ce que** ledit passage présente des parois internes (54) offrant des surfaces de guidage (56, 64) de l'élément de fermeture de plaie sous la forme d'éléments déflecteurs distincts disposés en saillie sur la paroi interne dudit passage et destinés à réduire de manière réversible l'extension dans l'espace d'un élément de fermeture de plaie pendant son passage dans l'outil de guidage en agissant sur un bord ou collet périphérique de l'élément de fermeture de manière à ce qu'il soit fléchi ou replié vers le bas à partir d'une position initiale essentiellement plane, si bien que ledit élément de fermeture de plaie peut passer au travers de ladite incision ou dudit orifice et, après son passage dans ladite incision ou ledit orifice, reprendre une forme telle qu'il soit en mesure d'exercer une action de fermeture sur ladite incision ou ledit orifice.
2. Outil selon la revendication 1, où lesdites surfaces de guidage (56) dans l'extrémité proximale dudit outil sont essentiellement planes et, en direction de l'extrémité distale, remontent et se courbent progressivement de manière à former une ouverture pratiquement conique à l'intérieur de l'outil et où les surfaces de guidage, à l'extrémité distale de l'ouverture, près de l'ouverture de sortie, atteignent une position telle que la section de l'ouverture est essentiellement circulaire.
 3. Outil selon la revendication 1 ou 2, où il existe au-dessus des surfaces de guidage (56) des rails de guidage (62) tels que les ailes ou bords (34) de l'élément de fermeture (30) sont maintenus en position basse pendant l'opération de poussée au travers de l'outil de guidage, lesdits rails de guidage (62) étant disposés de manière à éviter que l'élément de fermeture ne puisse inopinément basculer ou mal se positionner pendant son mouvement au travers de l'outil de guidage.
 4. Outil selon la revendication 1, où ladite ouverture d'introduction est plus grande que ladite ouverture de sortie et peut en option être dotée d'un bouchon étanche (53) destiné à éviter l'épanchement des fluides corporels.
 5. Outil selon la revendication 1, où lesdites surfaces de guidage (56) changent progressivement, entre l'extrémité proximale, où elles n'affectent pas la forme nominale de l'élément de fermeture de plaie (30), et l'extrémité distale, où elles forcent l'élément de fermeture de plaie (30) à prendre une forme correspondant à l'ouverture interne d'un tube d'introduction pouvant être connecté à l'extrémité distale dudit outil de guidage.
 6. Outil selon la revendication 1, où ledit passage est de forme conique, au moins dans la région distale dudit outil de guidage, et possède un diamètre suffisamment grand dans la région proximale de l'outil de guidage pour que la forme nominale de l'élément de fermeture de plaie (30) ne soit pas affectée et un diamètre suffisamment petit dans la région distale pour que l'élément de fermeture de plaie corresponde à l'ouverture interne d'un tube d'introduction pouvant être connecté à l'extrémité distale dudit outil de guidage.
 7. Outil selon la revendication 1, où la région proximale de l'outil est essentiellement cylindrique, formant un compartiment de stockage pour ledit élément de fermeture de plaie (30), où la forme nominale de celui-ci n'est pas affectée.
 8. Système pour l'introduction et la fixation d'un élément de fermeture de plaie dans une incision percutanée ou un orifice dans la paroi d'un vaisseau, d'un canal, d'une ouverture ou d'un organe creux du corps d'un être vivant, ladite incision ou ledit orifice étant plus petit que ledit élément de fermeture de plaie à l'état non replié ou non déformé, ledit système comprenant
 - un élément de fermeture de plaie (30),
 - un tube d'introduction (10) pour introduire ledit élément de fermeture de plaie dans ladite incision,
 - un dispositif de poussage permettant de faire passer ledit élément de fermeture de plaie dans ledit tube d'introduction, et
 - un outil selon la revendication 1, pouvant être connecté audit tube d'introduction.



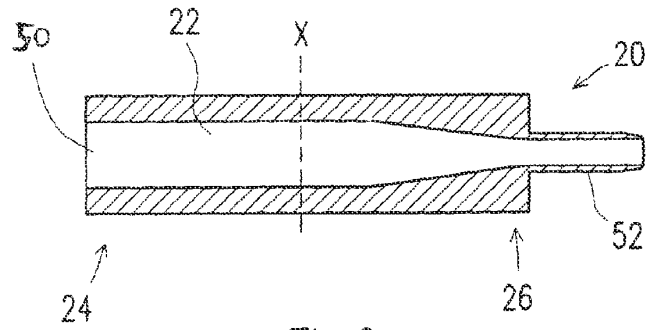


Fig. 2a

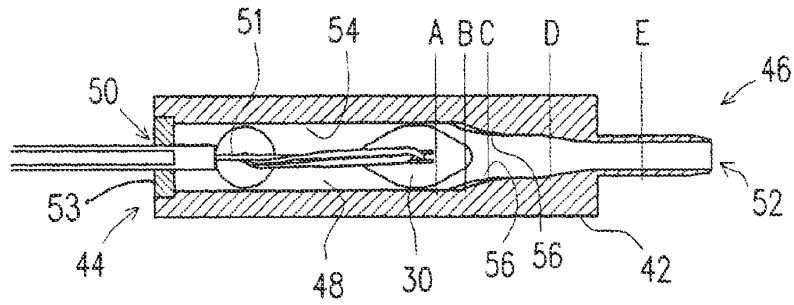


Fig. 2b

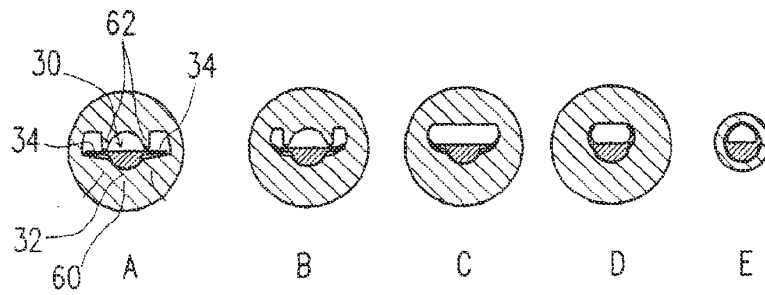


Fig. 2c

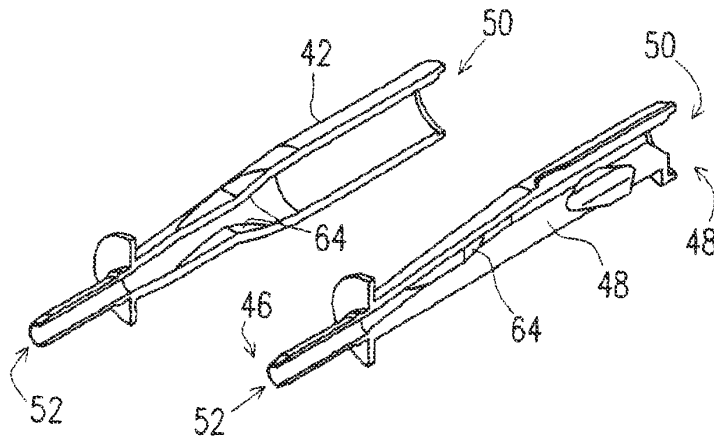


Fig. 2d

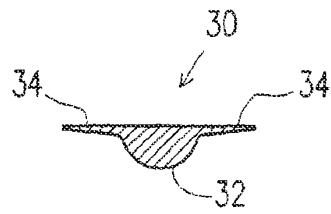


Fig. 3a

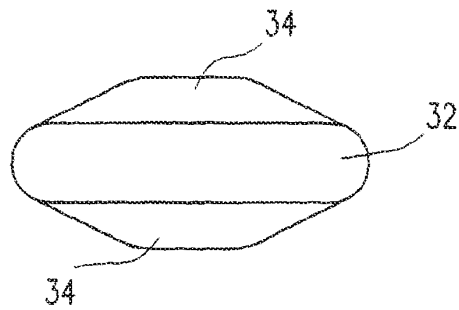


Fig. 3b



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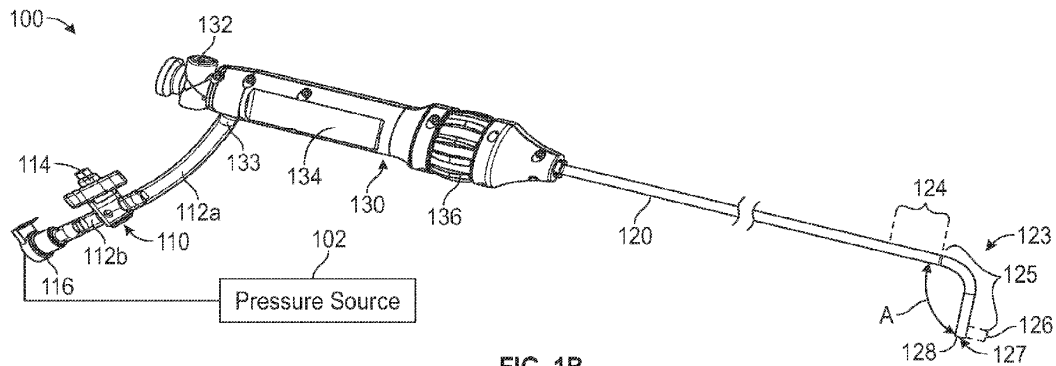


FIG. 1B

(57) Abstract: Disclosed herein are clot removal systems including steerable catheters, and associated systems and methods. In some embodiments, a clot removal system includes (i) an aspiration catheter having a proximal region and a distal region and (ii) a handle coupled to the proximal region of the catheter and having an actuator. The distal region of the catheter can include a deflectable member, and the clot removal system can include a pull wire extending between the actuator and the deflectable member. Actuation of the actuator is configured to pull the pull wire to deflect the deflectable member to deflect the distal region relative to the proximal region. The deflection can facilitate steering of the catheter to hard-to-reach (e.g., tortuous) portions of the anatomy of a patient.

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CATHETERS HAVING STEERABLE DISTAL PORTIONS,
AND ASSOCIATED SYSTEMS AND METHODS

CROSS-REFERENCE TO RELATED APPLICATION

[0001] This application claims the benefit of U.S. Provisional Patent Application No. 63/115,515, filed November 18, 2020, and titled "CATHETERS HAVING STEERABLE DISTAL PORTIONS, AND ASSOCIATED SYSTEMS AND METHODS," which is incorporated herein by reference in its entirety.

TECHNICAL FIELD

[0002] The present technology generally relates to clot removal systems including catheters (e.g., large bore aspiration catheters) having a steerable distal portion to, for example, facilitate positioning of the catheter in hard-to-reach regions of the vasculature of a patient.

BACKGROUND

[0003] Thromboembolic events are characterized by an occlusion of a blood vessel. Thromboembolic disorders, such as stroke, pulmonary embolism, heart attack, peripheral thrombosis, atherosclerosis, and the like, affect many people. These disorders are a major cause of morbidity and mortality.

[0004] When an artery is occluded by a clot, tissue ischemia develops. The ischemia will progress to tissue infarction if the occlusion persists. Infarction does not develop or is greatly limited if the flow of blood is reestablished rapidly. Failure to reestablish blood flow can lead to the loss of limb, angina pectoris, myocardial infarction, stroke, or even death.

[0005] In the venous circulation, occlusive material can also cause serious harm. Blood clots can develop in the large veins of the legs and pelvis, a common condition known as deep venous thrombosis (DVT). DVT arises most commonly when there is a propensity for stagnated blood (e.g., long distance air travel, immobility, etc.) and clotting (e.g., cancer, recent surgery, such as orthopedic surgery, etc.). DVT causes harm by: (1) obstructing drainage of venous blood from the legs leading to swelling, ulcers, pain, and infection, and (2) serving as a reservoir for blood clots to travel to other parts of the body including the heart, lungs, brain (stroke), abdominal organs, and/or extremities.

[0006] In the pulmonary circulation, the undesirable material can cause harm by obstructing pulmonary arteries—a condition known as pulmonary embolism. If the obstruction is upstream, in the main or large branch pulmonary arteries, it can severely compromise total blood flow within the lungs, and therefore the entire body, and result in low blood pressure and shock. If the obstruction is downstream, in large to medium pulmonary artery branches, it can prevent a significant portion of the lung from participating in the exchange of gases to the blood resulting in low blood oxygen and buildup of blood carbon dioxide.

[0007] There are many existing techniques to reestablish blood flow through an occluded vessel. One common surgical technique, an embolectomy, involves incising a blood vessel and introducing a balloon-tipped device (such as the Fogarty catheter) to the location of the occlusion. The balloon is then inflated at a point beyond the clot and used to translate the obstructing material back to the point of incision. The obstructing material is then removed by the surgeon. Although such surgical techniques have been useful, exposing a patient to surgery may be traumatic and best avoided when possible. Additionally, the use of a Fogarty catheter may be problematic due to the possible risk of damaging the inner lining of the vessel as the catheter is being withdrawn.

[0008] Percutaneous methods are also utilized for reestablishing blood flow. A common percutaneous technique is referred to as balloon angioplasty where a balloon-tipped catheter is introduced to a blood vessel (e.g., typically through an introducing catheter). The balloon-tipped catheter is then advanced to the point of the occlusion and inflated to dilate the stenosis. Balloon angioplasty is appropriate for treating vessel stenosis, but it is generally not effective for treating acute thromboembolisms as none of the occlusive material is removed and the vessel will re-stenosis after dilation. Another percutaneous technique involves placing a catheter near the clot and infusing streptokinase, urokinase, or other thrombolytic agents to dissolve the clot. Unfortunately, thrombolysis typically takes hours to days to be successful. Additionally, thrombolytic agents can cause hemorrhage and in many patients the agents cannot be used at all.

[0009] Various devices exist for performing a thrombectomy or removing other foreign material. However, such devices have been found to have structures which are either highly complex, cause trauma to the treatment vessel, or lack sufficient retaining structure and thus cannot be appropriately fixed against the vessel to perform adequately. Furthermore, many of the devices have highly complex structures that lead to manufacturing and quality control difficulties as well as delivery issues when passing through tortuous or small diameter catheters.

Less complex devices may allow the user to pull through the clot, particularly with inexperienced users, and such devices may not completely capture and/or collect all the clot material.

BRIEF DESCRIPTION OF THE DRAWINGS

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

[0011] Figures 1A and 1B are partially schematic side and isometric views, respectively, of a clot removal system in accordance with embodiments of the present technology.

[0012] Figure 2 is an enlarged, partially cut-away side view of a portion of a proximal region of a catheter of the clot removal system of Figures 1A and 1B in accordance with embodiments of the present technology.

[0013] Figure 3A is an enlarged, partially cut-away side view, and Figure 3B is an enlarged, partially cut-away isometric view, of a portion of an intermediate region of the catheter of Figures 1A and 1B in accordance with embodiments of the present technology.

[0014] Figures 4A and 4B are a distally-facing isometric view and an enlarged proximally-facing isometric view, respectively, of a deflectable member of a deflectable region of the catheter of Figures 1A and 1B in accordance with embodiments of the present technology.

[0015] Figures 4C and 4D are isometric views of a proximal ring and a distal ring, respectively, of the deflectable member of Figures 4A and 4B in accordance with embodiments of the present technology.

[0016] Figure 5A is a partially cross-sectional side view of a handle and a portion of the proximal region of the catheter of the clot removal system of Figures 1A and 1B in accordance with embodiments of the present technology; and Figure 5B is an enlarged cross-sectional isometric view of a portion of the handle shown in Figure 5A.

[0017] Figures 6A and 6B are a distally-facing isometric view and a side view, respectively, of a deflectable member in accordance with additional embodiments of the present technology.

[0018] Figure 6C is top view of a flat pattern that can be cut to integrally form a proximal ring and a tube portion of the deflectable member of Figures 6A and 6B in accordance with

embodiments of the present technology; and Figure 6D is an enlarged top view of a portion of the pattern shown in Figure 6C.

[0019] Figures 7A–7C are side views of a portion of the catheter of the clot removal system of Figures 1A and 1B during a procedure for removing clot material from within a blood vessel of a patient in accordance with embodiments of the present technology.

DETAILED DESCRIPTION

[0020] The present technology is generally directed to clot removal systems including aspiration catheters having a deflectable/steerable distal portion for improved flexibility through hard-to-reach (e.g., tortuous) vascular anatomy of a patient, and associated systems and methods. In some embodiments, a clot removal system in accordance with embodiments of the present technology includes (i) an aspiration catheter having a proximal region and a distal region and (ii) a handle coupled to the proximal region of the catheter and having an actuator. The distal region of the catheter can include a deflectable member, and the clot removal system can include a pull wire extending between the actuator and the deflectable member. Actuation of the actuator is configured to pull the pull wire to deflect the deflectable member to deflect the distal region relative to the proximal region. The deflection can facilitate steering of the catheter to the hard-to-reach portions of the anatomy of the patient.

[0021] In some embodiments, the deflectable member includes a proximal ring, a distal ring, and a tube portion extending between the proximal and distal rings. The proximal ring can include an annular member coupled (e.g., welded) thereto and configured to slidably receive the pull wire. The distal ring can be configured to be fixedly attached (e.g., welded) to the pull wire. The tube portion can include a plurality of openings (e.g., circumferentially extending openings) that define a plurality of ribs. The ribs can flex away from each other when the actuator is actuated to pull the pull wire. In some embodiments, the tube portion further includes a spine extending between the proximal and distal rings and generally aligned with the pull wire.

[0022] In some embodiments, the catheter further includes an intermediate region between the proximal and distal regions. The catheter can include a braid of wires extending along the proximal and distal regions, and a coil extending over the braid along the intermediate region.

[0023] In some aspects of the present technology, the catheter is configured to be steered to and positioned in difficult-to-reach regions of the anatomy of a patient while still having a relatively large size (e.g., 20 French, 24 French, greater than 24 French). More particularly, the

catheter can have an improved torque response and flexibility compared to conventional catheters having the same size. For example, the braid can provide good torque response along the proximal and intermediate regions of the catheter. Additionally, the deflectable region can be configured (e.g., shaped, sized) to be positioned within and steered/flexed into the difficult-to-reach regions of the anatomy. Further, the coil can provide increased hoop strength at the intermediate region while still allowing the catheter to flex. For example, the coil can inhibit or even prevent kinking or other unwanted movement of the catheter when the catheter is aspirated during a clot removal procedure.

[0024] Certain details are set forth in the following description and in Figures 1–7C to provide a thorough understanding of various embodiments of the present technology. In other instances, well-known structures, materials, operations, and/or systems often associated with intravascular procedures, clot removal procedures, catheters, and the like are not shown or described in detail in the following disclosure to avoid unnecessarily obscuring the description of the various embodiments of the technology. Those of ordinary skill in the art will recognize, however, that the present technology can be practiced without one or more of the details set forth herein, and/or with other structures, methods, components, and so forth.

[0025] The terminology used below is to be interpreted in its broadest reasonable manner, even though it is being used in conjunction with a detailed description of certain examples of embodiments of the technology. Indeed, certain terms may even be emphasized below; however, any terminology intended to be interpreted in any restricted manner will be overtly and specifically defined as such in this Detailed Description section.

[0026] The accompanying Figures depict embodiments of the present technology and are not intended to be limiting of its scope unless expressly indicated. The sizes of various depicted elements are not necessarily drawn to scale, and these various elements may be enlarged to improve legibility. Component details may be abstracted in the Figures to exclude details such as position of components and certain precise connections between such components when such details are unnecessary for a complete understanding of how to make and use the present technology. Many of the details, dimensions, angles and other features shown in the Figures are merely illustrative of particular embodiments of the disclosure. Accordingly, other embodiments can have other details, dimensions, angles and features without departing from the present technology. In addition, those of ordinary skill in the art will appreciate that further

embodiments of the present technology can be practiced without several of the details described below.

[0027] With regard to the terms "distal" and "proximal" within this description, unless otherwise specified, the terms can reference a relative position of the portions of a catheter subsystem with reference to an operator and/or a location in the vasculature. Also, as used herein, the designations "rearward," "forward," "upward," "downward," and the like are not meant to limit the referenced component to a specific orientation. It will be appreciated that such designations refer to the orientation of the referenced component as illustrated in the Figures. The systems of the present technology can be used in any orientation suitable to the user.

[0028] Figures 1A and 1B are partially schematic side and isometric views, respectively, of a clot removal system 100 in accordance with embodiments of the present technology. The clot removal system 100 can also be referred to as an aspiration assembly, a clot treatment system, and/or a thrombectomy system. Referring to Figures 1A and 1B together, the clot removal system 100 includes a tubing assembly 110 coupled to a catheter 120 via a handle 130. In general, the clot removal system 100 (i) can include features generally similar or identical to those of the clot removal systems described in detail in U.S. Patent Application No. 16/536,185, filed August 8, 2019, and titled "SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS," which is incorporated herein by reference in its entirety, and/or (ii) can be used to treat/remove clot material from a patient (e.g., a human patient) using any of the methods described in detail therein.

[0029] Referring to Figure 1A, the catheter 120 can include (i) a proximal region or portion 121, (ii) an intermediate region 122 adjacent to and distal of the proximal region 121, and (iii) a distal region 123 adjacent to and distal of the intermediate region 122. Referring to Figure 1B, the distal region 123 can further include a transition region 124, a deflectable region 125 (e.g., a flexible region, steerable region, deformable region) distal of the transition region 124, and a tip region 126 distal of the deflectable region 125. Referring again to Figures 1A and 1B together, the catheter 120 further defines a lumen 127 extending therethrough from the proximal region 121 to the tip region 126. The proximal region 121 defines a proximal terminus (obscured by the handle 130 in Figures 1A and 1B; e.g., a proximal terminus 529 shown in Figure 5A) of the catheter 120 that can be positioned within the handle 130, and the tip region 126 defines a distal terminus 128 of the catheter 120.

[0030] In some embodiments, the proximal region 121 has a first length, the intermediate region 122 has a second length less than the first length, and the distal region 123 has a third length less than the first and second lengths. For example, the first length can be between about 50–100 millimeters (e.g., about 80 millimeters), the second length can be between about 10–50 millimeters (e.g., about 25 millimeters), and the third length can be between about 1.0–10 millimeters (e.g., about 4.2 millimeters). In some embodiments, the transition region 124 can have a length of between about 0.1–5.0 millimeters (e.g., about 0.6 millimeters), the deflectable region 125 can have a length of between about 1.0–10 millimeters (e.g., about 3.0 millimeters), and the tip region 126 can have a length of between about 0.1–5.0 millimeters (e.g., about 0.6 millimeters). In other embodiments, the lengths of one or more of the regions 121–126 can be different. In some embodiments, the catheter 120 can have varying flexibilities, shapes, thicknesses, and/or other properties in/along the various regions 121–126.

[0031] In the illustrated embodiment, the handle 130 includes and/or is coupled to a valve 132. The valve 132 can include a branch or side port 133 configured to fluidly couple the lumen 127 of the catheter 120 to the tubing assembly 110, and can be integral with or coupled to the proximal region 121 of the catheter 120. In some embodiments, the valve 132 is a hemostasis valve that is configured to maintain hemostasis during a clot removal procedure by inhibiting or even preventing fluid flow in the proximal direction through the valve 132 as various components such as delivery sheaths, pull members, guidewires, interventional devices, other aspiration catheters, and so on are inserted through the valve 132 to be delivered through the catheter 120 to a treatment site in a blood vessel. In some embodiments, the valve 132 can be a valve of the type disclosed in U.S. Patent Application No. 16/117,519, filed August 30, 2018, and titled "HEMOSTASIS VALVES AND METHODS OF USE," which is incorporated herein by reference in its entirety.

[0032] In the illustrated embodiment, the tubing assembly 110 fluidly couples the catheter 120 to a pressure source 102, such as a syringe. The tubing assembly 110 can include one or more tubing sections 112 (individually labeled as a first tubing section 112a and a second tubing section 112b), at least one fluid control device 114 (e.g., a valve), and at least one connector 116 (e.g., a Toomey tip connector) for fluidly coupling the tubing assembly 110 to the pressure source 102 and/or other suitable components. In some embodiments, the fluid control device 114 is a stopcock that is fluidly coupled to (i) the side port 133 of the valve 132 via the first tubing section 112a and (ii) the connector 116 via the second tubing section 112b. The fluid control device 114 is externally operable by a user to regulate the flow of fluid therethrough and,

specifically, from the lumen 127 of the catheter 120 to the pressure source 102. In some embodiments, the connector 116 is a quick-release connector (e.g., a quick disconnect fitting) that enables rapid coupling/decoupling of the catheter 120 and the fluid control device 114 to/from the pressure source 102.

[0033] In the illustrated embodiment, the handle 130 includes a housing 134 and an actuator 136. The actuator 136 can be operably coupled to the catheter 120 and movable (e.g., rotatable) relative to the housing 134 to deflect (e.g., steer, flex) the deflectable region 125 from (i) a first position (e.g., an unflexed position, an aligned position) shown in Figure 1A in which the deflectable region 125 is generally aligned with the intermediate region 122 and/or the proximal region 121 to (ii) a second position (e.g., a flexed position) shown in Figure 1B in which the deflectable region 125 is deflected relative to the intermediate region 122 and/or the proximal region 121. That is, the actuator 136 can be configured to deflect the deflectable region 125 away from a longitudinal axis generally aligned with the proximal region 121 and/or the intermediate region 122. In some embodiments, the deflectable region 125 can have a bend angle A in the second position (Figure 1B) of greater than about 30 degrees, greater than about 50 degrees, greater than about 70 degrees, greater than about 90 degrees, or greater. In some embodiments, the bend angle A is about 90 degrees.

[0034] Figure 2 is an enlarged, partially cut-away side view of a portion of the proximal region 121 of the catheter 120 in accordance with embodiments of the present technology. Figure 3A is an enlarged, partially cut-away side view, and Figure 3B is an enlarged, partially cut-away isometric view, of a portion of the intermediate region 122 of the catheter 120 in accordance with embodiments of the present technology. Referring to Figures 1–3B together, the catheter 120 includes an outer sheath 240 and an inner liner 242 extending through/defining each of the regions 121–126. The outer sheath 240 is positioned over (e.g., radially outside of) the inner liner 242. The outer sheath 240 can also be referred to as an outer jacket, an outer shaft, or an outer layer, and the inner liner 242 can also be referred to as an inner layer, an inner sheath, or an inner shaft.

[0035] In some embodiments, the outer sheath 240 can be formed from a plastic material, elastomeric material, and/or thermoplastic elastomer (TPE) material. In some embodiments, the outer sheath 240 can be formed from a TPE manufactured by Arkema S.A., of Colombes, France, such as the TPEs manufactured under the trademark "Pebax." In some embodiments, the outer sheath 240 can have a varying hardness (e.g., durometer), thickness, flexibility, rigidity, and/or

other property in one or more of the different regions 121–126. For example, the outer sheath 240 can have (i) a first hardness along the proximal region 121 of between about 65D–75D (e.g., about 72D), (ii) a second hardness along the intermediate region 122 of between about 30D–40D (e.g., about 35D), (iii) a third hardness along the transition region 124 of between about 50D–60D (e.g., about 55D), (iv) a fourth hardness along the deflectable region of between about 20D–30D (e.g., about 25D), and (v) a fifth hardness along the tip region 126 of between about 50D–60D (e.g., about 55D). In other embodiments, the outer sheath 240 can have a different hardness or other property along one or more of the regions 121–126.

[0036] The inner liner 242 can be formed of a lubricious material that facilitates the movement (e.g., distal advancement, proximal retraction) of various components through the lumen 127, such as delivery sheaths, pull members, guidewires, interventional devices, other aspiration catheters, and the like. In some embodiments, the inner liner 242 can be formed from a polymer material, a fluoropolymer material (e.g., polytetrafluoroethylene (PTFE)), and/or another material having a high degree of lubricity. In some embodiments, the inner liner 242 can define a diameter D (Figure 2) of the lumen 127, and the diameter D can be greater than about 6 French, greater than about 10 French, greater than about 16 French, greater than about 20 French, greater than about 24 French, or greater. In some embodiments, the diameter D is about 8 French, about 16 French, about 20 French, or about 24 French. In certain embodiments, the diameter D of the inner liner 242 is the same in each of the regions 121–126 while, in other embodiments, the diameter D can vary along one or more of the regions 121–126.

[0037] The catheter 120 can further include a braid 244 extending along the proximal region 121 and the intermediate region 122 between the outer sheath 240 and the inner liner 242. In some embodiments, the braid 244 terminates at or before the distal region 123 such that the braid 244 does not extend along the transition region 124, the deflectable region 125, or the tip region 126. In the illustrated embodiment, the catheter 120 further includes a coil 346 (Figures 3A and 3B) extending at least partially along the intermediate region 122 between the braid 244 and the outer sheath 240. In some embodiments, the coil 346 extends only along the intermediate region 122 and does not extend into the proximal region 121 or the distal region 123.

[0038] The braid 244 can include wires, filaments, threads, sutures, fibers, or the like (collectively "wires 248") that have been woven or otherwise coupled, attached, formed, and/or joined together at a plurality of interstices 249. Accordingly, the braid 244 can also be referred to as a braided structure, a braided filament structure, a braided filament mesh structure, a mesh

structure, a mesh filament structure, and the like. In some embodiments, the wires 248 can comprise metals, polymers, and/or composite materials. In some embodiments, individual ones of the wires 248 can be rolled flat wires having a cross-sectional dimension of between about 0.0005–0.005 inch (e.g., about 0.002 inch) by about 0.002–0.005 inch (e.g., about 0.0033 inch).

[0039] In the illustrated embodiment, the coil 346 is a single wire wound around the braid 244 and the inner liner 242 along the intermediate region 122. In other embodiments, the coil 346 can include more than one wire wound about the braid 244. For example, the coil 346 can include multiple wires wound over one another and/or multiple wires wound to at least partially overlap one another to form a braided or overlapping coil structure on the braid 244. In other embodiments, the coil 346 can be formed directly over the inner liner 242, and the braid 244 can be formed over the coil 346. The coil 346 can be formed from a metallic or other suitably strong material, such as nickel-titanium alloys (e.g. nitinol), platinum, cobalt-chrome alloys, stainless steel, tungsten, and/or titanium.

[0040] Figures 4A and 4B are a distally-facing isometric view and an enlarged proximally-facing isometric view, respectively, of a deflectable member 450 of the deflectable region 125 of the catheter 120 in accordance with embodiments of the present technology. The deflectable member 450 can be positioned between the outer sheath 240 and the inner liner 242 (Figures 2–3B), which are both omitted in Figures 4A and 4B for clarity. In the illustrated embodiment, the deflectable member 450 includes a proximal ring 452, a distal ring 454, and a tube portion 456 extending between the proximal ring 452 and the distal ring 454. The deflectable member 450 can be formed from a flexible metallic material—such as nickel-titanium alloys (e.g. nitinol), platinum, cobalt-chrome alloys, stainless steel, tungsten, and/or titanium—or another suitably strong and flexible material. Similarly, the deflectable member 450 can be manufactured (e.g., laser cut) as a single integral piece, or one or more of the proximal ring 452, the distal ring 454, and the tube portion 456 can be separately manufactured and then coupled (e.g., welded, tack welded, adhered, fastened) together.

[0041] Figures 4C and 4D are isometric views of the proximal ring 452 and the distal ring 454, respectively, in accordance with embodiments of the present technology. Referring to Figures 4A–4C together, the proximal ring 452 can include an annular body 462 having an outer surface 461 and an inner surface 463. An annular member 464 can be coupled (e.g., welded, tack welded, adhered, fastened) to the inner surface 463 of the annular member 464 and can define/include a lumen 465. Referring to Figures 4A and 4D together, the distal ring 454 can

include an annular body 468 having an outer surface 467 and an inner surface 469. Referring to Figures 4A–4D together, the lumen 465 of the annular body 462 is configured to slidably receive a pull wire 458 (Figure 4D). The pull wire 458 can be coupled (e.g., welded, tack welded, adhered, fastened) to the inner surface 469 of the distal ring 454 and can extend from the distal ring 454 to the handle 130 (Figure 1), as described in greater detail below with reference to Figures 5A and 5B.

[0042] Referring again to Figures 4A and 4B together, the tube portion 456 can include a plurality of openings 451 extending partially about a circumference of the tube portion 456 to define a spine 453 and a plurality of ribs 455. In the illustrated embodiment, the spine 453 extends generally parallel to a longitudinal axis L (Figure 4A) of the deflectable member 450 and is generally aligned with the annular member 464 and the pull wire 458 (Figure 4D). That is, the pull wire 458 can extend through the tube portion 456 generally parallel to the spine 453. In some embodiments, the openings 451 are generally elongate openings that extend (i) generally parallel to one another and (ii) circumferentially about the longitudinal axis L such that, for example, the ribs 455 have a generally similar or identical shape. The openings 451 and/or the ribs 455 can all have the same dimensions as shown in Figures 4A and 4B while, in other embodiments, some or all of the openings 451 and/or the ribs 455 can have different dimensions and/or arrangements about the tube portion 456. In some embodiments, the tube portion 456 can be a laser-cut hypo tube.

[0043] Referring to Figures 2–4D together, in some embodiments the deflectable member 450 can be positioned between the outer sheath 240 and the inner liner 242 such that (i) the outer sheath 240 extends over/along the outer surface 461 of the proximal ring 452, an outer surface of the tube portion 456, and the outer surface 467 of the distal ring 454 and (ii) the inner liner 242 extends over/along the inner surface 463 of the proximal ring 452, an inner surface of the tube portion 456, and the inner surface 469 of the distal ring 454. In some embodiments, some or all of the pull wire 458 can be coated with PTFE or another suitable material (e.g., a fluoropolymer material). For example, the PTFE material can be omitted where the pull wire 458 is attached to the distal ring 454. The PTFE or other coating material can help inhibit the outer sheath 240 from adhering to the pull wire 458—thereby allowing the pull wire 458 to be moved relative to the deflectable member 450 after the outer sheath 240 is applied thereover.

[0044] Referring to Figures 1–3B together, in some embodiments the transition region 124 and the tip region 126 can include only the outer sheath 240 and the inner liner 242. In some

embodiments, the transition region 124 and/or the tip region 126 can include a marker band (not shown), such as a radiopaque marker configured to facilitate visualization of the position of the catheter 120 during a medical procedure (e.g., a clot removal procedure) using the catheter 120. For example, the transition region 124 and the tip region 126 can each include a radiopaque marker to facilitate visualization of the deflectable region 125 of the catheter 120.

[0045] Referring to Figures 1–4D together, in some embodiments, the catheter 120 can be formed about a mandrel or other elongate member. For example, the inner liner 232 can first be positioned about the mandrel. Then, the braid 244 can be formed (e.g., wound, braided) about the inner liner 242 around the mandrel (e.g., along the proximal and intermediate regions 121, 122) and/or the deflectable member 450 can be positioned about the inner liner 242 around the mandrel (e.g., along the deflectable region 125). Next, the coil 346 can be wound around the mandrel about the braid 244 over the intermediate region 122. Next, the outer sheath 240 can be positioned over the inner liner 242, the braid 244, the coil 346, and the deflectable member 450, and then heat shrunk or otherwise secured thereto. In some embodiments, the outer sheath 240 can be fused to the inner liner 242, the braid 244, the coil 346, and/or the deflectable member 450 to secure these components of the catheter 120 together.

[0046] Figure 5A is a partially cross-sectional side view of the handle 130 and a portion of the proximal region 121 of the catheter 120 in accordance with embodiments of the present technology. Figure 5B is an enlarged cross-sectional isometric view of a portion of the handle 130 shown in Figure 5A. Referring to Figures 5A and 5B, together, the housing 134 defines a proximal chamber 570 (e.g., a volume, lumen, compartment) and a distal chamber 572 that can be separated by the actuator 136. The valve 132 can be coupled to the housing 134 (e.g., a proximal portion of the housing 134) and positioned at least partially within the proximal chamber 570.

[0047] In the illustrated embodiment, the handle 130 includes a hollow tube member 574 positioned at least partially within the proximal chamber 570. The tube member 574 can include a proximal end portion 571a and a distal end portion 571b coupled to (e.g., secured to) the actuator 136. The tube member 574 can define a lumen 573 extending between the proximal and distal end portions 571a-b, and the tube member 574 can have a threaded inner surface 575 extending at least partially along the lumen 573. The actuator 136 can be a rotatable member, such as a wheel, grip wheel, or dial that is rotatable relative to the housing 134 to rotate the tube member 574 within the proximal chamber 570.

[0048] In the illustrated embodiment, the handle 130 further includes a catheter support or guide 576 extending at least partially through (i) the distal chamber 572, (ii) the actuator 136 (e.g., through a lumen in the actuator), (iii) the lumen 573 of the tube member 574, and (iv) the proximal chamber 570. In some embodiments, the catheter guide 576 defines a lumen 577 extending therethrough and includes a proximal flange portion 578 that can be secured to the housing 134. In some embodiments, the catheter guide 576 is fixed to the housing 134 such that the catheter guide 576 does not rotate when the actuator 136 is actuated to move the tube member 574. The proximal region 121 of the catheter 120 can extend into the handle 130, through the lumen 577 in the catheter guide 576, and to the valve 132. The proximal terminus 529 of the catheter 120 can be fluidly coupled to the valve 132. Accordingly, the catheter 120, the catheter guide 576, and the tube member 574 can be coaxially aligned. In other embodiments, the catheter guide 576 can be omitted.

[0049] The handle 130 can further include a shuttle member 580 positioned at least partially in the lumen 573 of the tube member 574 over the catheter guide 576 (e.g., over an outer surface thereof). In some embodiments, the shuttle member 580 is a hollow member slidably positioned over the catheter guide 576 and movable relative to the catheter 120. In the illustrated embodiment, the shuttle member 580 includes a threaded portion 582 having a threaded outer surface 583 and an anchor portion 584 extending from the threaded portion 582. The threaded outer surface 583 is configured to engage the threaded inner surface 575 of the tube member 574 such that, for example, movement of the tube member 574 drives the shuttle member 580 to move through the lumen 573 over the catheter guide 576 and relative to the catheter 120.

[0050] In the illustrated embodiment, the pull wire 458 extends along the catheter 120 into the handle 130 where it is secured to the anchor portion 584 of the shuttle member 580. More specifically, the pull wire 458 can extend from the distal ring 454 of the deflectable member 450 (Figure 4D) and through/along the transition, intermediate, and proximal regions 124, 122, 121 of the catheter 120 (Figures 1A and 1B) to the handle 130. For example, the pull wire 458 can be routed (i) through a lumen formed in the wall of the catheter 120 or (ii) simply between the outer sheath 240 and inner liner 242 (Figures 2–3B). In the illustrated embodiment, the pull wire 458 exits the catheter 120 and the catheter guide 476 (e.g., via openings therein) and enters the distal chamber 572. From the distal chamber 572, the pull wire 458 can extend through the actuator 136 and through the lumen 573 of the tube member 574 to the anchor portion 584. As best seen in Figure 5B, in some embodiments the pull wire 458 can be secured to anchor portion

584 via a screw 581 or other fastener. In some embodiments, the handle 130 can further include a biasing member 585, such as a coil spring, coupled to and/or over the pull wire 458. The biasing member 585 can be configured to smooth/distribute tension loads on the pull wire 458 during operation that might otherwise damage the pull wire 458 and/or various components of the handle 130.

[0051] Referring to Figures 1A, 1B, and 4A–5B together, the deflectable region 125 (and correspondingly the deflectable member 450) is in the first position and the handle 130 is in a corresponding first position in which the shuttle member 580 is positioned distally within the lumen 473 of the tube member 574 proximate to the actuator 136 and/or the distal end portion 571b of the tube member 574. To move the deflectable region 125 to the second (e.g., bent) position, a user can rotate the actuator 136 in a first direction to rotate the tube member 574. The rotation of the tube member 574 can drive the shuttle member 580 to move proximally through the lumen 573 in a direction toward the proximal end portion 571a of the tube member 574 via the engagement of the threaded outer surface 583 with the threaded inner surface 575. That is, the handle 130 is configured to translate the rotational movement of the actuator 136 into linear movement of the shuttle member 580. As the shuttle member 580 moves proximally, the shuttle member 580 pulls the pull wire 458 proximally and increases the tension therein. The pull wire 458 thus moves (e.g., slides) proximally through the lumen 465 in the annular member 464 of the deflectable member 450 and, because the pull wire 458 is fixedly attached to the distal ring 454 of the deflectable member 450, the pull wire 458 urges the distal ring 454 proximally relative to the proximal ring 452. This differential force causes the tube portion 456 of the deflectable member 450 to bend toward the second position shown in Figure 1B. More specifically, because the pull wire 458 is aligned with the spine 453 of the deflectable member 450, the spine 453 can define an inner radius of the bend while the ribs 455 flex away from one another, thereby increasing a size of the openings 451. To return the deflectable region 125 from the second position to the first position, the user can rotate the actuator 136 in a second direction opposite the first direction to translate the shuttle member 580 distally through the lumen 573 to decrease the tension in the pull wire 458, thereby allowing the deflectable member 450 to return to the relaxed position shown in Figures 4A and 4B.

[0052] In other embodiments, the handle 130 can include other features for moving/driving the shuttle member 580 through the housing 134 to tension the pull wire 458. For example, the actuator 136 can be a slider, clip, or other actuator movable relative to the housing 134.

[0053] Referring to Figures 1A–5B together, in some aspects of the present technology, the catheter 120 is configured to be steered to and positioned in difficult-to-reach regions of the anatomy of a patient while still having a relatively large size (e.g., 20 French, 24 French, greater than 24 French). More particularly, the catheter 120 can have an improved torque response and flexibility compared to conventional catheters having the same size. For example, the braid 234 can provide good torque response along the proximal and intermediate regions 121, 122 of the catheter 120. Moreover, the varying hardness (e.g., distally decreasing hardness) of the outer sheath 240 can provide (i) good torque response and/or pushability at the proximal region 121 and (ii) increased flexibility at the intermediate and distal regions 122, 123. Additionally, the deflectable region 125 is configured (e.g., shaped, sized) to be positioned within and steered/flexed into the difficult-to-reach regions of the anatomy. Further, the coil 346 can provide increased hoop strength at the intermediate region 122 while still allowing the catheter 120 to flex. For example, the coil 346 can inhibit or even prevent kinking or other unwanted movement of the catheter 120 when the lumen 127 is aspirated during a clot removal procedure.

[0054] Figures 6A and 6B are a distally-facing isometric view and a side view, respectively, of a deflectable member 650 in accordance with additional embodiments of the present technology. The deflectable member 650 is configured to be positioned in the deflectable region 125 of the catheter 120 (Figure 1) and can include some features generally similar or identical to the deflectable member 450 described in detail above with reference to Figures 4A–4D. For example, in the illustrated embodiment the deflectable member 650 includes a proximal ring 652, a distal ring 654, and a tube portion 656 extending between the proximal ring 652 and the distal ring 654. The proximal ring 652 includes an annular member 664 coupled thereto and configured to slidably receive the pull wire 458. The pull wire 458 can extend through the tube portion 656 and be fixedly secured (e.g., welded) to the distal ring 654.

[0055] In the illustrated embodiment, the tube portion 656 includes a plurality of openings 651 (identified individually as first openings 651a and second openings 651b) extending partially about a circumference of the tube portion 656 to define a plurality of ribs 655 (identified individually as first ribs 655a and second ribs 655b). In some embodiments, the first openings 651a are generally elongate openings that extend (i) generally parallel to one another and (ii) circumferentially about a longitudinal axis M of the deflectable member 650 such that, for example, the first ribs 655a have a generally similar or identical shape. Similarly, the second openings 651b can each have an elongate tapered shape and can extend (i) generally parallel to one another and (ii) circumferentially about the longitudinal axis M of the deflectable member

650 such that, for example, the second ribs 655b have a generally similar or identical shape. In the illustrated embodiment, the second ribs 655b have a smaller dimension (e.g. width) in a direction along the longitudinal axis M than the first ribs 655a. Accordingly, the second ribs 655b can be relatively more flexible than the first ribs 655a.

[0056] In some embodiments, the pull wire 458 can extend over/adjacent to the first ribs 655a. Accordingly, referring to Figures 5–6B together, actuation of the actuator can 136 pull the pull wire 458 to urge the distal ring 654 proximally relative to the proximal ring 652. This differential force causes the tube portion 656 of the deflectable member 650 to bend such that, for example, a portion of the first ribs 655a define an inner radius of the bend while the second ribs 655b flex away from one another, thereby increasing a size of the second openings 651b (e.g., and conversely decreasing a size of the first openings 651a).

[0057] In some embodiments, all or a portion of the deflectable member 650 can be manufactured as a single integral piece. For example, Figure 6C is top view of flat pattern that can be cut to integrally form the proximal ring 652 and the tube portion 656 of the deflectable member 650 in accordance with embodiments of the present technology. Figure 6D is an enlarged top view of a portion of the pattern shown in Figure 6C. Referring to Figures 6C and 6D together, the pattern can be laser cut from a single piece of material (e.g., stainless steel), formed to have the three-dimensional tubular shape shown in Figures 6A and 6B, and then welded or otherwise adhered together to form the deflectable member 650.

[0058] Figures 7A–7C are side views of a portion of the catheter 120 of the clot removal system 100 during a procedure for removing clot material PE (e.g., a pulmonary embolism) from within a blood vessel BV (e.g., a pulmonary blood vessel) of a patient (e.g., a human patient) in accordance with embodiments of the present technology. As noted above, in some embodiments the clot removal procedure illustrated in Figures 7A–7C can be generally similar or identical to any of the clot removal procedures disclosed in U.S. Patent Application No. 16/536,185, filed August 8, 2019, and titled "SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS," which is incorporated herein by reference in its entirety.

[0059] With reference to Figures 1A–7A together, the catheter 120 can be advanced through the patient toward and/or proximate to the clot material PE within the blood vessel BV (e.g., advanced to a treatment site within the blood vessel BV). In some embodiments, however, the blood vessel BV can include a hard-to-reach (e.g., tortuous) region, such as a region beyond a bend 790 in the blood vessel BV that can have a relatively small radius of curvature. The

region of the blood vessel BV distal of the bend 790 can be difficult to reach due to the required approach angle, varying anatomy of the blood vessel BV, and/or irregularities due to illness of the patient.

[0060] Accordingly, with reference to Figures 1A–5B and 7B together, the deflectable region 125 can be moved fully or partially from the first position (Figure 1A) to the second position (Figure 1B) before and/or during further advancement of the catheter 120 toward the clot material PE. More specifically, the user can actuate (e.g., rotate) the actuator 136 of the handle to pull the pull wire 458 to deflect the deflectable member 450 to deflect the deflectable region 125, as described in detail above. In some embodiments, the catheter 120 can be advanced through the blood vessel BV until the distal terminus 128 of the catheter 120 is positioned proximate to a proximal portion of the clot material PE. In some embodiments, the position of the distal terminus 128 can be confirmed or located via visualization of a marker band (not shown; e.g., in/along the tip region 126) using fluoroscopy or another imaging procedure (e.g., a radiographic procedure). In other embodiments, the distal terminus 128 can be positioned at least partially within the clot material PE or distal of the clot material PE.

[0061] In some aspects of the present technology, moving the deflectable region 125 to the second position helps the catheter 120 flex/bend around the bend 790 and into the hard-to-reach region of the blood vessel BV distal thereof. In some embodiments, before advancing the catheter 120 to the position shown in Figure 7B, the catheter 120 can be rotated to align the deflectable region 125 with the bend 790. In contrast, conventional catheters of the same size may be too stiff to easily position proximate the clot material PE. For example, such conventional catheters may "rainbow" over the clot material PE by following or tracking along the wall of the blood vessel BV at the outside of the bend 790. In addition to the deflectable region 125, both (i) the varying hardness of the outer sheath 240 (Figures 2–3B) and (ii) the flexibility of the braid 244 (Figures 2–3B) and the coil 346 (Figures 3B and 3C) can help the catheter 120 flex through the anatomy of the blood vessel BV to the desired position proximate the clot material PE.

[0062] Access to the pulmonary vessels can be achieved through the patient's vasculature, for example, via the femoral vein. In some embodiments, the clot removal system 100 can include an introducer (e.g., a Y-connector with a hemostasis valve; not shown) that can be partially inserted into the femoral vein. A guidewire (not shown) can be guided into the femoral vein through the introducer and navigated through the right atrium, the tricuspid valve, the right

ventricle, the pulmonary valve, and into the main pulmonary artery. Depending on the location of the clot material PE, the guidewire can be guided to one or more of the branches of the right pulmonary artery and/or the left pulmonary artery. In some embodiments, the guidewire can be extended entirely or partially through the clot material PE. In other embodiments, the guidewire can be extended to a location just proximal of the clot material PE. After positioning the guidewire, the catheter 120 can be placed over the guidewire and advanced to the position proximate to the clot material PE as illustrated in Figure 7B. In some embodiments, the guidewire can then be withdrawn while, in other embodiments, the guidewire can remain and can be used to guide other catheters (e.g., delivery catheters, additional aspiration guide catheters, etc.), interventional devices, etc., to the treatment site. It will be understood, however, that other access locations into the venous circulatory system of a patient are possible and consistent with the present technology. For example, the user can gain access through the jugular vein, the subclavian vein, the brachial vein, or any other vein that connects or eventually leads to the superior vena cava. Use of other vessels that are closer to the right atrium of the patient's heart can also be advantageous as it reduces the length of the instruments needed to reach the clot material PE.

[0063] With reference to Figures 1A, 1B, and 7C together, the pressure source 102 is configured to generate (e.g., form, create, charge, build-up) a vacuum (e.g., negative pressure) and store the vacuum for subsequent application to the catheter 120. For example, after positioning the catheter 120 proximate the clot material PE, a user can first close the fluid control device 114 before generating the vacuum in the pressure source 102 by, for example, withdrawing the plunger of a syringe coupled to the connector 116. In this manner, a vacuum is charged within the pressure source 102 (e.g., a negative pressure is maintained) before the pressure source 102 is fluidly connected to the lumen 127 of the catheter 120. To aspirate the lumen 127 of the catheter 120, the user can open the fluid control device 114 to fluidly connect the pressure source 102 to the catheter 120 and thereby apply or release the vacuum stored in the pressure source 102 to the lumen 127 of the catheter 120.

[0064] Opening of the fluid control device 114 instantaneously or nearly instantaneously applies the stored vacuum pressure to the tubing assembly 110 and the catheter 120, thereby generating a suction pulse throughout the catheter 120. In particular, the suction is applied at the tip region 126 of the catheter 120 to suck/aspirate at least a portion of the clot material PE into the lumen 127 of the catheter 120, as shown in Figure 7C. In one aspect of the present technology, pre-charging or storing the vacuum in the pressure source 102 before applying the

vacuum to the lumen 127 of the catheter 120 is expected to generate greater suction forces and corresponding fluid flow velocities at and/or near the tip region 126 of the catheter 120 compared to simply activating the pressure source 102 while it is fluidly connected to the catheter 120.

[0065] Sometimes, as shown in Figure 7C, discharging the vacuum stored in the pressure source to aspirate the lumen 127 of the catheter 120 may remove substantially all (e.g., a desired amount) of the clot material PE from the blood vessel BV. That is, a single aspiration pulse may adequately remove the clot material PE from the blood vessel BV. In other embodiments, a portion of the clot material PE may remain in the blood vessel BV. In such instances, the user may wish to again apply vacuum pressure (conduct an "aspiration pass") to remove all or a portion of the remaining clot material PE in the blood vessel BV. In such instances, the pressure source 102 can be disconnected from the tubing assembly 110 and drained (e.g., aspirated clot removal removed) before the pressure source 102 is reconnected to the tubing assembly 110 and activated once again. After removing a desired amount of the clot material PE, the catheter 120 can be withdrawn from the patient.

[0066] In some aspects of the present technology, the relatively great flexibility and torquability of the catheter 120 allow the catheter 120 to be positioned in difficult-to-reach areas of the blood vessel BV (or elsewhere in the vasculature of the patient) without decreasing the size of the lumen 127 and while keeping the lumen 127 of constant diameter throughout. It is expected that the increased size of the lumen 127 will provide greater suction forces over a smaller period of time (e.g., will provide a larger vacuum impulse). In some embodiments, the greater suction forces can facilitate the removal of clot material from a blood vessel of a patient even where the clot material is strongly lodged or attached within the blood vessel (e.g., a chronic clot). Accordingly, in contrast to conventional catheters, the catheter 120 can be used to generate greater aspirational forces for improved clot removal in hard-to-reach places of the vasculature. In additional aspects of the present technology, the coil 336 (Figures 3B and 3C) can provide a high hoop strength that inhibits or even prevents kinking or other unwanted movement of the catheter 120 when the pressure source 102 is used to generate a suction pulse at the distal region 123 of the catheter 120.

[0067] Although described in the context of removing clot material from pulmonary blood vessels, in other embodiments the clot removal system 100 can be used to remove clot from other locations in the body of the patient. For example, the clot removal system 100 can be used to aspirate or otherwise remove clot material (e.g., stationary or in transit) and/or vegetation from

the heart (e.g., the right atrium, tricuspid valve, pulmonary valve), the vena cava, the renal arteries, and so on.

[0068] Several aspects of the present technology are set forth in the following examples:

1. An aspiration catheter, comprising:
a proximal region; and
a distal region including a deflectable member, wherein the deflectable member includes—
a proximal ring;
a distal ring configured to be fixedly attached to a pull wire; and
a tube portion extending between the proximal and distal rings, wherein the tube portion includes a plurality of openings extending therethrough to define a plurality of ribs, and wherein the ribs are configured to flex away from each other when the pull wire is pulled proximally.
2. The aspiration guide catheter of example 1 wherein the tube portion includes a spine extending in a direction between the proximal and distal rings, wherein the ribs extend away from the spine, and wherein the spine is configured to extend generally parallel to and over the pull wire.
3. The aspiration catheter of example 1 or example 2 wherein the proximal region and the distal region define a lumen having a diameter of 20 French or greater.
4. The aspiration catheter of any one of examples 1–3, further comprising an intermediate region between the proximal and distal regions, wherein the proximal region and the intermediate region include a braid of wires extending therethrough.
5. The aspiration catheter of example 4 wherein the intermediate region includes a wire coiled around the braid.
6. The aspiration catheter of any one of examples 1–5 wherein the tube portion extends along a longitudinal axis in a relaxed state, and wherein the openings extend

circumferentially about the longitudinal axis and generally parallel to one another in the relaxed state.

7. The aspiration catheter of any one of examples 1–6 wherein the proximal ring includes an annular member configured to slidably receive the pull wire therethrough.

8. A clot removal system, comprising:
an aspiration catheter including a proximal region and a distal region, wherein the distal region includes a deflectable member;
a handle coupled to the proximal region of the aspiration catheter, wherein the handle includes an actuator; and
a pull wire extending between the actuator and the deflectable member, wherein actuation of the actuator is configured to pull the pull wire to deflect the deflectable member to deflect the distal region of the aspiration catheter relative to the proximal region.

9. The clot removal system of example 8 wherein the aspiration catheter extends along an axis, and wherein the actuation of the actuator is configured to deflect the distal region of the aspiration catheter away from the axis by about 90 degrees or greater.

10. The clot removal system of example 8 or example 9 wherein the aspiration guide catheter has a size of 20 French or greater.

11. The clot removal system of any one of examples 8–10 wherein the deflectable member has a tubular shape that extends along a longitudinal axis, and wherein the deflectable member includes (a) a spine extending parallel to the longitudinal axis and (b) a plurality of ribs extending from the spine and circumferentially about the longitudinal axis.

12. The clot removal system of example 11 wherein the deflectable member has a distal portion and a proximal portion, and wherein the pull wire is attached to the distal portion of the deflectable member.

13. The clot removal system of example 12 wherein the actuation of the actuator is configured pull the distal portion proximally relative to the proximal portion.

14. The clot removal system of example 12 or example 13 wherein the ribs define a plurality of openings therebetween, and wherein the actuation of the actuator is configured pull the distal portion of the deflectable member proximally relative to the proximal portion to bend the spine and increase a size of the openings.

15. The clot removal system of any one of examples 8–14 wherein the aspiration catheter further includes—

- an intermediate region between the proximal and distal regions;
- an inner liner extending through the proximal, intermediate, and distal regions;
- a braid of wires extending through the proximal and intermediate regions over the inner liner;
- a wire extending through the intermediate region and coiled around the braid; and
- an outer liner extending through the proximal, intermediate, and distal regions over the inner liner, the braid, and the wire, wherein the deflectable member is positioned between the inner and outer liners in the distal region.

16. The clot removal system of example 15 wherein—

- the distal region further includes a proximal transition region, a distal tip region, and a deflectable region between the proximal transition region and the distal tip region;
- the deflectable member is positioned in the deflectable region;
- the outer liner has a first hardness in the proximal transition region, a second hardness in the deflectable region, and a third hardness in the distal tip region; and
- the second hardness is less than the first hardness and less than the third hardness.

17. A method of removing clot material from a blood vessel, the method comprising:
advancing an aspiration catheter through the blood vessel, wherein the aspiration catheter includes a distal portion and a proximal portion;
actuating a handle coupled to the aspiration catheter to deflect the distal portion of the aspiration catheter away from a longitudinal axis of the proximal portion;

positioning a distal tip of the aspiration catheter proximate to the clot material;
activating a pressure source coupled to the aspiration catheter via a fluid control device,
while the fluid control device is closed, to generate a vacuum in the pressure
source; and
opening the fluid control device to apply the vacuum to the aspiration catheter to thereby
aspirate at least a portion of the clot material into the aspiration catheter.

18. The method of example 17 wherein actuating the handle to deflect the distal portion of the aspiration catheter includes deflecting the distal portion of the aspiration catheter away from the longitudinal axis in a deflection direction, and wherein the method further comprises rotating the aspiration catheter such that the deflection direction is at least partially aligned with a bend in the blood vessel.

19. The method of example 17 or example 18 wherein the aspiration catheter has a size of 20 French or greater.

20. The method of any one of examples 17–19 wherein the aspiration catheter includes a deflectable member positioned in the distal portion, and wherein actuating the handle includes rotating an actuator of the handle to pull a pull wire coupled to the deflectable portion proximally to deflect the deflectable member to deflect the distal portion of the aspiration catheter.

[0069] The above detailed descriptions of embodiments of the technology are not intended to be exhaustive or to limit the technology to the precise form disclosed above. Although specific embodiments of, and examples for, the technology are described above for illustrative purposes, various equivalent modifications are possible within the scope of the technology as those skilled in the relevant art will recognize. For example, although steps are presented in a given order, alternative embodiments may perform steps in a different order. The various embodiments described herein may also be combined to provide further embodiments.

[0070] From the foregoing, it will be appreciated that specific embodiments of the technology have been described herein for purposes of illustration, but well-known structures and functions have not been shown or described in detail to avoid unnecessarily obscuring the

description of the embodiments of the technology. Where the context permits, singular or plural terms may also include the plural or singular term, respectively.

[0071] Moreover, unless the word "or" is expressly limited to mean only a single item exclusive from the other items in reference to a list of two or more items, then the use of "or" in such a list is to be interpreted as including (a) any single item in the list, (b) all of the items in the list, or (c) any combination of the items in the list. Additionally, the term "comprising" is used throughout to mean including at least the recited feature(s) such that any greater number of the same feature and/or additional types of other features are not precluded. It will also be appreciated that specific embodiments have been described herein for purposes of illustration, but that various modifications may be made without deviating from the technology. Further, while advantages associated with some embodiments of the technology have been described in the context of those embodiments, other embodiments may also exhibit such advantages, and not all embodiments need necessarily exhibit such advantages to fall within the scope of the technology. Accordingly, the disclosure and associated technology can encompass other embodiments not expressly shown or described herein.

CLAIMS

I/We claim:

1. An aspiration catheter, comprising:
a proximal region; and
a distal region including a deflectable member, wherein the deflectable member includes—
a proximal ring;
a distal ring configured to be fixedly attached to a pull wire; and
a tube portion extending between the proximal and distal rings, wherein the tube portion includes a plurality of openings extending therethrough to define a plurality of ribs, and wherein the ribs are configured to flex away from each other when the pull wire is pulled proximally.
2. The aspiration guide catheter of claim 1 wherein the tube portion includes a spine extending in a direction between the proximal and distal rings, wherein the ribs extend away from the spine, and wherein the spine is configured to extend generally parallel to and over the pull wire.
3. The aspiration catheter of claim 1 wherein the proximal region and the distal region define a lumen having a diameter of 20 French or greater.
4. The aspiration catheter of claim 1, further comprising an intermediate region between the proximal and distal regions, wherein the proximal region and the intermediate region include a braid of wires extending therethrough.
5. The aspiration catheter of claim 4 wherein the intermediate region includes a wire coiled around the braid.
6. The aspiration catheter of claim 1 wherein the tube portion extends along a longitudinal axis in a relaxed state, and wherein the openings extend circumferentially about the longitudinal axis and generally parallel to one another in the relaxed state.

7. The aspiration catheter of claim 1 wherein the proximal ring includes an annular member configured to slidably receive the pull wire therethrough.

8. A clot removal system, comprising:
an aspiration catheter including a proximal region and a distal region, wherein the distal region includes a deflectable member;
a handle coupled to the proximal region of the aspiration catheter, wherein the handle includes an actuator; and
a pull wire extending between the actuator and the deflectable member, wherein actuation of the actuator is configured to pull the pull wire to deflect the deflectable member to deflect the distal region of the aspiration catheter relative to the proximal region.

9. The clot removal system of claim 8 wherein the aspiration catheter extends along an axis, and wherein the actuation of the actuator is configured to deflect the distal region of the aspiration catheter away from the axis by about 90 degrees or greater.

10. The clot removal system of claim 8 wherein the aspiration guide catheter has a size of 20 French or greater.

11. The clot removal system of claim 8 wherein the deflectable member has a tubular shape that extends along a longitudinal axis, and wherein the deflectable member includes (a) a spine extending parallel to the longitudinal axis and (b) a plurality of ribs extending from the spine and circumferentially about the longitudinal axis.

12. The clot removal system of claim 11 wherein the deflectable member has a distal portion and a proximal portion, and wherein the pull wire is attached to the distal portion of the deflectable member.

13. The clot removal system of claim 12 wherein the actuation of the actuator is configured pull the distal portion proximally relative to the proximal portion.

14. The clot removal system of claim 12 wherein the ribs define a plurality of openings therebetween, and wherein the actuation of the actuator is configured pull the distal portion of the deflectable member proximally relative to the proximal portion to bend the spine and increase a size of the openings.

15. The clot removal system of claim 8 wherein the aspiration catheter further includes—

- an intermediate region between the proximal and distal regions;
- an inner liner extending through the proximal, intermediate, and distal regions;
- a braid of wires extending through the proximal and intermediate regions over the inner liner;
- a wire extending through the intermediate region and coiled around the braid; and
- an outer liner extending through the proximal, intermediate, and distal regions over the inner liner, the braid, and the wire, wherein the deflectable member is positioned between the inner and outer liners in the distal region.

16. The clot removal system of claim 15 wherein—

- the distal region further includes a proximal transition region, a distal tip region, and a deflectable region between the proximal transition region and the distal tip region;
- the deflectable member is positioned in the deflectable region;
- the outer liner has a first hardness in the proximal transition region, a second hardness in the deflectable region, and a third hardness in the distal tip region; and
- the second hardness is less than the first hardness and less than the third hardness.

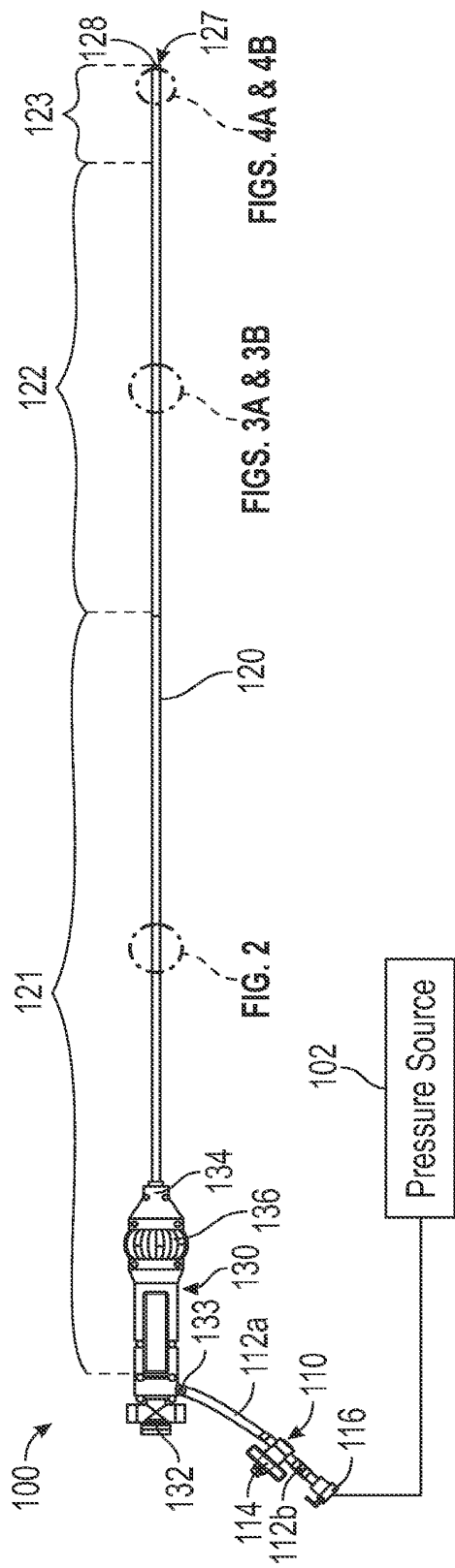
17. A method of removing clot material from a blood vessel, the method comprising:
advancing an aspiration catheter through the blood vessel, wherein the aspiration catheter includes a distal portion and a proximal portion;
actuating a handle coupled to the aspiration catheter to deflect the distal portion of the aspiration catheter away from a longitudinal axis of the proximal portion;
positioning a distal tip of the aspiration catheter proximate to the clot material;

activating a pressure source coupled to the aspiration catheter via a fluid control device, while the fluid control device is closed, to generate a vacuum in the pressure source; and
opening the fluid control device to apply the vacuum to the aspiration catheter to thereby aspirate at least a portion of the clot material into the aspiration catheter.

18. The method of claim 17 wherein actuating the handle to deflect the distal portion of the aspiration catheter includes deflecting the distal portion of the aspiration catheter away from the longitudinal axis in a deflection direction, and wherein the method further comprises rotating the aspiration catheter such that the deflection direction is at least partially aligned with a bend in the blood vessel.

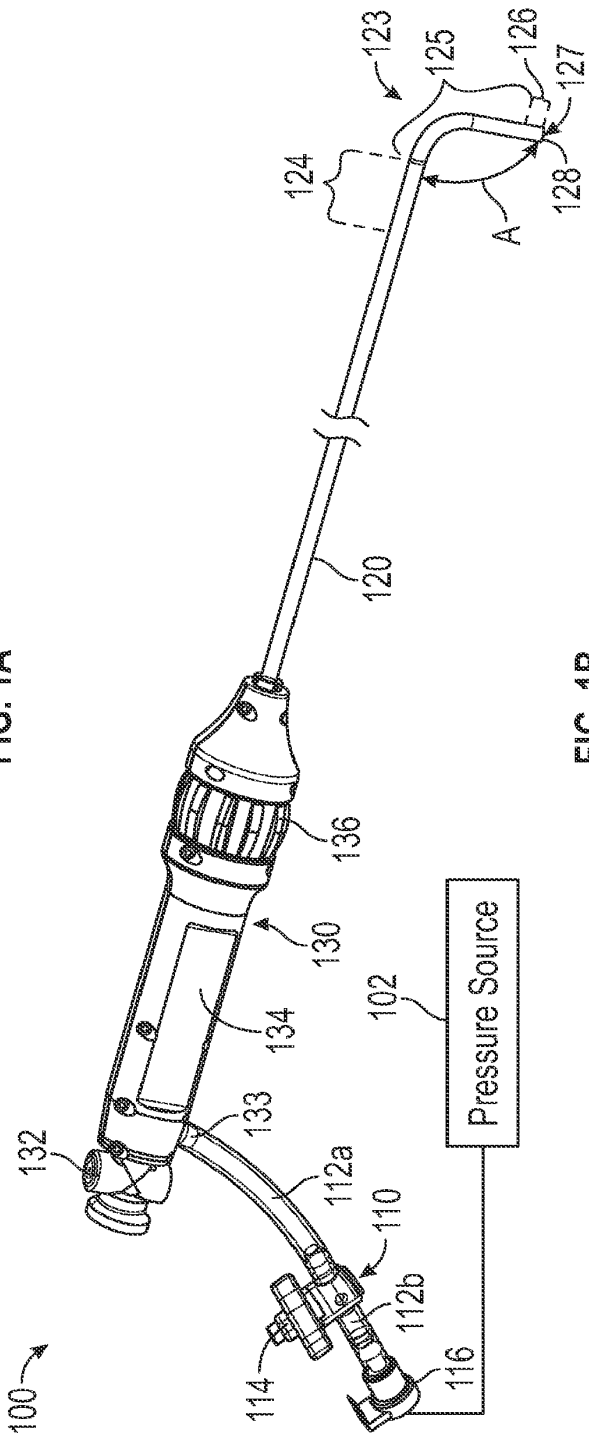
19. The method of claim 17 wherein the aspiration catheter has a size of 20 French or greater.

20. The method of claim 17 wherein the aspiration catheter includes a deflectable member positioned in the distal portion, and wherein actuating the handle includes rotating an actuator of the handle to pull a pull wire coupled to the deflectable portion proximally to deflect the deflectable member to deflect the distal portion of the aspiration catheter.



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FIG. 1A



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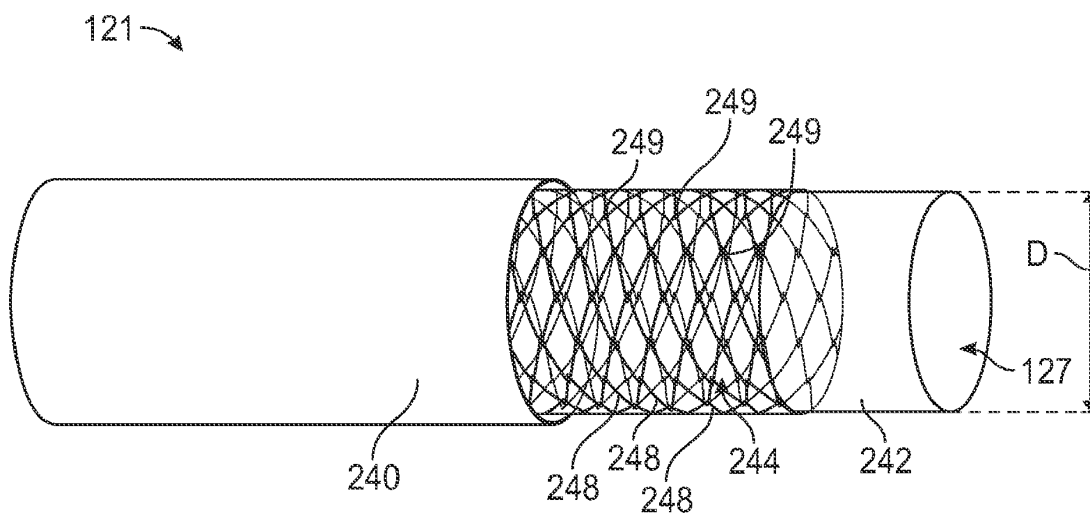


FIG. 2

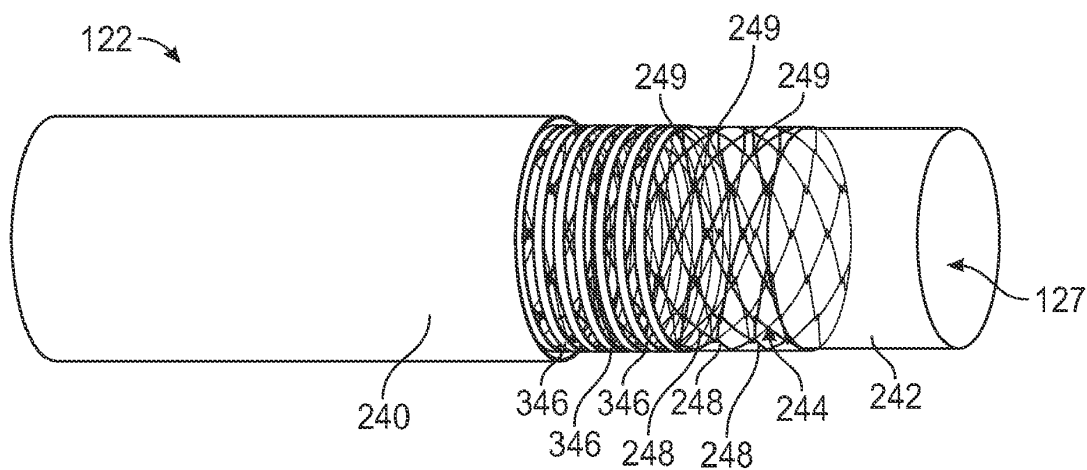


FIG. 3A

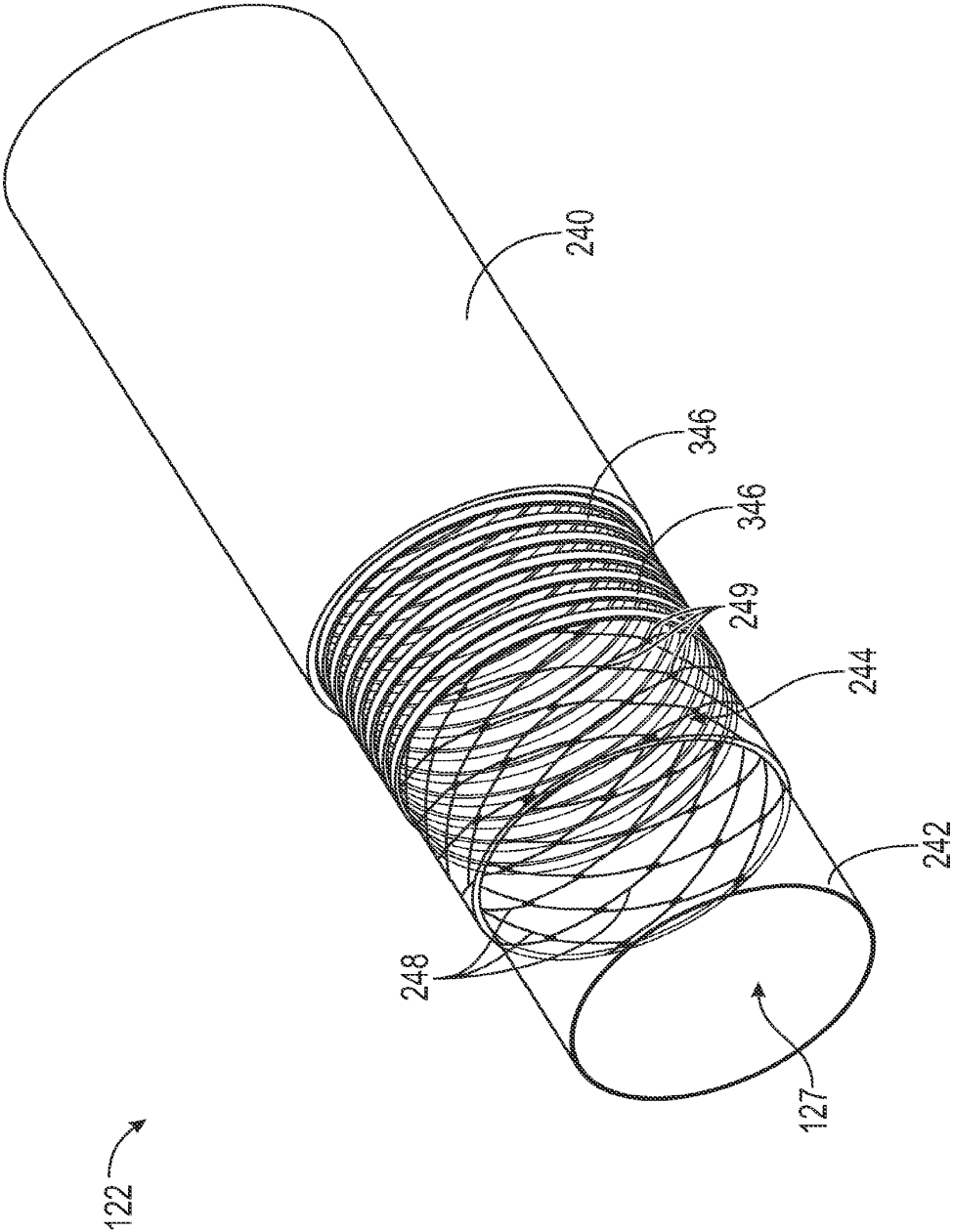


FIG. 3B

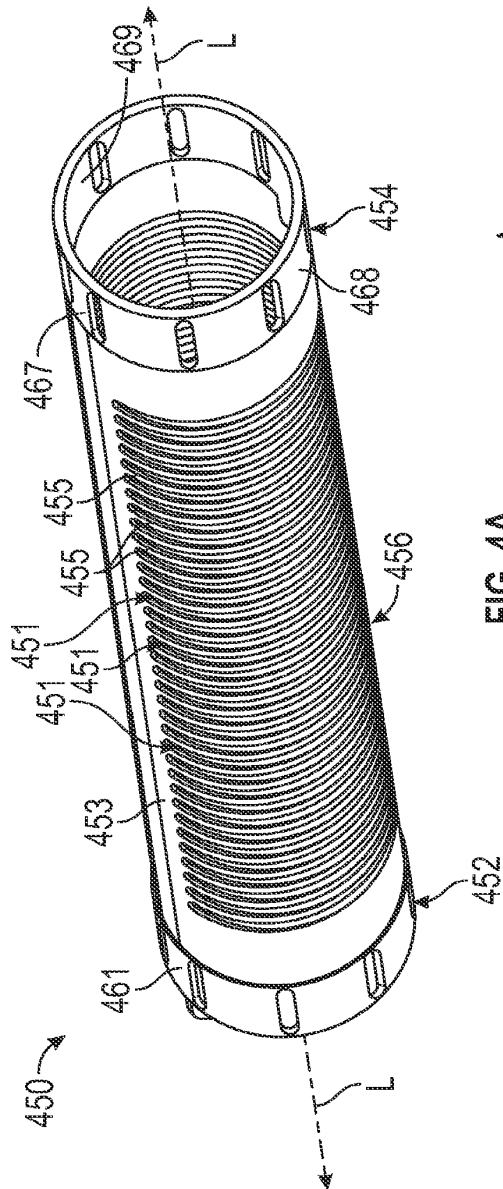


FIG. 4A

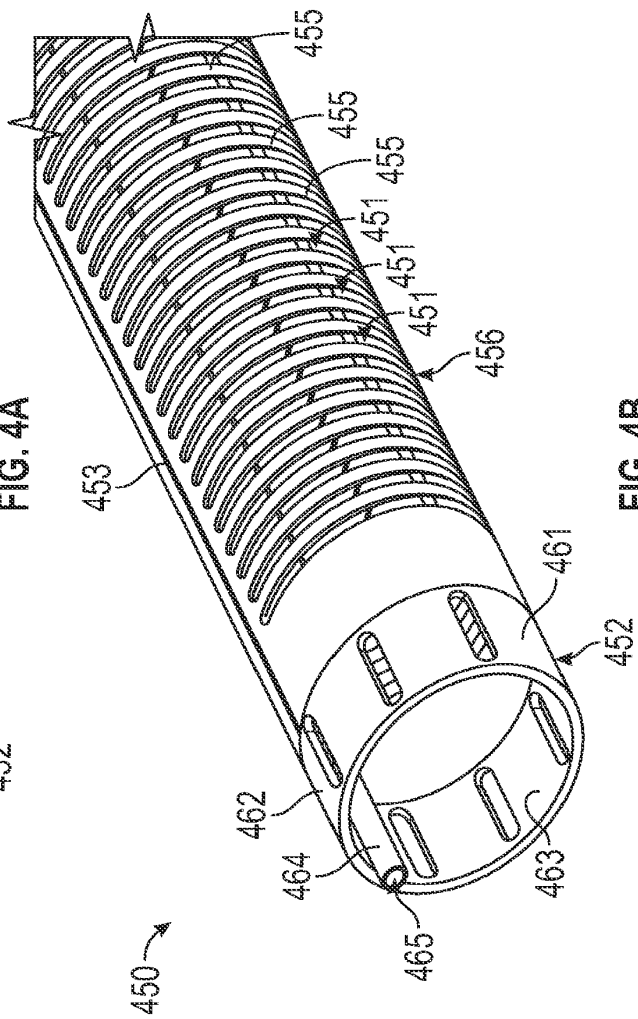


FIG. 4B

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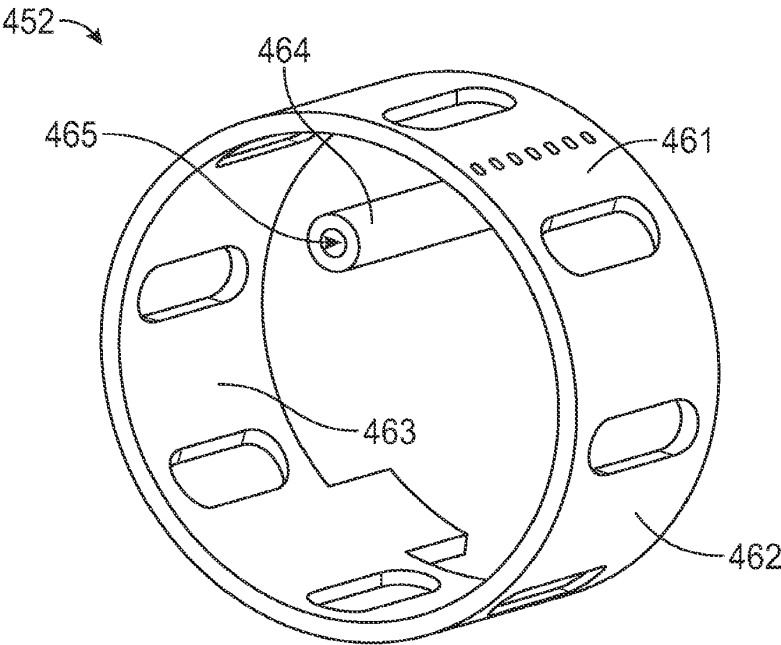


FIG. 4C

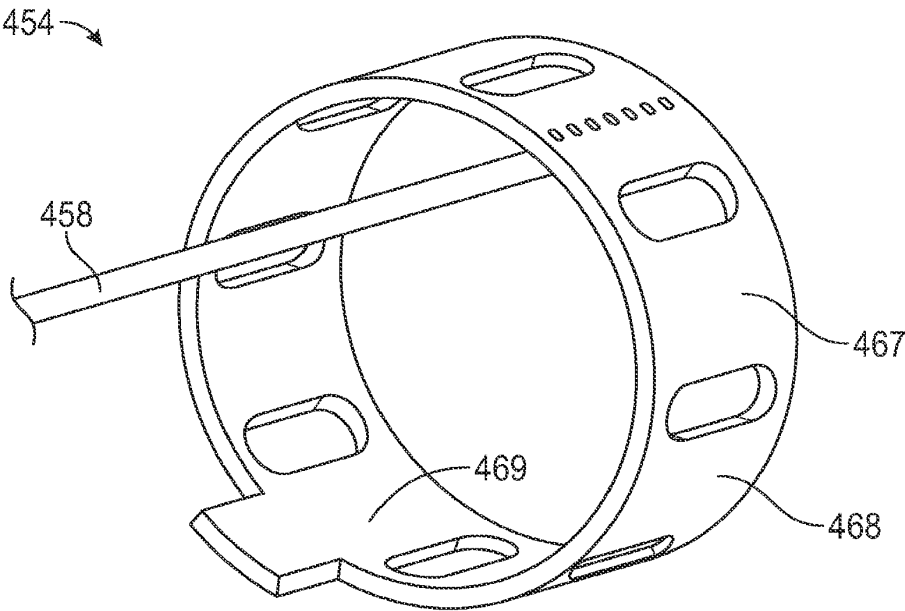


FIG. 4D

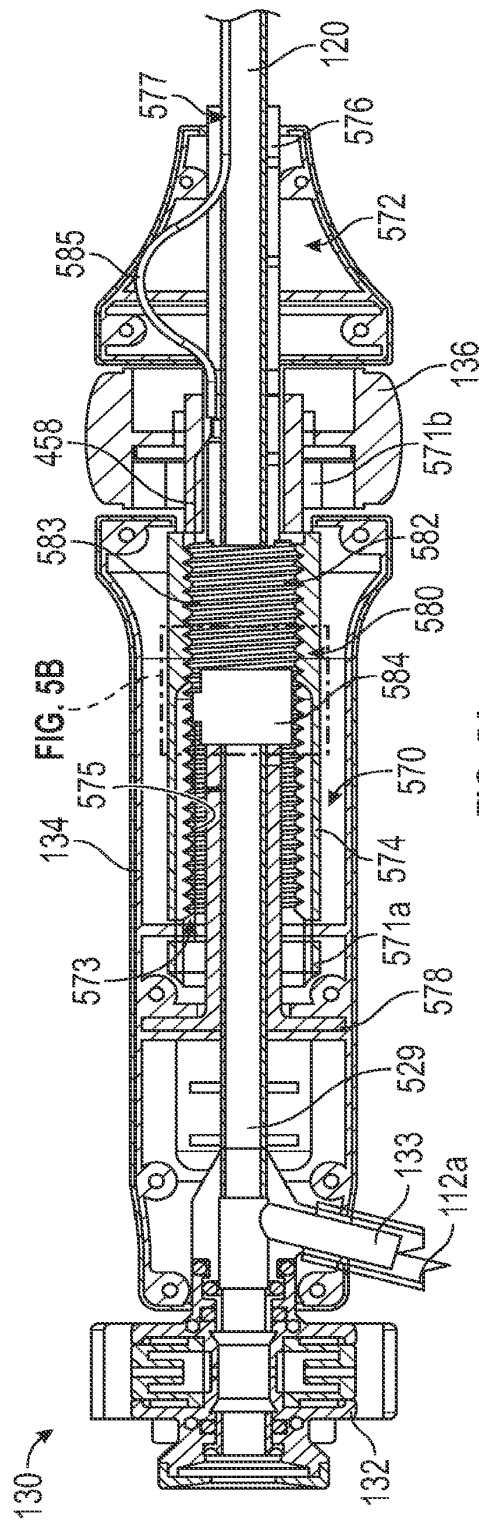


FIG. 5A

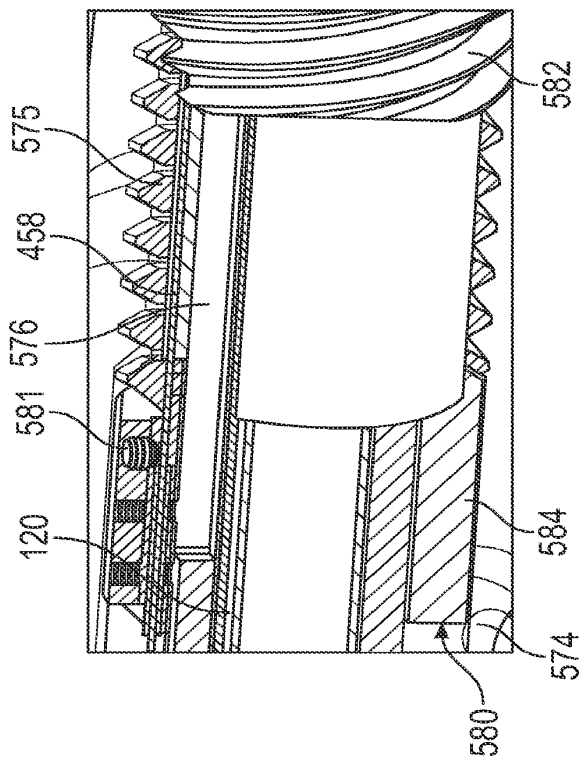


FIG. 5B

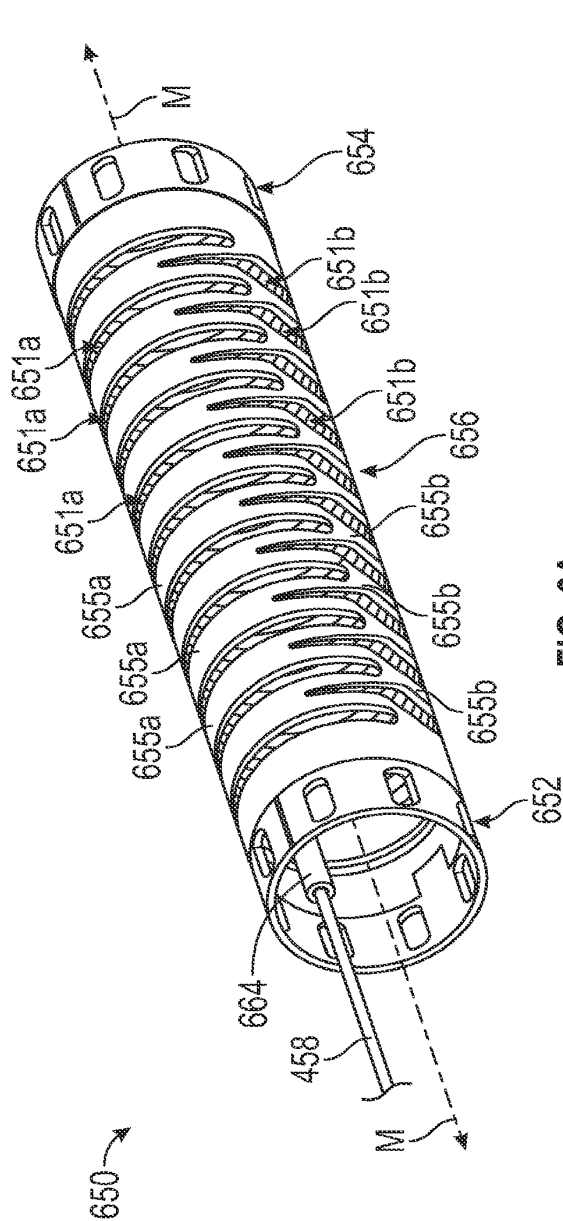


FIG. 6A

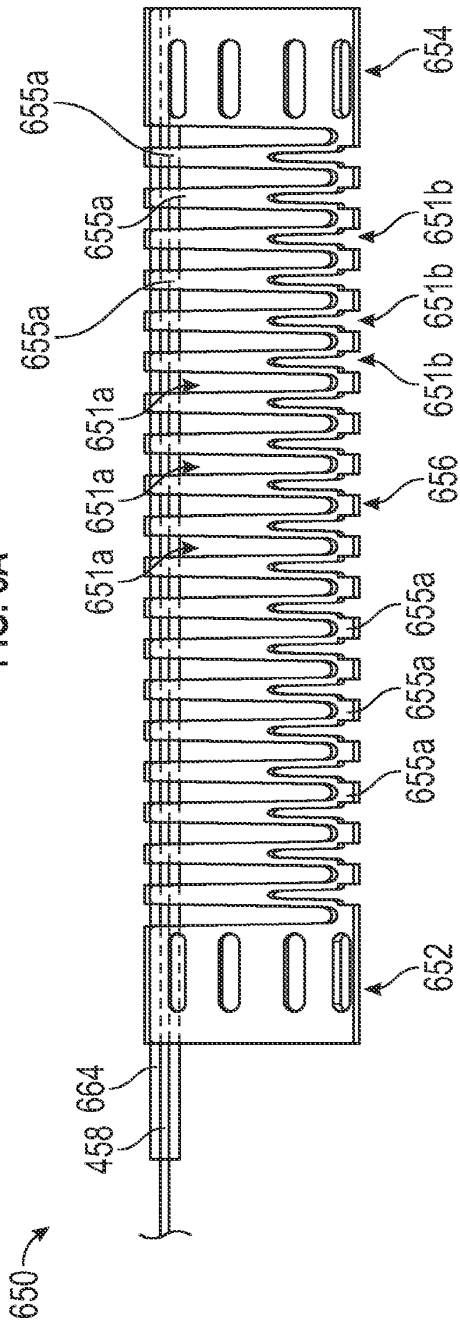
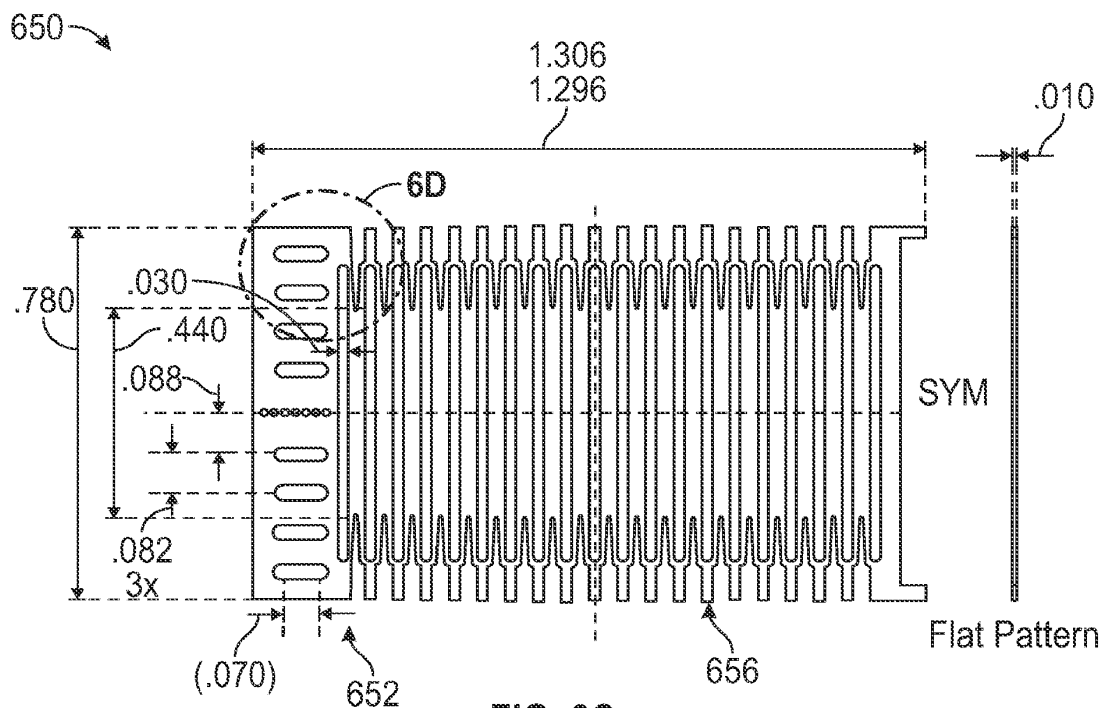
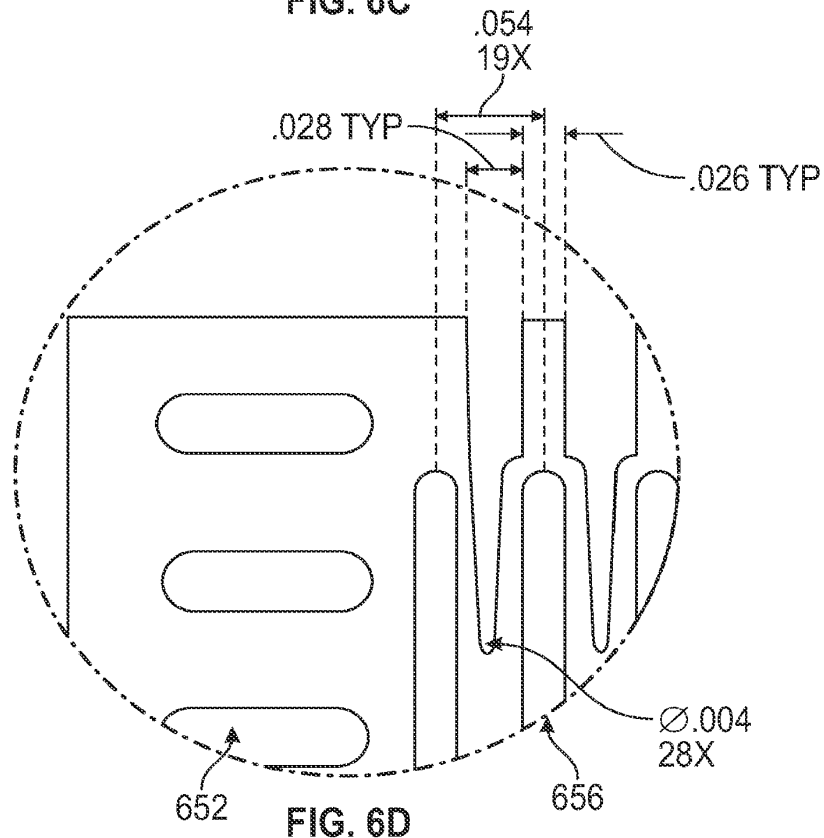


FIG. 6B

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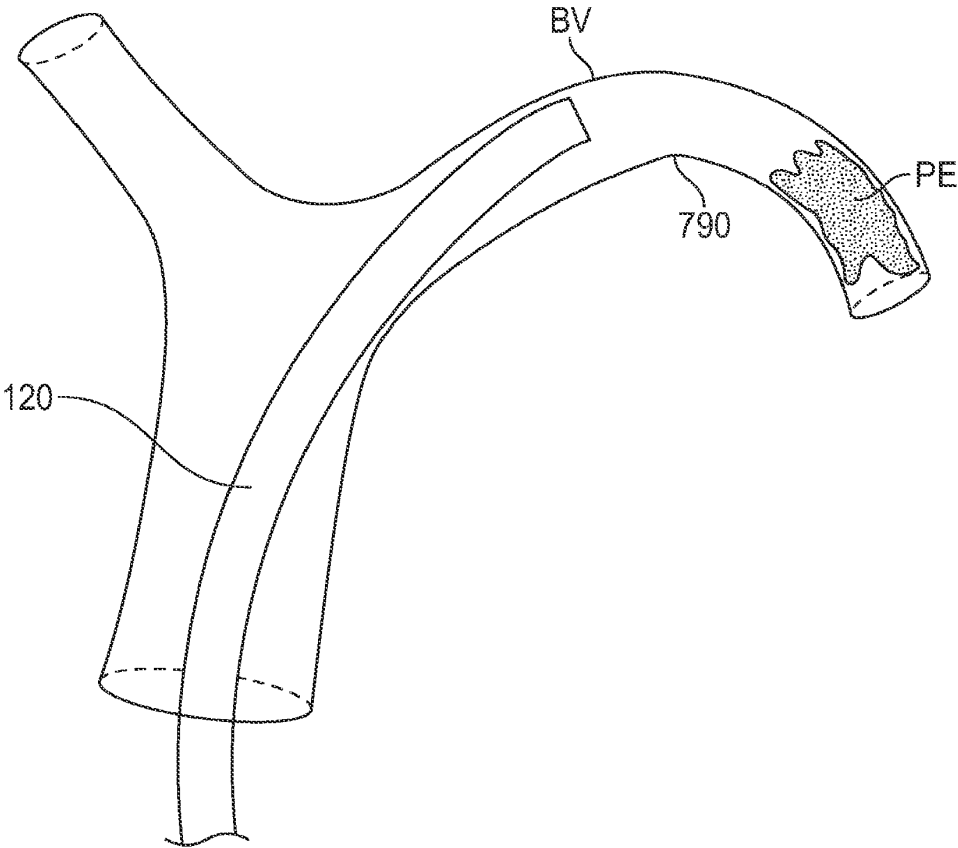


FIG. 7A

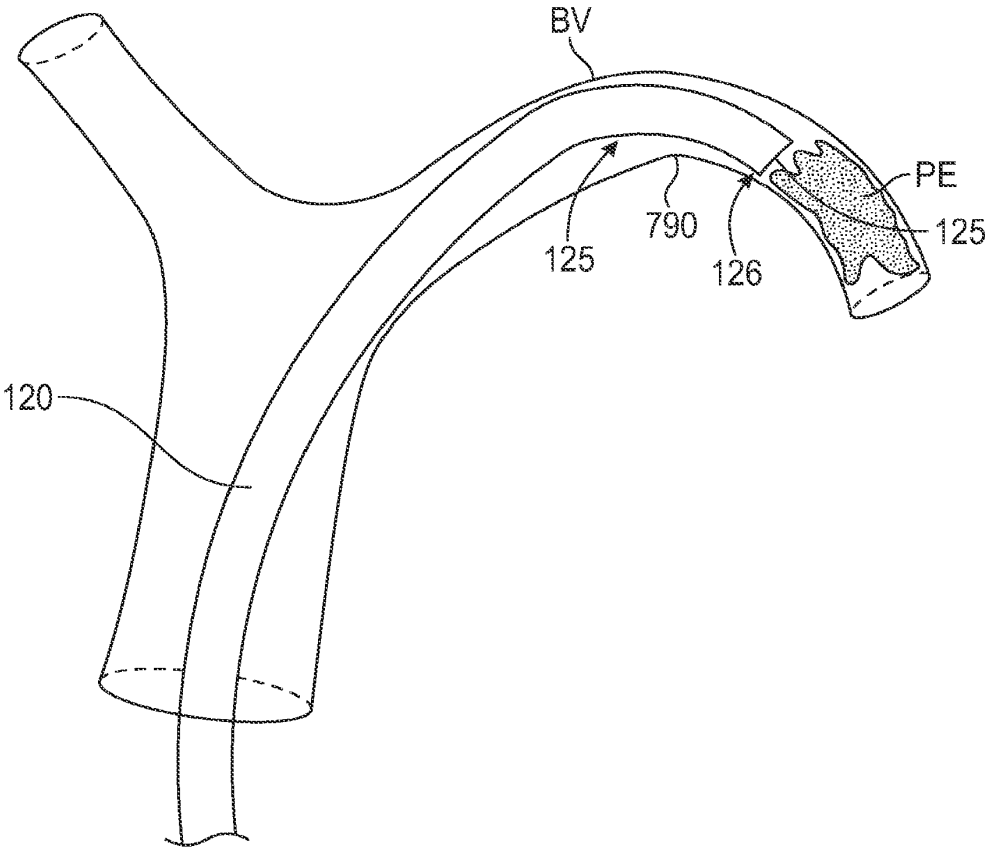


FIG. 7B

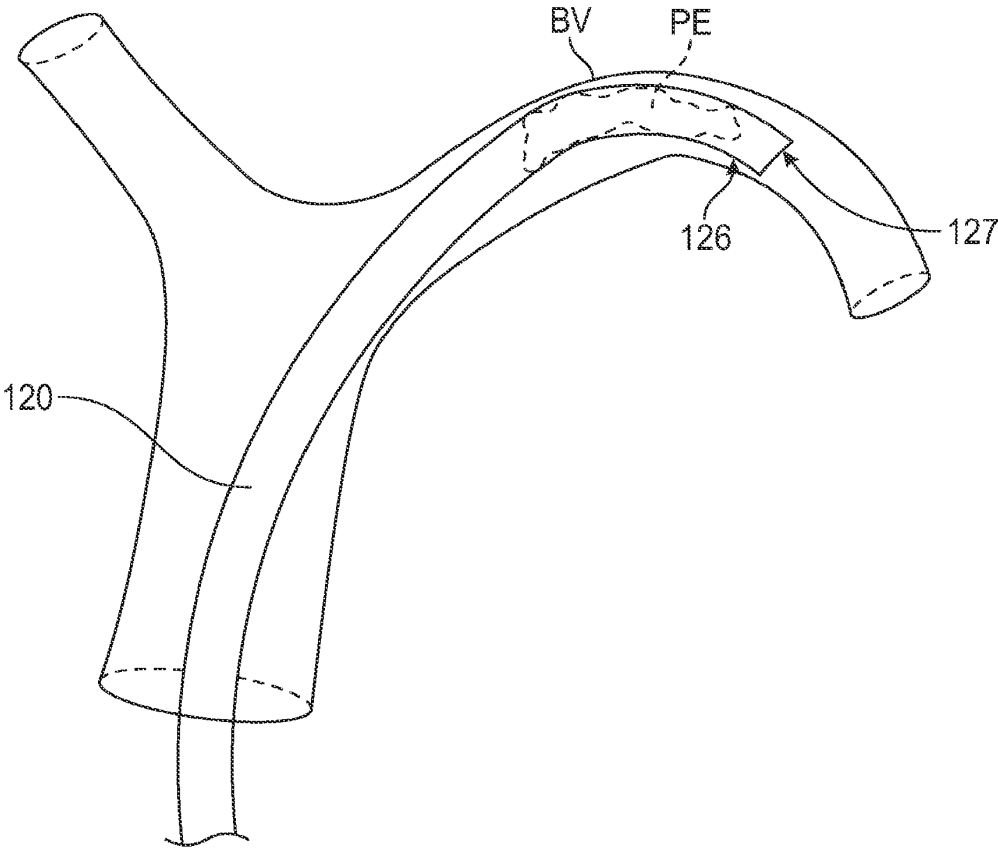


FIG. 7C

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 21/59735

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

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

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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

This International Searching Authority found multiple inventions in this international application, as follows:
This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I: Claims 1-7 directed to a proximal ring; a distal ring and a tube portion.

Group II: Claims 8-20 directed to a handle and an actuator.

-*-Continued in Supplemental Box-*-

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-7

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

Form PCT/ISA/210 (continuation of first sheet (2)) (July 2019)

INARI_019187

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 21/59735

A. CLASSIFICATION OF SUBJECT MATTER

IPC - A61M 25/00 (2022.01)

CPC - A61M 25/0147; A61M 25/0138

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

See Search History document

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

See Search History document

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

See Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2019/246240 A1 (INTUITIVE SURGICAL OPERATIONS, INC.) 26 December 2019 (26.12.2019), entire document, especially Fig 4A, 4C; para [0071]-[0084]	1-3, 6-7
Y		4-5
Y	US2010/0016837 A1 (Howat) 21 January 2010 (21.01.2010), entire document, especially Fig 1-8; para [0034]-[0042]	4-5
A	US 2004/0138525 A1 (Saadat et al.) 15 July 2004 (15.07.2004), entire document	1-7
A	US 2020/0113412 A1 (AMBU A/S) 16 April 2020 (16.04.2020), entire document	1-7
A	US 2009/0192495 A1 (Ostrovsky et al.) 30 July 2009 (30.07.2009), entire document	1-7

☐ Further documents are listed in the continuation of Box C.☐ See patent family annex.

* Special categories of cited documents:

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

"D" document cited by the applicant in the international application

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

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search

20 February 2022

Date of mailing of the international search report

MAR 22 2022

Name and mailing address of the ISA/US

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Form PCT/ISA/210 (second sheet) (July 2019)

INARI_019188

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 21/59735

-Box No. III - Observations where unity of invention is lacking-

The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

SPECIAL TECHNICAL FEATURES

The Invention of Group I includes the special technical feature of a proximal ring; a distal ring configured to be fixedly attached to a pull wire; and a tube portion extending between the proximal and distal rings, wherein the tube portion includes a plurality of openings extending therethrough to define a plurality of ribs, and wherein the ribs are configured to flex away from each other when the pull wire is pulled proximally, not required by Group II.

The invention of Group II includes the special technical feature of a handle coupled to the proximal region of the aspiration catheter, wherein the handle includes an actuator; and pull wire extending between the actuator and the deflectable member, wherein actuation of the actuator is configured to pull the pull wire, not required by the claims of Group I.

COMMON TECHNICAL FEATURES

Groups I-II share the common technical features of an aspiration catheter including a proximal region and a distal region, wherein the distal region includes a deflectable member; and a pull wire configured to deflect the deflectable member to deflect the distal region of the aspiration catheter relative to the proximal region. However, this shared technical feature does not represent a contribution over prior art as being anticipated by US 2004/0138525 A1 to Saadat et al. (hereinafter "Saadat"), which discloses an aspiration catheter (30; Fig 21A-21B; para [0097]; see analogous Fig 41, para [0125] describing tool arm 30 used for aspiration, wherein the tool arm 30 is interpreted as an aspiration catheter) including a proximal region (proximal half of 30; Fig 21A-21B; para [0097]; the proximal half of 30 being the bottom-most half of the entire tool arm 30 in the orientation shown in Fig 21A) and a distal region (distal half of 30; Fig 21A-21B; para [0097]; the distal half of 30 being the top-most half of the entire tool arm 30 in the orientation shown in Fig 21A), wherein the distal region includes a deflectable member (portion of 30 from bottom slot 132 to the distal-most end of 30; Fig 21A-21B; para [0097]); and a pull wire configured to deflect the deflectable member to deflect the distal region of the aspiration catheter relative to the proximal region (96; Fig 21A-21B; para [0097]; pullwire 96 is shown to be attached to the portion of 30 extending distally from distal-most slot 132 via fixation point 104 wherein pulling the pullwire 96 causes the distal tip of tool arm 30 to deflect relative to the proximal region of tool arm 30).

As the common technical features were known in the art at the time of the invention, these cannot be considered special technical feature that would otherwise unify the groups.

Therefore, Groups I-II lack unity under PCT Rule 13 because they do not share a same or corresponding special technical feature.

(19) 中华人民共和国国家知识产权局



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(51) Int. Cl.

A61B 17/22(2006. 01)

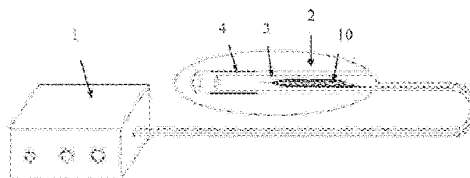
权利要求书1页 说明书4页 附图5页

(54) 发明名称

血管取栓系统

(57) 摘要

本发明提供一种血管取栓系统。所述取栓系统包括导引导丝、推拉导丝、外鞘管、能够相对于外鞘管移动的内管和取栓器,导引导丝穿过内管,内管则被套在外鞘管内,且内管能够沿着导引导丝移动,该取栓器与推拉导丝相连,安装好的推拉导丝和取栓器被压握入内管内,且所述取栓器能够通过推拉导丝推拉而在收回位置和展开位置之间转换,在收回位置,取栓器被回收至内管内,在展开位置,取栓器被推出内管。所述取栓系统还包括抽吸装置,该抽吸装置与内管相连通,且内管上设有抽吸孔。根据本发明的取栓系统,既可以方便的捕捉大块血栓,又可以通过抽吸防止小块血栓的脱落,解决了血管远端血管再次栓塞的问题,同时有效减少了取栓后并发症的概率。



CN 104068910 A

INARI_019190

1. 一种取栓系统,其特征在于,其包括导引导丝、推拉导丝、外鞘管、能够相对于外鞘管移动的内管和取栓器,导引导丝穿过内管,内管则被套在外鞘管内,且内管能够沿着导引导丝移动,该取栓器与推拉导丝相连,安装好的推拉导丝和取栓器被压握入内管内,且所述取栓器能够通过推拉导丝推拉而在收回位置和展开位置之间转换,在收回位置,取栓器被回收到内管内,在展开位置,取栓器被推出内管,所述取栓系统还包括抽吸装置,该抽吸装置与内管相连通,且内管上设有抽吸孔。

2. 根据权利要求 1 所述的取栓系统,其中取栓器包括外层支架和内层支架,内外层支架均构成为网状,且外层支架包覆在内层支架外,两者之间形成间隙。

3. 根据权利要求 2 所述的取栓系统,其中外层支架与内层支架在近端相连接或在近端和远端均相连接。

4. 根据权利要求 2 或 3 所述的取栓系统,其中内外层支架的近端和 / 或远端具有椭圆形开口或圆形开口,或为封闭的。

5. 根据权利要求 1-3 中任一项所述的取栓系统,其中推拉导丝与取栓器的牵引连接点布置成在展开位置贴近血管壁。

6. 根据权利要求 1-3 中任一项所述的取栓系统,其中取栓器在展开位置整体呈近似圆柱形。

7. 根据权利要求 1-3 中任一项所述的取栓系统,其中取栓器被构造有内凹和 / 或外凸的结构。

血管取栓系统

技术领域

[0001] 本发明涉及医疗器械,具体涉及一种介入血管的医疗器械,特别涉及一种血管取栓系统。

背景技术

[0002] 血管内血栓是临床上的常见病和多发病,而颅内血栓又是重中之重,它造成脑栓塞,具有发病率高、致残率高、死亡率高和复发率高的特点,是中老年人致死和致残的主要疾病。而随着老年人口的不断增加和生活水平的提高,脑血管病的发病率在不断升高。根据调查,我国目前每年有 300 万的新增脑血栓群体,而急性脑血栓占脑卒中的比例也由 55.8% 上升到 81.6%,成为脑部第一大疾病。

[0003] 血管的再通是治疗急性缺血性脑卒中的关键。目前颅内血栓的治疗方法主要有两种:药物溶栓和机械取栓。

[0004] 药物溶栓治疗是把溶栓剂注入病变所在的血管内的病灶附近,在病灶局部瞬间地形成很高的溶栓剂浓度,加快血栓溶解速度,进而增加血管再通的机会。但是,根据美国国立神经疾病与卒中研究院(NINDS)的研究结果,静脉溶栓应在发病 3 小时内进行,动脉溶栓时间窗为 6 小时之内。由于药物溶栓治疗时间窗较短,而且溶栓治疗只适用于体积较小的血栓,其对大体积血栓栓塞的治疗效果并不理想,所以最终大约只有 3~5% 的患者适合做药物溶栓治疗。

[0005] 机械取栓是将取栓器输送至病变位置,然后通过鞘管将血栓取出至体外。机械取栓包括以下几种方法:捕捉取栓、抽吸取栓、旋切取栓等。捕捉取栓在取大块血栓时效果最好,但是容易造成血管壁上的斑块和破碎的血栓块脱落后流向远端血管造成新的栓塞;抽吸取栓在取小块栓子时效果较好,在取大块血栓时为了防止堵塞抽吸管需要反复捣碎血栓后再抽吸,过程麻烦而且很容易伤到血管;旋切取栓对血管壁造成的损伤较大,很容易引起并发症。

[0006] 中国实用新型专利 CN201020104685.1 公开了一种用于人体血管内血栓抽吸导管,其包括依次连接的管座、加强管、单腔管、双腔管、尖端管和显影标记。该取栓系统在抽吸腔的远端有 1-4 个开孔,增加了导管的通过性和血栓抽吸能力,并减小在手术过程中对人体血管的损伤,同时提高导管的跟踪性和推送性。

[0007] 中国发明专利申请 CN201110222609.X 和中国实用新型专利 CN201120281795.X 公开了一种血栓抽吸导管,其包括抽吸管,所述抽吸管包括管座,所述管座连接导管,所述抽吸管的外壁上可活动的套设有套管,所述套管包括 Y 型连接头、双腔管及球囊,所述 Y 型连接头连接双腔管,球囊设置于双腔管的远端外壁上,所述抽吸管内可插入干扰金属丝,所述干扰金属丝的远端可伸出抽吸管的远端外。该取栓系统可以快速清除散布在血管广泛区域的血栓及处理冠脉末梢微血管的栓塞,而且当遇到体积大及高黏稠的血栓时,可利用干扰金属丝打散血栓后再进行抽吸。

[0008] 美国专利申请 US2010/0049147A1 公开了另外一种血栓抽吸导管。美国专利申请

US2007/0161963A1 也公开了一种血栓切除术抽吸导管系统。

[0009] 上述抽吸取栓系统在取小块栓子时效果较好,但是在取大块血栓时为了防止堵塞抽吸管需要反复捣碎血栓后再抽吸,过程麻烦而且很容易伤到血管。

[0010] 中国发明专利申请 01114889.6 公开了一种可用于颅内血管的可回收血栓临时滤器,其由过滤器、导向头、导引杆、连接件和外鞘组成,其中过滤器由形状记忆合金丝编织而成。美国专利申请 2011/0160763 也公开了一种可用于颅内血管的取栓装置,其包括骨架,骨架可由形状记忆合金丝编织而成,以捕获血栓。

[0011] 上述取栓系统在捕获血栓之后回收时,血栓固定不牢固、容易脱落,而且结构复杂。

[0012] 此外,利用目前的取栓装置,在取栓过程中血管壁上的斑块和破碎的血栓块很容易脱落,流向远端血管,造成新的栓塞。据报道,约有 70% 的血管介入取栓手术中观察到了有血栓碎片和碎块流向远端血管,这增加了患者血管再栓塞的风险。

[0013] 因此,需要一种改进的血管取栓装置,这种装置应满足以下几个条件:1)取栓过程简单、方便;2)柔顺性好,捕获率高,支撑力适中,取栓过程中不会损伤血管内壁;3)在捕获血栓之后回收时,血栓固定牢固、不易脱落。总之,既要具有良好的取栓效果,又要能够有效防止小血栓的脱落同时又不会损伤血管造成严重的并发症。

发明内容

[0014] 有鉴于此,本发明提供了一种改进的取栓系统,该系统解决了现有技术中存在的血管壁斑块和碎血栓块容易脱落而造成远端血管再次栓塞的问题,而且柔顺性好、捕获率高。

[0015] 根据本发明的一方面,本发明提出一种血管取栓系统,其包括导引导丝、推拉导丝、外鞘管、能够相对于外鞘管移动的内管和网状取栓器,导引导丝穿过内管,内管则被套在外鞘管内,且内管能够沿着导引导丝移动,该取栓器与推拉导丝相连,安装好的推拉导丝和取栓器被压握入内管内,且所述取栓器能够通过推拉导丝推拉而在收回位置和展开位置之间转换,在收回位置,取栓器被回收至内管内,在展开位置,取栓器被推出内管,所示取栓系统还包括抽吸装置,该抽吸装置与内管相连通,且内管上设有抽吸孔。本发明的取栓系统将捕捉取栓与抽吸取栓相结合,既可以方便的捕捉大块血栓,又可以通过抽吸防止小块血栓的脱落,解决了血管远端血管再次栓塞的问题,同时有效减少了取栓后并发症的概率。

[0016] 根据本发明的优选实施例,外鞘管在远端还设有可膨胀封堵球囊。

[0017] 根据本发明的优选实施例,内管上设有 1~4 个抽吸孔,这些抽吸孔可以是导管远端的开口,也可以是导管侧壁上的开孔。开口和开孔的形状可以是圆形、椭圆形或其他形状。开孔可以对称分布、间隔分布或随机分布。

[0018] 根据本发明的优选实施例,取栓器既可以通过激光切割金属管材、片材而获得,也可以通过金属丝编织而获得,其中金属管、片、丝材可以是镍钛合金、钴镍合金、不锈钢等。这样使取栓器的柔顺性和贴壁性良好。

[0019] 另外,优选地,取栓器的近端和远端均可以是开口的或封闭的。取栓器整体还可以是近似圆柱状、内凹状或外凸状等。取栓器还可以是单层结构,或是双层或多层结构。

[0020] 根据本发明的优选实施例,取栓器整体长度为 15~60mm,直径为 2~6mm,壁厚为

0.04 ~ 0.12mm。

[0021] 优选地, 推拉导丝与取栓器的牵引连接点布置成在展开位置贴近血管壁。这样可以提高大体积血栓的有效捕获率。

[0022] 优选地, 取栓器在展开位置整体呈近似圆柱形。这样使取栓器具有良好的径向支撑力, 从内管中释放到血管后具有较好的血管贴壁性。

[0023] 取栓时, 通过血管造影确定血栓的位置, 然后把内管输送至栓塞处远端, 回撤内管, 将取栓器从血栓中间释放, 利用封堵球囊在远端封堵住血管, 然后先回撤取栓器进入内管中, 之后再打开抽吸装置进行抽吸。然后, 关闭抽吸装置, 将内管向远端移动 5 ~ 20mm, 之后再次打开抽吸装置抽吸剩余小块血栓, 然后关闭抽吸装置。最后, 将内管收进外鞘管内, 撤出体外。

[0024] 根据本发明的血管取栓系统, 可以有效捕获斑块和血栓碎片, 增加了血栓捕获稳定性, 防止了血栓脱落, 从而降低再栓塞的风险。另外, 本发明的血管取栓系统结构简单, 取栓过程方便容易。

附图说明

[0025] 通过下面参照附图对本发明实施例进行的详细描述, 本发明的特征及其优点将是显而易见的。在图中:

[0026] 图 1 是本发明实施例的取栓系统的总体示意图。

[0027] 图 2-9 是本发明的内管的实施例的示意图。

[0028] 图 10-20 显示了本发明的取栓器的实施例的示意图。

具体实施方式

[0029] 下面参照图 1-20 详细描述本发明的实施例。

[0030] 为了便于描述, 以下描述使用了术语“近端”和“远端”, 其中“近端”指的是离操作端近的一端, 远端指的是远离操作端的一端。

[0031] 如图 1 所示, 取栓系统包括抽吸装置 1、外鞘管 2、内管 3 和取栓器 10 组成。取栓器 10 为网状并与取栓系统的推拉导丝(未示出)相连, 安装好的推拉导丝和取栓器 10 被压握入内管 3 内。取栓器 10 可通过推拉导丝的推拉而在收回位置和展开位置之间转换, 在收回位置, 取栓器 10 收回到内管 3 内, 在展开位置, 取栓器 10 被推出到内管 3 外。另外, 取栓系统还包括导引导丝(未示出), 导引导丝穿过内管 3, 用以在血管内引导取栓系统。外鞘管 2 在远端处设有可膨胀封堵球囊 4。

[0032] 此外, 取栓器 10 上还设有显影标记(未示出), 以帮助定位取栓器 10。可以理解的是, 内管 3 和外鞘管 2 上也可以设有显影标记。

[0033] 内管上设有 1 ~ 4 个抽吸孔, 这些抽吸孔可以仅是内管远端的开口, 如图 2 和 6 所示, 也可以是在远端开口基础上在导管侧壁上再开一些抽吸孔, 如图 3 ~ 5 和图 7 ~ 9 所示。开口和开孔可以是圆形、椭圆形或其他形状, 可以单独、对称、间隔或随机分布。

[0034] 取栓器可以是单层结构, 如图 10 ~ 14 的取栓器 10 所示。取栓器 10 的近端和远端均可以是封闭的或开口的。另外, 如图 14 所示, 取栓器 10 可以构造有外凸和内凹结构。

[0035] 取栓器也可以是双层结构。如图 15 ~ 20 所示。取栓器 10' 为支架套支架结构,

整体呈近似圆柱形,其包括两部分,即内层支架 20 和外层支架 30,其中内外层支架均构成为网状,外层支架包覆在内层支架外,且两者之间留有间隙。取栓器 10' 的内外层的近端远端可以是只近端连接,如图 16、17、19 和 20 所示,也可以是近远端都连接,如图 15 和 18 所示。连接可以是焊接连接、利用金属套管连接或利用金属丝缠绕连接等。

[0036] 当然,取栓器也可以是多层结构。

[0037] 取栓器通过激光切割具有形状记忆效应的金属管材(如镍铁合金等)而形成并经热处理定型。当然,取栓器也可以通过切割具有形状记忆效应的金属片材,然后卷曲,热处理定型而形成。取栓器的合适尺寸如下:长度为 15 ~ 60mm,直径为 2 ~ 6mm,壁厚为 0.04 ~ 0.12mm。也可以用高弹性的高分子材料来代替金属材料。上述合适的材料是本领域技术人员所熟知的,在此不再详细描述。

[0038] 推拉导丝与取栓器的牵引连接点布置为在展开位置贴近血管壁。这样可提高大体积血栓的有效捕获率。

[0039] 本发明的取栓系统的使用方法如下。

[0040] 介入治疗时,首先通过血管造影确定血管病变位置,然后将取栓装置 1 导入血管内,使导引导丝穿过病变位置,再使内管 3 沿导引导丝穿过病变位置并通过内管 3 上的显影标记(未示出)定位,期间取栓器 10 一直位于内管 3 内,处于收回位置。然后,回撤导引导丝,通过推拉导丝将取栓器 10 推到内管 3 远端,回撤内管 3 至病变位置,将取栓器 10 释放,通过取栓器 10 上的显影标记可定位取栓器 10。由于形状记忆金属的形状记忆效应或高弹性高分子材料的弹性作用,取栓器 10 在血液温度的作用下转换到展开位置,贴靠血管壁。然后,利用封堵球囊 4 在远端封堵住血管,拉动推拉导丝,回撤取栓器 10 捕获血栓,直至将取栓器 10 收回到内管 3 内。然后,打开抽吸装置 1 进行抽吸,之后关闭抽吸装置,接着将内管向远端移动 5 ~ 20mm,之后再次打开抽吸装置抽吸剩余小块血栓,然后关闭抽吸装置。再将内管 3 收回到外鞘管 2 中。最后,将取栓装置 1 整体撤出人体外,完成取栓过程。

[0041] 采用目前的取栓系统取栓时,血管壁上的斑块和破碎的血栓块很容易因外力作用破碎脱落,流向远端血管而造成新的栓塞,增加患者的手术风险。本发明的设计将捕捉血栓与抽吸取栓这两种方式相结合,在取栓时可以通过抽吸将脱落的小块血栓吸入抽吸管,同时通过捕获可以将大体积的血栓拉入抽吸管,避免了捕获取栓时小块血栓易脱落和抽吸取栓时不易捕获大块血栓的缺点,且操作方便,再通率高。

[0042] 本发明的取栓系统可适合于颅内血管取栓,也可以适合于其它血管内取栓。本领域技术人员可以理解,以上描述只是示例性的。在不背离本发明的思想和范围的情况下,本领域技术人员仍可以对本发明作出多种修改和变化。

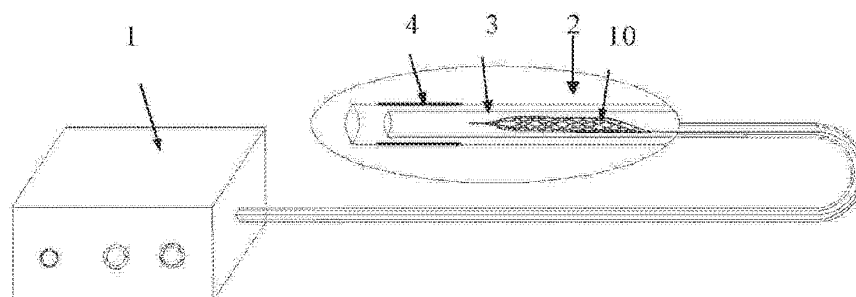


图 1



图 2

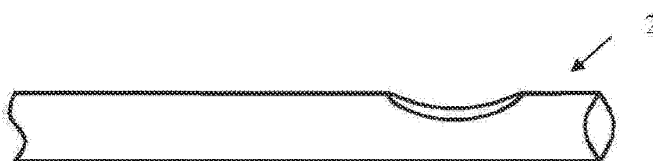


图 3



图 4

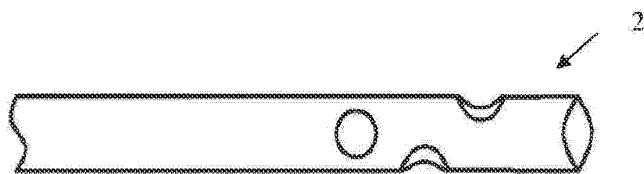


图 5

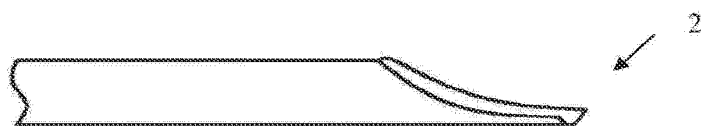


图 6



图 7

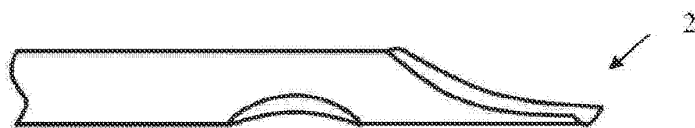


图 8



图 9

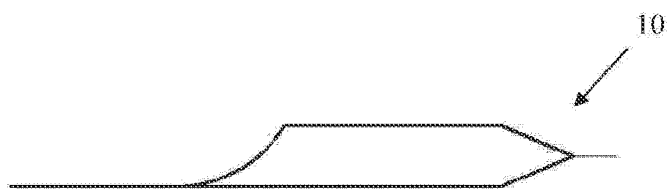


图 10

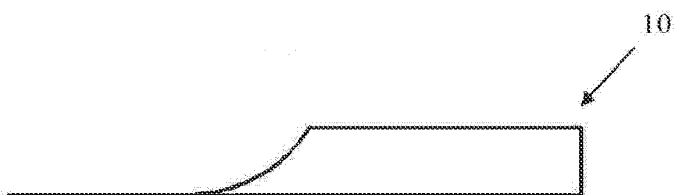


图 11



图 12

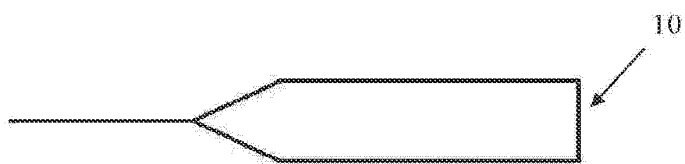


图 13

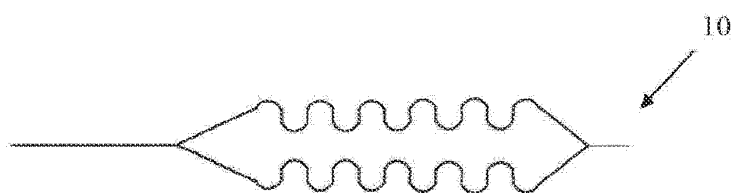


图 14

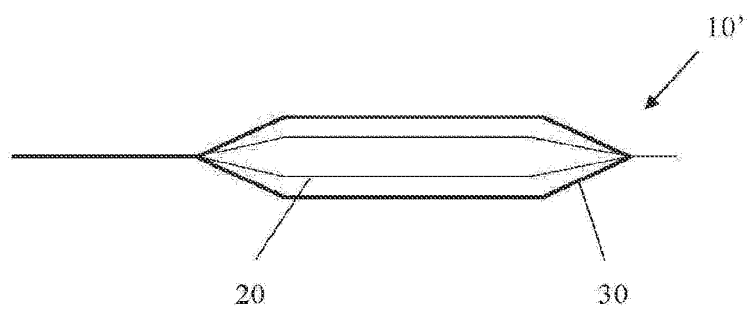


图 15

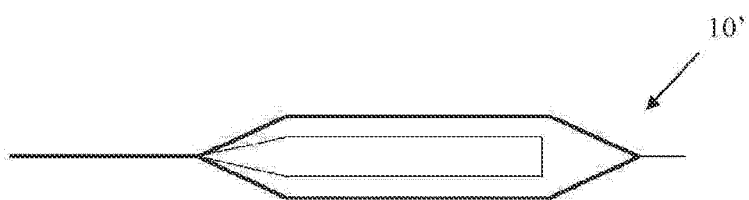


图 16

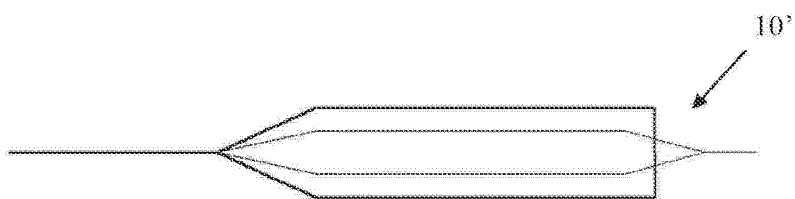


图 17

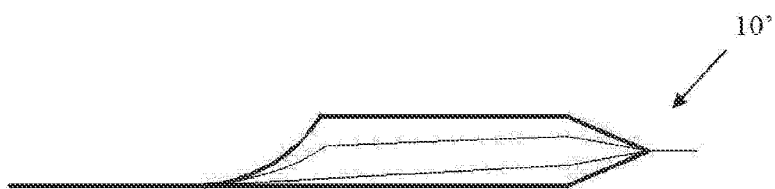


图 18

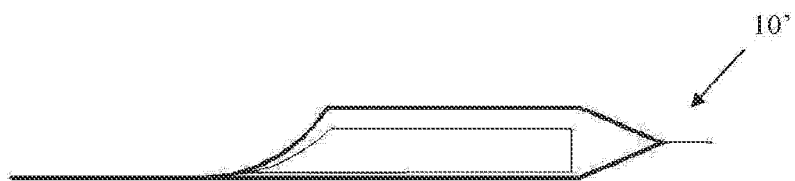


图 19

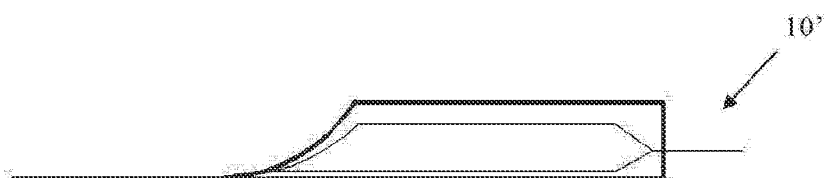


图 20



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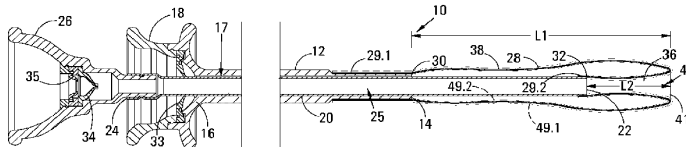


FIG 4

(57) Abstract: This invention relates to a gripping device (10), e.g. a surgical retrieval device. The device includes an invertible tubular member (28), which is composed of interengaged stitches of resiliently flexible filamentary material and which is progressively transformable between an everted condition and an inverted condition. The device includes also actuation means (12, 20) carrying the invertible tubular member and operable for effecting progressive inversion and eversion of the invertible tubular member. Through progressive inversion of the invertible tubular member, an object can be gripped thereby.

WO 2012/049652 A1

**AN INVERSIBLE TUBULAR MEMBER AND A GRIPPING DEVICE INCLUDING
SUCH A MEMBER**

5 THIS INVENTION relates to an inversible tubular member and to a gripping device including such a member.

According to a first aspect of the invention there is provided an inversible tubular member which is substantially round in cross-section and progressively transformable
10 between an everted condition and an inverted condition, with a transformation end being defined intermediate an everted length and an inverted length of the inversible tubular member during such transformation and with the inverted length and the everted length defining opposite to the transformation end respectively an inverted end and an everted end of the inversible tubular member, in which:

15 the inversible tubular member is composed of interengaged stitches of resiliently flexible filamentary material;

 with the inversible tubular member at least partially inverted, the inverted length has sufficient stiffness to cause eversion of the inversible tubular member at the transformation end upon axial displacement of the inverted end towards the
20 transformation end, for a length of the inverted length up to X times an average relaxed outer diameter of the inverted length;

$$X \geq 2.0;$$

 with the inversible tubular member at least partially everted, the everted length has sufficient stiffness to cause inversion of the inversible tubular member at the
25 transformation end upon axial displacement of the everted end towards the transformation end, for a length of the everted length up to Y times an average relaxed outer diameter of the inverted length; and

$$Y \geq 2.0.$$

In a particular embodiment of the inversible tubular member of the invention:

with the inversible tubular member at least partially everted, the everted length has sufficient stiffness to cause inversion of the inversible tubular member at the transformation end upon axial displacement of the everted end towards the transformation end, for a length of the everted length up to Z times the average relaxed outer diameter of the inverted length, whilst one half of a sphere of diameter 1.5 times an average relaxed outer diameter of the inverted length is received in the inversible tubular member at the transformation end; and

$$Z \geq 2.0.$$

The applicant has found that, by suitable selection of the filamentary material, pattern of the stitches, and so forth, the following values are achievable:

$$X \geq 5.0 \text{ with the inverted length not restrained against lateral buckling;}$$

$X \geq 30$ with the inverted length restrained against lateral buckling, for example by the everted length;

$$Y \geq 50; \text{ and}$$

$$Z \geq 3.0.$$

In a particular embodiment of the inversible tubular member, it may define in the everted condition a larger outer diameter than in the inverted condition. Preferably, the inner diameter of the inversible tubular member in the everted condition is larger than its outer diameter in the inverted condition. As a result, during inversion and eversion, friction between an inverted length and an everted length of the inversible tubular member will be minimized.

The stitches may be knitted stitches of at least one length of the filamentary material.

The stitches may be plaited stitches, each defining a loop.

The filamentary material may be a monofilament material, for example a polymer such as Nylon. Alternatively, the filamentary material may be a multifilament material, for example stranded stainless steel wiring.

The filamentary material may be a superelastic material.

The filamentary material may be a shape memory material, e.g. Nitinol.

- 5 The inversible tubular member may have a substantially constant cross-section along its length in each of the inverted and everted conditions.

10 Alternatively, the inversible tubular member may have a variable diameter along its length in each of the inverted and everted conditions. Such a variable diameter may be achieved by varying the stitch size, or the number of stitches per circumferential row, along the length. Alternatively, if the properties of the filamentary material permit, a variable diameter may be achieved by heating, setting, and cooling of the filamentary material. The Applicant believes that such variable diameter may be useful in at least one envisaged application of the inversible tubular member, i.e. grabbing of an object,
15 as is described below.

20 The filamentary material may be coated in a coating of a different material. The coating may, for example, serve to alter at least one surface property of the filamentary material, for example its coefficient of friction. In the case of the filamentary material being a multifilament material, the coating may serve to bind the filaments of the multifilament material together.

According to a second aspect of the invention there is provided a gripping device including:

- 25 an inversible tubular member which is substantially round in cross-section and progressively transformable between an everted condition and an inverted condition, with a transformation end being defined intermediate an everted length and an inverted length of the inversible tubular member during such transformation and with the inverted length and the everted length defining opposite to the transformation end respectively
30 an inverted end and an everted end of the inversible tubular member, the inversible tubular member being composed of interengaged stitches of resiliently flexible filamentary material; and

actuation means carrying the inversible tubular member and operable for effecting progressive inversion and eversion of the inversible tubular member,

the inversible tubular member defining a transformation end where the progressive inversion and eversion occurs, with such inversion providing for gripping an object in the inversible tubular member.

- 5 The gripping device may be used for gripping an object, as is described below. The inversible tubular member must have rigidity sufficient for performing the method.

In the gripping device, the inversible tubular member may be an inversible tubular member, in accordance with the first aspect of the invention. Accordingly, further
10 features of the inversible tubular member of the gripping device may be the same as any of the features of the inversible tubular member of the first aspect of the invention, as described above. Also, it is envisaged that the following relationship may apply in the inversible tubular member, where X and Y are as defined above:

15
$$X \geq Y \geq 5.0$$

The applicant envisages that the gripping device of the second aspect of the invention may be used for the retrieval of loose objects from small or deep cavities where other forms of access may be difficult or impossible. It may also be used for gripping objects
20 while they are being manipulated, modified, inspected, dissected, or excised. Typical applications could include capture and manipulation/removal of objects/organs during laparoscopic surgery, capture and removal of objects from natural body orifices, and capture and manipulation/removal of objects in/from pipes or machinery.

- 25 The gripping device may include a membrane over at least a part of a surface of the inversible tubular member which is an outer surface in the everted condition. Alternatively or additionally, the gripping device may include a membrane over at least a part of a surface of the inversible tubular member which is an inner surface in the everted condition.

30

In a particular embodiment of the gripping device, the actuation means includes:

an outer tubular member defining a distal end, i.e. a front end, and a proximal end, i.e. a rear end, and a longitudinal passage extending between the distal end and the

proximal end, the distal end being peripherally attached to an everted end of the inversible tubular member; and

an inner elongate member received within the passage and defining a distal end and a proximal end, the distal end being peripherally attached to an opposite inverted
5 end of the inversible tubular member,

the outer tubular member and the inner elongate member being slidably displaceable relative to each other to effect the progressive inversion and eversion.

In the said particular embodiment, the actuation means may include:

10 a first hand grip formation on the proximal end of the outer tubular member; and
a second hand grip formation on the proximal end of the inner elongate member,
the hand grip formations being manually relatively displaceable for effecting the relative
sliding displacement of these members.

15 Still in the said particular embodiment, the inversible tubular member may be retractable into the outer tubular member.

Still in the said particular embodiment, the inner elongate member may be received within the outer tubular member in a snug sliding fit to provide sealing between these
20 members to a required pressure, which is not less than 15 mmHg. Such sealing may be required in certain medical applications of the gripping device, as envisaged by the applicant.

Alternatively, the said particular embodiment may include sealing means, for example a
25 circular sealing ring, sealing between the inner elongate member and the outer tubular member to a required pressure, which is not less than 15 mmHg.

Still in the said particular embodiment, the inner elongate member may define therethrough a longitudinal passage, permitting insertion of an elongate surgical or other
30 instrument through it. This may be required in certain medical applications, for example laparoscopic applications, of the gripping device, as envisaged by the applicant. The inner elongate member may have sealing means sealing the longitudinal passage defined therethrough, the sealing means being configured to permit passage of an elongate surgical or other instrument through it and to seal around the instrument. The

sealing means may, for example, include a duckbill for sealing the longitudinal passage when there is no instrument in the passage and a circular seal for sealing around an instrument when present in the passage.

5 Still in the said particular embodiment, the inversible tubular member may be releasable from the outer tubular member and the inner elongate member. In this case, the gripping device may include a first coupling secured to the everted end of the inversible tubular member, the first coupling being releasably engageable with the distal end of the outer tubular member; and a second coupling secured to an end of an inverted length of
10 the inversible tubular member opposite to the transformation end, the second coupling being releasably engageable with the distal end of the inner tubular member. The first and second couplings may be interengageable through relative displacement of the outer tubular member and the inner elongate member.

15 Still in the said particular embodiment, the outer tubular member may include a distal end portion that is radially expandable for operatively accommodating therein a length of the inversible tubular member and an object therein where the size of the object requires radial expansion of the end portion. The distal end portion may define therein an arrangement of slits which are angularly spaced about the central axis of the tubular
20 member to provide for the expansion. The distal end portion may be resiliently flexible to provide for the expansion.

According to a third aspect of the invention, there is provided a method of gripping an object, the method including:

25 providing an inversible tubular member which is substantially round in cross-section and progressively transformable between an everted condition and an inverted condition with a transformation end being defined intermediate an everted length and an inverted length of the inversible tubular member during such transformation, the inversible tubular member being composed of interengaged stitches of resiliently flexible
30 filamentary material;

with at least a part of the length of the inversible tubular member in the everted condition, contacting the transformation end of the said part with the object; and

progressively inverting the said part at the transformation end, thus causing the inversible tubular member to grip the object.

Clearly, in order to perform the method, the inversible tubular member must have sufficient rigidity.

- 5 The inversible tubular member used in the method may be an inversible tubular member, in accordance with the first aspect of the invention.

The method may include at least partially drawing the object into the inversible tubular member by the progressive inverting of the inversible tubular member.

10

The applicant has found that, due to flexibility in the inversible tubular member, the method may be used to grip and draw into the inversible tubular member an object having a size substantially larger than the outer diameter of the said part of the length of the inversible tubular member in the everted condition. The applicant has further found
15 that, by suitably sizing the inversible tubular member, it is able to grip and draw in very fragile objects.

According to a fourth aspect of the invention there is provided a method of making an inversible tubular member, in accordance with the first aspect of the invention, the
20 method including forming stitches in a suitable filamentary material and inter-engaging them to define the inversible tubular member.

In one possible implementation of the method, both the forming and inter-engaging of the stitches may be performed in a knitting process.

25

In another possible implementation of the method, a series of the stitches may be formed in the filamentary material and thereafter the stitches may be interengaged in a knitting process. The series of stitches may, for example, be formed as a series of loops in the filamentary material by forming the filamentary material into a helix and then
30 flattening the helix.

The knitting process, where applicable, may be performed by means of a knitting spool.

Further features of the invention, in its various aspects, will become apparent from the description below of example embodiments of the invention, with reference to and as illustrated in the accompanying diagrammatic drawings. In the drawings:

- 5 Figure 1 shows a side/rear three-dimensional view of a first embodiment of a gripping device, in accordance with the invention, including an inversible tubular member, in accordance with the invention;
- Figure 2 shows an enlarged side/front three-dimensional view of a distal end portion of the device of Figure 1;
- 10 Figure 3 shows a broken side view of the device of Figure 1;
- Figure 4 shows a broken long section of the device of Figure 1;
- Figure 5 shows a detail long section of an end part of the device of Figure 1 and an object gripped thereby;
- Figure 6 shows a detail of an inverted length of the inversible tubular member of
- 15 Figure 1;
- Figure 7 shows a detail of an everted length of the inversible tubular member of Figure 1;
- Figure 8 shows a detail illustrating a step in a method, in accordance with the invention, of making the inversible tubular member of Figure 1;
- 20 Figure 9 shows a detail IX of Figure 8;
- Figure 10 shows a detail long section of an end part of a second embodiment of a gripping device, in accordance with the invention, and an object gripped thereby, the device being for the most part identical to the gripping device of Figure 1;
- Figure 11 shows a long section of a third embodiment of a gripping device, in
- 25 accordance with the invention;
- Figure 12 shows a detail XII of Figure 11;
- Figure 13 shows a detail XIII of Figure 12; and
- Figure 14 shows a three-dimensional view of a fourth embodiment of a gripping device, in accordance with the invention, including an inversible tubular member, in
- 30 accordance with the invention.

In Figures 1 to 4, a first embodiment of a gripping device, in accordance with the invention, more particularly a laparoscopic surgical retrieval device, is designated generally by the reference numeral 10.

The retrieval device 10 includes:

an outer tubular member 12 defining a distal end 14, a proximal end 16, and a longitudinal passage 17 extending from the distal end 14 to the proximal end 16;

5 a first hand grip formation 18 around the proximal end 16 of the outer tubular member 12;

an elongate inner member in the form of an inner tubular member 20 defining a distal end 22, a proximal end 24, and a longitudinal passage 25 extending from the distal end 22 to the proximal end 24, the inner tubular member 20 being snugly and
10 slidably received through the passage 17 of the outer tubular member 12;

a second hand grip formation 26 on the proximal end 24 of the inner tubular member 20; and

a tubular member 27.

15 The tubular member 27 comprises:

a first length 29.1, secured around the distal end 14 of the outer tubular member 12;

a second length 29.2, secured around the distal end 22 of the inner tubular member 20; and

20 a third length 28, which is an inversible tubular member, in accordance with the invention, and which extends from the length 29.1 to the length 29.2.

The entire tubular member 27 was formed as an inversible tubular member, in accordance with the invention. However, the lengths 29.1 and 29.2 of the tubular
25 member 27 clearly are now restrained and therefore no longer inversible.

The inversible tubular member 28 has:

an everted end 30, secured to the distal end 14 of the outer tubular member 12 via the first length 29.1; and

30 an opposite, inverted end 32, secured to the distal end 22 of the inner tubular member 20 via the second length 29.2.

It is known that in certain laparoscopic procedures, it is required for a surgical retrieval device to seal up to a particular pressure, being a pressure maintained inside a

peritoneal cavity during surgery. Accordingly, the retrieval device 10 includes a seal 33 effectively sealing between the inner tubular member 20 and the outer tubular member 12. The seal 33 seals up to a prescribed pressure, which is not less than 15 mmHg. Alternatively, the inner tubular member 20 may be received sufficiently snugly within the outer tubular member 12 to seal to a prescribed pressure, which is not less than 15 mmHg.

The passage 25 extends also through the hand grip formation 26. The retrieval device 10 includes also, within a widened proximal end of the passage 25, sealing means in the form of a circular seal 35 and a duckbill 34, both capable of sealing up to at least 15 mmHg. Another surgical device may be inserted through the retrieval device 10, particularly through the circular seal 35, the duckbill 34, and the passage 25. The circular seal 35 is for sealing around such a surgical device. The duckbill 34 is for sealing when there is no such surgical device present.

A length 38 of the inversible tubular member 28, having a length L_1 , is in an everted condition and a length 36 of the inversible tubular member 28, having a length L_2 , is in an everted condition. The inverted length 36 defines therein a cavity 40 which forms an extension of the passage 25. At a peripheral boundary between the inverted length 36 and the everted length 38 is defined a transformation end 41 of the inversible tubular member 28. As will be described below, the gripping device 10 is operable to effect progressive inversion and eversion of the inversible tubular member 28 at the transformation end 41, meaning that L_1 and L_2 are variable.

The inversible tubular member 28 has a total length $L = L_1 + L_2$ of about six times a natural or relaxed outer diameter of the inverted length 36. The diameter of the inversible tubular member 28 may be variable along its length when it is entirely everted. In an alternative embodiment (not shown), the diameter of the inversible tubular member may be at least substantially constant along its length when it is entirely everted.

With the inversible tubular member 28 completely everted (not shown), then by relative forward displacement of the hand grip formation 18 and the outer tubular member 12 with respect to the hand grip formation 26 and the inner tubular member 20, the end 30

of the inversible tubular member 28 is linearly relatively displaced towards the transformation end 41 and the inversible tubular member 28 is progressively inverted, i.e. the inverted length 36 and the space or cavity 40 defined therein are progressively extended away from the distal end 22 of the inner tubular member 20. The everted length 38 clearly must have sufficient rigidity to cause such inversion.

With reference particularly to Figure 5, by such inversion, an object 42 can be gripped by means of the inversible tubular member 28 and drawn into the cavity 40. Figure 5 will be referred to again below.

With the inversible tubular member 28 completely inverted (not shown) within the outer tubular member 12, then by relative rearward displacement of the hand grip formation 18 and outer tubular member 12 with respect to the hand grip formation 26 and the inner tubular member 20, the end 32 of the inversible tubular member 28 is linearly relatively displaced towards the transformation end 41 and the inversible tubular member 28 is progressively everted, i.e. the inverted length 36 and the space or cavity 40 defined therein are progressively shortened. The inverted length 36 clearly must have sufficient rigidity to cause such eversion.

With reference now to Figure 6, the inversible tubular member 28 (of which only a small portion is shown) is composed of interengaged plait stitches 43, each including a loop 44, the stitches 43 being made of a resiliently flexible filamentary material in the form of nylon filament 46. The same applies to the entire tubular member 27, of which the inversible tubular member 28 forms a part.

The loops 44 may be formed and interengaged in a knitting process, for example using a knitting spool. Alternatively, a series of the loops 44 may be formed in the nylon filament 46 prior to interengaging the loops in a knitting or similar process. This may be done by forming the filament 46 into a helix and then flattening the helix.

Figure 6 shows the portion of the inversible tubular member 28 in the inverted condition. Figure 7 shows essentially the same portion of the inversible tubular member 28 in the everted condition.

Figures 8 and 9 show a step in a method, in accordance with the invention, for making the inversible tubular member 28. The nylon filament 46 is knitted such as to form circumferential rows, of which three rows 48.1, 48.2, and 48.3 are shown, in a helix pattern. In this case, the rows 48.1 and 48.2 have already been completed and the row 48.3 is being formed. Two loops 44.1 and 44.2 respectively in the rows 48.2 and 48.3 have been interengaged and two loops 44.3 and 44.4 in the respective rows are about to be interengaged. Such stitches are known in relation to, for example, yarn as plaited stitches and therefore do not require further elaboration herein.

At the time of making the inversible tubular member 28, the loops 44 are in the arrangement shown in Figure 6, the loops 44 being on the inside of the inversible tubular member 28. This arrangement corresponds to the inverted condition of the inversible tubular member 28, as referred to herein. This arrangement is referred to below as the "inner loop arrangement".

By everting the inversible tubular member 28 into its everted condition, the loops 44 are transformed into the arrangement shown in Figure 7, in which the loops 44 are on the outside of the inversible tubular member 28. This arrangement is referred to below as the "outer loop arrangement".

The inventor has found in practice that an inversible tubular member such as the inversible tubular member 28 naturally defines in its inverted condition an outer diameter which is smaller than its outer diameter in the everted condition. The bias created in the knitting process as the loops 44 are formed causes adjacent loops to overlap in the inverted condition while they are constrained to a side-by-side arrangement in the everted condition. This creates two stable diameters respectively for the inversible tubular member 28 in the inverted and everted conditions, meaning that there is very low friction and minimal interference between the inverted length 36 and the everted length 38 (see Figure 4).

A possible further explanation of the two diameters is given below:

All of the loops 44, having been constructed as a helical spring either during or before the knitting process, have a tendency to want to return to a stacked, helical arrangement. This results in two forces on the loops:

A force pulling the loops 44 together due to the fact that the apex of the loop is highly flexed and creates a tendency for the loop to attempt to decrease its rate of flexure. As the loop is attached to its neighbouring loops by the roots 31 this effect pulls neighbouring loops together as each attempts to expand; and

A moment around the axis of symmetry of each loop 44 which attempts to return the loops to a parallel arrangement.

In the inner loop arrangement, the root 31 between loops in the next row passes on the inside of the curvature and the loops 44 are therefore not fully constrained in rotation and are able to rotate slightly about their axes. This rotation also allows them to overlap with the loops 44 to either side. As the loops 44 are not restricted from circumferential overlap, the force created by the highly flexed apex of the loops 44 is able to pull the loops 44 together and they partially overlap each other which results in a smaller circumference and, thus results in a smaller diameter.

In the outer arrangement the loops 44 are unable to rotate due to the root 31 of the next row now passing over the loops 44 and following the increased path of the outside of the curvature. This creates an inward force on the loops 44 and they are restricted from rotation and circumferential overlap (at 45 in Figure 7). The moment about their axes further tensions the roots and the side-by-side arrangement now creates a greater circumference and, thus results in a greater diameter.

The loops in the outer loop arrangement are also restricted from longitudinal overlap (at 47 in Figure 7), which increases the longitudinal stiffness and rigidity of the everted length of the inversible tubular member and provides the rigidity required for the everted length to withstand the forces of inversion and ingesting a captured object without crumpling and without the need for alternative support.

Referring now particularly to Figures 1 and 5, in order to use the retrieval device 10 for gripping the object 42, say during a laparoscopic procedure on a person, the hand grip formations 18 and 26 are pushed together until substantially the entire inversible tubular

member 28 is in the everted condition as an extension to the outer tubular member 12. The inversible tubular member 28 and outer tubular member 12 is then at least partially inserted into the body through a standard laparoscopic port. The object 42 is contacted by the transformation end 41 of the inversible tubular member 28. The hand grip
5 formations 18 and 26 are progressively pulled apart so that the inversible tubular member 28 grips the object 42 and draws it into the cavity 40. This is an example of the method of the third aspect of the invention.

In the inversible tubular member 28, the loops 44 on the outside of the everted length
10 38 point in the distal direction. As the loops 44 approach the transformation end 41 during inversion, they do not project past the outer diameter of the inversible tubular member 28. As they pass the end 41, they project inwardly into the cavity 40 and proximally for a short travel distance. This behavior of the loops 44 enhances grip of the loops 44 on the object 42.

The applicant has found with the prototype of the retrieval device 10 that the inversible tubular member 28 will stretch sufficiently for ingesting a sphere of a diameter of 1.5 times the average relaxed outer diameter of the inverted length 36. Take a case where the inversible tubular member 28 is halfway inverted when the sphere is halfway into the
20 inversible tubular member 28 at the transformation end 41. In this case, the applicant has found that further inversion occurs at the transformation end 41.

Optionally, a membrane 49.1 (shown in broken lines in Figure 4) may be applied over the surface of the inversible tubular member 28 which is an outer surface in the everted
25 condition. Alternatively or additionally, such a membrane 49.2 may be applied over the opposite surface. Such a membrane may, for example, serve to prevent spillage of toxins from tissue removed during a surgical procedure.

As was stated above, the diameter of the inversible tubular member 28 may be variable
30 along its length when it is entirely everted. This may be achieved by varying the sizes of the loops, or the number of loops per row, along the length of the inversible tubular member. Alternatively, if the properties of the filamentary material permit, a variable diameter may be achieved by heating, setting, and cooling of the material.

In Figure 10, a second embodiment of a gripping device in the form of a laparoscopic surgical retrieval device, in accordance with the invention, of which only a part is shown, is designated generally by the reference numeral 50.

5 The retrieval device 50 is for the most part identical to the retrieval device 10 of Figures 1 to 9 and therefore like features, where shown, will again be designated by the same reference numerals as before and these features will not be described again. Moreover, the retrieval device 50 differs from the retrieval device 10 only in respect of the orientation of its inversible tubular member 28. In this case, the loops 44 on the outside
10 of the everted length 38 of the length of the inversible tubular member 28 point in the proximal direction.

As the loops 44 approach the transformation end 41 during inversion, they project past the outer diameter of the inversible tubular member 28. As they pass the transformation
15 end 41, they do not project inwardly into the cavity 40. This behavior of the loops 44 means that the transformation end 41 can effectively gather material over an area larger than its outer diameter 28. This feature may also aid gripping and drawing in of an object 52 which tends to break apart.

20 In Figure 11, a third embodiment of a gripping device in the form of a laparoscopic surgical retrieval device, in accordance with the invention, of which only a part is shown, is designated generally by the reference numeral 54.

The retrieval device 54 is for the most part identical to the retrieval device 10 of Figures
25 1 to 9 and therefore like features, where shown, will again be designated by the same reference numerals as before and these features will not be described again.

With reference to Figures 11 to 13 generally, the retrieval device 54 includes:

30 a tubular first coupling 56 to which the everted end 30 of the inversible tubular member 28 is peripherally attached; and

a tubular second coupling 58 to which the inverted end 32 of the inversible tubular member 28 is peripherally attached.

By relative axial displacement, the second coupling 58 fits into the first coupling 56 in a snug fit. These couplings define complementary clip-in formations 60 for retaining the coupling 58 in the coupling 56.

- 5 The coupling 56 defines an outer screw thread 62 complementary to an inner screw thread 64 defined by the distal end of the outer tubular member 12.

The coupling 58 defines an inner screw thread 66 complementary to an outer screw thread 68 defined by the distal end of the inner tubular member 20.

10

The extractor device 54 provides the following operation. With the couplings 56 and 58 engaged respectively with the tubular members 12 and 20 by screwing them in, the device 54 is used similarly to the use of the retrieval device 10 as described above to grip an object in a body of, say, a person. The tubular members 12 and 20 are relatively
15 longitudinally displaced until the object is at least partially within the cavity 40 and the clip-in formations 60 are interengaged. The tubular members 12 and 20 are then unscrewed from the respective couplings 56 and 58, which may require the inversible tubular member 28 to be held by means of another surgical instrument.

- 20 The inversible tubular member 28 has a diameter which may vary substantially along its length to facilitate operative holding of an object received therein.

In Figure 14, a fourth embodiment of a gripping device in the form of a laparoscopic surgical retrieval device, in accordance with the invention, of which only a part is shown,
25 is designated generally by the reference numeral 70.

The retrieval device 70 is for the most part identical to the retrieval device 10 of Figures 1 to 9 and therefore like features, where shown, will again be designated by the same reference numerals as before and these features will not be described again.

30

An outer tubular member 12 of the retrieval device 70 is made of a resiliently flexible material, e.g. polypropylene. It includes an end portion 71 defining therein four elongate slits 72 (only two shown), angularly evenly spaced about its central axis. As such, the end portion 71 is split into four fingers 74 (only three shown). Distal ends of the fingers

74 have an everted end of a tubular member 27, which includes an inversible tubular member 28, secured to their outsides. An opposite end of the inversible tubular member 28 is secured to an inner tubular member (see reference numeral 20 in Figure 4).

5 The inversible tubular member 28 is shown almost entirely in an inverted condition. The fingers 74 are shown resiliently deformed into a flared out or expanded condition and similarly, the inversible tubular member 28 is shown in a radially expanded condition. Such expansion will, in use of the retrieval device 70, be caused by an "oversized" ingested object (not shown) in the inversible tubular member 28.

10

It will be understood that, in an ex-factory condition of the retrieval device 70, the fingers 74 were more closely spaced and defined a circumference substantially the same as that of the remainder of the tubular member 12.

15 Other features and operation of the retrieval device 70 are essentially the same as those of the retrieval device 10 of Figures 1 to 9. Expansion of the end portion 71 merely facilitates ingestion of larger objects than would have been the case with the retrieval device 10.

20 In all of the above examples, the gripping device of the invention was intended for surgical use. It must be appreciated, however, that a similar gripping device may be configured for other uses, for example an industrial use. It may be suitably scaled up or down for a required application. For certain heavier duty applications, the resiliently flexible filamentary material may, for example, be a multifilament material, for example
25 stranded stainless steel wiring or cabling.

It is envisaged that, generally in all practical embodiments of the gripping device of the invention, requirements a), b), and c) below will apply. The numbers in brackets refer to equivalent features of the retrieval device 10 of Figures 1 to 9.

30

a) With the inversible tubular member (28) at least partially inverted, the inverted length (36) must have sufficient stiffness to cause eversion of the inversible tubular member at the transformation end (41) upon axial displacement of the inverted end (32) towards the transformation end, for a length of the inverted length (L2) up to X times an

average relaxed outer diameter of the inverted length, with $X \geq 2.0$. In some possible embodiments, $X \geq 5.0$.

5 b) With the inversible tubular member (28) at least partially everted, the everted length (38) must have sufficient stiffness to cause inversion of the inversible tubular member at the transformation end (41) upon axial displacement of the everted end (30) towards the transformation end, for a length (L1) of the everted length up to Y times an average relaxed outer diameter of the inverted length, with $Y \geq 2.0$. In some possible
10 embodiments, $Y \geq 5.0$

c) With the inversible tubular member (28) at least partially everted, the everted length (38) must have sufficient stiffness to cause inversion of the inversible tubular member at the transformation end (41) upon axial displacement of the everted end (30) towards the transformation end, for a length (L1) of the everted length up to Z times the
15 average relaxed outer diameter of the inverted length, whilst one half of a sphere of diameter 1.5 times an average relaxed outer diameter of the inverted length is received in the inversible tubular member at the transformation end, with $Z \geq 2.0$.

CLAIMS:

1. A gripping device including:

an inversible tubular member which is substantially round in cross-section and progressively transformable between an everted condition and an inverted condition, with a transformation end being defined intermediate an everted length and an inverted length of the inversible tubular member during such transformation and with the inverted length and the everted length defining opposite to the transformation end respectively an inverted end and an everted end of the inversible tubular member, the inversible tubular member being composed of interengaged stitches of resiliently flexible filamentary material; and

actuation means carrying the inversible tubular member and operable for effecting progressive inversion and eversion of the inversible tubular member, the inversible tubular member defining a transformation end where the progressive inversion and eversion occurs, with such inversion providing for gripping an object in the inversible tubular member.

2. A gripping device as claimed in claim 1, in which:

with the inversible tubular member at least partially inverted, the inverted length has sufficient stiffness to cause eversion of the inversible tubular member at the transformation end upon axial displacement of the inverted end towards the transformation end, for a length of the inverted length up to X times an average relaxed outer diameter of the inverted length;

$X \geq 2.0$;

with the inversible tubular member at least partially everted, the everted length has sufficient stiffness to cause inversion of the inversible tubular member at the transformation end upon axial displacement of the everted end towards the transformation end, for a length of the everted length up to Y times an average relaxed outer diameter of the inverted length; and

$Y \geq 2.0$.

3. A gripping device as claimed in any of the preceding claims, in which:

$X \geq Y \geq 5.0$

4. A gripping device as claimed in any of the preceding claims, in which:

with the inversible tubular member at least partially everted, the everted length has sufficient stiffness to cause inversion of the inversible tubular member at the transformation end upon axial displacement of the everted end towards the transformation end, for a length of the everted length up to Z times the average relaxed outer diameter of the inverted length, whilst one half of a sphere of diameter 1.5 times an average relaxed outer diameter of the inverted length is received in the inversible tubular member at the transformation end; and

$$Z \geq 2.0$$

5. A gripping device as claimed in any of the preceding claims, which defines in the everted condition a larger outer diameter than in the inverted condition.

6. A gripping device as claimed in claim 5, of which the inner diameter in the everted condition is larger than its outer diameter in the inverted condition.

7. A gripping device as claimed in any of the preceding claims, in which the stitches are knitted stitches of at least one length of the filamentary material.

8. A gripping device as claimed in claim 7, in which the stitches are plaited stitches, each defining a loop.

9. A gripping device as claimed in any of the preceding claims, in which the filamentary material is a monofilament material.

10. A gripping device as claimed in any of the preceding claims, in which the filamentary material is a multifilament material.

11. A gripping device as claimed in any of the preceding claims, in which the filamentary material is a superelastic material.

12. A gripping device as claimed in any of the preceding claims, in which the filamentary material is a shape memory material.

13. A gripping device as claimed in any of the preceding claims, in which the inversible tubular member has a variable diameter along its length.

14. A gripping device as claimed in any of the preceding claims, which includes a membrane over at least a part of a surface of the inversible tubular member which is an outer surface in the everted condition.

15. A gripping device as claimed in any of the preceding claims, which includes a membrane over at least a part of a surface of the inversible tubular member which is an inner surface in the everted condition.

16. A gripping device as claimed in any of the preceding claims, in which the actuation means includes:

an outer tubular member defining a distal end, i.e. a front end, and a proximal end, i.e. a rear end, and a longitudinal passage extending between the distal end and the proximal end, the distal end being peripherally attached to an everted end of the inversible tubular member; and

an inner elongate member received within the passage and defining a distal end and a proximal end, the distal end being peripherally attached to an opposite inverted end of the inversible tubular member, the outer tubular member and the inner elongate member being slidably displaceable relative to each other to effect the progressive inversion and eversion.

17. A gripping device as claimed in claim 16, which includes:

a first hand grip formation on the proximal end of the outer tubular member; and a second hand grip formation on the proximal end of the inner elongate member, the hand grip formations being manually relatively displaceable for effecting the relative sliding displacement of these members.

18. A gripping device as claimed in any of claims 16 to 17, in which the inversible tubular member is retractable into the outer tubular member.

19. A gripping device as claimed in any of claims 16 to 18, in which the inner elongate member is received within the outer tubular member in a snug sliding fit to provide

sealing between these members to a required pressure, which is not less than 15 mmHg.

20. A gripping device as claimed in any of claims 16 to 18, which includes sealing
5 means sealing between the inner elongate member and the outer tubular member to a required pressure, which is not less than 15 mmHg.

21. A gripping device as claimed in any of claims 16 to 20, in which the inner elongate
10 member defines therethrough a longitudinal passage, permitting insertion of an elongate surgical or other instrument through it.

22. A gripping device as claimed in claim 21, in which the inner elongate member has
sealing means sealing the longitudinal passage defined therethrough, the sealing
means being configured to permit passage of an elongate surgical or other instrument
15 through it and to seal around the instrument.

23. A gripping device as claimed in any of claims 16 to 22, in which the inversible
tubular member is releasable from the outer tubular member and the inner elongate
member.
20

24. A gripping device as claimed in claim 23, which includes:
a first coupling secured to the everted end of the inversible tubular member, the
first coupling being releasably engageable with the distal end of the outer tubular
member; and

25 a second coupling secured to an end of an inverted length of the inversible tubular
member opposite to the transformation end, the second coupling being releasably
engageable with the distal end of the inner tubular member;

25. A gripping device as claimed in claim 24, in which the first and second couplings
30 are interengageable through relative displacement of the outer tubular member and the inner elongate member.

26. A gripping device as claimed in any of claims 16 to 25, in which the outer tubular
member includes a distal end portion that is radially expandable for operatively

accommodating therein a length of the inversible tubular member and an object therein where the size of the object requires radial expansion of the end portion.

27. A gripping device as claimed in claim 26, in which the distal end portion defines therein an arrangement of slits which are angularly spaced about the central axis of the tubular member to provide for the expansion.

28. A gripping device as claimed in any of claims 26 to 27, in which the distal end portion is resiliently flexible to provide for the expansion.

29. An inversible tubular member which is substantially round in cross-section and progressively transformable between an everted condition and an inverted condition, with a transformation end being defined intermediate an everted length and an inverted length of the inversible tubular member during such transformation and with the inverted length and the everted length defining opposite to the transformation end respectively an inverted end and an everted end of the inversible tubular member, in which:

the inversible tubular member is composed of interengaged stitches of resiliently flexible filamentary material;

with the inversible tubular member at least partially inverted, the inverted length has sufficient stiffness to cause eversion of the inversible tubular member at the transformation end upon axial displacement of the inverted end towards the transformation end, for a length of the inverted length up to X times an average relaxed outer diameter of the inverted length;

$X \geq 2.0$;

with the inversible tubular member at least partially everted, the everted length has sufficient stiffness to cause inversion of the inversible tubular member at the transformation end upon axial displacement of the everted end towards the transformation end, for a length of the everted length up to Y times an average relaxed outer diameter of the inverted length; and

$Y \geq 2.0$.

30. An inversible tubular member as claimed in claim 29, in which:

with the inversible tubular member at least partially everted, the everted length has sufficient stiffness to cause inversion of the inversible tubular member at the

transformation end upon axial displacement of the everted end towards the transformation end, for a length of the everted length up to Z times the average relaxed outer diameter of the inverted length, whilst one half of a sphere of diameter 1.5 times an average relaxed outer diameter of the inverted length is received in the inversible tubular member at the transformation end; and

$Z \geq 2.0$.

31. An inversible tubular member as claimed in any of claims 29 to 30, which defines in the everted condition a larger outer diameter than in the inverted condition.

32. An inversible tubular member as claimed in claim 31, of which the inner diameter in the everted condition is larger than its outer diameter in the inverted condition.

33. An inversible tubular member as claimed in any of claims 29 to 32, in which the stitches are knitted stitches of at least one length of the filamentary material.

34. An inversible tubular member as claimed in any of claims 29 to 33, in which the stitches are plaited stitches, each defining a loop.

35. An inversible tubular member as claimed in any of claims 29 to 34, in which the filamentary material is a monofilament material.

36. An inversible tubular member as claimed in any of claims 29 to 34, in which the filamentary material is a multifilament material.

37. An inversible tubular member as claimed in any of claims 29 to 36, in which the filamentary material is a superelastic material.

38. An inversible tubular member as claimed in any of claims 29 to 37, in which the filamentary material is a shape memory material.

39. An inversible tubular member as claimed in any of claims 29 to 38, which has a variable diameter along its length in each of the inverted and everted conditions.

40. An inversible tubular member as claimed in claim 39, in which the variable diameter has been achieved by heating, setting, and cooling of the filamentary material.

41. A method of gripping an object, the method including:

5 providing an inversible tubular member which is substantially round in cross-section and progressively transformable between an everted condition and an inverted condition with a transformation end being defined intermediate an everted length and an inverted length of the inversible tubular member during such transformation, the inversible tubular member being composed of interengaged stitches of resiliently flexible
10 filamentary material;

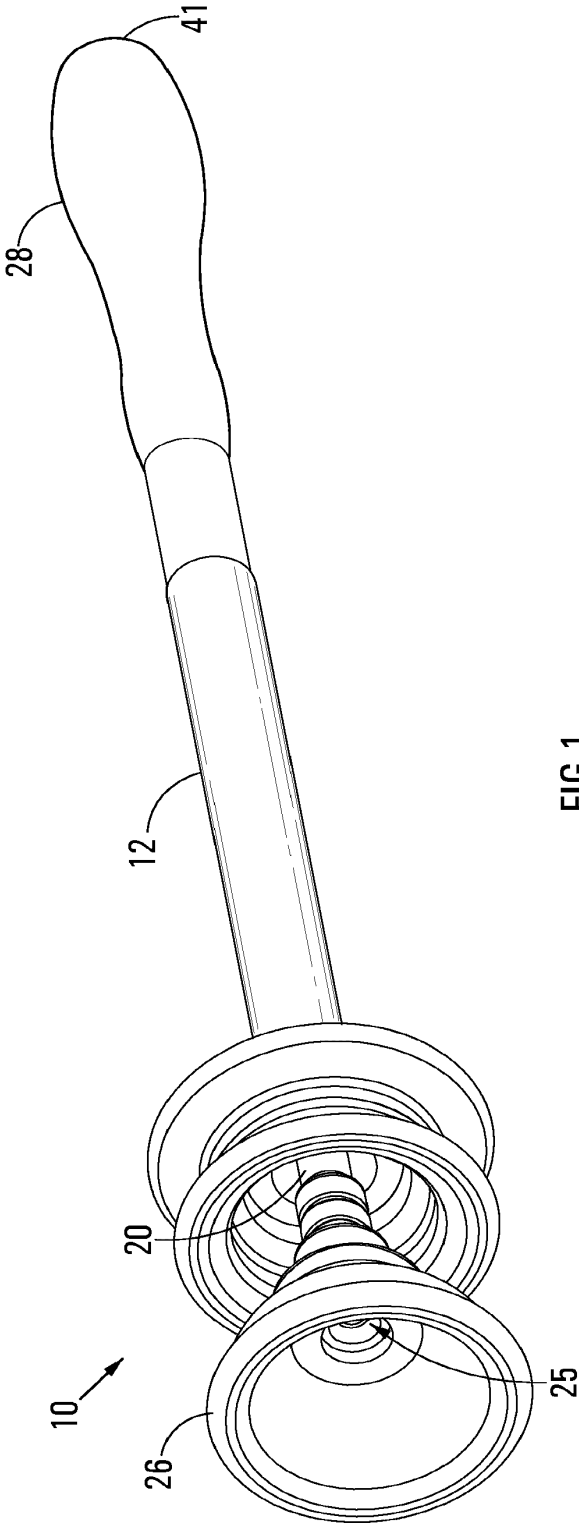
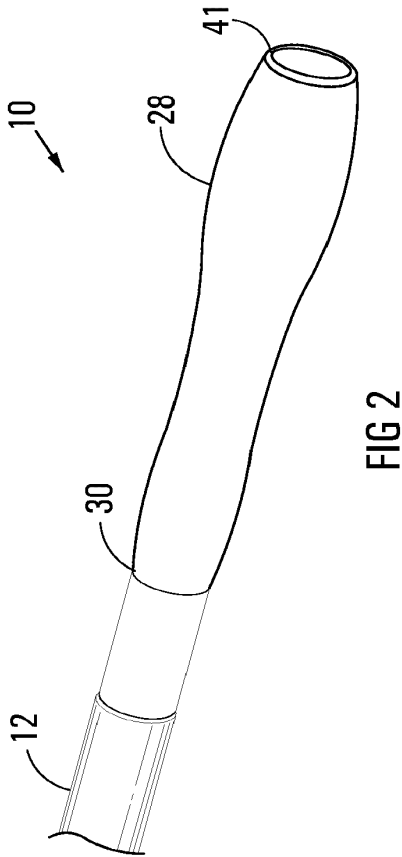
 with at least a part of the length of the inversible tubular member in the everted condition, contacting the transformation end of the said part with the object; and

 progressively inverting the said part at the transformation end, thus causing the inversible tubular member to grip the object.

15

42. A method as claimed in claim 41, in which the inversible tubular member is an inversible tubular member as claimed in any of claims 29 to 40.

43. A method as claimed in any of claims 41 to 42, which includes at least partially
20 drawing the object into the inversible tubular member by the progressive inverting of the inversible tubular member.



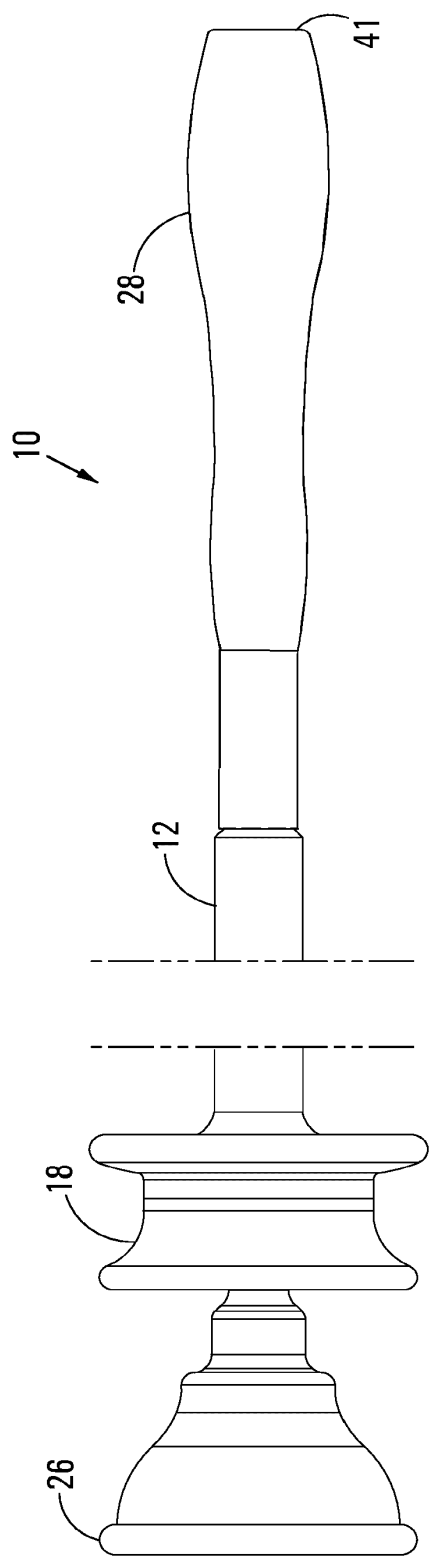


FIG 3

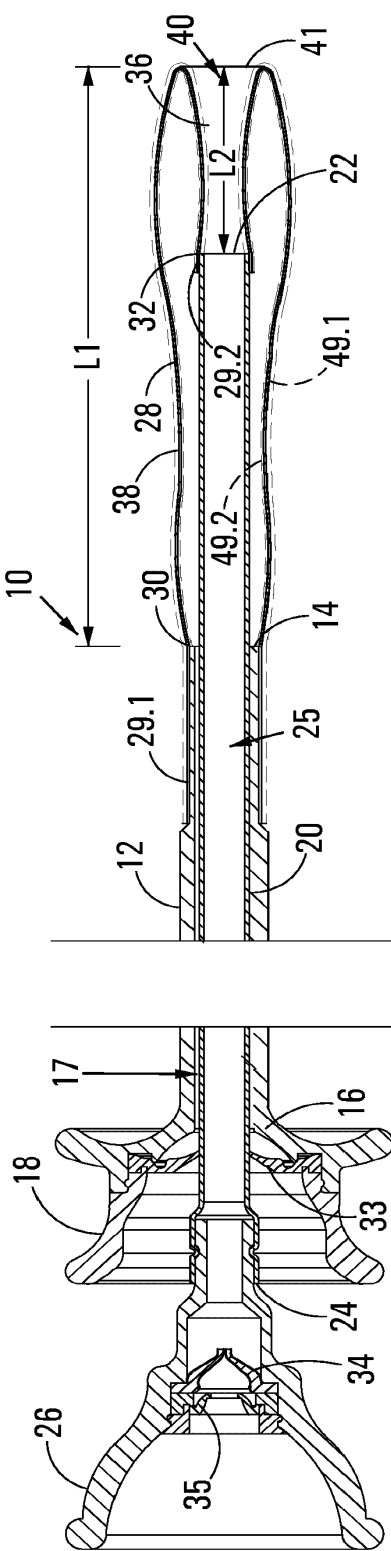


FIG 4

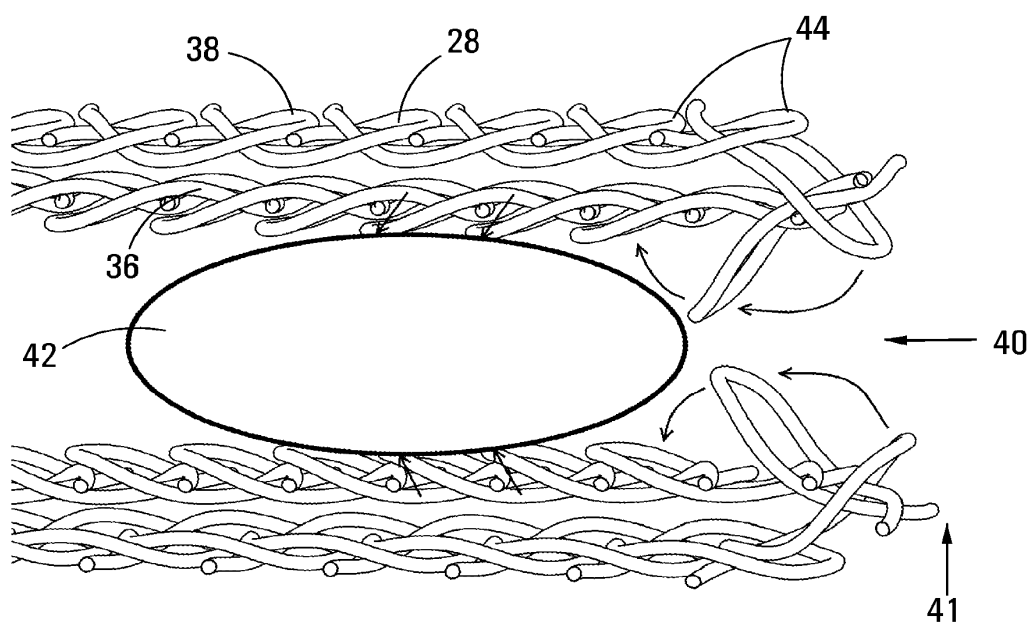


FIG 5

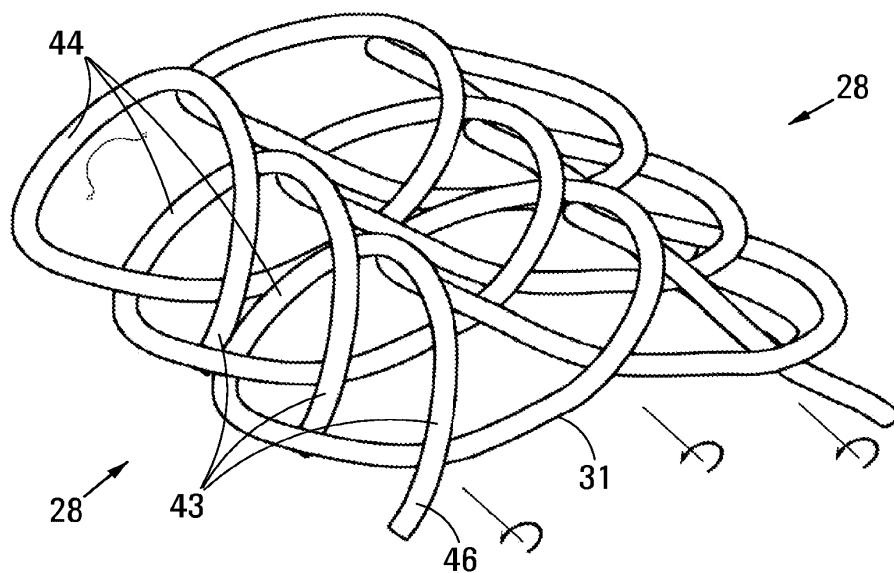


FIG 6

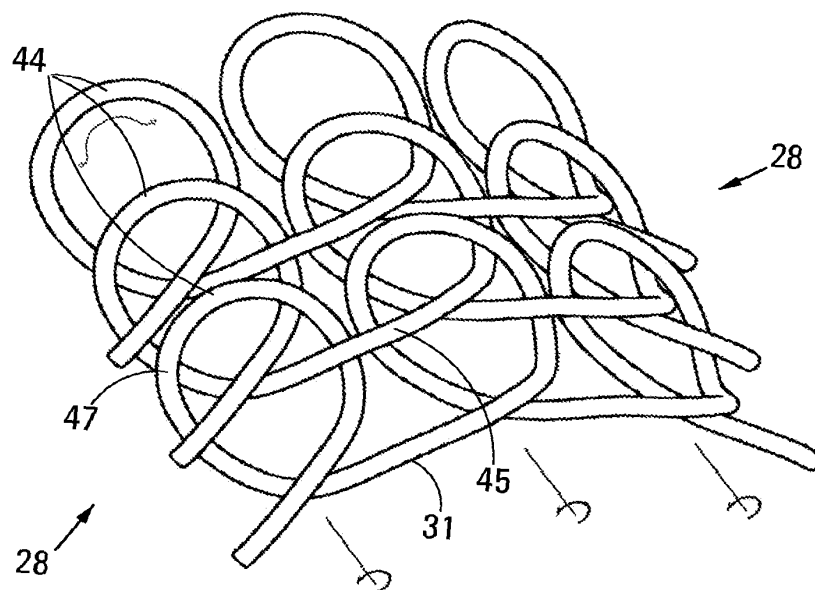


FIG 7

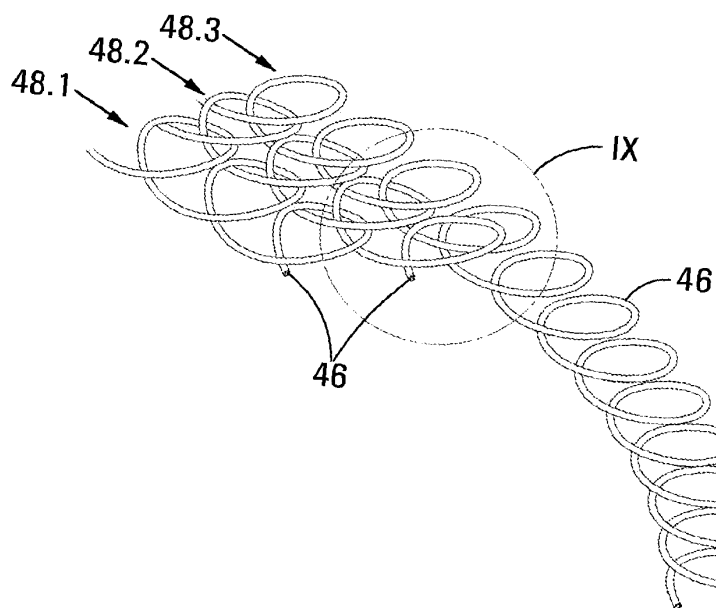


FIG 8

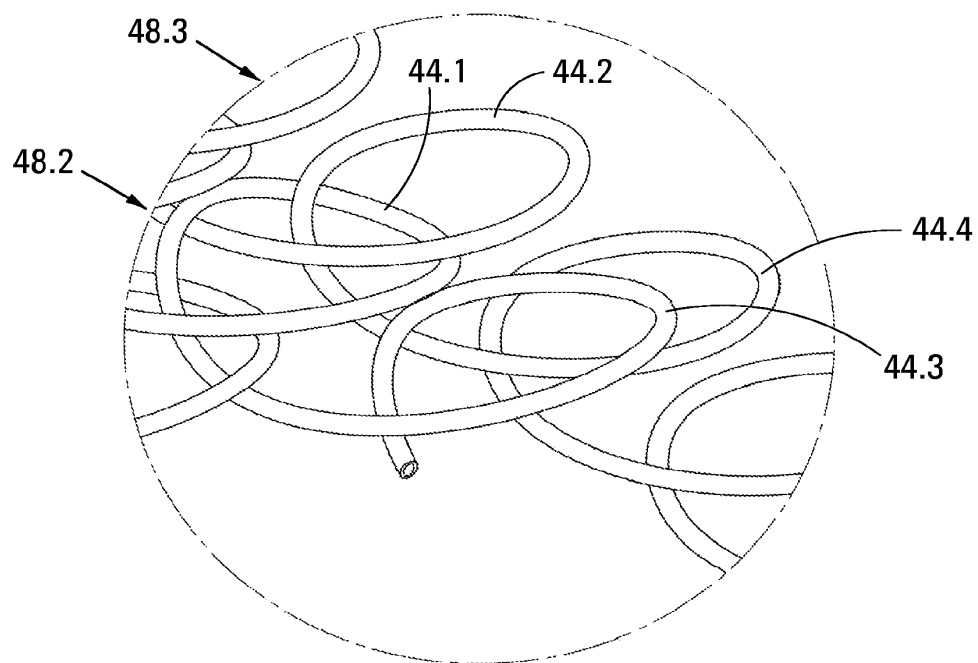


FIG 9

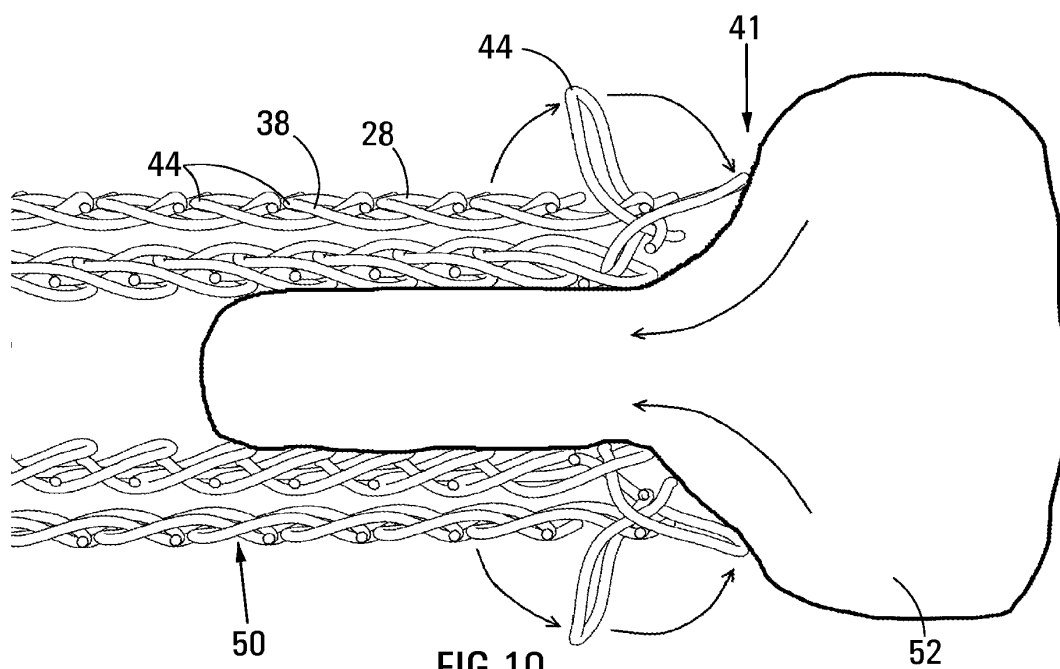
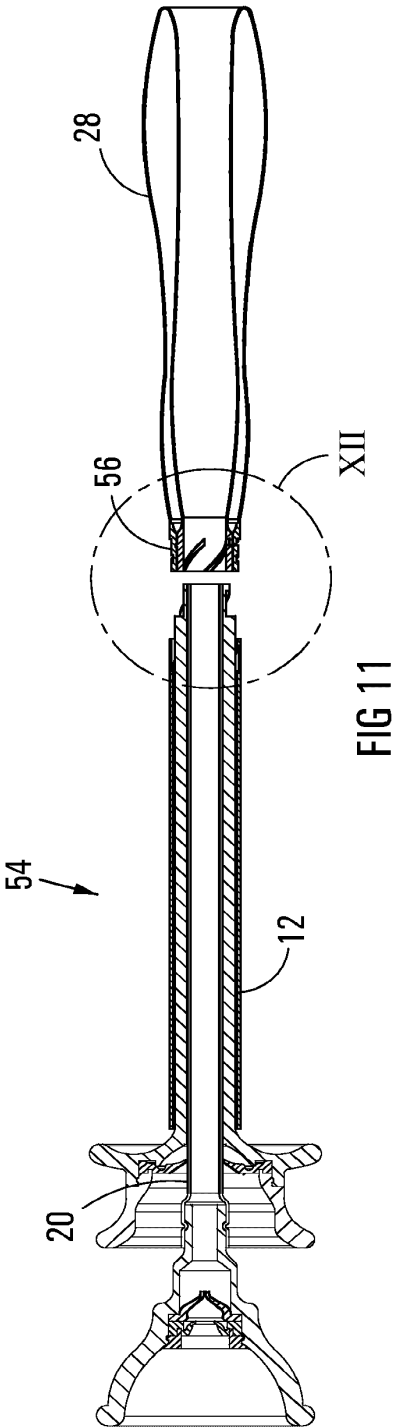
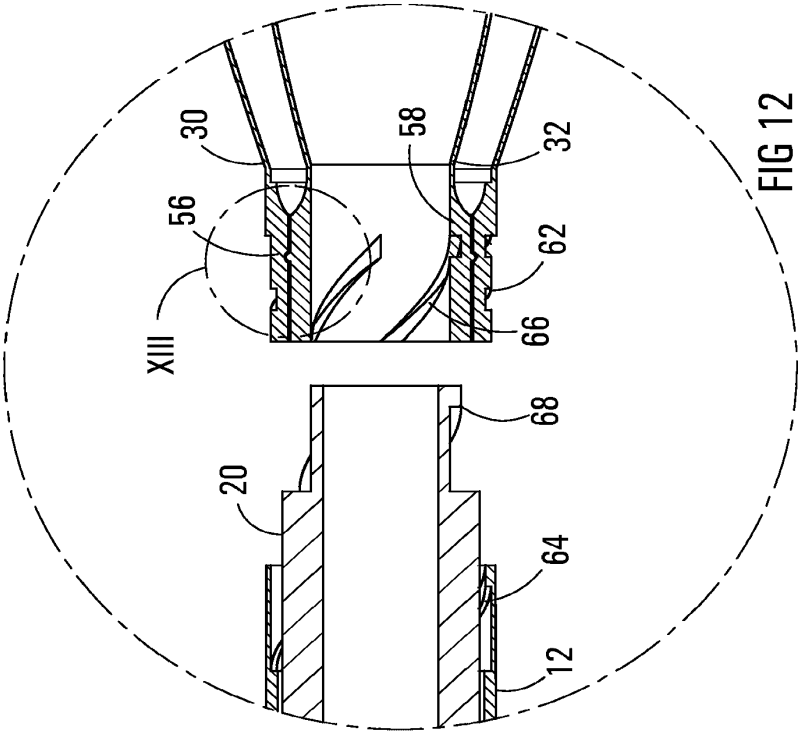
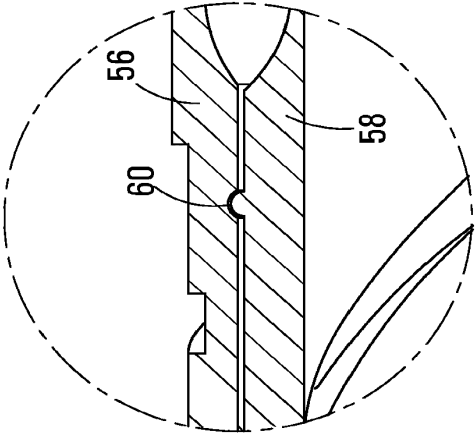


FIG 10



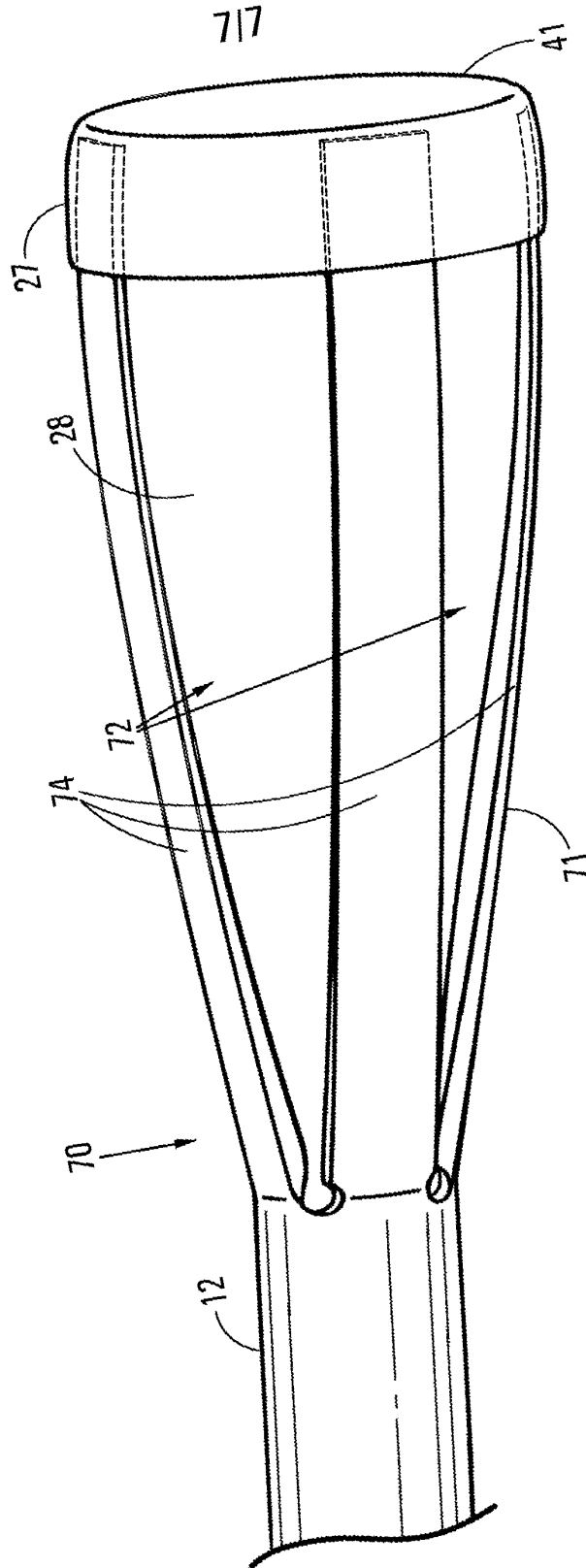


FIG 14

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2011/054535

A. CLASSIFICATION OF SUBJECT MATTER INV. A61B17/00 A61B17/22 A61B17/221 ADD.		
According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) A61B		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
Electronic data base consulted during the international search (name of data base and, where practical, search terms used) EPO-Internal		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2009/086482 A1 (LAZARUS EFFECT INC [US]; MARTIN BRIAN B [US]; FOLLMER BRETT [US]; AGUI) 9 July 2009 (2009-07-09) figures 13A,13B paragraph [0159] - paragraph [0162] -----	1-13,16, 17,21, 29-39 18
Y		
X	US 2010/137846 A1 (DESAI RUPESH [US] ET AL) 3 June 2010 (2010-06-03) figures 1-5 -----	1,7-13, 16,17,21
Y	US 2010/249815 A1 (JANTZEN ALEXANDRA E [US] ET AL) 30 September 2010 (2010-09-30) figures 1-5 -----	18
☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.		
* Special categories of cited documents : "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier document but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art. "&" document member of the same patent family		
Date of the actual completion of the international search		Date of mailing of the international search report
25 January 2012		20/03/2012
Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016		Authorized officer Schießl, Werner

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

INARI_019234

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IB2011/054535

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

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

1. ☒ Claims Nos.: 41-43
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy
2. ☒ Claims Nos.: 40
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
see FURTHER INFORMATION sheet PCT/ISA/210
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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

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

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-13, 16-18, 21, 29-39

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

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

1. claims: 1-13, 16-18, 21, 29-39

A gripping device providing specific ratios of the inverted / everted length and the average relaxed outer diameter of the inverted length for which the respective length has sufficient stiffness to cause eversion / inversion (see claims 2 to 4 and 29), or in which the inversible tubular member is retractable into the outer tubular member (claim 18). These features allow a more secure and complete gripping of objects having a diameter of about the average relaxed outer diameter of the inverted length.

2. claims: 14, 15

A gripping device including a membrane over the inner or outer surface of the inversible tubular member in the the everted condition (claims 14, 15)

3. claims: 19, 20, 22

A gripping device providing a sealing between the an outer tubular member and an inner elongate member of the actuation means, or of the longitudinal passage of the inner elongate member (claims 19, 20, 22) to enable use of the device in laparoscopic procedures.

4. claims: 23-28

A gripping device wherein the inversible tubular member is releasably engageable with the distal ends of the outer tubular member and the inner elongate member (claims 24), or wherein the distal end portion of the outer tubular member is radially expandable (claim 26). Thereby the device is capable to grip objects substantially larger than the outer diameter of the outer tubular member.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 41-43

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

Continuation of Box II.2

Claims Nos.: 40

Present claim 40 relates to a product defined by reference to a process of manufacturing it. In the present context this is considered to lead to a lack of clarity because the claim does not clearly identify the structural features encompassed by the manufacturing steps defined. This makes it impossible to compare the claim to the prior art. As a result, the application does not comply with the requirement of clarity under Article 6 PCT.

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guideline C-VI, 8.2), should the problems which led to the Article 17(2) declaration be overcome.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/IB2011/054535

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2009086482 A1	09-07-2009	CN 102036611 A	27-04-2011
		EP 2231037 A1	29-09-2010
		JP 2011508635 A	17-03-2011
		US 2009299393 A1	03-12-2009
		WO 2009086482 A1	09-07-2009

US 2010137846 A1	03-06-2010	EP 2355717 A1	17-08-2011
		US 2010137846 A1	03-06-2010
		WO 2010065556 A1	10-06-2010

US 2010249815 A1	30-09-2010	NONE	

Form PCT/ISA/210 (patent family annex) (April 2005)

INARI_019238



(51) International Patent Classification:

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A61B 17/22 (2006.01) A61M 1/00 (2006.01)
A61B 17/3207 (2006.01)

(21) International Application Number:

PCT/US2021/035965

(22) International Filing Date:

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(25) Filing Language:

English

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English

(30) Priority Data:

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(74) Agent: **WILLIAMS, Matthew S.** et al.; PERKINS COIE LLP, P.O. Box 1247, Seattle, Washington 98111-1247 (US).

(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM,

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

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

Published:

- with international search report (Art. 21(3))
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))

(54) Title: RECAPTURABLE FUNNEL CATHETERS, AND ASSOCIATED SYSTEMS AND METHODS



Fig. 10C

(57) Abstract: Systems and methods for the intravascular treatment of clot material within a blood vessel of a human patient are disclosed herein. In one embodiment, a funnel catheter assembly includes an outer shaft and an inner shaft extending through and coaxial with the outer shaft. An expandable funnel can be coupled to a distal portion of the inner shaft. The funnel catheter assembly further includes a control assembly operably coupled to the proximal portion of the outer shaft and configured to move the outer shaft between a first position and a second position. In the first position, the outer shaft is positioned at least partially over the funnel to constrain the funnel in a compressed state. In the second position, the outer shaft is retracted proximally relative to the funnel such that the funnel can expand to an expanded state.

RECAPTURABLE FUNNEL CATHETERS, AND ASSOCIATED SYSTEMS AND METHODS

CROSS-REFERENCE TO RELATED APPLICATION

[0001] This application claims the benefit of U.S. Provisional Patent Application No. 63/035,605, filed June 5, 2020, and titled "RECAPTURABLE FUNNEL CATHETERS, AND ASSOCIATED SYSTEMS AND METHODS," which is incorporated herein by reference in its entirety.

TECHNICAL FIELD

[0002] The present technology generally relates to systems, methods, and devices for embolic protection during procedures for extracting thrombi from blood vessels of human patients.

BACKGROUND

[0003] Thrombosis is the local coagulation or clotting of the blood in a part of the circulatory system, and a thrombus is a blood clot formed in situ within the vascular system. A venous thrombus is a blood clot that forms within a vein. A common type of venous thrombosis is a deep vein thrombosis (DVT), which is the formation of a blood clot within a deep vein (e.g., predominantly in the legs). Nonspecific signs of a thrombosis may include pain, swelling, redness, warmth, and engorged superficial veins.

[0004] If the thrombus breaks off (embolizes) and flows towards the lungs, it can become a life-threatening pulmonary embolism (PE) (e.g., a blood clot in the lungs). In addition to the loss of life that can arise from PE, DVT can cause significant health issues such as post thrombotic syndrome, which can cause chronic swelling, pressure, pain, and ulcers due to valve and vessel damage. Further, DVT can result in significant health-care costs either directly or indirectly through the treatment of related complications and inability of patients to work.

[0005] Three processes are believed to result in venous thrombosis. First is a decreased blood flow rate (venous stasis), second is an increased tendency to clot (hypercoagulability), and the third is changes to the blood vessel wall. DVT formation typically begins inside the valves of the calf veins where the blood is relatively oxygen deprived, which activates certain biochemical pathways. Several medical conditions increase the risk for DVT, including

diabetes, cancer, trauma, and antiphospholipid syndrome. Other risk factors include older age, surgery, immobilization (as with bed rest, orthopedic casts, and sitting on long flights), combined oral contraceptives, pregnancy, the postnatal period, and genetic factors. The rate of DVT increases dramatically from childhood to old age and, in adulthood, about 1 in 1,000 adults develop DVT annually.

[0006] Although current devices and methods of prevention and/or treatment of DVT exist, there are a number of shortcomings that have yet to be resolved, such as high incidence of DVT re-occurrence, use of devices not designed to remove large clot volumes, and/or complicated treatments involving multiple treatment devices and/or pharmaceuticals. Accordingly, new devices, systems, and methods of treating thrombus, and particularly DVT are desired.

BRIEF DESCRIPTION OF THE DRAWINGS

[0007] Many aspects of the present technology can be better understood with reference to the following drawings. The components in the drawings are not necessarily to scale. Instead, emphasis is placed on illustrating clearly the principles of the present disclosure.

[0008] Figure 1 is a partially transparent and partially cross-sectional side view of a funnel catheter assembly in accordance with embodiments of the present technology.

[0009] Figures 2A and 2B are side views of the funnel catheter assembly in a first position and a second position, respectively, in accordance with embodiments of the present technology.

[0010] Figure 3 is a side view of the funnel catheter assembly in the first position with a dilator inserted therethrough in accordance with embodiments of the present technology.

[0011] Figure 4 is a side view of the funnel catheter assembly including a non-self-expanding funnel in accordance with embodiments of the present technology.

[0012] Figures 5–8 are schematic views illustrating various thrombectomy techniques for removing a thrombus from a blood vessel of a human patient utilizing the funnel catheter assembly in accordance with embodiments of the present technology.

[0013] Figures 9A and 9B are enlarged, partially transparent side and side cross-sectional views, respectively, of a portion of a funnel catheter assembly in accordance with additional embodiments of the present technology.

[0014] Figures 10A–10C are side views of the funnel catheter assembly of Figures 9A and 9B in a sheathed position, a partially-unsheathed or intermediate position, and an unsheathed position, respectively, in accordance with embodiments of the present technology

[0015] Figure 11 is a flow diagram of a process or method for operating the funnel catheter assembly during an intravascular procedure in accordance with embodiments of the present technology.

DETAILED DESCRIPTION

[0016] The present technology is generally directed to methods and systems for removing clot material (e.g., a thrombus) from a blood vessel of a human patient. More particularly, the present technology is directed to funnel catheter assemblies configured to provide embolic protection during a clot removal or other intravascular procedure. In some embodiments, a funnel catheter assembly includes an outer shaft and an inner shaft extending through and coaxial with the outer shaft. An expandable funnel, such as a self-expanding funnel, can be coupled to a distal portion of the inner shaft. The funnel catheter assembly further includes a control assembly operably coupled to the proximal portion of the outer shaft. The funnel catheter assembly can be actuated by an operator (e.g., a physician) to move the outer shaft between a first position and a second position. In the first position, the outer shaft is positioned at least partially over the funnel to constrain the funnel in a compressed state. In the second position, the outer shaft is retracted proximally relative to the funnel such that the funnel can expand to an expanded state. Accordingly, the funnel catheter assembly enables the funnel to be unsheathed and sheathed during an intravascular procedure via the movement of the outer shaft between the first and second positions.

[0017] In one aspect of the present technology, the control assembly is operable to compress the funnel after it has been expanded within a blood vessel of a patient. This can permit the funnel catheter assembly to be repositioned within the blood vessel without fully withdrawing the funnel catheter assembly from the patient. Similarly, the funnel catheter assembly can be fully withdrawn from the patient (e.g., at the conclusion of a thrombectomy procedure) in the first position with the funnel compressed inside the outer shaft. Thus, the funnel catheter assembly is configured to inhibit or even prevent the funnel from contacting the wall of the blood vessel during movement of the funnel catheter assembly within the blood vessel. This can help inhibit injury/damage to the patient that could otherwise be caused by the moving the funnel through a blood vessel or an associated organ in the expanded state.

[0018] Although many of the embodiments are described below with respect to devices, systems, and methods for treating vascular thrombi (e.g., deep vein thrombosis (DVT)), other applications and other embodiments in addition to those described herein are within the scope of the technology (e.g., intravascular procedures other than the treatment of emboli, intravascular procedures for treating cerebral embolism, intravascular procedures for treating pulmonary embolism, etc.). In general, for example, the devices, systems, and methods of the present technology can be used to extract any formation of material in a vessel (e.g., a venous or arterial vessel), such as cancerous growths, vegetation, etc. Additionally, several other embodiments of the technology can have different configurations, states, components, or procedures than those described herein. Moreover, it will be appreciated that specific elements, substructures, advantages, uses, and/or other features of the embodiments described with reference to Figures 1–11 can be suitably interchanged, substituted or otherwise configured with one another in accordance with additional embodiments of the present technology. Furthermore, suitable elements of the embodiments described with reference to Figures 1–11 can be used as standalone and/or self-contained devices. A person of ordinary skill in the art, therefore, will accordingly understand that the technology can have other embodiments with additional elements, or the technology can have other embodiments without several of the features shown and described below with reference to Figures 1–11.

[0019] With regard to the terms "distal" and "proximal" within this description, unless otherwise specified, the terms can reference a relative position of the portions of a catheter subsystem with reference to an operator and/or a location in the vasculature. Also, as used herein, the designations "rearward," "forward," "upward," "downward," etc. are not meant to limit the referenced component to use in a specific orientation. It will be appreciated that such designations refer to the orientation of the referenced component as illustrated in the Figures; the systems of the present technology can be used in any orientation suitable to the user.

[0020] The headings provided herein are for convenience only and should not be construed as limiting the subject matter disclosed.

I. Selected Embodiments of Funnel Catheter Assemblies

[0021] Figure 1 is a partially transparent and partially cross-sectional side view of a funnel catheter assembly 100 in accordance with embodiments of the present technology. In the illustrated embodiment, the funnel catheter assembly 100 includes an elongate outer shaft 102 and an elongate inner shaft 104 coaxial with the outer shaft 102. The outer and inner shafts 102,

104 ("shafts 102, 104") can also be referred to as sheaths, catheters, hollow members, and so on. The outer shaft 102 defines a lumen 106 and includes a proximal portion 107a and a distal portion 107b. The inner shaft 104 extends through the lumen 106 of the outer shaft 102 and similarly defines a lumen 108 and includes a proximal portion 109a and a distal portion 109b. The proximal portions 107a and 109a can each terminate at a proximal end/terminus, and the distal portions 107b and 109b can each terminate at a distal end/terminus. The shafts 102, 104 can be elastic and/or flexible and can have any suitable length and diameter.

[0022] In the illustrated embodiment, the funnel catheter assembly 100 further includes a sealable hub 110 coupled to the proximal portion 109a of the inner shaft 104. In some embodiments, as described in greater detail below with reference to Figures 9A–9C, the sealable hub 110 can be rotatable coupled to the inner shaft 104 such that the sealable hub 110 can rotate independently of the inner shaft 104. The sealable hub 110 is configured to allow access to the lumen 108 of the inner shaft 104 and can be self-sealing and/or can comprise a self-sealing seal. For example, in the illustrated embodiment the sealable hub 110 is a hemostasis valve that is configured to maintain hemostasis (e.g., during a thrombus extraction procedure) by inhibiting or even preventing fluid flow in the proximal direction through the sealable hub 110 as, for example, various components (e.g., dilator assemblies, thrombus extraction devices, etc.) are inserted through the sealable hub 110 to be delivered through the inner shaft 104 to a treatment site in a blood vessel. More specifically, the sealable hub 110 can be a valve of the type disclosed in U.S. Patent Application No. 16/117,519, filed August 30, 2018, and titled "HEMOSTASIS VALVES AND METHODS OF USE," which is incorporated herein by reference in its entirety. The sealable hub 110 can include one or more buttons or actuators that enable an operator to selectively seal/unseal the sealable hub 110.

[0023] The funnel catheter assembly 100 can further include an aspiration port 112 connected to the sealable hub 110 (e.g., to a side port of the sealable hub 110) and/or the inner shaft 104 (e.g., to the proximal portion 109a of the inner shaft 104) via, for example, a connecting tube 114. The aspiration port 112 can be connected to a syringe connector 116 that can be selectively coupled to a syringe or other aspiration device, or the aspiration port 112 can be connected to other suitable elements. In some embodiments, the funnel catheter assembly 100 includes a fluid control device 118 configured to selectively fluidly connect the aspiration port 112 to the lumen 108 of the inner shaft 104. In the illustrated embodiment, the fluid control device 118 is a stopcock operably coupled to the connecting tube 114 between the lumen 108 of the inner shaft 104 and the aspiration port 112. In other embodiments, the fluid control device

118 can be a clamp or another suitable valve. In some embodiments, a vacuum source (not shown; e.g., a syringe) can be coupled to the syringe connector 116 and used to aspirate the lumen 108 of the inner shaft 104. In some embodiments, as described in greater detail below with reference to Figures 9A–9C, the aspiration port 112 and the connecting tube 114 can be rotatable relative to the sealable hub 110 and/or the inner shaft 104.

[0024] In the illustrated embodiment, a funnel 120 is coupled to the distal portion 109b of the inner shaft 104. As described in greater detail below, in operation of the funnel catheter assembly 100 during an intravascular procedure, the funnel 120 is configured to expand (e.g., radially expand) into apposition with a blood vessel and/or other bodily lumen (e.g., of an organ) and act as a proximal or distal thrombus/embolic protection device that inhibits any thrombus from moving past the funnel 120 and embolizing in an unwanted location (e.g., the right heart, the pulmonary arteries, another arterial space, etc.). The funnel 120 can be fused to the distal portion 109b of the inner shaft 104, and/or attached to the inner shaft 104 via welding, adhesives, fasteners, etc. In Figure 1, the funnel catheter assembly 100 is in a first position/state/configuration in which the distal portion 107b of the outer shaft 102 extends beyond the distal portion 109b of the inner shaft 104 such that the funnel 120 is at least partially (e.g., entirely) positioned within the lumen 106 of the outer shaft 102. The funnel 120 can be configured to expand (e.g., self-expand) and, accordingly, the funnel 120 can be in a first, constrained position/state/configuration when the funnel catheter assembly 100 is in the first position. In some embodiments, the funnel 120 can be formed from at least one of a castellated nitinol braid, a nitinol braided stent, a laser cut nitinol, a laser cut polymer tube, an injection molded polymeric structure, or an inflatable balloon. In some embodiments, the funnel 120 can comprise a mesh having a pore size sufficiently small to prevent the passage of thrombus through the pores of the mesh. In some embodiments, the funnel 120 can be permeable to blood. In some embodiments, the funnel 120 can include a covering over at least a portion thereof that is permeable or non-permeable to blood.

[0025] In the illustrated embodiment, the proximal portion 107a of the outer shaft 102 is operably coupled to a control assembly 130. The control assembly 130 is operable to move the outer shaft 102 distally and proximally relative to the inner shaft 104 to constrain and release the funnel 120 from within the lumen 106 of the outer shaft 102. More specifically, in the illustrated embodiment the control assembly 130 includes (i) a housing 132 having a proximal portion 133a and a distal portion 133b, and (ii) an actuation member 134 operably/movably coupled to the housing 132. The housing 132 defines a lumen 135 extending between the proximal and distal

portions 133a, b thereof. The proximal portion 133a of the housing 132 can be coupled to the sealable hub 110. In some embodiments, the proximal portion 133a of the housing 132 is integrally formed with the sealable hub 110.

[0026] In the illustrated embodiment, the actuation member 134 includes a body portion 136 positioned within the lumen 135 of the housing 132 and coupled to the proximal portion 107a of the outer shaft 102 via, for example, adhesive, fasteners, welding, etc. The actuation member 134 further includes one or more grip members 138 extending from the body portion 136 to outside of the lumen 135. More specifically, the grip members 138 can extend through corresponding slots 140 formed in/along the housing 132. The housing 132 can define a proximal terminus 142a and a distal terminus 142b for each of the slots 140. In some embodiments, the control assembly 130 can include one, or more than the illustrated two of the grip members 138 and corresponding slots 140.

[0027] In operation, an operator (e.g., a physician) can slide the actuation member 134 along the housing 132 to distally advance and proximally retract the outer shaft 102 relative to the inner shaft 104 to constrain and release the funnel 120, respectively. More specifically, Figures 2A and 2B are side views of the funnel catheter assembly 100 in the first position and in a second position, respectively, in accordance with embodiments of the present technology. Referring to Figures 1–2B together, to move the funnel catheter assembly 100 from the first position (Figures 1 and 2A) to the second position (Figure 2B), the operator can grip the grip members 138 of the actuation member 134 and slide the grip members 138 proximally (e.g., in the direction of arrow P in Figure 2A) relative to the housing 132 to drive the body portion 136 through the lumen 135 to thereby drive the outer shaft 102 proximally relative to the inner shaft 104. The funnel 120 is released/unsheathed from within the lumen 106 of the outer shaft 102 as the distal portion 107b of the outer shaft 102 moves proximally past the funnel 120, thereby allowing the funnel 120 to expand. In some embodiments, the actuation member 134 can abut the proximal termini 142a of the slots 140 in the second position such that the housing 132 inhibits further proximal movement of the outer shaft 102.

[0028] In some embodiments, the distal terminus of the outer shaft 102 is positioned at or proximal of the distal terminus of the inner shaft 104 in the second position such that the funnel 120 is fully released from (e.g., positioned fully outside of) the lumen 106 of the outer shaft 102. In other embodiments, the distal terminus of the outer shaft 102 can be positioned distal of the distal terminus of the inner shaft 104 in the second position such that the funnel 120 is only

partially released from the lumen 106 of the outer shaft 102. Moreover, as shown in Figure 2B, the funnel 120 can have a conically shaped portion 222 (e.g., a truncated-conically shaped portion) and a cylindrical portion 224 once expanded. In other embodiments, the funnel 120 can have other suitable shapes. For example, in some embodiments the funnel 120 can be inverted relative to the embodiment shown in Figure 2B. That is, the cylindrical portion 224 of the funnel 120 can be coupled to the distal portion 109b of the inner shaft 104 while the conically shaped portion 222 extends distally from the cylindrical portion 224.

[0029] To move the funnel catheter assembly 100 from the second position (Figure 2B) to the first position (Figures 1 and 2A), the operator can grip the grip members 138 of the actuation member 134 and slide the grip members 138 distally (e.g., in the direction of arrow D in Figure 2B) relative to the housing 132 to drive the body portion 136 through the lumen 135 to thereby drive the outer shaft 102 distally relative to the inner shaft 104. The funnel 120 is captured/sheathed in the lumen 106 of the outer shaft 102 as the distal portion 107b of the outer shaft 102 moves distally over the funnel 120, thereby collapsing/compressing the funnel 120 within the lumen 106. In some embodiments, the actuation member 134 can abut the distal termini 142b of the slots 140 in the first position such that the housing 132 inhibits further distal movement of the outer shaft 102.

[0030] In some embodiments the actuation member 134 is configured to be releasably secured/locked to the housing 132 in the first and second positions to inhibit or even prevent unintended movement of the actuation member 134. For example, referring again to Figure 1, the housing 132 of the control assembly 130 can include (i) proximal engagement members 144a (e.g., tabs, protrusions, etc.) configured to engage the actuation member 134 in the first position and (ii) distal engagement members 144b configured to engage the actuation member 134 in the second position. More specifically, in some embodiments the proximal and distal engagement members 144a, b can mate with corresponding slots/grooves in the actuation member 134 (e.g., formed in/on the grip members 138) to releasably secure the actuation member 134 in the first or second positions via a snap fit arrangement.

[0031] In some embodiments, the inner shaft 104 is sized to slidably receive one or more medical instruments inserted through the sealable hub 110 during an intravascular procedure using the funnel catheter assembly 100, such as a thrombectomy procedure. Figure 3, for example, is a side view of the funnel catheter assembly 100 in the first position with a dilator 350 inserted through the sealable hub 110 and the lumen 108 of the inner shaft 104 (Figure 1) in

accordance with embodiments of the present technology. The dilator 350 can extend entirely through the inner shaft 104 and past the distal terminus of the distal portion 107b of the outer shaft 102 such that a distal tip 352 (e.g., an atraumatic tip) is positioned beyond the distal terminus of the outer shaft 102.

[0032] In some embodiments, the dilator 350 and the funnel catheter assembly 100 together define an introducer assembly that can be inserted into a patient (e.g., a human patient) and subsequently used to introduce intravascular medical devices into the patient. For example, the dilator 350 and the funnel catheter assembly 100 can be inserted into and advanced together through a blood vessel of the patient to a target location in the blood vessel. The dilator 350 can then be retracted proximally through the funnel catheter assembly 100, and the funnel catheter assembly 100 can be moved to the second position to expand the funnel 120 at the target location.

[0033] Referring to Figures 1–3 together, in one aspect of the present technology the inner shaft 104 is the "working" shaft of the funnel catheter assembly 100 that can be aspirated and/or receive various medical components (e.g., the dilator 350). In contrast, the outer shaft 102 is used to compress/expand the funnel 120. Accordingly, the shafts 102, 104 can be sized to maximize the size of the inner shaft 104 to permit larger-sized components to be inserted therethrough, or to provide greater aspiration force/power. For example, the outer shaft 102 can have an inner diameter that is only slightly greater than an outer diameter of the inner shaft 104. In some embodiments, the inner shaft 104 can have an outer diameter of at least 10 French, at least 12 French, at least 14 French, at least 18 French, at least 20 French, at least 22 French, at least 26 French, greater than 26 French, between 10 French and 26 French, between 14 French and 24 French, between 15 French and 21 French, between 16 French and 22 French, and/or any other or intermediate size. In some embodiments, the lumen 108 of the inner shaft 104 can have an internal diameter of at least 2 French, at least 10 French, at least 14 French, at least 18 French, at least 20 French, at least 22 French, between 11 French and 12 French, between 10 French and 22 French, between 14 French and 21 French, between 16 French and 20 French, and/or any other or intermediate size.

[0034] In another aspect of the present technology, the control assembly 130 is operable, via the movement of the actuation member 134 from the second position to the first position, to compress the funnel 120 after it has been expanded within a blood vessel. This can permit the funnel catheter assembly 100 to be repositioned within the blood vessel without fully withdrawing the funnel catheter assembly 100 from the patient. For example, after (i)

introducing the funnel catheter assembly 100 into the blood vessel with the dilator 350 and (ii) removing the dilator 350, the funnel catheter assembly 100 can be repositioned proximally simply by moving the funnel catheter assembly 100 back to the first position to collapse the funnel 120 and then retracting the funnel catheter assembly 100 proximally. To reposition the funnel catheter assembly 100 distally, the dilator 350 can be reinserted and the funnel catheter assembly 100 pushed proximally in the first position with the funnel 120 compressed. Similarly, the funnel catheter assembly 100 can be fully withdrawn from the patient (e.g., at the conclusion of a thrombectomy procedure) in the first position with the funnel 120 compressed in the lumen 106 of outer shaft 102. Thus, the funnel catheter assembly 100 is configured to inhibit or even prevent the funnel 120 from contacting the wall of the blood vessel during advancement/withdrawal. This can help inhibit injury/damage to the patient that could otherwise be caused by the moving the funnel 120 through the blood vessel or an associated organ in the expanded state.

[0035] In some embodiments, the funnel catheter assembly 100 and/or methods of operating the funnel catheter assembly 100 can include some features the same as or similar to the thrombectomy systems (e.g., the introducer assemblies) described in detail in (i) U.S. Patent No. 9,700,332, filed September 16, 2016, and titled "INTRAVASCULAR TREATMENT OF VASCULAR OCCLUSION AND ASSOCIATED DEVICES, SYSTEMS, AND METHODS," and/or (ii) U.S. Patent No. 10,098,651, filed April 26, 2017, and titled "DEVICES AND METHODS FOR TREATING VASCULAR OCCLUSION," both of which are incorporated herein by reference in their entirety.

[0036] In other embodiments, the control assembly 130 can be configured to drive the distal and proximal movement of the outer shaft 102 in other manners. For example, the actuation member 134 can comprise a rotatable member (e.g., a ring gear, corkscrew, rotatable handle, etc.) coupled to the outer shaft 102. In some embodiments, the rotatable member can be a ratcheting member that is rotatable to a plurality of discrete positions between the first and second positions.

[0037] Similarly, in other embodiments the control assembly 130 can be operably coupled to the inner shaft 104 rather than the outer shaft 102. Accordingly, operation of the control assembly 130 can move the inner shaft 104 and the sealable hub 110 relative to the outer shaft 102 to move the funnel catheter assembly 100 between the first and second positions to constrain/compress and release/expand the funnel 120, respectively.

[0038] In yet other embodiments, the funnel 120 can be operably coupled to the outer shaft 102 such that movement of the outer shaft 102 between the first and second positions expands the funnel 120. More specifically, for example, Figure 4 is a side view of the funnel catheter assembly 100 including a non-self-expanding funnel 420 in accordance with embodiments of the present technology. In some embodiments, the funnel 420 can have a similar shape as the funnel 120 described in detail above with reference to Figures 1–3, but can be formed of one or more non-self-expanding materials such as metal (e.g., a non-heat-activated metal), plastic, fiber, polymer, etc. In the illustrated embodiment, the funnel 420 is coupled to (i) the distal portion 109b of the inner shaft 104 (Figure 1) and (ii) the distal portion 107b of the outer shaft 102 via a plurality of flexible tethers 426. The tethers 426 are configured (e.g., shaped, sized, and/or positioned) such that movement of the control assembly 130 from the first position to the second position pulls the tethers 426 to thereby pull and expand the funnel 420 as it is unsheathed from within the outer shaft 102.

[0039] In some embodiments, the funnel catheter assembly 100 can include one or more features for actuating/manipulating the funnel 420 (or the funnel 120 described in detail with reference to Figures 1–3). For example, the control assembly 130 can include an actuation member 454 (shown schematically) operably coupled to the funnel 420 via one or more control lines 462 (e.g., wires, tethers, rigid members etc.). The actuation member 454 can be a slider, rotatable member, or other component configured to exert a force on the funnel 420 via the control lines 462. In some embodiments, the control lines 462 can be asymmetrically/eccentrically coupled to the funnel 420 such that actuation of the actuation member 454 bends the funnel 420 away from a longitudinal axis of the shafts 102, 104. In one aspect of the present technology, this arrangement can be used to help steer the funnel 420 into a tortuous region of a patient (e.g., a tortuous vessel, the left atrial appendage (LAA), etc.) that may otherwise be difficult to position the funnel 420 in. Additionally or alternatively, the funnel catheter assembly 100 can include one or more components (e.g., pull wires) for steering (e.g., bending, deflecting, etc.) the outer shaft 102 and/or the inner shaft 104 to facilitate positioning of the funnel 420.

II. Selected Embodiments of Procedures Utilizing Funnel Catheter Assemblies for Embolic Protection

[0040] Referring to Figures 1–4 together, the funnel catheter assembly 100 can be used in a myriad of procedures to capture thrombi and inhibit the thrombi from embolizing in portions

of a patient's vasculature. For example, Figures 5–8 are schematic views illustrating various thrombectomy techniques for removing a thrombus T from a blood vessel BV of a human patient utilizing the funnel catheter assembly 100 in accordance with various embodiments of the present technology.

[0041] Referring first to Figure 5, in some embodiments the thrombus T (e.g., clot material) can be accessed through a popliteal access site 560. The funnel catheter assembly 100 can extend from the popliteal access site 560 to a deployment position 562 in the blood vessel BV at which the funnel 120 (or the funnel 420) can be deployed. The deployment position 562 can be proximate to and proximal of the thrombus T. The funnel 120 can at least partially appose a wall of the blood vessel BV after the funnel catheter assembly 100 is moved from the first position to the second position to expand the funnel 120, as described in detail above with reference to Figures 1–4.

[0042] In the illustrated embodiment, a thrombus extraction device 564 has been (i) inserted through the funnel catheter assembly 100, (ii) passed through the thrombus T in the direction of blood flow, and (iii) expanded distal of the thrombus T. The thrombus extraction device 564 can include a coring element 565 (e.g., a stent-like device) and a capture element 566 (e.g., a braided mesh bag). In some embodiments, some or all of the thrombus extraction device 564 can extend into one of the iliac veins and/or the inferior vena cava. After expansion distal of the thrombus T, the thrombus extraction device 564 can be retracted through the thrombus T and into the lumen 108 of the inner shaft 104 (Figure 1) through the funnel 120. During retraction, the coring element 565 can core/separate the thrombus T and the capture element 566 can capture all or a portion of the thrombus T. In some embodiments, the thrombus extraction device 564 and the associated thrombectomy procedure can be generally similar or identical to the thrombus extraction devices and associated methods described in detail in (i) U.S. Patent No. 9,700,332, filed September 16, 2016, and titled "INTRAVASCULAR TREATMENT OF VASCULAR OCCLUSION AND ASSOCIATED DEVICES, SYSTEMS, AND METHODS," and/or (ii) U.S. Patent No. 10,098,651, filed April 26, 2017, and titled "DEVICES AND METHODS FOR TREATING VASCULAR OCCLUSION," both of which are incorporated herein by reference in their entirety.

[0043] In one aspect of the present technology, as the thrombus extraction device 564 and the captured thrombus T are retracted through the funnel 120, the funnel 120 can capture/retain any of the thrombus T that breaks free of the thrombus extraction device 564 as the thrombus

extraction device 564 is compressed into the inner shaft 104. Accordingly, the funnel 120 can inhibit portions of the thrombus T from traveling upstream where they could potentially embolize. In some embodiments, a vacuum (e.g., a pre-charged vacuum) can be applied to the inner shaft 104 (e.g., via a syringe coupled to the syringe connector 116 shown in Figure 1) at any point during retraction of the thrombus extraction device 564. In some embodiments, application of the vacuum can generate instantaneous or nearly instantaneous suction at the distal portion 109b of the inner shaft 104 that can aspirate any remaining portions of the thrombus T into and/or through the inner shaft 104.

[0044] Referring next to Figure 6, in some embodiments the thrombus T (not shown in Figure 6; e.g., positioned lower in the iliac or femoral veins) can be accessed through an internal jugular access site 670, and the funnel catheter assembly 100 can be inserted into the patient's body via the internal jugular access site 670. The funnel catheter assembly 100 can extend from the internal jugular access site 670 to a deployment position 672 at which the funnel 120 (or the funnel 420) can be deployed proximal to the thrombus T. In the illustrated embodiment, the outer shaft 102 and the inner shaft 104 (obscured in Figure 6) extend from the internal jugular access site 670 through the superior vena cava and the inferior vena cava to the deployment position 672 in one of the common iliac veins. In some embodiments, the deployment position 672 can be located in, for example, the inferior vena cava, one of the iliac veins, the femoral vein, the popliteal vein, before or beyond the iliac arch, or any other location proximate to and/or proximal to the thrombus T. In some embodiments, the thrombus extraction device 564 can be inserted through the funnel catheter assembly 100 and withdrawn through the thrombus T to capture the thrombus T, as described in detail above with reference to Figure 5.

[0045] In one aspect of the present technology, accessing the thrombus T via the internal jugular access site 670 allows the funnel 120 to be positioned downstream of the thrombus T. Accordingly, the funnel 120 can capture any of the thrombus T that may break off and be carried downstream toward the heart during operation of the thrombus extraction device 564. In another aspect of the present technology, the funnel 120 can be compressed—for example, by moving the actuation member 134 from the second position to the first position as described in detail above with reference to Figures 1–4—before withdrawing the funnel catheter assembly 100 at the conclusion of the thrombectomy procedure. This prevents the funnel 120 from being withdrawn in the expanded configuration through the heart of the patient (e.g., through the right atrium) which could potentially damage the heart.

[0046] Referring next to Figure 7, in some embodiments the thrombus T can be accessed by the thrombus extraction device 564 through the popliteal access site 560 using a separate introducer assembly 774, while the funnel catheter assembly 100 can be inserted into the patient's body via the internal jugular access site 670 (Figure 6). The funnel 120 can be expanded at the deployment position 672 during a thrombectomy procedure using the thrombus extraction device 564. The funnel 120 can therefore capture any of the thrombus material T that may break away and flow downstream during the procedure. In the illustrated embodiment, the thrombus extraction device 564 is inserted through an outer shaft 776 of the introducer assembly 774. In one aspect of the present technology, in comparison to using the funnel catheter assembly 100 as the introducer for the thrombus extraction device 564, the outer shaft 776 can be made relatively larger than the inner shaft 104 because the outer shaft 102 need not be positioned thereabout for constraining the funnel 120. This can permit the thrombus extraction device 564 to be made larger and/or enable greater aspiration forces to be generated through the outer shaft 776.

[0047] Referring next to Figure 8, in some embodiments the thrombus T can be accessed by the thrombus extraction device 564 through the popliteal access site 560 using the introducer assembly 774, while the funnel catheter assembly 100 can be inserted into the patient's body via a femoral access site 880. The funnel catheter assembly 100 can traverse the common iliac veins to the deployment position 672, or another suitable deployment position.

[0048] In other embodiments, the funnel catheter assembly 100 can be inserted into a patient's body via other venous or arterial access sites, and can be used in a myriad of different procedures. For example, additional applications of the funnel catheter assembly 100 include but are not limited to:

[0049] Internal jugular vein (IJ) access for deployment in the inferior vena cava (IVC) for treatment of lower extremity deep vein thrombosis (DVT);

[0050] IJ access for deployment in the IVC for removal of IVC filters and/or treatment of thrombus located in the IVC;

[0051] IJ access for deployment in the deep veins of the lower extremity veins (iliac, femoral, popliteal veins, etc.) for treatment of lower extremity DVT;

[0052] Common femoral vein (CFV) access for deployment in the superior vena cava (SVC) for treatment of upper extremity DVT and/or SVC thrombus;

[0053] CFV access for deployment in the upper extremity veins (brachiocephalic, subclavian, axillary veins, etc.) for treatment of upper extremity DVT and/or SVC thrombus;

[0054] CFV access for deployment in the pulmonary arteries (PAs) for treatment of pulmonary embolism;

[0055] CFV access with transseptal access for deployment in the left atrium ostium and the left atrial appendage (LAA) for thrombus removal;

[0056] Internal Carotid Artery (ICA) access for deployment in the common carotid artery (CCA) for carotid endarterectomy (CEA);

[0057] ICA access for deployment in descending thoracic aorta for treatment of thoraco-abdominal and/or abdominal aortic (AA) thrombus and/or aorto-arterial thrombosis;

[0058] ICA access for deployment in the descending/thoracic aorta for treatment of renal thrombosis;

[0059] ICA access for intra-arterial placement for treatment of superior mesenteric artery (SMA) thrombosis (MAT);

[0060] Common Femoral Artery (CFA) access for treatment of atherosclerosis in the brachial artery, radial artery, popliteal artery, or dorsalis pedis artery;

[0061] CFA access for deployment in the common iliac artery for treatment of aorto-arterial thrombosis and/or occlusions;

[0062] CFA access for deployment in the abdominal aorta for treatment of renal artery thrombosis; and/or

[0063] CFA access for deployment in the aorta for treatment of thoraco-abdominal and/or AA thrombus and/or aorto-arterial thrombosis.

[0064] Figures 9A and 9B are enlarged, partially transparent side and side cross-sectional views, respectively, of a portion of a funnel catheter assembly 900 in accordance with additional embodiments of the present technology. Referring to Figures 9A and 9B together, the funnel catheter assembly 900 can include some features that are at least generally similar in structure and function, or identical in structure and function, to the corresponding features of the funnel catheter assembly 100 described in detail above with reference to Figures 1–8, and can operate

in a generally similar or identical manner to the funnel catheter assembly 100. In the illustrated embodiment, for example, the funnel catheter assembly 900 includes the sealable hub 110, the connecting tube 114, the aspiration port 112, the outer shaft 102, and the inner shaft 104 (obscured in Figure 9A). The funnel catheter assembly 900 further includes a control assembly 930 including a housing 932 and an actuation member 934 having a pair of grip member 938. As shown in Figure 9B, the actuation member 934 includes a hub 936 positioned within the housing 932 and coupled to the outer shaft 102 (e.g., the proximal portion 107a of the outer shaft 102). The actuation member 934 is movable (e.g., slidable) relative to the housing 932 to advance/retract the outer shaft 102 relative to the inner shaft 104 and a funnel (e.g., the funnel 120 shown in Figures 10B and 10C) attached to a distal portion thereof.

[0065] The funnel catheter assembly 900 is in a first, sheathed position in Figure 9A in which the funnel is constrained by the outer shaft 102 and in a second, unsheathed position in Figure 9B in which the funnel is not constrained by the outer shaft 102. Referring to Figure 9A, in some embodiments the housing 932 can include a marking 931 indicating a position of the actuation member 934 in which the funnel is in the unsheathed position. In some embodiments, a proximal portion 933a of the housing 932 can include gripping features, such as a groove 935, a cross-hatched pattern 937, and/or other features for increasing the grip-ability of the housing 932. In some embodiments, an operator can grip the housing 932 (e.g., via the groove 935 and/or the pattern 937) while moving (i) the actuation member 934 relative to the housing 932 and/or (ii) the housing 932 relative to the actuation member 934. In some embodiments, the funnel catheter assembly 900 can further include a lock mechanism 911 that can be attached to the sealable hub 110 (e.g., to buttons thereof) to lock the sealable hub 110 in the open/unsealed position.

[0066] In the illustrated embodiment, the funnel catheter assembly 900 further includes a rotatable side port 950 fluidly connecting the sealable hub 110, the connecting tube 114, and the inner shaft 104. Figure 9C is an enlarged isometric cross-sectional view of a portion of the sealable hub 110, the rotatable side port 950, and the control assembly 930 in accordance with embodiments of the present technology. Referring to Figure 9C, the side port 950 defines a lumen 952 that provides a fluid path from the inner shaft 104 to the sealable hub 110. In the illustrated embodiment, the side port 950 includes a first groove 954 and a second groove 956 that each extend circumferentially about an outer surface of the side port 950. The sealable hub 110 includes a first projection 964 positioned in the first groove 954 and the housing 932 includes a second projection 966 positioned in the second groove 956. The engagement of the first and

second projections 964, 966 in the first and second grooves 954, 956 couples the housing 932 to the sealable hub 110. Moreover, the first and second projections 964, 966 are rotatable within the first and second grooves 954, 956 such that the sealable hub 110, the side port 114, and the housing 932 can each rotate independently of one another while remaining coupled together.

[0067] In some embodiments, the control assembly 930 can further include a connector 958 coupled to the proximal portion 109a of the inner shaft 104 and positioned at least partially between the side port 950 and the housing 932. The connector 958 can be rotatable within the housing 932 such that the housing 932 can rotate independently of the connector 958 and the inner shaft 104. Accordingly, in some aspects of the present technology rotation of the sealable hub 110, the side port 950 (e.g., the aspiration port 112 shown in Figures 9B and 9C), and/or the housing 932 will not substantially rotate the inner shaft 104. This can help inhibit the funnel attached to the inner shaft 104 from rotating within a vessel during a procedure using the funnel catheter assembly 900—while still allowing for movement of the sealable hub 110, the side port 950, and/or other components of the funnel catheter assembly 900.

[0068] Figures 10A–10C are side views of the funnel catheter assembly 900 in the sheathed position, a partially-unsheathed or intermediate position, and the unsheathed position, respectively, in accordance with embodiments of the present technology. Referring to Figures 10A–10C together, the funnel catheter assembly 900 can be moved between the sheathed and unsheathed positions by moving the actuation member 934 relative to the housing 932 and/or by moving the housing 932 (and the coupled sealable hub 110) relative to the actuation member 934. In some embodiments, for example, the operator can slide the actuation member 134 relative to the housing 932 in the direction indicated by the arrow P in Figure 10B to retract the outer shaft 102 to unsheathe the funnel 120. In some aspects of the present technology, moving the actuation member 934 rather than the housing 932 moves only the outer shaft 102 such that the funnel 120 remains in a constant or generally constant position (e.g., stationary position). In other embodiments, the operator can advance the housing 932 relative to the actuation member 934 in the direction indicated by the arrow D in Figure 10A to unsheathe the funnel 120. In some aspects of the present technology, moving the housing 932 relative to the actuation member 934 advances the inner shaft 104 and the funnel 120 distally relative to the outer shaft 102.

[0069] In the unsheathed position shown in Figure 10C, the actuation member 934 can be positioned adjacent or near the marking 931 to indicate to the operator that the funnel 120 is deployed. In some embodiments, to re-sheathe the funnel 120 (e.g., from the unsheathed position

shown in Figure 10C to the sheathed position shown in Figure 10A), the operator can retract the housing 932 relative to the actuation member 934 (e.g., in the direction of the arrow P) to pull the funnel 120 into the outer shaft 102. In some aspects of the present technology, such a retracting motion can be intuitive to the user as the motion of the housing 932 is in the same direction as the removal/collapse of the funnel 120. Nevertheless, in other embodiments the operator can advance the actuation member 934 relative to the housing 932 to sheathe the funnel 120 within the outer shaft 102.

[0070] Figure 11 is a flow diagram of a process or method 1110 for operating the funnel catheter assembly 100 and/or the funnel catheter assembly 900 (collectively referred to as "the funnel catheter assembly") during an intravascular procedure in accordance with embodiments of the present technology. Although some features of the method 1110 are described in the context of the embodiments shown in Figures 1–10C for the sake of illustration, one skilled in the art will readily understand that the method 1110 can be carried out using other suitable systems and/or devices described herein.

[0071] At block 1111, the method 1110 includes inserting the funnel catheter assembly into a patient's body via a vascular site. For example, the dilator 350, the outer shaft 102, and inner shaft 104 can be inserted together through a venous or arterial access site.

[0072] At block 1112, the method 1110 includes advancing the funnel catheter assembly to a deployment position within the vasculature of the patient. For example, the dilator 350, the outer shaft 102, and inner shaft 104 can be advanced together through the vasculature to the selected deployment position. The funnel catheter assembly can be advanced in the first position such that the funnel 120 is constrained/compressed within the outer shaft 102. The deployment position can be a portion of a blood vessel, a portion of the heart, or another suitable location.

[0073] At block 1113, the method 1110 includes expanding the funnel 120 at the deployment position. For example, the control assembly 130 of the funnel catheter assembly 100 can be moved from the first position to the second position to release/unsheath the funnel 120 from within the outer shaft 102, thereby allowing the funnel 120 to expand at the deployment position. Likewise, the actuation member 934 can be slid relative to the housing 932 to unsheath the funnel 120. After expansion, the funnel 120 can appose/contact the anatomy surrounding the deployment position, such as a wall of a blood vessel. In some embodiments, the dilator 350 can be removed from the funnel catheter assembly before expanding the funnel 120.

[0074] At block 1114, the method 1110 optionally includes compressing and repositioning the funnel 120. For example, the control assembly 130 can be moved from the second position to the first position to constrain/sheathe the funnel 120 within the outer shaft 102. Likewise, the housing 932 of the funnel catheter assembly 900 can be retracted proximally relative to the actuation member (and/or the actuation member 934 can be advanced distally relative to the housing) to sheathe the funnel 120. Then, the funnel catheter assembly can be repositioned to a different deployment position (block 1112) and expanded once again (block 1113). In some embodiments, the dilator 350 can be reinserted into the funnel catheter assembly 100 before repositioning the funnel catheter assembly 100.

[0075] At block 1115, the method 1110 includes maintaining the funnel 120 in the expanded position during an intravascular procedure. As described in detail above, the funnel 120 can capture thrombi that break free during the intravascular procedure to inhibit their embolization elsewhere in the vasculature of the patient.

[0076] At block 1116, the method 1110 includes compressing the funnel 120 and withdrawing the funnel catheter assembly 100 from the patient. For example, the control assembly 130 of the funnel catheter assembly 100 can be moved from the second position to the first position to constrain/sheathe the funnel 120 within the outer shaft 102, and the funnel catheter assembly 100 can then be withdrawn proximally to and from the vascular access site. Likewise, the housing 932 of the funnel catheter assembly 900 can be retracted proximally relative to the actuation member (and/or the actuation member 934 can be advanced distally relative to the housing) to sheathe the funnel 120.

III. Examples

[0077] Several aspects of the present technology are set forth in the following examples:

1. A funnel catheter assembly, comprising:
 - an outer shaft defining a lumen;
 - an inner shaft extending through the lumen and having a proximal portion and a distal portion;
 - an expandable funnel coupled to the distal portion of the inner shaft; and
 - a control assembly configured to move the funnel between a first position and a second position, wherein—

in the first position, the funnel is constrained within the lumen of the outer shaft,
and
in the second position, the funnel is positioned at least partially outside the lumen
of the outer shaft such that the funnel can expand.

2. The funnel catheter assembly of example 1 wherein the control assembly is coupled to the outer shaft and configured to move the outer shaft relative to the inner shaft.

3. The funnel catheter assembly of example 1 or example 2 wherein the control assembly includes an actuator movable to move the funnel between the first and second positions.

4. The funnel catheter assembly of example 3 wherein the actuator is a slider.

5. The funnel catheter assembly of any one of examples 2–4 wherein the funnel includes a proximal portion and a distal portion, and wherein the proximal portion of the funnel is coupled to the distal portion of the inner shaft.

6. The funnel catheter of example 5 wherein the distal portion of the funnel is coupled to the outer shaft.

7. The funnel catheter assembly of any one of examples 1–6, further comprising a sealable hub and a side port, wherein the side port is rotatably coupled between the control assembly and the sealable hub.

8. A funnel catheter assembly, comprising:
an outer shaft defining an outer lumen;
an inner shaft extending through the outer lumen and having a proximal portion and a distal portion;
an expandable funnel coupled to the distal portion of the inner shaft; and
a control assembly operably coupled to the proximal portion of the outer shaft and configured to move the outer shaft between a first position and a second position, wherein—

in the first position, the outer shaft is positioned at least partially over the funnel to radially constrain the funnel, and
in the second position, the outer shaft is retracted proximally relative to the funnel such that the funnel can radially expand.

9. The funnel catheter assembly of example 8 wherein the control assembly includes a housing and an actuation member, wherein the actuation member is coupled to a proximal portion of the outer shaft, and wherein the actuation member is slidable along the housing to move the outer shaft between the first and second positions.

10. The funnel catheter assembly of example 8 or example 9 wherein the funnel is configured to self-expand.

11. The funnel catheter assembly of example 8 or example 9 wherein the funnel is non-self-expanding, wherein the funnel is further coupled to a distal portion of the outer shaft, and wherein movement of the outer shaft from the first position to the second position is configured to expand the funnel.

12. The funnel catheter assembly of example 11 wherein a distal portion of the funnel is coupled to the distal portion of the outer shaft via one or more tethers.

13. The funnel catheter assembly of any one of examples 8–12 wherein the inner shaft defines an inner lumen sized to receive a dilator.

14. A method of operating a funnel catheter assembly during an intravascular procedure on a patient, the method comprising:

at least partially inserting an inner shaft, an outer shaft, and a funnel of the funnel catheter assembly into the vasculature of the patient;
advancing the inner shaft, the outer shaft, and the funnel together to a deployment position within the vasculature of the patient, wherein the funnel is sheathed within a lumen of the outer shaft during the advancement;
moving the outer shaft relative to the inner shaft to unsheathe the funnel and permit the funnel to expand to an expanded position;

maintaining the funnel in the expanded position during at least a portion of the intravascular procedure;
moving the outer shaft relative to the inner shaft and/or moving the inner shaft relative to the outer shaft to sheath the funnel within the lumen of the outer shaft; and
withdrawing the funnel catheter assembly from the patient.

15. The method of example 14 wherein the funnel is self-expandable, and wherein moving the outer shaft relative to the inner shaft to unsheath the funnel includes permitting the funnel to self-expand to the expanded position.

16. The method of example 14 or example 15 wherein moving the outer shaft relative to the inner shaft to unsheath the funnel includes moving a slider of a control assembly of the funnel catheter assembly from a first position to a second position, and wherein the slider is coupled to a proximal portion of the outer shaft.

17. The method of any one of examples 14–16 wherein moving the outer shaft relative to the inner shaft to unsheath the funnel includes rotating a rotatable element of a control assembly of the funnel catheter assembly from a first position to a second position.

18. The method of any one of examples 14, 16, and 17 wherein the funnel is non-self-expanding, and wherein the method further comprises actuating the funnel to expand to the expanded position.

19. The method of any one of examples 14–18 wherein—
inserting the inner shaft, the outer shaft, and the funnel into the vasculature of the patient further includes at least partially inserting a dilator positioned within the inner shaft into the vasculature of the patient; and
advancing the inner shaft, the outer shaft, and the funnel further includes advancing the inner shaft, the outer shaft, the funnel, and the dilator together to the deployment position.

20. The method of any one of examples 14–19 wherein moving the outer shaft relative to the inner shaft to unsheath the funnel includes moving the outer shaft in a first

direction, and wherein the method further comprises moving the outer shaft relative to the inner shaft to sheath the funnel by moving the outer shaft in a second direction opposite to the first direction.

IV. Conclusion

[0078] The above detailed descriptions of embodiments of the technology are not intended to be exhaustive or to limit the technology to the precise form disclosed above. Although specific embodiments of, and examples for, the technology are described above for illustrative purposes, various equivalent modifications are possible within the scope of the technology as those skilled in the relevant art will recognize. For example, although steps are presented in a given order, alternative embodiments may perform steps in a different order. The various embodiments described herein may also be combined to provide further embodiments.

[0079] From the foregoing, it will be appreciated that specific embodiments of the technology have been described herein for purposes of illustration, but well-known structures and functions have not been shown or described in detail to avoid unnecessarily obscuring the description of the embodiments of the technology. Where the context permits, singular or plural terms may also include the plural or singular term, respectively.

[0080] Moreover, unless the word "or" is expressly limited to mean only a single item exclusive from the other items in reference to a list of two or more items, then the use of "or" in such a list is to be interpreted as including (a) any single item in the list, (b) all of the items in the list, or (c) any combination of the items in the list. Additionally, the term "comprising" is used throughout to mean including at least the recited feature(s) such that any greater number of the same feature and/or additional types of other features are not precluded. It will also be appreciated that specific embodiments have been described herein for purposes of illustration, but that various modifications may be made without deviating from the technology. Further, while advantages associated with some embodiments of the technology have been described in the context of those embodiments, other embodiments may also exhibit such advantages, and not all embodiments need necessarily exhibit such advantages to fall within the scope of the technology. Accordingly, the disclosure and associated technology can encompass other embodiments not expressly shown or described herein.

CLAIMS

I/We claim:

1. A funnel catheter assembly, comprising:
an outer shaft defining a lumen;
an inner shaft extending through the lumen and having a proximal portion and a distal portion;
an expandable funnel coupled to the distal portion of the inner shaft; and
a control assembly configured to move the funnel between a first position and a second position, wherein—
in the first position, the funnel is constrained within the lumen of the outer shaft,
and
in the second position, the funnel is positioned at least partially outside the lumen of the outer shaft such that the funnel can expand.
2. The funnel catheter assembly of claim 1 wherein the control assembly is coupled to the outer shaft and configured to move the outer shaft relative to the inner shaft.
3. The funnel catheter assembly of claim 1 wherein the control assembly includes an actuator movable to move the funnel between the first and second positions.
4. The funnel catheter assembly of claim 3 wherein the actuator is a slider.
5. The funnel catheter assembly of claim 1 wherein the funnel includes a proximal portion and a distal portion, and wherein the proximal portion of the funnel is coupled to the distal portion of the inner shaft.
6. The funnel catheter of claim 5 wherein the distal portion of the funnel is coupled to the outer shaft.

7. The funnel catheter assembly of claim 1, further comprising a sealable hub and a side port, wherein the side port is rotatably coupled between the control assembly and the sealable hub.

8. A funnel catheter assembly, comprising:
an outer shaft defining an outer lumen;
an inner shaft extending through the outer lumen and having a proximal portion and a distal portion;
an expandable funnel coupled to the distal portion of the inner shaft; and
a control assembly operably coupled to the proximal portion of the outer shaft and configured to move the outer shaft between a first position and a second position, wherein—
in the first position, the outer shaft is positioned at least partially over the funnel to radially constrain the funnel, and
in the second position, the outer shaft is retracted proximally relative to the funnel such that the funnel can radially expand.

9. The funnel catheter assembly of claim 8 wherein the control assembly includes a housing and an actuation member, wherein the actuation member is coupled to a proximal portion of the outer shaft, and wherein the actuation member is slidable along the housing to move the outer shaft between the first and second positions.

10. The funnel catheter assembly of claim 8 wherein the funnel is configured to self-expand.

11. The funnel catheter assembly of claim 8 wherein the funnel is non-self-expanding, wherein the funnel is further coupled to a distal portion of the outer shaft, and wherein movement of the outer shaft from the first position to the second position is configured to expand the funnel.

12. The funnel catheter assembly of claim 11 wherein a distal portion of the funnel is coupled to the distal portion of the outer shaft via one or more tethers.

13. The funnel catheter assembly of claim 8 wherein the inner shaft defines an inner lumen sized to receive a dilator.

14. A method of operating a funnel catheter assembly during an intravascular procedure on a patient, the method comprising:

at least partially inserting an inner shaft, an outer shaft, and a funnel of the funnel catheter assembly into the vasculature of the patient;
advancing the inner shaft, the outer shaft, and the funnel together to a deployment position within the vasculature of the patient, wherein the funnel is sheathed within a lumen of the outer shaft during the advancement;
moving the outer shaft relative to the inner shaft to unsheath the funnel and permit the funnel to expand to an expanded position;
maintaining the funnel in the expanded position during at least a portion of the intravascular procedure;
moving the outer shaft relative to the inner shaft and/or moving the inner shaft relative to the outer shaft to sheath the funnel within the lumen of the outer shaft; and
withdrawing the funnel catheter assembly from the patient.

15. The method of claim 14 wherein the funnel is self-expandable, and wherein moving the outer shaft relative to the inner shaft to unsheath the funnel includes permitting the funnel to self-expand to the expanded position.

16. The method of claim 14 wherein moving the outer shaft relative to the inner shaft to unsheath the funnel includes moving a slider of a control assembly of the funnel catheter assembly from a first position to a second position, and wherein the slider is coupled to a proximal portion of the outer shaft.

17. The method of claim 14 wherein moving the outer shaft relative to the inner shaft to unsheath the funnel includes rotating a rotatable element of a control assembly of the funnel catheter assembly from a first position to a second position.

18. The method of claim 14 wherein the funnel is non-self-expanding, and wherein the method further comprises actuating the funnel to expand to the expanded position.

19. The method of claim 14 wherein—

inserting the inner shaft, the outer shaft, and the funnel into the vasculature of the patient further includes at least partially inserting a dilator positioned within the inner shaft into the vasculature of the patient; and

advancing the inner shaft, the outer shaft, and the funnel further includes advancing the inner shaft, the outer shaft, the funnel, and the dilator together to the deployment position.

20. The method of claim 14 wherein moving the outer shaft relative to the inner shaft to unsheath the funnel includes moving the outer shaft in a first direction, and wherein the method further comprises moving the outer shaft relative to the inner shaft to sheath the funnel by moving the outer shaft in a second direction opposite to the first direction.

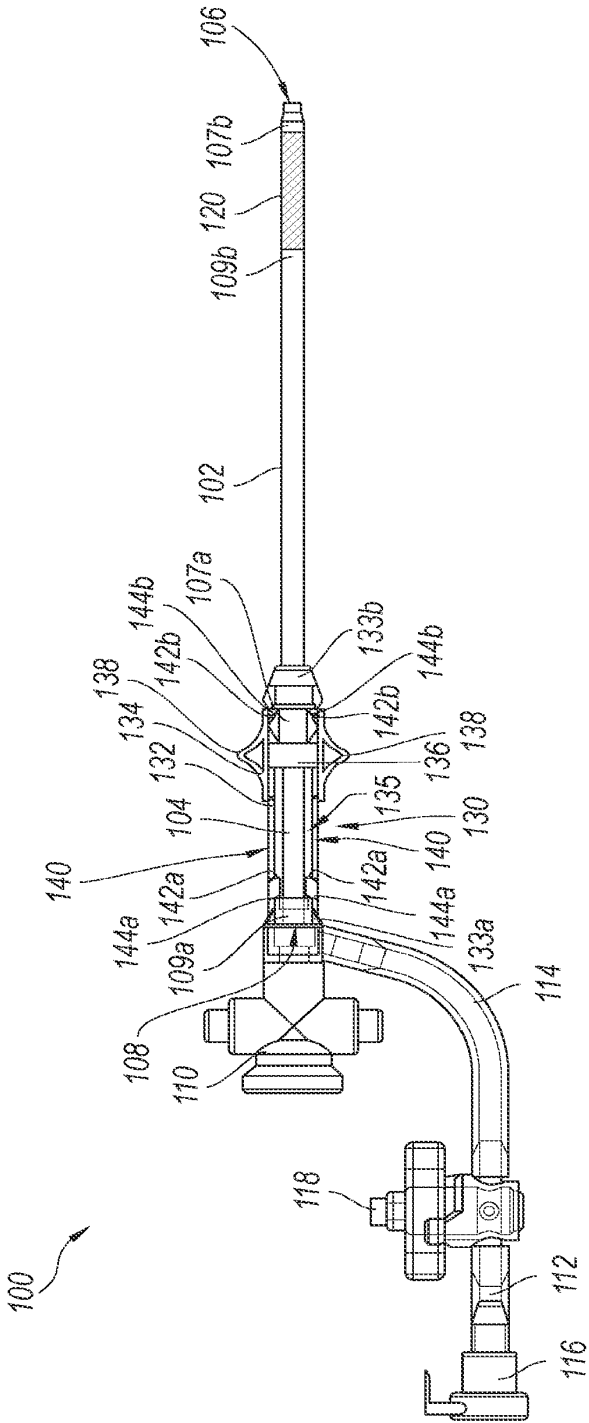


Fig. 1

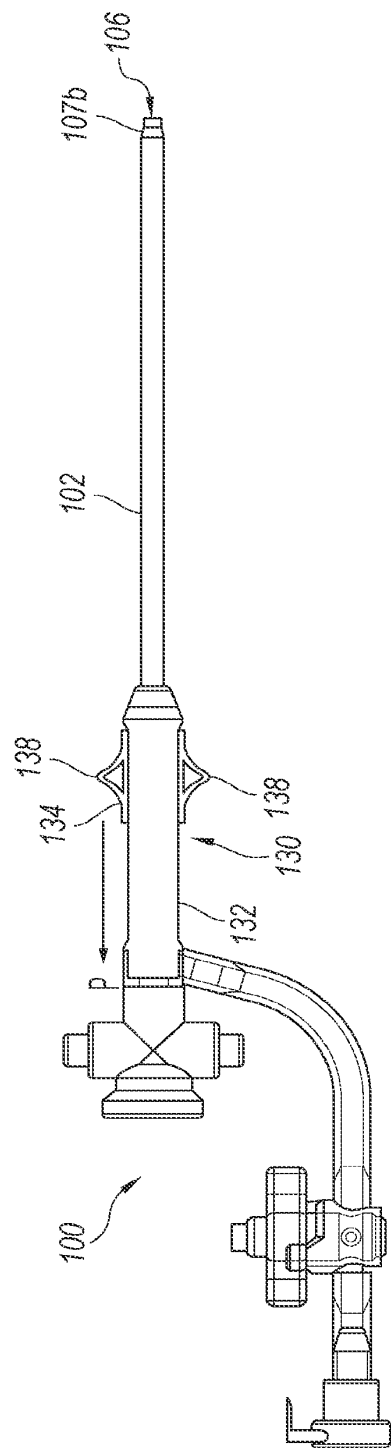


Fig. 2A

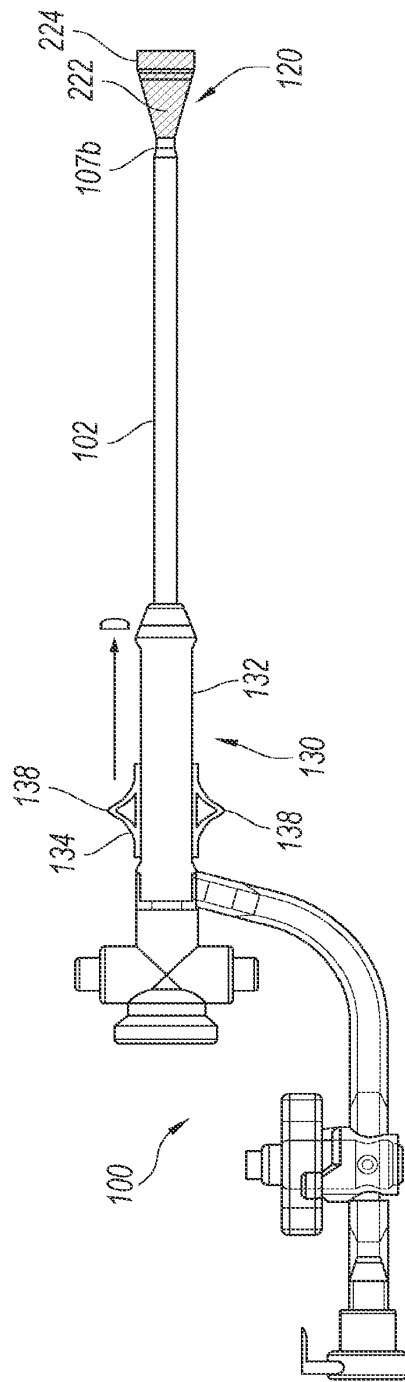


Fig. 2B

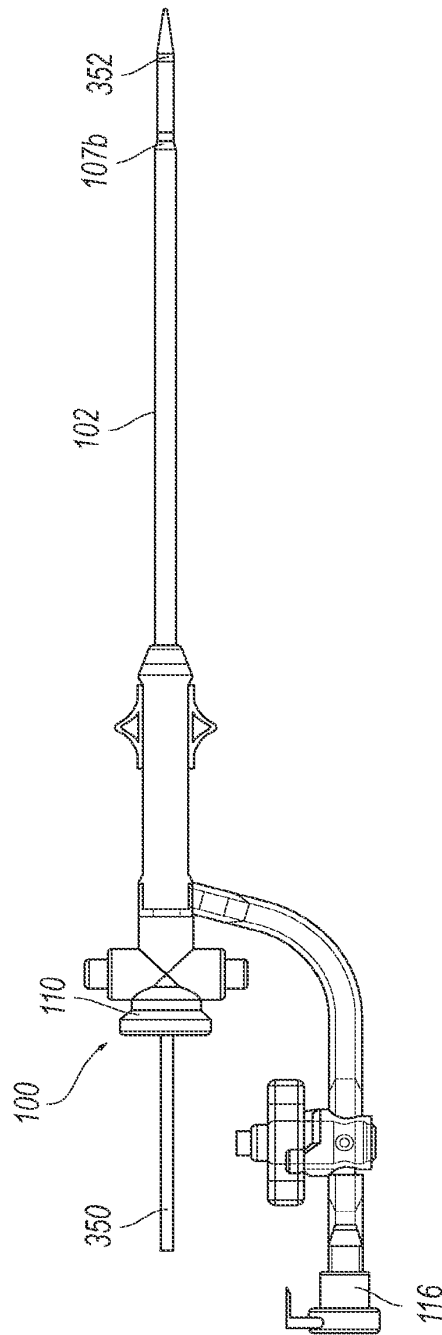


Fig. 3

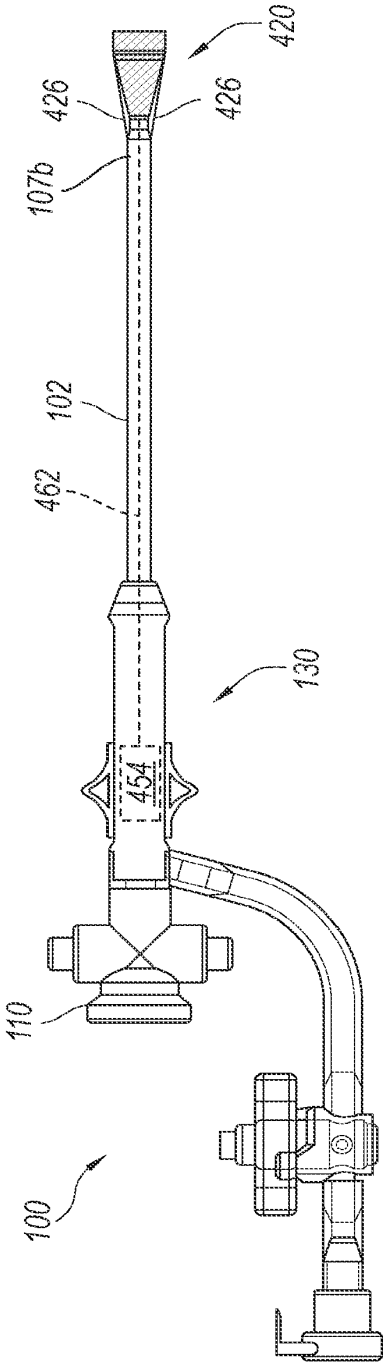


Fig. 4

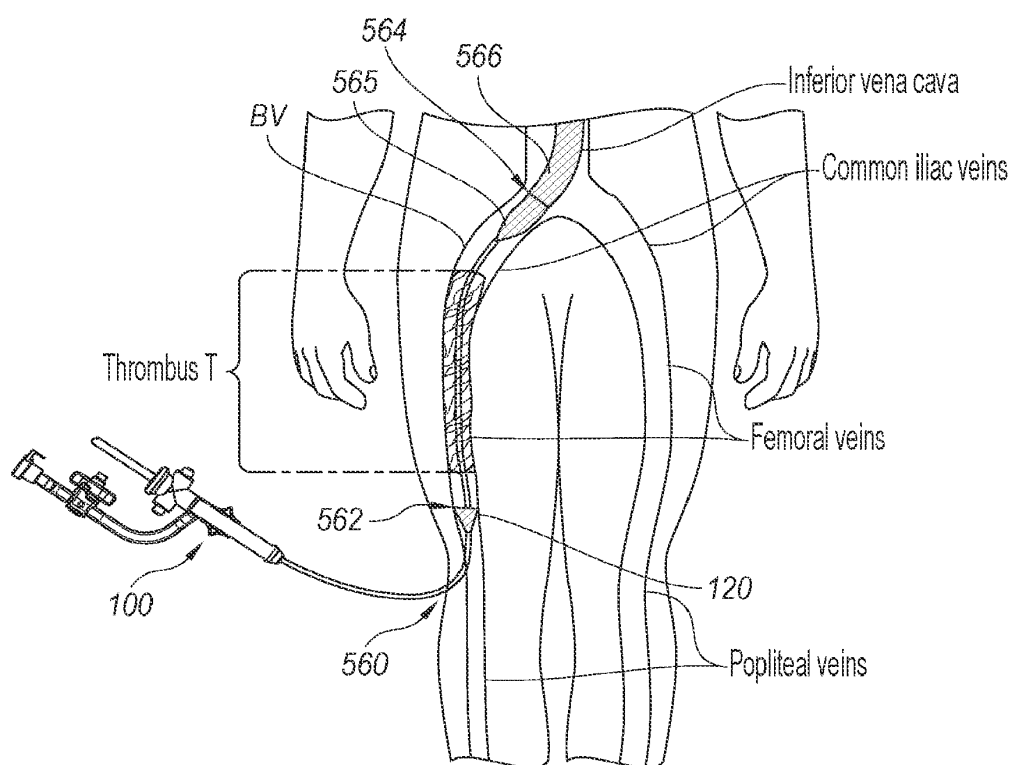


Fig. 5

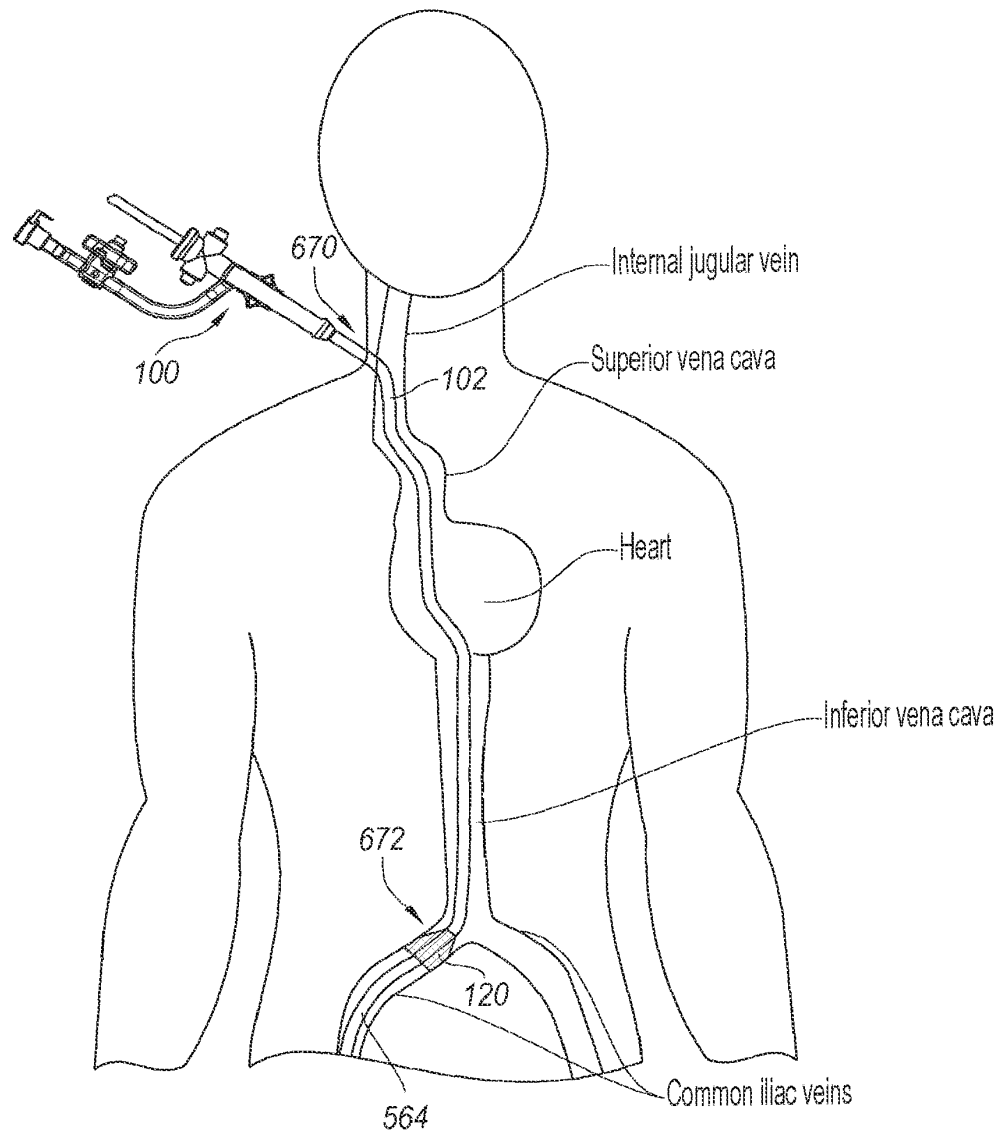
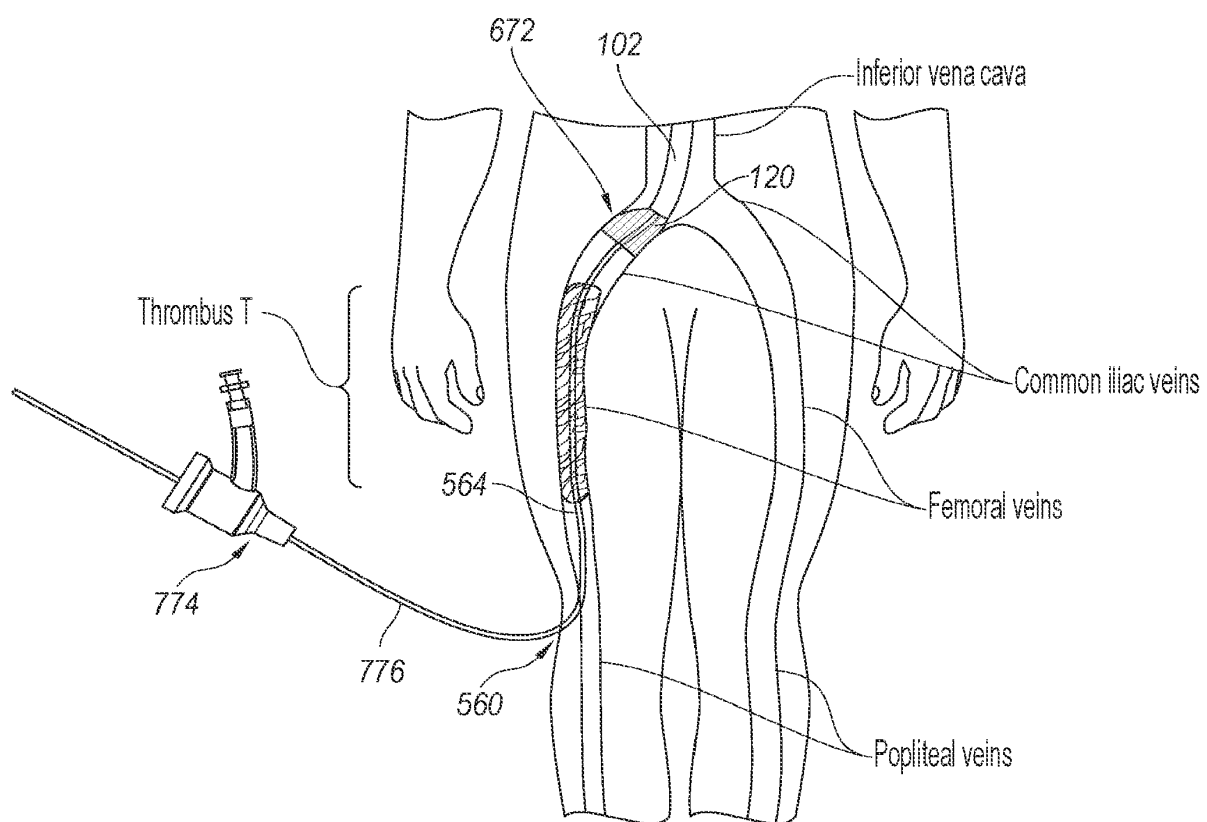


Fig. 6

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*Fig. 7*

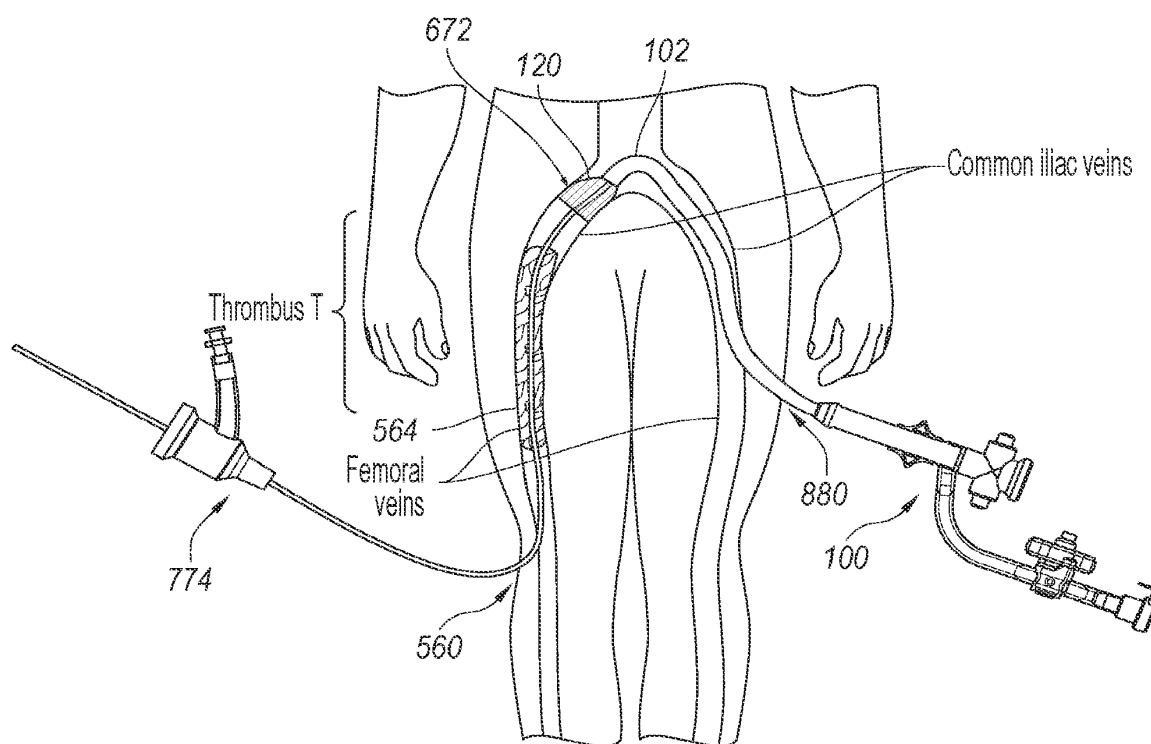


Fig. 8

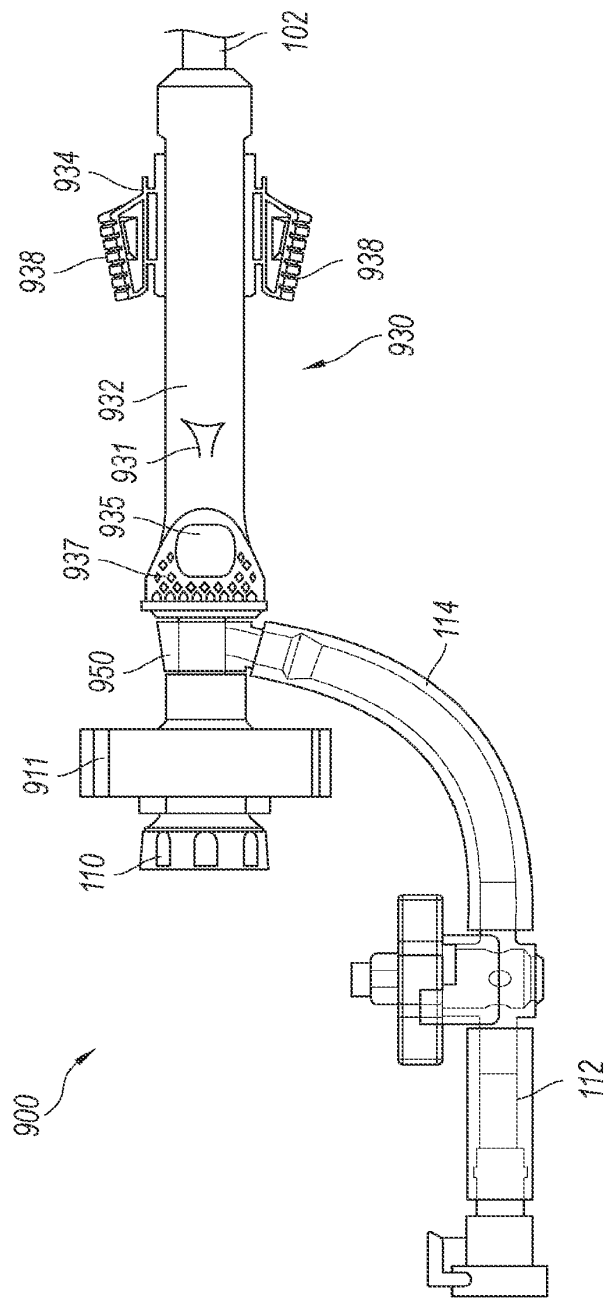


Fig. 9A

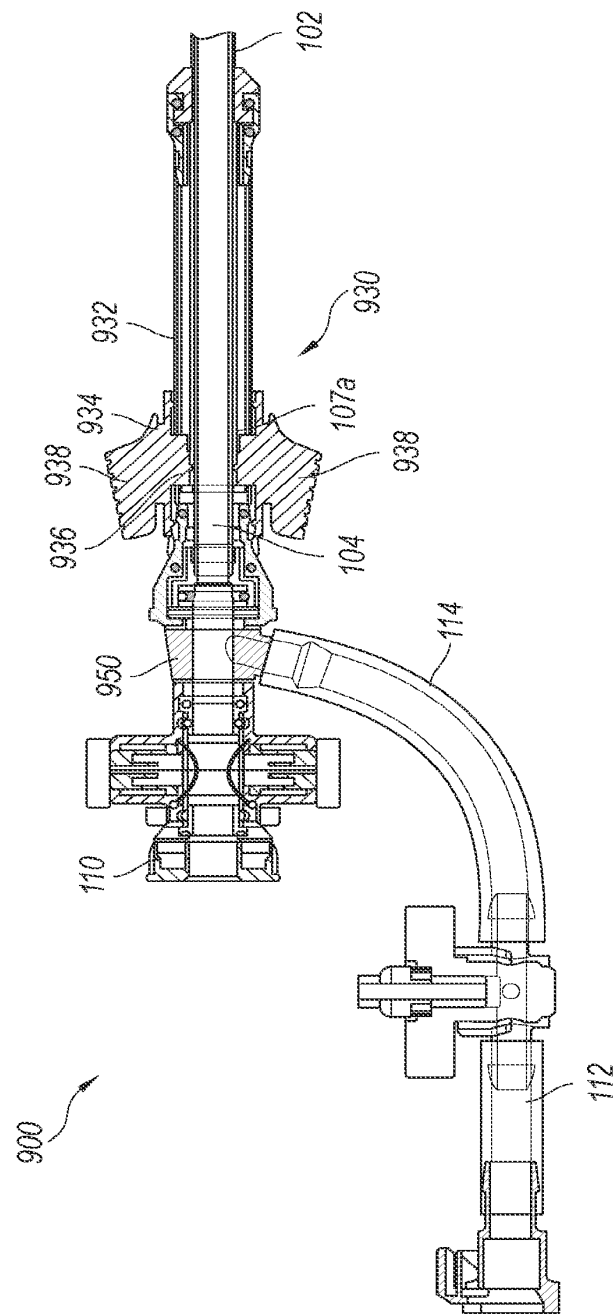


Fig. 9B

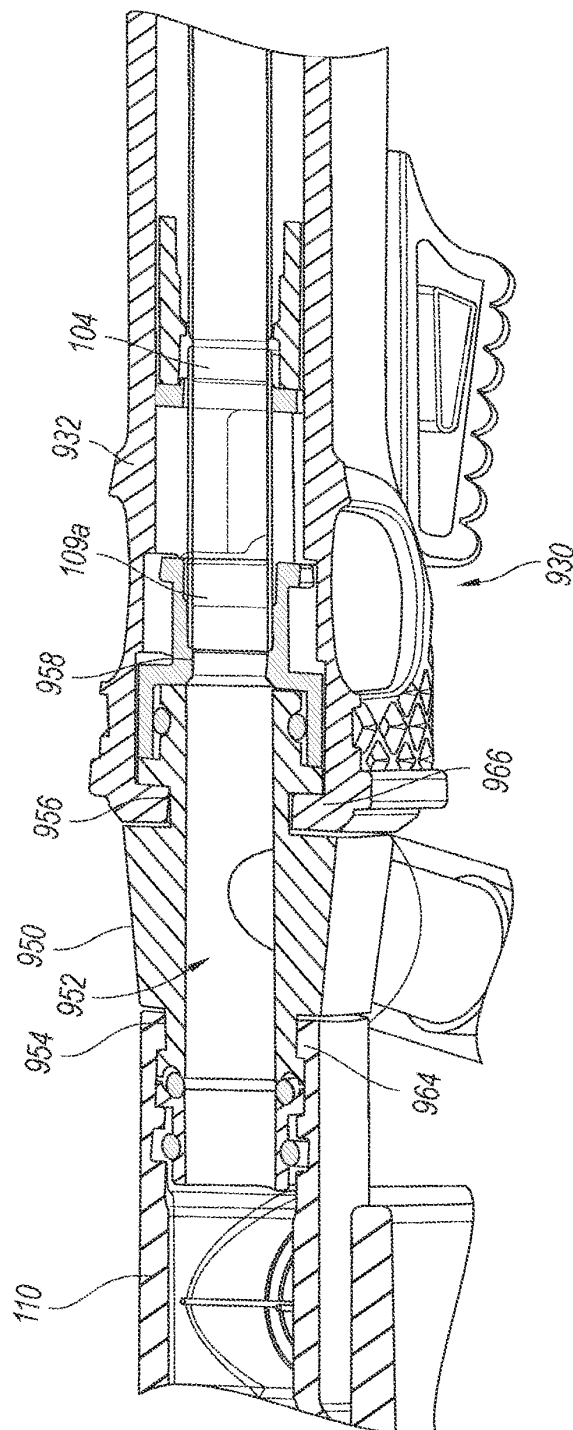


Fig. 9C

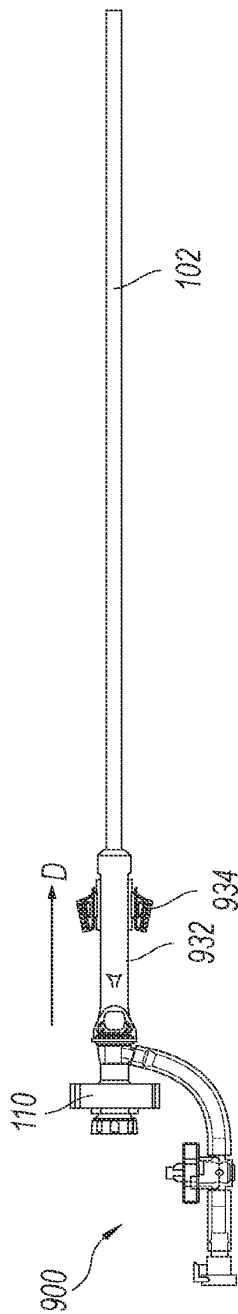


Fig. 10A



Fig. 10B

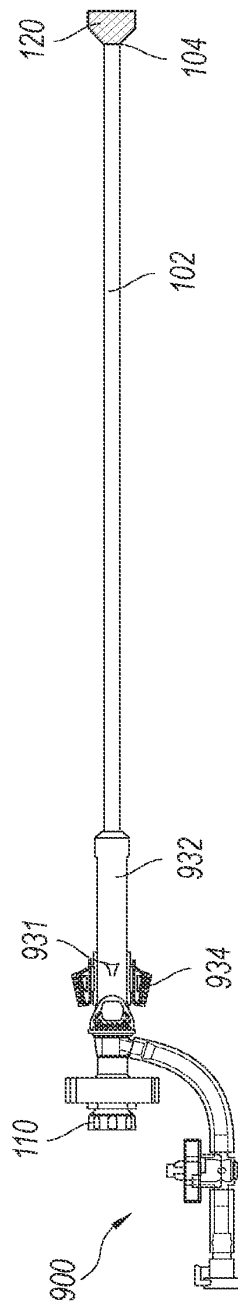
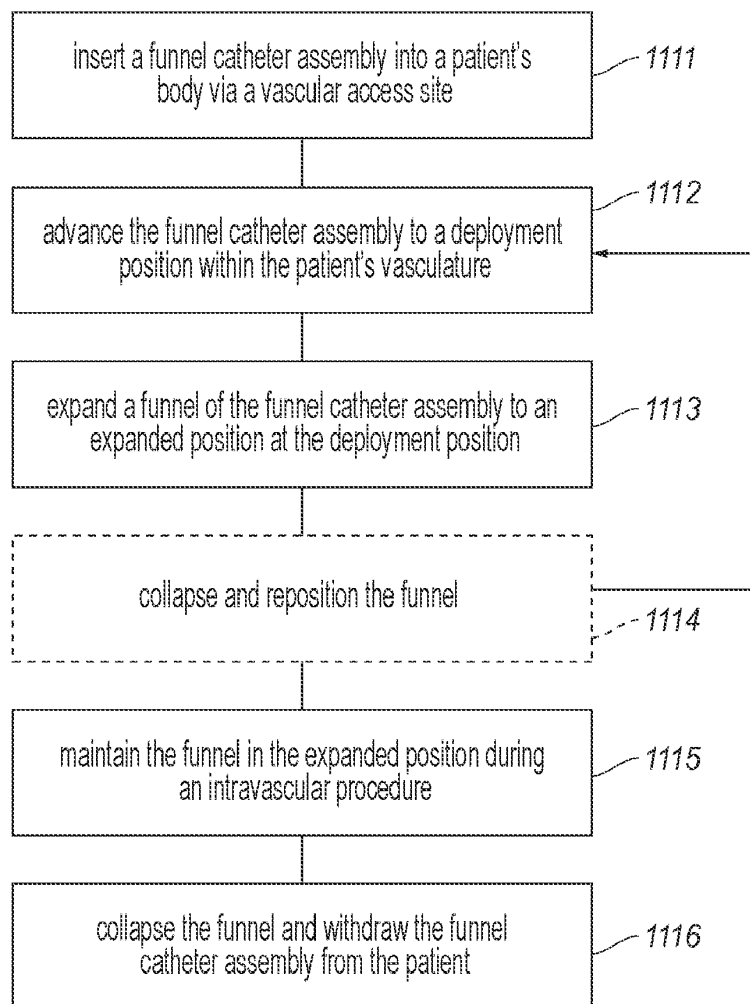


Fig. 10C

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1110

*Fig. 11*

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 21/35965

A. CLASSIFICATION OF SUBJECT MATTER

IPC - A61B 17/00, A61B 17/22, A61B 17/3207, A61M 25/10, A61M 1/00 (2021.01)

CPC - A61M 2025/1045, A61B 17/22, A61B 17/221, A61B 2217/005, A61M 2025/109

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

See Search History document

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

See Search History document

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

See Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X		1-10, 13-17, 19-20
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Y	US 5,011,488 A (Ginsburg) 30 April 1991 (30.04.1991), entire document	18
X	US 5,800,457 (Gelbfish) 1 Septemebr 1998 (01.09.1998), entire document	8, 11-12
Y	WO 2009/082513 A1 (Tex Medical) 2 July 2009 (02.07.2009), entire document	18
A	US 2002/0161392 A1 (Dubrul) 31 October 2002 (31.10.2002), entire document	1-20
A	WO 2018/148174 A1 (KP Medcure, Inc) 16 August 2018 (16.08.2018), entire document	1-20

☐ Further documents are listed in the continuation of Box C.☐ See patent family annex.

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(51) International Patent Classification ⁶ : A61B 17/22	A1	(11) International Publication Number: WO 98/33443 (43) International Publication Date: 6 August 1998 (06.08.98)
(21) International Application Number: PCT/US98/01894 (22) International Filing Date: 3 February 1998 (03.02.98) (30) Priority Data: 08/794,011 3 February 1997 (03.02.97) US (71) Applicant (for all designated States except US): ANGIO-GUARD, INC. [US/US]; 735 Aran Drive, Roswell, GA 30076 (US). (72) Inventor; and (75) Inventor/Applicant (for US only): YADAV, Jay, S. [US/US]; 735 Aran Drive, Roswell, GA 30076 (US). (74) Agents: DIPPert, William, H. et al.; Cowan, Liebowitz & Lataman, P.C., 1133 Avenue of the Americas, New York, NY 10036-6799 (US).		(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, GW, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i>
(54) Title: VASCULAR FILTER (57) Abstract <p>A removable vascular filter for blocking micro-emboli, and macro-emboli while allowing the continued perfusion of blood comprising a filter membrane (20), wherein the free end of the membrane sits tightly against the guide wire (10) when the filter membrane is in a collapsed state, and wherein the filter has a means for deploying the filter membrane in the interior of a lumen which is comprised of cables or spines (30) operable with a movable core (40), or fibers inside the guide wire which transitions the filter membrane from the collapsed state to the deployed state. The filter membrane is comprised of a fine mesh material which has a pore size capable of blocking emboli while allowing continued blood flow.</p> <div style="text-align: right;"> </div>		

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VASCULAR FILTER

FIELD OF THE INVENTION

The present invention relates to the treatment of vascular disease of either surgery or percutaneous angioplasty and stenting. More particularly, the invention relates to a device
5 that reduces macro- and micro-embolism during the treatment of vascular stenosis.

BACKGROUND OF THE INVENTION

A variety of surgical and non-surgical angioplasty
10 procedures have been developed for removing obstructions from blood vessels. Balloon angioplasty utilizes a balloon-tipped catheter which may be inserted within a stenosed region of the blood vessel. By inflation of the balloon, the stenosed region is dilated. Surgery involves either removing the plaque from
15 the artery or attaching a graft to the artery so as to bypass the obstructing plaque. Other techniques, such as atherectomy, have also been proposed. In atherectomy, a rotating blade is used to shave plaque from an arterial wall.

One problem common with all of these techniques is the
20 accidental release of portions of the plaque or thrombus, resulting in emboli which can lodge elsewhere in the vascular system. Such emboli are, of course, extremely dangerous to the patient, frequently causing severe impairment of the distal circulatory bed. Depending upon the vessel being treated, this
25 may result in a stroke or myocardial infarction or limb ischemia.

Vascular filters or embolism traps for implantation into the vena cava of a patient are well known, being illustrated by, for example, U.S. Patents. Nos. 4,727,873 and 4,688,553.
30 Additionally, there is a substantial amount of medical literature describing various designs of vascular filters and reporting the results of the clinical and experimented use thereof. See, for example, the article by Eichelter & Schenk entitled "Prophylaxis of Pulmonary Embolism," Archives of

Surgery, Vol. 97, August 1968, pp. 348 et seq. See, also, the article by Greenfield, et al., entitled "A New Intracaval Filter Permitting Continued Flow and Resolution of Emboli", Surgery, Vol. 73, No. 4, pp. 599-606 (1973).

5 Vascular filters are used, often during a postoperative period, when there is a perceived risk of a patient encountering a pulmonary embolus resulting from clots generated at the surgical site or the like. As a typical use of vascular filters, the filter is mounted in the vena cava to catch large
10 emboli passing from the surgical site to the lungs.

The vascular filters of the prior art are usually permanently implanted in the venous system of the patient, so that even after the need for the filter has abated, the filter remains in place for the lifetime of the patient, absent
15 surgical removal. U.S. Pat. No. 3,952,747 describes a stainless steel filtering device which is permanently implanted transvenously within the inferior vena cava. The filtering device is intended to treat recurrent pulmonary embolism. U.S. Pat. No. 4,873,978 describes a catheter device comprising a
20 catheter body having a strainer mounted at it distal end. The strainer is shiftable between an opened configuration where it extends substantially across the blood vessel to entrap passing emboli, and a closed configuration where it retains the captured emboli during removal of the catheter. A mechanism
25 actuatable at the proximate end of the catheter body allows selective opening and closing of the strainer. Typically, the strainer is a collapsible cone having an apex attached to a wire running from the distal end to the proximate end of the catheter body.

30 Permanent implantation is often deemed medically undesirable, but it has been done because vascular filters are implanted in patients primarily in response to potentially life threatening situations. Accordingly, the disadvantages of permanent implantations of a vascular filter are often
35 accepted.

To avoid permanent implantation, it would be highly desirable to provide an apparatus and method for preventing

embolisms associated with conventional surgery and angioplasty procedures. In particular, it would be desirable to provide a device which could be located within the vascular system to collect and retrieve portions of plaque and thrombus which have
5 dislodged during the surgery or angioplasty procedure.

OBJECT OF THE INVENTION

It is an object of this invention to provide a vascular filter for reducing macro- and micro-embolism.

10 It is also an object of the invention to provide a vascular filter which is readily removable from the vascular system, or elsewhere, of a patient when the filter is no longer needed.

15 It is a further object of the invention to provide a vascular filter having a configuration which does not require hooks to penetrate and grip the blood vessel walls, so that the implantation results in less blood vessel injury.

It is a yet further object of the invention to provide a vascular filter of very low profile which is part of a
20 guidewire and can be used in small vessels

These and other objects of the invention will become more apparent from the description below.

SUMMARY OF THE INVENTION

25 The present invention generally relates to the surgical and interventional treatment of vascular disease. For example, during angioplasty and stenting of carotid stenosis, there is occurrence of macro- and micro-embolism which increases the risk of a minor or major stroke. The device of the present
30 invention for reducing macro- and micro-embolism is very useful in helping to prevent the risk of stroke. However, this device would also be useful in any angioplasty or surgical procedure where embolization is a risk.

35 The filters of the present invention will decrease embolism while allowing brain, or other distal tissue, perfusion. The filters are incorporated into a guidewire which

is used for the entire procedure from crossing a lesion to deploying a stent. The filter consists of a thin membrane attached to the guidewire and supported by fine metal spines. The filter membrane has a pore size such that blood flow is not
5 impeded when the filter membrane is expanded but micro- and macro-emboli are blocked. The attachments of the filter membrane to the guidewire allow expansion of the filter membrane with a firm fit inside the artery. Expansion of the filter membrane is aided by the forward flow of blood against
10 the filter. The attachments also allow for collapse of the filter membrane at the end of the procedure so it fits tightly against the guidewire and can be withdrawn through the guide catheter. The filter design results in a very low profile so that the initial crossing of the lesion is minimally traumatic.
15 Also, the small diameter and small profile facilitate use of the device in small or larger arteries with minimal or no obstruction of blood flow.

BRIEF DESCRIPTION OF THE DRAWINGS

20 The above and other objects and advantages of the invention will be apparent upon consideration of the following detailed description, taken in conjunction with the accompanying drawings, in which the reference characters refer to like parts throughout and in which:

25 Fig. 1 is a lateral, partly cross-sectional view of the distal end of a guidewire of one embodiment of the invention with the filter membrane in a collapsed position;

Fig. 2 is a lateral, partly cross-sectional view of the distal end of a guidewire of Fig. 1 with the filter membrane in
30 an expanded, deployed position;

Fig. 3 is a proximal end-on view of the filter membrane shown in Fig. 2;

Fig. 4 is a lateral, partly cross-sectional view of another embodiment of the invention;

35 Fig. 5A is a lateral, partly cross-sectional view of a further embodiment of the invention;

Fig. 5B is a lateral, partly cross-sectional view of the embodiment of the invention shown in Fig. 5A with the filter membrane in an expanded, deployed position;

Fig. 6 is a partly cross-sectional view of a control
5 handle for the invention;

Fig. 7 is a partly cross-sectional view of another embodiment of the invention;

Fig. 8 is a partial cross-sectional view of an embodiment of the invention wherein the filter membrane has curved
10 supports;

Fig. 9 is a partial cross-sectional view of yet another embodiment of the invention wherein the filter membrane has a spiral wire;

Fig. 10 is a top, cross-sectional view of the embodiment
15 of the invention shown in Fig. 9;

Fig. 11 is a partial cross-sectional view of another embodiment of the invention having inflatable support spines; and

Figs. 12 and 13 represent partial cross-sectional views of
20 another embodiment of the invention in collapsed and deployed positions, respectively.

DETAILED DESCRIPTION OF THE INVENTION

The present invention relates to a vascular filter for use
25 in percutaneous angioplasty and stenting and provides for the prevention of distal embolism during endovascular procedures. Further, the filter device of the invention allows for distal perfusion while preventing embolism.

The device consists of a thin, perforated filter membrane
30 which is capable of blocking emboli and which is attached to the distal end of a guidewire. The device preferably uses thin fibers which are moveable and are attached to the filter membrane to deploy and collapse the filter membrane. The invention also contemplates the use of metal spines or
35 inflatable spines attached to the filter membrane to deploy the

filter membrane. The fibers or spines can also be attached to a moveable core which is slidable within the guidewire and is used to deploy and collapse the filter membrane.

The filter membrane deploys in an umbrella-like fashion with the unattached edge of the membrane moving upward, i.e., distally, and outward until it is in firm contact with an artery wall. When the filter membrane is deployed, it spans the cross-sectional area of the vessel lumen being treated for a stenosis such as carotid stenosis, or another condition likely to produce emboli.

The invention can perhaps be appreciated better by referring to the drawings. Fig. 1 illustrates a lateral, cross-sectional view of a distal end of a guidewire 10 with a filter membrane 20 attached thereto. Fig. 1 shows guidewire 10 with a shapeable, tapered soft tip 15 at its extreme distal end which provides flexibility and maneuverability to guidewire 10. The filter membrane in Fig. 1 is in a collapsed position. Filter membrane 20 has a fixed portion 24 which is movably attached to guidewire 10, and filter membrane 20 lies adjacent guidewire 10 proximal to fixed portion 24 when filter membrane 20 is in the collapsed state. A moveable core 40 runs through a center lumen 11 of guidewire 10 and preferably extends distally a short distance beyond fixed portion 24 of filter membrane 20. Deploying wires or fibers 30 are each firmly attached at one end 27 to moveable core 40 distal to fixed portion 21 of filter membrane 20. The deploying fibers 30 are attached at their other ends to filter membrane 20 at attachment points 22.

Collapsing fibers 35 are each firmly attached at one end 12 to the portion of moveable core wire 40 which is interior to filter membrane 20 when it is in the collapsed state. Collapsing fibers 35 are each attached at their other end 13 to filter membrane 20 at attachment points 22. Accordingly, collapsing fibers 35 lie interior to filter membrane 20 when filter membrane 20 is in the collapsed state.

Filter membrane 20 is deployed when the operator pulls moveable core 40 proximally through the interior of guidewire

10. Prior to retraction of moveable core 40, deploying fibers 30 are sufficiently relaxed so as not to create any tension at filter membrane attachment points 22. Upon retraction of moveable core 40, tension is created in deploying fibers 30.

5 There will preferably be from 2 to 6 each of evenly-spaced deploying fibers 30 and collapsing fibers 35, 3 or 4 being most preferred. The deploying fibers 30 and collapsing fibers 35 can be made of any flexible, medically acceptable material, including stainless steel, nitinol, or another metal or
10 metallic alloy or a non-metallic substance such as graphite or a suitable polymer. In addition, guidewire 10 and moveable core 40 can be made from similar materials, as would be appreciated by those skilled in the art. Typically, guidewire 10 could have an external diameter of from about 0.014 mm to
15 about 0.035 mm, a wall thickness of from about 0.002 mm to about 0.010 mm, and a length of from about 25 cm to about 300 cm. Also, moveable core 40 could have a diameter of from about 0.003 mm to about 0.010 mm and a length of from about 30 cm to about 350 cm.

20 Fig. 2 illustrates the filter device of the invention in a deployed position on the inside of an artery wall 60. Moveable core 40 is in a retracted state, i.e., pulled proximally through the interior of guidewire 10. Tension is created in deploying fibers 30, and filter membrane 20 extends to a
25 deployed position where the outer edge 14 of filter membrane 20 contacts artery wall 60. In this deployed position, collapsing fibers 35 are in a relaxed state and extend from filter membrane attachment points 22 to fixed attachment points 28 on moveable core 40.

30 The flow of blood in Fig. 2 is toward the distal end of guidewire 10. As such, the force of the flow of blood pushes on deployed filter membrane 20 and helps to maintain filter membrane 20 in the deployed position.

35 For withdrawal of guidewire 10 and the filter device, filter membrane 20 is collapsed so that it sits tightly against guidewire 10. This is accomplished by extending moveable core 40 distally through guidewire 10, thus relaxing deploying

fibers 30 and creating tension in collapsing fibers 35. The tension in collapsing fibers 35 collapses the filter membrane 20, allowing it to fit tightly against guidewire 10 in recess 16 as depicted in FIG. 1.

5 Fig. 3 illustrates the filter device of the invention from a distal end view in Fig. 2 with filter membrane 20 deployed. Guidewire 10 is centrally located, and structural wires 50 are seen extending from guidewire 10 to the outer edge 14 of filter membrane 20. These wires 50 provide structural integrity and
10 rigidity to filter membrane 20. Fig. 3 depicts four, evenly-spaced structural wires 50, but there can be more or less structural wires 50. Preferably there are from two to six structural wires 50, which may be spaced regularly or irregularly. The wires 50 may preferably be comprised of
15 stainless steel or another medically acceptable metal or alloy.

Filter membrane 20 of the invention is preferably a mesh such as that depicted in Fig. 3. The mesh should have pores of a size sufficient to block and capture any micro- and macro-emboli which may flow downstream from the site where the
20 stenosis is being treated, but large enough such that blood flow is not impeded. The mesh used in the filter device of the invention can have a pore size of from about 20 to about 300 microns, preferably from about 30 to about 100 microns, more preferably from about 40 to 60 microns. Moreover, the size of
25 filter membrane 20, i.e., the distance from guidewire 10 to free ends 22, is such as to allow a firm fit between filter membrane 20 and artery wall 60. The diameter of filter membrane 20 will be directly related to the artery being treated, with typical diameters ranging from about 2 mm to
30 about 40 mm, most preferably from about 2 mm to about 20 mm.

The membrane can be comprised of fabric or non-fabric meshes, such as those used in known hemodialysis filters or heart-lung bypass machine filters. Suitable materials include polymers or physiologically acceptable metals or alloys.

35 In alternative embodiments of the invention shown in Figs. 4, 5A and 5B, filter membrane 20 will be suspended between from two to six, preferably three or four, thin metal wires 51 which

serve as spines for filter membrane 20. Wires 51 may be comprised of stainless steel or another metallic alloy, nitinol, or another shape-memory material. Wires 51 will be constructed so that they assume a 90° angle with guidewire 10 when they are in an unconstrained state. This will result in expansion of the filter membrane 20 to a position normal to guidewire 10. A set of thin fibers 17 are attached at attachment points 18 to filter membrane outer edge 14 and are used to collapse filter membrane 20.

Fig. 4 shows an embodiment of this invention in which metal wires 51 are allowed to regain their 90° angle unconstrained state by use of a moveable core 40 that runs through guidewire 10. Prior to retraction of moveable core 40, fibers 17 are sufficiently tensed so as to restrain wires 51. Upon retraction of moveable core 40, tension in fibers 17 is released and wires 51 are allowed to revert to their relaxed shape, which will result in expansion of filter membrane 20 to a position normal to guidewire 10.

Figs. 5A and 5B show an embodiment of the invention wherein wires 51 are restrained by fibers 17 that run through guidewire 10 and that are controlled at a remote location. In Fig. 5A, there is sufficient tension in fibers 17 to maintain wires 51 in a constrained position. In Fig. 5B, tension in fibers 17 has been relaxed such that wires 51 are allowed to revert to their relaxed shape, which will result in expansion of filter membrane 20 to a position normal to guidewire 10.

Fig. 6 depicts a control handle especially suitable for the embodiment of the invention shown in Figs. 5A and 5B. The proximal end 32 of guidewire 10 is rotatably attached to handle 33, such that rotation of handle 33 causes handle 33 to move distally or proximally relative to proximal guidewire end 32. For example, handle 33 may have threads 34 which engage threads 35 on guidewire proximal end 32. Fibers 17 attached to filter membrane 20 are secured in a base 36 of handle 33. Then, as handle 33 is turned, the fibers 17 move distally or proximally to open or close filter membrane 20.

As handle 33 is turned clockwise in the direction of arrow A and fibers 17 are allowed to move distally in the direction of arrow C, the tension on the filter membrane fibers 17 decreases and wires 51 are allowed to assume their natural 90° angle with respect to the guidewire, resulting in opening of filter membrane 20. Similarly, when handle 33 is turned counter-clockwise in the direction of arrow B and fibers 17 are pulled proximally in the direction of arrow D, the tension on filter fibers 17 increases, causing filter membrane 20 to collapse tightly against guidewire 10. Of course, the direction of turn of handle 33 as discussed above can be reversed, as long as threads 34,35 are properly formed to allow appropriate movement of handle 33 relative to guidewire proximal end 32.

In yet another embodiment of the invention, shown in Fig. 11, filter membrane 20 can be supported by inflatable spines 135 supporting the filter membrane 20. Spines 135 supporting the filter membrane 20 are from two to six hollow plastic tubes which are inflatable using, for example, a standard balloon angioplasty inflation device or endoflator in fluid connection through channel 137 with spines 135. Inflation of spines 135 causes them to become rigid and deploys filter membrane 20. The underside of the filter membrane is attached to very thin fibers 17 which are attached to moveable core 40 inside hollow guidewire 10. Filter membrane 20 is collapsed by deflating the spines 135 and withdrawing the moveable core 40 in the direction of arrow E until the membrane 20 fits tightly against guidewire 10.

A catheter-based configuration is also possible, as shown in FIG. 7. In this design, the guidewire is not part of the filter catheter; the guidewire and filter catheter are two separate components. The filter catheter has an entry hole for the guidewire below the attachment of the filter membrane and the guidewire exits out the end of the filter catheter. The filter catheter could be designed to accommodate a variety of guidewire sizes, most commonly a 0.014 inch guidewire. The advantages of this design are that a variety of guidewires

could be used; the lesion could be crossed with the guidewire prior to crossing with the filter catheter; the filter catheter could be removed from the artery without removing the guidewire; and the filter catheter could be made smaller.

5 In the embodiment of the invention shown in Fig. 7 a catheter 101 comprises a longitudinally extending lumen 103, which has an annular recess 105 adjacent the distal end of catheter 101. Positioned within recess 105 is a filter 107 comprised of structural wires 109 and a filter membrane 111.
10 The distal end of each of wires 109 is attached at point 113 in recess 105. Fibers 117 extend from the proximal ends 119 of wires 109 proximally to a control means such as described in Fig. 6.

 Catheter 101 contains guidewire port 125 located proximal
15 to recess 105. It is intended that in use the distal portion 128 of a guidewire 127 will be threaded into the distal end 129 of catheter 101 and out through port 125.

 Alternatively, and not shown here, a catheter 101 could comprise a longitudinally extending lumen and a shorter
20 tracking lumen that extends from distal end 129 to a point proximal to recess 105. The distal end of guidewire 127 would then be threaded into the distal opening of the tracking lumen and out the proximal end of the tracking lumen.

 Spiral or curved structural wires may be used to deploy
25 the filter membrane instead of straight wires. Fig. 8 illustrates the use of four curved wires 120. The angulation of the filter attachment point of wires 120 relative to their guidewire attachment has the effect of wrapping the filter fabric around the guidewire in the undeployed state. This
30 leads to a lower profile for the undeployed filter.

 Figs. 9 and 10 illustrate the use of a single spiral structural wire 130 which is attached to the filter 107. As tension fiber 131 is released, wire 130 unwinds and deploys filter 107 in a conical configuration. This configuration has
35 the simplicity of using a single wire and, when the tension on fiber 131 is increased, allows filter 107 to be wrapped very

tightly around the guidewire shaft 131, resulting in filter 107 having a low profile in its undeployed state.

Another modification shown in Figs. 12 and 13 comprises a retractable sheath 140 at the distal end of guidewire 142 which
5 covers filter membrane 144 in the collapsed state. Sheath 140, the distal portion of which is affixed to guidewire tip 146, which is affixed to the distal end of moveable core 148, would prevent an edge 150 of filter membrane 144 from becoming entangled in an artery or guide catheter as it was being
10 withdrawn from a patient.

More specifically, when guidewire 142 with tapered tip 146 is inserted percutaneously into a patient, sheath 140 covers collapsed filter membrane 144. After the filter membrane is determined by fluoroscopy to be in proper position, moveable
15 core 148 is pushed distally to cause sheath 140 to "release" filter membrane 144, which has spines 152, to cause filter membrane 144 to deploy, as shown in Fig. 13.

It will be seen that the objects set forth above, among those made apparent from the preceding description, are
20 efficiently attained and, since certain changes may be made in carrying out the method and in the apparatus set forth without departing from the spirit and scope of the invention, it is intended that all matter contained in the above description and shown in the accompanying drawings shall be interpreted as
25 illustrative and not in a limiting sense.

It is also to be understood that the following claims are intended to cover all of the generic and specific features herein and described and all statements of the scope of the invention which, as a matter of language, might be said to fall
30 therebetween.

ITEM LISTING

	<u>No.</u>	<u>Item</u>
5	10	Guidewire
	11	Guidewire lumen
	12	End of collapsing fiber
	13	End of collapsing fiber
	14	Filter membrane outer edge
10	15	Guidewire soft tip
	17	Collapsing fiber
	18	Attachment point
	20	Filter membrane
	22	Filter membrane attachment point
15	24	Filter membrane fixed portion
	27	Fiber attachment point
	28	Fiber attachment point
	30	Deploying fibers
	32	Guidewire proximal end
20	33	Handle
	34	Handle threads
	35	Guidewire proximal end threads
	36	Handle base
	40	Moveable core wire
25	50	Structural wires
	51	Deploying wires
	60	Artery wall
	101	Catheter
	103	Lumen
30	105	Recess
	107	Filter mesh structure
	109	Filter wire
	111	Mesh
	113	Attachment point
35	117	Deployment collapse wire
	120	Curved filter structural wires
	125	Guidewire port
	127	Guidewire

	128	Guidewire distal end
	129	Spiral wire
	131	Fiber
5	132	Guidewire shaft
	135	Inflatable spines
	137	Inflation channel
	140	Sheath
	142	Guidewire
10	144	Filter member
	146	Tapered guidewire tip
	148	Moveable core
	150	Filter membrane edge
	152	Filter membrane spine

I claim:

1. A removable vascular filter device for blocking micro-and macro-emboli while allowing continued perfusion of blood, comprising:

a guidewire having distal and proximal portions, wherein there is a recess in the distal portion, the recess having distal and proximal ends,

a filter membrane having a fixed inner portion and a free outer portion, wherein the fixed inner portion is movably attached toward the distal end of the guidewire recess and wherein the free outer portion is positioned in the recess when the filter membrane is in a collapsed state; and

a deploying means for causing the filter membrane to assume a position substantially normal to the longitudinal axis of the guidewire.

2. The vascular filter of Claim 1, wherein the filter membrane is comprised of a porous mesh.

3. The vascular filter of Claim 2, wherein the pore size of the porous mesh is from about 40 to about 300 microns.

4. The vascular filter of Claim 1, wherein the guidewire is hollow and wherein the deploying means comprises a moveable core, the moveable core being slidably positioned in the interior of the guidewire.

5. The vascular filter of Claim 4, wherein the deploying means further comprises deploying fibers each having first and second ends and said filter membrane further comprises an outer edge, and wherein said deploying fibers are each attached at a first end to the moveable core and are attached at a second end to the outer edge of the filter membrane.

6. The vascular filter of Claim 4, wherein the moveable core creates a tension in the deploying fibers when it slides proximally in relation to the guidewire, and said tension causes the filter membrane to expand outwardly until the outer edge of the filter membrane is in firm contact with the lumen wall.

7. The vascular filter of Claim 5 further comprising a means for collapsing the filter membrane from a deployed state to a collapsed state.

8. The vascular filter of Claim 7, wherein the collapsing means further comprises collapsing fibers each having first and second ends, wherein said collapsing fibers are each attached at a first end to the moveable core and are further attached at a second end to the outer edge of the filter membrane.

9. The vascular filter of Claim 8, wherein the moveable core creates a tension in the collapsing fibers when it slides distally in relation to the guidewire, and said tension causes the filter membrane to collapse tightly against the guidewire.

10. The vascular filter of Claim 1, wherein the guidewire has a lumen extending distally from the proximal portion of the guidewire to at least the recess.

11. The vascular filter of Claim 1, wherein the guidewire has a tapered distal tip.

12. A removable vascular filter device for blocking micro-and macro-emboli while allowing continued perfusion of blood, comprising:

a guidewire having distal and proximal portions, wherein there is a recess in the distal portion, the recess having distal and proximal ends,

a filter membrane having a fixed inner portion and a free outer portion, wherein the fixed inner portion is attached toward the distal end of the guidewire recess and wherein the free outer portion is positioned in the recess when the filter membrane is in a collapsed state, and wherein the filter membrane in an unstressed position assumes a position substantially normal to the longitudinal axis of the guidewire, and

means for collapsing the filter membrane from a deployed state to a collapsed state.

13. The vascular filter of Claim 12, wherein the filter membrane comprises wires which assume a 90° angle with respect to the longitudinal axis of the guidewire in an unconstrained state.

14. The vascular filter of Claim 12, wherein the filter membrane comprises from 2 to 6 arcing wires.

15. The vascular filter of Claim 13, wherein the filter membrane comprises a single spiral wire.

16. The vascular filter of Claim 12, wherein the collapsing means comprises collapsing fibers each having first and second ends, wherein said collapsing fibers are each attached at a first end to the outer edge of the filter membrane and the second end of each fiber extends proximally through the guidewire to an actuator.

17. The vascular filter of Claim 16, wherein the actuator is a handle or shaft that can be rotated clockwise or counter-clockwise to release or collapse the filter membrane.

18. The vascular filter of Claim 12, wherein the filter membrane comprises a set of inflatable spines, said spines being hollow plastic tubes.

19. The vascular filter of Claim 18 which further comprises an inflator for inflating the spines, wherein said inflator is in fluid communication with said spines, which become rigid upon inflation.

20. The vascular filter of Claim 19, where the means of inflation is an endoflator.

21. The vascular filter of Claim 12, wherein the guidewire has a lumen extending distally from the proximal portion of the guidewire to at least the recess.

22. The vascular filter of Claim 12, wherein the guidewire has a tapered distal tip.

23. The vascular filter of Claim 12, which also comprises a sheath positioned concentric to the collapsed filter membrane, wherein said membrane causes the filter

member to be in a collapsed state but can be moved distally to allow the filter member to extend radially.

24. The vascular filter of Claim 23, wherein the sheath has proximal and distal portions and is attached at its distal end to a distal guidewire tip that is affixed to a moveable core extending proximally through the guidewire.

25. A removable vascular filter device for blocking micro-and macro-emboli while allowing continued perfusion of blood, comprising:

a catheter having distal and proximal portions, wherein there is a recess in the distal portion, the recess having distal and proximal ends, and the catheter has a longitudinally extending lumen;

a filter membrane having a fixed inner portion and a free outer portion, wherein the fixed inner portion is movably attached toward the distal end of the catheter recess, wherein the free outer portion is positioned in the recess when the filter membrane is in a collapsed state, and wherein the filter membrane is unstressed and extends substantially normal to the outer surface of the catheter; and

a collapsing means for causing the filter membrane to collapse into the catheter recess,

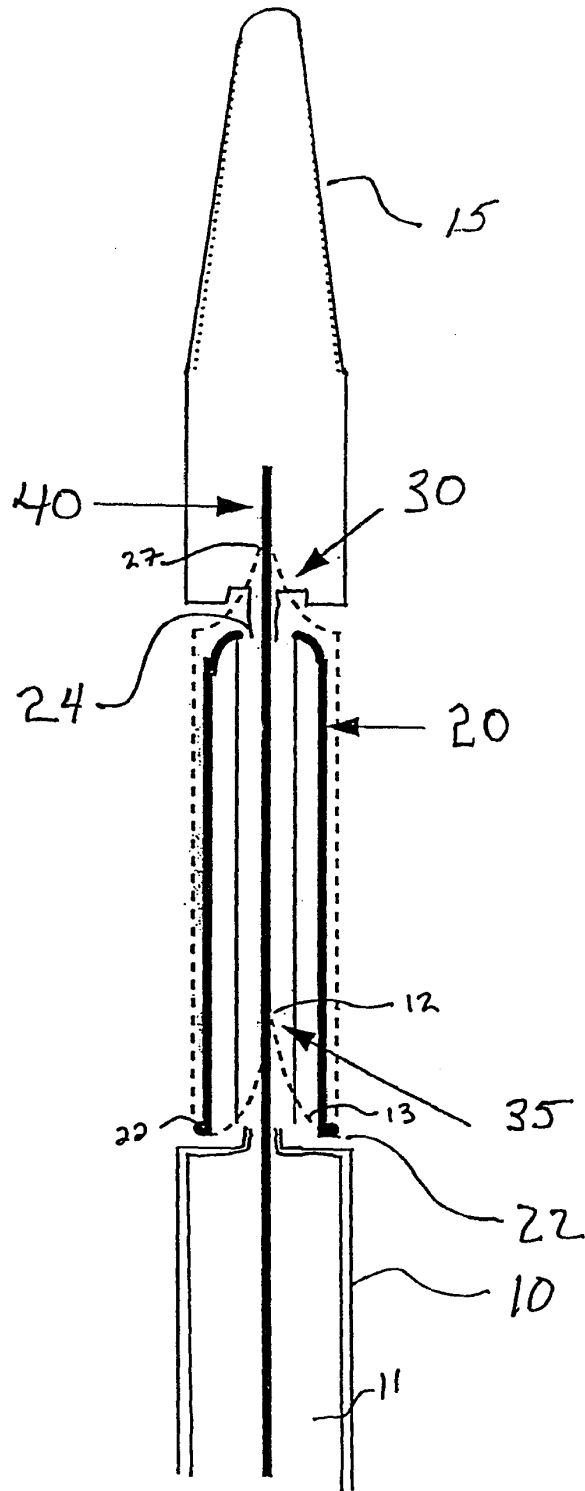
wherein the outer surface of the catheter has a guidewire port for receipt of a guidewire.

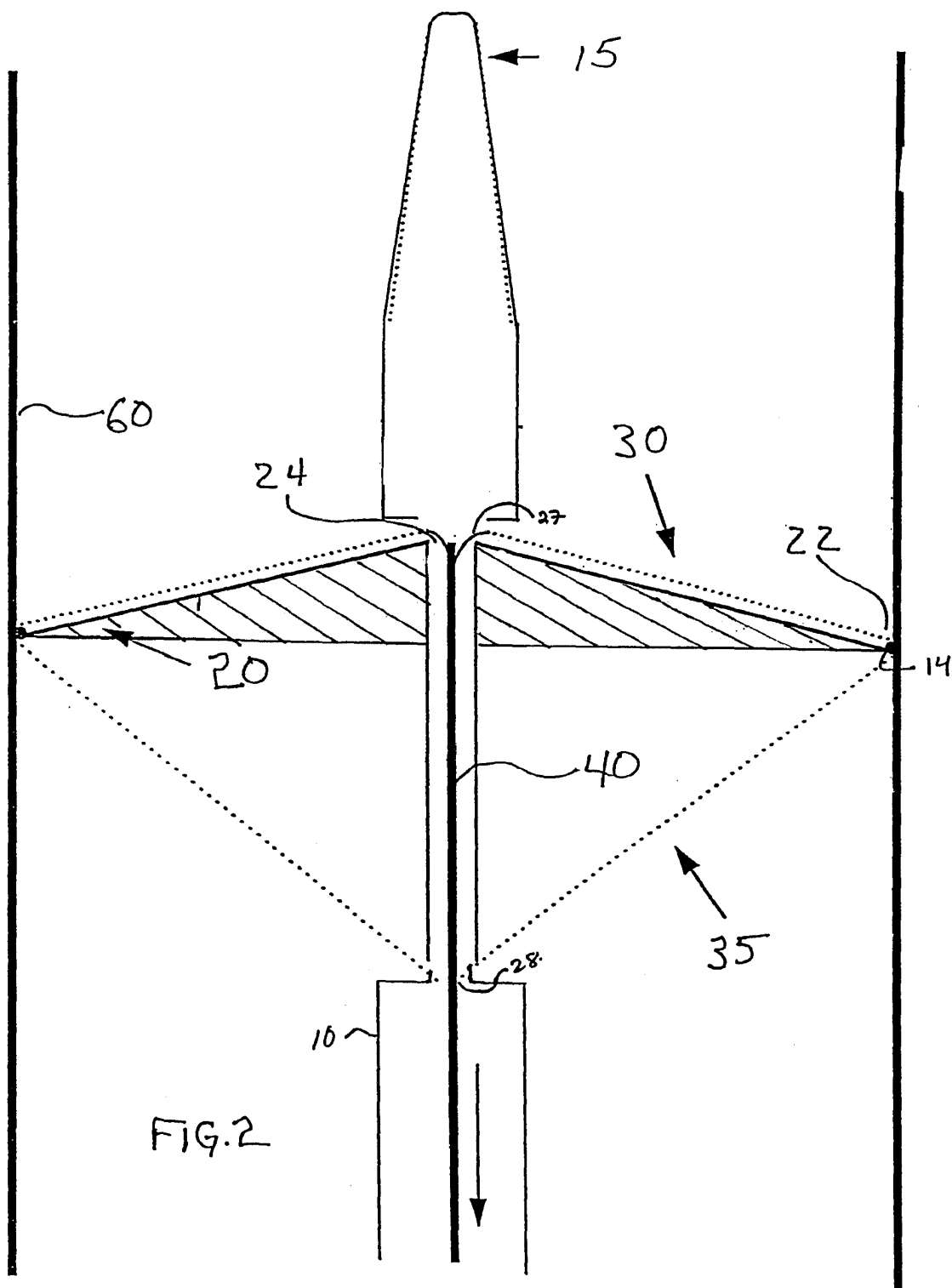
26. The vascular filter of Claim 25, wherein the filter membrane comprises a porous mesh.

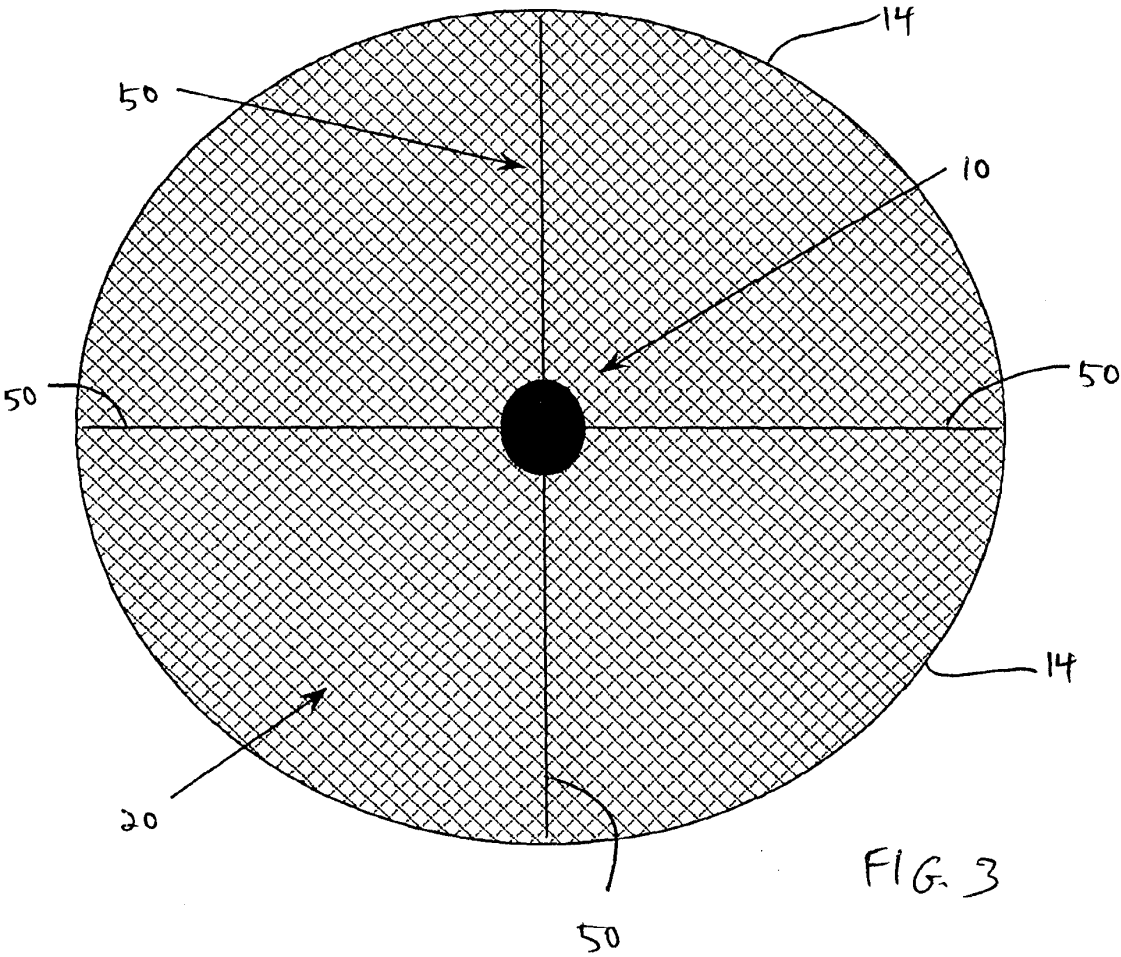
27. The vascular filter of Claim 26, wherein the pore size of the porous mesh is from about 40 to about 300 microns.

28. The vascular filter of Claim 25, wherein the collapsing means comprises fibers each having first and second ends and said filter membrane further comprises an outer edge, and wherein said collapsing fibers are each attached at a first end to a control mechanism and are attached at a second end to the outer edge of the filter membrane.

FIG. 1







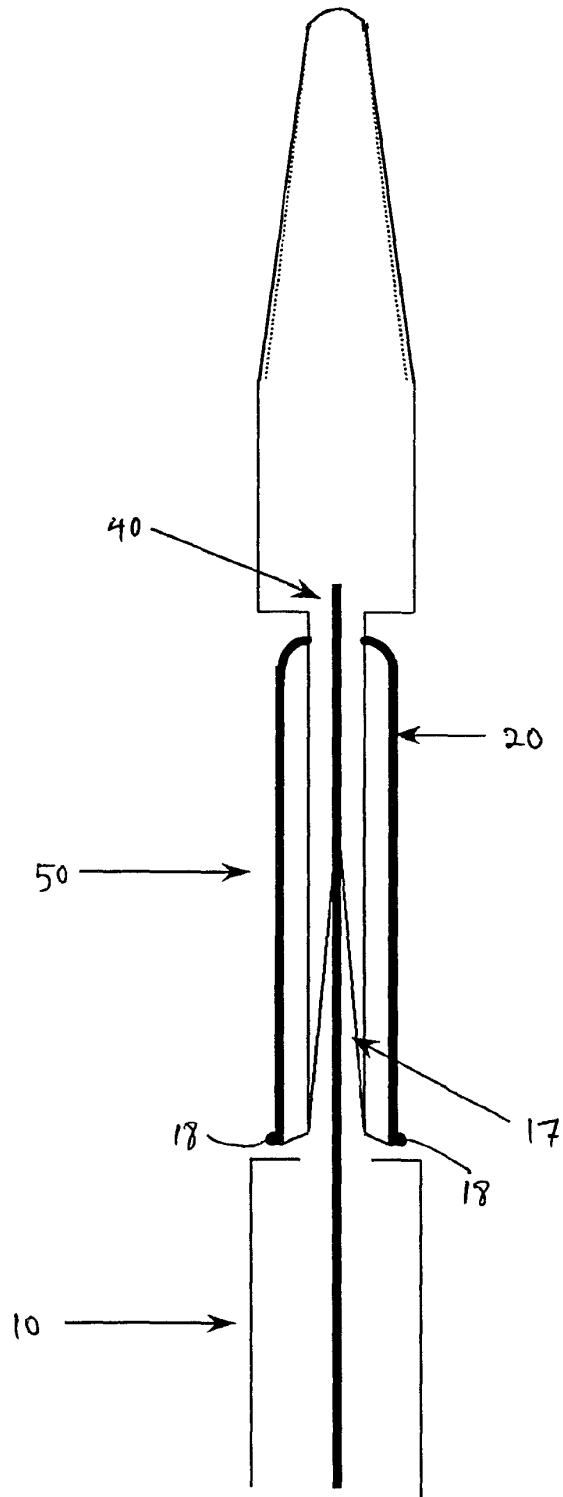
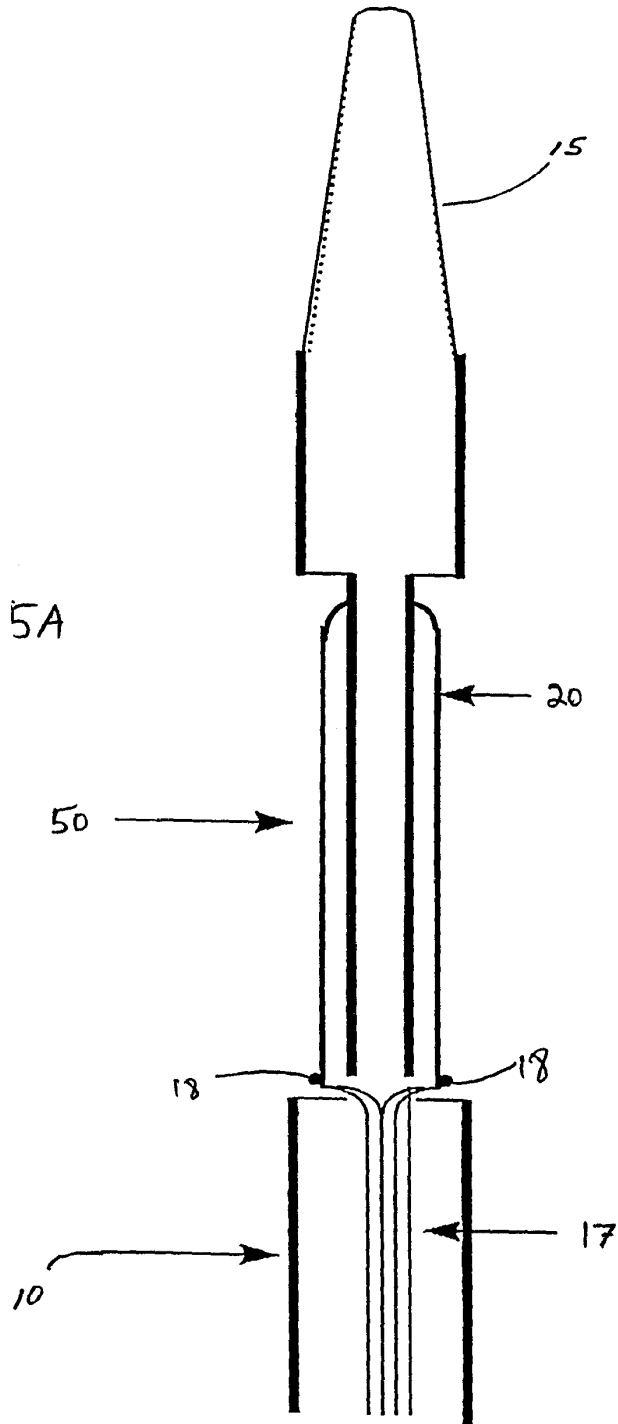
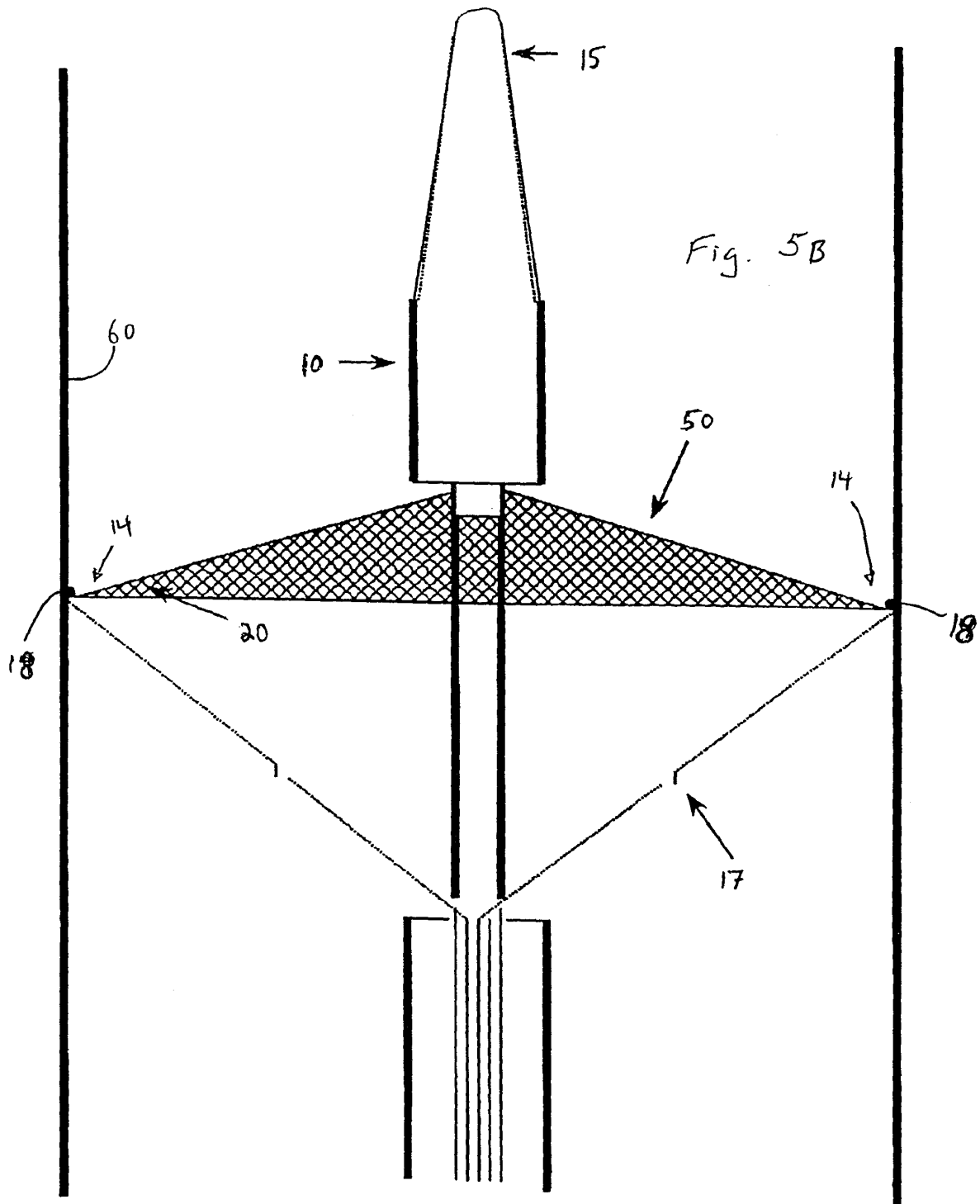


FIG. 4

Fig. 5A





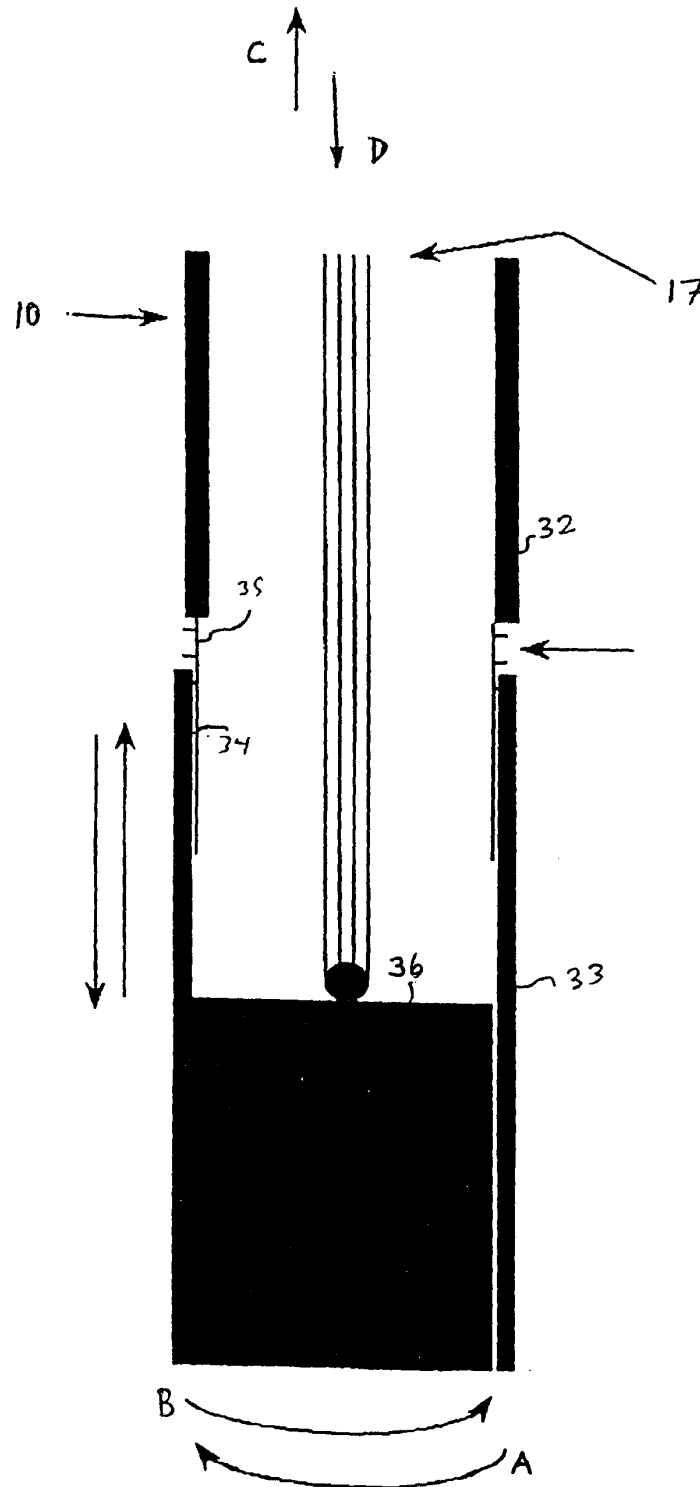


Fig. 6

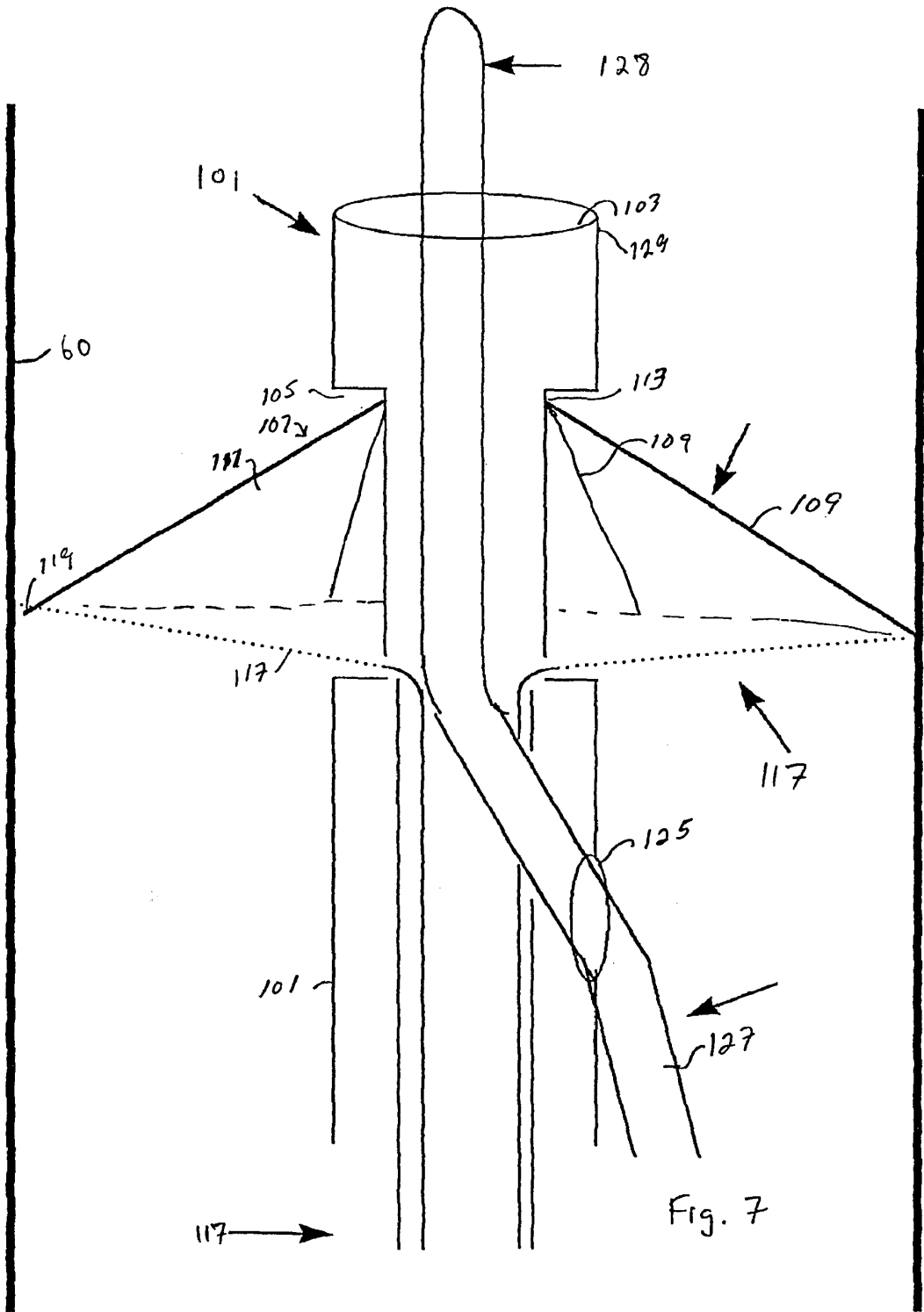
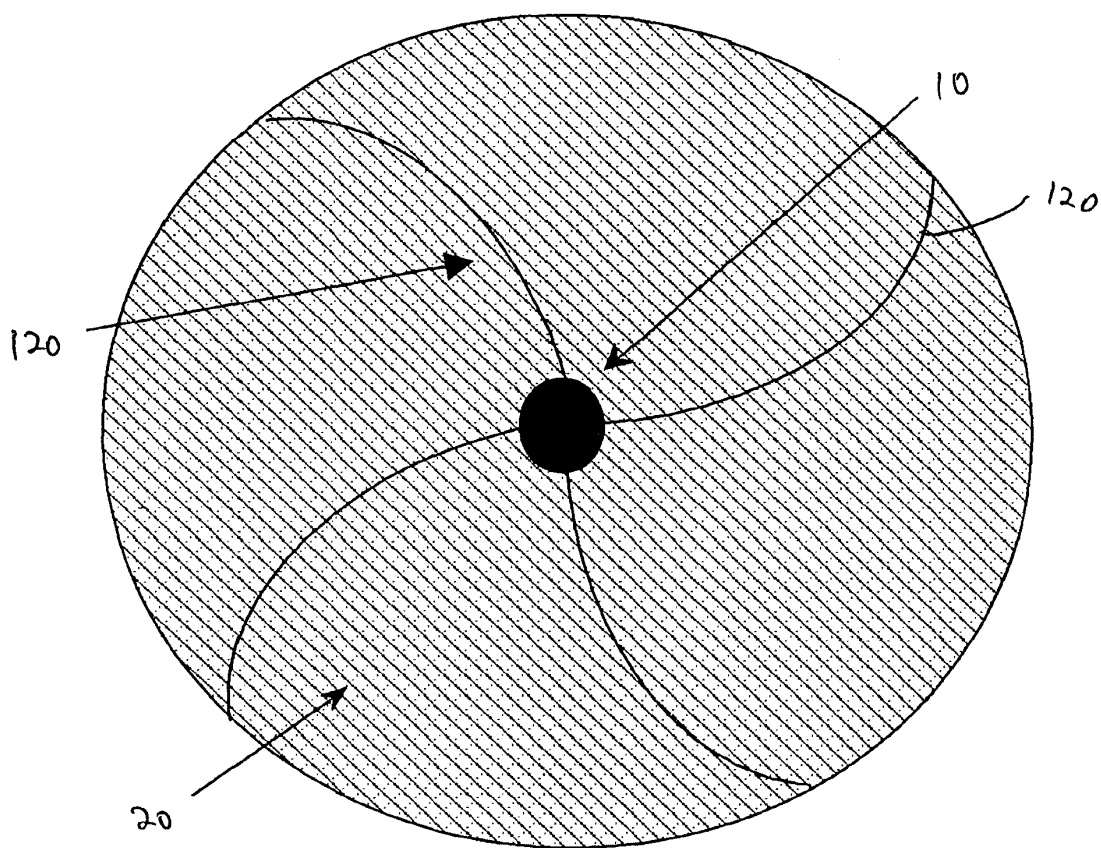


FIG. 8



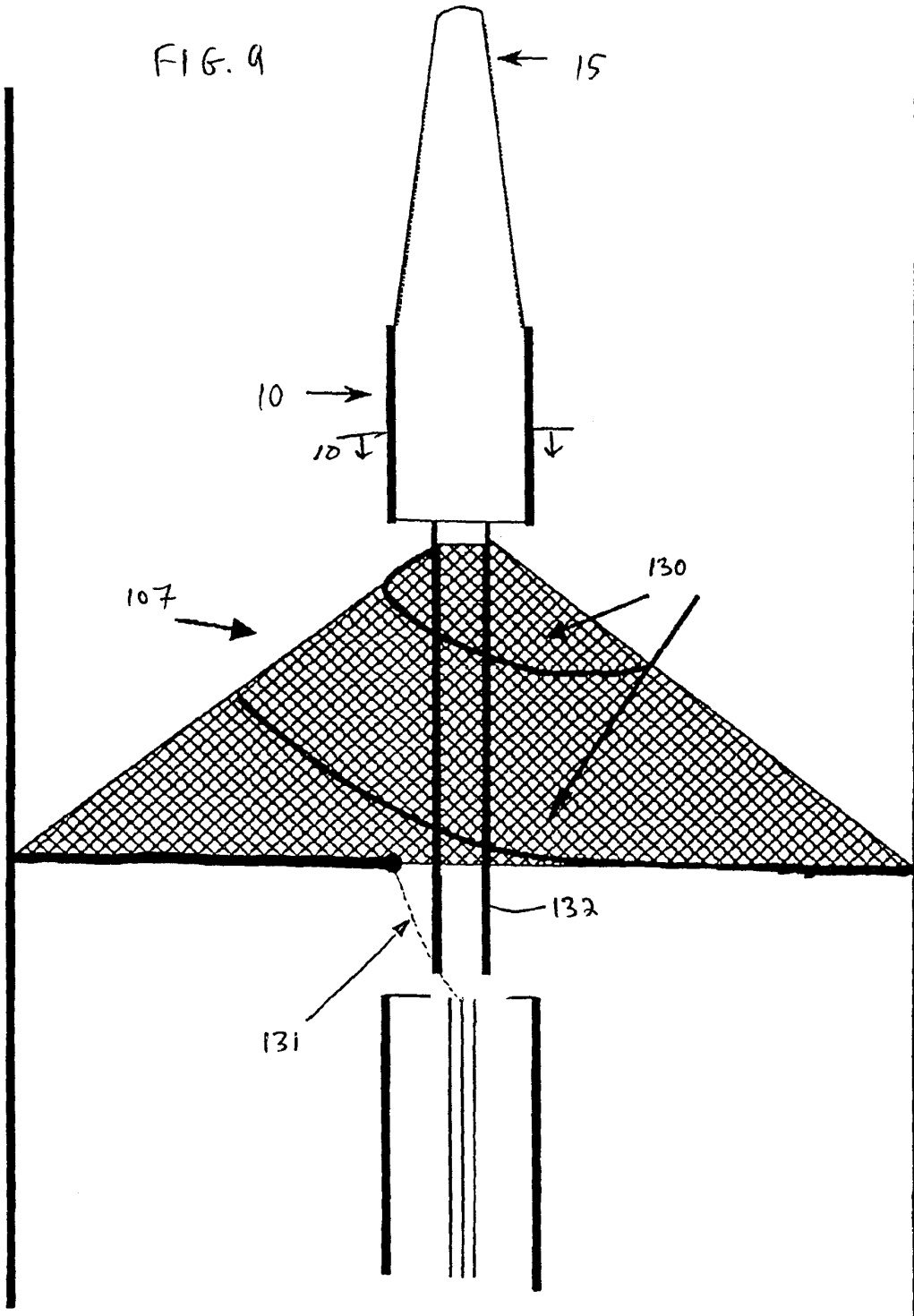
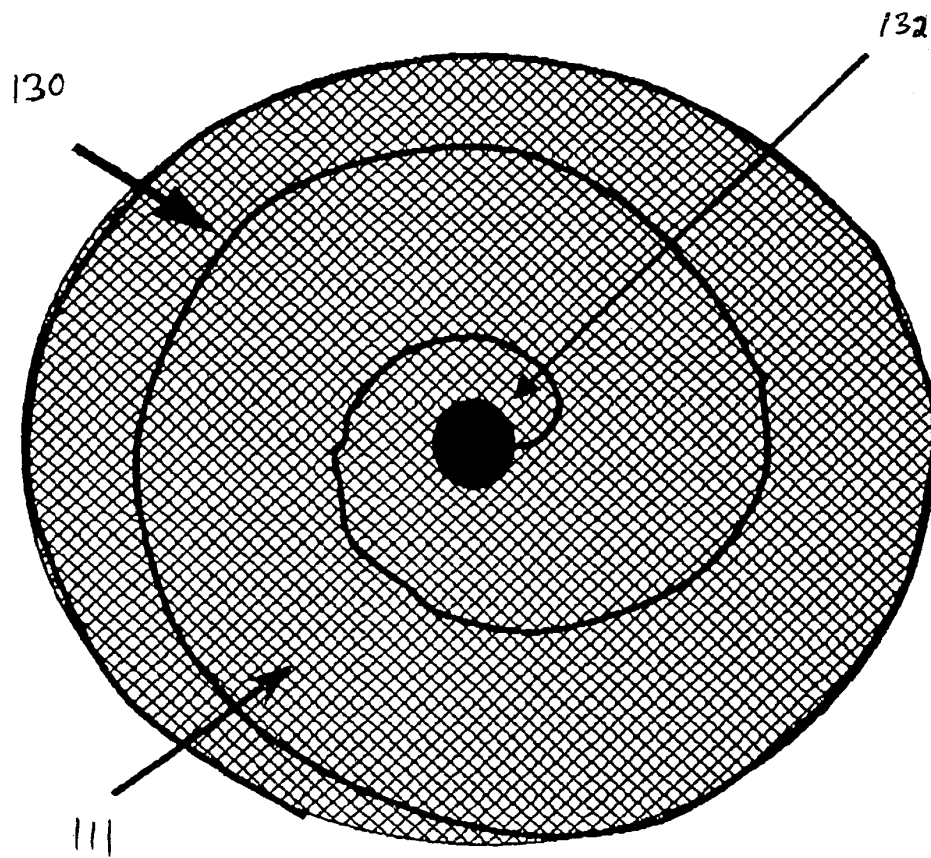
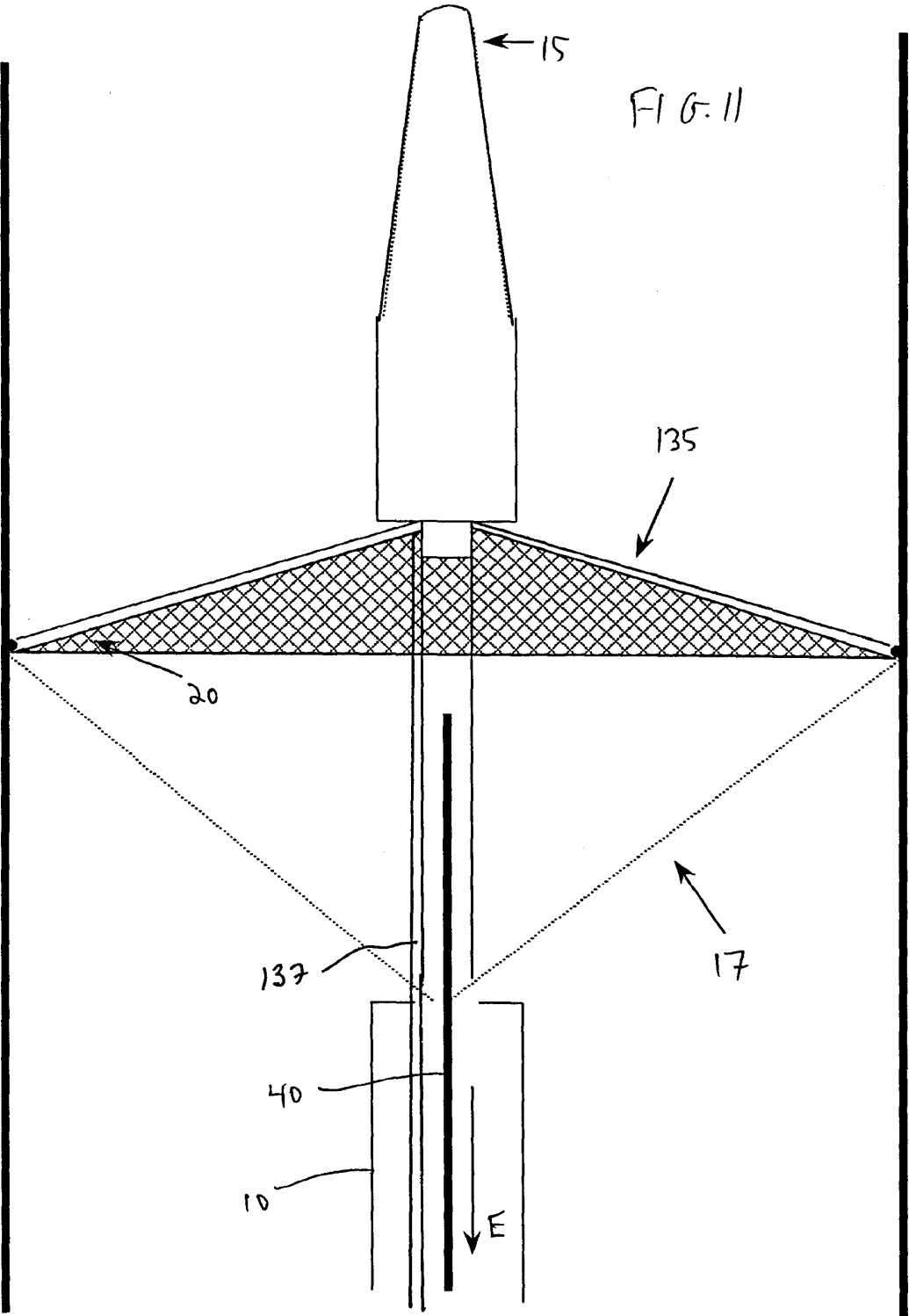
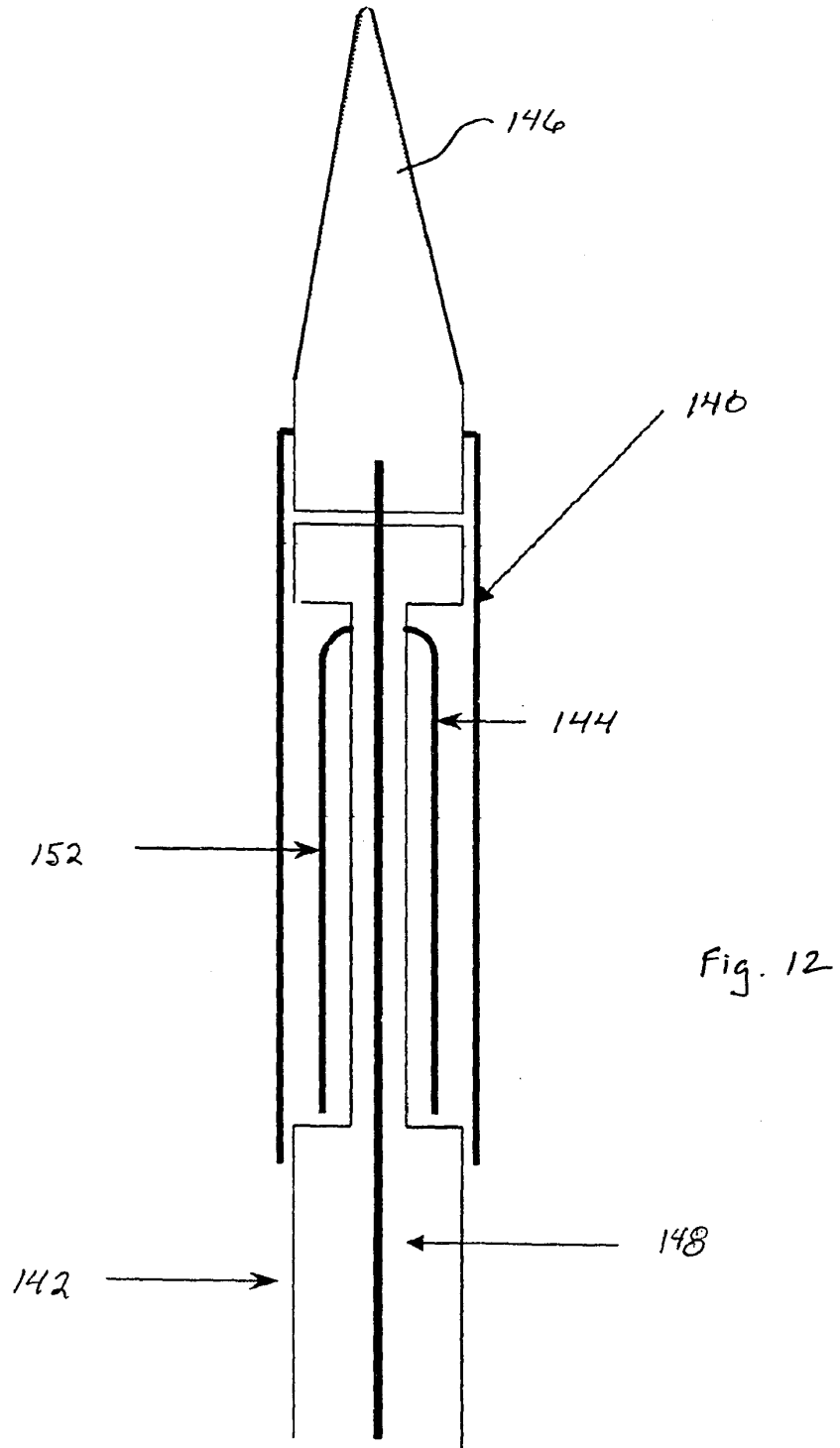
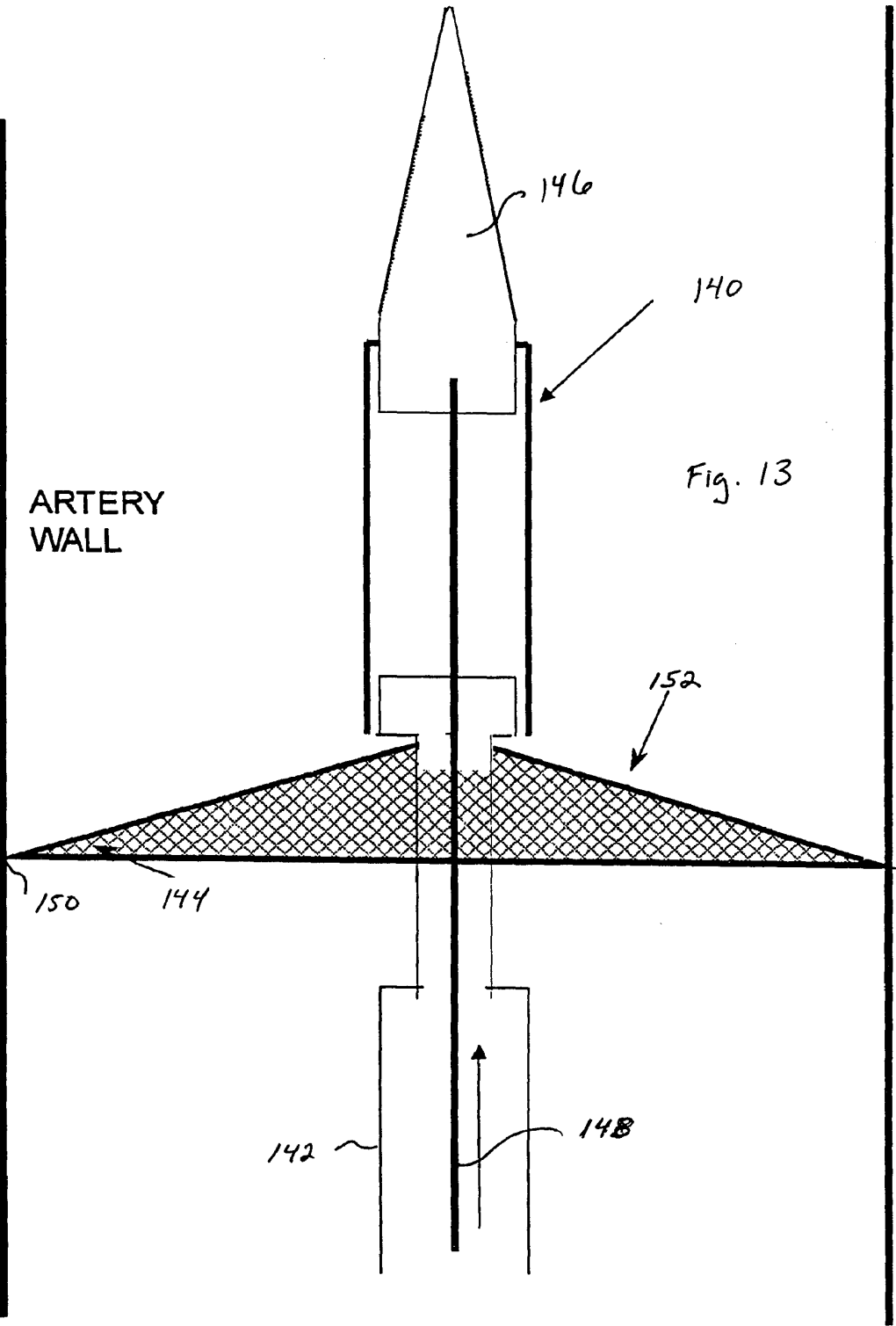


FIG. 10



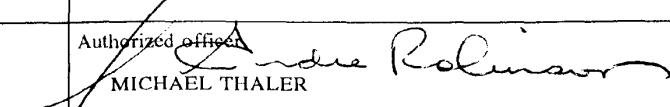






INTERNATIONAL SEARCH REPORT

International application No.
PCT/US98/01894

A. CLASSIFICATION OF SUBJECT MATTER IPC(6) : A61B 17/22 US CL : 606/200 According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) U.S. : 606/200 Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4,723,549 A (WHOLEY et al) 09 February 1988, entire document.	1-3
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Y		4-19
Y	US 5,053,008 A (BAJAJ) 01 October 1991, entire document.	4-19
☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.		
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Date of the actual completion of the international search 21 APRIL 1998		Date of mailing of the international search report 07 MAY 1998
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230		Authorized officer  MICHAEL THALER Telephone No. (703) 308-2981

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DESCRIPTION CN110652645A

110652645A

Multi-layer catheter main body and its catheter assembly

[0001]

Technical field

[0002]

The present invention mainly relates to a multi-layer catheter body and its catheter assembly for guiding, supporting or distally supporting for neurovascular applications.

In particular, the catheter body provides excellent distal flexibility and proximal stability for tracking inside the neurovascular, as well as excellent external and internal smoothness for implant delivery.

[0003]

Background technique

[0004]

Almost every neurovascular device placement or treatment occurs on or above the neck.

Therefore, catheters used in the neurovascular system must be able to traverse tortuous blood vessels.

When designing catheters for neurovascular applications, engineers must strike a balance between functionality and structure, with the main goals of tracking, flexibility, maneuvering, and torque transmission or torsion of the catheter.

[0005]

PTFE material has excellent wear resistance and high smoothness, and is an ideal choice for the inner wall of the catheter.

When the medical device is pushed through the tight catheter lumen, the smooth inner surface of the PTFE inner layer reduces the friction between the medical device and the catheter. Dip coating and extrusion are two common methods for manufacturing PTFE liners. The immersion plating method is a method to deposit a polytetrafluoroethylene lining. This process can be performed on the mandrel as part of the catheter body construction process. Once the coating is cured, additional components of the catheter, such as nylon sheath, braided tubing, are built on the cured dip coating mandrel. Although the dip coating process seems to be a simple process from the beginning, it has some bottlenecks. The dip coating may have an uneven surface that results in a large peel. Sometimes there are many cross-section lines on the surface of the dip coating, which is called furter, which is caused by the vibration during the dip coating process. The surface of the dip coating may also have pits, depressions, or even holes in the outer layer, which are caused by contaminants (including moisture) during the dip coating process. These defects will negatively affect the smoothness of the catheter lumen and seriously affect the use of the catheter. Although these defects can be solved in different ways, the high precision of the dip coating process usually brings greater cost and time.

[0006]

Extrusion of PTFE using is another way to make the inner layer of PTFE tubing.

Although extruded PTFE has the lowest coefficient of friction, a typical extruded PTFE tube has a wall thickness of about 0.001". This wall thickness may result in an increase in the overall rigidity of the catheter, which is not an ideal method to pass through tortuous passages in the nerves and blood vessels.

[0007]

The ideal neurovascular catheter should have the smallest outer diameter to pass most medical devices/implants through small blood vessels and the largest inner diameter.

This inevitably leads to the need for the inner layer of ultra-thin catheters. However, with the ultra-thin inner layer of the catheter, engineers need to incorporate the catheter body supporting components, such as the flat wire layer covering the inner layer of the catheter, the braided mesh layer or the coil layer, to enhance the punctability and bending resistance of the catheter. In order to maintain the integrity of the catheter structure, a minimum contraction pressure is required between the wire layer and the inner layer of the catheter. Generally, such a minimum contraction pressure will increase the roughness of the inner surface of the inner layer of the catheter and significantly reduce the smoothness of the inner surface.

[0008]

Therefore, it is necessary to develop a new catheter for neurovascular to meet the high standards of punctability, processability, flexibility and torsion power, and a large cavity is needed to achieve maximum suction flow. Such a flow, smaller outer diameter allows the catheter to penetrate into smaller blood vessels without causing additional vascular damage to the target treatment site, smooth outer surface, and extremely high inner surface smoothness to reduce blood.

[0009]

Summary of the invention

[0010]

The purpose of the present invention is to provide a multilayer catheter body and catheter assembly for the delivery and placement of medical equipment.

The invention can meet the goals of high standards of punctability, processability, flexibility and torsion power, and at the same time has a large cavity to achieve the maximum suction flow. A smaller outer diameter enables the catheter to go deeper in the blood vessel, it will not cause additional blood vessel damage to the target treatment location, the outer surface is smooth, at the same time, it has a very high inner surface smoothness.

[0011]

In the first aspect of the present invention, a multilayer catheter body is provided. The catheter body is used to deliver and place medical devices. The catheter body includes an inner layer, a first intermediate layer, and a second intermediate layer in order from the inside to the outside. And the outer layer, the inner layer is a thin-walled tube, and the tube bottom of the inner layer has a smooth wall pattern, the first middle layer is a coil layer, and the first middle layer is wound by flat wire. The ratio of the width to the thickness of the flat wire is at least 2:1, the second middle layer is a braided layer, and the second middle layer is braided by metal wires, the hardness of the distal end of the outer layer is less than that of the inner layer. The hardness of the proximal end of the outer layer, the outer layer is bonded to the inner layer through the wire gap between the first intermediate layer and the second intermediate layer.

[0012]

In another preferred embodiment, the outer layer is composed of multiple materials, wherein a material with soft hardness is used as the distal end of the outer layer, a material with medium hardness is used as the middle section of the outer layer, and a material with hard hardness is used as the proximal part of the outer layer.

[0013]

In another preferred embodiment, the ratio of the outer diameter of the inner layer of the catheter body to its wall thickness is at least 10:1.

[0014]

In another preferred embodiment, the smallest inner diameter of the inner layer of the catheter body is 0.8 mm.

[0015]

In another preferred embodiment, the maximum thickness of the flat wire of the first intermediate layer is 0.005 mm.

[0016]

In another preferred embodiment, the maximum width of the flat wire of the first intermediate layer is 0.08 mm.

[0017]

In another preferred embodiment, the first intermediate layer covers at least 30% of the outer surface of the inner layer.

[0018]

In another preferred embodiment, the maximum thickness of the second intermediate layer is 0.005 mm.

[0019]

In another preferred embodiment, the wall thickness of the catheter body is at least 0.03 mm.

[0020]