US006821285B2

(12) **United States Patent**
Laufer et al.

(10) **Patent No.: US 6,821,285 B2**
(45) **Date of Patent: Nov. 23, 2004**

(54) **TISSUE RECONFIGURATION**

(75) Inventors: **Michael D. Laufer**, Menlo Park, CA (US); **Jeffrey C. Cerier**, Franklin, MA (US); **Amos Cruz**, Franklin, MA (US); **Jonathan O'Keefe**, Scituate, MA (US); **Richard Andrews**, Lincoln, RI (US); **Ram Chuttani**, Dover, MA (US); **Vincent A. Puicci, Jr.**, Spencer, MA (US); **Michael Barenboym**, Ashland, MA (US); **Neal H. Marshall**, Bolton, MA (US); **Randall B. Chinnock**, Sturbridge, MA (US)

(73) Assignee: **ndo surgical, Inc.**, Mansfield, MA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 213 days.

(21) Appl. No.: **09/859,579**

(22) Filed: **May 18, 2001**

(65) **Prior Publication Data**

US 2002/0040226 A1 Apr. 4, 2002

Related U.S. Application Data

(63) Continuation-in-part of application No. 09/574,424, filed on May 19, 2000, now Pat. No. 6,494,888, which is a continuation-in-part of application No. 09/520,273, filed on Mar. 7, 2000, now Pat. No. 6,663,639, and application No. 09/519,945, filed on Mar. 7, 2000, now Pat. No. 6,506,196.

(60) Provisional application No. 60/140,492, filed on Jun. 22, 1999.

(51) **Int. Cl.**[7] **A61B 17/08**

(52) **U.S. Cl.** **606/153**; 606/151; 606/219

(58) **Field of Search** 606/153–158, 606/139, 142, 143, 144, 148, 216, 219, 221, 108, 151; 600/104; 227/175.1

(56) **References Cited**

U.S. PATENT DOCUMENTS

3,470,875	A	10/1969	Johnson	
3,551,987	A	1/1971	Wilkinson	
3,638,653	A	2/1972	Berry	
3,842,840	A	10/1974	Schweizer	
3,875,648	A *	4/1975	Bone	606/219
3,901,244	A	8/1975	Schweizer	
3,946,740	A	3/1976	Bassett	
4,006,747	A	2/1977	Kronenthal et al.	
4,164,225	A	8/1979	Johnson et al.	
4,235,238	A	11/1980	Ogiu et al.	

(List continued on next page.)

FOREIGN PATENT DOCUMENTS

EP	0 480 428	4/1992

(List continued on next page.)

OTHER PUBLICATIONS

International Search Report dated Oct. 16, 2000.

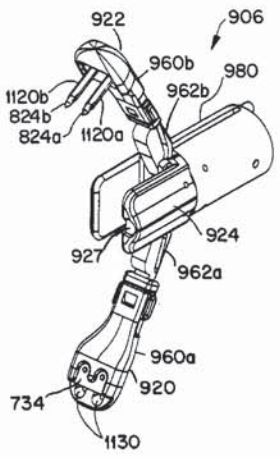
(List continued on next page.)

Primary Examiner—Julian W. Woo
(74) *Attorney, Agent, or Firm*—Fish & Richardson P.C.

(57) **ABSTRACT**

A medical instrument for engaging tissue includes a flexible shaft, a tissue piercing coil at a distal portion of the shaft, and a tissue stabilizer positioned over the shaft and biased in a distal direction such that as the tissue piercing coil enters tissue, the tissue stabilizer is urged against a surface of the tissue. A medical instrument for reconfiguring tissue includes a flexible shaft defining a lumen housing actuating controls, and a distal actuating assembly with a sealing portion configured to substantially seal the shaft lumen from contact with bodily fluids. A cartridge assembly includes first and second members configured for releasable attachment to a medical instrument, and a holder configured to receive the first and second members and to be released from the first and second members upon action of the first and second members attaching to the medical instrument.

61 Claims, 48 Drawing Sheets



U.S. PATENT DOCUMENTS

4,448,194	A		5/1984	DiGiovanni et al.
4,471,781	A		9/1984	DiGiovanni et al.
4,500,024	A		2/1985	DiGiovanni et al.
4,506,670	A		3/1985	Crossley
4,573,469	A		3/1986	Golden et al.
4,585,153	A		4/1986	Failla et al.
4,586,502	A		5/1986	Bedi et al.
4,591,085	A		5/1986	Di Giovanni et al.
4,605,004	A		8/1986	Di Giovanni et al.
4,606,345	A		8/1986	Dorband et al.
4,627,437	A		12/1986	Bedi et al.
4,696,300	A	*	9/1987	Anderson 606/219
4,705,040	A	*	11/1987	Mueller et al. 606/108
4,724,840	A		2/1988	McVay et al.
4,736,746	A		4/1988	Anderson
4,741,336	A		5/1988	Failla et al.
4,753,469	A		6/1988	Hiscott
4,809,695	A	*	3/1989	Gwathmey et al. 606/145
4,887,612	A		12/1989	Esser et al.
4,890,615	A		1/1990	Caspari et al.
4,935,027	A		6/1990	Yoon
5,015,249	A	*	5/1991	Nakao et al. 606/142
5,037,433	A		8/1991	Wilk et al.
5,080,663	A		1/1992	Mills et al.
5,088,979	A		2/1992	Filipi et al.
5,147,373	A		9/1992	Ferzli
5,222,963	A		6/1993	Brinkerhoff et al.
5,254,126	A		10/1993	Filipi et al.
5,336,263	A		8/1994	Ersek
5,346,504	A		9/1994	Ortiz et al.
5,356,416	A		10/1994	Chu et al.
5,358,508	A		10/1994	Cobb
5,364,408	A		11/1994	Gordon
5,395,030	A		3/1995	Kuramoto et al.
5,403,326	A		4/1995	Harrison et al.
5,433,721	A		7/1995	Hooven et al.
5,441,507	A		8/1995	Wilk
5,447,512	A		9/1995	Wilson et al.
5,451,406	A		9/1995	Lawin
5,465,894	A		11/1995	Clark et al.
5,486,189	A		1/1996	Mudry et al.
5,496,331	A		3/1996	Xu et al.
5,522,820	A		6/1996	Caspari et al.
5,549,618	A		8/1996	Fleenor et al.
5,558,665	A		9/1996	Kieturakis
5,571,090	A		11/1996	Sherts
5,571,116	A		11/1996	Bolanos et al.
5,573,496	A		11/1996	McPherson et al.
5,624,453	A		4/1997	Ahmed
5,626,613	A		5/1997	Schmieding
5,645,552	A	*	7/1997	Sherts 606/145
5,662,683	A		9/1997	Kay
5,665,096	A		9/1997	Yoon
5,674,230	A		10/1997	Tovey
5,676,674	A		10/1997	Bolanos et al.
5,697,940	A		12/1997	Chu et al.
5,722,421	A		3/1998	Francese et al.
5,725,524	A		3/1998	Mulier et al.
5,728,109	A		3/1998	Schulze et al.
5,735,861	A		4/1998	Peifer et al.
5,741,280	A		4/1998	Fleenor
5,749,898	A		5/1998	Schulze et al.
5,787,897	A		8/1998	Kieturakis
5,792,153	A		8/1998	Swain et al.
5,792,478	A		8/1998	Lawin
5,797,927	A		8/1998	Yoon
5,810,855	A	*	9/1998	Rayburn et al. 606/220
5,810,882	A		9/1998	Bolduc et al.
5,814,054	A		9/1998	Kortenbach et al.
5,826,776	A		10/1998	Schulze et al.
5,846,254	A		12/1998	Schulze et al.
5,853,409	A		12/1998	Swanson et al.
5,855,311	A		1/1999	Hamblin et al.
5,887,594	A		3/1999	LoCicero, III et al.
5,893,592	A		4/1999	Schulze et al.
5,897,562	A		4/1999	Bolanos et al.
5,901,895	A		5/1999	Heaton et al.
5,958,444	A		9/1999	Wallace
5,984,932	A		11/1999	Yoon
5,993,466	A		11/1999	Yoon
6,009,877	A		1/2000	Edwards
6,051,003	A		4/2000	Chu et al.
6,059,798	A		5/2000	Tolkoff
6,067,990	A		5/2000	Kieturakis
6,083,202	A		7/2000	Smith
6,086,600	A		7/2000	Kortenbach
6,086,603	A		7/2000	Termin et al.
6,098,629	A		8/2000	Johnson
6,113,609	A		9/2000	Adams
6,129,761	A		10/2000	Hubbell
6,152,935	A	*	11/2000	Kammerer et al. 606/144
6,159,146	A		12/2000	El Gazayerli
6,179,840	B1		1/2001	Bowman
6,221,084	B1		4/2001	Fleenor
6,258,064	B1		7/2001	Smith et al.
6,352,503	B1		3/2002	Matsui et al.
6,387,104	B1		5/2002	Pugsley, Jr. et al.
6,551,315	B2		4/2003	Kortenbach et al.
6,569,085	B2		5/2003	Kortenbach et al.
6,569,105	B1		5/2003	Kortenbach et al.
6,579,301	B1		6/2003	Bales et al.
6,632,227	B2		10/2003	Adams
6,645,201	B1		11/2003	Utley et al.
6,660,301	B1		12/2003	Vogel et al.
6,663,639	B1		12/2003	Laufer et al.
6,666,848	B2		12/2003	Stone
6,669,713	B2		12/2003	Adams
2001/0049537	A1		12/2001	Kortenbach
2001/0056282	A1		12/2001	Sonnenschein
2002/0063143	A1		5/2002	Adams et al.
2002/0068945	A1		6/2002	Sixto, Jr. et al.
2002/0068946	A1		6/2002	Kortenbach
2002/0078967	A1		6/2002	Sixto, Jr. et al.
2002/0082621	A1		6/2002	Schurr
2002/0138086	A1		9/2002	Sixto, Jr. et al.
2002/0173786	A1		11/2002	Kortenbach et al.
2002/0198537	A1		12/2002	Smith et al.
2002/0198538	A1		12/2002	Kortenbach et al.
2002/0198539	A1		12/2002	Sixto, Jr. et al.
2002/0198540	A1		12/2002	Smith et al.
2002/0198541	A1		12/2002	Smith et al.
2002/0198549	A1		12/2002	Sixto, Jr. et al.
2003/0019905	A1		1/2003	Adams et al.
2003/0188755	A1		10/2003	Milbocker
2003/0191478	A1		10/2003	Kortenbach et al.
2003/0192558	A1		10/2003	Durgin
2003/0192559	A1		10/2003	Durgin
2003/0195387	A1		10/2003	Kortenbach et al.
2003/0195509	A1		10/2003	Edwards et al.
2003/0196670	A1		10/2003	Durgin
2003/0199731	A1		10/2003	Silverman et al.
2003/0208209	A1		11/2003	Gambale et al.
2003/0208211	A1		11/2003	Kortenbach
2003/0216754	A1		11/2003	Kraemer et al.
2003/0220657	A1		11/2003	Adams
2003/0220660	A1		11/2003	Kortenbach et al.
2003/0236535	A1		12/2003	Onuki et al.
2003/0236536	A1		12/2003	Grigoryants et al

FOREIGN PATENT DOCUMENTS

EP	0 576 265	12/1993

EP	0 646 356 A2	4/1995
EP	0 975 263	10/2003
FR	2 768 324	3/1999
WO	WO 99/22649	5/1999
WO	WO 99/60931	12/1999
WO	WO 00/35529	12/2000
WO	WO 00/78227	12/2000
WO	WO 00/78229	12/2000
WO	00/78229	12/2000
WO	WO 02/24080	3/2002
WO	WO 02/40081	5/2002
WO	WO 02/45603	6/2002
WO	WO 02/094341	11/2002
WO	WO 03/000115	1/2003
WO	WO 03/004087	1/2003
WO	WO 03/007796	1/2003
WO	WO 03/015604	2/2003
WO	WO 03/082359	10/2003
WO	WO 03/090633	11/2003
WO	WO 03/092498	11/2003
WO	WO 03/092509	11/2003
WO	WO 03/094800	11/2003
WO	WO 03/096885	11/2003
WO	WO 03/099137	12/2003
WO	WO 03/099139	12/2003
WO	WO 03/099140	12/2003
WO	WO 03/099376	12/2003
WO	WO 03/105917	12/2003
WO	WO 2004/000129	12/2003

OTHER PUBLICATIONS

Carvalho PJPC et al., Fibrosis of gastric cardia after endoscopic sclerosis. Mechansism for control of experimental reflux? *Am Surg* 1990 Mar.;56(3):163–6.

Contractor QQ et al., Endoscopic esphagitis and gastroesophageal flap valve. *J Clin Gastroenterol* 1999 Apr.; 28(3):233–7.

Hill LD and Kozarek RA, The gastroesophageal flap valve. *J Clin Gastroenterol* 1999 Apr.:28(3):194–7.

Hill LD et al., Antireflux surgery. A surgeon's look. *Gastroenterol Clin North Am* 1990 Sep.:19(3):745–75.

Hill LD et al., The gastroesophageal flap valve: in vitro and in vivo observations. *Gastrointest Endosc* 1996 Nov.;44(5):541–7.

Hill LD, Intraoperative measurement of lower esophageal sphincter pressure. *J. Thorac Cardiovasc Surg* 1978 Mar.;75(3):378–82.

Hill LD, Mythis of the esophagus. *J Thorac Cardivasc Surg* 1989 Jul.;98(1):1–10.

Ismail T. et al., Yield pressure, anatomy of the cardia and gastro–oesophageal reflux. *Br. J Surg* 1995 Jul.;82(7):943–7.

Kadirkamanathan SS et al., An ambulant procine model of acid reflux used to evaluate endoscopic gastroplasty. *Gut* 1999 Jun.;44(6):782–8.

Kadirkamanathan SS et al., Antireflux operations at flexible endoscopy using enodluminal stitching techniques: an experimental study. *Gastrointest* Endosc 1996 Aug.;44(2):133–43.

Mason RJ et al., A new intraluminal antigastroesophageal reflux procedure in baboons. *Gastrointest Endosc* 1997 Mar.;45(3):283–90.

McGouran RC et al., Does measurement of yield pressure at the cardia during endoscopy provide information on the function of the lower oesophageal sphincter mechanism? *Gut* 1988 Mar.; 29(3):275–8.

McGouran RC et al., Is yield pressure at the cardia increased by effective fundoplication? *Gut* 1989 Oct.;30(10):1309–12.

O'Connor KW et al., An experimental endoscopic technique for reversing gastroesophageal reflux in dogs by injecting inert material in the distal esophagus. *Gastrointest Endosc* 1984 Oct.;30(5):275–80.

Rupp TH and Lehman GA, Endoscopic antireflux techniques. Endoluminal and lapaoscopic. *Gastrointest Endosc Clin N Am* 1994 Apr.;4(2):353–68.

Shafik A., Intraesophageal Polytef injection for the treatment of reflux esophagitis. *Surg Endosc* 1996 Mar.;10(3):329–31.

Slim K et al., Intraoperative esophageal manometry and fundoplications: prospective study. World J Surg 1996 Jan.;20(1):55–9.

Thor KBA et al., Reappraisal of the flap valve mechanism in the gastroesophageal junction. A study of a new valvuloplasty procedure in cadavers. *Acta Chir Scand* 1987 Jan.;153(1):25–8.

Boerema, M.D., "Hiatus hernai: Repair by righ–sided, subhepatic, anterior gastropexy," *Surgery,* 65:884–893 (1969).

Cecconello, "Esophagogastric Anastomosis with Valvuloplasty: An Experimental Study," *International Surgery,* 67:121–124 (1982).

Collis, M.D., "Surgical Control of Reflux in Hiatus Hernia," *The American Journal of Surgery,* 115:465–471 (1968).

Collis, M.D., "An Operation for Hiatus Hernia with Short Esophagus," *The Journal of Thoracic Surgery,* 34:768–778 (1957).

Cuschieri, et al., "Multicenter prospective evaluation of laparoscopic antireflux surgery," *Surgical Endoscopy,* 7:505–510 (1993).

DeMeester, M.D. et al., "Nissen Fundoplication for Gastroesophageal Reflux Disease," *Annals of Surgery,* 204:9–20 (1986).

Donahue, M.D., et al., "Endoscopic Control of Gastro–Esophageal Reflux: Status Report," *World Journal of Surgery,* 16:343–346 (1992).

Donahue, M.D., et al., "Endoscopic sclerosis of the gastic cardia for prevention of experimental gastroesophageal reflux," *Gastrointestinal Endoscopy,* 36:253–256 (1990).

Falk, et al., "Laparoscopic Fundoplication: A preliminary report of the technique and postoperative care," *Aust. N.Z. J. Surgery,* 62:969–972 (1992).

Hill, et al., "Surgery for Peptic Esophageal Stricture," 139–147.

Hill, M.D., "An Effective Operation for Hiatal Hernai: An Eight Year Appraisal," *Annals of Surgery,* 166:681–692 (1967).

Hill, et al., "The Esophagus, Medical and Surgicial Management," *WB Saunders Co.,* 135–8 (1988).

Hinder, et al. "The Surgical Option for Gastroesophageal Reflux Disease," Symposium on Gastroesophageal Reflux Disease, *Am J Med,* 103:144S–148S (1997).

Ismail, et al., "Yield Pressure: A New Concept in the Evaluation of Gerd?," *AJG,* 91:616–617 (1996).

Jamieson, et al., "The development of surgery for gastro–oesophageal reflux disease," *Surgery of the Oesophagus,* 233–245 (1988).

Jamieson, et al., "Laparoscopic Nissen Fundoplication," *Annals of Surgery,* 220:137–145 (1994).

Janssen, et al., "Prospective randomized comparison of teres cardiopexy and Nissen fundoplication in the surgical therapy of gastro–oesophageal reflux disease," *Br. J. Surg.* 80:875–878 (1993).

Jennings, et al., "A Novel Endoscopic Transgastric Fundoplication Procedure for Gastroesophageal Reflux: An Initial Animal Evaluation," *Journal of Laparoendoscopic Surgery,* 2:207–213 (1992).

Kahrilas, "Gastroesophageal Reflux Disease," *JAMA,* 276:983–988 (1996).

Kraemer, M.D., et al., "Laparoscopic Hill repair," *Gastrointestinal Endoscopy,* 40:155–159 (1994).

Little, M.D., "Mechanisms of Action of Antireflux Surgery: Theory and Fact," *World Journal of Surgery,* 16:320–325 (1992).

Mason, et al., "Nissen Fundoplication Prevents Shortening of the Sphincter During Gastric Distention," *Arch Surg.,* 132:719–726 (1997).

McGouran, M.D., et al., "A laser–induced scar at the cardia increases the yield pressure of the lower esophageal sphincter," *Gastronintestinal Endoscopy,* 36:439–443 (1990).

McKernan, "Laparoscopic repair of gastroesophageal reflux disease," *Surgical Endoscopy,* 8:851–856 (1994).

Nathanson, et al., "Laparoscopic Ligamentum teres (round ligament) cardiopexy," *Br. J. Surg.,* 78:947–951 (1991).

Nissen, "Eine einfache Operation zur Beeinflussung der Refluxoesophagitis," *Journal Suisee De Medecine,* 590–592 (1956).

O'Connor, et al., "Endoscopic placement of collagen at the lower esophageal sphincter to inhibit gastroesophageal reflux: a pilot study of 10 medically intractable patients," *Gastrointestinal Endoscopy,* 34:106–112 (1988).

Pedinielli, "Traitement Chirurgical de la Herinie Hiatale Par La Technique de Collet", *Ann. Chir.,* 18:1461–1474 (1964). (English Abstract).

Polk, et al. "Hiatol Hernia and Esophagitis: A survey of indications for operation and technic and results of fundoplication," *Ann. Surg.,* 173:775–781 (1971).

Rampal, et al., "Technique Chirurgicale, Traitement des hernies hiatales et du reflux aesophagien par la cardio–pexie avec le ligament round de foie," *La Presse Medicale,* 75:617–619 (1967).

Rich, "Simple GERD Treatment Offers New Alternative," (www.medicalpost.com website), Mar. 1999.

Singh, et al., "Evaluation of the Endoscopic Suturing System in the Treatment of GERD," *DDW,* May 16–19, 1999.

Skinner, et al., "Surgical management of esophageal reflux and hiatus hernia," *Journal of Thoracic and Cardiovascular Surgery,* 53:33–54 (1967).

Starling, et al. Assessment of the Angelchik Prosthesis for Treatment of Symptomatic Esophageal Reflux, *World J. Surg.* 11, 350–355 (1987).

Tocornal, M.D., et al., "A mucosol flap valve mechanism to prevent gastroesophageal reflux and esophagitis," *Surgery,* 64:519–523 (1968).

Wang, et al., "A new anti–flux procedure: cardiac oblique invagination," *Chung Hua Wai Ko Tsa Chih,* Feb.; 33(2) 73–5 (1995). (English Abstract).

Watson, et al., "Comparison of anterior, posterior and total fundoplication using a viscera model," *Dieseases of the Esophagus,* 10: 110–114 (1997).

Westbrook, et al., "Posterior Surgical Approaches to the Rectum," *Annals of Surgery,* 195:677–691 (1982).

Digestive Disease Week, Orange County Convention Center, p. A–802; 314.

Donahue, et al., "Endoscopic control of gastroesophageal reflux status report", World Journal of Surgery, 16: 343–346, 1992.

The American Journal of Gastroenterology, vol. 91, No. 3, 1996, pp. 616–617.

Ismail, T. et al. "Yield pressure, anatomy of the cardia and gastro–oesophageal reflux," British Journal of Surgery, 1995, vol. 82, No. 7.

* cited by examiner

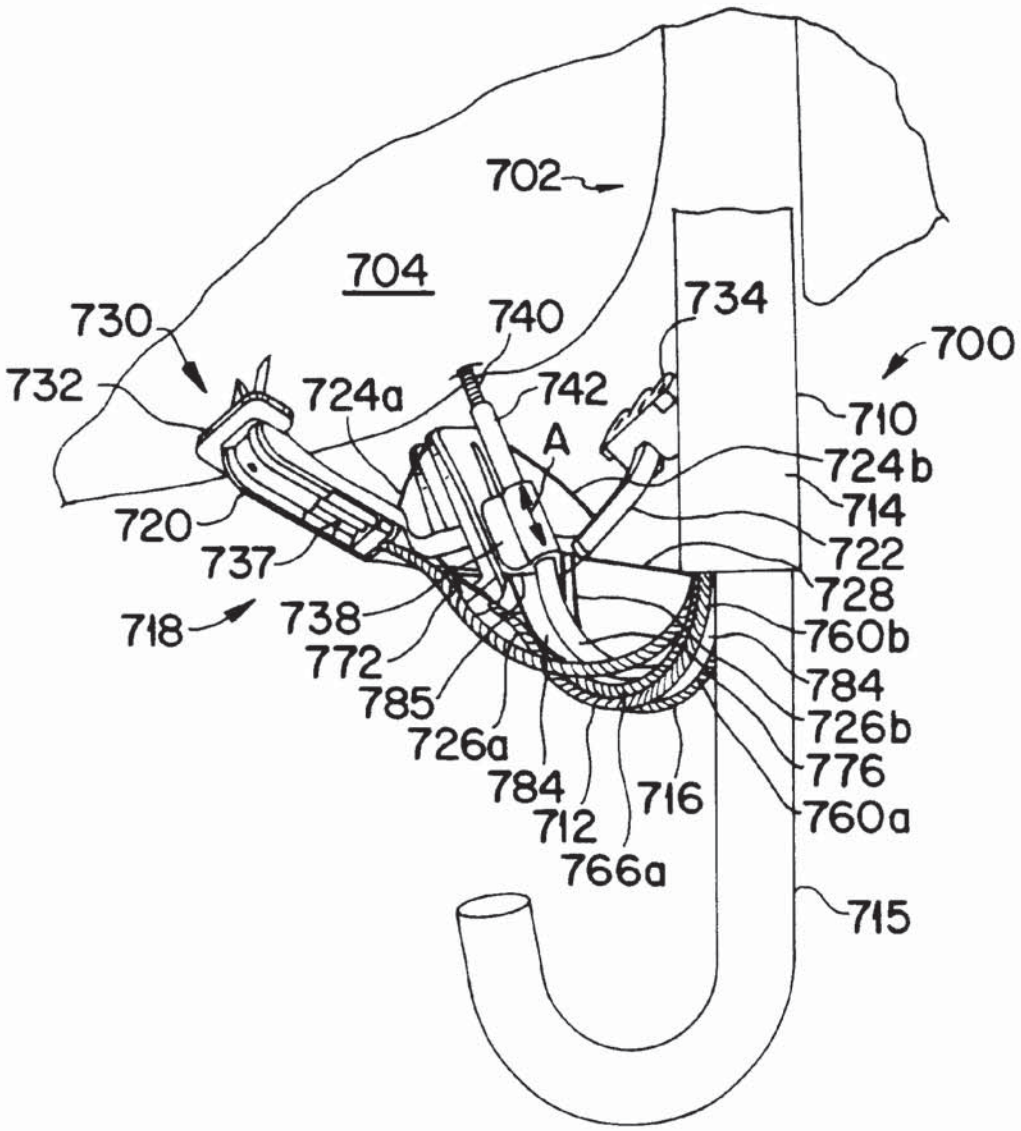

702
704
730
732
740
734
700
724a
742
710
A
724b
720
714
737
722
718
738
728
760b
772
784
785
726b
726a
776
784
716
760a
712
766a
715

FIG. 1

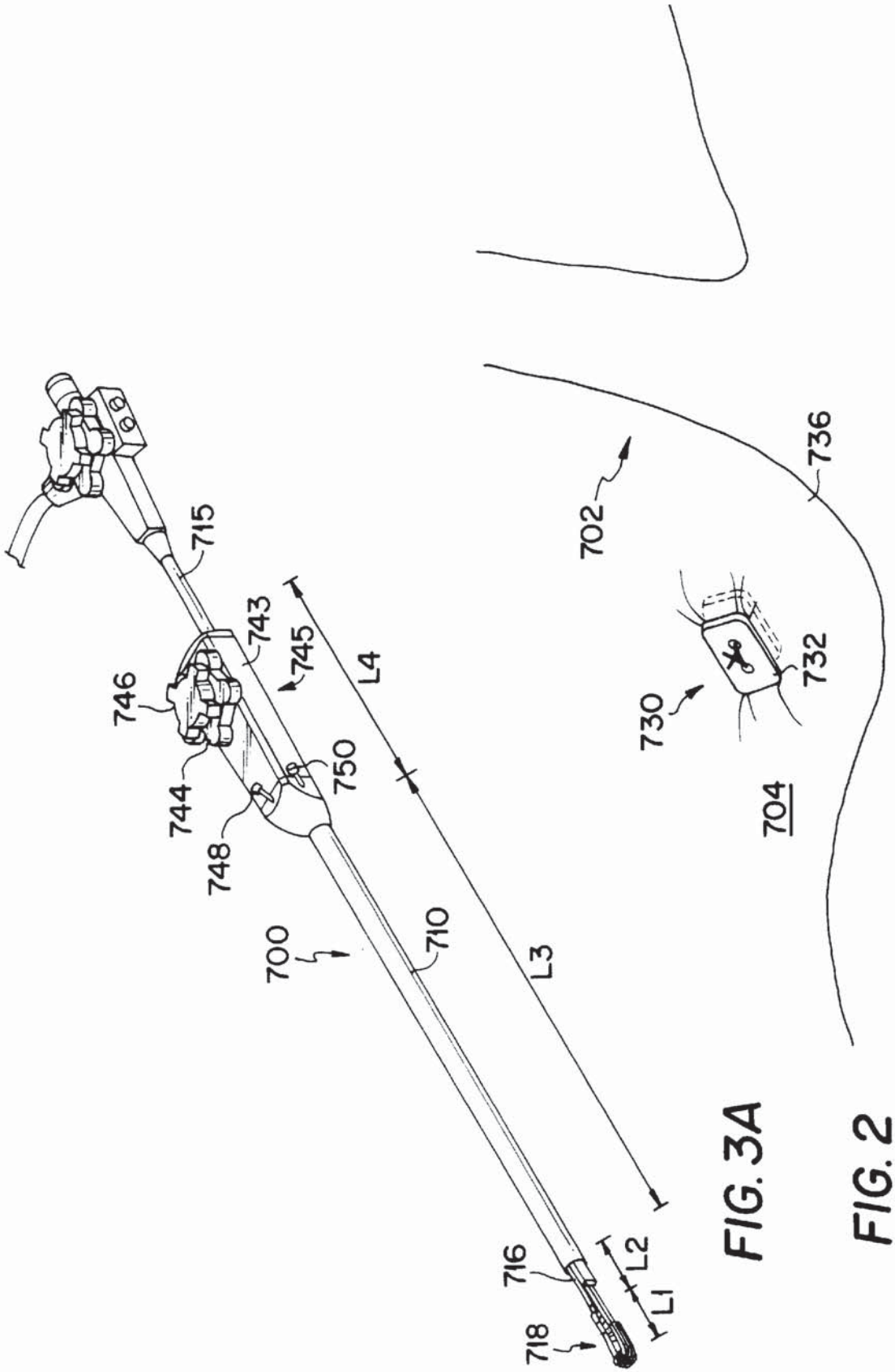

715
743
745
L4
746
744
750
748
700
710
L3
716
L2
L1
718
702
736
730
732
704

FIG. 3A

FIG. 2

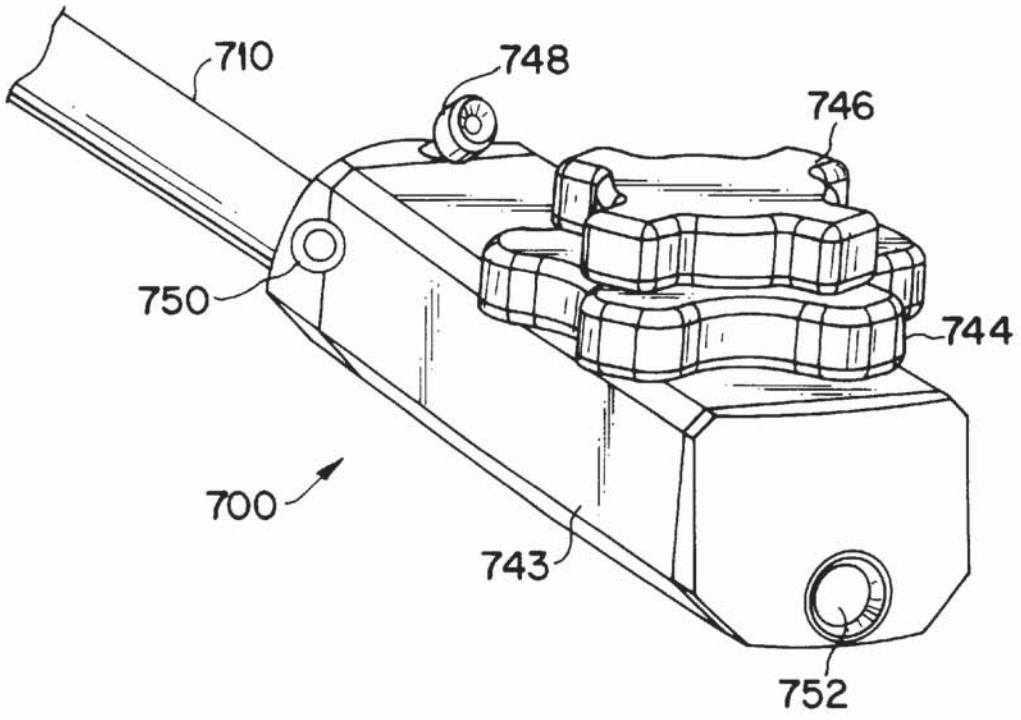


FIG. 3B

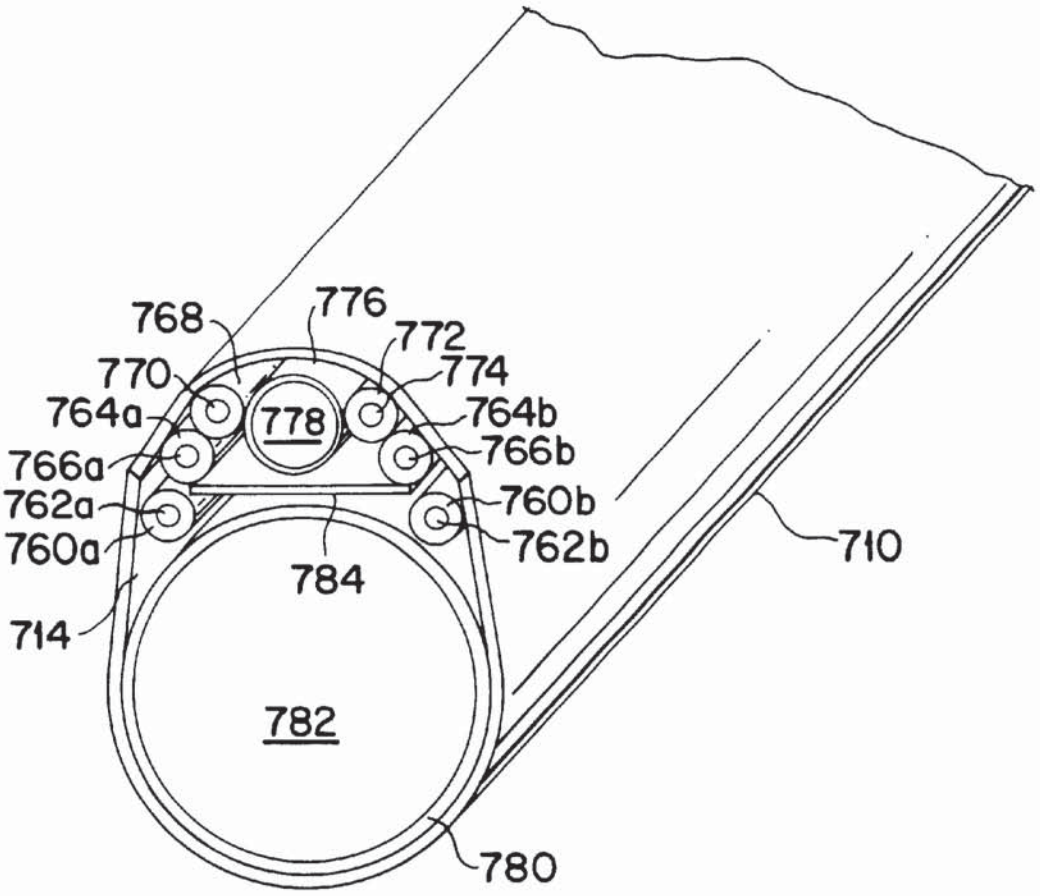

768
776
772
770
774
764a
778
764b
766a
766b
762a
760b
760a
762b
710
784
714
782
780

FIG. 3C

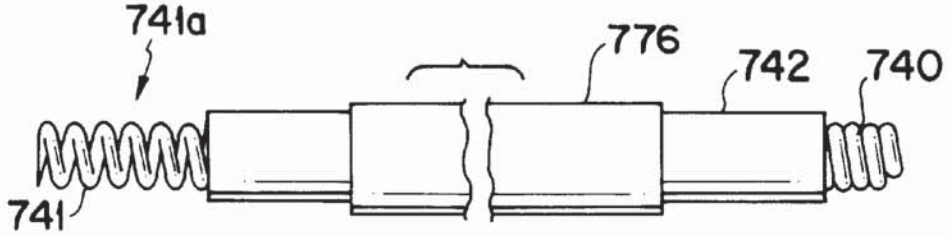

741a
776
742
740
741

FIG. 3D

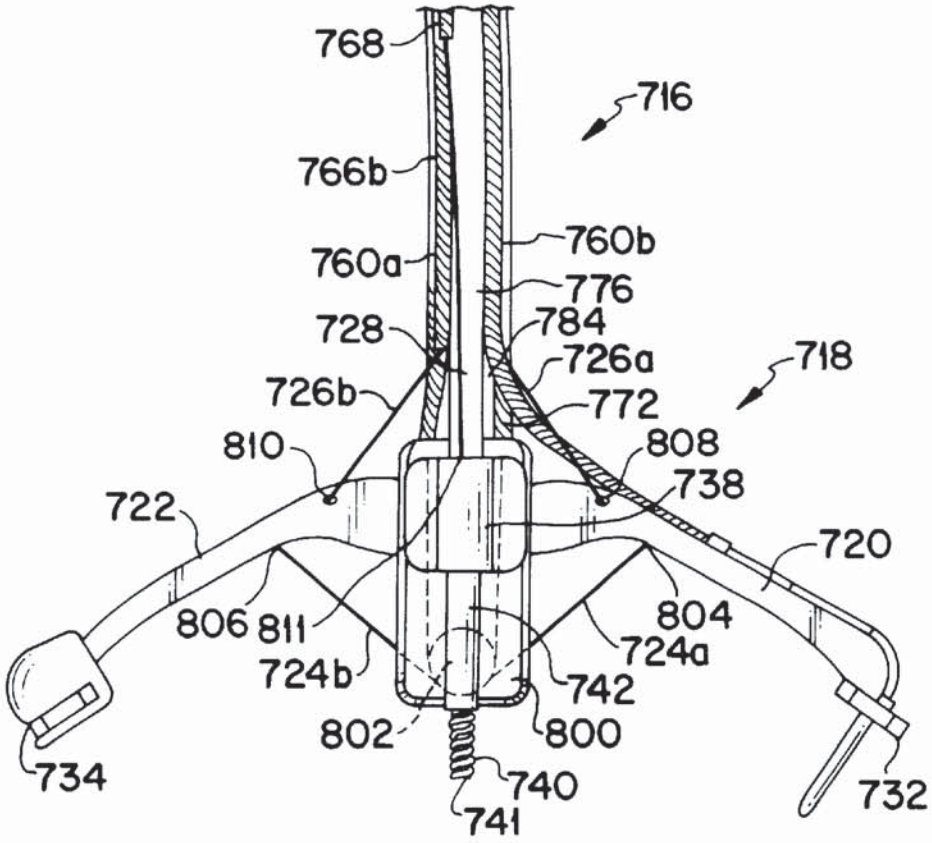

768
716
766b
760b
760a
776
728
784
726a
718
726b
772
810
808
738
722
720
806
811
804
724a
724b
742
802
800
734
740
732
741

FIG. 4A

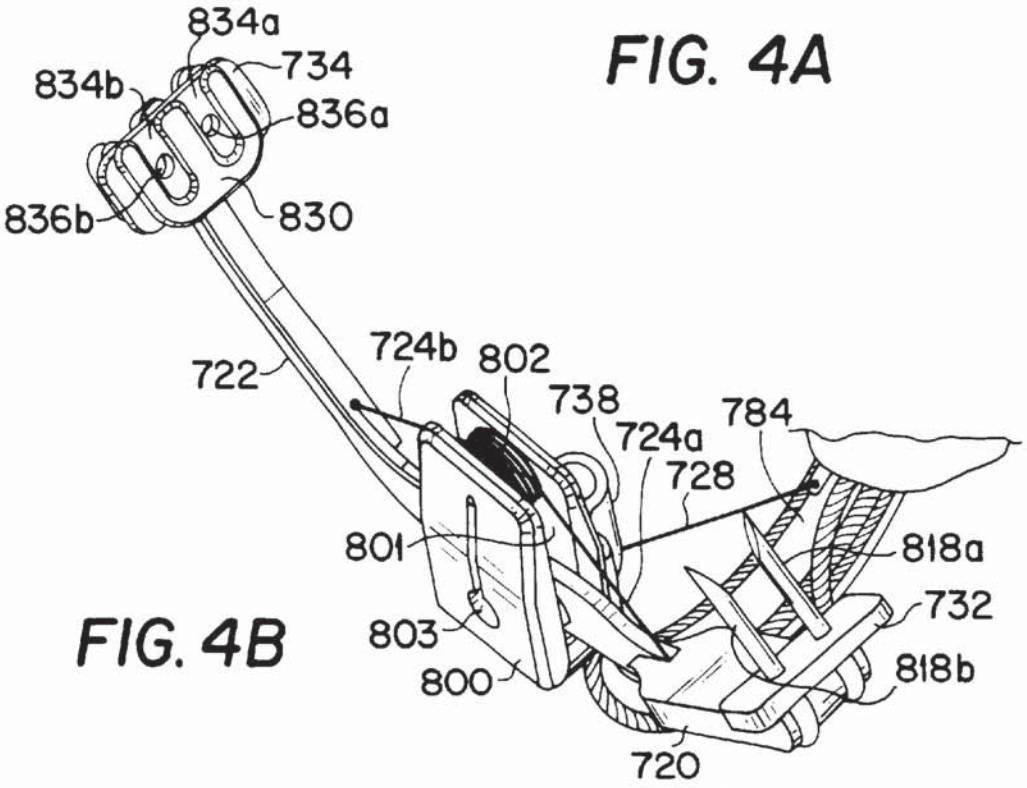

834a
734
834b
836a
836b
830
722
724b
802
738
724a
784
728
801
818a
732
803
818b
800
720

FIG. 4B

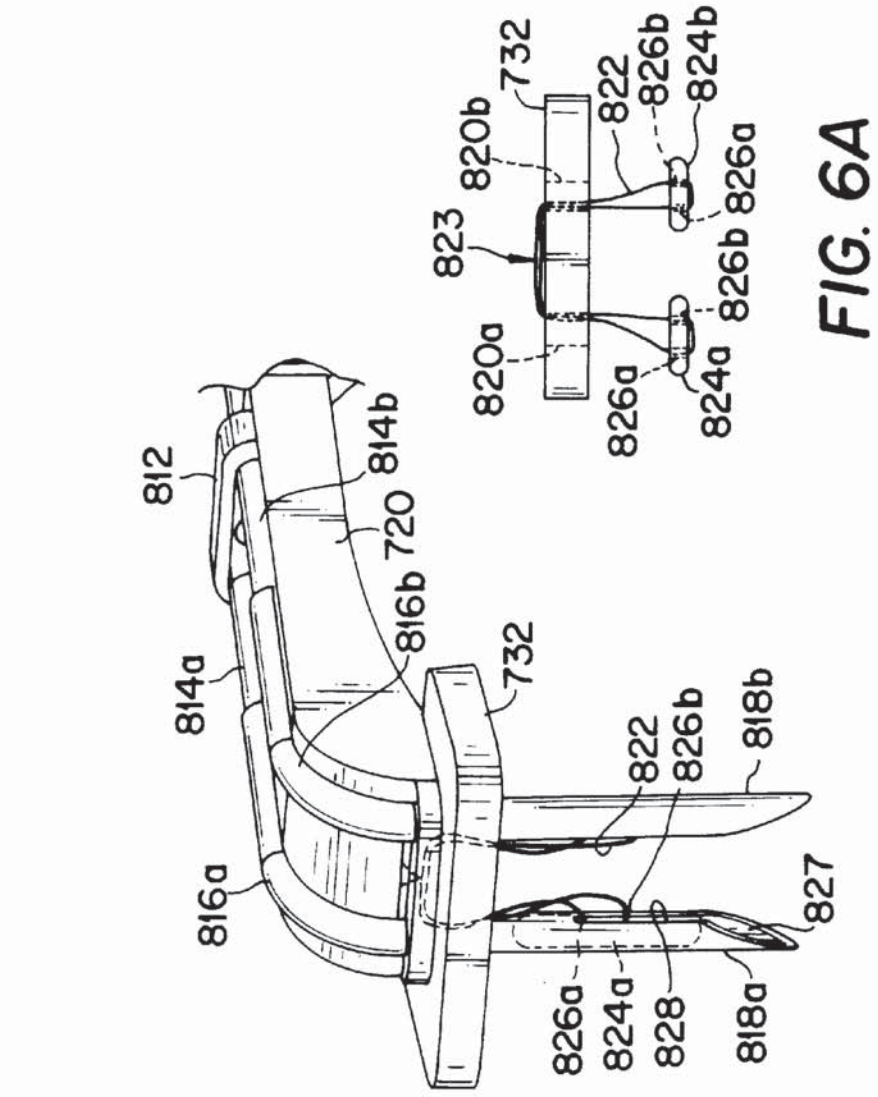


FIG. 6A

FIG. 6B

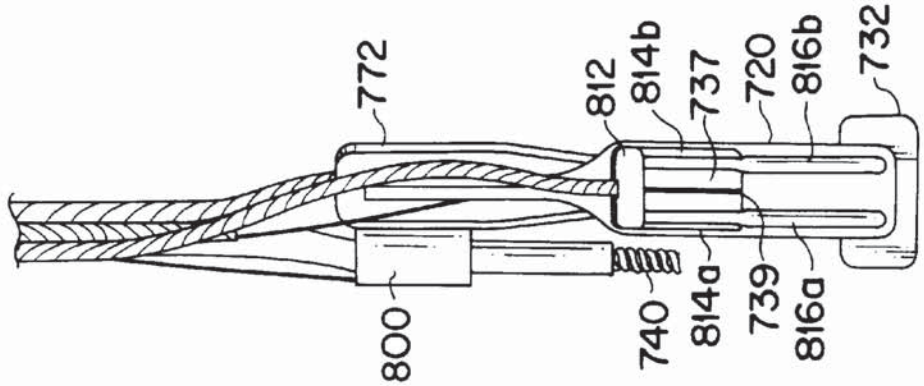


FIG. 5

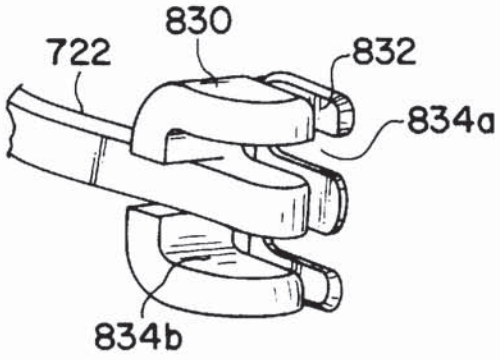


FIG. 7

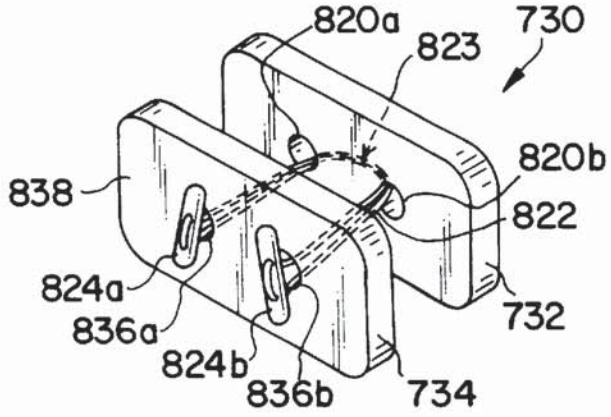


FIG. 8

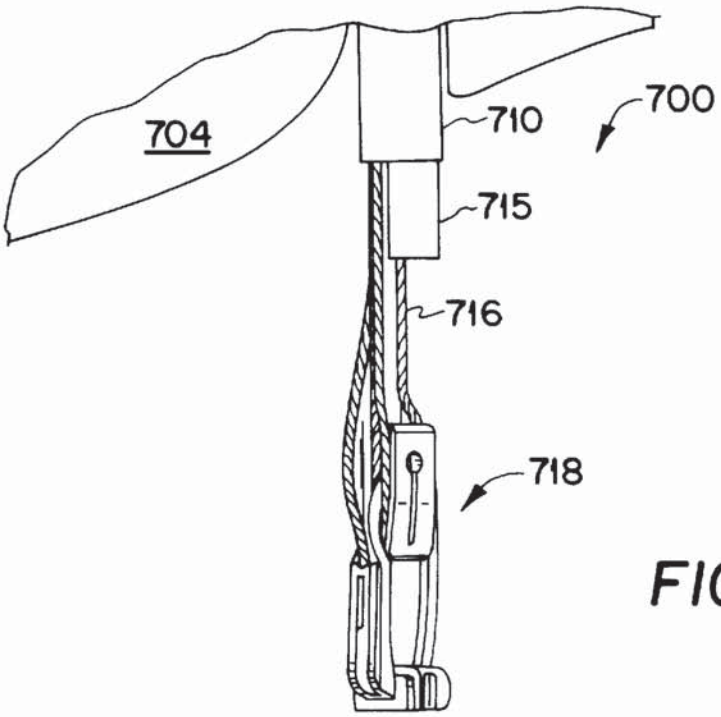


FIG. 9A

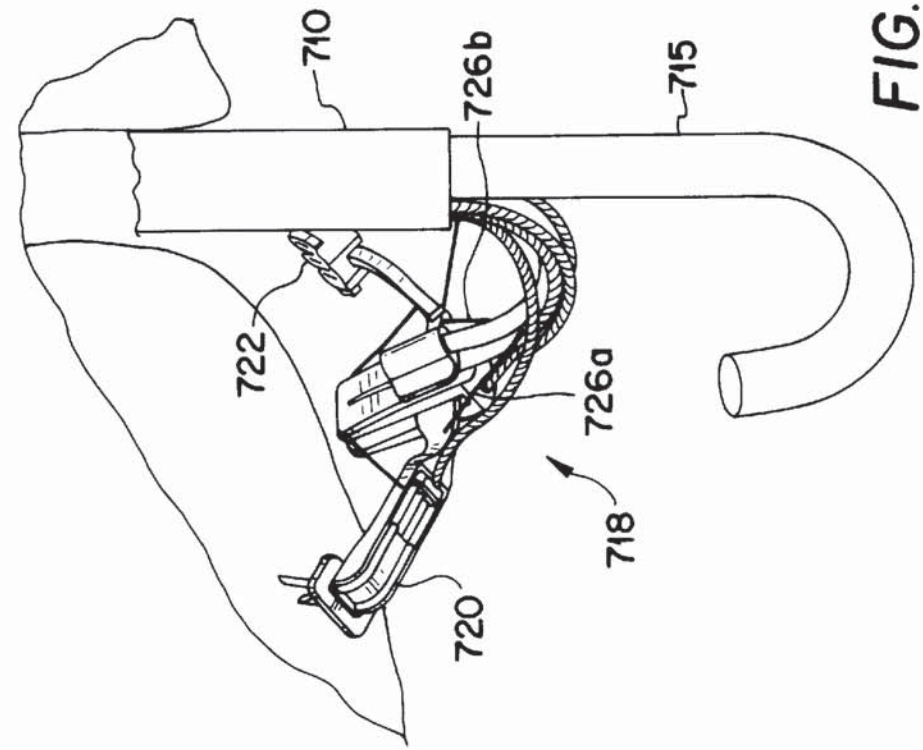


FIG. 9C

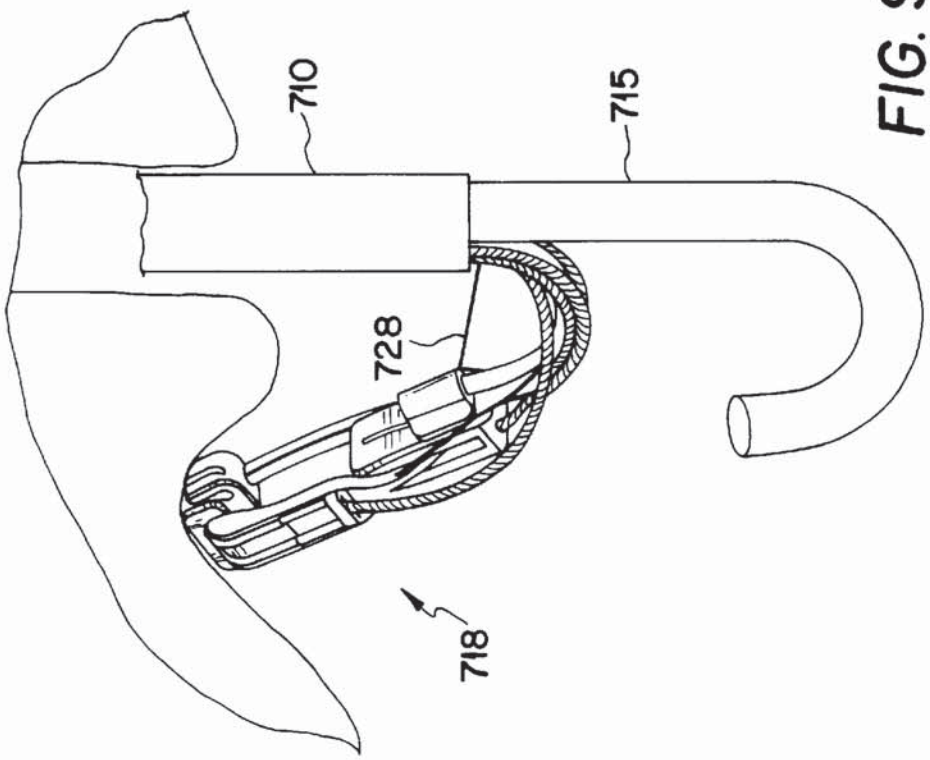


FIG. 9B

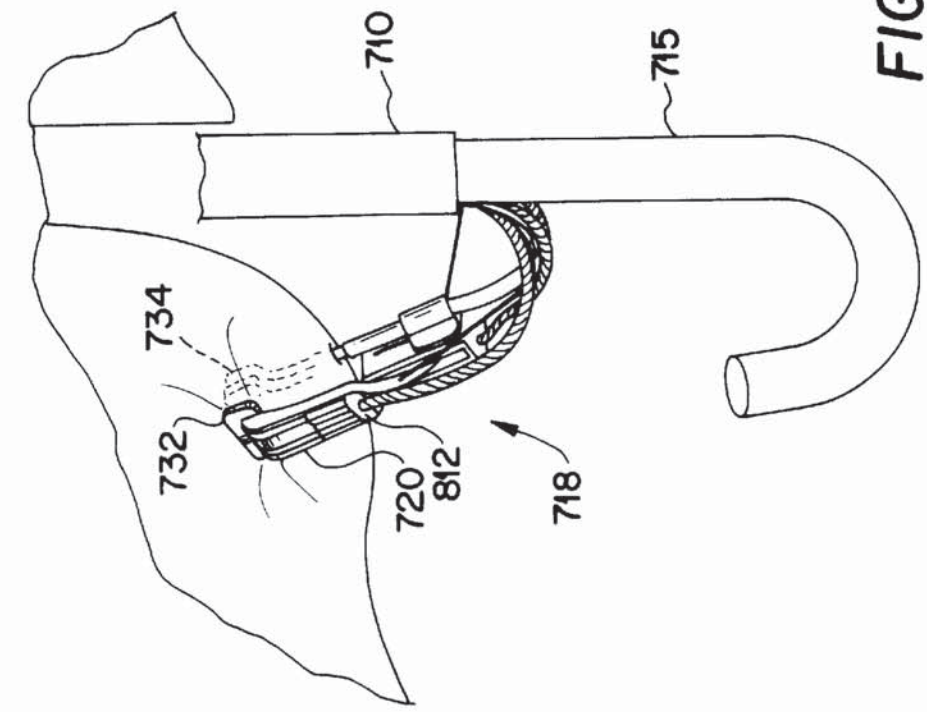

710
715
734
732
720
812
718

FIG. 9E

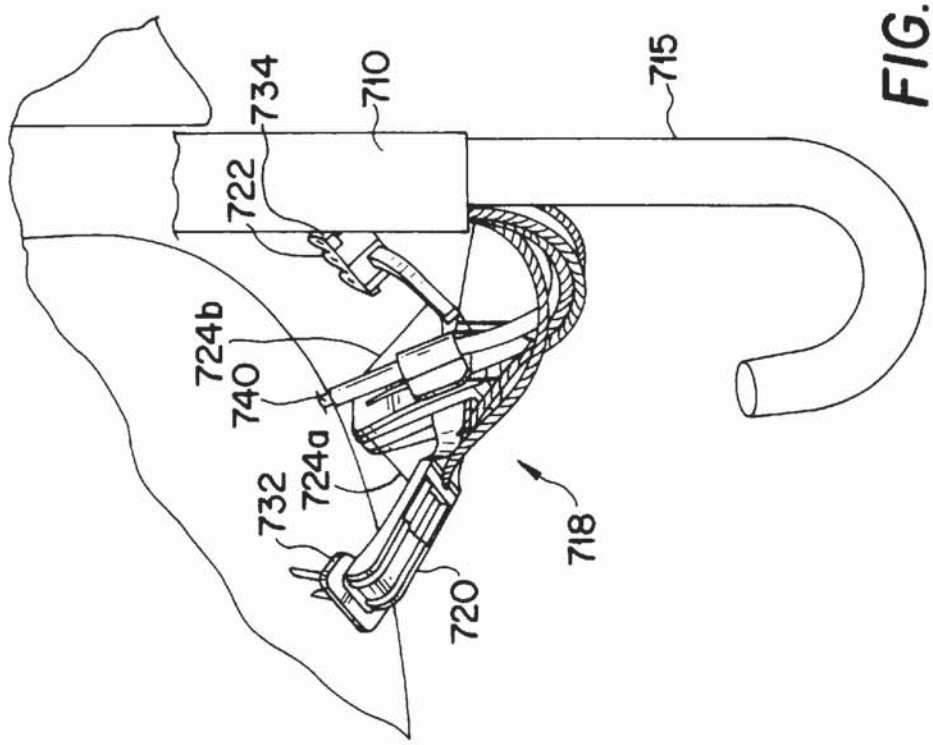

734
710
715
722
724b
740
724a
732
720
718

FIG. 9D

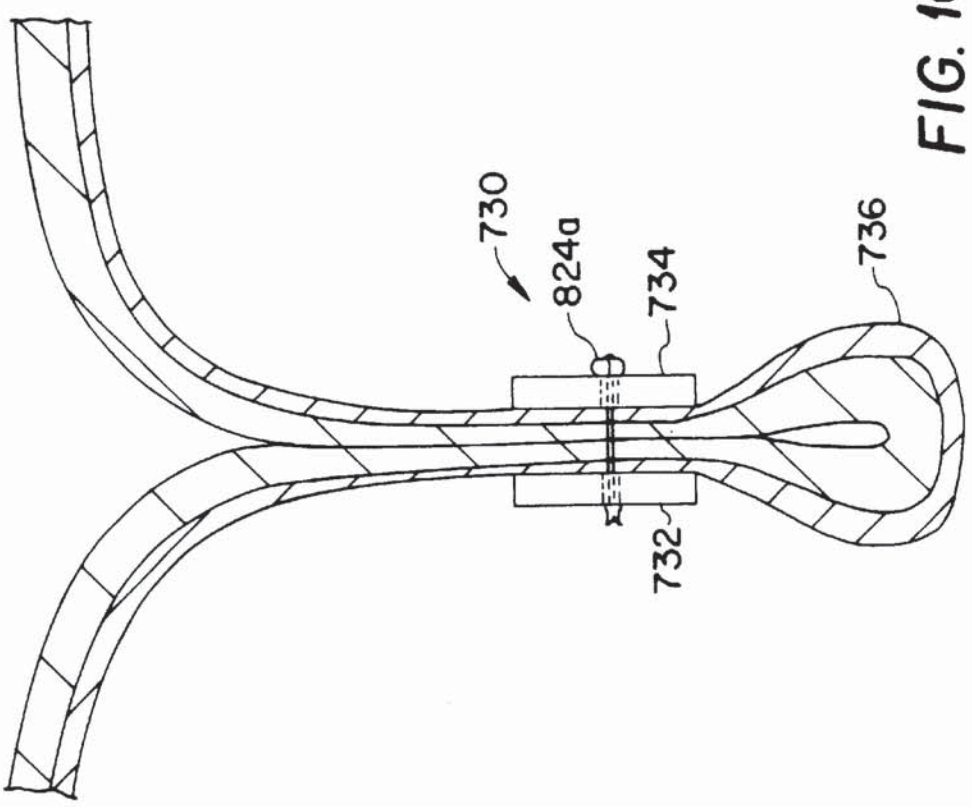


FIG. 10

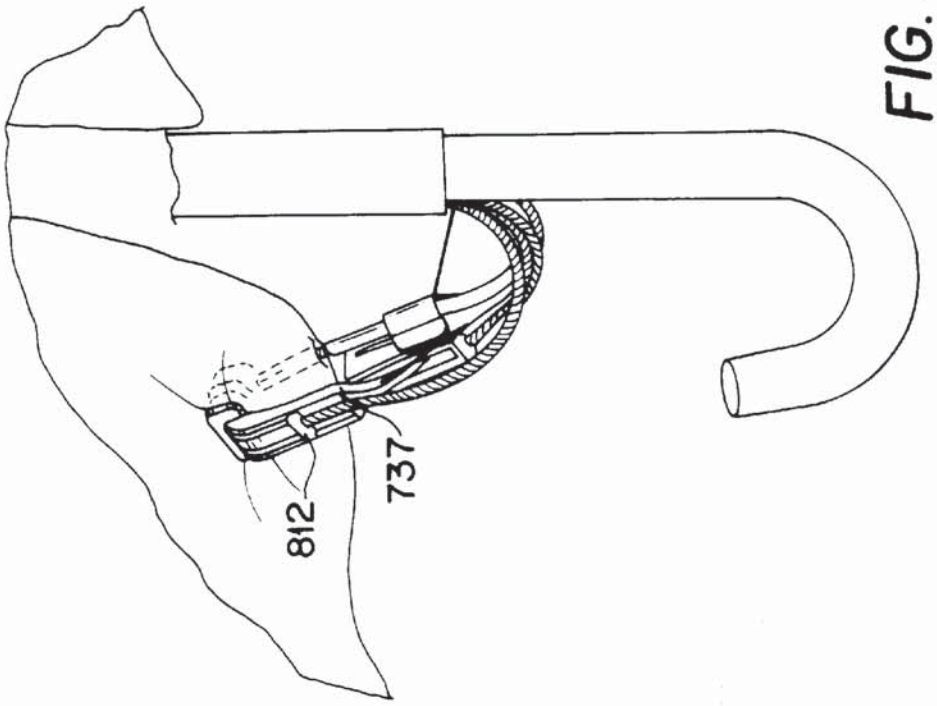


FIG. 9F

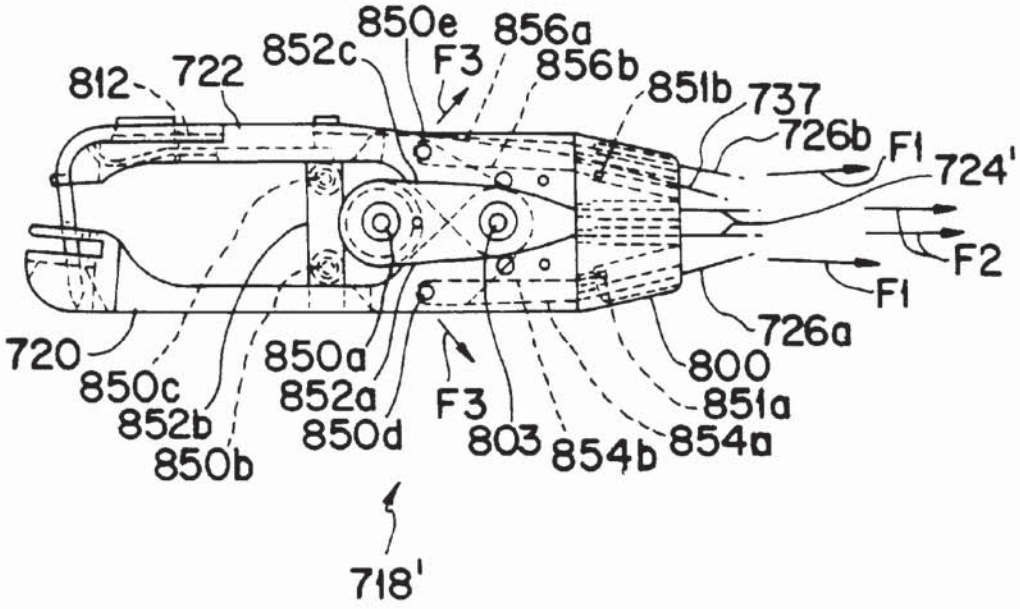


FIG. 11A

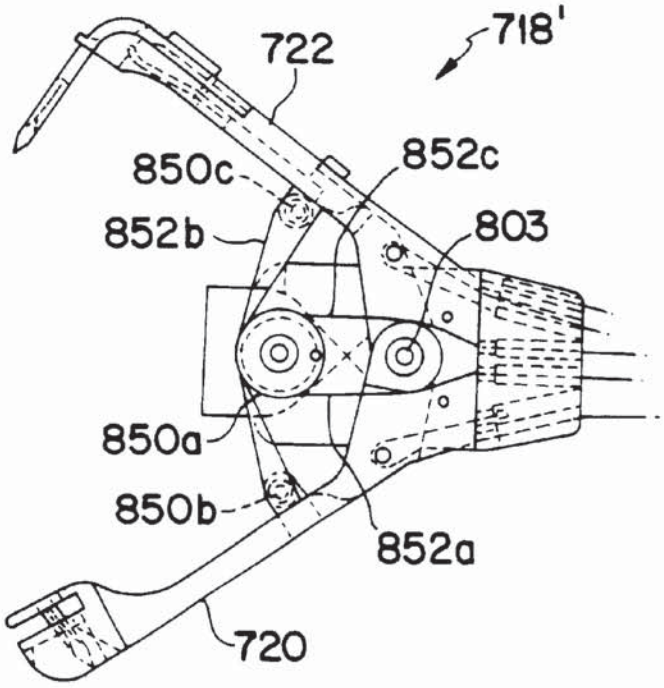


FIG. 11B

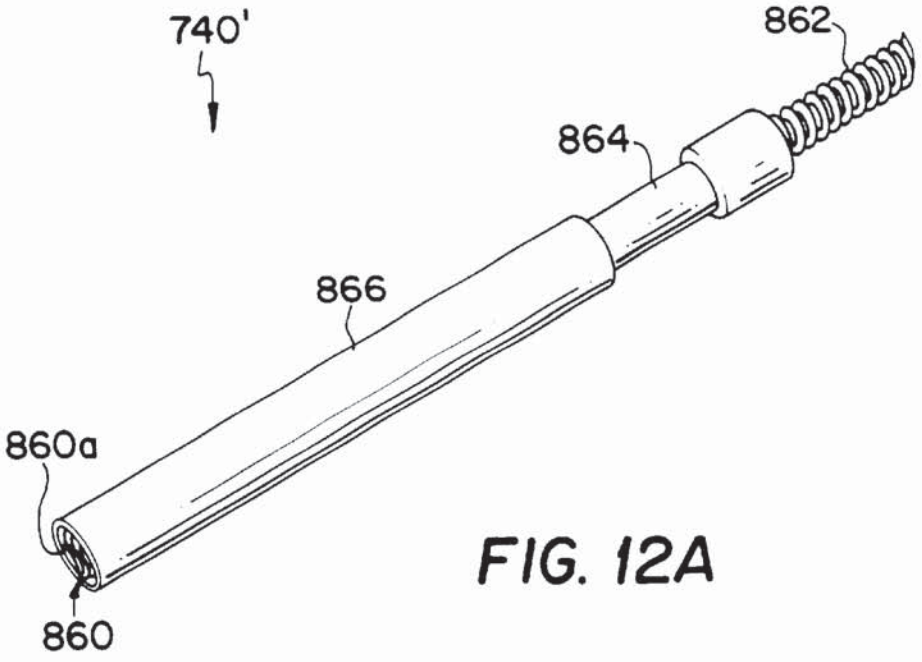


FIG. 12A

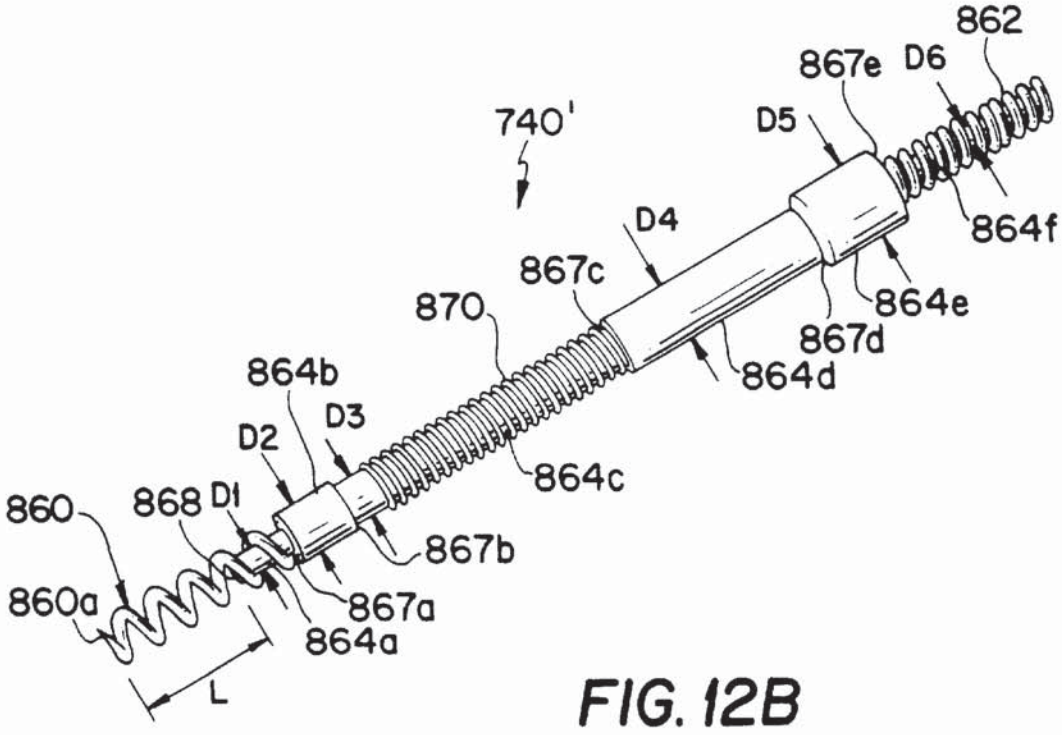


FIG. 12B

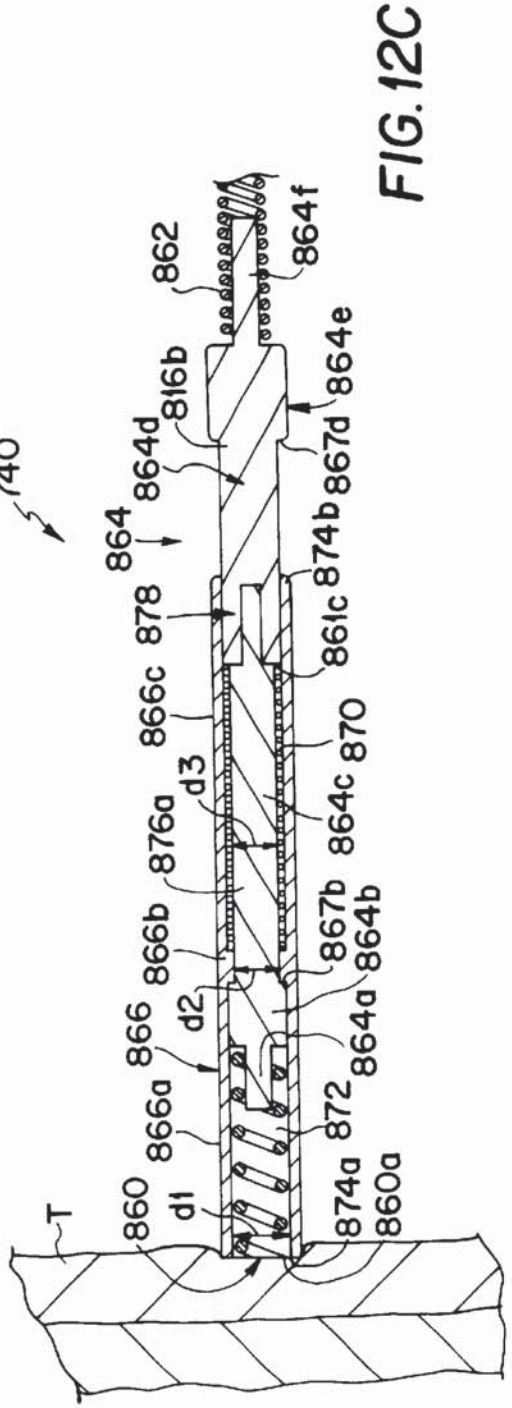


FIG. 12C

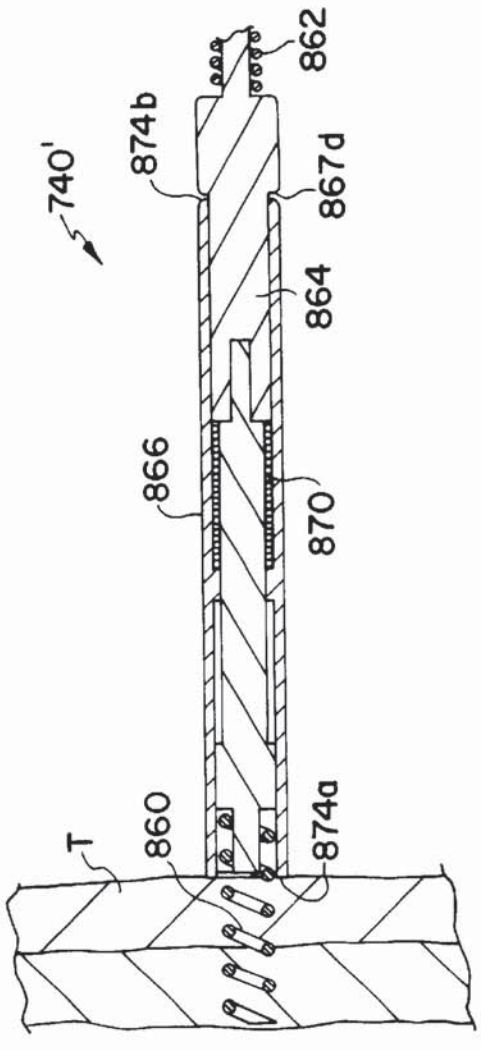


FIG. 12D

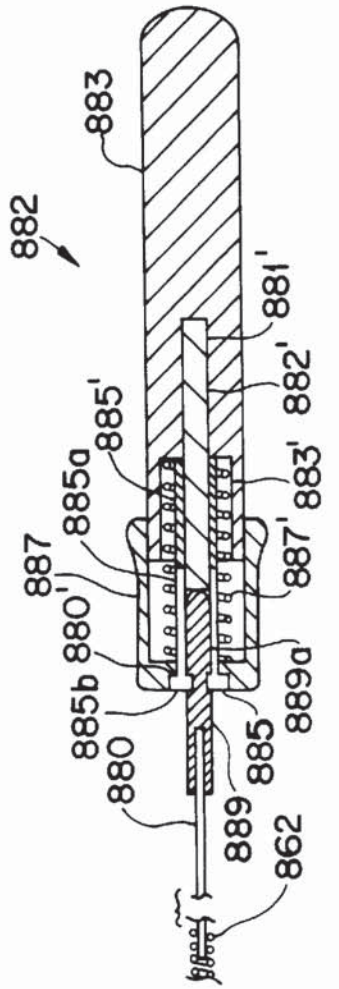


FIG. 13B

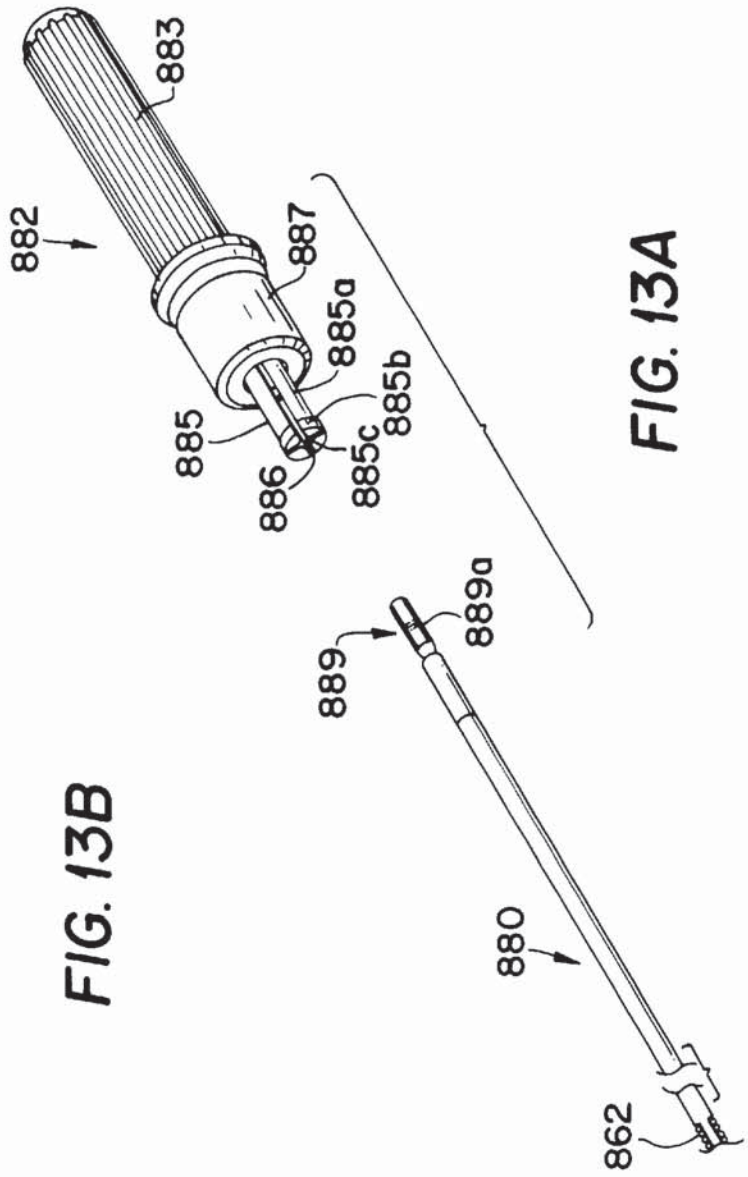


FIG. 13A

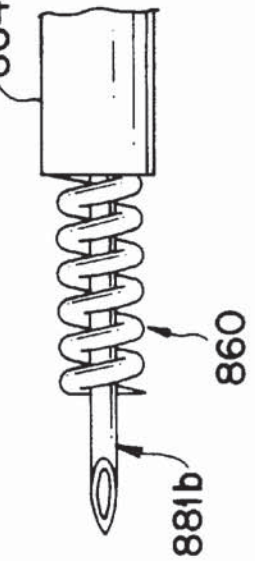


FIG. 14B

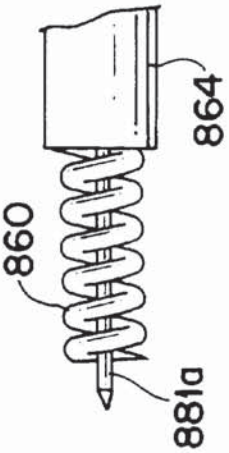


FIG. 14A

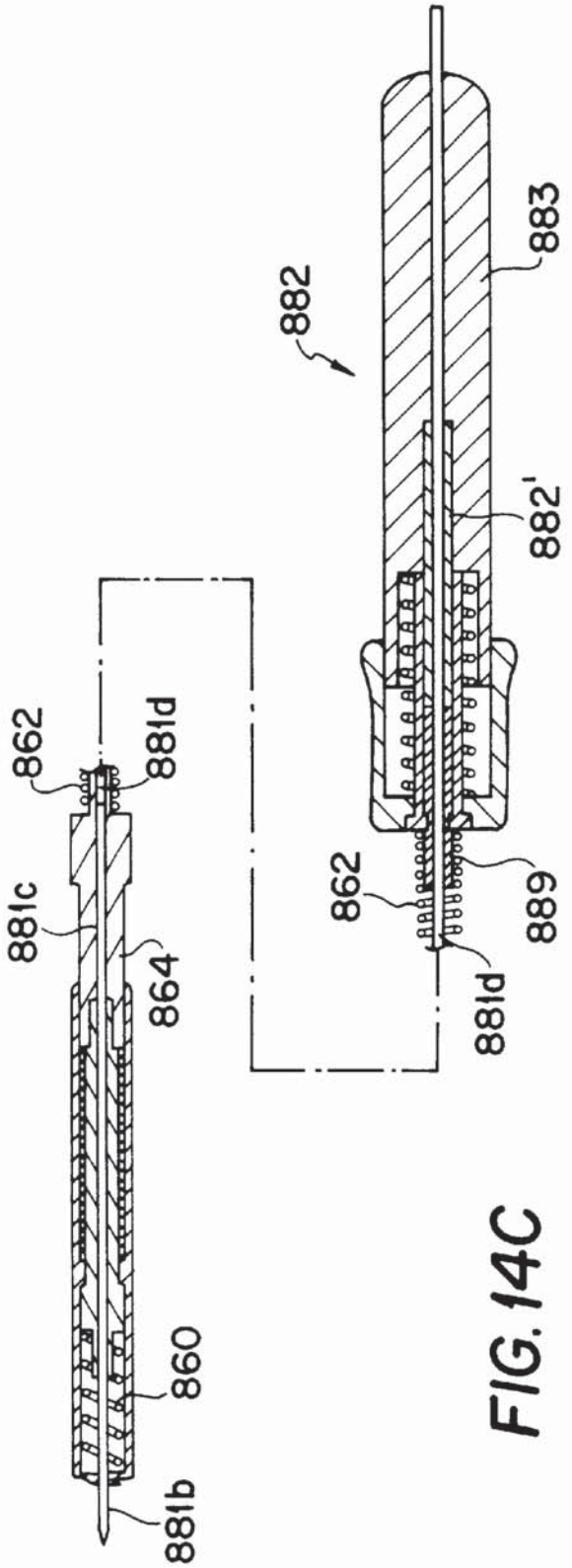


FIG. 14C

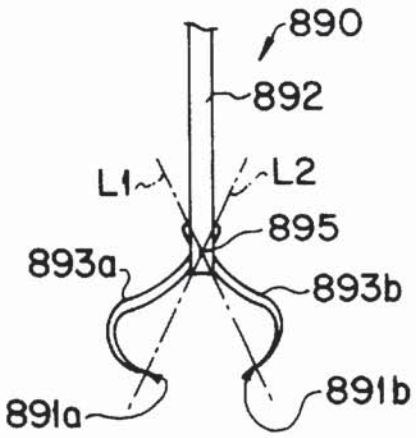


FIG. 15A

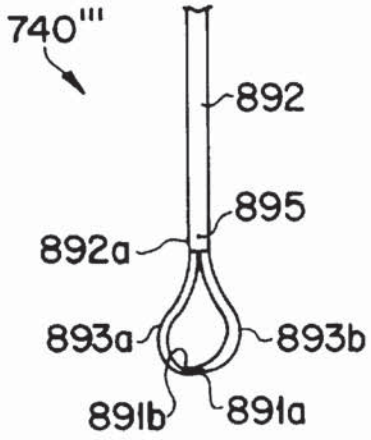


FIG. 15B

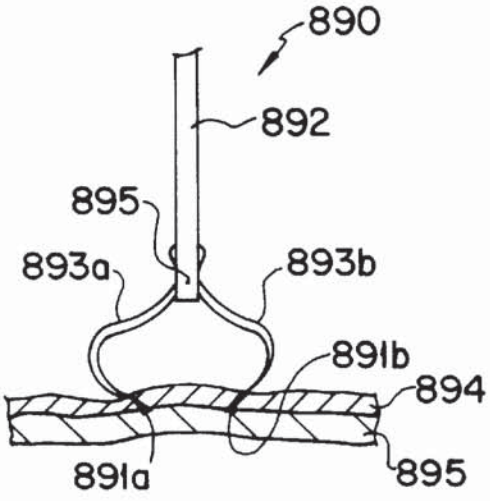


FIG. 15C

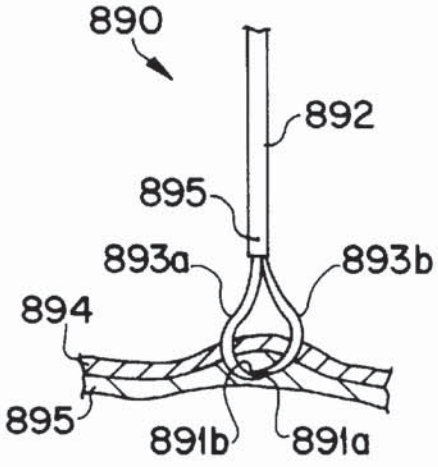


FIG. 15D

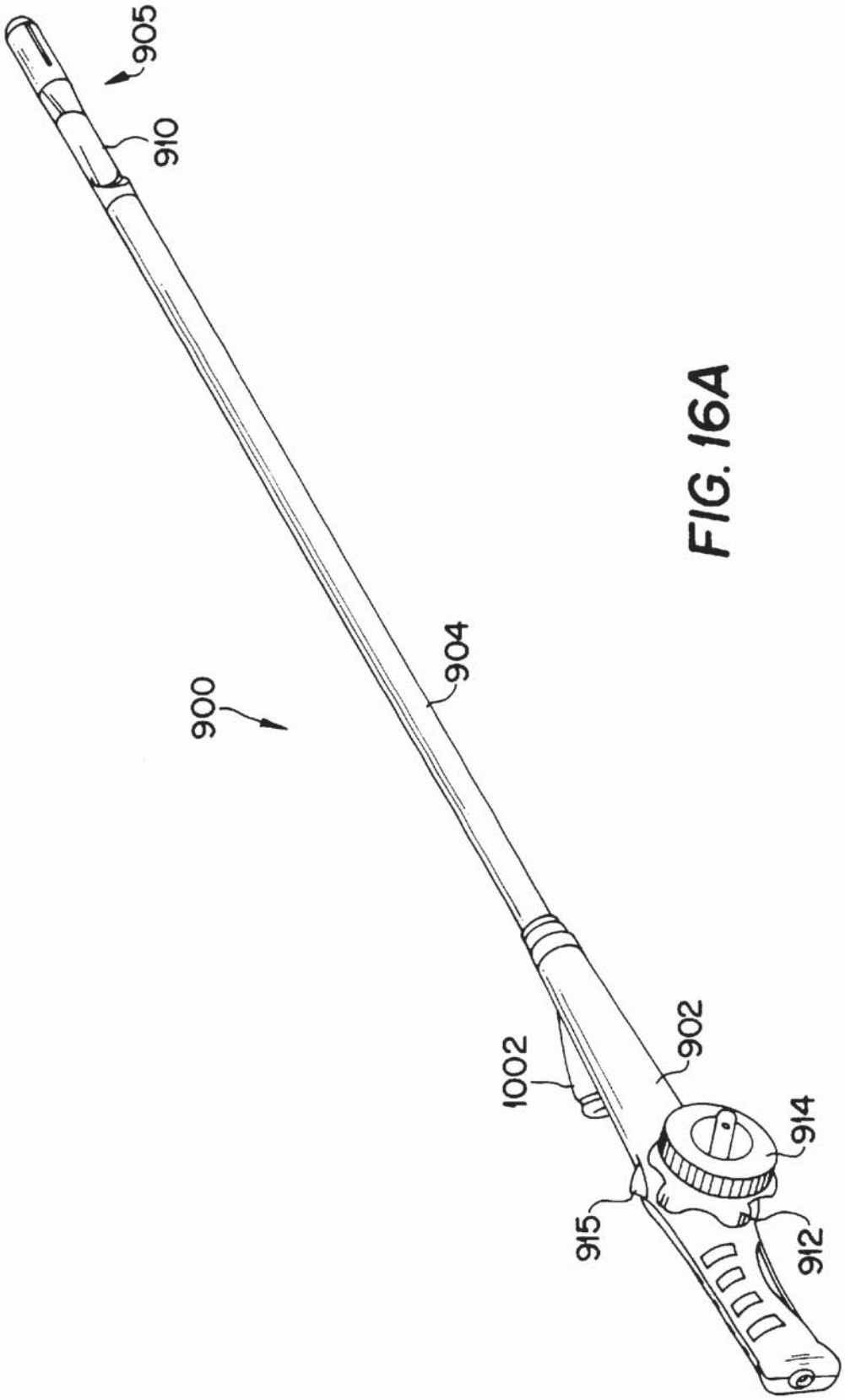


FIG. 16A

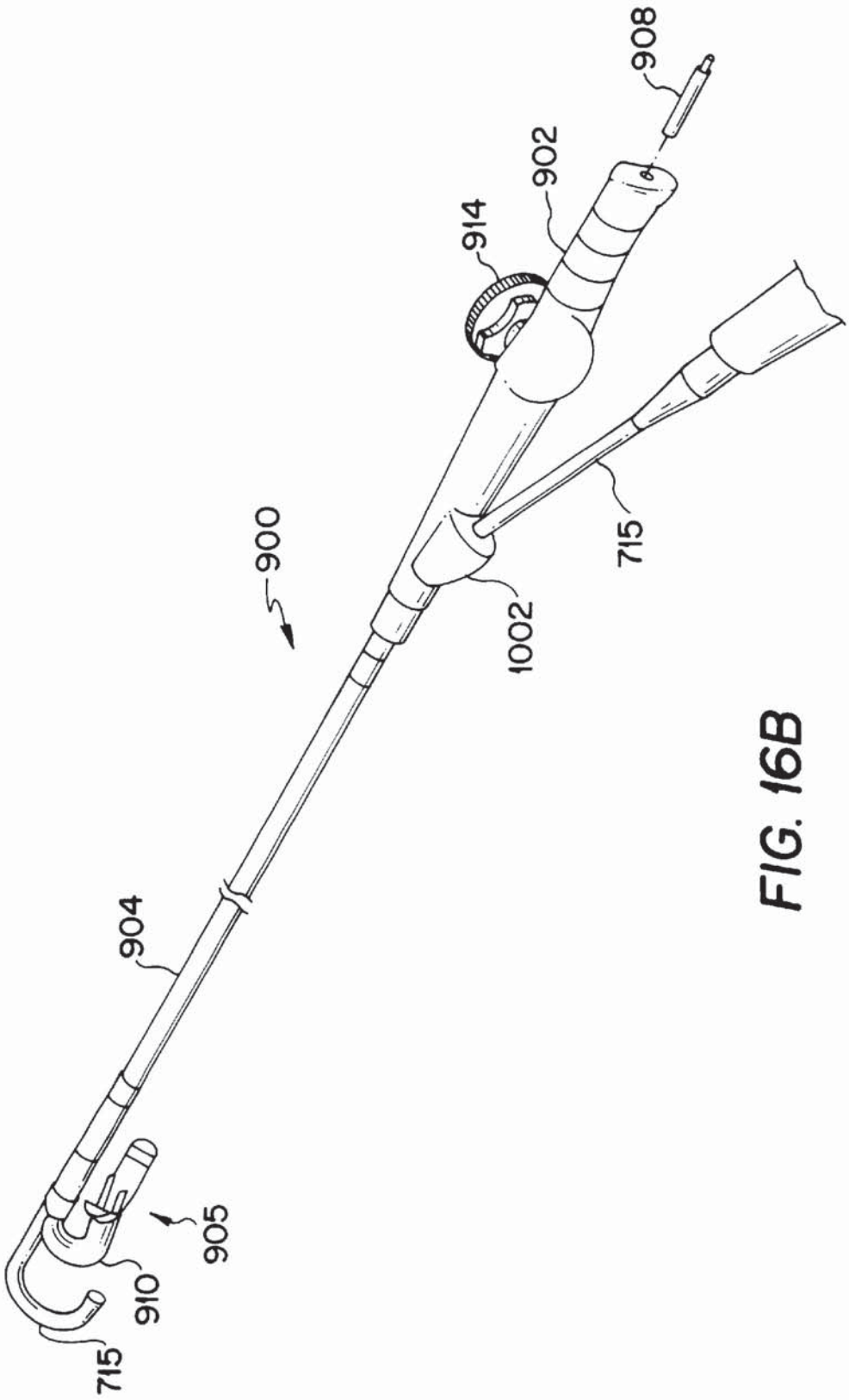


FIG. 16B

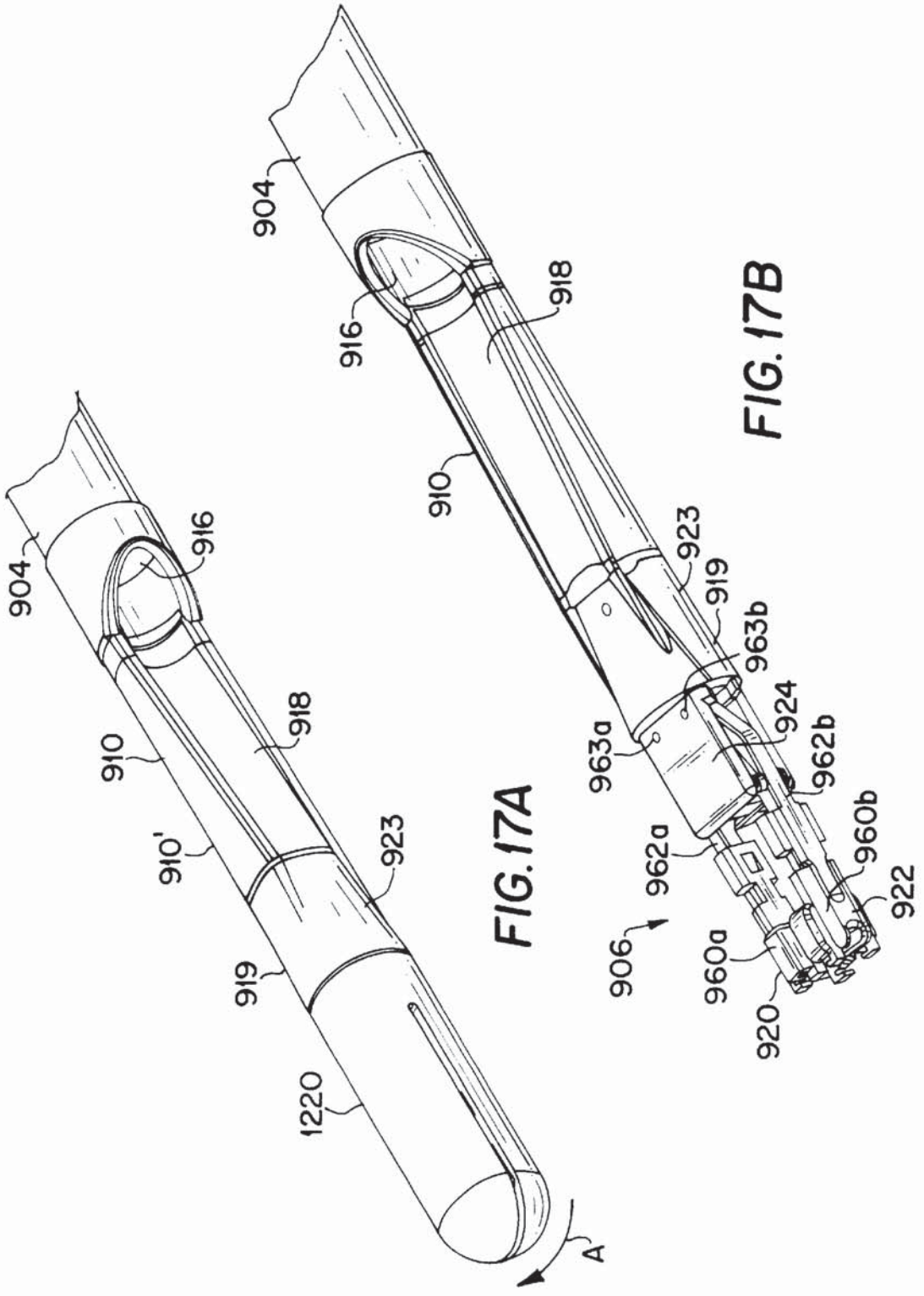


FIG. 17B

FIG. 17A

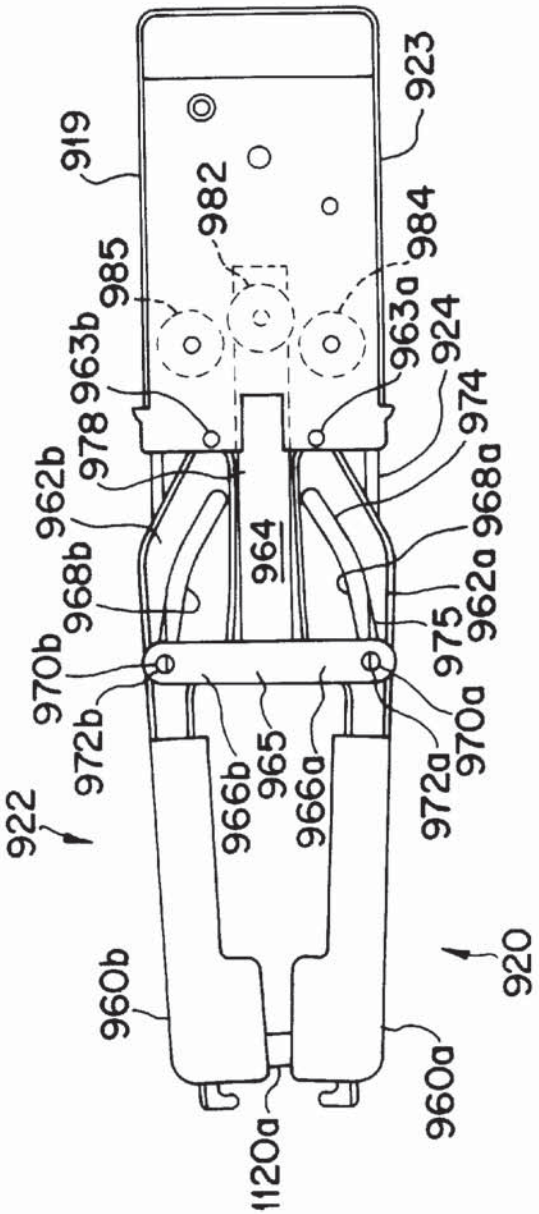


FIG. 17C

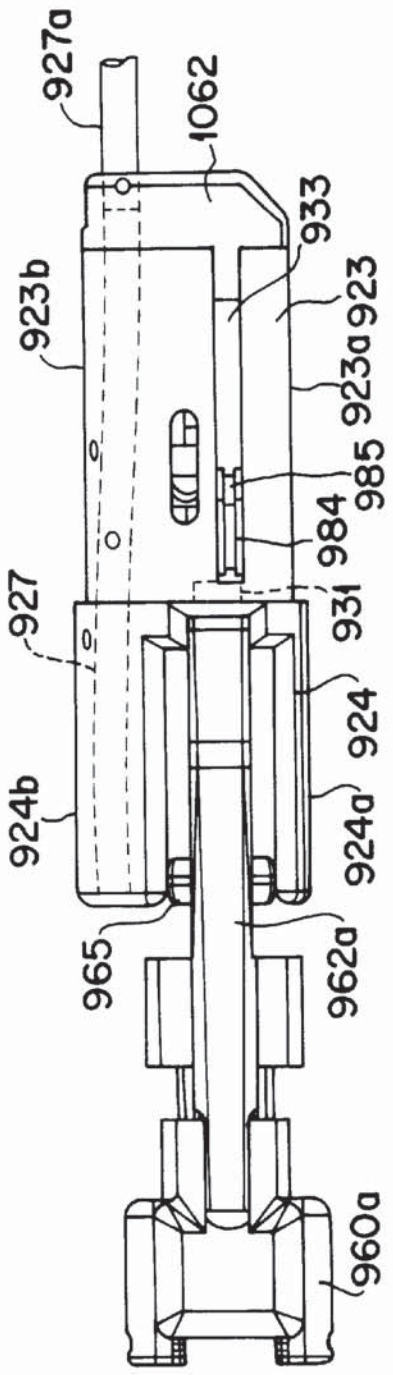


FIG. 17D

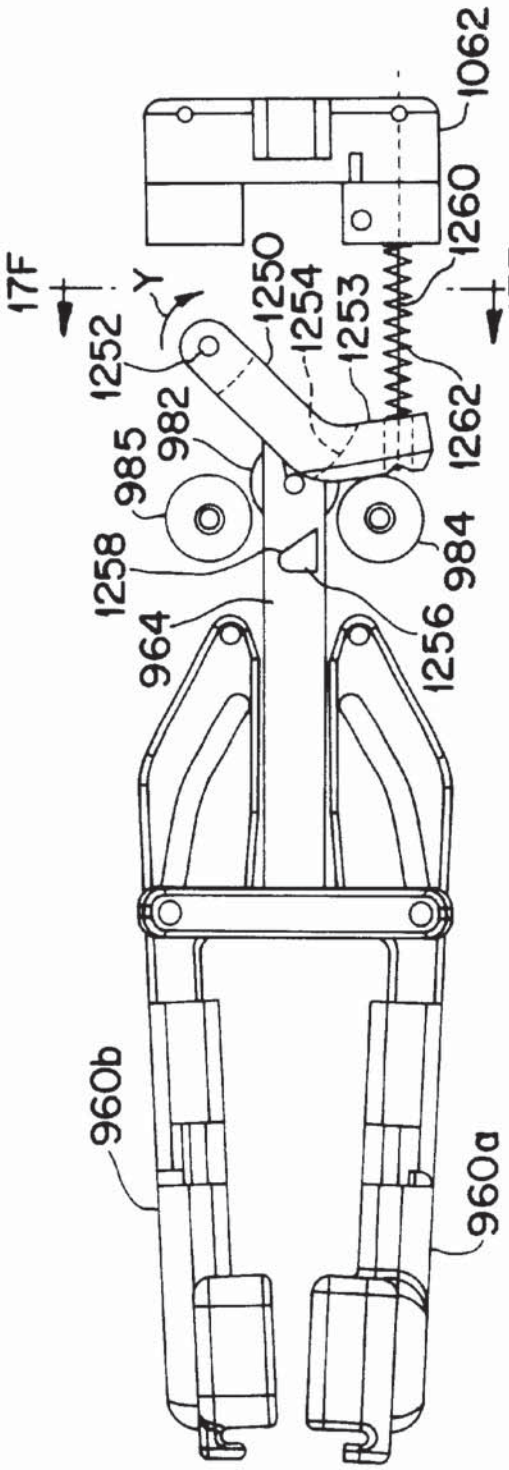


FIG. 17E

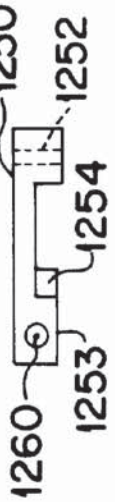


FIG. 17F

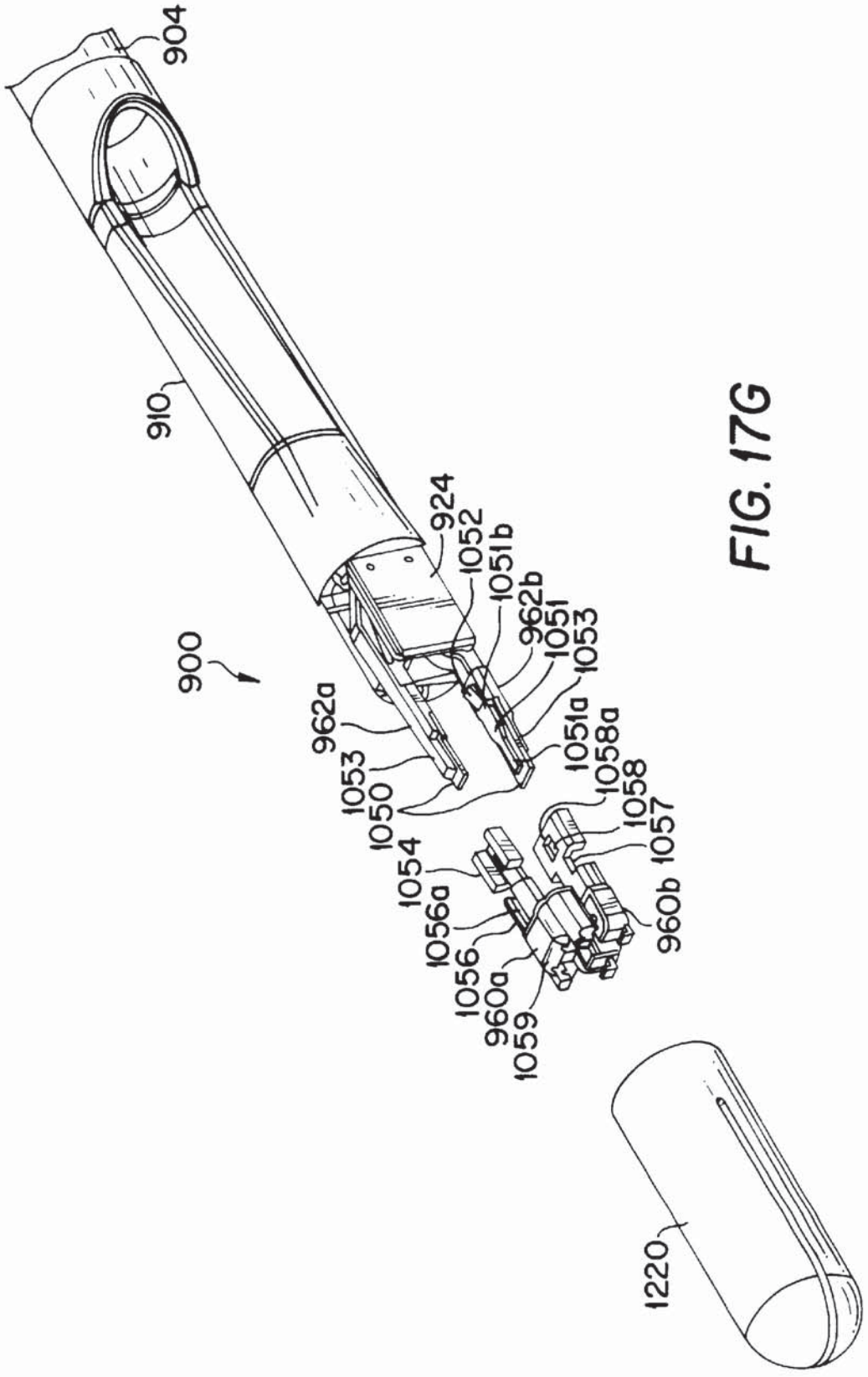

904
910
900
924
1052
1051b
962b
1051
1053
962a
1053
1050
1051a
1058a
1058
1057
1054
1056a
960b
1056
960a
1059
1220

FIG. 17G

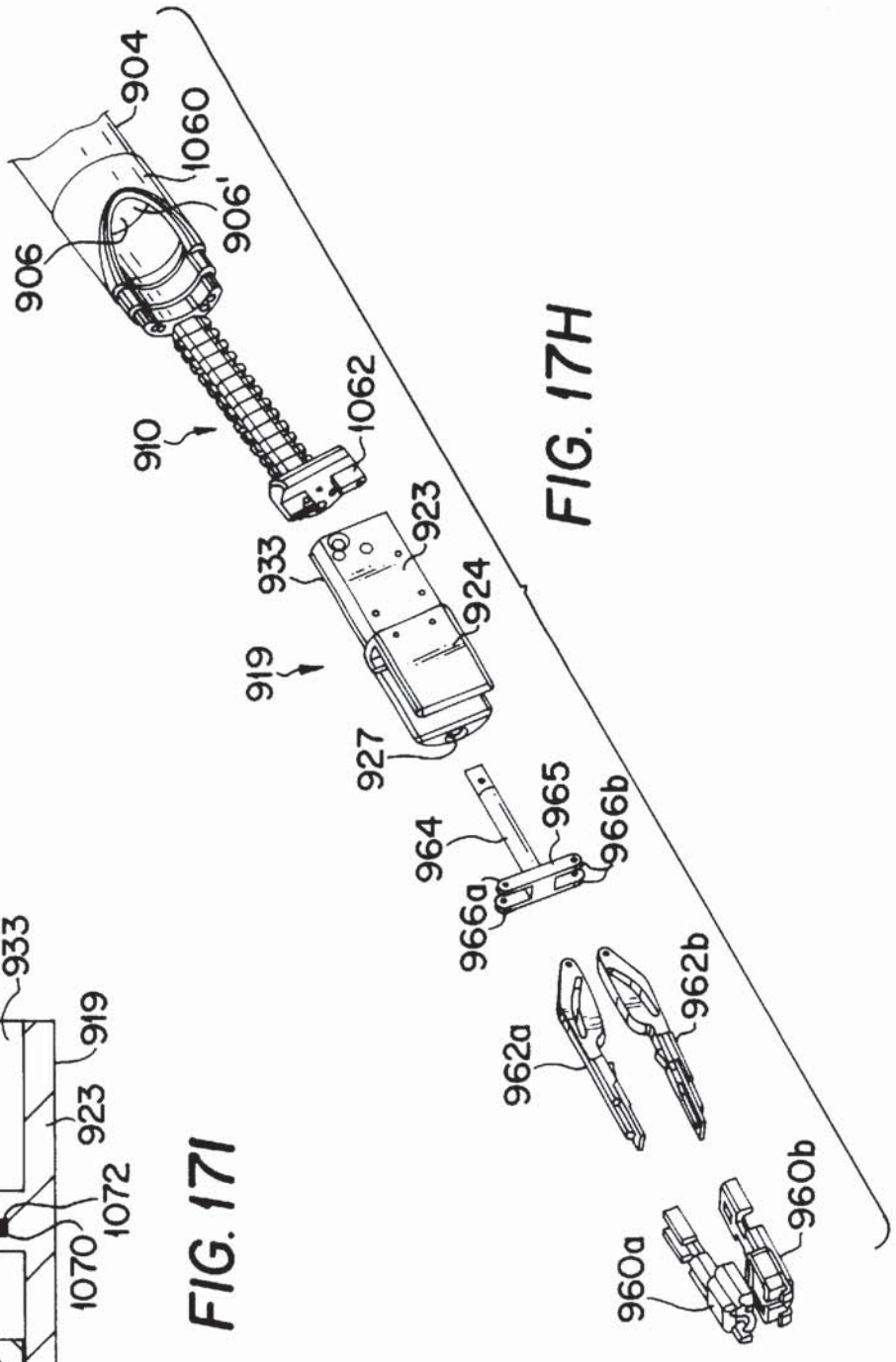


FIG. 17H

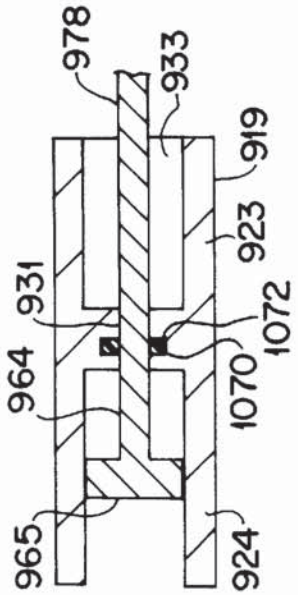


FIG. 17I

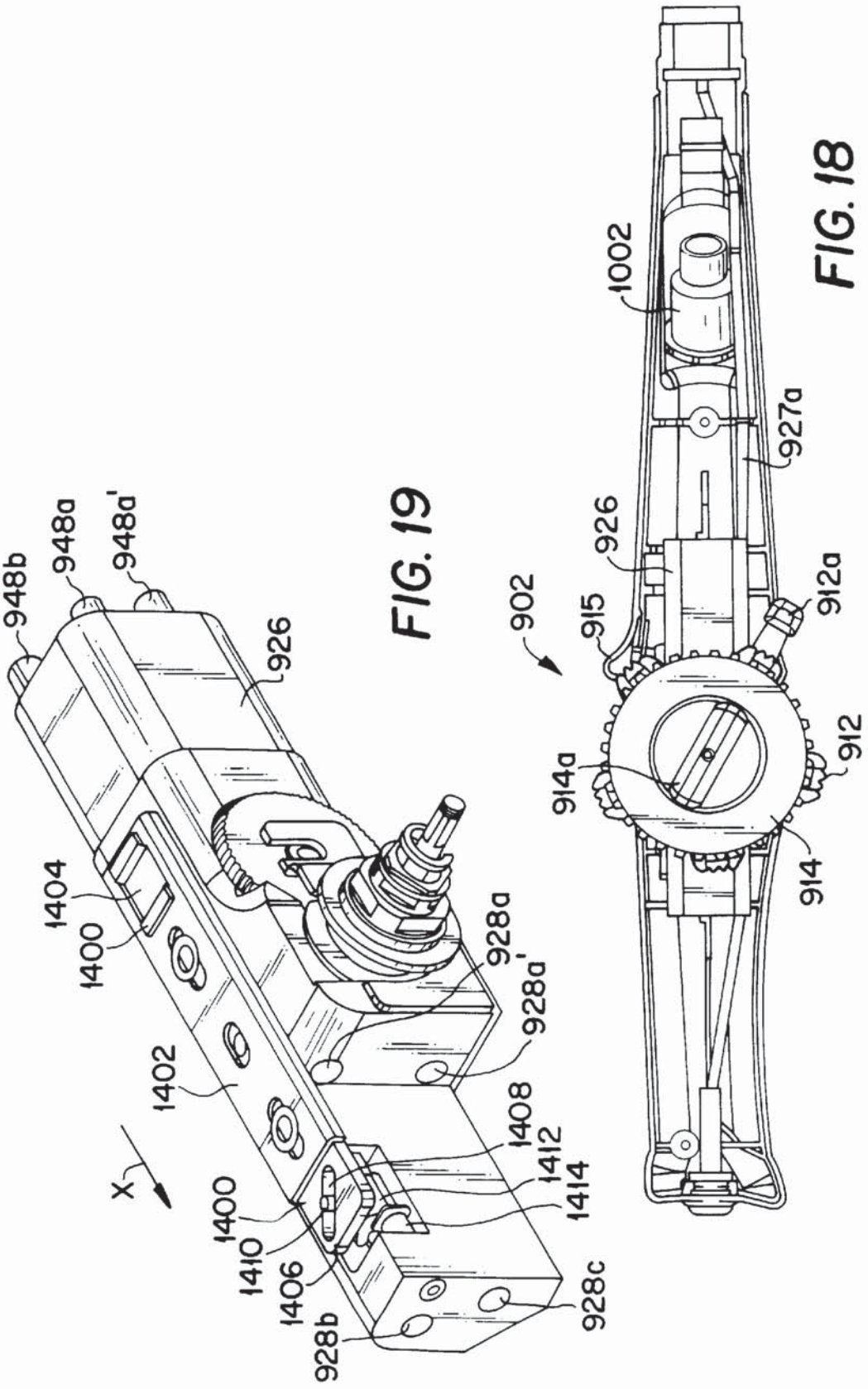

948b
948a
948a'
926
1404
1400
1402
1400
1410
1406
928b
928c
928a
928a'
1408
1412
1414
X
902
1002
927a
926
915
912a
912
914a
914

FIG. 19

FIG. 18

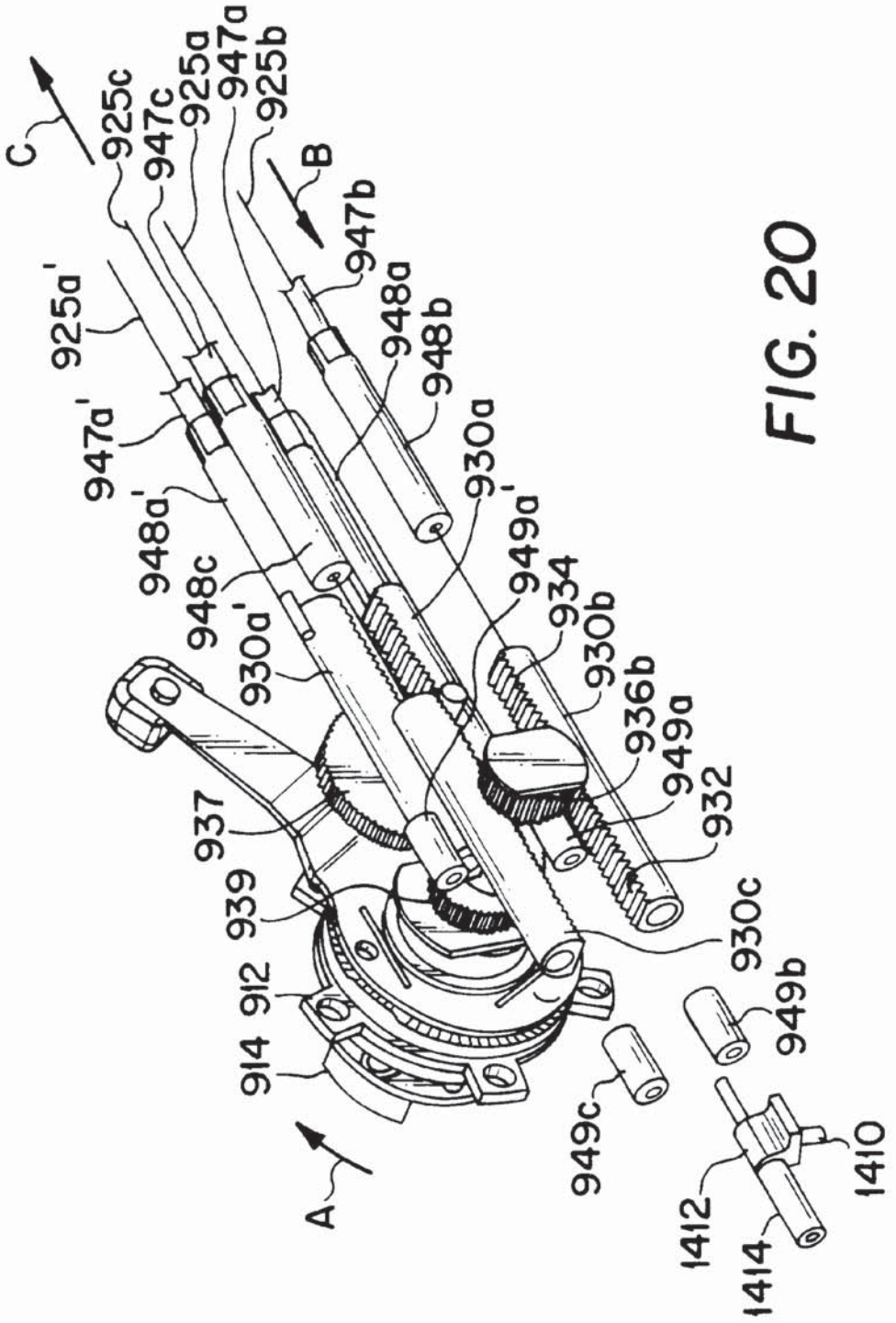

C
925c
947c
925a
947a
925b
B
947b
925a'
948a
948b
947a'
930a
948a'
949a'
948c
934
930a'
930b
936b
949a
937
932
939
930c
912
914
949b
949c
A
1412
1410
1414

FIG. 20

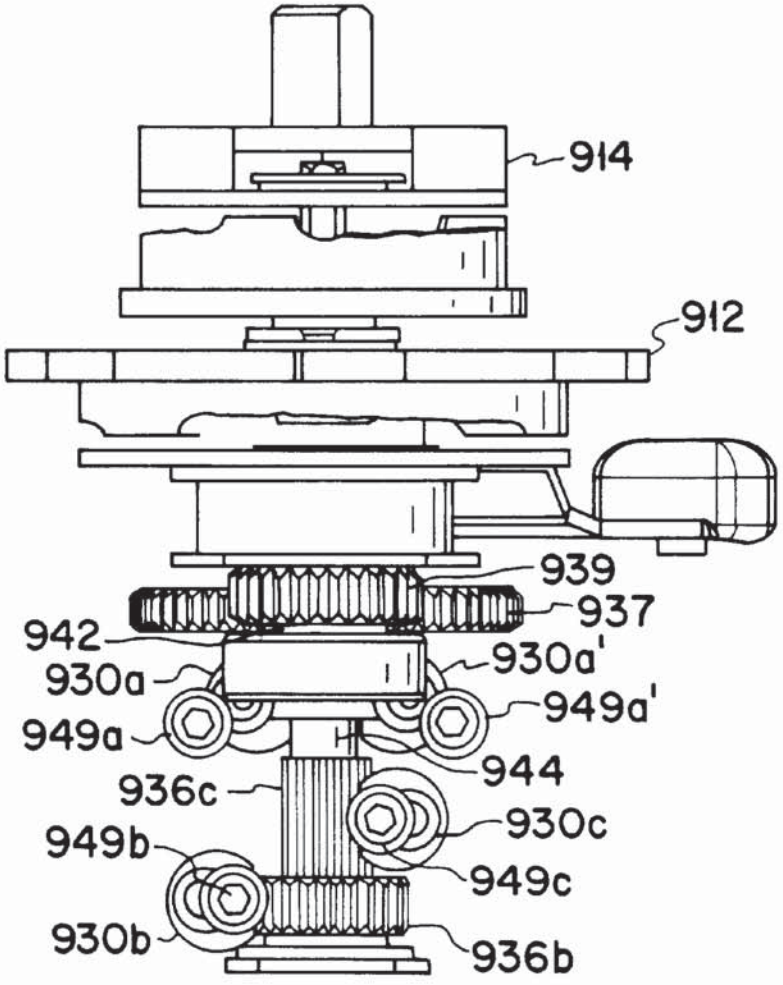

914
912
939
937
942
930a'
930a
949a'
949a
944
936c
930c
949b
949c
930b
936b

FIG. 21A

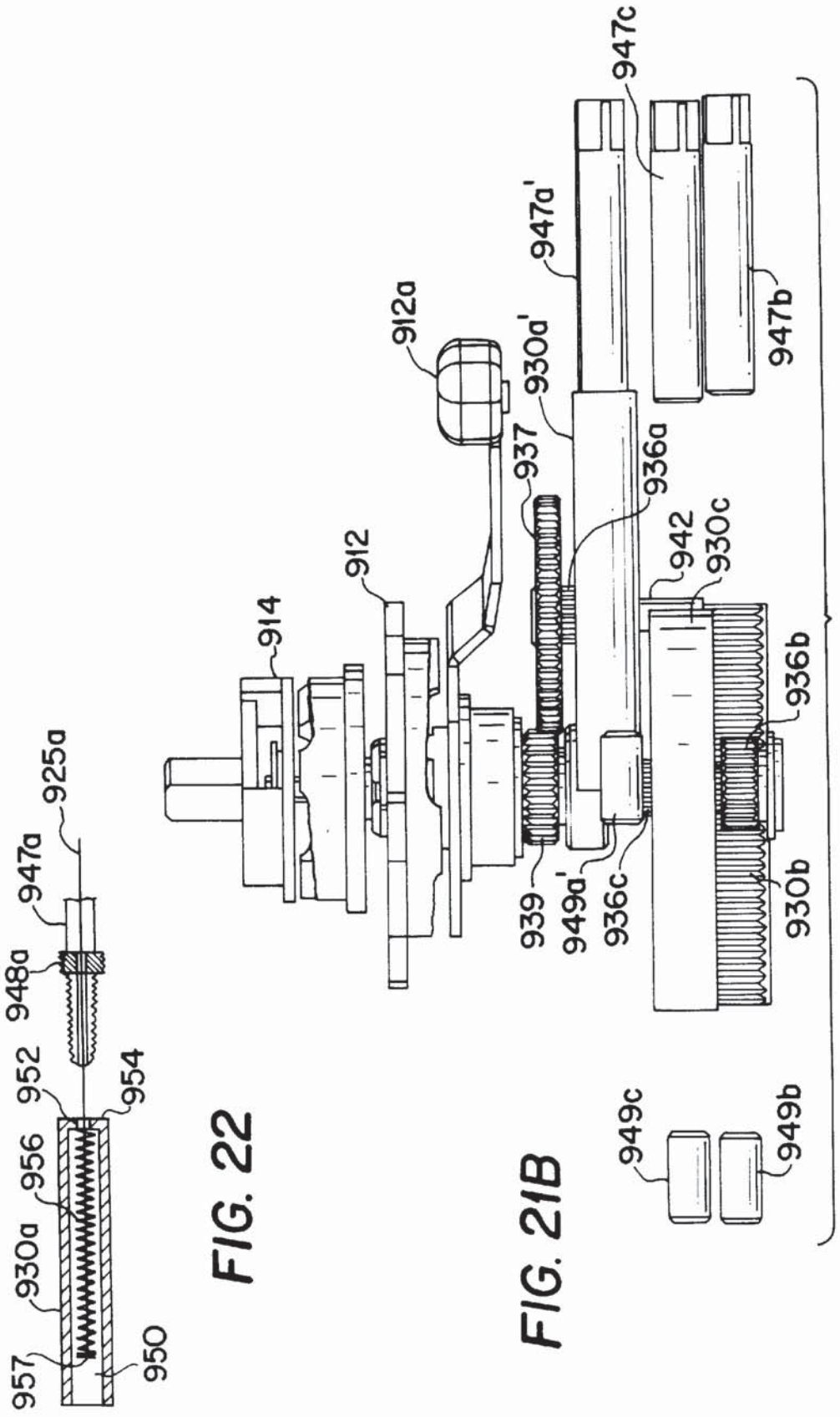


FIG. 21B

FIG. 22

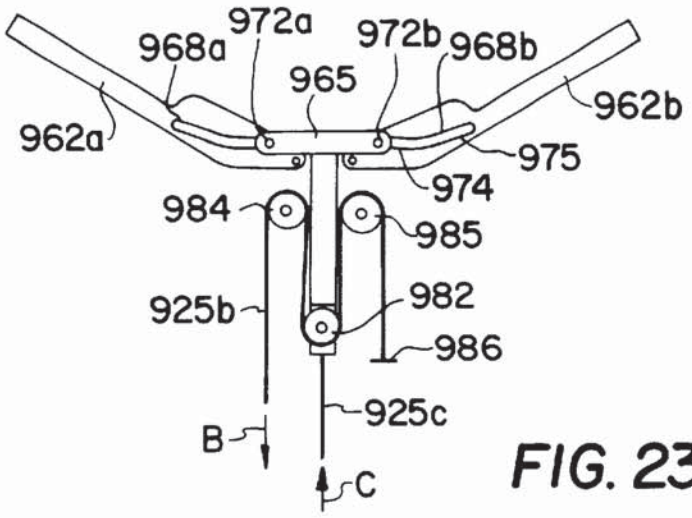


FIG. 23A

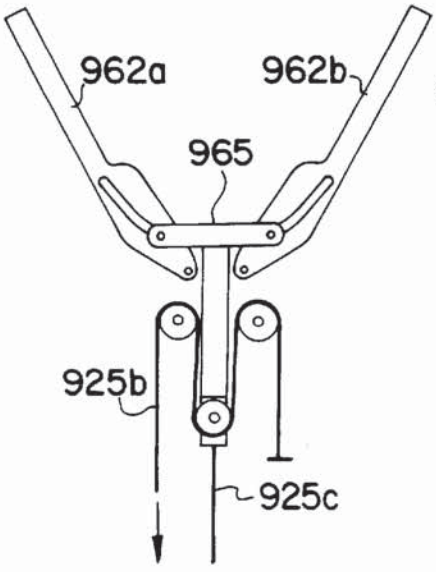


FIG. 23B

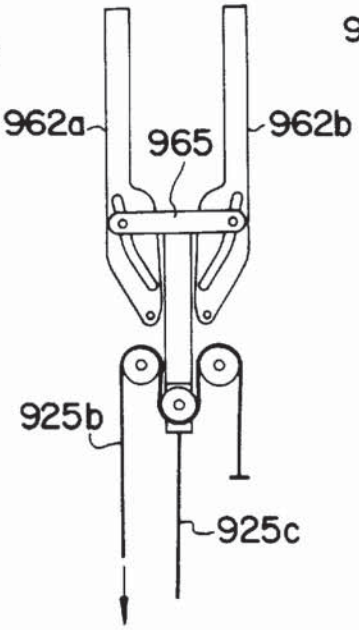


FIG. 23C

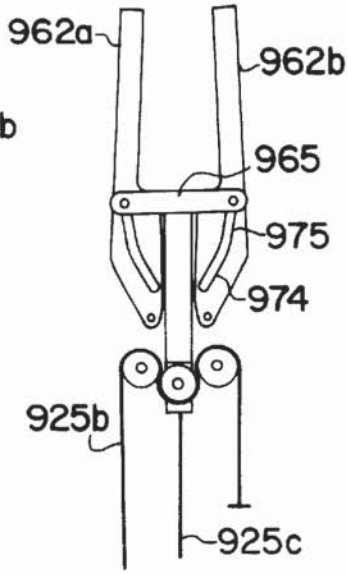


FIG. 23D

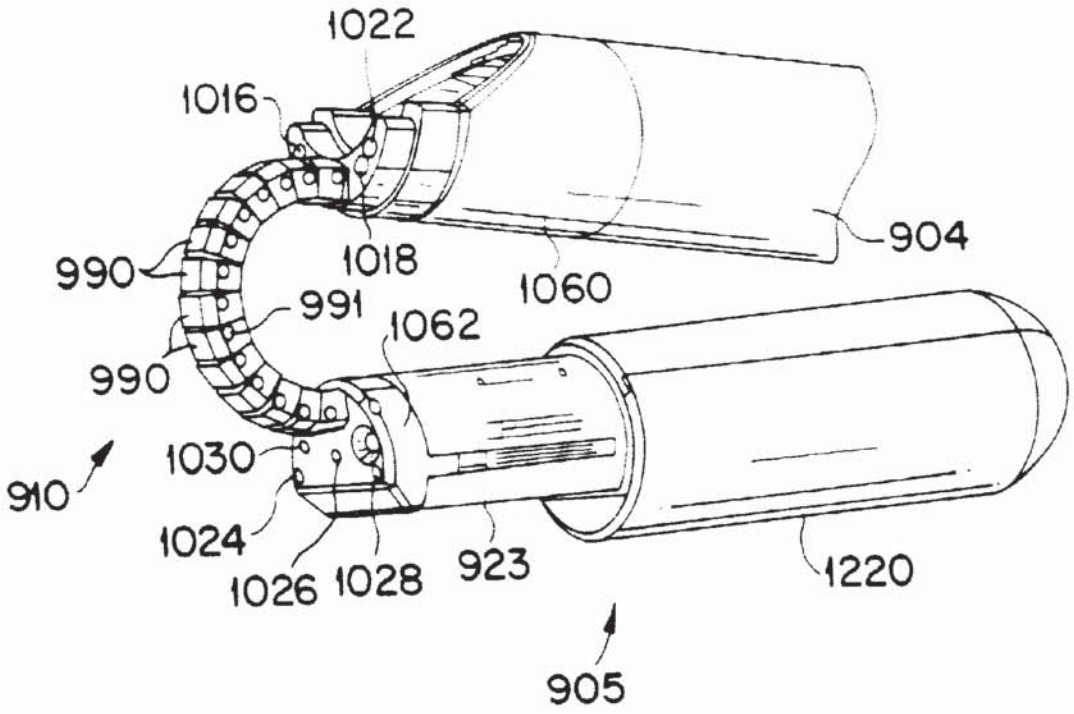


FIG. 24A

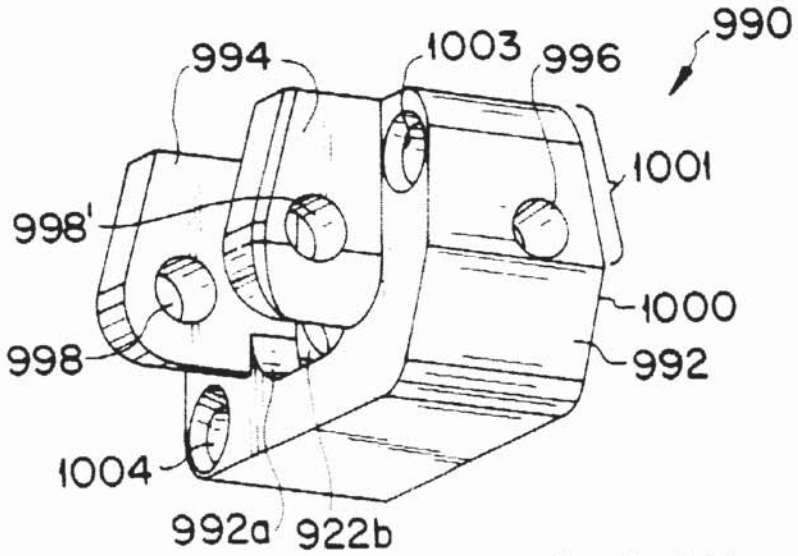


FIG. 24B

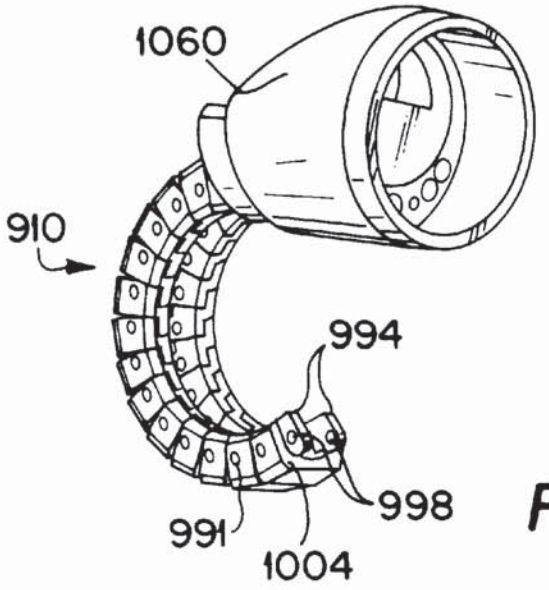


FIG. 24C

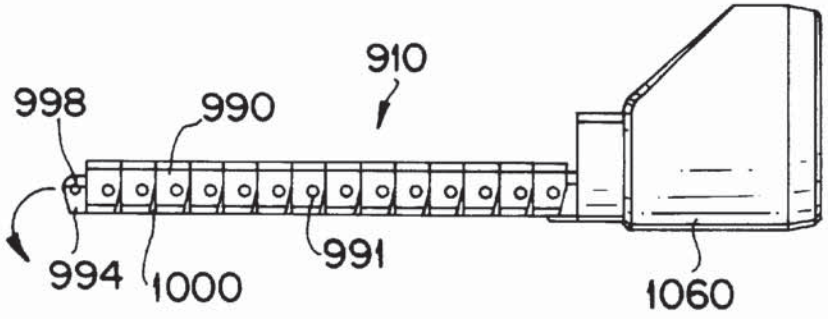


FIG. 24D

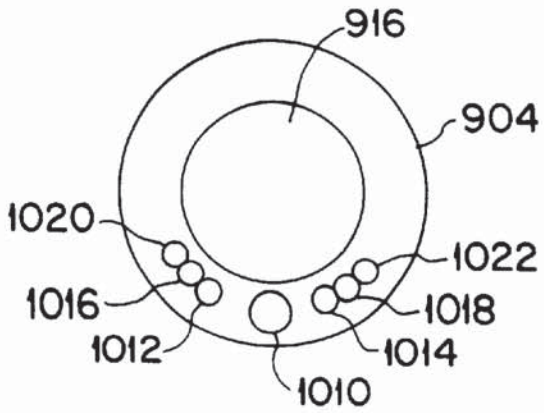


FIG. 25

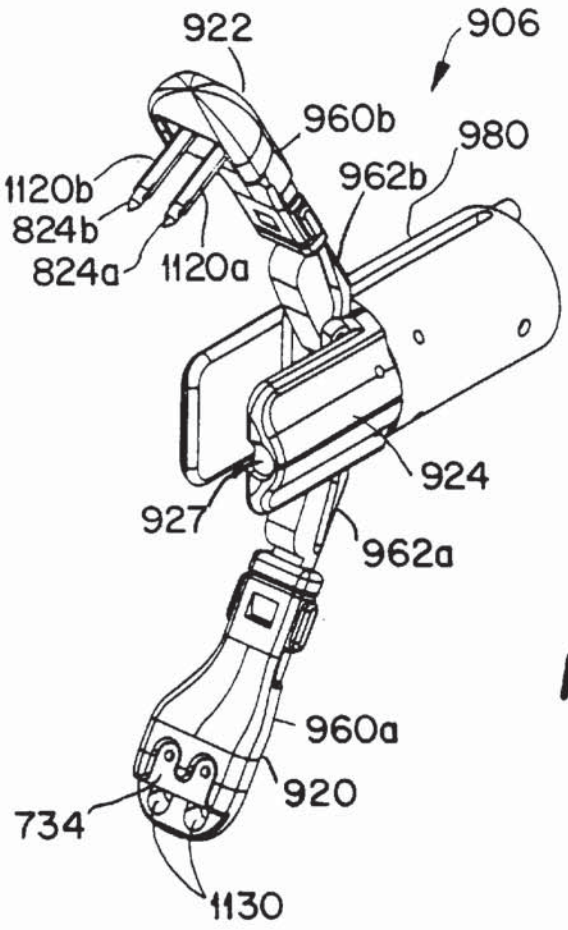

922
906
960b
980
962b
1120b
824b
824a
1120a
924
927
962a
960a
920
734
1130

FIG. 26

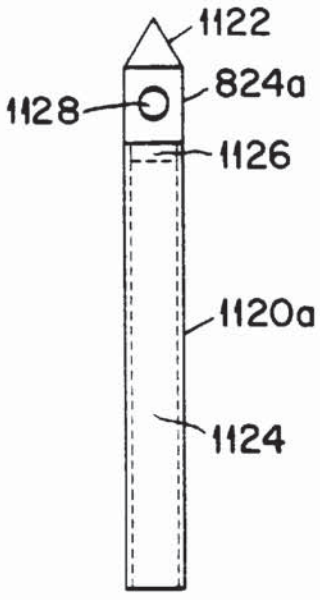

1122
824a
1128
1126
1120a
1124

FIG. 27

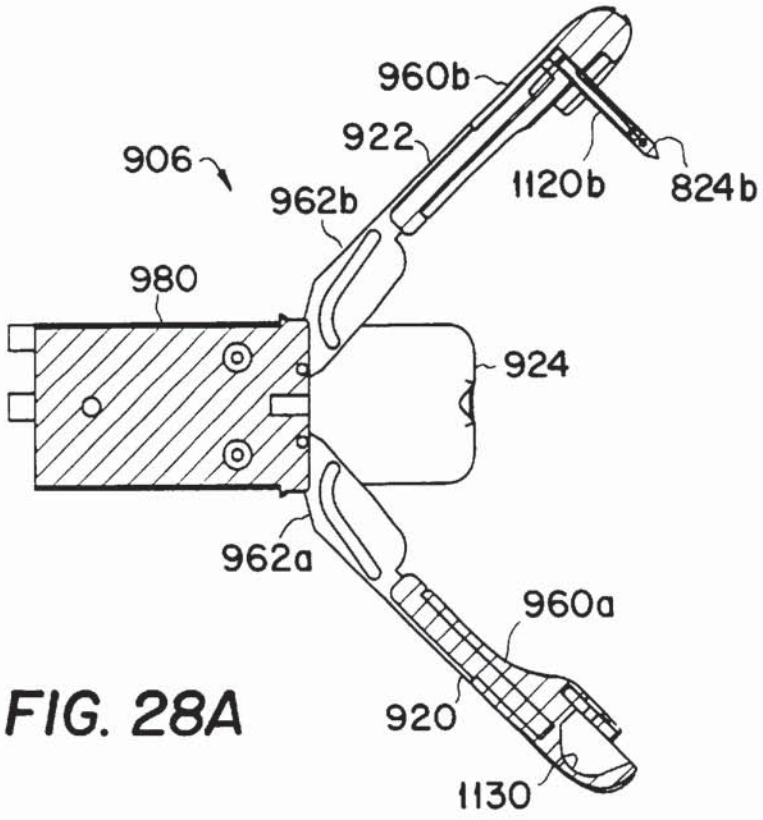


FIG. 28A

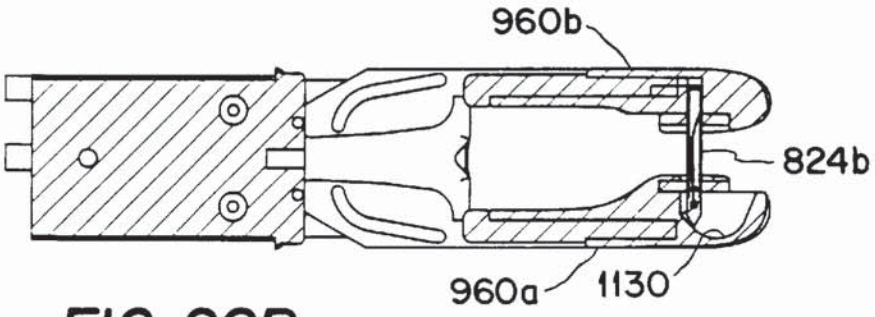


FIG. 28B

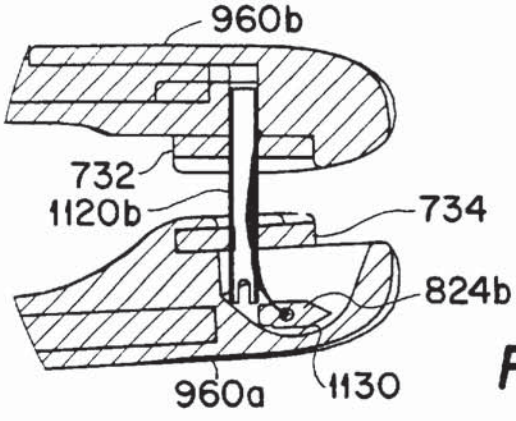


FIG. 28C

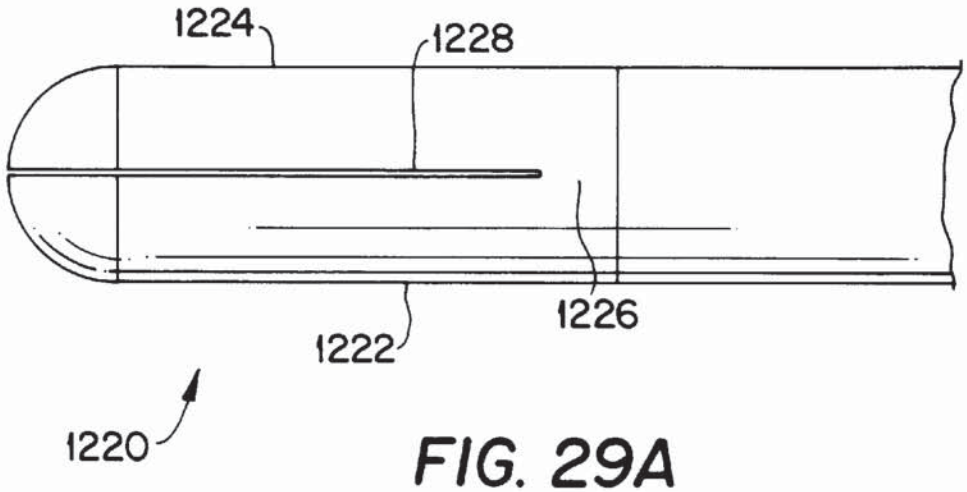


FIG. 29A

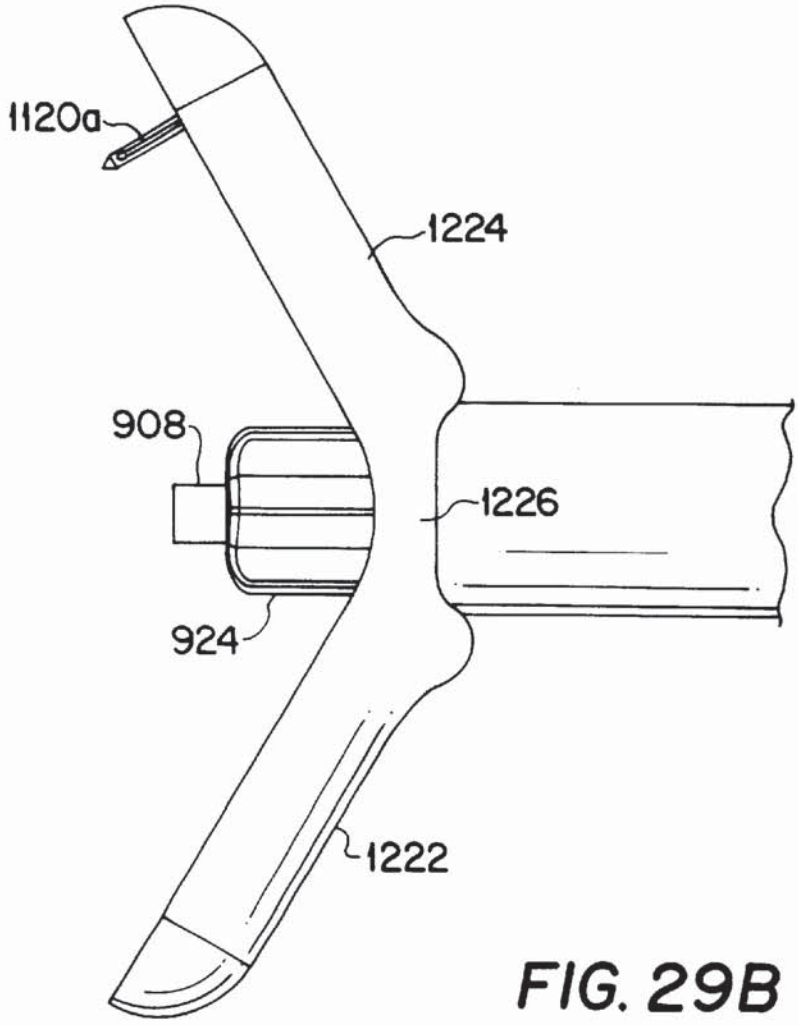


FIG. 29B

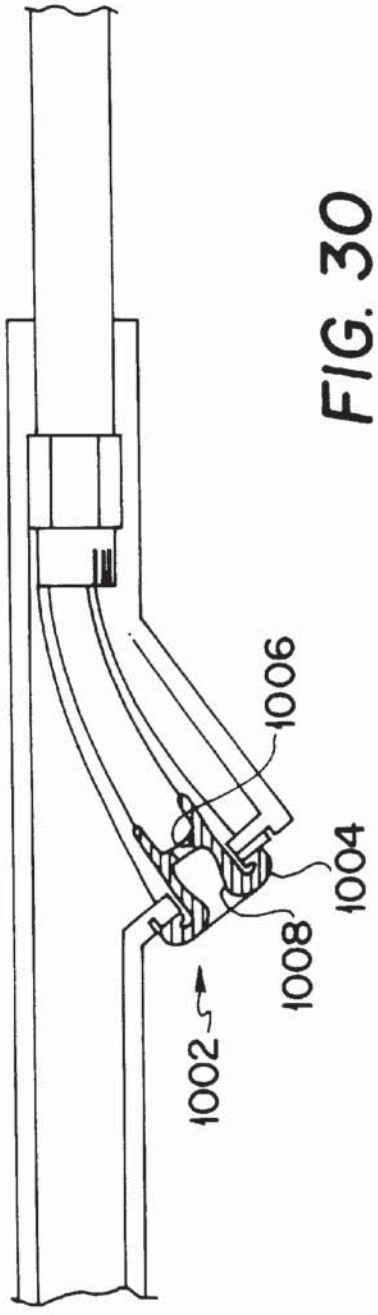


FIG. 30

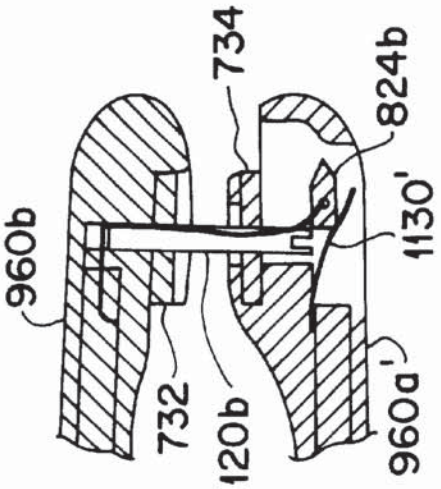


FIG. 31

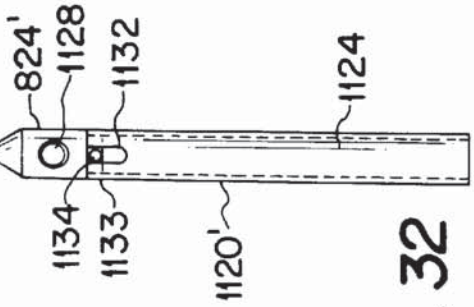


FIG. 32

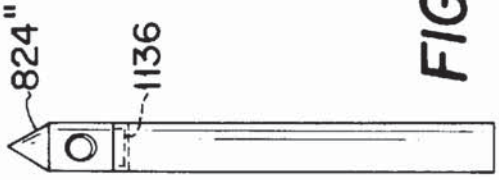


FIG. 33

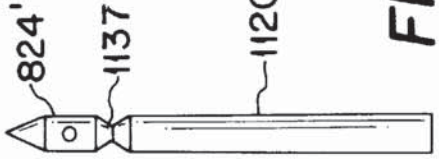


FIG. 34

FIG. 35B

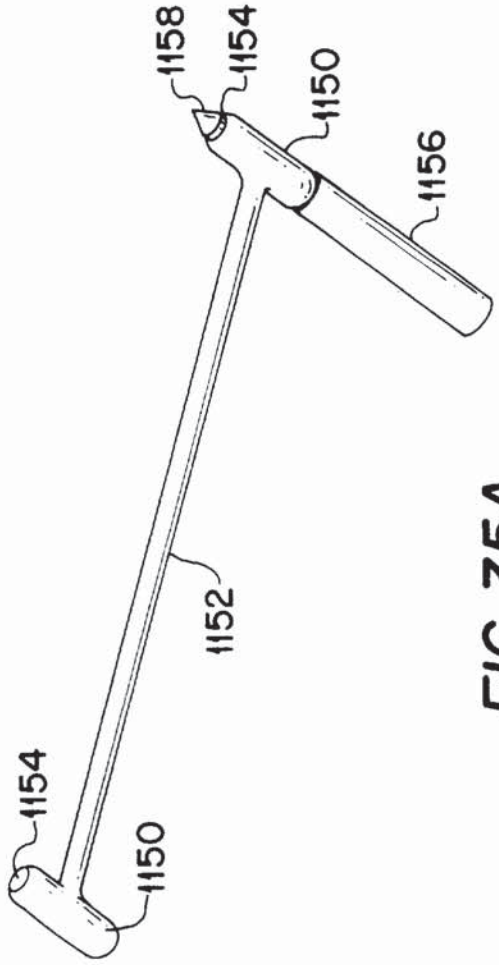


FIG. 35A

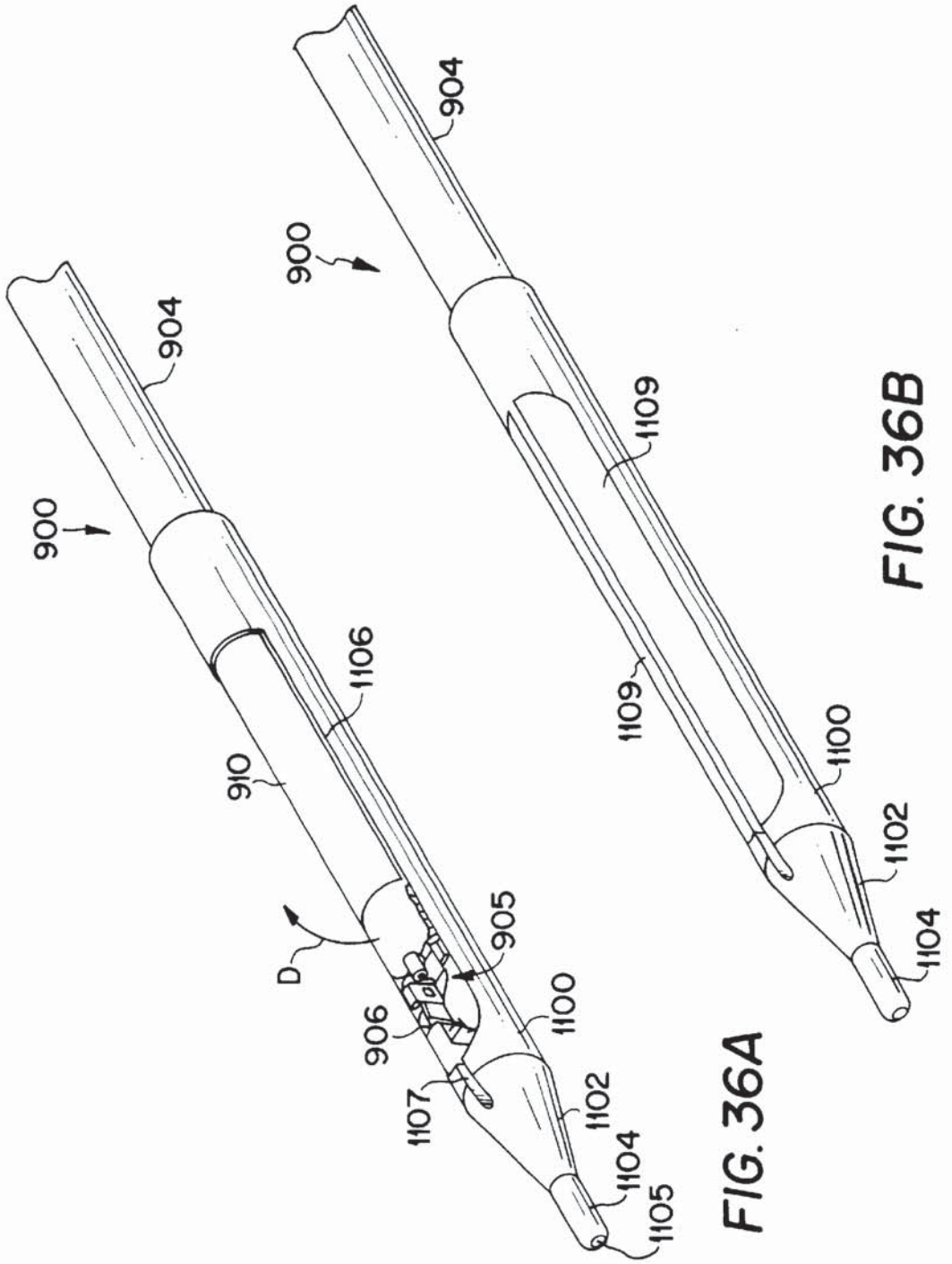


FIG. 36A

FIG. 36B

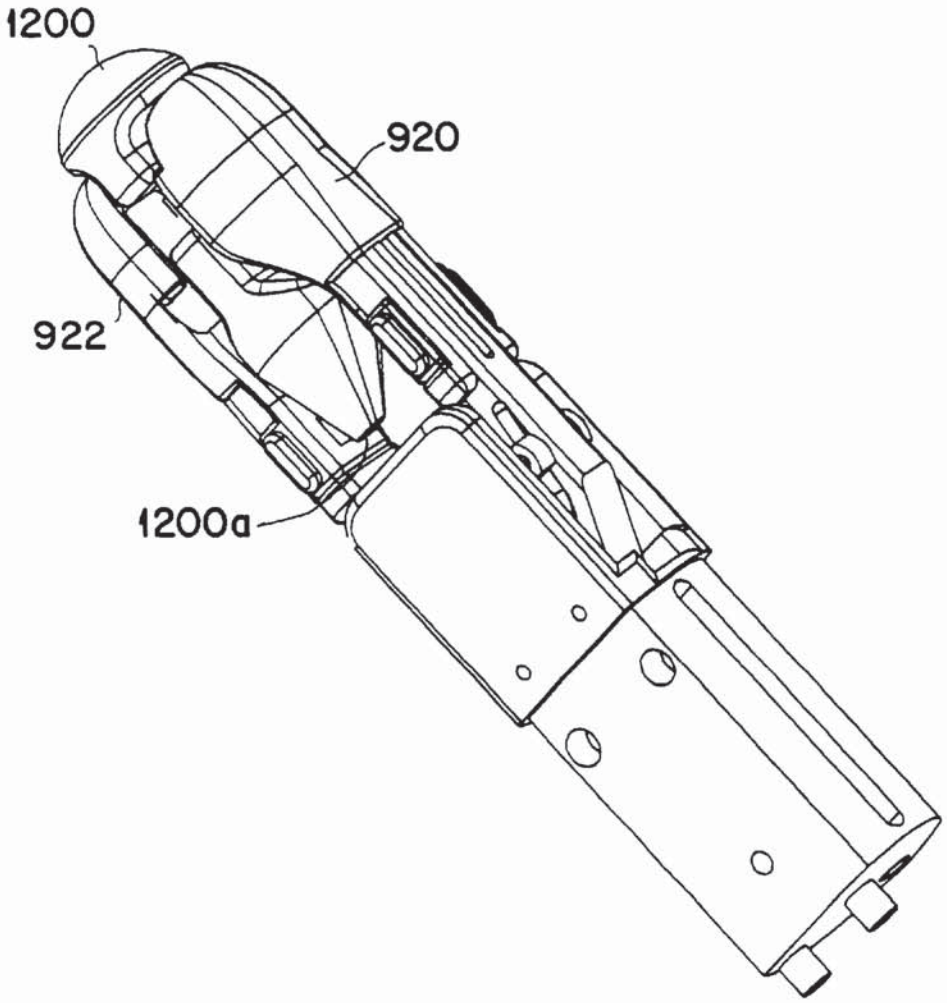


FIG. 37

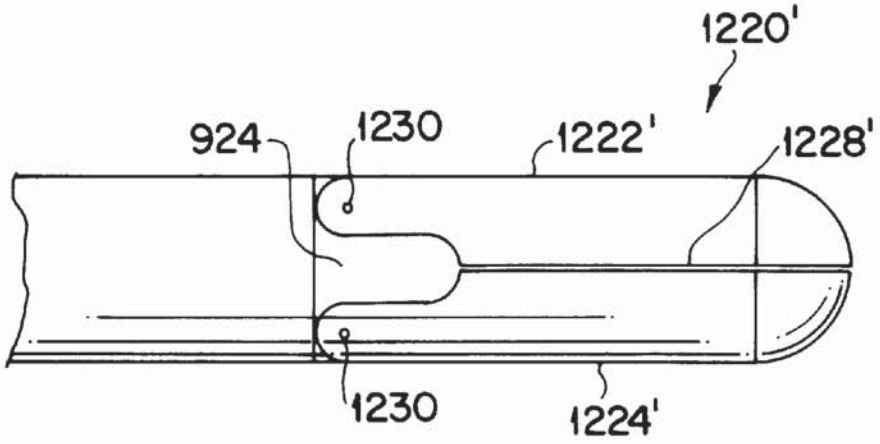


FIG. 38

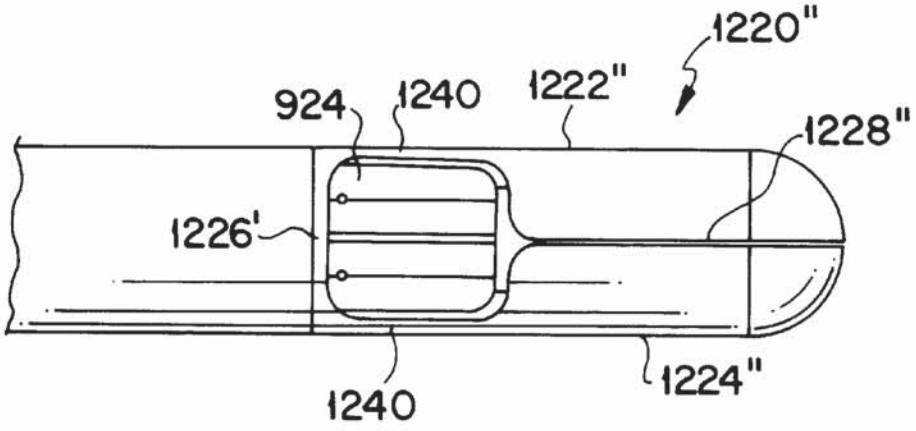


FIG. 39

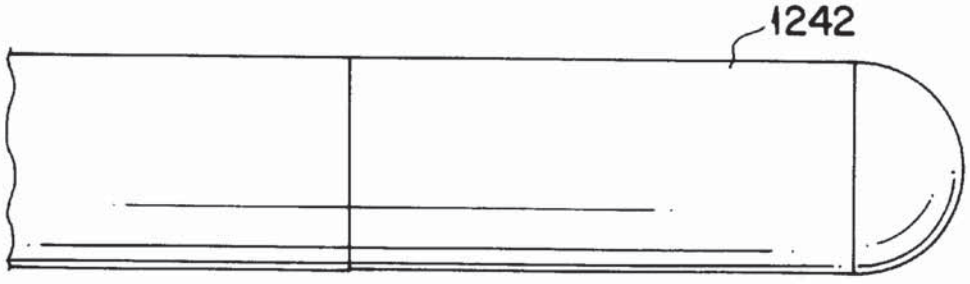


FIG. 40

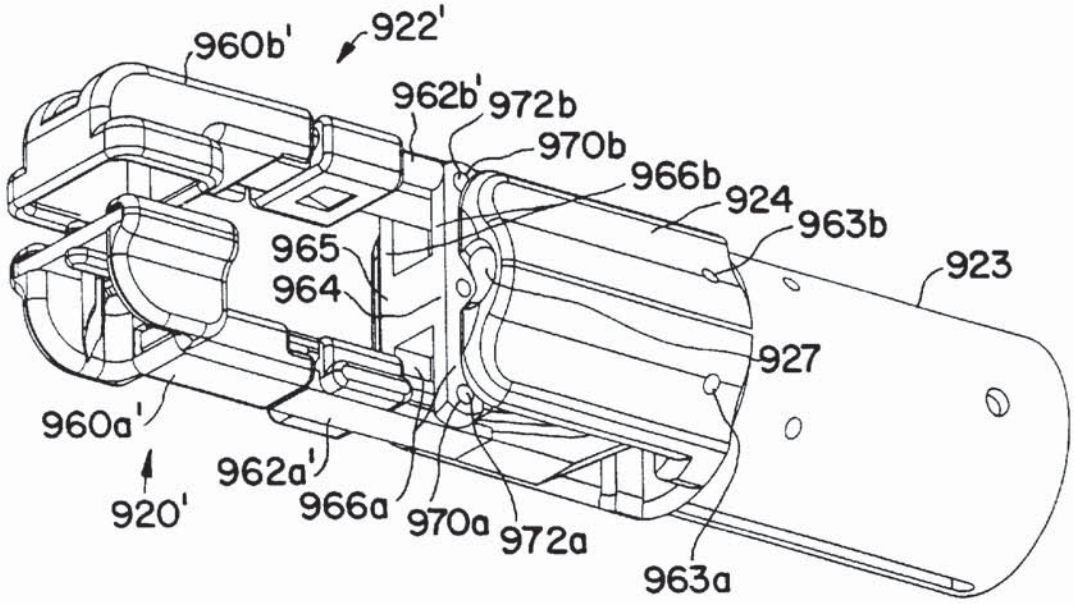


FIG. 41A

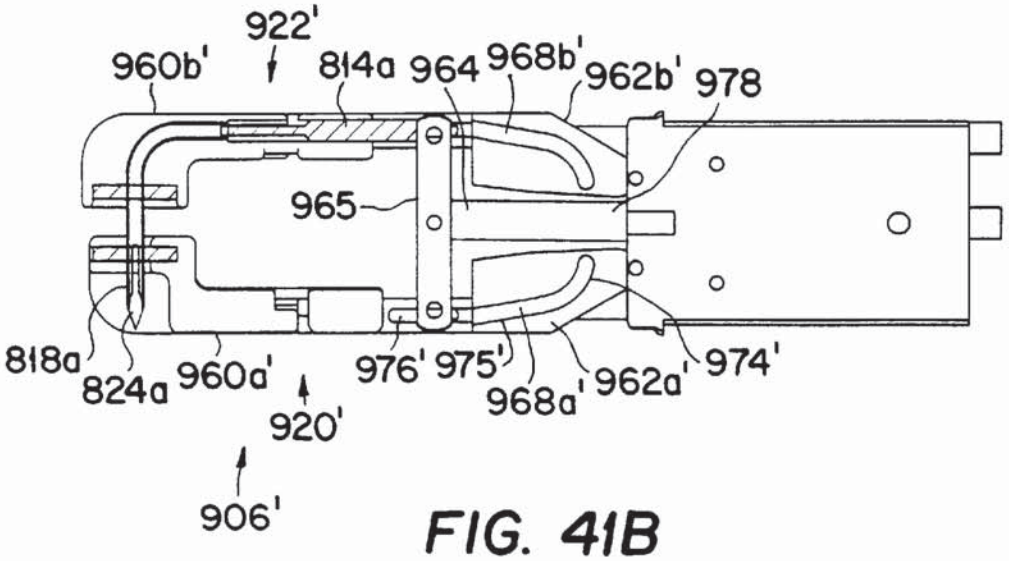


FIG. 41B

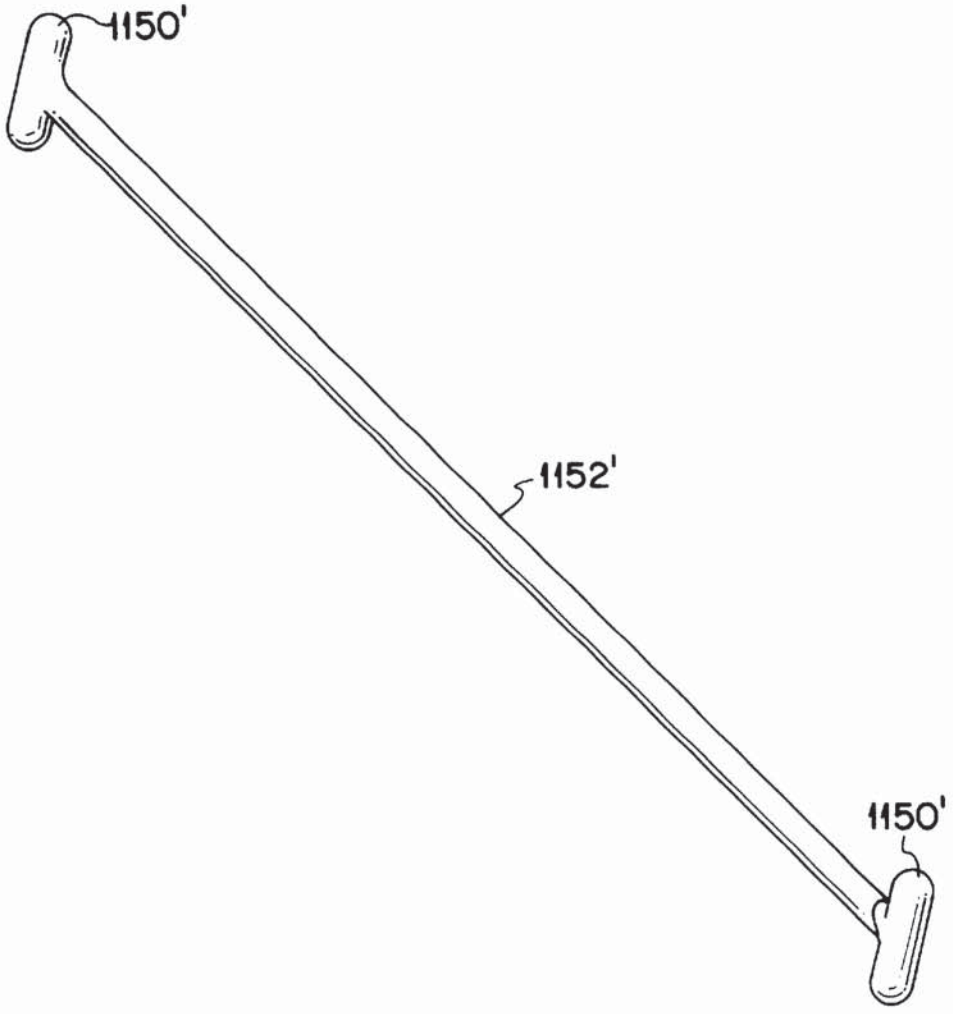


FIG. 42

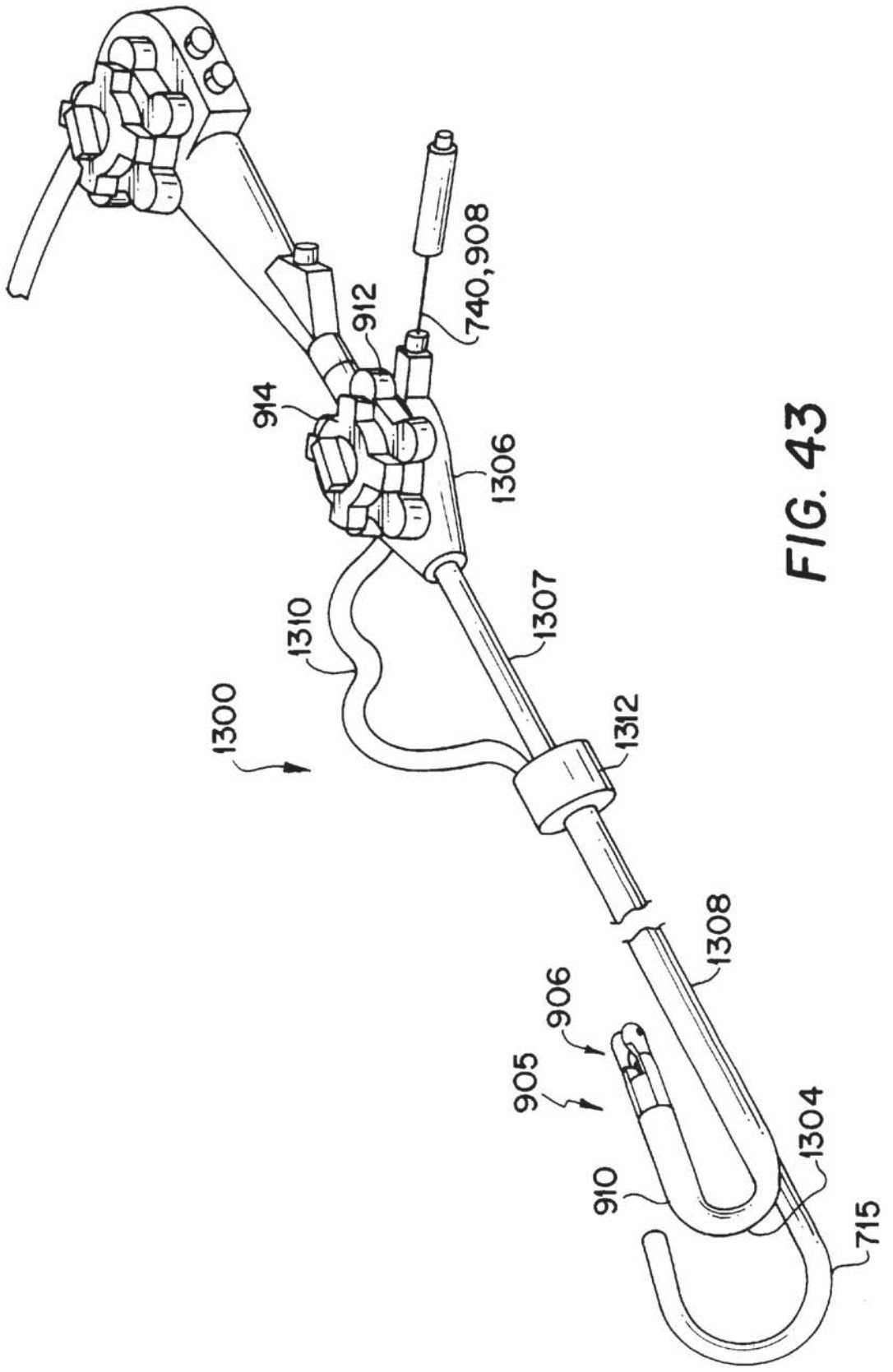

740,908
912
914
1306
1307
1310
1300
1312
1308
906
905
1304
910
715

FIG. 43

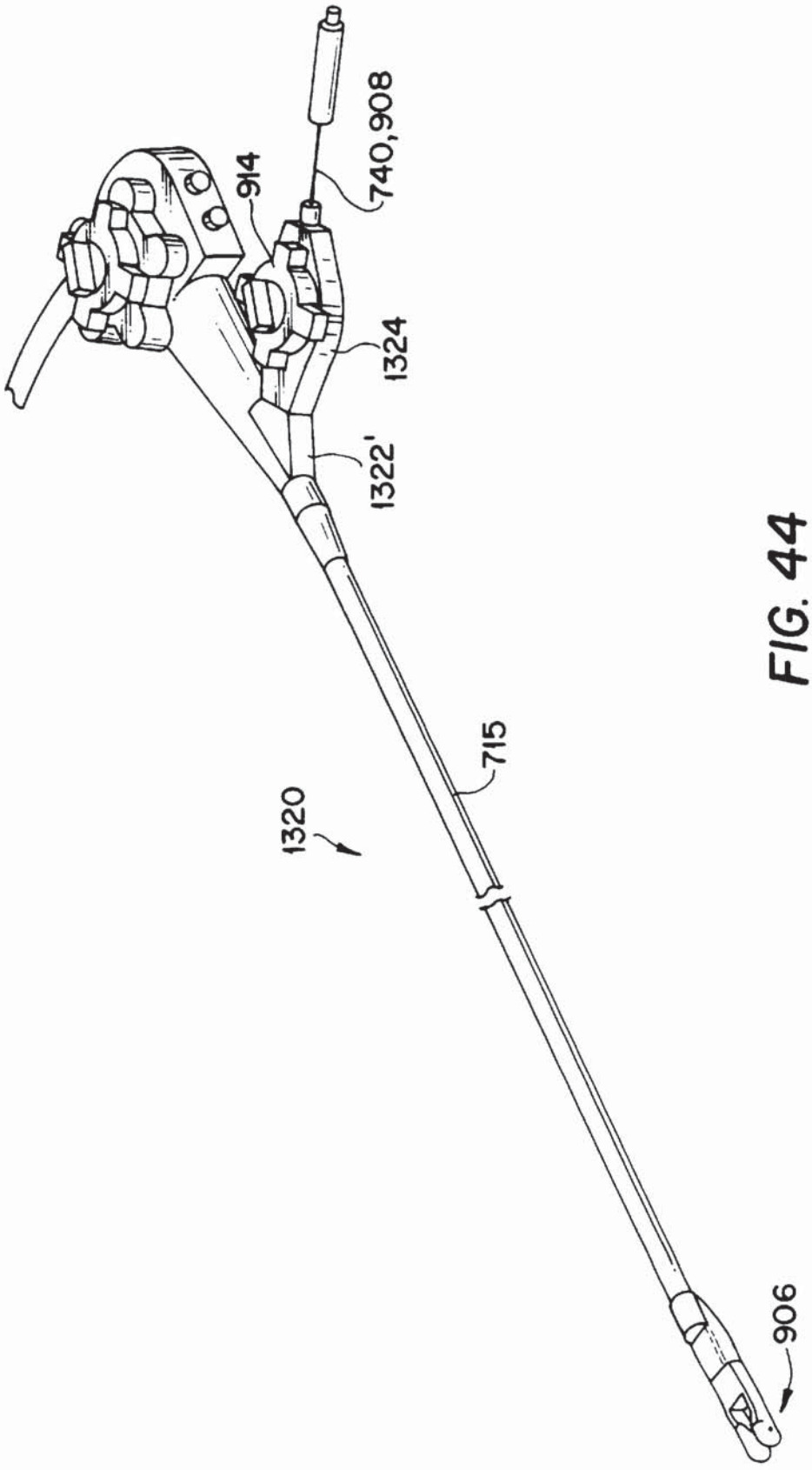


FIG. 44

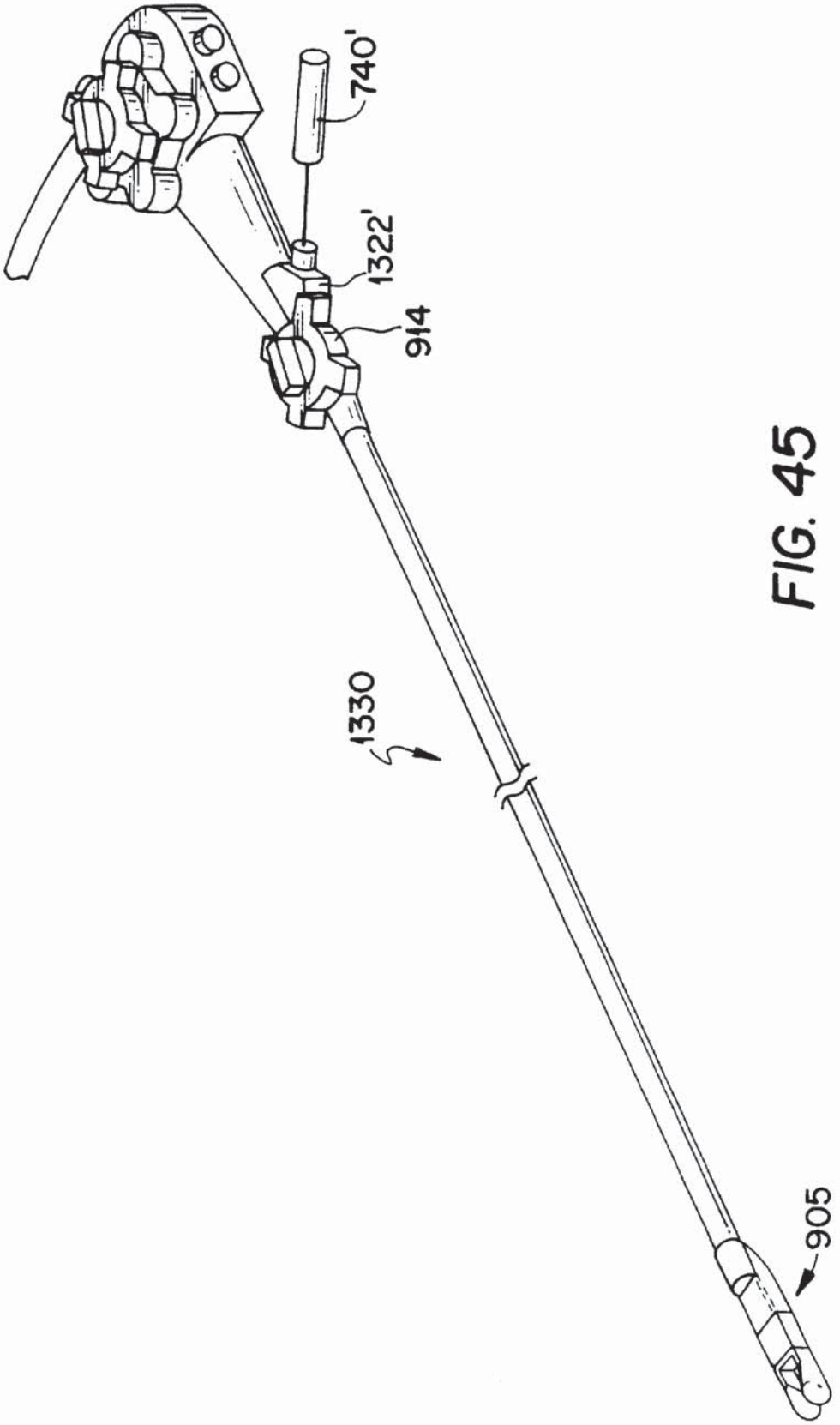


FIG. 45

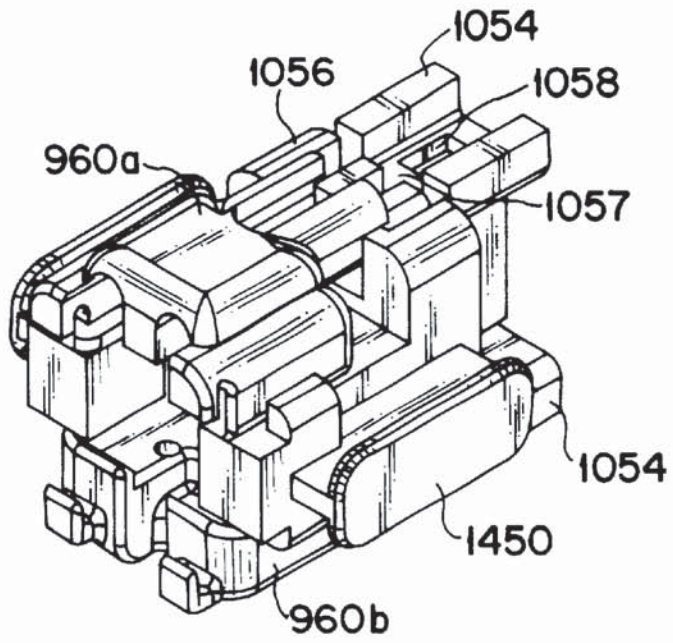


FIG. 46A

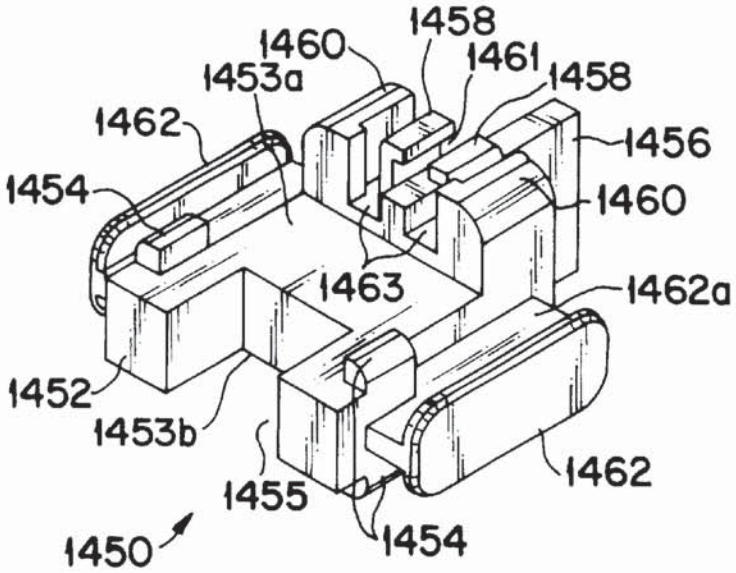


FIG. 46B

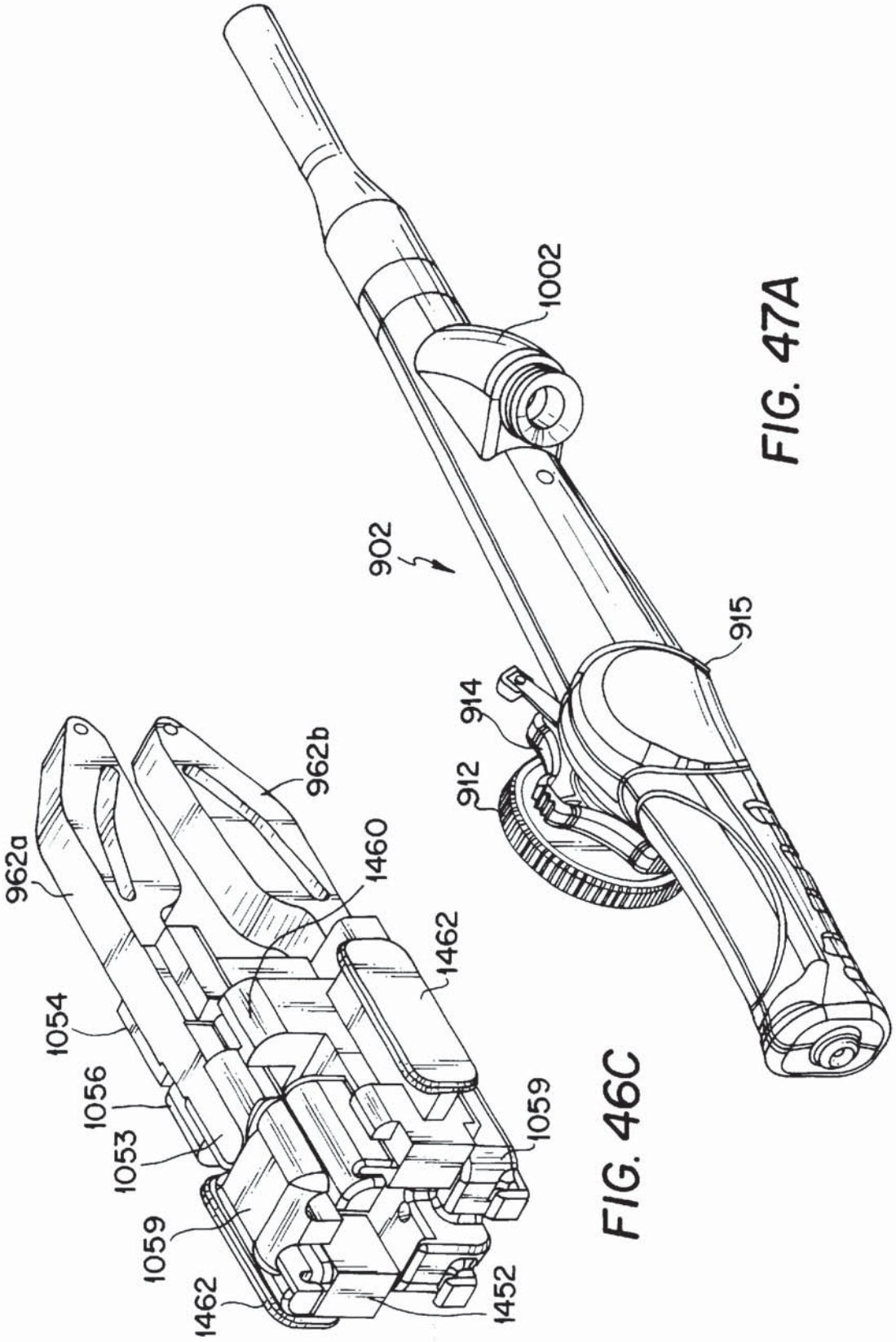


FIG. 46C

FIG. 47A

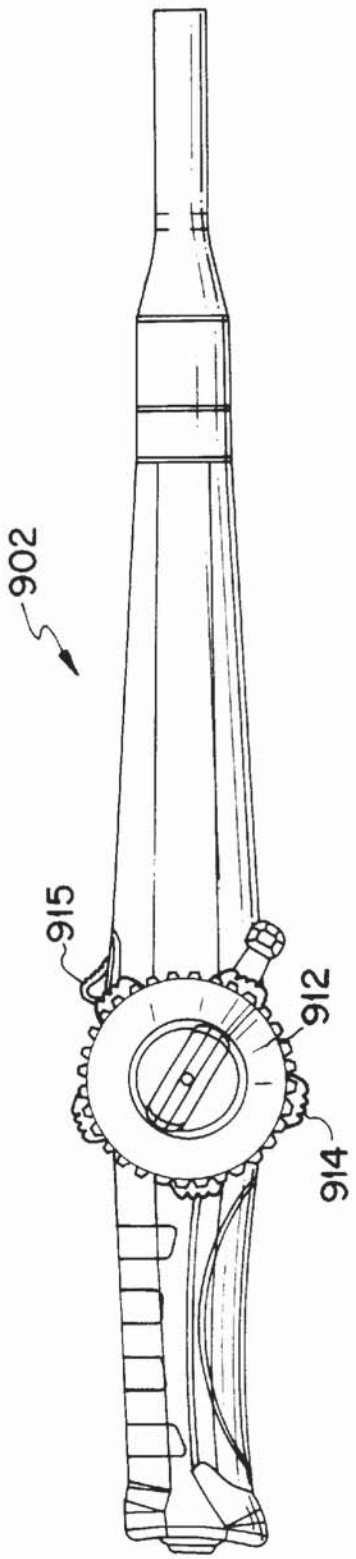


FIG. 47B

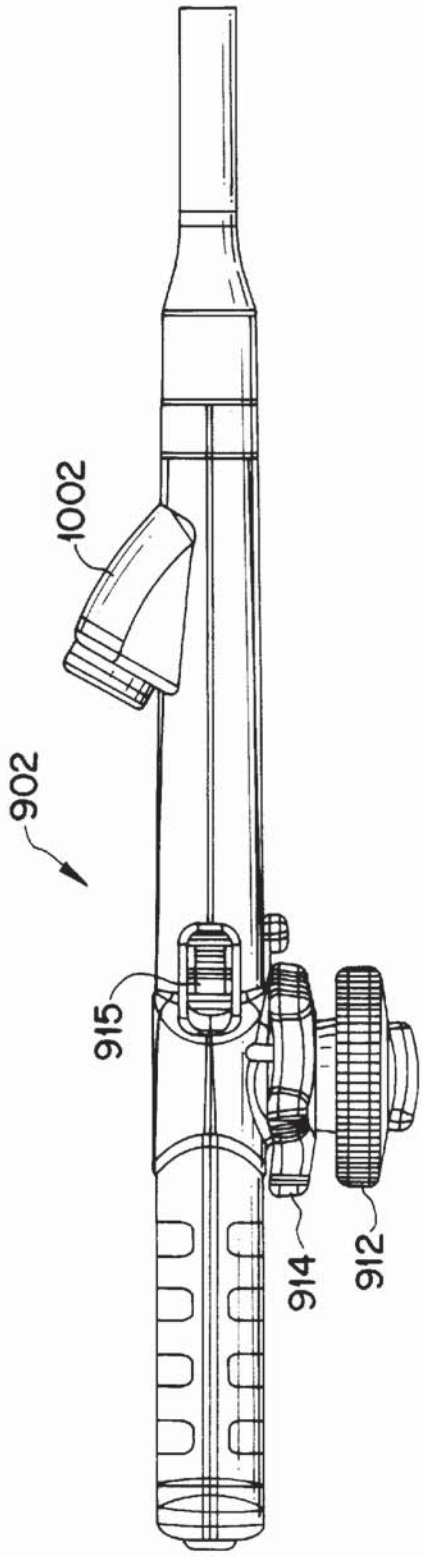


FIG. 47C

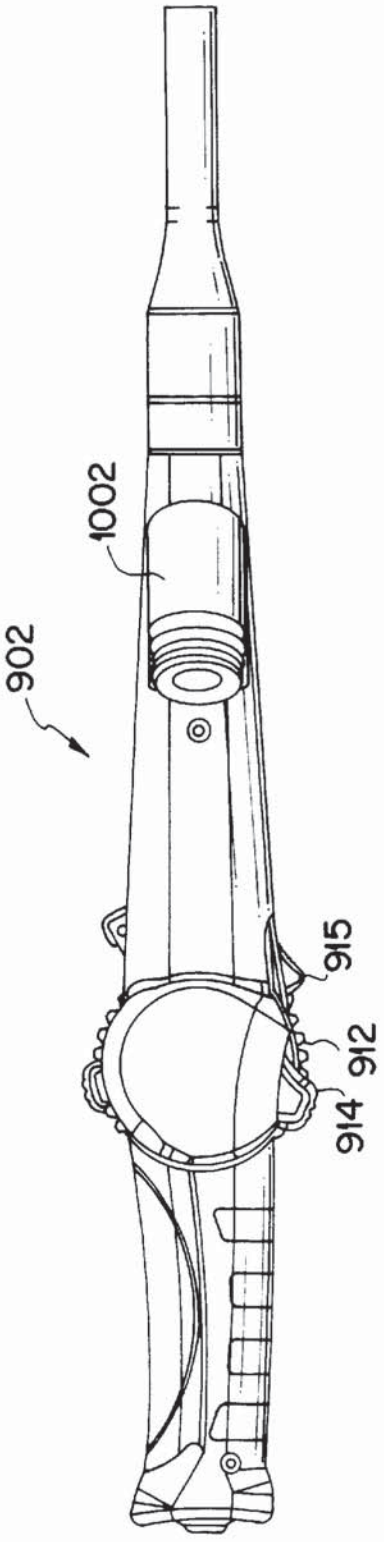


FIG. 47D

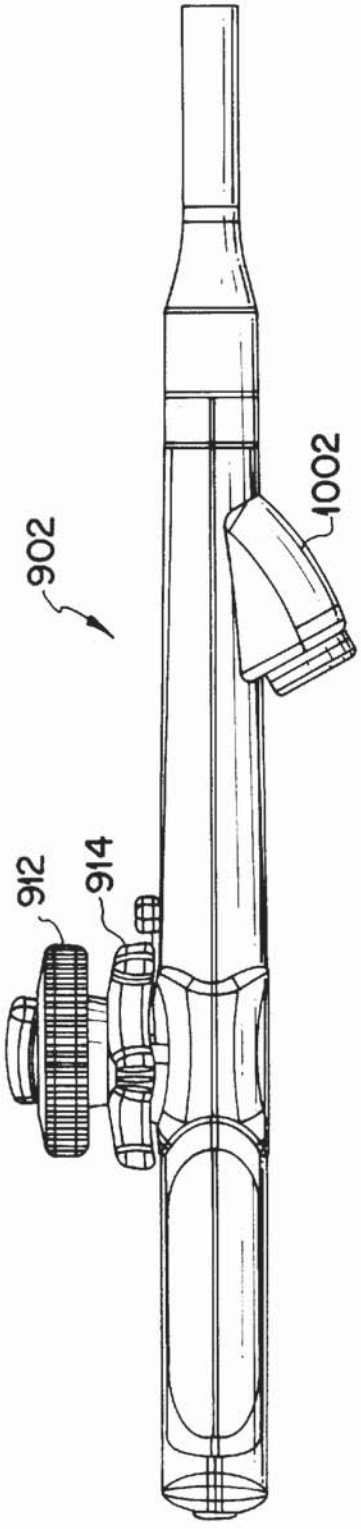


FIG. 47E

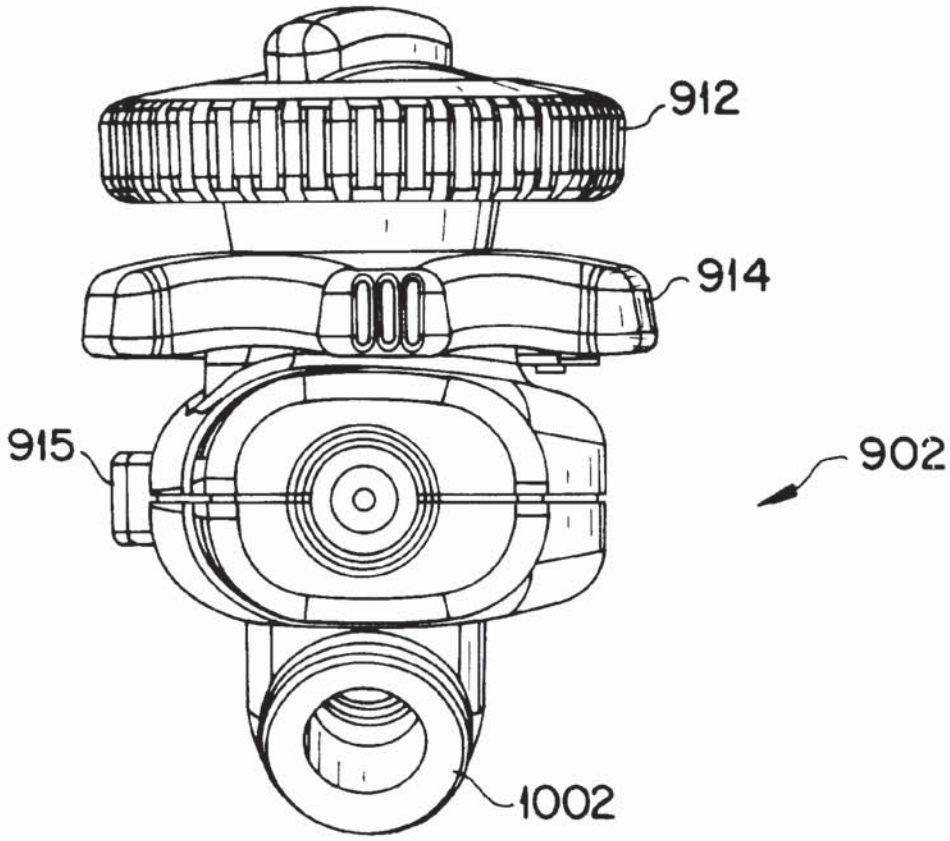


FIG. 47F

TISSUE RECONFIGURATION

This application is a continuation-in-part of application U.S. Ser. No. 09/574,424, filed May 19, 2000, U.S. Pat. No. 6,494,888, entitled TISSUE RECONFIGURATION, which is a continuation-in-part of application U.S. Ser. No. 09/520,273, filed Mar. 7, 2000, U.S. Pat. No. 6,663,639, entitled METHODS AND DEVICES FOR TISSUE RECONFIGURATION, and application U.S. Ser. No. 09/519,945, filed Mar. 7, 2000, U.S. Pat. No. 6,506,196, entitled DEVICE AND METHOD FOR CORRECTION OF A PAINFUL BODY DEFECT, which claim priority from provisional application U.S. Ser. No. 60/140,492, filed Jun. 22, 1999, entitled STOMACH ELEVATOR METHOD AND DEVICE, all hereby incorporated by reference in their entirety.

BACKGROUND

This invention relates to methods and apparatus for reconfiguring tissue, and more particularly to reconfiguring tissue in the vicinity of the gastroesophageal junction.

Gastroesophageal reflux disease (GERD) is a common upper-gastrointestinal disorder in which acidic contents of the stomach flow inappropriately from the stomach into the esophagus. Backflow of gastric contents into the esophagus results when gastric pressure is sufficient to overcome the resistance to flow that normally exists at the gastroesophageal junction (GEJ) or when gravity acting on the contents is sufficient to cause flow through the GEJ. Medication, open surgical procedures, minimally invasive surgical techniques, and endoscopic techniques are known for treating GERD.

SUMMARY

According to one aspect of the invention, a medical instrument for engaging tissue includes a flexible shaft, a tissue piercing coil at a distal portion of the shaft, and a member positioned over the shaft. The member and the coil are coupled for relative movement.

Embodiments of this aspect of the invention may include one or more of the following features. The member is biased, e.g., by a spring, in a distal direction. The shaft includes a length of coil. The shaft coil and the tissue piercing coil are wound in opposite directions.

According to another aspect of the invention, a medical instrument for engaging tissue includes a flexible shaft, a tissue piercing member at a distal portion of the shaft, and a tissue stabilizer coupled to the shaft for movement relative to the tissue piercing member. The tissue stabilizer is biased in a distal direction such that as the tissue piercing member enters tissue, the tissue stabilizer is urged against a surface of the tissue.

According to another aspect of the invention, a medical instrument for engaging tissue includes a tissue piercing coil, and a tissue stabilizer coupled to the coil for movement relative to the coil. The tissue stabilizer is biased in a distal direction such that as the coil enters tissue, the tissue stabilizer is urged against a surface of the tissue.

According to another aspect of the invention, a method of treatment includes advancing a flexible shaft to a treatment site, and piercing tissue with a coil portion of the shaft.

According to another aspect of the invention, a method of treatment includes advancing a flexible shaft to a treatment site, piercing tissue with a member located at a distal portion of the shaft, and stabilizing tissue being pierced by contacting a surface of the tissue with a tissue stabilizer biased in a distal direction such that as the tissue piercing member enters tissue, the tissue stabilizer is urged against the surface of the tissue.

According to another aspect of the invention, a method of treatment includes piercing tissue with a coil, and stabilizing tissue being pierced by contacting a surface of the tissue with a tissue stabilizer biased in a distal direction such that as the coil enters tissue, the tissue stabilizer is urged against the surface of the tissue.

According to another aspect of the invention, a medical instrument for reconfiguring tissue includes a flexible shaft defining a lumen housing actuating controls, and a distal actuating assembly. The distal actuating assembly includes a sealing portion configured to substantially seal the shaft lumen from contact with bodily fluids, and a tissue manipulator located distal of the sealing portion. The actuating member is coupled to the tissue manipulator such that the tissue manipulator is actuatable to deploy an implant located distal of the sealing portion.

Embodiments of this aspect of the invention may include one or more of the following features. The distal actuating assembly includes an implant located distal of the sealing portion. The sealing portion includes a cover over a section of the assembly. The sealing portion includes a seal surrounding an actuating member extending through the seal.

According to another aspect of the invention, a medical device includes first and second members and each member includes a body having a first attachment portion and a second attachment portion. The first attachment portion includes a member with a side wall defining a slot and a mating contour having a straight, proximal edge for releasably attaching the body to a distal portion of a medical instrument such that the body can be exchanged with a replacement body. The second portion is configured to releasably receive an implant.

Embodiments of this aspect of the invention may include one or more of the following features. The first attachment portion includes a flexing section between the side wall and the mating contour. The second portion includes tubes configured to pass through tissue.

According to another aspect of the invention, a medical device includes an implant including a suture, and first and second members configured to releasably attach to a distal portion of a medical instrument such that the members can be exchanged with replacement members. At least one of the members is configured to releasably receive the implant for delivery of the implant to a treatment site.

According to another aspect of the invention, a cartridge assembly includes first and second members configured for releasable attachment to a medical instrument, and a holder configured to receive the first and second members and to be released from the first and second members upon action of the first and second members attaching to the medical instrument.

The instrument and method of the invention advantageously provide an endoscopic approach to treating GERD that does not require the surgical formation of portals to access the GEJ. The procedure can be performed as an outpatient procedure done under sedation, without general anesthesia being required. The procedure can be performed by gastroenterologists rather than a surgeon, and takes less time, has fewer complications and side-effects and has lower overall procedure costs than surgical methods. The procedure recreates or augments the natural anatomy, and is easily reversible. The procedure creates a gastric plication without the need for the operator to tie knots.

Of particular advantage is that portions of the instrument that engage tissue can be provided sterile, while the remainder of the instrument only need be disinfected between procedures. In addition, a tissue engagement member of the instrument provides a safe and reliable means for remotely retracting tissue.

Other features, objects, and advantages of the invention will be apparent from the following detailed description, and from the claims.

DESCRIPTION OF DRAWINGS

FIG. **1** is a diagrammatic representation of an instrument in use to reconfigure tissue in the vicinity of the gastroesophageal junction of the stomach;

FIG. **2** shows a tissue fixation device deployed by the instrument of FIG. **1** in use to secure a bulge formed in the tissue;

FIG. **3**A is an illustration of the instrument of FIG. **1**;

FIG. **3**B shows a proximal end of the instrument;

FIG. **3**C shows the working channels in a shaft of the instrument;

FIG. **3**D is an illustration of a coil assembly of the instrument;

FIG. **4**A is a top view of a distal end of the instrument, shown with first and second jaw members in an open position;

FIG. **4**B shows the distal end of the instrument located off-axis relative to a shaft of the instrument;

FIG. **5** is a side view of the distal end of the instrument, turned 90 degrees relative to FIG. **4**A;

FIG. **6**A is an illustration of a first part of the tissue fixation device of FIG. **2**;

FIG. **6**B is an illustration of the first jaw member with the first part of the tissue fixation device mounted to the jaw member;

FIG. **7** is an illustration of the second jaw member;

FIG. **8** is an illustration of the tissue fixation device of FIG. **2**;

FIGS. **9**A–**9**F show the instrument of FIG. **1** in use;

FIG. **10** is an illustration of tissue secured with the tissue fixation device of FIG. **2**;

FIGS. **11**A and **11**B are illustrations of an alternative cable routing for an end effector;

FIG. **12**A is an isometric view of a tissue engaging member;

FIG. **12**B is an isometric view of the tissue engaging member of FIG. **12**A shown with an outer sheath removed;

FIG. **12**C is a cross-sectional view of the tissue engaging member of FIG. **12**A;

FIG. **12**D is a cross-sectional view of the tissue engaging member of FIG. **12**A shown piercing tissue;

FIG. **13**A is an isometric view of a proximal end the tissue engaging member of FIG. **12**A and a torque generator;

FIG. **13**B is a cross-sectional view of the torque generator of FIG. **13**A;

FIG. **14**A is an illustration of an alternative tissue engaging member;

FIG. **14**B is an illustration of an alternative tissue engaging member including a tissue bulking needle;

FIG. **14**C is a further illustration of the tissue engaging member of FIG. **14**B;

FIGS. **15**A–**15**D are illustrations of an additional alternative tissue engaging member;

FIG. **16**A is an isometric view of an instrument for reconfiguring tissue;

FIG. **16**B shown the instrument of FIG. **16**A receiving a gastroscope;

FIG. **17**A is an isometric view of the distal end portion of the instrument of FIG. **16**A

FIG. **17**B shows the distal end portion of the instrument with a hood member removed;

FIGS. **17**C–**17**E are side views of an end effector of the instrument of FIG. **16**A;

FIG. **17**F is a side view of a lock arm taken along lines **17**F–**17**F in FIG. **17**E;

FIG. **17**G is an illustration of disposable components of the instrument of FIG. **16**A;

FIG. **17**H is an exploded view of the instrument of FIG. **16**A;

FIG. **17**I is a cross-sectional view of a coupling member of the end effector;

FIG. **18** is a side view of a handle of the instrument of FIG. **16**A, shown with a cover removed;

FIG. **19** is an isometric view of a gearbox located in the handle of FIG. **18**;

FIG. **20** is an illustration of the mechanism inside the gearbox of FIG. **19**;

FIGS. **21**A and **21**B are end and side views, respectively, of the mechanism of FIG. **20**;

FIG. **22** is a cross-sectional view of a rack of the mechanism of FIG. **20**;

FIGS. **23**A–**23**D illustrate the closing of jaw members of the end effector;

FIG. **24**A is an illustration of the distal end portion in a flexed position;

FIG. **24**B is an isometric view of a link of a retroflex portion of the distal end portion;

FIGS. **24**C and **24**D show the retroflex portion flexed and straight, respectively;

FIG. **25** is a cross-sectional view of a shaft of the instrument of FIG. **16**A;

FIG. **26** is an isometric view of the distal end portion with the jaw members open;

FIG. **27** is an illustration of an implant bar of a tissue fixation device shown coupled to a tube of the jaw member;

FIGS. **28**A–**28**C illustrate deployment of the implant bar of FIG. **27**;

FIGS. **29**A and **29**B are illustrations of the hood member with the jaw members closed and open, respectively;

FIG. **30** is an illustration of a seal on the handle of FIG. **18**;

FIG. **31** is an illustration of an alternative deployment mechanism;

FIGS. **32**–**34** are illustrations of alternative means for coupling the implant bar to the tube of the jaw member;

FIG. **35**A is an isometric view and FIG. **35**B is a cross-sectional view of an alternative tissue fixation device;

FIGS. **36**A–**40** are illustrations of alternative means for providing an atraumatic distal end on the instrument of FIG. **16**A;

FIG. **41**A is an isometric view and FIG. **41**B is a side view in partial cross-section of an alternative embodiment of an end effector;

FIG. **42** is an illustration of a tissue fixation device for use with the end effector of FIG. **41**;

FIGS. **43–45** are illustrations of alternative configurations of an instrument for reconfiguring tissue;

FIGS. **46A–46C** are illustrations of a cartridge assembly to which the disposable cartridges of FIG. **17F** are mounted for handling and attachment to the instrument; and

FIGS. **47A–47F** are isometric, four side views, and an end view, respectively, of the handle of FIG. **18**.

DETAILED DESCRIPTION

Referring to FIG. **1**, an instrument **700** for reconfiguring stomach tissue, e.g., stomach tissue in the vicinity of the gastroesophageal junction (GEJ) **702**, such as tissue **704** of the lesser curvature of the stomach or any portion of the stomach within about 2 cm of the GEJ, is shown. The GEJ is the region of transition from the esophagus and the stomach. The lesser curvature of the stomach is a portion of the stomach located beyond the GEJ. Instrument **700** includes an elongated shaft **710** dimensioned to permit transoral access to the stomach, and a tissue manipulator **712** for manipulating stomach tissue. Positioned within a lumen **714** defined by shaft **710** is a standard GI endoscope **715** providing visual guidance of the reconfiguring procedure. Instrument **700** is particularly adapted for treating GERD. Using instrument **700**, as described below, a bulge, plication or tissue wrap is formed in the vicinity of gastroesophageal junction **702** to reduce reflux of stomach fluids into the esophagus.

Tissue manipulator **712** has an elongated cable assembly **716** housed within lumen **714** of shaft **710**, and a distal end effector **718** actuated to perform the various steps in the tissue reconfiguring procedure by cable assembly **716**. End effector **718** includes first and second jaw members **720**, **722** which engage tissue **704**. Cable assembly **716** includes first and second cable pairs **724***a*, **724***b*, and **726***a*, **726***b* for moving jaws **720**, **722** relatively toward and away from one another, respectively, in a first plane, and a third cable **728** for moving end effector **718** relative to shaft **710** in a second plane generally transverse to, and preferably perpendicular to, the first plane, as described further below. During insertion into the stomach, end effector **718** is aligned with shaft **710** (as shown in FIG. **3A**). Once positioned in the stomach, cable **728** is actuated to articulate end effector **718** out of alignment with shaft **710** (as shown in FIG. **1**).

Cable assembly **716** includes a spring beam **784**, formed from, e.g., stainless steel or Nitinol, extending into shaft **710**. End effector **718** is attached to beam **784** at a distal end **785** of beam **784**. Beam **784**, in its rest state, is biased toward a straight alignment. Pulling cable **728** bends beam **784**. When cable **728** is released, beam **784** returns toward the straight alignment.

Referring also to FIG. **2**, mounted to first jaw **720** is a first part **732** of a tissue securement member, e.g., a fixation device **730**, and mounted to second jaw **722** is a second part **734** of tissue fixation device **730**. As described further below, after jaws **720**, **722** engage tissue **704** and manipulate the tissue in a wrapping action to create a bulge **736** in, e.g., the lesser curvature of the stomach, tissue fixation device **730** is deployed to secure the engaged tissue together. Cable assembly **716** includes a fourth cable **737** for deploying fixation device **730**, as described further below.

End effector **718** further includes a tube **738** and a third tissue engaging member, e.g., a coil **740**, received within tube **738**, for purposes described below. Coil **740** is housed within an overtube **742**, and coil **740** and overtube **742** can be moved axially proximally and distally relative to jaws **720**, **722**, along the axis, A, of cable assembly **716**. Coil **740** can be rotatably advanced into tissue.

Referring to FIG. **3A**, instrument **700** has, at its proximal end **745**, a handle **743** with a control knob **744** for controlling cables **724***a*, **724***b*, **726***a*, **726***b* to close and open jaws **720**, **722**, and a control knob **746** for controlling cable **728** to move end effector **718**. Handle **743** includes a port **748** through which coil **740** and overtube **742** can be introduced into shaft lumen **714**, and a pull-knob **750** for deploying tissue fixation device **730**, as described below. As shown in FIG. **3B**, handle **743** defines a channel **752** through which endoscope **715** is introduced into shaft lumen **714**.

Referring to FIGS. **1** and **3C**, which shows the working channels in shaft **710** for receiving the various cables, overtube **742** and endoscope **715**, within lumen **714** of shaft **710** are cable housings **760***a*, **760***b* defining channels **762***a*, **762***b* in which cables **724***a*, **724***b* for closing jaws **720**, **722** are received, and cable housings **764***a*, **764***b* defining channels **766***a*, **766***b* in which cables **726***a*, **726***b* for opening jaws **720**, **722** are received. Within lumen **714** are also a cable housing **768** defining a channel **770** in which cable **728** for bending end effector **718** is received, and a cable housing **772** defining a channel **774** in which cable **737** for deploying fixation device **730** is received. Coil **740** and overtube **742** are received in a channel **778** defined in a coil housing **776** in lumen **714**. Housing **776** extends from port **748** to tube **738**. As shown in FIG. **3D**, coil **740** has a tissue penetrating tip **741** and a distal section **740***a* having a looser wound coil than the remainder of coil **740**. Endoscope **715** is received in a channel **782** defined in an endoscope housing **780** in lumen **715**.

Spring beam **784** is located generally between cable housing **776** and endoscope housing **780**, and extends about **4** inches into shaft **710** from the distal end of the shaft where beam **784** is mounted to shaft **710** by, e.g., silicone adhesive/sealant. The various cable housings and spring beam **784** do not move relative to shaft **710** and handle **743**. It is the movement of the cables within the cable housings that actuate end effector **718**. Shaft **710** is preferably formed from, e.g., heat-shrink tubing.

Referring again to FIG. **3A**, end effector **718** has a length, L**1**, of about 2 inches, cable assembly **716** extends axially by a length, L**2**, of about 2.5 inches from shaft **710**, shaft **710** has a length, L**3**, of about 23.5 inches, and handle **743** has a length, L**4**, of about 5 inches. Cable assembly **716**, spring beam **784**, and shaft **710** have the necessary flexibility to permit transoral placement of instrument **700** into the stomach. The length, L**1**, of relatively rigid end effector **718** is minimized to ensure the necessary flexibility of instrument **700** is maintained. The distance that cable assembly **716** extends axially from shaft **710** is selected to cantilever beam **784** permitting the desired bending of end effector **718** relative to shaft **710** to position jaws **720**, **722** against the inner surface of the stomach in the vicinity of the GEJ.

Distal end effector **718** is sized to fit through a 12–16 mm diameter channel (corresponding to the diameter of the esophagus) and-shaft **710** has an outer diameter of about 12 to 16 mm to enable transoral passage of instrument **700** into the stomach. Scope channel **782** has a diameter of either about 8 mm or 10 mm. An 8 mm diameter scope channel allows passage of 7.9 mm pediatric gastroscope, and a 10 mm diameter scope channel allows passage of a 9.8 mm adult gastroscope. Channel **778** has a diameter of about 2–3 mm for receiving cable **742**.

Distal end effector **718** is shown in more detail in FIGS. **4A** and **4B**. End effector **718** includes a central mount **800** defining a slot **801**. Spanning slot **801** and supported by mount **800** is a pin **803** to which **720**, **722** are pivotally

mounted. Central mount **800** also houses two pulleys **802** over which cables **724***a*, **724***b* are respectively passed for closing jaws **720**, **722**. Cables **724***a*, **724***b* terminate at points **804**, **806** on jaws **720**, **722**, respectively. Cables **726***a*, **726***b* for opening jaws **720**, **722** terminate at points **808**, **810** on jaws **720**, **722**, respectively, proximal of points **804**, **806**. Tube **738** of end effector **718** for receiving coil **740** and overtube **742** is attached to mount **800**, and cable **728** for bending end effector **718** terminates at point **811** on tube **738**.

Pulling cables **724***a*, **724***b* proximally moves jaws **720**, **722** toward one another generally in a first plane (in the plane of the paper in FIG. **4**A). Pulling cables **726***a*, **726***b* proximally moves jaws **720**, **722** away from one another generally in the first plane. Pulling cable **728** proximally bends beam **784** moving end effector **718** in a second plane (out of the plane of the paper in FIG. **4**A) generally perpendicular to the first plane.

Referring also to FIG. **5**, jaw **720** includes two guide tubes **816***a*, **816***b* and a slider **812** including two push rods **814***a*, **814***b* guided within tubes **816***a*, **816***b*, respectively. Slider **812** is mounted to jaw **720** to slide relative to jaw **720**. Tubes **816***a*, **816***b* curve about jaw **720** to terminate in tissue penetrating tips **818***a*, **818***b* (FIG. **6**B), respectively. Push rods **814***a*, **814***b* can be formed from molded plastic such as polyethylene or polypropylene or as a braided stainless steel cable to provide the flexibility to follow the curve of tubes **816***a*, **816***b*. Cable housing **772** is attached to slider **812** and cable **737** terminates at a fixed point **739** on jaw **720**. Actuation of cable **737** pushes slider **812** distally, as described below.

First part **732** of tissue fixation device **730** is shown in more detail in FIGS. **6**A and **6**B. First part **732** of tissue fixation device **730** defines through holes **820***a*, **820***b* (FIG. **6**A), and part **732** is loaded onto jaw **720** with tips **818***a*, **818***b* received in through holes **820***a*, **820***b*, respectively. Connected to part **732** with a suture **822** are two securing elements, e.g., bars **824***a*, **824***b*. Each bar **824***a*, **824***b* defines two through holes **826***a*, **826***b*. Suture **822** is threaded through holes **826***a*, **826***b* of the bars and through holes **820***a*, **820***b* of part **732**, and is tied together forming a knot **823** to secure bars **824***a*, **824***b* to part **732**. Tubes **818***a*, **818***b* each define a channel **827** for receiving one of bars **824***a*, **824***b*, and a slot **828** communicating with channel **827** for receiving suture **822** therethrough.

Referring particularly to FIGS. **4**B and **7**, jaw **722** has a distal member **830** defining a slot **832** for receiving second part **734** of fixation device **730**, and slots **834***a*, **834***b* for receiving tissue penetrating tips **818***a*, **818***b*. Second part **734** of fixation device **730** defines through holes **836***a*, **836***b* for receiving tips **818***a*, **818***b*. When jaws **720**, **722** are closed, tips **818***a*, **818***b* pass through slots **834***a*, **834***b* and holes **836***a*, **836***b*. Actuation of fixation device deployment cable **737** after closing jaws **720**, **722** pushes slider **812** and push rods **814***a*, **814***b* distally, advancing bars **824***a*, **824***b* out of tissue penetrating tips **818***a*, **818***b*, and locating bars **824***a*, **824***b* on the far side **838** of second part **734** of fixation device **730**, as shown in FIG. **8**.

Referring to FIGS. **9**A–**9**F, in use, under endoscopic guidance, the physician advances instrument **700** transorally to position end effector **718** in the stomach. During advancement into the stomach, end effector **718** is generally aligned along the axis of shaft **710**, as shown in FIG. **9**A. The physician then turns control knob **746** to pull cable **728** proximally, thereby bending beam **784** moving end effector **718** out of alignment with shaft **710** to the position shown in FIG. **9**B. By then turning control knob **744** to pull cables **726***a*, **726***b*, jaws **720**, **722** are pivoted about pins **803** to the open position shown in FIG. **9**C.

The physician then advances coil **740** and overtube **742** by pushing the coil and overtube distally in channel **778** advancing coil **740** and overtube **742** out of tube **738** and into contact with stomach tissue, preferably stomach tissue beyond the gastroesophageal junction, as shown in FIG. **1**. With overtube **742** pressing against the tissue to stabilize the tissue, the physician rotates coil **740** while applying slight distal pressure to advance the coil into the tissue, as shown in FIG. **9**D. Coil **740** and overtube **742** are then pulled proximally to pull tissue between jaws **720**, **722**. Jaws **720**, **722** are then closed by turning control knob **744** to pull cables **724***a*, **724***b* proximally, as shown in FIG. **9**E. The turning of the control knob can also be the action that pulls coil **740** and overtube **742** proximally, ensuring that coil **740** and overtube **742** are positioned out of the way of the closing of the jaws. A lockout can be incorporated to prevent the jaws from closing if coil **740** and overtube **742** are not in their proximal position.

The closing of the jaws places parts **732**, **734** of fixation device **730** in contact with two tissue sections, e.g., against two spaced tissue surfaces in the stomach, and causes tissue penetrating tips **818***a*, **818***b* to penetrate through the tissue and into holes **836***a*, **836***b* in second part **734** of fixation device **730**. To deploy fixation device **730**, the physician pulls cable **737** proximally removing slack from cable **737**. Because cable housing **772** is of fixed length and is non-movably attached to the handle, removing slack from cable **737** causes cable housing **772** to move distally, advancing slider **812** to push t-bars **824***a*, **824***b* out of tissue penetrating tips **818***a*, **818***b*, as shown in FIG. **9**F.

The physician then opens the jaws, disengages jaw **722** from second part **734**, returns the distal end effector to its original position generally aligned with shaft **710**, closes the jaws and removes instrument **700**. FIG. **10** shows a cross-section of the tissue with fixation device **730** in place securing bulge **736**.

Other embodiments are within the scope of the following claims.

For example, rather than a coil **740**, alternative tissue penetrating or grasping elements such as a T-bar suture or two small grasping jaws can be employed. Instrument **700** can be used without the third tissue engaging member.

Referring to FIGS. **11**A and **11**B, an end effector **718'** includes an alternative cable routing for actuating jaws **720**, **722**. End effector **718'** includes cables **726***a*, **726***b* for opening jaws **720**, **722**, a single cable **724'** for closing jaws **720**, **722**, and cable **737** for advancing slider **812**. End effector **718'** also includes pivot **803** and a series of pulleys **850***a*, **850***b*, **850***c*, **850***d*, and **850***e* around which the cables are routed.

Cable **724'** has a first portion **852***a* that is routed under (as viewed in FIGS. **11**A and **11**B) pulley **850***a* and over pulley **850***c*; a second portion **852***b* that extends between pulleys **850***c* and **850***b*; and a third portion **852***c* routed under pulley **850***b* and over pulley **850***a*. Cable **726***a* has a first portion **854***a* that extends to pulley **850***d* and a second portion **854***b* that extends between pulley **850***d* and anchor **851** a fixed to central mount **800**. Cable **726***b* has a first portion **856***a* that extends to pulley **850***e* and a second portion **856***b* that extends between pulley **850***d* and anchor **851***b* fixed to central mount **800**.

To open jaws **720** and **722**, the user applies a tensile force F1 to cables **726***a* and **726***b* (by turning control knob **744**).

The tensile force F1 draws the first portions **854***a*and **856***a* of cables **726***a* and **726***b* proximally in the same direction as force F1 and draws the second portions **854***b* and **856***b* of cables **726***a* and **726***b* distally around respective pulleys **850***e* and **850***d*. Turning knob **744** also produces slack in cable **724'**. A net force F3 results and draws jaws **720**, **722** open.

To close jaws **720**, **722**, the user applies a tensile force F2 to portions **852***a* and **852***b* of cable **724'** (by turning control knob **744** in the opposite direction, which also relieves tension in cables **726***a*, **726***b*). The tensile force F2 acts to shorten portion **852***b* of cable **724'**, thereby drawing pulleys **850***c* and **850***b* together and jaws **720**, **722** closed.

Referring to FIG. **12**A, in an alternative embodiment, a third tissue engagement member **740'** includes a tissue-engaging coil **860** with a tissue piercing end **860***a*, a helical drive shaft **862**, and a coupling member **864** for translating a torque applied by drive shaft **862** to coil **860**. Helical drive shaft **862** is preferably wound in a direction opposite that of tissue engaging coil **860**, for reasons described below. Positioned over and axially movable relative to coupling member **864** is a sprung sheath **866**. Tissue engagement member **740'** can be used alone or can replace tissue engagement member **740** of FIG. **1**. Coil **860** has, e.g., six loops with a pitch of 1½ mm from loop-to-loop and a diameter of 2 mm. Other configurations can be used, e.g., one loop and greater with the number of loops times the pitch corresponding to the desired penetration depth into the tissue.

Referring to FIG. **12**B, in which tissue engagement member **740'** is shown without spring sheath **866**, coupling member **864** includes a first, distal-most section **864***a* with a diameter, D1; a second section **864***b* with a diameter D2 larger than D1; a third section **864***c* with a diameter D3 between D1 and D2; a fourth section **864***d* with a diameter D4 about equal to D2; a fifth section **864***e* with a diameter D5 larger than D4; and a proximal-most section **864***f* having a diameter D6 about equal to D1. Diameters D1–D6 are, for example, about 0.04", 0.09", 0.06", 0.09", 0.12" and 0.04", respectively. Defined between sections **864***a* and **864***b* is a shelf **867***a*; defined between sections **864***b* and **864***c* is a shelf **867***b*; defined between sections **864***c* and **864***d* is a shelf **867***c*; defined between sections **864***d* and **864***e* is a shelf **867***d*; and defined between sections **864***e* and **864***f* is a shelf **867***e*. Drive shaft **862** is received over coupling member section **864***f* and coil **860** is received over coupling member section **864***a*. Drive shaft **862** and coil **869** are attached to coupling member **864** by, for example, soldering. Coil **860** has a coil length, L, of, for example, about 0.25", extending beyond the distal end **868** of section **864***a*. Positioned on coupling member section **864***c* between shelves **867***b* and **867***c* is a spring **870** that biases sprung sheath **866** distally.

Referring to FIG. **12**C, sprung sheath **866** defines a lumen **872** and has a first section **866***a* with an inner diameter d1, a second hub section **866***b* with an inner diameter d2 less than d1, and a third section **866***c* with an inner diameter d3 about equal to d1. Coil **860** is received within lumen **872** in sheath section **866***a*. Spring **870** is located within lumen **872** radially between coupling member section **864***c* and section **866***c* of sheath **866** and axially between hub **866***b* and shelf **867***c*. Sheath hub **866***b* is biased against shelf **867***b* by spring **870**. The spacing between coupling member shelf **867***d* and a proximal end **874***b* of sheath **866** permits axial, proximal movement of sheath **866** against the action of spring **870**.

To facilitate assembly of tissue engaging member **740'**, coupling member **864** is formed from two parts **876***a*, **876***b* having mating fingers **878** joined, for example, by compression fitting. This configuration permits sheath **866** to be slid over part **876***a* prior to joining part **876***b* to **876***a*.

Referring also to FIG. **12**D, in operation, the user places distal end **874***a* of sheath **866** against tissue T to be pierced to stabilize the tissue. The user then applies distal and rotational forces to drive shaft **862**, which causes coupling member **864** and coil **860** to move distally and rotate into the tissue, for example, the mucosal layer of tissue. As coil **860** advances into the tissue, distal end **874***a* of sheath **866** remains on the surface of the tissue, spring **870** is compressed, and shelf **867***d* advances toward sheath proximal end **874***b*. When coil **860** has been anchored in the tissue, for example, the muscle layer of tissue underlying the mucosal layer (which takes about 3 or 4 turns of the coil into the tissue), the user can manipulate the tissue with tissue engaging member **740'**. By engaging multiple layers of tissue, member **740'** provides a secure grasp on the tissue.

Sprung sheath **866** acts to stabilize both the tissue and coil **860** when coil **860** is advanced into the tissue. Sheath **866** compresses the tissue, facilitating initial penetration of the coil into the tissue, and helps keep the tissue from twisting as the coil rotates. Furthermore, the coil **860** tends to want to go off-axis as it rotates into the tissue. Sprung sheath **866** provides enough force against the tissue and has enough friction against the tissue surface to limit movement of sheath **866** as coil **860** is advanced into the tissue. This counteracts the tendency of the coil to want to go off-axis.

Due to the opposed winding of drive shaft **862** and coil **860**, the rotational force applied to drive shaft **862** causes a decrease in the diameter of drive shaft **862** upon encountering torsional resistance. This decrease in the diameter of drive shaft **862** limits contact of drive shaft **862** with the wall of an associated working channel in which drive shaft **862** is located and thus possible jamming in the working channel.

Referring to FIGS. **13**A and **13**B, to apply the distally and rotationally directed forces to drive shaft **862**, a torque generator **882** held by the user and a drive rod **880** releasably attached to torque generator **882** and extending through handle **743** are coupled to drive shaft **862**. Drive rod **880** runs a majority of the length of instrument **700** to provide high torque, with drive shaft **862** extending in the area of the retroflex region to provide high flexibility. Drive rod **880** and drive shaft **862** are coupled, e.g., by soldering. Torque generator **882** includes a handle **883**, a collet **885**, and a spring loaded cap **887**. Collet **885** includes a circumferential section **885'** and four legs **885***a* extending from section **885'**, each with an enlarged end **885***b*. Each leg **885***a* has a flat, inner facing surface **885***c* that together define a square opening **886**. Drive rod **880** has a coupling member **889** with four flat sides **889***a*. Coupling member **889** is received within opening **886** with flat sides **889***a* aligned with surfaces **885***c* such that when closed, torque generator **882** and drive rod **880** are rotationally locked.

Handle **883** defines a bore **881'** in which a pin **882'** is received, and a larger diameter bore **883'** in which pin **882'**, collet **885** and a spring **887'** are received. Cap **887** is biased distally by spring **887'**. Pin **882'** is press fit into bore **881'** and into circumferential section **885'** of collet **885**. To attach drive rod **880** to torque generator **882**, cap **887** is moved proximally against the force of spring **887'**, which allows legs **885***a* to be flexed outward permitting coupling member **889** to be positioned in opening **886**. The user releases cap **887**, and spring **887'** acts to move cap **887** distally closing legs **885***a* around coupling member **889**. Distal motion of cap **887** is limited by contact of a shelf **880'** of cap **887** against enlarged leg ends **885***b*.

Tissue engaging member **740'** is preferably a single use disposable product supplied sterile to the user. Member **740'** can be loaded into the instrument from the distal end of the instrument and then attached to torque generator **882**. This preserves the sterility of the distal end of member **740'**.

Referring to FIG. **14**A, in an alternative embodiment, rather than stabilizing tissue with sprung sheath **866** of FIG. **12**A, positioned within coil **860** is a solid needle **881***a*. Needle **881***a* extends from coupling member **864**. Needle **881** a facilitates the initial engagement of coil **860** with the tissue, and is particularly applicable to situations in which coil **860** approaches the tissue surface at an angle. Referring to FIGS. **14**B and **14**C, rather than a solid needle, positioned within coil **860** and extending to the proximal end of the tissue engagement member is a matter injector needle **881***b*, which can be advanced through coil **860**. Matter injector needle **881***b* has a metal tip **881***c* on a flexible, plastic tube **881***d*. Coupling member **864**, coupling member **889**, pin **882'**, and hand grip **883** define aligned through bores that slidably receive needle **881***b*. Needle **881***b* replaces drive rod **880**, and drive shaft **862** extends the length of the instrument.

Matter injector needle **881***b* can be used in "bulking" procedures to augment tissue in a selected region by injecting a biocompatible material, such as described, e.g., in U.S. Pat. No. 5,336,263 to Ersek et al., hereby incorporated by reference in its entirety. In use, coil **860** acts to anchor needle **881***b* in the tissue to counteract pressure created by the material injection, which would tend to push needle **881***b* out of the tissue. For matter injection, the tissue engaging instrument can be used through a working channel of an endoscope, or in conjunction with instrument **700**. Alternatively, the wire forming coil **860** can define a lumen and matter injected through the wire lumen.

Referring to FIGS. **15**A and **15**B, an alternative third tissue engagement member **740'"** includes an elongate member **892** that passes through a working channel of instrument **700** and a pair of pincers **893***a* and **893***b* pivotably mounted at a pivot **895** to the distal end **892***a* of elongate member **892**. Pincers **893***a* and **893***b* each include a respective pincer tip **891***a* and **891***b* suitable for piercing tissue. Pincers **893***a* and **893***b* are actuated, e.g., by one or more guidewires (not shown), as is described, e.g., in U.S. Pat. No. 5,613,499 to Palmer et al., hereby incorporated by reference in its entirety.

Pincers **893***a* and **893***b* are generally arcuate in shape with pincer tips **891***a* and **891***b* oriented substantially normal to lines L1, L2 defined by pivot point **895** and the end of each respective pincer tip. Pincers **893***a* and **893***b* are made from a rigid, sterilizable material capable of maintaining pincer tips **891***a* and **891***b* suitable for puncturing tissue and withstanding at least short term exposure to operating environments such as the stomach. As such, pincers **893***a* and **893***b* can be made from metals such as stainless steel and Co-Cr alloys.

Referring to FIGS. **15**C and **15**D, in operation, with pincers **893***a* and **893***b* in their opened position, the user advances tissue engagement member **740'"** into contact with a tissue surface such as a mucosal layer **894** on a muscle layer **895** in the stomach. The user then closes pincers **893***a* and **893***b* such that the pincer tips **891***a* and **891***b* penetrate through the mucosal layer **894** and into muscle layer **895**. Once the pincer tips **891***a* and **891***b* have been drawn together, the user retracts the pincers **893***a* and **893***b* from the engaged tissue using the elongate member **892**. Plication and/or bulking of the retracted tissue can follow as described elsewhere herein.

Due to the arcuate shape of pincers **893***a* and **893***b*, the initial closing of the pincers results in substantially distal translation of pincer tips **891***a*, **891***b*, with further closing of the pincers resulting in substantially transverse motion of pincer tips **891***a*, **891***b*. This distributes the retraction load applied by the pincers **893***a* and **893***b* for plication over a relatively large area of tissue, limiting the possibility of tearing the tissue during retraction.

Referring to FIGS. **16**A and **16**B, in accordance with another embodiment of the invention, an instrument **900** for reconfiguring stomach tissue includes a handle **902**, an elongated instrument shaft **904**, and a distal actuating assembly **905**. As discussed below, the configuration of assembly **905**, and the means of attachment of assembly **905** to instrument shaft **904**, substantially seals a lumen of shaft **904** that houses the actuating cables from contact with bodily fluids. As a result, only a disposable portion of assembly **905** need be supplied to the user in a sterile condition. The remainder of the instrument can simply be disinfected by manual cleaning and soaking in a disinfecting solution between procedures.

As in embodiments discussed above, instrument **900** receives gastroscope **715** and a tissue engagement member **908** (such as coil **740** or **740'** described above). Assembly **905** includes a retroflex portion **910** that is manipulated by the user to orient assembly **905** (as shown in FIG. **16**B). Handle **902** includes control knobs **912**, **914** that actuate assembly **905**, and a switch **915** that disengages a lock mechanism, as described below.

Referring to FIGS. **17**A and **17**B, shaft **904** defines a lumen **916** through which the end of gastroscope **715** protrudes. Retroflex portion **910** has a sloping curved wall section **918** against which the end of gastroscope **715** is received. When flexed, retroflex portion **910** is bent in a direction away from section **918** (arrow A). Assembly **905** further includes a coupling member **919** and an end effector **906**. Coupling member **919** includes a first portion **923** that attaches to retroflex portion **910**, and a mount **924** to which end effector **906** is pivotally mounted. End effector **906** includes jaw members **920**, **922**, each of which includes a tissue manipulating cartridge **960***a*, **960***b*, respectively, releasable mounted to a respective actuating arm **962***a*, **962***b*.

Covering retroflex portion **910** and coupling member portion **923** is a cover **910'**, and covering mount **924** and end effector **906** is a hood **1220**, discussed further below. Hood **1220** provides an atraumatic distal end for transoral placement of instrument **900**, and cover **910'** seals retroflex portion **910** and coupling member portion **923** from contact with bodily fluids.

In use, with gastroscope **715** in instrument lumen **916** and the end of the gastroscope residing in section **918**, the user advances instrument **900** transorally into the stomach. Once in the stomach, gastroscope **715** is independently manipulated to obtain the desired view. The user flexes instrument **900** (as shown in FIG. **16**B), opens jaws **920**, **922**, advances the tissue engagement member into engagement with the tissue to stabilize the tissue, closes jaws **920**, **922** such that cartridges **960***a*, **960***b* manipulate the tissue into a bulge, and deploys an implant, as described further below.

Referring to FIG. **17**C (coupling member **919** has been partially removed from FIG. **17**C for clarity), actuating arms **962***a*, **962***b* are pivotally coupled to mount **924** at pivots **963***a*, **963***b*, respectively. A pair of cables, discussed below, for opening and closing jaws **920**, **922** are coupled to the jaws via a yoke **964**. Yoke **964** has a generally H-shaped

section **965** with two legs **966***a* straddling arm **962***a*, and two legs **966***b* straddling arm **962***b*. Each arm **962***a*, **962***b* defines a slot **968***a*, **968***b*, and each leg **966***a*, **966***b* defines a through hole **970***a*, **970***b*. Received within slot **968***a* and holes **970***a* is a pin **972***a*, and received within slot **968***b* and holes **970***b* is a pin **972***b*. Slots **968***a*, **968***b* each have first and second sections **974**, **975**. Slot sections **974** are orientated at a greater angle relative to the axis of the instrument than that of slot sections **975**, for purposes described below. Yoke **964** includes a post **978** extending proximally from section **965**. Post **978** extends into coupling member **980**. Mounted to post **978** is a first pulley **982**, and mounted to coupling member **980** are two pulleys **984**, **985**, which a jaw closing cable is routed over, as described below.

Portion **923** and mount **924** of coupling member **919** have flat sides **923***a*, **924***a* and rounded sides **923***b*, **924***b*, as shown in FIG. **17**D. Rounded sides **923***b*, **924***b* define a through bore **927** for passage of the tissue engagement member. Mount **923** also defines a through bore **931** through which yoke **964** extends.

Referring to FIGS. **17**E and **17**F, located in portion **923** is a lock arm **1250** pivotally mounted at **1252**. Lock arm **1250** has a ridge **1253** with curved wall **1254** and yoke **964** defines a notch **1256** with a correspondingly shaped curved wall **1258**. After a predetermined amount of distal travel of yoke **964**, curved wall **1254** of ridge **1253** engages with curved wall **1258** of notch **1256** to limit further distal travel of yoke **964**. Lock arm **1250** is biased by a compression spring **1262** to rotate clockwise about pivot **1252** (arrow Y) such that when notch **1256** passes under lock arm **1250**, lock arm **1250** is rotated under the force of spring **1262** to engage curved walls **1254**, **1258**. Attached to lock arm **1250** is a cable **1260** for moving arm **1260** out of engagement with yoke **964** to allow further distal travel of yoke **964**.

FIG. **17**G illustrates the replaceable nature of cartridges **960***a*, **960***b*. Arms **962***a*, **962***b* each include a flat, rectangular member **1050** and a clip **1052**. Member **1050** has formations **1051**, **1053** extending from either side of member **1050**. Formations **1051** have a thin distal section **1051***a* that slopes to a wider proximal section **1051***b*, for purposes described below with reference to FIG. **46**. Cartridges **960***a*, **960***b* each include a first pair of side walls **1054**, a second pair of side walls **1056** defining slots **1056***a*, an opening **1058**, and a head **1059**. Opening **1058** is rectangular in shape, here shown square, though other shapes are suitable that have a mating contour with a flat proximal edge **1058***a*. Instead of an opening **1058**, an indentation in the cartridge that corresponds to the shape of clip **1052** can be employed. Side walls **1054**, **1056** are separated by a thin section **1057** which allows the cartridge to flex.

To attach cartridges **960***a*, **960***b* to arms **962***a*, **962***b*, respectively, the cartridge is slid over the arm with side walls **1054** aligning the cartridge to the arm. Rectangular member **1050** is received in slots **1056***a* while the cartridge flexes over clip **1052** such that clip **1052** is received within opening **1058** to lock the cartridge to the arm. To remove the cartridge, the user pushes on side walls **1054** to flex the cartridge away from clip **1052**, and the cartridge is then slid off the arm.

Referring to the exploded view of FIG. **17**H, retroflex portion **910** has a proximal mount **1060** that is, e.g., glued onto the end of shaft **904**, and a distal mount **1062** that is received within a slot **933** in mount **923**. Mounts **1062**, **923** are attached, e.g., by screws. Mount **1062** is preferably metal and coupling member **919** is preferably plastic.

Referring to FIG. **17**I, the only member of instrument **900** that extends from retroflex region **910** through the sealed section formed by cover **910'** is yoke **964**. To limit access of bodily fluids to retroflex portion **910**, coupling member portion **923** defines a space **1070** in which an o-ring **1072** is positioned to seal off through bore **931**.

Referring to FIGS. **18**–**20**, to control retroflex portion **910** and end effector **906**, knobs **912**, **914** interface with a series of cables **925***a*, **925***a'*, **925***b*, **925***c* (FIG. **20**) through a gear block mount **926** located in handle **902**. Block mount **926** defines through bores **928***a*, **928***a'*, **928***b*, **928***c* within each of which a rack **930***a*, **930***a'*, **930***b*, **930***c*, respectively, is located. Each rack **930***a*, **930***a'*, **930***b*, **930***c* is connected to a respective cable **925***a*, **925***a'*, **925***b*, **925***c*, as described below, and has a flat side **932** defining teeth **934**. Referring particularly to FIGS. **21**A and **21**B, associated with racks **930***a*, **930***a'* is a pinion **936***a*, and associated with each rack **930***b*, **930***c* is a respective pinion **936***b*, **936***c*. Racks **930***a*, **930***a'* are on opposite sides of pinion **936***a*, and racks **930***b*, **930***c* are on opposite sides of pinions **936***b*, **936***c*. Pinion **936***c* is preferably twice the diameter of pinion **936***b*, for reasons discussed below. Pinion **936***a* is driven by a reduction gear set **937**, **939**. Gear **939** is mounted to a shaft **942** that is integral with retroflex knob **912**. Pinions **936***b*, **936***c* are mounted to a shaft **944** that is integral with jaw actuating knob **914**, and passes through shaft **942**.

To manipulate retroflex portion **910**, the user turns knob **912**, which causes shaft **942** and pinion **936***a* to turn. Since racks **930***a*, **930***a'* are on opposite sides of shaft **946**, rotation of pinion **936***a* causes opposed linear motion of racks **930***a*, **930***a'*, which moves cables **925***a*, **925***a'* to flex and straighten retroflex portion **910**, as described further below. To manipulate the jaws, the user turns knob **914**, which causes shaft **946** and pinions **936***b*, **936***c* to rotate. Since racks **930***b*, **930***c* are on opposite sides of shaft **946**, rotation of pinions **936***b*, **936***c* causes opposed linear motion of racks **930***b*, **930***c*, which moves cables **925***b*, **925***c* to open and close the jaws, as described further below. Associated with knob **912** is a tension adjustment knob **912***a*, and associated with knot **914** is a tension adjustment lever **914***a*, as is well known in the art.

Referring to FIGS. **20** and **22**, mounted over each cable **925***a*, **925***a'*, **925***b*, **925***c* is a cable housing **947***a*, **947***a'*, **947***b*, **947***c*, respectively, and a cable housing adjustment screw **948***a*, **948***a'*, **948***b*, **948***c*, respectively. Cable housing adjustment screws **948***a*, **948***a'*, **948***b*, **948***c* are threadably received within respective block through bores **928***a*, **928***a'*, **928***b*, **928***c* (as shown in FIG. **19**). Rotation of screws **948***a*, **948***a'*, **948***b*, **948***c* translates cable housings **947***a*, **947***a'*, **947***b*, **947***c* distally and proximally along respective cables **925***a*, **925***a'*, **925***b*, **925***c* to provide an optimal working length for transmitting actuating forces. Cables **925***a*, **925***a'*, **925***b*, **925***c* move freely through their respective housings and screws.

On the opposite side of racks **930***a*, **930***a'*, **930***b*, **930***c* from screws **948***a*, **948***a'*, **948***b*, **948***c* are stops **949***a*, **949***a'*, **949***b*, **949***c* received within respective block through bores **928***a*, **928***a'*, **928***b*, **928***c*. Stops **949***a*, **949***a'*, **949***b*, **949***c* limit the travel of racks **930***a*, **930***a'*, **930***b*, **930***c*, respectively.

Referring particularly to FIG. **22**, cable **925***a* is received within a bore **950** defined in rack **930***a*. Cable **925***a* extends through a hole **952** defined in an end wall **954** of rack **930***a* into bore **950**. Located within bore **950** is a spring **956**. Cable **925***a* extends through spring **956** and has an enlarged terminal end **957** that maintains the position of cable **925***a* relative to spring **956**. Spring **956** acts to continually exert a slight tensile force upon cable **925***a* to keep the cable taught. Cables **925***b*, **925***c* are likewise coupled to racks **930***b*, **930***c*, respectively.

Referring again to FIG. **19**, attached to block mount **926** is a slide lever **1400** mounted within a bracket **1402**. Switch **915** is received within an opening **1404** in lever **1400** such that movement of switch **915** moves lever **1400**. Lever end **1406** defines a diagonal slot **1408** in which a pin **1410** is received. Pin **1410** is attached to a stop member **1412** that contacts a stop **1414** after jaw closing rack **930***b* has traveled a pre-set distance. Movement of lever **1400** in the direction of arrow X causes pin **1410** and stop member **1412** to rotate about the axis of stop member **1412**, disengaging stop member **1412** from stop **1414** to allow further movement of rack **930***b*. Cable **1260** attached to lock arm **1250** is attached at its opposite end to switch **915**. When switch **915** is moved in the direction of arrow X, cable **1260** moves lock arm **1250** to disengage lock arm **1250** (FIG. **17**E) from yoke **964** (discussed further below with reference to FIG. **23**). Bracket **1402** can be adjusted to fine tune the positioning of switch **915** relative to pin **1410** and lock arm **1250**.

As shown in FIGS. **23**A–**23**D, jaw closing cable **925***b* is wound around pulleys **984** and **982**, and terminates at a fixed point **986** connected to distal mount **1062** (FIG. **17**G). Jaw opening cable **935***c* is connected in a fixed relationship to post **978**. To close jaws **920**, **922**, the user turns knob **914** in the direction of arrow, A (FIG. **20**), which moves cable **925***b* in the direction of arrow, B, and permits slack in cable **925***c* allowing yoke **965** to move distally, in the direction of arrow, C. Due to the 2:1 ratio between pinions **936***b* and **936***c*, cable **925***b* moves twice the distance of cable **925***c*. (This is required due to the routing of cable **925***b* around pulleys **982**, **984**.) Pins **972***a*, **972***b* slide along slots **968***a*, **968***b* causing jaws **920**, **922** to close. To open the jaws, the user turns knob **914** in the direction opposite arrow, A, which tensions cable **925***c* and permits slack in cable **925***b*. The tension on cable **925***c* moves yoke **964** proximally, arrow, E, opening jaws **920**, **922**.

Due to the orientation of slot sections **974**, **975**, during the initial stage of jaw closing (FIG. **23**B) when the yoke is sliding along slot section **974**, there is a greater ratio of jaw closing for the distance the piston moves than during the later stage (FIG. **23**C) when the yoke is sliding along slot section **975**. There provides faster jaw closing with lower mechanical advantage when less closing force is needed (because the jaws are not yet contacting the tissue), and slower jaw closing with higher mechanical advantage when more closing force is needed as the jaws grasp the tissue and pierce through the tissue. After the jaws have reached the position of FIG. **23**C, pin hits stop in handle and lock arm notch **1254** and yoke notch **1256** engage to limit further closing of the jaws. The user then pushes switch **915** proximally to move stop member out of the way and to disengage lock arm **1250** from yoke **964**, this permits knob **914** to be further turned to completely close the jaws and deploy the implant (FIG. **23**D).

Referring to FIGS. **24**A–**24**D, retroflex portion **910** includes a series of links **990** that are hinged together with pins **991**. Each link **990** includes a generally U-shaped body **992** with a first section **992***a* defining a U-shaped opening and second section **992***b* defining a larger U-shaped opening. Extending from body **992** are two mating prongs **994**. Body **992** defines two transverse holes **996** (only one hole **996** being shown in FIG. **24**B), and each prong **994** defines a transverse hole **998**. When two links **990** are mated, prongs **994** lie within the U-shaped opening defined by section **992***b*. Holes **996**, **998** are aligned, and pin **991** is passed through holes **996**, **998** to join the two links. Body **992** has a side wall **1000** with a portion **1001** of the side wall set at an angle to allow the joined links to flex. Links **990** also define axial holes **1003**, **1004** for receiving cables **924***a*, **924***a*'. Cables **924***a*, **924***a*' terminate on mount **1062**. Pulling cable **924***a* flexes portion **910**, and pulling cable **924***a*' straightens portion **910**. Cover **910**' (FIG. **17**A) covers the links.

Referring also to FIG. **25**, in addition to lumen **916** for receiving gastroscope **715**, shaft **904** and mount **1060** define a lumen **1010** for receiving tissue engaging member **908**, a lumen **1012** for receiving flexing cable **924***a*, a lumen **1014** for receiving straightening cable **924***a*', a lumen **1016** for receiving closing cable **925***b*, a lumen **1018** for receiving opening cable **925***c*, a lumen **1020** for receiving locking cable **1260**, and an extra lumen **1022** if needed. Mount **1062** includes holes **1024** and **1026** for passage of cables **925***b*, **925***c*, respectively, a hole **1028** at which the end of closing cable **925***b* terminates, and a hole **1030** for passage of locking cable **1260**.

Tissue engaging member **908** is located in the U-shaped openings defined by U-shaped bodies **992** in retroflex portion **910**. Pins **991** are centered along the central axis of tissue engaging member **908** such that when flexed, tissue engaging member **908** is flexed along is central axis. Tissue engaging member **908** is surrounded by a sheath **927***a* (FIGS. **17**D and **18**). Sheath **927***a* runs from handle inlet **1002** to the proximal end of through bore **927** in coupling member **919**. Sheath **927***a* is sealed at one end to handle **902** and at the other end to coupling member **919**. This effectively seals the remainder of the instrument from contact with fluid that enters tissue engaging member **908**. Shaft lumen **906** likewise is lined with a sheath **906**' that seals the remainder of the instrument from contact with bodily fluids that enter lumen **906**.

Referring to FIGS. **26** and **27**, end effector **906** is configured for deployment of a tissue fixation member upon closing of jaws **920**, **922** without requiring further actuation. Cartridge **960***b* of jaw **922** includes tissue passing tubes **1120***a*, **1120***b*. Removably coupled to each tube **1120***a*, **1120***b* is a tissue fixation bar **824***a*, **824***b* having a pointed tip **1122** for penetrating tissue. Each tube **1120***a*, **1120***b* defines a through bore **1124**, and each bar **824***a*, **824***b* has a hub **1126** that fits within bore **1124**. Tubes **1120***a*, **1120***b* and bars **824***a*, **824***b* have the same outer diameter for ease of penetrating tissue. Bars **824***a*, **824***b* each define a through hole **1128** for receiving, for example, a suture (not shown), which is passed through both holes and tied off to itself. Bars **824***a*, **824***b* can be coupled to tubes **1120***a*, **1120***b*, respectively by a press fit, crimp, or spot laser welding. Crimping can be done around the entire perimeter of the bar, at two (opposing) sides of the bar, or at a single point along the perimeter of the bar.

Bars **824***a*, **824***b* are configured to detach from tubes **1120***a*, **1120***b* under the force applied by the closing of jaws **920**, **922**. Referring to FIGS. **26** and **28**A–**28**C, cartridge **960***a* defines two arcuate walls **1130** against which bars **824***a*, **824***b* are positioned upon closing of jaws **920**, **922**. As shown in FIG. **28**C, upon closure of jaws **920**, **922**, the arcuate walls **1130** apply a lateral force (i.e., substantially normal to the long axis of the tubes) to bars **824***a*, **824***b*, which causes the bars to be released from the respective tubes. When jaws **920**, **922** are opened, and instrument **900** pulled proximally, bars **824***a*, **824***b* and parts **732**, **734** (discussed above with reference to FIG. **8**) of the tissue fixation member are released from jaws **920**, **922**.

Referring to FIGS. **29**A and **29**B, jaws **920**, **922** are covered with hood **1220** formed from halves **1222** and **1224** connected at a region **1226** and defining a seam **1228**

therebetween. Each half **1222**, **1224** covers a respective jaw **920**, **922**. When the jaws are closed, as shown in FIG. **29**A, hood **1220** provides an atraumatic distal end for delivery through the esophagus. When the jaws are opened, as shown in FIG. **29**B, halves **1222**, **1224** separate at seam **1228**. Hood **1220** limits trauma to the tissue during transoral insertion of the instrument and eliminates the need for an outer sheath extending the length of the instrument.

Referring to FIG. **30**, handle **902** defines an inlet **1002** through which gastroscope **715** is introduced. Located at inlet **1002** is a seal **1004** for providing a hermetic seal between handle **902** and gastroscope **715**. Seal **1004** has a sealing area **1006** of restricted diameter, and an alignment area **1008** of restricted diameter spaced about 10 mm from area **1006**. Area **1006** has a diameter of about 9 mm, which is about the same or slightly smaller than (about 90% of) the diameter of gastroscope **715** (typically about 10 mm). Area **1008** has a diameter of about 11 mm, which is also about the same or slightly larger than (about 110% of) the diameter of gastroscope **715**. Alignment area **1008** provides support for gastroscope **715** to maintain a hermetic seal at sealing area **1006** during motion of the gastroscope. Seal **1004** is made from, e.g., rubber or other deformable material.

Other embodiments are within the scope of the following claims.

For example, referring to FIG. **31**, instead of curved surfaces **1130** of FIG. **28**, cartridge **960***a*' includes a spring member **1130**'. When bars **824***a*, **824***b* contacts members **1130**', member **1130**' deflects forming a curved surface resulting in a lateral force being applied to bars **824***a*, **824***b* that acts to dislodge the bars from needles **1120***a*, **1120***b*.

Referring to FIG. **32**, in an alternative embodiment, tubes **1120**' include a pair of radially opposed slots **1132** that impart flexibility to end **1133** of the tube to aid in release of the bars from the tubes. Bars **824**' can include a pair of guide nubs **1134** received in slots **1132** to radially orients bars **824**' relative to tubes **1120**'. Referring to FIG. **33**, bars **824**" include a bump or undercut **1136** that determine the force needed to remove the bars from the tubes. The tubes can be formed from plastic and molded as an integral component of the cartridges, and the bars can be insert molded into the tubes. Referring to FIG. **34**, bars **824**'" are connected to tubes **1120**" by a weak area **1137** of decreased diameter that breaks upon application of lateral force to bars **824**'".

Referring to FIGS. **35**A and **35**B, instead of bars attached by suture, the tissue fixation member includes bars **1150** connected by a flexible spanning member **1152**. Bars **1150** define through bores **1154** and are received on members **1156** having tissue penetrating tips **1158**. Members **1156** replace tubes **1120**.

Referring to FIG. **36**A, to aid in insertion of instrument **900** through the esophagus, end effector **906** and retroflex portion **910** are partially covered with an atraumatic hood **1100**. Hood **1100** has a tapered distal end **1102** terminating in a small diameter lead portion **1104**. Hood **1100** includes an opening **1106** through which end effector **906** and retroflex portion **910** are deployed, in the direction of arrow, D, after insertion of instrument **900** through the esophagus. Distal end **1102** defines a channel **1105** extending from lead portion **1104** to a slot **1107**. Instrument **900** can be introduced transorally over a guidewire (not shown) by threading the guidewire through channel **1105** entering at lead portion **1104** to exiting at slot **1107**. Hood **1100** is made from, e.g., metal, plastic, or elastomeric materials such as rubber, polyurethane or silicone.

As shown in FIG. **36**B, to further ensure trauma to tissue as the instrument is introduced transorally is avoided, a pair of flaps **1109** are provided covering assembly **905**. The flaps part when retroflex portion **910** is deployed.

Referring to FIG. **37**, rather than a hood covering end effector **906**, placed between jaws **920**, **922** is volume-filling bullet **1200** that creates a relatively smooth surface at the distal end of the instrument to facilitate insertion of the instrument into a patient. Bullet **1200** defines a through hole **1200***a* for delivery over a guidewire. Volume-filling bullet **1200** can be dissolvable in the operating environment, retrievable from the operating environment, or abandonable in the operating environment. For example, the guidewire can have a tip with a larger diameter than hole **1200***a* such that bullet **1200** is retained on the guidewire and removable therewith.

Referring to FIG. **38**, in another embodiment, a hood **1220**' includes halves **1222**', **1224**' that are connected to mount **924** at pivots **1230**. When the jaws are opened, halves **1222**', **1224**' pivot about pivots **1230** to separate at seam **1228**'. In FIG. **39**, halves **1222**", **1224**" of a hood **1220**" include spring beams **1240** joined in a region **1226**'. When the jaws are opened, halves **1222**", **1224**" separate at seam **1228**" and spring beams **1240** deform.

Alternatively, as shown in FIG. **40**, to provide an atraumatic distal end, an end cap **1242** is placed over the jaws. End cap **1242** can be removed by pushing it off distally using the tissue engagement member, can be dissolvable (e.g., made out of starch or gelatin), or can "break-away." when the jaws are opened. Providing a perforation along the length of cap **1242** can aid in break-away. After removal, cap **1242** can be abandoned in the operating environment, where it is dissolved or passed, or it can be retained by a guidewire so that it is withdrawn when the instrument is withdrawn.

Referring to FIGS. **41**A and **41**B, in an alternative embodiment, an end effector **906**' includes jaw members **920**', **922**', each of which includes a tissue manipulating cartridge **960***a*', **960***b*', respectively, releasable mounted to a respective actuating arm **962***a*', **962***b*'. Jaw **922**' contains a pusher rods **814***a*, **814***b* for deploying bars **824***a*, **824***b* as described above with reference to FIG. **5**. However, rather than employing a separate mechanism for actuating pusher rods **814***a*, **814***b*, pusher rods **814***a*, **814***b* are actuated by yoke **964**. Each arm **962***a*', **962***b*' defines a slot **968***a*', **968***b*" having a first arcuate section **974**', a second generally linear, angled section **975**', and a third generally linear, parallel section **976**'. Movement of yoke **964** along slot sections **974**' and **975**' closes jaws **920**', **922**'. To deploy tissue fixation device **730** (FIG. **2**), movement of yoke **964** along section **976**' of slots **968***a*, **968***b* moves pusher rods **814***a*, **814***b* distally advancing bars **824***a*, **824***b* out of tissue penetrating tips **818***a*, **818***b* to deploy fixation device **730**, as described above with reference to FIGS. **4**A and **4**B.

Referring to FIG. **42**, an alternative tissue fixation member for use with the embodiments of FIGS. **2** and **41**, includes bars **1150**' connected by a flexible spanning member **1152**.' Bars **1150**' replace bars **824***a*, **824***b*.

The instrument embodied in FIGS. **43**–**45** are configured to allow one person to control both the gastroscope and the tissue reconfiguring instrument. Referring particularly to FIG. **43**, an instrument **1300** for reconfiguring tissue includes a standard gastroscope **715** and a tissue manipulator **1304** mounted to gastroscope **715**. Tissue manipulator **1304** includes a control mount **1306** which the user mounts to gastroscope tube **1307** by, e.g., a friction fit. Control mount **1306** includes knobs **912**, **914**, described above. End effector **906** and retroflex portion **910** of assembly **905** are mounted to a sleeve **1308** through which gastroscope tube **1307**

extends. Sleeve **1308** defines conduits for the control cables as described above. Connecting control mount **1306** and sleeve **1308** is a flexible conduit **1310** enclosing the various cables for controlling end effector **906** and retroflex portion **910**, as discussed above. Sleeve **1308** includes a hand grip **1312**. Conduit **1310** permits axial movement of gastroscope **715** relative to tissue manipulator **1304**. In use, the operator holds the gastroscope handle with one hand, and operates all the controls and manipulates grip **1312** with the other hand, permitting a single operator to control all functions.

Referring to FIG. **44**, an instrument **1320** for reconfiguring tissue includes a standard gastroscope **715** to which the user mounts end effector **906**. Cables for actuating the jaws are attached to a jaw control mount **1324**. The cables are received in the standard biopsy channel **1322'** of the gastroscope. Retroflexing action is provided by gastroscope **715** and is controlled by the gastroscope controls. Jaw control mount **1324** includes knob **914** for actuating the jaw control cables. In the embodiment of FIG. **45**, rather than mounting the tissue reconfiguring instrument to a standard gastroscope, an integral instrument **1330** includes a knob **914** mounted directly to gastroscope **1330**. The control cables for actuating the jaws are integrated with the gastroscope control cables. The tissue engaging member, e.g., member **740'** of FIG. **12**, is introduced through the gastroscope channel **1322'**.

Referring to FIGS. **46**A and **46**B, cartridges **960***a*, **960***b* are supplied to the medical personnel in a holder **1450**. Holder **1450** includes a base section **1452** having a first side **1453***a* for receiving head **1059** of cartridge **960***a*, and a second side **1453***b* for receiving head **1059** of cartridge **960***b*. Base section **1452** defines an opening **1455** where tubes **1120***a*, **1120***b* are located. Extending from either side of base section **1452** are two sets of detents **1454** that are positioned on either side of the cartridge head **1059**. Extending proximally from base section **1452** is a fin **1456** with spring beams **1458** on either side of fin **1456** on both sides of base section **1452**. Located on either side of spring beams **1458** are guide rails **1460**. Between the spring beams is a slot **1461** and between each spring beam **1458** and guide rail **1460** is a slot **1463**. Holder **1450** includes finger grips **1462** for ease of handling. Hood **1220** is provided to the user with holder **1450**. To allow the user to hold finger grips **1462**, finger grips **1462** are attached to the remainder of the holder by a thin section **1462***a* over which the slot in the hood is positioned.

To load cartridges **960***a*, **960***b* in holder **1450**, each cartridge is in turn positioned over base section **1452** with thin section **1057** of the cartridge aligned with slot **1461**. By pushing down on the cartridge, spring beams **1458** are forced apart and thin section **1057** snaps into place in slot **1461**, with spring beams **1458** holding the cartridge in place. Cartridge head **1059** is located between detents **1454**, and side walls **1056** are partially within slots **1463** to align the cartridge and help hold the cartridge in position. With base section **1452** located between cartridges **960***a*, **960***b*, the cartridges are spaced such that the implant will not deploy (corresponding to the position shown in FIG. **23**C).

Referring also to FIG. **46**C, to attach cartridges **960***a*, **960***b* to arms **962***a*, **962***b*, respectively, while holding finger grips **1462**, the user slides the cartridges over the arms (with the arms positioned as shown in FIG. **23**C). Initially, formation **1051** on the inner surfaces of the arms slide between spring beams **1458** forcing the spring beams apart. Further sliding of the cartridge over the arms, positions rectangular member **1050** under arms **1056** and locates clip **1052** in hole **1058**. The cartridges are now attached to the arms. Because spring beams **1458** have been forced apart by formation **1051**, holder **1450** can now be released from cartridges **960***a*, **960***b* by opening the jaws and the instrument is ready for use.

Holder **1450** is preferably formed from plastic, and holder **1450** with cartridges **960***a*, **960***b*, hood **1220** and the implant are supplied to the surgical personnel in a sterile condition.

FIGS. **47**A–**47**F are various views of handle **902**.

What is claimed is:

1. A medical device, comprising:

first and second members each including a body having a first attachment portion and a second attachment portion,

the first attachment portion having a proximal portion, a distal portion, a first wall between the proximal and distal portions, and a second wall between the proximal and distal portions, wherein the first wall defines a slot therein and the second wall defines an opening therein having a straight, proximal edge, the slot and the opening for releasably attaching the body to a distal portion of a medical instrument such that the body can be exchanged with a replacement body,

the second attachment portion being configured to releasably receive an implant.

2. The medical device of claim **1** wherein the first attachment portion includes a flexing section between the side wall and the mating contour.

3. The medical device of claim **1** wherein the second portion includes tubes configured to pass through tissue.

4. A medical device, comprising:

an implant including a suture thread, and

first and second members configured to releasably attach to a distal portion of a medical instrument such that the members can be exchanged with replacement members, at least one of the members being configured to releasably receive the implant for delivery of the implant to a treatment site.

5. The medical device of claim **4** wherein the members each include a wall defining a slot for attaching the member to the medical instrument.

6. The medical device of claim **4** wherein the members each include a mating contour having a flat, proximal edge for attaching the member to the medical instrument.

7. The medical device of claim **6** wherein the mating contour comprises an opening.

8. The medical device of claim **4** wherein the members each include a flexing section.

9. The medical device of claim **4** wherein the members each include tubes configured to pass through tissue to which the implant is coupled.

10. The medical device of claim **4** wherein the suture has a predetermined length.

11. The medical device of claim **4** wherein the members and the implant are configured for remote deployment of the implant at the treatment site with the implant maintaining a pre-deployment shape.

12. A medical instrument, comprising:

a flexible shaft,

an implant including a suture thread, and

first and second members coupled to a distal end of the shaft and configured to releasably receive the implant for remote deployment of the implant at the treatment site with the implant maintaining a pre-deployment shape.

13. A medical device, comprising:

a body sized to be entirely received within an organ of a patient, the body having a first portion configured for releasable coupling to an actuating member having a width dimension, a thickness dimension, and a length dimension, the width dimension being transverse to a direction of actuation of the actuating member, and a second portion configured to receive an implant to be deployed within the patient, the first portion including:

an opening for receiving the actuating member, and

a slot configured to receive the actuating member, the slot being spaced from the opening in a direction corresponding to the width dimension of the actuating member.

14. An apparatus comprising:

first and second members configured to be operable at a distal portion of a flexible device, the first member including an implant having two rigid portions coupled by a flexible portion, the first and second members configured to interact to deploy the implant in a patient such that the rigid portions are deployed at a fixed relative distance predetermined by at least one of the members.

15. The apparatus of claim 14 wherein the flexible portion is formed of a material different than that of the rigid portions.

16. The apparatus of claim 14 wherein the flexible portion comprises suture.

17. The apparatus of claim 14 wherein the rigid portions each define a hole for receiving the flexible portion.

18. The apparatus of claim 14 wherein the second member includes a part of the implant.

19. The apparatus of claim 14 wherein the first member defines channels for receiving the rigid portions at the predetermined relative distance.

20. The apparatus of claim 19 wherein the first member further comprises tissue piercing elements defining the channels.

21. The apparatus of claim 20 wherein the second member defines apertures for receiving the tissue piercing elements.

22. The apparatus of claim 14 wherein the rigid portions are coupled to the first member at the predetermined fixed relative distance.

23. The apparatus of claim 14 wherein the rigid portions are configured for piercing tissue.

24. The apparatus of claim 14 wherein the rigid portions are frangibly connected to the first member.

25. The apparatus of claim 14 wherein the rigid portions are connected to the first member by one of a press fit, crimp, or spot laser welding.

26. The apparatus of claim 14 wherein the second member is configured to separate the rigid portions from the first member.

27. An apparatus comprising:

a member configured to pierce body tissue and including an implant having rigid portions connected by a flexible portion, the member configured to be operable at a distal portion of a flexible device to deploy the rigid portions of the implant through the body tissue at a fixed relative distance predetermined by the member.

28. The apparatus of claim 27 wherein the flexible portion is formed of a material different than that of the rigid portions.

29. The apparatus of claim 27 wherein the flexible portion comprises suture.

30. The apparatus of claim 27 wherein the rigid portions each define a hole for receiving the flexible member.

31. The apparatus of claim 27 further comprising a second member including a part of the implant.

32. The apparatus of claim 27 wherein the fixed member defines channels for receiving the rigid portions at the predetermined fixed relative distance.

33. The apparatus of claim 32 wherein the member further comprises elements defining the channels, the elements being configured to pierce body tissue.

34. The apparatus of claim 33 further comprising a second member defining apertures for receiving the elements.

35. The apparatus of claim 27 wherein the rigid portions components are connected to the member at the predetermined relative distance.

36. The apparatus of claim 27 wherein the rigid portions are configured to pierce body tissue.

37. The apparatus of claim 27 wherein the rigid portions are frangibly connected to the member.

38. The apparatus of claim 27 wherein the rigid portions are connected to the member by one of a press fit, crimp, or spot laser welding.

39. The apparatus of claim 27 further comprising a second member configured to separate the rigid portions from the first member.

40. An apparatus comprising:

two tissue piercing elements,

an implant including rigid portions connected by a flexible portion, the rigid and flexible portions being made from different materials, wherein the tissue piercing elements are configured to deploy the rigid portions of the implant through body tissue, the tissue piercing elements defining channels for receiving the rigid portions.

41. An apparatus comprising:

two tissue piercing elements,

an implant including rigid portions connected by a flexible portion, the rigid and flexible portions being made from different materials, wherein the tissue piercing elements are configured to deploy the rigid portions of the implant through body tissue, the rigid portions forming a distal portion of the tissue piercing elements.

42. The apparatus of claim 41 wherein the rigid portions are frangibly connected to the remainder of the tissue piercing elements.

43. The apparatus of claim 41 wherein the rigid portions are connected to the remainder of the tissue piercing elements by one of a press fit, crimp, or spot laser welding.

44. An apparatus comprising:

two tissue piercing elements, and

an implant including rigid portions connected by suture, the rigid portions forming a distal portion of the tissue piercing elements and being frangibly connected to the remainder of the tissue piercing elements, wherein the tissue piercing elements are configured to deploy the rigid portions of the implant through body tissue.

45. An apparatus comprising:

two tissue piercing elements, and

an implant including rigid portions connected by suture, the rigid portions forming a distal portion of the tissue piercing elements and being connected to the remainder of the tissue piercing elements by one of a press fit, crimp, or spot laser welding, wherein the tissue piercing elements are configured to deploy the rigid portions of the implant through body tissue.

46. A medical device, comprising:

first and second members each including a body having a first attachment portion and a second attachment portion,

the first attachment portion including a member with a side wall defining a slot and a mating contour having a straight, proximal edge, the slot and the mating contour for releasably attaching the body to a distal portion of a medical instrument such that the body can be exchanged with a replacement body,

the second attachment portion including tubes configured to pass through tissue and being configured to releasably receive an implant.

47. A medical device, comprising:

an implant including a suture, and

first and second members configured to releasably attach to a distal portion of a medical instrument such that the members can be exchanged with replacement members, at least one of the members being configured to releasably receive the implant for delivery of the in plant to a treatment site, the members each including tubes configured to pass through tissue to which the implant is coupled.

48. An apparatus comprising:

first and second members configured to be operable at a distal portion of a flexible device, the first member including an implant having two rigid portions coupled by at flexible portion, the first and second members configured to interact to deploy the implant in a patient such that the rigid portions are deployed at a predetermined relative distance, wherein the first member defines channels for receiving the rigid portions at the predetermined relative distance.

49. The apparatus of claim **48** wherein the first member further comprises tissue piercing elements defining the channels.

50. The apparatus of claim **49** wherein the second member defines apertures for receiving the tissue piercing elements.

51. An apparatus comprising:

first and second members configured to be operable at a distal portion of a flexible device, the first member including an implant having two rigid portions coupled by a flexible portion, the rigid portions being configured for piercing tissue, the first and second members configured to interact to deploy the implant in a patient such that the rigid portions are deployed at a predetermined relative distance.

52. An apparatus comprising:

first and second members configured to be operable at a distal portion of a flexible device, the first member including an implant having two rigid portions coupled by a flexible portion, the rigid portions being frangibly connected to the first member, the first and second members configured to interact to deploy the implant in a patient such that the rigid portions are deployed at a predetermined relative distance.

53. An apparatus comprising:

first and second members configured to be operable at a distal portion of a flexible device, the first member including an implant having two rigid portions coupled by a flexible portion, the rigid portions being connected to the first member by one of a press fit, crimp, or spot laser welding, the first and second members configured to interact to deploy the implant in a patient such that the rigid portions are deployed at a predetermined relative distance.

54. An apparatus comprising:

first and second members configured to be operable at a distal portion of a flexible device, the first member including an implant having two rigid portions coupled by a flexible portion, the first and second members configured to interact to deploy the implant in a patient such that the rigid portions are deployed at a predetermined relative distance, wherein the second member is configured to separate the rigid portions from the first member.

55. An apparatus comprising:

a member configured to pierce body tissue and including an implant having rigid portions connected by a flexible portion, the member configured to be operable at a distal portion of a flexible device to deploy the rigid portions of the implant through the body tissue at a predetermined relative distance, wherein the first member defines channels for receiving the rigid portions components at the predetermined relative distance.

56. The apparatus of claim **55** wherein the first member further comprises elements defining the channels, the elements being configured to pierce body tissue.

57. The apparatus of claim **56** wherein the second member defines apertures for receiving the elements.

58. An apparatus comprising:

a member configured to pierce body tissue and including an implant having rigid portions connected by a flexible portion, the rigid portions being configured to pierce body tissue, the member configured to be operable at a distal portion of a flexible device to deploy the rigid portions of the implant through the body tissue at a predetermined relative distance.

59. An apparatus comprising:

a member configured to pierce body tissue and including an implant having rigid portions connected by a flexible portion, the rigid portions being frangibly connected to the member, the member configured to be operable at a distal portion of a flexible device to deploy the rigid portions of the implant through the body tissue at a predetermined relative distance.

60. An apparatus comprising:

a member configured to pierce body tissue and including an implant having rigid portions connected by a flexible portion, the rigid portions being connected to the first member by one of a press fit, crimp, or spot laser welding, the member configured to be operable at a distal portion of a flexible device to deploy the rigid portions of the implant through the body tissue at a predetermined relative distance.

61. An apparatus comprising:

a member configured to pierce body tissue and including an implant having rigid portions connected by a flexible portion, the member configured to be operable at a distal portion of a flexible device to deploy the rigid portions of the implant through the body tissue at a predetermined relative distance, and

a second member configured to separate the rigid portions from the first member.

* * * * *