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Balbierz et al.

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(54) **ENDOSCOPIC PLICATION DEVICES AND METHODS**

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CPC ... A61B 17/068; A61B 17/072; A61B 17/115; A61B 17/0218; A61B 2017/306; A61B 2017/00827; A61B 2017/07214
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

1,408,865 A 3/1922 Cowell
3,663,965 A 5/1972 Lee et al.
(Continued)

FOREIGN PATENT DOCUMENTS

CH 680263 A5 7/1992
EP 0775471 5/1997
(Continued)

OTHER PUBLICATIONS

Stecco, K. et al., "Trans-Oral Plication Formation and Gastric Implant Placement in a Canine Model", Stecco Group, San Jose and Barosense, Inc., Redwood City, California (2004).
(Continued)

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(57) **ABSTRACT**

Described herein are endoscopic plicators passed transorally into the stomach and used to plicate stomach tissue by engaging tissue from inside of the stomach and drawing it inwardly. In the disclosed embodiments, the tissue is drawn inwardly into a vacuum chamber, causing sections of serosal tissue on the exterior of the stomach to be positioned facing one another. The disclosed plicators allow the opposed sections of tissue to be moved into contact with one another, and preferably deliver sutures, staples or other means for maintaining contact between the tissue sections at least until serosal bonds form between them. Each of these steps may
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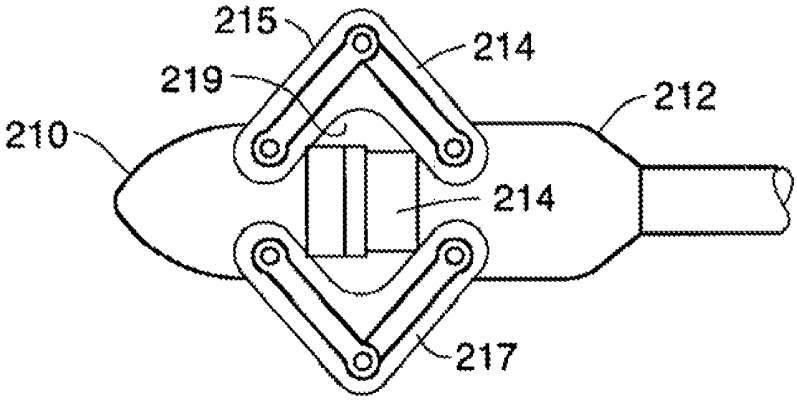

be performed wholly from the inside of the stomach and thus can eliminate the need for any surgical or laparoscopic intervention. After one or more plications is formed, medical devices may be coupled to the plication(s) for retention within the stomach.

13 Claims, 36 Drawing Sheets

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(56) **References Cited**

U.S. PATENT DOCUMENTS

4,134,405	A	1/1979	Smit
4,207,890	A	6/1980	Mamajek et al.
4,246,893	A	1/1981	Berson
4,315,509	A	2/1982	Smit
4,331,277	A	5/1982	Green
4,403,604	A	9/1983	Wilkinson et al.
4,416,267	A	11/1983	Garren et al.
4,417,360	A	11/1983	Moasser
4,441,215	A	4/1984	Kaster
4,467,804	A	8/1984	Hardy et al.
4,485,805	A	12/1984	Foster, Jr.
4,488,523	A	12/1984	Shichman
4,501,264	A	2/1985	Rockey
4,607,618	A	8/1986	Angelchik
4,641,653	A	2/1987	Rockey
4,648,383	A	3/1987	Angelchik
4,694,827	A	9/1987	Weiner et al.
4,723,547	A	2/1988	Kullas et al.
4,747,849	A	5/1988	Galtier
4,846,836	A	7/1989	Reich
4,848,367	A	7/1989	Avant et al.
4,899,747	A	2/1990	Garren et al.
4,925,446	A	5/1990	Garay et al.
4,946,440	A	8/1990	Hall
4,969,896	A	11/1990	Shors
4,997,084	A	3/1991	Opie et al.
5,006,106	A	4/1991	Angelchik
5,037,021	A	6/1991	Mills et al.
5,061,275	A	10/1991	Wallsten et al.
5,084,061	A	1/1992	Gau et al.
5,088,979	A	2/1992	Filipi et al.
5,163,952	A	11/1992	Froix
5,211,658	A	5/1993	Clouse
5,234,454	A	8/1993	Bangs
5,246,456	A	9/1993	Wilkinson
5,259,399	A	11/1993	Brown
5,263,629	A	11/1993	Trumbull et al.
5,290,217	A	3/1994	Campos
5,306,300	A	4/1994	Berry
5,314,473	A	5/1994	Godin
5,327,914	A	7/1994	Shlain
5,345,949	A	9/1994	Shain
5,355,897	A	10/1994	Pietrafitta et al.
5,401,241	A	3/1995	Delany
5,403,326	A	4/1995	Harrison et al.
5,405,377	A	4/1995	Cragg
5,431,673	A	7/1995	Summers et al.
5,484,694	A	1/1996	Lelental et al.
5,486,187	A	1/1996	Schneck
5,514,176	A	5/1996	Bosley, Jr.
5,535,935	A	7/1996	Vidal et al.
5,542,949	A	8/1996	Yoon
5,562,239	A	10/1996	Boiarski et al.
5,571,116	A	11/1996	Bolanos et al.
5,577,654	A	11/1996	Bishop
5,593,434	A	1/1997	Williams
5,597,107	A	1/1997	Knodel et al.
5,609,624	A	3/1997	Kalis
5,628,786	A	5/1997	Banas et al.
5,630,539	A	5/1997	Plyley et al.
5,647,526	A	7/1997	Green et al.
5,653,743	A	8/1997	Martin
5,662,713	A	9/1997	Andersen et al.
5,673,841	A	10/1997	Schulze et al.
5,674,241	A	10/1997	Bley et al.
5,706,998	A	1/1998	Plyley et al.
5,709,657	A	1/1998	Zimmon
5,720,776	A	2/1998	Chuter et al.
5,749,918	A	5/1998	Hogendijk et al.
5,762,255	A	6/1998	Chrisman et al.
5,771,903	A	6/1998	Jakobsson
5,785,684	A	7/1998	Zimmon
5,792,119	A	8/1998	Marx
5,820,584	A	10/1998	Crabb
5,839,639	A	11/1998	Sauer et al.
5,848,964	A	12/1998	Samuels
5,855,311	A	1/1999	Hamblin et al.
5,855,601	A	1/1999	Bessler et al.
5,856,445	A	1/1999	Korsmeyer
5,861,036	A	1/1999	Godin
5,868,141	A	2/1999	Ellias
5,887,594	A	3/1999	LoCicero et al.
5,897,562	A	4/1999	Bolanos et al.
5,910,144	A	6/1999	Hayashi et al.
5,922,019	A	7/1999	Hankh et al.
5,947,983	A	9/1999	Solar et al.
5,993,473	A	11/1999	Chan et al.
5,993,483	A	11/1999	Gianotti
6,016,848	A	1/2000	Egres, Jr.
6,051,015	A	4/2000	Maahs
6,086,600	A	7/2000	Kortenback
6,098,629	A	8/2000	Johnson et al.
6,102,922	A	8/2000	Jakobsson et al.
6,113,609	A	9/2000	Adams
6,120,534	A	9/2000	Ruiz
6,146,416	A	11/2000	Andersen et al.
6,159,146	A	12/2000	El Gazayerli
6,159,238	A	12/2000	Killion et al.
6,197,022	B1	3/2001	Baker
6,206,930	B1	3/2001	Burg et al.
6,245,088	B1	6/2001	Lowery
6,251,132	B1	6/2001	Ravenscroft et al.
6,254,642	B1	7/2001	Taylor
6,258,120	B1	7/2001	McKenzie et al.
6,264,700	B1	7/2001	Kilcoyne et al.
6,287,334	B1	9/2001	Moll et al.
6,302,917	B1	10/2001	Dua et al.
6,358,197	B1	3/2002	Silverman et al.
6,416,522	B1	7/2002	Strecker
6,425,916	B1	7/2002	Garrison et al.
6,454,785	B2	9/2002	De Hoyos Garza

(56) **References Cited**

U.S. PATENT DOCUMENTS

6,460,543 B1 10/2002 Forsell
6,461,366 B1 10/2002 Seguin
6,494,888 B1 12/2002 Laufer et al.
6,494,895 B2 12/2002 Addis
6,503,264 B1 1/2003 Birk
6,506,196 B1 1/2003 Laufer et al.
6,527,784 B2 3/2003 Adams et al.
6,540,789 B1 4/2003 Silverman et al.
6,544,291 B2 4/2003 Taylor
6,547,801 B1 4/2003 Dargent et al.
6,558,400 B2 5/2003 Deem et al.
6,558,429 B2 5/2003 Taylor et al.
6,572,627 B2 6/2003 Gabbay
6,572,629 B2 6/2003 Kalloo
6,575,896 B2 6/2003 Silverman
6,592,596 B1 7/2003 Geitz
6,596,023 B1 7/2003 Nunez et al.
6,607,555 B2 8/2003 Patterson et al.
6,627,206 B2 9/2003 Lloyd
6,632,227 B2 10/2003 Adamns
6,663,639 B1 12/2003 Laufer
6,675,809 B2 1/2004 Stack et al.
6,740,098 B2 5/2004 Abrams et al.
6,740,121 B2 5/2004 Geitz
6,746,460 B2 6/2004 Gannoe et al.
6,755,869 B2 6/2004 Geitz
6,764,518 B2 7/2004 Godin
6,773,440 B2 8/2004 Gannoe et al.
6,773,441 B1 8/2004 Laufer et al.
6,790,214 B2 9/2004 Kraemer et al.
6,790,237 B2 9/2004 Stinson
6,821,285 B2 11/2004 Laufer et al.
6,835,200 B2 12/2004 Laufer et al.
6,845,776 B2 1/2005 Stack et al.
6,916,332 B2 7/2005 Adams
6,932,838 B2 8/2005 Schwartz et al.
6,960,233 B1 11/2005 Berg et al.
6,966,875 B1 11/2005 Longobardi
6,981,978 B2 1/2006 Gannoe
6,981,980 B2 1/2006 Sampson et al.
6,994,715 B2 2/2006 Gannoe et al.
7,011,094 B2 3/2006 Rapacki et al.
7,020,531 B1 3/2006 Colliou et al.
7,025,791 B2 4/2006 Levine et al.
7,033,373 B2 4/2006 De la Torre et al.
7,033,384 B2 4/2006 Gannoe et al.
7,037,344 B2 5/2006 Kagan et al.
7,056,305 B2 6/2006 Garza
7,066,945 B2 6/2006 Hashiba et al.
7,083,629 B2 8/2006 Weller et al.
7,090,699 B2 8/2006 Geitz
7,097,650 B2 8/2006 Weller et al.
7,097,665 B2 8/2006 Stack et al.
7,111,627 B2 9/2006 Stack et al.
7,112,186 B2 9/2006 Shah
7,141,055 B2 11/2006 Abrams et al.
7,175,638 B2 2/2007 Gannoe et al.
8,469,977 B2 6/2013 Balbierz et al.
8,628,547 B2 * 1/2014 Weller A61B 17/072 227/175.1
2001/0020189 A1 9/2001 Taylor
2001/0020190 A1 9/2001 Taylor
2001/0021796 A1 9/2001 Silverman et al.
2001/0044595 A1 11/2001 Reydel et al.
2001/0049492 A1 12/2001 Frazier et al.
2002/0022851 A1 2/2002 Kalloo et al.
2002/0055757 A1 5/2002 Torre et al.
2002/0072761 A1 6/2002 Abrams et al.
2002/0082621 A1 6/2002 Schurr et al.
2002/0099439 A1 7/2002 Schwartz et al.
2002/0165563 A1 * 11/2002 Grant A61B 17/072 606/151
2002/0183767 A1 12/2002 Adams et al.
2002/0183768 A1 12/2002 Deem et al.
2003/0009236 A1 1/2003 Godin
2003/0028178 A1 * 2/2003 Chin A61B 46/13 606/1
2003/0040764 A1 * 2/2003 Adams A61B 1/00154 606/170
2003/0040804 A1 2/2003 Stack et al.
2003/0040808 A1 2/2003 Stack et al.
2003/0065359 A1 4/2003 Weller et al.
2003/0093117 A1 5/2003 Saadat
2003/0109892 A1 6/2003 Deem et al.
2003/0120289 A1 6/2003 McGuckin, Jr. et al.
2003/0132267 A1 7/2003 Adams et al.
2003/0158569 A1 8/2003 Wazne
2003/0183671 A1 10/2003 Mooradian et al.
2003/0191476 A1 10/2003 Smit
2003/0199989 A1 10/2003 Stack et al.
2003/0199990 A1 10/2003 Stack et al.
2003/0199991 A1 10/2003 Stack et al.
2003/0208209 A1 11/2003 Gambale et al.
2003/0220660 A1 11/2003 Kortenbach et al.
2004/0006351 A1 1/2004 Gannoe et al.
2004/0024386 A1 2/2004 Deem et al.
2004/0030347 A1 2/2004 Gannoe et al.
2004/0044353 A1 3/2004 Gannoe
2004/0044354 A1 3/2004 Gannoe et al.
2004/0044357 A1 3/2004 Gannoe et al.
2004/0044364 A1 3/2004 DeVries et al.
2004/0082963 A1 4/2004 Gannoe et al.
2004/0088023 A1 5/2004 Imran et al.
2004/0092892 A1 5/2004 Kagan et al.
2004/0092960 A1 5/2004 Abrams et al.
2004/0092974 A1 5/2004 Gannoe et al.
2004/0093091 A1 5/2004 Gannoe et al.
2004/0098043 A1 5/2004 Trout
2004/0107004 A1 6/2004 Levine et al.
2004/0117031 A1 6/2004 Stack et al.
2004/0138682 A1 7/2004 Onuki et al.
2004/0138761 A1 7/2004 Stack et al.
2004/0143342 A1 7/2004 Stack et al.
2004/0148034 A1 7/2004 Kagan et al.
2004/0153167 A1 8/2004 Stack et al.
2004/0158331 A1 8/2004 Stack et al.
2004/0162568 A1 8/2004 Saadat et al.
2004/0172141 A1 9/2004 Stack et al.
2004/0172142 A1 9/2004 Stack et al.
2004/0186502 A1 9/2004 Sampson et al.
2004/0210243 A1 10/2004 Gannoe et al.
2004/0215216 A1 10/2004 Gannoe et al.
2004/0220682 A1 11/2004 Levine et al.
2004/0225183 A1 11/2004 Michlitsch et al.
2004/0225305 A1 11/2004 Ewers et al.
2004/0236419 A1 11/2004 Milo
2004/0243152 A1 12/2004 Taylor et al.
2004/0243223 A1 12/2004 Kraemer et al.
2004/0267378 A1 12/2004 Gazi et al.
2005/0003326 A1 1/2005 Lampert
2005/0004430 A1 1/2005 Lee et al.
2005/0004681 A1 1/2005 Stack et al.
2005/0033345 A1 2/2005 DeLegge
2005/0055365 A1 2/2005 Briganti et al.
2005/0049718 A1 3/2005 Dann et al.
2005/0075654 A1 4/2005 Kelleher
2005/0080444 A1 4/2005 Kraemer et al.
2005/0085787 A1 4/2005 Laufer et al.
2005/0096673 A1 5/2005 Stack et al.
2005/0096750 A1 5/2005 Kagan et al.
2005/0149114 A1 7/2005 Cartledge et al.
2005/0159769 A1 7/2005 Alverdy
2005/0177181 A1 8/2005 Kagan et al.
2005/0183732 A1 8/2005 Edwards
2005/0192599 A1 9/2005 Demarais
2005/0192615 A1 9/2005 Torre et al.
2005/0203547 A1 9/2005 Weller et al.
2005/0203548 A1 9/2005 Weller et al.
2005/0216040 A1 9/2005 Gertner et al.
2005/0216042 A1 9/2005 Gertner
2005/0240279 A1 10/2005 Kagan et al.
2005/0251162 A1 10/2005 Rothe et al.
2005/0247320 A1 11/2005 Stack et al.
2005/0250980 A1 11/2005 Swanstrom et al.

(56) **References Cited**

U.S. PATENT DOCUMENTS

2005/0251158	A1	11/2005	Sadat et al.
2005/0256533	A1	11/2005	Roth et al.
2005/0256587	A1	11/2005	Egan
2005/0261712	A1	11/2005	Balbierz et al.
2005/0267405	A1	12/2005	Shah
2005/0267499	A1	12/2005	Stack et al.
2005/0267595	A1	12/2005	Chen et al.
2005/0267596	A1	12/2005	Chen et al.
2005/0273060	A1	12/2005	Levy et al.
2006/0015006	A1	1/2006	Laurence et al.
2006/0020278	A1	1/2006	Burnett et al.
2006/0058829	A1	3/2006	Sampson et al.
2006/0120289	A1	6/2006	Cunningham
2006/0129094	A1	6/2006	Shah
2006/0151568	A1	7/2006	Weller et al.
2006/0155259	A1	7/2006	MacLay
2006/0155311	A1	7/2006	Hashiba et al.
2006/0178560	A1	8/2006	Saadat et al.
2006/0178691	A1	8/2006	Binmoeller
2006/0195139	A1	8/2006	Gartner
2006/0271076	A1	11/2006	Weller et al.
2006/0282095	A1	12/2006	Stokes et al.
2007/0032800	A1	2/2007	Oritz et al.
2007/0043384	A1	2/2007	Oritz et al.
2007/0055292	A1	3/2007	Oritz et al.
2007/0175488	A1	8/2007	Cox et al.
2007/0191870	A1	8/2007	Baker et al.
2007/0191871	A1	8/2007	Baker et al.
2011/0011543	A1	1/2011	Zhu

FOREIGN PATENT DOCUMENTS

EP	1492478		1/2005
EP	1 602 336	A2	12/2005
EP	1602336		12/2005
FR	2768324	A1	3/1999
JP	09-168597		6/1997
WO	WO 91/01117		2/1991
WO	WO 97/47231	A2	12/1997
WO	WO 00/12027		3/2000
WO	WO 00/32137		6/2000
WO	WO 00/78227		12/2000
WO	WO 01/41671		6/2001
WO	WO 01/45485		6/2001
WO	WO 01/49359		7/2001
WO	WO 01/66018		9/2001
WO	WO 01/85034		11/2001
WO	WO 01/89393		11/2001
WO	WO 02/060328		8/2002
WO	WO 03/017882		3/2003
WO	WO 03/086246		10/2003
WO	WO 03/086247		10/2003
WO	WO 03/090633		11/2003
WO	WO 03/094784		11/2003
WO	WO 03/094785		11/2003
WO	WO 03/099137		12/2003
WO	WO 03/099137	A2	12/2003
WO	WO 04/019765		3/2004
WO	WO 04/019787		3/2004
WO	WO 04/032760		4/2004
WO	WO 04/032760	A2	4/2004
WO	WO 04/037064		5/2004
WO	WO 04/041133		5/2004
WO	WO 04/064680		8/2004
WO	WO 04/064685		8/2004
WO	WO 04/080336		9/2004
WO	WO 04/110285		12/2004
WO	WO 04/110285	A1	12/2004
WO	WO 05/037152		4/2005
WO	WO 05/037152	A1	4/2005
WO	WO 05/079673		9/2005
WO	WO 2005/079673	A2	9/2005
WO	WO 05/096991		10/2005
WO	WO 05/096991	A1	10/2005
WO	WO 05/105003		11/2005
WO	WO 06/016894		2/2006
WO	WO 06/016894	A1	2/2006
WO	WO 06/055365		5/2006
WO	WO 06/055365	A2	5/2006
WO	WO 06/127593		11/2006
WO	WO 07/041598		4/2007
WO	WO 07/041598	A1	4/2007

OTHER PUBLICATIONS

Stecco, K. et al., "Safety of A Gastric Restrictive Implant in a Canine Model", Stecco Group, San Jose and Barosense, Inc., Redwood City, California (2004).

International Search Report from PCT Patent Application No. PCT/US2002/027177 dated Feb. 14, 2003.

International Search Report from PCT Patent Application No. PCT/US2003/004378 dated Aug. 13, 2003.

International Search Report from PCT Patent Application No. PCT/US2003/033605 dated Mar. 29, 2004.

International Search Report from PCT Patent Application No. PCT/US2003/033606 dated Mar. 29, 2004.

International Search Report from PCT Patent Application No. PCT/US2003/004449 dated Aug. 13, 2003.

International Search Report from Pc Patent Application No. PCT/US2004/006695 dated Sep. 8, 2004.

International Search Report from PCT Patent Application No. PCT/US2004/033007 dated Feb. 9, 2005.

International Search Report from PCT Patent Application No. PCT/US2005/014372 dated Jul. 28, 2005.

International Search Report from PCT Patent Application No. PCT/US2006/019727 dated Apr. 19, 2007.

International Search Report from PCT Patent Application No. PCT/US2006/038684 dated Feb. 14, 2007.

Felsher, et al., "Mucosal apposition in endoscopic suturing", Gastrointestinal Endoscopy, vol. 58, No. 6, pp. 867-870, (2003).

* cited by examiner

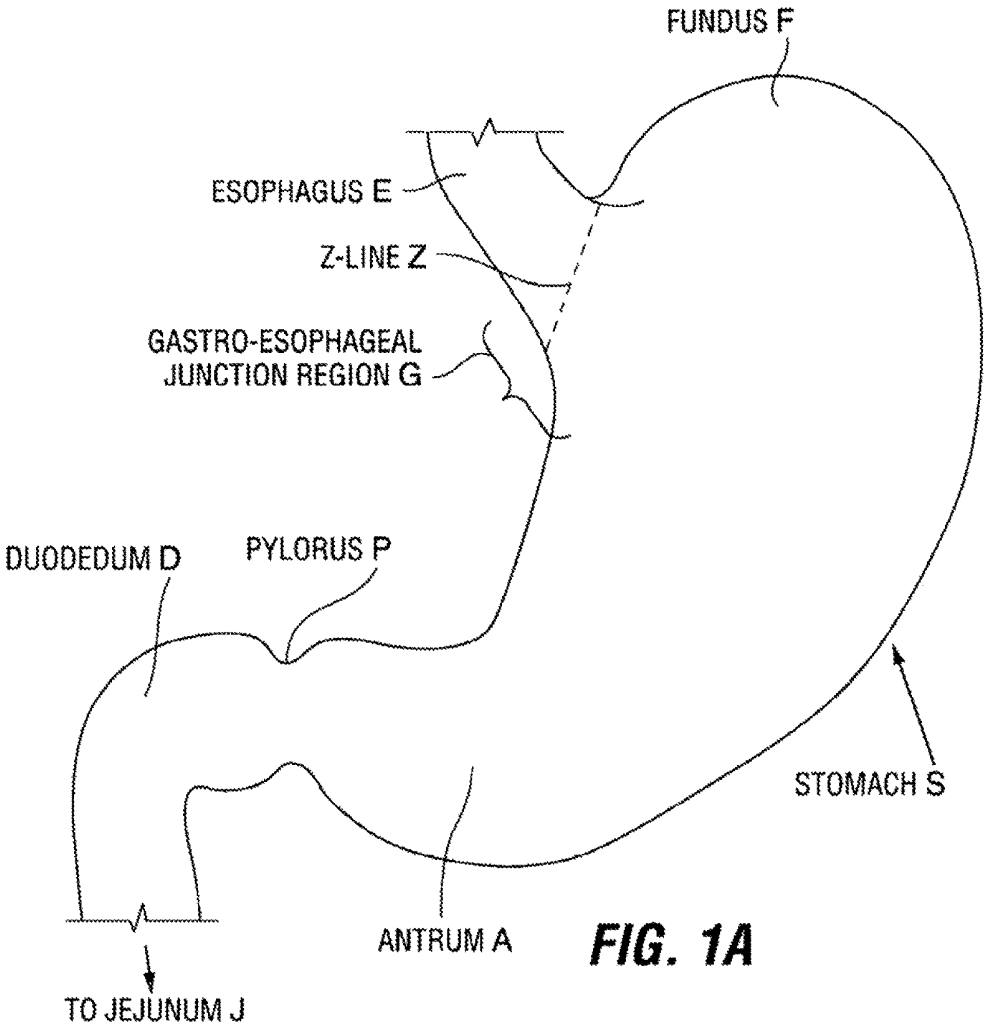
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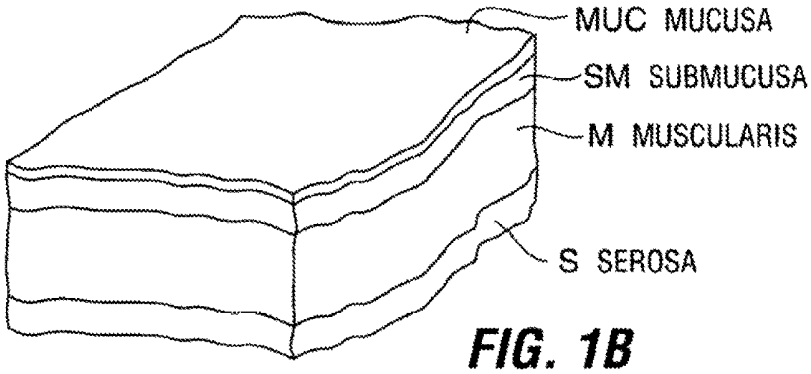
FIG. 1A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S SEROSA

FIG. 1B

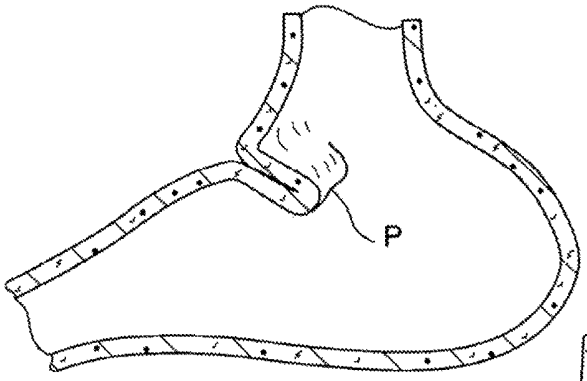


FIG. 2

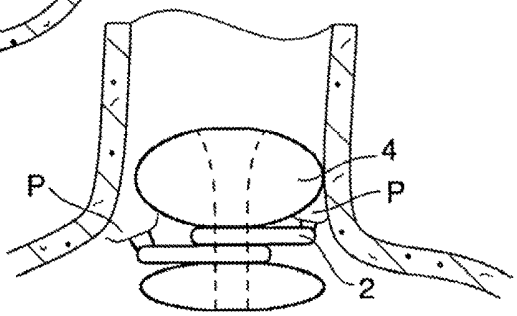


FIG. 5

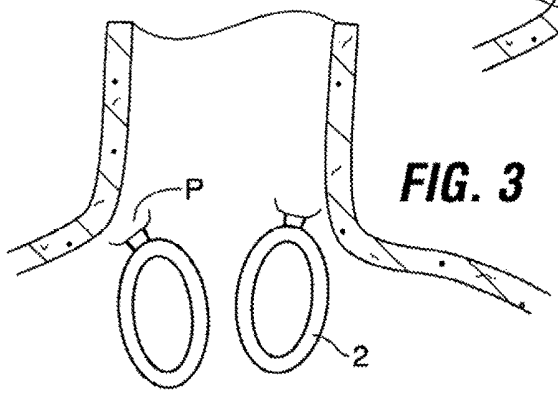


FIG. 3

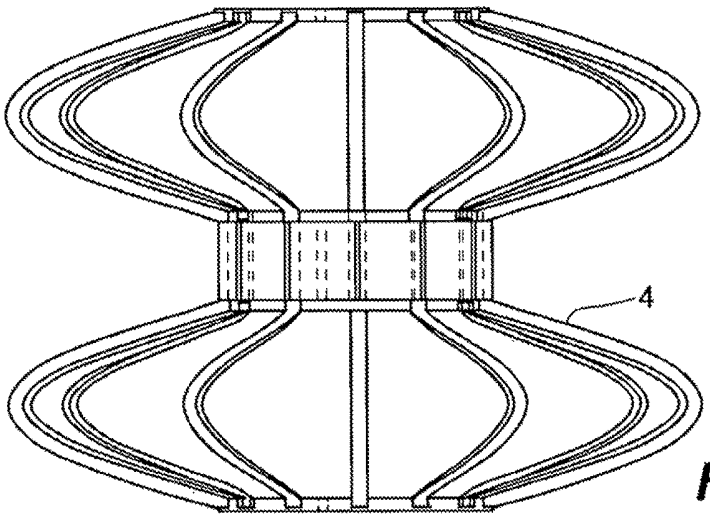


FIG. 4

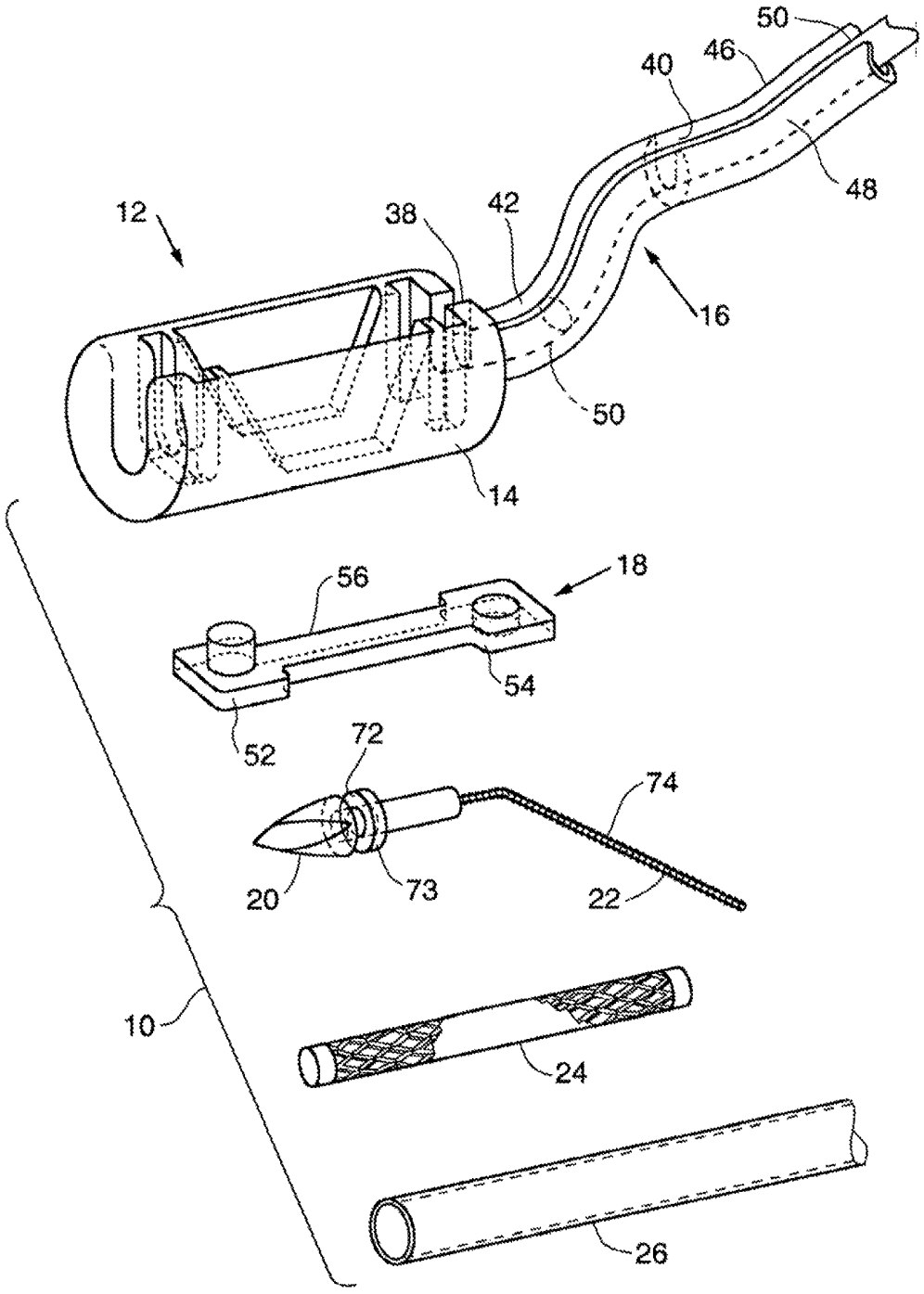


FIG. 6

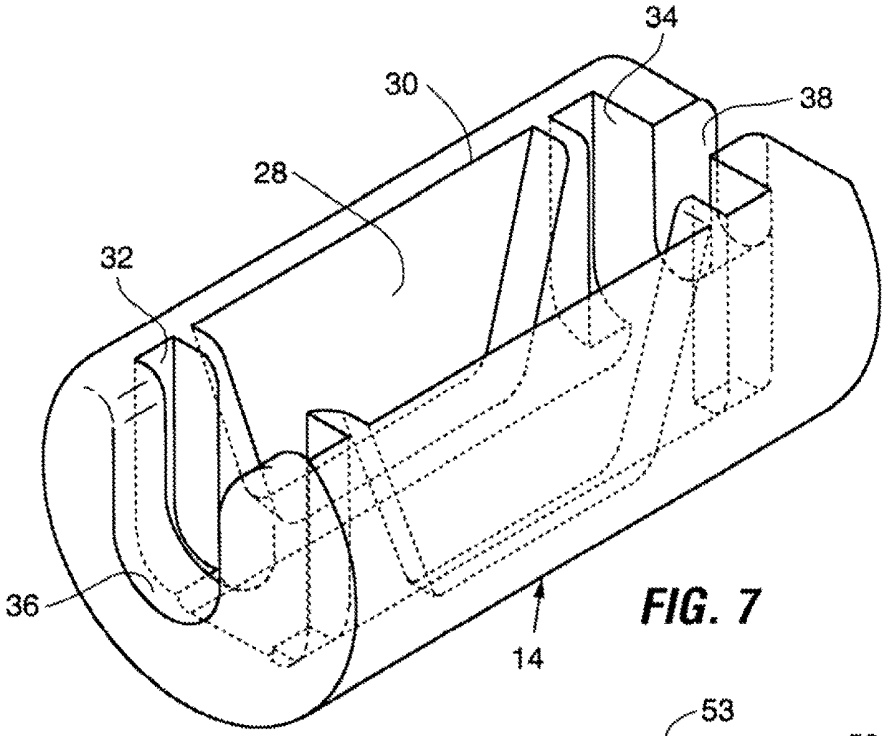


FIG. 7

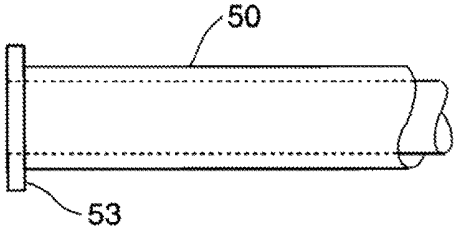


FIG. 8A

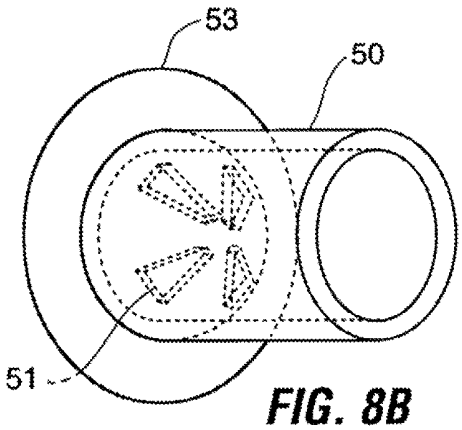


FIG. 8B

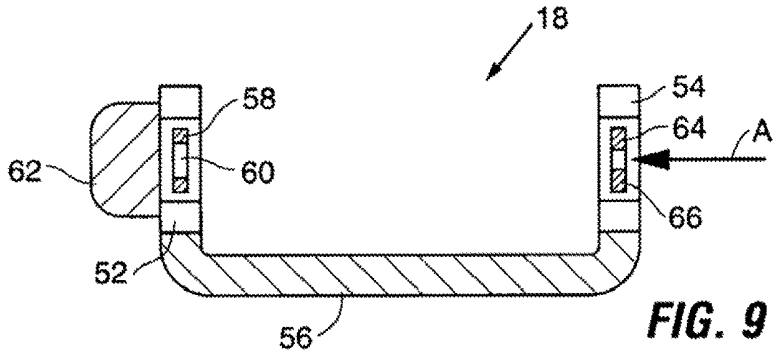


FIG. 9

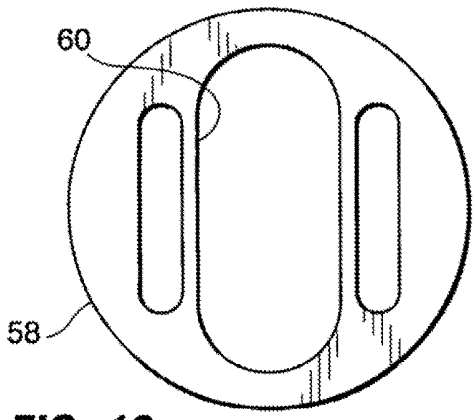


FIG. 10

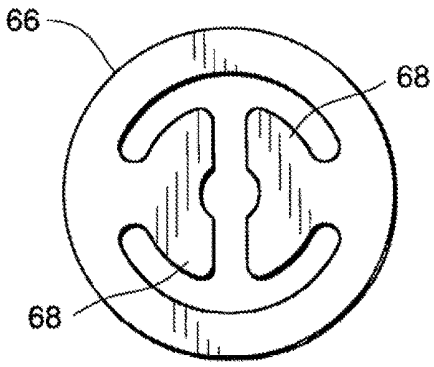


FIG. 11A

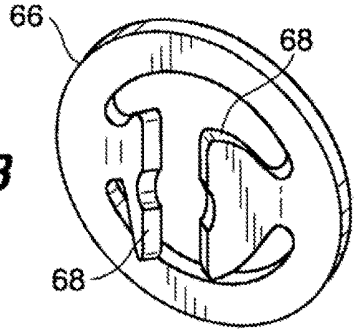


FIG. 11B

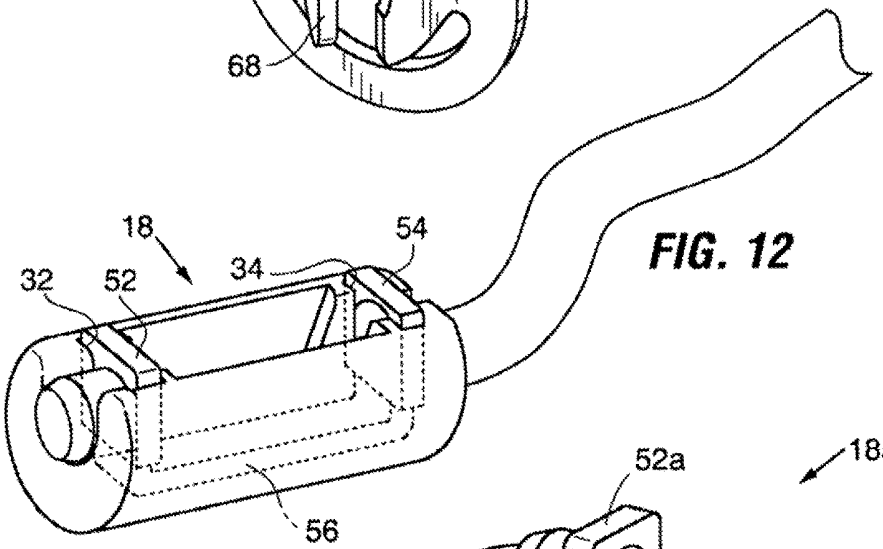


FIG. 12

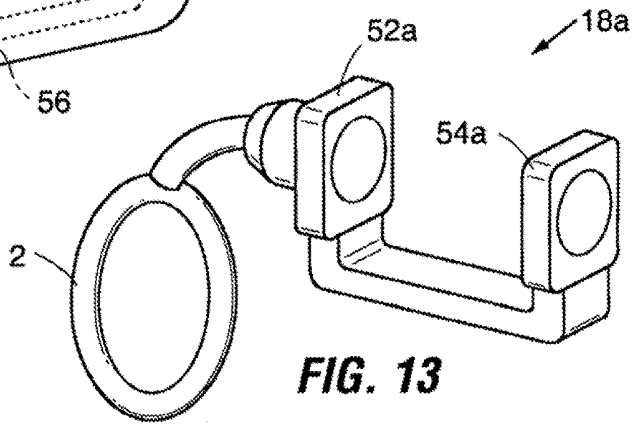


FIG. 13

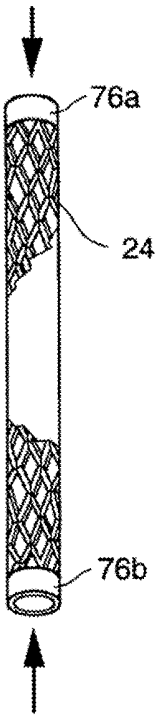


FIG. 14A

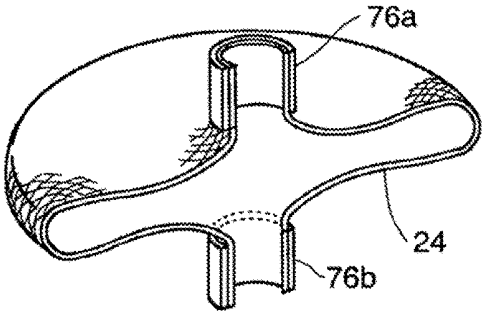


FIG. 14B

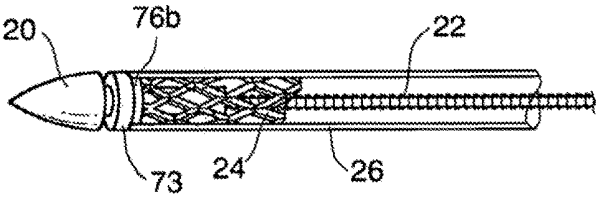


FIG. 15A

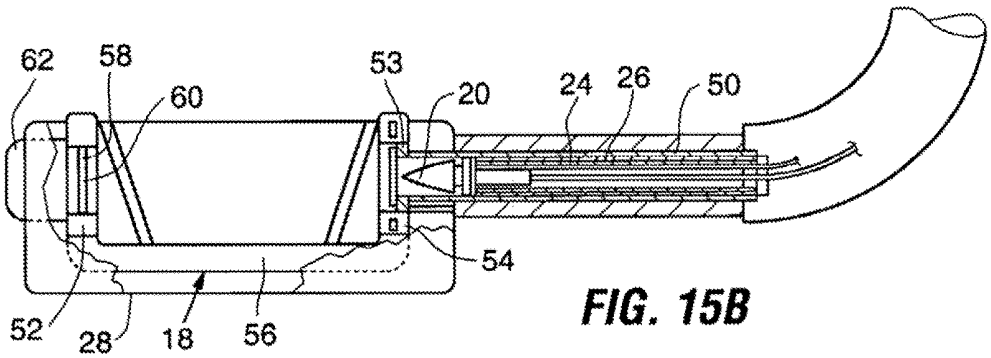


FIG. 15B

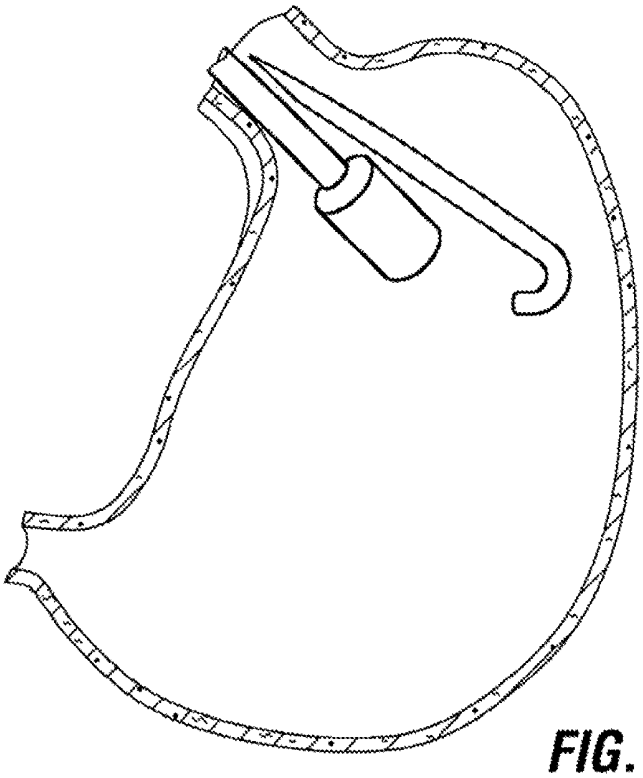


FIG. 16A

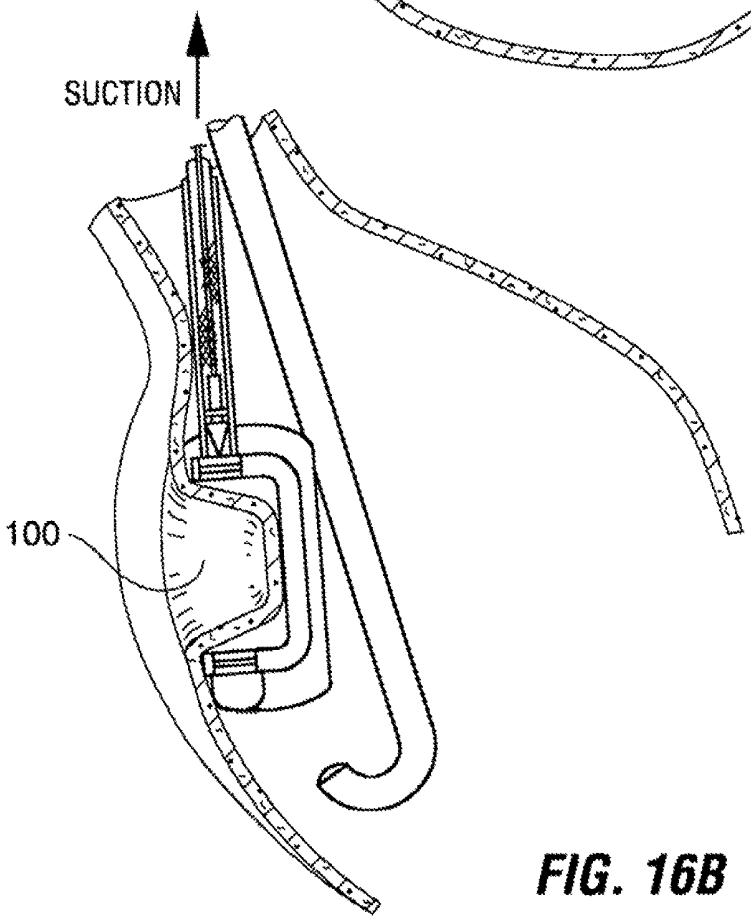


FIG. 16B

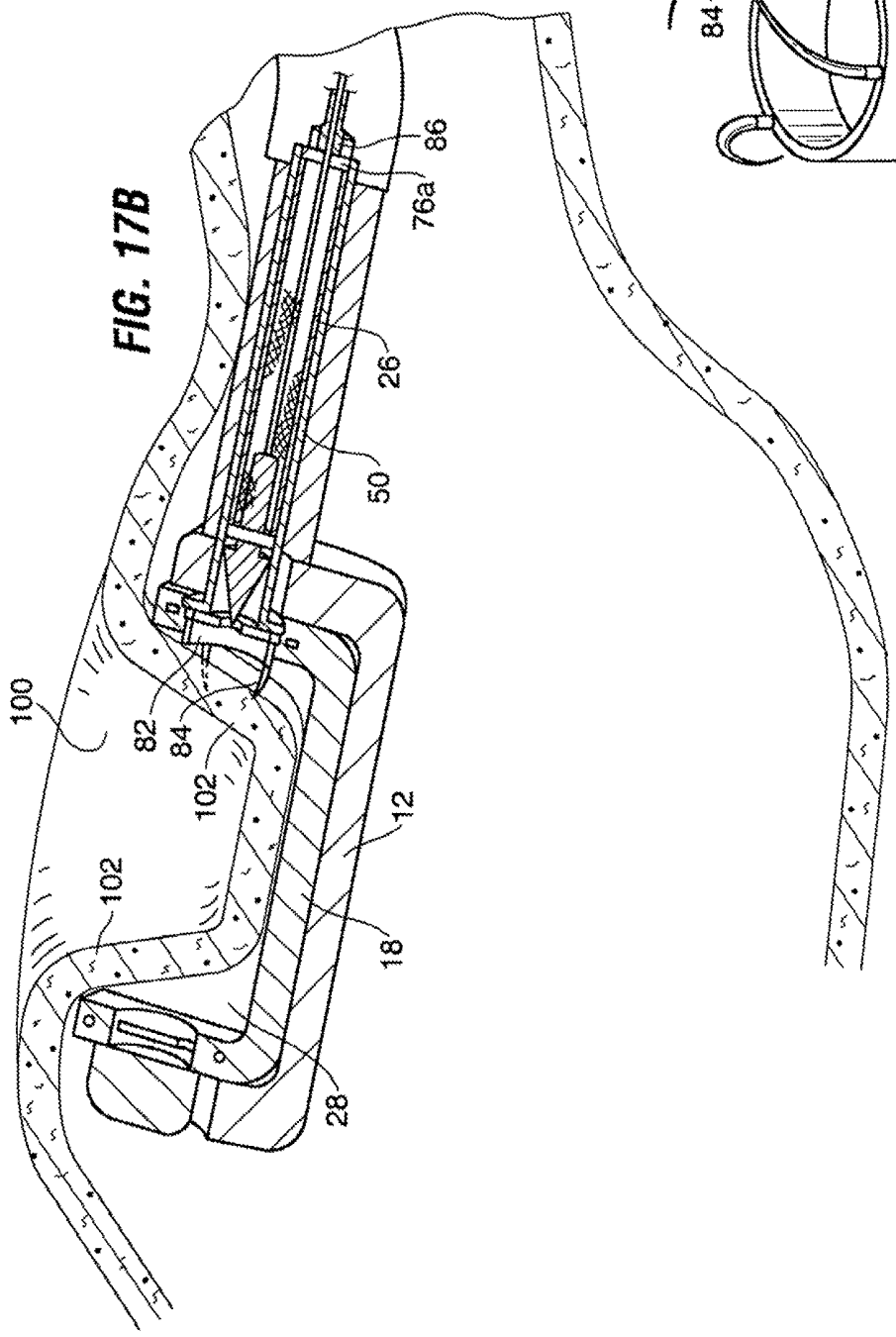


FIG. 17B

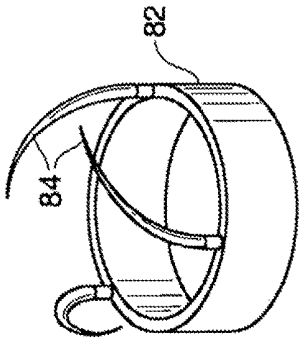


FIG. 17A

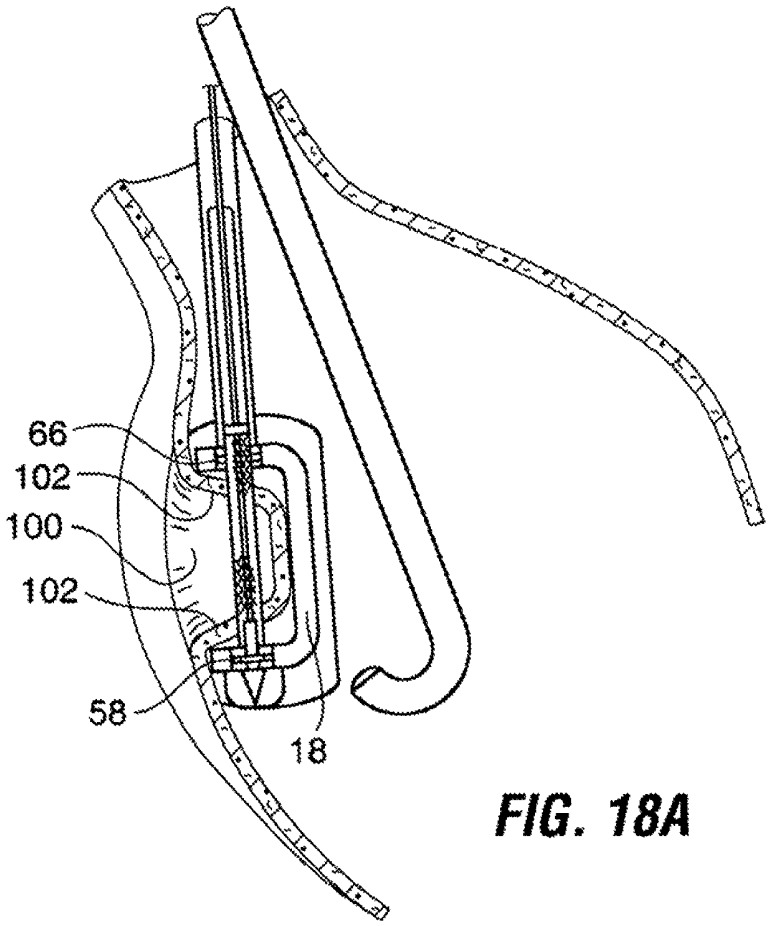


FIG. 18A

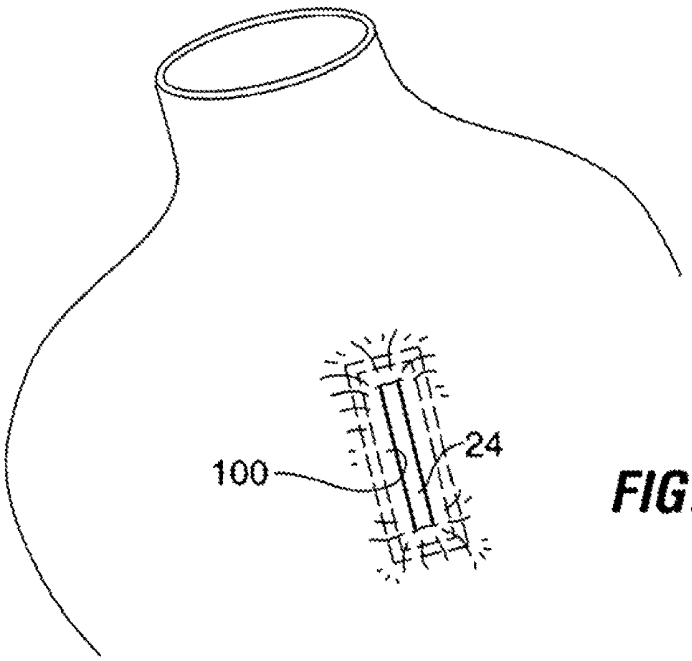


FIG. 18B

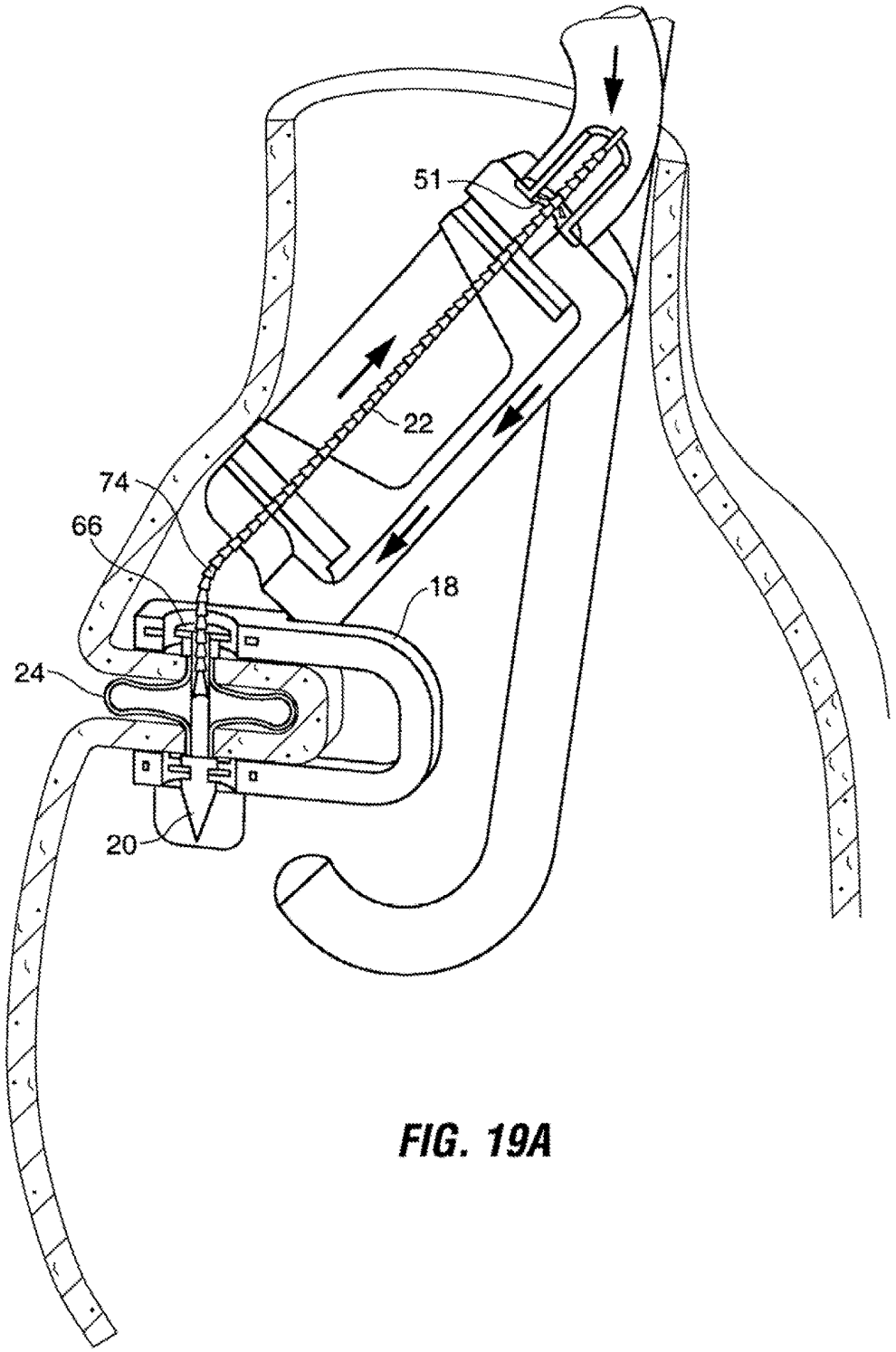


FIG. 19A

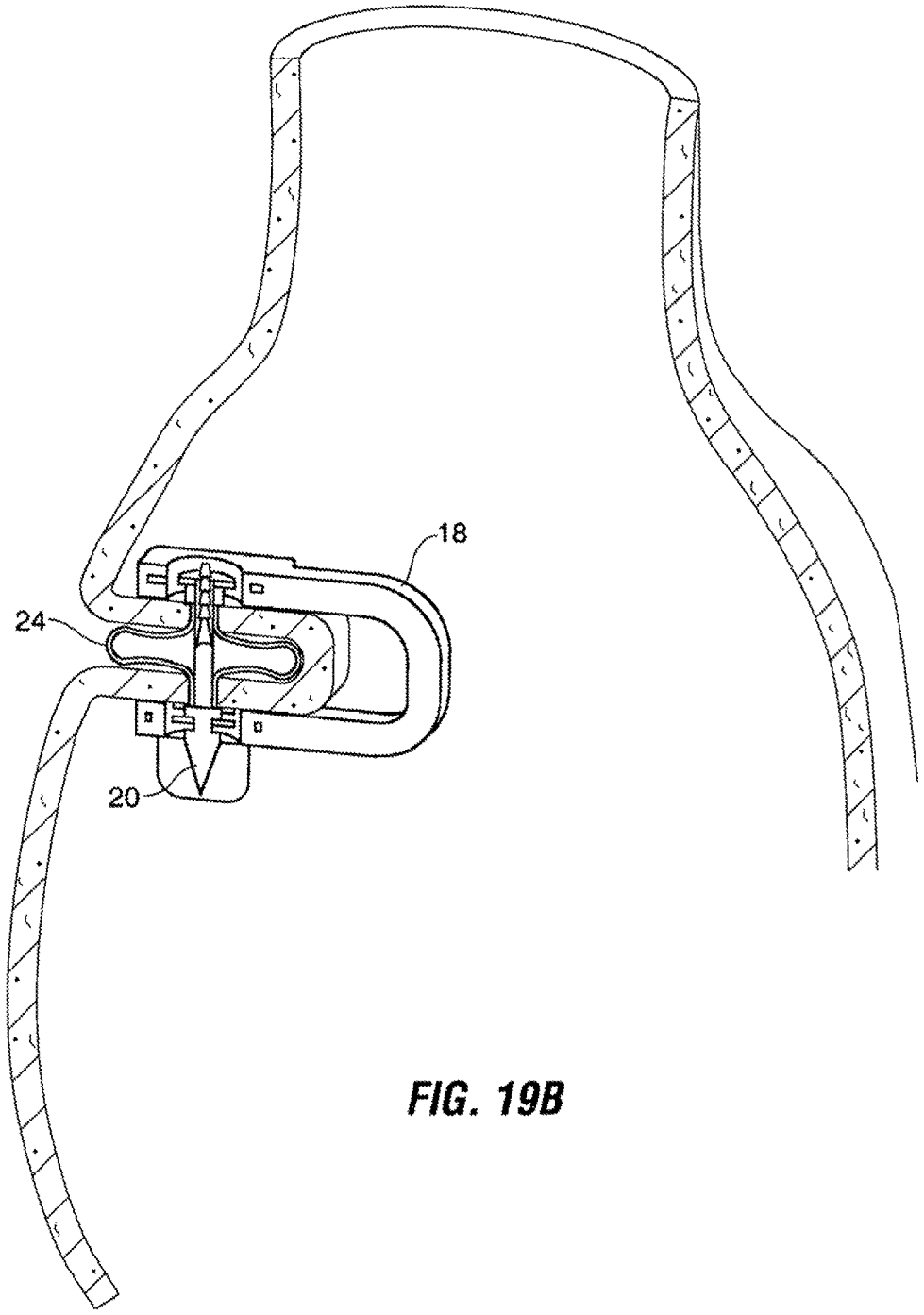


FIG. 19B

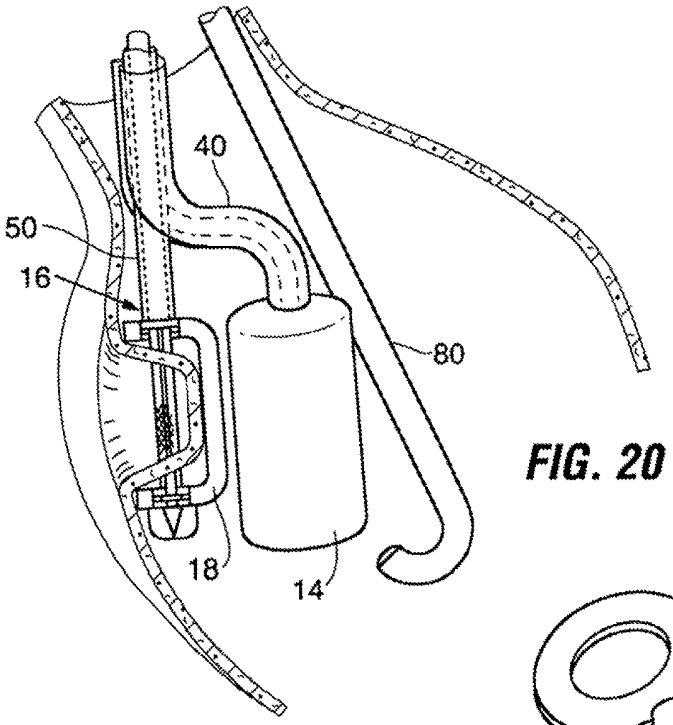


FIG. 20

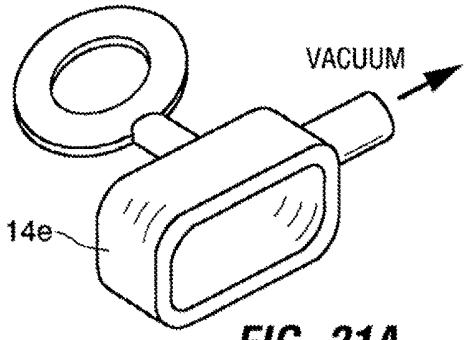


FIG. 21A

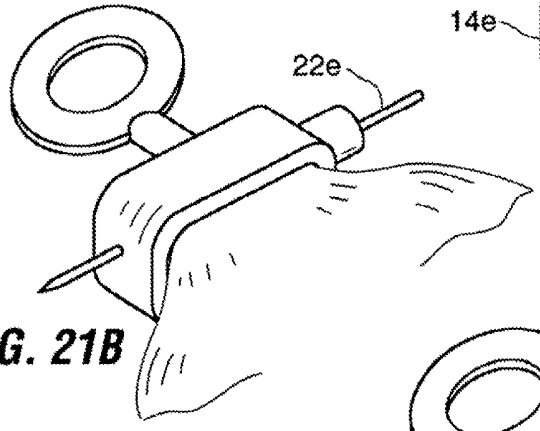


FIG. 21B

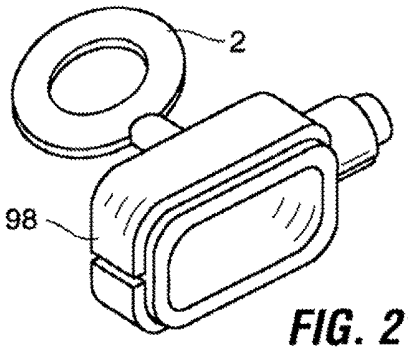


FIG. 21C

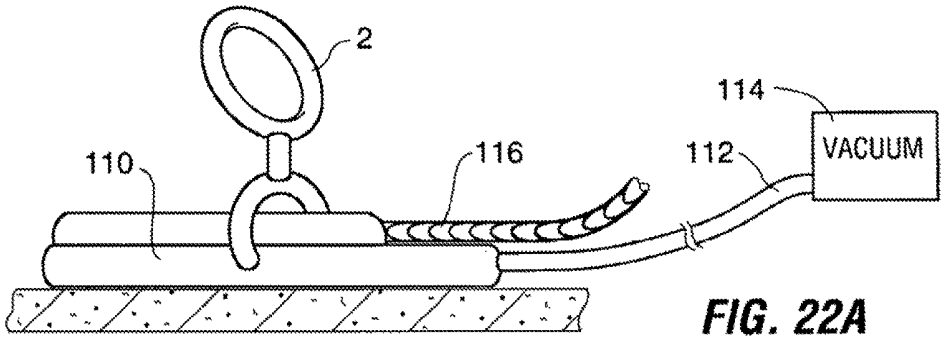


FIG. 22A

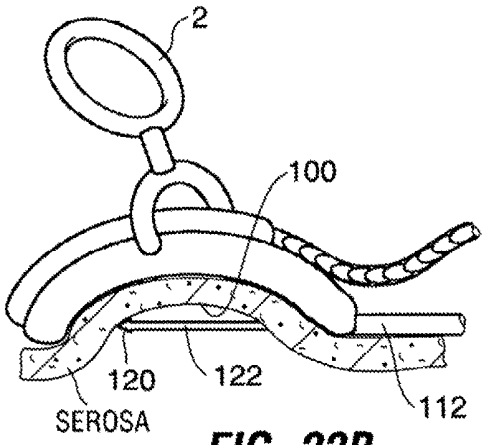


FIG. 22B

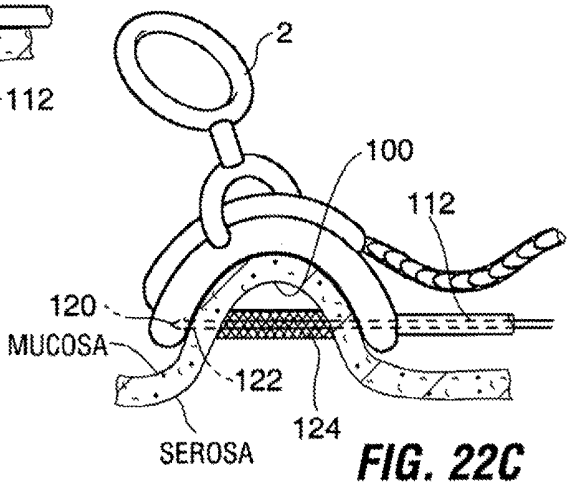


FIG. 22C

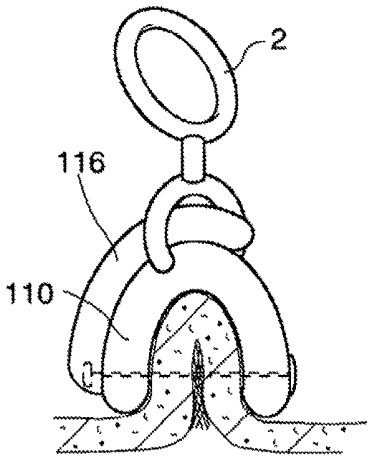


FIG. 22D

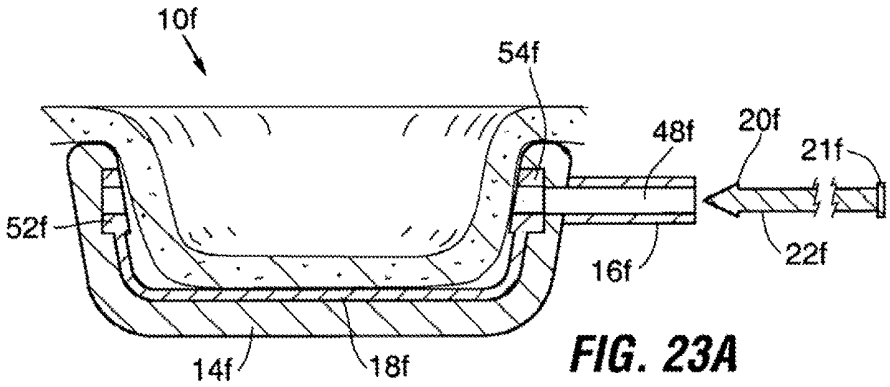


FIG. 23A

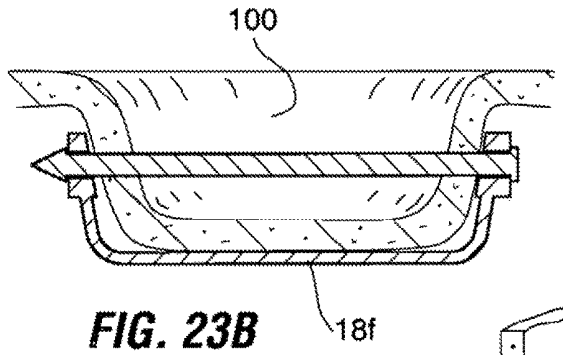


FIG. 23B

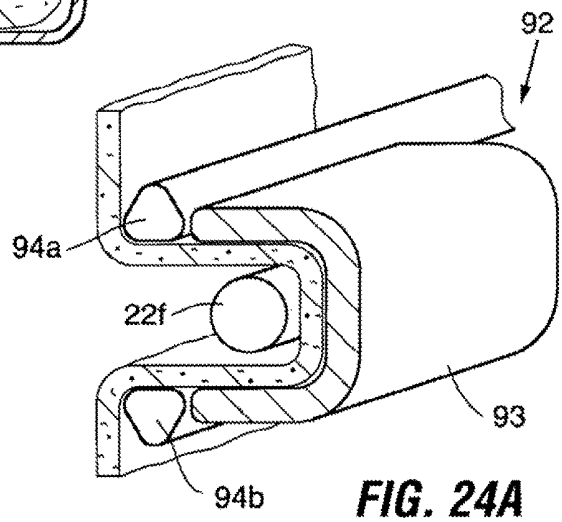


FIG. 24A

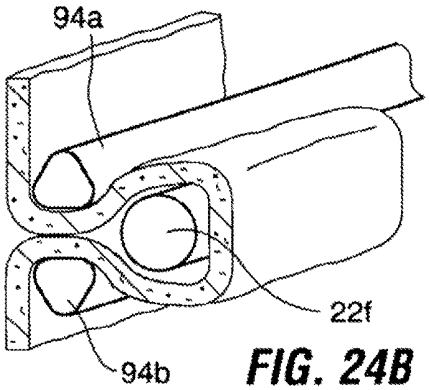


FIG. 24B

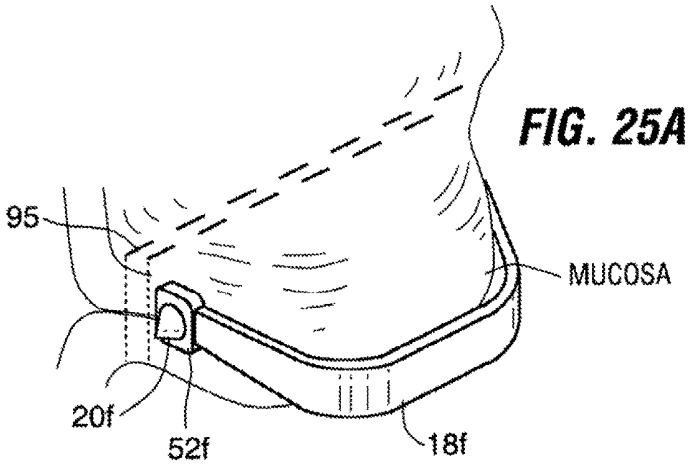


FIG. 25A

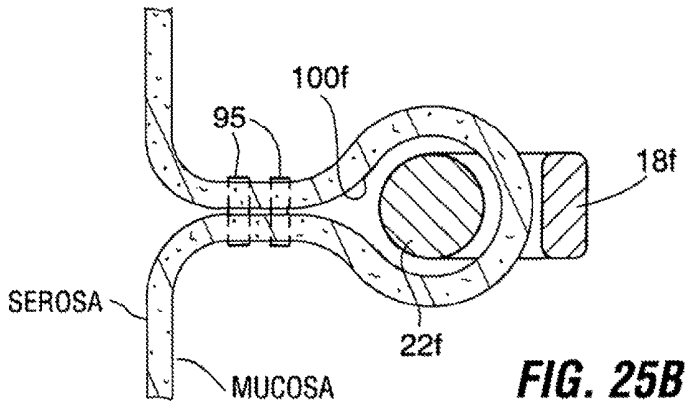


FIG. 25B

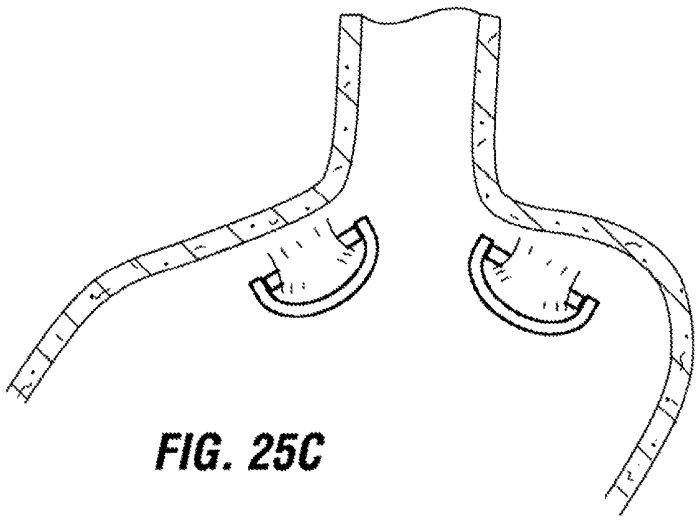


FIG. 25C

FIG. 26A

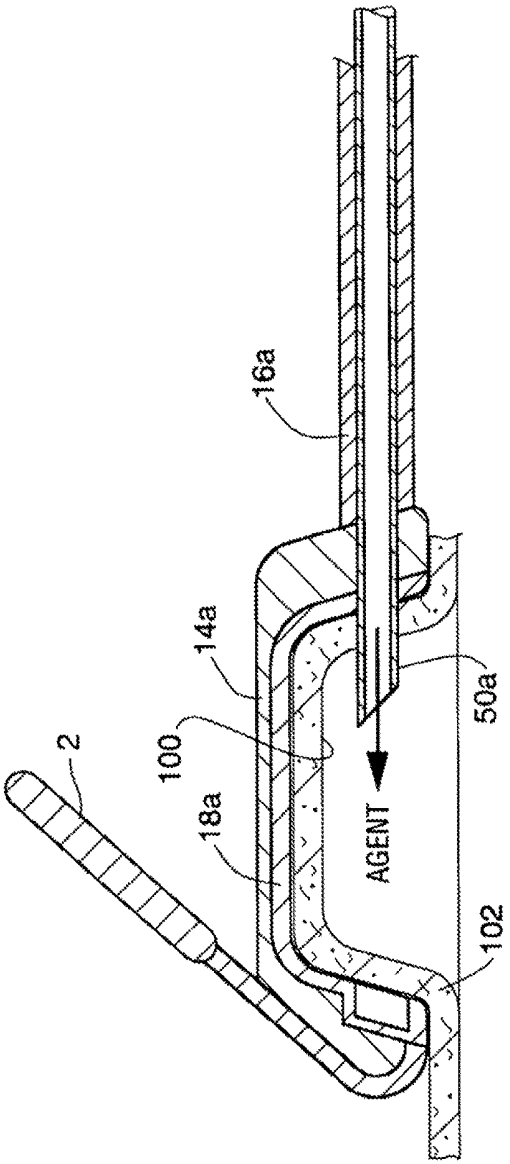
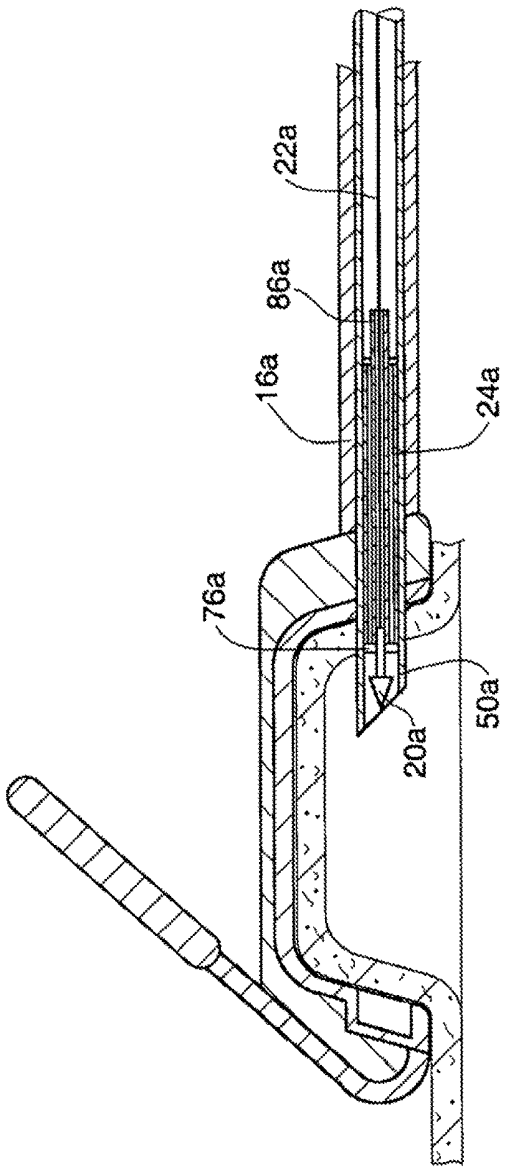


FIG. 26B



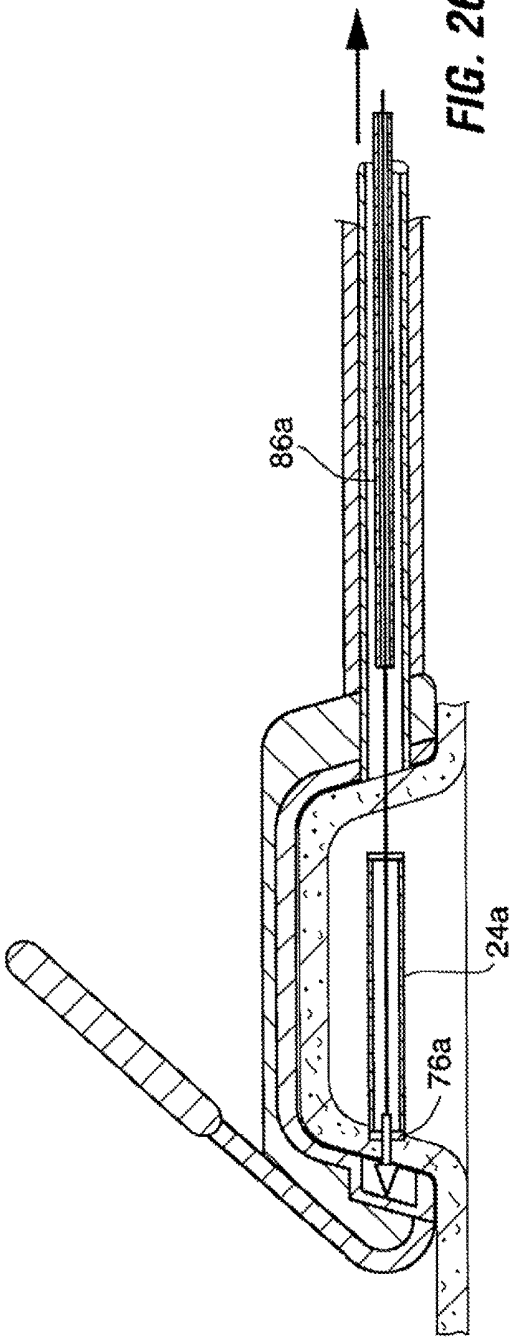


FIG. 26C

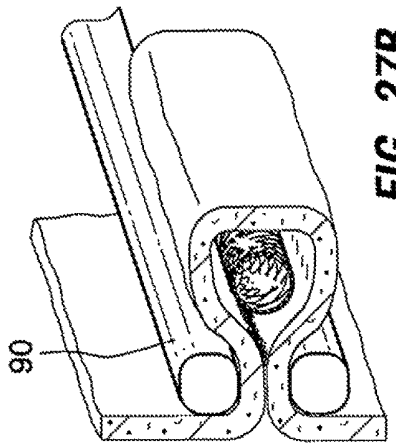


FIG. 27B

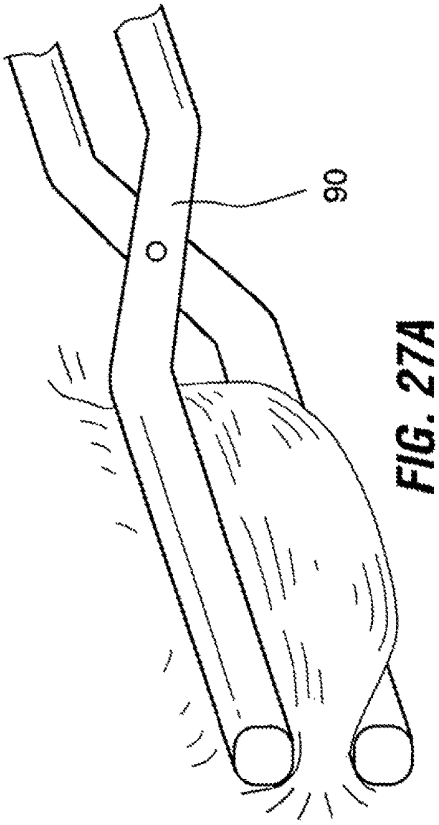


FIG. 27A

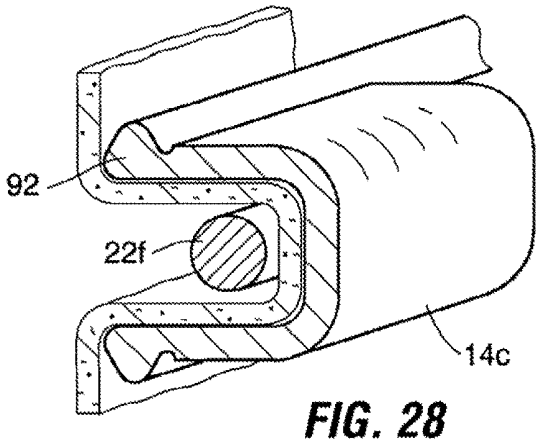


FIG. 28

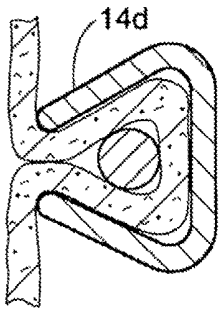


FIG. 29

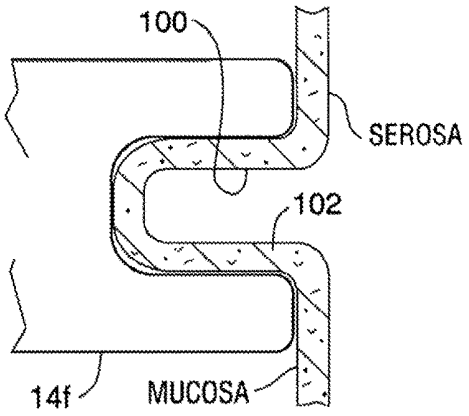


FIG. 30A

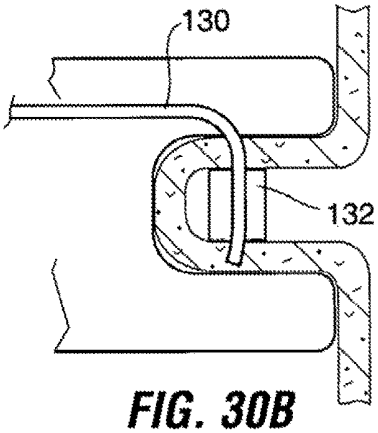


FIG. 30B

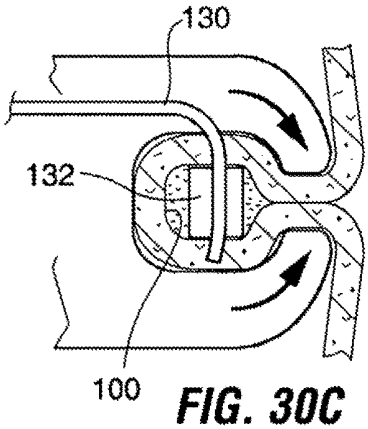


FIG. 30C

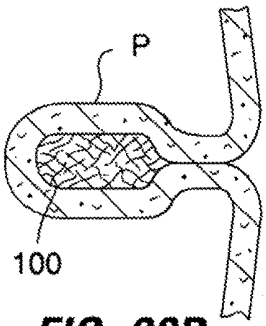


FIG. 30D

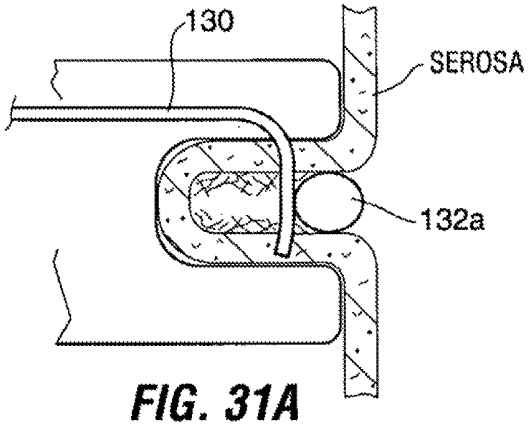


FIG. 31A

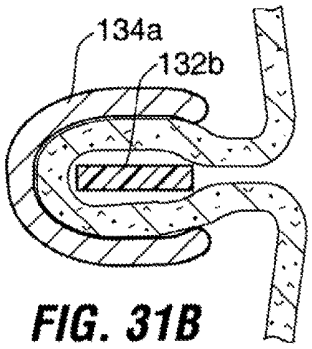


FIG. 31B

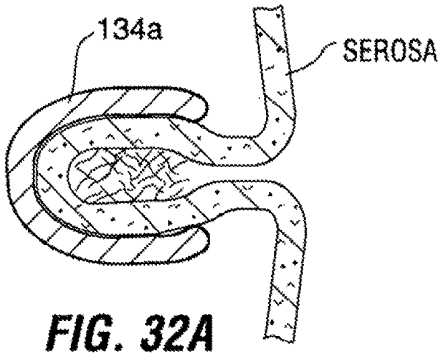


FIG. 32A

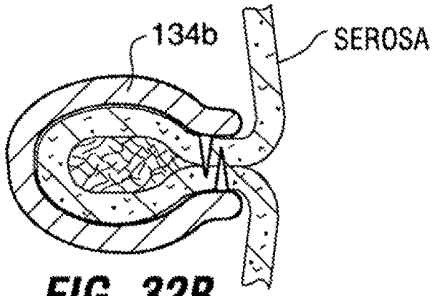


FIG. 32B

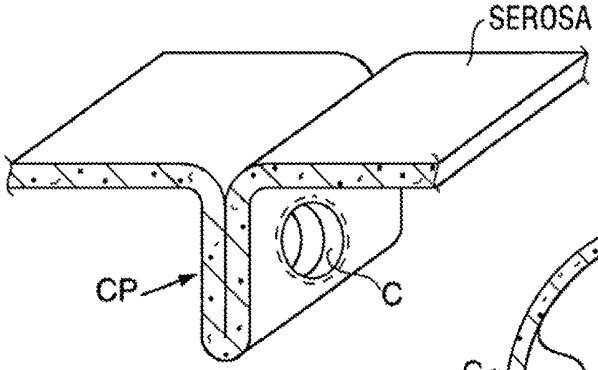


FIG. 33A

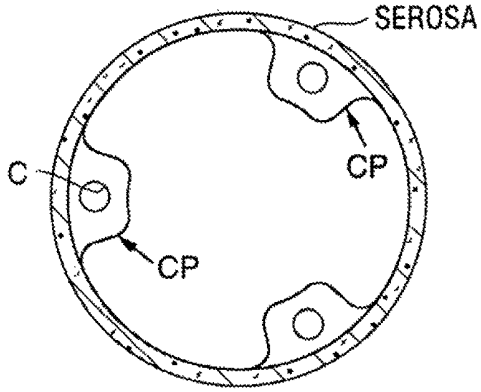


FIG. 33B

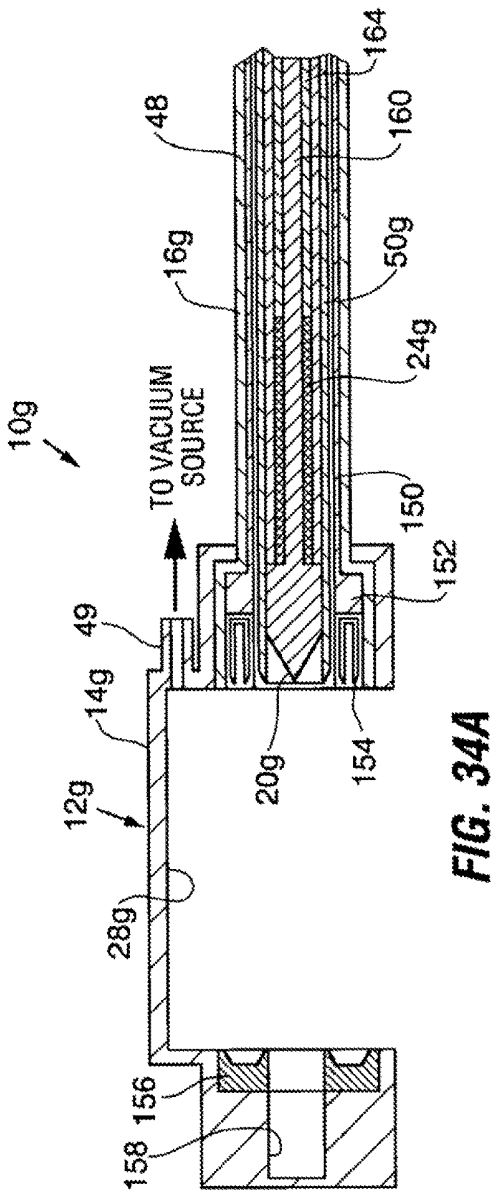


FIG. 34A

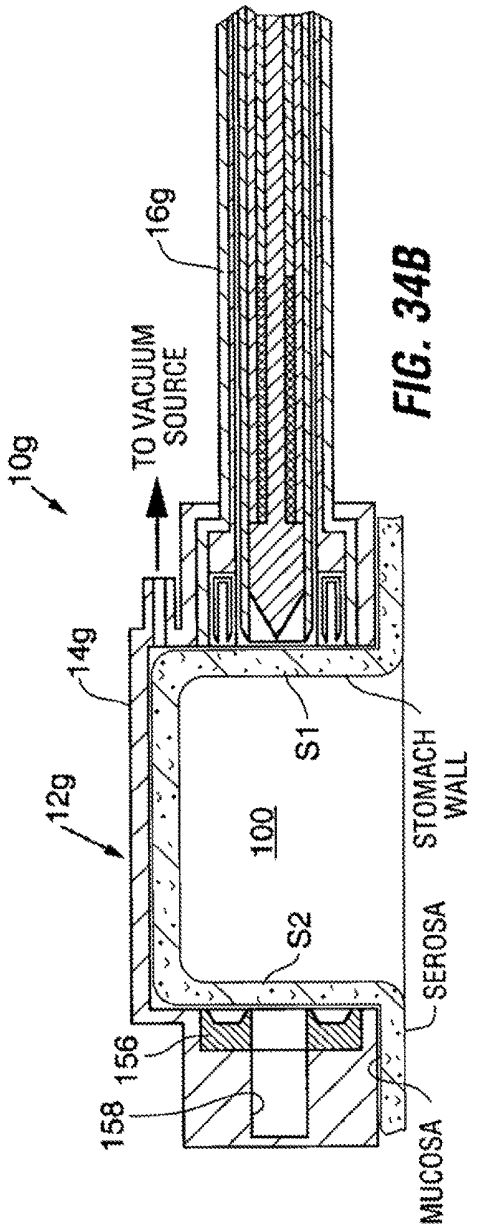


FIG. 34B

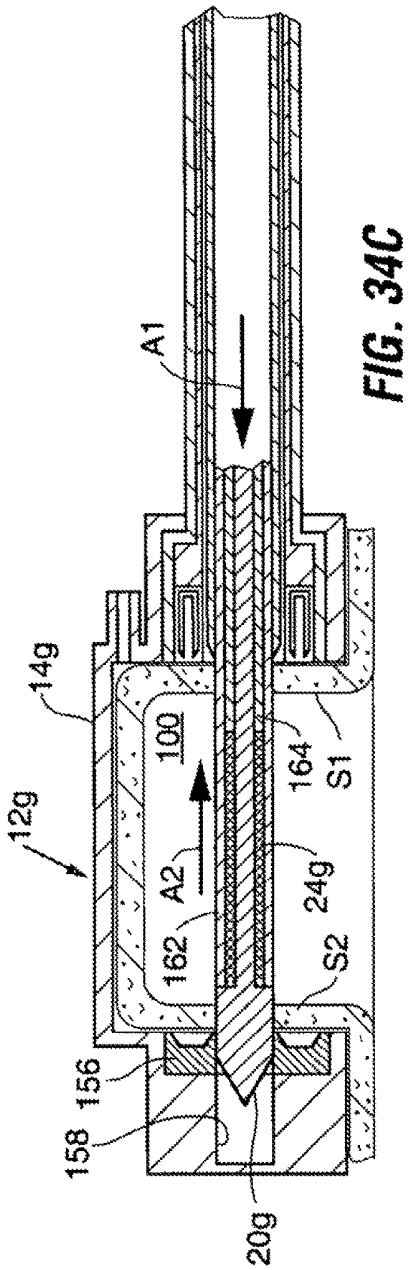


FIG. 34C

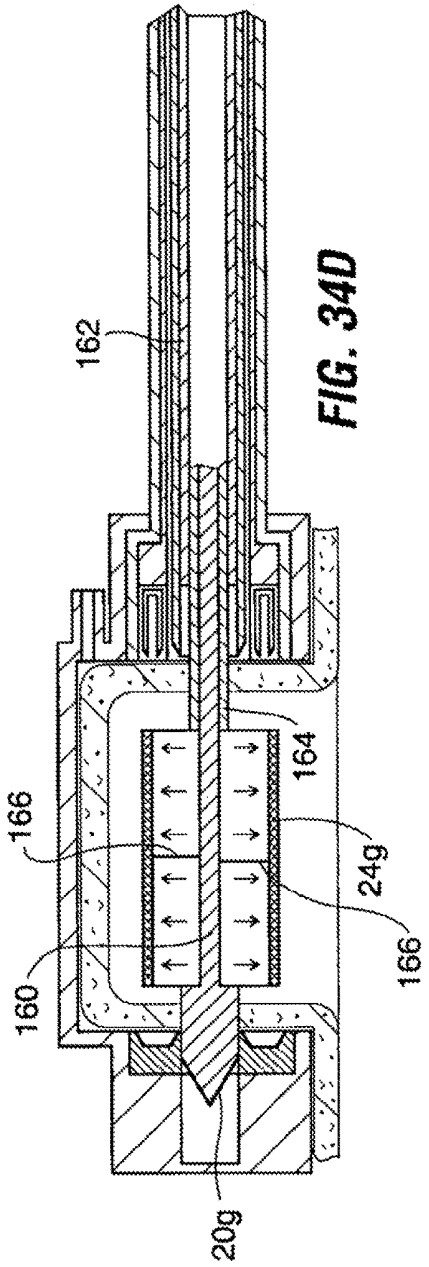


FIG. 34D

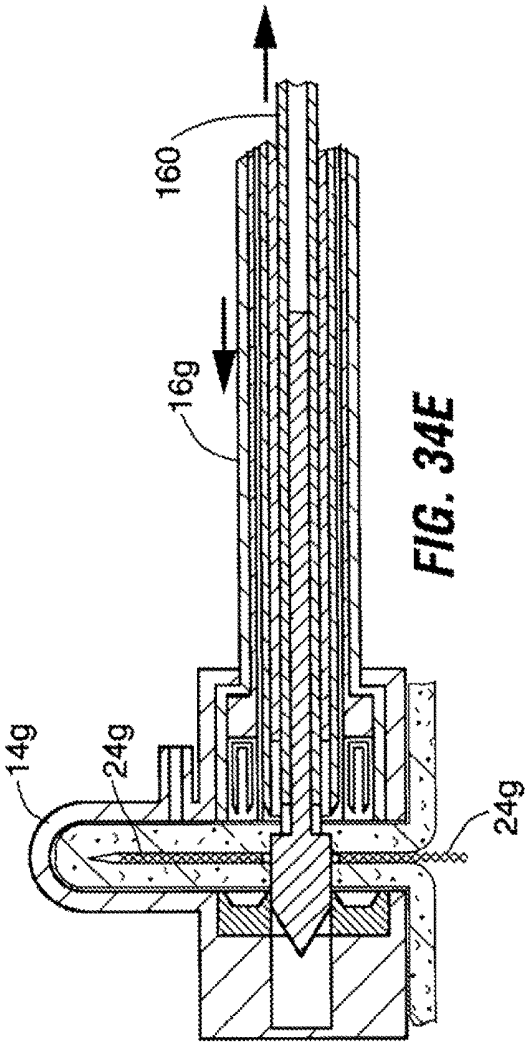


FIG. 34E

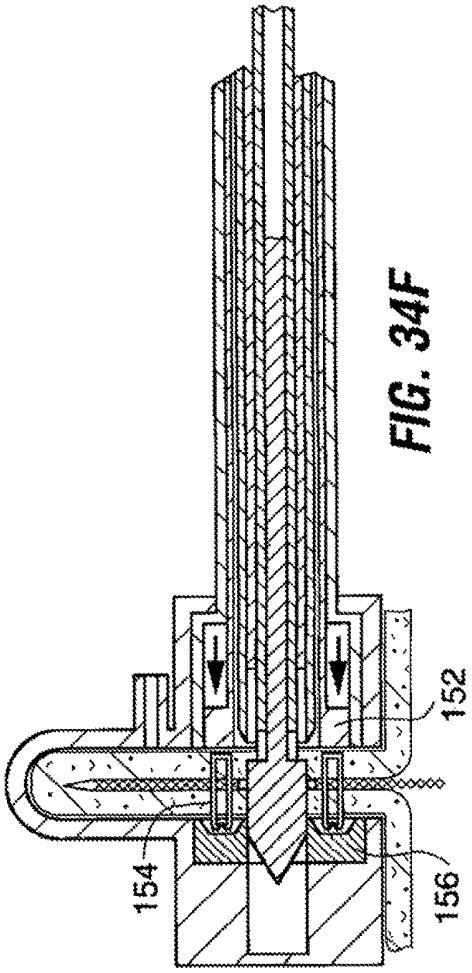


FIG. 34F

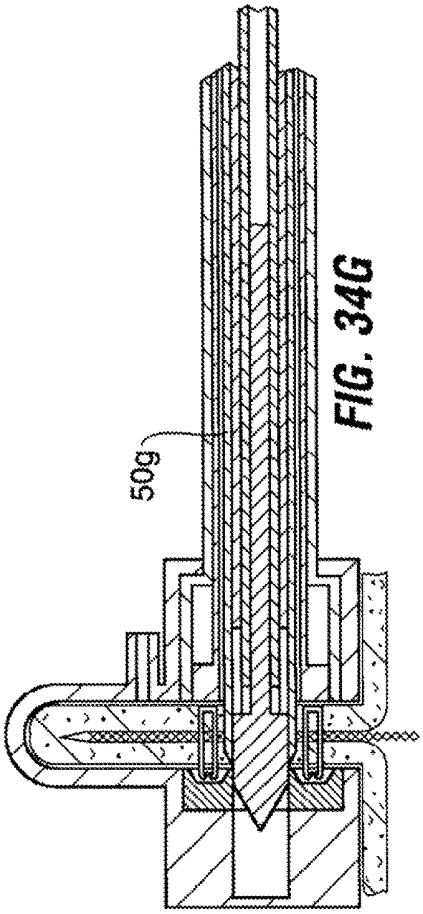


FIG. 34G

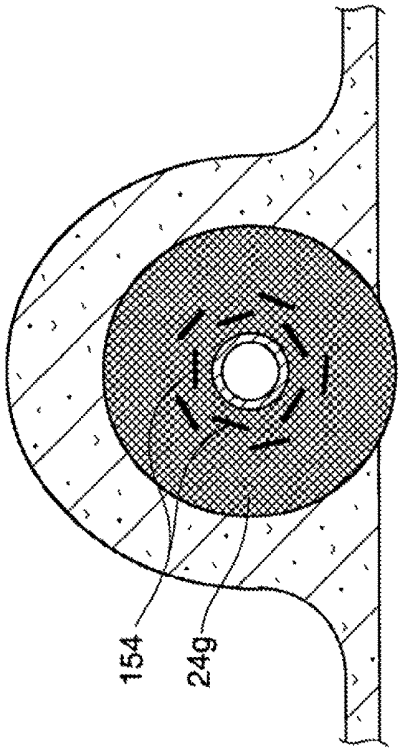


FIG. 35B

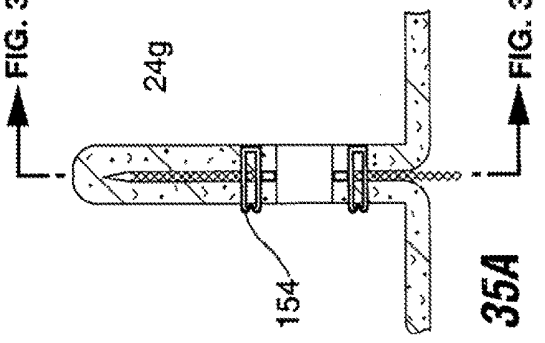
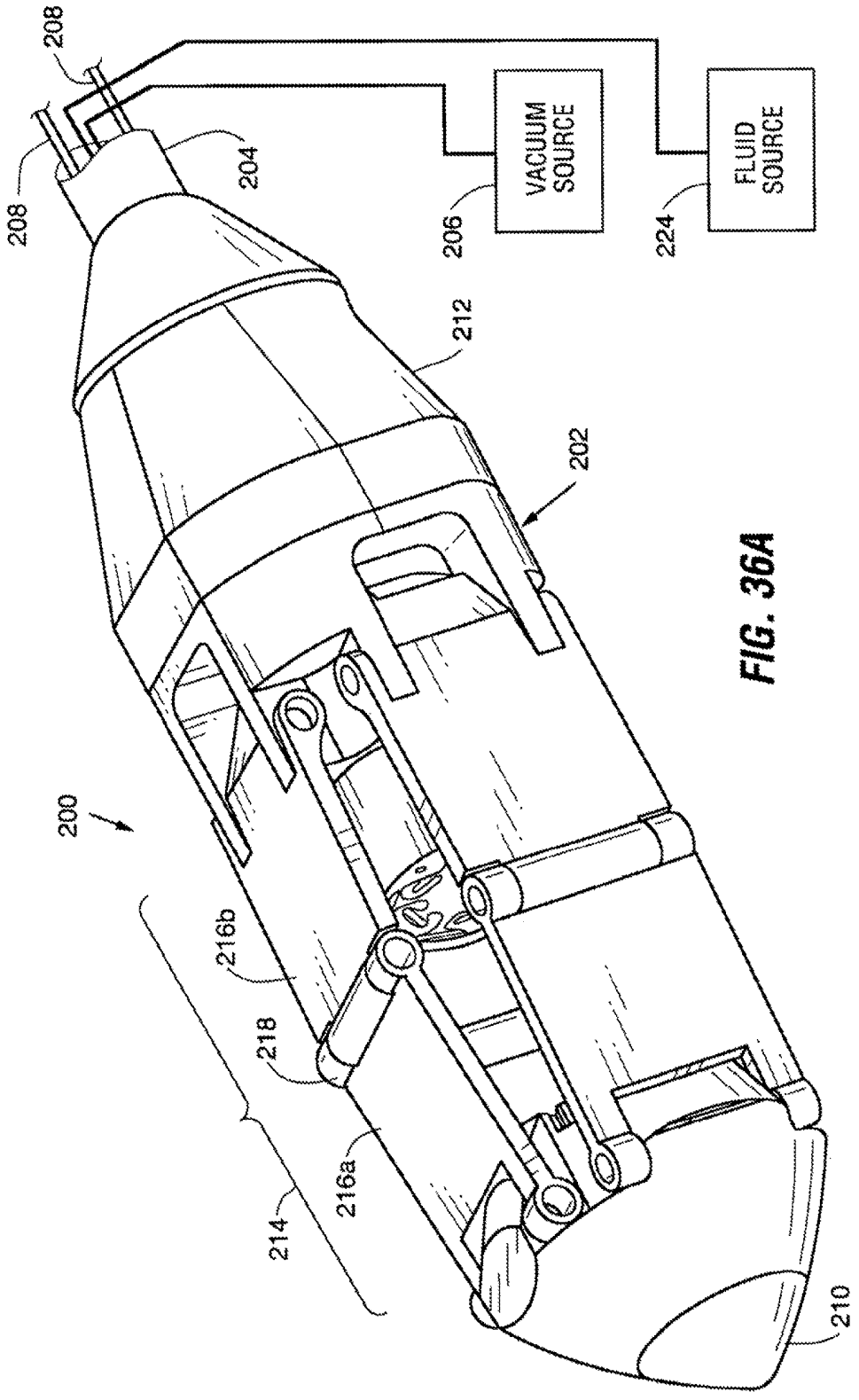


FIG. 35A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208
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206
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FLUID SOURCE
212
202
200
216b
218
216a
214
210

FIG. 36A

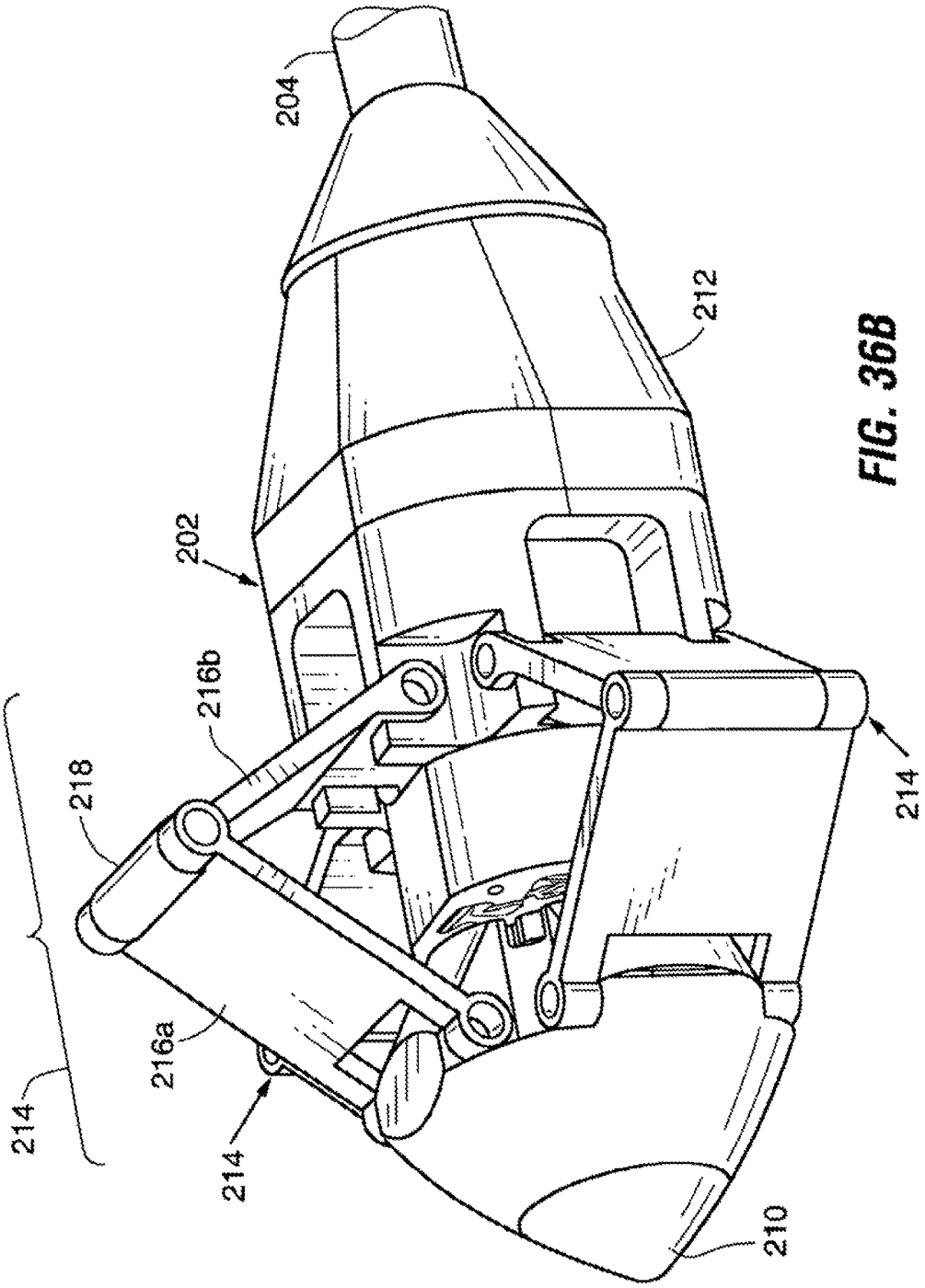
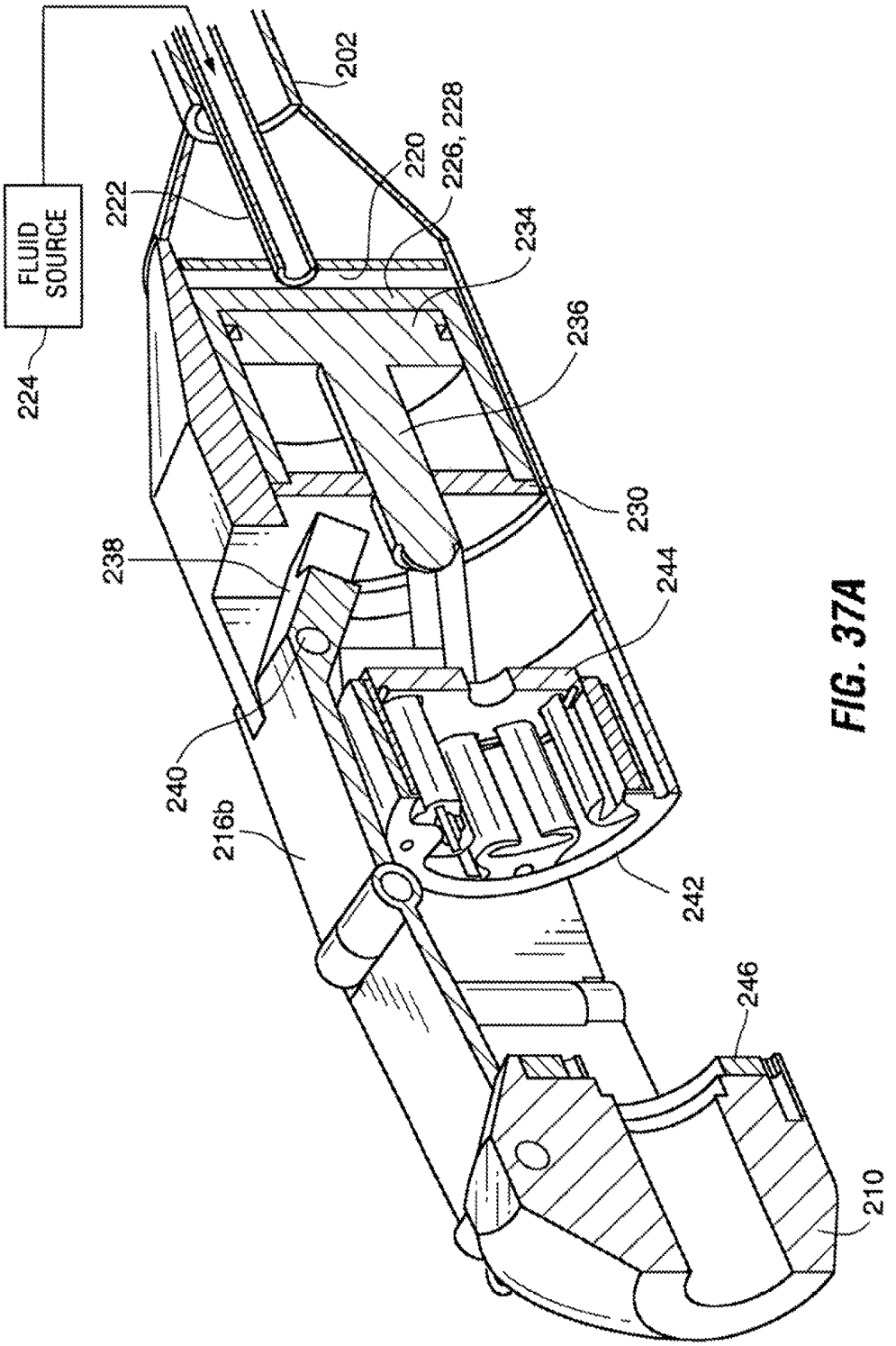


FIG. 36B


FLUID SOURCE
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216b
242
246
210

FIG. 37A

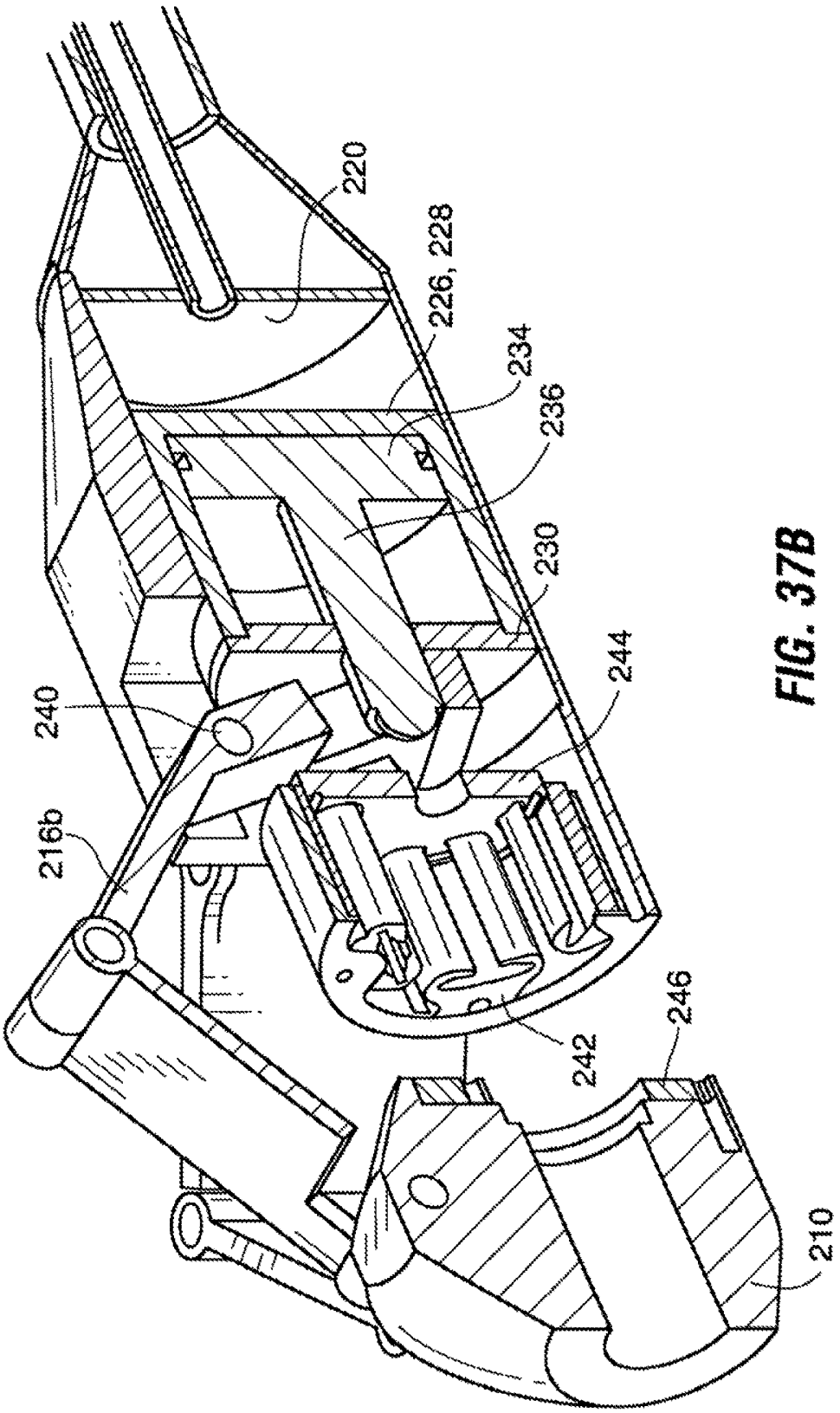

FIG. 37B

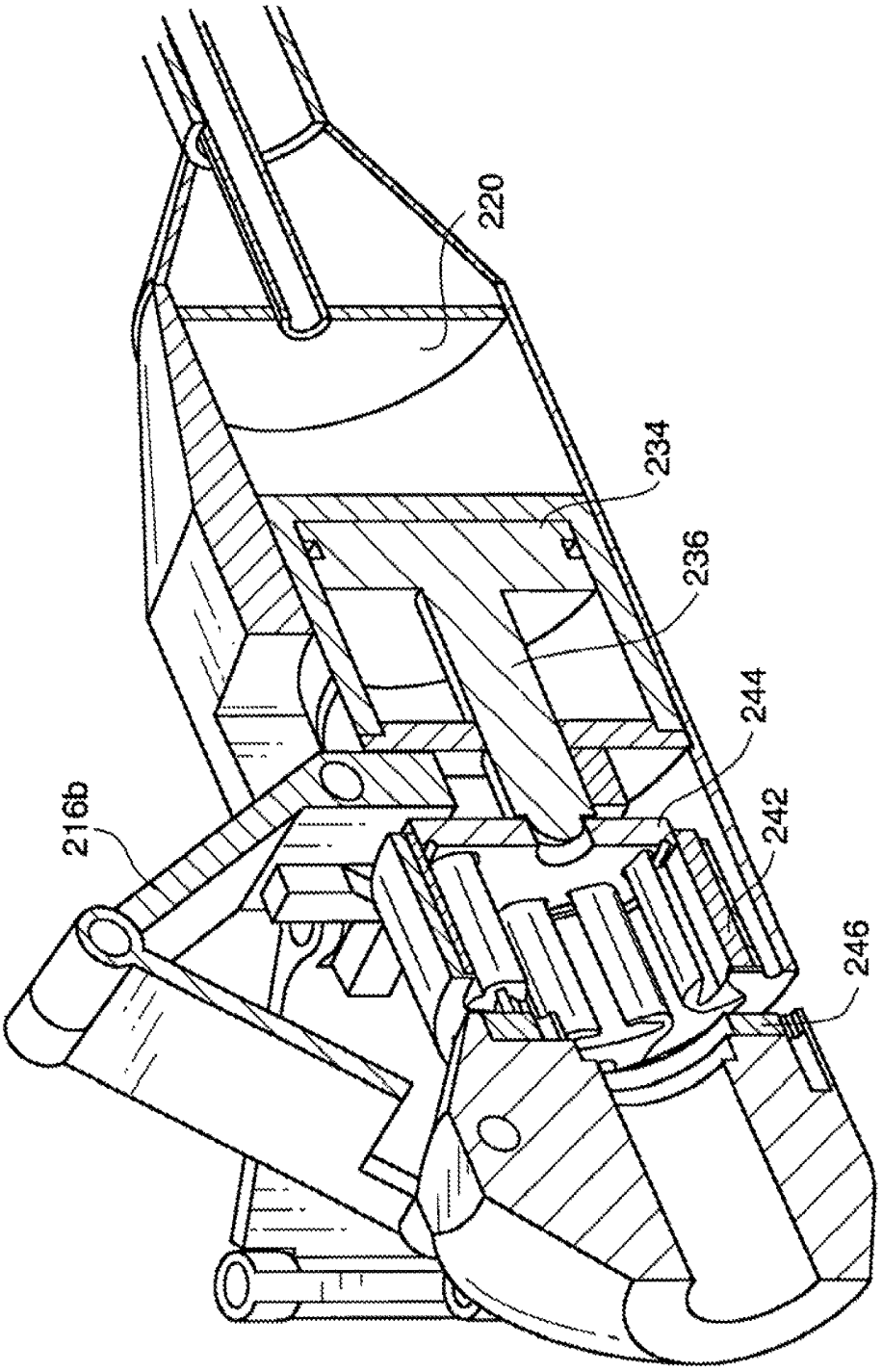

FIG. 37C

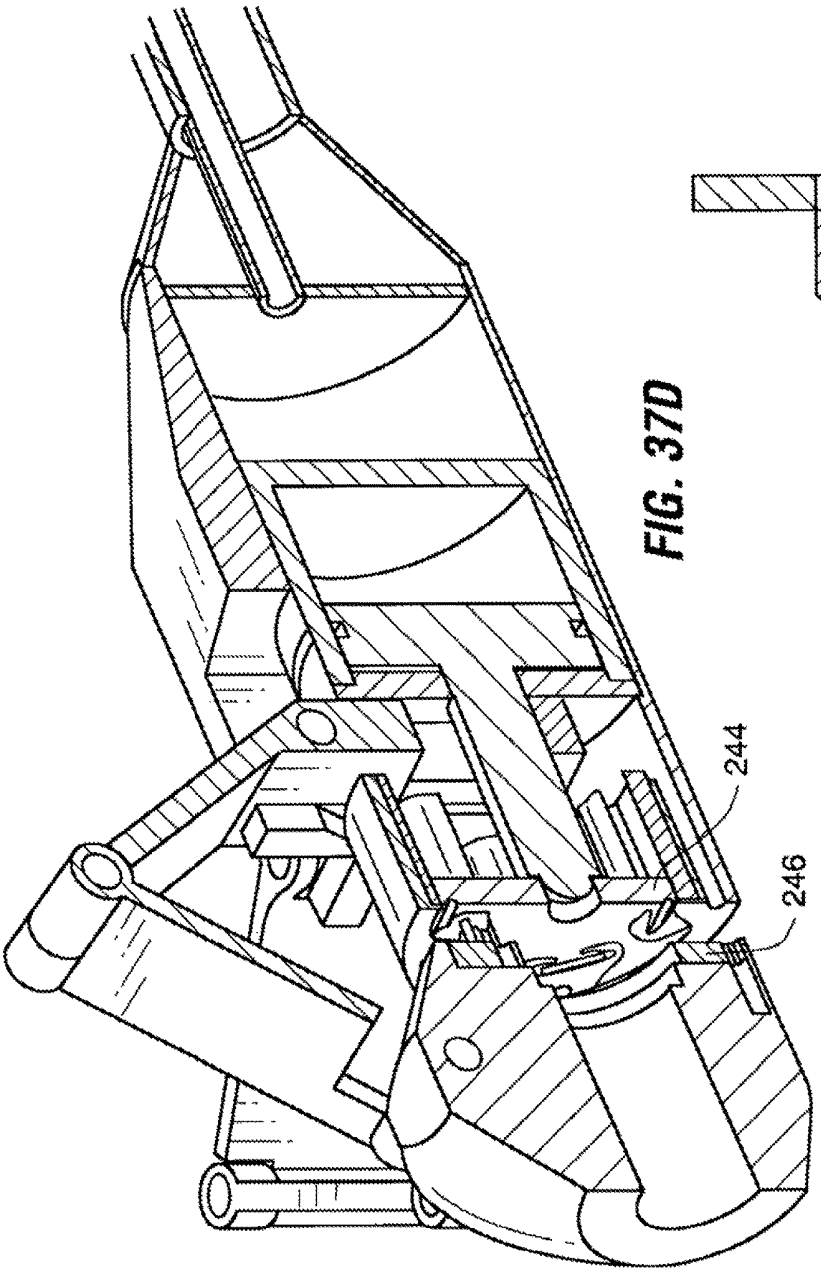

FIG. 37D

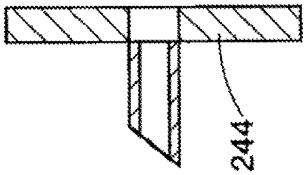

FIG. 40B

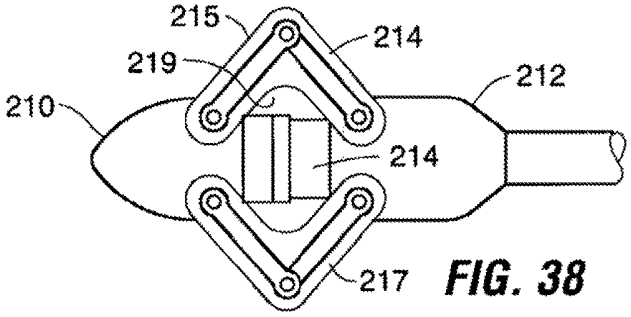

FIG. 38

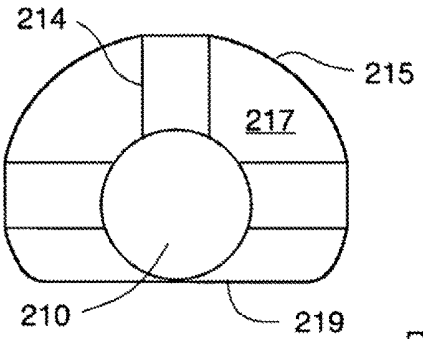

FIG. 39

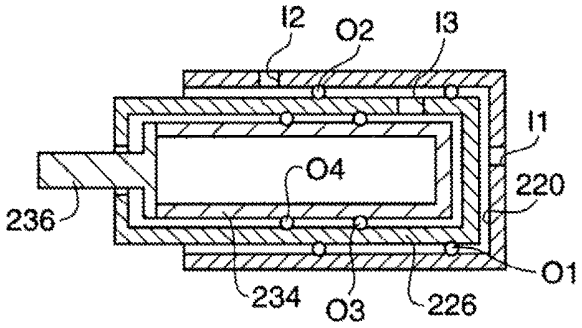

FIG. 40A

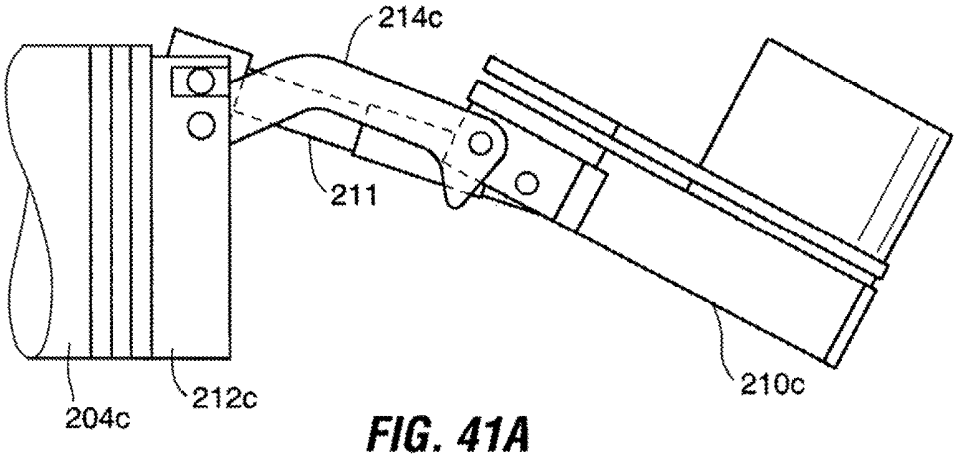

FIG. 41A

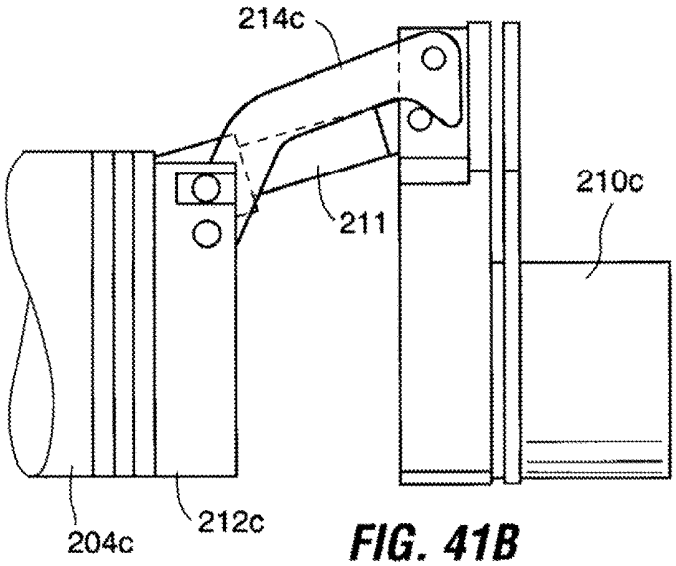

FIG. 41B

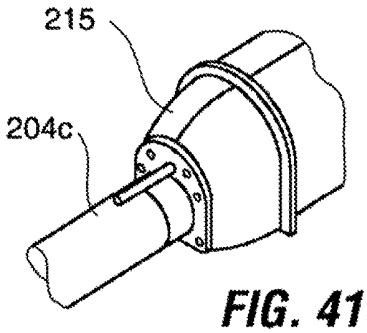

FIG. 41C

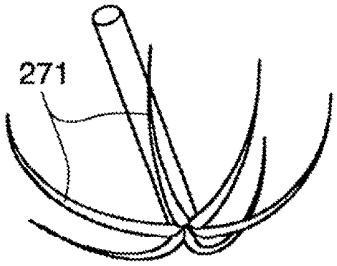

FIG. 42A

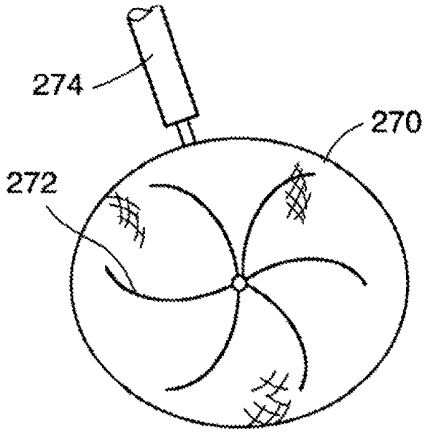

FIG. 42B

FIG. 43A

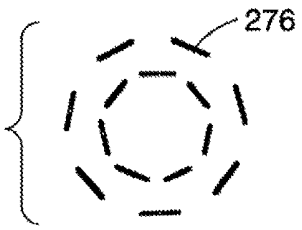

FIG. 43B

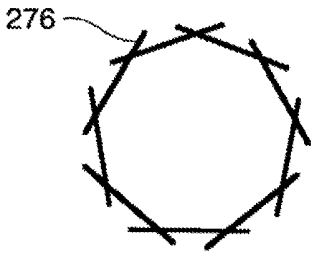

FIG. 43C

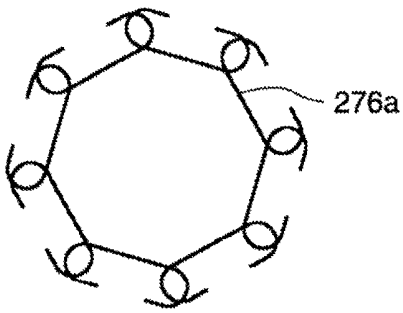

FIG. 43D

FIG. 43E

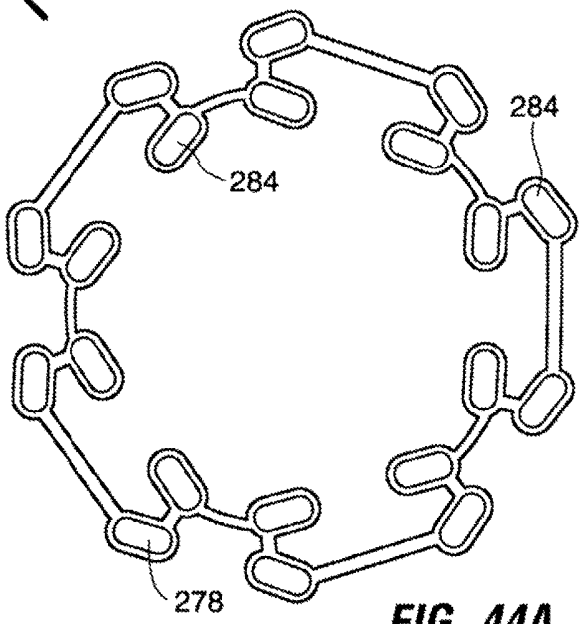

FIG. 44A

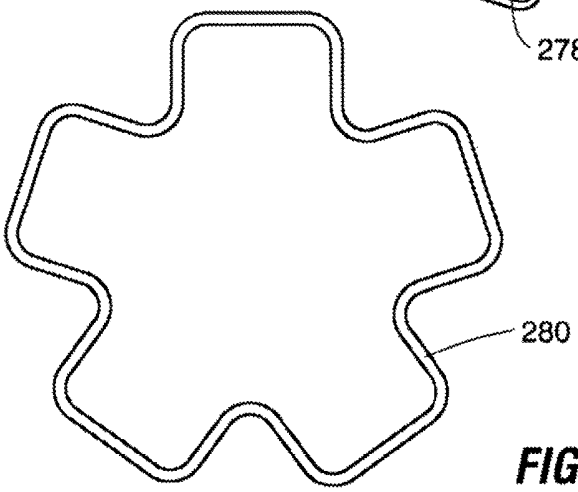

FIG. 44B

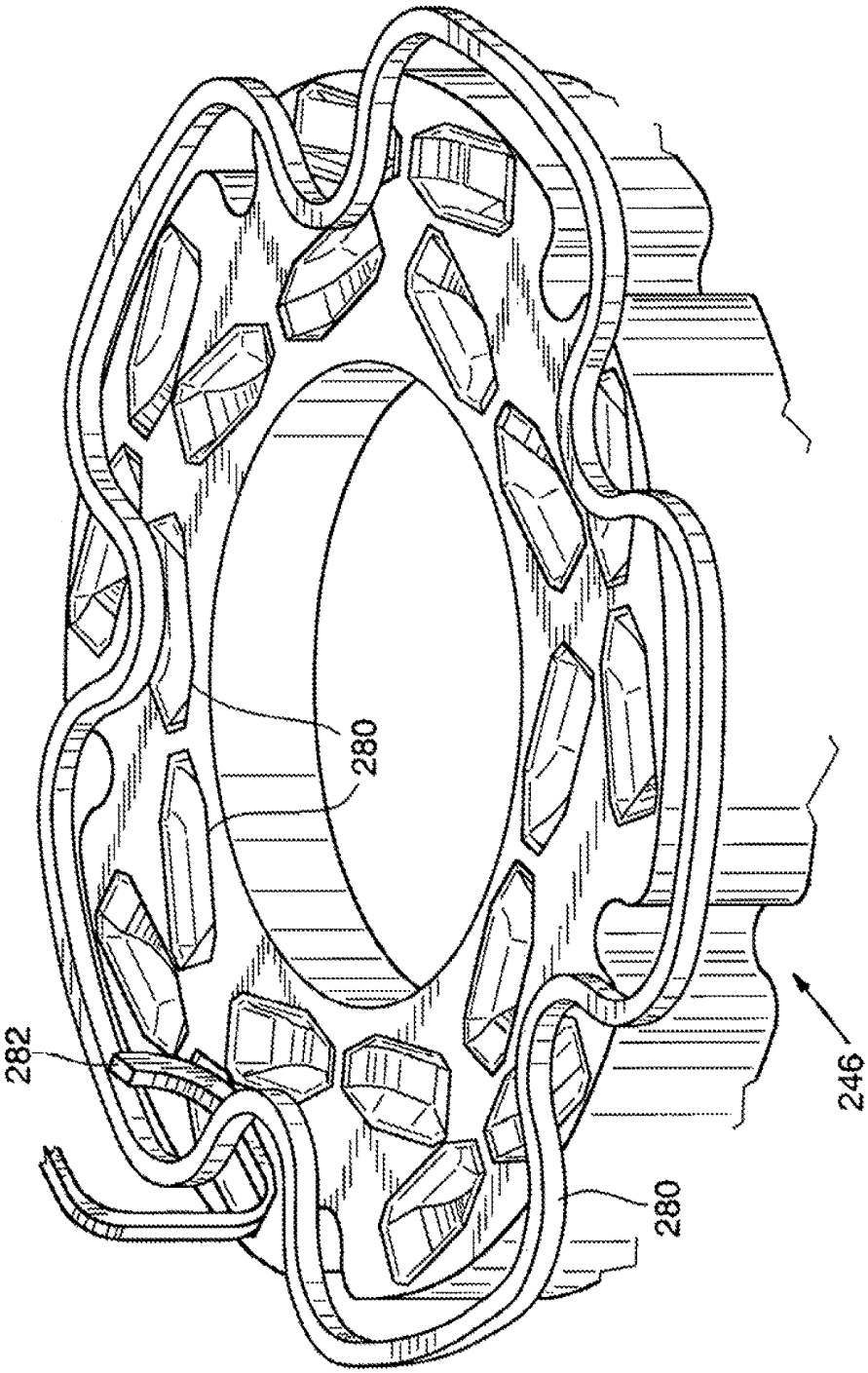

FIG. 45A

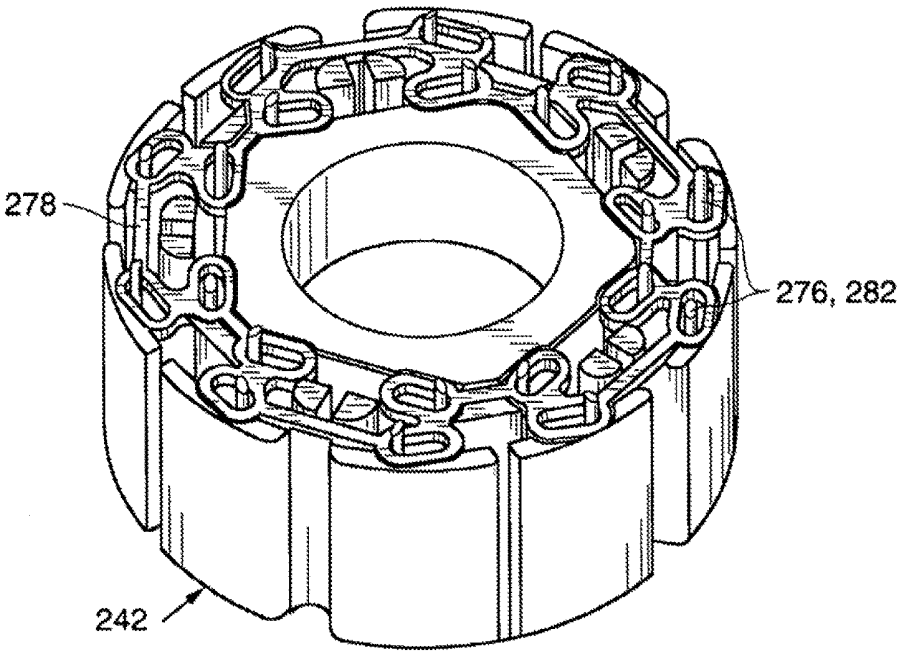

FIG. 45B

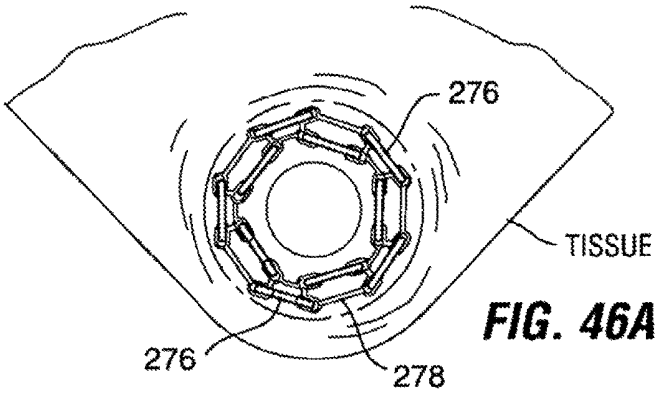

FIG. 46A

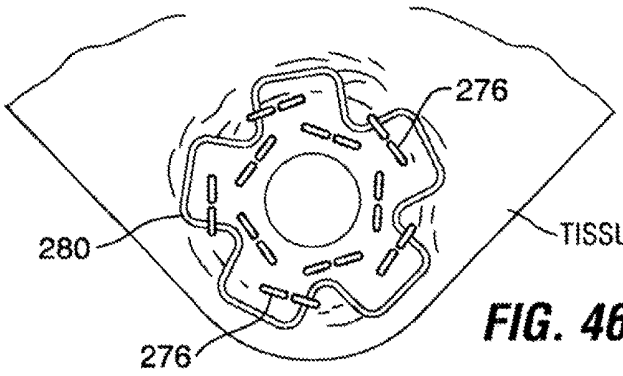

FIG. 46B

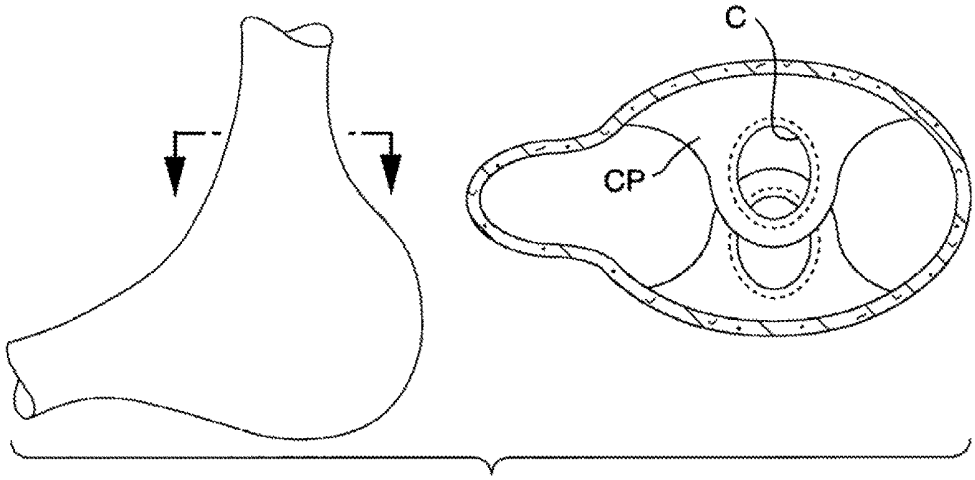

FIG. 47A

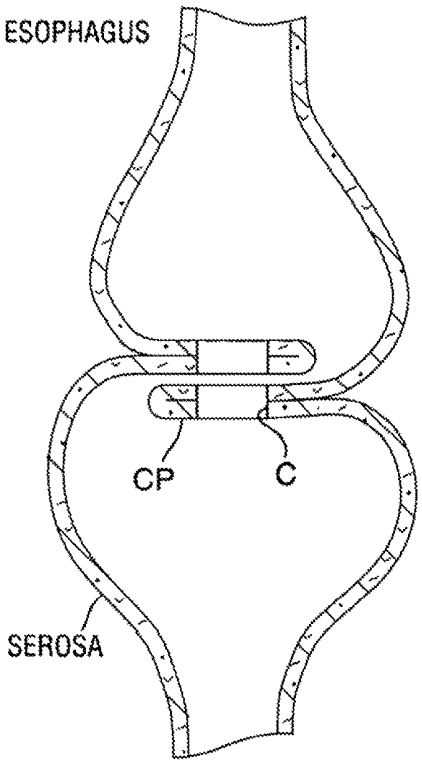

FIG. 47B

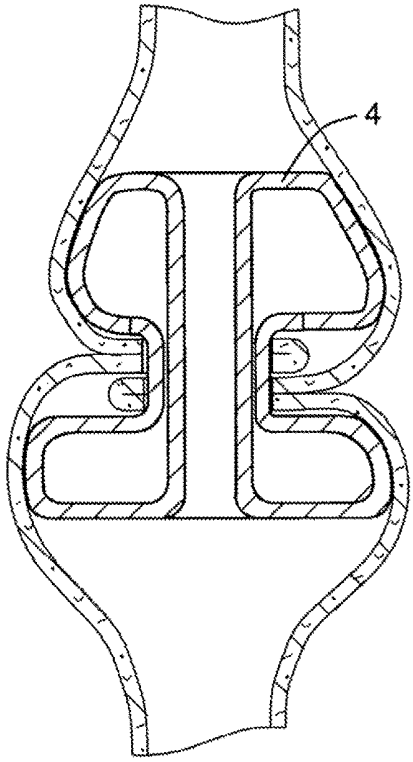

FIG. 47C

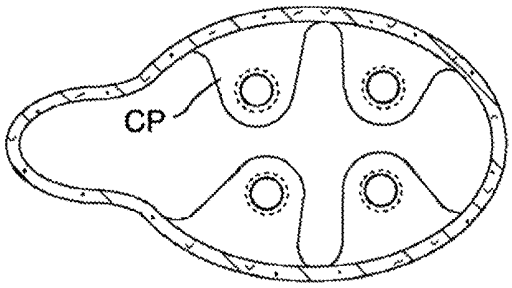

FIG. 48A

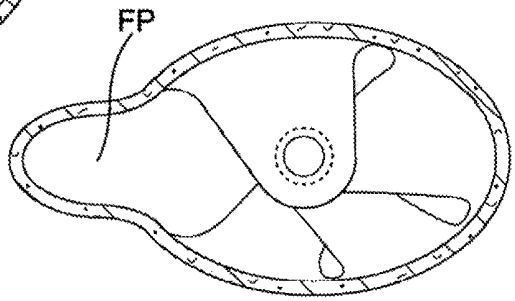

FIG. 48B

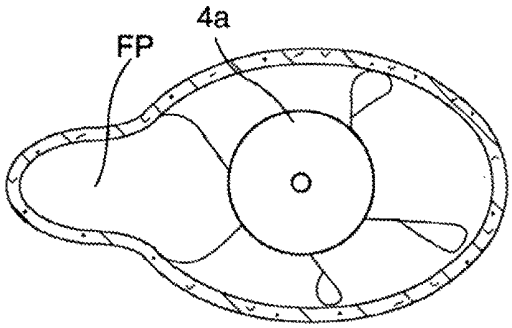

FIG. 48C

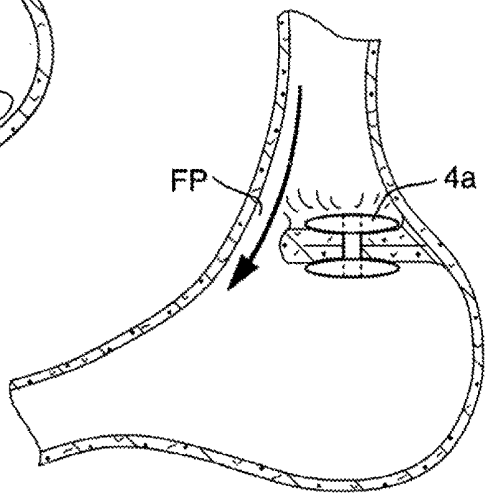

FIG. 48D

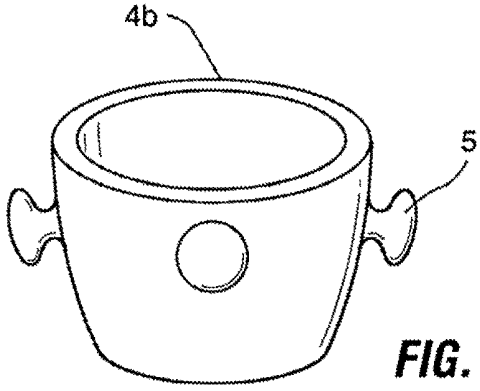

FIG. 49

ENDOSCOPIC PLICATION DEVICES AND METHODS

PRIORITY

This application is a continuation of U.S. application Ser. No. 11/542,457, filed Oct. 3, 2006, which is hereby incorporated by reference herein in its entirety. U.S. application Ser. No. 11/542,457 claims the benefit of priority from U.S. Provisional Application No. 60/723,160, filed Oct. 3, 2005; U.S. Provisional Application No. 60/754,417, filed Dec. 28, 2005; and U.S. Provisional Application No. 60/825,534, filed Sep. 13, 2006.

FIELD OF THE INVENTION

The present invention relates generally to the field of systems and methods for performing endoscopic surgery, and specifically to systems and methods for endoscopic plication of tissue within body cavities.

BACKGROUND OF THE INVENTION

An anatomical view of a human stomach S and associated features is shown in FIG. **1**A. The esophagus E delivers food from the mouth to the proximal portion of the stomach S. The z-line or gastro-esophageal junction Z is the irregularly-shaped border between the thin tissue of the esophagus and the thicker tissue of the stomach wall. The gastro-esophageal junction region G is the region encompassing the distal portion of the esophagus E, the z-line, and the proximal portion of the stomach S.

Stomach S includes a fundus F at its proximal end and an antrum A at its distal end. Antrum A feeds into the pylorus P which attaches to the duodenum D, the proximal region of the small intestine. Within the pylorus P is a sphincter that prevents backflow of food from the duodenum D into the stomach. The middle region of the small intestine, positioned distally of the duodenum D, is the jejunum J.

FIG. **1**B illustrates the tissue layers forming the stomach wall. The outermost layer is the serosal layer or "serosa" S and the innermost layer, lining the stomach interior, is the mucosal layer or "mucosa" MUC. The submucosa SM and the multi-layer muscularis M lie between the mucosa and the serosa.

Several prior applications sharing inventors with the present application, including International Application No. WO 2005/037152 having an international filing date of Oct. 8, 2004 and U.S. application Ser. No. 11/439,461, filed May 23, 2006 (both incorporated herein by reference) describe methods according to which medical implants are coupled to tissue structures formed within the stomach. According to these applications, devices for inducing weight loss (e.g. by restricting and/or obstructing flow of food into the stomach, and/or by occupying a portion of the stomach volume) may be coupled to tissue tunnels or plications P (FIG. **2**) formed from stomach tissue.

For example, U.S. application Ser. No. 11/439,461 (incorporated herein by reference in its entirety), describes a restrictive and/or obstructive implant system for inducing weight loss. In one embodiment, flexible loops **2** (FIG. **3**) are coupled to tissue plications P (FIG. **2**) formed in the gastroesophageal junction region of the stomach. An implant, such as a flow restrictive and/or obstructive implant **4** (FIG. **4**), is passed through the loops **2** and thus retained in the stomach as shown in FIG. **5**.

In other instances, tissue plications may themselves be sufficient to provide the necessary treatment. For example, the plications may be used to reduce stomach volume or form a flow restriction within the stomach.

Other types of implants may be coupled to such plications or other tissue structures for a variety of purposes. These implants include, but are not limited to prosthetic valves for the treatment of gastro-esophageal reflux disease, gastric stimulators, pH monitors and drug eluting devices that release drugs, biologics or cells into the stomach or elsewhere in the GI tract. Such drug eluting devices might include those which release leptin (a hormone which creates feelings of satiety), Ghrelin (a hormone which creates feelings of hunger), octreotide (which reduces Ghrelin levels and thus reduces hunger), Insulin, chemotherapeutic agents, natural biologics (e.g. growth factor, cytokines) which aid in post surgery trauma, ulcers, lacerations etc. Still other implants might be of a type which might provide a platform to which specific cell types can adhere, grow and provide biologically-active gene products to the GI tract, and/or a platform for radiation sources that can provide a local source of radiation for therapeutic purposes, or provide a platform whereby diagnostic ligands are immobilized and used to sample the GI tract for evidence of specific normal or pathological conditions, or provide an anchor point for imaging the GI tract via cameras and other image collecting devices.

The prior applications listed above, address the desirability of forming tissue plications, pockets or tunnels in a way that regions of serosal tissue (i.e. the tissue on the exterior surface of the stomach) are retained in contact with one another. Over time, adhesions formed between the opposed serosal layers create strong bonds that can facilitate retention of the plication/pocket/tissue over extended durations, despite the forces imparted on them by stomach movement and implanted devices. More durable plications can be created by placing any of a number of materials and/or substances (i.e. injectable sclerosing agents) between the serosal surfaces prior to plicating the serosal surfaces together. One example of material suitable for this purpose is polypropolyene mesh, commonly used for hernia repair, which when inserted in the plication fold provides a durable anchoring position within the GI tract.

Regardless of the application for which a plication is being formed, it is highly desirable to form that plication using steps carried out from within the stomach using instruments passed down the esophagus, rather than using more invasive surgical or laparoscopic methods. The present application describes endoscopic plicators which may be passed transorally into the stomach and used to form serosal-to-serosal plications in a stomach wall.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1**A is a schematic illustration of a human stomach and a portion of the small intestine.

FIG. **1**B is a cross-sectional perspective view of a portion of a stomach wall, illustrating the layers of tissue forming the wall.

FIG. **2** schematically illustrates a serosal tissue plication formed in stomach tissue.

FIG. **3** schematically illustrates a pair of loops attached to serosal tissue plications, prior to the positioning of a medical implant within the loops.

FIG. **4** is a cross-sectional side elevation view of a satiation implant.

FIG. **5** schematically illustrates the satiation implant of FIG. **4** coupled to the loops of FIG. **3**.

FIG. **6** is a perspective view of an endoscopic plication system.

FIG. **7** is a perspective view of the vacuum head of the system of FIG. **6**.

FIG. **8**A is a side elevation view of the cannula of the system of FIG. **6**.

FIG. **8**B is a perspective view of the distal end of the cannula of FIG. **8**A.

FIG. **9** is a cross-sectional side view of an anchor of the system of FIG. **6**.

FIG. **10** is a plan view of the catch of the anchor of FIG. **9**.

FIG. **11**A is a plan view of the spring element of the anchor of FIG. **9**.

FIG. **11**B is a perspective view of the spring element of FIG. **11**A, showing the spring tabs in the opened position.

FIG. **12** is a perspective view of the vacuum head of FIG. **7**, showing the anchor of FIG. **9** positioned within the vacuum head.

FIG. **13** is a perspective view of the anchor of FIG. **9**, which includes a loop of the type shown in FIG. **3**.

FIG. **14**A is a perspective view of the mesh tube of the system of FIG. **6**.

FIG. **14**B is cross-sectional perspective view showing the mesh tube of FIG. **14**A in the compressed orientation.

FIG. **15**A is a side elevation view showing the tip, cable, mesh tube, and sheath of FIG. **6** following assembly.

FIG. **15**B is a side elevation view of the plicator of FIG. **6** assembled for use.

FIG. **16**A schematically illustrates introduction of the assembled plicator and an endoscope into the stomach.

FIG. **16**B schematically illustrates creation of a tissue pocket using the plicator of FIG. **16**A.

FIG. **17**A is a perspective view of a barbed stabilizing cuff.

FIG. **17**B is a perspective view similar to FIG. **16**B, showing use of the barbed stabilizing cuff of FIG. **17**A to stabilize tissue within the pocket.

FIG. **18**A schematically illustrates positioning of the tip element and mesh tube following their deployment.

FIG. **18**B schematically illustrates the stomach exterior surface following deployment of the tip and anchor.

FIG. **19**A illustrates compression of the anchor using the plicator and cable.

FIG. **19**B shows the final anchor and mesh position following removal of the plicator and endoscope.

FIG. **20** illustrates an alternative method for compressing the anchor.

FIGS. **21**A through **21**C are perspective views illustrating an alternative vacuum chamber in which the vacuum chamber also forms the implantable anchor.

FIGS. **22**A through **22**D are a sequence of steps illustrating an alternative method using a vacuum paddle that additionally functions as an implantable anchor.

FIGS. **23**A through **23**B and **24**A through **24**B are a sequence of steps illustrating an alternative method which forms a serosal tunnel and positions a leg of an anchor within the serosal tunnel. FIGS. **23**A and **23**B are cross-sectional side views. FIGS. **24**A and **24**B are perspective views taken from within the stomach.

FIG. **25**A is a perspective view taken from within the stomach illustrating the serosal tunnel formed during the sequence of steps illustrated in FIGS. **23**A through **24**B.

FIG. **25**B is a cross-section view of the serosal tunnel and anchor shown in FIG. **25**A.

FIG. **25**C illustrates placement of two of the anchors of FIGS. **23**A-**24**B within a stomach.

FIGS. **26**A through **26**C are cross-sectional side views of a plication system and a stomach wall, illustrating an alternative method in which a sclerosing agent is injected into the serosal pocket prior to advancement of the tip element.

FIGS. **27**A and **27**B are cross-section views illustrating a method for sealing sclerosing agent within the serosal pocket using a clamp.

FIGS. **28** and **29**, in which FIG. **28** is a perspective view and FIG. **29** is a cross-section view of a distal end of a plication system and a portion of the stomach wall, illustrate methods for sealing sclerosing agent within the serosal pocket using the vacuum head.

FIGS. **30**A through **30**D are a sequence of side views of a stomach wall engaged by a vacuum chamber, and illustrate steps of an alternative method of forming a tissue plication using sclerosing agents.

FIGS. **31**A and **31**B illustrate alternate place holding elements for use in the method of FIGS. **30**A-**30**D.

FIGS. **32**A and **32**B illustrate the use of clamps to retain plications formed using the FIG. **30**A-**30**D method during healing of the plications.

FIG. **33**A is a perspective view of a serosal plication having a cutout formed through the tissue. FIG. **33**B is a cross-section view of a stomach illustrating three serosal plications of the type shown in FIG. **33**A.

FIG. **34**A is a cross-sectional side view of a second preferred embodiment of a plication system.

FIGS. **34**B-**34**G are a sequence of cross-sectional side views illustrating formation of a plication of the type shown in FIG. **33**A using the system of FIG. **34**A.

FIG. **35**A is a cross-section side view of the plication formed in accordance with the method of FIGS. **34**A-**34**G.

FIG. **35**B is a cross-sectional plan view taken along the plane designated **35**B-**35**B in FIG. **35**A.

FIG. **36**A is a perspective view of the plication head of an alternative embodiment of a plicator, shown in the streamlined positioned for transoral delivery to the stomach. The shroud is not shown to allow clear viewing of the underlying components.

FIG. **36**B is a perspective view similar to FIG. **36**A showing the plication head in the expanded position. The shroud is not shown to allow clear viewing of the underlying components.

FIGS. **37**A through **37**D are a sequence of cross-sectional perspective views of the plication head of FIGS. **36**A and **36**B, illustrating a method of using the plication head. The shroud is not shown to allow clear viewing of the underlying components.

FIG. **38** is a bottom plan view of the plication head of FIGS. **36**A-**37**C with the shroud in place and the hinge members in the expanded position.

FIG. **39** is a front elevation view of the plication head as positioned in FIG. **38**.

FIG. **40**A is a cross-sectional side views of the hydraulic chamber a piston assembly used for expanding the vacuum chamber, compressing tissue, and driving the staples in the embodiment of FIGS. **36**A-**39**.

FIG. **40**B is a cross-sectional side view of the staple driver of the embodiment of FIGS. **36**A-**37**D.

FIGS. **41**A and **41**B are side elevation views of a modified plication head with the shroud not shown to permit the underlying components to be seen.

FIG. **41**C is a perspective view of the plication head of FIGS. **41**A and **41**B, with the shroud shown.

FIG. **42**A is a perspective view of an expandable frame for deploying a reinforcing element. FIG. **42**B shows a reinforcing element on the frame of FIG. **42**A.

FIGS. **43**A and **43**B are plan views illustrating staple patterns.

FIGS. **43**C-**43**E are plan views illustrating interlocking staple patterns.

FIGS. **44**A and **44**B are plan views of reinforcing rings.

FIG. **45**A is a perspective view showing the reinforcing ring of FIG. **44**B on a stapler anvil.

FIG. **45**B is a plan view of the reinforcing ring of FIG. **44**A on a staple cartridge.

FIGS. **46**A and **46**B are plan views of a tissue plication, in which FIG. **46**A shows the side of the plication positioned on the staple cartridge side of the plicator, and FIG. **46**B shows the side of the plication position on the anvil side of the plicator.

FIG. **47**A is a cross-sectional top view of a stomach, illustrating movement of cutout plications into alignment in preparation for insertion of an implant through their cutouts.

FIG. **47**B is a cross-sectional side view of a stomach, illustrating the alignment step of FIG. **47**A.

FIG. **47**C is a cross-sectional side view similar to FIG. **47**B, with the implant in place within the cutouts.

FIG. **48**A is a cross-sectional top view of a stomach illustrating an arrangement of cutout plications.

FIG. **48**B is a cross-sectional top view similar to FIG. **48**A, showing the cutout plications drawn into alignment with one another.

FIG. **48**C is a cross-sectional top view similar to FIG. **48**B, showing an implant positioned in the aligned cutouts of the plications.

FIG. **48**D is a cross-sectional side view of the stomach, illustrating the formation of a food passage in the stomach using the arrangement of plications and the implant shown in FIG. **48**C.

FIG. **49** is a perspective view of a restrictive implant having buttons insertable through holes formed in stomach tissue plications.

DETAILED DESCRIPTION OF THE DRAWINGS

The present application describes endoscopic plicators which may be passed transorally into the stomach and used to plicate stomach tissue by engaging tissue from inside of the stomach and drawing it inwardly. In the disclosed embodiments, the tissue is drawn inwardly into a vacuum chamber, although tissue may be drawn inwardly using other components that do not involve the use of a vacuum. When a portion the stomach wall is drawn inwardly, sections of serosal tissue on the exterior of the stomach are positioned facing one another. The disclosed plicators allow the opposed sections of tissue to be moved into contact with one another, and preferably deliver sutures, staples or other means for maintaining contact between the tissue sections at least until serosal bonds form between them. Each of these steps may be performed wholly from the inside of the stomach and thus can eliminate the need for any surgical or laparoscopic intervention. After one or more plications is formed, medical devices (including, but not limited to any of the types listed above) may be coupled to the plication(s) for retention within the stomach.

Certain of the disclosed plicators pass a mesh element and/or a quantity of sclerosing agent through the stomach wall such that it is disposed between the opposed regions of serosal tissue thus enhancing serosal bonding. Some embodiments include a feature that forms a hole in a plication using the plication device, so that a portion of a medical implant may be passed through or linked to the hole the plications. Others of the embodiments are configured to couple an anchor to the plication as it is formed, so that a medical implant may later be coupled to the anchor.

While this application describes plication systems and methods with respect to the formation of plications in stomach tissue, the embodiments described herein have equal applicability for forming plications in parts of the body outside the GI system.

Plication System of the First Preferred Embodiment

FIG. **6** illustrates one embodiment of a system **10** for tissue plication that is suitable for endoscopic use, as well as surgical or laparoscopic use if desired.

Generally speaking, system **10** includes a plicator **12** having a vacuum head **14** and a shaft **16**. The system further includes a flexible anchor **18** for attachment to stomach tissue, a tissue penetrating tip element **20** having a cable **22**, a mesh element **24**, and a sheath **26**.

Referring to FIG. **7**, vacuum head **14** defines a vacuum chamber **28** having an opening that, during use, is positioned into contact with stomach tissue so as to draw the tissue into the chamber **28**. Vacuum head **14** further includes slots **32**, **34** sized to receive portions of the anchor **18** as described below. The distal and proximal ends of the vacuum head **14** include U-shaped openings **36**, **38**.

Referring once again to FIG. **6**, shaft **16** is a flexible elongate member extending from the proximal end of the vacuum head **14**. Shaft **16** is equipped with pull-wires (not shown) and/or alternative means for articulating the vacuum head **14** as needed for proper positioning within the stomach. Shaft **16** includes a distal portion **40** having a generally U-shaped slot **42** corresponding to the U-shaped opening **38** in the vacuum head. The proximal portion **46** of shaft **16** is tubular and includes at least one lumen **48** extending its length.

A tubular cannula **50** extends through the shaft **16** as shown in FIG. **6**. Cannula **50** is fluidly coupled to a source of negative pressure such as a syringe or vacuum pump. Application of suction to the cannula **50** creates a vacuum in the vacuum chamber as discussed in detail below. As most clearly visible in FIGS. **8**A and **8**B, cannula **50** includes an annular flange **53** (FIGS. **8**A and **8**B) surrounding its distal end. A plurality of proximally-oriented ratcheting elements **51** (FIG. **8**B) are positioned within the lumen of cannula **50**, adjacent to the cannula's distal end.

Anchor **18** includes a distal tab **52** and a proximal tab **54** on opposite ends of a central portion **56**. Anchor **18** is a flexible element formed of silicone or other flexible, biocompatible material. Its properties permit it to be deformed into the orientation shown in FIG. **9** for insertion into the vacuum head. More specifically, the anchor **18** is positionable within the vacuum head **14** as shown in FIG. **12** with the distal tab **52** disposed in distal slot **32** and the proximal tab **54** within proximal slot **34**.

As best seen in the cross-section view of FIG. **9**, a catch **58** is seated within a recess in the distal tab **52** of anchor **18**. Catch **58** may be formed of a resilient material such as stainless steel, nitinol, or resilient polymer that has been over-molded using rubber. As will described in detail below, catch **58** functions to engage a portion of the tip element **20** (FIG. **6**) after it has been advanced through the tissue undergoing plication. In the illustrated embodiment, catch **58** includes a cutout **60** proportioned to engage the tip **20**, however any alternative configuration for the cutout **60** and tip **20** that will permit engagement of the two is equally

suitable. A rubber protrusion **62** is positioned on the anchor **14** to receive the sharp tip of the tip element to prevent injury to surrounding tissue.

Referring again to FIG. **9**, proximal tab **54** includes an opening **64** within which a spring element **66** is positioned. Materials used for the spring element may be similar to those used for the catch **58**. Spring element functions to engage cable **22** to retain the anchor in position, and it should be appreciated that alternative features that can perform this function can instead be used. As best shown in FIG. **11**A, a preferred spring element **66** includes a pair of tabs **68** that can be pushed to a slightly outward orientation (see FIG. **11**B) when acted upon by a force shown by arrow A in FIG. **9**, but that will return to the closed orientation when the force is relieved. Tabs **60**, in their closed orientation, define a central cutout **70**.

It is appropriate to note that anchor **18** may take many alternate forms without departing from the scope of the invention. For example, in one alternative embodiment shown in FIG. **13**, anchor **18***a* includes a loop **2** of the type described in connection with FIGS. **2-5** coupled to its distal end.

Referring again to FIG. **6**, tip element **20** includes a piercing element that is sufficiently sharp to penetrate abdominal wall tissue when subjected to an appropriate amount of force. The tip element **20** may be formed of stainless steel or any other material suitable for this purpose. A preferred tip element includes a collar **73** which defines a recess **72** between the distal edge of the collar and the proximal edge of the tip. Recess **72** is proportioned to seat within the cutout **60** (FIG. **10**) of the anchor's distal catch **58** when the tip element is passed through the cutout **60**.

Cable **22** is coupled to the proximal portion of the tip element **20**. Cable **22** preferably includes a series of barbs **74**, teeth, or other engagement elements. As will be described in connection with FIG. **19**A, during use the cable is engaged by spring element **66** which allows the cable to slide in a proximal direction but that prevents movement of the cable in a distal direction. In other words, the cable functions in a manner similar to a cable tie found in hardware stores.

As discussed, the system is preferably designed to pass material between the serosal tissue layers so as to facilitate serosal tissue bonding. The material may be a synthetic or non-synthetic mesh (formed of nitinol or other material), porous or non-porous material, slotted material, or any other material through which adhesions will form or onto which tissue will grow. Examples include, but are not limited to, polypropylene, materials sold under the trade names Gore-tex or Dacron, or tissue graft material such as the Surgisis material sold by Wilson Cook Medical, Inc. The material may be treated with tissue-ingrowth promoting substances such as biologics.

The delivered material can be constructed into any shape or configuration that will achieve its purpose of promoting strong serosal adhesions. As illustrated in FIGS. **14**A and **14**B, a convenient form for the delivered material is that of a mesh tube **24** designed such that application of compressive forces between the proximal and distal ends will cause the mesh to take the form of a disk, or such that it will self-expand to a disk-like shape when released from a restrained position. Tubular caps **76***a*, **76***b* formed of a suitable polymeric material may be attached to the distal and proximal ends of the tube to minimize damage to the mesh during compression.

Exemplary Method of Using the First Preferred Embodiment

One method of using the system of FIG. **6** will next be described.

In preparation for use, tip **20**, cable **22**, mesh element **24**, and sheath **26** are assembled for insertion into cannula **50**. Specifically, as shown in FIG. **15**A, mesh tube **24** is threaded over cable **22** and positioned such that its distal cap **76***b* abuts the collar **73** of tip **20**. Sheath **26** is positioned over the mesh tube **24** and advanced such that its distal end is also in contact with the collar **73**.

Referring to FIG. **15**B, the assembled tip, cable, mesh element and sheath are inserted into the cannula **50**. Anchor **18** is seated within the vacuum chamber **28** as described above. The flange **53** of the cannula **50** is positioned in sealing contact with the anchor **18**. For example, the flange **53** may be inserted into the proximal opening **64** (FIG. **9**) of the anchor so as to create an interference fit between the two. Adequate sealing is desirable to prevent loss of vacuum pressure from the vacuum chamber **28** during use.

Next, the assembled plicator **12** is passed into the stomach S via the esophagus as shown in FIG. **16**A. An endoscope **80** is also passed into the stomach to provide visualization of the procedure. Although the endoscope **80** is shown as a separate component, the plicator **12** may be modified to include an integrated endoscope.

Referring to FIG. **16**B, the plicator **12** is advanced to a target location at which a plication is to be formed. The plicator is manipulated using pull wires or other steering elements to place vacuum chamber **28** against the stomach tissue. Suction is applied to the vacuum chamber **28** via cannula **50**, thus drawing stomach tissue into the vacuum chamber as shown. Consequently, a pocket **100** forms in the tissue such that if the stomach were to be viewed from the outside a depression in the stomach wall would be visible. Suction is maintained to stabilize the tissue within the vacuum chamber. If additional stabilization of the tissue is desired, the plicator **12** may be provided with a barbed stabilization cuff **82** of the type shown in FIG. **17**A. Cuff **82** includes a plurality of barbs **84** oriented to penetrate stomach tissue as shown in FIG. **17**B when the tissue is drawn into the chamber **28**, thus holding the proximal portion of the captured tissue in place during advancement of the tip member **20** and mesh **24** element. Other stabilizing mechanisms may alternatively be used in lieu of, or in addition to, the cuff and barbs.

At this point, the tissue is ready for advancement of the tip member **20** through the tissue, as well as deployment of the mesh tube **24** into the pocket **100**. Advancement of the tip and deployment of the mesh may be performed in a single step, or they may be formed as a sequence of steps. For simultaneous advancement and deployment, sheath **26** is advanced in a distal direction, thereby driving the tip **20** distally through the tissue walls **102** defining the pocket **100**. If the forces of friction between the tubular mesh element **24** and the sheath **26** are sufficiently large, the advancing sheath carries the mesh tube **24** into the pocket. Alternatively, a pushing mandrel **86** (shown in FIG. **17**B) may be advanced distally against the proximal cap **76***a* of the mesh element **24** to advance the mesh element **24** into the pocket **100**. If separate advancement of the tip member **20** and deployment of the mesh element **24** is preferred, the tip member **20** is first driven in a distal direction by distal movement of the sheath **26**, and the mesh element is then separately pushed over the cable **22** using the mandrel **86**.

Many alternative structures useful for separately or simultaneously applying pushing forces to the tip element **20** and the mesh element **24** are readily conceivable and may also be used.

Regardless of the mode of deployment, as the tip member **20** is advanced, its pointed distal end moves into contact with the spring element **66** on the anchor **18**, causing tabs **68** (FIGS. **9**, **11**A and **11**B) to push distally into the position shown in FIG. **11**B, and to then return to their substantially planar orientation (FIG. **11**B) once the tip member **20** has cleared the spring element **66**. The tip element **20** then passes through the walls **102** of tissue and into engagement with the distal catch **58** of the anchor **18** (i.e. the edges of the cutout **60** seat within recess **72** of the tip element **20**), thereby locking the tip element to the catch **58**. The distalmost portion of the tip element **20** embeds within the protrusion **62** of the anchor.

The cable **22** remains attached to the tip element **20** and thus extends through the walls **102**, through catch **58** and spring element **66**, and through the cannula **50**. The mesh tube **24** remains disposed around the cable **22**. FIG. **18**A is a cross-section view of the stomach illustrating the arrangement of the components after the tip element **20** and mesh tube **24** have been deployed. FIG. **18**B shows the outside of the stomach at this stage of the procedure.

The next series of steps are geared towards drawing the distal and proximal tabs **52**, **54** of the anchor **18** towards one another, so as to enclose the mesh element **24** within the pocket **100**. Referring to FIG. **19**A, the vacuum head **14** is moved in a lateral direction until it separates from the anchor **18** and the pocket **100**. (If a barbed stabilization cuff **82** of the type shown in FIG. **17**A has been used to engage the tissue, the cuff is first rotated to "unscrew" its barbs from the tissue. This might be achieved, for example, using a rotatable element (not show) that may be grasped and rotated by the user.) Vacuum head **14** is then positioned against the anchor **18** and used to impart a distally-oriented force against the proximal side of the anchor **18**. At the same time, traction is applied to cable **22** so as to impart proximally directed forces to the distal end of the anchor. Ratcheting elements **51** in the cannula **50** prevent the cable **22** from sliding distally in the event that traction of the cable **22** is momentarily released.

The opposed forces between cable **22** and vacuum head **14** result in compression of the anchor **18** and the mesh tube **24** into the illustrated positions. As the cable **22** tightened, the spring element **66** of the anchor sequentially engages barbs on the cable **22**. Once tension on cable **22** is released, the spring element **66** remains engaged with the adjacent barb on the cable so as to retain the anchor in the compressed position. Finally, the cable **22** is clipped, and the plicator **12** is withdrawn from the body, leaving the anchor **18** and mesh positioned as shown in FIG. **19**B. The procedure may be repeated to form multiple plications if needed. Following formation of the plication(s), a medical implant may be coupled to the anchor(s) **18** during the course of the same procedure or during a later procedure scheduled to permit sufficient formation of adhesions between the serosal tissue layers **102** to support the implant.

It should be noted with reference to FIG. **20** that in an alternative method, the cannula **50** may remain coupled to the anchor **18** during lateral movement of the vacuum head **14**, causing the proximal portion **40** of the shaft **16** to separate from the cannula **50**. According to this embodiment, the anchor **18** may be compressed by pressing the cannula **50** downwardly against the anchor **18** while applying tension to the cable **22**. Once the anchor has been secured as described with respect to FIGS. **19**A and **19**B, the cannula **50** is detached from the anchor **18** and withdrawn from the body.

Alternatives to the First Embodiments

One alternative system illustrated in FIGS. **21**A through **21**C is similar to the first preferred embodiment, but differs in that the vacuum head **14***e* is formed of a compliant material such as silicone and also functions as the anchoring device. During use of the vacuum head **14***e*, suction is applied to draw tissue into the vacuum head, and a cable **22***e* (or suture, etc) is passed through the compliant silicone material to form the tissue plication. If necessary, a removable rigid housing **98** may be positioned around the vacuum head to prevent it from collapsing during application of suction.

In another alternative system shown in FIGS. **22**A through **22**D, a flexible vacuum paddle **110** is positionable into contact with stomach tissue. In this embodiment, paddle **110** also serves as the anchor that will remain coupled to the tissue.

Paddle **110** includes an elongate tube **112** that extends through the esophagus and is connectable to a vacuum source **114** positioned outside the body. Paddle **110** is formed of silicone or other flexible material suitable for long term implantation. Loop **2** is integrally coupled to the paddle. An elongate spine **116** is positionable against the paddle **110**, and may include elements for temporarily engaging the paddle **110**. Spine **116** includes pull wires or other features that may be manipulated from outside the body to deflect it and the adjacent paddle **110** into nested curved positions as shown in FIG. **22**B, thus creating a pocket **100** in the tissue. A tip **120** coupled to a cable **122** may be advanced through the elongate tube **112** such that it penetrates the tissue lining the pocket **100** and advances into a portion of the paddle **110**, where it is engaged by a catch (e.g. see catch **58** of FIG. **8**A). A mesh element **124** may be advanced over the cable **122** as shown in FIG. **22**C, and the cable **122** may be cinched to form the plication using techniques such as those described above, leaving the paddle **110** and loop **2** in place.

An alternative system illustrated in FIGS. **23**A and **23**B is similar to the system of the first embodiment of FIG. **6**. Specifically, system **10***f* includes a vacuum head **14***f* mounted at the distal end of a shaft **16***f* of sufficient length to permit the vacuum head **14***f* to be positioned within the stomach while the proximal portion of the shaft **16***f* remains outside the oral cavity. The vacuum head is coupled to a source of suction, such as a syringe or vacuum pump.

A flexible anchor **18***f* is seated within vacuum head **14***f* prior to use, similar to the positioning of the anchor **18** of the first embodiment shown in FIG. **12**. The anchor **18***f* includes a distal tab **52***f* and a proximal tab **54***f* having corresponding openings longitudinally aligned with the lumen **48***f* of the shaft **16***f*. The system differs from the first embodiment in that the anchor **18***f* further includes an elongate leg **22***f* that is coupled to the tabs **52***f*, **54***f* during assembly to form the anchor **18***f* into a loop. Leg **22***f* includes a tip **20***f* and a catch **21***f* positioned to engage the distal tab **52***f* and the proximal tab **54**, respectively. The leg **22***f* may be manufactured of a flexible polymeric material such as silicon, or it could be formed of a mesh, braid, stent into which surrounding tissue will grow. However, the tip **20***f* should be capable of penetrating stomach wall tissue.

Prior to use, the leg **22***f* is positioned within the lumen **48***f* of shaft **16***f*. During implantation of the anchor **18***f*, serosal tissue is drawn into the vacuum head **14***f* as shown in FIG. **23**A. The leg **22***f* is advanced through the tabs **52***f*, **54***f*, and

the sections of stomach wall lying between the tabs, using a push rod (not shown) or other pushing mechanism as described above. The tip **20***f* engages with distal tab **52***f* and the catch **21***a* is restrained by proximal tab **54***f*. The vacuum head **14***f* is subsequently removed, leaving the anchor and leg forming a loop surrounding a portion of the stomach wall as shown in FIG. **23**B.

Although the method of implanting the anchor **18***f* may end with the anchor **18***f* positioned as shown in FIG. **23**B, it is preferable to bring some of the serosal tissue surfaces surrounding pocket **100** into contact with one another so as to trigger growth of serosal bonds between the contacting tissues surfaces, as described before. Methods for cinching the tissue to form a serosal plication are described above and may be modified for use with the FIGS. **23**A-**23**B method. Alternatively, elongate regions of tissue on opposite sides of the leg **22***f* may be brought into contact with one another and clamped, stapled and or otherwise held in contact to turn the pocket **100** into a sealed serosal pocket **100***f* surrounding the leg **22***f* and isolated from the sterile environment outside the stomach. For example, as shown in FIG. **24**A, a jaw-type stapling instrument **92** having a vacuum housing **93** may be endoscopically introduced into the stomach and positioned with the jaws **94***a*, **94***b* contacting mucosal tissue on opposite sides of the leg **22***f*. This instrument may be separate from the instrument used to couple the anchor **18***f* to the tissue, or the instrument of FIG. **23**A may be modified to include the stapler jaws **94***a*, **94***b*.

The jaws are clamped as shown in FIG. **24**B to bring the serosal tissue surfaces together, and staples are passed through the tissue using the jaws, enclosing the pocket **100** in the tissue and helping to retain the anchor using the re-shaped stomach tissue. After the instrument **92** is removed from the stomach, the serosal tissue surfaces remain held in contact by one or more staple lines **95** (FIGS. **25**A and **25**B). The staple lines **95** seal the pocket **100***f* and reduce the chance of infection by forming a barrier preventing gastric contents that might enter the pocket **100***f* from moving into the extra-gastric space. Adhesions will then form between the serosal tissue surfaces as described above. To optimize the strength of the adhesions, the leg **22***f* may include ingrowth-promoting features. For example, leg **22***f* may be configured to support macro-level ingrowth using a mesh design, or it may include micro-ingrowth promoting features such as a porous surface. Leg **22***f* might alternatively or additional have a surface coated or impregnated with sclerosing agents. Multiple anchors **18***f* may be implanted using this method, as shown in FIG. **25**C.

In alternate plication methods, one or more sclerosing agents may be used in conjunction with or in lieu of the mesh element **24**. Examples of sclerosing agents include but are not limited to Sodium Tetradecyl Sulfate (STS), Poliodocanol, Chromated Glycerin, Hypertonic saline, Sodium Morrhuate, Sclerodex (hypertonic saline in combination with Dextrose). Other substances that may be positioned with or in place of the mesh element **24** include methylmethacrylate, glues, adhesives, and biorubbers. These may be injected at the time of mesh placement or loaded into the mesh itself and eluded out over a period of time.

FIGS. **26**A through **26**F illustrates an alternative method in which a cannula **50***a* having a tissue-penetrating distal end is passed into the tissue pocket **100** for delivery of an agent. According to the alternative method, tissue pocket **100** is formed using methods similar to those described above. Cannula **50***a* is advanced through the shaft **16***a* of the plicator **12***a*, through anchor **18***a* and tissue **102**, and into the pocket **100**. The desired agent is passed through the cannula **50***a* and into the pocket.

Once the agent is administered, steps similar to those described above may be performed to form the plication and to attach anchor **18***a* to the plication. Tip **20***a* (FIG. **26**B) is thus advanced through the cannula **50***a* (or through a separate cannula introduced upon removal of the cannula) and advanced as described in connection with the first embodiment. If a mesh element **24***a* is to be introduced, it may be positioned around the cable **22***a* as described previously. A pusher tube **86***a* may be threaded over the cable **22***a*, through the interior of the mesh tube **24***a*, and into contact with proximal cap **76***a* on the mesh element **86***a*. Sliding the pusher tube **86***a* distally drives the tip **20***a* through the plication and into engagement with a distal catch **58***a* on the anchor, as also advances the mesh element **24***a* into the pocket **100**. In a final sequence of steps, the plication may be "cinched" using methods similar to those described above.

In certain instances, it might be desirable to completely close the serosal pocket **100** to avoid leakage of injected agents into the peritoneal cavity. The pocket **100** may be sealed using an elongate clamp **90** endoscopically introduced into the stomach and clamped over the tissue pocket to press the serosal surfaces into contact with one another as shown in FIGS. **27**A and **27**B. Alternatively, vacuum head **14***c* (FIG. **28**) may include clamping bars **92**, such as elongate rods or inflatable balloons, that are positioned on opposite sides of the pocket to clamp the pocket **100** between them. As yet another alternative, the vacuum head **14***d* may be biased or hinged to clamp the pocket **100** as shown in FIG. **29**.

An alternative method for forming plications using sclerosing agents to accelerate scar formation is illustrated in FIGS. **30**A through **30**E. This method is advantageous in that it allows plications to be formed without the use of sutures or cables, and thus can simplify the procedure.

As with previous methods, a pocket **100** or depression is formed on the serosal surface by drawing a portion of the stomach wall inwardly using a vacuum head **14***f* or other device introduced transorally into the stomach. A delivery member **130** is next introduced into the stomach. The delivery member **130** is an elongate tubular device having a lumen through which a sclerosing agent may be delivered, as well as a delivery means for delivering a place holding element **132** into the pocket **100**. The delivery member **130** preferably includes a sharpened distal tip capable of penetrating the stomach wall.

As shown in FIG. **30**B, the delivery member **130** is advanced through at least one portion of the stomach wall **102**, and used to deliver the place holding element **132** into the pocket **100**. The place holding element **102** functions to maintain separation between opposed serosal walls **102**, so that the volume between the walls can be filled by a sclerosing agent introduced by the delivery member **130** or a separate delivery method.

In one embodiment, the place holding element **132** may be delivered by pushing it through the lumen of the delivery member using a pushing mandrel. The place holding element might be a section of material that has a compact size and shape for delivery by the delivery member **130**, but that expands upon delivery into the pocket **100**. To give a few examples, the element may be formed of a structure having mechanical properties (e.g. sponge or nitinol mesh) that cause it to self-expand when released from the delivery member, or it may be an inflatable balloon tethered to an inflation lumen in the delivery member, or it may be a

swellable hydrogel that will increase in volume once exposed to fluid within the pocket (e.g. the sclerosing agent or other fluid injected into the body, and/or fluids present in the peritoneal cavity). In alternate embodiments the place holding element might be delivered directly to the outside of the stomach using laparoscopic methods.

The element may be formed of a permanent or semi-permanent material (such as the examples described in connection with mesh element **24** above), that will reinforce the plication and/or work together with the sclerosing agent to promote scar formation. Alternatively, the element may be one that is biodegradable or bioabsorbable over a period of time.

Once the place holding element **132** has been positioned, the vacuum head **14***f* or a separate clamping device is utilized to clamp and seal the pocket **100** as shown in FIG. **30**C (see, for example, the sealing methods described above). Sclerosing agent is injected through the delivery member **130** into the pocket **100**. Referring to FIG. **31**A, if the place holding element is an inflatable balloon **132***a* or another type of element that can seal against the tissue forming the pocket, it may be acceptable to eliminate the step of applying sealing forces to the pocket. Referring to FIG. **31**B, use of a sponge **132***b* in lieu of balloon **132***a* may minimize migration of sclerosing agent out of the cavity. The sponge **132***b* may be filled with sclerosing agent prior to its delivery into the pocket **100**, or it may instead absorb agent introduced into the pocket.

Sealing forces continue to be applied to the pocket **100** until ample scar tissue has formed within the pocket to maintain the P. Once adequate scar tissue has been formed, sealing forces may be released and the vacuum head removed from the stomach. If the balloon of FIG. **31**A is used in lieu of sealing forces, inflation of the balloon is maintained until the sclerosing agent has formed an adequate amount of scar tissue.

It should be noted with reference to FIGS. **32**A and **32**B that if sealing forces are needed over an extended during (i.e. to ensure sufficient tissue scarring to retain the plication), a clip **134***a* may be clipped around the plication to maintain the plication until sufficient scarring has occurred. If needed to prevent unwanted detachment of the clip, an alternative clip **134***b* (FIG. **31**B) may include prongs positioned to pass through the tissue.

Plication System of the Second Preferred Embodiment

In many instances it may be desirable to form serosal tissue plications of the type shown in FIG. **33**A, which include a cutout C or hole formed through the plication P. As shown in FIG. **33**B, multiple such plications may be formed within the stomach to provide a platform for mounting an intragastric device or for other purposes that will be described below.

When a cutout plication is formed, it may be beneficial to form a seal around the cutout C using staples, sutures or adhesives etc so as to prevent food material and/or gastric juices from passing between the opposed layers of serosal tissue where they can potentially cause infection between the tissue layers or within the extra gastric space. In the FIG. **33**A example, a circular array of staples is placed in the tissue surrounding the cutout C for this purpose. Sealing the cutout using staples provides the additional benefit of controlling the bleeding that will occur along the edges of the cutout. In forming the plication P, reinforcing mesh or other suitable material may be positioned between the opposed serosal layers so as to achieve the benefits discussed in connection with the first embodiment.

A second preferred embodiment of a plication system **10***g*, shown in cross-section FIG. **34**A, is particularly useful for forming a serosal plication having a cutout surrounded by a staple line, and also for positioning a reinforcing mesh element within the plication.

In general, system **10***g* includes a plicator **12***g* comprising a vacuum head **14***g* having a vacuum chamber **28***g* and a shaft **16***g* defining a lumen **48***g*. A port **49** is fluidly coupled to the vacuum chamber **28***g* and is connectable to an extracorporeal source of suction (e.g. a syringe or a vacuum pump).

An elongate staple driver **150** is longitudinally moveable within the lumen **48***g*. Staple driver may take the form of an elongate tube having a broadened annular head **152** positioned within the vacuum head **14***g*. A plurality of staples **154** is arranged adjacent to the staple head, preferably in a circular arrangement, but alternative arrangements are equally suitable. A circular anvil **156** is positioned within the vacuum head **14***g* opposite the staples. Staple driver head **152** is moveable in a distal direction to advance the staples across the vacuum chamber and into contact with the anvil **156**.

The system includes a tubular cannula **50***g* for forming the cutout C in the tissue. Cannula **50***g* extends through the lumen of the staple driver **150**, with its tissue-penetrating distal end oriented towards the vacuum chamber **28***g*. Cannula **50***g* may be advanced in a distal direction to extend through the vacuum chamber **28***g* and into a tubular channel **158** formed in the distalmost section of the vacuum head.

An elongate rod **160** having a pointed distal barb or tip **20***g* extends through the lumen of the cannula **50***g*. Tubular mesh element **24***g* surrounds a portion of the exterior surface of rod **160**, with its distal end adjacent to the proximal end of tip **20***g*. Mesh element **24***g* is preferably a self-expandable tubular element of the type described in connection with FIGS. **14**A and **14**B. When positioned on the rod **160**, the mesh element is compressed to a reduced-diameter position and retained in the compressed position using a retention sleeve **162**. A tubular support **164** may be positioned on the rod **160** in abutment with the proximal end of the mesh element **24***g*.

System **10***g* further includes a proximal handle (not shown) that remains outside the body during use of the system. The handle includes actuators, pull wires, push rods, or equivalent components that facilitate longitudinal advancement and withdrawal of the tip **20***g*, cannula **50***g*, retention sleeve **162**, and staple driver **150**, as well as deflection or articulation of the components, as needed to carry out the method for using the system described in the following section.

Exemplary Method for Using the Second Preferred Embodiment

A method for using the system of the second embodiment will next be described.

First, the vacuum head **14***g* is introduced into a stomach and endoscopically positioned with the vacuum chamber facing the interior surface of the stomach wall. This step is similar to the step illustrated in FIGS. **16**A-**16**B in connection with the first embodiment.

Suction is applied to the vacuum head **14***g* via port **49** to draw a portion of the stomach wall into the chamber as shown in FIG. **34**B, thus orienting sections S**1**, S**2** of the stomach wall with their serosal surfaces generally facing one another.

Next, the rod **160** is advanced to drive tip **20***g* through the sections S**1**, S**2**. Tip **20***g* is captured within the channel **158** adjacent to anvil **156**. The mesh element **24***g* is carried by

the rod **160** into position between the stomach wall sections S1, S2. The retention sleeve **162** is retracted, allowing the mesh element **24***g* to expand to the position shown in FIG. **34**D. One or more centering struts **166** extend between the mesh element **24***g* and rod **160** and maintain the mesh element in a generally centered orientation relative to the rod **160**.

After the mesh element **24***g* is deployed, the tissue is compressed to the position shown in FIG. **34**E to bring the opposed sections S1, S2 of the stomach wall into contact or close proximity with one another and to compress the mesh element **24***g* into a disk shape (also see FIG. **14**B). This folding/compressing step may be accomplished by folding the vacuum chamber **14***g* itself, such as by pushing the shaft **16***g* in a distal direction while maintaining traction on the rod **160**. After folding, the staple driver head **152** is pushed distally, driving the staples **154** through the tissue and against the anvil **156** as shown in FIG. **34**F. In a simultaneous or separate step illustrated in FIG. **34**G, the cannula **50***g* is advanced to core the tissue, thus forming the cutout C and snipping the centering struts **166** (not visible in FIG. **34**G) connecting the mesh element to the rod **160**. In forming the cutout C, the cannula **50***g* removes a margin of tissue surrounding the punctures created by tip **20***g* during its advancement towards channel **158**.

The cannula **50***g* and tip **20***g* are withdrawn into shaft **16***f*, and the vacuum head **14***g* is separated from the tissue, leaving the cutout reinforced plication as shown in FIGS. **35**A and **35**B.

Plication System of the Third Preferred Embodiment

A third embodiment of a plicator **200** is shown in FIGS. **36**A through **39**. Plicator **200** includes a plication head **202** positioned on the distal end of an elongate shaft **204**. As with prior embodiments, shaft **204** is of sufficient length to allow passage of the plication head **202** through the mouth and esophagus into the stomach, while the proximal end of the shaft remains outside the body. A vacuum source **206** is fluidly coupled to the proximal end of the shaft **202**. Pullwires **208** extend through the shaft **204** from a handle (not shown) in the proximal end of the shaft and are anchored to a more distal location within the shaft **204**, so that manipulation of the pullwires by a user allows for steering/deflection of the plication head **202**. Shaft **204** may be formed of a plurality of spine members that articulate relative to one another but that may be locked in a desired position to fix the spine a desired shape.

Plication head **202** includes a tapered, atraumatic, distal tip **210** and a proximal portion **212** coupled to one another by one, two or more hinge member **214**. In the FIGS. **36**A-**39** embodiment, three hinge members **214** are shown. Each of the illustrated hinge members includes distal and proximal hinge plates **216***a*, **216***b* joined together at central hinge **218**. The hinge members **214** are moveable between the generally elongated position shown in FIG. **36**A, and to the expanded position of FIG. **36**B in which the central hinge **218** extends outwardly and in which the distance separating distal tip **210** and proximal end **212** of the plication head is decreased. As shown as a transparent element in the bottom plan view of FIG. **38**A and the end view of FIG. **38**B, a membrane or shroud **215** covers the hinge members **214** and is connected to the distal tip **210** and proximal portion **212** of the plication head **202** to form a vacuum chamber **217**. An opening **219** in the shroud positionable in contact with stomach wall tissue to allow tissue to be drawn into the chamber during use. Shroud **215** is preferably formed of silicone, elastomeric material, or any other inelastic or elastic flexible or deformable biocompatible material capable of forming a vacuum chamber.

Referring to FIG. **37**A, the proximal portion **212** of the plication head **202** includes a hydraulic chamber **220**. The hydraulic chamber **220** is fluidly coupled by a fluid line **222** to a source of fluid **224**. An outer piston **226** is disposed within the hydraulic chamber **220**. In the illustrated embodiment, piston **226** is a hollow cylinder having a rear wall **228** and a front wall **230**. Front wall **230** includes a center cutout **232**. An inner piston **234** is disposed within the outer piston **226**, and includes a longitudinal plunger **236** extending through the cutout **232**.

Each of the proximal hinge plates **216***b* includes an inwardly-extending camming surface **238**. The hinge plates include proximal pivots **240** such that distally-oriented pressure against camming surfaces **238** causes the hinge plates **216***b* to pivot about the pivots **240** into the position shown in FIG. **37**B.

Proximal portion **212** of the plication head **202** includes a staple cartridge **242** containing staples arranged in an annular arrangement (not visible in the drawing), and a staple driver **244** positioned to drive staples from the distal end of the cartridge **242** when it is advanced in a distal direction into contact with the staples. Staple driver **244** may include a tissue penetrating element **248** (FIG. **40**B) sufficiently sharp to form a hole in tissue.

An anvil **246** on the distal tip **210** is positioned to receive the prongs of staples driven by staple driver **242** and to fold the prongs into a closed position. Staple cartridge and anvil arrangements are well known in the surgical and endoscopic stapling art and need not be discussed in further detail. The staples (and sutures) described for use herein may be permanent or bioerodible/biodegradable.

Exemplary Method for Using the Third Preferred Embodiment

As with the previously discussed methods, a method of using the plication system **200** of the third embodiment is carried out under visualization using an endoscope advanced via the esophagus into the stomach.

In preparation for use, the plication head is positioned with the hinge members **214** in the streamlined position shown in FIGS. **36**A and **37**A. The plication head **202** is introduced transorally into the stomach, through an introducer sheath if needed to ensure smooth passage through the esophagus. Pullwires **208** are manipulated to orient the plication head **202** so that the opening **219** in the vacuum chamber **217** (FIGS. **38** and **39**) is positioned in contact with stomach wall tissue at a location at which a plication is to be formed.

Next, as shown in FIG. **37**B, hydraulic fluid is injected from fluid source **224** into chamber **220**. The fluid pressure advances outer piston **226** in a distally direction, causing the front wall **230** of the piston **226** to contact the camming surfaces **238**, thus pivoting the pivot plates **216***b* about proximal pivots **240**. In response, hinge members **214** pivot as shown in FIG. **37**B until they reach the partially expanded position shown in FIG. **37**B. The vacuum source **206** is activated to create a vacuum which draws a pinch of tissue into the vacuum chamber **217**, with serosal tissue surfaces generally facing one another as has been described with the other embodiments (see e.g. FIG. **34**B). The flexible nature of the shroud forming the vacuum chamber **217** allows the vacuum chamber **217** to deform outwardly as tissue is drawn into the chamber.

Once tissue is drawn in to the vacuum chamber **217**, additional fluid is directed into the hydraulic chamber **220** to advance the outer piston **226** until the hinge members **214**

are in the fully expanded position shown in FIG. **37**C. Expansion of the hinge members **214** draws the distal tip **210** towards the proximal portion **212** of the plication head **202**. This compresses the tissue within the vacuum chamber **217**, bringing the opposed serosal tissue surfaces into contact or close proximity with each other similar to the tissue positions shown in FIG. **34**E. Once the tissue is compressed, staples from the cartridge **242** are fired through the tissue by passing the staple pusher **244** through the staple cartridge **242**. If the staple pusher **244** is provided with a tissue penetrating element **248** as shown in FIG. **40**B, the tissue penetrating element **248** penetrates the opposed layers of stomach wall tissue as the staples are driven through the tissue, forming a hole surrounded by an annular pattern of staples.

The staples fold against the anvil **246**. After stapling, the hinge members are moved to the collapsed position shown in FIG. **36**A. The plicator is separated from the tissue and withdrawn from the body. The tapered profile of the proximal portion **212** of the plication head **202** allows the plication head **202** to pass through the gastro-esophageal junction, esophagus, and mouth with minimal trauma.

In the illustrated embodiment, the staple pusher **244** is driven by the injection of hydraulic fluid into the cylindrical piston **226**. The fluid drives plunger **236** distally into contact with the staple pusher **244**, which in turns drives through the cartridge **242** to advance the staples. FIG. **40**A illustrates one arrangement of the pistons **226**, **234** within the hydraulic chamber **220** that will allow this to be achieved. As shown, hydraulic cylinder **220** includes first and second inlets I**1** and I**2**, and the piston **226** includes a third inlet I**3**. O-ring seals O**1**, O**2** are positioned on the exterior surface of piston **226** and o-ring seals O**3** and O**4** are positioned on the exterior surface of the inner piston **234**. When hydraulic pressure is applied to I**1**, the piston **226** advances distally (towards the left in the view shown) to expand the hinge members **214** (FIG. **37**C) and compress the tissue as discussed above. After o-ring seal O**2** has moved distally of inlet I**2**, fluid pressure can be directed through I**2** and into I**3**, causing inner piston **234** to be driven distally to advance the staple pusher **244** (FIG. **37**A). Although in the FIG. **40**A embodiment the hydraulics for tissue compression and stapling and combined on the proximal side of the plication head, these functions may be separated, with the hydraulics driving one function positioned distally of the vacuum chamber and the hydraulics driving the other function positioned proximally of the vacuum chamber.

FIGS. **41**A and **41**B are side elevation views of a modified plication head **202***c* in which the distal and proximal portions **210***c*, **212***c* are coupled by a hinge **214***c* that is actuated by a lead screw **211**. Lead screw is extended as shown in FIG. **41**A to elongate the plication head **202***c* for passage into the body and for expansion of the vacuum chamber which, as with the FIG. **36**A embodiment, is defined by a shroud **215** (FIG. **41**C). Once tissue is drawn into the chamber, the lead screw **211** is actuated to bring the distal and proximal portions **210***c*, **212***c* into alignment for compression and stapling of the tissue as described above.

Plication Reinforcements

Reinforcements of various types may be implanted in or on plications formed using the plication system. Such reinforcements may function to reinforce the staple array, help to more evenly distribute the forces applied to the tissue by the staples, and/or facilitate bonding between the opposed serosal layers. Suitable reinforcements include ones positionable on or between the serosal tissue layers ("serosal side reinforcements"), as well as those delivered on the side of the mucosal tissue ("mucosal side reinforcements").

Serosal side reinforcements have been discussed in connection with the first and second embodiments. A reinforcement similar to mesh element **24** described in connection with FIGS. **14**A, **14**B may serve as a permanent or semi-permanent implant that will reinforce the staple array applied to the tissue and/or facilitate serosal tissue bonding between the layers of stomach wall tissue that are to be stapled or sutured together. For this purpose, the material may be a synthetic or non-synthetic mesh (formed of nitinol, polyester, or other natural or synthetic material), porous or non-porous material, slotted material, or any other material through which adhesions will form or onto which tissue will grow. Examples include, but are not limited to, polypropylene, materials sold under the trade names Goretex or Dacron, or tissue graft material such as the Surgisis material sold by Wilson Cook Medical, Inc. The material may be treated with tissue-ingrowth promoting substances such as biologics.

In an alternative embodiment of a serosal side reinforcement shown in FIGS. **42**A and **42**B, a reinforcement **270** (which may be formed of a polyester fabric, mesh, or any other material including those listed elsewhere in this application) is carried by a frame **272** having a plurality of outwardly extending arms that spring to an expanded position when released from a hollow tube. The tube might be any of the tubes described above for delivering mesh or sclerosing agents etc. to the serosal tissue, e.g. tube **50***g* of FIG. **34**A. The hollow tube **274** is passed through stomach wall tissue so that its distal end is positioned between serosal layers (e.g., the position of needle **50***a* in FIG. **26**B). The frame **272** is advanced out the distal end of the needle to allow the arms of the frame to spread to the expanded position shown, thereby expanding the reinforcement between the opposed serosal layers. The reinforcement is fixed between the layers by the staples driven through the opposed regions of stomach wall, and the frame is withdrawn from the needle and out of the body.

Mucosal side reinforcements may take the form of reinforcements that are positioned on or adjacent to one or both of the mucosal surfaces lining the "pinch" of tissue that will form the plication. These reinforcements may be features of the staples or staple arrays, or they may be separate components engaged by staples as the staples are advanced through the tissue.

Referring to FIG. **43**A, conventional stapling procedures will often include two parallel rows of staples, in which the staples in one row are laterally offset from the staples of the other row. According to the disclosed method, it is useful to employ this technique to the circular staple pattern delivered using the plicators described above, to produce two concentric rings of offset staples **276**, as shown in FIG. **43**B. It has been found to be additionally beneficial to form mucosal side reinforcements by linking or interlocking the staples to provide greater structural reinforcement to the stapled tissue and/or to more evenly distribute forces applied to the tissue by the staples. Linked staple arrays may be formed by arranging the staples **276** in the cartridge of the plicator in a single circular pattern to interlock as shown in FIG. **43**C, or in a double circular pattern with two concentric rings of interlocked staples. The staples **276***a* may be curvilinear so as to form a locking pattern shown in perspective view of FIG. **43**D. A linear arrangement of staples **276** may also be linked as shown in FIG. **43**E.

In alternative embodiments, staples are linked together by reinforcing members formed of metallic or polymeric mate-

rials, such as nitinol, titanium, stainless steel PEEK, or other biocompatible materials including those that are bioerodible/biodegradable. According to these embodiments, the reinforcing members are positioned on one or both of the mucosal sides of the "pinch" of tissue engaged by the plication system such that they are captured by staples being driven through the tissue. In a preferred embodiment, the staples capture a cartridge side reinforcing ring **278** (FIG. **13**A) as they leave the cartridge and capture an anvil side reinforcing ring **280** (FIG. **44**B) as the anvil shapes and bends them. Upon completion of the plication, the staples are linked to one another so that they cannot separate or expand radially. The rings promote even distribution of forces around the ring of staples.

The reinforcing rings are preferably provided separate from the staples although they instead may be integral with the staples. In the illustrated embodiment, ring **280** is positioned against the staple anvil **246** as shown in FIG. **45**A. Ring **278** is seated within the cartridge **242** (FIG. **45**B), with the staples **276** aligned with their prongs **282** extending through a plurality of the loops **284** in the ring **278**. When staples **276** are driven from the cartridge, they capture ring **278** against the adjacent mucosal tissue as shown in FIG. **46**A. The staple legs/prongs **282** pass through the stomach wall tissue into contact with the indentations **286** of the anvil **246**. When they contact the anvil **246**, the prongs **282** fold around the staple ring **280** to capture the ring **280** and interlock the staples on the anvil side of the plication as shown in FIG. **46**B. Rings or other interlocking elements of this type may be used with single- or double-staple row configurations.

Rings **278**, **280** are shown as generally circular, although alternative reinforcements of different shapes and patterns may also be used, including those shaped to accommodate linear, oval and other staple patterns.

Applications for Cutout Plications

FIGS. **47**A through **49** illustrate examples of applications for cutout plications formed within the stomach using any methods or system, including those described above. As shown, the cutout plications can eliminate the need for anchor loops of the type described in connection with the first embodiment. Each of these applications is preferably (but optionally) performed in a separate procedure from that in which the plications are formed, so as to allow serosal bonding to occur before the plicated tissue is subjected to stresses imparted by implants and/or further manipulation.

A first application shown in FIGS. **47**A through **47**C uses two or more cutout plications CP, preferably formed at the gastro-esophageal junction region of the stomach. According to this application, the cutouts C of the plications are brought into partial or full alignment with one another (FIGS. **47**A and **47**B) using an endoscope or another endoscopic instrument. A restrictive implant such as the implant **4** shown in FIG. **4** is threaded through the aligned cutouts while in a radially-collapsed position, and is then allowed to expand to the position shown in FIG. **47**C. Instruments and methods for orienting and expanding an implant of this type are shown and described in U.S. application Ser. No. 11/439,461, filed May 23, 2006. Once in place, the implant greatly reduces the amount of food a patient can consume, by slowing the rate at which food can descend from the esophagus into the stomach.

In the method shown in FIG. **48**A, multiple cutout plications CP are formed in select positions allowing the plications to be drawn together so as to significantly narrow the channel through which food can pass through the stomach. For example, the plications CP of FIG. **48**A are arranged such that manipulating the plications to place their cutouts C in alignment causes the plications themselves to form a barrier against passage of food. This arrangement limits most food flow to a narrow food passage FP and creates a gastric pouch GP adjacent to the food passage. An implant **4***a* is positioned within the cutouts C as described above to retain the plications CP in their gathered arrangement. The implant **4***a* may have a similar configuration to the implant **4** of FIG. **4**, including a through-hole allowing some passage of food through the implant, or it may be impenetrable by food thus forming a plug largely preventing passage of food and gastric juices through the cutouts C. The implant may include a valve oriented to minimize restriction of food flow out of the stomach during vomiting. Other implants that will retain the gathered configuration of the plications CP may alternatively be used, including lengths of biocompatible material passed through the cutouts and knotted or otherwise fastened into loops. In other embodiments, the collective sizes and numbers of the plications may themselves be sufficient to restrict flow of food into the stomach, without the need for any implants to connect them to one another.

In either embodiment, if the implant **4**, **4***a* is to be removed or replaced with an implant of different dimensions (e.g. so as to slow the rate of weight loss following a period of significant weight loss, or to increase the rate of weight loss), endoscopic instruments may be used to withdraw the implant from the cutouts C and to remove the implant from the stomach.

In another embodiment shown in FIG. **49**, a restrictive pouch **4***b* may include anchors **5** that are inserted into cutout plications CP. Anchors **5** are shown as having a button shape, but they may alternatively be other structures including loops that close on themselves to prevent detachment from the cutout, or they might be legs of the type disclosed in WO 2005/037152.

As is evident from above, the disclosed endoscopic systems function to draw a tissue into the stomach to form a depression on the exterior surface of the stomach, and staple (or suture, or fasten or adhere etc) the opposed stomach wall sections lining the depression together another to form a plication. The system may additionally place material of a type that will promote strong tissue adhesion within the depression (on the exterior of the stomach) and retain the material between the serosal surfaces to enhance. Additionally or alternatively, mucosal reinforcements such as structures that interconnect the staples may be implanted. While these systems provide convenient embodiments for carrying out this function, there are many other widely varying instruments or systems may alternatively be used within the scope of the present invention. Moreover, the disclosed embodiments may be combined with one another in varying ways to produce additional embodiments. Thus, the embodiments described herein should be treated as representative examples of systems useful for forming endoscopic tissue plications, and should not be used to limit the scope of the claimed invention.

Any and all patents, patent applications and printed publications referred to above, including those relied upon for purposes of priority, are incorporated herein by reference.

We claim:

1. A stapler for fastening tissue, comprising:

a first portion including a staple cartridge;

a second portion including an anvil;

at least one hinge member coupling the first portion and the second portion; and

a flexible membrane covering an outside surface of the at least one hinge member, the flexible membrane defining an opening proximal to a distalmost end of the stapler;

wherein the flexible membrane forms a chamber in communication with a lumen of the stapler, such that applying a vacuum to the chamber via the lumen draws tissue into the chamber through the opening.

2. The stapler of claim **1**, wherein the at least one hinge member is movable between an elongated position and an expanded position by pivoting relative to the first portion about a first pivot axis and pivoting relative to the second portion about a second pivot axis different from the first pivot axis.

3. The stapler of claim **2**, wherein the at least one hinge member includes a central portion, and in the expanded position, the central portion is positioned radially outward relative to a position of the central portion in the elongated position.

4. The stapler of claim **2**, wherein movement of the at least one hinge member from the elongated position to the expanded position corresponds to movement of the first and second portions towards one another.

5. The stapler of claim **1**, wherein the at least one hinge member includes two hinge members, and the flexible membrane covers the two hinge members.

6. The stapler of claim **1**, wherein the staple cartridge includes staples arranged in an annular arrangement.

7. The stapler of claim **1**, further comprising a reinforcing ring.

8. A stapler for fastening tissue, comprising:

a first portion including a staple cartridge;

a second portion including an anvil;

at least one hinge member coupling the first portion and the second portion;

a flexible membrane extending along a longitudinal axis of the stapler, the flexible membrane covering outside surfaces of the first portion and second portion and defining an opening proximal to a distalmost end of the stapler; and

a source of vacuum;

wherein the flexible membrane forms a chamber that draws in tissue through the opening when the source of vacuum is activated.

9. The stapler of claim **8**, wherein the at least one hinge member includes three hinge members.

10. The stapler of claim **8**, wherein the membrane covers an outside surface of the at least one hinge member.

11. The stapler of claim **8**, wherein the at least one hinge member is configured to pivot relative to the first portion about a first pivot point and relative to the second portion about a second pivot point different from the first pivot point.

12. The stapler of claim **11**, wherein a central portion of the at least one hinge member includes a third pivot point different from each of the first pivot point and the second pivot point.

13. The stapler of claim **8**, wherein the staple cartridge includes staples arranged in an annular arrangement, the staple cartridge being configured to eject the staples in a direction along the longitudinal axis.

* * * * *

专利名称(译)	内窥镜折device装置和方法		
公开(公告)号	US10299796	公开(公告)日	2019-05-28
申请号	US14/707637	申请日	2015-05-08
[标]申请(专利权)人(译)	波士顿科学西美德公司		
申请(专利权)人(译)	BOSTON SCIENTIFIC SCIMED，INC.		
当前申请(专利权)人(译)	BOSTON SCIENTIFIC SCIMED，INC.		
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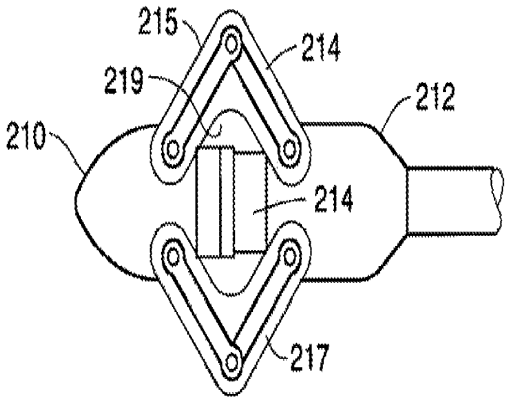
摘要(译)

本文描述了通过口腔进入胃并且通过从胃内部接合组织并将其向内拉入而使胃组织复位的内窥镜plicator。在所公开的实施例中，组织被向内抽入真空室，使得胃外部上的浆膜组织的部分彼此面对地定位。所公开的褶皱器允许组织的相对部分移动到彼此接触，并且优选地递送缝合线，U形钉或其他用于保持组织切片之间接触的装置，至少直到它们之间形成浆膜结合。这些步骤中的每一个可以完全从胃内部进行，因此可以消除对任何手术或腹腔镜介入的需要。在形成一个或多个褶皱之后，医疗装置可以连接到褶皱以保留在胃内。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