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Sugimoto et al.

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(54) **TISSUE ANCHOR AND ANCHORING SYSTEM**

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This patent is subject to a terminal disclaimer.

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A61B 17/04 (2006.01)
A61B 17/00 (2006.01)

(52) **U.S. Cl.**
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(58) **Field of Classification Search**
CPC A61B 17/0469; A61B 17/0487; A61B 2017/0496; A61B 17/00234; A61B 17/0401
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

2,143,910 A 1/1939 Didusch
3,674,014 A 7/1972 Tillander
(Continued)

FOREIGN PATENT DOCUMENTS

EP 1016377 7/2000
EP 2181670 5/2010
(Continued)

OTHER PUBLICATIONS

Cardiac Surgery Renaissance, Anatomical Landscape; Composite Profile of CABG and Valve Procedures, Apr. 25, 1996, Cardiology Roundtable Interviews.
(Continued)

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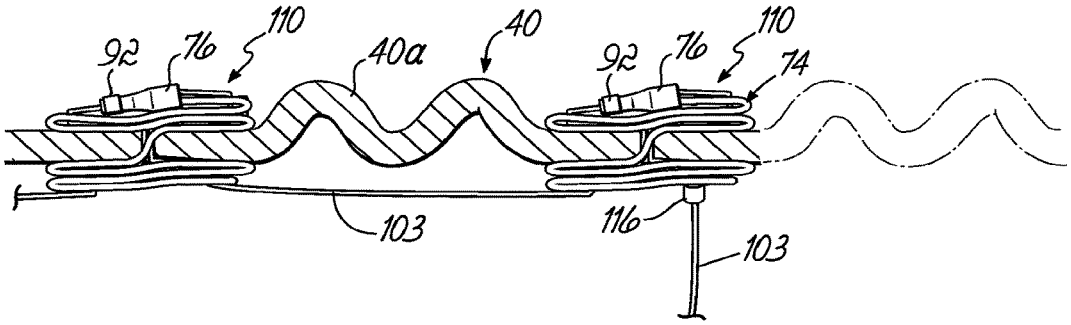
(57) **ABSTRACT**

A tissue anchor includes an anchor member formed from a generally flexible material. An activation member, which may be a tensioning member, causes proximal and distal end portions of the anchor member to move toward each other into a shortened configuration suitable for anchoring against the tissue. The tissue anchor can optionally be deployed and activated using a catheter device.

16 Claims, 15 Drawing Sheets



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(56) **References Cited**

U.S. PATENT DOCUMENTS

3,794,041	A		2/1974	Frei et al.
3,841,521	A		10/1974	Jarvik
3,959,960	A		6/1976	Santos
3,986,493	A		10/1976	Hendren, III
3,995,619	A		12/1976	Glatzer
4,042,979	A		8/1977	Angell
4,055,861	A		11/1977	Carpentier et al.
4,258,705	A		3/1981	Sorensen et al.
4,369,787	A		1/1983	Lasner et al.
4,489,446	A		12/1984	Reed
4,532,926	A		8/1985	O'Holia
4,809,713	A		3/1989	Grayzel
4,917,698	A		4/1990	Carpentier et al.
4,945,912	A		8/1990	Langberg
5,016,353	A		5/1991	Iten
5,041,129	A		8/1991	Hayhurst et al.
5,041,130	A		8/1991	Cosgrove et al.
5,061,277	A		10/1991	Carpentier et al.
5,104,407	A		4/1992	Lam et al.
5,123,914	A		6/1992	Cope
5,171,232	A		12/1992	Castillo et al.
5,171,259	A		12/1992	Inoue
5,192,302	A		3/1993	Kensey et al.
5,201,880	A		4/1993	Wright et al.
5,203,777	A		4/1993	Lee
5,304,190	A		4/1994	Reckelhoff et al.
5,306,234	A		4/1994	Johnson
5,306,296	A		4/1994	Wright et al.
5,337,736	A		8/1994	Reddy
5,360,444	A		11/1994	Kusuhara
5,364,365	A		11/1994	Wortrich
5,364,393	A		11/1994	Auth et al.
5,429,131	A		7/1995	Scheinman et al.
5,450,860	A		9/1995	O'Connor
5,452,513	A		9/1995	Zinnbauer et al.
5,464,023	A		11/1995	Viera
5,545,178	A		8/1996	Kensey et al.
5,565,122	A		10/1996	Zinnbauer et al.
5,571,215	A		11/1996	Sterman et al.
5,593,424	A		1/1997	Northrup
5,607,471	A		3/1997	Seguin et al.
5,623,943	A		4/1997	Hackett et al.
5,626,590	A		5/1997	Wilk
5,640,955	A		6/1997	Ockuly et al.
5,662,681	A	*	9/1997	Nash A61B 17/0057 604/285
5,669,919	A		9/1997	Sanders et al.
5,674,279	A		10/1997	Wright et al.
5,682,906	A		11/1997	Sterman et al.
5,690,656	A		11/1997	Cope et al.
5,706,827	A		1/1998	Ehr et al.
5,716,367	A		2/1998	Koike et al.
5,716,397	A		2/1998	Myers
5,716,399	A		2/1998	Love
5,776,080	A		7/1998	Thome et al.
5,776,189	A		7/1998	Khalid
5,797,939	A		8/1998	Yoon
5,813,996	A		9/1998	St. Germain et al.
5,824,066	A		10/1998	Gross
5,827,300	A		10/1998	Fleega
5,829,447	A		11/1998	Stevens et al.
5,830,224	A		11/1998	Cohn et al.
5,851,185	A		12/1998	Berns
5,860,920	A		1/1999	McGee et al.
5,868,733	A		2/1999	Ockuly et al.
5,879,366	A		3/1999	Shaw
5,888,240	A		3/1999	Carpentier et al.
5,906,579	A		5/1999	Vander Salm et al.
5,911,720	A		6/1999	Bourne et al.
5,928,224	A		7/1999	Laufer
5,931,818	A		8/1999	Werp et al.
5,944,738	A		8/1999	Amplatz et al.
5,980,515	A		11/1999	Tu
5,984,939	A		11/1999	Yoon
6,015,414	A		1/2000	Werp et al.
6,027,514	A		2/2000	Stine et al.
6,042,581	A		3/2000	Ryan et al.
6,050,472	A		4/2000	Shibata
6,050,936	A		4/2000	Schweich, Jr. et al.
6,068,637	A		5/2000	Popov et al.
6,068,648	A		5/2000	Cole et al.
6,071,292	A		6/2000	Makower et al.
6,080,182	A		6/2000	Shaw et al.
6,099,460	A		8/2000	Denker
6,102,945	A		8/2000	Campbell
6,113,611	A		9/2000	Allen et al.
6,126,647	A		10/2000	Posey et al.
RE36,974	E		11/2000	Bonutti
6,159,234	A		12/2000	Bonutti et al.
6,162,168	A		12/2000	Schweich, Jr. et al.
6,165,119	A		12/2000	Schweich, Jr. et al.
6,165,120	A		12/2000	Schweich, Jr. et al.
6,165,183	A		12/2000	Kuehn et al.
6,173,199	B1		1/2001	Gabriel
6,190,353	B1		2/2001	Makower et al.
6,197,017	B1		3/2001	Brock et al.
6,206,895	B1		3/2001	Levinson
6,210,432	B1		4/2001	Solem et al.
6,231,587	B1		5/2001	Makower
6,267,781	B1		7/2001	Tu
6,269,819	B1		8/2001	Oz et al.
6,285,903	B1		9/2001	Rosenthal et al.
6,287,317	B1		9/2001	Makower et al.
6,298,257	B1		10/2001	Hall et al.
6,306,133	B1		10/2001	Tu et al.
6,312,447	B1		11/2001	Grimes
6,319,263	B1		11/2001	Levinson
6,332,089	B1		12/2001	Acker et al.
6,332,893	B1		12/2001	Mortier et al.
6,352,543	B1		3/2002	Cole
6,385,472	B1		5/2002	hall et al.
6,401,720	B1		6/2002	Stevens et al.
6,402,680	B2		6/2002	Mortier et al.
6,402,781	B1		6/2002	Langberg et al.
6,406,420	B1		6/2002	McCarthy et al.
6,447,522	B2		9/2002	Gambale et al.
6,461,366	B1		10/2002	Seguin
6,500,184	B1		12/2002	Chan et al.
6,524,303	B1		2/2003	Garibaldi
6,530,952	B2		3/2003	Vesely
6,537,198	B1		3/2003	Vidlund et al.
6,537,314	B2		3/2003	Langberg et al.
6,542,766	B2		4/2003	Hall et al.
6,544,230	B1		4/2003	Flaherty et al.
6,554,852	B1		4/2003	Oberlander
6,562,019	B1		5/2003	Sell
6,565,562	B1		5/2003	Shah et al.
6,589,208	B2		7/2003	Ewers et al.
6,594,517	B1		7/2003	Nevo
6,596,014	B2		7/2003	Levinson et al.
6,619,291	B2		9/2003	Hlavka et al.
6,626,899	B2		9/2003	Houser et al.
6,626,919	B1		9/2003	Swanstrom
6,626,930	B1		9/2003	Allen et al.
6,629,534	B1		10/2003	St. Goar et al.
6,629,921	B1		10/2003	Schweich, Jr. et al.
6,655,386	B1		12/2003	Makower et al.
6,656,221	B2		12/2003	Taylor et al.
6,669,687	B1		12/2003	Saadat
6,669,707	B1		12/2003	Swanstrom et al.
6,676,702	B2		1/2004	Mathis
6,689,164	B1		2/2004	Seguin
6,699,263	B2		3/2004	Cope

(56) **References Cited**

U.S. PATENT DOCUMENTS

6,702,825 B2 3/2004 Frazier et al.
6,702,826 B2 3/2004 Liddicoat et al.
6,718,985 B2 4/2004 Hlavka et al.
6,723,038 B1 4/2004 Schroeder et al.
6,730,112 B2 5/2004 Levinson
6,733,509 B2 5/2004 Nobles et al.
6,736,808 B1 5/2004 Motamedi et al.
6,746,472 B2 6/2004 Frazier et al.
6,764,500 B1 7/2004 Muijs Van De Moer et al.
6,769,434 B2 8/2004 Liddicoat et al.
6,793,618 B2 9/2004 Schweich, Jr. et al.
6,866,673 B2 3/2005 Oren et al.
6,913,608 B2 7/2005 Liddicoat et al.
6,921,407 B2 7/2005 Nguyen et al.
6,923,823 B1 8/2005 Bartlett et al.
6,942,694 B2 9/2005 Liddicoat et al.
6,945,978 B1 9/2005 Hyde
6,964,683 B2 11/2005 Kowalsky et al.
6,976,995 B2 12/2005 Mathis et al.
7,004,958 B2 2/2006 Adams et al.
7,037,334 B1 5/2006 Hlavka et al.
7,101,395 B2 9/2006 Tremulis et al.
7,115,110 B2 10/2006 Frazier et al.
7,166,127 B2 1/2007 Spence et al.
7,211,094 B2 5/2007 Gannoe et al.
7,247,134 B2 7/2007 Vidlund et al.
7,731,732 B2 6/2010 Ken
7,749,250 B2 7/2010 Stone et al.
7,771,455 B2 8/2010 Ken
7,883,538 B2 2/2011 To et al.
7,931,580 B2 4/2011 Gertner et al.
8,172,871 B2 5/2012 Ken
2001/0005787 A1 6/2001 Oz et al.
2001/0039436 A1 11/2001 Frazier et al.
2001/0049492 A1 12/2001 Frazier et al.
2001/0051815 A1 12/2001 Esplin
2002/0013571 A1 1/2002 Goldfarb et al.
2002/0016628 A1 2/2002 Langberg et al.
2002/0019649 A1 2/2002 Sikora et al.
2002/0026198 A1 2/2002 Ockuly et al.
2002/0026216 A1 2/2002 Grimes
2002/0029080 A1 3/2002 Mortier et al.
2002/0042621 A1 4/2002 Liddicoat et al.
2002/0072758 A1 6/2002 Reo et al.
2002/0087169 A1 7/2002 Brock et al.
2002/0087173 A1 7/2002 Alferness et al.
2002/0087178 A1 7/2002 Nobles et al.
2002/0095167 A1 7/2002 Liddicoat et al.
2002/0100485 A1 8/2002 Stevens et al.
2002/0103532 A1 8/2002 Langberg et al.
2002/0107531 A1 8/2002 Schreck et al.
2002/0128708 A1 9/2002 Northrup, III et al.
2002/0156526 A1 10/2002 Hlavka et al.
2002/0165535 A1 11/2002 Lesh et al.
2002/0169359 A1 11/2002 McCarthy et al.
2002/0169502 A1 11/2002 Mathis
2002/0169504 A1 11/2002 Alferness et al.
2002/0173841 A1 11/2002 Ortiz et al.
2002/0183766 A1 12/2002 Sequin
2002/0183836 A1 12/2002 Liddicoat et al.
2002/0183837 A1 12/2002 Streeter et al.
2002/0183838 A1 12/2002 Liddicoat et al.
2002/0183841 A1 12/2002 Cohn et al.
2002/0188170 A1 12/2002 Santamore et al.
2003/0018358 A1 1/2003 Saadat
2003/0069593 A1 4/2003 Tremulis et al.
2003/0069636 A1 4/2003 Solem et al.
2003/0078465 A1 4/2003 Pai et al.
2003/0078654 A1 4/2003 Taylor et al.
2003/0078671 A1 4/2003 Lesniak et al.
2003/0083538 A1 5/2003 Adams et al.
2003/0105474 A1 6/2003 Bonutti
2003/0105520 A1 6/2003 Alferness et al.
2003/0120340 A1 6/2003 Liska et al.
2003/0130730 A1 7/2003 Cohn et al.
2003/0144697 A1 7/2003 Mathis et al.
2003/0160721 A1 8/2003 Gilboa et al.
2003/0171776 A1 9/2003 Adams et al.
2003/0171806 A1 9/2003 Mathis et al.
2003/0199974 A1 10/2003 Lee et al.
2003/0204205 A1 10/2003 Sauer et al.
2003/0208195 A1 11/2003 Thompson et al.
2003/0212453 A1 11/2003 Mathis et al.
2003/0220685 A1 11/2003 Hlavka et al.
2003/0233142 A1 12/2003 Morales et al.
2004/0003819 A1 1/2004 St. Goar et al.
2004/0019378 A1 1/2004 Hlavka et al.
2004/0024414 A1 2/2004 Downing
2004/0030382 A1 2/2004 St. Goar et al.
2004/0039442 A1 2/2004 St. Goar et al.
2004/0044364 A1 3/2004 DeVries et al.
2004/0049211 A1 3/2004 Tremulis et al.
2004/0092962 A1 5/2004 Thornton et al.
2004/0093023 A1 5/2004 Allen et al.
2004/0097865 A1 5/2004 Anderson et al.
2004/0122456 A1 6/2004 Saadat et al.
2004/0127983 A1 7/2004 Mortier et al.
2004/0133063 A1 7/2004 McCarthy et al.
2004/0147958 A1 7/2004 Lam et al.
2004/0152947 A1 8/2004 Schroeder et al.
2004/0162568 A1 8/2004 Saadat et al.
2004/0167539 A1 8/2004 Kuehn et al.
2004/0167620 A1 8/2004 Ortiz et al.
2004/0172046 A1 9/2004 Hlavka et al.
2004/0186486 A1 9/2004 Roue et al.
2004/0186566 A1 9/2004 Hindrichs et al.
2004/0193191 A1 9/2004 Starksen et al.
2004/0220473 A1 11/2004 Lualdi
2004/0236419 A1 11/2004 Milo
2004/0243153 A1 12/2004 Liddicoat et al.
2004/0243227 A1 12/2004 Starksen et al.
2004/0260317 A1 12/2004 Bloom et al.
2005/0033446 A1 2/2005 Deem et al.
2005/0049634 A1 3/2005 Chopra
2005/0049681 A1 3/2005 Greenhalgh et al.
2005/0055087 A1 3/2005 Starksen
2005/0055089 A1 3/2005 Macoviak et al.
2005/0065550 A1 3/2005 Starksen et al.
2005/0065601 A1 3/2005 Lee et al.
2005/0075723 A1 4/2005 Schroeder et al.
2005/0107810 A1 5/2005 Morales et al.
2005/0107812 A1 5/2005 Starksen et al.
2005/0107871 A1 5/2005 Realyvasquez et al.
2005/0119523 A1 6/2005 Starksen et al.
2005/0119734 A1 6/2005 Spence et al.
2005/0119735 A1 6/2005 Spence et al.
2005/0125011 A1 6/2005 Spence et al.
2005/0125031 A1 6/2005 Pupenhagen et al.
2005/0131438 A1 6/2005 Cohn
2005/0137700 A1 6/2005 Spence et al.
2005/0143811 A1 6/2005 Realyvasquez
2005/0148815 A1 7/2005 Mortier et al.
2005/0149014 A1 7/2005 Hauck et al.
2005/0159810 A1 7/2005 Filsoufi
2005/0177228 A1 8/2005 Solem et al.
2005/0184122 A1 8/2005 Hlavka et al.
2005/0197693 A1 9/2005 Pai et al.
2005/0216039 A1 9/2005 Lederman
2005/0234481 A1 10/2005 Waller
2005/0251157 A1 11/2005 Saadat et al.
2005/0251159 A1 11/2005 Ewers et al.
2005/0251202 A1 11/2005 Ewers et al.
2005/0251205 A1 11/2005 Ewers et al.
2005/0251206 A1 11/2005 Maahs et al.
2005/0251207 A1 11/2005 Flores et al.
2005/0251208 A1* 11/2005 Elmer A61B 17/0401 606/232
2005/0251209 A1 11/2005 Saadat et al.
2005/0251210 A1 11/2005 Westra et al.
2005/0267533 A1 12/2005 Gertner
2005/0267571 A1 12/2005 Spence et al.
2005/0283192 A1 12/2005 Torrie et al.
2005/0288694 A1 12/2005 Solomon
2006/0004410 A1 1/2006 Nobis et al.

(56) **References Cited**

U.S. PATENT DOCUMENTS

2006/0009784	A1	1/2006	Behl et al.
2006/0069429	A1	3/2006	Spence et al.
2006/0142756	A1	6/2006	Davies et al.
2006/0161040	A1	7/2006	McCarthy et al.
2006/0178682	A1	8/2006	Boehlke
2006/0212045	A1	9/2006	Schilling et al.
2007/0010857	A1	1/2007	Sugimoto et al.
2007/0055303	A1	3/2007	Vidlund et al.
2007/0080188	A1	4/2007	Spence et al.
2007/0106310	A1	5/2007	Goldin et al.
2007/0112424	A1	5/2007	Spence et al.
2008/0228165	A1	9/2008	Spence et al.
2008/0228198	A1	9/2008	Traynor et al.
2008/0228265	A1	9/2008	Spence et al.
2008/0228266	A1	9/2008	McNamara et al.
2008/0228267	A1	9/2008	Spence et al.
2008/0275503	A1	11/2008	Spence et al.
2009/0018655	A1	1/2009	Brunelle et al.

FOREIGN PATENT DOCUMENTS

WO	WO 9604852	2/1996
WO	WO 9900059	1/1999
WO	WO 0003759	1/2000
WO	WO 0044311	8/2000
WO	WO 0060995	10/2000
WO	WO 0067640	11/2000
WO	WO 0200099	1/2002
WO	WO 02051329	7/2002
WO	WO 02096275	12/2002
WO	WO 03001893	1/2003
WO	WO 03007796	1/2003
WO	WO 03053289	7/2003
WO	WO 03/077772	9/2003
WO	WO 2004/037317	5/2004
WO	WO 2004045378	6/2004
WO	WO 2004/112658	12/2004
WO	WO 2005011463	2/2005
WO	WO 2005013832	2/2005
WO	WO 2005025644	3/2005
WO	WO 2005058239	6/2005
WO	WO 2006/039296	4/2006
WO	WO 2006064490	6/2006
WO	WO 2006105008	10/2006
WO	WO 2007005394	1/2007
WO	WO 2008091391	7/2008

OTHER PUBLICATIONS

F. Maisano et al., The Double-Orifice Technique as a Standardized Approach to Treat Mitral Regurgitation Due to Severe Myxomatous Disease: Surgical Technique, European Journal of Cardio-thoracis Surgery, 1998.

Douglas P. Zipes, MD et al., Ablation of Free Wall Accessory Pathways, Catheter Ablation of Arrhythmias, Chapter 8, 7 pgs., 1994.

David L.S. Morales et al., Development of an Off Bypass Mitral Valve Repair, Department of Surgery, Columbia University, College of Physicians and Surgeons, New York, NY. Apr. 13, 1999.

Heart Surgery Forum, Aug. 8, 2000. p. 1. Tables 1-2.Web. http://www.hsforum.com/vol2/issue2/1999-4963_tables.html>.

Heart Surgery Forum, Aug. 8, 2000. pp. 1-4. Figures 1-8.Web. http://www.hsforum.com1vol2/issue2/1999-4963figures.html>.

"Heart Valves: The Duran Flexible Annuloplasty Band—for Surgeons "Partial" to Flexiblity." Medtronic. Feb. 23, 2001. Web. http://medtronic.com/cardiac/heartvalves/duran_band/>.

Zsolt L. Nagy et al., Mitral Annuloplasty With a Suture Technique, European Journal of Cardio-thoracic Surgery 18. Aug. 15, 2000, 1 pg.

* cited by examiner

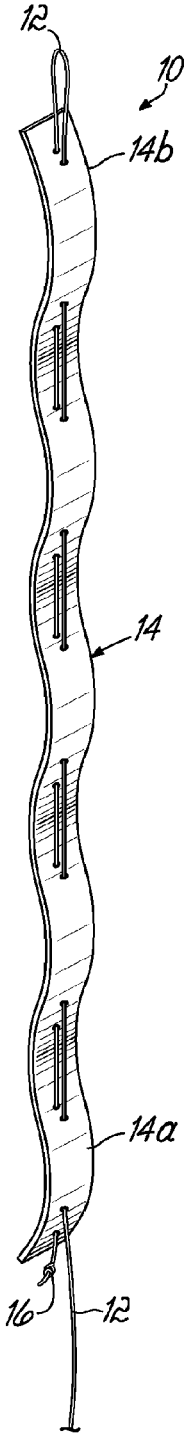


FIG. 1

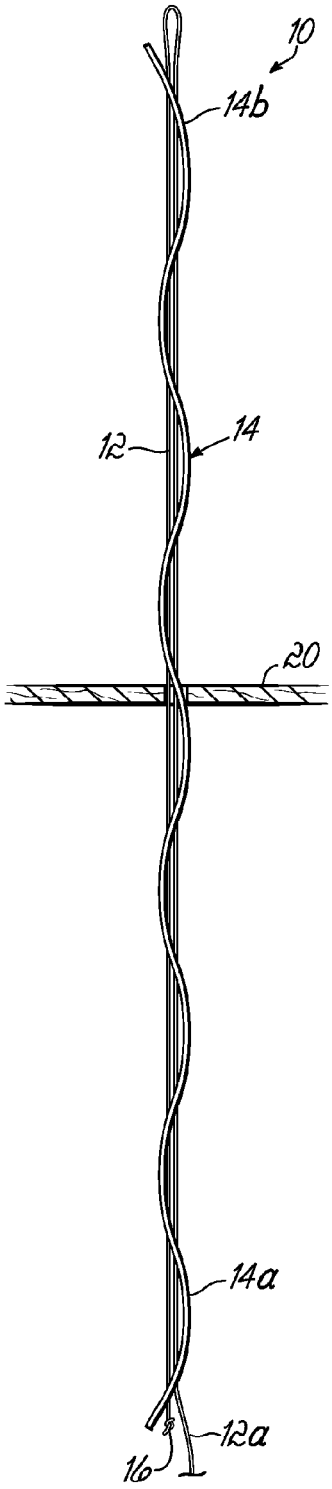


FIG. 2A

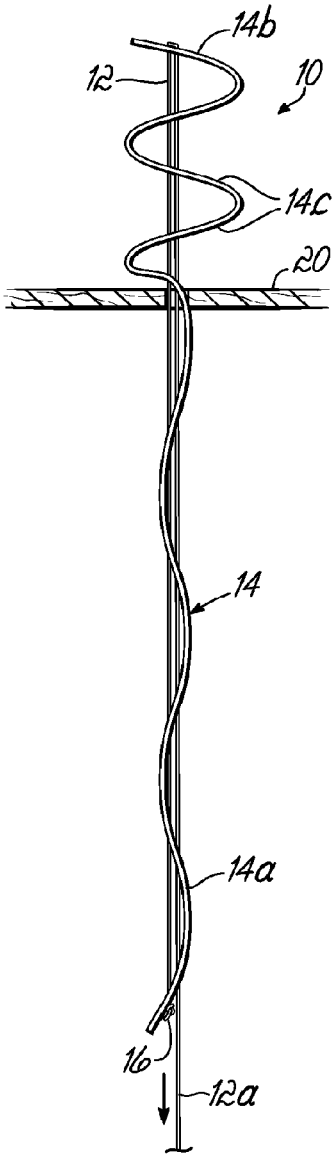


FIG. 2B

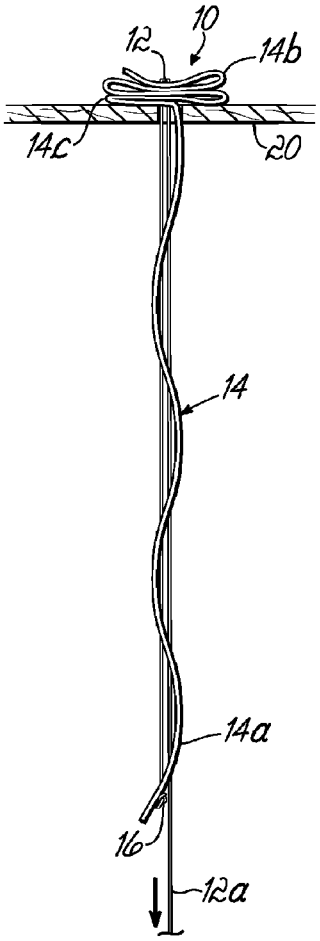


FIG. 2C

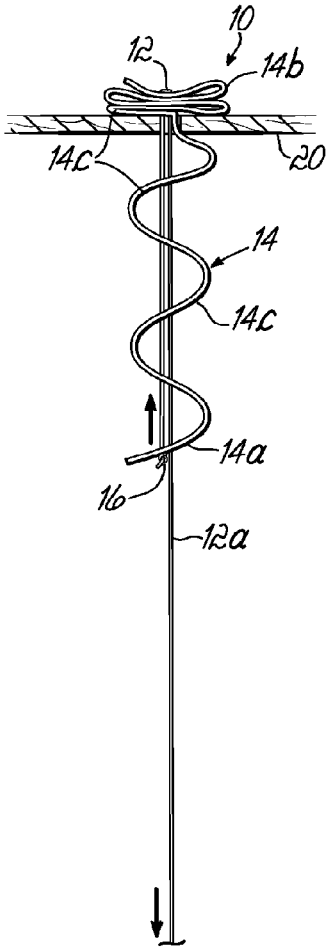


FIG. 2D

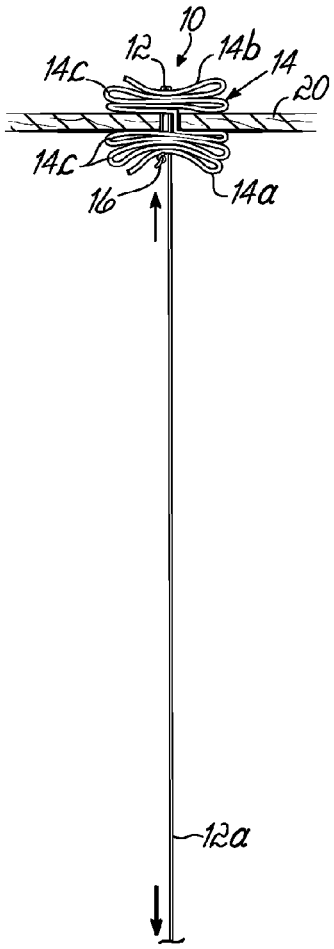


FIG. 2E

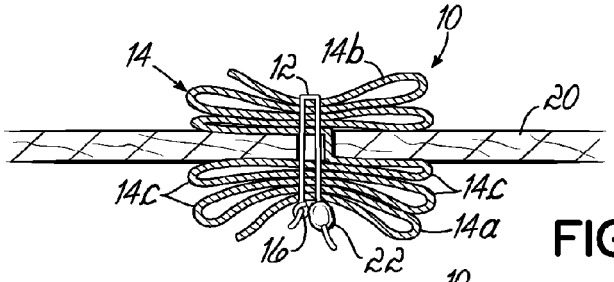


FIG. 2F

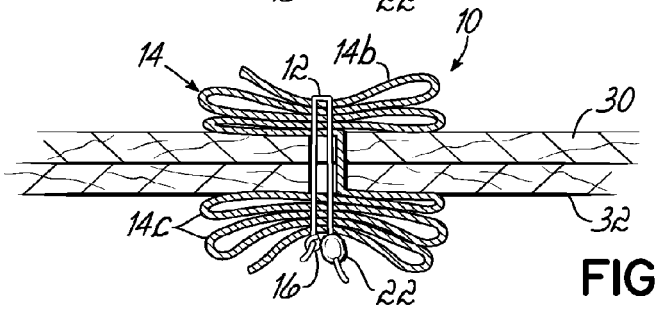


FIG. 3

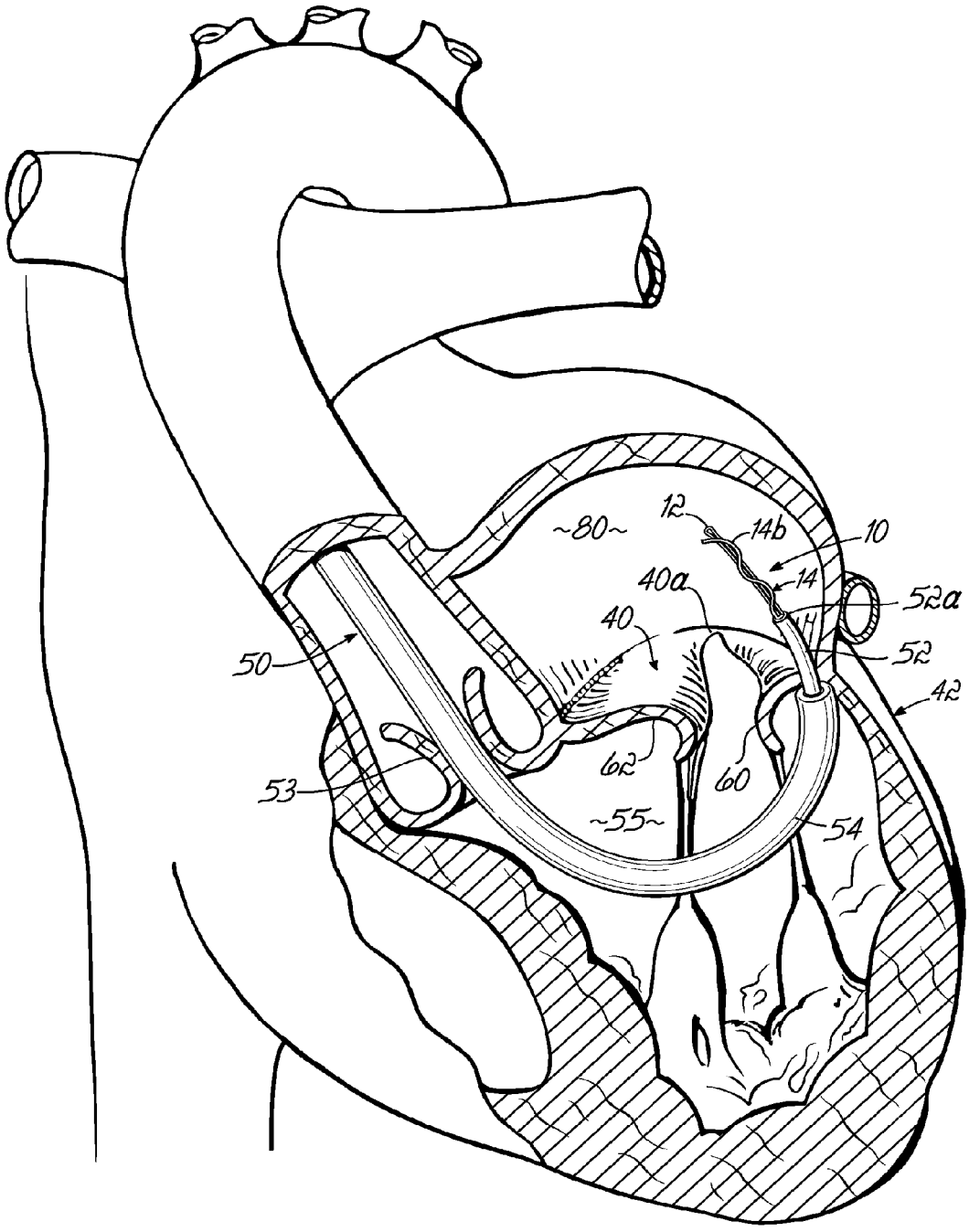
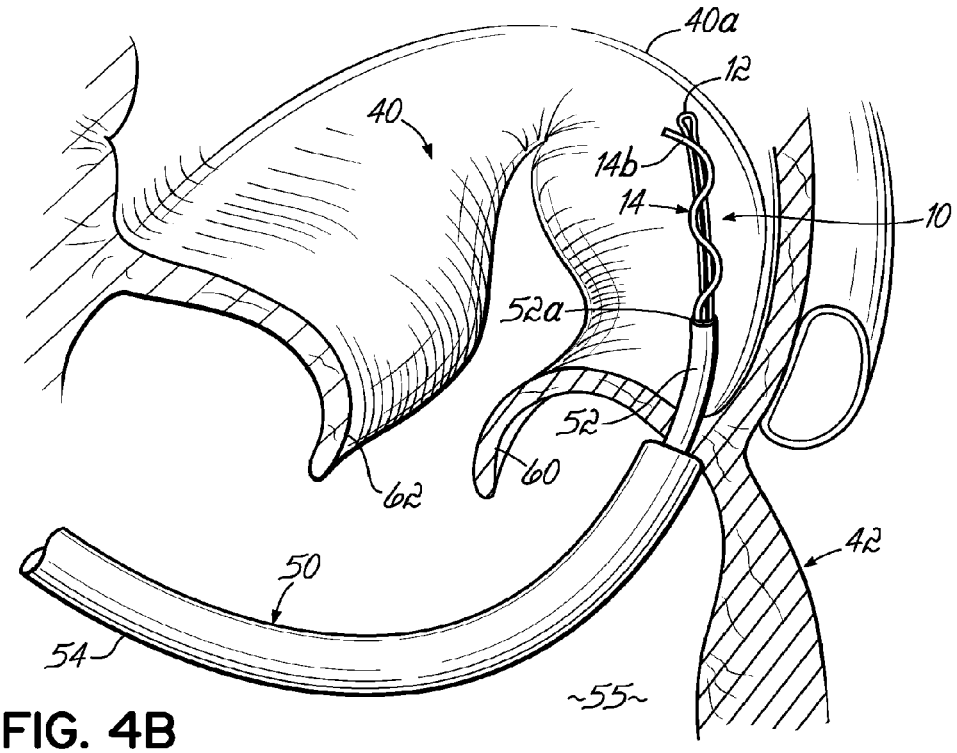


FIG. 4A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14b
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52a
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62
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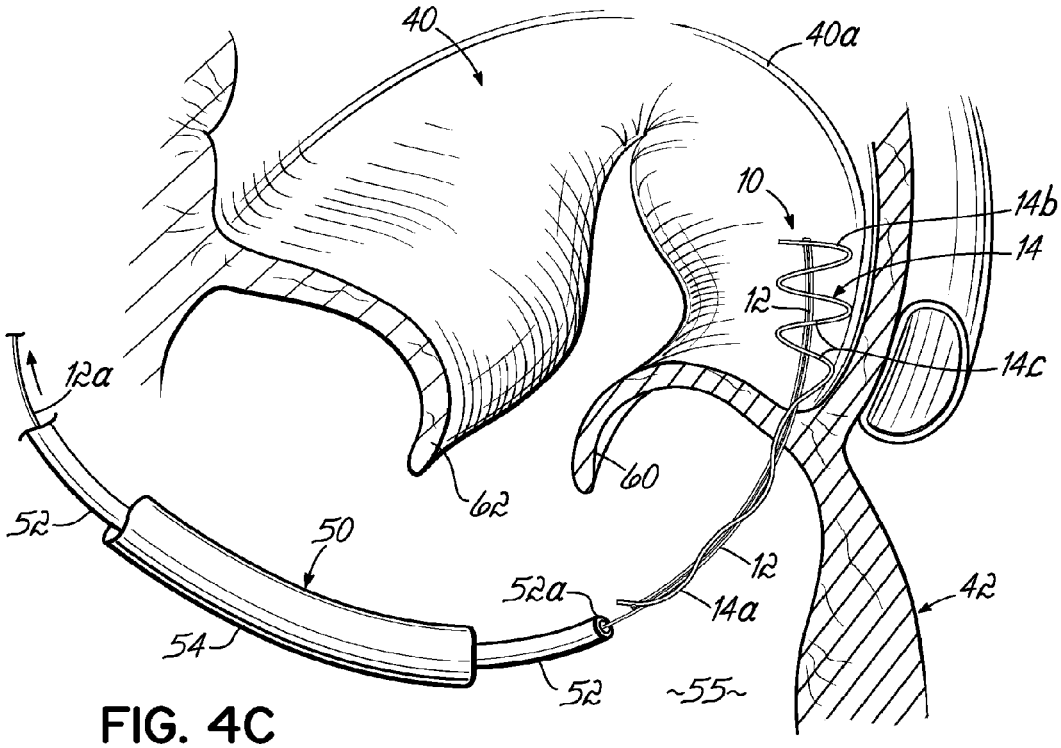
54
55

FIG. 4B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40a
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12a
14c
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12
52a
14a
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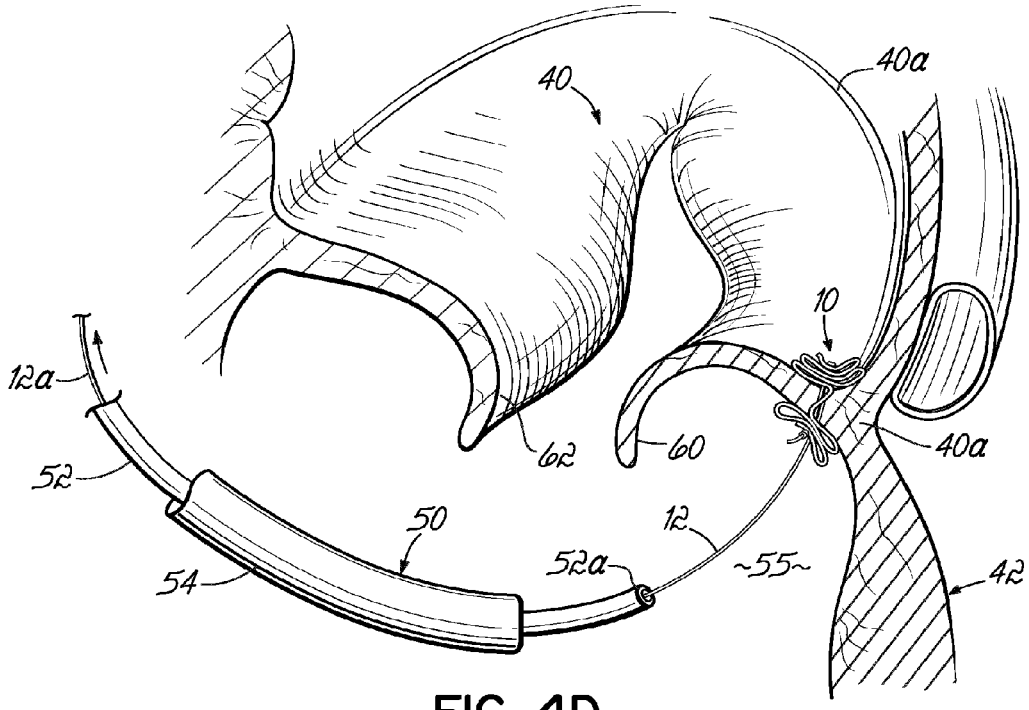
FIG. 4C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12a
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40a
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12
52a
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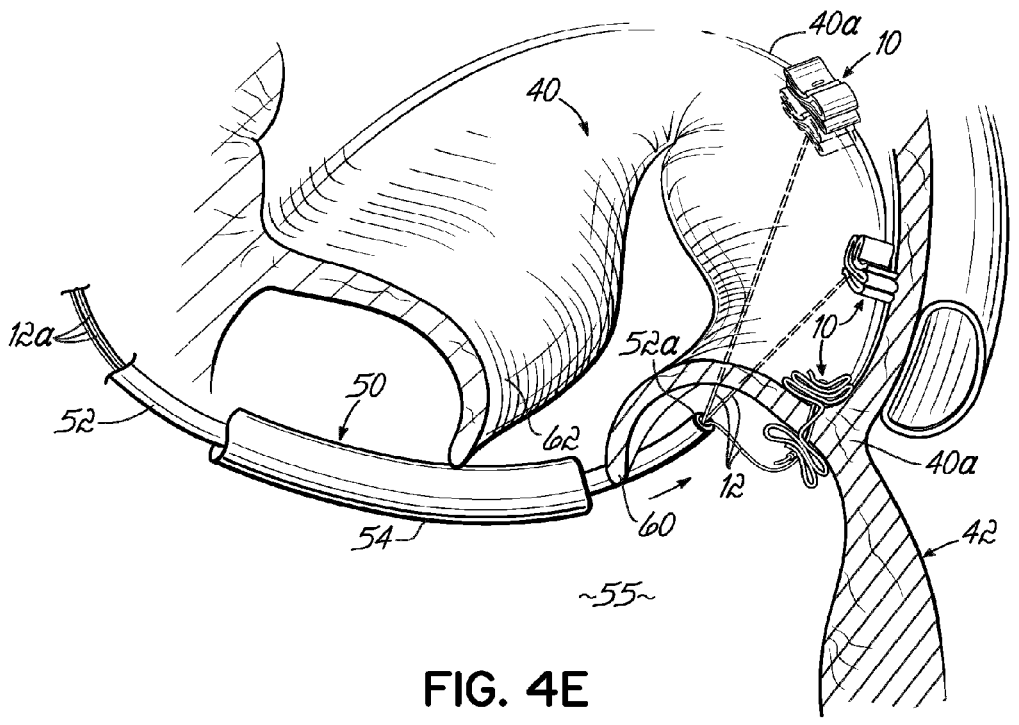
54
42

FIG. 4D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12a
10
52a
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52
62
40a
12
60
42
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FIG. 4E

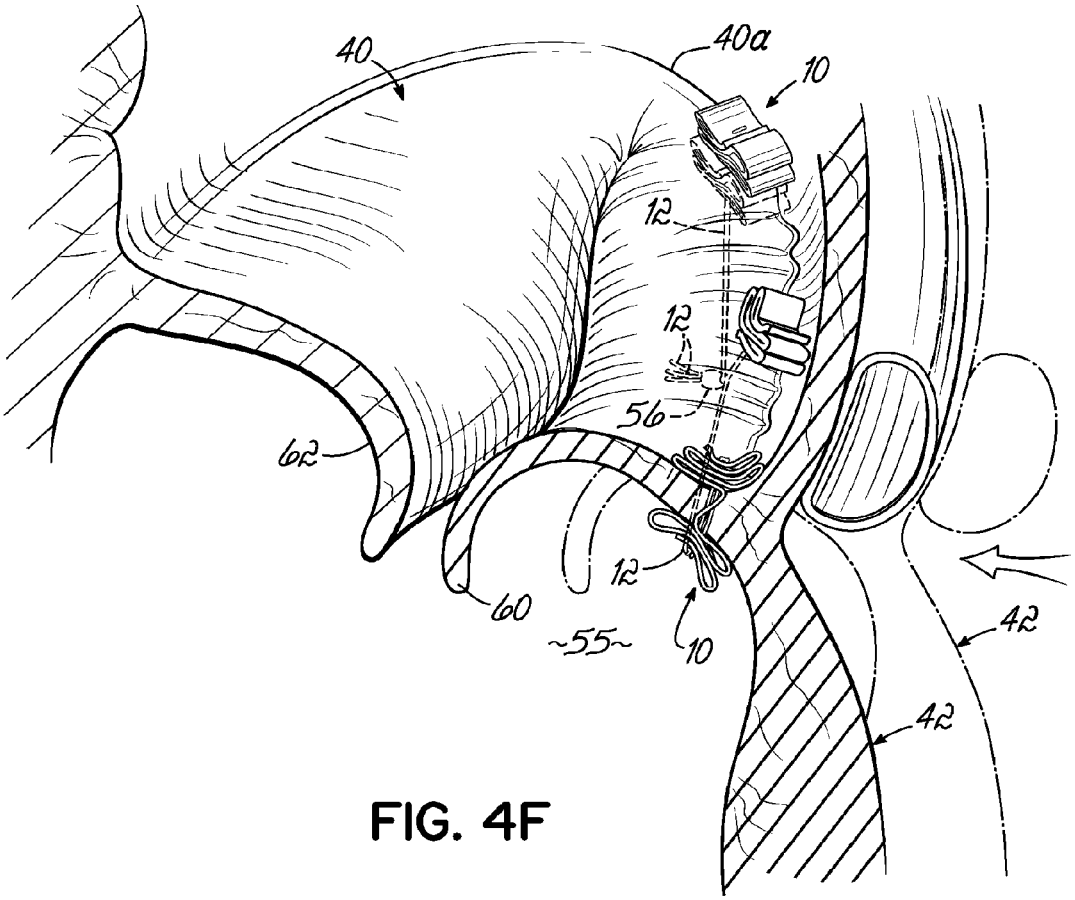
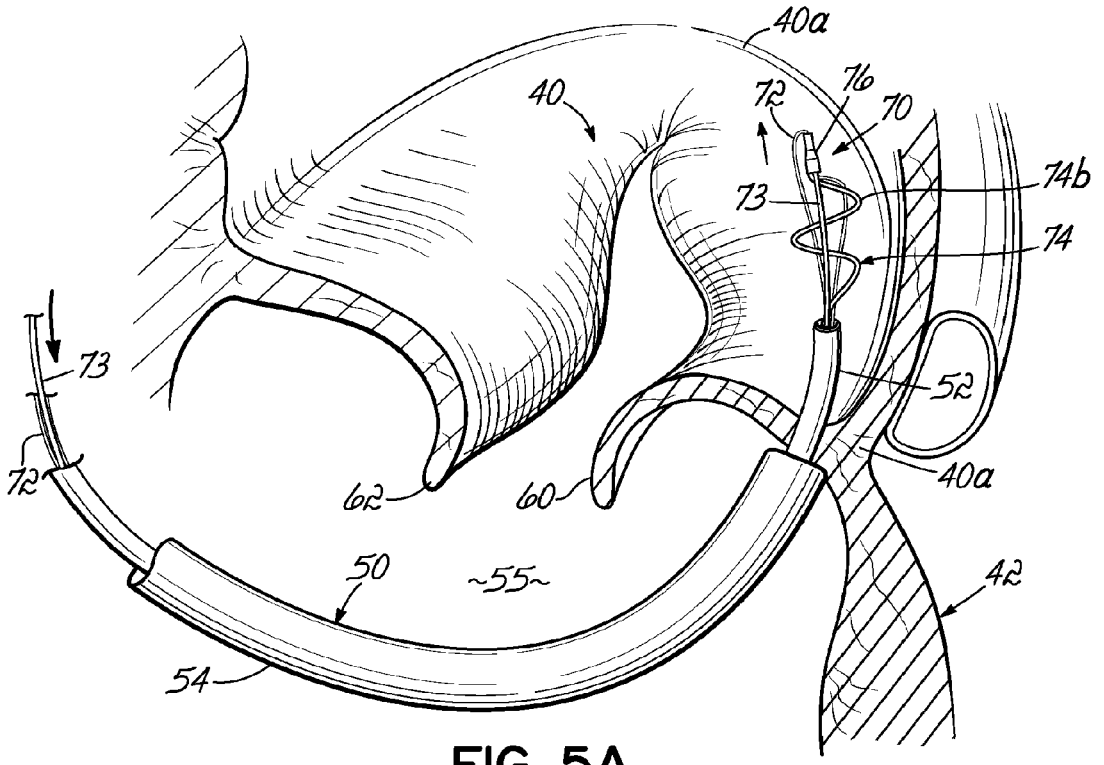


FIG. 4F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74b
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40a
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42
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FIG. 5A

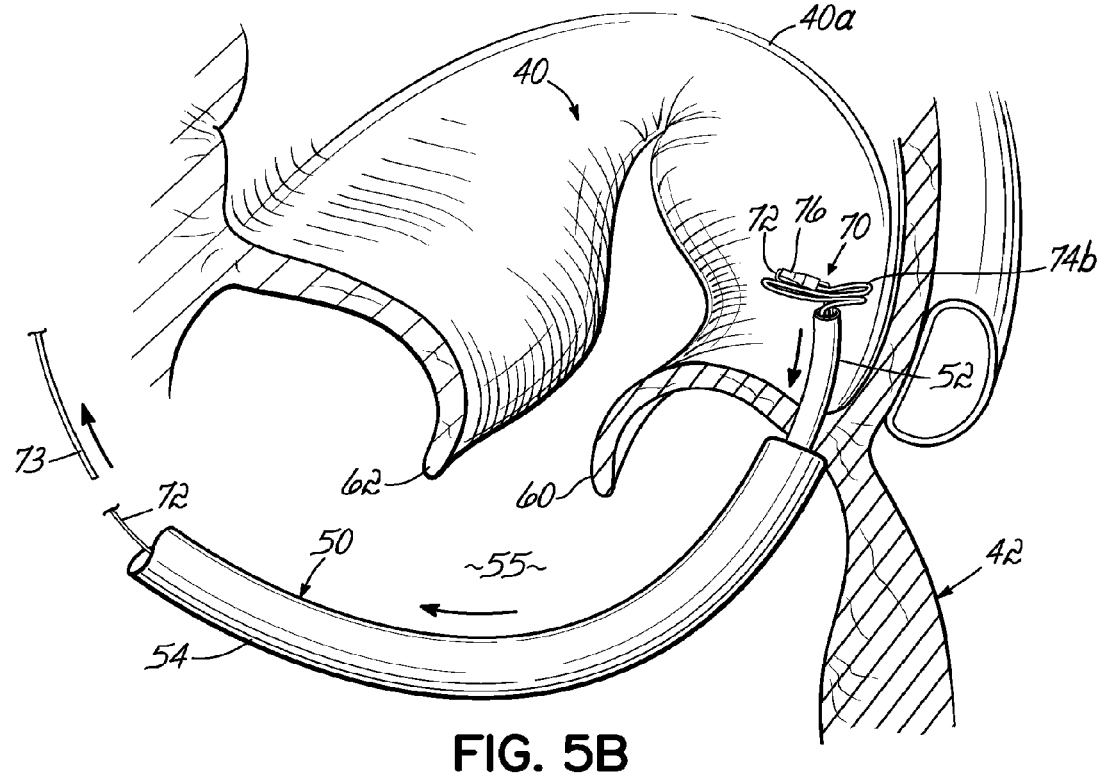
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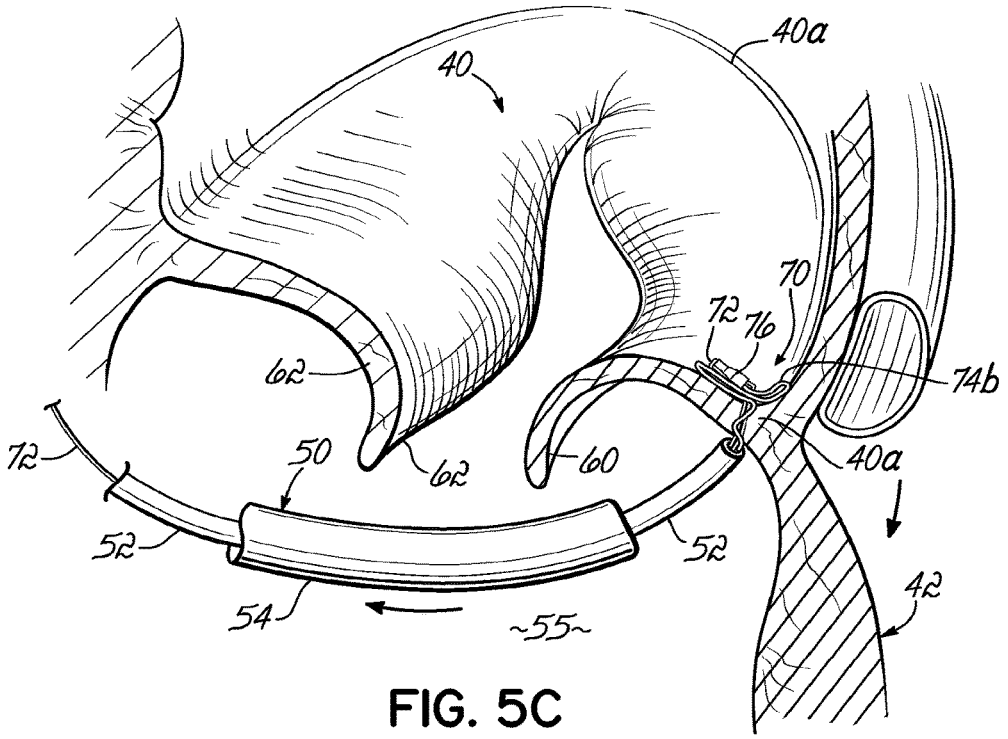
FIG. 5B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40a
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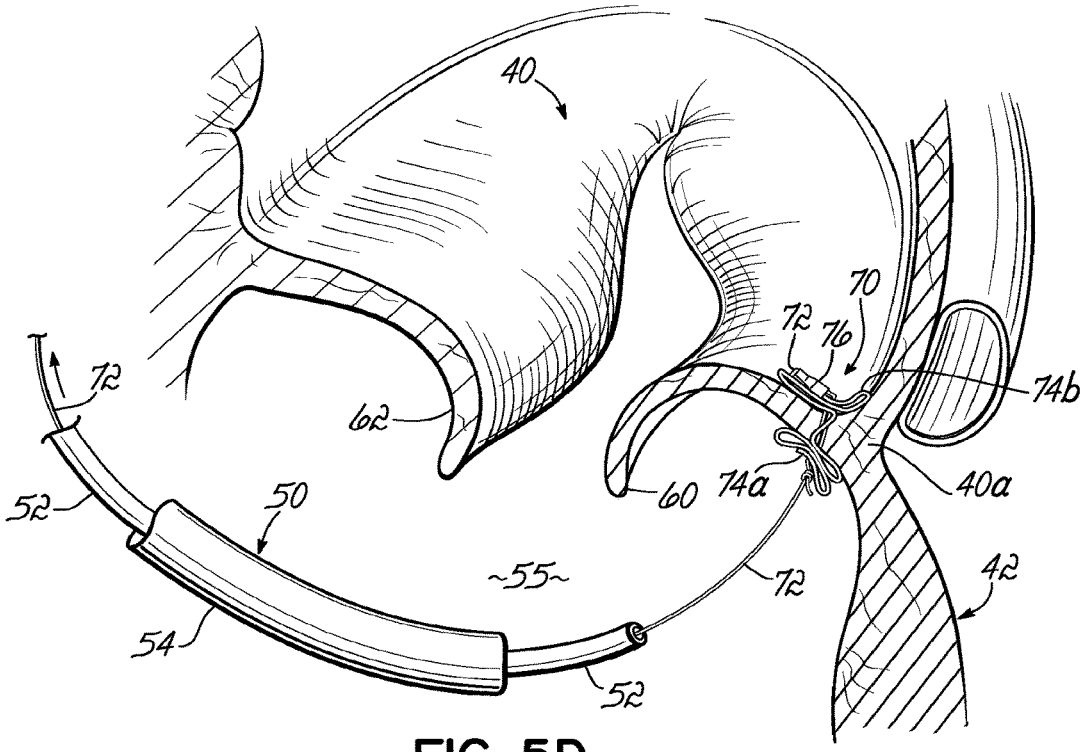
FIG. 5C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72
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52

FIG. 5D

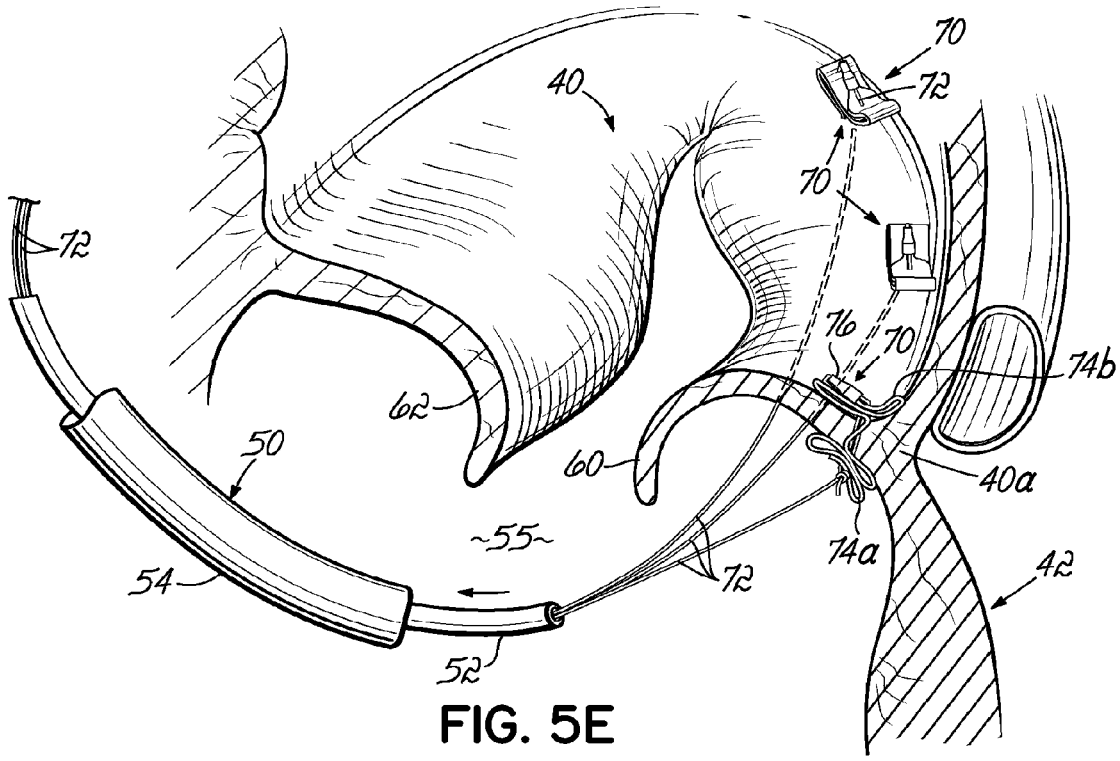


FIG. 5E

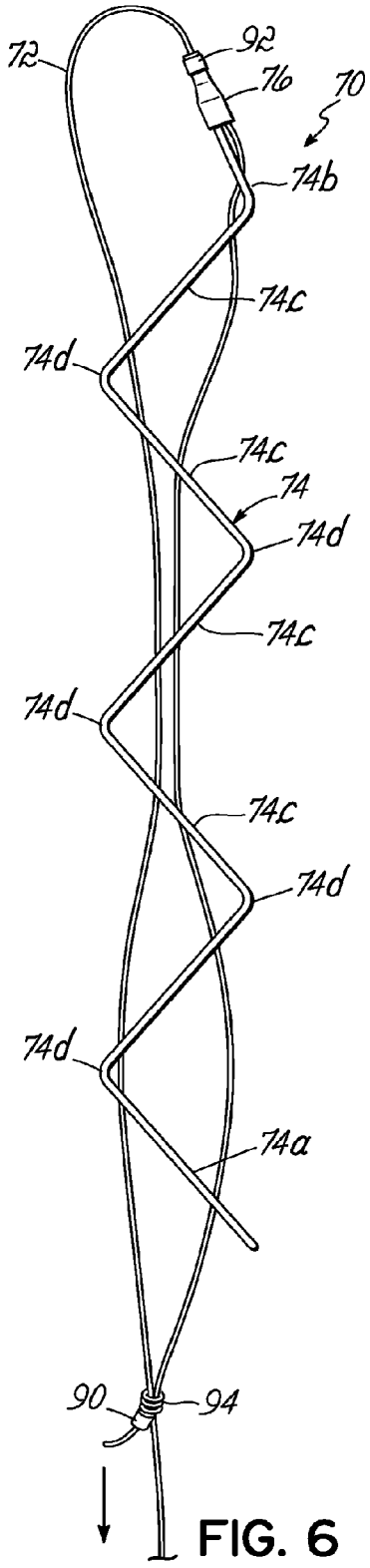


FIG. 6

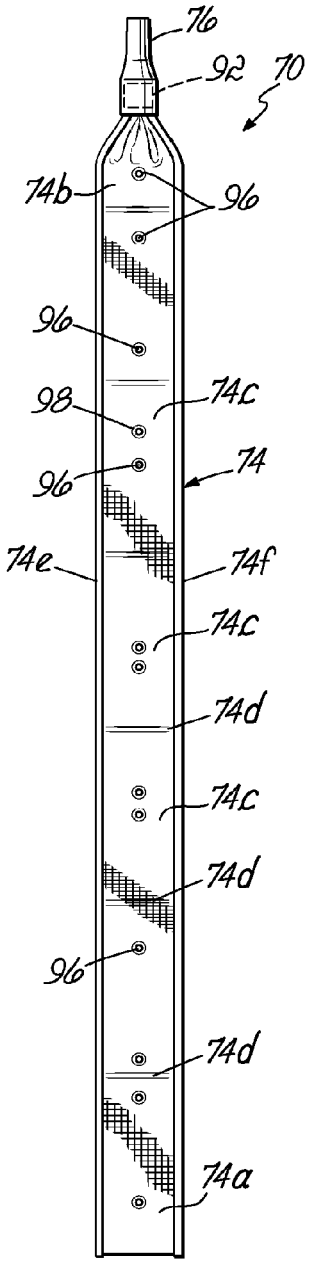


FIG. 7

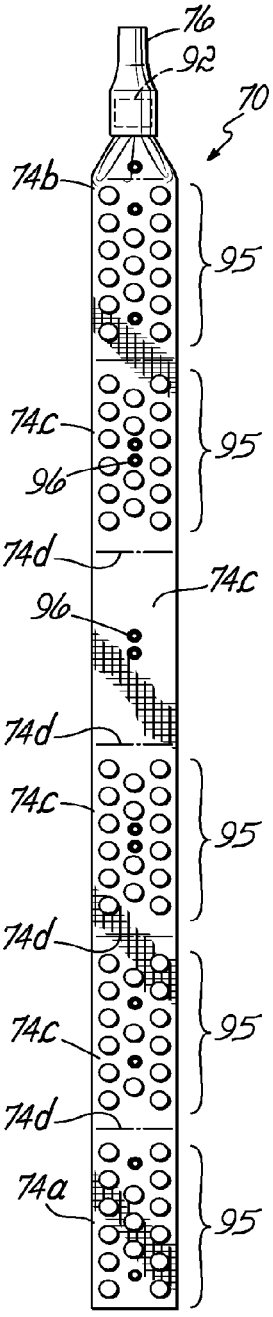


FIG. 7A

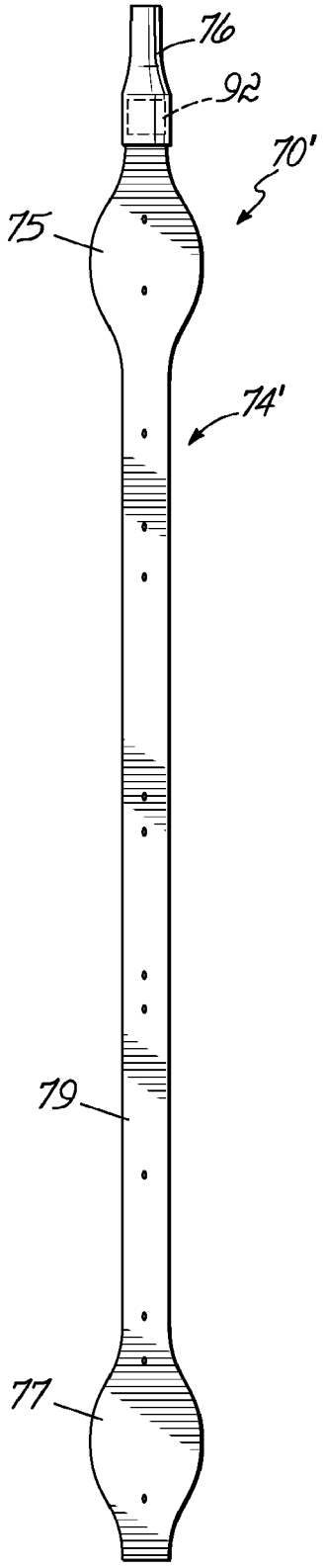

76
92
70'
75
74'
79
77

FIG. 7B

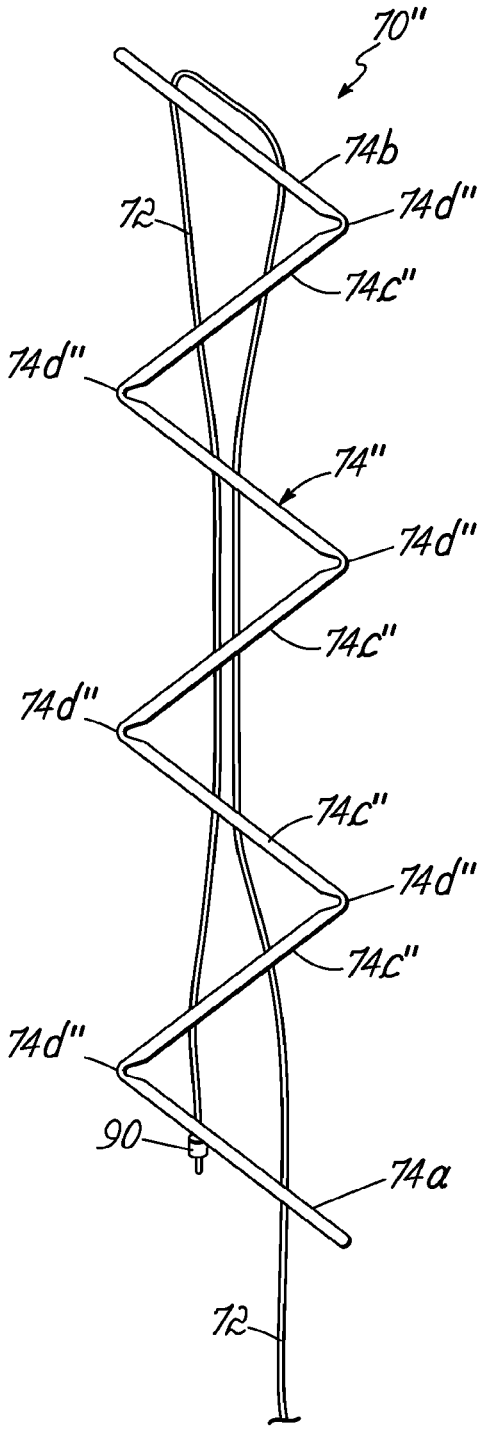

70"
74b
72
74d"
74c"
74d"
74"
74d"
74c"
74d"
74c"
74d"
74c"
74d"
90
74a
72

FIG. 7C

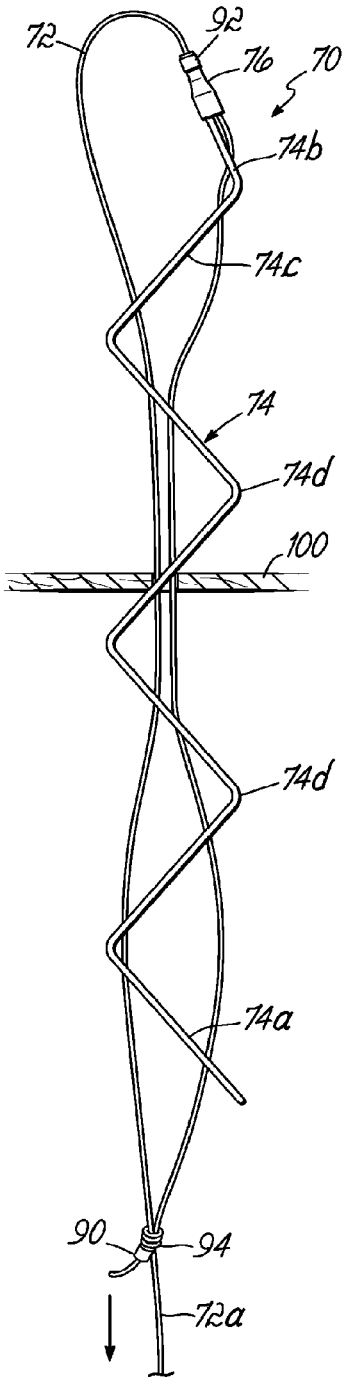


FIG. 8A

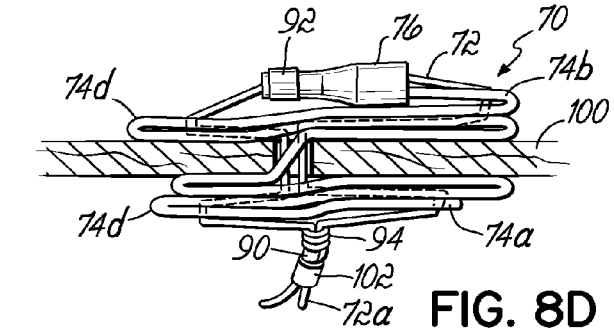


FIG. 8D

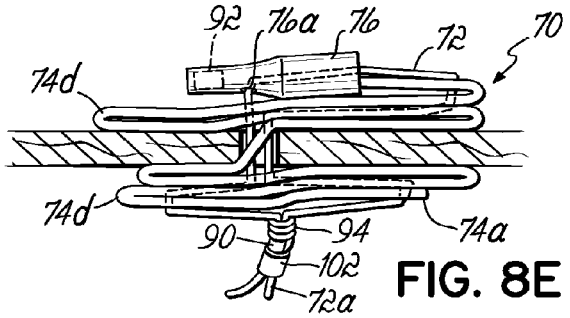


FIG. 8E

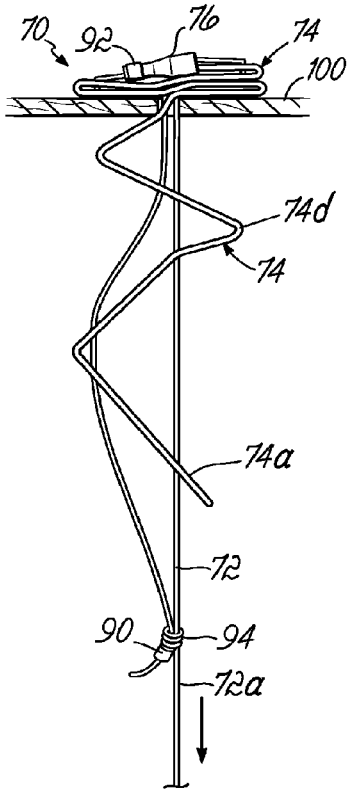


FIG. 8B

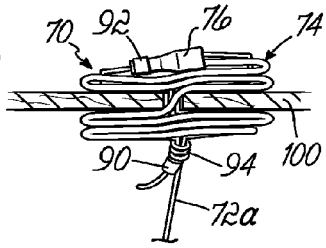


FIG. 8C

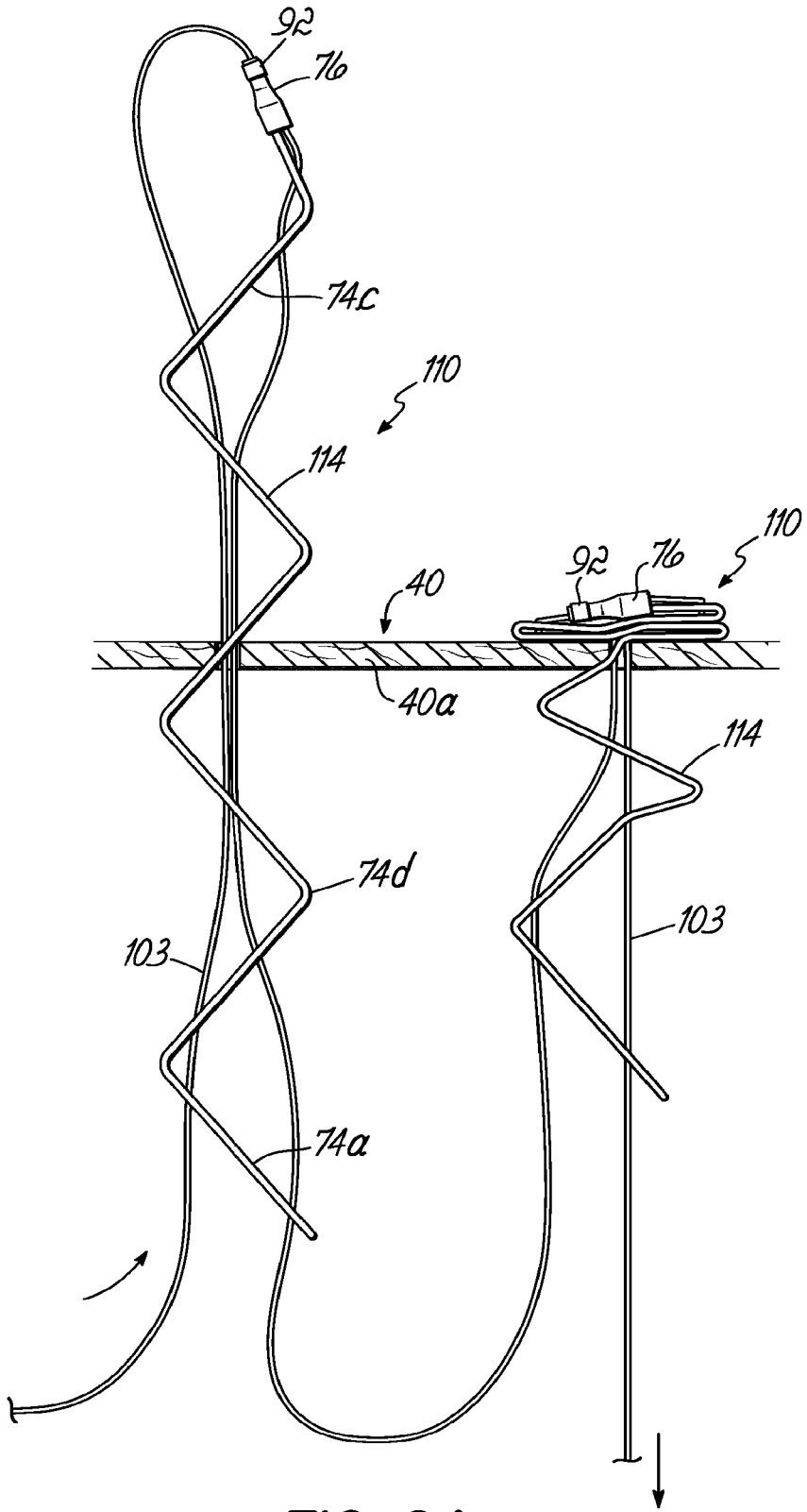
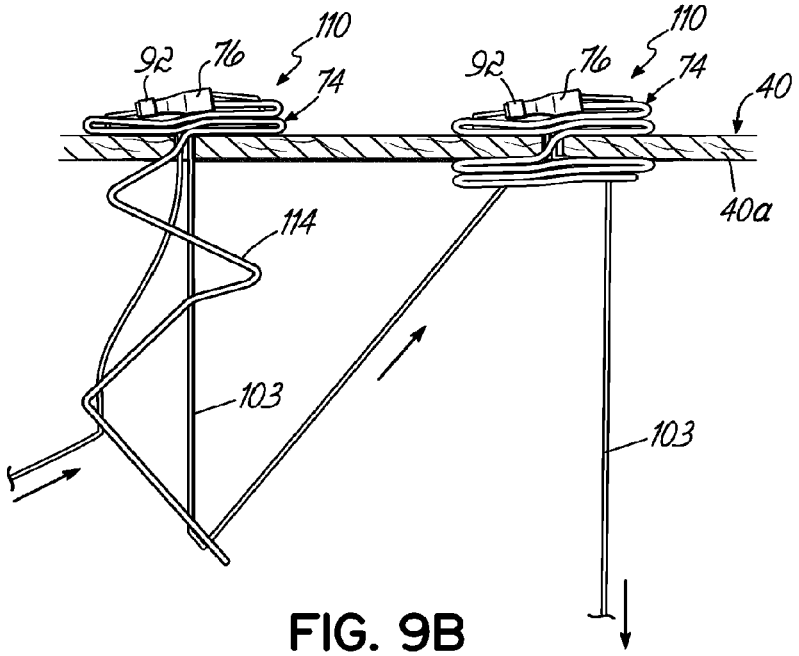


FIG. 9A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110
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40a
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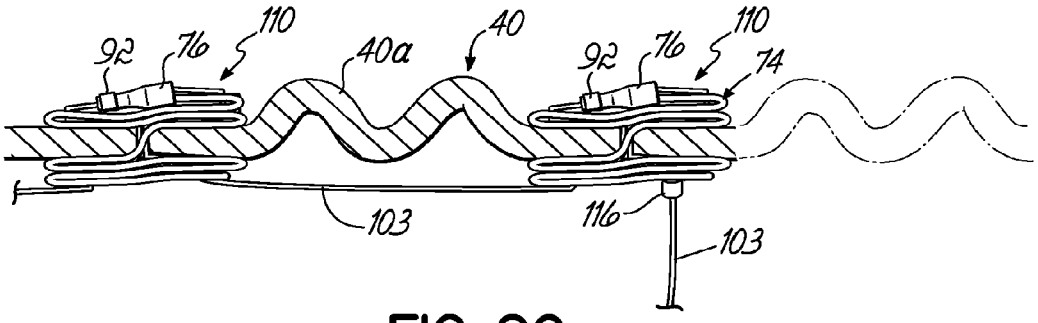
103

FIG. 9B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116
103

FIG. 9C

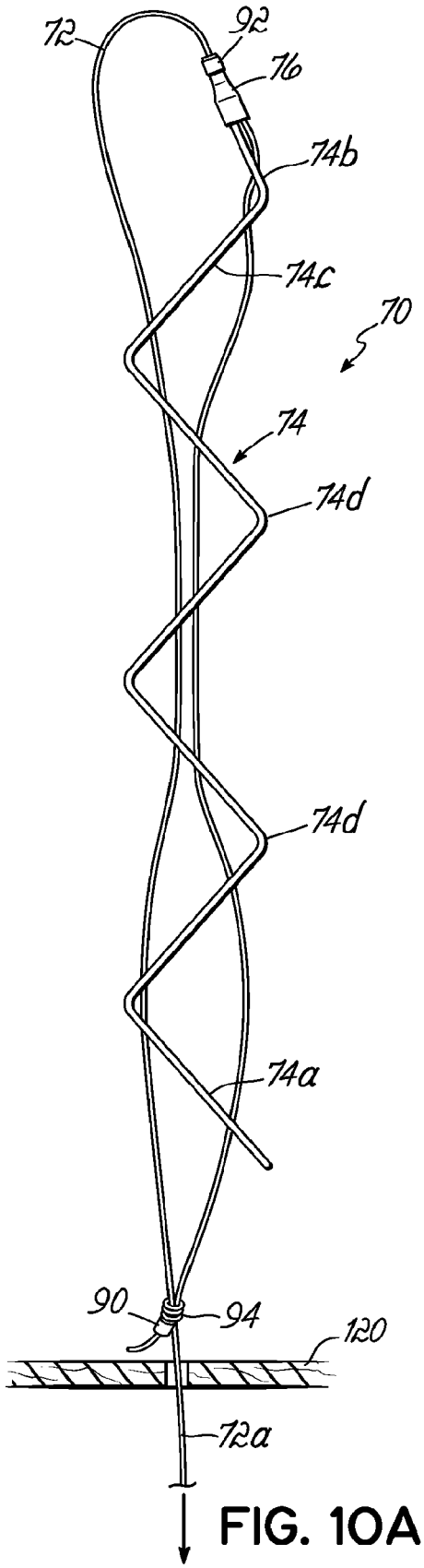

FIG. 10A

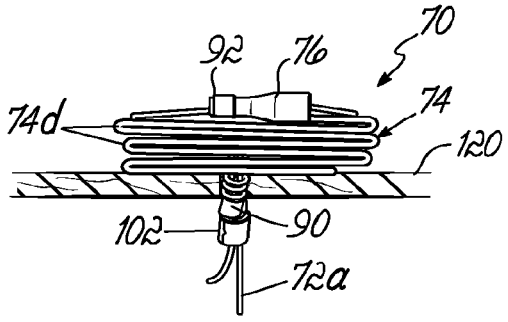

FIG. 10B

TISSUE ANCHOR AND ANCHORING SYSTEM

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation of Ser. No. 12/273,670, filed Nov. 19, 2008, which is a divisional of U.S. patent application Ser. No. 11/174,951, filed Jul. 5, 2005 (pending), the contents of each of which are incorporated by reference in their entireties.

TECHNICAL FIELD

The present invention generally relates to tissue anchors and, more particularly, anchors and methods of using such anchors to secure an element or otherwise provide an anchor point to biological tissue and/or to secure at least two tissue portions together.

BACKGROUND

Many different surgical procedures require that an anchor be used to either establish a strong point of connection for other securing elements or devices relative to a tissue location in a patient, and/or to secure two or more tissue layers (i.e., portions together. In this regard, the term "anchor", as used herein, is not to be limited to any particular type of tissue fastening or securement application but, rather, encompasses any hard and/or soft tissue-to-tissue securement, tissue-to-device securement, or any other tissue securement application.

One particular area that has received attention in recent years is that of catheter-based surgical procedures. Various tissue anchors have been developed for purposes of deployment and securement with catheter-based technology. However, there are still limitations in current technology. For example, insertion size versus deployment size must be strictly controlled due to the need for catheter diameters to be maintained relatively small. Many catheter-based tissue anchor systems have very specialized uses and are not versatile for use in many different tissue fastening or securement operations.

There is generally a need for a simpler, more versatile tissue anchor which may be deployed and securely fastened to tissue in a catheter-based operation or a non-catheter-based operation.

SUMMARY

In one aspect, the invention provides a tissue anchor comprising a generally flexible anchor member capable of being inserted through tissue and moving between an elongate configuration and a shortened configuration suitable for anchoring against at least one side of the tissue. The anchor member includes a proximal end portion, a distal end portion, and a compressible intermediate portion between the proximal end portion and the distal end portion. A tensioning member is operatively connected to the anchor member such that the anchor member can slide relative to the tensioning member. The tensioning member may be pulled to cause the anchor member to move relative to the tensioning member from the elongate configuration to the shortened configuration. In the shortened configuration, the compressible intermediate portion of the anchor member can compress or shorten and thereby adjust to the thickness of the tissue between the proximal and distal end portions.

In another aspect of the invention, a tissue anchor is provided comprising a flat, generally flexible anchor member capable of movement between an elongate configuration suitable for deployment and a shortened configuration suitable for anchoring against tissue. A tensioning member is operatively connected to the anchor member such that the anchor member can slide relative to the tensioning member. The tensioning member is capable of being pulled to cause the anchor member to move relative to the tensioning member from the elongate configuration to the shortened configuration.

In a further aspect of the invention, a tissue anchor is provided comprising a flat anchor member formed from a strip of fabric material and capable of movement between an elongate configuration suitable for deployment and a shortened configuration suitable for anchoring against tissue. A tensioning member is operatively connected to the anchor member such that the anchor member can slide relative to the tensioning member. The tensioning member is capable of being pulled to cause the anchor member to move relative to the tensioning member from the elongate configuration to the shortened configuration. A lock member is provided for securing the anchor member in the shortened configuration.

In a further aspect of the invention, a tissue anchor is provided comprising a flat, generally flexible anchor member capable of being inserted through tissue and moving between an elongate configuration suitable for deployment through a catheter and a shortened configuration suitable for anchoring against the tissue. A tensioning member is operatively connected to the anchor member such that the anchor member may slide relative to the tensioning member. The tensioning member is capable of being pulled to cause the anchor member to move relative to the tensioning member from the elongate configuration to the shortened configuration against the tissue.

In another aspect of the invention, a tissue anchor is provided comprising a flat elongate strip formed from a generally flexible material and having proximal and distal end portions. A tensioning member having first and second ends is operatively connected to the elongate strip such that pulling on the first end of the tensioning member causes the proximal and distal end portions of the elongate strip to move toward each other to a shortened configuration suitable for anchoring against the tissue.

In certain aspects, the anchor member is advantageously formed as a flat, generally flexible strip of material, while in other aspects it need not be a flat strip but may have other shapes, such as tubular, that may or may not be capable of assuming a flat shape. Various optional features may be incorporated into any or all of the various embodiments of the tissue anchor. For example, the tissue anchor may be formed from a material selected from at least one of: natural fibers, synthetic fibers, polymers, and metals. Such materials may be absorbable or nonabsorbable, and may be radiopaque or at least partially radiopaque. The tensioning member may further comprise a suture, or any other suitable flexible, semi-rigid or rigid tensioning member. The tensioning member may include a stop member engaged with the anchor member, such as a knot in the tensioning member, or a separate stop member (e.g., a crimp) engageable with the anchor member. The tensioning member may, for example, extend through the anchor member at multiple locations between the proximal end portion and the distal end portion. Such coupling of the tensioning member and the anchor member may be configured in many different manners depending, for example, on the desired configuration of the anchor member upon pulling the tensioning member and

moving the anchor member into the shortened configuration. In one embodiment, at least one fold is formed upon pulling the tensioning member. Multiple folds may be formed in a generally zig-zag or accordion fashion. A lock member may be provided and engageable with the tensioning member to retain the anchor member in the shortened configuration. The tissue anchor may include at least one radiopaque marker on one or both of the anchor member and the tensioning member. For example, a first radiopaque marker may be located near the proximal end portion when the anchor member is in the shortened configuration and a second radiopaque marker may be located near the distal end portion when the anchor member is in the shortened configuration. The distal end portion of the anchor member may include a relatively more rigid tip as compared to the anchor member and having a reduced width as compared to an adjacent portion of the anchor member. The anchor member itself may be designed in any of numerous manners, including designs that have a uniform width along the length thereof, and designs that have a varying width along the length. Other features may be incorporated such as edge portions that are slightly more rigid than a central area of the anchor member. Entire sections of the anchor member may be relatively rigid as compared to fold line portions thereof while still resulting in a generally flexible anchor member. As necessary, hinge portions, such as living hinges, may be designed into the anchor member to allow for folding or other shortening action of the anchor member. While a tensioning member is specifically disclosed herein for activation purposes (that is, activating the anchor member from the elongate configuration to the shortened configuration), the invention in various combinations may utilize other types of activation, such as compressive activation.

Each of the embodiments of the tissue anchor may be part of a catheter-based anchoring system having a delivery catheter and a suitable deploying device associated with the delivery catheter and operable to extend the anchor member from the delivery catheter. The deploying device may further comprise a deploying catheter at least partially containing the anchor member and at least partially contained within the delivery catheter.

The invention further provides for various methods of anchoring tissue as generally described herein. For example, in one aspect a method of anchoring tissue is provided comprising inserting a generally flexible elongate anchor member through the tissue, and pulling a first end of a tensioning member coupled for sliding movement relative to the first anchor member to draw the proximal and distal end portions toward each other and to compress the intermediate portion into the shortened configuration with at least one of the proximal and distal end portions engaged against the tissue.

In another aspect of the invention, a method of tissue anchoring is provided comprising inserting the generally flexible flat elongate strip having proximal and distal end portions through the tissue, and pulling a first end of a tensioning member operatively connected to the strip to draw the proximal and distal end portions of the strip toward each other into the shortened configuration engaged against the tissue.

In another aspect, a method of tissue anchoring is provided comprising inserting the generally flexible flat elongate strip having proximal and distal end portions through the tissue, and pulling a first end of a tensioning member operatively connected to the strip to configure at least a portion of the strip into a shortened configuration engaged against the tissue.

In each of the embodiments engagement of the anchor member against the tissue may be engagement against opposite sides of at least one tissue layer, or engagement against only one side of at least one tissue layer.

Additional features and advantages of the invention will become readily apparent to those of ordinary skill in the art upon review of the following detailed description of the illustrative embodiments taken in conjunction with the accompanying illustrative figures.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a perspective view of a tissue anchor constructed in accordance with a first embodiment of the invention.

FIG. **2**A is a side view of the tissue anchor shown in FIG. **1**, with the tissue anchor deployed through a layer of tissue.

FIG. **2**B is a side view similar to FIG. **2**A, but illustrating the distal portion of the tissue anchor being moved toward the layer of tissue.

FIG. **2**C is a side view similar to FIG. **2**B, but showing the distal portion fully compressed and engaged against the layer of tissue.

FIG. **2**D is a side view similar to FIG. **2**C but illustrating the proximal portion of the tissue anchor being moved toward the layer of tissue.

FIG. **2**E illustrates the proximal and distal portions of the tissue anchor fully compressed against opposite sides of the layer of tissue.

FIG. **2**F is an enlarged cross sectional view illustrating the fully deployed and fastened anchor with a layer of tissue between proximal and distal anchor portions.

FIG. **3** is a side cross sectional view similar to FIG. **2**F, but illustrating the fastening of two layers of tissue between the proximal and distal anchor portions.

FIGS. **4**A-**4**F are perspective views illustrating successive steps in an annuloplasty procedure on the mitral valve of a patient utilizing tissue anchors of the first embodiment.

FIGS. **5**A-**5**E are perspective views illustrating a mitral valve annuloplasty procedure utilizing tissue anchors constructed according to a second embodiment of the invention.

FIG. **6** is a side elevational view illustrating the tissue anchor constructed in accordance with the second embodiment.

FIG. **7** is a front view of the elongate strip portion of the anchor.

FIG. **7**A is a front elevational view similar to FIG. **7**, but illustrating one embodiment of radiopaque markers used on the elongate strip.

FIG. **7**B is a front elevational view of an alternative anchor strip having a varying width along its length.

FIG. **7**C is a side elevational view of another alternative anchor strip utilizing more rigid fold sections separated by living hinges.

FIGS. **8**A-**8**D are respective side views illustrating a sequence of steps used for securing the tissue anchor of the second embodiment to a layer of tissue.

FIG. **8**E is a view similar to FIG. **8**D, but illustrating an alternative tip and tensioning member arrangement.

FIGS. **9**A-**9**C are respective side elevational views illustrating an annuloplasty procedure in which two tissue anchors of the second embodiment are daisy-chained together with a single tensioning member to plicate the tissue between the anchors in a more integrated procedure.

FIGS. **10**A and **10**B are respective side elevational views illustrating the tissue anchor of the second embodiment used to provide an anchor or securement location on only one side of a tissue layer.

DETAILED DESCRIPTION OF ILLUSTRATIVE EMBODIMENTS

Referring first to FIG. **1**, a tissue anchor **10** constructed in accordance with a first embodiment of the invention generally includes a tensioning member **12**, such as a suture, extending through spaced apart points along a flat elongate strip **14** of flexible material, such as a surgical grade fabric. It will be appreciated that the tensioning member **12** may take other forms other than suture material, such as cable or any other small diameter member having a high enough tensile strength for the intended anchoring use. The elongate strip **14** may also take various forms such as woven or nonwoven fabrics, polymers, metals or other suitable materials or combinations of materials. One or more separate pledgets or other securement members (not shown) may be used in conjunction with the elongate strip **14** for added securement and/or concealing the elongate strip **14** and, for example, thereby inhibiting blood clotting within or adjacent to the folds that will be formed in the strip **14**.

A woven or nonwoven material may contain additional materials, such as threads, beads or other elements that cause at least portions of the strip **14** to be radiopaque. Currently, a surgical grade fabric constructed from polyester, such as Dacron®, is contemplated for use in constructing the strip **14**. One of many possible alternative materials for use in constructing strip **14** is polytetrafluoroethylene (PTFE). Tissue anchor **10** may be partly or wholly formed from materials that are absorbed into the patient's tissue over time, depending on the intended use. The edges and/or other portions of the strip **14** may be suitably modified to prevent fraying, such as by being coated with a material that locks the fibers in place, or otherwise modified in a manner that locks the fibers at least at the edges of the strip **14** in place.

The suture **12** may extend from a proximal end portion **14***a* of the fabric strip **14** to a distal end portion **14***b* and then loop back through spaced apart points of the fabric strip **14** to the proximal end portion **14***a* where a knot **16** or other stop member is located for reasons to be described below. As will become apparent, the suture **12** extends through spaced apart locations along the elongate strip **14** such that tensioning of the suture **12** or other tensioning member will cause the elongate strip **14** to form folded portions **14***c* when the tensioning member **12** is placed under tension or pulled. Thus, the elongate strip **14** is activated in this manner between essentially an elongate deployment orientation or configuration, such as shown in FIG. **1**, and a shortened configuration, such as a folded or otherwise shortened configuration having an expanded width in at least one dimension as compared to the elongate deployment configuration. It will be appreciated that the deployment orientation may take on various forms due to the flexible nature of the strip **14**, especially when using a highly flexible fabric or other material. For example, a fabric material or other similarly flexible materials may be folded or otherwise deformed for carrying purposes within a catheter and/or during deployment to a tissue site and then suitably activated at the tissue site.

More specifically referring to FIGS. **2**A-**2**E, the elongate strip **14** and attached suture **12** are initially inserted through at least one tissue layer **20** as generally shown in FIG. **2**A. One end or portion **12***a* of the suture **12** is then pulled and thereby placed under tension. It will be appreciated that, for catheter-based procedures, suture portion **12***a* may extend to a location outside the patient's body for pulling or tensioning, or it may be grasped by a suitable mechanism within the catheter and pulled or tensioned. Pulling suture portion **12***a* may initially draw the distal portion **14***b* of the elongate strip **14** toward the layer of tissue **20** as shown in FIG. **2**B. Once the distal portion **14***b* is compressed against the layer of tissue **20**, the proximal portion **14***a* begins to be drawn and compressed against a proximal side of the tissue **20** as shown in FIGS. **2**C-**2**E. This occurs because end **12***a* of the suture **12** is being pulled downwardly (as viewed for purposes of discussion in FIGS. **2**C-**2**E) and, since the suture **12** is looped in a reverse direction through distal end portion **14***b* of the elongate strip **14**, the knot **16** at the end of the suture **12** moves upwardly and brings the proximal portion **14***a* of the elongate strip **14** with it. In this manner, the proximal portion **14***a* of the elongate strip **14** is being folded and drawn along the suture **12** toward the layer of tissue **20** and then firmly compressed against the proximal side of the layer of tissue **20** as shown in FIG. **2**E. As further shown in FIG. **2**F, a suitable locker element, such as a crimp member **22**, a knot or other element may be used to maintain the suture **12** and elongate strip **14** in the positions shown in FIG. **2**F securely anchoring the proximal and distal portions **14***a*, **14***b* of the elongate strip **14** folded against opposite sides of the tissue **20**.

As further shown in FIG. **3**, the same general procedure may be used to secure two distinct tissue layers **30**, **32** together by initialing extending the elongate strip **14** and tensioning member **12** through at least two layers of tissue **30**, **32**. In this manner, for example, two layers of tissue **30**, **32** may be securely fastened together. This may, for example, involve two entirely different layers and even types of tissue or the same layer of tissue which has been folded over to effectively form two layers (i.e., portions) of tissue.

FIGS. **4**A-**4**E schematically illustrate an annuloplasty procedure performed on a mitral valve **40** of a heart **42** utilizing tissue anchors **10** as described above in regard to the first embodiment. Performance of the annuloplasty procedure may have many variations, but is generally illustrated by the placement of at least two tissue anchors **10** and securement of the two anchors **10** together, such as with one or more tensioning members **12** therebetween. For an additional illustrative description of catheter-based annuloplasty procedures that may utilize any of the tissue anchors within the scope of the present invention, reference may be made to U.S. patent application Ser. No. 10/948,922, filed on Sep. 24, 2004, assigned to the assignee of the present invention, and the disclosure of which is hereby entirely incorporated by reference herein.

As illustrated in FIG. **4**A, a first tissue anchor **10** is deployed through a catheter device **50** which may, for example, have an inner tubular member **52** or deploying catheter received within an outer tubular member **54** or delivery catheter. The tissue anchor **10** and tensioning member **12** are carried within the inner tubular member **52** and are deployed from a distal end **52***a* thereof. To ensure that proper force is applied to penetrate the tissue, tissue anchor **10** may be deployed or extended after the inner tubular member **52** has been inserted through tissue at the annulus **40***a* of the mitral valve **40**. This is best illustrated in FIG. **4**B. The inner tubular member **52** is withdrawn from the annulus tissue **40***a* either before, during or after activation of the distal end portion **14***b* of the elongate strip **14**. As previously described, activating (e.g., compression, folding or otherwise shortening) the elongate strip **14** by pulling the suture **12** causes the distal end portion **14***b* and then proximal end portion **14***a* to be securely compressed and folded against opposite sides of the annulus tissue **40***a*. This procedure is repeated at least one additional time to securely fasten an additional tissue anchor **10** at a location spaced from the

initial location. For example, the initial location may be at location P2 of the mitral valve annulus **40** while the second location may be spaced on either side of location P2. Catheter device **50** may be inserted into the location of annulus **40***a* in various manners, but is shown being inserted downwardly through the aortic valve **53** into the left ventricle **55**, and curving upward toward the mitral valve annulus **40***a*.

In the illustrative example shown in FIG. **4**E, three tissue anchors **10** have been deployed and securely fastened to the annulus tissue **40***a*. As shown in FIG. **4**F a suture locker **56** may then be deployed and used to maintain relative position and, therefore, tension between each of three respective tensioning members or sutures **12** associated with the three tissue anchors **10** after the tissue anchors **10** have been pulled closer to each other thereby plicating the tissue **40***a* between the anchors **10**. This essentially shortens the valve annulus **40***a* and pulls the posterior leaflet **60** toward the anterior leaflet **62** to prevent leakage through the valve **40**, i.e., to achieve better coaptation of the posterior and anterior leaflets **60**, **62** during systole.

FIGS. **5**A-**5**E illustrate a similar annuloplasty procedure on a mitral valve **40** utilizing a second embodiment of a tissue anchor **70** and a modified method of deployment and activation. In general, the differences between anchor **70** and anchor **10** will be described below with the understanding that all other attributes, options and features associated with anchor **70** may be as described above in connection with anchor **10**. As shown in FIG. **5**A, in this embodiment a tensioning member **72** is again used to activate a flexible, elongate flat strip **74** having proximal and distal end portions **74***a*, **74***b*. Strip **74** includes a tip **76** that is formed or otherwise secured on the distal end portion **74***b*. The tensioning member **72** and the tip **76** are arranged such that the tensioning member **72** slides relative to the tip **76**. More particularly, the tensioning member **72** can be threaded through the tip **76**. Tip **76** is made to be relatively rigid as compared to other flexible portions of strip **74** and of smaller diameter than the width of strip **74**. Therefore, tip **76** helps to penetrate the annulus tissue **40***a* as the inner tubular member **52** and the elongate strip **74** are extended through the tissue **40***a*. A wire **73** may be used to push the tip **76** out of the tubular member **52** at the desired time. The tip **76** may protrude slightly from the inner tubular member **52** as the tissue **40***a* is penetrated to assist with piercing the tissue **40***a*. The tip **76** may also assist with forcing distal portion or half **74***b* of strip **74** into a folded or otherwise shortened configuration. To help prevent the distal portion **74***b* of the elongate strip from pulling back through the tissue **40***a* as the inner tubular member **52** is withdrawn from the annulus tissue **40***a*, the free end of the tensioning member **72** is pulled while the inner tubular member **52** is still penetrated through the tissue **40***a* and into the left atrium **80** from the left ventricle **55**. This forms the distal portion **74***b* into a folded or otherwise shortened configuration as shown in FIG. **5**B. The inner tubular member **52** may then be withdrawn without also withdrawing the elongate flexible strip **74** with it, as shown in FIG. **5**C. The proximal portion **74***a* of the elongate strip **74** is then deployed by pulling the inner tubular member **52** further in a proximal direction, and thereby exposing the full length of strip **74**. The tensioning member **72** is pulled or tensioned so as to draw and compress the proximal portion **74***a* of the elongate strip **74** into a folded, shortened condition against an underside of the annulus tissue **40***a* as shown in FIG. **5**D. As with the previously described annuloplasty procedure using the first embodiment of the tissue anchor **10**, this is repeated as many times as necessary to create the necessary number of tissue plications. FIG. **5**E illustrates this by way of an exemplary view of three successive tissue anchor securement locations with tissue anchors **70** that may be drawn together and locked in place to achieve and retain the plications as described in connection with FIG. **4**F. Such plications reduce or close the gap between the posterior and anterior leaflets **60**, **62**. during systole

FIG. **6** is a side elevational view of the tissue anchor **70** as shown and described with respect to the annuloplasty procedure of FIGS. **5**A-**5**E. This embodiment differs from the first embodiment in a number of different manners, in addition to the use of a distal tip **76** for tissue penetration purposes. For example, the elongate strip **74** is somewhat shorter than the elongate strip **14** utilized in the first embodiment. For example, the strip **74** may be about 40 mm long by about 3 mm wide. Of course, any other desired dimensions and shapes may be used depending on application needs. This may be desirable to achieve a lower profile deployed and fastened configuration with fewer folds that may lead to more versatile applications, lower incidents of blood clotting, easier use, etc. In addition, respective proximal and distal radiopaque bands **90**, **92** are secured to the suture **72** at the proximal end portion of the strip **74** and to either the interior or exterior of the distal tip **76**. Under a fluoroscope, these bands or other markers **90**, **92** will indicate to the surgeon that the anchor **70** has been deployed, activated and fully compressed and/or fastened as necessary during the procedure. The tip **76** itself may alternatively be formed from a radiopaque material. In this second embodiment, the knot **94** formed in the suture **72** or other tensioning member is a slip knot through which another portion of the suture **72** slides during activation of the tissue anchor **70**. It will be appreciated that this slip knot **94** may be replaced by another element which serves essentially the same purpose but takes the form, for example, of a small tubular element or other feature similar in function to a slip knot.

As further shown in FIGS. **6** and **7**, the tensioning member or suture **72** can advantageously extend through respective fold portions **74***c* of the elongate strip **74** in essentially an hourglass configuration. Specifically, adjacent portions of the suture **72** located near the proximal and distal end portions **74***a*, **74***b* of the strip **74** are spaced farther apart than the adjacent portions of the suture **72** in the middle of the strip **74**. As further shown in FIG. **7**A, radiopaque markers, such as distinct areas of dots **95**, may be used for enabling the surgeon to visualize the folds of the elongate strip **74** during deployment and securement of the elongate strip **74**. These dots or other radiopaque markers may be printed on the strip **74**. For example, dots **95** or other markers may be formed with a platinum powder base ink or other suitable material that is radiopaque and biologically compatible. This radiopaque material may also add stiffness to the fold sections **74***c* thereby helping to maintain the fold sections **74***c* flat and increasing retention force on the tissue. Meanwhile, the fold lines **74***d* between fold sections **74***c* can remain highly flexible to create tight radius fold lines. As further shown in FIG. **7**, each of the holes **96** that the tensioning member or suture **72** is received through may be marked by circles **98** surrounding each hole **96** or other markers for visualizing purposes during assembly of the tensioning member or suture **72** with the elongate strip **74**. Optionally, holes **96** may be eliminated and the suture **72** may be threaded with a needle through the strip **74**. One could also, for example, choose different sets of holes **96** along strip **74** for receiving the tensioning member or suture **72** thereby changing the width of the folds and/or number of

folds and/or shape of the folds depending on the application needs or desires of the surgeon. The tensioning member or suture **72** may be threaded or otherwise attached along the strip **74** in any number of manners including, for example, x-patterns or other crossing patterns, zig-zag patterns, etc. that may alter the folded or otherwise shortened or compressed footprint of the anchor into various beneficial shapes, such as flower shapes, circular shapes or other rounded shapes, ball shapes or other configurations. Modifications of the manner in which the tensioning member or suture **72** is threaded or otherwise attached along the length of strip **74** may result in higher or lower tensioning force being required to compress the anchor and/or higher or lower friction holding force that may help maintain the anchor in the compressed or shortened configuration. The width of the elongate strip **74'** may be varied along its length, such as by tapering, stepping, or forming an hourglass shape or shapes along the length of the strip **14**. For example, as illustrated in FIG. **7**B, having proximal and distal end portions **75**, **77** of wider dimension than an intermediate or middle portion or portions **79** along the length of strip **74'** will allow these wider portions **75**, **77** may cover over the more intermediate folded portions **79** and prevent unnecessary contact with adjacent tissue during use. It will be appreciated that like reference numerals are used herein to refer to like elements in all embodiments and reference numerals with prime marks (') or double prime marks (") refer to like elements that have been modified in a manner as described herein or otherwise shown in the associated figure. Strip **74** may have variable stiffness including, for example, a relatively rigid perimeter or relatively rigid edges **74***e*, **74***f* (FIG. **7**) or intermittent relatively rigid sections **74***c*" separated by flexible sections such as living hinges **74***d*" (FIG. **7**C) that may aid in folding and securing the elongate strip **74**" into a folded condition.

FIGS. **8**A-**8**D illustrate a series of steps for deploying and securely fastening the tissue anchor **70** of the second embodiment to a layer of tissue **100**. Generally, as shown in FIG. **8**A, the combination of the elongate strip **74** and tensioning member or suture **72** is deployed through the layer of tissue **100**. One end or portion **72***a* of the suture **72** that extends through the slip knot **94** is then pulled. This causes the distal portion **74***b* of the elongate strip **74** to fold and compress against the distal side of the tissue layer **100**. As shown in FIG. **8**B, further pulling of the tensioning member **72** causes the slip knot **94** to ride upwardly or distally along the suture **72** and against a proximal portion **74***a* of the elongate strip **74** thereby folding and compressing the proximal portion **74***a* against the proximal side of the tissue layer **100** as shown in FIG. **8**C. As shown in FIG. **8**D, a suitable crimp or locking element **102** may be used to securely lock the slip knot **94** in place relative to the suture or tensioning member segment which extends therethrough. This will lock the entire anchor **70** in place with the respective proximal and distal folded strip portions **74***a*, **74***b* securely retaining the tissue layer or layers **100** therebetween. FIG. **8**D shows the tip **76** acting as a retainer on top of the distal end portion **74***b* to assist in holding the distal end portion **74***b* in place. FIG. **8**E shows an alternative in which the tensioning member is threaded through at least one hole **76***a* more centrally located in the tip. Yet another alternative would be to thread the tensioning member through two centrally located holes instead of through the proximal end of the tip **76** and one centrally located hole **76***a* as shown in FIG. **8**E. These alternatives allow the tip **76** to act more like a "T"-bar with forces acting in a more perpendicular or normal manner relative to the distal end portion **74***b* of the strip **74**.

FIGS. **9**A-**9**C illustrate another alternative embodiment of a plication procedure, for example, for use during annuloplasty on a mitral valve annulus **40***a*. In this regard, a single tensioning member, such as a suture **103** or other member may be used to deploy, fasten and draw together at least two separate tissue anchors **110**. As shown in FIG. **9**A, first and second tissue anchors **110** may be respectively deployed at spaced apart locations along the mitral valve annulus **40***a*. Each tissue anchor **110** includes an elongate strip **114** of flexible material, such as fabric or other material as described above, as well as a single suture **103** or tensioning member extending through each of the elongate strips **114**. Upon deployment of the two tissue anchors **110** through the tissue layer **40** at spaced apart locations, the free end of the suture **103** or tensioning member is pulled thereby securely fastening the first tissue anchor **110** as shown in FIGS. **9**A and **9**B and subsequently securely fastening the second tissue anchor **110** to the annulus tissue **40***a*. Upon further pulling or tensioning of the suture **103**, the tissue anchors **110** will be drawn together to plicate the tissue **40** therebetween as shown in FIG. **9**C. A crimp or other locker member **116** may then be used to lock in the desired amount of plication by crimping onto the free end of the suture **103** adjacent to the slip knot **94** of the first tissue anchor **110** as shown in FIG. **9**C. The free end of the suture **103** may then be cut to eliminate or reduce the length of the suture tail.

FIGS. **10**A and **10**B illustrate a tissue anchor **70** of the second embodiment, for example, being used to provide an anchor or securement location on only one side of a tissue layer **120**. In this regard, the tissue anchor **70** may be extended entirely through the tissue layer(s) **120**. The free end of the suture or tensioning member **72** is then pulled proximally to compress and fold the elongate strip **74** against the distal side of the tissue layer **120** as shown in FIG. **10**B. It will be appreciated that activation of strip **74** occurs similarly to the other described embodiments, except that the activated portion (that is, the folded or otherwise shortened portion) is located entirely on one side of the tissue layer **120**. As illustrated, the intermediate or middle portion between the proximal and distal end portions of the anchor member shortens to adjust to the amount of tissue contained therebetween (if any) or shortens during the compression process on only one side of the tissue.

While the present invention has been illustrated by a description of various illustrative embodiments and while these embodiments have been described in some detail, it is not the intention of the Applicant to restrict or in any way limit the scope of the appended claims to such detail. Additional advantages and modifications will readily appear to those skilled in the art. The various features of the invention may be used alone or in numerous combinations depending on the needs and preferences of the user.

What is claimed is:

1. A tissue anchoring system, comprising:

a first generally flexible continuous anchor member capable of being inserted through tissue and moving between an elongate configuration and a shortened configuration suitable for anchoring against at least one side of the tissue, said anchor member having a proximal end portion, a distal end portion, and a compressible intermediate portion between said proximal end portion and said distal end portion;

a second generally flexible continuous anchor member capable of being inserted through the tissue and moving

between an elongate configuration and a shortened configuration suitable for anchoring against at least one side of the tissue, said second anchor member having a proximal end portion, a distal end portion, and a compressible intermediate portion between said proximal end portion and said distal end portion;

a first tensioning member extending through the proximal end portion of the first anchor member and travels in a first direction, and to the distal end portion, and extending in an opposite second direction back to the proximal end portion of the first anchor member, wherein said first tensioning member is capable of being pulled to cause the first anchor member to move relative to said first tensioning member from said elongate configuration to said shortened configuration wherein the compressible intermediate portion can compress and thereby adjust to the thickness of the layer of tissue between the proximal and distal end portions; and

a second tensioning member extending through the proximal end portion of the second anchor member and travels in a first direction, and to the distal end portion, and extending in an opposite second direction back to the proximal end portion of the second anchor member, wherein said second tensioning member is capable of being pulled to cause the second member to move relative to said second tensioning member from said elongate configuration to said shortened configuration wherein the compressible intermediate portion can compress and thereby adjust to the thickness of the layer of tissue between the proximal and distal end portions;

wherein said distal end portions of said first and second anchor members each includes a rigid tip, said tips being of reduced widths relative to adjacent portions of said first and second anchor members.

2. The system of claim **1**, wherein at least one of the first tensioning member and the second tensioning member comprises a suture (**103**).

3. The system of claim **1**, further comprising: a lock member (**102**) engageable with at least one of the first and second tensioning members to retain at least one of the first and second anchor members in their respective shortened configurations.

4. The system of claim **1**, further comprising: a delivery catheter (**50**), and a deploying device (**52**) operatively associated with said delivery catheter and operable to extend at least one of the first and second anchor members from said delivery catheter.

5. The system of claim **4**, wherein said deploying device comprises a deploying catheter at least partially containing said anchor member and at least partially contained within said delivery catheter.

6. The system of claim **1**, wherein at least one of the anchor members is formed from a material selected from at least one of: natural fibers, synthetic fibers, polymers, and metals.

7. The system of claim **1**, further comprising a stop member engageable with at least one of said first and second anchor members.

8. The system of claim **1**, wherein said first and second anchor members are configured such that said first and second anchor member each can form at least one fold in said compressible intermediate portion.

9. The system of claim **1**, further comprising at least one radiopaque marker on at least one of said first anchor member, said second anchor member, or a said coupling structure.

10. The system of claim **1**, wherein said tips act as compressive force applying members against the distal end portions of the respective first and second anchor members when the first and second anchor members are in their shortened configurations.

11. The system of claim **1**, wherein the first and second anchors are disposed side-by-side in spaced relationship.

12. The system of claim **1**, wherein one free end of the first tensioning member comprises a stop member disposed at the proximal end portion and an opposite free end of the first tensioning member extends outwardly from the proximal end portion and wherein one free end of the second tensioning member comprises a stop member disposed at the proximal end portion and an opposite free end of the second tensioning member extends outwardly from the proximal end portion.

13. The system of claim **1**, wherein the first tensioning member forms a loop at the distal end portion of the first anchor member and the second tensioning member forms a loop at the distal end portion of the second anchor member.

14. The system of claim **3**, wherein the lock member is configured to engage the first and second tensioning members so as to shorten a distance between the first and second anchor members.

15. A tissue anchoring system, comprising:

a first generally flexible continuous anchor member capable of being inserted through tissue and moving between an elongate configuration and a shortened configuration suitable for anchoring against at least one side of the tissue, said anchor member having a proximal end portion, a distal end portion, and a compressible intermediate portion between said proximal end portion and said distal end portion;

a second generally flexible continuous anchor member capable of being inserted through the tissue and moving between an elongate configuration and a shortened configuration suitable for anchoring against at least one side of the tissue, said second anchor member having a proximal end portion, a distal end portion, and a compressible intermediate portion between said proximal end portion and said distal end portion;

a first tensioning member extending through the proximal end portion of the first anchor member and travels in a first direction, and to the distal end portion, and extending in an opposite second direction back to the proximal end portion of the first anchor member, wherein said first tensioning member is capable of being pulled to cause the first anchor member to move relative to said first tensioning member from said elongate configuration to said shortened configuration wherein the compressible intermediate portion can compress and thereby adjust to the thickness of the layer of tissue between the proximal and distal end portions; and

a second tensioning member extending through the proximal end portion of the second anchor member and travels in a first direction, and to the distal end portion, and extending in an opposite second direction back to the proximal end portion of the second anchor member, wherein said second tensioning member is capable of being pulled to cause the second member to move relative to said second tensioning member from said elongate configuration to said shortened configuration wherein the compressible intermediate portion can compress and thereby adjust to the thickness of the layer of tissue between the proximal and distal end portions;

wherein the distal end portions of each of the first and second anchors are configured to be disposed on one side of the tissue and the proximal end portions of the first and second anchors are disposed on an opposite side of the tissue.

16. A tissue anchoring system, comprising:

a first generally flexible continuous anchor member capable of being inserted through tissue and moving between an elongate configuration and a shortened configuration suitable for anchoring against at least one side of the tissue, said anchor member having a proximal end portion, a distal end portion, and a compressible intermediate portion between said proximal end portion and said distal end portion;

a second generally flexible continuous anchor member capable of being inserted through the tissue and moving between an elongate configuration and a shortened configuration suitable for anchoring against at least one side of the tissue, said second anchor member having a proximal end portion, a distal end portion, and a compressible intermediate portion between said proximal end portion and said distal end portion;

a first tensioning member extending through the proximal end portion of the first anchor member and travels in a first direction, and to the distal end portion, and extending in an opposite second direction back to the proximal end portion of the first anchor member, wherein said first tensioning member is capable of being pulled to cause the first anchor member to move relative to said first tensioning member from said elongate configuration to said shortened configuration wherein the compressible intermediate portion can compress and thereby adjust to the thickness of the layer of tissue between the proximal and distal end portions; and

a second tensioning member extending through the proximal end portion of the second anchor member and travels in a first direction, and to the distal end portion, and extending in an opposite second direction back to the proximal end portion of the second anchor member, wherein said second tensioning member is capable of being pulled to cause the second member to move relative to said second tensioning member from said elongate configuration to said shortened configuration wherein the compressible intermediate portion can compress and thereby adjust to the thickness of the layer of tissue between the proximal and distal end portions;

wherein at least one of the first anchor member and the second anchor member has an hourglass shape.

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