US009486203B2

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

(10) **Patent No.: US 9,486,203 B2**
(45) **Date of Patent: Nov. 8, 2016**

(54) **LATCHING ANCHOR DEVICE**

(71) Applicant: **NeoTract, Inc.**, Pleasanton, CA (US)

(72) Inventors: **Andrew Johnston**, Redwood City, CA (US); **Michael Wei**, Redwood City, CA (US); **Theodore C. Lamson**, Pleasanton, CA (US); **Matthew McLean**, San Francisco, CA (US); **Joseph Catanese, III**, San Leandro, CA (US); **Floria Cheng**, San Francisco, CA (US); **Ryan R. Braymer**, Clifton Park, NY (US); **Eric J. Claude**, Vienna, VA (US); **Christian L. Haller**, Alexandria, VA (US); **Ralph S. Paul**, Alexandria, VA (US); **Ashley K. Wallin**, Marietta, GA (US)

(73) Assignee: **NeoTract, Inc.**, Pleasanton, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 31 days.

(21) Appl. No.: **14/145,821**

(22) Filed: **Dec. 31, 2013**

(65) **Prior Publication Data**

US 2014/0236230 A1 Aug. 21, 2014

Related U.S. Application Data

(60) Division of application No. 12/852,939, filed on Aug. 9, 2010, now Pat. No. 8,668,705, which is a continuation-in-part of application No. 12/852,243, filed on Aug. 6, 2010, now Pat. No. 8,333,776, and a

(Continued)

(51) **Int. Cl.**

A61B 17/08	(2006.01)
A61B 17/04	(2006.01)

(Continued)

(52) **U.S. Cl.**

CPC ***A61B 17/0401*** (2013.01); *A61B 17/0218* (2013.01); *A61B 2017/00867* (2013.01); *A61B 2017/042* (2013.01); *A61B 2017/0454* (2013.01)

(58) **Field of Classification Search**

CPC A61B 17/0401; A61B 17/0469; A61B 2017/00274; A61B 2017/0417; A61B 2017/0419; A61B 2017/0464; A61B 2018/00547; A61F 2/04

See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

659,422 A 10/1900 Shidler
780,392 A 1/1905 Wanamaker

(Continued)

FOREIGN PATENT DOCUMENTS

DE 10159470 A1 6/2003
EP 0246836 12/1991

(Continued)

OTHER PUBLICATIONS

Bachavora, O.A., "The Effect of Rhodiolae Rosea Extract on Incidence Rate of Superficial Bladder Carcinoma Relapses", Kozin, (1995), 3 pgs.

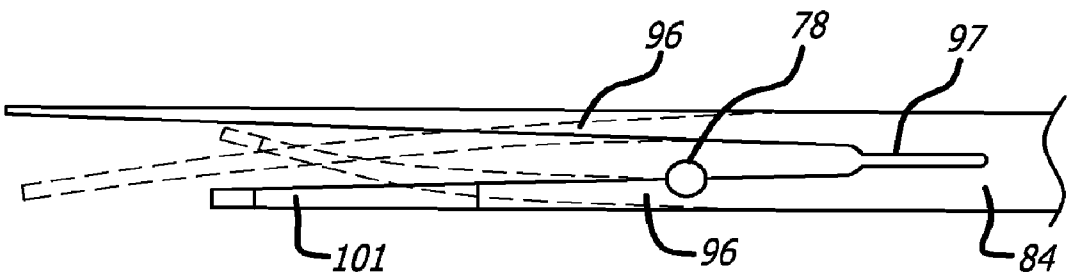
(Continued)

Primary Examiner — Gregory Anderson

(57) **ABSTRACT**

An anchor that secures to a connector as part of an anchor assembly is disclosed. The proximal anchor includes a pair of spaced apart prongs which join together at a slot inception. The prongs are shaped and sized of a configuration to define a catch or latching structure. The prongs are configured to capture and deform the suture between the protrusions and prevent the suture from disengaging from the slotted anchor device once engaged.

10 Claims, 10 Drawing Sheets



Related U.S. Application Data

continuation-in-part of application No. 12/512,674, filed on Jul. 30, 2009, now Pat. No. 8,216,254, said application No. 12/852,939 is a continuation-in-part of application No. 11/775,162, filed on Jul. 9, 2007, now Pat. No. 8,945,152, and a continuation-in-part of application No. 11/671,914, filed on Feb. 6, 2007, now Pat. No. 8,157,815, and a continuation-in-part of application No. 11/492,690, filed on Jul. 24, 2006, now Pat. No. 7,896,891, and a continuation-in-part of application No. 11/833,660, filed on Aug. 3, 2007, now Pat. No. 8,940,001, which is a continuation of application No. 11/318,246, filed on Dec. 22, 2005, now Pat. No. 7,645,286, said application No. 12/852,939 is a continuation-in-part of application No. 11/838,036, filed on Aug. 13, 2007, now Pat. No. 7,914,542, which is a continuation of application No. 11/134,870, filed on May 20, 2005, now Pat. No. 7,758,594.

(60) Provisional application No. 61/084,937, filed on Jul. 30, 2008.

(51) **Int. Cl.**

A61B 17/02	(2006.01)
A61B 17/00	(2006.01)

(56) **References Cited**

U.S. PATENT DOCUMENTS

2,579,192	A		12/1951	Kohl
2,646,298	A		7/1953	Leary
2,697,624	A		12/1954	Thomas
2,734,299	A		2/1956	Masson
2,825,592	A		3/1958	Mckenzie
3,326,586	A		6/1967	Frost
3,470,834	A		10/1969	Bone
3,521,918	A		7/1970	Hammond
3,713,680	A		1/1973	Pagano
3,716,058	A		2/1973	Tanner
3,756,638	A		9/1973	Stockberger
3,873,140	A		3/1975	Bloch
3,875,648	A		4/1975	Bone
3,931,667	A		1/1976	Merser
3,976,079	A		8/1976	Samuels
4,006,747	A		2/1977	Kronenthal
4,210,148	A		7/1980	Stivala
4,235,238	A		11/1980	Ogiu
4,291,698	A		9/1981	Fuchs
4,409,974	A		10/1983	Freedland
4,493,323	A		1/1985	Albright
4,513,746	A		4/1985	Aranyi
4,621,640	A		11/1986	Mulhollan
4,657,461	A		4/1987	Smith
4,669,473	A		6/1987	Richards
4,705,040	A		11/1987	Mueller
4,714,281	A		12/1987	Peck
4,738,255	A		4/1988	Goble
4,741,330	A		5/1988	Hayhurst
4,744,364	A		5/1988	Kensey
4,750,492	A		6/1988	Jacobs
4,762,128	A		8/1988	Rosenbluth
4,823,794	A		4/1989	Pierce
4,899,743	A		2/1990	Nicholson
4,926,860	A		5/1990	Stice
4,946,468	A		8/1990	Li
4,955,913	A		9/1990	Robinson
4,968,315	A		11/1990	Gatturna
5,002,550	A		3/1991	Li
5,041,129	A		8/1991	Hayhurst
5,046,513	A	*	9/1991	Gatturna et al. 128/898
5,053,046	A		10/1991	Janese
5,078,731	A		1/1992	Hayhurst
5,100,421	A		3/1992	Christoudias
5,123,914	A		6/1992	Cope
5,129,912	A		7/1992	Noda
5,160,339	A	*	11/1992	Chen et al. 606/158
5,192,303	A		3/1993	Gatturna
5,203,787	A		4/1993	Noblitt
5,217,470	A		6/1993	Weston
5,217,486	A		6/1993	Rice
5,234,454	A		8/1993	Bangs
5,236,445	A		8/1993	Hayhurst
5,258,015	A		11/1993	Li
5,269,809	A		12/1993	Hayhurst
5,330,488	A		7/1994	Goldrath
5,334,200	A		8/1994	Johnson
5,336,240	A		8/1994	Metzler
5,354,271	A		10/1994	Voda
5,358,511	A		10/1994	Gatturna
5,364,408	A		11/1994	Gordon
5,366,490	A		11/1994	Edwards
5,368,599	A		11/1994	Hirsch
5,370,646	A		12/1994	Reese
5,380,334	A		1/1995	Torrie
5,391,182	A		2/1995	Chin
5,403,348	A		4/1995	Bonutti
5,405,352	A		4/1995	Weston
5,411,520	A		5/1995	Nash
5,417,691	A		5/1995	Hayhurst
5,435,805	A		7/1995	Edwards
5,470,337	A		11/1995	Moss
5,472,446	A		12/1995	de la Torre
5,480,406	A		1/1996	Nolan
5,501,690	A		3/1996	Measamer
5,507,754	A		4/1996	Green
5,522,846	A		6/1996	Bonutti
5,531,763	A		7/1996	Mastri
5,536,240	A		7/1996	Edwards
5,540,704	A		7/1996	Gordon
5,545,171	A		8/1996	Sharkey
5,545,178	A		8/1996	Kensey
5,550,172	A		8/1996	Regula
5,554,162	A		9/1996	DeLange
5,554,171	A		9/1996	Gatturna
5,562,689	A		10/1996	Green
5,569,305	A		10/1996	Bonutti
5,571,104	A		11/1996	Li
5,573,540	A		11/1996	Yoon
5,578,044	A		11/1996	Gordon
5,591,177	A		1/1997	Lehrer
5,593,421	A		1/1997	Bauer
5,611,515	A		3/1997	Benderev
5,626,614	A		5/1997	Hart
5,630,824	A		5/1997	Hart
5,800,445	A		9/1998	Ratcliff
5,807,403	A		9/1998	Beyar
5,810,848	A		9/1998	Hayhurst
5,810,853	A		9/1998	Yoon
5,814,072	A		9/1998	Bonutti
5,830,221	A		11/1998	Stein
5,845,645	A		12/1998	Bonutti
5,846,254	A		12/1998	Schulze
5,861,002	A		1/1999	Desai
5,868,762	A		2/1999	Cragg
5,873,891	A		2/1999	Sohn
5,897,574	A		4/1999	Bonutti
5,899,911	A		5/1999	Carter
5,899,921	A		5/1999	Caspari
5,904,696	A		5/1999	Rosenman
5,908,428	A		6/1999	Scirica
5,919,198	A		7/1999	Graves
5,919,202	A		7/1999	Yoon
5,921,986	A		7/1999	Bonutti
5,928,252	A		7/1999	Steadman
5,931,844	A		8/1999	Thompson
5,944,739	A		8/1999	Zlock
5,948,001	A		9/1999	Larsen
5,948,002	A		9/1999	Bonutti
5,954,057	A		9/1999	Li
5,954,747	A		9/1999	Clark

(56) **References Cited**

U.S. PATENT DOCUMENTS

5,964,732	A	10/1999	Willard
5,971,447	A	10/1999	Steck
6,010,514	A	1/2000	Burney
6,011,525	A	1/2000	Piole
6,030,393	A	2/2000	Corlew
6,033,430	A	3/2000	Bonutti
6,036,701	A	3/2000	Rosenman
6,048,351	A	4/2000	Gordon
6,053,908	A	4/2000	Crainich
6,056,722	A	5/2000	Jayaraman
6,056,772	A	5/2000	Bonutti
6,068,648	A	5/2000	Cole
6,080,167	A	6/2000	Lyell
6,086,608	A	7/2000	Ek
6,110,183	A	8/2000	Cope
6,117,160	A	9/2000	Bonutti
6,117,161	A	9/2000	Li
6,120,539	A	9/2000	Eldridge
6,139,555	A	10/2000	Hart
RE36,974	E	11/2000	Bonutti
6,143,006	A	11/2000	Chan
6,159,234	A	12/2000	Bonutti
6,200,329	B1	3/2001	Fung
6,206,895	B1	3/2001	Levinson
6,228,096	B1	5/2001	Marchand
6,258,124	B1	7/2001	Darois
6,261,302	B1	7/2001	Voegele
6,270,530	B1	8/2001	Eldridge
6,280,460	B1	8/2001	Bolduc
6,290,711	B1	9/2001	Caspari
6,312,448	B1	11/2001	Bonutti
6,319,263	B1	11/2001	Levinson
6,322,112	B1	11/2001	Duncan
6,332,889	B1	12/2001	Sancoff
6,398,795	B1	6/2002	McAlister
6,425,900	B1	7/2002	Knodel
6,428,562	B2	8/2002	Bonutti
6,436,107	B1	8/2002	Wang
6,461,355	B2	10/2002	Svejkovsky
6,482,235	B1	11/2002	Lambrecht
6,488,691	B1	12/2002	Carroll
6,491,707	B2	12/2002	Makower
6,494,888	B1	12/2002	Laufer
6,500,195	B2	12/2002	Bonutti
6,506,190	B1	1/2003	Walshe
6,506,196	B1	1/2003	Laufer
6,517,569	B2	2/2003	Mikus
6,527,702	B2	3/2003	Whalen
6,527,794	B1	3/2003	McDevitt
6,530,932	B1	3/2003	Swayze
6,533,796	B1	3/2003	Sauer
6,547,725	B1	4/2003	Paolitto
6,551,328	B2	4/2003	Kortenbach
6,551,333	B2	4/2003	Kuhns
6,565,578	B1	5/2003	Peifer
6,569,187	B1	5/2003	Bonutti
6,572,626	B1	6/2003	Knodel
6,572,635	B1	6/2003	Bonutti
6,572,653	B1	6/2003	Simonson
6,592,609	B1	7/2003	Bonutti
6,596,013	B2	7/2003	Yang
6,599,311	B1	7/2003	Biggs
6,626,913	B1	9/2003	McKinnon
6,626,916	B1	9/2003	Yeung
6,626,919	B1	9/2003	Swanstrom
6,629,534	B1	10/2003	St. Goar
6,641,592	B1	11/2003	Sauer
6,656,182	B1	12/2003	Hayhurst
6,660,023	B2	12/2003	McDevitt
6,663,589	B1	12/2003	Halevy
6,663,639	B1	12/2003	Laufer
6,699,263	B2	3/2004	Cope
6,706,047	B2	3/2004	Tanner
6,709,493	B2	3/2004	DeGuiseppi
6,715,804	B2	4/2004	Beers
6,719,709	B2	4/2004	Whalen
6,730,112	B2	5/2004	Levinson
6,736,823	B2	5/2004	Darois
6,736,854	B2	5/2004	Vadurro
6,740,098	B2	5/2004	Abrams
6,767,037	B2	7/2004	Wenstrom
6,770,076	B2	8/2004	Foerster
6,773,438	B1	8/2004	Knodel
6,773,441	B1	8/2004	Laufer
6,790,213	B2	9/2004	Cherok
6,802,846	B2	10/2004	Hauschild
6,821,282	B2	11/2004	Perry
6,821,285	B2	11/2004	Laufer
6,821,291	B2	11/2004	Bolea
6,835,200	B2	12/2004	Laufer
6,905,475	B2	6/2005	Hauschild
6,908,473	B2	6/2005	Skiba
6,926,732	B2	8/2005	Derus
6,951,565	B2	10/2005	Keane
6,986,775	B2	1/2006	Morales
6,991,596	B2	1/2006	Whalen
6,991,647	B2	1/2006	Jadhav
6,997,940	B2	2/2006	Bonutti
7,001,327	B2	2/2006	Whalen
7,011,688	B2	3/2006	Gryska
7,015,253	B2	3/2006	Escandon
7,048,698	B2	5/2006	Whalen
7,048,747	B2	5/2006	Arcia
7,060,077	B2	6/2006	Gordon
7,081,126	B2	7/2006	McDevitt
7,083,638	B2	8/2006	Foerster
7,087,073	B2	8/2006	Bonutti
7,089,064	B2	8/2006	Manker
7,090,690	B2	8/2006	Foerster
7,093,601	B2	8/2006	Manker
7,105,004	B2	9/2006	DiCesare
7,108,655	B2	9/2006	Whalen
7,141,038	B2	11/2006	Whalen
7,153,314	B2	12/2006	Laufer
7,179,225	B2	2/2007	Shluzas
7,226,558	B2	6/2007	Nieman
7,232,448	B2	6/2007	Battles
7,288,063	B2	10/2007	Petros
7,303,108	B2	12/2007	Shelton
7,320,701	B2	1/2008	Haut
7,322,974	B2	1/2008	Swoyer
7,334,822	B1	2/2008	Hines
7,340,300	B2	3/2008	Christopherson
7,399,304	B2	7/2008	Gambale
7,402,166	B2	7/2008	Feigl
7,416,554	B2	8/2008	Lam
7,553,317	B2	6/2009	Weisenburgh
7,608,108	B2	10/2009	Bhatnagar
7,658,311	B2	2/2010	Boudreaux
7,674,275	B2	3/2010	Martin
7,727,248	B2	6/2010	Smith
2001/0044639	A1	11/2001	Levinson
2002/0095154	A1	7/2002	Atkinson
2002/0128684	A1	9/2002	Foerster
2002/0161382	A1	10/2002	Neisz
2002/0193809	A1	12/2002	Meade
2003/0109769	A1	6/2003	Lowery
2003/0191497	A1	10/2003	Cope
2003/0204195	A1	10/2003	Keane
2004/0030217	A1	2/2004	Yeung
2004/0043052	A1	3/2004	Hunter
2004/0078046	A1	4/2004	Barzell
2004/0193191	A1	9/2004	Starksen
2004/0193194	A1	9/2004	Laufer
2004/0194790	A1	10/2004	Laufer
2004/0243178	A1	12/2004	Haut
2004/0243179	A1	12/2004	Foerster
2004/0243180	A1	12/2004	Donnelly
2004/0243227	A1	12/2004	Starksen
2004/0260345	A1	12/2004	Foerster
2005/0055087	A1	3/2005	Starksen
2005/0065550	A1	3/2005	Starksen
2005/0107811	A1	5/2005	Starksen
2005/0107812	A1	5/2005	Starksen

(56) **References Cited**

U.S. PATENT DOCUMENTS

2005/0154401	A1	7/2005	Weldon
2005/0177181	A1	8/2005	Kagan
2005/0203344	A1	9/2005	Orban
2005/0203550	A1	9/2005	Laufer
2005/0216078	A1	9/2005	Starksen
2005/0267405	A1	12/2005	Shah
2005/0273138	A1	12/2005	To
2006/0025750	A1	2/2006	Starksen
2006/0025784	A1	2/2006	Starksen
2006/0025789	A1	2/2006	Laufer
2006/0025819	A1	2/2006	Nobis
2006/0026750	A1	2/2006	Ballance
2006/0030884	A1	2/2006	Yeung
2006/0058817	A1	3/2006	Starksen
2006/0089646	A1	4/2006	Bonutti
2006/0167477	A1	7/2006	Arcia
2006/0265042	A1	11/2006	Catanese
2006/0282081	A1	12/2006	Fanton
2007/0049929	A1	3/2007	Catanese
2007/0049970	A1	3/2007	Belef
2007/0060931	A1	3/2007	Hamilton
2007/0088362	A1	4/2007	Bonutti
2007/0112385	A1	5/2007	Conlon
2007/0142846	A1	6/2007	Catanese
2007/0173888	A1	7/2007	Gertner
2007/0260259	A1	11/2007	Fanton
2008/0009888	A1	1/2008	Ewers
2008/0021445	A1	1/2008	Elmouelhi
2008/0033488	A1	2/2008	Catanese
2008/0039894	A1	2/2008	Catanese
2008/0045978	A1	2/2008	Kuhns
2008/0058710	A1	3/2008	Wilk
2008/0065120	A1	3/2008	Zannis
2008/0082113	A1	4/2008	Bishop
2008/0086172	A1	4/2008	Martin
2008/0091220	A1	4/2008	Chu
2008/0091237	A1	4/2008	Schwartz
2008/0119874	A1	5/2008	Merves
2008/0154378	A1	6/2008	Pelo
2008/0195145	A1	8/2008	Bonutti
2008/0208220	A1	8/2008	Shiono
2009/0012537	A1	1/2009	Green
2010/0010631	A1	1/2010	Otte
2010/0114162	A1	5/2010	Bojarski
2010/0286106	A1	11/2010	Gat
2010/0286679	A1	11/2010	Hoey

FOREIGN PATENT DOCUMENTS

EP	0632999	A1	1/1995
EP	0464480		3/1995
EP	1082941		3/2005
EP	1016377		4/2006
EP	1006909		1/2007
EP	1852071	A2	11/2007
EP	1670361		4/2008
EP	1331886		12/2008
EP	1884198		3/2010
EP	1884199		1/2011
FR	2750031	A1	12/1997
JP	5836559	A	3/1983
JP	09122134	A	5/1997
JP	2004344427	A	12/2004
RU	2112571	C1	6/1998
RU	2128012	C1	3/1999
RU	2221501	C2	1/2004
SU	825094	A1	4/1981
SU	2062121	C1	10/1989
WO	WO-9210142		6/1992
WO	WO-9304727		3/1993
WO	WO-9315664		8/1993
WO	WO-0230335		4/2002
WO	WO-03039334		5/2003
WO	WO-03077772		9/2003
WO	WO-2004017845		3/2004
WO	WO-2004019787		3/2004
WO	WO-2004030569		4/2004
WO	WO-2004103189		12/2004
WO	WO-2007053516		5/2007
WO	WO-2007064906		6/2007
WO	WO-2008006084		1/2008
WO	WO-2008043044		4/2008
WO	WO-2008043917		4/2008
WO	WO-2009009617		1/2009
WO	WO-2010011832		1/2010

OTHER PUBLICATIONS

Berges, Richard, "Alternative Minimalinvasive Therapien Beim Benignen Prostatasyndrom", medizin, Jg, 104 heft 37, (Sep. 2007), 12 pgs.

Borzhievski, "Tactics of the Surgical Treatment of Patients With Prostatic Adenoma and Acute Urinary Retention", Urologia Nefrol (Mosk), (1), (Jan.-Feb. 1987), 39-43.

Hartung, Rudolf, "Instrumentelle Therapie der benegnen Prostatahyperplasie", Medizin, Deutsches Arzteblatt 97, Heft 15, (Apr. 2000), 8 pgs.

Hofner, Klaus, "Operative Therapie des benignen Prostatasyndroms", Medizin, Dtsch Arztebl, 194(36), (2007), 6 pgs.

Hubmann, R, "Geschichte der transurethralen Prostataeingriffe", Geschichte der Medizin, Urologe (B), 40, (2000), 152-160.

Jonas, U, "Benigne Prostatahyperplasie", Der Urologe, 45, (2006), 134-144.

Kruck, S, "Aktuelle Therapiemoglichkeiten des Benignen Prostata-Syndroms", J Urol Urogynakol 209,16 (1), 19-22.

Miyake, Osamu, "Medical Examination and Treatment For BPH", Pharma Med, vol. 22, No. 3, (2004), 97-103.

Reich, O, "Benignes Prostatasyndrom (BPS)", Der Urologe, A Issue, vol. 45, No. 6, (Jun. 2006), 769-782.

Schauer, P, "New applications for endoscopy: the emerging field of endoluminal and transgastric bariatric surgery", Surgical Endoscopy, (Apr. 24, 2006), 10 pgs.

Sharp, Howard T, "Instruments and Methods—The 4-S Modification of the Roeder Knot: How to Tie It", Obstetrics & Gynecology, vol. 90, No. 6, (Dec. 1997), 1004-1006.

Takashi, Daito, "Low-Invasive Treatment for BPH", Medico vol. 34, No. 10, 366-369.

Teruhisa, Osamu, "Urinary Dysfunction by Lower Urinary Tract Obstraction in Male", Pharma Medica, vol. 8, No. 8, 35-39.

Tomohiko, Koyanagi, "Surgery View of 21st Century", Urological Surgery, vol. 84, No. 1, 47-53.

Trapeznikov, "New Technologies in the Treatment of Benign Prostatic Hyperplasia", Urologia Nefrol(Mosk), (4), (Jul.-Aug. 1996), 41-47.

Yeung, Jeff, "Treating Urinary Stress Incontinence Without Incision with Endoscopic Suture Anchor & Approximating Device", Aleeva Medical, Inc, (2007), 31 pgs.

* cited by examiner

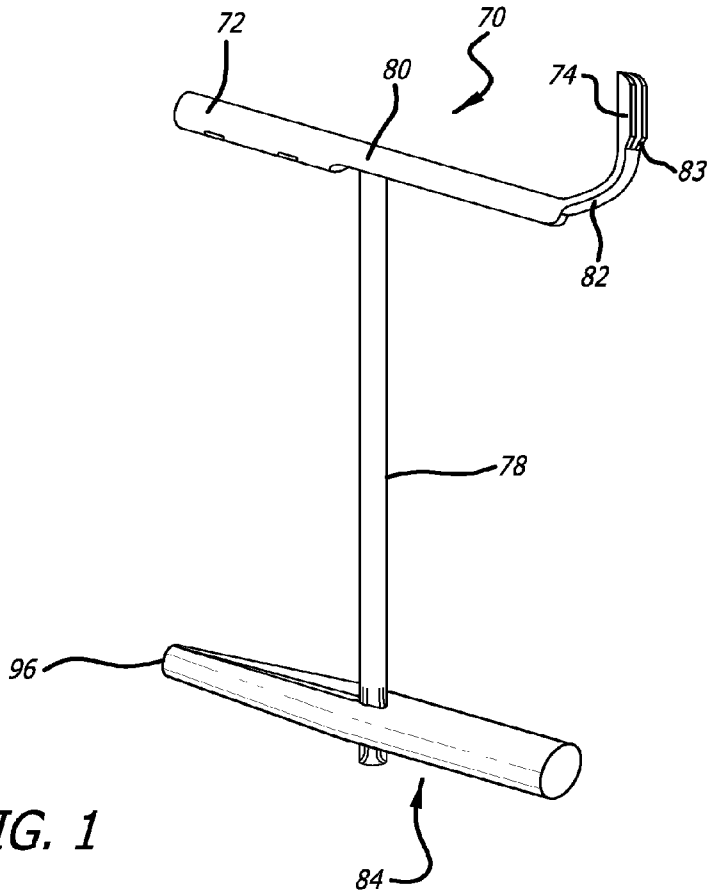


FIG. 1

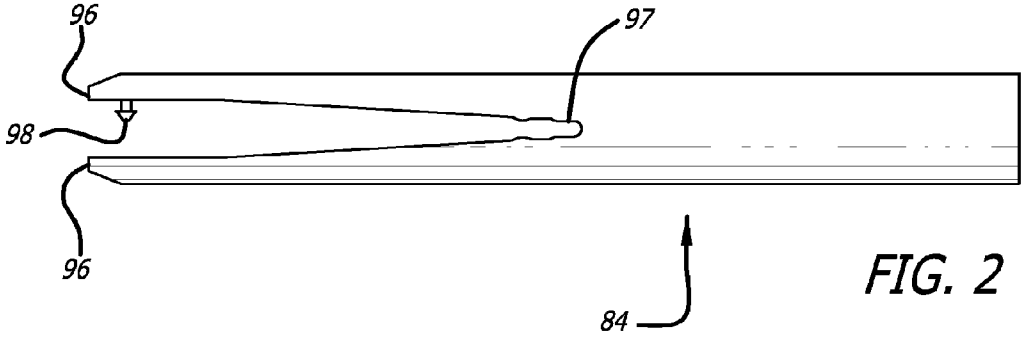


FIG. 2

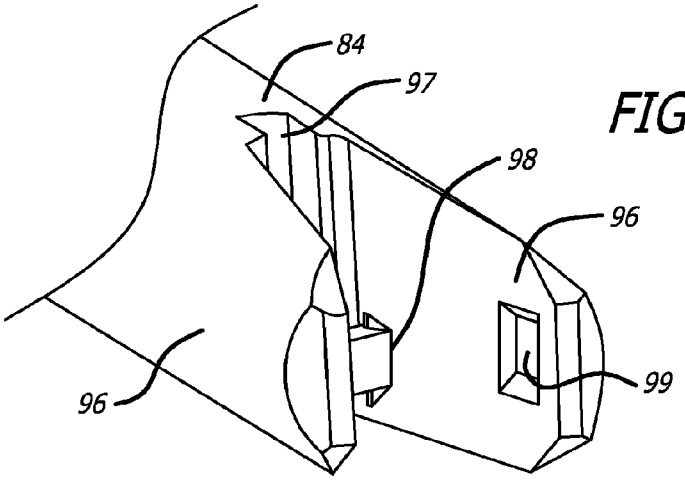


FIG. 3

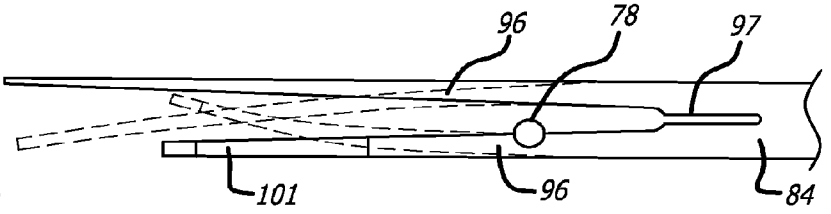


FIG. 4

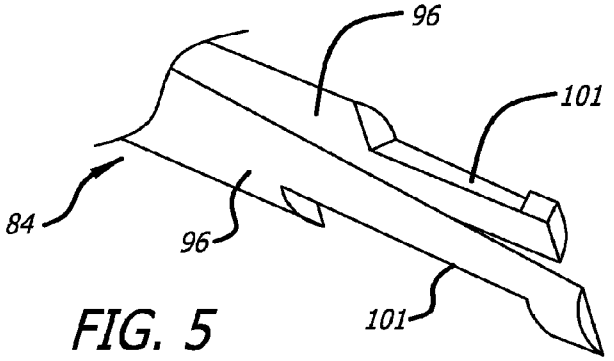


FIG. 5

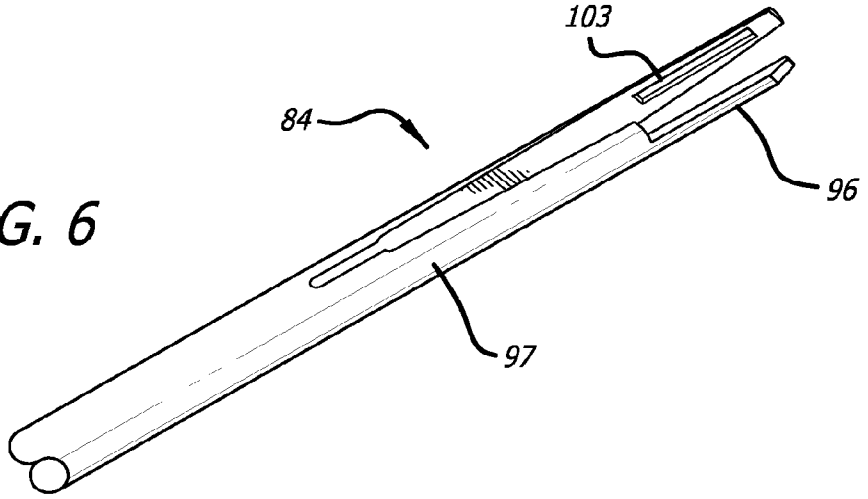


FIG. 6

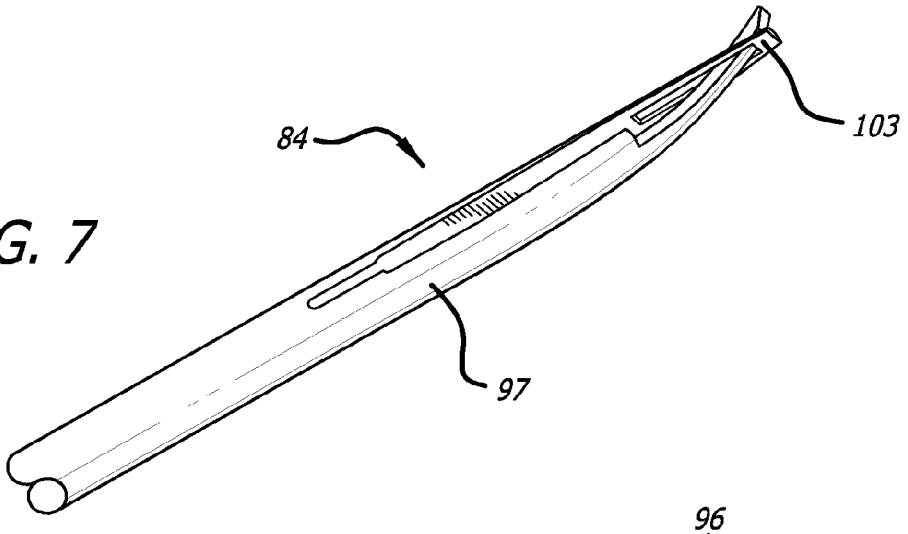


FIG. 7

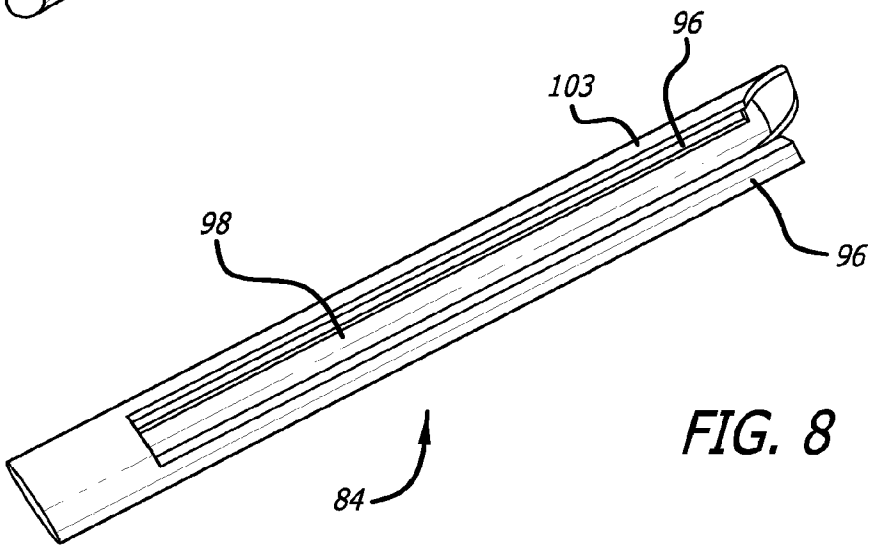
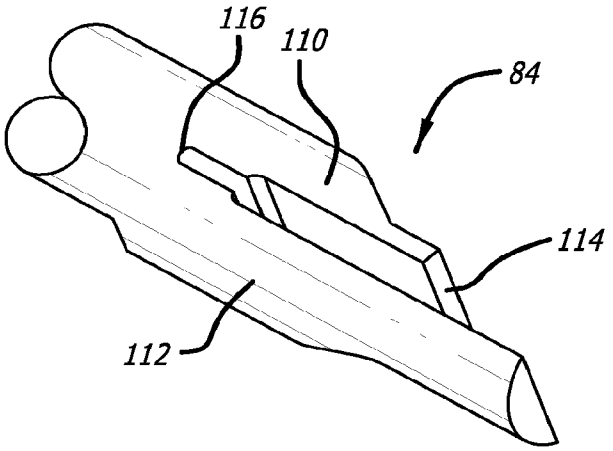


FIG. 8

FIG. 9A



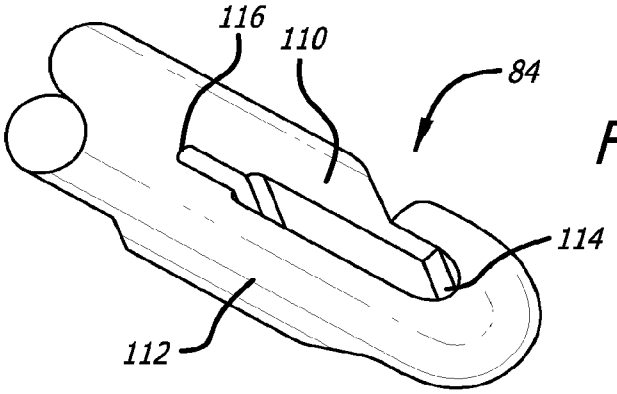


FIG. 9B

FIG. 10A

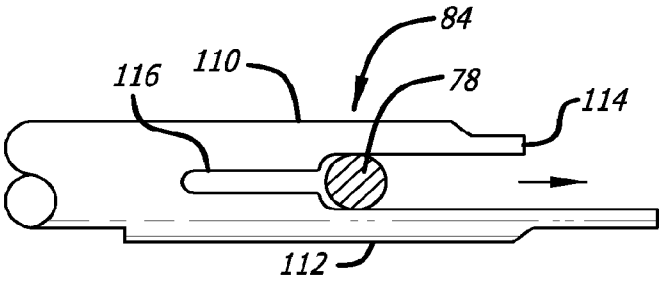
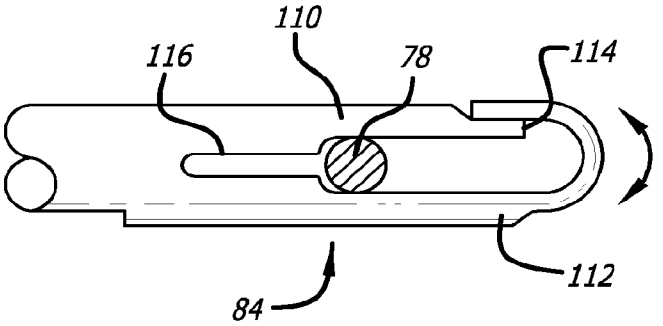


FIG. 10B



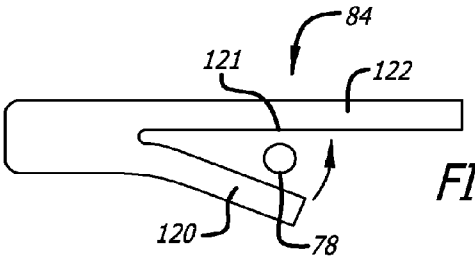


FIG. 11A

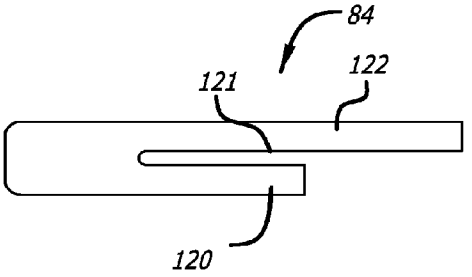


FIG. 11B

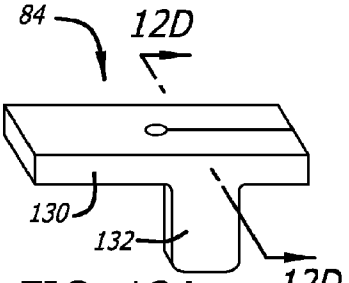


FIG. 12A

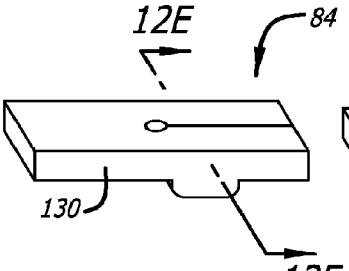


FIG. 12B

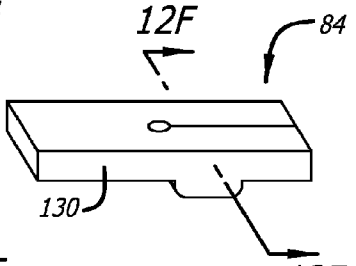


FIG. 12C

FIG. 12D

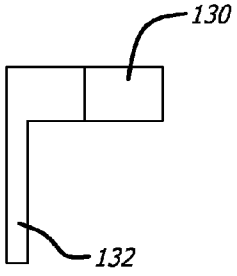


FIG. 12E

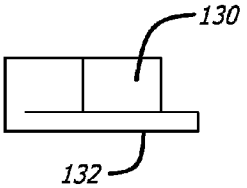
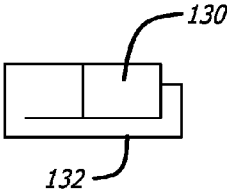


FIG. 12F



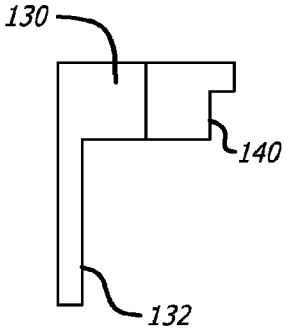


FIG. 13A

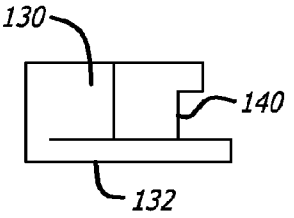


FIG. 13B

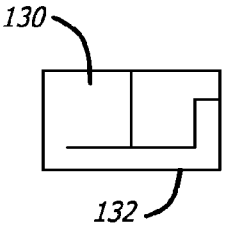


FIG. 13C

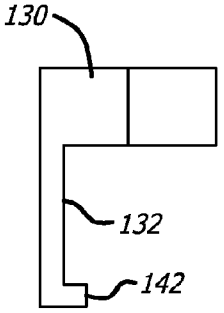


FIG. 14A

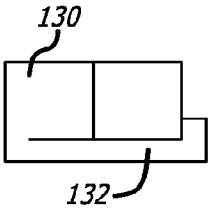


FIG. 14B

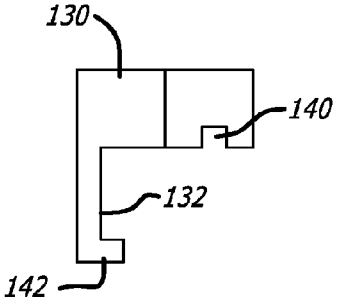


FIG. 15A

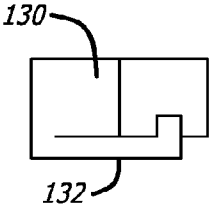


FIG. 15B

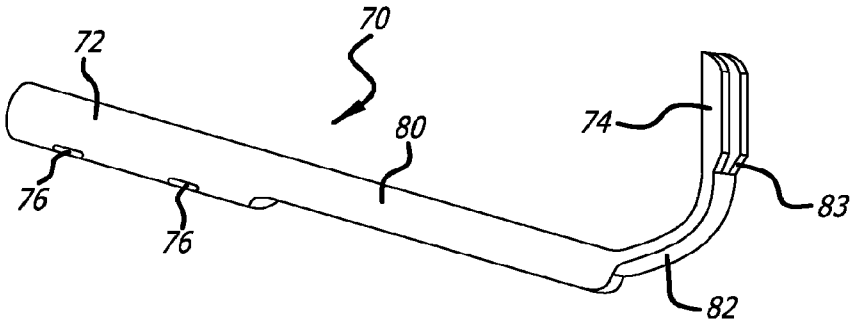


FIG. 16

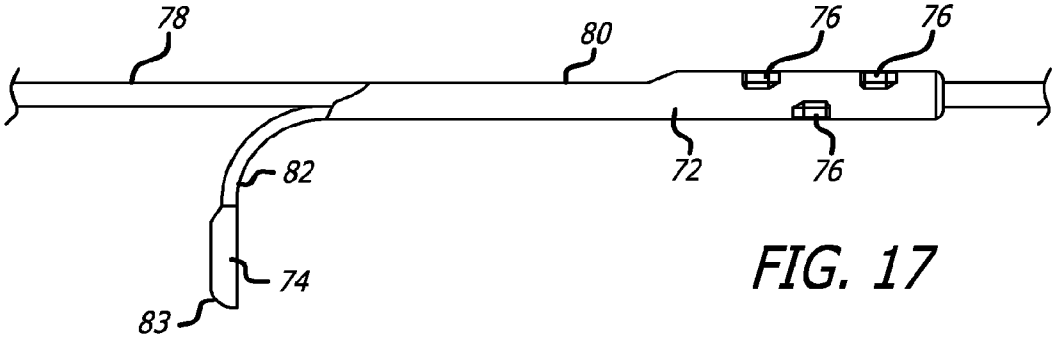
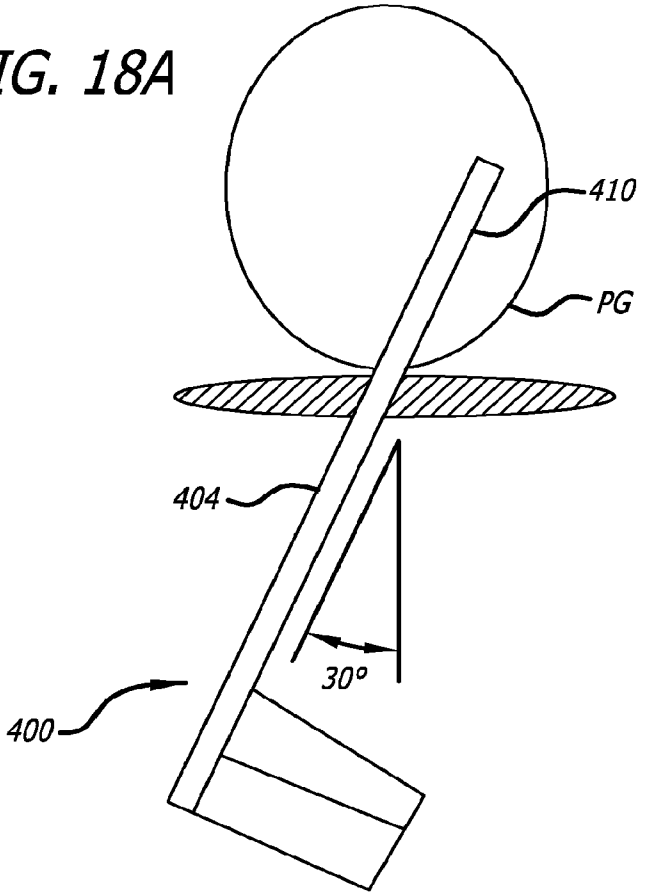


FIG. 17

FIG. 18A



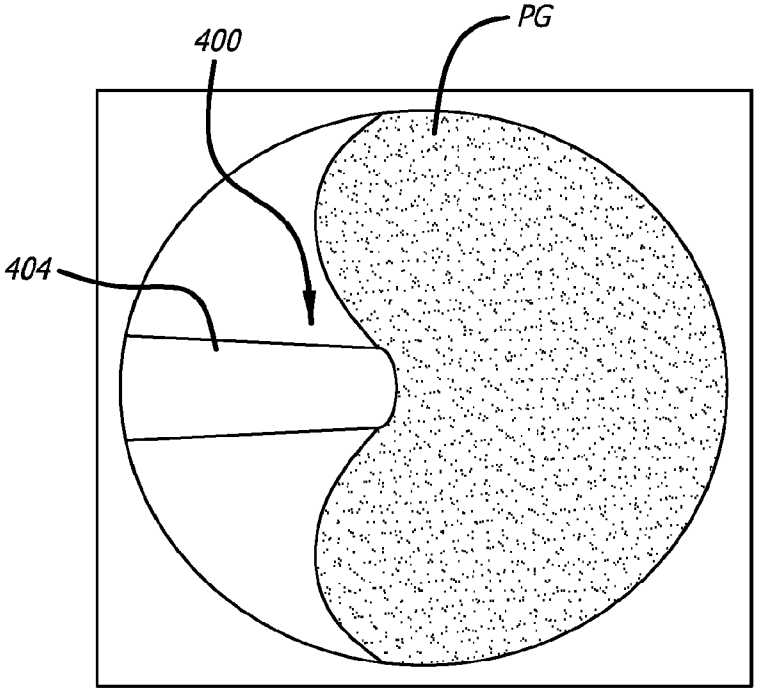


FIG. 18B

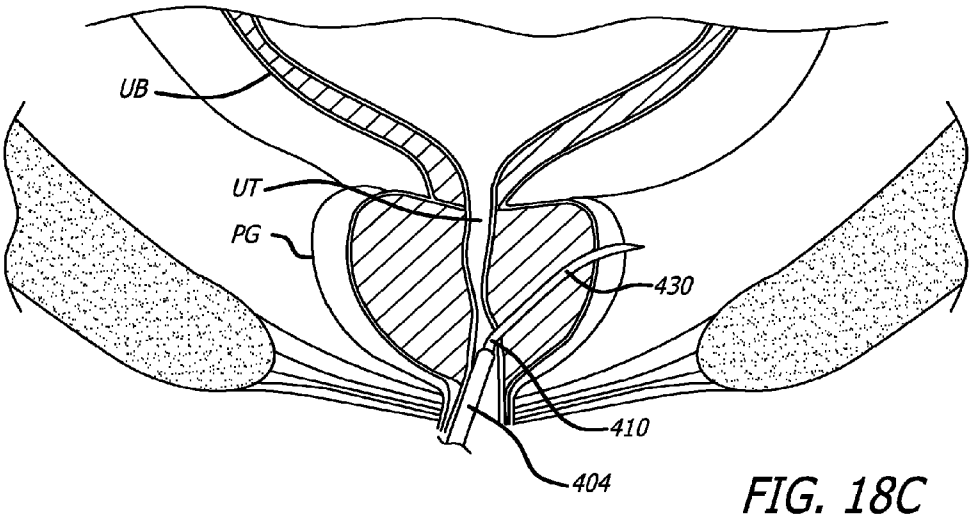


FIG. 18C

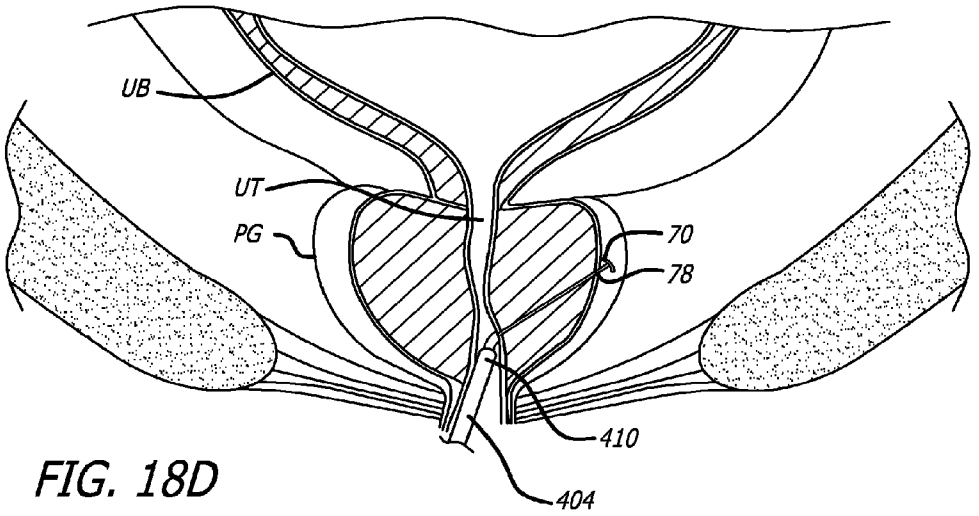


FIG. 18D

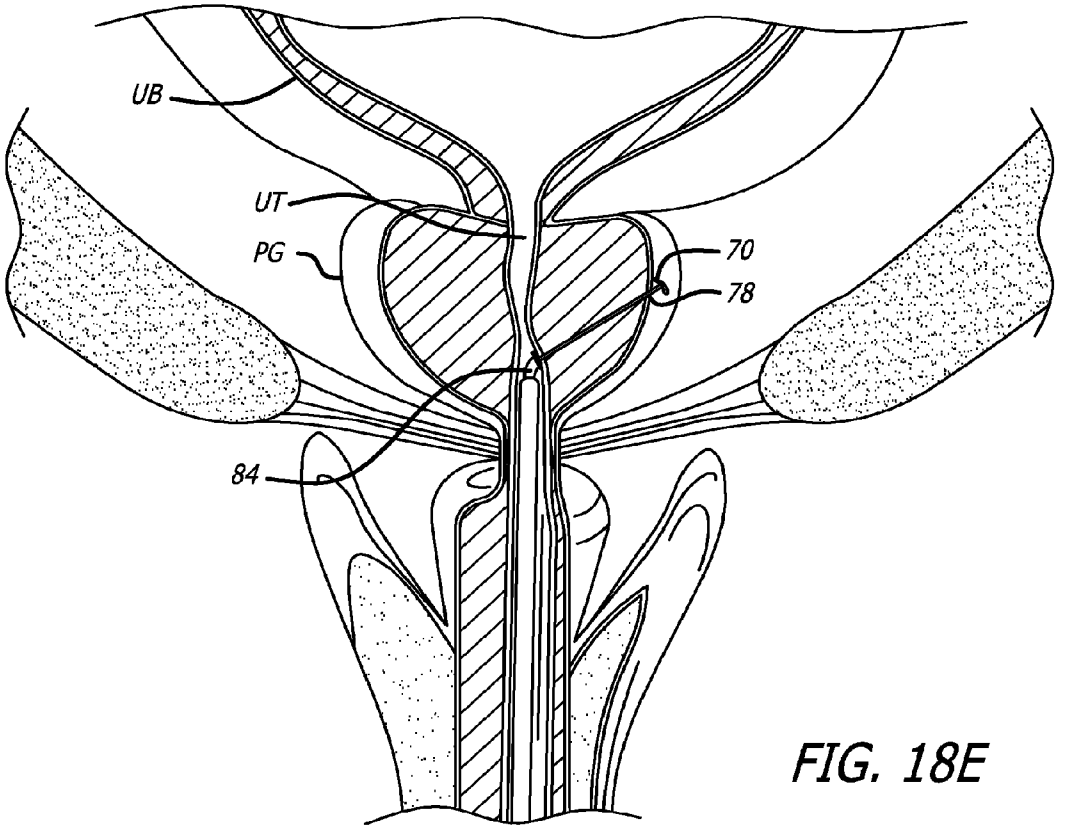


FIG. 18E

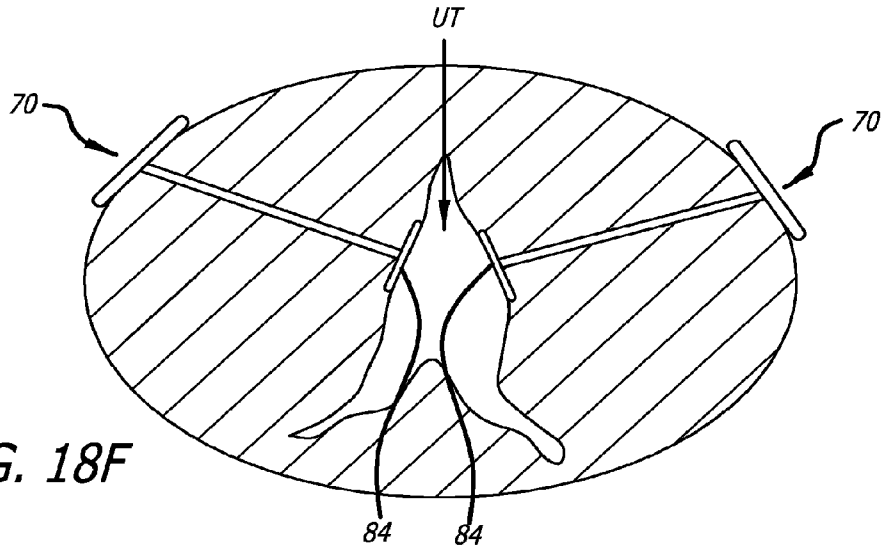


FIG. 18F

LATCHING ANCHOR DEVICE

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation of copending U.S. patent application Ser. No. 12/852,939, filed Aug. 9, 2010, which is a continuation-in-part of: 1) patented U.S. patent application Ser. No. 12/852,243, filed Aug. 6, 2010, now U.S. Pat. No. 8,333,776; 2) patented U.S. patent application Ser. No. 12/512,674, filed Jul. 30, 2009, now U.S. Pat. No. 8,216,254, which claims the benefit of Provisional Application Ser. No. 61/084,937; 3) copending U.S. patent application Ser. No. 11/775,162, filed Jul. 9, 2007: 4) patented U.S. patent application Ser. No. 11/671,914, filed Feb. 6, 2007, now U.S. Pat. No. 8,157,815; 5) patented U.S. patent application Ser. No. 11/492,690, filed on Jul. 24, 2006, now U.S. Pat. No. 7,896,891; 6) copending U.S. patent application Ser. No. 11/833,660, filed on Aug. 3, 2007, which is a continuation of patented U.S. patent application Ser. No. 11/318,246, filed on Dec. 20, 2005, now U.S. Pat. No. 7,645,286; and 7) patented U.S. patent application Ser. No. 11/838,036 filed on Aug. 13, 2007, now U.S. Pat. No. 7,914,542, which is a continuation of patented U.S. patent application Ser. No. 11/134,870 filed on May 20, 2005, now U.S. Pat. No. 7,758,594; the entire disclosures of each of which are expressly incorporated herein by reference.

FIELD OF THE INVENTION

The disclosed embodiments relate generally to medical devices and methods, and more particularly to systems and associated methods for manipulating or retracting tissues and anatomical or other structures within the body of human or animal subjects for the purpose of treating diseases or disorders.

BACKGROUND

There are a wide variety of situations in which it is desirable to lift, compress or otherwise reposition normal or aberrant tissues or anatomical structures (e.g., glands, organs, ligaments, tendons, muscles, tumors, cysts, fat pads, and the like) within the body of a human or animal subject. Such procedures are often carried out for the purpose of treating or palliating the effects of diseases or disorders (e.g., hyperplasic conditions, hypertrophic conditions, neoplasias, prolapses, herniations, stenoses, constrictions, compressions, transpositions, congenital malformations, and the like) and/or for cosmetic purposes (e.g., face lifts, breast lifts, brow lifts, and the like) and/or for research and development purposes (e.g., to create animal models that mimic various pathological conditions). In many of these procedures, surgical incisions are made in the body, and laborious surgical dissection is performed to access and expose the affected tissues or anatomical structures. Thereafter, in some cases, the affected tissues or anatomical structures are removed or excised. In other cases, various natural or man-made materials are used to lift, sling, reposition or compress the affected tissues.

Benign Prostatic Hyperplasia (BPH):

One example of a condition where it is desirable to lift, compress or otherwise remove a pathologically enlarged tissue is Benign Prostatic Hyperplasia (BPH). BPH is one of the most common medical conditions that affects men, especially elderly men. It has been reported that, in the United States, more than half of all men have histopathologic evidence of BPH by age 60 and, by age 85, approximately 9 out of 10 men suffer from the condition. Moreover, the incidence and prevalence of BPH is expected to increase as the average age of the population increases in developed countries.

The prostate gland enlarges throughout a man's life. In some men, the prostatic capsule around the prostate gland may prevent the prostate gland from enlarging further. This causes the inner region of the prostate gland to squeeze the urethra. This pressure on the urethra increases resistance to urine flow through the region of the urethra enclosed by the prostate. Thus, the urinary bladder has to exert more pressure to force urine through the increased resistance of the urethra. Chronic over-exertion causes the muscular walls of the urinary bladder to remodel and become stiffer. This combination of increased urethral resistance to urine flow and stiffness and hypertrophy of urinary bladder walls leads to a variety of lower urinary tract symptoms (LUTS) that may severely reduce the patient's quality of life. These symptoms include weak or intermittent urine flow while urinating, straining when urinating, hesitation before urine flow starts, feeling that the bladder has not emptied completely even after urination, dribbling at the end of urination or leakage afterward, increased frequency of urination particularly at night, urgent need to urinate, and the like.

In addition to patients with BPH, LUTS may also be present in patients with prostate cancer, prostate infections, and chronic use of certain medications (e.g. ephedrine, pseudoephedrine, phenylpropanolamine, antihistamines such as diphenhydramine, chlorpheniramine, and the like) that cause urinary retention especially in men with prostate enlargement.

Although BPH is rarely life threatening, it can lead to numerous clinical conditions including urinary retention, renal insufficiency, recurrent urinary tract infection, incontinence, hematuria, and bladder stones.

In developed countries, a large percentage of the patient population undergoes treatment for BPH symptoms. It has been estimated that by the age of 80 years, approximately 25% of the male population of the United States will have undergone some form of BPH treatment. At present, the available treatment options for BPH include watchful waiting, medications (phytotherapy and prescription medications), surgery and minimally invasive procedures.

For patients who choose the watchful waiting option, no immediate treatment is provided to the patient, but the patient undergoes regular exams to monitor progression of the disease. This is usually done on patients that have minimal symptoms that are not especially bothersome.

Medications for treating BPH symptoms include phytotherapy and prescription medications. In phytotherapy, plant products such as Saw Palmetto, African Pygeum, Serenoa Repens (sago palm) and South African star grass are administered to the patient. Prescription medications are prescribed as first line therapy in patients with symptoms that are interfering with their daily activities. Two main classes of prescription medications are alpha-1 a-adrenergic receptors blockers and 5-alpha-reductase inhibitors. Alpha-1 a-adrenergic receptors blockers block the activity of alpha-1 a-adrenergic receptors that are responsible for causing constriction of smooth muscle cells in the prostate. Thus, blocking the activity of alpha-1 a-adrenergic receptors causes prostatic smooth muscle relaxation. This, in turn, reduces urethral resistance thereby reducing the severity of the symptoms. 5-alpha-reductase inhibitors block the conversion of testosterone to di-hydro-testosterone. Di-hydro-testosterone causes growth of epithelial cells in the prostate

gland. Thus, 5-alpha-reductase inhibitors cause regression of epithelial cells in the prostate gland and, hence, reduce the volume of the prostate gland, which in turn reduces the severity of the symptoms.

Surgical procedures for treating BPH symptoms include Transurethal Resection of Prostate (TURP), Transurethral Electrovaporization of Prostate (TVP), Transurethral Incision of the Prostate (TUIP), Laser Prostatectomy and Open Prostatectomy.

Transurethal Resection of Prostate (TURP) is the most commonly practiced surgical procedure implemented for the treatment of BPH. In this procedure, prostatic urethral obstruction is reduced by removing most of the prostatic urethra and a sizeable volume of the surrounding prostate gland. This is carried out under general or spinal anesthesia. In this procedure, a urologist visualizes the urethra by inserting a resectoscope, that houses an optical lens in communication with a video camera, into the urethra such that the distal region of the resectoscope is in the region of the urethra surrounded by the prostate gland. The distal region of the resectoscope consists of an electric cutting loop that can cut prostatic tissue when an electric current is applied to the device. An electric return pad is placed on the patient to close the cutting circuit. The electric cutting loop is used to scrape away tissue from the inside of the prostate gland. The tissue that is scraped away is flushed out of the urinary system using an irrigation fluid. Using a coagulation energy setting, the loop is also used to cauterize transected vessels during the operation.

Another example of a surgical procedure for treating BPH symptoms is Transurethral Electrovaporization of the Prostate (TVP). In this procedure, a part of prostatic tissue squeezing the urethra is desiccated or vaporized. This is carried out under general or spinal anesthesia. In this procedure, a resectoscope is inserted transurethrally such that the distal region of the resectoscope is in the region of the urethra surrounded by the prostate gland. The distal region of the resectoscope consists of a rollerball or a grooved roller electrode. A controlled amount of electric current is passed through the electrode. The surrounding tissue is rapidly heated up and vaporized to create a vaporized space. Thus, the region of the urethra that is blocked by the surrounding prostate gland is opened up.

Another example of a surgical procedure for treating BPH symptoms is Transurethral Incision of the Prostate (TUIP). In this procedure, the resistance to urine flow is reduced by making one or more incisions in the prostate gland in the region where the urethra meets the urinary bladder. This procedure is performed under general or spinal anesthesia. In this procedure, one or more incisions are made in the muscle of the bladder neck, which is the region where the urethra meets the urinary bladder. The incisions are in most cases deep enough to cut the surrounding prostate gland tissue including the prostatic capsule. This releases any compression on the bladder neck and causes the bladder neck to spring apart. The incisions can be made using a resectoscope, laser beam, and the like.

Another example of a surgical procedure for treating BPH symptoms is Laser Prostatectomy. Two common techniques used for Laser Prostatectomy are Visual Laser Ablation of the Prostate (VLAP) and the Holmium Laser Resection/Enucleation of the Prostate (HoLEP). In VLAP, a neodymium: Yttrium-aluminum-gamet (NdYAG) laser is used to ablate tissue by causing coagulation necrosis. The procedure is performed under visual guidance. In HoLEP, a holmium: Yttrium-aluminum-gamet laser is used for direct contact ablation of tissue. Both these techniques are used to remove tissue obstructing the urethral passage to reduce the severity of BPH symptoms.

Another example of a surgical procedure for treating BPH symptoms is Photoselective Vaporization of the Prostate (PVP). In this procedure, laser energy is used to vaporize prostatic tissue to relieve obstruction to urine flow in the urethra. The type of laser used is the lithium triborate (LBO) laser. The wavelength of this laser is highly absorbed by oxyhemoglobin. This laser vaporizes cellular water and, hence, is used to remove tissue that is obstructing the urethra.

Another example of a surgical procedure for treating BPH symptoms is Open Prostatectomy. In this procedure, the prostate gland is surgically removed by an open surgery. This is done under general anesthesia. The prostate gland is removed through an incision in the lower abdomen or the perineum. The procedure is used mostly in patients that have a large (greater than approximately 100 grams) prostate gland.

Minimally invasive procedures for treating BPH symptoms include Transurethral Microwave Thermotherapy (TUMT), Transurethral Needle Ablation (TUNA), Interstitial Laser Coagulation (ILC), and Prostatic Stents.

In Transurethral Microwave Thermotherapy (TUMT), microwave energy is used to generate heat that destroys hyperplastic prostate tissue. This procedure is performed under local anesthesia. In this procedure, a microwave antenna is inserted in the urethra. A rectal thermosensing unit is inserted into the rectum to measure rectal temperature. Rectal temperature measurements are used to prevent overheating of the anatomical region. The microwave antenna is then used to deliver microwaves to lateral lobes of the prostate gland. The microwaves are absorbed as they pass through prostate tissue. This generates heat which in turn destroys the prostate tissue. The destruction of prostate tissue reduces the degree of squeezing of the urethra by the prostate gland, thus, reducing the severity of BPH symptoms.

Another example of a minimally invasive procedure for treating BPH symptoms is Transurethral Needle Ablation (TUNA). In this procedure, heat-induced coagulation necrosis of prostate tissue regions causes the prostate gland to shrink. It is performed using local anesthetic and intravenous or oral sedation. In this procedure, a delivery catheter is inserted into the urethra. The delivery catheter comprises two radiofrequency needles that emerge at an angle of 90 degrees from the delivery catheter. The two radiofrequency needles are aligned at an angle of 40 degrees to each other so that they penetrate the lateral lobes of the prostate. A radiofrequency current is delivered through the radiofrequency needles to heat the tissue of the lateral lobes to 70-100 degree Celsius at a radiofrequency power of approximately 456 KHz for approximately 4 minutes per lesion. This creates coagulation defects in the lateral lobes. The coagulation defects cause shrinkage of prostatic tissue which in turn reduces the degree of squeezing of the urethra by the prostate gland thus reducing the severity of BPH symptoms.

Another example of a minimally invasive procedure for treating BPH symptoms is Interstitial Laser Coagulation (ILC). In this procedure, laser-induced necrosis of prostate tissue regions causes the prostate gland to shrink. It is performed using regional anesthesia, spinal or epidural anesthesia or local anesthesia (periprostatic block). In this procedure, a cystoscope sheath is inserted into the urethra, and the region of the urethra surrounded by the prostate gland is inspected. A laser fiber is inserted into the urethra.

The laser fiber has a sharp distal tip to facilitate the penetration of the laser scope into prostatic tissue. The distal tip of the laser fiber has a distal-diffusing region that distributes laser energy 360° along the terminal 3 mm of the laser fiber. The distal tip is inserted into the middle lobe of the prostate gland, and laser energy is delivered through the distal tip for a desired time. This heats the middle lobe and causes laser-induced necrosis of the tissue around the distal tip. Thereafter, the distal tip is withdrawn from the middle lobe. The same procedure of inserting the distal tip into a lobe and delivering laser energy is repeated with the lateral lobes. This causes tissue necrosis in several regions of the prostate gland which, in turn, causes the prostate gland to shrink. Shrinkage of the prostate gland reduces the degree of squeezing of the urethra by the prostate, thus, reducing the severity of BPH symptoms.

Another example of a minimally invasive procedure for treating BPH symptoms is implanting Prostatic Stents. In this procedure, the region of urethra surrounded by the prostate is mechanically supported to reduce the constriction caused by an enlarged prostate. Prostatic stents are flexible devices that are expanded after their insertion in the urethra. They mechanically support the urethra by pushing the obstructing prostatic tissue away from the urethra. This reduces the constriction of the urethra and improves urine flow past the prostate gland thereby reducing the severity of BPH symptoms.

Although existing treatments provide some relief to the patient from symptoms of BPH, they have disadvantages. Alpha-1 a-adrenergic receptors blockers have side effects such as dizziness, postural hypotension, lightheadedness, asthenia and nasal stuffiness. Retrograde ejaculation can also occur. 5-alpha-reductase inhibitors have minimal side effects, but only have a modest effect on BPH symptoms and the flow rate of urine. In addition, anti-androgens, such as 5-alpha-reductase, require months of therapy before LUTS improvements are observed. Surgical treatments of BPH carry a risk of complications including erectile dysfunction; retrograde ejaculation; urinary incontinence; complications related to anesthesia; damage to the penis or urethra; need for a repeat surgery; and the like. Even TURP, which is the gold standard in treatment of BPH, carries a high risk of complications. Adverse events associated with this procedure are reported to include retrograde ejaculation (65% of patients), post-operative irritation (15%), erectile dysfunction (10%), need for transfusion (8%), bladder neck constriction (7%), infection (6%), significant hematuria (6%), acute urinary retention (5%), need for secondary procedure (5%), and incontinence (3%). Typical recovery from TURP involves several days of inpatient hospital treatment with an indwelling urethral catheter, followed by several weeks in which obstructive symptoms are relieved, but there is pain or discomfort during micturition.

The reduction in the symptom score after minimally invasive procedures is not as large as the reduction in symptom score after TURP. Up to 25% of patients who receive these minimally invasive procedures ultimately undergo a TURP within 2 years. The improvement in the symptom score generally does not occur immediately after the procedure. For example, it takes an average of one month for a patient to notice improvement in symptoms after TUMT and 1.5 months to notice improvement after ILC. In fact, symptoms are typically worse for these therapies that heat or cook tissue, because of the swelling and necrosis that occurs in the initial weeks following the procedures. Prostatic stents often offer more immediate relief from obstruction but are now rarely used because of high adverse effect rates. Stents have the risk of migration from the original implant site (up to 12.5% of patients), encrustation (up to 27.5%), incontinence (up to 3%), and recurrent pain and discomfort. In published studies, these adverse effects necessitated 8% to 47% of stents to be explanted. Overgrowth of tissue through the stent and complex stent geometries has made their removal quite difficult and invasive.

Thus, the most effective current methods of treating BPH carry a high risk of adverse effects. These methods and devices either require general or spinal anesthesia or have potential adverse effects that dictate that the procedures be performed in a surgical operating room, followed by a hospital stay for the patient. The methods of treating BPH that carry a lower risk of adverse effects are also associated with a lower reduction in the symptom score. While several of these procedures can be conducted with local analgesia in an office setting, the patient does not experience immediate relief and, in fact, often experiences worse symptoms for weeks after the procedure until the body begins to heal. Additionally, all device approaches require a urethral catheter placed in the bladder, and in some cases for weeks. In some cases, catheterization is indicated because the therapy actually causes obstruction during a period of time post operatively, and in other cases it is indicated because of post-operative bleeding and potentially occlusive clot formation. While drug therapies are easy to administer, the results are suboptimal, take significant time to take effect, and often entail undesired side effects.

Cosmetic or Reconstructive Tissue Lifting and Repositioning:

Many cosmetic or reconstructive surgical procedures involve lifting, compressing or repositioning of natural tissue, natural tissue or artificial grafts, or aberrant tissue. For example, surgical procedures such as face lifts, brow lifts, neck lifts, tummy tucks, and the like, have become commonplace. In many cases, these procedures are performed by creating incisions through the skin, dissecting to a plane beneath muscles and fascia, freeing the muscles, fascia and overlying skin from underlying structures (e.g., bone or other muscles), lifting or repositioning the freed muscles, fascia and overlying skin, and then attaching the repositioned tissues to underlying or nearby structures (e.g., bone, periostium, or other muscles) to hold the repositioned tissues in their new (e.g., lifted) position. In some cases, excess skin may also be removed during the procedure.

There have been attempts to develop minimally invasive devices and methods for cosmetic lifting and repositioning of tissues. For example, connector suspension lifts have been developed where one end of a standard or modified connector thread is attached to muscle and the other end is anchored to bone, periostium or another structure to lift and reposition the tissues as desired. Some of these connector suspension techniques have been performed through cannulas or needles inserted though relatively small incisions of puncture wounds.

There remains a need for the development of a suture lock or a suture anchor for use in various contemplated applications. In particular, there is a need for an anchor which can be easily configured to lockingly engage suture once access to an interventional site is achieved. The disclosed embodiments address these and other needs.

SUMMARY

Briefly and in general terms, the disclosed embodiments are directed towards an anchor assembly for use within a patient's body. In one embodiment, an anchor secures to a

connector in the form of a suture. The structures can further form an assembly including a distal anchor connected to a proximal anchor.

In various approaches, the anchor can include a solid generally cylindrical or alternatively a tubular back end. The anchor can also include a pair of spaced apart prongs including a catch or latching structure extending therefrom. The spaced prongs join together at a slot inception. The prongs can include inwardly facing protrusions that are configured to capture and deform the suture between the protrusions and prevent the suture from disengaging from the anchor device once engaged. The mechanism of suture attachment and strength of the assembly is a combination of compression of the suture between the prongs of the anchor as well as disruption of the suture surface by the edges of the anchor. The edges provide a surface contact area between anchor prongs and focus the compressive forces that cause the suture to conform around both internal and external faces.

In one specific approach, one of the prongs of the anchor includes a mushroom head fastener which is lockingly received in a corresponding recess. In another approach, the prongs define locking scissors. In yet another approach, the prongs of the anchor include complementary structures including a slotted hole for locking the prongs together.

In other aspects, the anchor can include a first prong and a second prong having a greater length. A terminal end of the longer prong can be configured about the shorter prong to define grasping structure. Alternatively, the shorter prong can be placed into an interference engagement with the longer prong. In yet further aspects, the anchor can include a body with an extension which is capable of being folded laterally to engage a connector. The extension can be folded about the body and can be further engaged within a receiving substructure formed in the anchor body.

Other features and advantages will become apparent from the following detailed description, taken in conjunction with the accompanying drawings, which illustrate by way of example, the features of the various embodiments.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a perspective view of one embodiment of an anchor assembly that includes a distal anchor and a proximal anchor secured together by a suture;

FIG. **2** is a top view of one embodiment of an anchor assembly;

FIG. **3** is a close up perspective view of the latching structure of the anchor assembly of FIG. **2**;

FIG. **4** is a side view of another embodiment of an anchor assembly;

FIG. **5** is an end view of the anchor assembly of FIG. **4**;

FIG. **6** is a perspective view of another approach to an anchor assembly;

FIG. **7** is a perspective view, depicting a deformed configuration of the anchor of FIG. **6**;

FIG. **8** is a perspective view, depicting latching anchor formed from a tube;

FIGS. **9**A-B are perspective views, depicting another approach to a latching anchor;

FIGS. **10**A-B are side views, depicting yet a further approach to a latching anchor;

FIGS. **11**A-B are side views, depicting a latching anchor with interference structure;

FIGS. **12**A-F are perspective and cross-sectional views, depicting yet a further approach to a latching anchor;

FIGS. **13**A-**15**B are cross-sectional views, depicting alternative embodiments of the anchor approach depicted in FIGS. **12**A-C;

FIG. **16** is a perspective view of the distal anchor with a orthogonally oriented tail portion;

FIG. **17** is a side view of the distal anchor with a orthogonally oriented tail portion of FIG. **16** and the suture; and

FIGS. **18**A-F are partial cross sectional views of an anchor assembly of FIG. **1** being implanted through the prostate of an individual with Benign Prostatic Hyperplasia.

DETAILED DESCRIPTION

Turning now to the figures, which are provided by way of example and not limitation, the disclosed embodiments are embodied in anchor assemblies configured to be delivered within a patient's body. As stated, the disclosed embodiments can be employed for various medical purposes including but not limited to retracting, lifting, compressing, supporting or repositioning tissues, organs, anatomical structures, grafts or other material found within a patient's body. Such tissue manipulation is intended to facilitate the treatment of diseases or disorders. Moreover, the disclosed embodiments have applications in cosmetic or reconstruction purposes, or in areas relating to the development or research of medical treatments. Referring now to the drawings, wherein like reference numerals denote like or corresponding components throughout the drawings and, more particularly to FIGS. **1**-**18**, there are shown aspects of an anchor assembly.

In such applications, one portion of an anchor assembly is positioned and implanted against a first section of anatomy. A second portion of the anchor assembly is then positioned and implanted adjacent to a second section of anatomy for the purpose of retracting, lifting, compressing, supporting or repositioning the second section of anatomy with respect to the first section of anatomy, as well as for the purpose of retracting, lifting, compressing, supporting or repositioning the first section of anatomy with respect to the second section of anatomy. It is also to be recognized that both a first and second portion of the anchor assembly can be configured to accomplish the desired retracting, lifting, compressing, supporting or repositioning of anatomy due to tension supplied thereto via a connector assembly (e.g., suture) affixed to the first and second portions of the anchor assembly.

In one embodiment of the anchor assembly, the anchor assembly is configured to include structure that is capable of being implanted within a patient's body. The anchor assembly may also be used in conjunction with a conventional remote viewing device (e.g., an endoscope) so that an interventional site can be observed.

In one embodiment, the anchor assembly can be placed at an intervention site using a delivery tool. One specific, non-limiting application of the delivery tool is for the treatment of benign prostatic hyperplasia. In this procedure, an implant is delivered to a prostatic lobe that is obstructing the urethral opening and restricting flow. The implant compresses the lobe, thereby increasing the urethral opening and reducing the fluid obstruction through the prostatic urethra.

Additionally, in one embodiment, the anchor assembly is embodied in a tissue approximation anchor (TAA). The tissue approximation anchor is an implant assembly that includes one tubular member (preferably comprised of Nitinol or other comparable material), referred to as the capsular anchor or, more generally, distal anchor **70**. The distal

anchor **70** is preferably connected by a suture **78** to a slotted, flattened-tubular member (preferably comprised of stainless steel), referred to as the urethral anchor or proximal anchor **84**. In one specific, non-limiting embodiment, the distal anchor **70** is comprised of an electro-polished Nitinol (nickel titanium alloy SE508, 55.8% nickel) tube.

The tissue approximation anchor is designed to be useable in an office environment (in contrast to requiring a hospital environment). The delivery tool is used through a 19Fr introducer sheath size in one preferred embodiment, while in another embodiment a sheath size of 21F is employed. Additionally, the material selection and construction of the tissue approximation anchor still allows for a subsequent TURP procedure to be performed, if necessary. In this suture-based, tissue approximation technique, a needle delivery mechanism is used to implant a nitinol distal anchor **70** and attached connector or suture **78**. In one approach, the introducer sheath is first placed within a patient's urethra. An anchor housed within the delivery tool is then placed through the introducer sheath and a distal portion of the delivery tool is placed at the interventional site. Once the distal anchor **70** and attached suture **78** have been deployed, with the needle retracted and the suture **78** tensioned, the anchor **84** is pushed by the delivery tool and captures the suture **78** transverse to the anchor axis.

In one embodiment, the nitinol tube is attached to a USP size 0 PET (Poly Ethylene Terephthalate) monofilament suture **78** by thermally forming the suture to locking features on the distal anchor **70** (See FIG. **1**). Referring again to the suture itself, the PET suture is a round monofilament extrusion/pulltrusion composed of a grade 8816 polyethylene terephthalate. Typically, the base material for the suture is annealed at approximately 191 degrees Celsius for approximately 5 minutes in a straight condition. In one non-limiting embodiment, the PET suture **78** has a diameter of 0.015 inches and a tensile strength greater than or equal to 6.0 pounds.

In one embodiment, as shown in FIGS. **2** and **3**, the anchor **84** is a 316L stainless steel member that is slotted, electro-polished, and passivated. The anchor **84** includes prongs **96** that can assume both open and closed positions and that grip and deform the suture **78** configured between the prongs **96**. The interior structure of the prongs function to disrupt the surface of the suture **78**, both biting into the suture **78** as well as compressing the suture **78** between the slotted prongs **96**. A mushroom head tab **98** extends from one or more of the prongs **96**, the tab **98** being configured to be lockingly received on a recess **99** formed in an opposing prong **96**.

In one embodiment, the prongs **96** extend from a solid generally cylindrical structure. The wider and smoother prongs **96** of the anchor **84** assist in preventing the prongs **96** from irritating and/or damaging tissue, which is more likely to occur with a thinner and pointier leg structure.

In certain approaches, the slotted anchor **84** includes a rigid generally cylindrical back end **95**, extending from which are a pair of spaced prongs **96**. Terminal ends of the prongs **96** may be tapered to receive a section of the suture **78**. Notably, the prong structure commences at a narrowed slot inception **97**, which steps outwardly to a wider dimension to thereby define the space between the prongs **96**. This narrow slot **97** provides the slotted anchor **84** with desired structure to receive the suture **78** and to facilitate locking engagement with the slotted anchor **84**. Notably, in one embodiment the space between the prongs **96** of the slotted anchor **84** is dimensionally relative to the diameter of the suture **78** such that is has sufficient gripping force to obviate the need for a securing end unit. Accordingly, in a preferred embodiment, a securing end unit is not needed.

In one embodiment, shaped tube raw stock is used to produce the anchor **84** using slot/profile cutting. Specifically, in one embodiment the raw stock may be cut by laser, wire-EDM, or stamped from a flat and formed into a shape. In one non-limiting embodiment, the raw stock has a total height ranging from 0.020 inches to 0.025 inches, and has a total width ranging from 0.038 inches to 0.042 inches. Thus, this raw stock is flatter and wider than a purely round tube would be.

The inwardly facing structure of the prongs **96** of the anchor is configured to grasp and deform the suture **78**. In one embodiment, the inner surface of the prongs **96** near the slot inception **97** is more of an extended landing than a simple U-shaped surface configuration. Thus, there is a longer dimension for better seating of the suture **78**.

In one embodiment, a 0.014 inch gap between prongs **96** provides a structure suitable for tissue interaction and use with a 0.015 inch suture **78**. It will be appreciated by those skilled in the art, that many variations in the slot parameters are possible for optimizing performance in different situations. Additionally, in some embodiments, the protrusions formed on opposite prongs may be of differing shapes. Such slot parameters include, by way of example only, and not by way of limitation: width, thickness, length, and profile. Optionally, the anchor assembly may be filled in with an RO material, or other therapeutic agent.

There can also be variations in the tab **98** and recess **99** configurations used to latch and lock the prongs **96** together as are approached to accomplish such locking. In contemplated approach for latching prongs **96** together, a delivery tool can include a sleeve (not shown) that is advanced over the prongs **96** to bring them into engagement, subsequent to positioning a connector between the prongs **96**.

As shown in FIGS. **4** and **5**, the anchor **84** can also include prongs **96** of different lengths configured to form a scissor-like arrangement. The prongs **96** can further include complementary cut-outs **101** which function to retain the prongs **96** in a closed, locking engagement after a connector **78** is placed as desired therebetween. Again, deflection of the prongs **96** into locking engagement can be accomplished in various conventional approaches, such as including structure that transmits a force in a lateral direction.

Turning now to FIGS. **6** and **7**, yet another approach to a latching anchor **84** is shown. Here, one prong **96** includes a slot **103** formed near a distal end thereof and which is sized and shaped to lockingly latch another prong **96**. In still yet another contemplated design (See FIG. **8**), the anchor **84** is formed of tubular structure. One prong lockingly engages a curved interior surface **98** of a second prong.

As shown in FIGS. **9**A-B and FIGS. **10**A-B, further approaches to a proximal anchor **84** can be embodied in a structure including prongs **110**, **112** having different lengths. The longer prong **112** is designed to be folded laterally over a terminal end **114** of the shorter prong **110** to define a latching assembly substructure. In one approach, the lateral fold can be pre-formed into the anchor **84**. Alternatively, the lateral fold can be formed in situ by advancing the anchor **84** against a curved wall or closed recess. Moreover, the slot **116** existing between the prongs **110**, **112** can be formed by two generally parallel walls such as that shown in FIGS. **9**A-B or alternatively, the slot **116** can be stepped as depicted in FIGS. **10**A-B. In one aspect, the stepped slot is contemplated to facilitate a robust engagement with a suture or connector **78** by providing desired deformation of the connector **78**.

In a related approach (FIGS. **11**A-B), a proximal anchor **84** can include prongs configured to define an interference connection therebetween. Rather than laterally folding a longer prong over a terminal end of a shorter prong, however, this approach involves translating a shorter prong **120** into an interference recess **121** formed in a longer prong **122**. Once the shorter prong **120** is placed into an interfering relationship with the longer prong **122**, a connector **78** placed between the prongs **120**, **122** can be fixedly engaged.

Various additional and related approaches to a latching proximal anchor with a pair of prongs are shown in FIGS. **12**A-F, **13**A-C, **14**A-B and **15**A-B. As shown in FIGS. **12**A-C, the proximal anchor **84** can include a body **130** with an extension **132** projecting perpendicularly therefrom. The extension **132** is folded transverse to a long dimension of the body **130** to capture a connector (not shown). In a first approach (FIGS. **12**D-F), the extension **132** is across a width of the body **130** and latched on an opposite side of the body **130**. In alternate approaches, the body can include a recess **140** (FIGS. **13**A-C and **15**A-B) into which the extension **130** can be received. Additionally, the extension **130** can include a pre-formed angled terminal end **142** received on an opposite of the body **130** from which the extension projects (FIGS. **14**A-B) or within the recess **140** (FIGS. **15**A and B). In each of these approaches, the extension **130** and body **132** cooperate to fixedly grasp the connector.

One embodiment of a distal anchor assembly **70** is depicted in FIGS. **16** and **17**. In its unconstrained configuration, the distal (e.g., capsular) anchor **70** includes a tubular (head) portion **72** which is generally orthogonally oriented to a tail portion **74**. It is to be noted, however, that while housed in a delivery assembly and prior to deployment at a target area, the distal anchor **70** is constrained to define a generally straight configuration, only subsequently assuming the unconstrained (i.e., orthogonally oriented) configuration upon deployment from a delivery device.

The distal anchor **70** is laser cut or wire EDM (electrical discharge machined) from a nitinol base stock that is generally-tubular is shape. The Nitinol distal anchor is shape-set to have a "flipping tail" and is electro-polished. The suture **78** is then attached to the distal anchor **70** as an adhesive free joint. Specifically, in one embodiment, the PET suture **78** is thermoformed onto locking features in the anchor **70**. The distal anchor **70** may be locally heated to re-flow the suture onto the end of the anchor **70** and into cutouts on the anchor **70**. Continuing, in one non-limiting embodiment, the post electro-polished distal anchor **70** has a 0.016 inner diameter and a 0.0253 outer diameter.

In one non-limiting embodiment, the tubular portion **72** of the distal anchor **70** includes a plurality of tabs **76** which can be deformed or deflected to accomplish affixing the distal anchor **70** to a suture **78**. It has been found that three such tabs **76**, two on one side of the tubular portion **72** and one on an opposite side, provide a sufficient connecting force and a desired balance between the suture **78** and distal anchor **70** and to move the distal anchor **70** by applying a force either in the proximal or distal direction. However, the distal anchor **70** may be attached to the suture **78** through any of several known techniques, such as by being attached to the distal end of the tubular portion **72**.

In another aspect of a non-limiting embodiment, it is contemplated that the distal anchor **70** can be laser cut from a tube formed of Nitinol or other appropriate material. A mid-section **80** of the distal anchor **70** provides a structural transition from the tubular portion **72** to the tail portion **74**. As such, a portion of a side wall is removed in the mid-section area **80**. A further portion of the side wall is removed to define a connector section **82** of the tail **74** which extends from the mid-section **80**. In one embodiment, this connector section **82** includes a bend that creates the orthogonally oriented configuration. This connector section **82** acts as a barb or deflected strut to cause flipping (creating a "flipping tail") and produce the relative unconstrained (orthogonally oriented) angle assumed between the tail **74** and tubular portion **72** of the distal anchor **70**. The recovered shape of the terminal end portion **83** of the anchor presents a transverse strut that engages tissue when the suture is tensioned.

Thus, in its pre-implanted form, the anchor assembly can include a distal anchor **70** (e.g., first anchor) whose initial engagement with a suture **78** is generally coaxial, and a proximal anchor **84** (e.g., second anchor) with an initial engagement being generally perpendicular with the suture **78**.

As stated above, an introducer sheath (not shown) can first be placed within a patient's urethra for the purpose of facilitating access to a treatment site. The distal anchor **70** is "unsheathed" from the needle delivery mechanism once positioned for reliable deployment eliminating predicate distal suture. This results in an adjustable implant length. This distal anchor **70** configuration also provides increased yield and strength.

With reference now to FIGS. **18**A-F, in one particular, non-limiting use in treating a prostate, an elongate tissue access portion **404** of a delivery device **400** is placed within a urethra (UT) leading to a urinary bladder (UB) of a patient. The delivery device can be placed within an introducer sheath previously positioned in the urethra or alternatively, the delivery device can be inserted directly within the urethra. The patient is positioned in lithotomy. The elongate portion **404** is advanced within the patient until a leading end **410** thereof reaches a prostate gland (PG). In a specific approach, the side(s) (i.e., lobe(s)) of the prostate to be treated is chosen while the device extends through the bladder and the device is turned accordingly. The device is first positioned at the bladder neck and then refracted approximately 1 cm while keeping the device parallel to the prostatic fossa and preserving mucosa. The distal end of the elongate portion can be used to push the urethra into the prostate gland. The inside of the prostate gland (i.e., adenoma) is spongy and compressible and the outer surface (i.e., capsule) of the prostate gland is firm. By the physician viewing with the endoscope, he/she can push the urethra into the prostate gland compressing the adenoma and creating the desired opening through the urethra. To accomplish this, the physician pivots the tool laterally about the pubic symphysis, generally about 20 to 30 degrees (See FIG. **18**A). The physician then rotates the tool anterior between 9 and 10 o'clock for the patient's side right lobe and between 2 and 3 o'clock for the patient's side left lobe. Viewing through the endoscope, the physician wants to have about the same amount of tissue protruding on both sides of the elongate shaft (See FIG. **18**B).

At the leading end **410** of the delivery device, as shown in FIG. **18**C, a needle **430** carrying an anchor assembly is ejected into and through tissue. The needle assembly can be configured so that it curves back toward the delivery tool as it is ejected. In use in a prostate intervention, the needle assembly **430** is advanced through and beyond a prostate gland (PG). The delivery device can be rotated anteriorly to lift a prostatic lobe.

Upon withdrawal of the needle assembly **430** (See FIG. **18**D), the distal anchor **20** is left beyond the prostate (PG). Next, steps are taken to implant the proximal anchor **84** within the urethra (FIG. **18**E). Either a single anchor assem-

bly or multiple anchor assemblies can be delivered and deployed at an intervention site by the deployment device (See FIG. **18**F). Additionally, a single anchor assembly component can for example, be placed on one side of a prostate or urethra while multiple anchor assembly components can be positioned along an opposite or displaced position of such anatomy. The number and locations of the anchor assemblies can thus be equal and/or symmetrical, different in number and asymmetrical, or simply asymmetrically placed. In the context of prostate treatment, the present invention is used for the compression of the prostate gland and the opening of the prostatic urethra, the delivering of an implant at the interventional site, and applying tension between ends of the implant. Moreover, drug delivery is both contemplated and described as a further remedy in BPH and over active bladder treatment as well as treating prostate cancer and prostatitis.

The disclosed embodiments contemplate both pushing directly on anchor portions of an anchor assembly as well as pushing directly upon the connector of the anchor assembly. Further, an anchor assembly can be delivered and deployed at an interventional site by a deployment device. Consequently, in the context of prostate treatment, the disclosed embodiments accomplish both compressing of the prostate gland and the opening of the prostatic urethra and applying tension between ends of the implant. Moreover, drug delivery is contemplated as a further remedy in BPH and overactive bladder treatment.

Once implanted, the anchor assembly of the disclosed embodiments accomplishes desired tissue approximation, manipulation, compression or retraction, as well as cooperates with the target anatomy to provide an atraumatic support structure. In particular, the shape and contour of the anchor assembly can be configured so that the assembly invaginates within target tissue, such as within natural folds formed in the urethra by the opening of the urethra lumen by the anchor assembly. In fact, in situations where the anchor assembly is properly placed, wispy or pillowy tissue in the area collapses around the anchor structure. Eventually, the natural tissue can grow over the anchor assembly, and new cell growth occurs over time. Such cooperation with target tissue facilitates healing and avoids unwanted side effects such as calcification or infection at the interventional site.

Furthermore, in addition to an intention to cooperate with natural tissue anatomy, the disclosed embodiments also contemplate approaches to accelerate healing or induce scarring. Manners in which healing can be promoted can include employing abrasive materials, textured connectors, biologics and drugs.

It has been observed that placing the anchors at various desired positions within the anatomy can extract the best results. For example, when treating a prostate, one portion of an anchor can be placed within a urethra. It has been found that configuring such anchors so that ten o'clock and two o'clock positions (when looking along the axis of the urethra) are supported or retained, effectively holds the anatomy open and also can facilitate invagination of the anchor portion within natural tissue. Typically, one to two pairs of anchor assemblies are implanted to create an anterior channel along the urethra within the prostate gland (FIG. **18**F). This is particularly true in the regions of anatomy near the bladder and the juncture at which the ejaculatory duct connects to the urethra.

Moreover, it is to be recognized that the foregoing procedure is reversible. In one approach, the connection of an anchor assembly can be severed and a proximal (or second) anchor component removed from the patient's body. For example, the physician can simply cut the connector and simultaneously remove the second anchor previously implanted for example, in the patient's urethra. It is to be recognized that various materials are contemplated for manufacturing the disclosed devices. Moreover, one or more components such as distal anchor **70**, proximal anchor **84**, suture **78**, of the one or more anchor assemblies disclosed herein may be designed to be completely or partially biodegradable or bio-fragmentable.

Further, as stated, the systems and methods disclosed herein may be used to treat a variety of pathologies in a variety of tubular structures comprising a cavity or a wall. Examples of such organs include, but are not limited to urethra, bowel, stomach, esophagus, trachea, bronchii, bronchial passageways, veins (e.g. for treating varicose veins or valvular insufficiency), arteries, lymphatic vessels, ureters, bladder, cardiac atria or ventricles, uterus, fallopian tubes, and the like.

Finally, it is to be appreciated that the invention has been described hereabove with reference to certain examples or embodiments, but that various additions, deletions, alterations and modifications may be made to those examples and embodiments without departing from the intended spirit and scope of the disclosed embodiments. For example, any element or attribute of one embodiment or example may be incorporated into or used with another embodiment or example, unless to do so would render the embodiment or example unpatentable or unsuitable for its intended use. Also, for example, where the steps of a method are described or listed in a particular order, the order of such steps may be changed unless to do so would render the method unpatentable or unsuitable for its intended use. All reasonable additions, deletions, modifications and alterations are to be considered equivalents of the described examples and embodiments and are to be included within the scope of the following claims.

The various embodiments described above are provided by way of illustration only and should not be construed to limit the disclosed embodiments. Those skilled in the art will readily recognize various modifications and changes that may be made to the disclosed embodiments without following the example embodiments and applications illustrated and described herein, and without departing from the true spirit and scope of the disclosed embodiments, which is set forth in the following claims.

What is claimed:

1. An anchor assembly, comprising:

a distal anchor, a connector and a proximal anchor, the proximal anchor comprising:

a back end; and

a pair of spaced prongs extending from the back end, the prongs being joined together at a slot inception and each prong has a terminal end, and wherein the prongs are shaped and sized of a configuration to provide deflection of the prongs;

wherein the prongs include inwardly facing structure configured to capture and deform the connector therebetween and a latching structure configured to maintain an engagement with the connector between the prongs;

wherein the latching structure is formed by a pair of crossing prongs and wherein the prongs cross proximal of the terminal end of each prong.

2. The anchor assembly of claim **1**, wherein each prong of the pair of crossing prongs includes a cut-out, the cut-out arranged to receive a portion of an opposing prong.

3. The anchor assembly of claim 1, wherein a first prong has a first length and the second prong has a second length, the first length being greater than the first length.

4. The anchor assembly of claim 1, wherein the proximal anchor is defined by a solid member.

5. The anchor assembly of claim 1, wherein the distal anchor is defined by a tubular member.

6. The anchor assembly of claim 1, the proximal anchor including a first prong and a second prong, the second prong having a greater length than the first prong.

7. The anchor assembly of claim 1, further comprising a slot inception, the slot inception is stepped and sized to accept and deform the connector.

8. The anchor assembly of claim 1, the distal anchor comprising a laterally oriented tail.

9. The anchor assembly of claim 8, the distal anchor further comprising a tubular portion which is generally perpendicular to a tail portion.

10. The anchor assembly of claim 9, wherein the tubular portion includes tabs for affixing the distal anchor to the connector.

* * * * *