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

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(54) **METHODS FOR DETECTION OF CARDIAC RHYTHM DISORDERS USING BASKET STYLE CARDIAC MAPPING CATHETER**

2018/00839;A61B 2018/00351; A61B 5/6858; A61B 2018/00029; A61B 2018/00214; A61B 1/00082; A61M 25/10; A61M 25/04

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(Continued)

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(56) **References Cited**

U.S. PATENT DOCUMENTS

(73) Assignee: **Topera, Inc.**, Menlo Park, CA (US)

3,326,207 A 6/1967 Egan
3,517,128 A 6/1970 Hines

(Continued)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

FOREIGN PATENT DOCUMENTS

(21) Appl. No.: **14/307,968**

EP 0689397 B1 7/2000
EP 1190671 B2 12/2006

(Continued)

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OTHER PUBLICATIONS

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PCT Search Report and Written Opinion for PCT/US2012/027220, dated May 29, 2012.

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Related U.S. Application Data

Primary Examiner — Joseph Stoklosa

Assistant Examiner — Brian M Antiskay

(63) Continuation of application No. 14/148,845, filed on Jan. 7, 2014, now Pat. No. 8,812,074, which is a (Continued)

(74) *Attorney, Agent, or Firm* — Hoffmann & Baron, LLP

(51) **Int. Cl.**
A61B 5/04 (2006.01)
A61B 5/042 (2006.01)

(Continued)

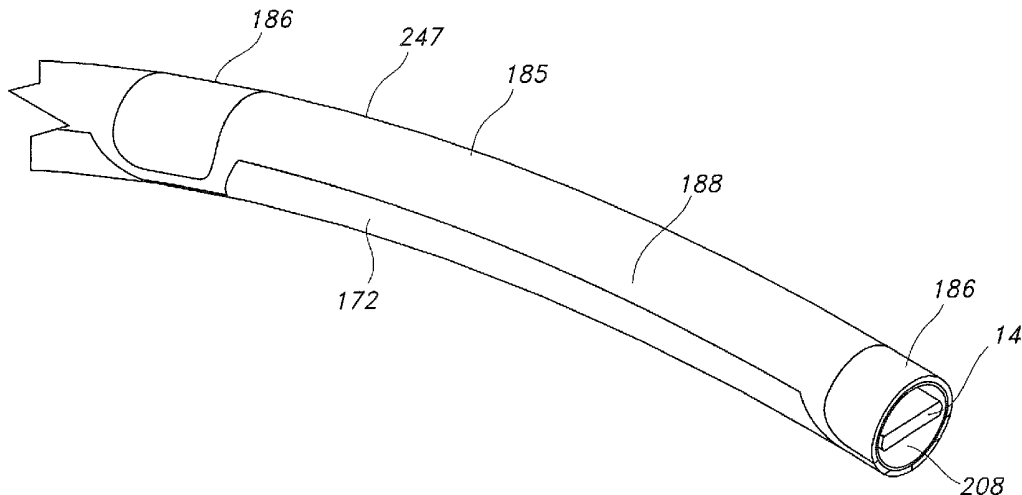
(57) **ABSTRACT**

A method for sensing multiple local electric voltages from endocardial surface of a heart, includes: providing a system for sensing multiple local electric voltages from endocardial surface of a heart, including: a first elongate tubular member having a lumen, a proximal end and a distal end; a basket assembly including: a plurality of flexible splines for guiding a plurality of exposed electrodes, the splines having proximal portions, distal portions and medial portions therein between, wherein the electrodes are substantially flat electrodes and are substantially unidirectionally oriented towards a direction outside of the basket.

(52) **U.S. Cl.**
CPC **A61B 5/0422** (2013.01); **A61B 5/042** (2013.01); **A61B 5/6858** (2013.01); (Continued)

(58) **Field of Classification Search**
CPC A61B 18/1492; A61B 5/0422; A61B 2018/0022; A61B 2018/00267; A61B

27 Claims, 44 Drawing Sheets



Related U.S. Application Data

- continuation of application No. 13/409,595, filed on Mar. 1, 2012, now Pat. No. 8,644,902.
- (60) Provisional application No. 61/555,190, filed on Nov. 3, 2011, provisional application No. 61/478,340, filed on Apr. 22, 2011.
- (51) **Int. Cl.**
A61B 5/00 (2006.01)
A61B 18/14 (2006.01)
A61N 1/00 (2006.01)
A61B 18/00 (2006.01)
- (52) **U.S. Cl.**
 CPC *A61B 5/6859* (2013.01); *A61B 18/1492* (2013.01); *A61B 2018/0016* (2013.01); *A61B 2018/00267* (2013.01); *A61B 2018/00351* (2013.01); *F04C 2270/0421* (2013.01); *Y10T 29/49117* (2015.01)
- (58) **Field of Classification Search**
 USPC 600/372-375, 381, 393, 509, 523; 606/41-50; 607/116, 119, 122
 See application file for complete search history.

5,279,299	A	1/1994	Imran
5,293,868	A	3/1994	Nardella
5,297,549	A	3/1994	Beatty et al.
5,309,910	A	5/1994	Edwards et al.
5,313,943	A	5/1994	Houser et al.
5,320,214	A	6/1994	Kordis
5,324,284	A	6/1994	Imran
5,327,889	A	7/1994	Imran
5,345,936	A *	9/1994	Pomeranz et al. 600/374
5,365,926	A	11/1994	Desai
5,383,917	A	1/1995	Desai et al.
5,397,339	A	3/1995	Desai
5,400,783	A	3/1995	Pomeranz et al.
5,404,638	A	4/1995	Imran
5,406,946	A	4/1995	Imran
5,409,000	A	4/1995	Imran
5,409,008	A	4/1995	Svenson et al.
5,411,025	A	5/1995	Webster, Jr.
5,425,364	A	6/1995	Imran
5,429,131	A	7/1995	Scheinman et al.
5,433,198	A	7/1995	Desai
5,454,370	A	10/1995	Avitall
5,465,717	A	11/1995	Imran et al.
5,471,982	A	12/1995	Edwards et al.
5,476,495	A	12/1995	Kordis et al.
5,482,037	A	1/1996	Borghi
5,487,391	A	1/1996	Panesco
5,499,981	A	3/1996	Kordis
5,500,011	A	3/1996	Desai
5,509,419	A	4/1996	Edwards et al.
5,526,810	A	6/1996	Wang
5,549,108	A	8/1996	Edwards et al.
5,549,661	A	8/1996	Kordis et al.
5,555,883	A	9/1996	Avitall
5,558,073	A	9/1996	Pomeranz et al.
5,571,164	A	11/1996	Ekwall et al.
5,575,810	A	11/1996	Swanson et al.
5,578,007	A	11/1996	Imran
5,628,313	A	5/1997	Webster, Jr.
5,636,634	A	6/1997	Kordis et al.
5,647,870	A	7/1997	Kordis et al.
5,657,755	A	8/1997	Desai
5,662,108	A	9/1997	Budd et al.
5,681,308	A	10/1997	Edwards et al.
5,687,737	A	11/1997	Branham et al.
5,722,401	A	3/1998	Pietroski et al.
5,725,525	A	3/1998	Kordis
5,730,128	A	3/1998	Pomeranz et al.
5,730,704	A	3/1998	Avitall
5,757,810	A	5/1998	Fall
5,782,239	A	7/1998	Webster, Jr.
5,782,899	A	7/1998	Imran
5,785,706	A	7/1998	Bednarek
RE35,880	E	8/1998	Waldman et al.
5,819,740	A	10/1998	Muhlenberg
5,823,189	A	10/1998	Kordis
5,836,947	A	11/1998	Fleischman et al.
5,846,196	A	12/1998	Siekmeyer et al.
5,846,238	A	12/1998	Jackson et al.
5,848,972	A	12/1998	Triedman et al.
5,853,411	A	12/1998	Whayne et al.
5,871,443	A	2/1999	Edwards et al.
5,881,727	A	3/1999	Edwards
5,891,135	A	4/1999	Jackson et al.
5,891,136	A	4/1999	McGee et al.
5,893,847	A	4/1999	Kordis
5,904,680	A	5/1999	Kordis et al.
5,911,739	A	6/1999	Kordis et al.
5,925,038	A	7/1999	Panesco et al.
5,928,228	A	7/1999	Kordis et al.
5,964,753	A	10/1999	Edwards
5,968,040	A	10/1999	Swanson et al.
6,014,579	A	1/2000	Pomeranz et al.
6,014,590	A	1/2000	Whayne et al.
6,016,437	A	1/2000	Tu et al.
6,021,345	A	2/2000	Karagueuzian et al.
6,052,607	A	4/2000	Edwards et al.
6,064,905	A	5/2000	Webster, Jr. et al.
6,088,614	A	7/2000	Swanson

(56) **References Cited**

U.S. PATENT DOCUMENTS

3,557,794	A	1/1971	Van Patten
3,825,015	A	7/1974	Berkovits
3,865,118	A	2/1975	Bures
3,903,897	A	9/1975	Woollons et al.
3,995,623	A	12/1976	Blake et al.
4,172,451	A	10/1979	Kline
4,254,766	A	3/1981	Kordis
4,281,660	A	8/1981	Fujiwara
4,289,138	A	9/1981	Halvorsen
4,360,031	A	11/1982	White
4,522,212	A	6/1985	Gelinas et al.
4,555,157	A	11/1985	Johnson et al.
4,573,473	A	3/1986	Hess
4,628,937	A	12/1986	Hess et al.
4,638,802	A	1/1987	Okada
4,641,649	A	2/1987	Walinsky et al.
4,649,924	A	3/1987	Taccardi
4,660,571	A	4/1987	Hess et al.
4,664,120	A	5/1987	Hess
4,677,990	A	7/1987	Neubauer
4,682,596	A	7/1987	Bales et al.
4,690,148	A	9/1987	Hess
4,699,147	A	10/1987	Chilson et al.
4,785,815	A	11/1988	Cohen
4,869,248	A	9/1989	Narula
4,882,777	A	11/1989	Narula
4,920,980	A	5/1990	Jackowski
4,922,912	A	5/1990	Watanabe
4,940,064	A	7/1990	Desai
4,960,134	A	10/1990	Webster, Jr.
4,976,710	A	12/1990	Mackin
5,010,894	A	4/1991	Edhag
5,041,973	A	8/1991	Lebron et al.
5,056,517	A	10/1991	Fenici
5,059,205	A	10/1991	El-Nounou et al.
5,078,717	A	1/1992	Parins et al.
5,117,828	A	6/1992	Metzger et al.
5,156,151	A	10/1992	Imran
5,215,103	A	6/1993	Desai
5,228,442	A	7/1993	Imran
5,231,995	A	8/1993	Desai
5,237,996	A	8/1993	Waldman et al.
5,239,999	A	8/1993	Imran
5,242,462	A	9/1993	El-Nounou et al.
5,255,679	A	10/1993	Imran
5,263,493	A	11/1993	Avitall

(56)

References Cited

U.S. PATENT DOCUMENTS

6,142,994 A 11/2000 Swanson et al.
 6,152,920 A 11/2000 Thompson et al.
 6,163,716 A 12/2000 Edwards et al.
 6,165,169 A 12/2000 Panescu et al.
 6,216,043 B1 4/2001 Swanson et al.
 6,216,044 B1 4/2001 Kordis
 6,224,612 B1 5/2001 Bates et al.
 6,233,491 B1 5/2001 Kordis et al.
 6,360,128 B2 3/2002 Kordis et al.
 6,400,981 B1 6/2002 Govari
 6,402,740 B1 6/2002 Ellis et al.
 6,428,536 B2 8/2002 Panescu et al.
 6,460,545 B2 10/2002 Kordis
 6,466,811 B1 10/2002 Hassett
 6,480,747 B2 11/2002 Schmidt
 6,522,905 B2 2/2003 Desai
 6,542,773 B2 4/2003 Dupree et al.
 6,615,073 B1 9/2003 Panescu et al.
 6,647,281 B2 11/2003 Morency
 6,647,617 B1 11/2003 Beatty et al.
 6,728,575 B2 4/2004 Hedberg
 6,728,579 B1 4/2004 Lindgren et al.
 6,738,655 B1 5/2004 Sen et al.
 6,738,673 B2 5/2004 Desai
 6,788,969 B2 9/2004 Dupree et al.
 6,799,064 B1 9/2004 Hassett
 6,805,131 B2 10/2004 Kordis
 6,826,420 B1 11/2004 Beatty et al.
 6,837,886 B2 1/2005 Collins et al.
 6,839,588 B1 1/2005 Rudy
 6,892,087 B2 5/2005 Osypka
 6,895,267 B2 5/2005 Panescu et al.
 6,944,490 B1 9/2005 Chow
 6,950,689 B1 9/2005 Willis et al.
 6,950,696 B2 9/2005 Bjorling et al.
 6,960,207 B2 11/2005 Vanney et al.
 6,970,730 B2 11/2005 Fuimaono et al.
 6,984,232 B2 1/2006 Vanney et al.
 6,990,370 B1 1/2006 Beatty et al.
 7,149,563 B2* 12/2006 Fuimaono A61B 5/0402
 128/899

7,184,811 B2 2/2007 Phan et al.
 7,189,208 B1 3/2007 Beatty et al.
 7,229,450 B1 6/2007 Chitre et al.
 7,245,973 B2 7/2007 Liu et al.
 7,289,843 B2 10/2007 Beatty et al.
 7,306,594 B2 12/2007 Collins et al.
 7,311,704 B2 12/2007 Paul et al.
 7,326,204 B2 2/2008 Paul et al.
 7,326,206 B2 2/2008 Paul et al.
 7,326,208 B2 2/2008 Vanney et al.
 7,331,959 B2 2/2008 Cao et al.
 7,338,436 B1 3/2008 Snell et al.
 7,416,552 B2 8/2008 Paul et al.
 7,419,489 B2 9/2008 Vanney et al.
 7,474,909 B2 1/2009 Phan et al.
 7,504,172 B2 3/2009 Irvine et al.
 7,505,810 B2 3/2009 Harlev et al.
 7,515,954 B2 4/2009 Harlev et al.
 7,526,342 B2 4/2009 Chin et al.

7,606,609 B2 10/2009 Muranushi et al.
 7,632,265 B2 12/2009 Hauck et al.
 RE41,334 E 5/2010 Beatty et al.
 7,715,604 B2 5/2010 Sun et al.
 7,729,752 B2 6/2010 Harlev et al.
 7,776,034 B2 8/2010 Kampa
 7,789,877 B2 9/2010 Vanney
 7,819,866 B2 10/2010 Bednarek
 7,822,484 B1* 10/2010 Zhao et al. 607/116
 7,826,881 B1 11/2010 Beatty et al.
 7,857,810 B2 12/2010 Wang et al.
 7,930,018 B2 4/2011 Harlev et al.
 7,953,475 B2 5/2011 Harlev et al.
 8,007,495 B2 8/2011 McDaniel et al.
 8,165,666 B1 4/2012 Briggs et al.
 8,167,845 B2 5/2012 Wang et al.
 8,224,431 B2 7/2012 Drew
 8,315,709 B2 11/2012 Corndorf
 8,489,171 B2 7/2013 Hauck et al.
 8,560,086 B2 10/2013 Just et al.
 8,588,885 B2 11/2013 Hall et al.
 2009/0171274 A1 7/2009 Harlev et al.
 2009/0264745 A1 10/2009 Markowitz et al.
 2010/0076426 A1 3/2010 De La Rama et al.
 2010/0094274 A1 4/2010 Narayan et al.
 2010/0274150 A1 10/2010 Harlev et al.
 2011/0251505 A1 10/2011 Narayan et al.
 2012/0184858 A1 7/2012 Harlev et al.
 2013/0006131 A1 1/2013 Narayan et al.
 2013/0150740 A1 6/2013 Narayan et al.
 2013/0150742 A1 6/2013 Briggs et al.
 2013/0172715 A1 7/2013 Just et al.
 2013/0172883 A1* 7/2013 Lopes A61B 5/6858
 606/41

2013/0178850 A1 7/2013 Lopes et al.
 2013/0190587 A1 7/2013 Lopes et al.
 2013/0197513 A1 8/2013 Lopes et al.
 2013/0296729 A1 11/2013 Datta
 2013/0304065 A1 11/2013 Lopes et al.
 2013/0345537 A1 12/2013 Thakur et al.
 2014/0018656 A1 1/2014 Hauck et al.
 2014/0025069 A1 1/2014 Willard et al.
 2014/0052120 A1 2/2014 Benscoter et al.
 2014/0088591 A1 3/2014 Just et al.

FOREIGN PATENT DOCUMENTS

EP 2641534 A1 9/2013
 WO 2013112844 A2 8/2013

OTHER PUBLICATIONS

U.S. Appl. No. 61/481,512 to Sanjiv Narayan et al., filed May 2, 2011.
 U.S. Appl. No. 61/481,607 to Carey Robert Briggs et al., filed May 2, 2011.
 U.S. Appl. No. 61/569,132 to Sanjiv Narayan et al., filed Dec. 9, 2011.
 U.S. Appl. No. 13/217,123 to Carey Robert Briggs et al., filed Aug. 24, 2011.

* cited by examiner

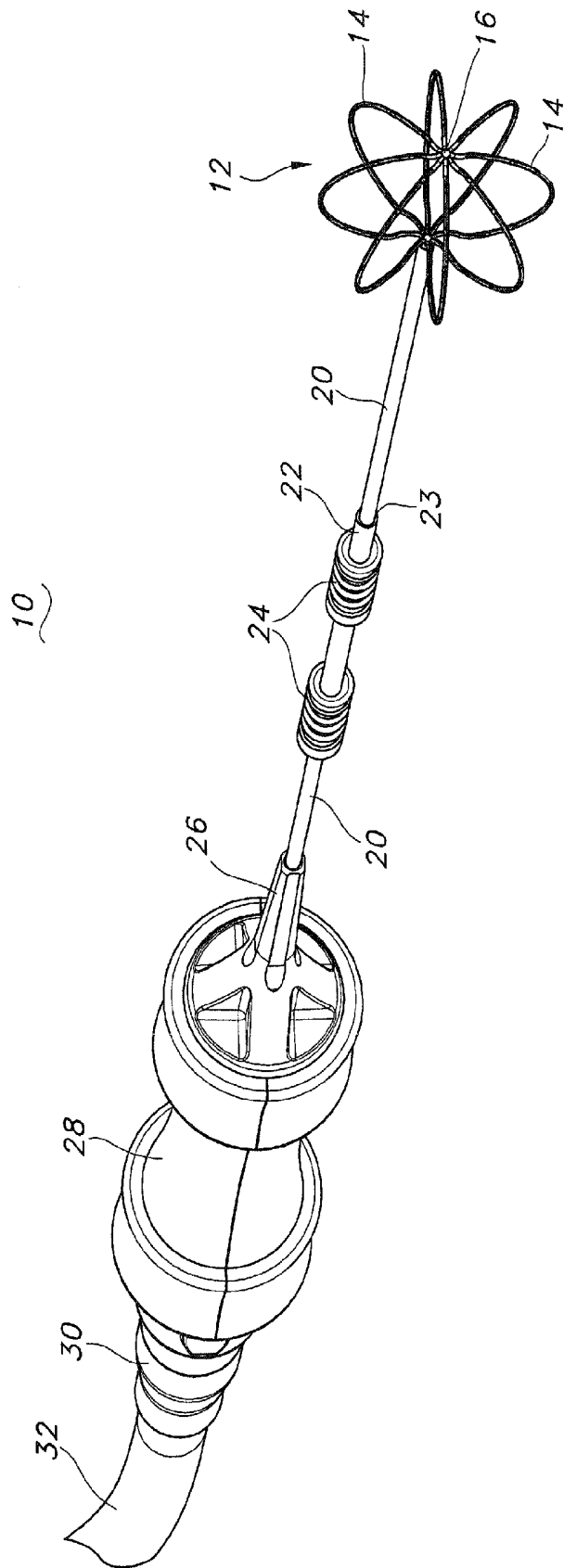


FIG. 1

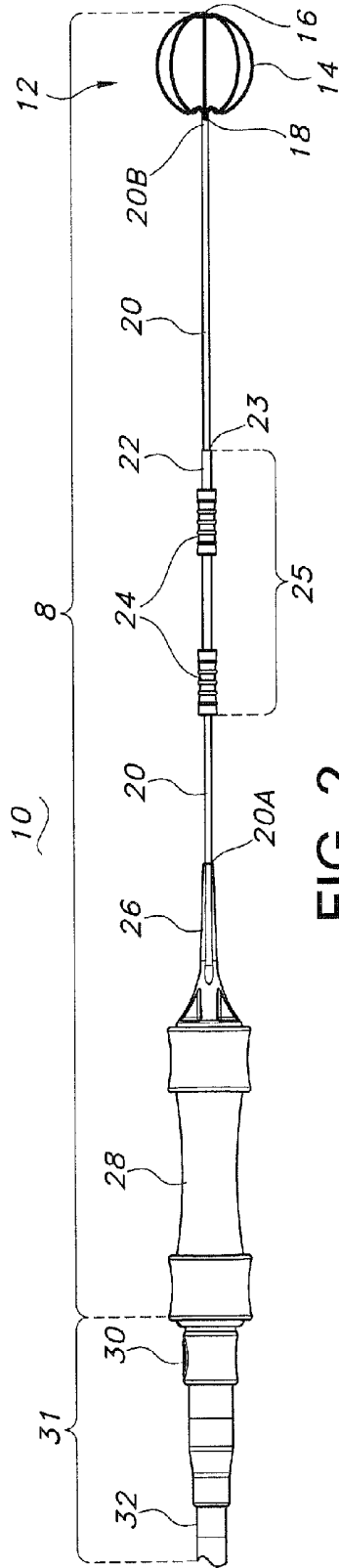


FIG. 2

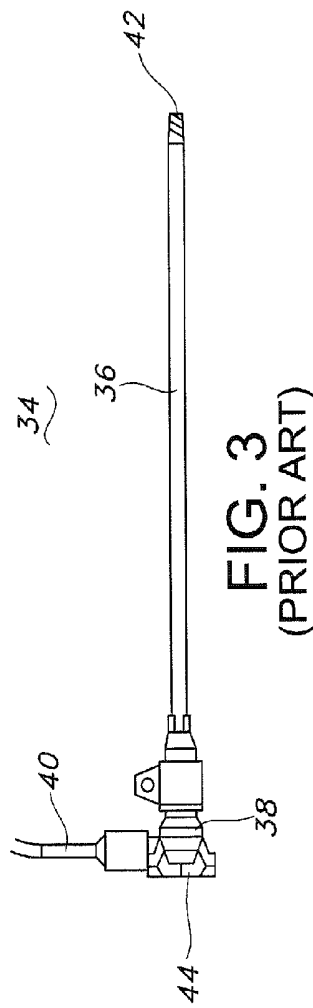


FIG. 3
(PRIOR ART)

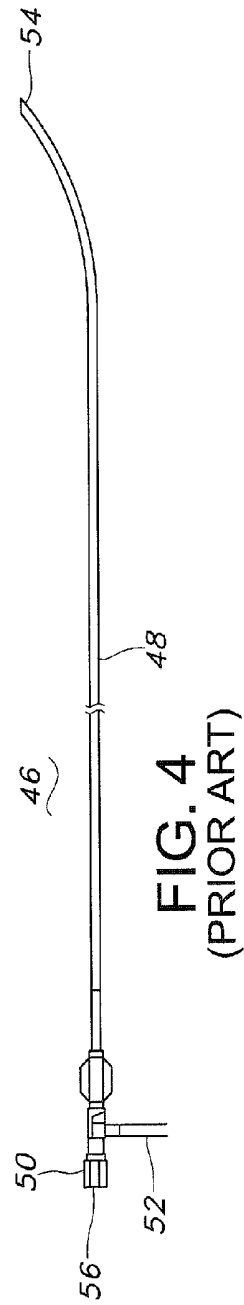


FIG. 4
(PRIOR ART)

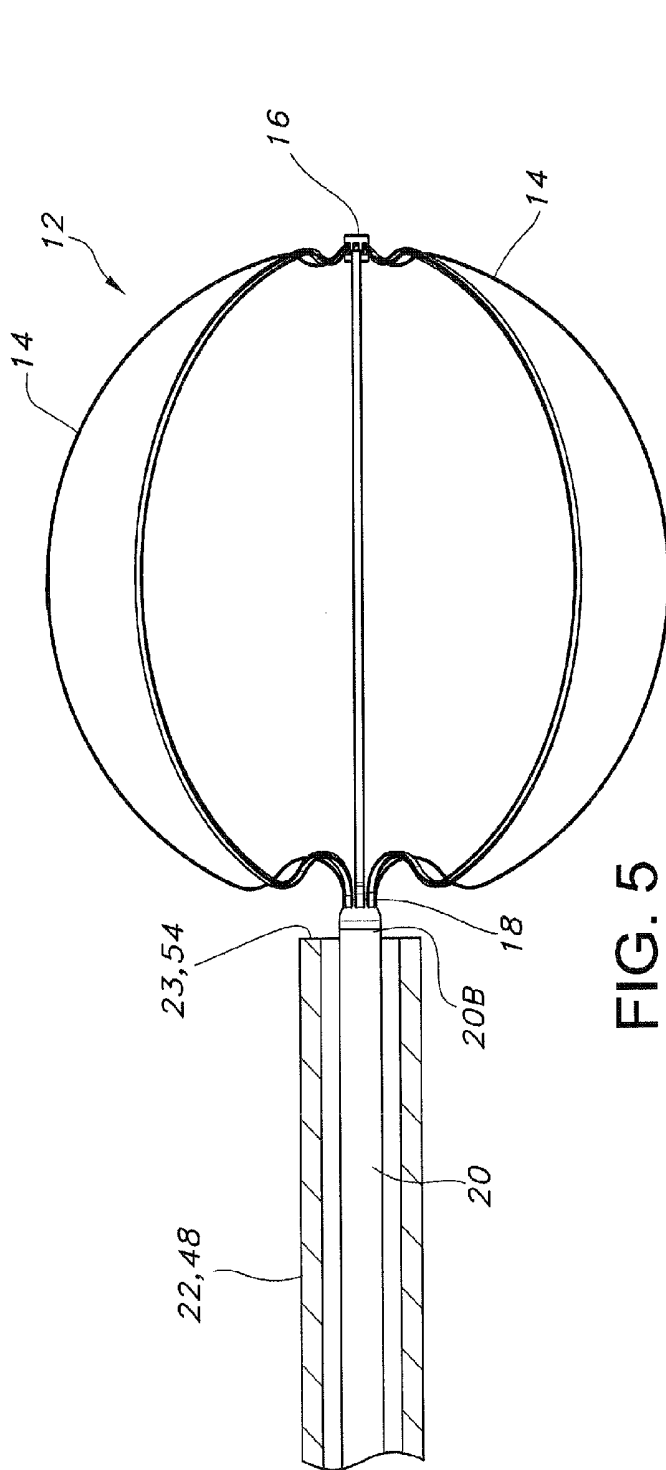


FIG. 5

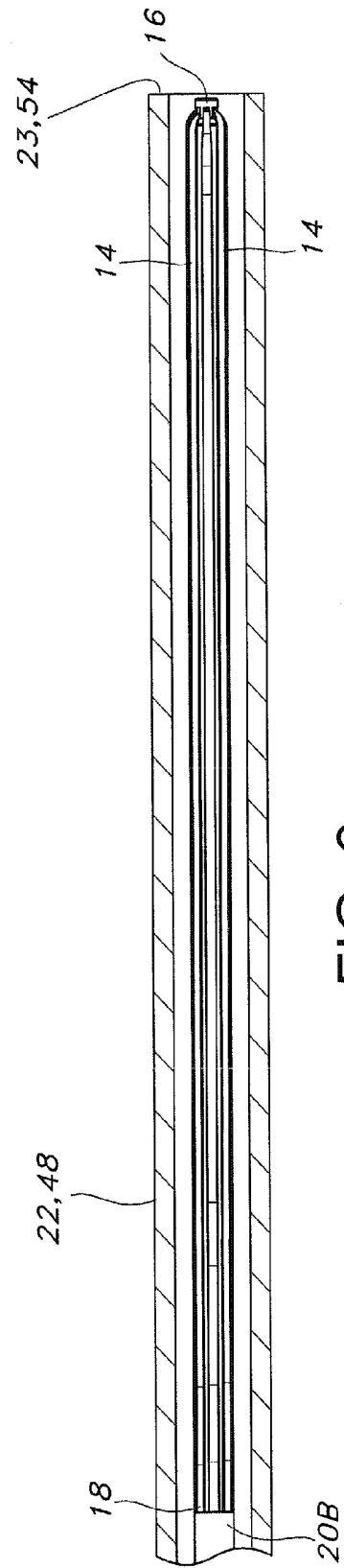


FIG. 6

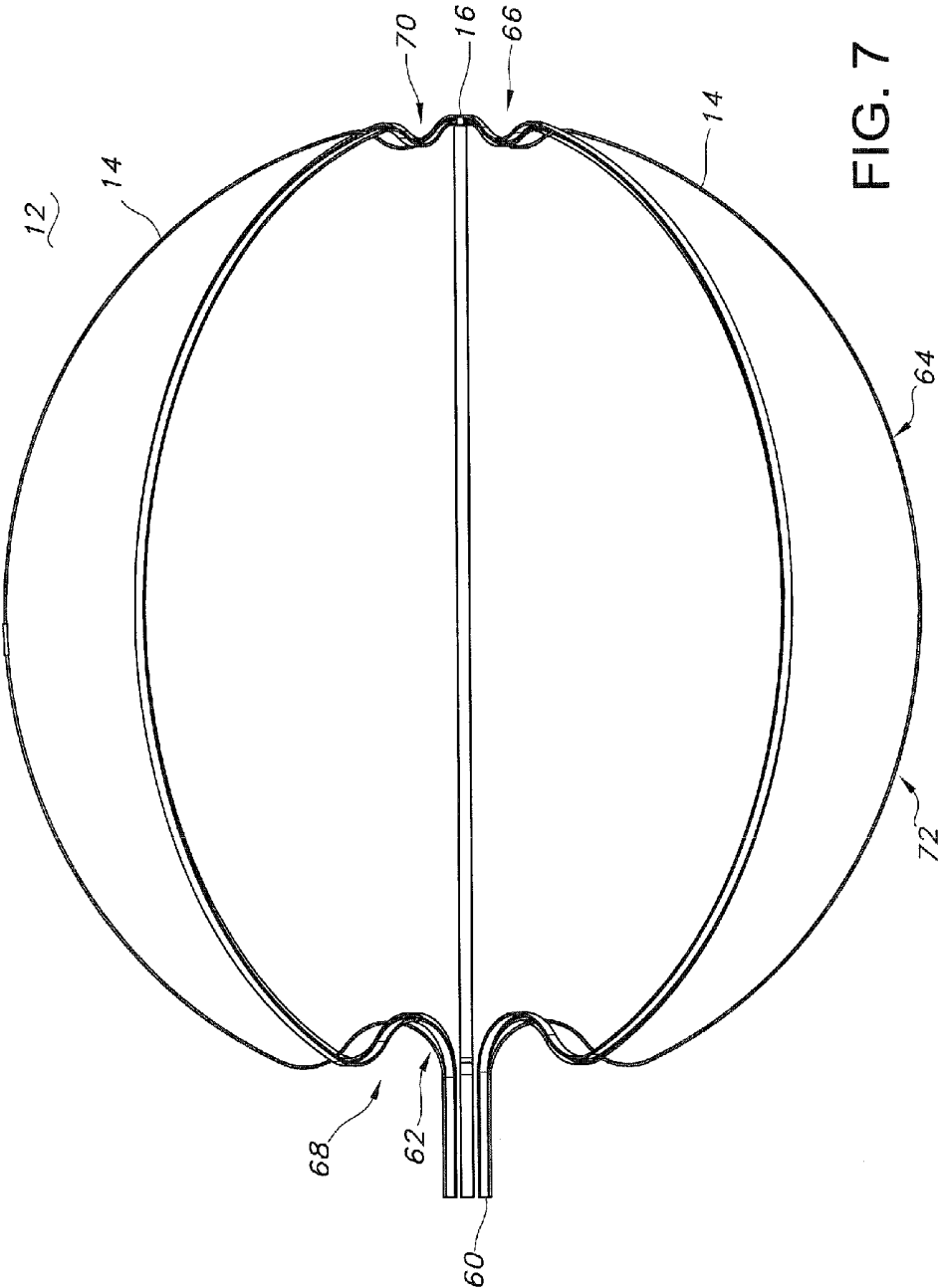


FIG. 7

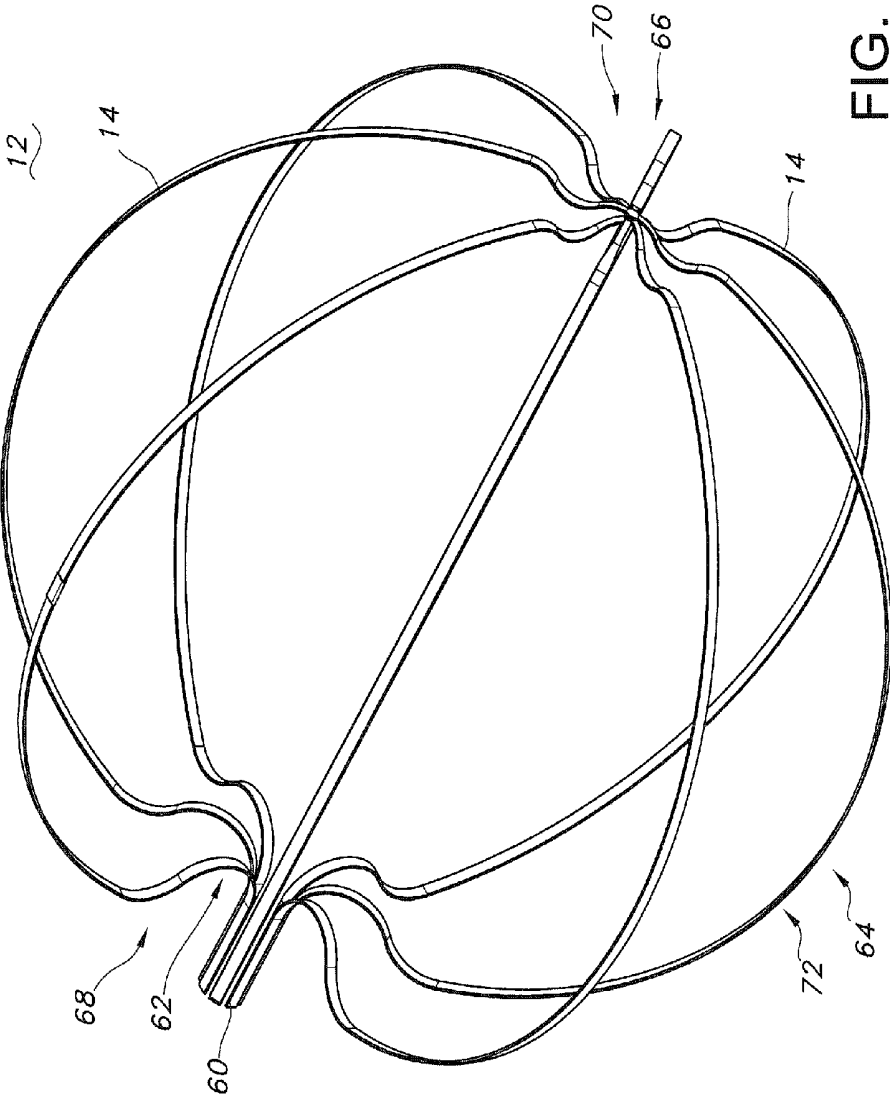
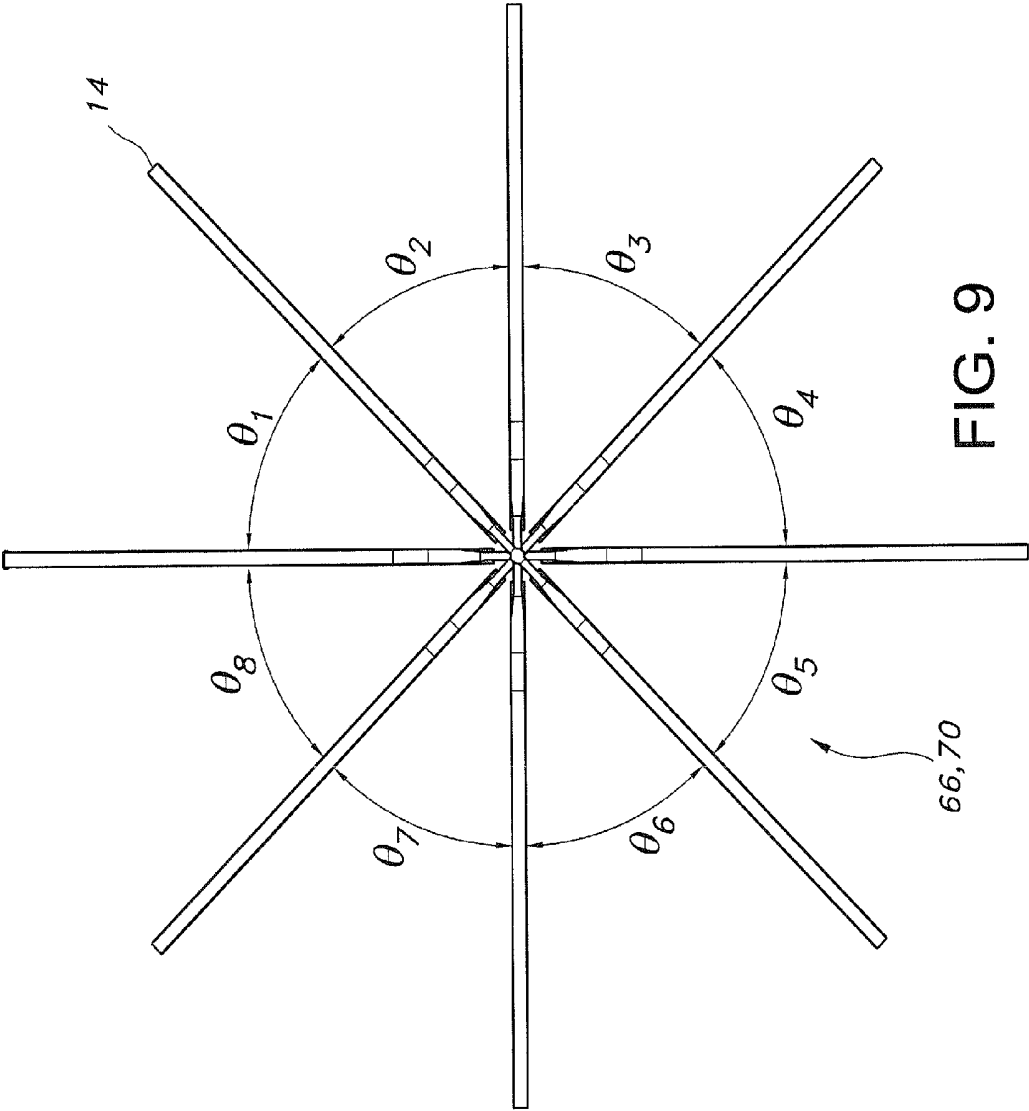


FIG. 8



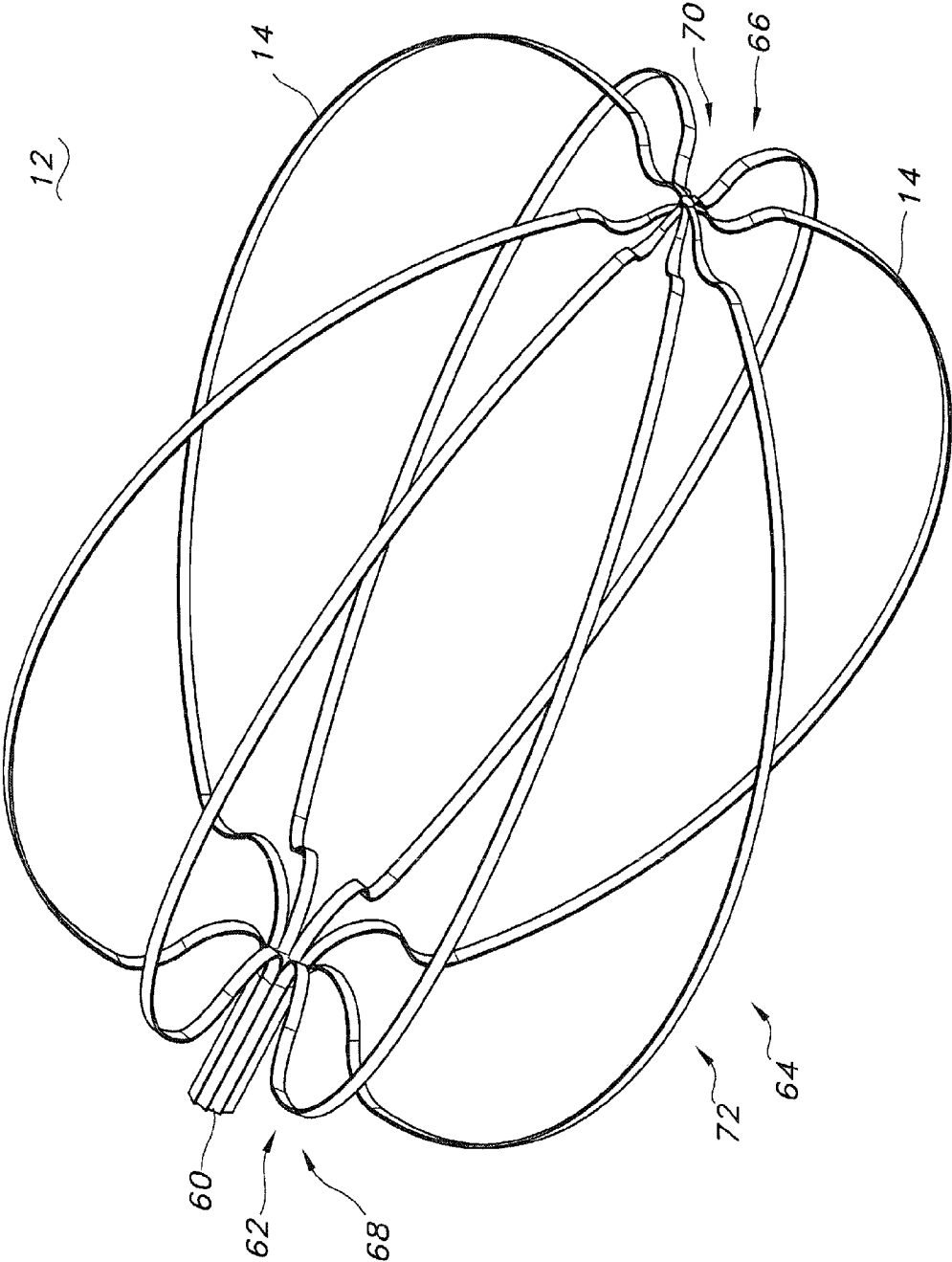


FIG. 10

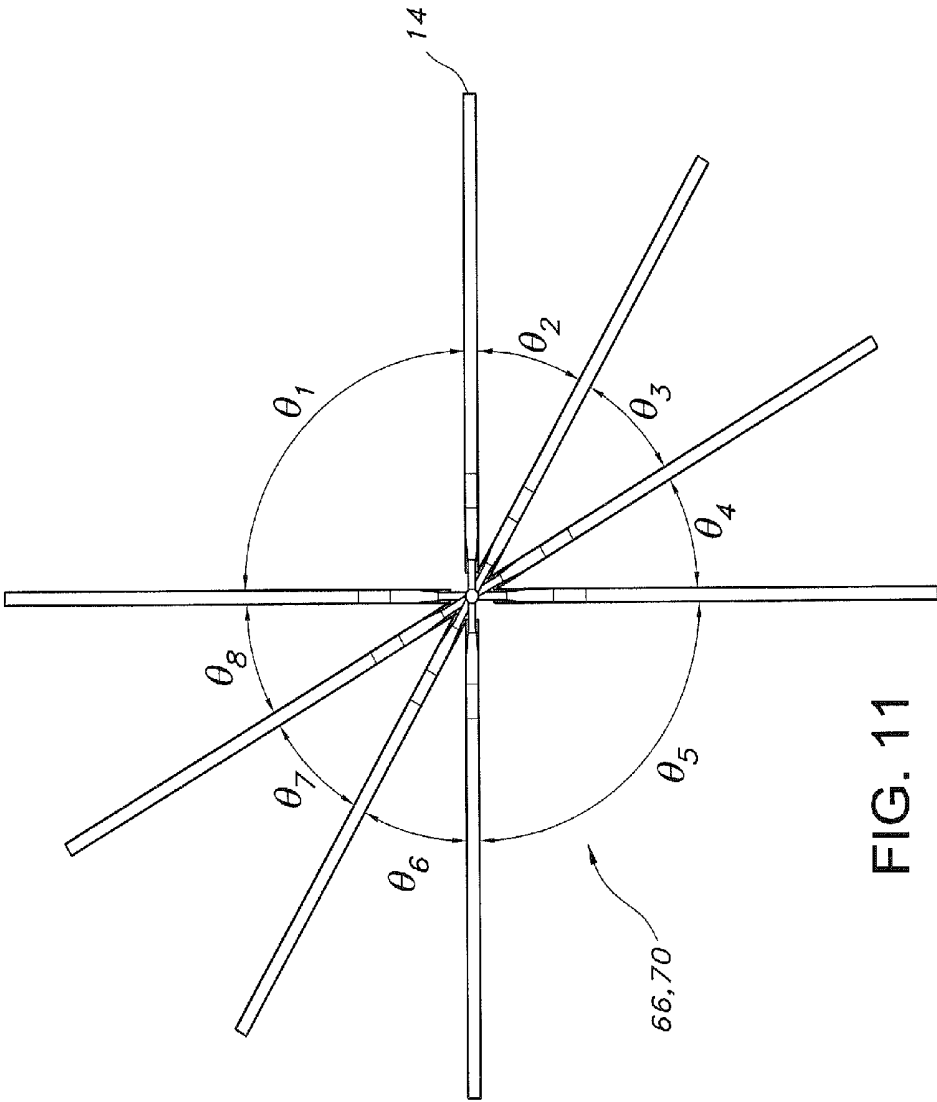


FIG. 11

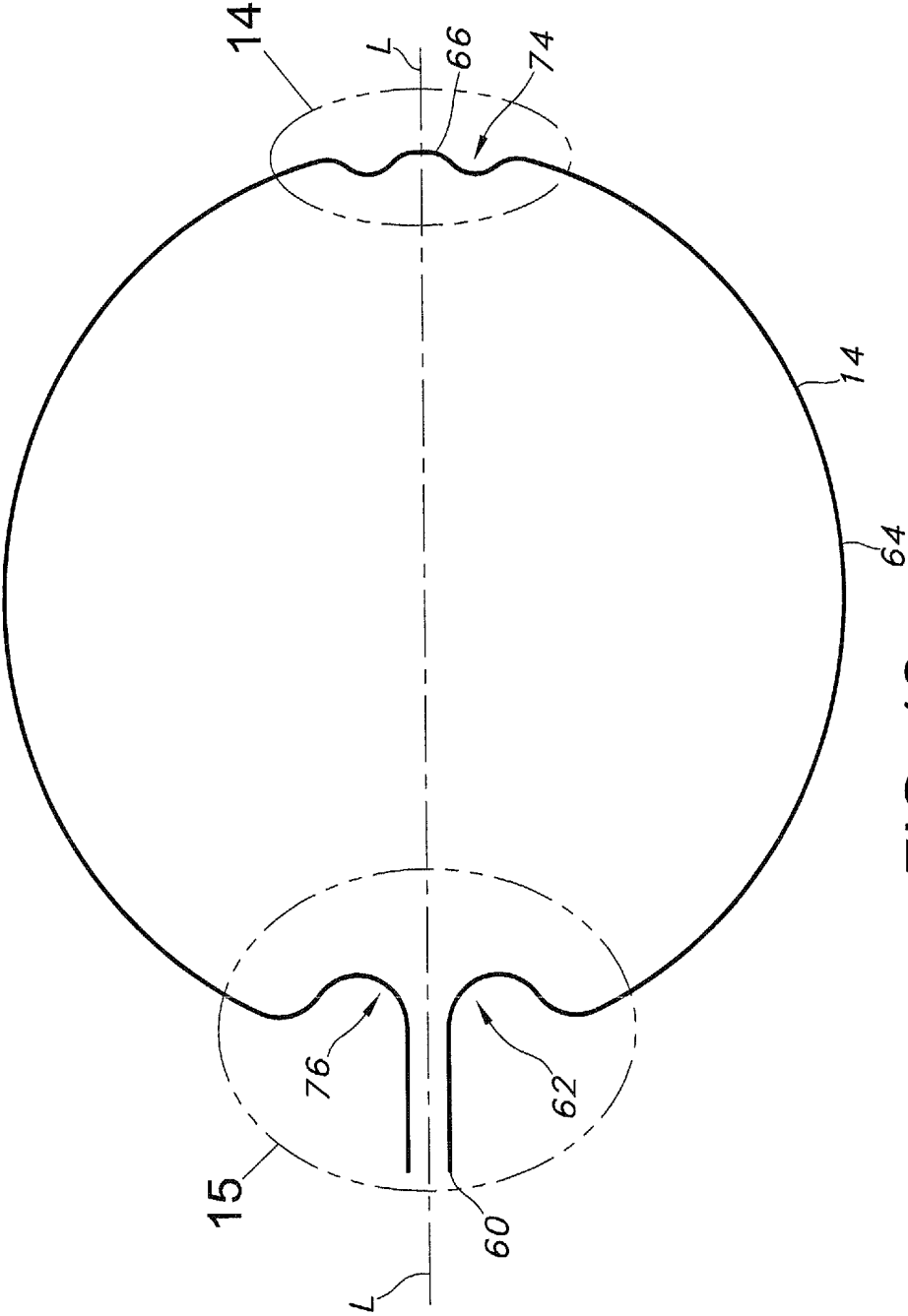


FIG. 12

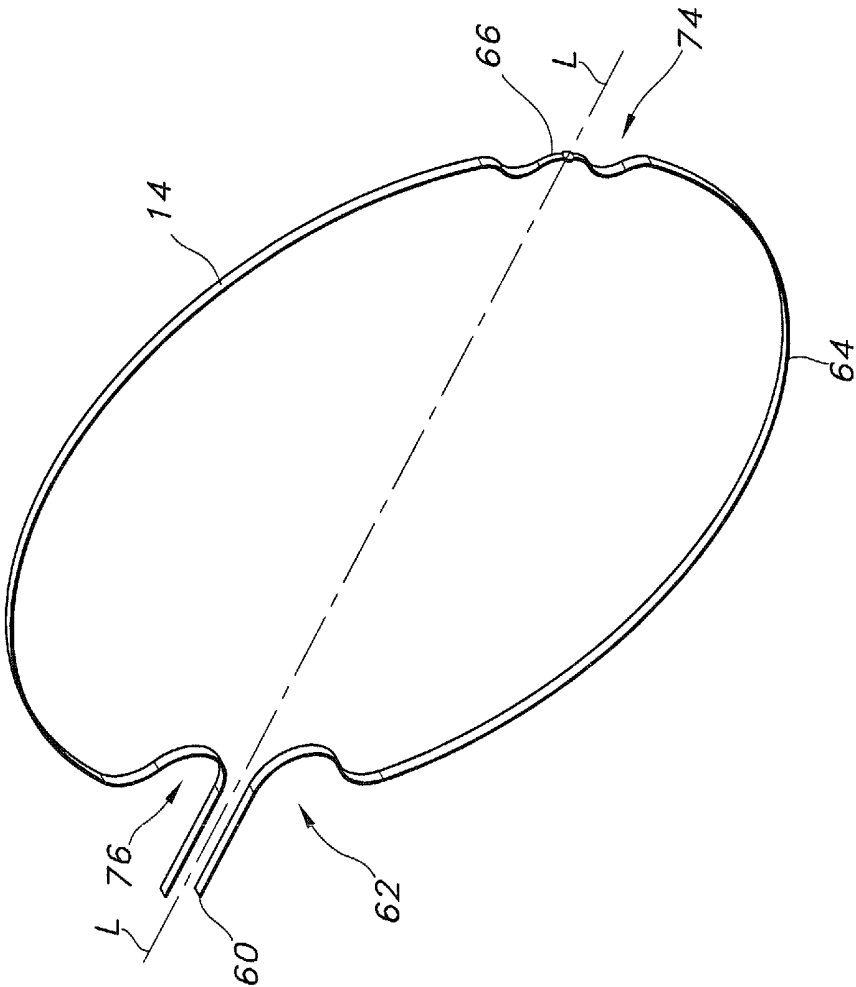


FIG. 13

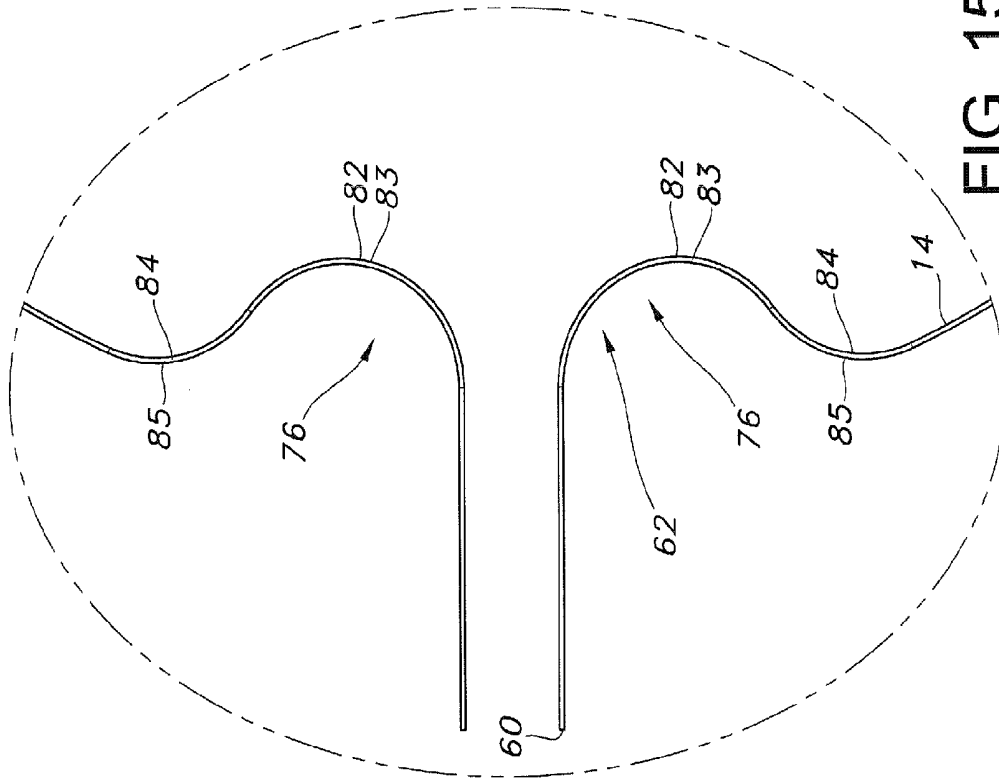


FIG. 15

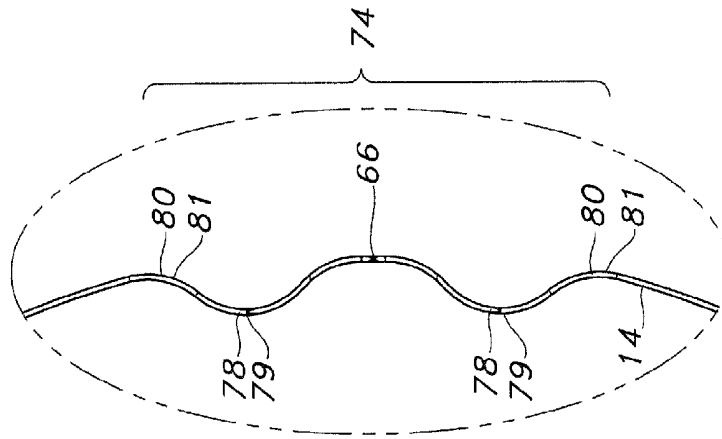


FIG. 14

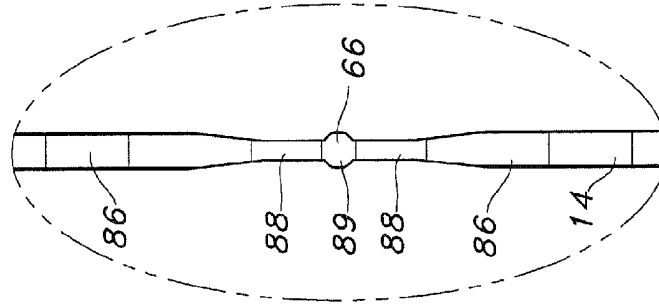


FIG. 16

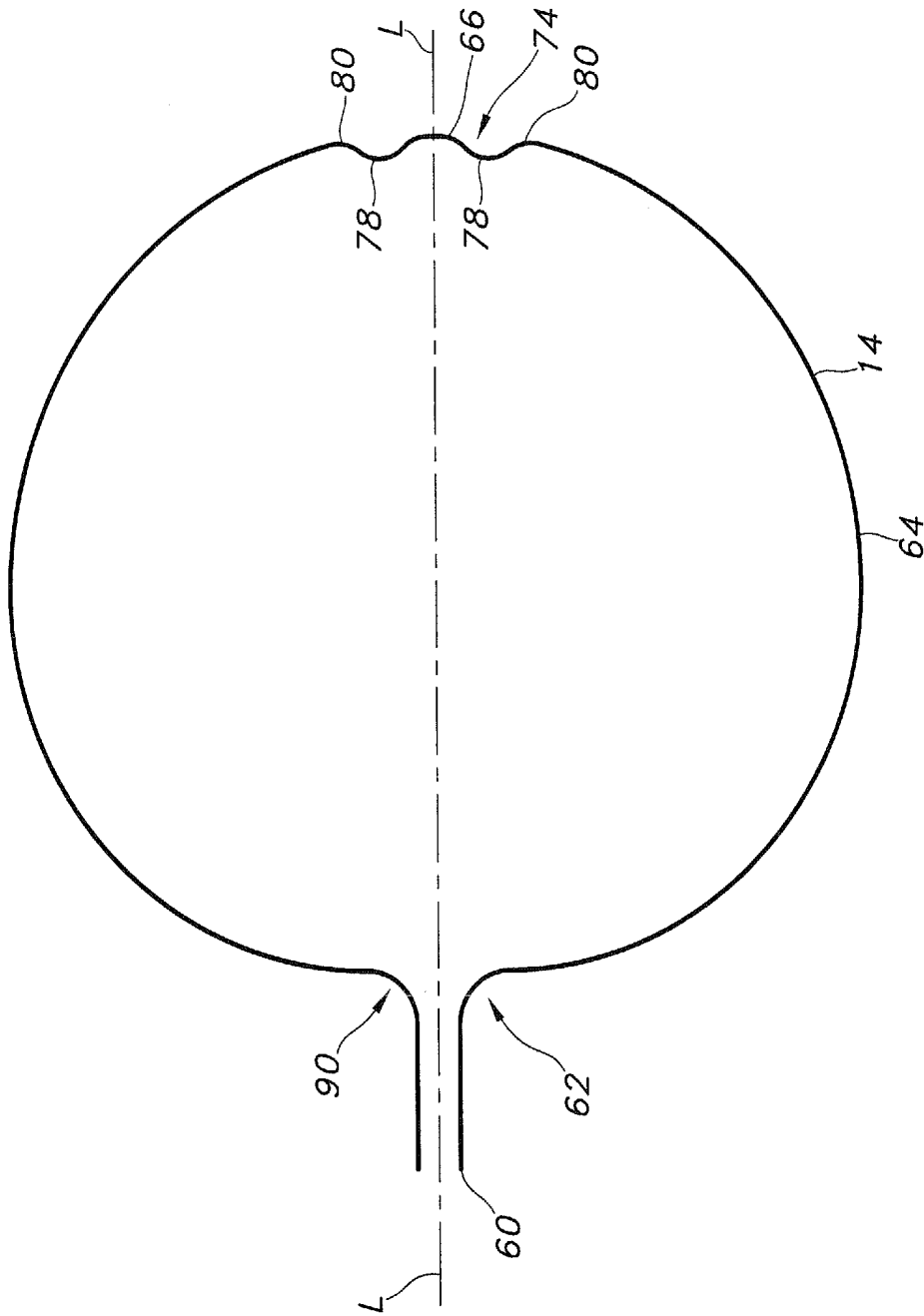
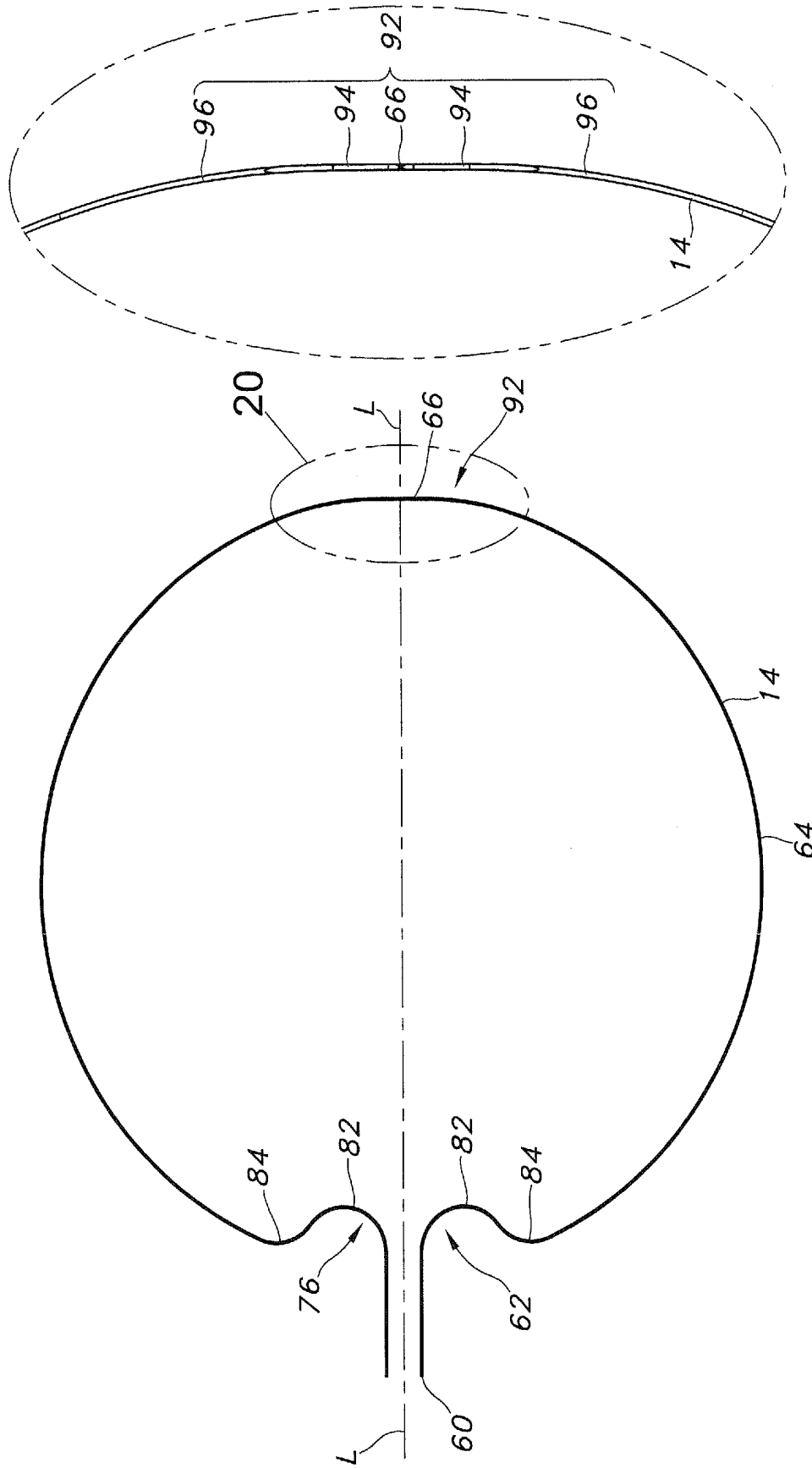


FIG. 17



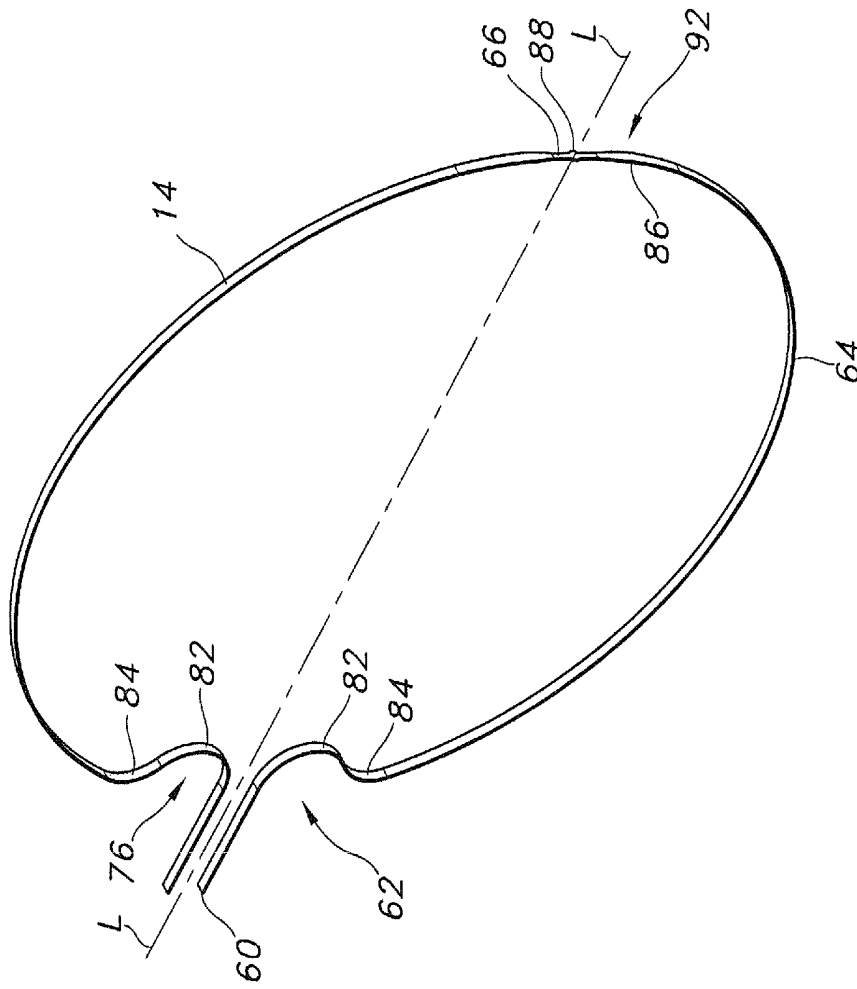


FIG. 19

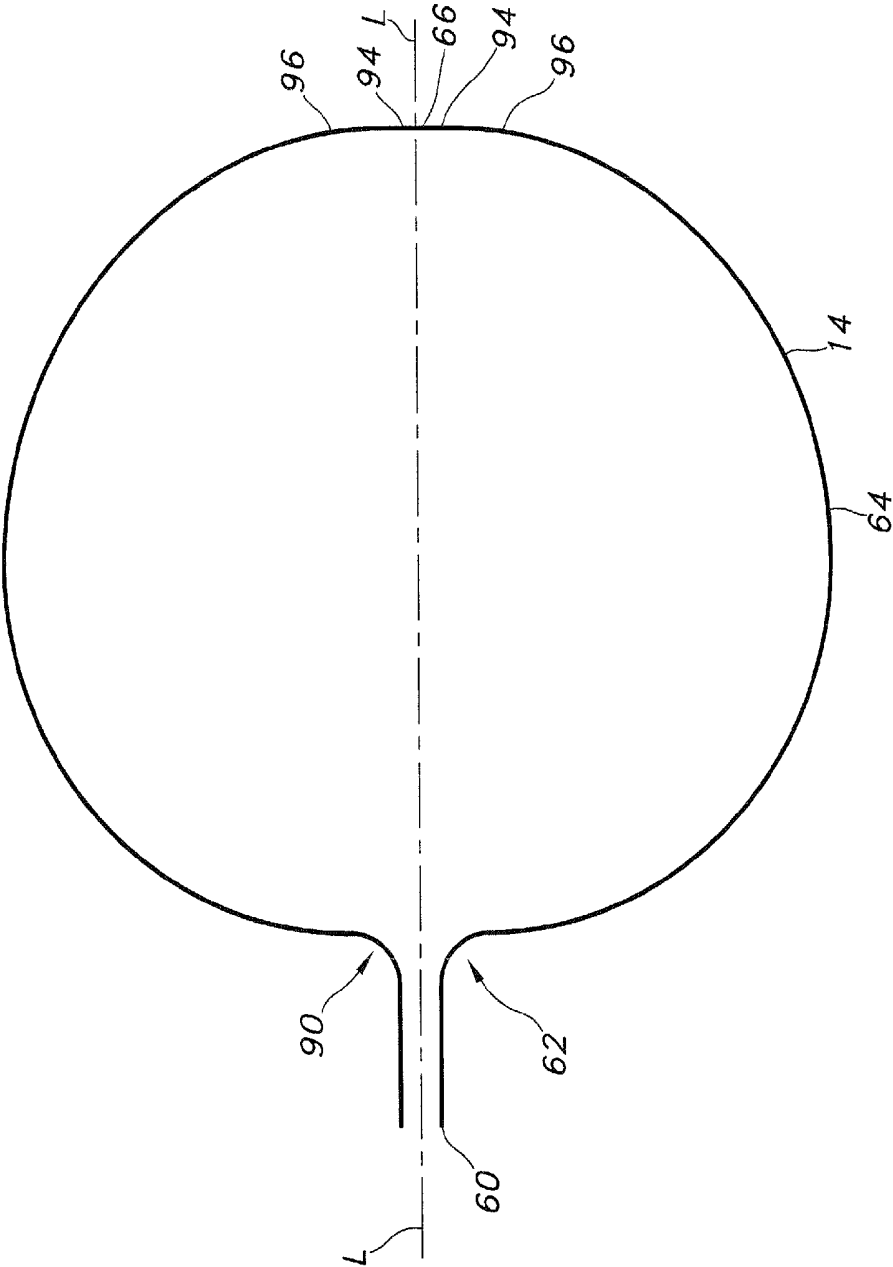
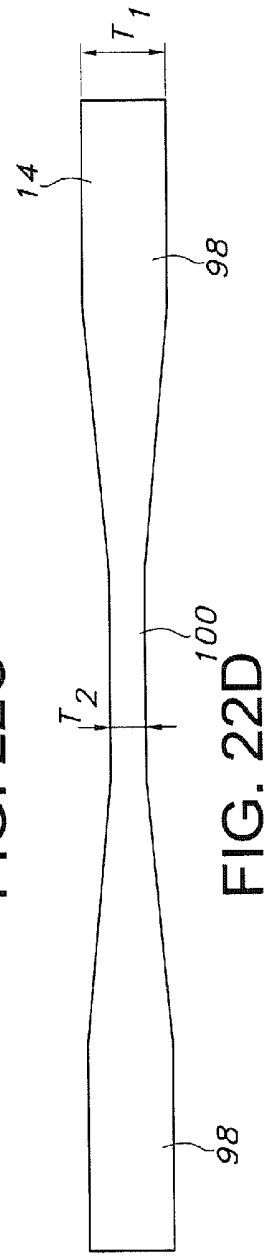
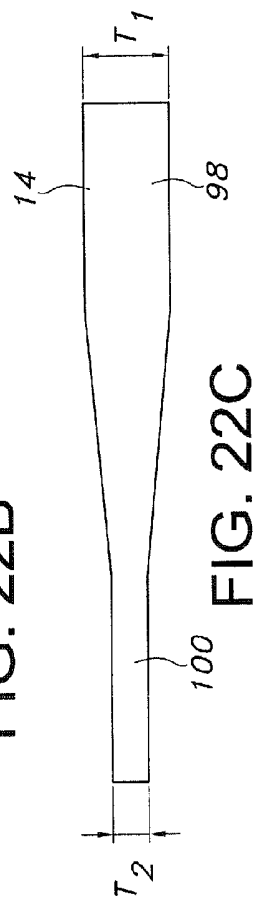
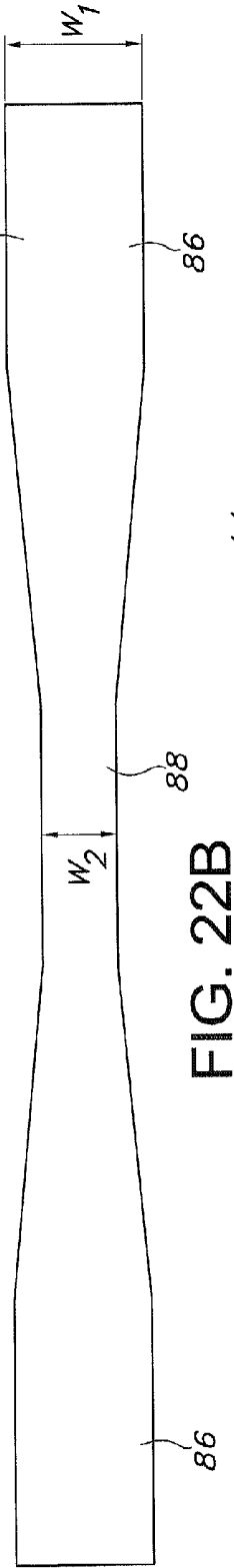
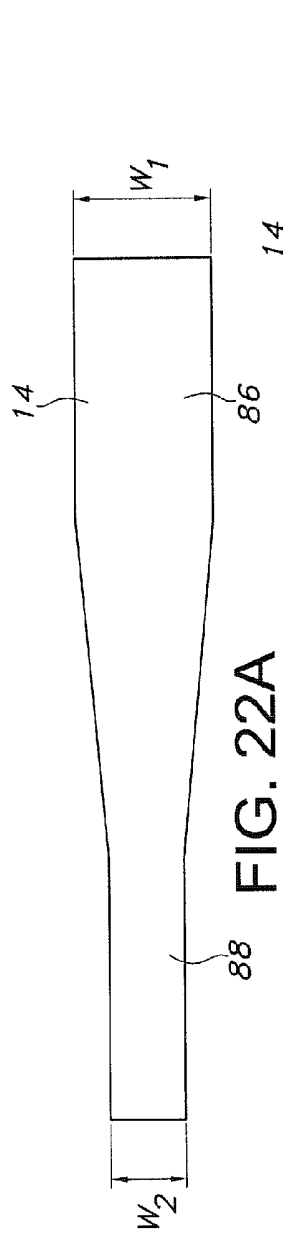


FIG. 21



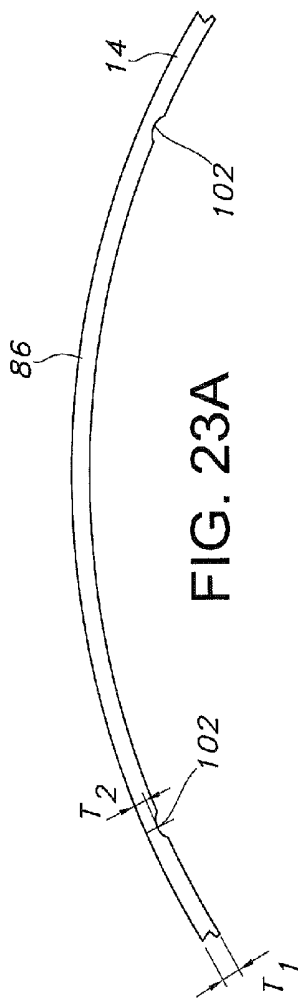


FIG. 23A

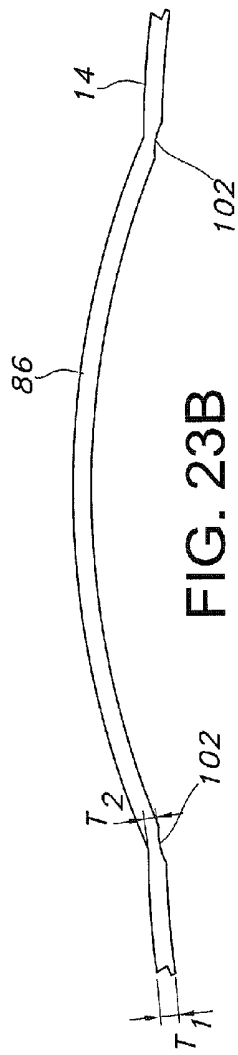


FIG. 23B

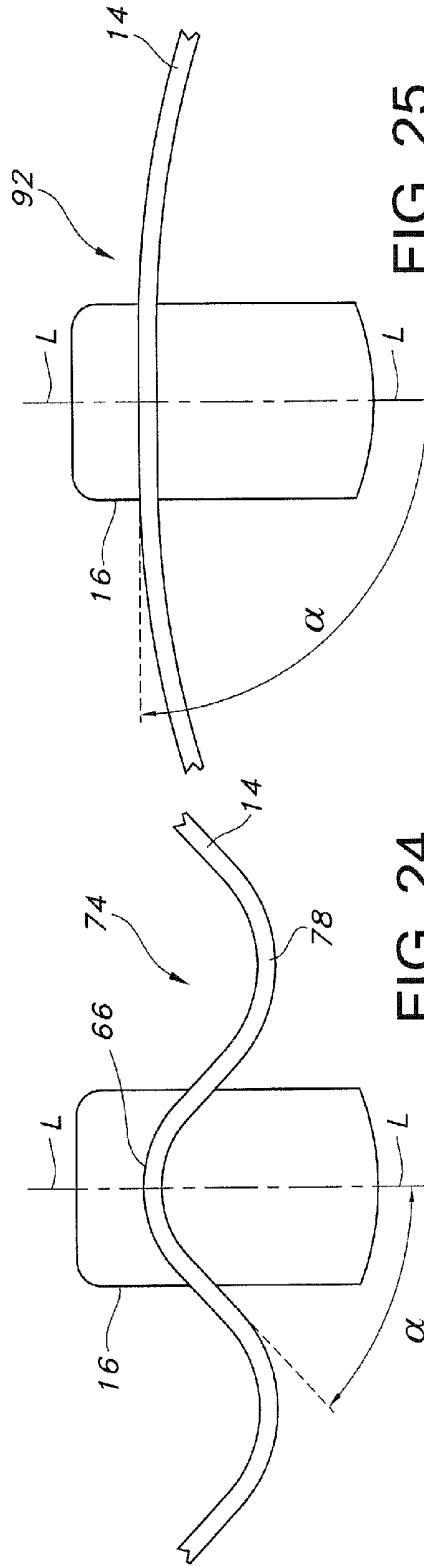


FIG. 24

FIG. 25

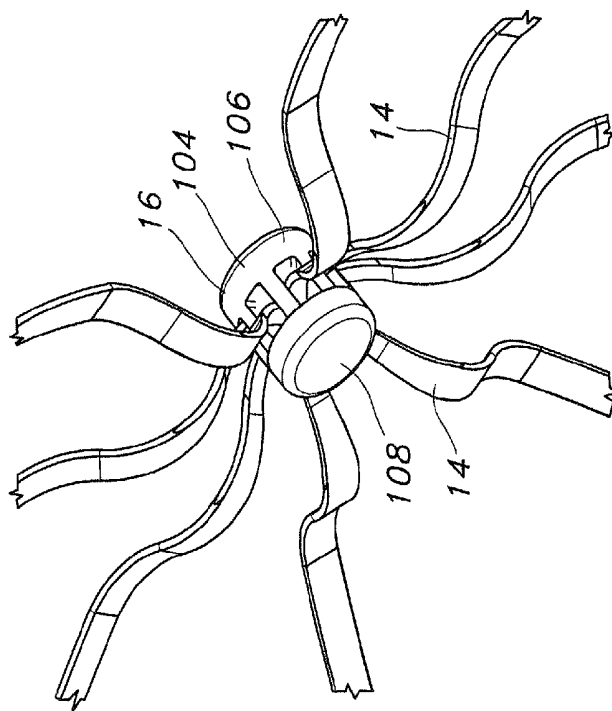


FIG. 26B

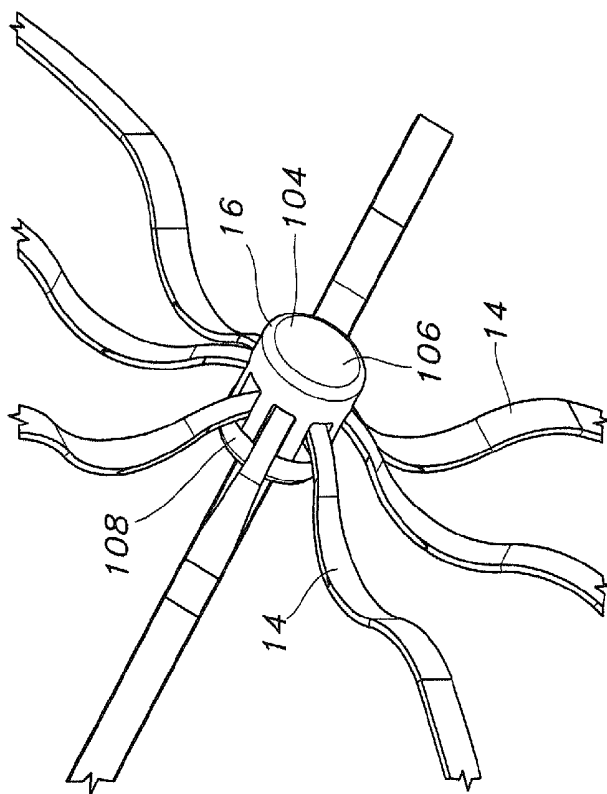


FIG. 26A

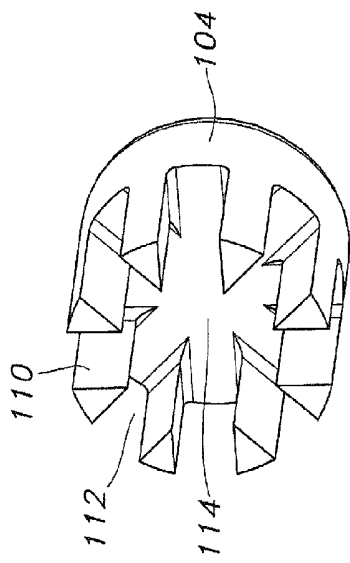


FIG. 26C

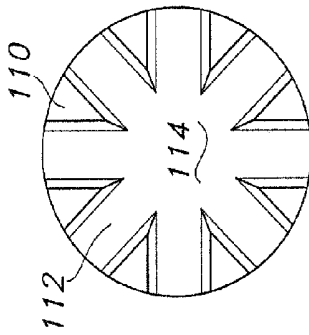


FIG. 26D

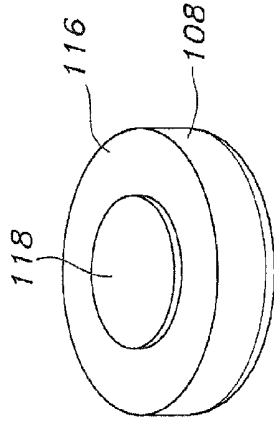


FIG. 26E

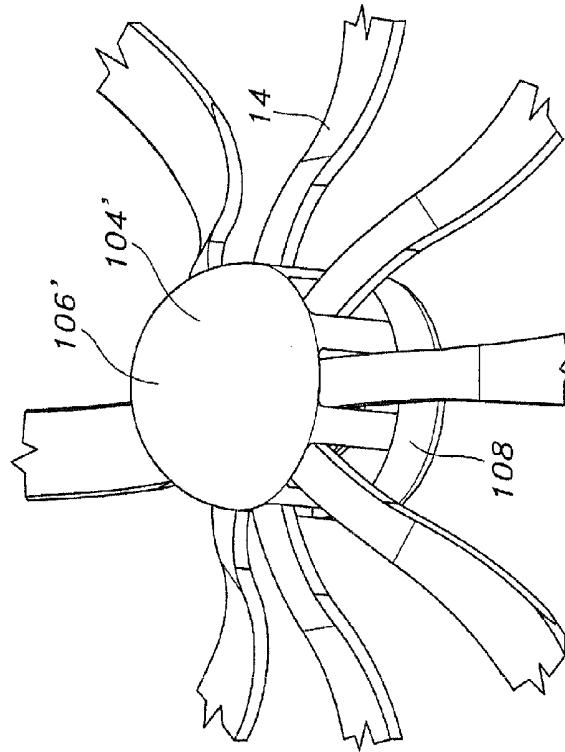


FIG. 26F

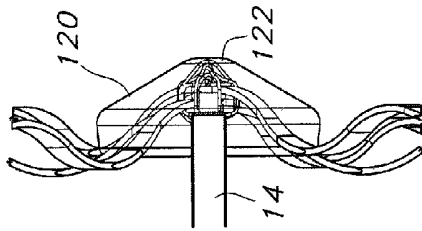


FIG. 27B

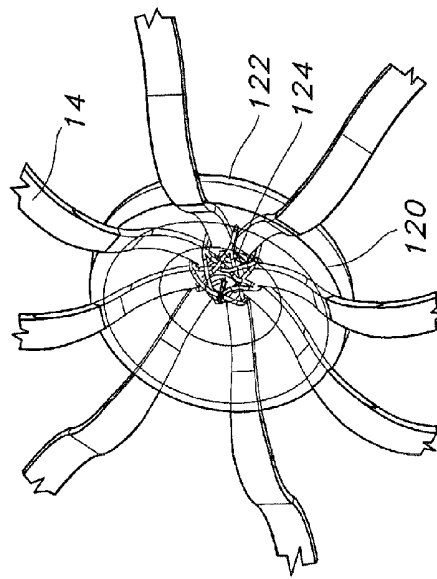


FIG. 27C

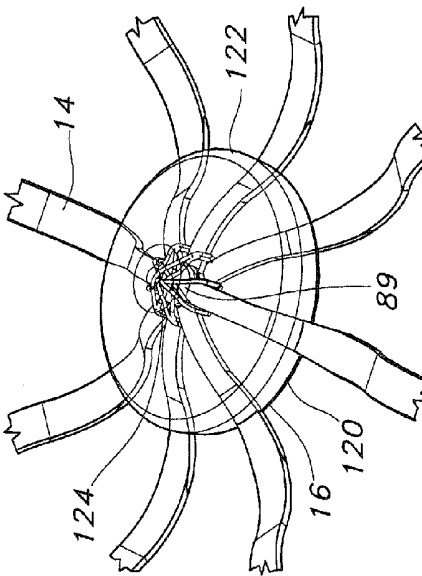


FIG. 27A

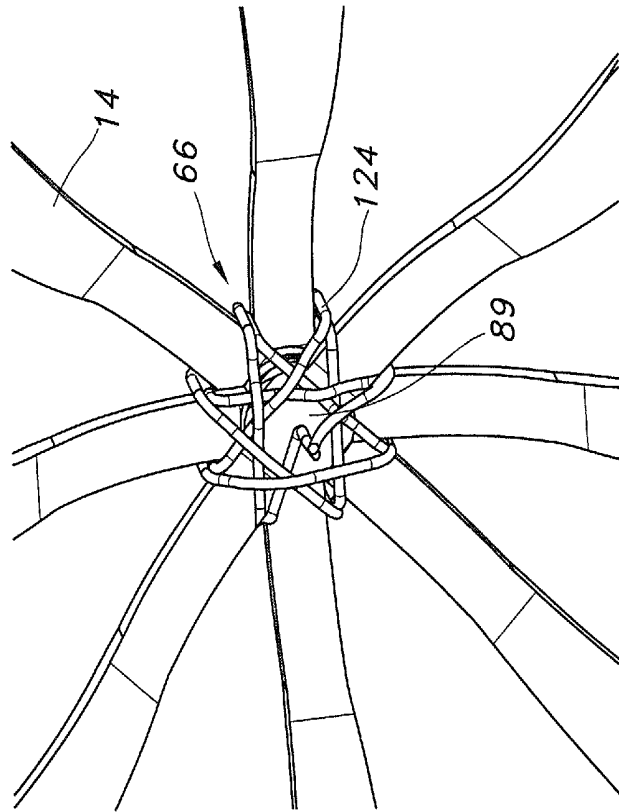


FIG. 27E

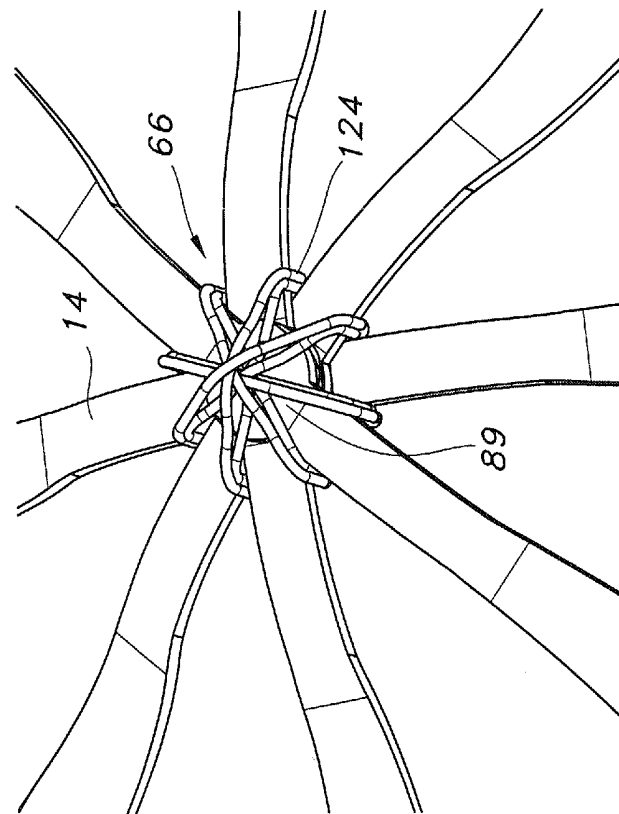


FIG. 27D

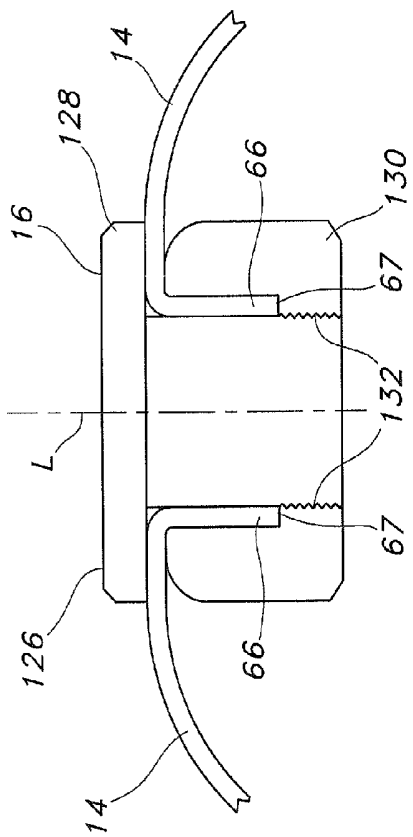


FIG. 28A

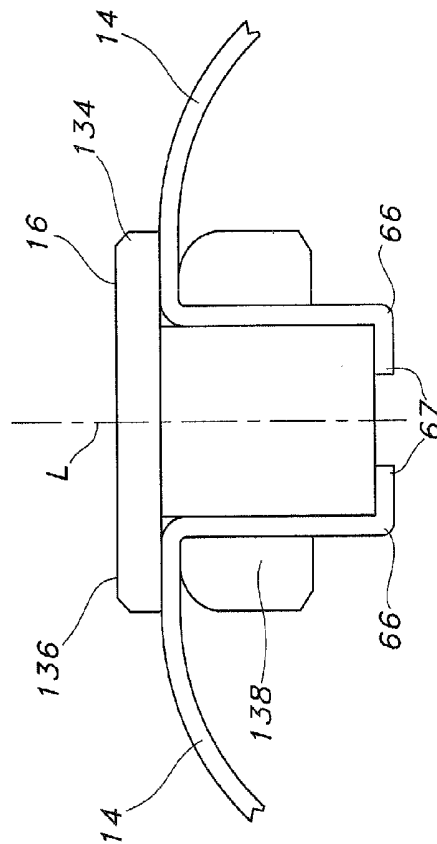


FIG. 28B

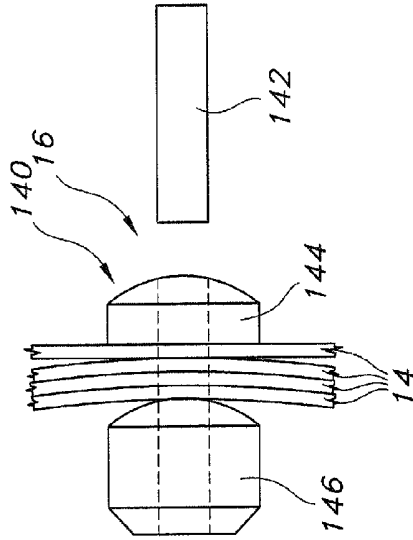


FIG. 28C

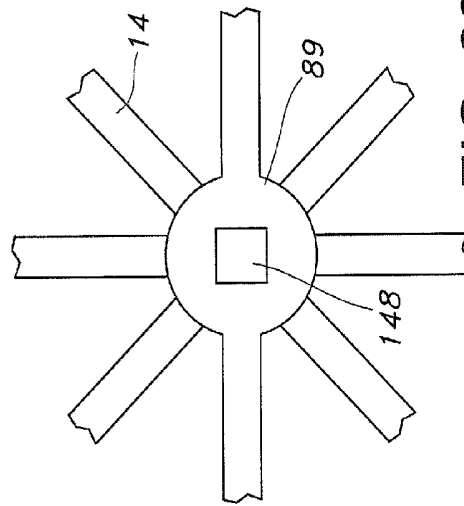


FIG. 28D

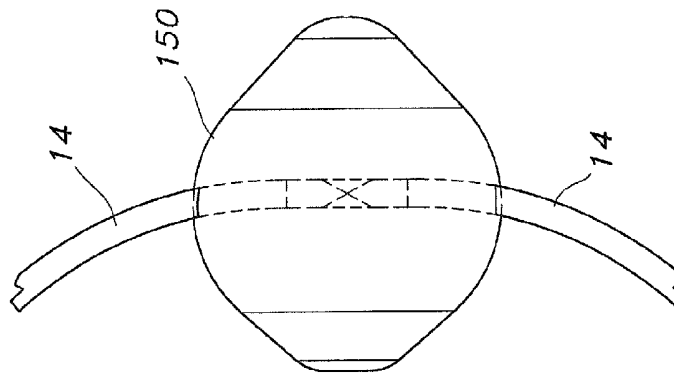


FIG. 29

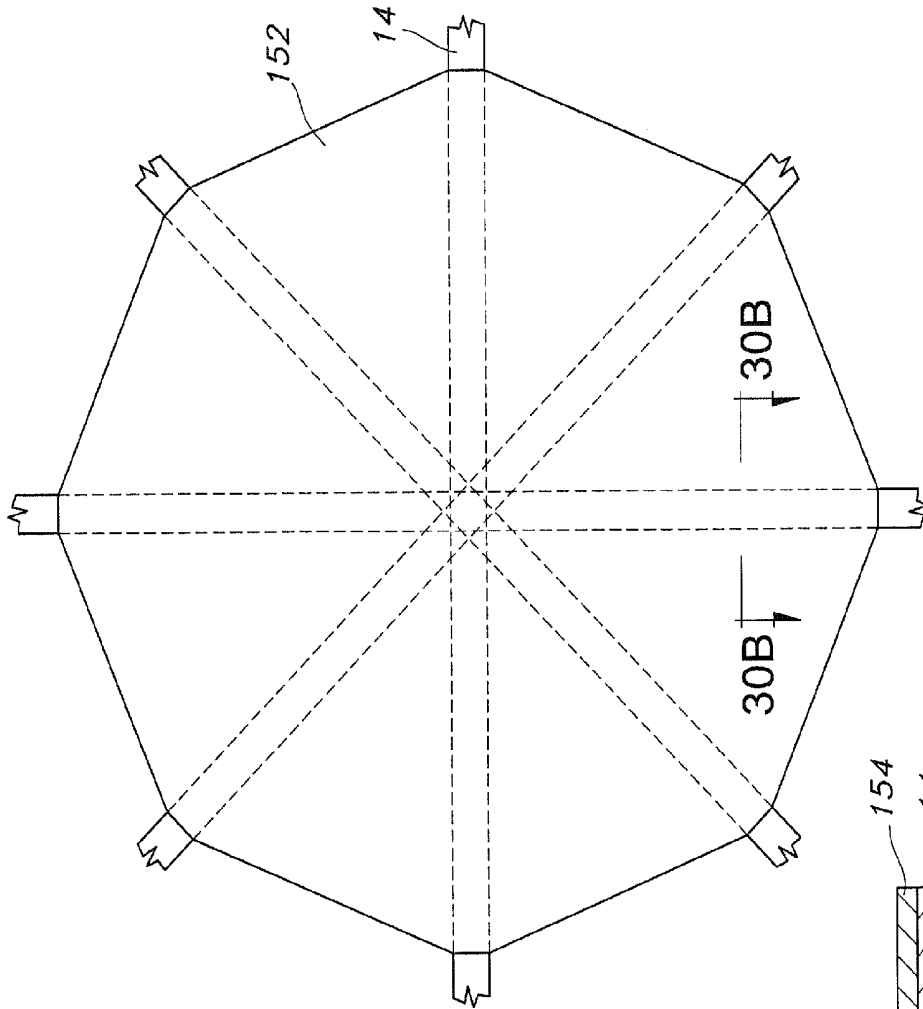


FIG. 30A

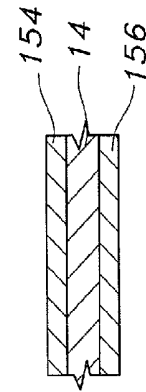


FIG. 30B

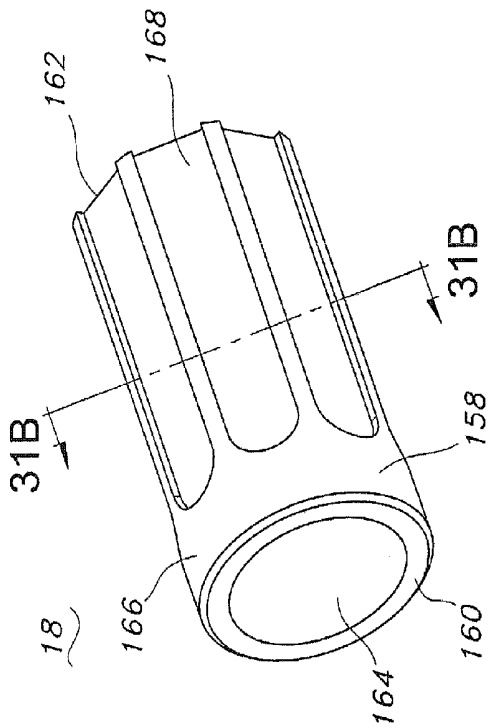


FIG. 31A

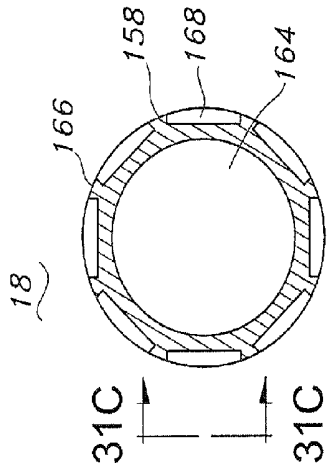


FIG. 31B

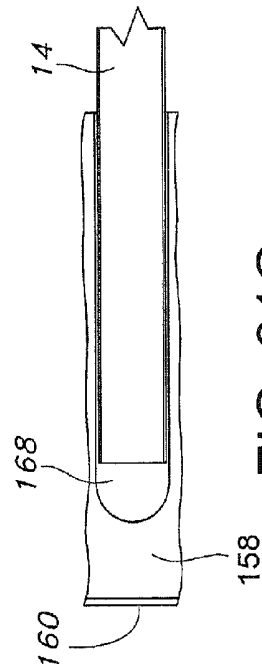


FIG. 31C

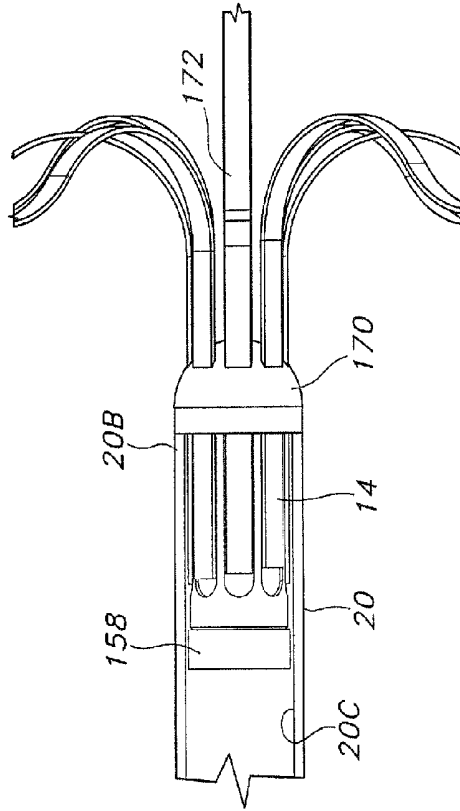


FIG. 31D

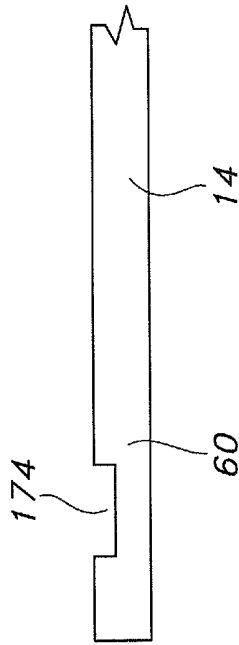


FIG. 32A

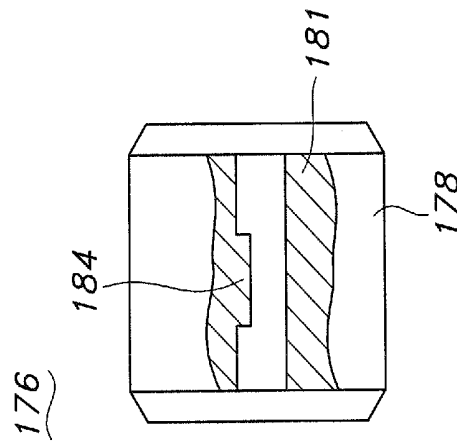


FIG. 32C

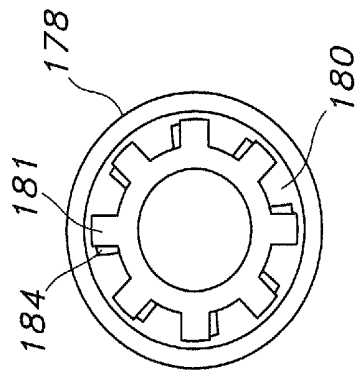


FIG. 32B

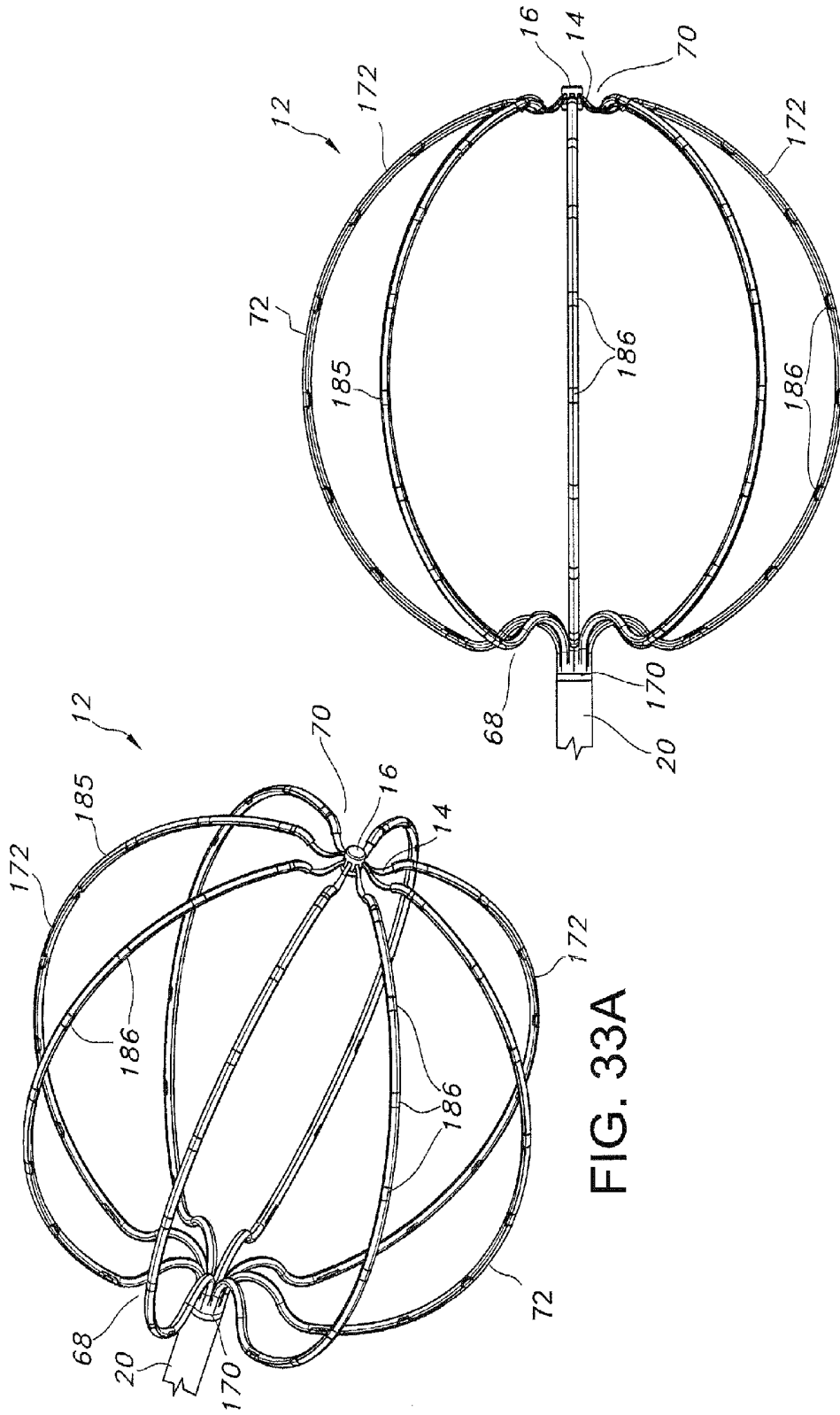


FIG. 33A

FIG. 33B

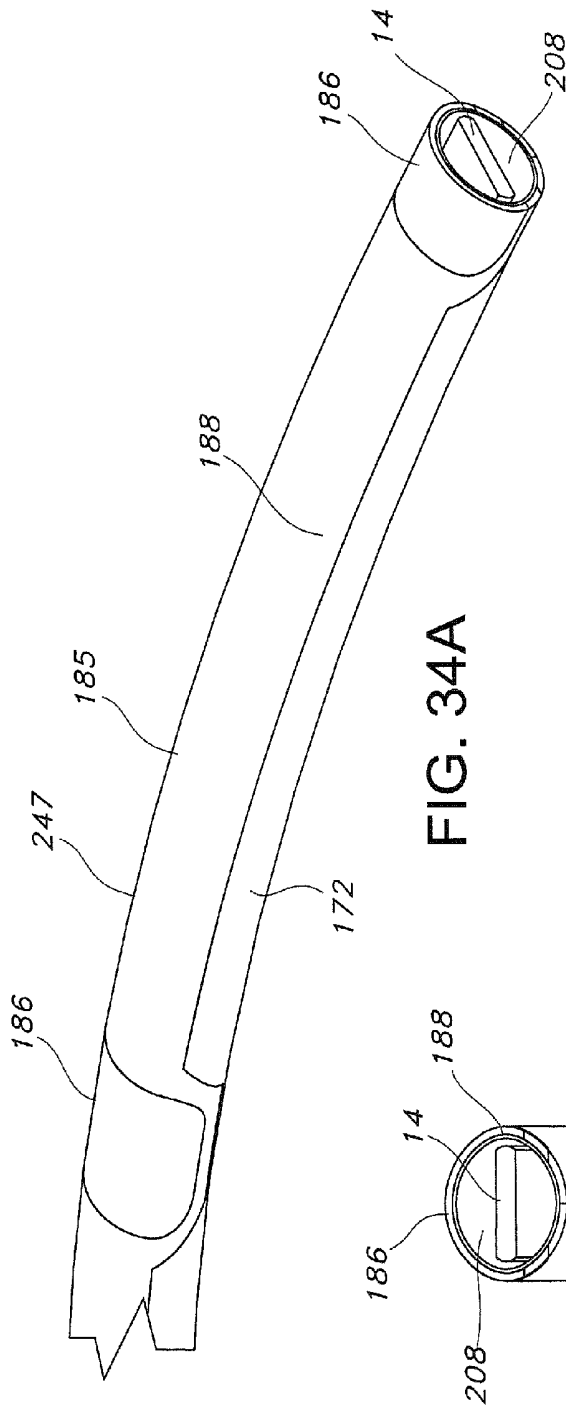


FIG. 34A

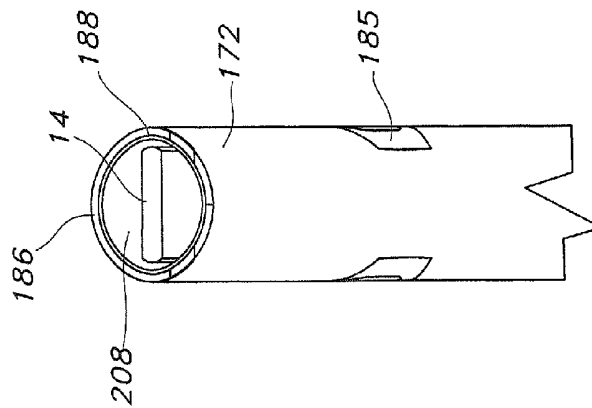


FIG. 34B

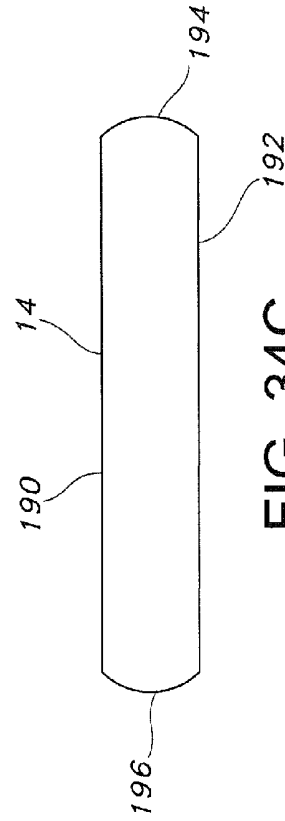


FIG. 34C

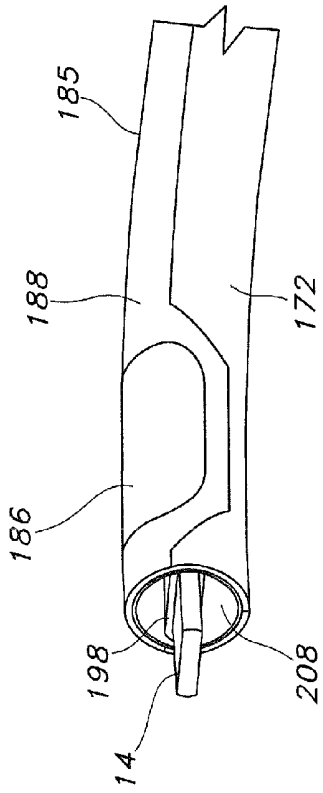


FIG. 34D

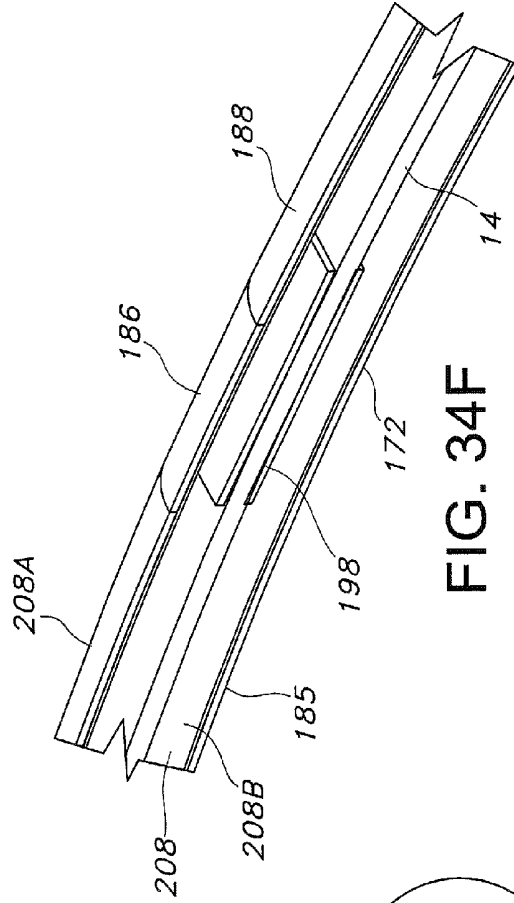


FIG. 34F

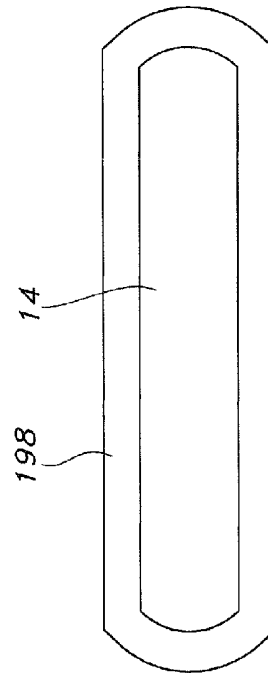


FIG. 34E

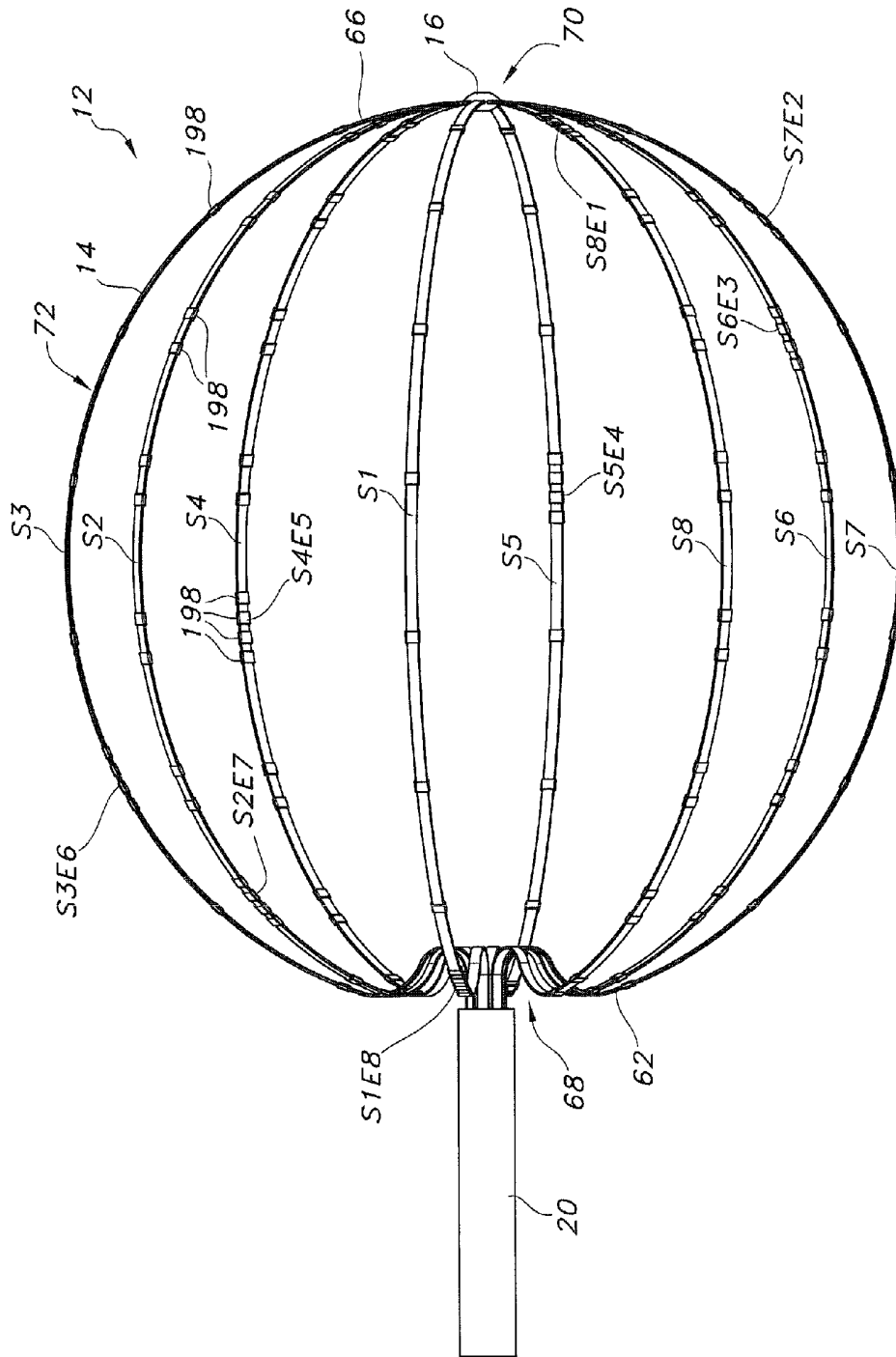


FIG. 34G

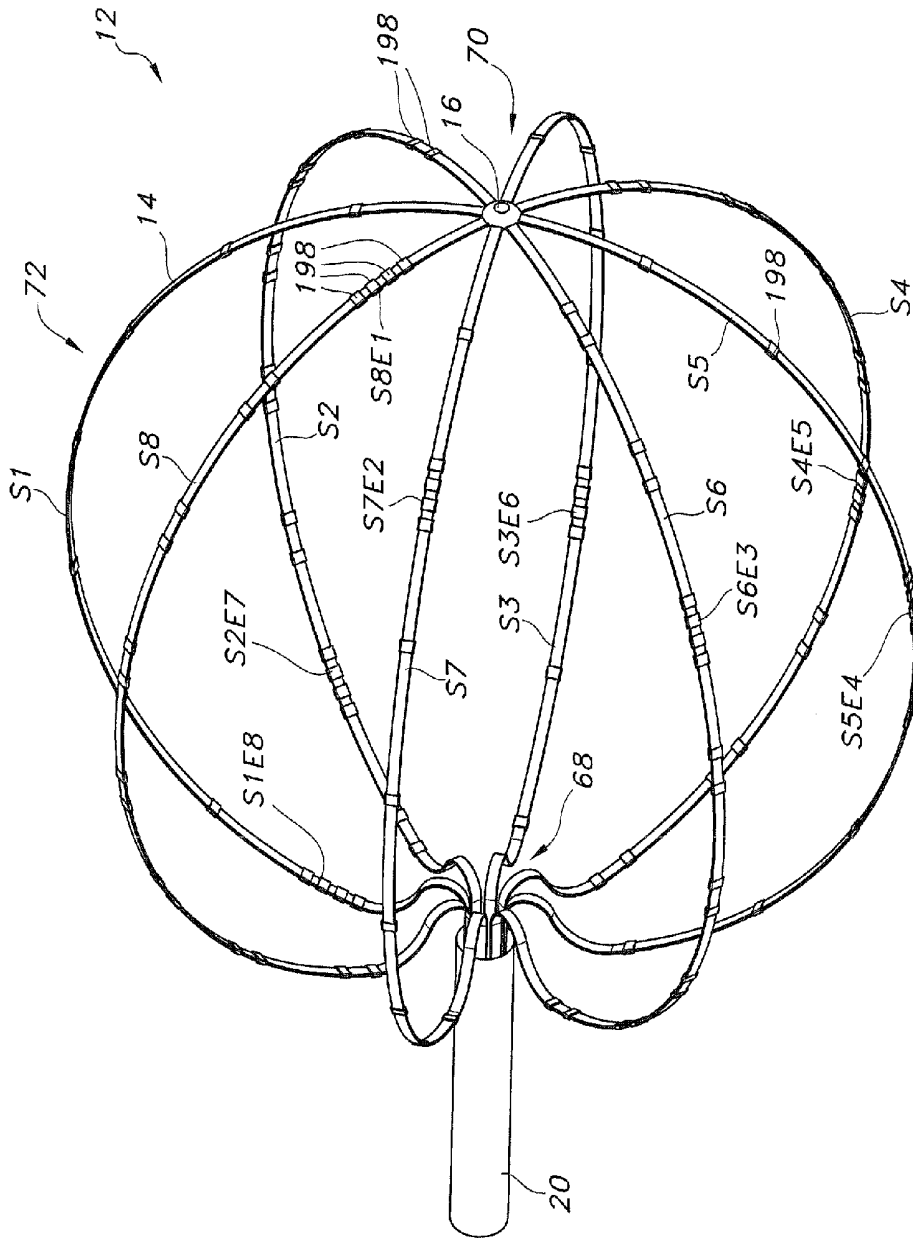


FIG. 34H

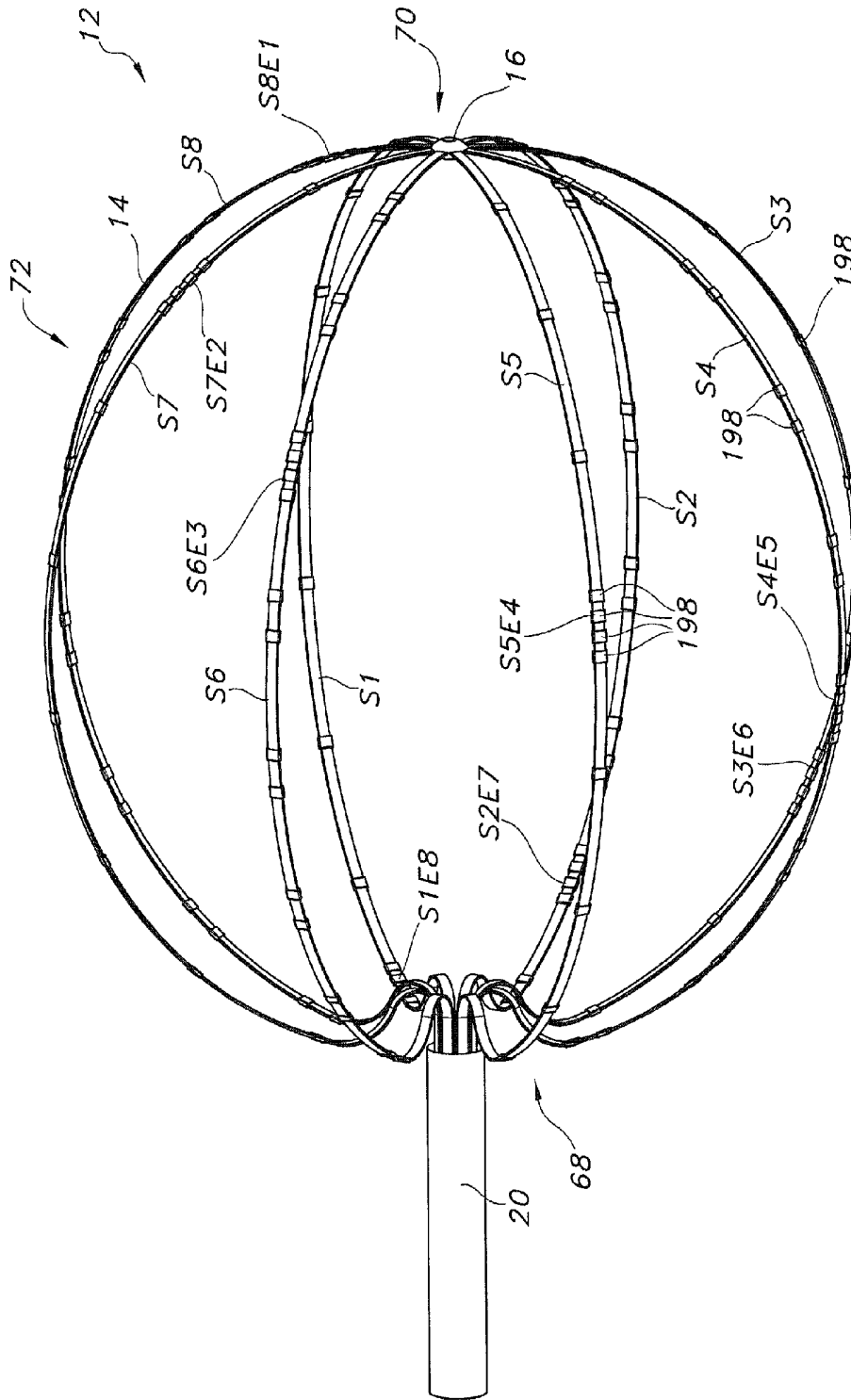


FIG. 34I

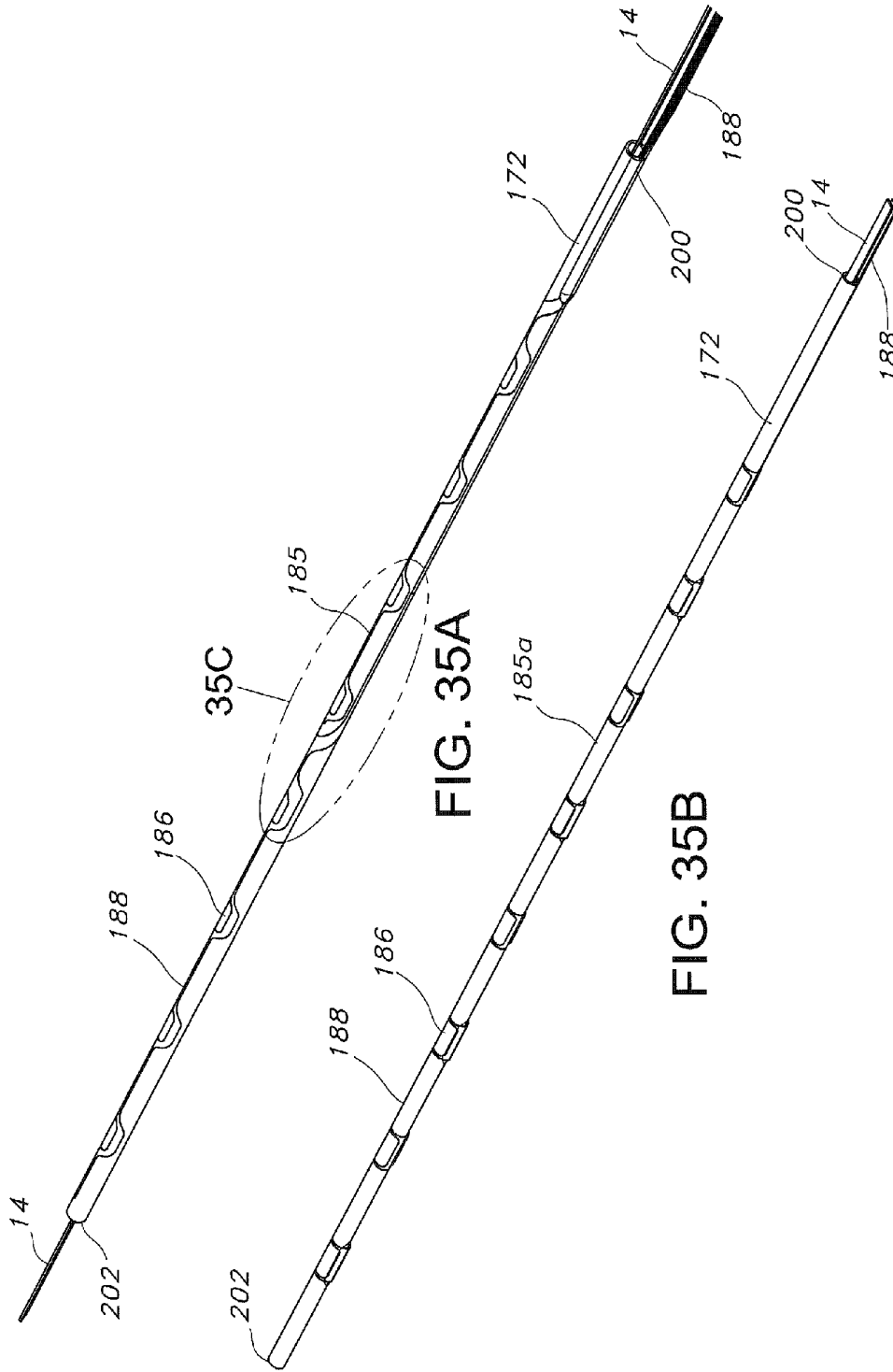


FIG. 35A

FIG. 35B

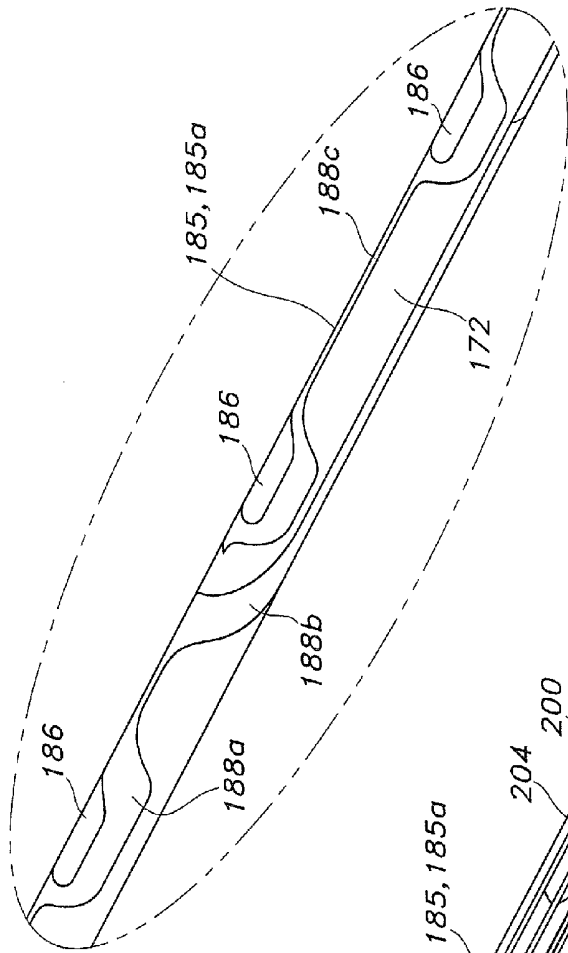


FIG. 35C

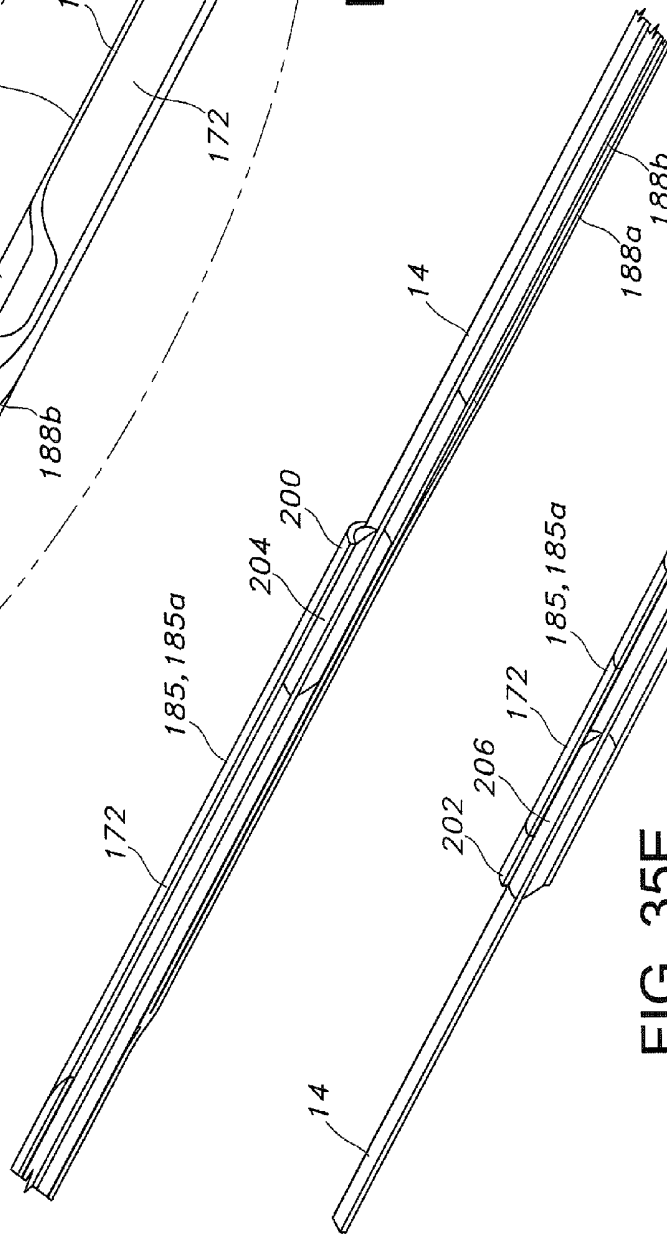


FIG. 35D

FIG. 35E

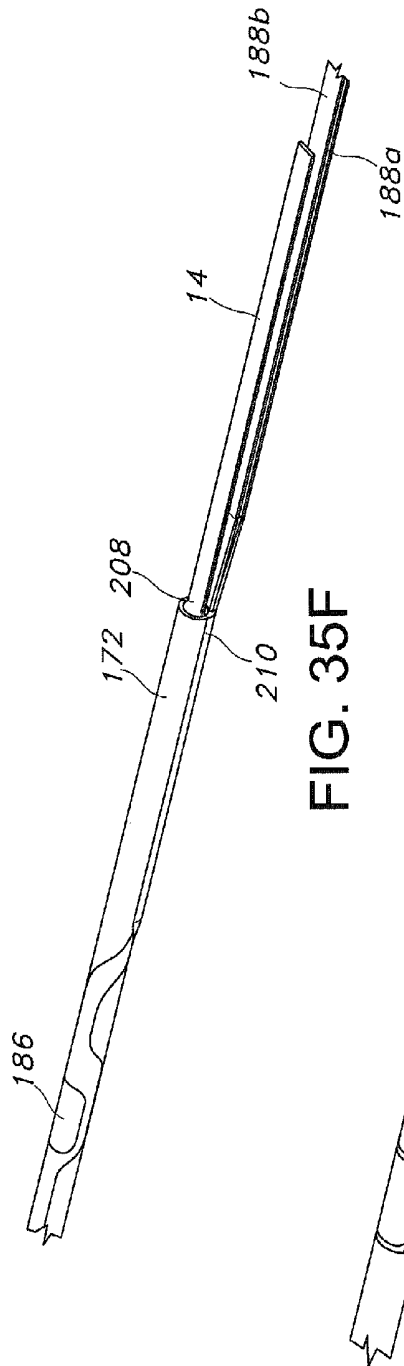


FIG. 35F

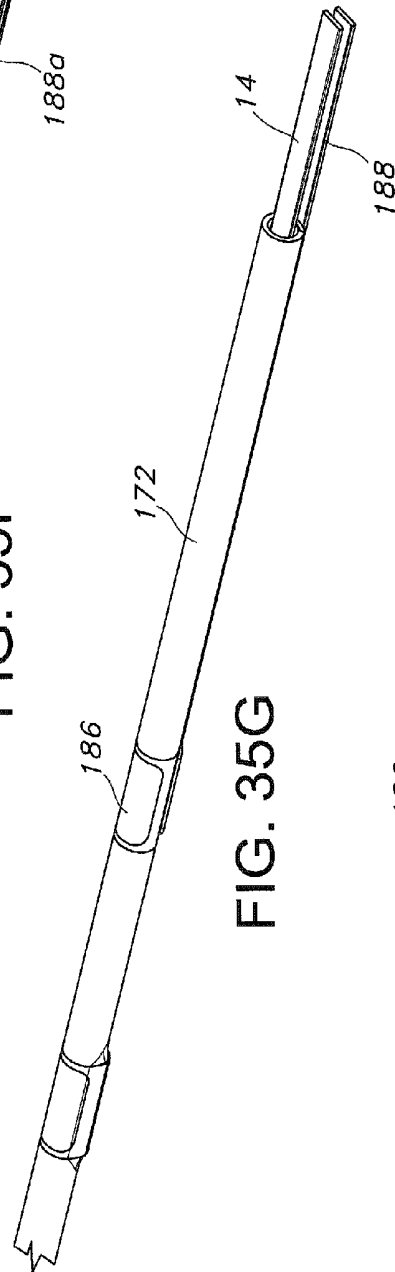


FIG. 35G

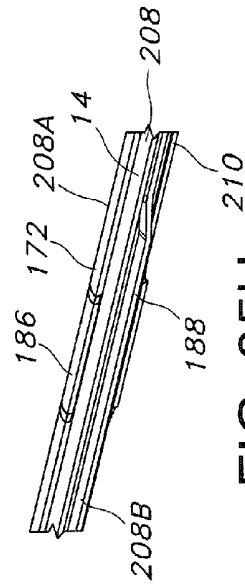
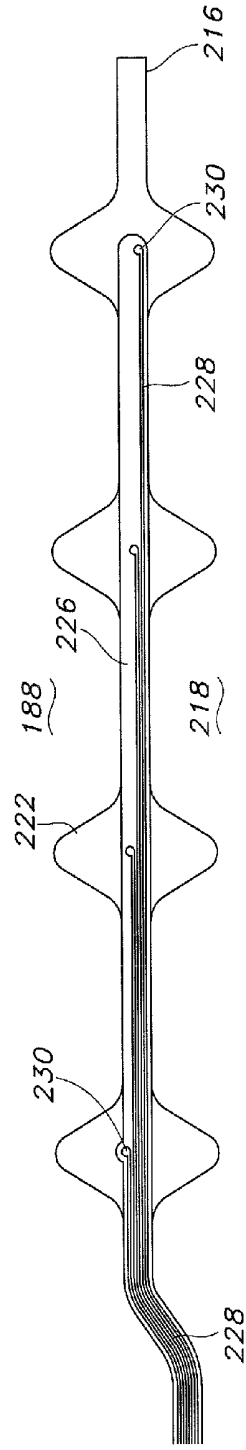
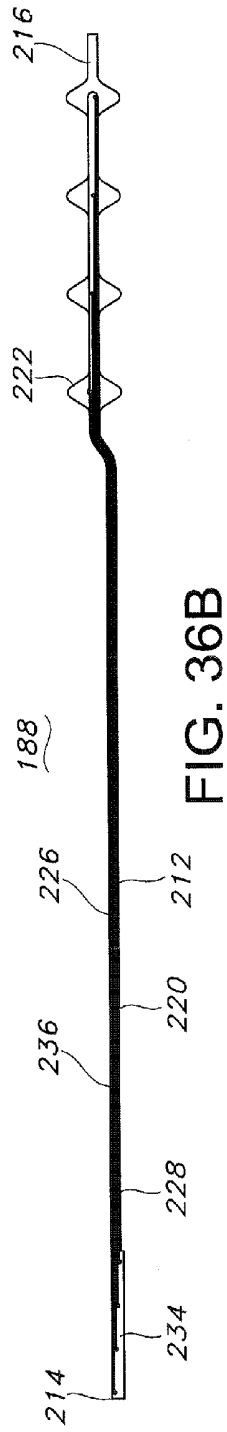
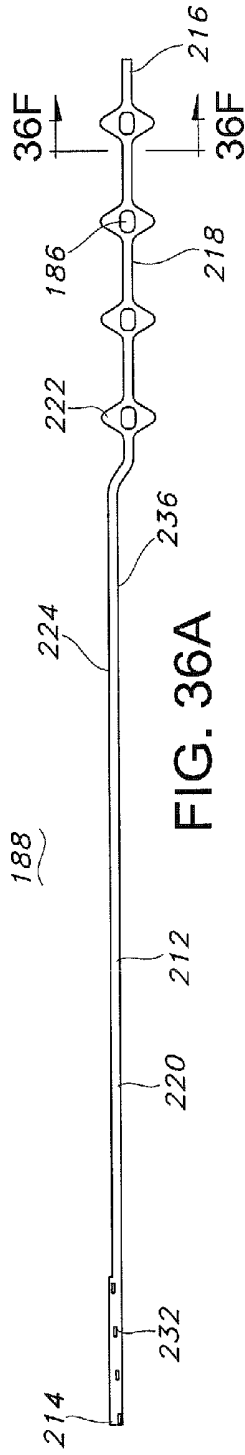


FIG. 35H



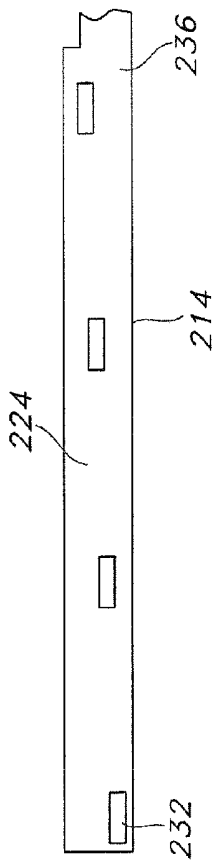


FIG. 36D

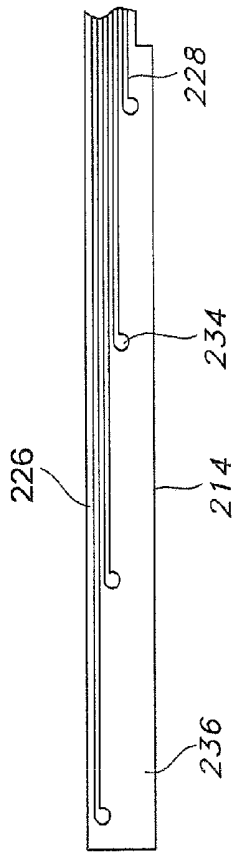


FIG. 36E

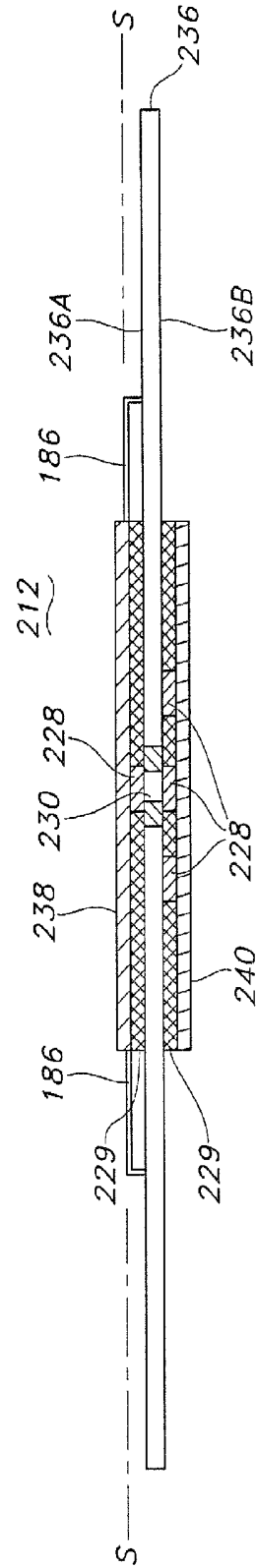


FIG. 36F



FIG. 37A

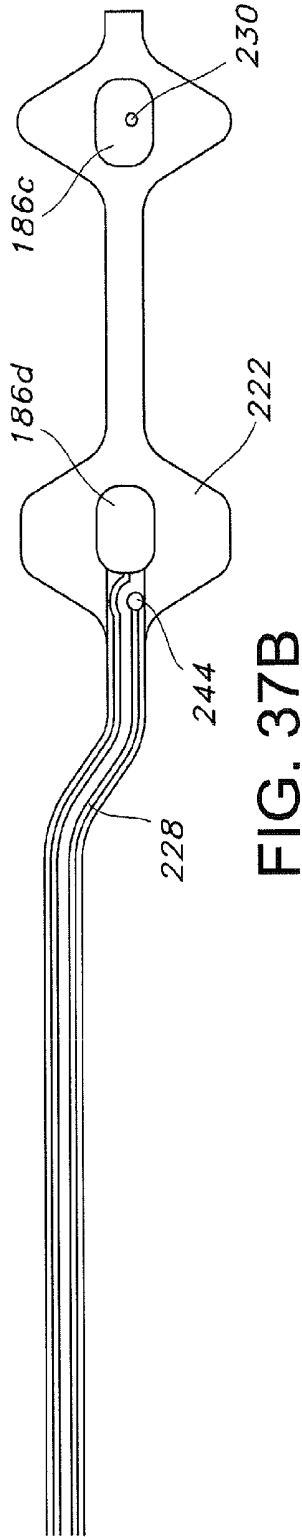


FIG. 37B

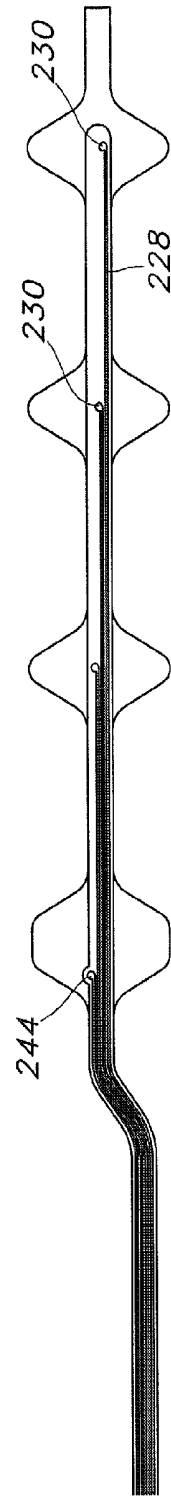


FIG. 37C

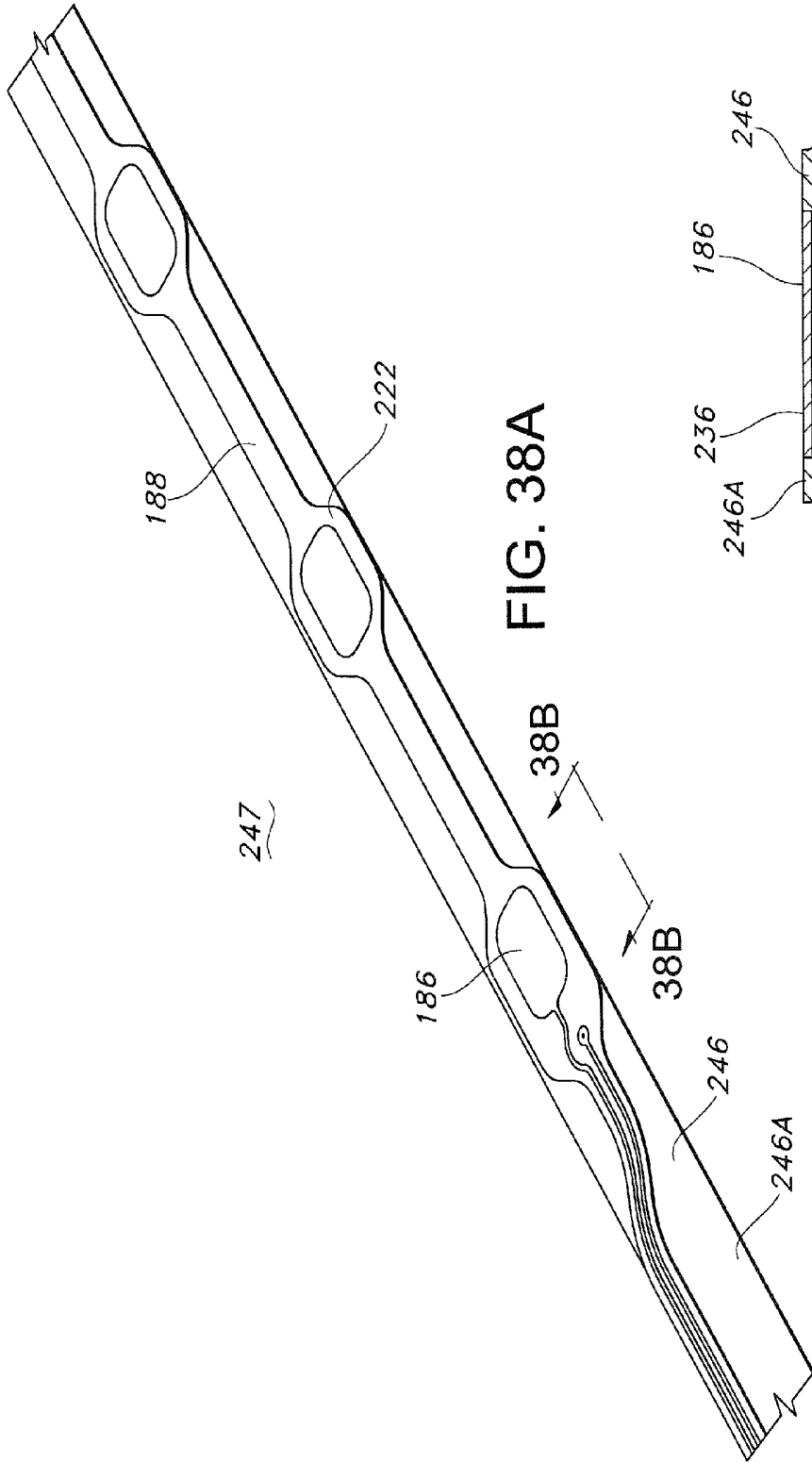


FIG. 38A

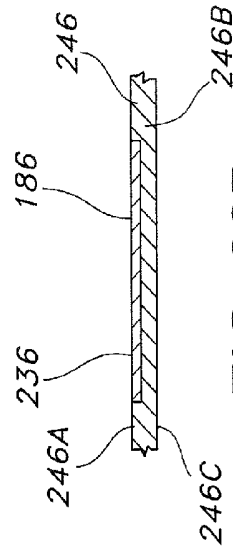


FIG. 38B

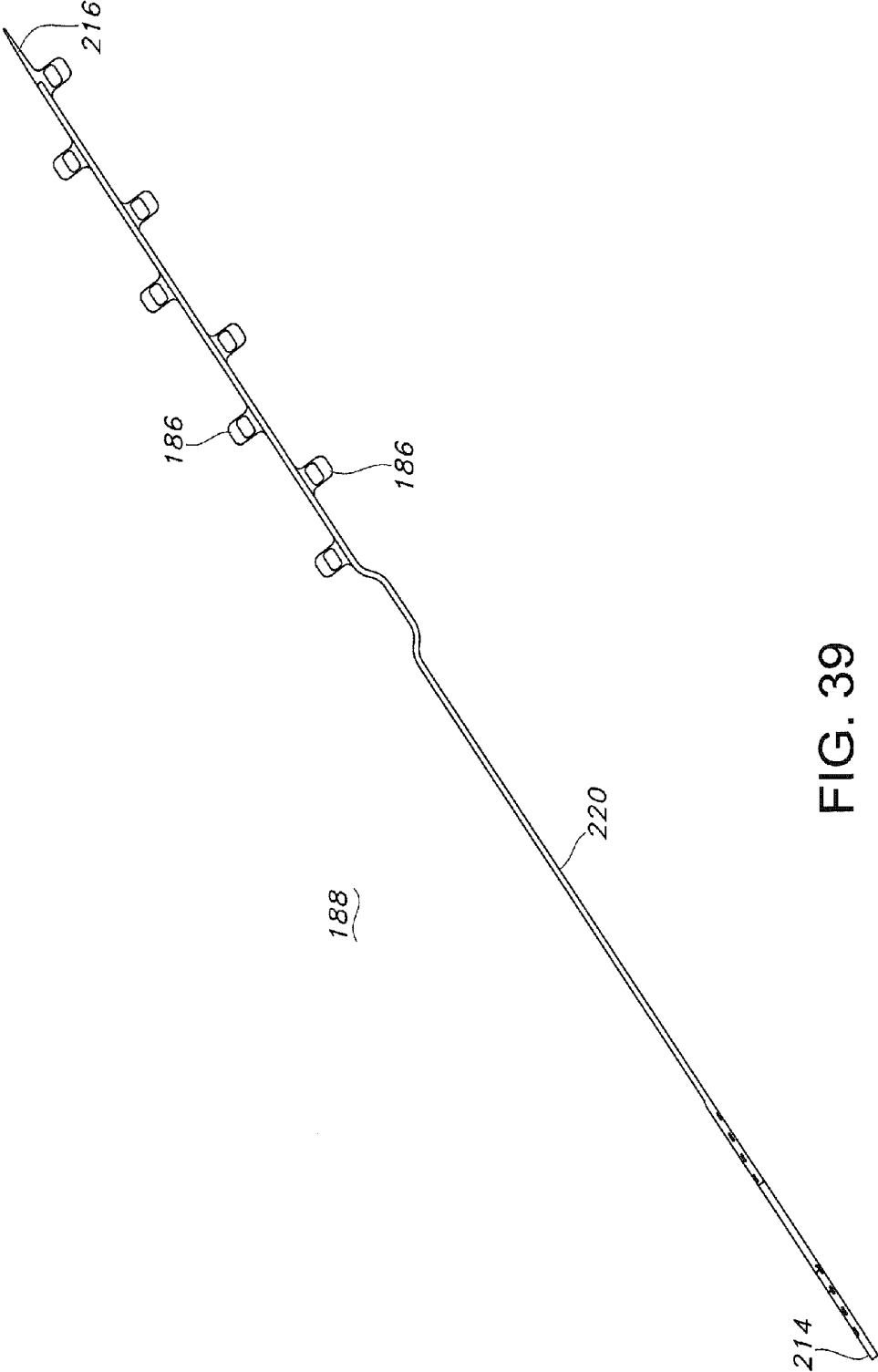


FIG. 39

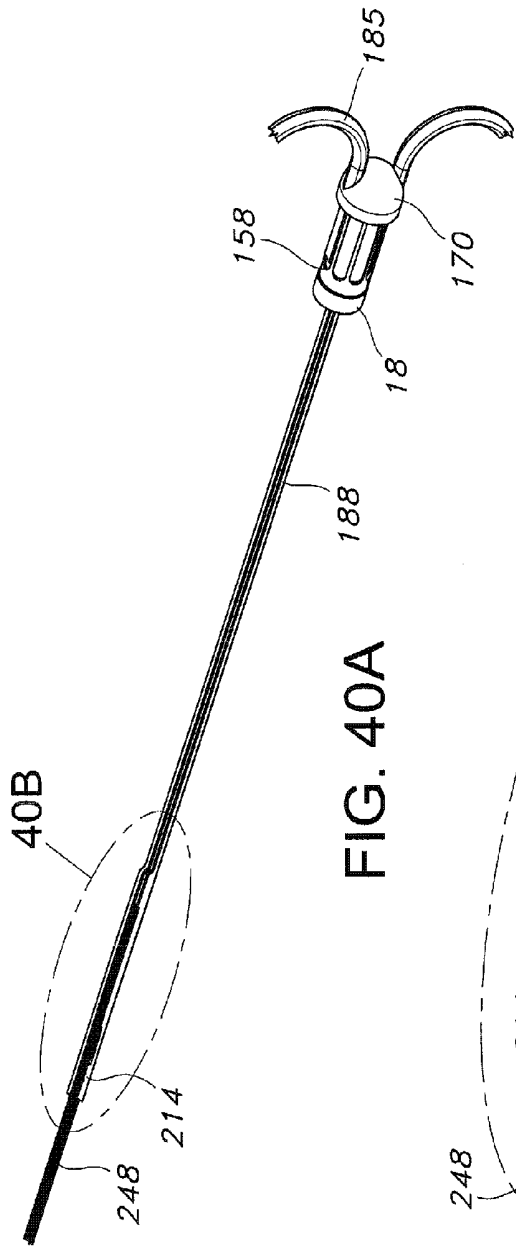


FIG. 40A

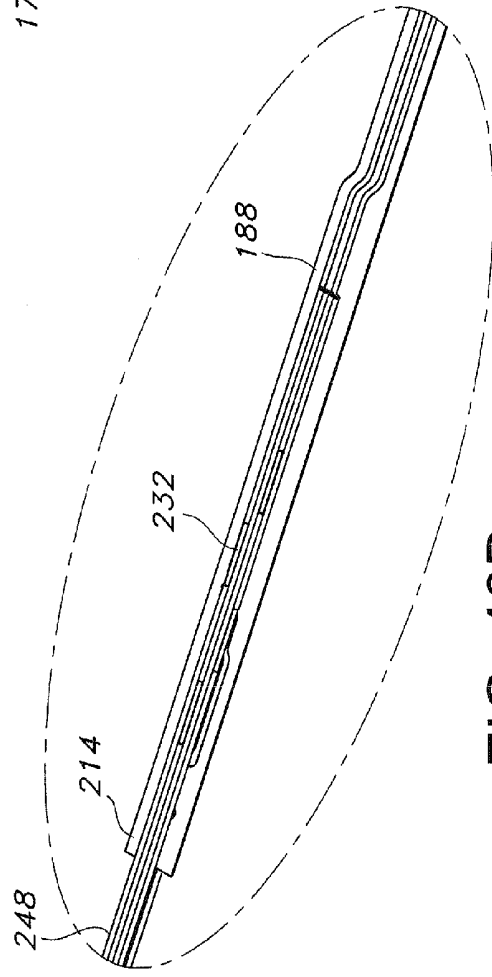


FIG. 40B

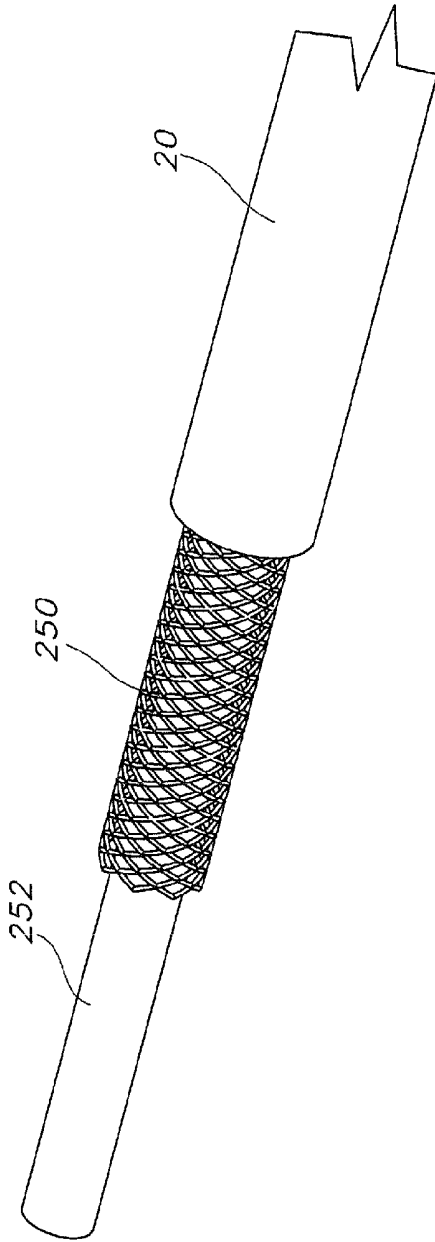


FIG. 41A

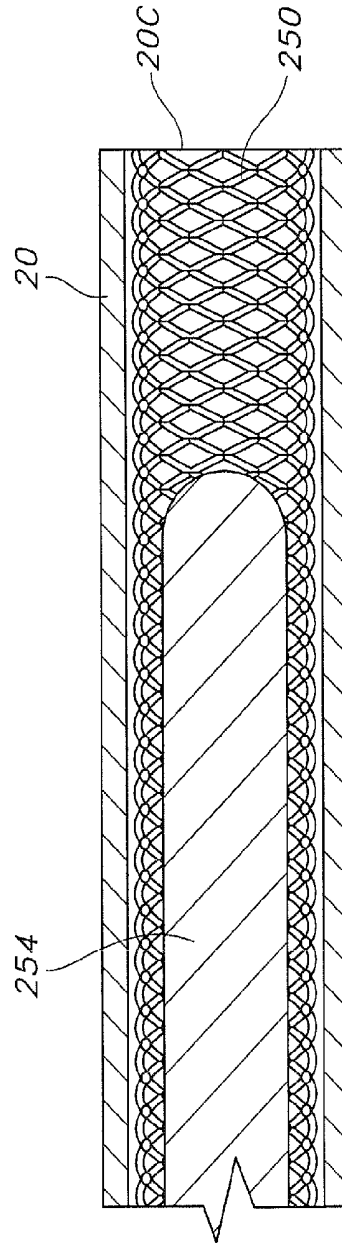


FIG. 41B

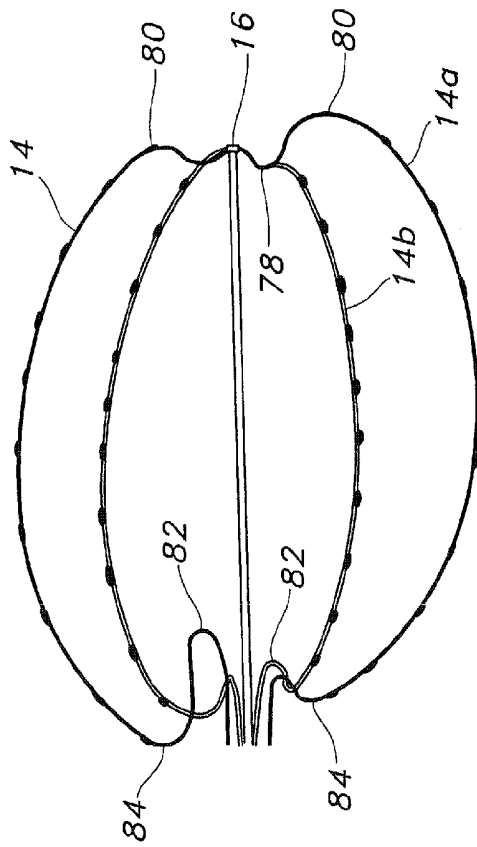


FIG. 42A

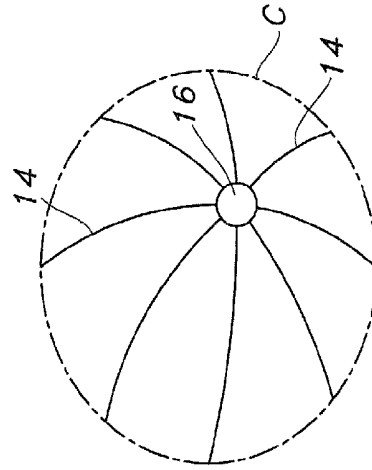


FIG. 42C

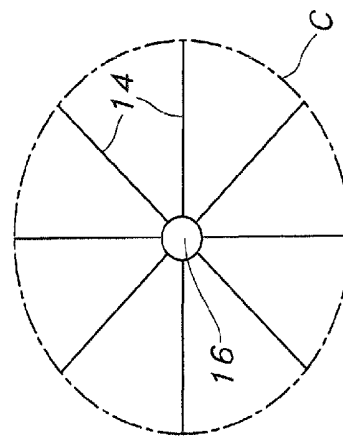


FIG. 42B

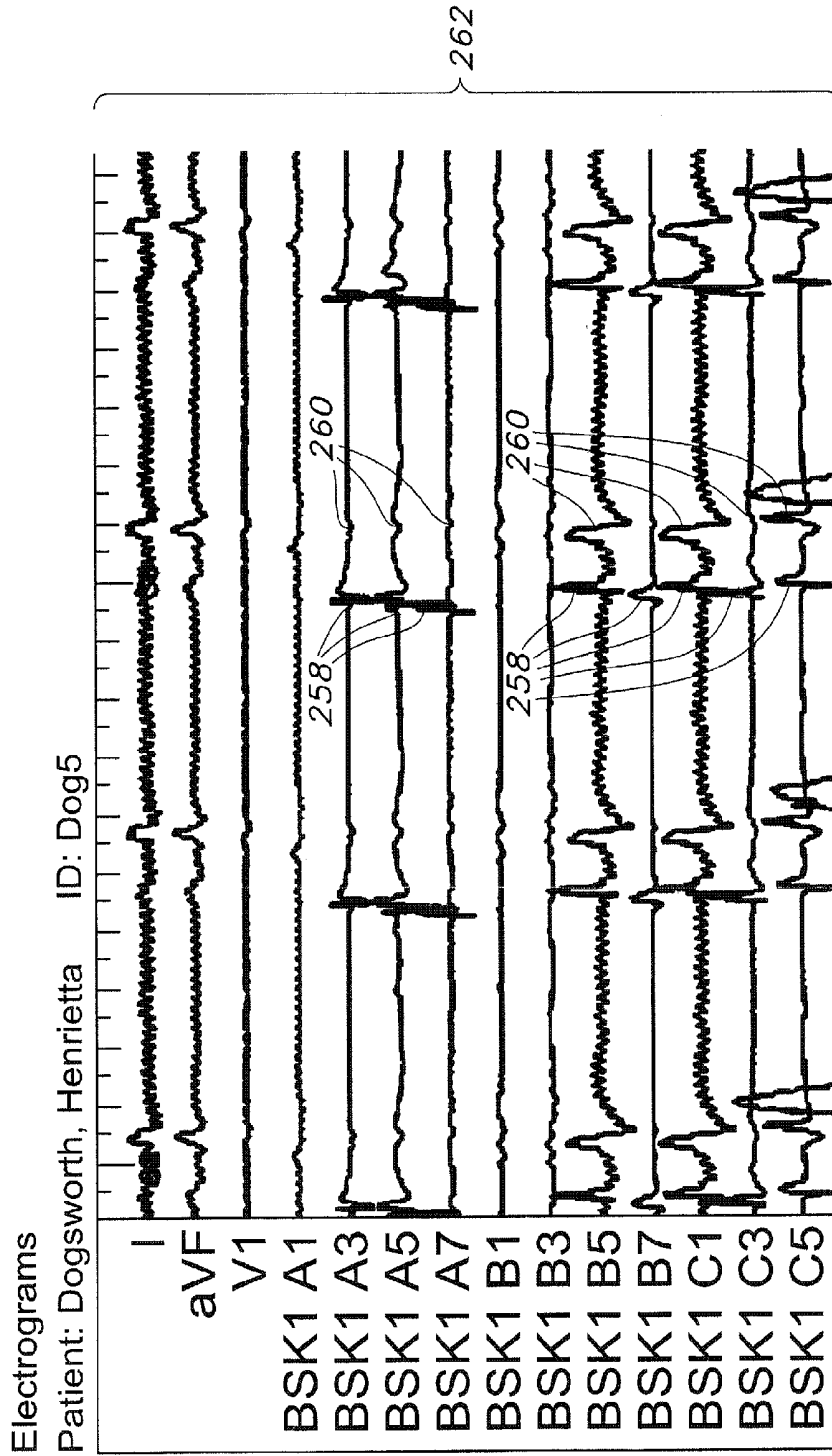


FIG. 43A

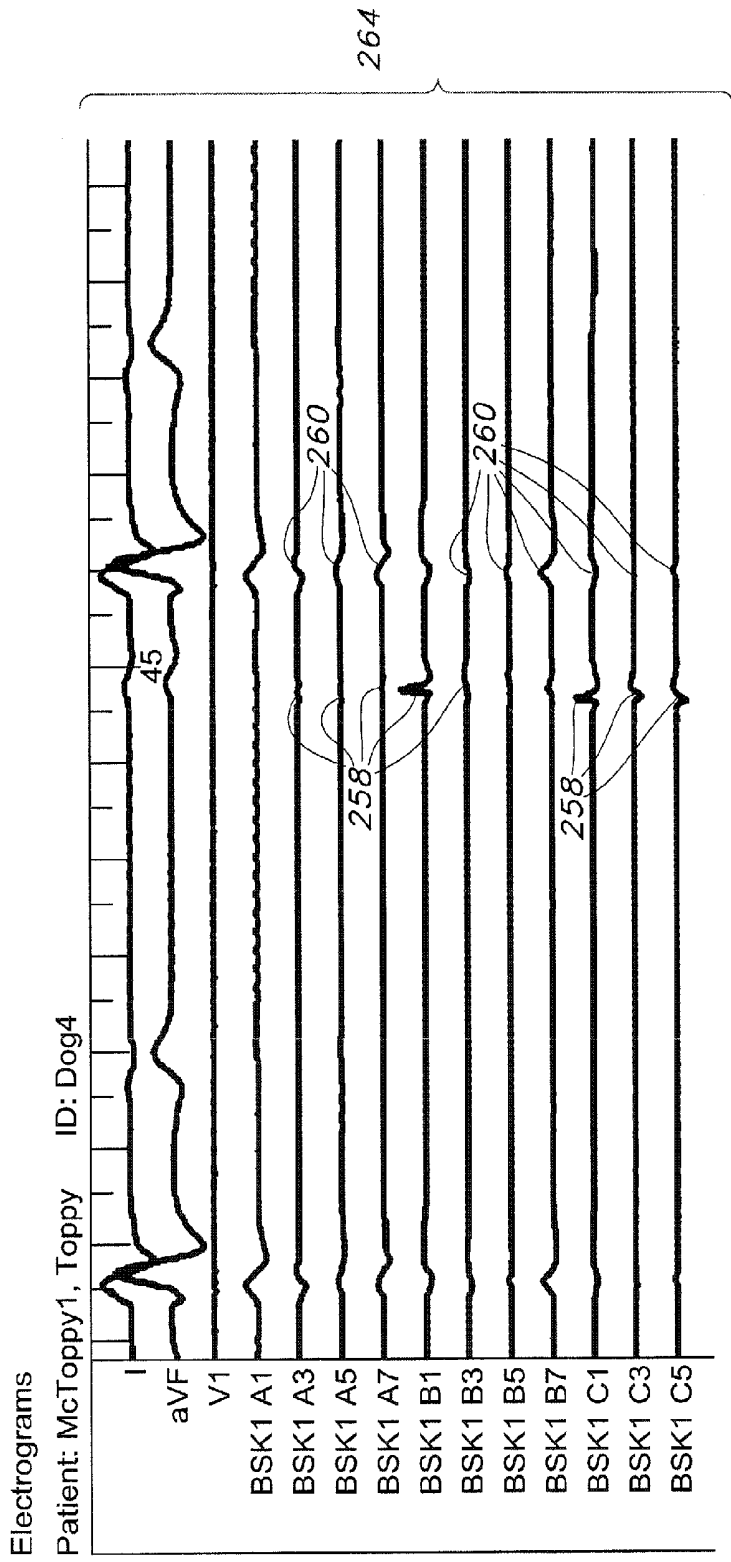


FIG. 43B

METHODS FOR DETECTION OF CARDIAC RHYTHM DISORDERS USING BASKET STYLE CARDIAC MAPPING CATHETER

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. application Ser. No. 14/148,845, filed Jan. 7, 2014, which is a continuation of U.S. application Ser. No. 13/409,595, filed Mar. 1, 2012, now U.S. Pat. No. 8,644,902, which claims the benefit of U.S. Provisional Application No. 61/555,190, filed Nov. 3, 2011, and U.S. Provisional Application No. 61/478,340, filed Apr. 22, 2011, the contents of all of which are incorporated by reference herein.

FIELD OF THE INVENTION

The present invention is related to methods for the detection of cardiac rhythm disorders by use of basket style cardiac mapping catheters. The present invention is further related to a method for sensing multiple local electric voltages from endocardial surface of a heart by using a basket with substantially flat and unidirectionally oriented electrodes on the basket.

BACKGROUND OF THE INVENTION

Heart rhythm disorders are very common in the United States, and are significant causes of morbidity, lost days from work, and death. Heart rhythm disorders exist in many forms, of which the most complex and difficult to treat are atrial fibrillation (AF), ventricular tachycardia (VT) and ventricular fibrillation (VF). Other rhythms may be easier to treat, but may also be clinically significant including supraventricular tachycardia (SVT), atrial tachycardia (AT), atrial flutter (AFL), premature atrial complexes/beats (PAC, APC) and premature ventricular complexes/beats (PVC). Under certain conditions, rapid activation of the normal sinus node can even cause a heart rhythm disorder such as inappropriate sinus tachycardia or sinus node reentry.

Definitive diagnosis has often been performed using electrode-bearing catheters placed within the heart chambers. Electrodes have been positioned along a catheter shaft or basket splines in an attempt to analyze or map the electrical activity within a heart chamber. Mapping typically involves the use or formation external (patches on skin) of electrograms and internal (catheters with electrodes) electrograms. A typical electrocardiogram of the cardiac cycle (heartbeat) consists of a P wave, a QRS complex and a T wave. During normal atrial depolarization, the main electrical vector is directed from the SA node, and spreads from the right atrium to the left atrium. Atrial depolarization is represented by the P wave on the electrocardiogram. The QRS complex reflects the rapid depolarization of the right and left ventricles. The T wave represents the repolarization (or recovery) of the ventricles.

Devices of the prior art, however, often do not provide a complete and stable map of the electrical activity within a heart chamber (recording electrograms). In particular, electrical activity in certain portions of the right atrium and the left atrium (e.g. atrial septum, region of right pulmonary veins) are often difficult to map because of the inability of devices of the prior art to adequately conform to the irregular shape of the atria and their varying shapes during beating of the heart. Further, devices of the prior art do not provide dimensionally and/or spatially stable and complete electro-

grams as the prior art devices often move as the heart beats, thereby moving some or all of the electrodes away from the heart tissue and making the relative position of the electrodes variable to corresponding position of atrial tissue.

Thus, there is a need in the art for a cardiac mapping catheter that is capable of providing improved and dimensionally and/or spatially stable signals for diagnosis, and more complete coverage of the heart tissue, typically in the form of electrograms.

SUMMARY OF THE INVENTION

The present invention provides devices, systems and methods for the detection of cardiac rhythm disorders by use of a percutaneous catheter designed to permit acquisition of numerous, simultaneous endocardial electrograms from a three dimensional array of surface electrodes, herein referred to as "a basket style cardiac mapping catheter."

In one embodiment of the present invention, a method for sensing multiple local electric voltages from endocardial surface of a heart, includes: providing a system for sensing multiple local electric voltages from endocardial surface of a heart, including: a first elongate tubular member having a lumen, a proximal end and a distal end; a basket assembly including: a plurality of flexible splines for guiding a plurality of exposed electrodes, the splines having proximal portions, distal portions and medial portions therein between, wherein the electrodes are substantially flat electrodes and are substantially unidirectionally oriented towards a direction outside of the basket; a proximal anchor for securably affixing the proximal portions of the splines; the proximal anchor being secured at the distal end of the first elongate tubular member; a distal tip for securably affixing the distal portions of the splines, the proximal anchor and the distal tip defining a longitudinal axis therein between about which the splines are disposed; wherein the splines approach the distal tip at an angle of about 90° or less than about 90° as measured from a line segment between the proximal anchor and the distal tip along the longitudinal axis; wherein the splines comprise a superelastic material such that the basket assembly exhibits a substantially cylindrical shape when radially compressed and exhibits a radially expanded non-spherical shape when not radially compressed; and wherein each of the splines in the radially expanded non-spherical shape contain a proximal recurve in the proximate portion of the spline at a location near to the proximal anchor of the basket assembly, the proximal recurve includes a proximal excurvate outward bend and a proximal incurvate inward bend between the proximal excurvate outward bend and the proximal anchor, where an apex of the proximal incurvate inward bend is disposed in a direction toward the distal tip and is further disposed inwardly closer toward the distal tip than the proximal excurvate outward bend; delivering the system to the heart so that the basket assembly is disposed within the right atrium of the heart; contacting proximal atrial tissue with the electrodes disposed on the proximal spline portions to detect multiple local electric voltages from endocardial surface thereat; and contacting atrial tissue with the electrodes disposed on the medial spline portions and the distal spline portions to detect multiple local electric voltages from endocardial surface thereat.

Desirably, the splines of the basket assembly are flexible to match the contours of the right atrium, and substantially all of the electrodes contact atrial tissue.

Further, substantially all of the electrodes may remain substantially spatially fixed with respect to atrial tissue.

Moreover, a substantial portion of atrial signals detected by the system have larger amplitudes than ventricular signals detected by the system.

These and other features and advantages of the present invention will become apparent from the following detailed description of illustrative embodiments thereof, which is to be read in connection with the accompanying drawings. Corresponding reference element numbers or characters indicate corresponding parts throughout the several views of the drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of the basket style cardiac mapping catheter system of the present invention.

FIG. 2 is a side elevational view of the basket style cardiac mapping catheter system of FIG. 1, according to the present invention.

FIG. 3 is a schematic view of an introducing catheter of the prior art useful for delivery of the basket style cardiac mapping catheter of FIG. 1 and guide catheter of FIG. 4 into a bodily lumen or organ.

FIG. 4 is a schematic view of a guide catheter of the prior art useful for delivery of the basket style cardiac mapping catheter of FIG. 1 into a bodily lumen or organ.

FIG. 5 is an expanded, partial cross-sectional view of a portion of the basket of the system of FIG. 1 showing an expanded basket beyond and outside a hemostat penetrator and/or a guide catheter, according to the present invention.

FIG. 6 is an expanded, partial cross-sectional view of a portion of the basket of the system of FIG. 1 showing a radially compressed basket within a hemostat penetrator and/or a guide catheter, according to the present invention.

FIG. 7 is an expanded side view of a portion of the basket of the system of FIG. 1 showing M-shaped, symmetric distal splines, according to the present invention.

FIG. 8 is a perspective view of the M-shaped basket embodiment of FIG. 7, according to the present invention.

FIG. 9 is a right side view of the M-shaped basket embodiment of FIG. 7 depicting symmetric spline angles, according to the present invention.

FIG. 10 is a perspective view of the basket of the system of FIG. 1 showing M-shaped, non-symmetric distal splines according to a basket embodiment of the present invention.

FIG. 11 is a right side view of the M-shaped basket embodiment of FIG. 10 depicting non-symmetric spline angles, according to the present invention.

FIG. 12 is a side elevational view of one of the splines of the M-shaped basket of FIG. 7 showing proximal spline recurves, according to the present invention.

FIG. 13 is a perspective view of the spline of FIG. 12, according to the present invention.

FIG. 14 is an exploded side view of a distal portion of the spline of FIG. 12, according to the present invention.

FIG. 15 is an exploded side view of a proximal portion of the spline of FIG. 12, according to the present invention.

FIG. 16 is an exploded right side view of a portion of the distal portion of the spline of FIG. 12 showing a distal thinned portion, according to the present invention.

FIG. 17 is an expanded side view of another embodiment of a basket of the system of FIG. 1 showing M-shaped distal spline portion and proximal tangential spline curves, according to the present invention.

FIG. 18 is an expanded side view of another embodiment of a basket of the system of FIG. 1 showing a distal spline D-shaped curve and proximal recurves, according to the present invention.

FIG. 19 is a perspective view of the spline of FIG. 18, according to the present invention.

FIG. 20 is an exploded view of a distal portion of the spline of FIG. 18, according to the present invention.

FIG. 21 is an expanded side view of another embodiment of a basket of the system of FIG. 1 showing a distal spline D-shaped curve and proximal tangential spline curves, according to the present invention.

FIGS. 22A through 22D depict thinned side view spline portions, according to the present invention.

FIG. 23A depicts side view of a portion of a spline in a neutral position having buckle points, according to the present invention.

FIG. 23B depicts side view of a portion of a spline in a deflected position having buckle points, according to the present invention.

FIG. 24 is a schematic illustration of a spline emerging from a distal tip at an acute angle, according to the present invention.

FIG. 25 is a schematic illustration of a spline emerging from a distal tip at a substantially perpendicular angle, according to the present invention.

FIG. 26A is a front perspective view of a two-part, welded distal tip, according to the present invention.

FIG. 26B is a rear perspective view of the distal tip of FIG. 26A, according to the present invention.

FIG. 26C is a front perspective view of a top part of the distal tip of FIG. 26A, according to the present invention.

FIG. 26D is a bottom view of the top part of the distal tip of FIG. 26A, according to the present invention.

FIG. 26E is a front perspective view of a bottom top part of the distal tip of FIG. 26A, according to the present invention.

FIG. 26F is a front perspective view of another embodiment of a two-part, welded distal tip having a rounded or domed upper portion, according to the present invention.

FIG. 27A is a front perspective view of an encapsulated, filament wound distal tip, according to the present invention.

FIG. 27B is a side elevation view of the distal tip of FIG. 27A, according to the present invention.

FIG. 27C is a rear perspective view of the distal tip of FIG. 27A, according to the present invention.

FIG. 27D is a top perspective view of the filament wrapping of the distal tip of FIG. 27A, according to the present invention.

FIG. 27E is a rear perspective view of the filament wrapping of the distal tip of FIG. 27A, according to the present invention.

FIG. 28A is a side cross-sectional view of another embodiment of a two-part distal tip with half splines, according to the present invention.

FIG. 28B is a side cross-sectional view of another embodiment of a two-part distal tip with half splines, according to the present invention.

FIG. 28C is a side cross-sectional view of another embodiment of a two-part riveted distal tip with full splines, according to the present invention.

FIG. 28D is a top view of aligned splines useful with the distal tip of FIG. 28C, according to the present invention.

FIG. 29 is a side elevational view of an encapsulated distal tip, according to the present invention.

FIG. 30A is a top view of a membrane distal tip, according to the present invention.

FIG. 30B is a partial cross-sectional view of the membrane tip of FIG. 30A.

FIG. 31A is a perspective view of a slotted proximal anchor, according to the present invention.

FIG. 31B is a right cross-sectional view of the slotted anchor of FIG. 31A, according to the present invention.

FIG. 31C is an exploded, partial side elevation view of the slotted anchor of FIG. 31A, according to the present invention.

FIG. 31D is a partial cross-sectional view of the slotted anchor of FIG. 31A securable disposed with a portion of the catheter body of the system of FIG. 1, according to the present invention.

FIG. 32A is a depiction of a proximal portion of a spline having a spline notch, according to the present invention.

FIG. 32B is a schematic illustration of an anchor useful for securing the spline of FIG. 32A, according to the present invention.

FIG. 32C is a partial exploded view of the anchor of FIG. 32B according to the present invention.

FIG. 33A is an exploded, perspective of the basket of the system of FIG. 1 showing splines with spline tube assemblies, according to the present invention.

FIG. 33B is a side elevational view of the basket of FIG. 33A, according to the present invention.

FIGS. 34A and 34B are cross-sectional views of a portion of the spline tube assembly of FIG. 33A, according to the present invention.

FIG. 34C is an exploded cross-section view of the spline of FIGS. 34A and 34B, according to the present invention.

FIG. 34D is a cross-sectional view of a spline tube assembly with a radiopaque marker, according to the present invention.

FIG. 34E is a cross-sectional view of the radiopaque marker of FIG. 34D, according to the present invention.

FIG. 34F is a partial cross-sectional view of a spline tube assembly along the length of the spline tube assembly with a radiopaque marker, according to the present invention.

FIG. 34G is a representation of a fluoroscopic image of a side elevation view of a basket with radiopaque marker arrangement to depict spline and electrode locations, according to the present invention.

FIG. 34H is a representation of a fluoroscopic image of a perspective view of the basket of FIG. 34G, according to the present invention.

FIG. 34I is a representation of a fluoroscopic image of a rotated side view of the basket of FIG. 34G, according to the present invention.

FIG. 35A is a perspective view of spline tube assembly, according to the present invention.

FIG. 35B is another perspective views of spline tube assembly, according to the present invention.

FIG. 35C is an exploded perspective view of a spline tube assembly, according to the present invention.

FIG. 35D is an exploded, partial cross-sectional view of a proximal portion of the spline tube assembly, according to the present invention.

FIG. 35E is an exploded, partial cross-sectional view of a distal portion of the spline tube assembly, according to the present invention.

FIG. 35F is an exploded, partial cross-sectional view of a proximal portion of the spline tube assembly showing two flex circuits embedded with a wall of the spline tube assembly, according to the present invention.

FIG. 35G is an exploded, partial cross-sectional view of a proximal portion of the spline tube assembly showing one flex circuit embedded with a wall of the spline tube assembly, according to the present invention.

FIG. 35H is an exploded, partial cross-sectional view of a portion of the spline tube assembly showing a flex circuit

transitioning into an inner lumen of the spline tube assembly, according to the present invention.

FIG. 36A is a top view of a flex circuit, according to the present invention.

FIG. 36B is a bottom view of the flex circuit of FIG. 36A, according to the present invention.

FIG. 36C is an exploded, right bottom view of a portion of the flex circuit of FIG. 36A, according to the present invention.

FIG. 36D is an exploded, left top view of a portion of the flex circuit of FIG. 36A, according to the present invention.

FIG. 36E is an exploded, left bottom view of a portion of the flex circuit of FIG. 36A, according to the present invention.

FIG. 36F is schematic, cross-sectional view of a portion of the flex circuit of FIG. 36A, according to the present invention.

FIG. 37A is a top view of another embodiment of a flex circuit, according to the present invention.

FIG. 37B is an exploded, right top view of a portion of the flex circuit of FIG. 37A, according to the present invention.

FIG. 37C is an exploded, right bottom view of a portion of the flex circuit of FIG. 37A, according to the present invention.

FIG. 38A is a perspective view of a flex circuit embedded or pressed into a substrate, according to the present invention.

FIG. 38B is a partial, side cross-sectional view of the flex circuit of FIG. 38A, according to the present invention.

FIG. 39 is a top view of another embodiment of a flex circuit, according to the present invention.

FIG. 40A is a partial perspective view of a quad wire assembly with a flex circuit, according to the present invention.

FIG. 40B is a partial cross-sectional view of the quad wire assembly with a flex circuit of FIG. 40A, according to the present invention.

FIG. 41A is a partial cut-away perspective view of a catheter shaft with a braided shield and anti-kink beading, according to the present invention.

FIG. 41B is a partial cut-away perspective view of another embodiment of a catheter shaft with a braided shield and anti-kink beading, according to the present invention.

FIG. 42A is a side elevational view of asymmetric catheter basket FIG. 13, according to the present invention.

FIG. 42B is a front elevational view of a symmetric basket, according to the present invention.

FIG. 42C is a front elevational view of an asymmetric basket, according to the present invention.

FIG. 43A is an electrogram obtained with the catheter basket system of the present invention.

FIG. 43B is an electrogram obtained with a catheter basket system of the prior art.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

FIG. 1 is a perspective view of basket style cardiac mapping system or assembly 10 of the present invention, and FIG. 2 is a side elevation view of the catheter system or assembly 10 of FIG. 1. As depicted in FIGS. 1 and 2, the catheter system or assembly 10 consists of three subassemblies: the mapping catheter assembly 8, including hemostat penetrator assembly 25, and the extension cable assembly 31. The mapping catheter assembly 8 includes a spline basket 12, which includes splines 14 with spline tube assemblies (not shown) having electrodes (not shown); a

catheter body or shaft 20; a hemostat penetrator assembly 25 (comprised of a hemostat penetrator tube 22 and hemostat penetrator handles 24); a handle strain relief 26; a handle 28, with an integral connector (not shown). The extension cable assembly 31 includes a mating connector 30 and an extension cable 32; interrelated as shown. The catheter assembly 8 allows ease of operation and precise positioning and control of the basket 12 within a patient. Desirably, connector 30 is round so there is no rotational bias as the basket 12 is disposed within a patient. A non-round connector grip, for example a rectangular connector grip (not shown) may provide a rotational bias which, if desired, may be used with the present invention. The mating connector cable assembly 31 is useful for connecting the catheter assembly 8 to external devices (not shown), such as devices that receive and analyze electrical signals from the catheter system 10. The strain relief section 26 is useful in providing kink resistance to the catheter body 20 especially when the catheter assembly 8 is disposed within a patient.

The splines 14 of the spline basket 12 are secured by a distal tip 16 at one end, i.e. the distal end, of the basket 12, and are further secured by a proximal anchor 18 at an opposed end, i.e. the proximal end, of the basket 12. The anchor 18 is secured to a distal end 20B of the catheter body 20 and/or within a lumen 20C of the catheter body 20 of the catheter 8 of the present invention. The proximal end 20A of the catheter body 20 is secured to the strain relief section 26 of the handle 28.

The spline basket 12 is deliverable through and into bodily organs, such as but not limited to the right atrium of a heart. One useful delivery technique includes the Seldinger delivery technique. The Seldinger techniques uses a short introducing catheter, such as the introducing catheter 34 as depicted in FIG. 3, and a longer catheter, such as the catheter 46, which may also be referred to as an guide catheter or delivery sheath when described with the system 10 of the present invention, as depicted in FIG. 4. The introducing catheter or introducer 34 is typically fairly short at about six inches in length and is used to navigate through muscle and into a desired vein. The catheter 46 is typically a long guide sheath, typically 60 mm to 80 long. In a typical Seldinger technique, a vessel or cavity is punctured with a sharp hollow needle or trocar (not shown). If desired, a guidewire (not shown) may be then advanced through the lumen of the trocar, and the trocar is withdrawn. The introducing catheter 34 may then be passed over the guidewire into the cavity or vessel. The introducing catheter 34 includes a hollow introducer lumen 36. The distal end 42 of the introducing catheter 34 is positioned with a vessel or cavity. The proximal end 44 of the introducing catheter 34 remains outside of the patient so as to allow a practitioner to control the position of the distal end of the introducing catheter 42. The proximal end 44 of the introducing catheter 34 may include a hemostat valve 38 and a saline flush lumen 40. The catheter lumen 48 of the guide catheter 46 is deliverable through the lumen 36 of the introducing catheter 34 to a desired bodily site. The guide catheter 46 includes a distal end 54 and a proximal end 56. The guide catheter 46 may also include a proximal hemostat valve 50 and a saline flush lumen 52.

As used herein the term "proximal" generally refers to a location or direction towards the practitioner. The term "distal" generally refers to a location or direction away from the practitioner. Further, the terms inner, inward and the like generally refer to a direction toward the inside of the basket 12, for example towards a longitudinal axis L between the distal tip 16 and the proximal anchor 18. The terms outer, outward and the like generally refer to a direction away from

the inside of the basket 12, for example away from a longitudinal axis L between the distal tip 16 and the proximal anchor 18.

In preparation for insertion of the basket catheter 8, the basket 12 is collapsed within the hemostat penetrator tube 22 of the hemostat penetrator assembly 25. The distal end 23 of the hemostat penetrator is insertable through the hemostat valve 50 of the Guide catheter 46. The basket 12 and a portion of the catheter body 20 are advanced and deliverable through lumen 48 and past the distal end 54 of the catheter 46. Typically, the strain relief portion 26, the handle 28, the mating connector 30 and the connector 32 of the system 10 of the present invention remain outside of the body or proximally past the proximal end 56 of the catheter 46. Upon withdrawal of the hemostat penetrator tube 22 from the guide sheath hemostat valve 50, the guide sheath hemostat valve with create a leak-proof seal against the outer wall of the catheter body 20, preventing the loss of blood through the introducer system.

FIGS. 5 and 6 depict an embodiment of the distal end of the basket style cardiac mapping catheter 8 of the present invention. As depicted in FIG. 5 the spline basket 12 is deliverable through and past the distal end 54 of the lumen 48 of the catheter 46 and deliverable through and past the distal end 23 of the hemostat penetrator 25, which also has an open lumen. The distal end 23 of the hemostat penetrator 25 is useful for penetrating the hemostat valve 56 on the proximal end of the guide catheter 46.

As depicted in FIG. 5, the splines 14 of the spline basket 12 are in an expanded state, such as a radially expanded state. The overall shape of the expanded basket 14 is depicted as being an expanded, non-cylindrical shape. While the expanded splines 14 are depicted in a spherical or somewhat spherical orientation, the present invention is not so limited. Indeed, in preferred embodiments of the present invention the expanded splines 14 assume a non-spherical or substantially non-spherical shape, preferably asymmetric, especially but not limited to the spline portions near the distal tip 16 and/or the spline portions near the proximal anchor 18. Such overall shapes are non-limiting, and other overall basket shapes, including substantially spherical shapes, asymmetric spherical shapes, non-spherical shapes, non-spherical asymmetric shapes and the like may suitably be used.

As depicted in FIG. 6, the splines 14 of the spline basket 12 may be in a compressed state within the lumen 48 of the guide catheter 46 and/or of the lumen of the hemostat penetrator tube 22. The splines 14 are depicted in FIG. 6 as being in a compressed approximate or substantial elongate cylindrical shape. In such a compressed state the effective length of the splines 14 between the distal tip 16 and the proximal anchor 18 are substantially the same. Effective spline lengths between the distal tip 16 and the proximal anchor 18 in the expanded basket shape of, for example, FIG. 5 are not so limited and, if desired, may vary as described in further detail below.

FIG. 7 is an expanded side view of a portion of the basket 12 of the system 8 of FIG. 1 showing M-shaped, symmetric distal splines, according to the present invention. The distal basket portion 70 has distal spline portions 66 secured to one and the other by the distal tip 16. The proximal basket portion 68 contains proximal spline portions 62. The proximal spline ends 60 are secured by the proximal anchor 18 (not shown). Medial basket portions 72 and medial spline portions 64 are disposed between the respective ends.

As depicted in FIG. 7, the splines 14, including medial portions 64 of the splines 14, expand or bow outwardly to

assume an expanded, non-cylindrical shape, with the basket 12 having a proximal basket portion 68, a distal basket portion 70 and a medial basket portion 72 there between. While the expanded splines are depicted in a spherical or somewhat spherical orientation, the present invention is not so limited. Indeed, in preferred embodiments of the present invention the expanded splines 14 assume a non-spherical or substantially non-spherical shape, preferably asymmetric.

FIG. 8 is a perspective view of the basket 12 of FIG. 7. Although eight splines 14 are depicted, the basket 12 of the present invention may have any useful number of splines. FIG. 9 is a right side view of the M-shaped basket embodiment of FIG. 7 depicting symmetric spline angles. As depicted in FIG. 9, the angles, $\theta 1$ through $\theta 8$, are all approximately equal at 45° . Such a relationship is a predetermined angular relationship to offer a symmetric or substantially symmetric basket 12 as viewed from a cross-sectional plane of the basket 12.

The present invention, however, is not so limited. For example, as depicted in FIGS. 10 and 11, a predetermined angular relationship where the angles, $\theta 1$ through $\theta 8$, may vary may suitably be used. As depicted in FIG. 11, the angles $\theta 1$ and $\theta 5$ are approximately 90° , and the angles $\theta 2$ through $\theta 4$ and $\theta 6$ through $\theta 8$ are approximately 30° . These angles are non-limiting and any suitable arrangement of angles may be used. Such a non-symmetric angular relationship as depicted in FIGS. 10 and 11 may be useful, if desired, to concentrate a greater number of splines 14 at a particular location within the body, for example the right atrium of the heart.

FIG. 12 a side elevational view of one of the splines 14 of FIG. 7 showing the M-shaped distal curve 74 of basket 12 at the distal spline portion 66. The spline 14 also contains a proximal recurve 76 at the proximal spline portion 62. Further the spline 14 is also depicted as being symmetric in its expanded state about a longitudinal axis L, which is determined by the line segment axis from the proximal anchor 18 to the distal tip 16. FIG. 13 is a perspective view of the spline 14 of FIG. 12, further depicting the spline curvatures at the proximal spline portion 62 and the distal spline portion 66.

FIG. 14 is an exploded view of the distal M-shaped spline curve 74. The M-shaped spline curve 74 contains distal incurvate inward bends 78 and excurvate outward bends 80. Bend 78 is described as incurvate and/or inward because an apex 79 is directed towards the interior of the basket 12. Bend 80 is described as excurvate and/or outward because apex 81 is directed away from the interior of the basket 12. Bends 78 are useful in controlling angles from which splines 14 exit from or emerge into the distal tip 16, i.e., directed toward the exterior of basket 12. The bends 80 turn the splines 14 back in a proximal direction towards the proximal anchor 18.

FIG. 15 is an exploded view of the proximal spline portion 62 of the spline 14 of FIG. 12. The proximal spline portions 62 contain proximal recurves 76. The proximal recurves 76 include proximal incurvate bends 82 having apices 83 and proximal excurvate bends 84 having apices 85. The proximal recurves 76 impart several important features to the basket 12 of the present invention. The proximal recurves 76 allow for the geometry and flexibility of individual splines 14 to vary at the proximal end 62 which allows the basket 12 to become asymmetric and to better conform to the contours of the right atrium, as described in conjunction with FIG. 42A below. Further, the proximal recurves 76 allow for better placement of electrodes (not shown) at the proximal atrial tissue. Baskets common in the

prior art do not often have good contact with proximal atrial tissue, thereby adversely effecting electrical activity detection thereat. Furthermore, the flexibility and geometry of the recurves 76 also permit enhanced electrode-tissue contact for the electrodes placed not only on the proximal spline portions 62, but also on the medial spline portions 64 and distal spline portions 66.

FIG. 16 is an exploded view of the distal spline portion 66. The splines 14 may contain portions of reduced spline widths 88 as compared to normal or non-reduced spline widths 86. Here the reduced spline widths 88 are depicted as being near the distal spline portion 66. Such reduced widths 88 may increase spline flexibility, as these spline portions are proximal to the distal tip 16 (not shown). The distal spline portion 66 may also include an alignment member 89 which, as described further below, is useful for aligning and/or securing the splines 14 within the distal tip 16 (not shown). The reduced width portions 88 at the spline distal portions also allows for less force to compress the basket 12, as depicted in FIG. 6, during removal of the basket 12 from the patient. Further, the reduced spline widths 88 aid in the basket 12 in achieving the substantially cylindrical shape, as depicted in FIG. 6. In other words, as compression of the basket 12 within a lumen 22, 48 goes from the medial basket portions 72 towards the distal basket portions 70, the reduced spline widths 88 allows the distal incurvate bends 78 to flex outward or away from the compression force so that the distal spline portions 66 do not retain the inward bends 78, or simply stated the bends 78 pop outward during radial compression of the basket 12. Another advantage of the distal M-Shaped spline curve 74 is that the distal tip 16 is directed towards the interior of the basket 12 when the basket 12 is deployed or is in its radially expanded state. This feature, if desired, keep the distal tip 16 away from distal heart tissue as the distal spline portions 66 may extend beyond the distal tip 16 in the longitudinal direction of the basket 14.

FIG. 17 is another embodiment of the spline 14 of FIG. 12. The spline 14 of FIG. 17 contains proximal tangential curves 90. While the tangential curve 90 may not offer the same degree of spline flexibility and basket stability as offered by the proximal spline recurve 76, such a proximal tangential curve 90 may be preferred by some practitioners in certain atrial procedures.

FIG. 18 is a side elevational view of another spline 14 useful with the present invention. The spline 14 in FIG. 18 has a similar proximal spline recurve 76 as the spline 14 of FIG. 12. However, the spline 14 of FIG. 18 has a D-shaped distal end portion 66. Such a D-shaped distal end 92 is useful with certain embodiments of distal tips 16 that are described below. FIG. 19 is a perspective view of the spline of FIG. 18 showing spline curvatures in further detail. FIG. 20 is an exploded view of the D-shaped spline portion 92 of FIG. 18. The distal spline portion 66 has substantially flat portions 94 followed by the curved portions 96. The curved portions 96 merge into the normal curvature of the overall basket shape. The substantially straight portion 94 are useful with certain distal tip 14 designs and where spline emergence or entrance angles at the distal tip 14 are desired to be about 90° .

FIG. 21 depicts yet another spline 14 embodiment. The spline 14 of FIG. 21 contains D-shaped distal portions 94, 96 at the distal spline portion 66 and proximal tangential curves 90 at the proximal spline portion 62. Thus, the assembly 10 of the present invention may use any combination of the above-described spline geometries.

Splines **14** may be flattened splines through the body of the spline **14** having a substantial rectangular shape with rounded sides (see, e.g., FIG. **34C**). Throughout at least a major portion of the splines **14**, the splines **14** may be about 0.013 to about 0.035 inches wide (W1) and about 0.002 to about 0.012 inches thick (T1), as depicted in FIGS. **22A** through **22D**. A preferred width (W1) is about 0.022 inches. Spline thickness (T1) may depend on the overall size of the basket **12** with small sized baskets, for example less than 60 mm in nominal diameter, the thickness may range from about 0.002 inches to about 0.010 inches, with 0.004 inches being preferred. For larger size baskets, for example greater than 60 mm in nominal diameter, the thickness may range from about 0.002 inches to about 0.012 inches, with 0.006 inches being preferred. These dimensions are not limiting and represent normal or typical spline width portions **86** and spline thickness portions **98**.

Some portions of the splines **14** may have reduced width portions **88** and/or reduced thickness portions **100**. Typically, these portions **88**, **100** are disposed at distal spline portions **66** near or at the distal tip **16**. However, the present invention is not so limited at these reduced portions **88**, **100** may be present in proximal spline portions **62** and medial spline portions **64**. The thinned spline portions **88**, **100** may have a reduction in width and or thickness of several thousands of an inch. For example, the thickness (T2) of certain spline portions **100** may be thinned down to several thousands of an inch or to a thickness of about 0.003 inches to 0.004 inches, or less. Such thinning of the distal spline segments **66** near the membrane tip **14** reduces stresses during capture of the splines **14** within the guide catheter **34**. Low stress is an advantageous feature during collapse for introduction, repositioning and withdrawal of the spline basket. The width (W2) of the narrowed spline segments **88** may be narrowed from about 0.013 to 0.035 inches to about 0.008 to 0.014 inches. Such thinning aids the splines **14**, when they fold up or collapse into the guide catheter **34**, to overcome their tendency to push themselves apart and avoid them occupying more space in the catheter **34**. Thus, a low profile catheter system **10** may be provided according to the present invention.

FIGS. **23A** and **23B** depict a spline portion, such as spline portion **86**, having a buckle point **102**. The buckle point **102** may be ground into the spline **14** or formed by any other suitable technique. The buckle point **102** is depicted as an inwardly curved notch, but other designs may suitably be used. As depicted in FIGS. **23A** and **23B**, the buckle points **102** provide the splines **14** with curvature inflection points, which provide the basket **12** with improved matching of the contours of the interior of the heart. The buckle points **102** may be disposed at any location along the proximal spline portions **62**, the medial spline portions **64** and/or the distal spline portions **66** shown in FIG. **21**. Further, the number or frequency of buckle points **102** may also vary.

As depicted in FIGS. **24** and **25**, the splines **14** may emerge from the distal tip **16** at any useful emergence angle, α , with respect to the longitudinal axis L, which is defined by a line segment from the proximal anchor **18** to the distal tip **16**. For example, as depicted in FIG. **24**, the emergence angle α may be about 45° or less than about 45°. As depicted in FIG. **25**, the emergence angle α may be about 90°. The splines **14** may include a bend **78** which is useful for, among things, controlling the shape of the expanded splines **14** or basket **12**. The distal tip **16** shown in FIGS. **24** and **25** is merely a schematic depiction of a general tip. Any of the below-described distal tips of the present invention may be used with any of the emergence angles described in con-

junction with FIGS. **24** to **25**. The angles are non-limiting, and any suitable emergence angle or combination of emergence angles may be used.

FIGS. **26A** through **26F** depict a two-part welded distal tip **16**, according to the present invention. FIG. **26A** is a front perspective of distal tip **16**; FIG. **26B** is a back or rear perspective of distal tip **16**; FIG. **26C** is perspective view of a top part of the distal tip **16**; FIG. **26D** is a bottom view of the top part of the distal tip **16**; FIG. **26E** is a top perspective view of the bottom part of distal tip **16**; and FIG. **26F** depicts an alternate embodiment of the distal tip **16**.

As depicted in FIGS. **26A** through **26E**, distal tip **16** may include a top part **104** and a bottom part **108**. The distal portions **66** of the splines **14** are securably disposed within the distal tip **16**. The top surface **106** of the top part **104** may have any suitable shape, such as a substantially flat surface **106** with rounded edges so that the distal tip **16** is an atraumatic tip, i.e., a tip that will not cause damage to atrial tissue. The bottom part **108** likewise should be free of any sharp edges or projections to avoid atrial tissue damage. The top part **104** and the bottom part **108** are secured to one and the other by any suitable means. One non-limiting means and useful means is welding the two parts together to provide a unitary distal tip **16**. Such securement is typically performed after proper placement of the distal spline portions **66** within the distal tip **16**.

As depicted in FIGS. **26C** through **26D**, the top part **104** of the distal tip **16** may include spline alignment posts **110**. The spline alignment posts **110** are spaced apart so that the splines **14** may fit between the spline alignment channels **112**. The spline alignment posts **110** do not extend completely into the center of the distal tip **16**, but terminate to provide a center spline alignment portion **114** of the top part **104** of the distal tip **16**. The center spline alignment portion **114** is useful for receiving the spline alignment members **89** of the distal portions **66** of the splines **14** into that region **114** of the distal tip **16**. The combination of the center spline alignment portion **114** and the spline alignment channels **112** provide for, among other things, securably holding the splines **14** in any desired predetermined angular relationship. The number of spline alignment posts **110** may vary as the number of splines **14** may vary within the distal tip **16**. The bottom part **108** of the distal tip **16** may contain flat top and inner surface **116**. The surface **116** may generally correspond to the bottom surfaces of the spline alignment posts **110**. The bottom part **108** may also include a raised central portion **118**. Desirably this raised central portion **118** is substantially flat. The raised portion **118** is sized so that it can be disposed within the center spline alignment portion **114** of the top part **104** of the distal spline **16**.

While the splines are securably held within the distal tip **16**, the spline alignment channels **112** allow some movement of the spline **14**. For example, spline portions may move upward and or downward with the spline alignment channel **112** to provide flexibility of the splines **14** at the distal tip **16**. If desired, an elastomeric material may also be placed within the two-part distal tip **16** to minimize tip voids and open spaces.

As depicted in FIG. **26F**, the two-part distal tip **16** may include a rounded or domed upper **106'** of the top part **104'**. Such a rounded or domed design may be useful in providing more rounded surfaces for the atraumatic distal tip **16**.

The distal tip **16** of FIGS. **26A** through **26F** may be made of any suitable biocompatible material. Although metal materials are preferred, plastic materials may be used.

FIGS. **27A** through **27C** depict an alternate embodiment of the distal tip **16** of the present invention, i.e., a filament

wound and encapsulated distal tip **120**, in which FIG. **27A** is a front perspective view of the filament wound and encapsulated distal tip **120**; FIG. **27B** is a side view of the filament wound and encapsulated distal tip **120**; and FIG. **27C** is a back or rear perspective view of the filament wound and encapsulated distal tip **120**. FIGS. **27D** and **27E** are exploded views of the filament wrapping for the filament wound and encapsulated distal tip **120**, in which FIG. **27D** is a top perspective view thereof and FIG. **27E** is a back or rear perspective view thereof. The filament **124** is wrapped over, under and between the splines **14** and over and under the spline alignment members **89** to secure the splines **14** in any desired predetermined angular relationship.

The splines **14** are secured to each other at the filament wound and encapsulated distal tip **120**. Tip **120** may be described as being a "filament wrapped and encapsulated" or a "suture wrapped and encapsulated" tip **16**. Tip **120** is not limited to the use of suture materials and any suitable filaments, threads, wires and the like may be suitably used. Advantageously, the filament wound and encapsulated distal tip **120** is a low profile tip. Further, filament wound and encapsulated distal tip **120** has no open spaces, such as slots or holes, common with some basket catheters of the prior art. Such open spaces or holes present in tips of the prior art allow for entry of blood cells, thereby causing or having the potential to cause blood clot formation or thrombogenesis. As described below, the splines **14** are secured to each other at their circular alignment members **89** by the use of a suture(s) **124**, filament(s) **124**, wire(s) **124** or thread(s) **124**. Multiple sutures **124**, filaments **124**, wires **124** or threads **124** may be used. After the splines **14** are so secured, the circular alignment members **89** of the splines **14**, including the securing suture(s) **124**, filament(s) **124**, wire(s) **124** or thread(s) **124** are fully or substantially or partially encapsulated with an encapsulant **122** to provide the filament wound and encapsulated distal tip **120**.

As depicted in FIGS. **27D** and **27E**, the circular tip spline alignment portions **89** of the splines **14** are aligned or substantially aligned with each other. Filament(s) **124** are laced, looped or wound between, over and under the splines **14** at the circular tip spline alignment portions **89**. A single filament or multiple filaments **124** may be used. Advantageously, the filament(s) **124** is laced, looped or wound between every adjacent spline portion. As depicted in FIGS. **27D** and **27E**, the filament(s) **124** is laced, looped or wound about opposite spline intersections or alternating spline intersections and then is crisscrossed in a similar fashion until all or substantially all of the spline intersection locations are secured.

The filament **124** may include any suitable material. The use of high tensile strength fibers, such as electrospun, braided or monofilament may be used. Some non-limiting examples include, but are not limited to, for example: Dyneema Purity® (Ultra High Molecular Weight Polyethylene or UHMWPE), Spectra® fiber (UHMWPE), Polyethyleneterephthalate or PET, polypropylene, etc. Metallic wires, such as stainless steel or nitinol, may also be used, but non-metallic fibers are preferred for their greater flexibility. The filament(s) **124** may be tied or twisted together to secure the circular tip or alignment portions **89** of the splines **14**. The filament(s) **124** may be twisted or tied together at locations interior to the spline basket **12**. The tied together circular tip or alignment portions **89** and the filament(s) **124** are then encapsulated with an encapsulant **122**. One useful encapsulant **122** is polyurethane, but other biocompatible encapsulants may suitably be used. The encapsulant **122** is

also disposed between the spline intersection points to provide the tip **120** of the present invention.

Some advantages of the filament wound and encapsulated distal tip **120** of the present invention include, but are not limited to improved flexibility over tips of the prior art; reduced thrombogenicity; significantly smaller overall tip size; transparency under fluoroscopy; no MR artifacts; superior strength, i.e., equal to or greater than 15 times the strength of steel of the same diameter; superior adhesive bond strength; resistance to cutting (scissor action); and very small diameters, as low as 25 decitex (dtex).

As depicted in FIGS. **27A** through **27C**, the filament wound and encapsulated distal tip **120** has an atraumatic profile with a smooth, somewhat rounded upper surface, an inwardly contoured bottom surface and smooth side surfaces. The amount of encapsulant **122** may be minimized to provide maximum spline flexibility.

FIG. **28A** depicts another embodiment of the distal tip **16** in which two-part welded distal tip **126** with half splines is provided. As depicted in FIG. **28A**, two-part tip **126** includes a top portion **128** insertable through a bottom portion **130**. A space or detent is provided in either or both portions **128**, **130** so that distal ends **67** of the splines **14** may be securably inserted therein. The portions **128**, **130** of the two-part tip **126** are securably joined together to securably affix the distal spline ends **67** therein. The portions **128**, **130** of the two-part tip **126** may be secured to each other by spot welds **132**, but other securing techniques may suitably be used. Although the splines **14** are depicted as emerging from the sidewall of the two-part tip **126**, the present invention is not so limited. If desired, the splines **14** may emerge from the top portion **128** (not shown) and/or the bottom portion **130** (not shown). The emergence angle of the splines **14** from the two-part tip **126** may include any of the above-described emergence angles. The splines **14** depicted in FIG. **28A** may be referred to as half-splines because these splines have both distal spline ends **67** and proximal spline ends **60**.

FIG. **28B** depicts another embodiment of the distal tip **16**, in which a nitinol shrink ring tip **134** according to another aspect of the present invention. Spline ends **67** may be disposed within the tip **134**. The tip **134** has a compression ring **138** and a core post **136**. The spline ends **67** are disposed within and secured by the tip **134**. The ring **138** may be made from metallic, nitinol shape memory metal, shrink tubes. It may be machined at room temperature to design specifications, and then chilled so it can be expanded and stored. One may slip the ring **138** over the mated spline ends **67** and post **136** and assemble quickly. As the ring **138** comes up to room temperature it shrinks and provides a very strong compression fitting to secure the spline **14** within the tip **134**.

FIG. **28C** depicts a tip **140** which may also be used with the present invention. A cap **144** and a base **146** may be secured to each other, by for example spot welding, via a square rivet **142**. The square rivet **142** is passed through alignment square holes **148** punched in splines **14**, as depicted in FIG. **28D**. The splines **14** do not directly pass through the distal tip members **144**, **146**. In other words, the splines **14** do not pass through a sidewall of tip **140**, as no sidewall is present between the distal tip members **144**, **146**.

In another embodiment of the present invention, the tips of the present invention may include a magnetic tip (not shown). With previously described constraining tips spline lengths should be about identical in order for the basket to collapse evenly into guide catheter. If atrium outline shape deviates from approximately cylindrical or oval, then equal length splines may not contact all endocardial surfaces. A

way to circumvent this problem is to allow the splines to be of different lengths (to match the atria), and allow the tip to “assemble” itself in situ when deploying. The tip may also “disassemble” itself when being captured into the guide catheter. This design may be achieved by using a small magnetic portion on each spline that “self assemble” themselves into a tip when deployed from the guide catheter, and disassemble themselves (i.e., magnets pull apart) when the basket is collapsed into the guide catheter. It may be necessary to place an elastic thread between each magnet, pulling them close enough for magnetic force to pull into assembly. If the splines follow the inside wall of the heart during diastole, then the splines need to buckle or deform during systole. The buckling will bring parts of the spline out of contact with the endocardium. Deformation will move the electrodes to different locations on the endocardium, confusing the mapping software. Note that, during atrial fibrillation, the heart remains close to its diastolic dimensions during its entire contraction cycle. This reduces the significance of this effect, making the basket design easier. In order for the basket to collapse into the guide catheter the splines need to be the same length but would need to be different lengths in order to follow locally distended parts of the atrium. A magnetic tip would disassemble as the catheter goes into the guide catheter. An elastic thread could be used between them so that the magnetic field then grabs them the rest of the way.

FIG. 29 depicts another embodiment of a distal tip 16, in which an encapsulated tip 150 is provided. The encapsulated tip may include any suitable flexible and/or elastomeric material. The overall profile of the tip 150 may be larger than for the filament and encapsulated tip 120 as tip 150 may not contain any filament wrapping or securement means. The encapsulated or molded tip 150 may be made from any suitable material. In one embodiment of the present invention, the encapsulated or molded tip 150 may be made from polyurethane, polyester block amide or silicone.

FIGS. 30A and 30B depict another embodiment of the distal tip 16, in which a membrane distal tip 152 is provided. The membrane tip 152 may include an inner membrane or film 156 and an outer membrane or film 154 for securing the distal portions 66 of the splines 14. The distal portions 66 of the splines 14 may simply cross each other between the two membranes 154, 156. The membranes 154, 156 may be bonded, for example adhesive bonding, thermal bonding, and the like, together to provide the membrane tip 152.

The splines 14 may simply cross within the membrane tip 152. No separate connection between the splines 14 within the membrane 152 is needed. If desired, a connection (not shown) between the splines 14 may be provided. The inner membrane 156 and the outer membrane 154 may be adhesively bonded to all splines 14 within the membrane tip 152. Further, the inner membrane 156 and outer membrane 154 may be adhesively bonded to each other at locations between the splines 14. All elements may then be placed into fixture (not shown) so as to ensure the proper linear and angular orientation of the elements and then heat bonded together.

The present invention is not limited to the use of the inner membrane 156 and outer membrane 154 to form the membrane tip 152. Additional membrane layers or films may be used. The membrane tip 152 may have any suitable shape, for example a circular shape, an octagonal shape, and the like. Further, matched diameter adhesive pads (not shown) may be placed between splines 14 to add additional support beyond just membranes 154, 156. The adhesive pads between the splines 14 at the membrane tip 152 may fill in

gaps between splines 14, thereby providing a slightly larger area for adhesive bonding, if desired. Thus, in either embodiment the width and/or thickness of the tip membrane 152 is minimal, i.e., less than the thickness of the splines 14, or about the same thickness of the splines 14 or even just slightly larger than the thickness of the splines 14. In any case, the tip membrane 152 does not have an appreciable sidewall as compared to the tips of the prior art.

Further, the tip membrane 152, including the inner membrane 156 and outer membrane 154, may be made from any suitable polymeric material, preferably non-elastic polymeric material, including flexible non-elastic polymeric material. In one embodiment the membranes 154, 156 may be made from a polyimide material. Desirably, the membranes 154, 156 are not made from polytetrafluoroethylene, i.e., PTFE, including expanded polytetrafluoroethylene, i.e., ePTFE.

FIGS. 31A through 31D depict an embodiment of the proximal anchor 18 of the present invention, in which a slotted proximal anchor is provided. FIG. 31A is a perspective view of the proximal end 160 of the slotted anchor 158. FIG. 31B is a cross-section view of the distal end 162 of the slotted anchor 158 taken along the 31B-31B axis. Slotted anchor 158 has an open diameter or open lumen 164. The open diameter or lumen 164 allows wires, flex circuits, etc. from the spline basket 12 to pass through the anchor 158. The proximal end 160 of the slotted anchor 158 presses into an inner diameter or lumen of a catheter shaft 20C or is otherwise connected to the catheter shaft 20. Anchor 158 also includes spline-receiving slots 168. The number of spline-receiving slots 168 typically is equal to the number of proximal spline end portions 60, and is shown in these drawings as a quantity of eight. As depicted in FIGS. 31A and 31B, the spline-receiving slots 168 may be evenly spaced to allow for the basket splines 14 to be equally spaced in the desired angular position. The present invention, however, is not so limited, and any number of proximal spline end portions 60 and spline-receiving slots 168, oriented at any desired relative angles may suitably be used.

One function of the anchor 158 is to attach the basket splines 14 to the catheter 20 and orient the splines 14 to give the basket 12 the proper shape and ensure it remains straight (not bent) upon collapse into the guide catheter 46. The anchor device 158 is a means by which to orient the basket splines 14 on the proximal end 68 of the spline basket 12 and to fasten them together. Additionally, the anchor 158 affixes the basket splines 14 to the catheter shaft 20. The anchor 158 may be fabricated from a single piece of material, e.g., a hypotube, or multiple sections that are attached (i.e. welded, glued, etc.) together. The slots 168 are sized to fit the basket splines 14 and the slot length ensures splines 14 are positioned accurately, which aids in even collapsing of the basket 12. The slots 168 have adequate length to allow for the variable positioning of the basket splines 14. The basket splines 14 may be attached to the anchor 158 by adhering with glue, welding, crimping or the like. Additionally, a ring (not shown) may be slid over the anchor 158 to hold the basket splines 14 in place. The outer ring (not shown) may be crimped, swaged, welded, glued, etc. to the outside 166 of the anchor 158 or the outside of the catheter shaft 20. The angular spacing of the slots 168 may be varied to accommodate the amount or number of basket splines 14 to be attached as well as to get the desired spacing of basket splines 14. As depicted in FIG. 31B, one typical angular spacing is 45° degrees. The proximal end 160 of the anchor 158 is sized to press fit into a catheter shaft. It can be changed to accommodate any desired catheter dimensions.

Additionally, the proximal end **160** can have geometry to mechanically lock the anchor into the catheter shaft (i.e., barb(s), serrated edges, ribs, etc.). The inner diameter or lumen **164** of the anchor **158** is open to allow for catheter wiring, flex circuits, etc. to pass through the catheter shaft. Additionally, the wiring, flex circuits, etc. could be, if desired, run on the outer diameter of the anchor device **158**. Additionally, when the splines **14** are inserted into the anchor **158** and it is press fitted into the catheter shaft **20C**, the anchor **158** locks into the catheter shaft **20C** to enable the shaft **20** to be rotated without the basket **12** slipping inside the catheter shaft **20C**. Some non-limiting advantages of the anchor **158** of the present invention include, but are not limited to, ease of allowing fastening or gathering of basket splines **14** made of any material; may be fabricated from any suitable material or multiple materials; allows for variable positioning (length and angular) of the basket splines **14** to ensure even collapsing into the recovery sheath device; and provides sufficient clearance for device wiring. Further, as depicted in FIG. **31D**, the anchor **158** may include a hemostat plug **170** into which a spline tube **172**, which may contain a spline **14**, passes to provide a sealed proximal spline tube lumen. The hemostat plug **170** may also be useful in securing the slotted anchor **158** to the catheter shaft **20**.

FIGS. **32A** through **32C** depict another embodiment of a proximal anchor **18** of the present invention, in which an anchor **176** is provided. The spline **14** may contain a notch **174** at the spline proximal end **60**. The anchor **176** includes an inner ring **181** having spline alignment slots **180** through which the spline ends **60** may pass. The spline ends **60** are interlocked with the anchor **176** via the spline notch **174** and alignment detent **184**. This interlock provides both excellent pull out retention and automatic, accurate alignment of all splines **14** with respect to each other so that they collapse neatly and reliably into the guide catheter **46** during introduction and removal of the catheter **20**. Once the splines **14** interlock with the anchor **176**, a second thin-walled tubing **178** is inserted over the anchor **176**. This tube **178** prevents the splines **14** from disengaging their interlocks in the anchor **181**. A complete lack of applicable forces on the internal anchor ring, adhesive and a slight interference fit between the external anchor and internal anchor rings prevents pull out of the inner anchor during use.

FIG. **33A** is a perspective view of the basket **12** showing spline tubes **172** having spline tube assemblies **185** and exposed electrodes **186**. FIG. **33B** is a side elevational view of the basket **12** of FIG. **33A**. The spline tubes **172** are disposed over the splines **14** except at distal basket portion **70** where the splines **14** emerge from the distal tip **16**. The exposed electrodes **186** are spaced along spline distal portions **66**, spline medial portions **64** and spline proximal portions **62**. The number of exposed electrodes **186** may vary. The electrodes **186** are part of a flex electrode circuit **188**, which will be described in further detail below.

FIGS. **34A** and **34B** are exploded partial cross-sectional views of the spline tubes **172** and spline tube assemblies **185**. The splines are disposed within a lumen **208** of the spline tubes **172**. As depicted in FIGS. **34A** and **34B** the splines **14** are not fixed to lumen **208** of the spline tube **172**. The spline tube **172** may be slidably assembled over the spline **14** to provide some interference there between. The spline tube **172** may desirably include a flexible material so that the lumen **208** of the spline tube **172** takes an elliptical shape substantially matching the cross-sectional extents of the spline **14**.

FIG. **34C** depicts a cross-section of the spline **14** of the present invention. As depicted in FIG. **10**, spline **14** may

have a flat or substantially flat upper surface **190**, a flat or substantially flat lower surface **192**, and rounded sidewalls **194**, **196**. The present invention, however is not so limited, and the upper surface **190** and/or the lower surface **192** may be rounded or otherwise have curvature, including concave and/or convex curvatures. The splines **14** desirably include and/or are made of a super-elastic material so that the splines bow outwardly into the basket shape **12**, including asymmetric basket shapes. Any suitably super-elastic material may be used. Preferably, the splines include or are made of nitinol. If desired, the spline material may also be a shape memory material, such as but not limited to shape memory nitinol. Further, the splines **14** may be about 0.013 to about 0.025 inches wide and about 0.002 to about 0.010 inches thick. These dimensions are non-limiting and other dimensions may suitably be used.

FIGS. **34D** through **34F** depict radiopaque markers **198** useful with the spline tubes **172** and spline tube assemblies **185** of the present invention. As depicted in these figures, the radiopaque marker **198** may be disposed over a portion of the spline **14** that is near an electrode **186**. Desirably, the radiopaque marker **198** is securably fixed to the spline **14**. A significant useful feature of the current design over prior art is the radiotransparency of the flex circuit electrodes **186** (described below). This feature allows the separation of the fluoroscopic images of the splines and electrodes provided by the radiopaque markers **198** from the signal gathering function of the electrodes. This feature allows distinguishable patterns of electrode markings to be produced under fluoroscopy without modifying or compromising the electrogram gathering performance of the electrodes **186**.

FIGS. **34G** through **34H** depict a non-limiting arrangement of radiopaque markers **198** with the spline basket **12** of the present invention. The number of radiopaque markers **198** may vary along each spline **14** and may vary from spline to spline. These figures represent the two-dimensional shadowgraphs produced by fluoroscopy. FIG. **34G** is a side perspective view of the basket **12** under fluoroscopy. Each spline **14** has four radiopaque markers **198** identifying a particular electrode on a particular spline **14**. For example, the four radiopaque markers **198** at **S1E8** refers to the unique combination set of {spline 1, electrode 8}; at **S2E7** refers to {spline 2, electrode 7}; at **S3E6** refers to {spline 3, electrode 6}; at **S4E5** refers to {spline 4, electrode 5}; at **S5E4** refers to {spline 5, electrode 4}; at **S6E3** refers to {spline 6, electrode 3}; at **S7E2** refers to {spline 7, electrode 2}; and at **S8E1** refers to {spline 8, electrode 1}. In addition other electrodes **186** are marked with one marker **198** or two markers **198**. Generally, even numbered splines have two markers **198** at each electrode position, and the odd numbered splines have one marker **198** at each electrode position not marked with the four markers. Such an arrangement, as depicted in FIG. **34H** allows a practitioner to easily note the orientation of the basket **12** under fluoroscopy, including the location of the distal tip **16** and all of the electrodes **198**. FIG. **34I** depicts that when the basket **12** of FIG. **34G** is rotated, individual splines **14** and electrodes **186** become apparent with the placement of the radiopaque markers **198**. For example, in FIG. **34I**, the identity of each pair of crossed splines (**S7** & **S8**, **S1** & **S6**, **S2** & **S5**, **S3** & **S4**) would be ambiguous on one side of the crossing if each electrode were marked with a single RO marker. Further, a portion of the catheter body **20** (not shown) may also include radiopaque markers (not shown) to further aid the practitioner under fluoroscopy.

FIGS. **35A** through **35H** depict the spline tubes **172** with the spline tube assemblies **185** of the present invention. As

depicted in FIG. 35A, the spline tube 172 is an elongate tubular member. The spline tube 172 or spline tube assembly 185 includes a proximal end 200 and a distal end 202. As depicted in FIG. 35A, a portion of the spline 14 may emerge from the tube distal end 202, where it may engage the distal tip 16. The present invention, however, is not limited to flexible tube assemblies 185 only with the use of the basket 12. The flexible spline tube assemblies 185 may be used by them themselves or with any other device where electrical activity within a body is to be monitored. In some cases spline tube assembly 185a may not need to have a spline portion 14 or similar component exiting from the distal end 202. The spline tube assembly 185 of FIG. 35A has two flex circuits 188, each with four electrodes 186, mounted sequentially on the spline tube 172, while the spline tube assembly of FIG. 35B has one flex circuit 188 with eight electrodes 186. These numbers of flex circuits and electrodes are non-limiting.

FIG. 35C is a partial exploded view of the spline tube assemblies 185, 185a of FIGS. 35A and 35B. As depicted in FIG. 35C, the spline tube assemblies 185, 185a may include a first flex circuit 188a having electrodes 186 and a second flex circuit 188c also having electrodes 186. The first flex circuit 188a may have a transition portion 188b where the first flex circuit 188a transitions to a position on the tube 173 below that of the second flex circuit 188c. In such a manner, multiple flex circuits may be placed on the tubes 172, while still orienting the electrodes 186 in substantially one direction, typically in an outward direction from the spline basket 12.

As depicted in FIGS. 35D and 35E, the proximal end 200 of the spline tube 172 may be sealed with a plug 204 of material. The material may be an adhesive, polymer or any other useful material having sealing characteristics. The distal end 202 of the tube 172 may also be sealed with a plug 206 of material. Such sealing closes the internal lumen 208 of the spline tube 172 against the flow of fluids, including body fluids, such as blood. Such sealing also secures the spline tube 172 to the spline 14. The present invention, however, is not limited to having just the proximal end and/or distal end so sealed or secured and intermediate portions may also be so sealed or secured.

As depicted in FIGS. 35F and 35G, the flex circuit portions 188a, 188b and 188 exiting the spline tubes 172 may be embedded into the wall of the spline tube 172. The present invention is, however, not so limited and as depicted in FIG. 35H, a portion of the flex circuit 188 may transition from the outer surface 208A and past the inner surface 208B so that it is disposed within the lumen 208 of the tube 172. The spline tube 172 and the spline tube assembly 185 may comprise a biocompatible polymer such as a polyether block amide material, such as Pebax®. Other flexible biocompatible polymers, such as polyesters, silicones (e.g. Silastic®), silicone rubber, urethanes (e.g. Texin® and Pellethane®), and the like may suitably be used.

FIGS. 36A through 36E depict an embodiment of the flex circuit 188 as a flex circuit strip 212 of the present invention. The flex circuit 212 includes a proximal end 214 and a distal end 216. Towards the distal end 216 is an electrode-containing portion 218. The medial portion 220 may be free of electrodes. The flex circuit strip 212 may contain wings 222. These wings are useful in securing the flex circuit 212 to tubular members, such as spline tubes 172, especially where it is desirable to keep the electrodes 186 as substantially unidirectional flat electrodes. The flex circuit or electrode assembly strip 188 may have a thickness from about 0.001

inches to about 0.010 inches, more desirably from about 0.005 inches to about 0.008 inches.

FIG. 36A is a top view of the flex circuit strip 212 showing electrodes 186 disposed on the upper surface 224 of the flex circuit substrate 236. The flex circuit substrate or polymeric substrate 236 may comprise a polyimide material, such as KAPTON polyimide available from DuPont, which is suitable for short term (single use medical device) or long term (medical implant) contact with skin, tissue or blood, depending on the intended application, but other suitable materials may be used, such as the above-described materials for the spline tube 172 or the spline tube assembly 185. At the proximal end 214 electrical pads are disposed on the upper surface 224. FIG. 36B is a bottom view of the flex circuit strip 212. Electrical traces 228 are disposed on the bottom surface 226 of the substrate 236. The traces run from location underneath the electrodes 186 to locations underneath the electrical pads 232. As depicted in FIGS. 36C through 36E, metal plated holes or vias 230 electrically connect individual traces to individual electrodes 186. In a similar fashion vias 234 connect individual electrical traces 228 to individual electrical pads 232.

As depicted in FIG. 36F, the flex circuit 212 may contain upper surface coverlays 238 to cover those areas of the upper substrate surface 236A not having electrodes 186 or connection pads 232. Likewise, if desired, bottom surface coverlays 240 may cover part or all of the electrical traces 228. Upper coverlays 238 and lower coverlays 240 are bonded to the substrate 236 with the use of suitable adhesive 239, usually acrylic adhesive. Desirably, the upper flex circuit axis S is substantially smooth, i.e., the coverlays 238 and the electrodes 186 being substantially the same height. The present invention, however, is not so limited, and electrodes may be raised slightly above the substrate surface with the use, for example, of strips of material disposed between the substrate 236 and the electrodes 186. Alternatively, the electrodes may be depressed slightly below the substrate surface, as shown in FIG. 36F. The coverlays 238, 240 may comprise a similar material as the substrate 236, but different materials may suitably be used.

FIGS. 37A through 37C depict an alternate embodiment of the flex circuit 188. As depicted, electrical traces may run on both sides of the flex circuit substrate 236. For example, four electrodes, 186a, 186b, 186c and 186d are depicted in FIG. 37A. In the top view of FIGS. 37A and 37B no electrical traces run on the upper surface 224 between the electrodes 186. However, proximal to the electrodes, electrical traces 228 for two electrodes 186c, 186d run on the upper surface 224, and the electrical traces for the other electrodes 186a, 186b run on the bottom surface 226 of the flex circuit substrate. The electrical trace 228 for electrode 186c transitions from the bottom surface 226 to the upper surface 224 by means of a trace-to-trace via 244. Such an arrangement of electrical traces 228 as depicted in FIGS. 37A through 37C may make for a more overall compact flex circuit.

FIGS. 38A and 38B depict a flexible electrode assembly strip 247. The flexible electrode assembly strip includes a flex circuit or electrode assembly strip 188, 236 pressed into the substrate 246 of a flexible polymeric material, such as any of the above-described materials for the spline tube 172 or the spline tube assembly 185. The flex circuit or electrode assembly strip 188, 236 may also be thermally, compressively and/or adhesively bonded onto or into the substrate 246. While the substrate 246 is depicted as being a strip or being planar, the present invention is not so limited. The substrate could be tubular with or without an open lumen. As

depicted in FIG. 38B the electrode assembly strip **188**, **236** is pressed into the substrate wall **246b** while leaving a substantially smooth upper surface **246A** and lower surface **246C**. If desired portions of the flex circuit **188**, **236**, for example those portions not containing electrodes, may be disposed between multiple two or more substrates **246**, either in planar or tubular form. When covering the electrodes with a cover or substrate of polymeric material, it is desirable to remove cover or substrate material so that the electrodes **186** remain exposed.

All components, i.e., splines, electrode flex circuits, electrode elevation strips (used to raise the surface of the electrodes above the substrate, if desired; not shown), radiopaque marker strips are desirably thin, flat, planar elements. In a simple design, these elements may be stacked and adhesively bonded to each other. Alternately, a length of flexible tubing or membrane can be slid over the bonded spline/radiopaque marker/flex circuit/electrode elevation strip in order to contain all parts within a single body. This tube or membrane can be shrunk in place for a tight, contained fit using either heat shrink tubing or tubing that is chemically expanded (e.g., by absorption of alcohol or other chemical) for assembly, and then contracts when the chemical evaporates.

FIG. 39 depicts yet another alternate embodiment of a flex circuit **188** having laterally staggered electrodes **186**.

FIGS. 40A and 40B depict the use of quad wires **248** which connect proximal end **214** of the flex circuit **188**. Individual quad wires **248** are connected to individual electrical pads **232** at the proximal ends **214** of the flex circuits. The quad wires **248** then are routed through the catheter body **20** and handle **28** to the catheter connector located at the proximal end of the handle **28**.

FIGS. 41A and 41B depict a portion of the catheter shaft **20** as having a braided shield **250** that minimizes possible electro-magnetic interference from outside sources. The catheter **20** may also have anti-kink beading sections **252** or **254**, which provide greater support to prevent kinking of the catheter **20**. Flexibility of the catheter body **20** may also be controlled which advantageously aids in having the basket **12** more closely match the contours of the heart.

FIGS. 42A through 42C further depict asymmetric basket shapes for basket **12**. FIG. 42A is a side view of the asymmetric basket shape is depicted. The basket shape is asymmetric in this view in that, among other things, the basket shape is not spherical and/or the proximal spline portions **62** may contain different degrees of curvature or bends **82**, **84**. These bends **82**, **84**, also known as a dimple end and/or a puckered end, allows the basket **12** to compress when the heart contracts. In other words, the proximal portion **68** of the basket **12** is designed with greater flexibility to ensure, among other things, improved contact of the splines **14** with interior surfaces of the heart wall.

While one overall basket shape is depicted in FIG. 42A, it may be desirable to have different basket shapes, for example, a right atrial basket shape and a left atrial basket shape. These different baskets may have different basket outline shapes and therefore different compliances of the individual splines. These differences may allow each shape to optimally conform to the differently shaped left atrium and right atrium. In addition, each shape may come in several different overall sizes. Note that the specific shape shown in FIG. 42 is not intended to represent an "atrial shaped basket", but is instead an arbitrary shape that illustrates the design features required to fabricate an asymmetric basket that will successfully collapse within a guide catheter.

FIGS. 42B and 42C are an end views of the basket **12** of FIG. 42A. As depicted in FIG. 42B, all spline portions are substantially equidistant from the center longitudinal axis L and/or tip **16** or are substantially in the center of the overall basket outline C as depicted. As depicted in FIG. 42C, all spline portions are not substantially equidistant from the center longitudinal axis L and/or tip **16** or are not substantially in the center of the overall basket outline C as depicted. Such asymmetry provides for improved basket performance by more closely matching the shape of the atria of the heart. The splines **14** in FIG. 42A have an equal or substantially equal longitudinal length. The varying distances of the medial portions **64** of the splines from the center longitudinal axis L results from, in part, the flexibility of the splines **14** at the proximal spline portions **62** due to the inclusion of the bends **82**, **84**. While the longitudinal lengths of the splines **14** are equal or substantially equal in FIG. 42A if the basket **12** is in its compressed state, the present invention is not so limited, and splines **14** of varying lengths may be suitably used. Such varying lengths may be achieved by imparting geometries to different bends **82**, **84**. For example, some bends may have greater inward longitudinal extents than other bends such that, when compressed with the guide catheter **46**, all the splines **14** of the basket **12** have an equal or substantially equal net line segment between the anchor **18** and the tip **16**. When the basket **12** is expanded, the bends **82**, **84** may "relax" and provide a basket assembly **12** with splines **14** of net different lengths, for example spline **14a** having an effective longer length than spline **14b**. Such asymmetry provided by, in part, splines **14** of varying lengths provide for a closer matching of the shape of the basket **12** with interior portions of the heart, i.e., the atria, as the heart is beating.

In a similar fashion, the bends **78**, **80** at the distal basket portion **70** also provide for asymmetry, if desired. As depicted, both proximal and distal spline portions **62**, **66** may have different recurves or incurvate bends to more effectively match the shape of a typical atrium. Different proximal recurves with different lengths and/or angles compensate for different spline lengths so that the basket may be disposed within the guide catheter where the splines would have the same or about the same effective length when the basket is compressed, but will have different effective lengths when the basket is expanded.

The apparatus, system or devices of the present invention may include electrodes are configured as Monophasic Action Potential (MAP) electrodes, where a single electrode at each site is configured to intimately contact the tissue, and a second electrode at each site is configured to face away from the tissue, acting as an MAP "reference" electrode. An electronic Data Acquisition System may be configured to record the electrograms produced by the catheter as MAP electrograms. The electronics Data Acquisition System may also be selected to record the electrograms produced by the catheter as either standard unipolar electrograms, bipolar electrograms or as MAP electrograms. Further, the electrodes may be configured as Modified Monophasic Action Potential (m-MAP) electrodes, where a single electrode at each site is configured to intimately contact the tissue, and a second electrode placed intermediate between two or more sensing (i.e., tissue facing) electrodes, which is configured to face away from the tissue, acting as an MAP "reference" electrode for multiple sensing electrodes. The curvature of the splines is specifically chosen to match the curvature of a "typical" atrium for the purpose of enhancing electrode to tissue contact, producing the contact force required for quality MAP mapping. The splines may be curved at the

proximal end with different length segments in order to compensate for the different spline lengths that result from matching the splines to the shape of a typical atrium; where equal spline total length (tissue contact segment plus recurve segment) is required to allow collapsibility for introduction and withdrawal of the catheter through the second elongate tube.

FIGS. 43A and 43B are bipolar electrograms 262, 264 obtained from animal studies. In FIG. 43A the electrograms 262 were obtained from the use of the system 10 of the present invention. In FIG. 43A, the atrial signals 258 are much larger than the ventricular signals 260 on electrodes A3, A5, A7, B7 and C3. Further in FIG. 43A, the atrial signals 258 are approximately equal to the ventricular signals 260 on electrodes B5, C1 and C5. Moreover, in FIG. 43A, the electrogram traces I, aVF and V1 are not basket signals. In general the atrial signals 258 are much larger than or equal to the ventricular signals 260. This allows a practitioner to more easily map the atrial signals within the heart to locate heart tissue causing heart fibrillations. The practitioner may suitably ablate such areas.

FIG. 43B depicts electrograms 264 obtained from animal studies using a commercially available prior art basket catheter. In FIG. 43B, atrial signals 258 are absent on electrodes A1, A5 and A7. Also in FIG. 43B, the atrial signals 258 are smaller than the ventricular signals 260 on electrodes A3, B5 and B7. Further in FIG. 43B, the atrial signals 258 are approximately equal to the ventricular signals 260 on electrode B3. Still further in FIG. 43B, the atrial signal 258 are larger than ventricular signals 260 on electrodes B1, C1, C3 and C5. Moreover, in FIG. 43B, the electrogram traces I, aVF and V1 are not basket signals. In general, the atrial signals 258, when present, are much smaller than ventricular signals 260 on some electrodes, but may also be larger on other electrodes. The recorded signals of FIG. 43A represent a significant improvement over the recorded signals of FIG. 34B. While not being bound by any theory, it is believed that the substantially flat, single sided flex electrodes 186 of the present invention with the described flex circuits and spline tube assemblies, superior contact and contact force generate higher atrial signals from the heart while reducing the ventricular signals from the heart.

Further, the improved basket geometries of the present invention also contribute to improve mapping of the atrial signals as the baskets of the present invention are not only more stable within the atrium of the beating heart, but also can flex and contour to the varying complexities of the beating heart.

The devices, systems and assemblies of the present invention are useful in overcoming the problems or deficiencies associated with mapping of the right atria and the left Atria, especially when used in conjunction with atrial fibrillation ablation. Problems or deficiencies with typical prior art or presently available commercial devices include (a) positional instability of basket during mapping and data analysis times, (b) positional instability of basket during ablation, (c) lack of proximal basket electrodes, (d) poor electrode contact with atrial tissue typically yields poor signal (atrial) to noise (ventricular) ratios, (e) lack of electrode contact (no measurable atrial signals), (f) radiofrequency (RF) noise interfering with atrial signals recording, (g) spline lateral bunching, (h) electrode sliding (i.e., changing position) during heart contraction, (i) poor spline/electrode identification under fluoroscopy, and/or (j) poor performance in left atrial (LA) transeptal procedures.

Positional instability of basket during mapping and data analysis times typically involves movement of shifting of the catheter basket. Different types of shifting include, but may not be limited to: rotation of the basket about its basket tip to anchor central axis; rotation of the basket about its axis normal to basket tip to anchor central axis; a linear shift of the basket along its catheter axis; a lateral shift of individual splines; and a combination thereof. As a result of shifting, some electrodes may come out of contact with endocardium, thereby providing an inadequate or incomplete map and data analysis of electrical signals from the heart. The basket electrodes are the "frame of reference" for all the maps generated from the electrical signals. The maps are typically produced by the software are "with respect to the basket electrode positions at the time the electrograms were recorded." As an example, the map may tell the practitioner to ablate heart tissue midway between, for example, Spline C, Electrode 5 and Spline D, Electrode 4. The practitioner will attempt to place an ablation catheter at this location, using the basket splines and electrodes as reference points. Any shift of the basket from its position at the time of recording to a different position at the time of ablation produces errors (rotational or linear) or distortions in the maps. The magnitudes of these errors are proportional to amount of shift of the electrodes. Such errors or distortions are problematic to the practitioner.

Positional instability of basket during ablation is another area of concern for a practitioner. Electrogram maps will indicate to the practitioner or clinician where to ablate "with respect to the spline and electrode positions at the time the map electrograms were recorded." The practitioner or clinician must insert an ablation catheter between splines of mapping basket and direct its steerable tip to various locations on the endocardium, using the splines and electrodes of the mapping basket as reference points within the heart. In order for the information on the electrogram maps to be useful, the spline and electrode positions of the mapping basket during ablation must be substantially equivalent to their positions during recording. Otherwise, practitioner or clinician will be relying on inaccurate reference locations.

A lack of electrodes on the proximal spline segments of the mapping basket is also a problematic for a practitioner or clinician. Mapping software gathers timing data at discrete electrode positions (a "sparse data array") and calculates continuous interpolated timing results for all areas of the heart that reside within the electrode coverage area. The software cannot extrapolate results beyond the electrode coverage area. Directed ablation is performed using the calculated, continuous interpolated space-time maps, using the electrodes as reference points. There can be no mapping or useful directed ablation on areas of the heart outside of the area of electrode coverage. Basket catheters of the prior art generally have no electrodes on the proximal segments of their basket splines. Thus, with typical prior art devices, the proximal segments of the atria (especially areas on the septal wall during transeptal mapping and ablation of the Left Atrium) cannot be mapped. Accordingly, these proximal wall segments of the atria cannot be ablated by a practitioner or clinician with the directional control of maps or reference electrodes.

Furthermore, poor electrode contact in zones where electrodes exist yields poor signal (atrial) to noise (ventricular) ratios. In the prior art devices, poor electrode contact results in decreased atrial signals (f-waves in atrial fibrillation and p-waves in sinus rhythm) as compared to background noise (ventricular depolarizations). Such a poor signal to noise ratio makes it difficult for software to automatically deter-

mine accurate f-wave timing. This results in poor automatic mapping and the need for trained human assistance in the recognition of f-waves.

A lack of electrode contact (no measurable atrial signals) is yet another concern with devices of the prior art. Electrodes that are sufficiently displaced from the endocardial surface will record no measurable f-waves. This produces holes in the sparse data array and poor resolution in zones of dropped data. While some interpolation of the missing data will occur with software, it will not be as accurate, since more widely spaced electrodes are used for such interpolation. The difference between poor electrode signal and no electrode signal is that, in the former case, a human operator may be able to assist the software algorithms in finding f-waves. However, in the latter case, there is nothing that the software or operator assistance can do to overcome the lack of available data.

RF noise may result from, among other things, a lack of shielding of the long signal conduction wires that run from the mapping catheter to the associated recorder. In a typical electrophysiology laboratory, there are many other pieces of equipment that may generate significant RF noise, which can be picked up by the long lengths of unshielded shielded wires and superimposed upon the millivolt level signals from the mapping catheter. Radiated noise is especially problematic when one attempts to compensate for low amplitude atrial signals (due to poor electrical contact) by increasing amplifier gain, because RF noise will be amplified along with the low amplitude signals.

Spline lateral bunching is also a concern with prior art devices. With the prior technology, multiple splines frequently "bunch up" (i.e., gather together) due to varying atrial wall shapes. This often puts many electrodes in close proximity to each other, leaving large zones of the endocardium lacking in electrode coverage where the splines are not "bunched-up". This will typically result in distortions in the calculated maps, with zones of unnecessarily high resolution (with extra splines and electrodes) adjacent to zones of poor resolution (lacking splines and electrodes).

Prior art devices typically do not guard against electrode sliding (i.e., changing position) during heart contraction. The mapping software typically assumes that the electrodes provide a signal from a single location on the endocardium. If electrodes slide during heart contraction, this assumption is violated. Fortunately, the valuable information for the detection of the f-wave during a-fib happens at the start of contraction for any given electrode. Motion that occurs after this event is not likely to negatively impact the mapping. Unfortunately, electrodes are typically ganged together in groups of eight on each spline. If one electrode starts to slide laterally during the contraction, it can (and will) drag the other seven electrodes on the same spline with it. The impact on the resultant map will be proportional to the difference between the assumed position and actual position of the electrode at the arrival of the f-wave, which is obviously problematic to a practitioner or clinician.

Poor spline/electrode identification under fluoroscopy is another concern for the practitioner or clinician with the devices of the prior art. With prior art devices, the eight splines are typically identified sequentially with the letters A through H. The electrodes are identified with the numbers one (most distal) to eight (most proximal). With prior technology, each electrode operates as its own radiopaque marker. This may be convenient for locating individual electrodes. Additionally, an extra dummy electrode is often placed adjacent to an index electrode on seven out of eight splines. For the prior art device, the index "Spline/Elec-

trodes" are A8, B7, C6, D5, E4, F3 and G2 electrodes. (H1 is typically not identified.) In principle, this scheme should allow the clinician to identify each spline and then each electrode. In reality, however, this system frequently produces ambiguous, difficult to resolve fluoroscopic images. As described above, the electrodes are the reference map by which the practitioner or clinician will ablate heart tissue. Difficulty in unambiguously identifying each spline and each electrode will result in uncertainty in ablation locations.

Poor performance of prior art devices in LA transeptal procedures is yet another area of concern for the practitioner or clinician. It is much more difficult to achieve a high proportion of electrodes in high quality contact with the endocardium in the left atrium than it is in the right atrium. The systems, devices and assemblies of the present invention offer improved electrode contact over the prior art in both the left atrium and the right atrium.

Some non-limiting causes of problems are described below.

Positional instability of basket during mapping and data analysis times may be due to the lack of "all direction" counter-pressure. For the prior art device, pressure on distal half of a basket often produces a net compressive force on the splines that possesses a lateral component, pushing the distal end of the catheter out of touch with the endocardium. The only force counteracting this force is provided by the catheter body shaft, which is free to float in the oversized inferior vena cava (IVC). Counterforce of basket shaft, however, is unpredictable and unreliable. Further, basket electrode shapes (typically round) and radial forces (very light) often result in extremely tenuous basket anchoring to atrial walls. Very slight loads or torques will cause baskets of the prior art to shift position.

Positional instability of baskets of the prior art during ablation may also result from the tenuous anchoring of the basket to the endocardium, which results in movement of the basket during insertion and manipulation of the ablation electrode. The practitioner or clinician must attempt to compensate for this motion by constantly repositioning the basket or by using educated estimations of the locations of relevant splines and electrodes at the time of mapping. This is complicated by the lack of proximal wall electrodes in the prior art devices, i.e., with the given shape of prior devices proximal electrodes would likely not contact endocardium. Consequently, manufacturers have chosen to place no electrodes on proximal segments of splines.

Poor electrode contact may result from misalignment of basket in atrial chamber; non-spherical atrial shape; basket/atrium size mismatch; lack of "all direction" counter pressure (causing distal electrodes to withdraw from endocardium as a result of heart contractions); inability of prior splines to track discontinuities in atrial wall curvature and/or very light radial spline force preventing splines from conforming to local recesses in the atrial wall.

A lack of electrode contact often results from the same causes as "poor electrode contact" and/or lack of proximal electrodes on splines.

RF noise results from the lack of RF shielding in catheter and extension cables.

Spline lateral bunching may occur when splines expand against endocardial surface. If that surface is at an oblique angle to the plane of the spline, a "side load" will be imparted on the spline. If the spline's lateral stiffness is too weak to resist this side load, then it will deform in that direction. Further, certain spline and electrode shapes (e.g.,

rectangular or substantially rectangular) are better suited to resist sideward sliding than other shapes (e.g., round).

For electrode sliding (i.e., changing position) during heart contraction, the same effects that may result in spline lateral bunching may be exacerbated during heart contraction. As a result, the splines can be forced to slide laterally (or twist helically) during systole. This spline movement (which carries the spline's electrodes) can produce improper electrode position or motion artifacts in the electrograms.

Poor spline/electrode identification under fluoroscopy of prior art devices is caused because each electrode acts as its own RO marker. This limits the possible schemes that one may employ to distinguish what are otherwise identical electrodes. Even if splines are definitively identified at the location of their "index electrodes", the splines always cross each other in the two dimensional fluoroscopic images. It is frequently difficult or impossible to identify splines after these crossings. See FIG. 34I for an example of this phenomenon. It can be readily appreciated in FIG. 34I that, if all electrodes appeared as a single radiopaque marker, then it would be difficult to identify each spline after such a crossing. However, by providing a distinguishable marking scheme on adjacent splines (i.e., single electrode markers versus double electrode markers on adjacent splines), then it becomes trivial to accurately identify all portions of all splines.

With regard to poor performance of prior art devices in LA transeptal procedure, a practitioner or clinician accesses the left atrium (LA) through a transeptal puncture. The practitioner or clinician pushes a specially designed needle through the septal wall separating the right atrium from the left atrium. The catheter guide sheath and mapping catheter are then advanced through this puncture site, and the mapping catheter deployed from this location. The transeptal puncture site frequently represents a very strong, misaligning constraint on the location of the proximal end of the basket. If not approximately centered in the left atrial chamber, this constraint can hold many (mostly proximal) electrodes off of the endocardium. If the transeptal puncture site is not approximately centered with respect to the left atrial chamber, the anchor portion of the basket will be drawn "off center" as well. This misalignment can have the effect of holding one sector of splines off of the proximal endocardium, while pushing the opposite sector into excess contact with its proximal endocardium. Currently, practitioners or clinicians attempt to compensate for this problem by using a "J tip" transeptal guide catheter, and directing the anchor portion of the catheter to a more centered location, or by deflecting the portion of the catheter body that is proximal to the septal wall puncture site.

The present inventions solves these problems of typical prior art devices.

Improved positional stability of basket during mapping and data analysis times is one area addressed by the present invention. First, poor solutions and non-solutions include use of larger basket, which frequently exacerbates, rather than cures, the problem; the use of inappropriate physical constraints on basket; the placing tip of basket into one of the left pulmonary veins; using J tip guide catheter to deflect distal end of catheter body, which puts an angular, as well as linear, deflection on anchor portion of basket; and/or advancing or retracting catheter body in an attempt to overcome or address the problems of the prior art. The correct solutions, as identified by the present invention, include, but are not limited to, design basket shape to fit atria; design basket shape to generate "all direction" counter pressure from its contact with endocardium; make basket

slightly oversized to diastolic size of atrium; allow basket to align itself to atrial shape; and/or relax all other constraints (as much as possible) and allow basket counter pressure to determine basket position; give electrodes and splines a shape (rounded rectangular) that is advantageous to the spline anchoring itself to the endocardium without causing trauma; and/or provide baskets in sufficiently small size increments so that a size can be chosen that will be both stable and non-traumatic.

To improve positional stability of basket during ablation, all of the position stabilization techniques described above may be used. Experience has shown that, when all splines are poorly anchored, a slight force applied to one spline will move the entire basket. When the splines are well anchored, however, slight pushing of one spline will deflect only that one spline. The other splines will retain their positions and, when the side force is removed from the one spline, the single displaced spline will return to its former position.

The devices of the present invention provide proximal wall electrodes by, for example, adjusting electrode spacing or adding additional electrodes on each spline. Further, since new spline shape will put proximal spline segments into contact with endocardium, electrodes mounted in this location contribute to map.

Improved electrode contact may be achieved with the devices of the present invention by, for example, the practitioner's use of baskets that are chosen to be slightly oversized to the patient's atrium. The use of an oversized basket will force the splines and the atrium to conform to the atrial shape will produce excellent electrode contact as the endocardium deforms to conform to each other's shape, which will reduce bridging effects, giving better electrode contact. Additional design elements that will improve electrode contact include, but are not limited to, the incorporation of break points in spline, or the inclusion of assisting tension members (e.g., elastic bands) adjacent to the splines, both said elements allowing short spline segment to flex independently of each other, providing improved electrode to endocardium contact. Additional steps to improve electrogram signal quality include: the reduction of areas of electrode exposed to far field ventricular (i.e., noise) inputs but not near field atrial signal, which improves signal to noise ratio; improved atria/basket size match by providing small increment basket sizes; and/or adding proximal curve to spline shapes allows severely distorted basket shapes that will match non-spherical atria, while being able to collapse into guide catheter.

The devices of the present invention may include RF noise shielding. An RF shield incorporated into catheter and extension cable will reduce amplifier pick up of radiated noise. Moreover, excellent electrode contact of the present invention will increase atrial signal magnitude and reduce the need for high amplifier gain.

Reduced spline lateral bunching is achieved by the present invention by giving the spline sufficient lateral stiffness to resist side loads and/or using spline and electrodes shape (rectangular or substantially rectangular) better suited to taking purchase on the endocardial wall while still providing a non-traumatic anchor.

The present invention achieves reduce electrode sliding by, for example, improved positional stability of baskets, improved anchoring of splines, relaxation of inappropriate constraints.

Improving spline/electrode identification under fluoroscopy may be achieved by several aspects of the present invention. The basket design of the present invention produces a radio-transparent electrode. Separate means (ra-

diopaque bands of metal or ink) may be varied from spline to spline, or from electrode to electrode, to produce highly distinguishable splines and electrodes, as seen in FIGS. 34G through 34I. The system described here (one marker at every electrode on odd numbered splines, two markers at every electrode on even numbered splines, and four markers on each "index electrode") produces an unambiguous fluoroscopic image.

For improved performance in LA transeptal procedure, it is desirable that the selection of puncture site be more central to left atrial chamber. Further, a reduction of constraint of anchor imposed by transeptal puncture site is also desirable.

Increased number of basket sizes by reducing step increment is also an important aspect of the present invention. Many of the prior technology's flaws are exacerbated by poor basket to atrium size match. Atria come in a continuum of sizes. The only way to achieve an adequate size match while avoiding endocardial trauma is to offer a multitude of basket sizes in relatively small increments.

One method according to the present for sensing multiple local electric voltages from endocardial surface of a heart, may comprise: providing a system (10) for sensing multiple local electric voltages from endocardial surface of a heart, comprising: a first elongate tubular member (20) having a lumen (20C), a proximal end (20A) and a distal end (20B); a basket assembly (12) comprising: a plurality of flexible splines (14) for guiding a plurality of exposed electrodes (186), the splines (14) having proximal portions (62), distal portions (66) and medial portions (64) therein between, wherein the electrodes (186) are substantially flat electrodes and are substantially unidirectionally oriented towards a direction outside of the basket assembly (12); a proximal anchor (18) for securably affixing the proximal portions (62) of the splines (14); said anchor (18) being secured at the distal end (20B) of the first elongate tubular member (20); a distal tip (16) for securably affixing the distal portions (66) of the splines (14), said proximal anchor (18) and said distal tip (16) defining a longitudinal axis (L) about which the splines (14) are disposed; wherein the splines (14) approach the distal tip (16) at an angle (α) of about 90° or less than about 90° as measured from a line segment between the proximal anchor (18) and the distal tip (16) along the longitudinal axis (L); wherein the splines (14) comprise a superelastic material such that the basket assembly (12) exhibits a substantially cylindrical shape when radially compressed and exhibits a radially expanded non-spherical shape when not radially compressed; and wherein each of the splines (14) in the radially expanded non-spherical shape contain a proximal recurve (76) in the proximate portion (62) of the spline (14) at a location near to the proximal anchor (18) of the basket assembly (12), the proximal recurve (76) comprises a proximal excurvate outward bend (84) and a proximal incurvate inward bend (82) between said proximal excurvate outward bend (84) and said proximal anchor (18), where an apex (83) of the proximal incurvate inward bend (82) is disposed in a direction toward the distal tip (16) and is further disposed inwardly closer toward the distal tip (16) than the proximal excurvate outward bend (84); delivering the system (10) to the heart so that the basket assembly (12) is disposed within the right atrium of the heart; contacting proximal atrial tissue with the electrodes (186) disposed on the proximal spline portions (62) to detect multiple local electric voltages from endocardial surface thereat; and contacting atrial tissue with the electrodes (186) disposed on the medial spline portions (64) and the distal spline portions (66) to detect multiple local electric voltages from endocardial surface thereat. The

splines (14) of the basket assembly (12) may be flexible to match the contours of the right atrium. Substantially all of the electrodes (186) may contact atrial tissue. Substantially all of the electrodes (186) may remain substantially spatially fixed with respect to atrial tissue. A substantial portion of atrial signals detected by the system (10) may have larger amplitudes than ventricular signals detected by the system (10). The splines (14) in the radially expanded non-spherical shape may contain a distal excurvate outward bend (80) disposed at the distal portion (66) of the spline (14) at a location near to the distal tip (16) of the basket assembly (12) to bend the splines (14) back towards the proximal anchor (18); and wherein the splines (14) have a distal incurvate inward bend (78) between said distal tip (16) and said distal excurvate outward bends (80). The splines (14) of the basket assembly (12) may be flexible to match the contours of the right atrium.

The devices of the present invention may suitably be used to detect or map cardiac rhythm disorders. Details of methods for detecting or mapping cardiac rhythm disorders may be found in U.S. Provisional Application No. 61/342,016, filed on Apr. 8, 2010, entitled "Methods, System And Apparatus For The Detection, Diagnosis And Treatment Of Biological Rhythm Disorders", which published as U.S. Patent Application Publication No. 2011/0251505 A1 for its corresponding Non-Provisional application Ser. No. 13/081,411, the contents of all which are incorporated herein by reference.

The following aspects, embodiments, and the like are part of the detailed description for the present invention. Embodiments directed to distal tip embodiments include, but are not limited to, as follows:

In one embodiment, a system (10) for sensing multiple local electric voltages from endocardial surface of a heart is provided. The system may comprise a first elongate tubular member (20) having a lumen (20C), a proximal end (20A) and a distal end (20B); and a basket assembly (12) comprising: a plurality of flexible splines (14) for guiding a plurality of exposed electrodes (186), the splines (14) having proximal portions (62) and distal portions (66); an anchor (18) for securably affixing the proximal portions (62) of the splines (14); said anchor (18) being secured at the distal end (20B) of the first elongate tubular member (20); an encapsulated and filament-wrapped distal tip (16, 120) comprising an encapsulant (122) and a filament (124) for securably affixing the distal portions (66) of the splines (14) in a predetermined angular relationship at said distal tip (16, 120); wherein the splines (14) comprise a superelastic material; and wherein the basket assembly (12) has a radially expanded non-cylindrical shape. The system (10) of may further comprise: a second elongate tubular member (46) having a lumen (48), a proximal end (56) and a distal end (54); wherein the basket assembly (12) is slidably compressible to fit within the lumen (48) of the second elongate tubular member (46); wherein the basket assembly (12) has a substantially cylindrical shape when compressed within the lumen (48) of the second elongate tubular member (46); and wherein the basket assembly (12) has said radially expanded non-cylindrical shape when not compressed within the lumen (48) of the second elongate tubular member (46) and disposed past the distal end (54) of the second elongate tubular member (46). The encapsulant may have a smooth, non-thrombogenic outer surface free of voids and slots which would permit the passage or entry of blood thereinto. The encapsulant (122) may comprise a thermoplastic material. The encapsulant (122) may also comprise a polyurethane material. The filament (124) may

comprise a polymeric filament, a metallic filament or combinations thereof. The filament (124) may be laced, looped or wound between, over and under the splines (14) to substantially align and secure the distal portions (66) of the splines (14) in said predetermined angular relationship. The flexible splines (14) may further comprise alignment members (89) at the distal portions (66) of the splines (14); and wherein the filament (124) is also laced, looped or wound between, over and under the alignment members (89). The alignment members (89) may comprise circular portions at the distal spline portions (66). The angles (θ1-θ8) between said splines (14) at said distal tip (16, 120) forming said predetermined angular relationship may be all substantially equal to each other. Alternatively, at least one angle (θ1-θ8) between said splines (14) at said distal tip (16, 120) forming said predetermined angular relationship may be different from another angle (θ1-θ8) between said splines (14) at said distal tip (16, 120). When basket assembly (12) is in said radially expanded non-cylindrical shape, the splines (14) may extend beyond the distal tip (16, 120) and may comprise excruciate bends (80) beyond the distal tip (16) to bend the splines (14) back towards the anchor (18).

In one embodiment, a system (10) for sensing multiple local electric voltages from endocardial surface of a heart, may comprise: a first elongate tubular member (20) having a lumen (20C), a proximal end (20A) and a distal end (20B); and a basket assembly (12) comprising: a plurality of flexible splines (14) for guiding a plurality of exposed electrodes (186), the splines (14) having proximal portions (62) and distal portions (66); an anchor (18) for securably affixing the proximal portions (62) of the splines (14); said anchor (18) being secured at the distal end (20B) of the first elongate tubular member (20); a distal tip (16, 150) comprising an elastomeric material for securably affixing the distal portions of the splines (14) in a predetermined relationship at said distal tip (16, 150); wherein the splines (14) comprise a superelastic material; and wherein the basket assembly (12) has a radially expanded non-cylindrical shape. The system may further comprise: a second elongate tubular member (46) having a lumen (48), a proximal end (56) and a distal end (54); wherein the basket assembly (12) is slidingly compressible to fit within the lumen (48) of the second elongate tubular member (46); wherein the basket assembly (12) has a substantially cylindrical shape when compressed within the lumen (48) of the second elongate tubular member (46); and wherein the basket assembly (12) has said radially expanded non-cylindrical shape when not compressed within the lumen (48) of the second elongate tubular member (46) and disposed past the distal end (54) of the second elongate tubular member (46). The distal tip (16, 150) may have a smooth, non-thrombogenic outer surface free of voids and slots which would permit the passage or entry of blood there into. Angles (θ1-θ8) between said splines (14) at said distal tip (16, 150) forming said predetermined angular relationship may be all substantially equal to each other. Alternatively, at least one angle (θ1-θ8) between said splines (14) at said distal tip (16, 150) forming said predetermined angular relationship is different from another angle (θ1-θ8) between said splines (14) at said distal tip (16, 150). The elastomeric material may comprise polyurethane, silicone and combinations thereof.

In one embodiment, a system (10) for sensing multiple local electric voltages from endocardial surface of a heart, may comprise: a first elongate tubular member (20) having a lumen (20C), a proximal end (20A) and a distal end (20B); a basket assembly (12) comprising: a plurality of flexible splines (14) for guiding a plurality of exposed electrodes

(186), the splines (14) having proximal portions (62) and distal portions (66); an anchor (18) for securably affixing the proximal portions (62) of the splines (14); said anchor (18) being secured at the distal end (20B) of the first elongate tubular member (20); a distal tip (16, 150) comprising a flexible material for securably affixing the distal portions of the splines (14); wherein the basket assembly (12) has a radially expanded non-cylindrical shape; wherein the splines (14) comprise a superelastic material; wherein said flexible material comprises a material selected from the group consisting of an elastomeric material, a non-elastic polymeric material, a thermoplastic material and combinations thereof; and wherein the splines (14) approach the tip (16) at an angle (α) of less than about 45° as measured from a line segment between the anchor (18) and the tip (16) along a longitudinal axis (L) between the proximal anchor (18) and the distal tip (16, 150). The system (10) of embodiment 19, may further comprise: a second elongate tubular member (46) having a lumen (48), a proximal end (56) and a distal end (54); wherein the basket assembly (12) is slidingly compressible to fit within the lumen (48) of the second elongate tubular member (46); wherein the basket assembly (12) has a substantially cylindrical shape when compressed within the lumen (48) of the second elongate tubular member (46); and wherein the basket assembly (12) has said radially expanded non-cylindrical shape when not compressed within the lumen (48) of the second elongate tubular member (46) and disposed past the distal end (54) of the second elongate tubular member (46). When basket assembly (12) is in said radially expanded non-cylindrical shape, the splines (14) may extend beyond the distal tip (16, 150) and may comprise excruciate bends (80) beyond the distal tip (16) to bend the splines (14) back towards the anchor (18). The angles (θ1-θ8) between said splines (14) at said distal tip (16, 150) forming said predetermined angular relationship may be all substantially equal to each other. Alternatively, at least one angle (θ1-θ8) between said splines (14) at said distal tip (16) forming said predetermined angular relationship may be different from another angle (θ1-θ8) between said splines (14) at said distal tip (16, 150).

In one embodiment, a system (10) for sensing multiple local electric voltages from endocardial surface of a heart, may comprise: a first elongate tubular member (20) having a lumen (20C), a proximal end (20A) and a distal end (20B); a basket assembly comprising: a plurality of flexible splines (14) for guiding a plurality of exposed electrodes (186), the splines (14) having proximal portions (62) and distal portions (66); an anchor (18) for securably affixing the proximal portions (62) of the splines (14); said anchor (18) being secured at the distal end (20B) of the first elongate tubular member (20); a distal tip (16, 104, 104', 126, 134, 140, 152) for comprising a first part and a second part that are securably affixed to one and the other; wherein the distal portions (66) of the splines (14) are securably and non-slidingly disposed within said distal tip (16) in a predetermined angular relationship; wherein the splines (14) approach the distal tip (16) at an angle (α) of about 90° or less than about 90° as measured from a line segment between the anchor (18) and the tip (16) along the longitudinal axis (L); wherein the basket assembly (12) has a radially expanded non-cylindrical shape; and wherein the splines (14) comprise a superelastic material. The system (10) may further comprise: a second elongate tubular member (46) having a lumen (48), a proximal end (56) and a distal end (54); wherein the basket assembly (12) is slidingly compressible to fit within the lumen (48) of the second elongate tubular member (46); wherein the basket assembly

(12) has a substantially cylindrical shape when compressed within the lumen (48) of the second elongate tubular member (46); and wherein the basket assembly (12) has said radially expanded non-cylindrical shape when not compressed within the lumen (48) of the second elongate tubular member (46) and disposed past the distal end (54) of the second elongate tubular member (46). Angles (01-08) between said splines (14) at said distal tip (16, 104, 104', 126, 134, 140, 152) forming said predetermined angular relationship may be all substantially equal to each other. Alternatively, at least one angle (01-08) between said splines (14) at said distal tip (16) forming said predetermined angular relationship may be different from another angle (01-08) between said splines (14) at said distal tip (16, 104, 104', 126, 134, 140, 152). When basket assembly (12) is in said radially expanded non-cylindrical shape, the splines (14) may extend beyond the distal tip (16, 104, 104', 126, 134, 140, 152) and may comprise excurve bends (80) beyond the distal tip (16, 104, 104', 126, 134, 140, 152) to bend the splines (14) back towards the anchor (18). The splines (14) may have distal end portions (67); and further wherein the distal spline end portions (67) may be securably and non-slidingly disposed within said distal tip (16, 104, 104', 126, 134, 140). The splines (14) may approach said distal tip (16) at an angle (α) of less than 45° as measured from a line segment between said anchor (18) and said distal tip (16, 104, 104', 126, 134, 140) along the longitudinal axis (L).

Embodiments directed to spline bends and recurves embodiments include, but are not limited to, as follows:

A system (10) for sensing multiple local electric voltages from endocardial surface of a heart, may comprise: a first elongate tubular member (20) having a lumen (20C), a proximal end (20A) and a distal end (20B); a basket assembly (12) comprising: a plurality of flexible splines (14) for guiding a plurality of exposed electrodes (186), the splines (14) having proximal portions (62), distal portions (66) and medial portions (64) therein between; a proximal anchor (18) for securably affixing the proximal portions (62) of the splines (14); said proximal anchor (18) being secured at the distal end (20B) of the first elongate tubular member (20); a distal tip (16) for securably affixing the distal portions (66) of the splines (14), said proximal anchor (18) and said distal tip (16) defining a longitudinal axis (L) therein between about which the splines (14) are disposed; wherein the splines (14) approach the distal tip (16) at an angle (α) of about 90° or less than about 90° as measured from a line segment between the proximal anchor (18) and the distal tip (16) along the longitudinal axis (L); wherein the splines (14) comprise a superelastic material such that the basket assembly (12) exhibits a substantially cylindrical shape when radially compressed and exhibits a radially expanded non-spherical shape when not radially compressed; and wherein at least some of the splines (14) in the radially expanded non-spherical shape contain a distal excurve outward bend (80) disposed at the distal portion (66) of the spline (14) at a location near to the distal tip (16) of the basket assembly (12) to bend the splines (14) back towards the proximal anchor (18). The system may further comprise: a second elongate tubular member (46) having a lumen (48), a proximal end (56) and a distal end (54); wherein the basket assembly (12) is slidingly compressible to fit within the lumen (48) of the second elongate tubular member (46); wherein the basket assembly (12) has said substantially cylindrical shape when compressed within the lumen (48) of the second elongate tubular member (46); and wherein the basket assembly (12) has said radially expanded non-spheri-

cal shape when not compressed within the lumen (48) of the second elongate tubular member (46) and disposed past the distal end (54) of the second elongate tubular member (46). When basket assembly (12) is in said radially expanded non-spherical shape, the splines (14) may extend beyond the distal tip (16); and, when basket assembly (14) is in said radially expanded non-spherical shape, apices (81) of the distal excurve bends (80) may be disposed beyond the distal tip (16). The distal spline portions (66) may be securably and non-slidingly disposed within said distal tip (16). The distal spline portions (66) may be securably and non-slidingly disposed within said distal tip (16) in a predetermined angular relationship, wherein angles (01-08) between said splines (14) at said distal tip (16) forming said predetermined angular relationship may be all substantially equal to each other; or wherein at least one angle (01-08) between said splines (14) at said distal tip (16) forming said predetermined angular relationship may be different from another angle (01-08) between said splines (14) at said distal tip (16). The splines (14) have distal end portions (67); and further wherein the distal spline end portions (67) may be securably and non-slidingly disposed within said distal tip (16). The splines (14) may approach said distal tip (16) at an angle (α) of less than about 45° as measured from the line segment between said proximal anchor (18) and said distal tip (16) along the longitudinal axis (L). The splines (14) may have a distal incurvate inward bend (78) between said distal tip (16) and said distal excurve outward bends (80). The distal tip (16) may have a non-thrombogenic outer surface free of voids and slots that would permit the passage or entry of blood thereto. The splines (14) may have reduced widths at said distal portions (66) near the tip (16) as compared to spline widths at said medial portions (64).

A system (10) for sensing multiple local electric voltages from endocardial surface of a heart, may comprise: a first elongate tubular member (20) having a lumen (20C), a proximal end (20A) and a distal end (20B); a basket assembly (12) comprising: a plurality of flexible splines (14) for guiding a plurality of exposed electrodes (186), the splines (14) having proximal portions (62), distal portions (66) and medial portions (64) therein between; a proximal anchor (18) for securably affixing the proximal portions (62) of the splines (14); said anchor (18) being secured at the distal end (20B) of the first elongate tubular member (20); a distal tip (16) for securably affixing the distal portions (66) of the splines (14), said proximal anchor (18) and said distal tip (16) defining a longitudinal axis (L) about which the splines (14) are disposed; wherein the splines (14) approach the distal tip (16) at an angle (α) of about 90° or less than about 90° as measured from a line segment between the proximal anchor (18) and the distal tip (16) along the longitudinal axis (L); wherein the splines (14) comprise a superelastic material such that the basket assembly (12) exhibits a substantially cylindrical shape when radially compressed and exhibits a radially expanded non-spherical shape when not radially compressed; and wherein each of the splines (14) in the radially expanded non-spherical shape contain a proximal recurve (76) in the proximate portion (62) of the spline (14) at a location near to the proximal anchor (18) of the basket assembly (12), the proximal recurve (76) comprises a proximal excurve outward bend (84) and a proximal incurvate inward bend (82) between said proximal excurve outward bend (84) and said proximal anchor (18), where an apex (83) of the proximal incurvate inward bend (82) is disposed in a direction toward the distal tip (16) and is further disposed inwardly closer toward the distal tip (16) than the proximal excurve outward bend (84). The system

(10) may further comprise: a second elongate tubular member (46) having a lumen (48), a proximal end (56) and a distal end (54); wherein the basket assembly (12) is slidably compressible to fit within the lumen (48) of the second elongate tubular member (46); wherein the basket assembly (12) has said substantially cylindrical shape when compressed within the lumen (48) of the second elongate tubular member (46); and wherein the basket assembly (12) has said radially expanded non-spherical shape when not compressed within the lumen (48) of the second elongate tubular member (46) and disposed past the distal end (54) of the second elongate tubular member (46). The splines (14) may approach said distal tip (16) at an angle (α) of less than about 45° as measured from the line segment between said proximal anchor (18) and said distal tip (16) along the longitudinal axis (L). The splines (14) in the radially expanded non-spherical shape may contain a distal incurvate outward bend (80) disposed at the distal portion (66) of the spline (14) at a location near to the distal tip (16) of the basket assembly (12) to bend the splines (14) back towards the proximal anchor (18); wherein the splines (14) may have a distal incurvate inward bend (78) between said distal tip (16) and said distal incurvate outward bends (80); and wherein, when basket assembly (12) is in said radially expanded non-spherical shape, the splines (14) may extend beyond the distal tip (16) and, when basket assembly (12) is in said radially expanded non-spherical shape, apices (81) of the distal incurvate bends (80) may be disposed beyond the distal tip (16). The distal tip (16) may have a non-thrombogenic outer surface free of voids and slots that would permit the passage or entry of blood thereto. The splines (14) may have reduced widths at said distal portions near the distal tip (16) as compared to spline widths at said medial portions (64). Each of the splines (14) have a length between said apex (83) of said proximal incurvate inward bend (82) and said proximal incurvate outward bend (84); and further wherein said length of at least one spline (14) may be different from said length of another of said splines (14). Alternatively, each of the splines (14) may have a substantially equal overall length between said proximal anchor (18) and said distal tip (16). Alternatively, each of the splines (14) may have a substantially equal overall length from said proximal anchor (18) and to said distal tip (16); and further wherein a length from said proximal incurvate outward bend (84) to said distal tip (16) for at least one of said splines (14) may be different from said length for another one of said splines (14).

A system (10) for sensing multiple local electric voltages from endocardial surface of a heart, may comprise: a first elongate tubular member (20) having a lumen (20C), a proximal end (20A) and a distal end (20B); a basket assembly (12) comprising: a plurality of flexible splines (14) for guiding a plurality of exposed electrodes (186), the splines (14) having proximal portions (62) and distal portions (66); a proximal anchor (18) for securably affixing the proximal portions (62) of the splines (14); said proximal anchor (18) being secured at the distal end (20B) of the first elongate tubular member (20); a distal tip (16) for securably affixing the distal portions (66) of the splines (14), said proximal anchor (18) and said distal tip (16) defining a longitudinal axis (L) about which the splines (14) are disposed; wherein the splines (14) approach the distal tip (16) at an angle (α) of less than about 45° as measured from a line segment between the proximal anchor (18) and the distal tip (16) along the longitudinal axis (L); wherein the splines (14) comprise a superelastic material such that the basket assembly (12) exhibits a substantially cylindrical shape when

radially compressed and exhibits a radially expanded non-spherical shape when not radially compressed; wherein the splines (14) in the radially expanded non-spherical shape contain a distal incurvate outward bend (80) disposed at the distal portion of the spline (14) at a location near to the distal tip (16) of the basket assembly (12) to bend the splines (14) back towards the proximal anchor (18); wherein the splines (14) have a distal incurvate inward bend (78) between said distal tip (16) and said distal incurvate outward bends (80); wherein, when basket assembly (12) is in said radially expanded non-spherical shape, the splines (14) extend beyond the distal tip (16) and, when basket assembly (12) is in said radially expanded non-spherical shape, apices (80) of the distal incurvate bends (80) are disposed beyond the distal tip (16); and wherein each of the splines (14) in the radially expanded non-spherical shape contain a proximal recurve (76) in the proximate portion (62) of the spline (14) at a location near to the proximal anchor (18) of the basket assembly (12), the proximal recurve (76) comprises a proximal incurvate outward bend (84) and a proximal incurvate inward bend (82) between said proximal incurvate outward bend (84) and said proximal anchor (18), where an apex (83) of the proximal incurvate inward bend (82) is disposed in a direction toward the distal tip (16) and is further disposed inwardly closer toward the distal tip (16) than the proximal incurvate outward bend (84). The system (10) may further comprise: a second elongate tubular member (46) having a lumen (48), a proximal end (56) and a distal end (54); wherein the basket assembly (12) is slidably compressible to fit within the lumen (48) of the second elongate tubular member (46); wherein the basket assembly (12) has said substantially cylindrical shape when compressed within the lumen (48) of the second elongate tubular member (46); and wherein the basket assembly (12) has said radially expanded non-spherical shape when not compressed within the lumen (48) of the second elongate tubular member (46) and disposed past the distal end (54) of the second elongate tubular member (46). The distal spline portions (66) may be securably and non-slidingly disposed within said distal tip (16). The splines (14) may have distal end portions (67); and further wherein the distal spline end portions (67) may be securably and non-slidingly disposed within said distal tip (16). Each of the splines (14) may have a substantially equal overall length from said proximal anchor (18) and to said distal tip (16); and further wherein a length from said proximal incurvate outward bend (84) to said distal tip (16) is for at least one of said splines (14) is different from said length for another one of said splines (14).

A system (10) for sensing multiple local electric voltages from endocardial surface of a heart, may comprise: a first elongate tubular member having a lumen (20C), a proximal end (20A) and a distal end (20B); a basket assembly (12) comprising: a plurality of flexible splines (14) for guiding a plurality of exposed electrodes (186), the splines (14) having proximal portions (62) and distal portions (66); a proximal anchor (18) for securably affixing the proximal portions (62) of the splines (14); said proximal anchor (18) being secured at the distal end (20B) of the first elongate tubular member (20); a distal tip (16) for securably affixing the distal portions (66) of the splines (14), said proximal anchor (18) and said tip (16) defining a longitudinal axis (L) about which the splines (14) are disposed; wherein the splines (14) comprise a superelastic material such that the basket assembly (12) exhibits a substantially cylindrical shape when radially compressed and exhibits a radially expanded non-spherical shape when not radially compressed; wherein each of the splines (14) in the radially

expanded non-spherical shape contain a proximal recurve (76) in the proximate portion of the spline (14) at a location near to the anchor (18) of the basket assembly (12), the proximal recurve (76) comprises a proximal excurvate outward bend (84) and a proximal incurvate inward bend (82) between said proximal excurvate outward bend (84) and said proximal anchor (18), where an apex (83) of the proximal incurvate inward bend (82) is disposed in a direction toward the distal tip (16) and is further disposed inwardly closer toward the distal tip (16) than the proximal excurvate outward bend (84); and wherein the proximal incurvate inward bends (82) of some splines (14) have a different geometry from the proximal incurvate inward bends (82) of other splines (14); and wherein one or more tissue-contacting portions of the individual splines (14) are of unequal length with respect to each other, and each of the proximal incurvate inward bend portions (82) of the splines (14) possess compensating lengths such that the sum of the tissue facing portion plus proximal incurvate inward bend portion (82) of all splines (14) are substantially the same. The system (10) may further comprise: a second elongate tubular member (46) having a lumen (48), a proximal end (56) and a distal end (54); wherein the basket assembly (12) is slidingly compressible to fit within the lumen (48) of the second elongate tubular member (46); wherein the basket assembly (12) has said substantially cylindrical shape when compressed within the lumen (48) of the second elongate tubular member (46); and wherein the basket assembly (12) has said radially expanded non-spherical shape when not compressed within the lumen (48) of the second elongate tubular member (46) and disposed past the distal end (54) of the second elongate tubular member (46). The splines (14) may have distal end portions (67); and further wherein the distal spline end portions (67) may be securably and non-slidingly disposed within said distal tip (16). The splines (14) in the radially expanded non-spherical shape may contain a distal excurvate outward bend (80) disposed at the distal portion (66) of the spline (14) at a location near to the distal tip (16) of the basket assembly (12) to bend the splines (14) back towards the proximal anchor (18); wherein the splines (14) may have a distal incurvate inward bend (78) between said distal tip (16) and said distal excurvate outward bends (80); and wherein, when basket assembly (12) is in said radially expanded non-spherical shape, the splines (14) may extend beyond the distal tip (16) and, when basket assembly (12) is in said radially expanded non-spherical shape, apices (81) of the distal excurvate bends (80) are disposed beyond the distal tip (16).

Embodiments directed to spline assemblies for basket catheters include, but are not limited to, as follows:

A system (10) for sensing multiple local electric voltages from endocardial surface of a heart, may comprise: an elongate tubular member (20) having a lumen (20C), a proximal end (20A) and a distal end (20B); a plurality of flexible splines (14) having proximal portions (62), distal portions (66) and medial portions (64) therein between, wherein the splines (14) comprise an outer surface (190), an inner surface (192) and two side surfaces (194, 196); an anchor (18) for securably affixing the proximal portions (62) of the splines (14), wherein the anchor (18) is securably affixed within the lumen (20C) of the elongate tubular member (20) at the distal end (20B) of the elongate tubular member (20); a tip (16) for securably affixing the distal portions (66) of the splines (14); and a polymeric member (185) comprising opposed a first open end (202) and a second open end (200) defining an open lumen (208) therein between and an inner member surface (208B) and an outer

member surface (208A), wherein at least one of the plurality of flexible splines (14) is at least partially disposed within the lumen (208) of said polymeric member; a flexible electrode assembly strip (188) with one or more exposed electrodes (186) disposed on at least a portion of the outer surface (208A) of said polymeric member (185); wherein the flexible electrode assembly strip (188) comprises: a polymeric substrate (236) having an inner surface (236B) and an opposed outer surface (236A); said one or more exposed electrodes (186) disposed over at least part of the outer surface (236A) of the polymeric substrate (236); and one or more electrical traces (228) disposed over at least a portion of the inner surface (236B) of the polymeric substrate (236) or over at least a portion of the outer surface (236A) of the polymeric substrate (236), said one or more electrical traces (228) being in electrical communication with said one or more exposed electrodes (186); wherein a portion of the flexible electrode assembly (188) transitions from the outer surface (208A) of said polymeric member (185) towards the inner surface (208B) of said polymeric member (185) prior to said anchor (18); and wherein another portion of the flexible electrode assembly (188) extends through at least a portion of said anchor (18) and into said lumen (20C) of said elongate tubular member (20). The system (10) may further comprise: a plurality of polymeric members (185) each comprising said flexible electrode assembly strip (188); wherein each of said plurality of flexible splines (14) are at least partially disposed within a different one of said plurality of polymeric members (185). The one or more electrical traces (228) may be disposed over at least a portion of the inner surface (236B) of the polymeric substrate (236) and may further comprise vias (230) to provide said electrical communication between said one or more electrical traces (228) and said one or more exposed electrodes (186). The one or more electrical traces (228) may be disposed over at least a portion of the outer surface (236A) of the polymeric substrate (236) and further comprising a polymeric covering (238, 240) over the outer surface (236A) of the polymeric substrate (236) and said electrical traces (228) with the one or more exposed electrodes (186) being substantially free of the polymeric covering (238, 240). The first opposed open end (202) of the polymeric member (185) may be secured to the distal spline portion (66) of said at least one of the plurality of flexible splines (14) at a position near to the distal tip (16) and the second opposed open end (200) of the polymeric member (185) may be secured to the proximal spline portion (62) of said at least one of the plurality of flexible splines (14) at a position near to the anchor (18). The first opposed open end (202) of the polymeric member (185) may be sealingly secured to the distal spline portion (66) at the position near to the distal tip (16) by a seal (206). Medial portions of the polymeric member (185) between said first opposed open end (202) and said second opposed open end (200) of the polymeric member (185) may not be secured to said medial portions (64) of said at least one of the plurality of flexible splines (14). At least one intermediate medial portion of the polymeric member (185) between said first opposed open end (202) and said second opposed open end (200) of the polymeric member (185) may be secured to at least one intermediate portion of said medial portions (64) of said at least one of the plurality of flexible splines (14). The one or more exposed electrodes (186) may comprise copper, gold, platinum, platinum black, platinum-iridium and combinations thereof. The outer surface (190) and the inner surface (192) of said plurality of flexible splines (14) may be substantially flat surfaces and the two side surfaces (194,

196) of said plurality of flexible splines (14) may be convexly rounded surfaces. The one or more exposed electrodes (186) may have a substantially flat upper surface.

A system (10) for sensing multiple local electric voltages from endocardial surface of a heart, may comprise: an elongate tubular member (20) having a lumen (20C), a proximal end (20A) and a distal end (20B); a plurality of flexible splines (14) having proximal portions (62), distal portions (66) and medial portions (64) therein between, wherein the splines (14) comprise an outer surface (190), an inner surface (192) and two side surfaces (194, 196); an anchor (18) for securably affixing the proximal portions (62) of the splines (14), wherein the anchor (18) is securably affixed within the lumen (20C) of the elongate tubular member (20) at the distal end (20B) of the elongate tubular member (20); a tip (16) for securably affixing the distal portions (66) of the splines (14); and a polymeric member (185) comprising opposed first (202) and second (200) open ends defining an open lumen (208) therein between and an inner member surface (208B) and an outer member surface (208A), wherein at least one of the plurality of flexible splines (14) is at least partially disposed within the lumen (208) of said polymeric member (185); a flexible electrode assembly strip (188) with one or more exposed electrodes (186) disposed on at least a portion of the outer surface (208A) of said polymeric member (185); wherein the flexible electrode assembly strip (188) comprises: a polymeric substrate (236) having an inner surface (236B) and an opposed outer surface (236A); said one or more exposed electrodes (186) disposed over at least part of the outer surface (236A) of the polymeric substrate (236); and one or more electrical traces (228) disposed over at least a portion of the inner surface (236B) of the polymeric substrate (236) or over at least a portion of the outer surface (236A) of the polymeric substrate (236), said one or more electrical traces (228) being in electrical communication with said one or more exposed electrodes (186); wherein the first opposed open end (202) of the polymeric member (185) is secured to the distal spline portion (66) of said at least one of the plurality of flexible splines (14) at a position near to the distal tip (16) and the second opposed open end (200) of the polymeric member (185) is secured to the proximal spline portion (62) of said at least one of the plurality of flexible splines (14) at a position near to the anchor (18); and wherein medial portions of the polymeric member (185) between said first opposed open end (202) and said second opposed open end (200) of the polymeric member (185) are not secured to said medial portions (64) of said at least one of the plurality of flexible splines (14). The system (10) may further comprise a seal (206) for sealingly engaging said first opposed open end (202) of the polymeric member (185) and said distal spline portion (66). A portion of the flexible electrode assembly (188) may extend through at least a portion of said anchor (18) and into said lumen (20C) of said elongate tubular member (20). The system (10) may further comprise: a plurality of polymeric members (185) each comprising said flexible electrode assembly strip (188); wherein each of said plurality of flexible splines (14) may be at least partially disposed within a different one of said plurality of polymeric members (185). The one or more electrical traces (228) may be disposed over at least a portion of the inner surface (236B) of the polymeric substrate (236) and may further comprise vias (230) to provide said electrical communication between said one or more electrical traces (228) and said one or more exposed electrodes (186). The one or more electrical traces (228) may be disposed over at least a portion of the outer surface (236A) of the poly-

meric substrate (236) and may further comprise a polymeric covering (238, 240) over the outer surface (236A) of the polymeric substrate (236) and said electrical traces (228) with the one or more exposed electrodes (186) being substantially free of the polymeric covering (238, 240). The one or more exposed electrodes (186) may comprise copper, gold, platinum, platinum black, platinum-iridium and combinations thereof. The outer surface (190) and the inner surface (192) of said plurality of flexible splines (14) may be substantially flat surfaces and the two side surfaces (194, 196) of said plurality of flexible splines (14) may be convexly rounded surfaces. The one or more exposed electrodes (186) have a substantially flat upper surface.

A system (10) for sensing multiple local electric voltages from endocardial surface of a heart, may comprise: an elongate tubular member (20) having a lumen (20C), a proximal end (20A) and a distal end (20B); a plurality of flexible splines (14) having proximal portions (62), distal portions (66) and medial portions (64) therein between, wherein the splines (14) comprise an outer surface (190), an inner surface (192) and two side surfaces (194, 196), wherein said inner and outer spline surfaces (190, 192) have a substantially flat portion with the substantially flat portions being parallel to one and the other, and further wherein the two side spline surfaces (194, 196) are convexly rounded to define a rounded-rectangular shape; an anchor (18) for securably affixing the proximal portions (62) of the splines (14), wherein the anchor (18) is securably affixed within the lumen (20C) of the elongate tubular member (20) at the distal end (20B) of the elongate tubular member (20); a tip (16) for securably affixing the distal portions (66) of the splines (14); and a plurality of polymeric members (185) each having opposed first (202) and second (200) open ends defining an open lumen (208) therein between, wherein the polymeric members (185) comprise an outer surface (208A), an inner surface (208B) and two side surfaces where a cross-sectional profile of the polymeric members is elliptical to match a cross-sectional profile of the rounded-rectangular shape of the splines (14) and is slightly larger than the cross-sectional profile of the rounded-rectangular shape of the splines (14) and wherein each of the plurality of flexible splines (14) is at least partially disposed within the lumen (208) of a different one of said plurality of polymeric members (185); a flexible electrode assembly strip (188) with one or more exposed electrodes (186) disposed on at least a portion of the outer surface (208A) of said polymeric members (185); wherein the flexible electrode assembly strip (188) comprises: a polymeric substrate (236) having an inner surface (236B) and an opposed outer (236A) surface; said one or more exposed electrodes (186) disposed over at least part of the outer surface (236A) of the polymeric substrate (236); and one or more electrical traces (228) disposed over at least a portion of the inner surface (236B) of the polymeric substrate (236) or over at least a portion of the outer surface (236A) of the polymeric substrate (236), said one or more electrical traces (228) being in electrical communication with said one or more exposed electrodes (186); wherein a portion of said flexible electrode assembly strip (188) extends through at least a portion of said anchor (18) and into said lumen (20C) of said elongate tubular member (20). The one or more electrical traces (228) may be disposed over at least a portion of the inner surface (236B) of the polymeric substrate (236) and may further comprise vias (230) to provide said electrical communication between said one or more electrical traces (228) and said one or more exposed electrodes (186). The one or more electrical traces (228) may be disposed over at least a portion

of the outer surface (236A) of the polymeric substrate (236) and may further comprise a polymeric covering (238, 240) over the outer surface (236A) of the polymeric substrate (236) and said electrical traces (228) with the one or more exposed electrodes (186) being substantially free of the polymeric covering (238, 240). The first opposed open end (202) of the polymeric member (185) may be sealingly secured to the distal spline portion (66) of said at least one of the plurality of flexible splines (14) at a position near to the distal tip (16) and the second opposed open end (200) of the polymeric member (185) may be secured to the proximal spline portion (62) of said at least one of the plurality of flexible splines (14) at a position near to the anchor (18). Medial portions of the polymeric member between said first opposed open end (202) and said second opposed open end (200) of the polymeric member (185) may not be secured to said medial portions (64) of said at least one of the plurality of flexible splines (14). At least one intermediate medial portion of the polymeric member (185) between said first opposed open end (202) and said second opposed open end (200) of the polymeric member (185) may be secured to at least one intermediate portion of said medial portions (64) of said at least one of the plurality of flexible splines (14). The one or more exposed electrodes (186) may comprise copper, gold, platinum, platinum black, platinum-iridium and combinations thereof. The one or more exposed electrodes (186) may have a substantially flat upper surface.

A system (10) for sensing multiple local electric voltages from endocardial surface of a heart, may comprise: an elongate tubular member (20) having a lumen (20C), a proximal end (20A) and a distal end (20B); a plurality of flexible splines (14) having proximal portions (62), distal portions (66) and medial portions (64) therein between, wherein the splines (14) comprise an outer surface (190), an inner surface (192) and two side surfaces (194, 196); an anchor (18) for securably affixing the proximal portions (62) of the splines (14), wherein the anchor (18) is securably affixed within the lumen (20C) of the elongate tubular member (20) at the distal end (20B) of the elongate tubular member (20); a tip (16) for securably affixing the distal portions (66) of the splines (14); and a plurality of polymeric members (185) each having opposed first (202) and second (200) open ends defining an open lumen (208) therein between and an outer surface (208A) and an inner surface (208B), wherein each of the plurality of flexible splines (14) is at least partially disposed within the lumen (208) of a different one of said plurality of polymeric members (185); a flexible electrode assembly strip (188) with one or more exposed electrodes (186) disposed on at least a portion of the outer surface (208A) of said polymeric members (185); wherein the flexible electrode assembly strip (188) comprises: a polymeric substrate (236) having an inner surface (236B) and an opposed outer surface (236A); said one or more exposed electrodes (186) disposed over at least part of the outer surface (236A) of the polymeric substrate (236); and one or more electrical traces (228) disposed over at least a portion of the inner surface (236B) of the polymeric substrate (236) or over at least a portion of the outer surface (236A) of the polymeric substrate (236), said one or more electrical traces (228) being in electrical communication with said one or more exposed electrodes (186); wherein the flexible electrode assembly strip (188) is compressed into the outer surface (208A) of the polymeric member (185); and wherein the flexible electrode assembly strip (188) is thermally or adhesively bonded to the outer surface (208A) of the polymeric member (185).

Embodiments directed to flex circuits and flexible electrode assemblies include, but are not limited to, as follows:

A device for insertion into a body lumen, may comprise: an electrode assembly strip (188) with exposed electrodes (186) comprising: a polymeric substrate (236) having an upper surface (236A) and an opposed lower surface (236B); one or more electrodes (186) disposed over a portion of the upper surface (236A) of the polymeric substrate (236); one or more electrical traces (228) disposed over a portion of the lower surface (236B) of the polymeric substrate (236) in electrical communication with the one or more electrodes (186) by way of metal plated holes (230) through the substrate (236); and a flexible polymeric substrate (246) having a substrate surface (246A) and a substrate wall (246C); wherein the electrode assembly strip (188) is compressingly and thermally bonded to the substrate surface (246A) of the flexible polymeric substrate (246) to define a flexible electrode assembly strip (247); and wherein the electrode assembly strip (188) has a thickness from about 0.0005 inches to about 0.008 inches. The electrode assembly strip (188) may have a thickness from about 0.002 inches to about 0.004 inches. The device may further comprise: a first polymeric covering (238) disposed portions of the substrate surface (236A) of the polymeric substrate (236) not having the one or more electrodes (186) thereon, said first polymeric covering (238) having holes disposed over the one or more electrodes (186) thereby defining one or more exposed electrodes (186); and a second polymeric covering (240) disposed over the one or more electrical traces (228) and portions of the lower surface (236B) of the substrate (236) not having the one or more electrical traces (228) thereon. The polymeric substrate (236), the first polymeric covering (238) and the second polymeric covering (240) may comprise a biocompatible polyimide material. The flexible polymeric substrate (236) may comprise a biocompatible polyether block amide material. The flexible polymeric substrate (236) may comprise a biocompatible polymer selected from the group consisting of polyesters, silicones, silicone rubbers, urethanes and combinations thereof. The flexible polymeric substrate (236) may be a sheet. Alternatively, the flexible polymeric substrate (236) may be an extruded tube having an open lumen.

A device for insertion into a body lumen, may comprise: an electrode assembly strip (188) with exposed electrodes (186) comprising: a polymeric substrate (236) having an upper surface (236A) and an opposed lower surface (236B); at least two electrodes (186) disposed over a portion of the upper surface (236A) of the polymeric substrate (236); at least two electrical traces (228) disposed over a portion of the lower surface (236B) of the polymeric substrate (236) in electrical communication with the at least two electrodes by way of metal plated holes (230) through the substrate (236); a first polymeric covering (238) disposed portions of the upper surface (236A) of the polymeric substrate (236) not having the at least two of said electrodes (186) thereon, said first polymeric covering (238) having holes disposed over the at least two of said electrodes (186) thereby defining at least two exposed electrodes (186); a second polymeric covering (240) disposed over the at least two of the electrical traces (228) and portions of the lower surface of the substrate not having the at least two electrical traces (228) thereon; a first flexible polymeric tube (185) having opposed open ends (200, 202) defining an open lumen (208) therein between and an inner tubular surface (208B) and an outer tubular surface (208A); wherein the electrode assembly strip (188) is disposed over the outer surface (208A) of the first flexible polymeric tube (185); and a second flexible poly-

meric tube (185) having opposed open ends (200, 202) defining an open lumen (208) therein between and an inner tubular surface (208B) and an outer tubular surface (208A), wherein the second flexible polymeric tube (185) is disposed over portions of the electrode assembly strip (188) not having the exposed electrodes (186); wherein the electrode assembly strip (188), the first flexible polymeric tube (185) and the second flexible polymeric tube (185) are compressingly and thermally bonded to each other to define a flexible electrode assembly strip (247); and wherein the electrode assembly strip (188) has a thickness from about 0.0005 inches to about 0.008 inches. The polymeric substrate (236), the first polymeric covering (238) and the second polymeric covering (240) may comprise a biocompatible polyimide material. The first and second flexible polymeric tubes (185) may comprise a polyether block amide material. The first flexible polymeric tube (185) may be an extruded tube. The flexible electrode assembly strip (247) may have a substantially smooth and atraumatic overall outer surface (246A). The device may further comprise: an elongate tubular member (20) having a lumen (20C), a proximal end (20A) and a distal end (20B); a plurality of flexible splines (14) having proximal portions (62), distal portions (66) and medial portions (64) therein between, wherein the splines (14) comprise an outer surface (190), an inner surface (192) and two side surfaces (194, 196); an anchor (18) for securably affixing the proximal portions (62) of the splines (14), wherein the anchor (18) is securably affixed within the lumen (20C) of the elongate tubular member (20) at the distal end (20B) of the elongate tubular member (20); and a tip (16) for securably affixing the distal portions (66) of the splines (14); wherein the flexible electrode assembly strip (247) is disposed over at least one of the plurality of splines (14). The device may further comprise a plurality of flexible electrode assembly strips (247), wherein each of said plurality of splines (14) has at least one of said plurality of flexible electrode assembly strips (247) disposed there over.

A device for insertion into a body lumen, may comprise: an electrode assembly strip (188) with exposed electrodes (186) comprising: a polymeric substrate (236) having an upper surface (236A) and an opposed lower surface (236B); one or more of substantially flat electrodes (186) disposed over a portion of the upper surface (236A) of the polymeric substrate (236); one or more of electrical traces (228) disposed over a portion of the lower surface (236B) of the polymeric substrate (236) in electrical communication with the one or more electrodes (186) by way of metal plated holes (230) through the substrate (236); a first polymeric covering (238) disposed portions of the upper surface (236A) of the polymeric substrate (236) not having the one or more of the electrodes (186) thereon, said first polymeric covering (238) having holes disposed over the one or more electrodes (186) thereby defining one or more exposed electrodes (186); a second polymeric covering (240) disposed over the over the one or more electrical traces (228) and portions of the lower surface (236B) of the substrate (236) not having the one or more electrical traces (228) thereon; and a flexible polymeric tube (185) having opposed open ends (200, 202) defining an open lumen (208) therein between and an inner tubular surface (208B) and an outer tubular surface (208A) defining a tubular wall (210) therein between; wherein the electrode assembly strip (188) is compressingly and thermally bonded to the outer surface (208A) of the flexible polymeric tube (185) to define a flexible electrode assembly strip (247); wherein substantial portions of the substantially flat electrodes (186) remain substantially flat to provide substantially flat exposed elec-

trodes (186); and wherein the electrode assembly strip (188) has a thickness from 0.0005 inches to about 0.008 inches. The polymeric substrate (236) may comprise a polyimide material. The first polymeric covering (238) and the second polymeric covering (240) may comprise a polyimide material. The flexible polymeric tube (185) may comprise a polyether block amide material. The flexible polymeric tube (185) may be an extruded tube. The electrode assembly strip (188) may be compressed into the tubular wall (210) of the flexible polymeric tube (185) to provide a substantially smooth and atraumatic overall outer surface for the flexible electrode assembly strip. The device may further comprise: an elongate tubular member (20) having a lumen (20C), a proximal end (20A) and a distal end (20B); one or more flexible splines (14) having proximal portions (62), distal portions (66) and medial portions (64) therein between, wherein the one or more splines (14) comprise an outer surface (190), an inner surface (192) and two side surfaces (194, 196); an anchor (18) for securably affixing the proximal portions (62) of the one or more splines (14), wherein the anchor (18) is securably affixed within the lumen (20C) of the elongate tubular member (20) at the distal end (20B) of the elongate tubular member (20); and a tip (16) for securably affixing the distal portions (66) of the one or more splines (14); wherein the flexible electrode assembly strip (247) is disposed over at least one of the one or more splines (14). The device may further comprise one or more of flexible electrode assembly strips (247), wherein each of said one or more of the splines (14) may have at least one of said one or more of the flexible electrode assembly strips (247) disposed there over.

A device for insertion into a body lumen, may comprise an electrode assembly strip (188) with exposed electrodes (186) comprising: a polymeric substrate (236) having an upper surface (236A) and an opposed lower surface (236B); at least two substantially flat electrodes (186) disposed over a portion of the upper surface (236A) of the polymeric substrate (236); at least two electrical traces (228) disposed over a portion of the lower surface (236B) of the polymeric substrate (236) in electrical communication with the at least two electrodes (186) by way of metal plated holes (230) through the substrate (236); a first polymeric covering (238) disposed portions of the upper surface (236A) of the polymeric substrate (236) not having the at least two of said electrodes (186) thereon, said first polymeric covering (238) having holes disposed over the at least two of said electrodes (186) thereby defining at least two exposed electrodes (186); a second polymeric covering (240) disposed over the over the plurality of electrical traces (228) and portions of the lower surface (236B) of the substrate (236) not having electrical traces (228) thereon; a first flexible polymeric tube (185) having opposed open ends (200, 202) defining an open lumen (208) therein between and an inner tubular surface (208B) and an outer tubular surface (208A); wherein the electrode assembly strip (188) is disposed over the outer surface (208A) of the first flexible polymeric tube (185); and a second flexible polymeric tube (185) having opposed open ends (200, 202) defining an open lumen (208) therein between and an inner tubular surface (208B) and an outer tubular surface (208A), wherein the second flexible polymeric tube (185) is disposed over portions of the electrode assembly strip (188) not having the exposed electrodes (186), wherein the electrode assembly strip (188), the first flexible polymeric tube (185) and the second flexible polymeric tube (185) are compressingly and thermally bonded to each other to define a flexible electrode assembly strip (247); wherein substantial portions of the at least two substantially

flat electrodes (186) remain substantially flat to provide at least two substantially flat exposed electrodes (186); and wherein the electrode assembly strip (188) has a thickness from about 0.0005 inches to about 0.008 inches. The polymeric substrate (236) may comprise a polyimide material. The first polymeric covering (238) and the second polymeric covering (240) may comprise a polyimide material. The first and second flexible polymeric tubes (185) may comprise a polyether block amide material. The first flexible polymeric tube (185) may be an extruded tube. The flexible electrode assembly strip (247) may have a substantially smooth and atraumatic overall outer surface. The device may further comprise: an elongate tubular member (20) having a lumen (20C), a proximal end (20A) and a distal end (20B); one or more flexible splines (14) having proximal portions (62), distal portions (66) and medial portions (64) therein between, wherein the splines (14) comprise an outer surface (190), an inner surface (192) and two side surfaces (194, 196); an anchor (18) for securably affixing the proximal portions (62) of the splines (14), wherein the anchor (18) is securably affixed within the lumen (20C) of the elongate tubular member (20) at the distal end (20B) of the elongate tubular member (20); and a tip (16) for securably affixing the distal portions (66) of the one or more splines (14); wherein the flexible electrode assembly strip (247) is disposed over at least one of the one or more of the splines (14).

Embodiments directed to methods for sensing multiple local electric voltages from endocardial surface of a heart include, but are not limited to, as follows:

A method for sensing multiple local electric voltages from endocardial surface of a heart, may comprise: providing a system (10) for sensing multiple local electric voltages from endocardial surface of a heart, comprising: a first elongate tubular member (20) having a lumen (20C), a proximal end (20A) and a distal end (20B); a basket assembly (12) comprising: a plurality of flexible splines (14) for guiding a plurality of exposed electrodes (186), the splines (14) having proximal portions (62), distal portions (66) and medial portions (64) therein between, wherein the electrodes (186) are substantially flat electrodes and are substantially unidirectionally oriented towards a direction outside of the basket assembly (12); a proximal anchor (18) for securably affixing the proximal portions (62) of the splines (14); said anchor (18) being secured at the distal end (20B) of the first elongate tubular member (20); a distal tip (16) for securably affixing the distal portions (66) of the splines (14), said proximal anchor (18) and said distal tip (16) defining a longitudinal axis (L) about which the splines (14) are disposed; wherein the splines (14) approach the distal tip (16) at an angle (α) of about 90° or less than about 90° as measured from a line segment between the proximal anchor (18) and the distal tip (16) along the longitudinal axis (L); wherein the splines (14) comprise a superelastic material such that the basket assembly (12) exhibits a substantially cylindrical shape when radially compressed and exhibits a radially expanded non-spherical shape when not radially compressed; and wherein each of the splines (14) in the radially expanded non-spherical shape contain a proximal recurve (76) in the proximate portion (62) of the spline (14) at a location near to the proximal anchor (18) of the basket assembly (12), the proximal recurve (76) comprises a proximal excurvate outward bend (84) and a proximal incurvate inward bend (82) between said proximal excurvate outward bend (84) and said proximal anchor (18), where an apex (83) of the proximal incurvate inward bend (82) is disposed in a direction toward the distal tip (16) and is further disposed inwardly closer toward the distal tip (16) than the proximal

excurvate outward bend (84); delivering the system (10) to the heart so that the basket assembly (12) is disposed within the right atrium of the heart; contacting proximal atrial tissue with the electrodes (186) disposed on the proximal spline portions (62) to detect multiple local electric voltages from endocardial surface thereat; and contacting atrial tissue with the electrodes (186) disposed on the medial spline portions (64) and the distal spline portions (66) to detect multiple local electric voltages from endocardial surface thereat. The splines (14) of the basket assembly (12) may be flexible to match the contours of the right atrium. Substantially all of the electrodes (186) may contact atrial tissue. Substantially all of the electrodes (186) may remain substantially spatially fixed with respect to atrial tissue. A substantial portion of atrial signals detected by the system (10) may have larger amplitudes than ventricular signals detected by the system (10). The splines (14) in the radially expanded non-spherical shape may contain a distal excurvate outward bend (80) disposed at the distal portion (66) of the spline (14) at a location near to the distal tip (16) of the basket assembly (12) to bend the splines (14) back towards the proximal anchor (18); and wherein the splines (14) have a distal incurvate inward bend (78) between said distal tip (16) and said distal excurvate outward bends (80). The splines (14) of the basket assembly (12) may be flexible to match the contours of the right atrium.

While various embodiments of the present invention are specifically illustrated and/or described herein, it will be appreciated that modifications and variations of the present invention may be effected by those skilled in the art without departing from the spirit and intended scope of the invention. Further, any of the embodiments or aspects of the invention as described in the claims or in the specification may be used with one and another without limitation.

What is claimed is:

1. A method for sensing multiple local electric voltages from endocardial surface of a heart and minimizing electromagnetic interference, comprising:

providing a system for sensing multiple local electric voltages from endocardial surface of a heart, comprising:

a first elongate tubular member having a lumen, a proximal end and a distal end;

a basket assembly comprising:

a plurality of flexible splines having proximal portions, distal portions and medial portions therein between, wherein the splines comprise an outer surface, an inner surface and two side surfaces;

a proximal anchor for securably affixing the proximal portions of the splines; said proximal anchor being secured at the distal end of the first elongate tubular member;

a distal tip for securing the distal portions of the splines, said proximal anchor and said distal tip defining a longitudinal axis therein between about which the splines are disposed;

a plurality of polymeric members each having opposed first and second open ends defining an open lumen therein between and an outer surface and an inner surface, wherein each of the plurality of flexible splines is at least partially disposed within the lumen of a different one of said plurality of polymeric members; and

a plurality of flexible electrode assembly strips each with one or more exposed electrodes directly disposed on at least a portion of the outer surface of a different one of each of said polymeric members;

wherein each of the plurality of flexible electrode assembly strips comprises:
 a polymeric substrate having an inner surface and an opposed outer surface; said one or more exposed electrodes disposed over at least part of the outer surface of the polymeric substrate; and
 one or more electrical traces directly disposed over at least a portion of the inner surface of the polymeric substrate, said one or more electrical traces being in electrical communication with said one or more exposed electrodes, and
 said one or more exposed electrodes being substantially flat electrodes and being substantially unidirectionally oriented towards a direction outside of the basket; and
 a second elongate tubular member having a lumen, a proximal end and a distal end, the second elongate tubular member having a braided shield disposed between the proximal end of the second elongate tubular member and the distal end of the second elongate tubular member to minimize electro-magnetic interference from sources outside of the second elongate tubular member;
 wherein the basket assembly is slidably compressible within the lumen of the second elongate tubular member;
 wherein the splines comprise a superelastic material such that the basket assembly exhibits a substantially cylindrical shape when radially compressed within the second elongate tubular member and exhibits a radially expanded non-spherical shape when not radially compressed within the second elongate tubular member;
 delivering the system to the heart;
 sliding the basket assembly beyond the distal end of the second elongate tubular member, whereby the splines radially expand into the radially expanded non-spherical shape to dispose the basket assembly within a chamber of the heart;
 contacting proximal heart tissue within the chamber of the heart with the substantially all of the one or more exposed electrodes disposed on the proximal spline portions;
 detecting multiple local electric voltages with the one or more exposed electrodes contacting the proximal heart tissue from endocardial surface thereat;
 contacting other heart tissue within the chamber of the heart with substantially all of the one or more exposed electrodes disposed on the medial spline portions and the distal spline portions;
 detecting multiple local electric voltages with the one or more exposed electrodes disposed on the medial spline portions and the distal spline portions contacting the other heart tissue from endocardial surface thereat; and
 minimizing electro-magnetic interference from sources outside of the second elongate tubular member while said one or more exposed electrodes are disposed beyond the distal end of the second elongate tubular member.

2. The method of claim 1, wherein the multiple local electric voltages form an electrocardiogram having a P wave, a QRS complex and a T wave.

3. The method of claim 1, wherein the splines approach the distal tip at an angle of about 90° or less than about 90° as measured from a line segment between the proximal anchor and the distal tip along the longitudinal axis.

4. The method of claim 1, wherein each of the splines in the radially expanded non-spherical shape contain a proximal

recurve in the proximate portion of the spline at a location near to the proximal anchor of the basket assembly, the proximal recurve comprises a proximal excurve outward bend and a proximal incurve inward bend between said proximal excurve outward bend and said proximal anchor, where an apex of the proximal incurve inward bend is disposed in a direction toward the distal tip and is further disposed inwardly closer toward the distal tip than the proximal excurve outward bend.

5. The method of claim 1, wherein the splines in the radially expanded non-spherical shape contain an distal excurve outward bend disposed at the distal portion of the spline at a location near to the distal tip of the basket assembly to bend the splines back towards the proximal anchor; and wherein the splines have a distal incurve inward bend between said distal tip and said distal excurve outward bends.

6. The method of claim 1, wherein, when the basket assembly is in said radially expanded non-spherical shape, the splines extend beyond the distal tip and apices of the distal excurve bends are disposed beyond the distal tip.

7. The method of claim 1, wherein the distal tip consisting essentially of means for only securably affixing the distal portions of the splines.

8. The method of claim 1, wherein the splines of the basket assembly are flexible and wherein the method further comprises:

matching contours of the chamber with the splines of the basket assembly.

9. The method of claim 1,

wherein the splines of the basket assembly are flexible; wherein the chamber of the heart is an atrium of the heart; and

wherein the method further comprises:

matching contours of the atrium with the splines of the basket assembly.

10. The method of claim 9, further comprising:

spatially fixing substantially all of the one or more exposed electrodes with respect to the proximal atrial tissue and the other atrial tissue.

11. The method of claim 1, further comprising:

minimizing exposure of the one or more exposed electrodes to ventricular signals whereby a substantial portion of atrial signals detected by the system have larger amplitudes than ventricular signals detected by the system.

12. The method of claim 1, wherein the one or more exposed electrodes are selected from the group consisting of copper electrodes, gold electrodes, platinum electrodes, platinum black electrodes, platinum-iridium electrodes and combinations thereof.

13. The method of claim 1, further comprising:

recording the multiple local electric voltages.

14. A method for sensing multiple local electric voltages from endocardial surface of a heart with fluoroscopic imaging, comprising:

providing a system for sensing multiple local electric voltages from endocardial surface of a heart, comprising:

a first elongate tubular member having a lumen, a proximal end and a distal end;

a basket assembly comprising:

a plurality of flexible splines having proximal portions, distal portions and medial portions therein between, wherein the splines comprise an outer surface, an inner surface and two side surfaces;

a proximal anchor for securably affixing the proximal portions of the splines; said proximal anchor being secured at the distal end of the first elongate tubular member;

a distal tip for securing the distal portions of the splines, said proximal anchor and said distal tip defining a longitudinal axis therein between about which the splines are disposed;

a plurality of polymeric members each having opposed first and second open ends defining an open lumen therein between and an outer surface and an inner surface, wherein each of the plurality of flexible splines is at least partially disposed within the lumen of a different one of said plurality of polymeric members; and

a plurality of flexible electrode assembly strips each with one or more exposed electrodes directly disposed on at least a portion of the outer surface of a different one of each of said polymeric members; wherein each of the plurality of flexible electrode assembly strips comprises:

a polymeric substrate having an inner surface and an opposed outer surface; said one or more exposed electrodes disposed over at least part of the outer surface of the polymeric substrate; and

one or more electrical traces directly disposed over at least a portion of the inner surface of the polymeric substrate, said one or more electrical traces being in electrical communication with said one or more exposed electrodes,

said one or more exposed electrodes being substantially flat electrodes, being radiotransparent and being substantially unidirectionally oriented towards a direction outside of the basket; and

a plurality of radiopaque markers where at least one radiopaque marker is directly disposed on each of said plurality of flexible splines at a location near and below at least one of said one or more exposed electrodes;

a second elongate tubular member having a lumen, a proximal end and a distal end;

wherein the basket assembly is slidably compressible within the lumen of the second elongate tubular member;

wherein the splines comprise a superelastic material such that the basket assembly exhibits a substantially cylindrical shape when radially compressed within the second elongate tubular member and exhibits a radially expanded non-spherical shape when not radially compressed within the second elongate tubular member;

delivering the system to the heart;

sliding the basket assembly beyond the distal end of the second elongate tubular member, whereby the splines radially expand into the radially expanded non-spherical shape to dispose the basket assembly within a chamber of the heart;

contacting proximal heart tissue within the chamber of the heart with the substantially all of the one or more exposed electrodes disposed on the proximal spline portions;

observing the plurality of radiopaque markers under fluoroscopy to provide fluoroscopic data on spline and electrode positioning;

detecting multiple local electric voltages with the one or more exposed electrodes contacting the proximal heart tissue from endocardial surface thereat;

contacting other heart tissue within the chamber of the heart with substantially all of the one or more exposed electrodes disposed on the medial spline portions and the distal spline portions;

detecting multiple local electric voltages with the one or more exposed electrodes disposed on the medial spline portions and the distal spline portions contacting the other heart tissue from endocardial surface thereat.

15 **15.** The method of claim **14**, wherein at least one radiopaque marker is directly disposed on each of said plurality of flexible splines at a location near and below each of said plurality of one or more exposed electrodes.

15 **16.** The method of claim **14**, wherein the multiple local electric voltages form an electrocardiogram having a P wave, a QRS complex and a T wave.

17. The method of claim **14**, wherein the splines approach the distal tip at an angle of about 90° or less than about 90° as measured from a line segment between the proximal anchor and the distal tip along the longitudinal axis.

20 **18.** The method of claim **14**, wherein each of the splines in the radially expanded non-spherical shape contain a proximal recurve in the proximate portion of the spline at a location near to the proximal anchor of the basket assembly, the proximal recurve comprises a proximal excurve outward bend and a proximal incurve inward bend between said proximal excurve outward bend and said proximal anchor, where an apex of the proximal incurve inward bend is disposed in a direction toward the distal tip and is further disposed inwardly closer toward the distal tip than the proximal excurve outward bend.

30 **19.** The method of claim **14**, wherein the splines in the radially expanded non-spherical shape contain an distal excurve outward bend disposed at the distal portion of the spline at a location near to the distal tip of the basket assembly to bend the splines back towards the proximal anchor; and wherein the splines have a distal incurve inward bend between said distal tip and said distal excurve outward bends.

40 **20.** The method of claim **14**, wherein, when the basket assembly is in said radially expanded non-spherical shape, the splines extend beyond the distal tip and apices of the distal excurve bends are disposed beyond the distal tip.

45 **21.** The method of claim **14**, wherein the distal tip consisting essentially of means for only securably affixing the distal portions of the splines.

22. The method of claim **14**, wherein the splines of the basket assembly are flexible and wherein the method further comprises:

matching contours of the chamber with the splines of the basket assembly.

23. The method of claim **14**,

wherein the splines of the basket assembly are flexible; wherein the chamber of the heart is an atrium of the heart; and

wherein the method further comprises:

matching contours of the atrium with the splines of the basket assembly.

24. The method of claim **23**, further comprising:

spatially fixing substantially all of the one or more exposed electrodes with respect to the proximal atrial tissue and the other atrial tissue.

25. The method of claim **14**, further comprising:

minimizing exposure of the one or more exposed electrodes to ventricular signals whereby a substantial portion of atrial signals detected by the system have larger amplitudes than ventricular signals detected by the system.

26. The method of claim 14, wherein the one or more exposed electrodes are selected from the group consisting of copper electrodes, gold electrodes, platinum electrodes, platinum black electrodes, platinum-iridium electrodes and combinations thereof.

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27. The method of claim 14, further comprising:
recording the multiple local electric voltages.

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摘要(译)

一种用于从心脏的心内膜表面感测多个局部电压的方法，包括：提供用于从心脏的心内膜表面感测多个局部电压的系统，包括：具有内腔，近端和远端的第一细长管状构件。结束；一种篮筐组件，包括：多个柔性花键，用于引导多个暴露的电极，所述花键具有近端部分，远端部分和其间的中间部分，其中所述电极是基本上扁平的电极并且基本上单向地朝向所述外部的方向定向。篮。

