(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
29 March 2007 (29.03.2007)

PCT

(10) International Publication Number
WO 2007/035554 A1

(51) International Patent Classification:
A61M 25/01 (2006.01) *A61B 18/14* (2006.01)
A61M 15/00 (2006.01)

(21) International Application Number:
PCT/US2006/036146

(22) International Filing Date:
15 September 2006 (15.09.2006)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
11/228,633 16 September 2005 (16.09.2005) US

(71) Applicant *(for all designated States except US)*: **BIOSENSE WEBSTER, INC.** [US/US]; 3333 Diamond Canyon Road, Diamond Bar, CA 91765 (US).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: **WORLEY, Seth, J.** [US/US]; 1525 Hillcrest Road, Lancaster, Pennsylvania 17603 (US). **SHARAREH, Shiva** [US/US]; 27751 Daisyfield Drive, Laguna Niguel, California 92677 (US).

(74) Agents: **JOHNSON, Philip, S.** et al.; Johnson & Johnson, One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933 (US).

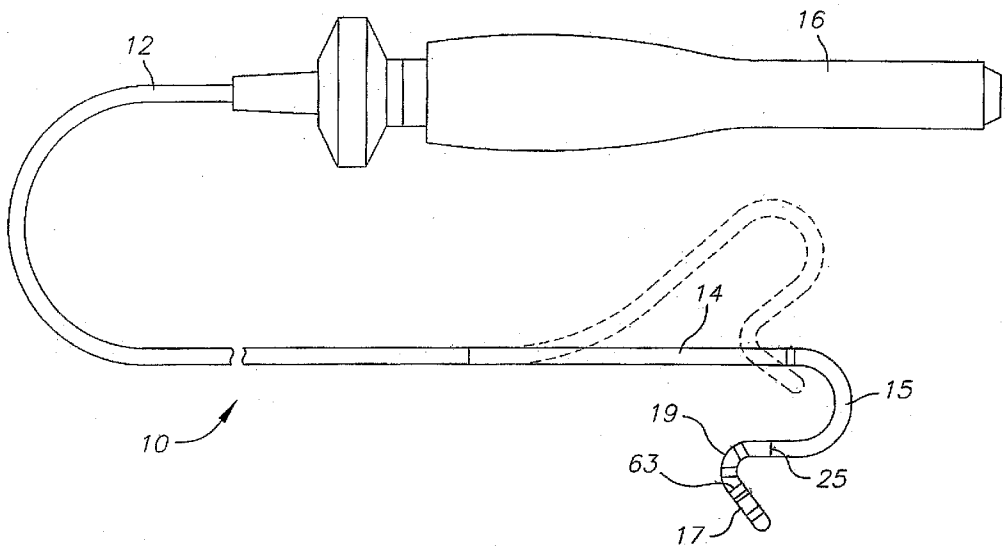
(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report*

[Continued on next page]

(54) **Title:** CATHETER WITH FLEXIBLE PRE-SHAPED TIP SECTION



(57) **Abstract:** A catheter for mapping and/or ablating continuous linear or circumferential lesions at the intersection of a generally flat structure, such as the left atrium, and the ostium of generally cavernous regions of the heart, including pulmonary vein and the pulmonary venous antrum, comprises a catheter body with an intermediate section that is connected to a tip assembly by a highly flexible section. The intermediate section has at its distal end a preformed section, e.g., a curve, the intermediate section being deflectable in a direction opposite to the curve. The highly flexible section presets the tip assembly at an off-axis and/or off-plane angles from the preformed section.

WO 2007/035554 A1

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

CATHETER WITH FLEXIBLE PRE-SHAPED TIP SECTION

FIELD OF THE INVENTION

The invention is directed to a catheter having a tip assembly for mapping and/or ablating regions of or near a heart, including an intersection between a generally flat region such as the body of the left atrium and a generally cavernous regions such as a pulmonary vein or the antrum of two or more pulmonary veins, the intersection being referred to as the ostium or opening of the generally cavernous region.

BACKGROUND OF THE INVENTION

Atrial fibrillation is a common sustained cardiac arrhythmia and a major cause of stroke. This condition is initiated by wavelets originating at or near the intersection of a generally cavernous region such as a pulmonary venous atrium or a pulmonary vein and a generally flat structure such as the left atrium. The condition is perpetuated by reentrant wavelets propagating in an abnormal atrial-tissue substrate. Various approaches have been developed to interrupt wavelets, including surgical or catheter-mediated atriotomy. A common procedure involves ablating a lesion to interrupt the wavelets using one or more electrodes mounted on the distal end of a generally-straight catheter. This procedure works well, for example, when ablating a line of block in the atria. In this case, the proximal portion and tip of the catheter are in contact with and supported/stabilized by the atria along the line of intended block. However, at the intersection of a generally

cavernous or tubular region and a generally flat region in or around the heart, this procedure can be less effective. For example, when the line of block to be ablated is about the circumference of the cavernous or tubular region, the catheter is not stabilized or supported except at the tip where it contacts the heart making it is difficult to manipulate and control the distal end of a straight catheter for an effective ablation about the circumference.

Catheters have been developed for ablating about an inner circumference of the tubular region, for example the pulmonary vein. For example, catheters using ultrasound transducers surrounded by an inflatable balloon have been used. The balloon in such a catheter is positioned inside the pulmonary vein. Balloons have also been used for stable placement inside the pulmonary vein, while ablating outside the pulmonary vein. However, due to the shape and material of the balloon, the balloon often becomes dislodged, thereby adversely affecting the accuracy of the lesion created outside the ostium of the pulmonary vein or pulmonary venous antrum. Moreover, due to the shape of regions near the pulmonary vein and/or the antrum of pulmonary veins, where a generally flat structure joins a generally cavernous structure, it is difficult to maintain a catheter in stable position. When the tip of the catheter approaches the intersection of a generally cavernous structure from the region of the generally flat structure the catheter section proximal the tip is not in contact with or supported/stabilized by the flat structure. Without supportive contact between this proximal catheter section and the tissue, motion of the heart during systole, diastole and respiration is not transmitted to this catheter section

except by contact between tissue and the catheter tip. As the heart moves during systole, diastole and respiration, the contact pressure at the tip of the catheter may vary from excessive to nonexistent. In a catheter that approaches the intersection of the ostium and the atrium in a "forward" direction, the disparity between the generally motionless (or out of synch) catheter and the heart makes it difficult to maintain stable contact between the catheter tip and the intersection of the flat and cavernous regions in a beating moving heart. An unsupported and thus unsynchronized catheter used in these regions may be inadvertently advanced into the pulmonary vein or venous antrum. Also, the nonuniform contours at the intersection of the pulmonary vein or venous antrum and surrounding tissue can make it difficult to contact recessed areas without excess pressure on the protruding areas increasing the risk of perforation. In addition, the catheter position is maintained only by contact between the tip and the nonuniform contours causing the catheter tip to frequently lose contact with the tissue during ablation or mapping as the heart moves independently during systole, diastole and with respiration.

Accordingly, a need still exists for a catheter capable of effectively mapping and ablating regions at or near the intersection of the left atrium and the ostium of a pulmonary vein or venous antrum, where the catheter is better configured and adapted for use in such regions so as to contact the nonuniform tissue surface without undue force and maintain stability during ablation and mapping despite the motion of beating heart in a breathing patient. A catheter of such design improves precision of mapping and/or

ablation and minimize risks of damage to the tissue, including tissue perforation and inadvertent entry into the pulmonary vein or pulmonary venous antrum causing stenosis of the cavernous structure.

SUMMARY OF THE INVENTION

The present invention is directed to a catheter configured for mapping and ablation at a junction of a generally flat open region of the heart such as the left atrium and a generally cavernous region of the heart, such as a pulmonary vein or an antrum of several (more than one) pulmonary veins, referred to as a pulmonary venous antrum. In one embodiment, the catheter has an intermediate section with a pre-shaped section at its distal end, and a tip assembly adapted for mapping and/or ablation that is attached distally to the pre-shaped section by a flexible section that allows the tip assembly to be moved generally independently of the intermediate section. In one embodiment, the catheter comprises an elongated flexible tubular catheter body having proximal and distal ends. The deflectable intermediate section is mounted on the distal end of the tubular body and comprises at its distal end the pre-shaped curve whose curvature is generally opposite of the direction of deflection and generally conforms to a pulmonary vein or pulmonary venous antrum. The tip assembly which can have a generally straight configuration is attached to the end of the pre-shaped curve of the intermediate section by the flexible section which is configured with preset angles to extend the tip assembly off-axis and/or off-plane relative to the pre-shaped curve of the intermediate section. The intermediate section of

the catheter is adapted to rest within the generally cavernous structure providing stability to the tip assembly. The flexible section improves the ability of the tip assembly to contact and remain in contact with surrounding tissues of variable contour without undue pressure. Moreover, the flexible tubing may be reinforced to provide the tip assembly with lateral stability. Accordingly, the catheter of the present invention has improved safety features and improved ablation and mapping capabilities.

In one embodiment, the tip assembly is configured as an ablation assembly that may be irrigated, comprising a plurality of irrigation ports in between which an ablation coil electrode is wound. A porous covering, preferably made of expanded polytetrafluoroethylene, covers the coil electrode and irrigation ports. Fluid passes through the irrigation ports to the porous covering, which then disperses the fluid around the ablation assembly. This irrigation generally enables the creation of deeper lesions.

In use, the distal end of the catheter is inserted into the heart of a patient. The pre-shaped section is deflected or otherwise positioned to sit in the generally cavernous region of the heart. The off-axis angle of the tip assembly readily allows the tip assembly to contact the surrounding tissue despite varied surface contour. As the user operates the catheter and maneuvers the tip assembly, the pre-shaped section advantageously maintains the tip assembly just outside the ostium of the cavernous region while the flexible section advantageously allows the tip assembly to flex from the preset off-axis angle as needed in order to remain in contact with the tissue. In one embodiment, as the tip assembly encounters protrusions and recesses outside

the ostium of the pulmonary vein or pulmonary venous antrum, the tip assembly is jarred from its preset off axis angle but the flexible section allows the tip assembly to conform and ride along on the uneven surface without displacing the pre-shaped curve.

By adjusting the preset angles of the flexible section, the off-axis and/or off-plane angles of the tip assembly relative to the pre shaped curve can be adapted to ablate and/or map most if not all regions around the ostium of the pulmonary vein, pulmonary venous antrum and other generally cavernous regions of the heart with uneven tissue surface. Accordingly, generally continuous linear and/or circumferential ablation and mapping can be accomplished by respectively dragging the catheter and/or rotating the catheter control handle despite uneven tissue surface.

BRIEF DESCRIPTION OF THE DRAWINGS

These and other features and advantages of the present invention will be better understood by reference to the following detailed description when considered in conjunction with the accompanying drawings, wherein:

FIG. 1 is an elevated side view of one embodiment of the catheter according to the invention;

FIG. 1a is a schematic perspective view of the distal end of the intermediate section, the flexible section and the tip assembly of the catheter of **FIG. 1** positioned within a generally cavernous region of the heart, such as the pulmonary venous antrum;

FIG. 2a is a side cross-sectional view of a catheter body according to the catheter of **FIG. 1**, including the junction between the catheter body and the intermediate

section;

FIG. 2b is a side cross sectional view taken of the side opposite that of **FIG. 2a** of the catheter body of **FIG. 2a**, including the junction between the catheter body and the intermediate section;

FIG. 2c is a side cross-sectional view of the intermediate section of the catheter of **FIGs. 2a** and **2b**, including the distal end of a puller wire and the proximal end of a shape memory support member;

FIG. 3 is a side cross-sectional view of the intermediate section of the catheter of **FIG. 1**, including the junction between the intermediate section and the flexible section;

FIG. 3a is a longitudinal cross-sectional view of the intermediate section of **FIG. 3** taken along line 3a-3a;

FIG. 3b is a side cross-sectional view of the flexible section of the catheter of **FIG. 1**, including the junction between the flexible section and the tip assembly;

FIG. 3c is a longitudinal cross-section view of the flexible section of **FIG. 3** taken along line 3d-3d;

FIG. 4 is an enlarged side view of the distal end of the intermediate section, the flexible section and the tip assembly according to the embodiment of **FIG. 1**;

FIG. 4b is a bottom end view of the distal curve of the intermediate section, the flexible section and the tip assembly of **FIG. 4**, with the flexible section preset to support the tip assembly in-plain with the distal curve of the intermediate section;

FIG. 4c is a bottom end view of the distal curve of the intermediate section, the flexible section and the tip assembly of **FIG. 4b**, with the flexible section preset to

support the tip assembly off-plane with the distal curve of the intermediate section;

FIG. 5a is a close-up side view of an embodiment of an irrigated ablation assembly;

FIG. 5b is a close-up longitudinal cross-sectional view of the ablation assembly depicted in **FIG. 5a** taken along line 5b-5b;

FIG. 6a is a schematic perspective view of **FIG. 1**, with the distal end of the intermediate section positioned within a pulmonary vein with the flexible section resting on the ostium of the pulmonary vein and the tip assembly of the catheter on the left atrium at the junction of the atria and ostium of the pulmonary vein; and

FIG. 6b is a schematic perspective view of the distal end of the intermediate section of **FIG. 1** in a deflected position, positioned within a pulmonary vein. The flexible section is at the ostium and the tip assembly is on the generally flat atrium.

DETAILED DESCRIPTION OF THE INVENTION

Referring to **FIG. 1,** the present invention provides a catheter **10** having a tip assembly **17** at its distal end. The catheter comprises an elongated catheter body **12** having proximal and distal ends, a deflectable intermediate section **14** at the distal end of the catheter body **12**, and a control handle **16** at the proximal end of the catheter body. In accordance with a feature of the present invention, the tip assembly **17** extends distally from a preformed section **15** at the distal end of the intermediate section **14** and is connected thereto by a flexible section **19**. In the illustrated embodiment, the tip assembly **17** is adapted for

ablation although it is understood by one of ordinary skill in the art that the tip assembly may be adapted for mapping applications, as well.

In the embodiment of **FIG. 1A**, the preformed section **15** is a curve which enables the catheter distal end when advanced and maneuvered in a generally cavernous region or structure such as a PV ostium **31** or antrum **33** to sit in and be cradled by the region with the tip assembly outside the cavernous structure. Where the cavernous structure is a pulmonary vein **35** or pulmonary venous antrum **33** the tip assembly will rest generally outside the ostium at a juncture of the pulmonary vein or venous antrum and the left atrium. The curve 15 minimizes inadvertent entry of the tip assembly into a pulmonary vein **35** or pulmonary venous antrum **33** especially where the curvature of the curve 15 is generally opposite the deflection of the intermediate section **14** (see **FIG. 1**). The curve 15 can therefore sit in conformity with the generally concave configuration of the ostium or antrum to urge the distal end of the catheter out of and away from entering the pulmonary vein or pulmonary venous antrum when a user advances the catheter in those regions. Accordingly, a feature of the present invention enables a user to approach the junction of the pulmonary vein or pulmonary venous antrum and the left atrium from more a "backward" direction or deflection. With the intermediate section 14 cradled in the cavernous structure the distal section of the catheter moves with the heart during systole, diastole and respiration. The tip assembly 17 is thus stable in a position at the junction of the left atrium and the pulmonary antrum/vein. The more stable backward approach with the intermediate section cradled in

the pulmonary vein or pulmonary venous antrum minimizes the risk of the tip assembly inadvertently entering the pulmonary vein or pulmonary venous antrum causing damage to the veins or ineffective ablation.

Moreover, as another feature of the present invention, the flexible section **19** has a bending modulus greater than that of the preformed section **15**, as discussed in detail further below. This greater flexibility enables the tip assembly **17** to flex and adjust to the contour of the tissue surface independently of the curve **15** of the intermediate section **14**. As shown in **FIG. 1A**, the distal end of the catheter **10** is therefore better equipped to adjust to and withstand jarring of the tip assembly **17** as it comes into contact with protrusion **37** in the tissue surface when the tip assembly **17** is dragged along it. In addition, the ablation to flex and adjust permits the tip assembly to contact tissue in recessed areas without exerting excess contact pressure in elevated areas reducing the risk of perforation To that end, as also discussed in further detail below, the flexible section **19** may be configured with an off axis angle and/or off-plane angle for use in the ostium of the pulmonary vein or ostium of the pulmonary venous antrum.

With reference to **FIGs. 2a** and **2b**, the catheter body **12** comprises an elongated tubular construction having a single, axial or central lumen **18**. The catheter body **12** is flexible, i.e., bendable, but substantially non-compressible along its length. The catheter body **12** can be of any suitable construction and made of any suitable material. A presently preferred construction comprises an outer wall **20** made of polyurethane or PEBAX. The outer wall **20** comprises

an embedded braided mesh of stainless steel or the like to increase torsional stiffness of the catheter body **12** so that, when the control handle **16** is rotated, the intermediate section **14** of the catheter **10** is able to rotate in a corresponding manner.

The outer diameter of the catheter body **12** is not critical, but is preferably no more than about 9 french, more preferably about 7 french. Likewise, the thickness of the outer wall **20** is not critical, but is thin enough so that the central lumen **18** can accommodate a puller wire, one or more lead wires, and any other desired wires, cables or tubes. If desired, the inner surface of the outer wall **20** is lined with a stiffening tube **21** to provide improved torsional stability. A particularly preferred catheter **10** has an outer wall **20** with an outer diameter of from about 0.090 inches to about 0.094 inches and an inner diameter of from about 0.061 inches to about 0.065 inches.

The intermediate section **14** comprises a short section of tubing **22** having multiple lumens, as shown in **FIG. 3a**. In one embodiment, a first lumen **30** carries one or more lead wires **50** and any other components (e.g., thermocouple wires **53** and **54** for monitoring tissue temperature) extending along the catheter (**FIG. 2a, 2c and 3**). A second lumen **32** carries a puller wire **64** in the more proximal region (**FIGS. 2a and 2c**), and a support member **24** in the more distal region (**FIGS. 2c and 3**) which enables shape memory curvature of the pre-formed curve 15. As also shown in **FIGs. 2b**, a third lumen **34** carries an electromagnetic sensor cable **74**, and a fourth lumen **35** carries an irrigation tube **61** for supplying fluid to the tip assembly **17**. The tubing **22** is made of a suitable non-toxic material that is preferably more flexible

than the catheter body **12**. A presently preferred material for the tubing **22** is braided polyurethane, i.e., polyurethane with an embedded mesh of braided stainless steel or the like. The number of lumens or the size of each lumen is not critical, but is sufficient to house the lead wires, puller wire, electromagnetic sensor cable, thermal sensors and/or irrigation tube(s) depending on the embodiment.

The useful length of the catheter **10**, i.e., that portion that can be inserted into the body excluding the tip assembly **17**, can vary as desired. Preferably the useful length ranges from about 110 cm to about 120 cm. The length of the intermediate section **14** is a relatively small portion of the useful length, and preferably ranges from about 3.5 cm to about 10 cm, more preferably from about 5 cm to about 6.5 cm.

A preferred means for attaching the catheter body **12** to the intermediate section **14** is illustrated in **FIGs. 2a** and **2b**. The proximal end of the intermediate section **14** comprises an outer circumferential notch **26** that receives the inner surface of the outer wall **20** of the catheter body **12**. The intermediate section **14** and catheter body **12** are attached by glue or the like.

If desired, a spacer (not shown) can be located within the catheter body between the distal end of the stiffening tube **21** and the proximal end of the intermediate section. The spacer provides a transition in flexibility at the junction of the catheter body and intermediate section, which allows the junction to bend smoothly without folding or kinking. A catheter having such a spacer is described in U.S. Patent No. 5,964,757, the entire disclosure of which is

incorporated herein by reference.

As shown in **FIG. 2a**, the puller wire **64** is provided for deflection of the intermediate section **14** (see **FIGs. 1** and **6b**). The puller wire **64** extends through the catheter body **12**, is anchored at its proximal end to the control handle **16**, and is anchored at its distal end to the intermediate section **14**. The distal end of the puller wire **64** is anchored within the intermediate section **14** at about the location of the termination of the proximal end of the support member **24**. The puller wire **64** is made of any suitable metal, such as stainless steel or Nitinol, and is preferably coated with Teflon® or the like. The coating imparts lubricity to the puller wire **64**. The puller wire **64** preferably has a diameter ranging from about 0.006 to about 0.010 inch.

A compression coil **66** is situated within the catheter body **12** in surrounding relation to the puller wire **64**, as shown in **FIG. 2a**. The compression coil **66** extends from the proximal end of the catheter body **12** to the proximal end of the intermediate section **14**. The compression coil **66** is made of any suitable metal, preferably stainless steel. The compression coil **66** is tightly wound on itself to provide flexibility, i.e., bending, but to resist compression. The inner diameter of the compression coil **66** is preferably slightly larger than the diameter of the puller wire **64**. The Teflon® coating on the puller wire **64** allows it to slide freely within the compression coil **66**. The outer surface of the compression coil **66** is covered by a flexible, non-conductive sheath **68**, e.g., made of polyimide tubing.

The compression coil **66** is anchored to the outer wall of the catheter body **12** by proximal glue joint **70** and at its

distal end to the intermediate section **14** by distal glue joint **71**. Both glue joints **70** and **71** preferably comprise polyurethane glue or the like. The glue may be applied by means of a syringe or the like through a hole made between the outer surface of the catheter body **12** and the central lumen **18**. Such a hole may be formed, for example, by a needle or the like that punctures the outer wall **20** of the catheter body **12** which is heated sufficiently to form a permanent hole. The glue is then introduced through the hole to the outer surface of the compression coil **66** and wicks around the outer circumference to form a glue joint about the entire circumference of the compression coil.

Longitudinal movement of the puller wire **64** relative to the catheter body **12**, which results in deflection of the intermediate section **14 (FIG. 1)**, is accomplished by suitable manipulation of the control handle **16**. Examples of suitable control handles for use in the present invention are disclosed in U.S. Patent Nos. Re 34,502 and 5,897,529, the entire disclosures of which are incorporated herein by reference. Deflection of the intermediate section **14** by longitudinal movement of the puller wire **64** generally results in deflection of the preformed shaped curve **15** of the intermediate section **14**, as well as the entire tip assembly **17**, without distortion of the curve **15**. Deflection of the intermediate section **14** in this manner enables better maneuverability of the curve **15** within the heart. In the illustrated embodiment, the puller wire is configured to deflect the intermediate section 14 in a direction away from the curvature of the curve 15. As understood by one of ordinary skill in the art, the puller wire may be configured as appropriate to enable deflection of the intermediate

section 14 in other directions.

The distal portion of the intermediate section **14**, containing the support member **24**, terminates in the preformed curve **15**, better shown in **FIGS. 4 and 4A**. The support member **24** (shown in broken lines) is made of a material having shape-memory, i.e., that can be straightened or bent out of its original shape upon exertion of a force and is capable of substantially returning to its original shape upon removal of the force. A particularly preferred material for the support member **24** is a nickel/titanium alloy wire or ribbon. Such alloys typically comprise about 55% nickel and 45% titanium, but may comprise from about 54% to about 57% nickel with the balance being titanium. A preferred nickel/titanium alloy is Nitinol, which has excellent shape memory, together with ductility, strength, corrosion resistance, electrical resistivity and temperature stability. As such, the support member **24** enables the catheter to be advanced atraumatically in the patient's body in a generally straight configuration through a vein or artery and yet be able to assume its preformed shape when it reaches the heart. The support member **24** extends proximally from a junction **25** of the intermediate section **14** and the flexible section 19, through the third lumen **34** (**FIG. 2c**) of the intermediate section **14** and terminates at about a third of the length of the intermediate section **14**, so as not to adversely affect the ability of the intermediate section **14** to deflect. The distal and proximal ends of the support member **24** are anchored to the lumen **32** by any suitable means, for example, adhesives forming glue joints **26** (**FIG. 2c**) and **27** (**FIG. 3**).

The preformed curve **15** is prepared by placing the

support member **24** in a delrin mold and heating the support member in the mold at about 550°C for about 15 minutes. The tubing **22** of the intermediate section **14** is also preformed to include the curve **15** by placing the tubing **22** in a delrin mold and heating the mold at about 100°C for about 30 minutes. The length of the curve **15** of the intermediate section **14** can vary as desired, but is preferably no longer than about 33 mm, preferably about 10 mm.

The curvature of the preshaped section 15 enables it to fit and sit within a generally cavernous structure such as a pulmonary vein **(FIGS. 6a and 6b)** or a pulmonary venous antrum (**FIG. 1A**) for pulmonary vein isolation. In the illustrated embodiments, the pre-shaped curve **15** is generally circular to conform to the overall shape and cavity of the pulmonary vein and pulmonary venous antrum. However, recognizing that pulmonary veins and pulmonary venous antrums can come in different shapes and sizes, the curve **15** may have a general diameter ranging between about 0.5 cm and 6.0 cm, more preferably between about 1.0 cm and 3.0 cm, and a curvature ranging between about 110 degrees and 270 degrees (a more closed or "hook" shape as shown in **FIG. 4A)**. The preferred shape is a generally U shape as shown in **FIG. 4** with a curvature of about 180 degrees . It is understood that the curve **15** may assume a variety of sizes and shapes as desirable or appropriate for the intended region of ablation or mapping. By conforming to the shape of the region, the curve **15** sits securely in the region and transmits the motion of the heart during systole, diastole and respiration to the entire catheter. The tip of the catheter is thus both stable and moves in synchrony with the heart. This allows the distal end of the

catheter to be maneuvered with minimal risk of the tip assembly inadvertently entering a tubular region in communication with the region. In the illustrated embodiment, the curve **15** tends to guide the distal end of the catheter out of the vein or venous antrum when the catheter body is advanced at or near the treatment site. As shown in **FIGS. 1A, 6 and 6a**, as the catheter is advanced in the vein or venous antrum, the curve **15** being in conformity with the shape of the vein or venous antrum predisposes the distal end of the catheter to turn back or curl on itself (along direction **37**) and out of the vein **35** or venous antrum **33**, as opposed to advancing in an opposite direction from the curvature of the curve **15** (along direction **39**) which may lead the tip assembly **17** downwardly into a pulmonary vein **35** or pulmonary venous antrum **33**.

In accordance with another feature of the present invention, the tip assembly **17** is attached to the distal end of the curve **15** of the intermediate section **14** by the flexible section 19.As shown in **FIGS 4 and 4A**, the flexible section **19** supports the tip assembly **17** at a preset off-axis from the distal end of the curve **15** . Using an angle **θ** to define the off-axis angle, the angle **θ** may range between about 10 degrees to about 180 degrees, preferably between about 70 degrees to 150 degrees, and more preferably about 120 degrees. In the embodiment of **FIG. 4**, the angle **θ** is about 120 degrees and in the embodiment of **FIG. 4A**, the angle θ is about 160 degrees. The angle **θ** generally allows the tip assembly to contact the surrounding tissue. The flexible section allows the angle θ to be varied from the initially set off axis angle to zero degrees with minimal force applied to the tip assembly through contact with the

tissue.

To enable the tip assembly **17** to remain in or return to contact with the tissue outside the ostium of the pulmonary vein or the pulmonary venous antrum while the distal end of the catheter is advanced, withdrawn or otherwise maneuvered in the ostium or antrum, the flexible section **19** is constructed with shape memory and/or sufficient flexibility and elasticity so that the tip assembly **17** can temporarily assume a different (greater or lesser) angle θ as needed for the tip assembly to pivot at its proximal end. The flexible section 19 can be sufficiently soft to allow the tip assembly **17** to be displaced from its preset off-axis angle θ to an on-axis angle where **θ** is about zero, and sufficiently elastic to return (or at least bias the return of) the tip assembly **17** to its preset off-axis angle **θ** thereafter, whether the displacement was caused by a formation **37** in the surrounding tissue, the tip assembly being caught or buried in the surrounding tissue, or a "steam pop" where a build up of pressure dislodges the tip assembly from contact with the surrounding tissue. To that end, the flexible section **19** has a relatively high flexural modulus measuring on a Durometer scale no greater than about 25 D to 35D and/or no greater than about 1/2 to 1/4 of the Durometer measurement of the curve **15**. As shown in **FIG. 1A**, the flexible section **19** acts as a "shock absorber" when the tip assembly is jarred or otherwise displaced from its preset position. The flexible section **19** enables the tip assembly **17** to pivot to away from the protrusion **37** independently of the intermediate section **14** so that the tip assembly can remain in contact with the tissue. As the catheter **10** is advanced, withdrawn or otherwise maneuvered around the treatment site,

the tip assembly **17** moves between a resting position **A** (solid lines) and a displaced position **B** (broken lines) without significantly displacing the curve **15** of the intermediate section **14** or changing its curvature. In one embodiment, the tip assembly **17** can be displaced from its preset off-axis angle (position A) under a force or weight of merely about 0.25 to about 2.0 oz, and more preferably about 1.0 ounce. As such, the flexible section **19** provides sufficient flexibility to reduce the risk of injury that can result from the tip assembly **17** inadvertently perforating tissue or being buried in the tissue and overheating. As understood by one of ordinary skill in the art, the force required to displace or capable of displacing the tip assembly from the preset off axis angle depends on the point of application of the force to the tip assembly, as well as the length of the tip assembly.

Referring to **FIGS. 4b** and **4c**, the highly flexible section **19** may also be configured to support the tip assembly **17** off-plane from the curve **15** at a variety of radial angles. Using angle γ to define the radial angle from a plane defined by the curve **15**, the angle γ may range between about 0 to 360 degrees, preferably about 20 to 90 degrees, and more preferably about 40 degrees. As understood by one of ordinary skill in the art, the angle γ can be preset to any degrees depending on the location and surrounding structures of the tissue to be ablated or mapped. In the embodiment of **FIG. 4b**, the angle γ is about zero degrees in that the tip assembly **17** lies in the plane of the curve **15** with the flexible section **19** extending the tip assembly in a direction or curvature generally opposite to the curvature of the curve **15**. In the embodiment of **FIG.**

4C, the angle γ is about 40 degrees. Moreover, to provide lateral stability in the tip assembly **17**, struts or ribbons **51** may be provided in walls of the tubing **45**, as shown in **FIG. 3c,** or elsewhere on or in the tubing as desirable. A pair of struts **51** can be aligned along a diameter that is generally perpendicular to a plane defined by the angle γ for maximum lateral stability while minimizing interference with movement of the tip assembly between the off-and on-axis positions.

The flexible section **19** comprises a short section of tubing **45** with a central lumen **47** through which the lead wires **50**, thermocouple wires **53** and **54**, sensor cable **74** and irrigation tube 61 extend distally and connect to the tip assembly **17**. A junction **25** of the intermediate section **14** and the flexible section **19** is shown in **FIG. 3**. The proximal end of the tubing **45** of the tip assembly **17** comprises an outer circumferential notch **49** that receives the inner surface of the tubing **22** of the intermediate section **14**. The intermediate section **14** and the flexible section **19** are attached by glue or the like. The tubing **45** of the flexible section can be made of polyurethane, PEBAX, silicone or combinations thereof and is preformed (used generally interchangeably with "preshaped" herein) with shape memory by placing the tubing **45** in a delrin mold and heating the mold at about 100°C for about 30 minutes. The length of the flexible section **19** can vary as desired and can range between about 0.1 cm and 2.0 cm, preferably between about 0.2 cm and 1.0 cm , and more preferably about 5.0 cm.

In illustrated embodiment, the tip assembly **17** comprises a short section of tubing **61 (FIGs. 3b, 5a and 5b)**

comprising four lumens **30a**, **32a**, **34a** and **35a**, generally corresponding to and aligned with the four lumens **30**, **32**, **34** and **35** respectively, of the intermediate section **14**. The length of the tip assembly **17** can vary as desired, but preferably ranges between about 8 mm to about 15 mm, and more preferably is about 10 mm. A junction 63 of the flexible section 19 and the tip assembly **17** is shown in **FIG. 3B**. The proximal end of the tubing **61** of the tip assembly **17** comprises an outer circumferential notch **65** that receives the inner surface of the tubing **45** of the flexible section **19**. The flexible section **19** and tip assembly **17** are attached by glue or the like.

FIG. 5a illustrates an embodiment of the tip assembly **17** configured as an ablation assembly. A coil electrode **82** is coiled around the length of the ablation assembly **17**. The longitudinal span of the coil electrode **82** may be made of any suitable metal, preferably platinum/iridium and ranges in length from about 6 to about 10 mm, preferably about 8 mm to generally match the length of the ablation assembly **17**.

In the disclosed embodiment, the ablation assembly **17** is irrigated and comprises a plurality of irrigation ports **80** disposed along most of the length of the ablation assembly **17** through which fluid can pass to the outer surface of the ablation assembly to cool the ablation site. In the illustrated embodiment, the coil and the irrigation ports **80** are arranged so that an irrigation port lies between each wind of the coil electrode **82**. The irrigation ports may comprise round holes formed on the surface of the tubing 61 on the side of the ablation assembly **17** in communication with the fourth lumen **35a** which is supplied

fluid by the irrigation tube **61** whose distal end is slightly proximal of the most proximal irrigation port. Any number of irrigation ports **80** may be used. In the illustrated embodiment, the tubing 61 of the ablation assembly **17** is configured with about 10 irrigation ports **80**. The circumference of each round hole can measure about 20/1000 inch. As shown in **FIGS. 5a and 5b**, a porous protective covering **84**, of, for example, expanded polytetrafluoroethylene (EPTFE), is disposed over the tubing 61in surrounding relation to and covering the coil electrode **82** and irrigation ports **80**

A tip electrode lead wire **50** (**FIG. 5b**) connects the coil electrode **82** to a suitable source of ablation energy (not shown), preferably radio frequency (RF) energy. The distal end of the lead wire **50** is attached to the proximal end of the coil electrode **82**. The proximal end of the lead wire **50** is electrically connected to the source of ablation energy as is known in the art. The lead wire **50** extends through the first lumen **30a** of the ablation assembly **17**, the central lumen **47** of the flexible section **19**, the first lumen **30** of the intermediate section **14**, the central lumen **18** of the catheter body **12**, and the control handle **16**, and terminates at its proximal end in a connector (not shown).

As shown in **FIG. 5a**, if desired, mapping and/or ablation ring electrodes **83a** and **83b** may be mounted on the ablation assembly **17**. The ring electrodes **83a** and **83b** can be mounted over the coil electrode **82** and underneath the porous covering **84**. In the illustrated embodiment, the first ring electrode **83a** is positioned in between the two distal most irrigation ports **80**. The second ring electrode **83b** is positioned in between the two proximal most

irrigation ports **80**. The ring electrodes **83a** and **83b** are mounted to the coil electrode **82** by any suitable means, for example by welding, soldering or the like. As such, the ring electrodes **83a** and **83b** are electrically connected to the coil electrode **82** and its associated lead wire for ablation purposes. The ring electrodes **83a** and **83b** serve in part to hold the coil electrode **82** in place on the tubing 61 of the ablation assembly. The ring electrodes **83a** and **83b** also serve to flatten the coil electrode **82** on the surface of the tubing **61**, thereby preventing any rough edges of the coil electrode **82** from cutting into the porous covering **84**.

Any conventional temperature sensors, e.g. thermocouples or thermistors, may be used. In the embodiment shown in **FIGs. 2a, 3** and **5a**, the temperature sensors comprise two thermocouples formed by two enameled wire pairs. One wire of each wire pair is a copper wire **53**, e.g., a number "40" copper wire. The other wire of each wire pair is a constantan wire **54**. The wires **53** and **54** of each wire pair are electrically isolated from each other except at their distal ends where they are twisted together, covered with a short piece of plastic tubing **55 (FIG. 5a)**, e.g., polyimide, and covered with epoxy. The wires **53** and **54** of each wire pair extend out a hole in the side wall of the tubing 61and are anchored to the outer surface of tubing 61. The hole in the side wall of the distal region is sealed by a plug. Any suitable seal may be used, for example glue or the like. Each plastic tubing **55** is mounted on the outer surface of the tubing 61 by polyurethane glue or the like. One of the two thermocouples is anchored immediately distal the distal most irrigation port **80**, as shown in **FIG. 5a**. The second of the two thermocouples is

anchored immediately proximal the proximal most irrigation port **80**. The wires **53** and **54** extend through the first lumen **30** in the ablation assembly **17** and intermediate section **14**, through the central lumen **18** of the catheter body **12** and out through the control handle **16** to a connector (not shown) connectable to a temperature monitor (not shown).

If desired, one or more mapping and/or ablation ring electrodes can be mounted on the tubing **45** of the flexible section **19** and tubing 61 of the ablation assembly **17**, as shown in **FIGs. 4** and **5a**. These ring electrodes might be desirable, for example, for mapping the region to be ablated before ablation begins or after ablation to assure that the lesions blocked the electrical activity as desired. A ring electrode **85a** can be mounted on the proximal end of the tubing 61 of the ablation assembly **17** over the porous covering **84** so that the proximal end of the porous covering **84** can be tucked underneath the ring electrode **85a** to lock the proximal position of the porous covering **84**. Also, a second ring electrode **85b** can be mounted on the distal end of the tubing 61 so that the distal end of the porous covering **84** can be tucked underneath the ring electrode **85b** to lock the distal position of the porous covering **84**.

In other embodiment, the tip assembly **17** whether adapted for mapping or ablation may be constructed with or without irrigation, with or without temperature sensors, using suitable ring electrodes for sensing and/or ablation, as understood by one of ordinary skill in the art. The relationship between the tip assembly and the flexible section remains generally as described herein.

In addition, as better shown in **FIGs. 4 and 4A**, two additional ring electrodes **86a** and **86b** for mapping are

mounted on the flexible section **19**. The first ring electrode **86a** is positioned approximately 5 mm proximal the proximal locking ring electrode **85a** and is used to confirm the position of the ablation assembly in the vein or venous antrum. The second ring electrode **86b** is positioned approximately 2.5 mm proximal the first ring electrode **86a** and is also used to confirm the position of the ablation assembly in the vein or venous antrum. If desired, an additional ring electrode **86c** can be mounted on the intermediate section **14** proximal the curve **15**, and distal the junction of the intermediate section **14** and catheter body **12**. This additional mapping ring electrode **86c** may be used to assure that the curve **15** of the intermediate section **14** is positioned in the desired location generally within the vein or venous antrum. As understood by one of ordinary skill in the art, the mapping electrodes may be mounted at different locations on the ablation assembly **17**, flexible section **19** and/or intermediate section **14** as desired.

In **FIG. 3**, each ring electrode **85a**, **85b**, **86a**, **86b** and **86c** is connected to a corresponding lead wire **50**. The distal end of each lead wire **50** is attached to the corresponding ring electrode. The proximal end of each lead wire **50** is electrically connected to a suitable monitoring device for monitoring electrical activity. Each lead wire **50** extends through the first lumen **30a** of the ablation assembly **17**, the central lumen **47** of the tubing **45**, the first lumen **30** of the intermediate section **14**, the central lumen **18** of the catheter body **12**, and the control handle **16**, and terminates at its proximal end in a connector (not shown).

As shown in **FIG. 2a**, the portion of each lead wire **50** extending through the control handle 16, the central lumen **18** of the catheter body **12**, and at least the proximal section of the intermediate section **14** is enclosed within a protective sheath **62** to prevent contact with other lead wires or other components of the catheter. The protective sheath **62** can be made of any suitable material, preferably polyimide. The protective sheath **62** is anchored at its distal end to the proximal end of the intermediate section **14** by gluing it in the first lumen **30** with polyurethane glue or the like. As would be recognized by one skilled in the art, the protective sheath **62** can be eliminated if desired.

As shown in **FIG. 5a**, an electromagnetic navigation sensor **72** may be contained within the ablation assembly **17**. The electromagnetic sensor **72** is preferably situated at the distal tip of the ablation assembly 17and is approximately 5 mm long. The electromagnetic sensor **72** is positioned in the third lumen **34a** of the ablation assembly **17**. The electromagnetic sensor **72** is mounted to the tubing 61 of the ablation assembly **17** by any suitable means, e.g. by polyurethane glue or the like.

The electromagnetic sensor **72** is connected to an electromagnetic sensor cable **74**, which extends through the third lumen **34a** in the ablation assembly **17,** the central lumen 47 of the flexible section **19,** the third lumen **34** of the intermediate section **14**, through the catheter body **12**, and out through the control handle **16**. The electromagnetic sensor cable **74** comprises multiple wires encased within a plastic covered sheath. In the control handle **16**, the sensor cable **74** is connected to a circuit board (not shown). The circuit board amplifies the signal received from the

electromagnetic sensor **72** and transmits it to a computer in a form understandable by the computer. Because the catheter is designed for a single use only, the circuit board may contain an EPROM chip which shuts down the circuit board approximately 24 hours after the catheter has been used. This prevents the catheter, or at least the electromagnetic sensor from being used twice.

Suitable electromagnetic sensors for use with the present invention are described, for example, in U.S. Patent Nos. 5,558,091, 5,443,489, 5,480,422, 5,546,951, and 5,391,199, the disclosures of which are incorporated herein by reference. A preferred electromagnetic sensor **72** has a length of from about 6 mm to about 7 mm, preferably about 5 mm, and a diameter of about 1.3 mm.

In **FIG. 3a**, the irrigation tube **61** may be made of any suitable material, and is preferably made of polyimide tubing. A preferred irrigation tube has an outer diameter of from about 0.032 inch to about 0.036 inch, and an inner diameter of from about 0.028 inch to about 0.032 inch. The irrigation tube **61** extends through the central lumen **18** of the catheter body **12 (FIG. 2b)**, the fourth lumen **35** of the intermediate section **14**, the central lumen **47** of the flexible section **19**, and the fourth lumen **35a** of the ablation assembly **17 (FIG. 3a)**, and terminates slight proximal of the most proximal irrigation port 80 in the ablation assembly **17**. The proximal end of the irrigation tube **61** extends through the control handle **16** and terminates in a luer hub or the like (not shown). Fluid is introduced into the irrigation tube **61** through the luer hub. The fluid, e.g. saline, is then introduced to the fourth lumen **35a** of the ablation assembly **17** by the irrigation tube **61**

and passes to the outer surface of the tubing 61through the irrigation ports **80 (FIG. 5a)**. The fluid is then dispersed over generally the entire surface of the ablation assembly **17** by the porous covering **84**. This irrigation enables creation of deeper lesions.

In use, the catheter **10** is inserted into the patient through a suitable guiding sheath whose distal end is positioned at a desired mapping or ablating location. An example of a suitable guiding sheath for use in connection with the present invention is the Preface™ Braided Guiding Sheath, commercially available from Biosense Webster, Inc. (Diamond Bar, California). The distal end of the sheath is guided into one of the atria. A catheter in accordance with the present invention is fed through the guiding sheath until its distal end extends out of the distal end of the guiding sheath. As the catheter **10** is fed through the guiding sheath, the tip assembly **17,** the flexible section **19** and the intermediate section **14** are generally straightened to fit through the sheath. Once the distal end of the catheter is positioned at the desired mapping or ablating location, the guiding sheath is pulled proximally, allowing the deflectable intermediate section **14,** the flexible section **19** and the tip assembly **17** to extend outside the sheath, and return to their original preformed shapes with the tip assembly **17** extending from the curve **15** at a predetermined off-axis angle θ and/or off-plane angle γ.

The curve **15** of the intermediate section **14** is then deflected or otherwise maneuvered to sit in the antrum (**FIG. 1A**) or vein (**FIGS. 6a and 6b**) which can be approached from a more "backward" direction being that the curvature of the curve **15** is generally opposite to the direction of

deflection. The user can then position the catheter **10** with minimal risk of the tip assembly **17** entering a pulmonary vein.

The curve **15** of the intermediate section **14** stabilizes the tip assembly **17** in the region and the tip assembly **17** makes contact with tissue in the region by means of the preset off-axis angle provided by the flexible section **19**. To create generally continuous lesions during ablation, the catheter is advanced, withdrawn and/or rotated to drag the tip assembly **17** along the tissue surface. As the ablation assembly encounters uneven formation such as a projection or recess in the tissue surface, the flexible section **19** flexes as the ablation assembly pivots from the preset off-axis angle to absorb the movement without displacing the curve **15** of the intermediate section **14** in the pulmonary venous antrum or pulmonary vein. Whether the tip assembly **17** is maneuvered linearly or rotated via the control handle **16** and/or the catheter body 12, the tip assembly 17 maintains continuous contact with the tissue for improved mapping and/or creation of lesions. In the embodiment of the catheter for mapping applications, similar manipulations of the catheter and the control handle enable the mapping electrodes **85a**, **85b**, **86a**, **86b** and **86c** to map in a linear or circumferential pattern.

The preceding description has been presented with reference to presently preferred embodiments of the invention. Workers skilled in the art and technology to which this invention pertains will appreciate that the Figures are not necessarily to scale and alterations and changes in the described structure may be practiced without meaningfully departing from the principal spirit and scope

of this invention. Accordingly, the foregoing description should not be read as pertaining only to the precise structures described and illustrated in the accompanying drawings, but rather should be read consistent with and as support for the following claims which are to have their fullest and fairest scope.

WHAT IS CLAIMED IS:

1. A catheter comprising:

an elongated flexible tubular catheter body having proximal and distal ends;

an intermediate section attached to the distal end of the catheter body, the distal end of the intermediate section having a preformed curve, wherein the curve of the intermediate section is adapted to sit in a generally cavernous region of or near the heart;

a tip assembly; and

a flexible section connecting the tip assembly to the preformed curve at a preset off-axis angle, the flexible section adapted to permit displacement of the tip assembly from the preset off-axis angle without displacement of the preformed curve in the generally cavernous region.

2. The catheter of claim 1, wherein the flexible section connects the tip assembly to the preformed curve at a preset off-plane angle.

3. The catheter of claim 2, wherein the flexible section comprises at least one lateral support structure to minimize movement of the tip assembly from the preset off-plane angle.

4. The catheter of claim 1, wherein the intermediate section is more flexible than the catheter body.

5. The catheter of claim 1, wherein the intermediate section is deflectable in a direction and the curve has a curvature generally opposite to said direction.

6. The catheter of claim 1, wherein the flexible section is more flexible than the intermediate section.

7. The catheter of claim 1, wherein the off-axis angle ranges between about 2 and 180 degrees.

8. The catheter of claim 1, wherein the off-plane angle ranges between 2 and 360 degrees.

9. The catheter of claim 1, wherein the displacement of the tip assembly is between the preset off-axis position and an on-axis position.

10. The catheter of claim 1, wherein the tip assembly is configured for mapping.

11. The catheter of claim 1, wherein the tip assembly is configured for ablation.

12. The catheter of claim 1, further comprising:

a control handle connected to the proximal end of the catheter body; and

a puller wire manipulated by the control handle and wire extending longitudinally relative to the catheter body, whereby longitudinal movement of the puller wire relative to the catheter body results in deflection of the intermediate section in a direction generally opposite to the preformed curve.

13. A catheter comprising:

an elongated flexible tubular catheter body having proximal and distal ends;

an intermediate section attached to the distal end of the catheter body, the distal end of the intermediate section having a preformed section with a configuration that conforms to a generally cavernous region of or near the heart;

a tip assembly; and

a flexible section connecting the tip assembly to the performed section, the flexible section having a flexibility greater than the preformed section and adapted to maintain the tip assembly in contact with the tissue during movement of the catheter without changing the configuration of the preformed curve in the generally cavernous region.

14. A catheter of claim 13, wherein the configuration of the preformed section is substantially U shaped.

15. A catheter of claim 13, wherein the configuration of the preformed section is substantially hook shaped.

16. A catheter of claim 13, wherein the configuration of the preformed section generally conforms to a pulmonary vein.

17. A catheter of claim 13, wherein the configuration of the preformed section generally conforms to a pulmonary venous antrum.

18. A catheter of claim 13, wherein contact between preformed section and the generally cavernous region

synchronizes a distal portion of the catheter to heart motion during systole, diastole or respiration.

19. A catheter of claim 13, wherein contact between preformed section and the generally cavernous region stabilizes position of the tip assembly.

20. A catheter of claim 13, wherein the tip assembly includes an ablation electrode.

21. A catheter of claim 13, wherein the tip assembly includes a mapping electrode.

22. The catheter of claim 13, further comprising:

a control handle connected to the proximal end of the catheter body; and

a puller wire manipulated by the control handle and extending longitudinally relative to the catheter body, whereby longitudinal movement of the puller wire relative to the catheter body results in deflection of the intermediate section in a direction generally opposite to the preformed curve.

23. A method for ablating tissue at an intersection of a generally flat region and an ostium of a generally cavernous region at or near the heart, the method comprising:

inserting into the heart a distal end of a catheter according to claim 1;

deflecting the preformed curve to generally sit in the generally cavernous region;

applying energy to the tip assembly configured for ablation while moving the tip assembly along a surface at said intersection wherein the tip assembly maintains contact with the surface to form a generally continuous lesion despite variable contour of the generally flat region.

24. A method of claim 23, wherein the tip assembly is dragged along the surface in a generally linear direction.

25. A method of claim 23, wherein the tip assembly is rotated about its axis by rotating a control handle of the catheter to form a circumferential lesion at or near said intersection.

26. A method for mapping tissue at an intersection of a generally flat region and an ostium of a generally cavernous region at or near the heart, the method comprising:

inserting into the heart a distal end of a catheter according to claim 1;

deflecting the preformed curve to generally sit in the generally cavernous region;

recording electrograms from the tip assembly configured for mapping while moving the tip assembly along a surface at said intersection wherein the tip assembly maintains contact with the surface despite variable contour of the generally flat region.

27. A method of claim 26, wherein the tip assembly is dragged along the surface in a generally linear direction.

28. A method of claim 26, wherein the tip assembly is rotated about its axis by rotating a control handle of the catheter at or near said intersection.

29. A catheter comprising:

an elongated flexible tubular catheter body having proximal and distal ends;

an intermediate section attached to the distal end of the catheter body, the distal end of the intermediate section having a preformed curve, wherein the curve of the intermediate section is adapted to sit in a generally cavernous region of or near the heart;

an ablation assembly; and

a flexible section connecting the ablation assembly to the preformed curve at a preset off-axis angle, the flexible section adapted to permit displacement of the ablation assembly from the preset off-axis angle without displacement of the preformed curve in the generally cavernous region.

30. The catheter of claim 29, wherein the ablation assembly comprises:

a plurality of irrigation ports;

a coil electrode; and

a porous covering in surrounding relation to the coil electrode and irrigation ports.

31. The catheter of claim 30, wherein the coil electrode has a length ranging from abut 8 mm to about 15 mm.

32. The catheter of claim 31, wherein the coil

electrode has a length of about10 mm.

33. The catheter of claim 30, wherein the porous covering comprises expanded polytetrafluoroethylene.

34. The catheter of claim 29, further comprising a temperature sensor mounted in the ablation assembly.

35. The catheter of claim 30, further comprising:

a proximal locking ring electrode mounted on a proximal region of the ablation assembly over the coil electrode and the porous covering; and

a distal locking ring electrode mounted on a distal region of the ablation assembly over the coil electrode and the porous covering.

36. The catheter of claim 29, further comprising one or more ring electrodes proximal of the ablation assembly.

37. The catheter of claim 29, further comprising:

a puller wire having proximal and distal ends extending through the catheter body, the distal end of the puller wire being fixedly attached within the proximal end of the intermediate section; and

a control handle connected to the proximal ends of the catheter body and puller wire for moving the puller wire longitudinally relative to the catheter body, whereby longitudinal movement of the puller wire relative to the catheter body results in deflection of the intermediate section.

38. The catheter of claim 29, further comprising an electromagnetic sensor mounted in the ablation assembly.

39. The catheter of claim 29, wherein the intermediate section further comprises a support member comprising a material having shape-memory to provide the performed curve.

40. The catheter of claim 29, further comprising an irrigation tube extending into the ablation assembly.

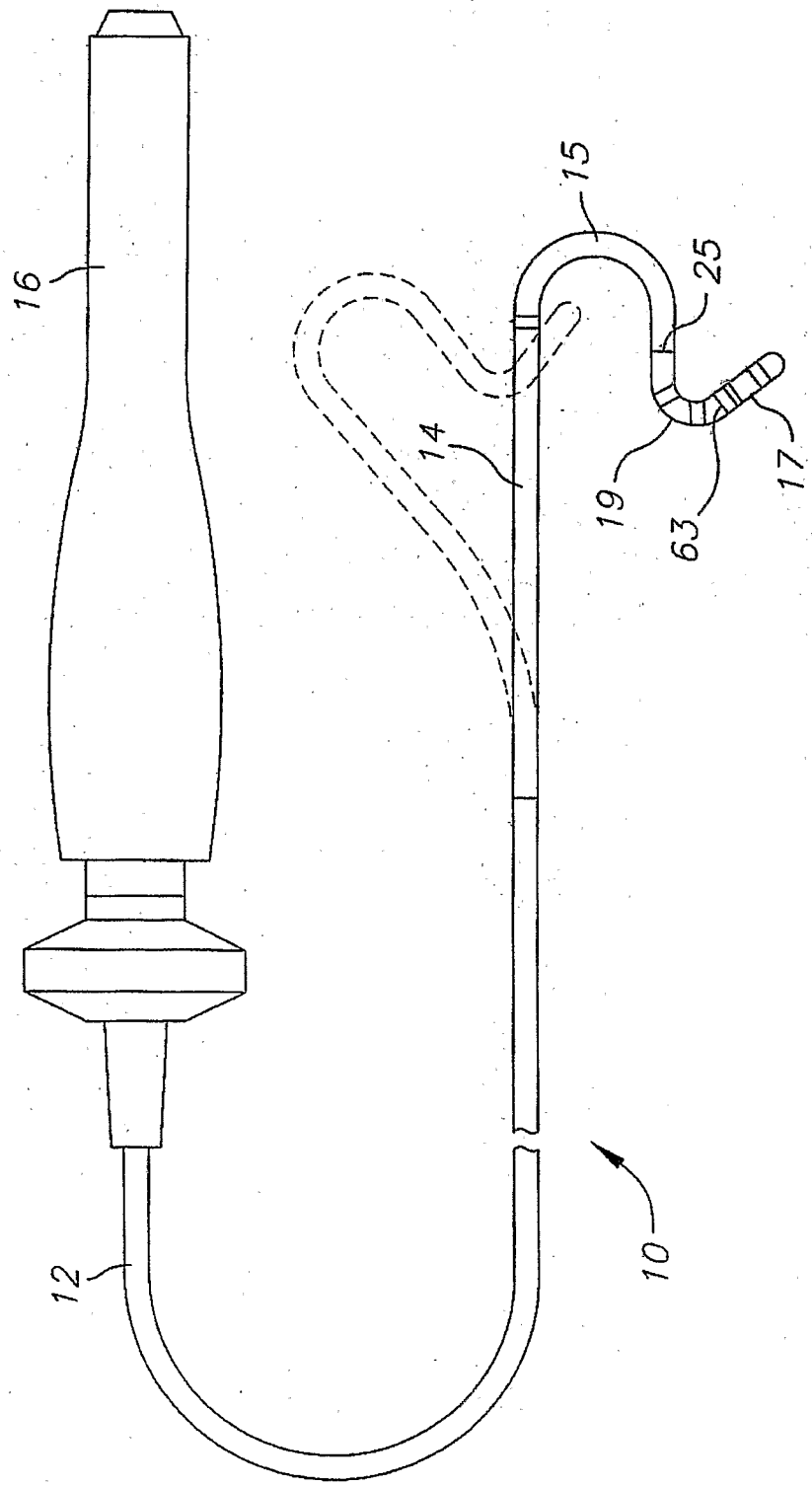


FIG. 1

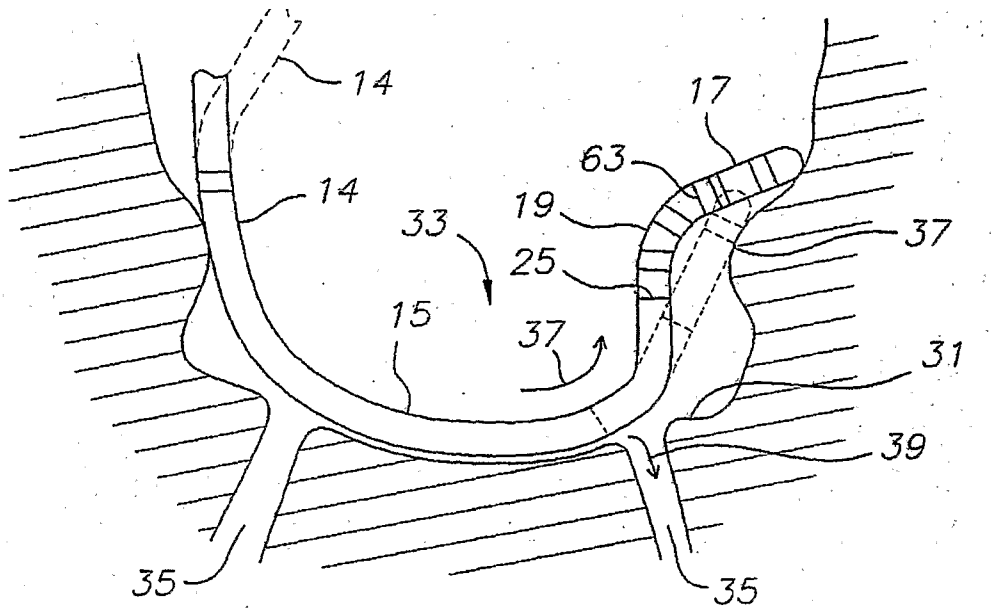
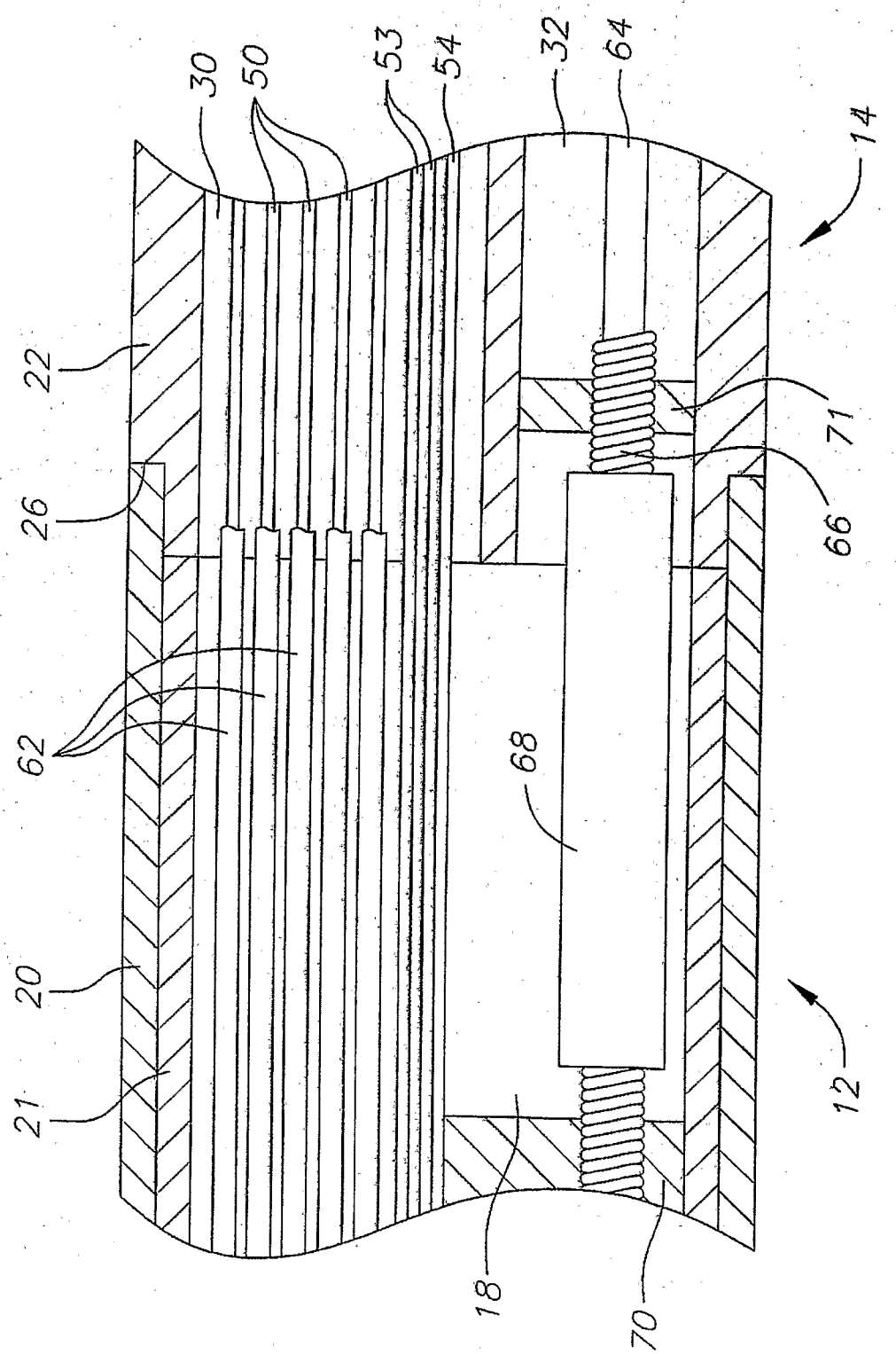


FIG. 1A

FIG. 2a



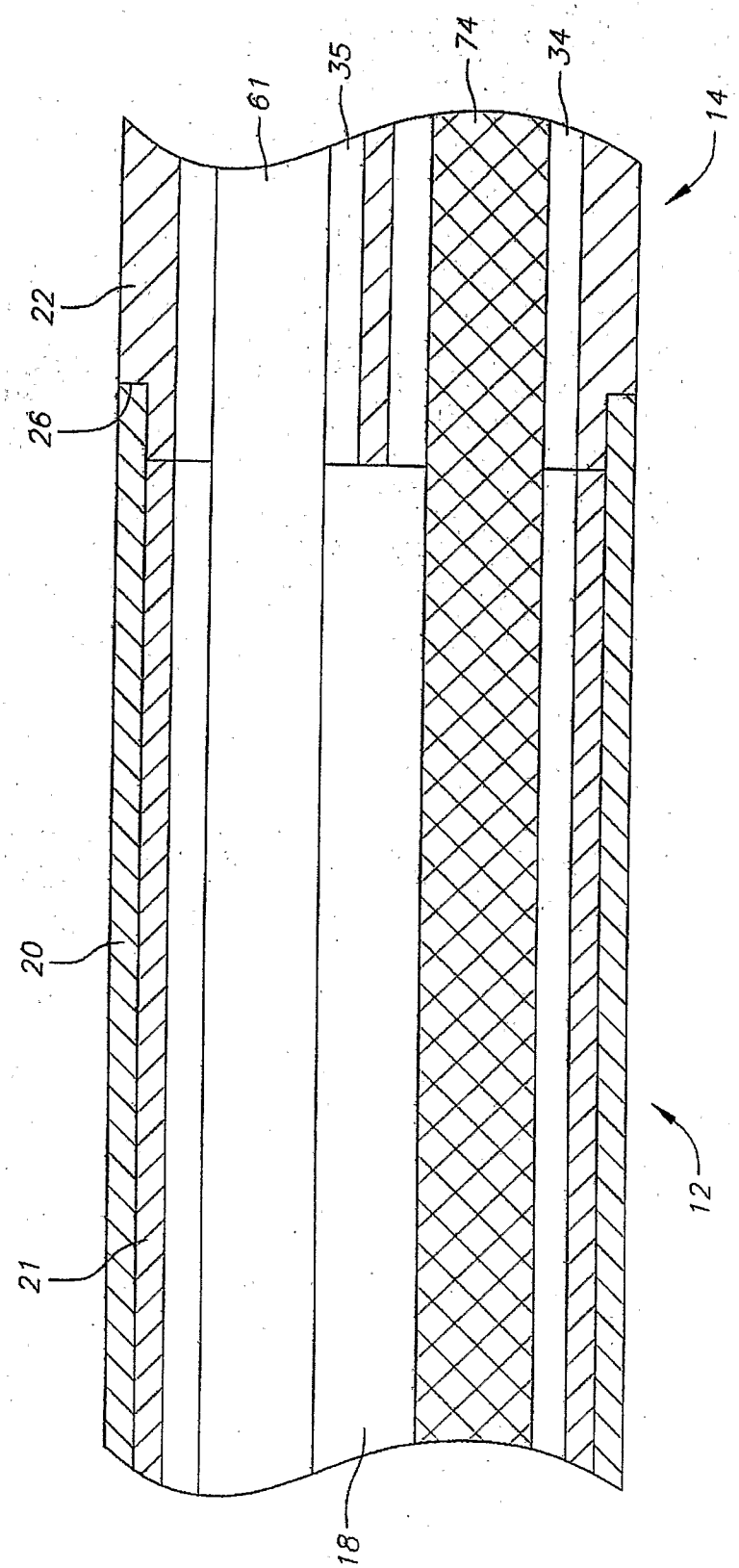


FIG. 2b

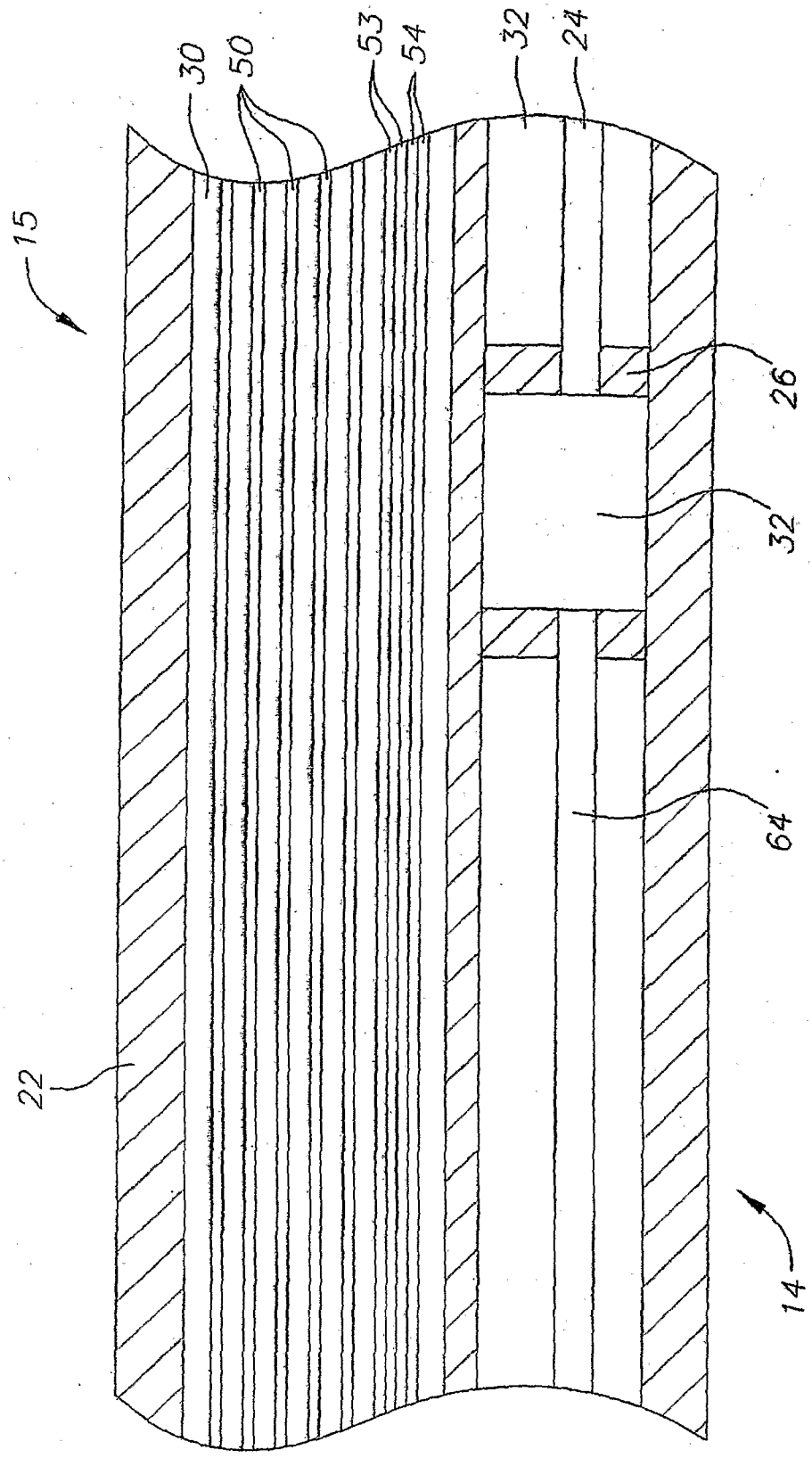


FIG. 2c

FIG. 3

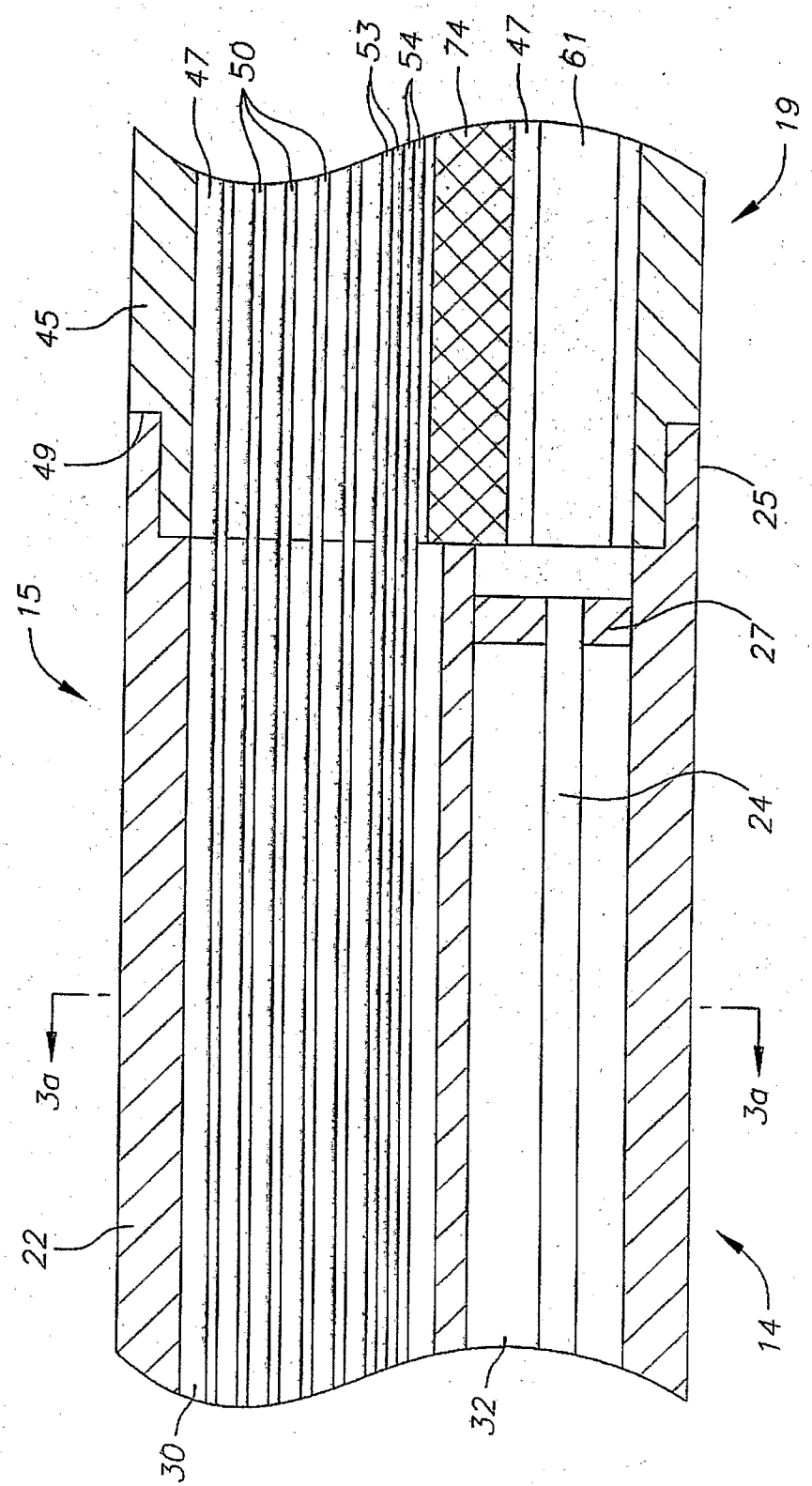
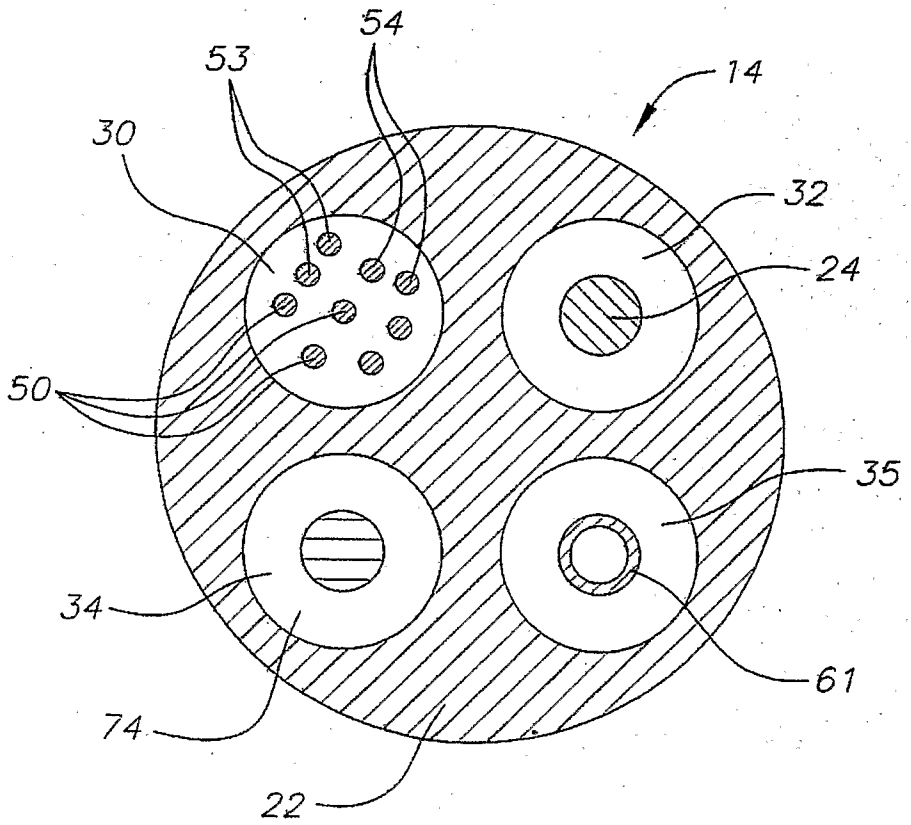


FIG. 3a



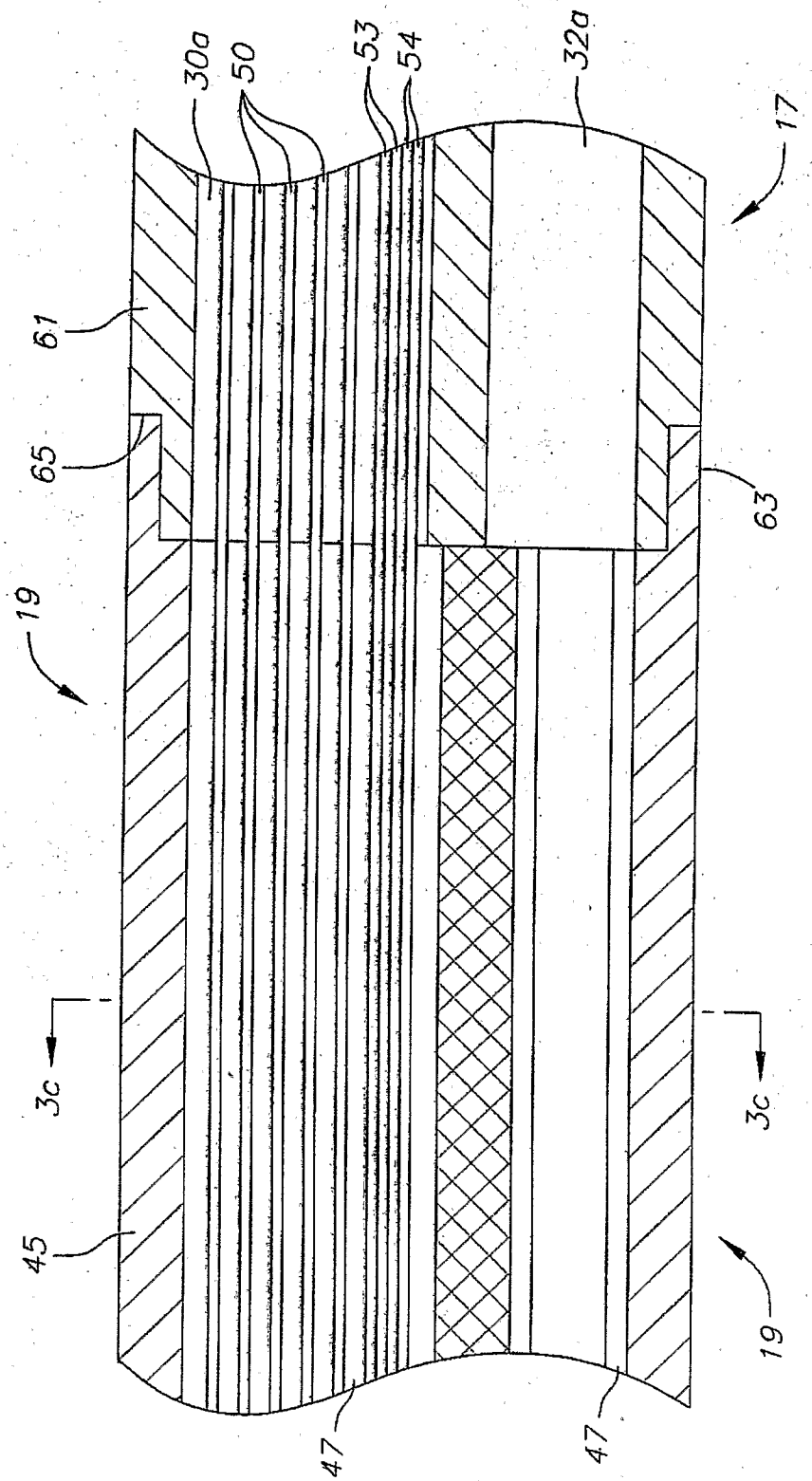


FIG. 3b

FIG.3c

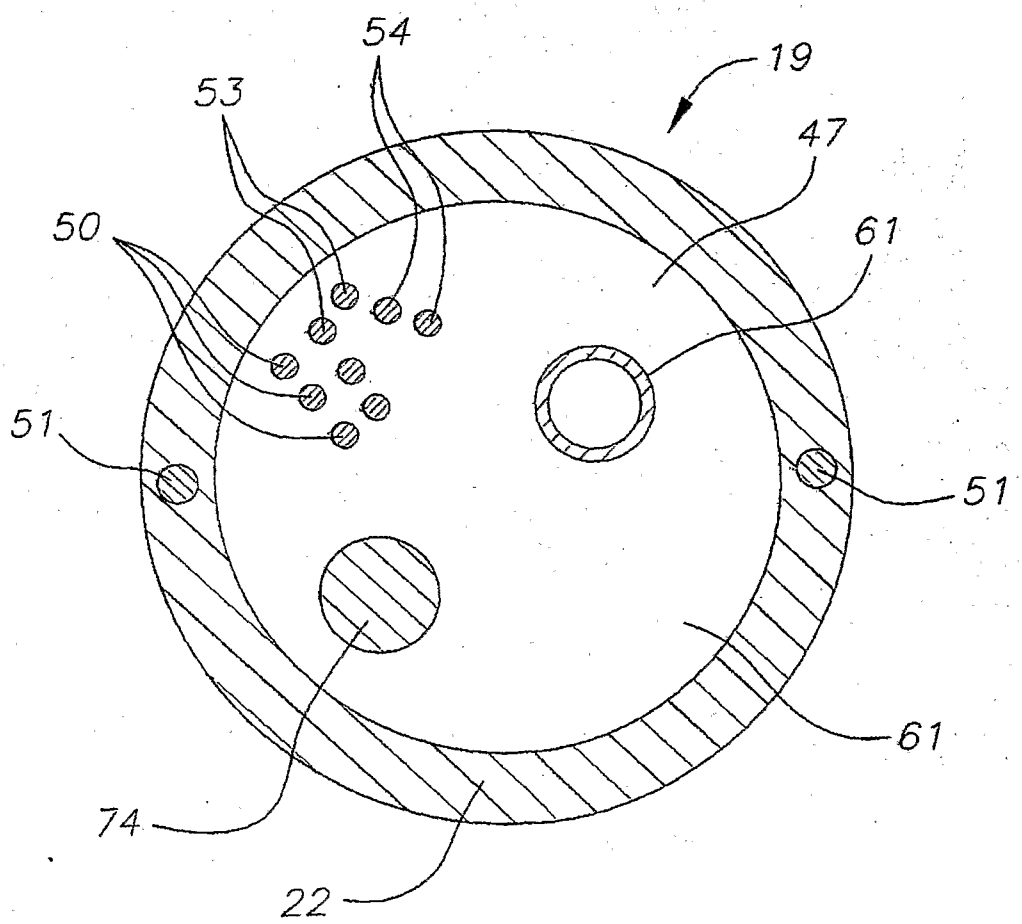


FIG. 4

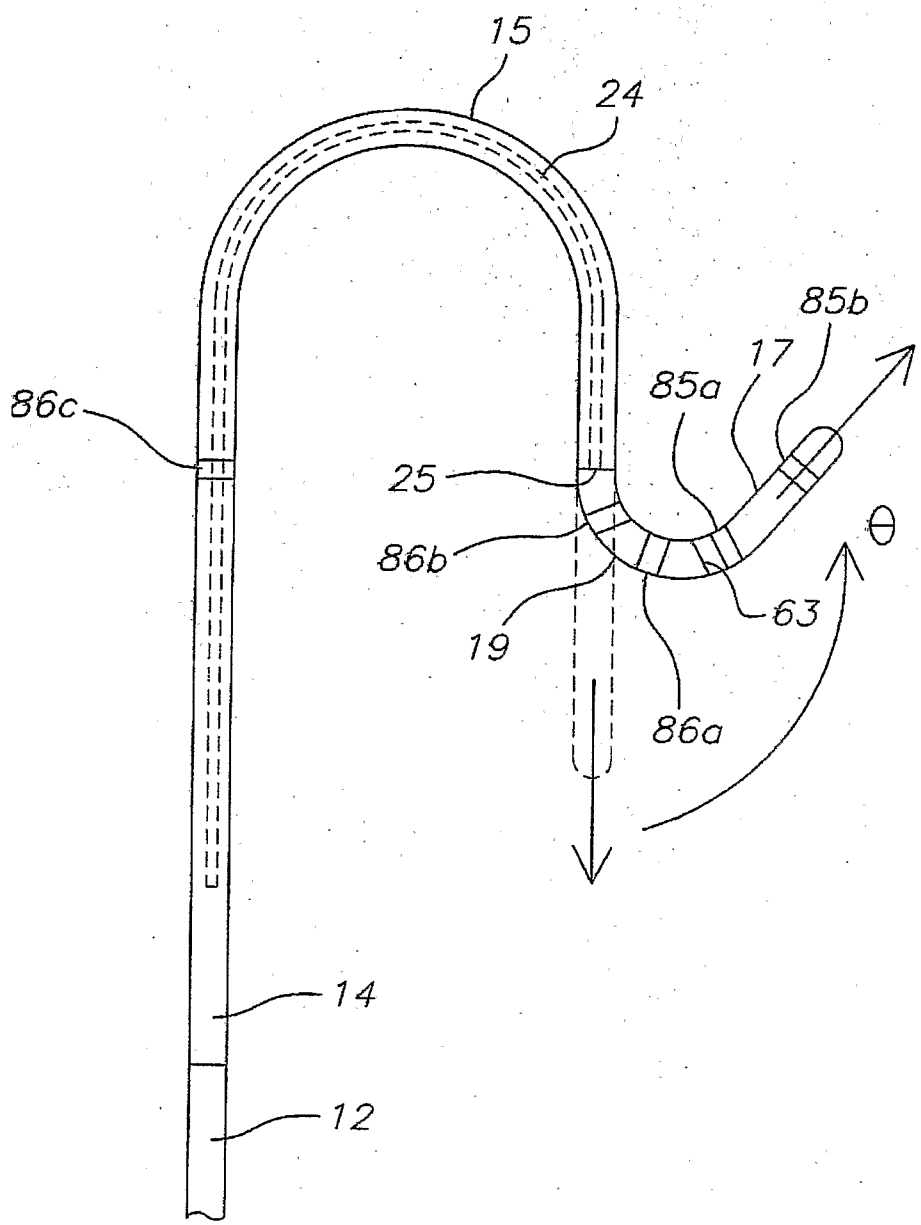


FIG. 4A

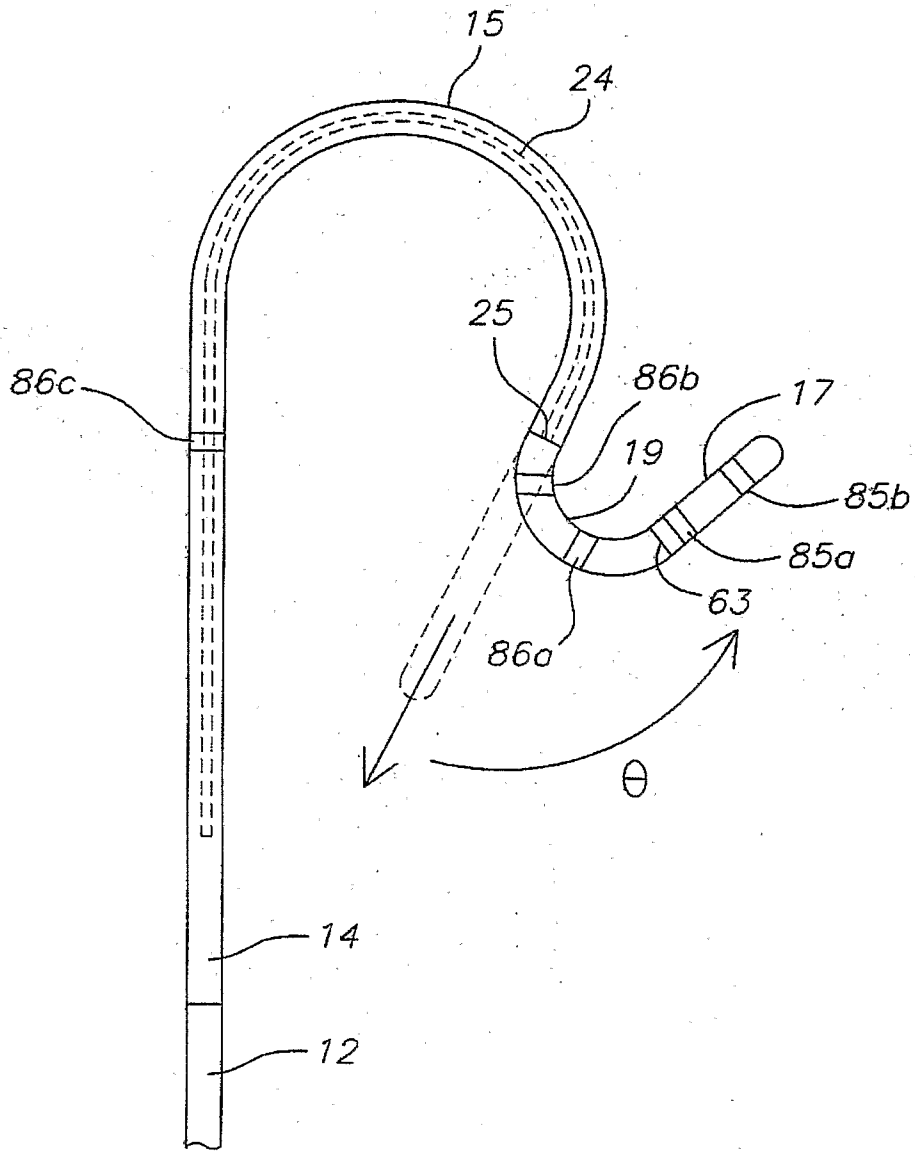


FIG. 4B

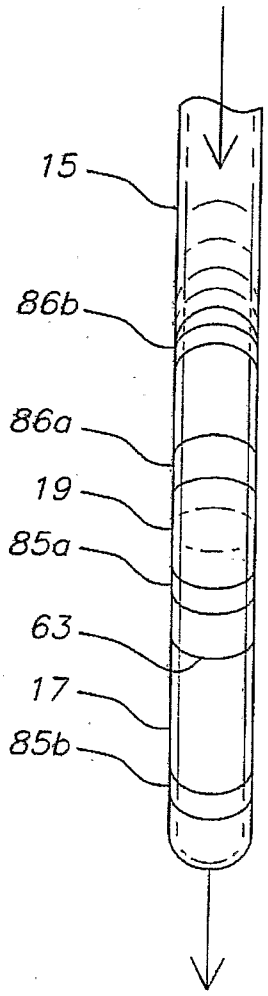


FIG. 4C

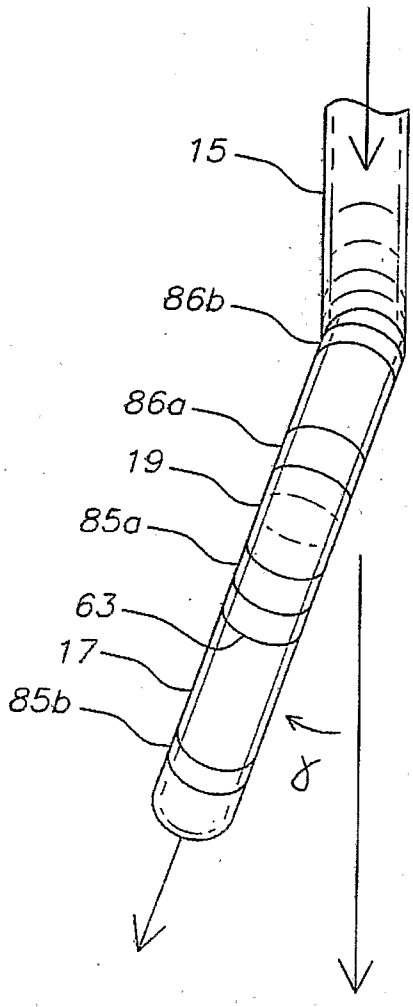


FIG. 5a

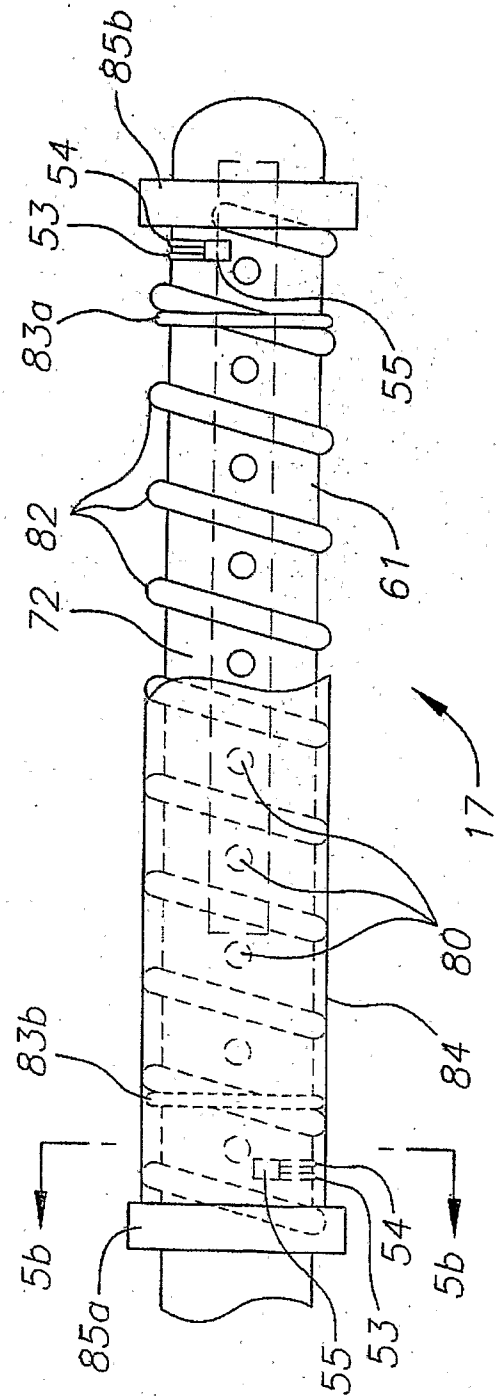
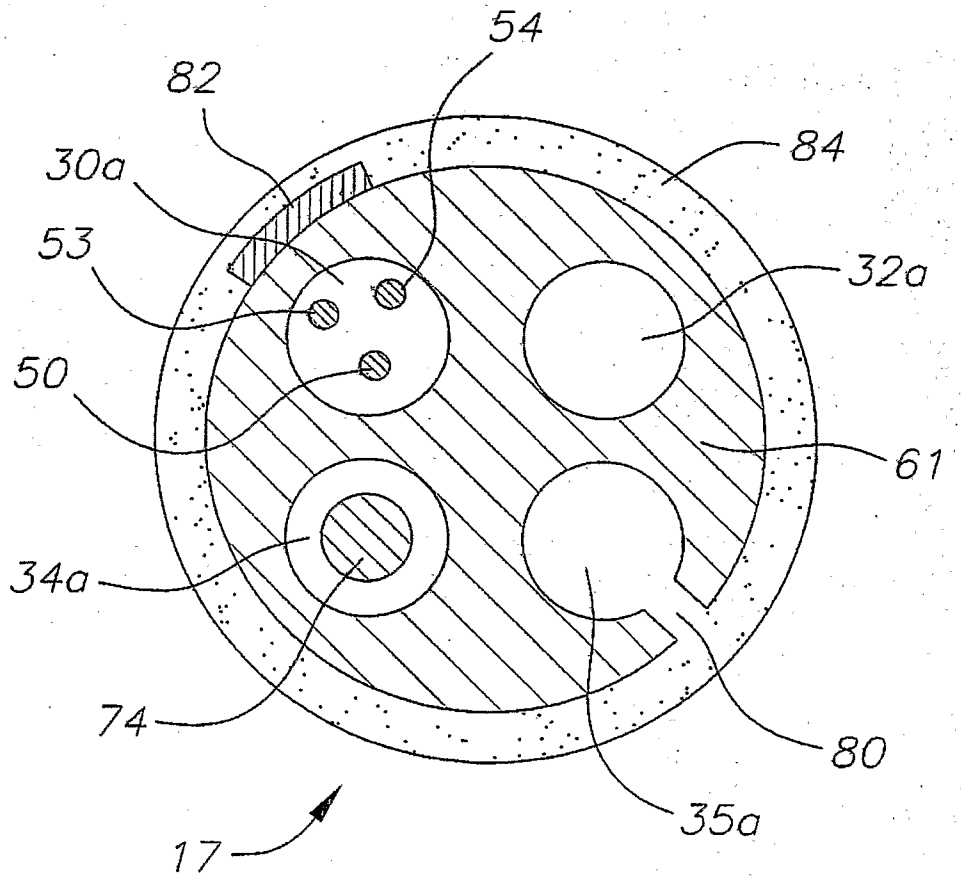


FIG.5b



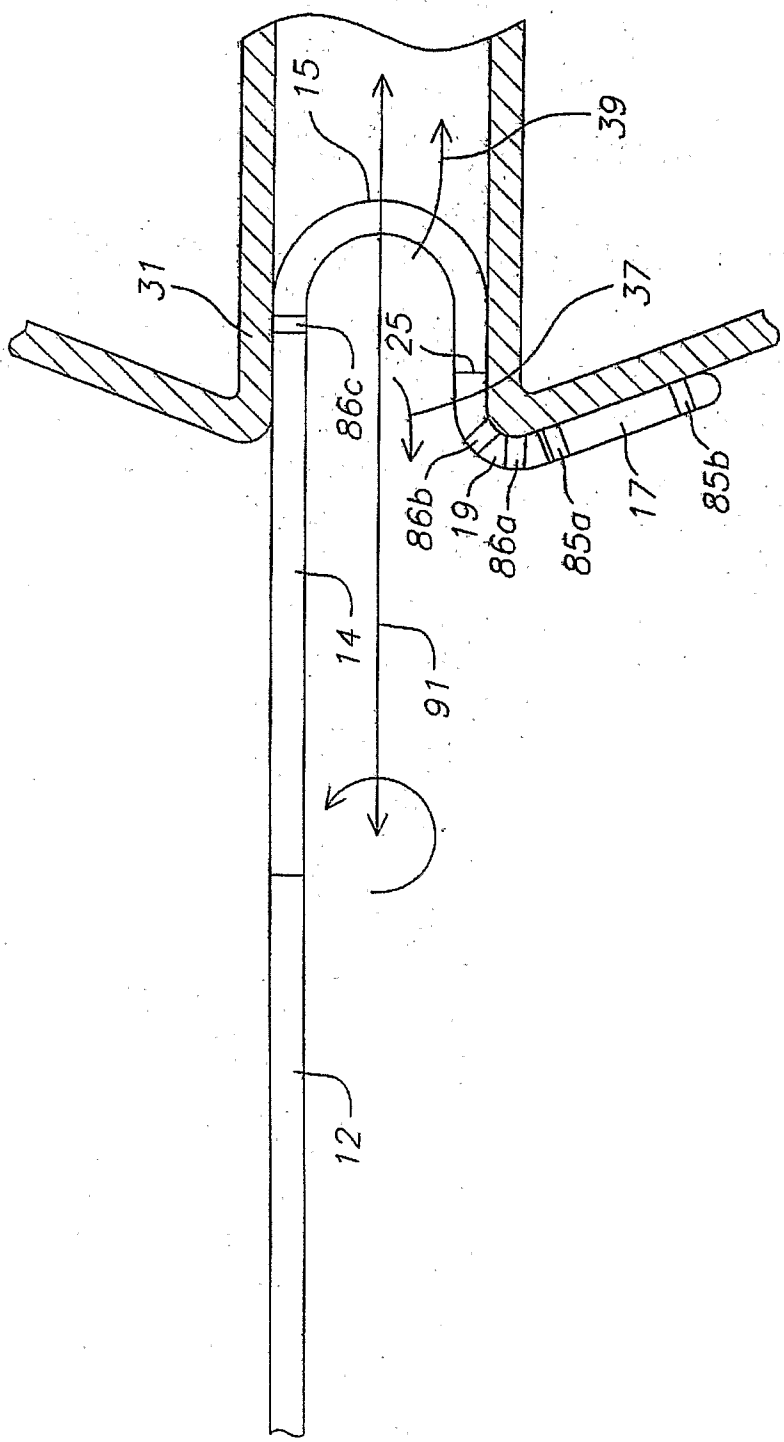


FIG. 6a

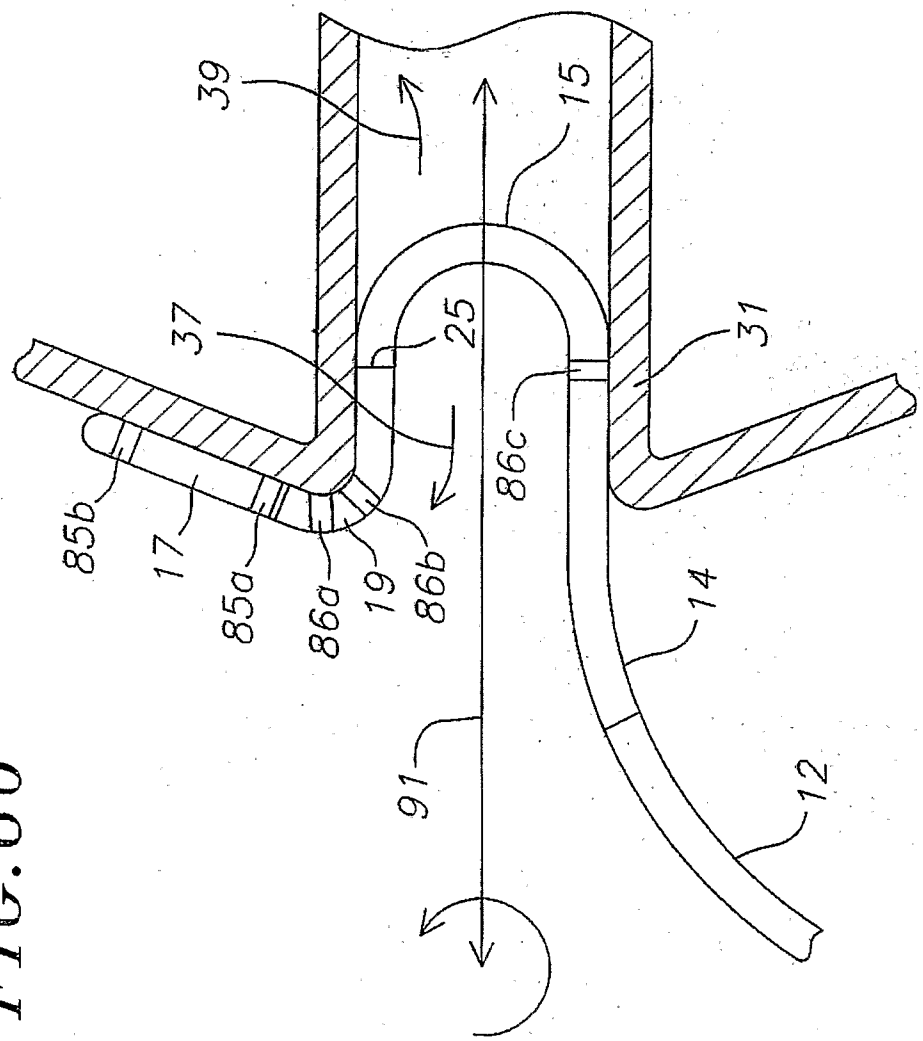


FIG. 6b

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2006/036146

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M25/01 A61M15/00 A61B18/14

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61M A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	EP 0 839 547 A1 (BARD INC C R [US]) 6 May 1998 (1998-05-06) the whole document	1-22,29, 34,36-39 30-33, 35,38,40
Y A	US 5 643 197 A (BRUCKER GREGORY G [US] ET AL) 1 July 1997 (1997-07-01) column 6, line 25 - column 11, line 43; figures 5-16	30-33, 35,38,40 1-22,29, 34,36, 37,39
X	US 2004/143175 A1 (COLEMAN JAMES H [US] ET AL) 22 July 2004 (2004-07-22) paragraphs [0029] - [0055]; figures 1-10	1-22,29, 36,37,39

-/--

[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
24 January 2007	02/02/2007

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	PASCAL, A

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2006/036146

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 617 854 A (MUNSIF ANAND [US]) 8 April 1997 (1997-04-08) column 7, line 50 - column 12, line 20; figures 3-16	1,2,5, 7-11,29, 38,39
X	US 6 224 587 B1 (GIBSON CHARLES A [US]) 1 May 2001 (2001-05-01) the whole document	1-22,29, 34,36-38
A	US 2004/147827 A1 (BOWE WADE [US]) 29 July 2004 (2004-07-29) the whole document	1-22, 29-39

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2006/036146

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 23-28
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] *As all required additional search fees were timely paid by the applicant, this International Search Report covers all* searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2006/036146

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 0839547 A1	06-05-1998	DE 69725087 D1	30-10-2003
		DE 69725087 T2	03-06-2004
		ES 2208803 T3	16-06-2004
		JP 3066827 B2	17-07-2000
		JP 10179759 A	07-07-1998
		US 5931811 A	03-08-1999
		US 5779669 A	14-07-1998
US 5643197 A	01-07-1997	AU 682938 B2	23-10-1997
		AU 1866695 A	10-07-1995
		CA 2179711 A1	29-06-1995
		DE 69432671 D1	18-06-2003
		DE 69432671 T2	11-03-2004
		EP 0746372 A1	11-12-1996
		JP 9506808 T	08-07-1997
		JP 3606328 B2	05-01-2005
		WO 9517222 A1	29-06-1995
		US 5462521 A	31-10-1995
		US 6017338 A	25-01-2000
US 2004143175 A1	22-07-2004	NONE	
US 5617854 A	08-04-1997	NONE	
US 6224587 B1	01-05-2001	CA 2391975 A1	31-05-2001
		EP 1231973 A1	21-08-2002
		WO 0137920 A1	31-05-2001
US 2004147827 A1	29-07-2004	US 2005107678 A1	19-05-2005