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(54) **Catheter having anchoring and stabilizing devices**

Katheter mit Verankerungs- und Stabilisierungsvorrichtungen

Cathéther comprenant des dispositifs d'ancrage et de stabilisation

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(56) References cited:
EP-A- 1 398 056
WO-A-00/51511
WO-A-01/37746
US-A- 5 443 489
US-A1- 2002 198 521
US-A1- 2004 059 327

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Description

[0001] The present invention is directed to a mapping and/or ablation catheter with a multi-spine anchoring device and, more particularly, to a mapping and/or ablation catheter with a multi-spine anchoring device for use in a tubular region in or near the heart.

[0002] Electrode catheters have been in common use in medical practice for many years. They are used to stimulate and map electrical activity in the heart and to ablate sites of aberrant electrical activity. In use, an electrode is inserted into a major vein or artery, such as the femoral artery, and guided into the chamber of the heart which is of concern. Often, the target area of the heart is a tubular region, such as the pulmonary vein, the coronary sinus, the superior vena cava and the inferior vena cava.

[0003] Electrode catheters are used to identify and/or ablate tissue in the region of the heart exhibiting the aberrant electrical activity. Often, electrode catheters are capable of both mapping the tissue to locate the site of aberrant electrical activity, and ablating the identified tissue. The ablation of this tissue isolates this tissue from the rest of the heart, thereby preventing the aberrant electrical pathways from extending into other areas of the heart. One area of the heart where such ablation is typically desirable is the pulmonary vein. Several catheters, such as those described in US-6024740 and US-6117101, are designed to ablate circumferential lesions inside the pulmonary vein. These catheters comprise an ablation element, such as an ultrasound transducer, surrounded by an inflatable balloon. To ablate the desired circumferential lesion, the balloon is inflated to anchor the catheter within the pulmonary vein, and the transducer is activated to form a circumferential lesion in the tissue engaged by the balloon.

[0004] Although they are effective for creating circumferential lesions in heart tissue, these balloon catheters have several disadvantages. For example, the balloon often is situated incorrectly within the pulmonary vein and/or becomes dislodged from the anchoring site. Also, the balloon does not allow blood to flow past it, resulting in a build up of blood at the distal end of the balloon, causing the blood to clot. Accordingly, a mapping and/or ablation catheter having a stabilized anchoring mechanism that enables blood flow and prevents clots is desirable.

[0005] US-A-2004/0059327 discusses loop structures for supporting diagnostic and therapeutic elements in contact with body tissue. It includes a first probe with a loop structure to support electrodes against body tissue and a second probe with a push structure that can urge the loop structure against body tissue.

[0006] The present invention is directed to a catheter having a catheter body whose distal end has an anchoring device and a stabilizing device that are adapted to respectively sit in and sit outside of an opening of a tubular region, such as an ostium of a pulmonary vein. A sheath covering the catheter body forms the anchoring device and the stabilizing device. In particular, the anchoring device comprises a plurality of slits cut into the sheath where the slits create spines of generally equal length and width in the sheath. Similarly, the stabilizing device comprises a plurality of slits cut into the sheath at a location proximal the anchoring device. The slits create spines of generally equal length and width in the sheath, the spines of the stabilizing device being longer than the spines of the anchoring device.

[0007] In one embodiment, the sheath is fixed at its distal end to the distal end of the catheter body. The spines of the anchoring device and the stabilizing device are deployed by distal movement of the sheath relative to the catheter body. Such distal movement of the sheath causes the spines of the anchoring and stabilizing devices to bow outwardly resulting in radial expansion of the anchoring and stabilizing devices. The distal end of catheter body is positioned in or near the heart such that the anchoring device is inside a tubular region, such as the pulmonary vein, and the stabilizing device is proximately and proximally to the ostium outside of the same tubular region. Upon radial expansion of the anchoring device, the spines of the anchoring device exert pressure against the walls of the tubular region thereby generally anchoring the distal end of the catheter body inside the tubular region against proximal and/or radial movement relative to the tubular region. Upon radial expansion of the spines of the stabilizing assembly, the spines of the stabilizing device exert pressure against the ostium of the tubular region thereby generally stabilizing the distal end of the catheter body against distal and/or radial movement relative to the tubular region. Accordingly, the pressure exerted on the walls of the tubular region by the anchoring device and on the ostium by the stabilizing device minimizes, if not prevents, the distal end of the catheter body against both translational and rotational movement. In particular, the pressure exerted on the ostium of the tubular region by the stabilizing device stabilizes the catheter within the heart for delivery of ablation energy to treat the desired area of the heart.

[0008] In an alternative embodiment, the distal end of the catheter body has a telescoping portion with a proximal telescoping member and a distal telescoping member. The sheath covers the proximal and distal telescoping members by extending from a distal end of the distal telescoping member to at least a proximal end of the proximal telescoping member. The distal end of the sheath is affixed to the distal end of the distal telescoping member and the proximal end of the sheath is affixed to the distal end of the catheter body proximal of the proximal telescoping member. A puller cable is attached to the distal end of the sheath which is fixed to the distal end of the distal telescoping member for effecting radial expansion of the anchoring and stabilizing devices. In particular, proximal movement of the puller cable draws in the distal and proximal telescoping members for radially expanding the spines of the anchoring and stabilizing

devices.

[0009] In either embodiment, the degree of radial expansion of both the anchoring and stabilizing devices is adjustable by adjusting the amount of relative translational movement between the sheath and the catheter body. The ability to adjust the degree of radial expansion of the anchoring and stabilizing devices enables the exertion of varying degrees of pressure on either the walls or the ostium of the tubular region. Accordingly, the anchoring and stabilizing devices are capable of conforming to differently shaped tubular regions. Also, in order to prevent undesired damage to the walls of the tubular region, the stabilizing device absorbs any excess pressure inadvertently exerted on the anchoring device. To that end, stops, for example in the form of rings fixedly mounted on the catheter body or the telescoping portion limit the amount of radial expansion of the anchoring device and/or the stabilizing device.

[0010] In another embodiment, a catheter comprises: an elongated catheter body having proximal and distal ends and at least one lumen extending therethrough; a non-conductive sheath mounted in surrounding relation to the catheter body, wherein the non-conductive sheath is slidable relative to the catheter body; an anchoring device comprising a plurality of spines formed by cutting longitudinal slits about a circumference of the distal end of the non-conductive sheath; a stabilizing device comprising a plurality of spines formed by cutting longitudinal slits about a circumference of the distal end of the non-conductive sheath at a location proximal the anchoring device; and a control handle mounted on the proximal end of the catheter body; wherein distal movement of the non-conductive sheath relative to the catheter body results in radial expansion of the spines of the anchoring device and the spines of the stabilizing device.

[0011] In a further embodiment, a catheter comprises: an elongated catheter body having proximal and distal ends and at least one lumen extending therethrough; a non-conductive sheath mounted in surrounding relation to the catheter body, wherein the non-conductive sheath is fixedly attached to the catheter body except at its distal end; an anchoring device comprising a plurality of spines formed by cutting longitudinal slits about a circumference of the distal end of the non-conductive sheath; a puller cable having proximal and distal ends, its distal end fixedly attached to the distal end of the non-conductive sheath; and a control handle mounted on the proximal end of the catheter body; wherein longitudinal movement of the puller cable relative to the catheter body results in radial expansion of the spines of the anchoring device. Each spine may have the the same length. Each spine may have the same width.

[0012] The catheter may further comprises a stabilizing device comprising a plurality of spines formed by cutting longitudinal slits about a circumference of the distal end of the non-conductive sheath at a location on the sheath proximal the anchoring device, wherein longitudinal movement of the puller cable relative to the catheter body results in radial expansion of the spines of the stabilizing device. The spines of the stabilizing device may be longer than the spines of the anchoring device. The spines of the stabilizing device may have the same length. The spines of the stabilizing device may have the same width.

[0013] The catheter may further comprise means for deflecting the distal end of the catheter body, the means for deflecting comprising a puller wire having a proximal end and a distal end, the proximal end of the puller wire being fixedly attached in the control handle, and the distal end of the puller wire is fixedly attached to the distal end of the catheter body, whereby longitudinal movement of puller wire results in deflection of the distal end of the catheter.

[0014] The catheter may further comprise an electromagnetic sensor mounted in the distal end of the catheter body.

[0015] According to another embodiment, a catheter comprises: an elongated catheter body having proximal and distal ends and at least one lumen extending therethrough; a non-conductive sheath mounted in surrounding relation to the catheter body, wherein the non-conductive sheath is fixedly attached to the catheter body except at its distal end; an anchoring device comprising a plurality of spines formed by cutting longitudinal slits about a circumference of the distal end of the non-conductive sheath; a stabilizing device comprising a plurality of spines formed by cutting longitudinal slits about a circumference of the distal end of the non-conductive sheath at a location proximal the anchoring device; a puller cable having proximal and distal ends, its distal end fixedly attached to the distal end of the non-conductive sheath; and a control handle mounted on the proximal end of the catheter body; wherein longitudinal movement of the puller cable relative to the catheter body results in radial expansion of the spines of the anchoring device.

[0016] Embodiments of the invention will now be described by way of example with reference to the accompanying drawings, in which:

FIG. 1 is a perspective view of an embodiment of a catheter according to the present invention;

FIG. 2 is an enlarged perspective view of the distal end of the catheter body according to one embodiment of the invention;

FIG. 2A is an enlarged perspective view of the catheter of FIG. 2, as deployed in a tubular region of a patient's heart;

FIG. 3 is an enlarged perspective view of the distal end of the catheter body according to another embodiment of the invention;

FIG. 3A is an enlarged perspective view of the catheter of FIG. 3, as deployed in a tubular region of a patient's heart;

FIG. 4 is a longitudinal cross-sectional view of a portion of a catheter body of FIGS. 2 and 2A;

FIG. 5 is a longitudinal cross-sectional view of a portion of a catheter body of FIGS. 3 and 3A;
FIG. 6 is an enlarged perspective view of the distal end of the catheter body according to another embodiment of the invention
FIG. 6A is an enlarged perspective view of the catheter of FIG. 6, as deployed in a tubular region of a patient's heart;
FIG. 7 is an enlarged perspective view of the distal end of the catheter body according to another embodiment of the invention;
FIG. 7A is an enlarged perspective view of the catheter of FIG. 7, as deployed in a tubular region of a patient's heart;
FIG. 8 is a perspective view of another embodiment of a catheter of the present invention without a stabilizing device; and
FIG. 9 is a perspective view of yet another embodiment of a catheter of the present invention without a stabilizing device.

[0017] The invention is directed to a catheter **10** having anchoring and stabilizing devices located at or near the catheter's distal end. As shown in **FIG. 1,** the catheter comprises an elongated catheter body **12** having proximal and distal ends **13** and **15,** a control handle **16** at the proximal end of the catheter body, and an anchoring device **17** located at the distal end of the catheter body **12.** The catheter may optionally further comprise a stabilizing device **19** located at the distal end of the catheter body **12** proximal the anchoring device **17.**

[0018] As shown in **Fig. 5,** the catheter body **12** comprises an elongated tubular construction having a single, axial or central lumen **18,** but can optionally have multiple lumens if desired. 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 **21** made of polyurethane or PEBAX (polyether block amide). The outer wall **21** comprises an imbedded 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 distal end of the catheter body **12** will rotate in a corresponding manner.

[0019] The outer diameter of the catheter body **12** is not critical, but is preferably no more than about 8 french, more preferably about 7 french. Likewise, the thickness of the outer wall **21** is not critical, but is preferably thin enough so that the central lumen **18** can accommodate a puller wire, lead wires, sensor cables and any other wires, cables or tubes. If desired, the inner surface of the outer wall **21** is lined with a stiffening tube **27** to provide improved torsional stability.

[0020] The anchoring device **17** is located at the distal end of the catheter body **12.** As shown in **FIG. 2,** the anchoring device **17** comprises at least two, and preferably at least four, spines **20** extending generally along a longitudinal axis of the catheter body, in radial symmetry about the catheter body. In the illustrated embodiment, the anchoring device **17** is formed by cutting slits in the circumference of a portion of a sheath **23** that generally extends the length of the catheter body and covers the catheter body **12** between the proximal and distal ends **13 and 15.** In the embodiment of **Fig. 2,** a distal end of the sheath **23** is fixed to the distal end 15 of the catheter body **12** with the remainder of the sheath **23** proximal thereof being slidable relative to the catheter body **12.** The slits in the sheath **23** form the spines **20** of the anchoring device **17.** The spines **20** of the anchoring device **17** of the illustrated embodiment are generally equal in length and width and are sufficiently long such that upon compression of the anchoring device **17,** the spines **20** expand radially to a degree sufficient to anchor the catheter within a tubular region **25,** such as the pulmonary vein, against proximal and/or rotational movement **(Fig. 2a).** It is understood by one of ordinary skill in the art that the spines **20** may be formed with unequal lengths and/or unequal widths, if desired, to provide the anchoring device **17** with a nonsymmetrical radial expansion.

[0021] The stabilizing device **19** proximal the anchoring device **17** by a non-expanding section of the sheath **27** also comprises at least two, and preferably at least four, spines **22** extending generally along a longitudinal axis of the catheter body, in radial symmetry about the catheter body **12.** The stabilizing device **19** is constructed substantially the same as the anchoring device **17.** Slits are cut about the circumference of a portion of the sheath **23** covering the catheter body **12** proximal the anchoring device **17.** These slits form the spines **22** of the stabilizing device **19.** The spines **22** of the stabilizing device **19** of the illustrated embodiment are generally equal in length and width but are generally longer than the spines **20** of the anchoring device **17** such that the spines **22** bow outwardly to a radial expansion greater than that of the spines **20.** As shown in **Fig. 2a,** the spines **21** bow out to a greater radial expansion such that the stabilizing device **19** can be flush against an ostium **31** of the pulmonary vein to stabilize the distal end of the catheter body against distal and/or rotational movement. It is understood by one of ordinary skill in the art that the slits may be formed with unequal lengths and/or unequal widths, if desired, to provide the stabilizing device with a nonsymmetrical radial expansion.

[0022] The sheath **23** is made of any flexible, nonconducting and noncompressible material such that upon distal movement compressing the sheath **23** toward the distal end **15** of the catheter body **12** the spines **20** of the anchoring device **17** bow outwardly to a desired degree of radial expansion, as shown in **Fig 2a..** The sheath may be made of a polymer or polymer blend or any other biocompatible material for use in a patient's body. In the illustrated embodiment, the anchoring device **17** may be deployed by manually advancing the sheath **12a** distally relative to the catheter body at or near the proximal end of the sheath that is outside of the patient's body, thereby

advancing distally the remainder of the sheath in the patient's body which in turn compresses the anchoring device **17** at the distal end of the sheath, and radially expands the spines **20.**

[0023] Preferably, the catheter body **12** comprises a stop for limiting the compression of the anchoring device. The catheter body may also comprise another stop for limiting the compression of the stabilizing device. The stops may take any suitable shape such that they limits the distal advancement of the sheath **23.** For example, as shown in **FIGS 2 and 2a,** the stops may comprise rings **30** and **32** fixedly positioned at predetermined locations on the catheter body **12.** In particular, the ring **30** is positioned at a location between the distal end **15** of the catheter body and a proximal end of the anchoring device **17** and the ring **32** is positioned between a proximal end and a distal end of the stabilizing device **19.** When the proximal end of the anchoring device **17** reaches the ring **30** the anchoring device cannot compress further and is at a radial maximum; likewise, when the proximal end of the stabilizing device **19** reaches the ring **32** the stabilizing device **19** cannot compress further and is at a radial maximum. As such, radial expansion of the anchoring device **17** and/or the stabilizing device **19** is limited in accordance with the fixed positioning of the rings **30** and **32,** respectively, on the catheter body **12.**

[0024] Longitudinal movement of the sheath **23** is accomplished, for example, by manual distal advancement by the user, or by suitable manipulation of the control handle **16.** If desired, the control handle **16** may include a stopping mechanism for locking the sheath **23** in place relative to the catheter body upon reaching the desired degree of radial expansion of the anchoring device **17** and/or the stabilizing device **19,** the stopping mechanism of the control handle working independently from the stop or the ring **30** of the anchoring device **17.** The stopping mechanism of the control handle may take any suitable shape such that the sheath **23** is locked in place, preventing any further distal and/or proximal movement of the sheath **12a.** For example, a clamp ring **34** may be provided on a proximal end of the sheath which is adapted to releasably clamp sheath to the catheter body to prevent distal and/or proximal movement of the proximal end of the sheath.

[0025] In accordance with the present invention, distal advancement of the sheath **23** relative to the catheter body **12** results in compression of the stabilizing device **19** and/or the anchoring device **17,** with generally but not necessarily compression of the anchoring device **17** occurring before compression of the stabilizing device **19.** In use, the catheter is advanced in its atraumatic configuration (see **Fig. 2)** in the patient's body until it reaches the heart chamber. There, the distal end of the catheter body is placed inside the tubular region **25,** e.g., the pulmonary vein, and the sheath **23** is advanced distally such that the anchoring device **17** is radially expanded to an appropriate level or until the proximal end of the anchoring device encounters the ring **30.** The stabilizing device **19** is also radially expanded by distal advancement of the sheath to an appropriate level or until the proximal end of the stabilizing device encounters the ring **32.** Accordingly, as shown in **FIG. 2A,** the radial expansion of the anchoring device secures the anchoring device to the inside of the pulmonary vein against rotational and/or proximal movement while the radial expansion of the stabilizing device presses the stabilizing device against the ostium **31** to prevent or at least minimize rotational and/or distal movement. With the distal end **15** of the catheter body **12** secured in this manner to the tubular region **25,** the catheter is ready for ablation by means of a distal electrode **40** and/or an ultrasonic ablation member **42,** as described in detail further below.

[0026] In accordance with the present invention, when the anchoring device **17** reaches its maximum degree of radial expansion, the stabilizing device **19** absorbs any excess pressure exerted by the continued advancement of the sheath **23.** This construction prevents the anchoring device **17** from absorbing any excess pressure, thereby preventing the anchoring device **17** from causing any undue damage to the walls of the tubular region. Alternatively, the stop, such as the rings **30** and **32,** may be used to prevent the anchoring device **17** and/or stabilizing device **19** from absorbing any excess pressure. The stopping mechanism, e.g., the clamp ring **34** may also be used to lock the stabilizing device **19** in radial expansion to press on the ostium of the pulmonary vein.

[0027] When the distal end **15** of the catheter body **12** needs to be withdrawn from the tubular region **25,** the clamp ring **34** is released and the sheath **23** is moved manually by the user in the proximal direction to minimize and reduce the radial expansion of the anchoring device **17** and the stabilizing device **19.** Having returned to its atraumatic configuration, the distal end **15** can be readily removed from the tubular region and reposition in another tubular region or removed altogether from the patient's body.

[0028] In an alternative embodiment, shown in **FIG. 4,** a sheath **23a** covers a distal end **15a** of a catheter body **12a** which is adapted with a telescoping portion **54** having two telescoping members **56** and **58.** In the illustrated embodiment, a sheath **23a** has a shortened length, extending from a distal end **60** of the telescoping portion **54** to only proximally past a proximal end **62** of the telescoping portion **54.** A distal end of the sheath **23a** is fixed to the distal end **60** of the telescoping portion and a proximal end of the sheath is fixed to the distal end of the catheter body **15.** An anchoring device **17a** formed from a distal portion of the sheath **23a** is located generally on the telescoping member **54** and a stabilizing device **19a** formed from a proximal portion of the sheath is located on the telescoping member **56.** A non-expanding section **27a** of the sheath separates the devices **17a** and **19a.** As described above, slits are cut around the circumference of the sheath **23a,** forming spines **20a** and **22a** of the anchoring device **17a** and the stabilizing device **19a,** which can be generally equal or generally unequal in

length and width. The stabilizing device **19a** proximal the anchoring device **17a** is longer than the anchoring device **17a,** but is sufficiently short to allow room on the distal end of the catheter body **12** for an ablation device to be mounted proximal the stabilizing device **19a,** such as ring electrodes discussed in detail further below.

[0029] For deploying the anchoring device **17a** and/or the stabilizing device **19a** into their radially expanded configuration, a noncompressible and generally stiff puller cable **60** extends through a lumen in the telescoping portion and the lumen **18a** of the catheter body **12a** and is fixed at its distal end to the distal end of the telescoping portion **54** which in turn is fixed to the distal end of the sheath **23a.** A proximal end of the puller cable **60** is located in the control handle **16** and connected to suitable control mechanism that moves the puller cable **60** proximally and distally. Proximal movement of the puller cable **60** results in compression of the anchoring device **17a** and/or the stabilizing device **19a.** This compression causes the spines **20a** and **22a** to bow outwardly, thereby causing the anchoring device and the stabilizing device to expand radially. The curvature of the spines **20a** and **22a,** and thus the degree of radial expansion of the anchoring device **17a** and the stabilizing device **19a,** can be adjusted by controlling the proximal distance in which the puller cable **60** is pulled. The telescoping member **56** may include a stop, such as a ring **30a,** for preventing further radial expansion of the anchoring device **17a** after reaching a predetermined degree of radial expansion. Likewise, the telescoping member **58** may include a stop, such as a ring **32a,** for preventing further radial expansion of the stabilizing device **19a** after reaching a predetermined degree of radial expansion. The rings **30a** and **32a** are fixedly positioned on the respective telescoping members **56** and **58** such that when the ring **32a** encounters the distal end of the catheter body **12,** the telescoping member **58** is prevented from further proximal movement, and/or when the ring **30a** encounters a distal end of the telescoping member **58** the telescoping member **56** is prevented from further proximal movement.

[0030] In accordance with the present invention, proximal movement of the puller cable **60** drawing in the distal end of the telescoping member **56** results in compression of the stabilizing device **19a** and/or the anchoring device **17a,** with generally but not necessarily compression of the stabilizing device **19a** occurring before compression of the anchoring device **17a.** In use, the catheter is advanced in its atraumatic configuration (see **Fig. 3)** in the patient's body until it reaches the heart chamber. There, the distal end of the telescoping member **56** is placed inside the tubular region **25,** e.g., the pulmonary vein, and the puller cable **60** is drawn proximally by suitable manipulation of the control handle **16** which in turn draws proximally the telescoping members **56** and **58.** As shown in **Fig. 3A,** the stabilizing device **19a** is radially expanded to an appropriate level or until the ring **32a** encounters the distal end **15** of the catheter body **12** and the anchoring device **17a** is radially expanded to an appropriate level or until the ring **30a** encounters the proximal end of the telescoping member **58.** Accordingly, the radial expansion of the anchoring device **17a** secures the anchoring device to the inside of the tubular region **25,** e.g., a pulmonary vein, against rotational and/or proximal movement while the radial expansion of the stabilizing device **19a** presses the stabilizing device against the ostium **31** of the tubular region to prevent or at least minimize rotational and/or distal movement. With the distal end of its catheter body secured in this manner, the catheter is ready for ablation by means of a distal electrode **40a** and/or an ultrasonic ablation member **42a,** as described in detail further below.

[0031] When the anchoring device **17a** reaches its maximum degree of radial expansion, the stabilizing device **19a** absorbs any excess pressure exerted by the continued advancement of the sheath **23a.** This construction prevents the anchoring device **17a** from absorbing any excess pressure, thereby preventing the anchoring device **17a** from causing any undue damage to the walls of the tubular region. Alternatively, the stops, such as the rings **30a** and **32a,** may be used to prevent the anchoring device **17a** and/or stabilizing device **19a** from absorbing any excess pressure. The mechanism controlling the puller cable **60** may also be adapted to lock the cable in place to prevent distal and/or proximal movement after the devices **17a** and **19a** have been deployed at or near the ostium of the pulmonary vein.

[0032] Accordingly, the puller cable **60** attached to the distal end of the sheath **23a** controls the radial expansion of both the anchoring device **17a** and the stabilizing device **19a.** Proximal movement of the puller cable **60** results in compression of both the anchoring device **17a** and the stabilizing device **19a.** This compression causes the spines **20a** and **22a** to bow outwardly, thereby causing the anchoring device **17a** and the stabilizing device **19** to expand radially. The curvature of the spines **20** and **20a,** and thus the degree of radial expansion of the anchoring device **17** and the stabilizing device **19,** can be adjusted by controlling the proximal distance by which the puller cable **60** is pulled. When the telescoping portion **54** needs to be withdrawn from the tubular region **25,** the control handle **16** is manipulated to advance the puller wire **60** so as to minimize and reduce the radial expansion of the anchoring device **17** and the stabilizing device **19.** It is understood by one of ordinary skill in the art that the puller cable **60** has sufficient stiffness and/or is appropriately supported by its own sheath such that it can adequately support and maintain the telescoping portion **54** in its distally extended configuration from the distal end of the catheter body when the catheter body is being advanced in the patient's body and also adequately extend the telescoping members **56** and **58** to return the distal end to its atraumatic configuration. Having returned to its atraumatic configuration, the catheter body **12** can be readily removed from the tubular region and repositioned in another tubular region or removed altogether from the patient's body.

[0033] It is understood by one of ordinary skill in the art that the telescoping portion **54** may also consist of merely one telescoping member or more than two telescoping members, as desired or appropriate to vary the compression of the anchoring device and/or the stabilizing device. Moreover, the ring **30** may be positioned on the telescoping **54** proximal of the section **27a,** as desired or appropriate to limit the compression of the stabilizing device. The maximum distal extension of the telescoping portion regardless of the plurality of telescoping member (s) is limited by the length of the puller cable **60** and/or the provision of a lip or flange at the corresponding ends of adjacent telescoping members which prevents the telescoping members from disconnecting.

[0034] In any of the above embodiments, the radial expansion of the anchoring device and the stabilizing device is adjustable. The ability to adjust the radial expansion of the anchoring device enables the exertion of varying degrees of pressure on the walls of the tubular region, e.g. the pulmonary vein. For example, a physician can manipulate the catheter to expand the devices until enough pressure is exerted on the walls of the tubular region to anchor the catheter within that region, and then activate the stopping mechanism to lock the devices in their position. Once locked, no more, or no less, pressure can be exerted on the walls of the tubular region and/or the ostium. The ability to adjust the radial expansion of the anchoring device enables the devices to conform to many different shapes within any tubular region or ostium. This ability, therefore, is extremely advantageous, since the shapes and contours of tubular regions and ostiums vary within the heart and vary in different patients. In addition, the ability to control the pressure exerted on the walls of the tubular region and the ostium enables the anchoring and stabilizing of the catheter against both translational and rotational movement. Because the stabilizing device is located proximal the anchoring device, the stabilizing device is capable of absorbing any excess pressure that may inadvertently be exerted on the anchoring device. Such a construction prevents the anchoring device from causing any undue or excessive damage to the walls of the tubular region.

[0035] As shown in **FIG. 8,** a catheter body **12c** may be configured with merely an anchoring device **17c** formed from a sheath **23c** whose distal end is fixed to a distal end **15c** of the catheter body. A maximum radial expansion of the device **17c** is set by a ring **30c** fixedly positioned on the catheter body **12c.** Moreover, as shown in **FIG. 9,** a catheter body **12d** may be configured with merely an anchoring device **17d** formed from a sheath **23d** whose distal end is fixed to a distal end of a telescoping member **56d** that is moved distally and proximally by a puller cable **60d.** A maximum radial expansion of the device **17d** is set by a ring **30d** fixedly positioned on the member **56d.** For either of these embodiments, an ultrasonic transducer and protective balloon may be mounted proximal of the anchoring device, if desired.

[0036] One or more ring electrodes may optionally be mounted on the sheath of either catheter embodiment. In particular, as shown in Figs. **2, 2a, 3** and **3a,** ring electrodes **28** are preferably mounted on the sheath distal the anchoring device and proximal the stabilizing device. The ring electrodes **28** may be used for mapping and/or ablation. Accordingly, each of the ring electrodes **28** is electrically connected to an appropriate mapping or monitoring system and/or source of ablation energy by means of an electrode lead wire **29,** as shown in **FIGs. 4 and 5.** Each electrode lead wire **29** extends through the control handle **16 and 16a,** through a lumen in the catheter body **12** and **12a,** and is connected to its corresponding ring electrode **28** (of which only one is shown in **FIGS. 4** and **5).** Each lead wire **29** is covered by a non-conductive covering and is attached to its corresponding ring electrode **28** by any suitable method.

[0037] A preferred method for attaching a lead wire **29** to a ring electrode **28** involves first making a small hole through the wall of the sheath **23** and **23a.** Such a hole can be created, for example, by inserting a needle through the sheath and heating the needle sufficiently to form a permanent hole. The lead wire **29** is then drawn through the hole by using a microhook or the like. The end of the lead wire **29** is then stripped of any coating and welded to the underside of the ring electrode **28,** which is then slid into position over the hole and fixed in place with polyurethane glue or the like. Alternatively, each ring electrode **28** is formed by wrapping a lead wire **29** around the sheath **23** and **23a** a number of times and stripping the lead wire **29** of its own insulated coating on its outwardly facing surfaces.

[0038] In the catheter **12** of **FIGs 2, 2a** and **4**, each lead wire **29** is significantly longer than the length between the ring electrode and the connection of the lead wire **29** to the control handle. This extra length of the lead wires **29** allows the lead wires **29** to move with the sheath **23** distally to radially expand the spines **20** of the anchoring device **17** and/or the spines **22** of the stabilizing device **19.** When the sheath is so moved, the lead wires **29** pass between the sheath **23** and the catheter body **12.** As would be recognized by one skilled in the art, the extra length of the lead wires **29** may be contained in the control handle **16** by a mechanism capable of deploying the extra length as needed.

[0039] Alternatively, as shown in **FIGS. 2, 2A, 3** and **3A,** the catheter body may carry a circumferential ablation device, such as an ultrasound transducer **65** mounted within the stabilization device **19** and **19a.** In such an arrangement, the stabilization device is covered with an expandable balloon **67** whose distal and proximal ends are fixed to the sheath **23** and **23a** to seal the ultrasound transducer **65** from blood and other fluids present in the heart and the tubular region. An example of such an ultrasound transducer and balloon mechanism suitable for use in the present invention is disclosed in US-6780183. Because the ultrasound transducer **65** cannot transmit ablation energy through the spines of the stabilizing device, a suitable embodiment of the stabilizing device **19**

preferably comprises at least two, but no more than three spines. Such a configuration allows the ultrasound transducer **65** to transmit ablation energy to the target site, but still stabilizes the catheter, e.g., about the ostium of the pulmonary vein.

[0040] In an alternative embodiment, as shown in **FIGS. 6, 6A, 7** and **7A,** the ultrasound transducer **65** is mounted on the sheath **23** and **23a** proximal the stabilizing device **19** and **19a** and is covered by an inflatable balloon **67** fixedly attached at its proximal and distal ends to the sheath. In this embodiment, the stabilizing device **19** and **19a** preferably comprises at least two, but no more than 3 spines, to enable the transducer **31** to transmit ablation energy around the stabilizing device **19.**

[0041] For any of the foregoing embodiments, the catheter optionally further comprises a means for deflecting the distal end of the catheter body **12** and **12a.** The deflection means comprises a puller wire **40** anchored at its distal end to the distal end of the catheter body, as shown in **FIGs. 4** and **5.** The puller wire **40** 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 **40.** The puller wire preferably has a diameter ranging from about 0.152 to about 0.254 mm (about 0.006 to about 0.010 inches).

[0042] A compression coil **42** is situated within the catheter body in surrounding relation to the puller wire **40.** The compression coil extends from the proximal end of the catheter to the distal end of the catheter. The compression coil **42** is made of any suitable metal, preferably stainless steel. The compression coil **42** is tightly wound on itself to provide flexibility, i.e., bending, but to resist compression. The inner diameter of the compression coil **42** is preferably slightly larger than the diameter of the puller wire **40.** For example, when the puller wire **42** has a diameter of about 0.178 mm (0.007 inches), the compression coil **42** preferably has an inner diameter of about 0.203 mm (0.008 inches). The Teflon coating on the puller wire **40** allows it to slide freely within the compression coil **42.** Along its length, the outer surface of the compression coil **42** is covered by a flexible, non-conductive sheath **44** to prevent contact between the compression coil **42** and the lead wires **29** within the catheter body **12.** A non-conductive sheath **44** made of polyimide is presently preferred.

[0043] The compression coil **42** is anchored at its proximal end to the proximal end of the stiffening tube **22** of the catheter body **12** by glue joint **50** and at its distal end to the distal end of the catheter body **12** by glue joint **51.** Both glue joints **50** and **51** 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 single lumen **18.** Such a hole may be formed, for example, by a needle or the like that punctures the wall of the catheter body **12** and the stiffening tube **22** which is heated sufficiently to make a permanent hole. The glue is then introduced through the hole to the outer surface of the compression coil **42** and wicks around the outer circumference to form a glue joint about the entire circumference of the compression coil **42.**

[0044] The puller wire **40** extends through the lumen of the catheter body **12** into the distal end of the catheter body **12.** The distal end of the puller wire **40** is anchored within the distal end of the catheter body **12.** The puller wire **40** extends through a plastic, preferably Teflon, sheath **45,** which prevents the puller wire **40** from cutting into the wall of the catheter body **12** when the distal end of the catheter body **12** is deflected. The puller wire **40** is deflected upon longitudinal movement of the puller wire **40** relative to the catheter body **12.**

[0045] An electromagnetic sensor **72** may be contained within the distal end of the catheter body **12.** The electromagnetic sensor **72** may extend from the distal end of the catheter body **12** to the distal end of the anchoring device **17.** Alternatively, the electromagnetic sensor **72** may extend partially into the anchoring device **17.** The electromagnetic sensor **72** is mounted to the distal end of the catheter body **12** by any suitable means, e.g. by polyurethane glue or the like.

[0046] The electromagnetic sensor **72** is connected to an electromagnetic sensor cable **74,** which extends through the lumen in 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.

[0047] Suitable electromagnetic sensors for use with the present invention are described, for example, in US-5558091, US-5443489, US-5480422, US-5546951, and US-5391199. A preferred electromagnetic sensor **72** has a length of from about 6 mm to about 7 mm and a diameter of about 1.3 mm.

[0048] Suitable control handle mechanisms for operating the puller cable 60 and/or the puller wire 40 may be found in US-6210407, US-6171277 and US-6198974.

Claims

1. A catheter (10) adapted for use at or in a tubular region of the heart, comprising:

an elongated catheter body (12, 12a, 12c, 12d) having proximal and distal ends;
an anchoring device (17, 17a, 17c, 17d);
a stabilizing device (19, 19a) proximal of the anchoring device (17, 17a, 17c, 17d) and adapted

to limit rotational and distal movement of the distal end of the catheter body (12, 12a, 12c, 12d) relative to the tubular region when said stabilizing device (19, 19a) is radially expanded;

characterised in that the anchoring device (17, 17a, 17c, 17d) and the stabilizing device (19, 19a) are formed from slits cut in a sheath (23, 23a, 23c) positioned on at least the distal end of the catheter body and adapted for distal and proximal movement relative to the catheter body to radially expand the devices and **in that** said anchoring device (17,17a, 17c,17d) is adapted to limit rotational and proximal movement of the distal end of the catheter body (12,12a,12c,12d) relative to the tubular region when said anchoring device (17,17a,17c,17d) is radially expanded.

2. A catheter of claim 1, wherein the anchoring device (17, 17a, 17c, 17d) is adapted for placement inside the tubular region and to press against a circumferential wall of the tubular region when radially expanded.

3. A catheter of claim 1, wherein the stabilizing device (19, 19a) is adapted for placement at or near an ostium of the tubular region and to press against the ostium when radially expanded.

4. A catheter of claim 1, wherein the anchoring device (17, 17a, 17c, 17d) is adapted for placement inside the tubular region,and to press against a circumferential wall of the tubular region when radially expanded, and further wherein the stabilizing device (19, 19a) is adapted for placement at or near an ostium of the tubular region and to press against the ostium when radially expanded.

5. A catheter according to claim 1, wherein the slits form spines (20, 20a, 22, 22a) extending in a longitudinal direction defined by the catheter body (12, 12a, 12c, 12d).

6. A catheter according to claim 5, wherein each spine (20, 20a) of the anchoring device (17, 17a, 17c, 17d) has the same length.

7. A catheter according to claim 5, wherein each spine (22, 22a) of the stabilizing device (19, 19a) has the same length.

8. A catheter according to claim 5, wherein the spines (20, 20a) of the anchoring device (17, 17a, 17c, 17d) differ in length from the spines of the stabilizing device (19, 19a).

9. A catheter of claim 1, wherein the sheath (23, 23a, 23c) is moved distally to radially expand at least one of the devices.

10. A catheter of claim 1, wherein the sheath (23, 23a, 23c) is moved proximally to radially expand at least one of the devices.

11. A catheter of claim 1, wherein the anchoring device (17, 17a, 17c, 17d) is fixed to the distal end of the catheter body (12, 12a, 12c, 12d) and the sheath (23, 23a, 23c) is moved distally to radially expand at least one of the devices.

12. A catheter of claim 1, wherein at least one of the anchoring device (17, 17a, 17c, 17d) and the stabilizing device (19, 19a) is positioned on a telescoping portion (54) distal of the distal end of the catheter body (12, 12a, 12c, 12d) and the telescoping portion (54) is moved proximally to radially expand at least one of the devices.

13. A catheter of claim 1, further comprising means (40, 42) for ablating tissue at or near the tubular region.

14. A catheter of claim 1, further comprising means for deflecting the distal end of the catheter body (12, 12a, 12c, 12d) comprising a puller wire having a proximal end and a distal end, the proximal end of the puller wire being fixedly attached in the control handle (16), and the distal end of the puller wire is fixedly attached to the distal end of the catheter body (12, 12a, 12c, 12d), whereby longitudinal movement of puller wire results in deflection of the distal end of the catheter.

15. A catheter of claim 1, further comprising an electromagnetic sensor (72) mounted in the distal end of the catheter body (12, 12a, 12c, 12d).

16. A catheter according to claim 1, further comprising at least one ring electrode (28) mounted on the nonconductive sheath distal the anchoring device (17, 17a, 17c, 17d).

17. A catheter according to claim 1, further comprising at least one ring electrode (28) mounted on the sheath proximal the anchoring device (17, 17a, 17c, 17d).

18. A catheter according to claim 1, further comprising at least one ring electrode (28) mounted on the nonconductive sheath distal the stabilizing device (19, 19a).

19. A catheter of claim 1, further comprising at least one ring electrode mounted (28) on the sheath proximal the stabilizing device (19, 19a).

20. A catheter of claim 1, further comprising a circum-

ferential ablation device (65) mounted within the stabilizing device (19, 19a).

21. A catheter of claim 20, wherein the circumferential ablation device (65) is an ultrasound transducer, and further wherein the stabilizing device (19, 19a) is covered by an expandable balloon (67).

22. A catheter of claim 1, further comprising a stop (30, 32) limiting the radial expansion of at least one of the devices.

23. A catheter according to claim 1, further comprising an ablation device (65) mounted on the sheath proximal the stabilizing device.

24. A catheter according to claim 23, wherein the ablation device is an ultrasound transducer (65) encased within an expandable balloon (67).

25. A catheter according to claim 1, wherein the anchoring device (17, 17a, 17c, 17d) has at least 4 spines.

26. A catheter according to claim 4, wherein the stabilizing device (19, 19a) has at least 4 spines.

Patentansprüche

1. Katheter (10), der zur Verwendung an oder in einem rohrförmigen Bereich des Herzens ausgelegt ist, mit:

einem länglichen Katheterkörper (12, 12a, 12c, 12d) mit einem proximalen und einem distalen Ende;
einer Verankerungsvorrichtung (17, 17a, 17c, 17d);
einer Stabilisierungsvorrichtung (19, 19a) proximal zur Verankerungsvorrichtung (17, 17a, 17c, 17d) und dazu ausgelegt, die Drehbewegung und die distale Bewegung des distalen Endes des Katheterkörpers (12, 12a, 12c, 12d) in Bezug auf den rohrförmigen Bereich zu beschränken, wenn die Stabilisierungsvorrichtung (19, 19a) radial aufgeweitet ist;

dadurch gekennzeichnet, dass die Verankerungsvorrichtung (17, 17a, 17c, 17d) und die Stabilisierungsvorrichtung (19, 19a) durch Schlitze gebildet sind, welche in eine Hülse (23, 23a, 23c) geschnitten sind, die auf wenigstens dem distalen Ende des Katheterkörpers angeordnet ist und für die distale und proximale Bewegung in Bezug auf den Katheterkörper ausgelegt ist, um die Vorrichtungen radial aufzuweiten, und dass die Verankerungsvorrichtung (17, 17a, 17c, 17d) dazu ausgelegt ist, die Drehbewegung und die proximale Bewegung des distalen Endes des Katheterkörpers (12, 12a, 12c, 12d) in Bezug auf den rohrförmigen Bereich zu beschränken, wenn die Verankerungsvorrichtung (17, 17a, 17c, 17d) radial aufgeweitet ist.

2. Katheter nach Anspruch 1, bei dem die Verankerungsvorrichtung (17, 17a, 17c, 17d) für die Anordnung innerhalb des rohrförmigen Bereiches und zum Andrükken gegen einen Umfangsbereich des rohrförmigen Bereiches, wenn sie radial aufgeweitet ist, ausgelegt ist.

3. Katheter nach Anspruch 1, bei dem die Stabilisierungsvorrichtung (19, 19a) für die Anordnung an oder nahe einem Ostium des rohrförmigen Bereiches und zum Drücken gegen das Ostium, wenn sie radial aufgeweitet ist, ausgelegt ist.

4. Katheter nach Anspruch 1, bei dem die Verankerungsvorrichtung (17, 17a, 17c, 17d) zur Anordnung innerhalb des rohrförmigen Bereiches und zum Drücken gegen eine Umfangswand des rohrförmigen Bereiches, wenn sie radial ausgeweitet ist, ausgelegt ist, und bei dem weiterhin die Stabilisierungsvorrichtung (19, 19a) zur Anordnung an oder nahe einem Ostium des rohrförmigen Bereiches und zum Drücken gegen das Ostium, wenn sie radial aufgeweitet ist, ausgelegt ist.

5. Katheter nach Anspruch 1, bei dem die Schlitze Speichen (20, 20a, 22, 22a) bilden, die sich in eine Längsrichtung erstrecken, welche durch den Katheterkörper (12, 12a, 12c, 12d) definiert ist.

6. Katheter nach Anspruch 5, bei dem jede Speiche (20, 20a) der Verankerungsvorrichtung (17, 17a, 17c, 17d) dieselbe Länge hat.

7. Katheter nach Anspruch 5, bei dem jede Speiche (22, 22a) der Stabilisierungsvorrichtung (19, 19a) dieselbe Länge hat.

8. Katheter nach Anspruch 5, bei dem sich die Speichen (20, 20a) der Verankerungsvorrichtung (17, 17a, 17c, 17d) in der Länge von den Speichen der Stabilisierungsvorrichtung (19, 19a) unterscheiden.

9. Katheter nach Anspruch 1, bei dem die Hülse (23, 23a, 23c) distal bewegt wird, um wenigstens eine der Vorrichtungen radial aufzuweiten.

10. Katheter nach Anspruch 1, bei dem die Hülse (23, 23a, 23c) proximal bewegt wird, um wenigstens eine der Vorrichtungen radial aufzuweiten.

11. Katheter nach Anspruch 1, bei dem die Verankerungsvorrichtung (17, 17a, 17c, 17d) an dem distalen Ende des Katheterkörpers (12, 12a, 12c, 12d) festgelegt ist und die Hülse (23, 23a, 23c) distal bewegt

wird, um wenigstens eine der Vorrichtungen aufzuweisen.

12. Katheter nach Anspruch 1, bei dem wenigstens eine, die Verankerungsvorrichtung (17, 17a, 17c, 17d) oder die Stabilisierungsvorrichtung (19, 19a) auf einem teleskopierenden Bereich (54) distal zum distalen Ende des Katheterkörpers (12, 12a, 12c, 12d) angeordnet ist und der teleskopierende Bereich (54) proximal bewegt wird, um wenigstens eine der Vorrichtungen radial aufzuweiten.

13. Katheter nach Anspruch 1, der weiter Mittel (40, 42) zum Abtragen von Gewebe an oder nahe dem rohrförmigen Bereich aufweist.

14. Katheter nach Anspruch 1, weiter mit Mitteln zum Ablenken des distalen Endes des Katheterkörpers (12, 12a, 12c, 12d), die einen Zugdraht mit einem proximalen Ende und einem distalen Ende aufweisen, wobei das proximale Ende des Zugdrahtes fest in dem Steuergriff (16) angebracht ist und das distale Ende des Zugdrahtes fest an dem distalen Ende des Katheterkörpers (12, 12a, 12c, 12d) angebracht ist, so dass die Längsbewegung des Zugdrahtes zu einer Ablenkung des distalen Endes des Katheters führt.

15. Katheter nach Anspruch 1, weiter mit einem elektromagnetischen Sensor (72), der in dem distalen Ende des Katheterkörpers (12, 12a, 12c, 12d) angeordnet ist.

16. Katheter nach Anspruch 1, weiter mit wenigstens einer Ringelektrode (28), die auf der nicht leitenden Hülse distal zur Verankerungsvorrichtung (17, 17a, 17c, 17d) angeordnet ist.

17. Katheter nach Anspruch 1, weiter mit wenigstens einer Ringelektrode (28), die auf der Hülse proximal zur Verankerungsvorrichtung (17, 17a, 17c, 17d) angeordnet ist.

18. Katheter nach Anspruch 1, weiter mit wenigstens einer Ringelektrode (28), die auf der nicht leitenden Hülse distal zur Stabilisierungsvorrichtung (19, 19a) angeordnet ist.

19. Katheter nach Anspruch 1, weiter mit wenigstens einer Ringelektrode (28), die auf der Hülse proximal zur Stabilisierungsvorrichtung (19, 19a) angeordnet ist.

20. Katheter nach Anspruch 1, weiter mit einem Umfangs-Ablationselement (65), das innerhalb der Stabilisierungsvorrichtung (19, 19a) angeordnet ist.

21. Katheter nach Anspruch 20, bei dem das Umfangs-Ablationselement (65) ein Ultraschall-Transducer ist und bei dem weiter die Stabilisierungsvorrichtung (19, 19a) von einem aufweitbaren Ballon (67) abgedeckt wird.

22. Katheter nach Anspruch 1, weiter mit einem Anschlag (30, 32), der die radiale Aufweitung wenigstens einer der Vorrichtungen beschränkt.

23. Katheter nach Anspruch 1, weiter mit einem Ablationselement (65), das auf der Hülse proximal zur Stabilisierungsvorrichtung angeordnet ist.

24. Katheter nach Anspruch 23, bei dem das Ablationselement ein Ultraschall-Transducer (65) ist, der innerhalb eines aufweitbaren Ballons (67) eingeschlossen ist.

25. Katheter nach Anspruch 1, bei dem die Verankerungsvorrichtung (17, 17a, 17c, 17d) wenigstens vier Speichen hat.

26. Katheter nach Anspruch 4, bei dem die Stabilisierungsvorrichtung (19, 19a) wenigstens vier Speichen hat.

Revendications

1. Cathéter (10) adapté pour être utilisé sur ou dans une région tubulaire du coeur, comprenant :

un corps de cathéter de forme allongée (12, 12a, 12c, 12d) comportant des extrémités proximale et distale ;
un dispositif d'ancrage (17, 17a, 17c, 17d) ;
un dispositif de stabilisation (19, 19a) situé de façon proximale par rapport au dispositif d'ancrage (17, 17a, 17c, 17d) et adapté pour limiter le déplacement rotatif et distal de l'extrémité distale du corps de cathéter (12, 12a, 12c, 12d) par rapport à la région tubulaire lorsque ledit dispositif de stabilisation (19, 19a) est radialement déployé ;

caractérisé en ce que le dispositif d'ancrage (17, 17a, 17c, 17d) et le dispositif de stabilisation (19, 19a) sont formés à partir de fentes découpées dans une gaine (23, 23a, 23c) positionnée sur au moins l'extrémité distale du corps de cathéter et adaptée pour un déplacement distal et proximal par rapport au corps de cathéter afin de déployer radialement les dispositifs, et **en ce que** ledit dispositif d'ancrage (17, 17a, 17c, 17d) est adapté pour limiter le déplacement rotatif et proximal de l'extrémité distale du corps de cathéter (12, 12a, 12c, 12d) par rapport à la région tubulaire lorsque ledit dispositif d'ancrage (17, 17a, 17c, 17d) est radialement déployé.

2. Cathéter selon la revendication 1, dans lequel le dispositif d'ancrage (17, 17a, 17c, 17d) est adapté pour être mis en place à l'intérieur de la région tubulaire et pour s'appuyer contre une paroi circonférentielle de la région tubulaire lorsqu'il est radialement déployé.

3. Cathéter selon la revendication 1, dans lequel le dispositif de stabilisation (19, 19a) est adapté pour être mis en place sur ou près d'un ostium de la région tubulaire et pour s'appuyer contre l'ostium lorsqu'il est radialement déployé.

4. Cathéter selon la revendication 1, dans lequel le dispositif d'ancrage (17, 17a, 17c, 17d) est adapté pour être mis en place à l'intérieur de la région tubulaire et pour s'appuyer contre une paroi circonférentielle de la région tubulaire lorsqu'il est radialement déployé, et dans lequel, en outre, le dispositif de stabilisation (19, 19a) est adapté pour être mis en place sur ou près d'un ostium de la région tubulaire et pour s'appuyer contre l'ostium lorsqu'il est radialement déployé.

5. Cathéter selon la revendication 1, dans lequel les fentes forment des nervures (20, 20a, 22, 22a) s'étendant dans une direction longitudinale définie par le corps de cathéter (12, 12a, 12c, 12d).

6. Cathéter selon la revendication 5, dans lequel toutes les nervures (20, 20a) du dispositif d'ancrage (17, 17a, 17c, 17d) ont la même longueur.

7. Cathéter selon la revendication 5, dans lequel toutes les nervures (22, 22a) du dispositif de stabilisation (19, 19a) ont la même longueur.

8. Cathéter selon la revendication 5, dans lequel les nervures (20, 20a) du dispositif d'ancrage (17, 17a, 17c, 17d) ont une longueur différente des nervures du dispositif de stabilisation (19, 19a).

9. Cathéter selon la revendication 1, dans lequel la gaine (23, 23a, 23c) est déplacée de manière distale pour déployer radialement au moins un des dispositifs.

10. Cathéter selon la revendication 1, dans lequel la gaine (23, 23a, 23c) est déplacée de manière proximale pour déployer radialement au moins un des dispositifs.

11. Cathéter selon la revendication 1, dans lequel le dispositif d'ancrage (17, 17a, 17c, 17d) est fixé à l'extrémité distale du corps de cathéter (12, 12a, 12c, 12d) et la gaine (23, 23a, 23c) est déplacée de manière distale pour déployer radialement au moins un des dispositifs.

12. Cathéter selon la revendication 1, dans lequel le dispositif d'ancrage (17, 17a, 17c, 17d) et/ou le dispositif de stabilisation (19, 19a) sont positionnés sur une partie télescopique (54) de façon distale par rapport à l'extrémité distale du corps de cathéter (12, 12a, 12c, 12d) et la partie télescopique (54) est déplacée de manière proximale pour déployer radialement au moins un des dispositifs.

13. Cathéter selon la revendication 1, comprenant en outre des moyens (40, 42) destinés à enlever le tissu situé sur ou près de la région tubulaire.

14. Cathéter selon la revendication 1, comprenant en outre des moyens destinés à dévier l'extrémité distale du corps de cathéter (12, 12a, 12c, 12d) comprenant un fil de tirage comportant une extrémité proximale et une extrémité distale, l'extrémité proximale du fil de tirage étant attachée de manière fixe dans la poignée de commande (16), et l'extrémité distale du fil de tirage est attachée de manière fixe à l'extrémité distale du corps de cathéter (12, 12a, 12c, 12d), moyennant quoi le déplacement longitudinal du fil de tirage conduit à la déviation de l'extrémité distale du cathéter.

15. Cathéter selon la revendication 1, comprenant en outre un capteur électromagnétique (72) monté dans l'extrémité distale du corps de cathéter (12, 12a, 12c, 12d) .

16. Cathéter selon la revendication 1, comprenant en outre au moins une électrode annulaire (28) montée sur la gaine non conductrice de manière distale par rapport au dispositif d'ancrage (17, 17a, 17c, 17d).

17. Cathéter selon la revendication 1, comprenant en outre au moins une électrode annulaire (28) montée sur la gaine de manière proximale par rapport au dispositif d'ancrage (17, 17a, 17c, 17d).

18. Cathéter selon la revendication 1, comprenant en outre au moins une électrode annulaire (28) montée sur la gaine non conductrice de manière distale par rapport au dispositif de stabilisation (19, 19a).

19. Cathéter selon la revendication 1, comprenant en outre au moins une électrode annulaire (28) montée sur la gaine de manière proximale par rapport au dispositif de stabilisation (19, 19a).

20. Cathéter selon la revendication 1, comprenant en outre un dispositif d'ablation circonférentielle (65) monté dans le dispositif de stabilisation (19, 19a).

21. Cathéter selon la revendication 20, dans lequel le dispositif d'ablation circonférentielle (65) est un transducteur à ultrasons, et dans lequel, en outre, le

dispositif de stabilisation (19, 19a) est recouvert d'un ballonnet extensible.

22. Cathéter selon la revendication 1, comprenant en outre une butée (30, 32) limitant le déploiement radial d'au moins un des dispositifs.

23. Cathéter selon la revendication 1, comprenant en outre un dispositif d'ablation (65) monté sur la gaine de manière proximale par rapport au dispositif de stabilisation.

24. Cathéter selon la revendication 23, dans lequel le dispositif d'ablation est un transducteur à ultrasons (65) enfermé dans un ballonnet extensible (67).

25. Cathéter selon la revendication 1, dans lequel le dispositif d'ancrage (17, 17a, 17c, 17d) comporte au moins 4 nervures.

26. Cathéter selon la revendication 4, dans lequel le dispositif de stabilisation (19, 19a) comporte au moins 4 nervures.

FIG. 1

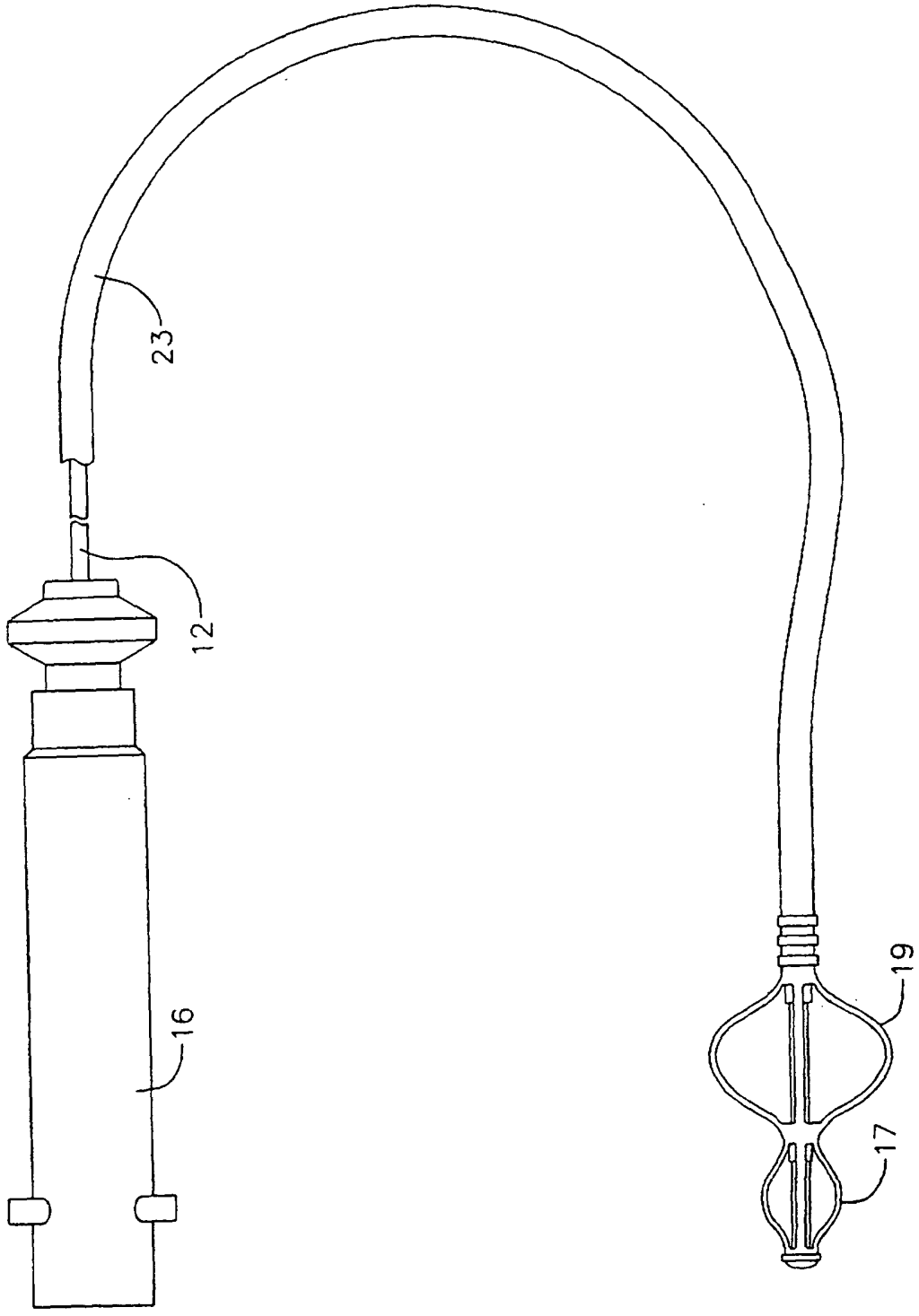
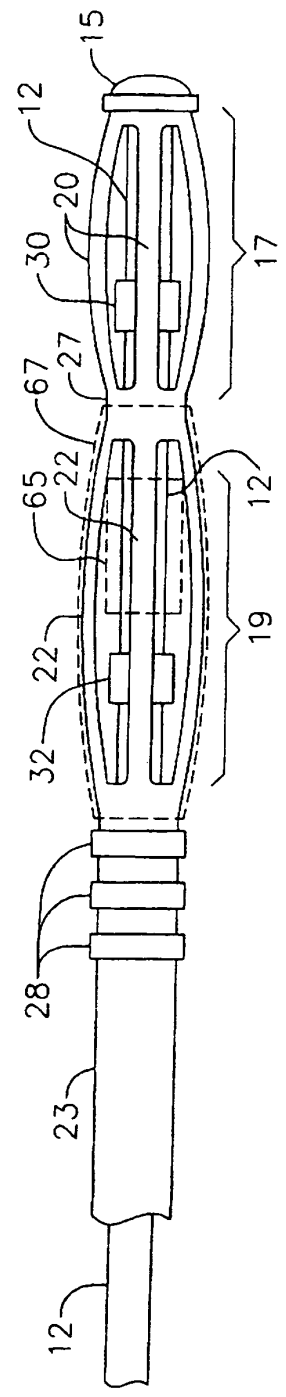


FIG.2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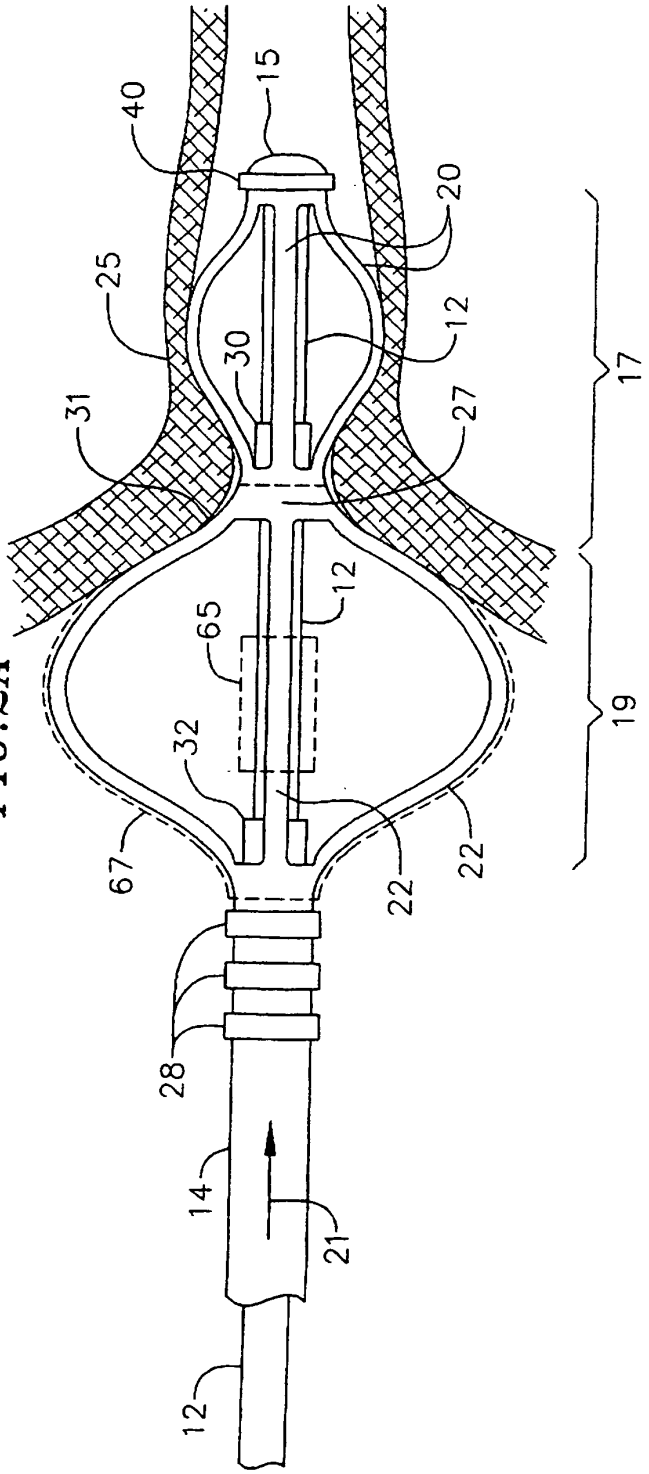
19
12

FIG.2A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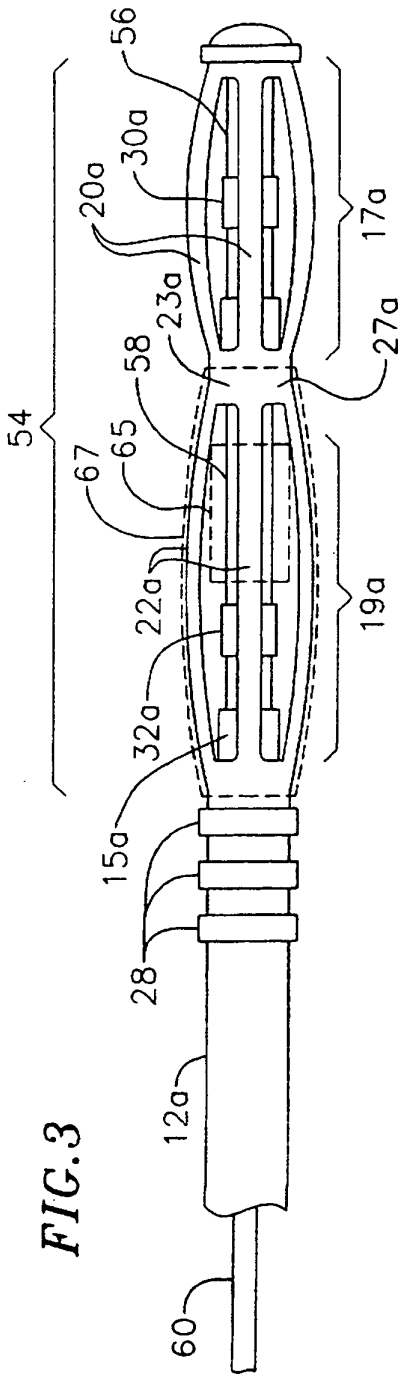
54
56
30a
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58
65
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32a
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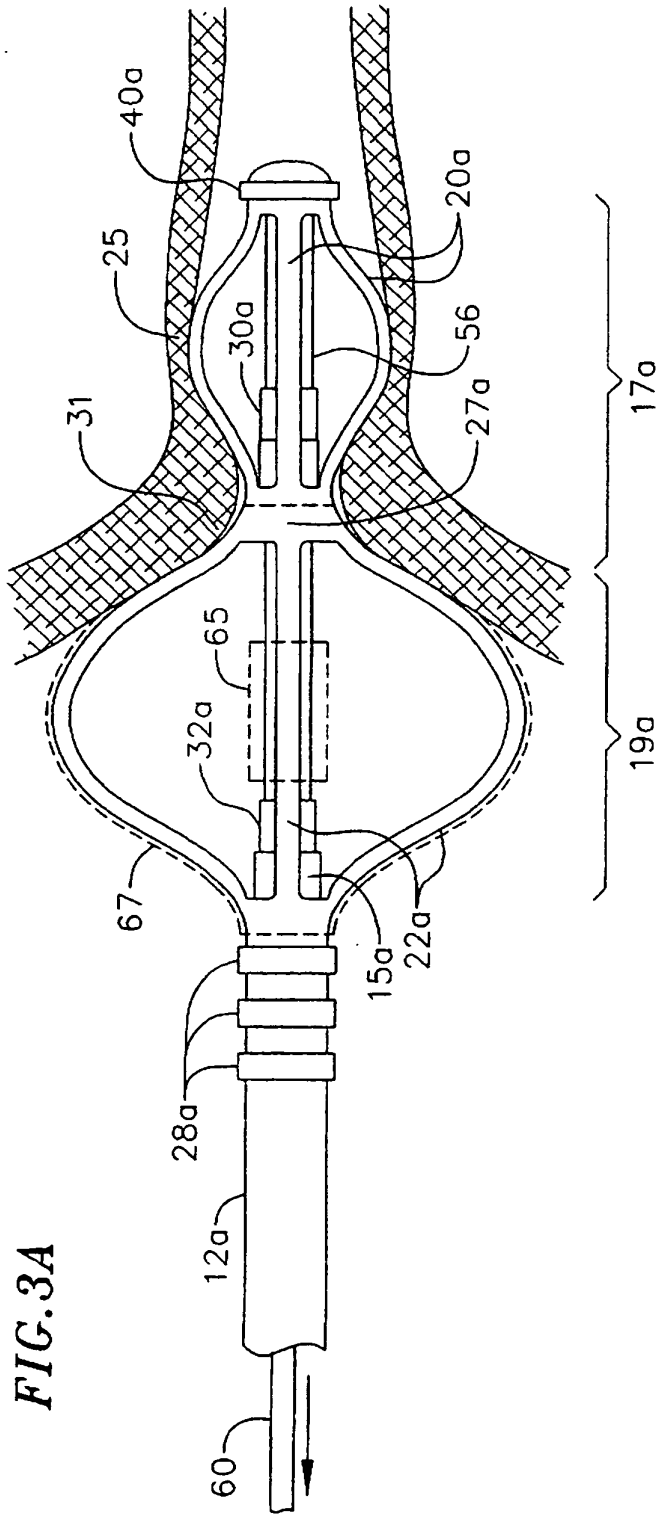
12a
60
17a
27a
19a

FIG.3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12a
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17a
19a

FIG.3A

FIG. 4

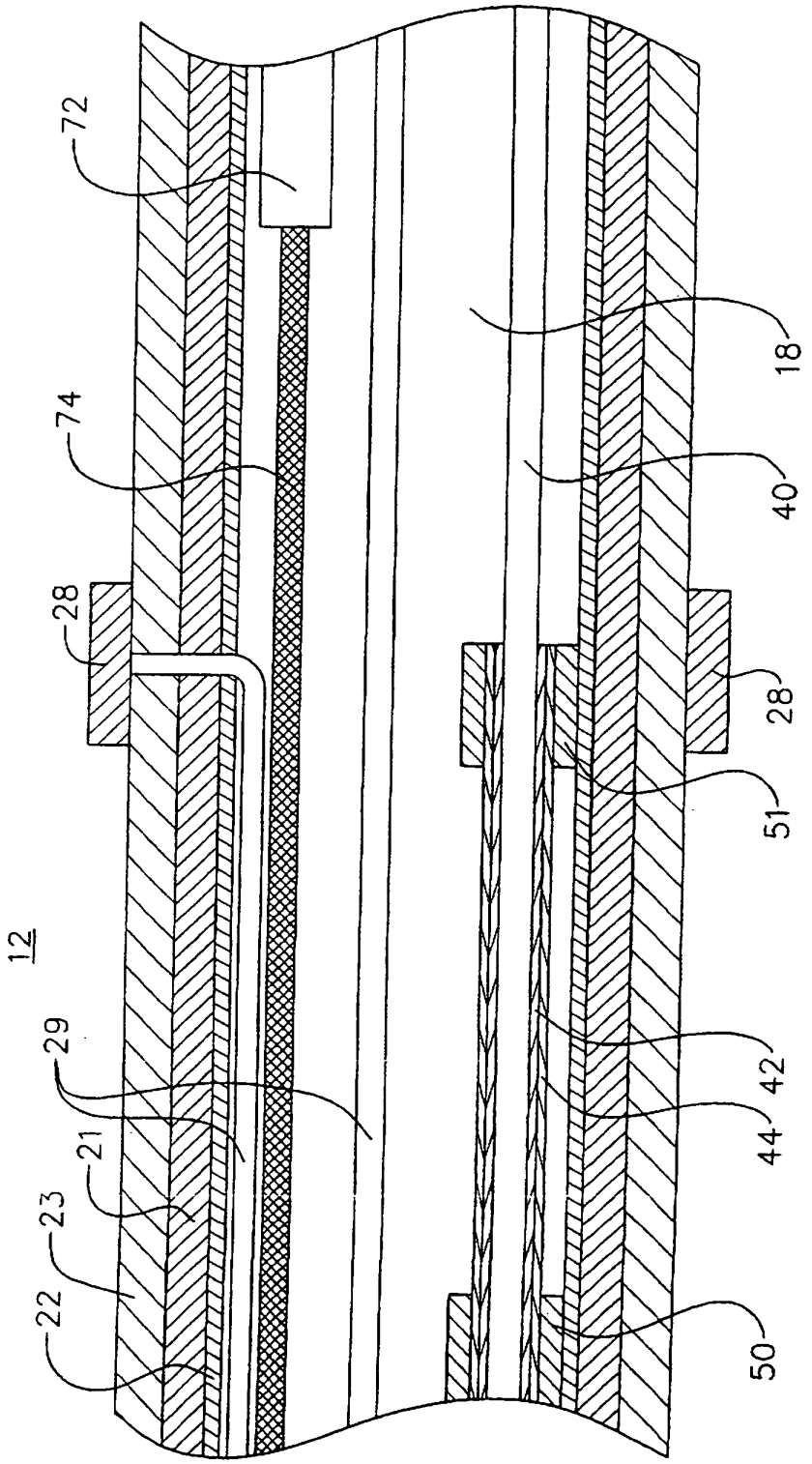


FIG. 5

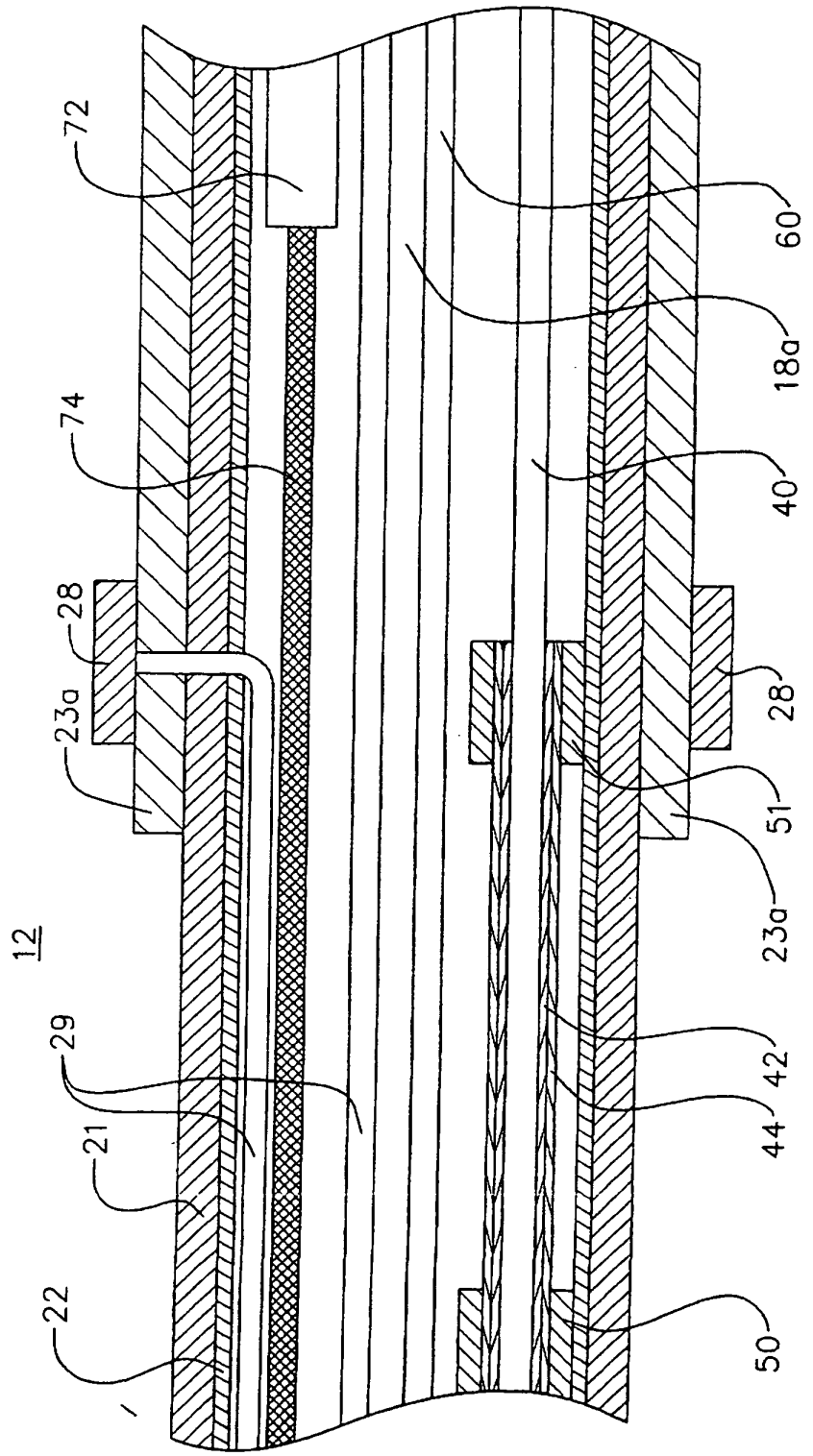
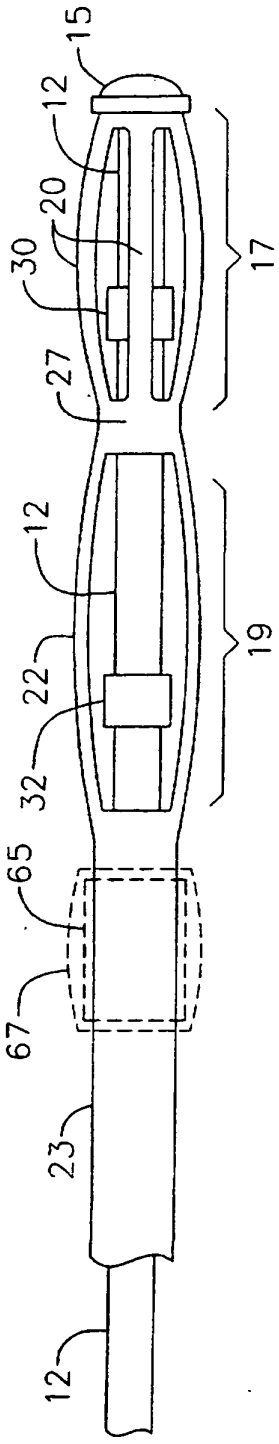


FIG. 6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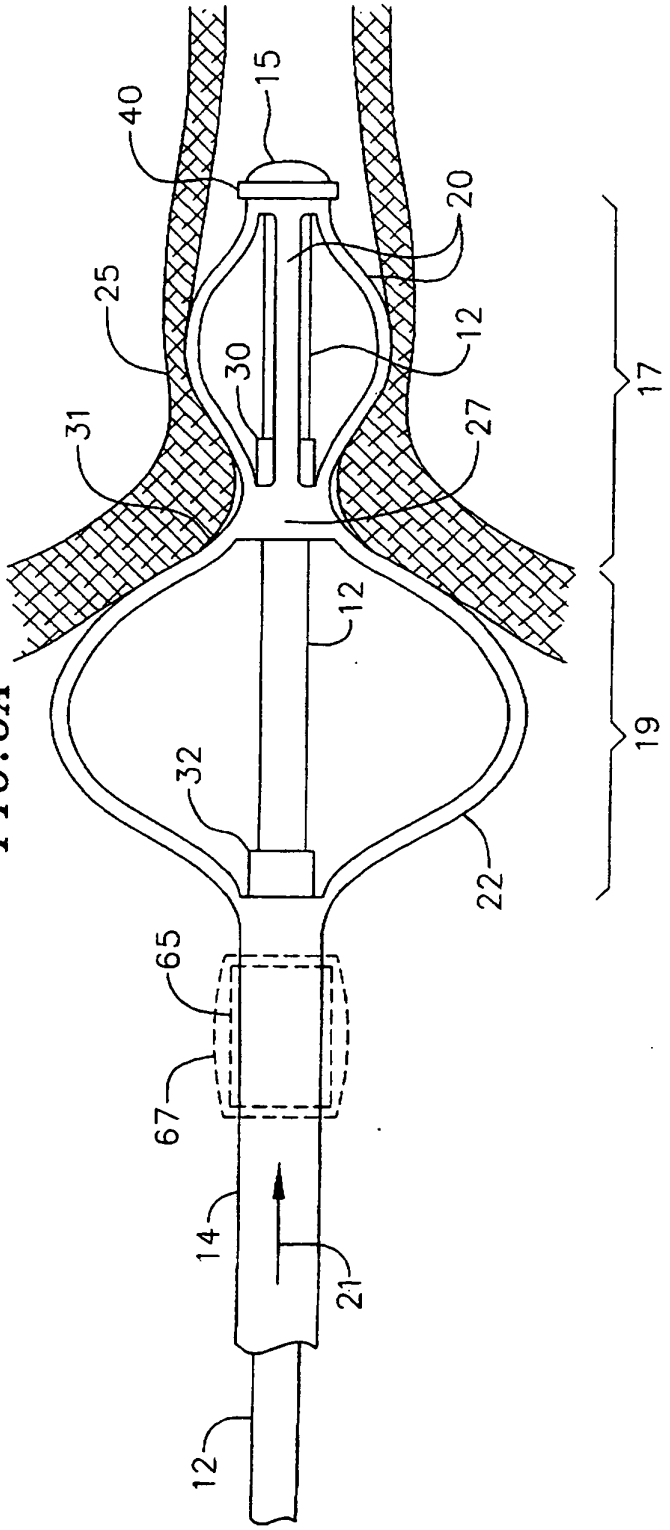
19
65
67
23
12

FIG. 6A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67
14
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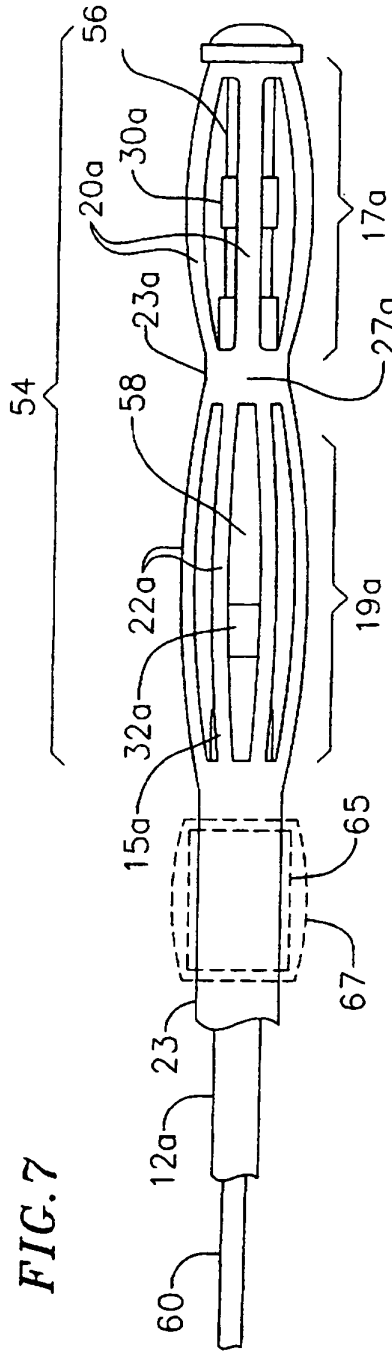
12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22a
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12a
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FIG. 7

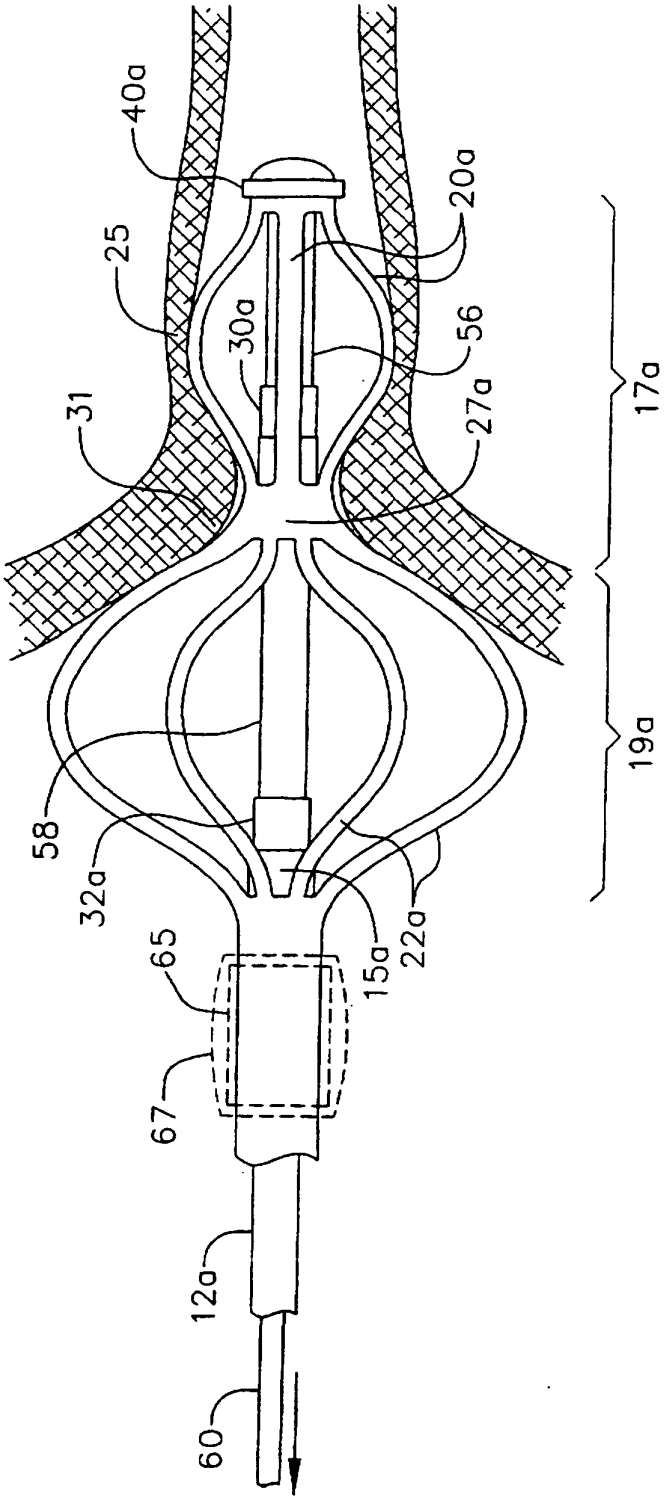
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FIG. 7A

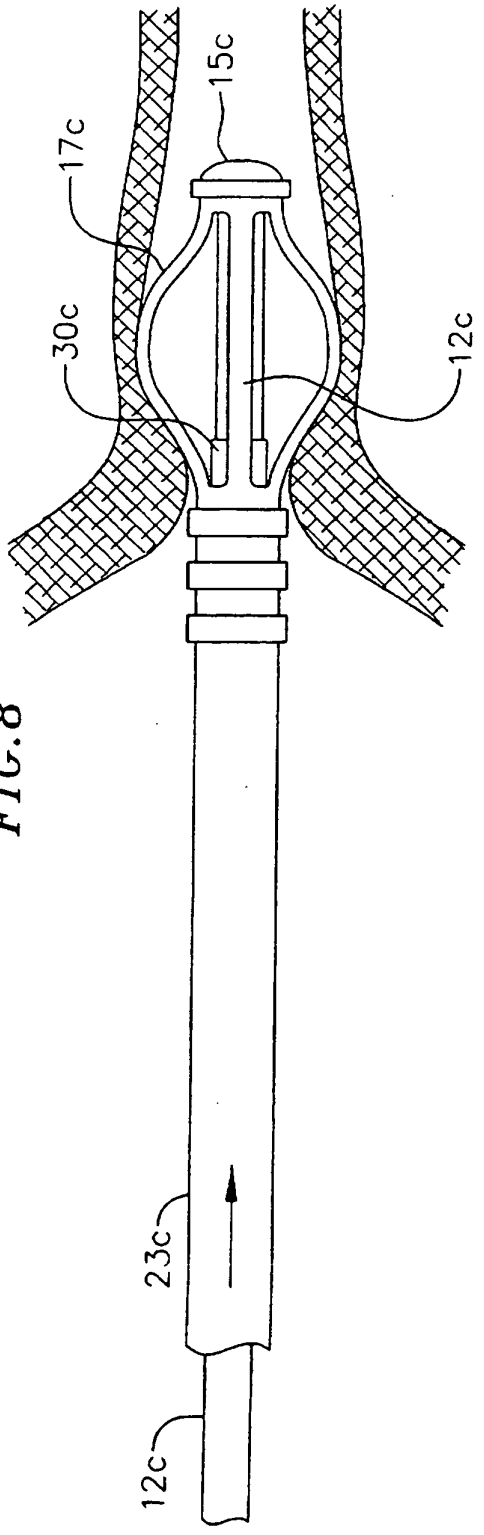

FIG.8

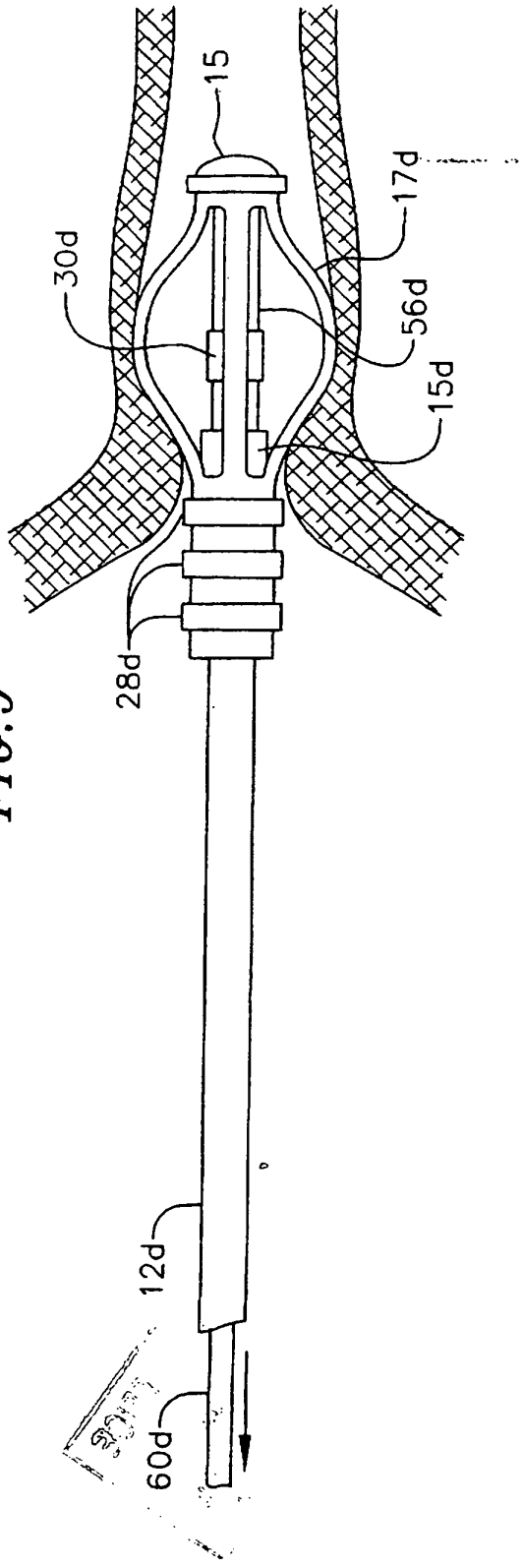

FIG.9

REFERENCES CITED IN THE DESCRIPTION

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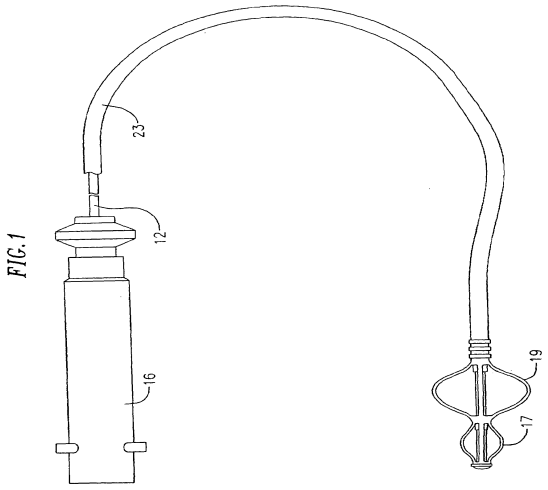
Patent documents cited in the description

- US 6024740 A **[0003]**
- US 6117101 A **[0003]**
- US 20040059327 A **[0005]**
- US 6780183 B **[0039]**
- US 5558091 A **[0047]**
- US 5443489 A **[0047]**
- US 5480422 A **[0047]**
- US 5546951 A **[0047]**
- US 5391199 A **[0047]**
- US 6210407 B **[0048]**
- US 6171277 B **[0048]**
- US 6198974 B **[0048]**

专利名称(译)	导管具有锚固和稳定装置		
公开(公告)号	EP1634541B1	公开(公告)日	2009-04-22
申请号	EP2005255489	申请日	2005-09-08
[标]申请(专利权)人(译)	韦伯斯特生物官能公司		
申请(专利权)人(译)	生物传感韦伯斯特，INC.		
当前申请(专利权)人(译)	生物传感韦伯斯特，INC.		
[标]发明人	ESPOSITO RICHARD		
发明人	ESPOSITO, RICHARD		
IPC分类号	A61B18/14 A61M25/10 A61F2/958		
CPC分类号	A61M25/04 A61B5/0422 A61B18/1492 A61B2018/00214 A61B2018/00279 A61B2018/00375		
优先权	10/941643 2004-09-14 US		
其他公开文献	EP1634541A1		
外部链接	Espacenet		

摘要(译)



提供了一种导管，其具有导管主体，该导管主体的远端具有锚定装置和稳定装置，所述锚定装置和稳定装置适于分别坐在管状区域（例如肺静脉口）的开口中并位于其外部。覆盖导管主体的护套形成锚固装置和稳定装置。特别地，锚固装置和/或稳定装置包括切入护套的多个狭缝，狭缝在该狭缝中形成脊柱。在一个实施例中，护套在其远端固定到导管主体的远端。通过护套相对于导管主体的远侧运动，锚固装置和稳定装置的脊部展开成径向扩张。在锚固装置径向扩张时，锚固装置的脊柱对管状区域的壁施加压力，从而通常将导管主体的远端锚固在管状区域内以抵抗近端和/或径向运动。相对于管状区域。在稳定组件的脊柱径向扩张时，稳定装置的脊柱对管状区域的口施加压力，从而通常稳定导管主体的远端以防止相对于管状区域的远侧和/或径向运动。因此，通过锚定装置施加在管状区域的壁上并且通过稳定装置施加在窦口上的压力最小化（如果不是防止的话）导管主体的远端抵抗平移和旋转运动。特别地，通过稳定装置施加在管状区域的口上的压力使导管稳定在心脏内，以输送消融能量以治疗心脏的所需区域。还设想了导管的其他实施例，例如具有从导管的远端向远侧延伸的伸缩部分的那些实施例。这样，部署了锚固和稳定装置通过拉线的近端移动，拉线的远端固定到伸缩部分的远端。