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(71) Applicant *(for all designated States except US)*: **CRYOCATH TECHNOLOGIES INC.** [CA/CA]; 16771 Chemin Ste-Marie, Kirkland, Québec H9H 5H3 (CA).

(72) Inventors: **WITTENBERGER, Dan**; 1967 Chemin Bord du Lac, L'ile Bizard, Québec H9E 2A6 (CA). **ABBOUD, Marwan**; 18501 Antoine-Faucon, Pierrefonds, Québec H9K 1M7 (CA). **DEAC, Ioana**; 56 Des Opales, L'ile-Perrot, Québec J7V 9H7 (CA).

(74) Agent: **MBM & CO.**; P.O. Box 809, Station B, Ottawa, Ontario K1P 5P9 (CA).

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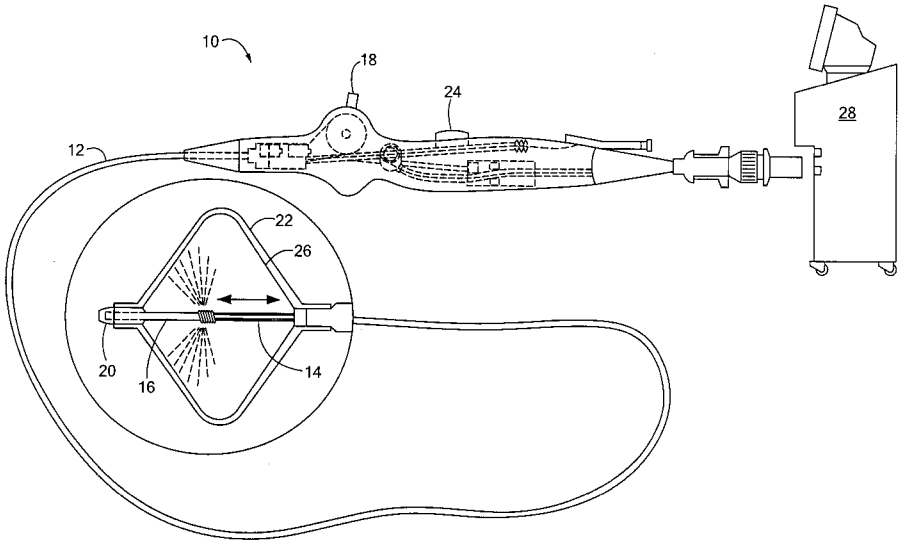
(54) Title: VARIABLE GEOMETRY COOLING CHAMBER



(57) Abstract: The present invention provides a medical device that may include a catheter body having proximal and distal portions, a fluid injection lumen disposed within elongate body, and a guidewire lumen disposed within the elongate body. A tip portion defining a cavity in fluid communication with the fluid injection lumen may be coupled to the distal end of the guidewire lumen, and an expandable element may be coupled to the distal portion of the catheter body and to the tip portion, such that the expandable element is in fluid communication with the fluid injection lumen. A shaping element may at least partially surround the expandable element, where the shaping element is configurable in a first geometric configuration and a second geometric configuration.

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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.

VARIABLE GEOMETRY COOLING CHAMBER

FIELD OF THE INVENTION

The present invention relates to a method and system having a variable geometry treatment element in a medical device, and in particular, to a cooling chamber of a medical device capable of having multiple geometric configurations.

BACKGROUND OF THE INVENTION

Minimally invasive devices, such as catheters, are often employed for surgical procedure, including those involving ablation, dilation, and the like. In a particular situation, an ablation procedure may involve creating a series of inter-connecting lesions in order to electrically isolate tissue believed to be the source of an arrhythmia. During the course of such a procedure, a physician may employ several different catheters having variations in the geometry and/or dimensions of the ablative element in order to produce the desired ablation pattern. Each catheter may have a unique geometry for creating a specific lesion pattern, with the multiple catheters being sequentially removed and replaced to create the desired multiple lesions. Exchanging these various catheters during a procedure can cause inaccuracies or movement in the placement and location of the distal tip with respect to the tissue to be ablated, and may further add to the time required to perform the desired treatment. These potential inaccuracies and extended duration of the particular procedure increase the risk to the patient undergoing treatment. Accordingly, it would be desirable to provide a single medical device having the ability to provide ablative patterns of various shapes, without the need for additional catheters or the like having a single geometric orientation, and thus, limited in the ability to provide multiple ablative patterns.

SUMMARY OF THE INVENTION

The present invention advantageously provides a medical device having an elongate body defining a proximal portion, a distal portion, and a fluid injection lumen. The medical device may also include a guidewire lumen at least partially disposed within the elongate body, wherein the guidewire lumen includes a proximal end and a distal end. A tip portion may be coupled to the distal end of the guidewire lumen, where the tip portion can define a cavity in fluid communication with the fluid injection lumen.

The medical device may further include an expandable element coupled to the elongate body, the expandable element defining a proximal end and a distal end, such that the proximal end may be coupled to the distal portion of the catheter body, with the distal end being coupled to either the tip portion or the guidewire lumen. The expandable element may also be in fluid communication with the fluid injection lumen. A shaping element may be provided such that the shaping element at least partially surrounds the expandable element, with the shaping element being configurable in a first geometric configuration and a second geometric configuration.

BRIEF DESCRIPTION OF THE DRAWINGS

A more complete understanding of the present invention, and the attendant advantages and features thereof, will be more readily understood by reference to the following detailed description when considered in conjunction with the accompanying drawings wherein:

FIG. 1 illustrates an embodiment of a medical device in accordance with the present invention;

FIG. 2 shows an additional view of an embodiment of a medical device in accordance with the present invention;

FIG. 3 shows a geometric configuration of an embodiment of a medical device in accordance with the present invention;

FIG. 4 depicts an additional geometric configuration of an embodiment of a medical device in accordance with the present invention;

FIG. 5 illustrates another geometric configuration of an embodiment of a medical device in accordance with the present invention;

FIG. 6 shows still another geometric configuration of an embodiment of a medical device in accordance with the present invention;

FIG. 7 depicts an additional geometric configuration of an embodiment of a medical device in accordance with the present invention;

FIG. 8 illustrates another geometric configuration of an embodiment of a medical device in accordance with the present invention;

FIG. 9 shows still another geometric configuration of an embodiment of a medical device in accordance with the present invention;

FIG. 10 shows still another geometric configuration of an embodiment of a medical device in accordance with the present invention;

FIG. 11 depicts an additional geometric configuration of an embodiment of a medical device in accordance with the present invention;

FIG. 12 illustrates another geometric configuration of an embodiment of a medical device in accordance with the present invention;

FIG. 13 shows still another geometric configuration of an embodiment of a medical device in accordance with the present invention;

FIG. 14 depicts an additional geometric configuration of an embodiment of a medical device in accordance with the present invention;

FIG. 15 illustrates an embodiment of a medical device in accordance with the present invention; and

FIG. 16 shows an embodiment of a medical device in accordance with the present invention.

DETAILED DESCRIPTION OF THE INVENTION

Now referring to FIGS. 1 and 2, an embodiment of the present invention provides a medical device 10 defining an elongate body 12 such as a catheter. The elongate body 12 may define a proximal portion and a distal portion, and may further include one or more lumens disposed within the elongate body thereby providing mechanical, electrical, and/or fluid communication between the proximal portion of the elongate body 12 and the distal portion of the elongate body. For example, the elongate body 12 may include an injection lumen 14 and an exhaust lumen defining a fluid flow path therethrough. In addition, the elongate body may include a guidewire lumen 16 extending along at least a portion of the length of the elongate body 12 for over-the-wire applications, where the guidewire lumen 16 may define a proximal end and a distal end. The guidewire lumen 16 may be disposed within the elongate body 12 such that the distal end of the guidewire lumen 16 extends beyond the and out of the distal portion of the elongate body 12.

The elongate body 12 may further include a deflection mechanism whereby the elongate body and components coupled thereto may be maneuvered in one or more planes of motion. For example, a pull wire with a proximal end and a distal end may have its distal end anchored to the elongate body at or near the distal end. The

proximal end of the pull wire may be anchored to a knob or lever 18 controllable and responsive to an input from an operator or physician.

The medical device 10 of the present invention may include a tip portion 20 towards the distal portion of the elongate body 12, which may be coupled to a portion of the guidewire lumen 16. For example, the tip portion 20 may circumscribe a portion of the distal end of the guidewire lumen 16. The tip portion 20 may define a cavity in fluid communication with the injection lumen 14, yet be isolated from fluid communication with the guidewire lumen 16, i.e., the tip portion 20 may be able to receive a fluid therein while the guidewire lumen 16 remains excluded form any fluid flow originating and/or flowing through the elongate body 12 of the catheter. Accordingly, the tip portion 20 may be able to receive a fluid flow, such as a coolant, thereby allowing the tip portion 20 to thermally affect a desired tissue region and/or to create a spot lesion or focalized ablative pattern.

The medical device 10 of the present invention may further include a shaping element 22 coupled to the distal portion of the elongate body 12 that is configurable into a plurality of geometric configurations, such as those shown in FIGS. 3-14. The shaping element 22 may define a mesh or wire structure, and may be constructed from a combination of elastic materials, non-elastic materials, and/or shape-memory materials, such as a nickel-titanium alloy or the like, for example. As used herein, the term "mesh" is intended to include any element having an openwork fabric or structure, and may include but is not limited to, an interconnected network of wire-like segments, a sheet of material having numerous apertures and/or portions of material removed, or the like. A particular geometric configuration of the shaping element 22 may be achieved through the application of mechanical force, thermal energy, and/or electrical energy. For example, the shaping element 22 may be predisposed and/or biased towards a first geometric configuration, which may include a substantially elongated, cylindrical shape. Upon the application of a particular mechanical, thermal, and/or electrical force, the shaping element 22 may be selectively transitioned from the first geometric configuration to a second geometric configuration, having a substantially spherical shape, for example.

As discussed, the transition from a first particular configuration to a second particular configuration of the shaping element 22 may be achieved by the application

of mechanical, thermal, or electrical forces. Further, the transition may be a result of particular material properties exhibited by the construction of the shaping element 22. For example, the shaping element 22 may include a mesh structure including components made from a shape-memory material, as well as components made from a relatively non-elastic material. The components made from the shape-memory material may be predisposed and/or biased towards a first geometric configuration, while the non-elastic components may be predisposed and/or biased towards a second geometric configuration. When the shaping element 22 is placed under a first thermal condition, such a temperature range between 10°C to 40°C, the shape-memory material may be dominant over the non-elastic components, causing the shaping element 22 to retain the first geometric configuration. When subjected to a second thermal condition, between -100°C and 10°C for example, the shape-memory components may become increasingly pliable, thereby allowing the non-elastic components to dominate and causing the shaping element 22 to assume the second geometric configuration.

An additional example of a shaping element 22 being configurable into multiple geometric configurations may include a shaping element 22 constructed from a single material being predisposed and/or biased towards a first geometric configuration. However, the medical device of the present invention may include an actuator element 24 that may impart a mechanical force on the shaping element 22 and/or a component coupled thereto to overcome the predisposition of the shaping element 22 to retain the first geometric configuration. As shown in FIGS. 1 and 2, the actuator element 24 may include a pull wire or the like affixed to a portion of the shaping element 22 and/or portions of the medical device in proximity to the shaping element, such as the guidewire lumen 16. For example, a portion of the shaping element 22 may be coupled to a portion of the movable guidewire lumen 16. Upon manipulation of the actuator element 24, the guidewire lumen 16 may be longitudinally moved in a proximal direction, whereby the predisposed first geometric configuration of the shaping element 22 is attained. However, the guidewire lumen 16 may then be moved in a distal direction, thereby tensioning the shaping element 22 in order to overcome the bias of the shaping element. As a result, the shaping element 22 attains a second geometric configuration different than the first geometric

configuration. Additionally, the actuator element 24 may include a push rod or other mechanical coupling for imparting a mechanical and/or physical force on the shaping element 22 to overcome and thereby dominate the first geometric configuration that the shaping element 22 may be predisposed to provide. For example, as shown in FIGS. 15 and 16, a pull wire 25 may be coupled to a portion of the shaping element 22 for tensioning and/or loosening of the shaping element 22 during a procedure. Moreover, the shaping element 22 may be slideably disposed about the guidewire lumen 16 such that the guidewire lumen 16 remains in place while the shaping element 22 is manipulated into the desired configuration.

In addition to providing desired geometric configurations, the shaping element 22 may be electrically conductive. For example, the shaping element 22 may be used to provide the ability to map electrical properties of a particular tissue region, such as in the heart, whereby an electrocardiogram may be obtained. Further, the shaping element 22 may be used to provide a conductive surface for delivering radiofrequency energy to a particular tissue site, and/or to provide the ability to measure a relative impedance and/or resistance for the purpose of fluid leak detection.

The medical device 10 of the present invention may further include an expandable element 26 at least partially disposed on the elongate catheter body 12, and may further be disposed within a portion of the shaping element 22. The expandable element 26 may include a balloon or other expandable structure, which may define a proximal end coupled to the distal portion of the elongate body 12 of the catheter, while further defining a distal end coupled to the tip portion and/or the distal end of the guidewire lumen 16. In addition, the expandable element 26 may have any of a myriad of shapes, and may further include one or more material layers providing for puncture resistance, radiopacity, or the like. The expandable element 26 may be in communication with the fluid injection and exhaust lumens of the medical device as described above, i.e., a fluid flow path may provide an inflation fluid, such as a cryogenic fluid or the like, to the interior of the expandable element 26. The expandable element 26 may be inflated within the shaping element 22, thereby conforming to the shape of the shaping element 22. As such, irrespective of whether the expandable element 26 has a particular shape or dimensional capacity, the shaping element 22 may be used to provide a guide and/or "shell" within which the

expandable element 26 may be inflated to ensure a desired geometric configuration and/or a desired volume.

The shaping element 22 may, therefore, limit certain portions of the expandable element 26 from expanding, while other areas or regions of the expandable element 26 may be stretched. As portions of the expandable element 26 are stretched, the particular thermal properties of that region may change, i.e., the stretched portions may more readily conduct thermal energy than portions of the expandable element 26 that have not been stretched to the same extent, if at all. Accordingly, the shaping element 22 may provide a particular shape or geometric configuration in which particular areas of the expandable element 26 are allowed to stretch to thereby conduct heat more readily, while other portions of the expandable element 26 are not stretched to provide a degree of thermal insulation. As a result, the shaping element 22 and thus the expandable element 26 may be configured to provide varying thermal conductivity to different regions of tissue while the medical device 10 remains in a fixed position.

In an exemplary system, the medical device of the present invention may be coupled to a console 28, which may contain a fluid supply and exhaust, as well as various control mechanisms for operation of the medical device 10.

An exemplary use of the medical device 10 of the present invention may include making multiple ablative lesions having varying geometric shapes and/or dimensions on a desired tissue region. In such a procedure, the distal portion of the medical device 10 may be positioned in proximity to a tissue region to be treated. Primarily, the tip portion 20 of the medical device 10 may be subjected to a fluid flow, including a cryogenic coolant or the like, to create a focalized and/or spot lesion within a desired tissue region. Additionally, the shaping element 22 of the medical device 10 may be in a first geometric configuration, such as an elongated cylindrical shape, for example. Subsequently, a fluid, such as a cryogenic coolant, may be used to expand the expandable element 26 such that the expandable element 26 substantially fills the interior cavity defined by the shaping element 22. The expandable element 26 may be inflated such that portions of the expandable element protrude through a mesh construct of the shaping element 22 to contact and/or be in position to thermally affect the desired tissue region, while substantially retaining the

geometric configuration of the shaping element 22. While the shaping element 22 ensures the expandable element 26 retains the first geometric configuration, coolant may be circulated through the expandable element 26 in order to thermally affect the tissue region and/or to create a tissue lesion having a desired shape, such as a linear tissue lesion.

Upon achieving the desired effect, the flow of coolant through the expandable element 26 may be discontinued such that the expandable element 26 s at least partially deflated. The medical device 10 may then be repositioned in proximity to a tissue region where additional thermal treatment may be performed. The shaping element 22 may subsequently be transitioned from the first geometric configuration to the second geometric configuration, which may include a substantially spherical shape, for example. The transition may be achieved by imparting a mechanical, thermal, and/or electrical force on the shaping element, and may further include manipulation of the actuator element 24. Once the desired geometric configuration has been achieved, the expandable element 26 may once again be inflated within the shaping element 22, using the aforementioned coolant, for example. Accordingly, the second geometric configuration may be used to impart a second tissue lesion and/or thermally affected area having a varied geometric pattern and/or dimension to that of the first tissue lesion, such as a substantially circular shape, for example.

Although the exemplary use described above employed first and second geometric configurations, it is contemplated that a shaping element capable of more than two configurations may be employed and achieved through a combination of mechanical, thermal, and/or electrical forces, as well as through characteristics provided through material selection in the construction of the shaping element. Moreover, while examples and illustrations of particular geometric configurations have been provided, it is understood that virtually any shapes, configurations, and/or dimensions may be included and/or achieved by the medical device of the present invention, including but not limited to those shapes illustrated and described herein. A particular geometric configuration may include circular, conical, concave, convex, rounded, or flattened features and/or combinations thereof. Accordingly, an embodiment of the medical device of the present invention may be able to provide

focal lesions, circular lesions, linear lesions, circumferential lesions, and combinations thereof.

It will be appreciated by persons skilled in the art that the present invention is not limited to what has been particularly shown and described herein above. In addition, unless mention was made above to the contrary, it should be noted that all of the accompanying drawings are not to scale. A variety of modifications and variations are possible in light of the above teachings without departing from the scope and spirit of the invention, which is limited only by the following claims.

What is claimed is:

1. A medical device, comprising:

a shaping element selectively transitionable from a first geometric configuration to a second geometric configuration; and

an expandable element at least partially disposed within the shaping element.

2. The medical device according to Claim 1, wherein the shaping element defines a mesh.

3. The medical device according to Claim 2, wherein the shaping element is at least partially constructed from a metallic alloy.

4. The medical device according to Claim 2, wherein the shaping element is at least partially constructed from a shape-memory material.

5. The medical device according to Claim 2, wherein the shaping element is at least partially constructed from a non-elastic material.

6. The medical device according to Claim 1, wherein either of the first and second geometric configurations include an elongated, substantially cylindrical shape.

7. The medical device according to Claim 1, wherein either of the first and second geometric configurations include a substantially spherical shape.

8. The medical device according to Claim 1, further comprising an actuator element coupled to the shaping element, wherein the actuator element is able to cause the shaping element to transition from the first geometric configuration to the second geometric configuration.

9. The medical device according to Claim 1, further comprising an elongate body defining a proximal portion, a distal portion, and a fluid injection lumen; wherein the expandable element is coupled to the elongate body in fluid communication with the fluid injection lumen.

10. The medical device according to Claim 9, wherein the shaping element defines a mesh configurable in a first geometric configuration having an elongated, substantially cylindrical shape and a second geometric configuration having a substantially spherical shape.

11. The medical device according to Claim 10, further comprising an actuator element coupled to the elongate body, wherein the actuator element is able to cause the mesh to transition from the first geometric configuration to the second geometric configuration.

12. The medical device according to Claim 9, further comprising a tip portion in proximity to the distal portion of the elongate body, wherein the tip portion defines a cavity in fluid communication with the fluid injection lumen.

13. The medical device according to Claim 12, further comprising a guidewire lumen movably disposed within at least a portion of the elongate body, wherein the guidewire lumen includes a proximal end and a distal end, the distal end being disposed outside the catheter body.

14. The medical device according to Claim 13, wherein the shaping element defines a mesh.

15. The medical device according to Claim 14, wherein the first geometric configuration includes an elongated, substantially cylindrical shape and the second geometric configuration includes a substantially spherical shape.

16. The medical device according to Claim 14, wherein the mesh is coupled to the guidewire lumen.

17. The medical device according to Claim 16, further comprising an actuator element coupled to the guidewire lumen for longitudinal movement thereof.

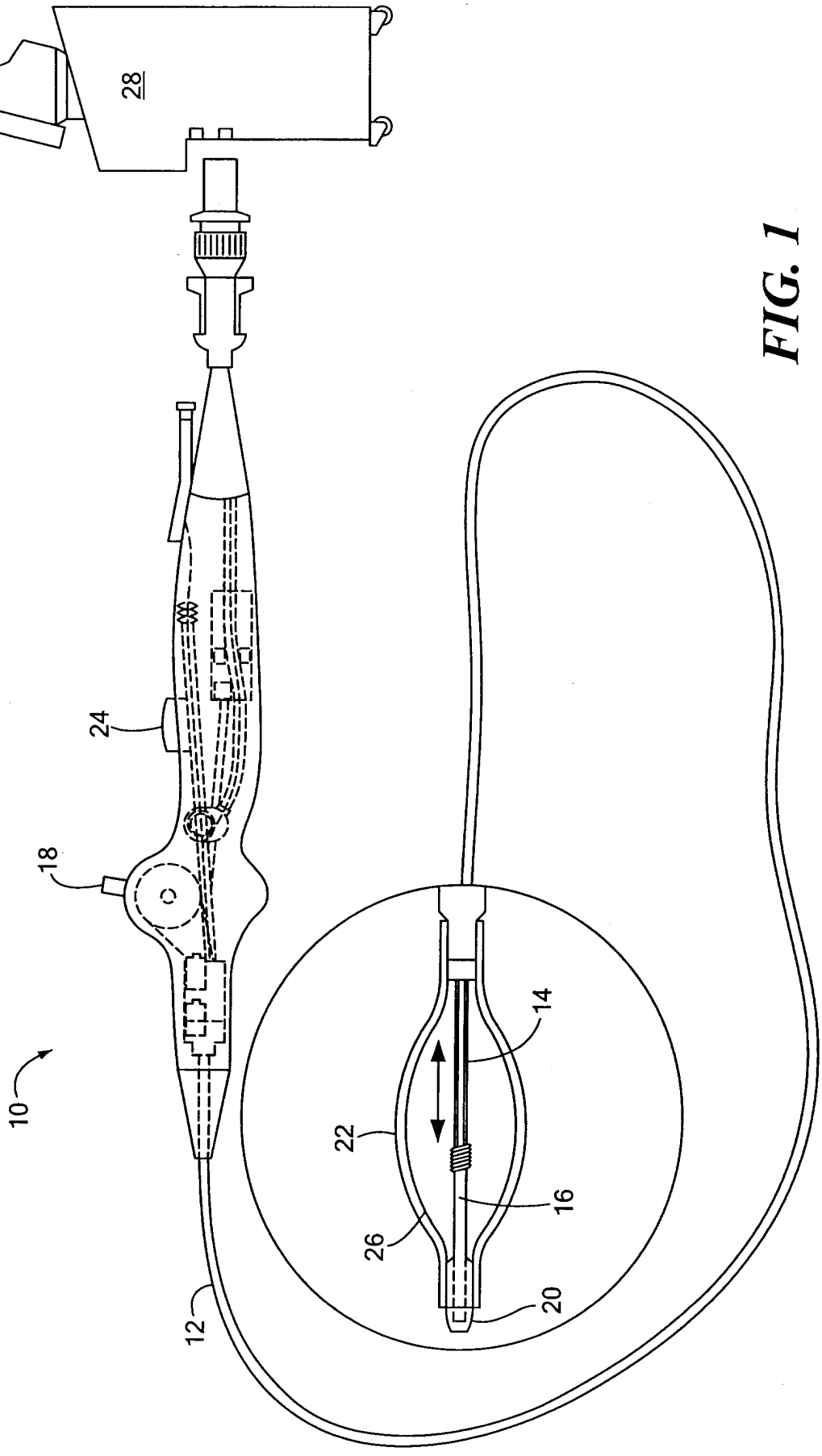

FIG. 1

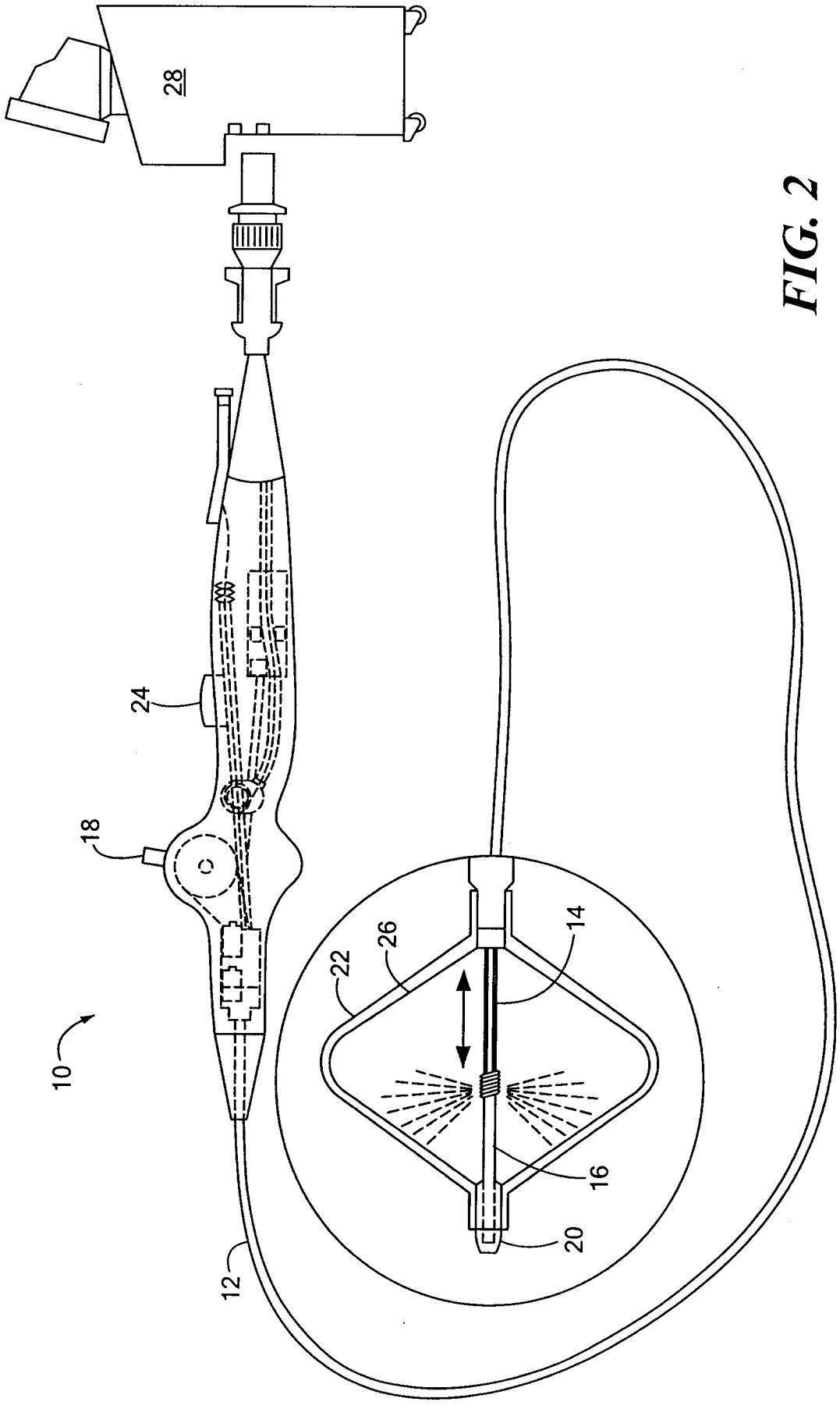

FIG. 2

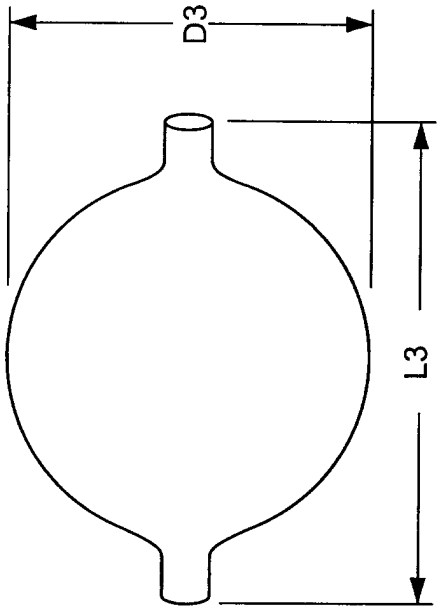

FIG. 4

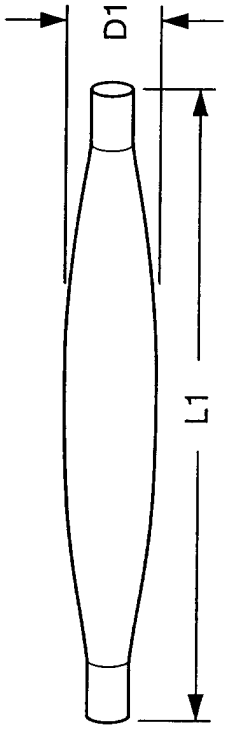

FIG. 6

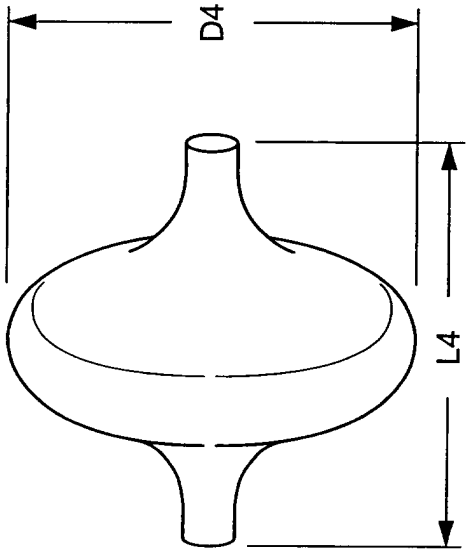

FIG. 3

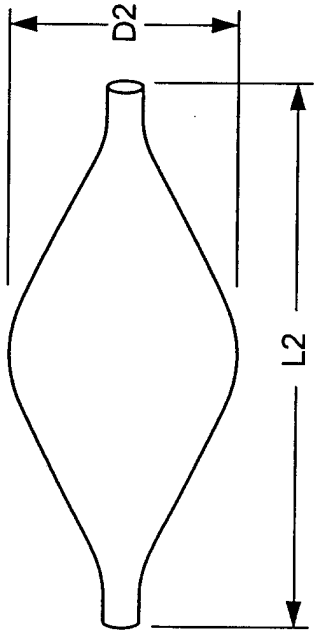

FIG. 5

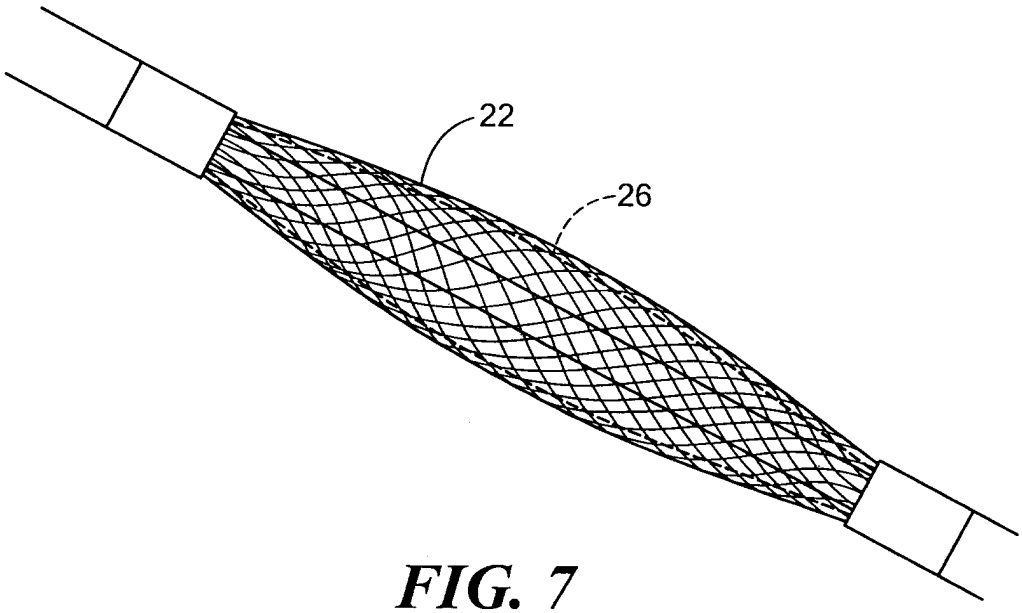

FIG. 7

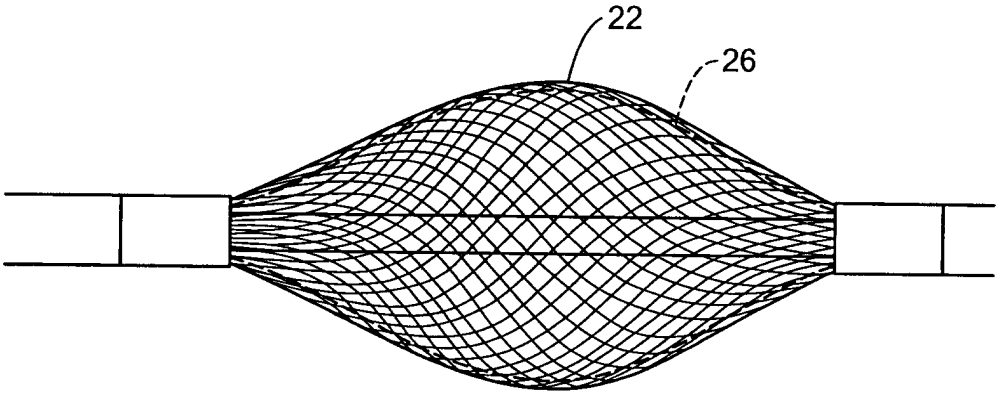

FIG. 8

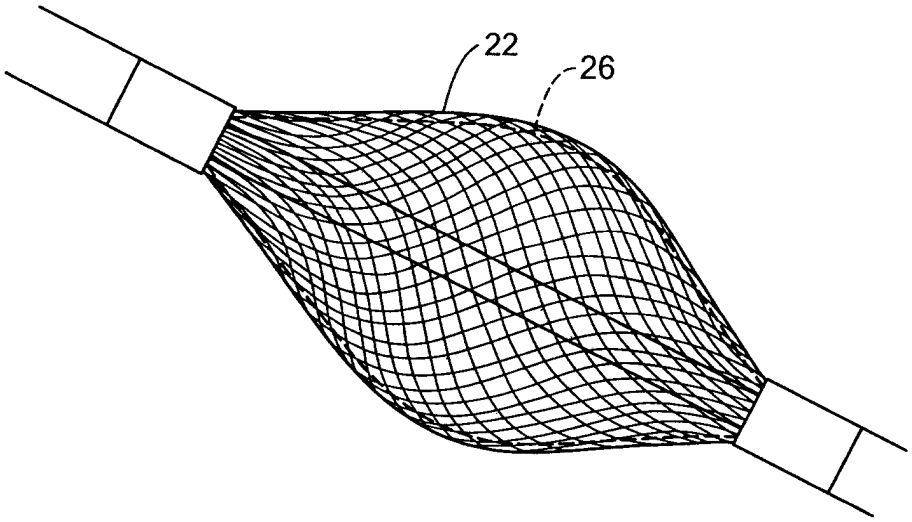

FIG. 9

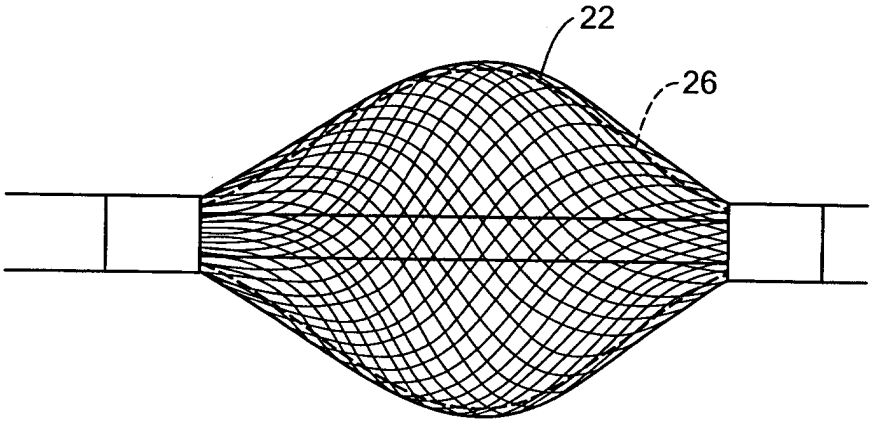

FIG. 10

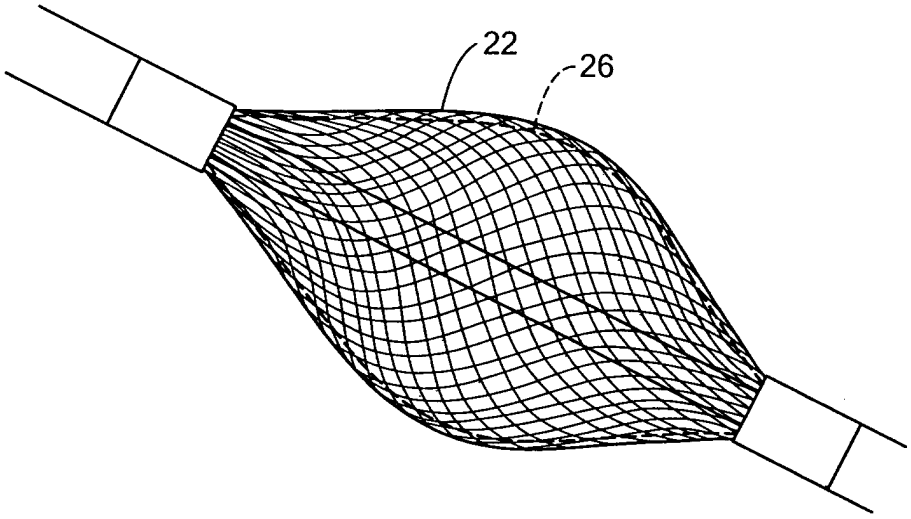

FIG. 11

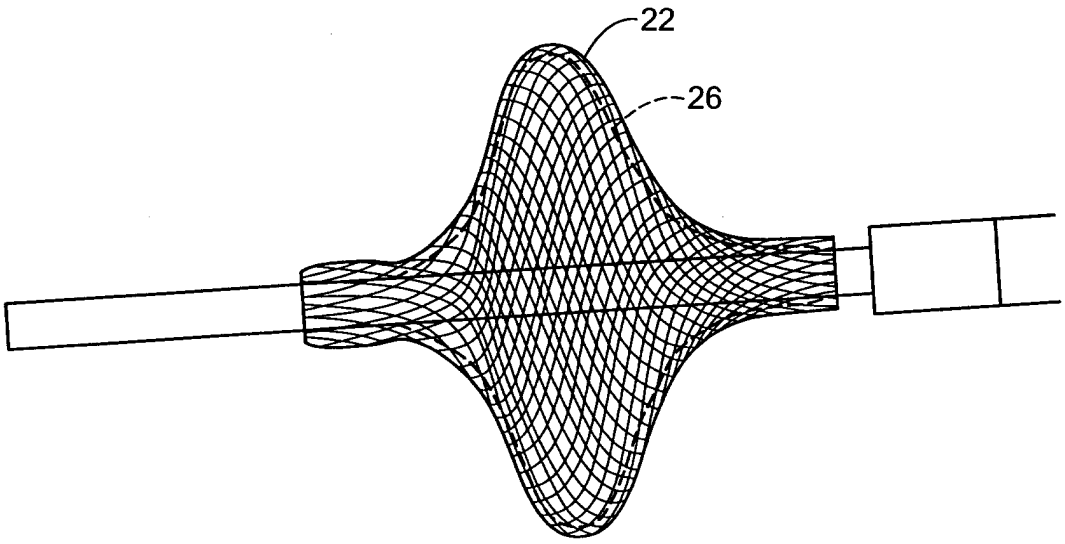

FIG. 12

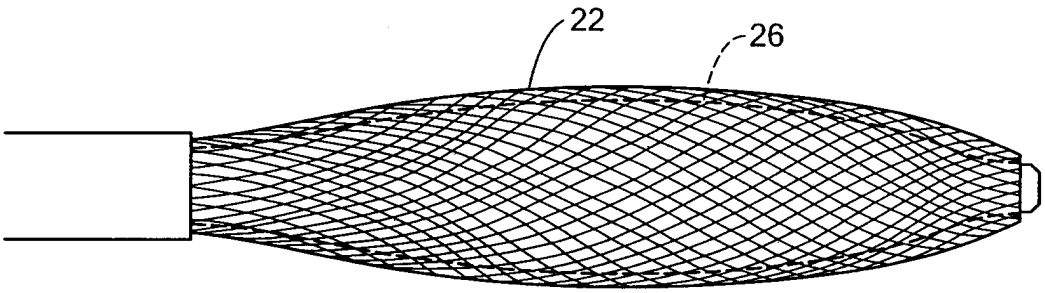

FIG. 13

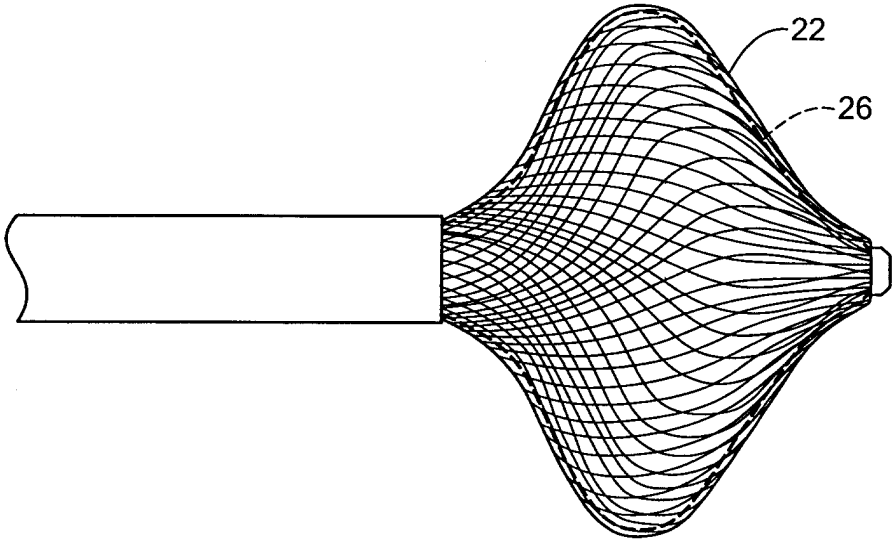

FIG. 14

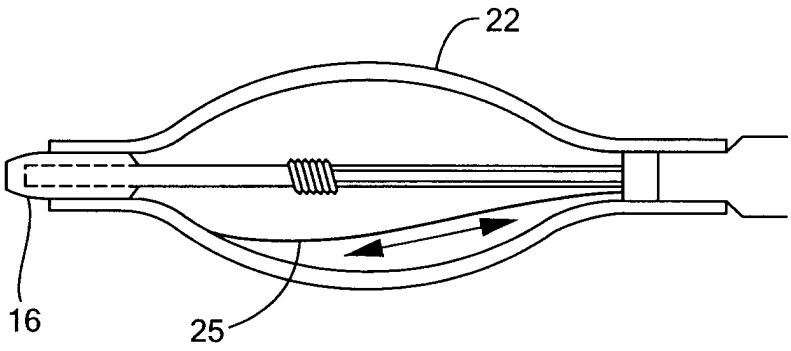

FIG. 15

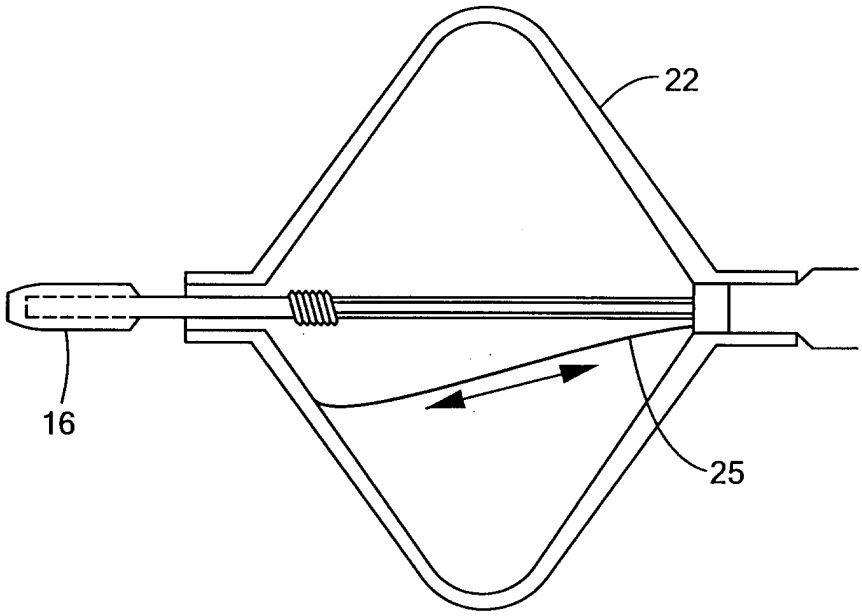

FIG. 16

INTERNATIONAL SEARCH REPORT

International application No.
PCT/CA2007/001075

A. CLASSIFICATION OF SUBJECT MATTER

IPC: ***A61M 25/00*** (2006.01) , ***A61B 17/00*** (2006.01) , ***A61F 2/82*** (2006.01) , ***A61M 25/10*** (2006.01) , *A61B 18/04* (2006.01)

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)

IPC7: A61M, A61B

USPC: 606/21, 606/22, 606/23, 604

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

Electronic database(s) consulted during the international search (name of database(s) and, where practicable, search terms used)

DELPHION, ESP@CENET, CPD

KEYWORDS: cryo*, mesh, memory, balloon, expand*

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6811550 B2 (HOLLAND, T. et al.) 02 November 2004 (02-11-2004) *Col. 6, line 10 - Col. 7, line 53; Fig. 3A; Figs 11A-11C*	1, 2, 5, 6, 8, 9, 12-14
Y		3, 4, 7, 10, 11, 15
X	WO 03/039338 A2 (IMETRX, INC.) 15 May 2003 (15-05-2003) *Paras. 0044 & 0046; Paras. 0064–0066; Figs 10A-10C*	1, 8, 9, 12-14
X	US 5772681 A (LEONI, G.) 30 June 1998 (30-06-1998) *Col. 3, line 53 - Col. 4, line 15*	1-3, 5, 6, 8, 9, 12-14
X	US 5910154 A (TSUGITA, R. et al.) 08 June 1999 (08-06-1999) *Col. 7, lines 15-40; Col. 8, lines 3-30; Col. 9, lines 40-57; Col. 10, lines 04-52; Figs. 1, 12A-12B, 13, 18-18B*	1-6, 8, 9, 12-14
Y	US 6312407 B1 (ZADNO-AZIZI, G. et al.) 06 November 2001 (06-11-2001) *Col. 4, lines 8-21 & 44-50; Col. 5, line 55 - Col. 6, line 3; Col. 6, line 62 - Col. 7, line 12; Fig. 8*	3, 4, 7, 10, 11, 15

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

[X] See patent family annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
18 October 2007 (18-10-2007)	22 October 2007 (22-10-2007)

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