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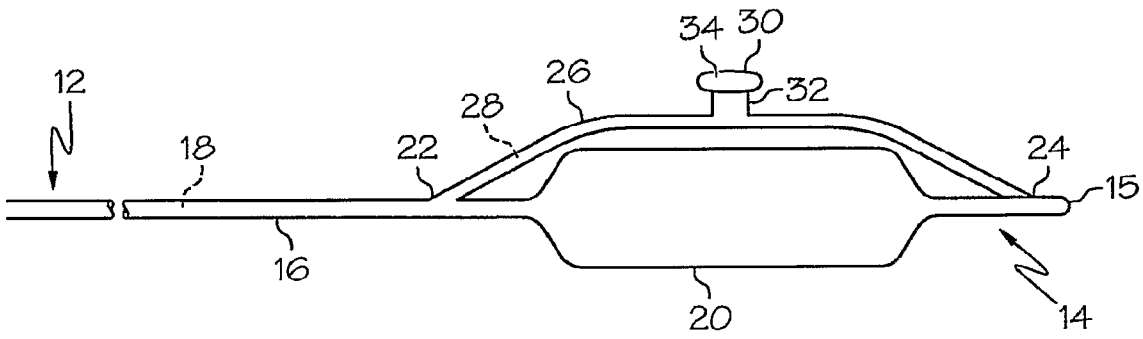

(57) Abstract: A balloon catheter (10) may comprise a primary inflation balloon (20) and a secondary inflation balloon (30) located to one side of the primary inflation balloon. The secondary balloon comprises a first portion and a second portion, the first portion located closer to the primary balloon. The second portion has a greater size than the first portion, and a portion of the second portion extends outwardly beyond the first portion and overhangs the first portion. In some embodiments, a cross-sectional shape of the secondary balloon in an inflated state comprises a mushroom shape.

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AUXILIARY BALLOON CATHETER

CROSS-REFERENCE TO RELATED APPLICATIONS

Not Applicable

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH

Not Applicable

BACKGROUND OF THE INVENTION

Field of the Invention

In some embodiments this invention relates to implantable medical devices, their manufacture, and methods of use. Some embodiments are directed to delivery systems, such as catheter systems of all types, which are utilized in the delivery of such devices. Some embodiments are directed to the manufacture and preparation of said delivery systems.

Description of the Related Art

Within the vasculature, it is not uncommon for stenoses to form at a vessel bifurcation. A bifurcation is an area of the vasculature or other portion of the body where a first (or parent) vessel is bifurcated into two or more branch vessels. Where a stenotic lesion or lesions form at such a bifurcation, the lesion(s) can affect only one of the vessels (i.e., either of the branch vessels or the parent vessel) two of the vessels, or all three vessels. Many prior art stents however are not wholly satisfactory for use where the site of desired application of the stent is juxtaposed or extends across a bifurcation in an artery or vein such, for example, as the bifurcation in the mammalian aortic artery into the common iliac arteries.

Stents intended for deployment at a vessel bifurcation often require specialized delivery systems that include more parts than a traditional delivery catheter. While auxiliary portions of a delivery system have been successful in expanding portions of stents into a side branch vessel, there remains a need for devices that are particularly suitable for expanding stents at a bifurcation to achieve an ideal expanded configuration.

The art referred to and/or described above is not intended to constitute an

admission that any patent, publication or other information referred to herein is "prior art" with respect to this invention. In addition, this section should not be construed to mean that a search has been made or that no other pertinent information as defined in 37 C.F.R. §1.56(a) exists.

All US patents and applications and all other published documents mentioned anywhere in this application are incorporated herein by reference in their entirety.

Without limiting the scope of the invention a brief summary of some of the claimed embodiments of the invention is set forth below. Additional details of the summarized embodiments of the invention and/or additional embodiments of the invention may be found in the Detailed Description of the Invention below.

A brief abstract of the technical disclosure in the specification is provided as well only for the purposes of complying with 37 C.F.R. 1.72. The abstract is not intended to be used for interpreting the scope of the claims.

BRIEF SUMMARY OF THE INVENTION

In at least one embodiment, the invention is directed to a balloon catheter comprising a catheter shaft having an internal catheter lumen, a primary balloon, a side branch shaft having an internal branch lumen and a secondary balloon. The secondary balloon comprises an inflatable body portion having an internal volume in fluid communication with the branch lumen. The inflatable body portion comprises a first portion and a second portion, the first portion being located closer to the primary balloon than the second portion. The first portion comprises a substantially tubular shape. The second portion has a larger cross-sectional area than the first portion.

In at least one other embodiment, the invention is directed to a balloon catheter comprising a catheter shaft having an internal catheter lumen, a primary balloon, a side branch shaft having an internal branch lumen and a secondary balloon. The secondary balloon comprises an inflatable body portion having an internal volume in fluid communication with the branch lumen. The inflatable body portion comprises a first portion and a second portion, the first portion being located closer to the primary balloon than the second portion. A first maximum distance measured across the first portion is less than a second maximum distance measured across the second portion.

The first maximum distance is measured at a location in the lower half of the height of the secondary balloon and the second maximum distance is measured at a location in the upper half of the height of the secondary balloon.

In at least one other embodiment, the invention is directed to a balloon catheter comprising a catheter shaft having an internal catheter lumen, a primary balloon, a side branch shaft having an internal branch lumen and a secondary balloon. The secondary balloon comprises an inflatable body portion having an internal volume in fluid communication with the branch lumen. The inflatable body portion comprises a first portion and a second portion, the first portion being located closer to the primary balloon than the second portion. The second portion has a larger cross-sectional area than the first portion, and the secondary balloon comprises a non-spherical shape.

In at least one other embodiment, the invention is directed to a method comprising providing a balloon catheter having a primary balloon, a secondary balloon and a stent. The secondary balloon is located beside the primary balloon. The secondary balloon comprises a first portion and a second portion, the second portion in an inflated state having a larger cross-sectional area than the first portion. The first portion is located closer to the primary balloon than the second portion. The stent comprises an outwardly expandable side branch petal structure. The stent is oriented about the balloon catheter with the secondary balloon positioned beneath the petal structure. The method further comprises delivering the stent to a deployment site at a vessel bifurcation having a side branch vessel, inflating the primary balloon to expand the stent, and inflating the secondary balloon to unfold the petal structure into the side branch vessel.

These and other embodiments which characterize the invention are pointed out with particularity in the claims annexed hereto and forming a part hereof. However, for further understanding of the invention, its advantages and objectives obtained by its use, reference can be made to the drawings which form a further part hereof and the accompanying descriptive matter, in which there is illustrated and described a embodiments of the invention.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S)

A detailed description of the invention is hereafter described with specific reference being made to the drawings.

Figure 1 shows an embodiment of a catheter having a shaped secondary balloon.

Figure 2 shows an embodiment of a catheter expanding a stent.

Figure 3 shows a cross-sectional view of an embodiment of a secondary balloon, as well as stent elements being unfolded by the secondary balloon.

Figure 4 shows an embodiment of a secondary balloon that assumes one inflated configuration at a first inflation pressure and a second inflated configuration at a second inflation pressure.

Figure 5 shows a cross-sectional view of another embodiment of a secondary balloon.

Figure 6 shows a cross-sectional view of another embodiment of a secondary balloon.

Figure 7 shows a cross-sectional view of another embodiment of a secondary balloon.

DETAILED DESCRIPTION OF THE INVENTION

While this invention may be embodied in many different forms, there are described in detail herein specific embodiments of the invention. This description is an exemplification of the principles of the invention and is not intended to limit the invention to the particular embodiments illustrated.

For the purposes of this disclosure, like reference numerals in the figures shall refer to like features unless otherwise indicated.

Figure 1 shows an embodiment of a balloon catheter 10 having a shaped secondary balloon 30. The catheter 10 comprises an elongate shaft 16 having an internal lumen 18 extending therethrough. The shaft 16 has a proximal portion 12 and a distal portion 14 that includes a tip 15. In some embodiments, a tip 15 may be softer and/or more flexible than other portions of the shaft 16.

A primary inflation balloon 30 is located in proximity to the distal portion 14 of the shaft 16. An internal volume of the primary balloon 20 is in fluid communication with the internal lumen 18 of the shaft 16, thus allowing the primary balloon 30 to be inflated and deflated.

The secondary balloon 30 is attached to a secondary shaft 26 having an internal lumen 28. An internal volume of the secondary balloon 30 is in fluid

communication with the internal lumen 28. A proximal end of the secondary shaft 26 connects to the catheter shaft 16 at a proximal connection location 22, and a distal end of the secondary shaft 26 connects to the catheter shaft 16 at a distal connection location 24. The proximal connection location 22 is located proximal to the primary balloon 20, and the distal connection location 24 is located distal to the primary balloon 20.

In some embodiments, the internal lumen 28 of the secondary shaft 26 is in fluid communication with the internal lumen 18 of the catheter shaft 16. Thus, in some embodiments, the secondary balloon 30 is arranged to inflate and/or deflate simultaneously with the primary balloon 30. In some embodiments, the connection between the two lumens 18, 28 is made at the proximal connection location 22, while the secondary shaft 26 is sealed at the distal connection location 24 or anywhere along the length of the secondary shaft 26 distal to the secondary balloon 30.

In some other embodiments, the secondary balloon 30 is arranged to be inflatable and deflatable independently from the primary balloon 20. In such embodiments, the catheter shaft 16 is provided with a second internal lumen that is in fluid communication with the secondary shaft lumen 28. A second internal lumen of the catheter shaft 16 can extend from the proximal connection location 22 to the proximal end 12 of the shaft 16. Some examples of multiple lumen catheters are discussed in published U.S. Patent Publication No. US2003/0163082, the entire disclosure of which is incorporated herein by reference in its entirety.

The secondary balloon 30 includes a first portion 32 and a second portion 34. In some embodiments, the second portion 34 is stacked above the first portion 32 such that the second portion 34 is located farther away from the catheter shaft 16 and the primary balloon 20 than the first portion 32, for example as measured in a direction radial to the catheter shaft 16. The second portion 34 is generally larger than the first portion 32 across at least one dimension, and in some embodiments, across at least two dimensions. In some embodiments, an internal volume of the second portion 34 is greater than an internal volume of the first portion 32. In some embodiments, the secondary balloon 30 comprises a three-dimensional "mushroom" shape.

Figure 2 shows an embodiment of a balloon catheter 10 expanding a stent 48. The stent 48 comprises a main cylindrical framework portion 21 and a plurality of outwardly deployable side branch petal structures 23. The main cylindrical framework portion 21 is expanded in diameter as the primary balloon 20 is inflated.

The side branch petals 23 are further outwardly deployed as the secondary balloon 30 is inflated.

Figure 3 shows a cross-sectional view of an embodiment of a secondary balloon 30. A first side 40 and a second side 42 of the balloon 30 are symmetrical across a secondary balloon central axis 11. In some embodiments, for example when the secondary balloon 30 comprises a circular cross-sectional shape, the first side 40 and the second side 42 comprise diametrically opposed regions. A diameter of the second portion 34 taken about the central axis 11 is larger than a diameter of the first portion 32. A distance across the second portion 34 as measured between opposing first 40 and second 42 sides is greater than a similar distance across the first portion 32.

The second portion 34 includes an outwardly extending portion 44 that extends outwardly in a radial direction with respect to the central axis 11. The outwardly extending portion 44 forms an outward inclination that overhangs the first portion 32.

In some embodiments, the first portion 32 includes sidewall portions 33 that extend substantially parallel to the central axis 11. In some embodiments, the first portion 32 is substantially tubular in shape. In some embodiments, the first portion 32 is substantially cylindrical in shape.

In some embodiments, a first maximum distance d_1 measured across the first portion 32 is less than a second maximum distance d_2 measured across the second portion 34. The first maximum distance d_1 and the second maximum distance d_2 can be measured parallel to one another. The first maximum distance d_1 and the second maximum distance d_2 can also be measured orthogonal to the central axis 11.

The secondary balloon 30 defines a height h that can be measured in the radial direction of the catheter shaft 16. In some embodiments, the height h can be measured from a central axis of the secondary shaft 26 to the top of the secondary balloon 30. In some embodiments, the height h can be measured from the bottom of the first portion 32 to the top of the second portion 34. In some embodiments, the first portion 32 can define approximately a lower half of the height h and the second portion 34 can define approximately an upper half of the height h.

In some embodiments, the first maximum distance d_1 is located in a lower half of the height h, and the second maximum distance d_2 is located in an upper half of the height h. In some other embodiments, the second maximum distance d_2 can

be located in an upper 1/4 of the height h or even an upper 1/8 of the height h. The second maximum distance d_2 is generally located farther away from the primary balloon 20 than the first maximum distance d_1.

The secondary balloon 30 can be used to extend or unfold portions of a stent into a side branch vessel at a bifurcation. Some stents include a dedicated side branch structure, wherein a plurality of "petals" may be outwardly deployed by a secondary balloon 30. Some examples of stents with side branch petal structures are disclosed in U.S. Patent Publication Nos. US 2003/0163082 and US 2005/0060027, and U.S. Patent Application Nos. 11/138202, 11/138196 and 11/138022, the entire disclosures of which are hereby incorporated herein by reference in their entireties.

Figure 3 shows portions of a stent including a main cylindrical framework portion 21 and an outwardly expandable side branch petal portion 23. Each petal 23 is connected to the main framework 21 at a connection 27. Prior to outward deployment of the petals 23, each unexpanded petal 23a may be aligned with the framework portion 21 and may be oriented substantially parallel to the catheter shaft 16. The secondary balloon 30 would be in a deflated and folded state beneath the unexpanded petal 23a.

During inflation of the secondary balloon 30 and the resulting unfolding deployment of the petals 23, each petal 23 generally pivots about at least one pivot point 31, or in some embodiments, a rotation axis. In some embodiments, the pivot point 31 comprises a connection 27 as the connection 27 yields.

A rotation angle 25 comprises an angle measured about the pivot point/axis 31 between the unexpanded petal 23a configuration and the deployed petal 23 configuration. The shape of the secondary balloon 30 allows the rotation angle to be greater than 90 degrees. Various embodiments of a secondary balloon 30 are configured to provide any suitable rotation angle 26, for example ranging from 90 degrees to 150 degrees or more. In some embodiments, a secondary balloon 30 may be shaped to provide rotation angles of 100 degrees, 110 degrees, 120 degrees, 130 degrees, 140 degrees, etc.

A stent may include a first petal 23 and a second petal 29 that are located opposite one another across the side branch structure. A distance may be measured between the rotation point/axis 31 of the first petal 23 and the rotation point/axis 31a of the second petal 29. In some embodiments of a secondary balloon 30, a distance across

the first portion 32 between opposing first 40 and second 42 sides is less than the distance between the rotation points 31, 31a of opposing petals 23, 29. A distance across the second portion 34 as measured between opposing first 40 and second 42 sides is greater than the distance between the rotation points 31, 31a of opposing petals 23, 29.

A secondary balloon 30 may be made using any suitable method. In some embodiments, a balloon 30 is injection molded. In some embodiments, a balloon 30 is blow molded from a preform. In some embodiments, the preform comprises a tube that forms both the secondary shaft 26 and the secondary balloon 30. In some embodiments, a balloon 30 is formed using a layer-by-layer deposit process that uses electrostatic interaction between oppositely charged particle layers, for example as described in US Patent Application Nos. 11/085780, 10/849742 and 11/085780, the entire disclosures of which are hereby incorporated herein by reference in their entireties.

In some embodiments, further operations are performed on a secondary balloon 30 to achieve desired wall configurations. For example, material may be removed from certain portions of the balloon 30 wall to achieve desired strength or flexibility characteristics. In some embodiments, score lines may be formed in the balloon 30 wall to encourage predetermined folding patterns. Such operations include drilling, notching, punching, abrasive machining, water-jet machining, computer-numeric-control (CNC) machining, laser ablation, chemically dissolution, etc

The balloons according to the invention may be formed from any suitable balloon material which can be molded as described. Suitable classes of materials include, but are not limited to, polyolefins, polyamides (e.g. nylons or aramids), polyesters and copolyesters, polyurethanes, polyethers, polyimides, polycarbonates, etc. Copolymers are suitable for use as well.

Examples of suitable polyesters include, but are not limited to, polyethylene terephthalate (PET), polybutylene terephthalate (PBT), polyethylene naphthalate (PEN), etc.

HYTREL®, polyester-ester elastomers available from DuPont Wilmington, DE and ARNITEL® polyester-esters and polyether-esters available from DSM Engineering Plastics - Americas in Evansville, IN may also be employed herein. These polymers are available in different grades depending on desired balloon

properties.

PEBA block copolymers, such as poly(ether-block-amide) block copolymers available under the tradename of PEBAX® from Arkema in Paris, France, may be employed herein. PEBAX® is available in different grades, for example, 6333, 7033 and 7233 are all suitable depending on the balloon properties desired. Suitable polyamides include, but are not limited to, nylon 6, nylon 10, nylon 11 and nylon 12.

Polyurethanes are available commercially under the tradenames of ISOPLAST® and PELLETHANE® from Dow Chemical Co. in Midland, MI.

These and other suitable balloon materials are described in U.S. Patent Nos. 4906244, 5556383, 5792415, 5948345, 6086556and 6270522, the entire contents of which are incorporated by reference herein. The present invention is not limited by the polymeric material which may be employed herein.

Reinforcement materials such as liquid crystal polymers may also be employed herein. Liquid crystal polymers are described for use in balloons in U.S. Patent Nos. 6242063, 6284333 and 6596219, the entire contents of which are incorporated by reference herein.

The above lists are intended for illustrative purposes only, and not intended to limit the scope of the present invention. Selection of balloon materials is known to those of skill in the art.

In some embodiments, the second portion 34 is made from a different material than the first portion 32.

In some embodiments, the second portion 34 of a secondary balloon 30 will assume a first inflated shape at a first pressure and a second inflated shape at a second, higher pressure, while the first portion assumes substantially the same shape at both the first and second pressures. In some embodiments, the compliance of the second portion 34 is different from the compliance of the first portion 32, and thus the secondary balloon 30 comprises a stepped compliance balloon.

Figure 4 shows a sectional view of an embodiment of a secondary balloon 30 capable of assuming different shapes at different pressures. When the balloon 30 is inflated to a first pressure, the second portion 34 assumes a first inflated configuration 50, wherein the sidewall 33 of the second portion 34 is generally parallel to the sidewall 33 of the second portion 32. The second portion 34 generally comprises

an extension of the first portion 32, and a diameter of the second portion 34 is substantially equal to the diameter of the first portion 32.

As the balloon 30 is inflated to a higher pressure, the shape of the first portion 32 remains substantially the same, while the shape of the second portion 34 changes. The second portion 34 assumes a second inflated configuration 52, wherein the second portion 34 includes an outwardly extending portion 44 that overhangs the first portion 32.

Such balloons 30 that are capable of assuming different shapes at different pressures may be manufactured according to any suitable method. In some embodiments, the balloon 30 may be molded to the second inflated configuration 52 under heat and high pressure, allowed to shrink by reducing the internal pressure, and then molded to the first inflated configuration 50 at a moderate pressure. Some embodiments may further be manufactured according to the methods disclosed in US 6352551 to Wang, the entire disclosure of which is hereby incorporated herein by reference in its entirety. Some other embodiments may be made by selectively treating either the first portion 32 or the second portion 34, for example to selectively strengthen or weaken either portion 32, 34 as desired. In some embodiments, operations are performed on the first portion 32 to cause cross-linking, resulting in a first portion 32 that is more resistant to yielding and strain elongation. In some embodiments, the first portion 32 is reinforced, for example by placing an overcoating such as a tube about the first portion 32. A portion of a balloon 30 may further be reinforced according to methods disclosed in US Patent Application No. 11/265388 to Noddin, the entire disclosure of which is hereby incorporated herein by reference in its entirety.

In some embodiments, the primary balloon 20 and the secondary balloon 30 have cooperatively arranged compliance curves, wherein the balloons 20, 30 assume various predetermined shapes at various predetermined pressures. For example, in some embodiments, the primary balloon 20 reaches its full expanded configuration at a first pressure and the secondary balloon 30 reaches its full expanded configuration at a second, higher pressure. In some embodiments, the primary balloon 20 reaches its full expanded configuration at a first pressure and the secondary balloon 30 reaches a first expanded shape 50 at a second, higher pressure. Upon further inflation, the secondary balloon 30 will expand to a second expanded shape 52 at a third, even higher pressure.

Figure 5 shows a sectional view of another embodiment of a secondary balloon 30, wherein the central axis 11 is oriented at a non-perpendicular angle 35 to the secondary shaft 26. Various non-perpendicular embodiments have an angle 35 of any suitable amount, for example ranging from less than 20 degrees to just under 90 degrees. The length of a sidewall 33 of the first portion 32 is longer on a first side 40 than the length of an opposed sidewall of the first portion 32 on the second side 42. It should be noted that various non-perpendicular embodiments can be oriented in any suitable direction, for example being slanted toward the distal end of the catheter, being slanted away from the distal end of the catheter, or being slanted in a non-axial direction of the catheter, such as being slanted in a direction that is circumferential with respect to the catheter.

The non-perpendicular angle 35 is well suited for vessel bifurcations where an angle between a main branch vessel and a side branch vessel is less than 90 degrees. Desirably, the angle 35 may be selected to match an angle between the main branch vessel and the side branch vessel.

The non-perpendicular angle 35 is also suitable for high stent petal 23 rotation angles 25 (see Figure 3). Some embodiments are suitable for deploying petals 23 at rotation angles 25 of 170 degrees or more.

Figure 6 shows a sectional view of another embodiment of a secondary balloon 30, wherein the central axis 11 of the first portion 32 and the second portion 34 is oriented at a non-perpendicular angle 35 to the secondary shaft 26. The balloon 30 comprises a base portion 36 having a central axis 11 that extends at an angle 37 to the central axis 11 of the first portion 32. The central axis 11 of the base portion 36 extends perpendicular to the secondary shaft 26.

Figure 7 shows a sectional view of another embodiment of a secondary balloon 30, wherein the second portion 34 comprises an asymmetrical shape. The first side 40 of the second portion 34 comprises an extension of the sidewall 33 of the first portion 32 that extends substantially parallel to the sidewall 33 of the first portion 32. The second side 42 of the second portion 34 comprises an outwardly extending portion 44 that overhangs the first portion 32.

In some embodiments, the first and second portions 32, 34 assume a tubular, substantially symmetrical shape at a first inflation pressure, and the second

portion 34 will further expand to the asymmetrical shape having the outwardly extending portion 44 at a second, higher pressure.

The above disclosure is intended to be illustrative and not exhaustive. This description will suggest many variations and alternatives to one of ordinary skill in this art. The various elements shown in the individual figures and described above may be combined or modified for combination as desired. All these alternatives and variations are intended to be included within the scope of the claims where the term "comprising" means "including, but not limited to."

Further, the particular features presented in the dependent claims can be combined with each other in other manners within the scope of the invention such that the invention should be recognized as also specifically directed to other embodiments having any other possible combination of the features of the dependent claims. For instance, for purposes of claim publication, any dependent claim which follows should be taken as alternatively written in a multiple dependent form from all prior claims which possess all antecedents referenced in such dependent claim if such multiple dependent format is an accepted format within the jurisdiction (e.g. each claim depending directly from claim 1 should be alternatively taken as depending from all previous claims). In jurisdictions where multiple dependent claim formats are restricted, the following dependent claims should each be also taken as alternatively written in each singly dependent claim format which creates a dependency from a prior antecedent-possessing claim other than the specific claim listed in such dependent claim below.

This completes the description of the invention. Those skilled in the art may recognize other equivalents to the specific embodiment described herein which equivalents are intended to be encompassed by the claims attached hereto.

This PCT application claims priority from U.S. Application No. 11/508,692, filed on August 23, 2006, the entire contents of which is hereby incorporated by reference.

CLAIMS:

1. A balloon catheter comprising:

a catheter shaft having an internal catheter lumen;

a primary balloon;

a side branch shaft having an internal branch lumen; and

a secondary balloon comprising:

an inflatable body portion having an internal volume in fluid communication with the branch lumen, the inflatable body portion comprising a first portion and a second portion, the first portion comprising a substantially tubular shape, the second portion having a larger cross-sectional area than the first portion, the first portion located closer to the primary balloon than the second portion.

2. The balloon catheter of claim 1, wherein a central axis of the secondary balloon is oriented at a nonperpendicular angle to a central axis of the primary balloon.

3. The balloon catheter of claim 1, wherein the second portion comprises an outwardly extending portion that overhangs the first portion.

4. The balloon catheter of claim 1, wherein a cross-sectional shape of the secondary balloon comprises a mushroom shape.

5. The balloon catheter of claim 1, wherein a cross-section of a sidewall of the second portion comprises a C-shape.

6. The balloon catheter of claim 1, wherein the second portion comprises a shape that is asymmetrical across a central axis of the secondary balloon.

7. The balloon catheter of claim 1, wherein the secondary balloon comprises a stepped compliance balloon.

8. The balloon catheter of claim 1, wherein the secondary balloon comprises a substantially cylindrical shape at a first inflation pressure.

9. The balloon catheter of claim 8, wherein the secondary balloon comprises a non-cylindrical shape at a second, higher inflation pressure.

10. The balloon catheter of claim 9, wherein the second portion assumes a shape having an outwardly extending portion that overhangs the first portion at said second, higher inflation pressure.

11. The balloon catheter of claim 1, wherein an internal volume of the second portion is greater than an internal volume of the first portion.

12. The balloon catheter of claim 1, the secondary balloon constructed and arranged to unfold a side branch petal structure of a stent into a side branch vessel, the petal structure pivoting at least 100 degrees as the secondary balloon is inflated.

13. The balloon catheter of claim 1, wherein the internal catheter lumen is in fluid communication with the internal branch lumen.

14. The balloon catheter of claim 1, the catheter shaft further comprising a second internal lumen in fluid communication with the internal branch lumen.

15. A balloon catheter comprising:

a catheter shaft having an internal catheter lumen;

a primary inflation balloon;

a side branch shaft having an internal branch lumen; and

a secondary inflation balloon comprising:

an inflatable body portion having an internal volume in fluid communication with the branch lumen, the inflatable body portion comprising a first portion and a second portion, the first portion located closer to the primary inflation balloon than the second portion, a first maximum distance measured across the first portion being less than a second maximum distance measured across the second portion;

wherein the inflatable body portion defines a height including a lower half and an upper half, the first maximum distance is measured at a location in the lower half of the height and the second maximum distance is measured at a location in the upper half of the height.

16. A method comprising:

providing a balloon catheter having a primary balloon, a secondary balloon and a stent, the secondary balloon located beside the primary balloon, the secondary balloon comprising a first portion and a second portion, the first portion comprising a substantially tubular shape, the second portion in an inflated state having a larger cross-sectional area than the first portion, the first portion located closer to the primary balloon than the second portion, the stent comprising an outwardly expandable side branch petal structure, the stent oriented about the balloon catheter with the secondary balloon positioned beneath the petal structure;

delivering the stent to a deployment site at a vessel bifurcation having a side branch vessel;

inflating the primary balloon to expand the stent; and

inflating the secondary balloon to unfold the petal structure into the side branch vessel.

17. The method of claim 16, wherein the petal structure pivots at least 100 degrees.

18. The method of claim 16, the secondary balloon assuming a first inflated shape at a first inflation pressure and a second inflated shape at a second, higher pressure, a portion of the second portion overhanging the first portion in the second inflated shape.

19. The method of claim 18, wherein the petal structure pivots less than 90 degrees as the secondary balloon is inflated to the first inflated shape.

20. The method of claim 19, wherein the petal structure becomes pivoted at least 100 degrees from its original configuration as the secondary balloon is inflated to the second inflated shape.

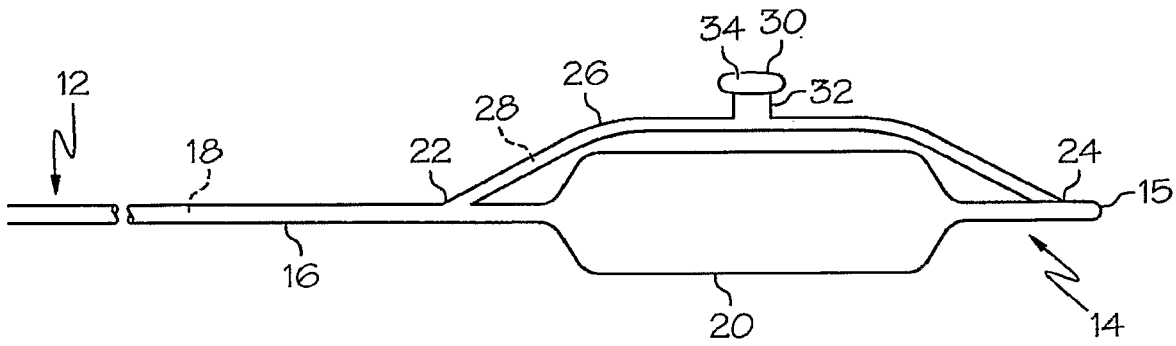
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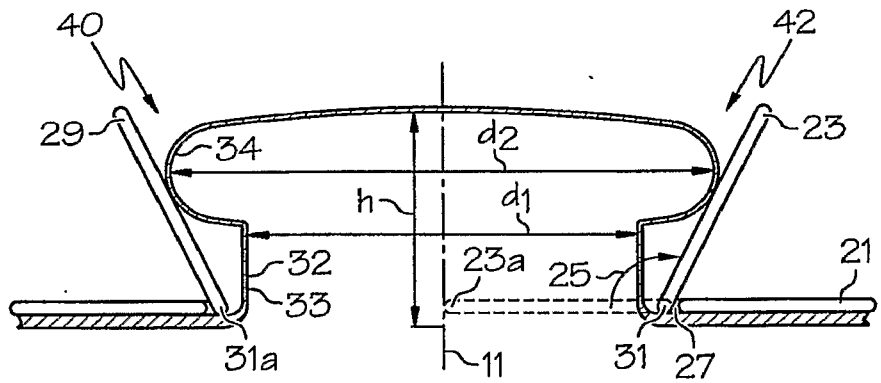
FIG. 1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34
23
d2
h
d1
32
33
23a
25
21
31a
11
31
27

FIG. 3

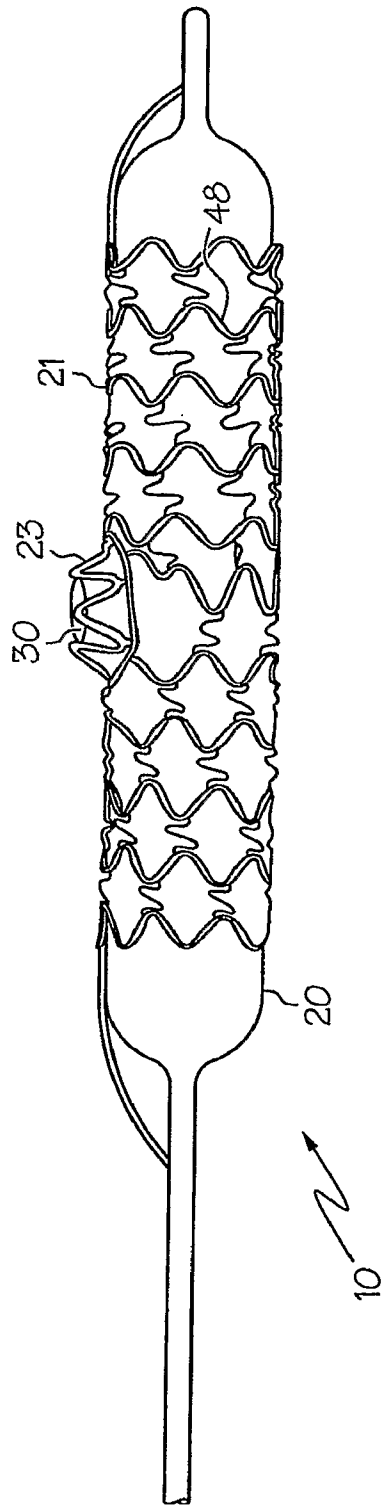

FIG. 2

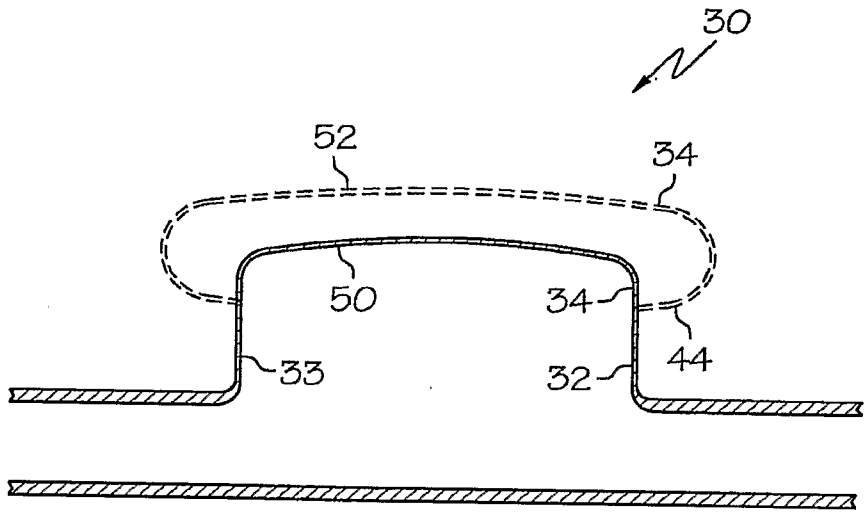

FIG. 4

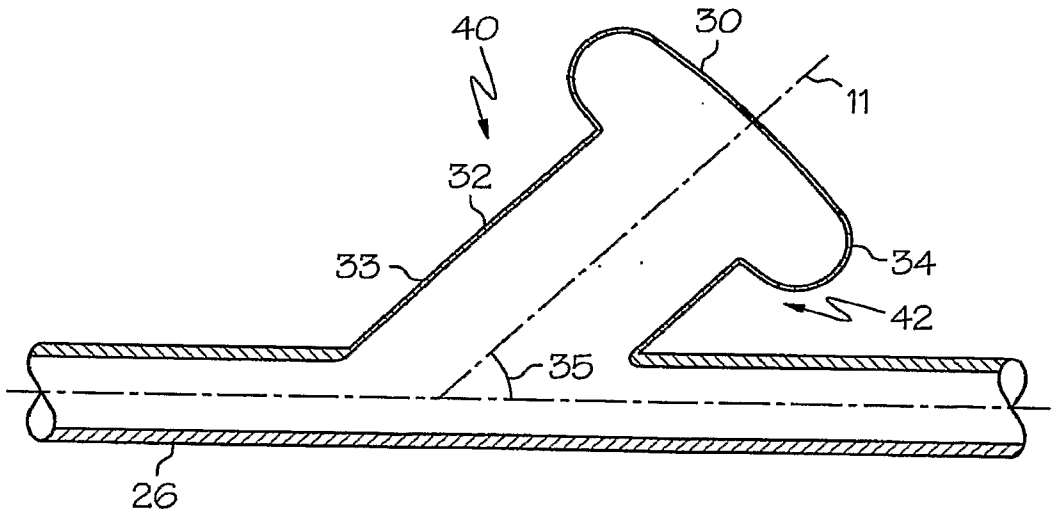

FIG. 5

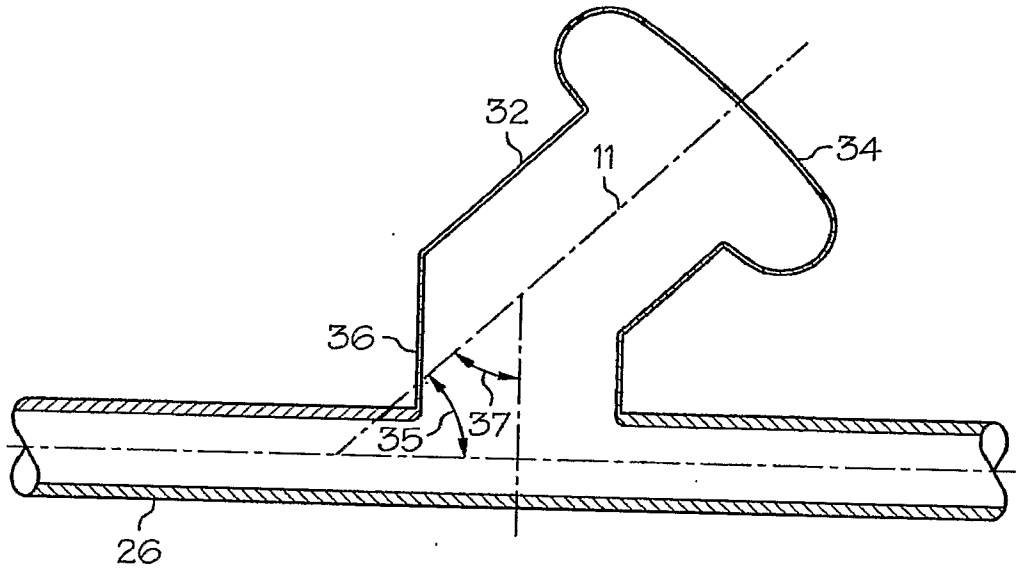

FIG. 6

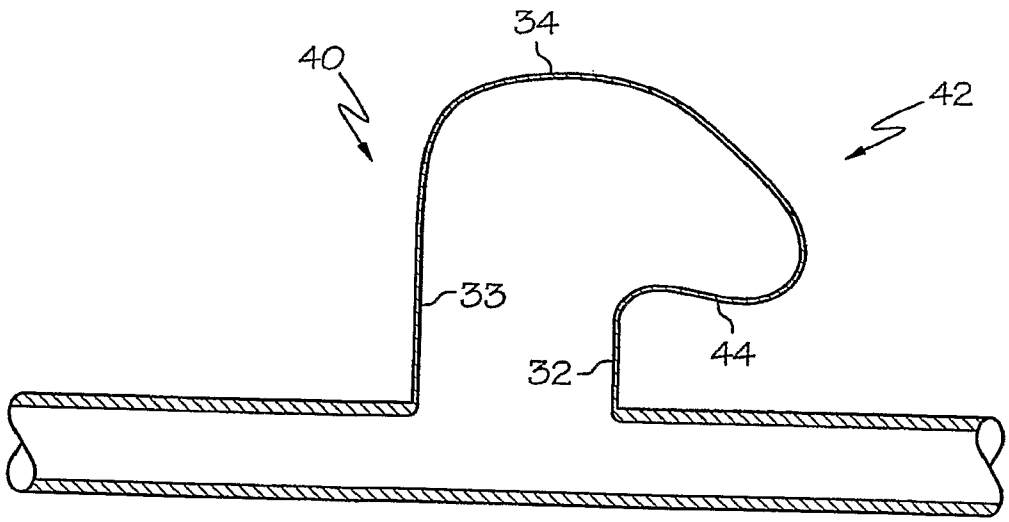

FIG. 7

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2007/017889

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M25/10 A61F2/84

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)
A61F A61M

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2006/053106 A (ADVANCED STENT TECH INC [US]) 18 May 2006 (2006-05-18) the whole document	1-4,8, 12-15
X	WO 03/074118 A (INVATEC S R L [IT]; VENTURELLI ANDREA [IT]) 12 September 2003 (2003-09-12)	1-6,8-15
Y	page 4, line 9 - page 6, line 13; figures 1-10	7
X	EP 1 369 097 A (CATHNET SCIENCE HOLDING AS [DK]) 10 December 2003 (2003-12-10) paragraphs [0027] - [0046]; figures 1-6	1-3,8, 11-15
X	WO 01/12255 A (WILSON COOK MEDICAL INC [US]) 22 February 2001 (2001-02-22) page 4, line 7 - page 6, line 18; figures 1-7	1,3,15

-/--

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

[X] See patent family annex.

* Special categories of cited documents :

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

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

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
16 January 2008	25/01/2008

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

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2007/017889

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A Y	US 2002/120320 A1 (WANG LIXIAO [US] ET AL) 29 August 2002 (2002-08-29) paragraphs [0047] - [0055]; figures 2-5	1,8-10 7
A	US 5 938 582 A (CIAMACCO JR SAM [US] ET AL) 17 August 1999 (1999-08-17) column 6, lines 7-12; figures 4,5	1,4
A	US 6 491 710 B2 (SATAKE SHUTARO [JP]) 10 December 2002 (2002-12-10) column 6, lines 9-11; figures 2,4.,5	1,4

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2007/017889

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 16-20
because they relate to subject matter not required to be searched by this Authority, namely:

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

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

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

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

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

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers allsearchable claims.

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

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

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

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

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

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2007/017889

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		US 2002029062 A1	07-03-2002