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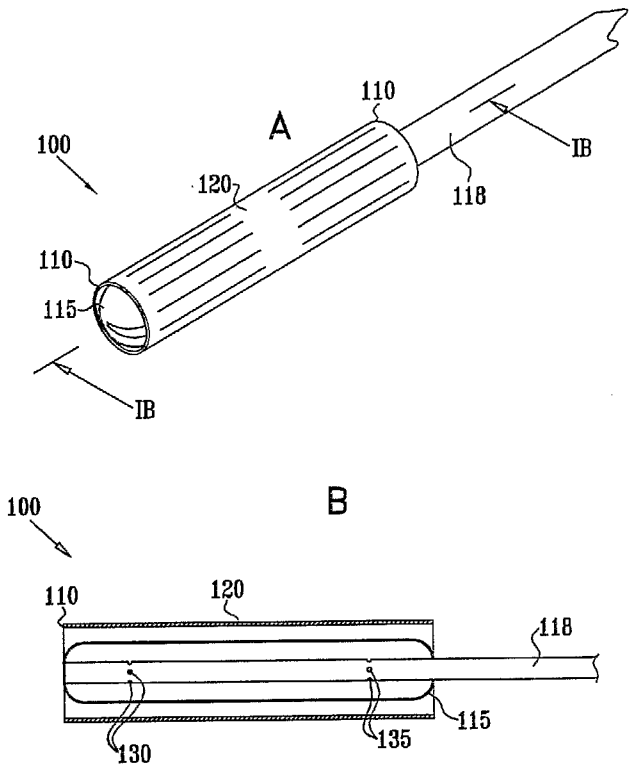
(54) Title: BALLOON INFLATION DEVICE



(57) Abstract: Apparatus for treatment of a body passage includes an expandable implant (100), including first and second expandable sections (110) and a central section (120) between the expandable sections. A balloon (115) is contained within the expandable implant. An inflation tube (118) is coupled to inflate the balloon via at least first and second inflation ports (130, 135), which are respectively disposed within the first and second expandable sections of the implant, such that pressurization of the balloon via the inflation tube causes the first and second expandable sections of the implant to expand to a greater diameter than the central section.

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BALLOON INFLATION DEVICE

CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims the benefit of U.S. Provisional Patent Application 60/696,857, filed July 5, 2005. This application is related to PCT Patent Application PCT/IL2003/000996, filed December 30, 2002 (published as WO 2004/058097), and to U.S. Patent Application 10/491,976, filed October 8, 2004 (published as US 2005/0055082). Both of these related applications are assigned to the assignee of the present patent application, and their disclosures are incorporated herein by reference.

BACKGROUND OF THE INVENTION

The above-mentioned US 2005/0055082 describes an implant for reducing blood flow in a blood vessel. The implant comprises a hollow element adapted for placement in the blood vessel defining a flow passage therethrough. The flow passage comprises at least two sections, one with a larger diameter and one with a smaller diameter, wherein the smaller diameter is smaller than the cross section of the blood vessel. In one embodiment, the implant is delivered by catheter into the coronary sinus of a patient, and is then expanded in place by inflating a balloon within the implant.

In a similar vein, the above-mentioned WO 2004/058097 describes a method for deploying an expandable implant in a body passage using a balloon having a radial dimension that varies, when the balloon is inflated, in accordance with the varying diameter of the body passage. The balloon is inserted, in a deflated state, into the body passage, with the expandable implant fitted radially around the balloon. The balloon is

inflated so as to cause the implant to open into an expanded shape that approximately matches the varying diameter of the body passage, thus anchoring the implant in the body passage. In an exemplary embodiment, the balloon is used to deploy an implant having expandable ends and a constricted central section in the coronary sinus.

SUMMARY OF THE INVENTION

Embodiments of the present invention provide methods and means for more efficient, secure inflation of implants having multiple expandable sections that are separated by an intervening section, such as those described in the above-mentioned publications.

There is therefore provided, in accordance with an embodiment of the present invention, apparatus for treatment of a body passage, including:

an expandable implant, including first and second expandable sections and a central section between the expandable sections;

a balloon, contained within the expandable implant; and

an inflation tube, coupled to inflate the balloon via at least first and second inflation ports, which are respectively disposed within the first and second expandable sections of the implant, such that pressurization of the balloon via the inflation tube causes the first and second expandable sections of the implant to expand to a greater diameter than the central section.

Typically, the central section is configured to maintain a narrower diameter than the first and second expandable sections when the balloon is inflated.

In a disclosed embodiment, the balloon and implant are adapted to be deployed through the vascular system by a catheter, which contains the inflation tube. The balloon and implant may be adapted to be deployed in a coronary sinus.

Optionally, the first inflation ports are larger than the second inflation ports. Additionally or alternatively, the inflation tube may contain a larger number of the first inflation ports than of the second inflation ports.

Typically, the inflation tube is adapted to deflate the balloon via the first and second inflation ports following expansion of the expandable sections of the implant.

In one embodiment, the implant is adapted so that full expansion of the balloon via the inflation ports causes the central section to expand so that the implant assumes a cylindrical shape.

There is also provided, in accordance with an embodiment of the present invention, a method for treatment of a body passage, including:

fitting an expandable implant over a balloon, the implant including first and second expandable sections and a central section between the expandable sections;

deploying the implant together with the balloon in the body passage; and

inflating the balloon via at least first and second inflation ports, which are respectively disposed within the first and second expandable sections of the implant, so as to cause the first and second expandable sections of the implant to expand to a greater diameter than the central section.

The present invention will be more fully understood from the following detailed description of the

embodiments thereof, taken together with the drawings in which:

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1A is a schematic, pictorial view of an exemplary implantable device in a non-expanded configuration, in accordance with an embodiment of the present invention;

Fig. 1B is a schematic sectional view of the device of Fig. 1A in the non-expanded configuration;

Fig. 2 is a schematic sectional view of the device of Fig. 1A during expansion of the device, in accordance with an embodiment of the present invention;

Fig. 3A is a schematic, pictorial view of the device of Fig. 1A in an expanded configuration, in accordance with an embodiment of the present invention;

Fig. 3B is a schematic sectional view of the device of Fig. 1A in the configuration of Fig. 3B; and

Fig. 4 is a schematic sectional view of an exemplary implantable device in an expanded configuration, in accordance with another embodiment of the present invention.

DETAILED DESCRIPTION OF EMBODIMENTS

Reference is now made to Figs. 1A and 1B, which schematically show, respectively, pictorial and sectional views of an implantable device 100 in a constricted state, in accordance with an embodiment of the present invention. Device 100 is adapted for use particularly in restricting blood flow through the coronary sinus, as described in the above-mentioned publications, as well as in PCT Publication WO 01/72239 and U.S. Patent 6,953,476, whose disclosures are incorporated herein by reference. Alternatively, devices in accordance with the principles of the present invention may be implanted elsewhere in the vascular system, as well as in other body passages. For the sake of simplicity and clarity, however, and not limitation, embodiments of the present invention are described hereinbelow with reference to implantation of flow-constricting devices in the coronary sinus.

Device 100 is of generally tubular construction with two expandable ends 110 and a central section 120. Alternatively or additionally, device 100 may comprise a mesh or coil. Ends 110 of device 100 comprise a deformable material, such as a suitable metal or plastic, as is known in the art, which is sufficiently flexible to be expanded by inflation of a balloon 115 within the device, but strong enough to hold its shape when it is deployed and expanded within a body passage. Central section 120, on the other hand, is constructed and/or externally constrained so as to maintain a narrower diameter than ends 110 even when balloon 115 is inflated. Further details of the construction and deployment of device 100 are described in the above-mentioned patent applications and publications.

Typically, device 100 is crimped over balloon 115, which is connected via an inflation tube 118 to a

pressurized fluid source outside the body. Ports 130 and 135 in the outer surface of inflation tube 118 permit fluid to flow between the inflation tube and balloon 115 at two or more locations along the length of the inflation tube. The locations are typically chosen so that at least one port or set of ports is located within each of ends 110. Inflation tube 118 may be contained within a catheter (not shown) that is used to pass device 100, together with balloon 115, through the vascular system to the location at which device 100 is to be implanted, such as the coronary sinus.

Fig. 2 is a schematic sectional view of device 100 during inflation of balloon 115, in accordance with an embodiment of the present invention. To inflate the balloon, pressurized fluid flows into the balloon through ports 130 and 135. Each lobe of the balloon, to either side of central section 120, is inflated via its own dedicated ports. As a result, both lobes of the balloon - both proximal and distal to central section 120 - are inflated simultaneously with roughly the same pressure.

If inflation ports were provided on only one side of central section 120, that side of the balloon would inflate more rapidly than the other, since passage of the inflation fluid to the other side would be inhibited, or possibly blocked entirely, by narrow central section 120 of device 100. Under such circumstances, there is a risk that device 100 might shift proximally or distally relative to the balloon during inflation, and/or that one of ends 110 might not be fully expanded. Inflating balloon 115 through both sets of ports 130 and 135 resolves these possible problems, and thus helps to ensure proper inflation of the balloon and correct, secure placement of device 100 in the proper location. Optionally, in order to provide a stronger flow of

inflation fluid in the distal lobe of the balloon than in the proximal lobe, the set of ports 130 may, for example, comprise a larger number of ports and/or ports of larger diameter than the set of ports 135. (Of course, these relations may be reversed to provide a stronger flow in the proximal lobe than in the distal.)

Figs. 3A and 3B schematically show, respectively, pictorial and sectional views of device 100, in its expanded state, in accordance with an embodiment of the present invention. Balloon 115 has been fully inflated, causing both ends 110 of device 100 to expand outward, while central section 120 remains constricted. Ends 110 anchor device 100 against the walls of the blood vessel (such as the coronary sinus) in which the device is deployed, while section 120 restricts the flow of blood through the vessel. At this stage, balloon 115 is typically deflated, by sucking the inflation fluid back via ports 130 and 135 through tube 118. The balloon and inflation tube are withdrawn from the body, leaving device 100 in place.

Fig. 4 is a schematic, sectional view of an implantable device 200 and balloon 210, in accordance with another embodiment of the present invention. In this case, device 200 is fully expanded over its entire length to assume a cylindrical shape, in the manner of conventional stents that are known in the art. Balloon 210 and device 200 are designed to permit such full expansion when the balloon is inflated via ports 130 and 135 to the appropriate pressure. In some cases, it is useful to design the implantable device and balloon so that the ends of the device are more pliable than the central section. Thus, when balloon 210 is partially inflated, device 200 will assume the general form shown in Fig. 2, before finally reaching the shape shown in

Fig. 4 upon full expansion. In this situation, the use of multiple spaced ports 130 and 135 is helpful, as described above, in ensuring that device 200 does not shift relative to balloon 210 and that device 200 is fully and properly expanded in the desired location.

Although the embodiments described above relate to certain particular clinical applications and balloon designs, the principles of the present invention may similarly be applied in conjunction with multi-lobed balloons of various other types and shapes. It will thus be appreciated that the embodiments described above are cited by way of example, and that the present invention is not limited to what has been particularly shown and described hereinabove. Rather, the scope of the present invention includes both combinations and subcombinations of the various features described hereinabove, as well as variations and modifications thereof which would occur to persons skilled in the art upon reading the foregoing description and which are not disclosed in the prior art.

CLAIMS

1. Apparatus for treatment of a body passage, comprising:

an expandable implant, comprising first and second expandable sections and a central section between the expandable sections;

a balloon, contained within the expandable implant; and

an inflation tube, coupled to inflate the balloon via at least first and second inflation ports, which are respectively disposed within the first and second expandable sections of the implant, such that pressurization of the balloon via the inflation tube causes the first and second expandable sections of the implant to expand to a greater diameter than the central section.

2. The apparatus according to claim 1, wherein the central section is configured to maintain a narrower diameter than the first and second expandable sections when the balloon is inflated.

3. The apparatus according to claim 1, wherein the balloon and implant are adapted to be deployed through the vascular system by a catheter, which contains the inflation tube.

4. The apparatus according to claim 3, wherein the balloon and implant are adapted to be deployed in a coronary sinus.

5. The apparatus according to claim 1, wherein the first inflation ports are larger than the second inflation ports.

6. The apparatus according to claim 1, wherein the inflation tube contains a larger number of the first inflation ports than of the second inflation ports.

7. The apparatus according to claim 1, wherein the inflation tube is adapted to deflate the balloon via the first and second inflation ports following expansion of the expandable sections of the implant.

8. The apparatus according to claim 1, wherein the implant is adapted so that full expansion of the balloon via the inflation ports causes the central section to expand so that the implant assumes a cylindrical shape.

9. A method for treatment of a body passage, comprising:

fitting an expandable implant over a balloon, the implant comprising first and second expandable sections and a central section between the expandable sections;

deploying the implant together with the balloon in the body passage; and

inflating the balloon via at least first and second inflation ports, which are respectively disposed within the first and second expandable sections of the implant, so as to cause the first and second expandable sections of the implant to expand to a greater diameter than the central section.

10. The method according to claim 9, wherein the central section is configured to maintain a narrower diameter than the first and second expandable sections when the balloon is inflated.

11. The method according to claim 9, wherein deploying the implant comprises conveying the balloon and the implant through the vascular system using a catheter,

which contains an inflation tube from which the inflation ports open into the balloon.

12. The method according to claim 11, wherein conveying the balloon and implant comprises deploying the implant in a coronary sinus.

13. The method according to claim 9, wherein the first inflation ports are larger than the second inflation ports.

14. The method according to claim 9, wherein the first inflation ports are more numerous than the second inflation ports.

15. The method according to claim 9, and comprising deflating the balloon via the first and second inflation ports following expansion of the expandable sections of the implant.

16. The method according to claim 9, wherein inflating the balloon comprises continuing to inflate the balloon via the inflation ports until the central section expands so that the implant assumes a cylindrical shape.

FIG. 1A

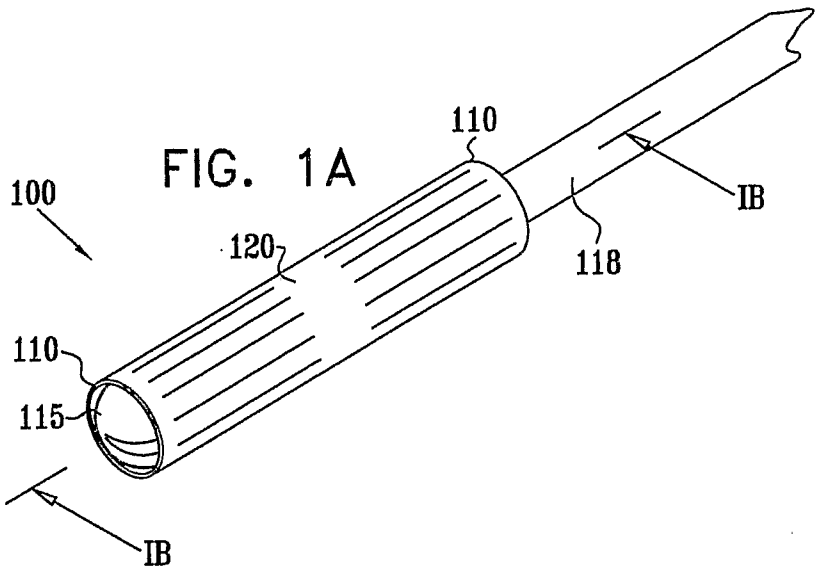

FIG. 1B

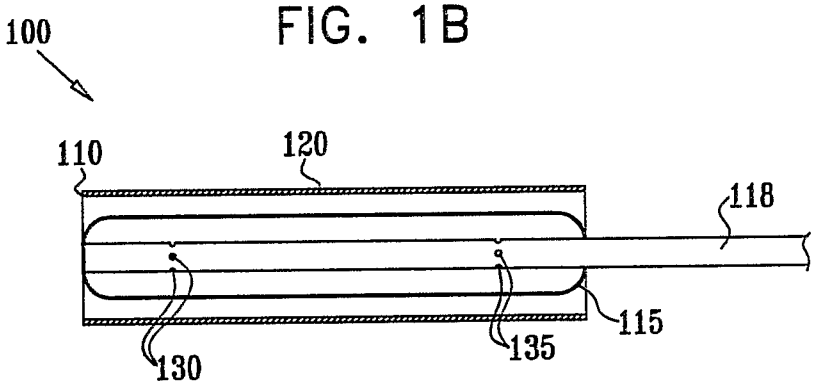

FIG. 2

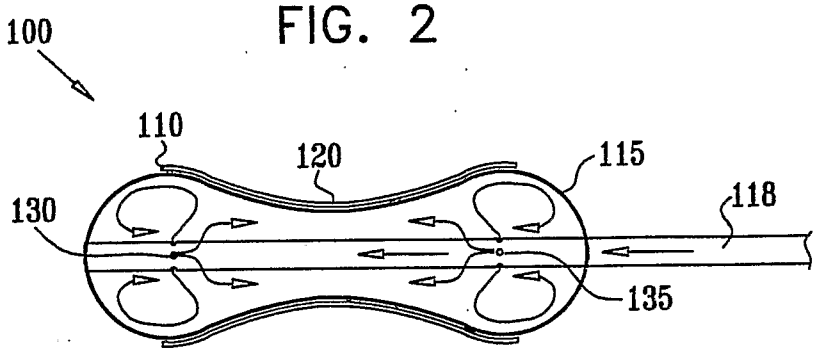

FIG. 3A

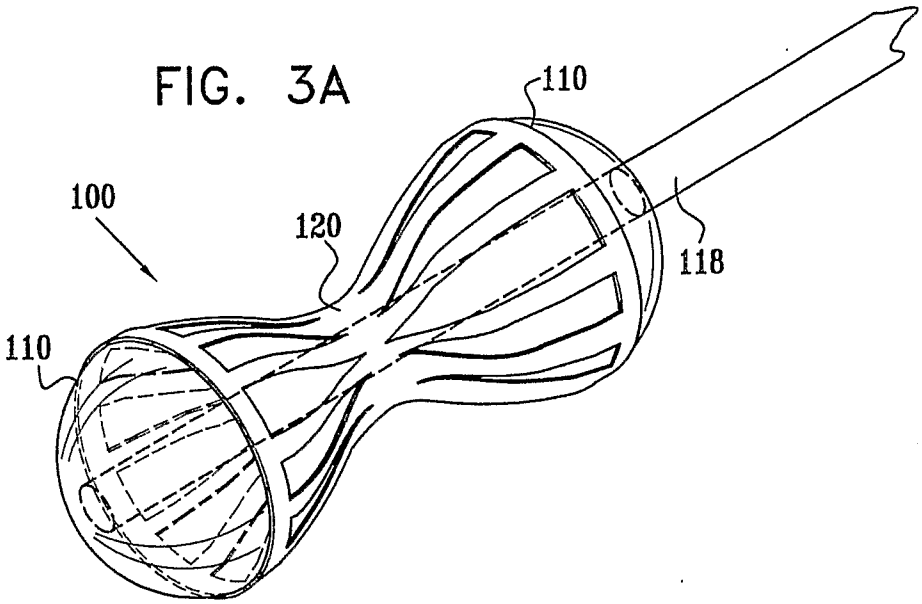

FIG. 3B

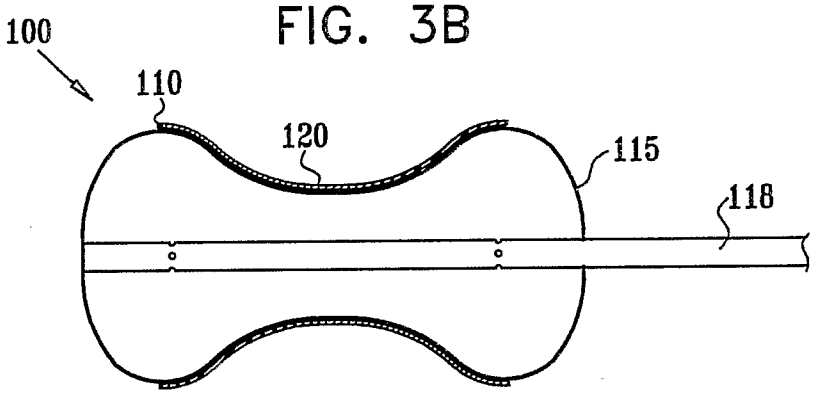

FIG. 4