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(54) Title: ANEURYSM DEVICES WITH ADDITIONAL ANCHORING MECHANISMS AND ASSOCIATED SYSTEMS AND METHODS

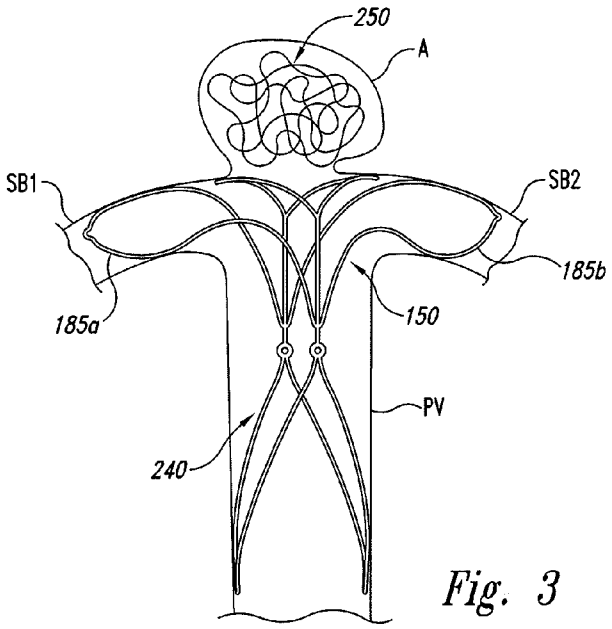

Fig. 3

(57) Abstract: The present technology relates to aneurysm devices with additional anchoring mechanisms, and associated systems and methods. In some embodiments, the aneurysm devices are endovascularly deliverable to a site proximate an aneurysm near a parent artery with bifurcating branches. The aneurysm devices can include a closure structure (102) comprising a distal- facing aspect configured to at least partially occlude the aneurysm and a proximal-facing aspect configured to arch over lumina of the bifurcating branches. The devices further include a supplemental stabilizer (103) connected to the closure structure. The supplemental stabilizer is configured to reside in the parent artery. The closure structure includes a hinge point (175) where the closure structure folds to form a loop element configured for anchoring within at least one of the bifurcating branches.

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ANEURYSM DEVICES WITH ADDITIONAL ANCHORING MECHANISMS AND ASSOCIATED SYSTEMS AND METHODS

CROSS-REFERENCE TO RELATED APPLICATION

[0001] The present application claims the benefit of pending U.S. Provisional Patent Application No. 61/493,356, filed on June 3, 2011, and incorporated herein by reference in its entirety.

TECHNICAL FIELD

[0002] The present technology relates to implantable therapeutic devices at a target site, such as an opening at a neck of an aneurysm. In particular, the present technology is generally directed to aneurysm devices with additional anchoring mechanisms and associated systems and methods.

BACKGROUND

[0003] Many of the currently available surgical approaches for closing openings and repairing defects in anatomical lumens and tissues (e.g., blood vessels), septal defects, and other types of anatomical irregularities and defects are highly invasive. Surgical methods for clipping brain aneurysms, for example, require opening the skull, cutting or removing overlying brain tissue, clipping and repairing the aneurysm from outside the blood vessel, and then reassembling tissue and closing the skull. The risks related to anesthesia, bleeding, and infection associated with these types of procedures are high, and tissue that is affected during the procedure may or may not survive and continue functioning.

[0004] Minimally invasive techniques for treating aneurysms are accordingly highly desirable. In general, the minimally invasive therapeutic objective is to prevent material that collects or forms in the aneurysm cavity from entering the bloodstream and to prevent blood from entering and collecting in the aneurysm. This is often accomplished by introducing various materials and devices into the aneurysm. For example, implantable vaso-occlusive metallic structures are well known and commonly used. Many conventional vaso-occlusive devices have helical coils constructed from a shape memory material or noble metal that forms a desired coil

configuration upon exiting the distal end of a delivery catheter. The function of the coil is to fill the space formed by an anatomical defect and to facilitate the formation of an embolus with the associated allied tissue. Multiple coils of the same or different structures may be implanted serially in a single aneurysm or other vessel defect during a procedure. Implantable framework structures are also used in an attempt to stabilize the wall of the aneurysm or defect prior to insertion of filling material such as coils.

[0005] It is crucial to accurately implant such vaso-occlusive devices within the internal volume of a cavity and to maintain the device within the internal volume of the aneurysm. Migration or projection of a vaso-occlusive device from the cavity may interfere with blood flow or nearby physiological structures and poses a serious health risk. In addition to the difficulties of delivering implantable occlusion devices, some types of aneurysms are challenging to treat because of structural features of the aneurysm or because of particularities of the site. Wide-neck aneurysms, for example, are known to present particular difficulty in the placement and retention of vaso-occlusive coils. Aneurysms at sites of vascular bifurcation are another example where the anatomical structure poses challenges to methods and devices that are effective in treating the typical sidewall aneurysms. It is therefore challenging to position conventional implantable devices during deployment, prevent shifting or migration of such devices after deployment, and preserve blood flow in neighboring vessels following after deployment.

BRIEF DESCRIPTION OF THE DRAWINGS

[0006] Figure 1 is a top plan view of an aneurysm device configured in accordance with an embodiment of the technology.

[0007] Figure 2 is a side view of the aneurysm device of Figure 1 in a partially deployed configuration.

[0008] Figure 3 is a view of the aneurysm device of Figures 1 and 2 deployed at the neck of an aneurysm and lodged at the bifurcated side artery branches.

DETAILED DESCRIPTION

[0009] The present disclosure describes implantable therapeutic devices and methods for endovascular placement of devices at a target site, such as an opening at a neck of an aneurysm.

In particular, selected embodiments of the present technology are directed to devices having additional anchoring mechanisms for lodging at bifurcated branches at the neck of the aneurysm. The following description provides many specific details for a thorough understanding of, and enabling description for, embodiments of the disclosure. Well-known structures, systems, and methods often associated with aneurysm treatment systems have not been shown or described in detail to avoid unnecessarily obscuring the description of the various embodiments of the disclosure. In addition, those of ordinary skill in the relevant art will understand that additional embodiments may be practiced without several of the details described below.

[0010] Figures 1 and 2 illustrate an embodiment of an aneurysm device 150 configured in accordance with the present technology. In particular, Figure 1 is a top plan view of the aneurysm device 150 in a substantially flat, pre-assembled configuration, and Figure 2 is a side view of the aneurysm device 150 in a deployed configuration. Referring to Figure 1, the aneurysm device 150 can comprise a closure structure 102 and a supplemental stabilizer or support 103 extending from the closure structure 102. The closure structure 102 can be a frame, scaffold, or other structure that at least partially occludes the neck of an aneurysm to prevent embolic coils or other coagulative material within the aneurysm from escaping into the bloodstream. The closure structure 102 includes a perimeter support 160 and an inner support 170. The perimeter support 160 and inner support 170 can be joined at junctions 162 and 164. The supplemental stabilizer 103 is shown in an unassembled stage in Figure 1. Once assembled, the proximally extending sides of the closure structure 102 and the supplemental stabilizer 103 hold the curved portion of the closure structure 102 at the neck of the aneurysm.

[0011] The aneurysm device 150 can have struts 180a-d projecting proximally from the junctions 162 and 164. Struts 180a and 180c can be connected at junction 162 and struts 180b and 180d are connected at junction 164 to form the supplemental stabilizer 103 with proximal anchoring segments. In one embodiment, the struts 180a-d each include a hinge point or bend point 175a-d. The hinge points 175a-d define collapse points and allow the struts 180a-d to preferentially fold down in a manner that forms additional supporting elements for the aneurysm device 150 that can be lodged in side artery branches at an aneurysm neck.

[0012] In the embodiment illustrated in Figure 1, the aneurysm device 150 is constructed from a substantially flat substrate by cutting, etching, stamping, or otherwise forming the framework of the closure structure 102, the unassembled supplemental stabilizer 103, and the

hinge points 175a-d. The closure structure 102 and the supplemental stabilizer 103 can be constructed from a flat sheet of material having substantially uniform thickness, but in other embodiments different regions of the sheeted material can have different thicknesses corresponding to the desired thickness for portions of the closure structure 102 and/or the supplemental stabilizer 103. Further, in other embodiments the aneurysm device 150 may be formed using different techniques and/or materials.

[0013] Figure 2 is a side view of the aneurysm device 150 in a partially deployed configuration. In particular, as the aneurysm device 150 is deployed from a delivery catheter 202, loop elements 185a and 185b form and begin to fully open. The loop elements 185a-b start to open as the delivery catheter 202 is being withdrawn and fully open when the delivery catheter 202 is fully withdrawn. As described in greater detail below with reference to Figure 3, the loop elements 185a-b are configured to provide a mechanism for the aneurysm device 150 to anchor in bifurcated side branches when deployed across the neck of an aneurysm. In other embodiments, the loop elements 185a-b can have a different arrangement and/or the aneurysm device 150 may include a different number of loop elements 185.

[0014] Figure 3 illustrates the aneurysm device 150 of Figures 1 and 2 deployed at the neck of an aneurysm A with anchoring legs 240. As mentioned above, when the aneurysm device 150 is deployed, the loop elements 185a-b open and can lodge in side branch vessels SB1 and SB 2, respectively. The lodging of the loop elements 185a-b within the side branch vessels SB 1 and SB 2 is expected to provide additional anchoring mechanisms for the aneurysm device 150 at the aneurysm A, and is expected to provide more secured lodging/deployment of the aneurysm device 150.

[0015] Figure 3 additionally illustrates the use of the aneurysm device 150 to retain debris and/or other materials, such as an embolic coil mass 250, within the aneurysm cavity. In one embodiment, for example, implantable devices of the present technology may be deployed to retain debris and/or previously placed materials within the aneurysm cavity. In another embodiment, implantable devices of the present technology may be deployed before placing materials, such as embolic materials, coils, and the like, in the aneurismal cavity, and then the materials may be placed through the openings in the closure structure. In this situation, the aneurysm device may be retracted following placement of the embolic materials, or it may be detached and left at the site.

Examples

1. An aneurysm device endovascularly deliverable to a site proximate an artery with bifurcating branches, the aneurysm device comprising:

a closure structure comprising a distal-facing aspect configured to at least partially block an opening to the aneurysm and a proximal-facing aspect configured to arch over lumina of the bifurcating branches; and

a supplemental stabilizer connected to the closure structure, the supplemental stabilizer configured to reside in the artery;

wherein the closure structure includes a hinge point at which the closure structure folds to form a loop element configured for anchoring within at least one of the bifurcating branches.

2. The aneurysm device of example 1 wherein the closure structure comprises struts.

3. The aneurysm device of example 2 wherein the hinge point is formed on one of the struts.

4. The aneurysm device of example 1 wherein the closure structure comprises four hinge points.

5. The aneurysm device of example 1 wherein the closure structure is transformable between a compressed configuration and a deployed configuration.

6. The aneurysm device of example 5, further comprising a catheter configured to retain the closure structure in the compressed configuration.

7. The aneurysm device of example 1 wherein the closure structure comprises two loop elements, each individual loop element configured to lodge in one of the bifurcating branches.

8. The aneurysm device of example 1 wherein the closure structure comprises a shape memory material.

9. A system for treating an aneurysm, the system comprising:

a distal framework portion comprising a distal-facing aspect configured to enclose the aneurysm, wherein the distal framework includes a plurality of struts, and wherein individual struts include a hinge point; and

a proximal support framework connected to the distal framework portion, the support framework configured to reside in the parent artery and biased to press outward against a luminal wall thereof.

10. The system of example 9, further comprising a delivery sheath configured to temporarily retain the distal framework in a compressed configuration.

11. The system of example 9 wherein the struts comprise a generally flexible material that preferentially bends at the hinge point.

12. The system of example 9 wherein the individual struts comprise a loop shape that bends at the hinge point.

13. The system of example 9 wherein the distal framework portion is formed from a generally flat, unassembled component into a three-dimensional, assembled component.

14. A method of treating an aneurysm located at a site proximate to a parent artery that bifurcates into downstream branches, the method comprising:

expanding an axially-compressed framework comprising a distal portion and a proximal portion at a site proximate to the aneurysm, wherein the distal portion comprises a plurality of struts having bend points; and

arching the distal portion of the framework unobtrusively over lumina of the downstream branches, wherein the struts comprise loops bent at the bend points, the loops configured to lodge in the downstream branches.

15. The method of example 14, further comprising forming the framework from a substantially flat material.

16. The method of example 14, further comprising delivering the framework to the site with a catheter, wherein delivering the framework comprises temporarily restraining the framework in a generally compressed configuration.

17. The method of example 14, further comprising extracting the framework from the parent artery.

18. The method of example 17 wherein extracting the framework comprises restraining the framework in a catheter in a generally compressed configuration.

19. The method of example 14, further comprising substantially enclosing the aneurysm with the distal portion of the framework.

20. The method of example 14, further comprising detaching the framework from a delivery device.

[0016] The above detailed descriptions of embodiments of the technology are not intended to be exhaustive or to limit the technology to the precise form disclosed above. Although specific embodiments of, and examples for, the technology are described above for illustrative purposes, various equivalent modifications are possible within the scope of the technology, as those skilled in the relevant art will recognize. For example, while steps are presented in a given order, alternative embodiments may perform steps in a different order. The various embodiments described herein may also be combined to provide further embodiments. In particular, the clot removal devices described above with reference to particular embodiments can include one or more additional features or components, or one or more of the features described above can be omitted.

[0017] From the foregoing, it will be appreciated that specific embodiments of the technology have been described herein for purposes of illustration, but well-known structures and functions have not been shown or described in detail to avoid unnecessarily obscuring the description of

the embodiments of the technology. Where the context permits, singular or plural terms may also include the plural or singular term, respectively.

[0018] Moreover, unless the word "or" is expressly limited to mean only a single item exclusive from the other items in reference to a list of two or more items, then the use of "or" in such a list is to be interpreted as including (a) any single item in the list, B all of the items in the list, or (c) any combination of the items in the list. Additionally, the term "comprising" is used throughout to mean including at least the recited feature(s) such that any greater number of the same feature and/or additional types of other features are not precluded. It will also be appreciated that specific embodiments have been described herein for purposes of illustration, but that various modifications may be made without deviating from the technology. Further, while advantages associated with certain embodiments of the technology have been described in the context of those embodiments, other embodiments may also exhibit such advantages, and not all embodiments need necessarily exhibit such advantages to fall within the scope of the technology. Accordingly, the disclosure and associated technology can encompass other embodiments not expressly shown or described herein.

CLAIMS

1. An aneurysm device endovascularly deliverable to a site proximate an artery with bifurcating branches, the aneurysm device comprising:

a closure structure comprising a distal-facing aspect configured to at least partially block an opening to the aneurysm and a proximal-facing aspect configured to arch over lumina of the bifurcating branches; and

a supplemental stabilizer connected to the closure structure, the supplemental stabilizer configured to reside in the artery;

wherein the closure structure includes a hinge point at which the closure structure folds to form a loop element configured for anchoring within at least one of the bifurcating branches.

2. The aneurysm device of claim 1 wherein the closure structure comprises struts.

3. The aneurysm device of claim 2 wherein the hinge point is formed on one of the struts.

4. The aneurysm device of claim 1 wherein the closure structure comprises four hinge points.

5. The aneurysm device of claim 1 wherein the closure structure is transformable between a compressed configuration and a deployed configuration.

6. The aneurysm device of claim 5, further comprising a catheter configured to retain the closure structure in the compressed configuration.

7. The aneurysm device of claim 1 wherein the closure structure comprises two loop elements, each individual loop element configured to lodge in one of the bifurcating branches.

8. The aneurysm device of claim 1 wherein the closure structure comprises a shape memory material.

9. A system for treating an aneurysm, the system comprising:

a distal framework portion comprising a distal-facing aspect configured to enclose the aneurysm, wherein the distal framework includes a plurality of struts, and wherein individual struts include a hinge point; and

a proximal support framework connected to the distal framework portion, the support framework configured to reside in the parent artery and biased to press outward against a luminal wall thereof.

10. The system of claim 9, further comprising a delivery sheath configured to temporarily retain the distal framework in a compressed configuration.

11. The system of claim 9 wherein the struts comprise a generally flexible material that preferentially bends at the hinge point.

12. The system of claim 9 wherein the individual struts comprise a loop shape that bends at the hinge point.

13. The system of claim 9 wherein the distal framework portion is formed from a generally flat, unassembled component into a three-dimensional, assembled component.

14. A method of treating an aneurysm located at a site proximate to a parent artery that bifurcates into downstream branches, the method comprising:

expanding an axially-compressed framework comprising a distal portion and a proximal portion at a site proximate to the aneurysm, wherein the distal portion comprises a plurality of struts having bend points; and

arching the distal portion of the framework unobtrusively over lumina of the downstream branches, wherein the struts comprise loops bent at the bend points, the loops configured to lodge in the downstream branches.

15. The method of claim 14, further comprising forming the framework from a substantially flat material.

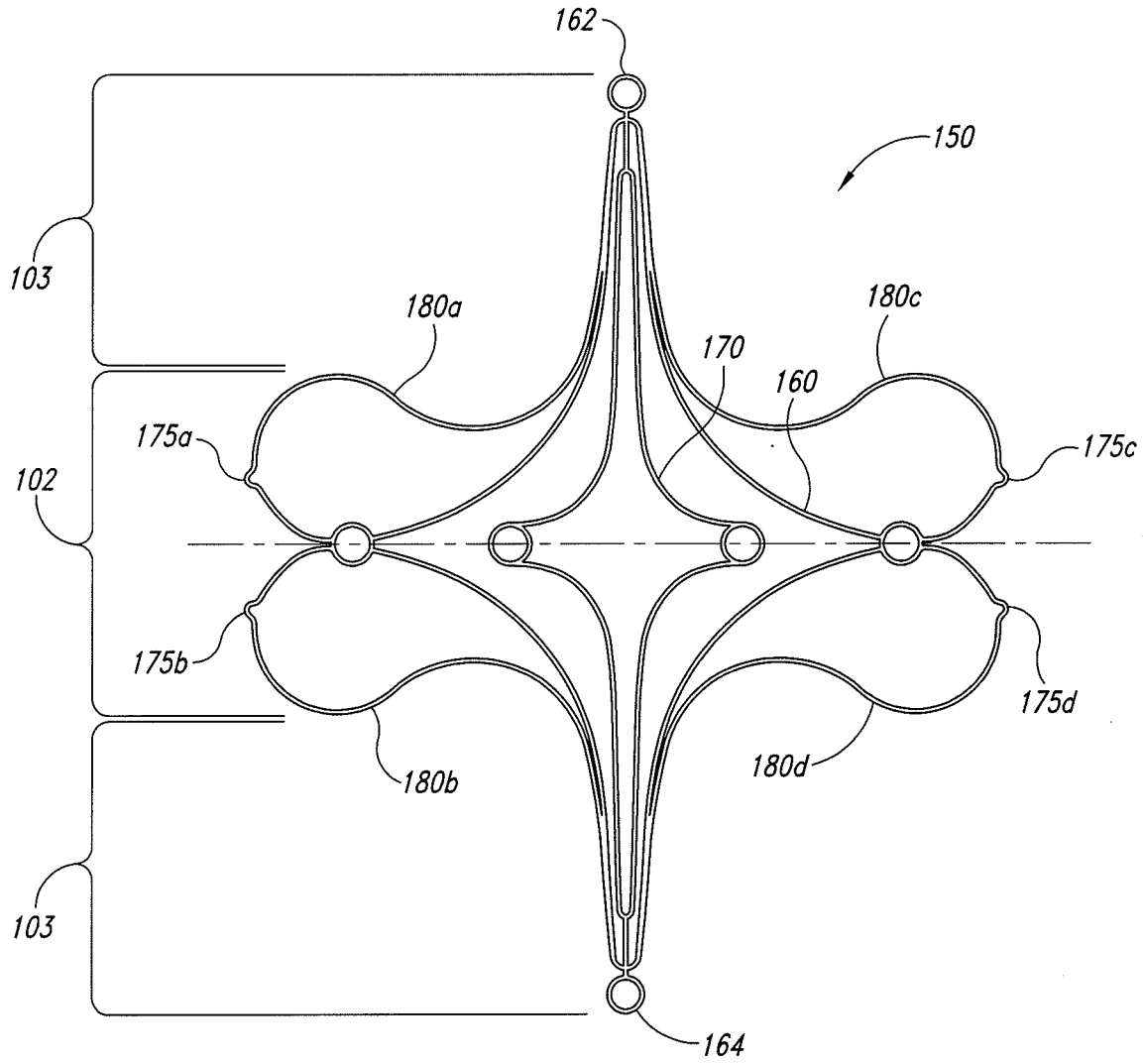
16. The method of claim 14, further comprising delivering the framework to the site with a catheter, wherein delivering the framework comprises temporarily restraining the framework in a generally compressed configuration.

17. The method of claim 14, further comprising extracting the framework from the parent artery.

18. The method of claim 17 wherein extracting the framework comprises restraining the framework in a catheter in a generally compressed configuration.

19. The method of claim 14, further comprising substantially enclosing the aneurysm with the distal portion of the framework.

20. The method of claim 14, further comprising detaching the framework from a delivery device.


162
150
103
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170
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102
175b
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164

Fig. 1

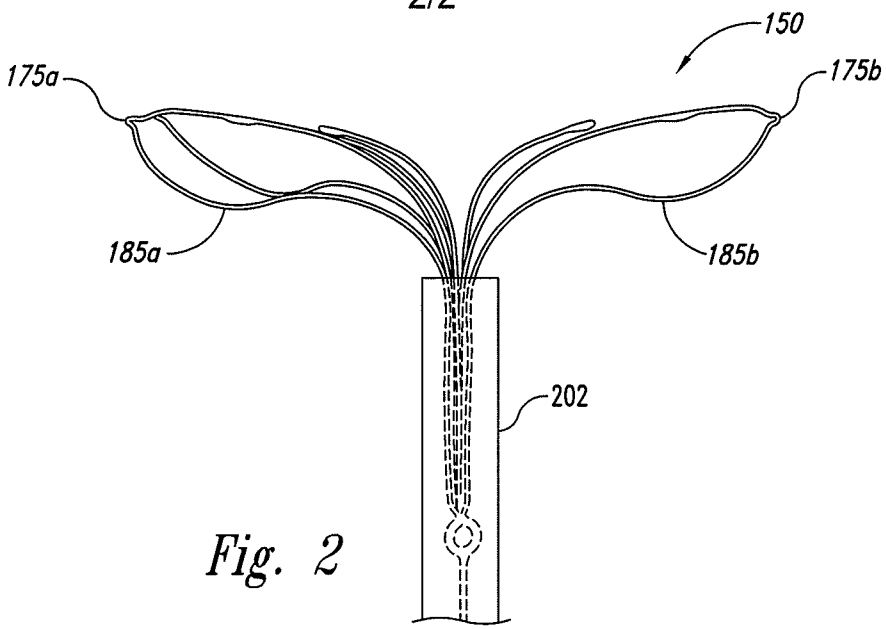

Fig. 2

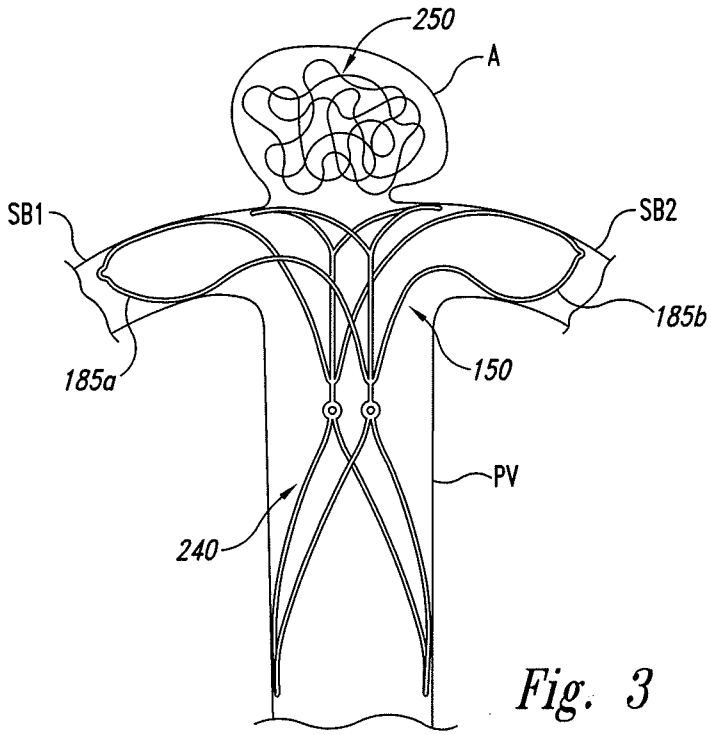

Fig. 3

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2012/040558

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/12
ADD.

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)
A61B

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

Electronic data base consulted during the international search (name of data base and, where practicable, 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 2011/029063 A2 (PULSAR VASCULAR INC [US]; CLARKE GILBERT [US]; GERBERDING BRENT [US];) 10 March 2011 (2011-03-10) the whole document -----	1-13
X	WO 2010/028314 A1 (PULSAR VASCULAR INC [US]; GERBERDING BRENT [US]; ABRAMS ROBERT M [US];) 11 March 2010 (2010-03-11) figures 2, 7,11,12-14 -----	1-13
X	DE 10 2008 028308 A1 (ACANDIS GMBH & CO KG [DE]) 23 April 2009 (2009-04-23) paragraph [0073] - paragraph [0077]; figure 7 -----	1-6,8-11
	-/--	

[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 application or patent 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
26 September 2012	08/10/2012

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, Fax: (+31-70) 340-3016	Herberhold, C

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Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2012/040558

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 2008/151204 A1 (SEQUENT MEDICAL INC [GB]; COX BRIAN J [US]; SCHAEFER DEAN [US]; ROSENB) 11 December 2008 (2008-12-11) page 34 - page 40; figures 20-24	1-13
A	EP 1 527 753 A2 (CORDIS NEUROVASCULAR INC [US]) 4 May 2005 (2005-05-04) figures 1-6	1-13

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2012/040558

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.: 14-20
because they relate to subject matter not required to be searched by this Authority, namely:

see FURTHER INFORMATION sheet PCT/ISA/210

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 all searchable 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 report covers only those claims for which fees were paid, specifically claims Nos.:

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

Remark on Protest

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

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 14-20

Claims 14-20 relate to a method of treating an aneurysm and comprises the steps of "expanding an axially -compressed framework ...at a site proximate to the aneurysm" and of "arching the distal portion of the framework unobtrusively over lumina of the downstream branches". Treatment of an aneurysm is a method of treatment by therapy. The particular steps of expanding the framework and arching the framework are performed in direct contact with the vessel wall and the aneurysm. Even if performed with the medical skills and the required care, these steps entail significant health risks as e.g. vessel perforation, bleeding and infection. The steps are thus of surgical nature. Consequently, the method is a method of the human or animal body by therapy and by surgery. No international search and no preliminary examination are required for such methods (Art. 17(2)(a)i, Rule 39.1(iv); Art. 34(4)(a)I, Rule 67.1(iv), PCTGL 9.08-9.10).

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2012/040558

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