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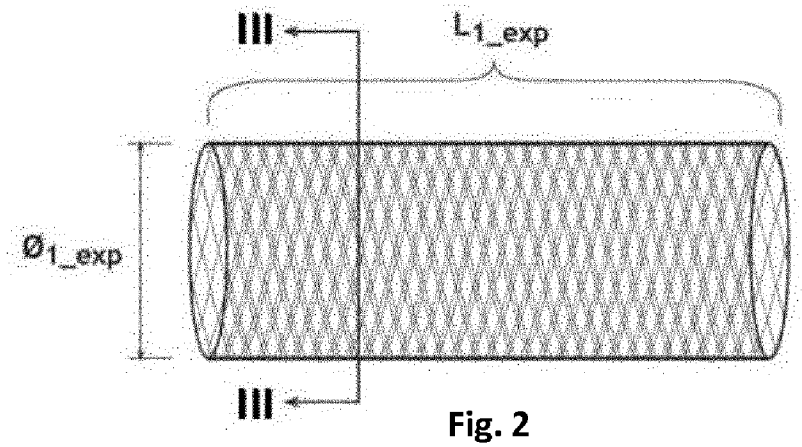

Fig. 2

(57) Abstract: The present invention refers to an implantable endoluminal prosthesis for use in the treatment of aneurysm involving branches having a multilayer configuration, comprising at least one self-expandable braided framework extending along an axis able to expand from a radially compressed state in a delivery configuration to a radially expanded state; the self-expandable braided framework being formed with at most 196 wires having a given wire diameter($Ø_{21}$); this self-expandable braided framework devoid of any impermeable cover layer,comprising a plurality of layers of wires made of biocompatible material; and forming a wall of the endoluminal prosthesis; each layer forming a mesh; the meshes forming a lattice with a plurality of wires of said layers; the meshes being interlocked, the wires being integrated in the mesh of at least one of the adjacent layers; the self-expandable braided framework comprising a lumen in a cylindrical form with a circular cross-section and a constant diameter; characterized in that, in radially expanded state, a ratio ($T_1/Ø_{21}$) of thickness (T_1) of a wall of the implantable endoluminal prosthesis in radially expanded state to the diameter ($Ø_{21}$) of wire (21) being greater than 3.0; and the surface coverage ratio (SCR) of said braided framework is at least 30% and at most 50%.

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IMPLANTABLE ENDOLUMINAL PROSTHESIS

Field of the invention

The present invention relates to implantable endoluminal prostheses. More particularly, it relates to an endoluminal prosthesis for treatment of aneurysm involving branches.

Background of the invention

Endovascular repair is known as a relatively new and minimally invasive technique for treatment of aortic aneurysm. It delivers an impermeable tube (graft) supported with metallic or plastic frame (stent) via a remote vessel. However, because of its impermeability, this technique cannot be applied to aneurysm repair in which the aneurysm involves important branches (e.g. the coronary arteries, the supra aortic branches, renal and middle suprarenal arteries, visceral arteries and internal iliac), otherwise it causes serious complications with occlusion of the branches.

Summary of the invention

A first object of the present invention is to provide a device implantable by endovascular approach for treatment of aneurysm involving branches.

Another object of the invention is ensuring patency of the branches while treating an aneurysm.

The subject of the present invention is defined in the appended independent claims. Preferred embodiment are defined in the depended claims.

A subject of the present invention is an implantable endoluminal prosthesis having a multilayer configuration and comprising at least one self-expandable braided framework. Said braided framework extends along an axis being able to expand from a radially compressed state in a delivery configuration to a radially expanded state. The braided framework is formed with at most 196 wires having a given diameter $Ø_{21}$. The braid framework is devoid of any impermeable cover layer and forms

a wall of the endoluminal prosthesis. The braided framework comprises a lumen in a cylindrical form with a circular cross-section and a constant diameter. A ratio $T_1/Ø_{21}$ of thickness T_1 of a wall of said endoluminal prosthesis in radially expanded state to the diameter $Ø_{21}$ of wire being greater than 2.0, preferably at least 2.5, more preferably at least 3.0, even more preferably at least 3.5, still even more preferably 4.0. The surface coverage ratio (SCR) of said endoluminal prosthesis is more than 30% and less than 70%, preferably more than 35% and less than 50% in radially expanded state.

The self-expandable braided framework preferably comprises at least 90 wires and at most 130 wires; and the diameter of the wires is at least 120 µm, preferably at least 200 µm and at most 220 µm.

In another preferred embodiment, in radially expanded state, the self-expandable framework comprises a plurality of layers of wires made of biocompatible material; each layer forming a mesh; the meshes forming a lattice with a plurality of wires of said layers; the meshes being interlocked, the wires being integrated in the mesh of at least one of the adjacent layers.

Brief Description of the Figures

Other particularities and advantages of the invention will be developed hereinafter, reference being made to the appended drawings wherein:

FIG.1 is a schematic front view of an endoluminal prosthesis according to the present invention

FIG.1a is a schematic magnified view of a portion of the front view shown in FIG.1.

FIG.2 is a side view of the endoluminal prosthesis shown in FIG.1.

FIG.3 is a section view of the endoluminal prosthesis shown in FIGs 1, 1a and 2 accroding to a cutting plane III-III.

FIG.3a is a schematic magnified view of an embodiment of a portion of the cross-section shown in FIG.3.

FIG.3b is a schematic magnified view of another embodiment of a portion of the cross-section shown in FIG.3.

FIG. 4 is a schematic magnified view of another portion of an endoluminal prosthesis according to the present invention.

FIGs 5 and 6 represent two stages of the healing process of an aneurysm wherein an endoluminal prosthesis according to the present invention has been implanted.

FIGs 7 and 8 show simulations of blood velocity at an orifice of an aortic branch respectively according to prior art stents and with an endoluminal prosthesis according to the present invention.

FIGs 9a and 9b show simulation of blood velocity in an aortic model respectively according to the prior art (without stent) and with an endoluminal prosthesis according to the present invention.

FIGs.10a and 10b are magnified views at the supra aortic branches orifices of the simulations shown in FIGs.9a and 9b, respectively.

FIGs.11a and 11b are ~~a~~ magnified views at the coronaries orifice of the simulation shown in FIGs.9a and 9b, respectively.

FIG.12 is a schematic cross-section view of the aorta showing how to measure the width and height of the aortic arch.

FIG.13 (a-d) show the different phases of the healing process of a saccular aneurysm involving a branch with an endoluminal prosthesis according to the present invention.

FIG.14 (a-d) shows the different phases of the healing process of a fusiform-shaped aneurysm involving a branch with an endoluminal prosthesis according to the present invention.

Detailed Description of the Invention

As used hereinafter, the term "implantable" refers to an ability of a medical device to be positioned at a location within a body vessel. Implantable medical device can be configured for transient placement within a body vessel during a medical intervention (e.g., seconds, minutes, hours), or to remain in a body vessel permanently.

The terms "endoluminal" or "transluminal" prosthesis refers to a device adapted for placement in a curved or straight body vessel by procedures wherein the prosthesis is advanced within and through the lumen of a body vessel from a remote location to a target site within the body vessel. In vascular procedures, a medical device can typically be introduced "endovascularly" using a catheter over a wire guide under fluoroscopic guidance. The catheters and wire guides may be introduced through conventional access sites in the vascular system.

The term "catheter" refers to a tube that is inserted into a blood vessel to access the target site. In the present description, a "catheter" will designate either a catheter per se, or a catheter with its accessories, meaning needle, guide wire, introducer sheath and other common suitable medical devices known by the man skilled in the art.

The term "permanent" refers to a medical device which may be placed in a blood vessel and will remain in the blood vessel for a long period of time (e.g. months, years) and possibly for the remainder of the patient's life.

The endoluminal prosthesis **1** is configured to take a compressed shape having a relatively small and relatively uniform diameter when disposed within a delivery system (i.e., "in compressed state"), and to spontaneously take a deployed shape with radially expanded diameter within the delivery location such as a body lumen (i.e., "in deployed state"). As used herein the terms "expanded shape" or "expanded state" refer to a shape or state resulting from the self-expanding properties of a self-spring-back object (e.g., braided framework **20**) when it is allowed to expand without any outer compression force (i.e., non-constricted state). Beside these definitions, the term "nominal diameter" designates the diameter of the implantable endoluminal prosthesis when placed in the targeted vessel. Generally, the nominal diameter ($Ø_{nor}$) of a self-expandable device designed to be placed permanently inside a body lumen is 10 to 25% smaller than the external diameter of said device when deployed without external compression force ($Ø_{exp}$).

The implantable endoluminal prosthesis **1** according to the present invention comprises at least one self-expandable braided framework **20** able to expand from a radially compressed state in a delivery configuration to a radially expanded state. The implantable endoluminal prosthesis **1** has a multilayer configuration either comprising at least two of the self-expandable braided frameworks **20** or comprising at least one self-expandable braided framework **20** having a plurality of interlocked layers (interlocked multilayer configuration) formed by braiding a plurality of wires. The braided framework **20** comprises a lumen in a cylindrical form with a circular cross-section and a constant diameter shown in FIGs 1, 1a and 2.

When the endoluminal prosthesis **1** having the multilayer configuration is observed normal with respect to a wall, meshes of the braided framework(s) **20** form a lattices with a plurality of level of wires **21**. FIG.3 shows a schematic cross-section of the endoluminal prosthesis **1** according to the present invention. FIG.3a shows a schematic magnified view of a portion of the endoluminal prosthesis **1** comprising a self-expandable framework **20**, and FIG.3b showing a portion of the endoluminal prosthesis **1** comprising two self-expandable frameworks **20**. A ratio $T_1/Ø_{21}$ of the thickness T_1 of a wall of the endoluminal prosthesis **1** to the diameter $Ø_{21}$ of wire **21** should be greater than 2.0. It characterizes the endoluminal prosthesis **1** having more than a single layer of mesh, namely multilayer configuration. The braided framework **20** is preferably made of a multilayer braid having a

thickness T_{20}. The term "interlocked multi-layer" refers to a framework comprising multiple layers, whose plies are not distinct at the time of braiding, for example a given number of wires of the plies of the first layer **22** being interlocked with the plies of the second layer **23** and/or other layers, for example, as schematically illustrated in FIG.4. Said interlocked multi-layer, for example, can be formed by using the braiding machine described in EP1248372.

Thanks to the thicker wall T_1 of the multilayered endoluminal prosthesis **1** as compared with the wall thickness of a conventional stent, endoluminal prosthesis **1** exhibits a three dimensional (3D) porosity. The thicker the wall is (regarding a given wire diameter $Ø_{21}$) the greater the 3D porosity effect..

One of the technical effects provided by the 3D porosity of endoluminal prosthesis **1**, is that the present endoluminal prosthesis **1** lets the blood flow into the aneurysm sac converts owing to its multilayer configuration, an undesired damaging turbulence in the aneurysmal sac into a smooth laminar flow **11** (as shown FIG.5), instead of mechanically/physically keeping out the blood flow from the aneurysm as would do a conventional stent-graft techniques. It results in excluding the aneurysm by forming a protecting organized thrombus **12**, known as layers of Zhan (see FIG.6), while keeping the branches and collaterals unobstructed. Thanks to the permeable multilayer structure of the endoluminal prosthesis **1**, additional repairs such as open debranching-bypass procedure and custom-made fenestrated/branched configuration for maintaining a blood flow are not required.

The surface coverage ratio (SCR) of endoluminal prosthesis **1** is between 30% and 70%, preferably more than 35% and less than 50%, even more preferably less than 45% in radially expanded state. The SCR of the endoluminal prosthesis is defined by the relation:

$$\mathbf{SCR} = S_w/S_t$$

Wherein "S_w" is the actual surface covered by wires **21** composed in the endoluminal prosthesis **1**, and "S_t" is the total surface are of the wall of the endoluminal prosthesis **1** when observed normal with respect to the wall.

Studies and experiments carried by the inventor led to surprising and unexpected conclusions. The perfusion in branches is improved in accordance with the increase of the ratio $T_1/Ø_{21}$ having the SCR of the endoluminal prosthesis between 30% and 70% instead of occluding these blanches. "Perfusion" is, in physiology, the process of a body delivering blood to capillary bed in its biological tissue. The terms "hypoperfusion" and "hyperperfusion" measure the perfusion level relative to a tissue's current

need to meet its metabolic needs. For example, the endoluminal prosthesis of the invention increases the perfusion in the supra aortic branches **30** when it covers the branches, resulting in that the functioning of the organs to which the supra aortic branches **30** carries the blood is improved. As shown in a simulation of FIG.7, a heavy turbulence is created at an orifice **34** of branch. On the contray, when the endoluminal prosthesis is placed in front of the orifice **34**, the chaotic flow is eliminated by passing through a wall of the endoluminal prosthesis and converted to a regulated laminar flow. It accelerates the flow in the branches covered by the endoluminal prosthesis **1.** Accordingly, the ratio $\mathbf{T_1/Ø_{21}}$ of the present endoluminal prosthesis **1** should be more than 2.0, preferably at least 2.5, more preferably at least 3.0, even more preferably at least 3.5, still even more preferably 4.0 while the SCR is between 30% and 70%, preferably between 35% and 50% in radially expanded state. A competed simulation of blood flow in an aorta model without and with the endoluminal prosthesis having more than 2.0 of $\mathbf{T_1/Ø_{21}}$ are shown in FIGs.9a and 9b, respectively. The aortic model was created based on an actual pathology of a patient. In FIG.9b, the endoluminal prosthesis is placed so as to cover the wall of the vessel from the coronaries **31** up to the supra aortic branches **30**. Processing so, surprisingly, the velocities of blood flow entering into the supra aortic branches **30** are notably increased of between 21% and 24% as shown in FIG.10b (magnified view of FIG.9b) at the orifices **34** of supra aortic branches **30**, when compared with the velocity without device shown in FIG.10a ~~as a~~(magnified view of FIG.9a). The flow velocity in the coronaries are also increased up to 20% as shown in FIG.11a and 11b.

Further distinguishing improvement of "perfusion" in the branches covered by the endoluminal prosthesis **1** was observed with this interlocked multilayer configuration. The braided framework **20** of the endoluminal prosthesis **1** is made of at most 196 wires **21**, preferably at least 90 wires at most 130 wires. The wires preferably have a diameter ($Ø_{21}$) of at least 120 µm, preferably at least 150 µm, more preferably at least 180 µm, even more at least 200 µm and at most 220 µm.

Another advantages of the present invention is that the implantable endoluminal prosthesis **1,** having higher value of the ratio $\mathbf{T_1/Ø_{21}}$, can effectively form a thrombus in the aneurysmal sac in comparison with a braided framework having lower $\mathbf{T_1/Ø_{21}}$ ratio. The ratio $\mathbf{T_1/Ø_{21}}$ of the wall thickness $\mathbf{T_1}$ of the endoluminal prosthesis **1** to the wire diameter $\mathbf{Ø_{21}}$ of wire **21** being more than 2.0 characterizes the endoluminal prosthesis **1** having more than a single layer of mesh. The greater the ratio $\mathbf{T_1/Ø_{21}}$, the more layers the endoluminal prosthesis **1** will comprise. Each wire forming multiple-layers works to make the blood flow be laminated which gets through the wall of the endoluminal prosthesis **1**.

The curve of the aortic arch **32** is generally defined by measuring the width W_{32} and height H_{32} of the curve as described by Ou et al. in *J. Thrac. Cardiovasc. Surg.* 2006; 132:1105-1111. Width W_{32} is measured as the maximal horizontal distance between the midpoints **35** of the ascending and descending aorta **32** close to the axial plane going through the right pulmonary artery; and height H_{32} of the aortic arch is measured maximal vertical distance between W_{32} and the highest midpoint **35** of the aortic arch W_{32} as depicted in FIG.12.

Interlocked multiple-layer configuration having a ratio $T_1/Ø_{21}$ of at least 2.5 brings an important advantageous technical property. When the aneurysm is located at the outer side of the curve, it is most important to set an optimal SCR and an optimal opening size of mesh at the outer side of the curve in order to form a protecting organized thrombus in the aneurysmal sac by converting an undesired damaging turbulence **33** into a smooth laminar flow **36** while keeping branches, such as supra aortic branches **30**, patent. Wires of the interlocked multiple-layer configuration of the invention shift to keep a regular distance between adjacent parallel, resulting in that the SCR can stays almost the same between in a curved state and in straight configuration. On the Contrary, when a conventional single-layer mesh-like tube having less than 2.0 of $T_1/Ø_{21}$ is deployed in a curved lumen, the SCR at the outer side of the curve are much lower than the SCR in a straight configuration. Therefore, the ratio $T_1/Ø_{21}$ of the present endoluminal prosthesis **1** should be more than 2.0, preferably at least 2.5, more preferably at least 3.0, even more preferably at least 3.5, still even more preferably at least 4.0.

As another surprising effect provided the present endoluminal prosthesis **1** having interlocked multiple-layer configuration, against the “normal” expectation that a space between an aneurysmal wall and endoluminal prosthesis would be occluded by thrombus as shown in FIG.6, the aneurysm including branches shrinks directly instead of forming thrombus in the aneurysmal sac while still maintaining the blood flow into the branches as shown FIGs 13 and 14. The inventor assumes that by sealing the beginning of the aorta with the enlarged, undesired turbulence **33** are eliminated and desired smooth flow **11** are created in this volume. It accelerates the non-turbulent blood flow entering the branches while decreasing the pressure under Venturi effect, resulting in shrinkage of the aneurysmal sac.

The biocompatible material used in the invention is preferably a metallic substrate selected from a group consisting of stainless steels (e.g., 316, 316L or 304); nickel-titanium alloys including shape memory or superelastic types (e.g., nitinol, Nitinol-DFT®-Platinum); cobalt-chrome alloys (e.g.,

elgiloy); cobalt-chromium-nickel alloys (e.g., phynox); alloys of cobalt, nickel, chromium and molybdenum (e.g., MP35N or MP20N); cobalt-chromium-vanadium alloys; cobalt-chromium-tungsten alloys; magnesium alloys; titanium alloys (e.g., TiC, TiN); tantalum alloys (e.g., TaC, TaN); L605;. Said metallic substrate is preferably selected from the group consisting of titanium, nickel-titanium alloys such as nitinol and Nitinol-DFT®-Platinum, any type of stainless steels, or a cobalt-chromium-nickel alloys such as Phynox®.

Claims

1. Implantable endoluminal prosthesis (**1**) for use in the treatment of aneurysm involving branches having a multilayer configuration, comprising at least one self-expandable braided framework (**20**) extending along an axis able to expand from a radially compressed state in a delivery configuration to a radially expanded state; the self-expandable braided framework (**20**) being formed with at most 196 wires (**21**) having a given wire diameter ($\emptyset_{21}$); this self-expandable braided framework (**20**) devoid of any impermeable cover layer, comprising a plurality of layers of wires (**21**) made of biocompatible material; and forming a wall of the endoluminal prosthesis (**1**); each layer forming a mesh; the meshes forming a lattice with a plurality of wires (**21**) of said layers; the meshes being interlocked, the wires being integrated in the mesh of at least one of the adjacent layers; the self-expandable braided framework (**20**) comprising a lumen in a cylindrical form with a circular cross-section and a constant diameter; characterized in that, in radially expanded state, a ratio ($T_1/\emptyset_{21}$) of thickness (T_1) of a wall of the implantable endoluminal prosthesis (**1**) in radially expanded state to the diameter ($\emptyset_{21}$) of wire (**21**) being greater than 3.0; and the surface coverage ratio (SCR) of said braided framework (**20**) is at least 30% and at most 50%.

2. Implantable endoluminal prosthesis (**1**) according to claim 4, wherein the ratio ($T_1/\emptyset_{21}$) is at least 3.5

3. Implantable endoluminal prosthesis (**1**) according to claim 5, wherein the ratio ($T_1/\emptyset_{21}$) is at least 4.0

4. Implantable endoluminal prosthesis (**1**) according to any one of preceding claims, the SCR of said braided framework (**20**) is more than 35%

5. Implantable endoluminal prosthesis (**1**) according to any one of preceding claims, wherein the self-expandable braided framework (**20**) comprises at least 90 wires and at most 130 wires.

6. Implantable endoluminal prosthesis (**1**) according to preceding claims, wherein the diameter of the wires (**21**) is at least 120 µm.

7. Implantable endoluminal prosthesis (**1**) according to claim 9, wherein the diameter of the wires (**21**) is at least 150 µm.

8. Implantable endoluminal prosthesis (**1**) according to claim 10, wherein the diameter of the wires (**21**) is at least 180 µm.

9. Implantable endoluminal prosthesis (**1**) according to claim 11, wherein the diameter of the wires (**21**) is at least 200 µm and at most 220 µm.

10. Implantable endoluminal prosthesis according to any one of preceding claims, wherein the biocompatible material is a metallic substrate selected from the group consisting of titanium, nickel-titanium alloys such as nitinol and Nitinol-DFT®-Platinum, any type of stainless steels, or a cobalt-chromium-nickel alloys such as Phynox®.

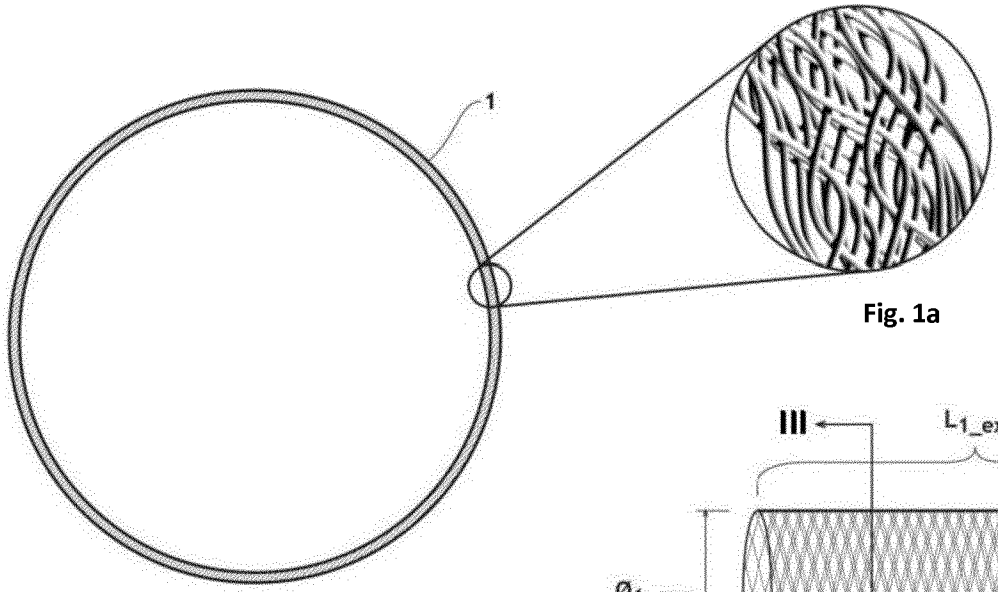

Fig. 1a

Fig. 1

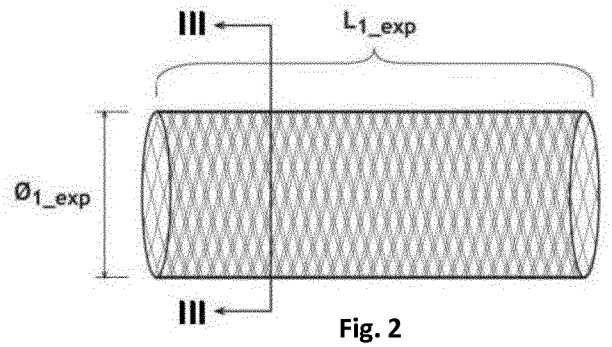

Fig. 2

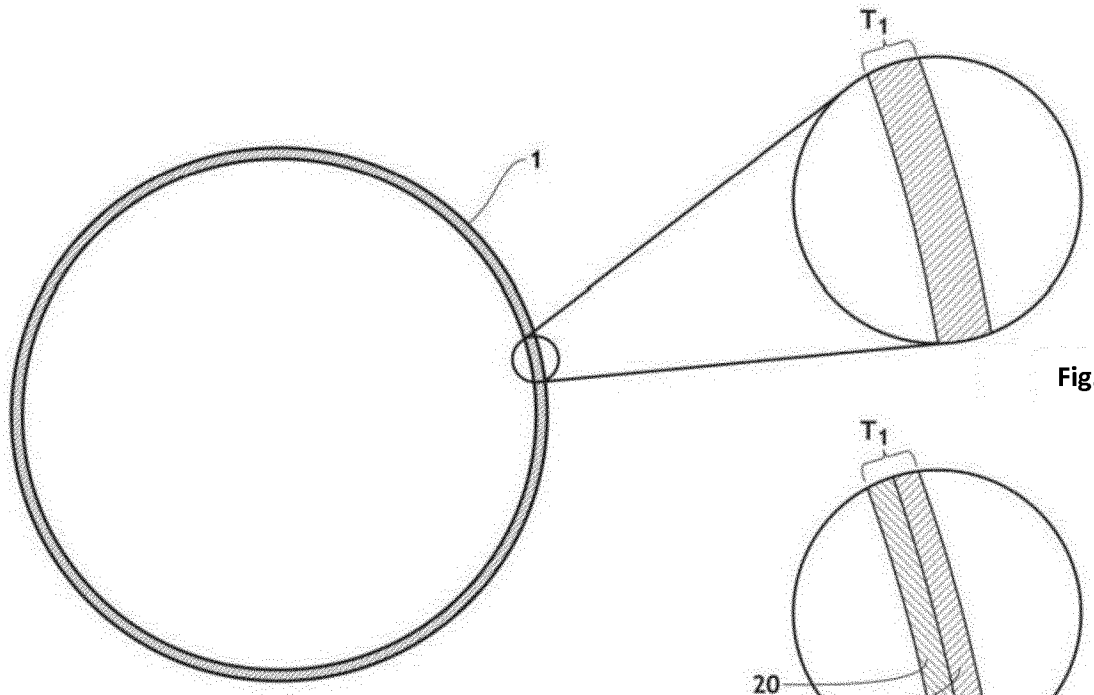

Fig. 3a

Fig. 3

Fig. 3b

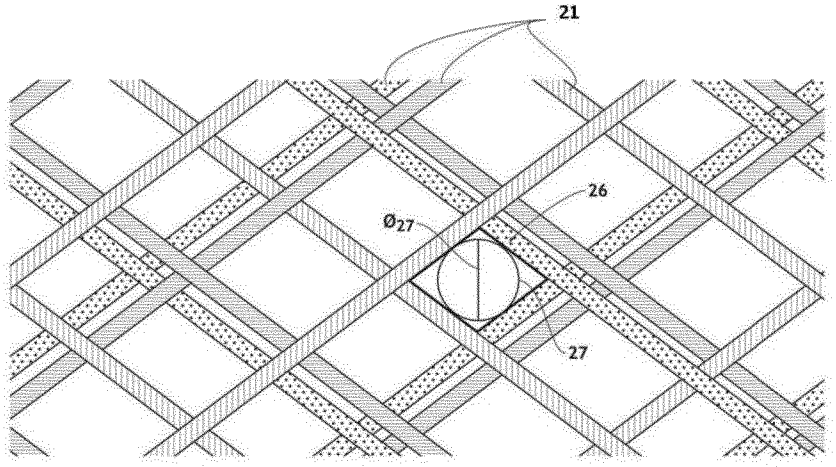

Fig. 4

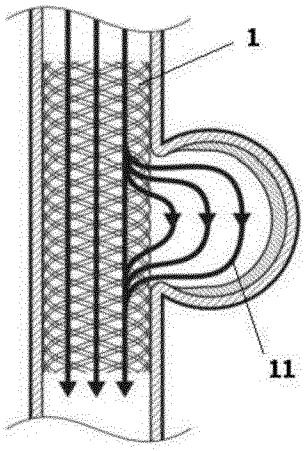

Fig. 5

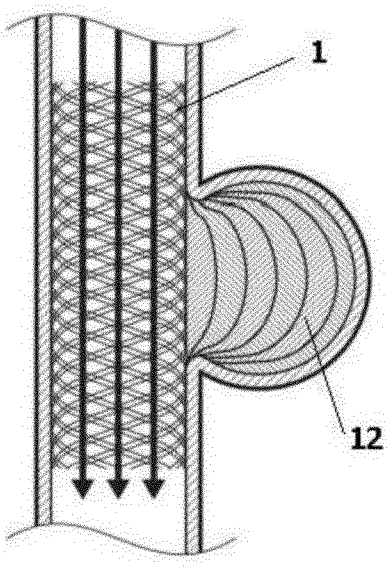

Fig. 6

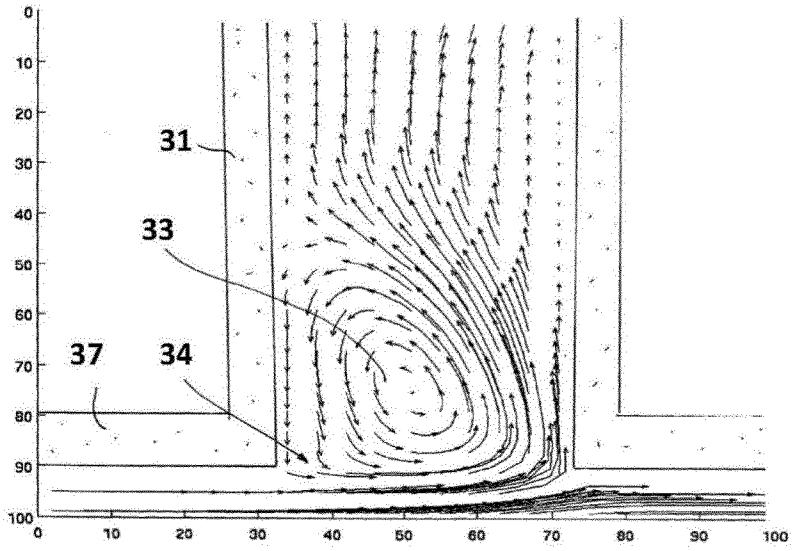

Fig. 7

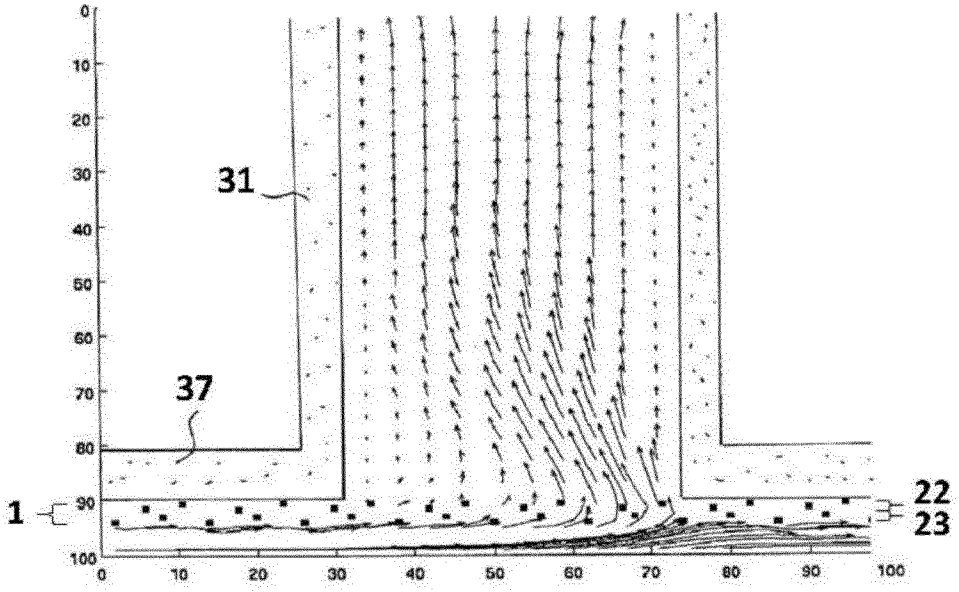

Fig. 8

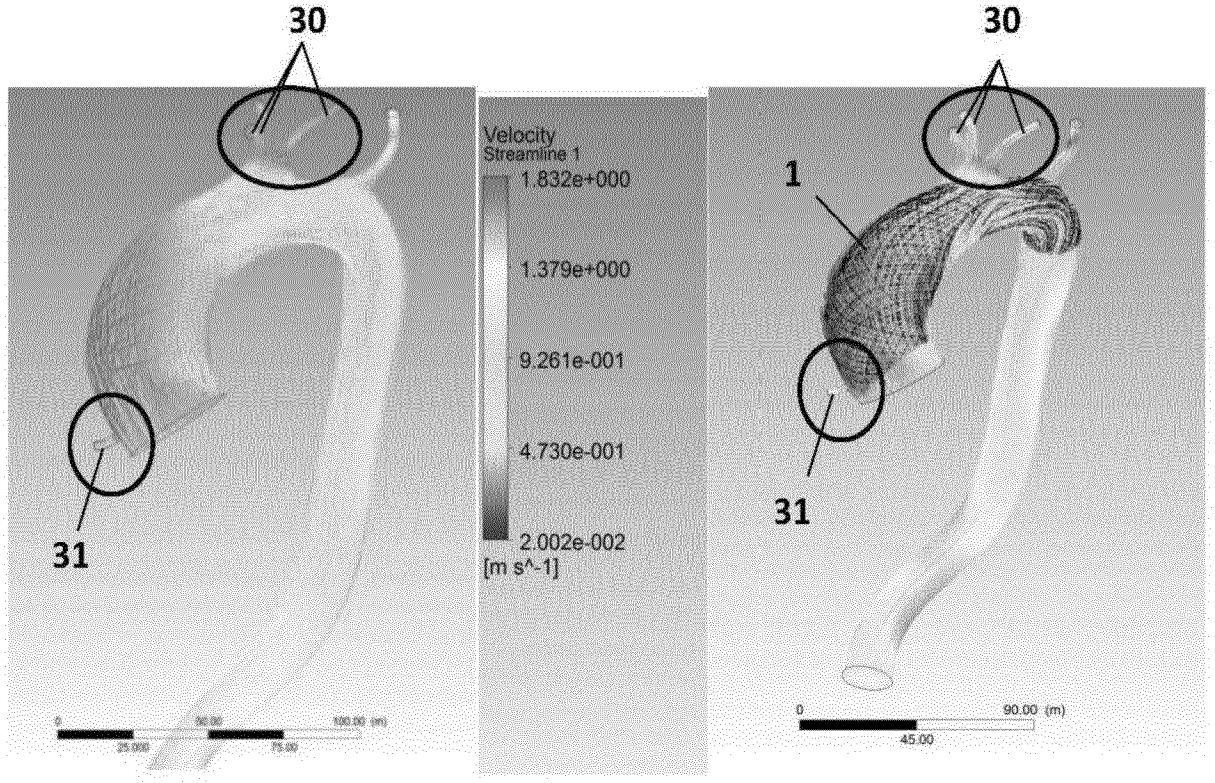

Fig. 9a

Fig. 9b

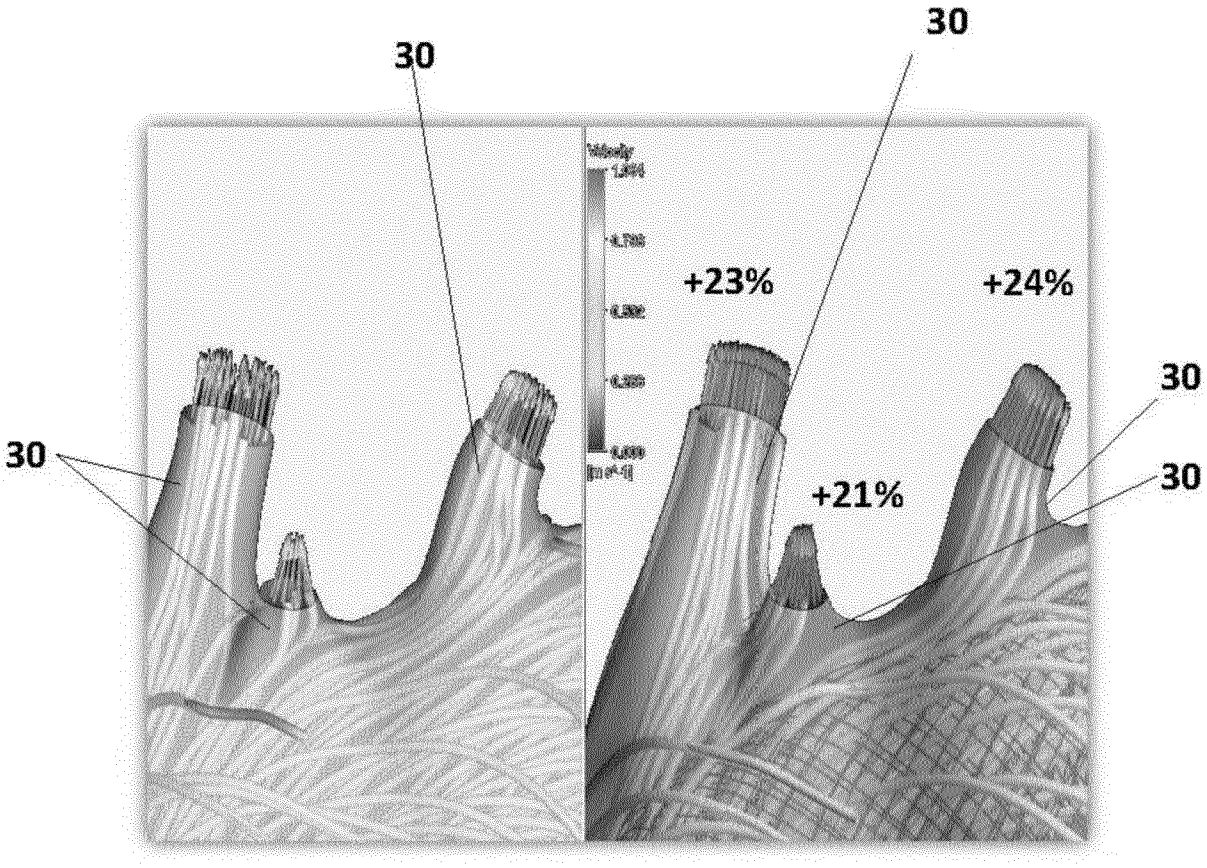

Fig. 10a Fig. 10b

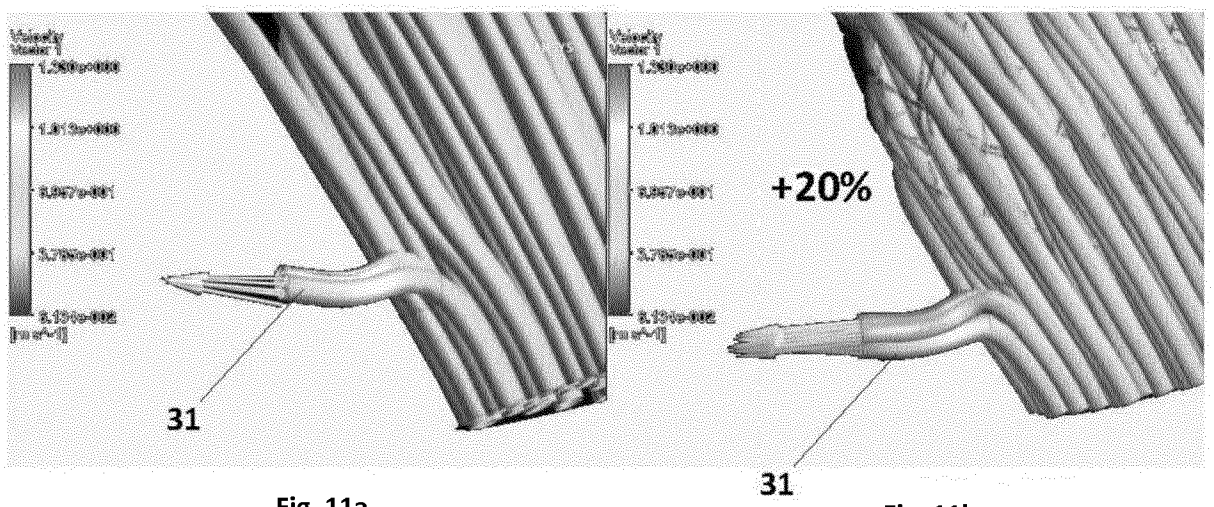

Fig. 11a Fig. 11b

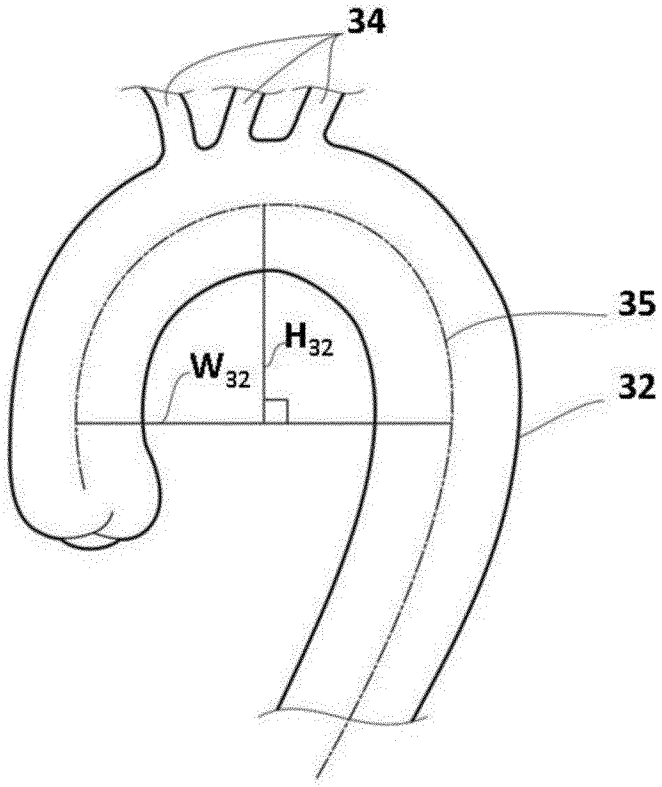

Fig. 12

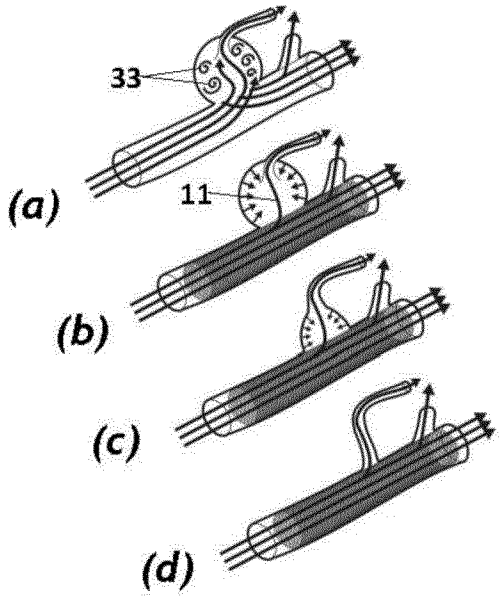

Fig. 13

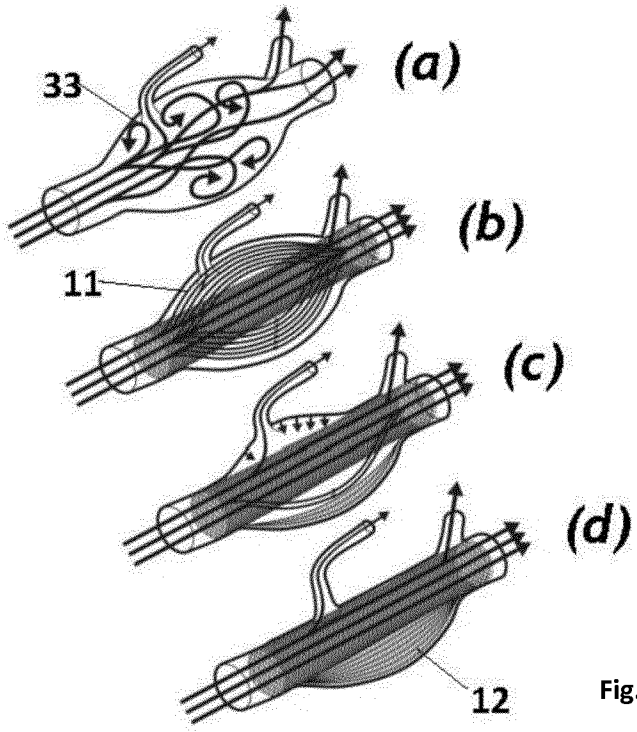

Fig. 14

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2016/077363

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F2/90
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)
A61F

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	US 2013/245745 A1 (VONG SHIRLEY [US] ET AL) 19 September 2013 (2013-09-19) paragraphs [0015], [0076] - [0100], [0150] - [0155]; figures 12-14, 62-66	1-10
A	US 2014/180397 A1 (GERBERDING BRENT C [US] ET AL) 26 June 2014 (2014-06-26) paragraphs [0037] - [0072]; figures 1-7	1-10
A	EP 2 777 640 A1 (DEPUY SYNTHES PRODUCTS LLC [US]) 17 September 2014 (2014-09-17) paragraphs [0021] - [0038]; figures 1-5	1-10

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
18 January 2017	25/01/2017

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	Porta, Marcello

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/EP2016/077363

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