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(54) **Title**: REDUCED FORESHORTENING STENT WITH BIO-RESORBABLE FIBERS

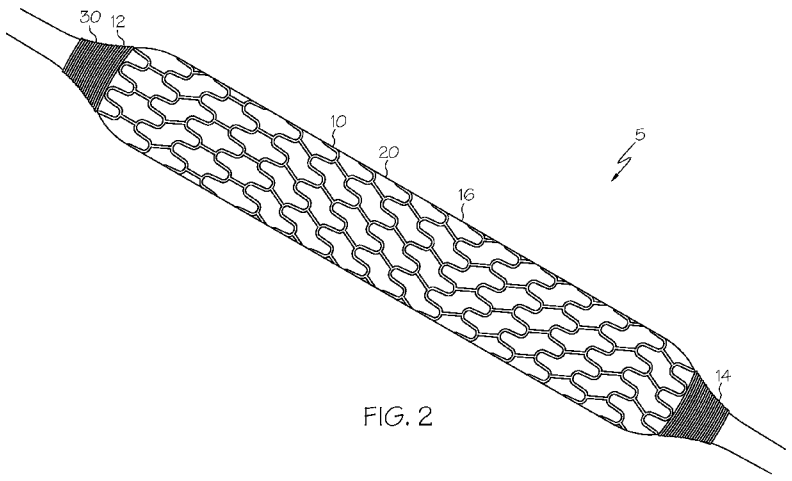

FIG. 2

(57) **Abstract**: A device and method for reducing stent foreshortening are provided herein. The device (5) includes a balloon (20) and stent (10) thereon. The stent has a first end portion (12) and a second end portion (14) and bio-resorbable fibers (30) disposed over at least a portion of the first end portion and the second end portion. The biO-resorbable fibers over the end portions prevent the ends of the stent from prematurely expanding, thereby reducing stent foreshortening.

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TITLE

Reduced Foreshortening Stent With Bio-Resorbable Fibers

CROSS-REFERENCE TO RELATED APPLICATIONS

This Application claims priority to US Provisional Application No. 61/491,032, filed May 27, 2011, the entire contents of which are herein incorporated by reference.

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH

Not Applicable

BACKGROUND OF THE INVENTION

Balloon deployable stents are known in a variety of designs and configurations. During the deployment of certain types of balloon stents, the balloon has a tendency to expand inwardly from the outer ends of the balloon toward the center. This, in turn, opens the outer ends of the stent prior to middle of the stent, which can lead to stent foreshortening.

Another problem encountered when deploying a stent with a balloon occurs when the balloon inflates from one side to the other side and pushes the stent longitudinally along the balloon. This can result in placement of the stent in an undesirable or less desirable location.

Consequently, there remains a need for a balloon stent assembly that reduces foreshortening and promotes proper stent placement.

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.

BRIEF SUMMARY OF THE INVENTION

An inflatable balloon and stent assembly comprises an inflatable balloon and a stent disposed over at least a portion of the inflatable balloon. The stent has a first end portion, a second end portion, and a middle portion therebetween. The balloon and stent assembly further comprises a plurality of bio-resorbable fibers. The bio-resorbable fibers are disposed over at least a portion of the first end portion and the second end portion of the stent.

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

FIGs. 1A and 1B show a cross-section of a PRIOR ART balloon-stent assembly.

FIG. 2 shows a perspective view of an embodiment of a balloon-stent assembly of the present disclosure.

FIGs. 3A-3C show cross-sectional view of the embodiment of FIG. 2.

FIGs. 4-6 show side views of embodiments of balloon-stent assemblies.

DETAILED DESCRIPTION OF THE INVENTION

A prior art balloon 20a and stent 10a are shown in cross-section in FIGs. 1A and 1B. FIG. 1A shows the balloon 20a as it begins to expand. Specifically, the balloon 20a is shown expanding at its ends before expanding along its middle. Consequently, the end portions 12a, 14a of the stent 10a expand before the middle portion 16a of the stent 10a.

Turning to FIG. 1B, as the balloon 20a is further expanded, the middle portion 16a of the stent 10a expands, propagating from the expanded end portion 14a to the other expanded end portion 12a. As a result of the end portions 12a, 14a expanding prior to the middle portion 16a, the stent 10a tends to foreshorten.

In addition to the foregoing, stent 10a can also undesirably move axially along the balloon 20a if one end of the balloon 20a inflates before the other end. This

can result in improper stent placement.

The immediate balloon and stent assembly 5 is designed to overcome these deficiencies and provide for better stent retention on the balloon. In accordance therewith, an inflatable balloon and stent assembly 5 is shown herein in at least one embodiment. As shown for example in FIG. 2, the assembly 5 comprises a stent 10 mounted on an inflatable balloon 20. The stent 10 has a plurality of bio-resorbable fibers 30 disposed around at least a portion of the stent 10. In particular, in some embodiments, the stent 10 has a first end portion 12 and a second end portion 14 around which the bio-resorbable fibers 30 are wound, spun, or otherwise disposed. In some embodiments, the bio-resorbable fibers 30 are located at a first end portion 12 and a second end portion 14 but not a middle portion 16 of the stent 10. The bio-resorbable fibers 30 on the end portions 12, 14 of the stent 10 prevent the end portions 12, 14, from expanding prior to middle portion 16. Thus, in turn, prevents or minimizes foreshortening of the stent 10 and promotes proper stent placement.

Turning now to FIGs. 3A and 3B, a cross-section of the assembly 5 is shown therein, with stent 10, inflatable balloon 20, and bio-resorbable fibers 30. FIG. 3A shows the assembly 5 as it expands from an unexpanded configuration. For example, the inflatable balloon 20 is expanded to approximately 10 atm, such that the middle portion of the inflatable balloon 20 has expanded but the bio-resorbable fibers 30 restrict expansion of the first and second end portions 12, 14.

As shown in FIG. 3B, as the pressure inside the inflatable balloon 20 is increased, for example to 11 atm, the first and second end portions 12, 14 increase in cross-section and the bio-resorbable fibers 30 expand.

In some embodiments, the bio-resorbable fibers 30 deform plastically upon expansion. In some embodiments, however, the bio-resorbable fibers 30 deform elastically upon expansion. Further, in some embodiments, the bio-resorbable fibers 30 deform elastically upon initial expansion of the balloon 20 and plastically upon further expansion of the balloon 20. In some embodiments, some or all of the bio-resorbable fibers 30 will break upon expansion of the balloon 20 to a desired size.

With regard to FIG. 3C, a view of the assembly of FIG. 3B is shown therein. In particular, FIG. 3C depicts the compressive force F_c applied to the stent 10 by the bio-resorbable fibers 30. The compressive force F_c is applied to at least a portion of

the outer surface of the stent 10. The compressive force F_c in turn provides a frictional force F_f between the stent 10 and the surface 32 of the inflatable balloon 20. The frictional force F_f helps to prevent stent foreshortening and axial displacement of the stent 10 relative to the inflatable balloon 20.

As shown in FIGs. 4-6, the stent 10 is crimped on the inflatable balloon 20. Referring specifically to FIG.4, in some embodiments, the bio-resorbable fibers 30 are disposed over portions of the stent 10, including portions of the first and second end portions 12, 14 and the middle portion 16. The number of bio-resorbable fibers 30 per unit length is greater at the end portions 12, 14 than at the middle portion 16. In some embodiments, the number of bio-resorbable fibers 30 per unit length gradually decreases from the end portions 12, 14 of the stent to the middle portion 16. In addition, in some embodiments, the bio-resorbable fibers 30 extend onto one or more portions of the inflatable balloon 20, for example beyond the end portions 12, 14 of the stent 10.

With reference to FIG. 5, in some embodiments, the bio-resorbable fibers 30 are layered. As shown, in some embodiments, the number of layers of bio-resorbable fibers 30 increases nearer the proximal end 22 and distal end 24 of the stent 10. Moreover, the number of layers decreases nearer the middle portion 16 of the stent 10. In some embodiments, the middle portion 16 does not have any bio-resorbable fibers 30 thereon. Alternatively, in some embodiments, the middle portion 16 has bio-resorbable fibers 30 therealong but to a lesser extent than the end portions 12, 14. In this way, bio-resorbable fibers 30 are built up to provide greater resistance to expansion at the end portions 12, 14 and, in some embodiments, at the proximal and distal ends 22, 24.

Turning to FIG. 6, in some embodiments, bio-resorbable fibers 30 at the end portions 12, 14 have a greater diameter than those nearer the middle portion 16. In some embodiments, the diameter of the bio-resorbable fibers 30 decreases longitudinally from the end portions 12, 14 to the middle portion 16. In this way, the stent 10 opens at the middle portion 16 prior to opening at the end portions 12, 14.

In some embodiments, the bio-resorbable fibers 30 are disposed over the stent 10, or portions thereof, by electrospinning. This can be carried out by placing the stent 10 over the inflatable balloon 20 and crimping or otherwise securing the stent 10 to the inflatable balloon 20. Once the stent 10 is in place, the bio-resorbable fibers 30 are added, as desired, to one or more portions of the stent 10 and/or inflatable balloon 20.

In some embodiments, the bio-resorbable fibers 30 are electrospun onto the stent 10 and/or inflatable balloon 20 by rotating the assembly 5 while the bio-resorbable fibers 30 are applied. The bio-resorbable fibers 30 are thereby disposed circumferentially around at least a portion of the assembly 5. In some embodiments, the fibers 30 are disposed directly on the outer surface of a metallic stent.

In some embodiments, the bio-resorbable fibers 30 are disposed on the stent 10, or at least portions thereof, prior to the stent 10 being placed on the balloon 20. Alternatively, in some embodiments, bio-resorbable fibers 30 are disposed on the balloon 20, or portions thereof, prior to the stent 10 being placed on the balloon 20. In this way, the bio-absorbable fibers 30 restrict expansion of certain portions of the balloon 20, as desired.

In addition to the particular examples described above, combinations of these examples are also within the scope of this disclosure. For example, in some embodiments, the number of bio-resorbable fibers 30 per unit length is greater at the end portions 12, 14 than at the middle portion 16, for example as shown in FIG. 4 and the diameter of the bio-resorbable fibers 30 decreases longitudinally from the end portions 12, 14 to the middle portion 16, for example as shown in FIG. 6. Other combinations of the aforementioned examples are also contemplated.

In some embodiments, the bio-resorbable fibers 30 are made of polymers, hydro polymers, hydro gels, collagen, or suitable combinations thereof. In some embodiments, the bio-resorbable fibers are made of poly(lactic-co-glycolic acid) (PLGA) or poly(lactic acid) (PLA). In some embodiments, the bio-resorbable fibers 30 are formed from a solution of 7% high molecular weight (HMW) PLGA. In some embodiments, the mixture ratio by weight is 7-10% HMW PLGA/solvent. Further, in some embodiments, the mixture is between 4-40% HMW PLGA by weight.

In some embodiments, for example with lower molecular weight PLA, PLGA copolymers, PLA-b-PEG-b-PLA triblock copolymers, and lactide, were prepared in N, N-dimethyl formamide (DMF) solvent. The concentration of the final solution is, in some embodiments, 30-50% polymer by weight. Other solvents include hexafluoroisopropanol (HFIP) chlorinated solvents, tetrahydrofuran, acetone, or ethyl acetate. Additional additives may include chloroform; N, N-dimethyl formamide (DMF); and 2, 2, 2-trifluoroethanol. Finally, in some embodiments, the solution is of 7% HMW

PLGA with HFIP.

In addition, in some embodiments, the ratio of lactide to glycolide in the PLGA is 50:50 (50% lactide and 50% glycolide). Some embodiments employ a 53:47 ratio of lactide to glycolide. Also, in some embodiments, the PLGA includes a lauryl ester group.

In some embodiments, the bio-resorbable fibers 30 are less than 25 microns in diameters, in some embodiments, between 100 nanometers and 25 microns in diameter, and in some embodiments between 200 and 25 microns in diameter. Further, in some embodiments, at least some of the bio-resorbable fibers 30 overlap each other.

Additionally, in some embodiments, the bio-resorbable fibers 30 provide edge protection of the stent 10 during delivery of the stent 10. In particular, in embodiments where the bio-resorbable fibers 30 are disposed over the end 22, 24, of the stent, and particularly the distal end, the bio-resorbable fibers 30 provide a smooth transition from the balloon 20 to the stent 10 as the catheter is being delivered to the patient's vasculature or other organs.

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.

CLAIMS:

What is claimed is:

1. An inflatable balloon and stent assembly comprising:

an inflatable balloon and a stent disposed over at least a portion of the inflatable balloon; the stent having a first end portion, a second end portion, and a middle portion therebetween; and

a plurality of bio-resorbable fibers disposed over at least a portion of the first end portion and the second end portion of the stent, wherein the bio-resorbable fibers have a diameter less than 25 microns.

2. The assembly of claim 1, wherein the bio-resorbable fibers are arranged in a circumferential direction.

3. The assembly of claim 1, wherein the stent is crimped on the inflatable balloon.

4. The assembly of claim 1 having an unexpanded configuration and a partially expanded configuration, wherein, in the partially expanded configuration, the middle portion of the balloon is expanded and the first and second end portions are restrained from expanding by the bio-resorbable fibers.

5. The assembly of claim 1, wherein the bio-resorbable fibers have a diameter greater than 100 nanometers.

6. The assembly of claim 1, wherein at least some of the bio-resorbable fibers extend onto the surface of the inflatable balloon.

7. The assembly of claim 1, wherein the bio-resorbable fibers are made of poly(lactic-co-glycolic acid).

8. The assembly of claim 1, wherein the bio-resorbable fibers are further disposed on the middle portion of the stent.

9. The assembly of claim 8, wherein the number of bio-resorbable fibers per unit length is greater at the first and second end portions than at the middle portion.

10. The assembly of claim 9, wherein the first end portion has a proximal end disposed at an end of the stent and the second end portion has a distal end disposed at an end of the stent, the number of bio-resorbable fibers per unit length decreasing from the proximal end to the middle portion and increasing from the middle portion to the distal end.

11. The assembly of claim 8, wherein the first end portion has a proximal end disposed at an end of the stent and the second end portion has a distal end disposed at an end of the stent, and the bio-resorbable fibers are disposed on the first and second end portions of the stent in a plurality of layers, the number of layers decreasing from the proximal end to the middle portion and increasing from the middle portion to the distal end.

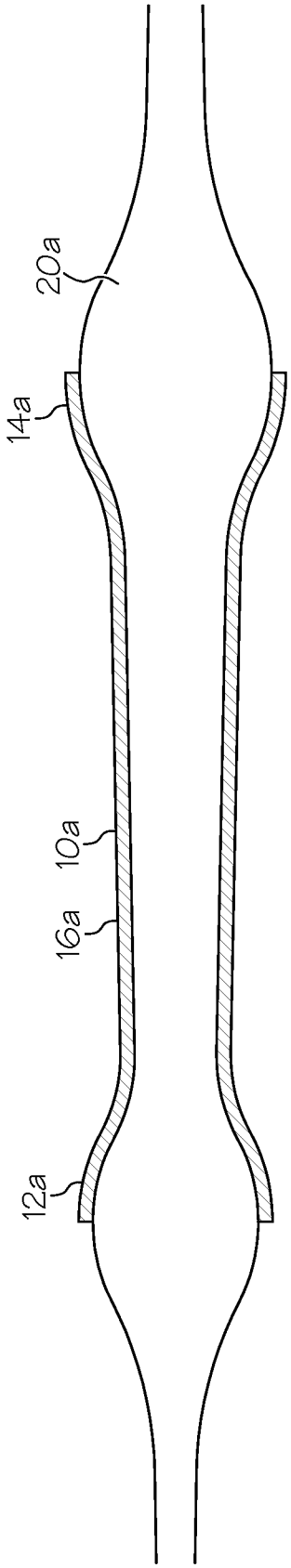

FIG. 1A
(PRIOR ART)

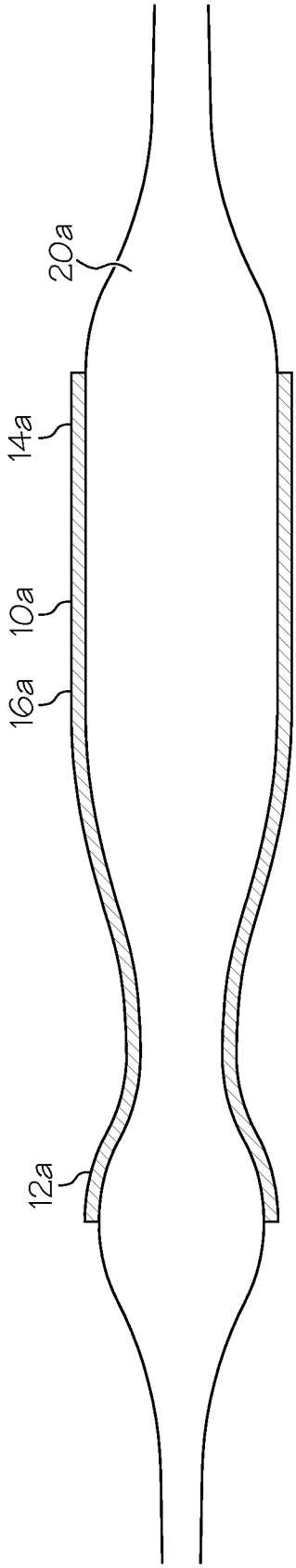

FIG. 1B
(PRIOR ART)

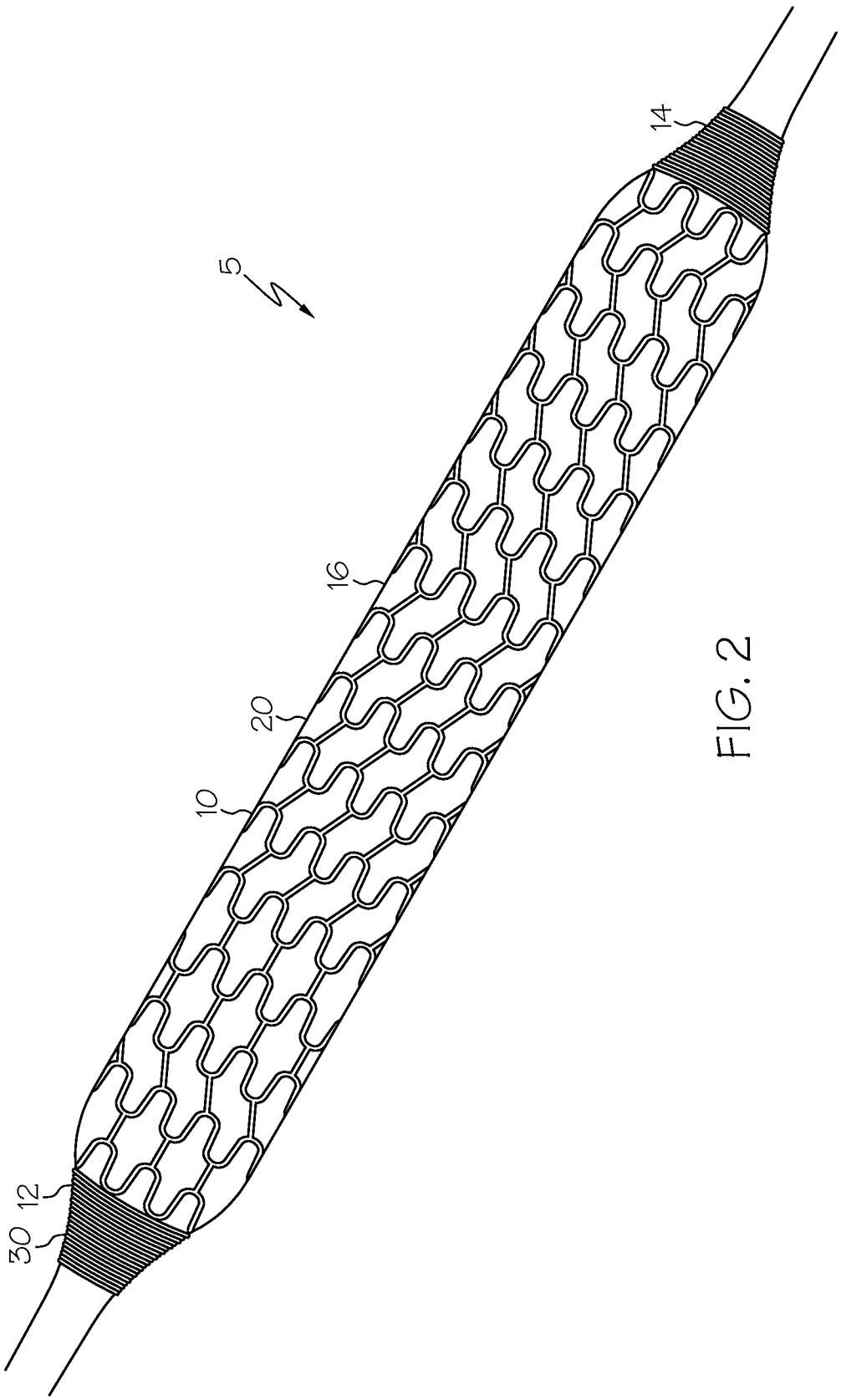

FIG. 2

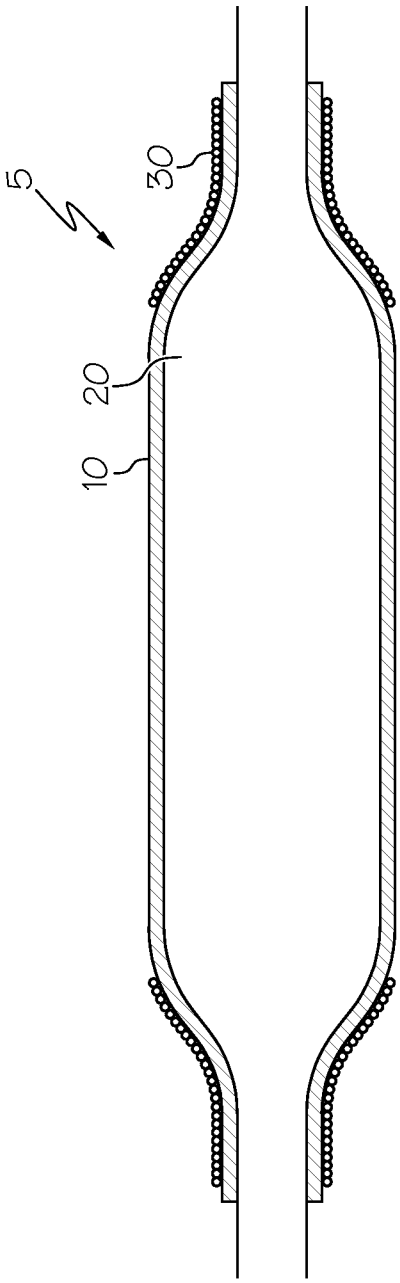

FIG. 3A

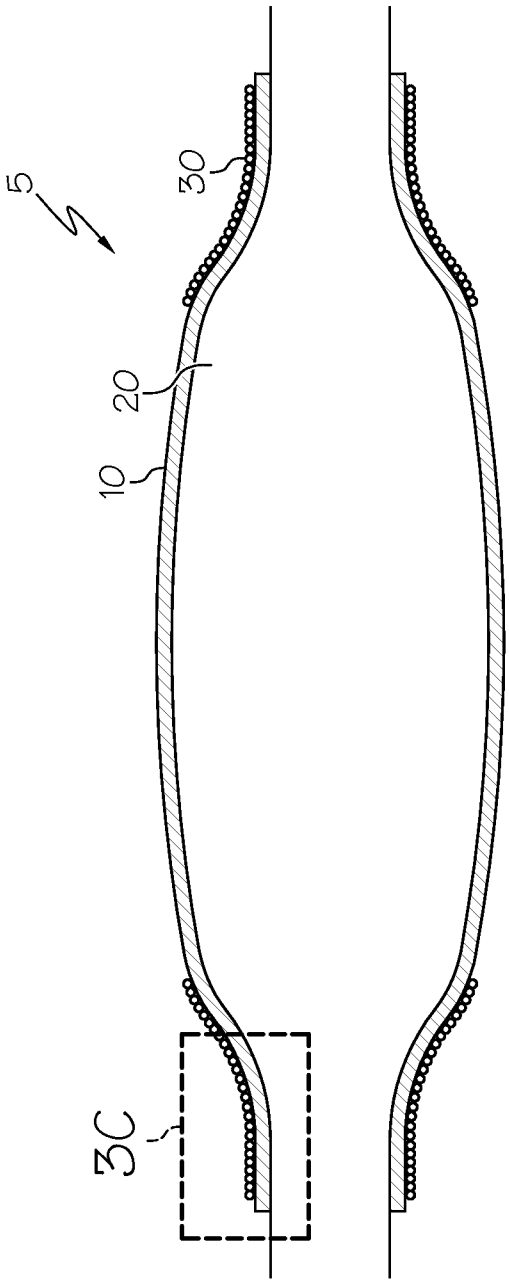

FIG. 3B

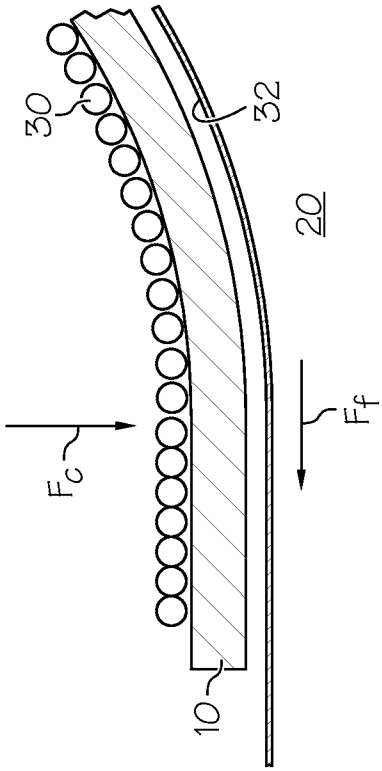

FIG. 3C

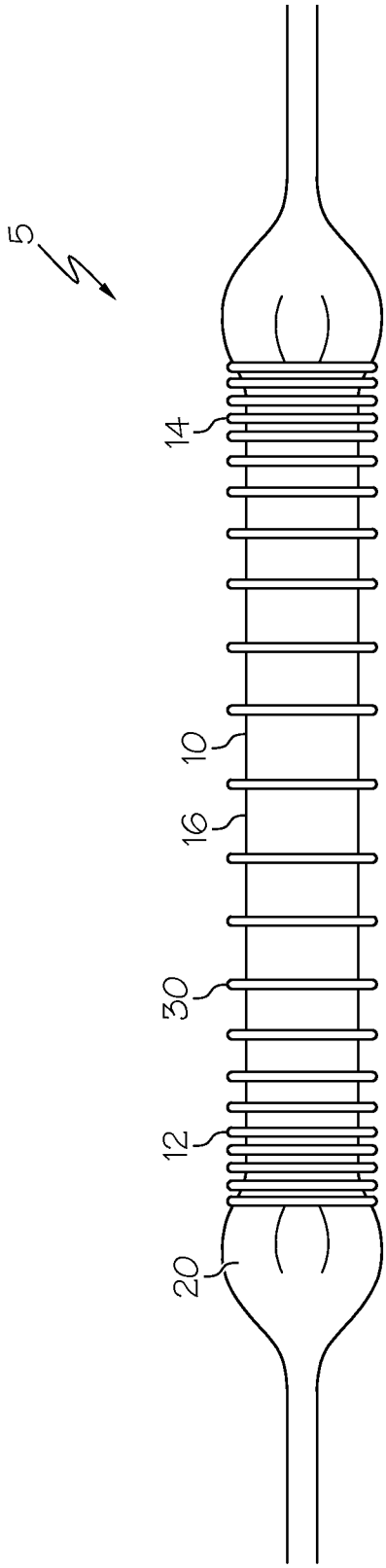

FIG. 4

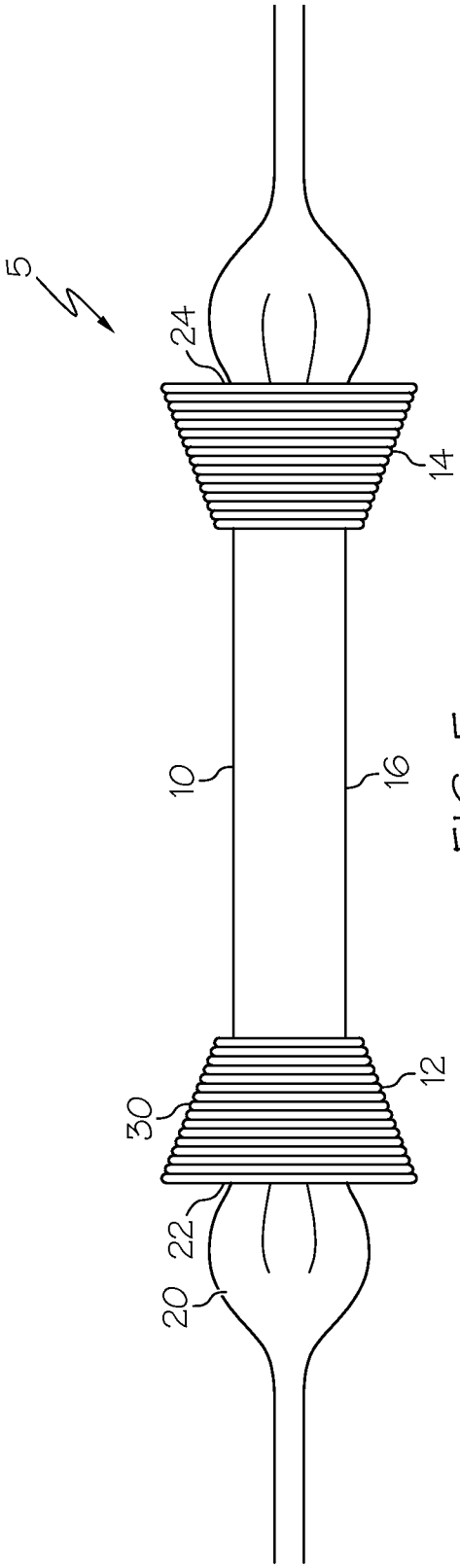

FIG. 5

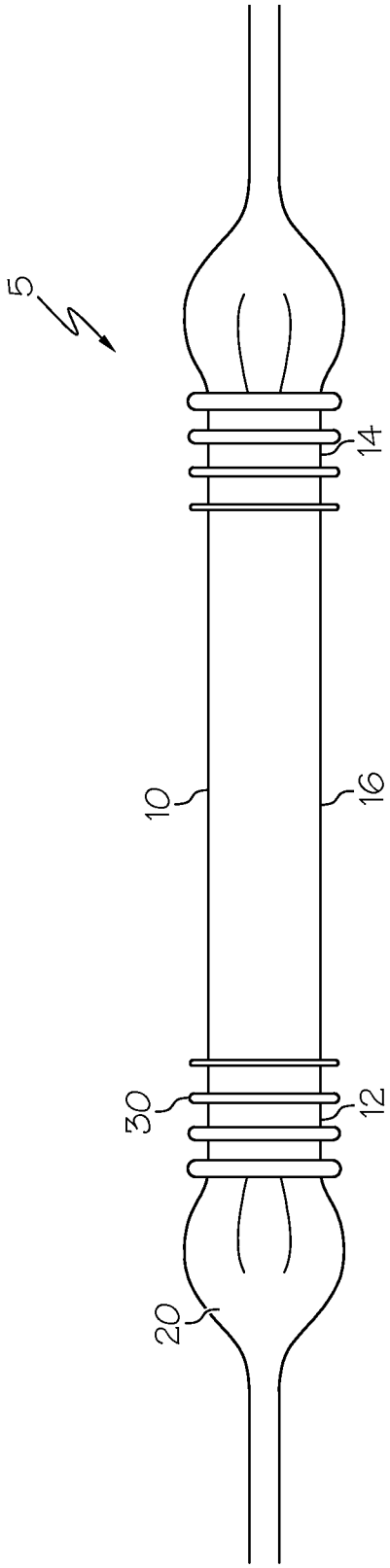

FIG. 6

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2012/038376

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F2/84
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 2007/219642 A1 (RICHTER JACOB [IL]) 20 September 2007 (2007-09-20) paragraphs [0060], [0063], [0071]; figure 11	1-11
A	WO 2008/030488 A2 (MED INST INC [US]; COOK INC [US]; LEEWOOD ALAN R [US]; GREWE DAVID D []) 13 March 2008 (2008-03-13) page 53, line 21 - page 54, line 12; figure 15	1-11
A	US 6 068 634 A (LORENTZEN CORNELIUS LINDA R [US] ET AL) 30 May 2000 (2000-05-30) column 5, line 24 - line 44; figures 5-9	1-11
A	US 2006/047336 A1 (GALE DAVID C [US] ET AL) 2 March 2006 (2006-03-02) paragraph [0093] - paragraph [0094]; figure 5	1-11

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

☒ 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

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"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

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"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
22 August 2012	29/08/2012

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	Skorovs, Peteris

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2012/038376

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