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(54) Title: STENT WITH SHEATH AND METAL WIRE RETAINER

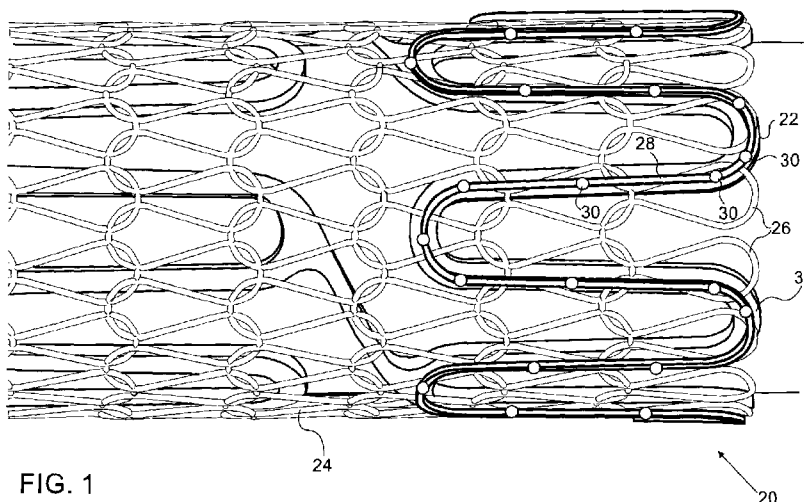


FIG. 1

(57) Abstract: A stent assembly (20) includes a stent (22) and a fiber mesh sleeve (24) covering the stent. A wire (28) runs along the stent over the sleeve and fastened to the stent at multiple points (30) so as to attach the sleeve to the stent.

WO 2012/085807 A1

STENT WITH SHEATH AND METAL WIRE RETAINER**CROSS-REFERENCE TO RELATED APPLICATION**

This application claims the benefit of U.S. Provisional Patent Application 61/424,650, filed December 5 19, 2010, which is incorporated herein by reference.

FIELD OF THE INVENTION

The present invention relates generally to implantable medical devices, and particularly to vascular implants.

10

BACKGROUND OF THE INVENTION

Stents are commonly used in percutaneous coronary revascularization procedures, as well as in treating stenoses in peripheral vasculature, such as in the carotid vessels, organs and extremities. The stent is 15 inserted through the vascular system in a contracted state, until it reaches the desired treatment location, and is then expanded *in situ* to press outward against the vessel wall. Stents typically comprise a mesh of large apertures, which can damage the surrounding stenotic 20 vessel during expansion and can release dangerous emboli into the bloodstream. The damaged tissue is prone to form new scar tissue, which protrudes through the mesh of the stent and can lead to restenosis.

Some stents are fitted with a tubular, flexible 25 jacket for preventing restenosis and reducing the risk of emboli. For example, PCT International Publication WO 2008/062414, whose disclosure is incorporated herein by reference, describes a stent assembly with a stent jacket, comprising an expandable fiber mesh structure 30 fastened around an expandable stent. When the stent is

expanded in a blood vessel, the jacket encourages formation of a stable layer of endothelial cells covering the fibers, while reducing platelet aggregation. WO 2008/062414 shows and describes a number of ways in which the stent jacket can be mounted to the stent, including both adhesive and sliding connections, made by knots.

SUMMARY

Embodiments of the present invention that are described hereinbelow provide improved jackets for implantable devices, and particular improved methods for attachment of a jacket to a device.

There is therefore provided, in accordance with an embodiment of the present invention, a stent assembly, including a stent and a fiber mesh sleeve covering the stent. A wire runs along the stent over the sleeve and fastened to the stent at multiple points so as to attach the sleeve to the stent.

The wire may be point-welded to the stent at the multiple points. In a disclosed embodiment, the stent includes multiple struts, and the wire is fastened to the stent along an outermost strut of the stent. Typically, the wire includes first and second wires, which are fastened to the stent over the sleeve at first and second ends of the stent, respectively, without additional fastening of the sleeve to the stent between the first and second ends.

In one embodiment, the sleeve includes a knit having multiple eyes, and the points at which the wire is fastened to the sleeve are inside the eyes of the knit.

There is also provided, in accordance with an embodiment of the present invention, a method for producing a stent assembly, which includes positioning a

fiber mesh sleeve over a stent. A wire is run along the stent over the sleeve and is fastened to the stent at multiple points so as to attach the sleeve to the stent.

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 DRAWING

Fig. 1 is a schematic, pictorial illustration of a stent assembly, in accordance with an embodiment of the present invention.

DETAILED DESCRIPTION OF EMBODIMENTS

The inventors have found that for optimal performance of a stent jacket of the type described above, it is desirable that the jacket be mounted on the stent in a manner that allows the fibers of the jacket to slide over the stent as the stent expands. Embodiments of the present invention provide means and methods for such mounting.

Fig. 1 is a schematic, pictorial illustration showing one end of a stent assembly 20 of this sort, in accordance with an embodiment of the present invention. Assembly 20 comprises a stent 22 made from a flexible, biocompatible material, typically a metal alloy such as stainless steel or Nitinol, as is known in the art. A fiber mesh sleeve 24 covers stent 22. The mesh in this embodiment is a knit comprising interlocking eyes 26, which define pores of a desired size when the stent assembly is expanded inside a blood vessel. It is desirable that all the eyes at the ends of sleeve 24 be

fastened to stent 22 in order to prevent the knit from unraveling or sliding off the stent.

After aligning sleeve 24 with stent 22, a metal wire 28 is used to attach the sleeve to the stent. Wire 28 is typically made from a biocompatible metal, such as stainless steel, Nitinol, CoCr or any other suitable biocompatible metal alloy, and has a diameter in the range of 10-100 μm . As shown in the figure, wire 28 runs along an outermost strut 32, at the end of stent 22, over the fibers of sleeve 24. The wire is fastened to the radial surface of the underlying strut, typically by multiple point-welds 30, which may be produced by a laser micro-welder, for example. Alternatively, other methods of metal-to-metal fastening may be used. Typically, to hold the sleeve securely and prevent unraveling, one point-weld is made inside each eye 26 of the sleeve that overlies the strut. A similar welded-wire connection is made at the opposite end of the stent assembly (not shown). To allow the sleeve to slide freely over the stent during expansion of the stent, there is typically no additional fastening of the sleeve to the stent between the two ends.

Alternatively, other weld patterns may be used. For example, point-welds 30 may be more closely spaced, with two or more point-welds in at least some of eyes 26. On the other hand, the point-welds may be more widely spaced, at least in some locations, skipping over at least some of the eyes.

The point-welding technique illustrated in Fig. 1 is advantageous in that it fastens sleeve 24 to stent 22 quickly, conveniently, and securely. Between point-welds 30, however, the fibers of sleeve 24 are free to move

between wire 28 and stent 22. Therefore, as stent assembly 20 expands, the fibers of sleeve 24 are able to shift relative to the stent in order to maintain relatively uniform pore sizes.

5 In an alternative embodiment (not shown in the figures), wire 28 runs along the axial, external edge of the outer strut of stent 22 and is point-welded to the edge, rather than to the radial surface as shown in Fig. 1. Further alternatively, other wire and weld
10 configurations may be used and are considered to be within the scope of the present invention. For example, a wire may be placed over the sleeve and welded to the stent at the center of the stent or at some other location between the ends of the stent, in addition to or
15 instead of the wires used at the ends of the stent as shown in the figure.

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
20 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
25 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

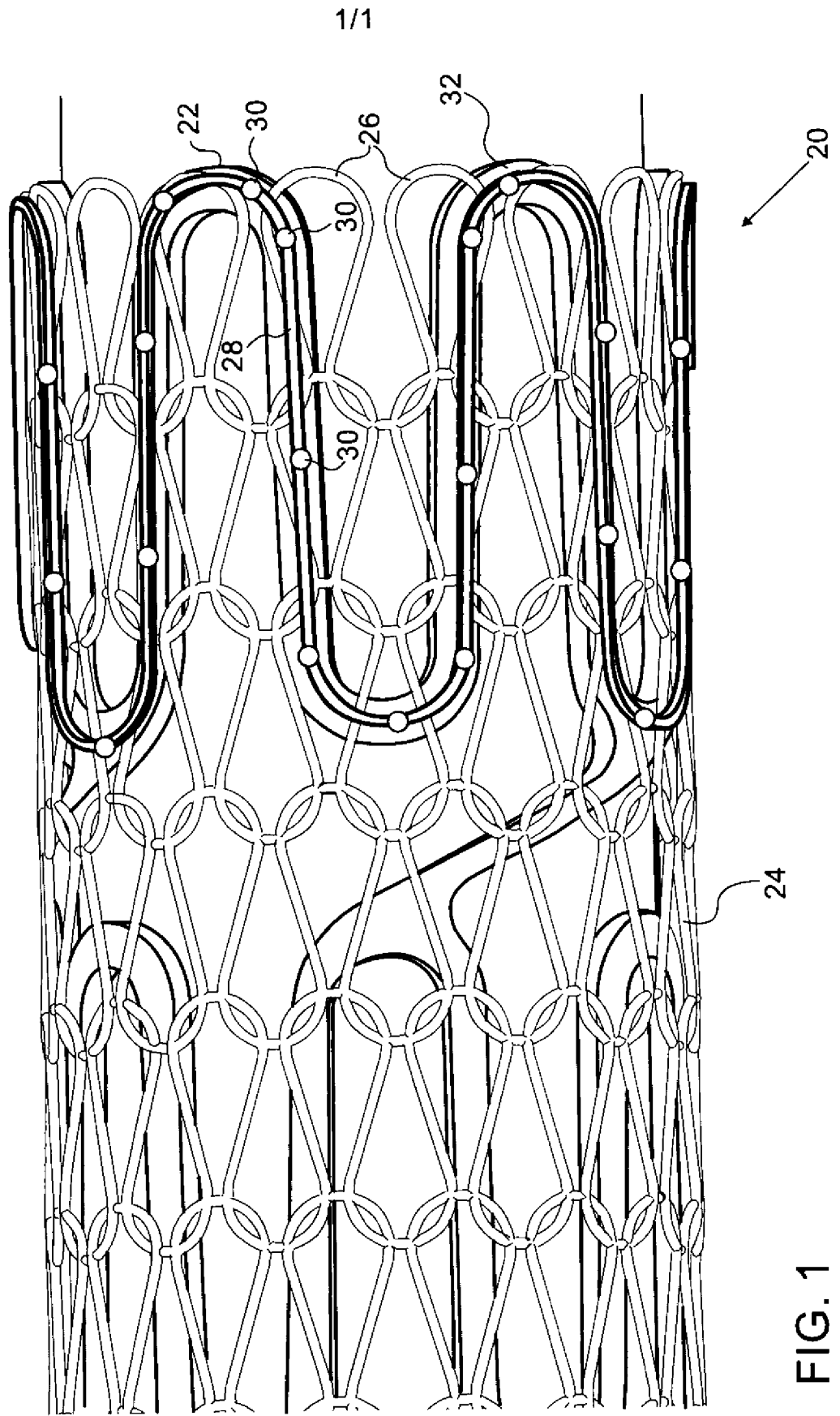
1. A stent assembly, comprising:
 - a stent;
 - a fiber mesh sleeve covering the stent; and
 - 5 a wire, running along the stent over the sleeve and fastened to the stent at multiple points so as to attach the sleeve to the stent.
2. The assembly according to claim 1, wherein the wire is point-welded to the stent at the multiple points.
- 10 3. The assembly according to claim 1 or 2, wherein the stent comprises multiple struts, and wherein the wire is fastened to the stent along an outermost strut of the stent.
4. The assembly according to claim 3, wherein the wire
15 comprises first and second wires, which are fastened to the stent over the sleeve at first and second ends of the stent, respectively, without additional fastening of the sleeve to the stent between the first and second ends.
5. The assembly according to any of claims 1-4, wherein
20 the sleeve comprises a knit having multiple eyes, and wherein the points at which the wire is fastened to the sleeve are inside the eyes of the knit.
6. A method for producing a stent assembly, comprising:
 - positioning a fiber mesh sleeve over a stent;
 - 25 running a wire along the stent over the sleeve; and
 - fastening the wire to the stent at multiple points so as to attach the sleeve to the stent.

7. The method according to claim 6, wherein fastening the wire comprises point-welding the wire to the stent at the multiple points.

8. The method according to claim 6 or 7, wherein the stent comprises multiple struts, and wherein fastening the wire comprises fixing the wire to the stent along an outermost strut of the stent.

9. The method according to claim 8, wherein fastening the wire comprises fixing first and second wires to the stent over the sleeve at first and second ends of the stent, respectively, without additional fastening of the sleeve to the stent between the first and second ends.

10. The method according to any of claims 6-9, wherein the sleeve comprises a knit having multiple eyes, and wherein the points at which the wire is fastened to the sleeve are inside the eyes of the knit.



INTERNATIONAL SEARCH REPORT

International application No.

PCT/IB 11/55758

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61F 2/86 (2012.01)

USPC - 623/1.32

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)
USPC-623/1.32

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
USPC-623/1.1, 1.13, 1.15, 1.44, 1.49, 1.54 (See search terms below)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
Dialog Classic (344, 345, 347, 348, 349, 371, 652, 654, 351), google patents, google
Search terms: vascular, stent, mesh, knit, porous, strut, stent jacket, biocompatible, point-weld, restenosis, coupling, ring, fastening

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X ----- Y	US 2010/0241214 A1 (Holzer et al.) 23 September 2010 (23.09.2010), Entire document especially Figs. 1 and 16, para [0191]	1, 3/(1), 6, and 8/(6) ----- 2, 3/(2), 4, 7, 8/(7) and 9
Y	US 2009/0248133 A1 (Bloom et al.) 1 October 2009 (1.10.2009), Figs. 5-8, para [0078]	2, 3/(2), 4, 7, 8/(7) and 9

Further documents are listed in the continuation of Box C.

* Special categories of cited documents:	"I" 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
"A" document defining the general state of the art which is not considered to be of particular relevance	"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
"E" earlier application or patent but published on or after the international filing date	"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
"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)	"&" document member of the same patent family
"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	

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/IB 11/55758

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. Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

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.: 5 and 10
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 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.