

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
29 March 2001 (29.03.2001)

PCT

(10) International Publication Number
WO 01/21105 A1

(51) International Patent Classification⁷: A61F 2/06

(21) International Application Number: PCT/US00/26000

(22) International Filing Date:
21 September 2000 (21.09.2000)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
09/404,418 23 September 1999 (23.09.1999) US

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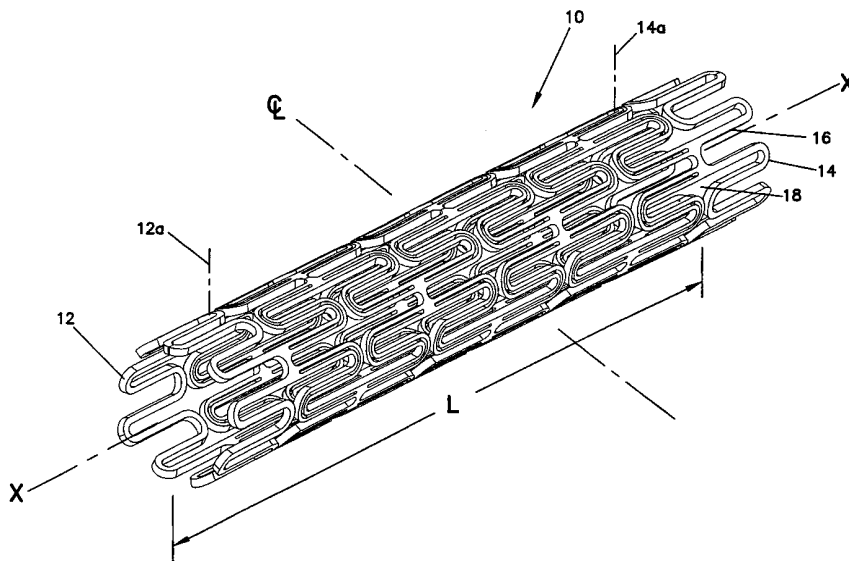
(81) Designated States (*national*): AE, AG, AL, AM, AT, AT (utility model), AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, CZ (utility model), DE, DE (utility model), DK, DK (utility model), DM, DZ, EE, EE (utility model), ES, FI, FI (utility model), GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KR (utility model), KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW.

(84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:
— With international search report.
— Before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments.

[Continued on next page]

(54) Title: STENT WITH ENHANCED FRICTION



(57) Abstract: A stent for placement in a body lumen is fabricated by forming a tube having an un-deployed diameter sized for the tube to be placed on a deployment balloon and advanced through a body lumen to a deployment site. The tube is expandable upon inflation of the balloon to an enlarged diameter sized for the tube to be retained within the lumen at the site upon deflation and withdrawal of the balloon. The tube has a stent axis extending between first and second axial ends of the tube. The tube has an exterior surface and an interior surface. The tube is polished to polish the exterior surface to a smooth surface finish and with at least a portion of the interior surface having a rough surface finish rougher than the surface finish of the exterior surface.



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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

STENT WITH ENHANCED FRICTION**I.****BACKGROUND OF THE INVENTION**

5

1. Field of the Invention

This invention pertains to stents for use in intraluminal applications. More particularly, this invention pertains to a stent with enhanced friction on a delivery catheter.

10

2. Description of the Prior Art

Stents are widely used for numerous applications where the stent is placed in the lumen of a patient and expanded. Such stents may be used in coronary or other vasculature, as well as other body lumens.

15

Commonly, stents are cylindrical members. The stents expand from reduced diameters to enlarged diameters. Frequently, such stents are placed on a balloon catheter with the stent in the reduced-diameter state. So placed, the stent is advanced on the catheter to a placement site. At the site, the balloon is inflated to expand the stent to the enlarged diameter. The balloon is deflated and removed, leaving the enlarged diameter stent in place. So used, such stents are used to expand occluded sites within a patient's vasculature or other lumen.

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Examples of prior art stents are numerous. For example, U.S. Patent No. 5,449,373 to Pinchasik et al. teaches a stent with at least two rigid segments joined by a flexible connector. U.S. Patent No. 5,695,516 to Fischell teaches a stent with a cell having a butterfly shape when the stent is in a reduced-diameter state. Upon expansion of the stent, the cell assumes a hexagonal shape.

25

To deliver a stent, the stent in a reduced diameter shape is placed surrounding a deflated tip of a balloon catheter. The catheter and stent are simultaneously advanced through a sheath to a deployment site in a body lumen. At the site, the balloon is inflated to expand the stent. Following such expansion, the balloon is deflated. The catheter is withdrawn leaving the expanded stent in place.

30

In order to prevent the presence of sharp corners and burrs which might otherwise damage a balloon, stents are highly polished to a mirror finish.

Unfortunately, a highly polished stent can slip off a balloon tip catheter. Also, when a balloon is inflated, the axially spaced ends of the balloon tend to inflate faster than the center of the balloon. This can result in a concave cross-section (when viewed from the side) in the balloon and stent at a point in time prior to full expansion of the stent. During this period, ends of the stent may slide toward one another on the balloon toward the center of the balloon resulting in an undesirable compression of the length of the stent.

II.

SUMMARY OF THE INVENTION

According to a preferred embodiment of the present invention, a stent for placement in a body lumen is fabricated by forming a tube having an un-deployed diameter sized for the tube to be placed on a deployment balloon and advanced through a body lumen to a deployment site. The tube is expandable upon inflation of the balloon to an enlarged diameter sized for the tube to be retained within the lumen at the site upon deflation and withdrawal of the balloon. The tube has a stent axis extending between first and second axial ends of the tube. The tube has an exterior surface and an interior surface. The tube is polished to polish the exterior surface to a smooth surface finish and with at least a portion of the interior surface having a rough surface finish rougher than the surface finish of the exterior surface.

III.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is perspective view of a stent;

Fig. 2 is the view of Fig. 1 with a nozzle poised to spray a particulate matter against the interior of the stent according to the present invention;

Fig. 3 is a cross-sectional view of a rib of the stent of Fig. 1 before treatment according to the present invention; and

Fig. 4 is the view of Fig. 3 following treatment according to the present invention.

IV.

DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring now to the several drawing figures in which identical elements are numbered identically, a description of the preferred embodiment of the present

invention will now be provided. Where several embodiments are shown, common elements are similarly numbered and not separately described with the addition of apostrophes to distinguish the embodiments.

In Fig. 1, a stent 10 is shown. The stent 10 is a hollow reticulated tube having an axis X – X and extending between first and second ends 12, 14. The stent 10 is shown in a reduced diameter state sized to be advanced through a human body lumen to a deployment site in the lumen. By way of non-limiting representative example, the stent may have an axial length L of about 9 mm – 76 mm depending on the intended use of the stent (e.g., for opening an occluded site in a coronary artery or other body lumen). By way of none limiting representative example, such a stent 10 may have a reduced or unexpanded diameter D of 2.0 mm and be expandable to an expanded diameter of 10 mm.

For purposes of illustration, the present invention is described with reference to a stent 10 having a structure such as more fully described in commonly assigned and copending U.S. patent application Ser. Nos. 09/049,486 filed March 27, 1998 and 09/069,347 filed April 29, 1998. Such a stent 10 is formed from a hollow, solid wall tube of stent material (e.g., titanium, Nitinol, stainless steel etc.). Excess material of the tube is removed through any suitable means such as laser cutting or chemical etching. Removal of the excess material leaves a stent 10 having a plurality of ribs 16 defining a plurality of open cells 18 extending through the wall thickness of the stent 10. The ribs 16 have interior surfaces 16a (Figs. 3 and 4) facing the axis X – X and exterior surfaces 16b facing away from the axis X – X. The interior and exterior surfaces 16a, 16b are joined by radial surfaces 16c.

In use, the reduced diameter stent 10 is placed on a balloon-tipped catheter. During such placement, the catheter balloon is deflated and the stent 10 is surrounding the balloon. The catheter and mounted stent are passed through the patient's lumen. Commonly, the catheter and stent are advanced through a catheter sheath pre-positioned within the lumen. The catheter and stent are advanced through an open distal end of the sheath to the deployment site within the lumen. At this point, the balloon is inflated to expand the stent 10 to the expanded diameter. After such expansion, the balloon is deflated and the catheter is withdrawn leaving the expanded stent 10 positioned within the lumen.

It will be appreciated that the foregoing description of stent 10 and its placement using a balloon-tipped catheter are previously known. Such description is provided to clarify the benefits of the present invention.

When forming a stent 10 from a solid wall tube as described, surface imperfections may be formed on the stent 10. For example, these can include sharp edges between surfaces 16a and 16c or surfaces 16b and 16c. Further, such imperfections may include burrs. Such imperfections are undesirable. A sharp surface imperfection at the interior surface 16a can damage a catheter balloon thereby degrading or precluding its desired performance. A surface imperfection on the exterior surface 16b can cause the stent 10 to be difficult to advance through a catheter sheath to the desired deployment site.

Recognizing the undesirability of such surface imperfections, the prior art uses polishing techniques to polish a stent 10 to a high degree of smooth surface finish for all of surfaces 16a, 16b and 16c. Unfortunately, such a highly polished stent 10 presents additional problems. Namely, the exterior surfaces of catheter balloons are slippery relative to the material of a highly polished stent 10. Therefore, a stent 10 can be displaced on or fall off a catheter balloon. Also, when a balloon is inflated, the axially spaced ends of the balloon tend to inflate faster than the center of the balloon. This can result in a concave cross-section (when viewed from the side) in the balloon. Since the highly polished stent 10 is slidable on the balloon, the ends 12, 14 of the stent 10 may tend to slide toward one another when the balloon is in the intermediate concave state. Such movement can result in an undesirable compression of the length L of a highly polished stent 10.

The prior art has suggested the use of so-called "sticky" balloon which are coated or otherwise formed with a material having an enhanced adhesion with a highly polished inner surface 16a of a stent 10. However, such balloons are difficult and expensive to manufacture.

The present invention selective roughens the interior surface 16a of the stent 10 to enhance friction between the stent 10 and a catheter balloon. Such a roughening is counter-intuitive since conventional stent construction theory calls for a smooth, highly polished stent to avoid or minimize raised areas which might otherwise provide sites for thrombus formation or platelet activation after the stent is

deployed. However, test data have indicated that a stent 10 with roughened surfaces as will be described does not exhibit excessive thrombus formation or platelet activation.

5 The interior surface 16a of the stent 10 is roughened to a rough surface finish rougher than the surface finish of the exterior surface 16b. In the roughening process as will be described, the radial surfaces 16c are also roughened.

In a preferred embodiment, only a limited area between ends 12, 14 of the interior surface 16a is roughened. This area is shown in Fig. 1 as bounded between lines 12a, 14a spaced about 4 mm into the interior of the stent 10 from ends 12, 14.
10 The roughened area completely surrounds the axis X – X. While the entire interior surface 16a could be roughened, it is preferred that at least areas on opposite sides of a center-line CL of the stent 10 be roughened to prevent axial shortening of the stent. Preferably, the boundaries 12a, 14a of the roughened area are as close as possible to ends 12, 14 to prevent even a small amount of axial shortening.

15 As shown in Fig. 2, the roughening is provided by a nozzle 30 positioned adjacent an end (e.g., end 12) of the stent 10. The nozzle 30 is positioned with a nozzle orifice 32 directing a particulate stream at an angle relative to the stent axis X – X. In a preferred embodiment, the orifice is positioned 1.0 mm from end 12 and the angle is 30°. By way of example, the nozzle 30 is a product sold under the name
20 “Microblaster” of Comco, Inc. and has an orifice diameter of .015 inch. The particulate stream is powder silicon carbide size of about 50 micron which is discharged from the orifice at a pressure of 60 psi. During the application of the particulate stream, the stent 10 is rotated 360° about its axis X – X. When it is desirable to limit the axial length of the roughened area, a rod (not shown) may be
25 inserted through the opposite end 14 of the stent 10 to expose only the area 12 to be roughened. Following roughening through end 12, the procedure is repeated on the opposite end 14 to uniformly roughen the surface 16a. If desired, a tube may be placed around the exterior surface 16b to insure the exterior surface 16b is not roughened by the process. In the roughening process, the radial surfaces 16c are also
30 roughened. Roughening of the radial surfaces 16c is not essential to the present invention. However, such roughening is not detrimental.

The surfaces 16a, 16c are uniformly covered with pits which are approximately 3 to 20 microns in size.

5 With a stent 10 as described, the stent 10 has enhanced friction on a deployment balloon. Slippage of the stent 10 on the balloon is reduced and integrity of the axial length L of the stent 10 is maintained. Also, and surprisingly, the stent 10 performs without undue thrombus formation or platelet activation in the roughened area of surface 16b.

10 From the foregoing, the present invention has been shown in a preferred embodiment. Modifications and equivalents are intended to be included within the scope of the appended claims.

What is claimed is:

1. An intraluminal stent comprising:

5 a tube having an un-deployed diameter sized for the tube to be placed on a deployment balloon and advanced through a body lumen to a deployment site;

10 said tube expandable upon inflation of said balloon to an enlarged diameter sized for said tube in said enlarged diameter to be retained within said lumen at said site upon deflation and withdrawal of said balloon;

said tube having a stent axis extending between first and second axial ends of said tube;

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said tube having an exterior surface and an interior surface;

said interior surface including at least a portion having a rough surface finish rougher than a surface finish of said exterior surface.

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2. A stent according to claim 1 wherein said portion includes first and second portion of said rough surface finish disposed on opposite sides of a center of said tube.

25 3. A stent according to claim 2 wherein said portion extends along substantially an entire axial length of said tube.

4. A method for fabricating a stent for placement in a body lumen, said method comprising:

30 forming a tube having an un-deployed diameter sized for the tube to be placed on a deployment balloon and advanced through a body lumen to a deployment site,

said tube expandable upon inflation of said balloon to an enlarged diameter sized for said tube in said enlarged diameter to be retained within said lumen at said site upon deflation and withdrawal of said balloon, said tube having a stent axis extending between first and second axial ends of said tube, said
5 tube having an exterior surface and an interior surface;

polishing said tube to polish said exterior surface to a smooth surface finish and with at least a portion of said interior surface having a rough surface finish rougher than said exterior surface finish.

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5. A method according to claim 4 wherein both said exterior surface and interior surface are polished to remove balloon threatening burrs and said portion of said interior surface is subsequently roughened to said rough surface finish.
- 15 6. A method according to claim 5 wherein said rough surface finish is applied at least on opposite sides of a center of said tube.
7. A method according to claim 6 wherein said rough surface finish is applied substantially entirely along an axial length of said interior surface.

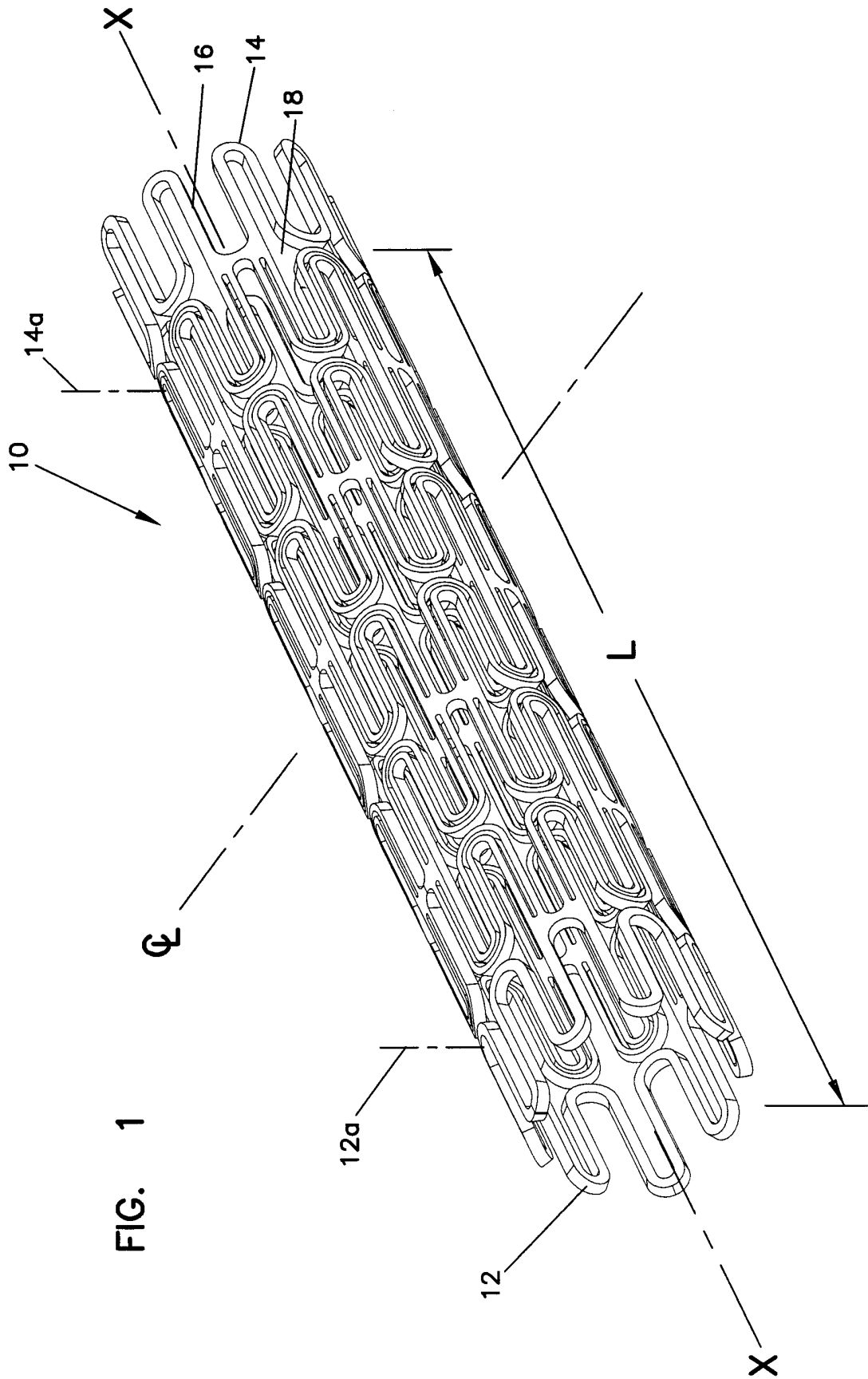


FIG. 2

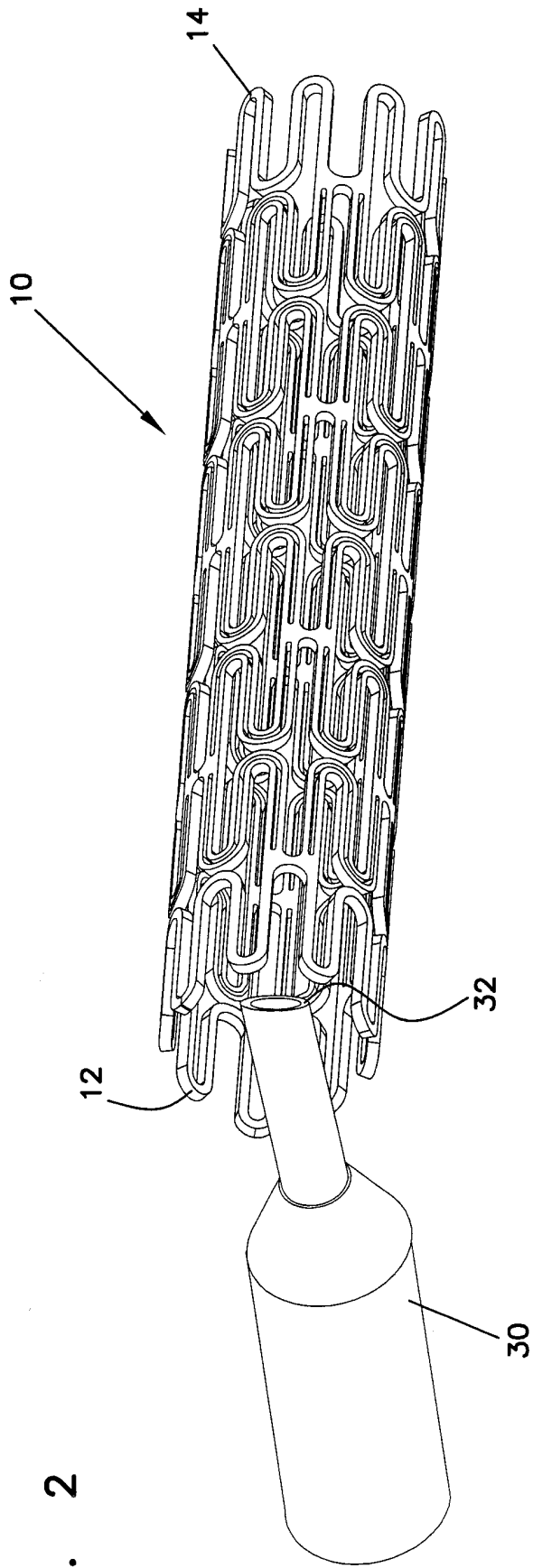


FIG. 3

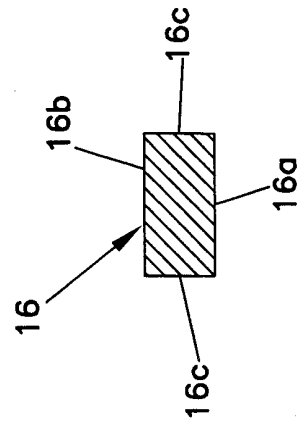
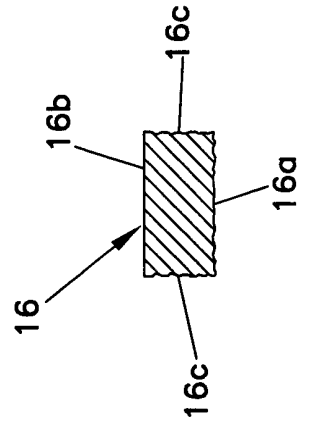


FIG. 4



INTERNATIONAL SEARCH REPORT

Intern. Application No PCT/US 00/26000

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/06

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)
IPC 7 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 practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0 850 604 A (SORIN BIOMEDICA SPA) 1 July 1998 (1998-07-01) column 4, line 1 - line 51; figures ---	1, 4
A	EP 0 688 545 A (TERUMO CORP) 27 December 1995 (1995-12-27) column 9, line 46 - line 49; figures ---	1, 4
A	EP 0 701 803 A (AO FORSCHUNGSINST) 20 March 1996 (1996-03-20) -----	

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

° Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
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- *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

22 January 2001

Date of mailing of the international search report

26/01/2001

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INTERNATIONAL SEARCH REPORT

Information on patent family members

Intern. Application No
PCT/US 00/26000

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