(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
24 January 2008 (24.01.2008)

PCT

(10) International Publication Number
WO 2008/011028 A1

(51) International Patent Classification:
A61F 2/84 (2006.01)

(21) International Application Number:
PCT/US2007/016200

(22) International Filing Date: 17 July 2007 (17.07.2007)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
11/489,309 18 July 2006 (18.07.2006) US

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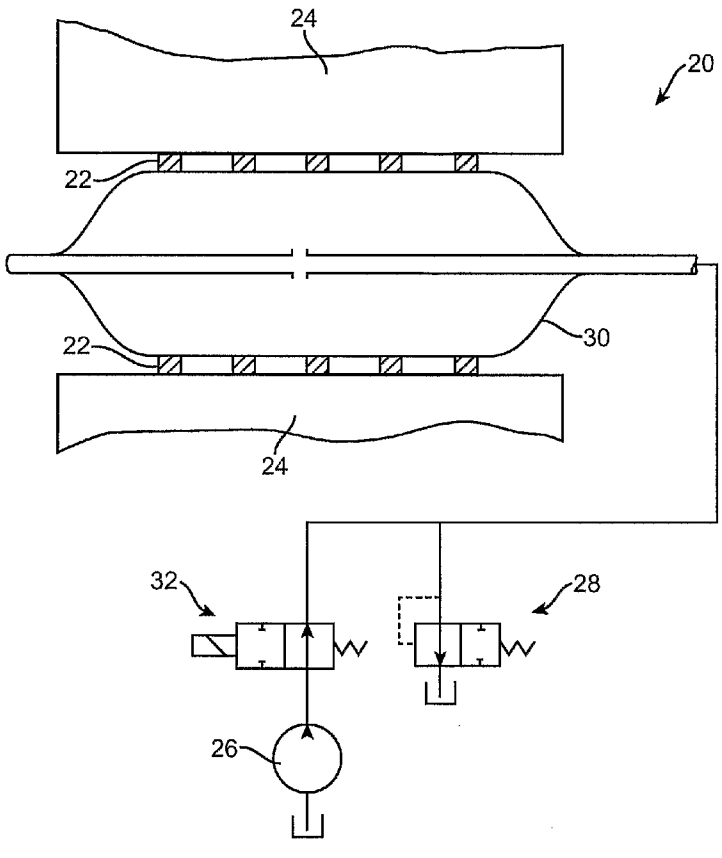
(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, MT, NL, PL,

[Continued on next page]

(54) Title: STENT CRIMPING APPARATUS AND METHOD



(57) Abstract: A method for crimping a stent onto a balloon includes inflating a balloon with a fluid, sliding a stent over the inflated balloon, crimping the stent onto the balloon, and controlling the pressure inside the balloon below a given value when the stent is being crimped onto the balloon.

WO 2008/011028 A1

PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, 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*

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STENT CRIMPING APPARATUS AND METHOD

FIELD OF THE INVENTION

This invention relates to an apparatus for crimping a stent and a method for crimping a stent.

BACKGROUND

A typical stent is a cylindrically shaped device, which holds open and sometimes expands a segment of a blood vessel or other anatomical lumen such as urinary tracts and bile ducts. Stents are often used in the treatment of atherosclerotic stenosis in blood vessels. "Stenosis" refers to a narrowing or constriction of the diameter of a bodily passage or orifice. In such treatments, stents reinforce body vessels and prevent restenosis following angioplasty. "Restenosis" refers to the reoccurrence of stenosis in a blood vessel or heart valve after it has been subjected to angioplasty or valvuloplasty.

A stent is typically composed of scaffolding that includes a pattern or network of interconnecting structural elements often referred to in the art as struts or bar arms. The scaffolding can be formed from wires, tubes, or sheets of material rolled into a cylindrical shape.

In the case of a balloon expandable stent, the stent is mounted on a balloon connected to a catheter. A typical conventional method of mounting the stent on the balloon is a two-step process. First, the stent is compressed or crimped onto the balloon. Second, the compressed or crimped stent is retained or secured on the balloon. The retained stent should have a sufficiently small diameter so that it can be transported through the narrow passages of blood vessels. The stent must be secured on the balloon

during delivery until it is deployed at an implant or treatment site within a vessel in the body of a patient. The stent is then expanded by inflating the balloon. "Delivery" refers to introducing and transporting the crimped stent through a bodily lumen to the treatment site in a vessel. "Deployment" corresponds to the expanding of the crimped stent within the lumen at the treatment site. Delivery and deployment of a stent are accomplished by positioning the stent about one end of a catheter, inserting the end of the catheter through the skin into a bodily lumen, advancing the catheter in the bodily lumen to a desired treatment location, inflating the stent at the treatment location, and removing the catheter from the lumen by deflating the balloon.

The stent should be firmly secured to the balloon to avoid detachment of the stent before it is delivered and deployed in the lumen of the patient. Detachment of a stent from the balloon during delivery and deployment can result in medical complications. A lost stent can act as an embolus that can create a thrombosis and require surgical intervention. For this reason, a stent must be securely attached to the catheter. Stent retention is greatly enhanced by protrusion of the balloon into the interstitial spaces or gaps between stent struts.

Stent retention for a polymer stent is especially challenging. Because polymers generally have lower strength than metals, a polymer stent requires wider struts than a metal stent to achieve the same mechanical strength. As a result, a polymer stent has smaller spaces or gaps between adjacent struts, making it more difficult for a balloon to protrude into the spaces to enhance stent retention. Additionally, a polymer stent may have a similar T_g as the balloon material so that there is a limitation on the use of high temperature to enhance balloon protrusion into stent gaps. When high temperature is used

during a crimping process, the stent tends to return to its original dimension and lose its preferred mechanical properties.

SUMMARY

The present invention overcomes the above disadvantage of the prior art. In an preferred embodiment of the present invention, the balloon may be inflated when the stent is crimped onto the balloon, allowing the balloon to extend into the gaps of the stent to enhance stent retention.

In accordance with one aspect of the invention, a method for crimping a stent onto a balloon includes inflating a balloon with a fluid such as a gas or a liquid, sliding a stent over the inflated balloon, crimping the stent onto the balloon, and controlling the pressure inside the balloon below a given value when the stent is being crimped onto the balloon.

In a preferred embodiment of the invention, the step of controlling includes releasing the fluid inside the balloon when the pressure exceeds the given value so that the pressure inside the balloon does not exceed the given value.

In another preferred embodiment of the invention, the step of releasing includes using a pressure release valve to control the fluid inside the balloon below the given value.

In still another preferred embodiment of the invention, the method includes placing the stent and balloon in a crimper before the stent is crimped onto the balloon.

In a further embodiment of the invention, the method includes soaking the balloon in a solvent to soften the balloon. The solvent may be acetone.

In accordance with another aspect of the invention, a method for crimping a stent onto a balloon includes sliding a stent over a balloon, placing the stent and balloon in a stent crimper, inflating the balloon with a fluid such as a gas or a liquid, crimping the stent onto the balloon, and controlling the pressure inside the balloon below a given value when the stent is being crimped onto the balloon.

In a preferred embodiment of the invention, the method includes reducing the crimper's inner diameter to the outer diameter of the stent before inflating the balloon with the fluid.

In another preferred embodiment of the invention, the step of controlling includes releasing the fluid inside the balloon when the pressure exceeds the given value so that the pressure inside the balloon does not exceed the given value.

In still another preferred embodiment of the invention, the step of releasing includes using a pressure release valve to control the fluid inside the balloon below the given value.

In a further embodiment of the invention, the method includes soaking the balloon in a solvent to soften the balloon. The solvent may be acetone.

In accordance with a further aspect of the invention, a stent crimping apparatus includes means for inflating a balloon with a fluid such as a gas or a liquid, means for crimping the stent onto the balloon, and means for controlling the pressure inside the balloon below a given value when the stent is being crimped onto the balloon.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 shows a perspective view of a stent.

Figure 2 shows one apparatus for crimping a stent according to the present invention.

Figure 3 shows portions of a balloon extending into the gaps of a stent.

DETAILED DESCRIPTION OF THE INVENTION

Those of ordinary skill in the art will realize that the following description of the invention is illustrative only and not in any way limiting. Other embodiments of the invention will readily suggest themselves to such skilled persons based on the disclosure herein. All such embodiments are within the scope of this invention.

Figure 1 illustrates a stent 10 that includes a number of interconnecting structural elements or struts 11. In general, the pattern of the stent struts is designed so that the stent can be radially compressed and expanded. The stent may include portions of struts that are straight or relatively straight, an example being a straight portion designated by reference numeral 12. The stent may also include portions of struts that are bent, such as the portions designated by reference numerals 13, 14, and 15. The bent portions 13, 14, and 15 may bend further when the stent 10 is crimped radially inwardly. The bent portions 13, 14, and 15 may bend less when the stent 10 is expanded radially outwardly.

A stent, as fabricated, is uncrimped and may have an outside diameter that is typically from about 1 mm and to about 4 mm. When the stent is crimped, the structural elements deform allowing the stent to decrease in diameter. The deformation occurs primarily at the bending elements. The balloon, when mounted on a catheter, may have an outside diameter of between about 0.7 mm and 0.8 mm. The outside diameter of a crimped stent may be approximately the same as the outside diameter of the balloon.

In some embodiments, a stent of the present invention may be formed from a tube by laser cutting the pattern of structural elements in the tube. The stent may also be formed by laser cutting a polymeric or metallic sheet, rolling the pattern into the shape of the cylindrical stent, and providing a longitudinal weld to form the stent. Other methods of forming stents are well known and include chemically etching a polymeric or metallic sheet and rolling and then welding it to form the stent. A polymeric or metallic wire may also be coiled to form the stent. The stent may be formed by injection molding of a thermoplastic or reaction injection molding of a thermoset polymeric material. Filaments of the compounded polymer may be extruded or melt spun. These filaments can then be cut, formed into ring elements, welded closed, corrugated to form crowns, and then the crowns welded together by heat or solvent to form the stent. Lastly, hoops or rings may be cut from tubing stock, the tube elements stamped to form crowns, and the crowns connected by welding or laser fusion to form the stent.

A stent can be made from one or more suitable materials. For example, a stent may be made from a metallic material. Alternatively, a stent may be made from a polymeric material. A stent may include a biodegradable material, such as a biodegradable polymer or metal. The biodegradable material may be a pure or substantially pure biodegradable polymer or metal. Alternatively, the biodegradable material may be a mixture of at least two types of biodegradable polymers and metals.

Representative examples of polymers that may be used to fabricate embodiments of stents, or more generally, implantable medical devices include, but are not limited to, poly(N-acetylglucosamine) (Chitin), Chitosan, poly(3-hydroxyvalerate), poly(lactide-co-glycolide), poly(3-hydroxybutyrate), poly(4-hydroxybutyrate), poly(3-hydroxybutyrate-co-3-hydroxyvalerate), polyorthoester, polyanhydride, poly(glycolic acid),

poly(glycolide), poly(L-lactic acid), poly(L-lactide), poly(D,L-lactic acid), poly(D,L-lactide), poly(L-lactide-co-D,L-lactide), poly(caprolactone), poly(L-lactide-co-caprolactone), poly(D,L-lactide-co-caprolactone), poly(glycolide-co-caprolactone), poly(trimethylene carbonate), polyester amide, poly(glycolic acid-co-trimethylene carbonate), co-poly(ether-esters) (e.g. PEO/PLA), polyphosphazenes, biomolecules (such as fibrin, fibrinogen, cellulose, starch, collagen, and hyaluronic acid), polyurethanes, silicones, polyesters, polyolefins, polyisobutylene and ethylene-alphaolefin copolymers, acrylic polymers and copolymers, vinyl halide polymers and copolymers (such as polyvinyl chloride), polyvinyl ethers (such as polyvinyl methyl ether), polyvinylidene halides (such as polyvinylidene chloride), polyacrylonitrile, polyvinyl ketones, polyvinyl aromatics (such as polystyrene), polyvinyl esters (such as polyvinyl acetate), acrylonitrile-styrene copolymers, ABS resins, polyamides (such as Nylon 66 and polycaprolactam), polycarbonates, polyoxymethylenes, polyimides, polyethers, polyurethanes, rayon, rayon-triacetate, cellulose acetate, cellulose butyrate, cellulose acetate butyrate, cellophane, cellulose nitrate, cellulose propionate, cellulose ethers, and carboxymethyl cellulose. Additional representative examples of polymers that may be especially well suited for use in fabricating embodiments of implantable medical devices disclosed herein include ethylene vinyl alcohol copolymer (commonly known by the generic name EVOH or by the trade name EVAL), poly(butyl methacrylate), poly(vinylidene fluoride-co-hexafluoropropene) (e.g., SOLEF 21508, available from Solvay Solexis PVDF, Thorofare, NJ), polyvinylidene fluoride (otherwise known as KYNAR, available from ATOFINA Chemicals, Philadelphia, PA), ethylene-vinyl acetate copolymers, poly(vinyl acetate), styrene-isobutylene-styrene triblock copolymers, and polyethylene glycol.

Figure 2 illustrates one apparatus 20 for crimping a stent 22 according to the present invention. In the present invention, to "crimp" a stent is to compress the stent radially inward to reduce its diameter. The apparatus 20 may include one or more crimping elements 24, a source 26 for pressurized fluid, and a pressure control device 28.

The crimping elements 24 can be used to crimp the stent 22. The crimping elements 24 may be any of the known crimping devices that can move radially to crimp the stent 22. Such crimping elements (or device) are well known in the art and will not be described in detail here.

The pressurized fluid source 26 can be used to supply pressurized fluid, such as pressurized gas or liquid, to inflate a balloon 30, on which the stent 22 is mounted. The balloon 28 may be part of a catheter (not shown). The pressurized fluid source 26 may be any device that can supply pressurized fluid, such as a pump or an accumulator. In the illustrated embodiment, the pressurized fluid source 26 is a pump 26. Preferably, a valve 32 is provided that can shut off the pressurized fluid supplied by the pump 26 to the balloon 30.

The pressure control device 28 may be used to control the pressure inside the balloon 30. For example, the pressure control device 28 may keep the pressure inside of the balloon 30 below a predetermined value. The pressure control device may be any suitable device for achieving this purpose. In the illustrated embodiment, the pressure control device 28 is a pressure relief valve 28.

To crimp the stent 22 on the balloon 30 in accordance with one method of the present invention, the balloon 30 is first inflated using the pressurized fluid supplied by the pump 26 (or any other suitable pressurized fluid source). To soften the balloon 30, the

balloon 30 may be soaked in a solvent, such as acetone, for a predetermine period of time. After the stent 22 at a first diameter value has been slid on the inflated balloon 30, the stent 22 and balloon 30 are placed in the stent crimping apparatus 20. Next, the crimping elements 24 may radially compress the stent 22 to reduce the stent's diameter to a second diameter value while the balloon remains inflated. During crimping, the balloon pressure may be kept at or below a first pressure value by the pressure relief valve 28. If the pressure inside the balloon 30 is above the first pressure value, the pressure relief valve 28 opens to discharge the pressurized fluid inside the balloon until the pressure reaches or is below the first pressure value. After the diameter of the stent has been reduced to the second diameter value, the balloon pressure may be kept at the first pressure value for a first period of time. Then the pressure inside the balloon may be released for a second period of time. Next the balloon is inflated again to a second pressure value, and the stent is crimped again until its diameter reaches a third diameter value. The balloon pressure may be kept at the second pressure value for a third period of time. Then the pressure inside the balloon may be released, and the stent and balloon may be removed from the stent crimping apparatus 20.

To crimp the stent 22 on the balloon 30 in accordance with another method of the present invention, the stent 22 is first slid on the balloon 30 without the balloon 30 being inflated. To soften the balloon 30, the balloon 30 may be soaked in a solvent, such as acetone, for a predetermine period of time. Then the stent 22 and balloon 30 are placed in the stent crimping apparatus 20. Next the stent 22 may be radially compressed from a first diameter value to a second diameter value while the balloon is not inflated. After the diameter of the stent has been reduced to the second diameter value, the balloon may be inflated to a first pressure value for a first period of time. Then the stent is crimped again

until its diameter reaches a third diameter value. The balloon pressure may be kept at the first pressure value for a second period of time. Then the pressure inside the balloon may be released, and the stent and balloon may be removed from the stent crimping apparatus 20.

Figure 3 shows that after the stent 22 has been crimped onto the balloon 30 using a method of the present invention, portions 34 of the balloon 30 extend into the gaps of the stent 22.

The following are two examples of stent crimping using a method of the present invention.

Example I

The outer diameter of a pre-crimp stent is 0.135 inches. The balloon is inflated to 39 psi, and the stent is mounted on the balloon. The stent and balloon are placed in a stent crimping apparatus, and the stent is crimped to 0.090 inches while the balloon pressure is kept at 39 psi. Next, the balloon pressure is kept at 39 psi for 20 seconds. Afterwards, the balloon may be deflated for a period of time. The crimper then reduces the outer diameter of the stent to 0.045 inches for 50 seconds without balloon pressure. The balloon is inflated again for 20 seconds under 39 psi. Then the balloon pressure is reduced to zero for 20 seconds. Finally, the stent and balloon are removed from the crimper.

Example II

The outer diameter of an uncrimped stent is 0.084 inches. The uncrimped stent is placed in a crimper, and the crimper's inner diameter is reduced to 0.084 inches, which is the outer diameter of the uncrimped stent. Next, the balloon is inflated under 30 psi

pressure for 20 seconds. The crimper then reduces the outer diameter of the stent to 0.032 inches under 30 psi for five seconds and then for 45 seconds without balloon pressure. The balloon is inflated again for 25 seconds under 30 psi. Then the balloon pressure is reduced to zero for 10 seconds. Finally, the stent and balloon are removed from the crimper.

While particular embodiments of the present invention have been shown and described, it will be obvious to those skilled in the art that changes and modifications can be made without departing from this invention in its broader aspects.

What is claimed is:

1. A method for crimping a stent onto a balloon, comprising:

inflating a balloon with a fluid;

sliding a stent over the inflated balloon;

crimping the stent onto the balloon; and

controlling the pressure inside the balloon below a given value when the stent is being crimped onto the balloon.

2. The method of claim 1, wherein the step of controlling includes releasing the fluid inside the balloon when the pressure exceeds the given value so that the pressure inside the balloon does not exceed the given value.

3. The method of claim 2, wherein the step of releasing includes using a pressure release valve to control the fluid inside the balloon below the given value.

4. The method of claim 1, further comprising placing the stent and balloon in a crimper before the stent is crimped onto the balloon.

5. The method of claim 1, further comprising soaking the balloon in a solvent to soften the balloon.

6. The method of claim 5, wherein the solvent is acetone.

7. A method for crimping a stent onto a balloon, comprising:

sliding a stent over a balloon;

placing the stent and balloon in a stent crimper;

inflating the balloon with a fluid;

crimping the stent onto the balloon; and

controlling the pressure inside the balloon below a given value when the stent is being crimped onto the balloon.

8. The method of claim 7, further comprising reducing the crimper's inner diameter to the outer diameter of the stent before inflating the balloon with the fluid.

9. The method of claim 7, wherein the step of controlling includes releasing the fluid inside the balloon when the pressure exceeds the given value so that the pressure inside the balloon does not exceed the given value.

10. The method of claim 9, wherein the step of releasing includes using a pressure release valve to control the fluid inside the balloon below the given value.

11. The method of claim 1, further comprising soaking the balloon in a solvent to soften the balloon.

12. The method of claim 11, wherein the solvent is acetone.

13. A stent crimping apparatus, comprising:

means for inflating a balloon with a fluid;

means for crimping the stent onto the balloon; and

means for controlling the pressure inside the balloon below a given value when the stent is being crimped onto the balloon.

14. A apparatus for crimping a stent onto a balloon, comprising:

a pressurized fluid source;

a stent crimper; and

a pressure regulator for keeping the pressure inside the balloon below a given value when the stent is being crimped onto the balloon by the stent crimper.

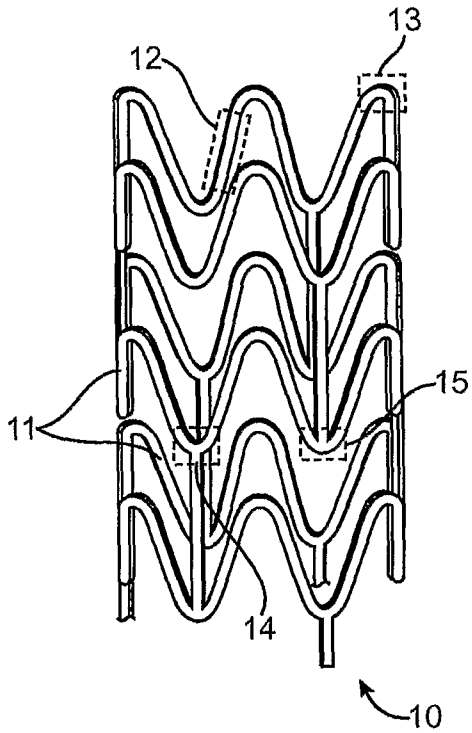

FIG. 1

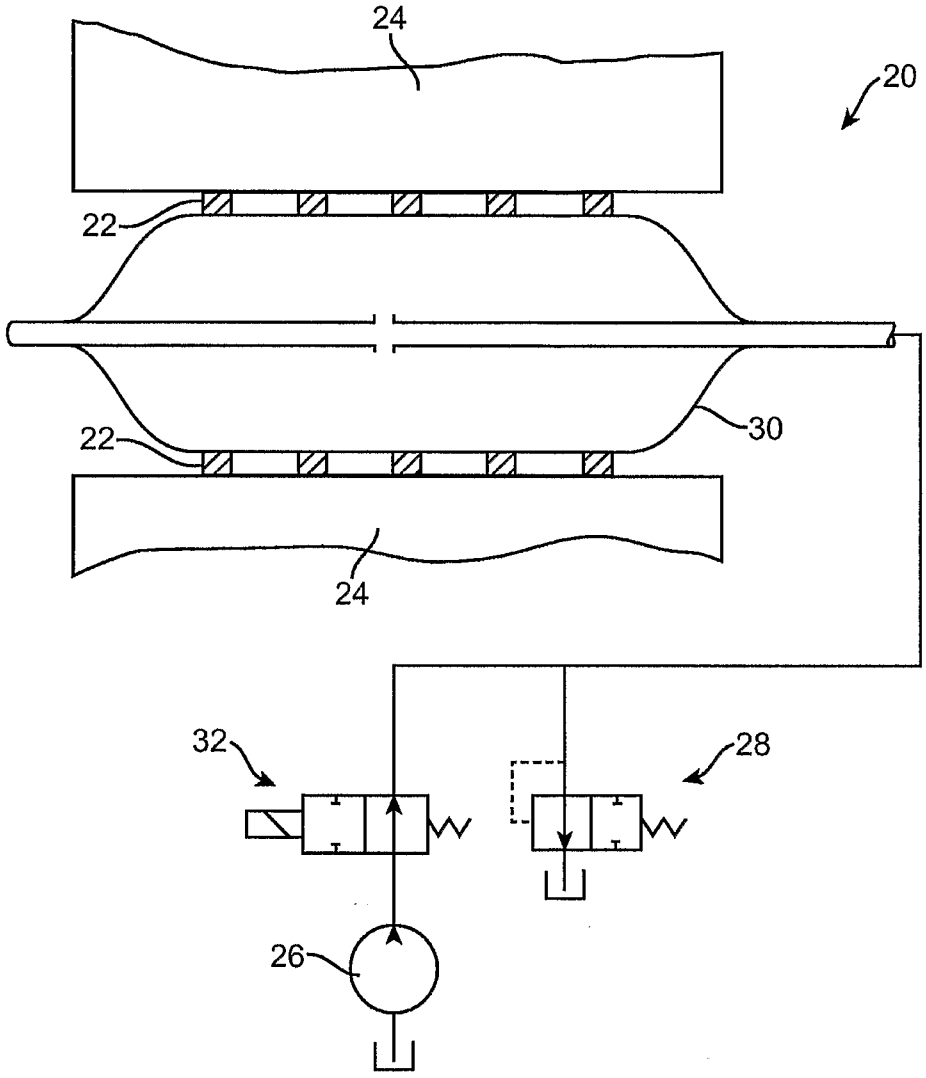

FIG. 2

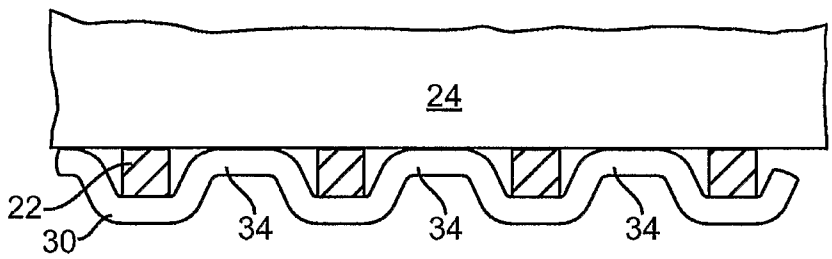

FIG. 3

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2007/016200

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F2/84

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 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.
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Y		5,6,11, 12
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A	WO 02/30487 A (MICRO THEREAPEUTICS INC [US]; WHALEN THOMAS J II [US]; GREFF RICHARD J) 18 April 2002 (2002-04-18)	6,12

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

☒ See patent family annex.

* Special categories of cited documents :

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"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

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Date of the actual completion of the international search	Date of mailing of the international search report
7 November 2007	21/11/2007

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, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Chevalot, Nicolas

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2007/016200

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