

(19) World Intellectual Property
Organization
International Bureau



(43) International Publication Date
28 July 2005 (28.07.2005)

PCT

(10) International Publication Number
WO 2005/068008 A1

(51) International Patent Classification⁷: **A61M 25/10**,
A61B 17/22

(21) International Application Number:
PCT/US2004/031852

(22) International Filing Date:
29 September 2004 (29.09.2004)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
10/742,162 19 December 2003 (19.12.2003) US

(71) Applicant (for all designated States except US): **SCIMED
LIFE SYSTEMS, INC.** [US/US]; One Scimed Place,
Maple Grove, MN 55311 (US).

(72) Inventor: **KUNIS, Christopher, G.**; 26228 Crescendo
Drive, Escondido, CA 92026 (US).

(74) Agents: **NYDEGGER, Neil, K.** et al.; Nydegger & Asso-
ciates, 348 Olive Street, San Diego, CA 92103 (US).

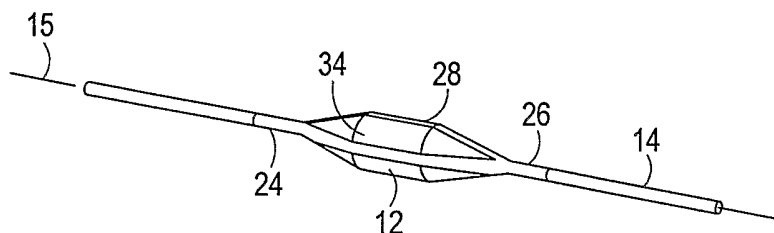
(81) Designated States (unless otherwise indicated, for every
kind of national protection available): AE, AG, AL, AM,
AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN,
CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI,
GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE,
KG, KP, KR, KZ, LC, LK, LR,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

*For two-letter codes and other abbreviations, refer to the "Guid-
ance Notes on Codes and Abbreviations" appearing at the begin-
ning of each regular issue of the PCT Gazette.*

(54) Title: **BALLOON REFOLDING DEVICE**



(57) **Abstract:** A device for folding a balloon of a balloon catheter onto a catheter tube during a balloon deflation includes a first band positioned on the catheter tube distal to the balloon and a second band positioned on the catheter tube proximal to the balloon. One or more elastic member(s) are attached to and extend between the bands for interaction with the outer surface of the balloon. During a balloon deflation, the elastic members cooperate to fold the balloon into pleats. When used on a cutting balloon, each elastic member is formed with a slot to allow a respective blade of the cutting balloon to extend through the elastic member. The elastic members fold the cutting balloon into a configuration in which each blade becomes nestled within a pair of adjacent balloon pleats to prevent the blade from inadvertently incising tissue during an *in-vivo* movement of the balloon catheter.

WO 2005/068008 A1

BALLOON REFOLDING DEVICE

FIELD OF THE INVENTION

The present invention pertains generally to medical catheters. More particularly, the present invention pertains to catheters having inflatable balloons. The present invention is particularly, but not exclusively, useful for
5 folding a balloon onto a catheter tube during a balloon deflation.

BACKGROUND OF THE INVENTION

Arterial blockages caused by the build up of plaque in the arteries of a patient can have grave consequences. Specifically, the build up of plaque in arteries can reduce and eventually block blood flow through the affected
10 vessel. When blood flow is reduced in a coronary artery, the heart muscle becomes deprived of oxygen, and the patient is prone to suffer angina. In severe cases of coronary artery blockage, the patient can suffer a heart attack.

Many modern surgical techniques have been developed to alleviate the
15 stenoses that are formed when plaque builds up in a patient's arteries. For example, a large number of balloon angioplasty devices exist for relieving arterial stenoses by compression of the stenosis. In several respects, balloon angioplasty devices afford numerous advantages over alternative methods. Foremost among these advantages is that open heart bypass surgery can
20 often be avoided by using angioplasty surgical techniques to relieve stenoses in the arteries that supply blood to the heart. For obvious reasons, it is preferable to avoid open heart surgery when possible because such surgery, as is well known, is invasive and typically requires a significant post-operative recovery time. Accordingly, it is preferable to use relatively simpler
25 angioplasty surgical procedures when such procedures are feasible. Importantly, angioplasty procedures are efficacious in the peripheral arteries as well as in the arteries that supply blood to the heart.

In angioplasty surgery, the balloon of a balloon catheter is initially attached to a catheter tube in a deflated configuration, with the catheter tube connecting a fluid source in fluid communication with the balloon. The balloon is then positioned at the desired location in the affected artery by advancing
5 the catheter through the artery until the balloon is positioned across a stenosis that is to be treated. Once the balloon has been properly positioned, fluid is infused into the balloon. As the balloon expands, it dilates the lumen of the artery and compresses the plaque which may then break up or flatten out against the arterial wall. The balloon is then deflated and, once in its deflated
10 configuration, it is either withdrawn from the artery or placed across another stenosis, to restore normal blood flow through the artery.

A particular problem associated with an angioplasty procedure exists during the deflation stage of the balloon, prior to its removal from the artery. Specifically, it is desirable that the balloon be deflated as tightly as practicable
15 to facilitate its removal from the arterial passageways. In any case, the key to removing the balloon catheter with ease is having the balloon collapse evenly and compactly during balloon deflation. Once deflated, the balloon catheter must often travel through the tortuous vasculature of the patient and it is, therefore, important for the balloon to deflate uniformly into a predictable
20 configuration. If the balloon fails to deflate in a uniform manner, an irregular bulge in the balloon may cause difficulties in withdrawing the balloon catheter from the artery.

In addition to the conventional, percutaneous, transluminal coronary angioplasty (PTCA) and percutaneous, transluminal angioplasty (PTA)
25 procedure described above, cutting balloons are currently viewed by many as the next generation treatment option for the revascularization of both coronary and peripheral vessels. The cutting balloon mechanism is unique in that the balloon pressure is distributed over one or more blades (i.e. microtomes). The blade(s) function as stress concentrators and cut initiators in PTCA and
30 PTA procedures. Consequently, PTCA and PTA procedures have been proven to minimize vessel recoil, lessen vessel injury and lower the rate of restenosis, as compared to conventional PTCA and PTA procedures.

However, the cutting blades used in cutting balloons are extremely sharp (e.g. three to five times sharper than a conventional scalpel), and in the absence of special precautions, have the potential to inadvertently incise non-target tissue during *in vivo* movement of the cutting balloon to and from a stenosis.

5 In light of the above, it is an object of the present invention to provide a device that is useful for folding a balloon predictably and compactly onto a catheter tube during balloon deflation to facilitate *in vivo* movement of the balloon catheter. Another object of the present invention is to provide a device for maintaining the balloon tightly wrapped on a balloon catheter when
10 the balloon is in a deflated configuration. It is yet another object of the present invention to provide a device that is useful for folding a cutting balloon during balloon deflation into a configuration in which the blades become nestled within a pair of adjacent balloon pleats to prevent the blades from inadvertently incising tissue during an *in vivo* movement of the balloon
15 catheter. Yet another object of the present invention is to provide a device which is relatively simple to manufacture, easy to use, and comparatively cost effective.

SUMMARY OF THE INVENTION

20 The present invention is directed to a device for folding a balloon of a balloon catheter onto a catheter tube during a balloon deflation. The device includes a first band that is positioned on the catheter tube distal to the balloon and a second band that is positioned on the catheter tube proximal to the balloon. The device further includes one or more elastic member(s) that are positioned for interaction with the outer surface of the balloon. Each
25 elastic member extends between a distal end that is attached to the first band and a proximal end that is attached to the second band.

 In a typical embodiment, the device includes three or four elastic members that are uniformly distributed around the circumference of the balloon. In addition, each elastic member assumes a substantially straight
30 shape and is axially aligned (i.e. aligned with an axis defined by the catheter

tube) when the balloon is in a deflated condition. On the other hand, during inflation of the balloon, each elastic member expands on the balloon in substantial conformation with the shape of the balloon's outer surface. When the balloon is subsequently deflated, each elastic member recovers its original shape (e.g. becomes straight), and in the process folds the balloon onto the catheter tube. Specifically, the balloon is folded into a plurality of axially aligned pleats with each pleat being formed between a pair of adjacent elastic members.

In one particular embodiment, the device may be configured for use on a cutting balloon having a plurality of longitudinally aligned blades that extend radially from the surface of an inflatable balloon. In this embodiment, each elastic member is formed with a slot to allow a respective blade to extend through the elastic member. With this cooperation of structure, the elastic members fold the cutting balloon into a configuration in which the blades become nestled within a pair of adjacent balloon pleats. This nestled configuration prevents the blades from inadvertently incising tissue during a movement of the balloon catheter through the vasculature of a patient.

BRIEF DESCRIPTION OF THE DRAWINGS

The novel features of this invention, as well as the invention itself, both as to its structure and its operation, will be best understood from the accompanying drawings, taken in conjunction with the accompanying description, in which similar reference characters refer to similar parts, and in which:

Fig. 1 is a perspective view of a balloon catheter with the balloon shown in the inflated condition;

Fig. 2 is a perspective view of a folding device shown in the expanded condition;

Fig. 3 is a perspective view of a folding device shown operationally positioned on a balloon catheter with the balloon shown in the inflated condition;

Fig. 4 is a perspective view of a folding device shown operationally positioned on a balloon catheter with the balloon shown in the deflated condition;

Fig. 5 is a cross sectional view as seen along line 5-5 in Fig. 4;

5 Fig. 6 is a perspective view of an embodiment of a folding device for use on a cutting balloon, shown with the folding device in the expanded condition;

Fig. 7 is a perspective view of a balloon catheter having a cutting balloon, shown with the cutting balloon in the inflated condition;

10 Fig. 8 is a cross sectional view as seen along line 8-8 in Fig. 7 after the folding device shown in Fig 6 has been operationally positioned on the cutting balloon shown in Fig. 7;

Fig. 9 is a cross sectional view as in Fig. 8 shown with the cutting balloon deflated; and

15 Fig. 10 is a cross sectional view as in Fig. 8 showing another embodiment of a folding device in which blades are mounted on the folding device.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring to Fig. 1, the distal portion of a typical balloon catheter is shown and is generally designated 11. As shown in Fig. 1, the catheter 11 includes an inflatable balloon 12 that is mounted on an elongated catheter tube 14, which defines a longitudinal axis 15. It can be further seen that the exemplary inflatable balloon 12 extends from a distal end 16 to a proximal end 18 and includes a substantially cylindrical working section 20. Those skilled in the pertinent art will appreciate that the catheter tube 14 can be used to establish fluid communication between the inflatable balloon 12 and a fluid pump / fluid source (not shown), which in turn, can be selectively activated to inflate and deflate the balloon 12 from an extracorporeal location. Functionally, the catheter 11 can be used to position the balloon 12 across a

20

25

stenosis whereupon the balloon 12 can be inflated to revascularize a diseased vessel such as a clogged artery.

Fig. 2 shows a folding device which is generally designated 22. Functionally, the folding device 22 is provided to fold an inflatable balloon 12 (Fig. 1) of a balloon catheter 11 onto a catheter tube 14 during a balloon deflation. As shown in Fig. 2, the folding device 22 includes a first cylindrical band 24, second cylindrical band 26 and a plurality of elastic members 28. For the exemplary embodiment shown, the plurality of elastic members 28 is four elastic members 28a-d. It can be further seen that each elastic member 28 extends between a distal end 30 that is attached to the first band 24 and a proximal end 32 that is attached to the second band 26.

The folding device 22 can be prepared from a starting tube (not shown) that is made of a low durometer, elastic material such as a silastic material. The tube 14 can then be cut, for example using a laser beam to create the elastic members 28. In some methods, the tube 14 can be expanded prior to cutting. In one embodiment, a starting tube 14 having an inner diameter, d , that is larger than the outer diameter, D , of the catheter tube 14 is used. The bands 24, 26 (which have an inner diameter, d , in the relaxed state) are then expanded to fit on the catheter tube 14. The residual tension in the bands 24, 26 is then used to hold the bands 24, 26 in place.

Fig. 3 shows the folding device 22 positioned on the balloon catheter 11. As shown, the band 24 is positioned on the catheter tube 14 distal to the balloon 12 and the band 26 is positioned on the catheter tube 14 proximal to the balloon 12. The bands 24, 26 can be bonded to the catheter tube 14, or as indicated above, the bands 24, 26 can be held in place using expanded bands 24, 26. Fig. 3 further shows that with the folding device 22 installed on the balloon catheter 11, the elastic members 28 are positioned for interaction with the outer surface 34 of the balloon 12. For the folding device 22 shown in Fig. 3, the four elastic members 28 are uniformly distributed around the circumference of the balloon 12.

As best seen in Fig. 4, each elastic member 28 assumes a substantially straight shape and is axially aligned when the balloon 12 is in a

deflated condition. On the other hand, during inflation of the balloon 12 (inflated balloon 12 shown in Fig. 3), each elastic member 28 expands (i.e. stretches) on the balloon 12 in substantial conformation with the shape of outer surface 34 of the balloon 12. As best seen in Fig. 5, when the balloon
5 12 is subsequently deflated, each elastic member 28 recovers its original shape (e.g. becomes straight), and in the process folds the balloon 12 onto the catheter tube 14. Specifically, as shown, the balloon 12 is typically folded into a plurality of axially aligned pleats 36 with each pleat 36 being formed between a pair of adjacent elastic members 28.

10 Fig. 6 shows an alternate embodiment of a folding device 22' in which the folding device 22' is configured for use on a balloon catheter 11' (Fig. 7) having a cutting balloon 38 and inflation tube 14'. As further shown in Figs. 7 and 8, the exemplary cutting balloon 38 has a plurality of longitudinally aligned blades 40 that extend radially from the surface 34' of an inflatable balloon 12'.
15 As best seen in Fig. 8, each blade 40 is typically embedded in a compliant blade pad 42, which in turn is bonded to the surface 32' of the inflatable balloon 12'.

For the folding device 22' shown in Fig. 6, each elastic member 28' is formed with a slot 44, which is typically elongated and axially aligned. Cross-
20 referencing Figs. 6 and 8, it can be seen that the slot 44 allows a respective blade 40 to extend through the elastic member 28'. As Fig. 9 shows, the elastic members 28' fold the cutting balloon 38 into a configuration in which the blades 40 become nestled within a pair of adjacent balloon pleats 36'. This nestled configuration prevents the blades 40 from inadvertently incising
25 tissue during a movement of the balloon catheter 11' through the vasculature of a patient (patient and patient vasculature not shown).

Fig. 10 shows another embodiment in which blades 40'' are mounted onto the elastic members 28''. For the embodiment shown, the blades 40'' are embedded in blade pads 42'' which in turn are bonded to the elastic
30 members 28''.

While the particular balloon refolding device as herein shown and disclosed in detail is fully capable of obtaining the objects and providing the advantages herein before stated, it is to be understood that it is merely illustrative of the presently preferred embodiments of the invention and that no
5 limitations are intended to the details of construction or design herein shown other than as described in the appended claims.

What is claimed is:

1. A device for folding a balloon of a balloon catheter onto a catheter tube during balloon deflation, said device comprising:
 - a first band positionable on the catheter tube distal to the
5 balloon;
 - a second band positionable on the catheter tube proximal to the balloon; and
 - at least one elastic member attached to said first and second bands for expansion on the balloon during a balloon inflation and to
10 fold the balloon onto the catheter tube during a deflation of the balloon.
2. A device as recited in claim 1 wherein said at least one elastic member is a plurality of elastic members uniformly distributed around the circumference of the balloon.
3. A device as recited in claim 1 wherein the balloon is a cutting
15 balloon having at least one blade and said at least one elastic member is formed with a slot to allow the blade to extend through said elastic member.
4. A device as recited in claim 1 wherein the device further includes a blade for incising tissue with said blade being mounted on said elastic member.
- 20 5. A device as recited in claim 1 wherein the catheter tube has an outer diameter, D , said bands are made of an elastic material, and each said band has an inner diameter, d , in an unstressed condition, with $D > d$ to affix each said band to the catheter tube.

6. A device as recited in claim 1 wherein the catheter tube defines a longitudinal axis and each said elastic member is axially aligned when the balloon is in a deflated condition.

7. A method for fabricating a balloon catheter, said method
5 comprising the steps of:

installing a balloon on a catheter tube;

positioning first and second bands on the catheter tube with said first band located distal to the balloon and said second band located proximal to the balloon; and

10 disposing at least one elastic member on the balloon for expansion thereon during a balloon inflation, said elastic member being attached to said first and second bands to fold the balloon onto the catheter tube during a deflation of the balloon.

8. A method as recited in claim 7 wherein said at least one elastic
15 member is a plurality of elastic members uniformly distributed around the circumference of the balloon.

9. A method as recited in claim 7 wherein said balloon is a cutting balloon comprising at least one blade and said at least one elastic member is formed with a slot to allow said blade to extend through said elastic member.

20 10. A method as recited in claim 7 wherein said catheter further includes a blade mounted on said elastic member for incising tissue.

11. A method as recited in claim 7 wherein said catheter tube has an outer diameter, D , said bands are made of an elastic material, and each said band has an inner diameter, d , in an unstressed condition, with $D > d$ to
25 affix each said band to said catheter tube.

12. A method as recited in claim 7 wherein said catheter tube defines a longitudinal axis and each said elastic member is axially aligned when said balloon is in a deflated condition.

13. A method as recited in claim 7 wherein said balloon is made of a compliant material.

14. A method as recited in claim 7 wherein said balloon is made of a non-compliant material.

15. A device for folding a cutting balloon having a plurality of incising blades onto a catheter tube during a cutting balloon deflation, said device comprising:

a first band positionable on the catheter tube distal to the cutting balloon;

a second band positionable on the catheter tube proximal to the cutting balloon; and

a plurality of elastic members attached to said first and second bands, each elastic member formed with a slot to allow a respective blade to extend through said elastic member, said elastic members for expansion on the balloon during a balloon inflation and to fold the cutting balloon onto the catheter tube during a deflation of the cutting balloon.

16. A device as recited in claim 15 wherein said elastic members are uniformly distributed around the circumference of the cutting balloon.

17. A device as recited in claim 15 wherein the catheter tube has an outer diameter, D , said bands are made of an elastic material, and each said
5 band has an inner diameter, d , in an unstressed condition, with $D > d$ to affix each said band to the catheter tube.

18. A device as recited in claim 15 wherein the catheter tube defines a longitudinal axis and each said elastic member is axially aligned when the balloon is in a deflated condition.

10 19. A device as recited in claim 15 wherein each said elastic member is made of a silastic material.

20. A device as recited in claim 15 wherein said plurality of elastic members is four elastic members.

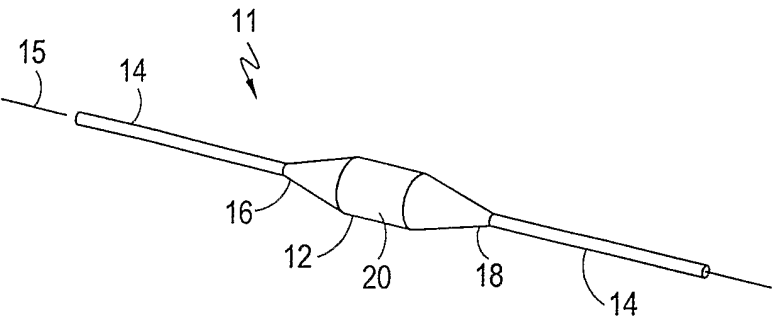


Fig. 1

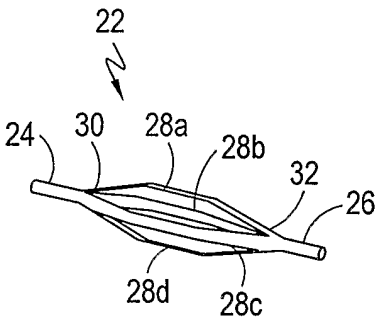


Fig. 2

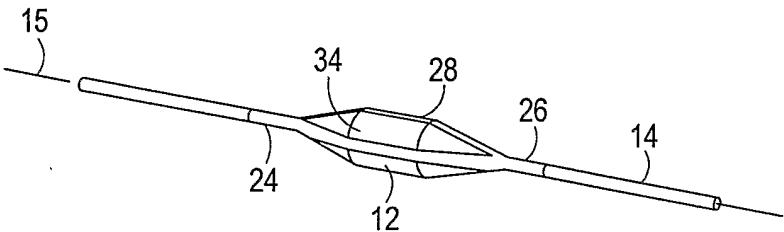


Fig. 3

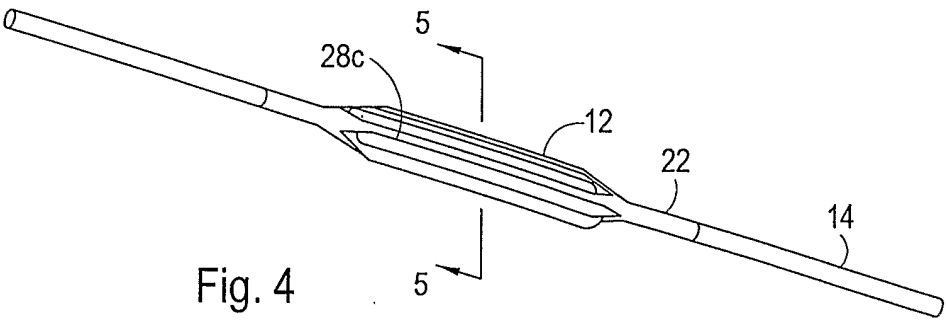


Fig. 4

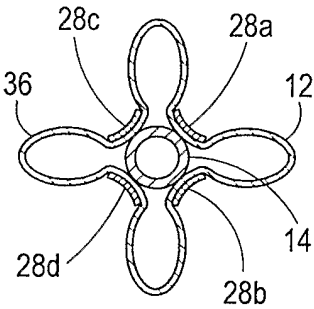


Fig. 5

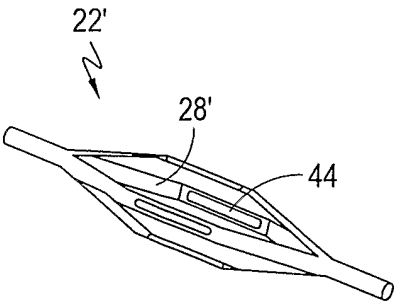


Fig. 6

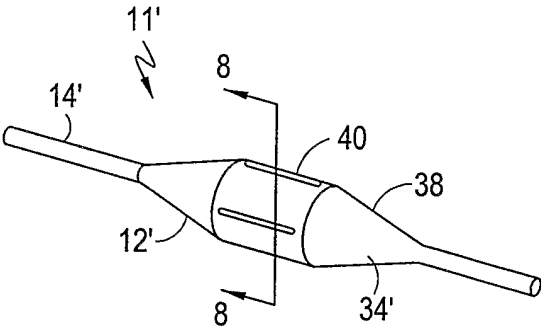


Fig. 7

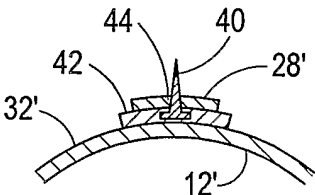


Fig. 8

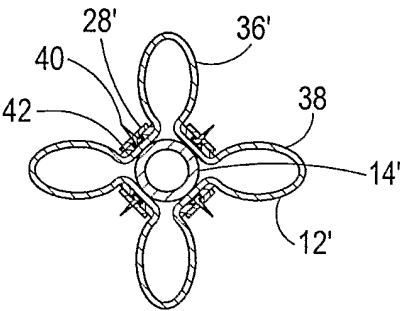


Fig. 9

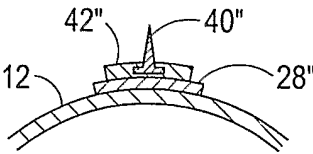


Fig. 10

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US2004/031852

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M25/10 A61B17/22

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 A61B A61M 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, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2003/153870 A1 (OGATA WAYNE M ET AL) 14 August 2003 (2003-08-14) paragraphs '0041!, '0042!; figures 12-15	1,2,4, 6-8,10, 13,14
X	US 4 723 549 A (KATZ ROBERT S ET AL) 9 February 1988 (1988-02-09) column 3, line 7 - column 4, line 19; figures 5,6	1,2,6-8, 12
A	US 6 071 285 A (HAARSTAD PHILIP J ET AL) 6 June 2000 (2000-06-06) column 7, line 19 - column 8, line 11; figures 7,7a,7b	1,7
A	EP 1 254 679 A (INTERVENTIONAL TECHNOLOGIES) 6 November 2002 (2002-11-06) abstract; figures 3a,3b	1,7
-/--		

☒ 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
- *E* earlier document but published on or after the international filing date
- *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)
- *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
- *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.
- *Z* document member of the same patent family

Date of the actual completion of the international search

20 January 2005

Date of mailing of the international search report

28/01/2005

Name and mailing address of the ISA

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

Authorized officer

Rosenblatt, T

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US2004/031852

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 616 149 A (BARATH PETER) 1 April 1997 (1997-04-01) column 5, lines 20-36; figures 12,13 -----	3,9,15

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US2004/031852

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 2003153870	A1	14-08-2003	EP 1480709 A1 WO 03068307 A1	01-12-2004 21-08-2003
US 4723549	A	09-02-1988	NONE	
US 6071285	A	06-06-2000	NONE	
EP 1254679	A	06-11-2002	US 6425882 B1 AU 9715101 A BR 0105918 A CA 2378277 A1 CN 1383901 A EP 1254679 A2 JP 2002336359 A TW 508253 B US 2002183779 A1	30-07-2002 07-11-2002 14-01-2003 01-11-2002 11-12-2002 06-11-2002 26-11-2002 01-11-2002 05-12-2002
US 5616149	A	01-04-1997	US 5196024 A US 5320634 A	23-03-1993 14-06-1994