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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
26 June 2003 (26.06.2003)

PCT

(10) International Publication Number
WO 03/051444 A1

(51) International Patent Classification[7]: A61M 25/01

(21) International Application Number: PCT/US02/30402

(22) International Filing Date:
25 September 2002 (25.09.2002)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
10/025,668 18 December 2001 (18.12.2001) US

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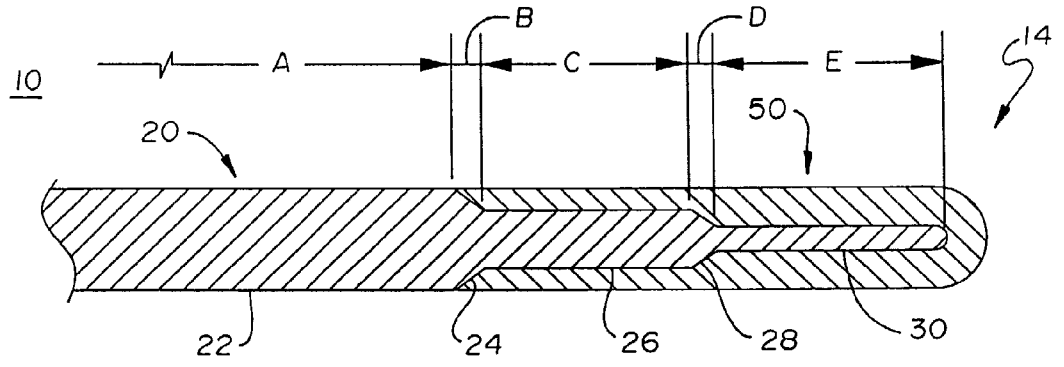
(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT,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

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, SK, TR), OAPI patent (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 "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: SUPER ELASTIC GUIDEWIRE WITH SHAPE RETENTION TIP



(57) Abstract: A guidewire (10) having a super elastic core (20) surrounded by a shape memory polymer jacket (50). The super elastic core wire permits the guidewire to be navigated through tortous vasculature without undergoing plastic deformation, and the shape memory polymer jacket permits the guidewire to be shaped by the physician.

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SUPER ELASTIC GUIDEWIRE WITH SHAPE RETENTION TIP

Field of the Invention

The present invention generally relates to intravascular guidewires. More specifically, the present invention relates to intravascular guidewires utilizing super elastic materials.

Background of the Invention

Intravascular guidewires are commonly used to navigate through a patient's vascular system for the diagnosis and treatment of a wide variety of vascular disorders. Guidewires conventionally utilize a stainless steel or nitinol (super elastic) core wire. Stainless steel core wires are advantageous because they are shapeable, but are disadvantageous because they may become deformed in tortuous vascular anatomy. Nitinol core wires are advantageous because they do not become deformed in tortuous vasculature, but are disadvantageous because they are not shapeable. Thus, there is a need for a guidewire that offers both advantages, namely a guidewire that is shapeable and that is not readily deformed in tortuous vasculature.

Summary of the Invention

To address this need, the present invention provides several design alternatives. For example, in one embodiment, the present invention provides a guidewire having a super elastic core wire surrounded by a shape memory polymer jacket. The super elastic core wire permits the guidewire to be navigated through tortuous vasculature without undergoing plastic deformation, and the shape memory polymer jacket permits the guidewire to be shapeable.

Brief Description of the Drawings

Figure 1 is a plan view of a guidewire according to the present invention, in combination with a balloon catheter;

Figure 2 is a foreshortened longitudinal cross-sectional view of a distal portion of a guidewire of the present invention, showing a polymer jacket surrounding a distal tip of a core wire;

Figure 3 is a foreshortened longitudinal cross-sectional view of a portion of a guidewire of the present invention, showing a polymer jacket surrounding a mid portion of a core wire; and

Figures 4 and 5 are side views of a distal tip portion of a guide wire showing a polymer jacket surrounding a distal portion of a spring tip and core wire, wherein the distal tip is deformed about a cylinder-shaped object.

Detailed Description of the Invention

The following detailed description should be read with reference to the drawings in which similar elements in different drawings are numbered the same. The detailed description and the drawings, which are not necessarily to scale, depict illustrative embodiments and are not intended to limit the scope of the invention.

Refer now to Figure 1 which illustrates a plan view of a guidewire 10 in combination with an intravascular device 100. In this particular example, the intravascular device 100 comprises a balloon catheter, but those skilled in the art will recognize that guidewires may be used alone or in combination with a wide variety of intravascular devices for coronary, peripheral and cerebral use, including balloon catheters, guide catheters, diagnostic catheters, micro-catheters, etc. For purposes of illustration only, intravascular device 100 is shown to be a balloon catheter 100 having an elongate shaft 100, a proximally disposed manifold 104, and a distally disposed inflatable balloon 106, all of which are conventional in the art. Guidewire 10 may extend through the entire length of the balloon catheter 100, and includes a proximal end 12 and a distal tip portion 14. The guidewire 10 may have a size (length and diameter) to navigate coronary, peripheral and/or cerebral vasculature, depending on the particular clinical application, and the distal tip portion 14 may be shaped to facilitate steering in such vascular anatomy.

As seen in Figure 2, the guidewire 10 may include a core wire 20 with a polymer jacket 50 surrounding a distal tip portion 14 thereof. Alternatively, the polymer jacket 50 may surround a mid portion of the guidewire 10 as shown in Figure 3. As shown in Figures 4 and 5, a radiopaque coil 40 may surround a distal portion 14 of the core wire 20, with a distal weld 42 connecting the distal end of the coil 40 to the distal end of the core wire 20 (not visible in Figures 4 and 5). In this latter instance, the polymer jacket 50 may surround the core wire 20 and the radiopaque coil

40. As a further alternative, the polymer jacket 50 may surround an inner polymer jacket (not shown) disposed on the core wire 20, resulting in a multi-layered polymer jacket arrangement, with layer thicknesses that may vary, but preferably do not exceed the proximal profile of the guidewire. In all embodiments, the polymer jacket 50 may incorporate radiopaque filler.

In all embodiments illustrated, the polymer jacket 50 may surround the core wire 20 and/or radiopaque coil 40 to establish contact therebetween or to establish an annular space therebetween. In addition, the polymer jacket 50 may surround and encase the core wire 20 and/or radiopaque coil 40 to encase the distal tip 14 as shown in Figures 2, 4 and 5, or merely surround a portion thereof without encasing as shown in Figure 3.

Core wire 20 may comprise a stainless steel metal or a super elastic metal such as nitinol (nickel titanium alloy) for purposes of navigating tortuous vasculature without causing plastic deformation thereof. Polymer jacket 50 may comprise a polymer and may have suitable dimensions and material characteristics that render the polymer jacket 50 more stiff than the distal tip portion 14 of the super elastic core wire 20 which it surrounds. As used herein, stiff or stiffness refers to the collective property defined by material characteristics and shape, as conventionally used in mechanical engineering design. In particular, the cross-sectional bending moment and the flexural modulus of the polymer jacket 50 may be selected such that when the tip 14 is deformed into a shape within the elastic limit of the super elastic core wire 20, and beyond the elastic limit of the polymer, the tip 14 substantially retains the shape, although some recoil may occur.

The polymer jacket 50 may comprise a shape memory polymer such as shape memory polyurethane available from Mitsubishi, polynorbornene polymers and copolymers (including blends with polyethylene and Kraton), polycaprolactone or (oligo)caprolactone copolymer, polymethylmethacylate, PLLA or PL/D LA copolymer, PLLA PGA copolymer, PMMA, cross-linked polyethylene, cross-linked polyisoprene, polycyclooctene, styrene-butadiene copolymer, or photocrosslinkable polymer including azo-dye, zwitterionic and other photoschromic materials (as referenced in Shape memory Materials, Otsuka and Wayman, Cambridge University press, © 1998).

With a shape memory polymer, the distal tip 14, including polymer jacket 50, core wire 20, and/or radiopaque coil 40, may be deformed into the desired shape. By way of example, not limitation, the distal tip portion 14 may be deformed about a cylindrical object 90 to impart a J-tip shape as shown in Figure 4, or a bent-L shape as shown in Figure 5. Although only basic shapes are shown, it is contemplated that a wide variety of simple and complex shapes may be achieved with the present invention. While the desired shape is maintained, the polymer jacket 50 may be subjected to heat at a temperature at or above the glass transition temperature (or near the melt temperature) of the shape memory polymer, and subsequently cooled to a temperature below the glass transition temperature. Once cooled, the distal tip 14 may be released from the constrained shape.

After releasing the distal tip 14 from the constrained shape, the elastic forces of the super elastic core wire 20 work against the polymer jacket 50, biasing the shape of the distal tip back to the original (e.g., straight) configuration. However, the polymer jacket 50 has sufficient stiffness, by virtue of its size and its material properties, to substantially oppose, if not completely offset, the biasing force of the super elastic core wire 20. The biasing force of the core wire 20 may be reduced by reducing the size (e.g., diameter) thereof, and the opposing force of the polymer jacket 50 may be increased by increasing the size (cross-sectional area moment) and/or the flexural modulus thereof. Thus, by substantially opposing, if not completely offsetting, the biasing force of the super elastic core wire 20, the polymer jacket 50 substantially maintains the deformed shape, although some recoil may occur. To compensate for such recoil, the deformed shape may be exaggerated relative to the desired final shape.

The distal tip 14 may be re-shaped by re-deforming the distal tip 14 and exposing the polymer jacket 50 to heat at a temperature at or above the glass transition temperature (or near the melt temperature) of the shape memory polymer, and subsequently cooled to a temperature below the glass transition temperature. The original (e.g., straight) configuration of the distal tip 14 may be recaptured by exposing the polymer jacket 50 to heat at a temperature at or above the transformation temperature of the shape memory polymer, followed by cooling. The distal tip 14 may be repeatedly shaped without compromising shapeability or guidewire performance.

The polymer jacket 50 may surround the distal tip portion 14 as shown in Figure 2 or a mid portion of the core wire 20 as shown in Figure 3. To accommodate the polymer jacket 50 and to provide a uniform outer profile, the core wire 20 may be ground to have a single taper or a series of tapers as shown in Figure 2 or ground to define a recess as shown in Figure 3.

In Figure 2, the distal portion 14 of the core wire 20 includes a series of tapers to accommodate the polymer jacket 50 and to provide a gradual reduction in stiffness toward the distal end thereof. For example, the core wire 20 may have a proximal uniform diameter portion 22 having a diameter of about 0.007 to 0.038 inches and a length "A" of about 100 to 260 cm, a mid uniform diameter portion 26 having a diameter of about 0.003 to 0.010 inches and a length "C" of about 5 to 30 cm, and a distal uniform diameter portion 30 having a diameter of about 0.0015 to 0.005 inches and a length "E" of about 5 to 30 cm. Alternatively, distal portion 30 may comprise a flat ribbon having a thickness of 0.0015 to 0.005 inches. The core wire 20 may also include tapered portions 24/28 between the uniform diameter portions 22/26/30, having tapering diameters and lengths "B" and "D" of about 0.1 to 10 cm to provide a smooth transition between the uniform diameter portions 22/26/30. As an alternative, the core wire 20 may have a continuous taper terminating in a radiopaque tip, and covered by the polymer jacket 50.

In Figure 3, a mid portion (i.e., a portion that is proximal of the distal end and distal of the proximal end) of the core wire 20 is provided with an optional recess having a uniform diameter portion 34 and two tapered portions 32/36. The position of the recess 34 and thus the position of the polymer jacket 50 in this embodiment is dictated by the length "F" of the proximal uniform diameter portion 22 and the length "J" of the distal uniform diameter portion 38. The length "H" of the recess portion 34 may be selected depending on the desired shapeable length of the core wire 20. The lengths "G" and "I" of the tapered portion 32/36 may be the same or similar to that of tapered portions 24/28 described previously.

Those skilled in the art will recognize that the present invention may be manifested in a variety of forms other than the specific embodiments described and contemplated herein. Accordingly, departures in form and detail may be made without departing from the scope and spirit of the present invention as described in the appended claims.

What is claimed is:

1. An intravascular guidewire, comprising:

an elongate core wire comprising a metal; and

a polymer jacket comprising a shape memory polymer surrounding a portion of the core wire, the polymer jacket being more stiff than the portion of the core wire which it surrounds.

2. An intravascular guidewire as in claim 1, wherein the metal comprises a stainless steel metal.

3. An intravascular guidewire as in claim 1, wherein the metal comprises a super elastic metal.

4. An intravascular guidewire as in claim 3, wherein the super elastic metal comprises a nickel titanium alloy.

5. An intravascular guidewire as in claim 1, wherein the shape memory polymer comprises shape memory polyurethane.

6. An intravascular guidewire as in claim 1, wherein the shape memory polymer comprises shape memory polynorbornene or copolymers or blends thereof.

7. An intravascular guidewire as in claim 1, wherein the shape memory polymer comprises shape memory polycaprolactone or (oligo)caprolactone copolymer.

8. An intravascular guidewire as in claim 1, wherein the shape memory polymer comprises shape memory polymethylmethacylate.

9. An intravascular guidewire as in claim 1, wherein the shape memory polymer comprises shape memory PLLA copolymer.

10. An intravascular guidewire as in claim 1, wherein the shape memory polymer comprises shape memory PLLA PGA copolymer.

11. An intravascular guidewire as in claim 1, wherein the shape memory polymer comprises shape memory PL/D LA copolymer.

12. An intravascular guidewire as in claim 1, wherein the shape memory polymer comprises shape memory PMMA copolymer.

13. An intravascular guidewire as in claim 1, wherein the shape memory polymer comprises shape memory cross-linked polyethylene.

14. An intravascular guidewire as in claim 1, wherein the shape memory polymer comprises shape memory cross-linked polyisoprene.

15. An intravascular guidewire as in claim 1, wherein the shape memory polymer comprises shape memory styrene-butadiene copolymer.

16. An intravascular guidewire as in claim 1, wherein the shape memory polymer comprises a photocrosslinkable polymer.

15. A method of shaping a guidewire, comprising the steps of:

providing a guidewire comprising an elongate core wire with a shape memory polymer jacket surrounding a portion of the core wire;

deforming the polymer jacket and the portion of the core wire which it surrounds into a shape;

heating the deformed polymer jacket to a temperature at or above a glass transition temperature of the shape memory polymer; and

cooling the deformed polymer jacket to a temperature below the glass transition temperature of the shape memory polymer to maintain the shape.

16. A method of shaping a guidewire as in claim 15, further comprising the steps of:

deforming the polymer jacket and the portion of the core wire which it surrounds into a different shape;

reheating the deformed polymer jacket to a temperature at or above a glass transition temperature of the shape memory polymer; and

cooling the deformed polymer jacket to a temperature below the glass transition temperature of the shape memory polymer to maintain the different shape.

17. A method of shaping a guidewire as in claim 16, further comprising the steps of:

reheating the deformed polymer jacket to a temperature at or above a glass transition temperature of the shape memory polymer such that the guidewire returns to its original shape; and

cooling the deformed polymer jacket to a temperature below the glass transition temperature of the shape memory polymer.

18. An intravascular guidewire, comprising:

an elongate core wire comprising a metal having an elastic limit; and

a polymer jacket surrounding a distal tip portion of the core wire, the polymer jacket comprising a polymer having an elastic limit, the polymer jacket being more stiff than the distal tip portion of the core wire which it surrounds such that when the tip is deformed into a shape within the elastic limit of the metal and beyond the elastic limit of the polymer, the tip substantially retains the shape.

19. An intravascular guidewire as in claim 18, wherein the metal comprises a stainless steel metal.

20. An intravascular guidewire as in claim 18, wherein the metal comprises a super elastic metal.

21. An intravascular guidewire as in claim 20, wherein the super elastic metal comprises a nickel titanium alloy.

22. An intravascular guidewire as in claim 18, wherein the shape memory polymer comprises shape memory polyurethane.

23. An intravascular guidewire as in claim 18, wherein the shape memory polymer comprises shape memory polynorbornene or copolymers or blends thereof.

24. An intravascular guidewire as in claim 18, wherein the shape memory polymer comprises shape memory polycaprolactone or (oligo)caprolactone copolymer.

25. An intravascular guidewire as in claim 18, wherein the shape memory polymer comprises shape memory polymethylmethacylate.

26. An intravascular guidewire as in claim 18, wherein the shape memory polymer comprises shape memory PLLA copolymer.

27. An intravascular guidewire as in claim 18, wherein the shape memory polymer comprises shape memory PLLA PGA copolymer.

28. An intravascular guidewire as in claim 18, wherein the shape memory polymer comprises shape memory PL/D LA copolymer.

29. An intravascular guidewire as in claim 18, wherein the shape memory polymer comprises shape memory PMMA copolymer.

30. An intravascular guidewire as in claim 18, wherein the shape memory polymer comprises shape memory cross-linked polyethylene.

31. An intravascular guidewire as in claim 18, wherein the shape memory polymer comprises shape memory cross-linked polyisoprene.

32. An intravascular guidewire as in claim 18, wherein the shape memory polymer comprises shape memory styrene-butadiene copolymer.

33. An intravascular guidewire as in claim 18, wherein the shape memory polymer comprises a photocrosslinkable polymer.

Fig. 1

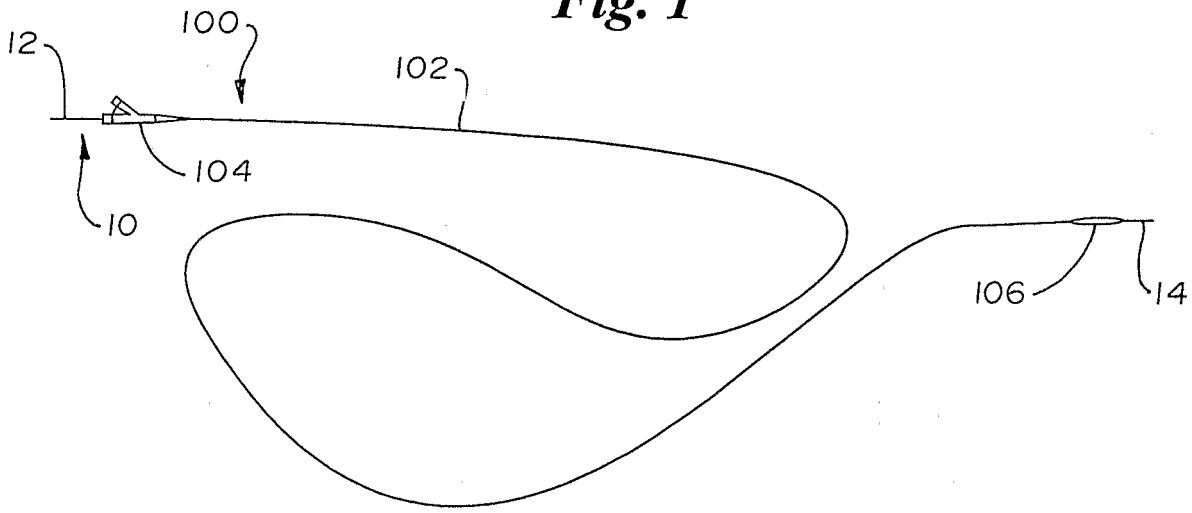


Fig. 2

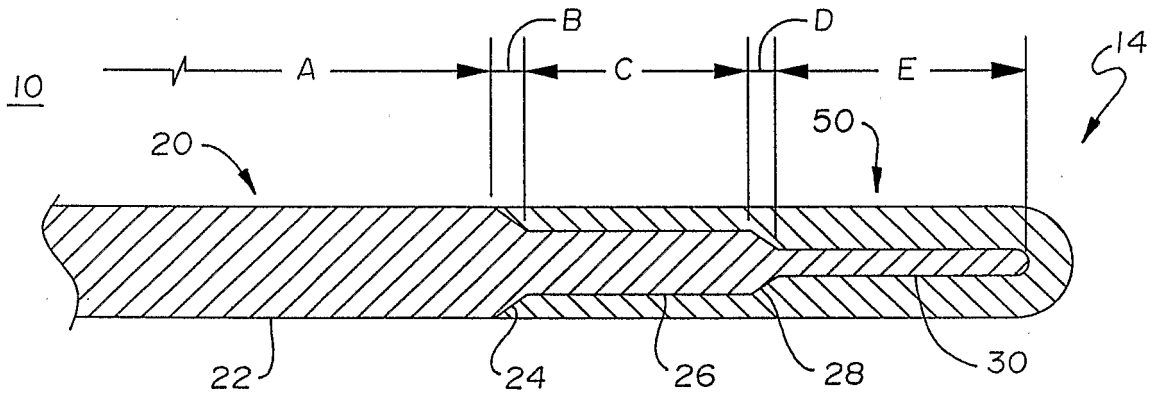
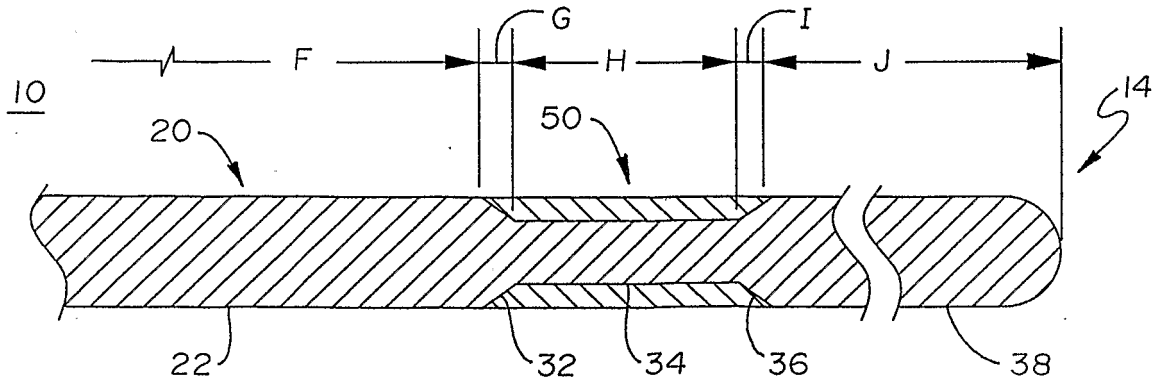


Fig. 3



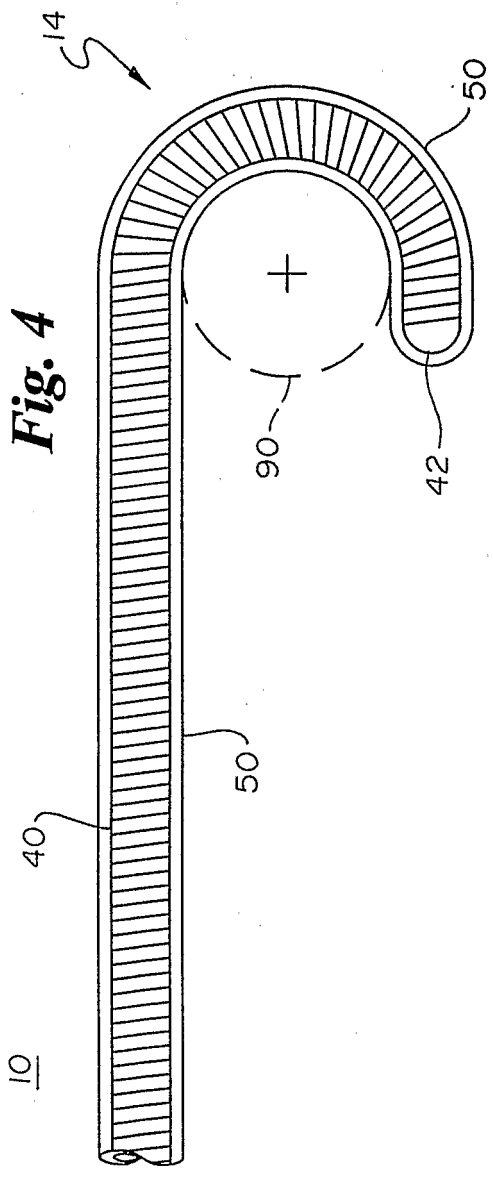


Fig. 4

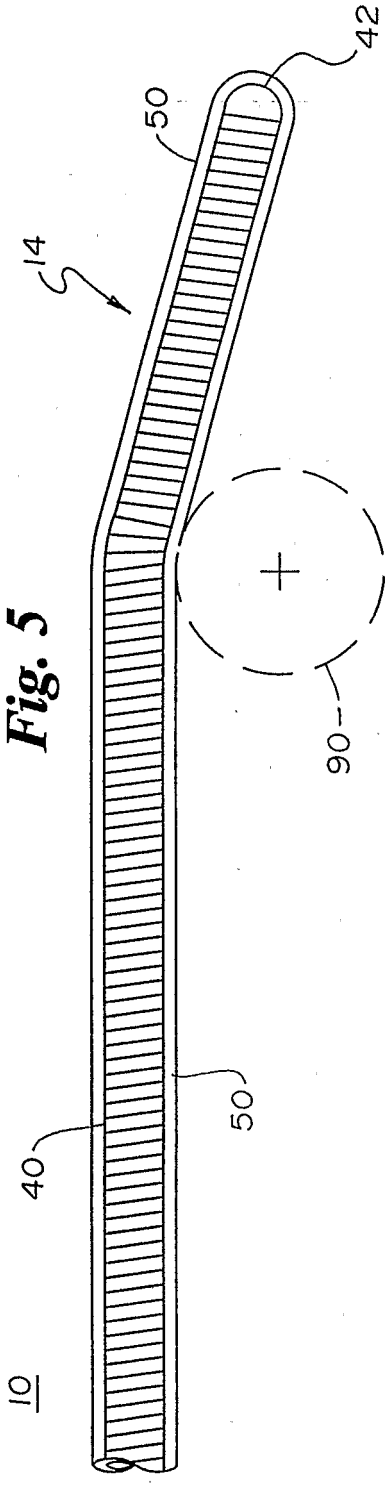


Fig. 5

INTERNATIONAL SEARCH REPORT

Inter nal Application No
PCT/US 02/30402

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M25/01

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 A61M

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.
Y	US 2001/009980 A1 (BIAGTAN EMANUEL ET AL) 26 July 2001 (2001-07-26)	1-7, 9-12,16, 20-26, 28-31, 34,35
A	page 1, paragraph 9 -page 2, paragraph 12 page 2, paragraph 20 -page 3, paragraph 25 page 3, paragraph 26 - paragraph 27 figures 7,11 page 3	8,13-15, 17,27, 32,33
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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

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Date of the actual completion of the international search	Date of mailing of the international search report
2 December 2002	09/12/2002

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	Amaro, H

INTERNATIONAL SEARCH REPORT

Inter nal Application No
PCT/US 02/30402

C.(Continuation) 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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INTERNATIONAL SEARCH REPORT

Information on patent family members

Inter nal Application No
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专利名称(译)	超弹性导丝，具有形状保持尖端		
公开(公告)号	EP1455880A1	公开(公告)日	2004-09-15
申请号	EP2002761822	申请日	2002-09-25
[标]申请(专利权)人(译)	波士顿科学有限公司		
申请(专利权)人(译)	BOSTON SCIENTIFIC LIMITED		
当前申请(专利权)人(译)	BOSTON SCIENTIFIC LIMITED		
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IPC分类号	A61L27/00 A61B5/00 A61M25/01 A61M25/09		
CPC分类号	A61L31/022 A61L31/10 A61L2400/16 A61M25/09 A61M2025/09141		
代理机构(译)	法思博事务所		
优先权	10/025668 2001-12-18 US		
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摘要(译)

一种具有由形状记忆聚合物护套（50）包围的超弹性芯（20）的导丝（10）。超弹性芯线允许导丝通过迂回脉管系统导航而不经历塑性变形，并且形状记忆聚合物护套允许医生将导丝成形。