PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61M 25/01	A1	(11) International Publication Number: WO 97/00705
		(43) International Publication Date: 9 January 1997 (09.01.97)

(21) International Application Number: PCT/US96/10606

(22) International Filing Date: 19 June 1996 (19.06.96)

(30) Priority Data:
08/492,921 20 June 1995 (20.06.95) US

(71) Applicant *(for all designated States except US)*: THE MICROSPRING COMPANY, INC. [US/US]; Building A - Unit 5, 77 Accord Park Drive, Norwell, MA 02061 (US).

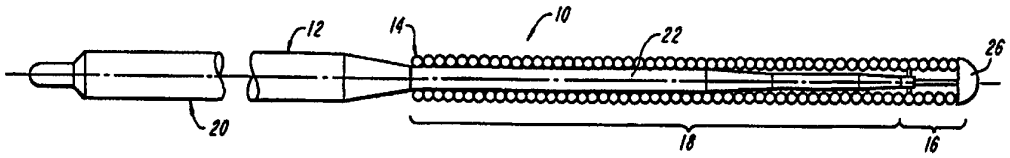
(72) Inventor; and
(75) Inventor/Applicant *(for US only)*: DOBSON, Paul, J. [US/US]; 235 Summer Street, Hingham, MA 02043 (US).

(74) Agents: LAMPERT, James, B. et al.; Hale and Dorr, 60 State Street, Boston, MA 02109 (US).

(81) Designated States: JP, US, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

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

(54) Title: RADIOPAQUE MEDICAL DEVICES



(57) Abstract

A method and apparatus for producing a guide wire including a core wire, a distal portion of which is surrounded by a helically wound spring. The coils forming the distal portion of the spring include an annular layer of radiopaque material, e.g., gold, ion deposited onto the stainless steel wire of the spring using unbalanced magnetron sputtering, ion implantation, or ion beam assisted deposition.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AM	Armenia	**GB**	United Kingdom	**MW**	Malawi
AT	Austria	**GE**	Georgia	**MX**	Mexico
AU	Australia	**GN**	Guinea	**NE**	Niger
BB	Barbados	**GR**	Greece	**NL**	Netherlands
BE	Belgium	**HU**	Hungary	**NO**	Norway
BF	Burkina Faso	**IE**	Ireland	**NZ**	New Zealand
BG	Bulgaria	**IT**	Italy	**PL**	Poland
BJ	Benin	**JP**	Japan	**PT**	Portugal
BR	Brazil	**KE**	Kenya	**RO**	Romania
BY	Belarus	**KG**	Kyrgystan	**RU**	Russian Federation
CA	Canada	**KP**	Democratic People's Republic of Korea	**SD**	Sudan
CF	Central African Republic			**SE**	Sweden
CG	Congo	**KR**	Republic of Korea	**SG**	Singapore
CH	Switzerland	**KZ**	Kazakhstan	**SI**	Slovenia
CI	Côte d'Ivoire	**LI**	Liechtenstein	**SK**	Slovakia
CM	Cameroon	**LK**	Sri Lanka	**SN**	Senegal
CN	China	**LR**	Liberia	**SZ**	Swaziland
CS	Czechoslovakia	**LT**	Lithuania	**TD**	Chad
CZ	Czech Republic	**LU**	Luxembourg	**TG**	Togo
DE	Germany	**LV**	Latvia	**TJ**	Tajikistan
DK	Denmark	**MC**	Monaco	**TT**	Trinidad and Tobago
EE	Estonia	**MD**	Republic of Moldova	**UA**	Ukraine
ES	Spain	**MG**	Madagascar	**UG**	Uganda
FI	Finland	**ML**	Mali	**US**	United States of America
FR	France	**MN**	Mongolia	**UZ**	Uzbekistan
GA	Gabon	**MR**	Mauritania	**VN**	Viet Nam

RADIOPAQUE MEDICAL DEVICES

Field of Invention

This invention relates to radiopaque medical devices and, more particularly, to guide wires used to introduce catheters into human cardiovascular systems and having a radiopaque distal end portion.

Background of Invention

There are in the art a number of flexible guide wires used in medical applications. Exemplary such devices are shown in U. S. Patents Nos. 3,545,390, 4,538,622, 4,619,274, 5,053,404, and 5,267,574, and in U.S. application serial no. 08/069,050 filed May 28, 1993 and owned by the assignee of the present application, all of which are here incorporated by reference. Some such devices, including those shown in patents nos. 4,538,622 and 5,052,404, include a flexible main spring of stainless steel having a short radiopaque (e.g., platinum, gold, tantalum, tungsten, iridium, rhenium) spring joined to its distal end. In others, such as those shown in patents nos. 3,545,390 and 5,267,574, the entire spring is made of a material (e.g., platinum or a platinum/ tungsten alloy, having a relatively high radiopacity. Whether the spring is one-piece or two-piece, a central core, which also may be stainless steel, typically extends coaxially within the entire length of the spring and is connected, e.g., by brazing or welding, to both the distal and proximal ends of the spring. When a two-piece spring is employed, the adjacent ends of the two pieces of the spring are generally brazed both to each other and to the central core of the guide wire assembly.

Medical devices in which an entire spring is made of a radiopaque material such as tungsten are expensive, and the material may have less desirable characteristics than does a

material such as stainless steel. Making only a portion, e.g., the distal end portion, of the spring of a radiopaque material somewhat reduces material costs, but requires two or more springs rather than one, along with the additional manufacturing costs and procedures that are required to insure a secure construction.

There have been attempts to provide guide wires having a two-piece construction in which a single stainless steel coil extends all the way to the tip, but these attempts have proved to be somewhat unsatisfactory. Neither the stainless steel itself, nor a layer of gold or the like plated onto the coil, has been sufficiently radiopaque.

There remains a need for a less-expensive spring device that is sufficiently radiopaque, and particularly for a guide wire having a radiopaque distal end.

Summary of the Invention

The present invention provides a medical device including a helical coil spring in which a length of the wire forming at least some of the spring coils includes an annular layer of radiopaque material surrounding the central cylindrical portion of the spring wire, the annular layer of radiopaque material being deposited on the length of wire that will form the coils before the spring is wound. In preferred embodiments, the medical device is a guide wire assembly in which a single helical coil extends proximally from the distal end, the length of wire forming the coils adjacent the distal end includes the annular radiopaque layer, the radiopaque material is placed on the length of wire and the entire helical coil spring wound before the wound spring is placed in position around the central core of the guide wire assembly. Preferred embodiments also feature springs in which the radiopaque material is gold, and in which the gold is deposited circumferentially onto a

length of the wire using an ion deposition procedure such as unbalanced magnetron sputtering (see, e.g., U.S. Patent No. 4,116,791, European Patents Nos. 668,369 and 707,663, German Patents Nos. 4,407,274 and 4,331,890, which are here incorporated by reference) or ion-beam implantation or ion-beam assisted deposition (see, e.g., U.S. Patents Nos. 5,236,509, 4,743,308 and 4,526,673 which also are here incorporated by reference). The ion deposition procedure increases the diameter of the uncoated spring wire by not more than about 0.002 in. (or about 0.05 mm.), and preferably by about 0.0003 to 0.001 in. (or about 0.0076 to 0.025 mm.).

Description of Drawings

Figure 1 is a sectional view of a guide wire assembly constructed in accord with the present invention.

Figure 2 is an enlarged sectional view of the tip portion of the guide wire assembly of Figure 1.

Figure 3 is a greatly enlarged sectional view of the coil in the distal tip portion of the guide wire assembly of Figure 1.

Figure 4 is a schematic view of the wire used in the coil of the guide wire assembly of Figure 1.

Description of Preferred Embodiment

Reference is now made to Figures 1-3 which illustrate a guide wire assembly generally designated 10. It will be appreciated that, largely because the guide wire is about 6' long and only about 0.014 in. in diameter, the longitudinal and transverse scales of the drawings are very different.

As shown, guide wire assembly 10 includes a core wire 12, a portion of which is surrounded by a coaxial, helically wound spring 14. A distal tip portion 16 of the guide wire assembly is about 2.7 centimeters (a little over 1 inch)

long. An intermediate portion 18 is about 25 centimeters (about 10 inches) long and extends from the proximal end of tip portion 16; and a main guide wire portion 20 extends some 140 centimeters (about 4 1/2 feet) proximally from the proximal end of the intermediate portion 18. Spring 14 extends from the distal end of the distal tip portion 16 to the proximal end of the intermediate portion 18, and both the proximal and distal end portions of spring 14 are welded or brazed to core wire 12.

The solid core wire 12 includes an approximately constant diameter portion (about 4 1/2 feet long and about 0.013 in. in diameter) forming main guide wire portion 20 of assembly 10, and a distal portion 22 of reduced diameter. Distal portion 22 extends, coaxially within spring 14, through the length of intermediate portion 18 to adjacent the distal end of tip portion 16. The distal end of distal portion 22 of core wire 12 terminates in a flat portion 24 that is secured (typically brazed or welded) to an essentially hemispherical tip 26.

The diameter of the stainless steel wire forming the coils of spring 14 is about 0.0025 in. The coils of spring 14 are typically formed by wrapping the stainless steel wire on a constant diameter mandrel so that the inner diameter of the spring coils is constant, and so that the spring has an overall outer diameter of about 0.013 in. (and a maximum diameter of a little over 0.014 in) throughout most of its length. As discussed below, the overall diameter of the wire forming the spring coils in the distal portion of guide wire 10 is slightly (e.g., about 0.0003 to 0.002 in. and typically about 0.0003 to 0.001 in.) greater than that of coils in the remaining portion of the spring, because in the distal portion the stainless steel wire has been increased by circumferentially deposited radiopaque material.

Alternatively, the wire forming the coils may be wrapped on a tapered or reduced diameter mandrel so that the overall outer diameter of the spring coil, or the diameter of the center of the stainless steel wire of the coils, is constant. When the diameter of the center of the wire of the coils is constant, the portion of the spring 14 in tip portion 16 will have an overall outer diameter that is slightly (by an amount equal to the difference in diameter of the coated coil wire caused by the radiopaque material deposited on the stainless steel) greater than that of the remaining, and major, portion of the spring in which there is no such radiopaque layer.

As seen most clearly in Figures 1 and 2, core wire 12 includes an annular ring 28, typically about 0.4 cm (about 0.1575 inches) in axial length) and, typically, about 0.019 cm. (about 0.0076 in.) in diameter, located approximately 2.7 cm (a little more than 1 inch) from the distal end of the core wire. The annular outer surface of ring 28 is brazed to the surrounding portion of spring 14, and the exact diameter of the ring 28 is selected so that the overall diameter of the portion of spring 14 brazed to it will be about 0.013 in. The portion of spring 14 surrounding and brazed to ring 28 typically is helically wound at about 60 coils per inch (about 24 coils per centimeter); the portion of spring 14 between ring 28 and tip 26 is wound at approximately 280 coils per inch (about 110 coils per centimeter); and the portion of spring 14 proximal of ring 28 is wound at about 334 coils per inch (about 131 coils per centimeter).

According to the present invention, the wire forming the coils in the distal approximately 2.5 cm. (about 1 inch) of spring 14 includes a annular, circumferentially surrounding layer 30 of radiopaque material having an outer diameter typically not more than about 0.002 in. (about 0.05

mm.) greater than that of the stainless steel central portion 32 of spring 14 on which the radiopaque material is deposited. In Figure 2, the spring coils which include layer 30 are cross-hatched; Figure 3, which is greatly enlarged, shows both annular layer 30 and the central portion 32 of the stainless steel wire that the layer 30 circumferentially surrounds. In the preferred embodiment the diameter of layer 32 is about 0.0003 to 0.001 in. (about 0.0076 to 0.0254 mm.) more than that of the stainless steel central portion 32.

As discussed above, it will be appreciated that layer 30 increases the overall outer diameter of spring 14 in the tip portion 16 of guide wire 10 by an amount substantially equal to that by which the layer increases the overall diameter of the wire forming the spring coils in the tip region. However, because the layer of radiopaque material is annular and circumferentially surrounds the wire forming the coils, the radiopacity of the spring in the tip portion 16 is much more than it would be if a layer of radiopaque material of the same thickness was simply deposited on the exterior surface of the spring after wire had been wound into a helical coil.

According to the preferred practice of the present invention, an ion deposition procedure is used to deposit the layer of radiopaque material onto the stainless steel wire that is then wound into spring 14. In such a process, deposited material is typically driven at least a short distance into the workpiece, i.e., the stainless steel wire of spring 14, as well as being deposited on the outer circumferential surface of the wire. Thus, and as shown in Figure 3, the "layer" 30 may extend below the surface 33 of the stainless steel wire onto which the material forming the layer is ion-deposited. This is particularly when, as in ion beam assisted deposition, relatively high energy ions

are deposited. In an instance in which deposited material is forced into the underlying stainless steel, the effective overall thickness of the radiopaque "layer" 30 will be greater than the amount by which the deposited material actually increases the radius of the stainless steel of central portion 32, and the procedure will result in a greater degree of radiopacity than would be obtained simply by plating a annular layer of the same material onto the base wire at a thickness that would produce the same amount of increase in the base wire's radius or diameter.

In a preferred practice of the invention, layer 30 is gold and is deposited using unbalanced magnetron sputtering, which involves deposition of relatively low energy ions from a plasma by means of an unbalanced magnetic field that loosely contains the plasma. In another practice of the invention, the gold layer 30 is ion-deposited using an ion beam assisted deposition procedure, such as that identified by Spire Corporation under its trademark "Spi-Sight", which employs an ion gun and evaporator to deposit higher energy ions.

In either procedure, the gold forming layer 30 is preferably deposited onto the stainless steel wire of spring 14 so as to increase the overall radius of the stainless steel by about 0.00015 in. to 0.0005 in. (and the diameter of both the stainless steel wire of the spring 14 and of the wound spring itself by about 0.0003 in. to about 0.001 in.). The effective thickness of layer 30, however, may be greater than the increase in radius.

Figure 4 illustrates a continuous length of the wire 100 used to make a plurality of springs 14, before it has been helically wound. As shown, circumferential layers 102 of gold, each about 22 inches long and about 0.00025 inches in radial thickness, are deposited onto axially spaced portions of the about 0.0025 inch. diameter 304 stainless

steel wire. The approximately 330 inches (about 840 cm) of wire 100 between each adjacent pair of gold layers 102, designated 104, may be bare, or the entire wire may be continuously ion beam coated.

About 11 inches of straight wire is required to form the radiopaque coils in the distal portion of a spring 14, i.e., the approximately 2.7 cm (a little over 1 inch) long portion extending from hemispherical tip 26 to a point just distal of annular ring 28. Another approximately 165 inches of straight wire are needed to form the bare coils of spring 14 that extend proximally about another 25 centimeters (about 10 inches) from the proximal end of the gold-layered distal portion coils.

It will thus be noted that the lengths of each gold layer 102 and bare portion 104 are about twice the length needed to form a helically wound spring wire 14. Thus, in forming a wire 14 for a guide wire assembly 10, the wire 100 is first helically wrapped into coils of the desired diameter and spacing, and the bare portions 104 and gold layer portions 102 of the wrapped coil are then cut approximately midway their respective lengths. A cut length may then be slipped over the core wire 12 (on the distal end of which hemispherical tip 26 has already been welded), and brazed into place. Short lengths of "scrap" may be removed at the distal and proximal ends of the helical coil 14 in the course of assembly and brazing.

In other embodiments, dense radiopaque materials other than gold (e.g., platinum, tantalum, tungsten, iridium, rhenium, or an alloy of two or more such materials) may be used to form the desired increased radiopacity annular layers on the stainless steel spring wire, the springs may be used in medical devices other than guide wires, and rather than 304 stainless steel the wires may be made of the materials sold under the tradenames Elgiloy (an alloy

containing cobalt, chromium, nickel and molybdenum), MP35N (an alloy containing cobalt, nickel, chromium and molybdenum) or Nitinol (an alloy containing nickel and titanium). In some circumstances layers of the desired radiopacity also may be produced using procedures other than unbalanced magnetron sputtering, ion implantation or ion beam assisted deposition.

These and other embodiments will be within the scope of the following claims.

What is claimed is:

1. In a guide wire assembly including

a longitudinally-extending core having a distal tip, and

a helically wound spring coaxially surrounding the core, secured to the distal tip and extending proximally therefrom, that improvement wherein:

the coils of a distal portion of the spring include an annular layer of radiopaque material circumferentially surrounding a central wire portion of a different material.

2. The guide wire assembly of claim 1 wherein said annular layer comprises radiopaque material deposited using a process selected from the group consisting essentially of unbalanced magnetron sputtering, ion beam implantation and ion beam assisted deposition.

3. The guide wire of claim 1 wherein said radiopaque material is selected from the group consisting of gold, platinum, tantalum, tungsten, iridium, rhenium, and two or more thereof.

4. The guide wire of claim 3 wherein said material is gold.

5. The guide wire of claim 3 wherein said material is deposited onto said central wire portion to form said layer deposited using a process selected from the group consisting essentially of unbalanced magnetron sputtering, ion beam implantation and ion beam assisted deposition.

6. The guide wire of claim 3 wherein said layer has an outer diameter not more than about 0.002 inches greater than that of said central wire portion onto which the said radiopaque material forming said layer is deposited.

7. The guide wire of claim 6 wherein said outer diameter is about 0.0003 to about 0.001 inches greater than that of said central wire portion of said spring, and said layer comprises gold.

8. The guide wire of claim 5 wherein said layer is gold and said outer diameter is not more than about 0.001 greater than that of said central wire portion.

9. In the method of making a guide wire assembly including a helically wound spring coaxially surrounding a central core and extending proximally from the distal tip of said guide wire, that improvement including the steps of:

providing a length of wire for making said spring;

depositing an annular layer of radiopaque material on an axially-extending portion of said length of wire;

winding said length of wire into a helically wound spring, one portion of said spring comprising coils formed from said axially-extending portion including said annular radiopaque layer and another portion of said spring comprising coils formed from a portion of said wire that does not include said annular radiopaque layer;

positioning said spring relative to a said central core such that said one portion of said spring extends from the distal tip of said guide wire assembly to a point proximal of said distal tip.

10. The method of claim 9 wherein said radiopaque material is selected from the group consisting of gold, platinum, tantalum, tungsten, iridium, rhenium, and two or more thereof.

11. The method of claim 10 wherein said depositing comprises depositing said material onto said axially-extending portion of said wire using a process selected from the group consisting essentially of unbalanced magnetron sputtering, ion beam implantation and ion beam assisted deposition.

12. The method of claim 11 wherein said depositing includes depositing gold onto said axially-extending portion of said wire.

13. The method of claim 9 wherein said depositing includes depositing said radiopaque material such that said layer has an outer diameter not more than about 0.0006 inches greater than that of said central core of said spring wire onto which the said radiopaque material forming said layer is deposited.

14. The method of claim 9 wherein said outer diameter is not more than about 0.002 inches greater than that of said central core of said spring wire, and said layer comprises gold deposited using a process selected from the group consisting essentially of unbalanced magnetron sputtering, ion beam implantation and ion beam assisted deposition.

15. The method of claim 9 wherein said radiopaque material is deposited such that said layer has an outer diameter about 0.0003 to about 0.001 inches greater than that of said central core of said spring wire.

16. The method of claim 9 wherein said core wire includes an annular ring adjacent the distal end of said distal portion of said core wire, and including the step of brazing or welding said one portion of said spring to said annular ring.

17. The guide wire of claim 1 wherein said tip portion of said guide wire includes a rounded tip attached to the distal end of said core wire and the distal end of said helical spring.

18. In a medical device including guide wire assembly including a helically wound spring, that improvement wherein:

the coils of a portion of the spring include an annular layer of radiopaque material deposited using a process selected from the group consisting essentially of unbalanced magnetron sputtering, ion beam implantation and ion beam assisted deposition and circumferentially surrounding a central wire portion of a different material.

19. The guide wire of claim 18 wherein said radiopaque material is selected from the group consisting of gold, platinum, tantalum, tungsten, iridium, rhenium, and two or more thereof.

20. The guide wire of claim 18 wherein the radius of the outer surface of said layer is not more than about 0.001 inches greater than that of said central wire portion onto which the said radiopaque material forming said layer is deposited.

21. The guide wire of claim 20 wherein said radius of said outer surface of said layer is not more than about 0.0005 inches greater than that of said central wire portion.

22. In the method of making a medical device including a helically wound spring, that improvement including the steps of:

providing a length of wire for making said spring;

depositing an annular layer of radiopaque material on an axially-extending portion of said length of wire using a process selected from the group consisting essentially of unbalanced magnetron sputtering, ion beam implantation and ion beam assisted deposition;

winding said length of wire into said helically wound spring, one portion of said spring comprising coils formed from said axially-extending portion including said annular radiopaque layer and another portion of said spring comprising coils formed from a portion of said wire that does not include said annular radiopaque layer.

23. The method of claim 22 wherein said radiopaque material is selected from the group consisting of gold, platinum, tantalum, tungsten, iridium, rhenium, and two or more thereof.

24. The method of claim 22 wherein said radiopaque material is deposited such that said layer has an outer diameter not more than about 0.002 inches greater than that of said wire onto which the said radiopaque material forming said layer is deposited.

25. The method of claim 24 wherein said outer diameter is not more than about 0.0003 to about 0.001 inches greater than that of said central core of said spring wire, and said layer comprises gold.

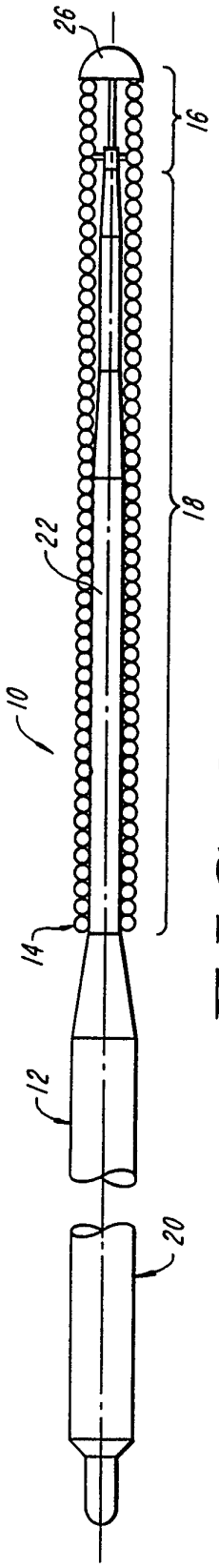


FIG. 1

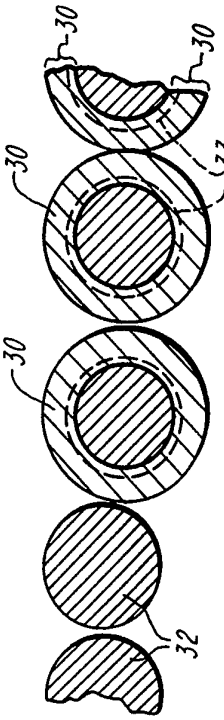


FIG. 3

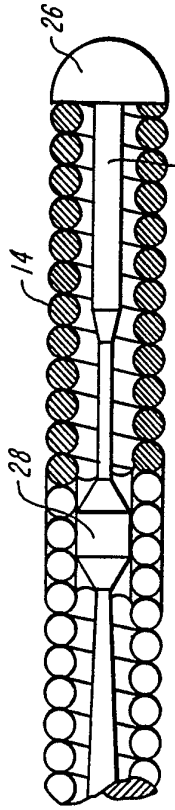


FIG. 2

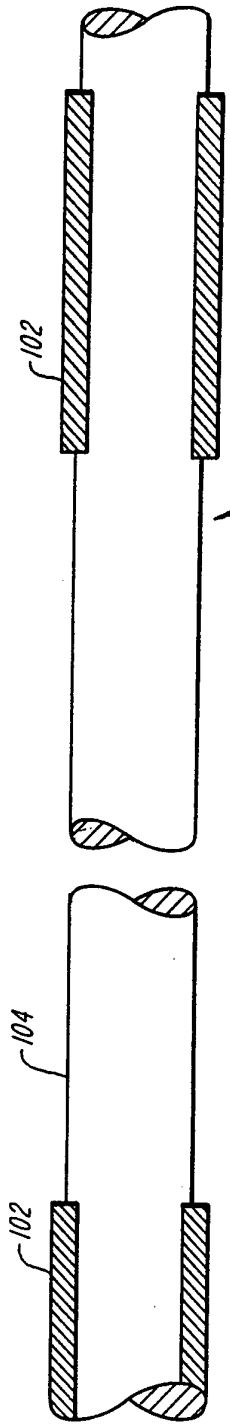


FIG. 4

INTERNATIONAL SEARCH REPORT

Inter nal Application No
PCT/US 96/10606

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 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 6 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)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	US,A,5 144 959 (GAMBALE RICHARD A. ET AL.) 8 September 1992 see abstract see column 1, line 45 - column 2, line 15 see column 3, line 14 - column 4, line 46; figures 1-6	1,3-13, 15-17 2,14, 18-25
Y	US,A,4 939 041 (KABACOFF LAWRENCE T. ET AL.) 3 July 1990 * The Whole Document *	2,14, 18-25
A	US,A,5 313 943 (HOUSER RUSSELL A ET. AL.) 24 May 1994 see abstract see column 7, line 34 - line 65	

☐ 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.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
28 October 1996	11. 11. 96

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	Michels, N

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

information on patent family members

Inter ›nal Application No
PCT/US 96/10606

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US-A-5144959	08-09-92	JP-A- 3133463	06-06-91
US-A-4939041	03-07-90	NONE	
US-A-5313943	24-05-94	WO-A- 9407413	14-04-94