PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61M 25/00	A1	(11) International Publication Number: WO 00/13735
		(43) International Publication Date: 16 March 2000 (16.03.00)

(21) International Application Number: PCT/US99/20399

(22) International Filing Date: 3 September 1999 (03.09.99)

(30) Priority Data:
60/099,079 4 September 1998 (04.09.98) US

(71) Applicant: PROLIFIX MEDICAL, INC. [US/US]; Suite 2, 680 West Maude Avenue, Sunnyvale, CA 94086 (US).

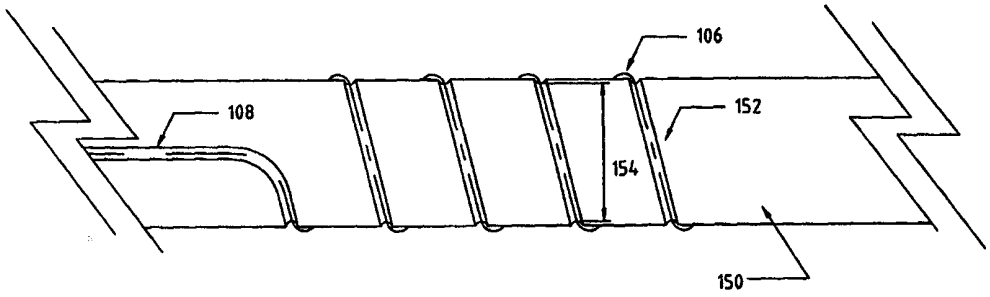
(72) Inventors: PASSAFARO, James, D.; 107 Belridge Drive, Los Gatos, CA 95032 (US). ROGERS, Larry; 542 Highland Avenue, Half Moon Bay, CA 94019 (US).

(74) Agents: HESLIN, James, M. et al.; Townsend and Townsend and Crew LLP, 8th floor, Two Embarcadero Center, San Francisco, CA 94111-3834 (US).

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

Published
With international search report.

(54) Title: SIMPLE PERFUSION DEVICE



(57) Abstract

The present invention relates to a perfusion device composed of a shape memory alloy, and being shaped in one of several geometries designed to perfuse a collapsed body lumen. The perfusion device is comprised of a core wire (106) having a shape set open structure on the distal end. The shape set open structure may be a corkscrew or a mixing beater shaped cage. The perfusion device can be easily that is quickly deployed in a damaged body lumen such as a blood vessel, and has a high flow through area relative to the size of the actual device. Methods of manufacturing, and using the perfusion device are also disclosed.

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.

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

SIMPLE PERFUSION DEVICE

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates generally to medical devices and methods. More particularly, the present invention relates to apparatus and methods for delivering temporary self expanding prostheses within blood vessels and other body lumens.

2. Description of the Prior Art

In percutaneous transluminal coronary angioplasty (PTCA) procedures, a catheter having an expansible distal end, usually in the form of a balloon, is positioned in a lumen of a blood vessel with the distal end disposed within a stenotic atherosclerotic region of the vessel. The expansible end is then expanded to dilate the vessel and, upon withdrawal, restores adequate blood flow through the diseased region.

While angioplasty has gained wide acceptance, it continues to be limited by two major problems, abrupt closure and restenosis. Abrupt closure refers to the acute occlusions of a vessel immediately after or within the initial hours following a dilation procedure. This complication occurs in approximately one in twenty cases and frequently results in myocardial infarction, bypass surgery, angina pectoris and possibly death if blood flow is not quickly restored. Restenosis refers to the re-narrowing of an artery after an initially successful angioplasty and occurs usually within the initial six months after angioplasty. Restenosis afflicts approximately one in three cases.

Many different strategies have been tried with varying degrees of success to reduce restenosis and abrupt closure, including pharmacologic (e.g., systemic and localized administration of anti-proliferative agents and other drugs) and mechanical treatments such as the placement of a stent, use of atherectomy devices, radiation therapy, radiofrequency therapy and lasers. In the event any of these procedures produce a perforation or dissection of the blood vessel it becomes necessary to dilate the blood vessel for extended periods of time to avoid emergency coronary bypass surgery. For example, prolonged dilations of several minutes may be employed on the occurrence of dissections, intimal flaps, acute thrombosis and vessel spasms.

A variety of techniques have been proposed to facilitate prolonged dilations. These include the use of pharmacologic agents to improve myocardial tolerance of ischemia, synchronized retroperfusion, mechanical pump distal perfusion and auto or passive perfusion.

The use of pharmacologic agents treats the symptoms of ischemia without addressing the cause. As a result this approach is inherently limited.

Synchronized retroperfusion involves pumping blood during diastole into the coronary sinus and then subselectively into the regional coronary veins which drains the jeopardized myocardium. While this approach potentially offers nearly complete myocardial perfusion, it is complicated and cumbersome. Mechanical pump distal perfusion involves pumping blood (or other perfusate) through a lumen of the PTCA catheter. As the name implies, this requires some form of mechanical pump which complicates the angioplasty equipment and procedure.

Most adults are able to withstand non-perfusion dilation of 30-60 seconds without significant side effects. However auto or passive perfusion has found increasing interest both for prolonged dilations as well as these shorter dilation procedures having a duration on the order of non-perfusion dilation. Typically in passive perfusion, the balloon catheter acts as a temporary stent. That is, a perfusion lumen is employed to provide a blood flow passage during balloon inflation. Typically, the perfusion lumen extends through the balloon envelope having an inlet proximal to the balloon envelope and a discharge distal to the balloon envelope. Proposed inlet configurations have included side openings in the catheter as well as a beveled opening to the blood flow channel. Proposed discharge configurations have included a main axial orifice and side openings. Clearly, the inlet, outlet and balloon volume have a direct effect on blood flow capacity. Further, pressure within the balloon envelope during balloon inflation has a tendency to compress a perfusion lumen within the envelope thereby potentially constricting the blood flow passage. On the other hand, countering this tendency by stiffening the perfusion lumen walls can seriously impact trackability of the catheter itself. The attachment of a projecting distal tip to provide side wall discharge can affect trackability as a result in changes of stiffness from material changes and/or the attachment itself.

It is to these dictates of the prior art that the present invention is directed. The present invention is a perfusion device which serves to obviate at least some of the short comings of the prior art.

A first object of the present invention is to provide a perfusion device having a larger flow through region.

A second objective of the present invention is to provide a perfusion device with a minimum of components and which can be deployed quickly.

A third objective of the present invention is to provide a perfusion device which can be used to determine the effective deployment of the perfusion device.

At least one of the objectives is satisfied in the disclosure of the present invention in following description of the specific embodiments and claims.

SUMMARY OF THE INVENTION

The following definitions are provided as a reference for the terminology herein.

By "tapered" we mean the core wire is ground down at one end over a length of 10 to 50 cm. The grinding of the core wire can be any variety of forms such that the wire has a gradually narrowing diameter from the point of contact of the grinding device to the core wire, to the end of the core wire at the distal end. The distal end is always that end of the core wire that has been ground down. The grind can be gradual and continuous from the start point to the distal tip of the core wire, or it can be a step wise reduction. E.G. the core wire may have a diameter of 0.014" and have a 30 cm grind length, consisting of three step down lengths and three lengths of constant diameter. The process for step and gradual grinds are well understood in the art of making guide wires and are not part of the present invention.

By "mandrel" we mean the shape setting template composed of a heat stable material at a temperature necessary for heat setting a shape memory alloy core wire. The mandrel has a groove for receiving the core wire and holding the core wire in place during the heating step. "Mandrel" refers to the shape setting template of a heat stable material without the core wire attached.

By "mandrel assembly" we mean the mandrel with a core wire properly wound around the mandrel and set into the groove for receiving the core wire. The mandrel assembly also includes a pair of core wire anchors which maintain the tension on the core wire so it will be set to the desired shape.

By "coil wire" we mean a small diameter wire wrapped around the tapered distal tip of the perfusion device. This coil wire is similar to the wire used in ordinary guide wires to increase distal tip diameter and improve atraumatic tip properties. In the

present invention the coil wire serves these functions and also provides a radiopaque reference system in which the preformed perfusion section can be viewed via fluoroscopy during a perfusion procedure. The coil wire may have different segments of varying radiopacity in order to produce reference distances, as well as location markers to assist in deployment, and spacing markers to assist in the determination of the distance between structural elements of the perfusion device during deployment. Alternatively the entire coil wire may be made of a radiopaque material such as platinum. The coil wire may be a round wire, ribbon wire or other special cross section.

By "distal tip wire" we mean a wire having a small diameter and short length that is fixedly attached to the distal tip of the core wire and used to bridge the distance between the tip of the core wire and the atraumatic tip. The distal tip wire may be composed of any suitable material and is generally asymetrically aligned relative to the core wire axis. The distal tip wire is fixedly attached to the autraumatic tip, usually in the form of a solder ball.

By "perfusion cage" we refer to any of a variety of shape set open structures, formed either directly on the distal end of the core wire, or in the form of an attached device that is partially attached to the core wire at substantially the distal end. The perfusion cage has the features of being able to open a dissected or diseased body lumen through an expansive force of the materials the perfusion cage is made of. Furthermore the perfusion cage has a large flow through area relative to the area of the perfusion cage itself.

A perfusion device is disclosed comprising a core wire having a proximal section and a tapered distal tip. The core wire is composed of a shape memory alloy. A perfusion section is located on at least part of the tapered distal tip. The perfusion section is a preformed radially expansible shape capable of compression to a relatively straight profile and expansion to substantially the shape set open structure. A coil wire is wrapped around the tapered distal tip such that the coil wire adds sufficient width to the tapered section of the core wire such that the perfusion device has substantially a uniform diameter through out its length and improve radiopacity.

In operation a perfusion device can take the place of other perfusion devices which may be used in interventional cardiology procedures, other coronary and vascular applications, arterial and venous, laryngeal edema or bronchospasm during anaphylaxis and as an alternative to acute intubation for patency of air passages. The

present invention can also be used to maintain fallopian tube patency or provide relief from benign prostate hyperplasia.

In the preferred embodiment of the present invention, a core wire composed of a shape memory alloy, such as is frequently used for making guide wires for interventional cardiology procedures, is used for making a perfusion device. The core wire length is determined by the type of procedure it is intended for and typically has a length between 150-300 cm. The distal section of the core wire is ground down to a smaller diameter than the proximal section. For example a core wire having a 0.014" diameter will have the distal section ground in a gradual taper (either continuous or stepped) so the perfusion section has a constant diameter ranging from 0.001" to 0.014". The actual tip of the core wire may be ground to a smaller diameter than the perfusion section. The tapered distal section is then heat treated to give it the desired shape.

The mandrel may be made of any material stable to temperatures upwards of 600 degrees centigrade. Ceramic materials such as quartz, glass and macor are excellent materials for the mandrel, the mandrel is also effective if made from metals such as brass or steel. The tapered distal section of the core wire is wrapped around the mandrel and secured tightly, at least at the distal end of the core wire, to the mandrel. The wire and mandrel assembly are then heated at a minimum temperature of 400 degrees Centigrade for at least one minute to set the shape. More preferably the mandrel assembly is heated at 500 to 550 degrees centigrade for about five minutes. Heating of the mandrel assembly may be achieved using an oven, a liquid salt bath or an infrared heating element. The actual temperature and heat time needed to produce a perfusion section on the tapered core wire is a function of the mandrel diameter, core wire thickness and manner in which the heat is applied. It is well understood that the greater thermal mass of a liquid salt bath can impart the necessary heat faster than an infrared heating element. Often a thicker core wire and larger mandrel require a greater heating time than those specific embodiments disclosed herein. Once the heating step is completed, the mandrel assembly is removed and the wire is cooled to room temperature. The mandrel assembly may be rapidly cooled by being emersed in a cold water bath or similar medium.

Once the core wire cools to room temperature, the ends are freed from the mandrel and the core wire is unwound from the mandrel. A coil wire is then attached to the tapered distal section. The coil wire may be any material normally used with guide wire. Materials of varying radiopacity can be alternatively positioned so that regions with

higher radiopacity are aligned with reference positions along the perfusion section in order to provide reference markers during use. The reference marker regions tend to use coil wire materials such as tungsten-platinum, iridium, gold, palladium or tantalum (row six or higher on the periodic table of elements). Multiple coil wires may be used to provide the desired alternating bands of radiopacity.

An atraumatic tip is required at the distal tip to prevent the perfusion device from dissecting a blood vessel during deployment and use. Preferably the atraumatic tip is formed by using a distal tip wire having a diameter in the range of 0.0015 to 0.003" and a length of 10 to 30 mm. The distal tip wire is fixedly attached directly to the distal tip of the core wire. Then a coil wire is advanced from the distal end of the core wire to the step down region proximal to the shape set region. Once the coil wire is in place it is fixedly attached to the core wire, usually by solder. A solder ball can be used at the distal tip of the perfusion device where the coil wire extends to the tip of the distal tip wire previously attached to the core wire. The atraumatic tip assists in steering the perfusion device during deployment as well as preventing any further injury or dissection to the vessel it is tracking through.

Preferably the mandrel possesses a groove along its surface which is sufficiently wide to accommodate the tapered distal section of the core wire. The groove helps secure the core wire in place and provides the perfusion section with any desired heat set path desired. Reference sections can be incorporated into the mandrel such that discrete and precise distances can be identified in any axis or plane. When the heat set tapered distal tip of the core wire is wrapped with a coil wire, these discrete and precise distances can be aligned with high visibility radiopaque sections of the coil wire. The alignment of these markers and sections permits a physician to accurately assess the deployment of the perfusion device under fluoroscopy by evaluating the position and orientation of the reference sections with matching lengths of radiopaque markers along the length of the perfusion section. Reference sections can be incorporated proximal, distal or within the perfusion section. It is also possible to attach the coil wire to a straight core wire, then heat the combination in the same manner previously described, to form the perfusion device. The mandrel must have a groove wide enough to accommodate the change in width of the wire combination to be treated.

A second embodiment of a perfusion device is a perfusion cage comprised of a plurality of struts forming a cage. The struts are preferably made of a shape memory alloy and arranged along the main axis of the core wire into a shape resembling a mixing

beater. The struts are preformed either as flat struts or with a fixed curvature so when exposed within a body lumen the struts expand outward from the main axis of the core wire into a beater shape. In the preferred embodiment, the struts are fixedly attached at the distal end to the core wire and attached to a slidable annular ring proximally. The slidable annular ring may be manually adjusted relative to the fixed distal end to further increase the diameter of the perfusion cage beyond the ordinary preformed shape of the struts. Alternatively both ends of the struts may be fixedly attached to the core wire so that when the shape set open structure is advanced outside the catheter, the structure automatically "pops up" into the mixing beater shape. In a third embodiment, the distal attachment may be the annular ring attached to a telescoping core wire and the proximal attachment of the struts are fixedly attached to a cylindrical housing through which the telescoping core wire extends. The movement of the slidable annular ring in the preferred and third embodiment above may be controlled through a hand piece on the proximal side. The relative position of the slidable annular ring may be regulated by a détente to prevent a physician from sliding the annular ring too close to the fixed attachment.

The perfusion cage can be deployed through a standard guide catheter to a treatment site, then advanced forward while the guide catheter is withdrawn. As the perfusion cage emerges from the guide catheter the struts will automatically expand and exert an outward radial force and perfuse the dissected vessel. In the even the radial force of the perfusion cage is not sufficient to produce the desired effect, the cage may be manually operated to either increase or decrease the outward radial force. Manual operation is handled by a single intermediate sleeve over the core wire to engage the annular ring as it is manipulated by a physician on the proximal side.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a cut away view of the perfusion device in a helical preformed shape.

Fig. 1A and 1B illustrate two variations of the core wire ground down in the distal end and perfusion section.

Fig. 2 shows a pair of head on views of the perfusion device preformed shape.

Fig 3 shows a profile view of the perfusion device with reference sections spaced evenly apart along the perfusion section.

Fig. 4 shows a cut away profile view of the perfusion device deployed in a blood vessel.

Fig. 5 shows the perfusion section loaded in a mandrel for heat setting.

Fig. 6 shows an alternative embodiment in the form of a multi-strut cage.

DESCRIPTION OF THE SPECIFIC EMBODIMENTS

Turning now to the drawings, Figure 1 illustrates a profile view of the perfusion section 100 of the perfusion device 10. The perfusion section 100 generally has a series of helical loops 102 of generally the same diameter. The helical diameter 104 refers to the outside diameter of the perfusion section 100 in an unconstrained environment. The helical diameter 104 is determined by the diameter of the mandrel 150 and can be any diameter desired. Generally for perfusion of coronary blood vessel diameters of 0.5 mm to 5.0 mm are desirable. In an alternative embodiment, the present invention can be used in bronchial passage expansion (not pictured) for the treatment of anaphylactic shock. In this instance the helical diameter 104 may range from 10 to 50 mm depending on the age and size of the patient. It is a matter of application choice to determine the appropriate mandrel diameter for forming an appropriate wire for a medical procedure.

Figure 1B illustrates a core wire 106 that has been ground down for use in the present invention. The core wire has a tapered region 120 which begins at the most proximal grind down 116, or at the point the core wire begins to taper if the grind down is a gradual and constant type (Fig 1A). In a step down grind configuration of the core wire 106, the barrels 118 between step down grinds 116, 116' and 116" have a constant diameter. In the preferred embodiment, three step down regions are used. However the present invention may be made with a single grind down that is either gradual along the entire length of the grind down region, or of variable decreasing diameter along the length of the grind down region. It should be appreciated that the strength of the perfusion section of the wire will be decreased as the diameter of the core wire is reduced. Thus it is preferred to maintain the core wire diameter along the length of the core wire to be consistent. The most distal barrel is the distal tip 108. The intermediate barrel forms the perfusion section 100 after heat setting. The proximal barrel is the proximal section 110. Proximal to the proximal grind 116 is unmodified core wire 106. Figure 1 also illustrates a transparent view of the tapered region 120 of the core wire 106 with the coil wire 122 wrapped over it. An atraumatic tip 114 is located at the most distal end of the distal tip

108. The perfusion section 100 is shown in its unconstrained form having a maximum helical diameter 104. The actual number of helical loops 102 can be any desired though at least two are required to produce a temporary stent (not shown).

Figure 2 illustrates a head on view of the perfusion section 100 and two different possible profiles. The invention is not limited to two and these are merely illustrative. The circular helix 302 has a single helical loop 102 in the foreground. The helical loop 102 continues to extend to the distal tip 108. The connection from the perfusion section 100 and the most proximal helical loop 102 is shown going to the proximal section 110.

Figure 3 illustrates the perfusion section 100 with alternating bands of radiopaque regions in the coil wire 122. Three radiopaque markers 124, 126, 128 are shown on the coil wire 122. A distal marker 124 on the distal region 108 is used to indicate the region directly distal to the perfusion section 100. The proximal marker 128 is used to indicate the proximal end 110 immediately proximal to the perfusion section 100. Between the various marker regions are regions of low radiopacity 130. The radiopaque markers are roughly the same length. There may be multiple markers used in the perfusion section 100 or multiple reference markers 124, 128 used on the coil wire 122. Alternatively the coil wire 122 may have no markers on it. One or more perfusion markers 126 are used to permit a physician to determine the orientation and expansion of the perfusion section 100 during use. The physician can evaluate the relative deployment of the perfusion section 100 by comparing the visual length of the reference markers (distal 124 and proximal 128) along with the perfusion section marker 126. If the perfusion section marker 126 is of substantially the same length as the reference markers 124, 128 and the perfusion section marker 126 is nearly perpendicular in orientation to the reference markers 124, 128 than a physician will know the perfusion section 100 is properly and nearly maximally deployed. A plurality of perfusion section markers 126, 126' will allow the physician to get a reading on the perfusion section 100 deployment without reorienting the fluoroscope (not shown).

Figure 4 illustrates a partial deployment of the perfusion section 100 in a blood vessel 700. The blood vessel 700 may be a diseased vessel or non-diseased vessel requiring some revascularization. As the perfusion device 10 is deployed from a catheter 702, the perfusion section 100 reverts to its unconstrained shape by radially expanding along the vessel axis. At the same time the mechanical force of the perfusion section 100 as it expands, pushes apart the blood vessel 700 perfusing the vessel and restoring

adequate blood flow through the blood vessel 700. Although not pictured it should be appreciated that the same effect can occur with various dimensioned wires deployed in other parts of the human anatomy.

Figure 5 illustrates the core wire 106 after the perfusion section 100 has been ground to the desired diameter as it is wrapped around a mandrel 150 prior to heat setting the desired shape. The mandrel 150 has a groove 152 for receiving the tapered region 120 of the core wire 10. The mandrel diameter 154 defines the shape of the perfusion section seen in Figure 3.

Figure 6 illustrates an alternative embodiment to the present invention. The perfusion device 10 is made in the form of a longitudinal cage 130. The core wire extends from the catheter 702, and has a plurality of atraumatic struts 132 attached near the distal tip. The struts 132 are attached proximally to an annular ring 134 which can be slidably moved along the length of the core wire. The struts can expand to a natural, preformed shape (similar to the shape of a mixing beater) or be adjusted manually by pushing the annular ring and causing the struts to "bow" out further. In this manner the dilation of the blood vessel may be manually controlled and the vessel may be expanded to a much greater diameter than the natural preformed shape of the struts. In this embodiment preformed struts may be made

While the present invention has been described in the above description, the scope of the present invention is broader than can be reasonably described in a single document as will be come clear to an individual of skill in the art upon review of the present disclosure and the appended claims.

WHAT IS CLAIMED IS:

1. A perfusion device composed of a core wire of a shape memory material, having a proximal end and a distal end, wherein said distal end comprises:

a shape set open structure capable of alternating between an open cylindrical shape and a substantially straight profile; and

an atraumatic tip located distal to said shape set open structure.

2. The perfusion device of claim 1, wherein said shape set open structure is a corkscrew formed upon at least a portion of said distal end.

3. The perfusion device of claim 1, wherein said distal end is housed within a coil wire.

4. The perfusion device of claim 1, wherein said shape set open structure is a cage comprised of a plurality of shape memory material struts, said struts having a distal end being fixedly attached to said core wire, and having a proximal end attached to a slidable annular ring.

5. The perfusion device of claim 4, wherein the slidable annular ring is engaged by a cylindrical sheath housing said core wire, said cylindrical sheath being capable of manual manipulation.

6. A perfusion device as in claim 1, wherein said perfusion device has a length not less than 25 centimeters.

7. A perfusion device as in claim 1, wherein said perfusion device preferably is 150 cm to 300 cm in length.

8. A perfusion device as in claim 1, wherein said shape set open structure of said core wire is ground to a diameter less than 0.100".

9. A perfusion device as in claim 1, wherein said shape set open structure of said core wire is ground to a diameter preferably in the range of 0.003" to 0.014".

10. A perfusion device as in claim 1, wherein said shape set open structure of said core wire is ground to a diameter more preferably in the range of 0.005" to 0.009".

11. A perfusion device as described in claim 1, wherein said shape memory material is nickel-titanium.

12. A perfusion device as described in claim 3, wherein said coil wire is made of any material that is at least partially radiopaque.

13. A perfusion device as described in claim 1, wherein said shape set open structure has a diameter between 0.5 mm and 50.0 mm.

14. A perfusion device as described in claim 1, wherein said shape set open structure more preferably has a diameter between 1.0 mm and 4.5 mm.

15. The perfusion device of claim 1, wherein said shape memory material is a two way shape memory alloy having a transition temperature below 30 degrees centigrade.

16. The perfusion device of claim 1, wherein said shape set open structure further comprises at least one radiopaque marker.

17. A method of making a perfusion device comprising the steps of:

(a) grinding a shape memory material core wire so that the core wire has a tapered section and a non tapered section;

(b) fixing said tapered section through a groove on a mandrel, said mandrel having a single contiguous groove for the tapered section to be secured within;

(c) heating the mandrel with said tapered wire secured in it,;

(d) cooling said tapered wire and said mandrel to room temperature;

(e) removing said tapered wire from said mandrel;

(f) securing at least one coil wire to said tapered section; and

(g) placing an atraumatic tip at the distal tip of said tapered section and coil wire.

18. The method of claim 17 where in step (c) further comprises heating the mandrel assembly to at least 400 degrees centigrade for at least one minute.

19. The method of claim 17 wherein step (c) preferably comprises heating the mandrel assembly to at least 500 degrees centigrade for five minutes.

20. A method of supporting a blood vessel using a perfusion device, comprising the steps of:

(a) introducing a guide wire into the body lumen and through the region in need of support;

(b) introducing a catheter over the guide wire and advancing said catheter distal of the area of said blood vessel in need of support;

(c) removing the guide wire;

(d) introducing a perfusion device through a lumen of said catheter, said perfusion guide wire having a support section with a preformed helical profile that has sufficient radially stiffness to hold open said blood vessel.

(e) retracting the catheter, relative to the perfusion device and allowing the perfusion device to expand in that portion of the vessel needing to be held open, thus allowing perfusion.

21. A kit comprising:

a guide wire;

a catheter;

a perfusion device;

instructions for use; and

a package holding said guide wire, said catheter, said perfusion device and said instructions for use.

22. A kit comprising:

a perfusion device:

instructions for use; and

a package holding said perfusion device and said instructions for use.

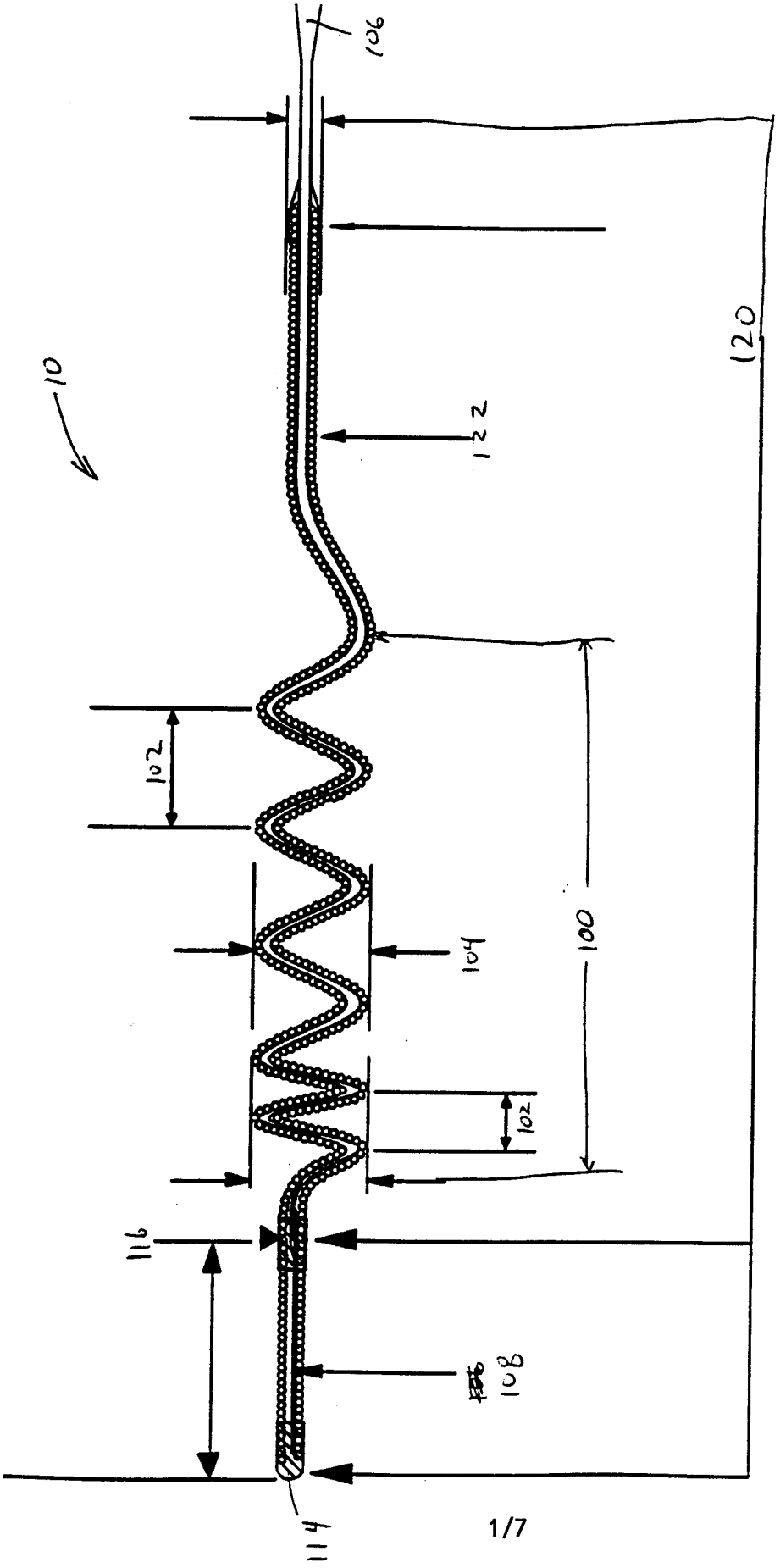


Fig 1

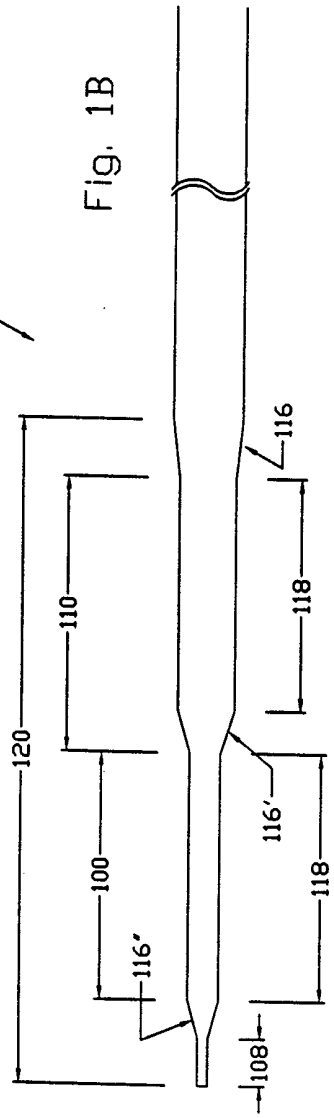


Fig. 1B

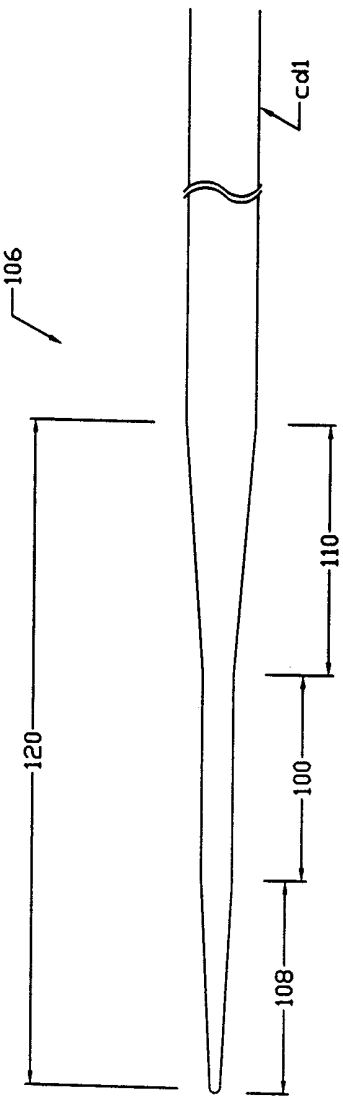
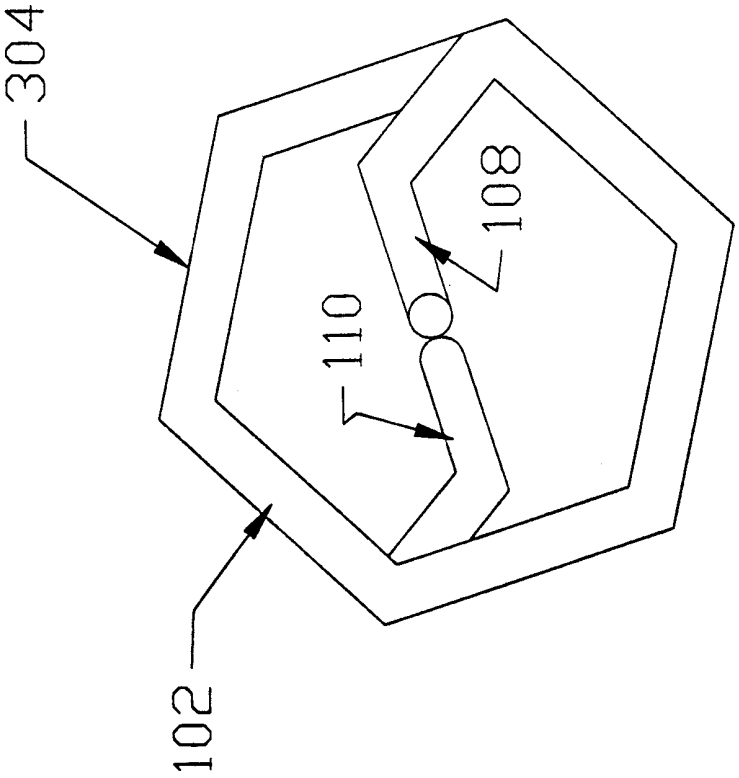


Fig. 1A



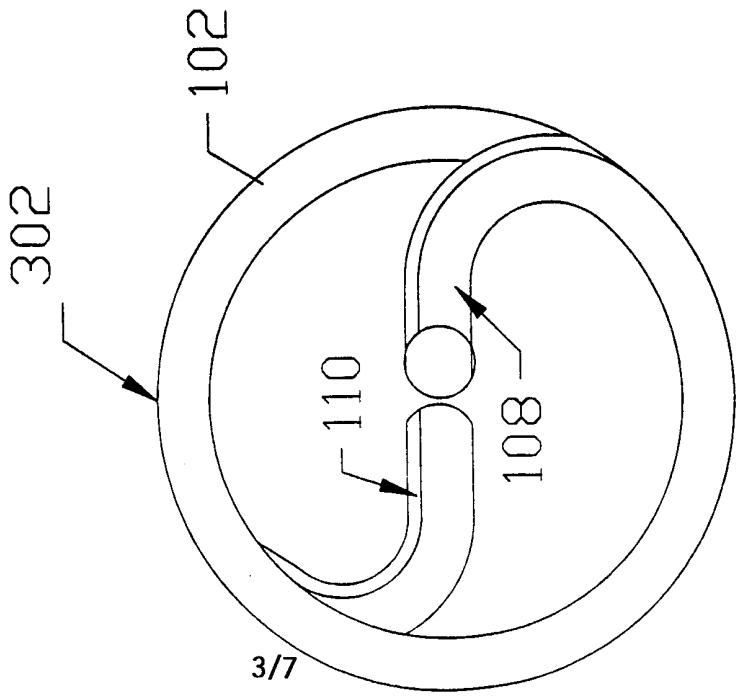


Fig. 2

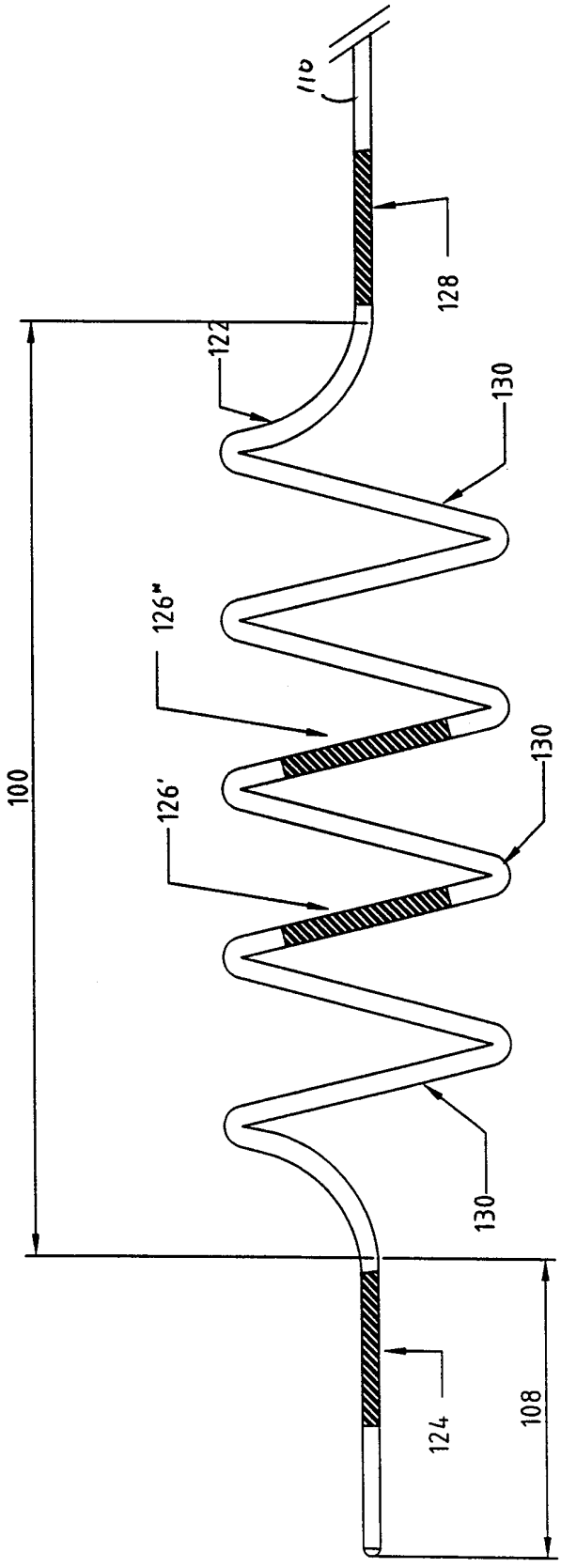


FIG 3

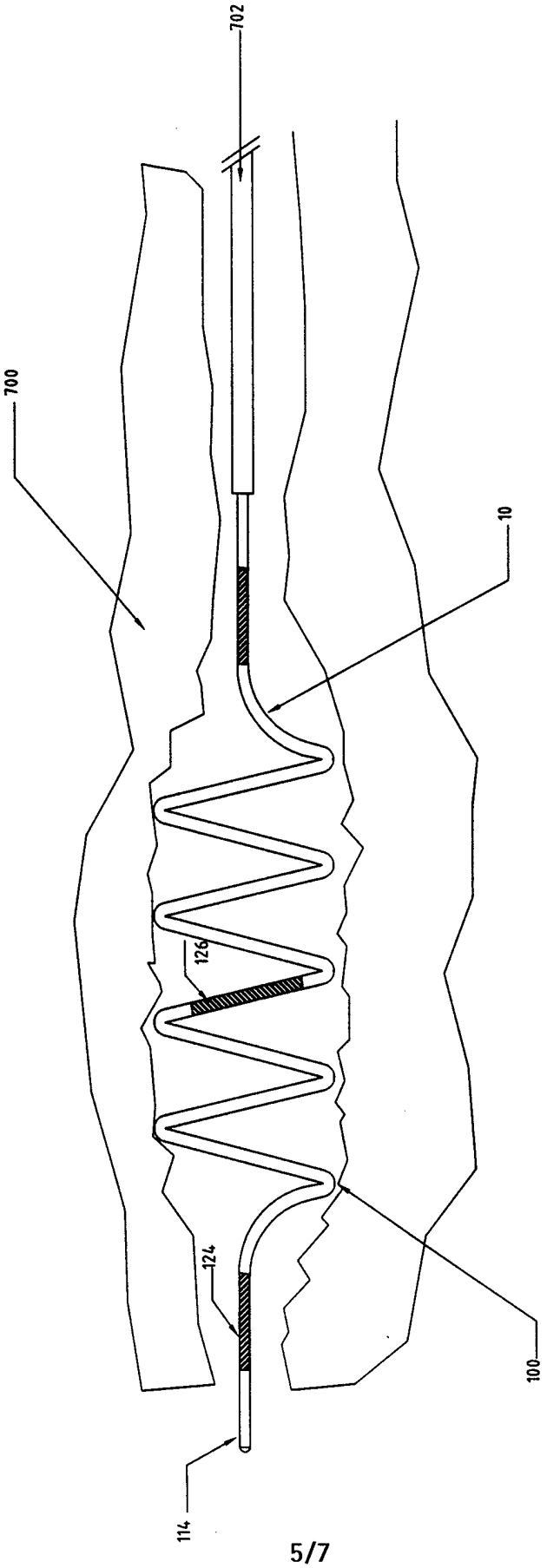


Fig 4

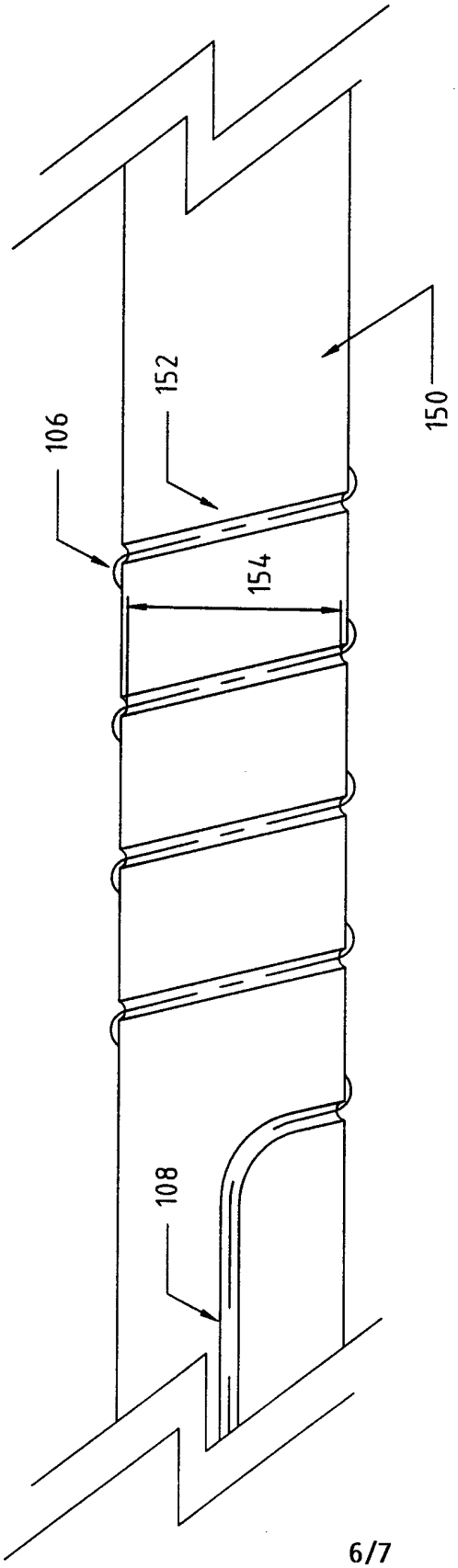


FIG. 5

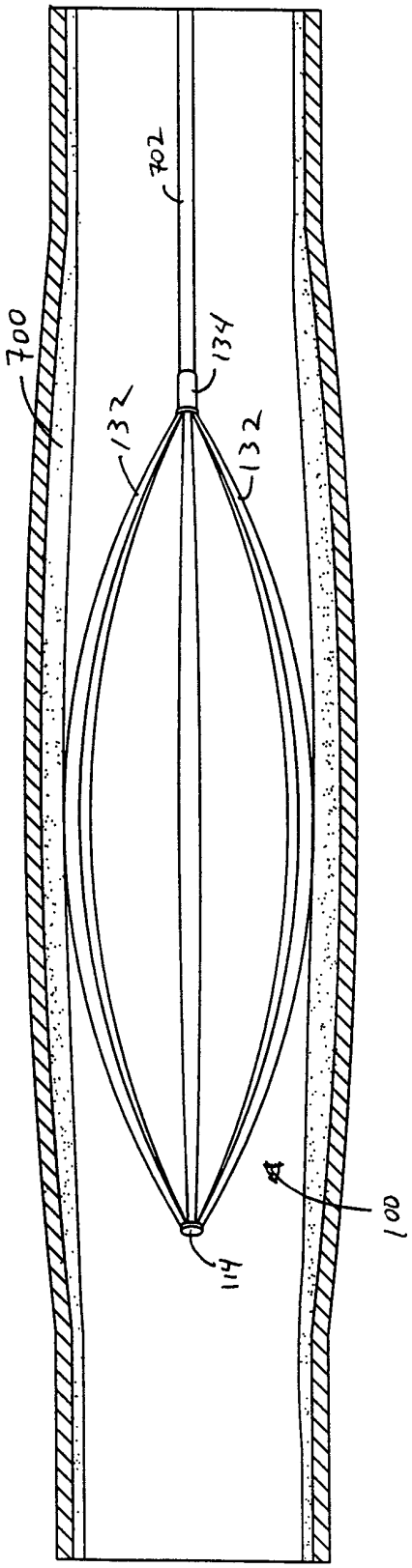


Fig. 6

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US99/20399

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61M 25/00
US CL :604/530

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)

U.S. : 604/530

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 practicable, 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.
Y, P	US 5,843,103 A (WULFMAN) 01 December 1998, entire patent.	1-22
Y, E	US 5,972,019 A (ENGLESON et al.) 26 October 1999, entire patent.	1-22

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"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
"A"	document defining the general state of the art which is not considered to be of particular relevance	"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
"E"	earlier document published on or after the international filing date	"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
"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)	"&"	document member of the same patent family
"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		

Date of the actual completion of the international search 01 DECEMBER 1999	Date of mailing of the international search report 22 DEC 1999
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer MANNY MENDEZ Telephone No. (703) 308-2221

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