

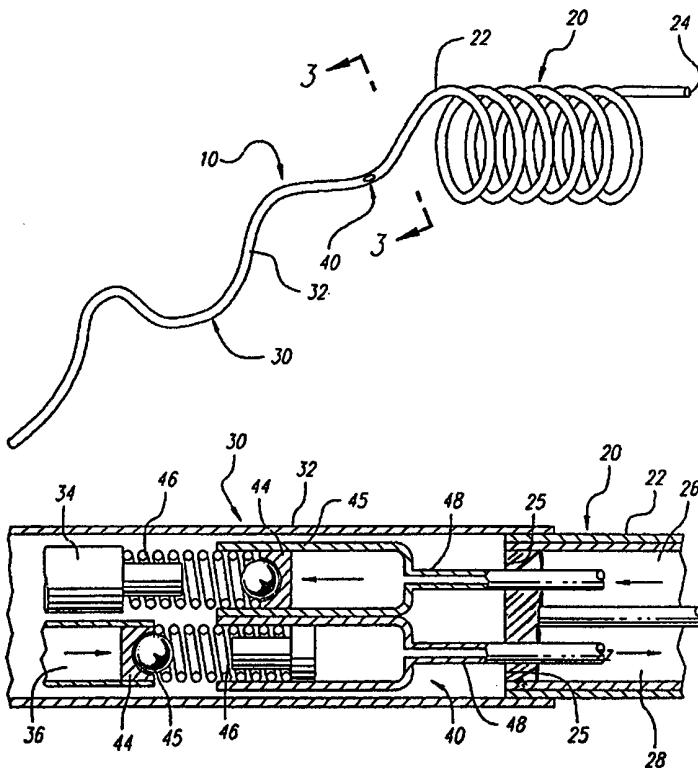
INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁷ : A61F 2/06	A1	(11) International Publication Number: WO 00/18327 (43) International Publication Date: 6 April 2000 (06.04.00)
(21) International Application Number: PCT/US99/22806		(81) Designated States: CA, JP, MX, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).
(22) International Filing Date: 30 September 1999 (30.09.99)		
(30) Priority Data: 60/105,768 30 September 1998 (30.09.98) US 09/321,496 27 May 1999 (27.05.99) US		Published <i>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.</i>
(71) Applicant: IMPRA, INC. [US/US]; 1625 West 3rd Street, P.O. Box 1740, Tempe, AZ 85280-1740 (US).		
(72) Inventors: EDWIN, Tarun; 1655 W. Tyson, Chandler, AZ 85224 (US). BANAS, Christopher; 102 Rock Squirrel, San Antonio, TX 78231 (US).		
(74) Agents: KIRCHANSKI, Stefan, J. et al.; Graham & James LLP, 14th Floor, 801 S. Figueroa Street, Los Angeles, CA 90017-5554 (US).		

(54) Title: FLUID CONTAINING ENDOLUMINAL STENT

(57) Abstract

An endoluminal stent contains a hollow passageway for the circulation of fluids to treat vascular walls affected with malignant growths or experiencing restenosis. The hollow passageway stent can have one or a plurality of passageways and is configured in a tubular shape with numerous coils, providing an empty tubular lumen through the center of the stent to allow blood flow. The stent is connected to a removable catheter that conducts fluid to the stent. Fluid flow may be regulated by valves incorporated in either the stent and/or the catheter. The stent and catheter are connected to avoid leakage of the fluid. Cryogenic, heated or radioactive fluids are circulated through the stent to treat the affected sites. A method of delivering drugs to the vascular wall is also provided by creating a stent with porous outer walls to allow diffusion of the drug.



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	ML	Mali	TR	Turkey
BG	Bulgaria	HU	Hungary	MN	Mongolia	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MR	Mauritania	UA	Ukraine
BR	Brazil	IL	Israel	MW	Malawi	UG	Uganda
BY	Belarus	IS	Iceland	MX	Mexico	US	United States of America
CA	Canada	IT	Italy	NE	Niger	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NL	Netherlands	VN	Viet Nam
CG	Congo	KE	Kenya	NO	Norway	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NZ	New Zealand	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	PL	Poland		
CM	Cameroon	KR	Republic of Korea	PT	Portugal		
CN	China	KZ	Kazakhstan	RO	Romania		
CU	Cuba	LC	Saint Lucia	RU	Russian Federation		
CZ	Czech Republic	LI	Liechtenstein	SD	Sudan		
DE	Germany	LK	Sri Lanka	SE	Sweden		
DK	Denmark	LR	Liberia	SG	Singapore		
EE	Estonia						

FLUID CONTAINING ENDOLUMINAL STENT

5

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates generally to endoluminal devices, and more particularly to stents.

10 2. Description of Related Art

Stents and similar endoluminal devices have been used to expand a constricted vessel to maintain an open passageway through the vessel in many medical situations, for example, following angioplasty of a coronary artery. In these situations, stents are useful to prevent restenosis of the 15 dilated vessel through proliferation of vascular tissues. Stents can also be used to reinforce collapsing structures in the respiratory system, the reproductive system, biliary ducts or any tubular body lumens. Whereas in vascular applications fatty deposits or "plaque" frequently cause the stenosis, in many other body lumens the narrowing or closing may be caused by 20 malignant tissue.

Fluids have traditionally been used to pressurize the angioplasty balloons used to open restricted vessels. The balloons may have a variety of shapes including a coiled form. In such a device fluid is injected into the balloon to inflate the device and maintain turgidity. Shturman (U.S. Patent 25 No. 5,181,911) discloses a perfusion balloon catheter wound into a helically coiled shape with one end attached to a fitting and the other to a syringe for inflating the balloon with fluid. When the balloon is inflated, its coiled form allows blood flow thorough the open center of the structure. At the same time it is possible to actually have fluid flow within the balloon structure so that the 30 syringe can deliver fluid into the balloon, fluid can flow through the balloon,

-2-

and fluid can then exit through a second lumen in a catheter attached to the syringe.

Coiled stents that are connected to a catheter apparatus, as in Wang et al. (U.S. Pat. No. 5,795,318), are used for temporary insertion into a patient. Wang et al. discloses a coiled stent of shape-memory thermoplastic tube that can be converted from a relatively narrow diameter to a larger coiled form by heating. The narrow diameter coil is mounted at the end of a catheter over a balloon and in a preferred embodiment a resistive heating element runs down the length of the thermoplastic element. An electric current is applied to heat the element thereby softening it while the balloon is expanded to enlarge the diameter of the coil. Upon cooling the enlarged coil hardens and the balloon is withdrawn. After the temporary stent has performed its duty, it is again heated and removed while in the softened state. In one embodiment the thermoplastic tube is supplied with an additional lumen so that liquid drugs can flow into the stent and delivered through apertures or semipermeable regions.

The attempt to kill or prevent proliferation cells is a common theme in clinical practice. This is generally true in vascular and non-vascular lumens. It is known that ionizing radiation can prevent restenosis and malignant growth. Although the effect of temperature extremes, e.g., cryogenic (cold) or hot temperatures, on cellular activity is not as well researched, it may provide a safer approach to control of tissue proliferation. Among the drawbacks of the prior art coiled balloons is that the balloon material is relatively weak so that expansion and contraction cause the balloon to fail. Failure of a balloon containing radioactive or cryogenic fluids could be catastrophic. It would be desirable to provide a catheter based, minimally invasive device for stenting support that could deliver hot or cryogenic or radioactive fluids or drugs and that would be sturdy and could remain in the body for extended periods of time, detached from the insertion device.

-3-

SUMMARY OF THE INVENTION

In its simplest embodiment the present invention is an endoluminal coil stent comprising a hollow tube formed into a series of loops or other known stent shapes which initially has a low profile and diameter. This 5 structure can be delivered into a patient's vascular system and expanded to full size. The present invention provides a stent that is hollow allowing the passage of fluid. The stent has either one or a plurality of passageways for fluid flow. The stent is attached to a catheter via a special fitting so that when engaged with the catheter, fluid flows freely from the catheter to the stent 10 with a possible return circuit through the catheter. When disengaged, the fitting prevents leakage from the stent permitting the stent to remain in place in a patient's vasculature.

This invention provides a way of treating vascular areas affected with malignant growths or experiencing restenosis from smooth muscle cell 15 proliferation, etc. The stent is inserted in a small diameter configuration and after being enlarged to a larger diameter, acts as a support device for the areas of restenosis or malignant growth. In addition, the stent can treat these affected areas in a unique way by flowing radioactive, heated or cryogenic fluids through the stent.

20 The present invention also provides a way of delivering drugs to an affected site. A stent to accomplish this purpose can be composed of several different materials. For example, the stent can be formed from a metal or other material with small pores machined or otherwise formed (e.g., with a laser). When such a stent is filled with a drug, that drug slowly disperses through the 25 pores. Alternatively, an entire metal tube or portions of the tube could be formed e.g., from sintered metal powder thereby forming a porous structure for drug delivery. Another embodiment would alternate a metal tube (for structural stability) with dispensing segments inserted at various intervals. The segments would be perforated to allow seepage of the drug or would be

-4-

otherwise formed from a porous material. Another embodiment employs an expanded polytetrafluoroethylene (PTFE) tube around a support wire or metal tube in the form of a coiled stent so that a hollow passageway is created between the metal and the PTFE. A drug is flowed into this space

5 and slowly dispensed through the porous PTFE.

One embodiment of the hollow stent of the present invention comprises a shape memory metal such as nitinol. Shape memory metals are a group of metallic compositions that have the ability to return to a defined shape or size when subjected to certain thermal or stress conditions.

10 Shape memory metals are generally capable of being deformed at a relatively low temperature and, upon exposure to a relatively higher temperature, return to the defined shape or size they held prior to the deformation. This enables the stent to be inserted into the body in a deformed, smaller state so that it assumes its "remembered" larger shape

15 once it is exposed to a higher temperature (i.e. body temperature or heated fluid) *in vivo*.

Special fittings are incorporated at the ends of the hollow stent. These fittings facilitate the injection and removal of fluid and also allow the stent to be detached from the insertion device to be left in place in a patient. The

20 hollow stent has an inlet and an outlet so that a complete fluid path can be created, and fluid can be continually circulated through the stent. In the simplest configuration the inlet and outlet are at opposite ends of the stent. However, if the stent is equipped with a plurality of lumens, two lumens can be connected at a distal end of the structure so that the outlet and inlet are

25 both together at one end. Other arrangements can be readily envisioned by one of ordinary skill in the art.

The stent is inserted into the body while connected to a catheter in a small, deformed state. Once inside the patient's body the stent is advanced to a desired position and expanded to its larger full size. If the stent is

-5-

composed of shape memory metal, for example, the stent expands from its small-deformed state to its remembered larger state due to the higher body temperature or due to the passage of "hot" fluid through the stent. Subsequently "treatment" fluid (e.g., heated, cryogenic or radioactive) is

5 pumped through the catheter to the stent where it is circulated throughout the stent, treating the adjacent vascular walls. The catheter can either be left in place for a certain period of time or removed, leaving the fluid inside the stent. This would particularly be the case with radioactive fluid or with a porous drug delivery stent.

10 The stent can be removed by reattaching the catheter allowing one to chill and shrink the stent (in the case of a memory alloy). Alternatively, the device can readily be used in its tethered form to remove memory alloy stents of the present invention or of prior art design. For this purpose a device of the present invention is inserted into the vasculature to rest within 15 the stent to be removed. Warm fluid is then circulated causing the stent to expand into contact with the memory alloy stent that is already in position. At this point cryogenic (e.g., low temperature) fluid is circulated causing the attached stent and the contacted stent to shrink so that the combination can be readily withdrawn.

20

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of a hollow coiled stent.

FIG. 2 is a perspective view of a valve assembly to be used with FIG. 1.

25 FIG. 3 is a sectional view of the hollow stent tube of FIG. 2.

FIG. 4 is a representation of the stent of FIG. 1 in the position for treatment.

FIG. 5 is a sectional view of a second embodiment of a hollow coiled stent.

-6-

FIG. 6 is a perspective view of a second embodiment of a hollow coiled stent.

FIG. 7 is a perspective view of a third embodiment of a hollow coiled stent.

5 FIG. 8 is a perspective view of a valve assembly to be used with FIG. 6.

FIG. 9 is a perspective view of a fourth embodiment of a hollow coiled stent.

FIG. 10 is a sectional view of the hollow stent tube of FIG. 8.

10 FIG. 11 (11a, 11b, and 11c) is an illustration of the method detailed in FIG. 12.

FIG. 12 is a flow diagram explaining use a stent of the present invention to retrieve a shape memory stent already in place.

15 DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring now to the drawings, in which like reference numbers represent similar or identical structures throughout the drawings, FIG. 1 depicts a preferred embodiment of this invention. Pictured in FIG. 1 is a medical apparatus 10 comprising an endoluminal stent 20 attached to a delivery catheter 30 by means of a valve assembly 40. In this representation endoluminal stent 20 is generally coiled in shape leaving a tubular space down the center of its length. Obviously, the principle of a hollow stent can be applied to stents of a zigzag or other construction other than simply coiled. The tubing 22 of the stent 20 is preferably composed of a metal material that can be crimped onto a balloon catheter (not shown) for insertion into a body. Once positioned inside of the body at the desired location, the balloon can be inflated, bringing the stent from a compact small size to its enlarged full size thus opening a pathway for blood flow.

Inside the tubing 22 of stent 20, two fluid pathways exist. These

-7-

pathways can be seen in the cross sectional view of FIG. 3. Pathways 26 and 28 have opposite flowing fluid streams and connect at the distal end 24 of stent 20. By allowing for opposite streams, radioactive, heated or cryogenic liquids can continuously flow through stent 20 for the purpose of
5 killing or preventing proliferation of cells. By "heated" or "hot" is meant temperatures above body temperature. By "cryogenic" or "cold" is meant temperatures below body temperature. The stent 20 can either remain connected to a delivery catheter 30 for temporary insertion, or be detached for a more permanent insertion. In either case, fluid flow can be circulated
10 throughout stent 20 prior to disconnection. In the simplest design, fluid passageways connected to the stent 20 are lumens of the delivery catheter so that when the catheter is withdrawn, fluid flow must cease. It is also possible to provide separate flexible tubes that are threaded through the catheter so that the delivery catheter can be withdrawn leaving the relatively
15 smaller fluid delivery tubes (not shown) behind. Preventing leakage of the fluid from the stent 20 after the catheter 30 is disconnected is accomplished through a valve mechanism contained in the catheter 30, or the stent 20 and/or both. In the example illustrated in FIG. 2 rubber or elastomer diaphragms 25 are penetrated by small hollow needles 48 in the valve
20 assembly 40. In addition, the valve 40 may comprise a simple back flow preventer. Thus, when pressure is applied from incoming fluid to the valve assembly 40, a ball 45 which sits in a ball seat 44 is forced back against a spring 46 and the valve 40 opens for the incoming fluid pathway 28. A similar arrangement allows pressure to open the outgoing fluid pathway 26. A check
25 ball valve is shown only as an example. Flap valves or any of a number of other back flow valve designs well known in the art can be employed. Complex systems in which a bayonet-type attachment automatically opens a valve are also possible.

The catheter 30 comprises a catheter shaft 32, which further contains

-8-

two fluid pathways 34 and 36 as seen in FIG. 2. At the distal end of catheter 30, the valve assembly 40 has small hollow needles 48 that are designed to puncture elastomer diaphragms 25. The catheter 30 is slightly larger in diameter than the stent member 20 so that the catheter tubing wall 32 forms

5 a friction fit over the stent wall 22. This creates a seal between the catheter 30 and the stent 20 for fluid delivery and removal. Upon detaching the catheter 30 leakage from the stent 20 is prevented due to the self-healing properties of the diaphragms 25. Obviously, the back flow preventer 40 could be on the stent 20 and the diaphragms be on the catheter 30.

10 As discussed above, stent 20 is inserted into the body to the desired site through the use of a catheter insertion device well known in the art. FIG. 4 depicts stent 20 in its enlarged form after it has been inserted into the body at the affected location and expanded. Other means of stent expansion other than a balloon catheter are possible. If the stent 20 is formed from shape

15 memory metal, such as nitinol, the heat of the body can cause the stent 20 to assume a larger, remembered form. Alternatively, heated fluid can be circulated through the stent to cause it to recover its remembered form. A self-expanding stent made of a spring-type alloy can also be employed. In that case the delivery catheter would be equipped with means (e.g., an outer

20 sheath) to keep the stent compressed until it was at the desired location.

By increasing the diameter of stent 20 at an affected location, the passageway is enlarged to permit increased blood flow. At the same time, fluids can also pass through the interior of tubes 22 the hollow stent 20 to treat the vascular wall. The walls of the vasculature can be treated by

25 running either a radioactive fluid through the stent 20 or a heated or a cryogenic liquid or a drug with a stent equipped for drug diffusion (e.g., through holes or a porous region).

FIG. 5 depicts a second embodiment of the invention. In this embodiment, the hollow stent 60 has only one fluid pathway 66, an inlet

-9-

without an outlet, and is used to deliver drugs to affected areas. Once the stent 60 is inserted into place and is in its enlarged configuration, drugs are delivered through the catheter to the stent 60. Stent 60 can be constructed in various ways to facilitate the delivery of drugs. In one case, as shown in FIG. 5 6, the stent 60 is constructed with regions or segments that have pores 64 to allow drug seepage from the tubing 62. Alternatively, continuously porous metal, porous plastic, or a combination of metal and plastic can be used. The perforations 64 or slits in the stent to facilitate drug delivery must be of sufficiently small size to allow the passage of the drug through the entire 10 length of the stent so that all areas can be treated. It will be apparent that pore size can control the rate at which the drug is dispensed. It is possible to cover the pores 64 with semipermeable membrane to further control and restrict drug outflow. A semipermeable membrane with inclusion of an 15 osmotic agent with the drug will result in water uptake and more rapid and controlled pressurized delivery of the drug.

A third embodiment of the invention, FIG. 7, has a hollow stent 70 containing a single fluid pathway. The tubing 72 can be made of any of the materials discussed above, but in this embodiment, the stent 70 has an inlet path 78 that carries the fluid to the distal end 74 of stent 70 where it then 20 runs through the coils. In this embodiment, a valve 80 connects the stent 70 to catheter 30. FIG. 8 shows a cross-sectional view of valve 80. The pressure from the liquid sent through the catheter causes the gate 82 of valve 80 to open to allow the fluid into the inlet path 78. The pressure that forces the opening of gate 82 causes the simultaneous opening of gate 84, allowing the 25 fluid that is circulated through the stent 70 to exit through pathway 36 of catheter 30. The fluid entering and exiting through catheter 30 must also go through a check ball valve assembly similar to the one shown in FIG. 2. Again, flaps or other "one way" valve mechanisms can be applied. After all incoming fluid has been delivered to the stent 70, the absence of pressure

-10-

causes gate 82 and gate 84 to close, thereby closing valve 80. This design can be used with any of the fluids mentioned above. The stent 70 can be used to circulate radioactive or cryogenic fluids for treatment of the vascular walls and can also be perforated for the delivery of drugs.

5 In a fourth embodiment, a hollow coiled stent 90 is formed from polytetrafluoroethylene (PTFE) 92. In FIG. 9, a perspective view of this embodiment can be seen. The stent 90 consists of a support wire 94 over which PTFE 92 is fitted. The pliable structure resulting is then formed into a coiled stent. The PTFE 92 is fitted around the wire 94 so that there is
10 sufficient room to allow the passage of fluid. FIG. 10 shows a cross-sectional view of stent 90, illustrating the pathway 96 created around the support wire 94 to allow the passage of fluid. In this embodiment, stretched expanded PTFE can be used to create a porous stent to facilitate the delivery of drugs. The wire 94 can also be hollow (passageway 95) so that the stent 90 can
15 simultaneously deliver drugs and radioactive fluid or temperature regulating fluid.

20 A fifth embodiment of the invention is depicted in FIG. 12 and a flow diagram shown in FIG. 12. This embodiment is a method for recapturing an existing shape memory metal stent already in the body. A shape memory metal stent A is inserted into the body in its small, deformed state through the use of an insertion device 112 well known in the art. The inserted stent A in its deformed state is placed into the center of a memory alloy stent B that is already in an enlarged support position in the body 114. The deformed stent A is then enlarged so that it comes in contact with stent B. This can be
25 accomplished in one of two ways. Either the stent A may enlarge due to the higher *in vivo* body temperature 115, or a hot liquid is pumped through stent A to cause it to expand 116. Once expanded and in contact with stent B, cryogenic liquid is pumped through stent A so that both stent A and stent B are chilled and either shrink down to their deformed states or become

-11-

sufficiently relaxed to allow ready removal 118. Once in a small, deformed or relaxed state, stents A and B are easily removed from the body 119 by withdrawing the catheter attached to stent A. FIG. 11a illustrates stent A in its reduced state being inserted into stent A. FIG. 11b shows an enlarged 5 version of stent A contacting stent B. Thereafter, a temperature change caused by fluid circulating through stent A will shrink both stents and enable their removal (FIG. 11c).

Having thus described a preferred embodiment of a hollow endoluminal stent, it should be apparent to those skilled in the art that certain 10 advantages of the within system have been achieved. It should also be appreciated that various modifications, adaptations, and alternative embodiments thereof may be made within the scope and spirit of the present invention. For example, a hollow stent with a coiled, tubular shape has been illustrated, however, many other possibilities exist for the shape and size of 15 the hollow stent. In addition, the passageways are illustrated as round but could take on a variety of other shapes. The described embodiments are to be considered illustrative rather than restrictive. The invention is further defined by the following claims.

-12-

CLAIMS

We Claim:

1. An endoluminal stent system comprising:
 - 5 a stent having a hollow passageway for containing a fluid; and a catheter wherein a proximal end remains outside of a body and a distal end is sealingly attached to the stent so that fluid can be delivered to the hollow passageway through the removable catheter.
 - 10 2. The endoluminal stent system as described in Claim 1 further comprising a connector for removable attachment of the catheter.
 3. The endoluminal stent system as described in Claim 2, wherein said connector further comprises valve means for controlling flow of fluid into or out of said endoluminal stent.
 - 15 4. The endoluminal stent system as described in Claim 1, wherein said catheter further comprises valve means for controlling flow of fluid.
 5. The endoluminal stent system as described in Claim 1, wherein said stent further comprises valve means for controlling flow of fluid.
 - 20 6. The endoluminal stent system as described in Claim 1, wherein said endoluminal stent further comprises at least one porous region through which liquid in the hollow passageway can diffuse.

-13-

7. The endoluminal stent system as described in Claim 1 further comprising a plurality of porous segments spaced apart from each other along a length of said stent.

8. The endoluminal stent system as described in Claim 1,
5 wherein said endoluminal stent is formed from metal.

9. The endoluminal stent device as described in Claim 8,
wherein said endoluminal stent has shape memory properties.

10. The endoluminal stent device as described in Claim 1,
wherein said endoluminal stent is formed from plastic.

11. The endoluminal stent device as described in Claim 1
further comprising a core and a plastic covering spaced apart from the core
so that liquid can flow therebetween.

12. The endoluminal stent device as described in Claim 11,
wherein said covering is expanded polytetrafluoroethylene.

15 13. The endoluminal stent device as described in Claim 11,
wherein said core contains a hollow passageway.

-14-

14. An endoluminal stent device comprising:

a stent having a hollow passageway for containing a fluid
wherein said endoluminal stent further comprises a
connector in communication with said hollow
passageway; and

5 a catheter wherein a proximal end of said catheter remains
outside of a body and a distal end of said catheter is
removably attached to the connector for delivering fluid
to the hollow passageway; and

10 valve means for controlling flow of fluid.

15. The endoluminal stent device as described in Claim 14,
wherein said valve means are contained within said stent.

16. The endoluminal stent device as described in Claim 14,
wherein said valve means are contained within said catheter.

15 17. The endoluminal stent device as described in Claim 14,
wherein said endoluminal stent further comprises at least one porous region
through which liquid in the passageway can diffuse.

18. The endoluminal stent device as described in Claim 14
further comprising a plurality porous segments spaced apart from each other
20 along a length of said stent.

19. The endoluminal stent device as described in Claim 14,
wherein said endoluminal stent is formed from metal.

-15-

20. The endoluminal stent device as described in Claim 19, wherein said endoluminal stent has shape memory properties.

21. The endoluminal stent device as described in Claim 14, wherein said endoluminal stent is formed from plastic.

5 22. The endoluminal stent device as described in Claim 14 further comprising a core and a plastic covering spaced apart from said core so that liquid can flow therebetween.

23. The endoluminal stent device as described in Claim 22, wherein said core contains a hollow passageway.

10 24. A method of recapturing a shape memory endoluminal stent comprising the steps of:

inserting a first stent attached to a catheter into an expanded shape memory alloy stent within a patient;

enlarging said first stent so that said enlarged first stent contacts said shape memory alloy stent;

15 cooling said first stent so the second stent reverts to a smaller or relaxed state enfolding said first stent; and withdrawing said catheter to remove said first stent and said shape memory alloy stent.

20 25. The method of Claim 24, wherein the first stent contains a hollow passageway and said cooling results from circulating cryogenic fluid through the hollow passageway.

-16-

26. An endoluminal stent comprising:
a stent core;
a hollow passageway through which fluid can flow; and
connector means for releasably establishing fluid
5 communication between a source and the hollow
passageway.

27. The endoluminal stent of Claim 26, wherein the hollow
passageway is within the stent core.

28. The endoluminal stent of Claim 26, wherein the hollow
10 passageway surrounds the stent core.

29. The endoluminal stent of Claim 26 further comprising
valv  means for controlling fluid flow within the hollow passageway.

-17-

30. A method of delivering drugs to a body lumen comprising:

providing an endoluminal stent having a hollow passageway for containing a fluid wherein said endoluminal stent further comprises at least one porous region in an outer surface of said stent; and

providing a removable catheter whose distal end is sealingly attachable to the stent so that fluid can be delivered to the hollow passageway through the catheter;

10 attaching said catheter to said endoluminal stent;

inserting said endoluminal stent and said catheter into a body, positioning said endoluminal stent at a desired location; and

15 delivering a drug through said catheter to the passageway within said endoluminal stent whereby the drug is released through the porous region.

31. The method of Claim 22, wherein valve means are provided for controlling flow of fluid.

-18-

32. A method of treating a vascular wall comprising:
providing a stent having a hollow passageway for containing a
fluid; and
providing a detachable catheter wherein a proximal end
5 remains outside of a body and a distal end is sealingly
attached to the stent so that fluid can be delivered to the
hollow passageway;
attaching said catheter to said endoluminal stent;
inserting said endoluminal stent and said catheter into a body,
10 positioning said endoluminal stent in a deformed state at
a desired location, wherein said endoluminal stent is
caused to expand to its full size; and
delivering a cryogenic, heated or radioactive fluid to said
endoluminal stent through said catheter.

1/5

FIG. 1

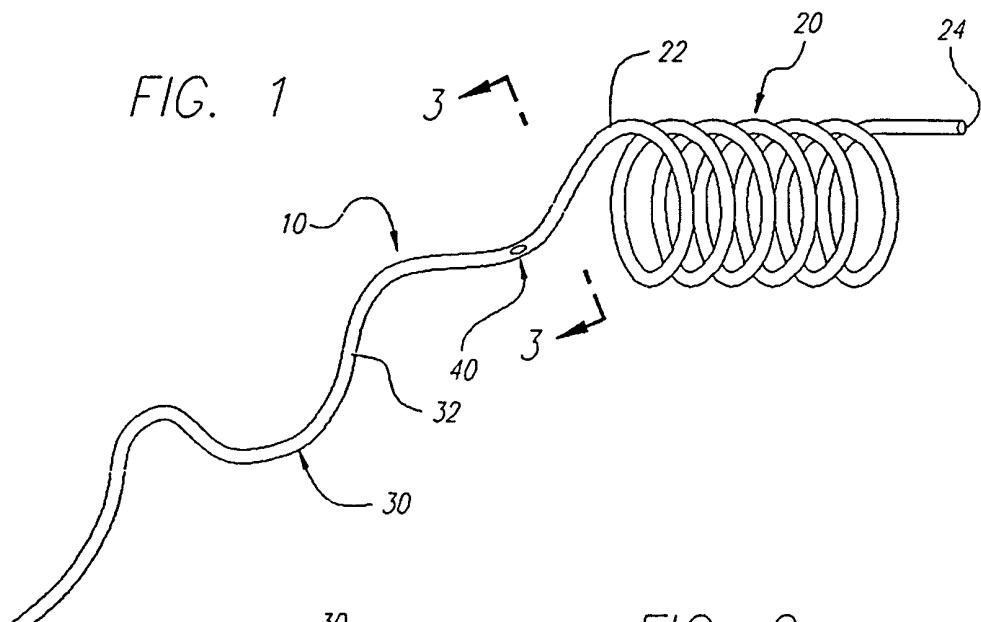


FIG. 2 20

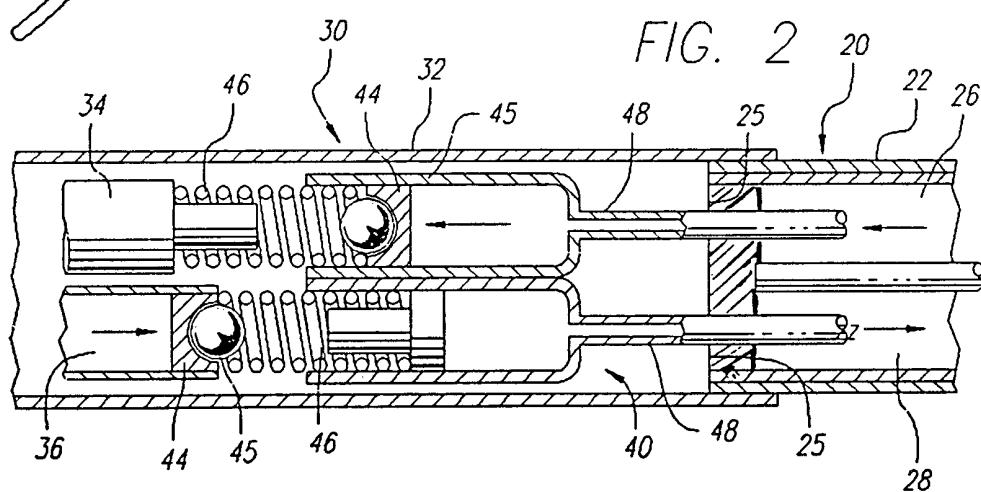


FIG. 3

2/5

FIG. 4

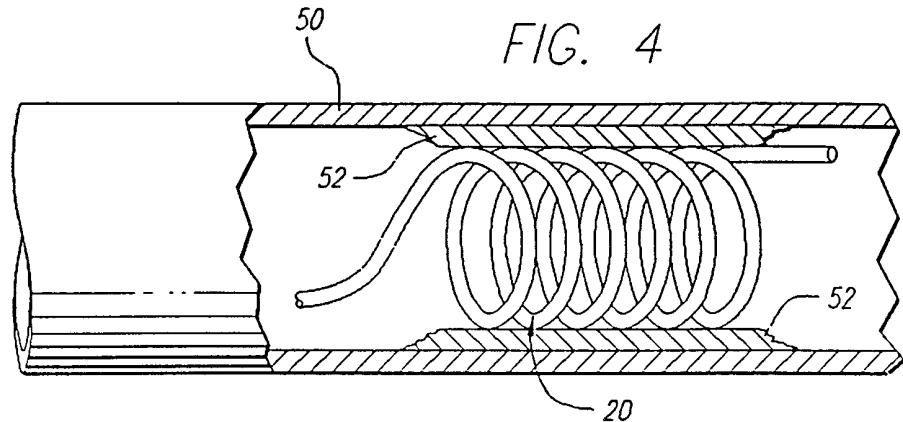
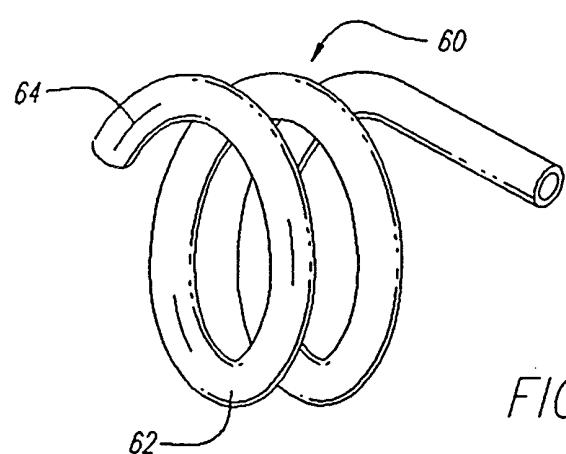
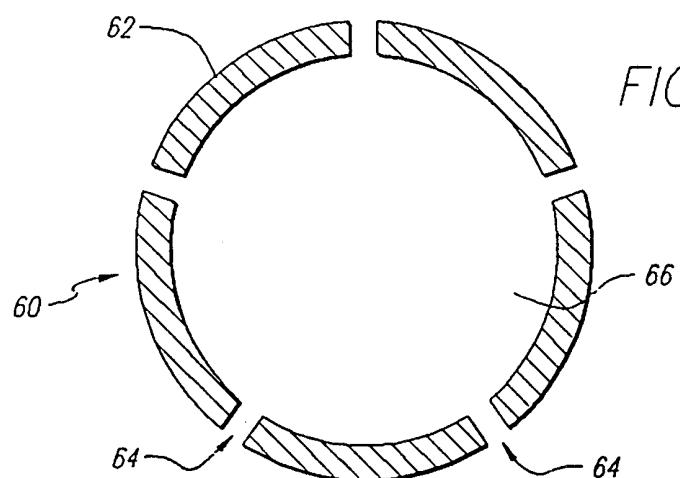


FIG. 5



3/5

FIG. 7

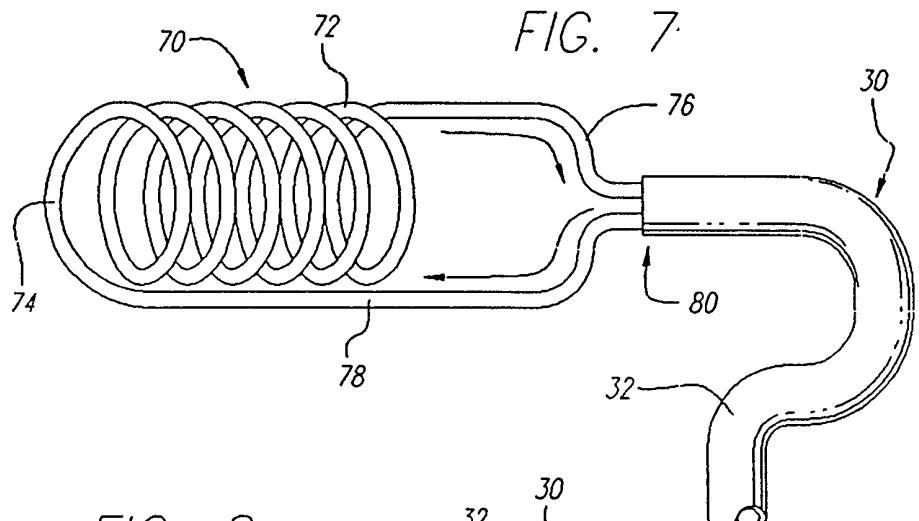


FIG. 8

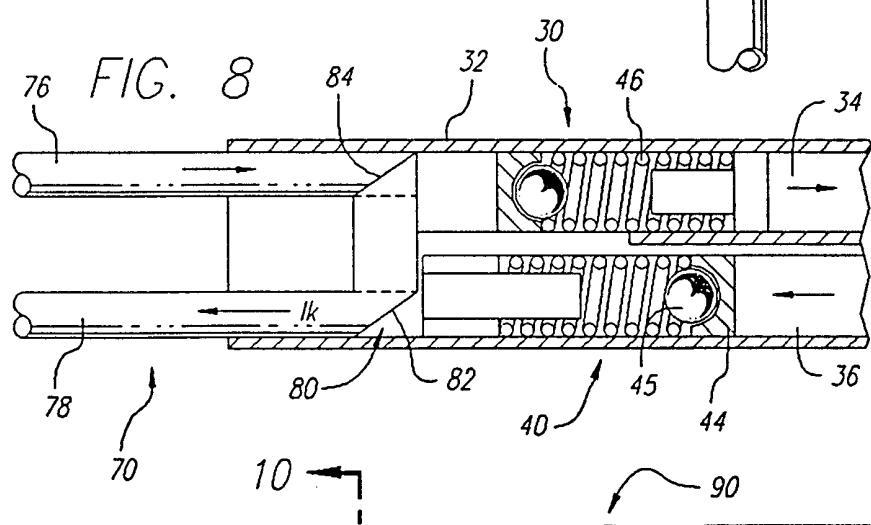


FIG. 9

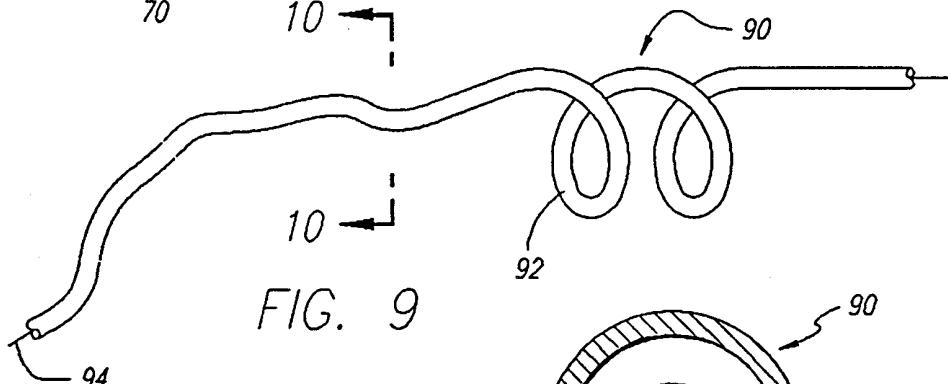
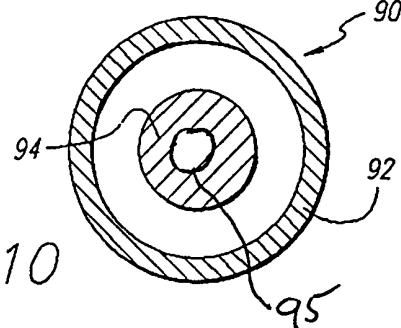


FIG. 10



4/5

FIG. 11a

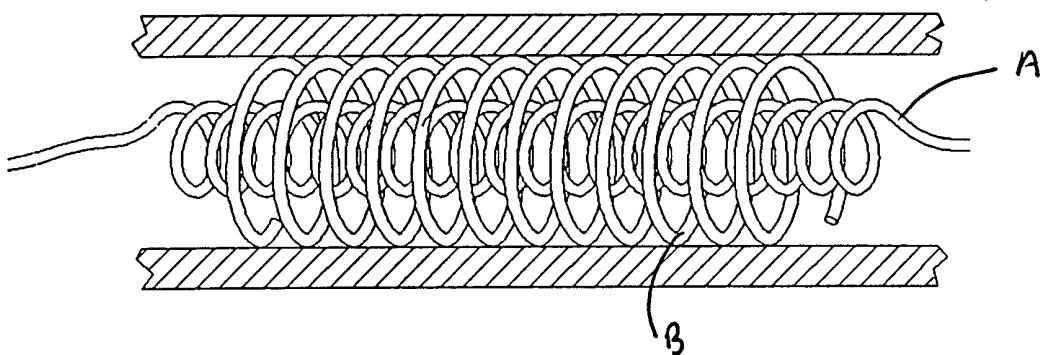


FIG. 11b

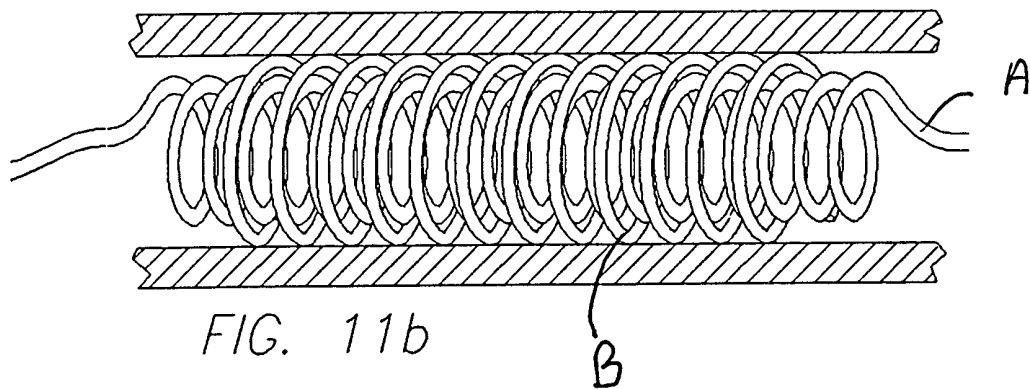
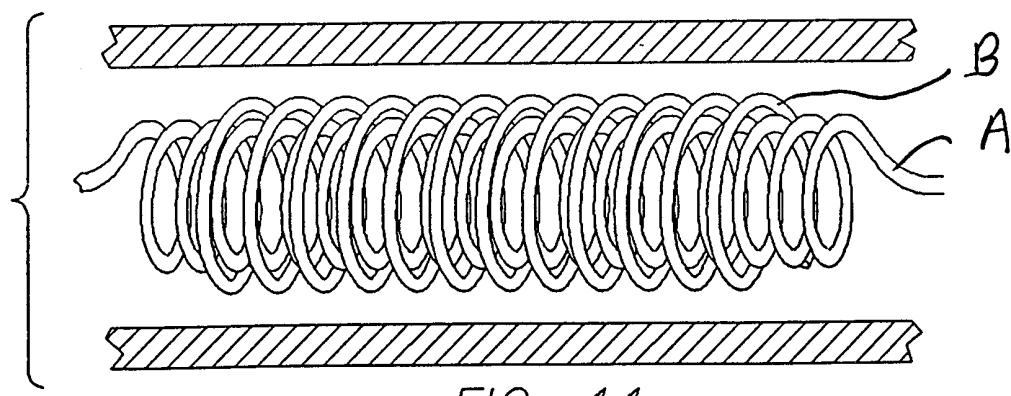
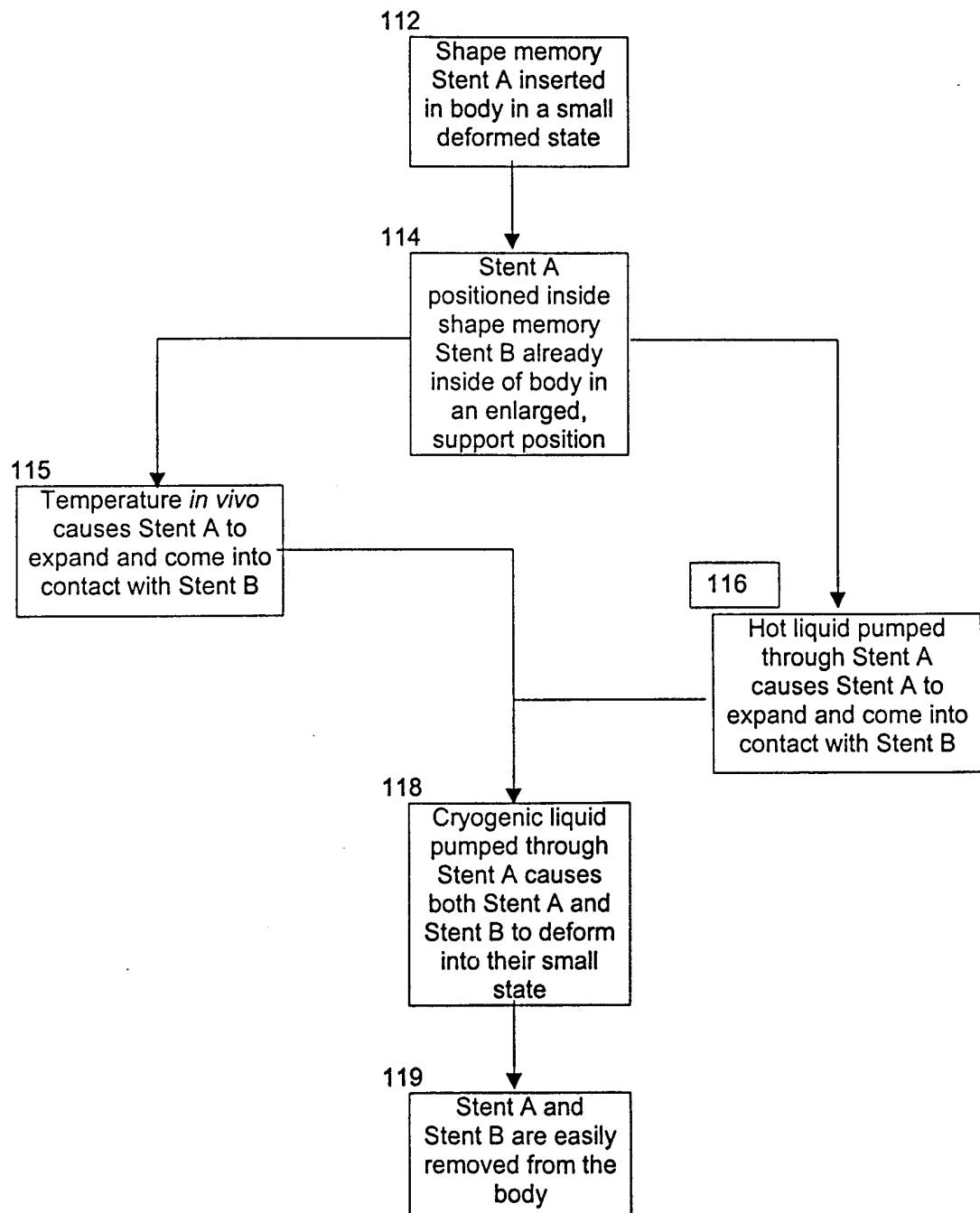


FIG. 11c



5/5

FIG. 12



INTERNATIONAL SEARCH REPORT

Int. Application No

PCT/US 99/22806

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/06

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 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)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 545 135 A (M. IACOB ET AL.) 13 August 1996 (1996-08-13)	1-7,11, 14-18, 21,26, 28,29
Y	column 4, line 10 -column 6, line 6; figures 1-1C	8,9,19, 20
A	---	10,22
Y	WO 96 26682 A (INSTENT, INC.) 6 September 1996 (1996-09-06)	8,9,19,
A	page 7, line 6 - line 16; figures	20 6,7
X	US 5 445 594 A (J.J. ELIST) 29 August 1995 (1995-08-29)	1-5,10, 11, 14-16, 21,22, 26,28,29
	the whole document	---
		-/-

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

17 January 2000

24/01/2000

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

Wolf, C

INTERNATIONAL SEARCH REPORT

Inte	rnal Application No
PCT/US 99/22806	

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 156 620 A (J.P. PIGOTT) 20 October 1992 (1992-10-20) column 4, line 4 -column 8, line 68; figures 1-5,16 ---	1-5, 10-12, 14-16, 21,22, 26,28,29
X	US 5 697 968 A (R.L. ROGERS) 16 December 1997 (1997-12-16) the whole document ---	1-5,10, 14-16,21
X	US 5 370 691 A (G. SAMSON) 6 December 1994 (1994-12-06) abstract; figure 1B ---	1-5,10, 14-16,21
A	WO 98 26731 A (atrium MEDICAL CORPORATION.) 20 October 1998 (1998-10-20) abstract column 4, line 40 -column 5, line 25 -----	6,7,10, 12,17,18

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 99/ 22806

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.: **24, 25, 30-32**
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT – Method for treatment of the human or animal body by surgery
2. Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

The additional search fees were accompanied by the applicant's protest.

No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

Int. Application No

PCT/US 99/22806

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
US 5545135	A	13-08-1996	NONE		
WO 9626682	A	06-09-1996	AU 5025096 A	18-09-1996	
			EP 0812165 A	17-12-1997	
US 5445594	A	29-08-1995	NONE		
US 5156620	A	20-10-1992	NONE		
US 5697968	A	16-12-1997	AU 6770396 A	05-03-1997	
			WO 9705833 A	20-02-1997	
US 5370691	A	06-12-1994	NONE		
WO 9826731	A	25-06-1998	US 5897587 A	27-04-1999	
			US 5824050 A	20-10-1998	
			AU 5898498 A	15-07-1998	