PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 :		(11) International Publication Number:
A61M 29/00	A1	WO 96/00596
		(43) International Publication Date: 11 January 1996 (11.01.96)

(21) International Application Number: PCT/US95/09153

(22) International Filing Date: 23 June 1995 (23.06.95)

(30) Priority Data:
08/268,999 30 June 1994 (30.06.94) US

(71) Applicant: BOSTON SCIENTIFIC CORPORATION [US/US]; One Boston Scientific Place, Natick, MA 01760 (US).

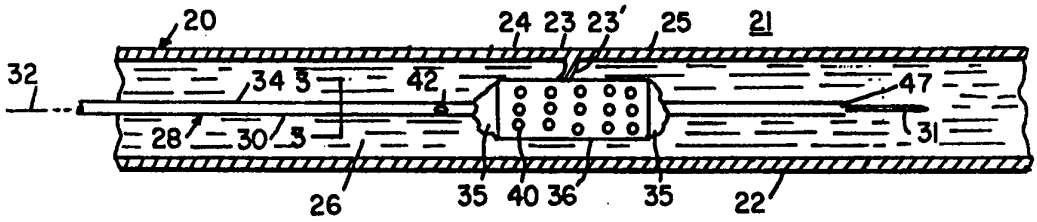
(72) Inventor: BARRY, James; 35 Jackson Circle, Marlboro, MA 01752 (US).

(74) Agent: HERBSTER, George, A.; Pearson & Pearson, 12 Hurd Street, Lowell, MA 01852 (US).

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

Published
With international search report.

(54) Title: STENT AND THERAPEUTIC DELIVERY SYSTEM



(57) Abstract

Apparatus and a method for treating an irregularity in a wall of a vessel (20) of a patient defined by an irregular or afflicted wall portion (23) with adjacent normal wall portions (24, 25) comprises a catheter (30) having a distal end portion (34) for being guided through the vessel to the site of the irregularity. A balloon (35) associated with said distal end portion of the catheter for selective inflating to contact the walls of the vessel urges a stent (36) carried by the distal end portion of the catheter in a constricted condition for passage through the vessel into an expanded form with the stent spanning the afflicted wall portion and contacting the adjacent wall portions. The catheter is formed with lumens (37, 38) for inflating the balloon, for receiving a guidewire (31) for guiding the catheter through the vessel, and for connecting a port (42) in the catheter proximate the afflicted wall portion to enable delivery of a therapeutic agent into the vessel to contact the stent and the irregular wall portion.

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.

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

Description

Stent and Therapeutic Delivery System

Technical Field

The present invention generally relates to percutaneous therapy and more particularly relates to a method and system for percutaneous transluminal delivery of a stent and therapeutic agent.

Background Art

Physicians often use medical guidewires and catheters in combination. Medical guidewires are devices navigatable through narrow passages in the body such as vessels, tubes, ducts, passages and the like, hereinafter collectively referred to as vessels. A physician controls the position and travel of a distal end of the guidewire by manipulating a steering mechanism at a proximal end outside the body. In other applications the physician guides the catheter through a laparoscope or endoscope. Medical catheters generally comprise hollow, flexible tubes that convey fluids, such as contrast, embolic, or pharmacological agents, to or from a vessel within a body.

Typically in transluminal procedures, a physician inserts and directs a medical guidewire through a vessel in a patient's body. The physician monitors the travel of the guidewire by a fluoroscope or other known device. Once positioned proximate the desired area, a steering mechanism is removed from the guidewire and a medical catheter is inserted into the vessel along the guidewire.

Oftentimes these catheters include specialized attachments for providing different treatment modalities. For example, the following references disclose catheters with attachments for administering a therapeutic agent and performing balloon therapy:

4,824,436 (1989) Wolinsky
4,832,688 (1989) Sagae et al.
5,254,089 (1993) Wang
08/105,737 (1993) Lennox et al.

United States Letters Patent No. 4,824,436 to Wolinsky discloses a multi-lumen catheter having opposed

ring balloons positionable on opposite sides of a plaque formation in a blood vessel. Inflation of the ring balloons define an isolated volume in the vessel about the plaque. Heparin is then injected into the volume between the ring to assist the body in repairing the plaque deposit. This patent also discloses a central balloon which can be employed to rupture the plaque prior to inflation of the ring balloon.

United States Letters Patent No. 4,832,688 to Sagae et al. discloses a multi-lumen catheter having an occlusion balloon positionable distally of a tear in a vessel wall. Inflating the balloon occludes the vessel and isolates at the tear. A therapeutic agent, such as heparin or thrombin, injected from the catheter into the volume reduces the risk of thrombosis or restenosis. The balloon is then deflated and moved adjacent the rupture and reinflated to repair the ruptured wall by coagulation of blood thereat.

United States Letters Patent No. 5,254,089 discloses a balloon catheter having an array of conduits disposed within the outer wall of the balloon. The conduits include apertures in the other wall for delivery of medications through the wall of the balloon into the body of a patient. This type of balloon is often referred to as a channeled balloon.

U.S. Application Serial No. 08/105,737 to Lennox et al., discloses catheters having spaced balloons for treating aneurysms. The inflated balloons define an isolated volume about the aneurysm. A port connects a vacuum source to evacuate the volume and draw the aneurysmal wall toward its ordinary position. Inflating a third balloon with a heated fluid to contact the aneurysmal wall effects the repair.

Therapeutic agent and balloon delivery systems must meet certain criteria. That is, the cross-sectional dimension of the catheter must be minimized to enable transit through the vessel while also having sufficient dimension to enable fluid flow to selectively inflate and

deflate the balloon, guidewires to pass therein, and therapeutic agents to flow therethrough for delivery along the catheter. Catheters must also have sufficient internal rigidity to prevent collapse of the lumens while having sufficient flexibility for passage along vessels.

The following references disclose stent delivery systems:

4,690,684 (1987) McGreevy et al.
4,922,905 (1990) Strecker
4,950,227 (1990) Savin et al.
5,059,211 (1991) Stack et al.
5,108,416 (1992) Ryan et al.
5,158,548 (1992) Lau et al.
5,234,457 (1993) Anderson
5,242,399 (1993) Lau et al.

Stent delivery systems, as disclosed by the Lau et al. and Ryan et al. patents, often include a catheter supporting a compacted stent for transport in a vessel and an expansible device for expanding the stent radially to implant the stent in the vessel wall. After removal of the catheter, the expanded stent keeps the vessels from closing.

The McGreevy et al. patent discloses a stent formed of biologically compatible material, such a frozen blood plasma or the like. According to McGreevy et al., a stent of this type carried by a catheter may be inserted into opposed ends of a ruptured vessel to support the separated vessel walls while the ends are bonded together. Once deployed, the heat from the bonding operation and the body eventually melt the stent and clear the vessel.

The Strecker, patent describes a stent and delivery system. The stent is knitted from metal or plastic filaments and has a tubular structure. The delivery system includes a balloon catheter and a coaxial sheath. The catheter supports and carries the compacted stent to a site within the body. The sheath covers the stent preventing premature deployment and facilitating transit of the stent through passages in the body. Exposure of

the stent by moving the sheath axially with respect to the catheter and expansion of a balloon urges the stent into contact with the walls of the vessel. Deflation of the balloon frees it from the stent and enables withdrawal from the vessel of the delivery system.

In the Savin et al. patent a stent delivery system includes a catheter having an expansible distal portion, a stent carried thereon in a contracted position for expansion thereby and sleeves that overlie the end portions of the stent. The sleeves protect the vessel and the stent during transit without substantially inhibiting deployment of the stent.

The Stack et al. patent discloses a stent delivery system comprising a catheter for delivering a compressed stent on a balloon or mechanical extension to the locus of a stenotic lesion. The balloon or mechanical extension proximate the distal end expands the stent and deflation of the balloon or retraction of the mechanical extension permits withdrawal of the distal end of the catheter through the stent. The stent comprises bioabsorbable porous material that reduces the likelihood of embolization and promotes tissue ingrowth in order to encapsulate the stent.

In accordance with the Anderson patent a stent delivery system includes a dissolvable material that impregnates a self-expanding stent in a compacted form. In one embodiment the removal of a sheath exposes the stent to body heat and liquids so that the material dissolves and the stent expands into a deployed position.

Stent delivery systems used in such procedures generally include catheters with selectively expansible devices to deliver and expand a contracted "stent" or restraints that can be removed to allow a self-expanding stent to assure an enlarged or expanded configuration. Stents are known and have a variety of forms and applications. For example, stents serve as prostheses and graft carriers in percutaneous angioplasty. Stents used as an endoprothesis and graft carriers to which the

present invention relates usually comprise radially expansible tubular structures for implant into the tissue surrounding "vessels" to maintain their patency. As is known, such stents are utilized in body canals, blood vessels, ducts and other body passages, and the term "vessel" is meant to include all such passages.

Like the previously described therapeutic agent and balloon therapy systems, stent delivery systems must conform to several important criteria. First, it is important to minimize the transverse dimension of the delivery system, so the stent must be capable of compaction against a delivery device, such as a catheter. Second, the delivery system must facilitate the deployment of the stent once located in a vessel. Third, the stent delivery system must easily disengage from the stent after the stent is deployed. Fourth, the procedure for removing the delivery system from the body must be straightforward. Fifth, the delivery system must operate reliably.

It has been found that the administration of therapeutic agents with a stent can reduce the risks of thrombosis or stenosis associated with stents. Stents administered along with seed cells, such as endothelial cells derived from adipose tissue, can accelerate the reformation of an afflicted area. Likewise, tears or other vessel damage associated with balloon angioplasty can be reduced by a deployed stent used in combination with a therapeutic agent.

When both therapeutic agent and stent therapies are required, a physician generally (1) steers a guidewire to the treatment locus, (2) guides a catheter over the guidewire, (3) operates the catheter to provide the first stage of treatment, (4) inserts an exchange guidewire to the guidewire, (5) withdraws the catheter, (6) guides a second catheter over the guidewire, and (7) operates the second catheter to provide the second stage of treatment. After this, the physician withdraws the guidewire, if not previously removed, and the catheter from the body of the patient.

Although percutaneous transluminal procedures have improved in recent years, it is still a fact that each insertion and extraction risks further damage to afflicted areas and damage to otherwise unaffected areas through which the instruments pass and can add to patient trauma. Moreover, insertion and withdrawal of additional instruments in sequence increases the time of the physician, staff, and medical facility, and the cost of multiple instruments. Thus, procedures and devices reducing the number of instruments necessarily inserted and withdrawn from a patient are generally preferred.

Thus, the above-described references generally disclose various forms of treatments or therapies using a balloon catheter in percutaneous transluminal procedures. Some combined with stent delivery systems, which may include a balloon for deploying the stent, while others combine balloon therapy and therapeutic agent delivery systems. However, none of these references disclose a delivery system having a sufficiently small cross section and flexibility for use within a patient's vessel while also providing sufficiently large cross section and strength to permit delivery of therapeutic agent and stent therapies. None provides a structure for improving the efficiency of percutaneous transluminal procedures by providing a combined stent and therapeutic agent delivery system. None disclose a delivery system and method capable of delivering a therapeutic agent upstream from a stent deployed by the system along an afflicted wall of an occluded vessel so that the agent contacts the stent and afflicted wall. Furthermore, none of these references disclose a system for delivery of encapsulated therapeutic agents which bond to the afflicted area and/or stent deployed by the system to provide continued therapeutic efficacy after withdrawal of the system.

Disclosure of Invention

Therefore, it is an object of this invention to provide a method and apparatus for percutaneous stent and therapeutic agent treatments at irregularities in a vessel of a patient including aneurysms, stenosis, ruptures, thrombosis, malignant and benign tumors and growths and other like vessel irregularities.

It is another object of this invention to provide a stent and therapeutic agent delivery system adapted for passage through the vessels of a patient while providing a sufficient platform for stent and therapeutic agent modality treatments.

Yet another object of this invention is to provide a method and apparatus which reduces the steps and time necessary to deliver a stent and therapeutic agent to an afflicted portion of a vessel in a patient.

It is a further object of this invention to provide a method and apparatus for delivering a stent and therapeutic agent to a vessel which is relatively simple and inexpensive to produce and use.

In accordance with one aspect of this invention an apparatus for treating an irregularity in a vessel wall includes a catheter for being guided through the vessel to the site of an irregularity with an expansible balloon at its distal end. The balloon inflates to contact the walls of the vessel and occlude the vessel. A port in the catheter delivers a therapeutic agent that then can contact the stent means in its expanded form.

According to another aspect of this invention, a method for treating an irregularity in a vessel wall includes the steps of positioning a distal end of a catheter proximate the irregularity, inflating a balloon operatively associated with the catheter to occlude the vessel and deploying a stent mounted on the balloon so as to span the irregularity. The treatment further includes introducing a therapeutic agent to contact the deployed stent and deflating the balloon reopens the vessel to

enable withdrawal of the catheter and balloon and the flow of liquid through the vessel.

A further aspect of this invention comprises a delivery system for delivering a stent and therapeutic agent to treat a vessel wall irregularity. The system includes a catheter guided through the vessel proximate the irregularity, a stent carried by the balloon for deployment in an expanded condition. The catheter includes an inflation lumen for enabling the balloon to expand and occlude the vessel. A delivery lumen exits the catheter at a delivery port position proximal the balloon for delivering a therapeutic agent to the occluded vessel in order to contact the stent.

Brief Description of Drawings

The appended claims particularly point out and distinctly claim the subject matter of this invention. The various objects, advantages and novel features of this invention will be more fully apparent from a reading of the following detailed description in conjunction with the accompanying drawings in which like reference numerals refer to like parts, and in which:

FIG. 1 depicts a single passage vessel with an irregularity comprising a tear in the wall of the vessel;

FIG. 2 depicts in side elevation an embodiment of a delivery system constructed in accordance with this invention for treating the irregularity in the vessel of FIG. 1 at a first stage in a treatment modality;

FIG. 3 is a view, partly in schematic and partly in perspective form, of portions of the delivery system taken along lines 3-3 in FIG. 2;

FIG. 4 depicts the delivery system of FIG. 2 at an intermediate stage of the treatment modality;

FIG. 5 depicts a repair vessel and the delivery system of FIG. 2 at final stage of the treatment modality prior to its removal from the vessel;

FIG. 6 depicts in side elevation another embodiment of a delivery system similar to FIG. 2 for treating an irregularity the vessel of FIG. 1;

FIG. 7 is a view, partly in schematic and partly in perspective form, of portions of the delivery system of FIG. 6 taken along lines 7-7 in FIG. 6;

FIG. 8 depicts in side elevation the embodiment of FIG. 6 at a first stage in a treatment modality;

FIG. 9 depicts in side elevation the embodiment of FIG. 6 at an intermediate stage in the treatment modality;

FIG. 10 depicts in side elevation the embodiment of FIG. 6 at a final stage of the treatment modality;

FIG. 11 depicts another embodiment of the delivery system of the present invention, similar to those of FIGS. 2 and 6, in the at a first stage in a treatment modality for treating an irregularity in the vessel of FIG. 1;

FIG. 12 is a view, partly in schematic and partly in perspective form, of portions of the delivery system of FIG. 11 taken along lines 12-12 in FIG. 11;

FIG. 13 depicts in side elevation the embodiment of FIG. 11 at a first stage in a treatment modality;

FIG. 14 depicts in side elevation the embodiment of FIG. 11 at an intermediate stage in the treatment modality;

FIG. 15 depicts in side elevation the embodiment of FIG. 11 at a final stage of the treatment modality; and

FIG. 16 depicts in side elevation an alternative balloon mounted on a catheter for use in the embodiments of the present invention.

Best Mode for Carrying Out the Invention

FIG. 1 depicts, in simplified form, a single-passage, tubular vessel 20 through tissue 21, such as peri-arterial tissue, defined by a vessel wall 22. Although FIG. 1, and the other similar figures, depict a vessel wall as comprising a single homogeneous layer, it will be recognized that an actual vessel wall has multiple layers. However, this invention can be understood by referring to the simplified, homogenous representation in the figures.

FIG. 1 illustrates an irregularity or abnormality in the wall of the vessel 20 at an afflicted or irregular wall portion 23 in the vessel wall 22 that is disposed

between essentially normal wall portions 24 and 25. In this case, the irregular wall portion 23 includes a flap 23' that can develop due to the weakening and/or stretching of the walls in otherwise normal wall 22. Such flaps frequently result either naturally or from, for example, stretching by dilation of the vessel during balloon angioplasty.

Blood 26 flows in a direction represented by arrow 27 within the vessel 20. If left untreated, the flap 23' can grow in size and occlude the vessel due to coagulation of blood thereat. Such flaps may also result in ruptures of the vessel. Other abnormalities in vessels of the type to which the present invention is applicable include aneurysms, ruptures, stenosis, and the like.

FIGS. 2 and 3 depict a delivery system 28 in accordance with this invention that includes a medical catheter 30 extending over a predisposed guidewire 31 generally along an axis 32. The catheter 30 includes a proximal end portion (not shown) and a distal end portion 34. The distal end portion supports an expansible balloon 35 with an expandable stent 36 carried in a constricted or compacted condition on the balloon. A plurality of lumens in the catheter 30 include a guidewire lumen 37 through which the guidewire 31 extends and an inflation lumen 38 connecting the balloon 35 with a inflation source 39 for selectively inflation and deflation.

The stent 36 depicted in FIGS. 2, 4 and 5 includes pores or apertures 40 for promoting tissue ingrowth as well as enabling flow to or from branches of the vessel connecting thereat. Those skilled in the art will recognize, however, such pores may in various procedures be unnecessary or, even, counterproductive. The stent 36 may also be formed of a bioabsorbable material, as well as, other known stent constructions (e.g., interlocking loops or mesh formed by filaments, etc.) and materials such as various plastic or metals, including tantalum, stainless steel or nitinol wire. Additionally, the stent

may also be formed as a graft-carrier, such as an aortic aneurysm graft, as is known in the art.

FIG. 4 depicts the apparatus 28 after the inflation source 39 expands the balloon 35 toward the wall 22 of the vessel 20. Expansion of the balloon urges the stent 36 into an expanded, deployed condition so that it spans the irregular wall portion 23 and contacts both the adjacent normal wall portions 24 and 25. Inflation of the balloon 35 in this case occludes the vessel 20 and defines a portion or volume 41 of the vessel that is proximal the balloon 35, the stent 36 and the irregular wall portion 23. Thus, in this embodiment the balloon is part of both balloon means associated with the catheter for selective inflating to contact the walls of the vessel and means associated with the catheter for enabling the deployment of the stent in its expanded form.

Referring again to FIGS. 2 and 3, the catheter 30 has a port 42 positioned proximally of the balloon 35. A therapeutic agent source 43 and the port are connected by lumen 44 to inject a therapeutic agent 45 into the volume 41. In this case, the port 42 and lumen 44 comprise means associated with the catheter for delivering a therapeutic agent proximal the inflated balloon and proximate the afflicted wall portions so that the agent contacts the stent in its expanded form.

The therapeutic agent 45 includes an active agent, such as a drug or endothelial cells. Examples of the drugs which would be appropriate active agents include antithrombins such as heparin and derivatives thereof; antiplatelet agents such as PPACK, iloprost, integrelin, and chimeric antibodies such as c7E3; genetic therapies including antisense oligonucleotides and various gene constructs; antipoliferatives such as angiopeptin; chemotherapeutic agents; antioxidants such as probucol; vasorelaxants such as nitroglycerin and papavarin or ones with multiple effects such as nitric oxide; and the like. The active agent would preferably have an affinity for the afflicted tissue, the stent 35, or both, or the active

agent could be encapsulated or attached to albumin, cells, fibrin and other matrix proteins, platelets, various natural and synthetic polymers, liposomes, red blood cells or the like having such an affinity if desired. In such case, the active agent, whether directly or due to its encapsulation, would attach on or near the irregular wall portion 23. Moreover, encapsulating the active agent in a dissolving material, such as albumin or various polymers which would effect a continuing release of the active agent proximate the irregular wall portion 23 during the patency of the encapsulating agent. Examples of such polymers would include pluronics gels, citric acid cycle polymers, such as polylactic acid, polyglycolic acid and derivatives thereof, polyanhydrides, polyphosphazenes, polysaccarides, such as alginic acid, chitin and derivatives thereof, collagen and derivatives thereof, and glycosaminoglycans such as hyaluronis acid and derivatives thereof.

Use of the present invention to treat irregularities in vessel walls generally comprises several stages of treatment. The steps usually include percutaneously inserting the guidewire 31 into a patient's vessel, guiding the guidewire to a position proximate the irregularity in the vessel 20, and inserting the guidewire lumen 37 of the catheter 30 over the guidewire 31 to enable the catheter to be directed to the irregularity, as represent in FIG. 2. Once the catheter 30 is positioned proximate the irregularity, the guidewire may be removed or otherwise remain.

Inflating the balloon 35 to contact the wall 22 substantially occludes the vessel 20 and inhibits blood flow therethrough, as depicted in FIG. 4. Inflation of the balloon 35 also urges the stent 36 from its compacted condition to its expanded, operative condition spanning the afflicted wall portion 23 and contacting the adjacent normal wall portions 24 and 25. In this case, the deployed stent 36 holds the flap 23' (see FIG. 2) proximate the wall of the vessel 20. With the vessel

occluded, as depicted in FIG. 4, therapeutic agent 45 from the source 43 (FIG. 3) enters the volume 41 proximally of the balloon 35 and the stent 36 at the port 42.

Deflation of the balloon 35, as depicted in FIG. 5, enables the therapeutic agent 45 to contact the stent 36 and afflicted wall portion 23 through the pores 40 and enables retraction of an extreme distal end 47 of the catheter through the stent and ultimately from the patient. After the deployment of the stent 36 and deflation of the balloon 35, the catheter 34 may be moved within the vessel to other sites for either or both therapeutic agent and balloon therapy. That is, thereafter the balloon 35 serves as a standard inflatable, catheter-mounted balloon with the port 42 also providing delivery of therapeutic agents as desired.

FIGS. 6 and 7 depict another embodiment of this invention as applied to the vessel 20 with an irregular wall portion 123 comprising an abnormal narrowing of the vessel or stenosis 123'. A delivery system 128 includes a catheter 130 having a distal portion 134. The catheter 130 carries the balloon 35 with the stent 36 for deployment within the vessel. The portion 134 also carries an inflatable balloon 137, which in this instance is positioned distally of the balloon 35, for occluding or substantially occluding the vessel. In some cases a second balloon 137' depicted in phantom lines may be positioned opposite the balloon 35 with respect to the first balloon 137 or even be used in place of the balloon 137.

Referring to FIGS. 6, 7 and 8, a second inflation source 138 inflates the balloon 137 into contact with the vessel wall 22 by urging inflating fluid along a lumen 139. The inflated balloon 137 defines a volume 141 in the vessel 20 proximally of the balloon 127 which includes the wall portion 123. Use of the balloon 137' would isolate the volume 141 about the wall portion 123 in which the stent 36 would be positioned. The therapeutic agent 45 enters the volume 141 through the port 42 proximally

adjacent the balloon 35. As previously discussed with respect to FIGS. 4 and 5, the therapeutic agent 45 preferably has an affinity for either or both the afflicted tissue and the stent 36.

Referring to FIGS. 8 and 9 inflation of the balloon 135 urges the stent 36 from its compacted condition. The deployed, expanded stent 36 spans the afflicted wall portion 123 and contacts the adjacent normal wall portions 24 and 25 to urge the stenotic portion 123' into a substantially normal position indicated as wall portion 123''. Introduction of the therapeutic agent 45 can occur prior to stent deployment, during stent deployment or after stent deployment, and the balloon 35 may be reinflated to aid disposition of the agent along the stent 36 and wall 123. Deflation of the balloons 137 and 35, as depicted in FIG. 10, enables retraction of the catheter 130 from the patient while the stent 36 remains at the repaired wall portion 123''.

This embodiment has been described in terms of a four-lumen catheter, although it will be appreciated that various modifications can be made. For example, the balloons 35 and 137 can be inflated from a common source through a common lumen when independent inflation is not needed. Those skilled in the art will recognize that this embodiment can also be employed as a common angioplastic catheter for treating, for example, stenotic irregularities by dilation of the vessel proximate the stenosis.

Specifically, the balloon 137 enables the dilation of vessels to dilate a stenotic vessel in a known manner, as well as other therapies involving either or both balloon and therapeutic agent therapies. However, in situations in which an irregularity of the type adapted for treatment by stent therapy, such as a flap, rupture or other irregularity results from the balloon therapy or is detected during such therapy, in which such irregularity is detected during the balloon therapy, the present invention enables stent and therapeutic agent therapy

without exchanging catheters or other delay. In such case, the catheter would be repositioned so as to enable the stent to be deployed at the irregular wall portion and the steps previously described would occur. Thus, this embodiment with a separate inflation balloon 137 permits a physician to provide balloon therapies, while also providing stent and therapeutic agent therapy as needed.

In FIGS. 11 and 12 the vessel 20 includes an aneurysmal wall portion 223 with a delivery system 228 for providing therapy for aneurysms positioned proximate thereto. The system 228 includes a catheter 230 having a deployment balloon 235 on which a stent 36 is carried for deployment.

As depicted in FIGS. 12 and 13, a vacuum source 231 connected through lumen 232 to port 233 evacuates the isolated volume 141 defined between inflated balloons 137 and 137'. Evacuation of the volume tends to draw the blood 26 from the volume 141 and the aneurysmal wall portion 223 toward the catheter 230 proximate the original position of the portion in line with the wall portions 24 and 25, as represented by the portion 223'. The therapeutic agent source injects the therapeutic agent 45 into the volume 141 usually after evacuation, although it may also follow stent deployment.

Referring to FIGS. 12 and 14, ionizable fluid 234 directed from the inflation source 39 along lumen 38 inflates the balloon 235 to contact the vessel wall 22 and deploy the stent 35 which may be a standard stent or graft carrying stent. Conductors 251 carried in the lumen 38 connect an rf heating source 252 with spaced electrodes 253 and 254 on the catheter 230 internally of the balloon. The heating source 252 energizes the electrodes 253 and 254 with the resulting current between the electrodes 253 and 254 heating the liquid 234 within the balloon 235, the stent 35 and the surrounding tissue including the weakened aneurysmal wall 223.

This heat thermally coagulates the weakened aneurysmal wall 223. Specifically, thermal coagulation

has the chronic effect of forming fibrous scar tissue in the weakened aneurysmal wall 223. This shrinks and thickens the aneurysmal wall 223 to reduce its compliance and arrest progression of the aneurysm formation which is further strengthened by the deployed stent 35. Preferable, a temperature sensor 255 connected through the conductors 251 to the rf heating source 252 provides a feedback control signal to accurately regulate the temperature of the liquid 48.

Upon completion of the treatment with the rf heating source 252 deenergized, the vacuum source 45 turned off, and the balloons 137 and 235 deflated, the delivery system 228 assumes the compact configuration depicted in FIG. 15. The blood 26 resumes flow in the direction 127 and the therapeutic agent 45 not adhering to the stent or wall 123' flows with the blood. Next a surgeon removes the apparatus 230 leaving the vessel 20 with a thickened and strengthened wall portion 223' with a stent 36 in place of the aneurysmal wall 223 of FIG. 13.

Stating that those skilled in the art will now appreciate that both with and without the rf heating the embodiment of FIGS. 11 through 15 enable a therapeutic agent to be administered and then be withdrawn using the vacuum source 45. For example, this can be particularly useful in cases where the therapeutic agent has particular toxic or other adverse effect on certain tissues of the body. Thus the physician can apply the drug to the affected area and then remove it to minimize any adverse impact from the therapeutic agent. In a case of an aortic aneurysm after evacuation, the physician can infuse a matrix protein or collagen to coat the graft for cell adherence in the wall of the graft. The vacuum is then used to suck out the free material. Thereafter, endothelial cells, which may be genetically altered are infused. These cells then bond to the protein matrix which preferably promotes cell growth and division of the infused endothelial cells.

The specific apparatus 228 in FIGS. 11 through 15 includes a catheter 230 with five discrete lumens. Certain functions of these lumens may be combined in a single lumen. For example, the vacuum source 231 and therapeutic agent source might connect directly to one lumen 44 by means of a valve 260. In addition, each of the individual components including the balloons 137 and the balloon 235 have conventional constructions. Apparatus for heating the liquid 234 in the balloon 235 through the use of rf energy applied to electrodes 253 and 254 and related systems including the temperature sensor 255 are also known in the art.

As depicted in FIG. 16, a balloon for deploying the stent need not fully occlude a vessel 20 and may be combined with the means for delivering the therapeutic agent. Here, a balloon 35' mounted on the catheter 30 in the vessel 20 comprises an inner impermeable layer or surface 300 and an apertured or otherwise porous layer or outer surface 310 (e.g., a channeled balloon). Lumens (not shown), such as lumen 38 and 44 of FIG. 3, have ports between the catheter 30 and the inner surface 300 and the surface 310, respectively. Through these lumens, the inflation fluid expands the surface 300 and the therapeutic agent 45 is delivered interiorly of the outer surface 310. As previously discussed, the stent 36 may be mounted on an expansible balloon, which in this instance is the balloon 35', for deployment.

Continuing to refer to FIG. 16, the inflation lumen delivers the inflation fluid interiorly of surface 300 to inflate the balloon toward the walls of a vessel in which the balloon is disposed and to expand a stent mounted thereon. The delivery lumen delivers the therapeutic agent intermediate the surfaces 300 and 310. Thus, the therapeutic agent 45 exits the balloon 35' through the apertures of the surface 310 to contact the stent 36 proximate thereto. It will be recognized that the apertured surface 310 comprises a port for the delivery of the therapeutic agent proximate the stent. Additionally,

the apertures in the surface 310 may be concentrated or entirely positioned in one area of the balloon 35'. Particularly, the apertures may be provided at the end of the balloon 35' closest the proximal end of the catheter.

Those skilled in the art will appreciate that, as discussed with respect to the embodiment of FIGS. 6 through 10, a second independent inflation balloon may be formed on the catheter 30 of FIG. 16 to provide a second means for dilating the vessel thereby. Additionally, the heating means of the embodiment of FIGS. 11 through 15 may also be included in either of such balloons, as appropriate for the application.

The means for expanding and deploying the stent the invention can include the stent itself. For example, certain stents react to heat or other conditions by expanding and deploying. Other stents expand and deploy upon release of a stent from removable sleeves. The apparatus shown in connection with the various figures is adapted for deploying such self-expanding stents. A removable sheath is disposed over the stent to protect the vessel and permit selective deployment of the stent. Employing such self-expanding stents eliminates the requirement for balloon expansion. However, the balloon still functions to occlude the vessel. Alternatively, as shown in FIGS. 11 through 15, the deployment balloon 35 of FIGS. 2 and 6, for example, can be provided with electrodes to heat a heat expansible stent to deploy the stent.

In summary, a delivery system according to each of the embodiments of this invention comprises a catheter having means for deploying an expandable stent and delivering a therapeutic agent for contacting the stent. Moreover, the operating techniques are analogous to standard medical procedures with respect to positioning the catheters in blood vessels, inflating the balloons, deploying the stents, and injecting therapeutic agents so the use of this apparatus is readily mastered. However, the apparatus eliminates the need for repetitive insertion

of apparatus for different treatment modalities and reduces the risk of additional trauma to the patient. The invention also improves the treatment of patients by allowing combined modalities of treatment relatively concurrently, as well as successively. The invention also increases the efficiency of doctors, staff, and medical facilities. Moreover, by using bioabsorbable stents no foreign objects, such as clips or tubes, permanently remain permanently in the patient after treatment. The invention also provides delivery systems sized for the treatment of irregularities in both large and relatively small vessels.

1. A catheter assembly for treating an irregularity in a vessel wall intermediate adjacent normal wall portions by dispensing a stent and administering a therapeutic agent, said catheter assembly comprising:

A. elongated flexible tube means including an inflation lumen and a delivery lumen and having distal and proximal end portions for delivering a stent positioned distally on said flexible tube means to the site of the irregularity in the vessel,

B. expansible balloon means positioned distally on said flexible tube means for being inflated and deflated through said inflation lumen, the inflation of said balloon means occluding the vessel, and

C. port means in said flexible tube means proximate the distal end thereof for delivering the therapeutic agent from said delivery lumen into the vessel so as to contact the stent and adjacent portions of the vessel.

2. An assembly as recited in claim 1 wherein said flexible tube means additionally includes a guidewire lumen intermediate the proximal and distal portions for receiving a guidewire.

3. An assembly as recited in claim 2 further comprising a second balloon means carried by said flexible tube means at a location that is spaced from said expansible balloon for inflation and deflation thereby to define an occluded volume between said expansible balloons.

4. An assembly as recited in claim 3 wherein said flexible tube includes a second inflation lumen for inflating and deflating said second balloon means independently.

5. An assembly as recited in claim 3 wherein said catheter includes a second inflation lumen for inflating and deflating said second balloon means independently whereby said catheter is adapted for

repositioning and whereby said second balloon means is adapted to dilate a second irregular portion of the vessel to provide balloon therapy thereat.

6. An assembly as recited in claim 3 wherein at least one of said first and second expansible balloon means comprises a balloon having an inner inflatable chamber and an outer chamber with an apertured, outer surface and said port means comprises said apertures in said outer surface of said balloon whereby a therapeutic agent dispenses through said apertures.

7. An assembly as recited in claim 2 wherein said expansible balloon means is a balloon having an inner inflatable chamber and an outer chamber with an apertured surface and said port means comprises said apertures in said outer chamber of said balloon.

8. An assembly as recited in claim 2 wherein said port means exits proximally of said balloon means and said balloon means is coextensive with the stent.

9. An assembly as recited in claim 2 wherein said balloon means carries the stent and constitutes a first balloon means wherein said assembly further comprises second and third balloon means positioned distally and proximally from said first balloon means, said elongated tube means including a second inflation lumen for the inflation and deflation of said second and third balloon means whereby said second and third balloon means upon inflation, contact the walls of the vessel define an isolated volume in the vessel in which said first balloon means is positioned.

10. An assembly as recited in claim 9 wherein said port exits said tube means proximally adjacent said first balloon means to enable delivery of the therapeutic agent proximally of the stent.

11. An assembly as recited in claim 9 wherein said first balloon means comprises an inner inflatable chamber and an outer chamber having an apertured surface and

said port means includes the apertures from said outer chamber.

12. An assembly as recited in claim 9 wherein said first balloon means includes spaced electrodes disposed interiorly of an exterior surface thereof for connection with an rf heating source and said first balloon means is inflated with an ionizable fluid directed through said inflation lumen whereby energization of said electrodes heats the fluid.

13. An assembly as recited in claim 2 wherein said balloon means includes spaced electrodes disposed interiorly thereof for connection with an rf heating source and said balloon means is inflated with an ionizable fluid directed through said inflation lumen whereby energization of said electrodes heats the fluid.

14. A method for treating an irregularity in a vessel wall adjacent normal wall portions by disposing a stent in contact with the vessel wall, said method comprising the steps of:

A. positioning a percutaneously administered distal end of a catheter proximate an irregular wall portion,

B. inflating a balloon at the distal end of the catheter through an inflation lumen to expand the balloon proximate the vessel walls to obstruct the flow of bodily fluid through the vessel and to deliver the stent in an expanded condition spanning the irregularity and contacting the adjacent normal wall portions,

C. introducing into the vessel through a second lumen in the catheter a therapeutic agent proximal the irregular wall portion and the stent thereby enabling the therapeutic agent to contact the stent, and

D. deflating the balloon to enable unobstructed flow of the bodily fluid through the vessel and

enable withdrawal of the distal end of the catheter through the deployed stent.

15. A method for treating an irregularity in the wall of a vessel as recited in claim 14 further comprising the step of defining an isolated volume in the vessel extending at least proximally the stent wherein said step of delivering the therapeutic agent delivers the therapeutic agent into the isolated volume.

16. A method for treating an irregularity in the wall of a vessel as recited in claim 14 further comprising the step of inflating a second balloon at the distal end of the catheter through a second inflation lumen in the catheter positioned proximate a stenotic portion of the vessel so as to dilate and open the vessel thereat wherein said steps of inflating the first balloon, deploying the stent and delivering the therapeutic agent treat occur after said step of inflating said second balloon.

17. A method for treating an irregularity in the wall of a vessel as recited in claim 14 further comprising inflating a second balloon spaced from said first balloon at the distal end of the catheter such that the isolated volume defined in the vessel by the first balloon extends between the first and second balloon and includes the irregular wall portion wherein said step of delivering the therapeutic agent delivery the therapeutic agent into the isolated volume.

18. A method for treating an irregularity in the wall of a vessel as recited in claim 17 further comprising the step of removing portions of the therapeutic agent delivery by said delivery step from the isolated volume.

19. A delivery system for delivering a stent and therapeutic agent to treat an irregularity in a vessel wall with adjacent normal wall portions, said system comprising:

A. a catheter for being guided to the site of an irregularity in a vessel, said catheter having a distal end and a proximal end, a guidewire lumen extending between said distal and proximal ends, an inflation lumen between said proximal end and a port position spaced from said distal end and a delivery lumen between said proximal end and a port position spaced proximally of said catheter distal end,

B. an expansible balloon formed on said catheter at the distal end thereof over said inflation lumen port position,

C. an expansible stent mounted on said balloon in a contracted condition for passage with said catheter and balloon to the site of the vessel irregularity whereby said stent can be expanded into the vessel wall at the vessel irregularity,

D. means for enabling the expansion of the balloon through said inflation lumen thereby to occlude the vessel, and

E. means for enabling the administration of the therapeutic agent through said delivery lumen, said balloon thereafter being deflated to permit removal of said catheter and balloon from the vessel.

20. A delivery system for delivering a stent and therapeutic agent as recited in 19 wherein said expansible stent is self-expanding and said catheter additionally comprises means for retaining said expansible stent in its contracted condition.

21. A delivery system for delivering a stent and therapeutic agent as recited in 19 wherein said expansible stent comprises a filamentary construction that locks said stent in an expanded condition such that inflation of said balloon urges said stent into its expanded locked condition.

22. A delivery system for delivering a stent and therapeutic agent as recited in claim 19 wherein said catheter includes a third lumen for receiving a guidewire steerable through the vessel.

23. A delivery system for delivering a stent and therapeutic agent as recited in claim 19 wherein said delivery lumen port position is located proximally of said balloon.

24. A delivery system for delivering a stent and therapeutic agent as recited in claim 19 wherein said balloon is comprised by a balloon having a first layer overlying said inflation lumen port position and a second outer apertured layer overlying said delivery lumen port position whereby the therapeutic agent is delivered through said outer apertured layer.

25. A delivery system for delivering a stent and therapeutic agent as recited in claim 19 additionally comprising a second expansible balloon mounted on said catheter and spaced from said first expansible balloon.

26. A delivery system for delivering a stent and therapeutic agent as recited in claim 25 wherein said catheter additionally comprises a fourth lumen extending between said catheter proximal end and said second balloon for expanding and contracting said second balloon independently of said first balloon.

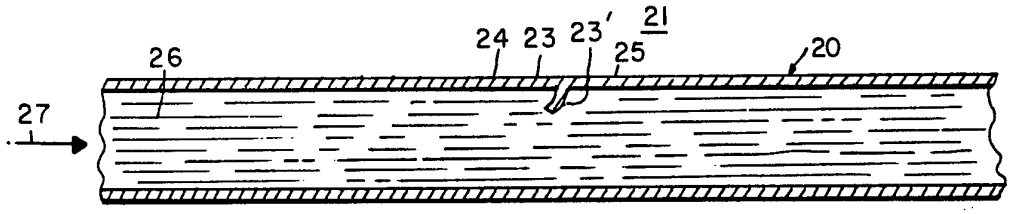


FIG.1

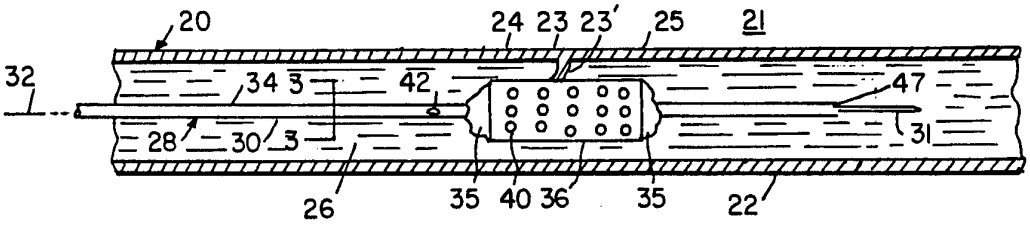


FIG.2

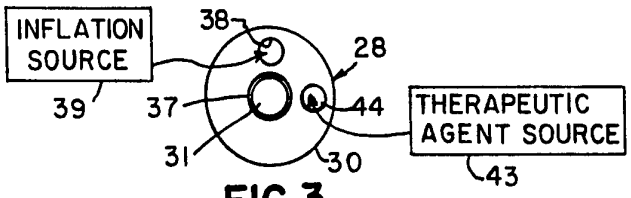


FIG.3

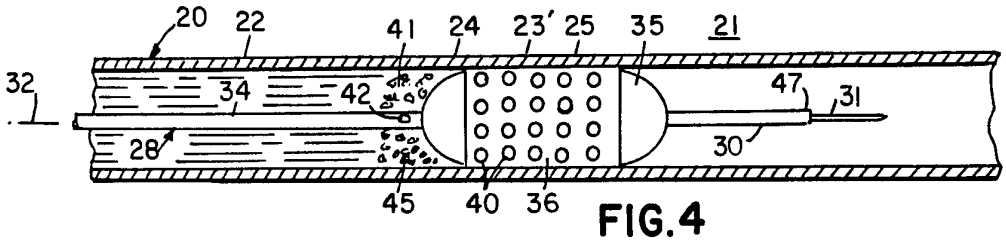


FIG.4

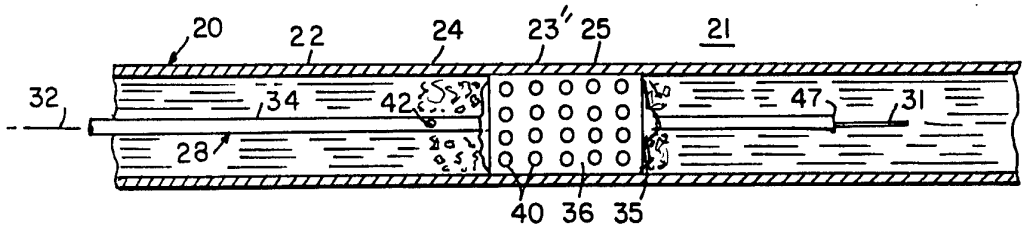


FIG.5

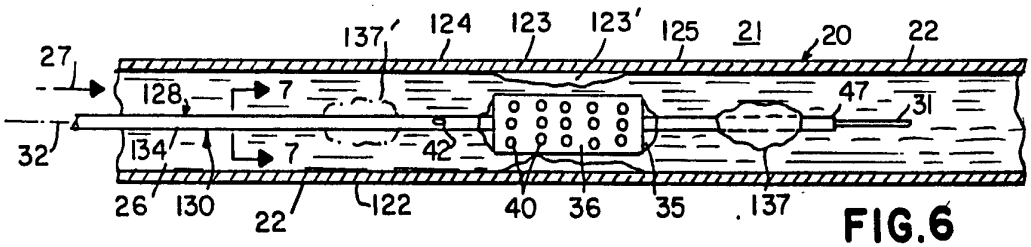


FIG.6

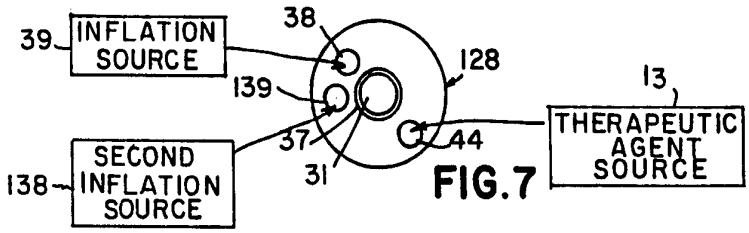


FIG.7

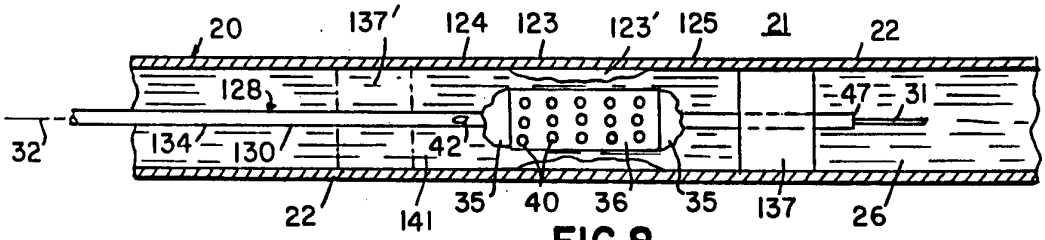


FIG.8

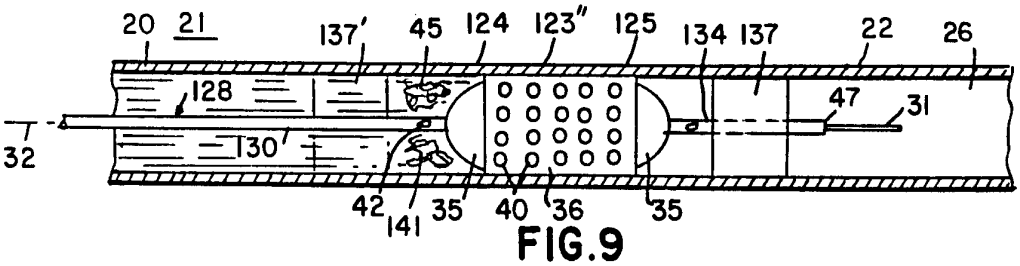


FIG.9

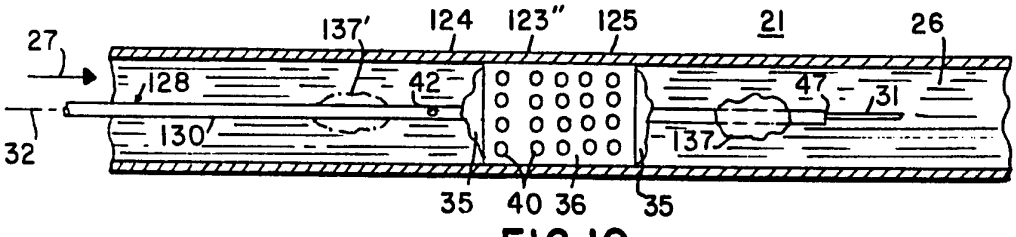


FIG.10

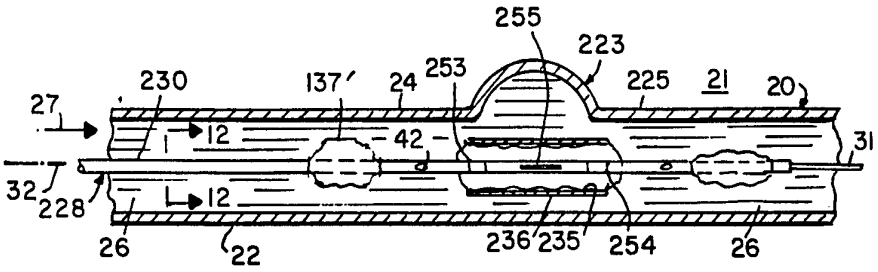


FIG.11

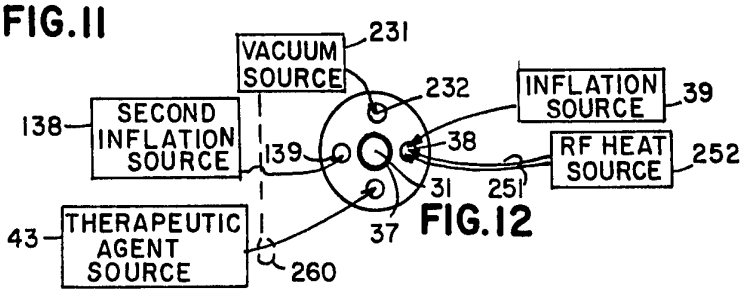


FIG.12

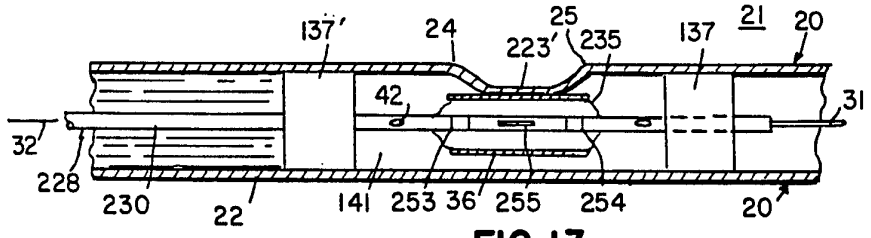


FIG.13

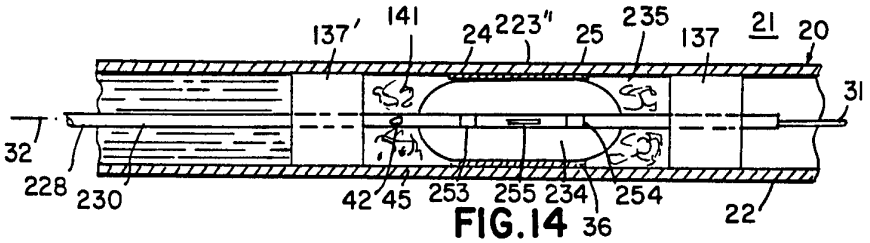


FIG.14

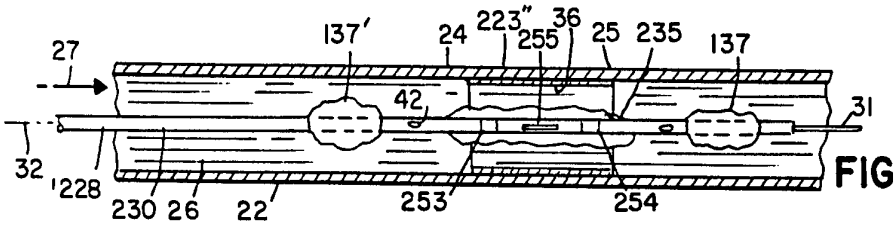


FIG.15

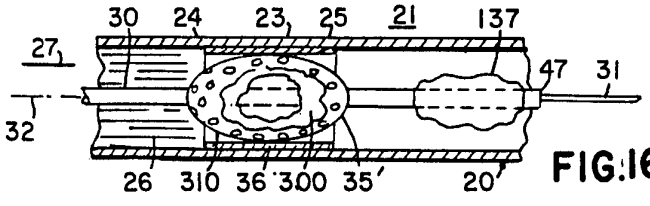


FIG.16

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US95/09153

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61M 29/00
US CL :604/96

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. : 604/52, 53, 101-104, 157-163; 606/192-194, 198

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US, A, 4,832,688 (SAGAE ET AL.) 23 May 1989, see entire document.	1-26
A	US, A, 4,824,436 (WOLINSKY) 25 April 1989, see entire document.	1-26
A	US, A, 4,950,227 (SAVIN ET AL.) 21 August 1990. see entire document.	1-26

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

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be part of particular relevance

"E" earlier document 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
23 AUGUST 1995	20SEP1995
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 JOHN YASKO, JR. Telephone No. (703) 308-2986

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