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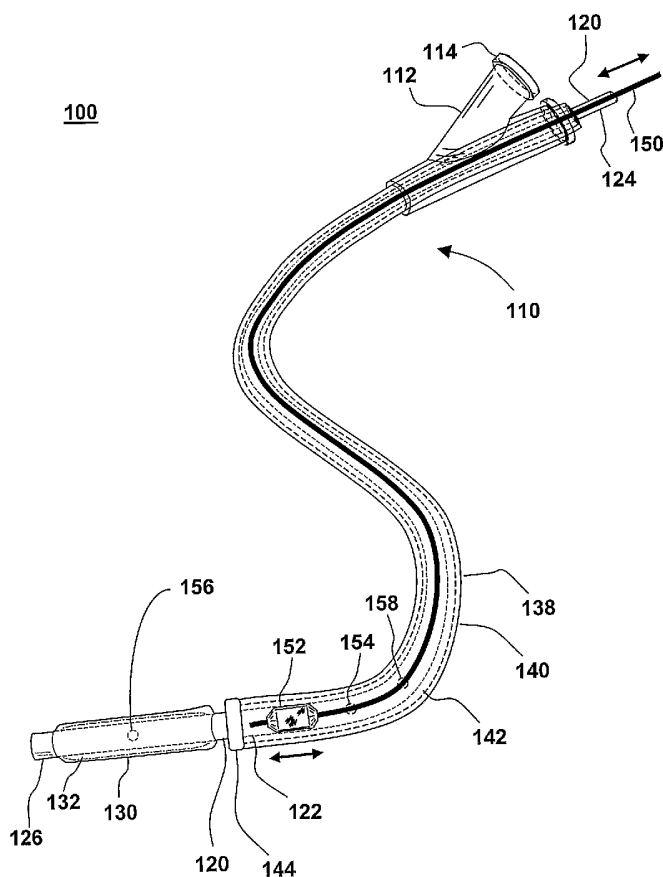
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(54) Title: OCCLUSION BALLOON CATHETER WITH DISTAL VALVE



(57) Abstract: The present invention provides a system for treating a blood vessel. The blood vessel treatment system includes a hollow guidewire having a central lumen, an occlusion balloon attached proximate to a distal end of the hollow guidewire, and an inflation catheter slidable over the hollow guidewire. An annular inflation lumen formed between the inflation catheter and the hollow guidewire fluidly communicates with the central lumen of the hollow guidewire, allowing inflation fluid to flow through the annular inflation lumen and into a distal portion of the central lumen to inflate the occlusion balloon.



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OCCLUSION BALLOON CATHETER WITH DISTAL VALVE

FIELD OF THE INVENTION

[0001] This invention relates generally to catheters and guidewire deployment of catheter-based treatment tools. More specifically, the invention relates to an occlusion catheter with a distal valve.

BACKGROUND OF THE INVENTION

[0002] Minimally invasive intravascular procedures are revolutionizing many surgical specialties including cardiac surgery, and are becoming common in the treatment of vascular disease. Today, balloon angioplasty is commonly used to alleviate stenotic lesions in blood vessels, thereby reducing the need for heart bypass operations. Medical balloon catheters also have been proven efficacious in treating a wide variety of blood vessel disorders such as intravascular restrictions due to atherosclerosis or restenosis.

[0003] Vascular stenoses, which may be partially or totally occluded, are often characterized by having a mineral component. A variety of different protocols have been developed for treating vascular diseases with these calcified areas. The treatment methodologies generally involve mechanically removing or reducing the size of the stenosis, mechanical debridement, atherectomy, balloon angioplasty, stenting, and bypass surgery procedures.

[0004] In exemplary intravascular procedures, a balloon catheter dilates an intravascular restriction, or an atherectomy catheter removes the restriction. Unfortunately, the intravascular procedures associated with these devices may result in embolic particles being dislodged while the restriction is dilated or cut. In addition, the dislodged embolic particles may move downstream from the area of restriction and cause another embolism to form, which, in turn, could compromise the flow of blood to the surrounding tissue.

[0005] In response to this problem of dislodged particles, occlusion balloon catheters and aspiration catheters have been developed to help prevent dislodged embolic particles from entering the blood stream. The occlusion balloon catheter blocks or impedes blood flow while the aspiration catheter aspirates and removes embolic particles from the area of the stenosis.

[0006] Occlusion balloon catheters are usually used in conjunction with other catheters, particularly an aspiration catheter. An occlusion catheter, which often includes an elongated shaft and a distally mounted occlusion or attenuation balloon, typically extends through a lumen of a primary dilation or atherectomy catheter. The balloon is advanced through a vessel, positioned distal to the site of the stenosis, and temporarily inflated to prevent embolic particles from flowing downstream as the occlusive restriction is being dilated or cut. After the restriction has been treated, the primary catheter can be removed from over the guidewire of the occlusion balloon catheter. An aspiration catheter can then be advanced proximal to the stenosis to reduce or eliminate the blockage by aspirating the treatment site. Once the embolic particles have been aspirated, the occlusion balloon is deflated and removed from a patient.

[0007] An exemplary occlusion catheter and associated occlusion and aspiration method uses a catheter and a guidewire having a hollow shaft and a flexible, shapeable guidewire distal tip. A deflated elastomeric occlusion balloon is located at the proximal end of the distal tip of the guidewire. The distal tip of the guidewire and the balloon crosses the lesion, an inflation device is attached to the proximal end of the catheter, and the occlusion balloon is inflated with dilute contrast agent. Following the inflation of the balloon, an angiogram using fluoroscopy may be taken to ensure complete occlusion by the balloon. The hollow guidewire can be used to infuse or deliver fluoroscopic material or therapeutic agents to the treatment site. The inflation device can be removed from the proximal end of the wire while the occlusion balloon remains inflated, and then a stent-delivery catheter may be exchanged to provide percutaneous transluminal angioplasty. With the occlusion balloon inflated, balloon angioplasty or stenting may be performed. The embolic particles that are released during a coronary angioplasty or stenting procedure remain trapped in the artery upstream of the occlusion

balloon. Following the removal of the angioplasty balloon catheter, an aspiration catheter may be introduced over the guidewire to aspirate the particles.

[0008] A specific example of an occlusion catheter is described by Rauker and others in "Occlusion Device", U.S. Patent 6,475,185 issued November 5, 2002. The occlusion device includes an elongated tubular shaft having an inflatable balloon disposed near the elongate shaft distal end with a proximal seal of a sufficiently small profile to allow a second catheter to pass over the distal occlusion device while the inflatable balloon remains uninflated. One occlusion device includes an elongated fluid displacement rod within the elongated shaft of the occlusion device, providing both a fluid pressure source and a seal.

[0009] Controlling the flow and sealing the inflation fluid into the balloon of the occlusion catheter can be challenging. Sell and others have used a valve of an inner tube that is closely fit into an outer tube, as disclosed in "Low Profile Valve and Balloon Catheter", U.S. Patent 6,090,083 issued July 18, 2000. The low-profile inflation valve includes a first thermoplastic tube with at least one region of decreased inner diameter, and a structure, which may be a tube, movably located inside the lumen. The region of decreased inner diameter of the first tube forms a seal with a portion of the structure.

[0010] Many medical procedures require that more than one catheter be advanced in and out of a body vessel. Various solutions have been suggested to allow a more rapid, safe, and unobstructed exchange of catheters. Improvements to catheter designs, fittings, valves, other parts of catheters, guidewires, and balloons have been suggested. One proposed improvement in the exchanging of catheters is to have a removable inflation fitting on the inflation tube that supplies fluid to a catheter balloon, as described in "Low Profile Angioplasty Catheter and/or Guide Wire and Method", Imran et al., U.S. Patent 5,520,645 issued May 28, 1996. The inflation fitting is removable so that the proximal extremity of the catheter is free of obstruction and another balloon catheter can be advanced over the proximal extremity.

[0011] Improvements to a balloon occlusion catheter and an associated method are proposed in "Low Profile Catheter Valve and Inflation Adaptor", Zadno-Azizi et al., U.S. Patent Application 20020133117 published September 19, 2002; "Exchange Method for Emboli Containment", Zadno-Azizi et al., U.S. Patent 6,544,276 issued April 8, 2003; "Method of Emboli Protection using a Low Profile Catheter", Zadno-Azizi et al., U.S. Patent 6,500,166 granted December 31, 2002; and "Low Profile Catheter Valve", U.S. Patent 6,355,014, Zadno-Azizi et al., granted March 12, 2002. The catheter includes a low-profile catheter valve with a movable sealer portion positioned within the inflation lumen of a catheter. The sealer portion forms a fluid tight seal with the inflation lumen by firmly contacting the entire circumference of a section of the inflation lumen. The sealer portion is positioned proximate to a side-access inflation port on the catheter, establishing an unrestricted fluid pathway between the inflation port and an inflatable balloon on the distal end of the catheter. The sealer portion can be moved to a position distal of the inflation port, thereby preventing fluid from being introduced into or withdrawn from the balloon via the inflation port. An inflation adaptor can be used for moving the sealer portion within the catheter to establish or close the fluid pathway between the inflation port and the inflatable balloon.

[0012] There is continued interest in improving minimally invasive treatments for vascular stenoses that use various intravascular catheters and associated devices. Of particular interest is the development of an improved occlusion catheter and associated devices and methods that provide faster inflation and deflation time for the occlusion balloon; improved robustness of the guidewire; more controlled advancement of the guidewire and occlusion balloon when crossing lesions in the vessel; greater control of fluoroscopic dye or other imaging fluid; and better visualization of the vessel after temporary occlusion with the occlusion balloon.

[0013] Therefore, it is desirable to have an improved blood vessel treatment system, providing the abovementioned desirable improvements that increase the utility and performance of the medical devices used during the treatment of a vascular condition.

SUMMARY OF THE INVENTION

[0014] One aspect of the invention provides a system for treating a blood vessel. The blood vessel treatment system includes a hollow guidewire having a central lumen, an occlusion balloon attached proximate to a distal end of the hollow guidewire, and an inflation catheter slidable over the hollow guidewire. An annular inflation lumen formed between the inflation catheter and the hollow guidewire fluidly communicates with the central lumen of the hollow guidewire. Inflation fluid is allowed to flow through the annular inflation lumen and into a distal portion of the central lumen to inflate the occlusion balloon. The system may include a distal valve coupled to the hollow guidewire to control the flow of inflation fluid between the hollow guidewire and the occlusion balloon.

[0015] Another aspect of the invention is an occlusion catheter for blocking flow through a vessel of a body. The occlusion catheter includes a hollow guidewire having a central lumen, an occlusion balloon attached proximate to a distal end of the hollow guidewire, and an inflation catheter slidable over the hollow guidewire. An annular inflation lumen formed between the inflation catheter and the hollow guidewire fluidly communicates with the central lumen of the hollow guidewire, allowing inflation fluid to flow through the annular inflation lumen and into a distal portion of the central lumen to inflate the balloon.

[0016] The present invention is illustrated by the accompanying drawings of various embodiments and the detailed description given below. The drawings should not be taken to limit the invention to the specific embodiments, but are for explanation and understanding. The detailed description and drawings are merely illustrative of the invention rather than limiting, the scope of the invention being defined by the appended claims and equivalents thereof. The foregoing aspects and other attendant advantages of the present invention will become more readily appreciated by the detailed description taken in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0017] Various embodiments of the present invention are illustrated by the accompanying figures, wherein:

[0018] **FIG. 1** is an illustration of a system for treating a vessel in a body, in accordance with one embodiment of the current invention;

[0019] **FIG. 2** shows a longitudinal cross-sectional view of a distal end of an occlusion catheter in a stenosed vessel, in accordance with one embodiment of the current invention;

[0020] **FIG. 3** shows a longitudinal cross-sectional view of a distal end of an occlusion catheter in a stenosed vessel, in accordance with another embodiment of the current invention;

[0021] **FIG. 4** shows a longitudinal cross-sectional view of a distal end of an occlusion catheter with a slightly retracted inflation catheter, in accordance with one embodiment of the current invention;

[0022] **FIG. 5** shows a longitudinal cross-sectional view of a distal end of an occlusion catheter, in accordance with another embodiment of the current invention;

[0023] **FIG. 6** shows a longitudinal cross-sectional view of a distal end of an occlusion catheter, in accordance with another embodiment of the current invention;

[0024] **FIG. 7** shows a longitudinal cross-sectional view of a distal end of an occlusion catheter, in accordance with another embodiment of the current invention;

[0025] **FIG. 8** shows a longitudinal cross-sectional view of a distal end of an occlusion catheter, in accordance with another embodiment of the current invention;

[0026] **FIG. 9** illustrates a valve actuator at the proximal end of an occlusion catheter, in accordance with one embodiment of the current invention; and

DETAILED DESCRIPTION OF THE
PRESENTLY PREFERRED EMBODIMENTS

[0027] FIG. 1 illustrates a system for treating a vessel in a body, in accordance with one embodiment of the present invention at **100**. Vessel treatment system **100** includes an occlusion catheter **110**. Occlusion catheter **110** comprises hollow guidewire **120**, distal occlusion balloon **130** attached to hollow guidewire **120**, and an inflation catheter **140** slidable over hollow guidewire **120**.

[0028] Occlusion catheter **110** is generally used to temporarily block or occlude a vessel in the body to stop the local flow of blood and fluids while medical procedures or treatments are completed within the vessel. While occlusion catheter **110** anchors hollow guidewire **120** to a vascular wall, hollow guidewire **120** may be used to guide to the treatment area other medical devices such as an angioplasty or dilation catheter, an atherectomy catheter, a stent-delivery catheter, a drug-delivery catheter, an ultrasound device, a measurement device, a laser catheter, an imaging catheter, a treatment catheter or a therapy catheter.

[0029] Occlusion catheter **110** can be used, for example, to rapidly inflate occlusion balloon **130** and temporarily occlude a blood vessel; to aspirate emboli and other debris in the blood vessel proximal to the temporary occlusion; to inject dye or contrast fluid into the stagnant fluid for stenosis visualization after vessel occlusion; and to provide an anchored guidewire for the subsequent deployment of a treatment catheter such as a stent-delivery catheter. An inflation connector **112** coupled to occlusion catheter **110** may have one or more ports **114** through which fluid is injected or aspirated for procedures such as the injection of inflation fluid into occlusion balloon **130**, the injection of dye into a vessel for visualization, or the aspiration of fluids and debris from within a vessel.

[0030] Hollow guidewire **120**, is a generally long, flexible, elongate tubular member with central lumen **122**. An exemplary hollow guidewire **120** may be made from a tube of stainless steel, nitinol, or other suitable tubing material sometimes referred to as a hypotube. Suitable hypotubing may have a small

outer diameter on the order of, for example, 0.014 inches, and a small inner diameter on the order of 0.008 inches. The length of hollow guidewire **120** may be on the order of 300 cm, allowing over-the-wire (OTW) catheters to be inserted into the body once hollow guidewire **120** is in place. In another example, hollow guidewire **120** may be on the order of 180 cm in length, suitable for guiding rapid-exchange type treatment catheters and zipper-type catheters. At proximal end **124** of hollow guidewire **120**, central lumen **122** is physically accessible for injecting fluid and inserting small wires such as core wires. At distal end **126** of hollow guidewire **120**, central lumen **122** is typically sealed and generally not physically accessible. Occlusion balloon **130** is attached proximate to distal end **126** of hollow guidewire **120**.

[0031] Occlusion balloon **130** is generally spherical or cylindrical elastic membrane having proximal and distal ends attached to an outside surface of hollow guidewire **120**, such that occlusion balloon **130** may be inflated and enlarged by filling an interior region **132** of occlusion balloon **130** with an inflation fluid without leakage either through the elastic membrane material or through the attached proximal and distal ends of occlusion balloon **130**. Occlusion balloon **130** may comprise, for example, one or more layers of expandable material such as polyurethane, radiopaque polyurethane material, thermoplastic polyurethane elastomers, aliphatic polyurethanes, aromatic polyurethanes, styrene-ethylene-butylene-styrene (SEBS) block copolymer, thermoplastic elastomers, low-density polyethylene, polyethylene terephthalate, polyethylene terephthalate glycol, silicone, copolymer of polyurethane and silicone, natural rubber, synthetic rubber, thermoplastic polyamide, nylon, latex, polyethylene, polyisoprene, polyisobutylene, thermoplastic elastomers, an elastomeric material, or combinations thereof. Attachment of occlusion balloon **130** to hollow guidewire **120** may be achieved with suitable adhesive, heat bonds, mechanical couplers, wire wraps, bands, or other types of balloon attachment techniques. When the inflation fluid is pushed into occlusion balloon **130**, the balloon enlarges in proportion to the amount of the fluid inside. When deployed in the body, occlusion balloon **130** is generally enlarged to fill region of the vessel and temporarily block flow through the vessel.

[0032] A removable inflation catheter **140** provides pathway for inflation fluid to fill occlusion balloon **130**. Inflation catheter **140** generally slides over hollow guidewire **120**. When placed over hollow guidewire **120**, occlusion catheter **110** becomes more rigid, enhancing its tactile feel and control with an increased robustness against kinking of hollow guidewire **120**.

[0033] In one embodiment, inflation catheter **140** is slid and abutted against mechanical stop **144** that is coupled to an exterior surface of hollow guidewire **120** proximal to occlusion balloon **130**. Mechanical stop **144** limits axial displacement of inflation catheter **140** over hollow guidewire **120**. In other embodiments, mechanical stop **144** cooperates with a distal end of inflation catheter **140** to form a distal seal.

[0034] Mechanical stop **144** may comprise a relatively inelastic material such as stainless steel, nitinol, tantalum, MP35N cobalt alloy, platinum, titanium, a thermoset plastic, a suitable biocompatible alloy, a suitable biocompatible material, or a combination thereof. Mechanical stop **144** may be made from or include a radiopaque marker comprising material such as platinum, barium, tantalum, iridium, gold or a combination thereof. Mechanical stop **144** is typically a collar or a shaped tube wrapping around a portion of hollow guidewire **120** and typically less than a few millimeters in length with an outer diameter that prevents excessive axial movement of inflation catheter **140** over hollow guidewire **120**, while retaining a sufficiently low profile, preferably less than the diameter of the collapsed balloon. In one embodiment, mechanical stop **144** is positioned adjacent to a proximal end of occlusion balloon **130**. In another embodiment, mechanical stop **144** is positioned a prescribed distance from the proximal end of occlusion balloon **130** for increased flexibility of hollow guidewire **120** near distal end **126** for easier navigation through tortuous vasculature.

[0035] During medical procedures with occlusion catheter **110**, inflation catheter **140** may be initially positioned over hollow guidewire **120** to form an annular inflation lumen **142** between an outer surface of hollow guidewire **120** and an inner surface of inflation catheter **140**. Annular inflation lumen **142** fluidly communicates with central lumen **122** of hollow guidewire **120**, allowing inflation fluid to flow through annular inflation lumen **142** and into a distal portion of central lumen **122** to inflate occlusion balloon **130**. In one example,

annular inflation lumen **142** fluidly communicates with central lumen **122** of hollow guidewire **120** through an inflation port **154** positioned between annular inflation lumen **142** and central lumen **122** of hollow guidewire **120**, generally at a point near the distal end of occlusion catheter **110**, proximal to balloon **130**. Annular inflation lumen **142** provides a larger cross-sectional area than central lumen **122** of hollow guidewire **120**, allowing for faster inflation and deflation of occlusion balloon **130** when compared to the time required to deliver fluid through central lumen **122** along the entire length of hollow guidewire **120**. With a distal valve, only a shorter distal portion of central lumen **122** fluidly communicates with occlusion balloon **130**. Inflation port **154** may comprise, for example, a hole, an aperture, or a series of holes and apertures through a sidewall of hollow guidewire **120**.

[0036] To inflate occlusion balloon **130**, central lumen **122** fluidly communicates with interior region **132** of occlusion balloon **130** through side port **156** in hollow guidewire **120**, side port **156** being positioned between central lumen **122** and occlusion balloon **130**. Side port **156** may comprise, for example, a hole or series of holes in a sidewall of hollow guidewire **120** between the proximal and distal ends of occlusion balloon **130**. Side port **156** allows inflation fluid from central lumen **122** to flow into interior region **132** of occlusion balloon **130**.

[0037] The distal end of inflation catheter **140** may be located close to the proximal end of occlusion balloon **130**, though in some cases the distal end of inflation catheter **140** is located a distance further from the proximal end of occlusion balloon **130**, thereby increasing the flexibility of hollow guidewire **120** and narrowing the effective cross-sectional area of the distal end of occlusion catheter **110** during the routing and positioning of occlusion balloon **130**.

[0038] When occlusion balloon **130** is inflated, inflation catheter **140** may be slidably removed from hollow guidewire **120**, allowing other treatment catheters to be placed over hollow guidewire **120** while blood flow in the vessel is blocked. To avoid inflation fluid from leaking out of inflation port **154** when inflation catheter **140** is removed, a distal valve coupled to hollow guidewire **120** controls the flow of inflation fluid between hollow guidewire **120** and occlusion balloon **130**.

[0039] In one example of a distal valve, sealing plug **152** is attached near a distal end of core wire **150**. Core wire **150** may comprise, for example, a thin wire or rod of stainless steel, nitinol, or other suitably flexible and strong material. Operating like a plunger, core wire **150** is slidably disposed within hollow guidewire **120**. Sealing plug **152** may comprise, for example, a silicone, an epoxy, or other wear-resistant, semi-compliant material. An axial displacement of a proximal end of core wire **150** displaces sealing plug **152** at a distal end of core wire **150** to open and close the distal valve. To close the distal valve, core wire **150** is pushed further into central lumen **122** of hollow guidewire **120** so that sealing plug **152** covers inflation port **154** or is positioned somewhere between inflation port **154** and side port **156**. To open the distal valve, core wire **150** is retracted slightly to axially displace sealing plug **152**, uncovering inflation port **154** so that inflation fluid may flow through inflation port **154** and to or from occlusion balloon **130** through a distal portion of central lumen **122** between inflation port **154** and side port **156**. Axial displacement of the proximal end of core wire **150** may be controlled, for example, with a detachable valve actuator coupled to proximal end **124** of hollow guidewire **120** to actuate the distal valve.

[0040] Occlusion catheter **110** may also be used to inject contrast fluid into the blood vessel during the positioning or after the inflating of occlusion balloon **130** in order to visualize and verify the location of a stenosis, blockage, or other therapeutic condition within the blood vessel. The contrast fluid may also serve as inflation fluid to inflate occlusion balloon **130**.

[0041] In one embodiment, an additional contrast fluid lumen **138** may be attached to or integrally formed within inflation catheter **140** to inject contrast fluid into the blood vessel. In another embodiment, inflation port **154** may be used to inject contrast fluid into the blood vessel when the distal valve is closed and inflation catheter **140** is removed, by pushing contrast fluid through central lumen **122** from proximal end **124** of hollow guidewire **120** to inflation port **154**. Alternatively, additional contrast fluid injection ports **158** may be used to inject contrast fluid from one or more contrast fluid injection ports **158** located proximally to occlusion balloon **130** after occlusion balloon **130** has been inflated and inflation catheter **140** has been removed. In another embodiment, contrast fluid may be injected into the blood vessel proximate

the inflated occlusion balloon **130** by a slight retraction of inflation catheter **140** to physically expose a distal end of annular inflation lumen **142**, so that contrast fluid can be injected in large amounts into the blood vessel.

[0042] **FIG. 2** shows a longitudinal cross-sectional view of a distal end of occlusion catheter **210** in a stenosed vessel, in accordance with one embodiment of the present invention at **200**. Occlusion catheter **210** includes an inflatable occlusion balloon **230** attached proximate to a distal end of hollow guidewire **220**. A distal valve comprising core wire **250** and sealing plug **252** is coupled to hollow guidewire **220** to control the flow of inflation fluid between central lumen **222** of hollow guidewire **220** and occlusion balloon **230**. Core wire **250** is slidably disposed within hollow guidewire **220**. An axial displacement of a proximal end of core wire **250** displaces sealing plug **252** at a distal end of core wire **250** to open and close the distal valve. In the embodiment illustrated, inflation fluid has been injected from central lumen **222** through side port **256** into an interior region **232** of occlusion balloon **230**, expanding occlusion balloon **230** to a diameter sufficiently large to temporarily occlude vessel **270** in the body. Sealing plug **252** is positioned distal to an inflation port **254** to maintain inflation fluid within occlusion balloon **230**. Blood flow within vessel **270** is temporarily blocked so that treatments can be applied to, for example, stenosis **272**.

[0043] In **FIG. 2**, an inflation catheter for inflating occlusion balloon **230** has been removed, allowing other treatment catheters such as a stent-delivery catheter to be slid over hollow guidewire **220** and rapidly positioned as desired within vessel **270**. With the inflation catheter removed, inflation port **254** and any additional contrast-fluid injection ports **258** can be used to inject radioscopic or fluoroscopic contrast fluid into vessel **270**, which helps a medical specialist to fluoroscopically locate, identify and visualize targeted stenosis **272** and/or other treatable sites within vessel **270**. Contrast fluid may flow to a distal end of hollow guidewire **220** through central lumen **222** while core wire **250** is disposed within hollow guidewire **220** and sealing plug **252** maintains inflation fluid within occlusion balloon **230**.

[0044] **FIG. 3** shows a longitudinal cross-sectional view of a distal end of occlusion catheter **310** in a stenosed vessel, in accordance with one embodiment of the present invention at **300**. Occlusion catheter **310** includes

hollow guidewire **320** with an inflatable occlusion balloon **330** located near a distal end of hollow guidewire **320**, and an inflation catheter **340** slid over hollow guidewire **320**.

[0045] In this figure, inflation catheter **340** forms an annular inflation lumen **342** between an inner surface of inflation catheter **340** and an outer surface of hollow guidewire **320**. Occlusion balloon **330** inflates with inflation fluid that enters at a proximal end of inflation catheter **340** and traverses through annular inflation lumen **342** to inflation port **354**. The inflation fluid flows through inflation port **354** into a distal portion of central lumen **322**, and then continues to flow through side port **356** positioned between central lumen **322** and occlusion balloon **330**, thereby filling and expanding occlusion balloon **330**. Mechanical stop **344** located proximal to occlusion balloon **330** provides a seal for annular inflation lumen **342** at the distal end of inflation catheter **340** and limits the travel of inflation catheter **340** over hollow guidewire **320**. A distal valve comprising core wire **350** with sealing plug **352** attached near a distal end of core wire **350** is openly positioned so that inflation fluid can ingress through inflation port **354** into central lumen **322** to inflate occlusion balloon **330**, thereby temporarily blocking flow of body fluid through vessel **370**.

[0046] When occlusion balloon **330** is properly inflated, sealing plug **352** is axially displaced into a closed position distal to inflation port **354**, so that inflation fluid is retained within interior region **332** of occlusion balloon **330**, allowing inflation catheter **340** to be slidably removed from hollow guidewire **320**. Treatment catheters can then be slid over hollow guidewire **320** for treating stenosis **372** and other conditions within vessel **370**. Additional contrast-fluid injection ports **358** can be used to inject radioscopic or fluoroscopic contrast fluid into vessel **370**.

[0047] **FIG. 4** shows a longitudinal cross-sectional view of a distal end of occlusion catheter **410** with a slightly retracted inflation catheter, in accordance with one embodiment of the present invention at **400**. Occlusion catheter **410** includes an inflatable occlusion balloon **430** attached near a distal end of hollow guidewire **420**. In this figure, inflation fluid has been injected into an interior region **432** of occlusion balloon **430**, enlarging occlusion balloon **430**, thereby blocking flow through vessel **470** so that

stenosis **472** or other condition within vessel **470** can be treated. Inflation fluid is retained within occlusion balloon **430** by the closure of a distal valve, which comprises sealing plug **452** attached at a distal end of core wire **450**, with core wire **450** slidably disposed within central lumen **422** of hollow guidewire **420**. Sealing plug **452** is positioned to block the flow of inflation fluid from side port **456** to inflation port **454** of hollow guidewire **420**.

[0048] To accurately image stenosis **472** once the flow of bodily fluid through vessel **470** has been blocked, radiopaque contrast media, also serving as inflation fluid, may be injected into the stagnant fluid within vessel **470** from the distal end of annular inflation lumen **442** by retracting inflation catheter **440** a sufficient distance to break the seal between the end of inflation catheter **440** and mechanical stop **444**. Radiopaque contrast media may be injected into the proximal end of inflation catheter **440** and emitted from the distal end of inflation catheter **440**. Alternatively, the contrast media may be injected through additional contrast fluid lumen **438** extending the length of inflation catheter **440**.

[0049] In yet another x-ray visualization technique, radiopaque contrast media may be injected through central lumen **422** of hollow guidewire **420** to inflation port **454** and/or any additional contrast fluid injection ports **458** for injecting into vessel **470** while core wire **450** is disposed within hollow guidewire **420** and sealing plug **452** maintains inflation fluid within occlusion balloon **430**. This method may be used when inflation catheter **440** has been slightly retracted, or even if it has been completely removed from hollow guidewire **420**.

[0050] **FIG. 5** shows a longitudinal cross-sectional view of a distal end of occlusion catheter **510**, in accordance with another embodiment of the present invention at **500**. Occlusion catheter **510** includes hollow guidewire **520** having central lumen **522**, an inflatable occlusion balloon **530** attached proximate to a distal end of hollow guidewire **520**, and mechanical stop **544** coupled near a proximal end of occlusion balloon **530**. In this figure, an inflation catheter has been slidably removed from over hollow guidewire **520** to reveal at least one inflation port **554** and at least one contrast fluid injection port **558**. Contrast fluid injection port **558** is positioned proximal to inflation port **554**, near a distal end of hollow guidewire **520**. When the inflation

catheter has been removed from hollow guidewire **520**, contrast fluid from central lumen **522** can be injected through contrast fluid injection port **558** and/or inflation port **554** into vessel **570**. Sealing plug **552**, attached near a distal end of core wire **550**, retains inflation fluid within interior region **532** of occlusion balloon **530** by blocking a distal portion of central lumen **522** between inflation port **554** and side port **556**. The contrast fluid is forced into central lumen **522** at a proximal end and traverses through a proximal portion of central lumen **522** until it is injected from inflation ports **554** and/or contrast injection ports **558**. The injected contrast fluid may be used to image stenosis **572** or other conditions within vessel **570**.

[0051] FIG. 6 shows a longitudinal cross-sectional view of a distal end of occlusion catheter **610**, in accordance with another embodiment of the present invention at **600**. Occlusion catheter **610** shows details of distal seal **648** between a distal end of an inflation catheter **640** and mechanical stop **644**. Distal seal **648** blocks inflation fluid traversing through annular inflation lumen **642** between an inner surface of inflation catheter **640** and an outer surface of hollow guidewire **620**, preventing inadvertent leakage of inflation fluid into a body vessel surrounding occlusion catheter **610**. The inflation fluid flows from annular inflation lumen **642** into a distal portion of central lumen **622** within hollow guidewire **620**. Sealing plug **652** attached near a distal end of core wire **650** is retracted from inflation port **654** to allow flow of inflation fluid into an inflatable occlusion balloon (not shown).

[0052] In this embodiment, mechanical stop **644** is attached to an outer surface of hollow guidewire **620**. Generally in the form of a band or a collar, mechanical stop **644** limits axial travel of inflation catheter **640** at a distal end of hollow guidewire **620**, and provides a mating surface against which the distal end **646** of inflation catheter **640** may be pressed and abutted to prevent the flow of fluid through distal seal **648**. Distal seal **648** may be held closed, for example, using a removable adapter or a retention mechanism coupled between inflation catheter **640** and hollow guidewire **620** near the proximal end of occlusion catheter **610**. The mating surface may be augmented with a compliant or elastic sealing material such as polyurethane, a silicone, or other suitable polymer to aid in the formation of a suitable seal. Alternatively, a radial seal may be formed at distal end **646** of inflation catheter **640** by the

inclusion of an elastomeric end cap or a distally mounted internal seal member capable of slidingly sealing along the outer surface of hollow guidewire **620** to provide distal seal **648**.

[0053] FIG. 7 shows a longitudinal cross-sectional view of a distal end of occlusion catheter **710**, in accordance with another embodiment of the present invention at **700**. Occlusion catheter **710** includes hollow guidewire **720** with a centrally disposed core wire **750** including sealing plug **752** attached near a distal end of core wire **750** to form a distal valve. The distal valve controls the flow of inflation fluid between inflation port **754** and an inflatable occlusion balloon (not shown). When sealing plug **752** is axially withdrawn, inflation fluid may traverse annular inflation lumen **742** formed between inflation catheter **740** and hollow guidewire **720**, flow through inflation port **754** into a distal portion of central lumen **722** of hollow guidewire **720**, and inflate an occlusion balloon attached proximate to a distal end of hollow guidewire **720**. When sealing plug **752** is axially withdrawn, the balloon may also be deflated by reversing the flow of inflation fluid along the same flow path described above.

[0054] Distal seal **748** is formed when distal end **746** of inflation catheter **740** is pressed against mechanical stop **744**. In this embodiment, a wedge or tapered surface aids in the formation of distal seal **748** by self-centering the distal end of inflation catheter **740** around a mating surface of mechanical stop **744**. The mating surfaces on either the distal end of inflation catheter **740** or mechanical stop **744** may be coated or covered with a polymeric sealing material such as polyurethane, silicone, or other suitable polymer to aid in the formation of distal seal **748**. Mechanical stop **744** may be adapted to have an engagement configuration that provides a friction-fit or snap-fit with the distal end of inflation catheter **740** or with a mating component disposed thereon.

[0055] FIG. 8 shows a longitudinal cross-sectional view of a distal end of occlusion catheter **810**, in accordance with another embodiment of the present invention at **800**. Occlusion catheter **810** includes hollow guidewire **820** having central lumen **822**, an inflatable occlusion balloon **830** attached proximate to a distal end of hollow guidewire **820**, and an inflation catheter **840** slidable over hollow guidewire **820**. Mechanical stop **844**, comprising a

band, collar or plate, is attached via sealing spring **836** to hollow guidewire **820** at a point near a proximal end of occlusion balloon **830**. Distal seal **846** is made between a distal end of inflation catheter **840** and mechanical stop **844** when distal end **848** of inflation catheter **840** is pressed and abutted against mechanical stop **844**, compressing sealing spring **836** and providing a leak-tight seal while occlusion balloon **830** is being inflated. Sealing spring **836** may comprise, for example, one or more turns of flexible stainless steel or nitinol. A gasket or other compliant material may be attached to the distal end of inflation catheter **840** or to a sealing surface of mechanical stop **844** to aid in the formation of distal seal **846**.

[0056] In this embodiment, inflation fluid, which is injected into an annular inflation lumen **842** formed between hollow guidewire **820** and inflation catheter **840**, flows through one or more inflation ports **854** positioned between annular inflation lumen **842** and central lumen **822** of hollow guidewire **820**. Sealing plug **852** is attached to core wire **850**, is centrally disposed within hollow guidewire **820**, and can be positioned at a location proximal to inflation ports **854** to open the distal valve. Sealing plug **852** can also be positioned at a location distal to inflation ports **854** to close the valve, thereby blocking the flow of inflation fluid to and from interior region **832** of occlusion balloon **830** through one or more side ports **856** located between a distal portion of central lumen **822** and interior region **832** of occlusion balloon **830**. Axial translation of sealing plug **852** to close the distal valve and block fluid flow between inflation port **854** and side ports **856** can be achieved by axially displacing a proximal end of core wire **850** with respect to hollow guidewire **820**. Axial travel of sealing plug **852** can be limited, for example, by abutment of the distal end of core wire **850** against the sealed end of hollow guidewire **820** or with an external valve actuator.

[0057] FIG. 9 illustrates one example of valve actuator **980** detachably coupled at the proximal end of an occlusion catheter, in accordance with the present invention at **900**. Typically hand held, valve actuator **980** can be removably coupled to proximal ends of hollow guidewire **920** and core wire **950**, the latter being disposed within central lumen **922** and extending from a proximal end of hollow guidewire **920**. Valve actuator **980** actuates a distal valve (not shown) coupled to hollow guidewire **920** to control the flow of

inflation fluid between hollow guidewire **920** and an inflatable occlusion balloon (not shown) attached proximate to a distal end of hollow guidewire **920**. Axial displacement of the proximal end of core wire **950** with respect to the proximal end of hollow guidewire **920** results in the opening and closing of the distal valve.

[0058] In one example, valve actuator **980** couples to hollow guidewire **920** and core wire **950** by inserting hollow guidewire **920** with an extending core wire **950** into valve actuator hole **982**. A hollow guidewire clamping mechanism comprising, for example, knurled knob **984** and an elastomeric ring **986**, clamps gently and securely onto an outer surface of hollow guidewire **920**. Tightening of knurled knob **984** compresses elastomeric ring **986** onto hollow guidewire **920**. A core wire clamping mechanism comprising, for example, knurled knob **988** and an elastomeric ring **990**, compresses and gently clamps elastomeric ring **990** securely onto an outer surface of core wire **950** when knurled knob **988** is tightened. Slidable piston **992** contained within an actuator body **996** can be pushed or pulled within actuator body **996** to axially displace core wire **950** within hollow guidewire **920**, thereby actuating a distal valve. Actuator stops **994** positioned on slidable piston **992** and actuator body **996** limit the stroke and axial motion of core wire **950**, avoiding excessive displacement of the distal valve and ensuring accurate operation of the distal valve. A proximal end of hollow guidewire **920** may be funneled through an inlet port of actuator body **996** and abutted against an angled surface of slidable piston **992** when the hollow guidewire **920** with extended core wire **950** are inserted into valve actuator **980**.

[0059] Before or after insertion of the occlusion catheter into the body, valve actuator **980** may be attached to the proximal ends of hollow guidewire **920** and core wire **950** to actuate a distal valve that controls the flow of inflation fluid between hollow guidewire **920** and an occlusion balloon. For example, core wire **950** is threaded through valve actuator **980**. Hollow guidewire **920** and an extended portion of core wire **950** are coupled to valve actuator **980**. Core wire **950** may be retracted a predetermined distance from hollow guidewire **920** by axially displacing slidable piston **992** that opens the distal valve. When the distal valve is opened, inflation fluid may be sent through an annular inflation lumen formed between hollow guidewire **920** and an inflation

catheter slid over hollow guidewire to inflate an occlusion balloon located at the distal end of hollow guidewire **920**. When the balloon is inflated to the desired diameter, the distal valve is closed by inserting core wire **950** a predetermined distance into hollow guidewire **920**.

[0060] Variations and alterations in the design, manufacture and use of the occlusion catheter and the distal valve are apparent to one skilled in the art, and may be made without departing from the spirit and scope of the present invention. While the embodiments of the invention disclosed herein are presently considered to be preferred, various changes and modifications can be made without departing from the spirit and scope of the invention. The scope of the invention is indicated in the appended claims, and all changes that come within the meaning and range of equivalents are intended to be embraced therein.

CLAIMS

What is claimed is:

1. A system for treating a vessel in a body, comprising:
a hollow guidewire having a central lumen;
an occlusion balloon attached proximate to a distal end of the hollow guidewire; and
an inflation catheter slidable over the hollow guidewire, wherein an annular inflation lumen formed between the inflation catheter and the hollow guidewire fluidly communicates with the central lumen of the hollow guidewire, allowing inflation fluid to flow through the annular inflation lumen and into a distal portion of the central lumen to inflate the occlusion balloon.
2. The system of claim 1 wherein the inflation catheter is removable from the hollow guidewire.
3. The system of claim 1 wherein the annular inflation lumen fluidly communicates with the central lumen of the hollow guidewire through an inflation port positioned between the annular inflation lumen and the central lumen of the hollow guidewire.
4. The system of claim 1 wherein the central lumen of the hollow guidewire fluidly communicates with an interior region of the occlusion balloon through a side port in the hollow guidewire, the side port positioned between the central lumen of the hollow guidewire and the occlusion balloon.
5. The system of claim 1 further comprising:
a distal valve coupled to the hollow guidewire to control the flow of inflation fluid between the hollow guidewire and the occlusion balloon.

6. The system of claim 5 wherein the distal valve comprises a core wire with a sealing plug at a distal end of the core wire, the core wire slidably disposed within the hollow guidewire, and wherein an axial displacement of a proximal end of the core wire displaces the sealing plug at the distal end of the core wire to open and close the distal valve.

7. The system of claim 5 further comprising:
a valve actuator detachably coupled at a proximal end of the hollow guidewire to actuate the distal valve.

8. The system of claim 1 further comprising:
a mechanical stop coupled to an exterior surface of the hollow guidewire proximal to the occlusion balloon, wherein the mechanical stop limits an axial displacement of the inflation catheter over the hollow guidewire.

9. The system of claim 8 wherein the mechanical stop and a distal end of the inflation catheter cooperate to form a distal seal between the inflation catheter and the hollow guidewire.

10. The system of claim 1 further comprising:
a contrast fluid lumen extending through the inflation catheter to transport contrast fluid to a distal end of the inflation catheter.

11. The system of claim 1 further comprising:
a contrast fluid injection port positioned near the distal end of the hollow guidewire, wherein contrast fluid from the central lumen of the hollow guidewire is injected through the contrast fluid injection port when the inflation catheter is slidably removed from the hollow guidewire.

12. An occlusion catheter for blocking flow through a vessel, comprising:
a hollow guidewire having a central lumen;
an occlusion balloon attached proximate to a distal end of the hollow guidewire; and

an inflation catheter slidable over the hollow guidewire, wherein an annular inflation lumen formed between the inflation catheter and the hollow guidewire fluidly communicates with the central lumen of the hollow guidewire, allowing inflation fluid to flow through the annular inflation lumen and into a distal portion of the central lumen to inflate the balloon.

13. The occlusion catheter of claim 12 further comprising:

a distal valve, wherein the distal valve includes a core wire with a sealing plug at a distal end of the core wire, the core wire slidably disposed within the hollow guidewire, and wherein an axial displacement of a proximal end of the core wire displaces the sealing plug at the distal end of the core wire to open and close the distal valve.

14. The occlusion catheter of claim 13 further comprising:

a valve actuator detachably coupled at a proximal end of the hollow guidewire to actuate the distal valve.

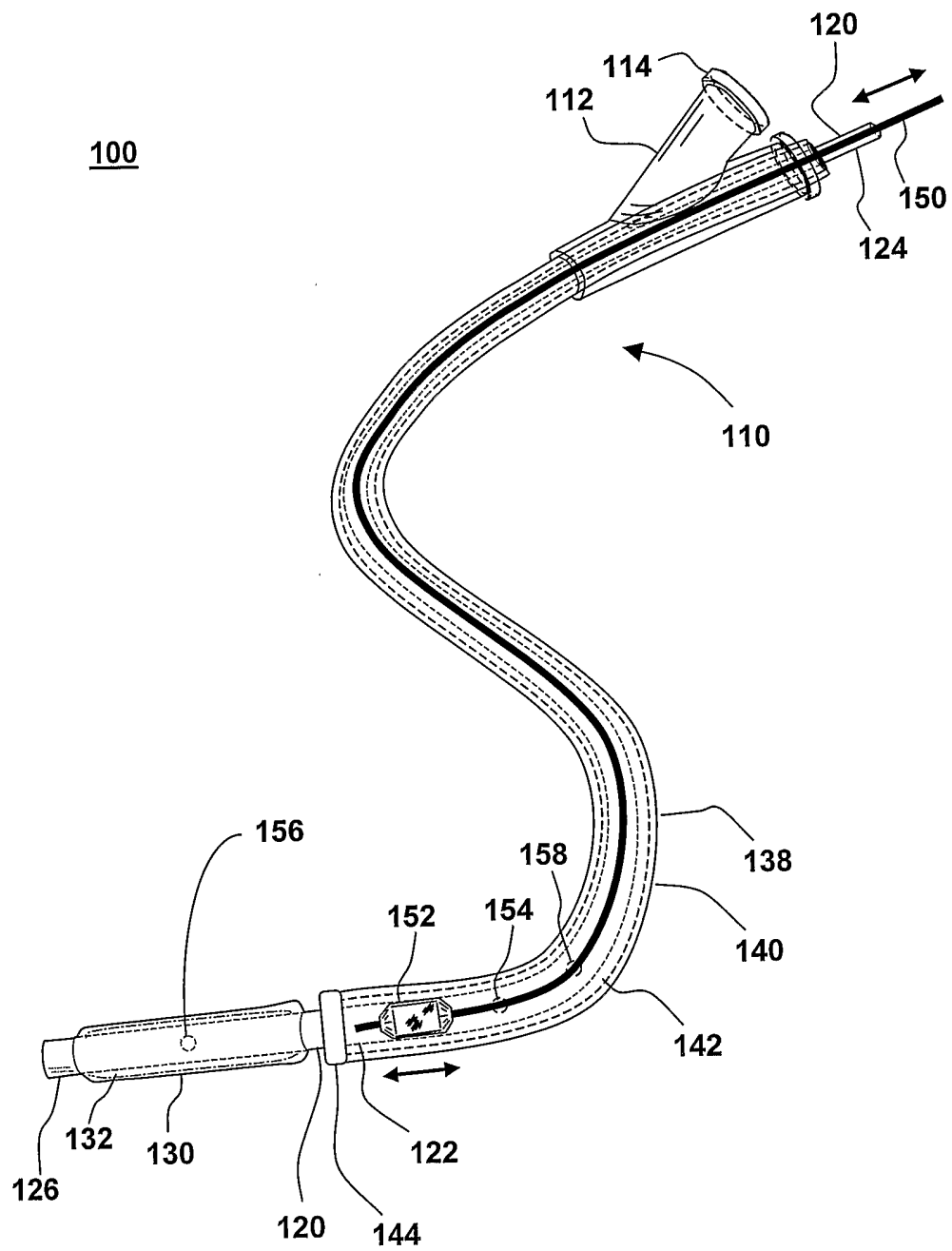
FIG. 1

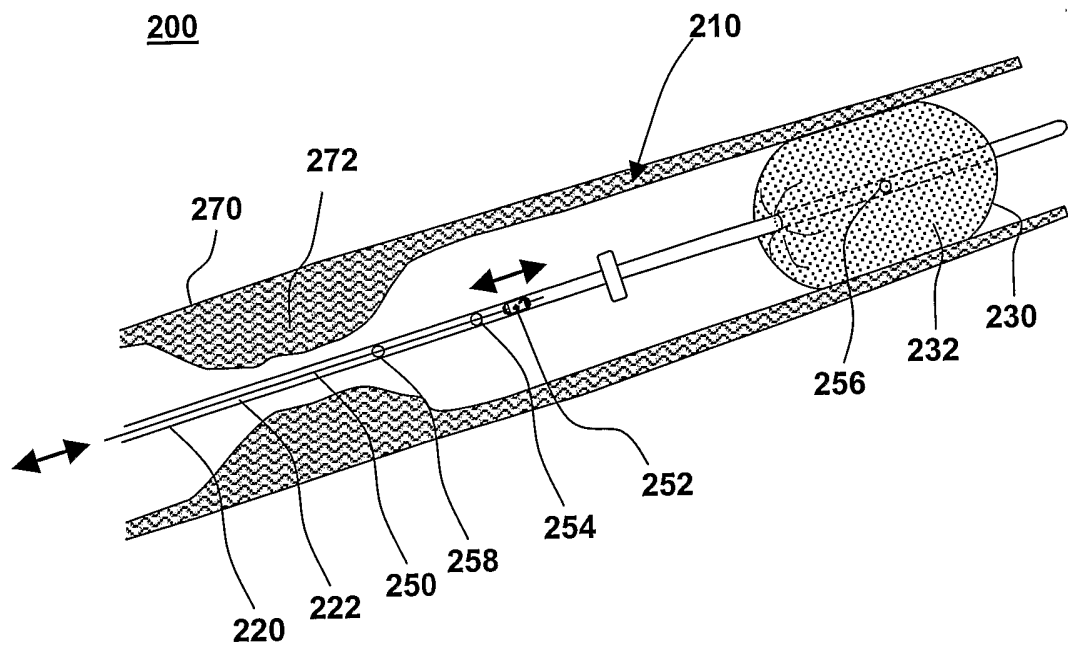
FIG. 2

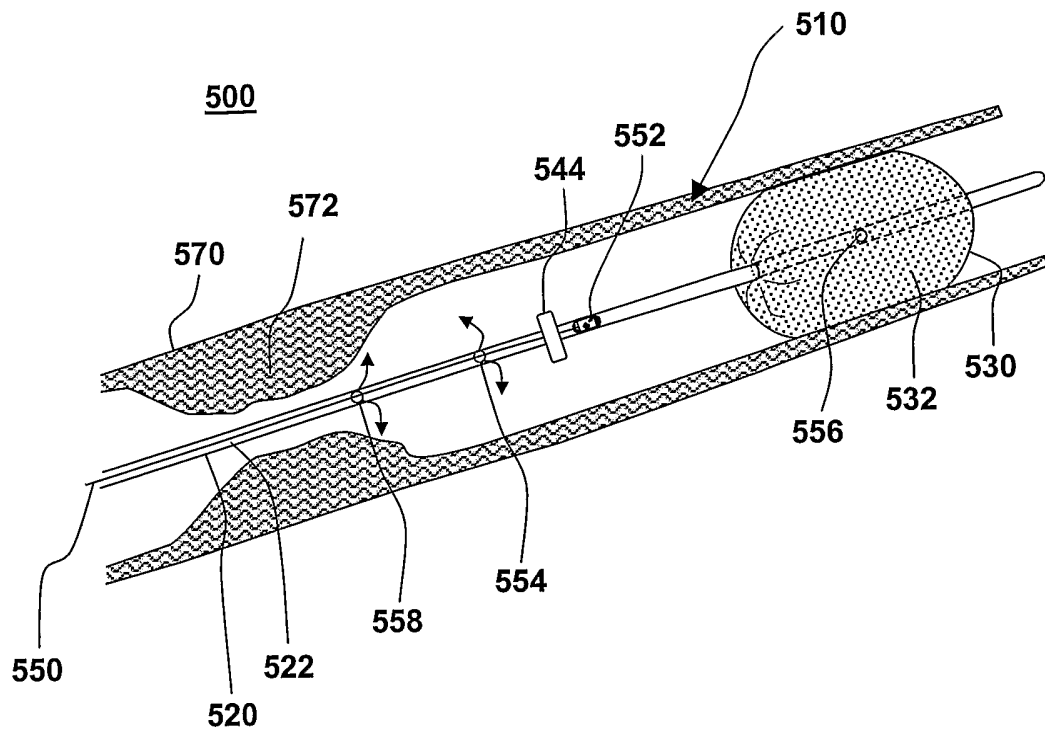
FIG. 5

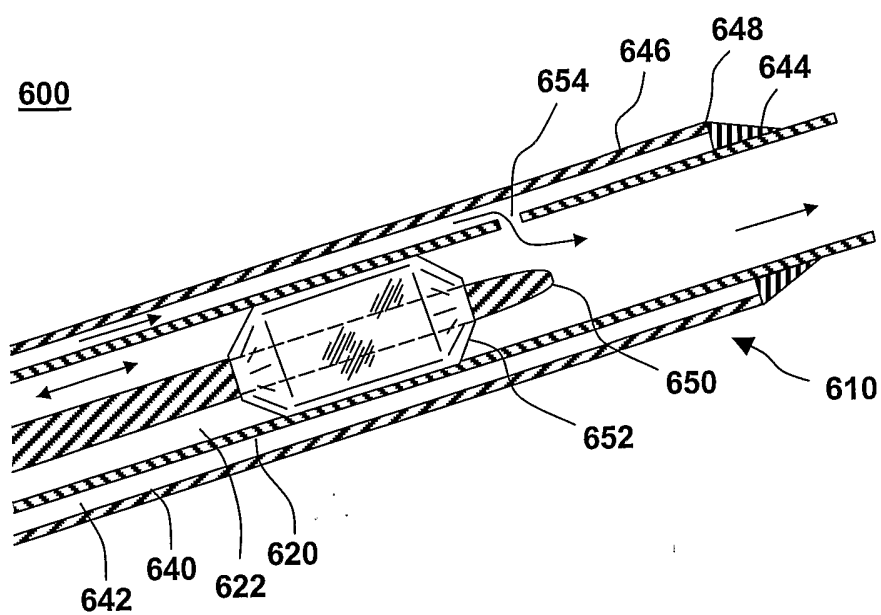
FIG. 6

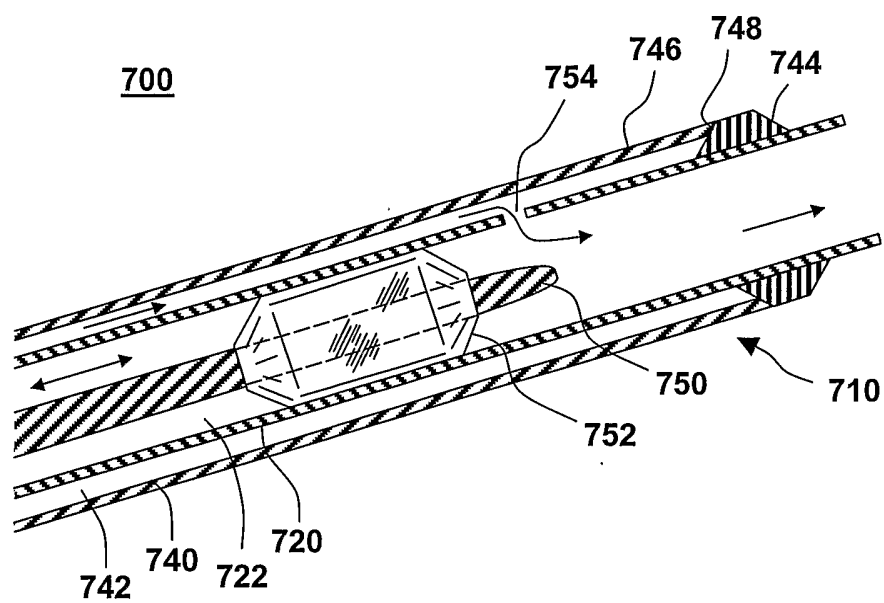
FIG. 7

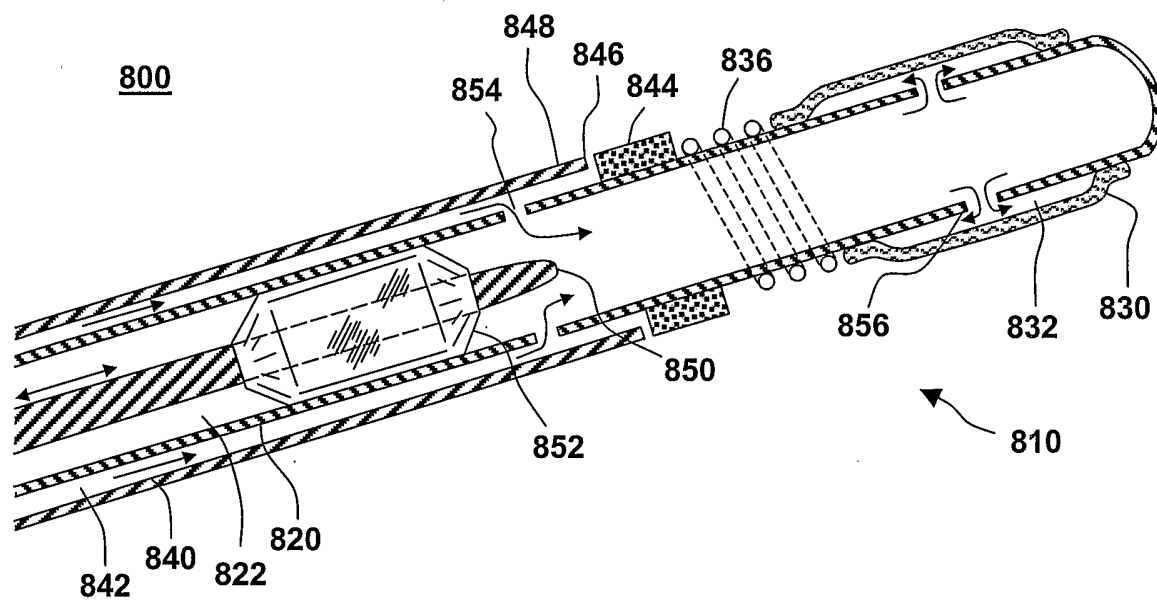
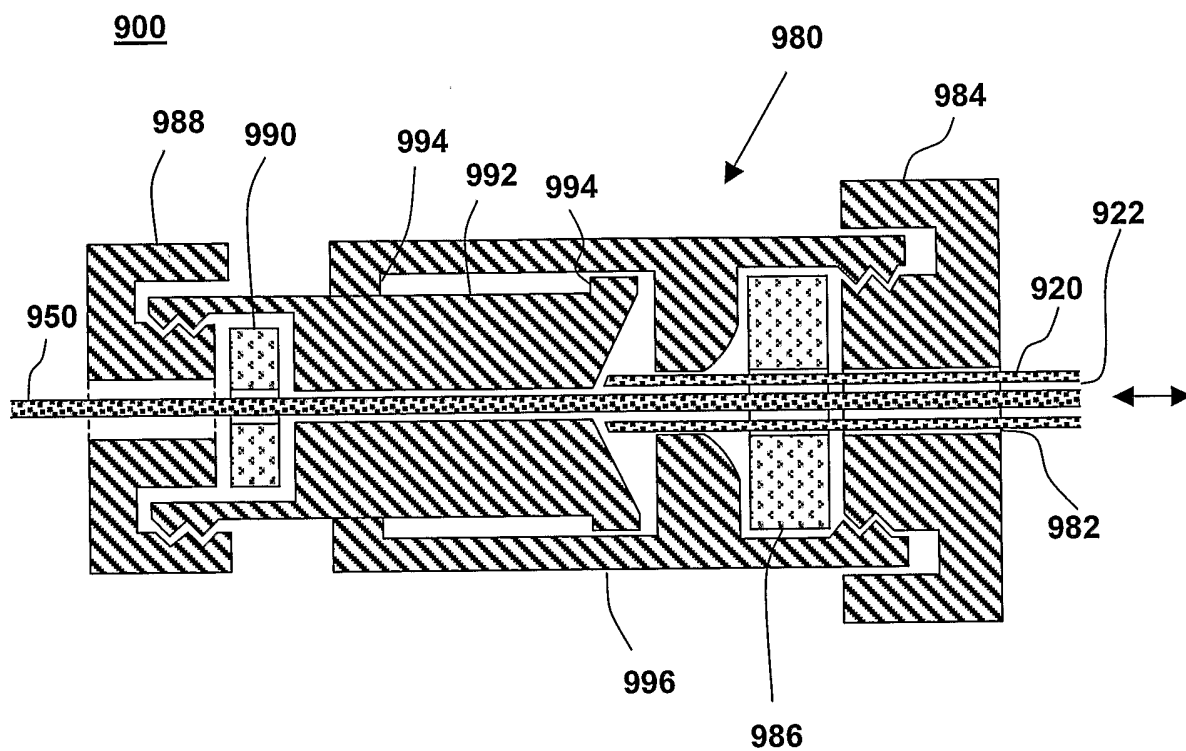
FIG. 8

FIG. 9

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US2004/017775

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M25/10

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61M

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

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Date of the actual completion of the international search

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
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