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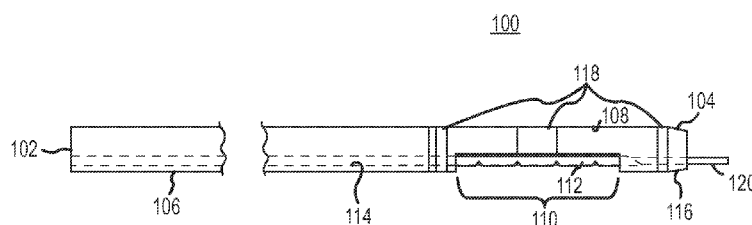


FIG. 1

(57) Abstract: The invention generally relates to method and apparatus for crossing an obstruction in a tubular member, and more particularly to a medical device method for crossing of a chronic occlusion in a subintimal or interstitial space of an artery.

REENTRY CATHETER AND METHOD THEREOF

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of United States Provisional Patent Application No. 61/503,477, filed on June 30, 2011, which is hereby incorporated by reference for all purposes as if fully set forth herein.

FIELD OF THE INVENTION

[0002] The invention generally relates to method and apparatus for crossing an obstruction in a tubular member, and more particularly to a medical device method for crossing of a chronic occlusion in a subintimal or interstitial space of an artery.

BACKGROUND OF THE INVENTION

[0003] Atherosclerosis is a common human ailment arising from deposition of fatty-like substance, such as atheroma, or plaque on the walls of major blood vessels. These deposits occur within the peripheral arterial system which feeds the limbs of the body and also occur within the coronary arterial system which feeds the heart. These deposits accumulate in localized areas, narrow the vascular lumen, and eventually causing restriction of normal blood flow. In some cases, the deposits result in a chronic partial or total occlusion. Such restriction can lead to a serious health risk including critical limb ischaemia. If blood flow cannot be adequately restored through surgical or endovascular intervention and the probability of limb amputation increases dramatically.

[0004] Until recently, chronic total occlusions have been treated by bypass which poses high procedural risks and is quite traumatic to the patient. Recently, catheter based intravascular procedures have been utilized. These techniques include step-by-step crossing of an occlusion using Excimer laser atherectomy devices and methods, crossing the occlusion with highly flexible and maneuverable guide wires, and other techniques known in the art. Once the lesion has been crossed, then standard endovascular devices such as laser atherectomy, angioplasty, stenting, and the like, can be used to enlarge the lumen and increase blood flow within the peripheral arterial system. These catheter-based intravascular procedures are typically preferred since they are much less traumatic to the patient, safer and cost-effective while delivering comparable long term vessel patency compared to more traumatic surgical alternatives.

[0005] Before catheter-based treatments can be used, with the exception of step-by-step Excimer laser methods, the guide wire must first pass through the total occlusion to provide access for the interventional catheter. Specifically, once a guide wire has

crossed the occlusion, it can then be used as a rail to support interventional catheters. In some cases, the physician can maneuver the guide wire through the total occlusion establishing access. In many instances, the physician encounters a calcified cap on the proximal end of the occlusion and is unable to maneuver the guide wire through the cap and across a calcified or fibrous lesion. In many cases, the guide wire inadvertently penetrates the subintimal space between the intimal layer and the adventitial layer of the blood vessel as the guide wire attempts to cross the lesion. Once in the subintimal space, it is difficult to direct the guide wire back into the vessel lumen making it nearly impossible to perform a catheter based intravascular procedure.

[0006] In one related art technique, Dr. Bolia developed a revascularization procedure as described in *Recanalisation of femoro-popliteal occlusions: Improving success rate by subintimal recanalisation*, Clinic Radiol, 40:325, 1989, by exploiting the subintimal space where a guidewire enters the subintimal space between the intima and adventitia layers, is subsequently advanced to a point distal to the occlusion, and then maneuvered to re-enter or puncture the vessel layers to enter the true lumen of the vessel. Once the guide wire has traversed through the subintimal layer and re-enters the true lumen of the vessel at a point distal to the occlusion, percutaneous balloon angioplasty is performed to restore blood flow through subintimal recanalization. This is a highly skilled technique with a low to moderate success level of consistent re-entry at the physician's preferred location just distal to the occlusion.

[0007] There are number of other related art catheters and methods for forming lateral penetrations through tissue to and from blood vessels past total occlusions, some of these are described in U.S. Pat. Nos. 5,443,497; 5,429,497; 5,409,019; 5,287,861; 6,231,546; 6,217,527; 6,506,178; 6,221,049; 6,235,000; 6,511,458; 6,719,725; 7,004,173; and 7,179,270, all of which are incorporated by reference for teaching reentry catheters, methods and for the purpose of written description and enablement requirements. These related art methods embody penetration of a needle exiting through either a side port or through a distal port, the needle must be oriented properly to ensure that the needle, when deployed, re-enters at a preferred location distal to the occlusion. One problem with these methods is a tendency of the catheter to back out as a result of the moment imposed by force required to penetrate the subintimal layers to gain access to the vessel true lumen. This is particularly problematic in the presence of calcified lesions causing an increase in the forces necessary for successful re-entry and, in many cases, requiring the physician to re-enter at a sub-optimal location.

SUMMARY OF THE INVENTION

[0008] The invention is directed to a medical device and method thereof that substantially obviates one or more of the problems due to limitations and disadvantages of the related art.

[0009] An advantage of the invention is the reduction in the forces required to cross the subintimal layer during device reentry into the true vessel lumen due to the articulating cannula or sharp member.

[0010] Yet another advantage of the invention is the reduction in the overall required size of the device since a long rigid element is not needed at the distal tip to support large reentry forces.

[0011] Still another advantage of the invention is improved stability and control of the distal tip during deployment of the cannula or interventional wire upon reentry from the subintimal space to the true vessel lumen thereby preventing against the device backing out or further separating the intima from the adventitia.

[0012] Yet another advantage of the invention is improved trackability and control, thereby allowing a physician or operator to re-enter the true vessel lumen at their preferred location close to the distal end of the total occlusion.

[0013] Additional features and advantages of the invention will be set forth in the description which follows, and in part will be apparent from the description, or may be learned by practice of the invention. The objectives and other advantages of the invention will be realized and attained by the structure particularly pointed out in the written description and claims hereof as well as the appended drawings.

[0014] To achieve these and other advantages and in accordance with the purpose of the present invention, as embodied and broadly described, is to provide a method for crossing an obstruction in a blood vessel. The method includes advancing a guide wire into an interstitial space of a vessel. Next, a catheter is advanced into the subintimal space with the aid of the guide wire. This may be accomplished using a traditional over the wire approach or using a rapid exchange catheter. For example, a rapid exchange reentry catheter method and catheter is described in U.S. Patent Application No. 61/503,477, which is hereby incorporated by reference as if fully set forth herein.

[0015] In one embodiment, a second wire or the original wire in an over the wire configuration, is advanced down a central lumen of a reentry member that is configured to deploy through at least one distal port to gain access to a vessel true lumen from a subintimal space.

[0016] In a preferred embodiment, the operator activates the reentry member through either a push or pull mechanism or the deployment of a balloon to direct the sharp from the subintimal space into the vessel lumen. Through this preferred embodiment, reentry into the true lumen of a vessel is accomplished at a location immediately distal to the total occlusion. It is noted that other locations may also be used for reentry. Preferably, the reentry member is configured to exit the lateral port and into the true lumen of the vessel from the subintimal space prior to advancement of an intervention wire through the lateral port.

[0017] Another aspect of the invention is directed towards a catheter system that includes a catheter having a proximal end, a distal end, lateral port, and at least one lumen. At least one lumen extends longitudinally through at least the lateral port of the catheter. The catheter includes a reentry member which is configured to gain access to a vessel true lumen from a subintimal space. The reentry member is configured to penetrate the vessel layers adjacent to the distal port. In a preferred embodiment, the reentry member has one or more sharpened edge surfaces along a distal portion of the cutting device. The reentry member is configured to have a hollow portion to receive an interventional guide wire.

[0018] Yet another aspect of the invention is directed towards a reentry catheter for use in forming a pathway in an interstitial space of an artery. The reentry catheter includes a catheter body including a proximal end, a distal end, at least one lumen, and at least one port. An exchange port is arranged on at least a distal portion of the catheter body and the exchange port includes at least one lumen configured to receive a guidewire and the catheter body is configured to track over the guidewire to a treatment site. A reentry member is slidably arranged within the lumen of the catheter body and is configured to deploy through the catheter body port. In one embodiment, the reentry member is configured to deploy from a first location within the interstitial space of an artery to a second location within a true lumen of the artery upon application of a substantially eccentric force to a distal portion of the reentry member.

[0019] Still yet another aspect of the invention is directed towards a reentry catheter for use in forming a pathway in an interstitial space of an artery. The reentry catheter includes a catheter body having a proximal end, a distal end, at least one lumen, and at least one port. An exchange port is arranged on at least distal portion of the catheter body. The exchange port is configured to receive a guidewire and the catheter body is configured to track over the guidewire to a treatment site. A reentry member having a proximal end, a distal end, at least one lumen is configured to be slidably positioned within the lumen of the

catheter body. The reentry member includes a portion having a sharp surface to permit dissection of a portion of an artery. A tether is coupled to a distal end portion of the reentry member and the reentry member is configured to deploy through the at least one port from a first location within the interstitial space of an artery to a second location within a true lumen of the artery upon application of a force to the tether.

[0020] It is to be understood that both the foregoing general description and the following detailed description are exemplary and explanatory and are intended to provide further explanation of the invention as claimed.

BRIEF DESCRIPTION OF THE DRAWINGS

[0021] The accompanying drawings, which are included to provide a further understanding of the invention and are incorporated in and constitute a part of this specification, illustrate embodiments of the invention and together with the description serve to explain the principles of the invention.

[0022] In the drawings:

[0023] FIG. 1 illustrates an exemplary side view of a reentry catheter according to an embodiment of the invention;

[0024] FIG. 2A illustrates an exemplary bottom-profile view of the reentry member illustrated in FIG. 1;

[0025] FIG. 2B illustrates an exemplary side-view of the reentry member illustrated in FIG. 1;

[0026] FIG. 2C illustrates an exemplary end-view of the reentry member illustrated in FIG. 1;

[0027] FIG. 3A illustrates an exemplary side view of the reentry member according to another embodiment of the invention;

[0028] FIG. 3B illustrates an exemplary end view of the reentry member according to FIG. 3A;

[0029] FIGS. 4A-4B illustrate a mechanism for controlling a reentry member according to another embodiment of the invention;

[0030] FIGS. 5A-5B illustrate a mechanism for controlling a reentry member according to another embodiment of the invention;

[0031] FIGS. 6A-6B illustrate a mechanism for controlling a reentry member according to another embodiment;

[0032] FIG. 7 illustrates an exemplary side view of a reentry catheter according to another embodiment of the invention; and

[0033] FIG. 8A-8H illustrates an exemplary method for using a medical device of FIG. 1 and FIG. 7.

DETAILED DESCRIPTION OF THE ILLUSTRATED EMBODIMENTS

[0034] The invention generally relates to a method and system for crossing an obstruction in a tubular member, e.g., crossing a chronic total occlusions in a blood vessel, and more particularly to a medical device method for crossing of an occlusion in a subintimal or interstitial space of an artery. Subintimal or interstitial region or space is at a location beneath at least a portion of intima and preferably at a location contained between the intima and the adventitia of the vessel. The terms tubular member, artery, vessel and bodily passable are used interchangeably throughout the specification.

[0035] An embodiment of invention is directed towards a catheter for insertion into a subintimal space. The catheter includes a proximal end, a distal end, at least one lateral port, and at least one lumen for receiving a guide wire. The at least one lumen extends longitudinally through at least the lateral port of the catheter. The catheter may also include an exchange port, e.g., RX port, arranged along an exterior portion of the catheter body and configured to receive a second wire or guide wire. The exchange port may be broken into two or more segments along the length of the catheter.

[0036] The catheter also includes a reentry member including at least one sharp surface and configured to operate out of a portion of the lateral port. In one embodiment, the reentry member is configured with one or more sharp surfaces near its distal end, e.g., in a tear drop cross-section configuration. Alternatively, the cutting surface may extend along the entire surface of the reentry member or only a predetermined portion. Preferably, the cutting surface is configured to gain access from the subintimal or interstitial region or space to the true lumen of the vessel. In one embodiment, the reentry member includes a lumen for receiving a guide wire or supplemental treatment device. These supplemental treatment devices may include guide wires, medical instruments, balloons, stents, laser catheters, optical fibers, visualization devices, medications and other medical instruments known in the art. In a preferred embodiment, the lumen portion of the reentry member is configured to receive a guide wire having a diameter in a range from about 0.01 inches to about 0.04 inches or larger.

[0037] In one embodiment, a catheter system includes a catheter body having a proximal end, a distal end, and at least one lumen wherein the lumen includes a lateral opening. A reentry member including at least one void space or cut out that enables flexing is formed in at least a distal portion of the reentry member. The reentry member is

configured to flex from a first a position to a second position upon application of a force to a distal region of the reentry member.

[0038] In another embodiment, a reentry catheter for use in forming a pathway in an interstitial space of an artery includes a catheter body including a proximal end, a distal end, at least one lumen, and at least one port. An exchange port is arranged on at least a distal portion of the catheter body. The exchange port includes at least one lumen configured to receive a guidewire and the catheter body is configured to track over the guidewire to a treatment site. A reentry member includes a proximal end and a distal end where distal end of the reentry member is configured to deploy through the at least one port from a first location within the interstitial space of an artery to a second location within a true lumen of the artery upon application of a substantially eccentric force to a distal portion of the reentry member.

[0039] Another embodiment is directed towards a reentry catheter for use in forming a pathway in an interstitial space of an artery. The reentry catheter includes a catheter body having a proximal end, a distal end, at least one lumen, and at least one port. An exchange port is arranged on at least distal portion of the catheter body. The exchange port includes at least one lumen configured to receive a guidewire and the catheter body is configured to track over the guidewire to a treatment site. The reentry member includes a proximal end, a distal end, at least one lumen extending from the proximal end to the distal end. A tether or flexible tension member is coupled to a distal end portion of the reentry member. The tether is configured to deploy at least a portion of the reentry member through the at least one port from a first location within the interstitial space of an artery to a second location within a true lumen of the artery upon application of a force to the tether.

[0040] Suitable materials for the reentry member include but are not limited to steel, alloys, nitinol, titanium, thermoplastics, including PEEK or polyimide, and combinations thereof and the like. The reentry member may also be configured to have a predetermined shape, i.e., resilient shape, straight shape, curved shaped, memory shape, and combinations thereof.

[0041] In one embodiment, the reentry member is moveable, flexible and/or bendable from first configuration to a second configuration, e.g., a retracted position to an operative position. The movement may be achieved upon application of a force, e.g., an eccentric force applied to a portion of the reentry member. In some embodiments, the force may be generated with at least one of a tether; a control wire; a guide wire with a hook; push member; pull member; ramp; wedge; balloon; electrically activated materials,

including electroactive polymers, thermo-active polymers, electroactive metals and combinations thereof.

[0042] The electrically activated materials may be activated with an electrical signal such as current or voltage as known in the art. For example, the catheter body or the reentry member may be constructed as described in U.S. Patent No. 7,951,186, which is hereby incorporated by reference.

[0043] In other embodiments, at least a portion of the reentry member may have a load or force built into the member. For example, the reentry member may have pre-resilient shape and contained within a shroud or other structure that prevents movement. After the shroud or other structure is removed, the reentry member is released from a first position to second position.

[0044] The catheter may be constructed from various materials as known in the art. For example, the catheter may be constructed from materials, such as polyesters; polyurethanes; polyamides; polyolefins including polyethylene and polypropylene; and any copolymers thereof. Some more specific examples of suitable materials include, but are not limited to: nylon; polyester elastomer; polyether/block polyamide, such as PEBAX, Hytrel, and/or Arnitel; polyamid such as Grilamid; fluoro-polymer, such as Kynar; polyether ether ketone (PEEK); polyethylene (PE); polyurethane; polyolefin copolymer (POC); tetrafluoroethylenes, such as polytetrafluoroethylene (PTFE).

[0045] Other suitable materials include steel, including laser cut stainless steel. The catheter may comprise coils as described in Fig. 9C as described in paragraphs [0101] and [0102] of U.S. Publication No. 2010/0063534, which is hereby incorporated by reference as if fully set forth herein. The catheter may comprise at least one lumen that is configured to allow supplemental treatment devices access to the interior of the lumen.

[0046] Another embodiment of the invention is directed towards a method for crossing an obstruction in blood vessel. The method includes advancing a first guide wire through a true lumen of vessel and into an interstitial space of the vessel. In some instances with severe calcification present, an undersized low profile balloon or other intervention dilation device may be used to pre-dilate the subintimal space prior to introduction of the reentry catheter. Next, the reentry catheter is advanced into the subintimal space through either an over the wire or via a rapid exchange technique with the reentry member in a stowed position. The catheter then advances through the subintimal space until the lateral port is distal to the total occlusion.

[0047] The orientation and the location of the catheter and its lateral port with respect to the occlusion may be directed through the use of radiopaque markers and visualization techniques known in the art. Once the catheter has been properly oriented, the operator moves the reentry member from the stowed or locked position and subsequently articulates the member such that a precise incision is made between the subintimal space and the true vessel lumen. A second interventional guide wire, in the case of a rapid exchange catheter, or the first guide wire for an over the wire configuration is advanced into the vessel lumen through the hollow portion of the reentry member. Once the intervention wire is in place, the reentry member may be retracted and the entire reentry catheter removed. Of course, more than one wire may also be used in the over the wire technique.

[0048] Yet another embodiment of the invention is directed towards a kit. The kit includes a catheter according to embodiments of the invention and optionally directions for use. The kit may also include a supplemental treatment device, e.g., a balloon, optical catheter, visualization catheter, stent, embolic protection device and the like. In addition, the kit may include valves and other devices that may be used in medical procedures.

[0049] FIG. 1 illustrates an exemplary side view of a reentry catheter according to an embodiment of the invention.

[0050] Referring to FIG. 1, a reentry catheter according to this embodiment is generally depicted as reference number 100. The catheter 100 is configured to permit a user to cross an obstruction, e.g., partial or total occlusion, in a subintimal space of a vessel. The catheter 100 also enables fast and simple true lumen reentry without the need for active visualization, e.g., IVUS visualization. Visualization may be used to assist procedures of the invention, e.g., the visualization may be active or passive. In one embodiment, visualization features are added as described with reference towards U.S. Patent Application Publication No. 2005/0171478, which is hereby incorporated by reference.

[0051] The catheter 100 is flexible and has a proximal end 102 and a distal end 104. The proximal end 102 is attached to a handle (not shown). A shaft 106 extends from the proximal end 102 of the catheter to the distal end of a rigid shroud or cover 108. The shaft 106 may be constructed of conventional techniques. In a preferred embodiment, the shaft includes braided, double braided, or by triplex construction as described in U.S. Patent Application No. 61/503,477, which is hereby incorporated by reference. A lateral port 110 is located near the distal end 104 and preferably in the rigid shroud 108. Alternatively, or in addition to, a lateral port (not shown) may also be located in the shaft 106. The shaft

106 includes at least one lumen 114 extending at least partially along the entire shaft 106 and exiting out the catheter distal end 104. In some embodiments, the lumen 114 may be used to provide supplemental treatment devices to the distal tip of the catheter 100.

[0052] The distal end of shaft 106 is connected to the proximal end of shroud 108 preferably by a laser weld, glue, over-molding or the like as known in the art. There may be more than one lateral port at a distal portion of the shroud 108.

[0053] Optionally, a flexible atraumatic tip 116 may be attached to the distal end of the shroud 108 preferably by a laser weld, glue, over-molding or the like as known in the art. Alternatively, the shroud or cover 108 may extend to the catheter distal end 104 and be formed with an atraumatic tip profile. Further, an over molded distal extension (not shown) of the catheter may be incorporated to provide additional support during device orientation and during launch of the reentry member 112. The reentry member 112 is docked in a straight position, as shown in FIG. 1 while traversing through an artery and into or reversed out of the subintimal vessel space. Alternatively, a retractable shroud or cover (not shown) may be used to protect the vessel during catheter transport through the body.

[0054] At least one marker, e.g., a radiopaque marker, 118 is disposed on the body of the catheter near its distal end or integrated within the body of the catheter. The radiopaque marker 118 is used with standard visualization techniques, e.g. fluoroscopy, to guide the catheter through the body and into position in the subintimal space, to position the lateral port 110 and reentry member 112 at a desired location distal to the occlusion, and to determine whether the reentry member 12 is in the stowed, ready, or in a fully articulated position. Radiopaque markers as described in U.S. Patent Application No. 61/503,477, U.S. Patent Application 2010/0317973, U.S. Patent 6,544,230, U.S. Patent 6,719,725, or U.S. Patent 6,231,546 may also be used, which are hereby incorporated by reference as if fully set forth herein.

[0055] The reentry member 112 may be configured to permit other devices or supplemental devices to be operated through the lumen of the member 112. The supplemental devices may include a balloon, a cutting device, thrombectomy device, a guide wire, a filters, e.g., an embolic filter, optical devices, e.g., RF or laser ablation devices, combinations and the like. In addition, the reentry member 112 may be configured to have a predetermined shape, i.e., pre-resilient shape, straight shape, curved shaped, memory shape.

[0056] In a preferred embodiment, the lumen of the reentry member 112 is sized to accommodate a wide range of guide wire diameters such as guide wire diameters in a range

from about 0.01 inches to about 0.04 inches or larger. Referring to FIG 1, guide wire 120 is shown passing through a lumen of the reentry member 112 in its stowed position and passing through the distal end 104 of the catheter as would be the case when the catheter travels through the body and into or out of the subintimal space.

[0057] FIG. 2A illustrates an exemplary bottom-profile view of the reentry member illustrated in FIG. 1. FIG. 2B illustrates an exemplary side-view of the reentry member illustrated in FIG. 1. FIG. 2C illustrates an exemplary end-view of the reentry member illustrated in FIG. 1.

[0058] Referring to FIGS. 2A - 2C, reentry member 112 is constructed with at least one void or cut geometry 124 that enables flexing. For example, when a force is placed at a distal region of the reentry member flexing or deflection of the distal region of the reentry may be achieved. In this embodiment, a diamond pattern 124 along the axis of the reentry member 112 is formed at least along a distal region of the reentry member 112. Though a diamond shape is illustrated in Figure 2A, it is understood that the diamond shape may be any suitable geometric shape or combination of different geometric shapes, e.g., squares, triangles, rectangles, ovals, circles, hexagons, octagons, pentagons, and combinations thereof. Furthermore, the cut geometry 124 may be spaced at different distances along the reentry member 112 and the number of cut geometries 124 along the articulating cutting device may be varied. As more cut geometry 124 are used, it is easier to flex the reentry member 112 upon application of a force.

[0059] At least one portion of the bottom distal edge of the reentry member 112 is formed with a sharp leading edge 126. The reentry member 112 is hollow with a lumen 128 that is continuous with catheter lumen 114. The cut out or void 124 may also be spaced at various locations around the circumference of the reentry member 112 relative to a leading edge 126, e.g., about 2 degrees to about 180 degrees. In a preferred embodiment, the center of the cut out or void 124 is about 180 degrees relative to a leading edge 126. A sharp edge 156 at distal tip of the reentry member 112 may also be utilized in this embodiment.

[0060] FIG. 3A illustrates an exemplary side view of the articulating cutting device according to another embodiment of the invention. FIG. 3B illustrates an exemplary end view of the articulating cutting device according to FIG. 3A.

[0061] Referring to FIGS. 3A-3B, the reentry member 112 in this embodiment includes a shaft or hollow tube with a bottom edge profile. The bottom edge profile may also contain void or cutout geometry 124 to provide flex or curvature during device reentry.

At least a portion of the bottom distal edge of the reentry member 112 is formed with a sharp leading edge 126. The reentry member 112 is hollow with a circular lumen 128 that is continuous with catheter lumen. An additional sharp edge 156 is arranged at distal tip of the reentry member 112.

[0062] FIG. 4A illustrates a mechanism for controlling the reentry member according to another embodiment of the invention. FIG. 4B illustrates a mechanism of FIG. 4A for controlling the reentry member.

[0063] Referring to FIG 4A and 4B, a control wire 130 is coupled at an end region 132 of the reentry member 112 along an axis eccentric to the longitudinal axis of the device. In this embodiment, the control wire 130 is coupled to an inside surface of the reentry member 112. The control wire 130 may be coupled to the reentry member by any suitable technique, including but not limited to bonding, welding, mechanically coupled or combinations thereof.

[0064] In another embodiment, the control wire 130 may be the guide wire 120 configured to attach to distal portion of the reentry member 112, for example with a hook on the end of the guide wire 120.

[0065] During reentry, an operator would mechanically control the reentry member 112 by holding the catheter 100 in place and by pulling the control wire 130 as shown with the arrow in FIG. 4B. The control wire 130 is configured to transmit force from the proximal end of the catheter 100 to articulating or flexing at least a portion of the reentry member 112. The eccentric location of the control wire 130 and the placement of the coupled end 132 are such that a moment is created on the device causing it to move from a first position in FIG. 4A to a second position in FIG. 4B. This movement, bending or articulation is from an orientation of about parallel to the vessel wall to an orientation between about 0 and about 180 degrees of the vessel wall and more preferably between about 5 and about 90 degrees with respect to the vessel wall and allowing the sharp edge 126 to penetrate the vessel wall.

[0066] The control wire may be comprised of at least one tendon, tether, coil, cable, linkage and made of a suitably flexible material capable of withstanding a high tension load such as Kevlar, Nylon, Nitinol, biocompatible metal wire, or other material known in the art.

[0067] FIGS. 5A-5B illustrate a mechanism for controlling the articulating cutting device according to another embodiment of the invention.

[0068] Referring to FIGS. 5A-5B, a tether element 136 is coupled at a location 132 near the distal end of the reentry member 112 and the tether element 136 is coupled at

proximal end of to the shroud 108 or catheter shaft 106 at a point proximal to the most proximal void or cut out 134.

[0069] During reentry, an operator would control the reentry member 112 by holding the catheter 100 in place and pushing the reentry member 112 in the direction of the arrow 140. The pushing force is configured to provide the necessary force to curve or flex the distal end of reentry member 112 from a first orientation, e.g., parallel to the vessel wall to a second orientation between about 0 and about 180 degrees of the vessel wall and more preferably between about 5 and about 90 degrees with respect to the vessel wall. Thereby, allowing a leading edge 156 of the reentry member 112 to penetrate the vessel wall and reenter a true lumen of the vessel. Alternatively the control wire 130 in FIG. 4 or the tether 136 in FIG. 5 may be comprised of a pull cable or mechanical linkage as known in the art. Optionally, mechanical advantage components such as levers, manual gearing or electro-mechanical gearing may be incorporated near the proximal end of the catheter and more preferably in the handle such that the reentry member 112 may be mechanically controlled through a simple one-handed operation. In a preferred embodiment, the tether element 136 includes a rigid linkage is coupled to the proximal end of the element and coupled to a translating actuator on a handle. Translational movement of the actuator would place the tether element in tension causing the reentry member to articulate through the lateral port. Alternatively, other actuating mechanisms such as knobs, and the like, as known in the art can be utilized.

[0070] FIGS. 6A-6B illustrate a mechanism for controlling the reentry member according to another embodiment of the invention.

[0071] Referring to FIGS. 6A-6B, the reentry member 112 is deployed with use of elastomeric device, e.g., a balloon, located inside the distal portion of the catheter near the lateral port 110. The reentry member 112 is shown in stowed position in FIG. 6B. In a preferred embodiment, a high pressure, non-compliant balloon 142 is located in the distal end region of the reentry catheter 100, preferably within the rigid shroud 108, and above the lateral port opening 110 and the reentry member 112. An inflation lumen 144 is in fluid communication with the deployment balloon 142 and an inflation port 146 located along the shaft 106 at a location proximal to the rigid shroud 108 or at or near a proximal hub the catheter (not shown).

[0072] After inflation of the balloon 142 the reentry member 112 moves to a second position or a non-stowed position. More specifically, the non-compliant balloon 142 exerts an eccentric load on the top edge of the reentry member 112 to deliver the necessary force

to curve or flex the distal portion of the reentry member 112 from an orientation about parallel to the vessel wall to an orientation between about 0 and about 180 degrees of the vessel wall and more preferably between about 5 and about 90 degrees with respect to the vessel wall.

[0073] After articulated to a predetermined position, the entire catheter body, if necessary, may be pulled proximally causing the intimal tissue to be forced against the sharp leading edge 156 creating a subintimal arteriotomy. This action may be controlled mechanically using the controls integrated in the proximal handle (not shown). The distal tip of the reentry member 112 would then be inside the true lumen of the vessel and a guide wire 120 or supplementary intervention device may be passed through the central lumen of the reentry member 112.

[0074] FIG. 7 illustrates an exemplary side view of a reentry catheter according to another embodiment of the invention. Referring to FIG. 7, a reentry catheter according to this embodiment is generally depicted as reference number 200. An exchange port 222, e.g., rapid exchange port, is eccentrically located near the distal end of shaft 206. The exchange port 222 may include a jacketed polyimide tube trimmed flush to the profile of the device after processing to facilitate tracking and back loading of a first guide wire 220. The exchange port 222 may be sized to extend past a distal end of the catheter, be flush with the distal end of the catheter, or terminate a location proximal the distal end of the catheter. Preferably, the guide wire 220 may have a diameter in a range from about 0.01 inches to about 0.04 inches or greater and be constructed of a range of materials as known in the art. In addition, the wire 220 may have lubricous coating, e.g., PVP thin film or PTFE, and/or a predetermined shape. Additionally, the wire 220 may be removed allowing supplemental treatment devices access to the distal tip of the catheter. Additionally, the wire 220 may be removed allowing supplemental treatment devices access to the distal tip of the catheter. The supplemental treatment devices include but are not limited to, guide wires, medical instruments, balloons, stents, laser catheters, medications, optical catheters and other medical instruments known in the art

[0075] The catheter 200 is flexible and has a proximal end 202 and a distal end 204. The proximal end 202 is attached to a handle (not shown). A shaft 206 extends from the proximal end 202 of the catheter to the distal end of a rigid shroud 208. The shaft 206 may be constructed of conventional techniques, e.g. braided or double braided, or by triplex construction as described herein. A lateral port 210 is located near the distal end and preferably in the rigid shroud 208. Alternatively, or in addition to, a lateral port (not

shown) may also be located in the shaft 206. The shaft 206 includes a lumen 214 extending at least partially along the entire shaft 206.

[0076] A reentry member 212 may be contained in the inner lumen of shaft 206 along substantially the length of catheter 200. In some embodiments, the reentry member 212 is hollow and allows for an optional second guide wire, cannula or other supplemental treatment device 224. The distal end 204 of shaft 206 is connected to the proximal end of shroud 208 preferably by a laser weld, glue, over-molding or the like as known in the art. There may be more than one lateral port at a distal portion of the shroud 208. Optionally, a flexible atraumatic tip 216 may be attached to the distal end of the shroud 208 preferably by a laser weld, glue, over-molding or the like as known in the art. Alternatively, the shroud 208 may extend to the catheter distal end 204 be formed with an atraumatic tip profile.

[0077] Further, an overmolded distal extension (not shown) of the catheter may be added to a distal end of the catheter 200 as described in U.S. Patent Application No. 61/503.477, which is hereby incorporated by reference as if fully set forth herein. The over molded distal extension is configured to provide additional support during device orientation and during launch of the reentry member 212. The reentry member 212 is docked in a straight position, while traversing through an artery and into or out of the subintimal vessel space. Alternatively, a retractable shroud cover (not shown) may be used to protect the vessel during catheter transport through the body. The reentry member 212 may be mechanically controlled through the use of a tension member, a tether member or a balloon as described herein. Optionally, an additional lumen may be contained within the catheter 200 that may be used for supplemental treatment devices.

[0078] The catheter 200 optionally may include at least one radiopaque marker 218. In a preferred embodiment, the radiopaque markers are configured to ensure orientation of the lateral port towards the true lumen of the vessel. The radiopaque markers may also be configured to determine a spatial relationship of other attributes of the catheter, e.g., the spatial location of the distal end of the catheter, confirmation of the stowed position of the reentry member, etc. In a preferred embodiment, at least one marker 218 is arranged near a distal portion of the catheter.

[0079] FIGS. 8A-8H illustrates an exemplary method for using a medical device of FIG. 1 and FIG. 7.

[0080] Referring to FIGS. 8A-8E, a guide wire 802 is advanced to an occlusion 806 in an attempt by the physician to cross the occlusion 806 to use conventional interventional

devices such as laser atherectomy catheters, balloons, drug delivery devices, stents and the like. This advancement of the guide wire 802 is done in accordance with techniques known in the field of cardiology, interventional radiology and the like. In some instances, the physician is unable to cross through the lesion from the proximal lesion end to a point distal the lesion through the true lumen of the vessel. In these instances, as shown in FIG 8A, the guide wire 802 may unintentionally or intentionally enter the subintimal space 804 after reaching the total occlusion 806. The guide wire 802 may include lubricious coating and have diameter in a range from about 0.01 inches to about 0.04 inches or larger. In addition, the guide wire 802 may be shapeable, deformable, or have other attributes designed for crossing an occlusion 806 directly or indirectly.

[0081] Referring to FIG. 8B, after the guide wire 802 has reached the subintimal space 804, a catheter 100 is advanced over the guide wire 802 into the subintimal space 804. Alternatively for the embodiment shown in FIG. 7, reentry catheter 200 would advance through RX port 222 into the subintimal space 804. Of course, any catheter described herein may also be used and reference to catheter 100 and 200 is done merely out of convenience. Next, the catheter 100 is advanced to a position distal of the occlusion 806.

[0082] Referring to FIG. 8C, the catheter 100 is oriented to position such that the lateral port 110 is distal the occlusion 806. In a preferred embodiment, the orientation of the catheter 100 may be conducted with utilization of the radiopaque markers 118 as described previously and with reference to U.S. Patent Application No. 61/503,477, which is hereby incorporated by reference as if fully set forth herein. For example, in a preferred embodiment the catheter 100 is configured such that different views on fluoroscopic images enable the operator to align the lateral port 110 so that the reentry member 112 or other instrument, e.g., guide wire, working element, and the like, are aligned with a true lumen of the vessel. It is noted that other active or passive visualization techniques as known in the art may also be utilized to orient the lateral port 110 with a true lumen. Other visualization techniques may also be used to aid in orientation including incorporation of an active visualization element, such as an ultrasonic transducer or optical sensing element at a location either within the at least one catheter lumen, on or within the catheter body, or on or near the lateral port.

[0083] Once the catheter 100 is in position at a location distal to the occlusion 806 and the lateral port 110 and the reentry member 112 are oriented to articulate and launch into the true vessel lumen, the operator retracts the guide wire 802 to a position within the

reentry member, as shown in Fig. 8D. The operator would then transition the reentry member 112 from a stowed, safe position, to a ready position in preparation for activation of the mechanical control for reentry. Alternatively this could involve retraction of a guard on the rigid shroud (not shown). Referring to FIG. 8E, reentry into the true vessel lumen is accomplished by the operator holding the catheter in place and articulating the reentry member 112 by either application of a tension load as described in FIGS. 4A-4B, a push mechanism as described in FIGS. 5A-5B or through inflation of an internal balloon as described in FIGS. 6A-6B. In the alternative or in addition to, the activation mechanism may be linked to a simple handle such that the operator either rotates a knob or activates a mechanical or electro-mechanical control element to transition from a ready to an articulated or flexed configuration. The intervention guide wire 802 or another appropriate device may be passed through the shaft lumen 114 and the lumen 128 of the reentry member 112 into the true vessel lumen.

[0084] Alternatively for a rapid exchange configuration as described in FIG. 7 and FIG. 8F, retraction of guide wire 802 is not required. As with the previous embodiment, the operator would transition the reentry member 212 from a stowed, safe position, to a ready position in preparation for activation of the mechanical control for articulation. Alternatively this could involve retraction of a guard on the rigid shroud (not shown). Reentry into the true vessel lumen is accomplished by the operator holding the catheter 200 in place and articulating the reentry member 212 by techniques as described with regard to FIGS. 4A-4B, a push mechanism as described with regard to FIGS. 5A-5B or through inflation of an internal balloon as described with regard to FIGS. 6A-6B.

[0085] The activation mechanism may be linked to a simple handle (not shown) such that the operator either rotates a knob or activates a mechanical or electro-mechanical control element to transition from a ready to an articulated or flexed configuration. The guide wire 802 or another appropriate device may be passed through the shaft lumen 214 and the lumen of the reentry member 212 and into the true vessel lumen. The intervention guide wire may be sized from about 0.10 inches to about 0.40 inches or larger and may contain a lubricous coating as known in the art.

[0086] The reentry member 212 reenters the vessel lumen at an angle in a range from about 5 degrees to about 180 degrees, more preferably at an angle in range from about between about 5 degrees to about 90 degrees. The sharp edge 156 and/or 126 on the reentry member dissects the vessel wall from the subintimal space 804 into the true vessel lumen. The cutting action significantly reduces the force required to safely and accurately

reenter the vessel lumen even in the presence of calcified tissue. This reentry force is significantly lower than the forces required for known reentry devices, which require lateral extension of the catheter and improved torsional control to support reentry forces. During reentry, the vessel wall tends to pull away from a more traditional reentry cannula tip during reentry such that penetration will require an increased force application and possible multiple attempts to successfully enter the lumen. The use of a reentry member overcomes this challenge posed by the prior art and allows the operator to reenter at their preferred location easily and repeatedly. Moreover, it is thought that the use of the reentry member results in more consistent reentry at a location closer to the distal point of the occlusion 806 as compared to the use of a simple curved cannula as known in the art.

[0087] Referring to FIGS. 8E-8H, after the proper reentry of the reentry member 112 has been confirmed to be directed towards the true lumen of the vessel, another instrument, e.g., guide wire, working element, and the like, exits the lateral port 110 and reenters the vessel. Once the intervention guide wire or intervention device is in position, the reentry member is retracted back into the lateral port 110 of the catheter 100 and the catheter is removed as shown in FIG. 8H. Optionally, both the catheter 100 and guide wire 802 may be left in place. Now that the total occlusion 806 is crossed various interventional procedures as known in the art may be performed. For example, a balloon catheter (not shown) may be used to dilate the subintimal space along with possible stent placement (not shown) to provide an alternative lumen through the subintimal space 804 and back into the true vessel to restore adequate blood flow post-procedure.

[0088] It will be apparent to those skilled in the art that various modifications and variation can be made in the present invention without departing from the spirit or scope of the invention. Thus, it is intended that the present invention cover the modifications and variations of this invention provided they come within the scope of the appended claims and their equivalents.

WHAT IS CLAIMED IS:

1. A catheter system, comprising:
a catheter body having a proximal end, a distal end, at least one lumen and a lateral opening; and
a reentry member comprising at least one void space in a circumferential portion of the reentry member that is configured to enable flexing from a first a position to a second position when an axial eccentric load is placed at a distal portion of the reentry member.
2. The catheter system of claim 1, wherein the axial eccentric load is applied with at least one of a control wire, a cabling device, a ramp, and an elastomeric member.
3. The catheter system of claim 1, wherein the reentry member comprises a material selected from the group consisting of an electroactive polymer, a thermo-active polymer, an electroactive metal and combinations thereof.
4. The catheter system of claim 3, wherein the axial eccentric load is applied with an electrical signal applied to the reentry member.
5. The catheter system of claim 1, wherein the reentry member comprises a pre-resilient shape.
6. The catheter of claim 1, wherein the reentry member comprises a material selected from the group consisting of stainless steel, nitinol, alloy, titanium, thermoplastics, polyether ether ketone (PEEK), polyimide, and combinations thereof.
7. The catheter of claim 1, wherein the catheter body further comprises a second lumen, wherein the second lumen is configured to received a guide wire having a range from about 0.01 inches to about 0.04 inches.
8. The catheter of claim 1, wherein the catheter body comprises a material selected from the group consisting of a polyester, a polyurethane, a polyamide, a polyolefin, a polyethylene, a polypropylene, a nylon, a polyester elastomer, a polyether/block polyamide, a PEBAX, a Hytrel, an Arnitel, a polyamide, a Grilamid, a flouro-polymer, a Kynar, polyether ether ketone, a polyethylene, a polyurethane, a polyolefin copolymer, a tetrafluoroethylenes, a polytetrafluoroethylene, a steel, a laser cut stainless steel and combinations thereof.
9. The catheter of claim 1, wherein the at least one lumen of the catheter body is configured to receive a supplemental treatment device.
10. The catheter of claim 9, wherein the supplemental treatment device is selected from the group consisting of a guide wire, a medical instrument, a balloon, a stent, a laser catheter, a medication, optical catheter and combinations thereof.

11. The catheter of claim 1, further comprising at least one radiopaque marker arranged on distal portion of at least one of a reentry member and catheter body.

12. The catheter of claim 1, wherein the at least one void space comprises a plurality of cut out sections.

13. The catheter of claim 12, wherein the plurality of cut out sections comprise at least one of the following geometrical configurations a tear drop configuration, a diamond configuration, a square configuration, a pentagon configuration, a hexagon configuration and combinations of the same.

14. The catheter of claim 1, further comprising an exchange port arranged on at least distal portion of the catheter body, wherein the exchange port comprises at least one lumen configured to receive a guidewire and the catheter body is configured to track over the guidewire to a treatment site.

15. A reentry catheter for use in forming a pathway in an interstitial space of an artery, comprising:

- a catheter body including a proximal end, a distal end, at least one lumen, and at least one port;

- an exchange port arranged on at a least distal portion of the catheter body, wherein the exchange port comprises at least one lumen configured to receive a guidewire and the catheter body is configured to track over the guidewire to a treatment site;

- a reentry member having a proximal end, a distal end, at least one lumen extending from the proximal end to the distal end, wherein the distal end includes a portion having a sharp surface to permit cutting, and wherein the reentry member is configured to be slidably advanced within the at least one lumen of the catheter body; and

- a tether coupled to a distal end portion of the reentry member, wherein a distal end portion of the reentry member is configured to deploy through the at least one port from a first location within the interstitial space of the artery to a second location within a true lumen of the artery upon application of a force to the tether.

16. A method of crossing an obstruction in a blood vessel, comprising the steps of:
advancing a first guide wire into a lumen of the vessel towards the obstruction in the vessel;

- advancing the first guide wire into a subintimal space of the vessel to a location distal of the obstruction;

- advancing a catheter comprising reentry member over the guide wire to a location where a port of the catheter is at a location distal of the obstruction; and

cutting with the reentry member from a first location within the subintimal space of the artery to a second location within a true lumen of the vessel.

17. The method of claim 13, further comprising the steps of:

returning the reentry member from the second location to the first location; and removing the reentry catheter from the vessel.

18. The method of claim 13, wherein the cutting step comprises inflating an elastomeric member.

19. The method of claim 16, wherein the cutting step comprises applying an electrical signal to the reentry member.

20. The method of claim 13, wherein the cutting step comprises applying a force to a control wire, cable, or tether element.

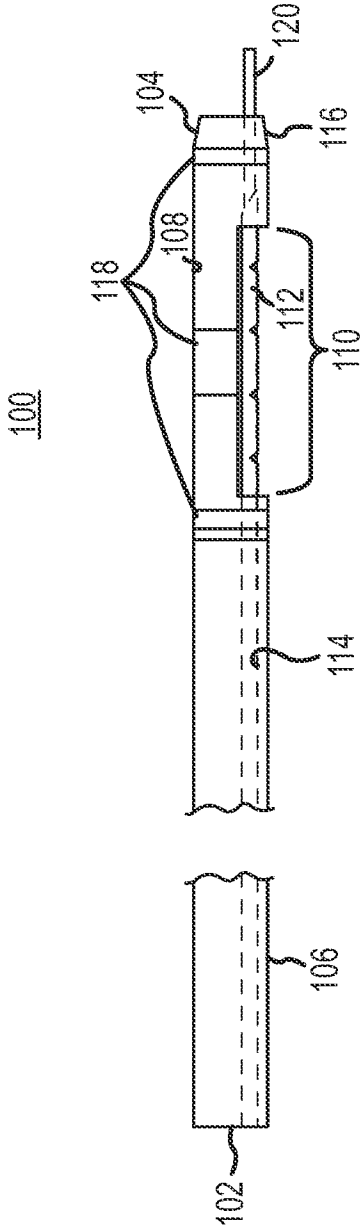


FIG.1

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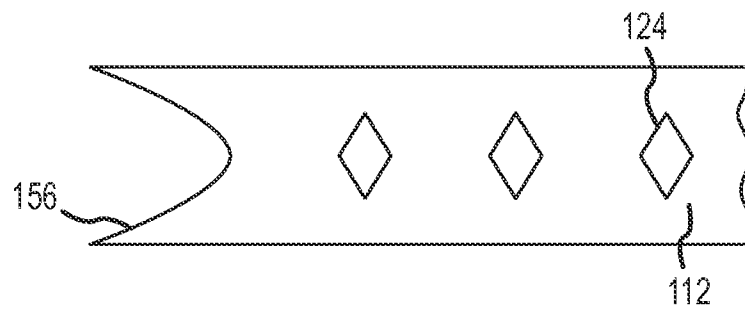


FIG. 2A

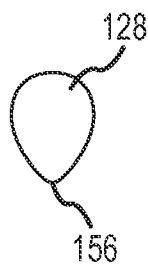


FIG. 2C

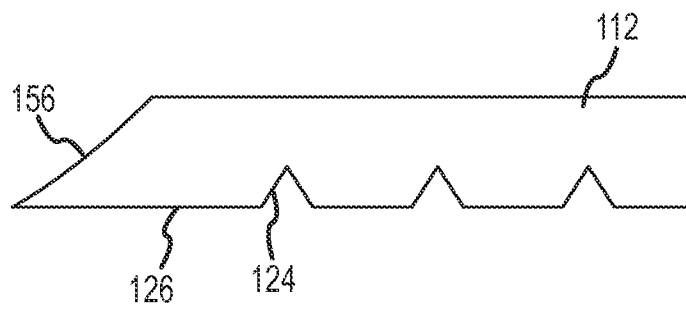


FIG. 2B

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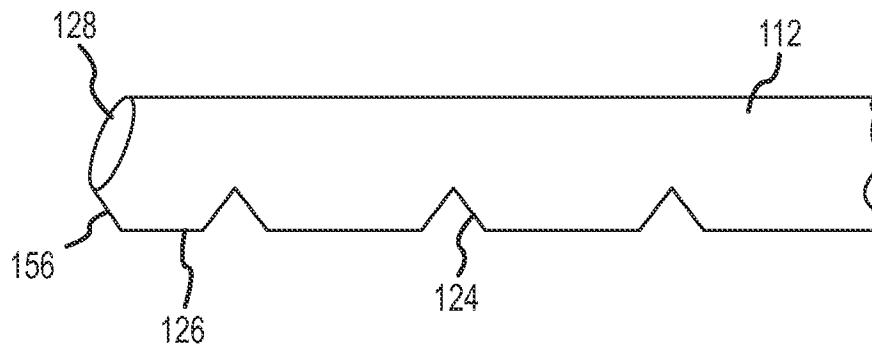


FIG. 3A

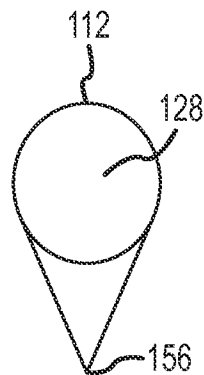


FIG. 3B

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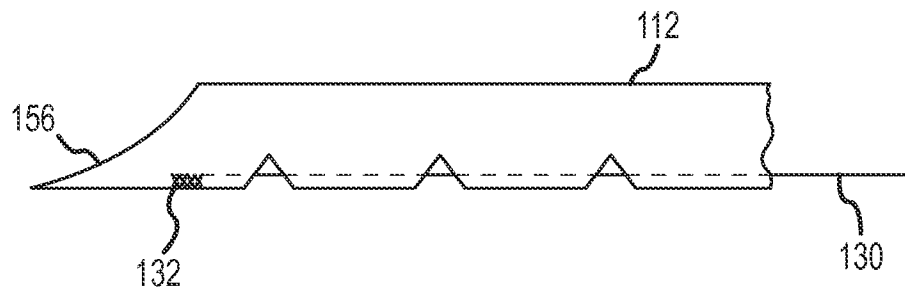


FIG. 4A

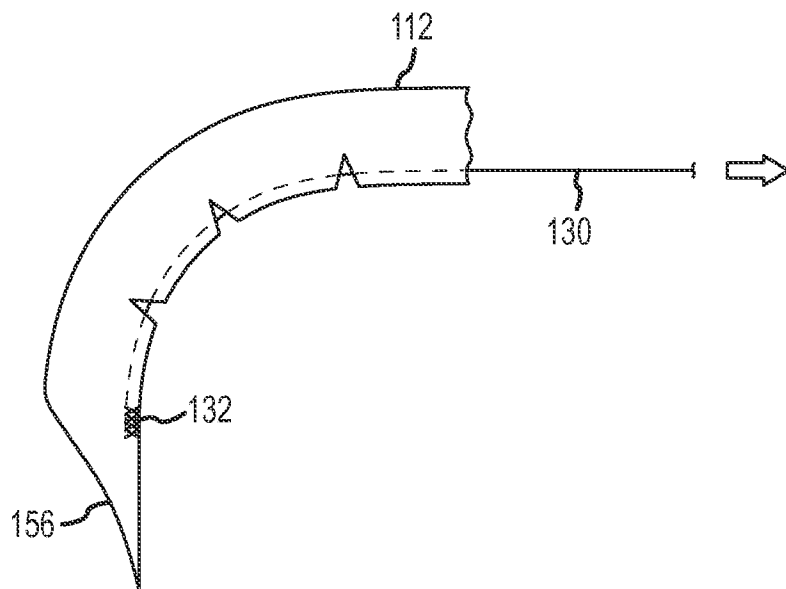


FIG. 4B

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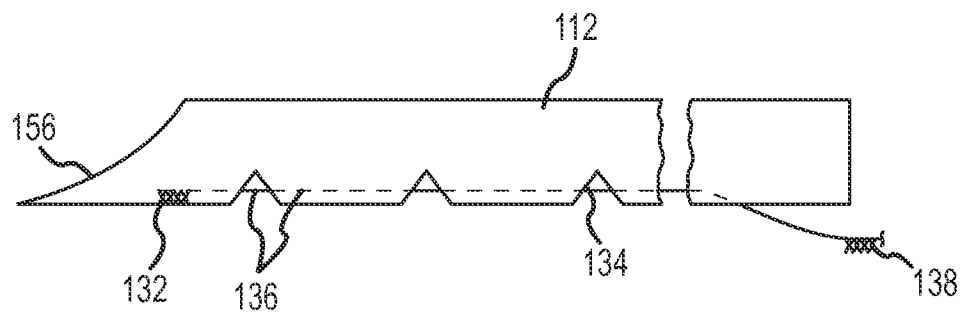


FIG. 5A

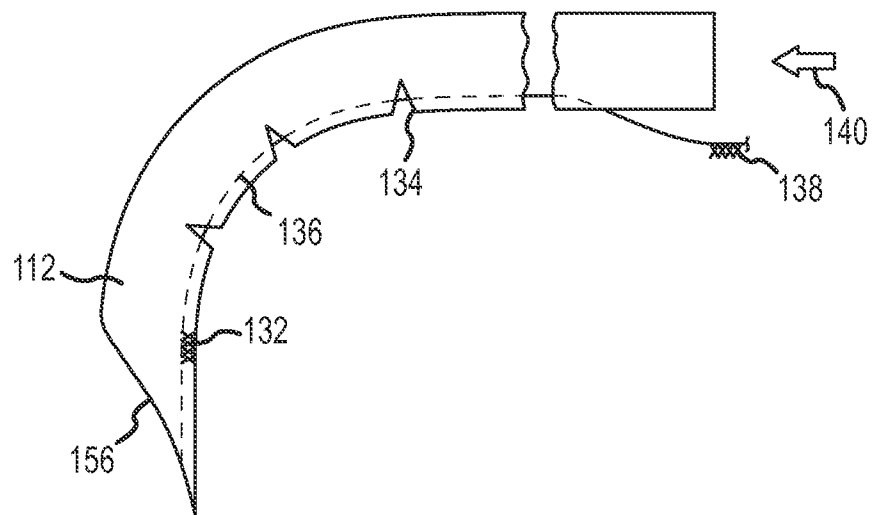


FIG. 5B

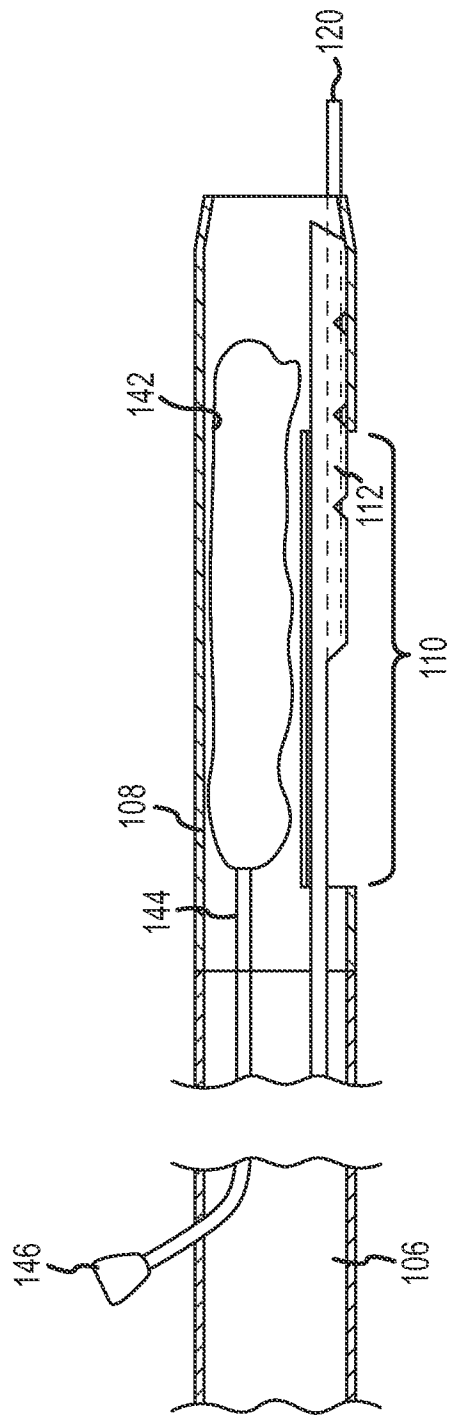


FIG. 6A

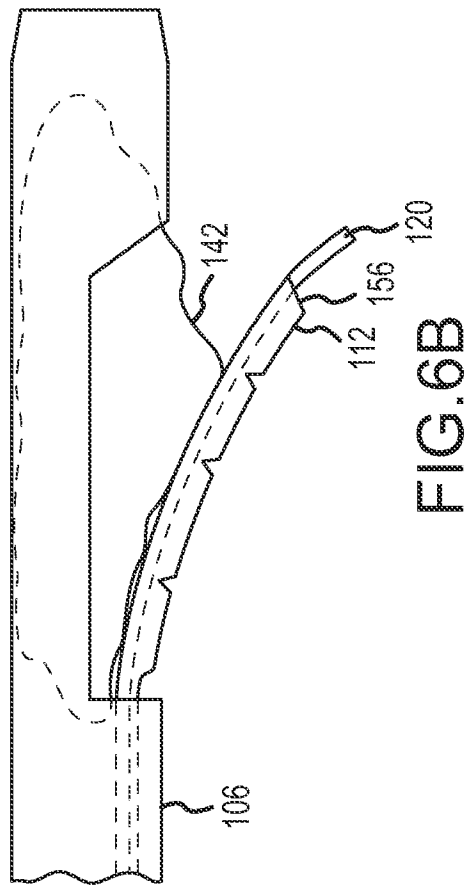


FIG. 6B

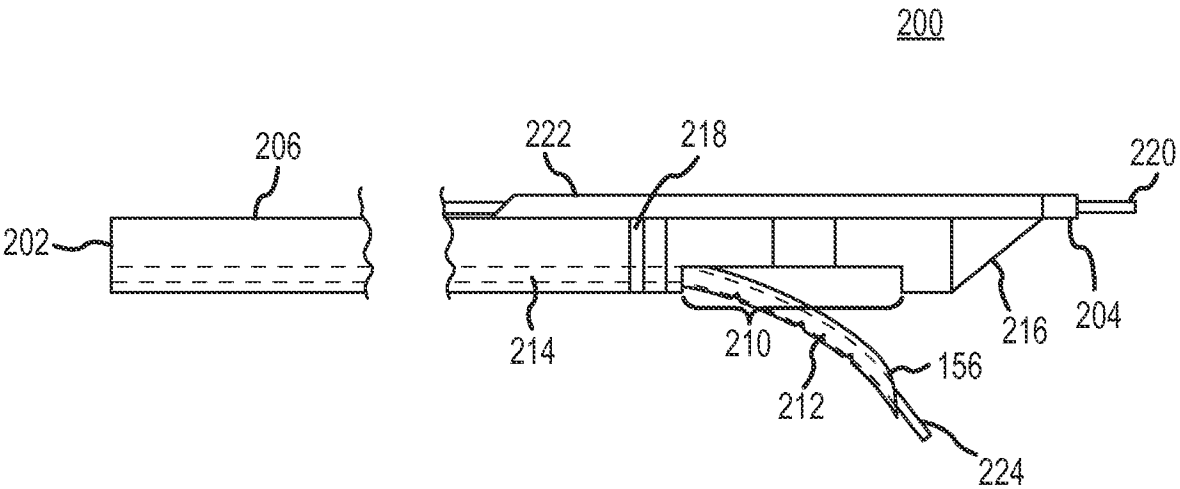


FIG.7

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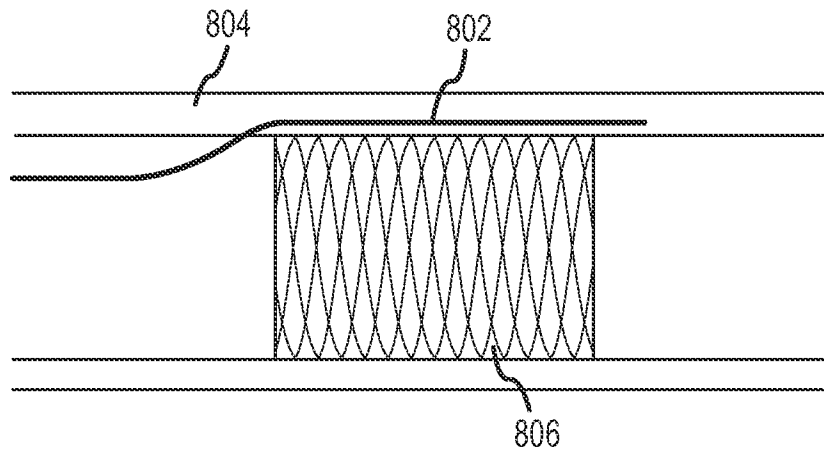


FIG. 8A

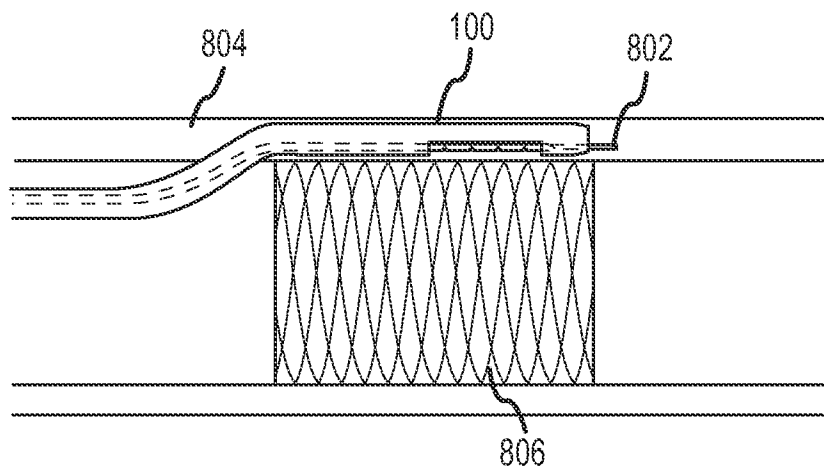


FIG. 8B

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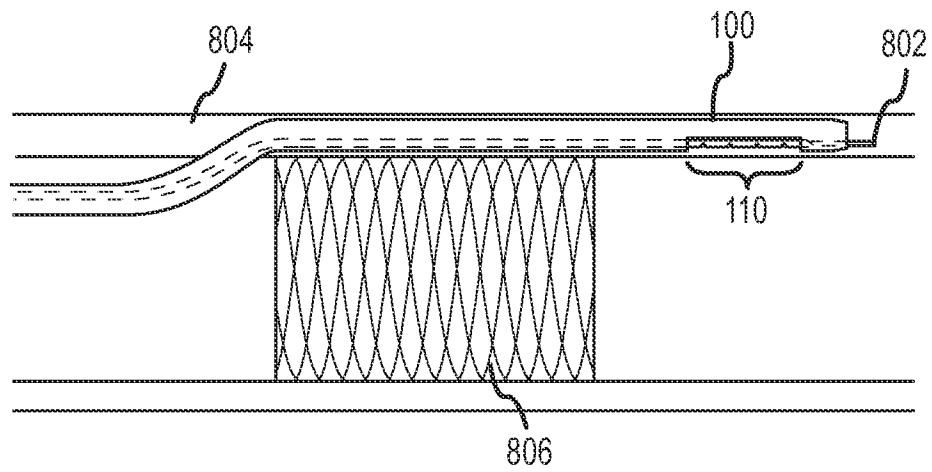


FIG. 8C

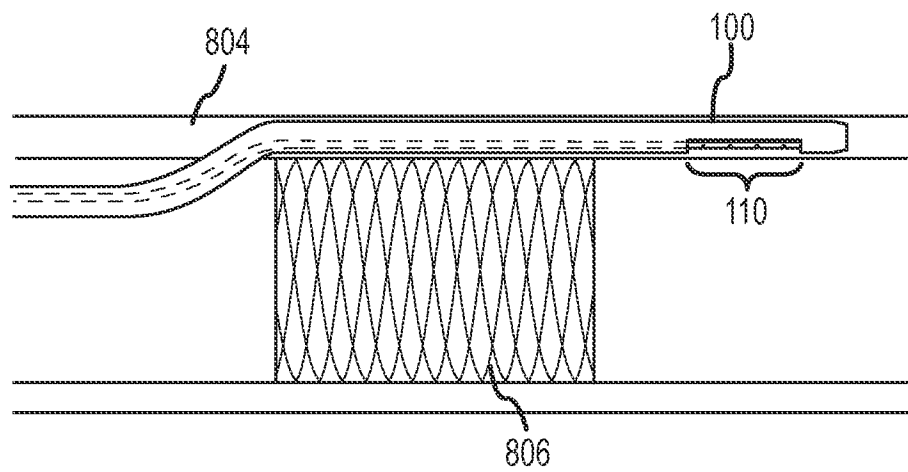


FIG. 8D

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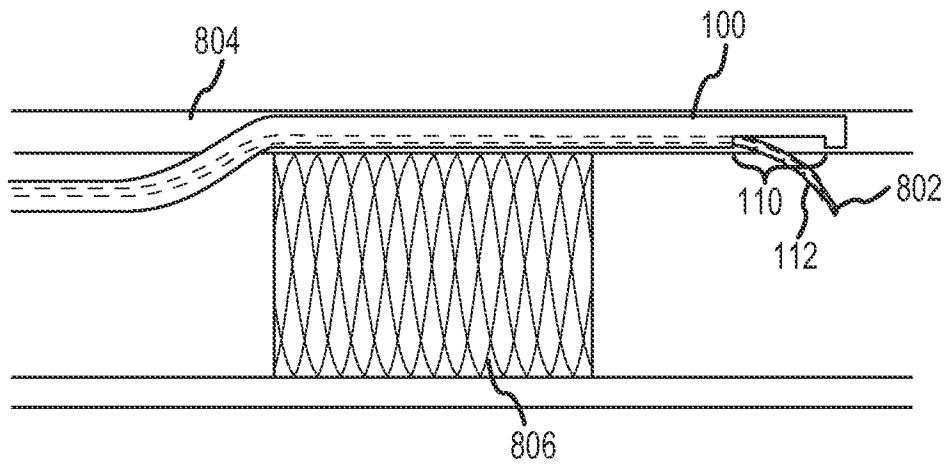


FIG. 8E

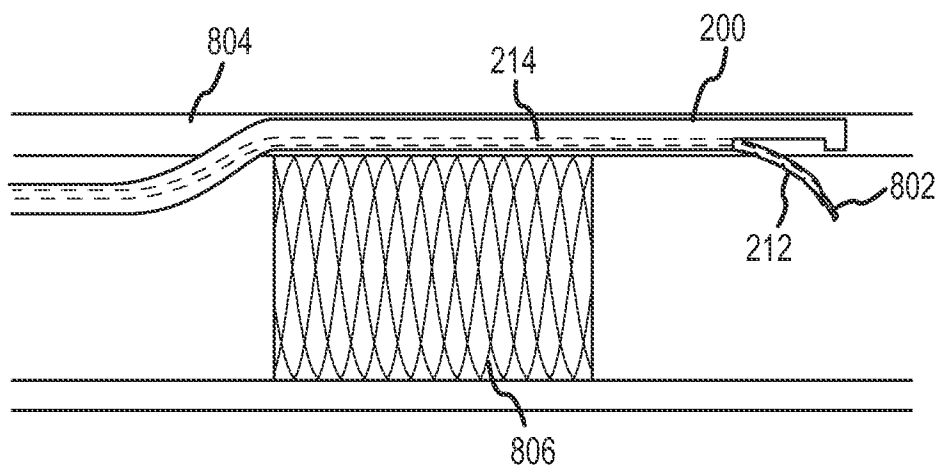


FIG. 8F

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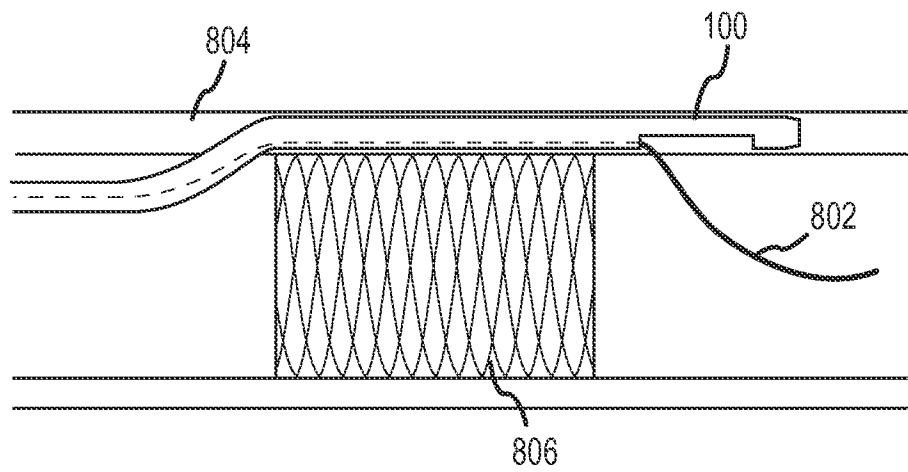


FIG. 8G

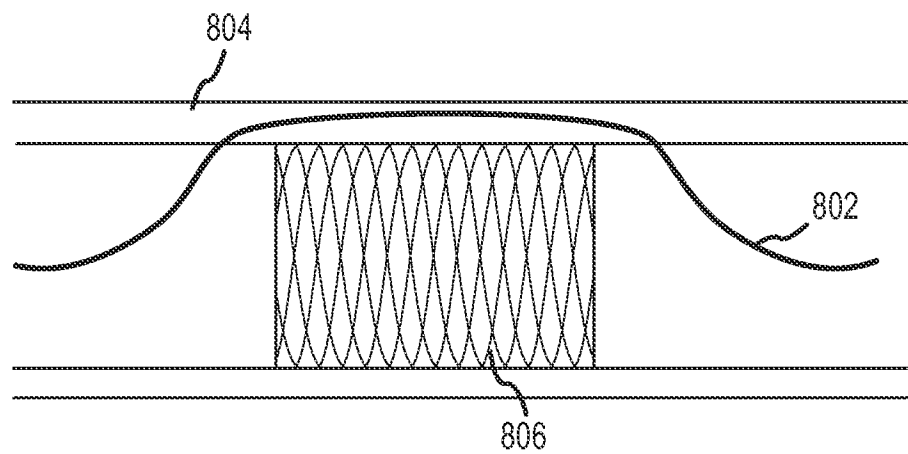


FIG. 8H

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 12/52858

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61M 25/01 (2012.01)

USPC - 604/528

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(8) - A61M 25/01 (2012.01)

USPC - 604/528

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

IPC(8) - A61M 25/00, 25/01, 25/06, 25/08, 25/088, 25/09, 25/092 (2012.01)

USPC - 604/19, 48, 93.01, 264, 523, 524, 525, 528

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

PubWEST (PGPB, USPT, EPAB, JPAB); PatBase; Google (Patents, Scholar, Web)

Search Terms: Catheter, opening, aperture, lateral, side, reentry, re-entry, member, element, occlusion, polyester, polyurethane, polyamide, polyolefin, polyethylene, polypropylene, nylon, polyetherblock, PEBAX, hytrel, amitel, polyamide, grilamid, fluoro-polymer,

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X =====	US 2001/0000041 A1 (Selmon et al.) 15 March 2001 (15.03.2001) Fig. 7-9, 13A-13C, 20; Para [0045]-[0046], [0049], [0058]	1-2, 5-7, 9-12, 14 =====
Y		3-4, 8, 13
Y	US 2007/0250036 A1 (Volk et al.) 25 October 2007 (25.10.2007) Fig. 1A-2C; Para [0010]-[0012], [0072], [0077], [0116]-[0117], [0133]-[0134]	3-4, 8
Y	US 2010/0286626 A1 (Petersen et al.) 11 November 2010 (11.11.2010) Fig. 3, 6A-6B; Para [0033]	13
A	US 2009/0209910 A1 (Kugler et al.) 20 August 2009 (20.08.2009) Fig. 1-17; Para [0046]-[0072]	1-14
A	US 2008/0154172 A1 (Mauch) 26 June 2008 (26.06.2008) Fig. 1-3, 4A-4G; Para [0018]-[0031]	1-14
A	US 2008/0125748 A1 (Patel) 29 May 2008 (29.05.2008) Fig. 1-3, 4A-4G; Para [0025]-[0039]	1-14
A	US 2007/0093780 A1 (Kugler et al.) 26 April 2007 (26.04.2007) Fig. 11A-C, 12A-C, 14A-H, 21A-B; Para [0072], [0073], [0076], [0079], [0092], [0093]	1-14

☐ Further documents are listed in the continuation of Box C.

* Special categories of cited documents:

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

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

12 December 2012 (12.12.2012)

Date of mailing of the international search report

25 JAN 2013

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US, Commissioner for Patents
P.O. Box 1450, Alexandria, Virginia 22313-1450

Facsimile No. 571-273-3201

Authorized officer:

Lee W. Young

PCT Helpdesk: 571-272-4300
PCT OSP: 571-272-7774

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 12/52858

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:
--- see continuation sheet ---

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-14

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 12/52858

Box III - Observations where unity of invention is lacking:

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Group I: claims 1-14 directed to a catheter system

Group II: claim 15-20 directed to a re-entry catheter

The groups of inventions above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical feature of the Group I claims is at least one void to enable flexing, which is not present in the claims of Group II.

The special technical feature of the Group II claims is a sharp cutting means, which is not present in the claims of Group I.

Groups I-II share the technical feature of a re-entry catheter comprising a catheter, port and re-entry member steered by an axial force. This generic feature does not avoid the prior art, as evinced by US 2007/0093780 A1 to Kugler et al (hereinafter Kugler) which notably teaches a re-entry catheter as described which further includes steering by the application of an axial force to a pull wire (para [0072], [0073], [0076], [0079], [0092], [0093], fig 11A-C, 12A-C, 14A-H, 21A-B).

Therefore, the listed inventions lack unity of invention under PCT Rule 13 because they do not share a same or corresponding special technical feature.

Note claims 17, 18, 20 are improperly appended to claim 13. For the purposes of this report, they have been assumed dependent on claim 16 and thus considered part of Group II.