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(54) **Title**: DEVICE AND METHOD FOR TREATING A CHRONIC TOTAL OCCLUSION

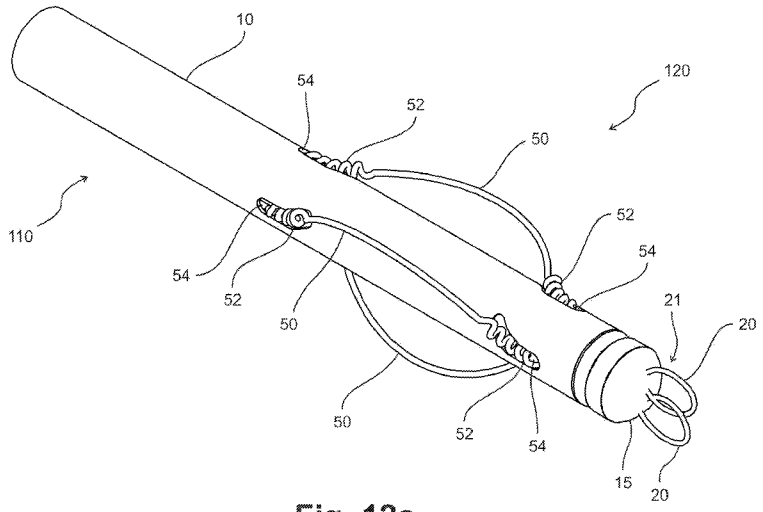

Fig. 12a

(57) **Abstract**: A device and method for opening blood vessel blockages, such as chronic total occlusions, is disclosed. The device has a drilling unit and a stationary unit having a plurality of curved alignment structures along its outer edge for bracing against the inner surface of a blood vessel wall. A torque-transmitting member (drive shaft) is disposed within the stationary unit and extends into the rotating drilling unit. The curved alignment structures along the outer surface of the device help to centrally align the device within the blood vessel, thereby preventing the device from deflecting and puncturing blood vessel walls. The drilling unit that has a plurality of loops on its distal tip is located at the distal region of the drilling unit. These loops break apart occlusions as the device advances and rotates through the blood vessel.

Device and Method for Treating a Chronic Total Occlusion

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This Application claims the benefit of U.S. Patent Application No. 14/080970, filed November 15, 2013, which is a continuation-in-part of U.S. Patent Application No. 13/801,228, filed on March 13, 2013, each of which is incorporated herein by reference in its entirety.

FIELD OF THE INVENTION

[0002] The present invention relates generally to a device and method for recanalizing blood vessels, and more particularly to a device and method for aligning a vascular drill within the center of a blood vessel for fracturing and opening chronic total occlusions.

BACKGROUND OF THE INVENTION

[0003] Chronic total occlusions (CTO) are vascular lesions that are totally occluded. These can occur anywhere in the human body such as coronary, carotid, visceral, iliac, femoral, and popliteal arteries and veins. Usually these lesions will develop over the course several months to years. Due to chronicity of their natural course, there usually will be an adequate amount time for development of collateral vessels to supply blood to tissue. However these collateral vessels barely provide enough blood flow to keep the end organs alive and are inadequate to support the function of dependent organs.

[0004] Chronic total occlusions can have serious medical consequences depending on their location. For example, blockages located in coronary arteries can cause heart muscle damage and heart failure, whereas blockages located in femoral and popliteal arteries can cause leg ulcers and gangrene.

[0005] Chronic total occlusions *per se* are not "total occlusions," but rather contain several intrinsic nonfunctional narrow channels. Traditionally, hydrophilic coated guidewires are used to penetrate through one or more of these narrow channels to create a contiguous passage between open vessel segments proximal and distal to an occlusion. This passage is

subsequently dilated to accommodate therapeutic devices such as balloons or stents.

[0006] Various surgical and minimally invasive methods have been in vogue for many years for revascularization of CTOs. Surgical grafts have been for many decades, designed to bypass blockages in coronary or peripheral vessels. Minimally invasive technologies include guidewires or CTO devices.

[0007] CTO lesions frequently contain extremely hard and calcified plaques, which makes them impenetrable. Guidewires, when used in CTOs, are sometimes risky as they can inadvertently damage or more ominously perforate the vessel wall. Often, the guidewire tip has insufficient support, and can buckle during an attempted penetration into the calcified plaque. The guidewire, when forced into a CTO, can also inadvertently be misdirected by the operator in an unintended direction, creating a dead end plane between the vessel wall and the plaque (i.e. a subintimal plane). If the guidewire fails to create successful passage through the CTO, the resulting subintimal tract prohibits the use of subsequent therapeutic devices such as a balloon, stent or atherectomy catheter. Another drawback in CTO devices includes shafts that are not robust enough to resist kinks when advanced inside of a CTO. Still another drawback is that the CTO device is not easily controlled, whereby the tip of the CTO device veers eccentrically away from the center of the blood vessel when the CTO device is pushed though the CTO. Due to these drawbacks, success rates with guidewires in CTO revascularization are marginal at best.

[0008] Several CTO technologies have been introduced in an attempt to overcome some of the difficulties faced when using guidewires and CTO devices to improve successful CTO penetration rates. In U.S. Patent No. 6,599,304 Selmon *et al*, teach "an intravascular catheter system for the treatment of occluded blood vessels that includes tissue displacement or hinged expansion members that are movable from a closed to an open position. A spreading or mechanical force may be thus applied to the vessel wall and occlusion so as to tear, fracture or otherwise disrupt the occlusion adjoining the vessel wall. This disruption of the occlusion may create a channel or passageway of sufficient size for the passage of guidewire or therapeutic catheter around or through at least a portion of the obstruction as part of an overall effort to restore regular circulatory function surrounding the occluded vascular region."

[0009] In U.S. Patent No. 8,062,316, Patel *et al.* teach a CTO catheter with a novel rotating cutting head with helical blades at its distal end and the tip is lodged in a protective

sheath. "Application of torque to an inner catheter or wire attached to the cutting head applies spin to the cutting head. Depending on the angle and nature of the cutting head's protruding blades, the blades may either may be designed to simply cut through the occluding material, without actually dislodging the occluding material from the body lumen, or alternatively the blades may be designed to both cut through the occluding material, and severe its links to the body lumen, thereby dislodging the occluding material from the body lumen."

[0010] In U.S. Patent App. No. 11/090,435, Hong teaches a system for opening CTOs, by using a catheter having multiple channels. In addition, the catheter may have a bullet-shaped distal tip and/or torqueing grooves in the proximal and distal shaft, which will facilitate advancing a catheter through CTO with manual torqueing action at the proximal end. Multiple channels running along the length of catheter are distensible and used to advance guidewires, balloons or stents into the lesion.

[0011] In U.S. Patent No. 8,021,330, McAndrew teaches a novel balloon catheter with a "no-fold balloon at a distal end thereof that surrounds a distal portion of a guidewire shaft having a compliant shaft or tubular section for selectively gripping a guidewire there within." Upon inflation, the compliant soft section of the guidewire shaft locks onto the guidewire. "This provides the clinician a conjoined balloon catheter and guidewire ensemble that together may be pushed through a tight stenosis such as chronic total occlusion."

[0012] In U.S. Patent App. No. 12/108,921, Duffy *et al.* teach a visualization and treatment system for treating CTO. The system includes an elongated member configured to be tracked to the chronic total occlusion. The elongated member has a transducer located at its distal end. Acoustically activated material will be packed at the distal end of elongated member. The system also includes an external imaging system constructed and arranged to create an image of the chronic total occlusion. The external imaging system may also be configured to generate ultrasonic energy waves which in turn vibrate the acoustically activated material located at the distal end of the elongated member. These vibrations in turn produce mechanical energy that may be used to penetrate and cross a CTO.

[0013] In U.S. Patent Application No. 13/553,659, Richter teaches an apparatus and method for guided penetration of chronic total occlusion. This invention relates to an apparatus that facilitates accurate placement of a guidewire and drilling tip within the blood vessel during

recanalization of CTO. The apparatus comprises an imaging system which can detect the lesion, vessel wall, and guidewire tip in real-time. "Preferably, this apparatus also facilitates the penetration of a CTO or other obstruction in a vessel. The method of using the apparatus of the invention facilitates treatment of the occlusion and avoids or reduces complications and risks associated with treating the occlusion, such as perforation of walls of the vessel and creation of a false lumen."

[0014] In U.S. Patent No. 7,763,012 Petrick *et al.* teach a catheter and method to cross CTOs. The catheter comprises of an elongated tubular member having a deflectable tip at the distal end. "The catheter is advanced to a region of interest in an artery proximal to a lesion. A control wire is operated to direct the deflectable tip toward the lesion. A guidewire is advanced through the lumen of the catheter and into the lesion to cross the lesion."

[0015] In U.S. Patent No. 8,241,315 Jensen *et al.* teach an apparatus and method configured to penetrate an occlusion while limiting inadvertent vessel damage. This device includes an elongated sheath and a stylet disposed within the elongated sheath. The stylet includes a lumen from proximal to distal ends, which will allow passage of a guidewire after the occlusion is penetrated. In use, "the stylet can be moved distally such that the distal region of the stylet penetrates at least partially into the occlusion. After the stylet has extended through the proximal cap, a guidewire can cross through the occlusion. Then the recanalization assembly can be further advanced through the occlusion and the balloon placed near the distal cap and the stylet centered and passed across the distal cap."

[0016] Still, success rates with these new technologies are reportedly varied from 50-70% due to various factors including operator's experience. In addition, costs, cumbersomeness, need for complex preparation and lengthy training required for proper usage of these CTO devices can prohibit their widespread and cost efficient usage. Hence, despite these technological developments, there is still a great need for a simple, safe, easy-to-operate, efficient and cost effective CTO devices.

SUMMARY OF THE INVENTION

[0017] The present invention provides a device and method for treatment of vascular occlusions. It is an object of the invention to disrupt vascular occlusions or other blockages

formed within blood vessels in order to provide pathways for the placement of guidewires, interventional devices and catheters as part of an overall effort to restore normal circulatory function having the advantages of a reinforced inner tube, easy controllability and a shape that prevents vessel damage but maximizes occlusion fracturing.

[0018] In a first embodiment of the present invention the vascular drilling device has a main body. The main body has several components that help direct and mechanically fracture the occlusion. The device has an outer tubular member. Inside of the outer tubular member is an inner tubular member interposed within. At the proximal end of the outer tubular member and inner tubular member is a distal cap that is sealed to both inner and outer tubular members. The distal cap preferably is a C-cup that does not have sharp edges to pierce vascular walls. At the distal end of the device is a plurality of distal end loops projecting from the distal end cap of the main body. A plurality of outer loops project from the outer tubular member proximal to the distal end loops. When the main body is advanced to the CTO, the operator spins the main body, either manually or mechanically. The loops on the distal end mechanically fracture the CTO in front of it. As the loops on the distal end advance forward into the CTO, the outer loops on the outer tubular member mechanically fracture the CTO nearer the vessel walls. Since all the loops have curved edges, even if the loops touch the vessel wall, it is unlikely that the device will pierce the vessel wall.

[0019] In one aspect of the invention, the inner tubular member is reinforced with one or more helically coiled wires. Preferably two helically coiled wires encircle the inner tubular member in a double helix fashion and are secured (by polymer glue or another securing substance) to the outer surface of the inner tubular member. The helically wrapped wire(s) allows flexibility of the main body to curve within the blood vessel lumen, and conform to the pathway of the blood vessel. Having wire(s) encircle the inner tubular member has the advantage of strengthening the shaft of the main body, such that the main body will not kink when curving along the pathway of the blood vessel. The coiled wires also have the advantage of improving steerability and pushability of the main body when advanced inside a diseased blood vessel or inside a hard fibrocalcific plaque of the occlusion.

[0020] In another aspect of the present invention, the device has an expandable material, such as a balloon, that envelops at least a portion of the main body and surrounds the outer tubular member of the main body. The distal end of the balloon is proximal to the outer loops.

Configured in this way, when the balloon is inflated, the balloon presses against the vessel walls and centers the main body of the device to the center of the vessel. The use of an inflatable balloon therefore has the advantage of centering the main body so that mechanical fracturing of the occlusion occurs near the center of the vessel, thus preventing unwanted veering of the main body and distal end of the device into a vessel wall.

[0021] A distal end cap is sealed to the proximal ends of the inner and outer tubular members, The cap a central hole which creates an opening from the lumen of the inner tubular member out of the device so that a guidewire can be inserted within the lumen of the device and exit through this central hole. The guidewire can be used for further therapeutic procedures. Additionally, the distal end cap may have paracentral holes that allow a plurality of wire loops to project from the cap and fracture the occlusion.

[0022] In another embodiment, the CTO device has a motor unit to aid in rotating the main body and/or drilling tip**.** The motor unit has an electric motor to provide torque to the main body which spins the pairs of opposing loops to fracture the CTO and threaded inner and out motor unit tubular bodies. The motor unit is connected to the main body via these motor unit inner and outer tubular members. To aid in rotation of main body, the motor unit tubular members have helically threaded grooved surfaces so that when an electric motor turns the tubular members, rotational force can be translated into a linear force, which can drive the distal end of the device through a CTO. A locking screw may lock the motor unit to the main body.

[0023] In another embodiment of the invention, the main body is segmented into two units: a drilling unit and a stationary unit. The stationary unit can still be linearly inserted and retracted within the blood vessel, but does not rotate when the motor unit rotates. Thus the stationary unit is a rotationally stationary unit. Instead of the motor unit being coupled to the main body of the device directly, the motor unit is coupled to a torque-transmitting member that is housed within the stationary unit. The stationary unit has a stationary unit outer tubular member and inner tubular member.

[0024] The torque-transmitting member (also known as a drive shaft) runs within the elongated lumen of the stationary unit inner tubular member and connects to the drilling unit via a coupling member. The drilling unit has the loops on its outer wall and distal end cap as previously described above.

[0025] An advantage of the main body separated into a stationary unit and a drilling unit is that only the small rotating portion of the main body (i.e. the drilling unit) rotates, instead of the entire main body rotating. A small rotating unit prevents unintended damage that may occur if the device rotates against a vessel wall, which would cause additive frictional forces that damage vessel walls.

[0026] In one aspect of the stationary unit and drilling unit embodiment, a guidewire tubule having a guidewire lumen is disposed between the inner and outer tubular members of the stationary unit, and a guidewire enters through a proximal hole and exits through a distal hole of the outer tubular member of the stationary unit. A guidewire can then be inserted through this lumen and left in the patient after the device is removed for use in further treatments.

[0027] In another aspect of the invention a motor sensor is incorporated into the distal end of the main body of the drilling unit, and a microprocessor is incorporated into the motor unit. The microprocessor acquires and analyzes data sent from the sensor about the motion of the drilling unit, and in turn sends commands to the motor unit that that operator is guiding. In this way, the speed and character of rotation of the distal end of the device or drilling unit can be more precisely controlled by the operator to suit CTO lesion characteristics.

[0028] In another embodiment of the invention, additional structures help align the vascular device within the center of a vessel lumen. The vascular drilling device has a stationary unit and a drilling unit. The stationary unit has an outer tubular member, and inner tubular member interposed within the outer tubular member and a plurality of curved alignment structures extending from the outer tubular member. A torque-transmitting member, known as a drive shaft, is interposed within the inner tubular member and provides rotation to the drilling unit without rotating the outer tubular member of the stationary unit. The curved alignment structures allow the vascular drill to be centered within the blood vessel and prevent the tip from deviating and puncturing vessel walls by the alignment structures providing a brace between the stationary unit and vessel walls. The rotating drilling unit is positioned at the distal end of the vascular drill, and is connected to the stationary unit via the drive shaft, which rotates the distal end tip at the distal end of the drilling unit. The distal end tip has distal end loops projecting from the tip that fracture an occlusion within the blood vessel when loops advance and rotate through the occlusion.

[0029] In another embodiment of the vascular drill with curved alignment structures extending from the outer tubular member, the stationary unit has a guidewire tubule interposed within, where a guidewire can be inserted through the proximal end of the vascular drill and exit the drill through a guidewire hole at the distal end of the stationary unit.

[0030] A method of traversing a vascular occlusion using the above stated device is also disclosed. The steps involved in traversing the occlusion include first positioning any of the devices described above, such that the distal end of the device is proximate to an occlusion. The distal end of the device is rotated so that the loops fracture the occlusion. As the device rotates, the operator advances the device through the occlusion. In another aspect of the method of traversing an occlusion, the operator advances a guidewire through the device.

BRIEF DESCRIPTION OF THE DRAWINGS

[0031] **FIG. 1A** illustrates a front cross sectional view of a main body of a vascular drilling device.

[0032] **FIG. 1B** illustrates a front view of the device of FIG. 1A.

[0033] **FIG. 1C** illustrates a side view of the device of FIG. 1A.

[0034] **FIG. 1D** illustrates a bottom view of the device of FIG. 1A.

[0035] **FIG. 1E** illustrates a bottom cross-sectional view of the device of FIG. 1A.

[0036] **FIG. 1F** illustrates a front view of the inner tubular member of the device of FIG. 1A.

[0037] **FIG. 2A** illustrates a front cross sectional view of the device of FIG. 1B having an inflatable balloon.

[0038] **FIG. 2B** illustrates a side view of the device of FIG. 1C having an inflatable balloon.

[0039] **FIG. 3A** illustrates a front cross-sectional view of an alternative embodiment of distal end of a vascular drilling device.

[0040] **FIG. 3B** illustrates a front view of the device of FIG. 3A having a drilling unit and a rotationally stationary unit.

[0041] **FIG. 3C** illustrates a side view of the device of FIG. 3A.

[0042] **FIG. 3D** illustrates a bottom cross-sectional view of the stationary unit of FIG. 3A.

[0043] **FIG. 4** illustrates a side cross sectional view of a proximal end of the device of FIG 3A.

[0044] **FIG. 5A** illustrates a side cross sectional view of the motor unit inner tubular member.

[0045] **FIG. 5B** illustrates a side view of the motor unit inner tubular member of FIG. 5A.

[0046] **FIG. 6A** illustrates a side cross sectional view of the motor unit outer tubular member.

[0047] **FIG. 6B** illustrates a perspective view of the motor unit outer tubular member of 6A.

[0048] **FIG. 7A** illustrates a side cross-sectional view of a motor unit inner tubular member interposed within a motor unit outer tubular member.

[0049] **FIG. 7B** illustrates a side view the motor unit inner tubular member interposed within a motor unit outer tubular member of 7A.

[0050] **FIG. 8A** illustrates a side view of an assembled motor unit over the main body of the CTO device inserted into a blood vessel.

[0051] **FIG. 8B** illustrates a cross sectional view of an assembled motor unit over the main body of a vascular drilling device.

[0052] **FIG. 9** is an exemplary view of a vascular drilling device inserted through a small hole in a patient's groin, the distal end of the vascular drilling device approaching an occlusion.

[0053] **FIG. 10A** is a side cross sectional view of the device of FIG. 1A within a blood vessel before entering an occlusion.

[0054] **FIG. 10B** is a side cross sectional view of the device of FIG. 1A within an occlusion.

[0055] **FIG. 10C** is a front cross sectional view of the device of FIG. 1A after passing through an occlusion and after a guidewire has been inserted.

[0056] **FIG. 11** is a front cross sectional view of the device of FIG. 3A after passing through an occlusion, and after a guidewire has been inserted.

[0057] **FIG. 12A** is a perspective view of a vascular drill having alignment structures extending from the outer tubular member of the drill.

[0058] **FIG. 12B** is a cross sectional view of the device of FIG. 12A.

[0059] **FIG. 13A** is a perspective view of a vascular drill having alignment structures extending form the outer tubular member, and a guidewire tubule and exit hole for placement of

a guidewire.

[0060] **FIG. 13B** is a cross sectional view of the device of FIG. 13A.

[0061] **FIG. 14** is a top view of the distal tip of any of the vascular drills illustrated in **FIGs.** 12A-13B.

[0062] **FIG. 15** is a cross section view of a vascular drill having an impedance sensor and wire transmitting impedance information through the driveshaft.

[0063] **FIG. 16** is a front view of the distal end of a device having a distal loop exposing a sensing region for sending impedance.

DETAILED DESCRIPTION OF THE EMBODIMENTS

[0064] The invention now will be described more fully hereinafter with reference to the accompanying drawings, in which embodiments of the invention are shown. This invention may, however, be embodied in many different forms and should not be construed as limited to the embodiments set forth herein. Rather, these embodiments are provided so that this disclosure will be thorough and complete, and will fully convey the scope of the invention to those skilled in the art. Although the description of the invention is in the context of treatment of blood vessels, the invention may also be used in any other body passageways where it is deemed useful.

[0065] It will be understood that when an element is referred to as being "on" another element, it can be directly on the other element or intervening elements may be present there between. Likewise, when an element is referred to as being attached to another element, it can be directly attached to the other element, or attached via intervening elements that may be present there between. As used herein, the term "and/or" includes any and all combinations of one or more of the associated listed items.

[0066] It will be understood that, although the terms first, second, third etc. may be used herein to describe various elements, components, regions, layers and/or sections, these elements, components, regions, layers and/or sections should not be limited by these terms. These terms are only used to distinguish one element, component, region, layer or section from another element, component, region, layer or section.

[0067] The terminology used herein is for the purpose of describing particular

embodiments only and is not intended to be limiting of the invention. As used herein, the singular forms "a", "an" and "the" are intended to include the plural forms as well, unless the context clearly indicates otherwise. It will be further understood that the terms "comprises" and/or "comprising," or "includes" and/or "including" or "having" and/or "has," when used in this specification, specify the presence of stated features, regions, integers, steps, operations, elements, and/or components, but do not preclude the presence or addition of one or more other features, regions, integers, steps, operations, elements, components, and/or groups thereof.

[0068] Furthermore, relative terms, such as "lower" or "bottom" and "upper" or "top," may be used herein to describe one element's relationship to another element(s) as illustrated in the Figures. It will be understood that relative terms are intended to encompass different orientations of the device in addition to the orientation depicted in the Figures.

[0069] The terms "distal" and "proximal" are used in the following description with respect to a position or direction relative to the treating clinician. "Distal" or "distally" describe a position distant from or in a direction away from the operator, and also refers to the tip of the CTO device closest to the occlusion. "Proximal" and "proximally" describe a position near or in a direction toward the operator and away from the occlusion.

[0070] Unless otherwise defined, all terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this invention belongs. It will be further understood that terms, such as those defined in commonly used dictionaries, should be interpreted as having a meaning that is consistent with their meaning in the context of the relevant art and the present disclosure, and will not be interpreted in an idealized or overly formal sense unless expressly so defined herein.

[0071] As shown in **FIGs. 1A-1E**, the main body **100** comprises two tubular members: an inner tubular member **11** disposed within the outer tubular member **10**. The inner tubular member **11** has a lumen **38** where a guidewire can be passed though. Guidewires coated with a hydrophilic polymer are commonly used for crossing occlusive lesions inside of blood vessels. The polymer on the guidewire is activated in contact with water, which makes the guidewire surface highly lubricious and facilitates advancement of guidewires across narrow cracks and holes contained inside the atherosclerotic plaque of a CTO. The guidewire can be used to facilitate the drilling through the CTO.

[0072] Between the inner tubular member **11** and outer tubular member **10** exists an intertubular space **12** which is sealed on both ends of the main body **100** by a distal cap **15** which may be in the shape of a C-cup that seals the distal ends of both tubular members **11**, **10**. In a preferred embodiment, the inner tubular member **11** is at least 5mm longer than the outer tubular member **10** such that the C-cup **15** has a depth of at least 5mm. The curved C-cup prevents sharp edges from contacting a blood vessel, which could possibly damage the blood vessel wall **50**.

[0073] The outer surface of the outer tubular member **10** may be coated with a highly lubricious hydrophilic polymer (such as polytetrafloroethylene or other hydrophilic polymer known to those having skill in the art) to facilitate free rotational and axial movement within the healthy or diseases blood vessels. The distal and proximal ends of the main body **100** and cap **15** may be sealed with a similar polymer. The main body **100** may be of a variety of lengths, but preferably, a main body **100** between 90cm and 130cm are suitable for a majority of clinical applications.

[0074] The outer surface of the inner tubular member **11** is reinforced with one or more wires. These wires may be coated with a hydrophilic polymer. As shown in **FIGs. 1A, 1E, 1F, 3A, 3B**, and **4**, the inner tubular member **11** is reinforced with two hydrophilic polymer coated wires **13**, **14**. These wires **13**, **14** are wrapped around the inner tubular member **11** in a double helical fashion.

[0075] In the embodiment illustrated in **FIGs. 1A-1E**, the distal cap **15** has a central hole **16** that is aligned with the inner tubular member **11** and provides an exit path for a guidewire to exit through the central lumen **38**. Near the central hole **16** is a pair of paracentral holes **17** as illustrated in **FIG. 1D**. Each of the paracentral holes **17** is approximately 180 degrees from each other around the circumference of the cap **15** when viewed in cross section. Proximal to the paracentral holes **17** is a pair of outer tubular member holes **18**. In one embodiment, the pair of outer tubular member holes 18 is proximally located between 0.5cm and 2.0cm from the most distal region of the distal cap **15**. In a preferred embodiment, the pair of outer tubular member holes **18** is approximately 1.0cm from the distal cap **15**. In the embodiment illustrated in **FIG. 1**, each of the outer tubular member holes **18** is positioned approximately 180 degrees from each other, and the outer tubular member holes **18** are orthogonally positioned relative to to the

paracentral holes **17**. In a preferred embodiment, each of the outer tubular member holes **18** is approximately 4.0mm to 5.0mm away from each other along the long axis of the outer tubular member of the main body **100**.

[0076] Each of the wires **13**, **14** are helically coiled around the shaft of the inner tubular member **11**. The wires **13**, **14** are drawn out through the paracentral holes **17**, **18** to form a distal end loops **20**, and a pair of outer loops **19**. The loops **18**, **19** are secured to the holes **17**, **18** with a spot fixing polymer. In some embodiments, the distal end loops **20** may be oriented slightly inward (not shown), toward the central axis. Presumably, this orientation will lessen the chances of vessel wall trauma caused by the distal loops **20** while the device is spinning.

[0077] This type of loop design and configuration where there is a distal pair of loops **20** pointed toward the occlusion, and outer loops **19** pointed in the direction of the vessel wall **50** is advantageous because as the device penetrates and advances through the CTO, the device will penetrate the CTO proximal cap at four different locations positioned approximately 90 degrees from each other at different depths of the CTO.

[0078] In a preferred embodiment, the main body of the device is approximately 5mm in diameter at the level of the outer loops **19**, which helps in keeping the distal end of the main body **100** in the centric part of the occlusion during device use. A device centrally positioned in the occlusion plaque has less chance of trauma to vessel walls and a higher chance of re-entry into the true lumen of the vessel located distal to the CTO. In contrast, a device whose distal end is positioned closer to the vessel wall has a higher chance of vessel trauma leading to dissection and/or perforation of the vessel wall. In addition, if the distal end of the device is disposed eccentrically and close to the vessel wall, its chances of re-entering the true lumen of the vessel is poor. If the device tip is closer to the vessel wall the tip may also create a subintimal dissection plane, which can advance within the vessel wall distal to the CTO, instead of the intended reentry into the true vessel lumen.

[0079] **FIG. 1F** illustrates the inner tubular member **11** without the outer tubular member **10**. Here, the wires **13**, **14** can be seen in double helix fashion around the inner tubule member, and forming the outer loops **20** and distal loops **19** projecting from the inner tubular member **11**. When assembled, the outer loops **19** project from the outer tubular member **10** and the distal loops project from the distal cap **15** as illustrated in **FIGs. 1A-1E**.

[0080] In another embodiment of the device, a dilation balloon **52** envelops a portion of the main body **100** as depicted in **FIG. 2A** and **2B**. In a preferred embodiment, the balloon **52** is approximately 5.0cm to 7.0cm in length, between 5.0mm and 6.0mm in diameter, and made of a polyethylene material. The balloon **52** is positioned over the outer tubular member **10** around at approximately 1 cm proximal to the outer loops **19**. In this embodiment, the intertubular space **12** between the outer tubular member **10** and inner tubular member **11** is used as infusion lumen. The balloon **52** communicates with the infusion lumen, which extends to the proximal end of the main body. When inflated with infusion media, the balloon **52** repositions the distal end of the main body **100** toward a centric position inside the vessel, and also dilates the passage made by the device inside the CTO, thus facilitation stent placement.

[0081] **FIGs. 3A-3D** illustrate another embodiment of the main body **100** of the CTO device. The main body **100** is segmented into a stationary unit **110** and a drilling unit **21**. The drilling unit **21** spins when torque is applied to it via a torque-transmitting member **26** that runs lengthwise through the lumen **38** of the main body **100**. The torque-transmitting member **26** can be a solid or hollow wire, tube, or shaft, made from a variety of materials, such as stainless steel (SS 304) or similar compatible material. The torque-transmitting member **26** is coupled to the drilling unit **21** via a coupler **27**, which connects the drilling unit to the stationary unit **110**, and forms the entire main body **100** of the CTO device. In one embodiment, the drilling unit **21** is approximately between 2.0 and 4.0cm in length. In a preferred embodiment, the drilling unit **21** is approximately 3.0 cm in length. The drilling unit **21** has the features of the distal end of the embodiment illustrated in **FIGs. 1A-1F**. However, in the embodiment of the drilling unit **21** shown in **FIGs. 3A-C**, there is no distal end cap hole **16** to allow a guidewire to pass through the lumen **38** of the distal cap **15**. The proximal end of the drilling unit **21** is covered with a proximal cap **42** and the distal end of the stationary unit **110** is covered with a distal cap **40**. The coupler **27** attaches to the proximal cap **42** on the drilling unit **21** to connect the stationary unit **110** to the drilling unit **21**.

[0082] One advantage of the segmented main body **100** embodiment of **FIGs. 3A-3C** is that the drilling unit **21** spins independently of the stationary unit **110**, which does not spin when the torque-transmitting member **26** rotates. Since only the small drilling unit **21** spins, most of the main body **100** within the blood vessel remains rotationally stationary, and thus does not produce any frictional forces against inner wall of the blood vessel. Hence the operator will

have a better control over the exact location of the drilling action of the device. This segmented main body **100** increases the safety of the device and prevents unwanted force on non-occluded areas of the blood vessel.

[0083] To accommodate a guidewire in this embodiment, a guidewire tubular member **44** is located within the intertubular space **12** of the stationary unit **110**, which has a guidewire lumen **28**. A guidewire **39** can be passed through the guidewire lumen **28** and exits the stationary unit **110** at guidewire exit hole **29**, so the guidewire can be used in later procedures. In one embodiment, the exit hole **29** is located between 0.5 and 5.0cm proximal to the distal end stationary unit **110**. In a preferred embodiment, the exit hole **29** is located approximately 1.0 cm proximal to the distal end of the stationary unit **110**. The helically coiled wires **13**, **14** are helically wrapped and secured around the stationary unit's inner tubular member **11**, and a second pair of wires **24**, **25** is wrapped around and secured to the inner tubular member **11** of the drilling unit **21**. In a preferred embodiment, a first wire **24** is helically wrapped around the inner tubular member 11 and forms two of the four loops **19**, **20** (projecting from one outer tubular member hole 18, and one paracentral distal cap hole **17**). A second wire **25** is helically wrapped around the inner tubular member **11** and forms the other two of four loops (projecting from the opposing outer tubular member hole **18**, and the opposing paracentral distal cap hole **17**). The loops **19**, **20** on the distal unit **21** are brought out through the holes **17**, **18**, and spot fixed as previously described in **FIGs. 1A-1E**.

[0084] **FIG. 4** illustrates the proximal end of the stationary unit **110** of **FIG. 3**. The torque-transmitting member **26** exits the proximal end of the stationary **110** to attach to a motor unit, which applies torque to the torque-transmitting member **26**. The guidewire tubular member **44** has a guidewire entrance hole 30 for insertion of a guidewire into the stationary unit **110**.

[0085] **FIGs. 5A** and **5B** illustrate a motor unit inner tubular member **31,** and **FIGs. 6A, 6B, 7A** and **7B** illustrate a motor unit outer tubule member **32** that fits over the motor unit inner tubular member **31**. An assembled motor unit **130** illustrating an electric motor **36**, inner and outer motor unit tubular members **31**, **32**, attached to the main body **100** of the device is illustrated in **FIGs. 8A** and **8B**.

[0086] In a preferred embodiment, the inner tubular member of the motor unit **31** is

between approximately 15cm and 20cm in length and disposed inside of the lumen **46** of the outer tubular member of the motor unit **32**, which in turn, is around 5 to 7 cm. The luminal diameter of the motor unit inner tubular member **31** is approximately 0.5mm to 1.0mm larger than the diameter of the outer tubular member of the main body 100 so that the motor unit **130** can easily slide on the main body **100** as shown in **FIGs. 7A** and **7B**. The outer surface **33** of the motor unit inner tubule member **31** is threaded in a helical configuration so that the so that the motor unit inner tubule member **31** can fit inside of the motor unit outer tubule member **32**, which has a corresponding threaded inner surface **34** to fit the motor unit inner tubule member **31**. The motor unit inner tubular member **31** can spin upwards or downwards within the outer tubular member **32**. The threaded configuration of the motor unit tubule members **31**, **32** converts part of the torque from an electric motor **36** into linear motion, thus facilitating the advancement of the distal end of the device through a CTO.

[0087] One embodiment of an electric motor has a gear system configured to generate oscillatory curvilinear torque motion in the rotor unit, which is attached to the main body **100**. In one embodiment the rotor unit in turn transmits the curvilinear oscillatory motioning involving one third of a circle the main body **110** of the device. This pendulum-like motion of the main body **100**, when transmitted to the proximal end of the main body **100** or drilling unit **21** will have less chance of plaque dislodgement and distal embolization when compared to the spinning movement. The motor unit **130** can be locked and unlocked with the main body via a locking screw device **35**, preferably made from a polyethylene material, or the like.

[0088] The electric motor **36** may be a DC or AC motor having a gear-box, the type being known by persons having skill in the art. In use, the operator inserts the main body **100** into the blood vessel through a small hole in the groin, and advances the distal end of the main body **100** adjacent to a CTO **37**, as shown in exemplary form in **FIG. 9**. The motor unit **130** is inserted coaxially over the main body **100** and advanced near to the skin entry point of the main body **100**. The motor unit inner tubular member **31** is then locked to the main body **100** using a lock screw member **35**. Then the electric motor **36** is inserted coaxially over the main body **110**, advanced, and locked to the distal end of the motor unit inner tubule member **31**. The electric motor **36** is powered, and the operator guides the inward and outward movement of the locked-in combination of the motor unit inner tubule member **31** and main body **100**. The torque created by the motor **36** and advancement of the inner tubular member **31** within the outer tubule member **32** transmits both linear and rotational movements to the distal end of the main body

100. In the embodiment of **FIGs. 1A-E**, the motor unit **130** transmits rotational movement to the entire main body **110**, while in the embodiment depicted in **FIG. 3A-D**, the motor unit **130** is connected to the torque-transmitting device **26**, and only transmits rotational movement to the drilling unit **21**.

[0089] As the main body **100** or the drilling unit **21** spins, the wire loops **19**, **20** in turn penetrate the proximal cap of the CTO and advances, as shown in **FIGs. 10A-C**. After successfully crossing the entire length of the occlusion **37**, the operator confirms the intraluminal position of the distal end of the main body **100** injecting small amount of radiopaque contrast though the guidewire lumen under fluoroscopy guidance. Then the operator advances a guidewire **39** though the device lumen **38** into the vessel lumen **48** as shown in **FIGs. 10C** and **11**.

[0090] In one embodiment of the device, the electric motor **36** rotates in a curvilinear oscillatory motion and does not comprise the inner and outer motor tubular members **31**, **32**. Here, the rotating axle of the electric motor **36** is attached directly to the torque-transmitting device **25** and torque would transmit directly from the axle of the motor **36** to the drilling unit **21**. In this embodiment, the operator gives linear motion to the main body **100** with an inward push as the motor **36** is providing the torque to the drilling unit **21** to fracture a CTO.

[0091] In the embodiment illustrated in **FIGs. 8A** and **8B**, the operator locks the motor **36** to the torque-transmitting device, advances the main body **100** gently into the blood vessel **48** and through the CTO **37** while the rotor unit of the electric motor **36** rotates the drilling unit in a curvilinear fashion via the torque-transmitting device **26**. Here, the operator adds the linear motion of the curvilinear movement of the advancing tip of the main body **100** and drilling unit **21** at the distal end of the main body **100**. In this embodiment, the motor unit **130** is not used for linear motion as the operator controls the forward motion of the main body **100.**

[0092] **FIG. 11** illustrates an exemplary embodiment of the device shown in **FIGs. 3A-D** inside of vessel **50** that has passed through a CTO **37**. Here, the guidewire **39** exits the hole **29** located approximately 1cm proximal to the distal end of the stationary unit **110**. The guidewire **39** remains in the vessel lumen **48** after the main body **100** is pulled out from the patient. The guidewire **39** can then be used for further therapeutic interventions.

[0093] **FIG. 12A** and **12B** illustrate and exemplary embodiment of vascular drill **120** having curved alignment structures **50** for centrally aligning the drill **120** within a blood vessel. **FIG. 12A** illustrates the drill **120** in a perspective view and **FIG. 12B** illustrates the drill **120** in cross-sectional view. There are two main sections of the drill **120**: a stationary unit **110**, and a rotating drilling unit **21**. The stationary unit **110** may move along the path of a blood vessel, but does not rotate when torque-transmitting member (drive shaft) **26** rotates. Surrounding the drive shaft **26** within the stationary unit **110** is an inner tubular member **11**. Surrounding the inner tubular member **11** is an outer tubular member **10**, which is spatially separated by an inner tubular space, or lumen. The inner tubular member **11** does not extend through the entirety of the drill **120**. Rather, the inner tubular member **11** has a termination region 66 where the drive shaft **26** exits the inner tubular member **11** and enters the rotating drilling unit **21**.

[0094] As the drive shaft **26** exits the enclosure of the inner tubular member **11** into the drilling unit **21**, the drive shaft **26** remains enclosed within the outer tubular member **10**, and enters an inner hypotube **56** that encloses the drive shaft **26** of the drilling unit **21** of the device **120**.

[0095] The curved alignment structures **50** are supported by the outer tubular member **10**, which may have an inner layer **56** to aid in attaching the curved alignment structures **50** to the outer tubular member **10**. The outer tubular member **10** and inner layer **56** keep the distal region (i.e. tip) of the drilling unit **21** from bending or binding. The inner hypotube **56** is secured to the drive shaft **26** either by an adhesive, epoxy, and/or welding **54**. The inner hypotube **56** is used as a way to join the drive shaft **26** to the tip of the drilling unit **21**, while maintaining a consistent surface to support the rotational loads. Between the inner hypotube **56** and outer tubular member is a hypotubular inner space (hypotube lumen) **64** that allows the drive shaft **26** to rotate without causing stationary unit **110** of the device **120** to rotate.

[0096] The distal end of the drilling unit **21** may have a curved atraumatic cap **15** to help prevent perforations of blood vessels. Extending from the distal end of the drilling unit **21** are distal loops **20**, (which have previously been described), for breaking occlusions as the drilling unit **21** rotates and advances through a blood vessel having one or more occlusions. The distal loops **20** may be in various configurations with respect each other, such as having an overlapping configuration (as illustrated in **FIGs. 12-14**) or offset from each other (as illustrated in **FIGs. 1-3**). To attach distal loops **20** to the drive shaft **26**, the non-looped end portions of the

distal loops **20** may extend at least partially down the drive shaft **26**, where the regions of distal loops **20** that run down the length of the drive shaft **26** can be secured to the drive shaft **26** and/or hypotube **56** via an adhesive, epoxy, and/or welding **58**. In a preferred embodiment, the proximal ends of the loops **20** terminate approximately between 1 mm and 2 mm down the driveshaft **26**.

[0097] To aid in centering the vascular drill in with the blood vessel, curved alignment structures **50** protrude from the outer tubular member **10**, through holes **54** in the outer tubular member **10**. In the embodiment shown, there are three equidistantly spaced curved alignment structures **50**. However, there can be any number of alignment structures, arranged in any number of ways that allow the vascular drill **120** to center within the lumen of the blood vessel when the curved alignment structures **50** brace against the inner wall of a blood vessel.

[0098] The curved alignment structures **50** may be made from any type of wire material, and specific embodiments may include wires made from a shape memory alloy that have superelastic properties, such as Nitinol. The curved alignment structures **50** may also be coated with a hydrophilic polymer coating to help in advancing the device through a blood vessel. The curved alignment structures **50** may be of any length, and any height, but preferable embodiments have the curved structure extend approximately between 3 mm and 8 mm from the surface of the outer tubular member **10** of the device. In a preferred embodiment, each of the curved alignment structures are attached at two positions along the stationary unit **110**, a proximal position, and a distal position, spaced approximately between 25 mm and 50 mm apart.

[0099] The curved alignment structures **50** press against the blood vessel without causing damage due to the curved alignment structures **50** not having any regions capable of piercing blood vessels, since the only protruding regions are curved and brace against the blood vessel wall, instead of puncturing it. Aiding in the bracing of the alignments structures **50** are coiled alignment member loops **52** at each end of each curved alignment structure **50**. These coils **52** allow the curved alignment structures **50** to collapse in tight spaces near to the surface of the outer tubular member **10** of the stationary unit **110** of the device. The coiled segment **52** of the alignment structures **50** makes it easy to bend the alignment structure **50** into collapsed position (when compared to a non-coiled alignment structure) while the device is being introduced and removed through a narrow guide catheter. Each of the coils **52** extends from the outer tubular member **10** through curved alignment structure openings (entry and exit holes) **54**,

and is secured on or within the outer tubular member **10** and/or inner layer of the outer tubular member **60** via an adhesive, epoxy, or welding. In one embodiment, the stationary unit holes on the outer tubular member **10** on the stationary unit **110** are configured in such a way that they are slanted approximately anywhere between **20** and **80** degrees. In one embodiment the entry and exit holes **54** are slanted approximately **60** degrees laterally against the long axis of the device **120**, **130** (rather than downwards or upwards). In preferred embodiments, the coils **52** comprise between four to ten loops before transitioning to the non-coiled region of the curved alignment structures **50**.

[0100] **FIGs. 13A** and **13B** illustrate a perspective view and a cross-sectional view, respectively, of a vascular drill **130** similar to the vascular drill **120** of **FIGs. 12A** and **12B**. The embodiment of **FIGs. 13A** and **13B** illustrate the added element of a guidewire tubule **44**, where a guidewire can be inserted through the vascular drill **130** and exit through a guidewire hole **29**. To accommodate the additional space needed for the guidewire tubule **44**, the proximal portion of the drive shaft **26**, and inner tubular member **11** are offset from the center of the lumen **12** to make space for the guidewire tubule **44**. As previously described with reference to **FIGs. 12A** and **12B**, the embodiments of **FIGs. 13A** and **13B** likewise have the drive shaft 26 connected to the drilling unit **21**, an inner hypotube **56**, and curved alignment structures **50** that align the distal portion of the stationary unit **110** and drilling unit **21** within the central region of the lumen of a blood vessel.

[0101] **FIG. 14** illustrates the top view of the distal tip with three curved alignment structures **50** spaced equidistantly, approximately **120** degree from each other, of the vascular drills **120**, **130** depicted in **FIGs. 12-13**. The equidistant alignment allows the curved alignment structures **50** to brace against the inner surface of the blood vessel and center the distal region of the device **120**, **130**. The curved alignment structures **50** may extend from the surface of the outer tubular member **10** in a variety of directions, but in a preferred embodiment, as illustrated in **FIG. 14**, the curved alignment structures **50** extend non-perpendicularly from the surface of outer tubular member **10.** In a preferred embodiment, the alignment structures **50** extend approximately 45 degrees from the surface of the outer tubular member **50**. In another embodiment, the curved alignment structures **50** extend from approximately a 60 degree against from outer tubular member surface. By extending non-perpendicularly, the alignment structures **50** are better able to collapse in tight spaces near to the surface of the outer tubular member **10**. This collapsibility is advantageous when introducing and withdrawing the device **120**, **130**

through a narrow guidesheath, and the alignment structures **50** more easily collapse compared to if the alignment structures **50** extend perpendicularly from the outer surface of the outer tubular member **10**. In a preferred embodiment, the guidesheath is approximately 2.0 to 2.2 mm in inner diameter, and the body of the device **120**, **130** around the outer tubular member is approximately 1.8 mm, however, the diameter of the entire device **120, 130,** when the alignment structures **50** are taken into account, are preferable approximately 5 mm to 6 mm in width when in open position, but when collapsed against the outer tubular member **10** the entire diameter of the device **120**, **130** is approximately 2 mm to fit through a guidesheath.

[0102] In another embodiment, a vascular drill **140** has an impedance sensor **51**, as illustrated in **FIG. 15** and **16**. **FIG. 15** illustrates a cross sectional view of the vascular drill **140**, and **FIG. 16** illustrates the vascular drill tip **21** showing an exposed sensor region **41** on the distal loops **20**. An impedance sensor **41** can be used in any of the embodiments of the vascular drills described above, such as impedance sensors and interfaces for the use of a variety of sensors in tissue ablations systems as described in U.S. Patent App. No. 12/893,707 to Cao et al, and U.S. Patent App. No. 11/438,678 to Werneth et al., both fully incorporated by reference in their entirety, herein. Signals from the sensor **41** may transmitted to a receiver located at the proximal end of the device via a transmitting wire **43** running through the drive shaft **26**. The drive shaft may have a hollow channel **45** that allows for placement of the transmitting wire **43** within the vascular drill. The mechanical impedance characteristics of adventitia are different from atherosclerotic non-calcified and calcified plaques. The impedance information therefore can be used to determine location of the distal loops **20** to calcified or non-calcified plaques, which in turn guides the operator to properly cross the lesion, minimizing chances of vessel wall dissection or perforation. The drill may have impedance sensing circuitry, and a location sensing and orientation circuitry for determining the location and orientation of the tip **21**, such as the circuitry and sensors disclosed in U.S. Patent App. No. 12/346,592 to Deno et al., fully incorporated by reference in its entirety, herein. The failure to successfully cross a CTO often occurs while negotiating a highly calcified plaque, and information from the impedance sensor will aid in safely guiding the distal loops **20** to successfully cross the CTO instead of dissecting or perforating blood vessels.

[0103] While all aspects of the present invention have been described with reference to the drawings, this description of various embodiments and methods shall not be construed in a limiting sense. The aforementioned is presented for purposes of illustration and description. It

shall be understood that all aspects of the invention are not limited to the specific depictions, configures or relative proportions set forth herein which depend on a variety of conditions and variables. The actual dimensions and materials of a device constructed according to the principles of the present invention may obviously vary outside of the listed ranges and materials without departing from those basic principles. The specification is not intended to be exhaustive or to limit the invention to the precise forms disclosed herein. Various modifications and insubstantial changes in form and detail of the particular embodiments of the disclosed invention, as well as other variations of the invention, will be apparent to a person skilled in the art upon reference to the present disclosure. It is therefore contemplated that the appended claims shall cover any such modifications or variations of the described embodiments as falling within the true spirit and scope of the invention.

CLAIMS

What is claimed:

1. A vascular drilling device for crossing an occluded blood vessel, said device having a main body comprising:

an outer tubular member;

an inner tubular member interposed within said outer tubular member;

a distal end cap secured to said outer tubular member and said inner tubular member;

a plurality of distal end loops projecting from said distal end cap for fracturing an occlusion; and,

a plurality of outer loops projecting from said outer tubular member for fracturing said occlusion,

whereby said distal end loops and said outer loops fracture an occlusion within a blood vessel when said distal end loops and said outer loops are rotated and pushed through said occluded blood vessel.

2. The device of claim 1, wherein said plurality of distal end loops is a pair of distal end loops, and wherein said plurality of outer loops are a pair of outer loops substantially orthogonal to said outer loops.

3. The device of claim 1, wherein said plurality of outer loops are positioned approximately between 0.5cm and 1.0cm from said distal end of said outer tubular member.

4. The device of claim 1 further comprising:

at least one wire helical coil encircling said inner tubular member,

whereby said helical coil improves the strength and flexibility of the said inner tubular member compared to the strength and flexibility of said inner tubular member without said at least one helical coil encircling said inner tubular member.

5. The device of claim 4, wherein said at least one wire helical coil has a hydrophilic polymer coating.

6. The device of claim 4, wherein said at least one wire helical coil are two wire helical coils.

7. The device of claim 4, wherein said plurality of distal loops and said plurality of outer loops are formed from said at least one wire helical coil.

8. The device of claim 1 further comprising

an expandable balloon configured for inflation, said expandable balloon envelops at least a portion of said outer tubular member,

whereby when said expandable balloon inflates, said expandable balloon dilates said occlusion and places said device in a vessel-centric position thereby substantially preventing unintended entry of said device into a subintimal plane of said blood vessel.

9. The device of claim 1, wherein said inner tubular member is characterized by having a central lumen for guidewire exchange, and said distal end cap is characterized by having a centrally positioned hole for guidewire exchange.

10. The device of claim 1, wherein said distal end cap is a C-cup distal end cap.

11. The device of claim 1, wherein said device further comprises:

a motor unit comprising

an electric motor;

a motor unit inner tubular member having a threaded outer surface;

a motor unit outer tubular member having a threaded inner surface configured to engage said threaded outer surface of said motor unit inner tubular member, said motor unit inner tubular member positioned within an inner lumen of said motor unit outer tubular member; and,

a locking screw for locking said motor unit to said motor unit inner tubular member,

whereby said electric motor transmits torque to said main body, thereby rotating said

plurality of distal loops and said plurality of outer loops to fracture said occlusion within said occluded blood vessel.

12. The device of claim 11, further comprising:

a motion sensor within said main body for measuring speed and character of rotation of said main body; and,

a microprocessor for receiving and analyzing speed and feedback data;

whereby said motion sensor and microprocessor, in conjunction with an operator's instructions, allow for better control of said device.

13. The device of claim 1, wherein said main body is characterized as segmented into a rotationally stationary unit and a drilling unit:

said rotationally stationary unit comprising:

a rotationally stationary unit outer tubular member;

a rotationally stationary unit inner tubular member interposed within said rotationally stationary unit outer tubular member;

a torque transmitting member interposed within said rotationally stationary unit inner tubular member, said torque transmitting member distally connected to said drilling unit;

said drilling unit comprising:

said outer tubular member;

said inner tubular member;

said distal end cap;

said plurality of distal end loops; and,

said plurality of outer loops,

whereby only said drilling unit of said main body rotates when said device rotates, thereby preventing unnecessary frictional forces against a blood vessel where there is no occlusion.

14. The device of claim 13, further comprising a guidewire tubular member disposed within said rotationally stationary unit for inserting a guidewire into a patient.

15. A method of traversing a vascular occlusion using a vascular drilling device comprising an outer tubular member, an inner tubular member interposed within outer tubular member, a distal end cap secured to said outer tubular member and said inner tubular member, a plurality of distal end loops projecting form said distal end cap, a plurality of outer loops projecting from said outer tubular member, the method comprising the steps of:

positioning said device such that the distal end of said device is proximate to an occlusion;

rotating at least a portion of said device for fracturing said occlusion; and,

advancing said device through said occlusion.

16. The method of claim 15, wherein said vascular drilling device further comprises an expandable balloon enveloping at least a portion of said outer tubular member, and further comprising the step of:

inflating said balloon for dilation of said occlusion.

17. The method of claim 15, further comprising the step of:

advancing a guidewire through said device.

18. A vascular drilling device for centrally aligning and crossing an occluded blood vessel, said device having a stationary unit and a drilling unit,

the stationary unit comprising:

an outer tubular member;

an inner tubular member interposed within said outer tubular member

a torque-transmitting member interposed within said inner tubular member extending from said stationary unit to said drilling unit;

a plurality of curved alignment structures extending said outer tubular member,

whereby said plurality of curved alignment structures align said device in a central region of a blood vessel, thereby preventing accidental puncturing of

blood vessel walls;

the drilling unit comprising:

a plurality of distal end loops projecting from a distal region of said drilling unit;

whereby said distal end loops fracture an occlusion when said loops rotate and advance though said occlusion.

19. The device of Claim 18,

wherein each of said curved alignment structures comprises a coiled alignment member integral with said curved alignment structure, thereby allowing said curved alignment structures to compress and expand; and,

wherein each of said coiled alignment members is attached to said stationary unit.

20. The device of Claim 19, wherein each of said coiled alignment members comprises between four and ten coils.

21. The device of Claim 18, wherein said torque-transmitting member is substantially enclosed by, and attached to, an inner rotatable hypotube.

22. The device of Claim 18, wherein said plurality of curved alignment structure loops are made from a composition comprising nitinol (nickel and titanium) and a hydrophilic polymer coating.

23. The device of Claim 18, wherein said plurality of curved alignment structures are three curved alignment structures substantially equally spaced from each other along said outer tubular member.

24. The device of Claim 18, wherein said plurality of curved alignment structures extend non-perpendicularly from said outer tubular member.

25. The device of Claim 24, wherein said plurality of curved alignment structures extend approximately 45 degrees from the surface of said outer tubular member.

26. The device of Claim 18,

wherein said curved alignment structures extend approximately between the range of 3 mm and 8 mm from an outer surface of said outer tubular member;

and wherein each of said curved alignment structures is approximately between 25 mm and 50 mm in length.

27. The device of Claim 18, further comprising:

a guidewire tubule interposed within said stationary unit of said vascular drill; and,

a guidewire tubule aperture within said outer tubular member, thereby allowing a practitioner to insert a guidewire through the device.

28. The device of Claim 18, further comprising:

a sensor coupled to said drilling tip, said sensor allows for measurement of mechanical impedance to indicate the presence or absence of calcified or non-calcified plaques, thereby allowing an operator to know the location of said distal tip relative to a plaque.

29. A vascular drilling device for centrally aligning and crossing an occluded blood vessel, said device having a stationary unit and a drilling unit,

the stationary unit comprising:

an outer tubular member;

an inner tubular member interposed within said outer tubular member

a torque-transmitting member interposed within said inner tubular member extending from said stationary unit to said drilling unit, wherein said torque-transmitting member is substantially enclosed by, and attached to, an inner rotatable hypotube;

a plurality of coiled curved alignment structures extending non-perpendicularly from said outer tubular member, wherein said curved alignment structures extend approximately between the range of 3 mm and 8 mm from an outer surface of said outer tubular member, and wherein each of said curved alignment structures is approximately between 25 mm and 50 mm in length;

whereby said plurality of curved alignment structures align said device in a central region of a blood vessel, thereby preventing accidental puncturing of blood vessel walls;

the drilling unit comprising:

a plurality of distal end loops projecting from a distal region of said drilling unit;

whereby said distal end loops fracture an occlusion when said loops rotate and advance though said occlusion.

30. A method of traversing a vascular occlusion using a vascular drilling device comprising a stationary unit and a drilling unit, the stationary unit comprising an outer tubular member, an inner tubular member interposed within said outer tubular member, a torque-transmitting member interposed within said inner tubular member extending from said stationary unit to said drilling unit, a plurality of curved alignment structures extending from said outer tubular member; the drilling unit comprising said torque-transmitting member, and a plurality of distal end loops projecting from a distal region of said drilling unit, the method comprising the steps of:

positioning said device such that the distal end of said device is proximate to an

occlusion;

rotating at least a portion of said device for fracturing said occlusion; and,

advancing said device through said occlusion.

31. The method of claim 12, further comprising the step of:

advancing a guidewire through said device.

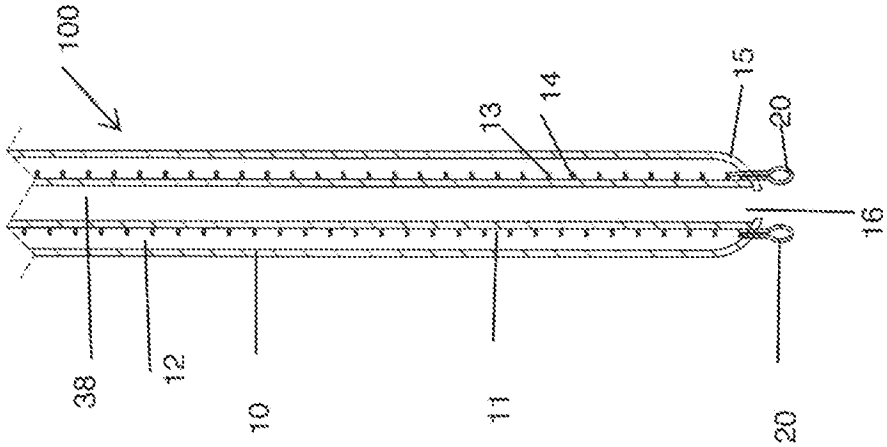

Fig. 1A

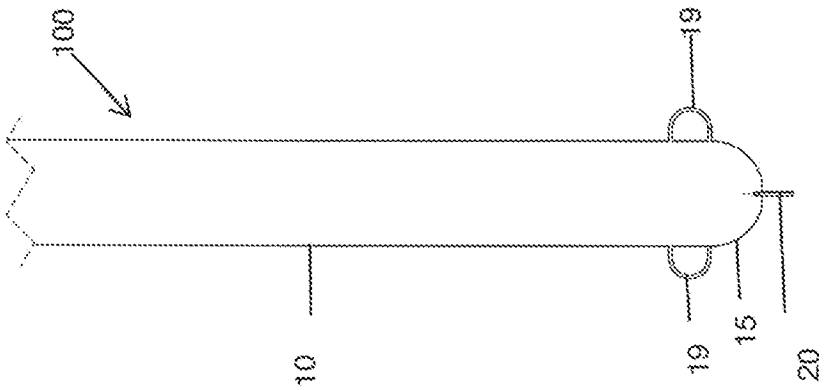

Fig. 1B

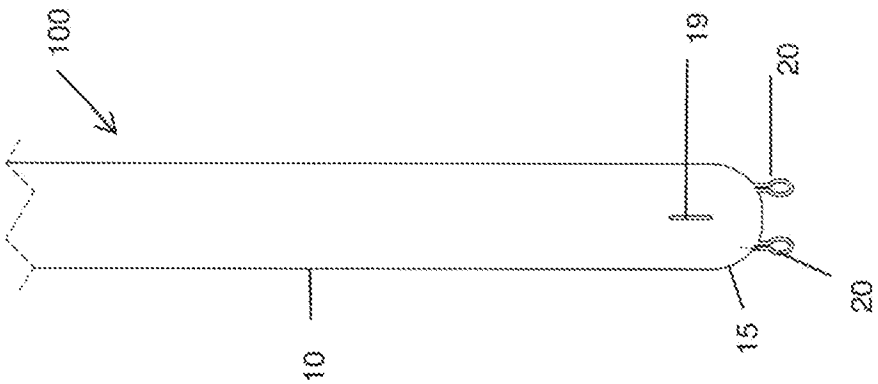

Fig. 1C

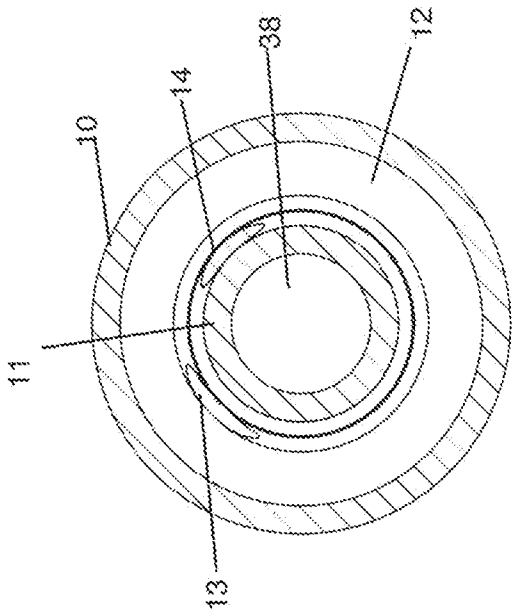

Fig. 1E

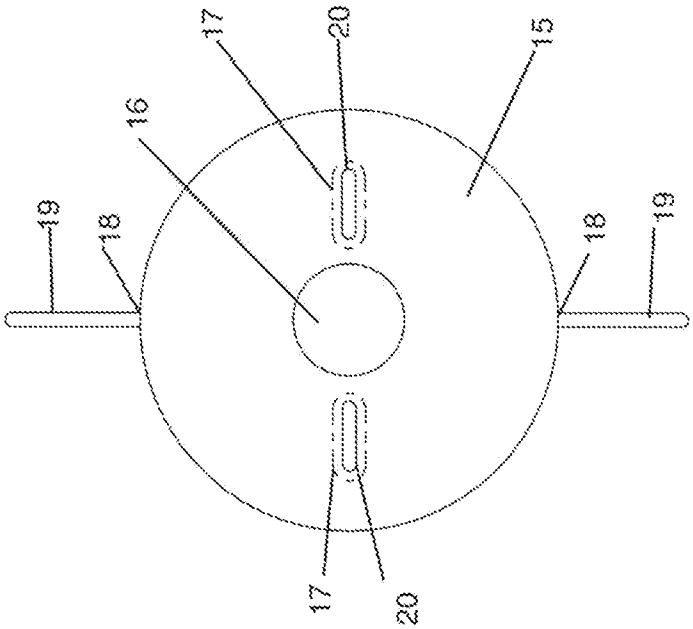

Fig. 1D

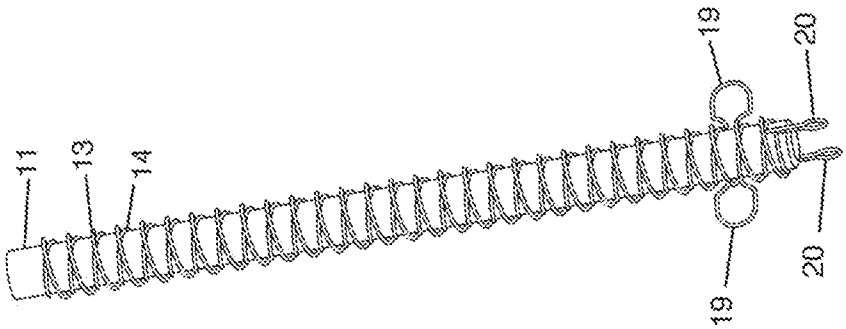

Fig. 1F

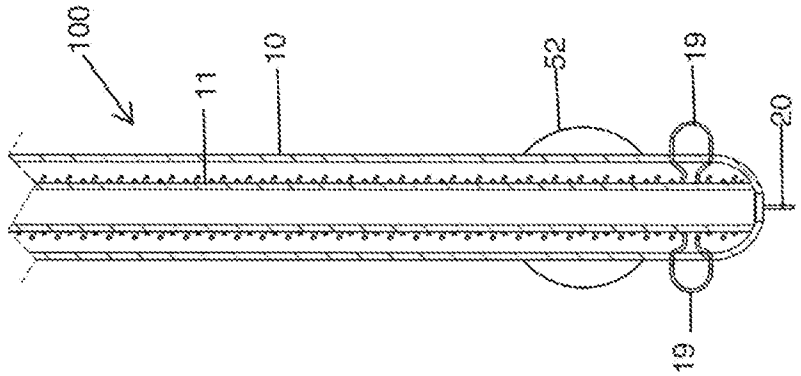

Fig. 2A

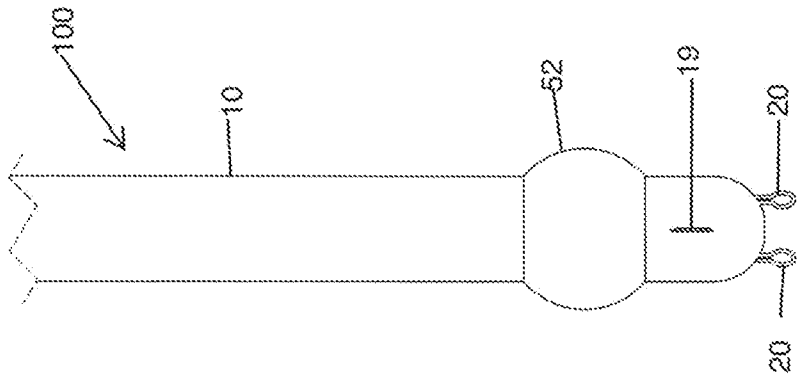

Fig. 2B

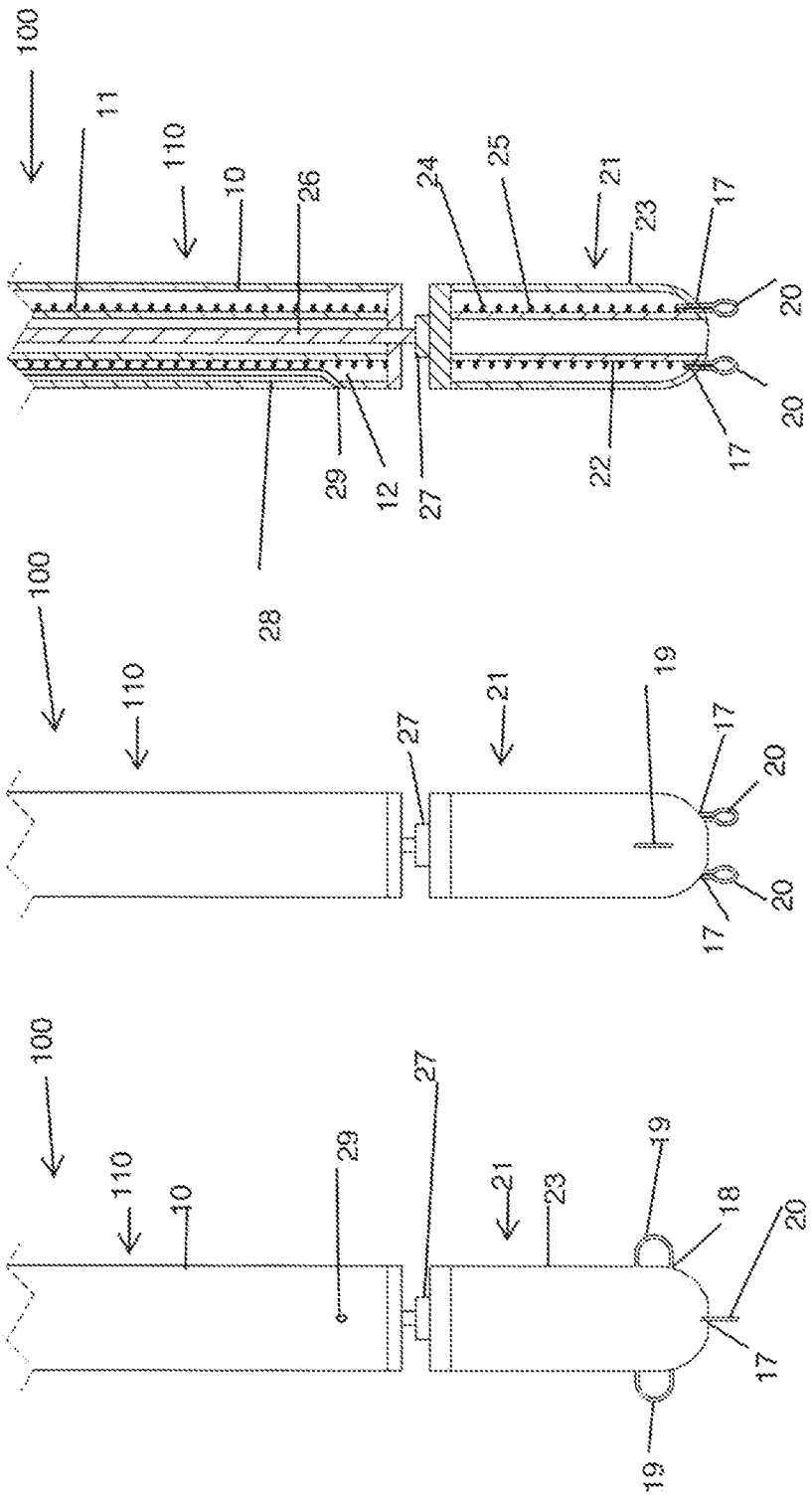

Fig. 3A

Fig. 3B

Fig. 3C

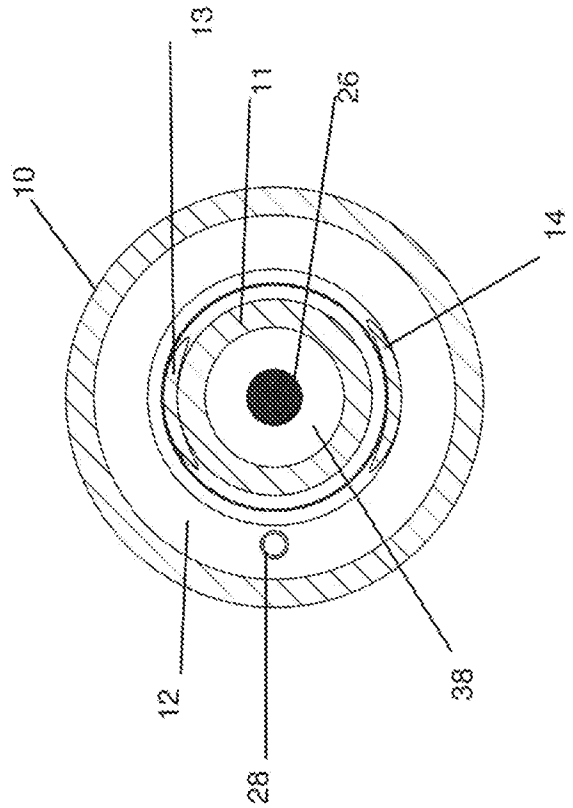

Fig. 3D

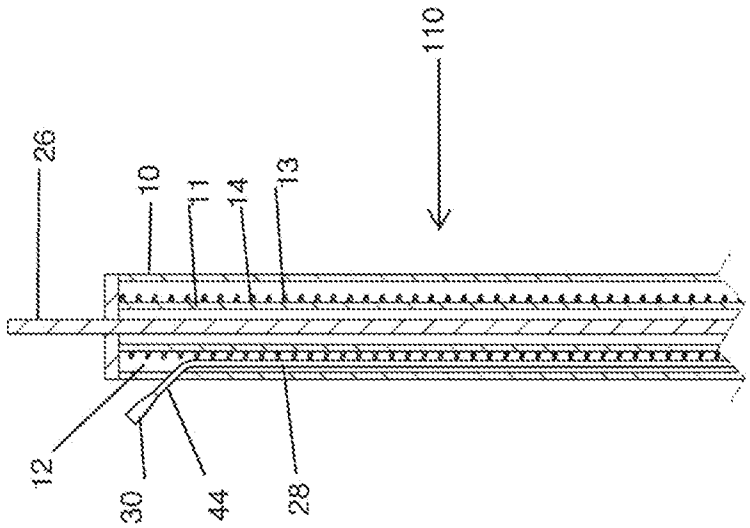

Fig. 4

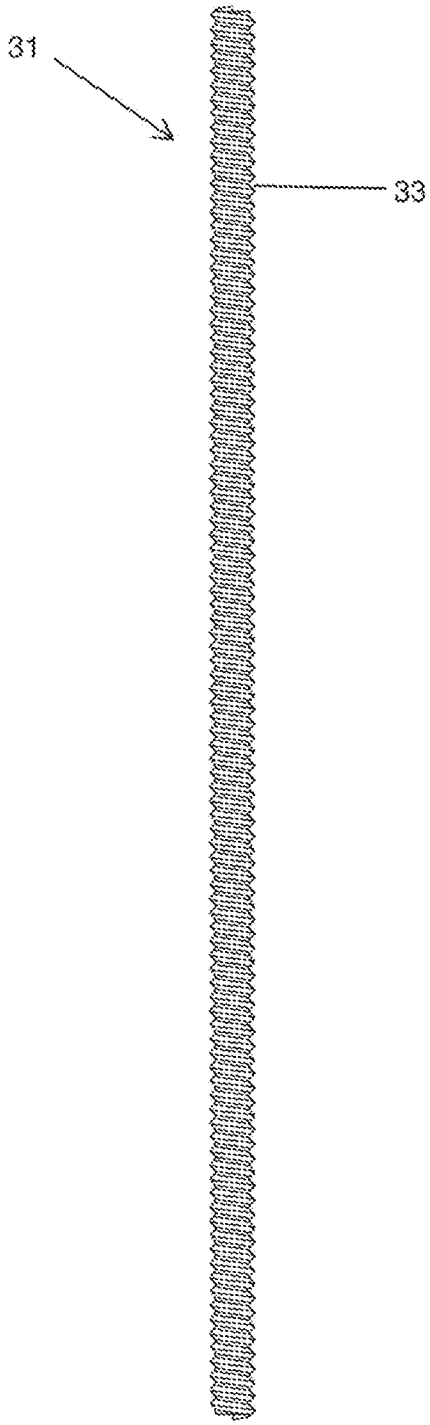

Fig. 5B

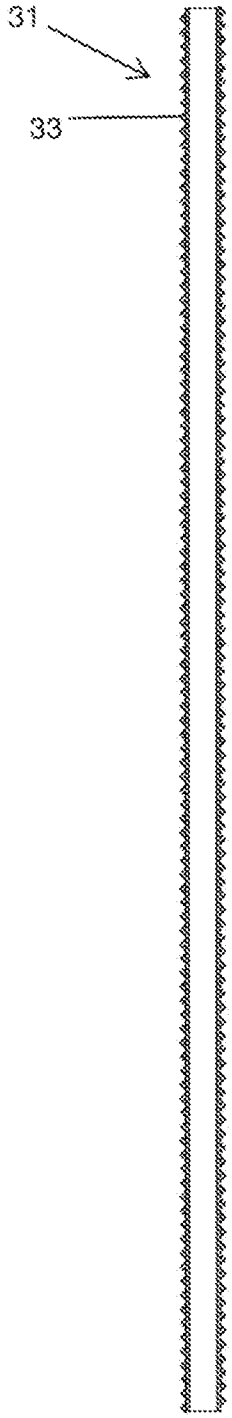

Fig. 5A

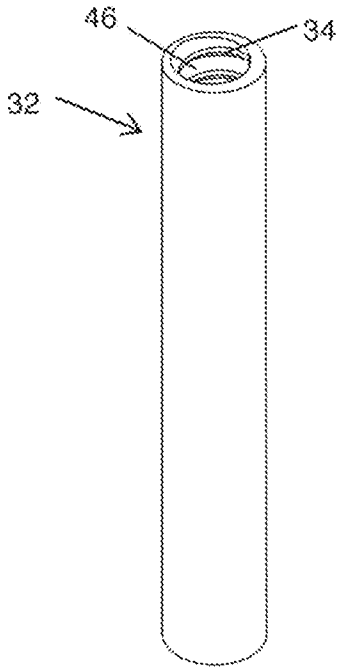

Fig. 6B

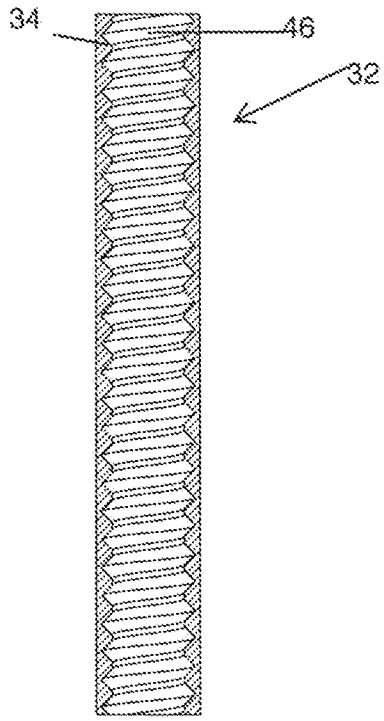

Fig. 6A

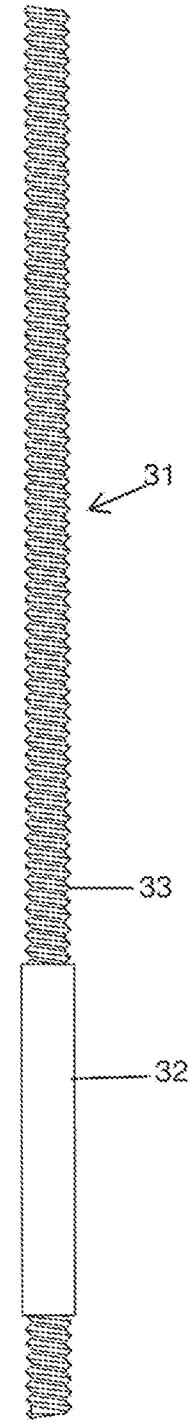

Fig. 7B

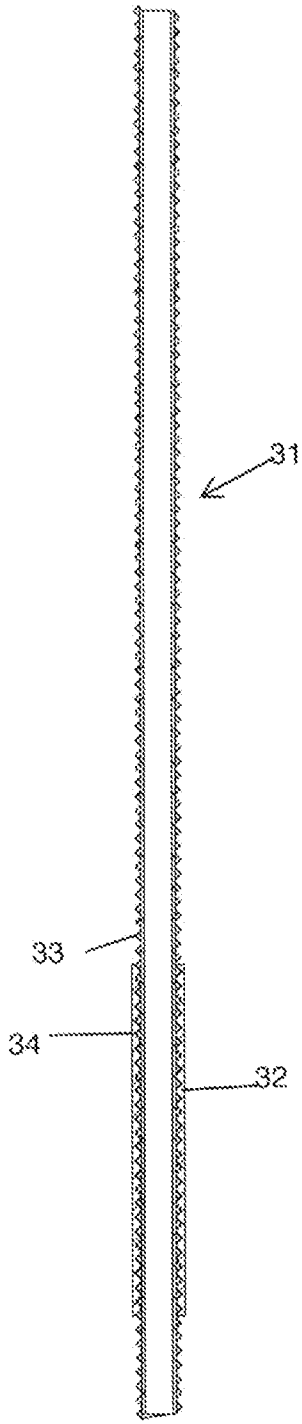

Fig. 7A

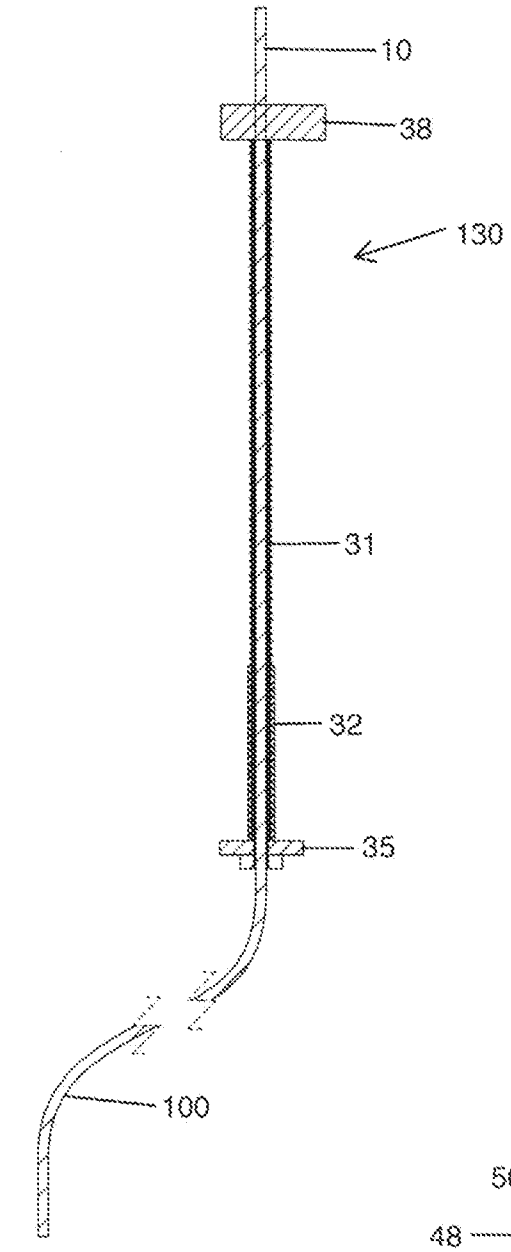

Fig. 8B

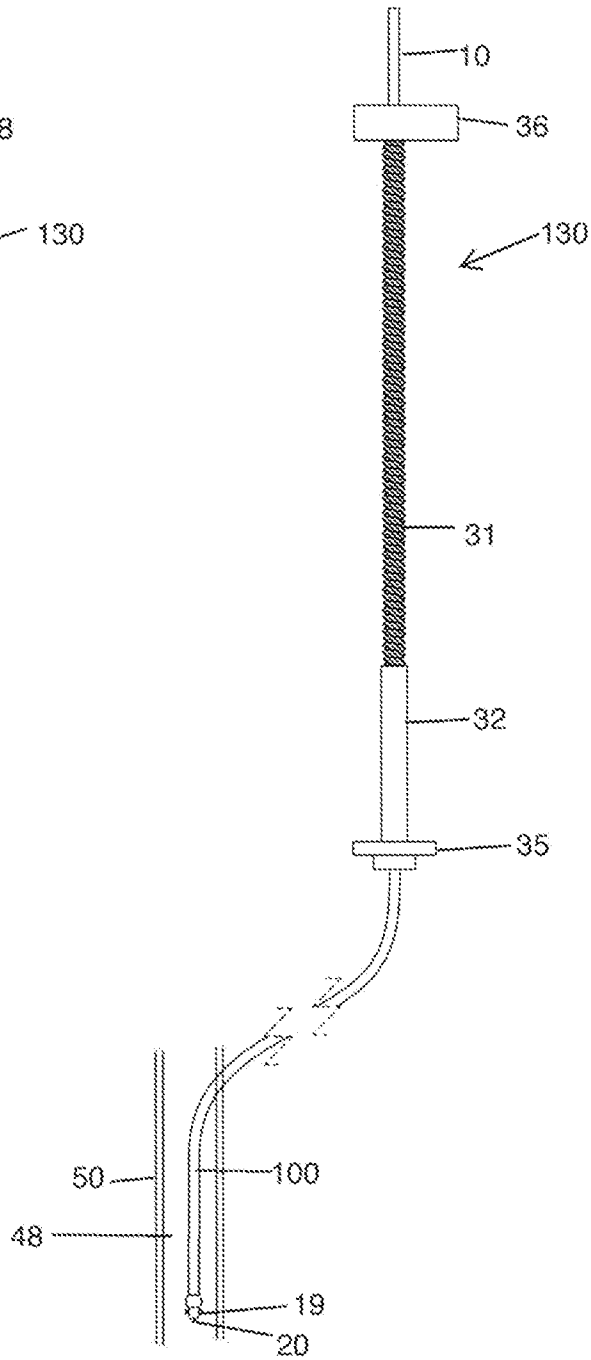

Fig. 8A

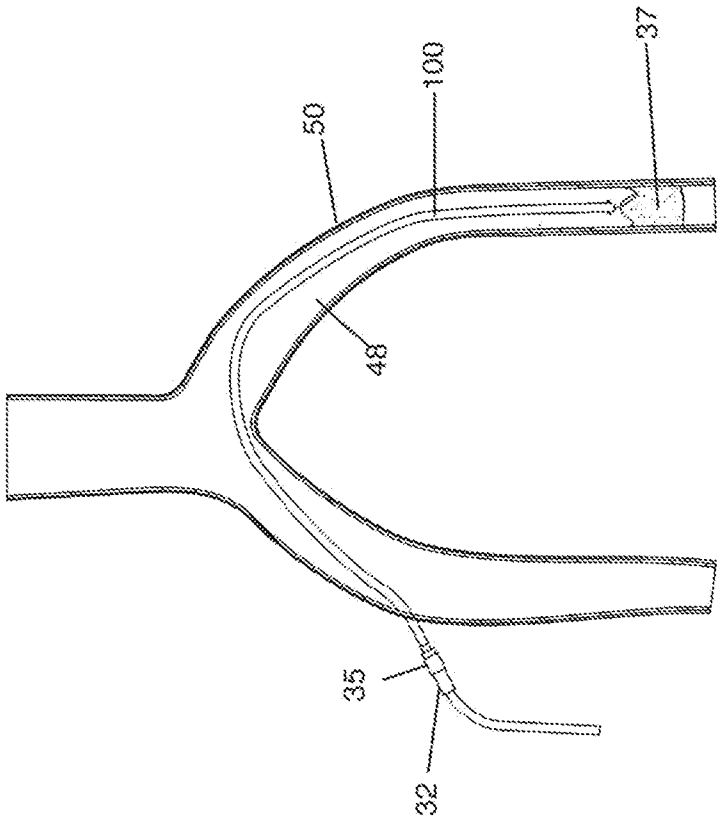

Fig. 9

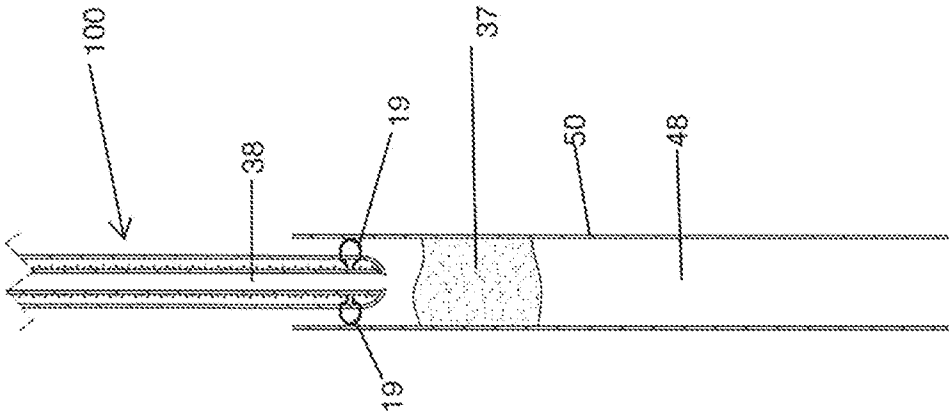

Fig. 10A

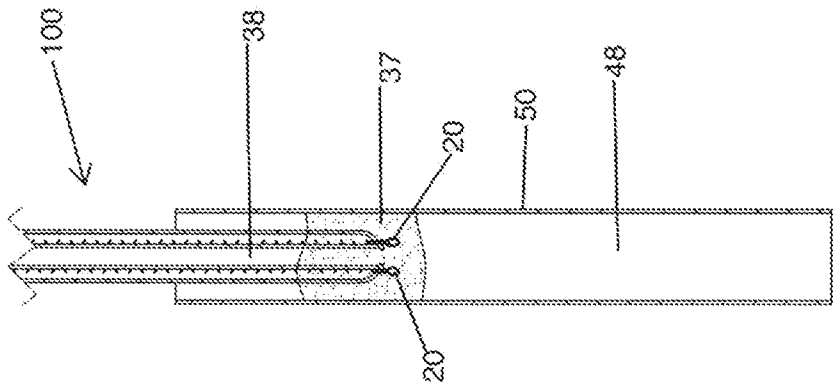

Fig. 10B

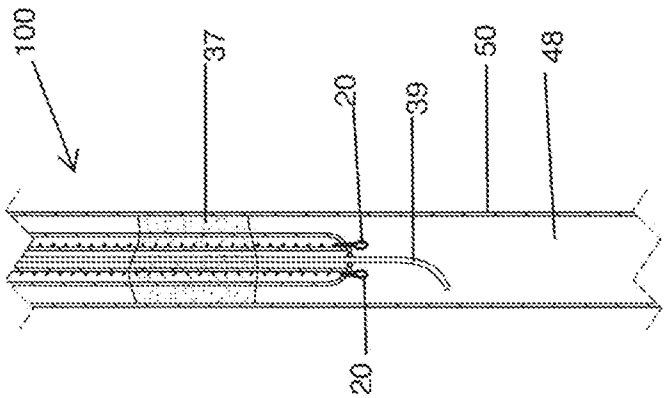

Fig. 10C

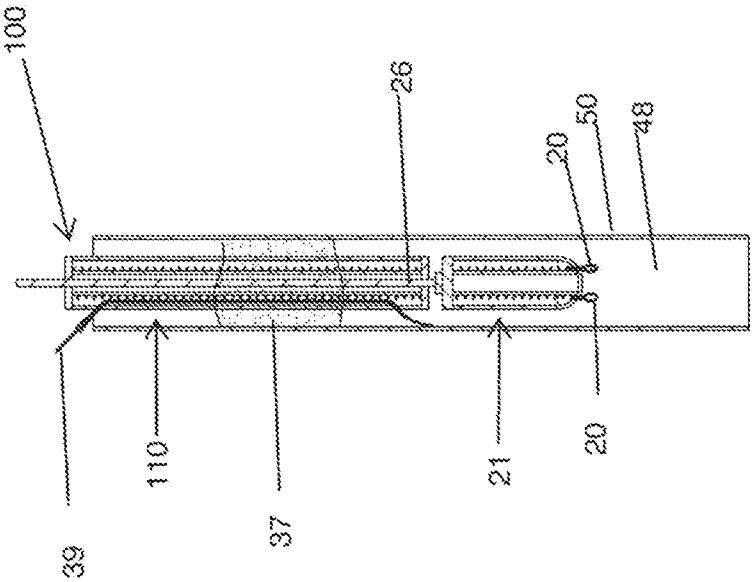

Fig. 11

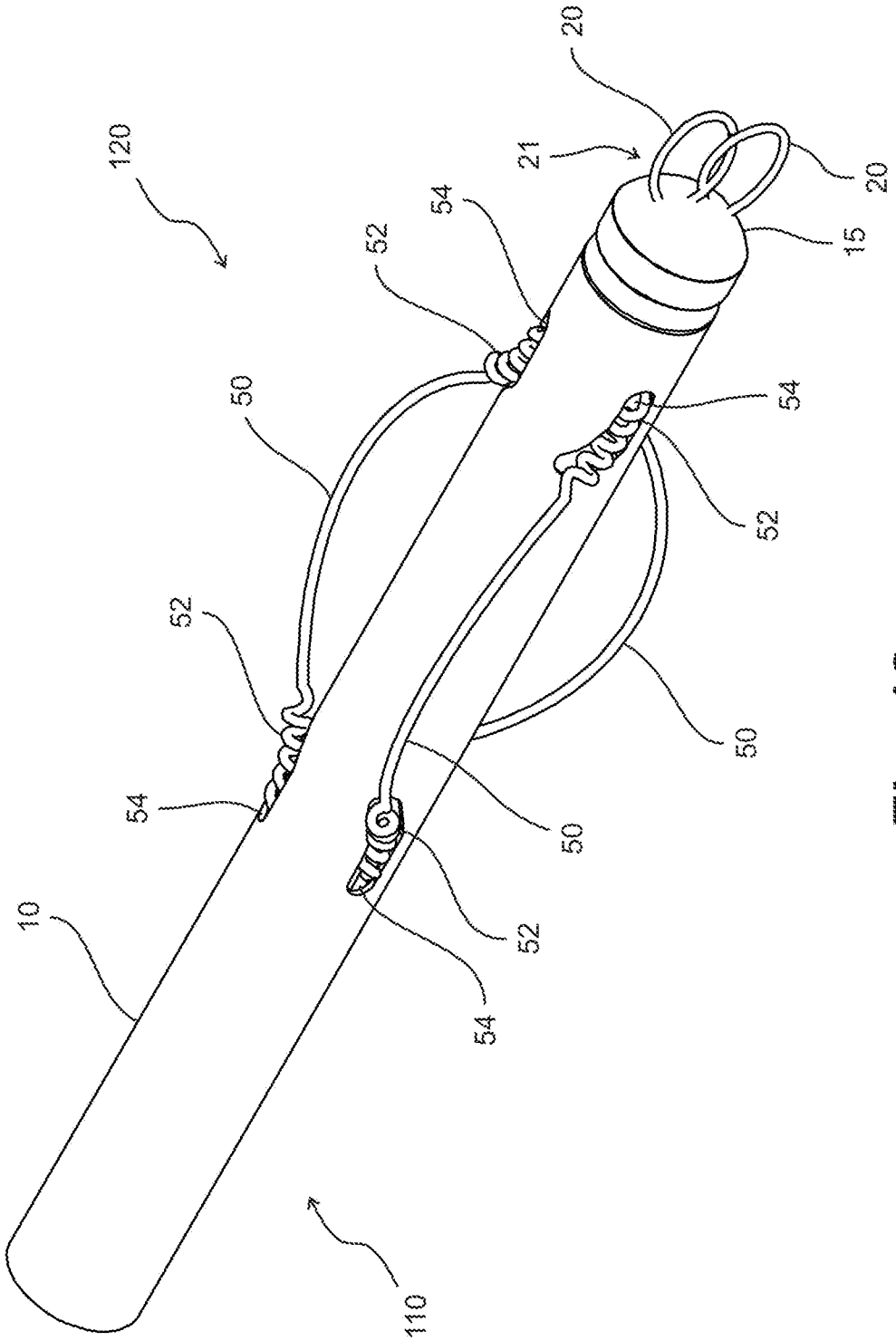

Fig. 12a

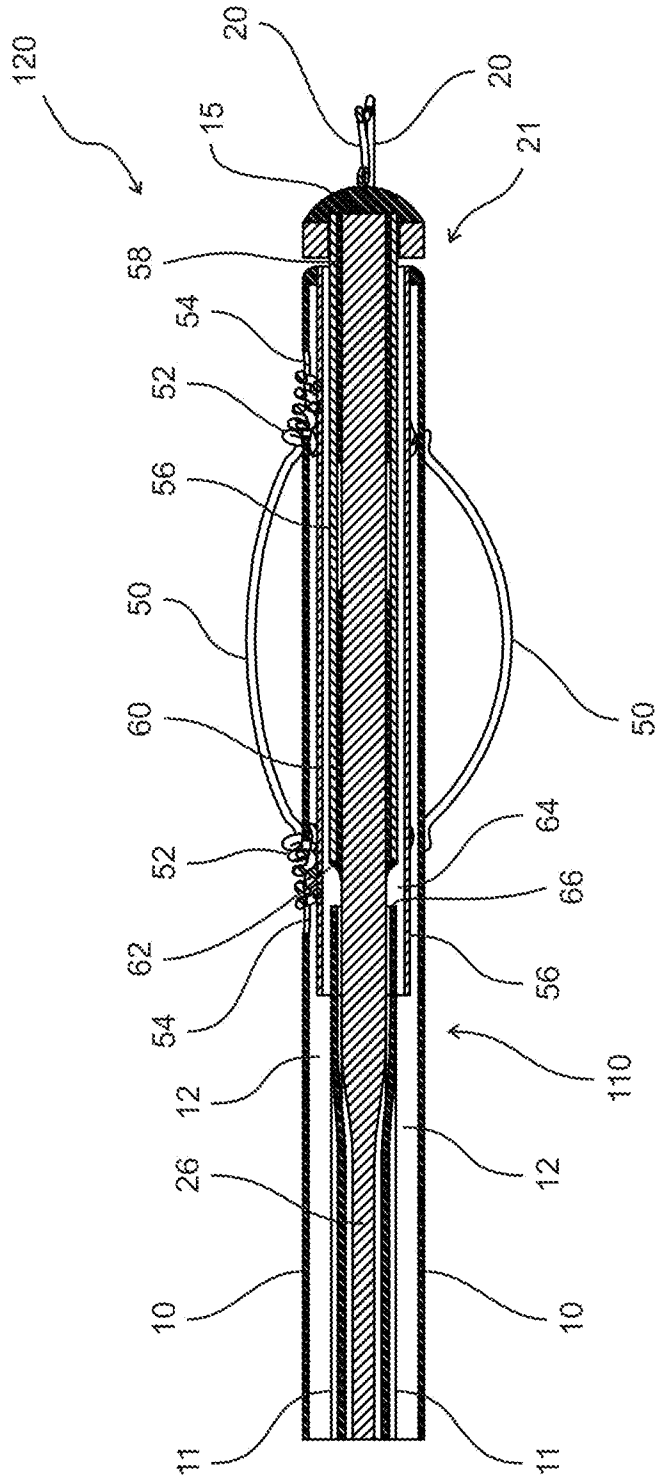
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Fig. 12b

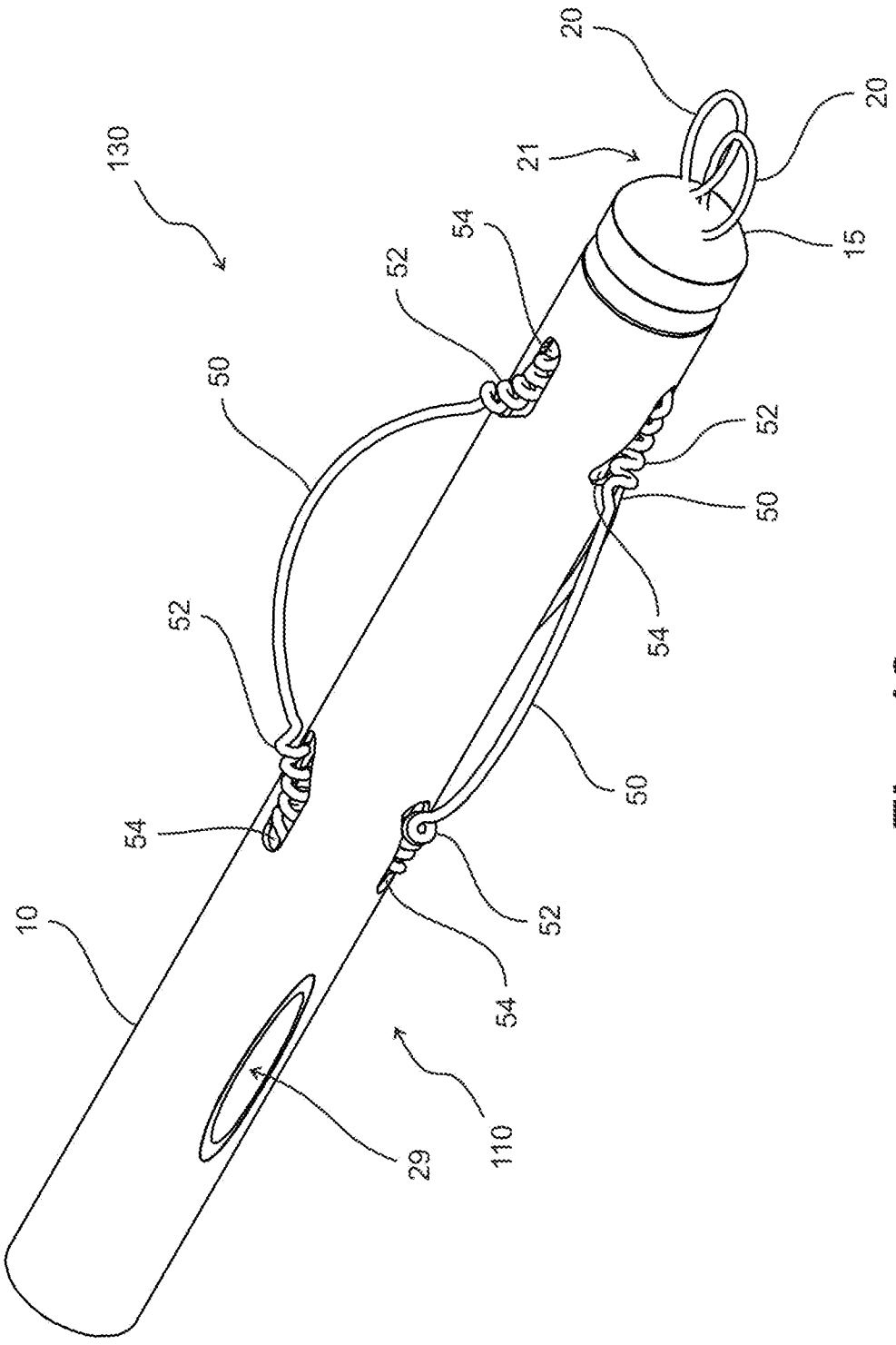

Fig. 13a

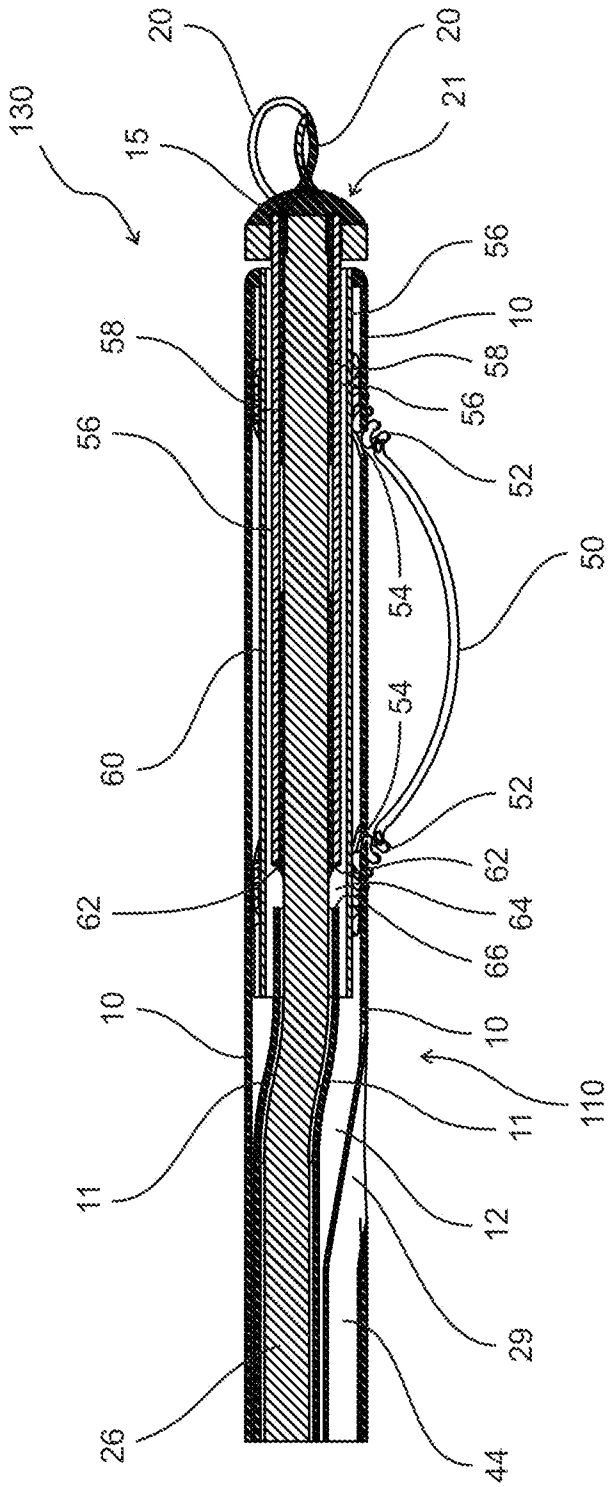
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Fig. 13b

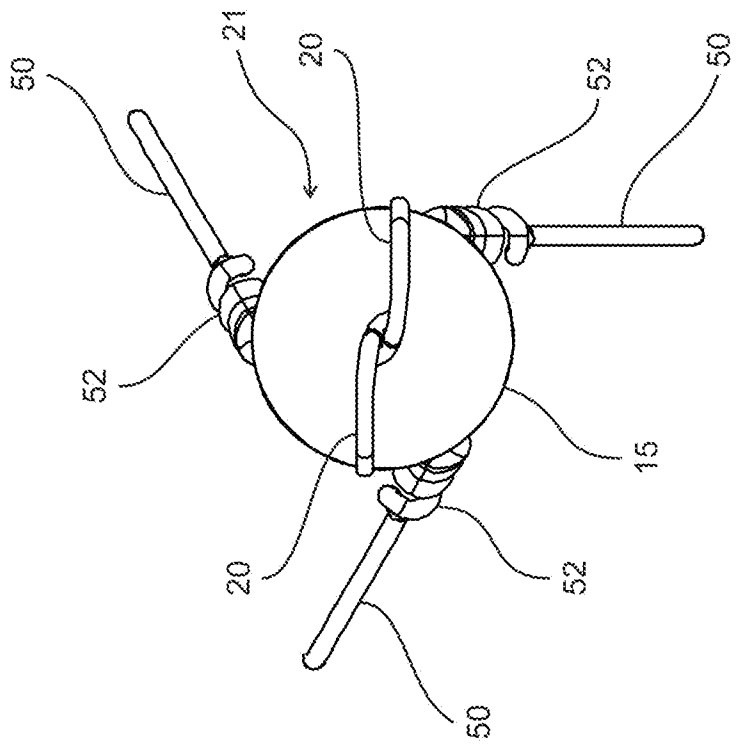

Fig. 14

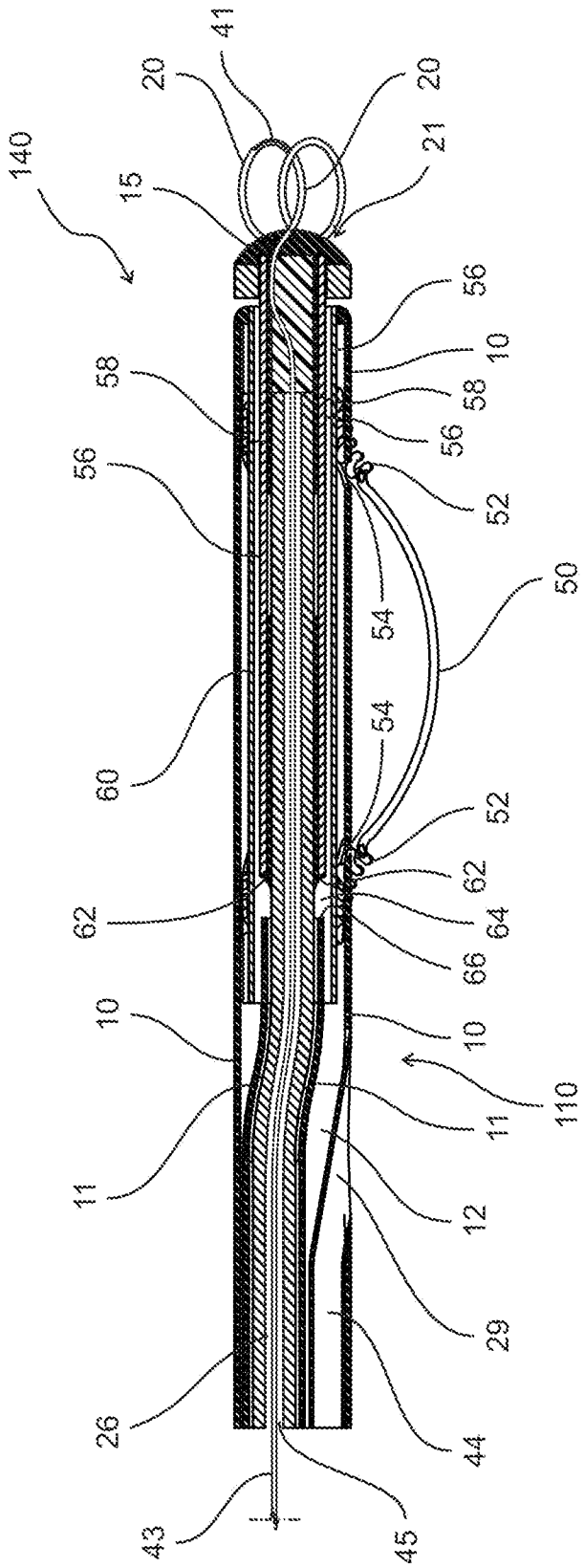
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Fig. 15

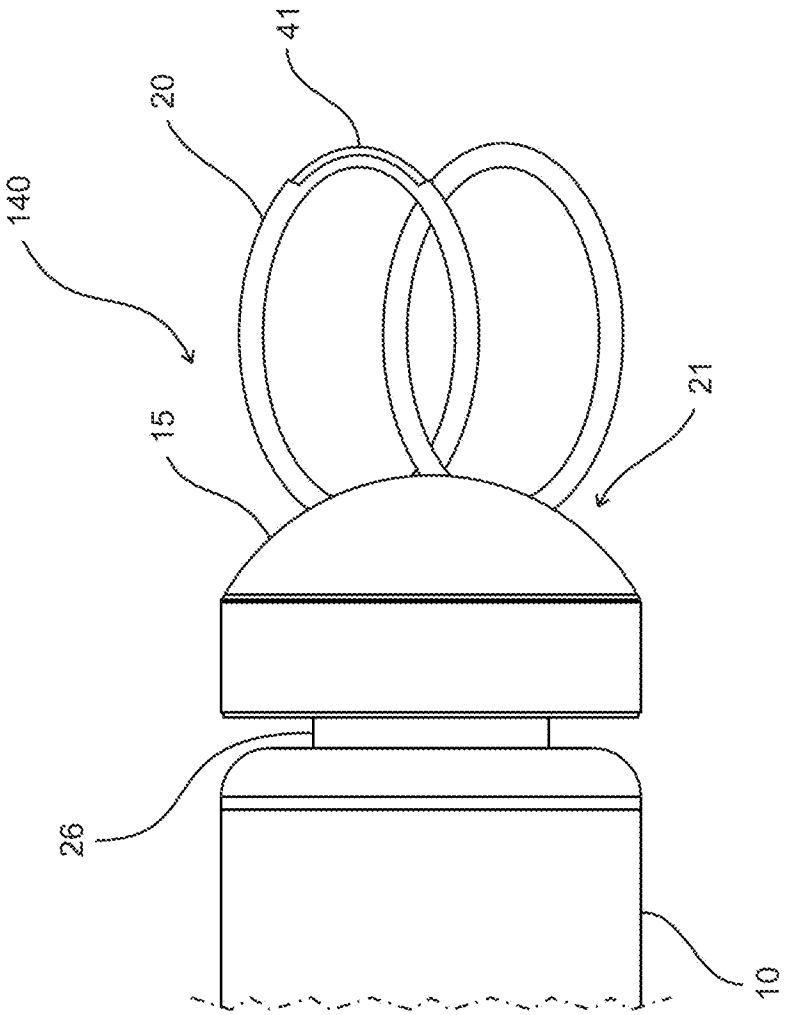

Fig. 16

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2014/020607

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61B 6/00 (2014.01)
USPC - 600/426
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) - A61B 6/00, 6/08, 17/00, 17/22 (2014.01)
USPC - 600/426, 427, 478; 606/158, 159

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
CPC - A61B 6/00, 6/08, 17/00, 17/22 (2014.02)

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2012/0253186 A1 (SIMPSON et al) 04 October 2012 (04.10.2012) entire document	1-10
A	US 2010/0082051 A1 (THORPE et al) 01 April 2010 (01.04.2010) entire document	1-31
A	US 8,361,094 B2 (TO et al) 29 January 2013 (29.01.2013) entire document	1-31

☐ 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	Date of mailing of the international search report
02 June 2014	20 JUN 2014
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: Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774