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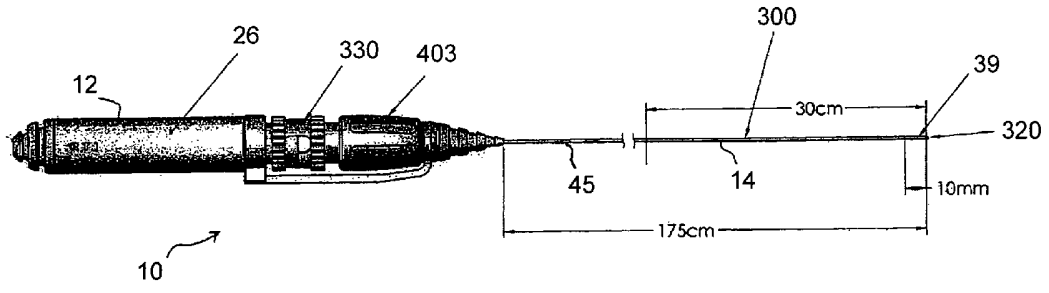
(54) Title: GUIDEWIRE FOR CROSSING OCCLUSIONS OR STENOSES



(57) Abstract: A deflectable and torqueable hollow guidewire device is disclosed for removing occlusive material and passing through occlusions, stenosis, thrombus, plaque, calcified material, and other materials in a body lumen, such as a coronary artery. The hollow guidewire generally comprises an elongate, tubular guidewire body that has an axial lumen. A mechanically moving core element is positioned at or near a distal end of the tubular guidewire body and extends through the axial lumen. Actuation of the core element (*e.g.*, oscillation, reciprocation, and/or rotation) creates a passage through the occlusive or stenotic material in the body lumen.

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GUIDEWIRE FOR CROSSING OCCLUSIONS OR STENOSES

CROSS-REFERENCES TO RELATED APPLICATIONS

[0001] The present application is a continuation-in-part of U.S. Patent Application Serial No. 10/999,457, filed November 29, 2004, entitled "Guidewire For Crossing Occlusions or Stenoses," which was a continuation-in-part of U.S. Patent Application Serial No. 09/644,201, filed August 22, 2000, entitled "Guidewire for Crossing Occlusions or Stenoses," and now U.S. Patent No. 6,824,550, which claimed benefit under 37 C.F.R. § 1.78 to U.S. Provisional Patent Application No. 60/195,154, filed April 6, 2000, entitled "Guidewire for Crossing Occlusions or Stenosis," the complete disclosures of which are incorporated herein by reference.

[0002] The present application is also related to U.S. Patent Application No. 09/030,657, filed February 25, 1998, entitled "Steerable Unitary Infusion Catheter/Guide Wire Incorporating Detachable Infusion Port Assembly," and now U.S. Patent No. 6,059,767, and U.S. Patent Application No. 09/935,534, filed August 22, 2001, entitled "Steerable Support System with External Ribs/Slots that Taper," and now U.S. Patent No. 6,746,422, the complete disclosures of which are incorporated herein by reference.

BACKGROUND OF THE INVENTION

[0003] The present invention is generally related to medical devices, kits, and methods. More specifically, the present invention provides a guidewire system for crossing stenosis, partial occlusions, or total occlusions in a patient's body.

[0004] Cardiovascular disease frequently arises from the accumulation of atheromatous material on the inner walls of vascular lumens, particularly arterial lumens of the coronary and other vasculature, resulting in a condition known as atherosclerosis. Atheromatous and other vascular deposits restrict blood flow and can cause ischemia which, in acute cases, can result in myocardial infarction or a heart attack. Atheromatous deposits can have widely varying properties, with some deposits being relatively soft and others being fibrous and/or calcified. In the latter case, the deposits are frequently referred to as plaque. Atherosclerosis occurs naturally as a result of aging, but may also be aggravated by factors such as diet, hypertension, heredity, vascular injury, and the like.

[0005] Atherosclerosis can be treated in a variety of ways, including drugs, bypass surgery, and a variety of catheter-based approaches which rely on intravascular widening or removal

of the atheromatous or other material occluding the blood vessel. Particular catheter-based interventions include angioplasty, atherectomy, laser ablation, stenting, and the like. For the most part, the catheters used for these interventions must be introduced over a guidewire, and the guidewire must be placed across the lesion prior to catheter placement. Initial guidewire placement, however, can be difficult or impossible in tortuous regions of the vasculature. Moreover, it can be equally difficult if the lesion is total or near total, i.e. the lesion occludes the blood vessel lumen to such an extent that the guidewire cannot be advanced across the lesion.

[0006] To overcome this difficulty, forward-cutting atherectomy catheters have been proposed. Such catheters usually can have a forwardly disposed blade (U.S. 4,926,858) or rotating burr (U.S. 4,445,509). While effective in some cases, these catheter systems, even when being advanced through the body lumen with a separate guidewire, have great difficulty in traversing through the small and tortuous body lumens of the patients and reaching the target site.

[0007] For these reasons, it is desired to provide devices, kits, and methods which can access small, tortuous regions of the vasculature and which can remove atheromatous, thrombotic, and other occluding materials from within blood vessels. In particular, it is desired to provide atherectomy systems which can pass through partial occlusions, total occlusions, stenosis, and be able to macerate blood clots or thrombotic material. It is further desirable that the atherectomy system have the ability to infuse and aspirate fluids before, during, or after crossing the lesion. At least some of these objectives will be met by the devices and methods of the present invention described hereinafter and in the claims.

BRIEF SUMMARY OF THE INVENTION

[0008] The present invention provides systems and methods for removing occlusive material and passing through occlusions, stenosis, thrombus, plaque, calcified material, and other material in a body lumen. More particularly, the present invention can be used for passing through stenosis or occlusions in a neuro, cardio, and peripheral body lumens. Generally, the present invention includes an elongate member, such as a hollow guidewire, that is advanced through a body lumen and positioned adjacent the occlusion or stenosis. An occlusive material (e.g., plaque) removal assembly is positioned at or near a distal tip of the hollow guidewire to create an opening in the occlusion. In one embodiment, the plaque removal assembly comprises a drive shaft having a distal tip that is oscillated, reciprocated (e.g., pecking), and/or rotated and advanced from within an axial lumen of the hollow guidewire.

Once the guidewire has reached the lesion, the guidewire with the exposed oscillating, reciprocating, and/or rotating drive shaft may be advanced into the lesion (or the guidewire may be in a fixed position and the drive shaft may be advanced) to create a path forward of the hollow guidewire to form a path in the occlusion or stenosis. To facilitate passing through the occlusion or stenosis, the distal end of the hollow guidewire can be steerable to provide better control of the creation of the path through the occlusion or stenosis. Optionally, the target site can be infused and/or aspirated before, during, and after creation of the path through the occlusion.

[0009] The hollow guidewire of the present invention has deflectability, flexibility, pushability, and torqueability to be advanced through the tortuous blood vessel without the use of a separate guidewire or other guiding element. Additionally, the hollow guidewire may be sized to fit within an axial lumen of a conventional support or access catheter system. The catheter system can be delivered either concurrently with the advancement of the hollow guidewire or after the hollow guidewire or conventional guidewire has reached the target site. The position of the hollow guidewire and catheter system can be maintained and stabilized while the drive shaft is rotated and translated out of the axial lumen of the hollow guidewire. The distal tip of the drive shaft can be deflected, coiled, blunted, flattened, enlarged, twisted, basket shaped, or the like. In some embodiments, to increase the rate of removal of the occlusive material, the distal tip is sharpened or impregnated with an abrasive material such as diamond chips, diamond powder, glass, or the like.

[0010] The drive shaft can be a counter-wound guidewire construction or be composed of a composite structure comprising a fine wire around which a coil is wrapped. The counter-wound or composite constructions are more flexible than a single wire drive shaft and can provide a tighter bending radius while still retaining the torque transmitting ability so that it can still operate as a lesion penetration mechanism.

[0011] In a specific configuration, the drive shaft has spiral threads or external riflings extending along the shaft. The spirals typically extend from the proximal end of the shaft to a point proximal of the distal tip. As the drive shaft is rotated and axially advanced into the occlusive material (concurrently with the hollow guidewire body or with the hollow guidewire body substantially stationary), the distal tip creates a path through the occlusion and removes the material from the body. The spirals on the shaft act similar to an "Archimedes Screw" and transport the removed material proximally through the axial lumen of the hollow guidewire and prevents the loose atheromatous material from escaping into the blood stream.

[0012] Systems and kits of the present invention can include a support system or access system, such as a catheter having a body adapted for intraluminal introduction to the target blood vessel. The dimensions and other physical characteristics of the access system body will vary significantly depending on the body lumen which is to be accessed. The body of the support or access system is very flexible and is suitable for introduction over a conventional guidewire or the hollow guidewire (e.g., having a removable hub) of the present invention. The support or access system body can either be for "over-the-wire" introduction or for "rapid exchange," where the guidewire lumen extends only through a distal portion of the access system body. Optionally, the support or access system can have at least one axial channels extending through the lumen to facilitate infusion and/or aspiration of material from the target site. Support or access system bodies will typically be composed of an organic polymer, such as polyvinylchloride, polyurethanes, polyesters, polytetrafluoroethylenes (PTFE), silicone rubbers, natural rubbers, or the like. Suitable bodies may be formed by extrusion, with one or more lumens that extend axially through the body. For example, the support or access system can be a support catheter, interventional catheter, balloon dilation catheter, atherectomy catheter, rotational catheter, extractional catheter, laser ablation catheter, guiding catheter, stenting catheter, ultrasound catheter, and the like.

[0013] In use, the access system can be delivered to the target site over a conventional guidewire. Once the access system has been positioned near the target site, the conventional guidewire can be removed and the elongate member (e.g., hollow guidewire) of the present invention can be advanced through an inner lumen of the access system to the target site. Alternatively, because the elongate member can have the flexibility, pushability, and torqueability to be advanced through the tortuous regions of the vasculature, it is possible to advance the elongate member through the vasculature to the target site without the use of the separate guidewire. In such embodiments, the access system can be advanced over the elongate member to the target site. Once the elongate member has been positioned at the target site, the drive shaft is rotated and advanced into the occlusive material or the entire elongate member may be advanced distally into the occlusion. The rotation of the distal tip creates a path forward of the elongate member. In some embodiments the path created by the distal tip has a path radius which is larger than the radius of the distal end of the elongate member. In other embodiments, the path created by the distal tip has a path radius which is the same size or smaller than the radius of the elongate member.

[0014] In one embodiment, a hollow guidewire for crossing an occlusion or stenosis within a body lumen comprises a hollow guidewire body comprising a proximal opening, a distal

opening, and an axial lumen extending from the proximal opening to the distal opening. A rotatable drive shaft is disposed within the axial lumen, wherein a distal tip of the rotatable drive shaft is adapted to extend distally through the distal opening in the guidewire body. At least one pull wire extends through the axial lumen and is coupled to a distal end portion of the guidewire body. The pull wire(s) comprise a curved surface that substantially corresponds to a shape of an inner surface of the axial lumen.

[0015] In one configuration, the hollow guidewire body is composed of a single, laser edged hypotube. In one configuration, a proximal portion of the hollow guidewire comprises one or more sections that comprise a constant pitch. A distal portion of the hollow guidewire may have at least one section that ha a pitch that decreases in the distal direction so as to increase a flexibility in the distal direction along the distal portion of the guidewire body.

[0016] In other configurations, the hollow guidewire body optionally comprises a section that comprises no helical windings and has a solid wall. In other configurations, the distal portion may have a pitch that is constant, or the pitch may increase in the distal direction. In many embodiments, the hollow guidewire body will have at least one section that has a right-handed coils and at least one section that has left handed coils. In some configurations, the sections with the right handed coils alternate with the sections that have the left handed coils.

[0017] The dimensions of the hollow guidewires of the present invention will vary but the largest radial dimension (e.g., outer diameter) is typically between approximately 0.009 inch and 0.040 inch, preferably between approximately 0.035 inch and approximately 0.009 inch, more preferably between approximately 0.024 inch and 0.009 inch, and most preferably between approximately 0.013 and approximately 0.018 inches. A wall thickness of the hollow guidewires of the present invention is typically between approximately 0.001 inch and approximately 0.004 inch, but as with the other dimensions will vary depending on the desired characteristics of the hollow guidewire. The construction of the hollow guidewire will typically provide a 1:1 torqueability and the hollow guidewire will have the torqueability, pushability, and steerability to be advanced through the body lumen without the need of an additional guidewire or other guiding element.

[0018] A distal end portion of the hollow guidewire may comprise a plurality of openings or thinned portions that extend circumferentially or radially about at least a portion of the distal end portion of the guidewire body. A rib or other supporting structure will be disposed between each of the openings so as to provide structural support to the distal end portion. The plurality of openings or thinned portions may be used to increase the flexibility and/or bendability of the distal end portion, such that when the pull wires are actuated, the distal end

portion is able to deflect without causing kinking in the distal end portion. The distal end portion may also include one or more radiopaque markers to assist in the fluoroscopic tracking of the hollow guidewire.

[0019] The hollow guidewires of the present invention may comprise only a single pull wire. In other embodiments, the hollow guidewire comprises two or more pull wires. The pull wires of the present invention may optionally be coated with Teflon® so as to reduce the friction coefficient of the surface and to reduce twisting of the pull wires. As noted above, the pull wires preferably comprise a curved surface that substantially corresponds to an inner surface of the axial lumen of the hollow guidewire. By providing a surface that substantially corresponds to a shape in the inner surface of the axial lumen, the pull wires are able to move radially outward away from the rotating drive shaft. The increased distance away from the center of the axial lumen provides a greater clearance between the pull wires and the rotating drive shaft, while maintaining a thickness and width of the pull wire.

[0020] The pull wires may take on a variety of cross-sectional shapes, but the pull wires typically have either a D-shape, a rectangular shape, a flat shape, a crescent shape, an oval shape, a round shape, or a square shape. As can be appreciated, other embodiments of the pull wires may have a cross-section that is circular, substantially flattened, substantially rectangular, or the like.

[0021] In some embodiments, in addition to the curved surface that substantially corresponds to the inner surface of the axial lumen, the pull wires typically comprise a flat surface that is adapted to be adjacent the rotating drive shaft. Since the flat surface of the pull wire will provides only a single point of contact with the rotating drive shaft, there is a reduced friction between the pull wire and the drive shaft and there is a reduced chance that the rotating drive shaft gets tangled with the pull wire.

[0022] The rotatable drive shaft of the present invention may be axially movable and rotatable within the axial lumen of the hollow guidewire body. Optionally, the rotatable drive shaft may be coated with Teflon® or other materials to improve the rotation of the drive shaft within the axial lumen. The hollow guidewire may comprise a rotating mechanism, such as a rotary drive motor, to control the rotation of the drive shaft. The rotating mechanism can be coupled to the proximal end of the drive shaft to rotate the drive shaft. Optionally, an actuator may be used to control the axial movement of the drive shaft and/or the rotation of the drive shaft. Activation of the actuator moves the drive shaft proximally and distally within the axial lumen of the hollow guidewire. The hollow guidewire may comprise an

additional actuator to control the steering or deflection of a distal portion of the hollow guidewire so as to assist in navigating the hollow guidewire through the body lumen.

[0023] The hollow guidewires of the present invention may comprise a removable housing coupled to the proximal portion of the hollow guidewire body. The removable housing may comprise a connector assembly that allows for infusion or aspiration, the actuator(s) (for controlling the rotation, axial movement of the drive shaft and/or steering of the distal end portion of the hollow guidewire body), a rotating member (e.g., drive motor), a control system, and/or a power supply. The removable housing allows for advancement of a catheter system over the hollow guidewire. Once the catheter or other elongate body is advanced over the hollow guidewire, the housing may be reattached so as to allow for actuation of the drive shaft.

[0024] In another aspect, the present invention provides a hollow guidewire that comprises a hypotube that comprises a proximal portion and a distal portion. At least a part of the distal portion of the hypotube comprise helical windings formed thereon so that the distal portion of the hypotube is more flexible than the proximal portion. While not described in detail herein, it should be appreciated that in other embodiments, the hollow guidewire may be comprised of a braided polymer, carbon, or other composite materials, and the hollow guidewires of the present invention are not limited to hypotubes.

[0025] In such configurations, the proximal portion of the hypotube will have a solid wall or helical windings that have a pitch that is larger than a pitch of the distal portion. Typically, a pitch of the helical windings on the distal portion decreases in the distal direction so that a flexibility of the distal end portion increases in the distal direction. Consequently, the proximal portion is the stiffest, an intermediate portion is less stiff, and the distal end is the most flexible. In other embodiments, the pitch may be constant throughout at least a portion of the distal portion, may increase in the distal direction, the pitch may vary throughout the distal portion, or the like.

[0026] The distal portion of the hypotube hollow guidewire may optionally comprise a plurality of ribs and openings or thinned portions that extend circumferentially about at least a portion of the distal end portion of the guidewire body. The distal portion may also comprise one or more radiopaque markers thereon.

[0027] Similar to the other embodiments, the hypotube hollow guidewire may comprise one or more pull wires. The pull wires preferably comprise a curved surface that substantially corresponds to an inner surface of the axial lumen of the hypotube hollow guidewire, but other conventional shaped pull wires that don't substantially correspond to the inner surface

of the axial lumen may also be used. The pull wire may be coupled to a removable proximal housing that is coupled to the proximal portion of the hypotube hollow guidewire body. A removable housing may be coupled to the hollow guidewire and may comprise a connector assembly that allows for infusion or aspiration, one of more actuators (for controlling the rotation, axial movement of the drive shaft and/or steering of the distal end portion of the hypotube hollow guidewire body), a rotating member (e.g., drive motor), a control system, and/or a power supply.

[0028] In a further aspect, the present invention provides a steerable guidewire comprising a hollow guidewire body that comprises a proximal end, a distal end, and an axial lumen that extends to the distal end. At least a portion of a plaque removal assembly is positioned at or near the distal end of the guidewire body. At least one pull wire extends through the axial lumen of the hollow guidewire body and is coupled at or near the distal end of the hollow guidewire body. A proximal force on the pull wire steers the distal end of the hollow guidewire.

[0029] The plaque removal assembly may be fixedly or movably disposed at the distal end of the hollow guidewire body. If the plaque removal assembly is movable, the plaque removal assembly may be movable from a first, axially retraced position in which the plaque removal assembly is disposed within the axial lumen of the hollow guidewire body to a second position in which the plaque removal assembly is positioned beyond the distal end of the guidewire body.

[0030] The plaque removal assembly typically comprises a rotatable drive shaft that has a shaped distal tip. In other embodiments, however, the plaque removal assembly may comprise a laser, an RF electrode, a heating element (e.g., resistive element), an ultrasound transducer, or the like. A lead of the plaque removal assembly may extend from proximally through an axial lumen of the hollow guidewire body.

[0031] In one configuration, the hollow guidewire body is composed of a single hypotube. The hollow guidewire body optionally comprises a helical coil or solid wall tubular proximal portion integrally formed with the distal end portion. The distal end portion may comprise helical windings formed thereon. A pitch between adjacent helical windings on the distal portion decreases in the distal direction so as to increase a flexibility in the distal direction along the distal portion of the guidewire body. In other embodiments, the distal portion may have one or more sections that have a pitch that is constant throughout the distal portion, a pitch that increases in the distal direction, or the like.

[0032] A distal end portion of the hollow guidewire may comprise a plurality support ribs and openings or thinned portions that extend circumferentially about at least a portion of the distal end portion of the guidewire body. The plurality of openings or thinned portions may be used to increase the flexibility and/or bendability of the distal end portion, such that when the pull wires are actuated, the distal end portion is able to deflect without kinking of the distal end portion. The distal end portion may also include one or more radiopaque markers to assist in the fluoroscopic tracking of the hollow guidewire.

[0033] Similar to the other embodiments, the hollow guidewire may comprise one or more pull wires. The pull wires preferably comprise a curved surface that substantially corresponds to an inner surface of the axial lumen of the hollow guidewire, but other conventional shaped pull wires that don't substantially correspond to the inner surface of the axial lumen may also be used. The pull wire may be coupled to a removable proximal housing that is coupled to the proximal portion of the hollow guidewire body. The removable housing may comprise a connector assembly that allows for infusion or aspiration, one of more actuators (for controlling the rotation, axial movement of the drive shaft and/or steering of the distal end portion of the hollow guidewire body), a rotating member (e.g., drive motor), a control system, and/or a power supply.

[0034] In yet another aspect, the present invention provides a hollow guidewire that comprises a proximal portion and a distal portion. At least a part of the distal portion comprises helical windings that have a pitch between adjacent windings that decreases in the distal direction so that a distal end of the hollow guidewire is more flexible than the proximal portion of the hollow guidewire.

[0035] In yet another aspect, the present invention provides a method of crossing an occlusion or stenosis within a body lumen. The method comprises positioning an hollow guidewire having a drive shaft in the body lumen. The drive shaft is rotated. The drive shaft is moved from a retracted configuration to an expanded configuration. In the expanded configuration, the drive shaft may be used to create a path that is at least as large as a largest radial dimension (e.g., diameter) of the distal end of the hollow guidewire The hollow guidewire body and/or the drive shaft may then advanced into the occlusion or stenosis to create the path in the occlusion or stenosis.

[0036] In another aspect, the present invention provides a method of crossing an occlusion or stenosis within a body lumen. The method comprises advancing a guidewire through the body lumen. An access or support system is moved over the guidewire to the occlusion or stenosis. The guidewire is removed from the body lumen and exchanged with a steerable

hollow guidewire having plaque removal assembly. The plaque removal assembly may then be used to remove at least a portion of the occlusion. For example, in one configuration the plaque removal assembly comprises a rotatable drive shaft. The drive shaft is rotated within a lumen of the hollow guidewire and is at least partially exposed through a distal opening in the hollow guidewire. The hollow guidewire and/or the drive shaft may be advanced to create a path through the occlusion or stenosis.

[0037] In another aspect, the present invention provides a kit. The kit has any of the hollow guidewire described herein and instructions for use that provide any of the methods described herein. In one configuration, the hollow guidewire comprises a plaque removal assembly, such as a rotatable drive shaft. The rotatable drive shaft has a shaped distal tip that is removably received within the axial lumen of the hollow guidewire. The instructions for use in passing occlusions or stenosis in a body lumen comprise rotating the inner wire within the steerable hollow guidewire and advancing the hollow guidewire and drive shaft or only advancing the rotating drive shaft into the occlusive or stenotic material to create a path through the occlusive or stenotic material. A package is adapted to contain the hollow guidewire, rotatable wire, and the instructions for use. In some embodiments, the instructions can be printed directly on the package, while in other embodiments the instructions can be separate from the package.

[0038] One exemplary deflectable hollow guidewire device for crossing an occlusion or stenosis within a body lumen comprises an elongate hollow guidewire body and a plaque removal assembly. The guidewire body has a proximal end, a deflectable distal end, and an axial lumen therebetween. The plaque removal assembly comprises a mechanically moving core element extending through the axial lumen of the guidewire body. The guidewire device of the present invention is particularly well suited to be steerable through tortuous blood vessels due to its deflectability, torqueability, and/or pushability characteristics.

[0039] In this preferred configuration, the elongate hollow guidewire body is composed of a unitary structure, such as a single hypotube. The tubular guidewire body may comprise a plurality of sections. For example, at least one section may comprise an interrupted helical pattern while another section may comprise a ribbed pattern, a solid-walled tubular member, or helical windings as already described above. The interrupted helical pattern typically comprises laser edged helical windings in a range from 90 degrees to 270 degrees, preferably 180 degrees, interrupted by segments in a range from 05 degrees to 225 degrees, preferably 30 degree segments which are uncut. Significantly, the interruptions help to preserve the integrity and continuity of the device, particularly when it is steered through tortuous blood

vessels. The ribbed pattern may comprise a plurality of support ribs and openings or thinned portions that extend circumferentially about at least a portion of the tubular guidewire body.

[0040] The hollow guidewire device may further comprise a pull tube for deflectability instead of a free-floating pull wire. The pull tube extends within and through the axial lumen and is coupled to the distal end portion of the guidewire body. Actuation of the pull tube deflects or bends the distal end of the guidewire body. The pull tube is distally tapered and may be formed from superelastic metal or shape memory alloy (e.g., nickel titanium, nitinol) or other comparable materials (e.g., stainless steel). Advantageously, the tapered pull tube provides for reduced friction between the surrounding mechanically moving core element and the pull tube structure. This reduces any tangling action between the pull tube and core element, which further prevents the pull tube from breaking. Additionally, the pull tube may be coated with Teflon® so as to further reduce the friction coefficient of the surface and to reduce twisting of the pull tube. A radiopaque coil may be disposed over at least a distal portion of the core element and within the guidewire body. The radiopaque coil separates the tapered pull tube from the mechanically moving core element, acting to further reduce any tangling on snapping action between the two. The radiopaque coil also assists in the fluoroscopic tracking of at least the distal portion of the hollow guidewire body.

[0041] The mechanically moving core element extending within and through the and through the axial lumen may be movably or fixedly disposed at the distal end of the hollow guidewire body. Generally, a distal tip of the core element, namely the mechanically moving core element, extends distally of the distal end of the guidewire body. Upon activation, the mechanically moving core element creates a passageway or enlarges a passageway through the occlusion or stenosis within the body lumen. The mechanically moving core element in this embodiment preferably comprises an oscillatory drive shaft. The mechanically moving core element may additionally or alternatively comprise an axially translatable drive shaft for reciprocation movement. Still further, the mechanically moving core element may additionally or alternatively comprise one of the rotating, axially translating, and/or vibrating drive shafts described above. Optionally, the mechanically moving core element may be coated with Teflon® or other materials to improve the movement of the drive shaft within the axial lumen of the guidewire body. The distal tip may take on a variety of configurations disclosed herein including a bullet, flat spatula, drill, or football shape. The distal tip may be deflected or shaped and/or include laser edgings thereon. As an added safety feature, a locking mechanism may be coupled to the distal end of the guidewire body so as to prevent

inadvertent release of distal tip into the body lumen, for example in the case of a break or crack in the mechanically moving core element.

[0042] A handle may be coupled to the proximal end of the guidewire body. The handle may be fixedly coupled to the guidewire body. In such an embodiment, the handle allows for independent torque transmission of the guidewire body and deflection of the distal end of the guidewire body (e.g., torque without deflecting or deflecting without torque). Torque transmission of the guidewire body and deflection of the guidewire body may also be carried out sequentially or simultaneously. The handle design further allows for and retains the continual ability to actuate torsional transmission and deflection of the guidewire device, either independently, sequentially, or simultaneously, as a physician steers through a tortuous blood vessel. This can advantageously be accomplished while maintaining the handle in a stationary configuration that is ergonomically easy to grasp and control. The handle may further comprise a drive motor to move (e.g., oscillate, reciprocate, translate, rotate, vibrate, or the like) the core element, actuators for steering the guidewire body, a control system including circuitry which provides feedback control as discussed in more detail below, and/or a power supply. The handle may alternatively be removably coupled to the guidewire body as described above.

[0043] In another aspect of the present invention, a non-deflectable, hollow guidewire device is provided. The device comprises an elongate hollow guidewire body having a proximal end, a pre-shaped distal end, and an axial lumen therebetween and a drive shaft extending through the axial lumen of the guidewire body.

[0044] In yet another aspect of the present invention, a deflectable hollow guidewire device for crossing an occlusion or stenosis within a body lumen is provided. The device comprises an elongate hollow guidewire body having a proximal end, a deflectable distal end, an axial lumen therethrough, and a plurality of sections therebetween. An oscillatory drive shaft further extends through the axial lumen of the guidewire body. At least one section comprises an interrupted helical pattern. The interrupted helical pattern may have a constant or variable (e.g., linear or non-linear) pitch, the same or different number of helical windings or interruptions, and a right handed or left handed direction of the interrupted helical pattern. Preferably, the interrupted helical pattern comprises laser edged helical windings or spirals at 180 degrees interrupted by 30 degree segments and will take on a right handed or clockwise helical direction. The interrupted helical pattern may comprise a variable pitch section alternated with a constant pitch section along an intermediate section of the guidewire body. Typically, a pitch of the interrupted helical windings will decrease in the distal direction so

that a flexibility of the guidewire body increases in the distal direction. A proximal section of the guidewire body will comprise a solid-walled tubular member for sufficient stiffness while a distal section of the guidewire comprises a ribbed pattern of ribs and radial slots for improved bendability or deflectability of the distal portion of the guidewire body.

[0045] In still another aspect of the present invention, a steerable hollow guidewire device is provided. The device comprises an elongate hollow guidewire body having a proximal end, a distal end, and an axial lumen therebetween. A drive shaft extends through the axial lumen of the guidewire body. A pull tube extends through the axial lumen and is coupled to the distal end portion of the guidewire body. Actuation of the pull tube deflects or bends the distal end of the guidewire body. As noted above, a radiopaque coil is disposed between the pull tube and the drive shaft to further reduce issues of twisting and for fluoroscopic viewing.

[0046] In a further aspect of the present invention, a method of crossing an occlusion or stenosis within a body lumen is provided. The method comprises positioning a hollow guidewire into the body lumen adjacent the occlusion or stenosis. A drive shaft within an inner lumen of the hollow guidewire is oscillated, wherein a distal tip of the drive shaft extends distally beyond the hollow guidewire. The distal tip of the drive shaft is then simultaneously or sequentially advanced into the occlusion or stenosis in the body lumen to create a path in the occlusion or stenosis. It will be appreciated that the hollow guidewire and/or the drive shaft may be advanced to create a path through the occlusion or stenosis. For example, once the guidewire has reached the occlusion, the guidewire together with the oscillating drive shaft may be advanced into the occlusion. Alternatively, the guidewire may be in a fixed position and only the oscillating drive shaft may be advanced into the occlusion.

[0047] The preferred operating mode of oscillation is of particular benefit to the present invention as it prevents tissue from wrapping around the distal tip of the plaque removal drive shaft. This in turn allows for enhanced penetration through, in, and/or out of the occlusive or stenotic material. Typically, the drive shaft will be oscillated so that it changes polarity after a period of time. The period of time may in a range from about 0.2 seconds to about 5.0 seconds, preferably in a range from about 0.3 seconds to 1.2 seconds, and more preferably in a range of about 0.7 seconds.

[0048] Advancing may further comprise reciprocating axial translation of the distal tip of the drive shape so as to completely cross the total occlusion. Oscillation and reciprocation of the drive shaft may be carried out sequentially or simultaneously. Generally, oscillation and/or reciprocation movement of the drive shaft are carried out by a drive motor. However, a device operator may also easily effect reciprocation by simply axially translating the device

by its handle manually. Advancing may further comprise extending the drive shaft from a retracted configuration to an extended configuration relative to the distal portion of the hollow guidewire body, wherein the drive shaft is simultaneously or sequentially extended and oscillated.

[0049] As mentioned above, the hollow guidewire of the present invention has a deflectability, flexibility, pushability, and torqueability which allows it to be positioned through the tortuous blood vessel without the use of a separate guidewire. For example, a distal end of the hollow guidewire may be deflected by actuating a pull tube. The handle further allows for transmitting torque to the hollow guidewire independently of deflecting a distal end of the hollow guidewire. Proper positioning at the occlusion site may further be verified by viewing a distal end of the hollow guidewire under fluoroscopy via the radiopaque coil. Generally, the drive shaft creates a path at least as large as a perimeter of a distal end of the hollow guidewire.

[0050] Electronic circuitry within the control system of the handle may measure a variety of characteristics for feedback control. For instance, the resistance encountered during advancement of the distal tip in the body lumen may be measured. In response, the torque speed may automatically be adjusted in line with the measured resistance. In another instance, a level of load encountered during advancement of the distal tip in the body lumen may be measured. In response, a visual or audio alarm may be signaled if the measured load is above or below a threshold value. For example, no load may be indicative of a break or fracture in the oscillating drive shaft distal tip. As discussed above, a locking mechanism on a distal end of the guidewire body further prevents inadvertent release of the distal tip of the drive shaft into the body lumen by locking it to a distal end of the hollow guidewire. Still further, the device may be automatically disabled in response to the no load measurement as an added safety feature. In still another instance, a use of the device based on time or number of revolutions or oscillations may be measured. The device may be automatically and permanently disabled once the measured time or number is above a threshold value. This safety feature protects against device fatigue and warrants that the device is not operable past its optimal lifetime use.

[0051] A support system may be positioned in the body lumen adjacent the occlusion or stenosis, wherein the hollow guidewire is sized to be received within an inner lumen of the support system. The support system, which is described in more detail in commonly owned U.S. Patent Application Serial No. 10/864,075, filed June 8, 2004, the disclosure of which is incorporated herein by reference, may be for over-the-wire introduction or for rapid

exchange. In one embodiment, positioning the support system comprises advancing a conventional guidewire through the body lumen to the occlusion or stenosis. The support system is then advanced over the guidewire. The guidewire is then removed from the body lumen and the hollow guidewire is advanced through the support system. Optionally, the support system can be delivered concurrently with the advancement of the hollow guidewire. The position of the hollow guidewire and/or support system may be maintained and stabilized during the advancing of the distal tip of the drive shaft. At the end of the plaque removal, the method may further comprise exchanging the hollow guidewire with the conventional guidewire.

[0052] These and other aspects of the invention will be further evident from the attached drawings and description of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

[0053] The following drawings should be read with reference to the detailed description. Like numbers in different drawings refer to like elements. The drawings, which are not necessarily to scale, illustratively depict embodiments of the present invention and are not intended to limit the scope of the invention.

[0054] FIG. 1 shows an elevational view of a system of the present invention.

[0055] FIG. 2 shows manual manipulation of a drive shaft of the present invention.

[0056] FIG. 3 shows a distal end of the elongate member and a distal tip of a drive shaft of the present invention.

[0057] FIG. 3A is a cross sectional view of the device FIG. 3.

[0058] FIG. 4 illustrates another embodiment of a hollow guidewire of the present invention.

[0059] FIG. 5A is a cross-sectional view of a hollow guidewire that comprises a drive shaft and a flattened or rectangular pull wire.

[0060] FIG. 5B is a cross sectional view of a hollow guidewire that comprises a drive shaft and a shaped pull wire.

[0061] FIG. 5C is a cross-sectional view of an embodiment that comprises a plurality of spaced, shaped pull wires.

[0062] FIG. 6 illustrates another embodiment of a hollow guidewire that includes a plurality of openings or thinned portion in the distal end portion that correspond to the number of pull wires.

[0063] FIG. 7 illustrates another embodiment of a hollow guidewire that comprises left hand coil portions and right hand coil portions, and a coil disposed at the distal tip.

[0064] FIG. 7A to 7C are cross sectional views at A-A, B-B, and C-C of a distal portion of the hollow guidewire of FIG. 7, respectively.

[0065] FIGS. 8A and 8B are helical coils that have a similar pitch but a different kerf.

[0066] FIG. 9 illustrates another embodiment of a hollow guidewire that comprises a window formed in the distal portion of the hollow guidewire.

[0067] FIG. 9A to 9C are cross sectional views at A-A, B-B, and C-C of the distal portion of the hollow guidewire of FIG. 9, respectively.

[0068] FIG. 10 shows a diamond chip embedded distal tip of the drive shaft.

[0069] FIG. 11A shows a deflected distal tip in a position forward of the distal end of the elongate member.

[0070] FIG. 11B shows the flexible deflected distal tip in a fully retracted position within the axial lumen of the elongate member.

[0071] FIG. 11C shows a deflected distal tip in a retracted position with the distal tip partially extending out of the elongate member.

[0072] FIG. 12A shows a sharpened deflected distal tip extending out of the elongate member.

[0073] FIGS. 12B and 12C show the cutting edges on the deflected distal tip of FIG. 12A.

[0074] FIG. 12D shows the distal tip deflected off of the longitudinal axis of the drive shaft;

[0075] FIGS. 12E and 12F is a partial cut away section of two counter-wound drive shafts of the present invention.

[0076] FIG. 12G shows the relative flexibility between a conventional drive shaft and a counter-wound drive shaft of the present invention.

[0077] FIGS. 13A to 13C illustrate a method of forming the deflected distal tip using a fixture.

[0078] FIGS. 14A-14K show a variety of tip configurations.

[0079] FIG. 14L shows a distal tip having a flattened and twisted configuration.

[0080] FIGS. 14M-14P show a method of manufacturing the distal tip of FIG. 14L.

[0081] FIG. 15 shows a drive shaft having spirals or external riflings which facilitate the proximal movement of the removed occlusive or stenotic material.

[0082] FIG. 16 shows a linkage assembly between the motor shaft and the drive shaft.

[0083] FIGS. 17A and 17B show an alternative linkage assembly coupling the motor shaft and the drive shaft.

[0084] FIGS. 18-20 show a luer connection assembly which couples the elongate member to the housing.

[0085] FIGS. 21 shows a system having an access system, a hollow guidewire with a deflectable distal end, and a drive shaft.

[0086] FIGS. 22A to 22E illustrate a method of the present invention.

[0087] FIGS. 23A to 23E illustrate another method of the present invention.

[0088] FIGS. 24A to 24B illustrate yet another method of the present invention.

[0089] FIG. 25 shows a kit of the present invention.

[0090] FIGS. 26A-26E illustrate an exemplary embodiment of a hollow guidewire device constructed in accordance with the principles of the present invention.

[0091] FIGS. 27-27G illustrate exploded side and cross sectional views of the drive shaft, pull tube, and radiopaque coil disposed within the hollow guidewire device of FIG. 26A.

[0092] FIGS. 28A and 28B illustrate two preferred configurations of a distal tip of the drive shaft disposed within the hollow guidewire device of FIG. 26A.

[0093] FIGS. 29A and 29B illustrate two further alternative configurations of the drive shaft distal tip.

[0094] FIGS. 30A and 30B illustrate exploded views of the handle of the hollow guidewire device of FIG. 26A.

DETAILED DESCRIPTION OF THE INVENTION

[0095] The systems, devices and methods according to the present invention will generally be adapted for the intraluminal treatment of a target site within a body lumen of a patient, usually in a coronary artery or peripheral blood vessel which is occluded or stenosed with atherosclerotic, stenotic, thrombotic, or other occlusive material. The systems, devices and methods, however, are also suitable for treating stenoses of the body lumens and other hyperplastic and neoplastic conditions in other body lumens, such as the ureter, the biliary duct, respiratory passages, the pancreatic duct, the lymphatic duct, and the like. Neoplastic cell growth will often occur as a result of a tumor surrounding and intruding into a body lumen. Removal of such material can thus be beneficial to maintain patency of the body lumen. While the remaining discussion is directed at passing through atheromatous or thrombotic occlusive material in a coronary artery, it will be appreciated that the systems and methods of the present invention can be used to remove and/or pass through a variety of occlusive, stenotic, or hyperplastic material in a variety of body lumens.

[0096] An apparatus 10 embodying features of the present invention is illustrated in FIG. 1. The apparatus 10 generally includes a housing 12 coupled to an elongate member 14 which has a proximal end 16, a distal end 18, and an axial lumen 20 therethrough. The apparatus

may comprise a plaque removal assembly, such as a rotatable drive shaft 22, for removing tissue and creating a path through the body lumen. The drive shaft 22 is movably received within the axial lumen 20 of the elongate member 14 and may be rotated and moved axially, as shown by arrows 23, 25. The distal tip 24 of the drive shaft 22 may have a shaped profile such that movement or positioning of the distal tip 24 beyond the distal end 18 of the elongate member and rotation of the drive shaft 22 may be used to create a cutting path forward of the distal end of the elongate member 14 for passing through the occlusive or stenotic material in the body lumen. In most configurations, wire leads 29 couple a drive motor 26 to a control system 27 and a power supply 28. In some embodiments, the power supply 28 is covered with a plastic sheath cover (not shown) so as to maintain a sterile environment.

[0097] The drive motor 26 is attachable to a proximal end of the drive shaft 22 to move (i.e., rotate, translate, reciprocate, vibrate, or the like) the drive shaft 22 and shaped distal tip 24. An actuator or input device 82 is attached to the housing 12 to actuate the movement (e.g., control the rotation and/or axial movement) of the drive shaft 22. While not shown, an additional actuator or input device may be attached to housing 12 to control the deflection of a distal portion of the elongate member 14. The proximal end 16 of elongate member 14 is coupled to the housing 12 through a connector assembly 30. The connector assembly 30 limits the motion of the elongate member 14 while allowing the drive shaft 22 to rotate and translate within the elongate member 14. Optionally, some embodiments of the connector assembly 30 includes an aspiration or infusion port (not shown) for facilitating fluid exchange (e.g., delivery or removal) at the target site through the axial lumen 20.

[0098] As shown in FIG. 2, in order to macerate clots and to penetrate soft lesions, some drive shafts 22 of the present invention can be configured to be manually rotated and translated as depicted by arrows 23' and 25'. In such embodiments, the proximal end of the drive shaft 22 can be grasped between the fingers and manually turned to rotate the distal tip 24 (shown schematically as a box). The proximal end can be optionally fit with a knurled knob 21 or other mechanism which allows manual manipulation of the proximal end of the drive shaft 22.

[0099] In one embodiment of the elongate member 14 is best seen in FIGS. 3 to 9C. The elongate member 14 is preferably a flexible, hollow guidewire that has the flexibility, pushability, and torqueability to allow a user to advance the hollow guidewire directly through a tortuous blood vessel to the target site. Because of the high columnar strength of

the hollow guidewire 14 there is typically no need for a separate guidewire to advance the hollow guidewire 14 to the lesion at the target site.

[0100] In the embodiment illustrated in FIG. 3, the hollow guidewire has an helically wound elongated shaft which defines the axial lumen 20 that receives the drive shaft 22. The axial lumen 20 may further be used for infusion or aspiration. The hollow guidewire 14 includes a proximal tube 32, an intermediate coil 34, and a distal coil tip 36. In some embodiments the intermediate coil 34 is made of a stainless steel or nitinol coil, while the distal coil tip 36 is composed of a flexible, radiopaque coil, such as platinum-iridium. As shown in FIG. 3, the intermediate coil 34 may be threadedly engaged with the proximal tube 32 and threadedly engaged with the distal tip 36. It will be appreciated, however, that the intermediate coil 34 can be connected to the proximal tube 32 and distal coil tip 36 by any conventional means, e.g. solder, adhesive, or the like. The proximal tube 32 of the hollow guidewire 14 can be coupled to a vacuum source or a fluid source (not shown) such that the target site can be aspirated or infused during the procedure, if desired.

[0101] Hollow guidewire 14 is typically sized to be inserted through coronary, neuro, or peripheral arteries and can have a variety of diameters. The largest radial dimension (e.g., outer diameter) of the hollow guidewire is typically between approximately 0.009 inch and 0.040 inch, preferably between approximately 0.009 inch and 0.035 inch, and more preferably between approximately 0.009 inch and 0.024 inch, and most preferably between about 0.013 inch and approximately 0.018 inch so as to ensure compatibility with existing interventional cardiology catheters and stent systems. The length of the hollow guidewire 14 may be varied to correspond to the distance between the percutaneous access site and the target site, but is typically about five feet in length. For example, for a target site within the heart that is being accessed through the femoral artery, the hollow guidewire will typically have a length of approximately 175 cm. It should be noted however, that other embodiments of the hollow guidewire 14 may have dimensions that are larger or smaller than the above described embodiments and the present invention is not limited to the above recited dimensions.

[0102] Referring now to FIG. 3A, a cross section of the embodiment of FIG. 3 is shown. An inner tube 38 and outer tube 40 are positioned around intermediate coil and distal coil tip 34, 36 to provide a flexible, structural support which prevents liquids from moving between the blood vessel and the axial lumen of the elongate member 14. A reinforcing pull wire 42 can be positioned between the inner tube 38 and the coils 34, 36 to provide for deflection or steering of the distal end 18. The reinforcing pull wire 42 can be formed of a material having

sufficient strength so that a thin profile is possible. For example, the reinforcing wire can be an at least partially flattened strip of stainless steel that can retain its shape until it is re-shaped to a different configuration. In one configuration, the reinforcing pull wire 42 is soldered or otherwise connected to the distal end of coil tip 36 and the remainder of the reinforcing pull wire 42 extends proximally through axial lumen 20 to the housing 12. Manipulation of an actuator or the proximal end of the reinforcing pull wire 42 that causes axial movement of the pull wire 42 allows the user to deflect or steer the distal end 18 without permanently impairing the inner structure of the hollow guidewire 14. The steerable distal end 18 provides a user with greater intraluminal control of removing the occlusive or stenotic material from the blood vessel and also aids in navigating the hollow guidewire to the target site. In another configuration, the reinforcing pull wire is 42 can be soldered or otherwise connected to both the distal end and to the junction between coils 34, 36. Therefore, if the coils 34, 36, break, the attached reinforcing pull wire 42 can prevent the coils 34, 36 from detaching from the apparatus 10. A more complete description of one hollow guidewire encompassed by the present invention can be found in commonly owned U.S. Patent Application No. 09/030,657, filed February 25, 1998, the complete disclosure of which was previously incorporated by reference.

[0103] FIG. 4 illustrates another embodiment of a hollow guidewire 14 that is encompassed by the present invention. In the embodiment of FIG. 4, the hollow guidewire 14 is composed of a single hypotube 37. A radiopaque marker 33 may be disposed on the distal portion 39 of the hypotube 37, and typically at the distal tip. At least the distal portion 39 of the hypotube 37 may be laser edged to create a plurality of helical windings or spirals 43. The helical windings 43 may have the same pitch through at least one section of the distal portion 39 (not shown) or the helical windings 43 may have a variable pitch through at least one section of distal portion 39. As can be appreciated, the pitch between adjacent windings will affect the flexibility of hypotube 37, and the pitch may be selected by the manufacturer depending on the desired characteristics of the hollow guidewire body 14. Because of the flexible nature of the present invention, the manufacturer may provide different configurations of the hollow guidewire so as to enhance the performance (e.g., provide personalized levels of torque response, flexibility, and deflection) of the guidewire body for the specific procedure.

[0104] In one configuration, the pitch between the helical windings 43 decreases in the distal direction so as to be increasingly flexible in the distal direction. Consequently, the distal portion 39 of the hypotube 37 will have an increasing flexibility in the distal direction. Advantageously, because the distal portion 39 is integrally formed with the proximal portion

45, there are no joints and there is an improved reliability and a reduced chance of disengagement between the distal portion 39 and the proximal portion 45. It may be desirable to have sections of the guidewire body to have no helical cuts, or to have laser cuts that have a pitch that increases in the distal direction so as to provide less flexibility over a portion of the hollow guidewire. The less flexible portion may be at the proximal portion, an intermediate portion, at or near the distal end of the hollow guidewire, or any combination thereof. For example, in one configuration, a proximal portion 45 of the hypotube may optionally have a solid wall with no laser cuts or helical spirals, and the remainder of the hypotube may have a helical laser edging (which may or may not have a decreasing pitch in the distal direction).

[0105] The laser cuts may extend all the way from the proximal end to the distal tip or the laser cuts may extend through less than all of the hypotube. The laser cuts used to create the helical windings may extend completely through the wall of the hypotube or it may extend only partially through the hypotube wall so as to create thinner wall portions (e.g., grooves).

[0106] Because the embodiment of FIG. 4 is composed of a single hypotube, there is a no need for the inner and outer support tubes 38, 40. Consequently, the effective outer diameter of the hypotube may be reduced and the diameter or the inner axial lumen 20 will be effectively increased to accommodate a larger drive shaft or pull wire(s) 42.

[0107] Similar to the embodiment of FIG. 3 and 3A, the guidewire 14 shown in FIG. 4 may comprise one or more reinforcing or pull wires 42. The pull wires 42 may comprise a plurality of different shapes, including, but not limited to, a rectangular wire, a flat wire, a crescent shape, a D-shape, an oval shape, round shape, square shape, or combination thereof. As shown in FIGS. 5A to 5C, because there is no inner support tube 38 to separate the pull wire(s) 42 from the drive shaft 22, the pull wire(s) 42 may be in direct contact with the drive shaft 22. Applicants have found that rotation of the drive shaft 22 may cause twisting in the pull wires, which increases the chance of the pull wire 42 breaking. To reduce the friction between the pull wire 42 and the drive shaft 22, the pull wire 42 and/or the drive shaft 22 may be coated with Teflon® so that the drive shaft is able to rotate without causing substantial twisting of the pull wire 42.

[0108] Optionally, the pull wire may also be shaped so as to better conform with an inner surface 47 of the hollow guidewire 14. Substantially conforming a surface 49 of the pull wire 42 with the inner surface 47 of the hollow guidewire 14 increases the space between the rotating drive shaft 22 and the pull wire(s) 42 by allowing the pull wire 42 to be moved radially outward away from the drive shaft 22 and to contact the inner surface 47 at a

tangential point. As shown in FIG. 5B, the surface 49 may be curved so as to conform to the curved inner surface 47 of the hypotube 37. The radius of curvature of the pull wire will typically be less than or equal to the radius of curvature of the inner surface 47 of hollow guidewire 14 so as to provide only one point of contact between the hollow guidewire and the pull wire 42.

[0109] The additional space between the drive shaft and the pull wire reduces the contact between the drive shaft 22 and the pull wire 42 and further reduces the possibility of breaking of the pull wire 42. For example, as shown in FIGS. 5A and 5B, for pull wires 42 that have substantially the same thickness T and width W, the pull wire with a surface 49 that conforms to the inner surface 47 (FIG. 5B) provides greater clearance between the drive shaft 22 and the pull wire 42 than a flat or rectangular pull wire. Additionally, the D-shaped pull wire will typically contact the inner surface 47 at one point, which reduces the friction between the pull wire and the guidewire body.

[0110] Optionally, pull wire 42 may have a flattened surface 200 adjacent the drive shaft 22. Applicants have found that having a flat surface facing the rotating drive shaft further reduces the binding and friction between the pull wire 42 and the drive shaft 22 because the rotating drive shaft would only contact the pull wire at a tangential point, therefore minimizing friction and a possibility of twisting between the pull wire and drive shaft. In alternative embodiments, however, surface 200 may be curved, if desired, but as noted, such embodiments tend to have an increased chance of tangling.

[0111] The pull wire 42 will generally have a thickness T of between about 0.002 inch and about 0.040 inch and width W between about 0.002 inch and 0.080 inch. As can be appreciated, the dimensions of pull wire 42 will depend on the dimension of the inner lumen and the largest radial dimension of the hollow guidewire 14, and the only requirement is that the pull wire fit within the inner lumen of the hollow guidewire.

[0112] When the pull wire is moved proximally, the distal tip will deflect. To improve the deflection of the distal tip of the hollow guidewire, the hypotube may optionally comprise one or more set of circumferential openings or thinned portions 202 and support ribs 204 on the distal portion of the hypotube 37, distal of the helical windings 43. If the hollow guidewire only comprises ones pull wire 42, the hollow guidewire 14 will typically only comprise one set of support ribs 204 and circumferential openings or thinned portions 202 (FIG. 4). But if the hollow guidewire comprises a plurality of pull wires 42 (FIG. 5C) the hollow guidewire 14 may comprise a corresponding number of sets of support ribs 204 and openings or thinned portions 202 (FIG. 6).

[0113] The radial slots, openings, and/or thinned portions 202 may be formed on the hypotube through laser edging that removes at least a portion of the material from the hypotube. The openings 202 will extend around less than the entire circumference of the hypotube, but if the laser merely creates thinner regions, it may be possible to have the thinner region extend completely around the hypotube. In preferred embodiments, however, the thinner portions and openings 202 typically extend between about 25% of the guidewire body (e.g., 90 degrees) and about 90% (e.g., 324 degrees) of the guidewire body.

[0114] FIGS. 7 and 9 (not to scale) illustrate two additional hollow guidewire bodies 14 that encompass some of the novel aspects of the present invention. In the illustrated embodiments, a proximal portion 45 of the hollow guidewire 14 comprises one or more sections of constant pitch helical windings. Each of the sections 206, 208 vary to some degree from an adjacent section. For example, either a different pitch from the adjacent section or one section has a left handed pitch and the other section has a right handed pitch. The sections may have the same number of helical windings or different number of helical windings. In one configuration, the hollow guidewire body comprises a first section 206 that spans 0.600 inches and has fifteen helical windings that have a pitch of 0.040 inch. The second section 208 spans 1.380 inches and has sixty-nine helical windings that have a pitch of 0.020 inch between the windings.

[0115] The adjacent helical windings is separated by a kerf. As shown in FIGS. 8A and 8B, the kerf typically corresponds to a width of the laser beam used to create the cuts. Applicants have found that a smaller kerf (FIG. 8B) provides improved floppiness/flexibility and torqueability of the hollow guidewire. The kerf on the hollow guidewire body 14 of the present invention typically ranges from 0.0005 inch to 0.004 inch preferably between about .001 inch and about .002 inch, but may be larger or smaller as desired.

[0116] Optionally, as noted above, the hollow guidewire body 14 may also comprises a section third section 210 that is distal to sections 206, 208 that comprises a pitch that decreases in the distal direction (or increases in the distal direction). The taper may be liner or non-linear. In one configuration, the variable pitch section 210 spans 7.872 inches and has 598 variable pitches in which the proximal pitch of the section is 0.020328 inch and the distal most pitch is 0.006 inch. As can be appreciated, the hollow guidewire body 14 may comprise any number sections, and the sections may have any desired taper to the pitch.

[0117] The hollow guidewire body typically has one or more sections 212 that do not have any coils formed thereon (e.g., solid walled throughout). Typically, the sections that do not have any coils formed thereon 212 are transition areas between adjacent sections 206, 208,

210. Such transition areas 212 typically have a length between about 0.001 inch and 0.007 inch, but could be larger or smaller, if desired.

[0118] For any of the embodiments described herein, the helical coils of the hollow guidewire body 14 may be "left-handed" or "right-handed". In some preferred embodiments, however, the different sections 206, 208, 210 of helical coils will have at least one left-handed coil section and at least one right-handed coil section. Typically, the left handed coil sections and the right handed coil sections are alternating along a length of the hollow guidewire body 141. As can be appreciated, when a right handed torque is applied to a coil that comprises all right-handed coils, the coils will torque without substantial "opening" of the coils. However, if a left-handed torque is applied to the same right-handed coils, the coils will tend to open and may affect the 1:1 torque transmission through the guidewire body 14. While the smaller kerf has been found to improve torque transmission, Applicants have found that having at least one left-handed section and at least one right-handed section further compensates for the opening of the coils when a torquing force is applied to the proximal end of the guidewire body. Consequently, similar amounts of torque may be transmitted to a distal tip of the hollow guidewire body when applying either a left-handed or right-handed torque.

[0119] Optionally, the hollow guidewire may comprise an integrally formed coil 214 at the distal tip. The distal coil 214 may be configured to threadedly receive a radiopaque coil, such as a platinum coil. The radiopaque coil may be soldered, glued, or otherwise attached to the distal coil 214 so as to provide a radiopaque marker for fluoroscopic tracking of the hollow guidewire body 14. The distal coil 214 may have any desired length and pitch, but in one configuration, the distal coil 214 is 0.027 inches long and has 5.75 helical windings that have a kerf of 0.0028 inch and a pitch of 0.005 inch.

[0120] Similar to the embodiments illustrated in FIGS. 4 and 6, the embodiments of FIGS. 7 and 9 may comprise a plurality of openings 202 and support ribs 204 to improve the bendability/deflectability of the distal portion of the guidewire body 14. A support rib 204 will typically be disposed between each opening 202. The openings 202 may take on a variety of different forms and may extend over any desired length of the distal portion. Each rib 204 along the distal portion may have a constant thickness in the axial direction or the ribs 204 may have a variable thickness along the axial length of the hollow guidewire body 14 (e.g., an axial thickness of a proximal most rib may be thicker or thinner than an axial thickness of a distal most rib). Moreover, each rib may extend completely around a circumference of the hollow guidewire body 14 or only around a portion of the hollow

guidewire body. As shown in FIGS. 7A to 7C and 9A to 9C, the support ribs 204 typically will extend between 100% (e.g., 360 degrees) and about 25% (e.g., 90 degrees) around the circumference of the hollow guidewire body 14. The thinned portions 202 (FIGS. 7C and 9C) will typically extend between about 25% (90 degrees) and about 90% (e.g., 324 degrees) of the hollow guidewire body 14.

[0121] For the embodiments of FIG. 9, if the ribs 204 extend around less than 100% of the circumference of the hollow guidewire, the pull wire (not shown) may be exposed through A window 216 created by the ribs 204 and openings 202. In such embodiments, a flexible tubing 218 may be placed over the ribs 204 and openings 202 so as to protect the pull wire (shown in dotted lines in FIGS. 9A to 9C). The flexible material may be comprised of a polymeric material, including, but not limited to polyethylene, Teflon®, or the like.

[0122] FIGS. 10-15 show various embodiments of the drive shaft 22 of the present invention. In most embodiments, the drive shaft 22 is a wire, a counter-wound multiple strand wire, or a plurality of braided wires having a body and a shaped distal tip 24. The proximal end of the drive shaft 22 can be removably coupled to a rotatable motor shaft 48 (FIGS. 16 and 17A) or manually manipulated (FIG. 2). The body of the drive shaft 22 extends through the elongate member 14 so that the distal tip 24 of the drive shaft is positioned near the distal end of the elongate member 14. The detachable connection to the motor shaft 48 allows the drive shaft 22 and elongate member 14 to be detached from the motor shaft 48 and connector assembly 30 so that an access or support system can be placed over the elongate member 14 and advanced through the body lumen.

[0123] As shown in FIG. 10 and 11A-11C, the distal tip can be shaped or deflected from the longitudinal axis 50 to extend beyond the radius of the elongate member 14 such that rotation of the drive shaft 22 creates a path radius 52 that is as at least as large as the radius 54 of the distal end of the elongate member 14. In other embodiments, the distal tip 24 will be deflected and shaped so as to create a path radius 52 which is the same or smaller than the radius of the distal end of the elongate member 14 (FIGS. 14B-14G). For example, in one configuration shown in FIG. 11C, a portion of the distal tip 24 extends beyond the distal end 18 of the elongate member when in the fully retracted position. When the drive shaft 22 is advanced out of the elongate member 14, the flexible distal tip 24 maintains a deflected shape (FIG. 11A). In alternative configurations, it is contemplated that the deflection at the distal tip 24 can straighten somewhat under the force from the walls of the elongate member 14 when the drive shaft 22 is retracted into the elongate member 14 (FIG. 11B). Thus, in the axially retracted configuration, the drive shaft 22 will have a profile that is smaller than the

radius of the distal tip of the elongate member. When the drive shaft is advanced out of the distal end of the elongate member, the drive shaft will expand to an axially extended configuration in which the distal tip of the drive shaft 22 will have a profile that is larger than the axially retracted configuration, and in some embodiments will have a larger profile than the distal end of the elongate member 14.

[0124] Referring again to FIG. 10, in some configurations a layer of abrasive material 56 can be attached and distributed over at least a portion of the distal tip 24 of the drive shaft 22 so that the abrasive material 56 engages the stenotic or occlusive material as the drive shaft 22 is advanced into the occlusion or stenosis. The abrasive material 56 can be diamond powder, diamond chips, fused silica, titanium nitride, tungsten carbide, aluminum oxide, boron carbide, or other conventional abrasive particles.

[0125] Alternatively, as shown in FIGS. 12A-12D, the distal tip 24 of the drive shaft 22 can be sharpened to facilitate passing through the occlusion or stenosis. A distal edge of the tip 24 can be sharpened so as to define a cutting edge 58 which rotatably contacts the occlusive or stenotic material. In an embodiment illustrated in FIGS. 12B-12C, a tip of the drive shaft can be sharpened to create a plurality of cutting edges 58. Furthermore, as shown in FIG. 12D and as described above, the distal tip 24 can be deflected from its longitudinal axis 50 to create the cutting path radius 52 of the drive shaft 24 that is smaller, larger, or the same length as the radius of the elongate member 14.

[0126] The drive shaft 22 can be composed of a shape retaining material, a rigid material, a flexible material, or can be composed of a plurality of materials. For example in some configurations, the drive shaft 22 can be comprised of nitinol, stainless steel, platinum-iridium, or the like. The distal tip 24 of the drive shaft 22 can have an enlarged tip, a preformed curve, or a preformed deflection (FIG. 11A). FIGS. 12E and 12F show embodiments of a counter-wound and composite drive shafts of the present invention. The counter-wound drive shaft 22 shown in FIG. 12E is made of a 0.004 inch OD center wire 67 having a right-hand wound surrounding wire 69 coiled around the center wire 67. The surrounding wire 69 can be soldered to the center wire at both ends of the center wire. In the embodiment of FIG. 12F, multiple strand wires 51 can be wound around a central coil 71 to form the drive shaft 22. The counter-wound drive shafts are significantly more flexible than a single wire guidewire and allows for a tighter bending radius over conventional guidewire. FIG. 12G illustrates the flexibility of both a 0.007 inch OD single wire stainless steel wire drive shaft 22a and a 0.007 inch OD counter-wound stainless steel drive shaft 22b. As shown

by FIG. 12G, the counter-wound drive shaft has better flexibility, while still maintaining its torqueability, maneuverability, and columnar strength.

[0127] Additionally, in some embodiments, the distal portion of the drive shaft 22 is radiopaque so that a physician can track the position of the drive shaft 22 using fluoroscopy. The drive shaft 24 typically has a diameter between approximately 0.010 inch and 0.005 inch. It should be appreciated that the dimension of the drive shaft will be slightly less than the inner diameter of the hollow guidewire so as to allow rotation without significant heat generation. Consequently, the dimensions of the drive shaft will vary depending on the relative inner diameter of the elongate member 14 and the present invention is not limited to the above described dimensions of the drive shaft.

[0128] In one embodiment, the distal tip 24 of the drive shaft is created using a shaped fixture 64. As shown in FIGS. 13A and 13B, the distal tip 24 is positioned on the fixture 64 and bent to a desired angle 66. The distal tip 24 can be bent to almost any angle 66 between 0° degrees and 90° degrees from the longitudinal axis 50, but is preferably deflected between 0° degrees and 50° degrees. As shown in FIG. 13C, a sharpened edge 58 can be created on the distal tip using a wafer dicing machine used in the production of silicon microchips (not shown). The angle of the sharpened edge 58 can be almost any angle, but the angle is typically between 0° degrees and 45° degrees, and is preferably between approximately 8° degrees and 18° degrees. Naturally, it will be appreciated that a variety of methods can be used to manufacture the distal tip of the drive shaft and that the present invention is not limited to drive shafts produced by the described method.

[0129] As mentioned above, the distal tip 24 can take various shapes. One embodiment having a deflected distal tip 24 is shown in FIG. 14A. In one configuration, the deflected tip is offset at an angle such that rotation of the drive wire 22 defines a profile or path that is at least as large as the outer diameter of the distal end of the elongate member 14. As shown in FIGS. 14B and 14C, in other embodiments, the tip can be deflected at other angles and may have a length that creates a path that is smaller or the same diameter as the distal end of the elongate member. The deflected distal tip can extend radially any feasible length beyond the perimeter or diameter of the elongate member 14. It should be understood that the invention is not limited to a single deflected tip. For example, the drive shaft can comprise a plurality of deflected tips. Alternatively, the drive shaft may have a distal tip 24 that is twizzle shaped, spring shaped, twisted metal shaped (FIG. 14D), ball shaped (FIG. 14E), a discontinuous surface (FIG. 14F), or the like. Alternatively, the drive shaft may comprise a plurality of filaments (FIG. 14G), rigid or flexible brush elements, a plurality of coils, or the like.

[0130] The distal tip of the drive shaft can be configured optimally for the type of occlusion or stenosis to be penetrated. Some lesions are made up substantially of clot or thrombotic material that is soft and gelatinous. FIGS. 14H and 14K shows distal tip embodiments which may be used to macerate a soft clot, thrombotic material, or stenosis. FIG. 14H shows a distal tip 24 having a basket like construction which is made up of a plurality of strands 59 that are connected at their ends 61, 63. In another embodiment illustrated in FIG. 14I, the distal tip 24 can be composed of a plurality of strands 59 that are unconnected at their distal ends 63. Additionally, the distal ends 63 of the strands 59 can be turned inward so that the distal ends 63 do not penetrate the body lumen when rotated. FIG. 14J shows a corkscrew spiral distal tip having a blunt distal end 63. FIG. 14K shows a distal tip having a loop configuration.

[0131] In another embodiment shown in FIG. 14L, the distal tip 24 of the drive shaft 22 can be flattened and twisted to create a screw like tip that can create a path through the occlusion. The flattened and twisted distal tip 24 can have a same width, a smaller width or a larger width than the drive shaft 24. For example, in one configuration for a drive shaft having an outer diameter of 0.007 inch, the distal tip 24 can be flattened to have a width between approximately 0.015 inch and 0.016 inch, or more. It should be appreciated, however, that the distal tip can be manufactured to a variety of sizes.

[0132] FIGS. 14M-14P show one method of manufacturing the flattened and distal tip of the present invention. The round drive shaft 22 (FIG. 14M) is taken and the distal end is flattened (FIG. 14N). The distal end can be sharpened (FIG. 14O) and twisted two or two and a half turns (FIG. 14P). If a different amount of twists are desired, the distal tip can be manufactured to create more (or less) turns.

[0133] In use, the distal tip 24 is rotated and advanced distally from a retracted position to an extended position into the soft material in the target lesion. If slow speed rotation is desired the user can rotate the drive shaft slowly by hand by grasping a knurled knob attached to the proximal end of the drive shaft (FIG. 2). If high speed rotation is desired, the proximal end of the drive shaft 22 can be attached to the drive motor 26. As the expanded wire basket tip is rotated, the tip macerates the soft clot and separates the clot from the wall of the body lumen. If a large diameter hollow guidewire working channel is used to deliver the drive shaft to the target area, the macerated clot can be aspirated through the guidewire working channel. Alternatively or additionally, a fluid, such as thrombolytic agents, can be delivered through the working channel to dissolve the clot to prevent "distal trash" and blockage of the vasculature with debris from the macerated clot.

[0134] As shown in FIGS. 15 and 21 in some embodiments the drive shaft 22 can optionally have spiral threads or external riflings 64 which extend along the body 44. As the drive shaft 22 is rotated and axially advanced into the atheromatous material, the distal tip 24 creates a path and removes the atheromatous material from the blood vessel. The rotating spirals 64 act similar to an "Archimedes Screw" and transport the removed material proximally through the axial lumen of the elongate member 14 and prevent the loose atheromatous material from blocking the axial lumen of the elongate member 14 or from escaping into the blood stream.

[0135] In use, drive shaft 24 is rotated and advanced to create a path distal of the elongate member 14 to create a path through the occlusion. The drive shaft 24 can be advanced and rotated simultaneously, rotated first and then advanced, or advanced first and then rotated. The drive shaft 22 is typically ramped up from a static position (i.e. 0 rpm) to about 5,000 rpm, 20,000 rpm with a motor. It should be noted, however, that the speed of rotation can be varied (higher or lower) depending on the capacity of the motor, the dimensions of the drive shaft and the elongate member, the type of occlusion to be bypassed, and the like. For example, if desired, the drive shaft can be manually rotated or reciprocated at a lower speed to macerate soft clots or to pass through lesions.

[0136] The distal tip 24 of the drive shaft 22 can extend almost any length beyond the distal portion of the hollow guidewire. In most embodiments, however, the distal tip typically extends about 5 centimeters, more preferably from 0.05 centimeters to 5 centimeters, and most preferably between 0.05 centimeter and 2 centimeters beyond the distal portion of the hollow guidewire.

[0137] Referring now to FIGS. 16, 17A, and 17B, the motor shaft 48 and the proximal end 46 of the drive shaft 22 are coupled together with a detachable linkage assembly 70. In one embodiment shown in FIG. 16, linkage assembly 70 has a first flange 72 attached to the motor shaft 48. The first flange can be snap fit, snug fit, or permanently attached to the drive shaft 48. A second flange 74 can be permanently or removably coupled to the proximal end 46 of the drive shaft 22 so that the first flange 72 of the motor shaft 48 can threadedly engage the second flange 74. In some embodiments, the proximal end of the drive shaft 46 can be enlarged so as to improve the engagement with the second flange 74. An o-ring 76 is preferably disposed within a cavity in the first flange 72 to hold the first flange 72 and second flange 74 in fixed position relative to each other.

[0138] As shown generally in FIGS. 17A and 17B, the motor 26 can be removably coupled to the housing 12. To detach the motor 26 and power supply 28 from the drive shaft 22, the user can unlock the luer assembly 30 so as to release the elongate member 14 from the

housing 12. The drive shaft 22 and elongate member 14 are then both free to move axially. The motor 26 can be moved proximally out of the housing 12 and the proximal end 46 of the drive shaft 22 can be detached from the motor shaft 48. After the motor 26, housing 12, and luer assembly 30 have been uncoupled from the elongate member 14 and drive shaft 22, a support or access system (not shown) can be advanced over the free proximal end of the elongate member 14. Thereafter, the luer assembly and motor shaft 48 can be recoupled to the elongate member 14.

[0139] In the embodiment shown in FIGS. 17A and 17B, the linkage assembly 70 includes a connecting shaft 78 that can be snugly fit over the motor shaft 48. The connecting shaft 78 preferably tapers from a diameter slightly larger than the motor shaft 48 to a diameter of that of the approximately the proximal end 46 of the drive shaft 22. In the embodiment shown, the connecting shaft 78 is coupled to the drive shaft through shrinkable tubing 80. Because the connecting shaft 78 is snug fit over the motor shaft, (and is not threadedly attached to the drive shaft) the size of the connecting shaft 78 can be smaller than the linkage assembly 70. While the embodiments of the connection assembly between the drive shaft and motor shaft have been described, it will be appreciated that drive shaft and motor shaft can be attached through any other conventional means. For example, the motor shaft 48 can be coupled to the drive shaft 22 through adhesive, welding, a snap fit assembly, or the like.

[0140] As shown in FIG. 17B, the drive shaft 22 extends proximally through the housing 12 and is coupled to the motor shaft 48. An actuator 82 can be activated to advance and retract the drive shaft 22. In some embodiments, the motor is press fit into the actuator housing 12. The drive shaft 22 is attached to the motor shaft 26 via o-rings such that the drive shaft 22 can be moved axially through axial movement of the actuator 82.

[0141] In most embodiments, actuation of the drive motor 26 and power supply 28 (e.g. rotation of the drive shaft) will be controlled independent from advancement of the drive shaft 22. However, while the actuator 82 is shown separate from the control system 27 and power supply 28 (FIG. 1), it will be appreciated that actuator 82 and control system 27 can be part of a single, consolidated console attached to the housing 12 or separate from the housing 12. For example, it is contemplated that that the drive shaft 22 can be rotated and advanced simultaneously by activation of a single actuator (not shown).

[0142] A connection assembly 30 is positioned on a proximal end of the housing to couple the elongate member 14 and the drive shaft 22 to the housing 12. In a preferred embodiment shown in FIGS. 18-20, the connection assembly 30 is a detachable luer which allows the drive shaft 22 to be moved (e.g. rotated, reciprocated, translated) while the elongate member

is maintained in a substantially static position. FIG. 18 best illustrates a luer connection assembly 30 which couples the elongate member 14 and the housing 12. The luer has a gland 86 which is rotatably connected to a fitting 88 and a tubular portion 90. Rotation of the gland 86 rotates and torques the elongate member 14 while the elongate member 14 is advanced through the blood vessel. Fitting 88 is threaded into the gland 86 such that a distal end of the fitting engages an o-ring 92 and a surface wall 94 of the gland. The longitudinal axis 96 of the fitting 88 and gland 86 are aligned so as to be able to receive the axial lumen of the elongate member 14. As the fitting 88 engages the o-ring 92, the o-ring is compressed radially inward to squeeze and maintain the position of the elongate member 14.

[0143] Accordingly, as illustrated in FIG. 19, when the drive shaft 22 is rotated within the elongate member 14, the o-ring 92 is able to substantially maintain the position and orientation of the elongate member 14. Tubular portion 90 attached to the proximal end of the fitting 88 threadedly engages the housing 12 and enables the luer connection assembly 30 to be removed from the housing 12 (FIG. 20). A more complete description of the connection assembly 30 can be found in commonly owned U.S. Patent Application No. 09/030,657, filed February 25, 1998, the complete disclosure of which was previously incorporated by reference. It should be appreciated that the present invention is not limited to the specific luer assembly described. Any luer assembly can be used to connect the elongate member 14 to the housing 12. For example, a Y-luer assembly (not shown) can be used with the system of the present invention to infuse or aspirate of fluids through the lumen of the hollow guidewire 14.

[0144] As shown in FIG. 21, systems of the present invention can further include an access or support system 98. The access or support system 98 can be an intravascular catheter such as a hollow guidewire support device, support catheter, balloon dilation catheter, atherectomy catheters, rotational catheters, extractional catheters, conventional guiding catheters, an ultrasound catheter, a stenting catheter, or the like. In the configuration shown in FIG. 21, the system includes an infusion or aspiration catheter which has at least one axial channel 100, and preferably a plurality of axial channels 100 which extends through the catheter lumen 102 to the distal end of the catheter. The elongate member 14 and drive shaft 22 can be positioned and advanced through the lumen 102 of the catheter. The axial channel 20 of the elongate member 14 and/or the axial channels 100 of the catheter 98 can also be used to aspirate the target site or infuse therapeutic, diagnostic material, rinsing materials, dyes, or the like.

[0145] The access or support system can be guided by the elongate member to the target site in a variety of ways. For example, as illustrated in FIGS. 22A to 22E, a conventional guidewire 104 can be advanced through the blood vessel BV from the access site (FIG. 22A). Once the guidewire 104 has reached the target site, the support or access system 98 can be advanced over the guidewire 104 (FIG. 22B). Alternatively, the guidewire 104 and support or access system 98 can be simultaneously advanced through the body lumen (not shown). Once the support or access system 98 has reached the target site, the conventional guidewire 104 can be removed and the hollow guidewire 14 having the drive shaft 22 can be introduced through the lumen 102 of the access system 98 (FIG. 22C). Even if the distal tip 24 of the drive shaft 22 is not fully retracted into the axial lumen 20, the lumen 102 of the support or access system protects the blood vessel BV from damage from the exposed distal tip 22. In most methods, the support or access system is positioned or stabilized with balloons, wires, or other stabilization devices 106 to provide a more controlled removal of the occlusive or stenotic material OM. Once the hollow guidewire 14 and drive shaft 22 have reached the target site, the drive shaft can be rotated and advanced into the occlusive or stenotic material OM to create a path (FIGS. 22D and 22E).

[0146] In another method of the present invention, the hollow guidewire 14 can be used to guide the support or access system to the target site without the use of a separate guide wire. The hollow guidewire 14 provides the flexibility, maneuverability, torqueability (usually 1:1), and columnar strength necessary for accurately advancing through the tortuous vasculature and positioning the distal end of the support or access system at the target site. The steerable distal portion can be deflected and steered through the tortuous regions of the vasculature to get to the target site. As shown in FIG. 23A, the hollow guidewire is advanced through the tortuous blood vessel to the target site. Due to the small size of the guidewire 14 relative to the blood vessel, even if the distal tip 24 of the drive shaft 22 extends partially out of the hollow guidewire 14, any potential damage to the blood vessel BV will be minimal.

[0147] Once the hollow guidewire reaches the target site within the blood vessel, the motor shaft 48, luer assembly 30, and housing 12 can be detached from the proximal end 46 of the drive shaft 22 so that the support or access system can be placed over the hollow guidewire. After the motor has been detached, the support or access system can be advanced over the guidewire and through the body lumen to the target site (FIG. 23B). To reattach the drive motor 26 to the drive shaft 22, the hollow guidewire 14 and drive shaft 22 are inserted through the luer assembly 30. The luer assembly 30 is tightened to lock the position of the hollow guidewire 14. The drive shaft 22 will extend proximally through the housing 12

where it can be recoupled to the motor shaft using the above described linkage assemblies 70 or other conventional linkage assemblies. Once at the target site, the position of the support or access system 98 can be stabilized by a balloon, wires, or other stabilizing devices 106, and the drive shaft 22 can be rotated and advanced into the occlusive or stenotic material OM (FIGS. 23C and 23D). The rotation of the drive shaft creates a path forward of the distal end 18 of the hollow guidewire 14. As noted above, the path can have the same diameter, smaller diameter, or larger diameter than the distal end of the hollow guidewire. Before, during, or after the rotation of the drive shaft, the user can steer or deflect the distal end 18 of the hollow guidewire 14 to guide the hollow guidewire to the desired location within the blood vessel. For example, as shown in FIG. 23E, once a portion of the occlusion or stenosis has been removed, the distal end 18 of the hollow guidewire 14 can be guided to angle the distal end so that the drive shaft is extended into a different portion of the occlusive or stenotic material OM.

[0148] While the apparatus of the present invention is sufficient to create a path through the occlusion OM without the use of a support or access system, the apparatus 10 of the present invention can be used in conjunction with other atherectomy devices to facilitate improved removal or enlargement of the path through the occlusion. For example as shown in the above figures, the hollow guidewire 14 and the atherectomy device 108 can be advanced through the body lumen and positioned adjacent the occlusion OM. The drive shaft 22 is rotated and advanced to make an initial path through the occlusion (FIG. 24A). The hollow guidewire 14 is then moved through the path in the occlusion and the atherectomy device 108 can then be advanced over the hollow guidewire 14 into the path in the occlusion OM to remove the remaining occlusion with cutting blades 110, or the like (FIG. 24B). While FIG. 24B shows cutting blades 110 to remove the occlusive material OM, it will be appreciated that other removal devices and techniques can be used. Some examples include balloon dilation catheters, other atherectomy catheters, rotational catheters, extractional catheters, laser ablation catheters, stenting catheters, and the like.

[0149] In another aspect, the invention provides medical kits. As shown in FIG. 25, the medical kit generally includes a system 10, instructions for use (IFU) 120 which describe any of the above described methods, and a package 130. The IFU can be separate from the package or they can be printed on the package. The kits can also optionally include any combination of a second guidewire, a motor, a power supply, a plastic sheath cover, connection assemblies, support or access systems, or the like.

[0150] An exemplary embodiment of the apparatus 10 constructed in accordance with the principles of the present invention is illustrated in FIG. 26A. The apparatus 10 generally includes a handle 12 coupled to an elongate hollow guidewire body 14 having a proximal portion 45, a deflectable distal portion 39, and a flexible intermediate portion 300 along a length therebetween. As shown in FIGS. 26B through 26E, the elongate hollow guidewire body 14 may be formed from a plurality of sections. In this preferred embodiment, the sections comprise a variety of patterns including an interrupted helical pattern and a ribbed pattern.

[0151] As shown in FIG. 26B, the intermediate portion 300 of the guidewire body includes five flexible sections 304, 306, 308, 310, 312 extending along about a 38 cm length of the guidewire body 14. It will be appreciated that this flexible section could be shorter or longer, as desired. Sections 304, 306, 308, 310 and 312 comprise an interrupted helical pattern, wherein sections 304, 308, and 312 have variable pitch sections that are alternated with constant pitch sections 306 and 310. For example, section 304 has a variable pitch in a range of 0.120 to 0.045 inches, section 308 has a variable pitch in a range of 0.045 to 0.026 inches, and section 312 has a variable pitch in a range of 0.026 to 0.006 inches, while section 306 has a constant pitch at 0.045 inch and section 310 has a constant pitch of 0.026 inch. The pitch of the interrupted helical sections decreases in the distal direction so that a flexibility of the guidewire body increases in the distal direction.

[0152] As shown in FIG. 26D, the interrupted helical pattern of the flexible intermediate portion 300 comprises laser edged helical windings or spirals 43 in range from 90 degrees to 270 degrees, preferably 180 degrees. The laser edging removes at least a portion of the material from guidewire body 14. Interruptions or breaks 314 have no laser cuts and are in a range from 5 degrees to 225 degrees, preferably 30 degree segments. Significantly the interruptions help tot preserve the integrity and continuity of the device 10, particularly when it is steered through tortuous blood vessels. Preferably, the interrupted helical pattern will have a clockwise helical direction and a kerf of 0.0010 inch. As can be appreciated, the hollow guidewire body 14 may comprise any number of sections, and the sections in turn may have any desired pitch or kerf, any number or degree of helical windings or interruptions, clockwise or counterclockwise helical directions, any length, etc.

[0153] As shown in FIG. 26C, the distal portion 39 of the guidewire may comprise a different patterned section 316 of ribs 204 and radial slots, openings, and/or thinned portions 202 that extend along about a 10 mm length of the guidewire body 14. It will be appreciated that this section could be shorter or longer, as desired. The radial slots 202 may be formed on

the guidewire body 14 through laser edging that removes at least a portion of the material from the guidewire body, as described above with respect to the helical windings. The openings 202 will extend around less than the entire circumference of the guidewire body 14. In preferred embodiments, the radial slots 202 typically extend between about 25% (e.g., 90 degrees) of the guidewire body to about 90% (e.g., 324 degrees) of the guidewire body. The support ribs 204 typically will extend between 100% (e.g., 360 degrees) to about 25% (e.g., 90 degrees) around the circumference of the hollow guidewire body 14.

[0154] As shown in FIG. 26C, the 37 support ribs 204 extend around 100% (e.g., 360 degrees) of the guidewire body while the 38 thinned portions 202 extend around 22% (e.g., 80 degrees) of the guidewire body. The ribbed pattern has a constant pitch of 0.006 inch and each radial slot 302 and rib 204 each have a width of about 0.003 inch. The ribbed pattern is of particular benefit as it provides for improved bendability or deflectability of the distal portion 39 of the guidewire body 14. It will be appreciated that the section may have any desired pitch or kerf, any number or degree of radial ribs 204 or slots 202, any length, any width, etc. The distal portion 39 of the guidewire body further includes a blunt actuating tip 320 including three slots 322 of equal spacing.

[0155] As shown in FIG. 26E, the hollow guidewire body 14 typically has one or more transition sections 212 that do not have any laser edgings (e.g., solid walled throughout). In this depiction, transitory section 212 bridges the interrupted helical pattern of the intermediate portion 300 of the guidewire 14 with the ribbed pattern of the distal portion 39 of the guidewire 14. Referring back to FIG. 26B, section 302 extends to the proximal portion 45 of the guidewire body 14 and comprises a solid walled tubular member (e.g., no laser cuts) for sufficient stiffness that extends roughly about 145 cm in length. Again, this section could be shorter or longer, as desired.

[0156] Generally, the guidewire body 14 will be composed of a unitary structure, such as a single hypotube. The hypotube may be formed from a variety of materials, including stainless steel, polymer, carbon, or other metal or composite materials and have diameter, thickness, and length dimensions as those already described above. In the embodiment of FIG. 26A, the guidewire tubular body 14 is formed from a stainless steel hypotube having an outer diameter of 0.0182 inch, an inner diameter of 0.0138 inch, and a guidewire length of about 175 cms. There are many benefits with the construction of the guidewire body 14 from a single hypotube. For example, because the distal portion 39 is integrally formed with the proximal portion 45, there are no joints and there is an improved reliability and a reduced

chance of disengagement between the distal portion 39 and the proximal portion 45. Further, there is no need for any inner or outer support tubes as described with respect to FIG. 3A

[0157] Referring now to FIG. 27, the plaque removal assembly comprising a mechanically moving core element 22, a tapered pull tube 324, and a radiopaque coil 326 are shown all disposed within an axial lumen 328 of the hollow guidewire body 14 of FIG. 26A. These elements may be better viewed in FIG. 27G, which omits the flexible intermediate portion 300 of the guidewire body 14.

[0158] The tapered pull tube 324 extends within and through the axial lumen 328 of the guidewire body 14, including the flexible intermediate portion 300 having laser edged helical windings 43 as depicted in FIG. 27A, which is a cross sectional view A-A of FIG. 27. The tapered pull tube 324 is further coupled to the distal end portion 39 of the guidewire body 14. Actuation of the tapered pull tube 324 via the deflecting wheel 330 on the handle 12 (FIG. 26A) deflects or bends the distal end 39 of the guidewire body 14. Advantageously, the tapered pull tube 324 provides for reduced friction between the surrounding mechanically moving core element 22 and the pull tube structure 324. This reduces any tangling action between the pull tube 324 and, which further prevents the pull tube 324 from breaking. Additionally, the plurality of openings or thinned portions 202 may be used to increase the flexibility and/or bendability of the distal end portion 39, such that when the tapered pull tube 324 is moved proximally, the distal end portion 39 is able to deflect without kinking of the distal end portion 39.

[0159] The pull tube 324 is tapered as best seen in the cross sectional views B-B and C-C of FIGS. 27B and 27C. Tapering acts to enhance the bendability of the deflectable distal tip 39. The taper, as depicted by arrow 332, may begin at an intermediate portion 300 or distal portion 39 of the guidewire body 14. The taper may be effected by a variety of removal means, including laser cutting a portion of the material from the tube 324 as described above. Typically, the tapered pull tube extends between about 0% (e.g., 0 degrees) to about 94% (e.g., 340 degrees) of the complete pull tube 324. The pull tube 324 will be tapered for a length less than the length of the guidewire body, which may be in a range from 0.050 inch to 0.500 inch.

[0160] The tapered pull tube 324 will have an overall length comparable to dimensions given above with respect to the hollow guidewire 14 and a diameter in a range from 0.005 inch to 0.039 inch and a thickness in a range from 0.0005 inch to 0.005 inch. As can be appreciated, the diameter and thickness of pull tube 324 will depend on the dimension of the inner lumen 328 and the largest radial dimension of the hollow guidewire 14, and the only requirement is

that the pull tube 324 be received within the inner lumen 328 of the hollow guidewire 14. The tapered pull tube 324 may be formed from superelastic metal or shape memory alloy (e.g., nickel titanium, nitinol) or other comparable materials (e.g., stainless steel). Additionally, the pull tube 324 may be coated with Teflon® so as to further reduce the friction coefficient of the surface and to reduce twisting of the pull tube 324.

[0161] As best shown in FIG. 27 and the cross sectional views C-C, D-D, E-E, and F-F depicted in FIGS. 27C-27F, the radiopaque coil 326 may be disposed over at least a distal portion of the mechanically moving core element 22 and within the guidewire body 14. The radiopaque coil 326 may extend along any length of the guidewire body 14, but preferably will extend from a point at the intermediate flexible section 300, as shown in FIG. 27C, through the transition section 212 as shown in FIG. 27D, and through a distal portion 39 of the guidewire body 14, as shown in FIGS. 27E (e.g., through rib 204) and 27F (e.g., through thinned portion 202). The radiopaque coil 326 separates the tapered pull tube 324 from the core element 22, acting to further reduce any tangling on snapping action between the pull tube 324 and assembly 22. The radiopaque coil 326 assists in the fluoroscopic tracking of at least the distal portion 39 of the guidewire body 14 in addition to or in the alternative of the previously disclosed radiopaque markers or radiopaque distal tip drive shafts. This in turn aids in proper positioning of the guidewire 39 at the occlusion site.

[0162] The radiopaque coil 326 may be formed or coated with a variety of materials including platinum, platinum iridium, platinum tungsten, and the like. The radiopaque coil may have any desired length, diameter, pitch or kerf, any number of helical windings, clockwise or counterclockwise coil directions, etc. Typically, the radiopaque coil 326 will have a length which is in a range from 0.200 inch to 1.5 inches, a diameter in a range from 0.004 inch to 0.035 inch, and a thickness in a range from 0.0005 inch to 0.005 inch. As can be appreciated, the diameter and thickness of radiopaque coil 326 will depend on the dimension of the inner lumen 328 of the hollow guidewire 14, the pull tube 324, and the mechanically moving core element 22.

[0163] The mechanically moving core element 22 extends within and through the axial lumen 328 of the guidewire body 14, as best shown in FIGS. 27A-27G. The assembly 22 may be movably or fixedly disposed at the distal end 39 of the hollow guidewire body 14. As shown in FIGS. 28A and 28B, a distal tip 24 of the mechanically moving core element 22 extends distally of the distal end 39 of the guidewire body 14. Upon activation, the mechanically moving the distal tip 24 of the core element 22 creates a passageway or enlarges a passageway through the occlusion or stenosis within the body lumen. Generally,

the distal tip 24 of the core element 22 creates a path at least as large as a perimeter of a distal end 39 of the hollow guidewire 14. However, as noted above, the path can also have the same perimeter or smaller perimeter than the distal 39 end of the hollow guidewire 14.

[0164] As shown in FIGS. 28A and 28B, the mechanically moving core element 22 in this embodiment preferably comprises an oscillatory drive shaft as depicted by arrow 334. The preferred oscillating operating mode 334 is of particular benefit to the present invention as it prevents tissue from wrapping around the distal tip 24 of the drive shaft 22. This in turn allows for enhanced penetration through, in, and/or out of the occlusive or stenotic material. Typically, the drive shaft 22 will be oscillated so that it changes polarity after a period of time. The period of time may in a range from about 0.2 seconds to about 5.0 seconds, preferably in a range from about 0.3 seconds to 1.2 seconds, and more preferably in a range of about 0.7 seconds.

[0165] The mechanically moving core element 22 may additionally comprise an axially translatable drive shaft as depicted by arrow 25 for axial or reciprocation movement so as to completely cross an occlusion. Oscillation movement 334 and reciprocation movement 25 of the drive shaft may be carried out sequentially or simultaneously. Generally, oscillation and/or reciprocation 334, 25 movement of the drive shaft 22 are carried out by a drive motor 26 within the handle 12 of the device 10 (FIG. 26A). Alternatively, a device operator may also manually oscillate and/or reciprocation the drive shaft 22 as described above with respect to FIG. 2. Additionally, the movable drive shaft 22 may be extended from a retracted configuration to an extended configuration relative to the distal portion 39 of the hollow guidewire body 14, wherein the drive shaft 22 is simultaneously or sequentially extended and oscillated.

[0166] The distal tip 24 of the drive shaft 22 may take on a variety of configurations as disclosed herein. In FIG. 28A, the distal tip 24 comprises a bullet shape. In FIG. 28B, the distal tip 24 comprises a flat spatula shape. In FIG. 29A, the distal tip 24 comprises a drill shape. In FIG. 29B, the distal tip 24 comprises a football shape. Any of the distal tip disclosed herein may additionally comprise laser edgings 336 thereon as further illustrated in FIG. 29A and optionally be deflected or shaped as described above.

[0167] Referring back to FIGS. 28A and 28B, a stationary locking mechanism 338 may be coupled to or integrated within the distal end 39 of the guidewire body 14, particularly to the slots 322 of the blunt actuating tip 320. The locking mechanism 338 receives and allows for axial movement of the drive shaft 22, including a thicker portion 340 of the drive shaft 22, until it mates with a proximal flange 342 coupled to or integrated with the drive shaft 22.

This added safety feature prevent inadvertent release of distal tip 24 into the body lumen in the case of a break or crack in the mechanically moving core element 22, which often occurs at a point proximal the flange 342. The thicker portion 340 of the shaft will have a diameter which still allows for movement within the axial lumen 328 of the guidewire body 14 and the locking mechanism 338. The proximal flange 342 will have a diameter which still allows for movement within the axial lumen of the guidewire body 14, but an equal or larger diameter than the locking mechanism 338 to safely prevent any further axial movement of the shaft 22 into the body lumen.

[0168] The drive shaft 22 may be formed from a variety of materials, including nitinol, stainless steel, platinum iridium, and like materials and have diameter, length, distal tip extension (e.g., of drive shaft beyond the distal portion of the hollow guidewire) dimensions as those already described above. The drive shaft tip 24 in the preferred embodiments of FIGS. 28A and 28B will preferably have an outer perimeter which is equal to or larger than a diameter of the hollow guidewire body 14 so as to create a path at least as large as a perimeter of the distal end 39 of the guidewire 14. As can be appreciated, the diameter and thickness of shaft 22 will depend on the dimension of the inner lumen 328 of the hollow guidewire 14, the pull tube 324, the locking mechanism 338, and/or the radiopaque coil 326. Additionally, to reduce friction between the drive shaft 22 and the pull tube 324, the drive shaft may be coated with Teflon® or other materials so that the drive shat 22 is able to oscillate without causing substantial twisting of the pull tube 324.

[0169] As mentioned above, the hollow guidewire 14 of the present invention has a deflectability, flexibility, pushability, and torqueability which allows it to be positioned through the tortuous blood vessel without the use of a separate guidewire. Once properly positioned adjacent the occlusion or stenosis, the distal tip 24 of the drive shaft 22 is oscillated and simultaneously or sequentially advanced into the occlusion or stenosis in the body lumen to create a path in the occlusion or stenosis. It will be appreciated that the hollow guidewire 14 and/or the drive shaft 22 may be advanced to create a path through the occlusion or stenosis. For example, once the guidewire 14 has reached the occlusion, the guidewire 14 together with the oscillating drive shaft 22 may be advanced into the occlusion. Alternatively, the guidewire 14 may be in a fixed position and only the oscillating drive shaft 22 may be advanced into the occlusion.

[0170] Referring now to FIGS. 30A and 30B, exploded views of the handle 12 of the guidewire device 10 of FIG. 26A are illustrated. The handle 12 in this preferred embodiment is fixedly coupled to the proximal end 45 of the guidewire body 14. The handle 12 generally

provides torque transmission via torque knob 403 from the proximal end 45 to the distal end 39 of the guidewire body 14 (e.g., entire device), typically in a 1:1 ratio. The handle 12 further provides directionality to the deflectable distal tip 39 via deflecting wheel 330. Significantly, the handle 12 allows for torque transmission of the guidewire body 14 independent of deflection of the distal end 39 of the guidewire body 14. The handle design 12 further allows for and retains the continual ability to actuate torsional transmission (via torque knob 403) and deflection of the guidewire device (via deflecting wheel 330), either independently, sequentially, or simultaneously, as a physician steers through a tortuous blood vessel. This can advantageously be accomplished while maintaining the handle 12 in a stationary configuration that is ergonomically easy to grasp and control. The handle 12 may further enclose a drive motor 26 to move (e.g., oscillate, reciprocate, translate, rotate, vibrate, or the like) the drive shaft 22, a control system 27 including circuitry which provides feedback control as discussed in more detail below, and/or a power supply 28.

[0171] The control handle 12 further includes distal and proximal flexible strain reliefs 401, 411 that protect the ends of the control handle. The distal strain relief 401 is mechanically press fitted into the top handle 402. The flexible distal strain relief 401 minimizes the transition between the hypotube 14 and the control handle 12 and can potentially avoid any kinking of the hypotube 14. Proximal strain relief 411 acts to seal the proximal end of the control handle.

[0172] The torquer knob 403 is mechanically attached to the hypotube 14 via a brass collet 413. The collet 413 resides within the top handle 402. When the top handle 402 is screwed into the torquer knob 403, the collet 413 closes and grasps the hypotube 14 radially with sufficient pressure to properly lock the two together without crushing the hypotube 14. The flexible washer component allows the torquer knob 403 to rotate independently from the deflecting wheel 330.

[0173] The deflecting wheel 330 translates rotational motion into axial movement of the pull component 324. This induces the deflecting tip 39 to bend and relax from its original position. An outer slide insert 412 acts as a hypotube stopper during the tip deflection process. A bearing washer located between inner slide handle 405 and the deflecting wheel 330 allows for the pull component 324 to rotate together with the hypotube 14 as the device 10 is being torqued. In particular, the inner handle 405 slides inside of the outer slide handle 404. This allows the pull component 324 to rotate together with the hypotube 14 as the unit is being torqued. As the pull component 324 is being placed under tension, the inner slide handle 405 moves closer to the bearing washer and a smooth fit is created allowing for

synchronized movement. The pull component 324 is mechanically attached to the inner slide 405. The drive shaft 22 is mechanically attached to the motor drive shaft 26 via a centering adapter which is mechanically secured in place by set screws.

[0174] Between the top handle 402 and the chamber handle 409 there is a brace handle 407 that provides structural support connecting the two main parts of the control handle 12. The ring brace 408 provides the proximal connection to the brace handle 407. The brace handle 407 slides over the handle at the proximal end and its mechanical attachment providing a secure connection between the distal and proximal end of the handle 12. A lock ring handle 414 is also shown.

[0175] The electronic components 27 reside within and are secured by handle chamber 409 and lid 410 which are mechanically attached. The motor 26 resides within the distal end of the handle chamber 409 and is mechanically secured to avoid any axial or oscillatory movement during the operation. An encoder is built into the motor assembly 26. The electronic circuitry provides power to the DC motor 26 to oscillate, reciprocate, and/or rotate the drive shaft 22. The operator may manually activate the motor 26 via an ON/OFF switch. Alternatively, the motor 26 may be activated by voice activation, wireless activation via infrared sensors, or Bluetooth® footswitch technology. Indicator lights connected to the encoder provide visual feedback as to whether the motor 26 is running in an appropriate mode. In addition, the encoder signal is amplified to provide an auditory feedback to the user. This audio tone is proportional to motor rpm and so changes in pitch as resistance is encountered. The audio feedback amplitude is user-adjustable. The unit may be powered by a 9V alkaline battery supply 28 having a voltage regulator which allows adjustment for optimum motor speed and torque.

[0176] Electronic circuitry within the control system 27 of the handle 12 may measure a variety of characteristics for feedback control. The resistance encountered during advancement of the distal tip 24 in the body lumen may be measured. In response, the torque speed may automatically be adjusted in line with the measured resistance. For example, the torque-speed characteristics of the DC motor 26 that powers the device 10 will deliver more torque as more resistance is encountered. As the resistance to rotation increases or decreases due to the encounter of hard or soft stenosis, the demand for power goes up or down resulting in an increase or decrease in torque which facilitates the breakage of the stenosis.

[0177] In another instance, a level of load encountered during advancement of the distal tip in the body lumen may be measured. In response, a visual or audio alarm may be signaled if the measured load is above or below a threshold value. Further, there may be a visual light or

audio tone that simply indicates the level of load measured via the motor encoder (e.g., no load the LED light is ON, as the device is facing load the LED light begins to dim). Still further, the device may be automatically disabled in response to the no load measurement as an added safety feature. The motor in this instance may still be restarted if desired. In still another instance, a use of the device based on time or number of revolutions or oscillations may be measured. The device may be automatically and permanently disabled once the a measured time has been exceeded or number of revolutions have been reached. For example, there may be a digital clock that reads the accumulated procedural time. This safety feature protects against device fatigue and warrants that the device is not operable past its optimal lifetime use.

[0178] While the above is a complete description of the preferred embodiments of the invention, various alternatives, modifications, and equivalents may be used. For example, while the above description focuses on a oscillatory drive shaft to remove material from the body lumen, the hollow guidewires of the present invention may incorporate other plaque removal assemblies. The plaque removal assembles may be fixedly positioned at the distal tip of the hollow guidewire or movable between a first position (e.g., retracted position) and a second position (e.g., deployed position). The plaque removal assembly may take on the form of a laser, LED, RF electrode or other heating element, an ultrasound transducer or the like. Thus, instead of a drive shaft, the above plaque removal assemblies may have a lead extend through the axial lumen to the plaque removal assembly that is fixedly or movably positioned at or near the distal end of the hollow guidewire. Moreover, while not explicitly illustrated, a person of ordinary skill in the art will recognize that aspects of one configuration of the hollow guidewire body may be used with other configurations of the hollow guidewire body. For example, while the guidewire body of FIG. 2 does not show thinned portions 202 near the distal end or varying pitch coils on its proximal portion, such a configuration would be encompassed by the present invention. Therefore, the above description should not be taken as limiting the scope of the invention which is defined by the appended claims.

WHAT IS CLAIMED IS:

1. A deflectable hollow guidewire device for crossing an occlusion or stenosis within a body lumen, the device comprising:

an elongate hollow guidewire body having a proximal end, a deflectable distal end, and an axial lumen therebetween; and

a mechanically moving core element extending through the axial lumen of the guidewire body.

2. The device of claim 1, wherein the elongate hollow guidewire body comprises a unitary structure having a plurality of sections.

3. The device of claim 2, wherein at least one section comprises an interrupted helical pattern.

4. The device of claim 3, wherein the interrupted helical pattern comprises laser edged helical windings at 180 degrees interrupted by 30 degree segments.

5. The device of claim 2, wherein at least one section comprises a ribbed pattern.

6. The device of claim 2, wherein at least a first section comprises an interrupted helical pattern and a second section comprises a ribbed pattern.

7. The device of claim 1, further comprising a pull tube extending through the axial lumen and coupled to the distal end portion of the guidewire body.

8. The device of claim 7, wherein actuation of the pull tube deflects or bends the distal end of the guidewire body.

9. The device of claim 7, wherein the pull tube is distally tapered.

10. The device of claim 7, wherein the pull tube is formed from nickel titanium.

11. The device of claim 1, further comprising a radiopaque coil disposed over at least a distal portion of the core element.

12. The device of claim 11, wherein the coil separates a pull tube extending through the axial lumen of the guidewire body from the core element.

13. The device of claim 1, wherein a distal tip of the core element extends distally of the distal end of the guidewire body and upon activation creates a passageway or enlarges a passageway through the occlusion or stenosis within the body lumen.

14. The device of claim 13, wherein the mechanically moving core element comprises an oscillatory drive shaft.

15. The device of claim 13, wherein the mechanically moving core element comprises an axially translatable drive shaft for reciprocation movement.

16. The device of claim 13, wherein the distal tip comprises a bullet, fluted bullet, flat spatula, drill, or football shape.

17. The device of claim 13, wherein the distal tip is deflected or shaped.

18. The device of claim 13, wherein the distal tip comprises laser edgings.

19. The device of claim 13, further comprising a locking mechanism coupled to the distal end of the guidewire body which prevents inadvertent release of distal tip into the body lumen.

20. The device of claim 1, further comprising a handle coupled to the proximal end of the guidewire body.

21. The device of claim 20, wherein the handle is fixedly coupled to the guidewire body.

22. The device of claim 21, wherein the handle allows for torque transmission of the guidewire body independent of deflection of the distal end of the guidewire body.

23. The device of claim 20, wherein the handle is removably coupled to the guidewire body.

24. The device of claim 20, further comprising circuitry within the handle which provides feedback control.

25. A non-deflectable, hollow guidewire device comprising:

an elongate hollow guidewire body having a proximal end, a pre-shaped distal end, and an axial lumen therebetween; and

a drive shaft extending through the axial lumen of the guidewire body.

26. A deflectable hollow guidewire device for crossing an occlusion or stenosis within a body lumen, the device comprising:

an elongate hollow guidewire body having a proximal end, a deflectable distal end, an axial lumen therethrough, and a plurality of sections therebetween, wherein at least one section comprises an interrupted helical pattern; and

an oscillatory drive shaft extending through the axial lumen of the guidewire body.

27. The device of claim 26, wherein the interrupted helical pattern comprises laser edged helical windings at 180 degrees interrupted by 30 degree segments.

28. The device of claim 26, further comprising another section comprising a ribbed pattern.

29. The device of claim 26, further comprising another section comprising a solid-walled tubular member.

30. A steerable hollow guidewire device comprising:

an elongate hollow guidewire body having a proximal end, a distal end, and an axial lumen therebetween;

a drive shaft extending through the axial lumen of the guidewire body; and

a pull tube extending through the axial lumen and coupled to the distal end portion of the guidewire body, wherein actuation of the pull tube deflects the distal end of the guidewire body.

31. The device of claim 31, further comprising a radiopaque coil disposed between the pull tube and the drive shaft.

32. A steerable hollow guidewire comprising:

an elongate hollow guidewire body comprising a proximal opening, a distal opening, and an axial lumen extending from the proximal opening to the distal opening;

a rotatable drive shaft disposed within the axial lumen, wherein a distal tip of the rotatable drive shaft is adapted to extend distally through the distal opening in the guidewire body; and

at least one pull wire extending through the axial lumen and coupled to a distal end portion of the guidewire body, the pull wire(s) comprising a curved surface that substantially corresponds to a shape of an inner surface of the axial lumen.

33. The steerable hollow guidewire of claim 32, wherein the hollow guidewire body comprises a solid wall tubular proximal portion integrally formed with the distal end portion, wherein the distal end portion comprises helical windings formed thereon.

34. The steerable hollow guidewire of claim 33, wherein the guidewire body comprises a single hypotube.

35. The steerable hollow guidewire of claim 33, wherein a pitch between adjacent helical windings decreases in the distal direction so as to increase a flexibility in the distal direction along the distal portion of the guidewire body.

36. The steerable hollow guidewire of claim 32, wherein the guidewire body has a largest radial dimension between about 0.009 inches and about 0.035 inches.

37. The steerable hollow guidewire of claim 32, wherein the distal end portion of the guidewire body comprises a plurality of openings or thinned portions that extend circumferentially about at least a portion of the distal end portion of the guidewire body.

38. The steerable hollow guidewire of claim 32, comprising a radiopaque marker disposed at the distal end portion of the guidewire body.

39. The steerable hollow guidewire of claim 32, wherein the pull wire further comprises a substantially flat surface that faces the rotatable shaft.

40. The steerable hollow guidewire of claim 32, wherein the pull wire comprises a D-shaped cross-section.

41. The steerable hollow guidewire of claim 32, wherein the pull wire comprises a crescent shaped cross section or oval shaped cross section.

42. The steerable hollow guidewire of claim 32, wherein the rotatable drive shaft is rotatable and advanceable axially within the axial lumen.

43. The steerable hollow guidewire of claim 32, wherein the at least one pull wire(s) comprise a single pull wire.

44. The steerable hollow guidewire of claim 32, wherein the at least one pull wire(s) comprises two or more pull wires.

45. The steerable hollow guidewire of claim 32, wherein at least one of the pull wire(s) and the rotatable drive shaft are at least partially coated with Teflon.

46. The steerable hollow guidewire of claim 32, comprising a removable housing coupled to a proximal portion of the hollow guidewire body.

47. A hollow guidewire comprising a hypotube that comprises a proximal portion and a distal portion, wherein at least a part of the distal portion of the hypotube comprise helical windings formed thereon so that the distal portion of the hypotube is more flexible than the proximal portion.

48. The hollow guidewire of claim 47, wherein at least a portion of the proximal portion is solid walled and tubular shaped.

49. The hollow guidewire of claim 47, wherein a pitch of the helical windings on the distal portion decreases in the distal direction so that a flexibility of the distal end portion increases in the distal direction.

50. The hollow guidewire of claim 47, wherein the guidewire body has a largest radial dimension between about 0.009 inches and about 0.035 inches.

51. The hollow guidewire of claim 47, wherein the distal end portion of the guidewire body comprises a plurality of openings or thinned portions that extend circumferentially about at least a portion of the distal end portion of the guidewire body.

52. The hollow guidewire of claim 47, comprising a radiopaque marker disposed at the distal portion of the guidewire body.

53. The hollow guidewire of claim 47, comprising a removable housing coupled to a proximal end of the proximal portion of the hollow guidewire body.

54. The hollow guidewire of claim 47, further comprising at least one pull wire extending through an axial lumen in the hypotube and coupled to the distal portion of the hypotube.

55. The hollow guidewire of claim 54, wherein the pull wire(s) comprise a curved surface that substantially corresponds to a shape of an inner surface of the axial lumen.

56. The hollow guidewire of claim 47, comprising a tissue removal assembly fixedly or movably disposed at the distal portion of the hollow guidewire.

57. The hollow guidewire of claim 56, wherein the tissue removal assembly comprises a rotatable drive shaft that extends through an axial lumen in the hollow guidewire and extends distally beyond a distal end of the hollow guidewire.

58. A steerable guidewire comprising:

a hollow guidewire body comprising a proximal end, a distal end, and an axial lumen that extends to the distal end;

a tissue removal assembly, wherein a portion of the tissue removal assembly is positioned at or near the distal end of the guidewire body; and

at least one pull wire that extends through the axial lumen and is coupled at or near the distal end of the hollow guidewire body, wherein a proximal force on the pull wire steers the distal end of the hollow guidewire.

59. The steerable guidewire of claim 58, wherein at least a portion of the tissue removal assembly is fixedly disposed at the distal end of the guidewire body.

60. The steerable guidewire of claim 58, wherein the tissue removal assembly is moveable from a first position in which the tissue removal assembly is disposed within the axial lumen, and a second position in which the tissue removal assembly is positioned beyond the distal end of the guidewire body.

61. The steerable guidewire of claim 58, wherein the tissue removal assembly comprises a laser, RF electrode, a resistive element, or an ultrasound transducer.

62. The steerable guidewire of claim 58, wherein the tissue removal assembly comprises a rotatable drive shaft that comprises a distal tip that extends beyond the distal end of the guidewire body.

63. The steerable guidewire of claim 58, wherein the hollow guidewire body comprises a solid tubular proximal portion integrally attached with a distal end portion, wherein the distal end portion comprises helical windings formed thereon.

64. The steerable guidewire of claim 63, wherein the guidewire body comprises a single hypotube.

65. The steerable guidewire of claim 64, wherein a pitch of the helical winding decreases in a distal direction so that a flexibility of distal end portion increases in the distal direction.

66. The steerable guidewire of claim 58, wherein the guidewire body has a largest radial dimension between about 0.009 inches and about 0.035 inches.

67. The steerable guidewire of claim 58, wherein a distal end portion of the guidewire body comprises a plurality of openings or thinned portions that extend circumferentially about at least a portion of the distal end portion of the guidewire body.

68. The steerable guidewire of claim 58, comprising a radiopaque marker disposed at the distal end of the guidewire body.

69. The steerable guidewire of claim 58, wherein the pull wire(s) comprising a curved surface that substantially corresponds to a shape of an inner surface of the axial lumen.

70. The steerable guidewire of claim 58, wherein the pull wire further comprises a substantially flat surface that faces a portion of the tissue removal assembly that extends through the axial lumen.

71. The steerable guidewire of claim 58, wherein at least one of the pull wire(s) and the tissue removal assembly are at least partially coated with Teflon.

72. The steerable guidewire of claim 58, comprising a removable housing coupled to a proximal portion of the hollow guidewire body.

73. A hollow guidewire comprising a proximal portion and a distal portion, wherein at least a part of the distal portion comprises helical windings that have a decreasing pitch between adjacent windings in the distal direction so that a distal end of the hollow guidewire is more flexible than the proximal portion of the hollow guidewire.

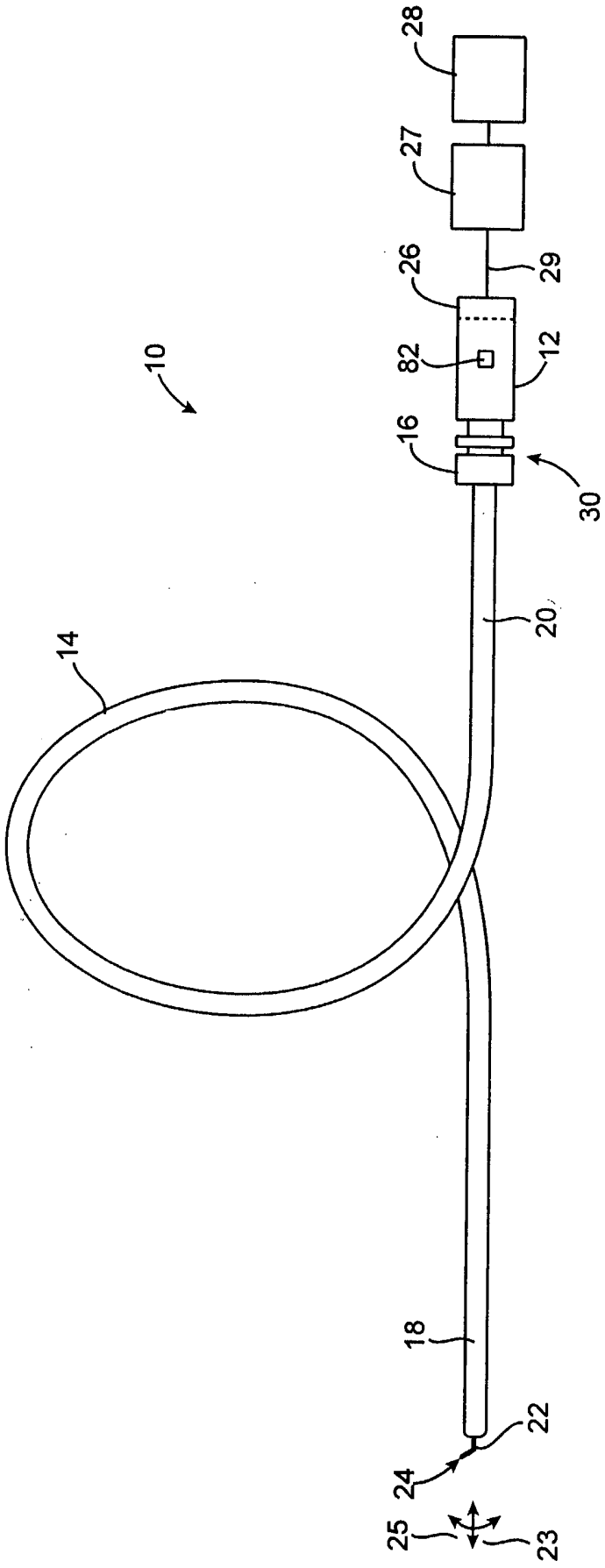

FIG. 1

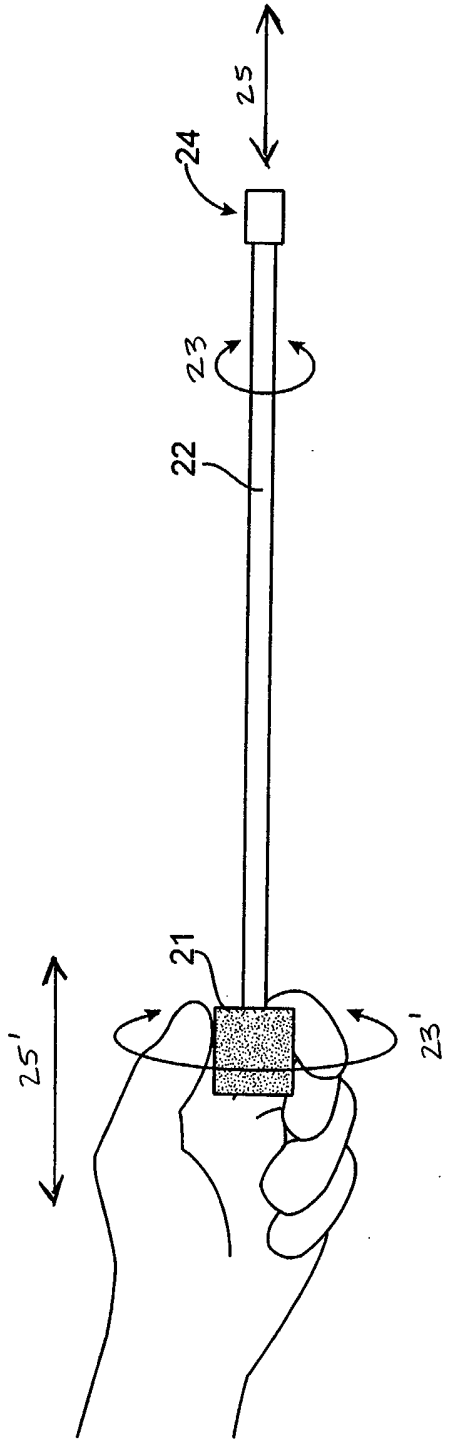

FIG. 2

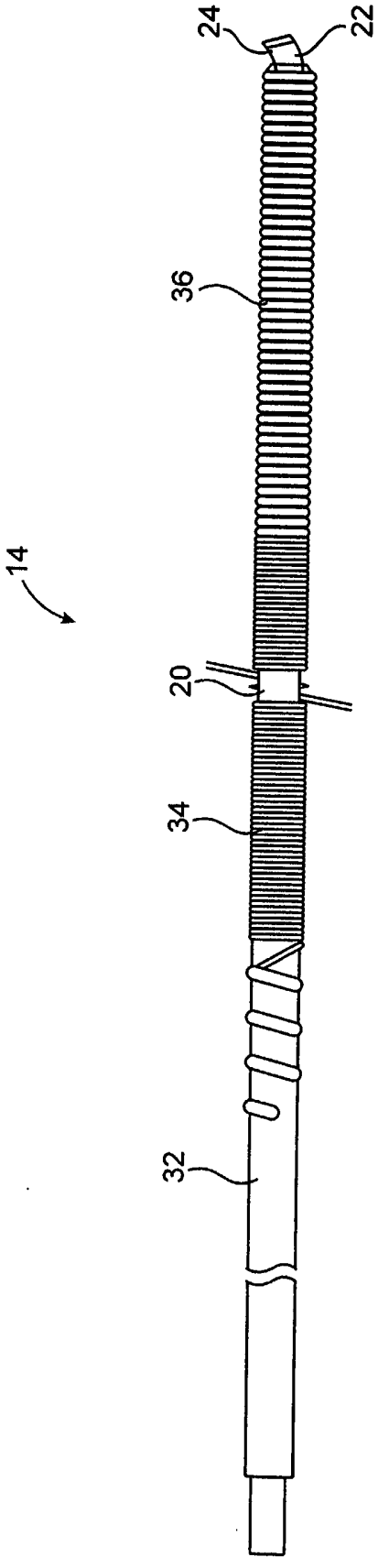

FIG. 3

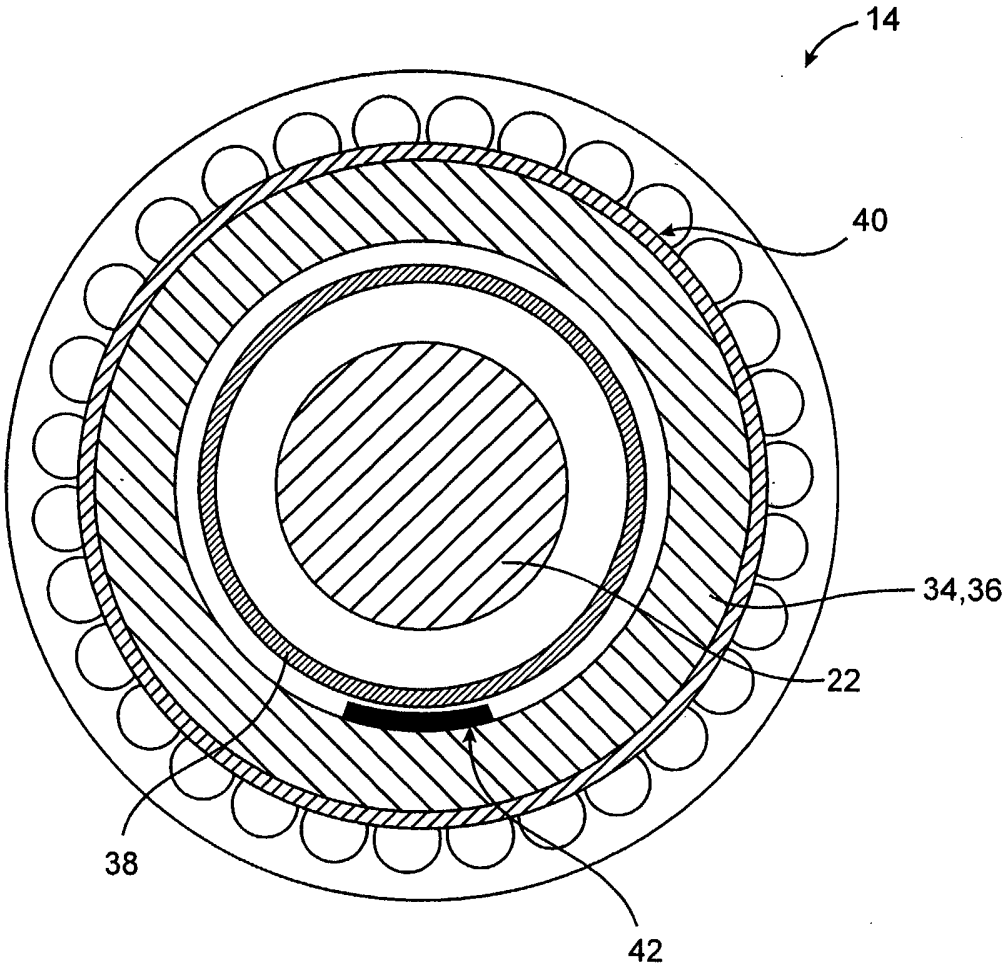

FIG. 3A

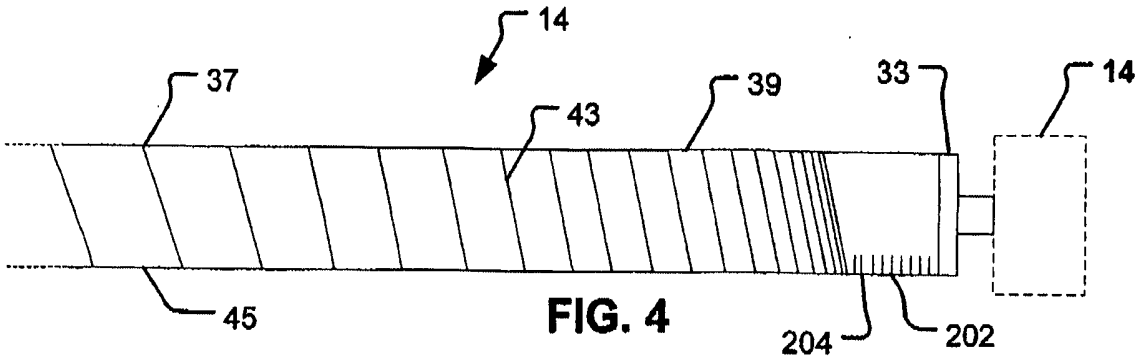

FIG. 4

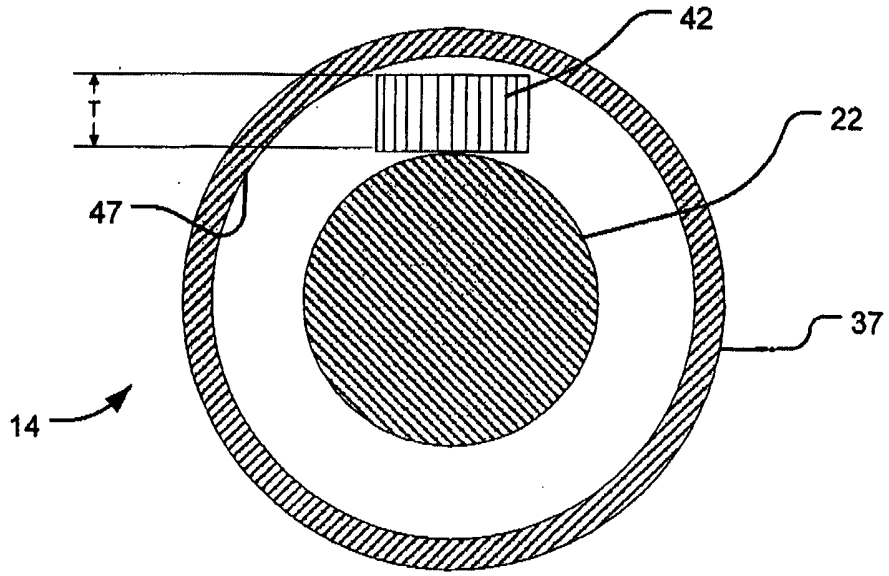

FIG. 5A

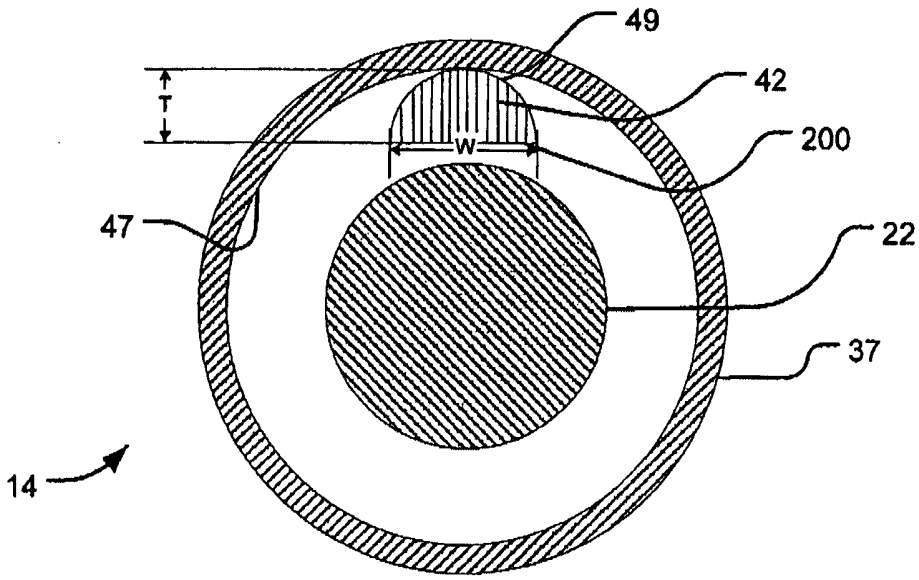

FIG. 5B

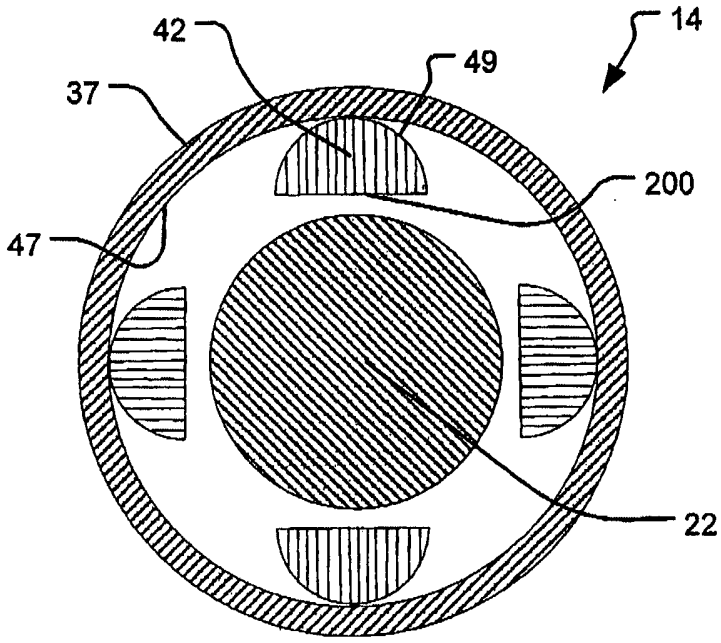

FIG. 5C

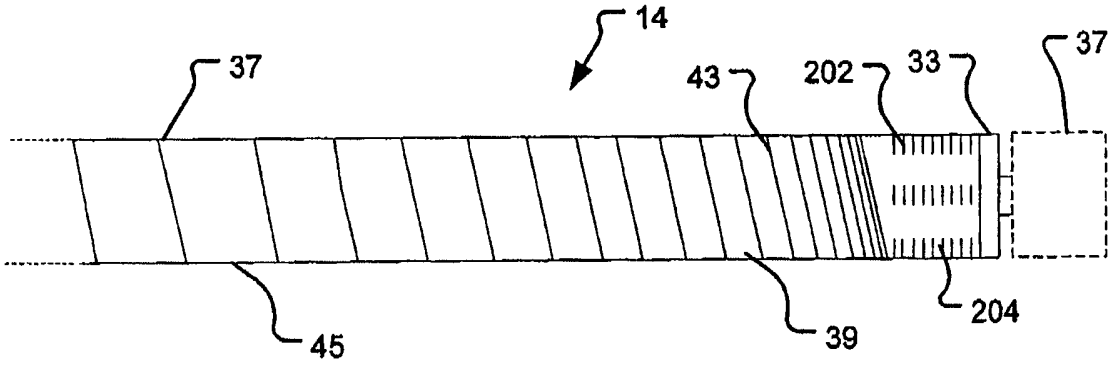

FIG. 6

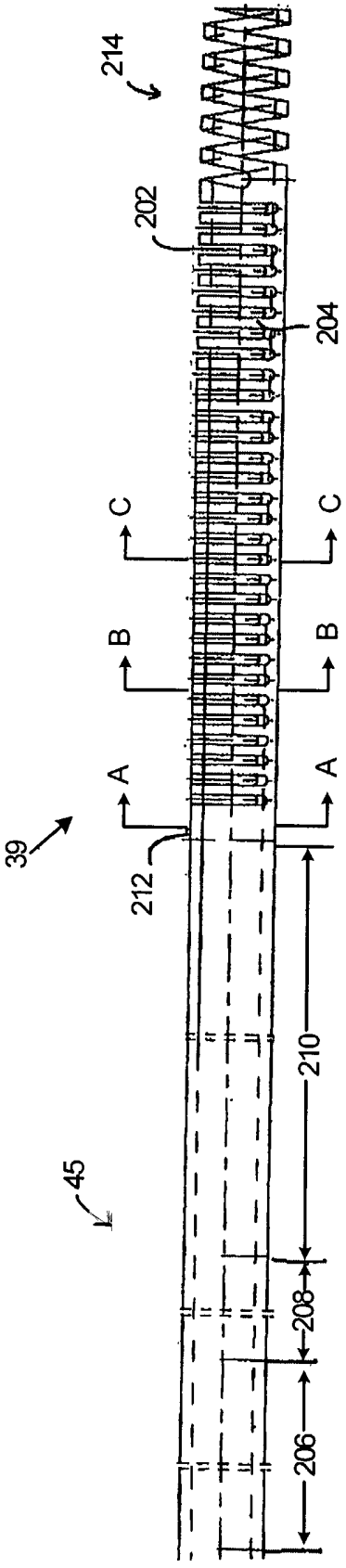

FIG. 7

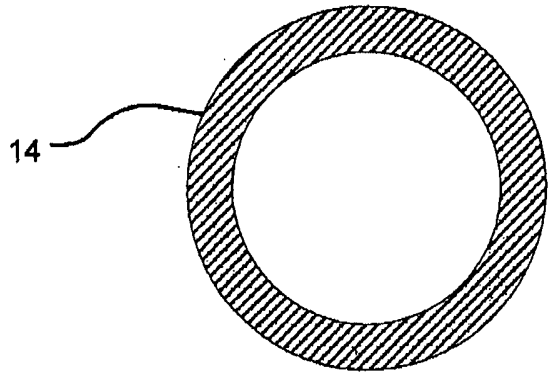

FIG. 7A

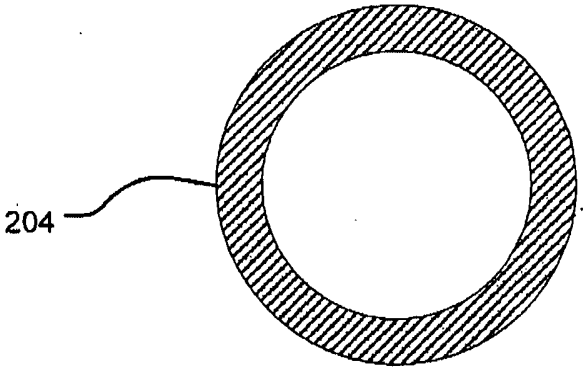

FIG. 7B

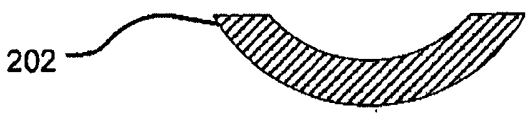

FIG. 7C

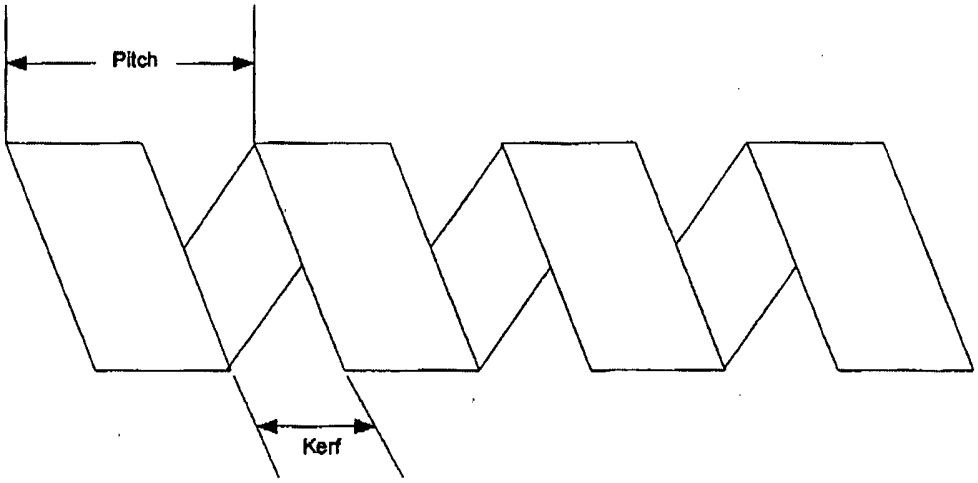

FIG. 8A

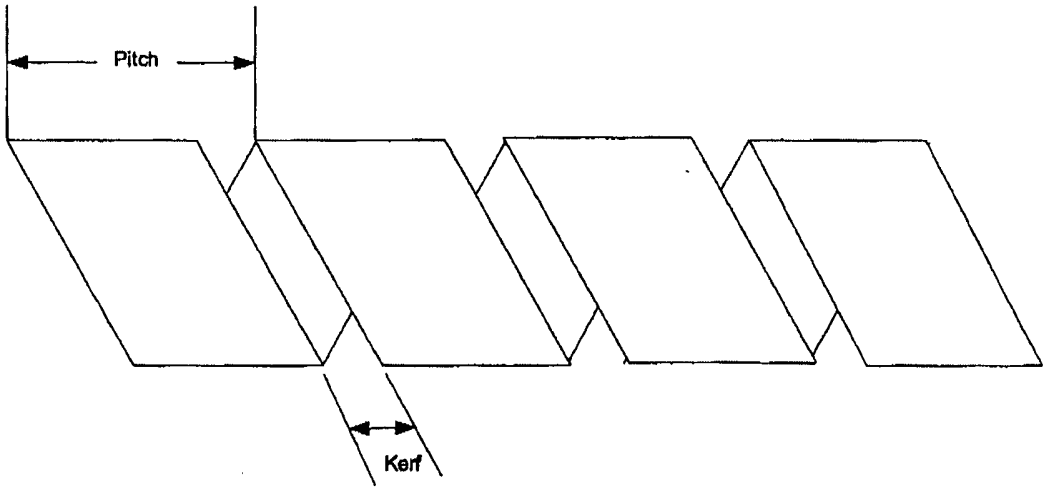

FIG. 8B

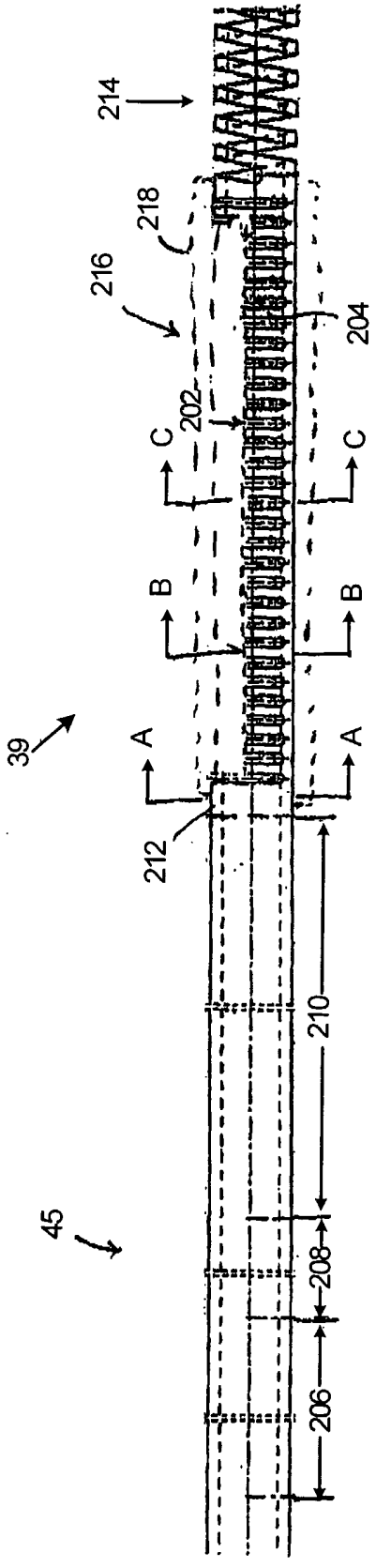

FIG. 9

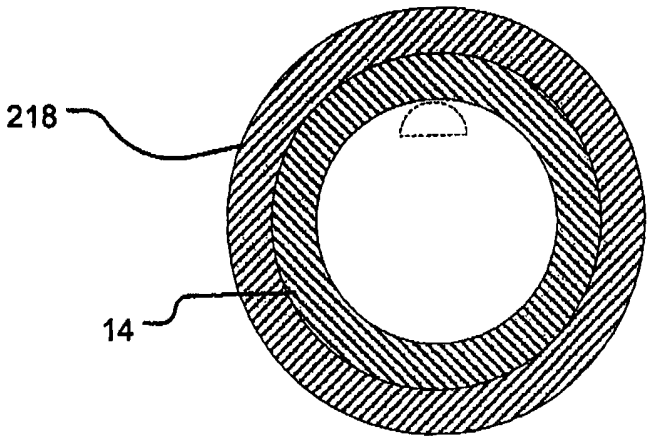

FIG. 9A

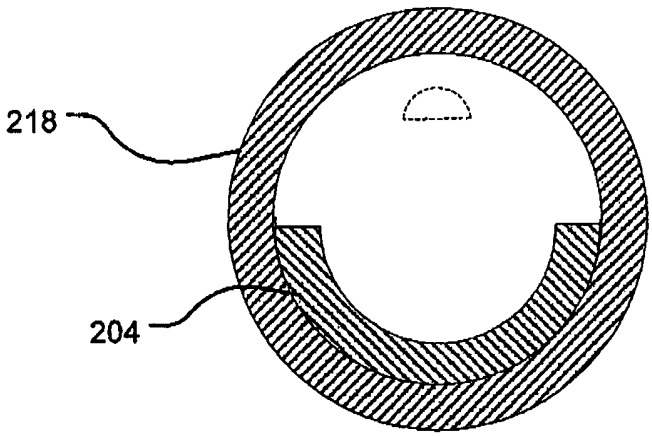

FIG. 9B

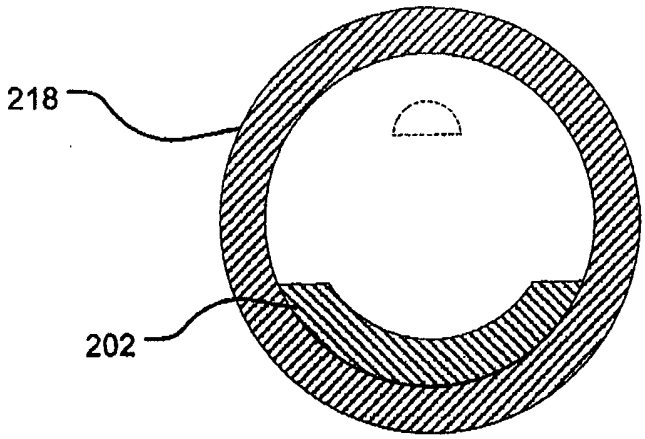

FIG. 9C

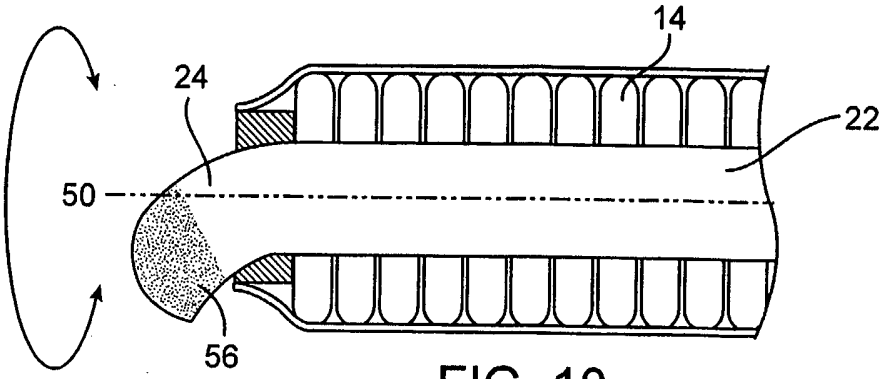

FIG. 10

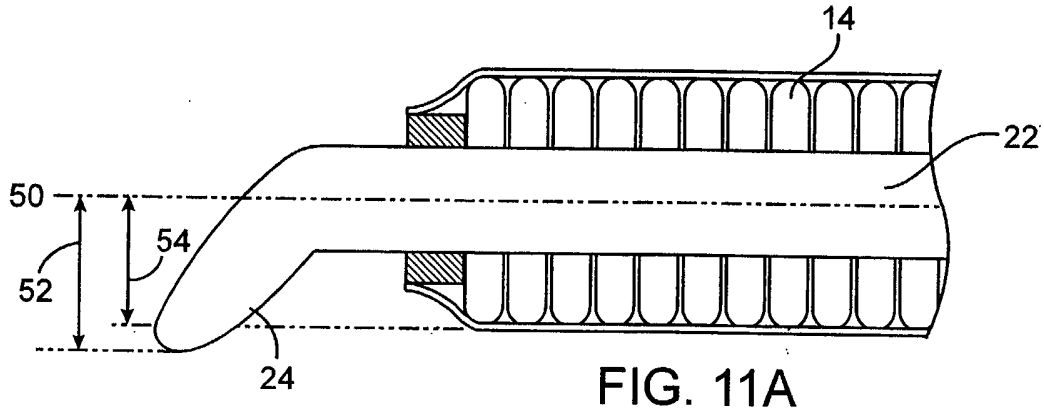

FIG. 11A

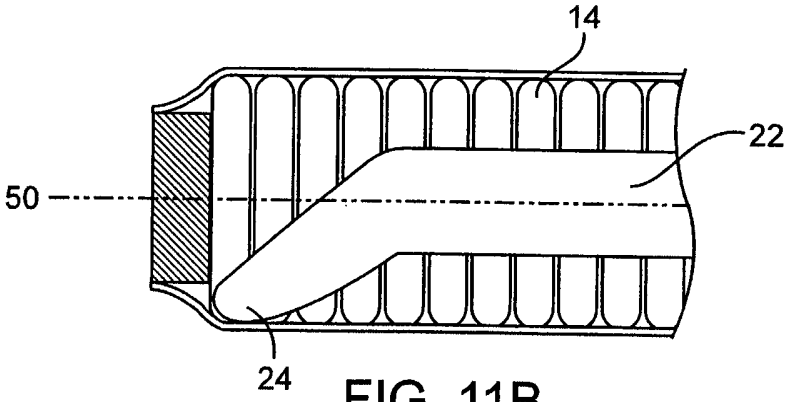

FIG. 11B

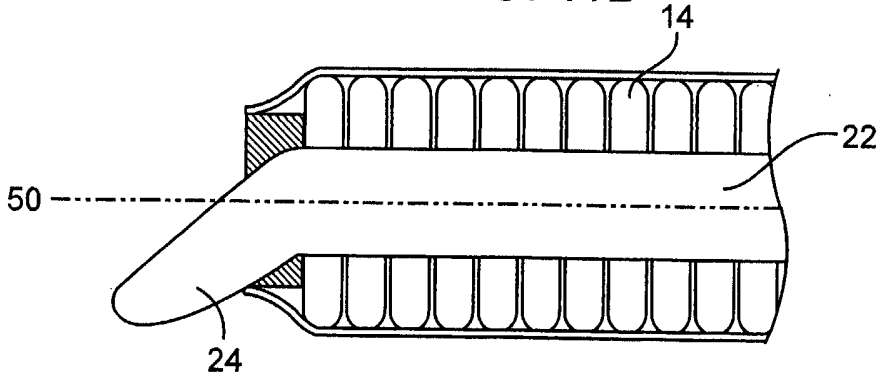

FIG. 11C

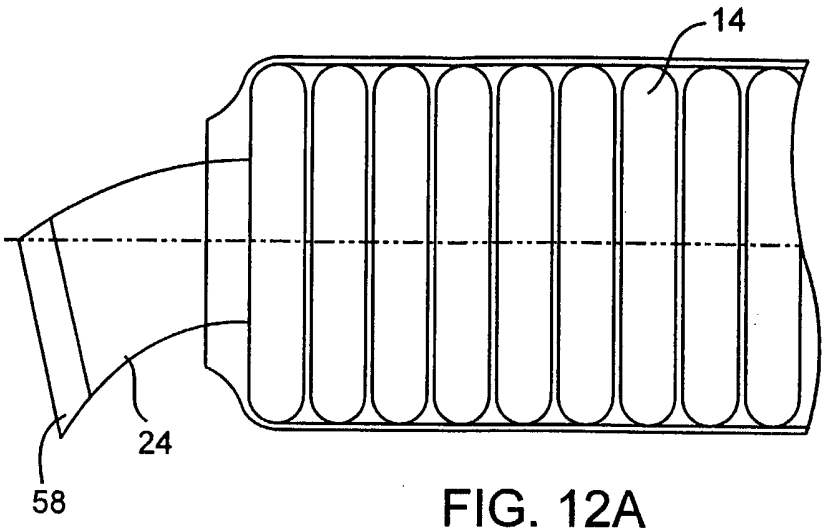

FIG. 12A

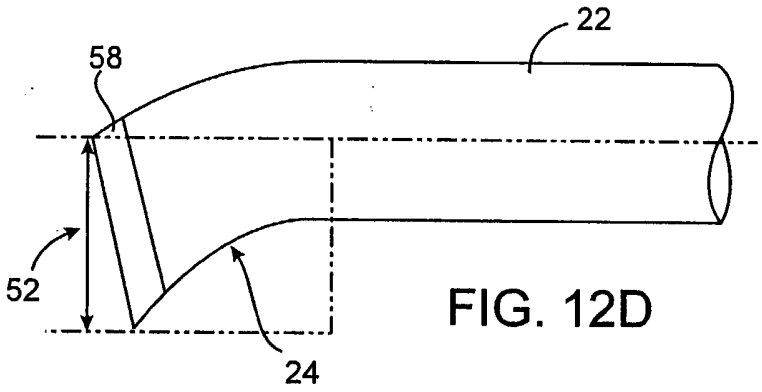

FIG. 12D

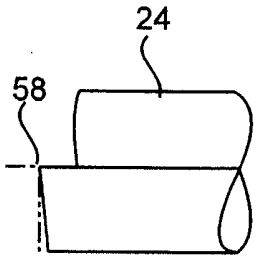

FIG. 12B

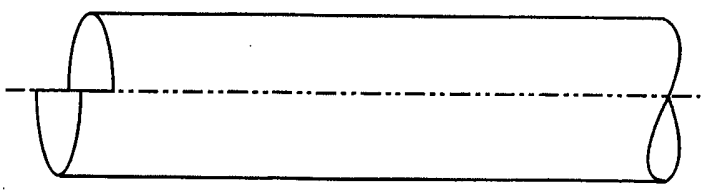

FIG. 12C

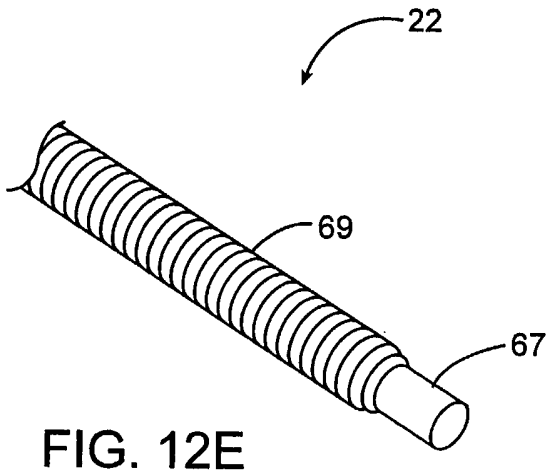

FIG. 12E

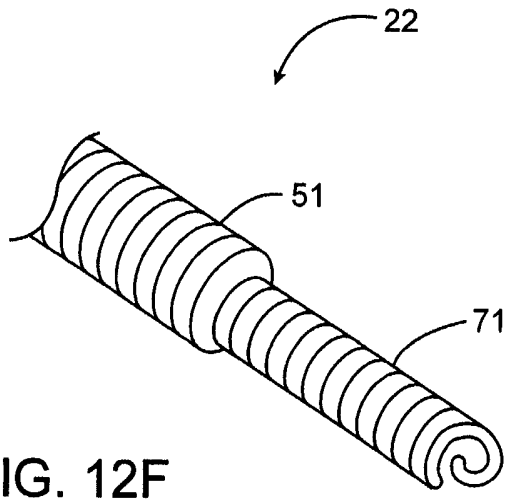

FIG. 12F

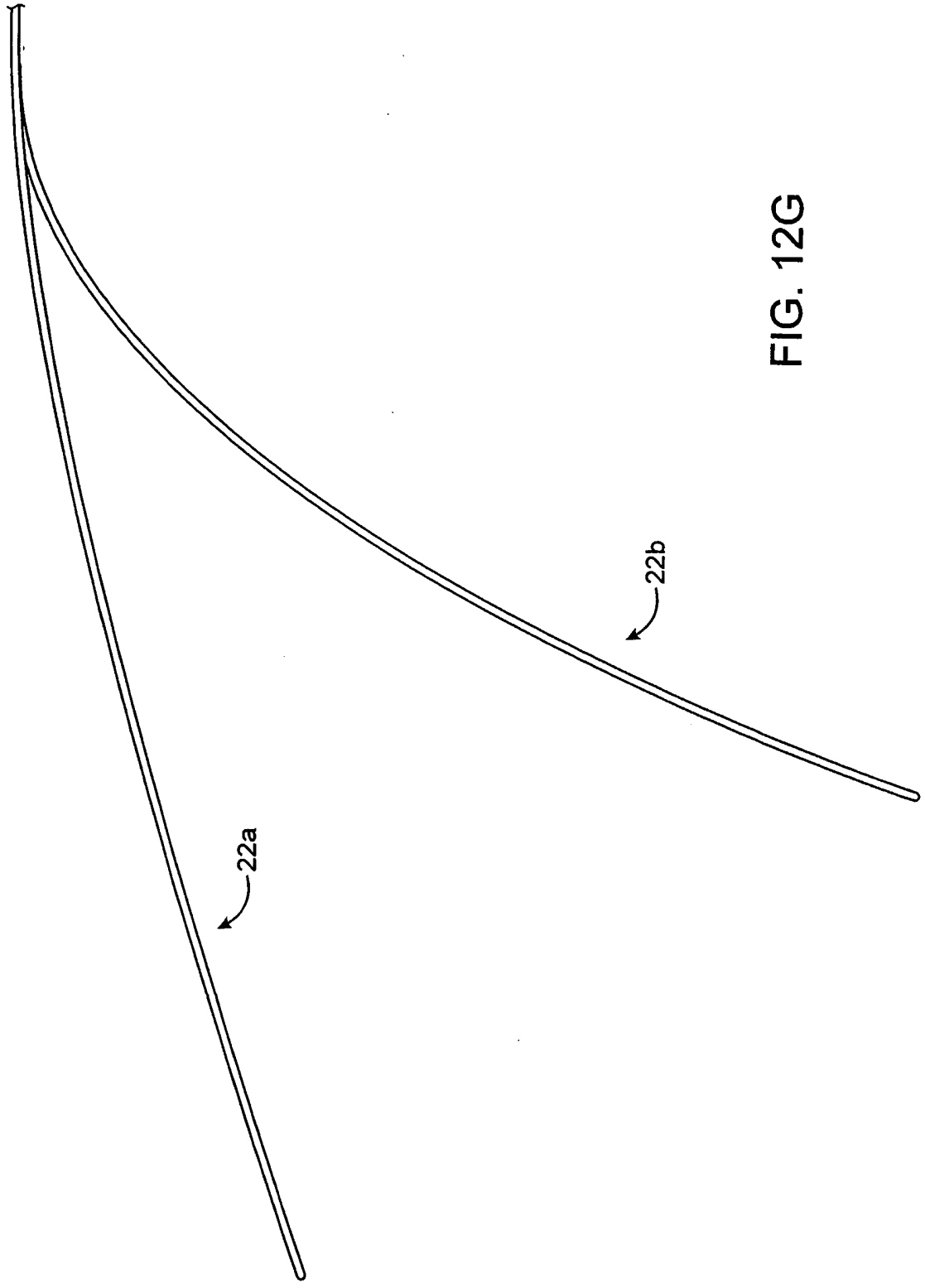

FIG. 12G

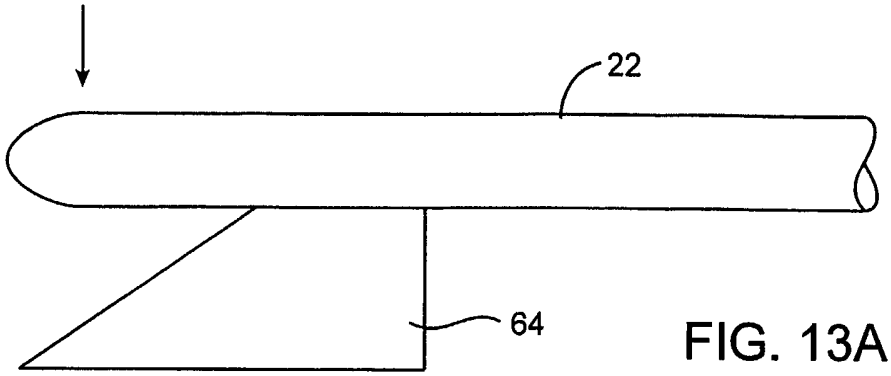

FIG. 13A

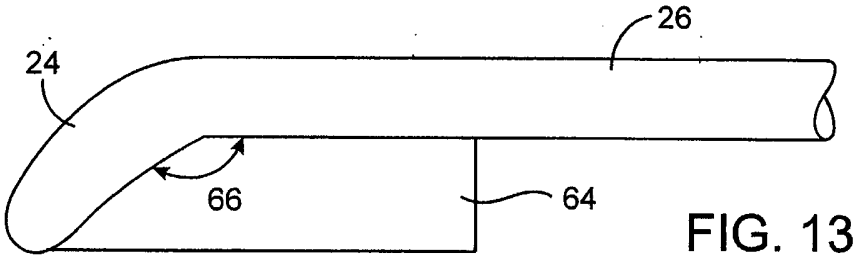

FIG. 13B

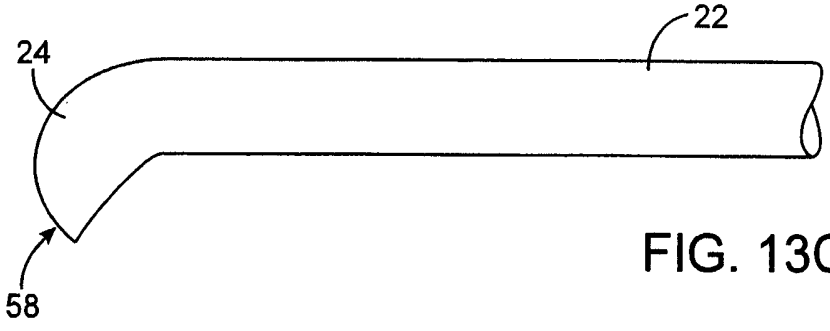

FIG. 13C

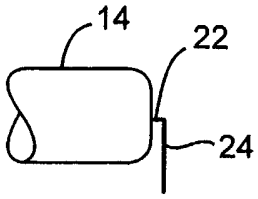

FIG. 14A

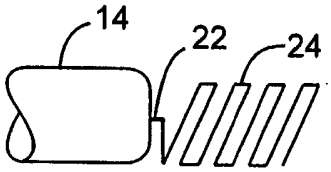

FIG. 14D

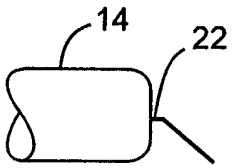

FIG. 14B

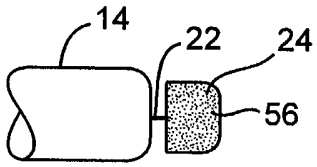

FIG. 14E

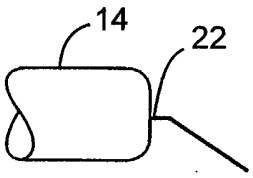

FIG. 14C

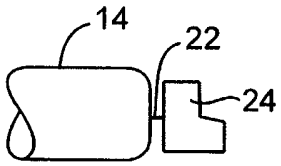

FIG. 14F

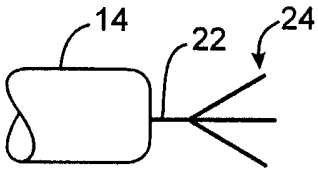

FIG. 14G

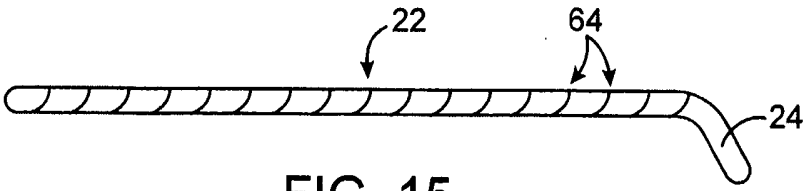

FIG. 15

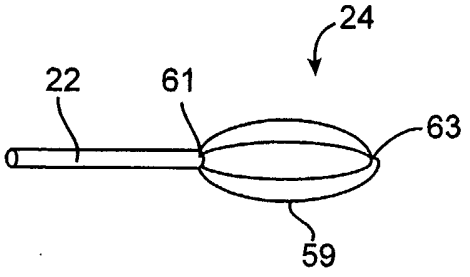

FIG. 14H

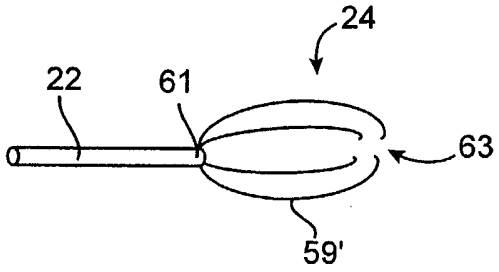

FIG. 14I

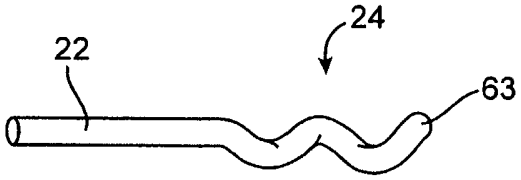

FIG. 14J

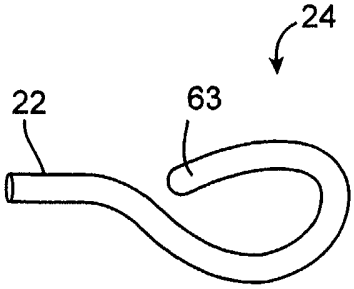

FIG. 14K

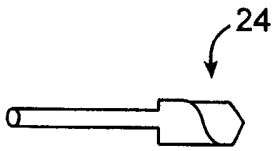

FIG. 14L

FIG. 14M

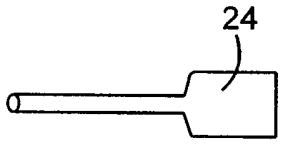

FIG. 14N

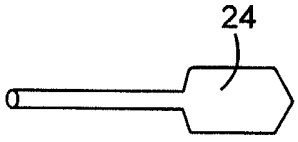

FIG. 14O

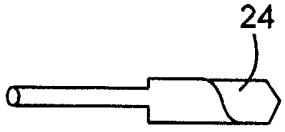

FIG. 14P

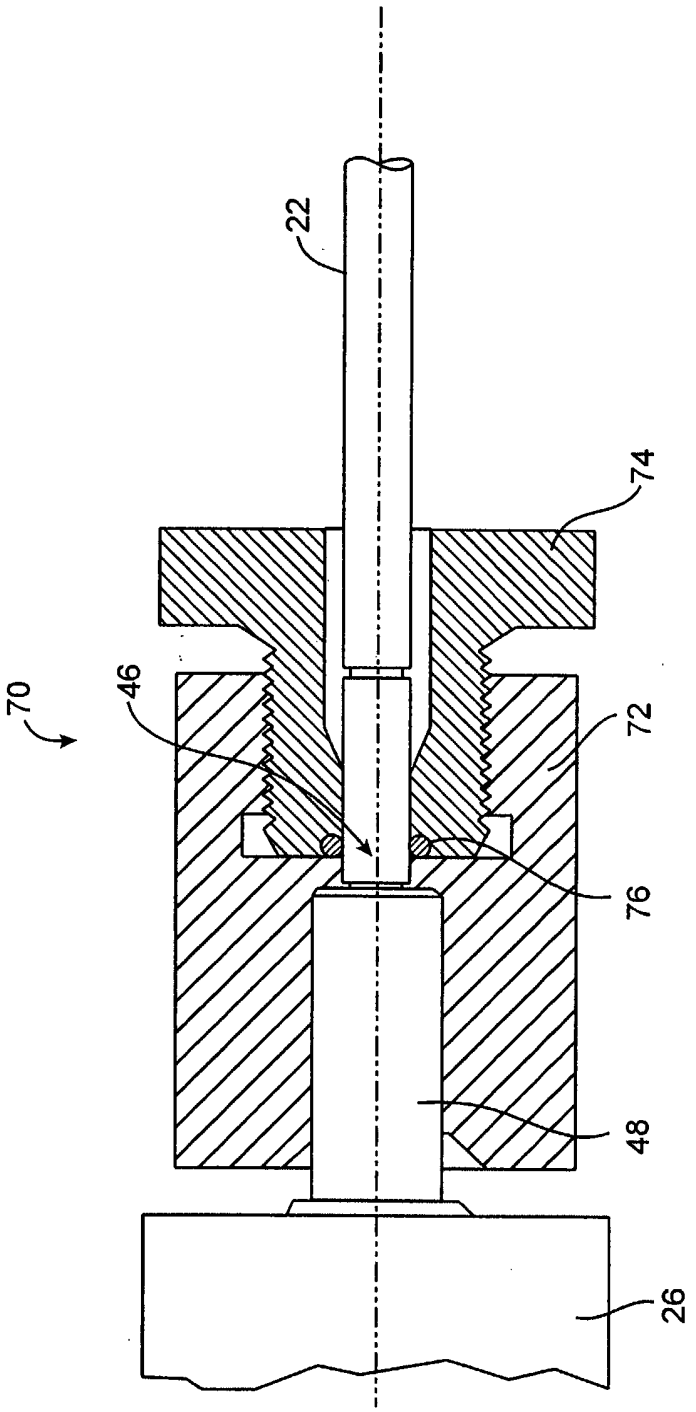

FIG. 16

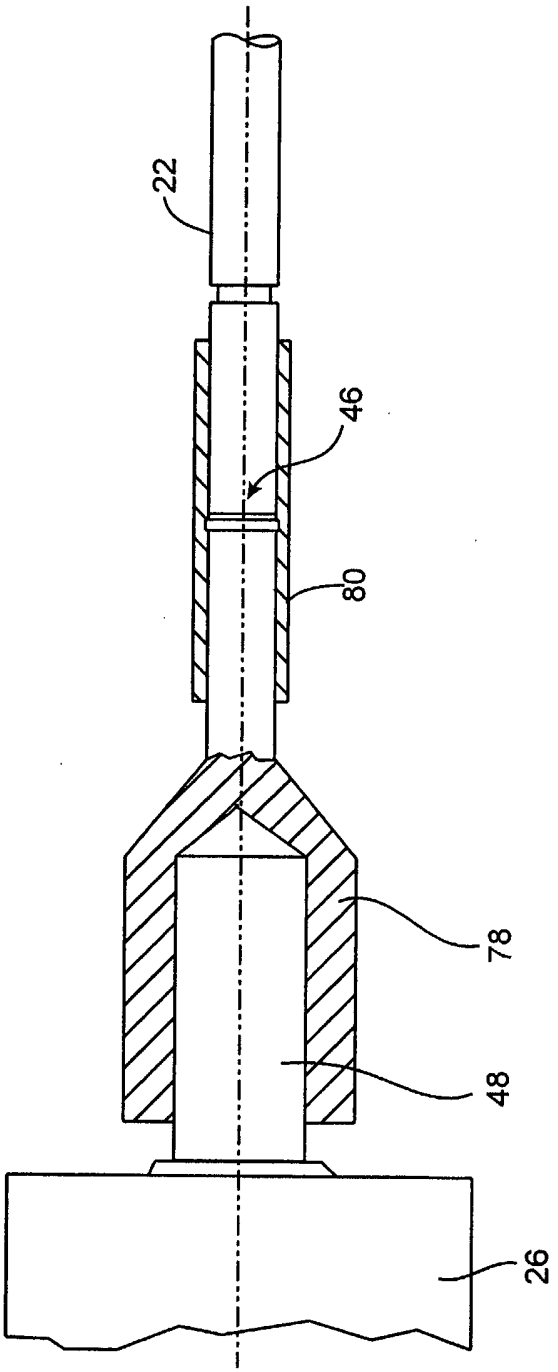

FIG. 17A

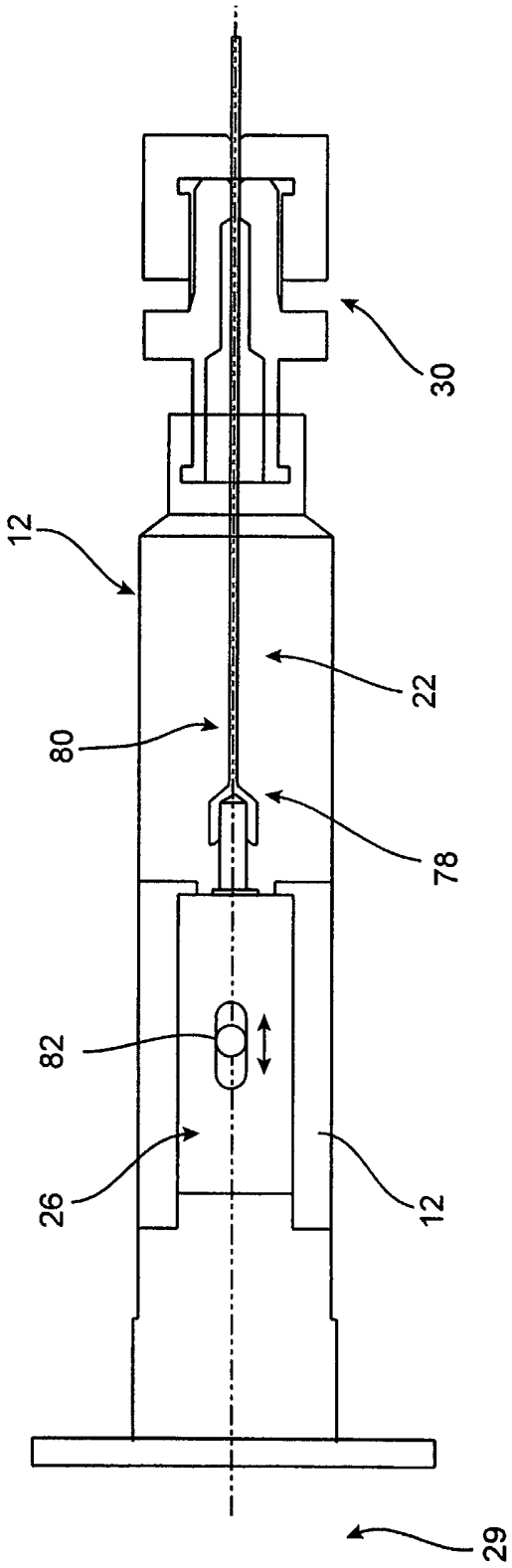

FIG. 17B

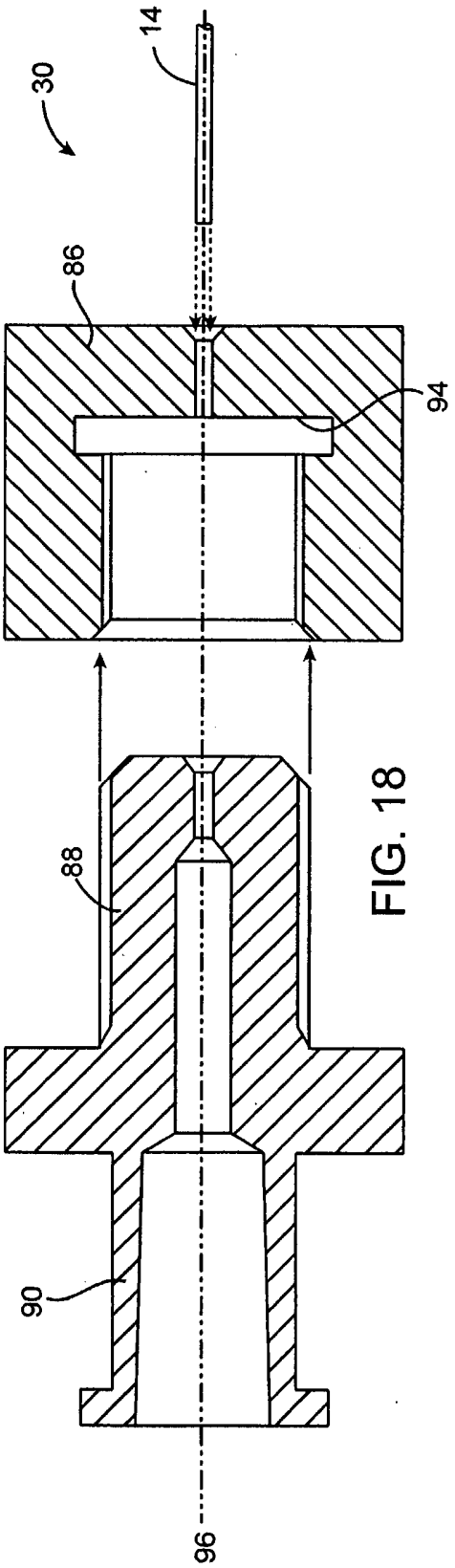

FIG. 18

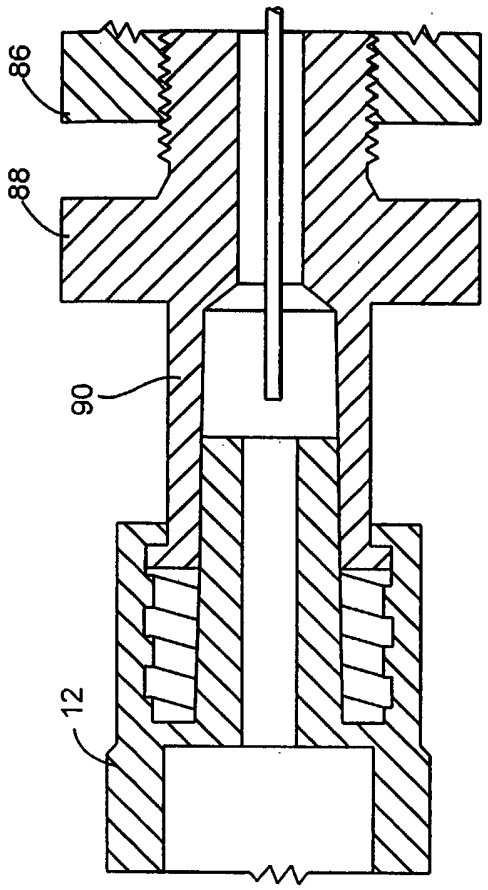

FIG. 20

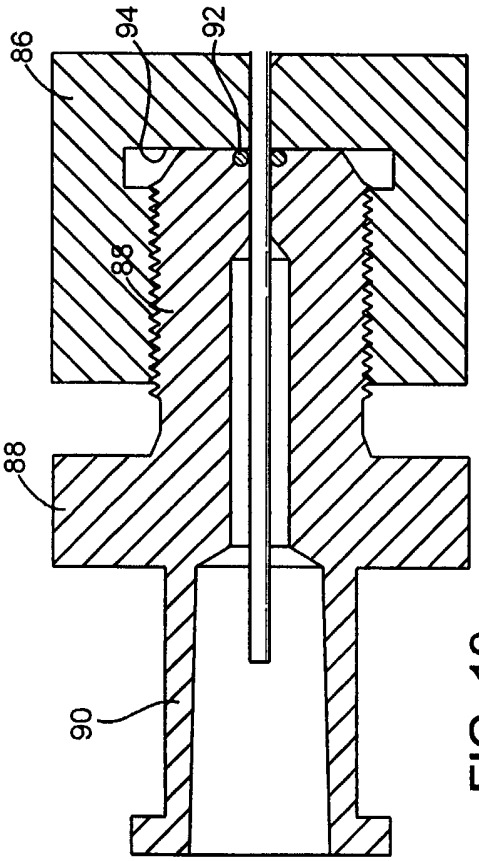

FIG. 19

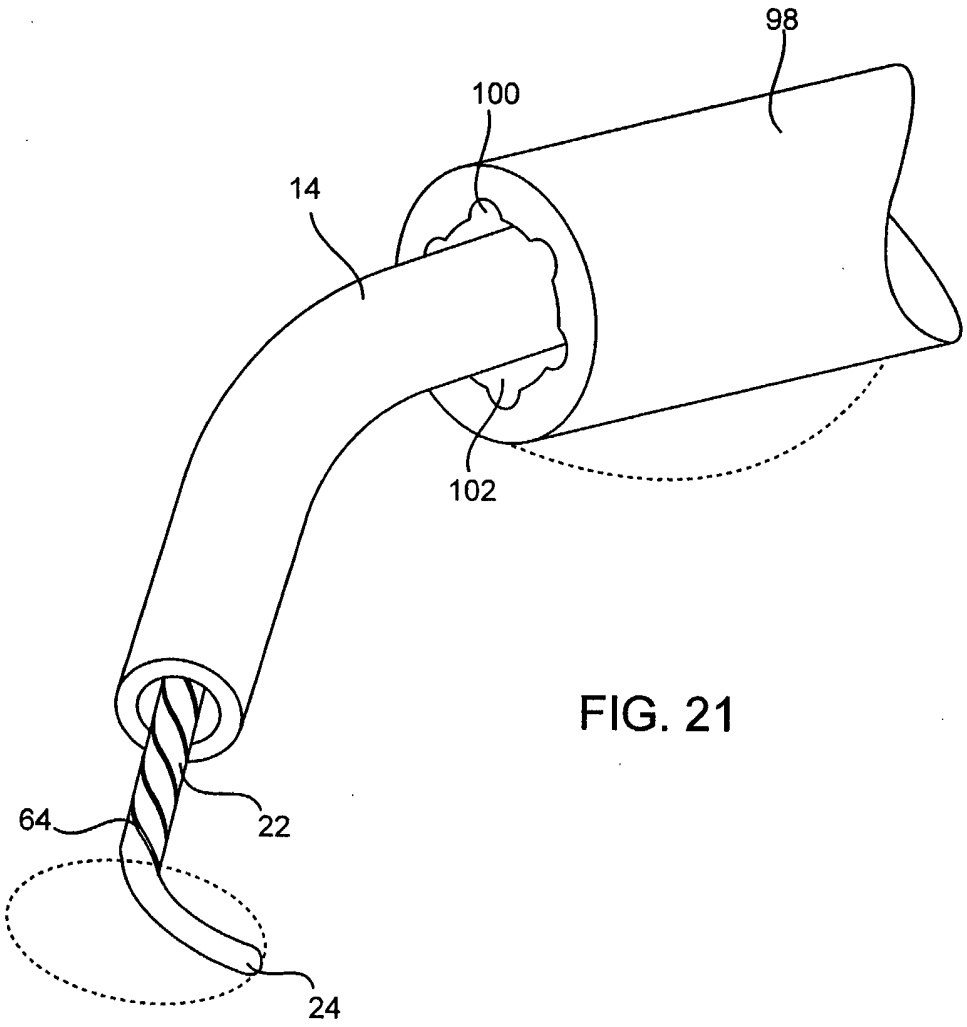

FIG. 21

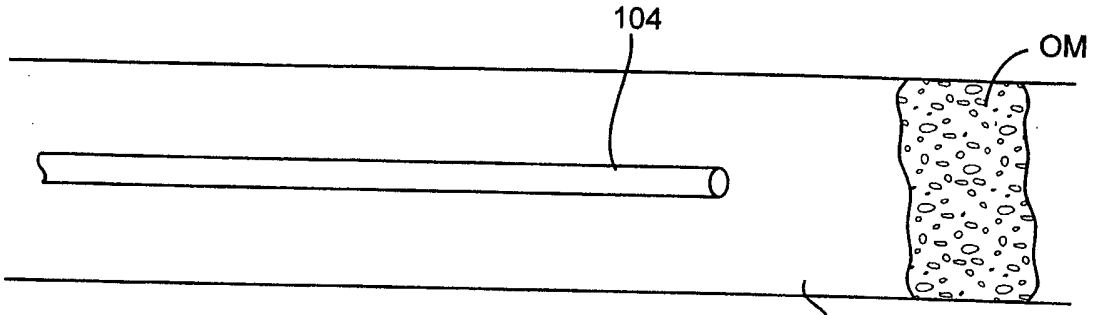

FIG. 22A

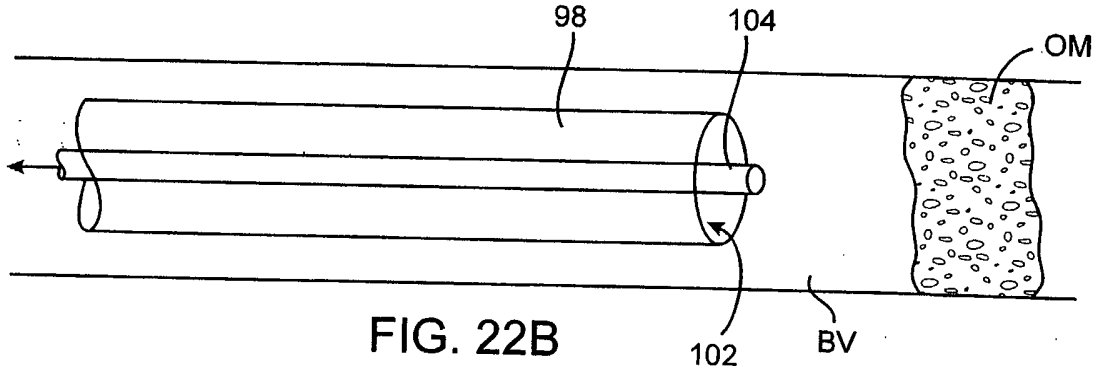

FIG. 22B

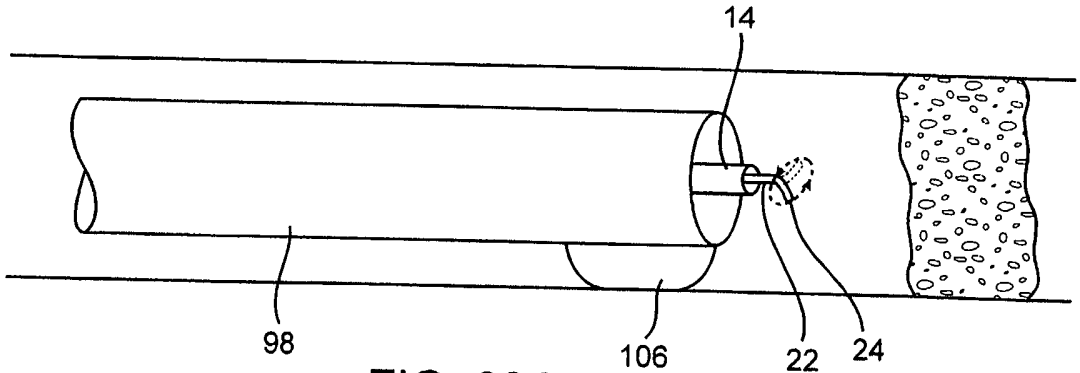

FIG. 22C

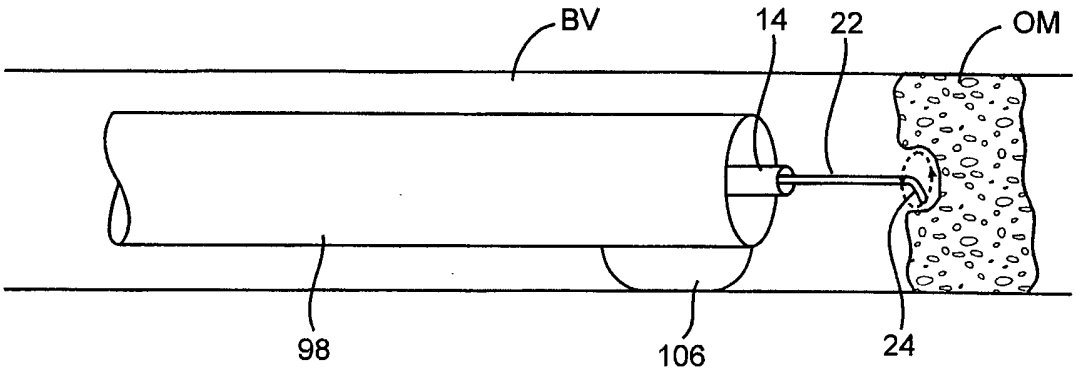

FIG. 22D

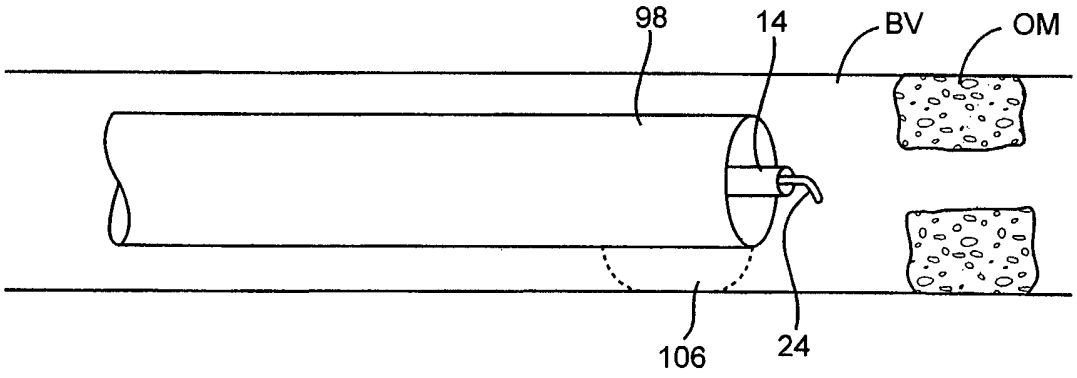

FIG. 22E

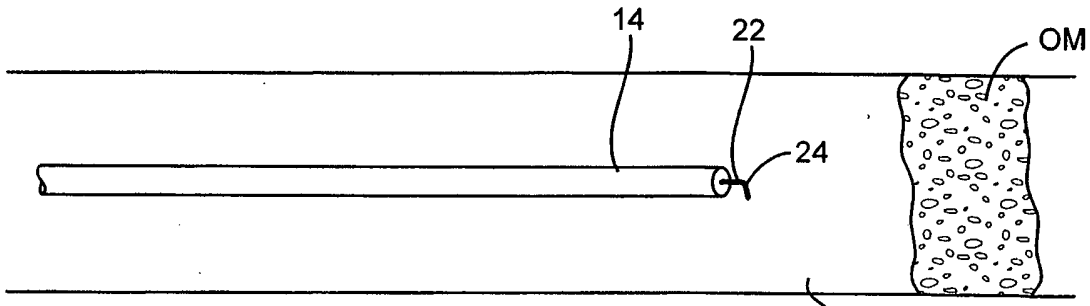

FIG. 23A

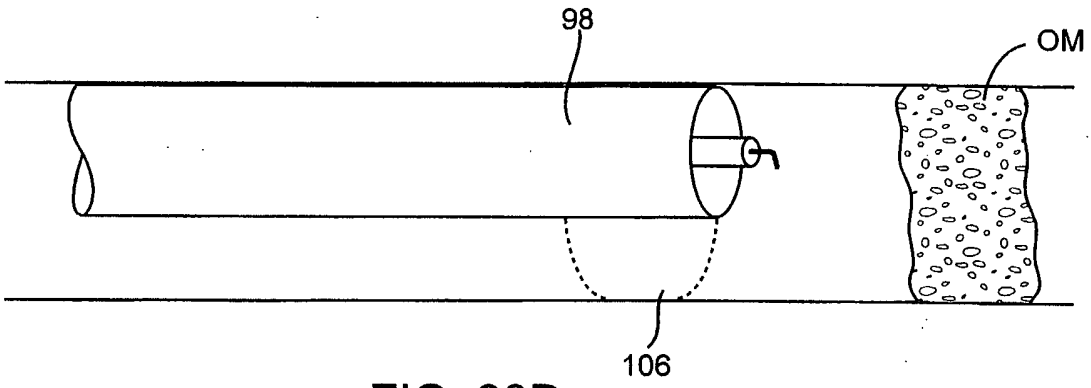

FIG. 23B

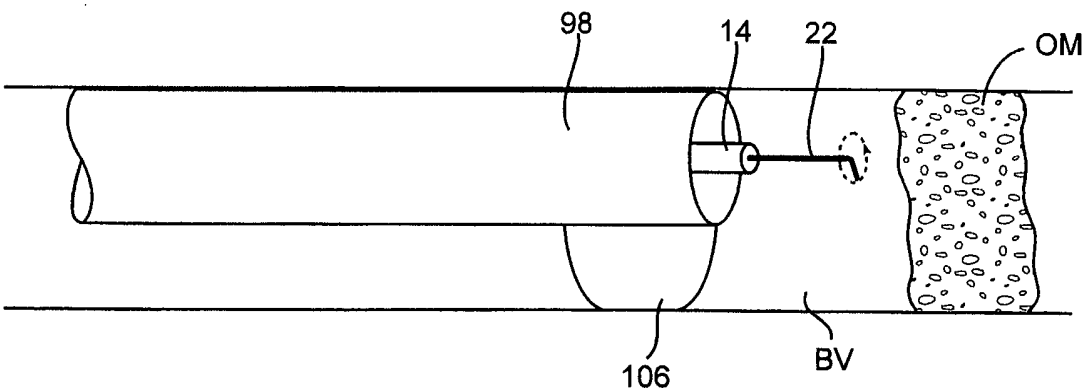

FIG. 23C

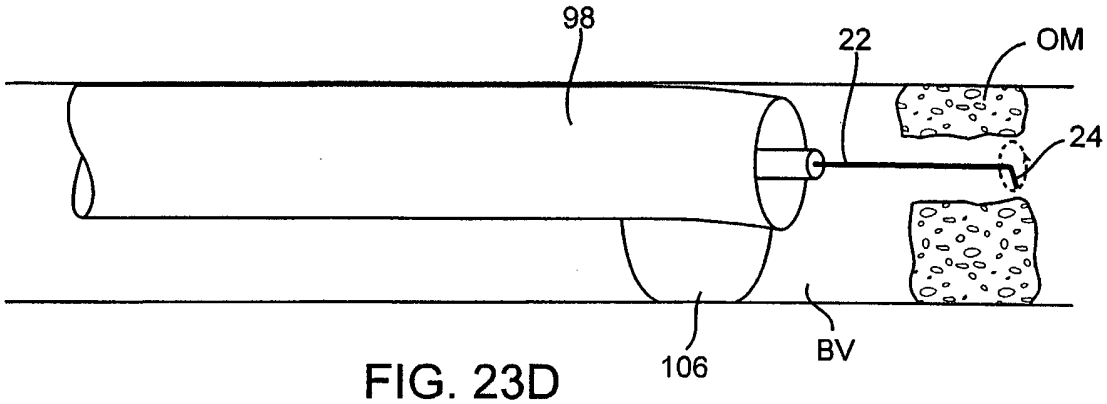

FIG. 23D

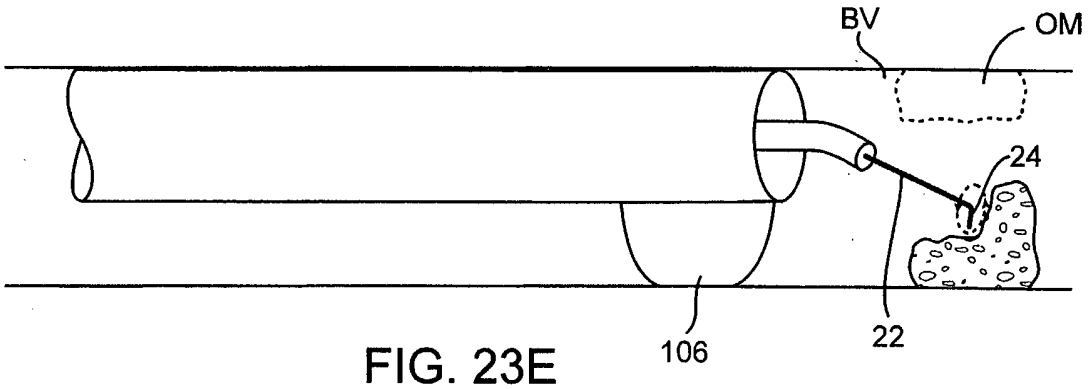

FIG. 23E

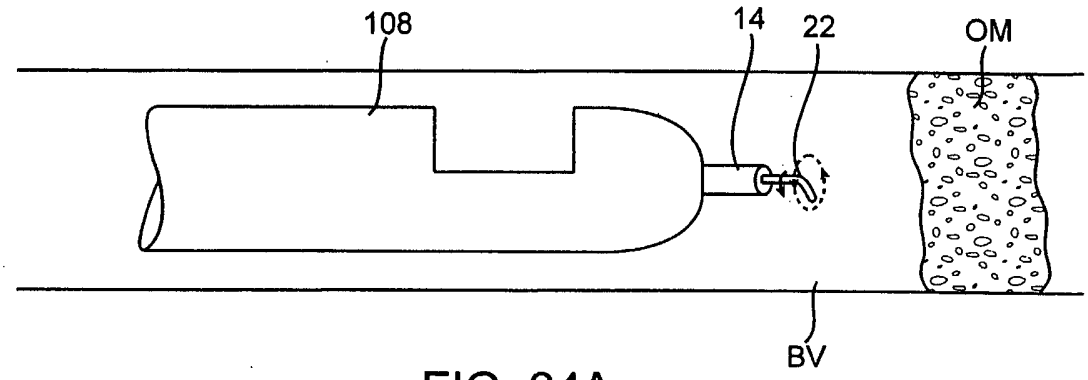

FIG. 24A

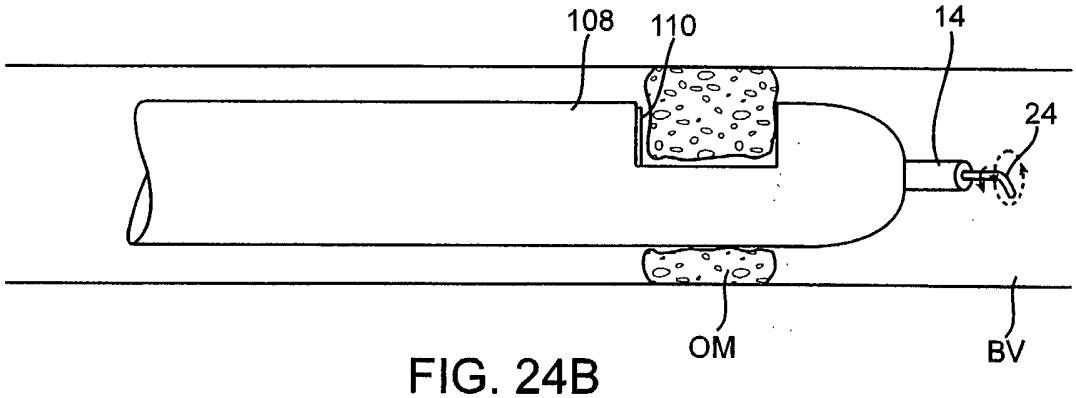

FIG. 24B

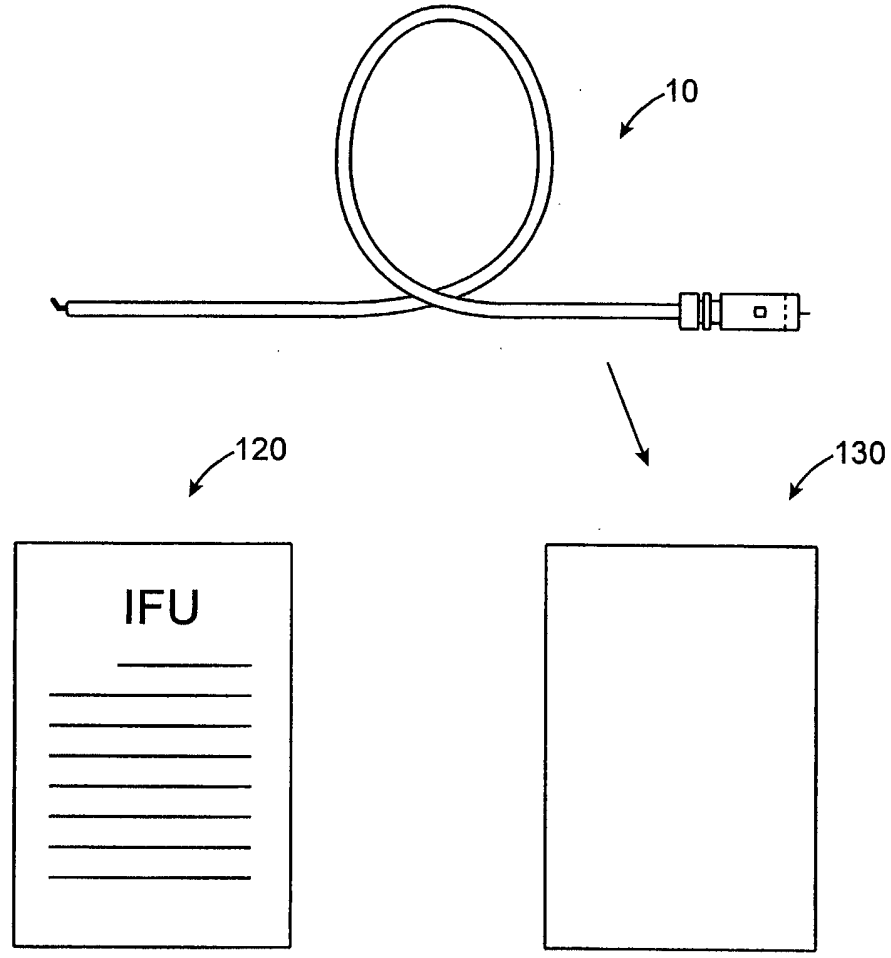

FIG. 25

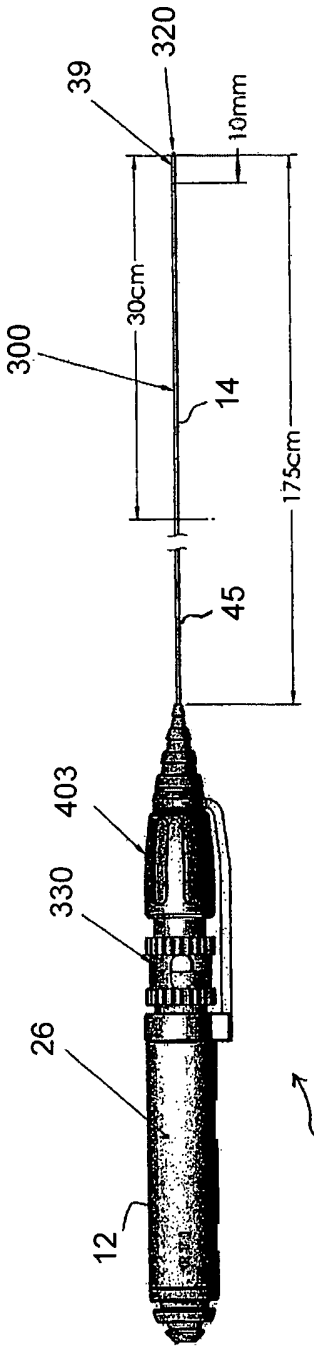

FIG. 26A

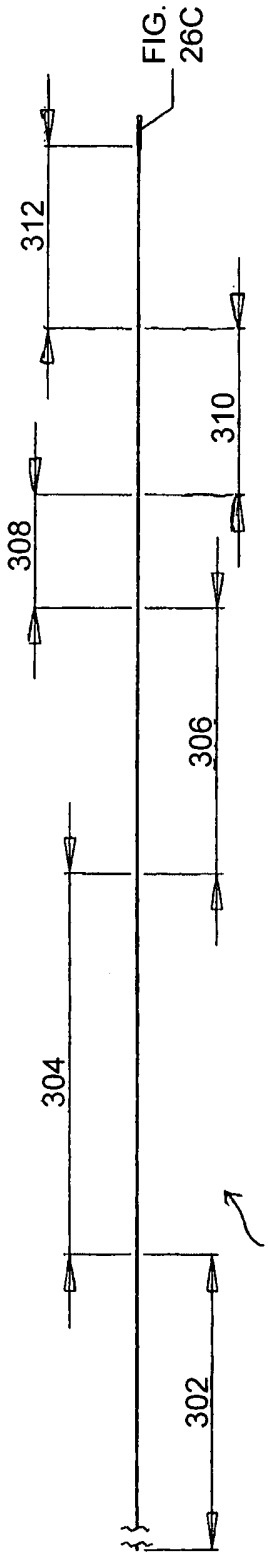

FIG. 26B

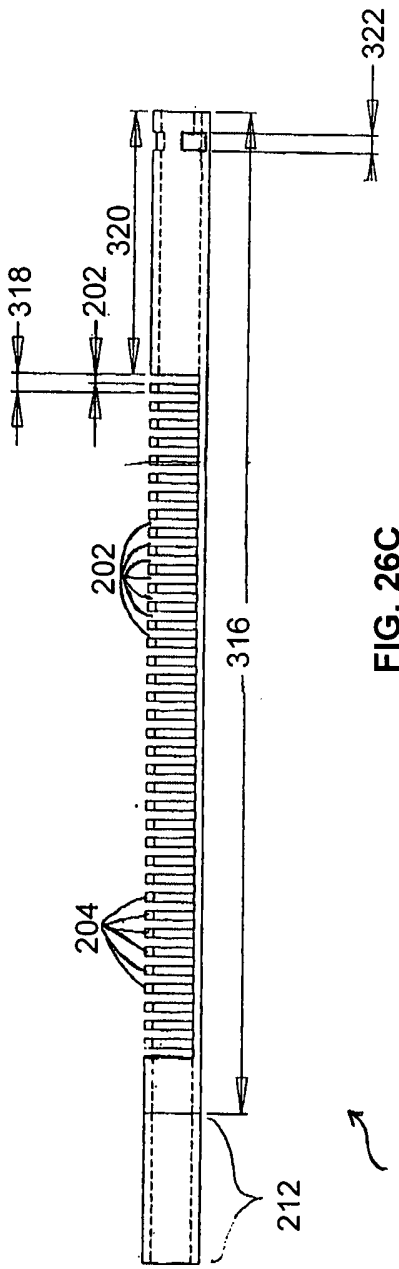

FIG. 26C

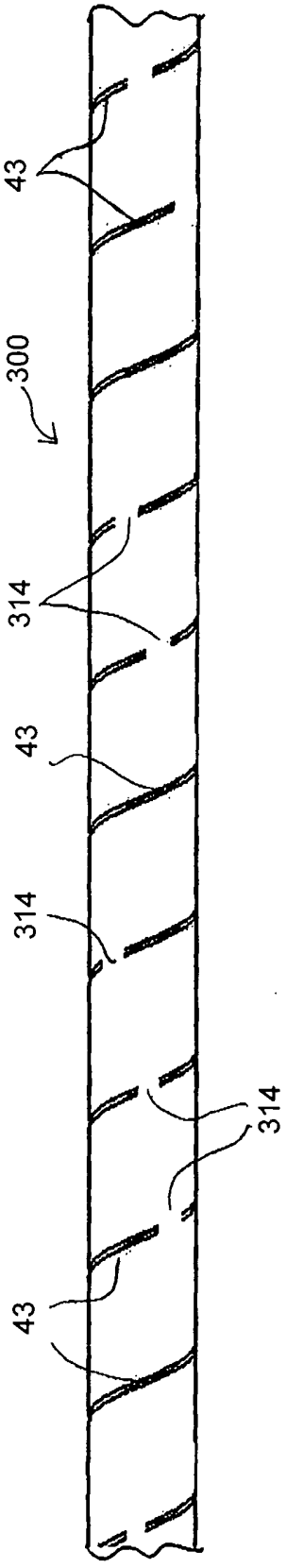

FIG. 26D

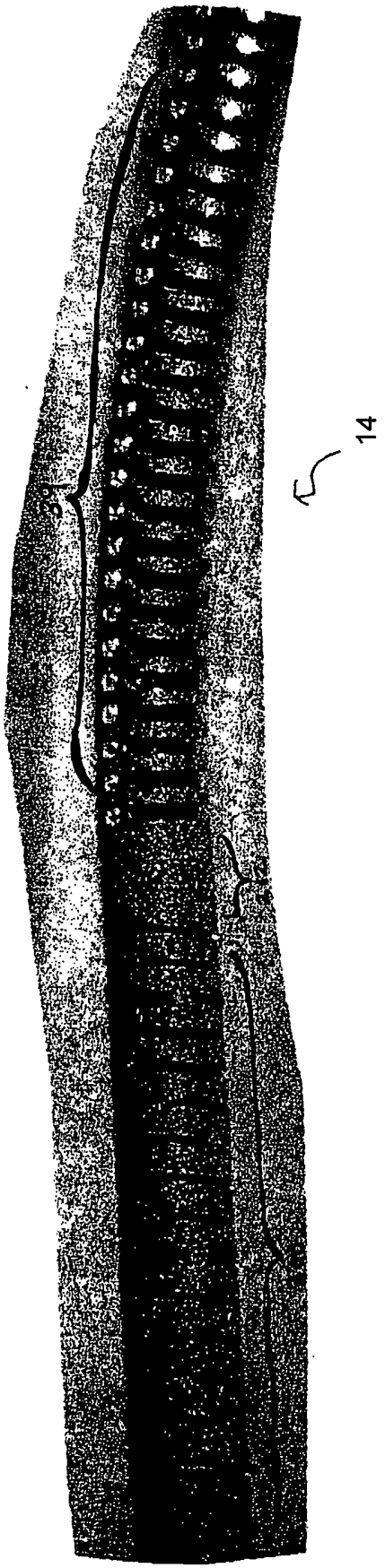

FIG. 26E

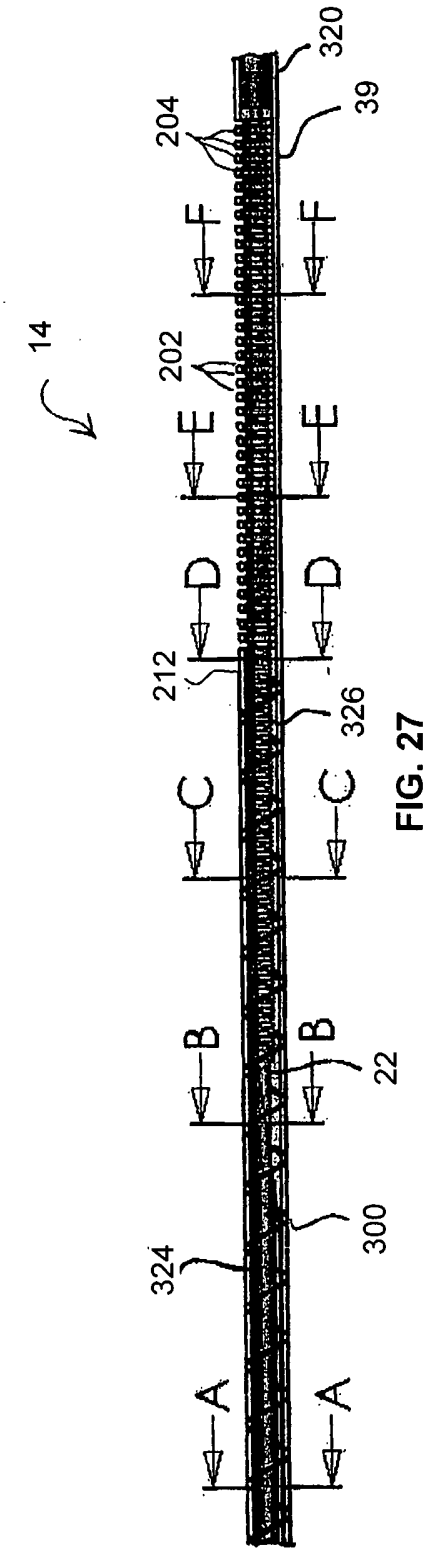

FIG. 27

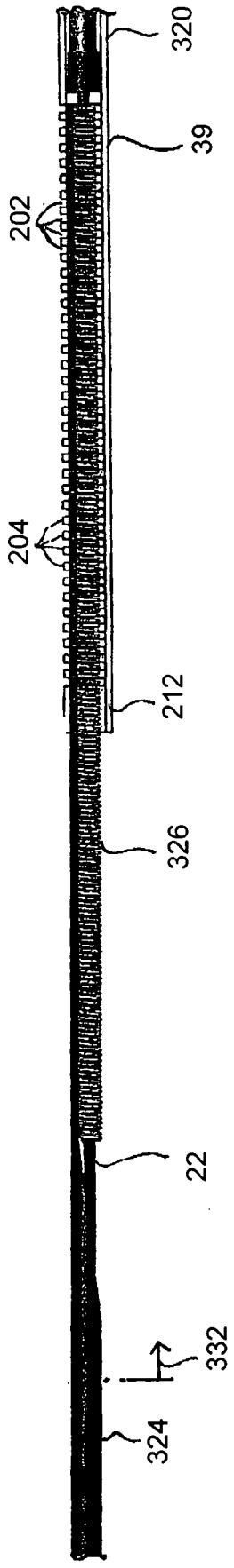

FIG. 27G

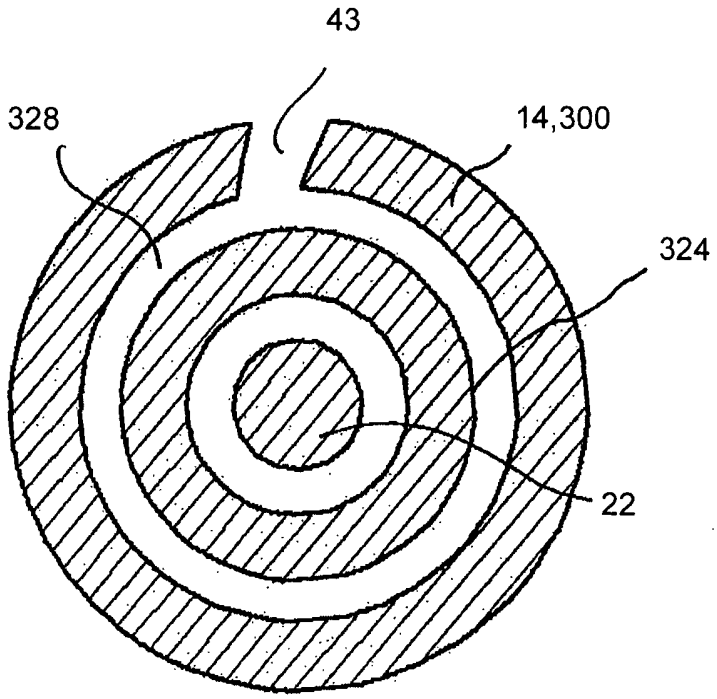

FIG. 27A

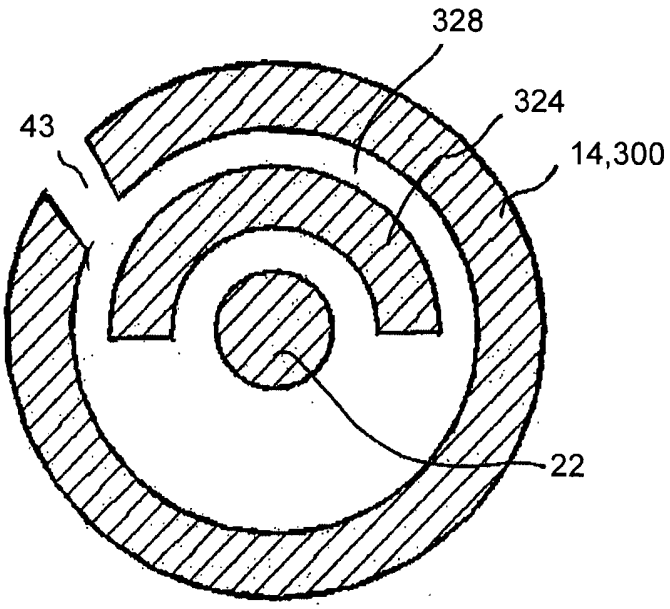

FIG. 27B

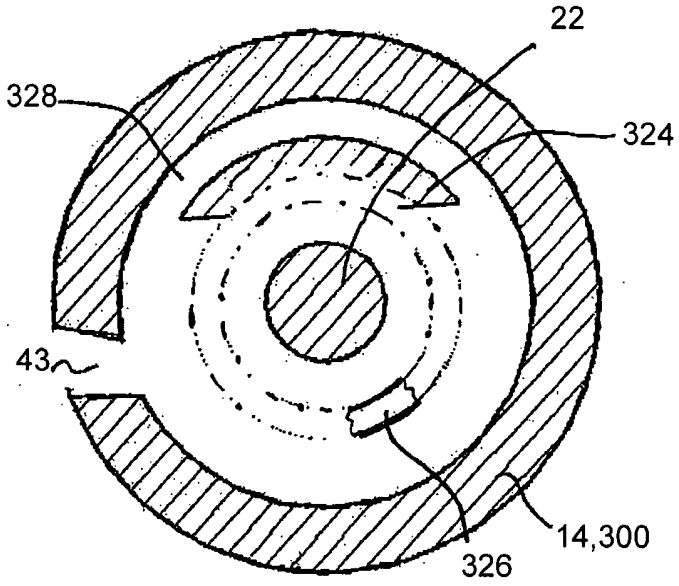

FIG. 27C

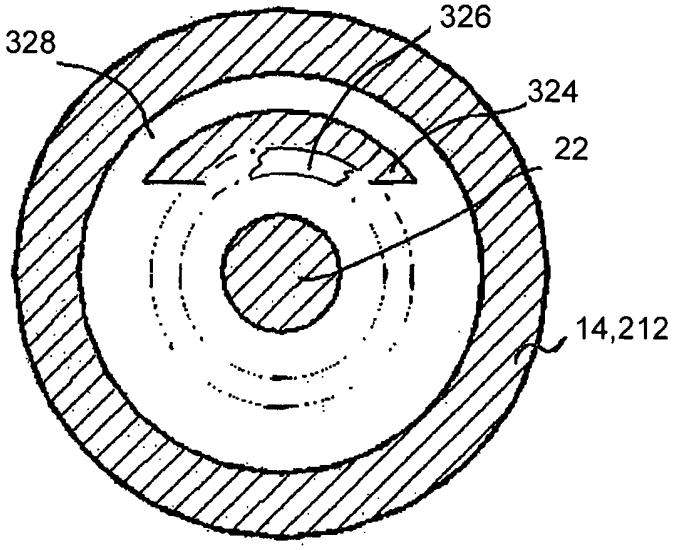

FIG. 27D

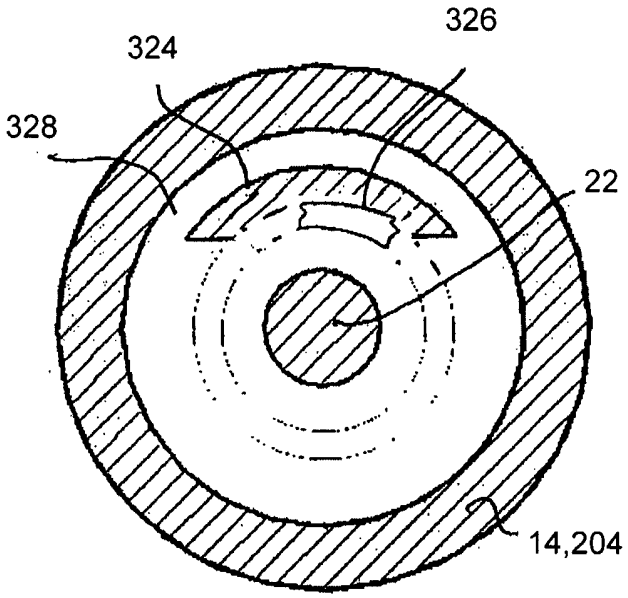

FIG. 27E

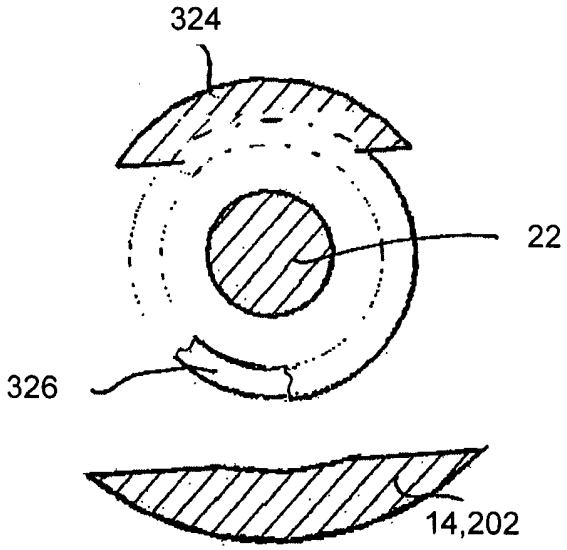

FIG. 27F

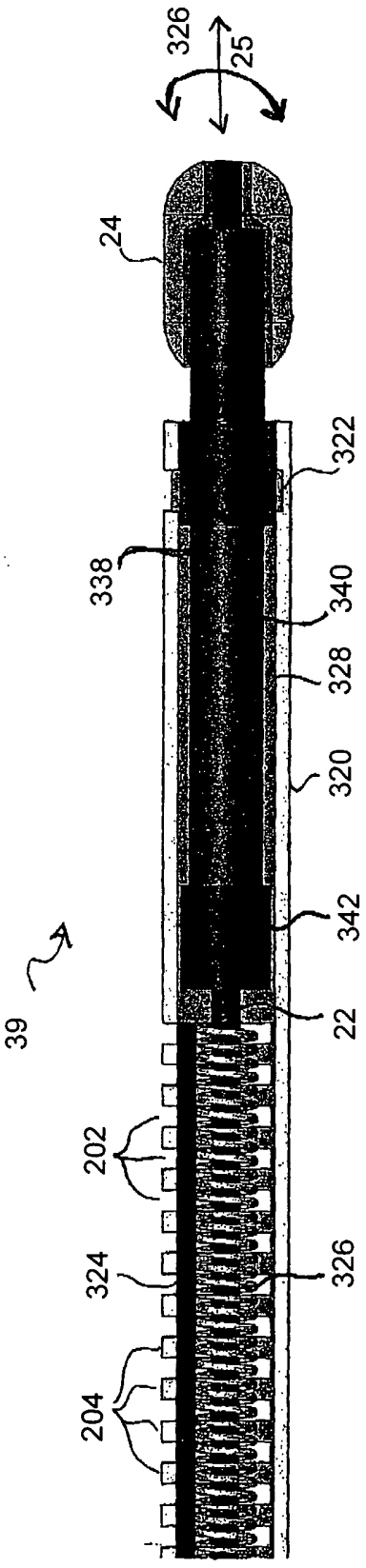

FIG. 28A

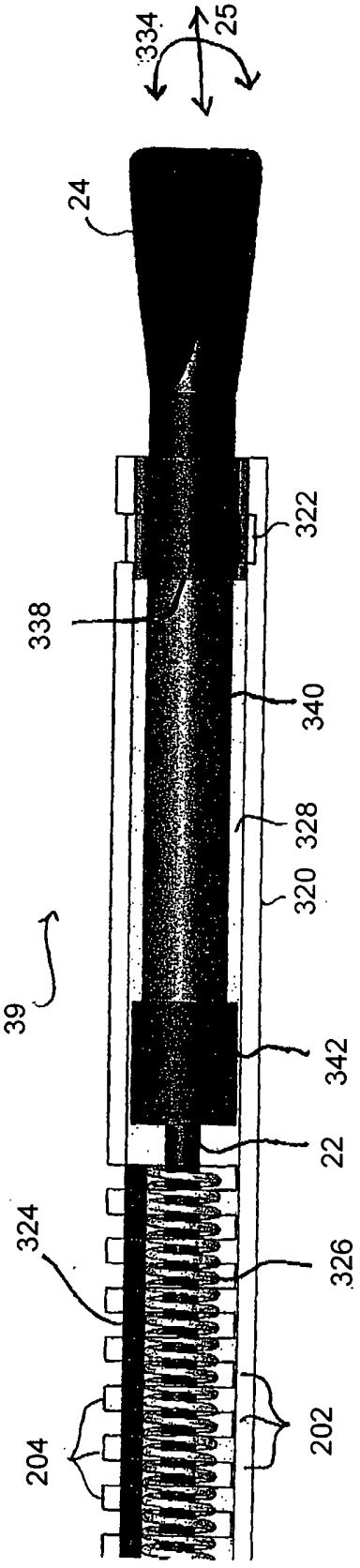

FIG. 28B

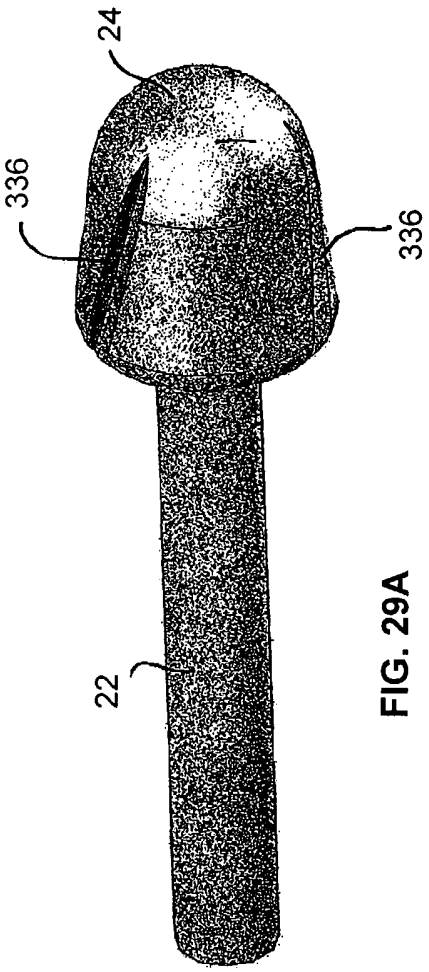

FIG. 29A

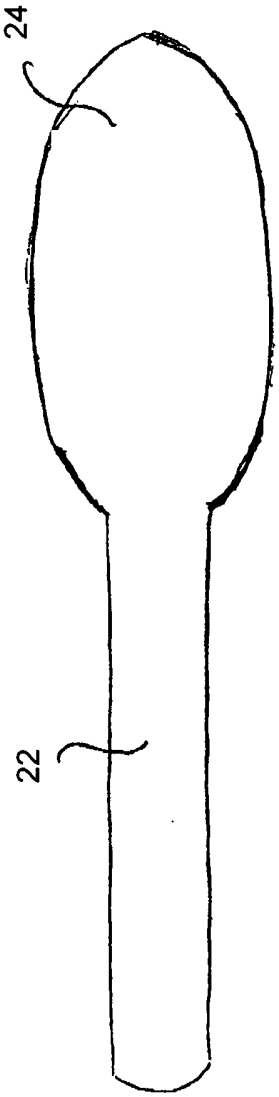

FIG. 29B

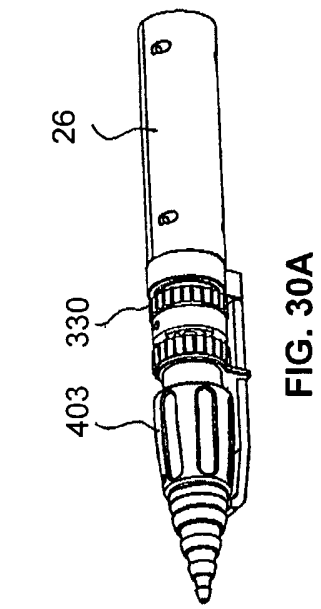

FIG. 30A

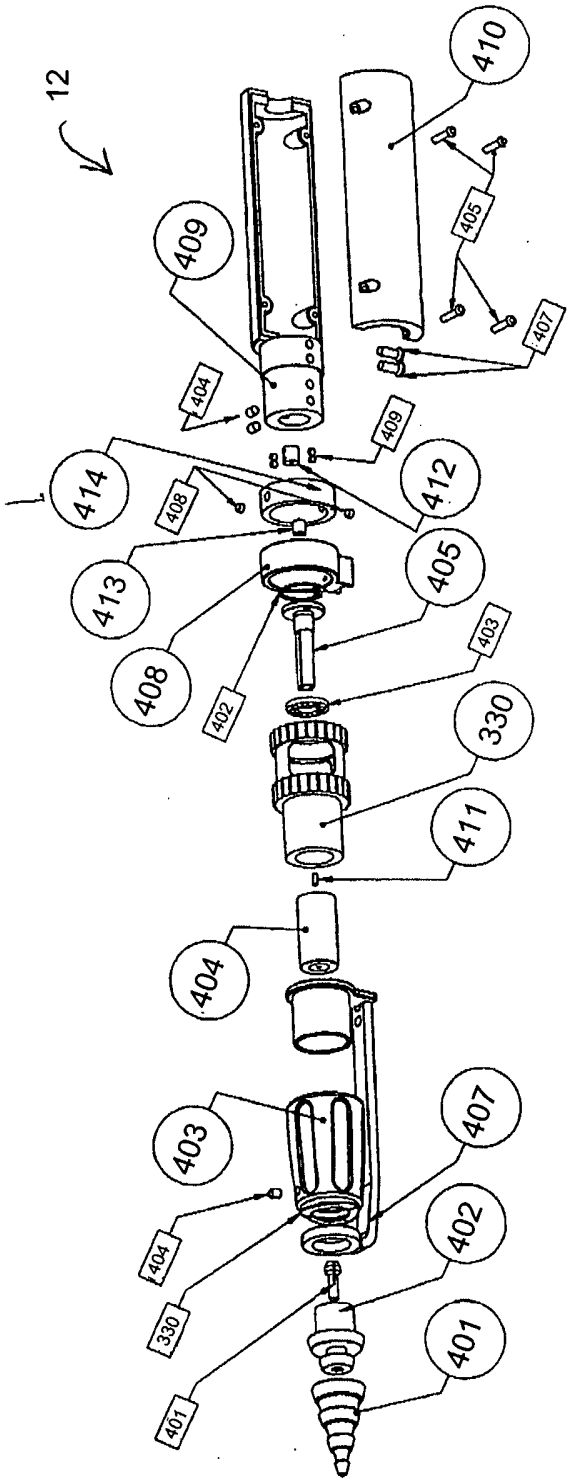

FIG. 30B