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(71) Applicant *(for all designated States except US)*: **KENSEY NASH CORPORATION** [US/US]; 735 Pennsylvania Drive, Exton, Pennsylvania 19341 (US).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: **FISHER, William, T.** [US/US]; 9 Dieber Road, Schwenksville, Pennsylvania 19473 (US). **YEAGER, David, E.** [US/US]; 4 Hill Road, Ivyland, Pennsylvania 18974 (US). **NASH, John, E.** [US/US]; 1201 North Chester Springs Road, P.O. Box 348, Chester Springs, Pennsylvania 19425 (US).

(74) Agent: **RAMBERG, Jeffrey, R.**; Law Office of Jeffrey R. Ramberg, 18 Old Manor Road, Newark, Delaware 19711 (US).

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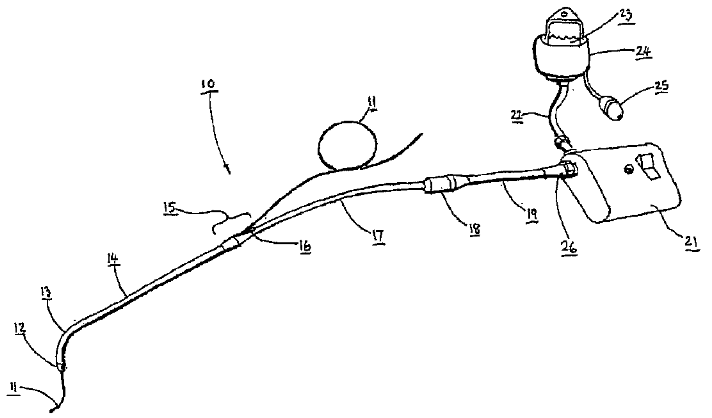
(54) **Title:** CATHETER FOR CONDUCTING A PROCEDURE WITHIN A LUMEN, DUCT OR ORGAN OF A LIVING BEING



(57) **Abstract:** In an embodiment, the invention provides a catheter suitable for use in performing a procedure within a vessel, lumen or organ of a living having a distal end which is steerable, such as upon the application of compression. The catheter may be of the over the wire type, or alternatively may be a rapid exchange catheter. The catheter may provide for a rotating element which may be used to open a clogged vessel, or alternatively to provide information about adjacent tissues, such as may be generated by imaging or guiding arrangements using tissue detection systems known in the art, e.g., ultrasound, optical coherence reflectometry, etc. For rapid exchange catheters having a rotating element, there is provided an offset drive assembly to allow the rotary force to be directed from alongside the guidewire to a location coaxial to and over the guidewire.

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CATHETER FOR CONDUCTING A PROCEDURE WITHIN A LUMEN, DUCT OR ORGAN OF A LIVING BEING

SPECIFICATION

TECHNICAL FIELD

[0001] The invention generally relates to catheters, specifically relating to catheters having a rotating working element at the distal end. The invention more particularly concerns a catheter capable of being used in conjunction with a guidewire, where the catheter provides a rotating working element at the distal end, such as may be used for traversing totally occluded vessels.

BACKGROUND ART

[0002] In the field of interventional cardiology there is a need for a percutaneously introduced intravascular device that can open totally occluded vessels. Many patients are found at diagnosis to have one or more totally occluded coronary vessels, and in the lower limbs there are even more aggressively closed vessels. Currently the options for solving these problems are as follows: A) attempt to traverse the blockage using guide wires and then follow up by dilatation and the placement of a stent: B) use a blunt dissection device like that manufactured by Cordis under the trade name 'Lumend' to ease the occlusion open enough to pass a wire, along which a subsequent dilatation balloon and stent are passed: C) use an electrocautery delivery wire, like that sold under the trade name 'Safecross" by Intra Luminal Therapeutics, to burn a hole through the blockage and then pass a subsequent balloon dilatation catheter with stent to open the vessel: D) if all else fails pass the patient on to surgery.

[0003] All methods A) through C) have their limitations. Method A) can be extraordinarily slow, as long as two hours. Method B) is also slow and has exhibited a high degree of perforation. Method C) works well and can deal with seriously calcified lesions but could benefit by having some additional features to reduce the procedure time. . Consequently there is the need for a device that can open these occlusions relatively rapidly with little risk of perforation.

[0004] The subject of this application is a device that delivers rotary energy to a an atraumatic rotating tip, such as a tissue penetrating element, which, in one embodiment, can best be described as half of an elliptical spheroid with a number of flats along its sides. These flats work rather like rotating a blunt screwdriver into a piece of soft wood with the flats gradually working the fibers of the wood apart. Based on our previously patented devices such as the Kensey Catheter (e.g., US Patent No. 4,747,821), we believe that such a tip can open the vessel with a low degree of trauma.

[0005] One disadvantage to current rotary devices is the need to pass the entire rotary drive over a guide wire, known as over-the-wire systems (OTW) to permit navigation of the tortuous anatomy on the way to the blockage. Such an arrangement requires a very long guide wire (300cm) to permit control of the wire from the proximal end when the rotary device is placed along or removed from the wire.

[0006] There is also the problem of navigation as one gets close to the blockage, because by definition the wire cannot be pushed past the blockage. These problems have made the use of rotary devices in such total occlusion applications limited to virtually straight vessel anatomy such as is found in the femoral artery. Consequently in order to make a more acceptable device one preferably would incorporate steering at the distal tip to overcome the navigation problem, and a optionally monorail wire guidance (also known as a rapid exchange system) which allows the guide wire to exit the catheter at some distance typically 10-20cm proximal from the distal tip, to allow the use of short, more manageable guide wires.

[0007] In addition there is the need for such a device to be very small in diameter (1mm or less) if the penetration of the occlusion is to liberate a minimum of debris and if the device is to be directed into distal coronary vessels of <2mm diameter.

[0008] All currently known rotary devices used by the cardiologist are total length OTW devices, requiring the use of 300cm wires in order for the device to be placed over a guidewire or removed from the guidewire. These rotary devices are placed over the guide-wire, with the guide-wire passageway being centrally located or coaxial to the device, in order to ensure the rotating portion remains centered about the guidewire. In order to be employed in a rapid exchange fashion, and be capable of being placed over shorter (e.g.150 cm) guide wires, the guide wire must exit from the revolving shaft at some point, typically about 10cm-20cm proximal of the distal tip. Such a requirement makes it necessary to provide for some manner of offset drive at this transition point, with the input drive shaft passing alongside the guide wire exit portion off center from the guide wire center.

[0009] It should be understood that the same problem of requiring a double length guide wire could also occur with other OTW devices such as rotary intravascular ultrasound scanners, and rotary optical scanners for optical coherence tomography. Hence the systems described in this application should be considered to be applicable to any device used within a living being that incorporates a rotary input and would benefit from a means to reduce the guide wire length.

[0010] Also, no small (3mm diameter or less) current rotary intraluminal devices incorporate a steerable distal tip. Innovative steering concepts are required to permit the steering function to exist alongside the rotary drive shafting.

[0011] In addition there are situations when special purpose guide wires such as those marketed under the name Safecross (mentioned elsewhere in this application) or other guide wires could benefit from passage through a firm steerable catheter tip which could provide backup or support in order to steer the guidewire into an adjacent furcation, where otherwise the soft wire would tend to buckle without the additional support provided by the steerable catheter tip.

[0012] There is also the need for a low friction steerable catheter tip to permit the passage of straight stiff guide wires into a selected branch of a furcation. The straight stiff wire is often needed to navigate and penetrate a firm blockage distal of the furcation, but the anatomy demands a guide wire with a prebent tip to allow entry into the preferred branch. Clearly these are conflicting requirements, and a steerable catheter capable of guiding the stiff wire to the desired location may be beneficially employed. It is recognized that the steerable catheter may also employ a rotating component through which the stiff wire is advanced within the steerable catheter, where the rotation will serve to minimize friction forces encountered when advancing the stiff wire through the guide catheter.

[0013] It is the intent of this invention to overcome these and other shortcomings of the prior art.

DISCLOSURE OF THE INVENTION

[0014] In an embodiment, a catheter for use within a living being may be used to conduct a procedure within a lumen, duct or organ of the living being. The catheter may preferably provide for a rotation of a working element, such as a tissue-penetrating tip, or alternatively, a tip to provide imaging or guiding information about adjacent tissues. Additionally, the catheter may provide for a deflectable distal end, in order to provide a steerable catheter. The catheter may be an over-the-wire (OTW) catheter, where the guidewire extends through the catheter's length. Alternatively, the catheter may be of a rapid exchange or monorail type catheter, where only a small portion of the entire length of the catheter would be placed over the wire. For the rapid exchange catheter embodiment, there is a need to provide for a transition segment, in order to allow for the guidewire to be oriented from alongside the catheter, and transition to a position inside of the catheter, and coaxial to the rotatable element. The transition segment must provide for the transmission of rotary power from a position adjacent to the guidewire, to a position coaxial about the guidewire, using an offset drive assembly.

[0015] The offset drive assembly may be a geared device, or more preferably, a friction drive arrangement to receive power input from a driveshaft alongside the guidewire, and transmit the rotary power to an output drive shaft, such as a tubular cable extended over some portion of the guidewire. A friction drive system may rely on an input roller and an output drive roller, housed in partial bearings and maintained in contact with each other in order to provide the necessary friction to transmit a rotary force. Alternatively, the offset drive subassembly may rely on a friction drive system utilizing an epicyclic friction arrangement to transmit the rotation. In the epicyclic system, a drive shaft is operatively connected to a planet roller, which as it turns, will turn against a nipper ring and an idler in the form of another planet roller. The rotation of the planet rollers will be transmitted by friction to the sun roller, itself connected to an output drive shaft, such as a tubular cable extended over some portion of the guidewire.

[0016] An embodiment may include a deflectable distal end, which allows for the steering of the device. The deflection of the distal end may be accomplished by transmitting a force such as compression or tension through at least the length of the catheter inserted into the body. In an embodiment, the deflection is accomplished by causing the deflection of spaced coils in compression, where a portion of the coils are locally frozen in position, and the deflection occurs from a reduction of space between adjacent coils away from the frozen region. Alternatively, the deflection may occur as a series of segments having pivot points are placed in compression, whereupon the segments pivot to form a curved section of the catheter. The steering may be controlled by means of a steering thimble on the catheter that remains outside of the patient when in use, where a rotation of the steering thimble may be transmitted, whether by tensioning a pull strap, or compression through a push rod, down the length of the catheter to the deflectable portion of the catheter.

BRIEF DESCRIPTION OF THE DRAWINGS

[0017] Fig. 1A) is a drawing showing a schematic perception of the entire device in an over the wire configuration, typical of current technology.

[0018] Fig. 1B) is a schematic of the entire device in the preferred monorail short length over-the-wire configuration.

[0019] Fig. 2A) is a longitudinal cross section of the distal revolving tip and drive shaft and the distal portion of one embodiment of steering mechanism

[0020] Fig. 2B) is a longitudinal cross section of the steering embodiment of Fig2A) with the tip and drive cable removed to show the action of the steering principle.

[0021] Fig. 3A) is a perspective view of a single element used in another steering mechanism.

[0022] Fig. 3B) shows an assembly of several of the elements of Fig. 3A) in line as they become installed inside a catheter jacket.

[0023] Fig3C) is a perspective sketch of the multi element assembly of Fig3Bb) formed into a curve as it would be in a catheter steerable portion.

[0024] Fig. 4A) is a longitudinal section of one concept, utilizing gears, for the offset drive that permits exit of the guide wire at a station somewhere along the catheter shaft

[0025] Fig. 4B) is a longitudinal section of an alternative concept for the offset drive, utilizing friction drive and two rollers side by side, that permits exit of the guide wire at a station somewhere along the catheter shaft

[0026] Fig. 4C) is a lateral cross section of a portion of the drive shown in Fig. 4B).

[0027] Fig. 4D shows the adoption of an epicyclic principle for yet another alternative concept for the offset drive utilizing friction drive that permits exit of the guide wire at a station somewhere along the catheter shaft

[0028] Fig4E) is a lateral cross section of a portion of the drive shown in Fig4D).

[0029] Fig. 4F) is an additional lateral section through the drive of Fig4D showing the location for steering push rods or tension straps or wires.

[0030] Fig5A) is a longitudinal section of an alternative steering mechanism using segments of an extrusion and two steering straps to curve the distal tip.

[0031] Fig. 5B) is a lateral cross section through the extrusion used in Fig5A).

[0032] Fig5C) is a longitudinal section of a variant of the construction shown in Fig5A) that utilizes one steering strap.

[0033] Fig. 6A) is a longitudinal section one type of tension transmission device, based on typical bicycle cable brake technology, that passes from the proximal end of the device to the offset drive location.

[0034] Fig6B) is a perspective view of the steering thimble sectioned in Fig6A).

[0035] Fig7A) is a longitudinal section of a steering thimble that applies compression to a spring or column to effect steering.

[0036] Fig7B) is a perspective view of the steering thimble mechanism shown in Fig7A).

[0037] Fig. 8A is a perspective view of an embodiment of a reversing mechanism.

[0038] Fig. 8B is a perspective view of an embodiment of a reversing mechanism providing a mechanical advantage.

[0039] Fig. 9 is a cross-sectional view of the distal end of an embodiment incorporating a rotary tip that has been subjected to a preloading force to minimize any gap between the proximal end of the rotating tip and distal end of the stationary adjacent surface.

MODES FOR CARRYING OUT THE INVENTION

[0040] Fig. 1A) and Fig. 1B) illustrates a device 10) having a rotating working element, typically in the form of a tissue penetrating member at its distal end, shown here as rotating tip 12, suitable for opening totally occluded vessels. It is recognized that the working element may also provide other functions, such as that of a rotating scanning element, which provides detailed information via a detection system, for example through the use of ultrasound, or optical coherence reflectometry to generate information about the surrounding tissue. The difference between the devices depicted in Fig. 1A and Fig. 1B is in the manner the device slides over the guide wire 11), consequently the description provided will generally refer to Fig. 1B as the preferred arrangement of this invention, however it will be largely applicable to the device shown in Fig. 1A as well.

[0041] In Fig. 1A the device is utilized in an over the wire manner, with a guide wire that enters at the tip 12) and exits at the proximal end of the drive pack 21). This device may be preferably utilized where a guidewire exchange is desired without the need to remove the catheter device, as the guidewire may simply be removed and replaced in an over the wire arrangement. In contrast the wire in Fig. 1B enters at the tip 12) and exits at a transition segment 15). All previously known, currently available, rotary devices utilize the over the wire system of Fig. 1A, and therefore require a double length wire to allow the removal and placement of the rotary device onto the wire. In contrast, the preferred embodiment of guidewire arrangement, as illustrated by the rapid exchange device of Fig. 1B, allows the user to pass the device along a guide wire 11) in a monorail fashion where the user needs only to thread the wire through the distal segment of the device which terminates at the transition segment 15). This distance where the guidewire is threaded through such a guide-wire passageway in the device is a fraction of the entire length of the device, typically of the range of 10 to 20 cm. The rest of the device is arranged to pass alongside the wire 11). With this rapid exchange catheter arrangement, the rapid exchange catheter may be placed onto or removed from a wire inserted into a patient, without requiring a double length wire, as only a short segment of the catheter is actually over the wire.

[0042] In the embodiment depicted in Fig. 1B, there is a need for an off-set drive mechanism, as there is a rotating working element arranged coaxially to guidewire 11, and the guide wire 11) is arranged to exit the distal segment 14 of the device 10 at the transition segment 15). In this embodiment, it is necessary to provide a means of transferring the drive power from a location alongside the guidewire 11, to a coaxial location, rotating around guidewire 11. It is recognized that drive power may be transmitted in any suitable form of rotary drive shaft from the drive pack 21), and then via the off-set drive mechanism, the rotary force transmission continues through drive cable 9) (as discussed later with reference to Fig. 2A), which is arranged concentrically around the guidewire 11. The offset drive mechanism is employed specifically to allow the transfer of rotary power from the side at a point within the transition segment 15). This offset drive is described more fully with relation to Figs. 4A) through 4E).

[0043] In order to make this device provide for the difficult task of opening total occlusions in tortuous narrow vessels (of the order 2-3mm diameter) the distal portion of the device may employ a steerable distal portion 13) which can be shaped into a curve by actuation of a steering thimble 18). Cardiologists have found that if the distal portion can be shaped into a curve with a radius of say 3mm-10mm, such devices can be maneuvered into branch vessels if the device is torqued (twisted) and fed forward at the same time. The distal catheter body 14) is typically about 10 to 20cm in length and of 1mm-2mm in diameter. In use, the cardiologist first places a guide catheter into the ostium of the appropriate coronary vessel and then maneuvers a guide wire through the guide catheter to a point as close to the total occlusion as can be reached. He then feeds the device of this invention over the wire to the same point, when the tip 12) may be just distal of the tip of the wire 11) or just proximal of the tip of the wire 11). In order to navigate the distal portions of the vessel, the user can control the deflection of the distal tip using the steerable portion 13) in concert with torsional twist applied through the proximal catheter body 17). Once the device is in place the rotary tip 12) can be actuated, and is powered by the drive pack 21) wherein power, typically electric power, for example from batteries, is supplied to a small motor (not shown) to revolve the tip 12 such that the device can then be advanced into and through the occlusion. Alternatively, the power may be supplied in form of compressed gas, which would operate a turbine motor, or other methods of generating a rotary force to be transmitted through the driveshaft. It is recognized that there might be a need to cool and lubricate the revolving tip 12), such as by supplying an irrigant 23) from a bag, optionally assisted by a pressure cuff 24). The irrigant 23 may then be directed through the device intermediate body 19) and proximal catheter body 17). This irrigant may include suitable non-thrombogenic drugs such as Heparin or abciximab (distributed by Eli Lilly) or Plavix® (distributed by Bristol-Myers Squibb/Sanofi Pharmaceuticals Partnership) or any other suitable drugs. Additionally, the irrigant may include saline, blood or plasma, contrast fluid, or other beneficial materials that may be introduced into a living being.

[0044] Fig. 2A) shows a cross section of a typical distal portion of this invention, and one possible embodiment of a steering mechanism capable of deflecting a catheter. A multifilar hollow cable 9), capable of transmitting a torquing force and preferably fabricated from a high strength metal alloy such as 304 stainless steel or nitinol, extends along the distal body 14) and is attached to a rotating tip12) by welds 20) or by adhesive. The tip and cable revolve in bush 3) and are located axially by a collar 4) which is welded to the cable 9). A jacket 29) encloses the assembly and is attached firmly to the bush by band 22). This jacket extends from the bush 3) to the transition segment 15) (as shown in Fig. 1B), is of 1 to 2mm in outside diameter, and is fabricated from a flexible plastic such as Pebax, which may, or may not, incorporate braiding using metal wires or fabric filaments to enhance the torsional properties. Jacket 29) may or may not be flared to a larger diameter to contain the offset drive where it meets transition segment 15). The cable 9) runs inside a steering spring 6), preferably formed as a coil wound from flat metal ribbon, that is installed around the cable and inside the jacket 21). This spring is close wound over the proximal portion of the spring and open wound over the distal 1-2 cm of spring length. In order to accomplish the steering function, the open wound portion is in effect frozen in the open wound condition on one side of the spring and allowed to remain open on the other side: this may be accomplished by welding a strap 7) to each coil with a weld 8) over the distal portion alone. A bush 3), optionally featuring a barb 28), as shown in Fig. 2A), or bush 27) as shown in Fig. 2B), is firmly attached to the distal end of the jacket 21) to resist the application of a compressive force to the steering spring 6) from the proximal end. When this axial force is applied to this spring 6) from the proximal end, the spring 6) will transmit the force evenly over a close-coiled proximal portion but the spring will buckle into a curve at the open wound portion where the strap 7) is welded to the coils and the spring is forced to respond to the force in an asymmetric manner. Fig. 2B) shows the steering spring 6) in a curved form, with the cable 9) removed, and the spring coils having been closed on the inside of the bend in response to a compressive force. Such a design provides for a minimum radius of curvature limit when the coils on the non-strap side touch as shown in Fig. 2B). It will be appreciated that open wound portions of the spring 6) could be constructed at any point in the length of the spring and that straps like that shown as item 7) could be attached on one side of the spring to locally immobilize the open wound portion. This could allow multiple portions of the catheter distal portion 13) to adopt curves in any direction and in any plane.

[0045] In another embodiment, and as depicted in Fig. 9, the catheter distal body 14) may be provided at its distal end with a rotating tip 12) that is attached to the rotating multifilar hollow cable 9) extending through jacket 29) as described previously. In the embodiment depicted by Fig. 9, however, the rotating tip 12) is maintained in close proximity to the adjacent stationary bush 3), and thereby minimizing any gap between the rotating tip 12) and non-rotating bush 3). This may be achieved, as depicted, by employing a bush 3) having an integrated spring section 3'), where the spring section 3' is preloaded and maintained in its axial location by a collar 4) which is welded or otherwise affixed to cable 9). The preloading force must be of a level such that there is little to no gap or clearance between the rotating tip 12) and the bush 3), however the preload applied to spring 3') must such that it allows the rotation of the tip 12) along with acceptable wear and temperature rise rates resulting from the friction between the components.

[0046] A benefit to reducing any gap between the rotating tip 12) and the bush 3) is that the potential for fibrous clot material to bind within the gap and thereby impede operation of the catheter is minimized. Additionally, the rotating tip may be designed to further prevent the accumulation of fibrous material at the juncture. For example, the profile of the rotating tip (as depicted in Fig. 9) is such that at least a portion of the tip is angled with respect to the axis of the catheter, such as a cone shape, or radius shape. By incorporating this angled portion, the fibrous material would tend to slide distally off the end of the working head, rather than be encouraged wrap around the tip, like string around a pencil, such as by having the fibers climb up the angle in a proximal direction, and potential accumulate at the juncture between the tip 12) and the bush 3). It is recognized that the shape of the rotating tip may include angled portions and flat portions alternating as the head is rotated, in order to tease apart the fibers as has been described previously. It is also recognized that the embodiment depicted in Figure 9 may incorporate or be combined with other features as described above and below, such as including a steerable or selectively deflectable portion, provide for fluid delivery, or provide for guidance or data to assist in navigation.

[0047] Figs. 3A) through 3C) depict an alternative form of steering mechanism that can be used in a deflectable catheter, such as the device shown in Fig. 1B). Though the steering mechanism of Fig. 3A and 3C may be used in combination with cable 9) and rotary tip 12) as shown in Fig. 2A), the steering mechanism is quite different. In Figs. 3A) through 3C), operation of the steering is accomplished by applying a compressive load to a column (not shown) that encircles the cable 9). This column can consist of semi flexible tube, or a close wound spring, or a stack of loose rings, which comprise the majority of the length of the distal catheter body 14). The distal 1cm –2cm however consists of several separate asymmetric elements 31) as shown in Fig. 3A), which are stacked in line as shown in Fig. 3B). When a compressive load is applied axially along the column the longer edges transmit the load and the shorter edges close together, thus forming the elements, and correspondingly any surrounding jacket (not shown), into a curve as shown in Fig. 3C). One advantage of this arrangement is that the edges 32) and 33) of neighboring elements 31) will close on each other as depicted in Fig3 C) and thus limit the minimum radius of curvature of the stack of elements. This limitation on minimum radius is important to provide protection for any employed spinning cable 9) (shown in phantom in Fig. 3C) by limiting the bending stress on the cable, or on any other component placed in the same central location.

[0048] Figs. 5A) through 5C) show two alternative embodiments of steering mechanisms, which differ from those previously shown in that the steering segments are formed from an extrusion having a cross section 51) as shown in Fig. 5B). In Fig. 5A) each segment 52) has flat cross cuts 53), 54), 55), 56), made at an angle away from the perpendicular to the main axis of the device. These cross cuts form ridges at which adjacent segments can pivot 57). The distal segment 58) may feature a recess 59) to accept bush 60), though the bush 60) may be affixed by other means known in the art. Cable 9) passes through the segments 52) and the bush 60) and is fastened to the tip 12) by weld or other convenient method. Steering is accomplished by tensioning or releasing straps 61) and 62), fastened to distal segment 58) by welds 63), which in turn cause the segments to pivot at contact points 57). Clearly such a design allows steering in two directions as shown by the arrows 'A' and 'B', direction 'A' being achieved by pulling on strap 61) and in direction 'B' by pulling on strap 62).

[0049] Fig. 5C) is a variant of the deflectable catheter depicted in Fig. 5A) and provides for steering in one direction only. In this embodiment, the segments 64), which may be formed from the extrusion 51), have only two cross cuts, 65) and 66), created at angles other than perpendicular to the main axis of the device to create pivot points 67) at the periphery. Although steering is limited to one direction 'A' in Fig. 5C) when tension is applied to strap 68), the bending moment is double that of the system of Fig. 5A) and can be used when that is important. In both configurations shown in Fig. 5A) and Fig. 5C) a catheter jacket 29) surrounds the assemblies of segments and straps.

[0050] Clearly many other forms of steering mechanism could be applied to this device, and the concepts shown above should not to be considered a limitation on the steering methods used.

[0051] It will be appreciated from the foregoing that steering can be accomplished by tension action or compression action. It may be advantageous to use tension in the proximal catheter body 17) and compression in the distal catheter body 14). If so, a reversing mechanism, such as the embodiments shown in Figs. 8A and 8B, is required. Such a reversing mechanism can be constructed using pulley principles, for example, using a fine cable 82 in tension passing over pegs or pulleys 84 to reverse the direction and provide compression. Such reversing by pulley action may be employed, for example, in embodiments providing a 1:1 mechanical ratio, as shown in Fig. 8A, or alternatively, mechanical advantage may be provided by doubling the wire 82 over more than one peg or pulley 84, as depicted in Fig. 8B, shown providing a 2:1 mechanical advantage.

[0052] One benefit of the steerable distal portion 13) of the device 10 of Fig. 1B with an inner rotating cable 9) (shown in detail in Fig. 2A) is the not so obvious reduction in friction as the guide wire 11) is passed through a rotating cable. Most often, the device 10) will be used in a manner where the operator feeds the device over the guide wire. But there will be times when the distal end of the guide wire is maintained proximally of the steerable portion 13) until the steerable portion has been placed in the selected branch of a furcation. The guide wire is then to be fed out from the device into the downstream lumen. However, a stiff guide wire, if employed may have a tendency to hang up and jam within the device as it tries to make the distal curve created in the device as it is steered into the selected branch, however the rotating cable 9) takes the friction vectors at right angles to the guide wire feed direction thus making it possible to navigate the curve, where a stiff wire would otherwise have not been capable of being advanced.

[0053] An embodiment providing a rotating element at the distal end of a catheter may be useful for various surgical or interventional applications. As discussed earlier, the tip may be useful for penetrating into partially or totally occluded vessels, where the rotating action and shape of the tip may serve to separate the tissue fibers or other material forming the blockage, thereby allowing the catheter to cross the occlusion. It is recognized that, in this or other embodiments, the rotation speed may be manipulated for various applications or tissue types encountered.

[0054] Another possible use of an embodiment is to provide information about the tissue type or location of tissue relative to the distal tip of the catheter, in order to allow diagnosis or assist in navigating the vessels or occlusion as the catheter is advanced. It is contemplated that such information could be obtained in a manner that presents a detailed image or picture (or synthesized into a picture) collected upon the rotation of the tip. This requires scanning an area for the collection of multiple contiguous streams of information, such as may be accomplished by collecting data during the rotation of the distal tip having a detection component. For example, it is known in the art to utilize a rotating element or distal tip of a catheter in order to direct energy waves, such as sound waves, or light beams, typically through a lens or prism, out in a radial or forward looking direction, to collect information about the nearby tissue as the energy wave is reflected back and detected by a detector. See for example U.S. Patent Nos. 6,134,003; 5,383,467; 5,439,000; 5,582,171; 6,485,413; and 5,321,501. Such systems that rely on generating an image from a stream of data taken at multiple points or other scanning arrangements can be considered to be imaging systems, and may generate pictures of vessel interiors, and map locations of different tissue types and locations.

[0055] Additionally, it is recognized that a single reading, or possibly a limited number of discontinuous readings generating separate points of information could be utilized to provide guidance information about the nearby tissue, without generating a detailed image or map. For example, a single reading or very limited data collection could be utilized to generate information about the type and proximity of tissue surrounding the distal tip, allowing a decision on the safety of advancing the device (go or no go decision), or with two or more discontinuous sampling points collectively serving to indicate which particular direction which may be acceptable for advancing the device. Such limited information could be collected in a manner similar to the techniques described in US. Patent Nos. 5,951,482; 6,842,639; and 6,852,109, all of which are incorporated by reference herein. While it is recognized that such a system could be incorporated into the rotating tip, it can also be incorporated into a guidewire utilized in conjunction with the rotating tip at the distal end of the catheter. In this manner, the guidance or warning information generated by such a non-rotating central guidewire could be beneficially utilized in conjunction with a rotating distal tip to proceed through tissue blocking a vessel, without harming non-target tissue.

Transition segment, offset drives

[0056] Figs. 4A) thru 4E) show several different embodiments of a drive subassembly that will allow the guide wire to exit the catheter body at a point somewhere between the distal and proximal ends of the device.

[0057] Fig. 4A) shows one possible offset drive subassembly relying on the principle of geared transmission of power, where the offset drive subassembly is arranged to allow the guide wire 11 to exit from within the cable 9) that drives the tip 12). In this embodiment, an input drive shaft 400) drives input gear 401) and thus output drive gear 402) which is integral with hub 405), the output gear allowing the guide-wire to exit at 403). The guide wire 11) passes through the hub and thence into the cable 9) the cable being fastened to the hub by any suitable means such as weld, adhesive, or mechanical crimp. The entire offset drive assembly is housed within the outer jacket 404). Since steering is achieved by twisting of the distal body 14) via transition segment 15) and via proximal body 17), the torsional characteristics of all these components needs to be symmetrical about the polar axis to ensure smooth transmission of angular position. This requirement for smooth transmission of angular position dictates that the jacket 404) be concentric with the cable 9) and guide wire 11). Such an arrangement dictates that the jacket 404) diameter is dominated by the diameter of the input gear 401) and the diameter of the output gear 402). In principle this idea is adequate, but the size of the components makes this solution impractical for a very small cardiovascular device capable of being directed into narrow vessels where the entire offset drive sub-assembly needs to reside within a transition segment of 3French to 6French total diameter (3French = 1mm), thus making the gear teeth of such a small a size that is not commercially feasible at this time.

[0058] For example if gears are used as shown in Fig. 4A), the dimensions of a typical assembly are likely to be of the order such that the outside diameter of the outer jacket could exceed 0.13 inch, or 10 French, well above an desirable level of not greater than 5 French.

[0059] Figs. 4B) through 4E) show two different arrangements of offset drives which transmit the drive by friction. Both of these concepts eliminate the gear tooth profiles and reduce diameter dramatically, and accordingly are capable of being utilized in narrow device applications, such as a very small cardiovascular device where the transition segment is able to be sized around 3French to 6French total diameter.

[0060] Fig. 4B) illustrates what could be described as a friction drive analog of the gear drive shown in Fig. 4A), with Fig. 4C) showing a cross section at the line AA in Fig. 4B). In the embodiment depicted in Figs. 4B and 4C, input drive roller 463) is pressed firmly against output drive roller 464) to permit friction drive transmission between the two rollers. The force between the rollers is applied by spring 460) through the two bearing blocks 462) and 461) to the contact point 466) between the two rollers. The guide wire 11) passes through the centerline of output drive roller 464). These two blocks can slide relative to each other in guides 467). The entire assembly is housed in outer jacket 450). Although this concept is acceptable for size, the friction losses in this system are not optimal because of the rubbing friction between the rollers 463) and 464) and their respective bearing blocks 461) and 462).

[0061] An alternative embodiment of an offset friction drive subassembly is shown in Figs. 4D) and 4E). This concept transmits drive from an input drive shaft 453) through planet 454) to sun 451) in an epicyclic fashion, with load between the rollers being supplied by nipper ring 455) and idler planet 452). Radial and axial location for the planets and sun 451) are maintained by four recesses 457) and two bores 459) provided for in the two end plates 458) and 468). The guide wire passes through the sun 451) and through the cable 9), with the joint between the sun and cable being made by any convenient method such as welding, adhesive or crimping. In order to provide radial load between the sun and planets the nipper ring is distorted with the nipper ring 455) internal diameter being less than the sum of the sun 451) diameter and the diameters of the two planets 454) and 452). The two planets 454) and 452), as well as the nipper ring 455), housed within the recesses and bores of the end plates 468) and 458) revolve as the input drive shaft 453) is turned, with the nipper ring 455) transmitting torque to the idler planet 452) which in turn transmits torque to the sun 451). In this arrangement the nipper ring 455) is rolling on the planets 452) and 454) thus reducing friction to low levels.

[0062] The entire epicyclic drive assembly is held together by housing 456) which is fastened to the two end plates 468) and 458) by any suitable means such as welding, adhesive, or crimping. This concept allows the use of very small components, for example, for components made from hardened stainless steel, a sun 451) of 0.026 inch diameter, planets 452) & 454) of 0.010 inch diameter, nipper ring 455) internal diameter of 0.043 inch, and nipper ring wall thickness of 0.003 inch. Such components allow a jacket 450) outside diameter of around 0.065 inch or 5F, much smaller than the smallest size (10.2F) currently feasible for the gear driven system of Fig. 4A).

[0063] In order to transmit a given torque the dimensions given for the components, and therefore the load between the rollers, can be adjusted by varying the axial length of the contacts between the sun, planets and nipper ring, the axial length being of the order 0.060

inch for the diameters quoted to transmit about 0.2 in oz of torque using steel components having a coefficient of friction around 0.15.

[0064] One aspect of the difficulties of dealing with such small drives is the extremely small tolerances that are required to get an acceptable range of torque transmission. For the device described in Fig. 4C) and Fig. 4D) the tolerances for the planet and sun diameters need to be of the order of 50 millionths of an inch, and the wall thickness of the nipper ring needs to be held within 200 millionths of an inch if the parts are to be made from high tensile heat treated steel such as 420F. One possible way to make the manufacturing tolerances more manageable is to use materials capable of exhibiting, super-elastic, or high damping properties (e.g., nitinol Ni-Ti Alloys, or Cu-Al-Ni alloys), for all or some of the components. By loading such super-elastic rollers (suns or planets) to a level which demands the function of the rollers in the super-elastic zone, the material strain level can be increased by more than a factor of 5:1, and the tolerances defining the nip between the nipper ring and the sun and planets can therefore be reduced.

[0065] It will be appreciated that in order to operate the steering mechanisms shown in Figs. 2B, 3A), 3B), 3C), 5A, 5B, and 5C), there is the need to transmit force from a steering thimble 18), past or through the transition segment 15), to the distal steerable portion 13).

[0066] This steering force can be in the form of tension via straps 61) or compression via pushrods (not shown), with the reactions taken through the outer jacket 29). One way of providing the action is by passing the straps or pushrods through the offset drive subassembly in the locations shown by numeral 469) in Fig. 4F), there being sufficient room between the nipper ring 455) and the sun 451) for straps of 0.006 thickness which can transmit loads of 10 pounds or more. Clearly this arrangement allows the transmission of tension or compression without increasing the diameter of the outer dimensions.

Transition segment, guide wire exit

[0067] The transition segment 15) of device 10) in Fig. 1B) is the region where the distal catheter body 14) of approximately 3F diameter changes to 5F diameter, or approximately 5F, recognizing that smaller sizes would be preferred, where the transition segment serves to accommodate an offset drive mechanism, such as any of the friction drive subassemblies described in Figs. 4A) through 4E), and provides a guide wire passageway segment that guides the guide wire from the center line of the device to a location outside the outer jacket. It is expected that, while the device 10 is in use in a patient, the distal catheter body 14) will be extended into narrow vessels approaching 2-3 mm in size, while the transition point is expected to remain in slightly larger vessels adjacent to the smaller vessels, and therefore the transition segment may be somewhat larger than the distal catheter body, typically 5F, though it is recognized that it may be somewhat larger if it is expected to remain in larger vessels or organs. The transition segment must provide for a force transmission element, such as a pushrod or alternatively a small cable and outer reaction jackets (not shown, but similar to those used in larger form for bicycle brake cables). Additionally, the transition segment must provide a space or lumen for the drive shaft to provide rotary force to the friction drive assembly, such as driveshaft 453) of Fig. 4D or Fig. 4E). In those embodiments utilizing an infusate or irrigant fluid, especially a cooling fluid, the transition segment must also provide for the passage of infusate 23). Such a component (not shown) can be made using a molded or fabricated portion made from Pebax or urethane polymers as is well known in the art, and may or may not incorporate inserts of metal, metal or synthetic braid, perforated or stamped metal, or the like, to provide for good torsional properties yet be flexible in bending.

Proximal catheter Body

[0068] Proximal catheter body 17), shown in Fig. 1B), is typically of 4F diameter and is the final proximal portion of the device passing into the patient. This component provides a first conduit for the drive shaft 453), a second conduit for a steering mechanism such as a cable with jacket as discussed above, and additional space for infusate to flow. An extrusion of nylon or Pebax can provide for this function and may be braided with fabric or metal filars to transmit torsion well. Alternatively this proximal body may be made from a metal tube, or from a metal tube with a multi lumen plastic insert to provide for the separation of the functions traversing this portion of the assembly. Details of this proximal catheter body are well known in the art and are not therefore shown in drawings.

Steering thimble

[0069] Steering thimble 18), as shown in Fig. 1B), provides a control unit for actuating the steering components of the device in order to selectively deflect the deflectable portion of the device. Steering thimble 18 is preferably a small light subassembly and may provide a tensioning force to pull a cable, or alternatively a thrust to push a column, where the force generated serves to operate the distal steering function. Since this subassembly is situated integral with the proximal catheter body 17), it must be small and light so that it does not have a significant effect on the torsional characteristics of the entire catheter body (items 13) 14), 15) and 17)) distal of the steering thimble. A steering thimble that is essentially circular in section and small in diameter (approximately 5-15 mm) fulfills this role. Figs. 6) and 7) show two examples of steering thimble construction.

[0070] Fig. 6A) shows an arrangement that is designed to apply tension to a cable or wire 601) that passes through outer reaction jacket 602) to operate a distal steering function, such as that shown in Figs. 5A) or 5C). Steering thimble 18) anchors proximal catheter body 17) and intermediate catheter body 19) in recesses in barrel 603) using adhesives or thermal bonding. Barrel 603) can be made from polycarbonate or nylon or other light polymer, with or without fillers. Any suitable adhesives capable of joining the components are suitable for this purpose, for example UV cured adhesives or anaerobic curing, wicking adhesives, such as Loctite 4011 may successfully be employed. In the depicted embodiment, two slots 604) are cut diametrically opposed to each other in barrel 603) for the purpose of receiving plate 605) which can slide along the axis of the thimble 18) under the action of threaded sleeve 606) and ferrule 607). Threaded sleeve 606) and ferrule 607) are both made from a light strong polymer such as polycarbonate and are bonded together at interface 608) using a suitable adhesive, such as Loctite 4011. Cover 609) provides protection for slots 604), limits infusate 23) leakage, and provides the distal portion of the thimble which is grasped and held stationery, whilst the proximal portion 606) is twisted to apply tension to the cable 601), as shown in Fig. 6B). The cable reaction is taken through outer reaction jacket 602) which terminates at insert 612 at the proximal end and the offset drive end plate 468) of Fig. 4D) at the distal end where the internal cable or wire 601) continues to pass through the offset drive as shown as item 469) in Fig. 4F) and down the distal catheter body 14) to operate, for example, the pull strap 68) shown in Fig. 5C), or other tensioning steering mechanisms.

[0071] Fig. 7A) is an axial section illustrating a steering thimble 18) for the operation of steering concepts using compression to drive the distal steerable portion 13) of Fig. 1B) as shown, for example, in Fig. 2B). Ferrule 701) provides the termination point for proximal catheter body 17) and threaded sleeve 702) anchors the intermediate catheter body 19). Both joints are secured using any suitable adhesive, such as Loctite 4011 adhesive. Ferrule 701) incorporates a threaded extension 703) on which is mated threaded sleeve 702). The component under compression, spring 704) is driven by thrust washer 705) from threaded sleeve 702). As mentioned earlier, the component under compression can be a close wound spring, a piece of tubing or a stack of cylinders, all of which can transmit compression yet provide for bending flexibility of the catheter body. Ferrule 701) and threaded sleeve 702) can be made from polycarbonate, nylon, or ABS or any other strong light polymer, or other suitable materials, such as metal alloys, such as alloys of aluminum, titanium or stainless steel. Thrust washer 705) can be made from polycarbonate or other hard polymer or a metal such as stainless steel, and can be coated with an antifriction material such as Teflon. Spring 704) extends distally from steering thimble 18, through proximal catheter body 17 and via pushrods (not shown) bypasses the transition segment 15), bypasses the offset drive as indicated by items 469) on Fig. 4F), and then operates a distal steering spring such as that shown as item 6) in Fig. 2B). Fig. 7B) shows an overview of the steering thimble of Fig. 7A) and shows the direction of torque application by arrow 706).

[0072] In both Fig. 6A) and Fig. 7A) the input drive shaft 453) traverses the steering thimble assembly, such that the transmission of rotary force from the drive pack 21 to the offset drive subassembly is not affected by the operation of steering thimble 18.

[0073] It will be noted that the steering thimble of Fig. 6A) has a design that keeps the proximal catheter body 17) and the intermediate catheter body 18) in rigid axial and rotational relationship, with the steering function provided by threaded sleeve 606) revolving about the barrel 603). In the design of Fig. 7A) the intermediate catheter body 19) revolves when the steering is activated and the intermediate body 19) moves axially relative to proximal body 17). Clearly the designs of Fig. 6A) or Fig. 7A) could both incorporate either feature if so desired.

Swivel

[0074] In order for the operator to use the steering function, the catheter in-toto, distal of the steering thimble, must be capable of being rotated about its axis in order to point the steerable portion 13) in the desired direction. For this to be achieved it is necessary to incorporate a swivel somewhere in the intermediate catheter body 19) that allows the independent rotation of one portion of the catheter independently from another portion of the device and permits the operator to rotate the catheter with as little drag as possible from the drive pack. In Fig. 1B) the swivel 26) is located at the drive pack 21), but it could just as well be situated at the proximal end of the steering thimble 18) or at somewhere along the intermediate catheter body. No design is shown for this feature since such swivels are well known in the art, the first being marketed in a product known as The Kensey Catheter by Cordis in the 1987 to 1992 time frame.

Drive pack

[0075] The drive pack 21) of Fig. 1B) is not shown in detail since all aspects of this drive are similar to a drive disclosed under Kensey Nash application 10/832,830 entitled "Thrombectomy and Soft Debris removal Device" and now approved for sale under the name "ThromCat™ Thrombectomy Catheter System". Basically the drive pack provides rotary power from a small DC motor, power from batteries for the motor, a power on/off switch, an indicator light, and for some applications a logic board and suitable power switching functions to permit motor speed to be varied as a function of time. For example the speed might be ramped up in one direction and then reversed and ramped up in the other direction, or the speed might be varied in saw tooth or sine waves in one direction. In addition the drive pack accepts infusate via lumen 22) from a bag with cuff 24) for delivery through swivel 26) to the intermediate catheter body 19) and subsequently to the area adjacent to the rotary tip 12).

[0076] In Fig. 1B the guide wire 11) passes through the drive pack and exits the drive pack via a hemostasis valve (not shown) as is common in the art for OTW applications

[0077] It is recognized that any features described in the present application may be used alone or in combination with other described features. Thus since the invention disclosed herein may be embodied in other specific forms without departing from the spirit or general characteristics thereof, some of which forms have been indicated, the embodiments described herein are to be considered in all respects illustrative and not restrictive, by applying current or future knowledge. The scope of the invention is to be indicated by the appended claims, rather than by the foregoing description, and all changes which come within the meaning and range of equivalency of the claims are intended to be embraced therein.

CLAIMS

What is claimed is:

1) A rapid exchange catheter for conducting a procedure within a lumen, duct or organ of a living being comprising:

a working element arranged at a distal portion of said catheter, said working element having an axis of rotation;

a guide-wire passageway arranged through said working element and co-axial with said axis of rotation; and

a drive input shaft having a rotary drive axis offset radially from said working element axis of rotation, wherein said drive input shaft is arranged to effect said rotation of said working element through an offset drive mechanism.

2. The rapid exchange catheter of claim 1, arranged to fit within a Number 5 French catheter.

3. The rapid exchange catheter of claim 2, wherein at least some of the components making up the offset drive comprise materials capable of exhibiting at least one of super-elasticity and high damping.

4. The rapid exchange catheter of claim 1, wherein said offset drive mechanism comprises a friction drive system.

5. The rapid exchange catheter of claim 4, wherein said offset drive mechanism comprises an epicyclic drive system comprising at least two planet rollers, a nipper ring and a sun roller.

6. The rapid exchange catheter of claim 5, wherein said epicyclic friction drive is arranged to receive power input from said drive input shaft arranged to cause the rotation of one of said planet rollers, whereupon said power is transmitted by friction in an epicyclic manner and is output from said sun roller to effect the rotation of said working element.

7. The rapid exchange catheter of claim 5, wherein at least one of the nipper ring, sun roller, or planet rollers comprises an alloy having superelastic properties.

8. The rapid exchange catheter of claim 6, wherein said sun roller is arranged to coaxially accept the slidable passage of a guidewire therethrough.

9. The rapid exchange catheter of claim 4, wherein said offset drive mechanism comprises a friction drive system comprising an input drive roller, an output drive roller, a partial bearing for each of said input and output drive rollers, and a spring providing a clamping force between said input and output rollers via said partial bearings in order to maintain said input and output rollers in contact with each other.

10. The rapid exchange catheter of claim 5 or 9, wherein the working element is a tissue penetrating element comprising an atraumatic rotating head arranged to separate tissue fibers to allow advancement of said rapid exchange catheter through a blockage in said lumen, duct or organ of a living being.

11. The rapid exchange catheter of claim 1, further comprising a drive motor and associated controls, said drive motor being arranged to effect the rotation of said drive input shaft.

12. The rapid exchange catheter of claim 11, further comprising a swivel located distally of said drive motor and associated controls, said swivel being arranged to allow the independent rotation of said rapid exchange catheter independently of said drive motor.

13. The rapid exchange catheter of claim 1 wherein the distal end is arranged to be deflected.

14. The rapid exchange catheter of claim 13, wherein said deflectable distal end comprises a coiled spring arranged to be deflected and thereby vary the shape of the distal end of the catheter.

15. The rapid exchange catheter of claim 14, wherein at least a portion of said coiled spring comprises a first side and a second side, where, on the first side, at least a portion of the coils are immobilized locally in an open coil relationship, such that upon application of a compressive load along the axis of said open coiled spring, said first side resists collapse on

the immobilized side, and said second side, which is not immobilized, collapses in response to the application of a compressive load, whereupon said coiled spring assumes a curved orientation.

16. The rapid exchange catheter of claim 13, wherein said deflectable distal end comprises a plurality of separate interlocking tubular elements, said interlocking tubular elements being arranged to form a curve when placed in compression.

17. The rapid exchange catheter of claim 16, wherein said interlocking tubular elements are arranged to limit the minimum radius of curvature achieved upon deflection of the deflectable distal end.

18. The rapid exchange catheter of claim 13, wherein said deflectable distal end is actuated by a steering thimble, arranged to be rotated to transmit a deflecting force distally through the rapid exchange catheter.

19. The rapid exchange catheter of claim 18, wherein said deflecting force is transmitted through a reversing mechanism to convert a tensile force into a compressive force.

20. The rapid exchange catheter of claim 1, wherein said rotation of said working element minimizes frictional resistance for the advancement of a guidewire through said guide-wire passageway.

21. The rapid exchange catheter of claim 1, further comprising a stationary element, where the working element is arranged to rotate against the stationary element with little or no clearance.

22. The rapid exhange catheter of claim 21, wherein said stationary element is preloaded to press against the rotating working element.

23. A catheter for conducting a procedure within a lumen, duct or organ of a living being comprising a deflecting mechanism arranged to vary the shape of the distal end of said catheter, wherein said deflection is arranged to be deformed upon the application of a compressive force.

24. The catheter of claim 23, further comprising:

a working element arranged at a distal portion of said catheter and having an axis of rotation; and

a guidewire passageway arranged through said working element and co-axial with said axis of rotation, wherein said working element is arranged to be rotated by an offset drive mechanism arranged to transfer a rotation force from a location offset radially to said working element.

25. The catheter of claim 24, wherein said rotation of said working element minimizes frictional resistance for the advancement of a guidewire through said guide-wire passageway.

26. A rapid exchange catheter for conducting a procedure within a lumen, duct or organ of a living being comprising a working element and a deflecting mechanism, said working element being arranged at a distal portion of said catheter and having an axis of rotation, and said deflecting mechanism being arranged to vary the shape of the distal end of the said catheter.

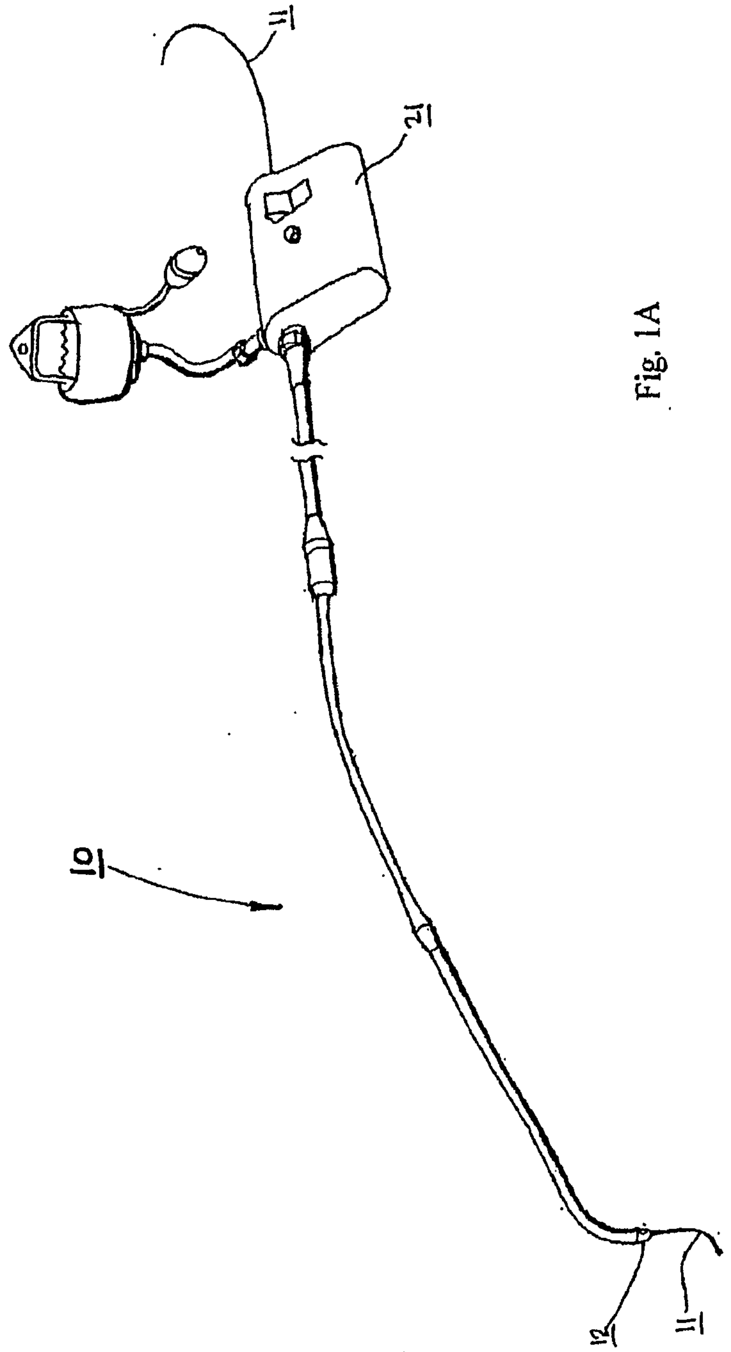

Fig. 1A

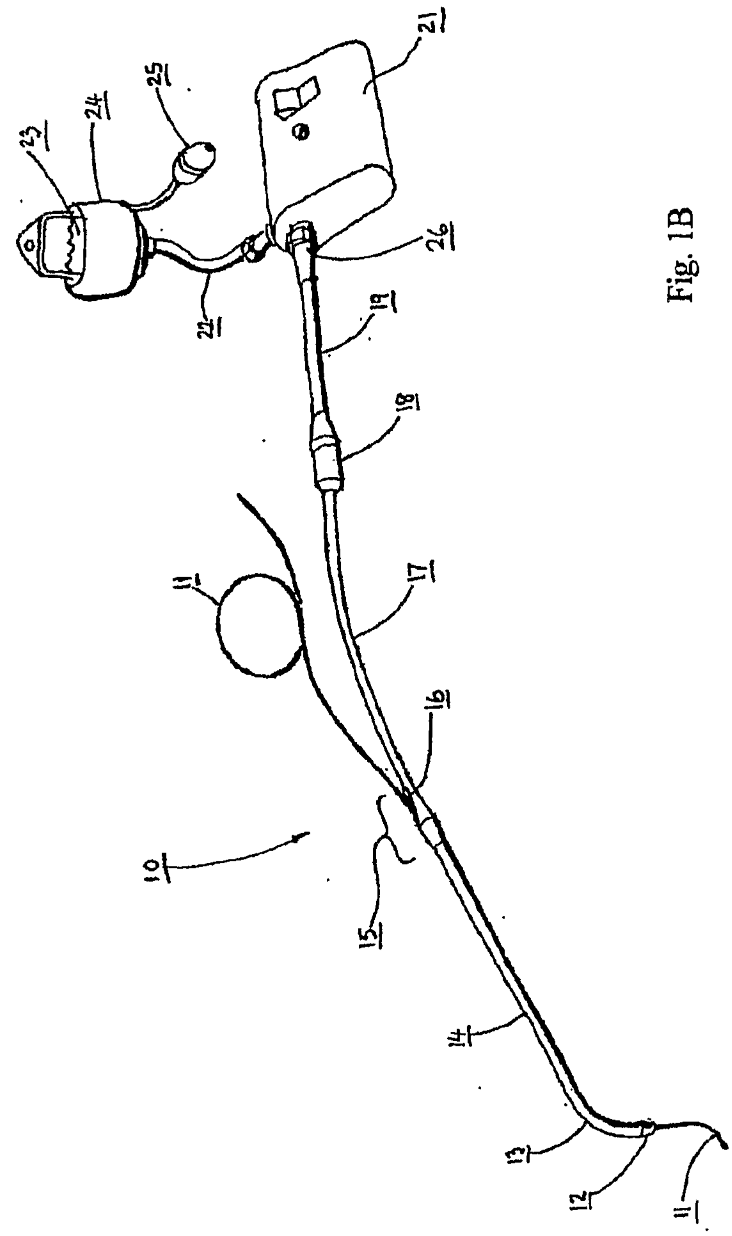

Fig. 1B

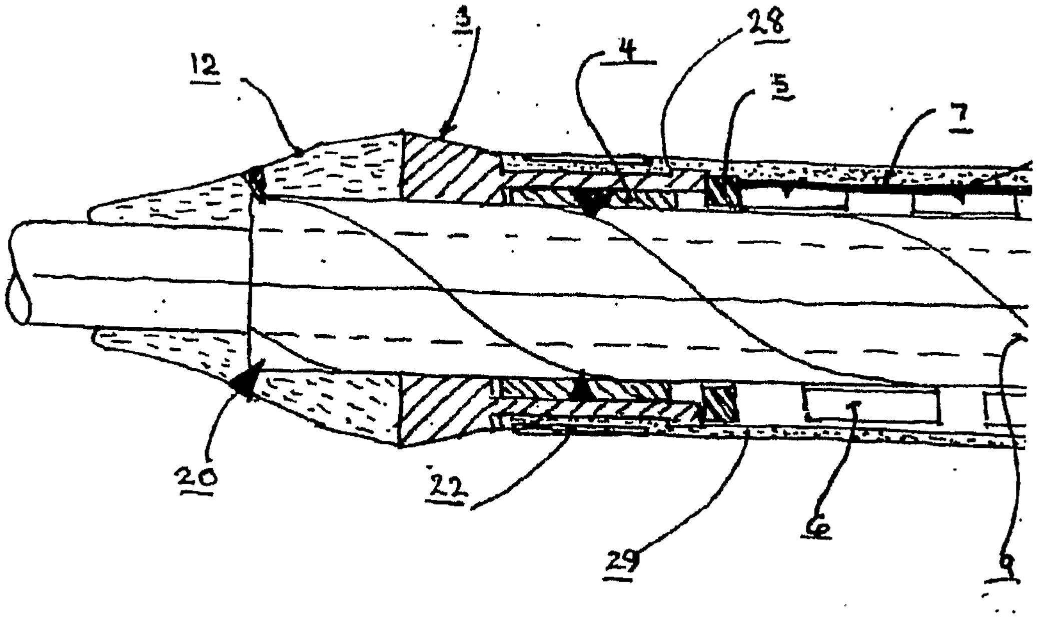

Fig. 2A

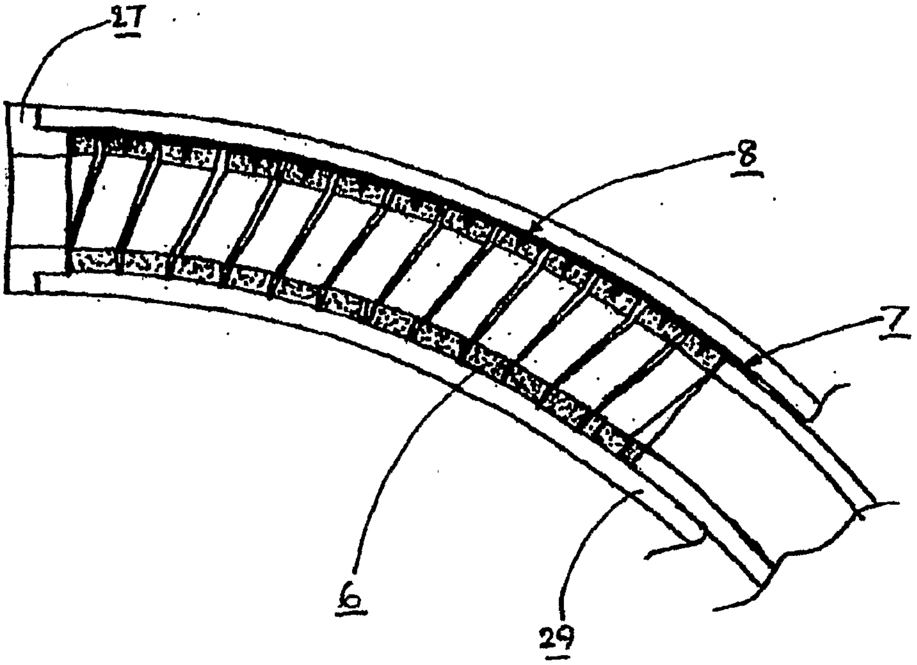

Fig. 2B

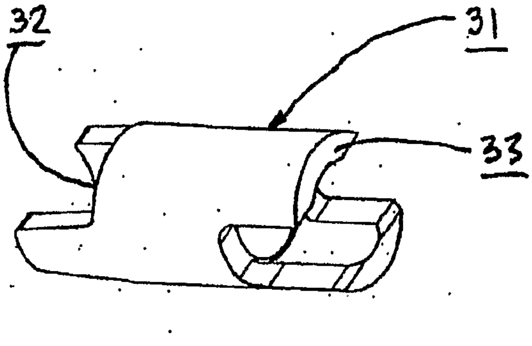

Fig. 3A

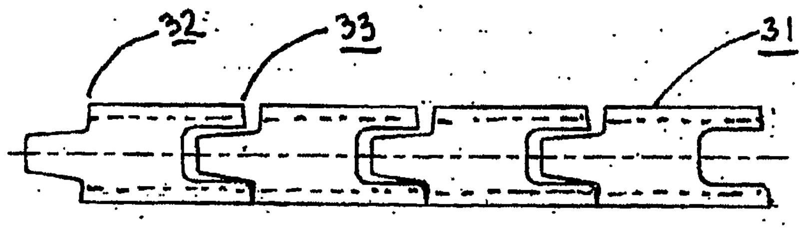

Fig. 3B

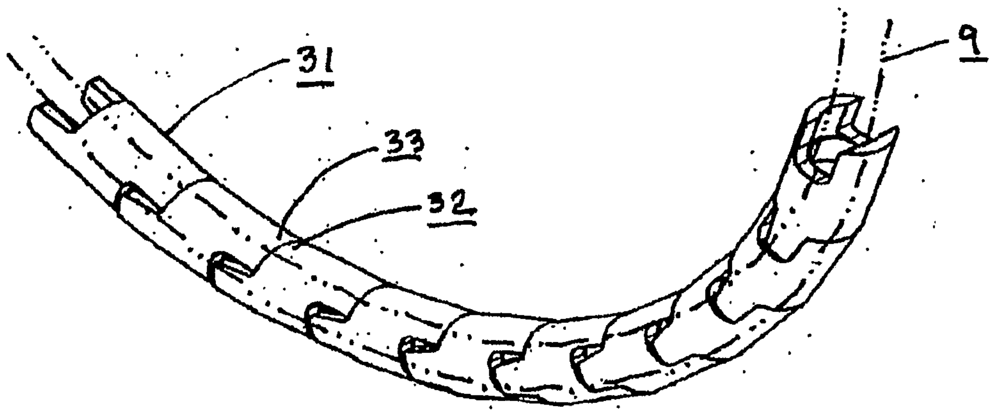

Fig. 3C

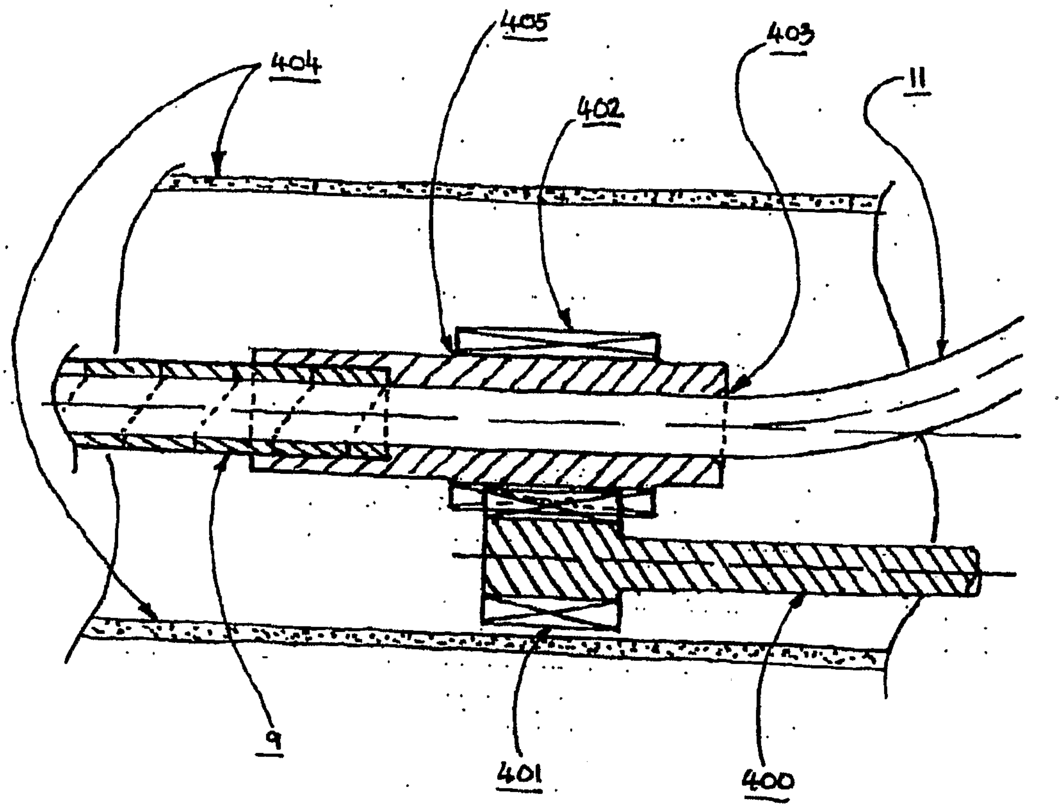

Fig. 4A

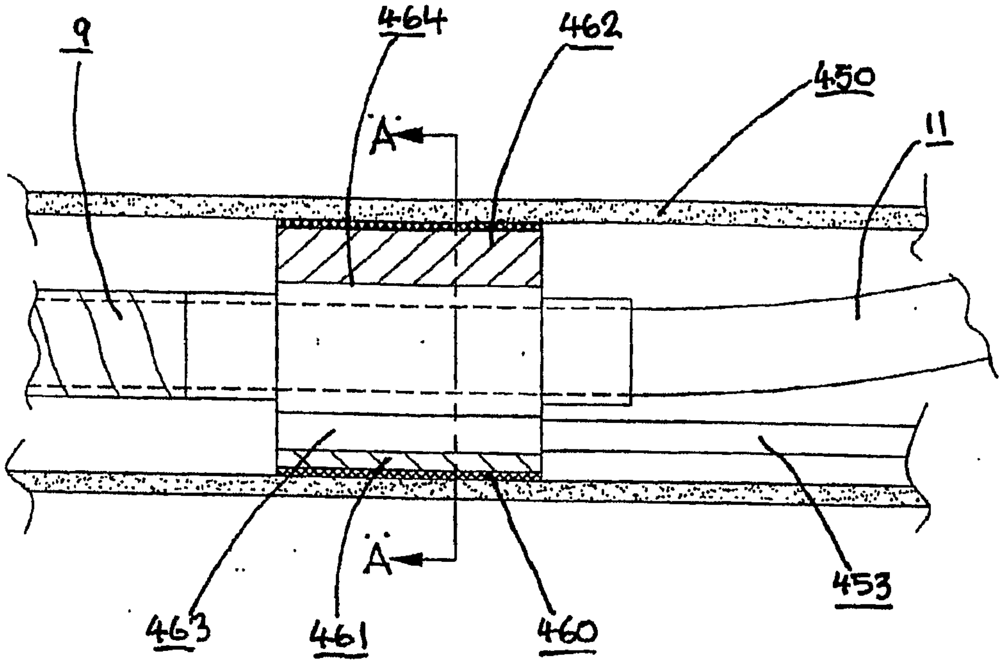
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Fig. 4B

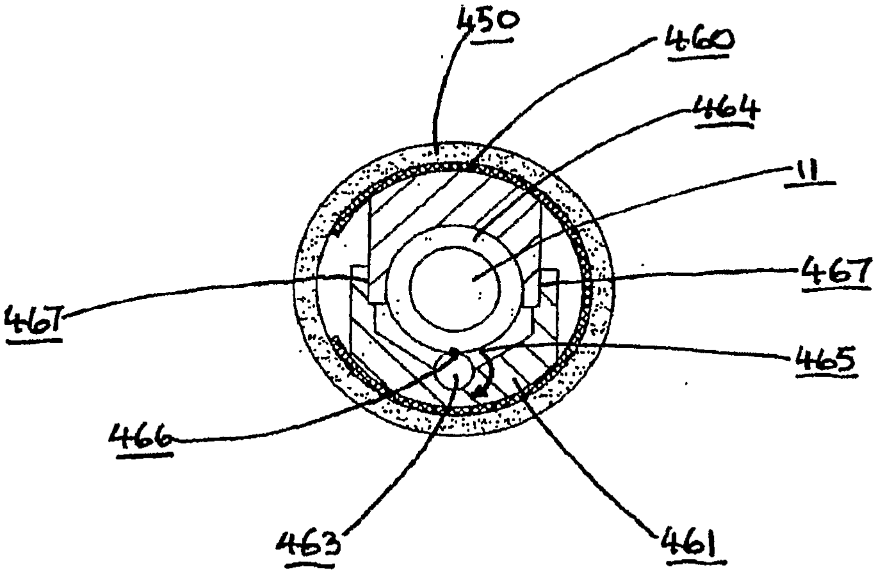
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Fig. 4C

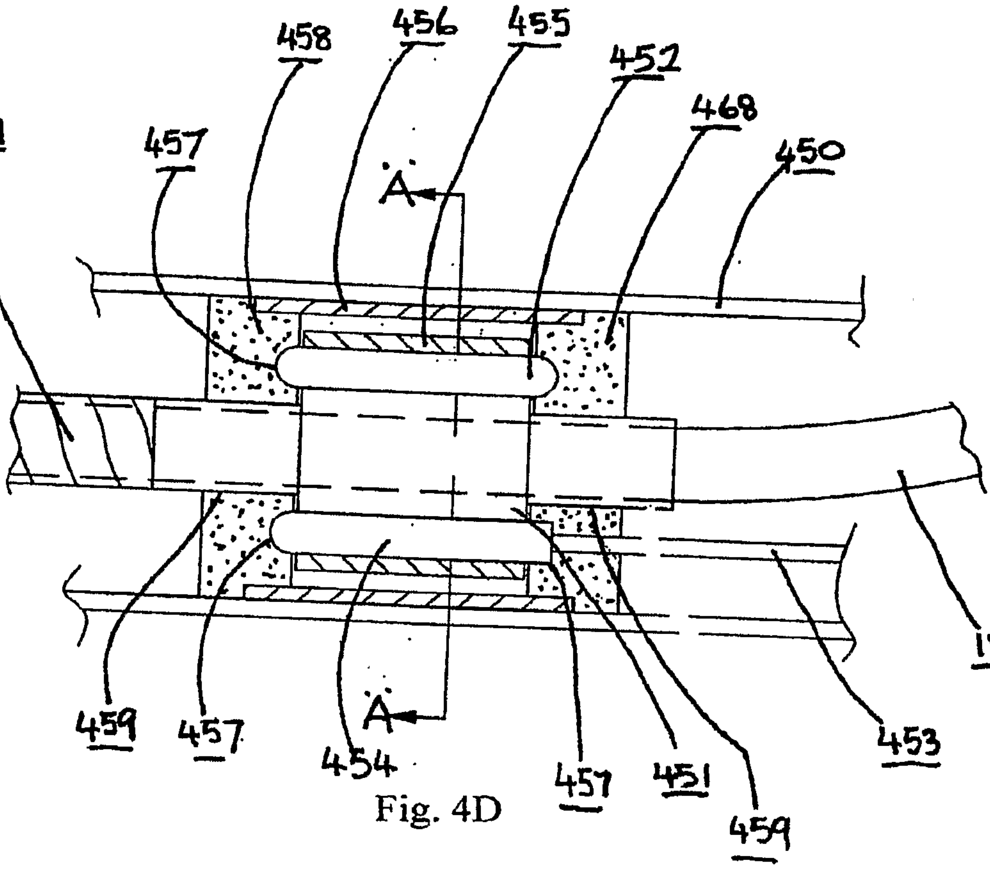
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Fig. 4D

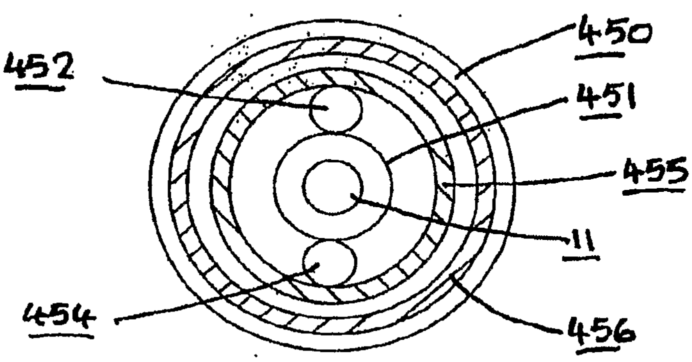
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Fig. 4E

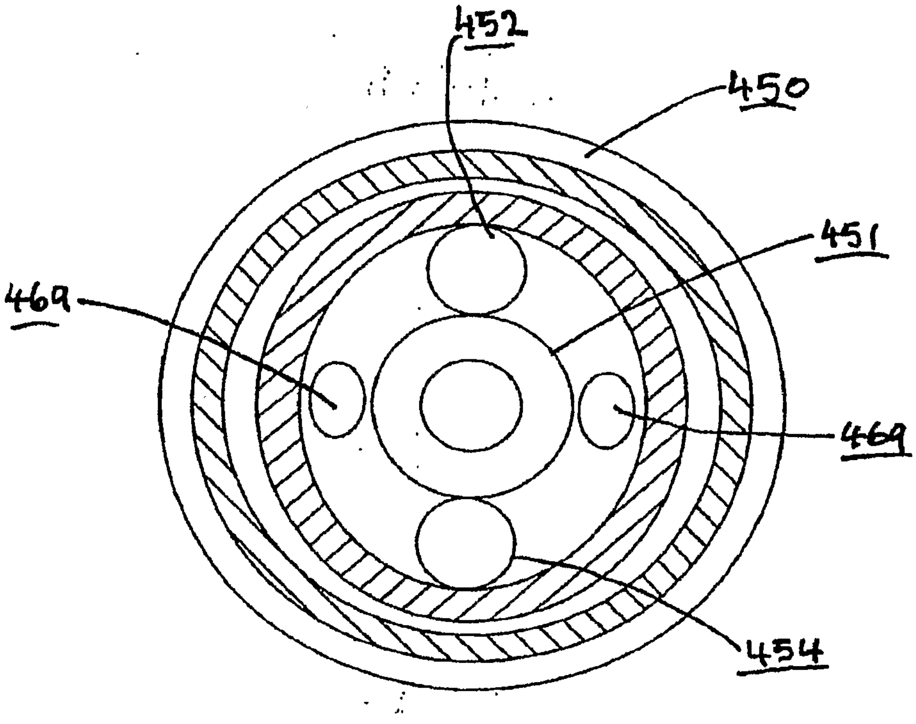


Fig. 4F

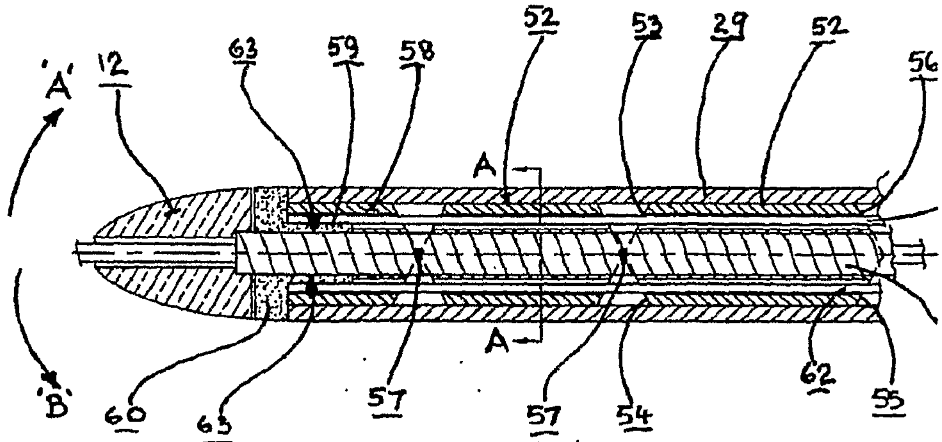


Fig. 5A

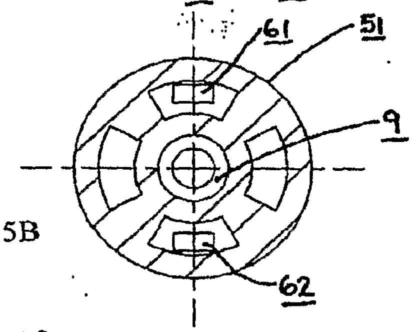


Fig. 5B

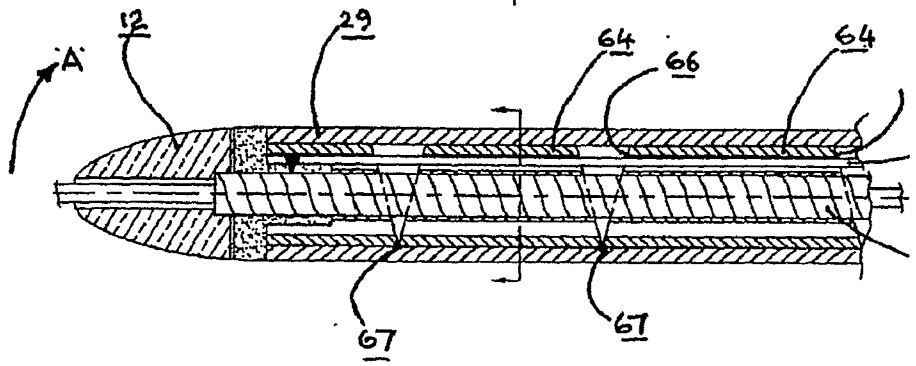
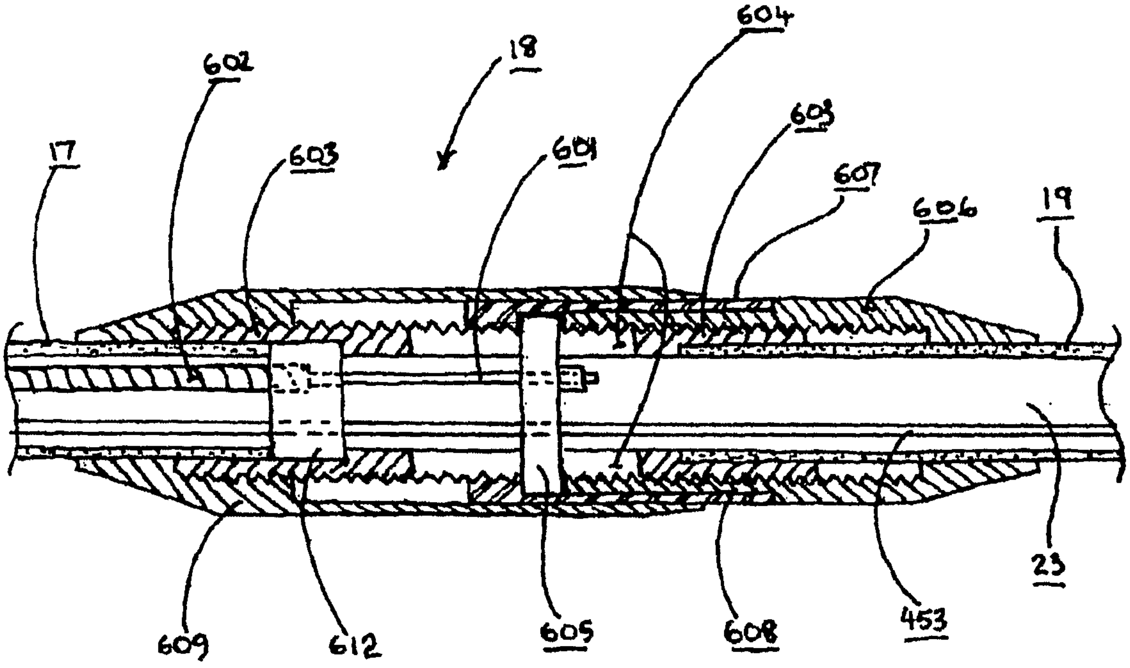


Fig. 5C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609

Fig. 6A

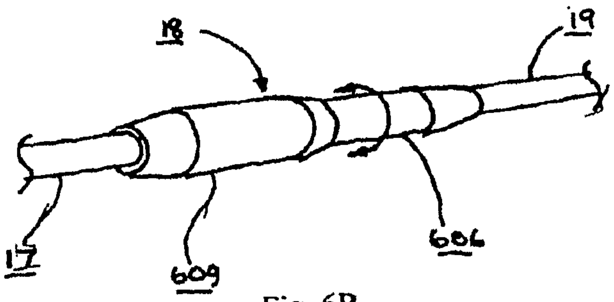
18
19
17
609
606

Fig. 6B

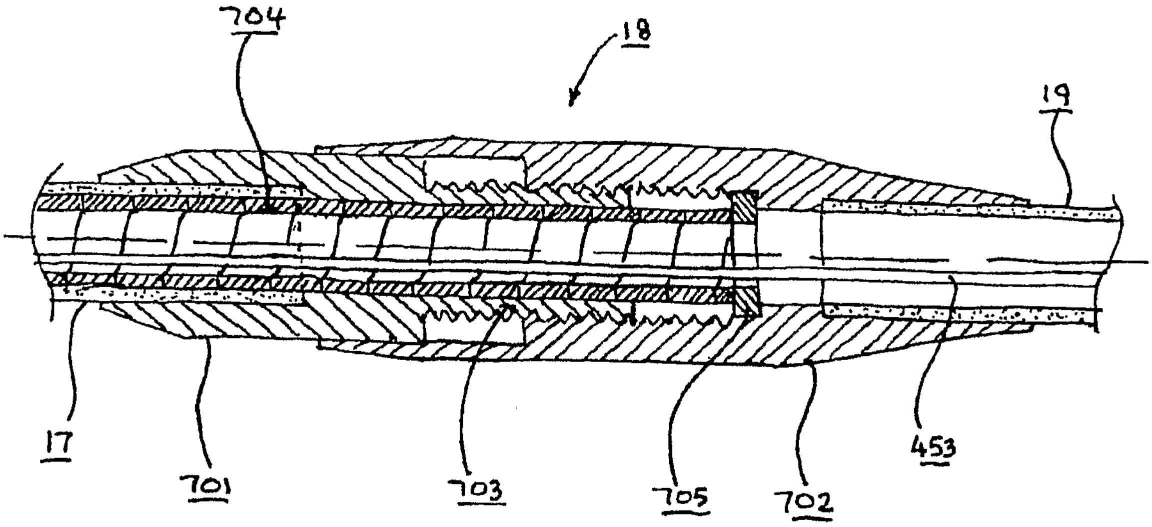

Fig. 7A

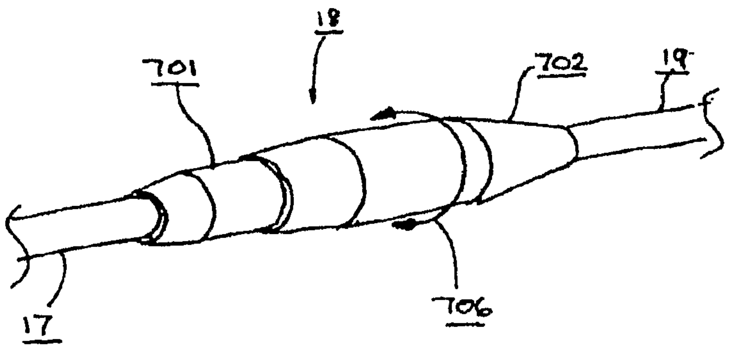

Fig. 7B

Fig. 8A

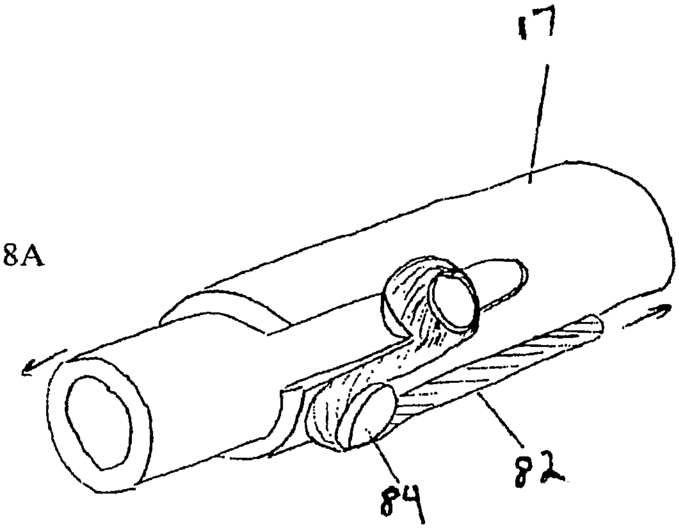

Fig. 8B

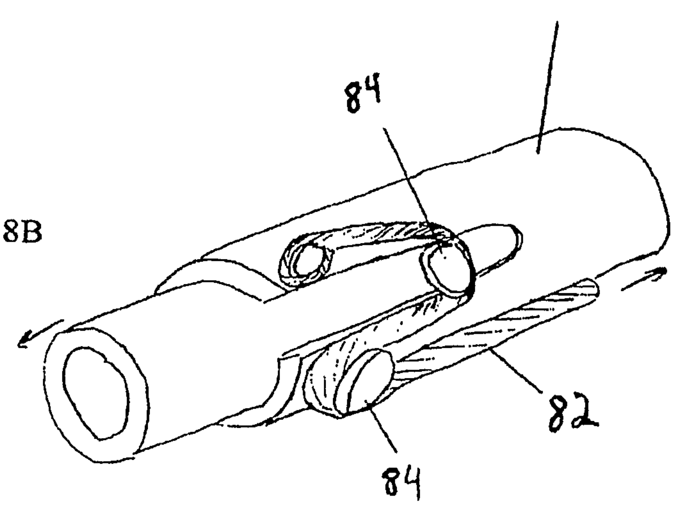

Fig. 9