AU9468140

(12) PATENT ABRIDGMENT (11) Document No. AU-B-68140/94
(19) AUSTRALIAN PATENT OFFICE (10) Acceptance No. 686165

(54) Title
DEVICE FOR REMOVAL OF INTRALUMINAL OCCLUSIONS

International Patent Classification(s)
(51)[6] **A61B 017/32**

(21) Application No. : **68140/94** (22) Application Date : **07.04.94**

(87) PCT Publication Number : **WO95/27443**

(43) Publication Date : **30.10.95**

(44) Publication Date of Accepted Application : **05.02.98**

(71) Applicant(s)
IRA C. EDELL

(70) Nominated Person
DERIO MEDICAL INSTRUMENTS LTD

(72) Inventor(s)
ARIEH SHER

(74) Attorney or Agent
GRIFFITH HACK , GPO Box 1285K, MELBOURNE VIC 3001

(56) Prior Art Documents
US 4749376
US 4923462
US 5195956

(57) Claim

1. A device for removal of intraluminal occlusions which comprises:

a catheter having a distal end for insertion into a patient and a proximal end;

a distal piston located within said distal end of said catheter for longitudinal reciprocating motion in said catheter in response to alternating longitudinal forces applied by said proximal end, said distal piston including a closed wave-shaped groove in a circumferential surface thereof which receives at least one stationary pin fixed to an inner portion of said distal end of said catheter, whereby said piston simultaneously moves longitudinally and rotationally in response to said longitudinal reciprocating motion; and

a cutting head, said cutting head being attached to said distal piston for simultaneous longitudinal and rotational movement together with said distal piston.

AUSTRALIAN PATENT OFFICE

OPI DATE 30/10/95 APPLN. ID 68140/94
AOJP DATE 14/12/95 PCT NUMBER PCT/US94/03439

AU9468140 T)

(51) International Patent Classification 6 : A61B 17/32 | A1

(11) International Publication Number: WO 95/27443

(43) International Publication Date: 19 October 1995 (19.10.95)

(21) International Application Number: PCT/US94/03439

(22) International Filing Date: 7 April 1994 (07.04.94)

(71) Applicant: EDELL, Ira, C. [US/US]; Suite 220, 1901 Research Boulevard, Rockville, MD 20850 (US).

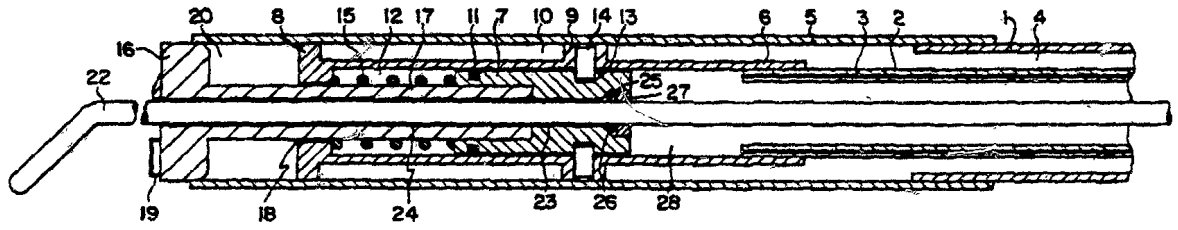
(74) Agent: EDELL, Ira, C.; Epstein, Edell & Retzer, Suite 220, 1901 Research Boulevard, Rockville, MD 20850 (US).

(81) Designated States: AT, AU, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, ES, FI, GB, GE, HU, JP, KG, KP, KR, KZ, LK, LU, LV, MD, MG, MN, MW, NL, NO, NZ, PL, PT, RO, RU, SD, SE, SK, TJ, TT, UA, UZ, VN, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).

Published
With international search report.

686165

(54) Title: DEVICE FOR REMOVAL OF INTRALUMINAL OCCLUSIONS



(57) Abstract

This invention is a method and device for removal of intra-luminal occlusions which includes a catheter having a cutting head (16) in a distal end thereof. The cutting head (16) undergoes a simultaneous longitudinal and rotational movement by means of fluid pressure applied to a distal piston (7) to which the cutting head (16) is attached. The proximal end of the catheter includes a reciprocating pump (53) which applies the fluid pressure to the distal piston. The cutting head (16) is retractable to a sheathed or retracted position during insertion and movement in a patient. Material removed by the cutting head can either be collected in a chamber located between the distal piston and the cutting head or aspirated through the proximal end of the catheter.

DEVICE FOR REMOVAL OF INTRALUMINAL OCCLUSIONS

Technical Field:

The present invention is directed to surgical instruments and procedures. More specifically, the present invention is directed to instruments and procedures for intravascular surgery and other surgical and in-body procedures.

Background Art:

Various types of devices have been suggested for removal of intraluminal occlusions. Generally, these devices may be classified according to the following aspects:

(a) The manner by which occluding tissues are removed, e.g., the use of mechanical cutters, lasers, ultrasonic devices, fluid jets, etc.

(b) The manner by which energy is transmitted to the cutting head, e.g., via flexible drive shafts, fluid power, electrical wires, etc.

(c) The manner by which loosened tissue debris is removed, e.g., collecting the tissue debris in a collecting chamber next to the cutting head, aspirating the tissue fragments, fragmenting the tissue to very small particles, etc.

The following U.S. Patents are believed to exemplify state-of-the-art surgical catheter devices.

U.S. Patent No. 4,316,465 to Dotson discloses an ophthalmic cutter that comprises a driving device having a

helical groove and helical ridges cooperating with the groove. A cutting device is connected to the driving device to sever any tissue which extends through an aspiration port of the aspiration needle.

U.S. patent No. 4,324,243 to Helfgott et al discloses an apparatus and process for aspirating and evacuating a pneumatically operated surgical instrument. A series of pneumatic pulses are generated and transmitted to a piston of a charging assembly and the surgical instrument to cause a hollow tube of the instrument to move toward the distal end of a cutting tube in a cutting stroke.

U.S. Patent No. 4,674,500 to DeSatnick discloses the use of a protective sheath for a cutting blade. The blade remains in the sheath until ready for use.

U.S. Patent No. 4,749,376 to Kensey et al discloses a reciprocating working head catheter. The catheter comprises a tubular body or jacket having a drive and a movable working head. The drive includes a drive wire that extends from the proximal end located outside the patient to the motion translation means. The cable is rotated at high speeds and the motion translation means converts the rotation of the drive cable to a rotating reciprocating motion of the working head.

U.S. Patent No. 4,790,813 to Kensey discloses a catheter having a working head which is adapted to be rotated by a turbine drive while the head is advanced into a restriction in a passageway. The turbine includes structure to coaxially supply a drive fluid through a central passage to a rotatable cutting head or turbine head which includes turbine blades.

U.S. Patent No. 4,819,635 to Shapiro discloses a tubular microsurgery cutting apparatus that includes an outer tubular member having an open end fixed to a housing of the driving end. An inner tubular sleeve has an open end and a cutting end that reciprocates within the tube. Reciprocation is produced by a piston which is driven by a source of pulsing air supplied through end cap through a tube.

U.S. Patent No. 4,850,957 to Summers discloses an atherectomy catheter having an outer catheter tube and an inner catheter tube. A hydraulic motor is housed within the inner catheter tube and includes a cutting element connected to a drive shaft of the hydraulic motor. Fluid under pressure is forced into a stator cavity to provide powder to turn or rotate a rotor.

U.S. Patent No. 4,957,482 to Shiber discloses an atherectomy system for cutting, ingesting and removing obstructions from within an artery. A flexible catheter is disposed over a flexible guide wire which is insertable into an artery. A hollow blade having teeth is provided at the distal end of the catheter. The catheter is rotated by a motor coupled to the catheter through a hub and belt.

U.S. Patent No. 5,024,651 to Shiber discloses an atherectomy system having a rotary flexible catheter for coring and ingesting obstructions. A flexible rotary-catheter has coring means at its distal end. The catheter is slidably disposed in a sleeve. The sleeve has a window region near its distal end. The sleeve defines in the vessel a trajectory for the coring means to move along. Negative pressure for aspirating cut material can be applied through a rotary joint.

U.S. Patent No. 5,047,008 to de Juan et al discloses a vitrectomy probe for removing vitreous materials having a blade which is located on the outer end of a tubular member which is attached to the end of a suction outlet tube. The blade is reciprocated by injecting pulsating pressurized fluid through a fluid inlet tube and port 22 into chamber 47. The pulses cause a diaphragm to push against a retainer connected to a suction outlet tube. The retainer and suction tube are urged away from the fluid chamber toward a stop ring causing a spring to be compressed and inner tubular member with blade to slide toward cutting position

The present invention is directed to a catheter device for the removal of intraluminal occlusions which provides particular advantages over the prior art as discussed below.

Disclosure of the Invention:

It is one object of the present invention to provide a surgical device and method for removing intraluminal occlusions.

According, therefore, to a first broad aspect of the present invention there is provided a device for removal of intraluminal occlusions which comprises:

a catheter having a distal end for insertion into a patient and a proximal end;

a distal piston located within said distal end of said catheter for longitudinal reciprocating motion in said catheter in response to alternating longitudinal forces applied by said proximal end, said distal piston including a closed wave-shaped groove in a circumferential surface thereof which receives at least one stationary pin fixed to an inner portion of said distal end of said catheter, whereby said piston simultaneously moves longitudinally and rotationally in response to said longitudinal reciprocating motion; and

a cutting head, said cutting head being attached to said distal piston for simultaneous longitudinal and rotational movement together with said distal piston.

Preferably said cutting head is positioned within the distal end of the catheter so that at a one position of a path of its longitudinal motion said cutting head is within a distal end of said catheter and at another position of the path of its longitudinal motion said cutting head extends beyond the distal end of said catheter.

Preferably said cutting head includes at least one cutting blade.

Preferably said catheter includes a chamber between said distal piston and said cutting head for receiving material cut by said cutting head and said cutting head includes at least one through bore through which the cut material can pass into said chamber.

AUSTRALIAN PATENT OFFICE

Preferably said chamber is connected to a passage which extends to said proximal end of said catheter.

Preferably said catheter includes a guide wire which extends through said distal piston and said cutting head.

Preferably said guide wire extends beyond said distal end of said catheter.

Preferably a pump means is provided at said proximal end of said catheter for applying fluid pressure to said distal piston for driving said distal piston.

According to a second broad aspect of the present invention there is provided a method for removing intraluminal occlusions which comprises:

providing a catheter having a distal end for insertion into a patient with a cutting head for simultaneous longitudinal and rotational movement;

inserting said distal end of said catheter into a lumen of a patient while maintaining said cutting head within said distal end of said catheter;

positioning said distal end of said catheter near an object to be removed and;

causing said cutting head to simultaneously move in both a longitudinal and a rotational movement so as to extend from said distal end of said catheter and cut said object to be removed, said step of causing including the steps of applying a pulsatile driving force to said cutting head to cause said cutting reciprocate longitudinally, and rotating said cutting head in response to longitudinal reciprocation of the cutting head, whereby said cutting head simultaneously moves longitudinally and rotationally in response to said longitudinal reciprocating motion.

Preferably the method further includes the step of collecting material cut by said cutting head in a chamber provided in said distal end of said catheter behind said cutting head.

Preferably the method further includes the step of aspirating material cut by said cutting head and

AUSTRALIAN PATENT OFFICE

removing said aspirated material from a proximal end of said catheter.

According to a third broad aspect of the present invention there is provided a device for removal of intraluminal occlusions comprises:

a catheter having a distal end for insertion into a patient and a proximal end;

a distal piston located within said distal end of said catheter for simultaneous longitudinal and rotational movement therein, said distal piston including at least one stationary pin fixed thereto which is received in a closed wave-shaped groove formed in an inner surface of said distal end of said catheter;

and

a cutting head attached to said distal piston for simultaneous longitudinal and rotational movement together with said distal piston, whereby said piston simultaneously moves longitudinally and rotationally in response to longitudinal reciprocating motion of said piston.

According to a fourth broad aspect of the present invention there is provided a device for removal of intraluminal occlusions comprising:

a catheter having a longitudinal axis and a distal end adapted for insertion into a passage in a patient's body;

a driven member located within said catheter;

means for simultaneously reciprocating said driven member longitudinally in said catheter and rotating said driven member about said longitudinal axis; and

a device head secured to said driven member for reciprocation longitudinally and rotating therewith, said device head projecting from said distal end when reciprocating longitudinally and rotating to remove occluding material from said passage in the patient's body;

wherein said means comprises:

driving means for longitudinally reciprocating said driven member within said catheter; and

AUSTRALIAN PATENT OFFICE

further means responsive to longitudinal reciprocation of said driven member for rotating said driven member about said longitudinal axis, whereby said driven member simultaneously moves longitudinally and rotationally in response to said longitudinal reciprocation.

According to a fifth broad aspect of the present invention there is provided a device for removing intraluminal occlusions, a method of simultaneously reciprocating a cutting head longitudinally and rotating the reciprocating cutting head, said method comprising the steps of:

longitudinally reciprocating said cutting head by applying a pulsating force to said device; and

in response to longitudinal reciprocation of said cutting head, directing said cutting head rotationally about its longitudinal axis, whereby said cutting head simultaneously moves longitudinally and rotationally in response to longitudinal reciprocation.

Brief Description of the Drawings

The present invention will be described with reference to the attached drawings which are given by way of non-limiting examples only. Wherever possible like reference numerals have been utilized to identify common elements throughout the figures.

Figure 1 is a sectional view of the distal end of the apparatus according to one embodiment of the present invention,

Figure 2 is an isometric view of the distal end of the embodiment of the invention of Fig. 1.

Figure 3 is an illustration of the wave-shaped groove which shows the cutouts that determine the direction of the rotation of the distal piston.

AUSTRALIAN PATENT OFFICE

Figure 4 is a cross sectional view of the proximal end of the apparatus according to one embodiment of the present invention.

Figure 5 is a cross sectional view of an alternate embodiment of the distal end of the apparatus of the present invention.

Figure 6 is a cross sectional view of an alternate embodiment of the proximal end of the apparatus of the present invention.

AUSTRALIAN PATENT OFFICE

Figure 7 is a sectional view of an alternative embodiment of the distal end of the apparatus in which the guide wire is of the fixed wire system type.

Best Mode for Carrying Out the Invention

Hereafter, the end of the catheter, which is designed to be inserted into the patient's body, shall be referred to as the "distal end". The other end, which is designed to remain outside a patient's body, shall be referred to as the "proximal end". In view of the above, "distal direction" or the term "distally" shall indicate a general direction from the proximal end to the distal end and "proximal direction" or "proximally" shall refer to an opposite direction.

The present invention provides for a catheter device which incudes a cutting head for removing intraluminal occlusions. The cutting head is reciprocally movable from a first position in which is it sheathed by or retracted in the end of a catheter tube, to a second position in which the cutting head extends beyond the end of the catheter tube.

In addition to being reciprocally movable, the cutting head simultaneously rotates as it is moved reciprocally.

The simultaneous reciprocal and rotating movement of the cutting head is achieved by application of fluid, e.g., gas or liquid, pressure directly on a piston to which the cutting head is attached. Upon application of the fluid pressure, this piston simultaneously reciprocates and rotates. This movement of the piston is directly transferred to the cutting head which is attached to the piston.

As will be discussed below, the fluid pressure is pulsatile and the movement of the cutting head to the first or sheathed position is assisted by means of a spring biasing force.

Because the fluid acts directly on a piston (referred to below as the distal piston) to drive the cutting head and does not pass through the piston, only one tube is required to transmit the fluid pressure. This design is a particular

advantage over prior devices which require multiple tubes to supply and remove fluid to turbines and other driving means.

The fluid pressure which acts on the distal piston is applied by another piston (to be referred to as the pressure piston) located at the proximal end of the catheter tube, which is connected to a reciprocating drive unit. The two above mentioned pistons move in unison. While pushing the pressure piston proximally, the pressure in the tube rises, resulting in movement of the distal piston in the same direction. Simultaneously, the distal piston undergoes a rotational movement as well, due to a wave-shaped groove located in its body, which is forced to rotate over stationary pins. As the pressure piston retracts proximally the pressure in the tube is reduced and the distal piston is forced to move proximally both by a spring force and by the vacuum created in the tube. Simultaneously, the distal piston and cutting head rotate in the same manner as explained above. This combined motion facilitates cutting of the occlusive material in the vessel.

The present invention provides means to remove tissue debris from the site at which the cutting head cuts an object, e.g., an occlusion. According to one embodiment of the present invention, removed debris is removed through an annular passage in the catheter. This annular passage is created when the above mentioned tube through which fluid pressure is applied to the distal piston is concentrically located inside another outer tube. In this embodiment it is possible to aspirate blood and cut material, e.g, tissue, debris by a third piston, (referred to below as the suction piston), located in the proximal end of the catheter device, or by a vacuum cylinder, or by an equivalent suction pump.

According to another embodiment of the present invention, tissue debris is removed by collecting the debris in a collection chamber which is located between the cutting head and the distal piston.

As note above, the cutting head can be positioned in a first sheathed or retracted position. When inserting and

moving the distal end of the catheter in a patient, the cutting head is maintained in the first sheathed or retracted position in order to ensure safe passage and prevention of vessel perforation.

Figs 1-3 depict the distal end of the catheter according to one embodiment of the present invention. As shown in Figs. 1 and 2 the catheter comprises an outer flexible tube 1. Concentrically positioned within outer tube 1 is an inner tube 2, which if desired can be provided, with a braided reinforcement 3.

An annular passage 4 is defined between outer tube 1 and inner tube 2. The distal end of outer tube 1 is located in a jacket 5. A cylinder 6 is concentrically located in jacket 5. Cylinder 6 contacts jacket 5 only by a plurality of protrusions 8 at its distal end and a plurality of protrusions 9 at its proximal end. The plurality of protrusions 8 and 9 are discrete and are spaced evenly around the outer circumference of cylinder 6. Because spacings are provided between adjacent protrusions, an open annular passage 10 is defined between cylinder 6 and jacket 5. As discussed below, passage 10 enables removal of blood and tissue debris.

Inner tube 2 is connected at its distal end to cylinder 6. A distal piston 7 is housed within cylinder 6. Distal piston 7 is driven by fluid 28 applied through inner tube 2. A sealing means (e.g., O-ring) 11 at the distal end of distal piston 7 provides fluid-tight seal between the inner tube 2 and chamber 12. The pressure of fluid 28, which originates at the proximal end of the apparatus, fluctuates. The manner in which the pressure fluctuates will be discussed below with reference to Fig. 4.

As the pressure of fluid 28 rises in inner tune 2 distal piston 7 is forced distally in a rotational movement. The rotational movement of distal piston 7 is effected the presence of a closed wave-shaped groove 13 formed in the outer circumferential surface of distal piston 7. The movement of distal piston 7 is directed by one or more stationary pins 14, which are assembled in cylinder 6 and protrude into wave-

shaped groove 13. The pattern of closed wave-shape groove 13 may vary according to the number of pins 14, and according to the desired ratio of reciprocating to rotational movement.

Following a reduction in the fluid pressure in inner tube 2, distal piston 7 is pushed proximally by spring means 15 and drawn by a vacuum created in inner tube 2. Simultaneously, piston 7 undergoes a rotational movement in the same way as previously described. That is, by the cooperating action of the wave-shape groove 13 and stationary pins 14.

A cutting head 16 is housed within jacket 5. The cutting head 16 has a stem 17 which passes through a central hole 18 in cylinder 6 and is connected to distal piston 7. The distal section of cutting head 16 has one or more cutting blades 19. Blood and tissue debris which are removed by the cutting head are drained to chamber 20 via openings 21 in cutting head 16 (Fig. 2). Because the cutting head 16 is connected to distal piston 7 it follows the same rotatory and reciprocating motion as distal piston 7. This combined movement facilitates the incision of an occlusion.

In Figs. 1 and 2 the cutting head 16 is shown at its most distal location. When no fluid pressure is applied to distal piston 7 through inner tube 2, spring 15 forces cutting head 16 to move proximally so that it is concealed in jacket 5. This manner of concealing the cutting head 16 ensures that no injury will be caused to lumenal walls during insertion of the catheter into and patient's vessel. The manner in which piston 7 rotates in a predetermined direction is explained with reference to Fig. 3 below.

A guide wire 22 extends distally in front of cutting head 16 for guiding the catheter through a patient's vessel. Guide wire 22 passes through inner tube 2 all the way up to the proximal end. At the distal end guide wire 22 passes through hole 23 in distal piston 7 and through hole 24 in stem 17. According to another embodiment, guide wire 22 can be shorter and its proximal end can be connected to the inner circumference of cylinder 6. The guide wire, as shown in Figs. 1 and 5, can extend through the catheter device.

Alternatively, the guide wire can be of the fixed wire system type as shown in Fig. 7 in which one end of the guide wire 22 is fixed to the housing 81 of the catheter device.

A sealing means is provided for forming a fluid-tight seal between guide wire 22 and distal piston 7. The sealing means (e.g., O-ring) 25 is mounted in recess 26 and is held in place by a retaining ring 27.

Fig. 3 depicts the way in which piston 7 is rotated in a predetermined direction. In Fig. 3 the development of closed wave-shaped groove 13 is shown. Dashed lines 1-1 and 2-2 represent the same spatial line. The wave-shaped groove 13 is longitudinally symmetrical and thus has no effect on the direction of rotation of distal piston 7. Sloped cutouts 30 and 31 determine the direction of rotation.

Proximal movement of distal piston 7 is equivalent to a rightward movement of closed wave-shaped groove 13 in Fig. 3. When cutouts 31 encounter stationary pins 14 upward movement of the distal piston is caused. This movement is equivalent to a counter-clock wise (CCW) rotation of distal piston 7 (when viewed proximally). Distal movement of distal piston 7 also will result in the same CCW rotation due to similar reasoning but this time it will encounter cutouts 30 rather than cutouts 31. The direction of rotation is dependent on the slope direction of cutouts 30 and 31. The effect causes reciprocating movement of distal piston 7 in a continuous CCW rotation.

Fig. 4 shows the proximal end of the apparatus according to one embodiment of the present invention. The proximal end provides several functions:

a) Aspiration of blood and tissue debris from the cutting head 16.

(b) Creation of fluctuating or pulsatile pressure required for the movement of distal piston 7.

(c) Control movement of guide wire 22 and fixing its position when necessary.

As shown in Fig. 4, outer tube 1 and inner tube 2 are connected to support block 40 which may generally have a

rectangular shape. As noted above, an annular passage 4 is defined between outer tube 1 and inner tube 2. Annular passage 4 serves for transferring blood and tissue debris from the distal end of the catheter to the proximal end thereof. As shown, passage 4 is opened to chamber 41.

A duct 42 connects chamber 41 and chamber 43. In operation, aspiration at the distal end of the catheter is performed when suction piston 44 moves upwards. Sealing means (e.g., O-ring) 45 maintains the vacuum in chamber 43. When a vacuum is created by the upward movement of suction piston 44 check valve 46 is opened and simultaneously check valve 47 is closed causing aspiration of blood and tissue debris from the distal end of the catheter into chamber 43.

After aspiration, suction piston 44 moves downwards. As the suction piston moves downwards check valve 46 is closed and check valve 47 is opened thus forcing out blood and tissue debris from chamber 43 into removable collecting bag 48 via tube 49. To maintain a vacuum, opening 42 and chamber 43 are closed with plate 50. Plate 50 contains sealing means (e.g., elastic gasket) 51 and is assembled to block 40 with screws 52.

Reciprocating drive unit 53 is fastened to plate 50 with screws 54. The drive unit 53 can be of any type that provides reciprocating motion e.g., linear actuator, crank mechanism, etc. Drive unit 53 is connected to suction piston 44 via rod 56, which passes through sealing means (e.g., O-ring) 57. Drive unit 53 is operated by switch 55.

A pressure piston 58 having a sealing means (e.g., O-ring) 59 is connected to rod 56, which is a part of drive unit 53. The reciprocating movement of drive unit 53 and the attached pressure piston 58 produces pressure fluctuations. These pressure fluctuations are transferred via opening 60, chamber 61, and inner tube 2 to distal piston 7. Fluid 28 can be added to inner tube 2 if desired via opening 62 and valve 63.

Block 40 contains another opening 64 through which guide wire 22 passes. A sealing means (e.g., O-ring) 65 is located

in recess 66 and forms a fluid-tight seal between block 40 and guide wire 22. Pressure on sealing means 65 is maintained by threaded fitting 67. Guide wire 22 passes through opening 68 and through chucks 69, that are part of fixing nut 70. Tightening fixing nut 70 squeezes chucks 69 against tapered recess 71 and against guide wire 22 thus preventing guide wire 22 from moving.

Fig. 5 depicts an alternate embodiment of the distal end of the catheter. The basic idea of this embodiment is similar to the one described in Figs. 1-3. The difference between the two embodiments is the way in which tissue debris are removed from the occlusion site. In the embodiment of Figs. 1-3 debris are aspirated via the catheter to the proximal end. In the embodiment shown in Fig. 5 debris are collected into a collecting chamber located next to the cutting head and removed from the collection chamber after the catheter is removed from the patient.

In Fig. 5 the catheter comprises a tube 80, which if desired can be provided with a braided reinforcement 83. The distal part of tube 80 is located in housing 81. A distal piston 7 is housed within housing 81. Distal piston 7 is driven by fluid 28 which is applied through tube 80. A sealing means (e.g., O-ring) 11 at the distal end of distal piston 7 provides fluid-tight seal between tube 80 and chamber 12. The pressure of fluid 28, which originates at the proximal end of the apparatus, fluctuates. The way the pressure fluctuates will be discussed below with reference to Fig. 6.

As the fluid pressure rises in tube 80 distal piston 7 is forced distally in a rotational movement. The rotation is effected by the presence of a closed wave-shaped groove 13 formed in the outer circumferential surface of distal piston 7. The movement of distal piston 7 is directed by one or more stationary pins 14, assembled in housing 81 which protrude into wave-shaped groove 13. The pattern of closed wave-shape groove 13 may vary according to the number of pins 14, and

according to the desired ratio of reciprocating to rotational movement.

Following a reduction in the fluid pressure in tube 80, distal piston 7 is pushed proximally by spring means 15 and drawn by a vacuum created in tube 80. Simultaneously, piston 7 undergoes a rotational movement in the same way as previously described.

A cutting head 16 is located within housing 81. Cutting head 16 has a stem 17 that passes through a central hole 18 in housing 80 and is connected to distal piston 7. The distal section of cutting head 16 has one or more cutting blades 19. Blood and tissue debris are drained via opening 21 in cutting head 16 and stored in chamber 82. Cutting head 16 is connected to distal piston 7 and therefore follows the same rotatory and reciprocating motion as distal piston 7. This combined movement facilitates an incision of the occlusion.

In Fig. 5 the cutting head 16 is shown at its most distal location. When no pressure is applied to distal piston 7, spring 15 forces cutting head 16 to move proximally so that it is concealed in housing 81. This manner of concealing the cutting head ensures that no injury will be caused during insertion of the catheter into a patient's vessel. The way in which piston 7 rotates in a predetermined direction is explained above in reference to Fig. 3.

As shown in Fig. 5, a guide wire 22 extends distally in front of cutting head 16 for guiding the catheter through a patient's vessel. Guide wire 22 passes through tube 80 all the way up to the proximal end. The distal end of guide wire 22 passes through hole 23 in distal piston 7 and through hole 24 in stem 17. Alternatively, guide wire 22 can be shorter and its proximal end can be connected to the inner circumference of housing 81. A sealing means is provided for forming a fluid-tight seal between guide wire 22 and distal piston 7. The sealing means (e.g., O-ring) 25 is mounted in recess 26 and is held in place by a retaining ring 27.

Fig. 6 shows an alternate proximal end of the apparatus. The proximal end shown in Fig. 6 provides two functions:

(a) Creation of fluctuating pressure required for the movement of distal piston 7.

(b) Control movement of guide wire 22 and fixing its position when necessary.

As shown in Fig. 6, a syringe pump 91 is fixed to housing of drive unit 96 by bracket 95 and clamp 92. The syringe piston 90 is connected to rod 94 via bracket 93. Rod 94 is a part of drive unit 96 which moves in a reciprocating movement. The drive unit 96 can be of any type that provides reciprocating motion e.g., linear actuator, crank mechanism, etc. The speed and direction of this movement is controlled by drive unit 96. Drive unit 96 is operated by switch 97. The movement of syringe piston 96 produces fluctuating pressure in fluid 28. This pressure is transferred to the distal end of the catheter via tube 80.

As shown in Fig. 6, the proximal end of the catheter also contains a T-shaped or branched fitting 98. Guide wire 22 passes through one opening in fitting 98. A sealing means 65 is located in recess 66 and forms a fluid-tight seal between block support fitting 98 and guide wire 22. Pressure on sealing means 65 (e.g., O-ring) is maintained by fitting 67. Guide wire 22 passes through opening 68 and through chucks 69, that are part of fixing nut 70. Tightening fixing nut 70 squeezes chucks 69 against tapered recess 71 and against guide wire 22 thus preventing guide wire 22 from moving.

The materials from which the various elements of this catheter are constructed can be selected from known materials which are conventionally utilized in catheters. The braided reinforcement elements noted above likewise can be constructed from woven or laminated strands of known materials such as nylon.

While the present invention has been described as a catheter device, it is noted that the general structure of the device can be readily adapted for any type of drilling apparatus, including large scale drilling such as oil drilling and earth boring.

Although the present invention has been described with reference to particular means, materials and embodiments, from the foregoing description, one skilled in the art can ascertain the essential characteristics of the present invention and various changes and modifications may be made to adapt the various uses and characteristics thereof without departing from the spirit and scope of the present invention as described in the claims which follow.

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1. A device for removal of intraluminal occlusions which comprises:

a catheter having a distal end for insertion into a patient and a proximal end;

a distal piston located within said distal end of said catheter for longitudinal reciprocating motion in said catheter in response to alternating longitudinal forces applied by said proximal end, said distal piston including a closed wave-shaped groove in a circumferential surface thereof which receives at least one stationary pin fixed to an inner portion of said distal end of said catheter, whereby said piston simultaneously moves longitudinally and rotationally in response to said longitudinal reciprocating motion; and

a cutting head, said cutting head being attached to said distal piston for simultaneous longitudinal and rotational movement together with said distal piston.

2. A device for removal of intraluminal occlusions as claimed in claim 1, wherein said cutting head is positioned within the distal end of the catheter so that at a one position of a path of its longitudinal motion said cutting head is within a distal end of said catheter and at another position of the path of its longitudinal motion said cutting head extends beyond the distal end of said catheter.

3. A device for removal of intraluminal occlusions as claimed in either claim 1 or 2, wherein said cutting head includes at least one cutting blade.

4. A device for removal of intraluminal occlusions as claimed in any one of claims 1 to 3, wherein said catheter includes a chamber between said distal piston and said cutting head for receiving material cut by said

AUSTRALIAN PATENT OFFICE

cutting head and said cutting head includes at least one through bore through which the cut material can pass into said chamber.

5. A device for removal of intraluminal occlusions as claimed in claim 4, wherein said chamber is connected to a passage which extends to said proximal end of said catheter.

6. A device for removal of intraluminal occlusions as claimed in any one of claims 1 to 5, wherein said catheter includes a guide wire which extends through said distal piston and said cutting head.

7. A device for removal of intraluminal occlusions as claimed in claim 6, wherein said guide wire extends beyond said distal end of said catheter.

8. A device for removal of intraluminal occlusions as claimed in claim 6, wherein said catheter includes a branched fitting near said proximal end thereof and said guide wire enters said catheter through said branched fitting.

9. A device for removal of intraluminal occlusions as claimed in claim 8, wherein said branched fitting includes means to secure said guide wire.

10. A device for removal of intraluminal occlusions as claimed in any one of claims 1 to 9, wherein a pump means is provided at said proximal end of said catheter for applying fluid pressure to said distal piston for driving said distal piston.

11. A device for removal of intraluminal occlusions as claimed in claim 10, wherein said pump means comprises a reciprocating pump means.

AUSTRALIAN PATENT OFFICE

12. A device for removal of intraluminal occlusions as claimed in either claim 10 or 11, wherein said pump means comprises dual pumping means to apply fluid pressure to said distal piston for driving said distal piston and for applying a vacuum to aspirate material cut by said cutting head from said distal end of said catheter.

13. A device for removal of intraluminal occlusions as claimed in claim 12, wherein said pump means includes a single piston which performs said dual pumping.

14. A device for removal of intraluminal occlusions as claimed in claim 12, wherein said pump means includes a chamber for collecting material aspirated from said distal end of said catheter.

15. A device for removal of intraluminal occlusions as claimed in any one of claims 10 to 14, wherein said pump means is attached to a support block through which a guide wire passes.

16. A device for removal of intraluminal occlusions as claimed in claim 15, wherein said support block includes means to secure said guide wire.

17. A method for removing intraluminal occlusions which comprises:

providing a catheter having a distal end for insertion into a patient with a cutting head for simultaneous longitudinal and rotational movement;

inserting said distal end of said catheter into a lumen of a patient while maintaining said cutting head within said distal end of said catheter;

positioning said distal end of said catheter near an object to be removed and;

causing said cutting head to simultaneously move

AUSTRALIAN PATENT OFFICE

in both a longitudinal and a rotational movement so as to extend from said distal end of said catheter and cut said object to be removed, said step of causing including the steps of applying a pulsatile driving force to said cutting head to cause said cutting reciprocate longitudinally, and rotating said cutting head in response to longitudinal reciprocation of the cutting head, whereby said cutting head simultaneously moves longitudinally and rotationally in response to said longitudinal reciprocating motion.

18. A method of removing intraluminal occlusions as claimed in claim 17, further including the step of collecting material cut by said cutting head in a chamber provided in said distal end of said catheter behind said cutting head.

19. A method of removing intraluminal occlusions as claimed in claim 17, further including the step of aspirating material cut by said cutting head and removing said aspirated material from a proximal end of said catheter.

20. A method as claimed in claim 17:

wherein said step of applying a pulsatile driving force includes applying said force to a piston secured to said cutting head and disposed in a chamber of said device; and

wherein said step of rotating comprises projecting a pin, positionally fixed relative to said chamber, radially into said chamber and into a closed wave-shaped groove defined circumferentially in said piston to guide said piston rotationally as the piston moves longitudinally.

21. A device for removal of intraluminal occlusions comprises:

a catheter having a distal end for insertion into

AUSTRALIAN PATENT OFFICE

a patient and a proximal end;

a distal piston located within said distal end of said catheter for simultaneous longitudinal and rotational movement therein, said distal piston including at least one stationary pin fixed thereto which is received in a closed wave-shaped groove formed in an inner surface of said distal end of said catheter;

and

a cutting head attached to said distal piston for simultaneous longitudinal and rotational movement together with said distal piston, whereby said piston simultaneously moves longitudinally and rotationally in response to longitudinal reciprocating motion of said piston.

22. A device for removal of intraluminal occlusions comprising:

a catheter having a longitudinal axis and a distal end adapted for insertion into a passage in a patient's body;

a driven member located within said catheter;

means for simultaneously reciprocating said driven member longitudinally in said catheter and rotating said driven member about said longitudinal axis; and

a device head secured to said driven member for reciprocation longitudinally and rotating therewith, said device head projecting from said distal end when reciprocating longitudinally and rotating to remove occluding material from said passage in the patient's body;

wherein said means comprises:

driving means for longitudinally reciprocating said driven member within said catheter; and

further means responsive to longitudinal reciprocation of said driven member for rotating said driven member about said longitudinal axis, whereby said driven member simultaneously moves longitudinally and rotationally in response to said longitudinal reciprocation.

AUSTRALIAN PATENT OFFICE

23. A device as claimed in claim 22 wherein said further means comprises:

a closed wave-shaped groove defined circumferentially in said driven member; and

a stationary pin projecting radially into said groove to cause said piston, while longitudinally reciprocating, to rotate as said pin rides along said groove, whereby said driven member simultaneously moves longitudinally and rotationally in response to said longitudinal reciprocation.

24. In a device for removing intraluminal occlusions, a method of simultaneously reciprocating a cutting head longitudinally and rotating the reciprocating cutting head, said method comprising the steps of:

longitudinally reciprocating said cutting head by applying a pulsating force to said device; and

in response to longitudinal reciprocation of said cutting head, directing said cutting head rotationally about its longitudinal axis, whereby said cutting head simultaneously moves longitudinally and rotationally in response to longitudinal reciprocation.

25. A device for removal of intraluminal occlusions substantially as herein before described with reference to Figures 1 to 3 or to Figure 4 or to Figure 5 or to Figure 6 or to Figure 7 of the accompanying drawings.

26. A method for removal of intraluminal occlusions substantially as herein before described with reference to Figures 1 to 3 or to Figure 4 or to Figure 5 or to Figure 6

AUSTRALIAN PATENT OFFICE

or to Figure 7 of the accompanying drawings.

Dated this 10th day of September 1997
IRA C EDELL
By their Patent Attorneys
GRIFFITH HACK
Fellows Institute of Patent
Attorneys of Australia

AUSTRALIAN PATENT OFFICE

68140/94

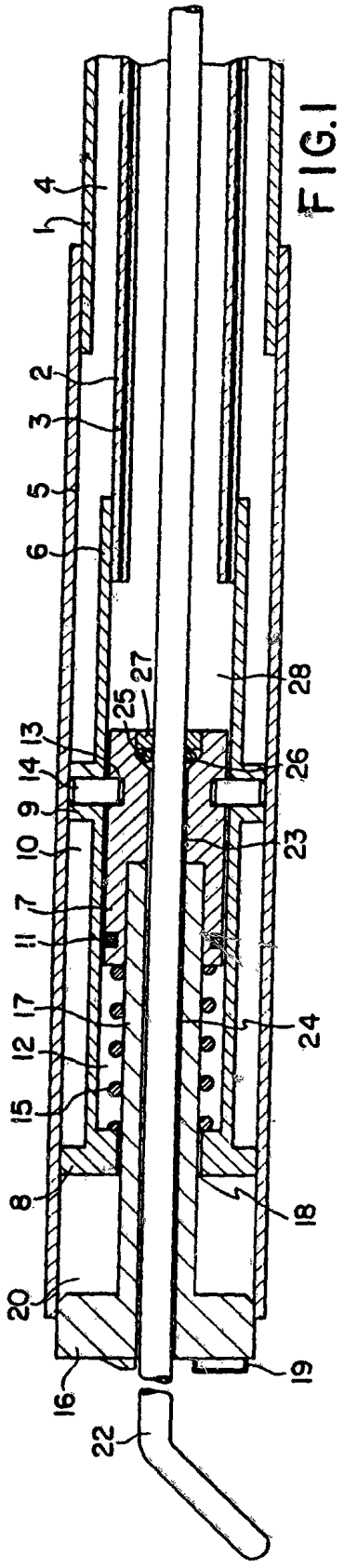


FIG.1

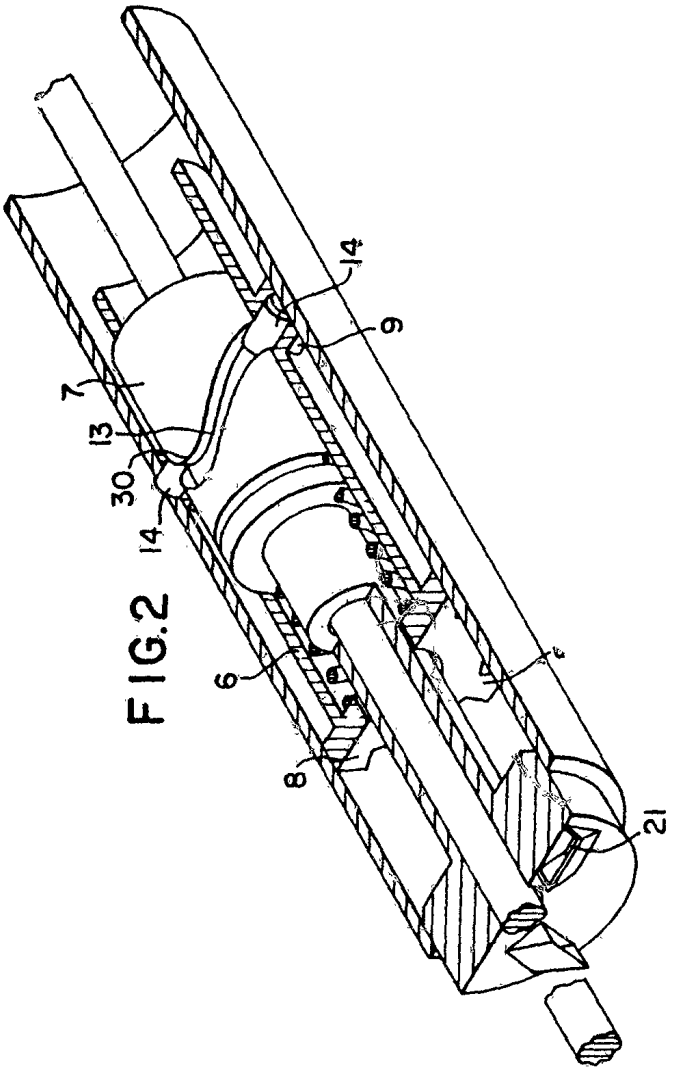


FIG.2

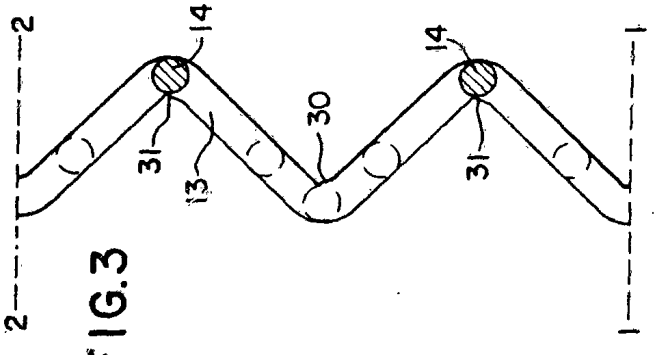


FIG.3

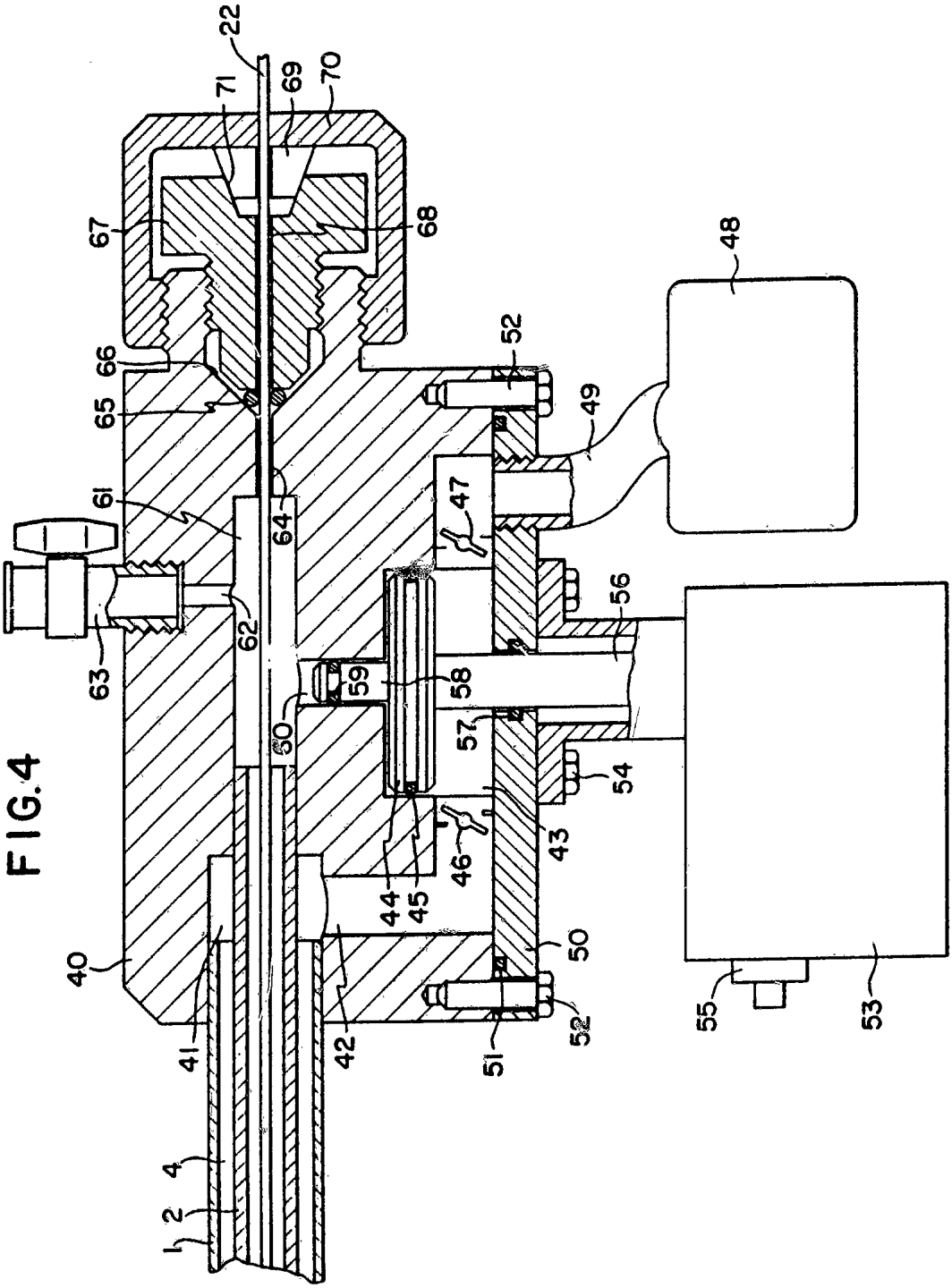

22
71
69
70
67
68
48
52
66
65
49
61
64
47
56
62
63
59
58
60
57
54
43
46
44
45
50
40
41
42
51
52
55
53
4
2
1

FIG.4

FIG.5

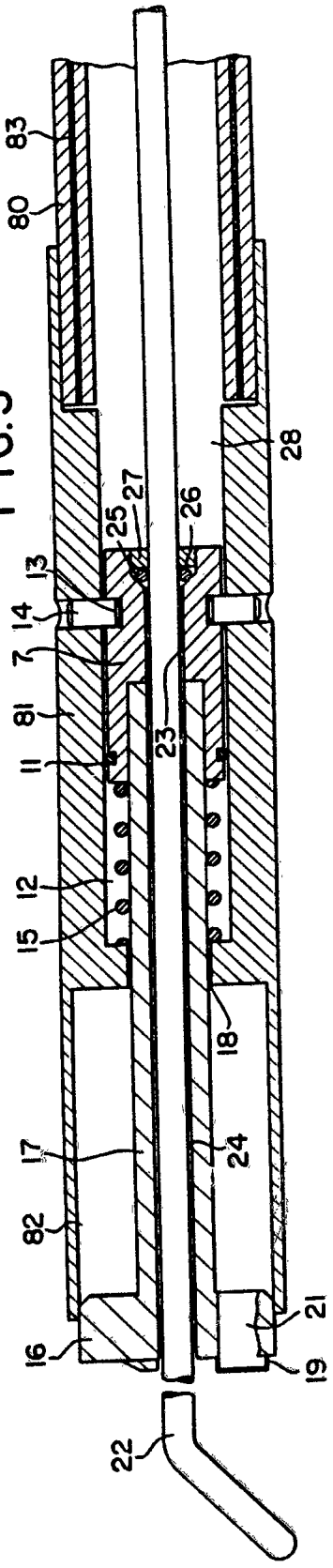

83
80
28
27
25
26
13
14
7
81
11
23
12
15
18
17
24
82
21
16
19
22

FIG.6

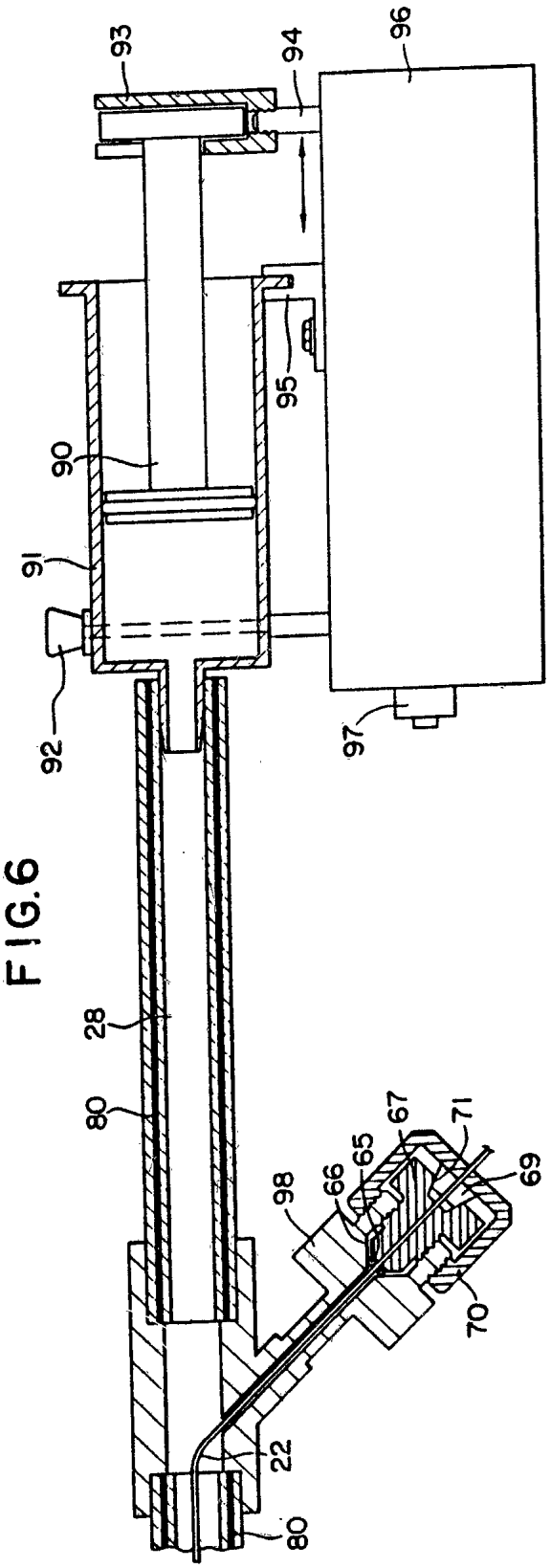
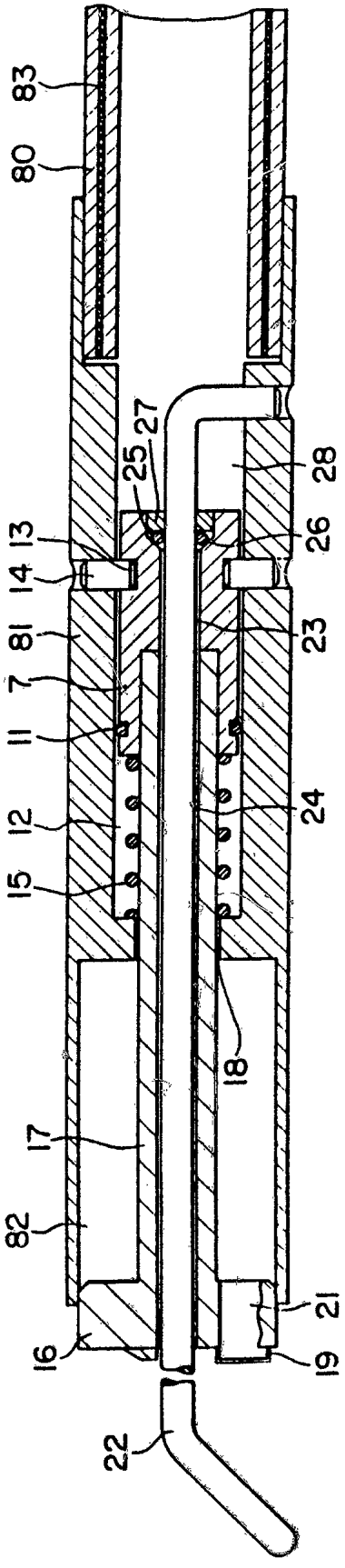

93
94
96
95
90
91
92
97
28
80
67
71
65
66
98
69
70
22
80

FIG.7



INTERNATIONAL SEARCH REPORT

International application No.
PCT/US94/03439

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61B 17/32
US CL :606/159, 171, 180

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 16/104.05, 104.14-104.16; 128/751, 755; 604/22; 606/159, 170, 171, 180

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

NONE

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

NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US, A, 4,749,376, (KENSEY ET AL.), 07 June 1988. See entire document.	1-20
A	US, A, 4,923,462, (STEVENS), 08 May 1990. See entire document.	1-20
A	US, A, 5,195,956, (STOCKMEIER), 23 March 1993. See entire document.	1-20

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be part of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 19 DECEMBER 1994	Date of mailing of the international search report JAN 25 1995
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer WILLIAM LEWIS Telephone No. (703) 308-0060

Form PCT/ISA/210 (second sheet)(July 1992)*