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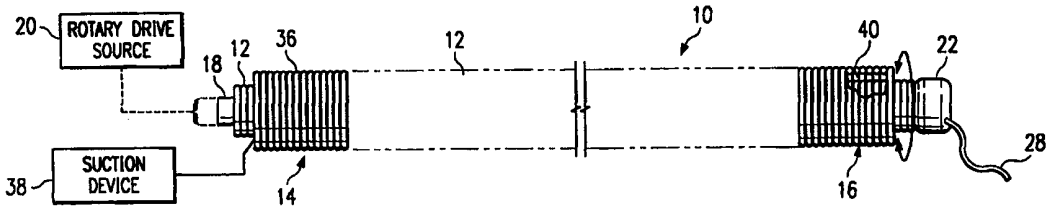

(57) Abstract

A device for transporting and dissolving friable/coagulated tissue and/or fluid from within a human body, such transportation and dissolution being achieved through the rotational interaction between a drive member and an encompassing member. A substantially helical fluid flow path is defined by ridges formed about both an outer periphery of the drive member and an inner periphery of the encompassing member. Rotation of the drive member induces proximal fluid flow as well as matter dissolution along the encompassed length of the flexible drive member.

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MEDICAL DEVICE FOR THE TRANSPORTATION AND DISSOLUTION OF FLUID AND MATTER FROM WITHIN THE HUMAN BODY

FIELD OF THE INVENTION

The present invention relates to a medical device to transport fluid and friable or coagulated tissue from within the environment of the human body, and in particular, to a medical device to evacuate fluid and solid/semi-solid tissue from a site within the human body and further dissolve the evacuated tissue during its transportation.

BACKGROUND OF THE INVENTION

A variety of medical devices are known to facilitate the physical destruction and removal of obstructive tissue (e.g., vascular plaque and thrombotic occlusions) or living tissue (e.g., the lining of a Fallopian tube for purposes of sterilization). A class of these devices include a motor, for providing a rotary drive, a cutting tip, and a drive shaft spanning therebetween.

The cutting tip of known devices commonly features a rigid or semi-rigid cutting portion. The cutting portion is used to destroy tissue positioned distal to the device. In addition to, or as an alternative, known devices may also incorporate whips or fibers positioned about a longitudinal, outer periphery of the device. The whips and fibers are intended to engage tissue which surrounds the longitudinal outer periphery of the device. Commonly, the cutting portions, whips, and fibers are constructed of a material sufficient to destroy friable and coagulated tissue as well as surrounding living tissue.

With regard to those devices having rotating or moving whips/fibers, the whips/fibers are commonly predisposed in a substantially normal orientation relative to the device, or they are caused to assume such orientation through the rotation of the device. Known devices of this nature include stiff bristles rotated at slow speeds to gather cell samples or to permanently entangle a thrombus. These devices have particular application in removing deposits or tissue surrounding the diametrical periphery of the bristles but have little

use in engaging material or tissue positioned distal to the device.

Rigid or semi-rigid cutting portions which are intended to engage material or tissue positioned distal to the cutting portion traditionally include aggressive rotating prongs, drill tips, or blade-like elements. For these devices, a user must precisely control the longitudinal movement of the device to achieve a desired depth of cut and avoid damage to surrounding tissue; however, because known devices tend to obstruct the view of the operator, if any, when in use, the necessary degree of control may be unachievable. Further, the cutting portions of these conventional devices do not include that which would prevent the destruction of living tissue, i.e., the cutting surfaces are equally suited to engage and destroy living tissue as well as other tissue or material (for example, blood deposits, thrombi, plaque, and the like). Guards, baskets, or shields can be incorporated to protect viable tissue from destructive cutters; however, visibility, compactness, and the effectiveness of the device can be compromised. Moreover, failure of a tissue protecting guard may precipitate the infliction of instant and severe trauma.

Consequently, a need exists for an intrinsically safe medical device permitting distally-positioned friable or coagulated tissue to be confronted and lysed, or dissolved, while avoiding the destruction of surrounding tissue or material. A further need exists for a device having at least one flexible member, such member generating a lysing zone which conforms to its operating environment and, when used with an endoscope, is transparent, planar, and normal to the distal tip of

an endoscope to enable direct visualization of both targeted and surrounding tissue. Even with a device to satisfy these needs, a further need exists for a device capable of forcibly removing fluid as well as partially lysed tissue (including tissue particles) from the lysing site.

A device consistent with the above needs would have a plurality of applications. As an example, an uncleared fundal pool of retained blood in a stomach can preclude complete visualization of the stomach interior during endoscopic evaluation. In cases of acute upper gastrointestinal bleeding, the inability to clear a fundal pool of clotted blood in the stomach at the time of emergent upper endoscopy can result in patient morbidity and mortality. Accordingly, a need exists for a device to clear a stomach fundus of blood and other fluids and materials in patients undergoing urgent endoscopy for acute upper gastrointestinal bleeding.

As another application example, thrombotic occlusions can result in myocardial infarctions (i.e., coronary occlusions) and strokes (i.e, cerebral occlusions). While in an emergency or in an instance that such occlusions cannot readily be treated with drugs, a need remains for a device to allow such thrombotic occlusions to be rapidly and safely removed without traumatizing the surrounding tissue.

With regard to the removal of solid and semi-solid tissue following lysing, atherectomy cutters and other devices designed to remove obstructive tissues such as a thrombus, an embolism, or a massive clot in the stomach, tend to produce liquid plus a range of resultant tissue

particles, including some that are large. Conventional suction of this mixture for removal and subsequent transport is frequently impossible when these particles clog a conventional, small-bore suction catheter or an endoscope working channel.

While conventional techniques include rotation of a patterned shaft within the bore of the suction catheters, this technique is susceptible to entrapping smaller tissue particles and obstructing the path of the suction catheter. In this instance, the trapped tissue merely rotates along the interior surface of the suction catheter but does not displace axially, thus preventing the transport of either tissue particles or fluid from the bodily region. Moreover, this assembly may prevent the admission and transport of larger tissue particles.

SUMMARY OF THE INVENTION

The present invention is directed to a mechanical device for transporting friable/coagulated tissue and fluid from within a human body. According to one aspect of the present invention, the device includes a drive member having a proximal end, a distal end, and a substantially helical path defined therebetween. The proximal end of the drive member is adapted to engage a rotary drive source. The device further includes a flexible member having one or more ridges formed along an inner diameter thereof, where the flexible member receives and encompasses at least a portion of the drive member. In operation, rotation of the drive member causes fluid/tissue to be drawn into an annular channel formed by the flexible member and the drive member.

In another embodiment, the drive member of a mechanical device for transporting friable/coagulated tissue and fluid from within a human is received and encompassed by a coil member. The coil member has a winding in a first spiral direction. For different aspects of this embodiment, the spiral direction of the coil member may be consistent with or counter to the direction of the substantially helical path of the drive member.

An object of the present invention is to overcome the limitations of those devices and instruments currently known so as to enable the performance of desired medical procedures.

Another object of the present invention is to provide a mechanical device for dissolving friable or

coagulated material within the human body, wherein the device can be positioned within, for example, a biopsy channel of a conventional endoscope. Moreover, this object further includes the ability to position the present invention after the insertion vehicle is positioned within the patient, thus minimizing patient discomfort, risk, and the time necessary to prepare the insertion device prior to placement within a patient.

Another object of the present invention is to provide a mechanical device for dissolving friable or coagulated tissue within the human body, where when such device is positioned within a biopsy channel of a conventional endoscope and operated, the device does not obstruct the field of view of the image sensing device of the hosting endoscope but allows full visibility of the dissolving zone in real time.

Another object of the present invention is to provide an intrinsically safe mechanical device for lysing friable or coagulated material within the human body, wherein a lysing member is suitable for dissolving engaged friable or coagulated material through shear and/or wear but is ill-suited for destroying surrounding living tissue.

Another object of the present invention is to provide a mechanical device for lysing plaque-like material on the walls of vessels within the human body.

Another object of the present invention is to provide an embodiment of the mechanical device for dissolving friable or coagulated tissue within a vessel,

wherein a lysing member automatically conforms during operation to an inner diameter of the vessel.

Another object of the present invention is to provide a mechanical device for the reliable removal and transport of lysed tissue particles and which further resists clogging.

Other objects and advantages of the present invention will be apparent to those of ordinary skill in the art having reference to the following Specification together with the drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Referring now to the drawings in which like reference numerals and letters indicate corresponding elements throughout the several views, if applicable:

Figure 1 is a mechanical device in accordance with a first embodiment of the present invention;

Figure 2 is a partial sectional view of a distal end portion of a mechanical device in accordance with another embodiment of the present invention;

Figure 3 is a perspective view of an alternative lysing member for the present invention;

Figure 4 is a partial sectional view of a mechanical device in accordance with another embodiment of the present invention;

Figure 5 illustrates an application of one embodiment of the mechanical device of the present invention;

Figure 6 illustrates an application of another embodiment of the mechanical device of the present invention;

Figure 7 illustrates an application of yet another embodiment of the mechanical device of the present invention; and

Figure 8a and 8b are sectional views of alternative embodiments of the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Figure 1 illustrates one embodiment of mechanical device 10 in accordance with the present invention. Mechanical device 10 includes flexible coil member 12 having a proximal end 14 and a distal end 16. Coil member 12 is formed of a medical grade material, for example, stainless steel, nitinol, or a plastic composition. Coil member 12 may have a variable length, such length being dependent upon the nature of the procedures to be performed. If device 10 is intended to be used with an endoscope (not shown), coil member 12 shall have a length sufficient to properly extend for the length of a flexible portion of the endoscope. Coil member 12 allows extreme flexibility along its length, thus enabling device 10 to follow and assume that distortion necessary to follow tortuous paths defined by guides (for example, endoscopes, insertion catheters, or guide wires) and/or the human body. While the illustrated embodiments of coil member 12 are shown having a close-coil configuration, an alternative construction for coil member 10 (or second member 36, as will be discussed in greater detail below) includes a spaced-coil configuration, having fixed or variable pitch, to optimize performance characteristics such as flexibility, tissue transport, or torsional strength.

Fixed within the proximal end 14, mounting collar 18 is provided to engage rotary drive source 20. Rotary drive source 20 may include an electric motor or an air-driven motor. In a preferred embodiment, rotary drive source 20 is a variable speed DC motor, capable of normally producing operational rotational speeds of 500 to more than 50,000 RPM.

Tip 22 is provided at distal end 16 of coil member 12. Tip 22 may be integrally formed with, frictionally engage, or joined (for example, using an adhesive, a weld, or the like) to coil member 12. Tip 22 may assume a conventional configuration and comprise any of a plurality of known rigid or semi-rigid cutting portions or known whip/fiber portions, as discussed above. In a preferred embodiment, however, tip 22 generally assumes a blunt form. Tip 22 serves to protect soft, internal tissue from the distal end 16 of coil member 12. As shown in Figure 2, passage 24 may extend through tip 22. Passage 24 is axially aligned with a generally longitudinal passage 26 of coil member 12. Tip may be alternatively solid or integrally formed of coiled wire (not shown).

For this preferred embodiment, extending from tip 22 are one or more members 28. Members 28 may be mono-filaments (Figure 1), stranded filaments (Figure 2), or a tape-like member (Figure 4). Alternative forms for member 28 could include flexible pre-formed shapes, for example, a thin-member, tapered helix formed from a plastic material or a coated filament (Figure 3), the coating being applied so that the stiffness of the filament decreases distally. For the latter configuration, the coating material could be of such a nature as to dissolve or the like to enable operational behavior consistent with non-coated filament members 28. Operationally, the tapered helix members 28 could be operated at low rotational speeds to spirally penetrate material/tissue to be dissolved, and then the rotational speed increased to enable the dissolution of the penetrated material/tissue.

For the preferred embodiment, members 28 are formed from a high density, fibrous material, for example, oriented, expanded polytetrafluoroethylene (PTFE) thread or Teflon® filament. Members 28, such as those shown in Figures 1 and 2, have a diameter of between approximately 0.025 mm and 0.510 mm.

Rotated members 28 create a largely planar dissolving zone having a diameter of up to two times the length of members 28 and a depth as little as the width of members 28. In operation, the high-speed rotation of members 28 shear fluid-based material or coagulated tissue to create a thin, planar zone of vortex-like turbulence. The shearing of members 28 as well as such turbulence cause the substantive material of fluid-based material or coagulated tissue to be torn apart and, effectively, dissolved.

Members 28 may also be formed with or later receive certain abrasive material, for example, microscopic diamond or sapphire crystals. These embodiments enable members 28 to dissolve tissue/material responsive to abrasive removal, for example, calcified arterial plaque, during rotation.

Members 28 are positioned relative to tip 22 (on a distal face) so that when coil member 12 is rotated, distal ends of members 28 extend beyond tip 22. The lithe nature of members 28, coupled with the drag of high-speed rotational contact with the tissue being dissolved as well as the positioning of members 28 relative to tip 22, prevents members 28 from assuming a substantially normal orientation relative to coil member 12 when coil member 12 is rotated. Instead, as a

function of their flexibility and length for at least one embodiment, members 28 assume a generally spiral shape about a longitudinal axis of coil member 12, thus creating a vortex-inducing path through the material/tissue being dissolved and/or allowing a greater proportion of the length of abrasive members 28 to come in contact with tissue/material to be dissolved.

The effective diameter of the spiral geometry of members 28 can be established by the operating environment as well as the operational parameters of device 10. "Operational parameters" may include the composition of the dissolving material; feed rate of tip 22 into the tissue; length, composition, and number of members 28; and the rotational speed of device 10. For vascular-type environments, for example, the maximum rotational diameter assumed by members 28 is defined by an inner vessel diameter; provided, however, the inner vessel diameter is equal to or less than two times the length of members 28.

While Figures 1 and 4 illustrate members 28 being fixed to preferred tip 22, Figure 2 illustrates an alternative embodiment. Member 28 passes through aperture 30 in tip 22 and extends proximally to proximal end 14. For this embodiment, member 28 may be extended and retracted during the course of insertion, conducting a procedure, or withdrawal in accordance with the desires of a user. To facilitate extension and withdrawal, members 28 may be provided with a rigid portion (not shown) at the proximal end 14 which may extend for a length distally.

In reference to Figures 1 and 2, tubing 32 is provided to deliver fluid, for example, pressurized air, water or saline, or a tissue dissolving fluid to distal end 16. A proximal end of tubing 32 is coupled to pressurized fluid source 34, and a distal end of tubing 32 extends into passage 24 formed in tip 22. It is preferred that tubing 32 remain substantially static relative to the rotation of coil member 12; however, in at least one embodiment, tubing 32 rotates with coil 12 and may also be constructed integral with coil 12.

Figure 4 illustrates another embodiment of the present invention. While device 10 maintains structure similar to that described above, device 10 of this embodiment further includes second member 36. Second member 36 is shown as a coil similar to that of coil member 12 and may include a thin, fluid impermeable sheath or membrane 27 encompassing its outer surface (Figure 2). As shown in Figures 6, 8a, and 8b, second member 36 may alternatively take the form of tubing or the like having characteristics in accordance with the features and functionality discussed below.

A distal end of second member 36 is positioned at or about distal end 16. A proximal end of second member 36 is coupled to suction device 38. Operatively, it is preferred that second member 36 remain substantially static relative to the rotation of coil member 12.

Second member 36 has an inner diameter substantially equal to or slightly greater than the outer diameter of coil member 12. Accordingly, annular channel 40 is formed between coil member 12 and second member 36. Rotation of coil member 12 in a direction consistent with

the winding of coil member 12 facilitates fluid and tissue particles to be drawn into channel 40 at distal end 16 and moved proximally to proximal end 14. In the preferred embodiment, the proximal movement of fluid and tissue is enhanced through second member 36 having a winding in a direction opposite of that of coil member 12. Where second member 36 is tubing, one or more helical or axial ridges 37 (Figure 7) or recesses may be formed within the bore of second member 36, for example, a helical groove spirals in a direction opposite to the winding of coil member 12.

Through rotation of coil member 12, the outer diameter of coil member 12 comes in contact with the inner diameter of second member 36. At greater rotational speeds, such contact produces strong pressure pulses which facilitate the proximal movement of fluid and tissue particles within channel 40. These pressure pulsations also serve to actively and aggressively dislodge any tissue which may tend to clog channel 40. The contact of individual coils of coil member 12 with individual coils (or groove surfaces) of second member 36 introduces a scissor-like, shear action in a direction traverse to the longitudinal direction of channel 40. This shear effect serves to dissolve that tissue/material drawn into channel 40. Moreover, whether rotary drive source 20 is moveable or selectively imparts movement, coil member 12 is axially moveable relative to second member 36.

To further increase the drawing effect and/or the dissolving interaction of coil member 12 and second member 36, the individual coils may have specialized cross-sectional shapes or may include sharpened

peripheral, interactive surfaces. Specifically, in addition to common circular or elliptical cross-sections (Figure 4), other embodiments could feature diamond cross-sections (Figure 2) or trapezoidal cross-sections (not shown).

Fluid and tissue which is drawn proximally through channel 40 may be carried away from device 10 using suction device 38. In addition to merely removing that fluid/material carried proximally through the relationship of coil member 12 and second member 36, suction device 38 may communicate a drawing force distally along the length of channel 40 to augment the interactive pumping action of members 12, 36.

Tubing 32 may be modified for device 10 of Figure 4 to further its material/tissue removing operations. Whether tip 22 is provided with passage 24 (Figures 1 and 2) or not, it is preferred that tubing 32 include one or more orifices (not shown) along its longitudinal length to dispense fluid, pressurized or otherwise, for the purpose of preventing blockages from forming, or clearing blockages which do form, in channel 40. As coil member 12 is preferably an open, spiral of material, coil member 12 is readily capable of passing fluid which has been delivered therein, outward into channel 40.

Discussing exemplary applications of the various embodiments of device 10 set forth above, the following discussion will focus, in turn, on device 10 being used with a suction/irrigation tube, as a flexible drainage tube, as a fundal blood pool evacuation device, and as a thrombotic occlusion removal device. While these applications are examples of possible use, one skilled in

the art will appreciate that further applications exist which would benefit from the unique features of the present invention.

In reference to Figure 5, device 10 having a semi-rigid shaft 12', for example, a conventional guide wire, is positioned within that portion of a suction/irrigation tube 50 which is inserted within a patient, for example, during surgery. Without device 10, suction of fluids and tissue material can result in the obstruction of inlets 52 and/or the central passage 54. In contrast, operation of device 10 within the suction/irrigation tube clears and/or prevents the formation of obstructions through shear and/or wear.

Depending upon the application, shaft 12' may be rigid. While shaft 12' may intrinsically possess an outer surface with a pattern (e.g., a guide wire), ridges and/or protrusions may be used to form a helical path about shaft 12' to facilitate functionality consistent with coil member 12. Moreover, shaft 12', or member 12, may take a variety of cross-sectional shapes, for example, circular, rectangular (Figure 8a), elliptical (Figure 8b), or the like.

In reference to Figure 6, one aspect of the present invention is incorporated within a drainage tube, catheter, or stent. In particular, a flexible drive member 12 having a helical ridge formed along its outer periphery is positioned within perforated, blind tubular catheter or stent casing 36. Catheter 36 has internal ridges or protrusions along its inner periphery (not shown). Perforations 52, which extend through the wall of catheter 36, may be round, oval, spiral, or of another

shape to optimize flow, safety, and tissue entry. Perforations 52 may be provided at the distal end of catheter 36 or along the body of catheter 36 for a prescribed distance. For this embodiment, tip 22 with member 28 is optional. While the ridge of member 12 is illustrated as continuous, member 12 may include one or more discrete ridges which are spaced apart, extend at least partially about member 12, and are oriented so as to transverse the axis of member 12.

Catheter 36 may be inserted, for example, into a bladder or general surgical site, in a convention manner with or without member 12. Should a blockage occur which reduces drainage or fluid flow from catheter 36, member 12 may be inserted (if not already so) and rotated to clear catheter 36 or perforations 52. As member 12 may be employed on a need only basis, patients are spared the discomfort of catheter replacements or the cost of employing this device unnecessarily.

As a stomach fundal blood pool dissolution and evacuation device, device 10 is used in conjunction with a conventional endoscope (not shown). Specifically, coil member 12 is inserted through the biopsy channel of a hosting endoscope. It is preferred that device 10 be capable of insertion through the biopsy channel even after the flexible portion of the endoscope, i.e., that portion in which the biopsy channel passes, is already positioned within the body of a patient. Consequently, the greatest diameter of tip 22 and coil member 12 (Figure 1) or second member 36 (Figure 4) is less than approximately 2.8 mm.

While device 10 with second member 36 may be scaled to fit within an endoscope biopsy channel, device 10 without second member 36 may also be used. In such instance, the inner diameter of the biopsy channel will function as a smooth-bore second member 36. For purposes of the following discussion, however, device 10 will assume the characteristics of Figure 4 but having a thread-like member 28.

In the event of acute upper gastrointestinal bleeding, a pool of blood and clotted blood will accumulate in the fundus of the stomach. An uncleared fundal pool of retained blood can preclude complete visualization of the stomach interior during endoscopic evaluation. Moreover, the solid and semi-solid blood matter which may be found in the fundal pool can prevent conventional suction devices from properly clearing the pool for purposes of endoscopy.

The flexible portion of an endoscope is first inserted into the gastrointestinal system of a patient. While device 10 can be inserted into a biopsy channel of the endoscope prior to its insertion into the patient, for purposes of this example, distal end 16 of device 10 is inserted and passed through the biopsy channel following the distal end of the endoscope being positioned within the patient's stomach.

To clear the fundal pool, thus enabling an inspection of the obscured stomach lining via an image sensing device positioned within the distal end of the endoscope, distal end 16 is positioned near the fundal pool. Rotary drive source 20 is initiated and brought to an appropriate rotational speed. The rotation of member

28 lyses the blood and blood matter when positioned in contact with the fundal blood pool, thus dissolving that which would ordinarily obstruct a convention suction device.

While an independent suction device may be used to clear the fundal pool once the material therein is lysed, device 10 allows suction of the material/fluid through the rotation of member 12. More specifically, the rotation of coil member 12 with respect to static second member 36 forcibly causes fluid, dissolved tissue, and tissue particles, to be drawn into annular channel 40 and moved proximally. Suction device 38 is initiated to remove that fluid and dissolved tissue pumped to the proximal end 14.

Throughout a clearing operation, the field of view of the endoscope image sensing device is not obstructed by the rotation of member 28. High-speed rotation of member 28 causes effective transparency within the field of view. The dissolving plane is circular, planar, generally normal to the optical axis, and can be located completely within and approximately equal to the optical field of view of the endoscope. The dissolving process zone is fully visible in real time through the optics of the endoscope and may be continuously or intermittently flushed with a fluid to aid visualization. The intensity of the dissolving action may be visually monitored for effectiveness and safety and to allow intensity adjustments to match tissue conditions and the proximity of member 28/tip 22 to surrounding mucosa or stomach lining.

Following proper observation of the stomach lining, or sufficient clearing of the fundal pool, device 10 and/or the endoscope may be withdrawn from the patient.

In reference to Figure 7, as a thrombotic occlusion removal device, device 10 is inserted into a vascular system via a catheter or a conventional vascular insertion sheath (not shown). The greatest diameter of tip 22 and second member 36 (Figure 3) is less than approximately 2.0 mm.

Although device 10 may be advanced within a vascular system without the assistance of guide wire 60, the hollow nature of coil member 12 and passage 24 through tip 22 facilitate usage of guide wire 60. Guide wire 60 may be of a conventional design and/or have a radio-opaque tip that could be an enlarged end stop of conventional design for positioning and x-ray visibility, such not being critical to the structure of the present invention.

In operation, device 10 is positioned upstream of vascular obstruction or blockage 70. Care should be taken when positioning guide wire 60 so as not to disrupt vascular obstruction 70, which could prematurely cause vascular obstruction 70, or portions thereof, to flow away from the obstructed site. For the purposes of this example, vascular obstruction 70 is positioned at a narrowing of vessel 72, such narrowing being due to plaque deposits 74 or the like.

To facilitate the safe removal of thrombotic obstruction 70, second member 36 could incorporate sealing balloon 62. In use, once second member 36 is

properly positioned, sealing balloon 62 is inflated. The inflated diameter of balloon 62 is greater than the natural diameter of the receiving vessel 72, so as to create a seal, but not of such diameter so as to compromise the integrity of the vessel 72. While inflation of balloon 62 prevents or reduces blood flow through vessel 72, adverse effects associated which the induced ischemia should be no greater than that caused by the thrombotic occlusion 70 given the brief time balloon 62 is to be inflated (for example, 20-30 seconds).

Balloon 62 is a thin membrane, inflation-type balloon which conforms to the outer periphery of second member 36 when uninflated. Balloon 62 is in fluid communication with inflation lumen 64. Inflation lumen 64 opens into the balloon interior and terminates at a proximal end, such proximal end being adapted to be coupled to an inflation device (not shown), for example, a syringe. In another embodiment, a second inflation balloon (not shown) could be provided downstream of thrombotic occlusion 70, thus allowing a lysing operation between balloon 62 and the second inflation balloon.

To lyse thrombotic occlusion 70, coil member 12 is initiated and brought to a desired rotational speed. Coil member 12 can be advanced along guide wire 60 to allow member 28 to come in contact with and enter thrombotic occlusion 70. Member 28 shears thrombotic occlusion 70, thus dissolving the occlusive matter. Unlike known systems which must closely manage the size and the advancement of their "disruption assemblies" to prevent damage to vessel 72 or disturbance of deposits 74, member 28 automatically conforms to the inner diameter of vessel 72/deposits 74.

Rotation of coil member 12 with respect to static second member 36 forcibly causes fluid, tissue particles, and dissolved thrombotic occlusion 70 to be drawn into annular channel 40 and moved proximally. Suction device 38 may be initiated to remove that fluid, particles of tissue, and dissolved matter caused to be pumped to the proximal end 14 as well as to contribute to the suction of fluid/tissue material proximally.

For vascular applications, coil member 12 and tip 22 are preferably constructed of a material which facilitates the observation of device 10 through a fluoroscope when device 10 is in an operative position.

This inventions provided here relate to co-pending application, Ser. No. _____, filed May 5, 1998.

While the invention has been described herein relative to a number of particularized embodiments, it is understood that modifications of, and alternatives to, these embodiments, such modifications and alternatives realizing the advantages and benefits of this invention, will be apparent to those of ordinary skill in the art having reference to this specification and its drawings. It is contemplated that such modifications and alternatives are within the scope of this invention as subsequently claimed herein, and it is intended that the scope of the invention claimed herein be limited only by the broadest interpretation of the appended claims to which the inventors are legally entitled.

WHAT IS CLAIMED IS:

1. A mechanical device for transporting friable/coagulated tissue and fluid from within a human body, the device comprising:

a drive member having a proximal end adapted to engage a rotary drive source, a distal end, and at least one ridge formed on an outer periphery; and

an encompassing member receiving and encompassing at least a portion of the drive member, wherein the encompassing member has at least one ridge formed along an inner periphery.

2. A device in accordance with Claim 1, wherein the drive member is a coil.

3. A device in accordance with Claim 1, wherein the encompassing member is a coil.

4. A device in accordance with Claim 1, wherein the at least one ridge of the drive member and the at least one ridge of the encompassing member cooperate to define a substantially helical fluid flow path between the drive member and the encompassing member.

5. A device in accordance with Claim 1, wherein the encompassing member and the drive member define an annular channel therebetween, and the at least one ridge of the encompassing member and the at least one ridge of the drive member are adapted to operatively cooperate to dissolve matter which is within the annular channel.

6. A device in accordance with Claim 1, wherein a ridge of the driving member includes a cutting surface.

7. A device in accordance with Claim 1, wherein a ridge of the encompassing member includes a cutting surface.

8. A mechanical device for transporting friable/coagulated tissue and fluid from within a human body, the device comprising:

a drive member having a proximal end adapted to engage a rotary drive source and a distal end; and

an outer member to receive and encompass at least a portion of the drive member, wherein the outer member has at least one flow orienting feature formed along an inner periphery thereof.

9. A device in accordance with Claim 8, the encompassing member is a coil.

10. A device in accordance with Claim 8, wherein the drive member has a longitudinal passage extending through at least a portion of the drive member to enable passage of a fluid.

11. A device in accordance with Claim 10, wherein a proximal end of the passage is adapted to be coupled to a fluid source.

12. A device in accordance with Claim 8, wherein the drive member has a non-circular cross-section.

13. A device in accordance with Claim 8, wherein the outer member and the drive member define a flow channel therebetween, and the at least one flow orienting feature of the outer member and the drive member are

adapted to operatively cooperate to dissolve matter which is within the flow channel.

14. A device in accordance with Claim 8, wherein one flow orienting feature of the outer member includes a cutting surface.

15. A mechanical device for transporting friable/coagulated tissue and fluid from within a human body, the device comprising:

a drive member having a proximal end adapted to engage a rotary drive source, a distal end, and a substantially helical flow orienting feature formed therebetween; and

an outer member to receive and encompass at least a portion of the drive member, wherein the outer member has at least one flow orienting feature formed along an inner periphery of the outer member.

16. A device in accordance with Claim 15, wherein a flow orienting feature of the outer member is helical.

17. A device in accordance with Claim 15, wherein a spiral direction of the substantially helical flow orienting feature of the drive member and a winding direction of the helical flow orienting feature of the outer member are in a same direction.

18. A device in accordance with Claim 15, wherein a spiral direction of the substantially helical flow orienting feature of the drive member and a winding direction of the helical flow orienting feature of the outer member are in an opposite direction.

19. A device in accordance with Claim 15, wherein a flow orienting feature of the outer member is longitudinal.

20. A device in accordance with Claim 15, wherein the helical flow orienting feature of the drive member and the at least one flow orienting feature of the outer member are adapted to at least intermittently contact during rotation of the drive member.

21. A device in accordance with Claim 20, wherein the outer member and the driving member define an annular channel therebetween, and the at least one flow orienting feature of the outer member and the at least one flow orienting feature of the drive member are adapted to operatively cooperate to dissolve matter which is within the annular channel.

22. A device in accordance with Claim 15, wherein a flow orienting feature of the driving member includes a cutting surface.

23. A device in accordance with Claim 15, wherein a flow orienting feature of the outer member includes a cutting surface.

24. A device in accordance with Claim 15, wherein the drive member is a coil.

25. A device in accordance with Claim 15, wherein the drive member has a longitudinal passage extending through at least a portion of the drive member to enable passage of a fluid.

26. A device in accordance with Claim 25, wherein a proximal end of the passage is adapted to be coupled to a fluid source.

27. A mechanical device for transporting friable/coagulated tissue and fluid from within a human body, the device comprising:

a drive member having a proximal end adapted to engage a rotary drive source, a distal end, and a substantially helical flow orienting feature formed therebetween; and

a coil member to receive and encompass at least a portion of the drive member, the coil member having a winding in a first spiral direction.

28. A device in accordance with Claim 27, wherein the first spiral direction and a spiral direction of the helical flow orienting feature are in an opposite direction.

29. A device in accordance with Claim 27, wherein the first spiral direction and a spiral direction of the helical flow orienting feature are in a same direction.

30. A device in accordance with Claim 27, wherein the coil member has a fluid impermeable membrane about and encompassing at least a portion of its outer periphery.

31. A device in accordance with Claim 27, wherein a proximal end of the coil member is adapted to be coupled to a suction device.

32. A device in accordance with Claim 27, wherein the drive member is a coil.

33. A device in accordance with Claim 27, wherein the drive member and the coil member are adapted to at least intermittently contact during rotation of the drive member.

34. A device in accordance with Claim 27, wherein the drive member has a longitudinal passage extending through at least a portion of the drive member to enable passage of a fluid.

35. A device in accordance with Claim 34, wherein a proximal end of the passage is adapted to be coupled to a fluid source.

36. A device in accordance with Claim 27, wherein the drive member and the coil member define a flow channel therebetween, and the coil member and the at least one flow orienting feature of the drive member are adapted to operatively cooperate to dissolve matter which is within the annular channel.

37. A device in accordance with Claim 27, wherein a flow orienting feature of the driving member includes a cutting surface.

38. A device in accordance with Claim 27, wherein an inner periphery of the coil member includes a cutting surface.

39. A method of evacuating at least bodily fluid from within a human body, comprising the steps of:

providing a transport device having:

a drive member with a proximal end engaging a rotary drive source, a distal end, and a substantially helical flow orienting feature formed therebetween, and

a second member receiving and encompassing the drive member for a length, wherein the second member has at least one flow orienting feature formed along an inner periphery thereof and an annular channel is formed between the second member and the drive member for the length;

positioning a distal end of the transport device at an evacuation site within a bodily region requiring withdrawal of at least fluid therefrom; and

initiating the drive source and increasing a rotational speed of the drive source to at least a predetermined rotational speed,

wherein the drive member and the second member are adapted to draw at least fluid into and proximally through the annular channel through rotation of the drive member at the at least predetermined rotational speed.

40. A method in accordance with Claim 39, wherein the drive member and the second member are adapted to further dissolve matter drawn into and proximally through the annular channel when the drive member is rotated at the at least predetermined rotational speed.

41. A method in accordance with Claim 39, further comprising the step of providing an insertion catheter having one or more inlets, wherein the catheter receives the transport device and carries at least the distal end of the transport device to the evacuation site.

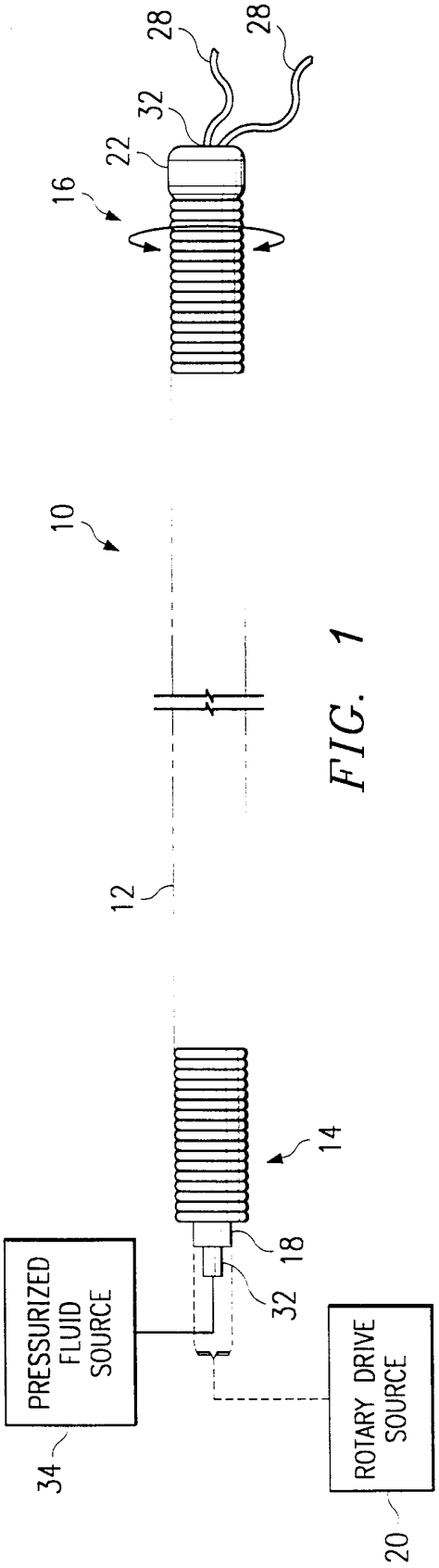

FIG. 1

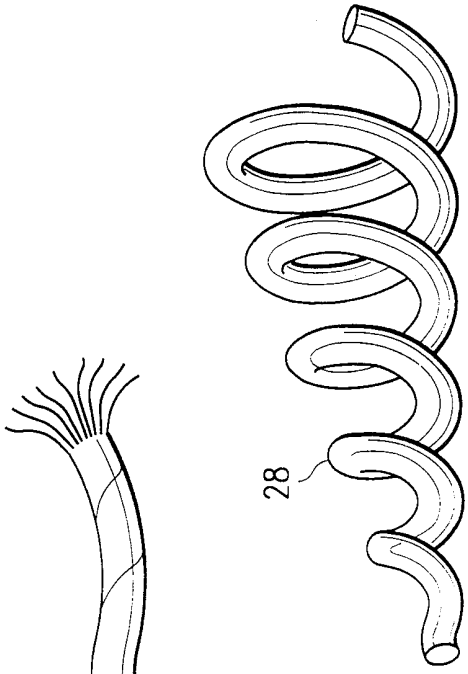

FIG. 3

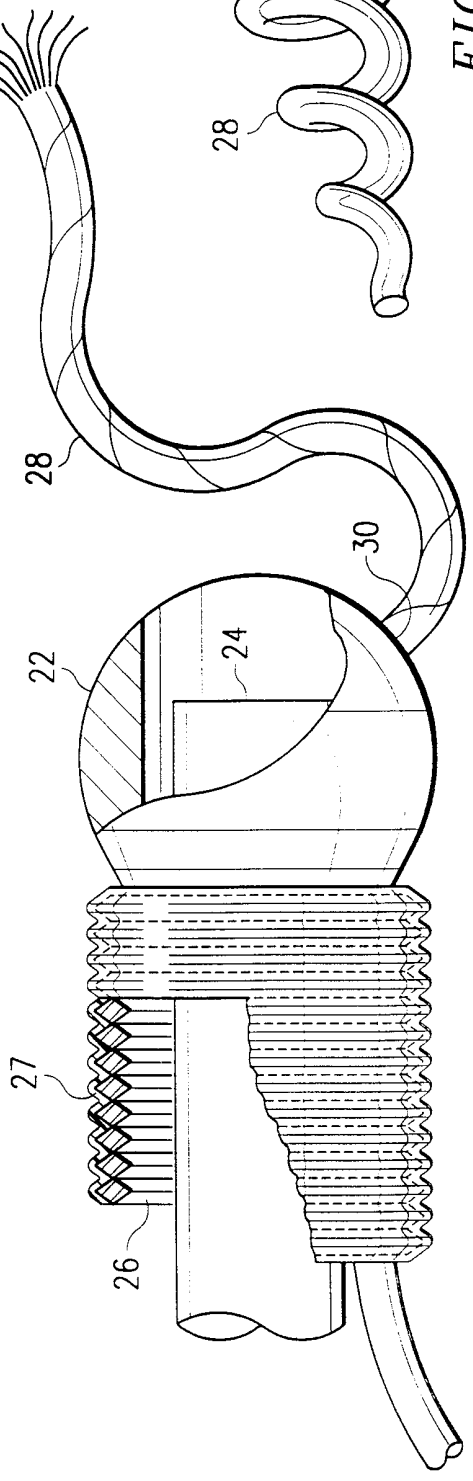

FIG. 2

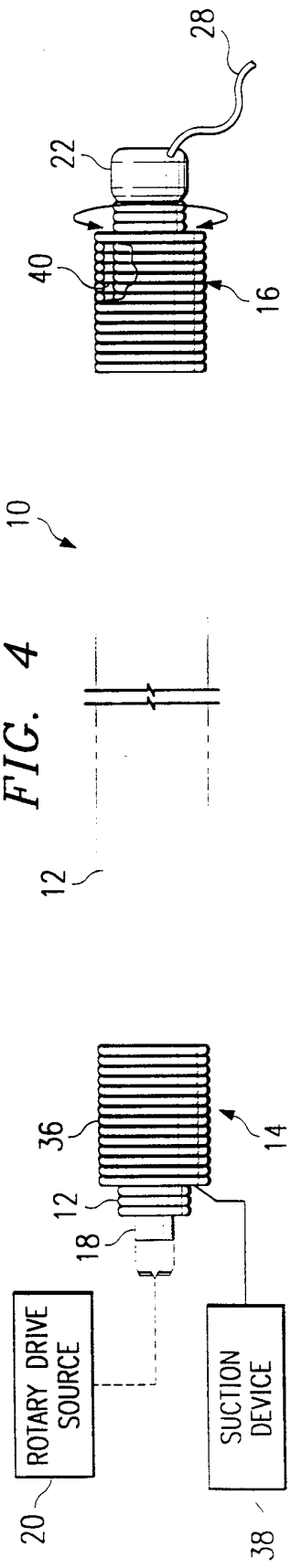

FIG. 4

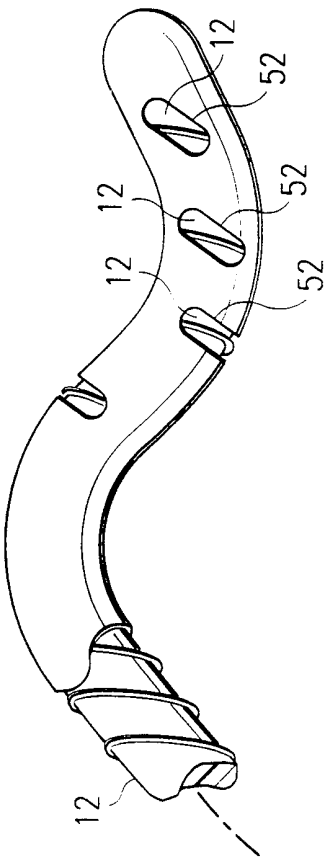

FIG. 6

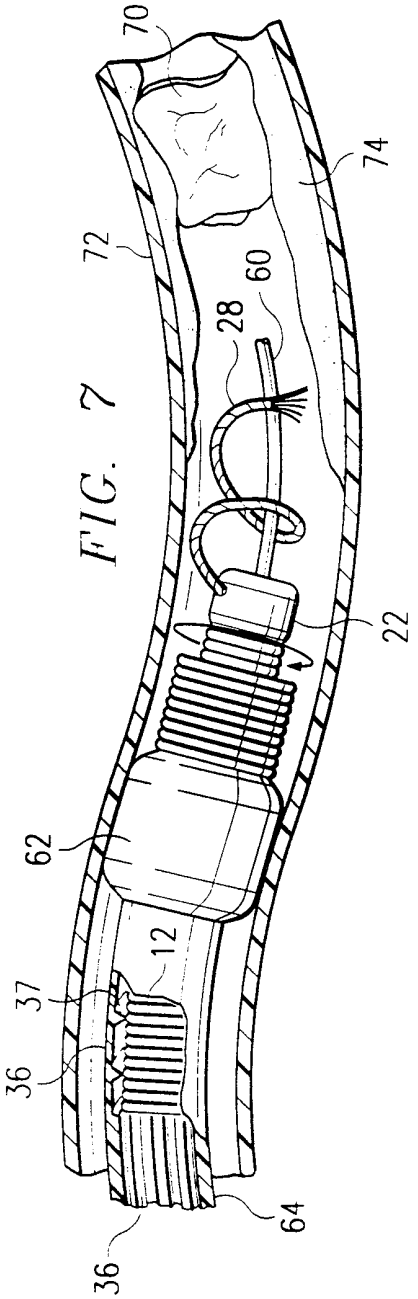

FIG. 7

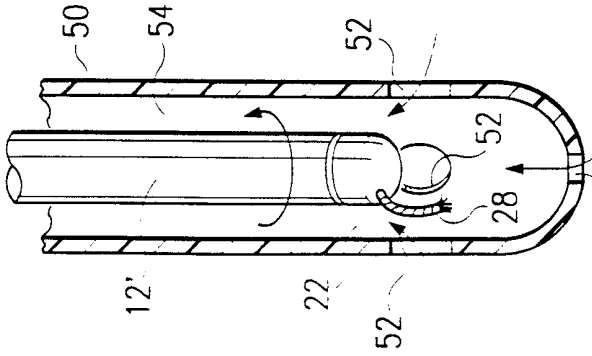

FIG. 5

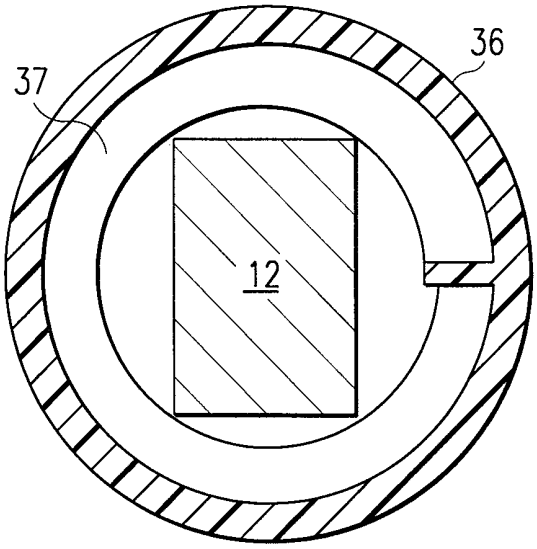

FIG. 8a

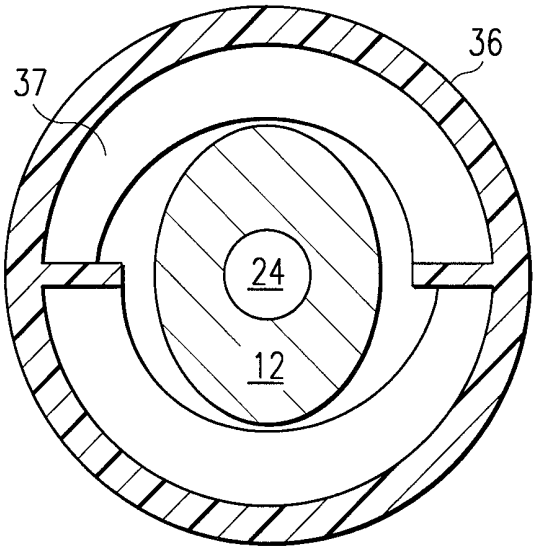

FIG. 8b

INTERNATIONAL SEARCH REPORT

Ir ational Application No
PCT/US 99/11354

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B17/22

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61B

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 94 24941 A (PX HOLDING) 10 November 1994 (1994-11-10) page 3, line 18 - page 5, line 4; figures 1-6	1,5-8, 10, 12-15, 19-23
X	US 4 061 146 A (BAEHR ET AL.) 6 December 1977 (1977-12-06) column 2, line 29 - line 58 column 3, line 23 - line 31; figure 2	1,8,15
X	US 4 857 046 A (STEVENS ET AL.) 15 August 1989 (1989-08-15) column 4, line 28 - line 42	27

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

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

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

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
12 August 1999	19/08/1999

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Moers, R

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INTERNATIONAL SEARCH REPORT

In ational Application No
PCT/US 99/11354

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 195 954 A (SCHNEPP-PESCH ET AL.) 23 March 1993 (1993-03-23) column 7, line 60 - column 8, line 13; figure 7 ---	1,8,15, 27
A	EP 0 360 791 A (KALIMAN) 28 March 1990 (1990-03-28) column 3, line 59 - line 64; figures 1-4 ---	1,8,15, 27
A	WO 96 29014 A (EVI) 26 September 1996 (1996-09-26) page 28, line 23 - page 29, line 29; figure 13 -----	1,8,15, 27

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 99/ 11354

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 39-41
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

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

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

In tional Application No
PCT/US 99/11354

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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