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Zacca et al.

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[54] **EXPANDABLE TIP ATHERECTOMY METHOD AND APPARATUS**

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Reissue of:

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Issued: **Jun. 8, 1993**
Appl. No.: **07/731,109**
Filed: **Jul. 15, 1991**

[51] **Int. Cl.**[7] **A61B 17/32**

[52] **U.S. Cl.** **606/159**; 606/170; 606/180

[58] **Field of Search** 606/159, 170, 606/171, 181; 604/22

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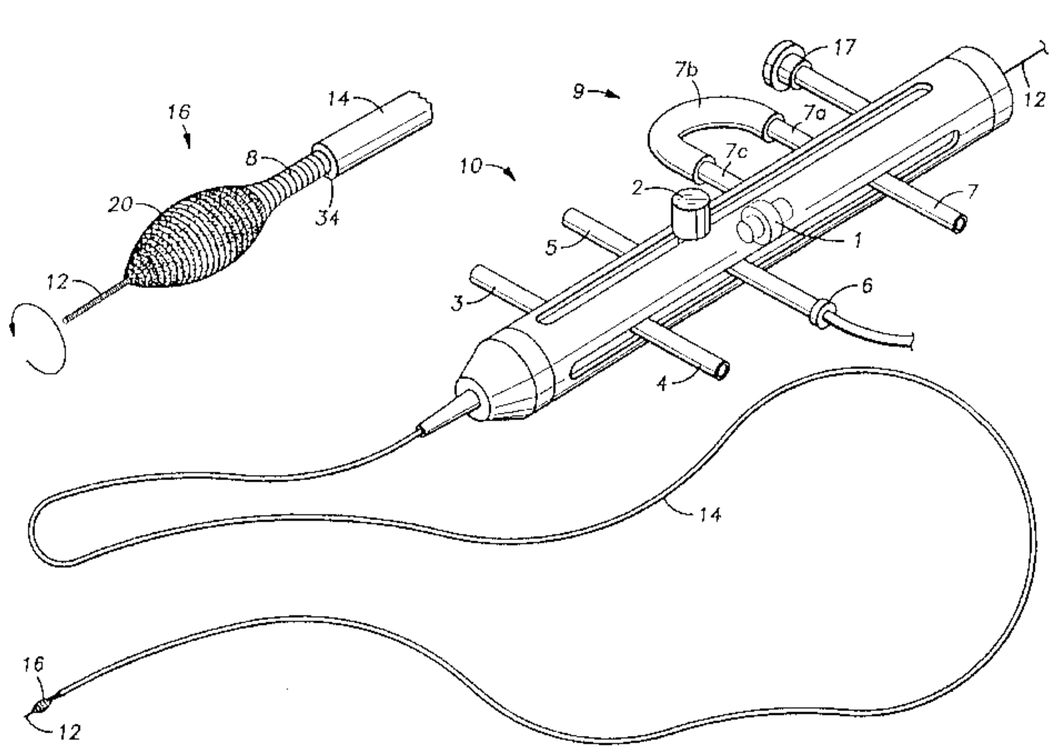
[57] **ABSTRACT**

A device for removing obstructions from vessels or small openings in the body, comprising a rotatable ablator tip which is guided to the obstruction in a reduced diameter configuration, expanded and rotated to remove the obstruction, and contracted to remove the device from the body. The variably expandable abrasive tip coil in one embodiment of the invention is actuated by a piston means disposed within the coil. A pair of collars is attached to the ends of the coil, and the piston effects relative longitudinal axial movement of the collars and, hence, the respective ends of the coil tip. When the ends of the coil tip are so moved with respect to one another, expansion and contraction of the diameter of the coil tip results. In another embodiment of the invention, the expansion tip coil is actuated by an expandable and contractible bellows means disposed within the coil, instead of the piston means. In another embodiment of the invention, the expansion and contraction of the coil tip are effected by longitudinal axial movement of an internal coil attached to one end of the coil tip, within an outer coil attached to the other end of the coil tip. In another embodiment of the invention, expansion and contraction of the coil tip are effected by an inflatable balloon disposed within the coil tip. The balloon expansion means enlarges preferably at the central portion of the coil to make a bulge.

The questions raised in reexamination request No. 90/003,360, filed Mar. 15, 1994, and 90/003,723 filed Feb. 14, 1995, have been considered and the results thereof are reflected in this reissue patent which constitutes the reexamination certificate required by 35 U.S.C. 307 as provided in 37 CFR 1.570(e).

111 Claims, 7 Drawing Sheets



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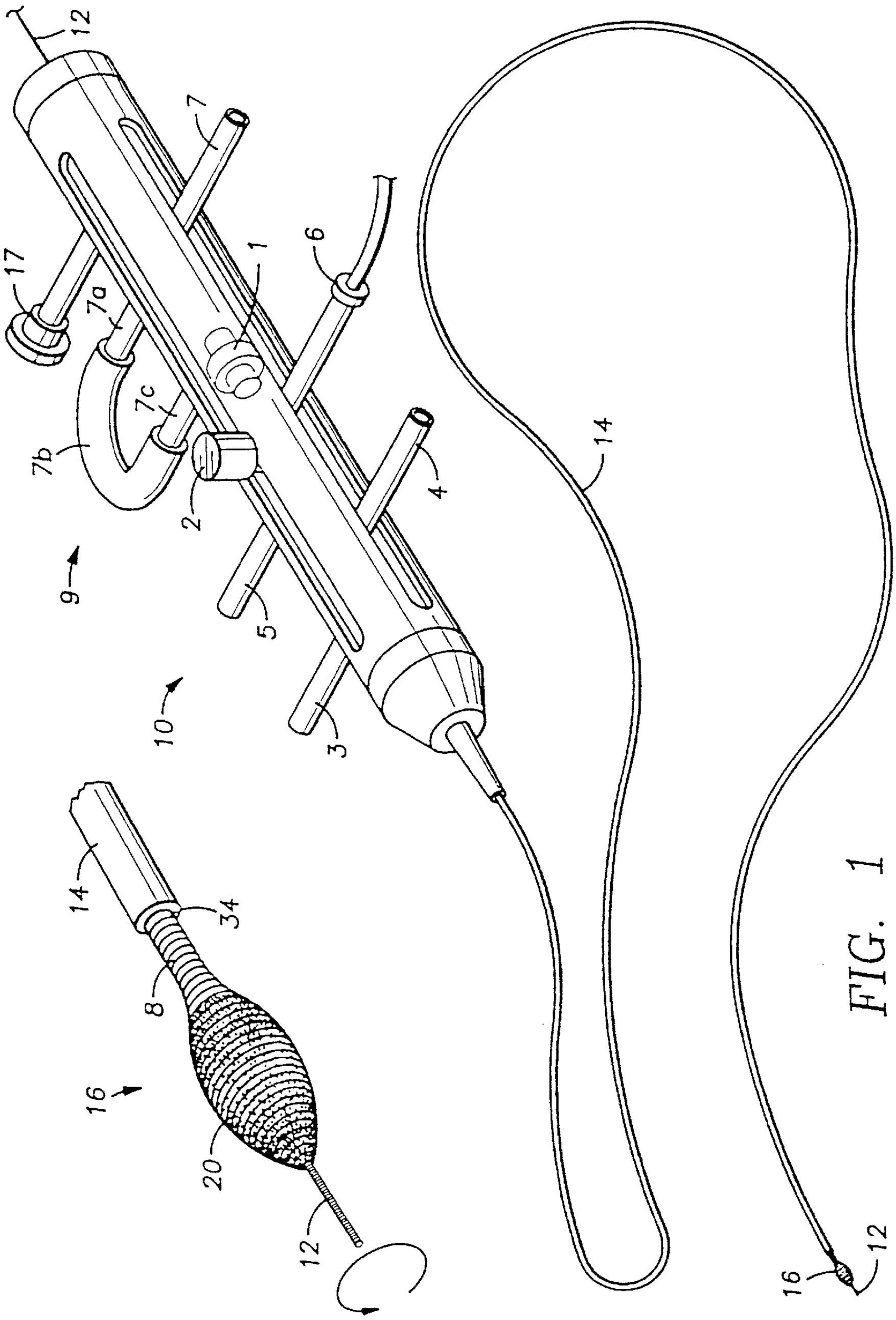

FIG. 1

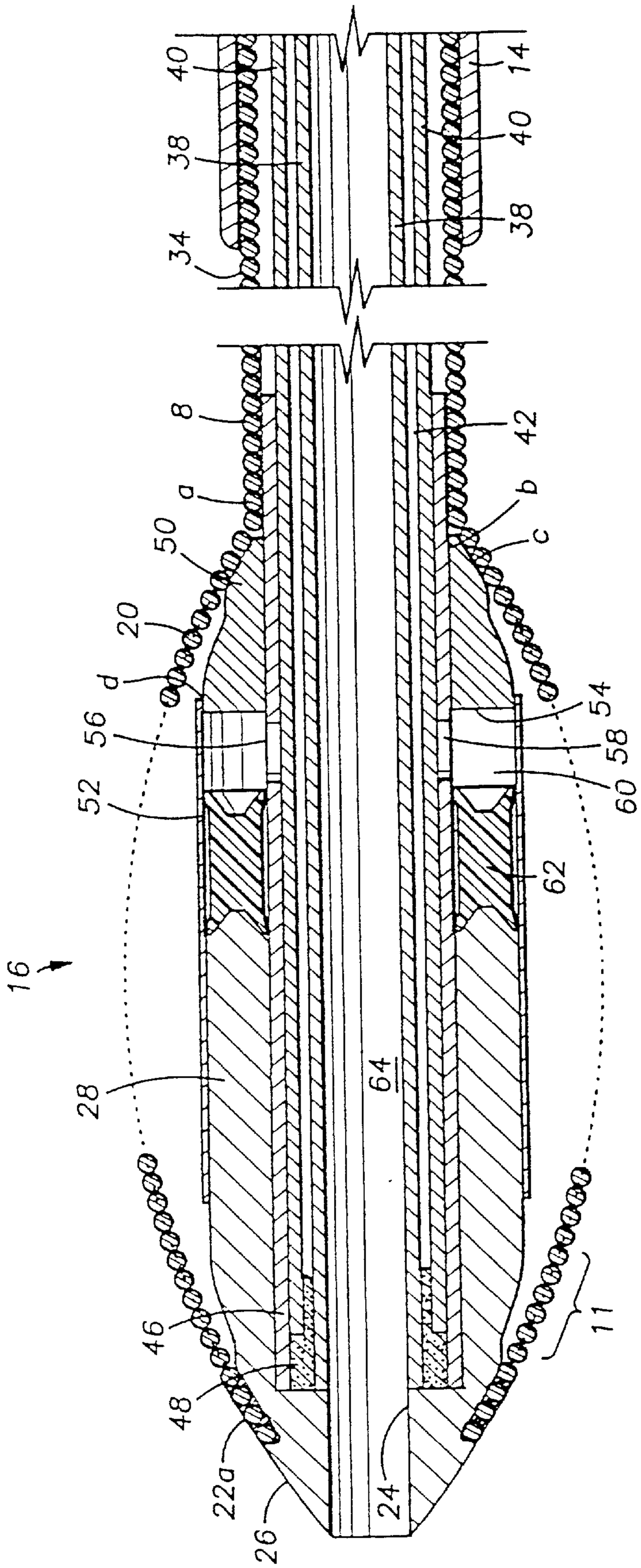
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FIG. 2

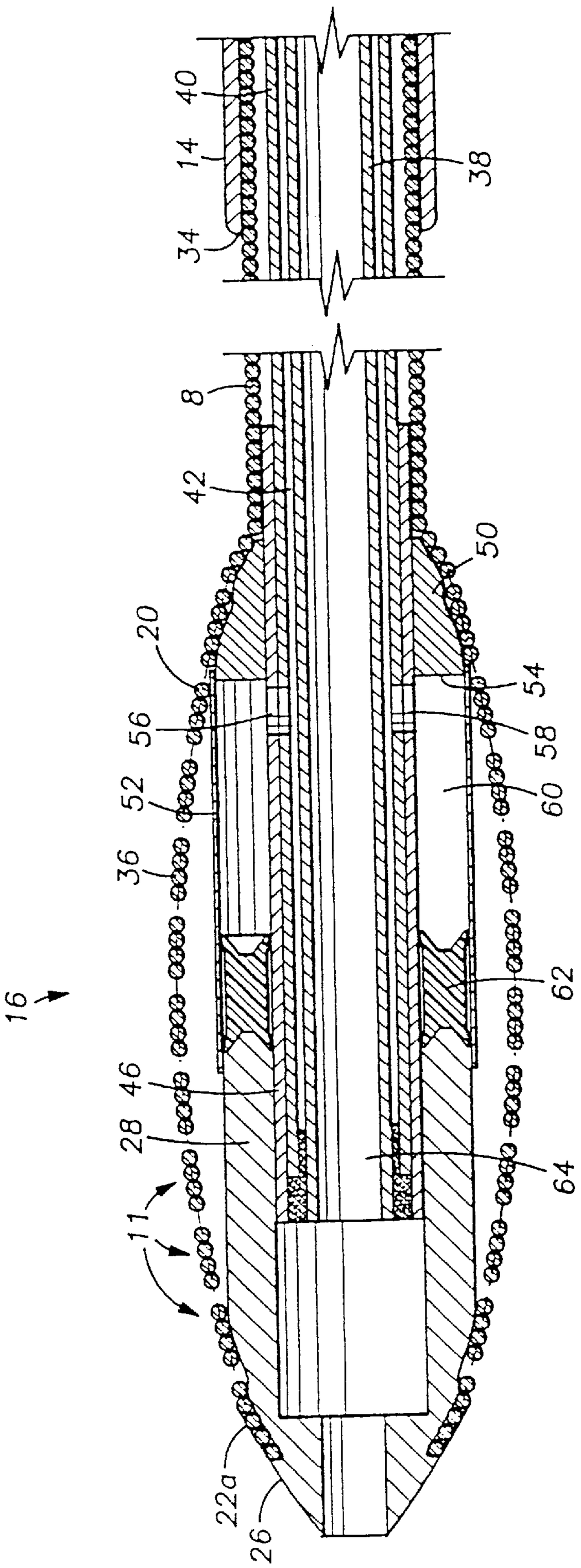

FIG. 3

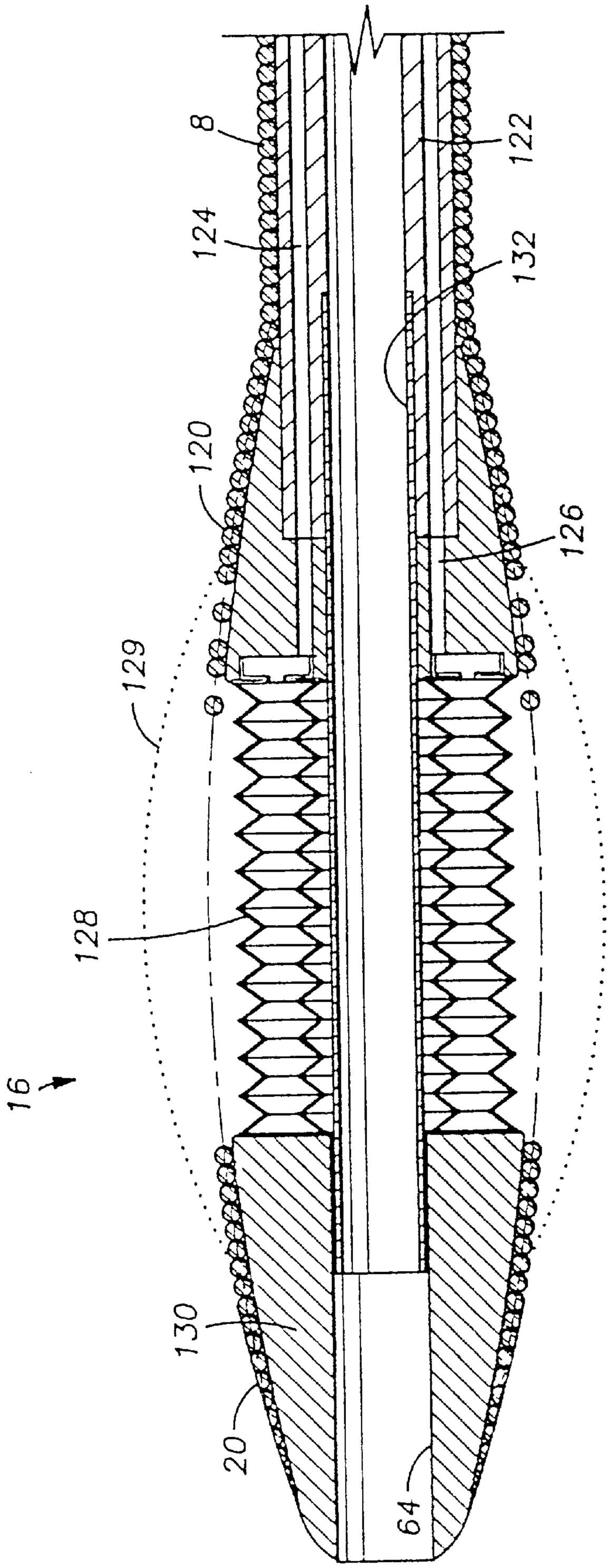

FIG. 4

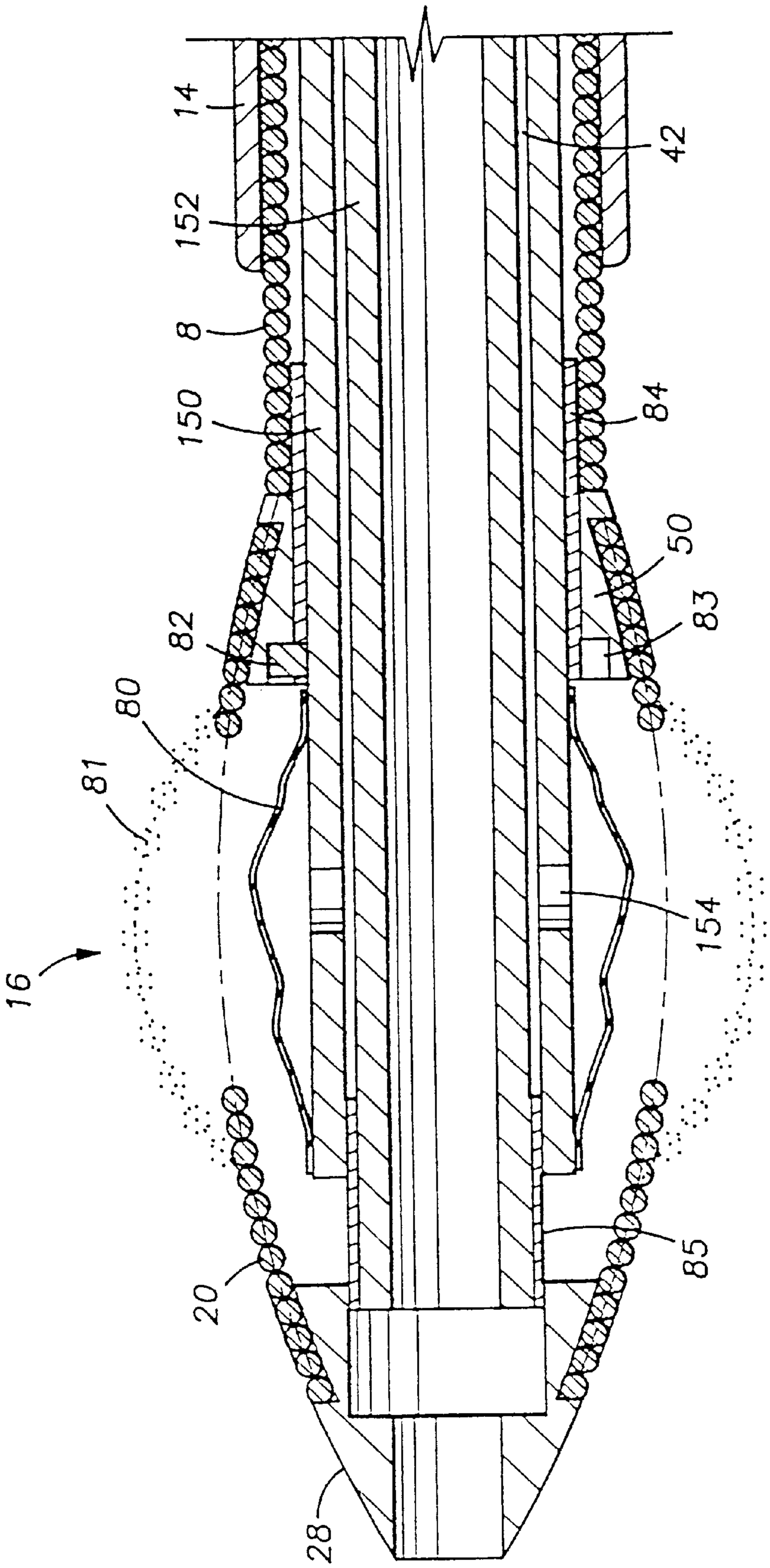

FIG. 5

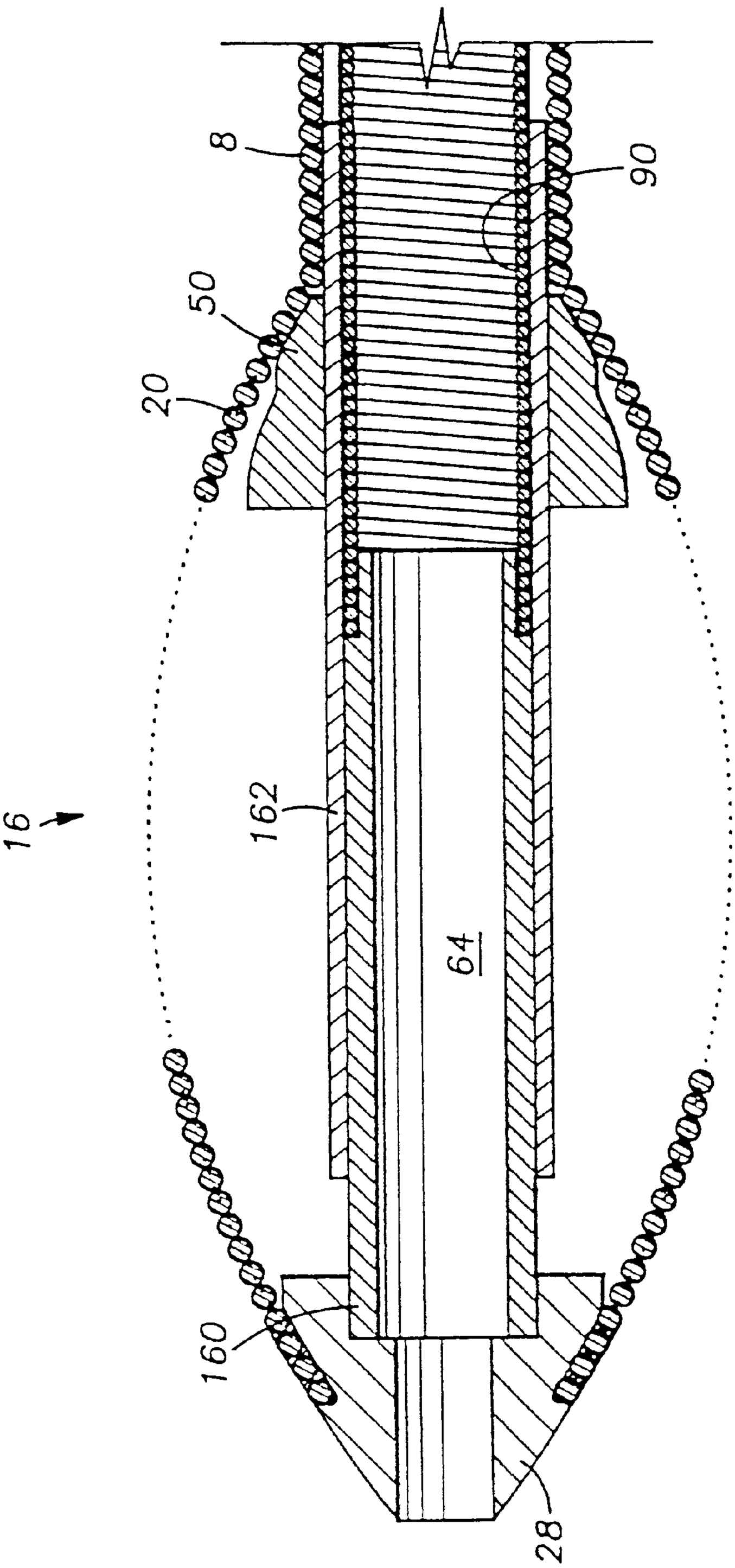

FIG. 6

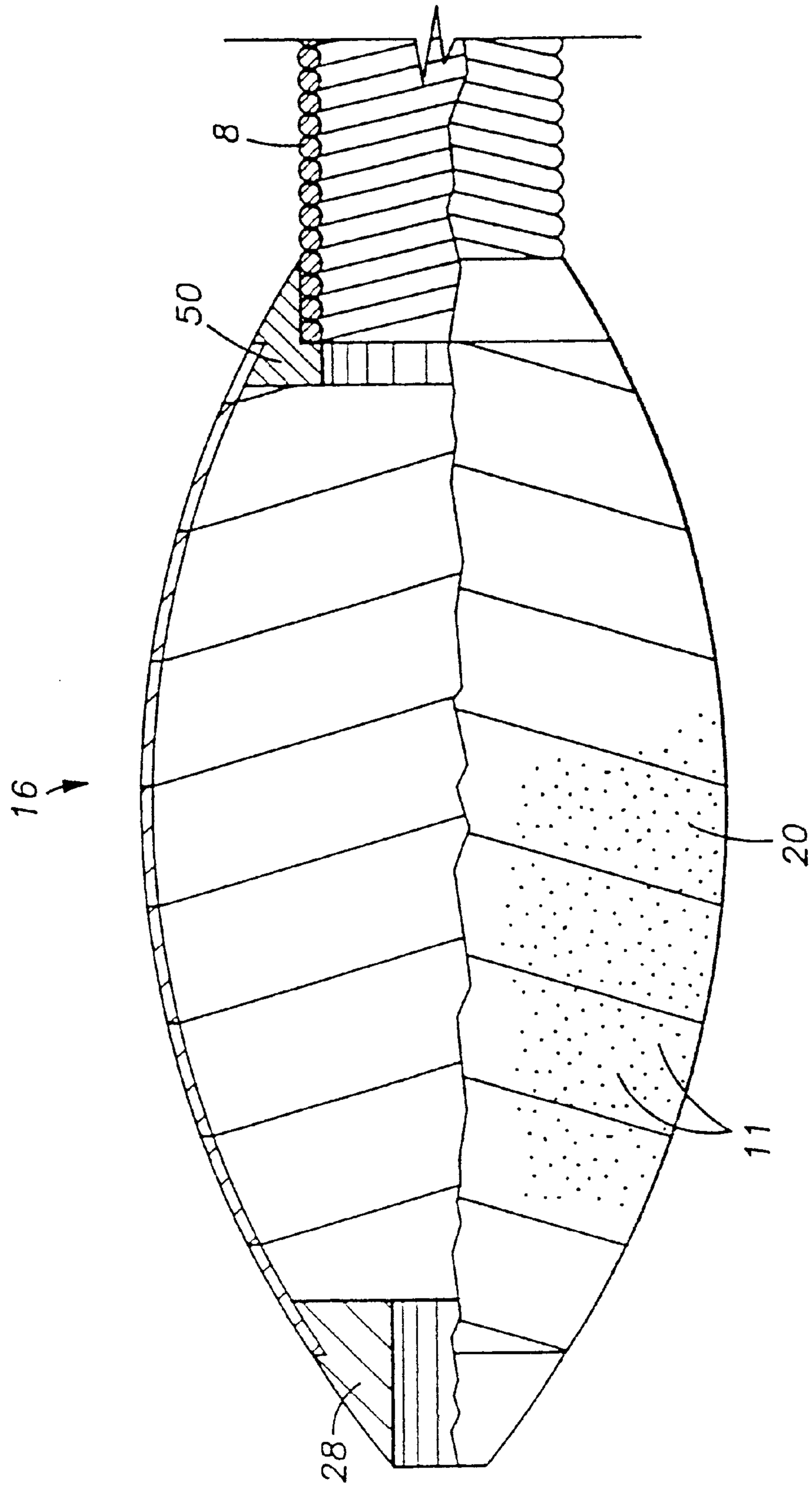

FIG. 7

EXPANDABLE TIP ATHERECTOMY METHOD AND APPARATUS

Matter enclosed in heavy brackets [ ] appears in the original patent but forms no part of this reissue specification; matter printed in italics indicates the additions made by reissue.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates in general to devices for removing obstructions from vessels or small openings in the body, and more particularly to a rotatable ablator tip which is guided to the obstruction in a reduced diameter configuration, expanded and rotated to remove the obstruction, and contracted to remove the device from the body.

2. Background Art

There has been great interest of late among those in the medical community in non-surgical means to remove obstructions from occluded vessels, particularly coronary arteries. Traditionally, patients have had to undergo relatively complex, invasive, and risky coronary bypass surgery in order to obviate or reduce the obvious health hazards presented by occluded coronary arteries. Coronary bypass surgery typically involves utilizing vascular tissue from another part of the patient's body, such as his leg, and constructing a shunt around the obstructed vessel. The obstruction can be formed of a relatively hard material, such as a plaque deposit, or a softer material such as a fibrinogen polymerized to form a thrombus.

An alternative to the traditional coronary bypass surgery which has become popular in recent years is a technique known as balloon angioplasty. In this technique, a deflated balloon is introduced by means of a catheter to the obstructed area. The balloon is then inflated to open the lumen of the vessel. The inflated balloon tends to crush or compact the obstructing material against the vessel walls as well as crack the obstructing material and dilate the vessel so as to increase the lumen or passageway therethrough, but does not remove the obstructing material from the vessel. Since the cracked and fractured obstructing material is not removed, there is a significant possibility that the vessel will become reoccluded at the treated area within a relatively short period of time, thus requiring additional treatment(s). The balloon angioplasty procedure has several additional drawbacks which tend to further reduce its desirability and/or effectiveness. In the case of a severely occluded vessel, it may be difficult to position the deflated balloon so that it spans the occlusion without causing undue trauma to the surrounding vasculature. This is because the leading portion of the balloon must first be forced through the occlusion into position for treatment. The balloon angioplasty procedure is not satisfactory for treating calcified and hard occlusions, since it may not be able to crack and dilate the obstructing material. The balloon angioplasty procedure also is not satisfactory for treating eccentric occlusions, i.e., occlusions which occur primarily on one side of the vessel, because the balloon tends to simply stretch the healthy vascular tissue and not to compress the occluding material. After the balloon is deflated, the healthy vascular tissue returns to its normal shape and the occlusion remains essentially untouched. Moreover, the balloon angioplasty technique is less suitable for treating lengthy occlusions or those occurring at curves and bends in the vessels, due to the difficulty of appropriately placing and properly inflating the

balloons without the high risk of dissections. In addition, during the balloon angioplasty technique, there is a period of time during which the vessel is essentially totally obstructed by the balloon. This could lead to further damage to tissues already damaged, or even to damage to previously healthy tissues. Moreover, when the balloon inflates, it may cause uncontrolled deep injury to the vessel, including the formation of intraluminal flaps, which may in turn result in abrupt closure or predispose to a high rate of restenosis.

Atherectomy is another technique developed of late for opening the lumen of an occluded vessel, and, like the balloon angioplasty technique, provides an alternative to the traditional coronary bypass surgery. Atherectomy involves physically breaking up the material which blocks or partially blocks the vessel. Several types of atherectomy devices have been developed. U.S. Pat. Nos. 4,990,134 and 4,445,509 to Auth disclose a rotatable burr with a fluted or abrasive surface that is introduced into the obstructed vessel. At the obstruction the burr is rotated at a high rate of speed to abrade or cut away at the obstruction. The burr is a solid tip that is introduced into the vessel with a catheter and remotely driven to rotate at the desired speed. The burr is introduced into the patient's body typically at the femoral artery and guided to the obstructed vessel.

The rotatable burr atherectomy devices of the prior art when properly used have several advantages over the balloon angioplasty technique. Unlike the balloon angioplasty technique, treating an occluded vessel with a rotatable burr essentially completely removes the obstructing material, leaving the vessel wall relatively smooth and eliminating the bits or flaps of tissue at the treatment site which often result from balloon angioplasty. Moreover, unlike the balloon angioplasty device, a rotatable burr can effectively remove eccentric occlusions, because the rotating burr tends to "slide off" the healthy vascular tissue on one side of the vessel and to selectively abrade the occluding material on the other side of the vessel. Furthermore, a rotatable burr, which abrades as it progresses, can effectively treat a relatively long occlusion, and tight and/or calcified occlusions.

One major drawback with traditional rotatable burr atherectomy devices is that they have a fixed working diameter. That is, the cutting size is fixed and cannot be varied to accommodate a range of vessel openings. When it is necessary to clear a relatively large vessel which has become severely occluded, typically a physician will be reluctant to use a burr of sufficient diameter to clear the vessel all at once. This necessitates the use of two or more successively larger diameter burrs. Moreover, many times the prior art atherectomy procedure must be assisted by a balloon procedure in order to achieve an adequate result. The above tends to lengthen and complicate the procedure and make it costly. In order to get a large diameter burr to the site of the obstruction, it must first be introduced into the patient's body through an introducer sheath, typically in the patient's leg, and guided through the patient's vascular system to the obstructed vessel. Large burrs require appropriately large introducer sheaths, which tend to cause increased vascular tissue trauma at the site of introduction. Large burrs also tend to cause increased vascular tissue trauma as they are guided through the patient's vascular system to the obstruction site. Large burrs might also interfere with or disturb other occlusions along the way to the target occlusion, such other occlusions being otherwise too small to indicate treatment. For example, it has been found that it is better not to treat or disturb occlusions of less than about 50%–60%, since treatment of such lesions entails greater risks to the patient's health than leaving them

untreated or undisturbed. A large diameter burr could tend to disturb such small lesions in passage, even to the extent that they become health-threatening. In addition, because prior art burrs have had an abrading surface on only their forward or distal surfaces, physicians have encountered difficulty in satisfactorily treating occlusions at curved vessel locations. Accordingly, physicians faced with the prospects of having to introduce, guide, and then manipulate in the obstructed area a relatively large burr might choose to avoid the rotatable burr technique altogether and fall back to a less desirable alternative, such as balloon angioplasty or even bypass surgery.

Thus, there is a clear need in the medical community for an atherectomy device which possesses all the advantages of the traditional rotatable burr device over the balloon angioplasty technique, but yet can be introduced into the patient's body with a relatively small introducer sheath, thus minimizing tissue trauma at the introduction site; can be guided to the obstruction site with minimal vascular tissue trauma and using smaller guiding catheters; can pass through non-targeted (smaller) occlusions with minimal contact; and can be used to treat openings of varying size during the same procedure. It will be appreciated that such a device would eliminate the need for multiple procedures with varying sized burrs, and would eliminate the reluctance of physicians to use the rotatable burr technique in the first place due to the disadvantages they see with the larger, fixed diameter burrs. There is also a need for such a device having an abrading surface on its proximal face as well as on its distal face, to facilitate treating occlusions at curved vessel sites.

Other atherectomy devices with rotatable expandable blades have been disclosed in U.S. Pat. No. 4,966,604 to Reiss and U.S. Pat. No. 4,895,560 to Papantonakos. Although the blades expand to accommodate variable vessel size, sensor devices or other means must be used during the expansion of the instrument and cutting because the blades can injure or puncture the vessel to be repaired in addition to cutting away the obstruction.

SUMMARY OF THE INVENTION

The present invention comprises apparatus and methods for removing obstructions from vessels or small openings in the body. The apparatus is guided into the vessel having the obstruction. The tip of the apparatus comprises a short length of ovaloid shaped coil that can be elongated, thereby decreasing its circumference as compared to its circumference in the normal wound configuration. Lengthening and rotating the coil reduce its circumference and facilitate its introduction to an obstructed area. The coil is then allowed to return to a normal wound configuration thereby increasing the overall circumference of the coil. At least part of the outer surface of the coil is abrasive. The coil can be enlarged to a preselected circumference between the normal wound configuration and the elongated smaller circumference. The coil is rotated at the point of the obstruction to break up the obstruction and clear the vessel. The above ovaloid shaped coil resembles a spiral lemon peel.

Preferably the coil is tightly wound and multifilar, preformed in an ovoid shape. The coil typically surrounds a means for facilitating introduction into the vessel where the obstruction is located, such as a catheter with a lumen for guide wire insertion. The coil is held at one end by a tapered tip at the end of the catheter. The coil is connected to a means for rotation.

The coil diameter can be selectively decreased and increased as desired to reach and treat, respectively, the

obstruction in the vessel. The coil's circumference can be increased or decreased over a range by a remotely actuated means that will elongate or retract the coil as desired. This permits the use of introducers and guiding catheters of smaller diameters than is common in the present practice of device introduction, resulting in less trauma to the patient's vessels at the site of introduction and en route to the obstruction, and also simplifying the procedure.

The present invention comprises a variably expandable abrasive tip coil which may be rotated at the point of obstruction. In one embodiment of the invention, the expansion tip coil is actuated by a piston means disposed within the coil. A pair of collars is attached to the ends of the coil, and the piston effects relative longitudinal axial movement of the collars and, hence, the respective ends of the coil tip. When the ends of the coil tip are so moved with respect to one another, expansion and contraction of the diameter of the coil tip results. In another embodiment of the invention, the expansion tip coil is actuated by an expandable and contractible bellows means disposed within the coil, instead of the piston means. In another embodiment of the invention, the expansion and contraction of the coil tip are effected by longitudinal axial movement of an internal coil attached to one end of the coil tip, within an outer coil attached to the other end of the coil tip. In another embodiment of the invention, expansion and contraction of the coil tip are effected by an inflatable balloon disposed within the coil tip. The balloon expansion means enlarges preferably at the central portion of the coil to make a bulge.

The ability of the tip to adjust to a desired diameter, within the maximum and minimum range, permits the progressive, from smaller to larger, enlargement of a passage through a stenotic obstruction. The variable tip diameter permits the use of a single device of the present invention to more fully clear a stenosis without the need to use two or more of the existing fixed diameter atherectomy devices. The present treatment of stenosis, with fixed diameter atherectomy devices, in addition to requiring the use of two or more cutting devices almost always requires the use of an angioplasty balloon catheter as a final treatment. A single device of the present invention will fully treat a stenosis, thus shortening the procedure, reducing trauma, and reducing procedure cost.

After an obstruction is cleared, it is possible to decrease the circumference of the coil by elongation and easily withdraw the coil and associated catheter from the vessel.

The coil tip is rotated at a desired speed during its passage through the stenosis. Once the obstruction is cleared, the coil is returned to its original smaller diameter and may be easily withdrawn from the vessel.

These and various other characteristics and advantages of the present invention will become readily apparent to those skilled in the art upon reading the following detailed description.

BRIEF DESCRIPTION OF THE DRAWINGS

For a detailed description of the preferred embodiments of the invention, reference will now be made to the accompanying drawings, wherein:

FIG. **1** is a schematic representation of the apparatus of the present invention with its drive-control unit at its proximal end and the drive coil, expandable tip, and guide wire disposed within the flexible outer catheter which surrounds the drive coil.

FIG. **2** is a length-wise cross sectional view of the expandable coil and the associated piston and inner catheter with the coil retracted and the coil circumference enlarged.

FIG. **3** is a length-wise cross sectional view of the coil of FIG. **2** in the elongated position with a smaller coil circumference.

FIG. **4** is a length-wise cross sectional view of an alternative embodiment of the coil with a bellows associated with the coil for expansion.

FIG. **5** is a length-wise cross sectional view of an alternative embodiment with an inflatable balloon used for coil expansion.

FIG. **6** is a length-wise cross sectional view of an alternative embodiment with a pair of concentrically and coaxially disposed, telescopingly slidable sleeves disposed within the coil and cooperable to effect coil expansion.

FIG. **7** is a length-wise cross sectional view of an alternative embodiment of the expandable coil wherein the coil comprises a helically wound ribbon-like metal strip.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS OF THE INVENTION

The drawings are illustrative of the apparatus of the present invention used for removing an obstruction from a vessel. The embodiments described are exemplary only, and can be modified in the practice of the invention.

FIG. **1** is a schematic representation of one type of system **10** adapted for use with some of the preferred embodiments of the adjustable tip atherectomy device of the invention. A drive-control unit **9** is attached to one end of a flexible catheter **14** which surrounds a drive shaft coil **8**. Drive shaft coil **8** is adapted for high speed rotation within the catheter **14**. Flexible catheter **14** is made of a suitable biocompatible material capable of withstanding the heat of friction generated when drive shaft coil **8** is rotated at high speed. Speeds of rotation of drive shaft coil **8** within flexible catheter **14** of about 100,000 to 300,000 revolutions per minute are contemplated for the present invention, which speeds may be generated, for example, by means of a conventional compressed air turbine or the like. An expandable, adjustable diameter coil tip **16** is attached to drive shaft coil **8** at its distal end. The proximal end of the drive shaft coil **8** is attached to a torque drive device **1**, such as the aforementioned compressed air turbine, which is centrally disposed within the drive-control unit **9**. Actuation of the torque drive device **1** drives the drive shaft coil **8** which in turn rotates the expandable, adjustable diameter coil tip **16**. The drive shaft coil **8** is preferably of a helically wound hollow wire configuration and is made of stainless steel or another suitable material capable of transmitting torque to drive the coil tip **16** at speeds as high as those referred to above which are contemplated for the present invention. Such helical coils with diameters as small as 0.032 inches have been used in the past for such high speed rotational torque transmission applications. Flexible catheter **14** assists in containing the forces acting on and transmitted by the drive shaft coil **8**, and protects the body's intervening vasculature from injury or trauma during rotation of the drive shaft.

An air inlet port **7** of drive-control unit **9** accepts air from a conventional air pressure control unit (not shown) commonly found in hospital settings and well known to those skilled in the present art. Air at controlled pressure is applied momentarily and for the desired duration of tip rotation. The pressurized air passes through the inlet port **7** and communicates to the torque drive device inlet port **7**c via air outlet port **7**a and connecting tube **7**b. Rotational speed is monitored by a conventional tachometer connected to tachometer cable connector **6** of drive-control unit **9**. The air pressure control unit (not shown) may be adjusted to result in application of the desired air pressure to the turbine or the like to effect the desired tip rotational speed.

Drive-control unit **9** also includes several ports which communicate to various lumens of the overall atherectomy device of the present invention. Generally, the various lumens permit the injection through the device of fluids, such as medication, hydraulic actuation fluids for actuating the means for adjusting the expandable tip **16** of the device, and cooling fluids for reducing friction heating during high speed rotation, as further described below. Cooling fluids, for example, are introduced into the flexible catheter **14** around the drive shaft coil **8** to bathe the coil **8** during rotation.

In practice it is necessary to visualize the stenotic obstruction to be treated by the device of the present invention. This is accomplished by the injection of a contrast medium and fluoroscopic visualization as is commonly practiced by those skilled in the art. The atherectomy device of the present invention permits the injection of a contrast medium through central lumen **64** and the annular space **34**, FIG. **1** and FIG. **2**, created between the outer surface of the drive shaft coil **8** and the inner surface of flexible outer catheter **14**. Port **3** of drive-control unit **9** communicates with the annular space **34** and, in addition to serving as a means for contrast medium injection, may be used to inject cooling fluid during high speed rotation. Port **4** of drive-control unit **9** communicates with central lumen **64**, shown in FIG. **2**, and may be used for the injection of a contrast medium, medication, and other fluids through the central lumen **64**.

Referring to FIG. **2**, it can be seen that central lumen **64** is created by a flexible catheter tube **38** which is disposed substantially concentrically and coaxially within a larger inner diameter flexible catheter tube **40**. These concentrically and coaxially disposed inner catheters extend proximally within the passage created by the drive shaft coil **8** and extend beyond the proximal end of the drive shaft coil **8** within the drive-control unit **9**. The concentric and coaxial disposition of flexible catheters **38** and **40** and the difference between the size of the outer diameter of catheter **38** and the inner diameter of catheter **40** creates an annular space lumen **42** which communicates to drive-control unit port **5**, thus creating a passage for the purpose of activating the expanding means used to adjust the diameter of the ablating coil tip **16**, as described further below.

The distal terminal ends of concentrically and coaxially disposed flexible catheters **38** and **40** are sealed by potting material **48** which serves to bond the tubes **38** and **40** together as well as to provide a distal seal for annular space lumen **42**.

Central lumen **64** extends from the terminal distal end of tip **16** through drive-control unit **9** at its extreme proximal end. Thus the central lumen **64** can be used to guide the atherectomy device tip **16** of the present invention to a selected vessel obstruction by introduction over a prelocated guide wire **12**, shown in FIG. **1**.

The atherectomy device of the present invention is introduced into the body by way of the brachial or femoral artery, utilizing the Grunzig technique, which method is well known to those who practice in the area of catheterization. The device of the present invention minimizes damage to the vessel selected for catheter introduction. Normally, an introducer sheath is used to access the vessel at the point of introduction. Through the prepositioned introducer sheath is placed a guiding catheter and a guide wire appropriate for directing the atherectomy device of the present invention to

the selected stenosis to be treated. The size, or diameter, of the introducer sheath and guiding catheter is determined by the size or diameter of the device to be introduced for treatment of the obstruction. Since existing atherectomy devices are of a fixed diameter, it is often necessary to introduce progressively larger diameter devices in order to fully clear a stenotic obstruction. This requires the use of introducer sheaths of a diameter sufficient to accept the larger diameter device, which results in greater vessel trauma at the point of vascular access. It is not uncommon, for example, to require use of introducer sheaths of up to a size 10F (10 French) in order to accommodate the desired diameter, for example about 2.25 to 2.5 millimeters, of prior art atherectomy tip. Applicant has even used a larger size introducer sheath, e.g., of size 11F (11 French), to accommodate a fixed diameter burr of about 2.75 to 3.0 millimeters, but to Applicant's knowledge, substantially no one else has used an introducer sheath so large as the 11F and a burr of the corresponding large size diameter without the need for balloon assistance for practicing the prior art atherectomy technique described above. In addition, as noted previously, the larger diameter atherectomy devices of the prior art may cause increased vascular tissue trauma as they are guided to the obstruction to be treated, and also may disturb, in passing, other, smaller vascular obstructions not otherwise indicated for treatment.

The present invention, due to its variable, adjustable diameter tip **16** may be introduced by the technique just described but can employ an introducer sheath and guiding catheter of a diameter that is less than its maximum expanded diameter. For example, it is contemplated that an introducer sheath of a size 6F, which is considerably smaller in diameter than the size 10F, can be used effectively with the expandable abrading tip of the present invention, even when removing obstructions that would require a 10F, 11F, or larger size sheath according to prior art techniques. This results in decreased vessel trauma at the vessel access site and also in decreased vessel trauma en route to the obstruction, which features offer a distinct advantage over existing atherectomy devices. The device of the present invention minimizes or avoids this vessel trauma because it is introduced and guided into position for treatment in its minimal diameter configuration.

Referring to FIGS. **2** and **3**, the variable diameter feature of the abrading coil tip **16** of the invention will be described. FIG. **2** shows a piston means for one preferred embodiment of the dynamic variation of the abrading tip coil **20**. FIG. **2** illustrates the abrading tip coil **20** in its maximum diameter condition and the activating means or piston in its deactivated condition. The piston is comprised of a proximal collar ring **50**, a cylindrical piston inner sleeve **46**, a cylindrical piston outer sleeve **52**, a slidable piston seal ring **62**, and a distal slidable piston collar **28** which also comprises the distalmost tapered abrading surface **26** of the device of the present invention.

The piston sleeves **46** and **52**, the proximal collar **50**, and the distal collar **28** are preferably made of stainless steel, but may be made of other materials suitable for the desired piston function and attachment described below.

Cylindrical piston inner sleeve **46** is attached to a number of the coil winds of drive shaft coil **8** at region "a" as well as to proximal collar **50** at region "b" by circumferential welding or the like. Outer piston sleeve **52** is circumferentially welded or the like to proximal collar **50** at region "d". Inner piston sleeve **46** is concentrically and coaxially disposed over flexible catheter tube **40** and bonded thereto to sealably fix the sleeve **46** around the flexible tube **40**. The seal between inner piston sleeve **46** and flexible tube **40** is created by a tight slip fit between the members and by epoxy bonding or the like.

The distal piston collar **28** is slidably and rotationally free to move or telescope between inner piston sleeve **46** and outer piston sleeve **52**. The slidable contacting surfaces of distal collar **28** and piston sleeves **46** and **52** may be deposited with a thin Teflon coating or the like to enhance the movement of distal collar **28** during piston function.

At the proximal termination of distal collar **28** and circumferentially disposed around inner piston sleeve **46** is slidable piston seal ring **62**. Preferably made of Teflon or other suitable material, seal ring **62** is the primary piston "O" ring seal and is free to slide longitudinally axially between piston sleeves **46** and **52**, thus creating a sliding seal between sleeves **46**, **52**.

Piston cavity **60** is an annular or circumferentially disposed, enclosed space bounded by the terminal distal face **54** of collar **50**, the proximal terminal face of piston seal ring **62**, the inner wall surface of sleeve **52**, and the outer wall surface of sleeve **46**.

Piston ports **56** and **58** access piston cavity **60**. The ports **56**, **58** are two, preferably, of a total of four piston ports that communicate through the wall of piston inner sleeve **46** and the wall of flexible tube catheter **40** to access annular space lumen **42**.

Adjustable diameter, ovaloid shaped coils **20** of tip **16** are circumferentially disposed around the internal piston elements. The distal terminus of ovaloid coils **20** is attached to the piston distal collar at region **22**a by circumferential welding or other suitable means. The distal attachment of coil **20** to distal collar **28** at region **22**a is such that the attachment preferably forms a smooth continuation of the outer ovaloid surface of the tip **16**. Thus, a smooth transition from the outer surface **26** of distal piston collar **28** to the coil **20** ovaloid surface is created.

Tightly wound ovaloid coil **20**, by its attachment to distal piston collar **28** at region **22**a and its attachment to proximal piston collar **50** at region "c", forms the piston's return spring.

As previously described, annular space lumen **42** communicates with port **5** of drive-control unit **9** and piston ports **56** and **58**. Application of hydraulic pressure, or other suitable fluid pressure, at port **5** of drive-control unit **9** will transmit the necessary force to cause piston seal **62** to move distally and push slidable distal piston collar **28** in a forward or distal direction. As pressure at port **5** is increased, the major diameter of ovaloid coil **20** at the tip **16** decreases and the ovaloid outer shape lengthens or stretches to an increasingly right circular cylindrical configuration. As piston activation pressure increases, the ovaloid coil **20** stretches and unwinds under the pulling force exerted at region **22**a by the distal movement of distal collar **28**. The piston may be provided with a helical groove or the like, in which rides a radially outwardly projecting pin or the like disposed on the sleeve **46**, to direct and channel the winding or unwinding movement of the coil winds as the piston is deactivated or activated, as the case may be.

FIG. **3** illustrates the effect of the piston activation at its maximum distal travel or movement. The ovaloid coil **20** shown in FIG. **3** comprises a quadrifilar coil which has been stretched and unwound in groups **36** of four winds per group when affected by the piston forces just described. Although a quadrifilar coil is shown, which coil stretches and unwinds also substantially as shown, other types or styles of coils, which stretch and unwind in other ways, may be used in the present invention.

The diameter of tip **16** can be varied from its maximum ovaloid diameter shown in FIG. **2** to its minimum elongated ovaloid diameter shown in FIG. **3**. The dynamic diameter of the ovaloid tip **16** is a function of the piston activation pressure applied to piston cavity **60**, and the return spring force of ovaloid coil **20**. It is thus possible to select any desired tip diameter within the range bounded by the maximum and minimum diameters by selecting the appropriate piston activation pressure applied at port **5** of drive-control unit **9**. The activation pressure can be set and monitored using standard gauges and pressure systems commonly used and well known to those of ordinary skill in the art.

Referring again to FIG. **1**, there is shown on drive-control unit **9** a button **17** which serves as an air valve actuator to activate an air clamp which is centrally and proximally disposed within the drive-control unit **9**. The air clamp is supplied by air from inlet port **7** and closes around and holds guide wire **12** in position at all times, except when the valve button is depressed. Thus the guide wire **12** is normally held during device rotation and released for advancement through the entire length of the atherectomy device.

The atherectomy device of the present invention will clear vascular stenoses by abrading or wearing away the stenotic material. The surface of the abrading tip **16** is deposited with particles, such as diamond dust **11**, which may partially or totally cover the outer surface of ovaloid tip **16**. The abrasive material surface may cover all or any portion, from the distalmost outer surface **26** of distal piston collar **28** to region "b" at the proximal termination of ovaloid tip **16**.

The particle size of the abrading material should be substantially uniform over the abrading surface of the tip. Particle diameter size should be in the range of about 10 to about 100 microns, with a preferred subrange of about 10 to about 20 microns. With abrading particles of about this size, rotated at the speeds contemplated for the present invention, the pieces of stenotic material abraded away will be about 5 to about 8 microns in diameter, which is less than the typical diameter of a red blood cell. At such a small particle size, the pieces of stenotic material abraded away can be disposed of naturally by the body through the capillary beds and there is no need for additional means of debris collection. Both soft and hard stenotic material may be removed by the cutting action of the tip **16**.

Alternately, the abrading property of the surface of the tip **16** may be imparted by other methods, such as peening.

The tip **16** of the device of the present invention, unlike the tips of prior art devices, is preferably capable of abrading in both the forward and reverse progressions of the tip through a stenosis. This is due to the grit **11** preferably being deposited on both the leading and trailing slopes of the ovaloid tip **16**.

Vascular recanalization of obstructions representing less than about 50% to 60% occlusion are not indicated. It has been found that the treatment for such occlusions by angioplasty or atherectomy more often aggravates the condition and accelerates the stenotic growth. In practice, those occlusions requiring treatment, the target stenoses, are not isolated, but rather are preceded by upstream and followed by downstream occlusions which preferentially should not be treated or should be bypassed by the treatment device.

Unlike existing atherectomy devices with fixed diameter ablators, the device of the present invention may be adjusted to its lower diameter and guided past and through non-target stenoses with reduced probability of aggravating these lesions.

Referring now to FIG. **4**, there is shown a longitudinal cross sectional view of an alternative embodiment of the tip

16 of the atherectomy device of the present invention in which a bellows **128** is substituted for the piston as a means of ovaloid coil expansion. The bellows comprises a longitudinally expandable and contractible, hollow annular member having a plurality of accordion-like folds along its length. Bellows **128** is made of deposited nickel or other suitable thin walled material. Bellows **128** is attached at its proximal end to the distal face of a proximal collar **120**, which in turn is attached to a plurality of winds of the coil **20** of tip **16** by circumferential welding or the like. A catheter tube **122** is sealably attached to the interior bore of the proximal end portion of collar **120**. Catheter tube **122** preferably comprises a pair of concentrically and coaxially disposed flexible tubes forming an annular space lumen **124** therebetween. Catheter tube **122** is concentrically and coaxially disposed within drive shaft coil **8**. Annular space lumen **124** communicates through passages **126** in collar **120** to the interior of bellows **128** at its proximal end. The distal end of bellows **128** is attached to the proximal face of a slidable distal tip collar **130**. A plurality of winds of the coil **20** at its distal end are attached to the outer surface of the tip **130** by circumferential welding or the like. A metal guide tube **132** is attached within and to the distal end of the catheter tube **122**, and projects therefrom through the bellows and into the central axial bore of the tip **130**. The tip **130** is free to slide rotationally and longitudinally axially on the guide tube **132**. Upon application of activation pressure, longitudinal expansion of the bellows **128** causes the tip coil **20** to stretch, reducing its circumference or diameter in a manner similar to that described in connection with the embodiment shown in FIGS. **2** and **3**. Removal of the activation pressure will cause the bellows to contract, because of the spring effect associated with the metal bellows configuration. When the bellows is in its contracted state, the diameter of the ovaloid tip **16** is at its maximum, and when the bellows is in its expanded state, the diameter of the tip is at its minimum. FIG. **4** illustrates the bellows in its expanded state. The increased diameter of the coil when the bellows is in its contracted state is indicated in the central portion of the figure by the dotted lines **129**.

Referring to FIG. **5**, there is shown a cross sectional view of an alternative embodiment of the tip **16** in which a high pressure balloon **80**, such as those commonly used in angioplasty devices, is used as the tip coil expansion means. In this embodiment the tip **16** is normally in its minimum diameter condition. As in the previously described embodiments, the annular space lumen **42** conveys the pressure required to expand the balloon **80**. As the balloon **80** expands, it expands the associated central portion of the tip coil **20**. This results in a tip diameter increase that simultaneously changes the ovaloid shape of the tip **16** to a modified ovaloid shape having a compound ovaloid or distended central portion **81**.

As seen in FIG. **5**, this embodiment may incorporate a pin **82** which rides in a 350° slot **83** which is circumferentially disposed around the inner wall surface of a proximal collar **50**. The pin is fixed to a proximal metal slide tube **84** by welding or the like. The proximal metal slide tube **84** is disposed around an outer catheter tube **150**. The proximal collar **50** is rotationally free to move over the surface of proximal metal slide tube **84** and may rotate a total of 350°, at which time it engages the drive pin **82**. The drive shaft coil **8** is weldably or otherwise attached to the proximal metal slide tube **84** and thus may drive the proximal collar **50** during high speed rotation. A distal collar **28** is weldably or otherwise attached to a plurality of winds of coil **20** at its distal end, and the proximal collar **50** is weldably or other-

wise attached to a plurality of winds of coil **20** at its proximal end. A metal slide tube **85** is mounted around the distal end of an inner catheter tube **152**, and is telescoped into a central axial counterbore in the proximal face of the distal collar **28**. The metal slide tube **85** is sealably disposed between the catheter tubes **150**, **152** and seals the distal ends of the tubes **150**, **152** The lumen **42** between the catheter tubes **150**, **152** communicates through ports **154** in the outer catheter tube **150** to the interior of balloon **80**, which is mounted on the outer surface of the outer catheter tube **150**. Air is introduced through the ports **154** to inflate the balloon **80**. The distal collar tip **28** is free to slide longitudinally axially and rotationally over the surface of metal slide tube **85**, and collar **50** is free to rotate over the surface of its associated slide tube **84**. Thus the coil **20** of tip **16** may unwind and wind as the coil expands and contracts, as the case may be, under the action of the balloon **80**. The balloon **80** at its maximum inflation forces the center of the ovaloid to its maximum diameter. Removing the air pressure from the balloon causes it to deflate, allowing the coil to return to its normal, reduced diameter state.

FIG. **6** is a cross sectional view of an alternative embodiment in which a second helical coil **90** is coaxially and centrally disposed within the drive shaft coil **8**. The innermost coil **90** is free to slide within the drive shaft coil **8** and extends through the entire length of the device. A pair of such coils as manufactured by Lake Region Manufacturing Company, Inc. of Chaska, Minn., may be found suitable for use in this embodiment, but other or equivalent coils can of course be used. The distal end of the inner coil **90** is attached to the distal tip collar **28** through an inner slide sleeve **160**. The ovaloid tip **16** coil **20** is attached to the distal and proximal collars **28**, **50** as previously described. An outer slide sleeve **162** is telescoped over the inner slide sleeve **160** and is disposed at its proximal end within the central axial bore of the proximal collar **50**. The inner slide sleeve **160** is free to telescope longitudinally axially within, and to rotate within, the outer slide sleeve **162**.

The tip **16** of FIG. **6** is normally in its maximum diameter condition and is caused to reduce its diameter by the longitudinal movement of the inner coil **90** within the drive shaft coil **8** in a distal direction. When the inner coil **90** is pushed and/or rotated distally within the drive shaft coil **8** the distal tip collar **28** moves forward, in relation to proximal collar **50** and causes the tip coil **20** to stretch. Thus the tip diameter may be reduced. The tip **16** diameter in this embodiment is a function of the longitudinal displacement of the distal collar **28** with respect to the proximal collar **50**. The tip coil **20** for this embodiment may be a continuation of the drive shaft coil **8**, as shown in FIG. **2**, or an individual coil segment, as shown in FIG. **5**.

Alternatively, the coil **20** of ovaloid tip **16** may be replaced by a deposited metal ovaloid such as nickel, preferably having a wall thickness of less than 0.002 inches. Further, the coil feature of the deposited metal tip may be cut into the previously deposited ovaloid shape such that the coil ribbons at the center, or apex, of the ovaloid are widest and decrease in width as the ovaloid slope descends to the distal and proximal minor ovaloid diameters. There may be one helix, or a plurality of adjacent helices, comprising the coil. The deposited metal coil alternative presents what may be described as a "lemon peel" feature. An illustration of such an embodiment is shown, for example, in FIG. **7**.

While preferred embodiments of the invention have been described, various modifications can be made to the preferred embodiments without departing from the principles of the present invention.

We claim:

1. An apparatus for removing an obstruction from a vessel, comprising:

a coil;

said coil being capable of elongation thereby reducing the circumference as said coil is elongated;

[means for selectively elongating**]** *an elongator engageable with said coil and movable between first and second positions wherein* said coil *is elongated in one of said positions*;

[means for introducing said coil**]** *an introducer extendable* inside **[**a**]** *the* vessel proximate to **[**an**]** *the* obstruction, *wherein said introducer supports said coil*;

said coil having **[**an abrasive surface covering**]** at least part of its outer surface *treated to form a roughened surface*; and

[means for**]** *a drive shaft attached to said coil and capable of* selectively rotating said coil.

2. An apparatus for removing an obstruction from a vessel according to claim **1**, wherein said coil is of substantially ovaloid configuration prior to elongation *and at least part of its outer surface has an abrasive coating*.

3. An apparatus for removing an obstruction from a vessel according to claim **1**, wherein approximately all of the outer surface of said coil is **[**an abrasive surface**]** *treated to form projections*.

4. An apparatus for removing an obstruction from a vessel, comprising:

a coil;

the circumference of said coil being capable of enlargement by unwinding and compressing the coil;

[means for selectively unwinding and compressing**]** *an elongator connected to said coil and movable between a first position and a second position wherein* said coil **[**for effecting such enlargement of**]** *is unwound and compressed in one of said positions to enlarge* the circumference of said coil;

[means for introducing said coil in**]** *an introducer extendable inside* the vessel proximate to the obstruction, *wherein said introducer supports said coil*;

said coil having **[**an abrasive surface**]** *projections* covering at least part of its outer surface *for frictionally engaging the obstruction for removal*; and

[means for**]** *a drive shaft attached to said coil and capable of* selectively rotating said coil.

5. An apparatus for removing an obstruction from a vessel according to claim **4**, wherein approximately all of the outer surface of said coil is **[**an abrasive surface**]** *covered with said projections*.

6. An apparatus for removing an obstruction from a vessel, comprising:

a length of coil preformed in an ovaloid shape;

[means for**]** *a drive shaft connected to said length of coil and capable of* rotating said length of coil;

said length of coil having an abrasive surface covering at least a part of its outer surface;

a tubular catheter with a central lumen *disposed within said rotating member*;

said catheter terminating in a tip with an opening in said tip communicating with the central lumen of said catheter;

said length of coil surrounding the terminal end of said catheter with the terminal end of said length of coil fixed to the terminal end of said tip of said catheter;

[means for elongating] *an elongator attached to said length of coil and movable between a first position and a second position wherein* said length of coil *is elongated in one of said positions* thereby reducing the circumference of said length of coil; and

said [elongation means] *elongator* being disposed between said catheter and said length of coil.

7. An apparatus for removing an obstruction from a vessel according to claim **6**, wherein said [means for rotating said length of coil] *drive shaft* comprises a drive shaft coil powered to rotate said ovaloid length of coil at selected speeds from 0 rpm up to about 300,000 rpm.

8. An apparatus for removing an obstruction from a vessel according to claim **6**, wherein said length of coil is comprised of multifilar coil wire.

9. An apparatus for removing an obstruction from a vessel according to claim **6**, wherein said length of coil is comprised of a wire with a flat outer surface.

10. An apparatus for removing an obstruction from a vessel according to claim **6**, wherein said length of coil is comprised of a *plurality of strands of* wire [with a rounded outer surface] *having an abrasive coating*.

11. An apparatus for removing an obstruction from a vessel according to claim **6**, wherein said length of coil is comprised of a coil of deposited metal having ribbon-shaped winds.

12. An apparatus for removing an obstruction from a vessel according to claim **6**, wherein said abrasive surface covers the approximate half of said length of coil adjacent to said tip of said catheter.

13. An apparatus for removing an obstruction from a vessel according to claim **6**, wherein said abrasive surface covers the approximate half of said length of coil adjacent to said tip of said catheter and the entire exposed surface of said tip of said catheter.

14. An apparatus for removing an obstruction from a vessel according to claim **6**, wherein said abrasive surface covers approximately all of the outer surface of said length of coil *with sharp projecting members*.

15. An apparatus for removing an obstruction from a vessel according to claim **6**, wherein said abrasive surface covers approximately all of the outer surface of said length of coil and the exposed outer surface of said tip of said catheter.

16. An apparatus for removing an obstruction from a vessel according to claim **6**, wherein said abrasive surface is selected from the group of diamond particles, synthetic diamond particles or a peened surface.

17. An apparatus for removing an obstruction from a vessel according to claim **6**, [wherein said tubular catheter is comprised of a flexible biocompatible material] *further including a guidewire passing through said central lumen*.

18. An apparatus for removing an obstruction from a vessel according to claim **17**, wherein said coil is comprised of a wire with a rounded outer surface.

19. An apparatus for removing an obstruction from a vessel according to claim **17**, wherein said coil is comprised of a coil of deposited metal having ribbon-shaped winds.

20. An apparatus for removing an obstruction from a vessel according to claim **17**, wherein said abrasive surface covers the approximate half of said coil adjacent to said tip of said catheter.

21. An apparatus for removing an obstruction from a vessel according to claim **17**, wherein said abrasive surface covers the approximate half of said coil adjacent to said tip of said catheter and the entire exposed surface of said tip of said catheter.

22. An apparatus for removing an obstruction from a vessel according to claim **17**, wherein said abrasive surface covers approximately all of the outer surface of said coil.

23. An apparatus for removing an obstruction from a vessel according to claim **17**, wherein said abrasive surface covers approximately all of the outer surface of said coil and the exposed outer surface of said tip of said catheter.

24. An apparatus for removing an obstruction from a vessel according to claim **17**, wherein said abrasive surface is selected from the group of diamond particles, synthetic diamond particles or a peened surface.

25. An apparatus for removing an obstruction from a vessel according to claim **17**, wherein said expandable means is comprised of a balloon that can be selectively inflated and deflated.

26. An apparatus for removing an obstruction from a vessel of claim **17**, wherein at least one end of said coil is fixed to said catheter.

27. An apparatus for removing an obstruction from a vessel according to claim **6**, wherein said elongation means is comprised of a remotely actuated piston engageable with said length of coil to retract and extend said length of coil to and from the ovaloid shape.

28. An apparatus for removing an obstruction from a vessel according to claim **6**, wherein said elongation means is comprised of a remotely actuated bellows engageable with said length of coil to retract and extend said length of coil to and from the ovaloid shape.

29. An apparatus for removing an obstruction from a vessel according to claim **6**, wherein said tubular catheter comprises an inner flexible catheter coil substantially concentrically and coaxially disposed within an outer flexible drive shaft coil, said tip of said tubular catheter being fixed to the terminal end of said inner flexible catheter coil, said terminal end of said length of coil which is attached to said tip of said tubular catheter being the distal end of said length of coil, said means for rotating said length of coil comprising said outer flexible drive shaft coil, said outer flexible drive shaft coil being fixed to the proximal end of said length of coil, said elongation means comprising an inner slide sleeve fixed at its distal end to said tip of said catheter and at its proximal end to said inner flexible catheter coil, an outer slide sleeve rotationally and longitudinally axially slidably disposed around said inner slide sleeve, the proximal end of said outer slide sleeve being disposed within said proximal end of said length of coil, said inner flexible catheter coil being longitudinally axially movable within said outer drive shaft coil.

30. An apparatus for removing an obstruction from a vessel according to claim **6**, wherein said tubular catheter is comprised of a flexible biocompatible material.

31. An apparatus for removing an obstruction from a vessel, comprising:

a coil capable of an enlarged circumference forming a bulge in said coil after partial unwinding and compression of said coil;

said coil having an abrasive surface covering at least part of its outer surface;

means for rotating said coil;

a tubular catheter with a central lumen;

said catheter terminating in a tip with an opening in the tip communicating with the central lumen of the catheter;

said coil surrounding the terminal end of said catheter;

an expandable means disposed between said catheter and said coil and engageable with the inner surface of said coil when activated to expand said coil and allow the

free end of said coil to unwind and at the same time to allow for compression of the length of said coil thereby enlarging the circumference and diameter of said coil, and upon deactivation contracting away from said inner surface of said coil allowing said coil to rewind and assume its smaller circumference and diameter; and

means for remotely activating the expandable means to selectively increase and decrease the diameter of said coil.

32. An apparatus for removing an obstruction from a vessel according to claim **31**, wherein said means for rotating said coil comprises a drive shaft coil powered to rotate said expandable coil at selected speeds from 0 rpm up to about 300,000 rpm.

33. An apparatus for removing an obstruction from a vessel according to claim **31**, wherein said coil is comprised of miltifilar coil wire.

34. An apparatus for removing an obstruction from a vessel according to claim **31**, wherein said coil is comprised of a wire with a flat outer surface.

35. An apparatus for removing an obstruction from a vessel, comprising:

a coil;

the diameter of said coil being changeable by winding and unwinding said coil;

means for selectively winding and unwinding said coil for effecting such change in diameter of said coil;

means for introducing said coil in the vessel proximate to the obstruction;

said coil having **[**an abrasive**]** *a grainy* surface covering at least part of its outer surface *for removing the obstruction by sanding*; and

means for selectively rotating said coil.

36. A method for removing an obstruction from a vessel, comprising **[**the steps of**]**:

introducing a variable diameter coil **[**with an abrasive**]** *treated to form a* surface *with sharp edges* covering at least part of its outer surface into the vessel proximate to the obstruction in a reduced coil diameter state;

unwinding the coil at the site of the obstruction to increase the diameter of the coil;

rotating the increased diameter coil at high speed *for the sharp edges* to **[**abrade**]** *grind* away the obstruction;

subsequent to such high speed rotation, rewinding the coil to reduce its diameter; and

withdrawing the coil from the vessel.

37. A method for removing an obstruction from a vessel according to claim **36**, comprising the additional step, prior to the introducing step, of winding the coil to reduce its diameter.

38. A method for removing an obstruction from a vessel, comprising **[**the steps of**]**:

introducing a variable diameter coil with **[**an abrasive**]** *a* surface *coated with an abrasive* covering at least part of its outer surface into the vessel proximate to the obstruction in a reduced coil diameter state;

axially compressing the coil at the site of the obstruction to increase the diameter of the coil;

rotating the increased diameter coil at high speed **[**to abrade away the obstruction**]**;

frictionally engaging the obstruction with the abrasive coating to remove the obstruction by grinding;

subsequent to such high speed rotation, axially elongating the coil to reduce its diameter; and

withdrawing the coil from the vessel.

39. A method for removing an obstruction from a vessel according to claim **38**, comprising the additional step, prior to the introducing step, of axially elongating the coil to reduce its diameter.

40. A method for removing an obstruction from a vessel, comprising the steps of:

introducing a variable diameter coil with an abrasive surface covering at least part of its outer surface into the vessel proximate to the obstruction in a reduced coil diameter state;

activating an expansion means disposed within said coil into expanding engagement with the interior of said coil to increase its diameter;

rotating the increased diameter coil at high speed to abrade away the obstruction;

subsequent to such high speed rotation, deactivating the expansion means to remove it from expanding engagement with the interior of said coil to reduce its diameter; and

withdrawing the coil from the vessel.

41. An apparatus for removing an obstruction from a vessel, comprising:

an adjustable diameter tip;

said adjustable diameter tip being capable of elongation thereby reducing its diameter as said tip is elongated;

an elongator engageable with said tip and movable between first and second positions wherein said adjustable diameter tip is elongated in one of said positions;

an introducer extendable inside the vessel proximate to the obstruction, wherein said introducer supports said adjustable diameter tip;

said adjustable diameter tip having at least part of its outer surface treated to form a roughened surface;

a drive shaft connected to said tip and being capable of selectively rotating said adjustable diameter tip; and

said roughened surface being formed by a plurality of projections on said outer surface.

42. An apparatus for removing an obstruction from a vessel according to claim 41 wherein said projections have a size of at least 10 microns.

43. An apparatus for removing an obstruction from a vessel according to claim 41 wherein said projections have sharp edges.

44. An apparatus for removing an obstruction from a vessel, comprising:

a coil;

said coil being capable of elongation thereby reducing the circumference as said coil is elongated;

an elongator attached to said coil and movable between first and second positions wherein said coil is elongated in one of said positions;

an introducer extendable inside the vessel proximate to the obstruction, wherein said introducer supports said coil;

said coil having at least part of its outer surface treated to form a roughened surface;

a drive shaft attached to said coil and capable of selectively rotating said coil; and

said coil including a wire-like member having a plurality of projections formed thereon and said wire-like member having an axis which is transverse to the longitudinal axis of the vessel.

45. An apparatus for removing an obstruction from a vessel according to claim 44 wherein said wire-like member forms a spiral.

46. An apparatus for removing an obstruction from a vessel, comprising:

a coil;

said coil being capable of elongation thereby reducing the circumference as said coil is elongated;

an elongator engageable with said coil and movable between first and second positions wherein said coil is elongated in one of said positions;

an introducer extendable inside the vessel proximate to the obstruction;

said coil having at least part of its outer surface treated to form a roughened surface;

a drive shaft attached to said coil and supported by said introducer; and

said drive shaft being capable of rotating said coil at least 100,000 revolutions per minute.

47. An apparatus for removing an obstruction from a vessel, comprising:

a coil;

said coil being capable of elongation thereby reducing the circumference as said coil is elongated;

an elongator engageable with said coil and movable between a first position and a second position wherein said coil is elongated in one of said positions;

said coil having at least part of its outer surface treated to form a roughened surface;

a drive shaft attached to said coil and being capable of selectively rotating said coil; and

said roughened surface being capable of frictionally engaging the obstruction and grinding the obstruction for removal.

48. An apparatus for removing an obstruction from a vessel, comprising:

an expandable removal member having a plurality of wire-like members which traverse the longitudinal axis of the vessel;

said expandable removal member being capable of elongation thereby reducing the circumference as said expandable removal member is elongated;

an elongator engageable with said expandable removal member and movable between a first position and a second position wherein said expandable removal member is elongated in one of said positions;

an introducer extendable inside the vessel proximate to the obstruction, wherein said introducer supports said expandable removal member;

said expandable removal member having at least part of its outer surface processed to form a roughened surface;

a drive shaft attached to said expandable removal member and being capable of selectively rotating said expandable removal member; and

said outer surface of said expandable removal member being processed to form a plurality of raised surfaces.

49. An apparatus for removing an obstruction from a vessel according to claim 48 wherein an abrasive material is added to said outer surface.

50. An apparatus for removing an obstruction from a vessel according to claim 49 wherein said abrasive material has particles with a diameter in the range of 10 to about 100 microns.

51. An apparatus for removing an obstruction from a vessel according to claim 48 wherein said outer surface is peened to form raised projections on said outer surface.

52. An apparatus for removing an obstruction from a vessel, comprising:

a coil of a wire-like member forming a plurality of spirals;

said coil having a first position wherein the circumference of said coil is reduced and a second position wherein the circumference of said coil is increased;

said coil forming a continuous outer surface in said second position wherein the passage of particles are prevented from the obstruction into the interior of said coil;

said coil having an abrasive surface covering at least the outer circumference of said outer surface;

a movable member attached to said coil and capable of moving said coil between said first and second positions;

an introducer member extendable inside the vessel proximate to the obstruction; and

a rotatable member attached to said coil and being capable of selectively rotating said coil and causing said abrasive surface to engage and remove the obstruction.

53. An apparatus for removing an obstruction from a vessel, comprising:

an abrasive member forming an expandable circumferential outer surface;

said abrasive member being capable of increasing the circumference of said outer surface;

said expandable circumferential outer surface forming a continuous surface without apertures therethrough which would otherwise allow the passage through said outer surface of particles removed from the obstruction;

said expandable continuous circumferential outer surface having an abrasive surface covering at least part of said outer surface;

an actuator attached to said coil and being movable between first and second positions wherein the circumference of said abrasive member is increased in one of said positions;

an introducer extending inside the vessel proximate to the obstruction wherein said introducer supports said abrasive member; and

a drive member attached to said abrasive member and being capable of selectively rotating said abrasive member.

54. The apparatus of claim 53 wherein said expandable circumferential outer surface is maintained as a continuous outer surface as the circumference of said abrasive member is increased.

55. The apparatus of claim 53 wherein said abrasive member is a coil having a plurality of spiral wire-like members which are in continuous contact as the circumference of said abrasive member is increased.

56. The apparatus of claim 55 wherein said spiral wire-like members form a continuous ridged outer surface.

57. An apparatus for removing an obstruction from a vessel, comprising:

a coil;

said coil being capable of having its circumference reduced;

said coil having an abrasive surface covering at least part of its outer surface;

a closure member disposed within said coil and being capable of preventing the passage into the apparatus of any particles removed from the obstruction;

a mover attached to said coil and being capable of moving said coil between first and second positions wherein the circumference of said coil is reduced in one of said positions;

an introducer extendable inside the vessel proximate to the obstruction wherein said introducer supports said mover; and

a drive shaft attached to said coil and being capable of selectively rotating said coil.

58. An apparatus for removing an obstruction from a vessel, comprising:

a removal member having an expandable and contractible circumference and first and second ends;

a stationary member connected to said first end wherein said first end is held against rotation;

a rotatable member connected to said second end wherein said second end is capable of being rotated with respect to said first end; and

said circumference being expanded upon rotation of said rotatable member in one direction and contracted upon rotation of said rotatable member in an opposite direction.

59. An apparatus for removing an obstruction from a vessel, comprising:

a removal member having an expandable surface and first and second ends;

an outer member connected to said first end;

an inner member extending through said removal member and connected to said second end;

one of said inner and outer members being rotatable with respect to the other; and

said removal member expanding upon said one of said inner and outer members being rotated with respect to the other.

60. The apparatus of claim 59 wherein said outer member includes a helically wound member.

61. The apparatus of claim 59 wherein said inner member includes a helically wound member.

62. The apparatus of claim 59 wherein said removal member winds upon said rotation.

63. The apparatus of claim 59 wherein said removal member includes at least one helically wound member processed to form sharp raised surfaces.

64. The apparatus of claim 59 wherein one of said first and second ends is a distal end of said removal member and includes an abrading surface.

65. An apparatus for removing an obstruction from a vessel, comprising:

a rotating member;

an expandable removal member insertable into the vessel;

said expandable removal member including a plurality of wire-like members which traverse the longitudinal axis of the vessel and extend to a tip on the distal end of said expandable removal member;

a hollow drive shaft operatively connecting said rotating member to said removal member and being capable of rotating said removal member within the vessel;

a hollow inner member passing through said removal member and said hollow drive shaft and engaging said tip;

said inner member being shiftable within said drive shaft and said removal member;

said wire-like members being responsive to shifting said inner member; and

a control member operatively connected to said inner member and being capable of positively shifting said inner member.

66. An apparatus for removing an obstruction from a vessel, comprising:

a motor;

an expandable removal member having a plurality of wire-like members insertable into the vessel;

a hollow drive shaft operatively connecting said motor to said removal member and being capable of rotating said removal member within the vessel;

a hollow inner member insertable through said removal member and said hollow drive shaft;

said inner member being shiftable within said drive shaft and said removal member;

said removal member being responsive to shifting said inner member;

a control member operatively connected to said inner member and being capable of positively shifting said inner member; and

a guidewire extending through said inner member.

67. The apparatus of claim 65 wherein said removal element includes an abrasive disposed thereon.

68. An apparatus for removing an obstruction from a vessel, comprising:

a motor;

an expandable removal member insertable into the vessel;

a hollow drive shaft operatively connecting said motor to said removal member and being capable of rotating said removal member within the vessel;

an inner member insertable through said removal member and said hollow drive shaft;

said inner member being shiftable within said drive shaft and said removal member;

said removal member being responsive to shifting said inner member;

a control member operatively connected to said inner member and being capable of positively shifting said inner member; and

said removal element having a proximal end and a distal end, said proximal end being connected to said drive shaft and said distal end being connected to an annular member with an aperture with said inner member extending into said aperture.

69. An apparatus for removing an obstruction from a vessel, comprising:

a motor;

an expandable removal member insertable into the vessel;

a hollow drive shaft operatively connecting said motor to said removal member and being capable of rotating said removal member within the vessel;

an inner member insertable through said removal member and said hollow drive shaft;

said inner member being shiftable within said drive shaft and said removal member;

said removal member being responsive to shifting said inner member;

a control member operatively connected to said inner member and being capable of positively shifting said inner member; and

said removal element having a distal end with a tip having an abrasive surface.

70. An apparatus for removing an obstruction from a vessel, comprising:

a motor;

an expandable removal member insertable into the vessel;

a hollow drive shaft operatively connecting said motor to said removal member and being capable of rotating said removal member within the vessel;

an inner member insertable through said removal member and said hollow drive shaft;

said inner member being shiftable within said drive shaft and said removal member;

said removal member being responsive to shifting said inner member;

a control member operatively connected to said inner member and being capable of positively shifting said inner member; and

said removal element including a plurality of helical wires forming a ridged surface.

71. An apparatus for removing an obstruction from a vessel, comprising:

a motor;

an expandable removal member insertable into the vessel;

a hollow drive shaft operatively connecting said motor to said removal member and being capable of rotating said removal member within the vessel;

an inner member insertable through said removal member and said hollow drive shaft;

said inner member being shiftable within said drive shaft and said removal member;

said removal member being responsive to shifting said inner member;

a control member operatively connected to said inner member and being capable of positively shifting said inner member; and

said drive shaft comprising a coil.

72. The apparatus of claim 71 further comprising a sheath over said coil.

73. An apparatus for removing an obstruction from a vessel, comprising:

a removal member which is expandable and insertable in the vessel for removing the obstruction;

an expansion control operatively associated with said expandable removal member and being capable of limiting expansion of said expandable removal member; and

said expansion control including a first member connected to one end of said removal member and a second member connected to another end of said removal member, said first and second members engaging to limit the expansion of said removal member.

74. An apparatus for removing an obstruction from a vessel, comprising:

a removal member which is expandable and insertable in the vessel to remove the obstruction;

an expansion control operatively associated with said expandable removal member to limit expansion of said expandable removal member; and

said expansion control including an expandable member having a first end connected to one end of said removal member and a second end connected to another end of said removal member to limit the expansion of said removal member.

75. A method for removing an obstruction from a vessel comprising:

navigating a guidewire to the obstruction;

navigating a removal member having a plurality of wire-like members to the obstruction over the guidewire;

compressing and expanding the wire-like members;

limiting the expansion of the wire-like members;

energizing the removal member to remove the obstruction; and

frictionally engaging the obstruction with an abrasive on the wire-like members to remove the obstruction.

76. A method for removing an obstruction from a vessel comprising:

navigating a guidewire to the obstruction;

navigating a removal member to the obstruction over the guidewire;

expanding the removal member;

engaging the removal member with another member disposed around the guidewire near the obstruction to limit the expansion of the removal member;

energizing the removal member to remove the obstruction; and

variably expanding the removal member.

77. A method for removing an obstruction from a vessel comprising:

navigating a guidewire to the obstruction;

navigating a removal member having a plurality of wire-like members to the obstruction over the guidewire;

expanding the removal member;

engaging the removal member with another member disposed around the guidewire near the obstruction to limit the expansion of the removal member;

energizing the removal member to remove the obstruction; and

supplying a fluid to the removal member.

78. A method for removing an obstruction from a vessel comprising:

navigating a guidewire to the obstruction;

navigating a removal member to the obstruction over the guidewire;

expanding the removal member;

limiting the expansion of the removal member;

energizing the removal member to remove the obstruction; and

expanding a dilating member adjacent the obstruction.

79. The method of claim 75 wherein the limiting element includes abutting members connected to the ends of the removal member.

80. The method of claim 75 further including activating a motor capable of rotating the removal member.

81. The method of claim 75 further including holding the guidewire in position.

82. The method of claim 75 further including locking the guidewire in position.

83. The apparatus of claim 1 wherein said coil forms ridges.

84. The apparatus of claim 1 wherein said coil has an elongated position with a reduced circumference and a contracted position with an enlarged circumference, said coil returning to said contracted position after said elongation.

85. The apparatus of claim 84 wherein said coil is preformed to return to said contracted position.

86. The apparatus of claim 1 wherein said at least part of its outer surface has a coating of an abrasive.

87. The apparatus of claim 1 wherein said coil includes a tip having a tapered cutting surface.

88. The apparatus of claim 1 wherein collars are disposed at each end of said coil.

89. The apparatus of claim 1 wherein a portion of said coil is radioscopically visible.

90. The apparatus of claim 1 wherein said coil includes a hollow interior for receiving a guidewire therethrough which extends through said coil.

91. An intravascular device for removing vascular occlusion material within a vascular lumen in a patient, the intravascular device comprising:

an expandable removal element having a proximal and distal end;

an inner drive shaft comprising a helix extending into the removal element and operatively connected to the distal end of the removal element to energize the removal element intravascularly; and

an outer drive shaft comprising a helix operatively coupled to the proximal end of the removal element to energize the removal element intravascularly wherein the inner drive shaft extends coaxially through the outer drive shaft and wherein the inner drive shaft and outer drive shaft are shiftable with respect to one another.

92. An intravascular device as defined in claim 91 further comprising:

rotating means operatively connected to the removal element through the inner and the outer drive shafts for rotating the removal element intravascularly.

93. A intravascular device as defined in claim 91 further comprising a distal tip located at the distal end of said removal element wherein an abrasive is deposited on the distal tip to create a cutting surface distally of the removal element to remove vascular occlusion material.

94. An intravascular device as defined in claim 91 wherein at least a portion of said expandable removal element is made from a radiopaque material.

95. A vascular occlusion material removal device for removing vascular occlusion material in a vascular lumen, the material removal device comprising:

an expandable material removal element having a first and a second end and including a plurality of wires generally disposed between the first and second ends of the removal element, and the expandable material removal element being movable between an expanded position and a contracted position;

a drive shaft connected to the first end of the expandable material removal element and being capable of rotating the removal element;

an elongator operatively connected to the second end of the removal element and movable between first and second positions wherein said material removal element is operatively variably moved between the expanded position and the contracted position; and

at least one of said wires being treated to form sharp projections on the surface of said wires.

96. A vascular occlusion material removal device as defined in claim 95 further comprising a removal element expansion control to positively control movement of the removal element between the expanded position and the contracted position, the control being adjacent the removal element.

97. A vascular occlusion material removal device as defined in claim 95 further comprising a dilatation member connected to the elongating member adjacent the removal element.

98. A vascular occlusion material removal device as defined in claim 95 further comprising an abrasive disposed on said at least one of the wires.

99. A vascular occlusion material removal device as defined in claim 98 wherein the abrasive comprises particles deposited on the surface of the wire.

100. A vascular occlusion material removal device as defined in claim 95 further comprising a cutting surface disposed distally on the removal element and capable of removing vascular occlusion material.

101. A vascular occlusion material removal device as defined in claim 95 wherein the expandable material removal element has an axial length and a radius; and wherein the axial length is reducible responsive to shifting of the elongator with respect to the drive shaft, wherein the radius is expanded.

102. A vascular occlusion material removal device as defined in claim 95 wherein the wires are preformed.

103. A vascular occlusion removal device as defined in claim 95 further comprising an expansion control to limit expansion of the expandable material removal element.

104. A vascular occlusion material removal device as defined in claim 95 wherein the elongation member comprises a cylindrical portion having a hollow interior with an aperture in the cylindrical portion to allow fluid to flow through the interior of the cylindrical portion.

105. A vascular occlusion material removal device as defined in claim 95 further comprising a balloon member connected to the elongating member.

106. The device of claim 95 wherein the expandable removal element is sufficiently deformable so that the element assumes a configuration corresponding to the configuration defined by the non-occluded diameter upon expansion of the element.

107. The device of claim 95 wherein said projections are formed by peening the surface of the wires.

108. The device of class 95 wherein said removal element includes a plurality of groupings of said wires.

109. An apparatus for removing an obstruction from a vessel, comprising:

a drive shaft disposed within a catheter;

a helical coil mounted on the end of said drive shaft;

said coil having at least part of its outer surface treated to form a roughened surface; and

said drive shaft being capable of selectively rotating said coil to remove the obstruction.

110. The apparatus of claim 109 wherein said coil includes a helical wire-like member.

111. The apparatus of claim 109 wherein said coil has an abrasive coating.

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