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(71) Applicant *(for all designated States except US)*: **AVINGER, INC.** [US/US]; 400 Chesapeake Drive, Redwood City, CA 94063 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **PATEL, Himanshu, N.** [US/US]; 400 Chesapeake Drive, Redwood City, CA 94063 (US). **SIMPSON, John, B.** [US/US]; 400 Chesapeake Drive, Redwood City, CA 94063 (US).

(74) Agents: **SHOOP, Richard, D.** et al.; Shay Glenn LLP, 2755 Campus Drive, Suite 210, San Mateo, CA 94403 (US).

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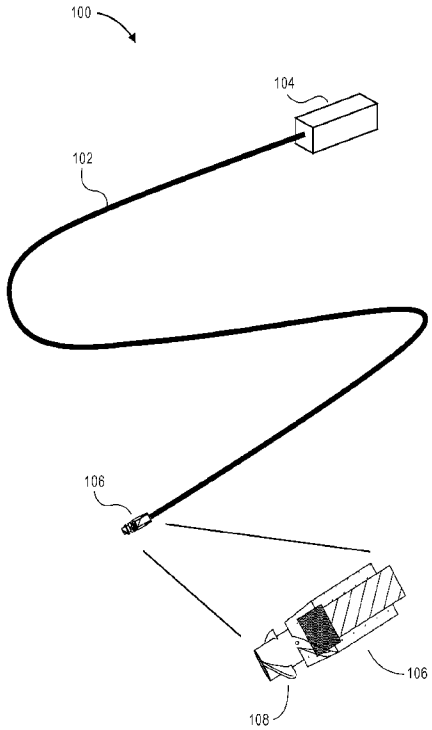
(54) Title: CATHETER SYSTEM AND METHOD FOR BORING THROUGH BLOCKED VASCULAR PASSAGES

FIG. 1



(57) Abstract: A rotating cutting head catheter for passage through chronic total occlusions or other refractory atherosclerotic plaque from diseased arteries is disclosed. The catheter's rotating cutting head is designed to reside safely within an outer protective sheath when not in use. The outer protective sheath contains one or more helical groves or slots, and the cutting head contains protruding blades or projections that fit into these helical groves or slots. Application of torque to an inner catheter or wire attached to the cutting head applies spin to the cutting head, and the force of the sheath's helical groves or slots against the cutting head's protruding blades or projections advances the cutting head outward from the protective sheath. Once extended, the cutting head may now rotate freely. The device may use a guidewire to direct the cutting head to the desired position.

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Title: Catheter System and Method for Boring through Blocked Vascular Passages

Background of the Invention

A number of vascular diseases, such as coronary artery disease and peripheral vascular disease, are caused by the build-up of fatty atherosclerotic deposits (plaque) in the arteries. These deposits limit blood flow to the tissues that are supplied by that particular artery. Risk factors for this type of disease include advanced age, diabetes, high blood pressure, obesity, history of smoking, and high cholesterol or triglycerides.

When these deposits build up in the arteries of the heart, the problem is called coronary artery disease (CAD). When these deposits build up in the arteries of a limb, such as a leg, the condition is called peripheral artery disease (PAD). Symptoms of CAD – angina, heart disease, and heart attacks, are well known. Symptoms of PAD can include pain on walking, and wounds that do not heal. If PAD is not treated, it can eventually produce critical limb ischemia (CLI), gangrene, and loss of limb. Roughly 30% of the population over the age of 70 suffers from PAD.

When the plaque builds up to the point where an artery is totally occluded, the obstruction is referred to as a Chronic Total Occlusion (CTO). CTOs can confound the treatment of CAD, because the sudden loss of heart muscle can lead to sudden death. A CTO that occludes the peripheral arteries for PAD patients is also extremely serious. PAD patients that suffer from a CTO often enter a downward spiral towards death. Often the CTO in a peripheral artery results in limb gangrene, which requires limb amputation to resolve. The limb amputation in turn causes other complications, and roughly half of all PAD patients die within two years of a limb amputation.

For both CAD and advanced PAD, prompt treatment of such blockages is thus essential. Here, less invasive angioplasty or atherectomy procedures have many advantages. In these procedures, a catheter is inserted into the diseased artery and threaded to the blocked region. There the blockage may be either squeezed into a hopefully more open

position by pressure from an inflated catheter balloon (balloon angioplasty), the blocked region may be kept open by a stent, or alternatively a physician may use a catheter to surgically remove the plaque from the inside of the artery (atherectomy).

As an example, for the treatment of PAD, atherectomy devices such as the Fox Hollow (now ev3) SilverHawk™ catheter (US patent 6,027,514), are often used. These catheters may be threaded (usually with the aid of a guidewire) up the artery to a blocked region. There, the physician will usually position the catheter to make multiple passes through the blocked region of the artery, each time shaving a way a ribbon of plaque. The shaved ribbons of plaque are stored in the hollow nose of the device. By making multiple passes, the plaque may be substantially reduced, blood circulation may be restored to the limb, and the limb in turn saved from amputation.

In order to effectively treat the plaque, however, most modern catheters need to be threaded past the blocked region of the artery. This is because the active portions of most catheters, which are used to treat the blockage, are usually located on the side of the catheter, rather than on the tip of the catheter. This is due to simple mechanical necessity. The tip of the catheter must have a very small surface area, and thus is able to treat only a very small portion of the diseased artery. By contrast, the side of the catheter has a much larger surface area, and the catheter side thus conforms nicely to the sides of the diseased artery. Thus stents, balloons, atherectomy cutting tools, etc., are usually mounted on the sides of the catheter. The catheter must be threaded past the blocked portion of the artery in order to function properly.

When the artery is only partially blocked by plaque, the catheter can usually be maneuvered past the obstruction, and the active portions of the catheter can thus be brought into contact with the diseased portion of the artery. However when the artery is totally blocked, as is the case with a CTO, this option is no longer possible. The tip of the catheter encounters the obstruction, and further forward motion is blocked.

Simply trying to force a typical catheter past the obstruction usually isn't possible. The obstructions are typically composed of relatively tough fibrous material, which often also includes hard calcium deposits as well. Often, when physicians attempt to force guide wires or catheters past such obstructions, the guidewire or catheter device may instead exit the artery and enter the lumen outside the artery. This further damages the artery, further complicates the procedure, and decreases the chance of success. As previously discussed, the consequences of such procedure failures have a high mortality rate. Thus improved methods to allow catheters and guide wires to more readily penetrate through hardened plaque and CTO are thus of high medical importance.

A good summary of the present state of the art may be found in an article by Aziz and Ramsdale, "Chronic total occlusions – a stiff challenge requiring a major breakthrough: is there light at the end of the tunnel?" Heart 2005;91;42-48.

Previous attempts to produce devices for cutting through hardened plaque include US patent 5,556,405 to Lary, 6,152,938 to Curry, and 6,730,063 to Delaney et. al.

Patent 5,556,405 teaches an incisor catheter which features a bladed head stored in a catheter housing, which contains a number of slits though which the blades protrude. The blade is activated by a push-pull catheter. When the push-pull catheter is pushed, the bladed head protrudes through the slits in the housing, and the blade thus comes into contact with hardened plaque material. The blade does not rotate, but rather delivers linear cuts.

Patent 6,152,938 teaches a general purpose catheter drilling device for opening a wide variety of different blocked (occluded) tubes. The device anchors the tip of the drill head against a face of the occlusion, and partially rotates the drill head using a rein attached to the drill head so that the drill head faces at an angle.

Patent 6,730,063 teaches a catheter device for chemically treating calcified vascular occlusions. The device is a fluid delivery catheter that delivers acidic solutions and other

fluids to calcified plaque with the objective of chemically dissolving the calcified material.

Several catheter devices for traversing CTO obstructions are presently marketed by Cordis Corporation, FlowCardia Technology, Kensey Nash Corporation, and other companies. Cordis Corporation, a Johnson and Johnson Company, produces the Frontrunner® XP CTO catheter (formerly produced by LuMend Corporation). This catheter, discussed in US patent 6,800,085 and other patents, has a front "jaw" that opens and closes as it traverses the catheter. The jaw itself does not cut, but rather attempts to pry open the CTO as the catheter passes.

Other catheter devices use various forms of directed energy to traverse CTOs. For example, FlowCardia Technology, Sunnyvale California, produces the Crosser system, taught in US patent 7,297,131 and other patents. This system uses an ultrasonic transducer to deliver energy to a non-cutting catheter head. This catheter head itself has a relatively small diameter and does not have any blades. Rather, the head, through rapid (ultrasonic) vibration is able to push its way through a variety of different occlusions.

Kensey Nash Corporation, Exton Pennsylvania (formerly Intraluminal Therapeutics, Inc.), produces the Safe-Cross CTO system. This system, taught in US patents and 6,852,109 and 7,288,087, uses radiofrequency (RF) energy. The catheter itself is also directed in its movement by an optical (near-infrared light) sensor which can sense when the tip of the catheter is near the wall of the artery. The optical sensor tells the operator how to steer the catheter, and the RF ablation unit helps the operator ablate material and cross occluded regions.

Although ingenious, the success rates with these devices still leave much to be desired. According to Aziz, the best reported success rates of overcoming CTOs with prior art devices range from 56% to 75%. Aziz further teaches that the average success rates are only in the 50-60% range. Given the huge negative impact that unsuccessfully cleared CTO's, have on patient morbidity and mortality, clearly further improvement is desirable.

An additional problem with these prior art CTO clearing devices is that simply cutting a small channel though the CTO may not be sufficient to totally resolve the medical problem. Occasionally, the device that traverses the CTO should also remove (debulk) a substantial portion of the occlusion. This is because as previously discussed, removal of a substantial portion of the occlusion may be required in order to allow catheters with side mounted stents, balloons, and atherectomy cutting tools to get access to the damaged portions of the artery and make more lasting repairs. Thus improved CTO "unclogging" devices that can do the more substantial amount of CTO debulking required to allow other types of catheters to pass are also desirable.

Thus there remains a need for devices that can effectively traverse CTOs and remove more substantial amounts of hardened or calcified plaque. Such devices would enable stents and other devices, such as SilverHawk atherectomy catheters, balloon catheters, etc. to be more successfully used in high occlusion situations. This in turn should lead to improved patient outcomes and a reduction in patient morbidity and mortality.

Summary of the Invention

The present invention teaches a novel rotating cutting head catheter for creating a passage through refractory material, such as chronic total occlusions, refractory atherosclerotic plaque, gallstones, kidney stones, etc. from diseased arteries, veins, or other body lumens. The catheter's rotating cutting head is designed to reside safely within an outer protective sheath head when not in use, and this sheath head is mounted on the distal end of the catheter.

The outer protective sheath head contains one or more helical groves or slots, and the cutting head contains protruding blades or projections that fit into these helical groves or slots. Application of torque to an inner torque communicating connector (a catheter or wire or coil, or any torque communicating mechanism attached to the cutting head) applies spin to the cutting head, and the force of the sheath head's helical groves against

the cutting head's protruding blades or projections advances the cutting head outward from the protective sheath. Once extended, the cutting head may now rotate freely. In some embodiments, the center of the catheter and even the cutting head itself may be hollow, and the device may use a guidewire to direct the catheter and the cutting head to the desired position. Alternatively the guide wire may be attached to a guide that is attached to the outside of the catheter tube. In at least some embodiments, this sheath head acts as motion stop, and may contain one or more motion stop elements (such as a mechanical barrier) designed to restrict the forward extension of the cutting head.

Depending upon the angle and nature of the cutting head's protruding blades, the blades may either be designed to simply cut thorough the occluding material, without actually dislodging the occluding material from the body lumen, or alternatively the blades may be designed to both cut through the occluding material, and sever its link to the body lumen, thereby dislodging the occluding material from the body lumen. In this case, the cutting head can act to actually remove (debulk) a substantial portion of the occlusion

Brief description of the drawings

Figure 1 shows an overview of the catheter device including the handle, the catheter, and the catheter head.

Figure 2 shows the exterior of the catheter head with the cutting head extended out from the sheath head.

Figure 3 shows a drawing of the catheter head (mounted on a guide wire) with the cutting head extended and cutting into a CTO plaque in an occluded artery.

Figure 4 shows a diagram of the cutting head unscrewing from protective shroud of the catheter head's sheath head.

Figure 5 shows a close up of the catheter head showing the cutting head screwed into a stored position inside the catheter head's protective sheath head.

Figure 6 shows a close up of a cutting head with an alternate protruding blade design.

Detailed Description

Although, throughout this discussion, applications of this device for creating a passage through refractory atherosclerotic plaque from arteries, particularly coronary or peripheral limb arteries, are frequently used as examples, it should be understood that these particular examples are not intended to be limiting. Other applications for the present technology may include removal of kidney stones, in which case the device will be intended to traverse the ureters; gallstones, in which case the device will be intended to traverse the bile duct; enlarged prostate blockage of the urethra, in which case the device will be intended to traverse the urethra; blocked fallopian tubes, in which case the device will be intended to traverse the fallopian tubes; treatment of blood clots, removal of material trapped in the lungs, etc. In general, any unwanted material occupying space in a body lumen may be surgically removed by these techniques. Similarly, although use in human patients is cited in most examples, it should be evident that the same techniques may be useful in animals as well.

Helical drill bits and self-tapping screw bits are widely known to be highly effective at penetrating through materials as soft as wax and as refractory as rock and metal, and indeed such devices are widely used for such purposes. Although effective, drill bits are typically considered to be both powerful and extremely crude. As anyone who has ever attempted to use an electric drill can attest, drill devices, although admittedly effective at removing material, would seem to be totally unsuited for delicate vascular surgery, particularly at sites hidden deep within the body. Helical self-tapping screw bits are designed slightly differently. Although just as effective at cutting through various materials, drill bits are configured to both cut and then remove the material, while self-

tapping screw bits are designed primarily for cutting a passage through the material. For either type of device, the problem is not the efficacy of cutting or occlusion removal; the problem is one of preventing inadvertent damage to the surrounding artery.

Surprisingly however, the present invention teaches that if the prejudice against such crude and powerful methods is overcome, and suitable protection and control devices are devised to control the crude and apparently overwhelming power of such "drill bit" devices, catheter "drill bit" devices suitable for delicate vascular surgery, which are both powerful at cutting or removing occlusions, yet specific enough to avoid unwanted damage to artery walls, may be produced.

Thus, in a first aspect of the present invention, the superior material cutting/removing properties of a "drill bit" like material removal device (or self-threading helical screw bit) are combined with suitable protection and catheter guidance mechanisms which allow such powerful cutting devices to be safely and effectively used within the confines of delicate arteries and other body lumens.

To do this, precise control must be exerted over the cutting edge of the "drill bit". The bit or "cutting head" should normally be sheathed or shielded from contact with artery walls, so that inadvertent damage to artery walls can be avoided while the head of the catheter is being threaded to the artery to the occluded region. Once at the occlusion, the cutting portion of the cutting head (bit) should be selectively exposed only to the minimal extent needed to perform the relevant occlusion cutting activity. The rotation direction of the cutting head may optionally be varied, for example by rotating the head counter-clockwise to produce a blunt dissection through the obstacle or occlusion, and then clockwise while pulling back on the entire assembly. Once the desired cuts are made, the cutting head should then be quickly returned to its' protective sheath. The entire device should operate within the millimeter diameters of a typical artery, and should be capable of being threaded on a catheter for a considerable distance into the body.

Suitable techniques to achieve these objectives are taught in the following figures and examples.

Figure 1 shows an overview of the catheter device (100) including the catheter body (102), the catheter handle (104), and the catheter head (106). The catheter body and catheter head, and often even the cutting head, are often hollow and are capable of accommodating a guide wire (not shown). A magnified view of the catheter head, showing the rotating cutting head in an extended configuration (108), extended outside of the sheath portion of the catheter head (here this sheath is called the "sheath head") (106) is also shown.

Figure 2 shows the exterior of the sheath head portion of the catheter head (106) with the cutting head (108) extended. This cutting head will normally have one or more projecting side blades or with cutting edges (202), and additionally will often have cutting edges on the front (204) as well. The center of sheath head portion of the catheter head (106) and catheter (102) may be hollow to accommodate a guide wire. In some embodiments, the guide wire will exit the sheath portion of the catheter head (106) on the side of catheter head (106) prior to cutting head (108) by a side opening (not shown). In other embodiments, cutting head (108) will itself be hollow and the guide wire will exit the end of cutting head (108) through opening (206).

In the closed configuration, the rotating cutting head (108) is retracted inside the sheath head portion of catheter head (106) and the cutting edges or projections (202) from the cutting head (108) fit into helical slots or groves (208). This sheathed configuration prevents projecting side cutting edges (202) and front cutting edges (204) from accidentally contacting the walls of the artery.

Figure 3 shows a drawing of the catheter head (106) (with the cutting head extended from the sheath head) cutting into a CTO (304) in an occluded artery (306). In this example, the catheter and catheter head are mounted on and guided by a guide wire (302), however this will not always be the case.

As should be clear, the cutting edge of the "drill bit/screw-thread" like cutting head can easily damage artery lining (306). In order to avoid such accidental damage, precise control over the extent of cutting head exposure is needed. Methods to achieve such precise control are shown in Figure 4.

Figure 4 shows some of the details of how the cutting head (108) is unscrewed from the helical slots or groves (208) of the sheath head portion of catheter head (106), thus exposing cutting edges (202) and (204). In (402), the cutting head (108) is shown fully exposed. The cutting head has become fully unscrewed from helical slots (208) and is fully extended. An optional projecting post or guide (404) mounted on cutting head (108) may act to guide the rotating cutting head into and out of the helical screw-like slots (208). The coupling (406) that couples cutting head (108) with a torque transmitting (torque communicating connector) inner catheter tube or cable (408) is in the extreme distal position inside of the sheath head portion of catheter head (106).

In (410), the cutting head is shown in its fully retracted position. Normally the cutting head will be stored in this fully retracted position so that it can be introduced into the artery via a guide wire, and be directed to the occlusion or plaque region, without damaging non-target regions of the artery. Note that the coupling (406) is in the fully distal position in the sheath head portion of catheter head (106), and that the protruding cutting blades (202) of cutting head (108) are fully screwed into helical screw slots (208).

In some situations, a guide wire [Figure 3 (302)] leading to the obstruction will already have been introduced. In fact, a previous attempt to perform atherectomy may have already been made, and this attempt may have been frustrated by refractory plaque, such as a plaque covered with hard calcium deposits, whereupon the physician may make a decision to use the present cutting device to punch through this refractory plaque.

In use, the catheter head (106) and catheter tube (102) are attached to the guide wire and are then introduced into the artery via an appropriate incision. The catheter handle (104)

will remain outside of the body. The location of the obstruction will generally be known, and in fact the obstruction may be imaged by fluoroscopy or other technique. Catheter head (106) is brought up against the obstruction, and the operator will then apply torque, often via a device mounted on catheter handle (104). This torque is usually transmitted to the catheter head (106) via an inner torque conducting catheter or wire (408), here termed a "torque communicating connector". Usually outer catheter (102) will not conduct torque. Outer catheter (102) remains approximately stationary (i.e. does not rotate) and similarly the sheath head portion of catheter head (106) and the helical screw slots or groves (208) also do not rotate.

The torque is communicated via coupling (406) to cutting head (108). This torque essentially causes cutting head (108) to "unscrew" from its retracted position in the sheath head portion of catheter head (106) via the action of the protruding blade edges (202) against helical slots or groves (208). This "unscrewing" circular motion is shown by the curved arrow (412). As cutting head (108) unscrews, it starts to advance and protrude outside of the protective sheath head shroud.

In (420), the cutting head (108) is now shown in a partially unscrewed or partially extended position. Note that the protruding blade edges (202) have moved relative to the helical sheath head screw slots or groves (208). Thus the blade edges (202) are now partially unscrewed from the helical screw slots (208) and are partially exposed. Cutting head (108) now is protruding out from the sheath head portion of catheter head casing or shroud (106), and the coupling (406) has moved partially toward the distal end of the catheter.

It should be evident that by reversing the direction of the torque, the cutting head may be again retracted into the sheath head when this is desired. The catheter can be repositioned for another cut, and the process of cutting head extension, cutting, and retraction can be repeated as many times as necessary.

Thus the present invention controls the aggressive cutting power of the "drill bit" cutting head by exposing only as much of the cutting head at a time as needed for the task at hand.

Figure 5 shows a close up of the sheath head portion of the catheter head showing the cutting head screwed into a stored position inside the protective sheath head shroud. This angle allows the helical screw slots or groves (208) to be easily seen, and cutting head (108) can also be seen inside of the sheath head portion of catheter head (106).

Figure 6 shows a close up of an alternate design cutting head (108) with spiral shaped protruding cutting edges (202).

The sheath head portion of catheter head (106) will normally be between about 1 to 2.2 millimeters in diameter, and the catheter body (102) will typically also have a diameter of approximately 1 to 3 millimeters (3-9 French), and a length between 50 and 200 cm. The sheath head may be made from various materials such as hard plastics, metals, or composite materials. Examples of such materials include NiTi steel, platinum/iridium or stainless steel.

Although sheath head (106) contains slots or groves designed to impart forward motion to cutting head (108) when cutting head is rotated, and although these slots or groves are referred to as "helical" groves or slots, due to the short length of the sheath head and overall catheter head, the slots or groves do not have to be in the exact mathematical shape of a helix. In fact a variety of shapes that differ somewhat from a mathematically pure helix configuration will suffice. In general, the slot or grove must be such that torque applied to the cutting head causes the cutting head to both rotate and advance, and any such slot or grove is here designated as a "helical" slot or grove. Also, for this discussion, a "slot" is considered to be an opening that extends from the inside to the outside of the hollow catheter head (106), while a "grove" is similar to a rifle grove in that a "grove" does not extend all the way from the inside of the hollow sheath head to the outside, but rather only penetrates partway through the sheath head material.

The cutting head (108) will often be made of materials such as steel, carbide, or ceramic. The blades of the cutting head (202), (204) can optionally be hardened by coating with tungsten carbide, ME-92, etc. Materials suitable for this purpose are taught in US patents 4,771,774; 5,312,425; and 5,674,232. The angle of the blades and the details of their design will differ depending upon if the head is intended to simply cut through the occluding material, of if it is intended to cut through and actually remove (debulk) portions of the occlusion. For example, blades intended for to remove material may curve at an angle such that they will tend to sever the link between the occluding material and the body lumen, while blades intended just for cutting will have an alternate angle that tends not to sever this link.

In some embodiments, the catheter may be composed of two different tubes. In this configuration, there may be an outer catheter tube (102), which will often be composed of a flexible biocompatible material. There may also be an inner tube (408) chosen for its ability to transmit torque from the catheter handle (104) to the cutting head (108) (via coupling (406)). The inner torque transmitting tube (which is one possible type of "torque communicating connector") is able to twist relative to the outer catheter tube so that when torque is applied to the inner tube at the handle end (104), the cutting head (108) will rotate, but the catheter sheath head itself, which is connected to the outer catheter tube, will remain roughly stationary. Alternatively a cable may be used in place of inner tube (408).

The outer catheter body (102) may often be made from organic polymer materials extruded for this purpose, such as polyester, polytetrafluoroethylene (PTFE), polyurethane, polyvinylchloride, silicon rubber, and the like. The inner torque conducting catheter (408) may be composed of these materials or alternatively may be composed from metal coils, wires, or filaments.

In many embodiments, the catheter will be designed to be compatible with a monorail guidewire that has a diameter of about 0.014", or between 0.010" and 0.032". For

example, the outer catheter jacket may contain attached external guides for the monorail guidewire. In this case, the guidewire may exit these external guides either prior to the catheter head, or midway through the catheter head. Alternatively, the catheter may be hollow, and be located over the guidewire for the entire length of the catheter.

The catheter handle (104) will normally attach to both outer catheter tube (102), and inner tube or cable (408). Usually handle (104) will contain at least a knob, dial, or lever that allows the operator to apply torque to the inner torque transmitting tube or cable (408). In some embodiments, sensors may be used to determine how much the cutting head (108) has rotated or extended relative to the sheath head portion of catheter head (106), and these sensors, possibly aided by a mechanical or electronic computation and display mechanism, may show the operator how much the cutting head has rotated and or extended.

In some embodiments, the catheter handle (104) will be designed with knobs or levers coupled to mechanical mechanisms (such as gears, torque communicating bands, etc.) that manually rotate and advance/retract the catheter tip, and the operator will manually control the tip with gentle slow rotation or movement of these knobs or levers. In other embodimentsthe catheter handle will contain a mechanism, such as an electronic motor, and a control means, such as a button or trigger, that will allow the user to rotate and advance the cutting head in a precise and controlled manner. This mechanism may, for example, consist of a microprocessor or feedback controlled motor, microprocessor, and software that may act to receive information from a cutting head rotation or extension sensor, and use this rotation feedback data, in conjunction with operator instructions delivered by the button or trigger, to advance or retract the cutting head by a precise amount for each operator command. This way the operator need not worry about any errors induced by the spring action of the inner torque transmitting tube or cable (408). The microprocessor (or other circuit) controlled motor can automatically compensate for these errors, translate button or trigger presses into the correct amount of torque, and implement the command without requiring further operator effort. Alternatively non-microprocessor methods, such as a vernier or a series of guided markings, etc., may be

used to allow the operator to compensate for differences in the rotation of the torque communicating connector and the rotation of the cutting head, or for the extent that which said cutting head exits said hollow sheath head.

In some embodiments, the catheter head may be equipped with additional sensors, such as ultrasonic sensors to detect calcified material, optical (near infrared) sensors to detect occlusions or artery walls, or other medically relevant sensors. If these sensors are employed, in some cases it may be convenient to locate the driving mechanisms for these sensors in the catheter handle (104) as well.

Additional means to improve the efficacy of the cutting head may also be employed. Thus the cutting head may be configured to vibrate at high (ultrasonic) frequency, perform radiofrequency (RF) tissue ablation, generate localized areas of intense heat, conduct cutting light (e.g. laser or excimer laser), or other directed energy means.

The cutting head may be composed of alternative designs and materials, and these designs and materials may be selected to pick the particular problem at hand. As an example, a cutting head appropriate for use against a calcified obstruction may differ from the cutting head appropriate for use against a non-calcified obstruction. Similarly the cutting head appropriate for use against a highly fibrous obstruction may be less appropriate against a less fibrous and fattier obstruction. The length or size of the obstruction may also influence head design.

Although multiple catheters, each composed of a different type of cutting head, may be one way to handle this type of problem, in other cases, a kit composed of a single catheter and multiple cutting heads (108) and optionally multiple sheath heads (106) may be more cost effective. In this type of situation, the cutting heads (108) may be designed to be easily mounted and dismounted from coupling (406). A physician could view the obstruction by fluoroscopy or other technique, and chose to mount the cutting head design (and associated sheath head design) best suited for the problem at hand. Alternatively, if the blades (202), (204) on cutting head (108) have become dull or

chipped from use during a procedure, a physician may chose to replace dull or chipped cutting head (108) with a fresh cutting head, while continuing to use the rest of the catheter.

For some applications, it may also be useful to supply various visualization dyes or therapeutic agents to the obstruction using the catheter. Here, the dye or therapeutic agent may be applied by either sending this dye up to the catheter head through the space between the exterior catheter (102) and the interior torque catheter (408), or alternatively if torque catheter (408) is hollow, through the interior of torque catheter (408). If cutting head (108) also has a hollow opening (206), then the dye or therapeutic agent may be applied directly to the obstruction, even while cutting head (108) is cutting through the obstruction.

Examples of useful dyes and therapeutic agents to apply include fluoroscopic, ultrasonic, MRI, fluorescent, or luminescent tracking and visualization dyes, anticoagulants (e.g. heparin, low molecular weight heparin), thrombin inhibitors, anti-platelet agents (e.g. cyclooxygenase inhibitors, ADP receptor inhibitors, phosphodiesterase inhibitors, Glycoprotein IIB/IIIA inhibitors, adenosine reuptake inhibitors), anti-thromboplastin agents, anti-clot agents such as thrombolytics (e.g. tissue plasminogen activator, urokinase, streptokinase), lipases, monoclonal antibodies, and the like.

In some embodiments, it may be useful to construct the cutting head out of a material that has a radiopaque signature (different appearance under X-rays) that differs from the material used to construct the hollow sheath head portion of the catheter head. This will allow the physician to directly visualize, by fluoroscopic or other x-ray imaging technique, exactly how far the cutting head has advanced outside of the catheter sheath head.

Claims

1. A catheter comprising a catheter tube and a rotatable cutting head;

said rotatable cutting head being positioned within the catheter tube;

in which torque applied to said rotatable cutting head causes the cutting head to interact with the catheter tube, causing said cutting head to rotate and extend forward at least partially outside of said catheter tube.

2. The catheter of Claim 1, in which cutting head contains at least one protrusion, and the catheter tube contains one or more slots or groves;

in which the mechanical interaction between at least one protrusion on said cutting head and the one or more slots or groves causes said cutting head to both rotate and extend forward at least partially outside of said catheter tube.

3. The catheter of Claim 1, in which at least some of the one or more slots or groves are helical.

4. The catheter of Claim 1, in which the forward extension of the cutting head is restricted by one or more motion stop elements attached to the catheter tube.

5. The catheter of Claim 1, in which the forward extension of the cutting head is not restricted by the catheter tube.

6. The catheter of Claim 1, wherein said catheter tube is hollow and contains a torque communicating connector, and wherein application of torque to said torque communicating connector causes said rotatable cutting head to rotate.

7. The catheter of Claim 6, wherein the torque is applied to the torque communicating connector by a manual mechanism or by a feedback controlled electronic motor.

8. The catheter of Claim 6, wherein a therapeutic agent or visualization dye agent is dispensed through the hollow catheter tube.

9. The catheter of Claim 6, in which a guide wire is threaded inside the hollow catheter tube, and in which the guide wire exits the hollow tube through an opening in the center of the rotatable cutting head.

10. The catheter of Claim 1, in which only a portion of the catheter tube contains the rotatable cutting head, and in which a guide wire is threaded though guides attached to the outside of the catheter tube, and in which the guide wire exits the guides before the portion of the catheter tube that contains the rotatable cutting head.

11. The catheter of Claim 1, wherein said rotatable cutting head contains one or more blade edges.

12. The catheter of Claim 1, wherein the progress of the extension of said cutting head outside of said catheter is monitored by a sensor.

12. The catheter of Claim 1, wherein the cutting effectiveness of said cutting head is enhanced by ultrasonic vibration, radiofrequency (RF) energy, or light energy.

13. The catheter of Claim 1, wherein the cutting head has a radiopaque signature that is different from the radiopaque signature of the catheter.

14. The catheter of Claim 1, in which said catheter is used to remove refractory atherosclerotic plaque or chronic total occlusions from coronary arteries or peripheral limb arteries.

15. The catheter of Claim 14, in which said catheter is used as a pretreatment for blocked coronary arteries or peripheral limb arteries, and in which the blocked artery is then

subjected to atherectomy, stenting, or balloon angioplasty following the use of said catheter.

16. A catheter comprising:

a catheter tube;

a hollow sheath head affixed at the distal portion of said catheter tube; and

a rotatable cutting head positioned at least partially inside said hollow sheath head;

in which rotation of said cutting head causes said cutting head to interact mechanically with said sheath head, causing said cutting head to both rotate and advance further outside of said hollow sheath head.

17. The catheter of Claim 16, in which said hollow sheath head contains an opening and one or more helical slots or groves;

said rotatable cutting head contains at least one protrusion which is capable of engaging with said helical slots or groves;

and in which the mechanical interaction between at least one protrusion on said rotatable cutting head and the one or more helical slots or groves causes said cutting head to both rotate and advance through said opening in said hollow sheath head.

18. The catheter of Claim 16, wherein said catheter tube is hollow and contains a torque communicating connector, and wherein application of torque to said torque communicating connector causes said rotatable cutting head to rotate.

19. The catheter of Claim 18, wherein the torque is applied to the torque communicating connector by a manual mechanism or by a feedback controlled electronic motor.

19. The catheter of Claim 18, wherein a therapeutic agent or visualization dye agent is dispensed through the hollow catheter tube.

20. The catheter of Claim 18, in which a guide wire is threaded inside the hollow catheter tube, and in which the guide wire exits the hollow tube through an opening in the center of the rotatable cutting head.

21. The catheter of Claim 18, in which a guide wire is threaded through guides attached to the outside of the catheter tube, and in which the guide wire exits the guides either before the hollow sheath head, or through an opening on the side of the hollow sheath head.

22. The catheter of Claim 16, wherein said rotatable cutting head contains one or more blade edges.

23. The catheter of Claim 16, wherein the progress of the advancement of said cutting head outside of said hollow sheath head opening is monitored by a sensor.

24. The catheter of Claim 16, wherein the cutting effectiveness of said cutting head is enhanced by ultrasonic vibration, radiofrequency (RF) energy, or light energy.

25. The catheter of Claim 16, wherein the cutting head has a radiopaque signature that is different from the radiopaque signature of the hollow sheath head.

26. The catheter of Claim 16, in which said catheter is used to remove refractory atherosclerotic plaque or chronic total occlusions from coronary arteries or peripheral limb arteries.

27. The catheter of Claim 26, in which said catheter is used as a pretreatment for blocked coronary arteries or peripheral limb arteries, and in which the blocked artery is then subjected to atherectomy, stenting, or balloon angioplasty following the use of said catheter.

28. A catheter comprising:

a hollow catheter tube;

a hollow sheath head affixed at the distal portion of said catheter tube;

said hollow sheath head containing an opening and one or more helical slots or groves;

a rotatable cutting head positioned at least partially inside said hollow sheath head;

said rotatable cutting head containing at least one protrusion which is capable of engaging with said helical slots or groves;

a torque communicating connector, wherein application of torque to said torque communicating connector causes said rotatable cutting head to rotate;

in which the mechanical interaction between at least one protrusion on said rotatable cutting head and the one or more helical slots or groves causes said cutting head to both rotate and advance through said opening in said hollow sheath head.

29. The catheter of Claim 28, wherein torque is applied to the torque communicating connector either manually, or by a microprocessor controlled electronic motor, and in which the microprocessor controlled electronic motor compensates for differences in rotation between the rotation of the electric motor and the rotation of the cutting head.

30. The catheter of Claim 28, wherein a therapeutic agent or visualization dye agent is dispensed through the hollow catheter tube.

31. The catheter of Claim 28, in which a guide wire is threaded inside the hollow catheter tube, and in which the guide wire exits the hollow tube through an opening in the center of the rotatable cutting head.

32. The catheter of Claim 28, in which a guide wire is threaded through guides attached to the outside of the catheter tube, and in which the guide wire exits the guides either before the hollow sheath head, or through an opening on the side of the hollow sheath head.

33. The catheter of Claim 28, wherein said rotatable cutting head contains one or more blade edges.

34. The catheter of Claim 28, wherein the progress of the advancement of said cutting head outside of said hollow sheath head opening is monitored by a sensor.

35. The catheter of Claim 28, wherein the cutting effectiveness of said cutting head is enhanced by ultrasonic vibration, radiofrequency (RF) energy, or light energy.

36. The catheter of Claim 28, wherein the cutting head has a radiopaque signature that is different from the radiopaque signature of the hollow sheath head.

37. The catheter of Claim 28, in which said catheter is used to remove refractory atherosclerotic plaque or chronic total occlusions from coronary arteries or peripheral limb arteries.

38. The catheter of Claim 37, in which said catheter is used as a pretreatment for blocked coronary arteries or peripheral limb arteries, and in which the blocked artery is then subjected to atherectomy, stenting, or balloon angioplasty following the use of said catheter.

39. A method to treat an atherosclerotic occlusion or lesion in a vascular lumen, said method comprising:

threading a catheter tube through said vascular lumen to said occlusion or lesion;

rotating a torque communicating connector mounted inside said catheter tube;

said torque communicating connector being connected to a rotatable cutting head mounted inside a hollow sheath head on the distal end of said catheter tube, said sheath head shielding said rotatable cutting head from contact with said vascular lumen and said occlusion or lesion in the absence of such rotation;

wherein mechanical interactions between said rotatable cutting head and said hollow sheath head cause said cutting head to both rotate and at least partially exit said hollow sheath head, thus allowing said rotating rotatable cutting head to contact said occlusion or lesion and cut said occlusion or lesion.

40. The method of Claim 39, in which said hollow sheath head contains an opening and one or more helical slots or groves;

said rotatable cutting head contains at least one protrusion which is capable of engaging with said helical slots or groves;

and in which the mechanical interaction between at least one protrusion on said rotatable cutting head and the one or more helical slots or groves causes said cutting head to both rotate and advance through said opening in said hollow sheath head.

41. The method of Claim 39, in which the rotation of the torque communicating connector is adjusted to compensate for differences in the rotation of the torque communicating connector and the rotation of the cutting head, or for the extent that which said cutting head exits said hollow sheath head.

42. The method of Claim 39, in which the catheter tube is hollow.

43. The method of Claim 42, further comprising dispensing a therapeutic agent or visualization dye agent through the hollow catheter tube.

44. The method of Claim 39, in which the catheter tube is threaded through said vascular lesion using a guide wire.

45. The method of Claim 39, in which the occlusion or lesion is cut by one or more blade edges mounted on said rotatable cutting head.

46. The method of Claim 39, further comprising applying ultrasonic vibration, radiofrequency (RF) energy, or light energy to the cutting head, occlusion, or lesion .

47. The method of Claim 39, in which said method is used as to pretreat blocked coronary arteries or peripheral limb arteries, and in which the blocked artery is then further treated by atherectomy, stenting, or balloon angioplasty during the same procedure.

AMENDED CLAIMS
received by the International Bureau on 8 September 2009 (08.09.2009).

Claim 1. A catheter for delivering a guidewire across an occlusion, the catheter comprising:

a catheter tube;

a rotatable cutting head comprising a helical protrusion;

a protective sheath at the distal end of the catheter tube comprising one or more helical slot extending proximally through the sidewall of the sheath, wherein the rotatable cutting head is configured to extend distally from the protective sheath by rotating the helical protrusion out of the slot;

a torque communicating connector configured to apply a torque to the rotatable cutting head from the proximal end of the catheter to rotate and extend the cutting head distally forward at least partially outside of said protective sheath; and

a guidewire passageway extending proximally to distally through the catheter tube.

Claim 2. (Cancelled)

Claim 3. The catheter of Claim 1, in which the one or more helical slot extends proximally along a side portion of the protective sheath.

Claim 4. The catheter of Claim 1, in which the forward extension of the cutting head is restricted by one or more motion stop elements.

Claim 5. The catheter of Claim 1, in which the forward extension of the cutting head is not restricted by the catheter tube.

Claim 6. The catheter of Claim 1, wherein the catheter tube contains the torque communicating connector, and wherein application of torque to said torque communicating connector causes said rotatable cutting head to rotate.

Claim 7. The catheter of Claim 1, wherein the torque communicating connector comprises a feedback controlled electronic motor.

Claim 8. (Cancelled)

Claim 9. The catheter of Claim 1, wherein the guidewire passageway is configured to exit distally through an opening in the center of the rotatable cutting head.

Claim 10. The catheter of Claim 1, wherein the guidewire passageway is configured to exit distally from the catheter before the portion of the catheter tube that contains the rotatable cutting head.

Claim 11. The catheter of Claim 1, wherein said rotatable cutting head contains one or more blade edges.

Claim 12. The catheter of Claim 1, further comprising a sensor to monitor the progress of the extension of said cutting head outside of said catheter.

Claim 13. The catheter of Claim 1, further comprising a transducer to enhance the cutting effectiveness of said cutting head by emitting ultrasonic vibration, radiofrequency (RF) energy, or light energy.

Claim 14. The catheter of Claim 1, wherein the cutting head has a radiopaque signature that is different from the radiopaque signature of the catheter.

Claim 15. (Cancelled)

Claim 16. (Cancelled)

Claim 17. A catheter for delivering a guidewire across an occlusion, the catheter comprising:

a catheter tube;

a hollow sheath at the distal portion of said catheter tube comprising one or more helical slots extending proximally through the sidewall of the sheath;

a rotatable cutting head positioned at least partially inside said hollow sheath, wherein the rotatable cutting head is configured to extend distally from the hollow sheath and retract into the hollow sheath by rotating out of the slots of the hollow sheath;

a torque communicating connector configured to apply torque to rotate the rotatable cutting head from the distal end of the catheter; and

a guidewire passageway extending through the catheter tube and out of the distal end of the hollow sheath.

Claim 18. The catheter of Claim 17, in which said rotatable cutting head contains at least one helical protrusion which is configured to engage with said helical slots so that mechanical interaction between at least one protrusion on said rotatable cutting head and the one or more helical slots advances said cutting head in or out said hollow sheath head.

Claim 19. The catheter of Claim 17, wherein said catheter tube and said torque communicating connector are hollow and the guidewire passageway extends through both the catheter tube and the torque communicating connector.

Claim 20. The catheter of Claim 17, further comprising a feedback controlled electronic motor configured to apply torque to the torque communicating connector to rotate the rotatable cutting head.

Claim 21. (Cancelled)

Claim 22. The catheter of Claim 17, wherein the guidewire passageway is configured to exit distally through an opening in the center of the rotatable cutting head.

Claim 23. (Cancelled)

Claim 24. The catheter of Claim 17, wherein said rotatable cutting head contains one or more blade edges.

Claim 25. The catheter of Claim 17, further comprising a sensor to measure the progress of the advancement of said cutting head outside of said hollow sheath.

Claim 26. The catheter of Claim 17, further comprising a transducer to enhance the cutting effectiveness of said cutting head by emitting ultrasonic vibration, radiofrequency (RF) energy, or light energy.

Claim 27. The catheter of Claim 17, wherein the cutting head has a radiopaque signature that is different from the radiopaque signature of the hollow sheath.

Claim 28. (Cancelled)

Claim 29. (Cancelled)

Claim 30. A catheter for delivering a guidewire across an occlusion, the catheter comprising:

a hollow catheter tube;

a hollow sheath head affixed at the distal portion of said catheter tube; said hollow sheath head containing an opening and one or more helical slots or groves;

a rotatable cutting head positioned at least partially inside said hollow sheath head; said rotatable cutting head containing at least one protrusion which is capable of engaging with said helical slots or groves; and

a torque communicating connector, wherein application of torque to said torque communicating connector causes said rotatable cutting head to rotate; and

a guidewire passageway extending through the catheter tube and through the rotatable cutting head.

Claim 31. The catheter of Claim 30, further comprising a microprocessor controlled electronic motor, wherein the microprocessor controlled electronic motor is configured to compensate for differences in rotation between the rotation of the electric motor and the rotation of the cutting head.

Claim 32. (Cancelled)

Claim 33. (Cancelled)

Claim 34. (Cancelled)

Claim 35. The catheter of Claim 30, wherein said rotatable cutting head contains one or more blade edges.

Claim 36. The catheter of Claim 30, further comprising a sensor to monitor the progress of the advancement of said cutting head outside of said hollow sheath head opening.

Claim 37. (Cancelled)

Claim 38. The catheter of Claim 30, wherein the cutting head has a radiopaque signature that is different from the radiopaque signature of the hollow sheath head.

Claim 39. (Cancelled)

Claim 40. (Cancelled)

Claim 41. A method to deliver a guidewire across an atherosclerotic occlusion or lesion in a vascular lumen, said method comprising:

threading a catheter tube through said vascular lumen to said occlusion or lesion;

rotating a torque communicating connector positioned within said catheter tube to rotate a rotatable cutting head at the distal end of said catheter tube, wherein the cutting head comprises one or more helical protrusions;

extending said rotatable cutting head from a sheath head at the distal end of said catheter tube, said sheath head comprising one or more helical slots through the side wall of the sheath head configured for shielding said rotatable cutting head from contact with said vascular lumen and said occlusion or lesion when the cutting head is retracted;

advancing said catheter tube across said occlusion or lesion to cut occluding material without removing the occluding material; and

passing a guidewire through a guidewire passageway extending distally through the catheter tube.

Claim 42. (Cancelled)

Claim 43. The method of Claim 41, in which the rotation of the torque communicating connector is adjusted to compensate for differences in the rotation of the torque communicating connector and the rotation of the cutting head.

Claim 44. (Cancelled)

Claim 45. The method of Claim 41, further comprising dispensing a therapeutic agent or visualization dye agent through the catheter tube.

Claim 46. The method of Claim 41, in which the catheter tube is threaded through said vascular lesion before extending said guide wire.

Claim 47. The method of Claim 41, in which the occlusion or lesion is cut by one or more blade edges mounted on said rotatable cutting head.

Claim 48. The method of Claim 41, further comprising applying ultrasonic vibration, radiofrequency (RF) energy, or light energy to the cutting head, occlusion, or lesion.

Claim 49. The method of Claim 41, in which said method is used to insert a guidewire across a blocked coronary artery or peripheral limb artery, and in which the blocked artery is then further treated by atherectomy, stenting, or balloon angioplasty during the same procedure.

FIG. 1

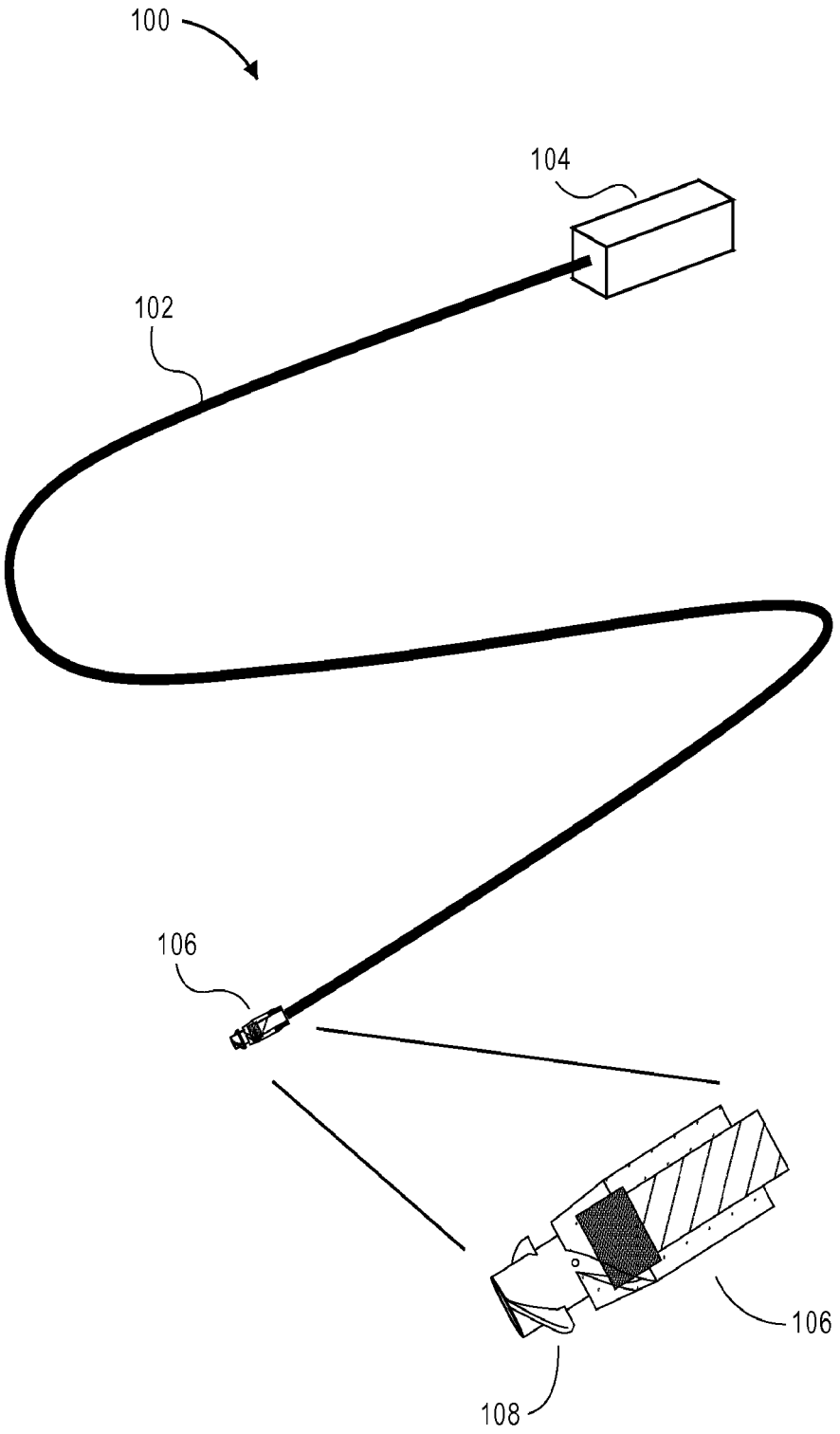

FIG. 2

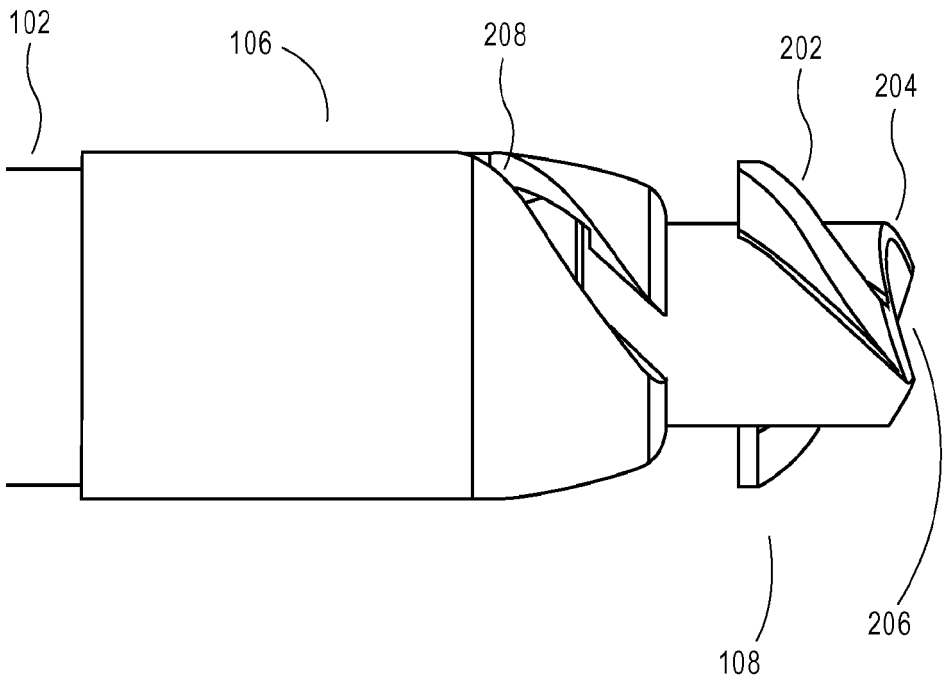

FIG. 3

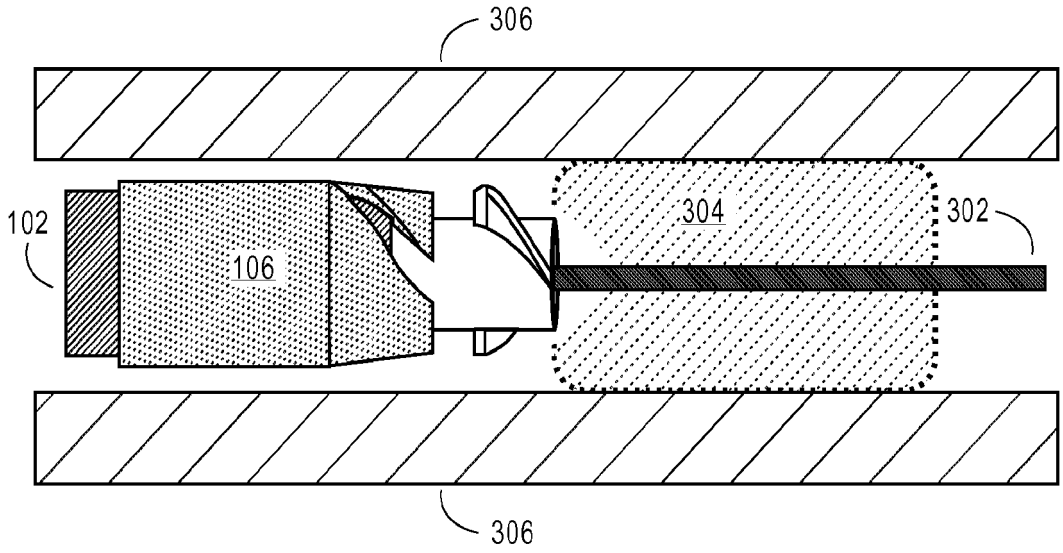

FIG. 4

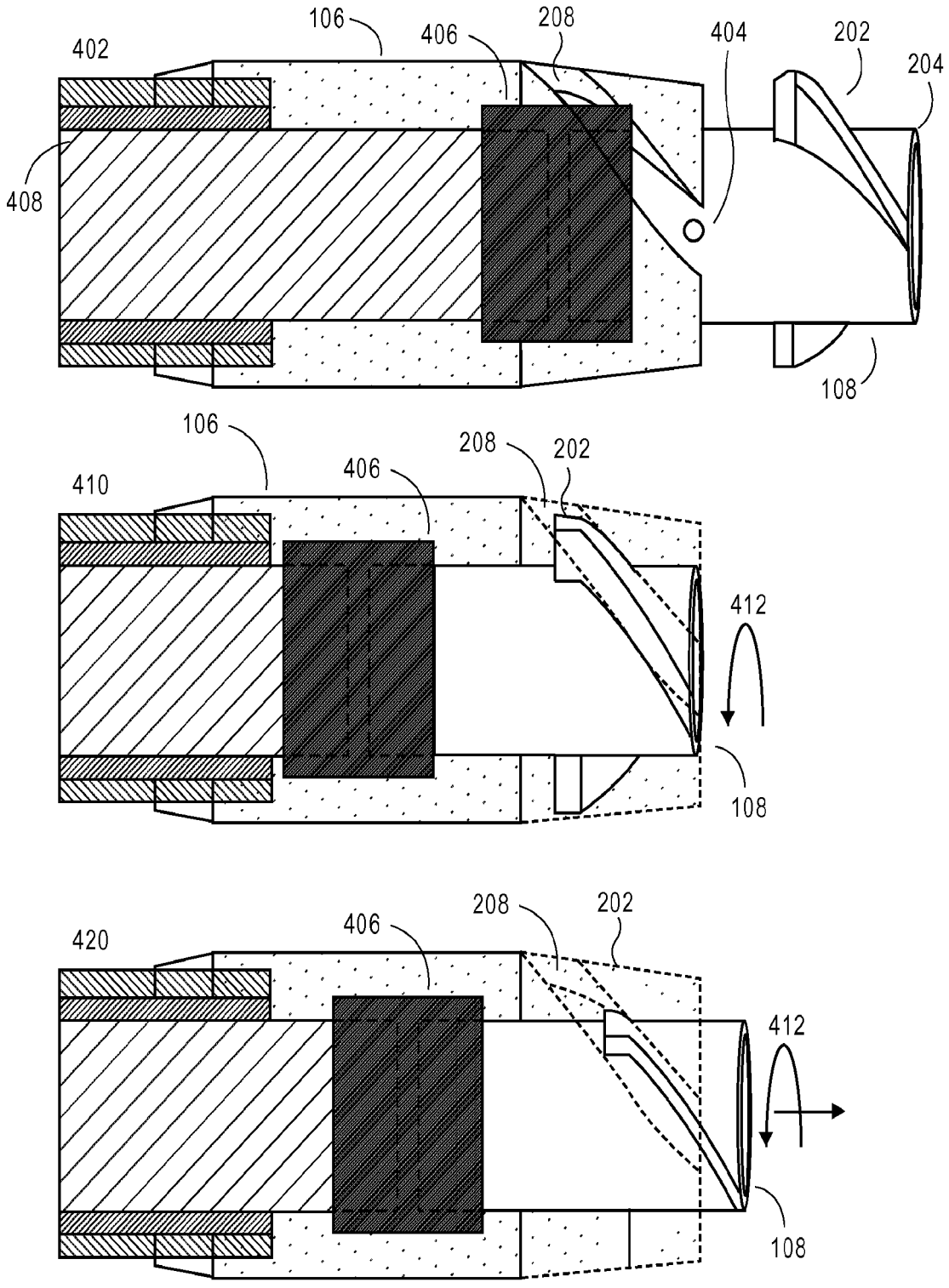
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FIG. 5

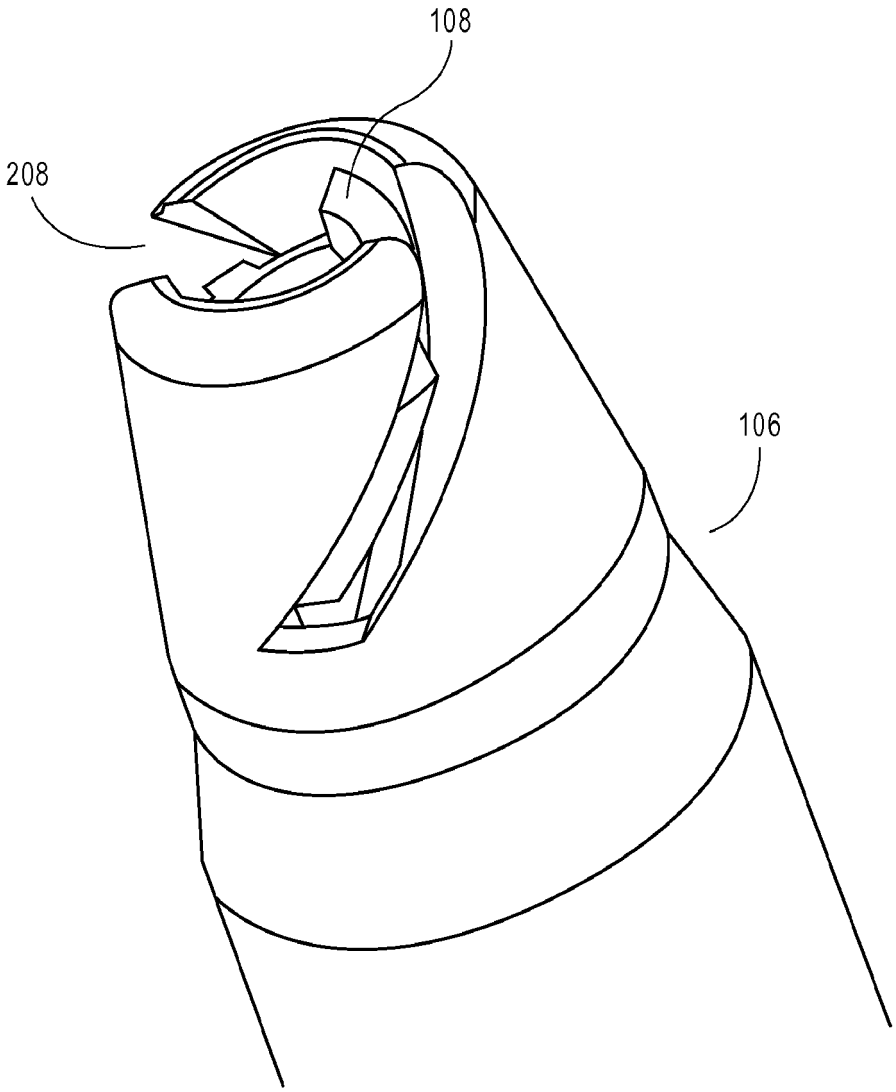
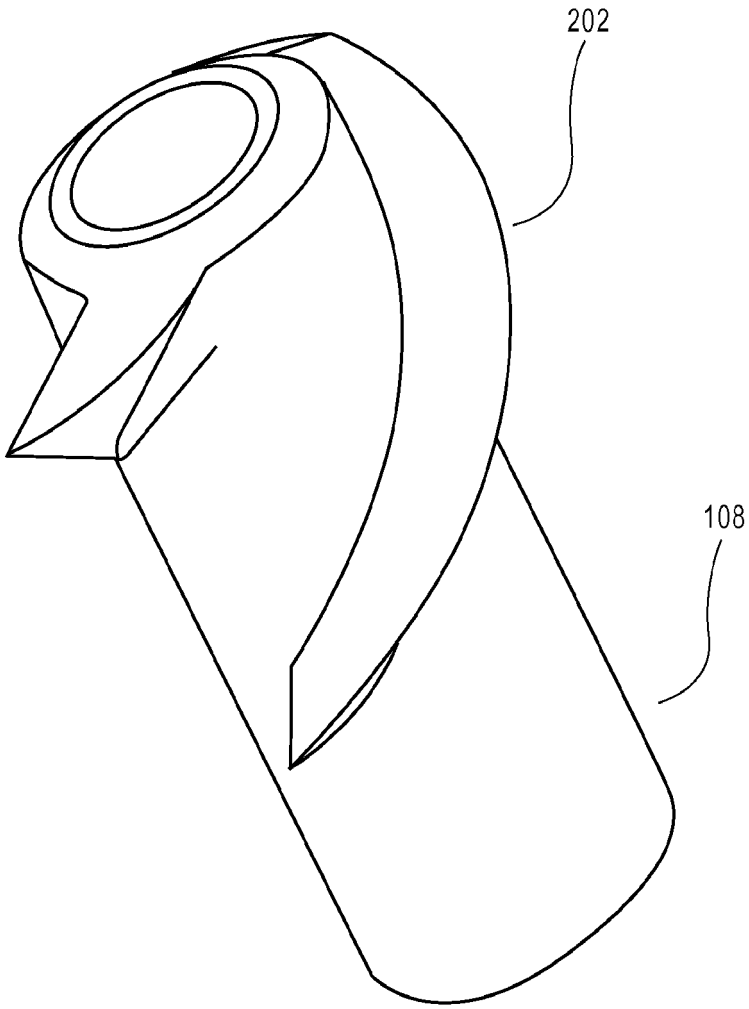


FIG. 6



INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 09/41579

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61B 17/22 (2009.01)
USPC - 606/159
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)
IPC8 : A61B 17/22 (2009.01)
USPC : 606/159

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
IPC8 : A61B 17/32, A61B 17/3205, A61B 17/3207, A61M 25/00 (2009.01)
USPC : 606/167, 606/170, 606/180, 606/127, 606/169, 606/171, 604/22, 604/264, 604/267, 604/266

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PubWEST (PGPB,USPT,EPAB,JPAB), Google Scholar
guidewire, slot, channel, groove, pin, protru$, peg, detent, screw$, spiral$, helic$, helix, twist$, rotat$, torqu$, advanc$, exten$, forward$, catheter, atherect$, drill$, reamer, reaming, bore, borer, boring, burr, revascular$, vascular$, radiopaque

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2001/0004700 A1 (HONEYCUTT et al) 21 June 2001 (21.06.2001) see especially para [0028], [0029], [0046], [0053], [0071], [0075], [0087], [0088], [0092], [0093], [0112], [0113], [0114], figs 2, 6	1-11, 12a, 12b, 13-18, 19a, 19b, 20-47
Y	US 5,192, 291 A (PANNEK Jr) 9 March 1993 (09.03.1993) see especially col 4, ln 33-39, col 4, ln 59 to col 5, ln 5, col 6, ln 25-33 figs 3, 4	1-11, 12a, 12b, 13-18, 19a, 19b, 20-47
Y	US 5,358,472 A (VANCE et al) 25 October 1994 (25.10.1994) see especially col 4, ln 49 to col 5, ln 12, col 5, ln 25-32, fig 2	10, 21, 32
Y	US 6,007,530 A (DORNHOFER et al) 28 December 1999 (28.12.1999) see especially col 5, ln 42-63, col 7, ln 14-43, fig 3	12b, 24, 35, 46
Y	US 2005/0222663 A1 (SIMPSON et al) 6 October 2005 (06.10.2005) see especially para [0079], [0098], [0104]	13, 25, 36

☐ Further documents are listed in the continuation of Box C. ☐

* 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 application or patent 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
26 June 2009 (26.06.2009)	07 JUL 2009
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (April 2007)

专利名称(译)	用于穿过阻塞的血管通道的导管系统和方法		
公开(公告)号	EP2278926A1	公开(公告)日	2011-02-02
申请号	EP2009735792	申请日	2009-04-23
[标]申请(专利权)人(译)	阿维格公司		
申请(专利权)人(译)	AVINGER INC.		
当前申请(专利权)人(译)	AVINGER INC.		
[标]发明人	PATEL HIMANSHU N SIMPSON JOHN B		
发明人	PATEL, HIMANSHU, N. SIMPSON, JOHN, B.		
IPC分类号	A61B17/22 A61B17/3207 A61B18/14 A61B18/24		
CPC分类号	A61B17/32002 A61B17/22012 A61B17/32075 A61B17/320758 A61B18/1492 A61B18/24 A61B2017/00336 A61B2017/00398 A61B2017/22094		
优先权	12/108433 2008-04-23 US		
其他公开文献	EP2278926B1 EP2278926A4		
外部链接	Espacenet		

摘要(译)

公开了一种用于通过患病动脉的慢性完全闭塞或其他难治性动脉粥样硬化斑块的旋转切割头导管。导管的旋转切割头设计成在不使用时安全地位于外保护套内。外保护套包含一个或多个螺旋槽或槽，并且切割头包含突出的刀片或突出部，其配合到这些螺旋槽或槽中。将扭矩施加到连接到切割头的内导管或线上，将旋转施加到切割头上，并且护套的螺旋槽或槽抵靠切割头的突出刀片或突出部的力使切割头从保护套向外推进。一旦伸展，切割头现在可以自由旋转。该装置可以使用导丝将切割头引导到期望的位置。