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(54) **METHODS AND DEVICES FOR CUTTING TISSUE**

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(63) Continuation-in-part of application No. 10/288,581, filed on Nov. 4, 2002, which is a continuation-in-part of application No. 10/027,418, filed on Dec. 19, 2001.

(60) Provisional application No. 60/272,273, filed on Feb. 27, 2001. Provisional application No. 60/257,704, filed on Dec. 20, 2000. Provisional application No. 60/381,632, filed on May 17, 2002.

Publication Classification

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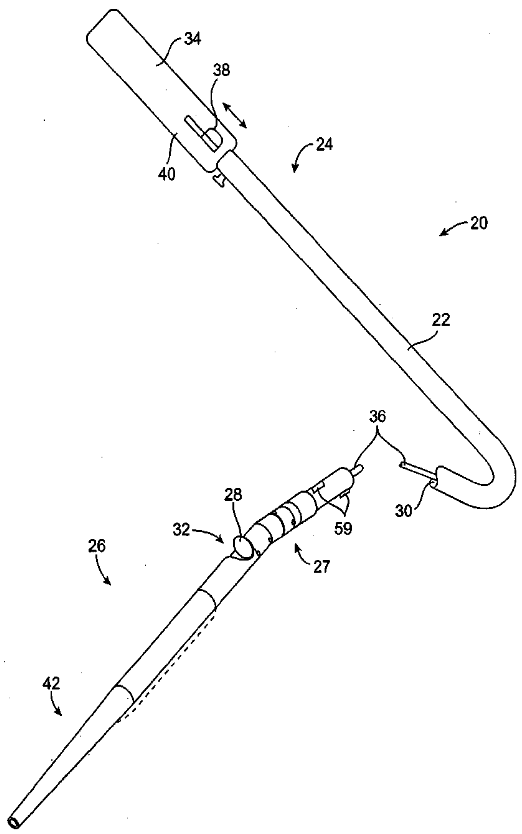
(57) **ABSTRACT**

A method of removing material from a blood flow lumen generally includes providing a device having a cutting element and an opening, advancing the device through the blood flow lumen to a site where material is to be removed, forcing the opening toward a wall of the site where material is to be removed, and moving the cutting element and the opening so that material in the blood flow lumen is cut by the cutting element and directed into the opening for removal as the cutting element and opening are moved through the blood flow lumen. In some embodiments, the device may be deflected or bent to force the opening toward a wall to remove material. The cutting element may be rotatable and may have an axis that is movable, that is not parallel to the longitudinal axis of the device, or both. In some embodiments, the cutting element is movable between retracted and deployed positions for advancing the device to a site for treatment and for removing material, respectively.



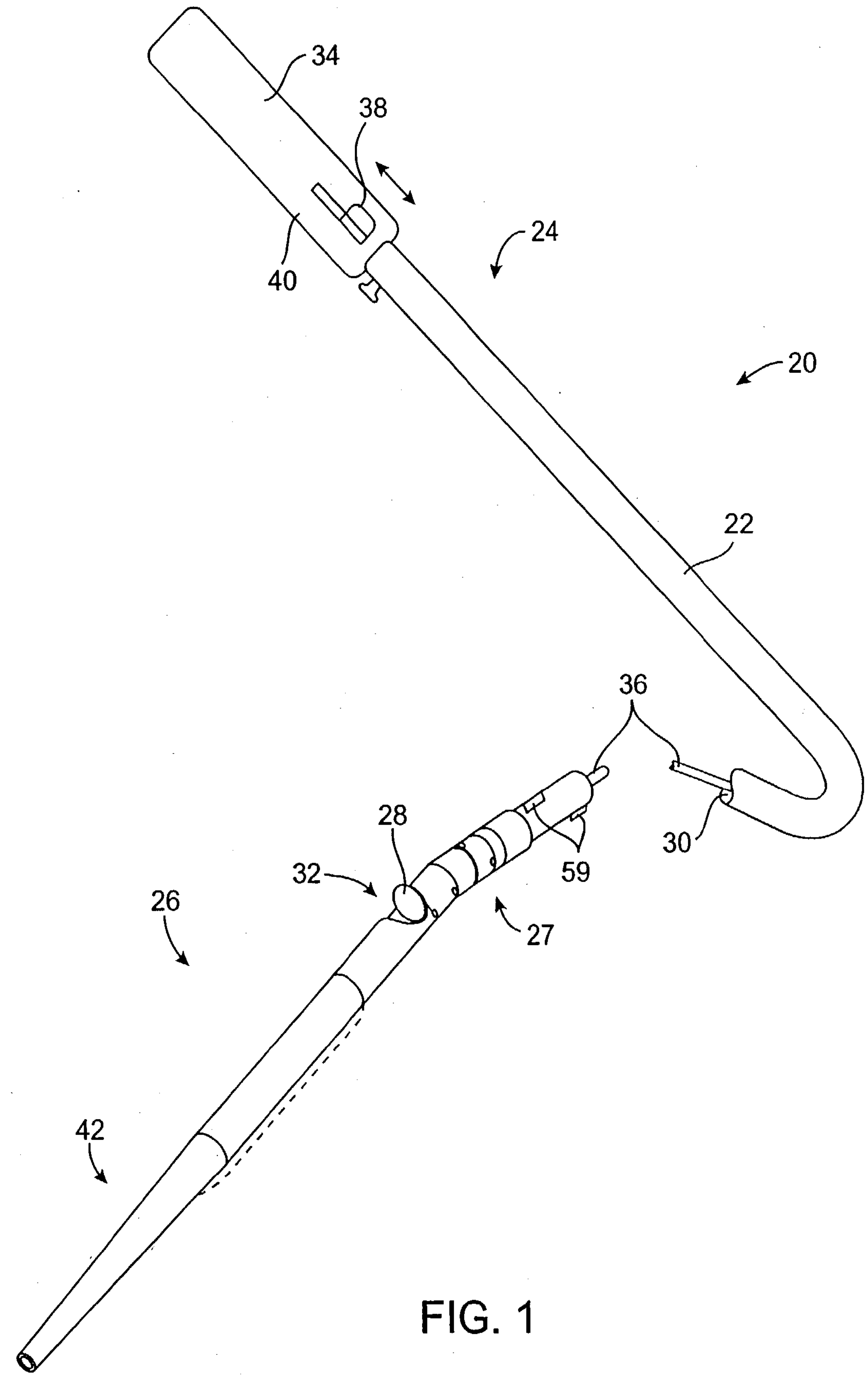


FIG. 1

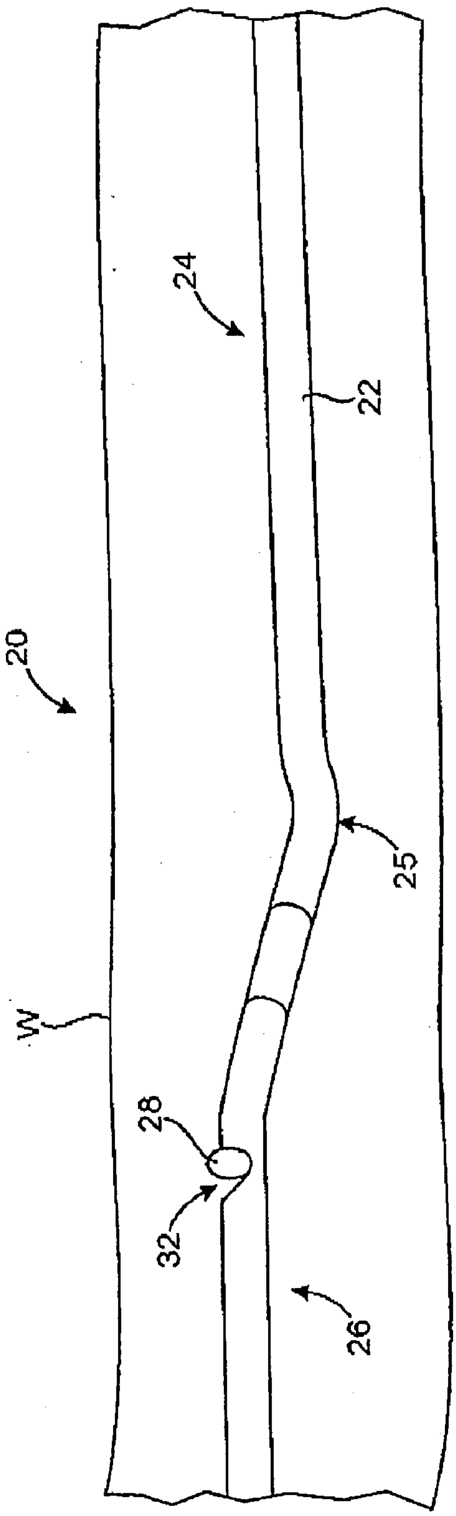


FIG. 1A

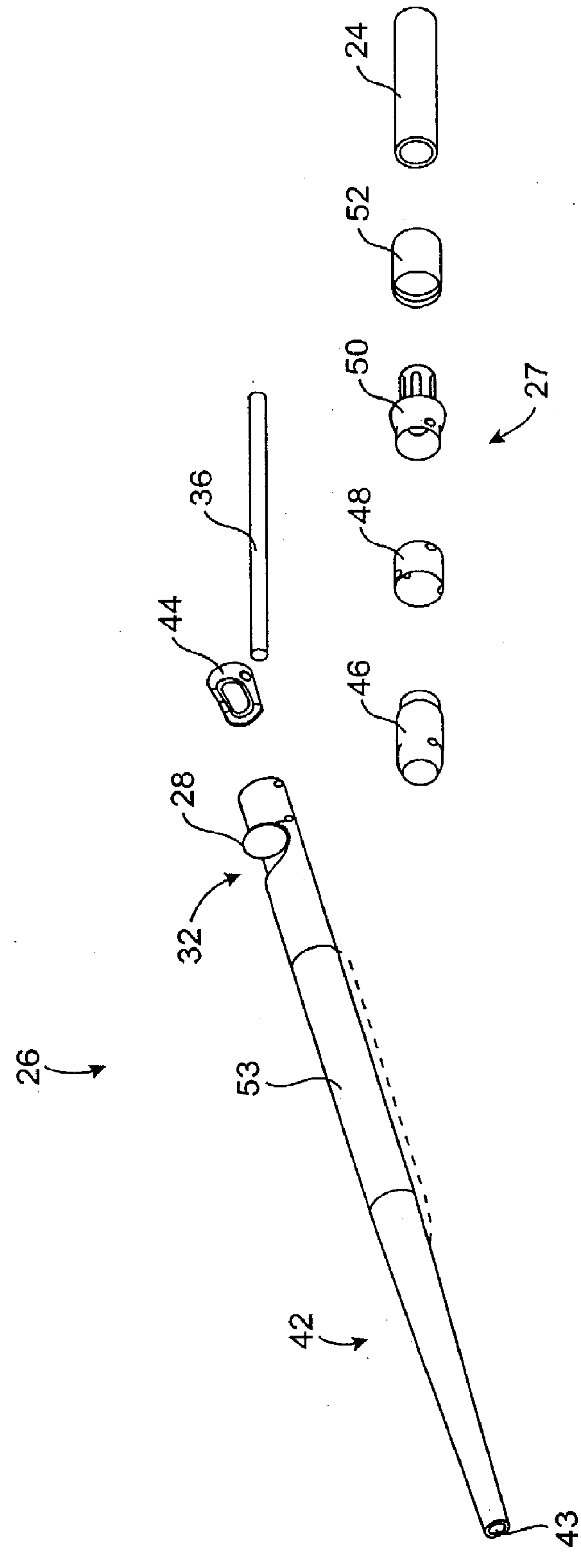


FIG. 2

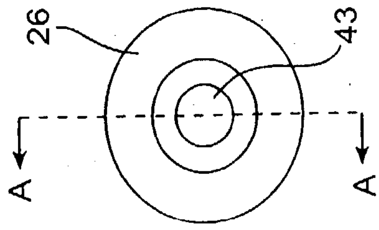


FIG. 3 A

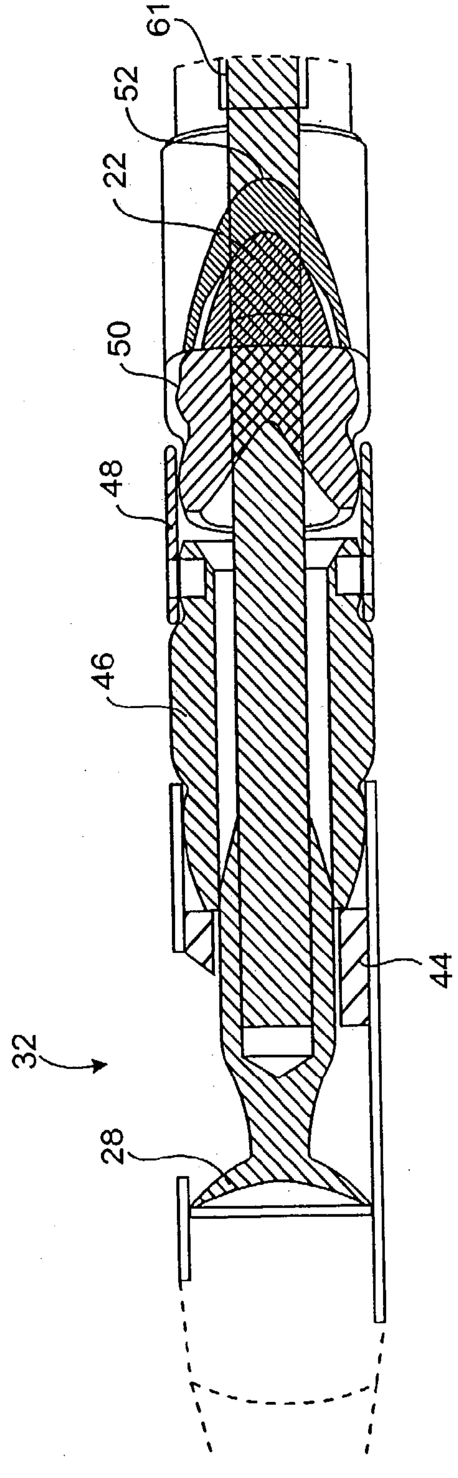


FIG. 3B

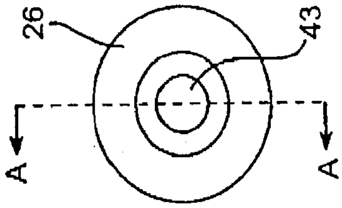


FIG. 3C

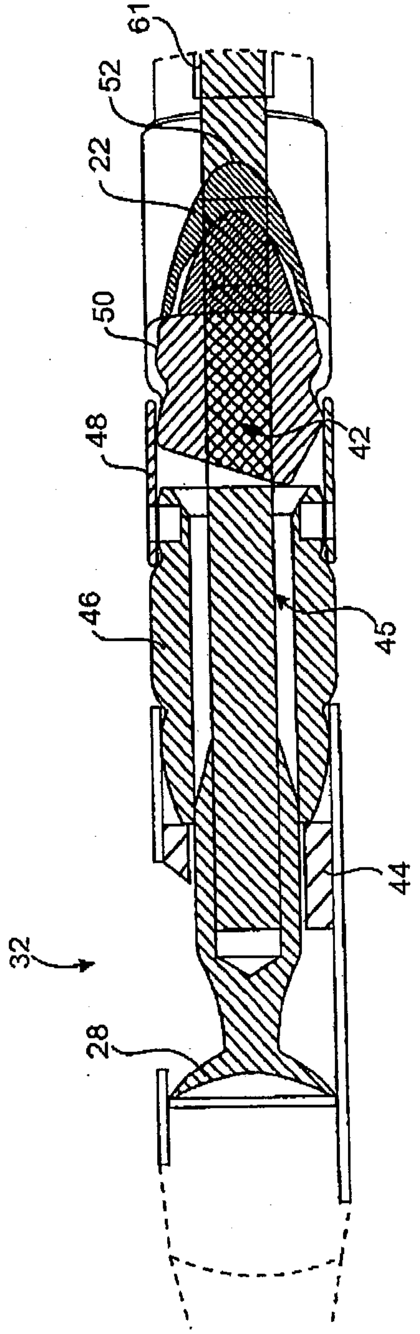


FIG. 3D

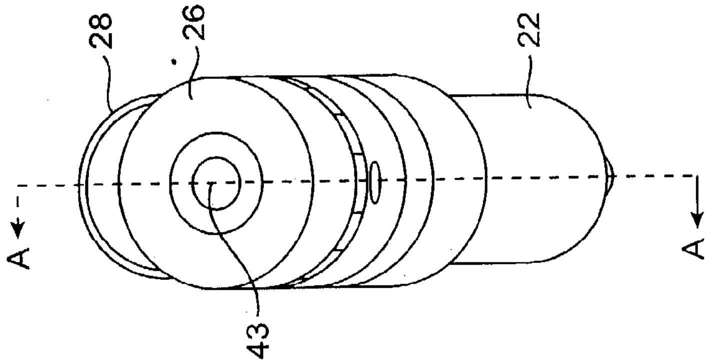


FIG. 4A

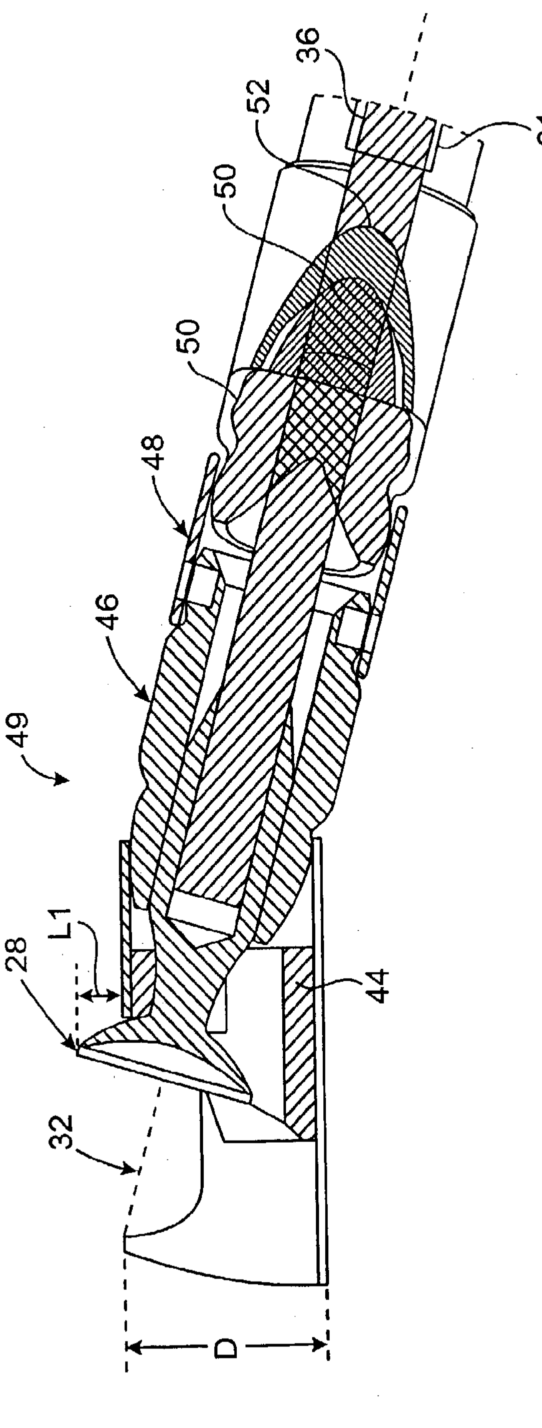


FIG. 4B

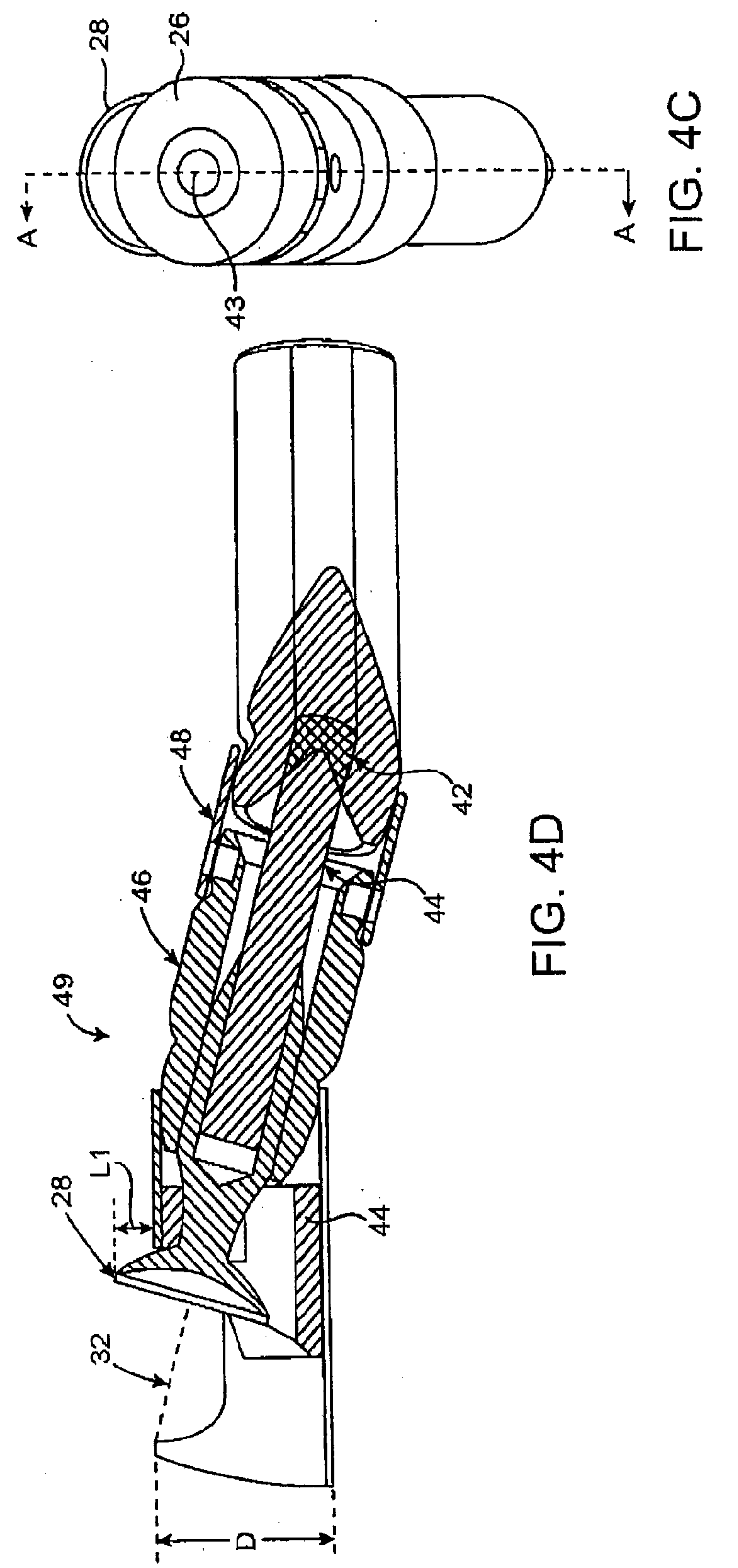


FIG. 4C

FIG. 4D

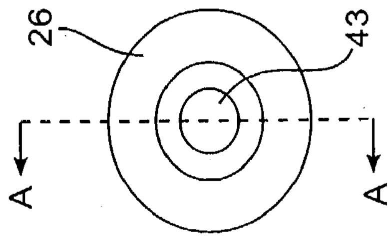


FIG. 5A

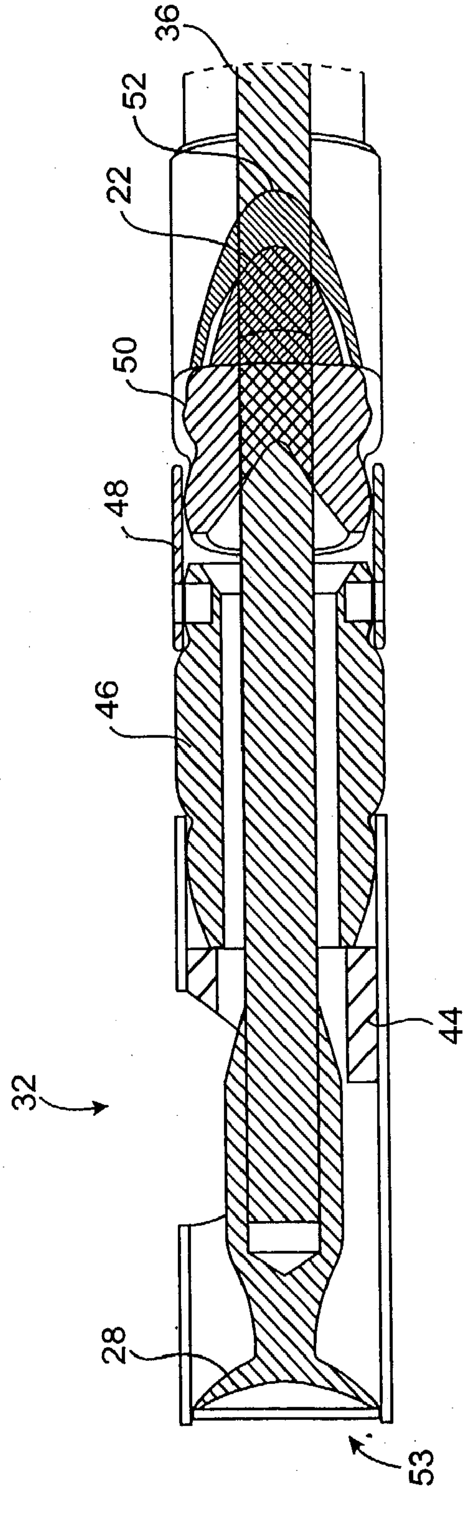


FIG. 5B

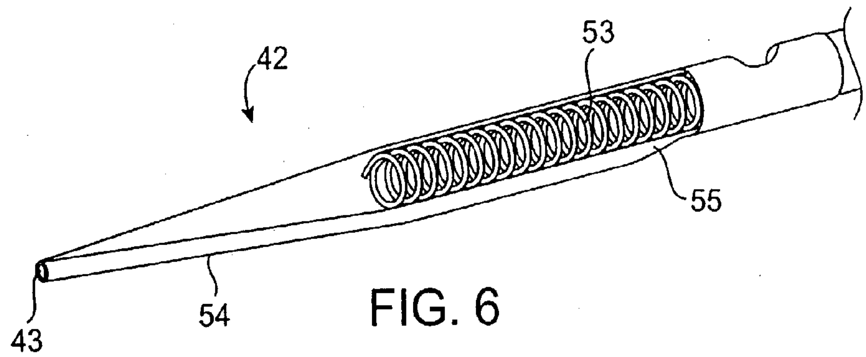


FIG. 6

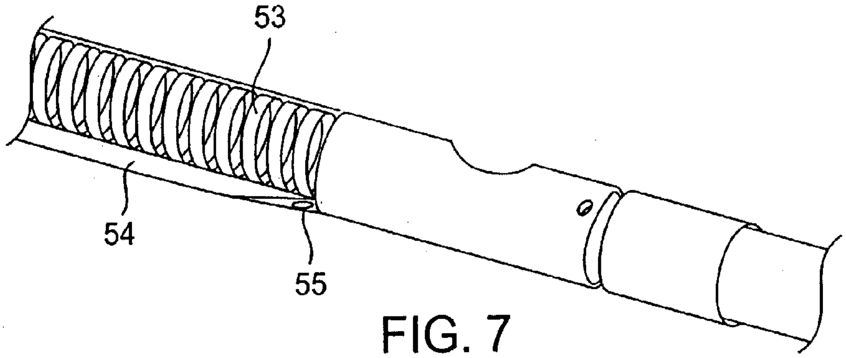


FIG. 7

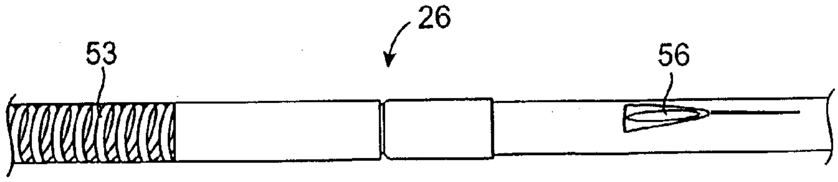


FIG. 8

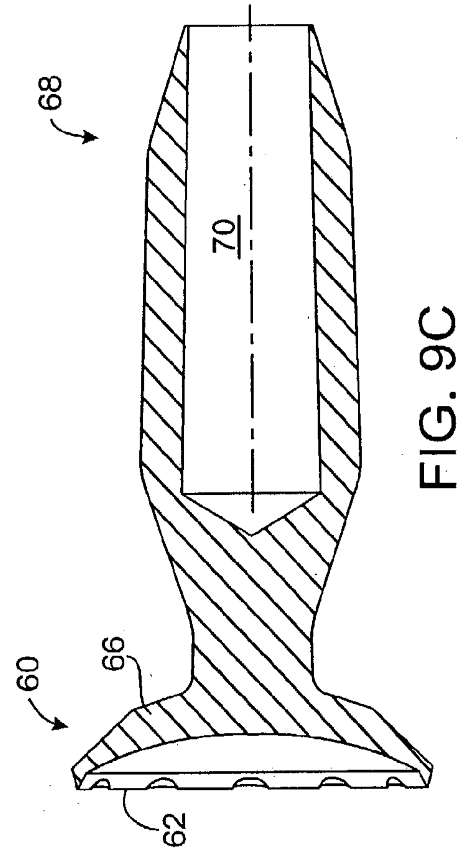


FIG. 9C

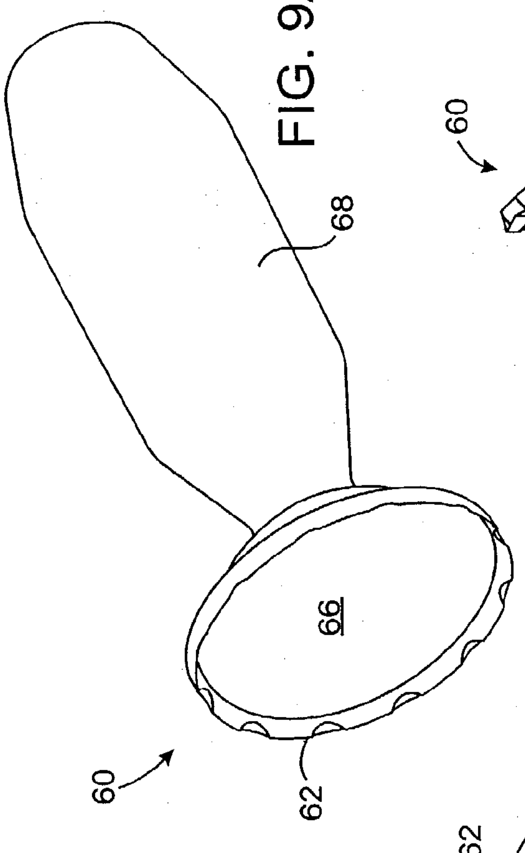


FIG. 9A

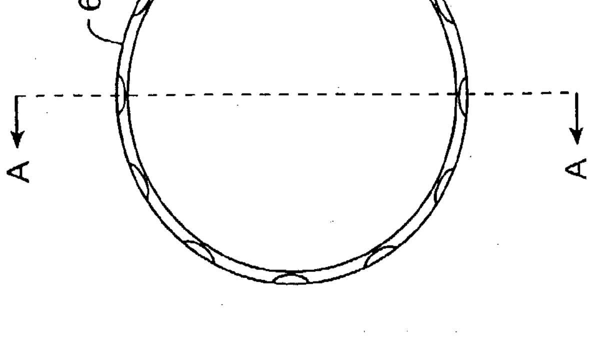


FIG. 9B

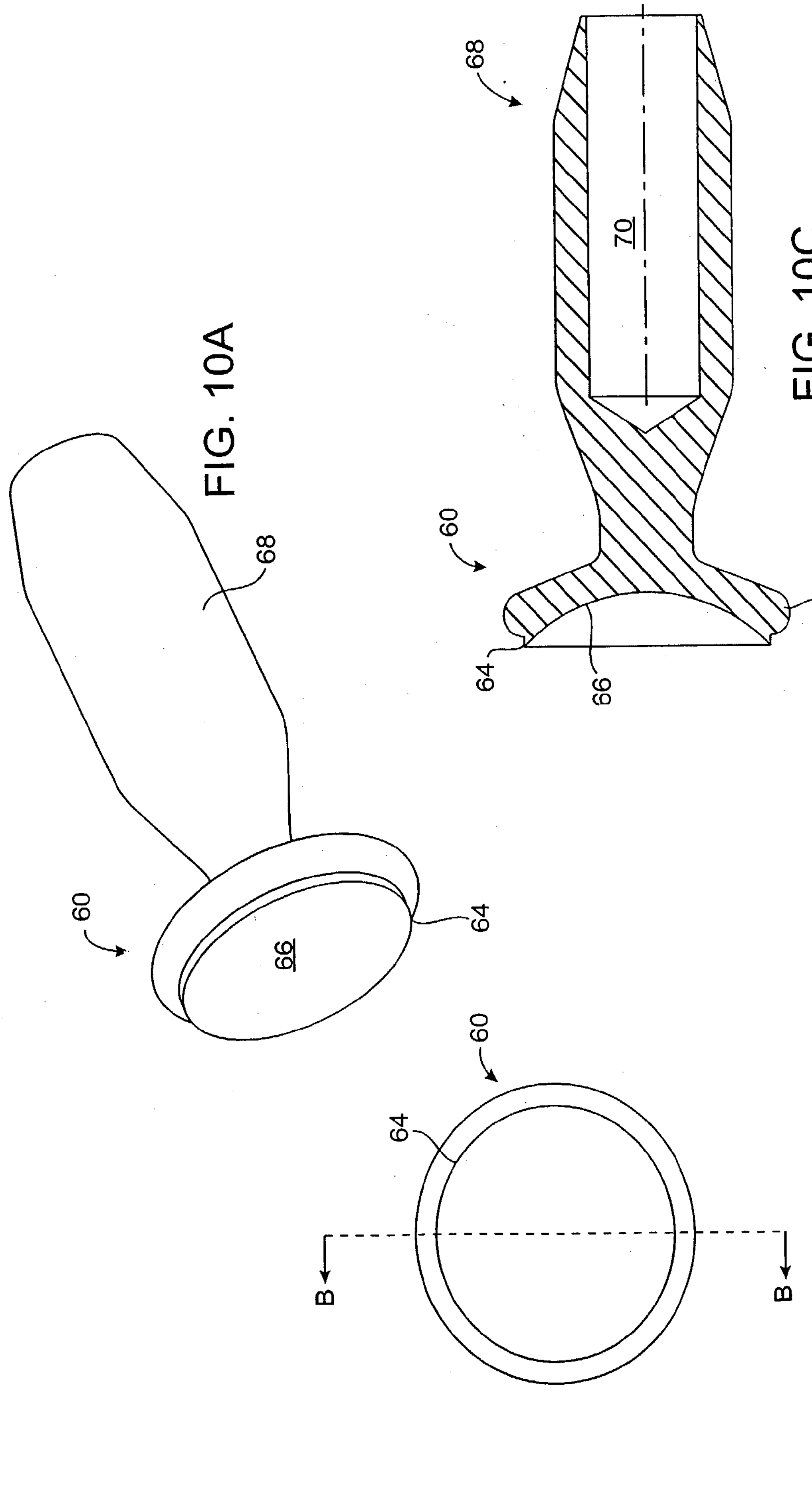


FIG. 10A

FIG. 10B

FIG. 10C

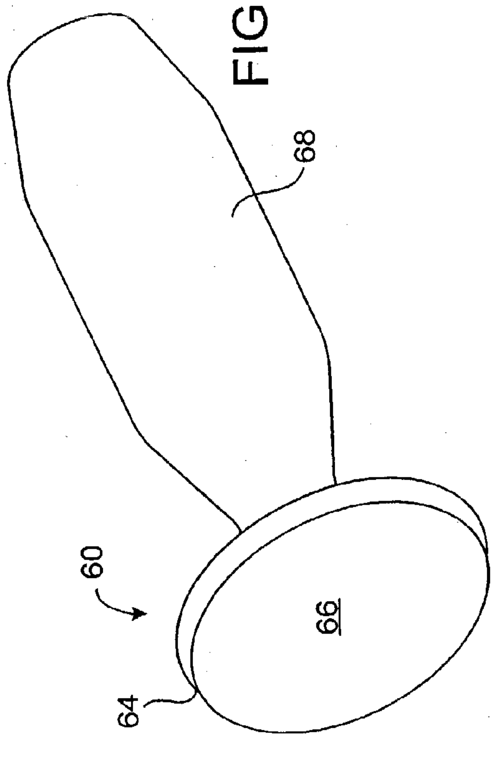


FIG. 11A

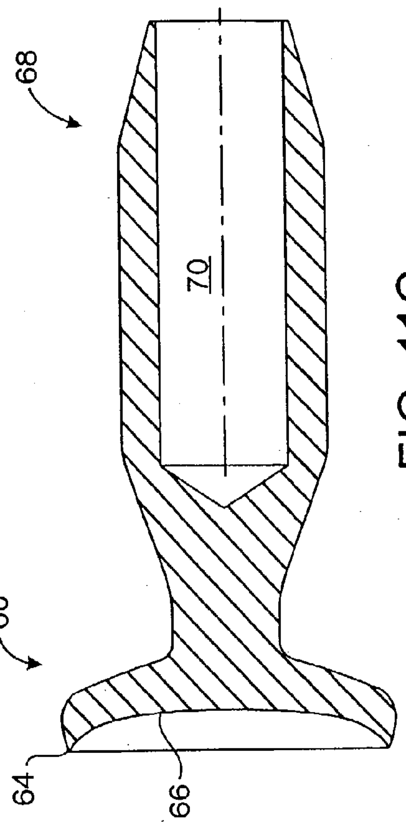


FIG. 11C

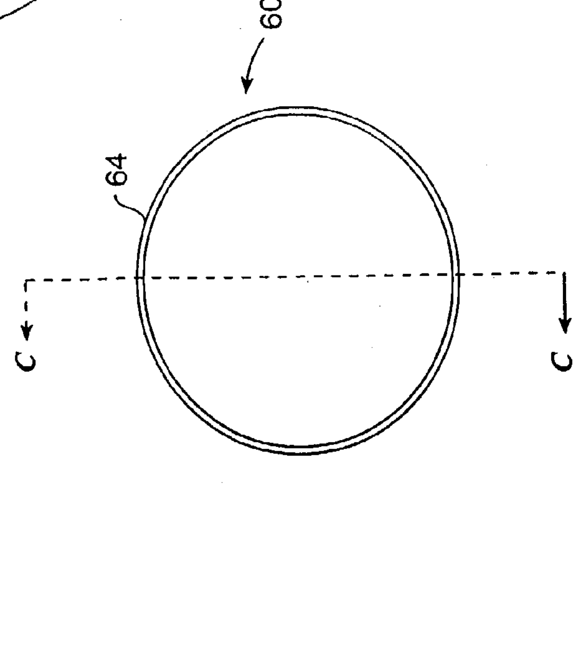


FIG. 11B

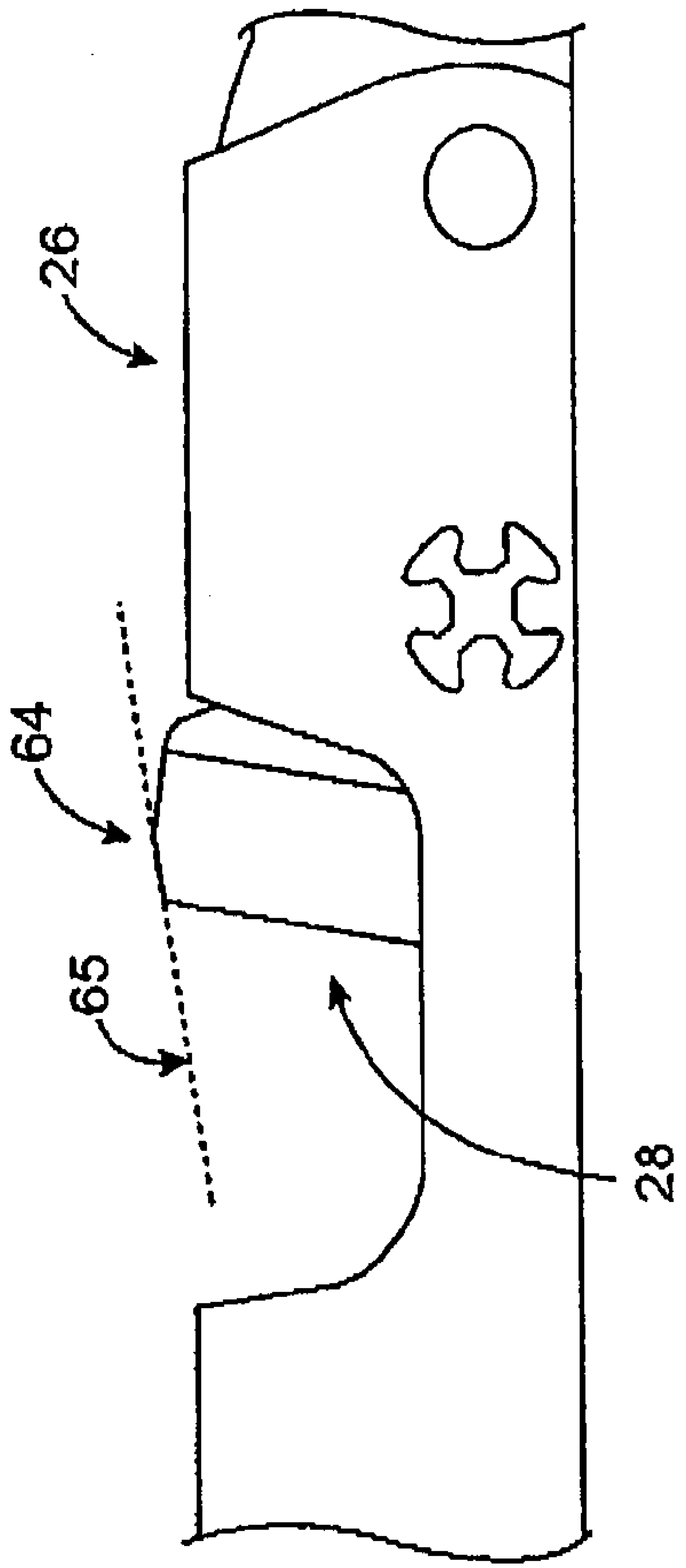


FIG. 11D

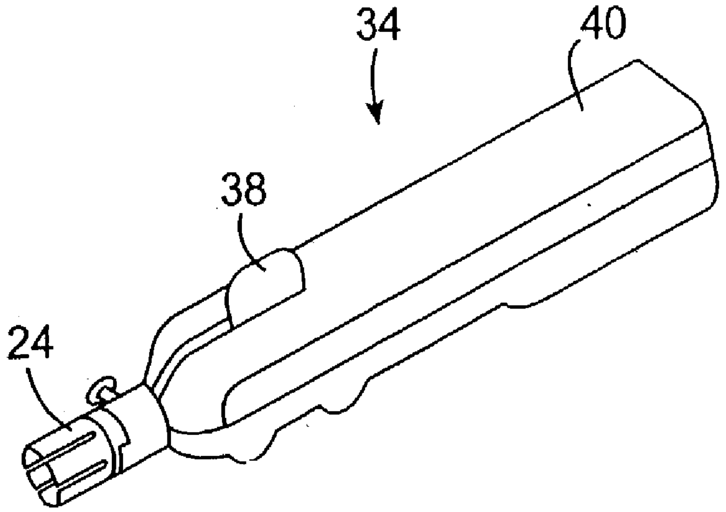


FIG. 12

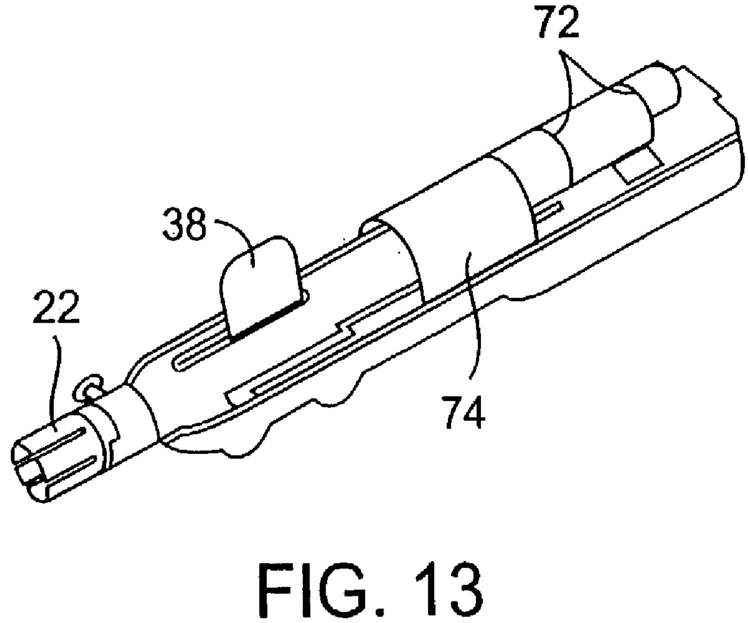


FIG. 13

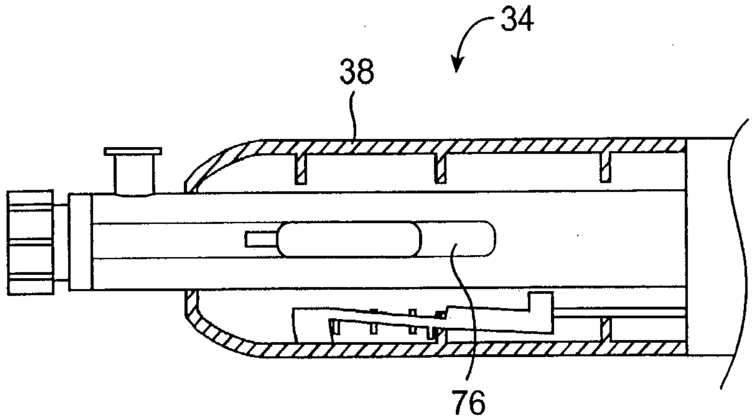


FIG. 14

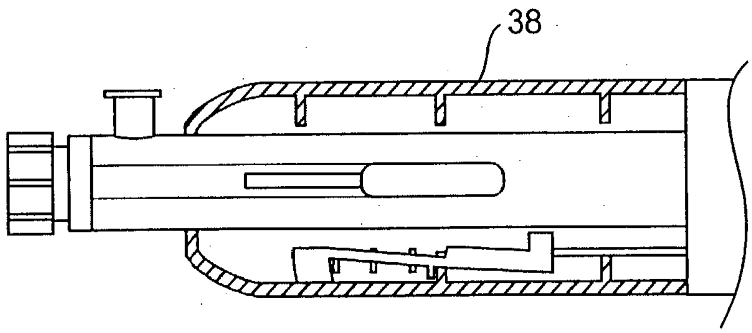


FIG. 15

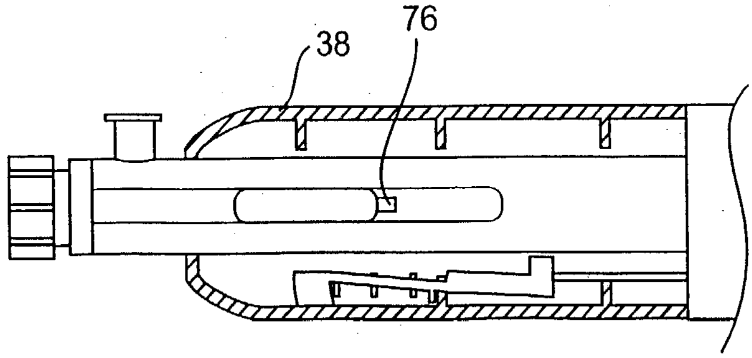
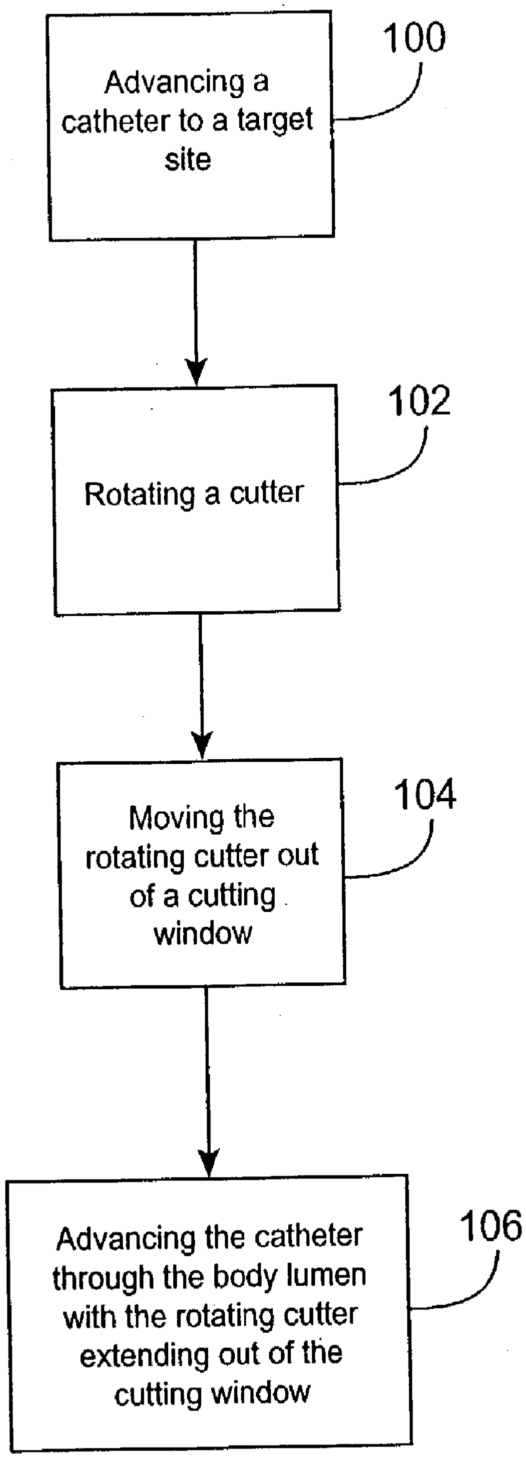


FIG. 16



Advancing a catheter to a target site
100
Rotating a cutter
102
Moving the rotating cutter out of a cutting window
104
Advancing the catheter through the body lumen with the rotating cutter extending out of the cutting window
106

FIG. 17

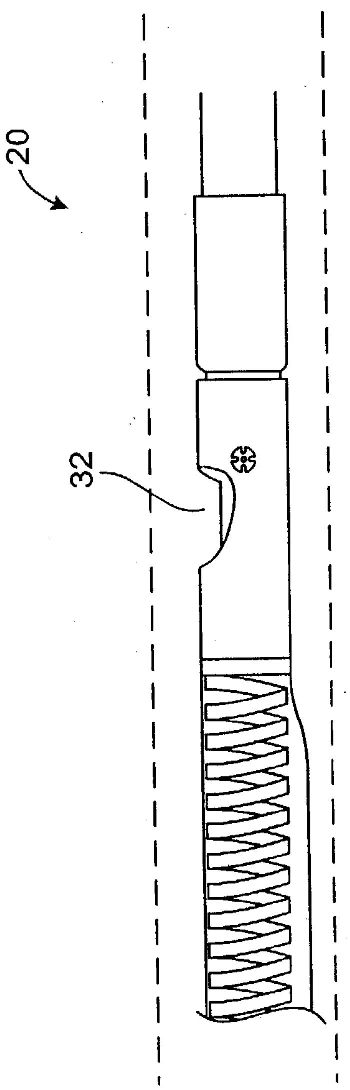


FIG. 18

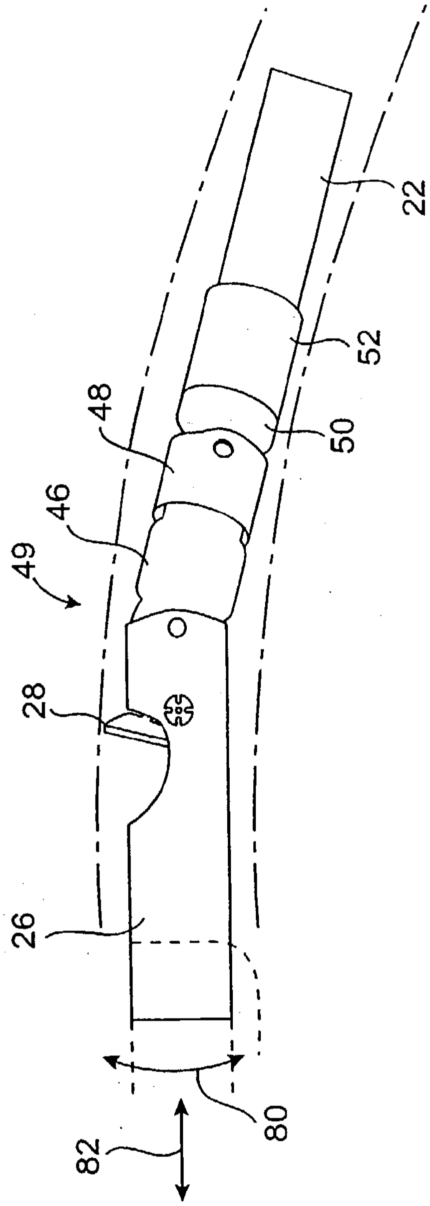


FIG. 19

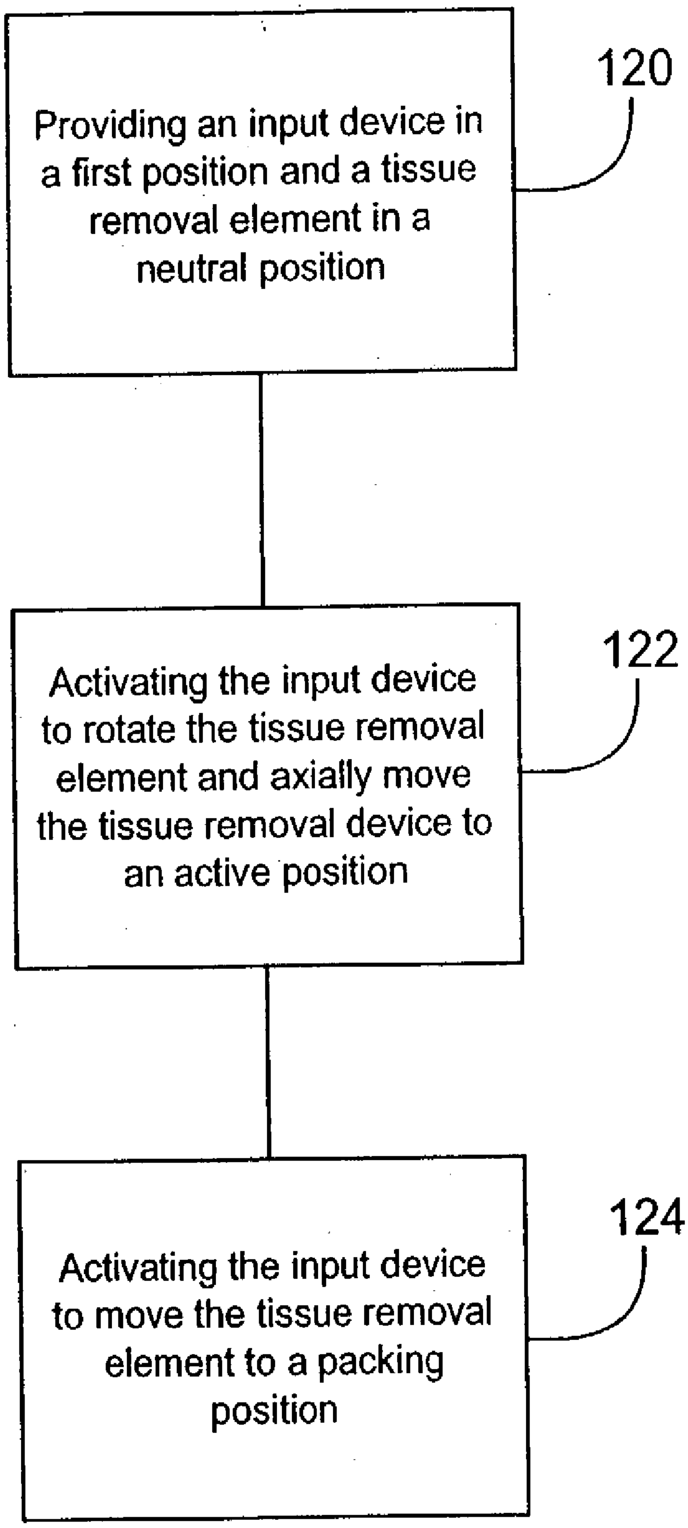

Providing an input device in a first position and a tissue removal element in a neutral position
120
Activating the input device to rotate the tissue removal element and axially move the tissue removal device to an active position
122
Activating the input device to move the tissue removal element to a packing position
124

FIG. 20

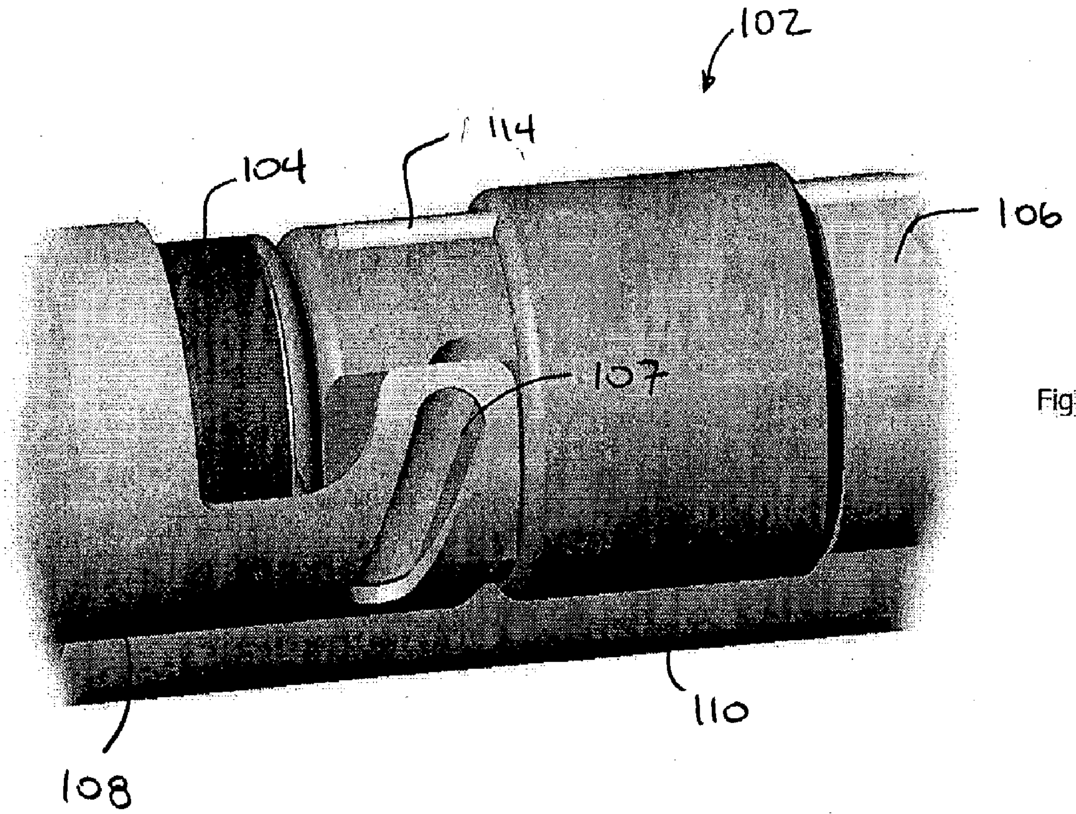


Fig. 21

FIG. 21

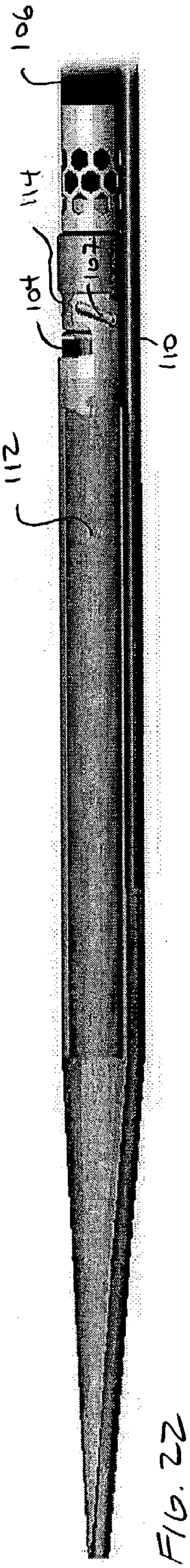


FIG. 22

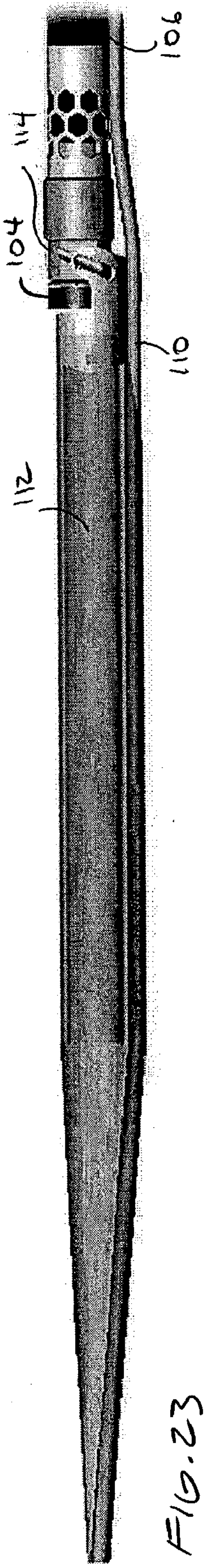


FIG. 23

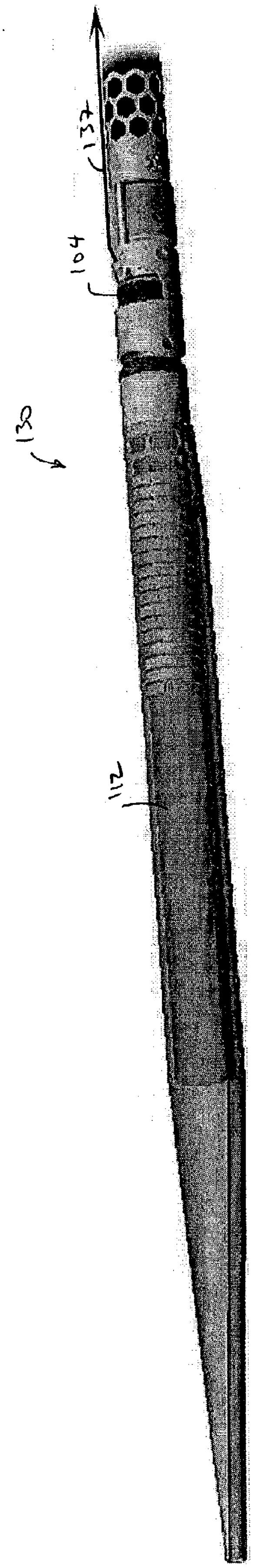


FIG. 24

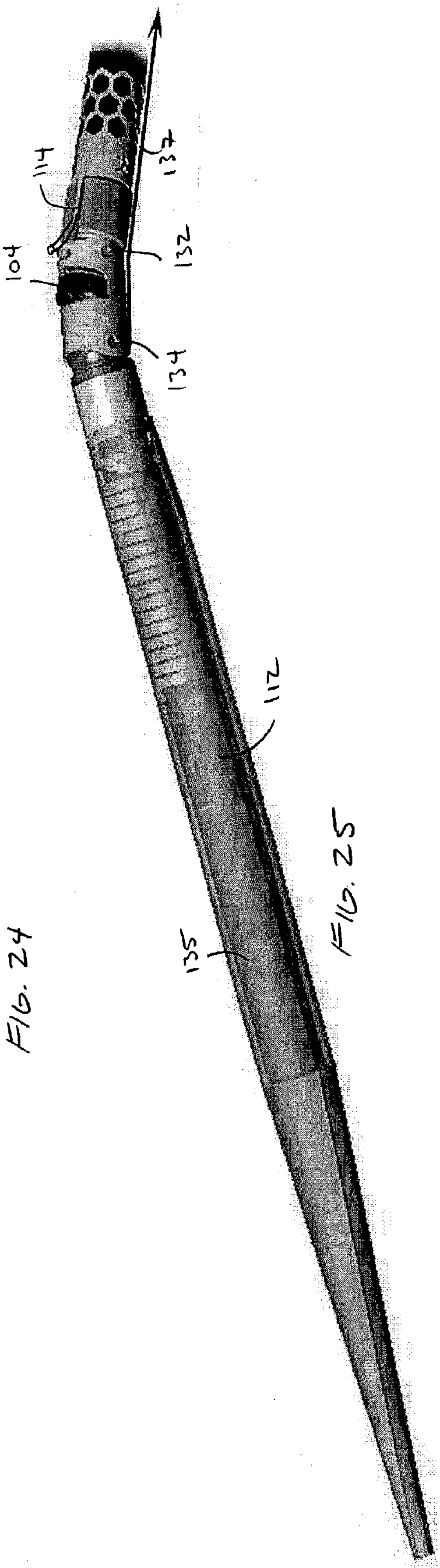


FIG. 25

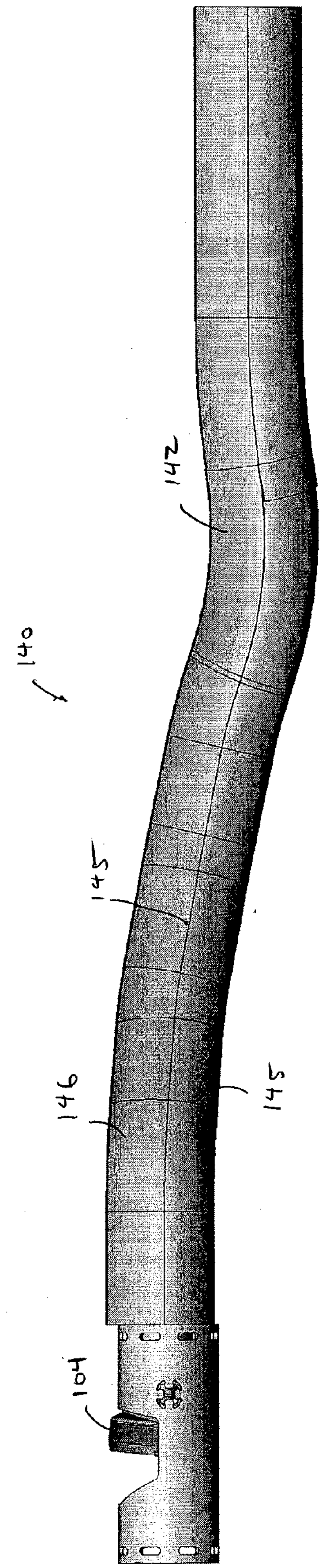


FIG. 26A

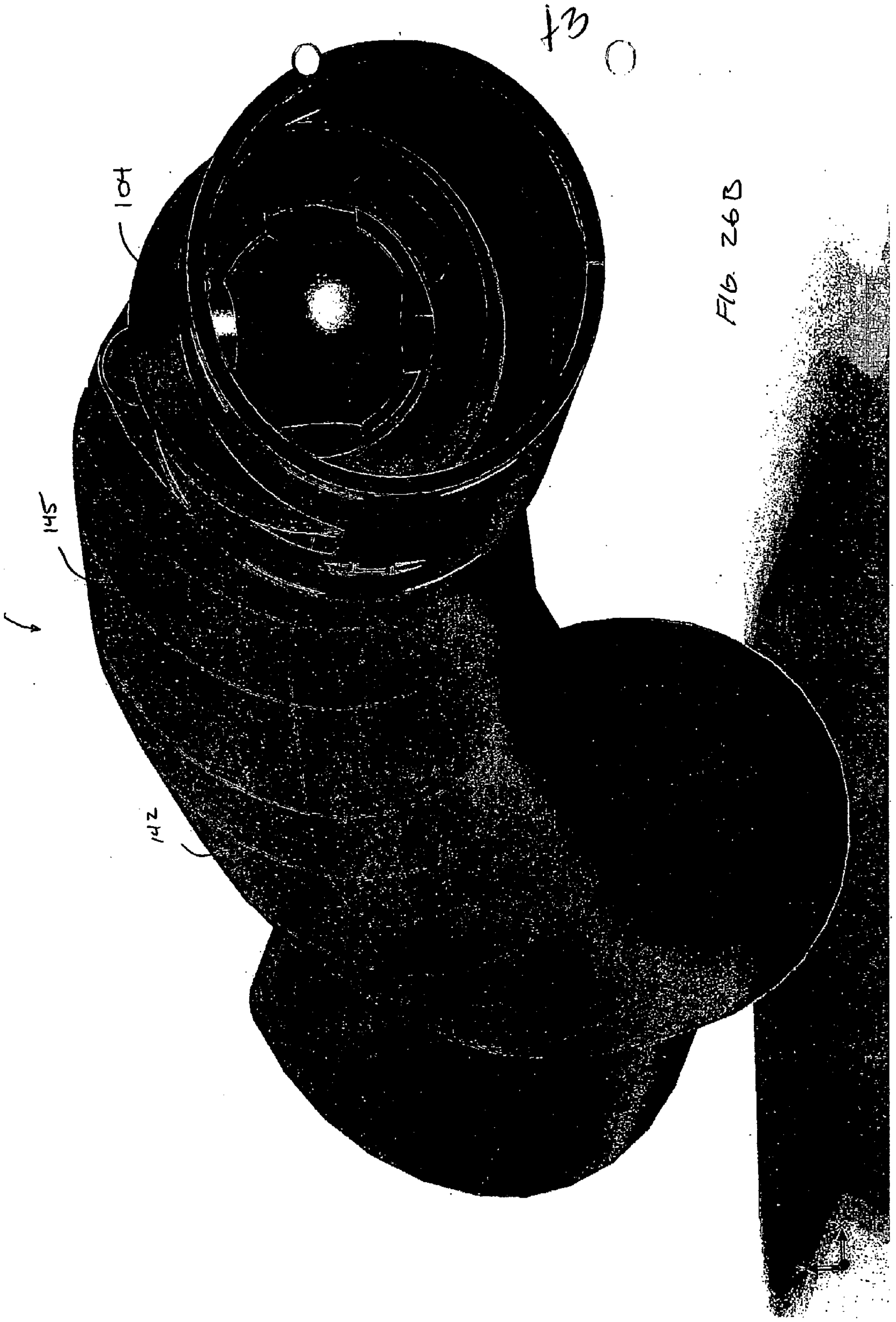


FIG. 26B

144

FIG. 27A

144

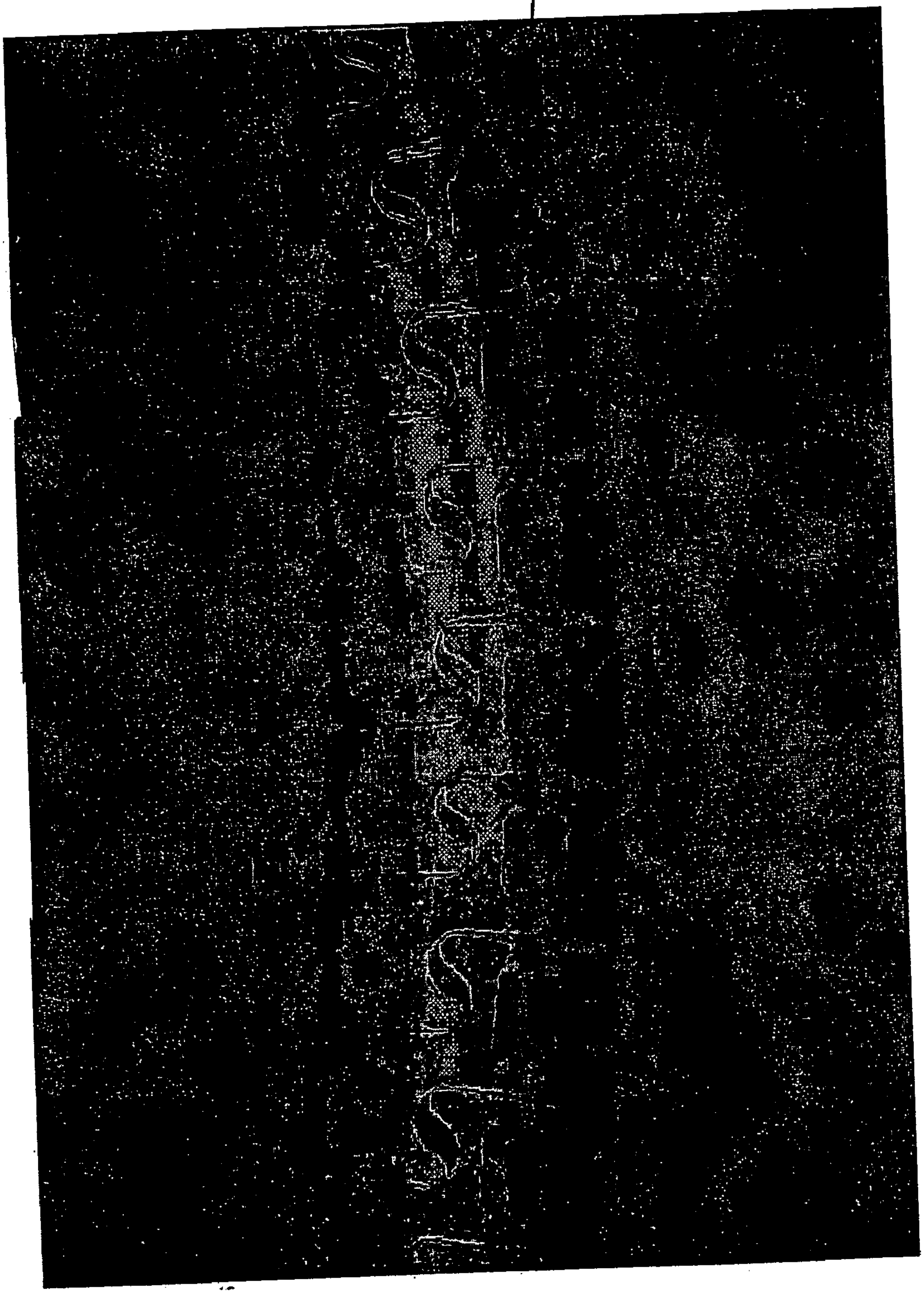


FIG. 27B

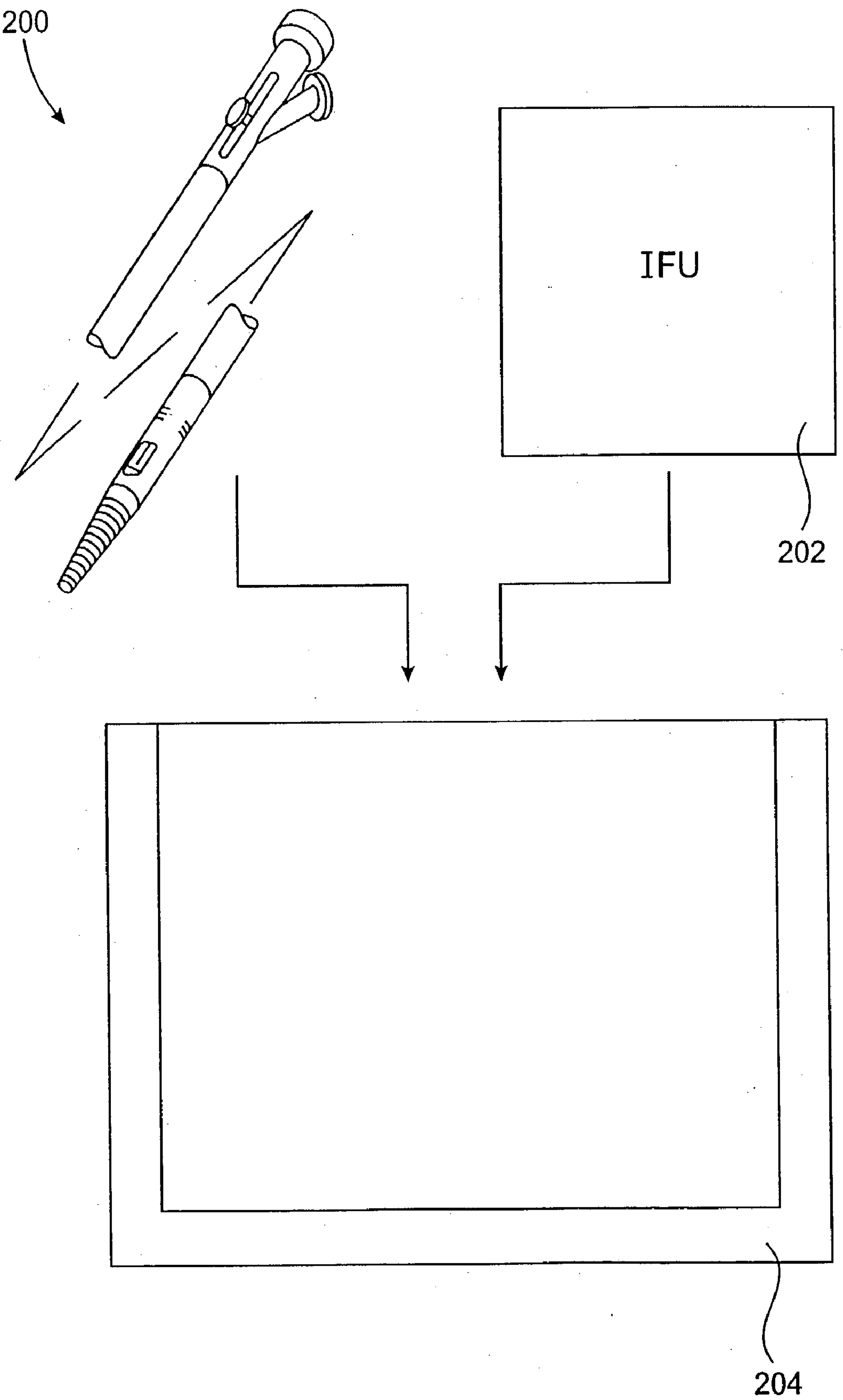


FIG. 28

METHODS AND DEVICES FOR CUTTING TISSUE

CROSS-REFERENCES TO RELATED APPLICATIONS

[0001] The present application is a continuation-in-part of U.S. patent application Ser. No. 10/288,581, (Attorney Docket No. 018489-002540US), which is a continuation-in-part of U.S. patent application Ser. No. 10/027,418, filed Dec. 19, 2001, entitled "Debulking Catheter", which claims the benefit of Provisional Patent Application Serial No. 60/257,704, filed Dec. 20, 2000, entitled "Debulking Catheter" and Provisional Patent Application Serial No. 60/272,273 filed Feb. 27, 2001, entitled "Debulking Catheter", the complete disclosures of which are incorporated herein by reference.

[0002] The present application also claims the benefit of Provisional Application No. 60/381,632, filed on May 19, 2002, entitled "Debulking Catheter", the complete disclosure of which is incorporated herein by reference.

[0003] The present application is also related to U.S. patent application Ser. No. 09/377,884, filed Aug. 19, 1999, entitled "Apparatus and Methods for Material Capture and Removal" and Ser. No. 09/377,894, filed Aug. 19, 1999, entitled "Apparatus and Methods for Removing Material From a Body Lumen," the complete disclosures of which are incorporated by reference.

BACKGROUND OF THE INVENTION

[0004] The present invention relates generally to systems and methods for debulking body lumens. More particularly, the present invention relates to atherectomy catheters for excising atheroma and other materials from blood vessels and from stents.

[0005] Cardiovascular disease frequently arises from the accumulation of atheromatous material on the inner walls of vascular lumens, particularly arterial lumens of the coronary and other vasculature, resulting in a condition known as atherosclerosis. Atherosclerosis occurs naturally as a result of aging, but may also be aggravated by factors such as diet, hypertension, heredity, vascular injury, and the like. Atheromatous and other vascular deposits restrict blood flow and can cause ischemia which, in acute cases, can result in myocardial infarction. Atheromatous deposits can have widely varying properties, with some deposits being relatively soft and others being fibrous and/or calcified. In the latter case, the deposits are frequently referred to as plaque.

[0006] One conventional treatment for cardiovascular disease is the use of stents. Endoluminal stents are commonly used to treat obstructed or weakened body lumens, such as blood vessels and other vascular lumens. Once deployed in the blood vessel, the stent can remain in the body lumen where it will maintain the patency of the lumen and/or support the walls of the lumen which surround it. One factor impeding the success of stent technology in endoluminal treatments is the frequent occurrence of in-stent restenosis, characterized by proliferation and migration of smooth muscle cells within and/or adjacent to the implanted stent, causing reclosure or blockage of the body lumen.

[0007] Atherosclerosis and restenosis can be treated in a variety of ways, including drugs, bypass surgery, and a variety of catheter-based approaches which rely on intravascular debulking or removal of the atheromatous or other material occluding a blood vessel. Of particular interest to the present invention, a variety of methods for cutting or dislodging material and removing such material from the blood vessel have been proposed, generally being referred to as atherectomy procedures. Atherectomy catheters intended to excise material from the blood vessel lumen generally employ a rotatable and/or axially translatable cutting blade which can be advanced into or past the occlusive material in order to cut and separate such material from the blood vessel lumen. In particular, side-cutting atherectomy catheters generally employ a housing having an aperture on one side, a blade which is rotated or translated by the aperture, and a balloon to urge the aperture against the material to be removed.

[0008] Although atherectomy catheters have proven very successful in treating many types of atherosclerosis and in-stent restenosis, improved atherectomy catheters and methods are continuously being pursued. For example, many currently available side-cutting atherectomy catheters have difficulty in capturing occluding material in the cutting aperture. To facilitate material capture, the cutting aperture is frequently elongated to increase the area into which the material can penetrate. Such elongation typically requires an equivalent lengthening of the cutter housing. Since most cutter housings are rigid, such lengthening makes it more difficult to introduce the distal end of the catheter through tortuous regions of the vasculature.

[0009] Another shortcoming of many currently available atherectomy catheters is that they typically require a balloon positioned opposite the cutting window to urge the cutting window into contact with occluding material. Such balloons, however, unduly increase the size of the distal portion of the catheter. Even with the balloon, the amount of material that can be removed by conventional atherectomy catheters is limited by the size of the cutting window. Other disadvantages of some catheters include cutting elements with less than ideal hardness, inadequate storage space within the catheter for containing removed material, sub-optimal guide wire lumens, and/or the like.

[0010] For these reasons, it would be advantageous to have atherectomy catheters, and methods for their use, which could access small, tortuous regions of the vasculature and remove atheromatous and other occluding materials from within blood vessels and stents in a controlled fashion. In particular, it would be desirable to have atherectomy catheters and methods which could facilitate capturing and invagination of atheromatous materials. Ideally, such catheters and methods would be adaptable for use in a variety of body lumens, including but not limited to coronary and other arteries. At least some of these objectives will be met by the present invention.

BRIEF SUMMARY OF THE INVENTION

[0011] The present invention provides catheters and methods for removing material from (or "debulking") a body lumen. Catheters of the present invention may be used in a variety of body lumens, including but not limited to intravascular lumens such as coronary arteries. Typically, debulking catheters are used to remove occlusive material, such as atherosclerotic plaque, from vascular lumens, but they may alternatively be used to remove other materials.

Generally, debulking catheters include a proximal portion, a distal portion having an opening (or "window"), and a cutting element (or "tissue debulking assembly") which may be exposed through the opening to contact material in a body lumen. The catheter debulks a body lumen when it is moved while the cutting element is in contact with the material in the lumen.

[0012] In one aspect of the present invention, a method of removing material from a blood flow lumen comprises: providing a device having a cutting element and an opening; advancing the device through the blood flow lumen to a site where material is to be removed; forcing the opening toward a wall of the site where material is to be removed; and moving the cutting element and the opening after the forcing step so that material in the blood flow lumen is cut by the cutting element and directed into the opening for removal as the cutting element and opening are moved through the blood flow lumen. Optionally, the moving step may be carried out with the cutting element and the opening moving together in unison through the blood flow lumen.

[0013] In some embodiments, the forcing step is carried out by bending the device so that the opening is forced against the wall of the site. Also in some embodiments, the providing step is carried out with the cutting element being rotatable, with the moving step being carried out with the cutting element rotating when severing the material. When the cutting element is rotatable, the providing step may be carried out with the device having a longitudinal axis, and with the moving step being carried out with the cutting element rotating around an axis which is not parallel to the longitudinal axis of the device. In some embodiments, the providing step is carried out with the cutting element having an axis of rotation which is movable relative to a longitudinal axis of the device.

[0014] In some embodiments, the moving step is carried out with the cutting element cutting a continuous piece of material. Optionally, in such embodiments, the providing step may be carried out with the opening being on a side of the device; the forcing step may be carried out to force the side against the blood flow lumen; and the moving step may be carried out with the cutting element extending out of the opening, the cutting element directing the continuous piece of material into the opening. In some embodiments, the moving step is carried out by moving the cutting element and window in a distal direction, with the cut material being stored in the device at a location distal to the cutting element. Also in some embodiments, the providing step is carried out with the cutting element being movable relative to the opening.

[0015] In still other embodiments, the providing step is carried out with the cutting element being movable between a deployed position and a retracted position, the cutting element extending out of the opening when in the deployed position and being contained within the opening when in the retracted position. In such embodiments, the advancing step is typically carried out with the cutting element in the retracted position and the moving step is carried out with the cutting element being in the deployed position. For example, the providing step may be carried out with the cutting element extending beyond the opening a distance of about 0.025 mm to about 0.64 mm. Generally, the providing step may be carried out with the opening being positioned along a side of the device.

[0016] In still another aspect of the present invention, a device for cutting tissue is provided which has an elongate body with an opening therein. A rotatable cutting element is coupled to a torque transmitting element which extends through the body. A visualization element is movable from a stored position to a working position which is at a radially outward position on the body.

[0017] In yet another aspect of the present invention, a device for cutting tissue is provided which has a movable cover coupled to the body. The cover is movable from a stored position, in which the rotatable cutting element is covered by the cover, to a working position, in which at least part of the rotatable cutting element is exposed. The cover may be linearly movable relative to the body so that the cover essentially translates without deforming.

[0018] In another aspect of the invention, a method of removing material from a vascular location is provided. The body may be deformed before advancing the cutting element and opening through the vascular region to cut and remove a continuous piece of material as describe herein. The deformable portion of the body may take any suitable shape such as S-shaped or helical providing the step of forcing the opening toward a wall of the site where material is to be removed. The deformable portion may be relatively long, such as at least 1 cm or even at least 2 cm, to help stabilize the device.

[0019] In another aspect of the invention, a device for cutting tissue is provided which has two pivot points on opposite sides of the cutting element. The pivot points both help to move the cutting element into the cutting position and force the opening toward a wall. In particular the cutting or working position presents the cutting element at an orientation which may be advantageous when advancing the entire device through the vasculature as describe herein to cut and remove a continuous piece of material.

[0020] For a further understanding of the nature and advantages of the invention, reference should be made to the following description taken in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0021] **FIG. 1** is a perspective view of a debulking catheter of the present invention;

[0022] **FIG. 1A** is a side view of a portion of a debulking catheter as in **FIG. 1**, where the body has a rigid distal portion with a bend, according to one embodiment of the present invention;

[0023] **FIG. 2** is an exploded view of an exemplary distal portion of the debulking catheter of the present invention;

[0024] **FIG. 3A** is an end view of the distal portion of the debulking catheter of **FIG. 1** in which the cutter is in a closed position in the catheter body;

[0025] **FIG. 3B** is a sectional view along Line A-A of **FIG. 3A**;

[0026] **FIGS. 3C and 3D** are views of the distal portion of a debulking catheter, where the distal portion has a locking shuttle mechanism;

[0027] **FIG. 4A** is an end view of the distal portion of the debulking catheter of **FIG. 1** in which the cutter is in an open position outside of the cutting window;

[0028] **FIG. 4B** is a sectional view along Line A-A of **FIG. 4A**;

[0029] **FIGS. 4C and 4D** are views of the distal portion of a debulking catheter, where the distal portion has a locking shuttle mechanism;

[0030] **FIG. 5A** is an end view of the distal portion of the debulking catheter of **FIG. 1** in which the cutter is in a packing position within a tip of the catheter;

[0031] **FIG. 5B** is a sectional view along Line A-A of **FIG. 5A**;

[0032] FIGS. **6** to **8** illustrate a monorail delivery system of the present invention;

[0033] **FIG. 9A** is a perspective view of a cutter of the present invention;

[0034] **FIG. 9B** is an end view of the cutter of **FIG. 9A**;

[0035] **FIG. 9C** is a sectional view of the cutter along Line A-A of the cutter of **FIGS. 9A and 9B**;

[0036] **FIG. 10A** is a perspective view of a in-stent restenosis cutter of the present invention;

[0037] **FIG. 10B** is an end view of the cutter of **FIG. 10A**;

[0038] **FIG. 10C** is a sectional view of the cutter along Line B-B of the cutter of **FIGS. 10A and 10B**;

[0039] **FIG. 11A** is a perspective view of another in-stent restenosis cutter of the present invention;

[0040] **FIG. 11B** is an end view of the cutter of **FIG. 11A**;

[0041] **FIG. 11C** is a sectional view of the cutter along Line C-C of the cutter of **FIGS. 11A and 11B**;

[0042] **FIG. 11D** is a side view of another embodiment of a cutter, shown partially within a catheter body;

[0043] **FIG. 12** illustrates a proximal handle and cutter driver of the present invention;

[0044] **FIG. 13** illustrates a cutter driver with a handle cover removed;

[0045] FIGS. **14** to **16** illustrate three positions of the lever for controlling the cutter;

[0046] **FIG. 17** is a simplified flow chart illustrating a method of the present invention;

[0047] **FIGS. 18 and 19** illustrate a method of the present invention;

[0048] **FIG. 20** schematically illustrates another method of the present invention

[0049] **FIG. 21** shows another device for cutting tissue with the device having a movable cover;

[0050] **FIG. 22** shows the device of **FIG. 21** with the cover in a stored position;

[0051] **FIG. 23** shows the device of **FIG. 21** with the cover in a working position which exposes part of the rotatable cutting element;

[0052] **FIG. 24** shows still another device for cutting tissue having two pivot points on opposite sides of the cutting element;

[0053] **FIG. 25** shows the device of **FIG. 24** after articulating the device at the pivot points to put the cutting element in a cutting position;

[0054] **FIG. 26A** is a side view of the elongate body or shaft forming a helical shape.

[0055] **FIG. 26B** is a perspective view looking at the distal end of the device;

[0056] **FIG. 27A** shows a tube which forms part of the elongate body of **FIG. 26** in a straight configuration;

[0057] **FIG. 27B** shows the tube of **FIG. 27A** in a bent configuration; and

[0058] **FIG. 28** illustrates a kit of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

[0059] The catheters and methods of the present invention are designed to debulk atheroma and other occlusive material from diseased body lumens, and in particular coronary arteries, de novo lesions, and in-stent restenosis lesions. The catheters and methods, however, are also suitable for treating stenoses of body lumens and other hyperplastic and neoplastic conditions in other body lumens, such as the ureter, the biliary duct, respiratory passages, the pancreatic duct, the lymphatic duct, and the like. Neoplastic cell growth will often occur as a result of a tumor surrounding and intruding into a body lumen. Debulking of such material can thus be beneficial to maintain patency of the body lumen. While the remaining discussion is directed at debulking and passing through atheromatous or thrombotic occlusive material in a coronary artery, it will be appreciated that the systems and methods of the present invention can be used to remove and/or pass through a variety of occlusive, stenotic, or hyperplastic material in a variety of body lumens.

[0060] Apparatus according to the present invention will generally comprise catheters having catheter bodies adapted for intraluminal introduction to the target body lumen. The dimensions and other physical characteristics of the catheter bodies will vary significantly depending on the body lumen which is to be accessed. In the exemplary case of atherectomy catheters intended for intravascular introduction, the proximal portions of the catheter bodies will typically be very flexible and suitable for introduction over a guidewire to a target site within the vasculature. In particular, catheters can be intended for "over-the-wire" introduction when a guidewire channel extends fully through the catheter body or for "rapid exchange" introduction where the guidewire channel extends only through a distal portion of the catheter body. In other cases, it may be possible to provide a fixed or integral coil tip or guidewire tip on the distal portion of the catheter or even dispense with the guidewire entirely. For convenience of illustration, guidewires will not be shown in all embodiments, but it should be appreciated that they can be incorporated into any of these embodiments.

[0061] Catheter bodies intended for intravascular introduction will typically have a length in the range from 50 cm to 200 cm and an outer diameter in the range from 1 French to 12 French (0.33 mm: 1 French), usually from 3 French to 9 French. In the case of coronary catheters, the length is typically in the range from 125 cm to 200 cm, the diameter is preferably below 8 French, more preferably below 7

French, and most preferably in the range from 2 French to 7 French. Catheter bodies will typically be composed of an organic polymer which is fabricated by conventional extrusion techniques. Suitable polymers include polyvinylchloride, polyurethanes, polyesters, polytetrafluoroethylenes (PTFE), silicone rubbers, natural rubbers, and the like. Optionally, the catheter body may be reinforced with braid, helical wires, coils, axial filaments, or the like, in order to increase rotational strength, column strength, toughness, pushability, and the like. Suitable catheter bodies may be formed by extrusion, with one or more channels being provided when desired. The catheter diameter can be modified by heat expansion and shrinkage using conventional techniques. The resulting catheters will thus be suitable for introduction to the vascular system, often the coronary arteries, by conventional techniques.

[0062] The distal portion of the catheters of the present invention may have a wide variety of forms and structures. In many embodiments, a distal portion of the catheter is more rigid than a proximal portion, but in other embodiments the distal portion may be equally as flexible as the proximal portion. One aspect of the present invention provides catheters having a distal portion with a reduced rigid length. The reduced rigid length can allow the catheters to access and treat tortuous vessels and small diameter body lumens. In most embodiments a rigid distal portion or housing of the catheter body will have a diameter that generally matches the proximal portion of the catheter body, however, in other embodiments, the distal portion may be larger or smaller than the flexible portion of the catheter.

[0063] A rigid distal portion of a catheter body can be formed from materials which are rigid or which have very low flexibilities, such as metals, hard plastics, composite materials, NiTi, steel with a coating such as titanium nitride, tantalum, ME-92®, diamonds, or the like. Most usually, the distal end of the catheter body will be formed from stainless steel or platinum/iridium. The length of the rigid distal portion may vary widely, typically being in the range from 5 mm to 35 mm, more usually from 10 mm to 25 mm, and preferably between 6 mm and 8 mm. In contrast, conventional catheters typically have rigid lengths of approximately 16 mm.

[0064] The side opening windows of the present invention will typically have a length of approximately 2 mm. In other embodiments, however, the side opening cutting window can be larger or smaller, but should be large enough to allow the cutter to protrude a predetermined distance that is sufficient to debulk material from the body lumen.

[0065] The catheters of the present invention can include a flexible atraumatic distal tip coupled to the rigid distal portion of the catheter. For example, an integrated distal tip can increase the safety of the catheter by eliminating the joint between the distal tip and the catheter body. The integral tip can provide a smoother inner diameter for ease of tissue movement into a collection chamber in the tip. During manufacturing, the transition from the housing to the flexible distal tip can be finished with a polymer laminate over the material housing. No weld, crimp, or screw joint is usually required.

[0066] The atraumatic distal tip permits advancing the catheter distally through the blood vessel or other body lumen while reducing any damage caused to the body lumen by the catheter. Typically, the distal tip will have a guidewire channel to permit the catheter to be guided to the target lesion over a guidewire. In some exemplary configurations, the atraumatic distal tip comprises a coil. In some configurations the distal tip has a rounded, blunt distal end. The catheter body can be tubular and have a forward-facing circular aperture which communicates with the atraumatic tip. A collection chamber can be housed within the distal tip to store material removed from the body lumen. The combination of the rigid distal end and the flexible distal tip is approximately 30 mm.

[0067] A rotatable cutter or other tissue debulking assembly may be disposed in the distal portion of the catheter to sever material which is adjacent to or received within the cutting window. In an exemplary embodiment, the cutter is movably disposed in the distal portion of the catheter body and movable across a side opening window. A straight or serrated cutting blade or other element can be formed integrally along a distal or proximal edge of the cutting window to assist in severing material from the body lumen. In one particular embodiment, the cutter has a diameter of approximately 1.14 mm. It should be appreciated however, that the diameter of the cutter will depend primarily on the diameter of the distal portion of the catheter body.

[0068] In exemplary embodiments, activation of an input device can deflect a distal portion of the catheter relative to the proximal portion of the catheter. Angular deflection of the distal portion may serve one or more purposes in various embodiments. Generally, for example, deflection of the distal portion increases the effective "diameter" of the catheter and causes the debulking assembly to be urged against material in a lumen, such as atherosclerotic plaque. In other embodiments, deflection of the distal portion may act to expose a debulking assembly through a window for contacting material in a lumen. In some embodiments, for example, activation of the input device moves the debulking assembly over a ramp or cam so that a portion of the rigid distal portion and flexible tip are caused to drop out of the path of the debulking assembly so as to expose the debulking assembly through the window. In some embodiments, deflection may both urge a portion of the catheter into material in a lumen and expose a tissue debulking assembly.

[0069] Some embodiments further help to urge the debulking assembly into contact with target tissue by including a proximal portion of the catheter body having a rigid, shaped or deformable portion. For example, some embodiments include a proximal portion with a bend that urges the debulking assembly toward a side of the lumen to be debulked. In other embodiments, one side of the proximal portion is less rigid than the other side. Thus, when tension is placed on the catheter in a proximal direction (as when pulling the debulking assembly proximally for use), one side of the proximal portion collapses more than the other, causing the catheter body to bend and the debulking assembly to move toward a side of the lumen to be debulked.

[0070] In exemplary embodiments, the debulking assembly comprises a rotatable cutter that is movable outside the window. By moving the cutter outside of the cutting window beyond an outer diameter of the distal portion of the catheter, the cutter is able to contact and sever material that does not invaginate the cutting window. In a specific configuration, the rotating cutter can be moved over the cam within the rigid, or distal, portion of the catheter body so that the cutting edge is moved out of the window. Moving the rotating cutter outside of the cutting window and advancing the entire catheter body distally, a large amount of occlusive material can be removed. Consequently, the amount of material that can be removed is not limited by the size of the cutting window.

[0071] As will be described in detail below, in some situations it is preferable to provide a serrated cutting edge, while in other situations it may be preferable to provide a smooth cutting edge. Optionally, the cutting edge of either or both the blades may be hardened, e.g., by application of a coating. A preferred coating material is a chromium based material, available from ME-92, Inc., which may be applied according to manufacturer's instructions. In some embodiments, the cutter includes a tungsten carbide cutting edge. Other rotatable and axially movable cutting blades are described in U.S. Pat. Nos. 5,674,232; 5,242,460; 5,312,425; 5,431,673; and 4,771,774, the full disclosures of which are incorporated herein by reference. In some embodiments, a rotatable cutter includes a beveled edge for removal of material from a body lumen while preventing injury to the lumen. In still other embodiments, a tissue debulking assembly may include alternative or additional features for debulking a lumen. For example, the debulking assembly may include, but is not limited to, a radio frequency device, an abrasion device, a laser cutter and/or the like.

[0072] The catheters of the present invention may include a monorail delivery system to assist in positioning the cutter at the target site. For example, the tip of the catheter can include lumen(s) that are sized to receive a conventional guidewire (typically 0.014" diameter) or any other suitable guidewire (e.g., having diameters between 0.018" and 0.032") and the flexible proximal portion of the catheter body can include a short lumen (e.g., about 12 centimeters in length). Such a configuration moves the guidewire out of the rigid portion so as to not interfere with the debulking assembly.

[0073] In other embodiments, however, the guidewire lumen may be disposed within or outside the flexible proximal portion of the catheter body and run a longer or shorter length, and in fact may run the entire length of the flexible portion of the catheter body. The guidewire can be disposed within lumen on the flexible portion of the catheter body and exit the lumen at a point proximal to the rigid portion of the catheter. The guidewire can then enter a proximal opening in the tip lumen and exit a distal opening in the tip lumen. In some embodiments, the catheter has a distal guidewire lumen on its flexible distal tip and a proximal guidewire lumen on its flexible body. For example, in some embodiments the distal lumen may have a length of between about 2.0 cm and about 3.0 cm and the proximal lumen may have a length of between about 10 cm and about 14 cm. In yet further embodiments, a distal tip guidewire lumen may be configured to telescope within a proximal guidewire lumen, or vice versa. A telescoping guidewire lumen may enhance performance of the catheter by preventing a guidewire from being exposed within a body lumen.

[0074] The present invention may optionally employ any of a wide variety of conventional radiopaque markers, imaging devices, and/or transducers. In exemplary embodiments, the catheters of the present invention can include a radiopaque distal portion and/or radiopaque markers disposed on a distal portion of the catheter body, such as proximal and distal of the cutting window, on the cam or ramp, so as to allow the user to track the position of the cutter, or the like. The catheters of the present invention will also be particularly useful with ultrasonic transducers, such as an IVUS, of a type which may be deployed linearly within the catheter body or circumferentially on the debulking assembly. Linear deployment will allow viewing along a discrete length of the catheter axis, preferably adjacent to the cutting point, usually over a length in the range from 1 mm to 30 mm, preferably 2 mm to 10 mm. Circumferentially deployed phased arrays may subtend a viewing arc in the range from 5° to 360°, usually from 180° to 360°. For imaging transducers located on cutting blades within a housing or second cutting element, the field of imaging will generally be limited by the dimensions of the aperture. In some cases, however, it might be possible to fabricate all or a portion of the cutter blade/housing out of an ultrasonically translucent material. A more complete description of suitable imaging catheters are described more fully in U.S. patent application Ser. No. 09/378,224, filed Aug. 19, 1999, and entitled "Atherectomy Catheter with Aligned Imager," now U.S. Pat. No., 6,299,622 B1, the complete disclosure of which is incorporated herein by reference. In addition to ultrasonic array transducers, the imaging devices of the present invention may comprise optical coherence tomography devices, such as described in U.S. Pat. No. 5,491,524, the full disclosure of which is incorporated herein by reference, as well as Huang et al. (1991) Science 254:1178-1181; Brezinski et al. (1997) Heart 77:397-403; and Brezinski et al (1996) Circulation 93:1206-1213. In some instances, the present invention may also provide optical imaging using optical wave guides and the like.

[0075] Referring now to **FIG. 1, a** catheter **20** constructed in accordance with principles of the present invention comprises a catheter body **22** having a proximal portion **24** and a distal portion **26**. Proximal portion **24** can be coupled to distal portion **26** with a connection assembly **27** to allow pivoting or deflection of distal portion **26** relative to proximal portion **24**. A proximal end of the catheter body **22** can have a handle **40** for manipulation by a user, a luer for connection to an aspiration or fluid delivery channel, or the like.

[0076] A debulking assembly, such as a cutter **28**, abrasive member, or the like, is disposed within a lumen **30** of the catheter body **22**. The cutter **28** is typically rotatable within the distal portion **26** about an axis that is parallel to the longitudinal axis of the distal portion **26** of catheter **20** and axially movable along the longitudinal axis. The cutter **28** can access target tissue through a side opening window **32** which is typically large enough to allow the cutter **28** to protrude through and move out of the window **32** a predetermined distance. The cutter is coupled to a cutter driver **34** through a coiled drive shaft **36**. Actuation of a movable actuator or other input device **38** can activate the drive shaft **36** and cutter, move cutter **28** longitudinally over a cam so as to deflect the distal portion and move the cutter **28** out of cutting window **32**. Camming of the cutter **28** can cause the distal portion **26** to pivot or deflect relative to the proximal portion **24** so as to deflect and urge the cutter into the tissue in the body lumen.

[0077] In some embodiments, the distal portion **26** of the catheter may be moved to an angled or offset configuration from the longitudinal axis of the proximal portion **24** of the catheter and the cutter **28**. In some embodiments, the cutter **28** can also be deflected off of the axis of the proximal and/or distal portion of the catheter. Moving the distal portion **26** to an angled/offset position may cause a portion of the catheter to urge against a target tissue, may expose the cutter **28** through the window **32** or both, in various embodiments.

[0078] In catheters **20** of the present invention, proximal portion **24** is typically relatively flexible and distal portion **26** is typically relatively rigid. Additionally, many embodiments include a flexible distal tip **42**. The flexible proximal portion **24** of the catheter is typically a torque shaft and the distal portion **26** is typically a rigid tubing. The torque shaft **24** facilitates transportation of the catheter body **22** and cutter **28** to the diseased site. The proximal end of the torque shaft **24** is coupled to a proximal handle **40** and the distal end of the torque shaft is attached to the distal, rigid portion **26** of the catheter through the connection assembly **27**. The drive shaft **36** is movably positioned within the torque shaft **24** so as to rotate and axially move within the torque shaft **24**. The drive shaft **36** and torque shaft **24** are sized to allow relative movement of each shaft without interfering with the movement of the other shaft. The catheter body will have the pushability and torqueability such that torquing and pushing of the proximal end will translate motion to the distal portion **26** of the catheter body **22**.

[0079] Referring now to **FIG. 1A**, a catheter **20** as in **FIG. 1** may have a flexible proximal portion **24** which additionally includes urging means **25**. As shown in **FIG. 1A**, urging means **25** may comprise a rigid bent or curved shape towards the distal end of proximal portion **24**, which may help urge the cutter **28** or other debulking apparatus toward a wall of a body lumen to enhance treatment. Such a rigid bend increases the working range of the catheter by allowing the cutter to be urged into a lumen wall across a wider diameter lumen.

[0080] In other embodiments, urging means **25** may take many other suitable forms. For example, a similar result to the rigid bend may be achieved by including a rigid distal portion that is not permanently bent but that is more rigid on one side than on the opposite side of catheter body **22**. Thus, when proximal tension is applied to the proximal portion **24**, as when proximal force is applied to the debulking apparatus to expose the cutter **28** through the window **32**, the urging means **25** (i.e., the rigid distal portion of proximal portion **24**) will cause the catheter body **22** to bend toward the less rigid side. The less rigid side will typically be the same side as the window **32**, so that the window **32** and/or the cutter **28** will be urged against a wall of a body lumen by the bend. In still other embodiments, a shaped element may be introduced into catheter body to act as urging means **25**. Any suitable urging means is contemplated.

[0081] **FIG. 2** illustrates an exploded view of a distal end of the catheter. In such embodiments, the catheter **10** includes a connection assembly **27**, a rigid housing **26**, a distal tip **42** that at least partially defines a collection chamber **53** for storing the severed atheromatous material, and a lumen that can receive the guidewire. The distal tip **42** can have a distal opening **43** that is sized to allow an imaging guidewire or conventional guidewire (not shown) to be advanced distally through the tip. In some embodiments, the distal tip **42** may also include a distal guidewire lumen (not shown) for allowing passage of a guidewire. For example, some embodiments may include a distal guidewire lumen having a length of between about 1.0 cm and about 5.0 cm, and preferably between about 2.0 cm and about 3.0 cm. Such a distal guidewire lumen may be used alone or in conjunction with a proximal guidewire lumen located on another, more proximal, portion of the catheter **20**.

[0082] In embodiments including a distal guidewire lumen and a proximal guidewire lumen, the distal lumen may be configured to partially telescope within a portion of the proximal guidewire lumen, or vice versa. Such telescoping lumens may be used in embodiments where the distal portion **26** of catheter body **22** is movable relative to the proximal portion **24**. A telescoping lumen may enhance performance of the catheter **20** by allowing a guidewire to be maintained largely within a lumen and to not be exposed within the body lumen being treated. Telescoping lumens may have any suitable diameters and configurations to allow for sliding or otherwise fitting of one lumen within another.

[0083] A ramp or cam **44** can at least partially fit within the distal portion **26**. As will be described in detail below, in many embodiments proximal movement of the cutter **28** over the ramp **44**, causes the deflection of the distal housing **26** and guides cutter **28** out of cutting window **32**. (In other embodiments, a ramp may be used to deflect the distal portion without extending the cutter out of the window.) Attached to the ramp **44** is a housing adaptor **46** that can connect one or more articulation member **48** to the distal tip to create an axis of rotation of the distal portion **26**. The housing adaptor **46** and articulation member **48** allow the distal end of the catheter to pivot and bias against the body lumen. In the illustrated embodiment there are only one housing adaptor **46** and one articulation member **48**, but it should be appreciated that the catheters of the present invention can include, two, three, or more joints (e.g., axis of rotation), if desired. Moreover, the axes of rotation can be parallel or non-parallel with each other.

[0084] The catheter can also include a shaft adaptor **50** and collar **52** to couple articulation member **48** to the torque shaft **22**. Shaft adaptor **50** can connect the housing to the torque shaft and collar **52** can be placed over a proximal end of the shaft adaptor and crimped for a secure attachment. It should be appreciated by one of ordinary skill in the art that that while one exemplary catheter of the present invention has the above components that other catheters of the present invention may not include more or fewer of the components described above. For example, some components can be made integral with other components and some components may be left out entirely. Thus, instead of having a separate ramp **44**, the ramp may be integrated with the distal tip to direct the cutter out of the cutting window.

[0085] As shown in FIGS. **3-5**, the cutters **28** of the present invention will generally be movable between two or more positions. During advancement through the body lumen, the cutter will generally be in a neutral position (**FIGS. 3A and 3B**) in which the cutter **28** is distal of cutting window **32**. In some embodiments, an imaging device (not shown) can be coupled to cutter **28** so as to image the body lumen through cutting window **32** when cutter **28** is in the neutral position. Once the catheter **20** has reached the target site, the cutter **28** can be moved to an open position (**FIGS. 4A and 4B**) in which the cutter **28** is moved to a proximal end of the cutting window **32** and will extend out of the cutting window **32** a distance L_1 beyond an outer diameter D of the rigid portion **26**. In most embodiments, in the open position, the cutter will have deflected the distal portion and the cutter's axis of rotation will generally be in line with connection assembly **27** but angled or offset from longitudinal axis of the distal portion of the catheter body.

[**0086**] Optionally, in some embodiments, cutter **28** can be moved to a packing position, in which the cutter is moved distally, past the neutral position, so as to pack the severed tissue into a distal collection chamber **53** (**FIGS. 5A and 5B**). It should be appreciated however, that while the exemplary embodiment moves the cutter to the above described positions, in other embodiments of the present invention the cutter can be positioned in other relative positions. For example, instead of having the neutral position distal of the cutting window, the neutral position may be proximal of the window, and the open position may be along the distal end of the cutting window, or the like.

[**0087**] Referring again to **FIGS. 4A and 4B**, the interaction of the components of the rigid distal portions **26** in one exemplary embodiment of the present invention will be further described. As shown in **FIG. 4B**, the cutting window **32** is typically a cutout opening in the distal portion **26**. While the size of the cutting window **32** can vary, the cutting window should be long enough to collect tissue and circumferentially wide enough to allow the cutter to move out of the cutting window during cutting, but sized and shaped to not expel emboli into the vasculature. Cams or ramp **44** (shown most clearly in **FIG. 4B**) can be disposed in the distal portion of the catheter body to guide or otherwise pivot the cutter **28** out of the cutting window **32** as the cutter **28** is pulled proximally through tensioning of drive shaft **36**.

[**0088**] A joint is located proximal to the cutting window **32** to provide a pivot point for camming of the distal portion **26** relative to the proximal portion **24**. The bending at a flexible joint **49** is caused by the interaction of cams or ramps **44** with cutter **28** and the tensile force provided through drive shaft **36**. In the exemplary configuration, the joint includes a housing adaptor **46** that is pivotally coupled to the distal rigid portion **26**. As shown in **FIGS. 4A and 4B**, the resulting pivoting of the rigid distal portion **26** relative to the proximal portion causes a camming effect which urges the distal housing against the body lumen wall without the use of urging means (e.g., a balloon) that is positioned opposite of the cutting window. Thus, the overall cross sectional size of the catheter bodies can be reduced to allow the catheter to access lesions in smaller body lumens. In exemplary embodiments, the distal housing can deflect off of the axis of the proximal portion of the catheter typically between 0° degrees and 30° degrees, usually between 5° degrees and 20° degrees, and most preferably between 5° degrees and **10**° degrees. The angle of deflection relates directly to the urge. Urge, however, does not necessarily relate to force but more to the overall profile of the catheter. For example, the greater the angle of deflection, the larger the profile and the bigger the lumen that can be treated. The ranges were chosen to allow treatment of vessels ranging from less than 2 mm to greater than 3 mm within the limits of mechanical design of the components. It should be appreciated however, that the angles of deflection will vary depending on the size of the body lumen being treated, the size of the catheter, and the like.

[**0089**] In some embodiments, the deflection of the distal portion **26** of the catheter urges the cutter into position such that distal advancement of the entire catheter body can move the rotating cutter through the occlusive material. Because the cutter is moved a distance L_1 beyond the outer diameter of the distal portion of the catheter and outside of the cutting window, the user does not have to invaginate the tissue into the cutting window. In some embodiments, for example, the cutter can be moved between about 0.025 mm and about 1.016 mm, and preferably between about 0.025 mm and about 0.64 mm, beyond the outer dimension of the distal housing. It should be appreciated that the cutter excursion directly relates to the depth of cut. The higher the cutter moves out of the cutting window the deeper the cut. The ranges are chosen around efficacy without risk of perforation of the body lumen.

[**0090**] Some embodiments of the catheter include a shuttle mechanism or other similar mechanism for temporarily locking the catheter in a cutting position. **FIGS. 3C and 3D** illustrate such an embodiment in the neutral, non-cutting position. Such embodiments generally include a shuttle member **45** and a shuttle stop member **42**. The shuttle stop member **42** is typically disposed at an angle, relative to a longitudinal axis through the catheter. **FIGS. 4C and 4D** show the same embodiment in the cutting position. When the cutter **28** is moved into the cutting position in such embodiments, the shuttle member **45** falls into the shuttle stop member **42** and thus locks the debulking apparatus in a cutting position. To unlock the debulking apparatus, the cutter **28** may be advanced forward, distally, to release the shuttle member **45** from the shuttle stop member **42**.

[**0091**] Some embodiments including a shuttle mechanism will also include two joints in catheter body **22**. Thus, catheter body **22** will include a proximal portion **26**, a distal portion **24** and a middle portion. When shuttle mechanism is activated to expose cutter **28** through window **32**, the middle portion may orient itself at an angle, relative to the proximal and distal portions, thus allowing cutter to be urged towards a side of a lumen. Such a two-jointed configuration may provide enhanced performance of the catheter **20** by providing enhanced contact of the cutter **28** with material to be debulked from a body lumen.

[**0092**] Pushing the entire catheter across a lesion removes all or a portion of the lesion from the body lumen. Severed tissue from the lesion is collected by directing it into a collection chamber **53** in the tip via the cutter **28**. Once the catheter and cutter **28** have moved through the lesion, the cutter **28** can be advanced distally to a "part off position" in which the cutter is moved back into the cutting window **32** (**FIG. 3B**). The tissue is collected as the severed pieces of tissue are directed into a collection chamber **53** via the distal movement of cutter **28** and catheter. The collection chamber **53** of the tip and distal portion **26** acts as a receptacle for the severed material, to prevent the severed occlusive material from entering the body lumen and possibly causing downstream occlusions. The cutter **28** can interact with the distal edge of the cutting window to part off the tissue and thereafter pack the severed tissue into collection chamber **53** (**FIG. 3B**). In exemplary embodiments, the driver motor can be programmed to stop the rotation of the cutter at the part off position so that the cutter **28** can move to a third position (**FIG. 5B**) and pack the material in the collection chamber in the tip without rotation. Typically, the collection chamber **53** will be large enough to allow multiple cuts to be collected before the device has to be removed from the body lumen. When the collection chamber is full, or at the user's discretion, the device can be removed, emptied and reinserted over the guidewire via a monorail system, as will be described below.

[**0093**] In various embodiments, enhancements to the collection chamber **53** may be included. For example, in some embodiments the collection chamber **53** may be configured to be partially or completely translucent or radiolucent and a portion of the catheter surrounding or adjacent to the window **32** will be radiopaque. This combination of radiolucent collection chamber **53** and radiopaque material adjacent window **32** will enhance the ability of a user to determine how full the collection chamber **53** is, because the fullness of the collection chamber will be directly related to the distance the cutter **28** can advance forward into the collection chamber **53**. By facilitating the assessment of collection chamber filling, these embodiments will reduce the need for manually withdrawing the catheter to examine the collection chamber **53**.

[**0094**] In some embodiments, the collection chamber **53** may connect to the rigid housing by means of interlocking components, which interlock with complementary components on the rigid housing. Such components may resemble a screw-in configuration, for example. Interlocking components will provide a stable connection between the collection chamber **53** and the rigid housing while not increasing the outer diameter of either the chamber **53** or the housing. Generally, collection chamber **53** may be given any suitable configuration, shape or size. For example, collection chamber **53** in FIGS. **6-8** has a helical configuration. Alternatively, collection chamber **53** may include a series of circular members, straight linear members, one solid cylindrical or cone-shaped member or the like.

[**0095**] **FIGS. 6 through 8** illustrate one exemplary monorail delivery system to assist in positioning the cutter **28** at the target site. For example, tip **42** of the catheter can include a lumen **54** having a distal opening **43** and a proximal opening **55** that is sized to receive a guidewire, having a diameter of about 0.014 in., about 0.018 in., about 0.032 in. or any other suitable diameter.

[**0096**] As shown in **FIG. 8**, the flexible proximal portion of the catheter body may also include a short lumen **56** (e.g., about 12 centimeters in length). In some embodiments, however, the guidewire lumen **56** may be disposed within or outside the flexible proximal portion of the catheter body and run a longer or shorter length, and in fact may run the entire length of the flexible portion **24** of the catheter body. In use, the guidewire can be disposed within lumen **56** on the flexible portion of the catheter body and exit the lumen at a point proximal to the rigid portion **26** of the catheter. The guidewire can then re-enter a proximal opening **55** in the tip lumen **54** and exit through distal opening **43** in the tip lumen. By moving the guidewire outside of the rigid portion **26** of the catheter body, the guidewire will be prevented from tangling with the cutter **28**. Typically, tip lumen **54** will be disposed along a bottom surface of the tip and the lumen **56** will be disposed along a side of the proximal portion **22** of the catheter body so that the guidewire will be in a helical configuration. In various embodiments, the tip lumen **54** and the proximal lumen **56** can have any suitable combination of lengths. For example, in one embodiment the tip lumen **54** may have a length between about 1 cm and about 5 cm, more preferably between about 2 cm and about 3 cm, and the proximal lumen may have a length of between about 8 cm and about 20 cm, more preferably between about 10 cm and about 14 cm.

[**0097**] Referring now to **FIGS. 22A and 22B**, some catheters **120** of the present invention include a proximal guidewire lumen **126** coupled with the proximal portion of the catheter body **123**, and a telescoping distal guidewire lumen **124** coupled with either the distal tip **122**, part of the distal portion of the catheter body, or both. The telescoping lumen **124** will typically be attached to the tip **122** or a distal portion, but will also include an unattached portion **121**, which will not be directly attached to any part of the catheter body. This unattached portion **121** (or "free floating lumen") protects a guidewire from contacting a body lumen in which the device is used and also allows the device to be moved more freely, without bending or kinking the guidewire. The telescoping guidewire **124** extends within the proximal lumen **126** at the distal opening **127** of proximal lumen **126**. Again, the telescoping feature allows for movement of the catheter body while preventing or reducing bending of the guidewire. For example, in some embodiments catheter **120** allows for deflection of distal tip **122** and the distal portion of the catheter **120** relative to the proximal portion **123**, for example by movement about a pivot point **129**. Telescoping distal lumen **124** and proximal lumen **126** allow for this movement by allowing distal lumen **124** to telescope within proximal lumen **126**. At the same time, distal lumen **124** protects a guide wire from exposure to a body lumen and/or bodily fluids.

[**0098**] Any suitable configurations and sizes of distal lumen **124** and proximal lumen **126** are contemplated. For example, in one embodiment distal lumen **124** may telescope within proximal lumen **126** by a distance of approximately 1 cm. Furthermore, a telescoping lumen **124** may be longer than distal lumens in other embodiments. For example, telescoping lumen **124** may have a length of between about 2 cm and about 10 cm, and preferably between about 5 cm and about 8 cm. As is apparent from the drawing figures, the outer diameter of telescoping distal lumen **124** is configured to fit within the inner diameter of proximal lumen **126**. Generally, any combination of sizes, lengths, diameters and shapes of distal lumen **124** and proximal lumen **126** may be used, to allow telescoping of one into another.

[**0099**] The catheters of the present invention can include radiopaque markers so as to allow the user to track the position of the catheter under fluoroscopy. For example, as already described, a point or area around or adjacent to the window may be made radiopaque. In other embodiments, the rigid distal portion **26** can be radiopaque and radiopaque markers can be disposed on the flexible shaft. Typically, the markers **59** will be disposed along the top, proximal to the cutting window, and on the bottom of the catheter to let the user know the position of the cutter and cutting window relative to the target site. If desired, the top and bottom markers can be different shaped so as to inform the user of the relative orientation of the catheter in the body lumen.

Because the guidewire will form a helix in its transition from lumen **56** to tip lumen **54**, the user will be able to view the top and bottom radiopaque markers **59** without interference from the guidewire. Some embodiments of the catheter can also include a radiopaque cutter stop **61** (**FIG. 3B**) that is crimped to driveshaft **36** proximal of the cutter that moves with the cutter so as to let the user know when the cutter is in the open position.

[0100] **FIGS. 9A through 11D** show some exemplary embodiments of the cutter **28** of the present invention. The distal portion **60** of the rotatable cutter **28** can include a serrated knife edge **62** or a smooth knife edge **64** and a curved or scooped distal surface **66**. The distal portion **60** may have any suitable diameter or height. In some embodiments, for example, the diameter across the distal portion **60** may be between about 0.1 cm and about 0.2 cm. A proximal portion **68** of the cutter **28** can include a channel **70** that can be coupled to the drive shaft **36** that rotates the cutter. As shown in FIGS. **10A-10**C, some embodiments of the cutters can include a bulge or bump **69** that is provided to interact with a stent so as to reduce the interaction of the cutting edge with the stent. In any of the foregoing embodiments, it may be advantageous to construct a serrated knife edge **62**, a smooth knife edge **64**, or a scooped distal surface **66** out of tungsten carbide.

[0101] Another embodiment of a cutter **28** suitable for use in the present invention is shown in side view within a catheter body distal portion **26** in **FIG. 11D**. In this embodiment, the cutter **28** has a beveled edge **64**, made of tungsten carbide, stainless steel, titanium or any other suitable material. The beveled edge **64** is angled inward, toward the axis of rotation (or center) of the cutter **28**, creating a "negative angle of attack"**65** for the cutter **28**. Such a negative angle of attack may be advantageous in many settings, when one or more layers of material are desired to be debulked from a body lumen without damaging underlying layers of tissue. Occlusive material to be removed from a vessel typically has low compliance and the media of the vessel (ideally to be preserved) has higher compliance. A cutter **28** having a negative angle of attack may be employed to efficiently cut through material of low compliance, while not cutting through media of high compliance, by allowing the high-compliance to stretch over the beveled surface of cutter **28**.

[0102] **FIGS. 12 through 16** illustrate an exemplary cutter driver **34** of the present invention. As shown in **FIG. 12** and **13**, cutter driver **34** can act as the handle for the user to manipulate the catheters **20** of the present invention as well as a power source. Typically, the cutter drivers **34** of the present invention include a single input device, such as a lever **38** that controls the major operations of the catheter (e.g., axial movement to cause urging, rotation to cause cutting, and axial movement for packing). As shown in **FIGS. 13 and 14**, cutter driver **34** includes a power source **72** (e.g., batteries), a motor **74**, a microswitch **76** for activating motor **74**, and a connection assembly (not shown) for connecting the drive shaft **36** to the driver motor **74**. In some embodiments, the drive motor can rotate drive shaft **36** between 1,000 rpm and 10,000 rpm or more, if desired.

[0103] **FIGS. 14 through 16** illustrate one exemplary method of operating cutter driver **34**. In use, the catheter will be delivered to the target site with cutter driver unattached and the cutter in the neutral position (**FIG. 3B**). The cutter driver can be attached with the urge lever **38** in a neutral position (**FIG. 14**), which indicates that the cutter is closed, but not in a packing position. The user can then move the catheter (and cutter driver unit, if desired) to position the distal portion **26** of the catheter adjacent the target tissue. As shown in **FIG. 15**, to activate the rotation of the cutter, the urge lever **38** can be moved proximally from the neutral position to move the cutter proximally and out of cutting window **32** (**FIG. 4B**) and simultaneously depressing microswitch **76** to activate motor **74**. At the end of the cutting procedure, as shown in **FIG. 16**, the user can push urge lever **38** completely forward to a distal position to push the cutter into a packing position (**FIG. 5B**). After the urge lever passes the middle of the travel, the microswitch **76** can be released so as to deactivate the cutter before reaching the packing position such that packing can occur without the cutter rotating. It should be appreciated, while the figures illustrate the use of an urge lever or thumb switch as an input device, the present invention can use other type of input devices, such as labeled buttons (e.g., close window, debulk tissue, and pack), or the like.

[0104] Advantageously, cutter driver **34** provides an automatic on/off control of the cutter **28** that is keyed to the position of the cutter. Such a configuration frees the user from the complicated task of remembering the sequence of operations to activate and deactivate the rotation and axial movement of the cutter.

[0105] While the cutter driver **34** is illustrated as a disposable battery powered unit, it should be appreciated that in other embodiments, the cutter driver can use other power sources to control the cutter driver. It should further be appreciated that other cutter drivers can be used with the present invention. While not preferred, it is possible to have separate controls to control the axial movement of the cutter and the rotation of the cutter.

[0106] Some exemplary methods of the present invention will now be described. One method of the present invention comprises delivering a catheter to a target site in the body lumen. A distal portion of the catheter can be deflected relative to a proximal portion of the catheter to expose a tissue debulking device in the catheter. The body lumen can be debulked with the exposed debulking device. Specifically, as shown schematically in **FIG. 17**, one specific method comprises advancing a catheter to a target site (Step **100**). A cutter can be rotated and moved out of the cutting window (Steps **102**, **104**). Preferably, a distal portion of the catheter can be pivoted or deflected so as to position the cutter adjacent the target material. Thereafter, the catheter and the rotating cutter can be moved through the body lumen to remove the target material from the body lumen (Step **106**).

[0107] As shown in **FIGS. 18 and 19**, the catheter can be percutaneously advanced through a guide catheter or sheath and over a conventional or imaging guidewire using conventional interventional techniques. The debulking catheter **20** can be advanced over the guidewire and out of the guide catheter to the diseased area. As shown in **FIG. 18**, the window **32** will typically be closed (with the cutter or other debulking device **28** in a first, distal position). As shown in **FIG. 19**, catheter **20** will typically have at least one hinge or pivot connection to allow pivoting about one or more axes of rotation to enhance the delivery of the catheter into the tortuous anatomy without dislodging the guide catheter or other sheath. The cutter can be positioned proximal of the lesion. Optionally, a transducer, IVUS, or other imaging assembly can be used to verify the position of the debulking catheter.

[0108] Once the position of the catheter is confirmed, the cutter **28** will be retracted proximally and moved out of cutting window **32** to its second, exposed position. In some embodiments, movement of the cutter can deflect the distal portion of the catheter to increase the profile of the catheter at the target site. Movement of the cutter is typically caused by proximal movement of lever **38** and tensioning of drive shaft **36**. Movement of the lever can be scaled to any desired ratio or a direct 1:1 ratio of movement between the handle and cutter. When the cutter is moved proximally it contacts ramp or cam surfaces so as to guide the cutter up and at least partially out of the cutting window **32**. Additionally, as shown by arrow **80**, the distal portion of catheter body **26** rotates about the joint **49** to provide an urging force for the cutter (and catheter body) to move toward the diseased area.

[0109] Thereafter, as shown by arrow **82** the operator can move the entire catheter body **22** through the lesion to dissect the tissue. As the cutter **28** and catheter body **22** are advanced distally through the lesion, tissue that is trapped between the cutting edge **52** and the cutting window **32** is severed from the body lumen. To part off the tissue, the operator can stop pushing the device distally and the cutter can be advanced distally inside the cutting window by advancing the handle **38**. During the distal movement of the cutter, the cutter **28** rides back over the ramps **44** and directs the cutter back inside of the cutting window **32**. Such movement causes the distal portion **26** of the catheter to move in line with the cutter and proximal portion **24** (**FIG. 5B**). When the cutter has moved to its distal position, the cutter parts off the severed tissue and urges the severed tissue inside of a collection chamber **53** in the distal tip **42**. Optionally, after the cutter **28** has parted off the tissue, the lever **38** and thus the non-rotating cutter **38** can be advanced distally to pack the tissue into the collection chamber **53** (**FIG. 5B**). Use of the cutter to pack the severed tissue will allow the operator multiple specimens to be collected prior to removing the catheter **20** from the body lumen. When it is determined that the collection chamber is fill, the catheter can be removed from the body lumen and the collection chamber can be emptied.

[0110] In another method of the present invention, as shown in **FIG. 20**, an input device is disposed in a first position to position a tissue removal element in a neutral position (Step **120**). The input device is activated to rotate the tissue removal element and to axially move the tissue removal device to an active position (Step **122**). The input device can then be activated again to move the tissue removal element to a packing position (Step **124**). In an exemplary embodiment, the input device is a lever or thumb switch that can be moved to correspond to the movement of a cutting element on the catheter. Thus, as the lever is moved proximally, the cutter is rotated and moved proximally to an open position. When the lever is moved to a distal position, the rotation of the cutter can be stopped and the cutter can be moved distally to pack severed tissue into a collection chamber.

[0111] Referring to FIGS. **21-24**, still another device **102** for cutting and/or removing material is shown. The device **102** has a cutting element **104** which may be any suitable cutting element **104** such as those described herein. The device **102** has an elongate body **106** and a visualization element **114** coupled to the body **106**. A cover or tip **108** is positioned at the distal end of the device **102**. The cover **108** is movable from the stored position of **FIGS. 21 and 22** to the working position of **FIG. 23** in which at least part of the cutting element **104** is exposed

[0112] The cover **108** may be movable relative to the elongate body **106** in any suitable manner. For example, the cover **108** and body **106** may engage one another with a slot and pin engagement **107** so that the cover **108** translates linearly relative to the body **106**. The cover **108** may be naturally biased or held in the stored position with the user actuating the device to move the cover **108** to the working position. For example, the cover **108** may be coupled to a lumen **110**, such as a guidewire lumen, with the user tensioning, or even compressing, the lumen **110** and/or body **106** to move the cover **108** to the working position. The cover **108** has a longitudinal axis which may remain substantially parallel to the longitudinal axis of the elongate body **106**. Furthermore, the cover **108** may be movable to a number of different positions which expose varying amounts of the cutting element **104** so that the depth of cut may be selected or varied by the user. The cover or tip **108** may have a recess or cavity **112** in which material to be removed is held as is described herein.

[0113] The visualization element **114** may be any suitable visualization element such as a fiberoptic and lens or an ultrasound element. The visualization element **114** may be movable or fixed relative to the body **106**. The visualization element **114** is positioned on a radially outer, and preferably outermost, portion of the body **106** so that the element **114** may be pressed against or moved adjacent to the tissue of interest. This may provide advantages when using certain types of visualization elements **114** such as optical elements which may emit or receive energy which is partially absorbed by blood or other fluids present. Various examples of a suitable visualization element are described in U.S. Pat. Nos. 6,191,862, 6,445,939, 6,134,003, 5,459,570 and 5,321,501 which are hereby incorporated by reference.

[0114] Referring to **FIGS. 24 and 25**, still another device **130** for cutting and/or removing material is shown wherein the same or similar reference numbers refer to the same or similar structure. The device **130** may be used to cut or remove material from a vascular location using any method described herein. The device **130** has the cutting element **104** which may be coupled to the torque transmitting element extending through the elongate body **106**. A first pivot point **132** and a second pivot point **134** are positioned on opposite sides of the cutting element **104**. When moving to the working position of **FIG. 25**, the cutting element **104** moves into engagement with the tissue to be cut or removed. The device **130** may also have the visualization element **114** positioned on the radially outermost part of the device **130**. The visualization element may be moved from the stored position of **FIG. 24** to the working position of **FIG. 25**. The device **130** has a tip **135** which has a recess or cavity **112** or other structure to receive material to be removed. The device **130** may be naturally biased toward the working or stored position with the other position being created by tensioning a pull wire **137** on one or the other side of the device **130**.

[0115] Referring to **FIGS. 26A and 26B**, another device **140** is shown having an elongate body **142** which is deformable to a generally helical shape. The elongate body **142** is moved to the deformed or helical shape to help stabilize the device **140** within the vessel. Stabilization of the device **140** may be particularly helpful when moving the entire device **140** through the vessel when removing material as described herein. The helical shape of the body may help to stabilize the device, depending upon the particular shape of the vasculature, and may specifically help resist or reduce twisting of the device **140** within the vasculature as the device is advanced during cutting. The helical shape may be formed in any suitable manner. Referring to **FIGS. 27A and 27B**, for example, a tube **144** may be cut with a pattern which naturally forms the helical shape when a compressive force is applied to the tube **144**. The tube **144** is contained in a sheath **146** which holds the tube **144** but permits the tube **144** to deform as necessary. As can be appreciated from **FIGS. 26A and 26B**, the helical shape may be somewhat subtle. Surface lines **145** have been added for clarity in visualizing the shape of the body **142**. In one embodiment, the diameter of the body **142** is 1.0 to 2.5 mm while the diameter of the helical shape is about 2.0 to 7.5 mm. In still another aspect, the helical shape has less than 360 degrees of rotation over it's length and preferably about 180 degrees. The deformed part of the elongate body **142, 152** may be relatively long. For example, the deformed part may be at least 1 cm and may even be at least 2 cm when measured in a relaxed or straightened configuration. Of course, the elongate body **142** which may also be deformed to a generally S-shape rather than helical shape.

[0116] The shaft or body of **FIGS. 26A and 26B** may be used with any of the devices or methods described herein. For example, the helical body **142** may be used with the device **102** of FIGS. **21-23**. Initial compression of the tube **144** may cause the body **142** to assume the helical shape. Continued compression of the tube **144** displaces the tip or cover **108** to expose the cutting element. The entire device **102** may then be moved through the vessel to cut a continuous piece of material which is directed into the recess or cavity **112** in the cover **108**. Thus, it can be appreciated that many combinations are within the scope of the present invention with any of the working ends of the device being used with any of the shafts or elongate bodies.

[0117] Referring now to **FIG. 28**, the present invention will further comprise kits including catheters **200**, instructions for use **202**, and packages **204**. Catheters **200** will generally be as described above, and the instruction for use (IFU) **202** will set forth any of the methods described above. Package **204** may be any conventional medical device packaging, including pouches, trays, boxes, tubes, or the like. The instructions for use **202** will usually be printed on a separate piece of paper, but may also be printed in whole or in part on a portion of the packaging **204**.

[0118] While all the above is a complete description of the preferred embodiments of the inventions, various alternatives, modifications, and equivalents may be used. For example, while preferred cutters are moved proximally to move the cutter out of the cutting window, alternative embodiments may move the cutter distally to move the cutter out of the cutting window. Additionally, while most embodiments employ a cutter that extends out beyond the outer diameter of the cutting window, it may be possible to incorporate a cutter that stays within the diameter catheter body. Additionally, in some embodiments, the debulking assembly may be exposed through the window without causing a deflection of the distal portion of the catheter. Moreover, instead of having a distal tip that is rotatable relative to the proximal portion of the catheter, the catheter can include a shape memory material such that the catheter forms a jog or a pre-bent shape when it reaches its target area.

[0119] Although the foregoing invention has been described in detail for purposes of clarity of understanding, it will be obvious that certain modifications may be practiced within the scope of the appended claims.

What is claimed is:

1. A device for cutting tissue, comprising:

an elongate body having an opening therein;

a rotatable cutting element having a torque transmitting element extending through the elongate body; and

a visualization element, the visualization element being movable from a stored position to a working position, the visualization element moving to a radially outward position relative to the elongate body when in the working position.

2. The device of claim 1, wherein:

the visualization element emits energy selected from the group of ultrasound and infrared.

3. The device of claim 1, wherein:

the visualization element moves to a position proximate to the opening at a position radially outward relative to the opening.

4. The device of claim 1, wherein:

the rotatable cutting element is movable from a stored position to a working position, the cutting element moving to a position which exposes at least part of the cutting element through the opening when moving from the stored position to the working position.

5. The device of claim 1, wherein:

the cutting element is movable to a number of different working positions to expose varying amounts of the cutting element.

6. The device of claim 1, wherein:

the elongate body has a deformable portion with a length of at least 2 cm

7. A device for cutting tissue, comprising:

an elongate body;

a rotatable cutting element, the rotatable cutting element being coupled to a torque transmitting element which extends through the elongate body; and

a movable cover coupled to the body, the cover being movable from a stored position, in which the rotatable cutting element is covered by the cover, to a working position, in which at least part of the rotatable cutting element is exposed.

8. The device of claim 7, wherein:

the cover also has a tissue collection chamber, wherein tissue cut by the cutting element is directed into the collection chamber.

9. The device of claim 7, wherein:

the cover is disposed at the distal end of the elongate body and forms a tip.

10. The device of claim 7, wherein:

the cover is slidable relative to the elongate body.

11. The device of claim 7, wherein:

the cover is slidable relative to the elongate body in a number of different working positions to expose varying amounts of the rotatable cutting element.

12. The device of claim 7, wherein:

the cover translates when moving to the working position without substantial deformation of the cover.

13. The device of claim 7, further comprising:

a visualization element positioned at a radially outer position relative to the elongate body.

14. The device of claim 13, wherein:

the visualization element is movable relative to the elongate body.

15. The device of claim 7, wherein:

the elongate body has a longitudinal axis; and

the cover also has a longitudinal axis which is aligned with a longitudinal axis of the elongate body when the cover is in the stored position, wherein the longitudinal axis of the cover remains substantially parallel to the longitudinal axis of the elongate body when the cover is in the working position.

16. The device of claim 7, wherein:

the cover is naturally biased to the stored position.

17. The device of claim 7, wherein:

the cover translates without substantially deforming.

18. The device of claim 17, wherein:

the cover is linearly slidable relative to the elongate body at an angle which is not parallel to a longitudinal axis of the elongate body.

19. A method of removing material from a vascular location, comprising the steps of:

providing a cutting device having an elongate body and a rotatable cutting element, the elongate body having an opening therein, the rotatable cutting element being coupled to a torque transmitting element which extends through the elongate body, the elongate body having a deformable portion;

advancing the cutting device through a patient's vascular system, the cutting element being in a stored position in which the cutting element is not exposed;

deforming the deformable portion after the advancing step; and

moving the cutting element and the opening through the vascular system with the cutting element being in a working position, wherein at least part of the rotatable cutting element is exposed to cut tissue which is directed through the opening.

20. The method of claim 19, wherein:

the deforming step is carried out with the deformable portion being S-shaped when in the deformed position.

21. The method of claim 19, wherein:

the elongate body has a first pivot point and a second pivot point, the first and second pivot points being positioned on opposite sides of the cutting element.

22. The method of claim 19, wherein:

the deformable portion forms a helical shape.

23. The method of claim 22, wherein:

the helical shape has a diameter of about 2.0 to 7.5 mm and the elongate body has an outer diameter of about 1.0 to 2.5 mm

24. The method of claim 22, wherein:

the deformable part has a length of at least 1 cm.

25. A device for cutting tissue, comprising:

an elongate body movable between a stored position and working position, the elongate body having an opening in the working position;

a rotatable cutting element, the rotatable cutting element being coupled to a torque transmitting element which extends through the elongate body, the cutting element directing material cut by the cutting element through the opening;

a first pivot point on the elongate body on one side of the rotatable cutting element; and

a second pivot point on the other side of the rotatable cutting element.

26. The device of claim 25, further comprising:

a tissue collection chamber, wherein tissue cut by the cutting element is directed through the opening and into the collection chamber.

27. The device of claim 25, further comprising:

a visualization element positioned at a radially outer position relative to the elongate body.

28. The device of claim 27, wherein:

the visualization element is movable relative to the elongate body.

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外部链接	Espacenet USPTO		

摘要(译)

从血流腔移除材料的方法通常包括提供具有切割元件和开口的装置，使装置穿过血流腔前进到要移除材料的位置，迫使开口朝向部位的壁其中材料将被移除，并且移动切割元件和开口，使得当切割元件和开口移动通过血流腔时，切割元件切割血流腔中的材料并将其引导到开口中以便移除。在一些实施例中，装置可以被偏转或弯曲以迫使开口朝向墙壁以移除材料。切割元件可以是可旋转的并且可以具有可移动的轴，该轴不平行于装置的纵向轴，或两者。在一些实施例中，切割元件可在缩回和展开位置之间移动，以分别将装置推进到用于处理和移除材料的位置。