

**(57) Abstract:** An atherectomy catheter is provided having a tissue collection chamber capable of being cleaned out in a simple, fast and effective way, and also provides methods of using said catheter to remove material from a blood vessel lumen. In one embodiment the tissue collection chamber has an expandable tip having a first closed position capable of retaining material in the chamber and having a second open position that may allow expulsion of material from the chamber. In a second embodiment the tissue collection chamber has a displaceable tip having a first closed position to retain material in the chamber and having a second open position to allow expulsion of material from the chamber.

## **EASILY CLEANED ATHERECTOMY CATHETERS AND METHODS OF USE**

**[0001]** This application claims the benefit of U.S. Provisional Patent Application No. 61/178,119, filed May 14, 2009, entitled “Easily Cleaned Atherectomy Catheters and Methods Of Use”, the contents of which are hereby incorporated by reference herein.

### **Field of the Invention**

**[0002]** The present invention relates to catheters used to remove material from a site in a body lumen. More particularly, this invention pertains to removal of material stored in such a catheter.

### **Background of the Invention**

**[0003]** Atherosclerosis is a progressive disease of the vascular system whereby atheroma is deposited on the inner walls of blood vessels. Over time atheromatous deposits can become large enough to reduce or occlude blood flow through the vessels, leading to symptoms of low blood flow such as pain in the legs (on walking or at rest), skin ulcer, angina (at rest or exertional), and other symptoms. To treat this disease and improve or resolve these symptoms it is desirable to restore or improve blood flow through the vessel.

**[0004]** Various means are used to restore or improve blood flow through atheromatous vessels. The atheroma deposits can be displaced by diametrically expanding the vessel by inflating balloons, expanding stents, and other methods. However these methods undesirably tear and stretch the vessel, causing scar formation in a high percentage of patients. Such scar tissue (restenotic material), once formed, blocks flow in the vessel and often needs to be removed. The deposits can be pulverized using lasers and other methods. However pulverization alone of atheromatous material allows microemboli to flow downstream and lodge in distal

vascular beds, further compromising blood flow to the tissue affected by the disease. Atherectomy catheters can be used to remove atheromatous deposits from the blood vessel and can present an ideal solution when the deposits removed from the vessel are captured and removed from the body. One way to capture and remove such deposits is to store the deposits within the catheter and to subsequently remove the catheter from the body.

[0005] One problem that occurs when storing material or deposits in a catheter is that the catheter can have insufficient storage capacity. The portion of the vessel to be treated can be quite extensive. For example, the portion of the vessel to be treated can extend over a vessel length of 200mm or longer. If the storage chamber in the catheter becomes filled with material the catheter must be removed from the body, the deposits removed from the catheter, and the catheter re-inserted into the body for more deposit removal and storage. However, present methods for removing deposits from catheter collection chambers can be time consuming.

[0006] What is needed is a catheter having a simple, fast and effective way of removing deposits from a catheter collection chamber.

#### Summary of the Invention

[0007] The present invention provides an atherectomy catheter having a tissue collection chamber capable of being cleaned out in a simple, fast and effective way, and also provides methods of using the catheter to remove material from a blood vessel lumen. In one embodiment the tissue collection chamber has an expandable tip having a first closed position capable of retaining material in the chamber and having a second open position that may allow expulsion of material from the chamber. In a second embodiment the tissue collection chamber has a displaceable tip having a first closed position to retain material in the chamber and having a second open position to allow expulsion of material from the chamber.

[0008] The invention provides an atherectomy catheter comprising: a body having an opening; a rotatable shaft coupled to the body, the rotatable shaft being rotatable about a longitudinal axis of the shaft; a tissue collection chamber coupled to the body and positioned distal to the cutting element; and a cutting element coupled to the rotatable shaft, the cutting element having a cup-shaped surface and a cutting edge, the cup-shaped surface being configured to re-direct tissue cut by the cutting edge in a distal direction when the cup-shaped surface moves in the distal direction. The tissue collection chamber has a first closed position capable of retaining cut tissue in the chamber and a second open position capable of allowing expulsion of cut tissue from the chamber. The tissue collection chamber comprises an expandable tip at a distal region of the catheter, the expandable tip having a first closed position capable of retaining cut tissue in the chamber and a second open position capable of allowing expulsion of cut tissue from a distal opening at a distal end of the chamber.

[0009] The invention provides an atherectomy catheter comprising: a body having an opening; a rotatable shaft coupled to the body, the rotatable shaft being rotatable about a longitudinal axis of the shaft; a tissue collection chamber coupled to the body and positioned distal to the cutting element; and a cutting element coupled to the rotatable shaft, the cutting element having a cup-shaped surface and a cutting edge, the cup-shaped surface being configured to re-direct tissue cut by the cutting edge in a distal direction when the cup-shaped surface moves in the distal direction. The tissue collection chamber has a first closed position capable of retaining cut tissue in the chamber and a second open position capable of allowing expulsion of cut tissue from the chamber. The tissue collection chamber comprises a displaceable tip at a distal region of the catheter, the displaceable tip having a first closed position capable of retaining cut tissue in the chamber and a second open position capable of allowing expulsion of cut tissue from the chamber, the displaceable tip being attached to the atherectomy catheter in both the first closed and second open positions.

**[0010]** The invention provides a method of removing material from a body lumen, the method comprising: providing an atherectomy catheter, the atherectomy catheter comprising: a body having an opening; a rotatable shaft coupled to the body, the rotatable shaft being rotatable about a longitudinal axis of the shaft; a tissue collection chamber coupled to the body and positioned distal to the cutting element; and a cutting element coupled to the rotatable shaft, the cutting element having a cup-shaped surface and a cutting edge, the cup-shaped surface being configured to re-direct tissue cut by the cutting edge in a distal direction when the cup-shaped surface moves in the distal direction, wherein the tissue collection chamber has a first closed position capable of retaining cut tissue in the chamber and a second open position capable of allowing expulsion of cut tissue from the chamber, and wherein the tissue collection chamber comprises an expandable tip at a distal region of the catheter, the expandable tip having a first closed position capable of retaining cut tissue in the chamber and a second open position capable of allowing expulsion of cut tissue from a distal opening at a distal end of the chamber; placing the catheter in the body lumen; and moving the catheter in the body lumen to contact the cutting element with the material in the body lumen.

**[0011]** The invention provides a method of removing material from a body lumen, the method comprising: providing an atherectomy catheter, the atherectomy catheter comprising: a body having an opening; a rotatable shaft coupled to the body, the rotatable shaft being rotatable about a longitudinal axis of the shaft; a tissue collection chamber coupled to the body and positioned distal to the cutting element; and a cutting element coupled to the rotatable shaft, the cutting element having a cup-shaped surface and a cutting edge, the cup-shaped surface being configured to re-direct tissue cut by the cutting edge in a distal direction when the cup-shaped surface moves in the distal direction, wherein the tissue collection chamber has a first closed position capable of retaining cut tissue in the chamber and a second open position capable of allowing expulsion of cut tissue from the chamber, and wherein the tissue collection chamber comprises a displaceable tip at a distal region of the catheter,

the displaceable tip having a first closed position capable of retaining cut tissue in the chamber and a second open position capable of allowing expulsion of cut tissue from the chamber, the displaceable tip being attached to the atherectomy catheter in both the first closed and second open positions; placing the catheter in the body lumen; and moving the catheter in the body lumen to contact the cutting element with the material in the body lumen.

[0012] These and other aspects of the invention will become apparent from the following description of the preferred embodiments, drawings and claims. The details of one or more embodiments of the invention are set forth in the accompanying drawings and the description below. Other features, objects, and advantages of the invention will be apparent from the description and drawings, and from the claims.

#### Brief Description of the Drawings

[0013] FIG. 1 illustrates an isometric view of an atherectomy catheter.

[0014] FIG. 2 illustrates an isometric cross-sectional view of a portion of the atherectomy catheter illustrated in FIG. 1 with a cutting element in a stored position.

[0015] FIG. 3 illustrates an isometric cross-sectional view of a portion of the atherectomy catheter illustrated in FIG. 1 with a cutting element in a working position.

[0016] FIG. 4 illustrates an isometric view of an embodiment of a cutting element.

[0017] FIG. 5 illustrates an end view of an embodiment of a cutting element.

[0018] FIGS. 6 and 7 illustrate partial cross section views of a portion of an atherectomy catheter.

[0019] FIG. 6A illustrates an end view of the atherectomy catheter illustrated in FIG. 6.

[0020] FIG. 8 illustrates a side view of a portion of the catheter illustrated in FIGS. 6, 6A and 7.

[0021] FIGS. 9, 10 and 11 illustrate partial cross section views of a portion of the atherectomy catheter illustrated in FIGS. 6, 6A, 7 and 8 in various stages of use.

[0022] FIGS. 12 and 13 illustrate partial cross section views of a portion of another atherectomy catheter.

[0023] FIGS. 14 and 15 illustrate partial cross section views of a portion of the atherectomy catheter illustrated in FIGS. 12 and 13 in various stages of use.

#### Detailed Description

[0024] The invention provides an atherectomy catheter comprising: a body having an opening; a rotatable shaft coupled to the body, the rotatable shaft being rotatable about a longitudinal axis of the shaft; a tissue collection chamber coupled to the body and positioned distal to the cutting element; and a cutting element coupled to the rotatable shaft, the cutting element having a cup-shaped surface and a cutting edge, the cup-shaped surface being configured to re-direct tissue cut by the cutting edge in a distal direction when the cup-shaped surface moves in the distal direction. The tissue collection chamber has a first closed position capable of retaining cut tissue in the chamber and a second open position capable of allowing expulsion of cut tissue from the chamber. The tissue collection chamber comprises an expandable tip at a distal region of the catheter, the expandable tip having a first closed position capable of retaining cut tissue in the chamber and a second open position capable of allowing expulsion of cut tissue from a distal opening at a distal end of the chamber. In an embodiment, the tissue collection chamber comprises a sheath having a lumen.

[0025] In one embodiment, the tissue collection chamber comprises one or more slots in a distal region of the sheath. In another embodiment, the tissue collection chamber comprises two or more slots in a distal region of the sheath. The distal region of the sheath may comprise 2, 3, 4, 6, 8, 12, or 16 slots. In an

embodiment, the distal region of the sheath has a distally tapering diameter. In one embodiment, the tissue collection chamber has a distal opening in the first closed position.

**[0026]** In an embodiment, the tissue collection chamber comprises a shim sleeve disposed within the lumen of the sheath, the shim sleeve being axially slidable relative to the sheath, and the shim sleeve having a lumen. In one embodiment, the shim sleeve may comprise a window. In an embodiment, the cutting element may be deployed through the shim sleeve window and the opening of the catheter. In an embodiment, the distal region of the sheath can be expanded by moving the shim sleeve distally. In one embodiment, the sheath is pre-programmed to assume the first closed position.

**[0027]** In one embodiment, the cutting element can be extended distally through the lumen of the shim sleeve. In an embodiment, the cutting element can be extended distally through a distal opening of the sheath when the tissue collection chamber is in the second open position. In one embodiment, the tissue collection chamber comprises a guidewire lumen.

**[0028]** In one embodiment, the tissue collection chamber comprises one or more slots in a distal region of the sheath, the distal region of the sheath has a distally tapering diameter, and the tissue collection chamber comprises a shim sleeve disposed within the sheath, the shim sleeve being axially slidable relative to the sheath, and the shim sleeve having a lumen. In an embodiment, the distal region of the sheath can be expanded by moving the shim sleeve distally.

**[0029]** The invention provides an atherectomy catheter comprising: a body having an opening; a rotatable shaft coupled to the body, the rotatable shaft being rotatable about a longitudinal axis of the shaft; a tissue collection chamber coupled to the body and positioned distal to the cutting element; and a cutting element coupled to the rotatable shaft, the cutting element having a cup-shaped surface and a cutting edge, the cup-shaped surface being configured to re-direct tissue cut by the cutting edge in a distal direction when the cup-shaped surface moves in the distal direction. The tissue



collection chamber has a first closed position capable of retaining cut tissue in the chamber and a second open position capable of allowing expulsion of cut tissue from the chamber. The tissue collection chamber comprises a displaceable tip at a distal region of the catheter, the displaceable tip having a first closed position capable of retaining cut tissue in the chamber and a second open position capable of allowing expulsion of cut tissue from the chamber, the displaceable tip being attached to the atherectomy catheter in both the first closed and second open positions. In one embodiment, the tissue collection chamber comprises a sheath having a lumen. In an embodiment, the displaceable tip is axially slidable relative to the sheath. In an embodiment, the displaceable tip is disposed on a push shaft that is axially slidable relative to the sheath. In one embodiment, the push shaft is received within the lumen of the sheath. In an embodiment, the push shaft has a partially circular cross section. In another embodiment, the push shaft has an approximately semi-circular cross section.

**[0030]** In an embodiment, a proximal portion of the displaceable tip has a reduced diameter and is capable of being received within the lumen of the sheath. In one embodiment, a distal region of the displaceable tip has a distally tapering diameter.

**[0031]** In one embodiment, the cutting edge is a radially outer edge of the cutting element. In an embodiment, the cutting element is movable between a stored position and a cutting position relative to the opening. In one embodiment, the cutting element is moved between the stored position and the cutting position by sliding the cutting element against a cam surface. In one embodiment, a distal portion of the catheter relative to a proximal portion is deflected by sliding the cutting element against the cam surface.

**[0032]** The invention provides a method of removing material from a body lumen, the method comprising: providing an atherectomy catheter, the atherectomy catheter comprising: a body having an opening; a rotatable shaft coupled to the body, the rotatable shaft being rotatable about a longitudinal axis of the shaft; a

tissue collection chamber coupled to the body and positioned distal to the cutting element; and a cutting element coupled to the rotatable shaft, the cutting element having a cup-shaped surface and a cutting edge, the cup-shaped surface being configured to re-direct tissue cut by the cutting edge in a distal direction when the cup-shaped surface moves in the distal direction, wherein the tissue collection chamber has a first closed position capable of retaining cut tissue in the chamber and a second open position capable of allowing expulsion of cut tissue from the chamber, and wherein the tissue collection chamber comprises an expandable tip at a distal region of the catheter, the expandable tip having a first closed position capable of retaining cut tissue in the chamber and a second open position capable of allowing expulsion of cut tissue from a distal opening at a distal end of the chamber; placing the catheter in the body lumen; and moving the catheter in the body lumen to contact the cutting element with the material in the body lumen. In one embodiment, the catheter is moved in a distal direction to contact the cutting edge with the material in the body lumen. In an embodiment, the catheter is placed in the body lumen with the cutting element in a stored position and the catheter is moved to contact the material with the cutting element in a cutting position.

**[0033]** In one embodiment, the method further comprises collecting the material in the tissue collection chamber, removing the catheter from the body lumen, and removing the material from the tissue collection chamber after the catheter has been removed from the body lumen. In an embodiment, the catheter is removed from the body lumen with the tissue collection chamber in the first closed position and the material is removed from the tissue collection chamber with the tissue collection chamber in a second open position capable of allowing expulsion of cut tissue from the chamber.

**[0034]** The invention provides a method of removing material from a body lumen, the method comprising: providing an atherectomy catheter, the atherectomy catheter comprising: a body having an opening; a rotatable shaft coupled to the body, the rotatable shaft being rotatable about a longitudinal axis of the shaft; a

tissue collection chamber coupled to the body and positioned distal to the cutting element; and a cutting element coupled to the rotatable shaft, the cutting element having a cup-shaped surface and a cutting edge, the cup-shaped surface being configured to re-direct tissue cut by the cutting edge in a distal direction when the cup-shaped surface moves in the distal direction, wherein the tissue collection chamber has a first closed position capable of retaining cut tissue in the chamber and a second open position capable of allowing expulsion of cut tissue from the chamber, and wherein the tissue collection chamber comprises a displaceable tip at a distal region of the catheter, the displaceable tip having a first closed position capable of retaining cut tissue in the chamber and a second open position capable of allowing expulsion of cut tissue from the chamber, the displaceable tip being attached to the atherectomy catheter in both the first closed and second open positions; placing the catheter in the body lumen; and moving the catheter in the body lumen to contact the cutting element with the material in the body lumen. In one embodiment, the catheter is moved in a distal direction to contact the cutting edge with the material in the body lumen. In an embodiment, the catheter is placed in the body lumen with the cutting element in a stored position and the catheter is moved to contact the material with the cutting element in a cutting position.

**[0035]** In one embodiment, the tissue collection chamber comprises a sheath having a lumen. In one embodiment, the displaceable tip is axially slidable relative to the sheath.

**[0036]** In one embodiment, the method further comprises collecting the material in the tissue collection chamber, removing the catheter from the body lumen, and removing the material from the tissue collection chamber after the catheter has been removed from the body lumen. In an embodiment, the catheter is removed from the body lumen with the tissue collection chamber in the first closed position and the material is removed from the tissue collection chamber with the tissue collection chamber in a second open position capable of allowing expulsion of cut tissue from the chamber.

**[0037]** Referring to Figs. 1 to 4, an atherectomy catheter 2 is shown which has a cutting element 4 which is used to cut material from a blood flow lumen such as a blood vessel. The cutting element 4 is movable between a stored position (FIG. 2) and a cutting position (FIG. 3) relative to an opening 6 in a body 8 of the catheter 2. The cutting element 4 moves outwardly relative to the opening 6 so that a portion of the element 4 extends outwardly from the body 8 through the opening 6. In one embodiment the cutting element 4 may be positioned relative to the body 8 and opening 6 so that less than 90 degrees of the cutting element 4 is exposed to cut tissue. In other embodiments more of the cutting element 4 may be exposed without departing from numerous aspects of the invention.

**[0038]** Distal end of catheter 2 is positioned near a treatment site in a vessel with cutting element 4 in the stored position. Then catheter 2 is moved distally through the vessel with the cutting element 4 in the working or cutting position as described in further detail below. As the catheter 2 moves through the blood vessel with the cutting element 4 in the working or cutting position the tissue material is cut by the cutting element 4 and is directed into a tissue chamber 12 positioned distal to the cutting element 4. The tissue chamber 12 may be somewhat elongated to accommodate the tissue which has been cut.

**[0039]** In some embodiments catheter 2 has a working length of 30 to 200 cm. In one embodiment catheter 2 has a working length of 135 cm. In some embodiments catheter 2 has a diameter of 4 Fr to 12 Fr (1.3 mm to 4 mm). In one embodiment catheter 2 has a diameter of 7 Fr (2.3 mm).

**[0040]** To expose cutting element 4 through opening 6 cutting element 4 is moved proximally from the stored position so that a cam surface 14 on the cutting element 4 engages a ramp 16 on the body 8 of the catheter 2. The interaction between the cam surface 14 and the ramp 16 causes the cutting element 4 to move to the cutting position and also causes a tip 18 to deflect which tends to move the cutting element 4 toward the tissue to be cut.

**[0041]** The cutting element 4 is coupled to a shaft 20 that extends through a lumen 21 in the catheter 2. Catheter 2 is coupled to exemplary cutter driver 5. Cutter driver 5 is comprised of motor 11, power source 15 (for example one or more batteries), microswitch (not shown), housing 17 (upper half of housing is removed as shown), lever 13 and connection assembly (not shown) for connecting shaft 20 to driver motor 11. Cutter driver 5 can act as a handle for the user to manipulate catheter 2. Lever 13, when actuated to close a microswitch, electrically connects power source 15 to motor 11 thereby causing rotation of cutting element 4. The cutting element 4 is rotated about a longitudinal axis LA when the shaft 20 rotates. The cutting element 4 is rotated at about 1 to 160,000 rpm but may be rotated at any other suitable speed depending upon the particular application. Further description of catheters similar to catheter 2 is found in U.S. Patent Application Serial No. 10/027,418 (published as US 2002/0077642 A1) to Patel et al., entitled “Debulking Catheter”, the contents of which are incorporated by reference herein.

**[0042]** Referring to FIG. 5, the cutting element 4 is shown when viewed along the longitudinal axis LA. The term “along the longitudinal axis” as used herein shall mean for example the view of FIG. 5 that shows the distal end of the cutting element 4 when viewed in the direction of the longitudinal axis and/or the axis of rotation. The cutting element 4 has a cutting edge 22 that may be a continuous, uninterrupted, circular-shaped edge although it may also include ridges, teeth, serrations or other features without departing from the scope of the invention. The cutting edge 22 may be at a radially outer edge 23 of the cutting element 4 when the cutting element 4 is in the cutting position.

**[0043]** The cutting element 4 has a cup-shaped surface 24, which directs the tissue cut by the cutting edge 22 into the tissue chamber 12. The cup-shaped surface 24 may be a smooth and continuous surface free of throughholes, teeth, fins or other features, which disrupt the smooth nature of the surface 24 for at least half the distance from the longitudinal axis LA to the outer radius at the cutting edge 22. The cup-shaped surface 24 may also be free of any such features throughout an area of at

least 300 degrees relative to the longitudinal axis LA. Optionally, one or more raised elements 26 extend outwardly from the cup-shaped surface 24 with FIG. 5 showing two raised elements 26. The raised element 26 is a small wedge of material that rises relatively abruptly from the cup-shaped surface 24. Optionally, some of or all of the cutter may be comprised of an abrasive surface. Further description of additional embodiments usable as cutters in catheter 2 is found in U.S. Patent Application Serial No. 61/173,845 to Moberg et al., entitled "Methods And Devices For Cutting/Abrading Tissue", the contents of which are incorporated by reference herein.

[0044] Figs. 6, 6A, 7 and 8 illustrate one embodiment of an easily cleaned tissue chamber. Tissue collection chamber 12 is comprised of outer sheath 61 having inward extending edges 61a, one or more slots 61b and distal opening 64 and further comprised of shim sleeve 63 having lumen 68 and window 63w. Shim sleeve 63 is axially slidable relative to outer sheath 61 and inward edges 61a limit the distalmost excursion of shim sleeve 63. Cutter 4 is slidably received within lumen 68 of shim sleeve 63 and can extend through window 63w and window 6. The portion of shim sleeve 63 distal to window 63w is circular in cross section to promote uniform circumferential expansion of distal region 65 when shim sleeve 63 is distally advanced, and is partially circular in cross section proximal to window 6 to allow catheter 2 to bend in the vicinity of ramp 16 (see FIG. 9). Distal region 65 of outer sheath 61 has an expandable diameter due to presence of slots 61b. Distal region 65 forms an expandable tip. In various embodiments 2, 3, 4, 6, 8, 12, 16 or more slots 61b are contemplated. In some embodiments outer sheath 61 is pre-programmed to assume a normally closed position in which distal opening 64 is small or functionally closed such that deposits collected in tissue chamber 12 cannot exit through distal opening 64. With shim sleeve 63 in a first position (FIG. 6) outer sheath distal region 65 has a distally tapering diameter, optionally with distal opening 64. With shim sleeve 63 in a second position (FIGS. 7 and 8) outer sheath distal region 65 has an enlarged diameter, through which cutter 4 can be slidably received. In some embodiments cutter 4 can be extended out of distal opening 64 of outer sheath with

shim sleeve 63 in the second position (FIG. 8) due to increased width of slots 61b and enlarged distal diameter of sheath 61. In some embodiments chamber 12 is further comprised of guidewire lumen 66 having proximal opening 66p and distal opening 66d.

**[0045]** Outer sheath 61 may be comprised of thermoplastic polymer, thermoset polymer, thermoplastic elastomer, rubber, nylon, polyimide, polyurethane, or other materials and may further comprise a backbone of resilient material such as for example nitinol or stainless steel. Processes such as extrusion or other processes may be used to fabricate outer sheath 61. Processes such as insert molding, polymer reflow, compression molding, or other processes may be used to fabricate distal end of outer sheath 61. Inward edges 61a can be made by deforming the edges inward, heating the edges in the deformed position and removing the heat to allow the edges to cool and retain the deformed state. Slots 61b can be made by cutting, stamping, laser cutting, may be molded in, or can be made by other processes. Shim sleeve 63 may be comprised of rigid polymer or metal such as polyetheretherketone (PEEK), polyimide, polyester, liquid crystal polymer, nitinol, stainless steel, or other materials, and may be fabricated by processes such as extrusion. Guidewire lumen 66 may be comprised of a tube bonded to outside of sheath 61. In another embodiment sheath 61 may be comprised of bilumen tubing. Guidewire lumen 66 may be comprised of a lumen formed from the wall of outer sheath 61 using thermal processes at least in part.

**[0046]** Exemplary methods of using atherectomy catheter 2 comprised of tissue chamber 12 to cut and remove material from a body of a patient are now described. Using techniques known in the art, a guidewire GW is percutaneously inserted into a patient's body and advanced to a region of interest in a patient's blood vessel V. Using imaging techniques such as fluoroscopy a diseased portion of the vessel is identified and an atherectomy catheter (such as catheter 2) comprised of tissue chamber 12 having appropriate characteristics for treatment site T is chosen. Shim sleeve 63 is positioned such that window opening 63w and window opening 6 are aligned. Catheter 2 is advanced over the guidewire to the treatment site with the

cutting element in a stored position (FIG. 2). Using imaging techniques such as fluoroscopy the cutting element is positioned at a desired location relative to (in some methods proximal to) the treatment site.

**[0047]** The main body of catheter 2 is held stationary and cutting element 4 is then moved proximally so that the ramp 16 and cam surface 14 engage to move the cutting element 4 to the cutting position of FIG. 3 (i.e. exposed through windows 6 and 63w) and to deflect the tip of the catheter 2 to move the cutting element 4 toward the tissue to be cut. Cutting element rotation about longitudinal axis LA is activated using lever 13. Catheter 2 is advanced distally causing cutter blade 22 to cut material M from luminal surface LS of vessel V. Cup shaped surface 24 directs cut fragments F of material M through windows 6 and 63w into lumen 68 of tissue collection chamber 12 (FIG. 9).

**[0048]** When the catheter operator decides to empty fragments F from tissue collection chamber 12, cutter 4 is advanced distally to move cutter 4 into the stored position and rotation of the cutting element is stopped (FIG. 10). Catheter 2 is retracted proximally and removed from the body. Shim sleeve 63 is next advanced distally to deflect distal portion of sheath 61, causing opening 64 to enlarge and width of slots 61b to widen. In some methods shim sleeve 63 is advanced to contact inward edges 61a of sheath 61. Cutter 4 may then be advanced to expel fragments F from lumen 68 of chamber 12 (FIG. 11) through distal opening 64.

**[0049]** If further material removal from treatment site T is desired, cutting element 4 may be withdrawn to the storage position and shim sleeve 63 can be withdrawn to the first position thereby causing distal region 65 of sheath 61 to return to the closed position. Catheter 2 can then be re-inserted into vessel V and further material may be removed from luminal surface LS as described above.

**[0050]** FIGS. 12 and 13 illustrate another embodiment of an easily cleaned tissue chamber. Tissue collection chamber 12' is comprised of outer sheath 121 having lumen 128 and push shaft 123 attached to tip 125. Push shaft 123 is axially slidable relative to outer sheath 121, is approximately semi-circular in cross



section and is received within lumen 128 of sheath 121. Tip 125 has reduced diameter proximal portion 125p which is slidably received within lumen 128 of sheath 121. Cutter 4 is slidably received within lumen 128 of sheath 121 at the same time push shaft 123 is also within lumen 128. Push shaft 123 is rotationally aligned such that window 6 is not blocked by push shaft 123. Distal region 125d of tip 125 may be tapered to a smaller diameter than proximal portion of tip 125p. With push shaft 123 and tip 125 in a first position (FIG. 12) tip proximal portion 125p is slidably received within lumen 128 of sheath 121 and fragments of material removed from the luminal wall of the vessel cannot exit lumen 128 from distal end 121d of sheath 121. With push shaft 123 in a second position (FIG. 13) tip 125 is displaced from distal end 121d of sheath 121 by a distance D and fragments of material removed from the luminal surface of a vessel can exit lumen 128 through distal end 121d of sheath 121. In some embodiments cutter 4 can be extended out of distal end 121d of outer sheath 121 to displace fragments from lumen 128. In some embodiments chamber 12' is further comprised of guidewire lumen 126 having proximal portion 126p and distal portion 126d.

**[0051]** Outer sheath 121 may be comprised of thermoplastic polymer, thermoset polymer, polyimide, polyetheretherketone (PEEK), nylon, or other materials. Processes such as extrusion or other processes may be used to fabricate outer sheath 121. Push shaft 123 may be comprised of rigid polymer or metal such as PEEK, polyimide, polyester, liquid crystal polymer, nitinol, stainless steel, or other materials, and may be fabricated by processes such as extrusion. Tip 125 may be comprised of thermoplastic elastomer, polyether block amide (PEBAX), silicone rubber, or other materials, and may be fabricated by processes such as extrusion, molding, insert molding, dipping, machining, or other processes. Guidewire lumen 126 may be comprised of a tube bonded to outside of sheath 121 and tip 125. In another embodiment sheath 121 may be comprised of bilumen tubing, and in yet another embodiment tip 125 may be comprised of a guidewire lumen therethrough.

Guidewire lumen 126 may also be comprised of a lumen formed from wall of outer sheath 121 using thermal processes at least in part.

**[0052]** Exemplary methods of using atherectomy catheter 2 comprised of tissue chamber 12' to cut and remove material from a body of a patient are now described. Using techniques known in the art, a guidewire GW is percutaneously inserted into a patient's body and advanced to a region of interest in a patient's blood vessel V. Using imaging techniques such as fluoroscopy a diseased portion of the vessel is identified and an atherectomy catheter (such as catheter 2) comprised of tissue chamber 12' having appropriate characteristics for treatment site T is chosen. Push shaft 123 is withdrawn to the first position such that distal end 121d of sheath 121 is sealed shut by tip 125. Catheter 2 is advanced over the guidewire to the treatment site with the cutting element in a stored position (FIG. 2). Using imaging techniques such as fluoroscopy the cutting element is positioned at a desired location relative to (in some methods proximal to) the treatment site.

**[0053]** The main body of catheter 2 is held stationary and cutting element 4 is then moved proximally so that the ramp 16 and cam surface 14 engage to move the cutting element 4 to the cutting position of FIG. 3 (i.e. exposed through window 6) and to deflect the tip of the catheter 2 to move the cutting element 4 toward the tissue to be cut. Cutting element rotation about longitudinal axis LA is activated using lever 13. Catheter 2 is advanced distally causing cutter blade 22 to cut material M from luminal surface LS of vessel V. Cup shaped surface 24 directs cut fragments F of material M through window 6 into lumen 128 of collection chamber 12' using methods similar to that illustrated in FIG. 9.

**[0054]** When the catheter operator decides to empty fragments F from collection chamber 12 cutter 4 is advanced distally to move cutter 4 into the stored position and rotation of the cutting element is stopped (FIG. 14). Catheter 2 is retracted proximally and removed from the body. Push shaft 123 is next advanced distally to separate tip 125 from distal end 121d of sheath 121 by distance D, allowing

fragments F to exit from distal end of lumen 128. In some methods cutter 4 may be advanced to expel fragments F from lumen 128 of chamber 12' (FIG. 15).

[0055] If further material removal from treatment site T is desired, cutting element 4 may be withdrawn to the storage position and push shaft 123 can be withdrawn to the first position thereby causing tip 125 to return to the closed position. Catheter 2 can then be re-inserted into vessel V and further material may be removed from luminal surface LS as described above.

[0056] In addition to use in blood vessels the invention is envisioned to be useful for removal of blockages in other lumens such as natural or artificial grafts, stent-grafts, anastomotic sites, fistulae, or other lumens.

[0057] The present invention has been described in connection with preferred embodiments but may, of course, be practiced while departing from the above described embodiments.

[0058] The above description and the drawings are provided for the purpose of describing embodiments of the invention and are not intended to limit the scope of the invention in any way. It will be apparent to those skilled in the art that various modifications and variations can be made without departing from the spirit or scope of the invention. Thus, it is intended that the present invention cover the modifications and variations of this invention provided they come within the scope of the appended claims and their equivalents. Further, while choices for materials and configurations may have been described above with respect to certain embodiments, one of ordinary skill in the art will understand that the materials and configurations described are applicable across the embodiments.

What is claimed is:

1. An atherectomy catheter comprising:  
a body having an opening;  
a rotatable shaft coupled to the body, the rotatable shaft being rotatable about a longitudinal axis of the shaft;  
a tissue collection chamber coupled to the body and positioned distal to the cutting element; and  
a cutting element coupled to the rotatable shaft, the cutting element having a cup-shaped surface and a cutting edge, the cup-shaped surface being configured to re-direct tissue cut by the cutting edge in a distal direction when the cup-shaped surface moves in the distal direction,  
wherein the tissue collection chamber has a first closed position capable of retaining cut tissue in the chamber and a second open position capable of allowing expulsion of cut tissue from the chamber, and  
wherein the tissue collection chamber comprises an expandable tip at a distal region of the catheter, the expandable tip having a first closed position capable of retaining cut tissue in the chamber and a second open position capable of allowing expulsion of cut tissue from a distal opening at a distal end of the chamber.
2. The catheter of claim 1, wherein the tissue collection chamber comprises a sheath having a lumen.
3. The catheter of claim 2, wherein the tissue collection chamber comprises one or more slots in a distal region of the sheath.
4. The catheter of claim 2, wherein the tissue collection chamber comprises two or more slots in a distal region of the sheath.

5. The catheter of claim 2, wherein a distal region of the sheath has a distally tapering diameter.
6. The catheter of claim 3, wherein the tissue collection chamber has a distal opening in the first closed position.
7. The catheter of claim 2, wherein the tissue collection chamber comprises a shim sleeve disposed within the lumen of the sheath, the shim sleeve being axially slidable relative to the sheath, and the shim sleeve having a lumen.
8. The catheter of claim 7, wherein the shim sleeve comprises a window.
9. The catheter of claim 8, wherein the cutting element can be deployed through the shim sleeve window and the opening of the catheter.
10. The catheter of claim 7, wherein a distal region of the sheath can be expanded by moving the shim sleeve distally.
11. The catheter of claim 3, wherein the distal region of the sheath comprises 2, 3, 4, 6, 8, 12, or 16 slots.
12. The catheter of claim 2, wherein the sheath is pre-programmed to assume the first closed position.
13. The catheter of claim 7, wherein the cutting element can be extended distally through the lumen of the shim sleeve.

14. The catheter of claim 13, wherein the cutting element can be extended distally through a distal opening of the sheath when the tissue collection chamber is in the second open position.

15. The catheter of claim 1, wherein the tissue collection chamber comprises a guidewire lumen.

16. The catheter of claim 2, wherein the tissue collection chamber comprises one or more slots in a distal region of the sheath, the distal region of the sheath has a distally tapering diameter, and the tissue collection chamber comprises a shim sleeve disposed within the sheath, the shim sleeve being axially slidable relative to the sheath, and the shim sleeve having a lumen.

17. The catheter of claim 16, wherein the distal region of the sheath can be expanded by moving the shim sleeve distally.

18. The catheter of claim 1, wherein the cutting edge is a radially outer edge of the cutting element.

19. The catheter of claim 1, wherein the cutting element is movable between a stored position and a cutting position relative to the opening.

20. The catheter of claim 19, wherein the cutting element is moved between the stored position and the cutting position by sliding the cutting element against a cam surface.

21. The catheter of claim 20, wherein a distal portion of the catheter relative to a proximal portion is deflected by sliding the cutting element against the cam surface.

22. An atherectomy catheter comprising:  
a body having an opening;  
a rotatable shaft coupled to the body, the rotatable shaft being rotatable about a longitudinal axis of the shaft;  
a tissue collection chamber coupled to the body and positioned distal to the cutting element; and  
a cutting element coupled to the rotatable shaft, the cutting element having a cup-shaped surface and a cutting edge, the cup-shaped surface being configured to re-direct tissue cut by the cutting edge in a distal direction when the cup-shaped surface moves in the distal direction,  
wherein the tissue collection chamber has a first closed position capable of retaining cut tissue in the chamber and a second open position capable of allowing expulsion of cut tissue from the chamber, and  
wherein the tissue collection chamber comprises a displaceable tip at a distal region of the catheter, the displaceable tip having a first closed position capable of retaining cut tissue in the chamber and a second open position capable of allowing expulsion of cut tissue from the chamber, the displaceable tip being attached to the atherectomy catheter in both the first closed and second open positions.

23. The catheter of claim 22, wherein the tissue collection chamber comprises a sheath having a lumen.

24. The catheter of claim 23, wherein the displaceable tip is axially slidable relative to the sheath.

25. The catheter of claim 24, wherein the displaceable tip is disposed on a push shaft that is axially slidable relative to the sheath.

26. The catheter of claim 25, wherein the push shaft is received within the lumen of the sheath.

27. The catheter of claim 26, wherein the push shaft has a partially circular cross section.

28. The catheter of claim 26, wherein the push shaft has an approximately semi-circular cross section.

29. The catheter of claim 24, wherein a proximal portion of the displaceable tip has a reduced diameter and is capable of being received within the lumen of the sheath.

30. The catheter of claim 24, wherein a distal region of the displaceable tip has a distally tapering diameter.

31. The catheter of claim 22, wherein the cutting edge is a radially outer edge of the cutting element.

32. The catheter of claim 22, wherein the cutting element is movable between a stored position and a cutting position relative to the opening.

33. The catheter of claim 32, wherein the cutting element is moved between the stored position and the cutting position by sliding the cutting element against a cam surface.

34. The catheter of claim 33, wherein a distal portion of the catheter relative to a proximal portion is deflected by sliding the cutting element against the cam surface.



35. A method of removing material from a body lumen, the method comprising:

- providing an atherectomy catheter, the atherectomy catheter comprising:
  - a body having an opening;
  - a rotatable shaft coupled to the body, the rotatable shaft being rotatable about a longitudinal axis of the shaft;
  - a tissue collection chamber coupled to the body and positioned distal to the cutting element; and
  - a cutting element coupled to the rotatable shaft, the cutting element having a cup-shaped surface and a cutting edge, the cup-shaped surface being configured to re-direct tissue cut by the cutting edge in a distal direction when the cup-shaped surface moves in the distal direction, wherein the tissue collection chamber has a first closed position capable of retaining cut tissue in the chamber and a second open position capable of allowing expulsion of cut tissue from the chamber, and wherein the tissue collection chamber comprises an expandable tip at a distal region of the catheter, the expandable tip having a first closed position capable of retaining cut tissue in the chamber and a second open position capable of allowing expulsion of cut tissue from a distal opening at a distal end of the chamber;
- placing the catheter in the body lumen; and
- moving the catheter in the body lumen to contact the cutting element with the material in the body lumen.

36. The method of claim 35, wherein the catheter is moved in a distal direction to contact the cutting edge with the material in the body lumen.

37. The method of claim 35, wherein the catheter is placed in the body lumen with the cutting element in a stored position and the catheter is moved to contact the material with the cutting element in a cutting position.

38. The method of claim 35, further comprising collecting the material in the tissue collection chamber, removing the catheter from the body lumen, and removing the material from the tissue collection chamber after the catheter has been removed from the body lumen.

39. The method of claim 38, wherein the catheter is removed from the body lumen with the tissue collection chamber in the first closed position and the material is removed from the tissue collection chamber with the tissue collection chamber in a second open position capable of allowing expulsion of cut tissue from the chamber.

40. A method of removing material from a body lumen, the method comprising:

- providing an atherectomy catheter, the atherectomy catheter comprising:

- a body having an opening;

- a rotatable shaft coupled to the body, the rotatable shaft being rotatable about a longitudinal axis of the shaft;

- a tissue collection chamber coupled to the body and positioned distal to the cutting element; and

- a cutting element coupled to the rotatable shaft, the cutting element having a cup-shaped surface and a cutting edge, the cup-shaped surface being configured to re-direct tissue cut by the cutting edge in a distal direction when the cup-shaped surface moves in the distal direction, wherein the tissue collection chamber has a first closed position capable of retaining cut tissue in the chamber and a second open position capable of allowing expulsion of cut tissue from the chamber, and wherein the tissue collection chamber comprises a displaceable tip at a distal region of the catheter, the displaceable tip having a first closed position capable of retaining cut tissue in the chamber and a second open position capable of allowing expulsion of cut tissue from

the chamber, the displaceable tip being attached to the atherectomy catheter in both the first closed and second open positions;

placing the catheter in the body lumen; and

moving the catheter in the body lumen to contact the cutting element with the material in the body lumen.

41. The method of claim 40, wherein the catheter is moved in a distal direction to contact the cutting edge with the material in the body lumen.

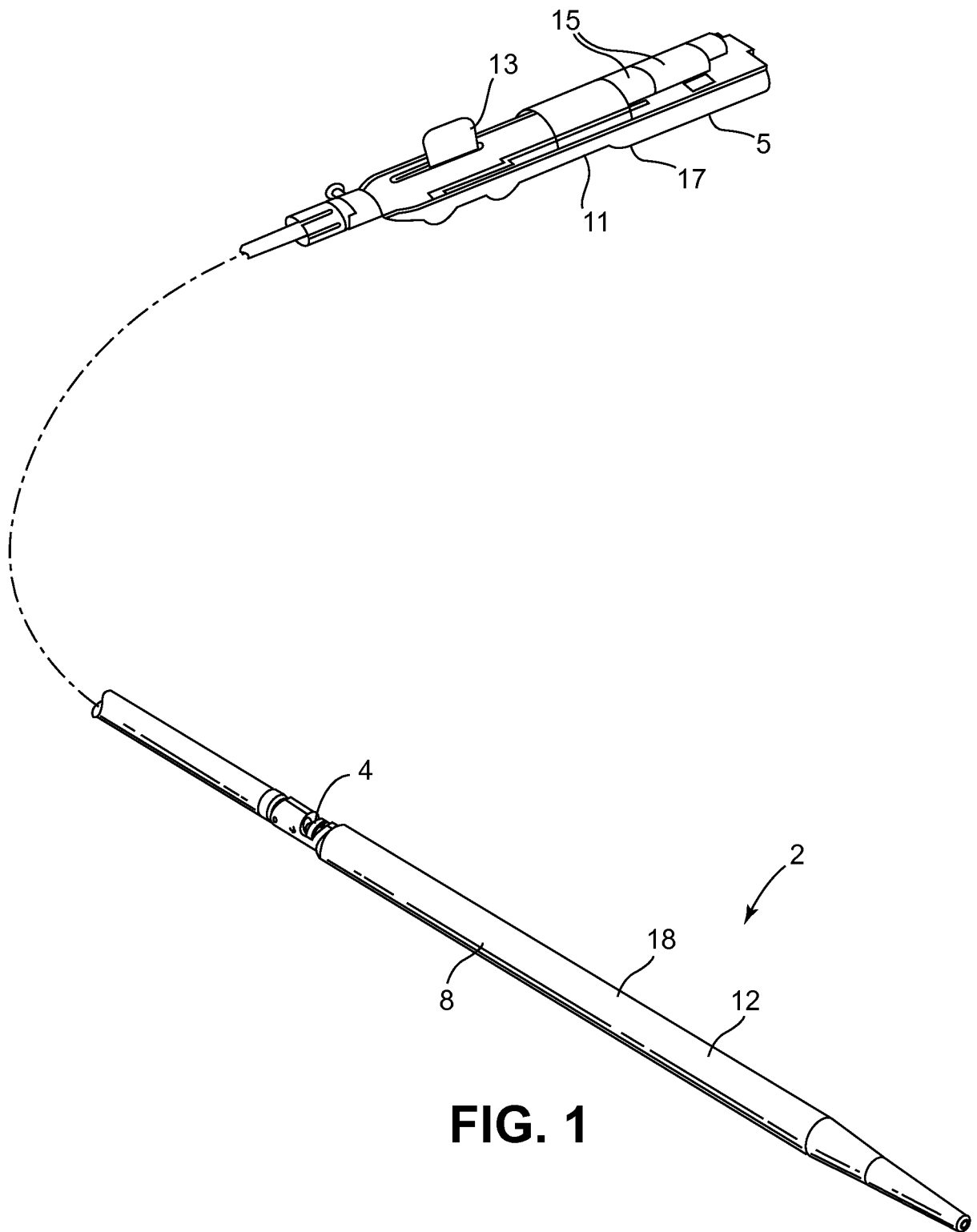
42. The method of claim 40, wherein the catheter is placed in the body lumen with the cutting element in a stored position and the catheter is moved to contact the material with the cutting element in a cutting position.

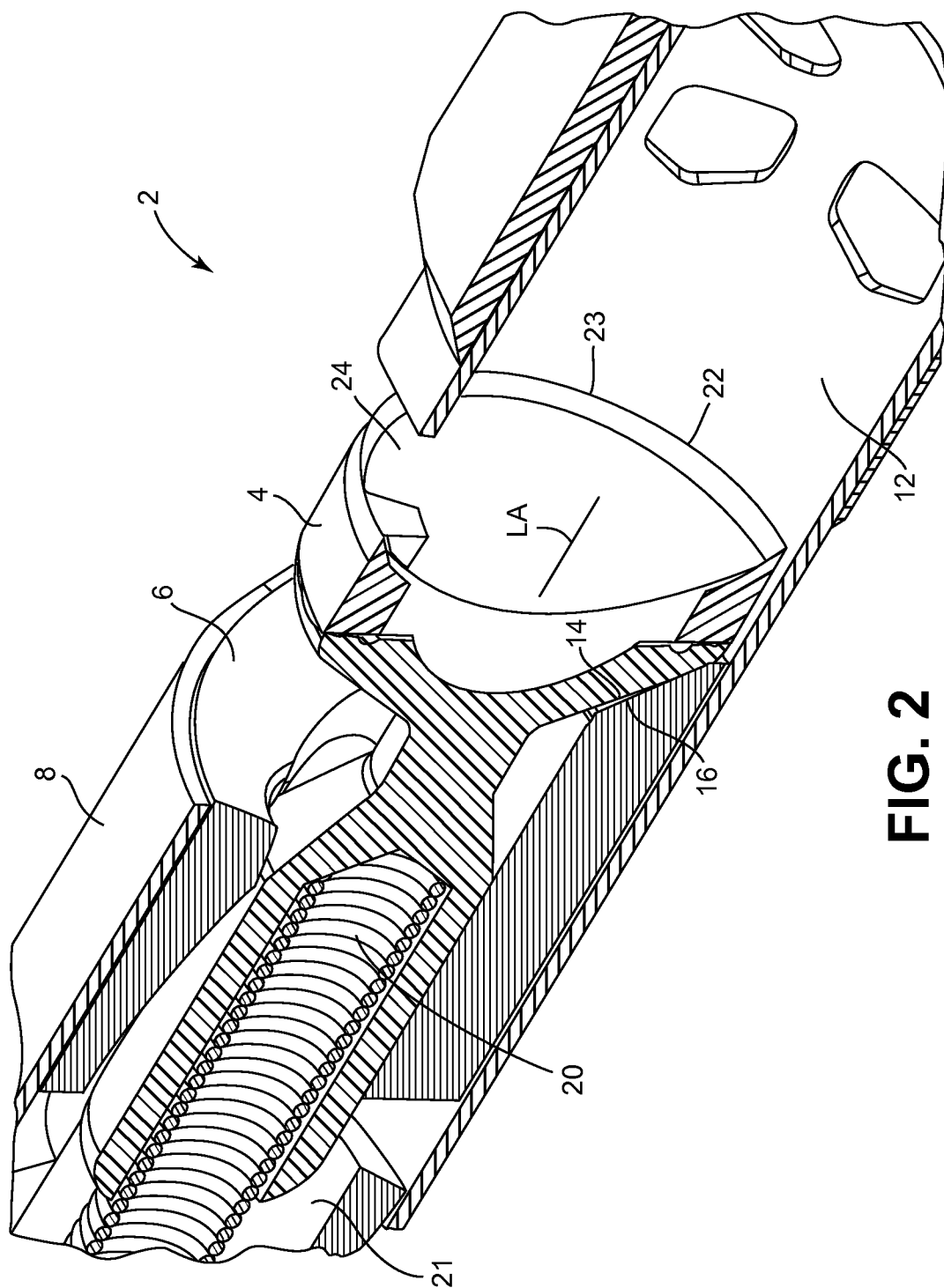
43. The method of claim 40, wherein the tissue collection chamber comprises a sheath having a lumen.

44. The method of claim 43, wherein the displaceable tip is axially slidable relative to the sheath.

45. The method of claim 40, further comprising collecting the material in the tissue collection chamber, removing the catheter from the body lumen, and removing the material from the tissue collection chamber after the catheter has been removed from the body lumen.

46. The method of claim 45, wherein the catheter is removed from the body lumen with the tissue collection chamber in the first closed position and the material is removed from the tissue collection chamber with the tissue collection chamber in a second open position capable of allowing expulsion of cut tissue from the chamber.





## FIG. 2

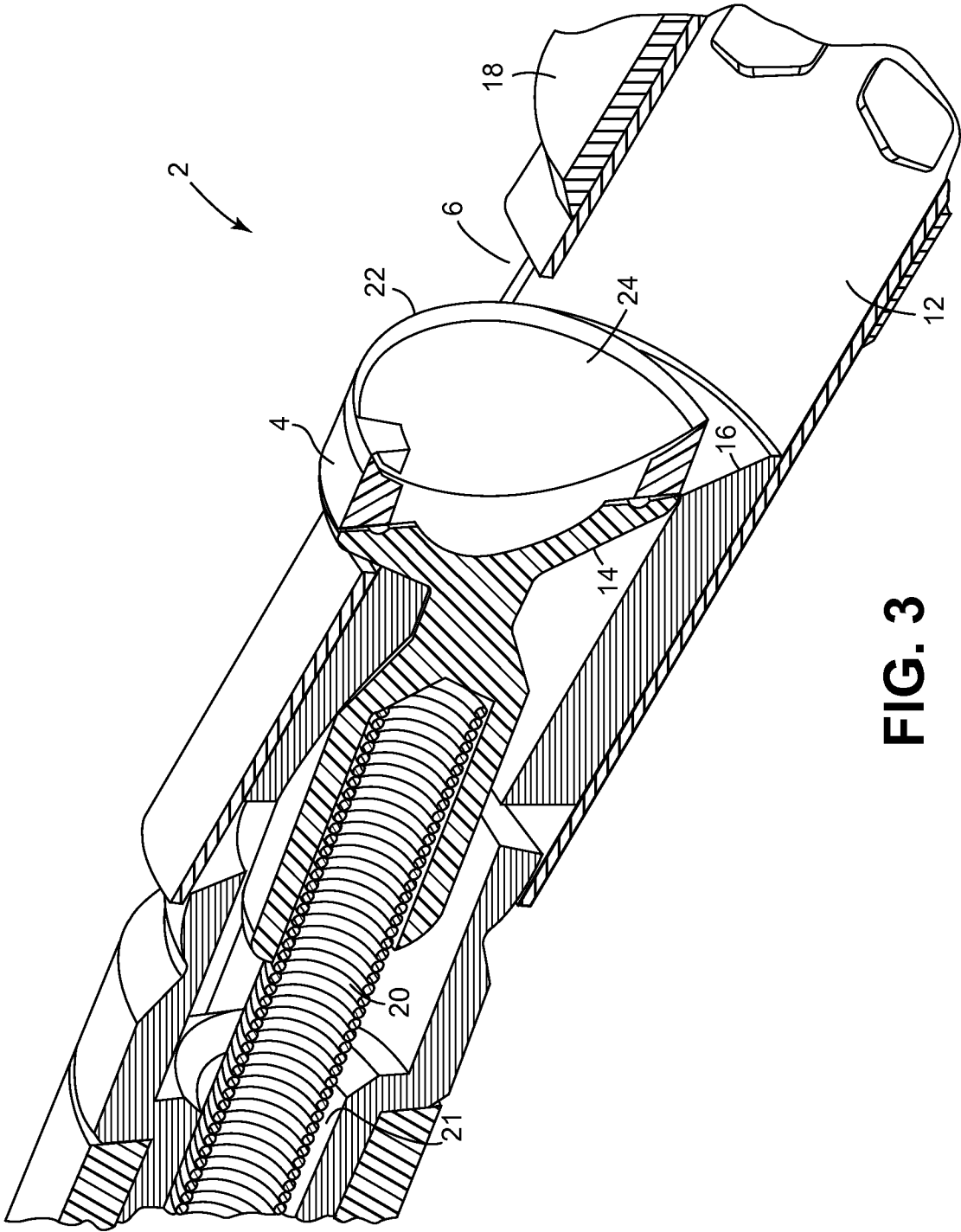
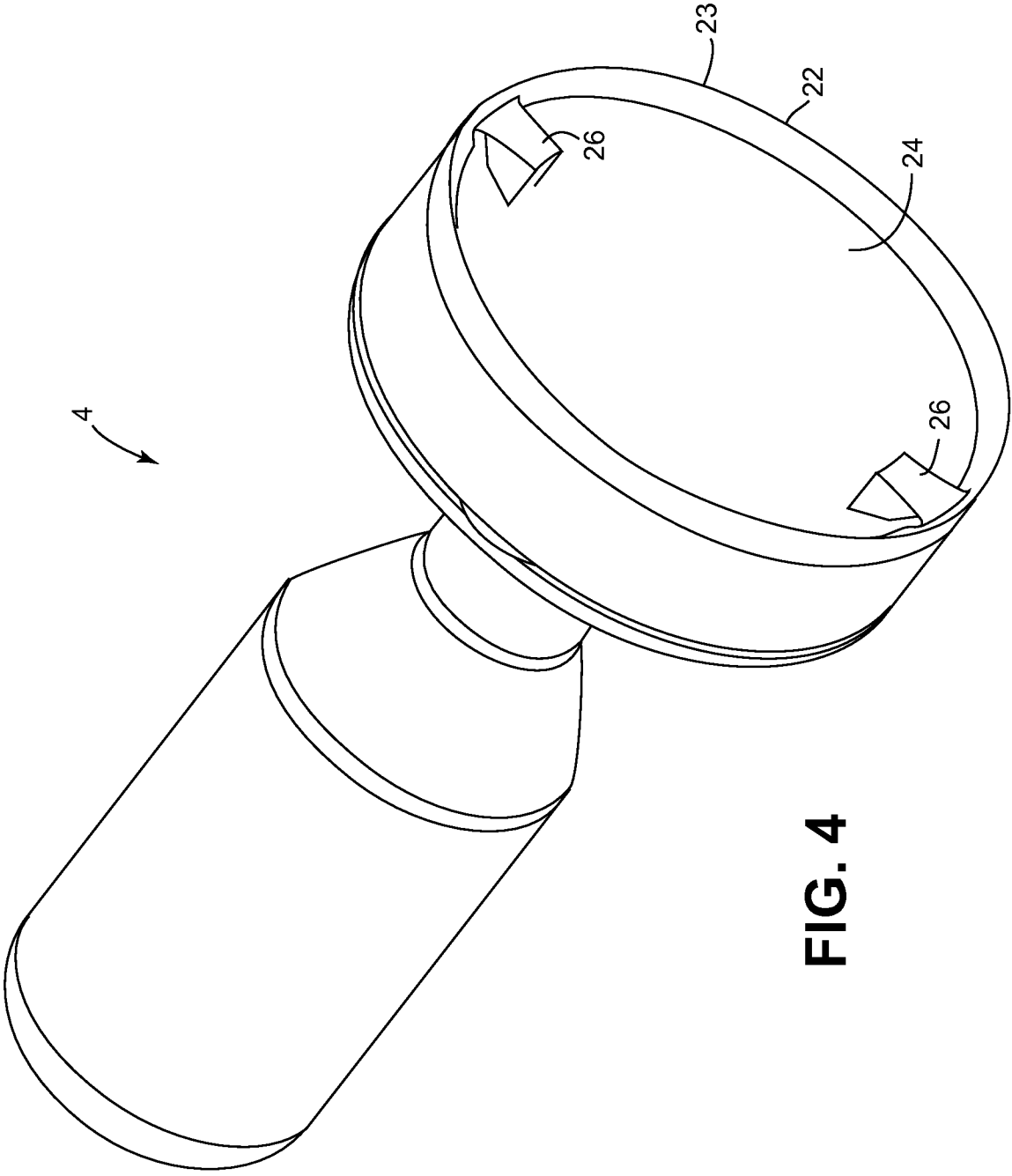
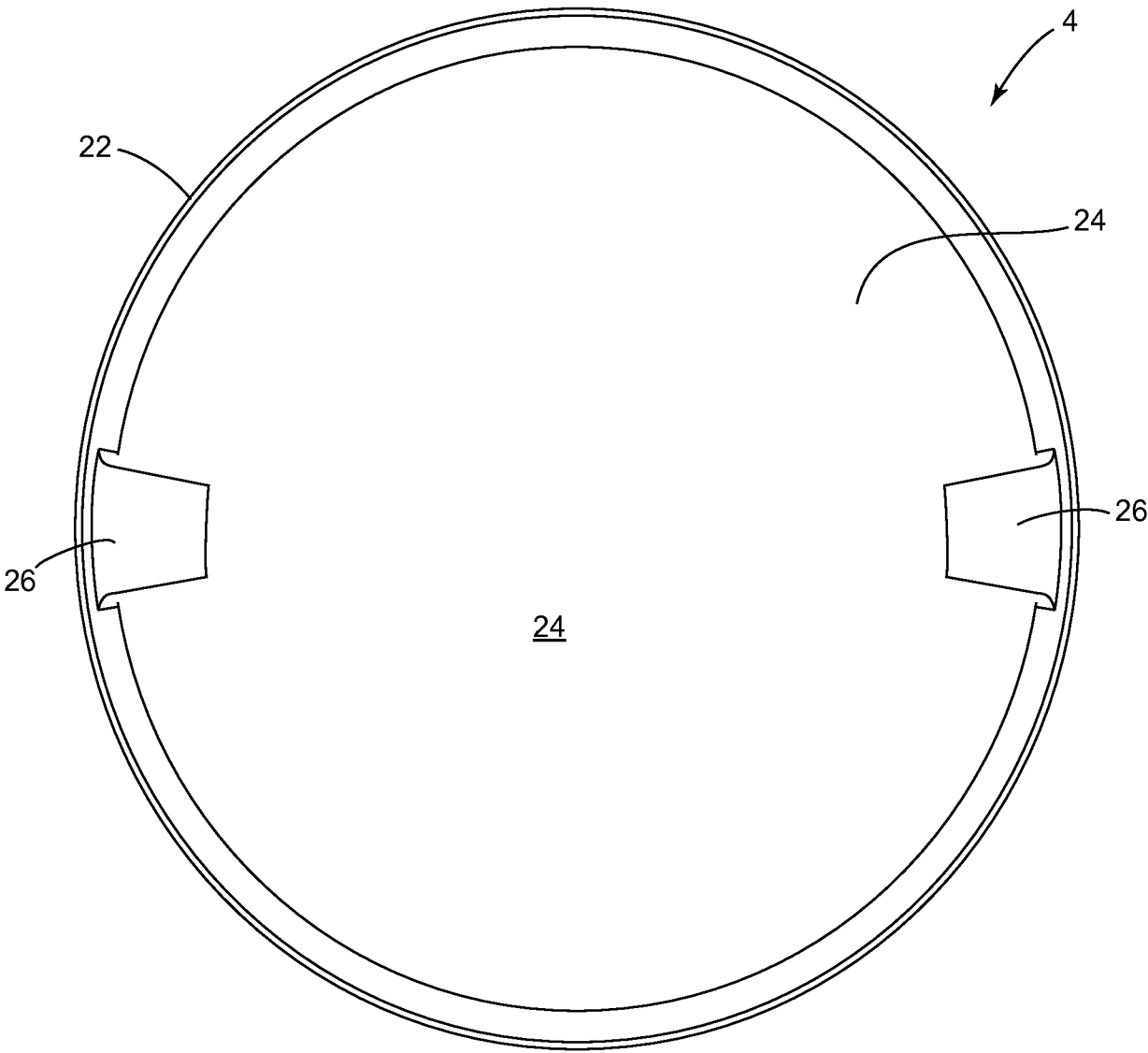


FIG. 3

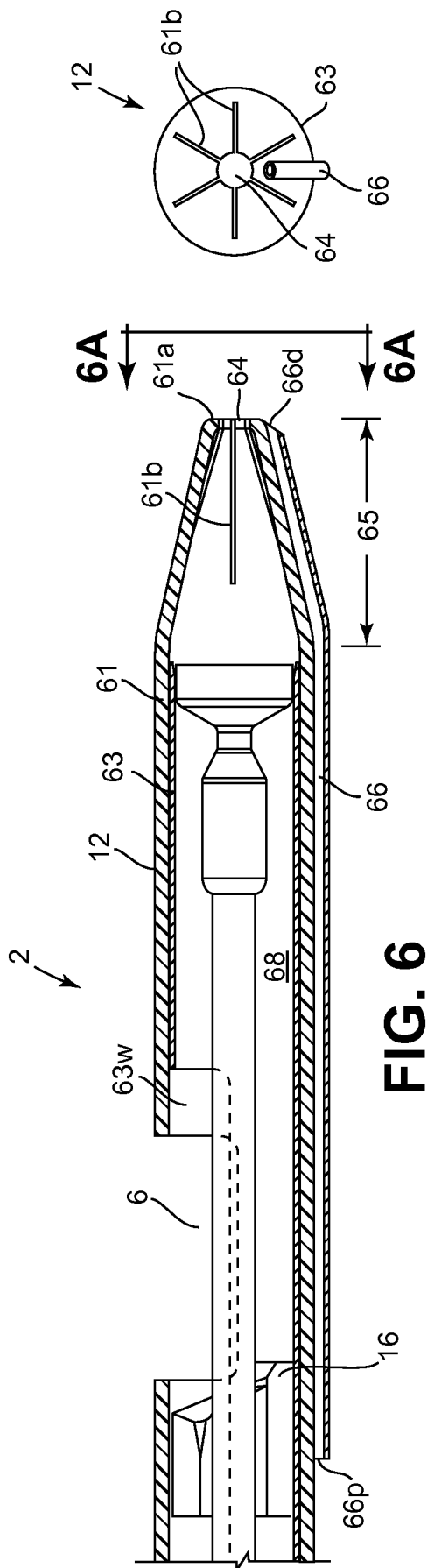


**FIG. 4**



**FIG. 5**





**FIG. 6A**

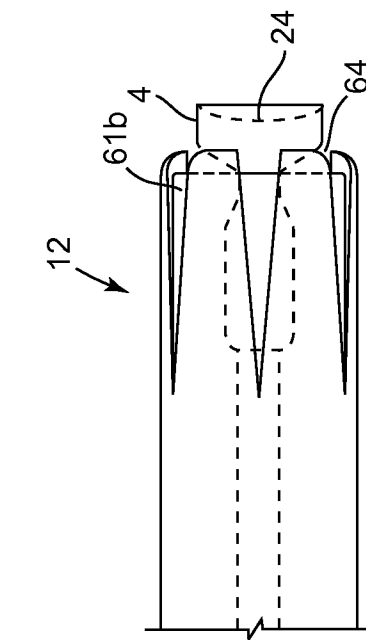
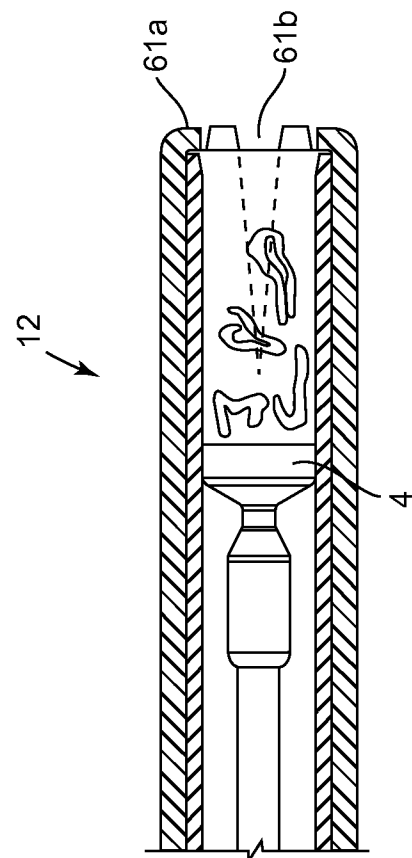
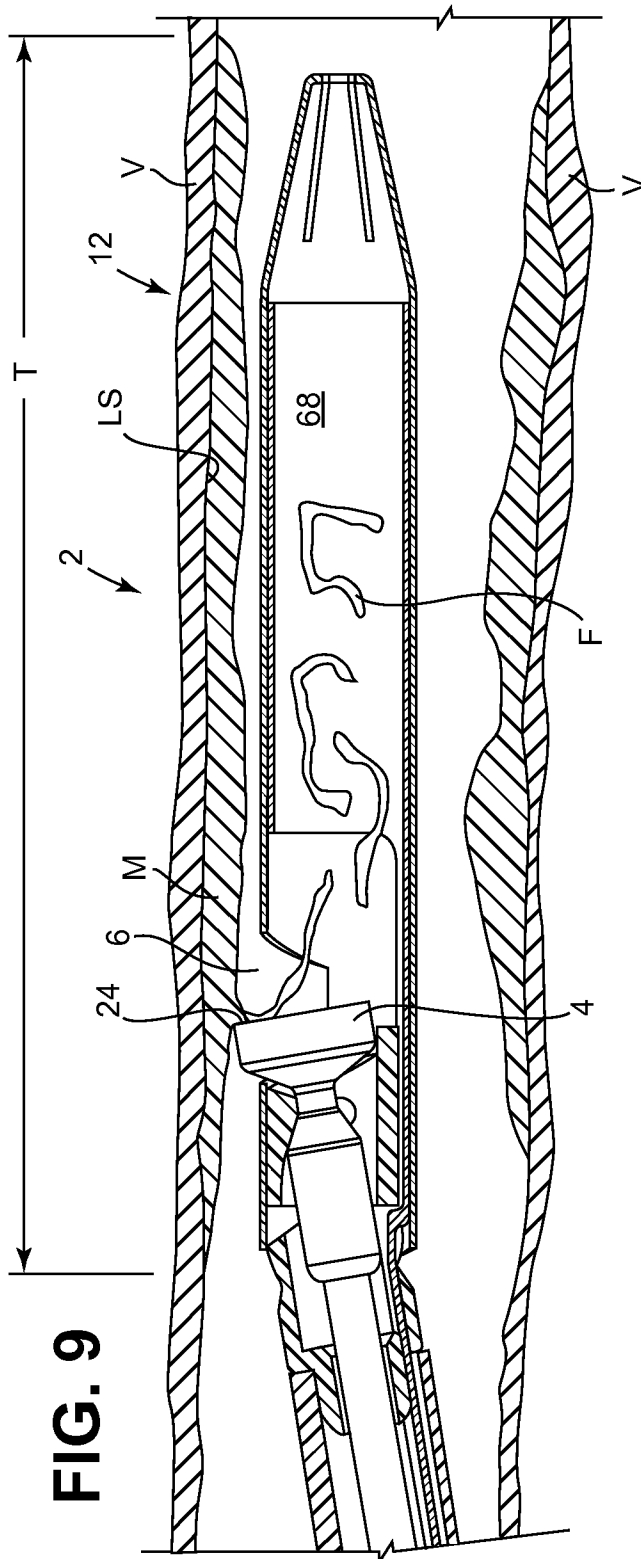


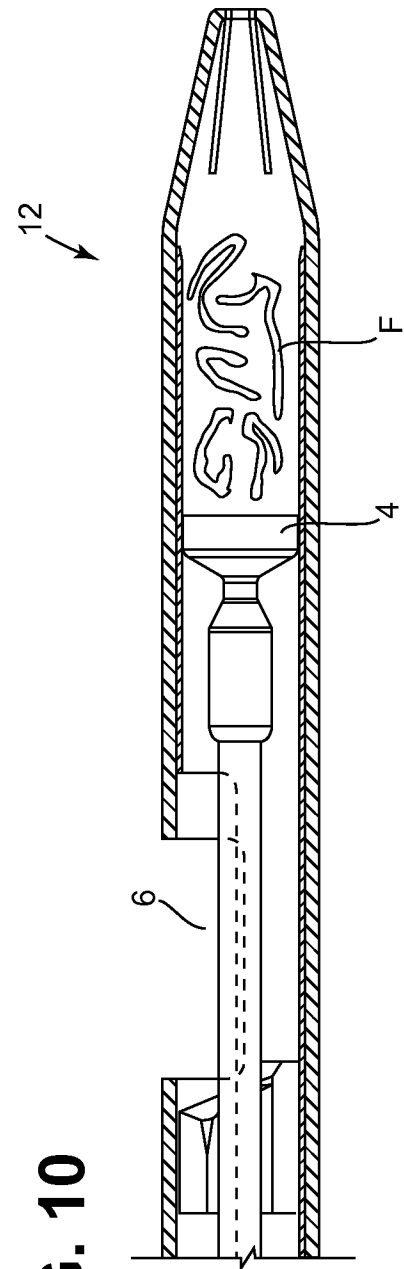
Fig. 8



**FIG. 7**



**FIG. 9**



**FIG. 10**

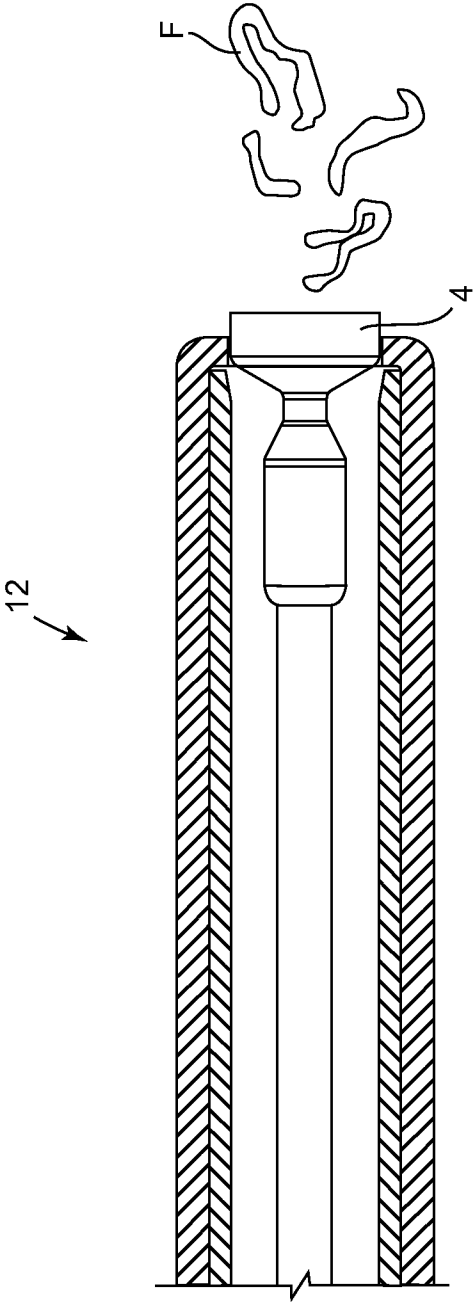


FIG. 11

FIG. 12

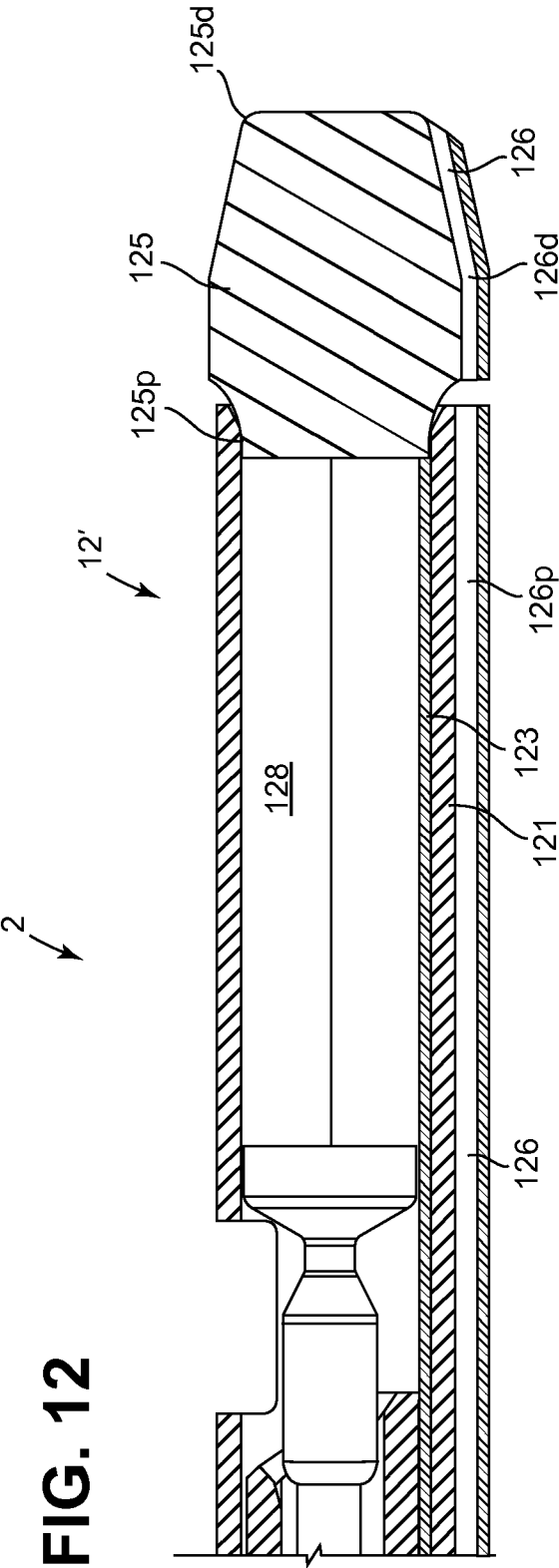
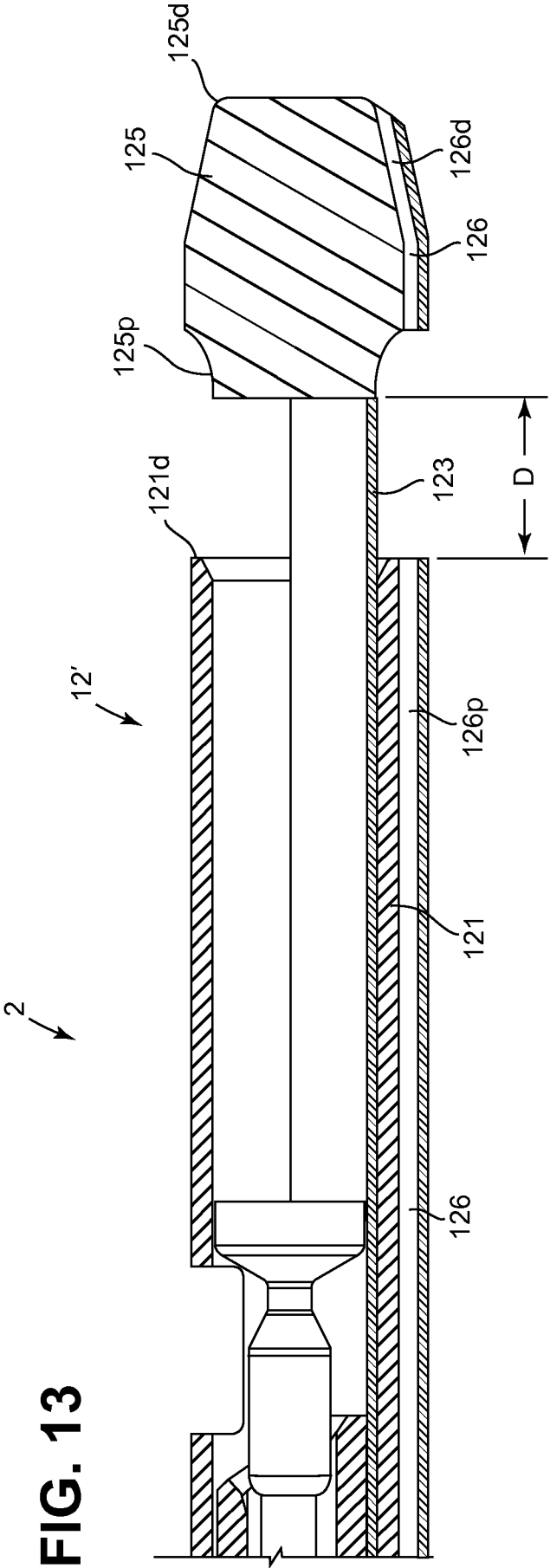
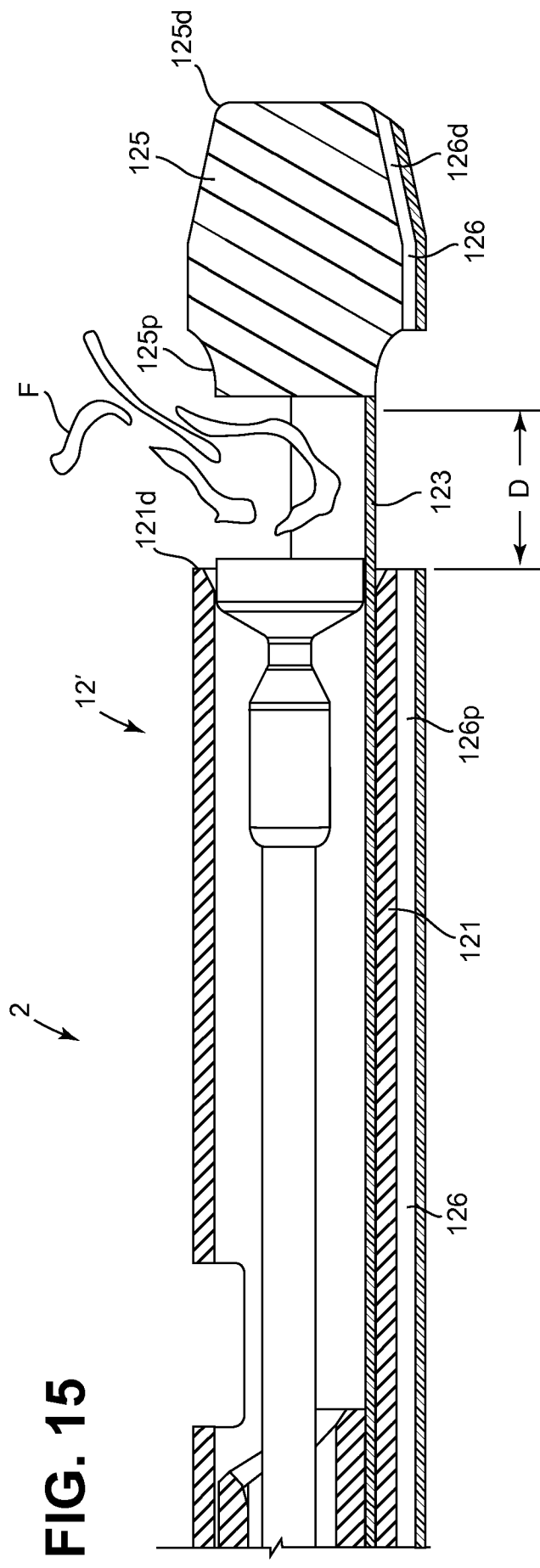
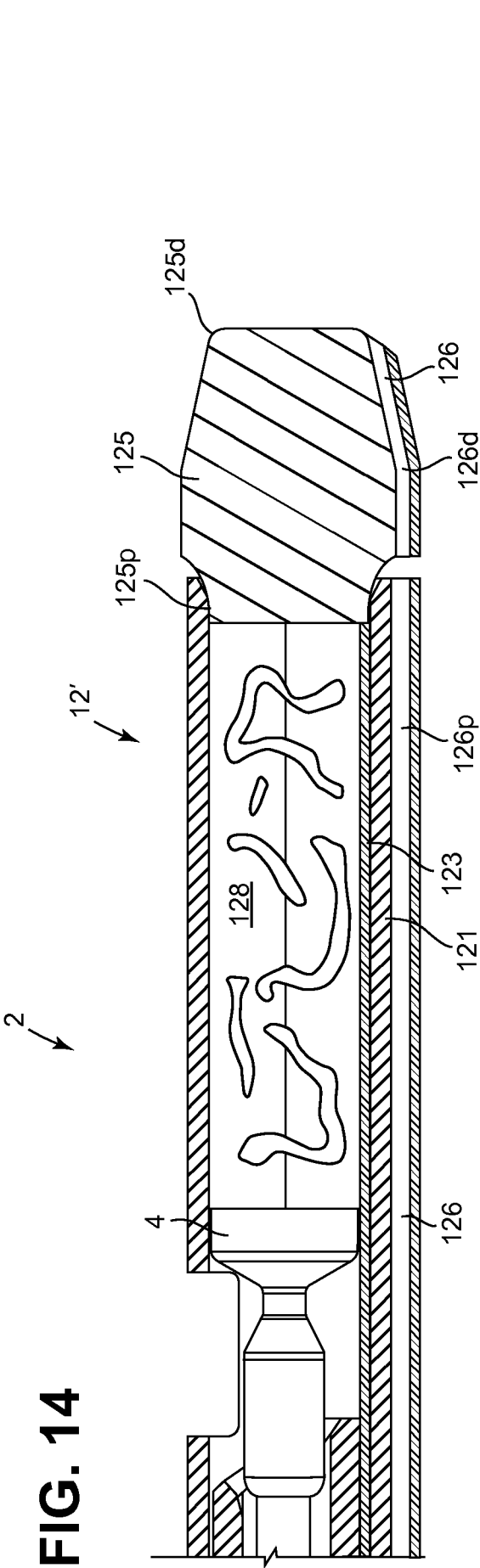


FIG. 13





# INTERNATIONAL SEARCH REPORT

International application No  
PCT/US2010/034868

## A. CLASSIFICATION OF SUBJECT MATTER

INV. A61B17/3207  
ADD.

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

## B. FIELDS SEARCHED

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

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

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

EPO-Internal

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2002/077642 A1 (PATEL HIMANSHU [US] ET AL) 20 June 2002 (2002-06-20) cited in the application figures -----	1-34
A	WO 92/07500 A2 (DEVICES VASCULAR INTERVENTION [US]) 14 May 1992 (1992-05-14) page 17, line 34 - page 18, line 14; figures -----	1-34



Further documents are listed in the continuation of Box C.



See patent family annex.

### \* Special categories of cited documents :

- \*A\* document defining the general state of the art which is not considered to be of particular relevance
- \*E\* earlier document but published on or after the international filing date
- \*L\* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- \*O\* document referring to an oral disclosure, use, exhibition or other means
- \*P\* document published prior to the international filing date but later than the priority date claimed

- \*T\* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- \*X\* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- \*Y\* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- \*G\* document member of the same patent family

Date of the actual completion of the international search

24 August 2010

Date of mailing of the international search report

31/08/2010

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2  
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Authorized officer

Held, Günter

# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US2010/034868

## Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 35-46  
because they relate to subject matter not required to be searched by this Authority, namely:  
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:  
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

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

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

### Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2010/034868

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2002077642	A1	20-06-2002	NONE
WO 9207500	A2	14-05-1992	CA 2092992 A1 26-04-1992
		EP 0554395 A1 11-08-1993	
		JP 6502562 T 24-03-1994	
		US 5242460 A 07-09-1993	