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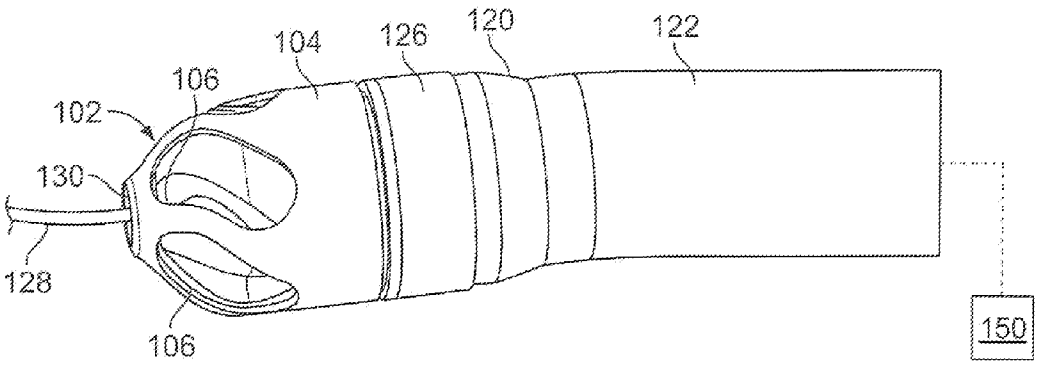
(54) Title: ATHERECTOMY DEVICES AND METHODS



(57) Abstract: The devices and methods generally relate to treatment of occluded body lumens. In particular, the present devices and method relate to removal of the occluding material from the blood vessels as well as other body lumens.

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ATHERECTOMY DEVICES AND METHODS

BACKGROUND OF THE INVENTION

Field of the Invention

[0001] The devices and methods described below generally relate to treatment of occluded body lumens. In particular, the present devices and method relate to removal of the occluding material from the blood vessels as well as other body lumens.

Description of the Background Art

[0002] Atherosclerosis is a progressive disease. In this disease, lesions of the arteries are formed by accumulation of plaque and neointimal hyperplasia causing an obstruction of blood flow. Often plaque is friable and may dislodge naturally or during an endovascular procedure, leading to embolization of a downstream vessel.

[0003] Endovascular clearing procedures to reduce or remove the obstructions to restore luminal diameter allows for increased blood flow to normal levels are well known. Removing the plaque has the effect of removing diseased tissue and helps to reverse the disease. Maintaining luminal diameter for a period of time (several to many weeks) allows remodeling of the vessel from the previous pathological state to a more normal state. Finally, it is the goal of an endovascular therapy to prevent short term complications such as embolization or perforation of the vessel and long term complications such as ischemia from thrombosis or restenosis.

[0004] Various treatment modalities may help to accomplish treatment goals. In atherectomy, plaque is cut away, or excised. Various configurations are used including a rotating cylindrical shaver or a fluted cutter. The devices may include shielding by a housing for safety. The devices may also remove debris via trapping the debris in the catheter, in a downstream filter, or aspirating the debris. In some cases a burr may be used instead of a cutter, particularly to grind heavily calcified lesions into very small particle sizes. Aspiration may also be used with a burr-type atherectomy device.

[0005] Balloon angioplasty is another type of endovascular procedure. Balloon angioplasty expands and opens the artery by both displacing the plaque and compressing it.

Balloon angioplasty is known to cause barotrauma to the vessel from the high pressures required to compress the plaque. This trauma leads to an unacceptably high rate of restenosis. Furthermore, this procedure may not be efficient for treatment of elastic-type plaque tissue, where such tissue can spring back to occlude the lumen.

[0006] When clearing such obstructions it is desirable to protect the vessel wall or wall of the body lumen being cleared and to debulk substantially all of a lesion. In additional cases, the procedure that clears obstructions may also be coupled with placement of an implant within the lumen. For example, it may be desirable to deploy a stent to maintain patency of a vessel for a period of time and/or to achieve local drug delivery by having the stent elute a drug or other bioactive substance.

[0007] On their own, stents fail to perform well in the peripheral vasculature for a variety of reasons. A stent with the necessary structural integrity to supply sufficient radial force to reopen the artery often does not perform well in the harsh mechanical environment of the peripheral vasculature. For example, the peripheral vasculature encounters a significant amount of compression, torsion, extension, and bending. Such an environment may lead to stent failure (strut cracking, stent crushing, etc.) that eventually compromises the ability of the stent to maintain lumen diameter over the long-term. On the other hand, a stent that is able to withstand the harsh mechanical aspects of the periphery often will not supply enough radial force to open the vessel satisfactorily. In many cases, medical practitioners desire the ability to combine endovascular clearing procedures with stenting. Such stenting may occur prior to, after, or both before and after the endovascular clearing procedure.

[0008] Accordingly, a need remains for devices that allow for improved atherectomy devices that clear materials from body lumens (such as blood vessels) where the device includes features to allow for a safe, efficient and controlled fashion of shaving or grinding material within the body lumen.

SUMMARY OF THE INVENTION

[0009] Devices and methods described herein provide improved means of clearing obstructions within body lumens, especially the vasculature. The features of the devices and methods allow for controlled removal of occlusive materials. In some variations, the methods and devices also have features to convey the materials away from the operative site without

the need to remove the devices from the body lumen. Additional aspects include controlled rates of tissue removal as well as other safety features to prevent accidental cutting of the lumen wall. Although the devices and methods described herein discuss removal of materials from a blood vessel, in certain cases the devices and methods have applicability in other body lumens as well. It should be noted that the variations and features of the devices described below may be incorporated selectively or in combination with a basic device configuration that includes a flexible body having a cutter head, where the cutter head includes a housing and a cutter, where the housing and cutter are able to rotate relative to each other. Variations include a cutter that rotates within the housing, a housing that rotates about the cutter, and combinations thereof.

[0010] One variation of the device described herein includes a device configured to remove material from body structures. The device may be a vascular device and have the required structure and configuration to navigate tortuous anatomy. Alternatively, the device may be a cutter that has features that are desired when used in other parts of the anatomy.

[0011] In any case, such a device may include a catheter body having a proximal end and a distal end, a cutter assembly located at the distal end of the catheter body, the cutter assembly comprising a housing having at least one opening and a cutter having at least one cutting surface configured to rotate relative to the housing, where movement of the cutting surface relative to the vessel removes occlusive material, a rotating shaft extending through the catheter body and coupled to the cutter, the shaft having a proximal end adapted to couple to a first rotating mechanism, and a deflecting member extending along the catheter body, such that the deflection member can cause deflection of the cutter assembly relative to an axis of the catheter.

[0012] Variations of the deflecting member may include steerable sheaths adapted to deflect in shape. In some variations the steerable sheath may include a deflecting wire extending through a portion of the sheath, such that axial movement of the deflecting wire deflects the sheath. The deflecting wire can be affixed to the cutter assembly, to a portion of the catheter body that extends out of the deflecting sheath, or to other parts of the device as needed.

[0013] The deflecting member can also include a pre-shaped mandrel, or tube where such features are slidable within or relative to the device to produce movement of the cutting head

relative to an axis of the device. The devices described herein may have any number of features that allow for locking the device after it is articulated. This feature provides a consistent diameter when sweeping or navigating through the anatomy.

[0014] As discussed herein, some variations of the devices have the ability to articulate. This articulation allows for steering the device to the target site as well as creating a sweeping motion of tissue removal. Accordingly, deflectable sheath used in the device can be rotatable about the catheter body, or about an axis of the catheter.

[0015] The devices described herein may have a cutter assembly having a portion of its housing having a curved surface and where the opening forms a plane across the curved surface such that as the cutting surface rotates across the opening, a portion of the cutting surface extends out of the housing through the opening. The cutter assembly may also have various other features as described below that improve the safety of the device as it is articulated while cutting. Furthermore the cutter may have a number of features to impel or drive cut tissue into the cutter assembly for eventual removal by one or more conveying members.

[0016] As noted, the devices described herein may have one or more conveying members that convey materials and/or fluids through the device. Such a feature is useful to remove cut tissue and debris from the site during the procedure. In some variations, the device may include multiple conveyors to deliver fluids and remove debris. However, the devices of the present invention may also have containers for use in capturing debris or other materials generated during the procedure.

[0017] Another feature for use with the inventions herein is the use of a grinding burr rotatably coupled to a tip of the device. The burr can be useful to remove tissue that is otherwise not conducive to cutting with the cutter assembly.

[0018] In another variation, the invention may comprise a device having a straightening tube, with a straight distal portion, a catheter body having a proximal end and a distal end, the catheter body having a flexible section located towards the distal end, such that when located in the straight distal portion of the straightening tube the flexible section is less curved, a cutter assembly located at the distal end of the catheter body, the cutter assembly comprising a housing having at least one opening and a cutter having at least one cutting surface configured to rotate relative to the housing, where movement of the cutting surface removes

material, and a rotating shaft extending through the catheter body and coupled to the cutter, the torque shaft having a proximal end adapted to couple to a first rotating mechanism.

[0019] In such a case, placement of the straight distal portion over the catheter allows for manipulation of the degree of curvature of the catheter. This feature allows for steering of the device.

[0020] As described herein, such a device may have the ability to sweep over an arc to deliver a larger cutting diameter than the diameter of the cutter assembly.

[0021] The devices described herein may use a guidewire for advancement through the body. In such cases the devices will have guide-wire lumens located within or about the catheter. Alternatively, a guide-wire section may be affixed to a portion of the device.

[0022] Devices of the present invention typically include a torque shaft to deliver rotational movement to components in the cutter assembly. Alternatively, a torque shaft or other such assembly may be used to produce the sweeping action described herein. In any case, the torque shaft may include one or more lumens. Alternatively, the torque shaft may be a solid or hollow member. Variations of the torque shaft also include those aspects known in catheter-type devices such as counter-wound coils, stiffening members, etc. In some variations, the torque shaft may have the conveying member integrally formed about the exterior or an interior surface of the shaft. Alternatively, or in combination, the conveying member may be placed on (or within) the torque shaft as described herein.

[0023] The invention also includes various methods of debulking material within body structures. These structures include occluded blood vessels (whether partially or totally occluded), various organs, cavities within the body, or other body lumens.

[0024] In one variation a method includes inserting a catheter body having a cutter assembly within the blood vessel, rotating the cutter assembly to remove the material and form a first opening in the body lumen, deflecting the first cutter assembly relative to an axis of the catheter body, rotating the deflected catheter tip while rotating the cutter to form a second opening in the body lumen where the second is larger than the first opening.

[0025] The methods may include the use of any of the devices or features of the devices described herein. In one variation, the methods include circulating fluid for contrast to better visualize the obstruction.

[0026] As noted herein, combinations of aspects of the devices, systems, and methods described herein may be combined as needed. Furthermore, combinations of the devices, systems and methods themselves are within the scope of the disclosure.

BRIEF DESCRIPTION OF THE DRAWINGS

[0027] Fig. 1A illustrates an exemplary variation of a device according to the present invention;

[0028] Fig. 1B shows an exploded view of the device of Fig. 1A;

[0029] Fig. 1C shows a cross sectional view of the cutting assembly;

[0030] Figs. 2A shows alignment of the cutting edges with openings of a housing;

[0031] Fig. 2B shows a side view of the cutting assembly demonstrating the secant effect;

[0032] Fig. 2C illustrates a positive rake angle;

[0033] Fig. 3 shows a partial cross sectional view of a variation of a torque shaft having counter wound coils;

[0034] Fig. 4A shows a variation of a device configured for rapid exchange;

[0035] Fig. 4B illustrates an example of centering a tip of a cutting assembly over a guide wire;

[0036] Fig. 5A shows a conveyor within the device;

[0037] Fig. 5B shows a second conveyor within a torque shaft;

[0038] Fig. 6A illustrates articulation of a tip of the device;

[0039] Fig. 6B-6D shows sweeping of the cutting assembly;

[0040] Fig. 6E illustrates another variation where the catheter body includes a set curve in an area that is adjacent to the cutting assembly;

[0041] Fig. 7 shows placement of housing windows to prevent damage to the vessel walls;

[0042] Figs. 8A-8I show variations of the device for articulating the cutting head;

[0043] Fig. 9 shows a device with a burr tip;

[0044] Figs. 10A-10C provide examples of fluid delivery systems;

[0045] Fig. 11 shows the device placed within a stent or coil;

[0046] Figs. 12A-12I show variations of devices; and

[0047] Figs. 13A-13C show a system for visualizing and crossing total occlusions.

DESCRIPTION OF AN EMBODIMENT

[0048] Fig. 1A illustrates an exemplary variation of a device **100** according to the present invention. As shown the device **100** includes a cutter assembly **102** affixed to a catheter body **120**. As shown, the catheter body may be optionally located within an outer sheath **122**.

[0049] Fig. 1B illustrates an exploded view of the device **100** of Fig. 1A. As shown, the cutter assembly **102** includes a housing **104** with a plurality of openings **106**. A cutter **108** is located within the housing **104**. The cutter **108** includes one or more flutes **110** each of which includes an edge or cutting surface **112**. The cutter is coupled to a rotating mechanism **150**. In this variation the rotating mechanism couples to the cutter via a torque shaft **114** that transmits rotational energy from the rotating mechanism **150** (e.g., an electric, pneumatic, fluid, gas, or other motor) to the cutter **108**. Variations of the devices include use of a rotating mechanism **150** located entirely within the body of the device **100**. In one variation, the rotating mechanism **150** may be outside of the surgical field (i.e., in a non-sterile zone) while a portion of the device (e.g., the torque shaft – not shown) extends outside of the surgical field and couples to the rotating mechanism. Figure 1B also shows a variation of the device **100** as having a deflecting member **124** (the deflecting member may be a tendon, wire, tube, mandrel, or other such structure). As described in detail below, the devices **100** can have deflecting members to articulate the cutting head and allow for a sweeping motion of cutting.

[0050] In another variation, the device **100** may have a catheter body that comprises a soft or flexible portion. In one variation, this soft or flexible portion may be on a single side of the device **100** to allow flexure of the device **100** to articulate the cutting head. The flexure may be obtained with a curved sheath, mandrel, or other means as known to those skilled in the art.

[0051] The device **100** may also include a vacuum source or pump **152** to assist in evacuation of debris created by operation of the device. Any number of pumps or vacuum sources may be used in combination with the device. For example, a peristaltic pump may be used to drive materials from the device and into a waste container. Fig. 1B also shows the device **100** coupled to a fluid source **154**. As with the rotating mechanism, the vacuum source and/or fluid source may be coupled to the device from outside the surgical field.

[0052] It may be advantageous to rotatably couple the torque shaft to the drive unit electromagnetically, without physical contact. For example, the torque shaft **114** can have magnetic poles installed at the proximal end, within a tubular structure that is attached to the

sheath around the torque shaft. The stationary portion of the motor can be built into a handle that surrounds the tubular structure. This allows the continuous aspiration through the sheath without the use of high speed rotating seals.

[0053] As shown in Fig. 1C, in certain variations, the housing **104** can have a distal nose with a center lumen **142** for receiving a mating piece **140** of the cutter **108**. Such features assist in centering the cutter **104** concentrically inside the housing **104**. The housing is preferably made of a strong, wear resistant material such as hardened steels, cobalt chromium, carbides or titanium alloys with or without wear resistant coatings like TiNi. In particular the use of coatings will allow the use of tool steels which, unless coated, do not have acceptable corrosion resistance and biocompatibility. As noted below, variations of the devices include the addition of a burr element (as shown below) for grinding hard tissue such as calcified plaque.

[0054] The geometry of the cutter **108** and housing **104** can be used to tailor the desired degree of cutting. The housing **104** and orientation of the openings **106** can be used to limit the depth of cutting by the cutter **108**. In addition, the distal end of the housing **104** may be domed shaped while the proximal end may have a cylindrical or other shape. For example, by creating larger windows **106** in the housing a larger portion of cutter **108** may be exposed and the rate of cutting increased (for a given rotation speed). By placing the cutting window **106** on a convex portion of the housing, the debulking effectiveness is much less sensitive to the alignment of the cutter housing to the lesion, than if the window were on the cylindrical portion of the housing. This is a key performance limitation of traditional directional atherectomy catheters. In addition, placement of the window on the convex portion of the housing creates a secant effect (as described below).

[0055] Fig. 2A illustrates an additional variation of the device **100** where the openings **106** may be helical slots that may or may not be aligned with the cutting surfaces **112** of the cutter **108**. For aggressive cutting, the slots **106** and cutting edges **112** are aligned to maximize exposure of the tissue to cutting edges. In other words, the cutting edges **112** and openings **106** are in alignment so all cutting edges **112** are exposed at the same time to allow simultaneous cutting. Alternatively, alignment of the openings and edges **112** may be configured so that fewer than all the cutting edges **112** are exposed at the same time. For example, the alignment may be such that when one cutting edge **112** is exposed by an opening

106, the remaining cutting edges **112** are shielded within the housing **104**. Variations of such a configuration allow for any number of cutting edges to be exposed at any given time.

[0056] However, to even out the torque profile of the device when cutting, the cutter **108** is configured such that the number edges/cutting surfaces **112** of the flutes **110** that are aligned with the housing openings **106** does not vary throughout the rotational cycle. This prevents the catheter from being overloaded with torque spikes and cyclic torque variations due to multiple cutting edges/flutes engaging with tissue in synchrony. In other words, the length of the cutting surface **112** exposed through the openings **106** of the housing **104** remains the same or constant.

[0057] In the variation shown in Fig. 2B, the cutting surface **112** is configured to capture debris as it cuts. Typically, the device **100** may be designed with a secant effect. This effect allows for a positive tissue engagement by the cutter. As the cutter rotates through the opening, the cutting edge moves through an arc, where at the peak of the arc the cutting edge slightly protrudes above a plane of the opening. The amount of positive tissue engagement can be controlled through selection of the protrusion distance through appropriate design of the housing geometry (for example, by a combination of location and size of the window and radius of curvature of the housing). As shown, the cutting surface **112** extends out of the housing **104** through the window **106** as it rotates. This structure can also be designed to drive or impel the debris to the conveying member **118**. In this case, the flutes **110** within the cutter **108** are helically slotted to remain in fluid communication with the conveying member **118**. Variations of the device **100** can also include a vacuum source **152** fluidly coupled to the conveying member **118**. In order to improve the impelling force generated by the cutters, variations of the cutter have helical flutes **110** and sharp cutting edges **112** that are parallel to each other and are wound from proximal to distal in the same sense as the rotation of the cutter. When the cutter rotates, it becomes an impeller causing tissue debris to move proximally for evacuation.

[0058] As shown in Fig. 2C, variations of the device may have cutting surfaces **112** with positive rake angles α– that is the cutting edge is pointed in the same direction as that of the cutter rotation. This configuration maximizes the effectiveness of the impelling and cutting action (by biting into tissue and avoiding tissue deflection). The cutter is preferably made of hard, wear-resistant material such as hardened tool or stainless steels, Tungsten carbide,

cobalt chromium, or titanium alloys with or without wear resistant coatings as described above. However, any material commonly used for similar surgical applications may be employed for the cutter. The outer surfaces of the proximal end of the cutter **108** is typically blunt and is designed to bear against the housing **104**. Typically, these surfaces should be parallel to the inner surface of the housing.

[0059] Figs. 2A-2B also show a surface of the cutter **108** having a curved-in profile distally and is close to the housing **104** surface. Note that housing slots **106** with this curved profile allows the cutting edge **112** to protrude beyond the housing's outer surface. In other words, the openings **106** form a secant on the curved surface of the housing **104**. Such a feature allows improved cutting of harder/stiffer material like calcified or stiff fibrous tissue where such tissue does not protrude into the housing **104**.

[0060] By controlling the number of cutting edges **112** that are exposed through openings **106** in the housing **104**, it is possible to control the relative amount of cutting engagement (both length of cutting and depth of cut, together which control the volume of tissue removed per unit rotation of the cutter). These features allow independent control of the maximum torque load imposed on the device **100**. By carefully selecting the geometry of the flutes and or cutting edges **112** relative to the openings **106** in the housing, it is possible to further control the balance of torque. For example, the torque load imposed on the device is caused by the shearing of tissue when the cutter edge is exposed by passing through the housing window. If all cutter edges simultaneously shear, as for example when the number of housing windows is an even multiple of cutter edges, the torque varies cyclically with rotation of the cutter. By adjusting the number of cutters and windows so one is not an even multiple of the other (for example, by using 5 windows on the housing and 4 cutting edges on the cutter), it is possible to have a more uniform torque (tissue removal from shearing action) during each cycle of the cutter.

[0061] Fig. 3 shows a partial sectional view of a torque shaft **114** that is a set of counter-wound coils, with the outer coil wound at the proper (greater) pitch to form the conveying member **118**. Winding the coils counter to each other automatically reinforces the torque shaft **114** during rotation. Alternatively, the torque shaft **114** may be made out of a rigid plastic, rendered flexible by incorporation of a conveying member **118**. Although the shaft may be fabricated from any standard material, variations of the shaft include a metal braid

embedded in polymer (PEBAX, polyurethane, polyethylene, fluoropolymers, parylene) or one or more metal coils embedded in a polymer such as PEBAX, polyurethane, polyethylene, fluoropolymers or parylene. These constructions maximize torsional strength and stiffness, as well as column strength for "pushability", and minimize bending stiffness for flexibility. Such features are important for navigation of the catheter through tortuous vessels but allow for smooth transmission of torque over the long length of the catheter. In the multi-coil construction, the inner coil should be wound in the same sense as that of the rotation so that it would tend to open up under torque resistance. This ensures that the guidwire lumen remain patent during rotation. The next coil should be wound opposite the inner to counter the expansion to keep the inner coil from binding up against the outer catheter tube.

[0062] Fig. 3 also shows a torque shaft **114** having a central lumen **130**. Typically the lumen will be used to deliver a guidewire. In such cases, the central lumen may be coated with a lubricious material (such as a hydrophilic coating or Parylene) or made of a lubricious material such as PTFE to avoid binding with the guidewire. However, in some variations a guidewire section is affixed to a distal end of the housing. Moreover, the central lumen of the torque shaft **114** may also be used to deliver fluids to the operative site simultaneously with the guidewire or in place of the guidewire.

[0063] Fig. 4A illustrates a variation of a device **100** configured for rapid exchange. As shown, the device **100** includes a short passage, lumen, or other track **136** for the purpose of advancing the device **100** over a guidewire **128**. However, the track **136** does not extend along the entire length of the device **100**. Moreover, an additional portion of the track **136** may be located at a distal end of the catheter to center a guidewire **128**.

[0064] This feature permits rapid decoupling of the device **100** and guidewire **128** by merely holding the guidewire still and pulling or pushing the catheter **100** over the guidewire **128**. One benefit of such a feature is that the guidewire **128** may remain close to the site while being decoupled from the device **100**. Accordingly, the surgeon can advance additional devices over the guidewire and to the site in a rapid fashion. This configuration allows for quick separation of the catheter from the wire and introduction of another catheter over the wire since most of the wire is outside of the catheter.

[0065] As shown in Fig. 4B, centering the tip of the cutting assembly **102** over a guide wire **128** improves the control, access and positioning of the cutting assembly **102** relative to

a body lumen or vessel **2**. To accomplish this, the cutting assembly **102** can have a central lumen to accommodate a guide wire **128**. Variations of the device **100** includes a central guide wire lumen runs the length of the catheter through all central components including the torque shaft and the cutter. As noted above, a guidewire **128** can be affixed to the housing **104** or other non-rotational component of the cutting assembly **102**. In such a case, the guidewire **128** may preferably be a short segment that assists with navigation of the device through an occluded portion of a body lumen. However, the devices **100** can also operate without a guidewire since the head is steerable like a guidewire.

[0066] Fig. 5A illustrates a partial cross-sectional view of the device **100**. As shown, this variation of the device **100** includes a conveyor member **118** located within the device **100**. The conveyor member **118** may be an auger type system or an Archimedes-type screw that conveys the debris and material generated during the procedure away from the operative site. In any case, the conveying member **118** will have a raised surface or blade that drives materials in a proximal direction away from the operative site. Such materials may be conveyed to a receptacle outside of the body or such materials may be stored within the device **100**. In one variation, the torque shaft **114** and conveying member **118** extend along the length of the catheter.

[0067] In some variations, the conveying member **118** may be integral to the shaft **114** (such as by cutting the conveying member **118** into the torque shaft **114** or by extruding the torque shaft **114** directly with a helical groove or protrusion. In an additional variation as shown in Fig. 5B, an additional conveying member **118** may be incorporated on an inside of the torque shaft, where the internal conveying member is wound opposite to that of the external conveying member **118**. Such a configuration allows for aspiration and debris (via the external conveying member **118**) and infusion (via the internal conveying member **118**). Such a dual action can enhance the ability to excise and aspirate plaque by: (1) thinning the blood, whether by viscosity alone or with the addition of anti-coagulants such as heparin or warfarin (cumadin), (2) improving the pumpability (aspirability) of the excised plaque by converting it into a solid-liquid slurry that exhibits greater pumping efficiency, and (3) establishing a flow-controlled secondary method of trapping emboli that are not sheared directly into the housing, by establishing a local recirculation zone.

[0068] As noted above, the conveying member **118** can be wound in the same directional sense as the cutter flutes and in the same direction of rotation to effect aspiration of tissue debris. The impeller action of the cutter **108** moves the tissue debris from inside the housing **104** openings **106** into the torque shaft. The pitch of the cutting edges **112** may be matched in to that of the conveying member **118** to further optimize aspiration. Alternatively, the pitch of the conveying member **118** may be changed to increase the speed at which material moves once it enters the conveying member **118.** As discussed herein, debris can be evacuated outside the body by the conveying member **118** action along the length of the catheter and with or without supplement of the vacuum **152** pump connected to the catheter handle. Alternatively, the debris may be accumulated in a reservoir within the device.

[0069] The device may also include a ferrule **116**, as shown in Fig. 1B, that permits coupling of the catheter body **120**to the cutter assembly **102**. The ferrule **116** may serve as a bearing surface for rotation of the cutter **108** within the cutter assembly **102**. In the illustrated variation, the torque shaft **114** rotates inside the outer catheter body **120** and ferrule **116** to rotate the cutter and pull or aspirate tissue debris in a proximal direction. The clearance between the catheter tube and conveying member **118**, as well as the pitch and thread depth of the conveying member **118**, are chosen to provide the desired pumping effectiveness.

[0070] In one variation of the device, the housing **104** is connected to the catheter body **120** via the ferrule **116** and thus is static. The cutter **108** rotates relative to the housing **104** such that the cutting surface **112** on the cutter **108** shears or cleaves tissue and trap the tissue inside the housing **104** so that it can be evacuated in a proximal direction using the impeller action of the helical flutes and vacuum from the torque shaft.

[0071] The ferrule **116** can have a distal bearing surface to bear against the proximal surface of the cutter **108** and keeps the cutter axially stable in the housing **104**. It can be rigidly bonded/linked to the housing **104** using solder, brazing, welding, adhesives (epoxy), swaging, crimped, press-fit, screwed on, snap-locked or otherwise affixed. As shown, the ferrule **116** can have holes or other rough features that allow for joining with the catheter body. While adhesives and heat fusing may be employed in the construction, such features are not required. Often adhesives are unreliable for a small surface contact and heat fusing can cause the tube to degrade. The use of a mechanical locking ring **126** allows the cutting

assembly **102** to be short. Such a feature is important for maximizing the flexibility of the distal section of the catheter as it is required to navigate tortuosity in blood vessels.

[0072] In another aspect of the invention, devices **100** can be adapted to steer to remove materials that are located towards a side of the body passage. Such devices may include a deflecting member that permits adjusting the orientation or offset of the cutter assembly **102** relative to a central axis of the device. In Fig. 1B, the deflecting member comprises a sheath **122** with a deflecting member **132** (such as a tendon, wire, tube, mandrel, or other such structure.) However, as described herein, other variations are within the scope of the device.

[0073] Fig. 6A illustrates an example of a variation of a device **100** equipped to have an articulating or steerable cutter assembly **102.** The ability to steer the tip of the device **100** is useful under a number of conditions. For example, when debulking an eccentric lesion as shown, the cutting assembly **102** should be pointed towards the side of the vessel **2** having the greater amount of stenotic material **4**. Naturally, this orientation helps prevent cutting into the bare wall/vessel **2** and focuses the cutting on stenotic tissue **4**. As shown in when in a curved section of the vessel **2**, without the ability to steer, the cutting assembly **102** would tend to bias towards the outside of the curve. Steering allows the cutting assembly **102** to point inward to avoid accidental cutting of vessel wall **2**.

[0074] The ability to steer the device **100** also allows for a sweeping motion when cutting occlusive material. Fig. 6B shows the rotation of the cutting assembly **102**. As shown in Fig. 6C, when the cutting assembly **102** deflects relative to the axis of the catheter, rotation of deflected portion **102** creates a sweeping motion. It is noted that rotation or articulation of the cutting assembly also includes rotation or articulation of the catheter to allow the cutting assembly to deflect relative to an axis of the catheter. Fig. 6D shows a front view taken along an axis of the vessel to illustrate the sweeping motion causing the cutting assembly **102** to "sweep" over a larger region than the diameter of the cutting assembly. In most cases, when deflected, the deflected portion of the device will be rotated to sweep over an arc or even a full circle. The rotation of the cutter may or may not be independent of the rotation of the deflected portion. A user of the device may couple the sweeping motion of the cutting assembly with axial translation of the catheter for efficient creation of a larger diameter opening over a length of the occluded vessel. The combination of movement can be performed when the device is placed over a guidewire, for example by the use of a lead screw

in the proximal handle assembly of the device. In another aspect of the devices described herein, the angle of articulation may be fixed so that the device sweeps in a uniform manner when rotated.

[0075] A number of variations to control the deflection of the device **100** are described herein. For example, as shown in Fig. 6 the sheath **122** itself may have a pre-set curve. In such a case, the area of the catheter body **120** adjacent to the cutting assembly **102** will be sufficiently flexible so as to assume the shape of the curved sheath **122**.

[0076] Fig. 6E illustrates another variation where the catheter body **120** includes a set curve in an area that is adjacent to the cutting assembly **102**. In this case, the outer sheath **122** can be made to be straight relative to the catheter body **120**. Accordingly, advancement of the curved portion of the catheter body **120** out of the sheath **122** causes the catheter body **120** to assume its curved shape. The degree of articulation in such a case may be related to the degree of which the catheter body **120** is advanced out of the sheath **122**.

[0077] In addition, the shape of the housing **104** as well as the location of the windows **106** can be chosen so that when the device **100** is substantially aligned with the lesion, or engages it at less than some critical attack angle, it will cut effectively. However, when pivoted at an angle greater than the critical angle, the cutting edges or grinding element will not engage the lesion as shown in Fig. 7. This means that at large deflections, as the catheter tip approaches the vessel wall, it automatically reduces its depth of cut and ultimately will not cut when the critical angle is exceeded. For example, the cutter distal tip is blunt and does not cut. As the catheter tip is deflected outward, the blunt tip contacts the vessel and keeps the cutting edges proximal to the tip from contacting the vessel wall. Also the wire in combination with the device can also act as a buffer to prevent the cutting edges from reaching the vessel.

[0078] As mentioned above, variations of the device **100** allow directional control of the cutting assembly **102**. In those variations where a slidable, torqueable sheath advances relative to the catheter body **122** (either external or internal to the catheter body) that can be flexed at the distal end. With the sheath flexed the catheter tip is pointed in the direction of the flex and the degree of bias is affected by the amount of flex on the sheath. The sheath can be rotated about the catheter or vessel long axis to change the direction of the cutting assembly. Also as noted above, this rotation can also effect a sweep of the cutting assembly

102 in an arc or a circle larger than a diameter of the cutter **102** (e.g. see Fig.6D). Such a feature eliminates the need to exchange the device for a separate cutting instrument having a larger cutting head. Not only does such a feature save procedure time, but the device is able to create variable sized openings in body lumens.

[0079] As shown in Fig. 8A, the tension on a slidable wire **132** in the wall of the sheath **122** can cause flexure of the sheath 122. Compression of the wire can also cause flexure of the sheath in the opposite direction. In one variation, the sheath **122** can be attached to the housing **104** of the cutting assembly **102**. Since the housing **104** is rotatable relative to the cutter **108** and the torque shaft **114**, the sheath **122** can rotate independently of the torque shaft **114** and cutter **108** to either sweep the cutting assembly **102** or to change direction of the articulated cutting assembly **102** at an independent rate.

[0080] In another variation of the device **100**, as shown in Fig. 8B, a preshaped curved wire or mandrel **134** can be advanced in a lumen in either the sheath **122** or catheter **120**. As the mandrel **134** advances, the device takes the shape as shown in Fig. 8C. Figs. 8D-8I illustrate additional mechanisms for flexing the device **100**. Such mechanisms can include side balloons **160**, meshes, wire loops **164**, coils **166**, and arms or mandrels **168** and other such structures. These features can be incorporated into catheter body **120** itself or into the sheath **122**. If located in the catheter body **122**, the entire catheter can be rotated to steer the tip in different directions. A curved or helical guidewire **170** can also be used to effect the flexion of the catheter tip as shown in Figs. 8D-8E. The wire can also be actively flexed to control the degree of catheter flexion. All of these deflecting mechanisms can cause the catheter to be deflected in one plane or it can be deflected in three dimensions. The curve on the wire can be in one plane or in 3 dimensions. The sheath can be flexed in one plane or 3 dimensions. Another way to achieve flexion at the distal tip of the catheter is to only partially jacket the distal end with one or more polymers. A bevel at the distal end and/or varying combinations of jacketing and polymers can be used to change the position of the moment arm. This changes the flexibility of the distal end and allows proper deflection.

[0081] In addition to providing a means for deflecting the catheter, and allowing the user to sweep the distal tip to engage the lesion as desired, it is also possible to link a separate torque control device to manually or automatically control the sweep of the catheter, independent of the axial control of the catheter insertion and the rotation control of the cutter

within the housing. Automatic control may be performed open-loop by user entered settings and activating a switch, or with feedback control designed to further optimize cutting effectiveness, procedural efficiency, and safety. Example structures of how to lock the articulation of the sheath/catheter into place include a lockable collar, a stopper, and friction lock detect mechanisms with one or more springs, coils, or hinges.

[0082] Additional components may be incorporated into the devices described herein. For example, it can be desirable to incorporate transducers into the distal region of the catheter to characterize the plaque or to assess plaque and wall thickness and vessel diameter for treatment planning; also transducers may be desired to indicate the progression of debulking or proximity of cutter to vessel wall. For example, pressure sensors mounted on the catheter housing can sense the increase in contact force encountered in the event that the housing is pressed against the vessel wall. Temperature sensors can be used to detect vulnerable plaque. Ultrasound transducers can be used to image luminal area, plaque thickness or volume, and wall thickness. Optical coherence tomography can be used to make plaque and wall thickness measurements. Electrodes can be used for sensing the impedance of contacted tissue, which allows discrimination between types of plaque and also vessel wall. Electrodes can also be used to deliver impulses of energy, for example to assess innervation, to either stimulate or inactivate smooth muscle, or to characterize the plaque (composition, thickness, etc.). For example, transient spasm may be introduced to bring the vessel to a smaller diameter easier to debulk, then reversed either electrically or pharmaceutically. Electrical energy may also be delivered to improve the delivery of drugs or biologic agents, by causing the cell membrane to open in response to the electric stimulation (electroporation). One method of characterization by electrical measurement is electrical impedance tomography.

[0083] As shown in Fig. 9, a cutter assembly **102** can also have a burr protruding out its nose. Although the burr **180** may have any type of abrasive surface, in one variation, this burr is blunt and has fine grit (such as diamond grit) to allow for grinding of heavily calcified tissue without injuring adjacent soft tissue. This combination of a burr and cutter allow the distal assembly to remove hard stenotic tissue (calcified plaque) using the burr while the sharp-edged, shaving cutter removes softer tissue such as fibrous, fatty tissue, smooth muscle proliferation, or thrombus. In variations, the burr can also have helical flutes to help with

aspiration, or the burr can be incorporated to a portion of the cutting edge (for example, the most distal aspect of the cutter).

[0084] Infusing solutions (flush) into the target treatment site may be desirable. Infused cool saline can prevent heating of blood and other tissue, which reduces the possibility of thrombus or othertissue damage. Heparinized saline can also prevent thrombus and thin out the blood to help maximize effectiveness of aspiration. The flush can also include drugs such as Clopidegrel, Rapamycin, Paclitaxel or other restenosis-inhibitors. This may help to prevent restenosis and may result in better long term patency. The flush may include paralytics or long-acting smooth muscle relaxants to prevent acute recoil of the vessel. Figs. 10A-10C illustrate variations of flushing out the device **100**. The flush can be infused through the guide wire lumen (Fig. 10A), a side lumen in the catheter shaft (Fig. 10B) or tube, the space between the flexing sheath and the catheter and/or the sideports in the guidwire (Fig.10C). Flush can come out of a port at the distal end of the cutter head pointing the flush proximally to facility aspiration . Alternatively, by instilling the flush out the distal end of the cutter housing over the rounded surface, the flow may be directed rearward by the Coanda effect. The restenosis-inhibitors can be carried by microcapsules with tissue adhesives or vecro-like features on the surface to stick to inner vessel surface so that the drug adheres to the treatment site, and to provide a time-release controlled by the resorption or dissolving of the coating to further improve efficacy. Such velcro-like features may be constructed with nanoscale structures made of organic or inorganic materials. Reducing the volume of foreign matter and exposing remaining tissue and extracellular matrix to drugs, stimulation, or sensors can make any of these techniques more effective.

[0085] Another way to infuse fluid is to supply pressurized fluid at the proximal portion of the guidewire lumen (gravity or pressure feed) intravenous bag, for example. A hemostatic seal with a side branch is useful for this purpose; tuohy-borst adapters are one example of a means to implement this.

[0086] Balancing the relative amount of infusion versus fluid volume aspirated allows control over the vessel diameter; aspirating more fluid than is instilled will evacuate the vessel, shrinking its diameter, and allow cutting of lesion at a greater diameter than the atherectomy catheter. This has been a problem for certain open cutter designs that use aspiration, because the aggressive aspiration required to trap the embolic particles evacuates

and collapses the artery around the cutter blades; this is both a performance issue because the cutter can bog down from too high torque load, and the cutter can easily perforate the vessel. The shielded design described here obviates both problems, and further requires less aggressive aspiration to be effective, giving a wider range of control to the user.

[0087] The devices of the present invention may also be used in conjunction with other structures placed in the body lumens. For example, as shown in Fig. 11, one way to protect the vessel and also allow for maximum plaque volume reduction is to deploy a protective structure such as a thin expandable coil or an expandable mesh **182** within a lesion. As this structure expands after deployment, the thin wire coil or the struts push radially outward through the plaque until it becomes substantially flush with the vessel wall. This expansion of thin members requires minimal displacement of plaque volume and minimizes barotrauma produced in balloon angioplasty or balloon expanded stent delivery. Once the protective structure has expanded fully, atherectomy can be performed to cut away the plaque inside to open up the lumen. The vessel wall is protected by the expanded structure because the structure members (coil or struts) resist cutting by the atherectomy cutter, and are disposed in a way that they cannot invaginate into the cutter housing (and thereby be grabbed by the cutter). It is also possible to adjust the angle of the windows on the atherectomy catheter cutter housing so that they do not align with the struts or coils; the adjustment to orientation may be accounted for in the coil or strut design, in the cutter housing design, or both. Furthermore, the protective member can be relatively flexible and have a low profile (thin elements), so that it may be left in place as a stent. Because the stent in this case relies mainly upon atherectomy to restore lumen patency, it may be designed to exert far less radial force as it is deployed. This allows usage of greater range of materials, some of which may not have as high of stiffness and strength such as bioresorbable polymers and metal alloys. Also, this allows a more resilient design, amenable to the mechanical forces in the peripheral arteries. It also minimizes flow disruption, to minimize hemodynamic complications such as thrombosis related to the relatively low flows found in the periphery. It is also possible to perform atherectomy prior to placing the protective structure, whether or not atherectomy is performed after placing the structure.

[0088] Additional variations of systems include devices **100** having a cutting assembly **170** comprising spinning turbine-like coring cutter **172** as shown in Fig. 12A. Fig. 12B

shows a side veiw of the coring cutter **170**. In use, the coring cutter can be hydraulically pushed to drive the sharp edge through tissue. The turbine like cutters has helical blades **174** on the inside of the sharp cylinder housing **176** (shell). The coring cutter **170** may also have spokes or centering devices **184** as shown to center the shell about the guidewire. This helps to keep the cut of the plaque centered about the vessel wall for safety. The spokes also act as an impeller to pull stenotic tissue back and this helps to drive the cutter forward as well as achieve aspiration to minimize embolization. In the hydraulically driven cutter design, an anchor **186** is deployed in tissue and is connected to a backstop **192**. A balloon or hydraulic chamber **188** is then pressurized to expand and pushes the cutting blade **190** forward through the lesion (See Fig. 12I). One advantage of this approach may be that the technique is similar to angioplasty (which involves pumping up a balloon with an endoflator). One means of anchoring is to use an anchoring guidewire, for example, a guidewire with an inflatable balloon to be placed distal to the atherectomy catheter. Alternatively, the technique of anchoring distally can be used with the previously described torque shaft driven atherectomy catheter.

[0089] It is also possible to use the devices and methods described here to restore patency to arterial lesions in the coronary circulation and in the cerebralvalscular circulation, both by debulking de novo lesions and by debulking in stent restenosis.

[0090] For this reason, it can be advantageous to couple atherectomy with stenting. By removing material, debulking the lesion, a lesser radial force is required to further open the artery and maintain lumen diameter. The amount of debulking can be tuned to perform well in concert with the mechanical characteristics of the selected stent. For stents that supply greater expansion and radial force, relatively less atherectomy is required for satisfactory result. An alternative treatment approach is to debulk the lesion substantially, which will allow placement of a stent optimized for the mechanical conditions inherent in the peripheral anatomy. In essence, the stent can support itself against the vessel wall and supply mild radial force to preserve luminal patency. The stent may be bioresorbable, and/or drug eluting, with the resorption or elution happening over a period for days to up to 12 weeks or more. A period of 4 to 12 weeks matches well with the time course of remodeling and return to stability as seen in the classic wound healing response, and in particular the known remodeling time course of arteries following stent procedures. In addition, the stent geometry

can be optimized to minimize thrombosis by inducing swirl in the blood flow. This has the effect of minimizing or eliminating stagnant or recirculating flow that leads to thrombus formation. Spiral construction of at least the proximal (upstream) portion of the stent will achieve this. It is also beneficial to ensure that flow immediately distal to the stent does not create any stagnant or recirculation zones, and swirl is a way to prevent this also.

[0091] The devices and methods described herein also work particularly well in lesions that are challenging to treat with other methods: at bifurcations, in tortuous arteries, and in arteries which are subject to biomechanical stresses (such as in the knee or other joints).

[0092] In a further variation of the devices described here, the motor drive unit may be powered by a controller that varies the speed and torque supplied to the catheter to optimize cutting efficiency or to automatically orbit the cutter using variable speed with a fixed flexible distal length of catheter (or providing further orbiting control by controlling the length of the distal flexible section of the catheter).

[0093] It is also possible to use feedback control to operate the catheter in a vessel safe mode, so that the rate of cutting is decreased as the vessel wall is approached. This may be accomplished through speed control, or by reducing the degree to which the cutting blades penetrate above the housing window by retracting the cutter axially within the housing. Feedback variables could be by optical (infrared) or ultrasound transducer, or by other transducers (pressure, electrical impedance, etc.), or by monitoring motor performance. Feedback variables may also be used in safety algorithms to stop the cutter, for example in a torque overload situation.

[0094] The atherectomy catheter may be further configured with a balloon proximal to the cutter, for adjunctive angioplasty or stent delivery. The catheter may optionally be configured to deliver self-expanding stents. This provides convenience to the user and greater assurance of adjunctive therapy at the intended location where atherectomy was performed.

[0095] Further methods include use of similar devices to debulk stenosis in AV hemodialysis access sites (fistulae and synthetic grafts), as well as to remove thrombus. By removing the cutter housing and recessing the fluted cutter within the catheter sheath, a suitable non-cutting thrombectomy catheter may be constructed.

[0096] Other methods of use include excising bone, cartilage, connective tissue, or muscle during minimally invasive surgical procedures. For example, a catheter that includes cutting

and burr elements may be used to gain access to the spine for performing laminectomy or facetectomy procedures to alleviate spinal stenosis. For this application, the catheter may be further designed to deploy through a rigid cannula over part of its length, or have a rigid portion itself, to aid in surgical insertion and navigation.

[0097] Fig. 13 illustrates another variation of a device for clearing obstructions within body lumens. In some cases where a vessel is totally occluded, a tough fibrous or calcific cap 6 completely or almost completely blocks the lumen. Because of this blockage, fluid cannot flow past the occlusion. This stagnation also makes it difficult or impossible to properly insert a wire across the lesion with an atherectomy device or stiff catheter.

[0098] In a typical case of a total occlusion, it is also difficult if not impossible to visualize the lumen near the occlusion because any injected contrast agents cannot flow through the occlusion site.

[0099] Fig. 13A shows a system for treating total occlusions. The system can include a support catheter comprising a support tube or catheter **200**, having a central lumen **202**, the catheter may include side lumens or ports **206**, for flush and aspiration. The catheter central lumen **202** can be used to deliver contrast agents **208**. In addition, tip centering mechanisms, and an atraumatic tip can be useful. The support catheter can be used with any lumen-creating device **210**, such as the devices **100** described above, a laser catheter, an RF probe, or an RF guidewire. When using a coring cutter as shown in Fig. 13, the cutter can have a sharp edge at its tip, helical flutes, helical grooves, or any other mechanism that enables penetration of the fibrous or calcific cap. The cutter and the shaft can be advanced forward within the support catheter, and one or more balloons or baskets can also be deployed by the support catheter to help center it in the vessel.

[0100] The lumen-creating device **200** can optionally be made to have a shoulder **212** at its distal end, as shown in Figure 13A. The shoulder **212** acts as a stop to limit the depth at which the device **200** protrudes beyond the support catheter **200**. Such a safety measure may be desired to protect the vessel wall. Driving the device **200** through the tough fibrous cap creates a lumen in the cap. A guidewire may then be placed into the lumen created in the fibrous cap. The coring cutter may be removed with the core.

[0101] Next, a guidewire can be used with a cutter assembly to remove some or all of the remaining mass in the vessel. Alternatively, the initial lumen made may be adequately large

without further atherectomy. Technical success is typically less than 30 percent or less than 20 percent residual stenosis. Also, balloon angioplasty with or without stenting may be performed following establishment of a guidewire lumen with a support catheter and a lumen-creating catheter.

[0102] Contrast injection and aspiration ports near the distal end of the support circulate contrast agents, enabling the use of fluoroscopy to visualize the lumen adjacent to the total occlusion during diagnosis or treatment. The central lumen **202** of the support catheter **200** can also be used to inject or aspire the contrast agents **208**. The contrast agents can circulate through the center lumen **202** in the support catheter **200** and at least one port **206** in various configurations. The fluid can circulate about the distal tip of the catheter, the motion of the fluid being circular as shown in Fig. 13B. For example, the fluid can be injected through the central lumen **202**, travel around the distal tip, and then is aspirated back into the support catheter through ports **206** on the side of the surface of the support catheter **200.** To illustrate another possible configuration, the fluid can be ejected through the side ports, and then aspired through the central lumen. This recirculation of the contrast agent permits imaging of the vessel at the site of the occlusion.

[0103] It is noted that the descriptions above are intended to provide exemplary embodiments of the devices and methods. It is understood that, the invention includes combinations of aspects of embodiments or combinations of the embodiments themselves. Such variations and combinations are within the scope of this disclosure.

CLAIMS

We claim:

1. A device for removing material from body lumens, the device comprising:

a catheter body having a proximal end and a distal end;

a cutter assembly located at the distal end of the catheter body, the cutter assembly comprising a housing having at least one opening and a cutter having at least one cutting surface configured to rotate relative to the housing, where movement of the cutter relative to the housing removes tissue surrounding the housing;

a rotating shaft extending through the catheter body and coupled to the cutter, the shaft having a proximal end adapted to couple to a first rotating mechanism; and

a deflecting member extending along the catheter body, such that movement of the deflecting member causes deflection of the cutter assembly relative to an axis of the catheter.

2. The device of claim 1, where the catheter body is coupled to a fluid source.

3. The device of claim 1, where the catheter body is coupled to a vacuum source.

4. The device of claim 1, where the rotating shaft is coupled to a rotating mechanism.

5. The device of claim 1, where the deflecting member comprises a steerable sheath adapted to deflect in shape.

6. The device of claim 5, where the steerable sheath comprises a deflecting wire extending through a portion of the sheath, such that axial movement of the deflecting wire deflects the sheath.

7. The device of claim 6, where the deflecting wire is affixed to the cutter assembly.

8. The device of claim 6, where the deflecting wire is affixed to a portion of the catheter body that extends out of the deflecting sheath.

9. The device of claim 5, where the sheath is rotatable about the catheter body.

10. The device of claim 5, where the sheath is rotatable about an axis of the catheter.

11. The device of claim 1, where the deflecting member comprises a pre-shaped mandrel slidably located in the catheter body, where at least the distal end of the catheter body assumes the shape of the pre-shaped mandrel when the mandrel is advanced therein.

12. The device of claim 1, where the deflecting member comprises a pre-shaped tube slidably located in the catheter body, where at least the distal end of the catheter body assumes the shape of the pre-shaped tube when the pre-shaped portion of the tube is advanced therein

13. The device of claim 12, where a degree of deflection of the catheter body increases as the pre-shaped portion of the tube advances therein.

14. The device of claim 1, where the deflecting member comprises a slidable sheath having a fixed curved shape, such that advancement of the slidable sheath over the flexible portion of the catheter body causes the catheter body to assume the curved shape of the sheath.

15. The device of claim 14, where the sheath is rotatable about the catheter body.

16. The device of claim 14, where the catheter body is rotatable within the sheath.

17. The device of claim 1, where the deflecting member comprises a steerable guidewire extending through the catheter body.

18. The device of claim 1, where the deflecting member comprises a mandrel slidably located in the catheter body and extendable out of a distal surface of the catheter body, where upon extending out of the distal surface pushes against tissue to deflect the distal end of the catheter body.

19. The device of claim 1, where a portion of the housing comprises a curved surface and the opening forms a plane across the curved surface such that as the cutting surface rotates across the opening, a portion of the cutting surface extends out of the housing through the opening.

20. The device of claim 1, where the torque shaft and cutter each have a lumen allowing for advancement of a guidewire therethrough.

21. The device of claim 1, further comprising a guidewire track having a lumen, where at least a portion of the guidewire track is exterior to the catheter body.

22. The device of claim 1, cutter comprises a plurality of flutes and the cutting surface is an edge of the flute.

23. The device of claim 22, where the cutting surface of the flute is helical.

24. The device of claim 22, where each flute is arranged relative to the openings in the housing such that during operation, a total length of the cutting surface exposed through the housing openings remains the same.

25. The device of claim 1, further including a ferrule linking the housing to the said outer tube on the catheter body.

26. The device of claim 1, where the torque shaft has at least one helical conveyor member wound about an exterior such that rotation of the torque shaft conveys material along the length of the torque shaft.

27. The device of claim 1, where the helical conveyor member is wound in the same rotational sense as the helical flutes on the cutter

28. The device of claim 1, where a guide-wire portion is fixedly attached to the distal end of the cutter.

29. The device of claim 1, further comprising a burr rotatably located on a tip of the cutter assembly.

30. The device of claim 1, where the deflecting member is lockable to fix the deflection of the catheter.

31. The device of claim 1, where the deflecting member has sufficient friction to lock the catheter relative to the deflecting member.

32. A device for removing material from body lumens, the device comprising:

a straightening tube, having a straight distal portion;

a catheter body having a proximal end and a distal end, the catheter body having a flexible distal section, such that when located in the distal portion of the shaping tube the flexible distal section takes the shape of the shaping tube;

a cutter assembly located at the distal end of the catheter body, the cutter assembly comprising a housing having at least one opening and a cutter having at least one cutting surface configured to rotate relative to the housing, where movement between the housing opening and the cutting surface removes material surrounding the housing; and

a rotating shaft extending through the catheter body and coupled to the cutter, the torque shaft having a proximal end adapted to couple to a first rotating mechanism.

33. The device of claim **32**, where the flexible section of the catheter body comprises a curved shape and the straight distal portion of the straightening tube comprises a substantially straight shape such that when located in the straight distal portion the flexible section of the catheter straightens.

34. The device of claim 33, where the catheter body is coupled to a second rotating mechanism, such that when the curved section is advanced out of the straightening tube, rotation of the catheter body causes the cutter assembly to move in curved path about the catheter body axis.

35. The device of claim 34, further comprising a locking hub configured to lock the catheter body relative to the straightening tube such that the arc may have a constant radius.

36. The device of claim 32, where the flexible section of the catheter body comprises a substantially straight shape and the distal portion comprises a curved shape such that when located in the stiff distal section the flexible section of the catheter assumes the curved shape.

37. The device of claim 36, where the outer sheath is coupled to a second rotating mechanism, such that when advanced over the in the stiff distal section, rotation of the catheter body causes the cutter assembly to move in an arc.

38. The device of claim 37, further comprising a locking hub configured to lock the catheter body relative to the steering member body relative to the steering member such that the arc may have a constant radius.

39. The device of claim 32, where a portion of the housing comprises a curved surface and the opening forms a plane across the curved surface such that as the cutting surface rotates across the opening, a portion of the cutting surface extends out of the housing through the opening.

40. The device of claim 32, where the torque shaft and cutter assembly each have a lumen allowing for advancement of a guidewire therethrough.

41. The device of claim 32, cutter comprises a plurality of flutes where the cutting surface is an edge of the flute.

42. The device of claim 41, where the cutting surface of the flute is helical.

43. The device of claim 41, where each flute is arranged relative to the openings in the housing such that during a total length of the cutting surface exposed in the housing opening remains the same.

44. The device of claim 32, further including a ferrule linking the housing to the said outer tube on the catheter body.

45. The device of claim 32, where the shaft has at least one helical conveyor member wound about an exterior such that rotation of the torque shaft conveys material across a length of the torque shaft.

46. The device of claim 32, where the helical conveyor member is wound in the same rotational sense as the helical flutes on the cutter

47. The device of claim 32, where a guide-wire portion is fixedly attached to the cutter.

48. The device of claim 32, where the deflecting member comprises a wire extending along a length of the flexible catheter.

49. A device for removing material from body lumens, the device comprising:

a steering member;

a catheter body having a stiffer proximal portion and a more flexible distal portion;

a steering member located along the catheter body, the steering member having a curved section located towards the distal end such that as the curved section advances further along the flexible distal portion, the flexible distal portion begins to assume a curved shape;

a cutter assembly located at the distal end of the catheter body, the cutter assembly comprising a housing having at least one opening and a cutter having at least one cutting surface configured to rotate relative to the housing, where movement between the housing opening and the cutting surface removes material surrounding the housing; and

a rotating shaft extending through the catheter body and coupled to the cutter, the torque shaft having a proximal end adapted to couple to a first rotating mechanism.

50. The device of claim 49, where the deflecting member comprises a mandrel slidably located in the catheter body and extendable out of a distal opening of the catheter body, where upon extending out of the distal opening to push against tissue to deflect the distal end of the catheter body.

51. The device of claim 49, where a portion of the housing comprises a curved surface and the opening forms a plane across the curved surface such that as the cutting surface rotates across the opening, a portion of the cutting surface extends out of the housing through the opening.

52. The device of claim 49, where the torque shaft and cutter each have a lumen allowing for advancement of a guidewire therethrough.

53. The device of claim 49, cutter comprises a plurality of flutes and the cutting surface is an edge of the flute.

54. The device of claim 53, where the edge of the flute is helical.

55. The device of claim 53, where each flute is arranged relative to the openings in the housing such that during a total length of the cutting surface exposed in the housing opening remains the same.

56. The device of claim 49, further including a ferrule linking the housing to the said outer tube on the catheter body.

57. The device of claim 49, where the shaft has at least one helical conveyor member wound about an exterior such that rotation of the torque shaft conveys material across a length of the torque shaft.

58. The device of claim 49, where the helical conveyor member is wound in the same rotational sense as the helical flutes on the cutter

59. The device of claim 49, where a guide-wire portion is fixedly attached to the cutter.

60. The device of claim 49, where the deflecting member comprises a wire extending along a length of the flexible catheter.

61. The device of claim 49, further comprising a burr rotatably located on a tip of the cutter assembly.

62. A method for debulking material within a totally or partially occluded blood vessel, the method comprising:

inserting a catheter body having a cutter assembly near a distal end of the catheter body within the blood vessel;

rotating a cutter in the cutter assembly to remove the material and form a first opening in the body lumen;

deflecting a distal portion of the catheter relative to an axis of the catheter body; and

rotating the deflected distal portion of the catheter while rotating the cutter to form a second opening in the body lumen where the second is larger than the first opening.

63. The method of claim 62, further comprising providing a burr surface on a distal end of the catheter body, and grinding a hardened material in the blood vessel with the burr surface.

64. The method of claim 62, where the cutter assembly comprises at least one cutter edge, where the cutter edge protrudes beyond an outer surface of a housing surrounding the cutter assembly to cut tissue outside the housing

65. The method of claim 62, where, the cutter is rotated such that only a partial number of cutter edges are aligned with the openings in the housing.

66. The method of claim 62, where the catheter body includes a guidewire lumen and where inserting the catheter body within the blood vessel comprises advancing the catheter body over a guidewire.

67. The method of claim 62, where the catheter head is deflected by a deflecting sheath coupled to the catheter body.

68. The method of claim 67, where the deflecting sheath is rotated to orient the deflected tip in the desired direction.

69. The method of claim 62, where the catheter head is deflected by a pre-shaped mandrel slidably located in the catheter body, where at least the distal end the catheter body assumes the shape of the pre-shaped mandrel when advanced therein.

70. The method of claim 62, where the catheter head is deflected by a pre-shaped tube slidably located in the catheter body, where at least the distal end the catheter body assumes the shape of the pre-shaped mandrel when advanced therein

71. The method of claim 62, where deflecting the catheter body comprises advancing a pre-curved sheath distally along the catheter body.

72. The method of claim 62, where the catheter tip is deflected by positioning the offset curve on the wire near the catheter tip.

73. The method of claim 62, where deflecting the cutter assembly relative to the axis of the catheter body further includes locking the cutter assembly in position relative to the axis of the catheter body.

74. The method of claim 62, where a distal portion of the catheter body includes at least one fluid port coupled to a fluid source, and further comprising delivering fluid through the fluid port.

75. The method of claim 62, further comprising withdrawing fluid and the material through the cutter assembly.

76. The method of claim 75, further comprising providing a helical conveyor member within the catheter body and transporting the debris material out of the body via helical conveyor member.

77. The method of claim 62, further comprising providing a guidewire through the cutter assembly, where the guidewire includes a fluid delivery lumen terminating in a guidewire fluid delivery port, the method further comprising delivering fluid through the guidewire fluid delivery port

78. A device for removing material from body lumens, the device comprising:

a catheter body having a proximal portion and a distal portion;

a steering tube having varying stiffness along its circumference at the distal portion;

a cutter assembly located at the distal end of the catheter body, the cutter assembly comprising a housing having at least one opening and a cutter having at least one cutting surface configured to rotate relative to the housing, where movement between the housing opening and the cutting surface removes material surrounding the housing; and

the distal portion of the steering tube is attached to the cutter assembly.

79. A device of claim 78, where tension on the steering tube deflects the distal portion of the catheter

80. A device of claim 78, where compression of the steering tube deflects the distal portion of the catheter.

81. A vascular device for circulation of fluid for contrast, the device comprising:

a support catheter body having a proximal end and a distal end, the distal end containing at least one port on the surface for injection or aspiration of fluid.

82. The device of claim 81, where the support catheter body contains a mechanism to position itself within the vessel.

83. The device of claim 82, where the mechanism is at least one balloon.

84. The device of claim 82, where the mechanism is at least one basket.

85. The device of claim 82, where the mechanism is at least one coil.

86. The device of claim 82, where the mechanism is at least one leg.

87. The device of claim 82, where the mechanism is at least one loop.

88. The device of claim 81, where the support catheter body comprises a shoulder at the distal end that acts as a stop for a cutter.

89. The device of claim 81, where the support catheter comprises an atraumatic tip.

90. The device of claim 82, where the expanding member is configured to expand asymmetrically to angle the distal aspect of the support catheter relative to the proximal axis of the proximal vessel lumen.

91. A device for supporting a catheter within a lumen of the body comprising:

a proximal and a distal end;

a central lumen;

an expandable member near a distal portion of the device, where the member is configured to expand to position the centerline of the device at its distal end at some angular rotation and position relative to the centerline of the body lumen.

92. A device for debulking material in an occluded body lumen, the device comprising:

a support catheter with a proximal and a distal end;

a coring cutter with a mechanism that enables it to create a lumen through a fibrous or calcific cap.

93. The device of claim 92, where the support catheter comprises a support catheter body having a proximal end and a distal end, the distal end containing at least one port on the surface for injection or aspiration of fluid.

94. The device of claim 92, where the support catheter contains a mechanism to position itself within the vessel.

95. The device of claim 92, where the support catheter body comprises a shoulder at the distal end that acts as a stop for the coring cutter.

96. The device of claim 92, where the coring cutter comprises a shoulder at the distal end that allows it to stop against the shoulder of the support catheter.

97. The device of claim 92, where the coring cutter comprises a sharp edge at its tip at the distal end.

98. The device of claim 92, where the coring cutter comprises helical flutes.

99. The device of claim 92, where the coring cutter comprises helical grooves.

100. A method for circulating fluid for contrast, the method comprising:

inserting the support catheter within the blood vessel, where the support catheter comprises a support catheter body having a proximal end and a distal end, the distal end containing at least one port on the surface for injection or aspiration of fluid;

injecting the fluid for contrast through a lumen or port in the support catheter body; and

aspirating the fluid for contrast into a lumen or port in the support catheter body.

101. The method of claim 100, where the support catheter is centered within the blood vessel using at least one basket or at least one balloon.

102. The method of claim 100, further comprising:

inserting a catheter body having a coring cutter assembly within the blood vessel;

driving the coring cutter assembly through the tough fibrous cap in the vessel to form a first body opening in the vessel;

removing the coring cutter assembly from the body;

inserting a second cutter assembly with a guidewire, where the guidewire is inserted through the first opening.

103. The method of claim 128, where the coring cutter assembly contains a shoulder that rests upon the support catheter.

104. The method of 128, where the coring cutter assembly comprises a helical groove or cylinder to drive itself through the tough fibrous cap.

105. The method of claim 128, where the coring cutter collects the cored-out portion of the tough fibrous cap.

106. A method for non-invasively imaging a vessel, the method comprising:

advancing a device having a first lumen and a second lumen;

delivering a contrast agent through the first lumen of the device into the vessel at a location adjacent to an occlusion in the vessel, where the occlusion prevents flow of the contrast agent distally to the occlusion;

aspirating the contrast agent from the vessel through the second lumen; and

non-invasively imaging the contrast agent in the vessel.

107. The method of claim 106, where the occlusion comprises a total occlusion.

108. The method of claim 106, further creating a passage through the occlusion with the device.

109. The method of claim 108, where the device further includes a cutter assembly located at the distal end of the device, the cutter assembly comprising a housing having at least one opening and a cutter having at least one cutting surface configured to rotate relative to the housing, where movement between the housing opening and the cutting surface removes material located therebetween; and where creating the passage comprises rotating the cutter assembly such that the cutter removes portions of the occlusion.

110. The method of claim 108, where the device further includes a coring cutter, and where the coring cutter creates the passage through the occlusion.

111. The method of claim 106, further comprising passing a guidewire through the occlusion.

112. The method of claim 106, where the device further includes a cutter assembly located at the distal end of the device, further comprising sweeping the cutter assembly in an expanded profile to remove portions of the occlusion.

113. The method of claim 106, further comprising conveying debris from the occlusion through the device.

114. The method of claim 113, where the device further comprises at least one helical conveyor member extending therethrough such that that rotation conveyor member causes debris to move through the device.

115. The method of claim 106, where the device further comprises a burr rotatably located on a tip of the device, and where the occlusion comprises a fibrous cap, the method further comprising rotating the burr against the fibrous cap.

116. A method for circulating a contrast agent in a vessel proximal to a site of a total occlusion, the method comprising:

advancing a device to the site, where the total occlusion prevents fluid flow distally through the vessel;

delivering the contrast agent to the site through the device;

aspirating the contrast agent from the site through the device; and

non-invasively imaging the contrast agent in the vessel.

117. The method of claim 116, where the device comprises at least two lumens, where a first lumen delivers the contrast agent, and the second lumen aspirates the contrast agent.

118. The method of claim 116, creating a passage through the occlusion with the device until the non-invasive imaging shows the contrast agent to pass through the site of the occlusion.

119. The method of claim 118, where the device further includes a cutter assembly located at the distal end of the device, the cutter assembly comprising a housing having at least one opening and a cutter having at least one cutting surface configured to rotate relative to the housing, where movement between the housing opening and the cutting surface removes material located therebetween; and where creating the passage comprises rotating the cutter assembly such that the cutter removes portions of the occlusion.

120. The method of claim 118, where the device further includes a coring cutter, and where the coring cutter creates the passage through the occlusion.

121. The method of claim 116, further comprising passing a guidewire through the occlusion.

122. The method of claim 116, where the device further includes a cutter assembly located at the distal end of the device, further comprising sweeping the cutter assembly in an expanded profile to remove portions of the occlusion.

123. The method of claim 116, further comprising conveying debris from the occlusion through the device.

124. The method of claim 123, where the device further comprises at least one helical conveyor member extending therethrough such that that rotation conveyor member causes debris to move through the device.

125. The method of claim 116, where the device further comprises a burr rotatably located on a tip of the device, and where the occlusion comprises a fibrous cap, the method further comprising rotating the burr against the fibrous cap.

126. A method for circulating fluid for contrast, the method comprising:

inserting a support catheter within the blood vessel, where the support catheter comprises a support catheter body having a proximal end and a distal end, the distal end containing at least one port on the surface for injection or aspiration of fluid;

injecting the fluid for contrast through a lumen or port in the support catheter body; and

aspirating the fluid for contrast into a lumen or port in the support catheter body.

127. The method of claim 126, where the support catheter is centered within the blood vessel using at least one basket or at least one balloon.

128. The method of claim 126, further comprising:

inserting a catheter body having a coring cutter assembly within the blood vessel;

driving the coring cutter assembly through the tough fibrous cap in the vessel to form

a first body opening in the vessel;

removing the coring cutter assembly from the body;

inserting a second cutter assembly with a guidewire, where the guidewire is inserted through the first opening.

129. The method of claim 128, where the coring cutter assembly contains a shoulder that rests upon the support catheter.

130. The method of 128, where the coring cutter assembly comprises a helical groove or cylinder to drive itself through the tough fibrous cap.

131. The method of claim 128, where the coring cutter collects the cored-out portion of the tough fibrous cap.

132. A method for clearing a total occlusion from a vessel, the method comprising:

advancing a support catheter the vessel and adjacent to the occlusion,

centering the support catheter in the vessel and adjacent to the occlusion;

advancing a lumen creating device within the support catheter to the occlusion;

circulating a contrast agent adjacent on a single side of the occlusion to visualize the vessel adjacent to the occlusion; and

creating a passage in the occlusion with the lumen creating device.

133. The method of claim 132, where circulating the contrast agent comprises injecting the contrast agent to the vessel through the support catheter and aspirating the contrast agent from the vessel through the support catheter.

134. The method of claim 132, where circulating the contrast agent comprises injecting the contrast agent to the vessel through the lumen creating device and aspirating the contrast agent from the vessel through the lumen creating device.

135. The method of claim 132, where circulating the contrast agent comprises injecting the contrast agent to the vessel through the support catheter and aspirating the contrast agent from the vessel through the lumen creating device.

136. The method of claim 132, where the lumen creating device is selected from the group consisting of a cutting device, a laser catheter, an RF probe, and an RF guidewire.

137. The method of claim 132, where the lumen creating device comprises a coring cutting device.

138. The method of claim 132, where the lumen creating device further comprises a shoulder to limit the degree of which the lumen creating device extends from the support catheter.

139. The method of claim 132, where the lumen creating device device further includes a cutter assembly located at the distal end of the device, the cutter assembly comprising a housing having at least one opening and a cutter having at least one cutting surface configured to rotate relative to the housing, where movement between the housing opening and the cutting surface removes material surrounding the housing; and where creating the passage comprises rotating the cutter assembly such that the cutter removes portions of the occlusion.

140. The method of claim 132, further comprising passing a guidewire through the passage.

141. The method of claim 132, further comprising conveying debris from the occlusion through the lumen creating device.

142. The method of claim 141, where the device further comprises at least one helical conveyor member extending therethrough such that that rotation conveyor member causes debris to move through the device.

143. The method of claim 132, where the lumen creating device further comprises a burr rotatably located on a tip of the lumen creating device, and where the occlusion comprises a cap, the method further comprising rotating the burr against the cap.

144. The method of claim 132, where the cap is a fibrous cap or a calcific cap.

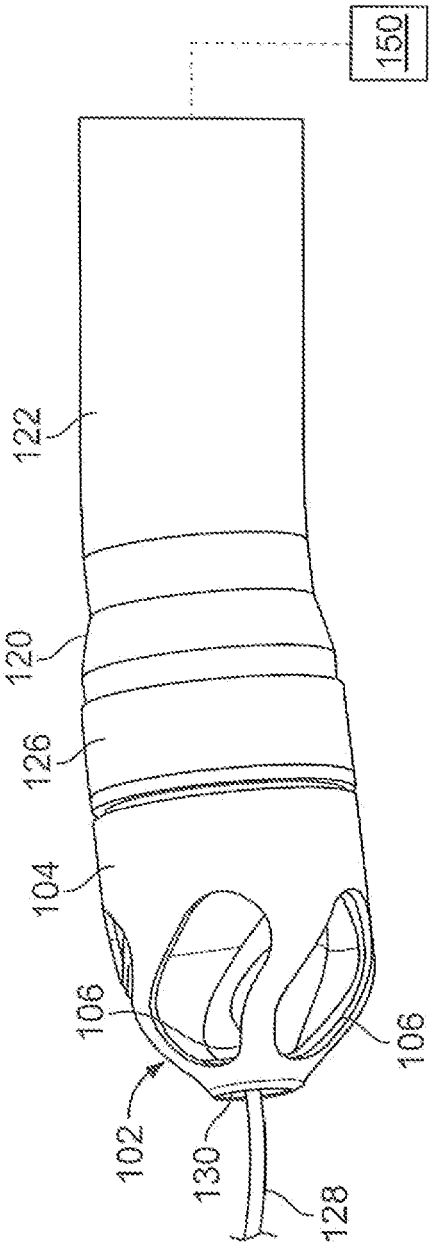
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FIG. 1A

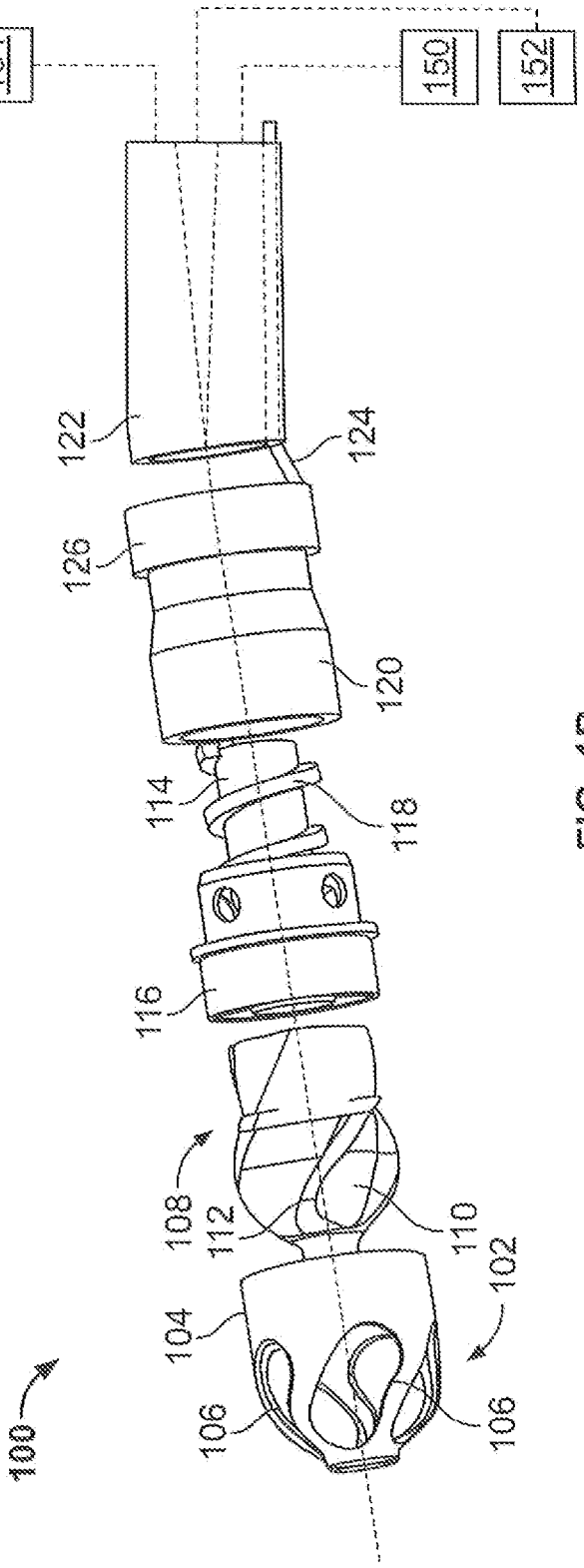
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FIG. 1B

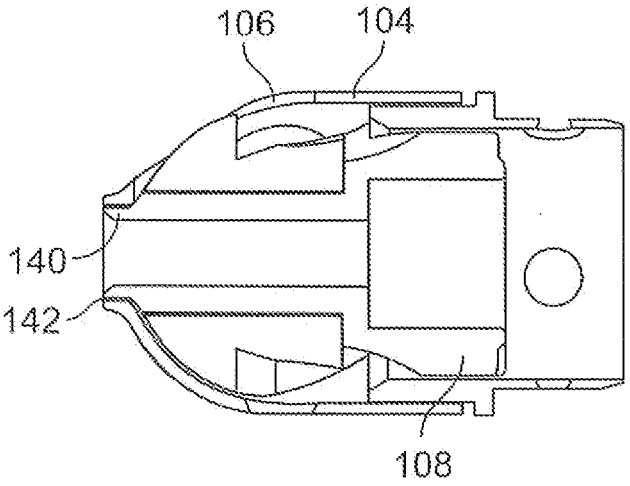

FIG. 1C

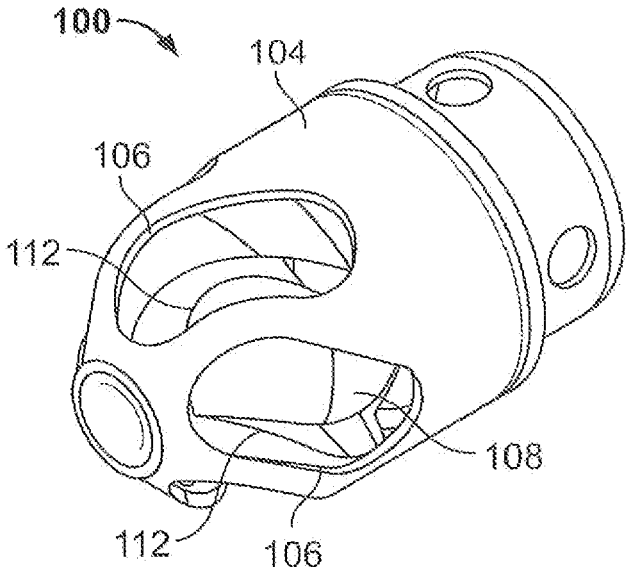

FIG. 2A

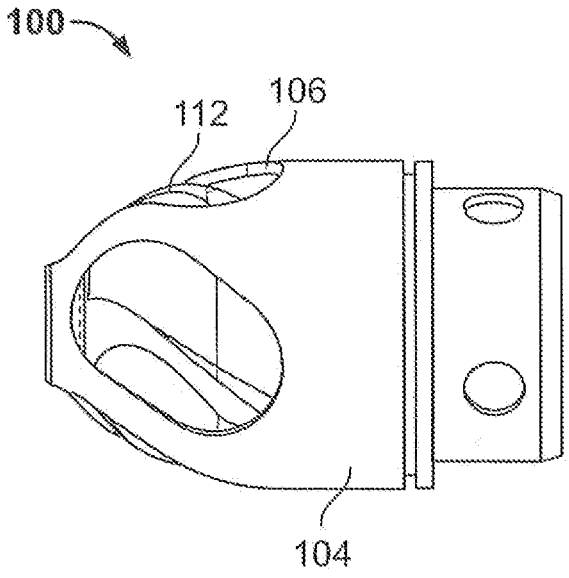

FIG. 2B

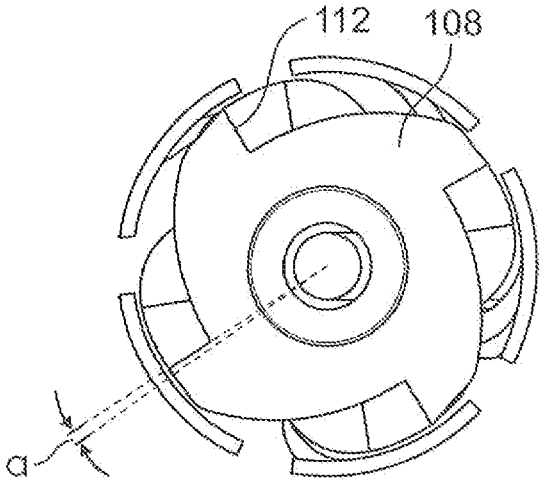

FIG. 2C

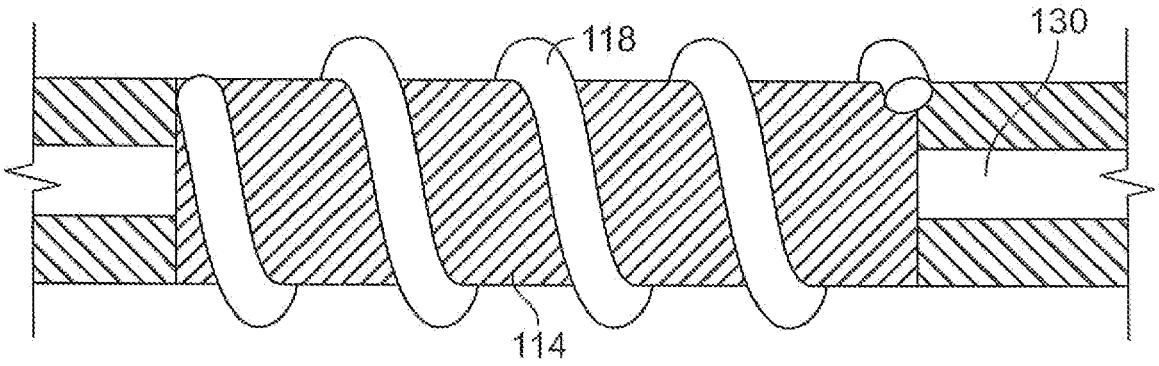

FIG. 3

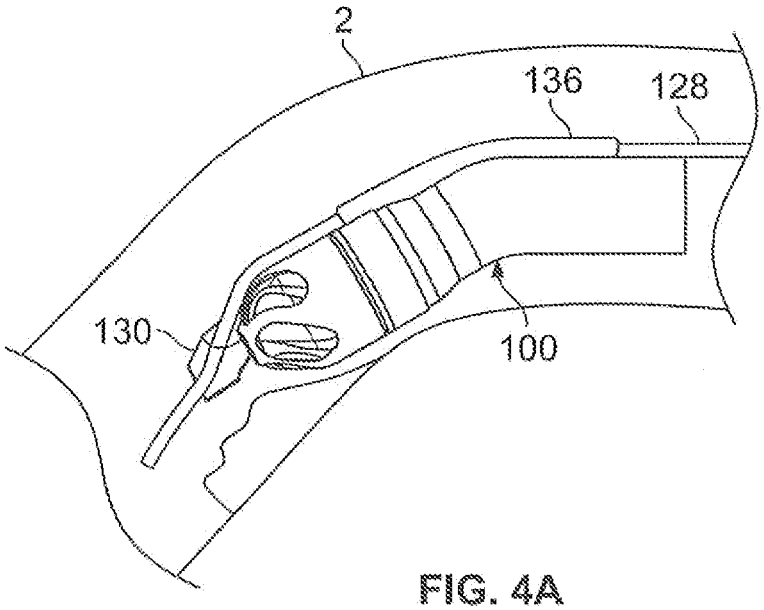

FIG. 4A

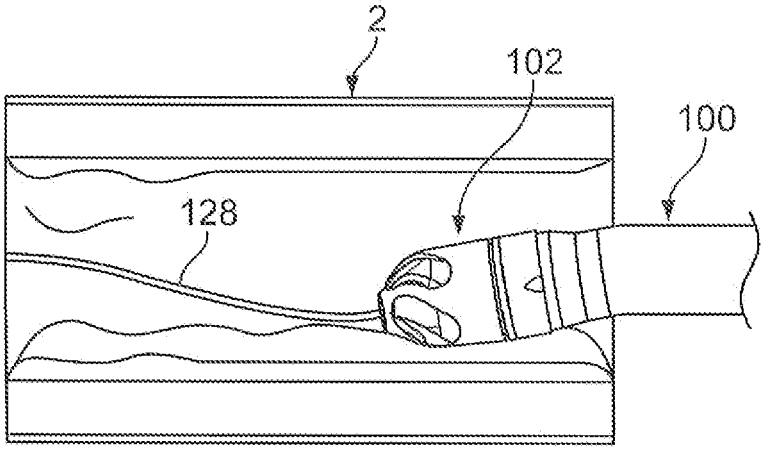

FIG. 4B

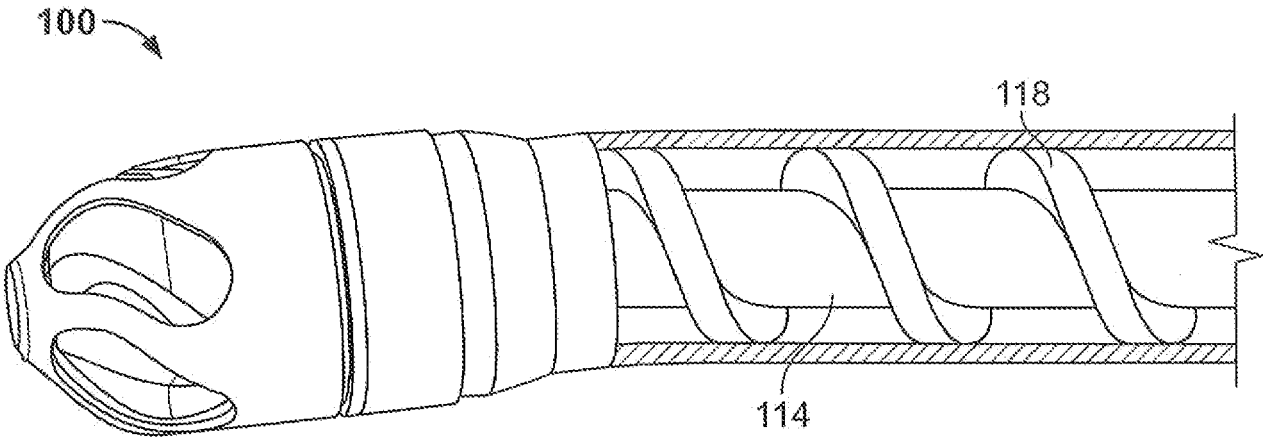

FIG. 5A

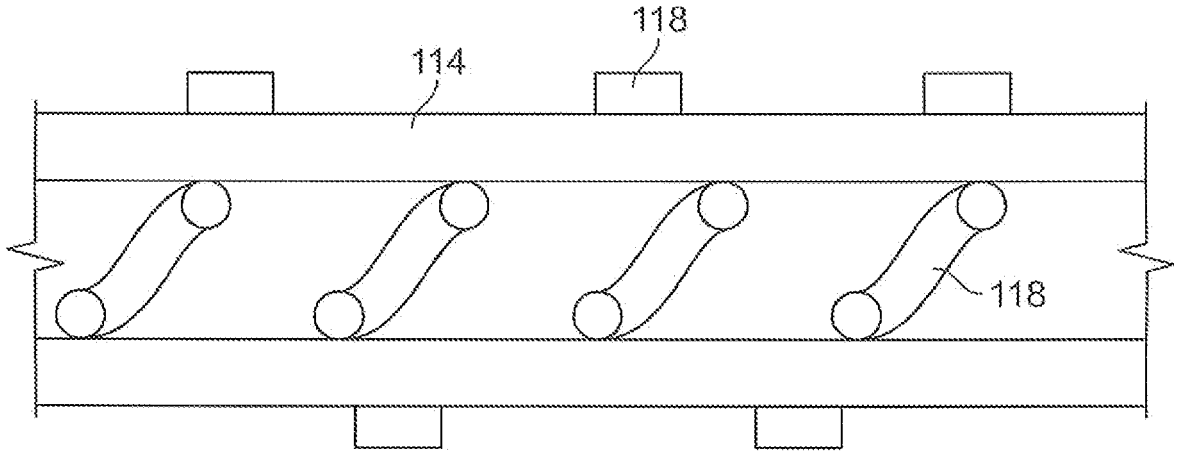

FIG. 5B

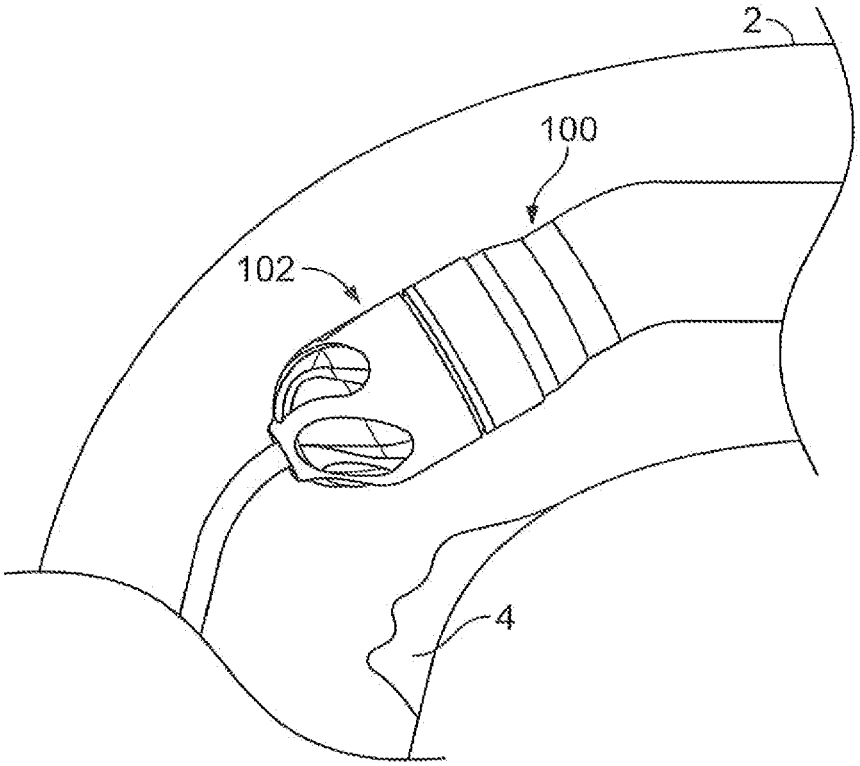

FIG. 6A

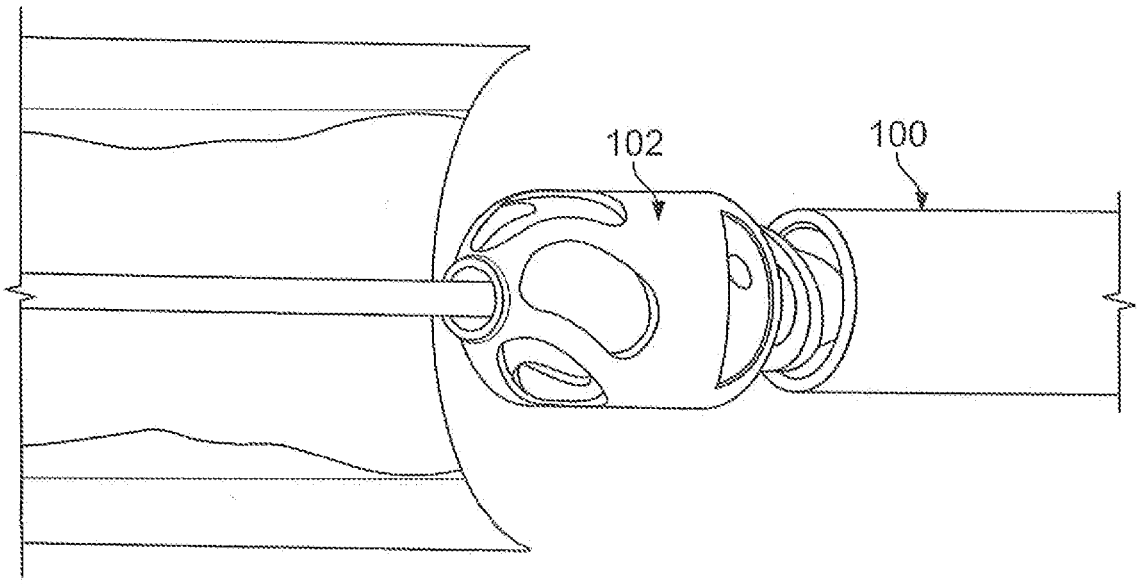

FIG. 6B

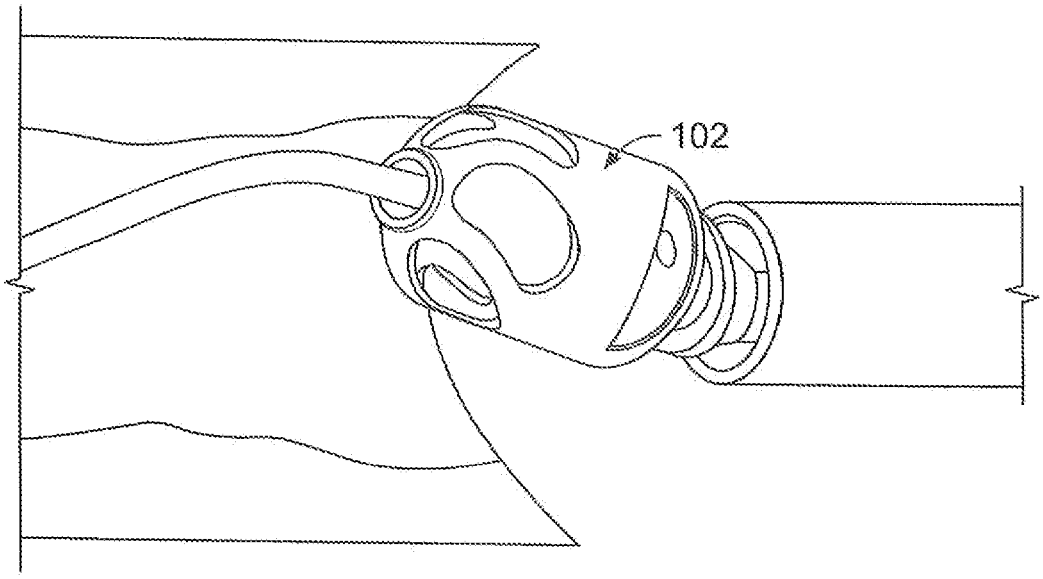

FIG. 6C

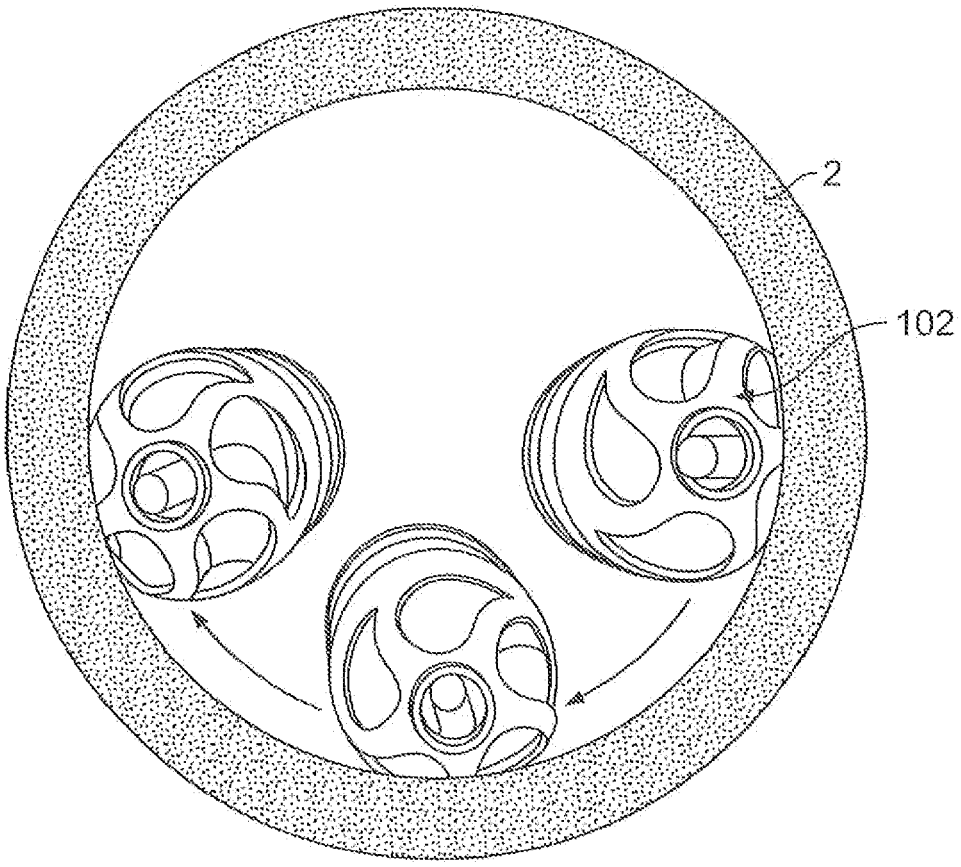

FIG. 6D

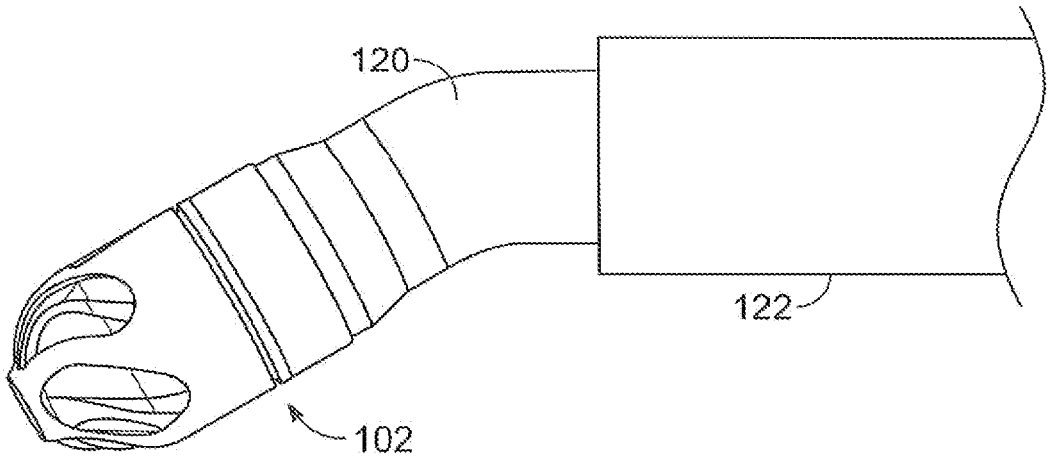

FIG. 6E

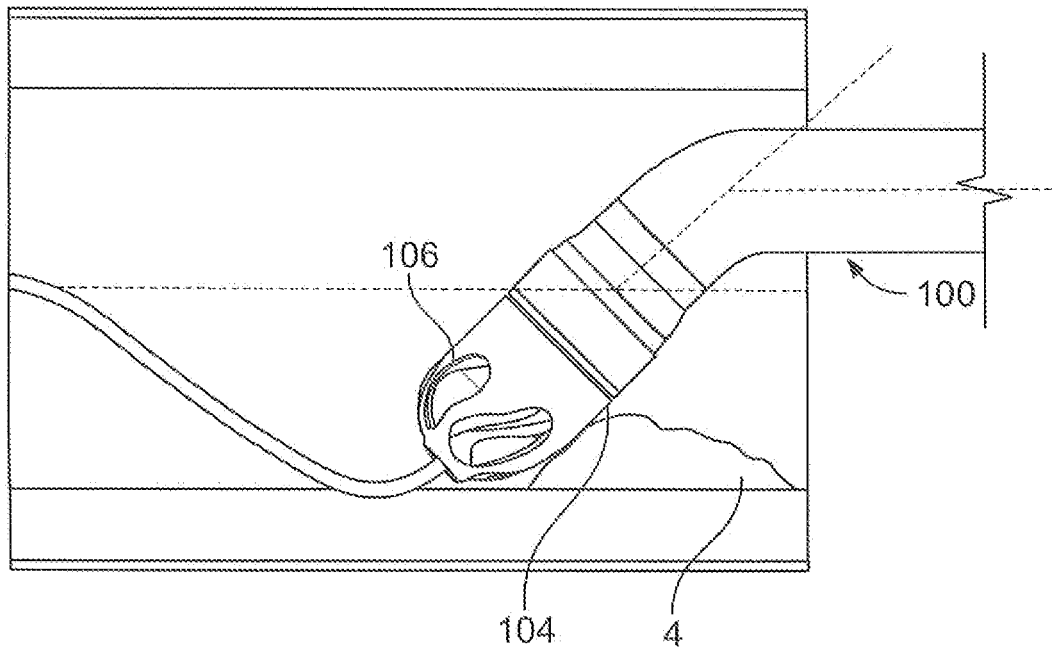

FIG. 7

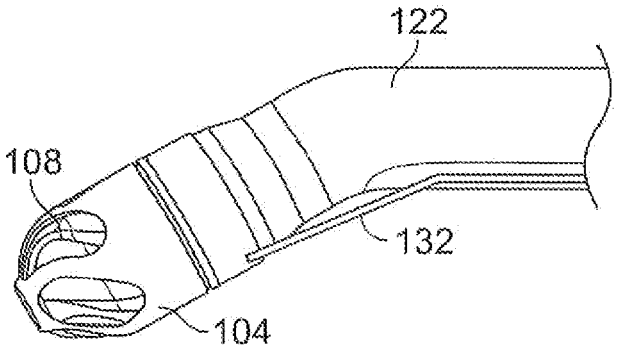

FIG. 8A

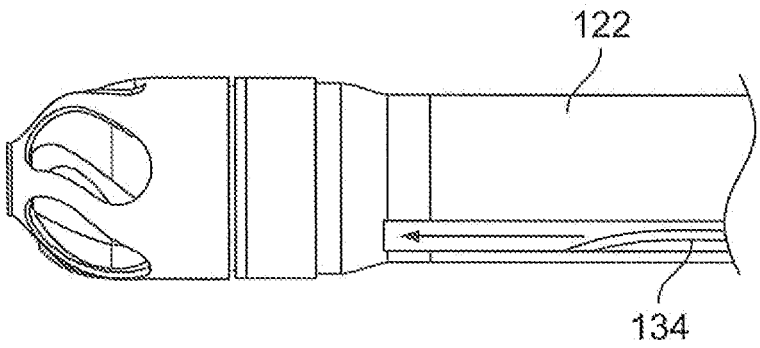

FIG. 8B

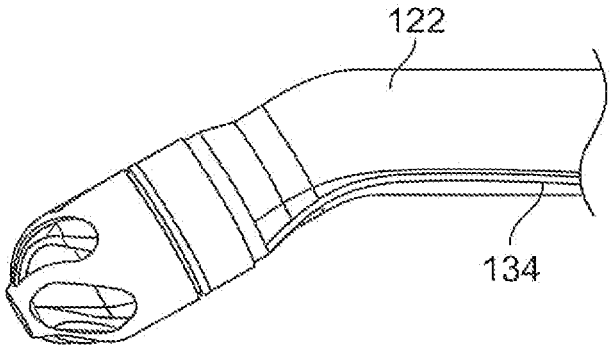

FIG. 8C

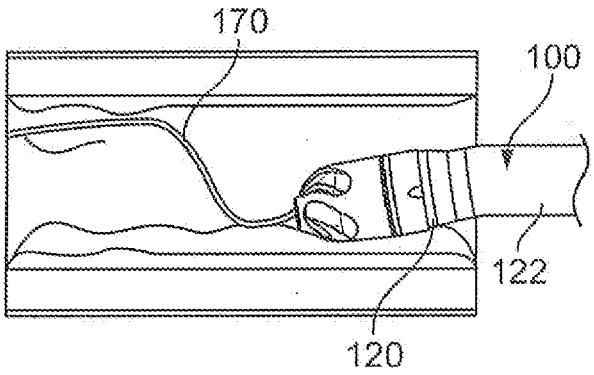

FIG. 8D

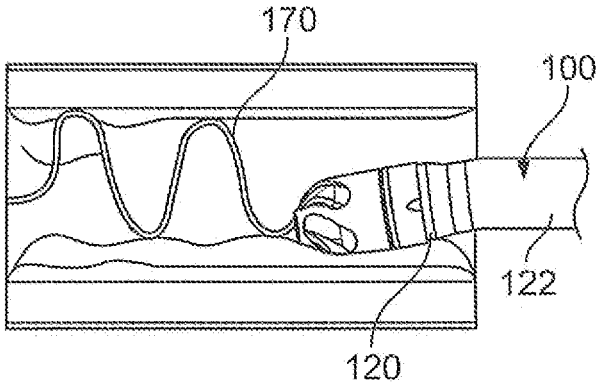

FIG. 8E

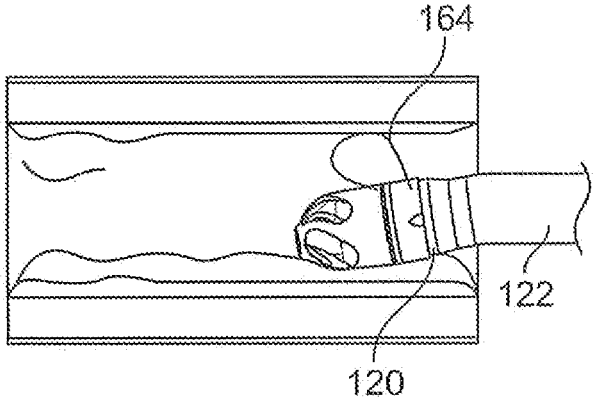

FIG. 8F

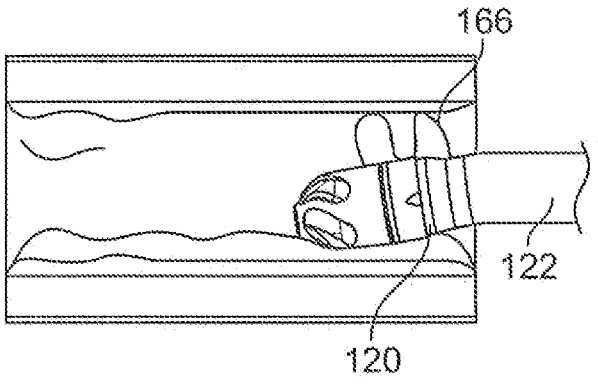

FIG. 8G

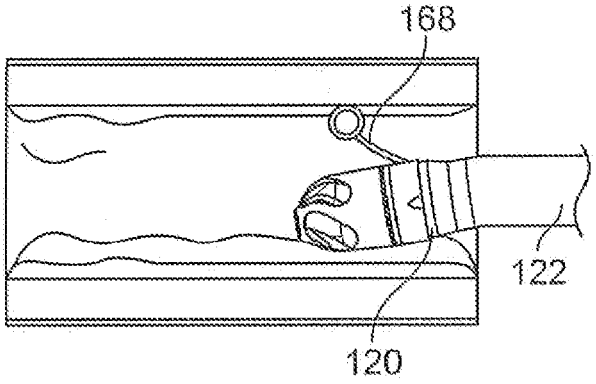

FIG. 8H

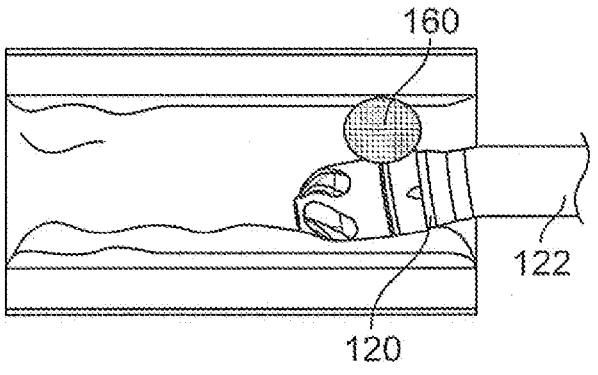

FIG. 8I

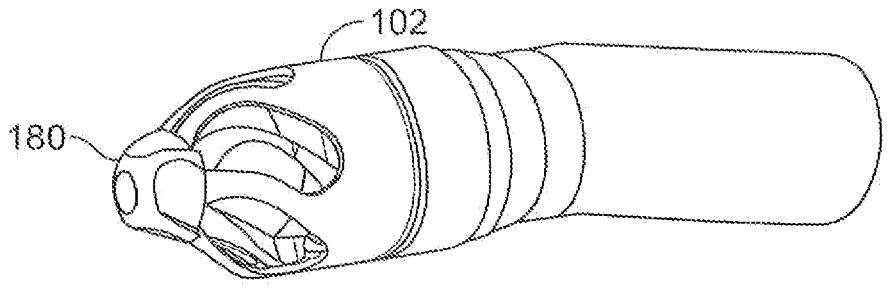

FIG. 9

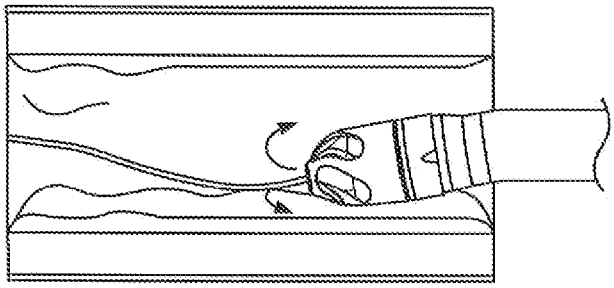

FIG. 10A

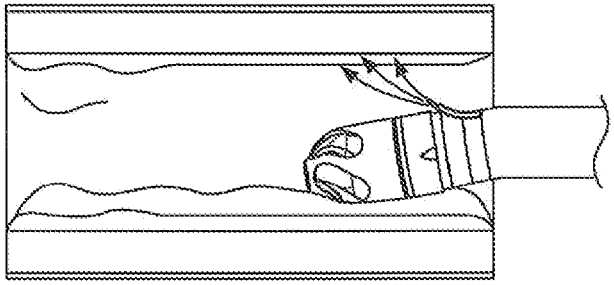

FIG. 10B

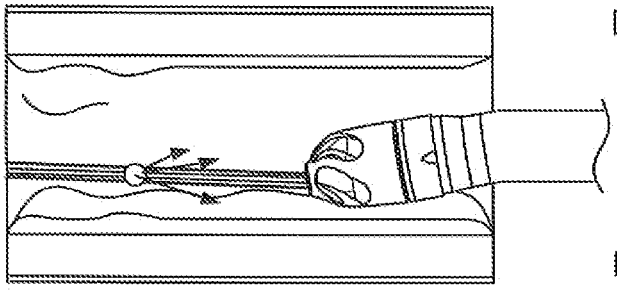

FIG. 10C

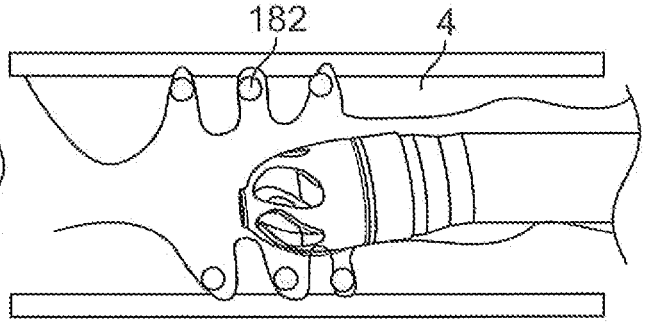

FIG. 11

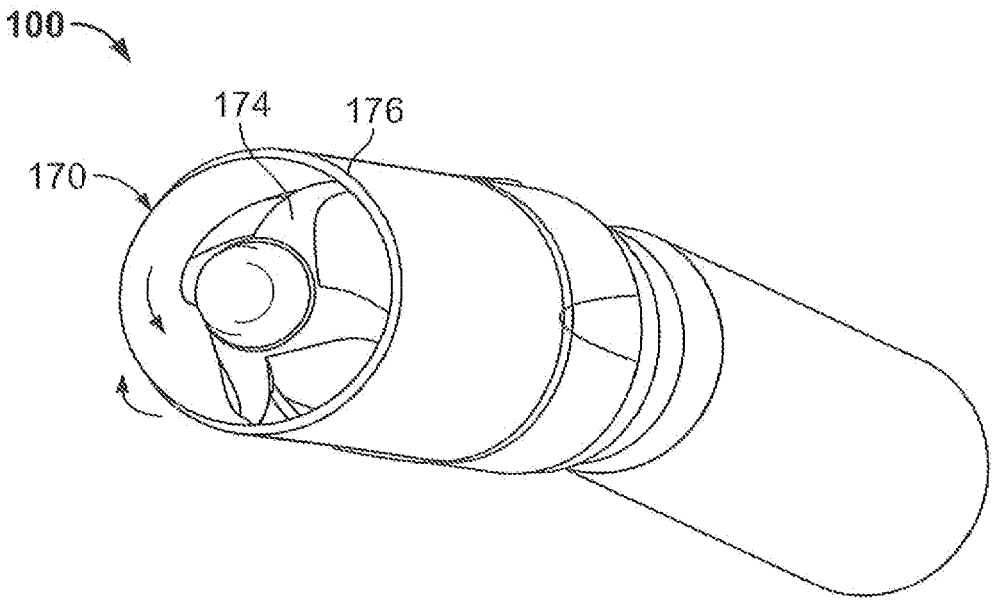

FIG. 12A

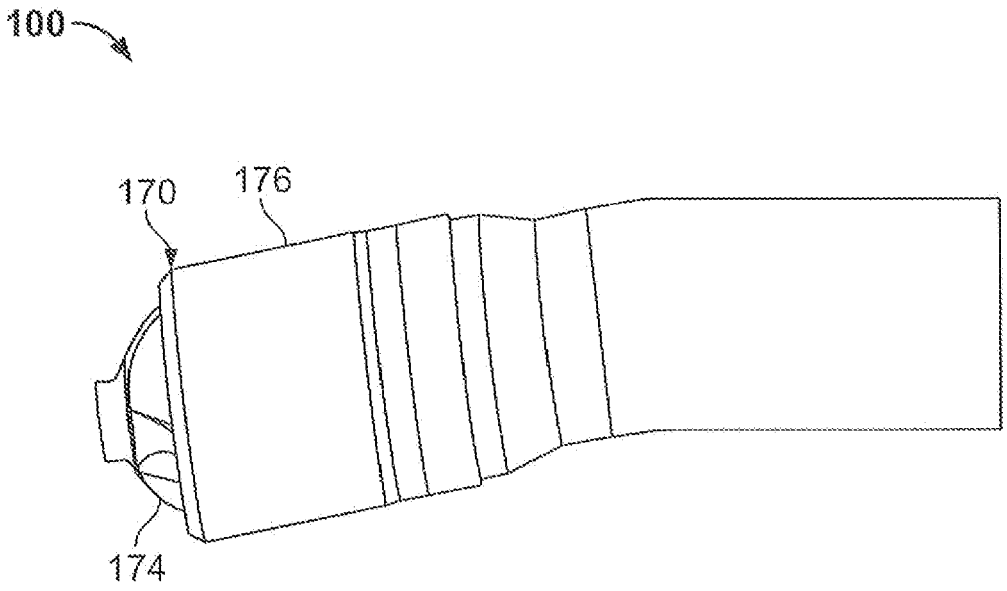

FIG. 12B

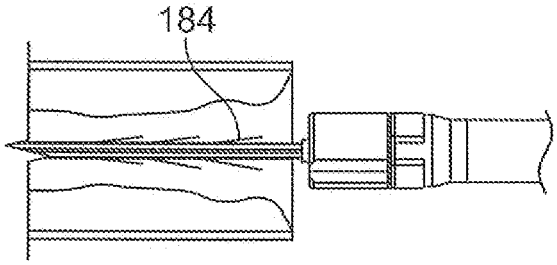

FIG. 12C

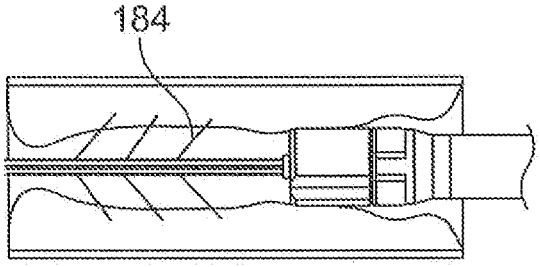

FIG. 12D

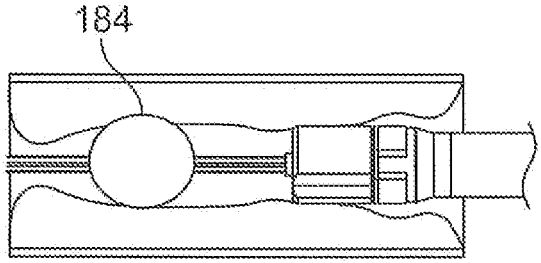

FIG. 12E

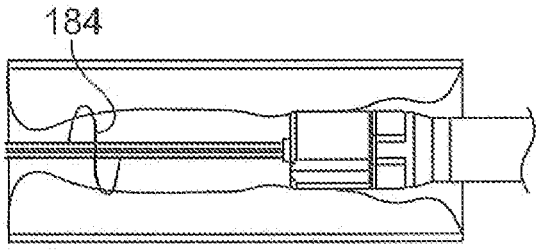

FIG. 12F

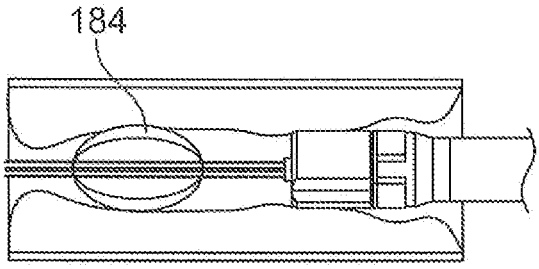

FIG. 12G

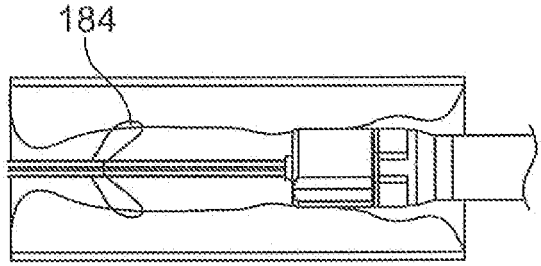

FIG. 12H

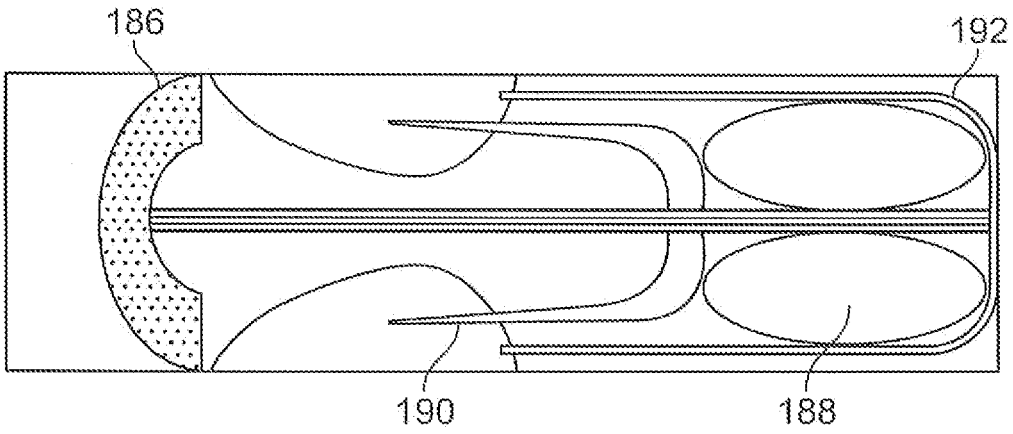

FIG. 12I

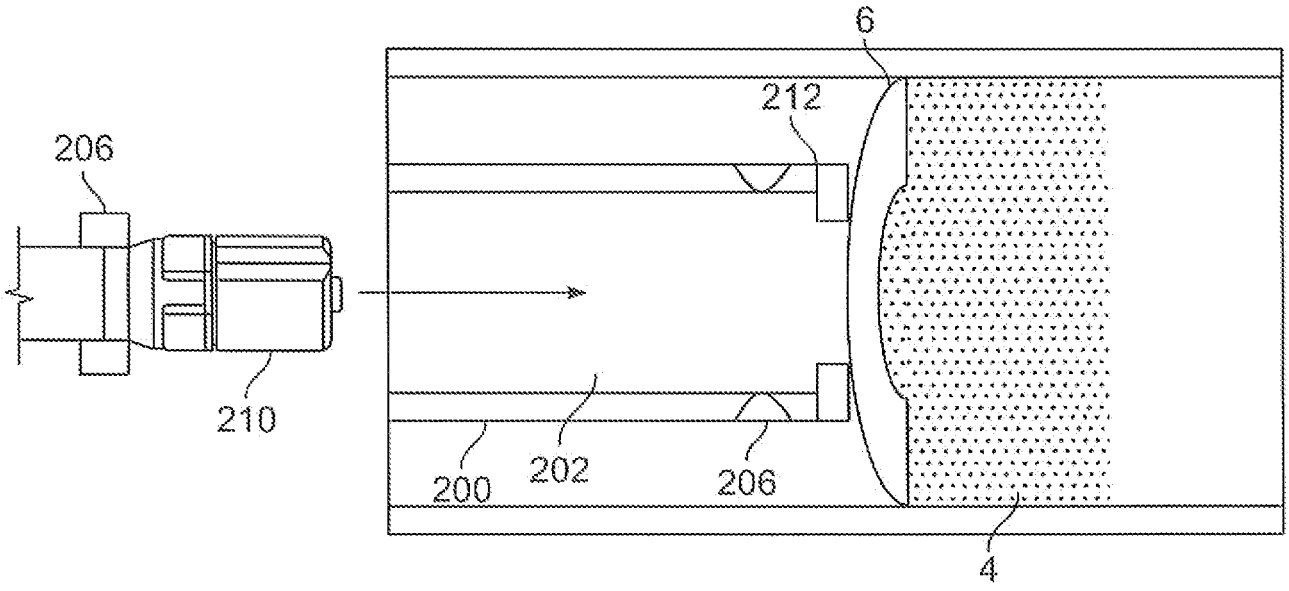

FIG. 13A

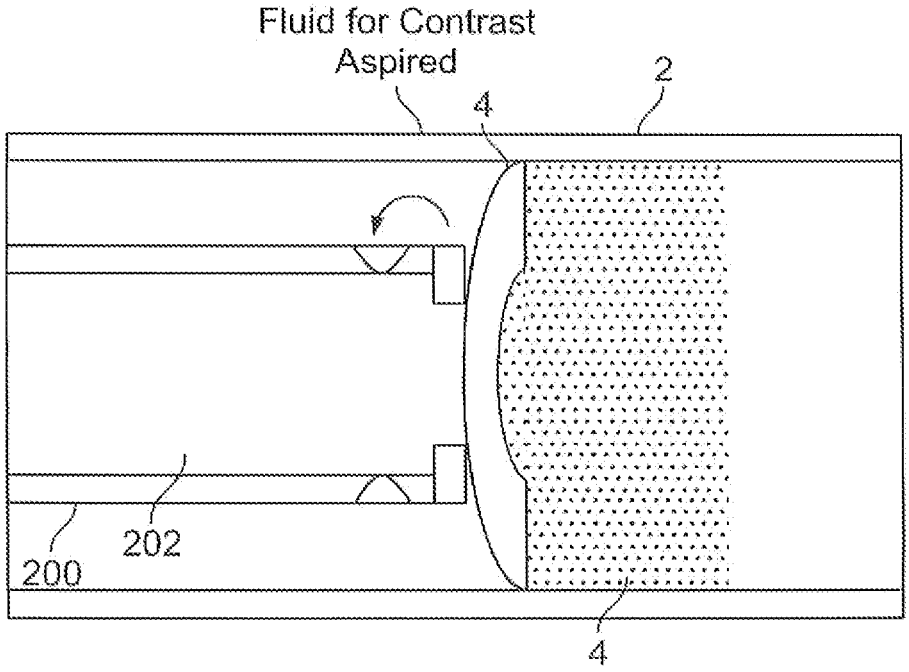

FIG. 13B

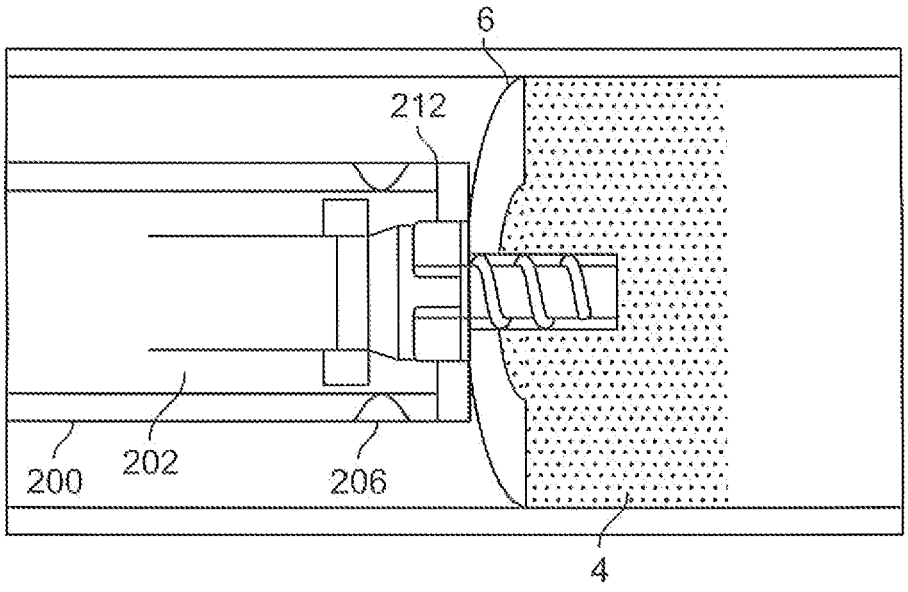

FIG. 13C