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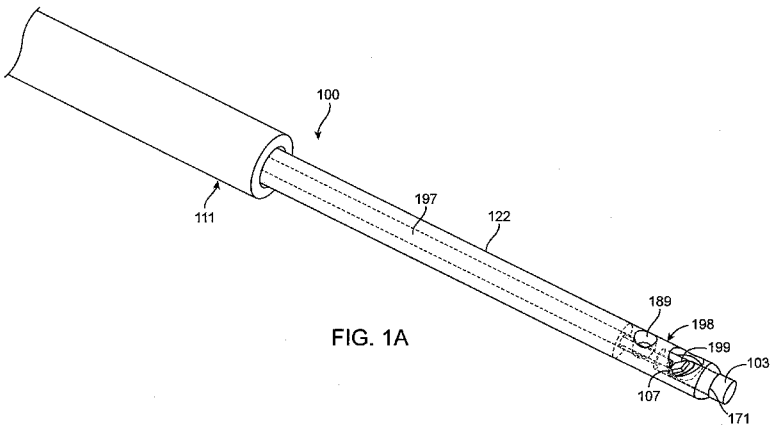

FIG. 1A

(57) **Abstract**: An imaging device includes a hollow flexible shaft having a central longitudinal axis and an imaging window therein. An optical fiber extends within the hollow flexible shaft substantially along the central axis. A distal tip of the optical fiber is attached to the hollow flexible shaft and aligned with the imaging window so as to transfer an optical coherence tomography signal through the imaging window. A handle is attached to the hollow flexible shaft configured rotate the hollow flexible shaft at speeds of greater than 1,000rpm.

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CHRONIC TOTAL OCCLUSION CROSSING DEVICES WITH IMAGING

INCORPORATION BY REFERENCE

[0001] All publications and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication or patent application was specifically and individually indicated to be incorporated by reference.

BACKGROUND

[0001] Peripheral artery disease (PAD) and coronary artery disease (CAD) affect millions of people in the United States alone. PAD and CAD are silent, dangerous diseases that can have catastrophic consequences when left untreated. CAD is the leading cause of death for in the United States while PAD is the leading cause of amputation in patients over 50 and is responsible for approximately 160,000 amputations in the United States each year.

[0002] Coronary artery disease (CAD) and Peripheral artery disease (PAD) are both caused by the progressive narrowing of the blood vessels most often caused by atherosclerosis, the collection of plaque or a fatty substance along the inner lining of the artery wall. Over time, this substance hardens and thickens, which may interfere with blood circulation to the arms, legs, stomach and kidneys. This narrowing forms an occlusion, completely or partially restricting flow through the artery. Blood circulation to the brain and heart may be reduced, increasing the risk for stroke and heart disease.

[0003] Interventional treatments for CAD and PAD may include endarterectomy and/or atherectomy. Endarterectomy is surgical removal of plaque from the blocked artery to restore or improve blood flow. Endovascular therapies such as atherectomy are typically minimally invasive techniques that open or widen arteries that have become narrowed or blocked. Other treatments may include angioplasty to open the artery. For example, a balloon angioplasty typically involves insertion of a catheter into a leg or arm artery and positioning the catheter such that the balloon resides within the blockage. The balloon, connected to the catheter, is expanded to open the artery. Surgeons may then place a wire mesh tube, called a stent, at the area of blockage to keep the artery open.

[0004] Such minimally invasive techniques (e.g., atherectomy, angioplasty, etc.) typically involve the placement of a guidewire through the occlusion. Using the guidewire, one or more interventional devices may be positioned to remove or displace the occlusion. Unfortunately, placement of the guidewire, while critical for effective treatment, may be difficult. In particular, when placing a guidewire across an occlusion, it may be difficult to pass the guidewire through the occlusion while avoiding damage to the artery. For example, it is often difficult to prevent

the guidewire from directing out of the lumen into the adventitia and surrounding tissues, potentially damaging the vessel and preventing effective treatment of the occlusion.

[0005] As a result, occlusion-crossing devices, intended to assist in the passing of the guidewire through the occlusion, have been developed. Many of the devices, however, are ill equipped to be used with imaging, thereby making placement of the guidewire cumbersome and difficult. Moreover, many of the occlusion-crossing devices are too large to be used in small-diameter peripheral arteries or in coronary arteries.

[0006] Accordingly, occlusion crossing catheter devices designed to address some of these concerns are described herein.

SUMMARY OF THE DISCLOSURE

[0002] Described herein are occlusion-crossing devices having a low profile so as to be usable in small vessels, such as coronary arteries.

[0003] In general, in one embodiment, an imaging device includes a hollow flexible shaft having a central longitudinal axis and an imaging window therein. An optical fiber extends within the hollow flexible shaft substantially along the central axis. A distal tip of the optical fiber is attached to the hollow flexible shaft and aligned with the imaging window so as to transfer an optical coherence tomography signal through the imaging window. A handle is attached to the hollow flexible shaft configured rotate the hollow flexible shaft at speeds of greater than 1,000rpm.

[0004] This and other embodiments may include one or more of the following features. The optical fiber can extend substantially along the central axis for the entire length of the fiber. The device can be less than 0.1 inches, .08 inches, or .05 inches in diameter. The hollow flexible shaft can be made of tungsten. The hollow flexible shaft can be made of multiple layers of wound filars. The filars can be counterwound. The hollow flexible shaft can further include a mirror therein configured to reflect light from the optical fiber into adjacent tissue. The device can include an outer sheath extending around the hollow flexible shaft. The outer sheath can include an optically clear annular section at the distal end thereof.

[0005] In general, in one embodiment, an imaging assembly includes a catheter having a cutter and a lumen extending the length of the catheter. A hollow flexible shaft is configured to be inserted within the lumen of the catheter. The hollow flexible shaft includes a central longitudinal axis and an imaging window therein. An optical fiber extends within the hollow flexible shaft substantially along the central axis. A distal tip of the optical fiber is attached to the hollow flexible shaft and aligned with the imaging window so as to transfer an optical coherence tomography signal through the imaging window.

[0006] This and other embodiments can include one or more of the following features. The catheter can include a cutter at a distal end. The hollow flexible shaft can further include a handle attached thereto configured rotate the hollow flexible shaft at speeds of greater than 1,000rpm. The optical fiber can extend substantially along the central axis for the entire length of the fiber. The imaging assembly can further include an outer sheath extending around the hollow flexible shaft. The outer sheath can include an optically clear annular section at the distal end thereof. The hollow flexible shaft can be made of tungsten. The hollow flexible shaft can be made of multiple layers of wound filars. The filars can be counterwound. The hollow flexible shaft can further include a mirror attached to the distal end configured to reflect light from the optical fiber into adjacent tissue.

[0007] In general, in one embodiment, a method of imaging a body lumen includes: inserting a catheter into the body lumen; inserting an imaging device into a lumen of the catheter, the imaging device including a hollow flexible shaft having a central longitudinal axis with an imaging window therein and an optical fiber extending within the hollow flexible shaft and attached to the hollow flexible shaft , the optical fiber extending substantially along the central longitudinal axis; rotating the hollow flexible shaft within the lumen of the catheter; and collecting images of the body lumen through the imaging window with the optical fiber.

[0008] This and other embodiments can include one or more of the following features. Rotating the hollow flexible shaft within the lumen can include rotating the hollow flexible shaft at speeds of greater than 1,000 rpm. Collecting images of the body lumen can include collecting images of the body lumen at rates of greater than 10 frames per minute. The body lumen can be a coronary artery or a peripheral artery. The catheter can include a cutter thereon, and the method can further include cutting tissue of the body lumen with the catheter to pass through an occlusion in the body lumen. The method can further include removing the imaging device from the lumen of the catheter and advancing a guidewire through the lumen of the catheter after passing the cutter through the occlusion.

[0009] In general, in one embodiment, an occlusion crossing device includes a rotatable hollow flexible shaft having a central longitudinal axis and an imaging window therein. The occlusion crossing device further includes an optical fiber extending within the hollow flexible shaft substantially along the central axis. A distal tip of the optical fiber is aligned with the imaging window so as to transfer an optical coherence tomography signal through the imaging window. A cutter is attached to a distal end of the hollow flexible shaft.

[00010] This and other embodiments can include one or more of the following features. The optical fiber can extend substantially along the central axis for the entire length of the fiber. The occlusion crossing device can further include an outer sheath extending around the hollow

flexible shaft. A monorail guidewire can be attached to the outer sheath. The outer sheath can include an optically clear annular section at the distal end thereof. The hollow flexible shaft can be made of tungsten. The hollow flexible shaft can be made of multiple layers of wound filars. The filars can be counterwound. The device can be less than 0.1, less than 0.08, or less than 0.05 inches in diameter. The cutter can include a fluted distal end. The cutter can further include a slanted proximal end and a mirror attached to the proximal end configured to reflect light from the optical fiber into adjacent tissue. The optical fiber can be configured to remain stationary relative to the hollow flexible shaft. The optical fiber can be attached to the hollow flexible shaft and configured to rotate therewith. The occlusion crossing device can further include a handle attached to the flexible shaft configured to rotate the hollow flexible shaft at speeds of greater than 1,000rpm.

[00011] In general, in one embodiment, a method of crossing an occlusion in a blood vessel includes: inserting an occlusion crossing device into the vessel, the occlusion crossing device including a hollow flexible shaft having a central longitudinal axis and an imaging window therein, an optical fiber extending within the hollow flexible shaft substantially along the central axis to transfer an optical coherence tomography signal, and a cutter attached to a distal end of the hollow flexible shaft; rotating the hollow flexible shaft and cutter so as to separate tissue of the occlusion; collecting images of the vessel through the imaging window with the optical fiber; and passing the cutter through the occlusion.

[00012] This and other embodiments can include one or more of the following features. Rotating the flexible shaft and cutter can include rotating at speeds of greater than 1,000 rpm. Collecting images of the vessel can include collecting images at rates of greater than 10 frames per minute. The method can further include rotating the optical fiber with the hollow flexible shaft. Rotating the hollow flexible shaft can include rotating the imaging shaft while keeping the fiber rotationally fixed. The vessel can be a coronary artery or a peripheral artery.

[00013] In general, in one embodiment, an occlusion crossing device includes an elongate body and a drive shaft extending through the elongate body having a perforating tip attached thereto. The occlusion crossing device further includes a deflectable tip having a wedged distal end attached to the elongate body and a guidewire lumen extending through the deflectable tip.

[00014] This and other embodiments can include one or more of the following features. The occlusion crossing device can further include an imaging element attached to the drive shaft. The imaging element can be an optical coherence tomography imaging element. The deflectable tip can be configured to be deflected by axial movement of the drive shaft. The device can be less than 0.1 inches, less than .08 inches, or less than .05 inches in diameter.

BRIEF DESCRIPTION OF THE DRAWINGS

[00015] The novel features of the invention are set forth with particularity in the claims that follow. A better understanding of the features and advantages of the present invention will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the invention are utilized, and the accompanying drawings of which:

[00016] FIGS. 1A-1C show an occlusion crossing device having an optical fiber for imaging running down the center of the device. FIG. 1A shows an outer view of the device. FIG. 1B shows a close-up of the imaging and cutting portion of the device of FIG. 1A. FIG. 1C is a cross-section of the device of FIG. 1A.

[00017] FIGS. 1D-1E show exemplary cutting tips for use with the device of FIG. 1A.

[00018] FIG. 2A shows placement of the device of FIGS. 1A-1C in a passive configuration in a vessel. FIG. 2B shows placement of the device of FIGS. 1A-1C in an active configuration in a vessel.

[00019] FIGS. 3A-3B show a handle for use with the device of FIGS. 1A-1C. FIG. 3A is an outer view of the handle. FIG. 3B is a cross-section of the handle.

[00020] FIG. 4A shows a cross-section of an exemplary occlusion crossing device having a stationary optical fiber and rotating outer sheath. FIG. 4B shows the device of FIG. 4A with an outer sheath therearound.

[00021] FIGS. 5A-5E show an exemplary occlusion crossing device with a deflectable wedged distal tip. FIG. 5A shows a cross-section of the device with the deflectable tip in a closed configuration. FIG. 5B shows a cross-section of the device with the deflectable tip in an open configuration. FIG. 5C shows a cross-section of the device with the deflectable tip in an open configuration and the cutting edge extended distally. FIG. 5D is an end-view of the deflectable tip. FIG. 5E is an isometric view of the deflectable tip.

DETAILED DESCRIPTION

[00022] Described herein are occlusion-crossing devices having a low profile so as to be usable in small-diameter arteries and coronary arteries. In general, the devices described herein can have on-board imaging, such as optical coherence tomography (OCT) imaging. The optical fiber for the OCT imaging can substantially along the central of the device, thereby decreasing the profile of the device and allowing for single direction rotation at high speeds. A monorail guidewire lumen can be attached to the devices described herein.

[00023] In some embodiments, a catheter device, such as an occlusion-crossing device, can include an imaging shaft with a fiber running down the center of the catheter. The fiber can be

rotated with a fiber optic junction so as to rotatable at high speeds in a single direction. A monorail guidewire lumen can extend along the outside of the device parallel to the central axis of the catheter.

[00024] Referring to FIGS. 1A-1C, an exemplary catheter device 100 is shown. The catheter device 100 can include an imaging shaft 122. The imaging shaft 122 can be hollow and can have an inner diameter of approximately 0.005" to 0.010", e.g., 0.009" or .008". The imaging shaft 122 could have an outer diameter of approximately 0.01 - 0.038". Further, the imaging shaft 122 can be sized to work inside the lumen of another catheter, e.g., a catheter having a lumen diameter of 0.014", 0.018", or 0.035". In some embodiments, the imaging shaft 122 can be made of a wire material, such as stainless steel or tungsten, or, alternatively can be made from a flexible tube such as a plastic or laser cut tube. Further, in some embodiments, the imaging shaft 122 can include multiple filar layers. For example, the imaging shaft 122 can include two layers of 8 counterwound filars per layer or three layers of 12 counterwound filars per layer or the number of filars could vary by layer (e.g., 12 filars over 8 filars). Advantageously, by using multiple layers of filars, the imaging shaft 122 can be configured to rotate at speeds of over 1,000rpm.

[00025] The catheter 100 can further include an imaging element. Thus, an optical fiber 197 can extend through the hollow imaging shaft 122 such that the optical fiber 197 runs substantially along the central axis of the catheter for the entire length of the fiber 197. The fiber 197 can be attached at the distal end of the imaging shaft 122 (such as in the bulb 198 described below), but can be otherwise free to float within the imaging shaft 122. The imaging fiber 197 can transfer an optical coherence tomography (OCT) signal for imaging of the vessel in which the device 100 is placed. In some embodiments, the imaging fiber 197 can have a polyimide coating therearound within the length of the shaft 122 to support and protect the fiber 197 as it spins within the shaft 122.

[00026] The optical fiber 197 can end in a hollow bulb 198 at the end of the imaging shaft 122. The bulb 198 can be made of the same material as the imaging shaft 122, such as stainless steel. The bulb 198 can include a mirror 199 oriented at an angle (such as a 30-60 degree angle, e.g., 45 degrees) with respect to the central axis of the fiber 197 such that light coming out of the fiber 197 will bounce off the mirror 197 and into the adjacent tissue. The bulb 198 can include glue therein to hold the distal end of the optical fiber 197 in place. The glue can have a refractive index configured to be appropriately mismatched with the refractive index of the fiber, as described in U.S. Patent Application No. 12/790,703, titled "OPTICAL COHERENCE TOMOGRAPHY FOR BIOLOGICAL IMAGING," filed 5/28/2010, Publication No. US-2010-0305452-A1; and International Patent Application titled "OPTICAL COHERENCE

TOMOGRAPHY WITH GRADED INDEX FIBER FOR BIOLOGICAL IMAGING," filed herewith, both of which are incorporated by reference in their entireties. Further, the glue can have a meniscus shape along its outer edge, as described in International Patent Application titled "OPTICAL COHERENCE TOMOGRAPHY WITH GRADED INDEX FIBER FOR BIOLOGICAL IMAGING," filed herewith, already incorporated by reference herein. The meniscus shape can advantageously ensure that the light reflected back from the surface of the glue and back into the fiber 197 is significantly less than the light referenced.

[00027] The bulb 198 can further include an imaging window 107 therein aligned with the mirror 199 such that the light bouncing off the mirror can travel therethrough into the tissue. In some embodiments, the bulb 198 can include a second hole 189 therein that is proximal to the window 107. The second hole 189 can be configured to allow for the placement of additional glue to hold the fiber 197 in place.

[00028] Referring to FIGS. 1B and 1D-E, in some embodiments, the bulb 198 can include a cutter 103 connected to the distal end thereof. The cutter can be configured, for example, to separate, dissect, or shred tissue. As shown in FIG. 1B, the cutter 103 can have proximal end oriented an angle so as to support the angled mirror 199. Further, the cutter 103 can have a distal sharp cutting edge that extends out of a distal hole 171 in the bulb 198. In some embodiments, the cutter 103 can include multiple sharp flutes that come to a point in the center of the device. Two exemplary cutters 103a, 103b are shown in FIGS. 1D and 1E. The cutter 103a of FIG. 1D includes two spiral flutes while the cutter 103b of FIG. 1D includes four spiral flutes.

[00029] The imaging shaft 122, and thus the optical fiber 197, can be configured to rotate at high speeds, such as greater than 1,000rpm, in a single direction to provide OCT imaging around the inner circumference of the vessel. Such high speed rotation in a single direction (as opposed to requiring rotation alternately in both directions to manage the optical fiber) allows for the gathering of image data more quickly, thereby providing more accurate and up-to-date images during use of the device 100. For example, images can be generated at a rate of greater than 10 frames per section (fps), such as greater than 10 fps, such as approximately 16.67 fps. In an exemplary embodiment, the rate of Laser sweep, such as approximately 20 KHz, can be configured to keep up with at 16.67 frames per second with about 1200 lines per frame.

[00030] The catheter 100 can further include a sheath 111, such as a sheath that is less than 0.060" in diameter, such as less than 0.050" in diameter. The sheath 111 can extend annularly around the imaging shaft 197. The sheath 111 can include an optically clear annular section 121 (e.g., optically transparent at a wavelength of 1300nm) at the distal end thereof, as shown in FIGS. 2A-2B. The optically clear annular section 121 can be made, for example, of tecothane or fluorinated ethylene propylene (FEP). In some embodiments, the optically clear annular section

121 can have a refractive index of between 1.35 and 1.45 that is close to the refractive index of saline, thereby reducing the back-reflection caused when saline is flushed through the sheath 111. The optically clear annular section 121 can advantageously allow for imaging with the OCT fiber 197 without extending the imaging shaft 122 out of the sheath 111, thereby allowing for imaging without cutting. Thus, the imaging shaft 197 can rotate within the sheath 111 and move axially (proximally and distally) within the sheath 111. Allowing the imaging shaft 122 to rotate and translate within the sheath 111 advantageously allows such actions to occur without changing the position of the sheath 111 when in use within a vessel.

[00031] Referring to FIGS. 2A-2B, the catheter 100 can further include a guidewire lumen 180, which can be a monorail extending along the distal end of the sheath 111. The guidewire lumen 180 can have an inner diameter, for example, of 0.010" to 0.020", such as approximately .016" in diameter, such as to hold, for example, a .014" guidewire. The guidewire lumen 180 can be made, for example, of polyimide. In other embodiments, the catheter 100 can be fabricated or used without a guidewire lumen. For example, the catheter 100 (including the sheath 111) can be inserted into the vessel, tunneled through an occlusion through the use of the cutter 103, and then the imaging shaft 122 can be removed, leaving the sheath in place. A guidewire could then be inserted through the sheath 111 to get the guidewire across the occlusion.

[00032] Advantageously, because the optical fiber 197 runs through the center of the device 100, the device 100 can be small in diameter. For example, the outer diameter of the device 100 (including the sheath and monorail) can be less than 0.10", such as less than 0.08", such as less than 0.07", less than 0.06", or less than 0.05". Accordingly, the device 100 can advantageously be used in small-diameter peripheral arteries and coronary arteries.

[00033] Referring to FIGS. 2A-2B, in use, the device 100 can be inserted into a vessel 215 in a passive configuration where the imaging shaft 122 and cutter 103 are entirely within the sheath 111 (as shown in FIG. 2A). To do so, the device 100 can be extended over a guidewire that has been placed within the vessel (i.e., the guidewire lumen 180 can extend over the guidewire). The imaging shaft 122 can be rotated, thereby obtaining an image with the fiber 197 through the clear annular section 121 of the sheath 111.

[00034] In some embodiments, the resulting image will have a wire artifact caused by the guidewire obstructing the OCT beam as the imaging shaft 122 is rotated. The wire artifact in the image can be used to determine the direction to point or orient the catheter. That is, in some embodiments, the wire artifact can be used to align the device 100 with a fluoroscopic image and/or to orient a fixed jog or deflection point in the catheter that has a set orientation relative to the guidewire lumen. Alignment of markers with fluoroscope images and orientation of jogged

portions of a catheter using markers is described further in U.S. Patent Application No. 13/433,049, titled "OCCLUSION-CROSSING DEVICES, IMAGING, AND ATHERECTOMY DEVICES," filed 3/28/2012, Publication No. US-2012-0253186-A1, the entirety of which is incorporated herein by reference.

[00035] The guidewire can then be retracted until the wire artifact in the image is gone, thereby fully removing the guidewire from potential entanglement with the rotating cutter 103.

[00036] The imaging shaft 122 can then be extended distally, thereby extending the cutter 103 distally until the cutter 103 is past the distal end of the sheath 111 such that the device 100 takes an active configuration (as shown in FIG. 2B). The imaging shaft 122 can then be rotated, thereby both imaging the vessel and cutting through plaque or tissue in the vessel. The imaging shaft 122 can then be retracted into the sheath 111. The guidewire can then be advanced, and the process repeated until the device 100 has crossed the occlusion.

[00037] The rotation or translation of the imaging shaft 122 can be controlled through a handle attached the device 100. An exemplary handle 300 is shown in FIGS. 3A-3B. The handle 300 can include a rotational torque knob 311 attachable to the sheath 111 and configured to provide torque to the sheath 111. In some embodiments, the handle 300 can include a flush port, such as an RHV style flush port. The handle 300 can further include a mechanism, such as a fiber optic rotary junction, therein configured to allow for rotation of the shaft 122 and optical fiber 197 without rotating the fiber from the light source. Further, the handle 300 (or the catheter 100) can be configured to be attached to a drive system, such as through an optical connector 313. The drive system can include a rotary optical junction configured to rotate the fiber. Exemplary drive systems that could be used in conjunction with the devices herein are described in U.S. Patent Application No. 13/654,357, titled "ATHERECTOMY CATHETERS AND NON-CONTACT ACTUATION MECHANISM FOR CATHETERS," filed 10/17/2012 and International Patent Application titled "ATHERECTOMY CATHETER DRIVE ASSEMBLIES," filed herewith, each incorporated herein by reference in its entirety.

[00038] In some embodiments, the device 100 can be fabricated without the cutter 103, and the device 100 can instead be used as an imaging guidewire, imaging wire, or imaging component that can be placed within another device, such as an occlusion crossing device, atherectomy device, guide catheter, guiding sheath, over-the-wire balloon catheter, or support catheter, to provide imaging during procedures. In such instances, the device 100 could be used with the sheath 111 or without (and the device in which device 100 is inserted could act as a sheath). Further, in such instances, the catheter within which the device 100 is placed can include a cutter. Exemplary devices with which the device 100 could be used as an imaging guidewire or imaging component are described in: U.S. Patent Application No. 12/689,748, titled

"GUIDEWIRE POSITIONING CATHETER," filed 1/19/2010, Publication No. US-2010-0274270-A1; U.S. Patent Application No. 12/108,433, titled "CATHETER SYSTEM AND METHOD FOR BORING THROUGH BLOCKED VASCULAR PASSAGES," filed 4/23/2008, now Patent No. 8,062,316; U.S. Patent Application No. 12/829,267, titled "CATHETER-BASED OFF-AXIS OPTICAL COHERENCE TOMOGRAPHY IMAGING SYSTEM," filed 7/1/2010, Publication No. US-2010-0021926-A1; U.S. Patent Application No. 13/433,049, titled "OCCLUSION-CROSSING DEVICES, IMAGING, AND ATHERECTOMY DEVICES," filed 3/28/2012, Publication No. US-2012-0253186-A1; International Patent Application titled "OCCLUSION-CROSSING DEVICES," filed herewith; U.S. Patent Application No. 12/829,277, titled "ATHERECTOMY CATHETER WITH LATERALLY-DISPLACEABLE TIP," filed 7/1/2010, Publication No. US-2011-0004107-A1; U.S. Patent Application No. 13/175,232, titled "ATHERECTOMY CATHETERS WITH LONGITUDINALLY DISPLACEABLE DRIVE SHAFTS," filed 7/1/2011, Publication No. US-2012-0046679-A1; U.S. Patent Application No. 13/654,357, titled "ATHERECTOMY CATHETERS AND NON-CONTACT ACTUATION MECHANISM FOR CATHETERS," filed 10/17/2012; U.S. Patent Application No. 13/675,867, titled "OCCLUSION-CROSSING DEVICES, ATHERECTOMY DEVICES, AND IMAGING," filed 11/13/2012; International Patent Application titled "ATHERECTOMY CATHETERS WITH IMAGING," filed herewith; International Patent Application titled "BALLOON ATHERECTOMY CATHETERS WITH IMAGING," filed herewith, the entireties of which are incorporated herein by reference.

[00039] In some embodiments, an occlusion crossing device can include a stationary optical fiber for optical coherence tomography imaging.

[00040] For example, referring to FIG. 4A, an occlusion crossing device 400 can include a hollow rotatable imaging shaft 422. The rotatable imaging shaft 422 can be made of a coiled structure that can be optimized (such as the number of filars or the filar size) to provide the desired stiffness.

[00041] The occlusion crossing device 400 can further include an imaging element. Thus, an optical fiber 497 can extend through the hollow rotatable imaging shaft 422 so as to extend substantially along the central axis of the device 400. The optical fiber 497 can be configured to as to stay stationary during rotation of the imaging shaft 422. For example, the optical fiber 492 can be attached to a bearing at the distal end of the imaging shaft 422.

[00042] A cutter 403 can be attached to the imaging shaft 422, such as through a connecting collar 433. The cutter 403 can include a fluted distal end 412 configured to bore through tissue. Further, the cutter 403 can include a mirror 499 affixed to the proximal end thereof at an angle, such as between 35 and 55 degrees, e.g., 45 degrees, relative to the central axis of the fiber 497.

[00043] The imaging shaft 422 can further include an imaging window 407 therein. The imaging window 407 can be placed in such a location as to allow the light deflected off of the mirror 499 to travel through the window 407 into adjacent tissue.

[00044] The imaging shaft 422 can be configured to rotate, thereby rotating the cutter 403, including the distal cutting edge 412 (to cut tissue) as well as the mirror 499. By rotating the mirror 499, the beam traveling through the fiber 497 will bounce off the mirror 499 and be sent into, and received back from, areas all around the circumference of the vessel in which the device 400 is placed.

[00045] Advantageously, by rotating the mirror 499 rather than the optical fiber 497, complicated fiber management mechanisms are eliminated. Moreover, the imaging shaft 422 can be rotated at high speeds, such as greater than 1,000rpm, to provide better drilling with the cutting edge 412 as well as higher imaging rates, such as rates of greater than 10 frames per section (fps), such as greater than 10 fps, such as approximately 16.67 fps. In an exemplary embodiment, the rate of Laser sweep, such as approximately 20 KHz, can be configured to keep up with at 16.67 frames per second with about 1200 lines per frame. Furthermore, by having the fiber 497 extend through the center of the device 400, the device 400 can advantageously be less than 0.03" in diameter, such as less than 0.02" in diameter, such as approximately 0.018" in diameter. Accordingly, the device 400 can advantageously be used in small-diameter peripheral arteries and coronary arteries.

[00046] In some embodiments, referring to FIG. 4A, the device 400 can include an outer sheath 411 therearound. The outer sheath 411 can be stationary relative to the rotatable imaging shaft 422, thereby making it easier for a user to hold onto the device. In some embodiments, the outer sheath can be attached to the imaging shaft 422, such as through a bearing. In other embodiments, the outer sheath 411 can be unattached to the remainder of the device. In some embodiments, the outer sheath 411 can include a clear annular section similar to the annular section 121 described above with respect to FIGS. 1A-2B.

[00047] In some embodiments, the device 400 can further include a monorail guidewire lumen similar to the device 100 described above.

[00048] The device 400 can be attached to a drive system to provide a light source for OCT imaging and/or to provide torque for rotation of the imaging shaft.

[00049] In some embodiments, an occlusion-crossing device can include a deflectable tip configured to protect the distal tip when in use.

[00050] For example, referring to FIGS. 5A-5E, an occlusion-crossing device 500 can include a catheter body 501, a cutter 503, and a deflectable distal tip 505 at the distal end. The catheter body 501 can include an outer shaft 511 and an imaging shaft 513 extending therein. As

described above with respect to devices 100 and 400, the device 500 can include an imaging element 492, such as an optical fiber extending through the imaging shaft 513 so as to run substantially along the central axis of the catheter body 501. A mirror 599 oriented at 35-55 degrees, such as 45 degrees, can be configured to project the light into the tissue at a 90 degree angle relative to the optical fiber. The cutter 503 can be attached to the imaging shaft 513. The cutter 503 can include a perforating tip 572 extending off of the distal end thereof. The perforating tip 572 can be configured to penetrate tissue as it is advanced and/or rotated. For example, the perforating tip 572 can be shaped as a fluted end mill or drill or a plurality of shape-set sharp whiskers. The perforating tip 472 can have a diameter that is smaller than the diameter of the rest of the cutter 503 and/or the elongate body 501, thereby advantageously providing a sharper or more pronounced point for drilling. The size of the perforating tip 572 can further be approximately the size of the guidewire 590, thereby helping to provide a hole through which the guidewire can extend.

[00051] In some embodiments, a guidewire lumen 580, such as a monorail guidewire lumen 580 can run along the outside of the device to hold a guidewire 590. Further, in some embodiments, as shown in FIGS. 5A-5C, the guidewire lumen 580 can extend through the distal tip 505 and extend out of the distal-most end 551 of the distal tip 505.

[00052] The deflectable distal tip 505 can be attached to the outer shaft 511 at a hinge point 583, such as at a hinge pin. The deflectable distal tip 505 can have a wedged distal edge 555, best shown in FIGS. 5D-5E. The wedged distal edge 555 can advantageously be aligned with a hard or dense occlusion such that the distal-most end 551 of the distal tip 505 is oriented partially around the occlusion (along the side of the vessel). When the distal tip 505 is deflected, this position can be enhanced, allowing the guidewire lumen 550 and guidewire 590 to aim around the occlusion. Using a guidewire 590 having a curved distal end, as shown in FIGS. 590, can help the guidewire slide along the occlusion even as the distal-most edge 551 of the tip 505 (and thus the guidewire lumen 580) is pointed towards the vessel wall.

[00053] Further, the deflectable distal tip can have a cut-out 587 configured to house the perforating tip 572 therein. The deflectable distal tip can be deflected, for example, by pulling or pushing on the drive shaft 513, similar to embodiments described in International Patent Application titled "BALLOON ATHERECTOMY CATHETERS WITH IMAGING," filed herewith; U.S. Patent Application No. 13/175,232, titled "ATHERECTOMY CATHETERS WITH LONGITUDINALLY DISPLACEABLE DRIVE SHAFTS," filed 7/1/2011, Publication No. US-2012-0046679-A1; U.S. Patent Application No. 12/829,277, titled "ATHERECTOMY CATHETER WITH LATERALLY-DISPLACEABLE TIP," filed 7/1/2010, Publication No. US-2011-0004107-A1; International Patent Application titled "ATHERECTOMY CATHETERS

WITH IMAGING," all of which are incorporated by reference herein. The deflectable distal tip 505 can thus have a closed configuration, as shown in FIG. 5A, wherein the deflectable tip 505 covers the perforating tip 572, and an open configuration where the deflectable tip 505 exposes the perforating tip 572.

[00054] In some embodiments, the imaging shaft 513 can be moved proximally and distally. Distal extension of the imaging shaft 513 when the deflectable distal tip 505 is deflected can advantageously extend the perforating tip 572 past the distal end of the tip 505 to provide for drilling with the deflectable tip 572 out of the way.

[00055] Because the optical fiber runs through the center of the device, the imaging shaft 513 can advantageously be rotated at high speeds in a single direction, such as greater than 1,000rpm, to provide better drilling with the cutting edge 412 as well as higher imaging rates, as described above with respect to devices 100 and 400. Furthermore, by having the fiber of the imaging sensor 592 extend through the center of the device 500, the device 500 can advantageously be less than 0.10", such as less than 0.08", such as less than 0.07", less than 0.06", or less than 0.05". Accordingly, the device 500 can advantageously be used in small-diameter peripheral arteries and coronary arteries.

[00056] In operation, the device 500 can be advanced through the vasculature with the tip 505 in the non-deflected position (shown in FIG. 5A). At the target lesion or CTO, the device 500 can continue to be advanced until an obstruction is encountered that cannot be passed by the device 500. At this point, the imaging sensor 592 can be used to identify structures in the vessel that could potentially be easier to pass through (non-ossified material). The device 500 can then be re-oriented the tip 505 deflected (as shown in FIG. 5C) to facilitate 'aiming' the guide wire lumen 580 in the direction of the more penetrable structure. The guide wire 590 can then be advanced along a new trajectory while being supported by the guide wire lumen 580. Once the guide wire 590 has traversed some distance through the obstacle, the tip 505 of the device can be returned to the normal (non-deflected) position to facilitate passage over the guide wire. If further obstacles are encountered, the process can be repeated until complete passage of the lesion or CTO had been achieved. In embodiments where the distal tip 503 includes a perforating tip 572, a hole can be created in the occlusion to help pass the guidewire therethrough.

[00057] Any of the catheters described herein can be shape-set or include shape-set features to enhance trackability and navigability.

[00058] As used herein, an imaging element can include the OCT optical fiber, such as the distal end of the optical fiber, as well as the mirror and adhesive used to hold the mirror and optical fiber in place.

[00059] As described above, the catheters described herein can include optical coherence tomography imaging, such as common path OCT. Such OCT systems are described in U.S. Patent Application No. 12/829,267, titled "CATHETER- BASED OFF-AXIS OPTICAL COHERENCE TOMOGRAPHY IMAGING SYSTEM," filed 7/1/2010, Publication No. US-2010-0021926-A1; U.S. Patent Application No. 12/790,703, titled "OPTICAL COHERENCE TOMOGRAPHY FOR BIOLOGICAL IMAGING," filed 5/28/2010, Publication No. US-2010-0305452-A1; and International Patent Application titled "OPTICAL COHERENCE TOMOGRAPHY WITH GRADED INDEX FIBER FOR BIOLOGICAL IMAGING," filed herewith, all of which are incorporated by reference in their entireties. Alternatively, other types of imaging could be used with the catheters described herein. For example, the devices described herein could be configured to work with infrared spectroscopy or ultrasound.

[00060] Additional details pertinent to the present invention, including materials and manufacturing techniques, may be employed as within the level of those with skill in the relevant art. The same may hold true with respect to method-based aspects of the invention in terms of additional acts commonly or logically employed. Also, it is contemplated that any optional feature of the inventive variations described may be set forth and claimed independently, or in combination with any one or more of the features described herein. Likewise, reference to a singular item, includes the possibility that there are a plurality of the same items present. More specifically, as used herein and in the appended claims, the singular forms "a," "and," "said," and "the" include plural referents unless the context clearly dictates otherwise. It is further noted that the claims may be drafted to exclude any optional element. As such, this statement is intended to serve as antecedent basis for use of such exclusive terminology as "solely," "only" and the like in connection with the recitation of claim elements, or use of a "negative" limitation. Unless defined otherwise herein, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this invention belongs. The breadth of the present invention is not to be limited by the subject specification, but rather only by the plain meaning of the claim terms employed.

[00061] When a feature or element is herein referred to as being "on" another feature or element, it can be directly on the other feature or element or intervening features and/or elements may also be present. In contrast, when a feature or element is referred to as being "directly on" another feature or element, there are no intervening features or elements present. It will also be understood that, when a feature or element is referred to as being "connected", "attached" or "coupled" to another feature or element, it can be directly connected, attached or coupled to the other feature or element or intervening features or elements may be present. In contrast, when a feature or element is referred to as being "directly connected", "directly attached" or "directly

coupled" to another feature or element, there are no intervening features or elements present. Although described or shown with respect to one embodiment, the features and elements so described or shown can apply to other embodiments. It will also be appreciated by those of skill in the art that references to a structure or feature that is disposed "adjacent" another feature may have portions that overlap or underlie the adjacent feature.

[00062] Terminology used herein is for the purpose of describing particular embodiments only and is not intended to be limiting of the invention. For example, as used herein, the singular forms "a", "an" and "the" are intended to include the plural forms as well, unless the context clearly indicates otherwise. It will be further understood that the terms "comprises" and/or "comprising," when used in this specification, specify the presence of stated features, steps, operations, elements, and/or components, but do not preclude the presence or addition of one or more other features, steps, operations, elements, components, and/or groups thereof. As used herein, the term "and/or" includes any and all combinations of one or more of the associated listed items and may be abbreviated as "/".

[00063] Spatially relative terms, such as "under", "below", "lower", "over", "upper" and the like, may be used herein for ease of description to describe one element or feature's relationship to another element(s) or feature(s) as illustrated in the figures. It will be understood that the spatially relative terms are intended to encompass different orientations of the device in use or operation in addition to the orientation depicted in the figures. For example, if a device in the figures is inverted, elements described as "under" or "beneath" other elements or features would then be oriented "over" the other elements or features. Thus, the exemplary term "under" can encompass both an orientation of over and under. The device may be otherwise oriented (rotated 90 degrees or at other orientations) and the spatially relative descriptors used herein interpreted accordingly. Similarly, the terms "upwardly", "downwardly", "vertical", "horizontal" and the like are used herein for the purpose of explanation only unless specifically indicated otherwise.

[00064] Although the terms “first” and “second” may be used herein to describe various features/elements, these features/elements should not be limited by these terms, unless the context indicates otherwise. These terms may be used to distinguish one feature/element from another feature/element. Thus, a first feature/element discussed below could be termed a second feature/element, and similarly, a second feature/element discussed below could be termed a first feature/element without departing from the teachings of the present invention.

[00065] As used herein in the specification and claims, including as used in the examples and unless otherwise expressly specified, all numbers may be read as if prefaced by the word "about" or “approximately,” even if the term does not expressly appear. The phrase “about” or

"approximately" may be used when describing magnitude and/or position to indicate that the value and/or position described is within a reasonable expected range of values and/or positions. For example, a numeric value may have a value that is +/- 0.1% of the stated value (or range of values), +/- 1% of the stated value (or range of values), +/- 2% of the stated value (or range of values), +/- 5% of the stated value (or range of values), +/- 10% of the stated value (or range of values), etc. Any numerical range recited herein is intended to include all sub-ranges subsumed therein.

CLAIMS

What is claimed is:

1. An imaging device comprising:

a hollow flexible shaft having a central longitudinal axis and an imaging window therein;

an optical fiber extending within the hollow flexible shaft substantially along the central axis, a distal tip of the optical fiber attached to the hollow flexible shaft and aligned with the imaging window so as to transfer an optical coherence tomography signal through the imaging window; and

a handle attached to the hollow flexible shaft configured rotate the hollow flexible shaft at speeds of greater than 1,000rpm.

2. The imaging device of claim 1, wherein the optical fiber extends substantially along the central axis for the entire length of the fiber.

3. The imaging device of claim 1, wherein the device is less than 0.1 inches in diameter.

4. The imaging device of claim 3, wherein the device is less than 0.08 inches in diameter.

5. The imaging device of claim 4, wherein the device is less than 0.05 inches in diameter.

6. The imaging device of claim 1, wherein the hollow flexible shaft is made of tungsten.

7. The imaging device of claim 1, wherein the hollow flexible shaft is made of multiple layers of wound filars.

8. The imaging device of claim 7, wherein the filars are counterwound.

9. The imaging device of claim 1, wherein the hollow flexible shaft further includes a mirror therein configured to reflect light from the optical fiber into adjacent tissue.

10. The imaging device of claim 1, further comprising an outer sheath extending around the hollow flexible shaft.

11. The imaging device of claim 10, wherein the outer sheath includes an optically clear annular section at the distal end thereof.

12. An imaging assembly comprising:

a catheter having a cutter and a lumen extending the length of the catheter;

a hollow flexible shaft configured to be inserted within the lumen of the catheter, the hollow flexible shaft having a central longitudinal axis and an imaging window therein; and

an optical fiber extending within the hollow flexible shaft substantially along the central axis, a distal tip of the optical fiber attached to the hollow flexible shaft and aligned with the imaging window so as to transfer an optical coherence tomography signal through the imaging window.

13. The imaging assembly of claim 12, wherein the catheter includes a cutter at a distal end.

14. The imaging assembly of claim 12, wherein the hollow flexible shaft further includes a handle attached thereto configured rotate the hollow flexible shaft at speeds of greater than 1,000rpm.

15. The imaging assembly of claim 12, wherein the optical fiber extends substantially along the central axis for the entire length of the fiber.

16. The imaging assembly of claim 15, further comprising an outer sheath extending around the hollow flexible shaft.

17. The imaging assembly of claim 16, wherein the outer sheath includes an optically clear annular section at the distal end thereof.

18. The imaging assembly of claim 12, wherein the hollow flexible shaft is made of tungsten.

19. The imaging assembly of claim 12, wherein the hollow flexible shaft is made of multiple layers of wound filars.

20. The imaging assembly of claim 19, wherein the filars are counterwound.

21. The imaging assembly of claim 12, wherein the hollow flexible shaft further includes a mirror attached to the distal end configured to reflect light from the optical fiber into adjacent tissue.

22. A method of imaging a body lumen, the method comprising:

inserting a catheter into the body lumen;

inserting an imaging device into a lumen of the catheter, the imaging device including a hollow flexible shaft having a central longitudinal axis with an imaging window therein and an optical fiber extending within the hollow flexible shaft and attached to the hollow flexible shaft, the optical fiber extending substantially along the central longitudinal axis;

rotating the hollow flexible shaft within the lumen of the catheter; and

collecting images of the body lumen through the imaging window with the optical fiber.

23. The method of claim 22, wherein rotating the hollow flexible shaft within the lumen comprises rotating the hollow flexible shaft at speeds of greater than 1,000 rpm.

24. The method of claim 22, wherein collecting images of the body lumen comprises collecting images of the body lumen at rates of greater than 10 frames per minute.

25. The method of claim 22, wherein the body lumen is a coronary artery.

26. The method of claim 22, wherein the body lumen is a peripheral artery.

27. The method of claim 22, wherein the catheter includes a cutter thereon, the method further comprising cutting tissue of the body lumen with the catheter to pass through an occlusion in the body lumen.

28. The method of claim 27, further comprising removing the imaging device from the lumen of the catheter and advancing a guidewire through the lumen of the catheter after passing the cutter through the occlusion.

29. An occlusion crossing device comprising:

a rotatable hollow flexible shaft having a central longitudinal axis and an imaging window therein;

an optical fiber extending within the hollow flexible shaft substantially along the central axis, a distal tip of the optical fiber aligned with the imaging window so as to transfer an optical coherence tomography signal through the imaging window; and

a cutter attached to a distal end of the hollow flexible shaft.

30. The occlusion crossing device of claim 29, wherein the optical fiber extends substantially along the central axis for the entire length of the fiber.

31. The occlusion crossing device of claim 29, further comprising an outer sheath extending around the hollow flexible shaft.

32. The occlusion crossing device of claim 31, further comprising a monorail guidewire lumen attached to the outer sheath.

33. The occlusion crossing device of claim 31, wherein the outer sheath includes an optically clear annular section at the distal end thereof.

34. The occlusion crossing device of claim 29, wherein the hollow flexible shaft is made of tungsten.

35. The occlusion crossing device of claim 29, wherein the hollow flexible shaft is made of multiple layers of wound filars.

36. The occlusion crossing device of claim 35, wherein the filars are counterwound.

37. The occlusion crossing device of claim 29, wherein the device is less than 0.1 inches in diameter.

38. The occlusion crossing device of claim 29, wherein the device is less than 0.08 inches in diameter.

39. The occlusion crossing device of claim 29, wherein the device is less than .05 inches in diameter.

40. The occlusion crossing device of claim 29, wherein the cutter includes a fluted distal end.

41. The occlusion crossing device of claim 29, wherein the cutter further includes a slanted proximal end and a mirror attached to the proximal end configured to reflect light from the optical fiber into adjacent tissue.

42. The occlusion crossing device of claim 29, wherein the optical fiber is configured to remain stationary relative to the hollow flexible shaft.

43. The occlusion crossing device of claim 29, wherein the optical fiber is attached to the hollow flexible shaft and configured to rotate therewith.

44. The occlusion crossing device of claim 29, further comprising a handle attached to the flexible shaft configured to rotate the hollow flexible shaft at speeds of greater than 1,000rpm.

45. A method of crossing an occlusion in a blood vessel, the method comprising:

inserting an occlusion crossing device into the vessel, the occlusion crossing device including a hollow flexible shaft having a central longitudinal axis and an imaging window therein, an optical fiber extending within the hollow flexible shaft substantially along the central axis to transfer an optical coherence tomography signal, and a cutter attached to a distal end of the hollow flexible shaft;

rotating the hollow flexible shaft and cutter so as to separate tissue of the occlusion;

collecting images of the vessel through the imaging window with the optical fiber; and

passing the cutter through the occlusion.

46. The method of claim 45, wherein rotating the flexible shaft and cutter comprises rotating at speeds of greater than 1,000 rpm.

47. The method of claim 45, wherein collecting images of the vessel comprises collecting images at rates of greater than 10 frames per minute.

48. The method of claim 45, further comprising rotating the optical fiber with the hollow flexible shaft.

49. The method of claim 45, wherein rotating the hollow flexible shaft comprises rotating the imaging shaft while keeping the fiber rotationally fixed.

50. The method of claim 45, wherein the vessel is a coronary artery.

51. The method of claim 45, wherein the vessel is a peripheral artery.

52. An occlusion crossing device comprising:

an elongate body;

a drive shaft extending through the elongate body having a perforating tip attached thereto;

a deflectable tip having a wedged distal end attached to the elongate body; and

a guidewire lumen extending through the deflectable tip.

53. The occlusion crossing device of claim 52, further comprising an imaging element attached to the drive shaft.

54. The occlusion crossing device of claim 53, wherein the imaging element is an optical coherence tomography imaging element.

55. The occlusion crossing device of claim 52, wherein the deflectable tip is configured to be deflected by axial movement of the drive shaft.

56. The occlusion crossing device of claim 52, wherein the device is less than 0.1 inches in diameter.

57. The occlusion crossing device of claim 56, wherein the device is less than 0.08 inches in diameter.

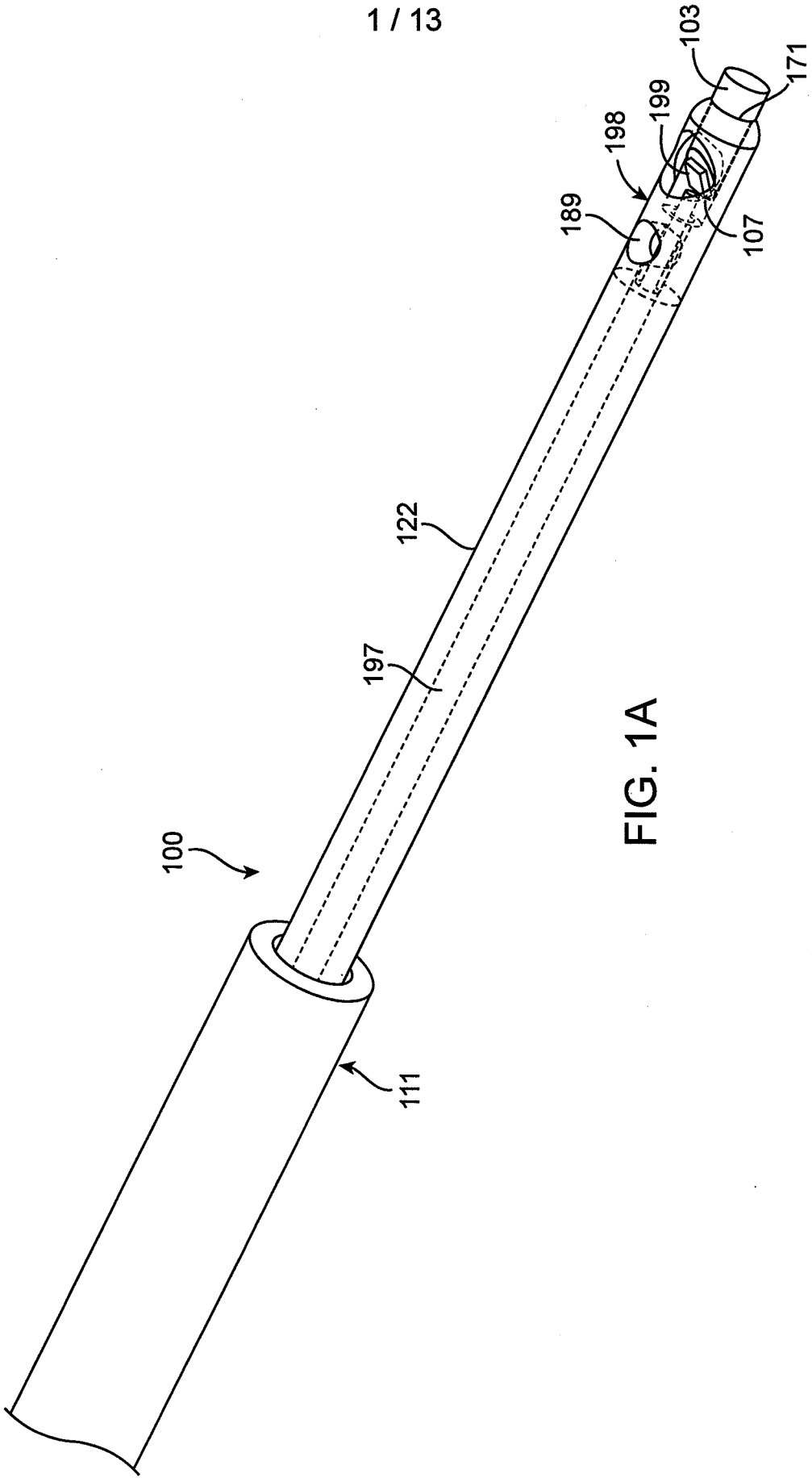

FIG. 1A

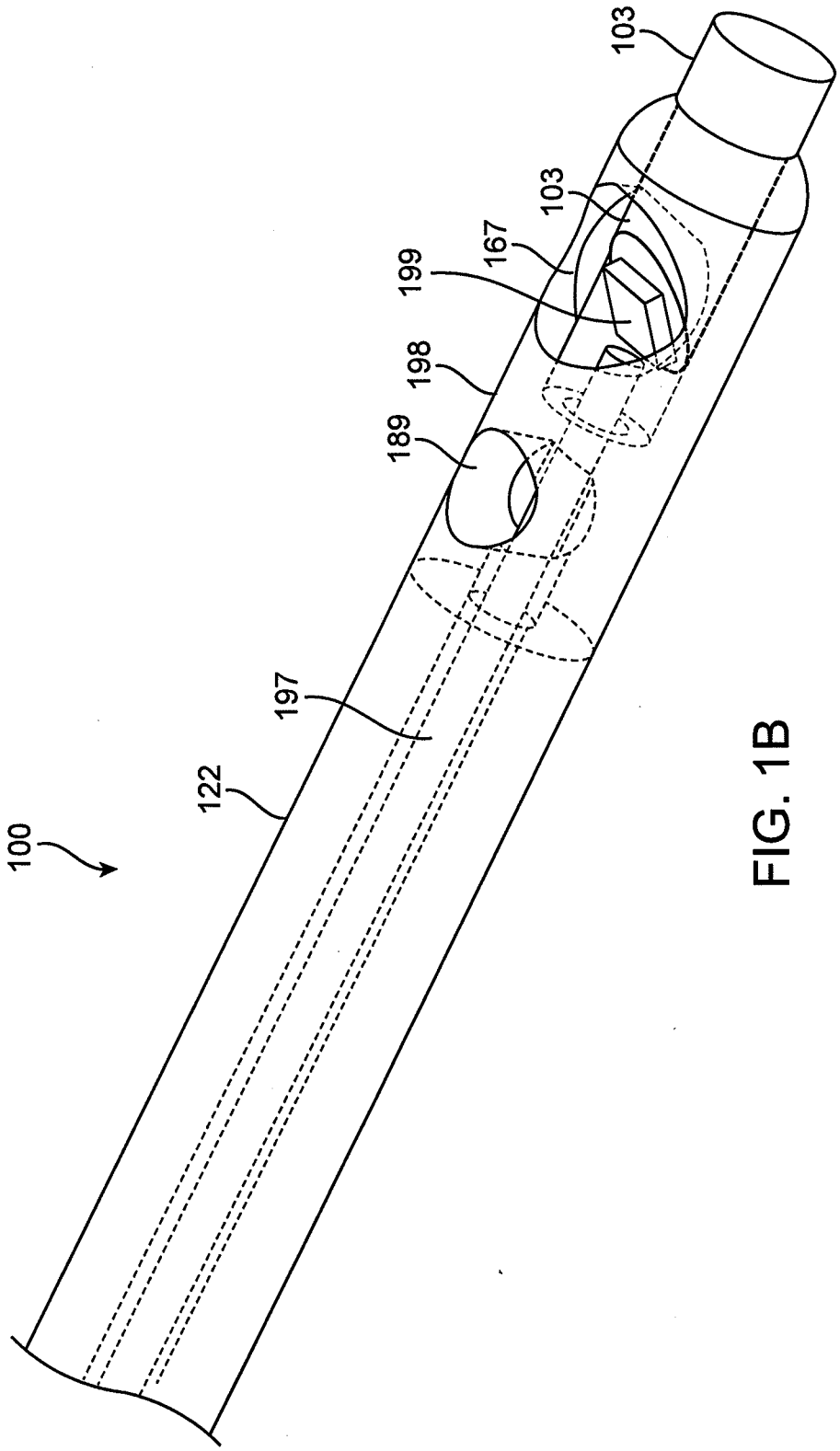

FIG. 1B

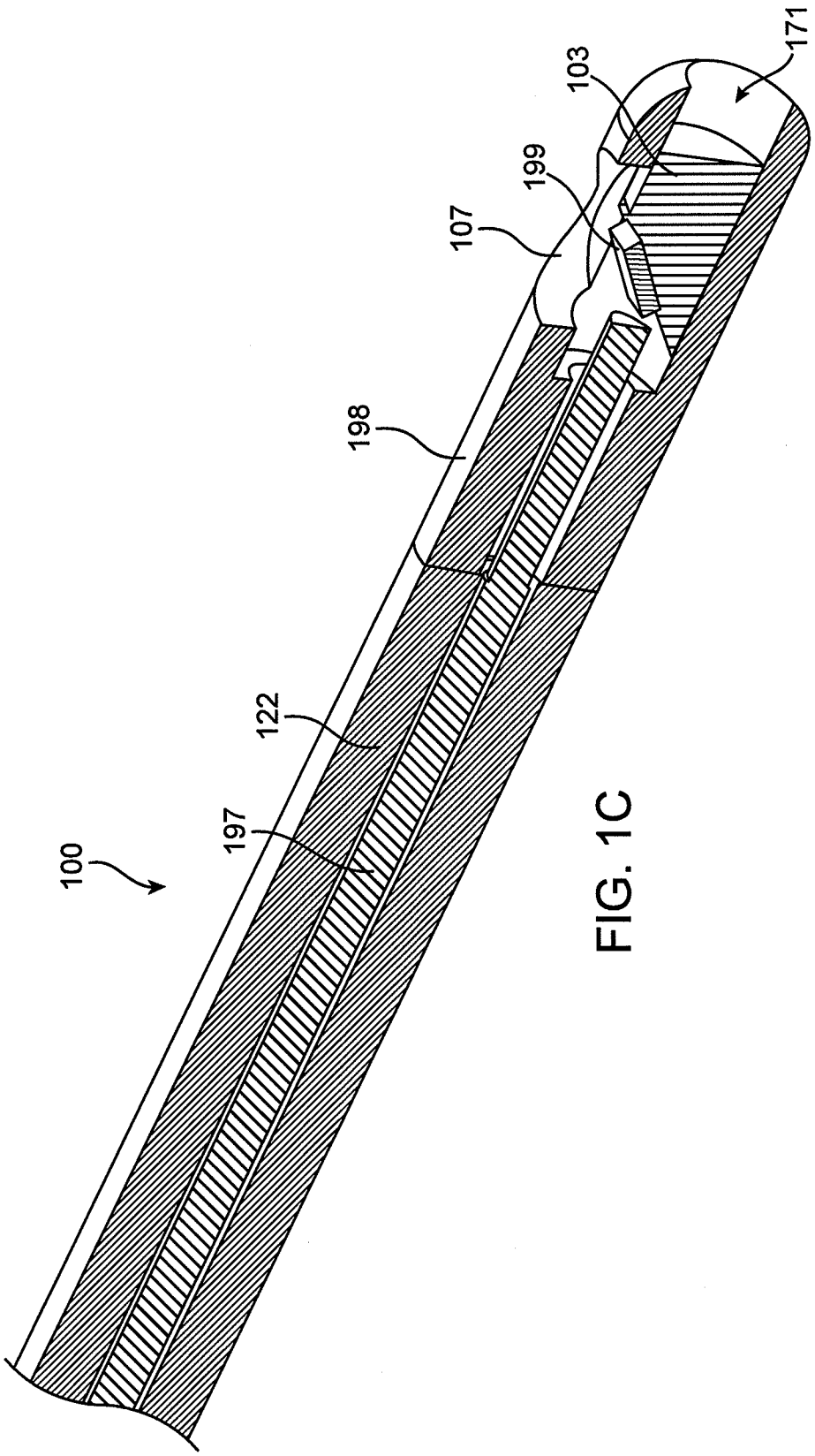

FIG. 1C

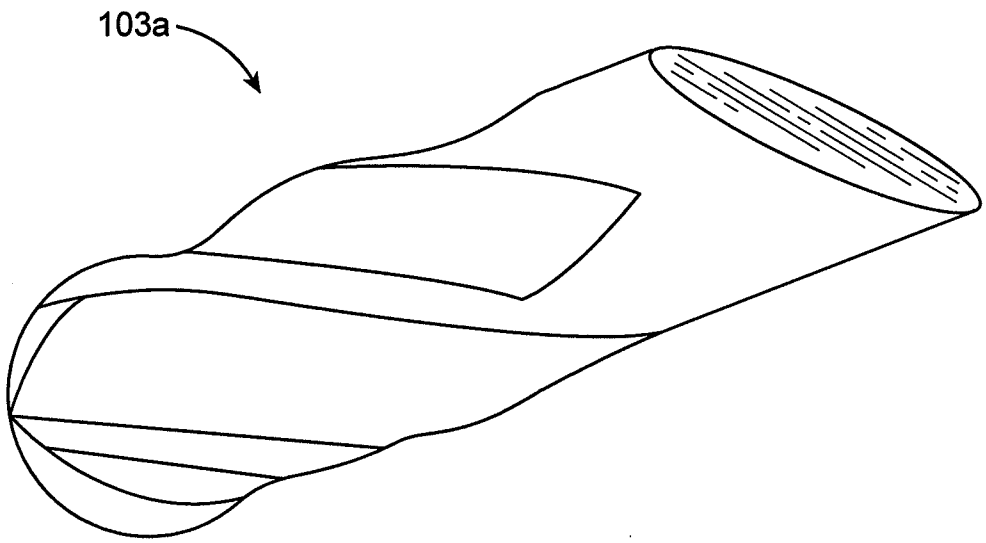

FIG. 1D

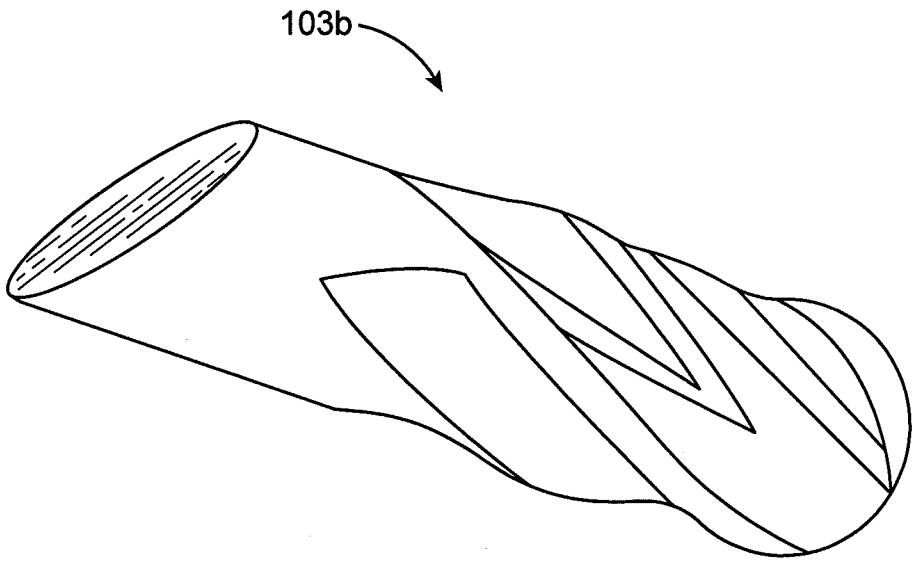

FIG. 1E

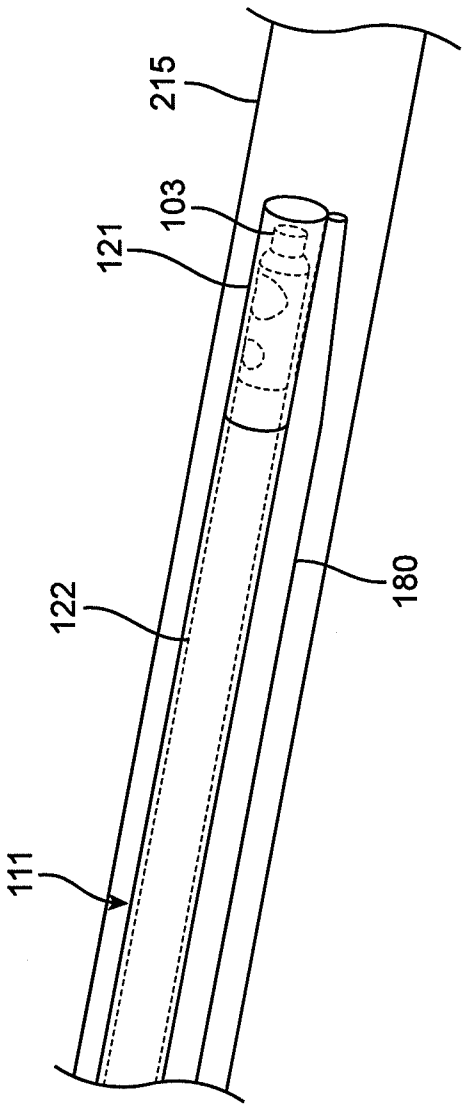

FIG. 2A

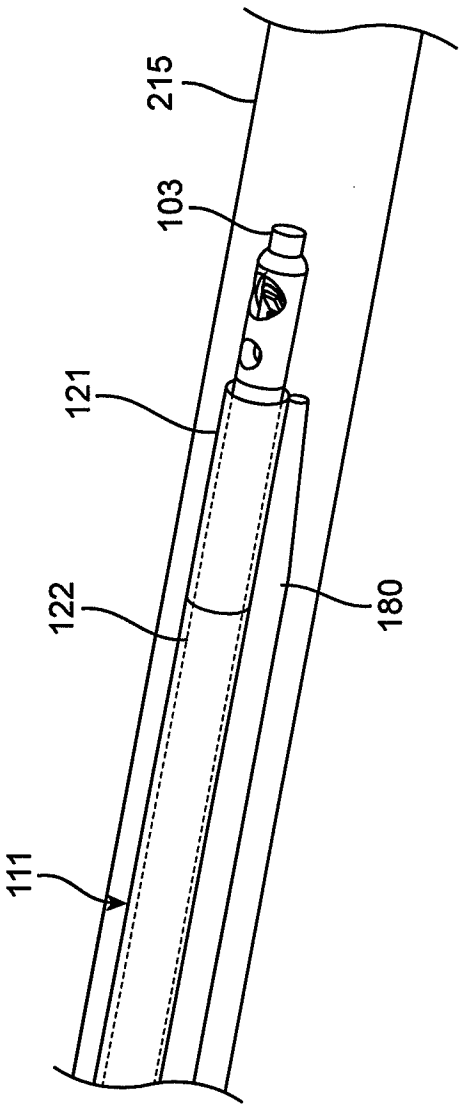

FIG. 2B

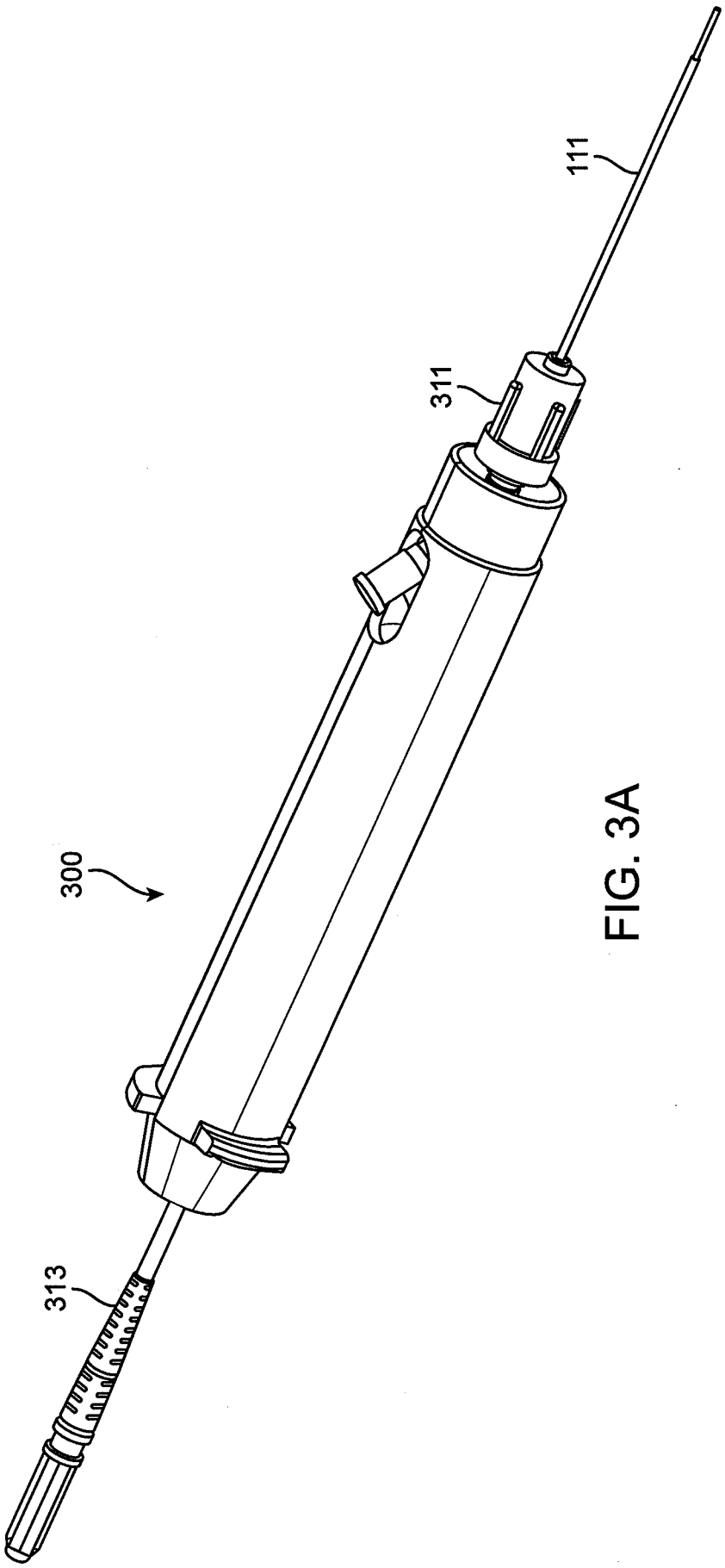

FIG. 3A

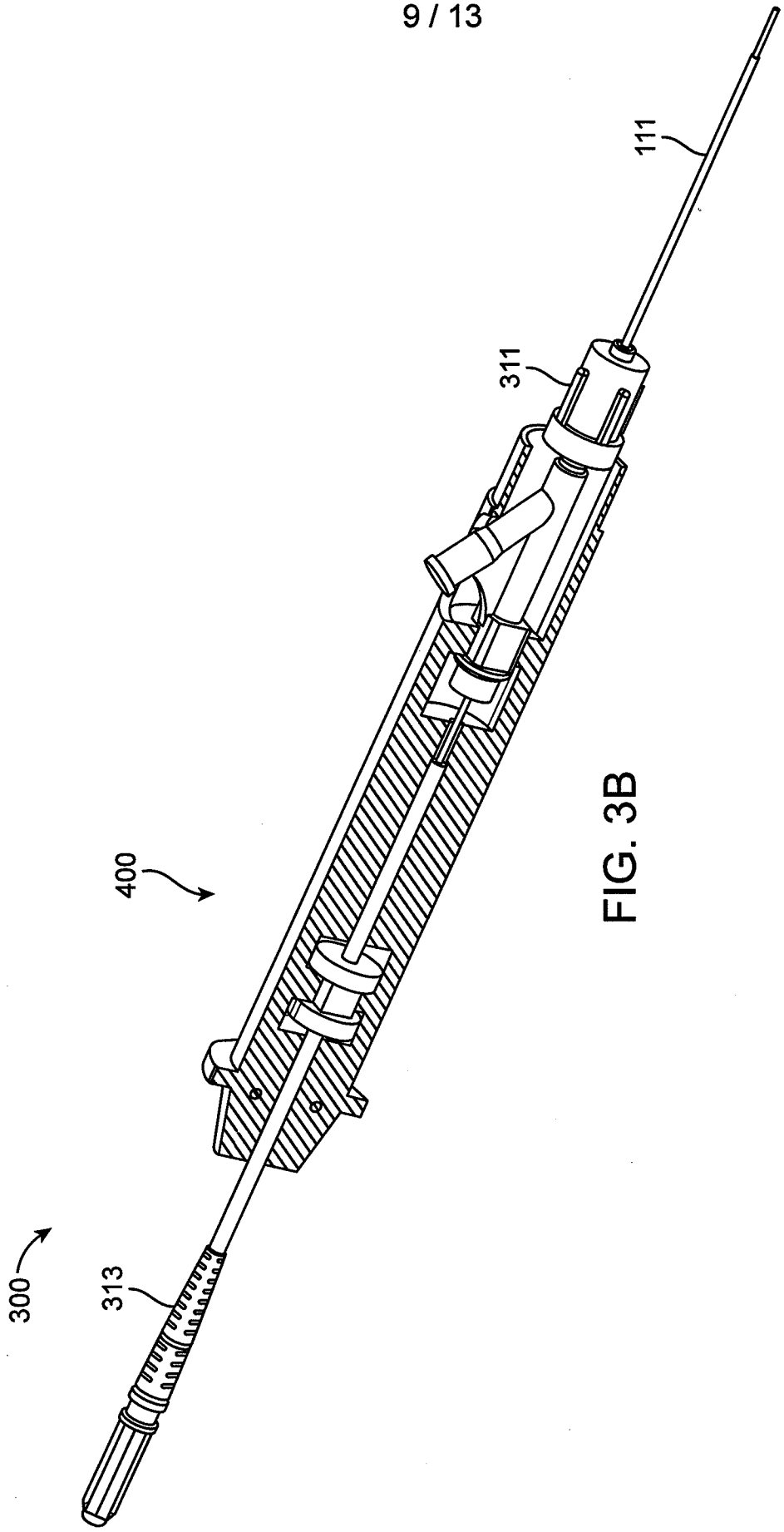

FIG. 3B

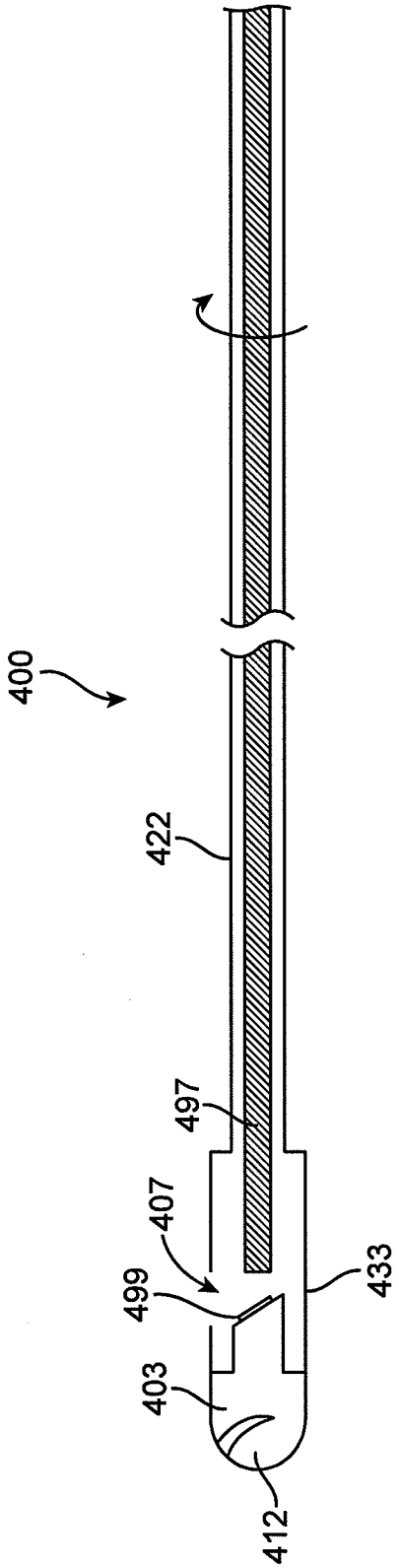

FIG. 4A

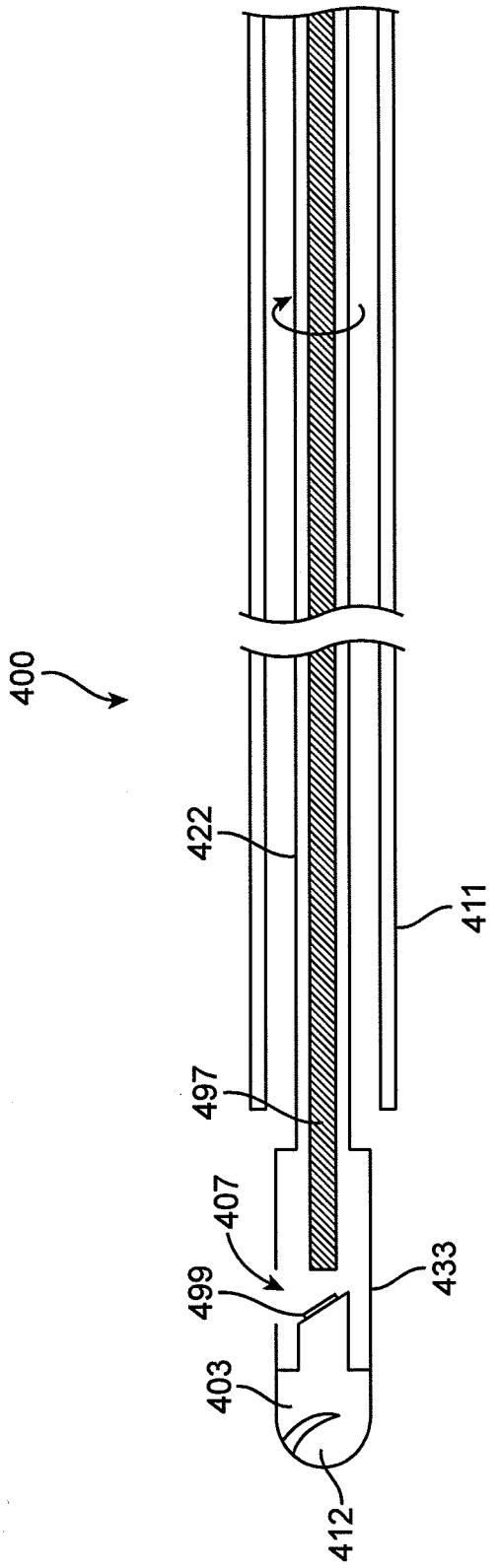

FIG. 4B

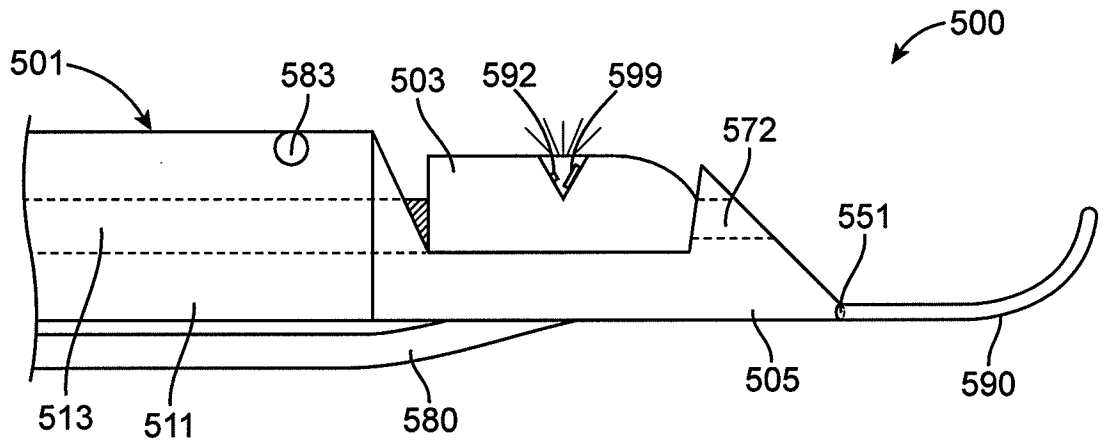
500
501
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FIG. 5A

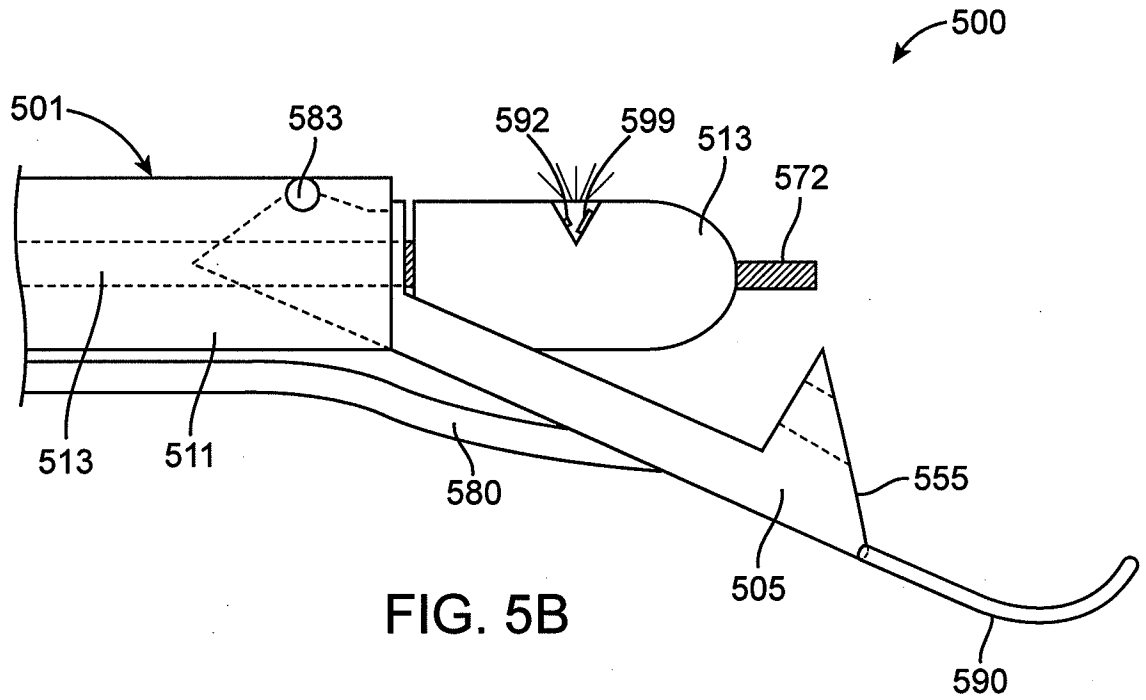
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FIG. 5B

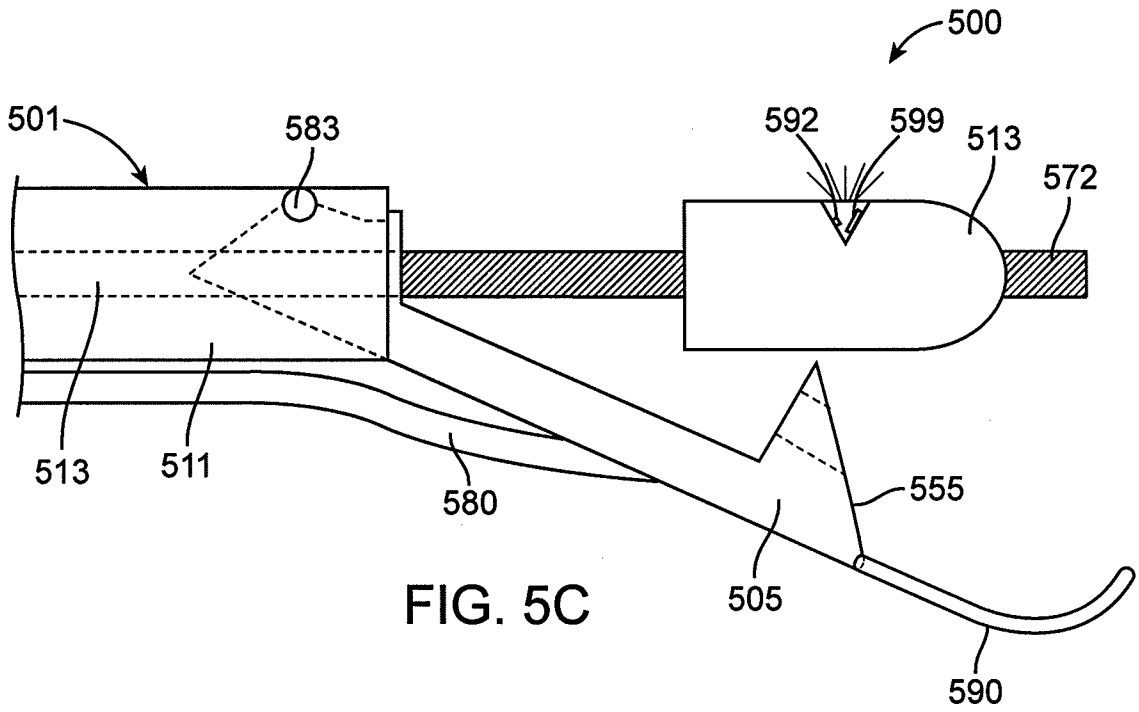

FIG. 5C

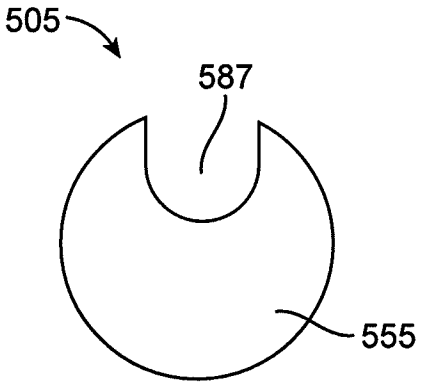

FIG. 5D

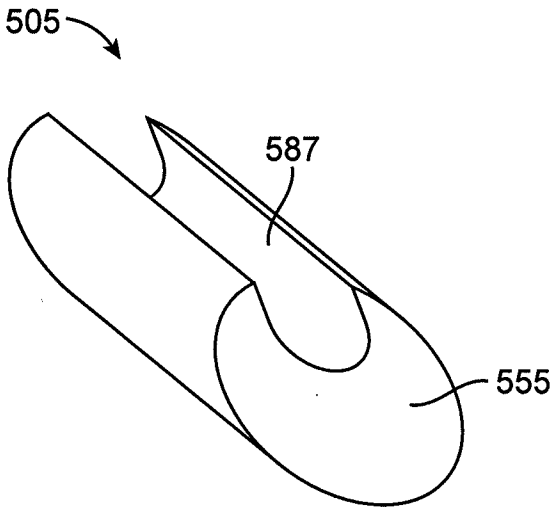

FIG. 5E

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2013/032679

A. CLASSIFICATION OF SUBJECT MATTER

A61B 5/0215(2006.01)i, A61B 5/027(2006.01)i

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B 5/0215; A61B 17/22; A61B 6/00; A61B 5/00; A61B 5/027

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
Korean utility models and applications for utility models
Japanese utility models and applications for utility models

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
eKOMPASS(KIPO internal) & Keywords:catheter, OCT, rotate, optical fiber, cutter, window

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2010-0305452 A1 (JOHN F. BLACK et al.) 02 December 2010 See abstract, paragraphs [0068]-[0069], [0087]-[0092], claims 1-15, 64-72 and figures 2A-2B, 4A-12.	1-21,29-44
A		52-57
Y	US 2004-0186368 A1 (KAMAL RAMZIPOOR et al.) 23 September 2004 See abstract, paragraphs [0025]-[0031], [0039]-[0047], claims 44-53 and figures 1-7B.	1-21,29-44
X	US 2012-0046679 A1 (HIMANSHU N. PATEL et al.) 23 February 2012 See abstract, paragraphs [0064]-[0091], [0101], [0112]-[0114], [0121], claims 1-12 and figures 1-21B.	52-57
A	US 2005-0187571 A1 (MICHAEL MASCHKE) 25 August 2005 See abstract, paragraphs [0022]-[0026], claims 10-16 and figure 1.	1-21,29-44,52-57
A	US 2008-0065125 A1 (WILLIAM JOHN OLSON) 13 March 2008 See abstract, paragraphs [0033]-[0038], [0064]-[0067], claims 1-10 and figures 1-5B.	1-21,29-44,52-57

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

☒ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of citation or other special reason (as specified)
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"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents,such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
18 December 2013 (18.12.2013)	**19 December 2013 (19.12.2013)**

Name and mailing address of the ISA/KR
Korean Intellectual Property Office
189 Cheongsa-ro, Seo-gu, Daejeon Metropolitan City, 302-701, Republic of Korea
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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2013/032679

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

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

1. ☒ Claims Nos.: 22-28, 45-51
because they relate to subject matter not required to be searched by this Authority, namely:
Claims 22-28, 45-51 pertain to methods for treatment of the human body by therapy or surgery, as well as diagnostic methods, and thus relate to a subject matter which this International Searching Authority is not required to search under Article 17(2)(a)(i) of the PCT and Rule 39.1(iv) of the Regulations under the PCT.

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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

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

1. ☐ As all required addtional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

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

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
PCT/US2013/032679

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2010-0305452 A1	02/12/2010	AU 2010-253912 A1	02/12/2010
		AU 2010-253912 A1	22/12/2011
		CA 2763324 A1	02/12/2010
		CA 2767017 A1	06/01/2011
		CN 102460118 A	16/05/2012
		CN 102469940 A	23/05/2012
		EP 2435815 A2	04/04/2012
		EP 2448472 A2	09/05/2012
		JP 2012-528342 A	12/11/2012
		JP 2012-531972 A	13/12/2012
		US 2011-0021926 A1	27/01/2011
		WO 2010-138927 A2	02/12/2010
		WO 2010-138927 A3	14/04/2011
		WO 2010-138927 A8	02/12/2010
		WO 2010-138927 A9	02/12/2010
		WO 2011-003013 A2	06/01/2011
		WO 2011-003013 A3	31/03/2011
US 2004-0186368 A1	23/09/2004	AU 2003-300095 A1	19/11/2004
		US 2010-0185054 A1	22/07/2010
		US 7715896 B2	11/05/2010
		US 8005529 B2	23/08/2011
		WO 2004-093666 A1	04/11/2004
US 2012-0046679 A1	23/02/2012	CA 2803992 A1	05/01/2012
		EP 2588012 A2	08/05/2013
		WO 2012-003430 A2	05/01/2012
		WO 2012-003430 A3	12/04/2012
US 2005-0187571 A1	25/08/2005	DE 102004008371 A1	15/09/2005
		DE 102004008371 B4	24/05/2006
		US 8359086 B2	22/01/2013
US 2008-0065125 A1	13/03/2008	AU 2002-231074 A8	01/07/2002
		AU 2002-31074 A1	01/07/2002
		CA 2605178 A1	26/10/2006
		CA 2622716 A1	29/03/2007
		EP 1345542 A2	24/09/2003
		EP 1345542 B1	23/02/2011
		EP 1622501 A2	08/02/2006
		EP 1622523 A2	08/02/2006
		EP 1622523 B1	09/05/2012
		EP 1767159 A1	28/03/2007
		EP 1871244 A2	02/01/2008
		EP 1938196 A2	02/07/2008
		EP 2019634 A2	04/02/2009
		EP 2353526 A1	10/08/2011
		EP 2353526 B1	04/09/2013
		EP 2481364 A1	01/08/2012

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
PCT/US2013/032679

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
		EP 2481365 A1	01/08/2012
		JP 2004-516073 A	03/06/2004
		JP 4080874 B2	23/04/2008
		US 2002-0077642 A1	20/06/2002
		US 2003-0120295 A1	26/06/2003
		US 2003-0125757 A1	03/07/2003
		US 2003-0125758 A1	03/07/2003
		US 2004-0167553 A1	26/08/2004
		US 2004-0167554 A1	26/08/2004
		US 2005-0042238 A1	24/02/2005
		US 2005-0154407 A1	14/07/2005
		US 2005-0177068 A1	11/08/2005
		US 2005-0222519 A1	06/10/2005
		US 2005-0222663 A1	06/10/2005
		US 2006-0032508 A1	16/02/2006
		US 2006-0235366 A1	19/10/2006
		US 2006-0236019 A1	19/10/2006
		US 2006-0239982 A1	26/10/2006
		US 2007-0010840 A1	11/01/2007
		US 2007-0078469 A1	05/04/2007
		US 2008-0065124 A1	13/03/2008
		US 2009-0299394 A1	03/12/2009
		US 2010-0121360 A9	13/05/2010
		US 2010-0198240 A1	05/08/2010
		US 2011-0060606 A1	10/03/2011
		US 2012-016395 A1	19/01/2012
		US 7699790 B2	20/04/2010
		US 7708749 B2	04/05/2010
		US 7713279 B2	11/05/2010
		US 7771444 B2	10/08/2010
		US 7794413 B2	14/09/2010
		US 7887556 B2	15/02/2011
		US 7927784 B2	19/04/2011
		US 8052704 B2	08/11/2011
		US 8226674 B2	24/07/2012
		US 8246640 B2	21/08/2012
		US 8328829 B2	11/12/2012
		US 8469979 B2	25/06/2013
		WO 02-049690 A2	27/06/2002
		WO 02-049690 A3	19/09/2002
		WO 2004-093660 A2	04/11/2004
		WO 2004-093660 A3	09/04/2009
		WO 2004-093661 A2	04/11/2004
		WO 2004-093661 A3	15/09/2005
		WO 2006-065383 A2	22/06/2006
		WO 2006-066012 A2	22/06/2006
		WO 2006-066012 A3	30/04/2009
		WO 2006-113494 A2	26/10/2006
		WO 2006-113494 A3	19/04/2007
		WO 2007-035909 A2	29/03/2007

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
PCT/US2013/032679

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
		WO 2007-035909 A3	07/05/2009
		WO 2008-020905 A2	21/02/2008
		WO 2008-020905 A3	06/11/2008