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(54) Title: DEVICE FOR MINIMALLY INVASIVE DELIVERY OF TREATMENT SUBSTANCE

(57) Abstract: Systems, methods, and devices for delivering ablation fluid to a location of interest within a body (e.g., a location with the lung) are described herein. Ablation fluid delivery systems and devices can include flexible delivery needles (2010) within which a plurality of smaller flexible needles (2040) is housed. The smaller flexible needles can be configured to articulate or bend with respect to the flexible delivery needle to increase an effective delivery area for the ablation fluid. The smaller flexible needles can include apertures or other openings (2042) to facilitate delivery of the ablation fluid to the location of interest.

DEVICE FOR MINIMALLY INVASIVE DELIVERY OF TREATMENT SUBSTANCE

Cross Reference to Related Applications

[0001] This application claims priority to and the benefit of U.S. provisional patent application serial No. 61/779483 filed on March 13, 2013 entitled "Device for Minimally Invasive Delivery of Treatment Substance," the entire disclosure of which is hereby incorporated by reference as if set forth in its entirety for all purposes.

Technical Field

[0002] Embodiments of the invention relate generally to the field of medical devices, and in particular, to methods, systems, and devices for navigating to and delivering chemicals or other substances to tissue such as lung nodules or other sites of interest. In particular, certain embodiments described herein use a flexible delivery needle with internal flexible needles to deliver substances to a site of interest within the body.

BACKGROUND

Description of the Related Art

[0003] Early diagnosis of potentially cancerous tissue is an important step in the treatment of cancer because, the sooner that cancerous tissue can be treated, and the better the patient's chances are for survival. Typical diagnostic procedures involve biopsying tissue at a site of interest. In the case of lungs, lung cancer can be difficult to diagnose due to the difficulties in accessing airways near areas of interest. Areas of interest may present as lung nodules—small tissue masses in the lung that may range in size between 0.5-30 mm — that typically are biopsied to ascertain whether the tissue therein is cancerous or otherwise diseased. In some instances treatment of tissue in an area of interest can include delivery of chemicals (e.g., ablative chemicals) or other substances.

[0004] Existing systems typically are constrained by difficulties in accessing lung nodules, especially in the smaller peripheral airways that may be too narrow to accommodate larger catheters and biopsy/substance delivery apparatuses. Further, the

biopsy/substance delivery needles normally are straight and relatively inflexible. Thus, the biopsy/substance delivery needles can limit the articulation of a bronchoscope or can be difficult to pass through a working channel of a bronchoscope when the bronchoscope is articulated around a tight corner. In some instances, the material of the needle may inelastically yield, which can result in a bent needle that is difficult to control. In addition, the straight biopsy needles obtain samples along an axis of the needle through back and forth cycling of the needle. Thus, obtaining multiple samples from different regions of a single nodule, for example, can be difficult and can require repeated repositioning of the bronchoscope or guide sheath, for example. Furthermore, delivery of substances to different regions of a single nodule can be difficult.

SUMMARY

[0005] Accordingly, embodiments described herein relate generally to methods, systems, and devices for navigating to and biopsying tissue at a site of interest. In particular, embodiments described herein may be used for biopsying tissue in a lung (such as lung nodules or lymph nodes) using a flexible transbronchial biopsy aspiration needle system. Certain embodiments provide for the flexible biopsy needle to be steerable or guidable to a location of interest. Further embodiments provide for a visualization system (e.g., ultrasound) to be provided in a flexible, miniaturized configuration, and this visualization system may be combined with the flexible biopsy needle.

[0006] In one embodiment, a system for obtaining a tissue sample in or near an airway comprises:

[0007] a flexible needle with distal and proximal ends, the distal end of the needle comprising a less flexible distal tip region and a more flexible proximal region, the less flexible distal tip region comprising a piercing tip configured to obtain a tissue sample, and the more flexible proximal region configured to bend;

[0008] a catheter, wherein the catheter comprises at least one interior lumen, the flexible needle being slidably received within the at least one interior lumen; and

[0009] a suction source in fluid communication with the flexible needle.

[00010] Additional embodiments comprise a steering mechanism configured to steer the flexible needle toward a site of the tissue to be sampled. The steering mechanism may comprise at least one guidewire extending longitudinally along the exterior of the flexible needle or the at least one interior lumen. In some configurations, the steering mechanism may comprise a guidewire extending within an interior lumen of

the flexible needle. In some embodiments, the guidewire is removable from the interior lumen of the flexible needle. The system may also comprise a navigation system. The navigation system can utilize an ultrasound probe. In some embodiments, the ultrasound probe is located at a distal end of the catheter. In some embodiments, the catheter comprises a second lumen and the ultrasound probe is received within the second lumen. In some embodiments, the catheter is received within the working channel of a bronchoscope. Some configurations may provide for the catheter being received within a bronchoscope comprising a second steering mechanism, wherein the second steering mechanism can steer independently of the steering mechanism configured to steer the flexible needle.

[0011] In another embodiment, a method for obtaining a tissue sample in or near an airway comprises:

[0012] identifying a location in the airway in close proximity to a tissue sample site;

[0013] introducing a flexible needle into the airway;

[0014] navigating the flexible needle to the location in the airway;

[0015] articulating the flexible needle in a direction toward a tissue sample site; and

[0016] obtaining a tissue sample from the tissue sample site, wherein the flexible needle pierces into the tissue sample site, and wherein suction is applied to the flexible needle so as to collect tissue from the tissue sample site.

[0017] In some embodiments, the flexible needle is articulated by a steering mechanism. In some embodiments, the flexible needle is inserted into a lumen of a catheter. In some embodiments, the step of navigating comprises locating the flexible needle with a radioopaque marker situated on the flexible needle and/or the catheter. In some embodiments, the flexible needle is inserted into a lumen of a bronchoscope.

[0018] In some embodiments, a flexible needle configured to access a location near an airway, has a length and comprises a proximal end and a distal end comprising a piercing tip. The needle can include a flexible proximal tip region located along the length of the flexible needle between the distal end and the proximal end, the flexible proximal tip region having one or more flexibility increasing features and configured to bend. In some embodiments, the flexible needle includes a flexible distal tip region located along the length of the flexible needle between the flexible proximal tip region and the distal end, wherein the flexible distal tip region is less flexible than the proximal

tip region. The flexibility increasing feature can be, for example, one or more cuts in the flexible needle. In some embodiments, the one or more cuts extend in a spiral fashion along flexible proximal tip region. In some embodiments, the one or more cuts are arranged in a jigsaw configuration. In some embodiments, the one or more cuts are arranged in a serpentine configuration. In some embodiments, the one or more cuts comprise an interrupted spiral pattern where the flexible needle has cut and uncut portions along a same spiral path. In some embodiments, the one or more cuts are distributed asymmetrically on a portion of the length of flexible needle such that the cuts are located on only a portion of a radial circumference of the flexible needle.

[0019] According to some embodiments, the flexible needle and any variants thereof can be used in combination with a catheter comprising at least one interior lumen, the flexible needle being slidably received within the at least one interior lumen, and with a suction source in fluid communication with the flexible needle. Such a combination can form a system for accessing tissue near an airway. The system can include a steering mechanism configured to steer the flexible needle toward the tissue sample site. In some embodiments, the steering mechanism comprises at least one guidewire extending longitudinally along the exterior of the flexible needle or the at least one interior lumen. In some embodiments, the steering mechanism comprises a guidewire extending within an interior lumen of the flexible needle. In some embodiments, the guidewire is removable from the interior lumen of the flexible needle. According to some variants, the system includes a navigation system. The navigation system can be an ultrasound probe. The ultrasound probe can be located at a distal end of the catheter. The catheter can include a second lumen and the ultrasound probe is received within the second lumen. In some embodiments, the catheter is received within the working channel of a bronchoscope. In some embodiments, the catheter is received within a bronchoscope comprising a second steering mechanism, and the second steering mechanism can steer independently of the steering mechanism configured to steer the flexible needle.

[0020] In some embodiments, a method of manufacturing a flexible needle can include providing a tube shaped length of resilient material having a distal end and a proximal end, forming an angled tip on the distal end of the tube shaped length of resilient material, and forming one or more flexibility increasing features on the tube shaped length of resilient material, such that the flexible needle has a flexible proximal tip region located along the tube shaped length of resilient material between the distal end and the proximal end, the flexible proximal tip region having one or more flexibility

increasing features and configured to bend, and such that a flexible distal tip region located along the tube shaped length of resilient material between the flexible proximal tip region and the distal end, wherein the flexible distal tip region is less flexible than the proximal tip region. In some embodiments, forming the one or more flexibility increasing features includes cutting one or more cuts into a wall of the tube shaped length of resilient material. In some embodiments, cutting the one or more cuts includes water jetting the wall of the tube shaped length of resilient material. In some embodiments, cutting the one or more cuts includes laser cutting the wall of the tube shaped length of resilient material. In some embodiments, cutting the one or more cuts includes chemical etching the wall of the tube shaped length of resilient material.

[0021] A method for obtaining a tissue sample near an airway can include identifying a location in the airway in close proximity to a tissue sample site, introducing a flexible needle into the airway, navigating the flexible needle to the location in the airway, articulating the flexible needle in a direction toward the tissue sample site, and obtaining a tissue sample from the tissue sample site, wherein the flexible needle pierces the airway and into the tissue sample site, and wherein suction is applied to the flexible needle so as to collect tissue from the tissue sample site. The method can include articulating the flexible needle using a steering mechanism. In some embodiments, the flexible needle is inserted into a lumen of a catheter. In some embodiments, the step of navigating comprises locating the flexible needle with a radioopaque marker situated on the flexible needle and/or the catheter. In some embodiments the flexible needle is inserted into a lumen of a bronchoscope.

[0022] Various example embodiments of the disclosure can be described in view of the following clauses:

[0023] Clause 1: a flexible needle configured to access a location near an airway, the flexible needle having a length and comprising: a proximal end; a distal end comprising a piercing tip; a flexible proximal tip region located along the length of the flexible needle between the distal end and the proximal end, the flexible proximal tip region having one or more flexibility increasing features and configured to bend; and a flexible distal tip region located along the length of the flexible needle between the flexible proximal tip region and the distal end, wherein the flexible distal tip region is less flexible than the proximal tip region.

[0024] Clause 2: the flexible needle of Clause 1, wherein the flexibility increasing feature comprises one or more cuts in the flexible needle.

[0025] Clause 3: the flexible needle of Clause 2, wherein the one or more cuts extend in a spiral fashion along flexible proximal tip region.

[0026] Clause 4: the flexible needle of Clause 2, wherein the one or more cuts are arranged in a jigsaw configuration.

[0027] Clause 5: the flexible needle of Clause 2, wherein the one or more cuts are arranged in a serpentine configuration.

[0028] Clause 6: the flexible needle of Clause 2, wherein the one or more cuts are arranged in an interrupted spiral pattern where the flexible needle has cut and uncut portions along a same spiral path.

[0029] Clause 7: the flexible needle of and of Clauses 2-6, wherein the one or more cuts are distributed asymmetrically on a portion of the length of flexible needle such that the cuts are located on only a portion of a radial circumference of the flexible needle.

[0030] Clause 8: a system for accessing tissue near an airway, the system comprising: the flexible needle of Clause 1; a catheter comprising at least one interior lumen, the flexible needle being slidably received within the at least one interior lumen; and a suction source in fluid communication with the flexible needle.

[0031] Clause 9: the system of Clause 8, further comprising a steering mechanism configured to steer the flexible needle toward the tissue sample site.

[0032] Clause 10: the system of Clause 9, wherein the steering mechanism comprises at least one guidewire extending longitudinally along the exterior of the flexible needle or the at least one interior lumen.

[0033] Clause 11: the system of either of Clauses 9 or 10, wherein the steering mechanism comprises a guidewire extending within an interior lumen of the flexible needle.

[0034] Clause 12: the system of Clause 11, wherein the guidewire is removable from the interior lumen of the flexible needle.

[0035] Clause 13: the system of any of Clauses 8-12, further comprising a navigation system.

[0036] Clause 14: the system of Clause 13, wherein the navigation system is an ultrasound probe.

[0037] Clause 15: the system of Clause 14, wherein the ultrasound probe is located at a distal end of the catheter.

[0038] Clause 16: the system of Clauses 14 or 15, wherein the catheter comprises a second lumen and the ultrasound probe is received within the second lumen.

[0039] Clause 17: the system of any of Clauses 8-16, wherein the catheter is received within the working channel of a bronchoscope.

[0040] Clause 18: the system of any of Clauses 9-17, wherein the catheter is received within a bronchoscope comprising a second steering mechanism, and wherein the second steering mechanism can steer independently of the steering mechanism configured to steer the flexible needle.

[0041] Clause 19: a method of manufacturing a flexible needle comprising: providing a tube shaped length of resilient material having a distal end and a proximal end; forming an angled tip on the distal end of the tube shaped length of resilient material; forming one or more flexibility increasing features on the tube shaped length of resilient material, such that the flexible needle comprises: a flexible proximal tip region located along the tube shaped length of resilient material between the distal end and the proximal end, the flexible proximal tip region having one or more flexibility increasing features and configured to bend; and a flexible distal tip region located along the tube shaped length of resilient material between the flexible proximal tip region and the distal end, wherein the flexible distal tip region is less flexible than the proximal tip region.

[0042] Clause 20: the method of Clause 19, wherein forming the one or more flexibility increasing features includes cutting one or more cuts into a wall of the tube shaped length of resilient material.

[0043] Clause 21: the method of Clause 20, wherein cutting the one or more cuts includes water jetting the wall of the tube shaped length of resilient material.

[0044] Clause 22: the method of Clause 20, wherein cutting the one or more cuts includes laser cutting the wall of the tube shaped length of resilient material.

[0045] Clause 23: the method of Clause 20, wherein cutting the one or more cuts includes chemical etching the wall of the tube shaped length of resilient material.

[0046] Clause 24: a method for obtaining a tissue sample near an airway, the method comprising: identifying a location in the airway in close proximity to a tissue sample site; introducing a flexible needle into the airway; navigating the flexible needle to the location in the airway; articulating the flexible needle in a direction toward the tissue sample site; and obtaining a tissue sample from the tissue sample site, wherein the flexible needle pierces the airway and into the tissue sample site, and wherein suction is applied to the flexible needle so as to collect tissue from the tissue sample site.

[0047] Clause 25: the method of Clause 24, wherein the flexible needle is articulated by a steering mechanism.

[0048] Clause 26: the method of any of Clauses 24 or 25, wherein the flexible needle is inserted into a lumen of a catheter.

[0049] Clause 27: the method of Clause 26**Error! Reference source not found.**, wherein the step of navigating comprises locating the flexible needle with a radioopaque marker situated on the flexible needle and/or the catheter.

[0050] Clause 28: the method of Clause 24, wherein the flexible needle is inserted into a lumen of a bronchoscope.

[0051] A needle assembly for delivery a treatment substance to a site within the body can comprise: a delivery needle defining a delivery lumen and having a delivery needle wall, a proximal end, and a distal end, the delivery needle wall having one or more cut patterns to increase the flexibility of the delivery needle; a plurality of internal needles, each internal needle defining an internal needle lumen and having an internal needle wall, a proximal end, and a distal end, the plurality of needles configured to transition between a contracted position and an expanded position; and a treatment substance source in fluid communication with the internal needle lumens of the plurality of internal needles; wherein each of the plurality of internal needles is configured to extend in a distal direction and flare outward from the distal end of the delivery needle when in the extend position and wherein the plurality of internal needles are housed within the delivery lumen when the contracted position. In some embodiments, an internal surface of the delivery needle wall is coated with a substance configured to reduce or eliminate the likelihood that the internal needles will stick to or catch on the delivery needle wall when the internal needles are transitioned between the contracted position and the expanded position. In some embodiments, the internal needles walls of the internal needles include cut features, the cut features facilitating fluid communication between the internal needle lumen and an exterior of the internal needles. According to some variants, the needle assembly comprises a flexible shaft having a distal end and a proximal end, the distal end of the flexible shaft coupled with the proximal ends of the internal needles. In some embodiments, the needle assembly comprises three internal needles. In some embodiments, each of the internal needles had a distal aperture in fluid communication with the internal needle lumen. The distal ends of the internal needles can be sharpened and/or beveled. The distal end of the delivery needle can be sharpened and/or beveled.

BRIEF DESCRIPTION OF THE DRAWINGS

[0052] The foregoing and other features, aspects and advantages of the present disclosure are described in detail below with reference to the drawings of various embodiments, which are intended to illustrate and not to limit the disclosure. The drawings comprise the following figures in which:

[0053] Figure 1 is a perspective view of a transbronchial needle aspiration system comprising an ultrasound sensor.

[0054] Figure 2 illustrates a side view of an embodiment of a flexible needle.

[0055] Figures 3A-G illustrate various configurations for interruptions that may be made along one or more portions of embodiments of the flexible needles.

[0056] Figure 4 illustrates a close-up view of the flexible shaft portion of an embodiment of a flexible needle.

[0057] Figure 5 illustrates a side view of another embodiment of the flexible needle.

[0058] Figures 6A-D illustrate schematic cross-section views of different embodiments of a steerable, flexible needle assembly.

[0059] Figure 7 illustrates a side view of an embodiment of a steerable, flexible needle assembly.

[0060] Figure 8 illustrates an embodiment of a steerable, flexible needle assembly comprising an inner guidewire.

[0061] Figure 9 illustrates the proximal end of an embodiment of a flexible needle assembly comprising an inner guidewire.

[0062] Figure 10 is a fluoroscopy image of an embodiment of a flexible needle with an inner guidewire.

[0063] Figures 11A-B illustrate front and side cross sectional views of an embodiment of a multi-lumen, steerable catheter in a relaxed state. Figure 11C illustrates a side cross sectional view of the catheter in an articulated state.

[0064] Figures 12A-C are illustrations of a bronchoscope showing various degrees of articulation achievable without any biopsy needle, with a conventional straight biopsy needle, and with an embodiment of a flexible biopsy needle.

[0065] Figures 13A-C are illustrations of an embodiment of a flexible needle with steering wires.

[0066] Figures 14A-B are illustrations of an embodiment of a flexible needle inserted into a multi-lumen, steerable catheter.

[0067] Figures 15A-C are illustrations of a bronchoscope comprising an ultrasound probe and showing various degrees of articulation achievable without any biopsy needle, with a conventional straight biopsy needle, and with an embodiment of a flexible biopsy needle.

[0068] Figures 16A-C are illustrations of an embodiment of a flexible needle.

[0069] Figure 17 is an illustration of a handle that may be used to manipulate and control embodiments of the flexible needles described herein.

[0070] Figure 18 is an illustration of an embodiment of a flexible needle showing the distal tip thereof.

[0071] Figure 19 is a fluoroscopy image of an embodiment of a flexible needle with an inner guidewire.

[0072] Figure 20A is a partial cross-section view of a delivery needle in which one or more internal needles are positioned.

[0073] Figure 20B is an elevated end view of the delivery needle of Figure 20A from the viewing plane 20B-20B of Figure 20A.

[0074] Figure 21A is a partial cross-section view of the delivery needle of Figure 20A wherein the one or more internal needles are deployed outside of the delivery needle.

[0075] Figure 21B is an elevated end view of the delivery needle and one or more deployed internal needles of Figure 21A from the viewing plane 21B-21B of Figure 21A.

[0076] Figure 22A illustrates a delivery needle in communication with an area of interest within the body.

[0077] Figure 22B illustrates a delivery needle with deployed internal flexible needles in communication with an area of interest within the body.

[0078] Figure 23A illustrates an isometric view of a delivery needle with a spiral scribe on the distal tip, which may be used to reflect ultrasound waves.

[0079] Figures 23B illustrates a side view of a delivery needle with a spiral scribe on the distal tip, which may be used to reflect ultrasound waves.

DETAILED DESCRIPTION

[0080] Various embodiments of a flexible transbronchial needle aspiration system, a minimally invasive substance delivery system, and their related components

and parts will now be described with reference to the accompanying figures. The terminology used in the description presented herein is not intended to be interpreted in any limited or restricted manner. Rather, the terminology is simply being utilized in conjunction with a detailed description of embodiments of the systems, methods and related components. Furthermore, embodiments may comprise several novel features, no single one of which is solely responsible for its desirable attributes or is believed to be essential to practicing the disclosure herein described. For example, while references may be made herein to using the embodiments described herein with terms such as "lung," "airway," "nodule," and so forth, these terms are broad and the embodiments described may be used without limitation and unless otherwise indicated can be used to access to other vessels, passages, lumens, body cavities, tissues, and organs present in humans and animals. For example, lumens such as the gastrointestinal system may be accessed with the embodiments described herein.

[0081] Presently, various companies offer products directed to transbronchial needle aspiration systems, some of which include visualization systems to direct the needle to a site to be biopsied. For example, Olympus manufactures an ultrasound system (the Endobronchial Ultrasound Transbronchial Needle Aspiration system (EBUS-TBNA)) substantially as illustrated in Figure 1. As shown, the system 100 employs an ultrasound probe 102 situated at the distal end of a specialized bronchoscope 106. A rigid needle 104 extends at an angle from an aperture 108. The needle 104 is sheathed prior to deployment by a catheter or sheath 110 that contains coils 112. The coils 112 preferably surround the needle 104 to reduce the likelihood of the needle 104 perforating a working channel of the bronchoscope 106. Because the needle 104 is rigid and its range of motion constrained, the system 100 is limited in the area of tissue that can be easily biopsied. Although some medical practitioners may occasionally bend needles similar to the needle 104 so as to be able to biopsy tissue at larger angles relative to the axis of the bronchoscope, these needles remain rigid (albeit bent) and still limit the area of tissue that can be biopsied.

[0082] Figure 2 illustrates an embodiment of a flexible needle 200. As will be discussed, embodiments of this flexible needle 200, as well as the other embodiments described herein, may be used in conjunction with existing systems and methods (such as the system 100 illustrated in Figure 1) for locating, navigating to, and biopsying regions (e.g., lung nodules, lymph nodes) of interest. Use of a flexible needle can permit biopsying tissue and cells in a much larger area and over a wider range of angles

compared to existing systems, and certain embodiments allow for greater articulation of a bronchoscope or endoscope so as to gain access to tortuous areas of the anatomy. Accordingly, the use of such embodiments can provide increased sample quality, greater diagnostic yields, and a reduction of erroneous diagnostic results (e.g., false positives or negatives). It will be noted that although bronchoscopes are referred to herein, other endoscopes may be usable (e.g., gastric endoscopes, colonoscopes). As such, other lumens may be explored, navigated to, and biopsied using the embodiments described herein.

[0083] A proximal end of the needle 200 comprises a proximal shaft portion 202. The distal end comprises a flexible shaft portion 204 that is more flexible than the proximal shaft portion and preferably able to selectively bend, curve, and articulate such that the respective ends of the needle 200 are not necessarily collinear. Flexible shaft portion 204 may be provided with a laser cut feature, for example a spiral cut, to improve the flexibility in this region. For example, due to the flexible nature of the needle 200, the needle 200 is capable of at least two different deflections in radial directions to angles that would exceed the yield strength of a solid needle formed of the same material. At the extreme distal end, the flexible shaft portion 204 comprises a short distal tip portion 206. This distal tip portion 206 is configured with a piercing tip used to obtain biopsy cell and/or tissue samples. The distal tip portion 206 preferably is more rigid than the flexible shaft portion 204. It is contemplated that the needle is formed unitarily of a single material.

[0084] In some embodiments, the flexible transbronchial needle 200 can be advanced to peripheral airways and can easily penetrate into the lung parenchyma. In a preferred configuration, the needle 200 can penetrate tissue at a depth of at least 15 mm. In some embodiments, the distal end 204, 206 of the needle 200 can articulate such that it can bend over 90 degrees relative to a more proximal portion. In a preferred embodiment and when inserted into a bronchoscope working channel (such as the BF-P180™ bronchoscope manufactured by Olympus), the needle 200 can articulate at least 130 degrees when the needle tip 206 is flush with the end of the bronchoscope. When inserted into a system 100 similar to that illustrated in Figure 1, embodiments of the needle 200 can articulate approximately 110 degrees. Due to its relatively low-profile construction, embodiments of the flexible needle 200 may be miniaturized, in conjunction with a catheter or guide sheath, so as to fit into working channels (e.g., of a bronchoscope) that are as small as or smaller than 2.0mm. For example, certain

embodiments of the needle 200 can be used with small guide sheaths with a minimum inner diameter of 1.7mm.

[0085] The flexible needle 200 can be formed from any suitable material. In some configurations, the flexible needle 200 may be formed from a metal or metal alloy, such as stainless steel, nitinol or the like. In some arrangements, the flexible needle 200 can comprise a polymer or other suitable covering over at least a portion of the length of the flexible needle 200. In some configurations, the flexible needle 200 can comprise a heat shrink material that covers substantially the entire length of the flexible needle 200. In some configurations, one or more of the inner and outer surfaces can receive a coating of any suitable material. The coating can improve the lubricity of the coated surface or increase the smoothness of the coated surface. In some configurations, the flexible needle 200 is constructed from a hypotube. Preferably, the hypotube is constructed to be relatively smooth along at least a proximal portion such that when introduced into a device such as a catheter lumen, for example but without limitation, the hypotube is able to relatively freely slide, rotate, or otherwise move along the lumen.

[0086] Embodiments described herein (for example but without limitation, the embodiment illustrated in Figure 2) may be used with any suitable visualization device, such as the ultrasound system 100 of Figure 1, navigation system or the like. By using the flexible transbronchial needle 200, access to regions of interest in the lung or in other tissues can be easier and more straightforward, because the flexible needle 200 is able to articulate, bend, and/or curve to a greater degree than a straight, inflexible needle, and independently from the angle or articulation that a bronchoscope or endoscope may have at the same time. This may, for example, enable biopsying of tissue at an angle close to perpendicular from the bronchoscope. In addition, the flexible needle 200 can bend in a region between the distal piecing tip 206 and the distal end of any protective guide sheath or catheter. Further, the coils 112 present in the sheath 110 of the existing system 100 can be made shorter or eliminated entirely due to the flexibility of the needle. In other words, the flexibility of the distal portion 204 of the flexible needle 200 reduces the likelihood of perforating the working channel of the bronchoscope. The increased flexibility also decreases the radial forces exerted by the distal tip 206 of the needle 200 during navigation through the working channel of the bronchoscope, for example but without limitation.

[0087] In some embodiments, visualization of the needle 200 may be enhanced (in particular for ultrasound) by including signature markers 2059 that will

enhance the visibility of the needle 200, particularly at the distal tip. Signature markers may include forming dimples, scallops, a spiral scribe which may be laser cut, or the like on the needle 200, which dimples, scallops, a spiral scribe which may be laser cut, or the like can reflect ultrasound. Such features provide echogenic surface for detection by ultrasound. Of course, other markers visible for different visualization methods can be used, such as radioopaque markers located on various elements of the catheter or sheath used to deploy the needle 200, as well as the needle 200 itself.

[0088] Although ultrasound has been found to be a preferable system for visualization due to the relatively high penetration depth (10-18mm) of ultrasound, other systems also may be used. In some configurations, a spiral ultrasound probe can be used to provide improved visualization over an ultrasound probe that provides visualization in only a single plane. Other systems for locating and navigating to tissues of interest, such as lung nodules and lymph nodes, may include using a bronchoscope with an optical channel, fluoroscopy, optical coherence tomography, and magnetic resonance imaging. Any other suitable navigation systems also can be used, including commercial systems using X-ray computed tomography assisted visualization (such as, for example but without limitation, the Bf Navi™ system sold by Olympus and the i-Logic™ system sold by SuperDimension).

[0089] Figures 3A-G illustrate various configurations for flexibility increasing features (e.g,. slots, openings, or grooves) that may be formed along various regions of transbronchial needles to increase flexibility. For example, such flexibility increasing features may be made into the flexible shaft portion 204 of Figure 2. Generally, one or more flexibility increasing features, or cut patterns, 304 such as cuts for example but without limitation, may be made onto the needle wall 300 of the needle; these cuts 304 may then define one or more regions of increased flexibility 302. These cuts 304 permit the region of increased flexibility 302 on the flexible shaft portion to selectively articulate and bend more easily and to a greater degree than an equivalent portion that is uncut, thereby permitting navigation and biopsying of tissue in tortuous regions of, for example, an airway, that may not be possible using a traditional rigid needle.

[0090] The flexibility of the region of increased flexibility 302 may be tailored as desired for a particular application. The flexibility can be changed, for example, by modifying the thickness of the needle wall 300, the materials used therein, and the spacing, pitch, and angle between the flexibility increasing features 304 in the region of increased flexibility 302. Preferably, the cuts 304 extend in a spiral fashion

along the region of increased flexibility 302. In preferred embodiments, the features 304 are cut with a thickness between about 0.0010 and about 0.0025 inches, and even more preferably a range between about 0.0015 and about 0.0020 inches.

[0091] Additionally, the region of increased flexibility 302 does not need to have features such as the single pitch illustrated in Figure 3A, but, with reference to Figure 3B, can instead have features that are of a variable pitch, wherein the spacing or pitch can be changed in a continuous or stepwise fashion, for example but without limitation. Additionally, although the cuts shown in these figures are made in a continuous and single cut, high flexibility regions may be made using one or more discontinuous cuts. In these figures, the flexibility increasing features 304 that constitute the region of increased flexibility 302 are made in a "jigsaw" configuration that forms a sawtooth or zigzag pattern. Other possible features can have a pattern that is a "serpentine" configuration where the cuts are smoother, more rounded, and with a longer amplitude than the jigsaw pattern, for example but without limitation. Other types are possible and envisioned, including straight cuts, partial or dashed cuts, zigzag cuts, sinusoidal cuts, and so on. In some configurations, axially asymmetric cuts may be made so as to enhance flexibility in only one direction relative to the axis, for example as discussed below in relation to Figure 3F. Moreover, continuous patterns are desired over interrupted patterns because of improved resistance to fatigue failures and improved flexure characteristics.

[0092] Figure 3C illustrates an embodiment of the region of increased flexibility 302 comprising overlapping discontinuous straight reliefs 304, each extending around approximately half of the circumference of the needle wall 300 in the illustrated configuration. In this embodiment, holes 306 may be provided at one or more of the ends of each relief. The holes 306 may in some cases be made as part of a laser cutting process used to create the reliefs 304, although the reliefs 304 and/or the holes 306 may be made using any suitable process, for example chemical etching or water jetting. The holes 306 may also be useful in providing additional strength to the needle wall 300, as it is believed that the holes 306 may aid in reducing or eliminating the likelihood of crack propagation when the needle wall 300 undergoes various stresses.

[0093] Figure 3D illustrates an embodiment with a region of increased flexibility 302 comprising a single, continuous spiral cut 304. Holes 306, similar to those described above, may be present at the respective ends of the cut 304. Preferably, and as illustrated here, the pitch is substantially constant throughout the length of the cut 304; in

some embodiments, however, one or more portions of the cut 304 may have a varied pitch. In some embodiments, a region of increased flexibility 302 may be manufactured that resembles the embodiment illustrated here by using a closely-spaced stacked wire , flat wire coil or cable tube. Of course, other embodiments may be manufactured using other types of cutting (e.g., laser cutting) discussed herein.

[0094] Figure 3E is similar to the embodiment illustrated in Figure 3C. Here, however, the region of increased flexibility 302 comprises an interrupted spiral pattern where the tube has cut and uncut portions along the same spiral path 304 that have substantially the same pitch along the entire length of the region 302.

[0095] Figure 3F illustrates an embodiment with an asymmetric region of increased flexibility 302. Here, cuts 304 can be positioned along only one side of the needle wall 300; in other words, the cuts 304 are arranged such that only a portion of the entire radial circumference along the axial length of the needle wall 300 is interrupted. In other words, when viewed along a certain direction along the axial length of the needle wall 300, the cuts 304 forming a region of increased flexibility 302 will be seen along at least a portion of one of the sides, while a side opposite the cuts 304 will be substantially lacking cuts. Arranged in this manner, the flexibility of the needle wall 300 along the region of increased flexibility 302 will be asymmetrically flexible so as to permit increased bending or flexibility in one direction or plane while being less flexible in another direction.

[0096] Embodiments of needle walls 300 with asymmetrical regions of increased flexibility may be useful in conjunction with bronchoscopes or other navigational devices by increasing the maneuverability of the needle wall 300 while in the bronchoscope. In particular, some bronchoscopes may be more adapted to bending in a particular plane—alignment of the asymmetrical region of increased flexibility 302 in this plane may thus be useful. For example, asymmetric bending of the needle wall 300 can force the needle wall 300 to rotate about its longitudinal axis as the navigational device bends and flexes. Such rotation can help to ensure that certain features of the needle could be maintained in a substantially consistent alignment with regard to the navigational device. For example, the bevel of the distal tip of the needle and/or ultrasonic reflective zones of the needle walls 300 could be maintained at a substantially consistent rotational orientation with respect the navigational device (e.g., a bronchoscope). Further, rotation of the needle wall 300 along its axial length may also aid navigation and maneuverability, as certain embodiments with asymmetrical regions of

increased flexibility 302 have been demonstrated to rotate in the path of least resistance, typically the smallest possible radius.

[0097] The cuts 304 may not necessarily be straight and perpendicular to the longitudinal axis of the needle wall 300. As illustrated in Figure 3G, the cuts 304 that comprise the asymmetrical region of increased flexibility 302 may be contoured, and may preferably further comprise a hole 306 located in at least one of the ends 310 of one or more of the cuts 304.

[0098] Several characteristics of the cuts 304 may be altered to tailor the stiffness, bending resistance, torqueability, and other material parameters of the region of increased flexibility 302. For example, the kerf, or cut width, in each cut 304 may be larger at some points than at others, which may enhance flexibility. In some embodiments, the kerf at a midpoint 311 of a cut 304 may be wider than the kerf at one or more of the ends 310. In such a configuration, the flexibility may be increased when the needle wall 300 is bent in the direction or plane of the asymmetrical region of increased flexibility 302, while reducing or minimizing flexibility (progressively or in a stepwise manner) as the bend location moves away from the direction or plane of the region of increased flexibility, as a result of the change in kerf toward the ends 310. It may also be preferable to have a thinner kerf to reduce the amount of torque that can be applied to the needle wall 300 before the tube interlocks. Additionally, the kerf may be modified along the length of the region of increased flexibility 302. For example, the kerf in a proximal section may be wider and taper to a narrower kerf at the distal end, which may provide for a needle wall 300 that is flexible but that will stiffen when rotated.

[0099] Other characteristics of the region of increased flexibility 302 may be modified. In addition to the kerf, the pitch spacing, the length and/or amount that a cut 304 extends around the needle wall 300, and the distance between cuts 304 may be modified to tailor the wall 300 as desired. In some embodiments, the minimum longitudinal distance point between the cuts 304 can be varied along the length of the needle wall 302. In some such embodiments, the flexibility of the needle wall 302 can vary along the length of the needle (e.g., more flexibility as the minimal longitudinal distance between the cuts 304 is reduced). Accordingly, the flexibilility, torqueability, and other characteristics of the region of increased flexibility may be modified. Further, some embodiments may provide for a needle wall 300 comprising multiple asymmetrical regions of increased flexibility 302. In some embodiments, the multiple regions 302 may

be staggered at differing orientations, for example in mutually orthogonal directions (i.e., at 90° angles to each other).

[0100] In practice, in tailoring the region of increased flexibility 302 and the reliefs 304 that can constitute this region of increased flexibility 302, it may be desirable to find a suitable balance between the flexibility required and the type of relief. For example, while wider or larger reliefs may provide additional flexibility, these may in some cases weaken the needle wall 300 to an unacceptable extent. Different patterns also may perform more or less satisfactorily in fatigue testing. Additionally, certain patterns may cause portions of the region of increased flexibility 302 to abrade the working channel of the catheter or other instrument the needle is inserted in, or else the tissue being biopsied (although this may be desirable in certain applications, as described below). Postprocessing after creation of the reliefs may include steps such as deburring, electropolishing, extrude honing, microblasting, or ultrasonic cleaning, which may at least partially alleviate or reduce such concerns. The type of reliefs 304 described above may also be adjusted in accordance with the length of the one or more regions of increased flexibility 302. Prototypes have been constructed with regions of increased flexibility measuring approximately 3-4cm. Preferably, the extreme distal end of the needle wall 300 is left uncut or otherwise generally solid to reduce the likelihood of buckling and so that a piercing point can be made onto the needle. In some arrangements, the piercing point is ground or honed and the generally solid portion of the extreme distal end assists in the formation of a point or tip. In some embodiments, the generally solid distal region measures between about 8 mm and about 10 mm. Other configurations are possible.

[0101] Figure 4 shows an embodiment of a flexible transbronchial needle 400 that comprises a distal tip portion 402 and a flexible region 404. In one embodiment, the distal tip portion 402 has a sharply angled tip to core or scrape cells from tissue to be sampled. The flexible region 404 preferably comprises one or more reliefs or cuts 406. In one embodiment, the cuts 406 are a jigsaw cut. In other embodiments, the cuts 406 may be a different type of cut, for example as described above in Figures 3A-G. In one embodiment, a covering 408, which may comprise polymer coatings and/or heat shrink wrap, can be used to cover the cuts 406 on the needle 400. The covering 408 may in some embodiments also comprise coils of a resilient material (e.g., metals or polymers) that surround at least a portion of the flexible region 404 to provide additional support against buckling or collapse, while remaining flexible enough to provide selective articulation and/or bending of the needle 400.

[0102] Obtaining a cored tissue sample may be preferable for pathology or histology samples where a largely-intact sample of tissue is desired. For such applications, the needle is preferably in a relatively larger size range of approximately 17-19 gauge, possibly with a smaller 21 gauge needle within. Such needle sizes have been found to produce a "cored" tissue sample satisfactory for histology applications. Obtaining biopsy cells and fluid for cytology may however use a smaller, non- or minimally-coring distal tip portion 402, for example. Because biopsies for cytological applications typically apply suction while performing agitation (moving back and forth) of the needle in the biopsy site, sharper and/or rougher needles may perform better and obtain additional cells. For such applications, smaller needle sizes in the range of 21-23 gauge may also be preferable. In some embodiments, the distal tip portion 402 may be cut and/or angled differently for different applications. In some applications, a hole, port, slot or other structure also can be provided just proximal of the distal end. In some applications, the hole, port, slot or other structure can be provided on a surface of the needle that is opposite from the surface of the needle having the most proximal portion of the beveled opening formed at the tip. In some applications, the hole, port, slot or other structure is positioned within a region defined between the distal tip and the most proximal portion of the opening formed by the beveled surface of the opening at the tip. A vacuum source may also be provided so as to aspirate a tissue sample or samples. Other configurations also are possible.

[0103] The cuts 406 on the flexible region 404 may be suitable for cytological biopsy procedures. Here, a cut may provide rougher edges that can scrape cells along the path of the needle 400. For example, when the interrupted surface of the needle is bent, the cuts can create a scalloped surface. In particular, sinusoidal, "jigsaw," "serpentine," or zigzag cuts may provide for rougher edges, which—especially when the needle 400 is bent or articulated—can abrade the surrounding tissue and thus sample additional cells. These abraded cells can then be aspirated via the needle 400 along with any other sample being biopsied. If no coating and/or heat shrink wrap 408 is present over the cuts 406, the resulting small openings may also be used to aspirate the abraded cells into the needle 400. Such an uncoated portion of the cut section 406, if present, is preferably located at the distal end of the needle 400 such that surrounding tissue may ingress into the inner lumen during suction.

[0104] To increase this scraping or scalloping effect, several steps may be taken. If the cuts 406 are made by water jetting, the needle 400 may be extrude honed to

push burrs outward, increasing the roughness of the flexible region 404. Likewise, laser cutting the cuts 406 may in some cases provide additional roughness. In some cases, a polishing or deburring step may be necessary. Dimpling or grinding of the cuts 406 and/or the region 404 may also be useful. The kerf (or width) of the cuts 406 may also be increased, either in part or in whole, along the flexible region 404, which may consequently enhance the scraping or scalloping effect.

[0105] The needle 400 may also be flushed after being withdrawn so as to obtain any remaining cells. In some cases, the operator using a needle 400 with cuts 406 will preferably navigate the needle 400 so as to reduce the likelihood of abrading or puncturing blood vessels in the biopsy region, because the resulting jagged edges may take longer to stop bleeding than a cut resulting from a biopsy needle lacking cuts. In some configurations, a dual-needle configuration, with a relatively smooth needle used to puncture into the biopsy site, followed by larger diameter, flexible needle that can include scalloped surfaces that can be used to scrape the tissue. Quick-clotting or cauterizing features could also be incorporated into the needle 400 or various other system components to minimize bleeding when piercing tissue.

[0106] Figure 5 illustrates an embodiment of a flexible transbronchial needle 500. The needle 500 comprises several interconnected portions. A proximal end of the needle 500 comprises a less flexible shaft portion 502. A distal end of the needle 500 comprises a more flexible shaft portion 504. The less flexible shaft portion 502 and the more flexible shaft portion 504 can be connected together by the tapered shaft section 524 in the illustrated configuration. In some configurations, however, the less flexible shaft portion 502 and the more flexible shaft portion 504 can be integrally formed. The more flexible shaft portion 504 comprises a distal tip portion 508 and a cut section 510. Cuts 512 are located within the cut section 510. The cuts can be formed in any suitable manner. In one embodiment, the cuts 512 are a "jigsaw" cut, as described above with reference to Figures 3A-C. In other embodiments, the cuts 512 may be cut differently.

[0107] This embodiment of a flexible transbronchial needle 500 has several advantages, as on one hand the needle 500 becomes more torquable and pushable while also retaining flexibility at its distal end. The less flexible shaft portion 502 at the proximal end is preferably more rigid and stiffer than the more flexible shaft portion 504, so as to facilitate torque and force transmission to the thinner, more flexible shaft portion 504. In one embodiment, this is accomplished by constructing the needle 500 so as to become progressively thinner from the proximal end to the distal end, such that the

flexible shaft portion 504 remains flexible and bendable. By constructing the needle 500 in a manner that it becomes thinner at the tapered shaft portion 524, the needle becomes more flexible, while also reducing resistance to rotation in the distal end comprising the flexible shaft portion 504. Additionally, the more rigid portion 502 is more durable and better able to transmit torque or force, while being situated in a portion of the needle 500 where flexibility is less important.

[0108] The less flexible shaft portion 502 has an outside diameter D1 514. The more flexible shaft portion 504 has an outside diameter D2 516. The tapered shaft section 524 has a proximal end 518 and a distal end 520, with the outside diameter D3 522 being located at the proximal end of the tapered shaft section 518 and the outside diameter D4 520 being located at the distal end of the tapered shaft section 520. Preferably, the outside diameter D3 522 is equal to the outside diameter D1 514. The outside diameter D4 520 is preferably equal to the outside diameter D2 516. The outside diameter of the tapered section 524 may vary linearly or nonlinearly between D3 and D4. It will also be understood that in some embodiments, the tapered section 524 may extend into all or part of the flexible shaft portion 504 and/or the less flexible shaft portion 502, and that in some embodiments there may be additional tapered sections. Further, although the tapered section 524 reduces in diameter going in a proximal to distal direction, the opposite configuration may be useful in some embodiments.

[0109] Typically, the portions 502, 524, 504 will be constructed from a length of material (e.g., metals such as stainless steel or nitinol) of a substantially uniform thickness, and as such, the inside diameters of the respective portions will generally correlate to the outside diameters referred to above. However, it is contemplated that materials of varying thicknesses may be used to construct the needle, and the thickness defined by the inside and outside diameters may differ along the length of the device. This may be accomplished, for example, by constructing the needle 500 in a piecewise fashion from separate parts, or by drawing out the needle in a single unit so as to create sections of varying thickness. Such varying thicknesses may be used, for example, to tailor factors such as the rigidity, strength, torquability, or flexibility of the resulting needle to the desired application.

[0110] Figures 6A–D illustrate different embodiments of steerable, flexible transbronchial needle aspiration assemblies. Such assemblies may be manipulated by an operator to steer the needle to a site identified to be of interest. Preferably, such assemblies may also permit a flexible needle to be steered independently of a

bronchoscope or other endoscope. While the examples discussed below in Figures 6A-D discuss a needle aspiration assembly, in some embodiments, a guide sheath provided with the steerable features discussed below may also be used. In such an embodiment, a needle, preferably a flexible needle, may be insertable there through.

[0111] In Figure 6A, a flexible transbronchial needle aspiration assembly 600A comprises a flexible transbronchial needle 602A and a steering wire 604A. In Figure 6B, a flexible transbronchial needle aspiration assembly 600B comprises a flexible transbronchial needle 602B, a first steering wire 604B and a second steering wire 606B. In Figure 6C, a flexible transbronchial needle aspiration assembly 600C comprises a flexible transbronchial needle 602C, a first steering wire 604C, a second steering wire 606C and a third steering wire 608C. In Figure 6D, a flexible transbronchial needle aspiration assembly 600D comprises a flexible transbronchial needle 602D, a first steering wire 604D, a second steering wire 606D, a third steering wire 608D and a fourth steering wire 610D. These steering wires can be arranged in different manners to achieve different steering characteristics. Certain embodiments provide for the steering wires to angle or bend the needle 602 at an angle of up to 45 degrees. Certain embodiments may be small enough to fit within a 2.0mm working channel of a bronchoscope, and may be miniaturized further.

[0112] In these preceding figures, the steering wires may be manipulated by the operator to guide a flexible transbronchial needle to a site of interest. Preferably, this is accomplished by using the one or more steering wires to pull (and thereby bend) the flexible needle in the direction desired. The wires may be attached to the flexible needle in any suitable manner, on the interior or exterior of the flexible needle. In some configurations, the wires are secured by welding them to the flexible needle. When wires are attached to the interior of the flexible needle, such embodiments may allow for insertion into a smaller sheath or working channel. In certain embodiments, this may be accomplished by having the steering wire comprise one or more pull wires. Bowden cables may be used in some embodiments. Nitinol wires, which contract after being heated past a transition temperature may also be used, possibly in conjunction with a heating element controllable by the operator (for example, by using resistive heating).

[0113] Figure 7 shows an embodiment of a steerable, flexible transbronchial needle aspiration assembly 700. The needle 700 comprises a flexible shaft portion 702 at the distal end. The flexible shaft portion 702 comprises a distal tip portion 704 and a flexible section 706 that may be selectively elastically bent or angled such that the

respective ends are no longer collinear. The flexible section 706 comprises cuts 707 that may be covered and/or sealed with a coating 709, for example a polymer and/or heat shrink. The cuts 707 may be of the type previously described, and could be, for example, "jigsaw" cuts.

[0114] In some embodiments, a steering wire 708 is located along the exterior of the flexible shaft portion 702. In other embodiments, multiple steering wires 708 are located along the exterior of the flexible shaft portion 702; these may be arranged as depicted above in Figures 6A-D. The steering wire or wires 708 may, as described in Figures 6A-D, be used to guide the needle 700 to the site to be biopsied. Preferably, a seal 710 covers at least a portion of the exterior of the steering wires 708 and the flexible shaft portion 702 to reduce the likelihood of the steering wires snagging equipment or body tissue, and preferably is constructed from a pliable polymer.

[0115] The proximal end of the needle 700 may be part of or joined to a steel hypotube 711. The proximal end of the hypotube 711 may also have a connection 714 (for example, a luer fitting) so that a source of vacuum (for example, a pump or syringe 712) can be used to pull a vacuum along the length of the hypotube 711. In a preferred embodiment, the hypotube 711 is manufactured from any suitable material.

[0116] Figure 8 illustrates an embodiment of a flexible steerable needle 800 comprising an inner guidewire 810. Here, the inner guidewire 810 can be positioned along a central lumen of an embodiment of a flexible needle 800, which may be designed in a similar manner as other embodiments described herein. In some configurations, the guidewire 810 has a length that is greater than the length of the needle 800.

[0117] The needle 800 preferably comprises a distal tip portion 802 with a distal opening 803. A flexible section 804 preferably is configured to be more flexible than the distal tip portion, and may comprise cuts 806 of the type previously described. These cuts 806 confer additional flexibility to the needle 800 and permit it to bend or curve. In some embodiments, all or part of the flexible section 804 (and the cuts 806) may be covered with a coating 808, which may be a polymer and/or heat shrink, for example but without limitation.

[0118] The guidewire 810 preferably is constructed from a shape memory material (metal or polymer) such as Nitinol. Preferably, the guidewire 810 is set in a form that will curve when heated, but is inserted into the needle 800 while in a straightened configuration. While the guidewire 810 is inserted into the needle 800, heating of the guidewire 810 will cause it to curve, thereby curving the needle 800 along

its flexible section 804. In some configurations, the guidewire 810 simply is inelastically deformed to provide non-linear region proximate the distal end. In such configurations, simply inserting the guidewire 810 into the needle 800 can cause the needle to bend.

[0119] In use, the curved guidewire 810 can be used to steer the needle 810 by rotating the guidewire 810 relative to the needle 810. The curve or bend in the guidewire 810 will cause the flexible portion of the needle 810 to deflect such that the direction of the needle 810 can be varied. In some embodiments, rotational alignment of the curved guide wire 810 with respect to the needle 800 can be controlled using an asymmetric distribution of cuts on the needle wall (e.g., as described above with regard to Figures 3F and 3G). For example, asymmetric cuts on the needle wall can cause the needle 800 to rotate about its longitudinal axis as the needle 800 bends to conform to the bent shape of the guidewire 810. In some embodiments, asymmetric cuts in the needle wall help to ensure that the guidewire 810 remains aligned in the same plane of the needle 800 as the bent portion of the guidewire 810 passes through the flexible section 804 of the wire 800. The guidewire 810 may also be used to navigate the needle 800 to the site of interest. Here, the guidewire 810 is guided to the region of interest (e.g., a lung nodule), and the needle 810 is then pushed along the guidewire 810 until the region of interest has been reached. The guidewire 810 may then be withdrawn so as to permit aspiration and biopsying of the region of interest. Partly because the guidewire 810 is located inside the needle 800 and thus provides a very small diameter probe, such a system may be employed to navigate to peripheral lung regions of a reduced diameter and that are inaccessible with a bronchoscope. Additionally, because the guidewire 810 is positioned inside of the needle 800, such a configuration may be preferable for biopsying samples via scraping or scalloping of tissue with the flexible section 804. When the guidewire 810, or another component associated with one or more of the guidewire 810 and the needle 800, is radioopaque, fluoroscopy or the like may be used to navigate the guidewire to a region of interest. Typically, the needle 800 and guidewire 810 are contained within a catheter or sheath. Upon reaching an airway wall proximate to a region of interest, either the needle 800 or the guidewire 810 can be extended into a nodule or other tissue at the region of interest. In some configurations, the needle 800 may extend between 15-20mm into the adjacent tissue from the end of the catheter or sheath. In some embodiments, the needle 800 may be configured to extend up to about 40mm into adjacent tissue.

[0120] In certain embodiments, the curved guidewire 810 may be part of a system used for providing repeatable access and/or navigation to regions of the lung. Such embodiments are described in Provisional Application Serial No. 61/604,462, filed February 28, 2012, titled "PULMONARY NODULE ACCESS DEVICES AND METHODS OF USING THE SAME", and the application is hereby incorporated by reference in its entirety. Such embodiments are also described in U.S. Patent Application 13/778,008 (Attorney Docket No. SPIRTN.082A), filed February 26, 2013, titled "PULMONARY NODULE ACCESS DEVICES AND METHODS OF USING THE SAME" and published as U.S. Patent Publication No. US 2013-0226026 A1 , and the publication is hereby incorporated by reference in its entirety.

[0121] Figure 9 illustrates an embodiment similar to that illustrated in Figure 8. Here, a connector 814 is connected to the proximal end of the hypotube of the needle 800. The connector 814 used here can be any type of suitable connector, including for example a luer connector. The guidewire 810 is introduced through the connector 814, and at the proximal end of the guidewire 810 is a handle 816 that permits the guidewire 810 to be pushed, pulled, and rotated with respect to the needle 800. After the guidewire 810 has used to guide the needle 800 to the biopsy site, the guidewire 810 is removed from the connector 814. A source of vacuum (e.g., a syringe) is then attached to the connector 814 to aspirate the biopsy sample from the needle 800.

[0122] Figure 10 is an annotated fluoroscopy image of a curved guidewire similar to that described in Figure 8 being used to biopsy a lung nodule. Here, the catheter 1000 extends from the distal end of a bronchoscope 1014. The lung passages here were too small to permit navigation of the bronchoscope to an area near the lung nodule, and as such, the catheter 1000 was advanced via fluoroscopy to the suspected nodule site 1012. The distal end of the lumen 1002 containing the flexible needle 1006 also contains coils 1004, which reinforces the lumen 1002 while the needle is located within the lumen and also serves as a fiducial radioopaque marker helpful for visualization of the catheter 1000 in relation to the nodule site 1012. Additional fiducials may also be added to various components of the catheter 1000 (e.g., barium sulfate markers). Extending distally to the needle 1006 is a guidewire 1008, which, being curved, aids in guiding the flexible needle 1006 to the nodule site 1012. In use, the flexible needle 1006 is pushed over the guidewire 1008 to the nodule 1012, the guidewire 1008 is withdrawn and biopsy tissue samples are aspirated through the flexible needle 1006.

[0123] A method of obtaining a tissue sample may comprise advancing the bronchoscope 1014 toward a tissue site (e.g., a lung nodule 1012 or lymph node). Within the bronchoscope 1014, the catheter 1000 may be movably disposed. In some embodiments, and preferably when advancing to tissue regions in small or convoluted airways that may not permit navigation with the bronchoscope 1014, a guide sheath surrounding the catheter 1000 may be advanced beyond the bronchoscope 1014 instead of or in conjunction with the guidewire 1008. In some embodiments, the guide sheath may be used without the bronchoscope 1014. The guide sheath may be used in conjunction with a location device, such as fiducial markers (e.g., coils 1004) or an ultrasound probe (e.g., as described below in Figures 11A-C). Preferably, the location device is present on the catheter 1000, although a location device may be instead or also present on the guide sheath. Once proximate the tissue site, the catheter 1000 may be advanced beyond the guide sheath and navigated to the tissue site (e.g., using the location device placed thereon) so as to obtain a sample with the flexible needle 1006. The entire assembly may then be withdrawn, or certain portions thereof (e.g., coils 1004) may be implanted proximate the tissue site to serve as a marker.

[0124] Figure 11A shows a cross section view of an embodiment of a multi-lumen, steerable catheter 1100 which may be configured for introduction into a bodily space (for example, pulmonary passages) via an endoscope such as a bronchoscope. The catheter 1100 preferably comprises a first lumen 1102 and a second lumen 1104, although other embodiments may comprise a catheter 1100 with more than two lumens. The first lumen 1102 may be larger than the second lumen 1104. In a preferred embodiment, the first lumen 1102 may be used to introduce a miniaturized ultrasound probe, which may then be used to provide real-time location information of the bodily tissues to be examined. For example, when used in the lungs an ultrasound probe can be useful to locate nodules or other locations (e.g., lymph nodes) of suspected or actual cancerous tissue which may be difficult or impossible to locate visually. Preferably, the second lumen 1104 is used to introduce various tools, including but not limited to transbronchial aspiration needles, cytology brushes, biopsy forceps, guiding devices, and so forth.

[0125] The catheter 1100 also preferably comprises at least one steering wire 1106, which preferably is connected to the second lumen 1104 to permit selective articulation and bending of the distal end of the second lumen 1104. The steering wire 1100 is preferably of the type that may be used in the embodiments described above in Figures 11A-D. It is to be noted that whereas the embodiments illustrated in Figure 8

have an inner guidewire 810 introduced within the inner diameter of the needle 800, the embodiments illustrated in Figures 11A-C disclose steering wires positioned on the outside of the needle. This is not to say that the two approaches are mutually incompatible—embodiments may be designed using both inner and outer steering.

[0126] Figures 11B and C illustrate side views of an embodiment of a multi-lumen, steerable catheter 1100. This catheter 1100 comprises a first lumen 1102 and a second lumen 1104. The second lumen 1104 comprises a steering wire 1106. Figure 11B illustrates the second lumen 1104 in a relaxed, non-articulated state.

[0127] Figure 11C shows a side view of an embodiment of a multi-lumen, steerable catheter 1100 used to visualize and conduct a biopsy on a target nodule 1112 located behind an airway wall 1110. Here, the catheter 1100 is illustrated with an ultrasound probe 1116 inserted into the first lumen 1102. The ultrasound probe 1116 is preferably a miniaturized ultrasound probe configured to be inserted into a small catheter or endoscope, and can be for example the UM-S20-17S radial endoscopic ultrasound probe manufactured by Olympus. Such miniaturized ultrasound probes may be advantageous for localization and visualization in peripheral lung passages where visual observation (i.e., via a bronchoscope) is extremely difficult due to the small size of such passages. The second lumen 1104 is illustrated with a flexible needle 1114 inserted therethrough and preferably moveable in a longitudinal back and forth direction so as to biopsy the target nodule 1112. In the illustration, the steering wire 1106 is pulled, thus selectively articulating the second lumen 1104 at an angle with respect to the first lumen 1102. In a preferred embodiment, the needle 1114, when fully extended, can articulate or bend at an angle of about 40 degrees with respect to the first lumen 1102. In some embodiments, the steering wire 1106 may angle or articulate both lumens 1102 and 1104. Some embodiments may also provide for multiple steering wires 1106 capable of both lumens 1102 and 1104 independently. In further embodiments, the steering wires may be provided directly onto the flexible needle 1114 and/or ultrasound probe 1116.

[0128] Articulating the distal end of the second lumen 1104 of the catheter 1100 allows tools, in this case distal end of the needle 1114, to be angled toward the target nodule 1112 while the ultrasound probe 1116 remains in the airway providing real-time location confirmation that the needle 1114 has reached the target nodule 1112. Accordingly, the angle of the second lumen 604 preferably is adjusted and aligned such that the needle 1114 and nodule 1112 simultaneously remain in the field of view 1118 of the ultrasound probe 1116. Embodiments of the catheter 1100 have been constructed

wherein the needle 1114 is able to articulate up to 20 degrees relative to the ultrasound probe. Some embodiments have been constructed that are compatible with a 3.2mm bronchoscope working channel, and may be miniaturized further.

[0129] Figures 12A-C illustrate a bronchoscope in various degrees of articulation. Figure 12A illustrates the articulation of a bronchoscope without any biopsy needle inserted within. Here, the angle of articulation is approximately 130 degrees. Figure 12B illustrates the articulation achievable by the same bronchoscope with a conventional straight rigid biopsy needle and catheter inserted therein. The articulation angle here is only about 90 degrees. Finally, Figure 12C shows the same bronchoscope with an embodiment of a flexible needle inserted therein. The needle may for example be of the type illustrated in Figure 2. Due to the flexibility of the needle, the articulation angle achieved here is approximately 130 degrees, and the bronchoscope's overall flexibility is minimally altered in comparison to the bronchoscope without any needle inserted.

[0130] Figures 13A-C illustrate an embodiment of a flexible needle with steering wires similar to those illustrated in Figures 6A-D and Figure 7. Figures 13A-B show that the needle, with the steering wire pulled, can achieve an articulation of approximately 45 degrees. Figure 13C illustrates a closeup of the distal end of the needle. A polymeric covering coats or covers the distal end just short of the distal tip of the needle and covers the steering wire or wires underneath.

[0131] Figures 14A-B illustrate an embodiment of a flexible needle 1002 inserted into a multi-lumen, steerable catheter 1000 similar to Figure 11C. The probe 1006 may be a miniaturized ultrasound probe, and is preferably inserted into one of the catheter lumens. In Figure 14A, the flexible needle 1002 is shown in a retracted configuration and is inside a sheath 1004. Figure 14B shows the flexible needle 1002 in an extended position and articulated. The needle 1002 may be articulated, for example, using the steering wires described above in relation to the embodiment in Figure 11C. Here, the needle can achieve an articulation of approximately 20 degrees relative to the distal end of the probe 1006.

[0132] Figures 15A-C illustrate various states of articulation of a bronchoscope comprising an ultrasound probe similar to that illustrated in Figure 1. First, Figure 15A shows the articulation of the bronchoscope without any biopsy needle inserted therein. The bronchoscope can achieve an articulation of approximately 110 degrees. Figure 15B shows the bronchoscope with a conventional straight biopsy needle

and catheter inserted therein. The bronchoscope's articulation is reduced to approximately 50 degrees, with the straight needle providing approximately 20 degrees of additional angle (for a total of 70 degrees). Figure 15C shows the same bronchoscope with a flexible needle and catheter inserted therein similar to the embodiment illustrated in Figure 2. Here, the bronchoscope can bend to approximately 90 degrees, with the flexible needle providing approximately additional 20 degrees of additional angle (for a total of 110 degrees). It is important to note that the flexible needle illustrated in Figure 15C is not being articulated independently of the bronchoscope, and an additional independent articulation mechanism (including for example but without limitation the embodiments illustrated in Figures 6A-D and/or Figure 8) can provide for additional angulation and articulation of the needle to permit access to tortuous spaces.

[0133] Figures 16A-C illustrate another embodiment of a flexible needle and catheter, of which the needle may be similar to the embodiment illustrated in Figure 2. Figures 16A-B depict the articulation of the needle independent of any steering mechanism, and show that the needle can bend approximately 90 degrees. Figure 16C is a close up of the flexible needle 1002, and illustrates a needle sheath or catheter 1004 covering the more proximal section of the flexible needle 1002. The flexible needle 1002 extends past the distal end of the sheath 1004, and has a flexible section 1008 (similar to the flexible shaft portion 204 discussed above) that comprises spiral "jigsaw" cuts covered with a layer of heat shrink material. The extreme distal tip 1010 of the flexible needle is uncovered and lacks cuts, and is sharpened so as to pierce into tissue.

[0134] Figure 17 illustrates a handle 1701 that may be used to manipulate and control embodiments of the flexible needles described herein. The handle 1701 is connected to a catheter 1700 with a flexible needle hypotube within, and the handle 1701 can control the extension of the needle from the catheter.

[0135] Figure 18 is a closeup view of an embodiment of a flexible needle 1802. This embodiment has a flexible section 1804 comprising a spiral cut 1806, and which extends close to the extreme distal tip 1810 of the flexible needle 1802. The distal tip 1810 is preferably beveled and sharpened so as to penetrate into tissue. The proximal end 1809 of the flexible needle may be optionally covered by a polymeric sheath 1812 with coils 1814 underneath and overlying the body of the flexible needle 1802. Preferably, the coils 1814 provide structural support to the needle 1802 to reduce or eliminate the likelihood that the needle 1802 will prolapse or collapse, in particular when the needle 1802 is bent or articulated.

[0136] Figure 19 is a fluoroscopy image similar to that illustrated in Figure 10. Here, a bronchoscope of the right side of the image has a catheter extending from it. The catheter comprises a coil at its distal end that may aid visualization of the device. A flexible needle also extends from the distal end of the catheter and is depicted here piercing into and biopsying a lung nodule (the darker circular object on the left). The flexible needle is guided by an inner guidewire similar to the embodiment illustrated in Figure 8.

[0137] It will be understood that the present descriptions of the lung biopsy systems, apparatuses, and methods described herein as being used in a lung and for lung nodules are not limiting, and that these embodiments may be used for biopsying, navigating, and locating areas of interest in other locations on a patient, including gastric, endoscopic, or other suitable locations. Similarly, a bronchoscope is not necessary, and other suitable devices capable of accommodating the embodiments described herein may also be used, including without limitation various endoscopes or laparoscopic cannulas.

[0138] As illustrated in Figure 20A, a substance delivery system 2000 can include a delivery needle 2010. In some embodiments, the delivery needle 2010 can be similar to or the same as the flexible TBNA needles described herein. The delivery needle 2010 can be hollow. In some embodiments, the delivery needle 2010 defines a delivery lumen 2012 and has a delivery needle wall 2019. The delivery needle wall has an internal surface 2021 and an outside surface 2022.The delivery lumen 2012 can extend through the distal end 2014 of the delivery needle 2010. In some embodiments, the delivery lumen 2012 extends through the entire length of the delivery needle 2010. The delivery needle 2010 can include a solid (e.g., without an internal lumen) portion (not shown) at and/or near a proximal end of the delivery needle 2010. In some embodiments, the distal end 2014 of the delivery needle 2010 can be configured to pierce tissue within the body. For example, the delivery needle 2010 can be beveled or otherwise sharpened at its distal end 2014. The delivery needle 2010 can be navigated to a site of interest (e.g., a nodule, lesion, or other site of interest) within the body via the working channel of a delivery device (e.g., a bronchoscope, endoscope). In some embodiments, the delivery needle 2010 is navigated to the site of interest using a catheter. The delivery needle 2010 can be positioned within a sheath to protect the distal end 2014 and/or the working channel of the delivery device or catheter from damage. The sheath can be retracted from the delivery needle 2010 prior to deploying the needle 2010 to the site of interest. In

some embodiments, the delivery needle 2010 can be advanced distally past the distal end of the sheath in a manner similar to the needles described above.

[0139] In some embodiments, at least a portion of the length of the delivery needle 2010 is flexible. For example, delivery needle 2010 can include flexibility increasing features similar to or the same as those described with respect to the flexible and/or transbronchial needles above. Such flexibility increasing features can include cuts in the wall 2011 of the delivery needle 2010. In some embodiments, one or more cut patterns can be cut into portions of the wall 2011 of the delivery needle 2010. For example, jigsaw cuts, straight cuts, spiral cuts, interrupted spiral cuts, partial or dashed cuts, zigzag cuts, sinusoidal cuts, and/or any combination of these or similar cuts would be made in a portion of or along the entire length of the wall 2011 of the delivery needle 2010.

[0140] According to some variants, the wall 2011 of the delivery needle 2010 is coated. For example, the interior surface and/or exterior surface of the wall 2011 can include a heat shrink material or some other coating. The coating can be configured to reduce or eliminate the likelihood that fluid would leak through the wall 2011 between the delivery lumen 2012 and the surroundings of the lumen 2012.

[0141] As illustrated in Figures 20A-20B, one or more internal flexible needles 2040 can be positioned within the delivery needle 2010. For example, the internal flexible needles 2040 can be sized (e.g., have diameters) such that three internal needles 2040 can be stored within the delivery needle 2010. Many variations in the number of needles 2040 configured to fit within the delivery needle 2010 are possible (e.g., 2 needles, 4 needles, 6 needles).

[0142] In some embodiments, the internal needles 2040 extend the length of the delivery needle 2010 (e.g., from the proximal end of the delivery needle 2010 to the distal end 2014 of the delivery needle 2010). Preferably, the internal needles 2040 can be attached to a flexible shaft 2030. The flexible shaft 2030 can comprise a tube comprise a polymer tube, a metallic or polymer coil, and/or a laser or chemical cut hypotube. In some embodiments, the internal needles 2040 are attached to the distal end of the flexible shaft 2030 via a collar 2020. The collar 2020 can be, for example, an adhesive binding. In some embodiments, the collar 2020 can be constructed from a metallic material onto which the interior needles 2040 can be welded or otherwise adhered. In some embodiments, the internal needles 2040 are coupled with the flexible shaft 2030 directly, without the use of a collar 2020.

[0143] As illustrated in Figure 20B, the internal needles 2040 can be hollow and can define internal needle lumens 2048. The internal needle lumens 2048 can be in fluid communication with an interior lumen of the flexible shaft 2030. In some embodiments, the proximal ends of the flexible shaft 2030, the internal lumen 2012, and/or internal needle lumens 2048 are in fluid communication with a delivery fluid source. For example, the internal needle lumens 2048 can be in fluid communication with an external fluid source (e.g., a syringe, a peristaltic pump), either directly or via the interior lumen of the flexible shaft 2030.

[0144] The flexible shaft 2030 and/or internal needles 2040 can be configured to move in the distal and/or proximal directions with respect to the delivery needle 2010. For example, the internal needles 2040 can be connected to a proximal handle (not shown), either directly or via the flexible shaft 2030. The proximal handle can be configured to move the flexible shaft 2030 and/or internal needles 2040 in the proximal and distal directions with respect to the delivery needle 2010. In some embodiments, a first proximal handle can be connected to the flexible shaft 2030 and a second proximal handle can be connected to the internal needles 2040. In some embodiments, the internal needles 2040 can be moved in the proximal and distal directions with respect to the flexible shaft 2030 and/or the collar 2020. In some embodiments, each of the internal needles 2040 can be individually (or, e.g., in subsets of the whole set of internal needles 2040) connected to a proximal handle. In some such embodiments, each (e.g., or each subset) of the internal needles 2040 can be moved in the distal and proximal directions with respect to the other internal needles 2040.

[0145] The internal needles 2040 can be constructed from a metal or metal alloy, such as stainless steel, steel, titanium, or some other appropriate material. In some embodiments, the internal needles 2040, or some portion thereof, are constructed from a polymer or other non-metallic material. Preferably, at least a portion of each of the internal needles 2040 is constructed from nitinol or some other shape-memory material.

[0146] In some embodiments, the internal needles 2040 are configured to transition between a contracted position (e.g., as illustrated in Figures 20A-20B) and an expanded position (e.g., as illustrated in Figures 21A-21B). In the expanded position, the internal needles 2040 can flare out from the distal end 2014 of the delivery needle 2010. In some embodiments, the internal needles 2040 transition from the contracted position to the expanded position as the distal ends 2046 of the internal needles 2040 pass the distal end 2014 of the delivery needle 2010. In some embodiments, the wall 2011 of the

delivery needle 2010 includes one or more apertures through which the internal needles 2040 can pass when transitioning between the contracted position and the expanded position. The extent to which the internal needles 2040 flare out from the distal end 2014 of the delivery needle 2010 can, in some embodiments, be controlled by the relative distal movement of the internal needles 2040 relative to the delivery needle 2010. For example, once past the distal end 2014 of the delivery needle 3010 (or, e.g., through the apertures in the wall 2011 of the delivery needle 2010), the distal ends 2046 of the internal needles 2040 can be configured to flare out further from the delivery needle 2010 as the flexible shaft 2030 and/or internal needles 2040 are advanced in the distal direction relative to the delivery needle 2010. The interior surface of the wall 2011 of the delivery needle 2010 can include a coating to reduce or eliminate the likelihood that the internal needles 2040 would catch on the interior surface of the wall 2011 as the internal needles 2040 translate in the proximal and/or distal directions with respect to the delivery needle 2010.

[0147] The internal needle lumen 2039, having walls 2041, of the internal needles 2040 can include cut (e.g., laser cut and/or chemical cut) features 2042 such as, for example, holes or slits. The cut features 2042 can facilitate fluid communication between the internal needle lumens 2048 and the tissue into which the internal needles 2040 are deployed. The cut features 2042 can be placed on the sides of the internal needles 2040 that are compressed and stretched as the needles 2040 deploy from the distal end 2014 of the delivery needle 2010In some embodiments, the cut features 2042 are made into thc sides of the needlcs 2040 tangential to the direction of bending as the needles 2040 extend from the distal end 2014 of the delivery needle 2010 (e.g., as illustrated in Figure 21A). According to some variants, the cut features 2042 are located at various points around the wall of the needles 2040. In some embodiments, the distal ends 2046 of the internal needles 2040 include distal apertures 2044 at a distal end 2045 in fluid communication with the internal needle lumens 2048 of the internal needles 2040.

[0148] The internal needles 2040 and/or delivery needle 2010 can be configured (via, e.g., cut features and/or cut patterns in the walls 2041, 2011 of the needles 2040, 2010) to be flexible such that the delivery needle 2010 can be navigated to and/or through narrow and/or tortuous lumens within the body. As such, the substance delivery system 2000 can be delivered to a site of interest within the body using the body's natural orifices (e.g., the mouth). In some embodiments, piercing of tissue within the body (other than piercing an airway wall to access extrinsic areas of interest outside of the airway) can be avoided by using a flexible substance delivery system 2000 as

described. According to some variants, the delivery needle 2010 and internal needles 2040 can be navigated to the site of interest (e.g., nodule, tumor, lesion) to be treated using a bronchoscope of other delivery device. For example, the delivery needle 2010 can be delivered to a site of interest in the lung via a bronchoscope inserted through the airways of the throat and lung. In some embodiments, the delivery needle 2010 is navigated to the site of interest thoracoscopically (e.g., through an incision in torso of the patient). In some embodiments, the delivery needle 2010 can be navigated to the site of interest using a delivery catheter similar to or the same as the delivery catheter 1100 described above with respect to Figure 11C. For example, an ultrasound probe 1116 can be used to navigate the delivery needle 2010 to the site of the interest. The ultrasound probe 1116 can facilitate real-time tracking of the needle 2010 as the needle 2010 is navigated to the site of interest.

[0149] Figure 22A illustrates an embodiment of a delivery needle 2010 used to treat an area of interest 2002 (e.g., a nodule, tumor, lesion). Used alone, a delivery needle 2010 (or other single-lumen needle) can have zone of efficacy 2050 within and/or around the area of interest 2002. For example, the delivery needle 2010 can be delivered to the area of interest 2002 and be inserted (e.g., piercably) into the area of interest 2002. A syringe or other fluid source (not shown) can be connected to the proximal end 2015 of the delivery needle 2010 and can be used to introduce a treatment substance (e.g., an ablative chemical solution) to the area of interest 2002 through the needle 2010. The treatment substance can travel through the distal end 2014 of the needle 2010 to affect a zone of efficacy 2050. The zone of efficacy 2050 can generally comprise the area treated or otherwise affected by the treatment substance.

[0150] As illustrated in Figure 22B, the use of multiple internal needles 2040 can increase the size of the zone of efficacy 2050a compared to the zone of efficacy 2050 realized using a single-lumen, single needle treatment approach. For example, the delivery needle 2010 can be navigated to the area of interest 2002. The distal end 2014 of the delivery needle 2010 can be inserted (e.g., piercably) into the site of interest 2002. The internal needles 2040 can be moved distally with respect to the distal end 2014 of the delivery needle 2010 to further penetrate the site of interest 2002. As described above, the internal needles 2040 can be configured to flare outward from the distal end 2014 of the delivery needle 2010 as the internal needles 2040 are advanced out of the delivery needle 2010 in the distal direction. A syringe or other fluid source can be connected to the proximal end of the internal needles 2040 and/or flexible tube 2030 and can be used to

introduce a treatment substance (e.g., an ablative chemical solution) to the area of interest 2002 through the internal needles 2040. In some embodiments, the treatment substance is ethanol, which can be used to treat and/or destroy tumors. The treatment substance can travel through the cut features 2042 and/or distal aperture 2044 to disperse the treatment substance and create a zone of efficacy 2050a that can be greater in size than the zone of efficacy 2050 realized using a single lumen, single needle treatment approach.

[0151] Although this invention has been disclosed in the context of certain embodiments and examples, those skilled in the art will understand that the present invention extends beyond the specifically disclosed embodiments to other alternative embodiments and/or uses of the invention and obvious modifications and equivalents thereof. In addition, while several variations of the invention have been shown and described in detail, other modifications, which are within the scope of this invention, will be readily apparent to those of skill in the art based upon this disclosure. It is also contemplated that various combinations or sub-combinations of the specific features and aspects of the embodiments may be made and still fall within the scope of the invention. It should be understood that various features and aspects of the disclosed embodiments can be combined with, or substituted for, one another in order to form varying modes or embodiments of the disclosed invention. Thus, it is intended that the scope of the present invention herein disclosed should not be limited by the particular disclosed embodiments described above.

WHAT IS CLAIMED IS:

1. A needle assembly for delivery of a treatment substance to a site within the body, the needle assembly comprising:

a delivery needle (2010) defining a delivery lumen (2012) and having a delivery needle wall (2019), a proximal end (2015), and a distal end (2014), the delivery needle wall having one or more cut patterns (304) to increase the flexibility of the delivery needle;

a plurality of internal needles (2040), each internal needle defining an internal needle lumen (2039) and having an internal needle wall (2041), a proximal end, and a distal end (2045), the plurality of needles configured to transition between a contracted position and an expanded position; and

a treatment substance source in fluid communication with the internal needle lumens of the plurality of internal needles;

wherein each of the plurality of internal needles is configured to extend in a distal direction and flare outward from the distal end of the delivery needle when in the expanded position; and

wherein the plurality of internal needles are housed within the delivery lumen when in the contracted position.

2. The needle assembly of claim 1, wherein an internal surface of the delivery needle wall (2021) is coated with a substance configured to reduce or eliminate the likelihood that the internal needles will stick to or catch on the delivery needle wall when the internal needles are transitioned between the contracted position and the expanded position.

3. The needle assembly of claim 1, wherein the delivery needle is coated on an outside surface (2022) with quick clotting features, cauterizing features, or both.

4. The needle assembly claim 2, wherein the internal surface of the delivery needle wall includes one oe more cut features (2042), the one or more cut features facilitating fluid communication between the internal needle lumen and an exterior of the internal needles.

5. The needle assembly of claim 4, wherein the needle assembly further comprises a flexible shaft (2030) having a distal end and a proximal end, the distal end of the flexible shaft coupled with the proximal ends of the internal needles.

6. The needle assembly of claim 1, wherein the needle assembly comprises three internal needles.

7. The needle assembly of claim 6, wherein each of the internal needles has a distal aperture (2044) in fluid communication with the internal needle lumen.

8. The needle assembly of claim 1, wherein each of the distal ends of the internal needles are sharpened.

9. The needle assembly of claim 8, wherein each of the distal ends of the internal needles form a continuous beveled surface, wherein the angle changes continuously along the bevel.

10. The needle assembly of claim 1, wherein the distal end of the delivery needle is sharpened.

11. The needle assembly of claim 10, wherein the distal end of the delivery needle forms a continuous beveled surface, wherein the angle changes continuously along the bevel.

12. The needle assembly of claim 1, wherein the needle assembly further comprises a connection to a suction source, a steering mechanism, or both.

13. A multi-lumen catheter assembly, comprising:

a biopsy needle contained within one lumen;

an ultrasound probe (1116) contained within a second lumen; and

a mechanism for adjusting the angle of the distal tip of the biopsy needle, comprising one or more steering wires (1106).

14. The needle assembly of claim 13, wherein the one or more steering wires is a bowden wire.

15. A method of obtaining a tissue sample, comprising:

inserting a needle assembly in a bronchoscope;

advancing a one or more flexible needles (204) through a distal tip of the needle assembly;

visualizing the tip position with the aid of one or more signature markers (2059); and

manipulating a position of the distal tip to optimally obtain the tissue sample.

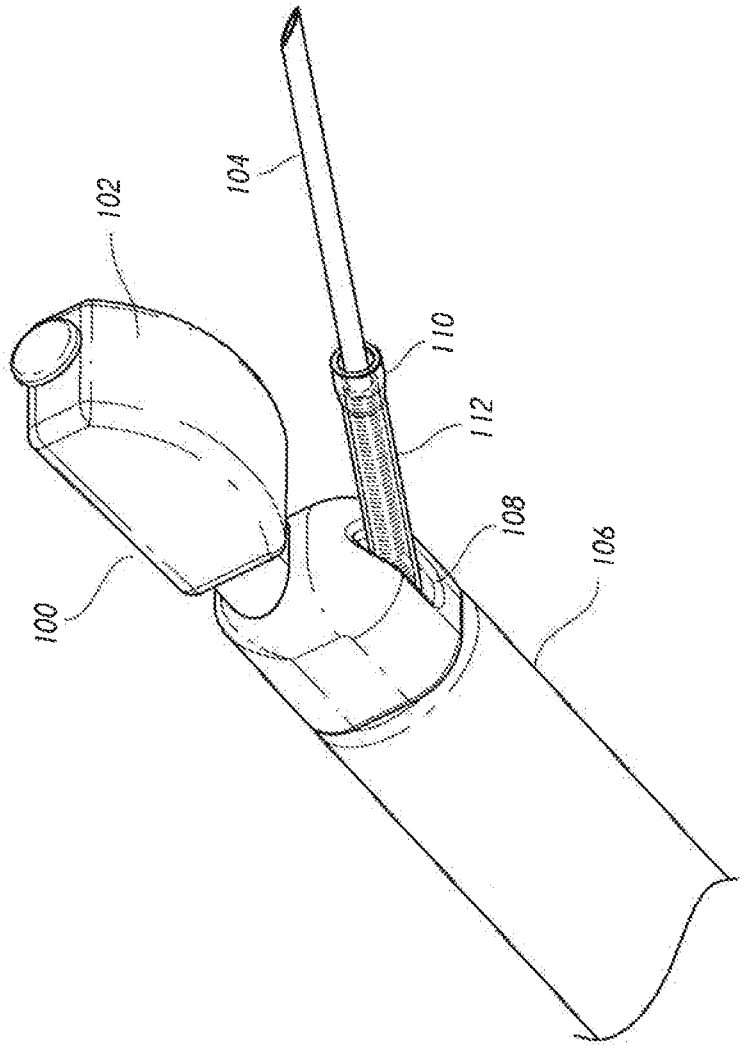

FIG. 1

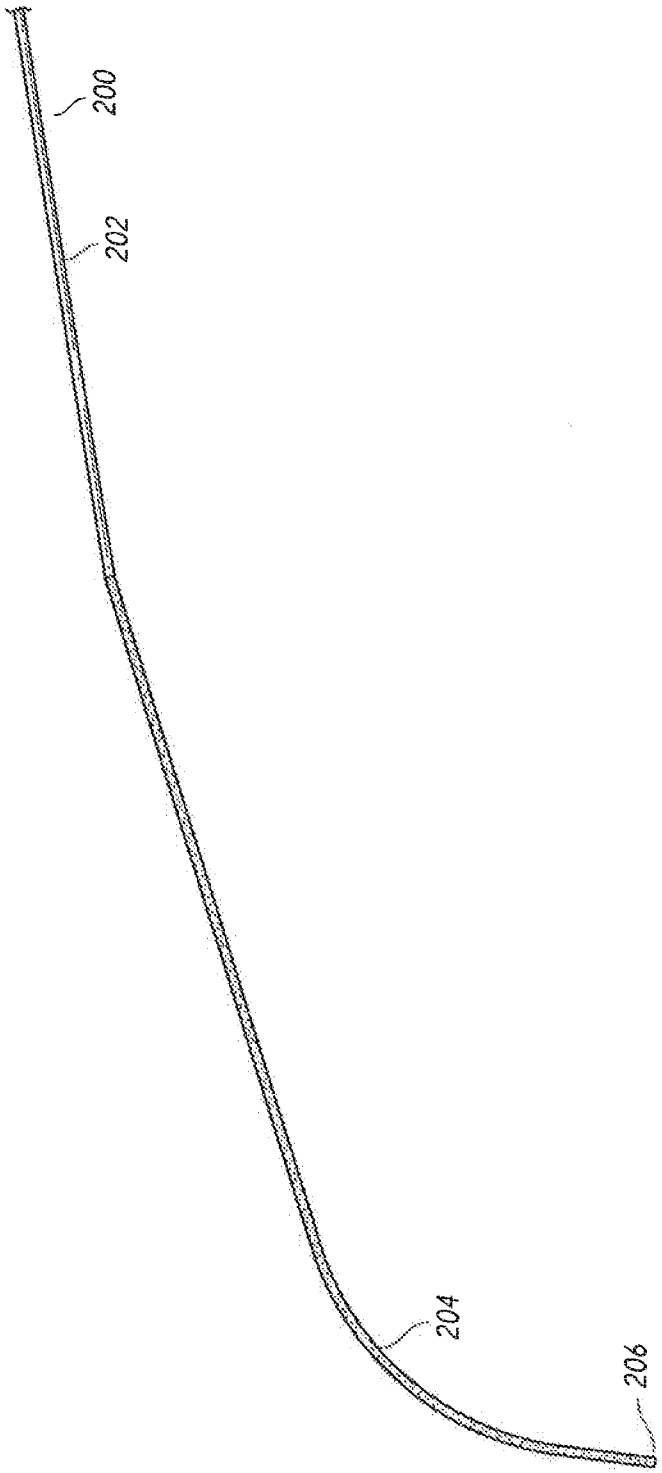

FIG. 2

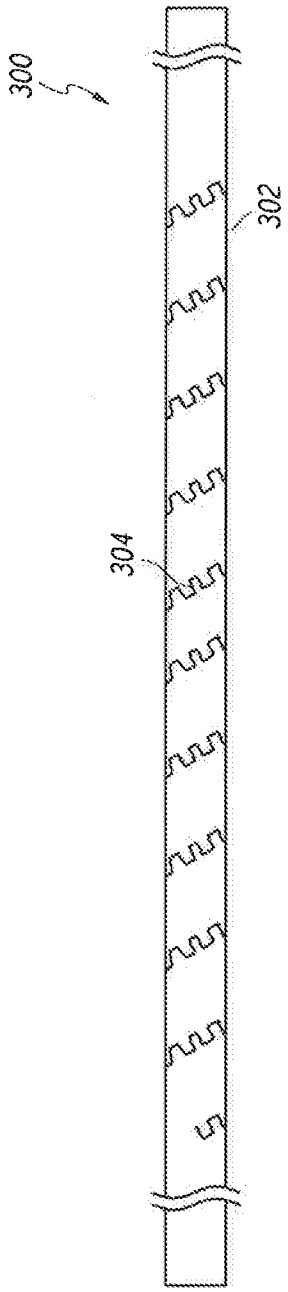

FIG. 3A

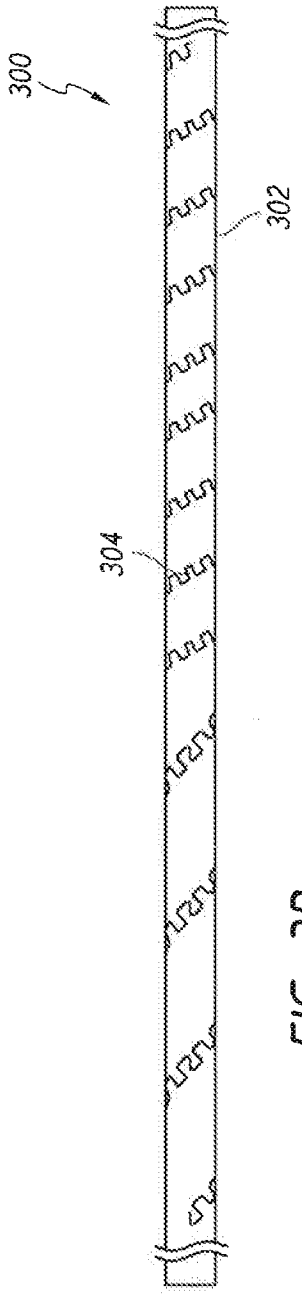

FIG. 3B

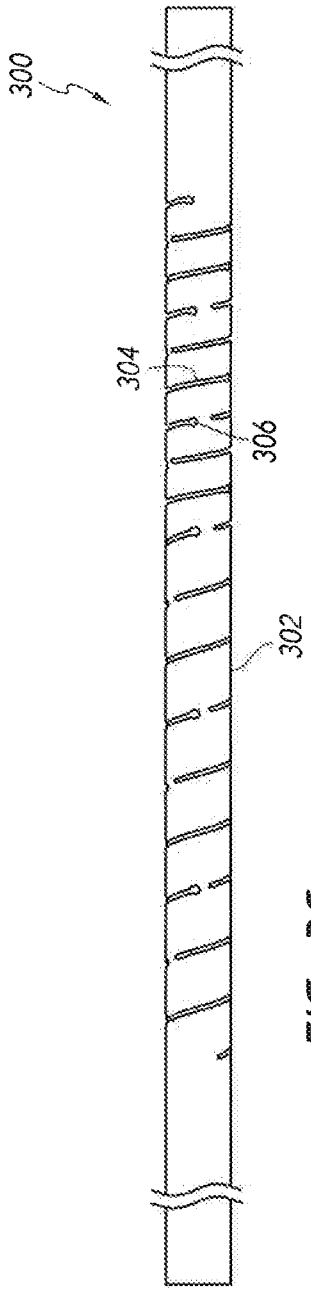

FIG. 3C

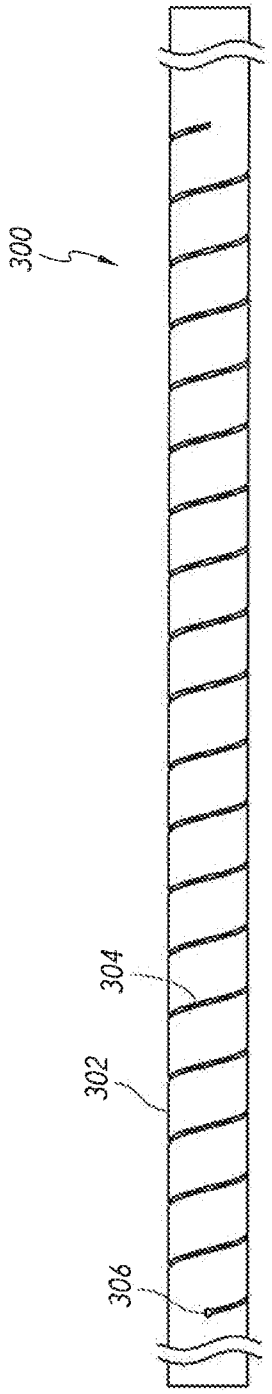

FIG. 3D

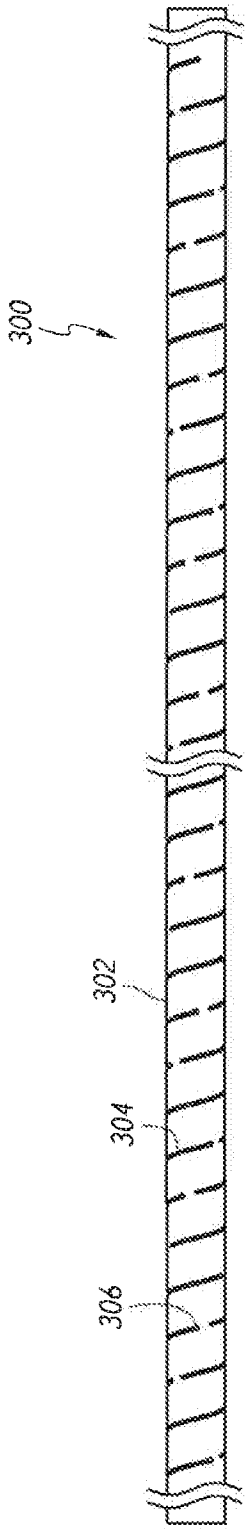

FIG. 3E

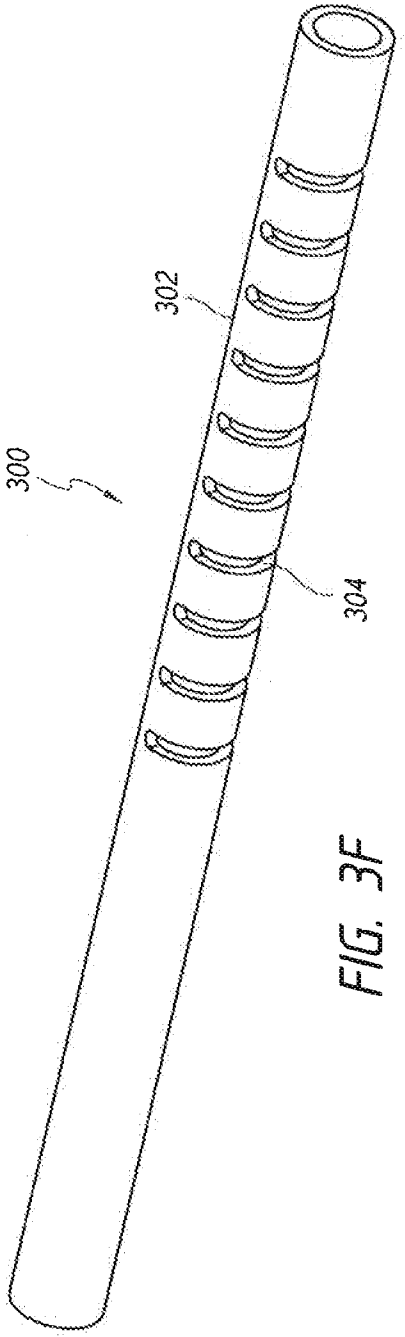

FIG. 3F

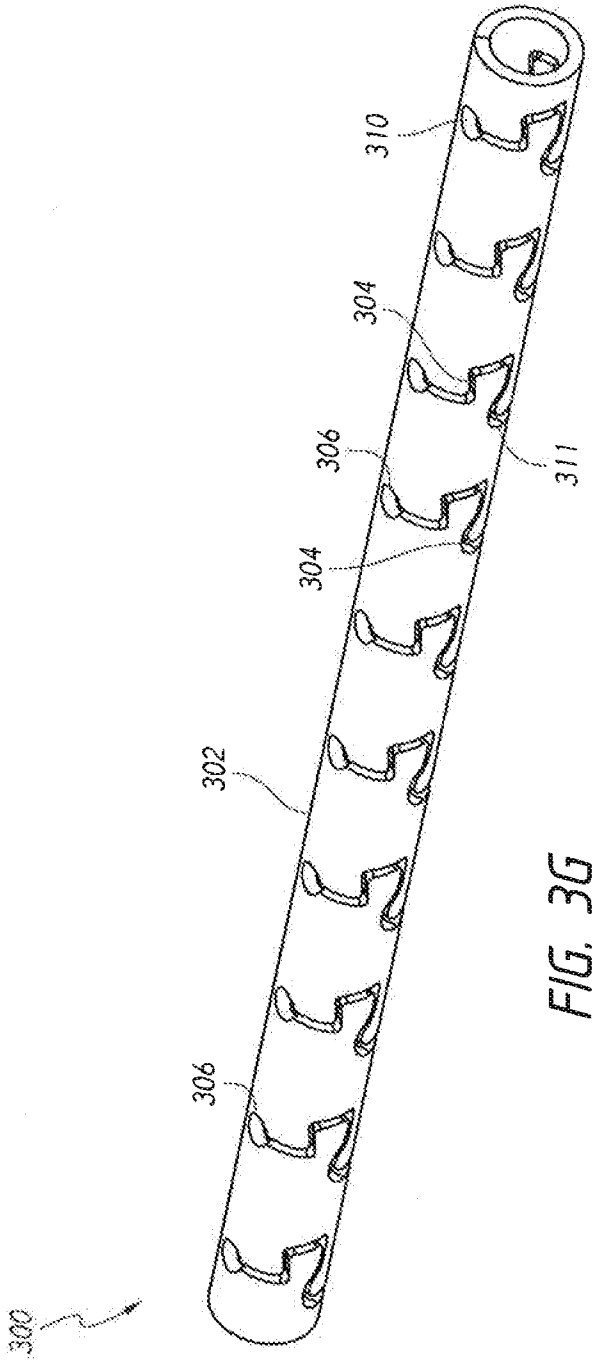

FIG. 3G

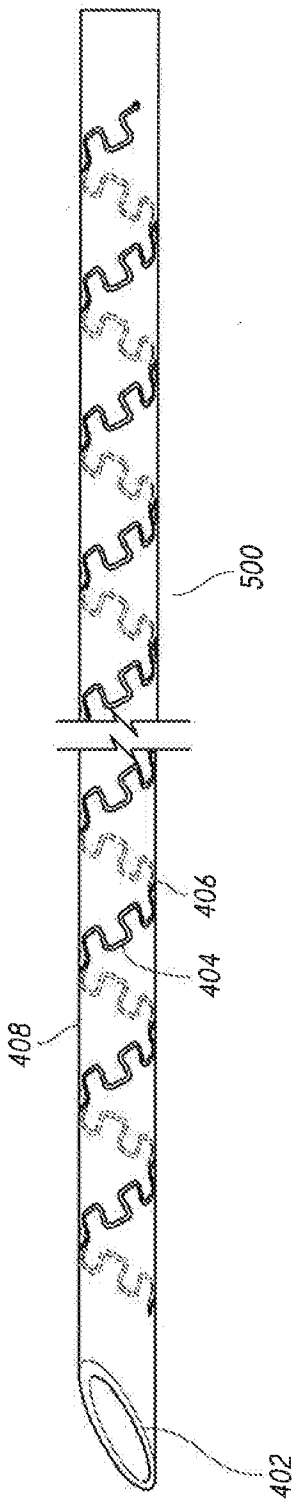

FIG. 4

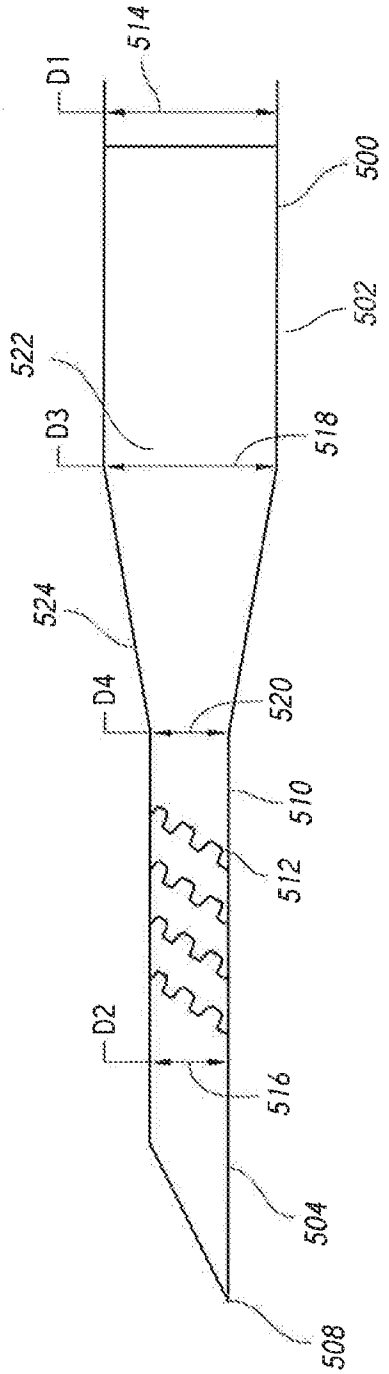

FIG. 5

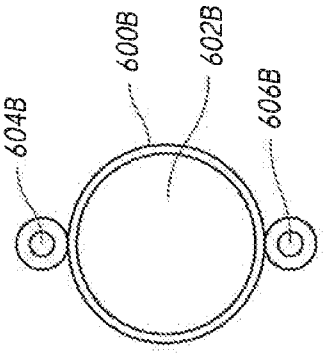

FIG. 6B

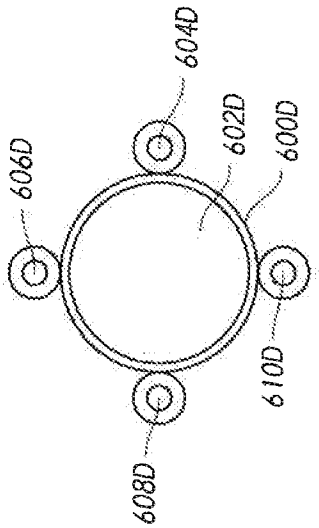

FIG. 6D

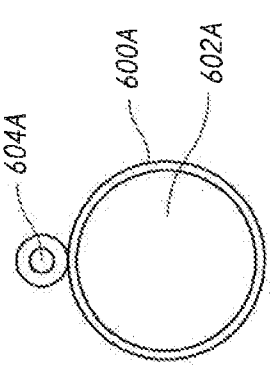

FIG. 6A

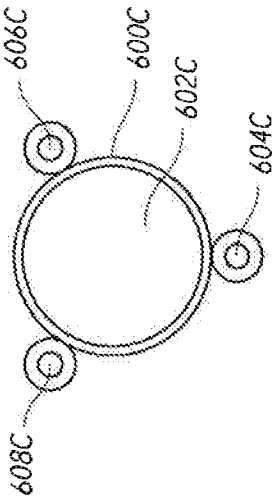

FIG. 6C

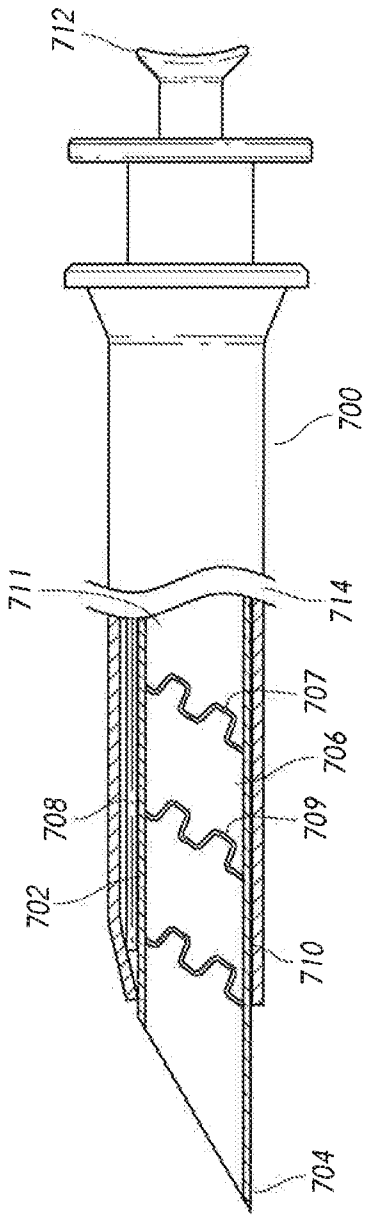

FIG. 7

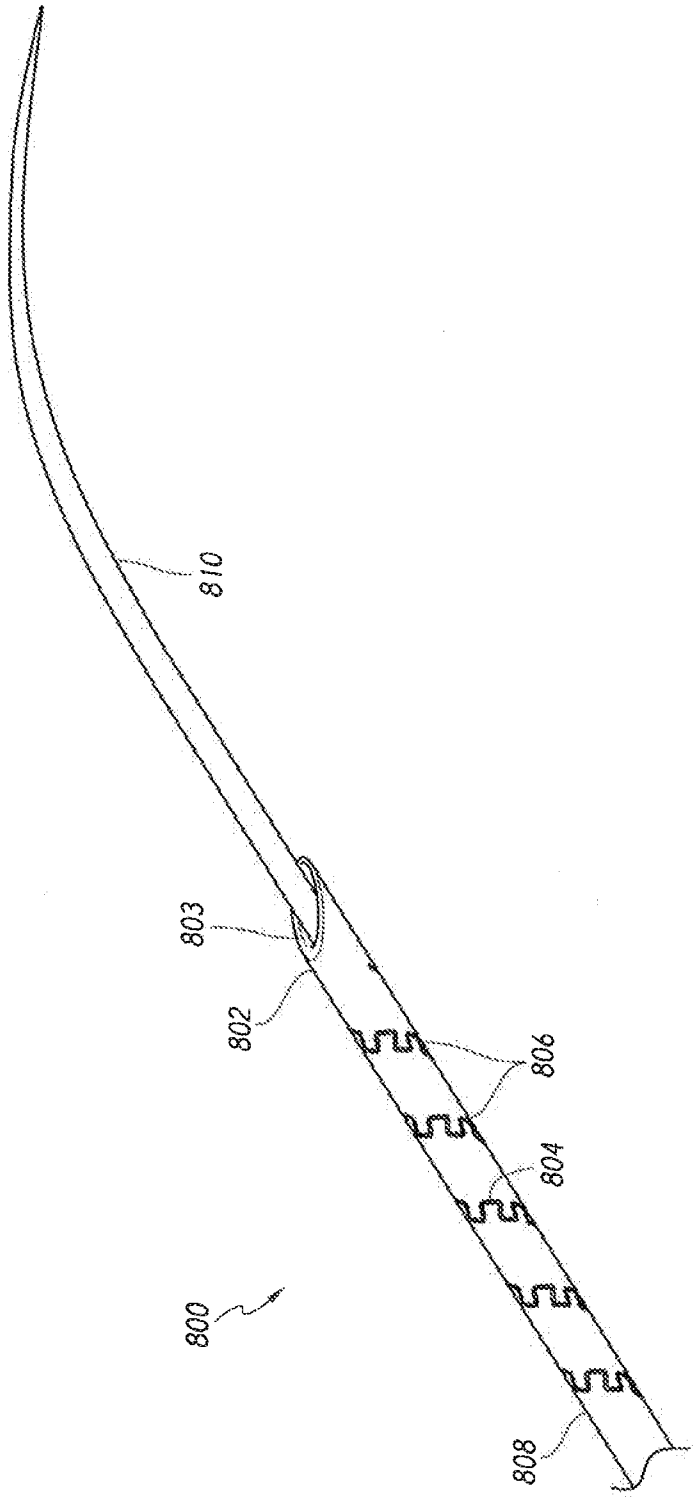

FIG. 8

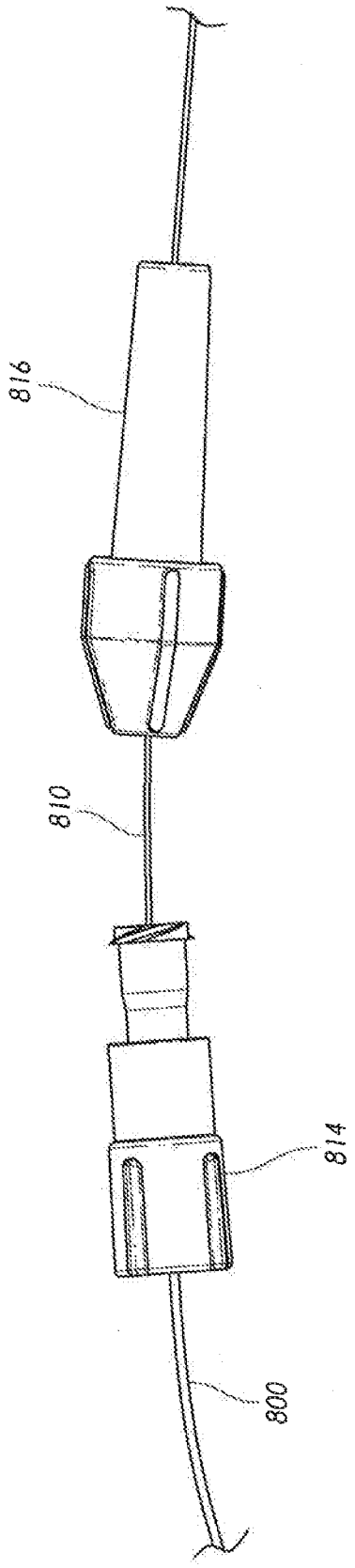

FIG. 9

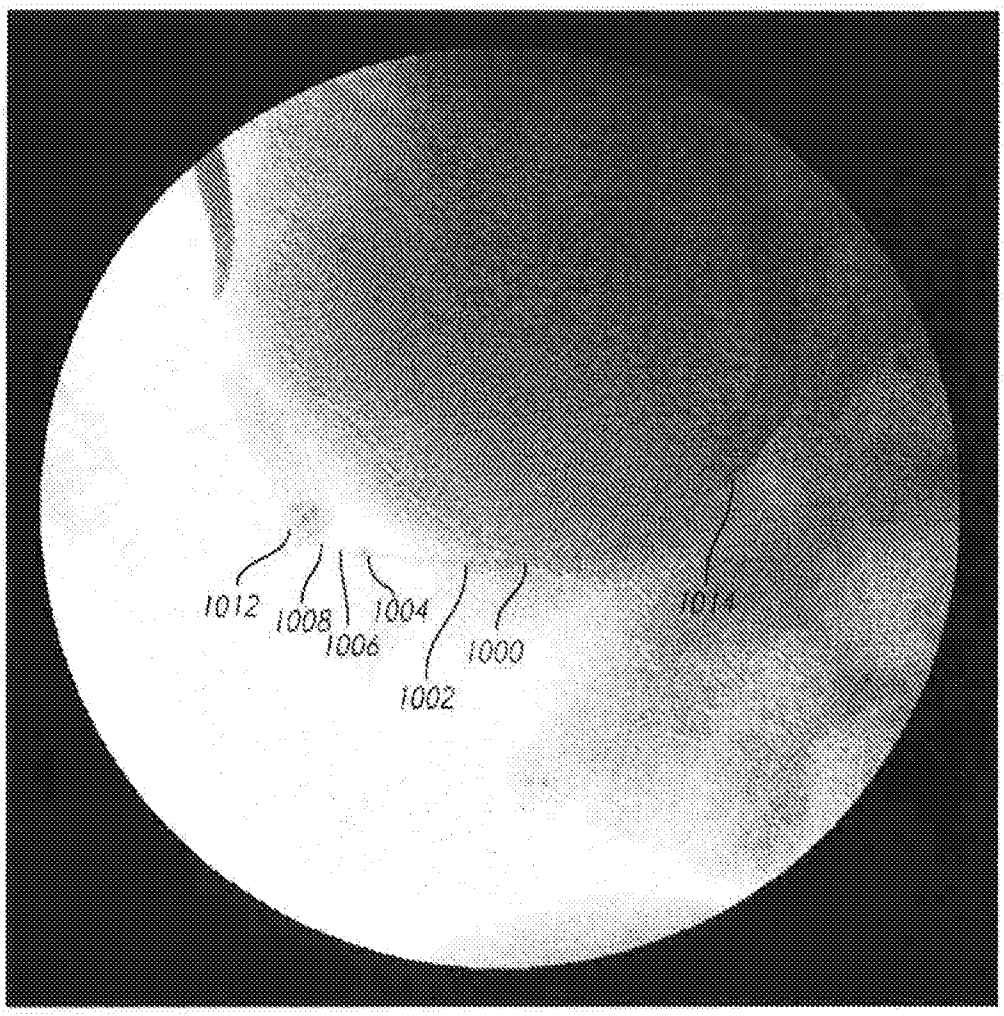

FIG. 10

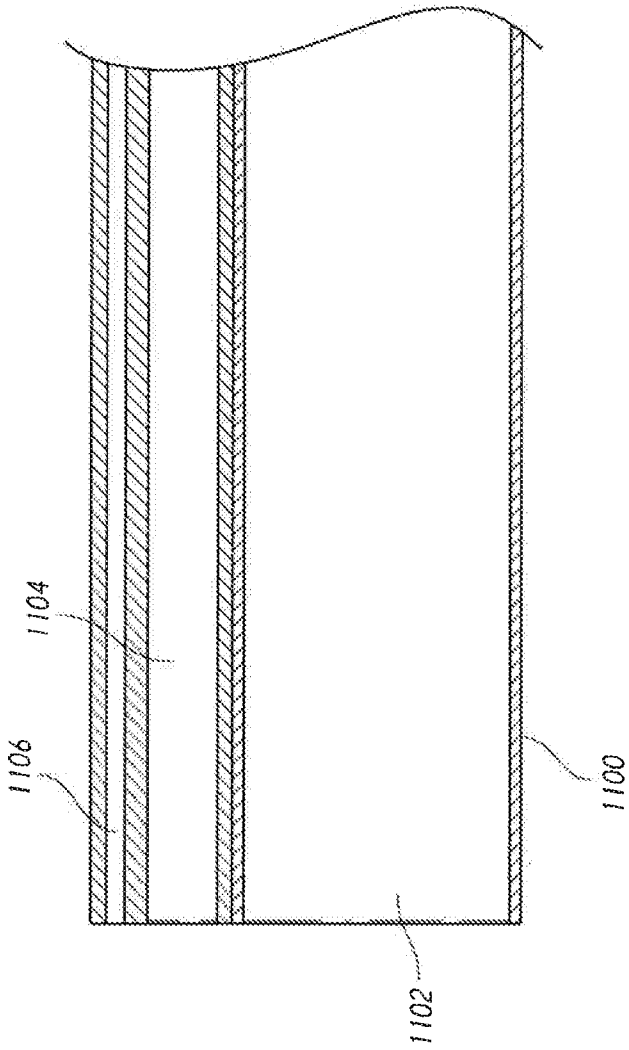

FIG. 11B

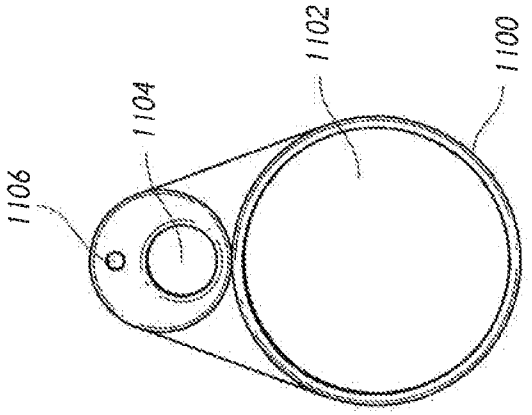

FIG. 11A

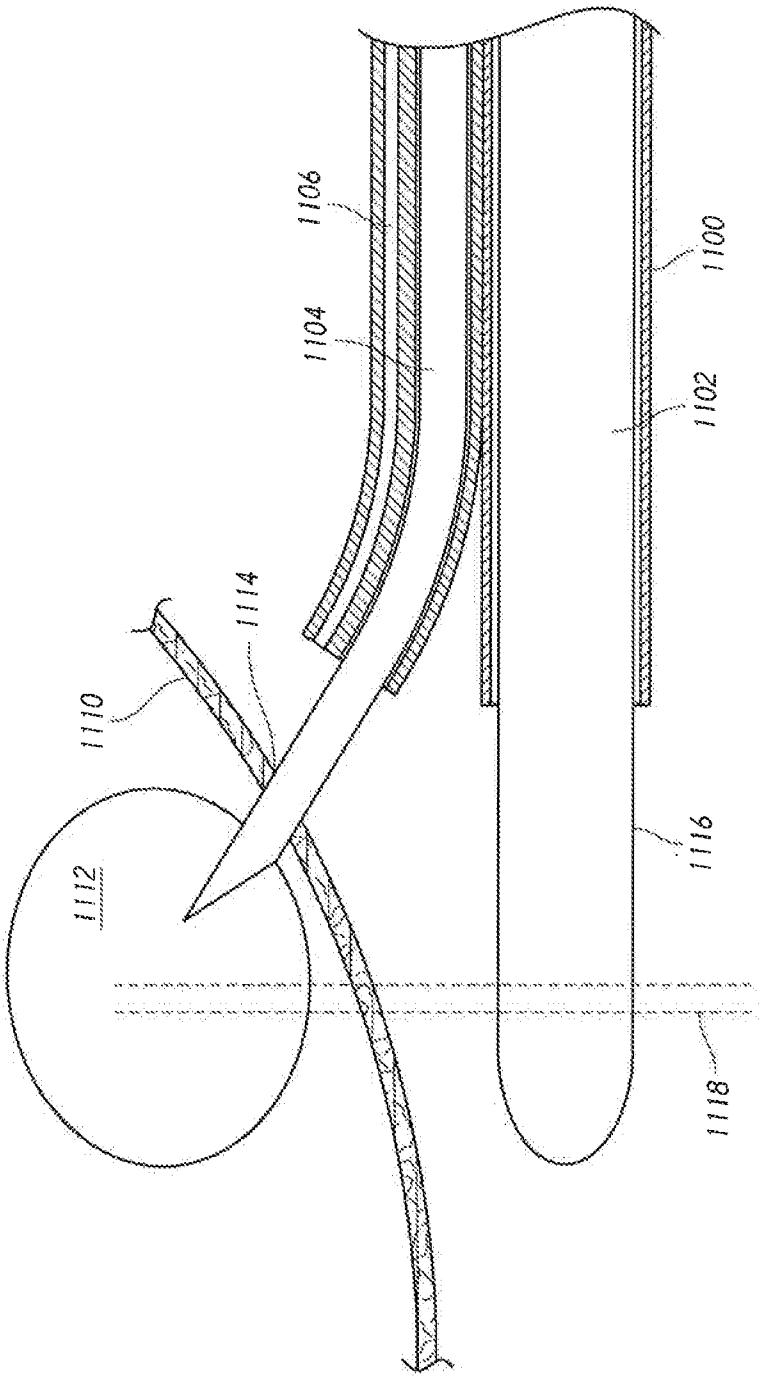

FIG. 11C

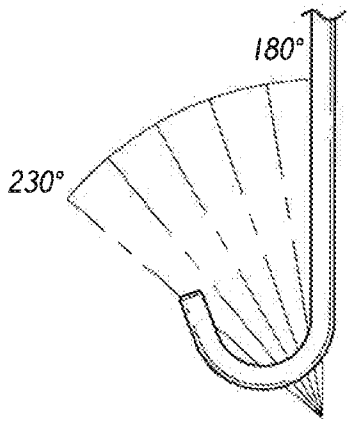

FIG. 12A

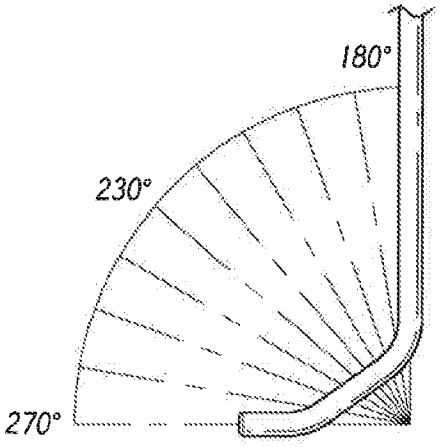

FIG. 12B

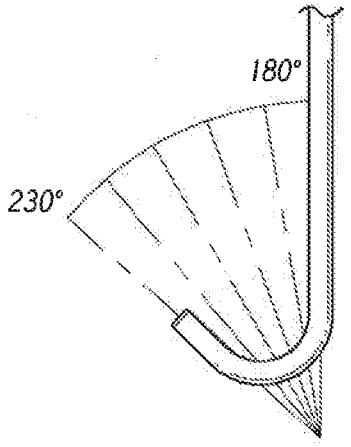

FIG. 12C

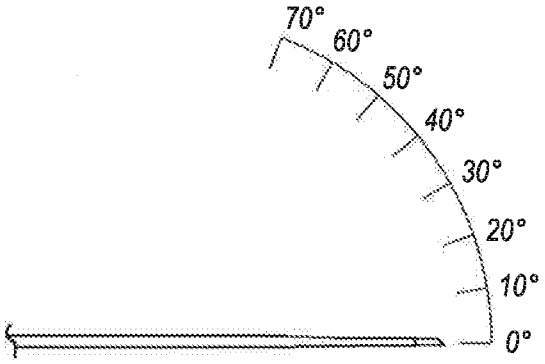

FIG. 13A

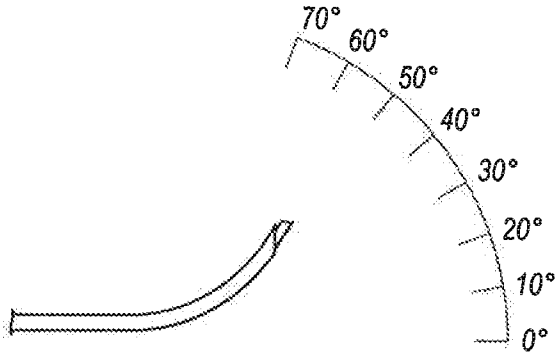

FIG. 13B

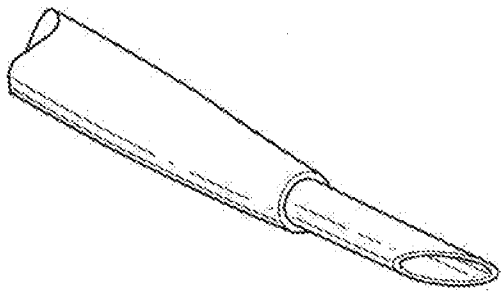

FIG. 13C

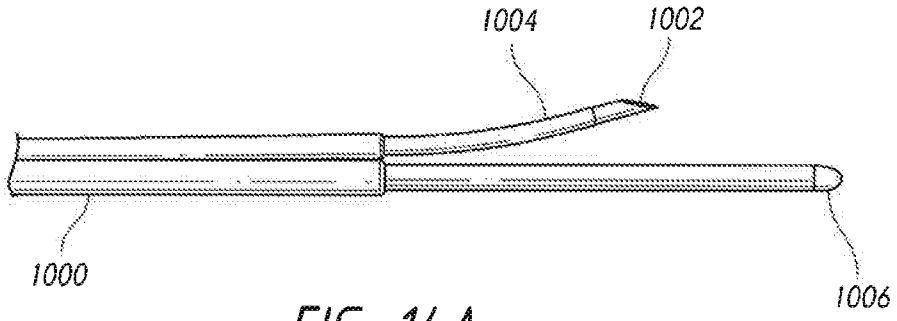

FIG. 14A

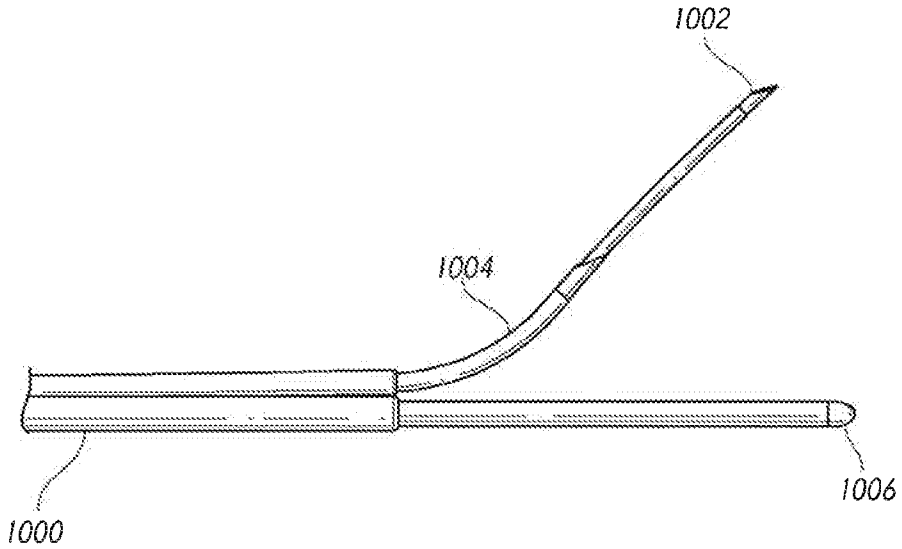

FIG. 14B

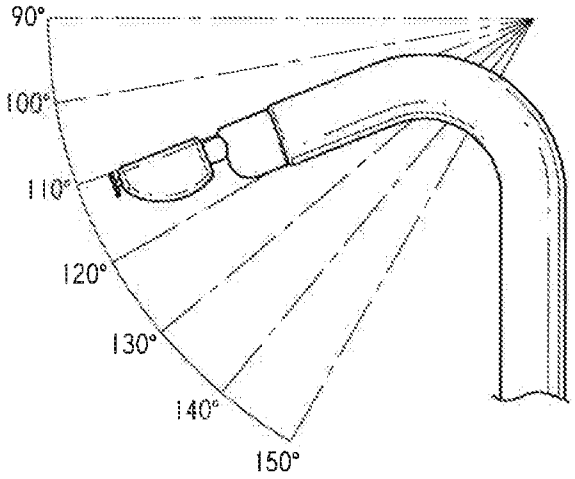

FIG. 15A

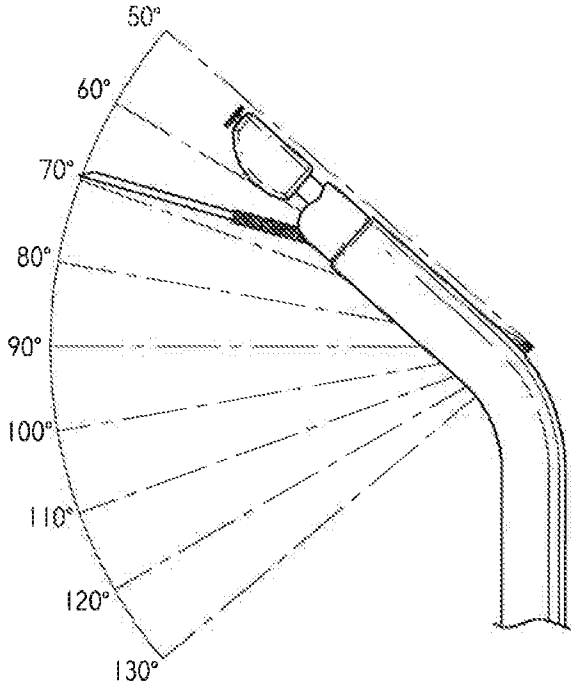

FIG. 15B

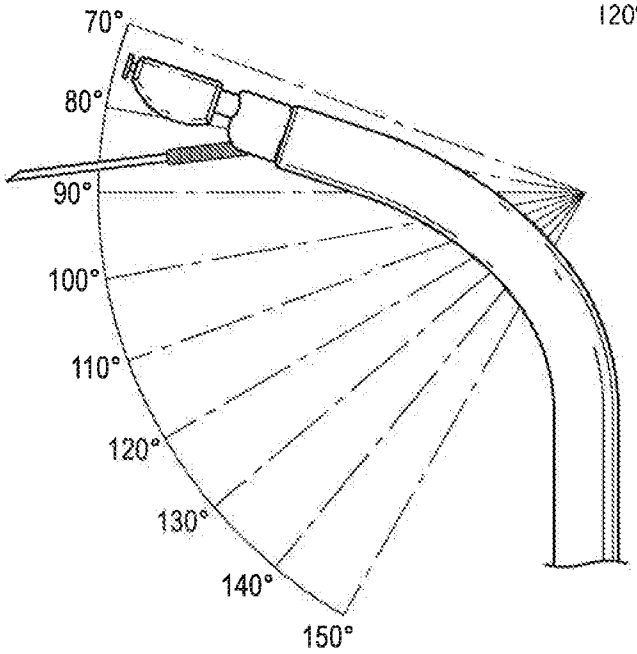

FIG. 15C

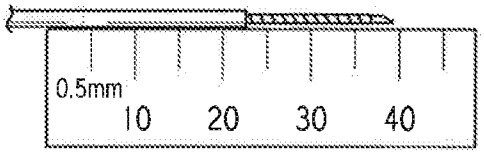

FIG. 16A

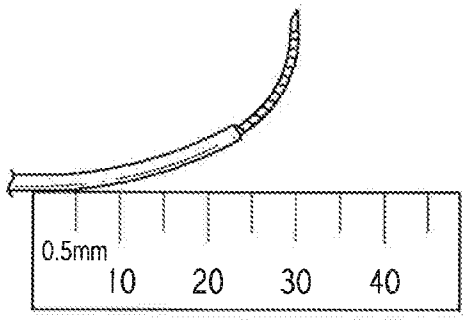

FIG. 16B

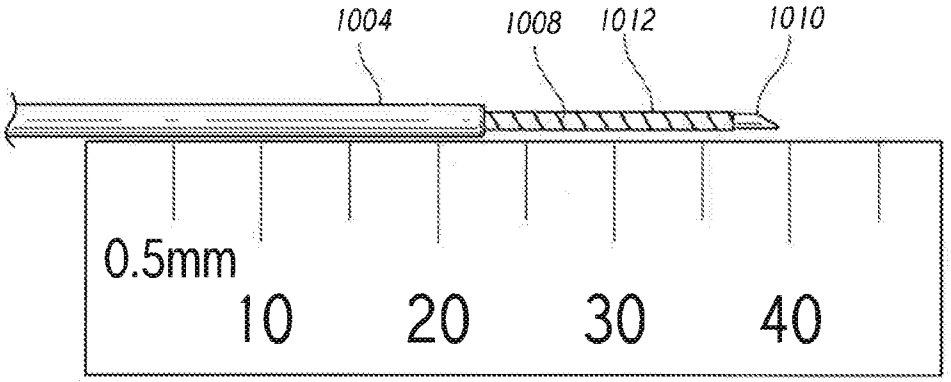

FIG. 16C

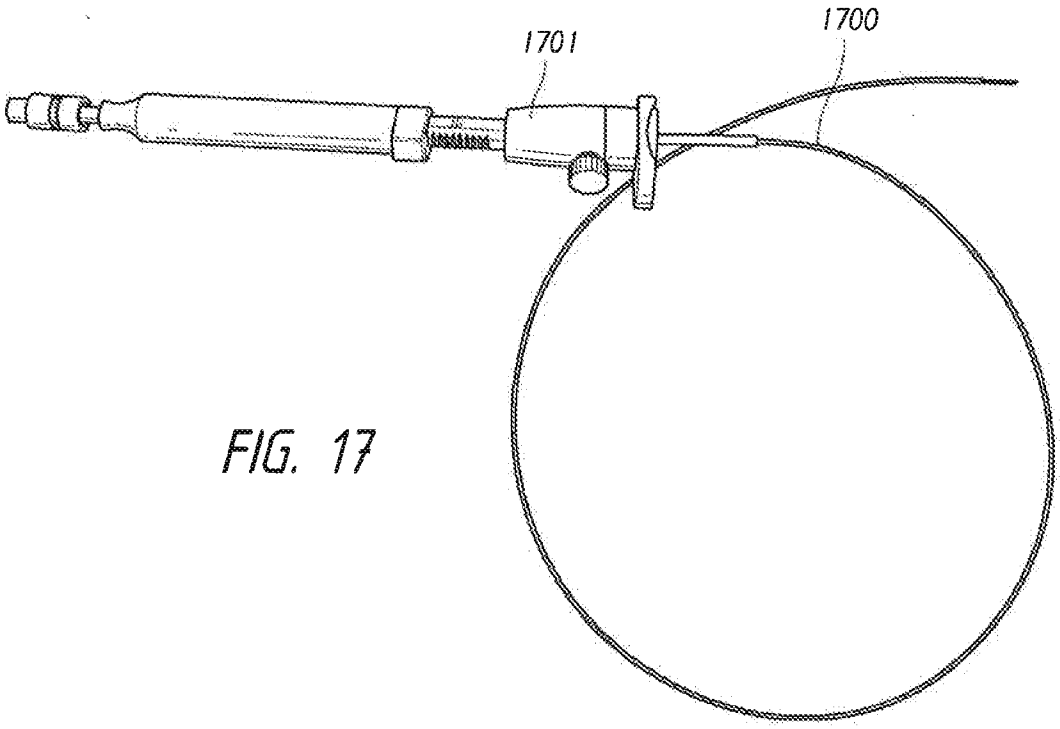

FIG. 17

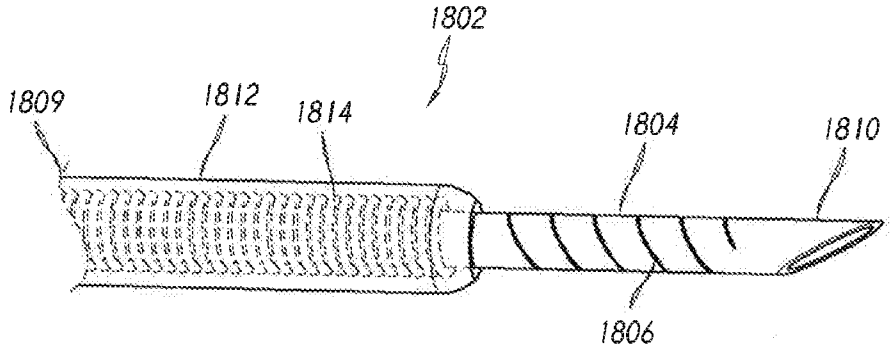

FIG. 18

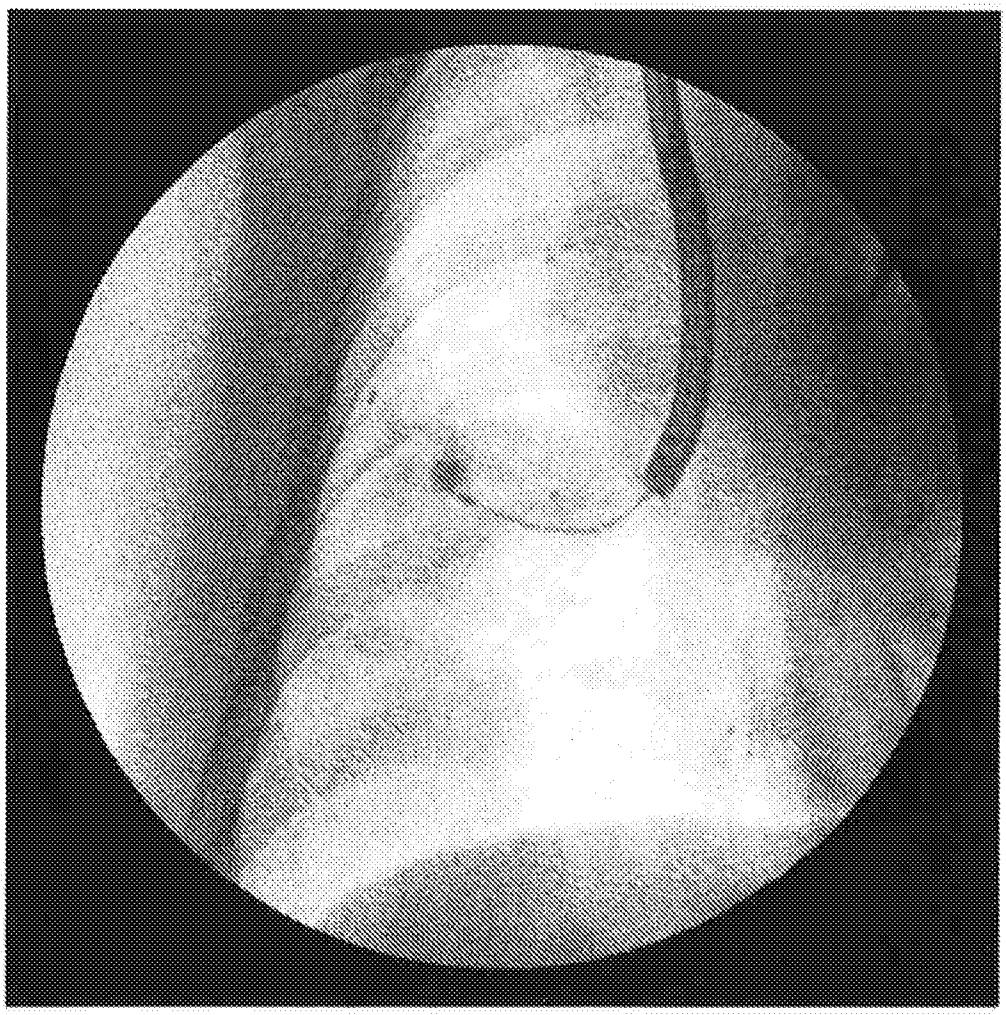

FIG. 19

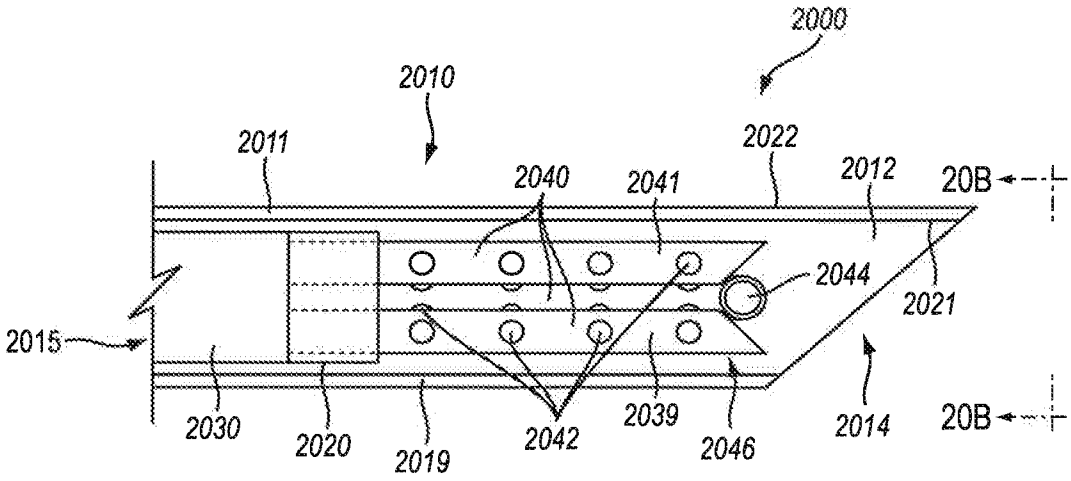

FIG. 20A

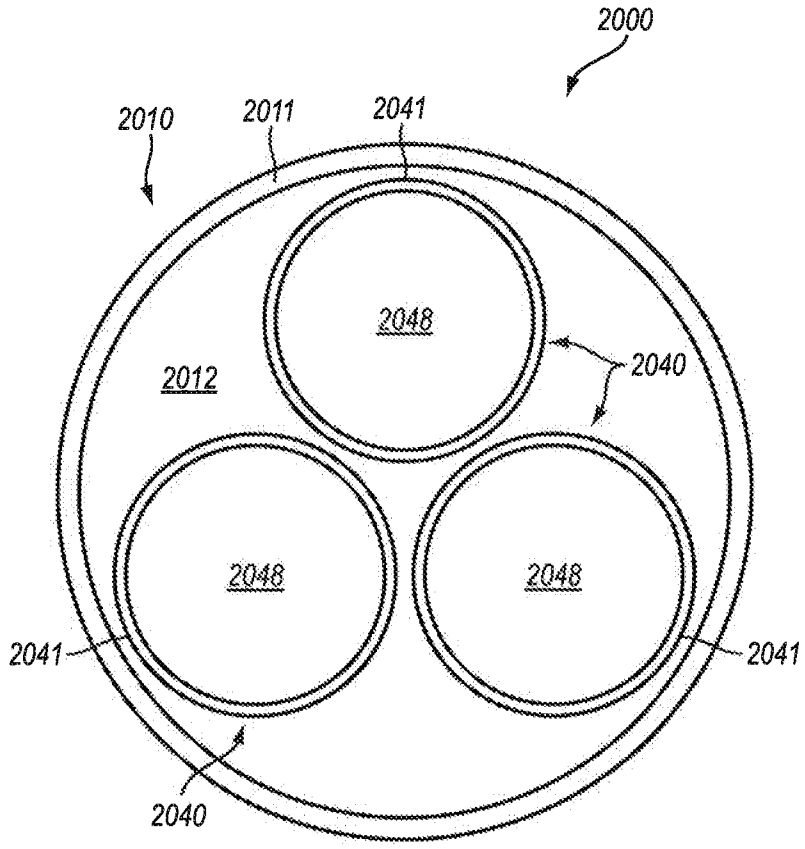

FIG. 20B

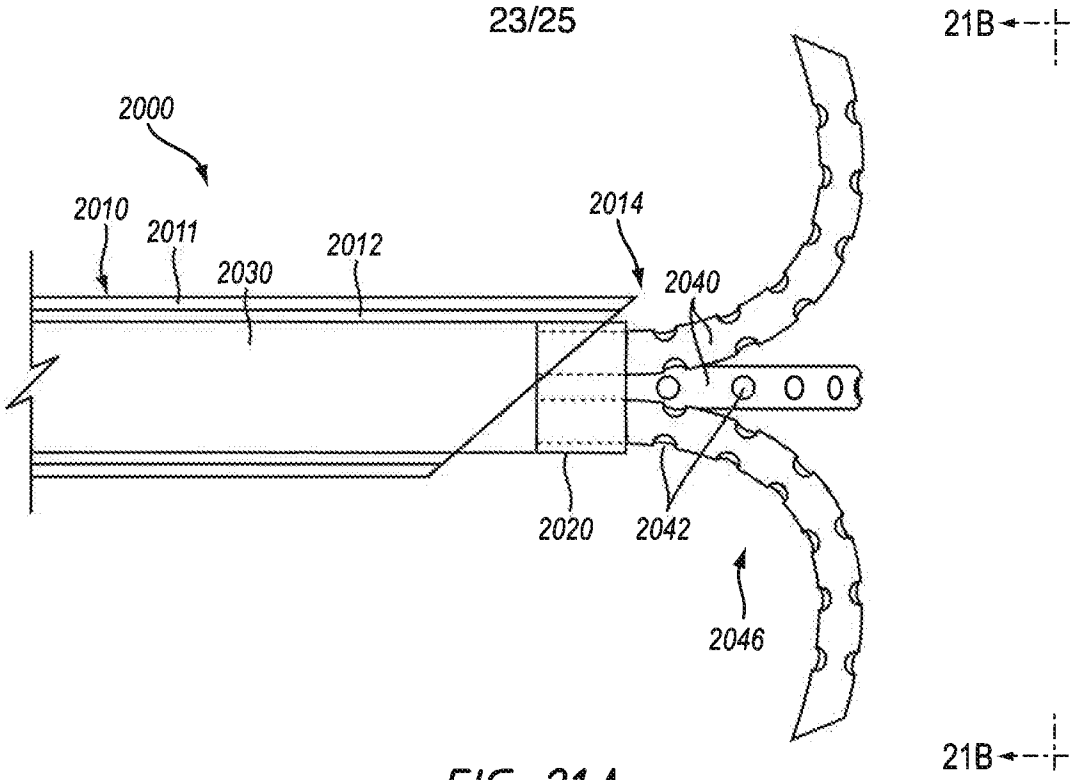

FIG. 21A

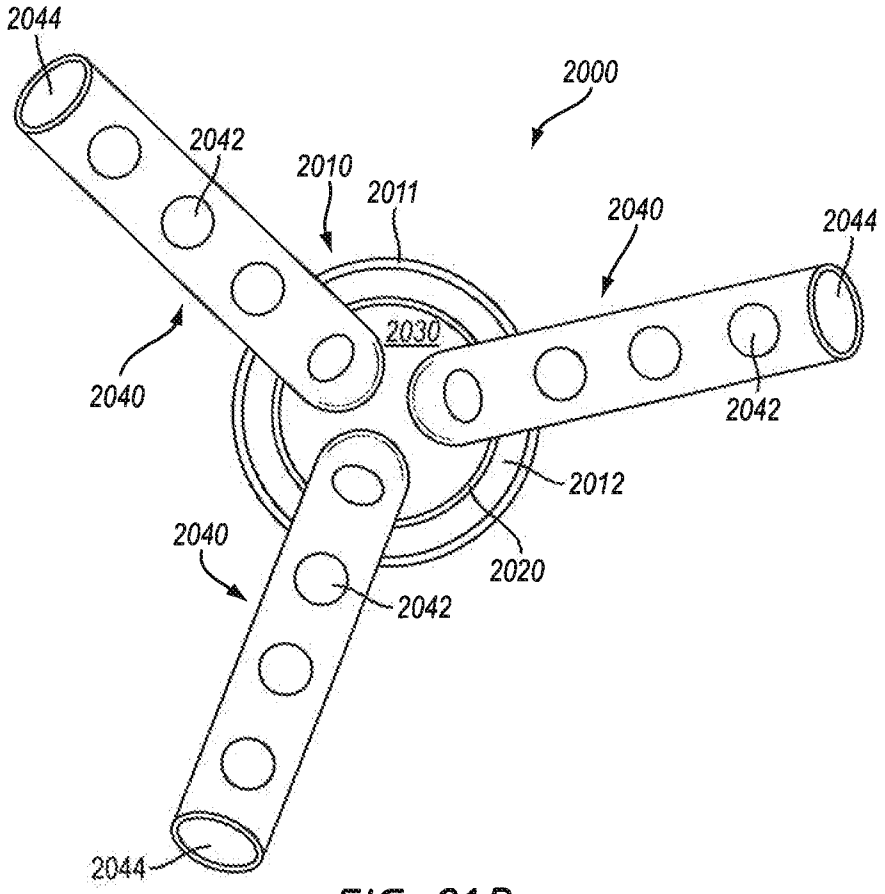

FIG. 21B

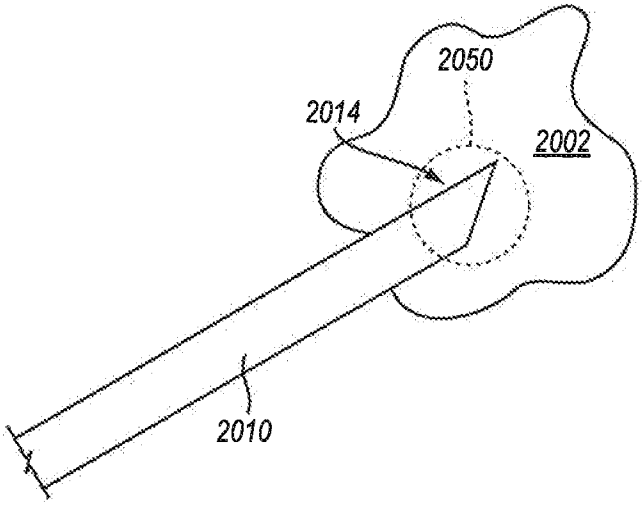

FIG. 22A

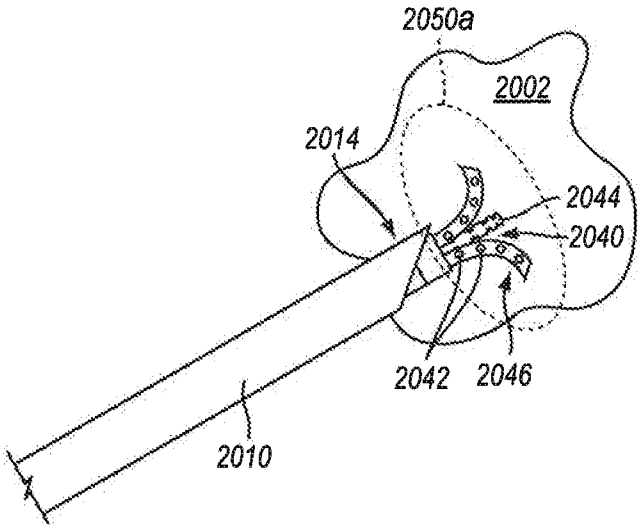

FIG. 22B

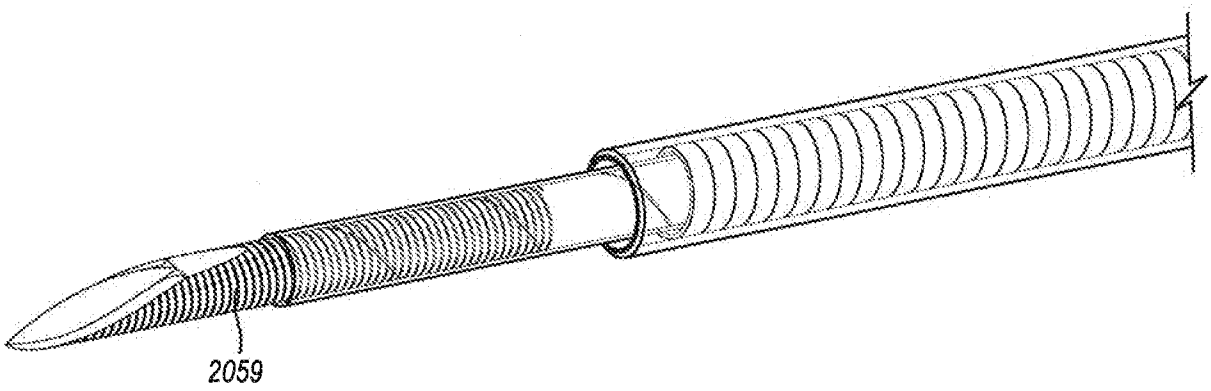

FIG. 23A

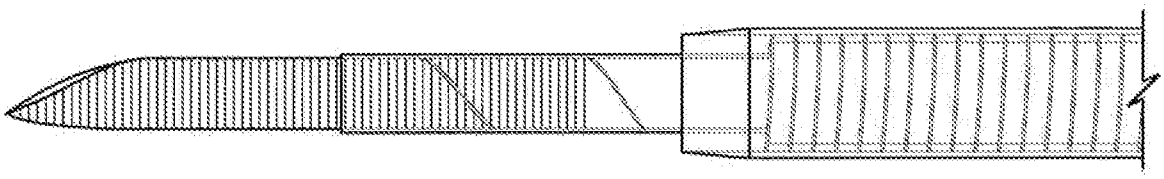

FIG. 23B

专利名称(译)	用于微创递送治疗物质的装置		
公开(公告)号	EP2852328A2	公开(公告)日	2015-04-01
申请号	EP2014712967	申请日	2014-03-07
[标]申请(专利权)人(译)	斯波瑞申有限公司		
申请(专利权)人(译)	SPIRATION INC.D.B.A.奥林巴斯呼吸AMERICA		
当前申请(专利权)人(译)	SPIRATION INC.D.B.A.奥林巴斯呼吸AMERICA		
[标]发明人	HOFFMAN PETER		
发明人	HOFFMAN, PETER		
IPC分类号	A61B10/04		
CPC分类号	A61B10/0233 A61B10/0266 A61B10/04 A61B2010/045 A61B2018/00023 A61B2018/00095 A61B2018/00208 A61B2018/00541 A61B2018/00577 A61B2018/00595 A61B2018/00982 A61B2018/046 A61B2090/376 A61B2090/3966 A61M2025/0087 A61M2025/0089 A61B1/018 A61B1/2676 A61B8/0841 A61B8/12 A61B8/445 A61B17/3417		
代理机构(译)	MANITZ，FINSTERWALD & PARTNER GBR		
优先权	61/779483 2013-03-13 US		
外部链接	Espacenet		

摘要(译)

本文描述了用于将消融流体输送到身体内的感兴趣位置（例如，具有肺的位置）的系统，方法和装置。消融流体输送系统和装置可包括柔性输送针（2010），其中容纳有多个较小的柔性针（2040）。较小的柔性针可以构造成相对于柔性输送针铰接或弯曲，以增加消融流体的有效输送区域。较小的柔性针可包括孔或其他开口（2042），以便于将消融流体输送到感兴趣的位置。