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Dillard et al.

(54) **LUNG BIOPSY NEEDLE**

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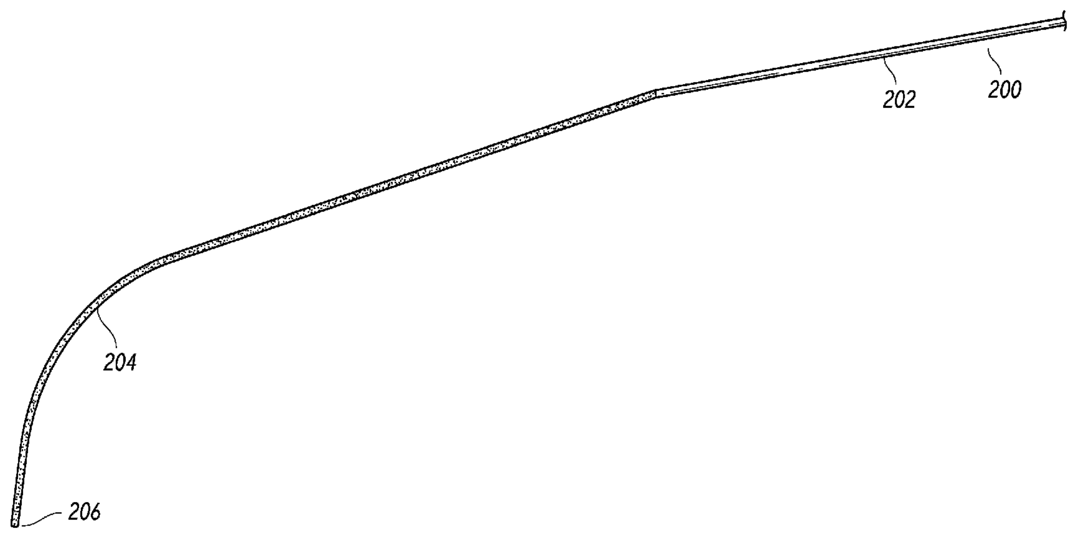
USPC **600/439**; 600/567; 600/566; 29/896.9

(57) **ABSTRACT**

Systems, methods, and devices for biopsying tissue, in particular lung nodules, with a flexible needle are described herein. Preferably, the flexible needle is able to articulate or bend so as to provide access to areas previously difficult or impossible to biopsy. Further embodiments provide for steering and navigating the flexible needle to a region to be biopsied.



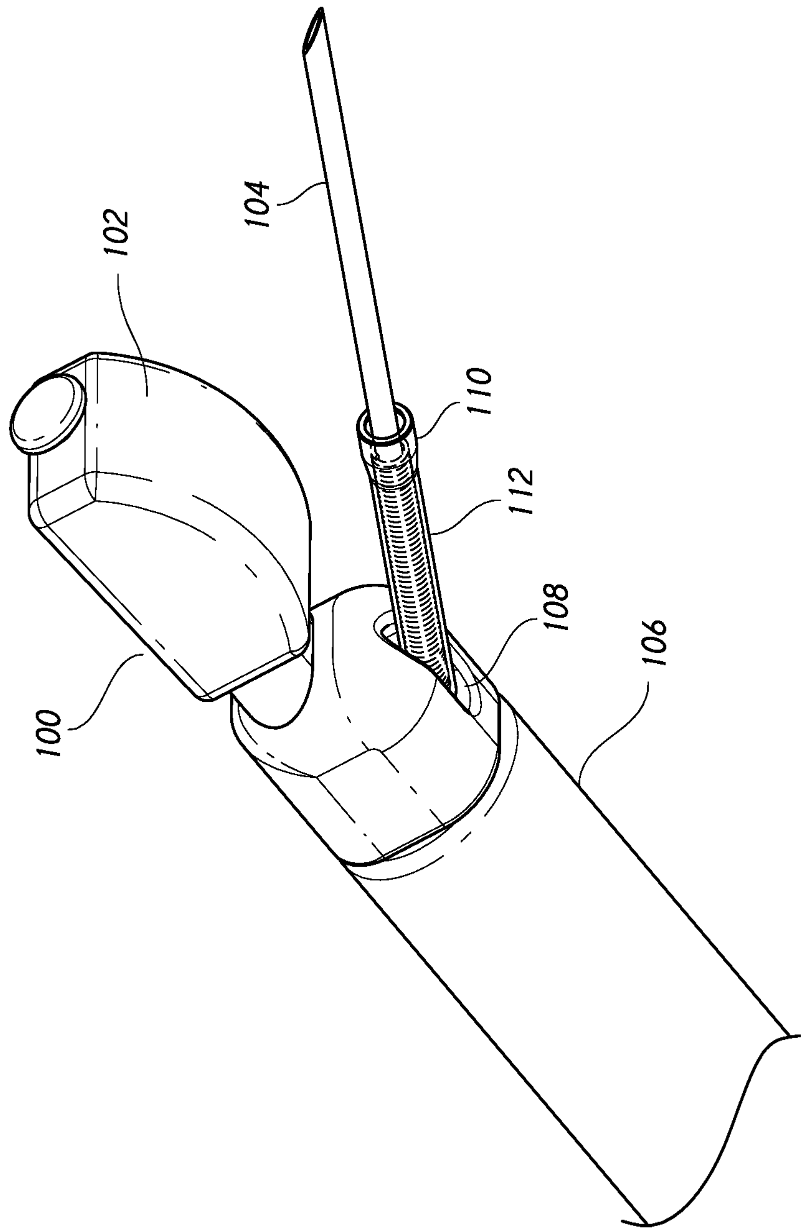


FIG. 1

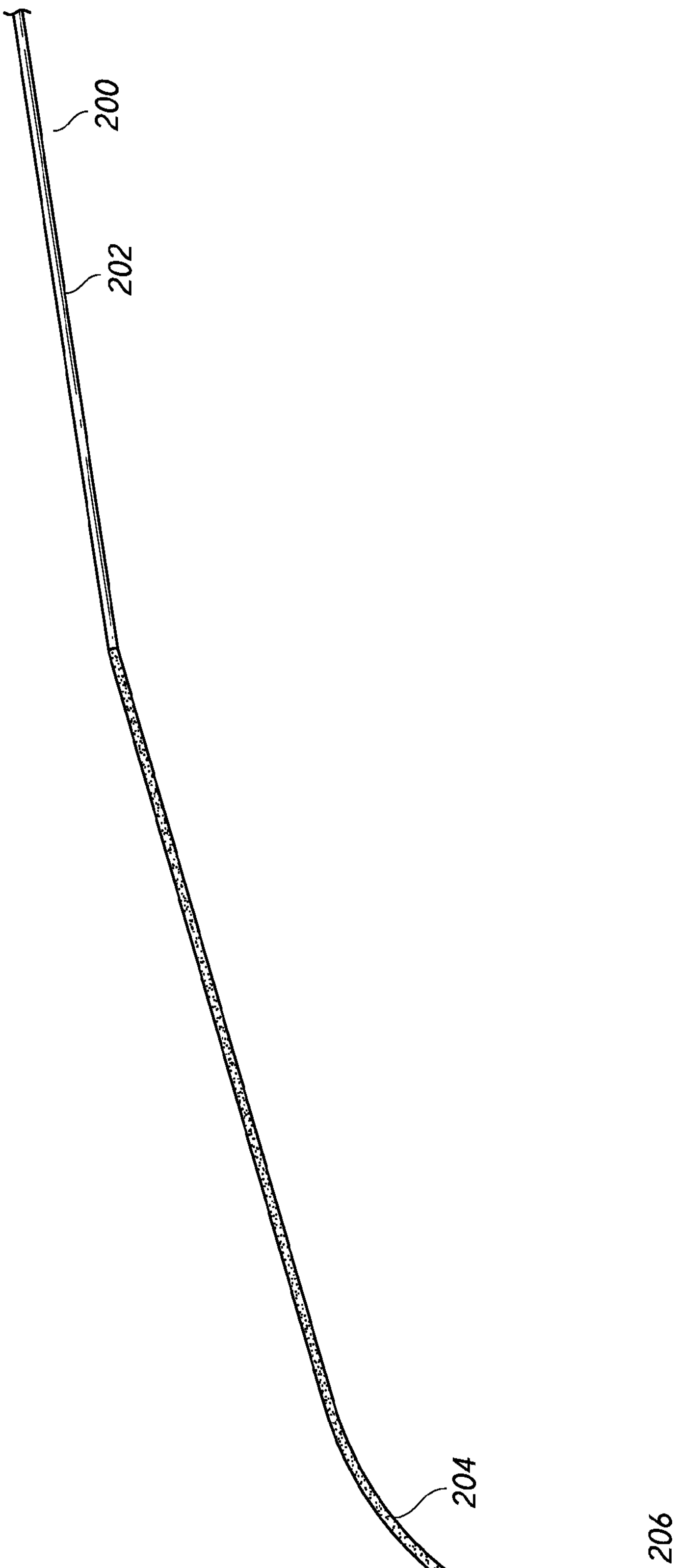


FIG. 2

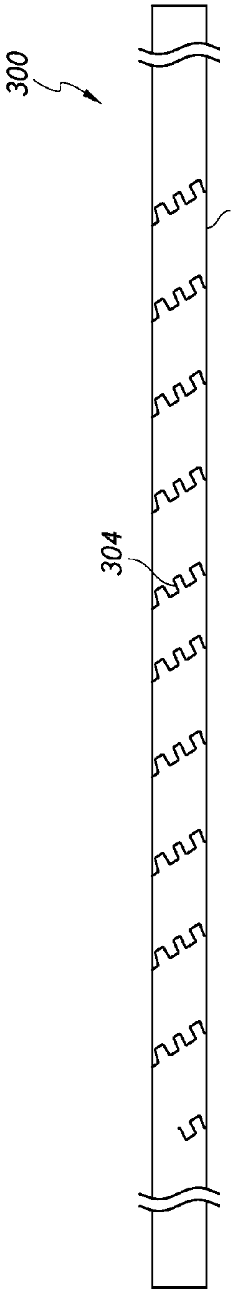


FIG. 3A

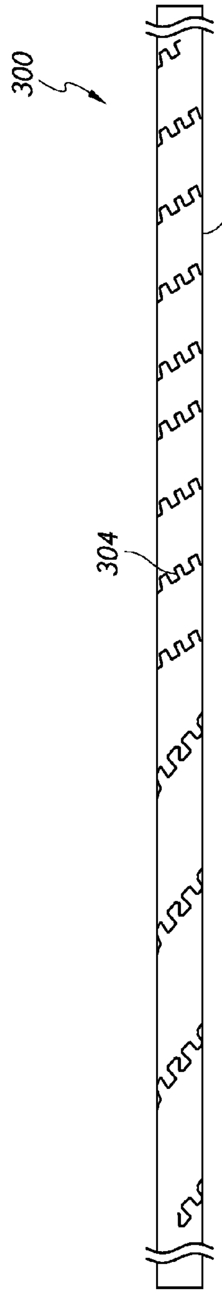


FIG. 3B

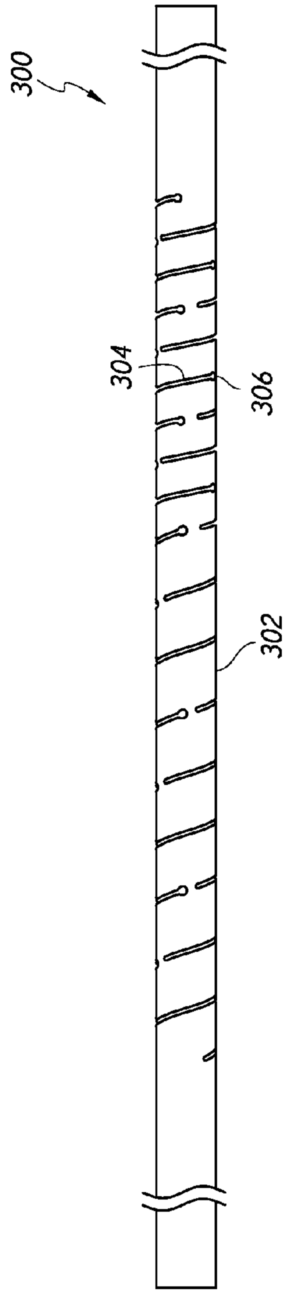


FIG. 3C

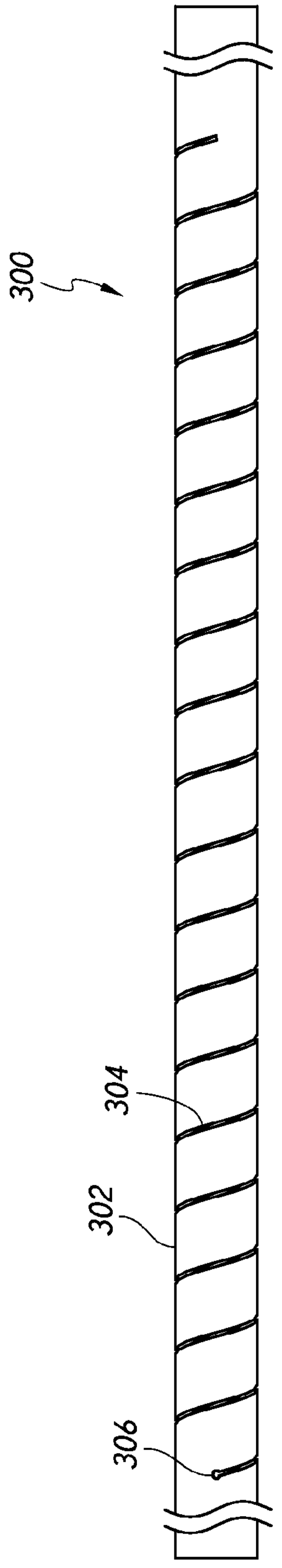


FIG. 3D

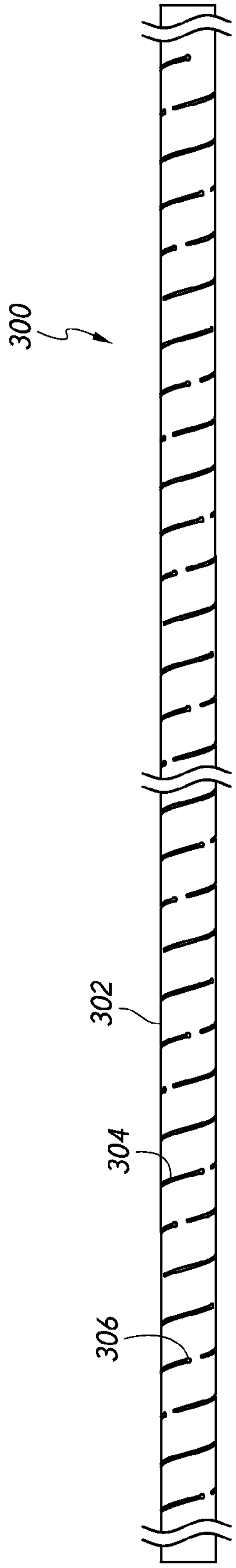


FIG. 3E

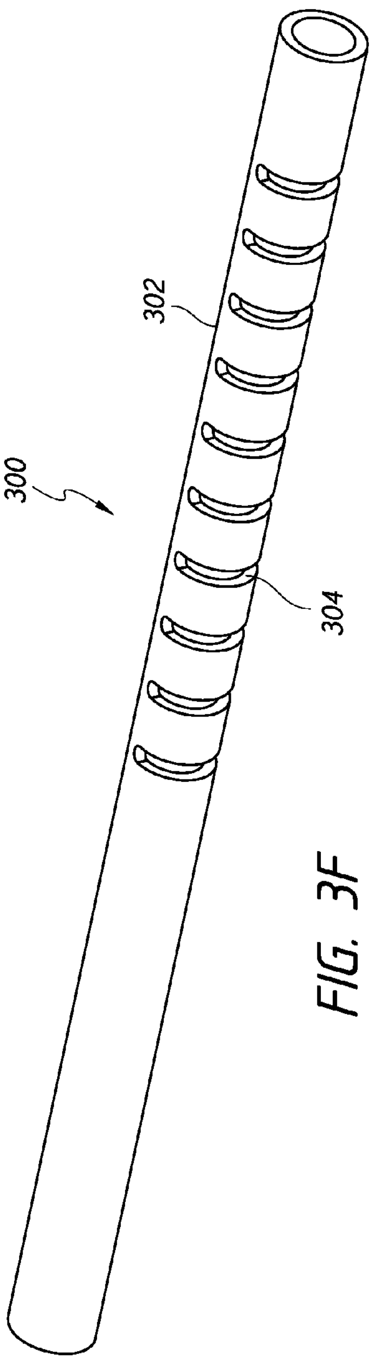


FIG. 3F

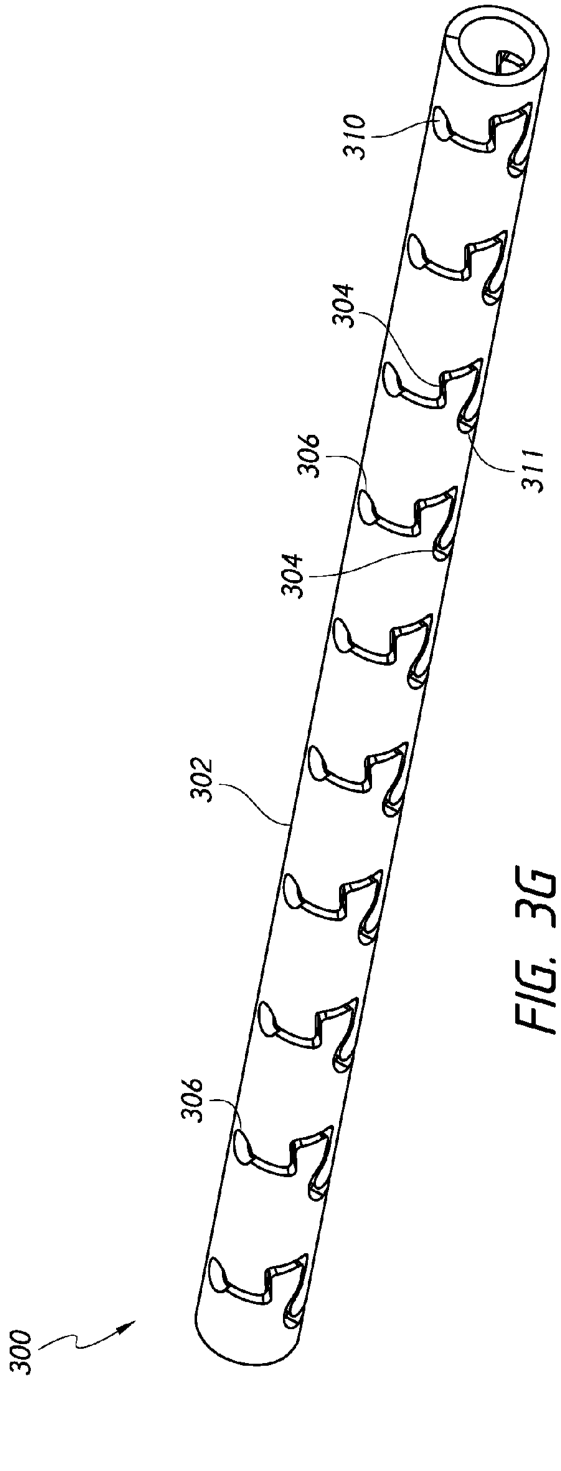


FIG. 3G

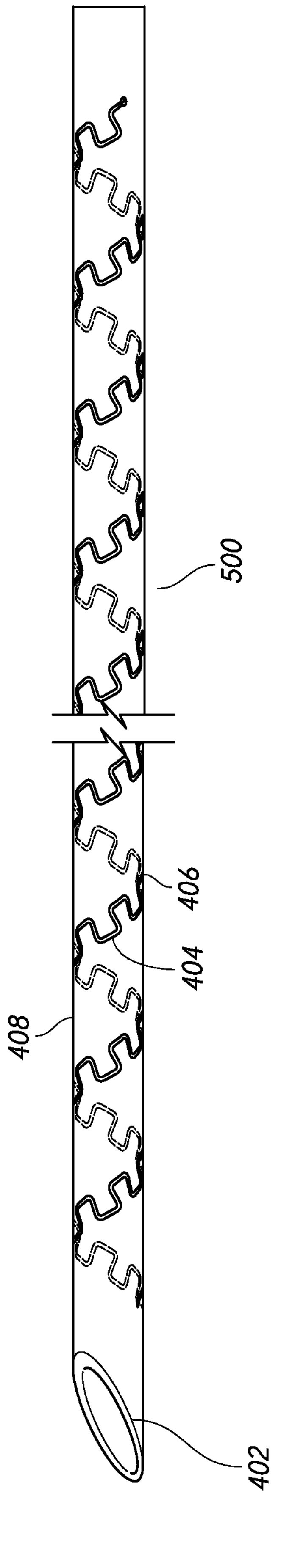


FIG. 4

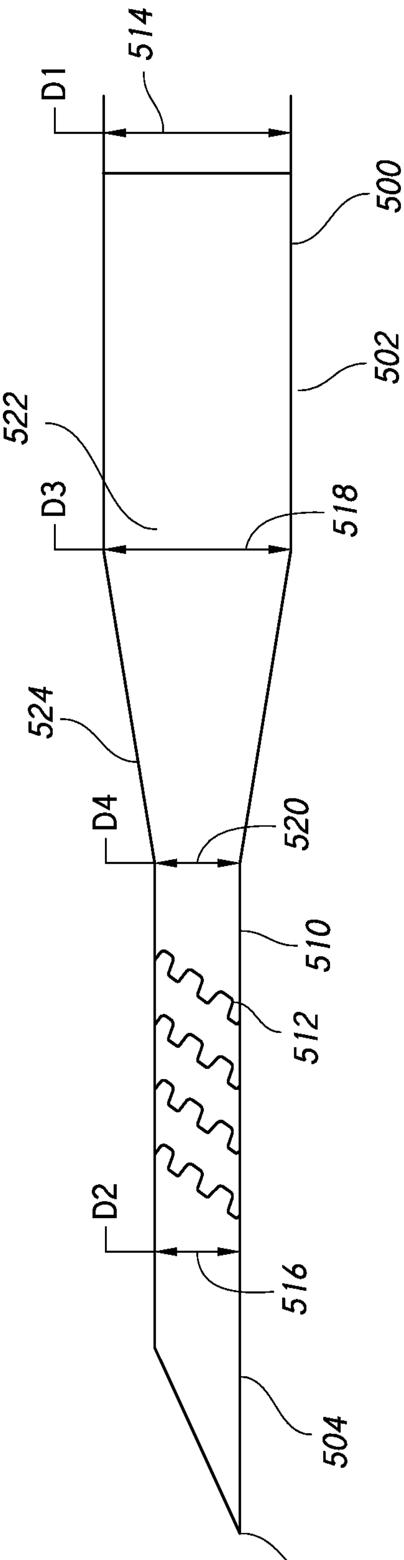


FIG. 5

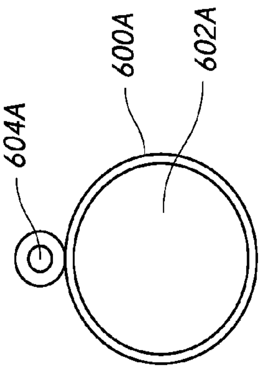


FIG. 6A

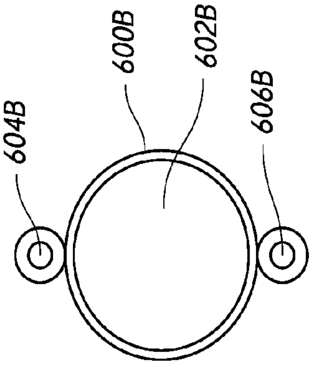


FIG. 6B

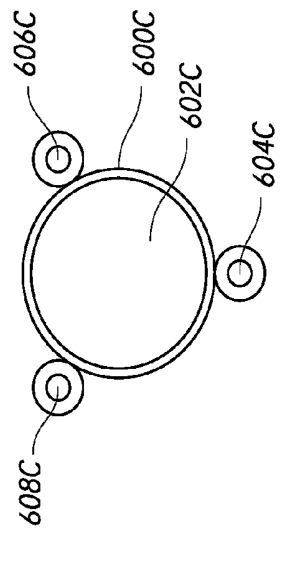


FIG. 6C

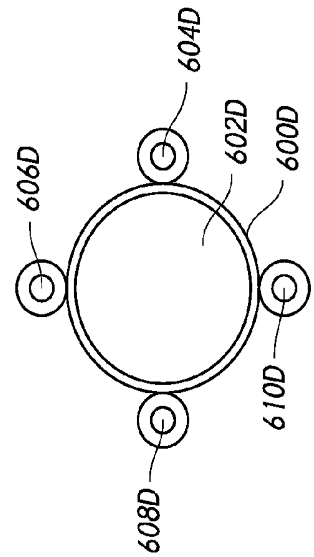


FIG. 6D

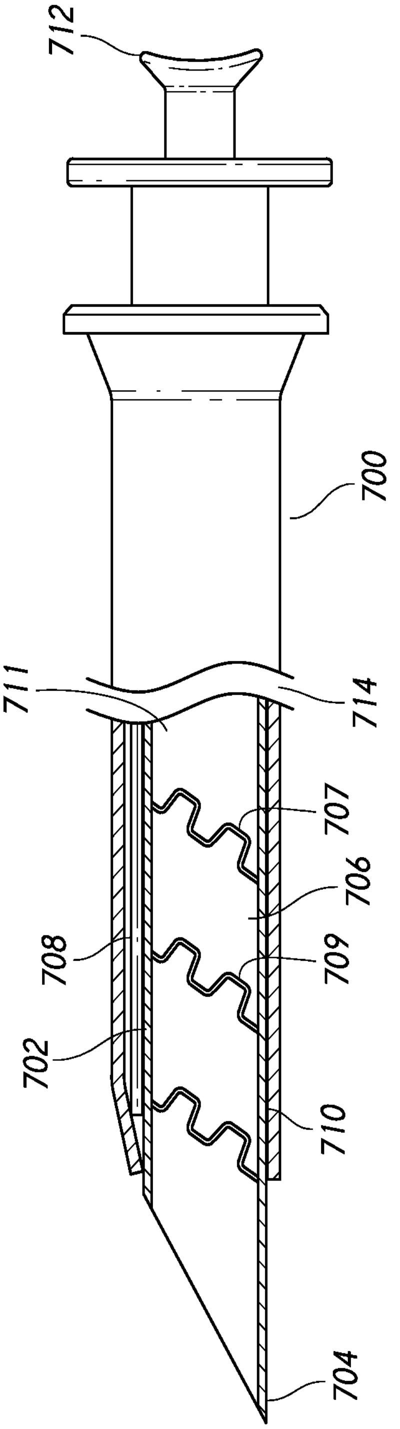


FIG. 7

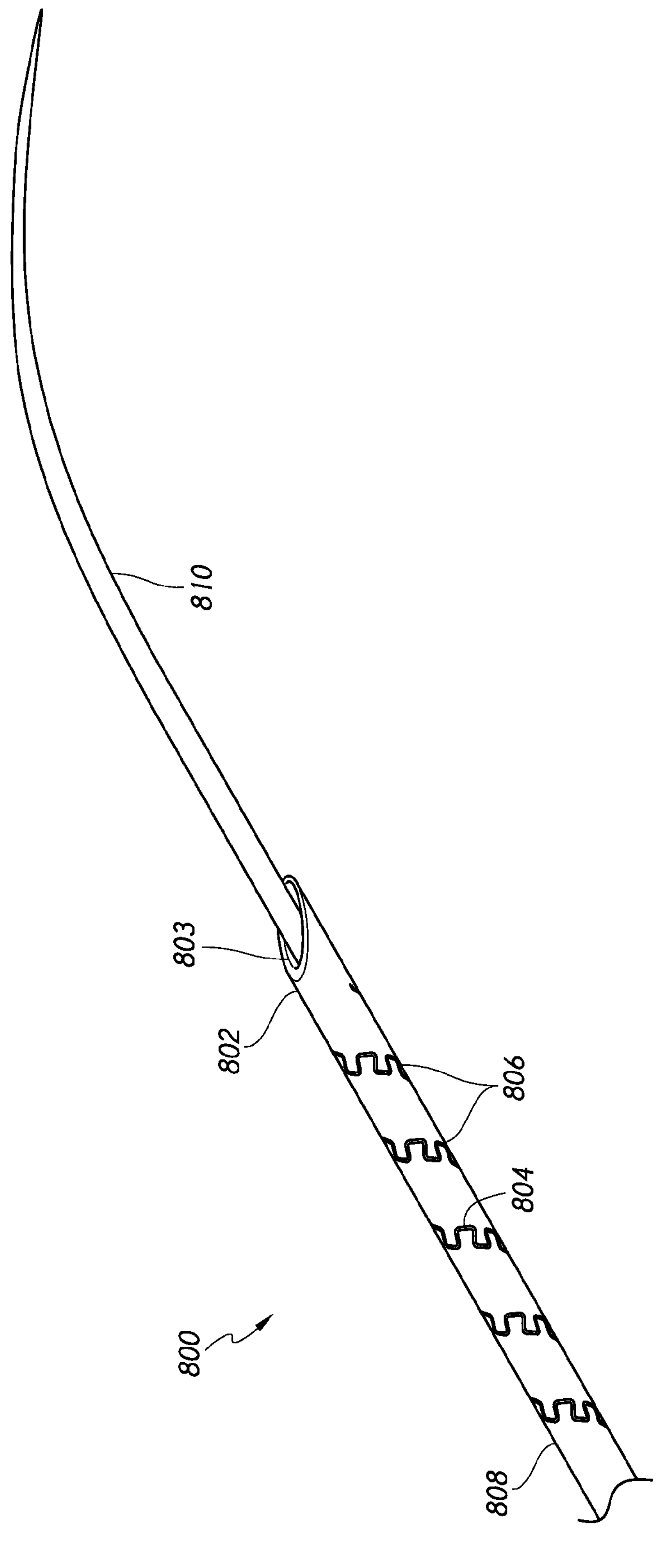


FIG. 8

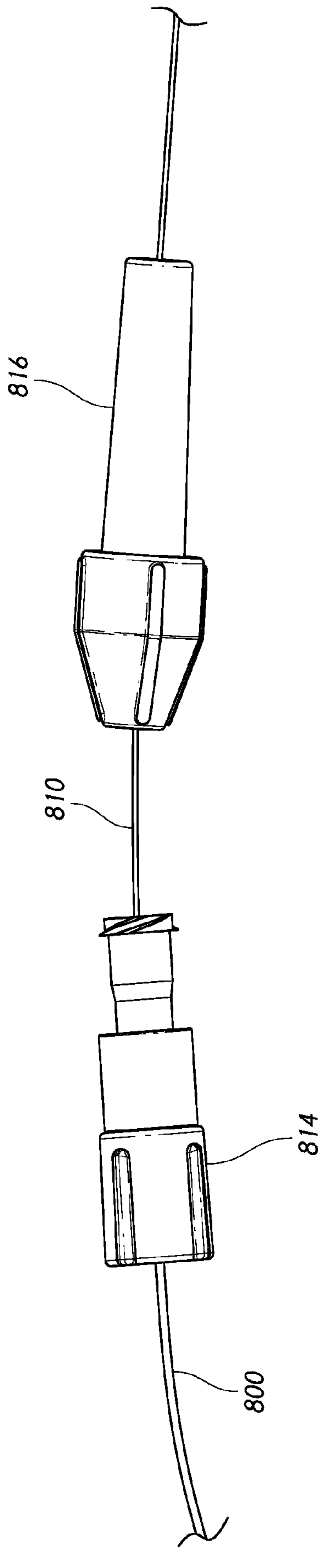


FIG. 9

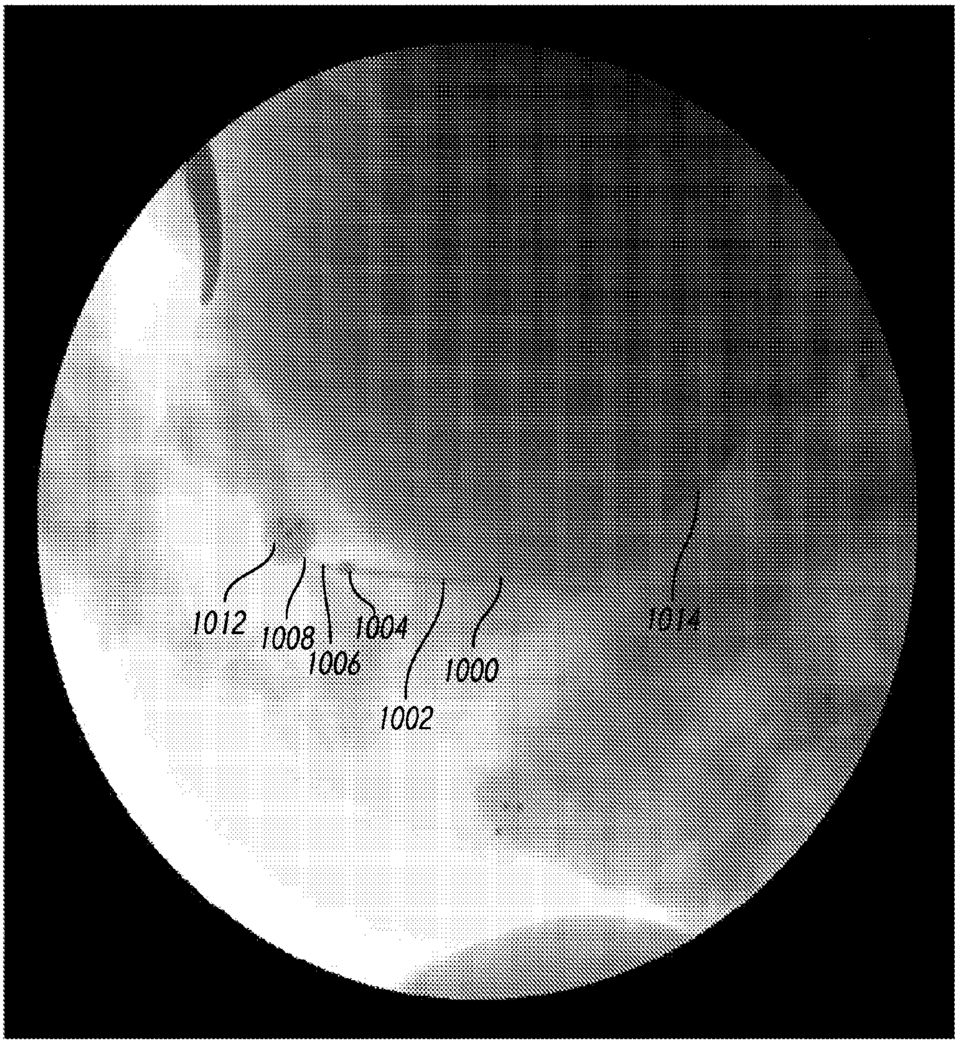


FIG. 10

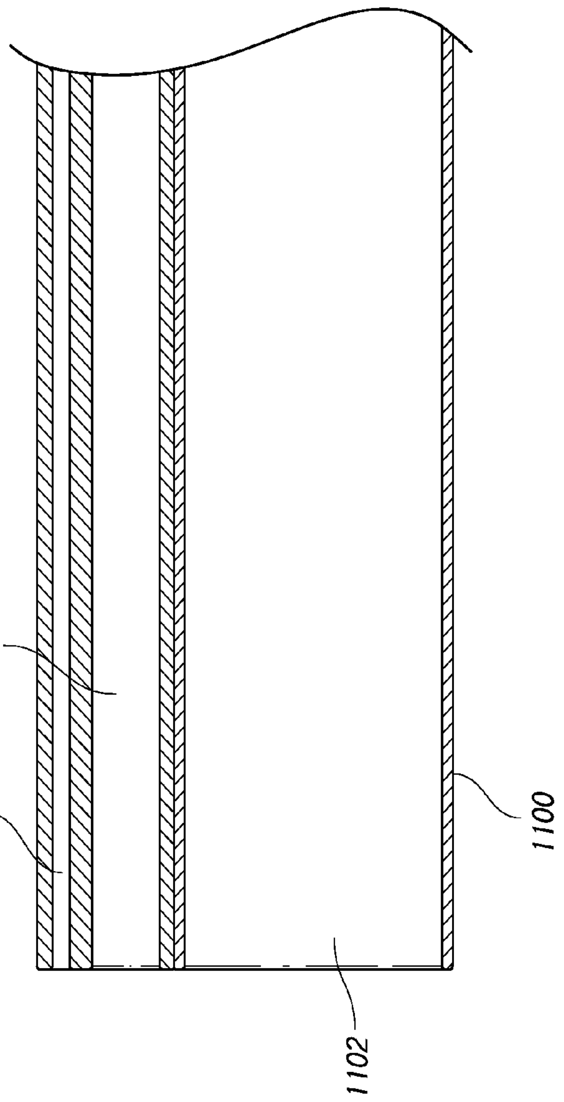


FIG. 11B

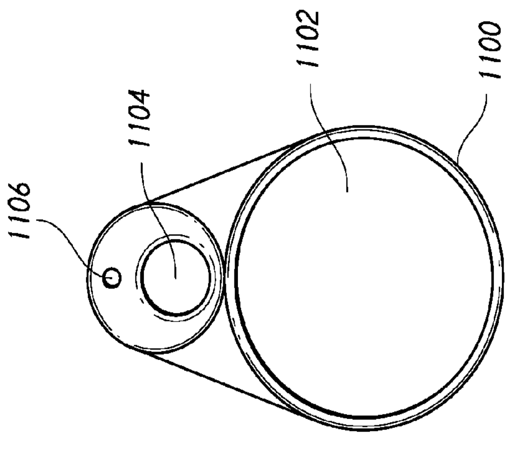


FIG. 11A

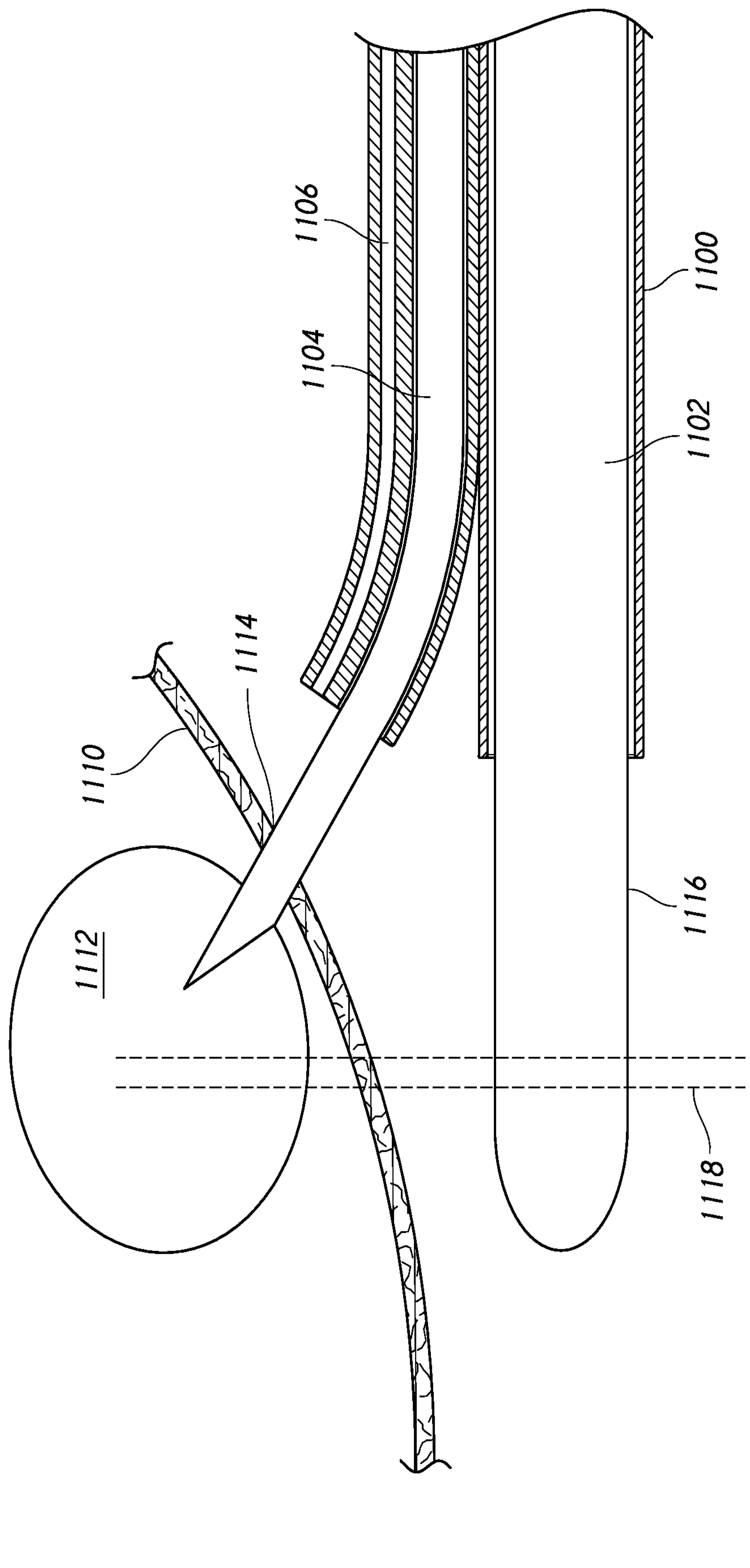


FIG. 11C

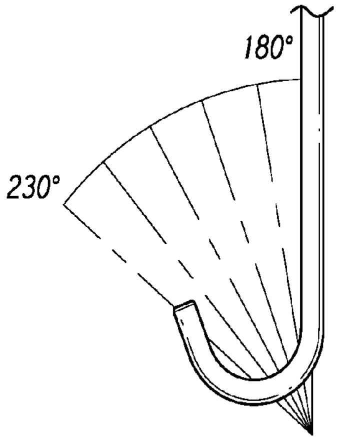


FIG. 12A

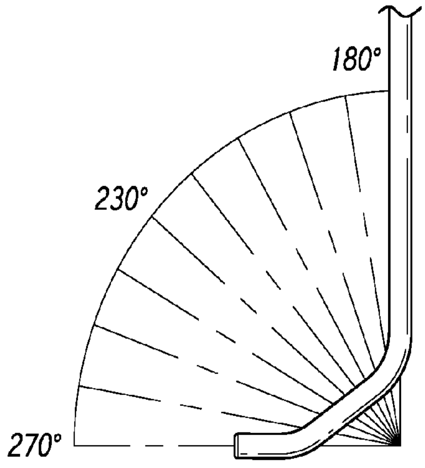


FIG. 12B

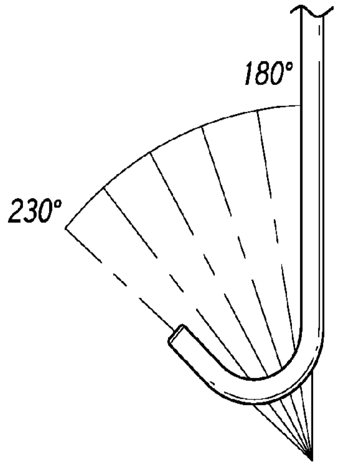


FIG. 12C

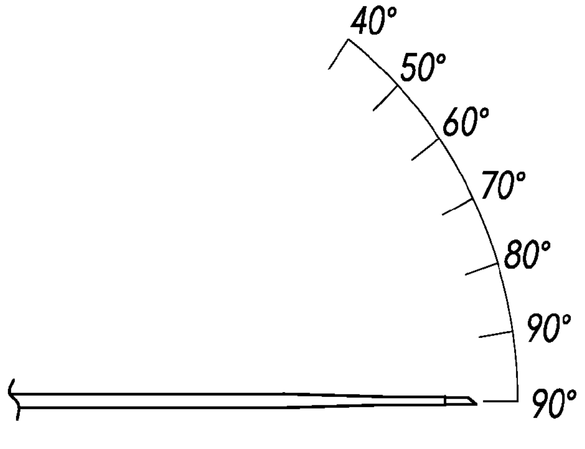


FIG. 13A

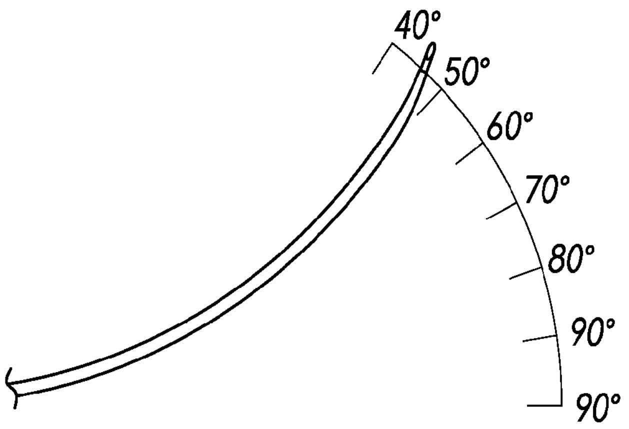


FIG. 13B

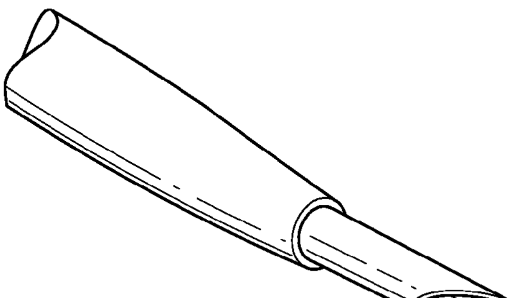


FIG. 13C

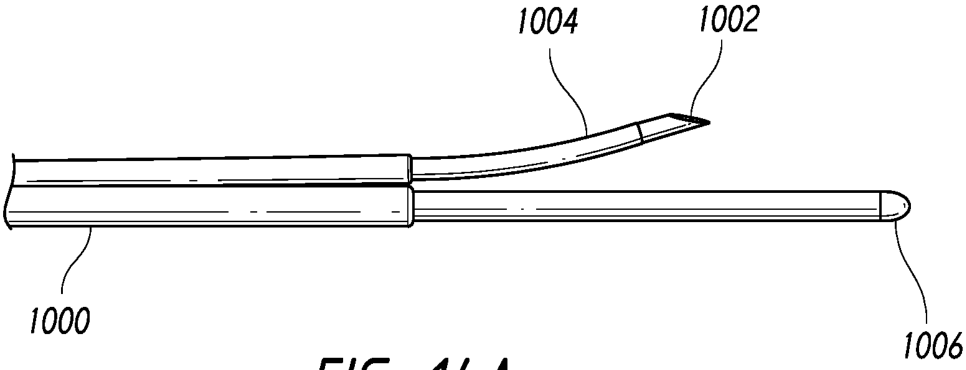


FIG. 14A

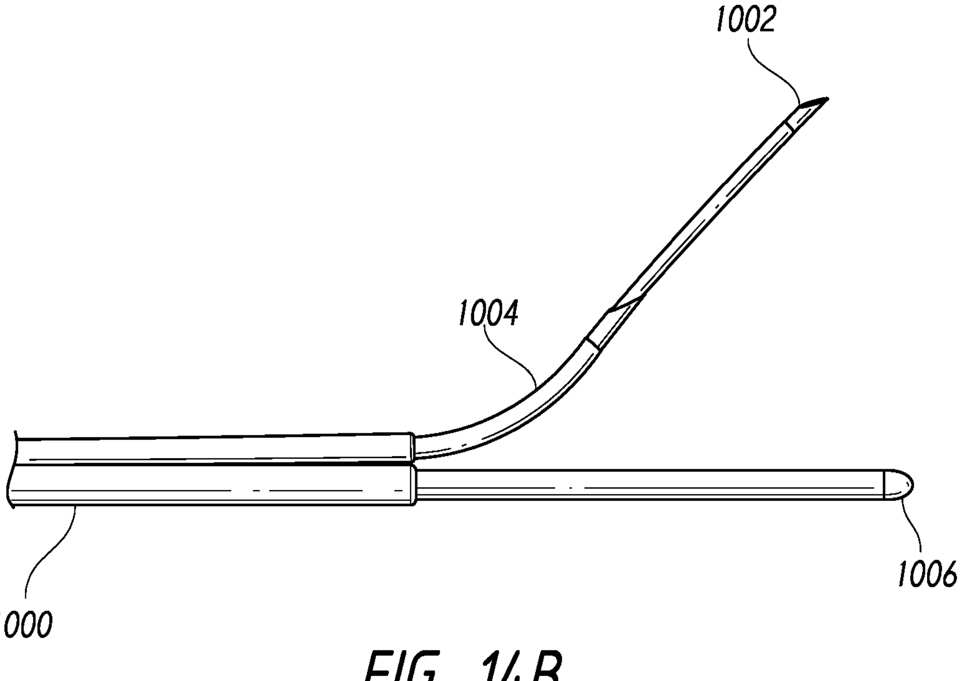


FIG. 14B

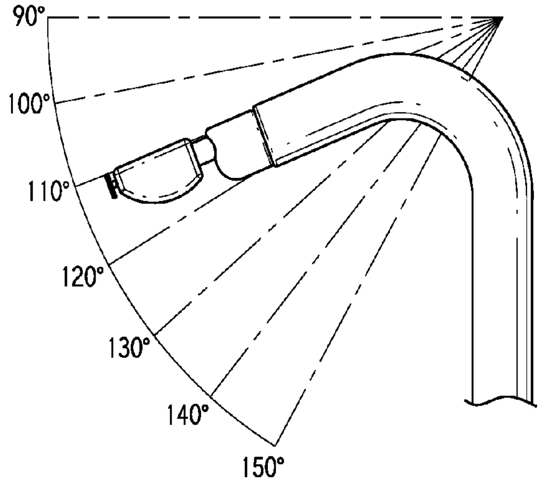


FIG. 15A

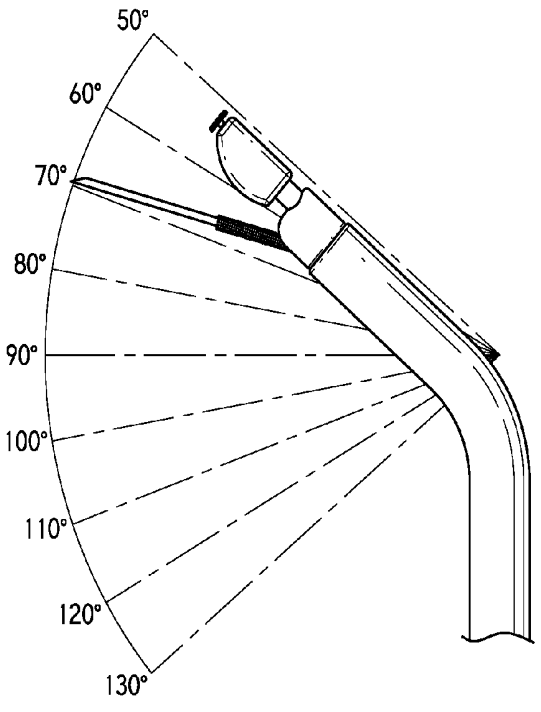


FIG. 15B

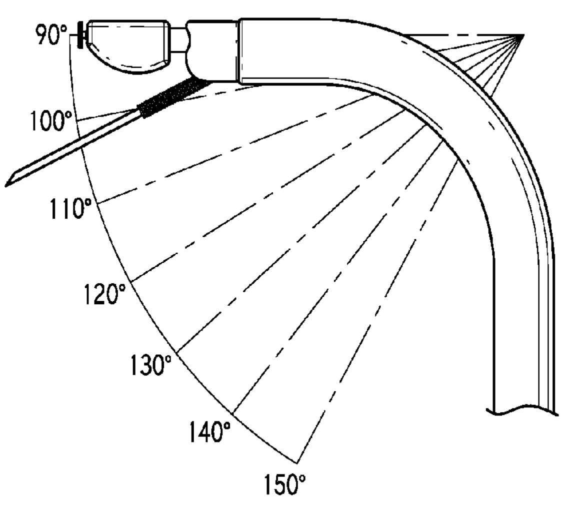


FIG. 15C

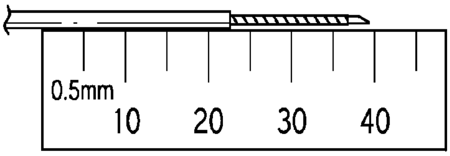


FIG. 16A

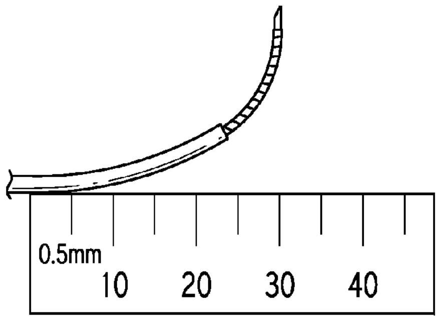


FIG. 16B

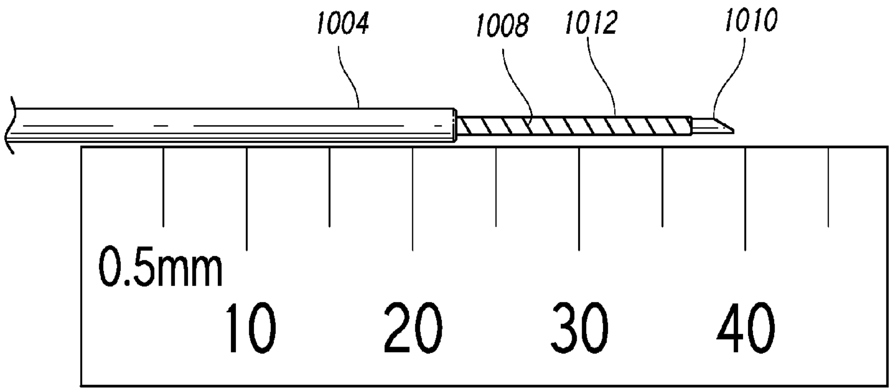


FIG. 16C

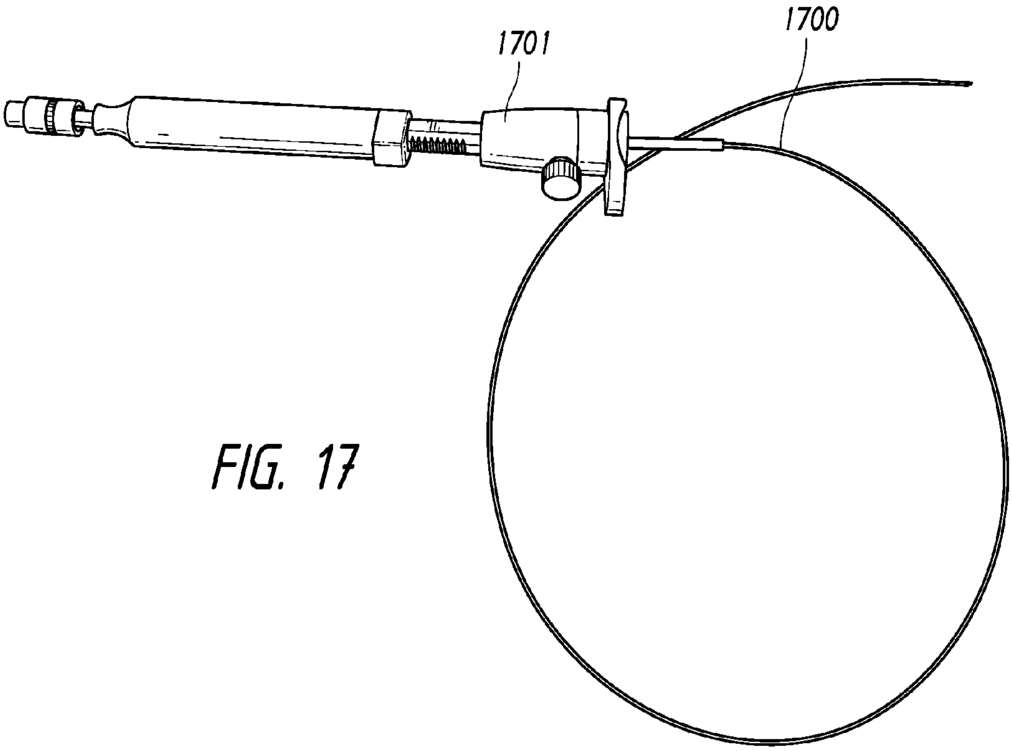


FIG. 17

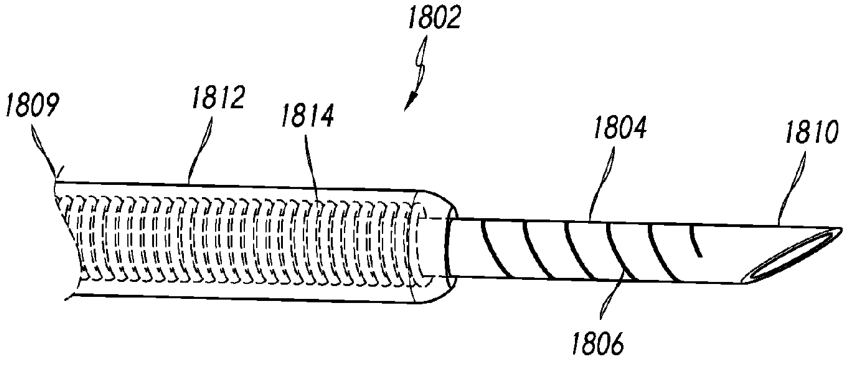


FIG. 18

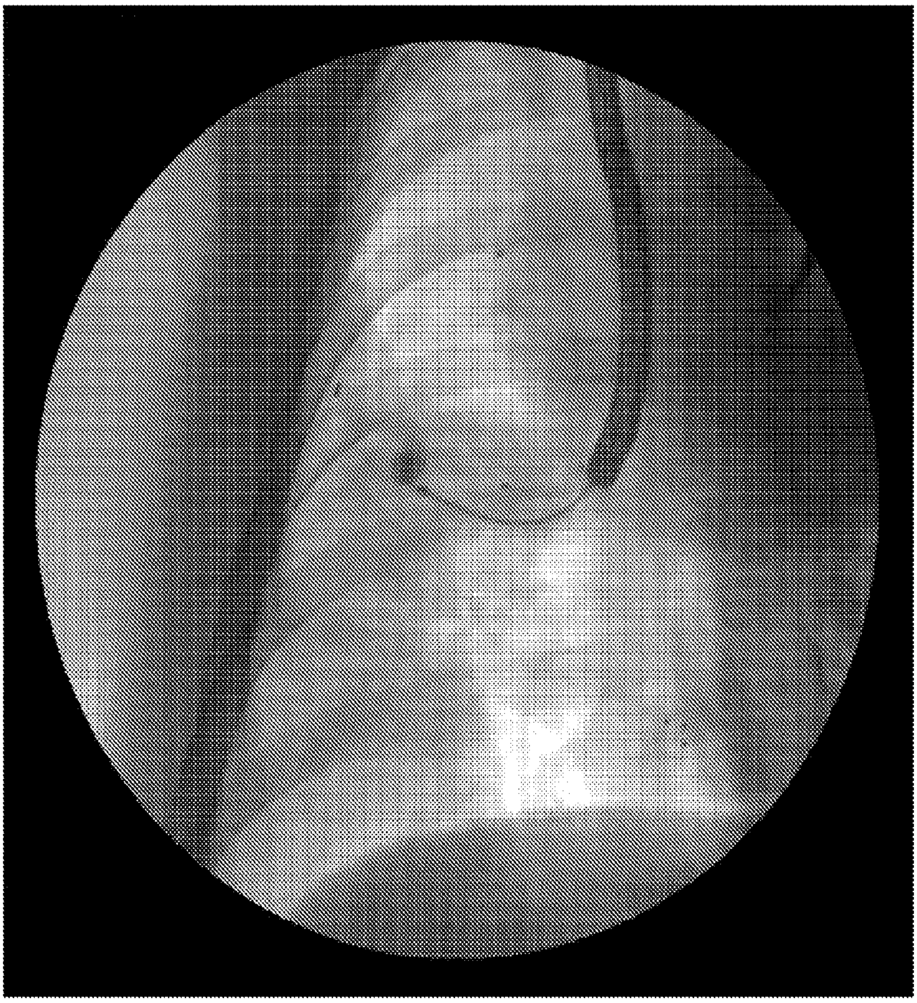


FIG. 19

LUNG BIOPSY NEEDLE

RELATED APPLICATIONS

[0001] Any and all priority claims identified in the Application Data Sheet, or any correction thereto, are hereby incorporated by reference under 37 CFR 1.57.

BACKGROUND

[0002] 1. Technical Field

[0003] Embodiments of the invention relate generally to the field of medical devices, and in particular, to methods, systems, and devices for navigating to and biopsying tissue such as lung nodules or nodes at a site of interest. In particular, certain embodiments described herein use a flexible needle to biopsy tissue.

[0004] 2. Description of the Related Art

[0005] 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 5-25 mm—that typically are biopsied to ascertain whether the tissue therein is cancerous or otherwise diseased.

[0006] 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 apparatuses. Further, the biopsy needles normally are straight and relatively inflexible. Thus, the biopsy 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.

SUMMARY

[0007] 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.

[0008] In one embodiment, a system for obtaining a tissue sample in or near an airway comprises:

[0009] 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;

[0010] 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

[0011] a suction source in fluid communication with the flexible needle.

[0012] 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.

[0013] In another embodiment, a method for obtaining a tissue sample in or near an airway comprises:

[0014] identifying a location in the airway in close proximity to a tissue sample site;

[0015] introducing a flexible needle into the airway;

[0016] navigating the flexible needle to the location in the airway;

[0017] articulating the flexible needle in a direction toward a tissue sample site; and

[0018] 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.

[0019] 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.

[0020] 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.

[0021] 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.

[0022] 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.

[0023] 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.

[0024] Various example embodiments of the disclosure can be described in view of the following clauses:

[0025] 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.

[0026] Clause 2: the flexible needle of Clause 1, wherein the flexibility increasing feature comprises one or more cuts in the flexible needle.

[0027] Clause 3: the flexible needle of Clause 2, wherein the one or more cuts extend in a spiral fashion along flexible proximal tip region.

[0028] Clause 4: the flexible needle of Clause 2, wherein the one or more cuts are arranged in a jigsaw configuration.

[0029] Clause 5: the flexible needle of Clause 2, wherein the one or more cuts are arranged in a serpentine configuration.

[0030] 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.

[0031] 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.

[0032] 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.

[0033] Clause 9: the system of Clause 8, further comprising a steering mechanism configured to steer the flexible needle toward the tissue sample site.

[0034] 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.

[0035] 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.

[0036] Clause 12: the system of Clause 11, wherein the guidewire is removable from the interior lumen of the flexible needle.

[0037] Clause 13: the system of any of Clauses 8-12, further comprising a navigation system.

[0038] Clause 14: the system of Clause 13, wherein the navigation system is an ultrasound probe.

[0039] Clause 15: the system of Clause 14, wherein the ultrasound probe is located at a distal end of the catheter.

[0040] 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.

[0041] Clause 17: the system of any of Clauses 8-16, wherein the catheter is received within the working channel of a bronchoscope.

[0042] 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.

[0043] 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.

[0044] 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.

[0045] 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.

[0046] 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.

[0047] 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.

[0048] 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.

[0049] Clause 25: the method of Clause 24, wherein the flexible needle is articulated by a steering mechanism.

[0050] Clause 26: the method of any of Clauses 24 or 25, wherein the flexible needle is inserted into a lumen of a catheter.

[0051] Clause 27: the method of Clause 26, wherein the step of navigating comprises locating the flexible needle with a radioopaque marker situated on the flexible needle and/or the catheter.

[0052] Clause 28: the method of Clause 24, wherein the flexible needle is inserted into a lumen of a bronchoscope.

BRIEF DESCRIPTION OF THE DRAWINGS

[0053] The foregoing and other features, aspects and advantages of the present invention are described in detail below with reference to the drawings of various embodiments, which are intended to illustrate and not to limit the invention. The drawings comprise the following figures in which:

[0054] FIG. **1** is a perspective view of a transbronchial needle aspiration system comprising an ultrasound sensor.

[0055] FIG. **2** illustrates a side view of an embodiment of a flexible needle.

[0056] FIGS. **3**A-G illustrate various configurations for interruptions that may be made along one or more portions of embodiments of the flexible needles.

[0057] FIG. **4** illustrates a close-up view of the flexible shaft portion of an embodiment of a flexible needle.

[0058] FIG. **5** illustrates a side view of another embodiment of the flexible needle.

[0059] FIGS. **6**A-D illustrate schematic cross-section views of different embodiments of a steerable, flexible needle assembly.

[0060] FIG. **7** illustrates a side view of an embodiment of a steerable, flexible needle assembly.

[0061] FIG. **8** illustrates an embodiment of a steerable, flexible needle assembly comprising an inner guidewire.

[0062] FIG. **9** illustrates the proximal end of an embodiment of a flexible needle assembly comprising an inner guidewire.

[0063] FIG. **10** is a fluoroscopy image of an embodiment of a flexible needle with an inner guidewire.

[0064] FIGS. **11**A-B illustrate front and side cross sectional views of an embodiment of a multi-lumen, steerable catheter in a relaxed state. FIG. **11**C illustrates a side cross sectional view of the catheter in an articulated state.

[0065] FIGS. **12**A-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.

[0066] FIGS. **13**A-C are illustrations of an embodiment of a flexible needle with steering wires.

[0067] FIGS. **14**A-B are illustrations of an embodiment of a flexible needle inserted into a multi-lumen, steerable catheter.

[0068] FIGS. **15**A-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.

[0069] FIGS. **16**A-C are illustrations of an embodiment of a flexible needle.

[0070] FIG. **17** is an illustration of a handle that may be used to manipulate and control embodiments of the flexible needles described herein.

[0071] FIG. **18** is an illustration of an embodiment of a flexible needle showing the distal tip thereof.

[0072] FIG. **19** is a fluoroscopy image of an embodiment of a flexible needle with an inner guidewire.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

[0073] Various embodiments of a flexible transbronchial needle aspiration system and its 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.

[0074] 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 FIG. **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.

[0075] FIG. **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 FIG. **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.

[0076] 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. 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**.

[0077] 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 FIG. **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 2.0 mm. For example, certain embodiments of the needle **200** can be used with small guide sheaths with a minimum inner diameter of 1.7 mm.

[0078] 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.

[0079] Embodiments described herein (for example but without limitation, the embodiment illustrated in FIG. **2**) may be used with any suitable visualization device, such as the ultrasound system **100** of FIG. **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.

[0080] In some embodiments, visualization of the needle **200** may be enhanced (in particular for ultrasound) by including signature markers that will enhance the visibility of the needle **200**. Signature markers may include forming dimples, scallops or the like on the needle **200**, which dimples, scallops or the like can reflect 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.

[0081] Although ultrasound has been found to be a preferable system for visualization due to the relatively high penetration depth (10-18 mm) 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 BfNavi™ system sold by Olympus and the i-Logic™ system sold by SuperDimension).

[0082] FIGS. **3**A-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 FIG. **2**. Generally, one or more flexibility increasing features **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 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.

[0083] 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.

[0084] Additionally, the region of increased flexibility **302** does not need to have features such as the single pitch illustrated in FIG. **3**A, but, with reference to FIG. **3**B, 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 FIG. **3**F. Moreover, continuous patterns are desired over interrupted patterns because of improved resistance to fatigue failures and improved flexure characteristics.

[0085] FIG. **3**C 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.

[0086] FIG. **3**D 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.

[0087] FIG. **3**E is similar to the embodiment illustrated in FIG. **3**C. 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**.

[0088] FIG. **3**F 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.

[0089] 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.

[0090] The cuts **304** may not necessarily be straight and perpendicular to the longitudinal axis of the needle wall **300**. As illustrated in FIG. 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**.

[0091] 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.

[0092] 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 flexibility, 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).

[0093] 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 3-4 cm. 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.

[0094] FIG. **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 FIGS. 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**.

[0095] 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.

[0096] 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.

[0097] 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.

[0098] 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.

[0099] FIG. **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 FIGS. 3A-C. In other embodiments, the cuts **512** may be cut differently.

[0100] 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.

[0101] 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.

[0102] 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.

[0103] FIGS. **6**A-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 FIGS. **6**A-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.

[0104] In FIG. **6**A, a flexible transbronchial needle aspiration assembly **600**A comprises a flexible transbronchial needle **602**A and a steering wire **604**A. In FIG. **6**B, a flexible transbronchial needle aspiration assembly **600**B comprises a flexible transbronchial needle **602**B, a first steering wire **604**B and a second steering wire **606**B. In FIG. **6**C, a flexible transbronchial needle aspiration assembly **600**C comprises a flexible transbronchial needle **602**C, a first steering wire **604**C, a second steering wire **606**C and a third steering wire **608**C. In FIG. **6**D, a flexible transbronchial needle aspiration assembly **600**D comprises a flexible transbronchial needle **602**D, a first steering wire **604**D, a second steering wire **606**D, a third steering wire **608**D and a fourth steering wire **610**D. 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 2.0 mm working channel of a bronchoscope, and may be miniaturized further.

[0105] 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).

[0106] FIG. **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.

[0107] 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 FIGS. **6**A-D. The steering wire or wires **708** may, as described in FIGS. **6**A-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.

[0108] 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.

[0109] FIG. **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**.

[0110] 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.

[0111] 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.

[0112] 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 FIGS. **3**F and **3**G). 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 15-20 mm 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 40 mm into adjacent tissue.

[0113] 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 Ser. No. 61/604,462, filed Feb. 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 Ser. No. ______ (Attorney Docket No. SPIRTN.082A), filed Feb. 26, 2013, titled "PULMONARY NODULE ACCESS DEVICES AND METHODS OF USING THE SAME" and published as U.S. Patent Publication No. ______, and the publication is hereby incorporated by reference in its entirety.

[0114] FIG. **9** illustrates an embodiment similar to that illustrated in FIG. **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**.

[0115] FIG. **10** is an annotated fluoroscopy image of a curved guidewire similar to that described in FIG. **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**.

[0116] 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 FIGS. **11**A-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.

[0117] FIG. **11**A 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.

[0118] 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 FIGS. **11**A-D. It is to be noted that whereas the embodiments illustrated in FIG. **8** have an inner guidewire **810** introduced within the inner diameter of the needle **800**, the embodiments illustrated in FIGS. **11**A-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.

[0119] FIGS. **11**B 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**. FIG. **11**B illustrates the second lumen **1104** in a relaxed, non-articulated state.

[0120] FIG. **11**C 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**.

[0121] 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 3.2 mm bronchoscope working channel, and may be miniaturized further.

[0122] FIGS. **12**A-C illustrate a bronchoscope in various degrees of articulation. FIG. **12**A illustrates the articulation of a bronchoscope without any biopsy needle inserted within. Here, the angle of articulation is approximately 130 degrees. FIG. **12**B 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, FIG. **12**C shows the same bronchoscope with an embodiment of a flexible needle inserted therein. The needle may for example be of the type illustrated in FIG. **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.

[0123] FIGS. **13**A-C illustrate an embodiment of a flexible needle with steering wires similar to those illustrated in FIGS. **6**A-D and FIG. **7**. FIGS. **13**A-B show that the needle, with the steering wire pulled, can achieve an articulation of approximately 45 degrees. FIG. **13**C 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.

[0124] FIGS. **14**A-B illustrate an embodiment of a flexible needle **1002** inserted into a multi-lumen, steerable catheter **1000** similar to FIG. **11**C. The probe **1006** may be a miniaturized ultrasound probe, and is preferably inserted into one of the catheter lumens. In FIG. **14**A, the flexible needle **1002** is shown in a retracted configuration and is inside a sheath **1004**. FIG. **14**B 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 FIG. **11**C. Here, the needle can achieve an articulation of approximately 20 degrees relative to the distal end of the probe **1006**.

[0125] FIGS. **15**A-C illustrate various states of articulation of a bronchoscope comprising an ultrasound probe similar to that illustrated in FIG. **1**. First, FIG. **15**A shows the articulation of the bronchoscope without any biopsy needle inserted therein. The bronchoscope can achieve an articulation of approximately 110 degrees. FIG. **15**B 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). FIG. **15**C shows the same bronchoscope with a flexible needle and catheter inserted therein similar to the embodiment illustrated in FIG. **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 FIG. **15**C is not being articulated independently of the bronchoscope, and an additional independent articulation mechanism (including for example but without limitation the embodiments illustrated in FIGS. **6**A-D and/or FIG. **8**) can provide for additional angulation and articulation of the needle to permit access to tortuous spaces.

[0126] FIGS. **16**A-C illustrate another embodiment of a flexible needle and catheter, of which the needle may be similar to the embodiment illustrated in FIG. **2**. FIGS. **16**A-B depict the articulation of the needle independent of any steering mechanism, and show that the needle can bend approximately 90 degrees. FIG. **16**C 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.

[0127] FIG. **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.

[0128] FIG. 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 prevent it from prolapsing or collapsing, in particular when the needle 1802 is bent or articulated.

[0129] FIG. 19 is a fluoroscopy image similar to that illustrated in FIG. 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 FIG. 8.

[0130] 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.

[0131] 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 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.

2. The flexible needle of claim 1, wherein the flexibility increasing feature comprises one or more cuts in the flexible needle.

3. The flexible needle of claim 2, wherein the one or more cuts extend in a spiral fashion along flexible proximal tip region.

4. The flexible needle of claim 2, wherein the one or more cuts are arranged in a jigsaw configuration.

5. The flexible needle of claim 2, wherein the one or more cuts are arranged in a serpentine configuration.

6. The flexible needle of claim 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.

7. The flexible needle of claim 2, 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.

8. A system for accessing tissue near an airway, the system comprising:
- the flexible needle of claim 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.

9. The system of claim 8, further comprising a steering mechanism configured to steer the flexible needle toward the tissue sample site.

10. The system of claim 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.

11. The system of claim 9, wherein the steering mechanism comprises a guidewire extending within an interior lumen of the flexible needle.

12. The system of claim 11, wherein the guidewire is removable from the interior lumen of the flexible needle.

13. The system of claim 8, further comprising a navigation system.

14. The system of claim 13, wherein the navigation system is an ultrasound probe.

15. The system of claim 14, wherein the ultrasound probe is located at a distal end of the catheter.

16. The system of claim 14, wherein the catheter comprises a second lumen and the ultrasound probe is received within the second lumen.

17. The system of claim 8, wherein the catheter is received within the working channel of a bronchoscope.

18. The system of claim 9, 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.

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.

20. The method of claim **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.

21. The method of claim **20**, wherein cutting the one or more cuts includes water jetting the wall of the tube shaped length of resilient material.

22. The method of claim **20**, wherein cutting the one or more cuts includes laser cutting the wall of the tube shaped length of resilient material.

23. The method of claim **20**, wherein cutting the one or more cuts includes chemical etching the wall of the tube shaped length of resilient material.

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.

25. The method of claim **24**, wherein the flexible needle is articulated by a steering mechanism.

26. The method of claim **24**, wherein the flexible needle is inserted into a lumen of a catheter.

27. The method of claim **26**, wherein the step of navigating comprises locating the flexible needle with a radioopaque marker situated on the flexible needle and/or the catheter.

28. The method of claim **24**, wherein the flexible needle is inserted into a lumen of a bronchoscope.

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摘要(译)

本文描述了用于使用柔性针对组织，特别是肺结节进行活组织检查的系统，方法和装置。优选地，柔性针能够铰接或弯曲，以便提供进入先前难以或不可能进行活组织检查的区域的通路。进一步的实施例提供将柔性针转向和导航到待活检的区域。