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(54) **APPARATUS TO PROVIDE AN ADJUSTABLE MECHANISM FOR RADIAL ULTRASOUND PORT AND FLUSH PORT**

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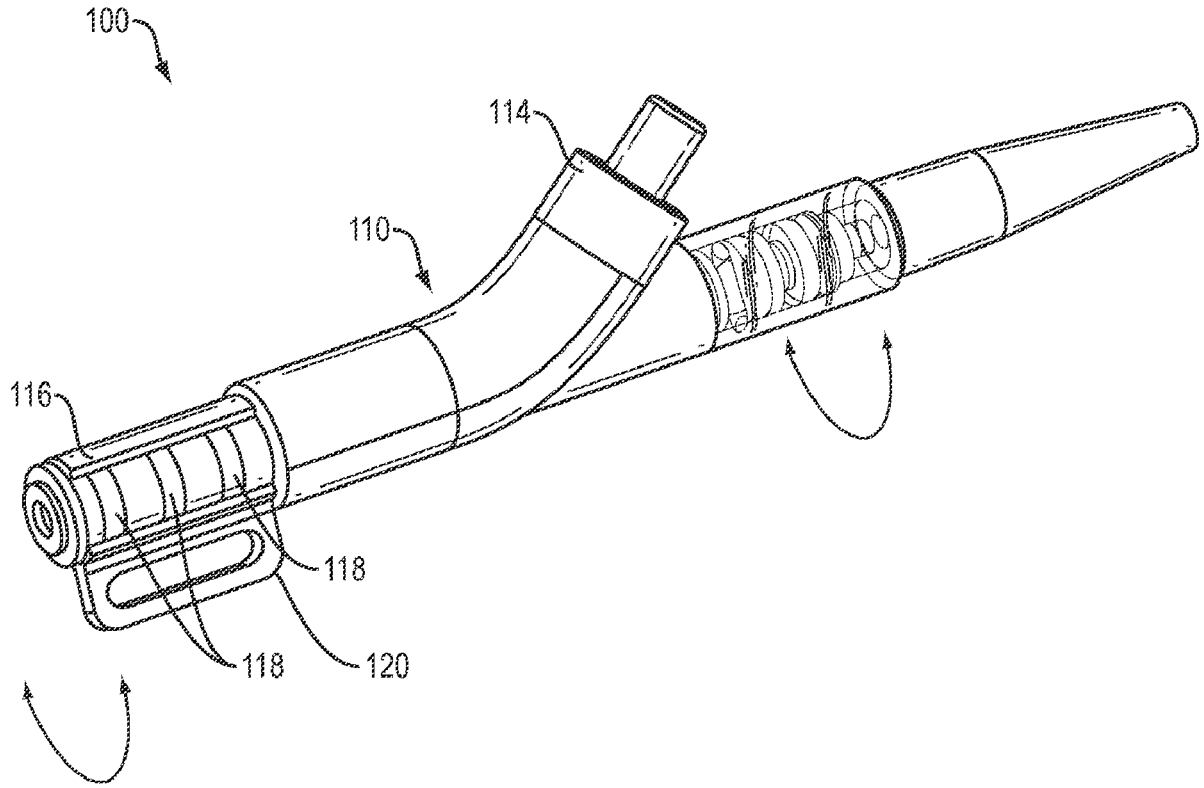
(57) **ABSTRACT**

The present disclosure relates generally to the field of medical devices. In particular, the present disclosure relates to an assembly with an adjustable ultrasound port and flush port for lateral and axial positioning of a radial ultrasound probe within a patient.



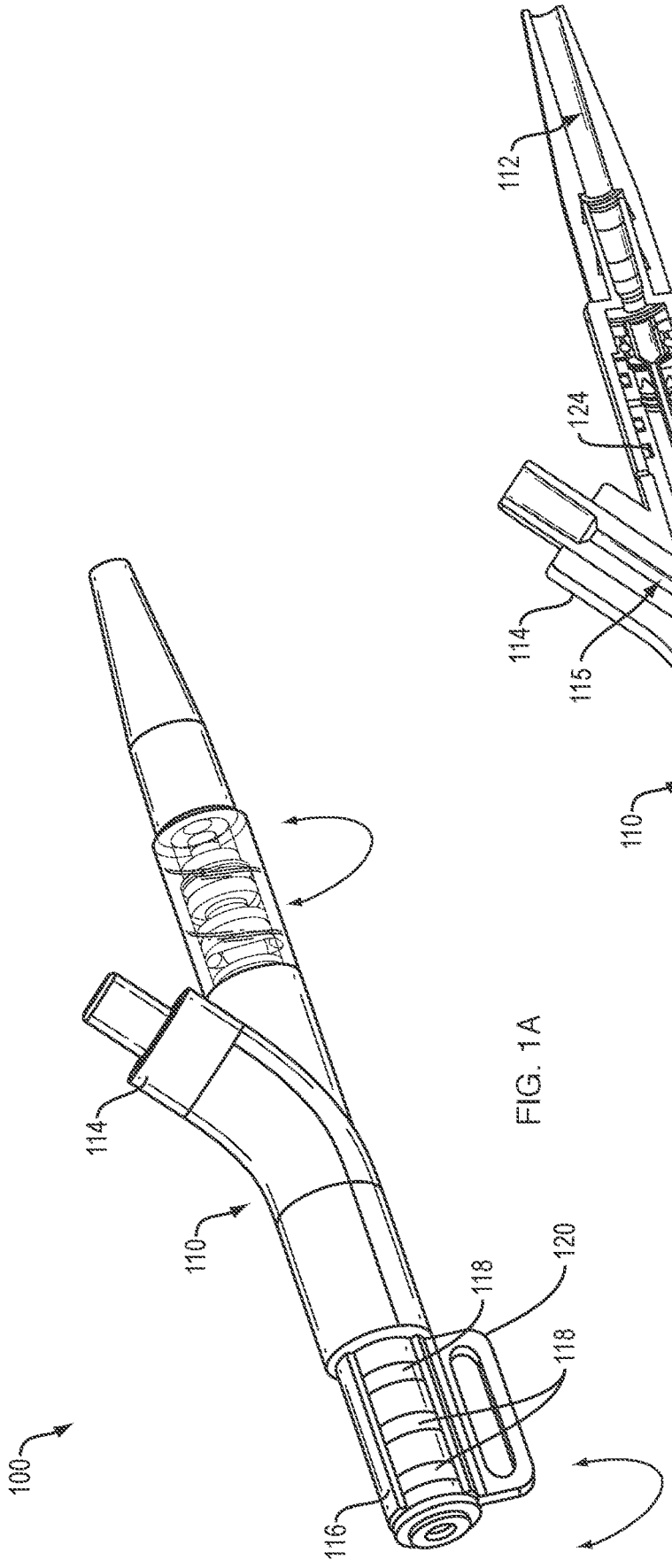


FIG. 1A

FIG. 1B

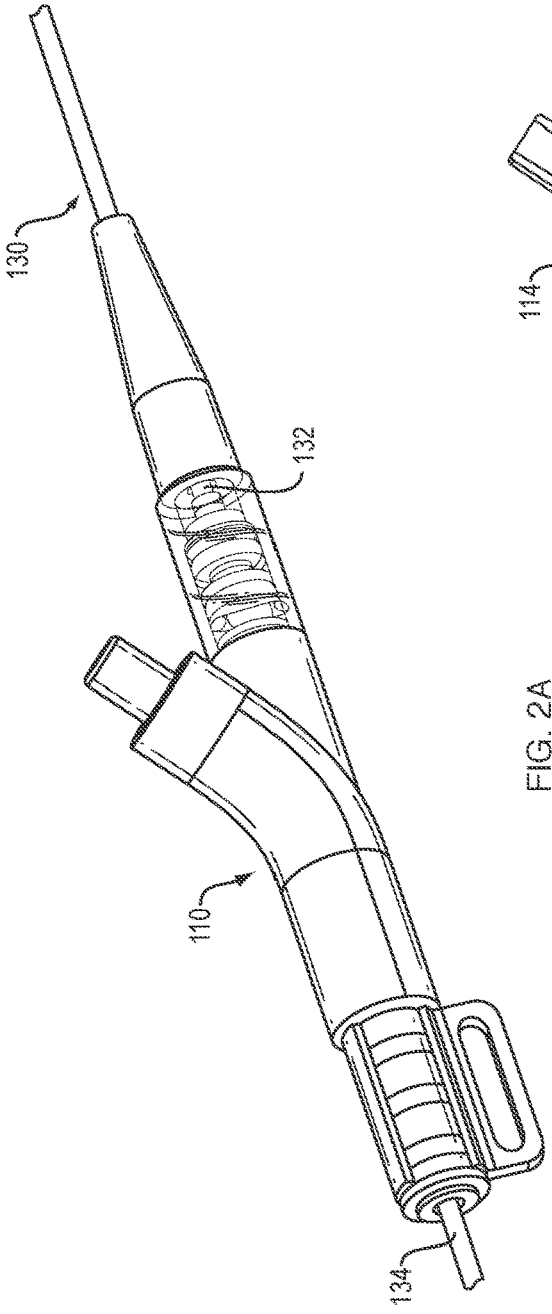

130
132
110
134

FIG. 2A

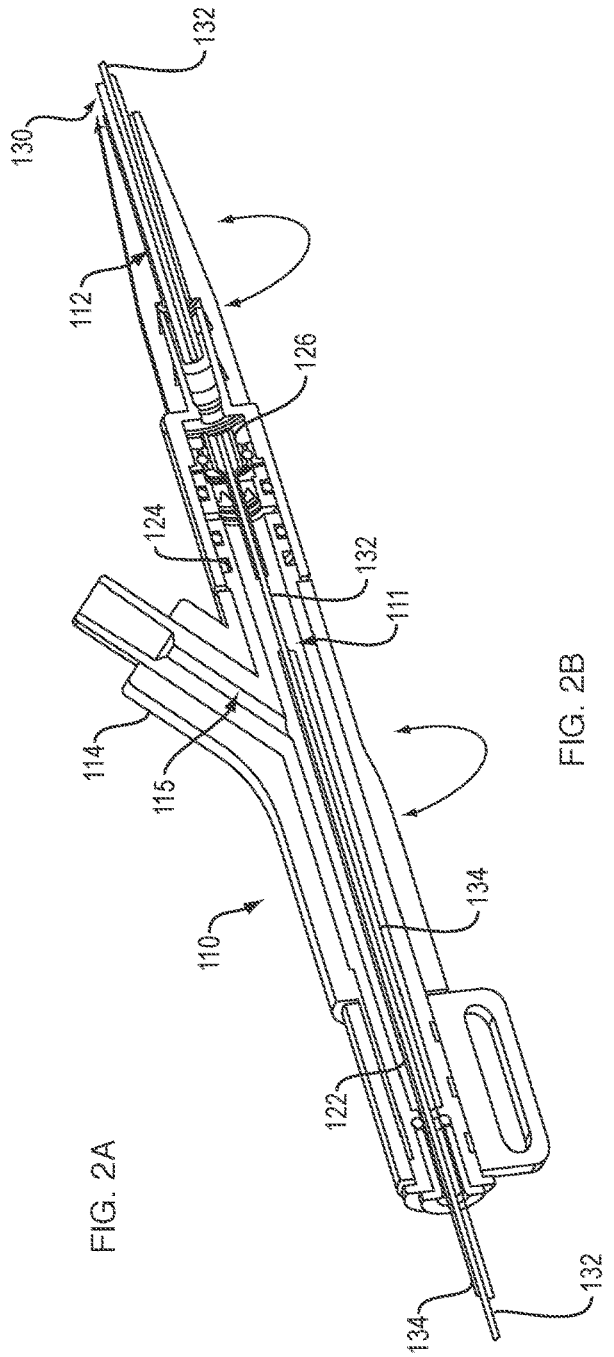

132
130
112
126
124
132
111
114
115
110
134
122
134
132

FIG. 2B

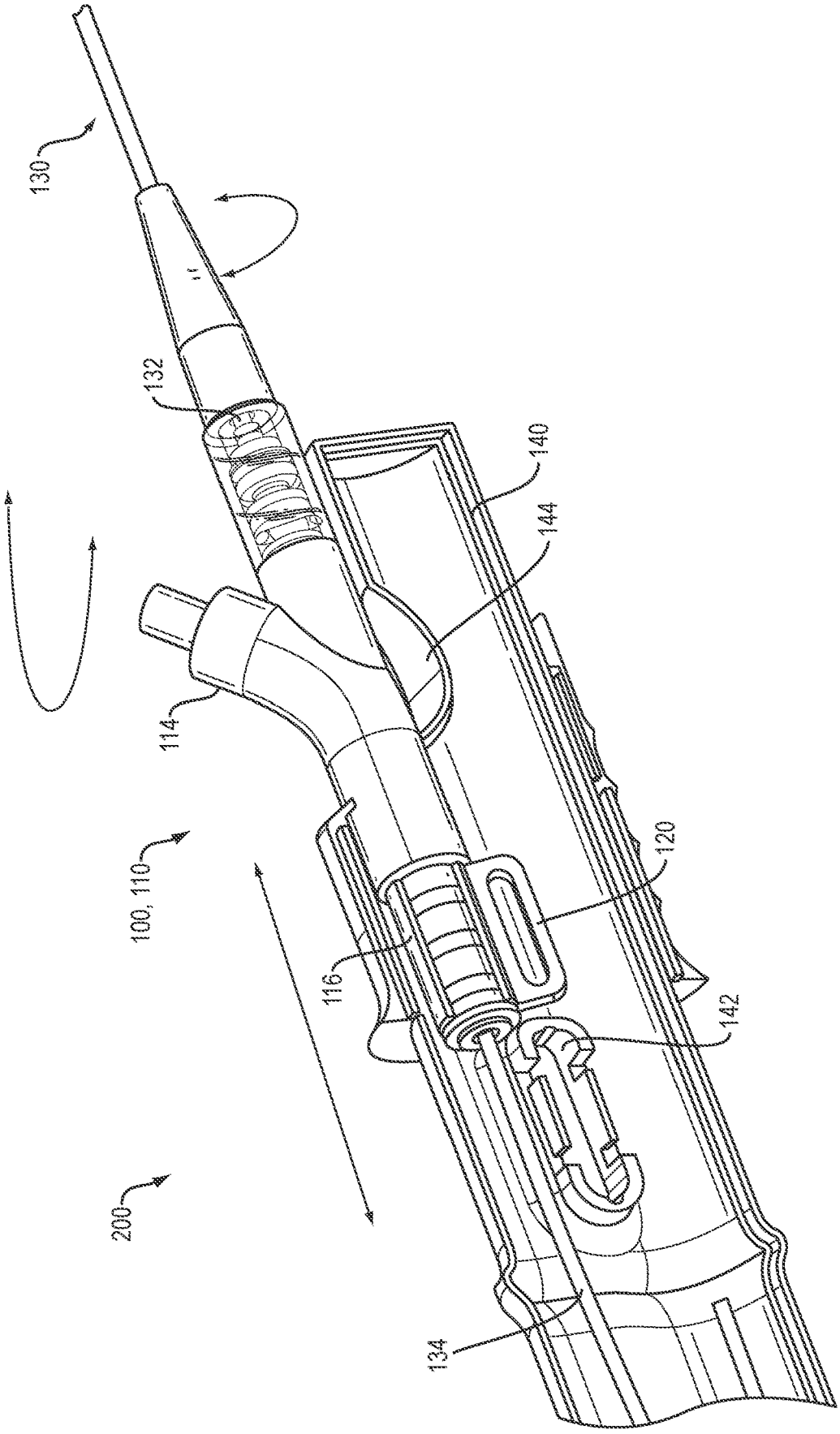


FIG. 3A

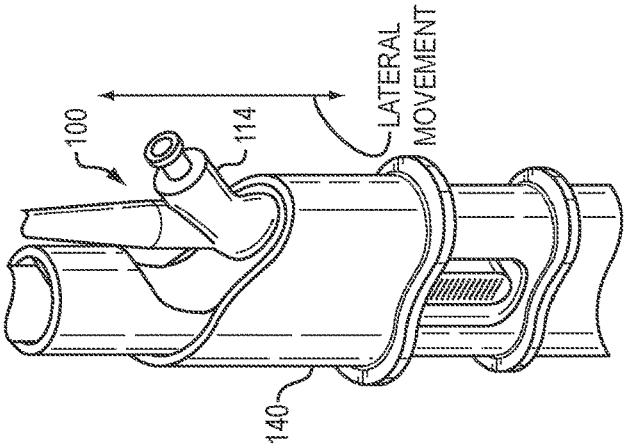


FIG. 3D

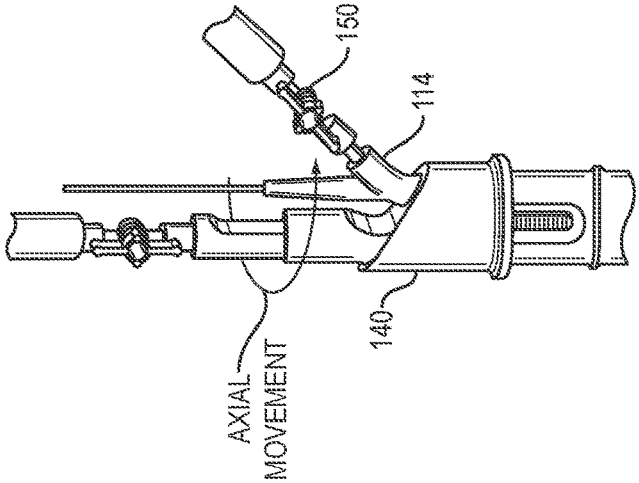


FIG. 3C

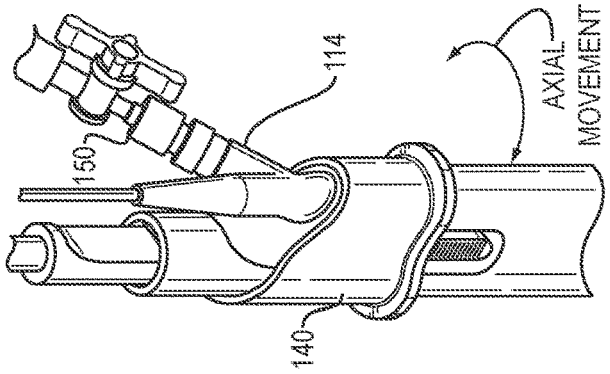


FIG. 3B

APPARATUS TO PROVIDE AN ADJUSTABLE MECHANISM FOR RADIAL ULTRASOUND PORT AND FLUSH PORT

RELATED APPLICATIONS

[0001] This application claims the benefit of priority under 35 U.S.C. § 119 to U.S. Provisional Application No. 62/849,311, titled "Devices to Access Peripheral Regions of the Lung for Direct Visualization with Tool Attachment", filed on May 17, 2019, the entirety of which is incorporated herein by reference.

[0002] This application claims the benefit of priority under 35 U.S.C. § 119 to U.S. Provisional Patent Application No. 62/849,649, titled "Apparatus to Provide an Adjustable Mechanism for Radial Ultrasound Port and Flush Port", filed on May 17, 2019, the entirety of which is incorporated herein by reference.

[0003] This application claims the benefit of priority under 35 U.S.C. § 119 to U.S. Provisional Patent Application No. 62/849,307, titled "Radial Ultrasound Needle Biopsy Devices", filed on May 17, 2019, the entirety of which is incorporated herein by reference.

FIELD

[0004] The present disclosure relates generally to the field of medical devices. In particular, the present disclosure relates to an assembly with an adjustable ultrasound port and flush port for lateral and axial positioning of a radial ultrasound probe within a patient.

BACKGROUND

[0005] A port for a radial ultrasound catheter may lack the ability to maintain visual imaging of pulmonary nodules within the peripheral regions of the lung while simultaneously repositioning a port for a radial ultrasound probe and/or port for flushing fluid through a lumen or lumens of the radial ultrasound catheter housing the same.

[0006] A variety of advantageous medical outcomes may therefore be realized by the adjustable assemblies, systems and methods of use thereof, of the present disclosure.

SUMMARY

[0007] In one aspect, the present disclosure relates to an adjustable probe assembly comprising a housing defining an internal chamber. An ultrasound port may be formed within a proximal portion of the housing. The ultrasound port may be coextensive with the internal chamber. A flush port may be disposed along a middle portion of the housing. The flush port may define a fluid channel therethrough. The fluid channel may be coextensive with the internal chamber. A fitting may be disposed around a distal portion of the housing. The housing may be configured to rotate relative to the fitting to alter an axial position of the flush port relative to the fitting.

[0008] In the described and other embodiments, an outer surface of the distal portion of the housing may include a surface feature configured to frictionally engage an inner surface of the fitting. The fitting may include a projection. A first seal may be disposed within a distal portion of the internal chamber. A second seal may be disposed within a proximal portion of the internal chamber. A bearing may be disposed within a proximal portion of the internal chamber and proximal to the second seal. The housing and ultrasound port may be configured to receive a radial ultrasound probe therethrough. The bearing may be configured to support rotation of the radial ultrasound probe. The radial ultrasound probe may include a drive cable. The drive cable may extend through the ultrasound port and may be supported by the bearing. The radial ultrasound probe may include a sheath. A proximal end of the sheath may be disposed within the housing between the first and second seals. The housing may be configured to rotate relative to the fitting to alter an axial position of the radial ultrasound probe. The proximal portion of the housing may be configured to rotate relative to a remaining portion of the housing to alter an axial position of the radial ultrasound probe.

[0009] In another aspect, the present disclosure relates to a system comprising a handle of a catheter. An adjustable probe assembly may be attached to the handle. The adjustable probe assembly may be configured to move laterally and axially relative to the handle. A radial ultrasound probe may extend through the adjustable probe assembly, the handle and a shaft of the catheter.

[0010] In the described and other embodiments, the adjustable probe assembly may include a housing defining an internal chamber. An ultrasound port may be formed within a proximal portion of the housing. A flush port may be disposed along a middle portion of the housing. The radial ultrasound probe may include a drive cable. The drive cable may extend through the ultrasound port. The flush port may include a fluid channel configured to deliver fluid into the internal chamber and through a sheath of the radial ultrasound probe. A first seal may be disposed within a distal portion of the internal chamber. A second seal may be disposed within a proximal portion of the internal chamber. The first and second seals may prevent fluid introduced through the flush port from exiting the internal chamber.

[0011] In yet another aspect, the present disclosure relates to a method comprising attaching an adjustable probe assembly to a handle of a catheter such that a radial ultrasound probe attached to the adjustable probe assembly may extend through the handle and a shaft of the catheter. A lateral position of the adjustable probe assembly may be adjusted relative to the handle. An axial position of the adjustable probe assembly may be adjusted relative to the handle.

[0012] In the described and other embodiments, a lateral position of the adjustable probe assembly may be re-adjusted relative to the handle to alter a lateral position of the radial ultrasound probe within a lumen of the catheter shaft. A housing of the adjustable probe assembly may be rotated relative to the handle to rotate the radial ultrasound probe within the lumen of the catheter. A housing of the adjustable probe assembly may be rotated relative to the handle to alter an axial position of a flush port disposed along a middle portion of the housing relative to the handle. A fluid may be introduced through the flush port and into an internal chamber of the adjustable probe assembly.

BRIEF DESCRIPTION OF THE DRAWINGS

[0013] Non-limiting embodiments of the present disclosure are described by way of example with reference to the accompanying figures, which are schematic and not intended to be drawn to scale. In the figures, each identical or nearly identical component illustrated is typically represented by a single numeral. For purposes of clarity, not every component is labeled in every figure, nor is every compo-

nent of each embodiment shown where illustration is not necessary to allow those of ordinary skill in the art to understand the disclosure. In the figures:

[0014] FIGS. **1**A-**1**B provide perspective (FIG. **1**A) and cross-sectional (FIG. **1**B) views of an adjustable probe assembly, according to one embodiment of the present disclosure.

[0015] FIGS. **2**A-**2**B provide perspective (FIG. **2**A) and cross-sectional (FIG. **2**B) views of a radial ultrasound probe disposed within an adjustable probe assembly, according to one embodiment of the present disclosure.

[0016] FIGS. **3**A-**3**D provide cross-sectional (FIG. **3**A) and perspective (FIGS. **3**B-**3**D views of an adjustable probe assembly attached to a handle of a catheter with radial ultrasound and needle biopsy capability, according to one embodiment of the present disclosure.

DETAILED DESCRIPTION

[0017] The present disclosure is not limited to the particular embodiments described herein. The terminology used herein is for the purpose of describing particular embodiments only, and is not intended to be limiting beyond the scope of the appended claims. Unless otherwise defined, all technical terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which the disclosure belongs.

[0018] Although embodiments of the present disclosure are described with specific reference to probe assemblies, systems and methods of use thereof, and particularly leak-proof assemblies, which include an adjustable ultrasound port and/or flush port designed to maintain visual imaging of a peripheral pulmonary nodule while allowing lateral and/or axial repositioning of the radial ultrasound probe and/or flush port, it should be appreciated that such probe assemblies, systems and methods may be used to visualize and manipulate a variety of tissues within a variety of different body lumens and/or body passages.

[0019] As used herein, the singular forms "a," "an," and "the" are intended to include the plural forms as well, unless the context clearly indicates otherwise. It will be further understood that the terms "comprises" and/or "comprising," or "includes" and/or "including" when used herein, specify the presence of stated features, regions, steps elements and/or components, but do not preclude the presence or addition of one or more other features, regions, integers, steps, operations, elements, components and/or groups thereof.

[0020] As used herein, the term "distal" refers to the end farthest away from the medical professional or physician when introducing a device into a patient, while the term "proximal" refers to the end closest to the medical professional or physician when introducing a device into a patient.

[0021] In various embodiments, the present disclosure relates generally to an adjustable and leak-proof probe assembly configured for use with a bronchial radial ultrasound system to provide real-time imaging and targeting of difficult to access pulmonary nodules. For example, the adjustable probe assembly may include an adjustable ultrasound port and flush port configured to allow a physician to laterally (e.g., along a longitudinal axis) and/or axially (e.g., about or around a longitudinal axis) position/reposition components of the bronchial radial ultrasound system (e.g., ultrasound probe, flush port and/or probe assembly) within a peripheral region of the lung while maintaining a leak-proof seal to simultaneously flush fluid through a lumen of a radial ultrasound probe.

[0022] Referring to FIGS. **1**A-**1**B, in one embodiment, an adjustable probe assembly **100** of the present disclosure may include a housing **110** defining an internal chamber **111**. An ultrasound port **112** (e.g., first port) may be formed within or otherwise extend through a proximal portion of the housing **110**. In various embodiments, the ultrasound port **112** may be coextensive (e.g., substantially aligned with, etc.) with the internal chamber **111**. A flush port **114** (e.g., second port) defining a fluid channel **115** therethrough may be disposed along (e.g., attached to, integrally formed with, etc.) a middle portion of the housing **110**. A fitting **116** may be disposed around a distal portion of the housing **110**. In various embodiments, the housing **110** may be configured to rotate 360° (e.g., move axially) within the fitting **116** to alter a position of the flush port **114** relative to a longitudinal axis of the adjustable assembly **100** and/or rotate (e.g., alter an axial position of) a radial ultrasound probe extending through the housing **110** (as discussed below). An outer surface of the distal portion of the housing may include a surface feature **118** configured to frictionally engage a corresponding inner surface of the fitting **116**. By way of non-limiting example, the surface feature may include a rubber seal or O-ring configured to maintain or lock an axial position of the housing **110** relative to the fitting **116** until a threshold level of rotational force is exerted on the housing **110** (e.g., a sufficient amount of force exerted by a physician's hand). In various embodiments, an outer surface of the housing **110** and/or flush port **114** may include a non-slip surface (e.g., over-molded or coated with rubber, etc.) to provide a physician with sufficient grip to manipulate the housing **110**, e.g., when wearing wet gloves, etc. An arm or projection **120** may extend from an outer surface of the fitting **116** to anchor or lock the housing of the probe assembly within a handle **140** of a catheter with radial ultrasound and needle biopsy capability (FIG. **3**A).

[0023] In one embodiment, a first seal **122** (e.g., O-ring, etc.) may be disposed within a distal portion of the internal chamber **111** (e.g., proximal to a distal opening of the housing **110**) and a second seal **124** may be disposed within a proximal portion of the internal chamber **111** (e.g., distal to a proximal opening of the housing **110**). The first and second seals **122**, **124** may be configured to prevent fluid introduced (e.g., flushed) through the fluid channel **115** of the flush port **114** from exiting the internal chamber **111** (e.g., flowing/leaking distally beyond the first seal **122** or proximally beyond the second seal **124**). A bearing **126** may be disposed within the proximal portion of the internal chamber **111** proximal to the second seal **124**. In various embodiments, the housing **110** and ultrasound port **112** may be configured to receive a proximal portion of a radial ultrasound probe **130** therethrough (FIG. **2**A-**2**B). The bearing **126** may be configured to receive an outer surface of the radial ultrasound probe **130** to support/facilitate rotation of the radial ultrasound probe **130** within the housing **110**.

[0024] Referring to FIGS. **2**A-**2**B, in one embodiment, a proximal portion of a radial ultrasound probe **130** may extend through the ultrasound port **112** and internal chamber **111** of the housing **110**. In various embodiments, the radial ultrasound probe **130** may include a drive cable **132** rotatably disposed within a sheath **134**. A radial ultrasound transducer (not shown) may be attached to a distal end of the

drive cable **132**, e.g., to provide an ultrasound image within a body lumen. A proximal portion of the drive cable **132** may extend through the probe assembly **100**, including the internal chamber **111**, and beyond a proximal end of the housing **110** to connect to an external motor drive unit (MDU). In addition, a proximal end of the sheath **134** may extend into the internal chamber **111** such that an open proximal end of the sheath **134** is disposed between the first and second seals **122**, **124**. A distal portion of the radial ultrasound probe (e.g., drive cable **132** and sheath **134**) may extend beyond a distal end of the housing **110**, e.g., through a handle **140** of a catheter with radial ultrasound and needle biopsy capability (FIGS. **3**A-**3**D) and a lumen of a dual-lumen shaft (not shown) attached to the catheter handle. The MDU may be configured to rotate the drive cable **132** at the requisite high-speed of rotation within the internal chamber **111** and throughout the full length of the sheath **134** to impart the requisite high speed of rotation to the radial ultrasound transducer. In various embodiments, the bearing **126** may be configured to dampen, insulate or otherwise minimize noise, vibrations or other outside forces acting on the housing **110** that might interfere with or corrupt the ultrasound signal propagated through the radial ultrasound probe **130** (e.g., along/through drive cable **132**). In addition, or alternatively, the proximal portion of the housing, e.g., which includes the ultrasound port **112**, may include a support structure configured to eliminate or reduce bending or kinking of the proximal portion of the radial ultrasound probe **130** (e.g., sheath **134** and/or drive cable **132**) and/or dampen outside forces, which may impair or otherwise negatively affect ultrasound image quality.

[0025] Referring to FIGS. **3**A-**3**D, in one embodiment, a system **200** of the present disclosure may include an adjustable probe assembly **100** disposed within handle **140** of a catheter with radial ultrasound and needle biopsy capability. A radial ultrasound probe **130** may extend through the housing **110** such that a drive cable of the radial ultrasound probe may be connected to an external MDU and a distal portion of the radial ultrasound probe may extend through a shaft (e.g., a dual-lumen shaft) of a catheter (not shown) attached to a distal end of the handle **140**. In various embodiments, the dual-lumen catheter may extend through a working channel of an endoscope, e.g., within a body lumen of a patient. In various embodiments, the adjustable probe assembly **100** may be configured to move laterally and/or axially relative to (e.g., within) the handle **140**. For example, the arm or projection **120** may be disposed between first and second surface features **142**, **144** extending from an inner wall of the handle **140**. In various embodiments, the first surface feature **142** may define an opening configured to receive a corresponding lock button/tab to lock a needle slider associated with the handle **140** in position, while surface **144** is a boundary of the handle where the probe assembly exits the handle proximally. A lateral position of the probe assembly **100** within the handle **140** may be varied by moving (e.g., sliding) the housing **110** distally and proximally between the first and second surface features **142**, **144**. In various embodiments, the lateral position of the probe assembly within the handle **140** may provide (e.g., set) the desired length of the radial ultrasound probe extending through and distal to the end of a lumen of the dual-lumen catheter. For example, the lateral position of the probe assembly **100** within the handle **140** may be set or adjusted to vary the position of a radial ultrasound transducer at the distal end of the radial ultrasound probe relative to a distal end of the shaft (e.g., dual-lumen shaft) of the catheter within which the radial ultrasound probe is housed. In one embodiment, the ability to alter/adjust a lateral position of the probe assembly **110** within the handle **140** may provide a physician with fine-tune lateral control of the radial ultrasound probe within and extending from the dual-lumen catheter (e.g., to adjust the location of the radial ultrasound probe relative to a target pulmonary nodule) without adjusting/altering the position of the catheter handle within the working channel of the endoscope, or the position of the endoscope itself through which the dual-lumen catheter of the handle **140** extends. In various embodiments, a set-screw or other locking member (not shown) may extend through a wall of the handle **140** to engage/contact an outer surface of the fitting **116** to lock/secure the housing **110** at the desired lateral position within the handle **140**. With the position of the radial ultrasound transducer set (e.g., relative to the distal end of the dual-lumen catheter), the handle **140**, and probe assembly **100** attached thereto, may be distally advanced and/or proximally retracted to distally advance and/or proximally retract the dual-lumen catheter within/through the endoscope working channel, e.g., to advance the radial ultrasound transducer into the peripheral regions of the lung using ultrasound guidance. In addition, the housing **110** may be rotated relative to the handle **140** to axially rotate the radial ultrasound probe within the dual-lumen catheter. The proximal portion of the housing (e.g., defining the ultrasound port **112**) may also be rotated independent of the remaining portion of the housing **110** (e.g., including flush port **114** and fitting **116**) to rotate the radial ultrasound probe within the dual-lumen catheter. The axial rotation of the flush port **114** with the housing **110** may orient the flush port **114** to a position that is accessible to the physician so that fluid may be flushed through the channel **115** into the internal chamber **111** and through the sheath **134**. In one embodiment, a proximal end of the flush port **114** may be configured to receive a fluid source **150** (FIGS. **3**B-**3**C) configured to flush fluid through the fluid channel **115** into the internal chamber **111** and through the sheath **134**. In various embodiments, the first and second seals **122**, **124** may prevent fluid from exiting the housing **110** (e.g., leaking) as the housing **110** is moved laterally and/or axially within the handle **140**. Other adjustable ultrasound port and flush port techniques, features, and/or components that may be used herein are disclosed in U.S. Non-Provisional patent application titled "Devices to Access Peripheral Regions of the Lung for Direct Visualization with Tool Attachment", attorney docket number 8150.0581, filed even date herewith, the entirety of which is incorporated herein by reference, and/or U.S. Non-Provisional patent application titled "Medical Imaging Devices, Systems, and Methods", attorney docket number 8150.0746, filed even date herewith, the entirety of which is incorporated herein by reference.

[0026] All of the devices and/or methods disclosed and claimed herein can be made and executed without undue experimentation in light of the present disclosure. While the devices and methods of this disclosure have been described in terms of preferred embodiments, it may be apparent to those of skill in the art that variations can be applied to the devices and/or methods and in the steps or in the sequence of steps of the method described herein without departing from the concept, spirit and scope of the disclosure. All such similar substitutes and modifications apparent to those

skilled in the art are deemed to be within the spirit, scope and concept of the disclosure as defined by the appended claims.

What is claimed is:

1. An adjustable probe assembly, comprising:
a housing defining an internal chamber;
an ultrasound port formed within a proximal portion of the housing, wherein the ultrasound port is coextensive with the internal chamber;
a flush port disposed along a middle portion of the housing, the flush port defining a fluid channel therethrough, wherein the fluid channel is coextensive with the internal chamber; and
a fitting disposed around a distal portion of the housing;
wherein the housing is configured to rotate relative to the fitting to alter an axial position of the flush port relative to the fitting.

2. The adjustable probe assembly of claim **1**, wherein an outer surface of the distal portion of the housing includes a surface feature configured to frictionally engage an inner surface of the fitting.

3. The adjustable probe assembly of claim **1**, wherein the fitting includes a projection.

4. The adjustable probe assembly of claim **1**, further comprising a first seal disposed within a distal portion of the internal chamber and a second seal disposed within a proximal portion of the internal chamber.

5. The adjustable probe assembly of claim **4**, further comprising a bearing disposed within a proximal portion of the internal chamber and proximal to the second seal.

6. The adjustable probe assembly of claim **5**, wherein the housing and ultrasound port are configured to receive a radial ultrasound probe therethrough.

7. The adjustable probe assembly of claim **6**, wherein the bearing is configured to support rotation of the radial ultrasound probe.

8. The adjustable probe assembly of claim **7**, wherein the radial ultrasound probe includes a drive cable, and wherein the drive cable extends through the ultrasound port and is supported by the bearing.

9. The adjustable probe assembly of claim **8**, wherein the radial ultrasound probe includes a sheath, and wherein a proximal end of the sheath is disposed within the housing between the first and second seals.

10. The adjustable assembly of claim **9**, wherein the housing is configured to rotate relative to the fitting to alter an axial position of the radial ultrasound probe, and wherein the proximal portion of the housing is configured to rotate relative to a remaining portion of the housing to alter an axial position of the radial ultrasound probe.

11. A system, comprising:
a handle of a catheter;
an adjustable probe assembly attached to the handle, wherein the adjustable probe assembly is configured to move laterally and axially relative to the handle; and
a radial ultrasound probe extending through the adjustable probe assembly, the handle and a shaft of the catheter.

12. The system of claim **11**, wherein the adjustable probe assembly includes a housing defining an internal chamber, an ultrasound port formed within a proximal portion of the housing and a flush port disposed along a middle portion of the housing.

13. The system of claim **12**, wherein the radial ultrasound probe includes a drive cable, and wherein the drive cable extends through the ultrasound port.

14. The system of claim **12**, wherein the flush port includes a fluid channel configured to deliver fluid into the internal chamber and through a sheath of the radial ultrasound probe.

15. The system of claim **14**, further comprising a first seal disposed within a distal portion of the internal chamber and a second seal disposed within a proximal portion of the internal chamber, wherein the first and second seals prevent fluid introduced through the flush port from exiting the internal chamber.

16. A method, comprising:
attaching an adjustable probe assembly to a handle of a catheter such that a radial ultrasound probe attached to the adjustable probe assembly extends through the handle and a shaft of the catheter;
adjusting a lateral position of the adjustable probe assembly relative to the handle; and
adjusting an axial position of the adjustable probe assembly relative to the handle.

17. The method of claim **16**, further comprising readjusting the lateral position of the adjustable probe assembly relative to the handle to alter a lateral position of the radial ultrasound probe within a lumen of the catheter shaft.

18. The method of claim **17**, further comprising rotating a housing of the adjustable probe assembly relative to the handle to rotate the radial ultrasound probe within the lumen of the catheter.

19. The method of claim **16**, further comprising rotating a housing of the adjustable probe assembly relative to the handle to alter an axial position of a flush port disposed along a middle portion of the housing relative to the handle.

20. The method of claim **19**, further comprising introducing a fluid through the flush port and into an internal chamber of the adjustable probe assembly.

* * * * *