US 20250255473A1

(19) United States
(12) Patent Application Publication
(10) Pub. No.: US 2025/0255473 A1
(43) Pub. Date: Aug. 14, 2025
Kheir et al.

(54) DEVICES AND METHODS FOR TWO CHANNEL BRONCHOSCOPY

(71) Applicant: **Beth Israel Deaconess Medical Center, Inc.**, Boston, MA (US)

(72) Inventors: **Fayez Kheir**, Boston, MA (US); **Adnan Majid**, Boston, MA (US); **Daniel Ospina-Delgado**, Boston, MA (US)

(21) Appl. No.: **19/049,876**

(22) Filed: **Feb. 10, 2025**

Related U.S. Application Data

(60) Provisional application No. 63/551,642, filed on Feb. 9, 2024.

Publication Classification

(51) **Int. Cl.**

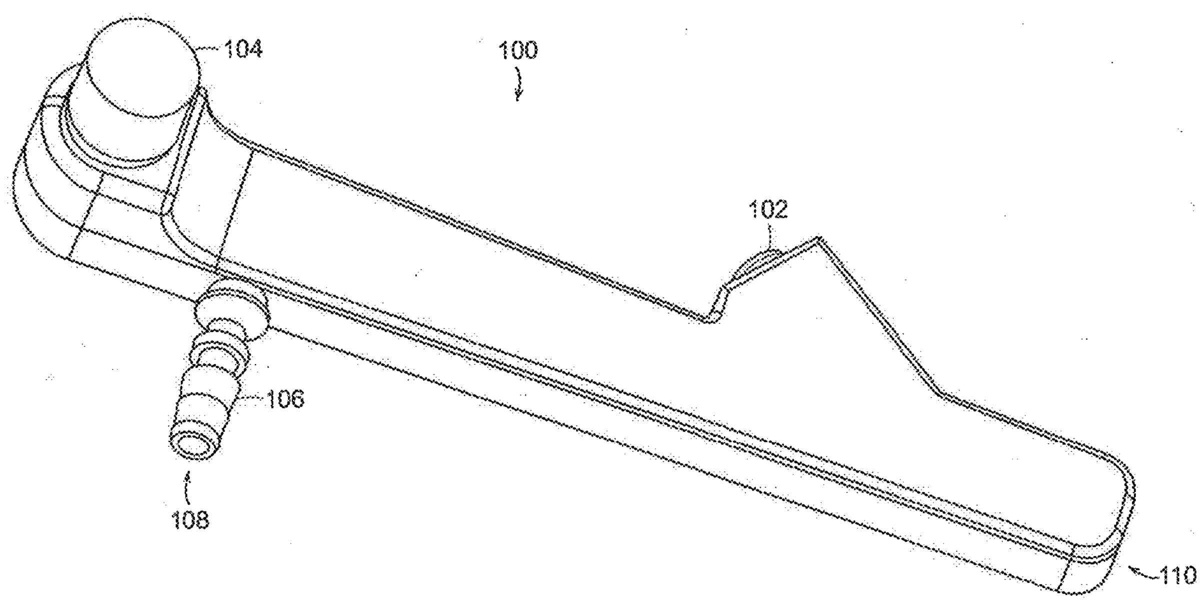
A61B 1/267	(2006.01)
A61B 1/00	(2006.01)
A61B 1/005	(2006.01)
A61B 1/015	(2006.01)
A61B 1/018	(2006.01)
A61B 1/04	(2006.01)
A61B 1/07	(2006.01)
A61B 17/00	(2006.01)

(52) **U.S. Cl.**

CPC ***A61B 1/2676*** (2013.01); ***A61B 1/00105*** (2013.01); ***A61B 1/00128*** (2013.01); ***A61B 1/0051*** (2013.01); ***A61B 1/015*** (2013.01); ***A61B 1/018*** (2013.01); ***A61B 1/04*** (2013.01); ***A61B 1/07*** (2013.01); ***A61B 17/00234*** (2013.01); *A61B 2017/003* (2013.01); *A61B 2017/0034* (2013.01); *A61B 2217/005* (2013.01)

(57) **ABSTRACT**

The present disclosure relates to bronchoscope devices and method of use for the visualization and surgical treatment of pulmonary conditions within the lungs of a patient. The bronchoscope assembly comprises a first working channel and a second working channel that respectively provide complementary functions for accessing the surgical site and a plurality of surgical applications.



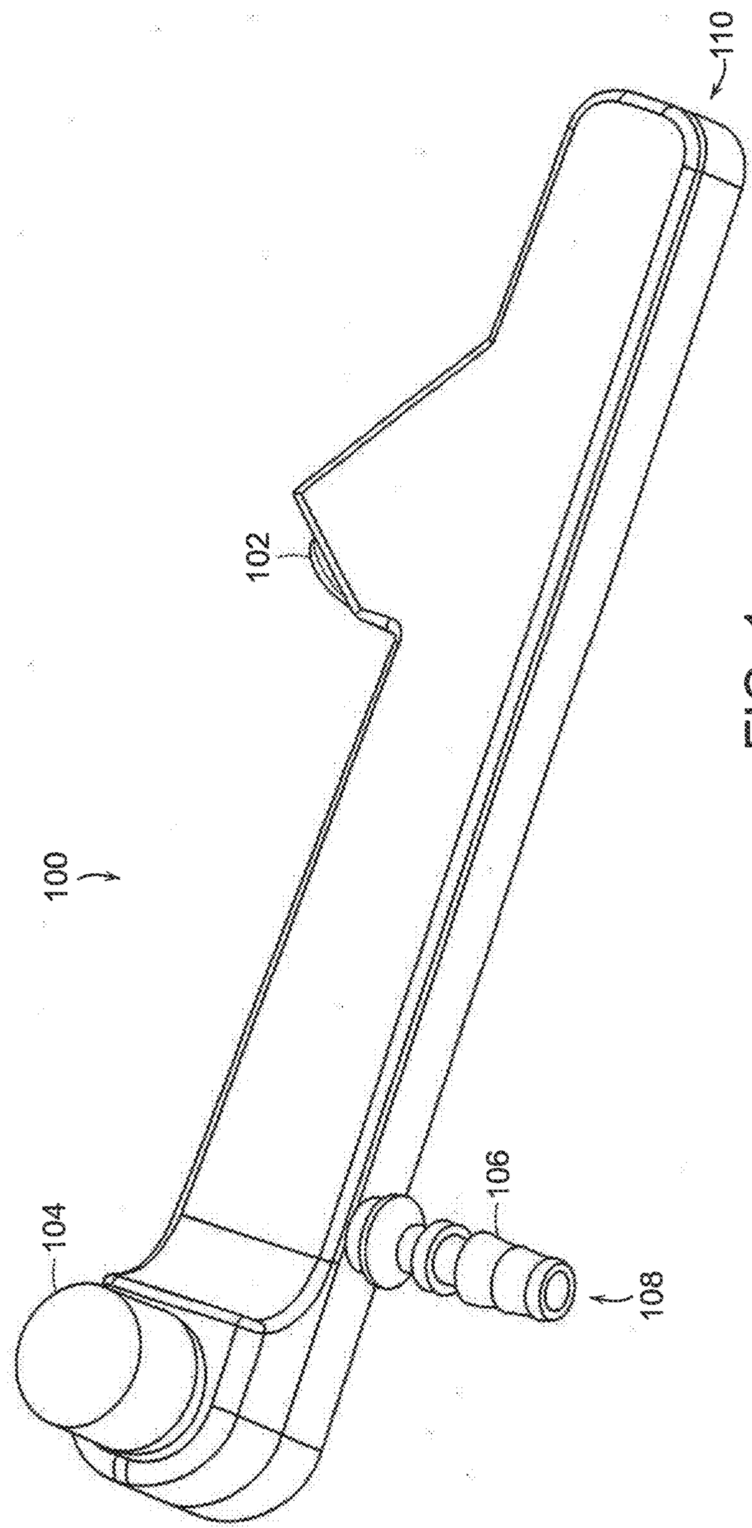


FIG. 1

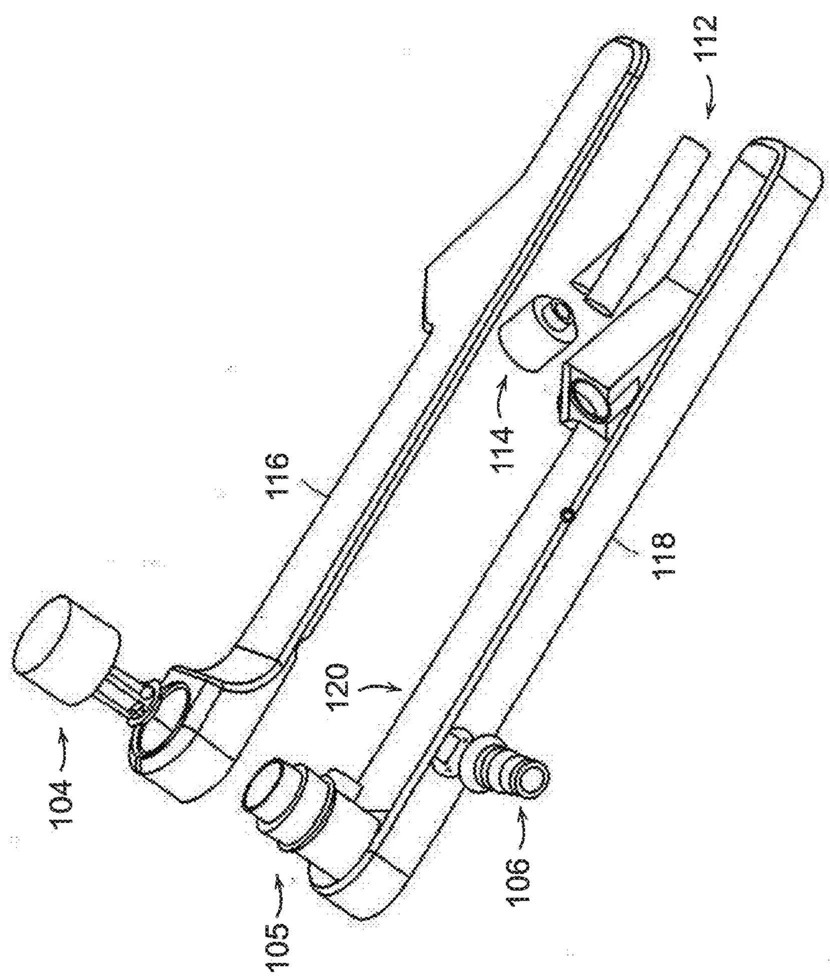


FIG. 2A

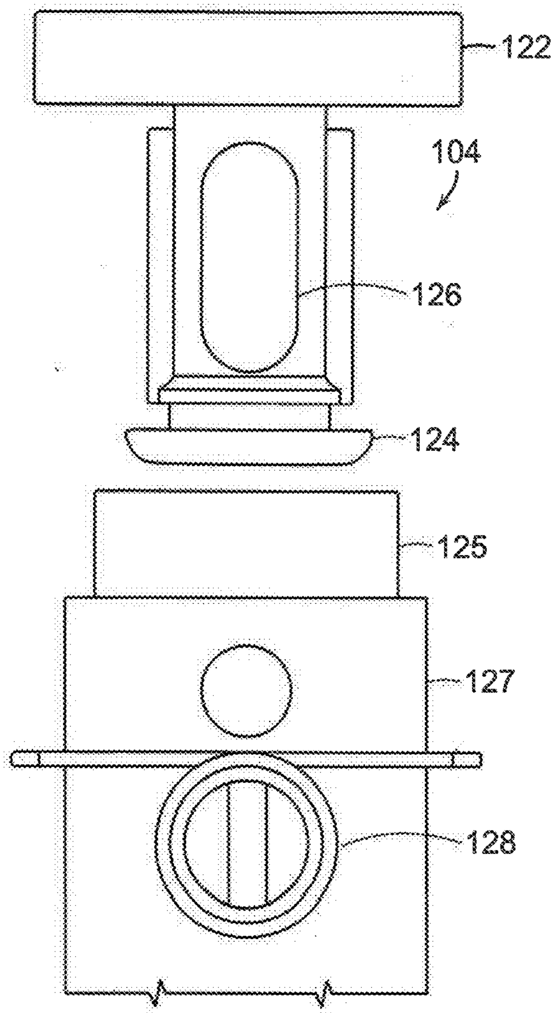


FIG. 2B

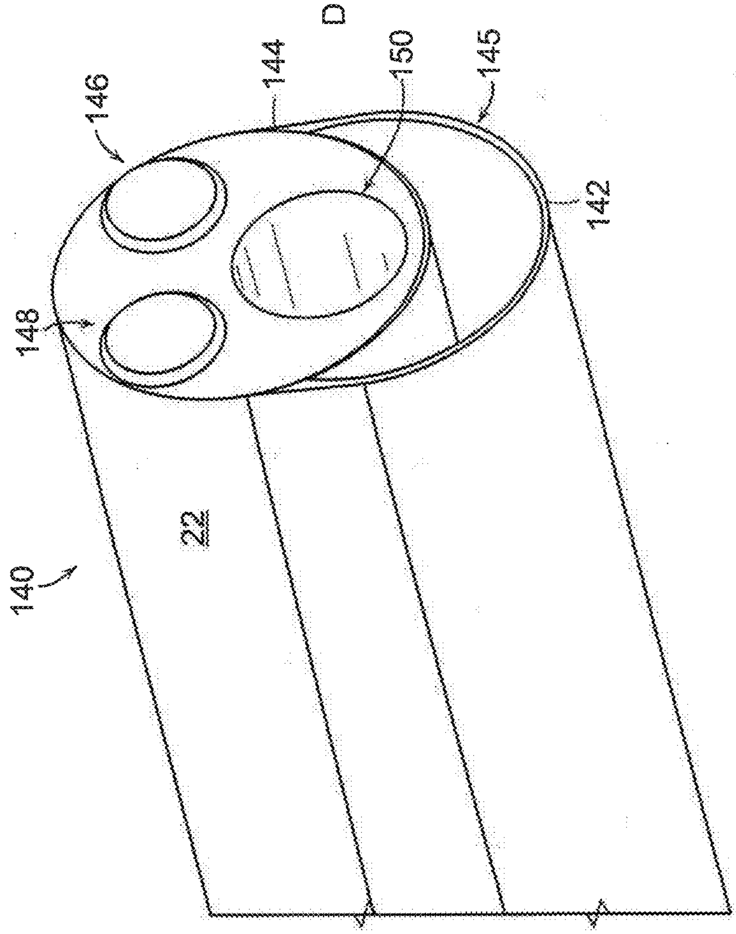


FIG. 3A

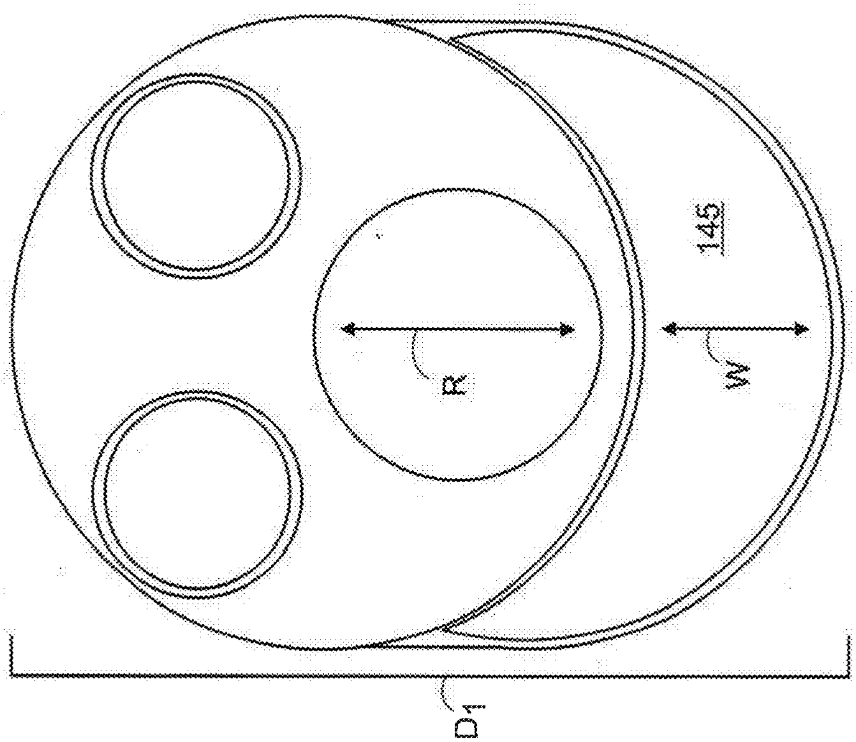


FIG. 3B

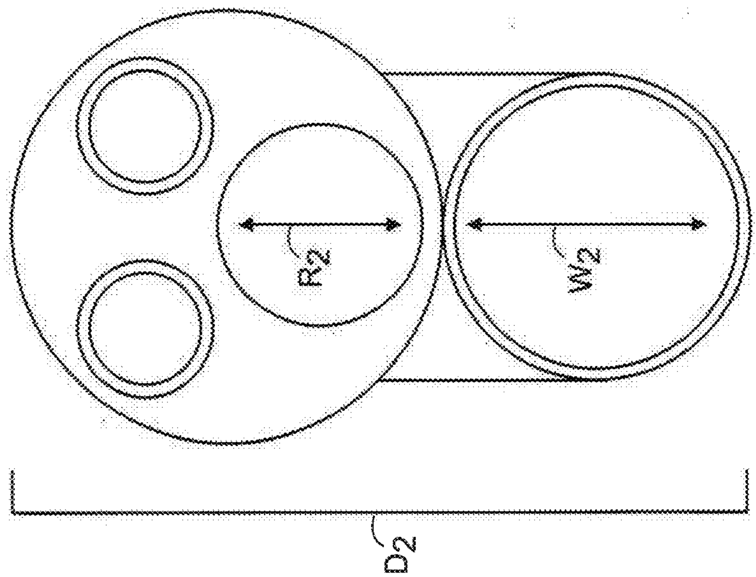


FIG. 4B

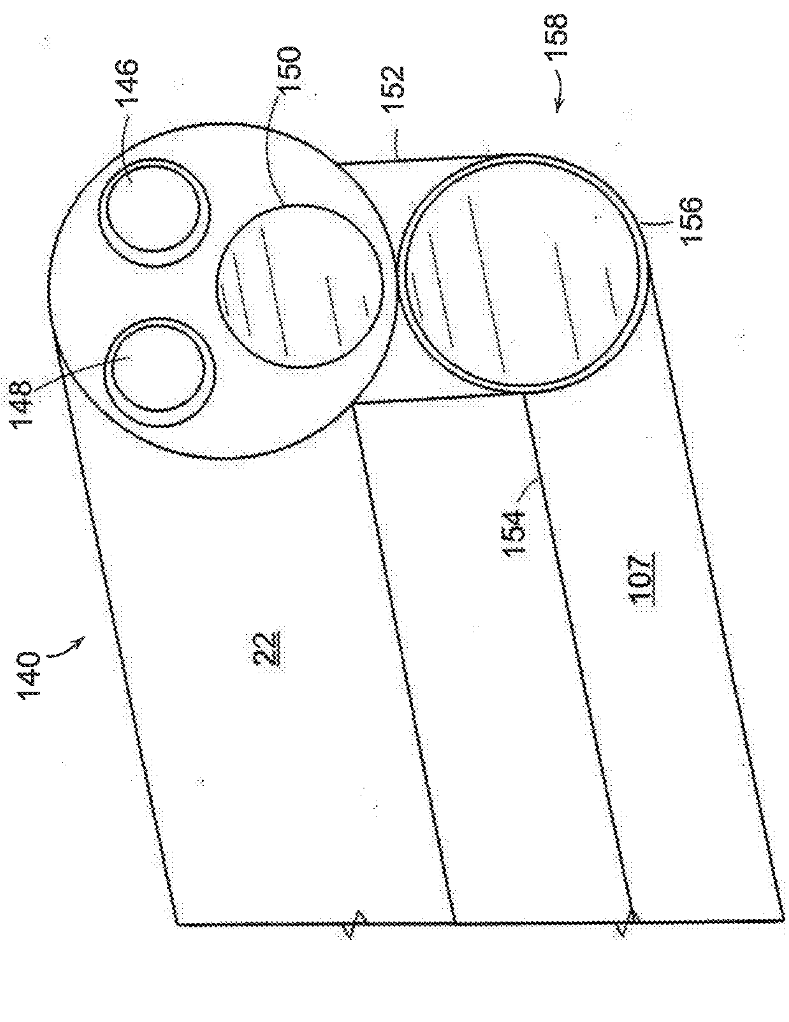


FIG. 4A

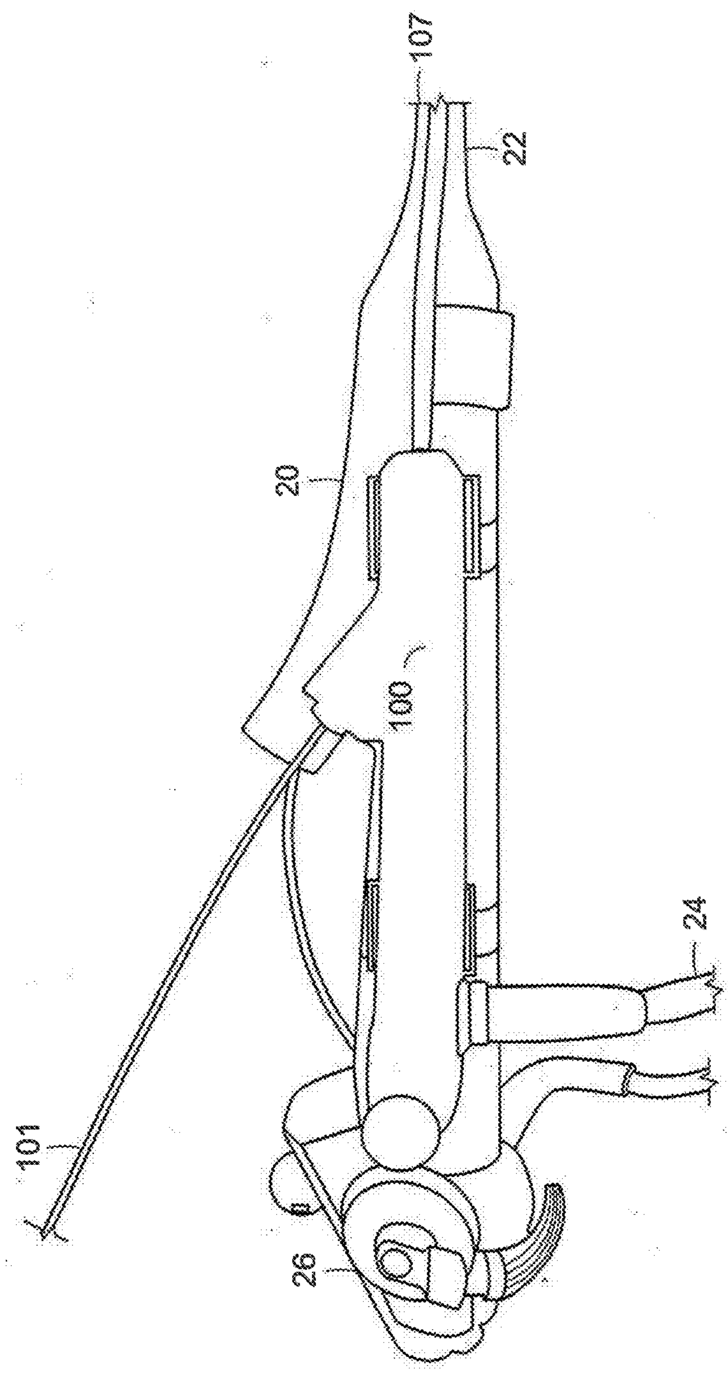


FIG. 5

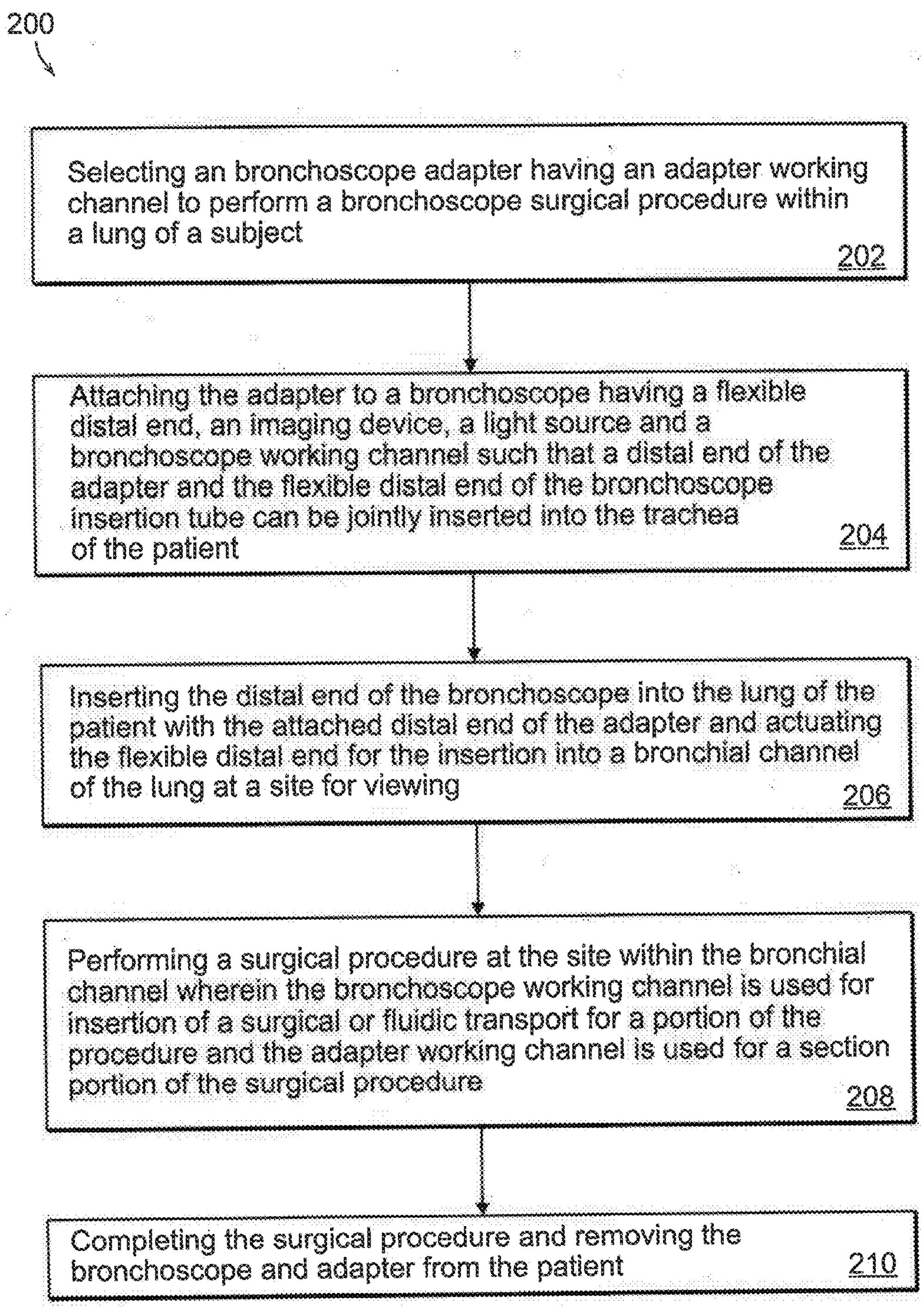

200
Selecting an bronchoscope adapter having an adapter working channel to perform a bronchoscope surgical procedure within a lung of a subject
202
Attaching the adapter to a bronchoscope having a flexible distal end, an imaging device, a light source and a bronchoscope working channel such that a distal end of the adapter and the flexible distal end of the bronchoscope insertion tube can be jointly inserted into the trachea of the patient
204
Inserting the distal end of the bronchoscope into the lung of the patient with the attached distal end of the adapter and actuating the flexible distal end for the insertion into a bronchial channel of the lung at a site for viewing
206
Performing a surgical procedure at the site within the bronchial channel wherein the bronchoscope working channel is used for insertion of a surgical or fluidic transport for a portion of the procedure and the adapter working channel is used for a section portion of the surgical procedure
208
Completing the surgical procedure and removing the bronchoscope and adapter from the patient
210

FIG. 6

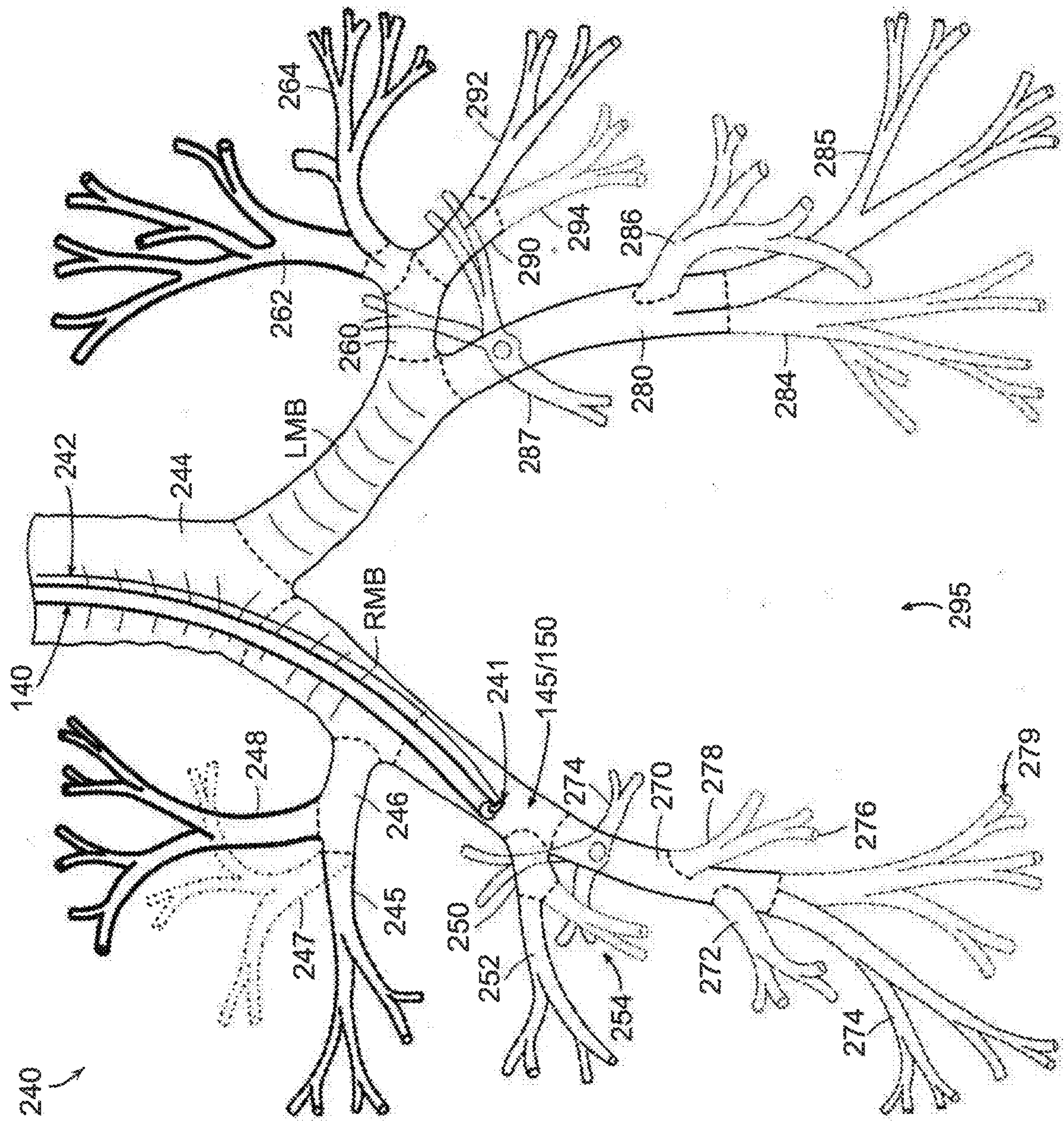

240
140
242
244
LMB
RMB
241
145/150
245
246
247
248
250
252
254
260
262
264
270
272
274
274
276
278
279
280
284
285
286
287
290
292
294
295

FIG. 7

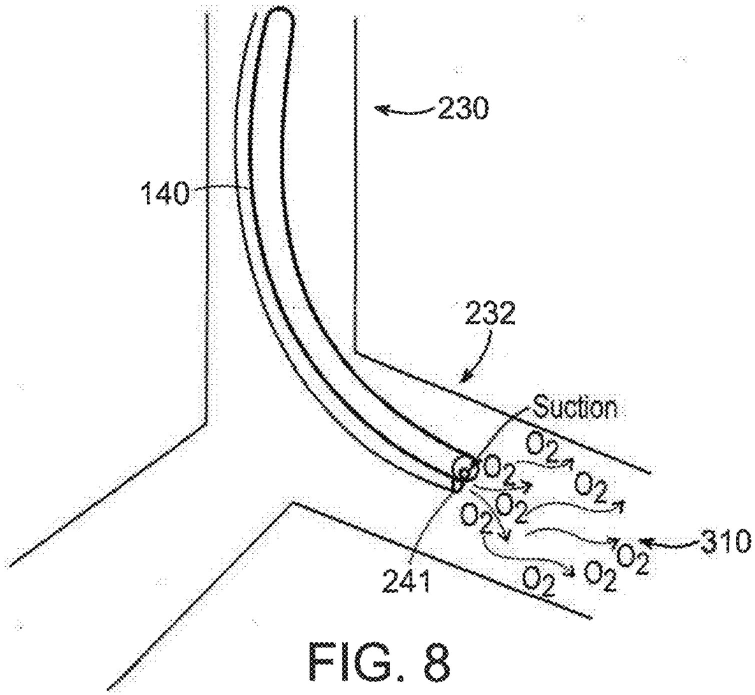


FIG. 8

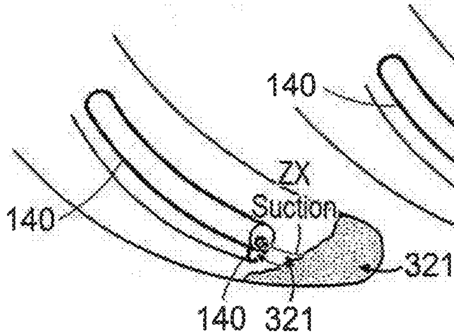


FIG. 9A

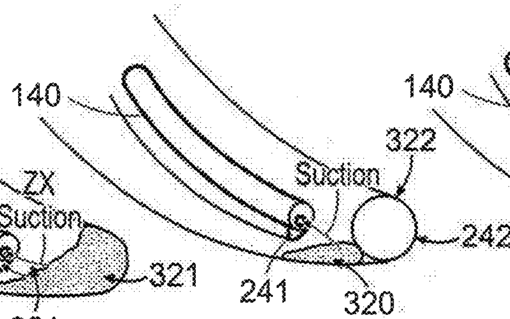


FIG. 9B

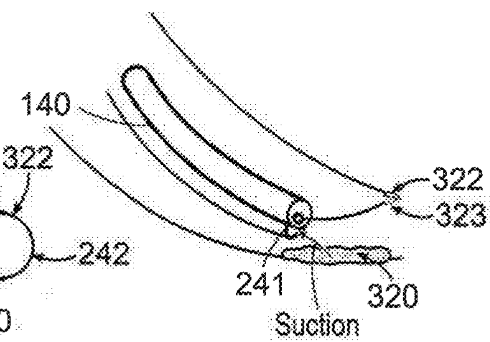


FIG. 9C

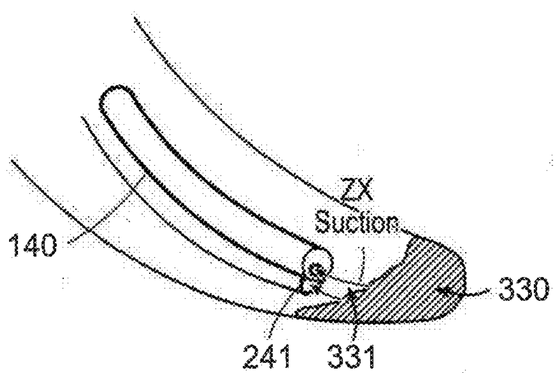


FIG. 10A

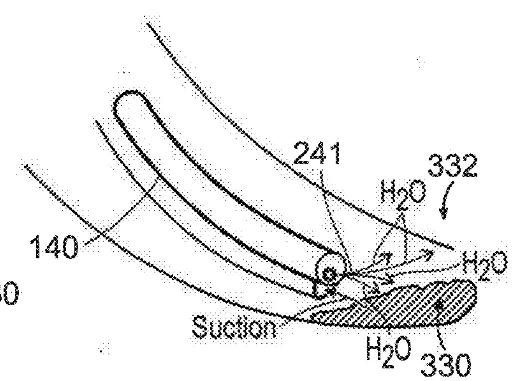


FIG. 10B

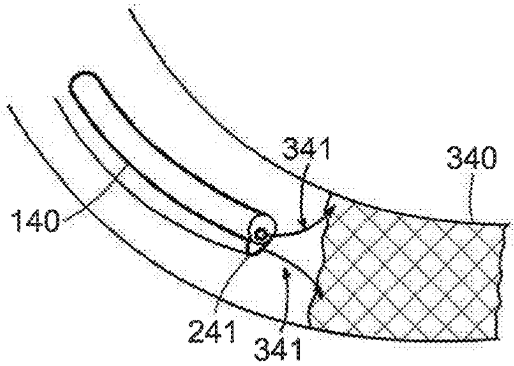


FIG. 11A

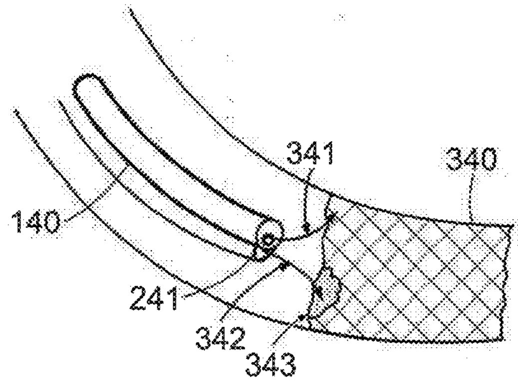


FIG. 11B

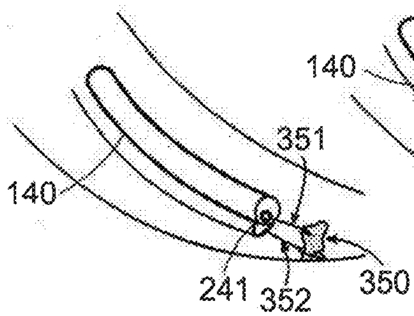


FIG. 12A

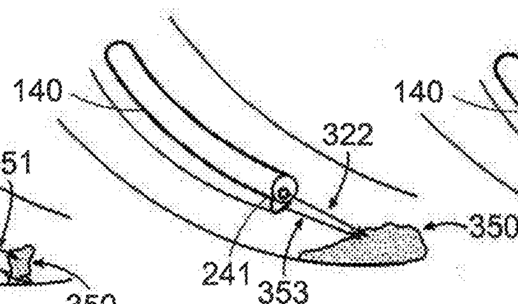


FIG. 12B

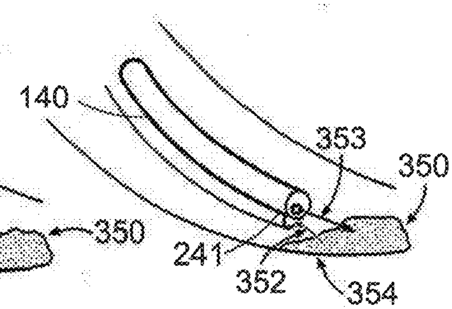


FIG. 12C

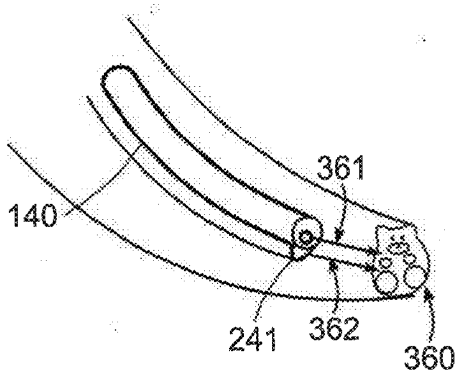


FIG. 13A

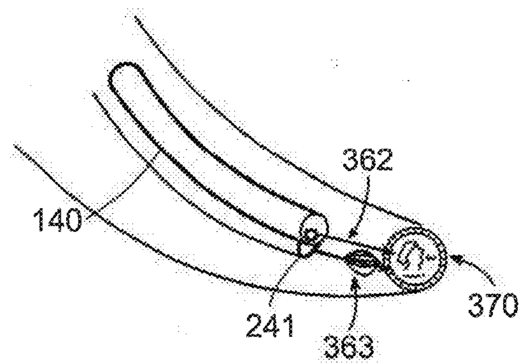


FIG. 13B

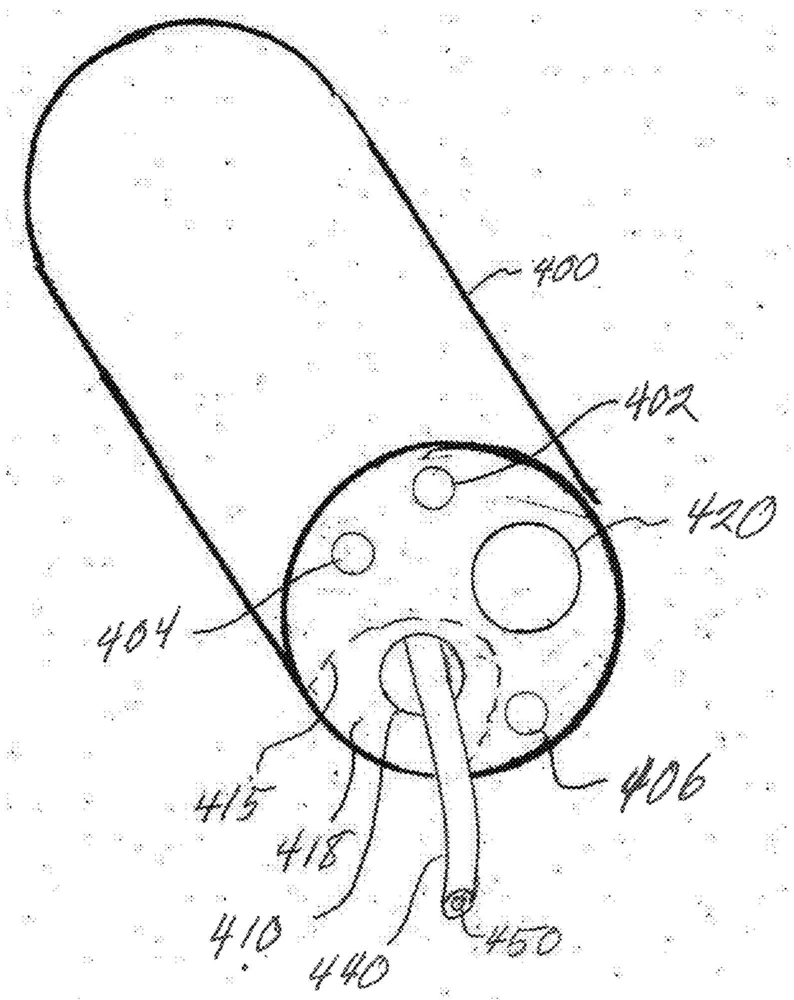


Fig. 14

DEVICES AND METHODS FOR TWO CHANNEL BRONCHOSCOPY

[0001] This application claims priority to U.S. Provisional Application No. 63/551,642 filed on Feb. 9, 2024. The entire contents of the above application is incorporated herein by reference.

BACKGROUND

[0002] Bronchoscopes have been developed for viewing of the lungs to aid in the diagnosis and disease. Many such devices have been provided with a flexible tip to aid in directional navigation of the bronchoscope into the bronchial tree of the lungs so that conditions can be visualized that impact respiratory function. It is often desirable to perform further procedures such as the biopsy of tissue samples from the bronchial system to aid in diagnosis, the delivery and removal of fluid that can impact oxygenation by the lungs and the delivery of supplemental oxygen should this essential function of the lungs be impaired.

[0003] Existing endoscopes typically include a camera to image tissue, a light source for illuminating the lungs during bronchoscopy and a working channel by which various functions can be performed during such procedures. As the airway passages within the bronchial tree get progressively smaller as the tip of the bronchoscope is steered from the trachea into smaller passageways so that the distal diameter of the bronchoscope must be limited. Thus, there is limited cross-sectional area at the distal end of the endoscope insertion tube with the working channel being 2 mm in diameter or less, for example, so that the remainder of the distal surface area can also accommodate the imaging and illumination apertures needed for visualization. These apertures typically use a light guide lens for illumination and an objective lens to couple light from the field of view to the imaging device. Flexible bronchoscopes must include a mechanical mechanism to adjust the angular orientation of the distal end relative to the longitudinal axis of the insertion tube that extends through the trachea. This typically entails the use of wires that extend through the insertion tube wall to apply tension on different sides of the distal end of the bronchoscope so that the user can manipulate a handle mechanism to steer the distal end as required. This typically requires a wide angulation range of over 100 degrees in two opposite directions to achieve to achieve the desired steerability.

[0004] As the working channel must be used to provide these various different functions, time is needed to transition between the different procedures. If a biopsy is being performed, for example, this requires a forceps tool to be inserted through the working channel, which thus prevents the working channel from serving other functions until the forceps has been removed. If fluid in the lungs impairs viewing during the biopsy, it can be necessary to remove the biopsy tool, attach a source for suctioning of the fluid to the working channel, remove the fluid to restore adequate imaging of the biopsy site, remove the suction and return the biopsy tool through the working channel. Consequently, procedures can extend for many hours to sequence through the various steps needed to complete the procedure. In the case of an hypoxic patient, it can be necessary to supply supplemental oxygen to the patient through the working channel periodically during the procedure or risk the occurrence of hypoxia which can affect the patient for many hours after completion of the procedure. Biopsies are conducted using a flexible bronchoscope as described herein where a biopsy probe can be inserted into the lung and related anatomical structures described and illustrated herein to remove tissue and/or fluid samples from different location within the bronchial tree including lymph nodes that can be accessed using the working channels described herein.

[0005] Thus, a need exists for further improvements in bronchoscope design and function to improve the treatment of patients with pulmonary disease or injury.

SUMMARY

[0006] Preferred implementations of the invention provide for the use of a second working channel for bronchoscopy procedures that enable the insertion of the flexible bronchoscope into the bronchial tree for visualization and treatment. This eliminates the need to disrupt a procedure where a second working channel can be used to provide additional operative functions while a first working channel is being used for a critical procedural function.

[0007] A preferred embodiment utilizes an adapter that can be attached to an existing bronchoscope in which the adapter includes a working channel that works separately from the existing bronchoscope working channel. The adapter thus comprises a second working channel that can be used in tandem with the first working channel of the existing bronchoscope. The adapter can include a proximal assembly, a tube attached to the exterior surface of the bronchoscope or a shaped body that conforms to the exterior surface wherein the tube or shaped body extends from the proximal assembly to a flexible distal end having a distal aperture for the second working channel.

[0008] The adapter can have a plurality of operative elements including a second working channel port, a connector that connects to a negative pressure source to provide suction and a suction actuator to facilitate the application of suction to the working channel. The port can include a y connector to sidewall access to the adapter working channel.

[0009] The adapter working channel can comprise a plurality of different shapes and sizes to enable the user to utilize the adapter working channel for different applications. The adapter can consequently be configured to be use the additional working channel for the hypoxic patient that requires a flexible bronchoscopy. It has been reported that up to 35% of patients that undergo bronchoscopy and do not receive any kind of oxygen supplementation can develop hypoxemia (See Milman N, Faurschou P, Grode G, Jørgensen A. Pulse oximetry during fibreoptic bronchoscopy in local anaesthesia: Frequency of hypoxaemia and effect of oxygen supplementation. *Respiration.* 1994; 61(6):342-347. doi:10.1159/000196366). Patients diagnosed with COPD, asthma, COVID, OSA, or other diseases that impair the gas exchange in the lungs or oxygen delivery might develop hypoxia during the procedure that can extend up to 4 hours postoperatively. This limits the ability of the bronchoscopist to navigate the airways, prolongs the surgical time, and can lead to situations in which it is hard to recover adequate oxygen saturation or even to hypercapnic respiratory failure. In their guidelines for diagnostic flexible bronchoscopy, the British Thoracic Society (See Du Rand I A, Blaikley J, Booton R, et al. British Thoracic Society guideline for diagnostic flexible bronchoscopy in adults. *Thorax.* 2013; 68(SUPPL. 1). doi:10.1136/thoraxjnl-2013-203618) recommends using oxygen supplementation when desaturation is significant (pulse oximeter oxygen saturation (SpO2)>4% change, or SpO2<90%) and prolonged (>1 min) to reduce the risk of hypoxemia-related complications. This can prove challenging in most occasions in which the working channel of the bronchoscope is used, as patients can only be ventilated through the area in between the inner diameter of the endotracheal tube and the outer diameter of the bronchoscope, unless the bronchoscope is removed.

[0010] Tracheal oxygen supplementation through a working channel has previously proven to be feasible and safe in preventing and correcting hypoxemia during flexible bronchoscopy, with the caveat of having to stop the procedure to supply the oxygen. The addition of a second working channel allows the physician to use an independent channel to supply oxygen to the patient throughout the procedure, thereby avoiding the development of hypoxia, and with it, preventable complications. The mechanism through which the tracheal supplementation of oxygen works might be similar to the one in transtracheal oxygen therapy, the anatomical dead space is bypassed with the working channel leading to better oxygen delivery and requiring less volume than when a nasal cannula is used.

[0011] Other therapeutic applications of the second working channel attachment include, but are not limited to the following procedures. With improved suction hemoptysis can be performed to provide improved cleanup before coagulation or better visualization of the lesion while ablation. Enhanced suction can address mucus plugging where concomitant irrigation helps remove thick mucus. Two tools can be used through the two working channels to facilitate manipulation and retrieval of stents and can avoid the need to redeploy. Two tools can also be used for the resection of endobronchial tumors thereby leading to better outcomes and shorter surgical times. Two tools can be used for removal of foreign bodies that are difficult to grasp.

[0012] Further applications can include whole lung lavage where one channel can be used for suction while the other can be used for irrigation, creating a loop that can greatly improves efficiency and reduces surgical times.

[0013] Additional therapeutic procedures can include bronchial thermoplasty/Rheox for patients with asthma and chronic bronchitis. Another application involves fibrin glue application for BPF/APF to prevent the two components of the fibrin glue from combining inside the working channel, rendering the bronchoscope useless. Thus, one component is delivered with a first tube through the first channel and the second component is delivered through a second tube with the second channel to allow a more precise application while combining the components at the site of glue application. Percutaneous endoscopic gastrostomy (PEG) can involve placement of a tube with a bronchoscope which can aid in insufflation of the stomach and guidewire advancement to the stomach (see Folch E, Kheir F, Mahajan A, Alape D, Ibrahim O, Shostak E, Majid A. Bronchoscope-Guided Percutaneous Endoscopic Gastrostomy Tube Placement by Interventional Pulmonologists: A Feasibility and Safety Study. J Intensive Care Med. 2020 September; 35(9):851-857. doi:10.1177/0885066618800275. Epub 2018 Sep. 24. PMID: 30244635).

[0014] Additionally, diagnostic procedures that can be enhanced with a second working channel such as cryobiopsy where suction is used while performing the biopsy to improve visualization. This enables the use of a thermoablative tool immediately after the biopsy if bleeding is detected. The biopsy sample can be grasped with another tool to avoid losing it when the probe thaws. Biopsies can be used to obtain tissue or fluid samples within the lung thoracic wall as described herein by appropriate positioning of the distal end of the bronchoscope system as described herein with a smaller diameter distal end or the insertion of a smaller diameter tool that can extend from the distal end of the bronoscope through one of the working channels described herein. A further example of a bronchoscope as described herein can comprise a single outer tube with two separate workings channels of the same or different sizes.

[0015] Another example is transbronchial biopsy where suction is used in case of bleeding to maintain a clean field of view. This further enables the use of a thermoablative tool or the placement of a tamponade balloon immediately after the biopsy if bleeding is detected. Thus the second channel can generally be used to maintain clean field of view during therapeutic bronchoscopy depending on the application.

DESCRIPTION OF THE DRAWINGS

[0016] FIG. **1** is a perspective view of an adapter proximal assembly in accordance with preferred embodiments hereof;

[0017] FIG. **2**A is an exploded view of the adapter proximal assembly of FIG. **1**;

[0018] FIG. **2**B is a detailed view of a suction actuator for a preferred embodiment hereof;

[0019] FIGS. **3**A and **3**B are perspective and end views of the distal end of a bronchoscope in connection with preferred embodiments;

[0020] FIGS. **4**A and **4**B are perspective and end views of a bronchoscope in connection with further preferred embodiments;

[0021] FIG. **5** is a side view of a proximal adapter assembly mounted onto an available bronchoscope;

[0022] FIG. **6** is a process flow diagram illustrating surgical procedures for preferred embodiments of the invention.

[0023] FIG. **7** illustrates the lung with the bronchial tree wherein the bronchoscope assembly described herein can be inserted and steered into smaller branches to perform a plurality of therapeutic and diagnostic procedures.

[0024] FIG. **8** illustrates a bronchoscope assembly inserted into the bronchial tree to perform administration of transtracheal oxygen.

[0025] FIGS. **9**A, **9**B, and **9**C illustrate a bronchoscope assembly inserted into the bronchial tree to perform hemoptysis treatment.

[0026] FIGS. **10**A and **10**B illustrate a bronchoscope assembly inserted into the bronchial tree to perform removal of a mucus plug.

[0027] FIGS. **11**A and **11**B illustrate a bronchoscope assembly inserted into the bronchial tree to perform deployment, revision, or removal of a stent.

[0028] FIGS. **12**A, **12**B, and **12**C illustrate a bronchoscope assembly inserted into the bronchial tree to perform resection of endobronchial tumors.

[0029] FIGS. **13**A and **13**B illustrate a bronchoscope assembly inserted into the bronchial tree to perform removal of a foreign body.

[0030] FIG. **14** schematically illustrates a bronchoscope having two working channels in a cylindrical perspective end view in which a catheter is extended distally from a working channel to access smaller bronchial channels in accordance with the implementations described herein.

DETAILED DESCRIPTION

[0031] Shown in FIG. **1** is a proximal assembly of an adapter **100** for a bronchoscope in which the proximal assembly comprises a housing **110** that can be formed of two molded components that can be joined and configured to attach to a bronchoscope. The proximal assembly housing **110** can include a port **102** which can be located on a first side of housing **110** so that instruments can be inserted into an internal working channel that extends into a tube attached to a distal end of the proximal assembly. At the proximal end of the housing **110** a valve **104** can be positioned that enables a user to quickly actuate fluid flow within the adapter working channel. The valve **104** can have a button or knob that can be manually adjusted by the user to open, close, or regulate fluid flow within the working channel. A second port **106** on a second side of the housing can be used to attach a suction tube or other fluid source to the housing thereby enabling fluid flow into or out of the proximal assembly. Note that fluid can also be introduced through port **102**. As seen in the exploded view of FIG. **2**A, the housing **110** can include a working channel chamber **114** coupled to the port **102** aperture where the chamber **114** is connected at one end to one arm of a y connector **112** at port **102** so as to provide entry into the working channel exiting the distal end of housing **110**. The second arm of connector **112** is in fluid communication with the valve chamber **105** which is in fluid communication with second port connector **106** so that fluid can flow into or out of aperture **108** of port **106** so as to enable fluid flow between aperture **108** and the adapter working channel.

[0032] As seen in the exploded view of valve **104** in FIG. **2**B, the valve can include a manually grasped knob or button used to operate the valve, an internal valve body **104** with an opening **126** such that the valve chamber **105** can be moved or rotated to align opening **126** with the working channel port **128** in the external valve body **127** that is statically connected to lower section **118** of housing **110**. In this exemplary implementation, knob **122** is rotated relative to upper section **116** of housing **110**. The internal valve body **104** is placed within the external valve body **127** through an opening in upper rim **125** that has an inner cylindrical wall contacted by seal **124** that forms a fluid tight seal with the inner cylindrical wall.

[0033] The distal end of the proximal assembly is connected to an outer wall **107** of the adapter working channel. The outer wall **107** can comprise a tube or shaped housing that attaches to an exterior surface of the bronchoscope insertion tube **22**. As seen in the exemplary implementation of FIGS. **3**A and **3**B, the outer wall **107** can have a concave surface that attaches to the outer convex surface of insertion tube **22**. In this implementation a flange **144** can be snap connected to the exterior surface of tube **22**, although various mechanical means can be used to provide for attachment of the outer wall **107** of the adapter and the surface of tube **22**. In this embodiment, the bronchoscope has a distal imaging channel **146**, a distal illumination channel **148**, and a distal aperture for the bronchoscope working channel. The adapter working channel **145** has an outer wall **142** wherein the aperture can have a non-circular shape to maximize the channel area while keeping the width W of the adapter working channel **145** smaller than the diameter R of the bronchoscope working channel **150**.

[0034] In the exemplary embodiment of FIGS. **4**A and **4**B, the bronchoscope can have similar features to the bronchoscope of FIGS. **3**A and **3**B, for example, or the features can have different dimensions and operative characteristics, however, the adapter working channel in this embodiment has a circular geometry with a diameter W**2** that is either larger (as shown) than the diameter R**2** of the bronchoscope working channel, or alternatively can be the same size, or smaller, depending the requirements of the procedure. Note that the diameter DI along the long axis of the assembly in FIG. **3**B can be greater or less than the diameter D**2** along the long axis of FIG. **4**B. The diameters D**1** and D**2** can be selected depending upon the order (or size) of the bronchi in which the surgical procedure is to be performed within the bronchial tree of the patient. The smaller bronchi further into the bronchial tree require a smaller diameter for the assembly. As bronchoscope insertion tubes can vary in size from about 4 mm in diameter (less than 3 mm in pediatric patients) to about 9 mm in diameter, and working channel sizes can vary depending upon the application and needs for a particular procedure. The overall diameters D_1 and D_2 can be in the range of 3 mm to 6 mm, or alternatively, in the range of 4 mm to about 7 mm to provide the desired two working channel flexible bronchoscope. Further embodiments can comprise a single cylindrical bronchoscope tube for insertion into the lungs having two working channels. The two working channels can be the same size, or have different sizes as described herein to facilitate the use of two different tools depending on the specific application. The single bronchoscope implementation is preferably less than 6 mm in diameter, but can be larger for certain applications such as when a small diameter catheter can be used through one of the working channels to reach smaller bronchial features within the bronchial tree such as the alveoli.

[0035] Shown in FIG. **5** is an exemplary adapter **100** mounted onto a bronchoscope handle assembly **20** in which the bronchoscope handle has an actuator **26** to operate the bronchoscope tip angulation for navigating the tip through different stages of the bronchial tree. The bronchoscope handle **20** can include an imaging sensor and/or light source **26** at the proximal end that is coupled to the distal end with a plurality of optical fibers configured as an imaging bundle **146**, and/or illumination bundle or optical fiber array **148**, respectively, at the distal end. Alternatively, the imaging sensor can be a distally mounted small diameter imaging chip such as those available from Omnivision Technologies, Santa Clara, California, such as the OV6948, which has an outer diameter of less than 1 mm and a resolution or 400 pixels with an integrated distal lens. Such distal imaging detectors at 146 can have diameters of 3 mm or less (e.g. OVM6946) with 400×400 pixels and including an onboard controller and serial peripheral interface (SPI) that outputs 30 frames per second for video output. The insertion tube **107** of the adapter in which the adapter working channel extends can be statically mounted to the outer wall surface of the bronchoscope insertion tube **22**. The static mounting of the handle assembly can optionally use flaps that that grasp the bronchoscope handle, that rigidly attach to the bronchoscope handle with elastic bands with retention elements that engage the bronchoscope handle and/or that use Velcro, tape, adhesive and or double-sided microsuction tape to adhere to surfaces on the bronchoscope handle. A tool or fluid insertion tube **101** is shown inserted into the adapter port **102**. A suction tube **24** can be attached to the port **106** of the adapter housing **110**.

[0036] Shown in FIG. **6** is an exemplary surgical procedure illustrating a method **200** of using the adapter with a bronchoscope as generally described herein. The user, such as a bronchoscopic surgeon, selects a bronchoscope having a diameter and operating characteristics suitable for the procedure and then selects **202** an adapter configured to be mounted on the selected bronchoscope. The adapter is attached **204** to the bronchoscope which typically has a steerable distal end having the required flexibility at the distal end of the insertion tube for insertion into the bronchial tree of the patient. The flexibility of the distal end of the adapter is configured to match the distal flexibility of the bronchoscope. Similar biocompatible materials are used in both components to enable complementary movement with a smooth surface for tissue contact along the outer surfaces.

[0037] Optionally, an outer sheath, such as an elastic outer sleeve, can be placed over both components at the distal end to stabilize the distal movement of the assembly and provide a smooth frictionless tissue contact surface. After insertion **206** through the trachea and into a lung of the patient, the distal end is steered into the bronchial tree for visualization of the surgical site. The procedure is performed **208** wherein a certain portion of the procedure is conducted through the bronchoscope working channel and a second portion of the procedure is performed through the adaptor working channel. After completing the surgical procedure, the bronchoscope and adapter are removed **210** from the patient. The distal imaging of the procedure can be recorded and stored in the patient medical record. The adapter can comprise a single use disposable product or can be partially or completely sterilized after use. For example, the insertion portion of the adapter can be removed and disposed whereas the adapter assembly can be fabricated with materials for sterilization.

[0038] Illustrated in FIG. **7** is a sectional view of a lung **240** that is bounded by the thoracic wall surrounding the pleural cavity that includes the bronchial tree. The bronchial tree includes the right upper lobe **246** with the anterior **245**, posterior **247** and apical **248** segments, the right middle lobe **250** with the lateral **252** and medial **254** segments, the right lower lobe **270** with the superior **271** lateral **272**, posterior **274**, anterior **278**, and medial **278** segments, the left upper lobe **260** with the apico-posterior **262** and anterior **264** segments, the linguia **290** with the superior **292** and inferior **294** segments, and the left lower lobe **280** with the antero-medial **284**, superior **285**, posterior **286** and lateral **287** segments. The ends of the lobes extend to alveoli **279** that transport oxygen into the blood. The scope **140** as described herein has a distal end that can be steered into smaller branches of the system so that the distal openings of working channels **145** and/or **150** can be positioned adjacent to tissue to be treated whereby a tool can be inserted through one of the working channels such a distal end **241** of a tool, such as a biopsy tool can be positioned within a larger or smaller branch for treatment.

[0039] The small tools can have diameters less than 4 mm, less than 3 mm and less than 2 mm depending on their function and the depth within the bronchial tree required for placement. The tools can include biopsy forceps, cytology brushes, transbronchial needle aspiration tools (TBNA needles, a grasping tool to provide for removal of foreign bodies within the lungs, coagulation electrodes, a spatula knife or other cutting tool, a spray catheter, a balloon catheter, an airway sizing kit for bronchial valves and the delivery of such valves, and a tool or catheter for stent delivery. Exemplary tools and use thereof are described with regards to FIGS. **8**-**13**B.

[0040] FIG. **8** illustrates a bronchoscope assembly **140** inserted into the bronchial tree to perform administration of transtracheal oxygen **310**. The assembly **140** having two working channels is useful for treating a hypoxic patient. Up to 35% of patients who undergo bronchoscopy and do not receive any kind of oxygen supplementation can develop hypoxemia. Patients diagnosed with COPD, asthma, COVID, OSA, or other diseases that impair the gas exchange in the lungs or oxygen delivery are at a high risk of developing hypoxia during the procedure, which can linger up to four hours postoperatively. This limits the ability of bronchoscopist to navigate the airways, prolongs the surgical times, and can lead to situations in which it is hard to recover adequate oxygen saturation or even hypercapnic respiratory failure. In their guidelines for diagnostic flexible bronchoscopy, the British Thoracic Society recommends using oxygen supplementation when desaturation is significant (pulse oximeter oxygen saturation (SpO_2)>4% change or SpO_2<90% and prolonged (>1 min) to reduce risk of hypoxemia-related complications. When the working channel of a conventional bronchoscope is being used, the patient can only be ventilated through the area between the inner diameter of the endotracheal tube and the outer diameter of the bronchoscope unless the bronchoscope is removed, leading to a higher risk of hypoxia.

[0041] Tracheal oxygen supplementation through a single working channel has previously proven to be feasible and safe in preventing and correcting hypoxemia during flexible bronchoscopy, with the caveat of having to stop the procedure to supply oxygen. The addition of a second working channel allows the physician to use an independent channel to supply oxygen to the patient throughout the procedure, avoiding the development of hypoxia and with it preventable complications. The mechanism through which the tracheal supplementation of oxygen works might be similar to the one in transtracheal oxygen therapy; the anatomical dead space is bypassed with the working channel leading to a better oxygen delivery to respiratory bronchioles and alveoli with a requirement of fewer litters than when a nasal cannula is used.

[0042] FIGS. **9**A, **9**B, and **9**C illustrate a bronchoscope assembly **140** inserted into the bronchial tree to perform hemoptysis treatment. The second working channel of the assembly **140** enhances suction **321** and enables the use of an occlusion balloon **322** to stop bleeding and better locate the lesion **320** in the bronchial tree while maintaining adequate suction through the bronchoscope assembly's **140** main working channel. Furthermore, once the lesion **320** is identified, the second working channel allows for continued use of the main working channel, providing improved suction that enhances cleanup before coagulation occurs and offers better visualization of the lesion **320** while an ablation tool **323** is utilized via the second working channel, potentially reducing surgical time and complications.

[0043] FIGS. **10**A and **10**B illustrate a bronchoscope assembly **140** inserted into the bronchial tree to perform removal of a mucus plug **330**. In this embodiment, the second working channel can serve as a secondary suction port **331** to improve the removal of the mucus plug **330** or to simultaneously irrigate **332** the airway while suctioning, which could soften the mucus plug **330** and help eliminate thick mucus in the airways.

[0044] FIGS. **11**A and **11**B illustrate a bronchoscope assembly **140** inserted into the bronchial tree to perform deployment, revision, or removal of a stent **340**. The second working channel may allow for the simultaneous use of two forceps **341** during stent deployment, which can facilitate the manipulation of tracheal and bronchial stents, avoiding the need to redeploy the stent **340** and thereby reducing surgical times and potential medical waste. The second working channel may allow the bronchoscopist to use a second forceps **341** or an ablation device **342** to better handle the stent and remove granulation tissue **343** when necessary.

[0045] FIGS. **12**A, **12**B, and **12**C illustrate a bronchoscope assembly **140** inserted into the bronchial tree to perform resection of endobronchial tumors **350**. The second working channel may allow for use of two tools, for example a forceps **351** and an ablation catheter **352**, a forceps **351** and a snare **353**, a forceps **351** and a balloon, ablation, and suction **353**, and many other combinations that may lead to better surgical outcomes and shorter surgical times while providing more flexibility to the bronchoscopist performing the procedure.

[0046] FIGS. **13**A and **13**B illustrate a bronchoscope assembly **140** inserted into the bronchial tree to perform removal of a foreign body **360**. The second working channel may enable bronchoscopists to simultaneously use a basket **363** with forceps **362** or use forceps **362** with a cryoprobe **361** to more effectively grasp foreign bodies that might otherwise be difficult to handle or could come loose and fall back into the airway, potentially leading to complications or extended procedure times.

[0047] The second working channel may provide further benefits to certain procedures. For example, the second working channel may provide bronchoscopists with the ability to use the main bronchoscope channel for suction while utilizing the additional channel for irrigation. This creates a loop system that significantly improves efficiency and reduces surgical time, addressing one of the most cumbersome and time-consuming aspects of bronchoscopic treatment for pulmonary alveolar proteinosis (PAP).

[0048] Bronchial thermoplasty/Rheox procedures can be prolonged due to the vast amount of mucus in the airways of patients with asthma and COPD. The second working channel may provide suction while the main bronchoscope working channel remains occupied by the thermoplasty/Rheox probe. Additionally, oxygen therapy can be provided if needed during the procedure.

[0049] The second working channel may help prevent the two components of fibrin glue from combining inside of the working channel of the bronchoscope which may lead to solidification of the glue, rendering the bronchoscope useless. Being able to apply each of the components of the glue inside the airways that provides more precise application, leading to better outcomes for treatment of bronchopleural fistulas or alveolar-pleural fistulas.

[0050] The second working channel may allow the bronchoscopist to insufflate the stomach using oxygen while the guidewire is advanced to the stomach via the main bronchoscope working channel. This percutaneous endoscopic gastrostomy (PEG) tube procedure increases the success rate while ensuring adequate apposition of the stomach wall to the abdominal wall, preventing complications.

[0051] The second working channel may also improve diagnostic procedures. For example, the second working channel may be utilized for suction while the main working channel operates a cryoprobe, ensuring improved visualization during the diagnostic procedure. Once the biopsy is completed, the second working channel can simultaneously deploy a thermoablative tool or an occlusion balloon to address any bleeding, enhancing patient safety. Additionally, the second working channel may be used to grasp and secure the frozen biopsy tissue with tools such as forceps or a basket, preventing tissue loss during probe thawing and thereby improving the biopsy yield.

[0052] In a further implementation, a bronchoscope having a single cylindrical shaped tubular body can also be used in which a first and a second working channel can be used in which both working channels have the same size or they have different sizes to enable use of different tools or therapeutic applications. As shown in FIG. **14**, the bronchoscope **400** has a distal end having a distally mounted imaging chip **402**, one or more light emitters **404**, **406** such as white light emitting diodes (LEDs) a larger working channel **420** and a smaller working channel **410**. A catheter **440** having a distal end **450** with imaging aperture or a small diameter tube to view or conduct procedures as previously described herein within the smaller diameter bronchial airways of the patient's lung. An embodiment of this design can include a channel **415** in which a working channel insert can be mounted that slides into position and is connected to the adapter assembly. This embodiment rigidly aligns the two components at the distal end to create a cylindrical tubular body and can enable the use of different size working channels within the working channel inert.

[0053] The second working channel may allow use of suction in case of bleeding to maintain a clean field of view. Like the cryobiopsy example, the second working channel may be used to operate a thermoablative tool immediately after the biopsy if bleeding is detected.

[0054] It will be appreciated by those skilled in the art that modifications to and variations of the above-described systems and methods may be made without departing from the inventive concepts disclosed herein. Accordingly. the disclosure should not be viewed as limited except as by the scope and spirit of the appended claims.

1. A bronchoscope system comprising:

a bronchoscope having a fiberoptic illumination channel extending through a tubular body, an imaging detector, and a first working channel extending through the tubular body:

a directional actuator to control deflection of a distal tip of the bronchoscope; and

an adapter device attachable to an exterior surface of the tubular body, the adapter device including a second working channel including a port at a proximal end for coupling to an oxygen source.

2. The system of claim **1** wherein the directional actuator positions the distal tip of the bronchoscope in a first direction and a second direction orthogonal to the first direction.

3. The system of claim **1** further comprising a release actuator that separates the adapter device from the bronchoscope.

4. The system of claim **1** wherein the imaging detector is mounted in a proximal section or a distal section of the bronchoscope.

5. The system of claim **1** further comprising a fluid exchange system coupled to at least one bronchoscope channel.

6. The system of claim **1** wherein the tubular body has a diameter in a range of 4 to 8 mm.

7. The system of claim **1** wherein the bronchoscope further comprises a light source.

8. A bronchoscope comprising;

a bronchoscope handle connected to a tubular body for insertion into a bronchial airway of a lung wherein the tubular body has an outer diameter of less than 6 mm and comprises a first working channel, a second working channel, an imaging device and an illumination device, the first working channel having an inner diameter of at least 1.6 mm; and

a port at a proximal end of the second working channel to connect to a fluid source;

a flexible distal tip on a distal end of the tubular body for steering the tubular body through the bronchial tree, the flexible distal tip being operative is response to a directional actuator.

9. The bronchoscope of claim **8** wherein the fluid source comprises an oxygen source.

10. The bronchoscope of claim **8** wherein the second working channel extends through a detachable adapter that extends along the tubular body.

11. The bronchoscope of claim **8** wherein the port is configured to connect to a negative pressure source to apply suction through the second channel.

12. The bronchoscope of claim **8** wherein the first working channel is configured to receive a tool that can be extended through a distal opening of the first working channel.

13. The bronchoscope of claim **12** wherein a further tool is insertable through the second working channel to perform a surgical operation with the bronchial airway.

14. The bronchoscope of claim **12** wherein the tool comprises at least one of a snare, a forceps, a tissue ablation device, a suction tool, a cryoprobe, a retrieval basket, a balloon and a catheter.

15. A method for treating a bronchial condition comprising:

inserting a bronchoscope through the trachea and into a bronchial airway, the bronchoscope have a tubular body, an imaging detector, a light source to illuminate a region within the bronchial airway, a first working channel and a second working channel extending from a proximal end of the tubular body to a distal end;

viewing a portion of the bronchial airway with the bronchoscope;

performing a first operation using the first working channel to treat a condition of the bronchial airway;

during the first operation, performing a therapeutic procedure at a selected location along the bronchial airway using the second working channel.

16. The method of claim **15** wherein a distal end of the bronchoscope has a diameter less than 6 mm.

17. The method of claim **15** wherein the distal end of the bronchoscope is inserted into a depth in at least a third bronchial tree.

18. The method of claim **15** wherein the first operation comprises at least one of a hemoptysis procedure, mucus removal, deployment or removal of a stent, resection of a bronchial tumor, or foreign body removal.

19. The method of claim **15** wherein the bronchoscope comprises a handle attached to the tubular body, an imaging sensor, and a light source.

20. The method of claim **15** further comprising inserting a tool through at least one of the working channels.

21. The method of claim **20** wherein the tool comprises at least one of a snare, a forceps, a tissue ablation device, suction tool, a cryoprobe, a retrieval basket, a balloon, and a catheter.

22. The method of claim **15** further comprising applying suction through at least one of the first working channel and the second working channel.

23. The method of claim **15** wherein the step of inserting the bronchoscope further comprises attaching a working channel adapter, that includes the second working channel, to an outer surface of the bronchoscope.

24. The method of claim **23** wherein a sidewall of the working channel adapter has a concave sidewall having a radius of curvature corresponding to an outer wall of the tubular body.

25. The method claim **23** further comprising coupling a fluid source to a port on the working channel adapter.

26. The method of claim **15** further comprising coupling an oxygen source to at least one of the first working channel and the second working channel.

27. The method of claim **15** further comprising coupling a fluid source to flush a region of a patient's lung through the first working channel and suctioning fluid through the second working channel.

* * * * *