(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
22 January 2004 (22.01.2004)

PCT

(10) International Publication Number
WO 2004/006767 A2

(51) International Patent Classification[7]: A61B 5/107

(21) International Application Number:
PCT/US2003/021901

(22) International Filing Date: 15 July 2003 (15.07.2003)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
10/196,513 15 July 2002 (15.07.2002) US
10/254,392 24 September 2002 (24.09.2002) US

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(81) Designated States *(national)*: AE, AG, AL, AM, AT (utility model), AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ (utility model), CZ, DE (utility model), DE, DK (utility model), DK, DM, DZ, EC, EE (utility model), EE, ES, FI (utility model), FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK (utility model), SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

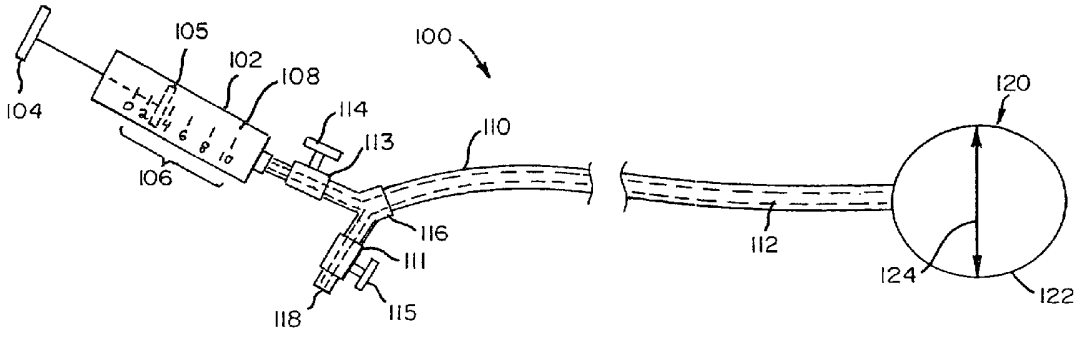
(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Declaration under Rule 4.17:
— *of inventorship (Rule 4.17(iv)) for US only*

Published:
— *without international search report and to be republished upon receipt of that report*

[Continued on next page]

(54) Title: DEVICE AND METHOD FOR MEASURING THE DIAMETER OF AN AIR PASSAGEWAY



(57) Abstract: AbstractThe invention provides a device for measuring an inside diameter of a body lumen, such as an air passageway. The device includes a flexible catheter (110, 310) having an inflation lumen (112, 312), a fluid dispenser (102, 200) in fluid communication with the inflation lumen and operable to communicate a measurable fluid volume change with the inflation lumen (112, 312), and an expandable member (120) in fluid communication with the inflation lumen and having a known relationship between volume and a changeable transverse dimension, the transverse dimension being changeable in response to fluid volume changes of the fluid dispenser and arranged for placement adjacent to opposing portions of an interior wall of the air passageway (80). The expandable member (120) may be dimensioned for transoral placement into the air passageway (80, and may comprise a balloon that includes a complaint material or a non-compliant material.

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DEVICE AND METHOD FOR MEASURING THE DIAMETER OF AN AIR PASSAGEWAY

Background

[0001] The present invention is generally directed to devices and methods for measuring the inside diameter of a body lumen and, more particularly, of air passageways. The present invention is more particularly directed toward measuring an inside diameter of an air passageway by transorally inserting a balloon having a known volume-to-diameter relationship in the air passageway, expanding the balloon with a volume of fluid to a known transverse diameter, and determining that the transverse diameter is adjacent to opposing portions of an interior wall of the air passageway.

[0002] Several emerging technologies employ devices placed in the air passageways to diagnose and treat conditions of the lung, conditions of organs and body structures that are in proximity to the lungs, and conditions that are systemic. For example, a treatment for Chronic Obstructive Pulmonary Disease (COPD) involves placing obstructing devices in selected air passageways to collapse lung portions distal of the obstructing devices. The devices are typically placed in air passageways between approximately 4 and 10 mm in diameter.

[0003] The performance of intra-bronchial devices may be enhanced by sizing the device to fit the air passageway. However, no method or device presently exists for determining the inside diameter of an air passageway. There is a need in the art for quickly and economically measuring the inside diameter of an air passageway to assist in selecting the size of an obstructing device.

[0004] In view of the foregoing, there is a need in the art for a new and improved apparatus and method for measuring the inside diameter of air passageways.

Summary

[0005] The invention provides a device for measuring an inside diameter of a body lumen, such as an air passageway. The device includes a flexible catheter, and a member carried on a distal tip of the catheter, the member having a known transverse dimension and arranged for placement adjacent to opposing portions of an interior wall of the air passageway.

[0006] The invention further provides a device for measuring the diameter of an air passageway. The device includes a flexible catheter having an inflation lumen, a fluid dispenser in fluid communication with the inflation lumen and operable to communicate a measurable fluid volume change with the inflation lumen, and an expandable member in fluid communication with the inflation lumen and having a known relationship between fluid volume and a changeable transverse dimension, the transverse dimension being changeable in response to fluid volume changes of the fluid dispenser and arranged for placement adjacent to opposing portions of an interior wall of the air passageway. The expandable member may include a balloon of compliant material. The expandable member may be dimensioned for transoral placement into the air passageway. The expandable member may have a collapsed configuration for placement in the air passageway and an expanded configuration for measuring a diameter of the air passageway. The expandable member may be arranged to transition from an expanded configuration to a collapsed configuration while in the air passageway, and then to transition from the collapsed configuration to a re-expanded configuration for measuring the diameter of another air passageway. The catheter may include configuration to be steerable within bronchi. The transverse dimension of the expandable member may be arranged to have a maximum transverse dimension of between 3 mm and 12 mm. The fluid dispenser may comprise a syringe or a syringe pump, and may further include gradations corresponding to air passageway diameters. The fluid communicated to the expandable member may include a radiopaque contrast substance. The expandable member may include a radiopaque contrast marker arranged for visualization of the changeable transverse dimension by fluoroscopy. The catheter may have a distal end, and the expandable member may be carried on the catheter proximal to the distal end. The device may further include a visualization device for observing adjacency of the transverse dimension and opposing portions of the interior wall of the air passageway. The visualization device may include a bronchoscope or a fluoroscope.

[0007] The invention still further provides an assembly for measuring an inside diameter of an air passageway. The assembly includes a flexible catheter having an inflation lumen, the inflation lumen being arranged for fluid coupling with a fluid dispenser operable to communicate a measurable fluid volume change with the inflation lumen, and an expandable member in fluid communication with the inflation lumen and having a known relationship between fluid volume and a changeable transverse dimension, the

transverse dimension of the expandable member being changeable in response to fluid volume changes of the fluid dispenser and arranged for placement adjacent to opposing portions of an interior wall of the air passageway. The expandable member may be carried on the catheter. The catheter may have a distal end, and the expandable member may be carried proximate to the distal end of the catheter. The expandable member may comprise a complaint material, and may be a balloon. The assembly may further include a visualization device for observing adjacency of the transverse dimension and opposing portions of the interior wall of the air passageway. The visualization device may include a bronchoscope or a fluoroscope. According to one alternative embodiment, adjacency of the expandable member with the passageway wall is determined by measuring a change in fluid pressure of the fluid within the inflation lumen and/or the expandable member.

[0008] The invention also provides a method of measuring an air passageway diameter. The method includes the steps of placing a balloon member in the air passageway having a known transverse dimension, and determining that the known transverse dimension is adjacent to opposing portions of an inner periphery of the air passageway.

[0009] In accordance with one embodiment, the method includes the steps of placing an expandable member in the air passageway, the expandable member changeable in a transverse dimension and having a known relationship between fluid volume and changeable transverse dimension, changing the changeable transverse dimension of the expandable member to a known transverse dimension by changing the fluid volume of the expandable member, and determining that the known expanded transverse dimension is adjacent to opposing portions of an inner periphery of the air passageway. The method may include the further step of placing a fluid dispenser operable to communicate a measurable fluid volume change into fluid communication with the expandable member, and the step of changing to a known transverse dimension includes the further step of measurably changing the volume of fluid in the expandable member with the fluid dispenser. The fluid dispenser may comprise a syringe. The fluid dispenser may include gradations related to air passageway diameter, and the step of determining air passageway diameter may include the further step of observing the gradations. The step of placing an expandable member in the air passageway may include the further step of transorally placing the expandable member in the air passageway. The step of determining may include the further step of visually observing adjacency, which may include using a

visualization device or a fluoroscope. The expandable member may include a radiopaque contrast substance arranged to enhance viewing the changeable transverse dimension, and the step of determining adjacency may use fluoroscopy. The expandable member may include a balloon of compliant material.

[0010] The invention further provides a device for measuring an inside diameter of a body lumen is provided. The device includes means for placing an expandable member having a known transverse dimension in the air passageway, and means for determining that the known transverse dimension is adjacent to opposing portions of an inner periphery of the air passageway.

[0011] The invention still further provides a device for measuring an inside diameter of an air passageway. The device includes means for placing an expandable member in the air passageway, the expandable member changeable in a transverse dimension and having a known relationship between volume and changeable transverse dimension, means for changing the changeable transverse dimension to a known transverse dimension, and means for determining that the known transverse dimension is adjacent to opposing portions of an inner periphery of the air passageway.

[0012] These and various other features as well as advantages of the present methods and devices will be apparent from reading the following detailed description and a review of the associated drawings.

Brief Description of the Drawings

[0013] The features of the present invention which are believed to be novel are set forth with particularity in the appended claims. The invention, together with further objects and advantages thereof, may best be understood by making reference to the following description taken in conjunction with the accompanying drawings, in the several figures of which like referenced numerals identify like elements, and wherein:

[0014] Figure 1 is a sectional view of a healthy respiratory system;

[0015] Figure 2 is a perspective view of the bronchi emphasizing the upper right lung lobe;

[0016] Figure 3 illustrates a respiratory system suffering from COPD;

[0017] Figure 4 illustrates an air passageway inside diameter measuring device in accordance with the present invention;

[0018] Figure 4a

[0019] Figure 5 illustrates an initial step in measuring an inside diameter of an air passageway at a measuring location with the measuring device of FIG. 4, in accordance with an aspect of the invention;

[0020] Figure 5a

[0021] Figure 6 illustrates intermediate step in measuring an inside diameter of an air passageway at measuring location with the measuring device of FIG. 4, in accordance with an aspect of the invention; and

[0022] Figure 7 illustrates a final step in measuring an inside diameter of an air passageway at measuring location with the measuring device of FIG. 4, in accordance with an aspect of the invention.

[0023] Figure 8 illustrates an embodiment of a measuring device including a pressure sensor;

[0024] Figure 9 illustrates an embodiment of a measuring device including an automatic controller;

[0025] Figure 10 illustrates an embodiment of a measuring device including an integral fluid dispenser;

[0026] Figure 11 illustrates an embodiment of a measuring device including a catheter with a plurality of lumens extending therethrough; and

[0027] Figure 12 illustrates a cross-sectional view of the device of Figure 11.

Detailed Description

[0028] In the following detailed description of exemplary embodiments of the invention, reference is made to the accompanying drawings, which form a part hereof. The detailed description and the drawings illustrate specific exemplary embodiments by which the invention may be practiced. These embodiments are described in sufficient detail to enable those skilled in the art to practice the invention. It is understood that other embodiments may be utilized, and other changes may be made, without departing from the spirit or scope of the present invention. The following detailed description is therefore not to be taken in a limiting sense, and the scope of the present invention is defined only by the appended claims.

[0029] Throughout the specification and claims, the following terms take the meanings explicitly associated herein unless the context dictates otherwise. The meaning of "a", "an", and "the" include plural references. The meaning of "in" includes "in" and "on." Referring to the drawings, like numbers indicate like parts throughout the views.

The term "coupled" means either a direct connection between the things that are coupled, or an indirect connection through one or more intermediary devices. Additionally, a reference to the singular includes a reference to the plural unless otherwise stated or inconsistent with the disclosure herein.

[0030] FIG. 1 is a sectional view of a healthy respiratory system. The respiratory system 20 resides within the thorax 22 that occupies a space defined by the chest wall 24 and the diaphragm 26.

[0031] The respiratory system 20 includes trachea 28; left mainstem bronchus 30 and right mainstem bronchus 32 (primary, or first generation); and lobar bronchial branches 34, 36, 38, 40, and 42 (second generation). FIG. 1 also illustrates segmental branches 44, 46, 48, and 50 (third generation). Additional sub-branches are illustrated in FIG. 2. The respiratory system 20 further includes left lung lobes 52 and 54 and right lung lobes 56, 58, and 60. Each bronchial branch and sub-branch communicates with a different portion of a lung lobe, either the entire lung lobe or a portion thereof. As used herein, the term "air passageway" is meant to denote either a bronchi or bronchioli, and typically means a bronchial branch of any generation.

[0032] A characteristic of a healthy respiratory system is the arched or inwardly arcuate diaphragm 26. As the individual inhales, the diaphragm 26 straightens to increase the volume of the thorax 22. This causes a negative pressure within the thorax. The negative pressure within the thorax in turn causes the lung lobes to fill with air. When the individual exhales, the diaphragm returns to its original arched condition to decrease the volume of the thorax. The decreased volume of the thorax causes a positive pressure within the thorax, which in turn causes exhalation of the lung lobes.

[0033] FIG. 2 is a perspective view of the bronchi emphasizing the upper right lung lobe 56. In addition to the bronchial branches illustrated in FIG. 1, FIG. 2 illustrates subsegmental bronchial branches 80, 82, 84, 86, 88, and 89 (fourth generation) providing air circulation to superior right lung lobe 56. The fifth- and sixth-generation bronchial branches are illustrated, but not given reference numbers.

[0034] The air passageways branch out, much like the roots of a tree. The bronchial segments branch into six generations or orders, and the bronchioles branch into approximately another three to eight generations or orders. Typically, each generation has a smaller diameter than its predecessor. The inside diameter of a generation varies depending on the particular bronchial branch, and further varies between individuals. For

example, a typical lobar bronchus 42 (third generation) providing air circulation to the upper right lobe 56 has an internal diameter of approximately 1 cm. A typical segmental bronchi 48 (fourth generation) has an internal diameter of approximately 4 to 7 mm. The fifth and sixth generations (no reference numbers) are each proportionately smaller. The bronchial segments include annular ligaments and irregularly located cartilages that provide structure and resilience. The cartilages become increasingly sparse as the bronchial segments become smaller in diameter. The bronchioles do not have ligaments and cartilages.

[0035] FIG. 3 illustrates a respiratory system suffering from COPD. In contrast to the lobes of FIG. 1, here it may be seen that the lung lobes 52, 54, 56, 58, and 60 are enlarged and that the diaphragm 26 is not arched but substantially straight. Hence, this individual is incapable of breathing normally by moving diaphragm 26. Instead, in order to create the negative pressure in thorax 22 required for breathing, this individual must move the chest wall outwardly to increase the volume of the thorax. This results in inefficient breathing causing these individuals to breathe rapidly with shallow breaths.

[0036] It has been found that the apex or segmental portions 62 and 66 of the upper lung lobes 52 and 56, respectively, are most affected by COPD. Hence, bronchial sub-branch obstructing devices are generally employed for treating the apex 66 of the right, upper lung lobe 56. The insertion of an obstructing member or a plurality of obstructing members treats COPD by deriving the benefits of lung volume reduction surgery without the need of performing the surgery. The intra-bronchial obstructions may be anchored in the air passageway to prevent movement or expulsion. In addition to treating COPD, it is presently contemplated that the intra-bronchial obstructions will be used for other purposes, including delivery of therapeutic substances.

[0037] The COPD treatment contemplates permanent collapse of a lung portion using at least one intra-bronchial obstruction. The collapse leaves extra volume within the thorax for the diaphragm to assume its arched state for acting upon the remaining healthier lung tissue. This should result in improved pulmonary function due to enhanced elastic recoil, correction of ventilation/perfusion mismatch, improved efficiency of respiratory musculature, and improved right ventricle filling. The treatment of COPD may include several intra-bronchial obstructing members being inserted in air passageways to form a redundant array. For example, if the volume of apex 66 of the right, upper lung lobe 56 were to be reduced, obstructing devices may be deployed in the four, fifth-generation air

passageways branching off of the fourth-generation bronchial branches 80 and 82, redundant obstructing members placed in the fourth-generation bronchial branches 80 and 82, and another redundant obstructing member placed in the third-generation branch 50.

[0038] The physical characteristics of the obstructing devices currently available limit the range of air passageway diameters that a particular device can obstruct. The limiting characteristics include both the range of air passageway diameters that a single device can obstruct, and the range of air passageway diameters that can be engaged by anchors of the obstructing device. Use of anchors can allow the obstructing member to be relatively loosely fitted against the air passageway wall, which may preserve mucociliary transport of mucus and debris out of the collapsed lung portion. Thus, obstructing devices are provided in a variety of sizes for the various sizes of air passageways.

[0039] The present system supports the use of intra-bronchial obstructing devices by enabling the inside diameter of the air passageway to be measured so that an appropriately sized obstructing device may be selected. As will be appreciated by those skilled the in art, the present invention may be used in conjunction with placing any type of obstructing member in an air passageway, including a plug, or a member that allows air passage in one direction but not another.

[0040] FIG. 4 illustrates an air passageway inside diameter measuring device 100, in accordance with one embodiment of the present invention. Measuring device 100 includes a fluid dispenser 102, a fluid 108, a flexible catheter 110, stopcocks 111 and 113, a junction 116, and an expandable member 120. FIG. 4a illustrates an alternative embodiment of the present invention in which the stopcocks are omitted.

[0041] The fluid dispenser (illustrated as a syringe 102) may be any device known in the art suitable for ejecting a measurable volume of the fluid 108 in amounts necessary to fill the expandable member 120. The syringe 102 includes visually readable gradations 106 that correspond to air passageway diameters, and is illustrated with air passageway diameters ranging between zero and 10 mm. The gradations 106 may reflect any range of anticipated air passageway diameters. The syringe 102 also includes a handle 104 connected to a piston 105, and arranged such that moving the handle 104 transmits the motion to the piston 105, and the motion is further transmitted to the fluid 108.

[0042] The fluid 108 may be any fluid suitable for use within the human body, such as a saline solution. A gas may be used, but a fluid is preferred to provide ease of use

and readability in the syringe 102. The fluid 108 may include a radiopaque contrast substance, such as diatrizoates and lohexol.

[0043] The flexible catheter 110 may be any flexible, steerable, elongated tubular member arranged for transoral or transnasal insertion into an air passageway, and may be made from any suitable material known in the art, such as polyethylene. The catheter 110 includes an inflation lumen 112 arranged to be in fluid communication with the syringe 102. The catheter 110 is also arranged to carry and be in fluid communication with the expandable member 120. In an embodiment, catheter 110 has an external diameter of approximately 2 mm. The catheter 110 may include opaque markings visible under fluoroscopy, such as gold or stainless steel, or other markings visible under other visualization methods.

[0044] The stopcocks 111 and 113 can be opened and closed by operating handles 112 and 114 respectively. The stopcocks 111 and 113 may be made from any material suitable for extracorporeal use. Tubular member 118 is used to direct any fluid 108 drained from the device 100.

[0045] The expandable member (illustrated as expandable balloon 120) includes a changeable transverse dimension 126, an outer periphery 122 of the changeable transverse dimension 126, and an interior inflatable cavity. The inflatable balloon 120 is generally arranged for intra-bronchial use, and may be made of any thin, flexible non-complaint or complaint or elastic surgical material suitable for use in air passageways, such as polyurethane, silicone, and natural latex which are often used for low pressure balloons. A balloon made of non-compliant material requires only a relatively low pressure for expansion. The balloon material provides a measurable or determinable relationship between balloon volume and the changeable transverse dimension 124. An elastic or compliant material provides a backpressure to reduce the changeable transverse dimension 124 once the measurement is taken.

[0046] Balloon 120 may have any transverse cross-sectional shape that can be expanded adjacent to opposing portions of an air passageway wall. For example, while balloon 120 is generally described herein as having a round, expanded cross-section with a generally uniform single transverse dimension, the balloon 120 may be any shape having a transverse dimension that can be expanded to contact opposing portions of an interior wall of an air passageway. For example, the balloon 120 may be an ellipsoidal transverse cross-section having a changeable transverse dimension that is expandable adjacent to opposing

portions of an interior wall 80 of air passageway 81. For purposes of clarity, aspects of the invention are described herein using a balloon 120 that expands into a round cross-section having an expanded transverse dimension that is a diameter. However, as stated above, the invention is not so limited. The balloon 120 may be carried on the distal end of the catheter 110, or proximate to the distal end of the catheter 110.

[0047] In FIG. 4, the balloon 120 is illustrated in a partially expanded state. The balloon 120 and the catheter 110 are arranged for transoral placement into an air passageway using minimally invasive methods, such as a working lumen of a bronchoscope. The balloon 120 has a deflated configuration for insertion and passage through a working lumen, and for movement within air passageways. In its deflated state, the balloon 120 is approximately 10 mm in length and has a collapsed diameter suitable for passage through a working channel of a bronchoscope, e.g. about 2-3 mm in diameter. In its expanded state, the balloon 120 should be capable of expanding to more than the anticipated cross-sectional area of the air passageway being measured. Typically, the air passageway inside diameters being measured are not expected to exceed about 10 mm in diameter, thus in one embodiment, the balloon 120 can have a maximum expanded diameter of approximately 12 mm. Because the air passageway diameter changes noticeably over a short distance, both the deflated and inflated lengths of the balloon are minimized so that a measurement for a particular location is not affected by the distal narrowing or proximal widening.

[0048] As shown in Figure 4, fitting member 116 joins the lumen 112 of catheter 110 to the lumens of stopcocks 111 and 113 in fluid communication. The fluid 108 contained in syringe 102 is arranged to be injected into the interior cavity of balloon 120 through the lumen of stopcock 113 and the lumen 112 of catheter 110. The syringe 102 and the balloon 120 are placed in fluid communication such that, when stopcock 113 is open, any change in the fluid volume of the syringe 102 corresponds to an inverse change in the fluid volume of the balloon 120. The fluid 108 and any air contained in the interior cavity of balloon 120 or lumen 112 may be drained through the lumen of stopcock 111 and out tubular member 118 by moving handle 115 to an open position.

[0049] The air passageway diameter gradations 106 may be marked in millimeter gradations on the syringe 102 because the balloon 120 provides a known relationship between the volume of the balloon 120 and its transverse dimension. The gradations 106 may start at "0" or another convenient increment such as 2 mm, and are

calibrated to correspond to the transverse dimension of the expanded balloon 120, and thus the air passageway. As the handle 104 is pushed from the starting gradation, a volume of the fluid 108, measurable by the gradations 106, is ejected from the syringe 102 and forced into the balloon 120 through fluid communication by the lumen 112 of catheter 110. Because the relationship between the volume and the changeable transverse dimension of the balloon 120 is known, the transverse dimension 124 of the expanded balloon 120 is known from the volume of the fluid 108 ejected from the syringe 102. The transverse dimension 124 is known or determined by observing the location of the syringe piston 105 with respect to the gradations 106. In an alternative embodiment, the gradations 106 may be marked in volume gradations, such as milliliters, and a conversion table used to convert volume to transverse dimension 124.

[0050] Correlation between volume and transverse dimension 124 for a particular balloon configuration may be established using a test bench. Balloon 120 is expanded in a series of openings with several known diameters, and a correlation is established between the expanded volumes of the test balloon 120 and the several known diameters. The syringe gradations 106 are established correlating the volume of the fluid 108 displaced by movement from the "0" gradation with the known diameter. Each individual measuring device 100 may have its gradations determined on a test bench. Alternatively, the physical parameters of the syringe 102 and the balloon 120 may be standardized, allowing standardized gradation markings 106.

[0051] FIG. 5 illustrates an initial step in measuring an inside diameter 126 of an air passageway 81 at a measuring location 128 with the measuring device 100 of FIG. 4, in accordance with an aspect of the invention. In an embodiment, the measuring device 100 is provided with its elements fluid coupled together and filled with fluid 108. The syringe 102, the lumen 112, and the collapsed balloon 120 are filled with saline solution as fluid 108, and any air bubbles in the fluid 108 have been removed. Further, the device 100 may be generally provided with the balloon 120 deflated to a minimum transverse dimension 124 of about 2 mm for insertion and movement, all air bubbles eliminated from the fluid 108, and the syringe piston 105 aligned with a gradation 106 representing the transverse dimension 124. For clarity, inside diameter 126 is illustrated slightly displaced from measuring location 128. However, it is contemplated that measuring device 100 will measure the inside diameter 126 at the measuring location 128.

[0052] An initial step includes transorally placing the distal end of catheter 110 and the balloon 120 into the trachea 28 and steering them into the air passageway 81 of the bronchus 80 to the measuring location 128. This may be accomplished by any method and/or device known in the art. The catheter 110 may be steered into air passageway 81 by being carried in a working lumen 134 of a bronchoscope 130; associated with and then steered by the bronchoscope 130; inserted after the bronchoscope 130 is proximate to the measuring location 128 and steered adjacent to the shaft of the bronchoscope 130; or steered using imaging/visualization techniques, such as computed tomography or radiography.

[0053] Continuing with FIG. 5, an embodiment is illustrated where a distal tip of the bronchoscope 134 has been steered into air passageway 81 for dimensioning. Once the distal tip is in proximity to measuring location 128, another step includes deploying the balloon 120 and the distal end of the catheter 110 from the working lumen 134. The deployment may be observed with viewing element 132 of the bronchoscope 130. A further initial step includes advancing the balloon 120 until its transverse dimension 124 is about a balloon length proximal of the measuring location 128.

[0054] In an alternative embodiment, illustrated in Figures 4a and 5a, the distal end of catheter 110 can be associated with the bronchoscope 130 by cinching with a loop of material carried in the working lumen 134, such as filament 138. The distal end of the bronchoscope 130, with the associated distal end of the catheter 110 and the balloon, 120, are steered into air passageway 81 for dimensioning. Alternatively, the catheter and bronchoscope can be steered to the measuring location 128 separately. Before inflating or expanding the balloon 120, the catheter 110 may be disassociated from the bronchosope 130 by releasing one end of the filament loop 138 and pulling the other end from the working lumen 134.

[0055] As also shown in Figures 4a and 5a, the expandable member 120 can comprise a balloon made from a non-compliant balloon material. A balloon made of non-compliant material requires only a relatively low pressure for expansion. A non-compliant balloon material provides a measurable or determinable relationship between balloon volume and the changeable transverse dimension 124. Although the balloon is generally described herein as having a circular cross-section, the balloon 120 can comprise any cross-sectional shape having a transverse dimension that can be expanded to contact opposing portions of an interior wall of an air passageway. For example, the balloon 120 may be an

ellipsoidal transverse-cross-section having an expandable transverse dimension that is expandable adjacent to opposing portions of an interior wall of air passageway 80.

[0056] FIG. 6 illustrates another step in measuring an inside diameter 126 of an air passageway 81 at measuring location 128 with a measuring device 100, in accordance with another embodiment of the invention. An intermediate step includes expanding the balloon 120 in the air passageway 81 to a first trial transverse dimension of the transverse dimension 124. The expansion is by opening stopcock 113 and advancing the handle 105 of the syringe 102 to eject a known volume of the fluid 108 into the inflation lumen 112 and correspondingly into the balloon 120. The ejected volume and resulting first trial transverse dimension are known by the gradations 106. The endoscopist may select the first trial transverse dimension to be slightly less than an estimated air passageway inside diameter 126. The endoscopist may estimate an air passageway inside diameter 126 based on the particular bronchial branch diameter to be measured.

[0057] For example, in a targeted bronchial branch with an estimated air passageway inside diameter 126 between five and six millimeters, a first trial transverse dimension of four millimeters may be selected. In such a case, the stopcock handle 114 is moved to an open position, and the handle 104 pressed until the plunger 105 aligns with the 4 mm gradient of gradations 106. The stopcock handle 114 is then moved to a closed position, preventing the compliant characteristic of balloon 120 or contact with the air passageway 81 from forcing fluid 108 back into the syringe 102.

[0058] Another step includes advancing the balloon 120 distally within the air passageway 81 until the transverse dimension 124 is proximate to the measuring location 128. The viewing element 132 is used to visually examine the periphery 122 of the balloon 120 at transverse dimension 124 to determine whether first trial transverse dimension is adjacent to the inside wall of the air passageway 81. As used herein, "adjacent" or "adjacency" means closing the space between the periphery 122 of the balloon 120 at transverse dimension 124 and an interior periphery of an interior wall of the air passageway 81. FIG. 6 illustrates a situation where the first trial transverse dimension does not result in the transverse dimension 124 being adjacent to opposing portions of an inner periphery of the air passageway wall 81. Failure of first trial transverse dimension 124 to achieve adjacency can be observed through the viewing element 132. The endoscopist may select a second trial transverse dimension, which may be 5 mm based on the separation observed between the periphery 122 and the inner periphery of the air passageway wall 81.

[0059] FIG. 7 illustrates a final step in measuring an inside diameter 126 of an air passageway 81 at measuring location 128 with measuring device 100 of FIG. 4, in accordance with an aspect of the invention. The balloon 120 is retracted from measuring location 128 by about a balloon length to allow room to change to the second trial transverse dimension, which is 5 mm in the example being illustrated herein. To change the transverse dimension 124 to the second trial transverse dimension, the endoscopist changes the volume of fluid 108 in the balloon 120 in substantially the same manner as the first trial transverse dimension was established. If the first trial transverse dimension had been larger than the inside diameter 126, the handle 104 would be retracted until the piston 105 aligns with a different second trial transverse dimension.

[0060] Another step includes re-advancing the balloon 120 distally within the air passageway 81 until the transverse dimension 124 is located at the measuring location 128. The viewing element 132 is used to visually examine the periphery 122 of the balloon 120 at transverse dimension 124 to determine whether second trial transverse dimension 124 is adjacent to the inside wall of the air passageway 81. FIG. 7 illustrates the transverse dimension 124 adjacent to opposing portions of an inner periphery of the air passageway 81. If adjacency is not achieved, the endoscopist selects additional trial transverse dimensions and continues as described above until adjacency is achieved.

[0061] When the periphery 122 of transverse dimension 124 is adjacent to an interior periphery 81 of the air passageway 80, the expanded transverse dimension 124 of the balloon 120 is the same as the inside diameter 126 of the air passageway 81. In the embodiment illustrated in FIG. 7, adjacency between the periphery 122 of the balloon 120 and the inside wall of the air passageway 81 at measuring location 128 is visually confirmed by observation through the viewing element 132 of the bronchoscope 130. When adjacency exists, the diameter 126 at measuring location 128 is read by the alignment of the syringe piston 105 with one or more of the gradations 106, which would be 5 mm in the example above. When the balloon 120 has an expandable transverse cross-section that is not round, the changeable transverse dimension 124 is expanded to a point where a portion of its periphery 122 at the measuring location 128 is adjacent to opposing portions of the interior periphery 81 of the interior wall of the air passageway 80.

[0062] After the measurement is taken, the measuring device 100 is arranged to allow the balloon 120 to be deflated by opening stopcock 113 and drawing the fluid 108 back into the syringe 102 while the balloon 120 is within the air passageway 81. The

catheter 110 and the deflated balloon 120 may then be steered to another measuring location to measure another air passageway diameter 126.

[0063] FIG. 8 illustrates another embodiment of an air passageway inside diameter measuring device 140 in accordance with the present invention. In the present embodiment, the adjacency of the balloon 120 with the internal surface of the bronchial wall 80 can be determined by measuring a fluid pressure within the balloon 120 and lumen 112. Measuring device 140 is similar to measuring device 100 of FIG. 4, and includes a port 144 coupled to inflation lumen 112 for sensing pressure within the lumen, and a pressure indicator 142. The port 144 may be incorporated in syringe 102, or optionally may be a separate component coupled to syringe 102 by a coupler 146. Pressure indicator 142 may be any device known to those in the art operable to sense and indicate the pressure of the fluid 108 in the inflation lumen 112. Pressure indicator 142 may be any type of device or combination of devices operable to sense and indicate pressure, including mechanical, electrical, or a combination thereof.

[0064] The structure and resilience of the bronchi resist expansion beyond the bronchi's natural or normal diameter. This resistance provides a discernable pressure increase, or a pressure spike, in the inflation lumen 112 of the balloon 120 when expansion beyond the normal or natural diameter is attempted. Because of the resistance to further expansion, contact may also be tactilely perceived by an increase in the force required to eject the fluid 108 from the syringe 102. In an alternative embodiment, a controller may be used to sense this pressure increase, and/or to prevent further ejection of fluid by the syringe. The controller may be mechanical or electronic, or a combination.

[0065] In operation, the catheter 110 and the balloon 120 of the measuring device 140 are placed in the air passageway 81 in the same manner as described for measuring device 100 in FIGS. 5 and 6. Instead of visually confirming when the expanded balloon 120 is adjacent to a wall of the air passageway 81, the pressure of the fluid 108 in the inflation lumen 112 is monitored. The inflation lumen 112 pressure during expansion of the balloon 120 should typically be relatively uniform and in the neighborhood of 300 mmHg. A pressure spike in the neighborhood of 500 mmHg should occur when the balloon 120 contacts the wall of the air passageway 81 and further expansion should be opposed by the structure of the bronchus 80. When the pressure in the inflation lumen equals a predetermined level, which is 500 mmHg for this embodiment, movement of the

syringe handle 104 is terminated and the gradations 106 are read to determine the diameter of the air passageway 81.

[0066] FIG. 9 illustrates another embodiment of an air passageway inside diameter measuring device 160 in accordance with the present invention. The measuring device 160 is similar to the measuring device 140, and additionally includes a controller 170 and an automatic fluid dispenser illustrated as a syringe pump 180. The controller 170 includes a digital display 172, an indicator light 174, and a pressure sensor 176.

[0067] The controller 170 is coupled to the syringe pump 180, and to the pressure sensor 176 that is coupled to the inflation lumen 112. Controller 170 is operable to control fluid ejection from the syringe pump 180, sense pressure in the inflation lumen 112, determine volume of fluid 108 ejected from the syringe 102 before a predetermined pressure occurs in the inflation lumen 112, correlate volume of fluid 108 ejected to diameter of the balloon 120, determine air passageway diameter in response to volume of fluid 108 ejected, and display determined air passageway diameter on the digital display 172. Controller 170 may also be operable to activate the indicator display 174, and optionally to activate an audible indicator (not shown) when pressure in the inflation lumen 112 exceeds a predetermined level. Controller 170 may be any device, including electrical, mechanical, or a combination thereof, and may include a computing device, an ASIC, and/or a microprocessor.

[0068] Syringe pump 180 may be any device known in the art, including electrical, mechanical, or a combination thereof, arranged to eject a measurable volume of the fluid 108, which may be from a syringe such as the syringe 102, in response to controller 170. Sensor 176 may be any device known in the art, including electrical, mechanical, or a combination thereof, arranged to provide a signal to controller 170 in response to the pressure in inflation lumen 112. Digital display 172 may be any device known in the art, including an LCD, a series of LEDs, or an electrical or mechanical device, or a combination thereof, arranged to provide a numerical display representing an air passageway diameter. Indicator light 174 may be any device known in the art, including an LED, arranged to illuminate in response a signal from controller 170.

[0069] In operation, the catheter 110 and balloon 120 of measuring device 160 are placed in the air passageway 81 in the same manner as described for measuring device 100 in FIGS. 5 and 6. The controller 170 activates the syringe pump 180, and controls the ejection of a volume of the fluid 108 from the syringe 102 into inflation lumen 112. The

balloon 120 expands in response to the ejected fluid 108, and the sensor 176 senses pressure in the inflation lumen 112 and provides a signal to the controller 170. Instead of visually confirming when the expanded balloon 120 contacts the wall of the air passageway 81, the pressure of the fluid 108 in the inflation lumen 112 is monitored by controller 170. When the balloon 120 contacts the wall of the air passageway 81 and further expansion is opposed by the structure of the air passageway 80, a predetermined pressure occurs in the lumen 112 that is sensed by the sensor 176, which provides a signal to the controller 170. The controller 170 stops ejection of the fluid 108, determines the volume of the fluid 108 ejected from the syringe 102, correlates the volume to the diameter of the balloon 120 according to a look-up table or other data stored in the controller 170 to determine the diameter of the balloon 120, and displays the diameter of the balloon 120 as the diameter of the air passageway 81 on the display 172. Optionally, the controller 170 also activates indicator light 174 and the audible device (not shown) when the predetermined pressure occurs in the lumen 112.

[0070] FIG. 10 illustrates an alternative embodiment of an air passageway inside diameter measuring device 200 with a partial cross-section illustrating an integral fluid dispenser 210. Measuring device 200 is similar to the devices described above, with the addition of an integral fluid dispenser rather than an external fluid dispenser.

[0071] The integral fluid dispenser 210 includes shaft 103, handle 104, piston 105, gradations 106, a portion of the proximal portion of the lumen 112, an index mark or point 107. The structure for changing the fluid volume of the intgral fluid dispenser 210 is formed by the piston 105 and a proximal portion of the lumen 112 cooperatively acting as a piston/cylinder combination for communicating a measurable volume of fluid 108 into the interior inflatable cavity of the balloon 120. Shaft 103 rigidly couples handle 104 to piston 105. Gradations 106 can be incorporated into shaft 103, and read by alignment with index point 107 o the proximal end of the catheter 110 in substantially the same manner as the gradations 106 of the devices described above.

[0072] In operation, measuring device 200 and fluid dispenser 210 are arranged and function substantially similarly to measuring device 100 and its syringe as described above. When the handle 104 is advanced, the piston 105 communicates a measurable fluid volume change with the balloon 120, which is represented by gradations 106.

[0073] FIGS. 11 and 12 illustrate an air passageway inside diameter measuring device 300 with a catheter 310 having a plurality of lumens 312 and 314, in accordance

with another embodiment of the present invention. FIG. 12, is a cross-sectional view of the catheter 310. Measuring device 300 is substantially similar to the embodiments described above with the advantageous addition of a plurality of lumens. The catheter 310 of the present embodiment comprises an inflation lumen 312 and a purge lumen 314. A junction fitting 316 has two lumens that individually are in fluid communication with lumens 312 and 314, one lumen arranged to fluid couple the purge lumen 314 to the stopcock 111, and the other lumen arranged to fluid couple the inflation lumen 312 to the stopcock 113.

[0074] In operation, the purge lumen 314 promotes flow of entrapped air out of the syringe 102, catheter 310 and the balloon 120. A source of fluid 108 for purging which may be a syringe similar to the syringe 102, is fluid coupled to junction fitting 316, and lumen 312. Stopcocks 111 and 113 are opened by appropriately moving handles 115 and 114 respectively, and fluid 108 is ejected from the syringe and flowed through collapsed balloon 120 to purge air from measuring device 300. Air and fluid 108 are drained from the measuring device 300. Air and fluid 108 are drained from the measuring device 300 from the lumen of stopcock 111 at tubular member 118. The presence of the lumen 314 for purging air and fluid 108 from the balloon 120 facilitates purging entrapped air from the device 300. Once all air is purged, stopcocks 111 and 113 are closed. The purging source of fluid 108 is removed from junction fitting 316, and syringe 102 is then coupled. Measuring device 300 can then be used to measure the inside diameter of a body lumen as described in conjunction with measuring device 100.

[0075] The above description includes embodiments of the invention providing a device and method for measuring an insie diameter of a body lumen, such as an air passageway in conjunction with placing an obstructing or valve device in the air passageway for reducing a lung volume. However, the invention should not be limited to such a device or method. Other embodiments of the invention may be used to measure inside diameters of an air passageway for placing other types of devices or having other treatment objectives. Further, other embodiments of the invention may be used to measure a diameter of other body lumens for other procedures, including preparation for and implanting a device or other medical procedure.

[0076] Although the present invention has been described in detail with reference to certain preferred embodiments, other embodiments are possible. Therefore, the spirit or scope of the appended claims should not be limited to the description of the

embodiments contained herein. It is intended that the invention resides in the claims hereinafter appended.

WHAT IS CLAIMED IS:

1. A device for measuring an inside diameter of a body lumen, the device comprising:

a flexible catheter; and

a member carried on a distal tip of the catheter, the member having a known transverse dimension and arranged for placement adjacent to opposing portions of an interior wall of the body lumen.

2. A device for measuring an inside diameter of an air passageway, the device comprising:

a flexible catheter having an inflation lumen;

a fluid dispenser in fluid communication with the inflation lumen and operable to communicate a measurable fluid volume change with the inflation lumen; and

an expandable member in fluid communication with the inflation lumen and having a known relationship between fluid volume and a changeable transverse dimension, the transverse dimension being changeable in response to fluid volume changes of the fluid dispenser and arranged for placement adjacent to opposing portions of an interior wall of the air passageway.

3. The device of claim 2, wherein the expandable member includes dimensioning for transoral placement into the air passageway.

4. The device of claim 2, wherein the catheter is adapted to be steerable within bronchi.

5. The device of claim 2, wherein the expandable member comprises a balloon that includes a complaint material.

6. The device of claim 2, wherein the transverse dimension of the expandable member is arranged to have a maximum transverse dimension of between 3 mm and 12 mm.

7. The device of claim 2, wherein the expandable member has a collapsed configuration for placement in the air passageway and an expanded configuration for measuring a diameter of the air passageway.

8. The device of claim 7, wherein the expandable member is arranged to transition from the expanded configuration to the collapsed configuration while in the air passageway, and then to transition from the collapsed configuration to a re-expanded configuration for measuring the diameter of another air passageway.

9. The device of claim 2, wherein the fluid dispenser comprises a syringe.

10. The device of claim 2, wherein the fluid dispenser comprises a syringe pump.

11. The device of claim 2, wherein the fluid dispenser further comprises gradations corresponding to air passageway diameters.

12. The device of claim 2, wherein fluid communicated to the expandable member includes a radiopaque contrast substance.

13. The device of claim 2, wherein the expandable member includes a radiopaque contrast marker arranged for visualization of the changeable transverse dimension by fluoroscopy.

14. The device of claim 2, wherein the catheter has a distal end, and the expandable member is carried on the catheter proximal to the distal end.

15. The device of claim 2, wherein the expandable member includes a balloon of compliant material.

16. The device of claim 2, further including a visualization device for observing adjacency of the transverse dimension and opposing portions of the interior wall of the air passageway.

17. The device of claim 16, wherein the visualization device includes a bronchoscope.

18. The device of claim 16, wherein the visualization device includes a fluoroscope.

19. An assembly for use in measuring the inside diameter of an air passageway, the assembly comprising:

a flexible catheter having an inflation lumen, the inflation lumen being arranged for fluid coupling with a fluid dispenser operable to communicate a measurable fluid volume change with the inflation lumen; and

an expandable member in fluid communication with the inflation lumen and having a known relationship between fluid volume and a changeable transverse dimension, the transverse dimension of the expandable member being changeable in response to fluid volume changes of the fluid dispenser and arranged for placement adjacent to opposing portions of an interior wall of the air passageway.

20. The assembly of claim 19, wherein the expandable member is carried on the catheter.

21. The assembly of claim 20, wherein the catheter has a distal end, and the expandable member is carried proximate to the distal end of the catheter.

22. The assembly of claim 19, wherein the expandable member comprises a complaint material.

23. The assembly of claim 19, wherein the expandable member includes a balloon of compliant material.

24. The assembly of claim 19, further including a visualization device for observing adjacency of the transverse dimension and opposing portions of the interior wall of the air passageway.

25. The device of claim 24, wherein the visualization device includes a bronchoscope.

26. The assembly of claim 24, wherein the visualization device includes a fluoroscope.

27. A method of measuring an inside diameter of a body lumen, the method including the steps of:

placing a member having a known transverse dimension in the body lumen; and

determining that the known transverse dimension is adjacent to opposing portions of an inner periphery of the body lumen.

28. A method of measuring an inside diameter of an air passageway, the method including the steps of:

placing an expandable member in the air passageway, the expandable member changeable in a transverse dimension and having a known relationship between fluid volume and changeable transverse dimension;

changing the changeable transverse dimension of the expandable member to a known transverse dimension by changing the fluid volume of the expandable member; and

determining that the known expanded transverse dimension is adjacent to opposing portions of an inner periphery of the air passageway.

29. The method of claim 28, including the further step of placing a fluid dispenser operable to communicate a measurable fluid volume change into fluid communication with the expandable member, and the step of changing to a known transverse dimension includes the further step of measurably changing the volume of fluid in the expandable member with the fluid dispenser.

30. The method of claim 28, wherein the fluid dispenser comprises a syringe.

31. The method of claim 30, wherein the fluid dispenser comprises gradations related to air passageway diameter, and the step of determining air passageway diameter includes the further step of observing the gradations.

32. The method of claim 28, wherein the step of placing an expandable member in the air passageway includes the further step of transorally placing the expandable member in the air passageway.

33. The method of claim 28, wherein the step of determining includes the further step of visually observing adjacency.

34. The method of claim 33, wherein the step of visually observing adjacency includes using a visualization device

35. The device of claim 34, wherein the visualization device includes a bronchoscope.

36. The assembly of claim 34, wherein the visualization device includes a fluoroscope.

37. The method of claim 28, wherein the expandable member includes a radiopaque contrast substance arranged to enhance viewing the changeable transverse dimension.

38. The method of claim 28, wherein the expandable member includes a radiopaque contrast substance arranged to enhance viewing the changeable transverse dimension, and further wherein the step of determining adjacency uses fluoroscopy.

39. The method of claim 28, wherein the expandable member includes a balloon of compliant material.

40. A device for measuring an inside diameter of an air passageway, the device comprising:

means for placing a member having a known transverse dimension in the air passageway; and

means for determining that the known transverse dimension is adjacent to opposing portions of an inner periphery of the air passageway.

41. A device for measuring an inside diameter of an air passageway, the device comprising:

means for placing an expandable member in the air passageway, the expandable member changeable in a transverse dimension and having a known relationship between volume and changeable transverse dimension;

means for changing the changeable transverse dimension to a known transverse dimension by changing the volume of the expandable member; and

means for determining that the known transverse dimension is adjacent to opposing portions of an inner periphery of the air passageway.

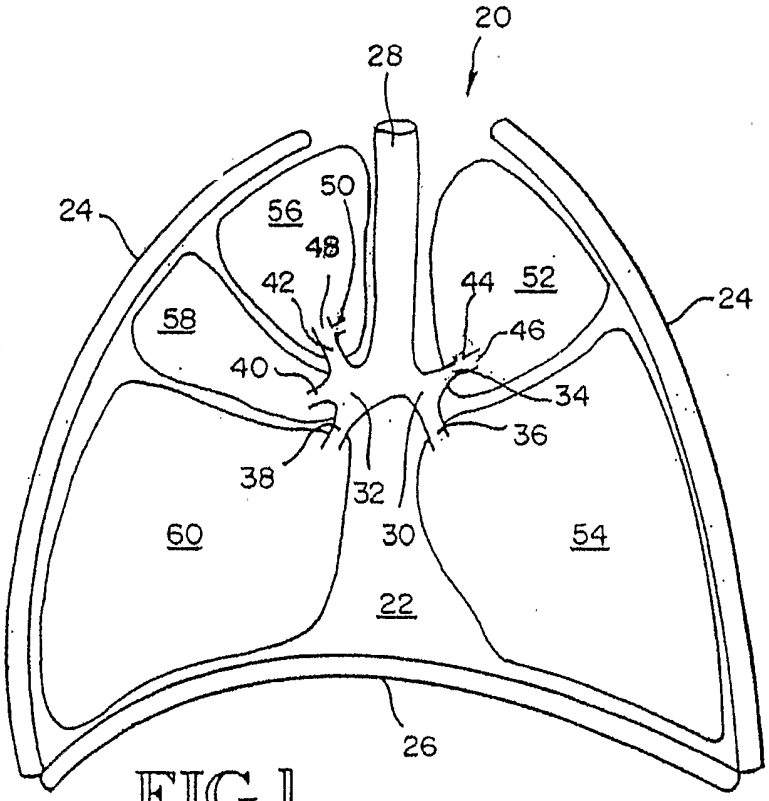
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FIG. 1

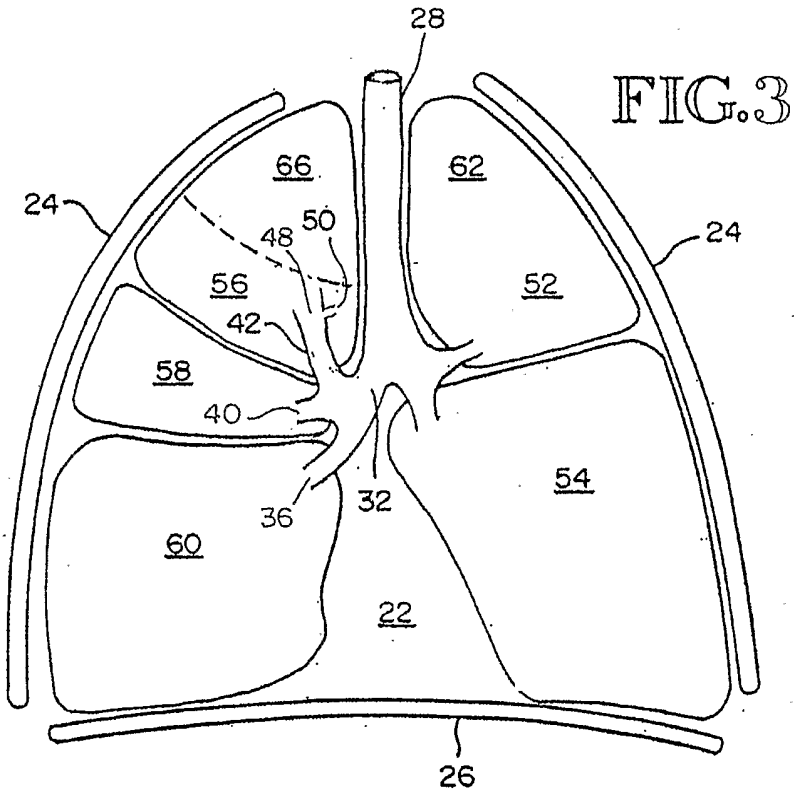
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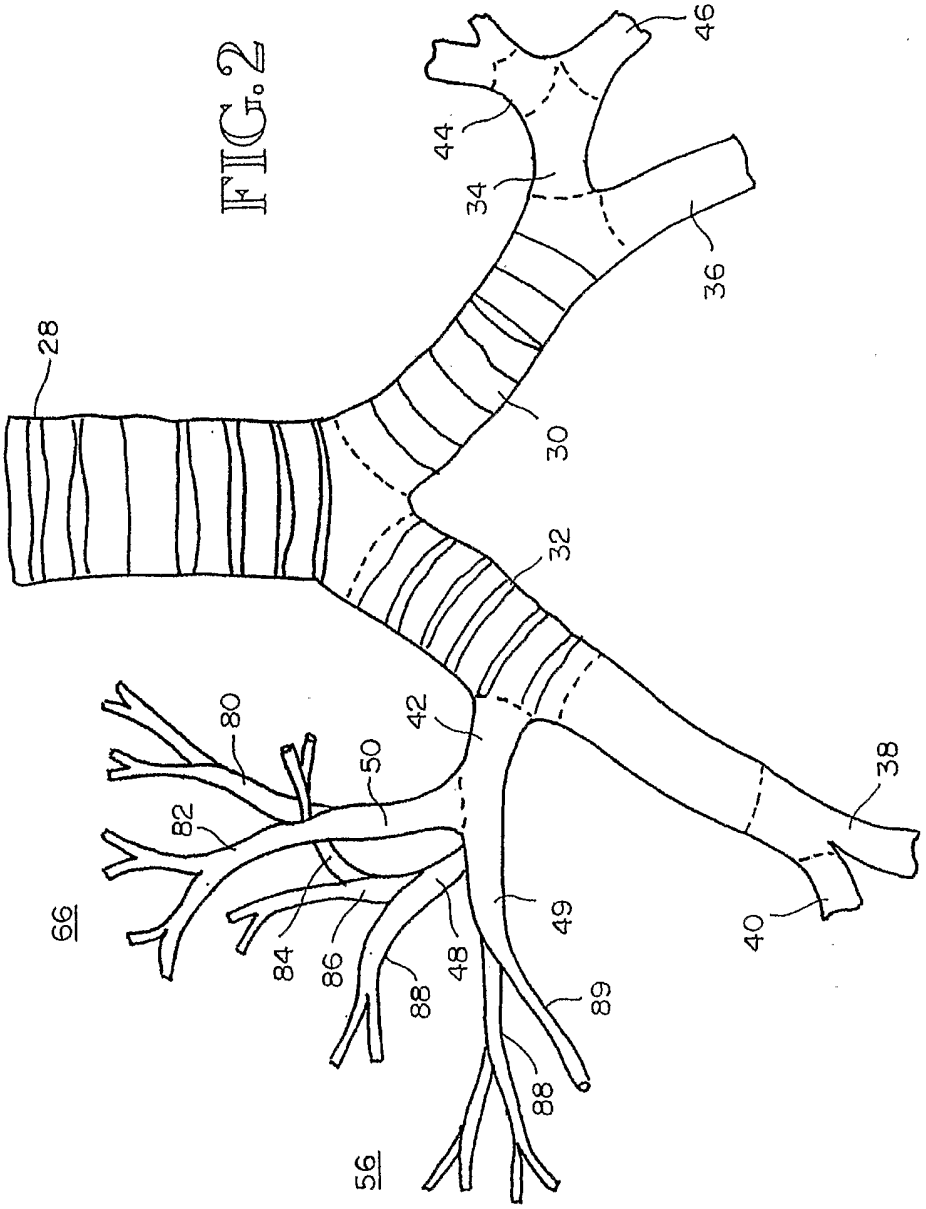
FIG. 3

FIG. 2



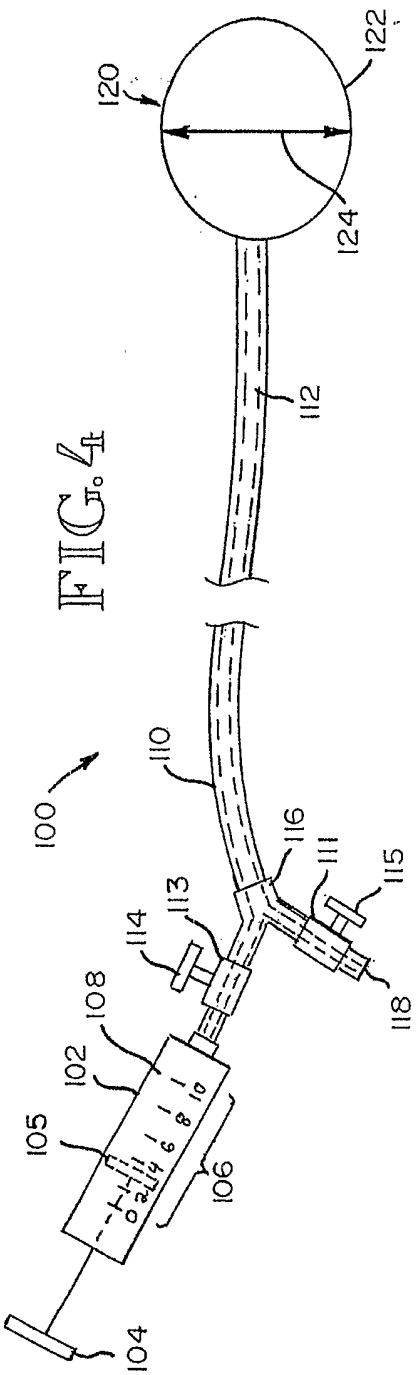

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FIG. 4

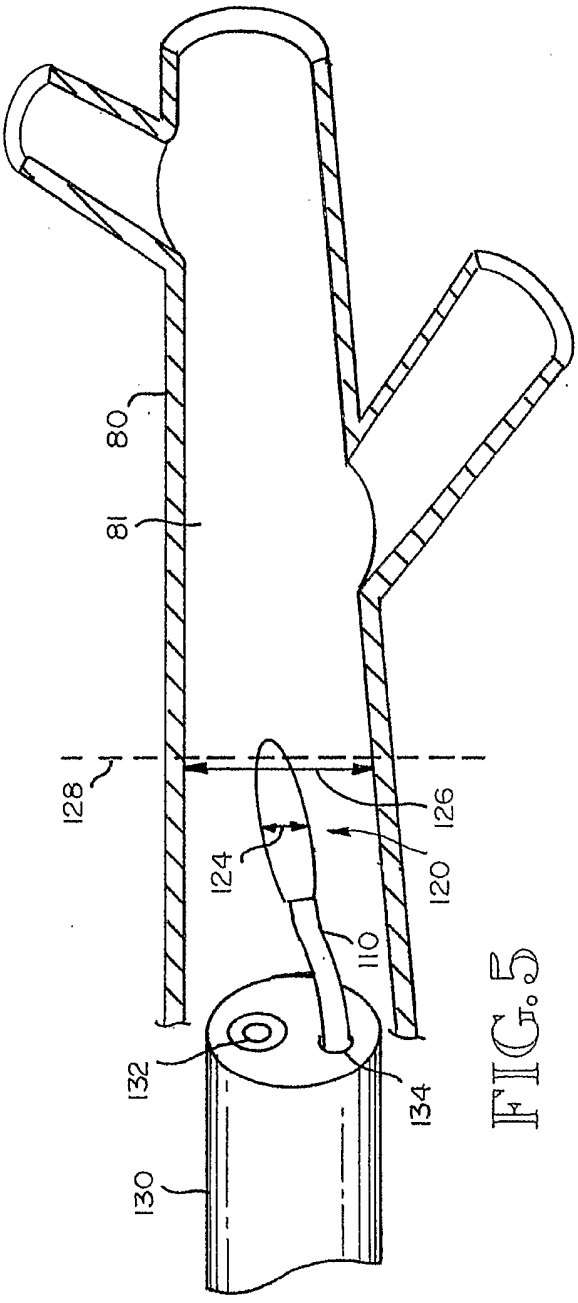
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FIG. 5

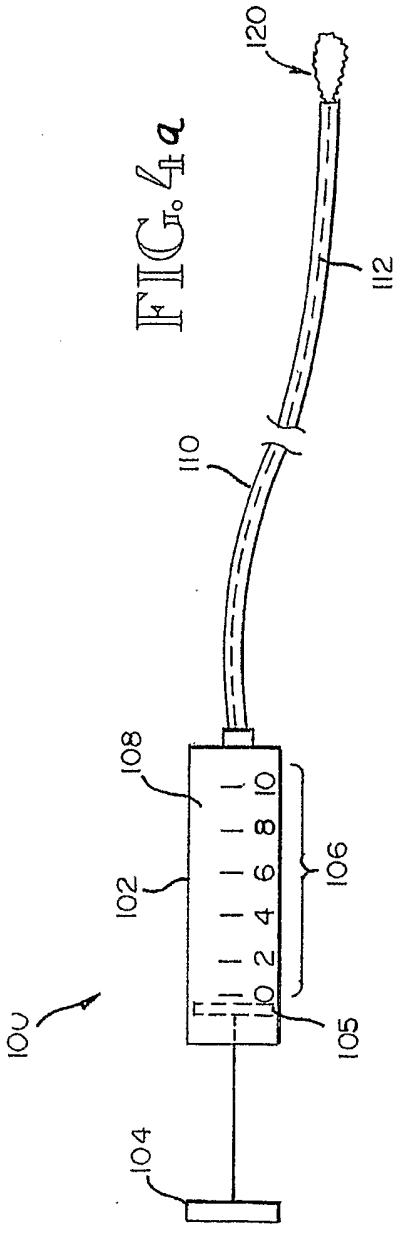
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FIG. 4a

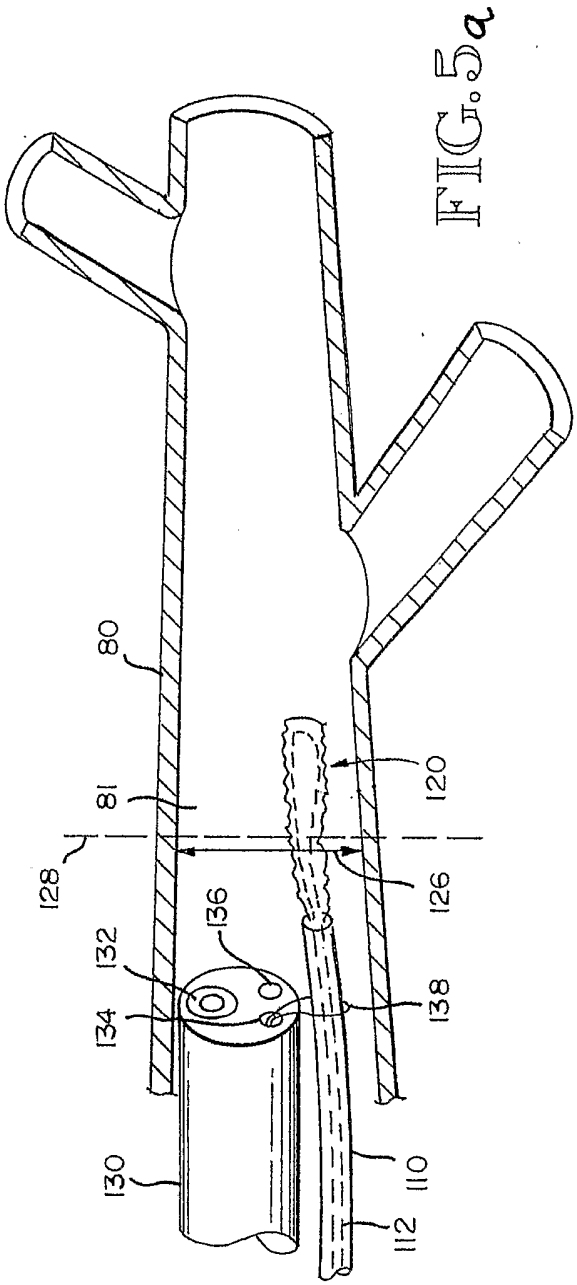
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FIG. 5a

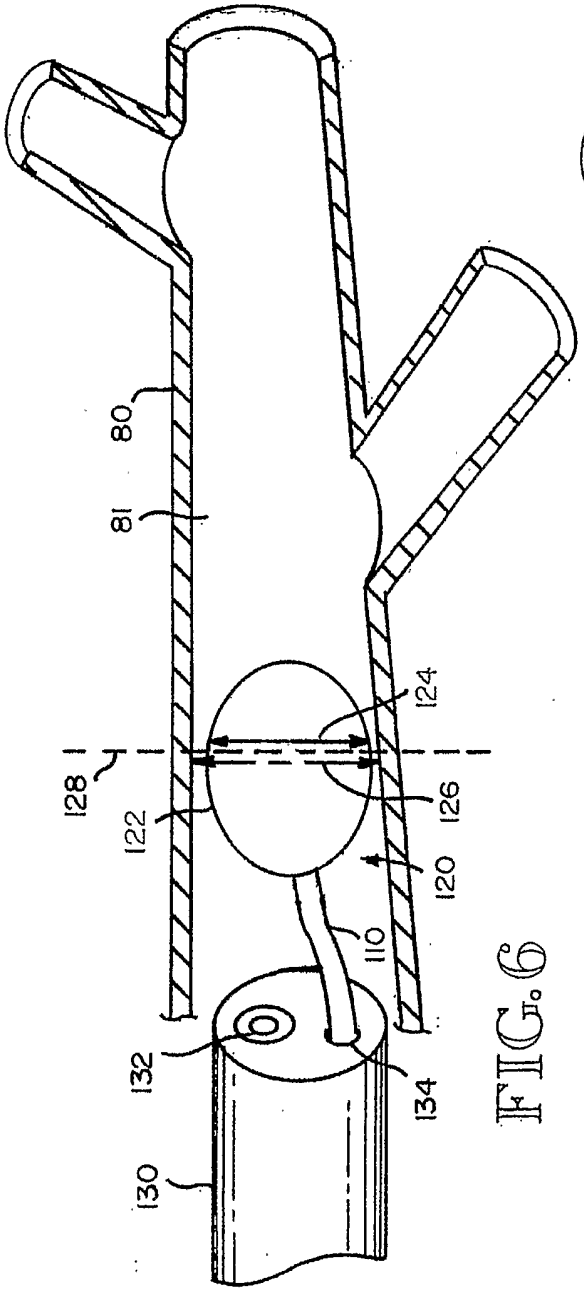
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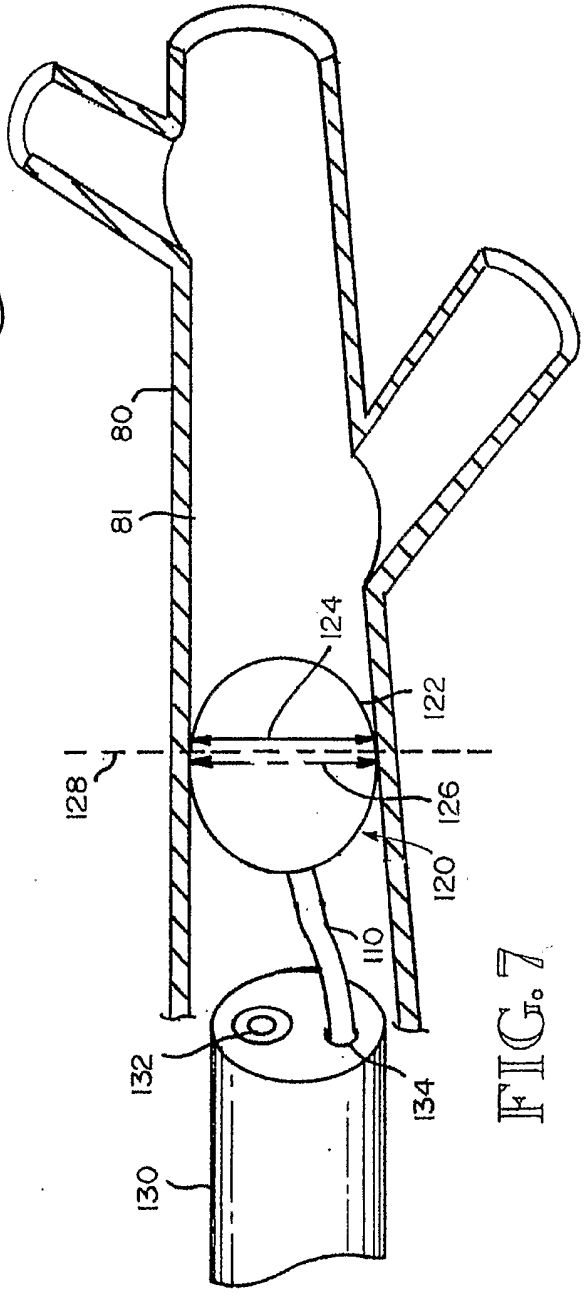
FIG. 6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130

FIG. 7

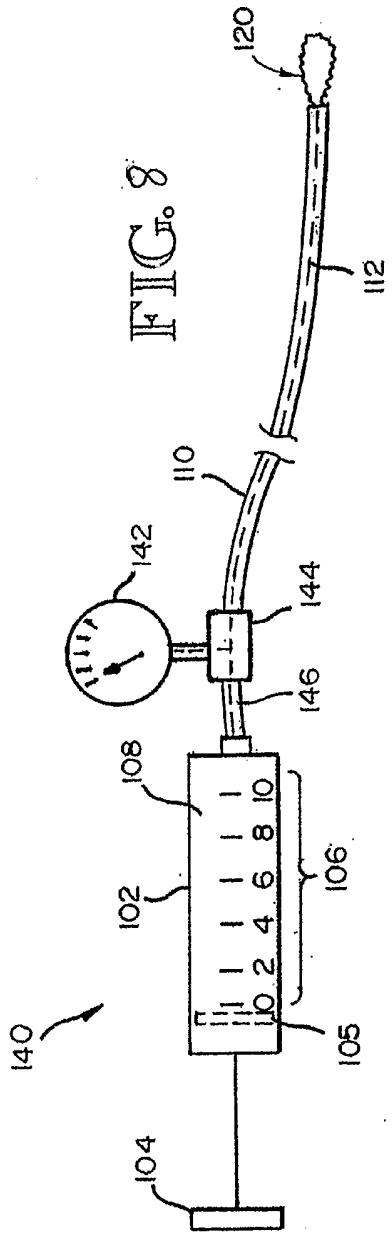
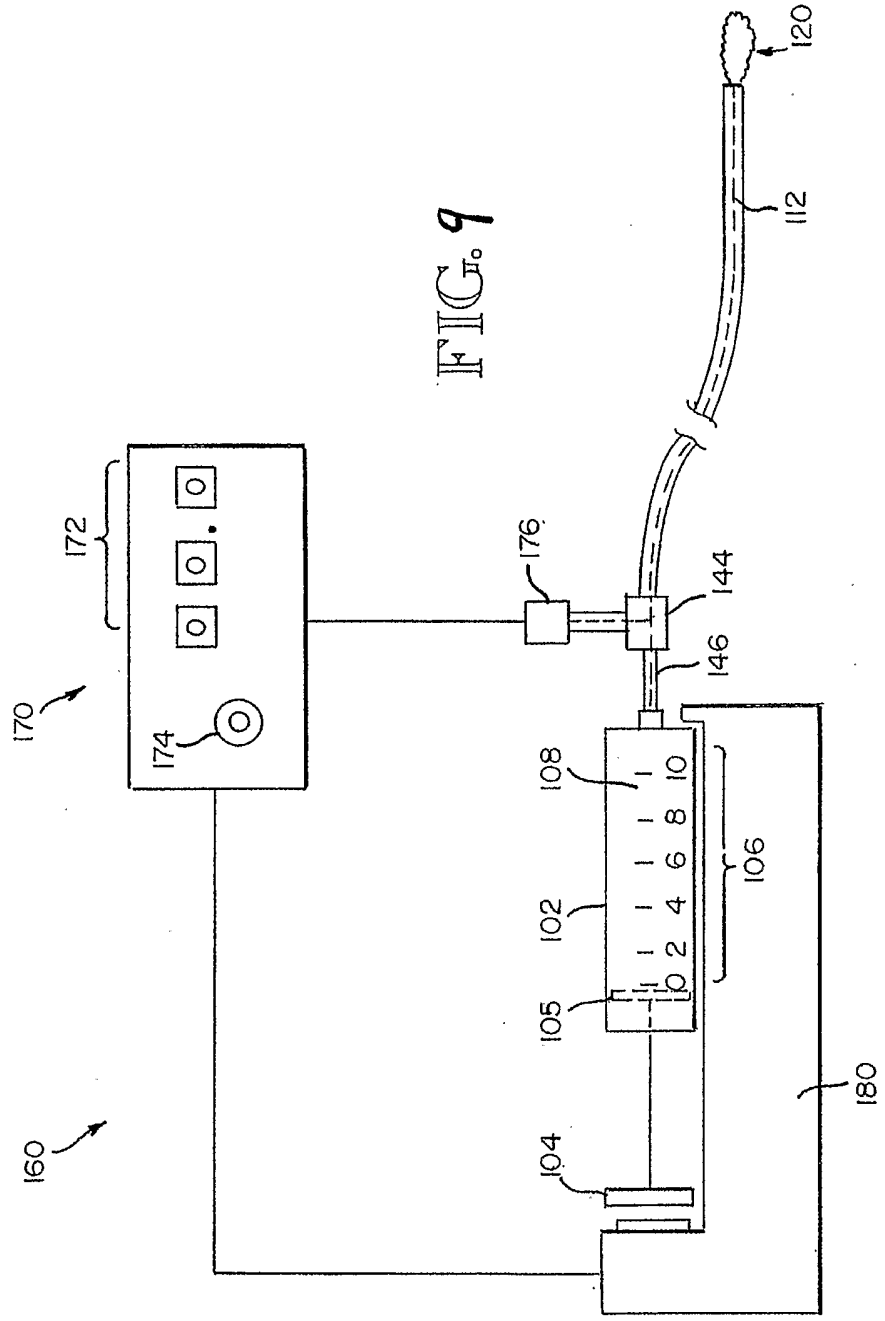


FIG. 8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174
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102
106
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180
160
104

FIG. 9

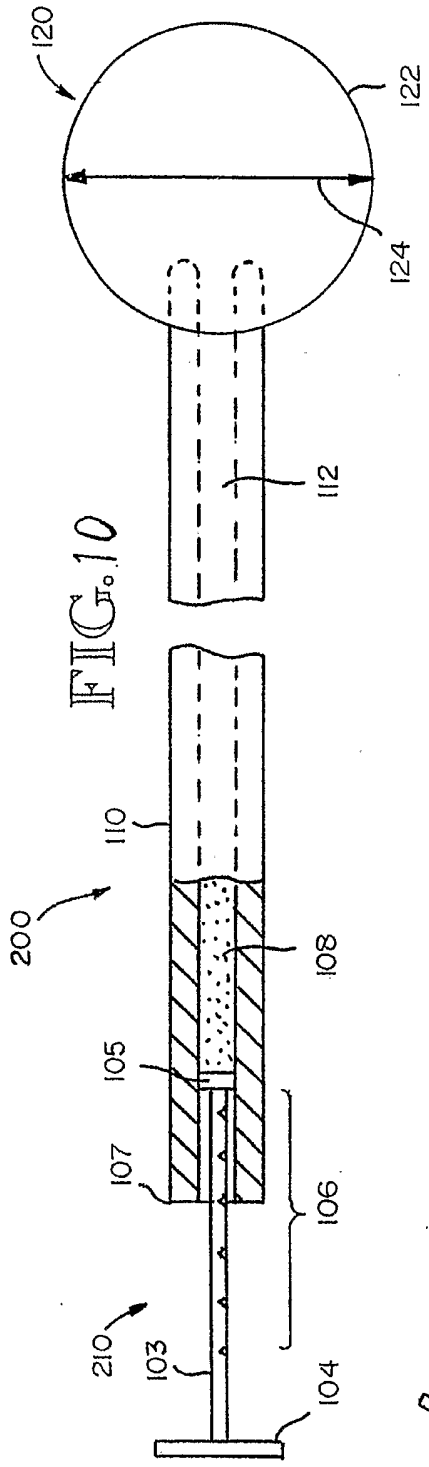

FIG. 10

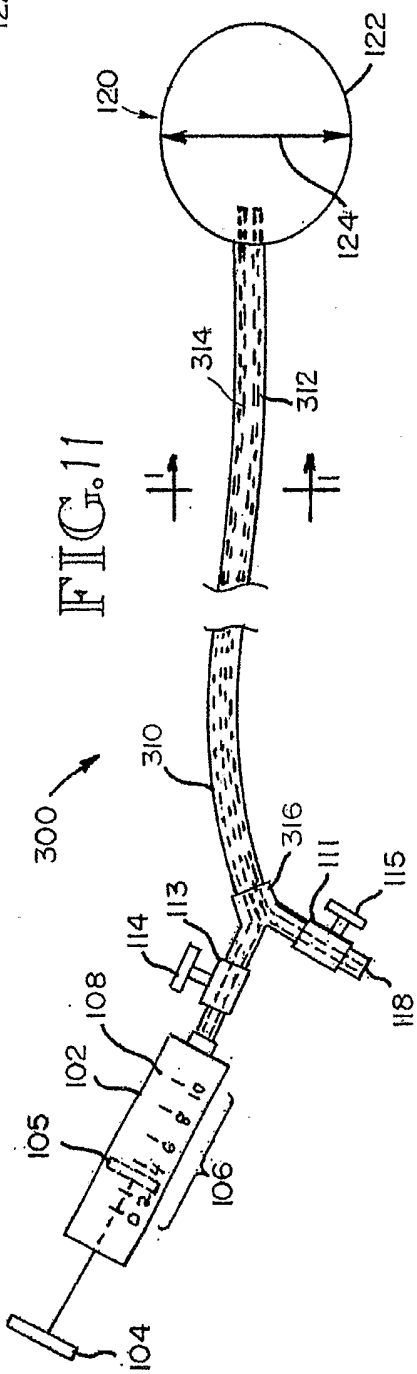

FIG. 11

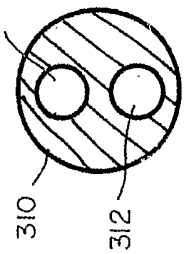

FIG. 12