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(54) METHODS AND DEVICES FOR PASSIVE RESIDUAL LUNG VOLUME REDUCTION AND FUNCTIONAL LUNG VOLUME EXPANSION

(75) Inventors: **Nikolai Aljuri**, Revere, MA (US); **Rodney C. Perkins**, Woodside, CA (US)

Correspondence Address:
TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER, EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834 (US)

(73) Assignee: **PULMONx**, Palo Alto, CA (US)

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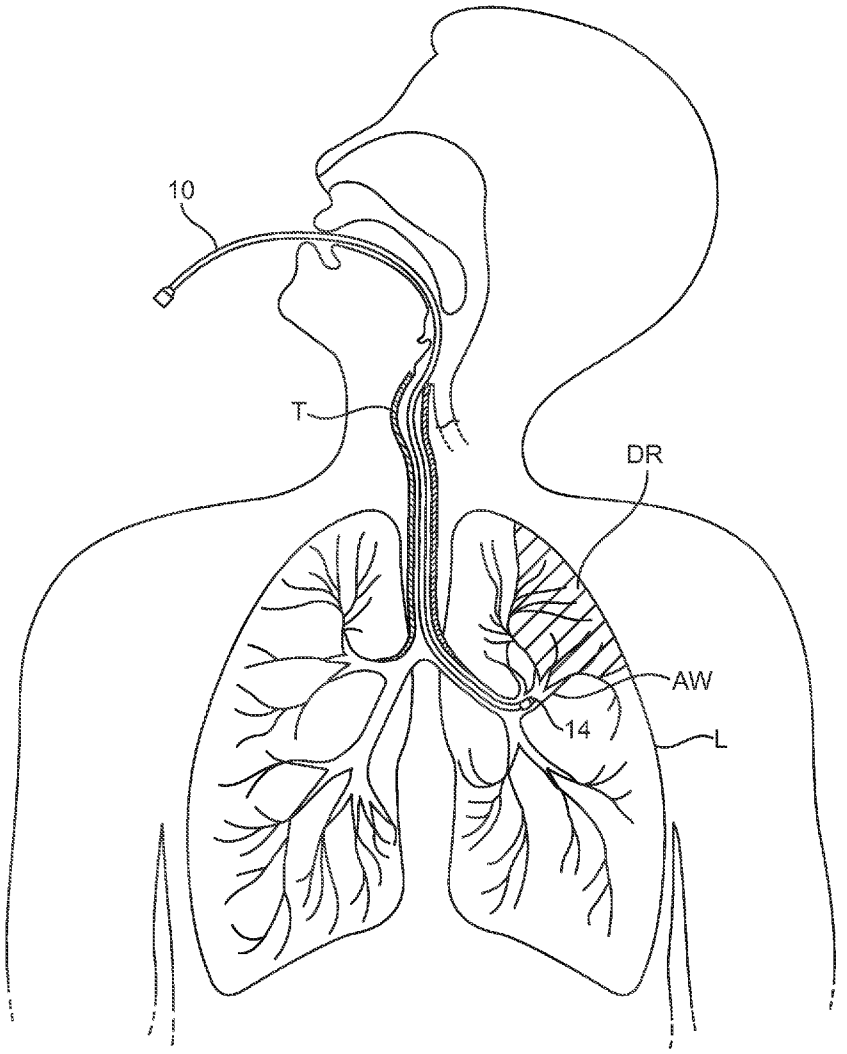
(57) **ABSTRACT**

The volume of a hyperinflated lung compartment is reduced by sealing a distal end of the catheter in an airway feeding the lung compartment. Air passes out of the lung compartment through a passage in the catheter while the patient exhales. A one-way flow element associated with the catheter prevents air from re-entering the lung compartment as the patient inhales. Over time, the pressure of regions surrounding the lung compartment cause it to collapse as the volume of air diminishes. Residual volume reduction effectively results in functional lung volume expansion. Optionally, the lung compartment may be sealed in order to permanently prevent air from re-entering the lung compartment.



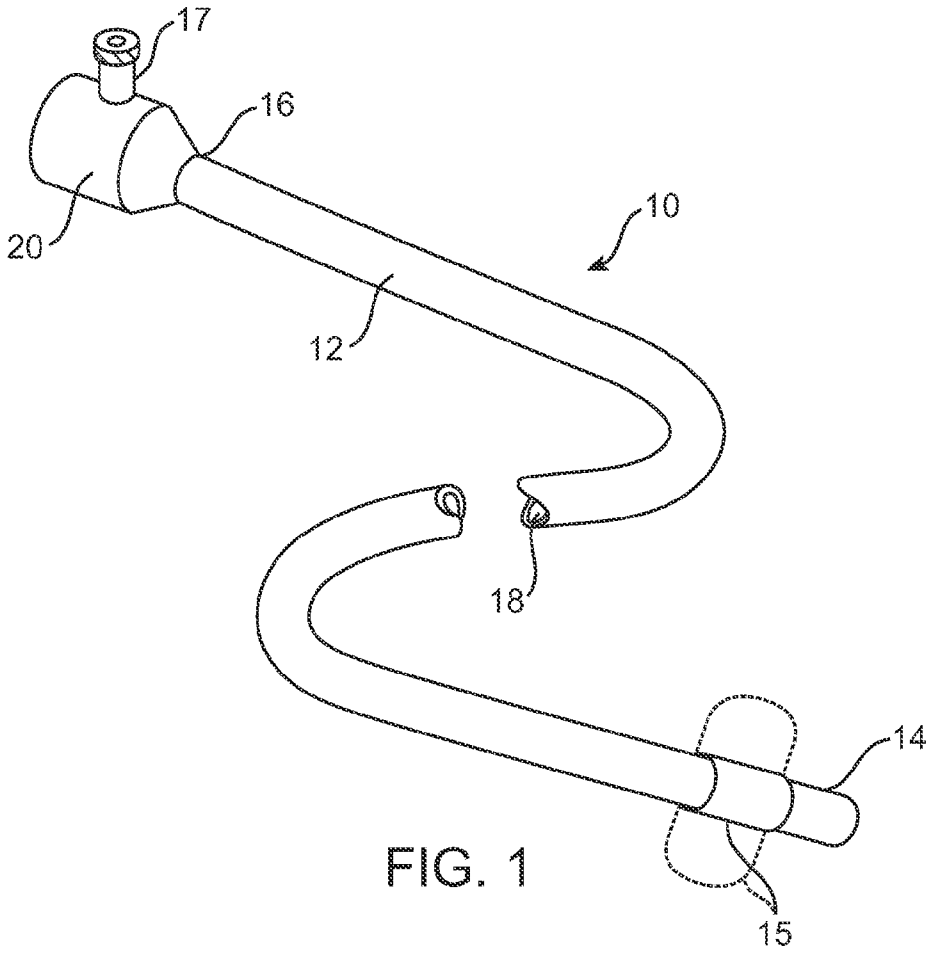


FIG. 1

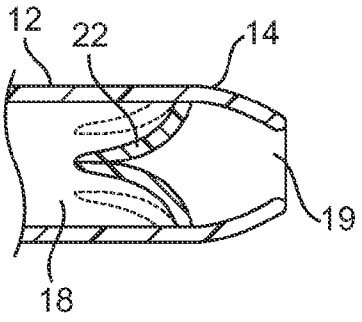


FIG. 2

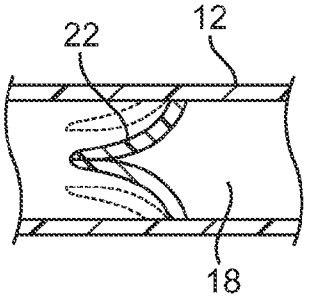


FIG. 3

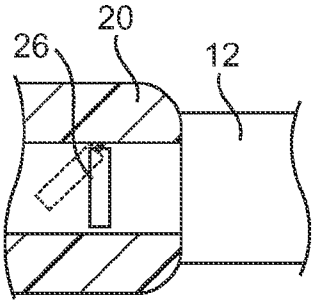


FIG. 4

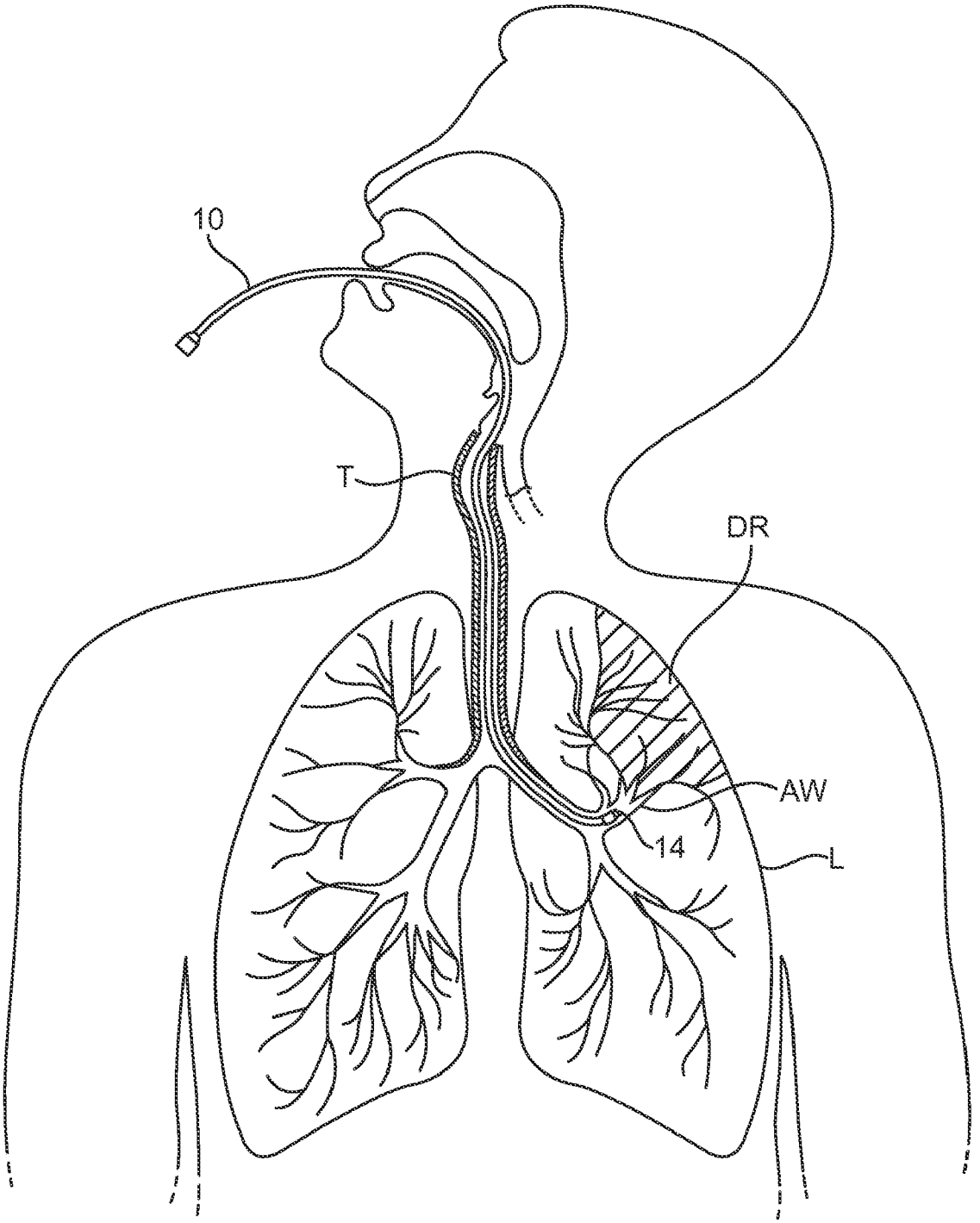


FIG. 5

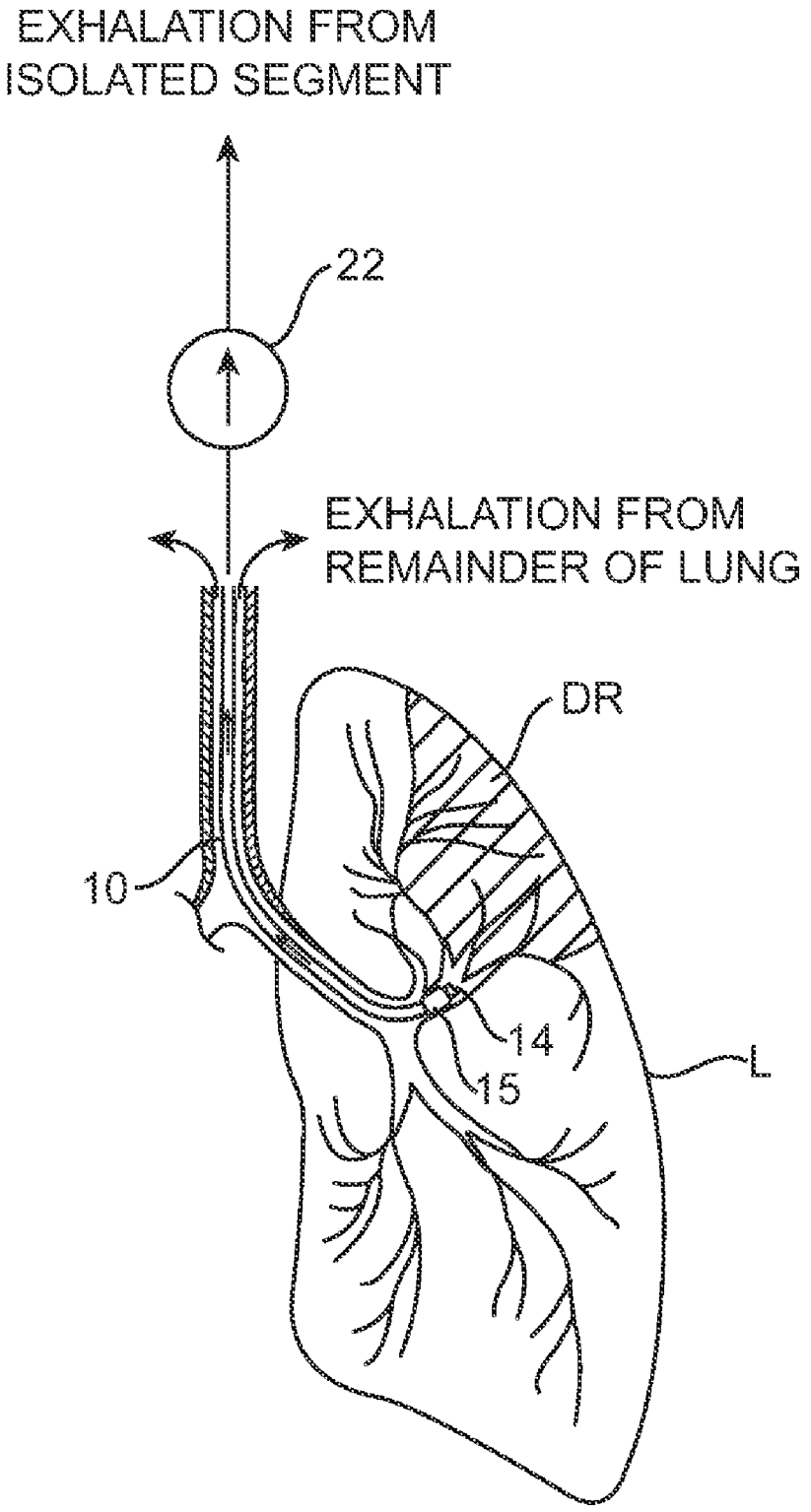

EXHALATION FROM
ISOLATED SEGMENT
22
EXHALATION FROM
REMAINDER OF LUNG
DR
10
14
15
L

FIG. 6A

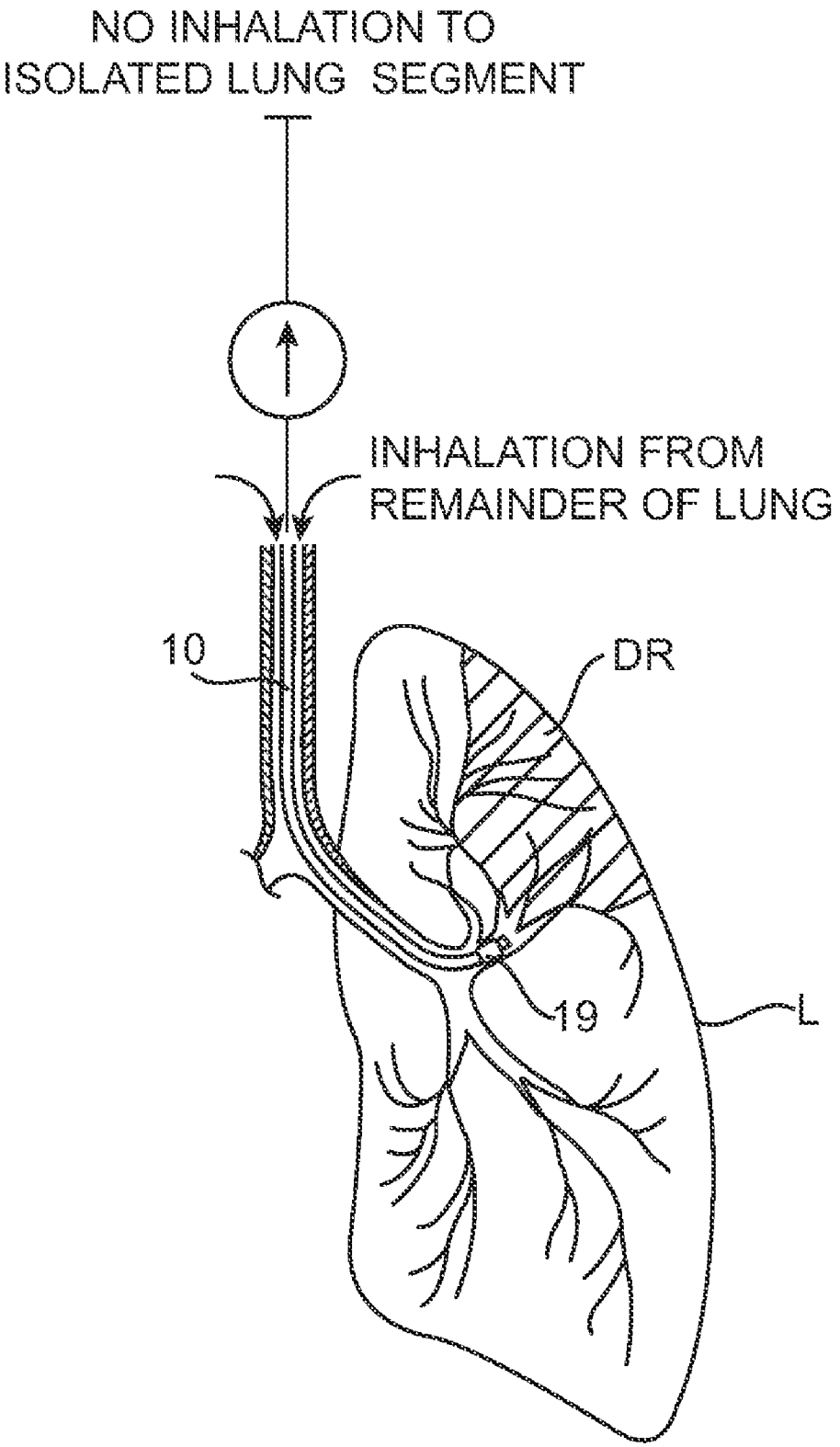

NO INHALATION TO
ISOLATED LUNG SEGMENT
INHALATION FROM
REMAINDER OF LUNG
10
DR
19
L

FIG. 6B

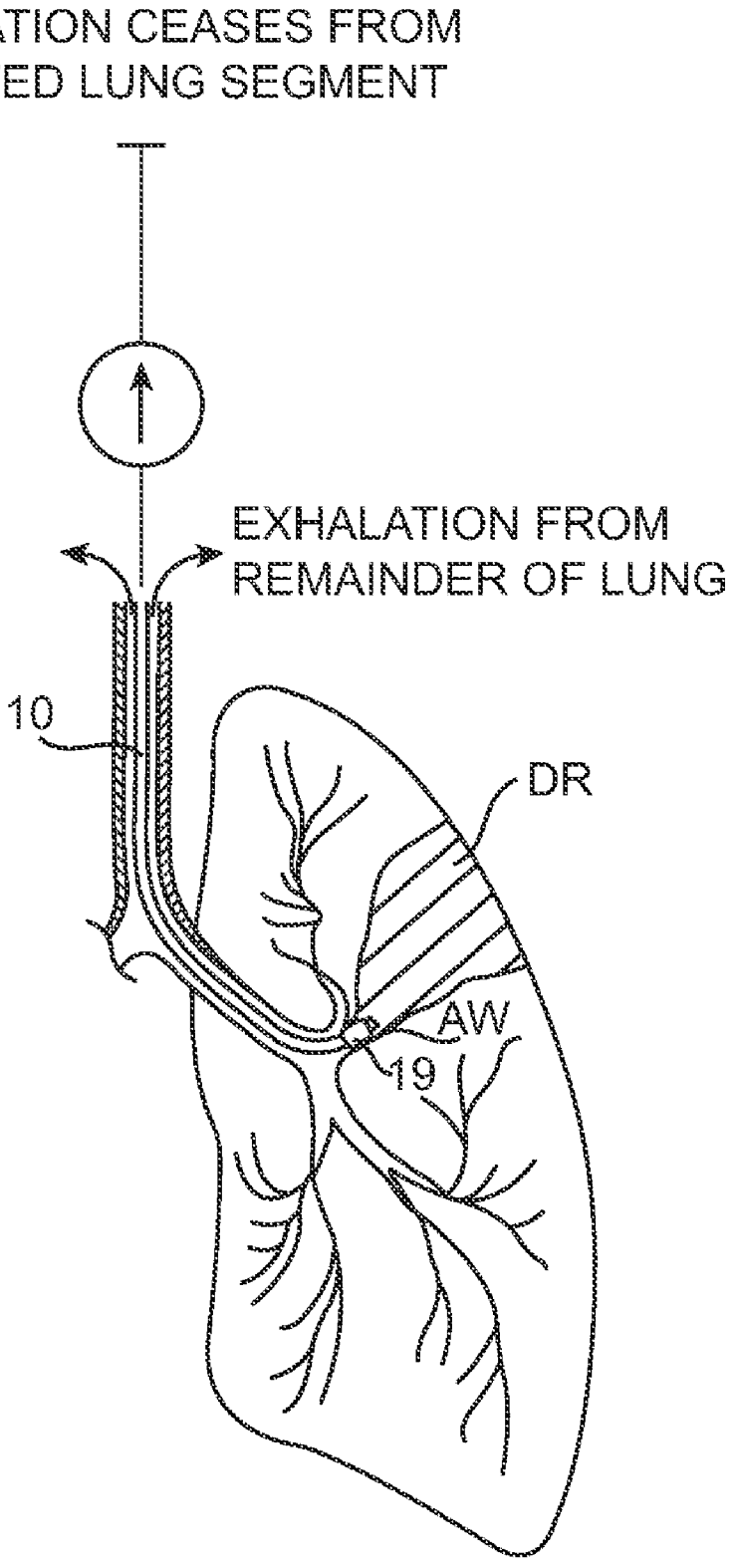

EXHALATION CEASES FROM
ISOLATED LUNG SEGMENT
EXHALATION FROM
REMAINDER OF LUNG
10
DR
AW
19

FIG. 6C

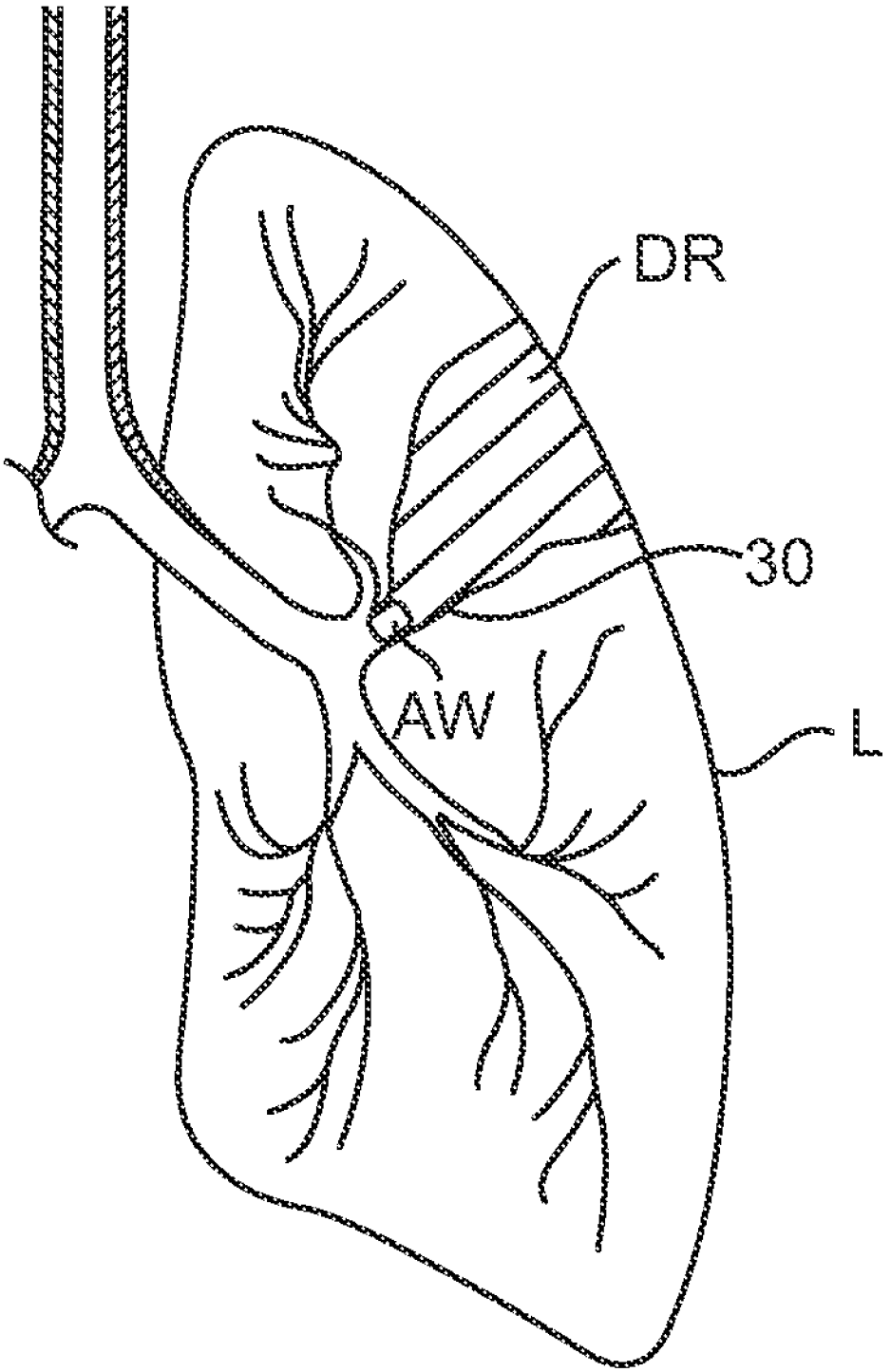


FIG. 6D

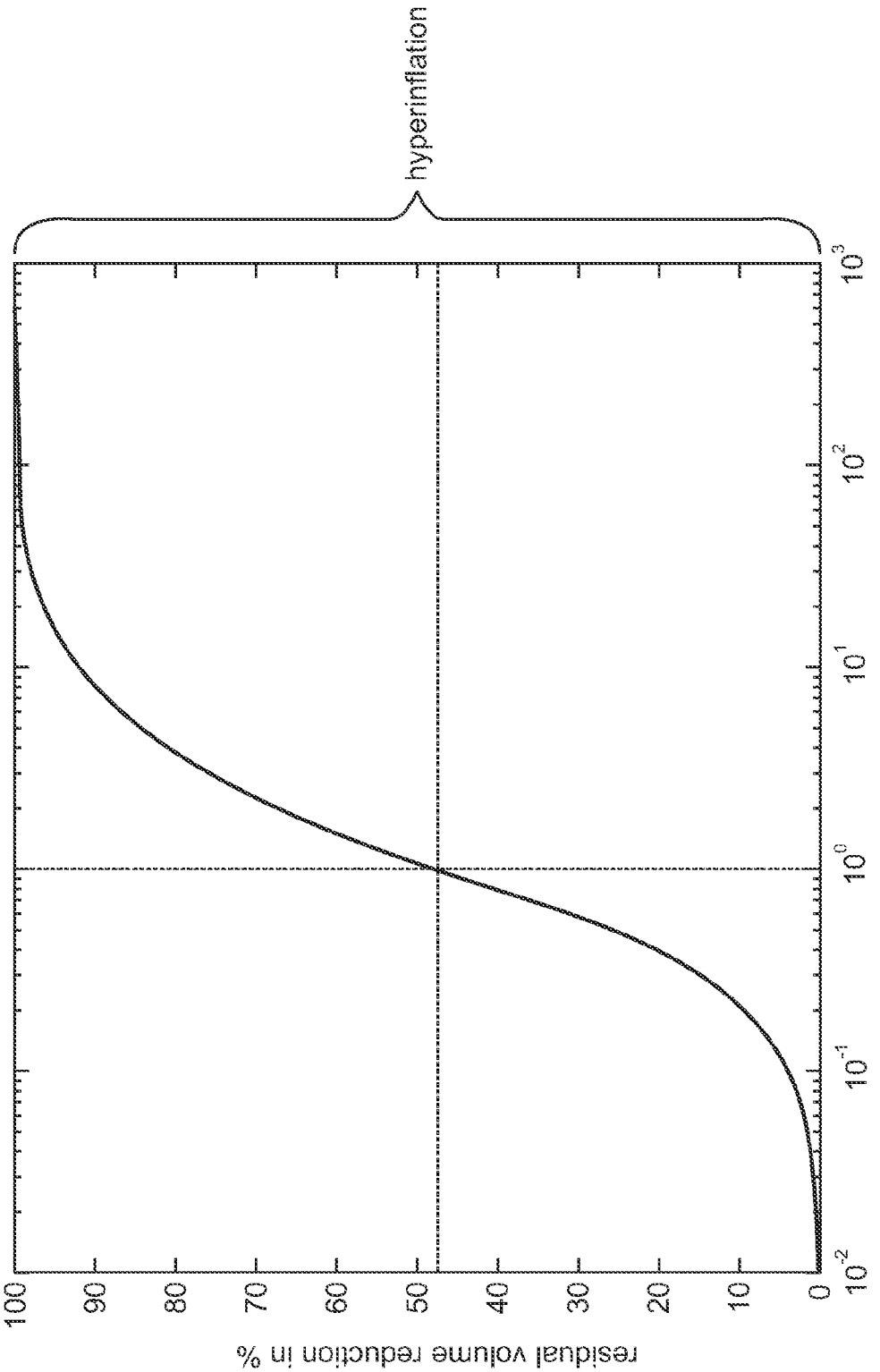

hyperinflation
residual volume reduction in %
100
90
80
70
60
50
40
30
20
10
0
10^{-2}
10^{-1}
10^{0}
10^{1}
10^{2}
10^{3}
R_{coll} in cm H_2O/(ml/s)

FIG. 7

METHODS AND DEVICES FOR PASSIVE RESIDUAL LUNG VOLUME REDUCTION AND FUNCTIONAL LUNG VOLUME EXPANSION

BACKGROUND OF THE INVENTION

[0001] 1. Field of the Invention

[0002] The present invention relates generally to medical methods and apparatus. More particularly, the present invention relates to methods and apparatus for endobronchial residual lung volume reduction by passive deflation of hyperinflated segments with functional lung volume expansion as a result.

[0003] Chronic obstructive pulmonary disease is a significant medical problem affecting 16 million people or about 6% of the U.S. population. Specific diseases in this group include chronic bronchitis, asthmatic bronchitis, and emphysema. While a number of therapeutic interventions are used and have been proposed, none are completely effective, and chronic obstructive pulmonary disease remains the fourth most common cause of death in the United States. Thus, improved and alternative treatments and therapies would be of significant benefit.

[0004] Of particular interest to the present invention, lung function in patients suffering from some forms of chronic obstructive pulmonary disease can be improved by reducing the effective lung volume, typically by resecting diseased portions of the lung. Resection of diseased portions of the lungs both promotes expansion of the non-diseased regions of the lung and decreases the portion of inhaled air which goes into the lungs but is unable to transfer oxygen to the blood. Lung volume reduction is conventionally performed in open chest or thoracoscopic procedures where the lung is resected, typically using stapling devices having integral cutting blades.

[0005] While effective in many cases, conventional lung volume reduction surgery is significantly traumatic to the patient, even when thoracoscopic procedures are employed. Such procedures often result in the unintentional removal of healthy lung tissue, and frequently leave perforations or other discontinuities in the lung which result in air leakage from the remaining lung. Even technically successful procedures can cause respiratory failure, pneumonia, and death. In addition, many older or compromised patients are not able to be candidates for these procedures.

[0006] As an improvement over open surgical and minimally invasive lung volume reduction procedures, endobronchial lung volume reduction procedures have been proposed. For example, U.S. Pat. Nos. 6,258,100 and 6,679,264 describe placement of one-way valve structures in the airways leading to diseased lung regions. It is expected that the valve structures will allow air to be expelled from the diseased region of the lung while blocking reinflation of the diseased region. Thus, over time, the volume of the diseased region will be reduced and the patient condition will improve.

[0007] While promising, the use of implantable, one-way valve structures is problematic in at least several respects. The valves must be implanted prior to assessing whether they are functioning properly. Thus, if the valve fails to either allow expiratory flow from or inhibit inspiratory flow into the diseased region, that failure will only be determined after the valve structure has been implanted, requiring surgical removal. Additionally, even if the valve structure functions properly, many patients have diseased lung segments with collateral flow from adjacent, healthy lung segments. In those patients, the lung volume reduction of the diseased region will be significantly impaired, even after successfully occluding inspiration through the main airway leading to the diseased region, since air will enter collaterally from the adjacent healthy lung region. When implanting one-way valve structures, the existence of such collateral flow will only be evident after the lung region fails to deflate over time, requiring further treatment.

[0008] For these reasons, it would be desirable to provide improved and alternative methods and apparatus for effecting residual lung volume reduction in hyperinflated and other diseased lung regions. The methods and apparatus will preferably allow for passive deflation of an isolated lung region without the need to implant a one-way valve structure in the lung. The methods and apparatus will preferably be compatible with known protocols for occluding diseased lung segments and regions after deflation, such as placement of plugs and occluding members within the airways leading to such diseased segments and regions. Additionally, such methods and devices should be compatible with protocols for identifying and treating patients having diseased lung segments and regions which suffer from collateral flow with adjacent healthy lung regions. At least some of these objectives will be met by the inventions described hereinbelow.

[0009] 2. Description of the Background Art

[0010] Methods for performing minimally invasive and endobronchial lung volume reduction are described in the following patents and publications: U.S. Pat. Nos. 5,972,026; 6,083,255; 6,258,100; 6,287,290; 6,398,775; 6,527,761; 6,585,639; 6,679,264; 6,709,401; 6,878,141; 6,997,918; 2001/0051899; and 2004/0016435.

BRIEF SUMMARY OF THE INVENTION

[0011] The present invention provides methods and apparatus for passively reducing the residual volume (the volume of air remaining after maximal exhalation) of a hyperinflated or otherwise diseased lung compartments or segments. By "passively reducing," it is meant that air can be removed from the diseased lung region without the use of a vacuum aspiration to draw the air from the region. Typically, such passive reduction will rely on a non-implanted one-way flow structure which permits air to be exhaled or exhausted from the lung region while preventing or inhibiting the inspiration of air back into the lung region. Thus, the methods of the present invention will not require the permanent implantation of valves or other structures prior to actually achieving the desired residual lung volume reduction, as with the one-way implantable valve structures of the prior art.

[0012] The methods and apparatus of the present invention can be terminated and all apparatus removed should it appear for any reason that the desired residual lung volume reduction is not being achieved. Commonly, such failure can be the result of collateral flow into the diseased lung region from adjacent healthy lung region(s). In such cases, steps can be taken to limit or stop the collateral flow and allow resumption of the passive lung volume reduction protocols. In other cases, it might be desirable or necessary to employ open surgical, thoracoscopic, or other surgical procedures for lung resection.

[0013] Patients who successfully achieve residual volume reduction of hyperinflated or other diseased lung regions in accordance with the principles of the present invention will typically have those regions sealed permanently to prevent

reinflation. Such sealing can be achieved by a variety of known techniques, including the application of radiofrequency or other energy for shrinking or sealing the walls of the airways feeding the lung region. Alternatively, synthetic or biological glues could be used for achieving sealing of the airway walls. Most commonly, however, expandable plugs will be implanted in the airways leading to the deflated lung region to achieve the sealing.

[0014] In a first aspect of the present invention, methods for reducing the residual volume of a hyperinflated lung compartment comprise sealingly engaging a distal end of a catheter in an airway feeding the lung compartment. Air is allowed to be expelled from the lung compartment through a passage in the catheter while the patient is exhaling, and air is blocked from re-entering the lung compartment through the catheter passage while the patient is inhaling. As the residual volume diminishes, the hyperinflated lung compartment reduces in size freeing up the previously occupied space in the thoracic cavity. Consequently, a greater fraction of the Total Lung Capacity (TLC), which is the volumetric space contained in the thoracic cavity that is occupied by lung tissue after a full inhalation becomes available for the healthier lung compartments to expand and the volume of the lung available for gas exchange commonly referred to in clinical practice as the lung's Functional Vital Capacity (FVC) or Vital Capacity (VC) increases, the result of which is effectively a functional lung volume expansion.

[0015] The hyperinflated lung compartment will usually be substantially free of collateral flow from adjacent lung compartments, and optionally the patient can be tested for the presence of such collateral flow, for example using techniques taught in copending, commonly assigned application Ser. Nos. 11/296,951 (Attorney Docket No.: 017534-002820US), filed on Dec. 7, 2005; Ser. No. 11/550,660 (Attorney Docket No. 017534-003020US), filed on Oct. 18, 2006; and application Ser. No. 11/428,762 (Attorney Docket No. 017534-003010US), filed on Jul. 5, 2006, the full disclosures of which are incorporated herein by reference.

[0016] Alternatively, the methods of the present invention for reducing residual lung volume can be performed in patients having collateral flow channels leading into the hyperinflated or other diseased lung compartment. In such cases, the collateral flow channels may first be blocked, for example, by introducing glues, occlusive particles, hydrogels or other blocking substances, as taught for example in copending application no. 60/_____ (Attorney Docket No. 017534-004000US), filed on the same day as the present invention, the full disclosure of which is incorporated herein by reference. In other cases, where the flow channels are relatively small, those channels will partially or fully collapse as the residual lung volume is reduced. In such cases, the patient may be treated as if the collateral flow channels did not exist. The effectiveness of reduction in hyperinflation however will depend on the collateral resistance between the hyperinflated compartment and the neighboring compartments, as illustrated in FIG. **7**, where residual volume reduction is negligible when the resistance to collateral flow R_{coll} is very small (significant collateral flow channels) and maximally effective when R_{coll} is very high (no collateral flow channels).

[0017] In all of the above methods, it may be desirable to introduce an oxygen-rich gas into the lung compartment while or after the lung volume is reduced in order to induce or promote absorption atelectasis. Absorption atelectasis promotes absorption of the remaining or residual gas in the compartment into the blood to further reduce the volume, either before or after permanent sealing of the lung volume compartment or segment.

[0018] In a second aspect, the present invention provides catheters for isolating and deflating hyperinflated and other diseased lung compartments. The catheter comprises a catheter body, an expandable occluding member on the catheter body, and a one-way flow element associated with the catheter body. The catheter body usually has a distal end, a proximal end, and at least one lumen extending from a location at or near the distal end to a location at or near the proximal end. At least a distal portion of the catheter body is adapted to be advanced into and through the airways of a lung so that the distal end can reach an airway which feeds a target lung compartment or segment to be treated. The expandable occluding member is disposed near the distal end of the catheter body and is adapted to be expanded in the airway which feeds the target lung compartment or segment so that said compartment or segment can be isolated with access provided only through the lumen or catheter body when the occluding member is expanded. The one-way flow element is adapted to be disposed within or in-line with the lumen of the catheter body in order to allow flow in a distal-to-proximal direction so that air will be expelled from the isolated lung compartment or segment as the patient exhales. The one-way flow element, however, inhibits or prevents flow through the lumen in a proximal-to-distal direction so that air cannot enter the isolated lung compartment or segment while the patient is inhaling.

[0019] For the intended endobronchial deployment, the catheter body will typically have a length in the range from 20 cm to 200 cm, preferably from 80 cm to 120 cm, and a diameter near the distal end in the range from 0.1 mm to 10 mm, preferably from 1 mm to 5 mm. The expandable occluding member will typically be an inflatable balloon or cuff, where the balloon or cuff has a width in the range from 1 mm to 30 mm, preferably from 5 mm to 20 mm, when inflated. The one-way flow element is typically a conventional one-way flow valve, such as a duck-bill valve, a flap valve, or the like, which is disposed in the lumen of the catheter body, either near the distal end or at any other point within the lumen. Alternatively, the one-way flow element could be provided as a separate component, for example be provided in a hub which is detachably mounted at the proximal end of the catheter body. In other instances, it might be desirable to provide two or more one-way flow elements in series within the lumen or otherwise provided in-line with the lumen in order to enhance sealing in the inspiratory direction through the lumen.

BRIEF DESCRIPTION OF THE DRAWINGS

[0020] FIG. **1** is a perspective view of an isolation and deflation catheter constructed in accordance with the principles of the present invention.

[0021] FIGS. **2-4** illustrate alternative placements of one-way flow elements within a central lumen of the catheter of FIG. **1**.

[0022] FIG. **5** illustrates the trans-esophageal endobronchial placement of the catheter of FIG. **1** in an airway leading to a diseased lung region in accordance with the principles of the present invention.

[0023] FIGS. **6**A-**6**D illustrate use of the catheter as placed in FIG. **5** for isolating and reduction of the volume of the diseased lung region in accordance with the principles of the present invention.

[0024] FIG. **7** is a graph showing the relationship between collateral resistance R_{coll} and residual volume reduction in an isolated lung compartment

DETAILED DESCRIPTION OF THE INVENTION

[0025] Referring to FIG. **1**, an endobronchial lung volume reduction catheter **10** constructed in accordance with the principles of the present invention includes an elongate catheter body **12** having a distal end **14** and a proximal end **16**. Catheter body **12** includes at least one lumen or central passage **18** extending generally from the distal end **14** to the proximal end **16**. Lumen **18** will have a distal opening **19** at or near the distal end **14** in order to permit air or other lung gases to enter the lumen and flow in a distal-to-proximal direction out through the proximal end of the lumen. Optionally, a hub **20** will be provided at the proximal end, but the hub is not a necessary component of the catheter.

[0026] The present invention relies on placement of a one-way flow element within or in-line with the lumen **18** so that flow from an isolated lung compartment or segment (as described hereinbelow) may occur in a distal-to-proximal direction but flow back into the lung compartment or segment is inhibited or blocked in the proximal-to-distal direction. As shown in FIGS. **2**-**4**, a one-way flow element **22** may be provided in the lumen **18** near the distal end **14** of the catheter body **12**, optionally being immediately proximal of the distal opening **19**. As shown, the one-way flow element **22** is a duck-bill valve which opens as shown in broken line as the patient exhales to increase the pressure on the upstream or distal side of the valve **22**. As the patient inhales, the pressure on the upstream or distal side of the valve is reduced, drawing the valve leaflets closed as shown in full line.

[0027] Alternatively or additionally, the one-way flow element **22** could be provided anywhere else in the lumen **18**, and two, three, four, or more such valve structures could be included in order to provide redundancy.

[0028] As a third option, a one-way valve structure **26** in the form of a flap valve could be provided within the hub **20**. The hub **20** could be removable or permanently fixed to the catheter body **12**. Other structures for providing in-line flow control could also be utilized.

[0029] Use of the endobronchial lung volume reduction catheter **10** to reduce the residual volume of a diseased region DR of a lung L is illustrated beginning in FIG. **5**. Catheter **10** is introduced through the patient's mouth, down past the trachea T and into a lung L. The distal end **14** of the catheter **10** is advanced to the main airway AW leading into the diseased region DR of the lung. Introduction and guidance of the catheter may be achieved in conventional manners, such as described in commonly-owned U.S. Pat. Nos. 6,287,290; 6,398,775; and 6,527,761, the full disclosures of which are incorporated herein by reference.

[0030] Referring now to FIGS. **6**A-**6**D, functioning of the one-way valve element in achieving the desired lung volume reduction will be described. After the distal end **14** of the catheter **10** is advanced to the feeding airway AW, an expandable occluding element **15** is expanded to occlude the airway. The expandable occluding element may be a balloon, cuff, or a braided balloon as described in copending application 60/823,734 (Attorney Docket No. 017534-003800US), filed on Aug. 28, 2006, and 60/828,496 (Attorney Docket No. 017534-003900US) filed on Oct. 6, 2006, the full disclosures of which are incorporated herein by reference. At that point, the only path between the atmosphere and the diseased region DR of the lung is through the lumen **18** of the catheter **10**. As the patient exhales, as shown in FIG. **6**A, air from the diseased region DR flows outwardly through the lumen **18** and the one-way valve element **22**, causing a reduction in residual air within the region and a consequent reduction in volume. Air from the remainder of the lung also passes outward in the annular region around the catheter **10** in a normal manner.

[0031] As shown in FIG. **6**B, in contrast, when the patient inhales, no air enters the diseased regions DR of the lung L (as long as there are no significant collateral passageways), while the remainder of the lung is ventilated through the region around the catheter. It will be appreciated that as the patient continues to inhale and exhale, the air in the diseased region DR is incrementally exhausted, further reducing the lung volume as the external pressure from the surrounding regions of the lung are increased relative to the pressure within the diseased region.

[0032] As shown in FIG. **6**C, after sometime, typically seconds to minutes air flow from the isolated lung segment will stop and a maximum or near-maximum level of residual lung volume reduction within the diseased region DR will have been achieved. At that time, the airway AW feeding the diseased region DR can be occluded, by applying heat, radiofrequency energy, glues, or preferably by implanting an occluding element **30**, as shown in FIG. **6**D. Implantation of the occluding element may be achieved by any of the techniques described in commonly-owned U.S. Pat. Nos. 6,287,290; and 6,527,761, the full disclosures of which have been previously incorporated herein by reference.

[0033] While the above is a complete description of the preferred embodiments of the invention, various alternatives, modifications, and equivalents may be used. Therefore, the above description should not be taken as limiting the scope of the invention which is defined by the appended claims.

What is claimed is:

1. A method for reducing the residual volume of a hyperinflated lung compartment, said method comprising:

sealing a distal end of a catheter in an airway feeding the lung compartment;

allowing air to be expelled from the lung compartment through a passage in the catheter while the patient is exhaling; and

blocking air from entering the lung compartment through the catheter passage while the patient is inhaling.

2. A method as in claim **1**, wherein the hyperinflated lung compartment is substantially free of collateral flow from adjacent lung compartments prior to sealing the catheter distal end.

3. A method as in claim **1**, wherein the hyperinflated lung compartment has collateral flow channels with one or more adjacent lung compartments prior to sealing the catheter distal end.

4. A method as in claim **3**, wherein the collateral flow channels at least partially collapse as the volume of the hyperinflated lung compartment is reduced.

5. A method as in claim **2**, further comprising introducing an oxygen-rich gas into the lung compartment after the volume is reduced to induce or promote absorption atelectasis.

6. A method as in claim **1**, wherein reducing the residual volume of a hyperinflated lung compartment causes functional lung volume expansion of the remaining lung compartments.

7. A catheter for isolating and deflating a hyperinflated lung compartment, said catheter comprising:

a catheter body having a distal end, a proximal end, and at least one lumen extending from the distal end to the proximal end, wherein at least a distal portion of the catheter body is adapted to be advanced through the airways of the lung;

an expandable occluding member disposed near a distal end of the catheter body, wherein said occluding member is adapted to be expanded in an airway which feeds the hyperinflated lung compartment such that access to the compartment is provided only through the lumen when the occluding member is expanded; and

a one-way flow element adapted to be disposed within or in-line with the lumen so that flow in a distal-to-proximal direction is allowed and flow in a proximal-to-distal direction is inhibited or prevented.

8. A catheter as in claim **7**, wherein the catheter body has a length in the range from 20 cm to 200 cm and a diameter near the distal end in the range from 0.1 mm to 10 mm.

9. A catheter as in claim **7**, wherein the expandable occluding member is an inflatable balloon, cuff, or braided balloon.

10. A catheter as in claim **7**, wherein the expandable occluding member has a width in the range from 1 mm to 30 mm when fully expanded.

11. A catheter as in claim **7**, wherein the one-way flow element is disposed in the lumen.

12. A catheter as in claim **11**, wherein the one-way flow element is disposed in the lumen near the distal end of the catheter body.

13. A catheter as in claim **7**, further comprising a hub disposed on a proximal end of the catheter body.

14. A catheter as in claim **13**, wherein the one-way flow element is disposed in the hub.

15. A catheter as in claim **14**, wherein the hub is removable and can be attached in-line with the lumen.

* * * * *