Title: ENDOBRONCHIAL BLOCKING DEVICE

Abstract: An endobronchial blocking device (10) for use in blocking a selected mainstem bronchus under visualization of a tip-deflectable bronchoscope. The blocking device comprises an elongated member having a plurality of lumens therein, the elongated member having a proximal portion (12) and a distal portion (14), the proximal portion having a first diurometer and the distal portion having a second diurometer, the first diurometer being greater than the second diurometer. An inflatable blocker balloon (16) is disposed about the distal portion of the elongated member. A first lumen of the blocking device has a diameter sufficient for receiving the bronchoscope, and a second lumen communicates with an interior of the balloon to accomplish inflation. The distal portion of the elongated member is deflectable responsive to the deflection of the tip of the bronchoscope, to enable the elongated member to be positioned at a desired site in the selected mainstem bronchus.
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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.
ENDBRONCHIAL BLOCKING DEVICE

BACKGROUND

[0001] 1. Technical Field. The present invention relates to endobronchial blocking devices, and more particularly, to an endobronchial blocker for use in combination with a single-lumen tracheostomy tube.

[0002] 2. Background Information. Patients who are critically ill or undergoing surgical procedures involving the lungs (thoracic surgery) frequently require a lung, or a portion of a lung, to be isolated from mechanical ventilation. The lungs are located in the chest cavity and bounded by the chest wall and the diaphragm, a thin muscular membrane. The lungs are held next to the chest wall by negative pressure and a thin fluid layer. The space of opposition is the pleural space. The lungs comprise the trachea, an air conduit, and the lung tissue which abuts against the chest wall. The trachea divides in the chest cavity into two separate air conduits, a right-sided air conduit (the right mainstem bronchus) and a left-sided air conduit (the left mainstem bronchus).

[0003] Ventilation is a physiologic process which supplies oxygen to the body and removes carbon dioxide, a gaseous waste product. Ventilation is provided by the rhythmic back and forth motion of air in the trachea, caused by the rhythmic contraction and relaxation of the diaphragm. In surgical patients and in the critically ill, ventilation can be assisted by utilizing a mechanical ventilator connected to an endotracheal tube. An endotracheal tube is a balloon–tipped single or double-lumen catheter that is open at both ends, and positioned in the mid-tracheal region.

[0004] Isolation of ventilation is commonly required in medical procedures. For example, in thoracic surgery the chest wall is incised, the lung opened and the pleural space entered. As a result, the lung will collapse, and ventilation can escape. Ventilation to the non-operative lung must be isolated before opening the operative lung segment. If ventilation is not isolated before beginning the thoracic surgery, a risk of harm to the patient exists due to the escape of ventilation through the surgical lung opening. Other conditions may also require isolation from mechanical ventilation. These conditions include the isolation of a diseased
portion of the lung, infections of the lung (pneumonia), bleeding in the lungs (hemoptysis), and the presence of a non-surgical opening into the pleural space (pneumothorax).

[0005] Double lumen endotracheal tubes have long been used to achieve isolation of ventilation. A double lumen endotracheal tube generally comprises two endotracheal tubes of unequal length fused together, and incorporates two balloons. One balloon envelopes the tracheal position of the two fused endotracheal tubes (the tracheal balloon), and the second balloon envelopes the longer tube portion and extends into either the right or left mainstem bronchus (the bronchial balloon). The double lumen tube isolates ventilation when the balloons are inflated, and the longer tube portion is positioned in the right or left mainstem bronchus.

[0006] Certain drawbacks have been associated with the use of double lumen endotracheal tubes. For example, a double lumen endotracheal tube is larger in outer diameter than a conventional single lumen endotracheal tube, yet its internal cross-sectional area is substantially the same as a single lumen tube. This extended outer diameter can cause damage to the vocal chords, as well as the nerves for the vocal chords. In addition, a larger diameter double lumen endotracheal tube is generally longer, and more challenging to insert and position than a single lumen tube. In patients where the normal airway anatomy is altered, the use of double lumen endotracheal tubes can result in additional patient trauma. Furthermore, due to the complexity and size of a double lumen endotracheal tube, the length of time that may be required to correctly place the device in the airway may subject the patient to a greater risk of hypoxic brain damage. Also, a double lumen endotracheal tube cannot be left in place for long periods of time. Due to its size, extended use of such a tube can cause damage to the tracheal bronchial tree.

[0007] Another known medical device for achieving isolation of ventilation is an endobronchial blocker. An endobronchial blocker is a balloon-tipped catheter which is positioned in either the right or left mainstem bronchus using a fiberoptic bronchoscope. When the device is properly positioned, the balloon is inflated to
achieve isolation of ventilation in the selected bronchus. Some endobronchial blockers are not directly coupled to the motion of a fiberoptic bronchoscope. As a result, the operation of the fiberoptic bronchoscope and the balloon-tipped blocker are entirely independent, which can cause difficulty when positioning the blocker. Correct placement normally requires several attempts before the device is properly positioned. Some of these devices utilize a removable stiff mandrel wire, placed in the lumen of the blocker, to allow manipulation during placement. Such wire can cause tissue trauma due to the stiffness of the end portion. In addition, such blockers only incorporate a single lumen in the design. This lumen accepts the removable mandrel wire and allows inflation of the balloon with the mandrel wire removed. The single lumen design can obstruct gas from being properly aspirated from or added to the blocked section, irrigation fluids from being added to the blocked section, and irrigation fluid, secretions or blood from being removed from the blocked section. In addition, the balloon used with such devices is generally a low volume, low compliance, high pressure, spherical or elliptical balloon. This type of balloon can cause damage by transmitting excessive pressure to the tracheal wall, and it has no mechanism to sense the inflation pressure.

[0008] An improved endobronchial blocker is described in U.S. Patent No. 5,904,648, incorporated by reference herein. The device of the '648 patent is a wire-guided double lumen blocker that has a guide loop extending from a distal end-hole of the tube. The guide loop provides a mechanism to link the endobronchial blocker to a bronchoscope that is used to navigate the sharp bends of the tracheal bronchial tree. As a result, the blocker can be more easily guided to the desired location of a bronchial occlusion than earlier blockers. Following withdrawal of the bronchoscope and the loop, the balloon is inflated to provide obstruction of a portion of the lung from ventilation. This device has been found to be very effective in allowing accurate placement of the endobronchial blocker. However, if the blocker inadvertently becomes disengaged at some point during the medical procedure, it can be difficult to reinsert the loop and/or to reposition the blocker. In such instances it is generally necessary for the physician to repeat the insertion procedure with a new blocker. Although it would be possible to
retain the guide loop in the bronchial mainstem throughout the procedure in order to simplify the possible re-positioning of the blocker, the maintenance of the guide loop in this manner would occupy space in the lumen that is then not available for other uses, such as providing additional ventilation space to the patient. Thus, it is normally considered good practice to remove the guide loop.

[0009] Another commercially available device that has been used to achieve isolation of ventilation is the UNIVENT tube. The UNIVENT tube is a double lumen endotracheal tube that includes a large lumen and a small lumen. The large lumen allows ventilation by conventional means, and the smaller lumen accepts an endobronchial blocker. The endobronchial blocker is advanced into the right or left mainstem bronchus, and the balloon is inflated to achieve isolation of ventilation. The remaining portion of the UNIVENT tube remains in the trachea in the same fashion as a conventional endotracheal tube. A disadvantage associated with the use of the UNIVENT tube is that the endobronchial blocker can be difficult to place. This can be particularly problematic for placement in the left mainstem bronchus, which necessitates traversing a greater angle than does placement in the right mainstem bronchus. The device should be placed using a fiberoptic bronchoscope; however the motion of the fiberoptic bronchoscope and the blocker are entirely independent. In clinical practice, the UNIVENT tube is generally larger in diameter than a conventional endotracheal tube. This can lead to difficulty in placement, and possible damage to the vocal chords. In addition, the ventilation lumen of the UNIVENT tube is smaller in cross-section than that of a similar-sized conventional endotracheal tube. In patients with severe pulmonary disease, this smaller cross-sectional area can make removal of the UNIVENT tube at the conclusion of surgery difficult. The effort involved in breathing through this small lumen is higher, and there is the risk of ventilatory failure.

[0010] Yet another commercially available blocker is the Cohen Tip-Deflecting Endobronchial Blocker, available from Cook Critical Care, of Bloomington, Indiana. This endobronchial blocker allows single-lung ventilation by incorporating a tip-directing feature to enable placement of the tip to be deflected left or right into the desired bronchial passage. The blocker can also be
easily moved from one lung to another, and provides precision control to manually
torque the device for delicate airway placement. This device is further described
in U.S. Patent Application Ser. No. 10/984,175, titled "Tip-Deflecting
Endobronchial Blocker", incorporated by reference herein. This device provides
very favorable control to the physician; however, the device requires additional
structure and complexity to provide the tip-deflecting feature that may not be
required in all cases.

[0011] It would be desired to provide an endobronchial blocking device that
may be readily positioned via a fiberoptic bronchoscope in either the right or left
mainstem bronchus, that may be used with a single lumen endotracheal tube, that
may be readily re-positioned in the bronchus in the event of dislodgement, and that
requires only a minimum amount of structural features.

BRIEF SUMMARY

[0012] The problems of the prior art are addressed in the inventive
endobronchial device.

[0013] In one form thereof, the present invention comprises an endobronchial
blocking device for use in blocking a selected mainstem bronchus under
visualization of a tip-deflectable bronchoscope. The blocking device comprises an
elongated member having a plurality of lumens therein, the elongated member
having a proximal portion and a distal portion, the proximal portion having a first
durometer and the distal portion having a second durometer, the first durometer
being greater than the second durometer. An inflatable blocker balloon is
disposed about the distal portion of the elongated member. A first lumen has a
diameter sufficient for receiving the bronchoscope, and a second lumen
communicates with an interior of the balloon to accomplish inflation. The distal
portion of the elongated member is deflectable responsive to a deflection of the tip
of the bronchoscope for positioning the elongated member at a desired site in the
selected mainstem bronchus.

[0014] In another form thereof, the invention comprises a method for
positioning an endobronchial blocker in a selected mainstem bronchus of a patient
under visualization from a tip-deflectable bronchoscope. An endotracheal tube is
positioned in the trachea of a patient, and the distal end of the endobronchial blocker is inserted through the endotracheal tube. The endobronchial blocker comprises an elongated member having a proximal portion and a distal portion, and having a plurality of lumens therein, the proximal portion having a first durometer and the distal portion having a second durometer, wherein the first durometer is greater than the second durometer. An inflatable blocker balloon is disposed about the distal portion of the elongated member. A first lumen is sized for receiving the bronchoscope and a second lumen communicates with an interior of the balloon to accomplish inflation. The distal end of the bronchoscope is inserted into the first lumen, and advanced such that the distal end portion of the bronchoscope extends distally at least as far as the endobronchial blocker distal end. The distal portion of the bronchoscope is deflected in a manner such that the bronchoscope is aligned for entry into the selected mainstem bronchus. Deflection of the distal end of the tip-deflecting bronchoscope causes a corresponding deflection of the lower durometer distal portion of the elongated body. The respective distal ends of the bronchoscope and the endobronchial blocker are further advanced such that the blocker distal end is positioned within the selected mainstem bronchus. The balloon is then inflated to block the selected mainstem bronchus. Proper positioning of the blocker may be confirmed through the bronchoscope prior to withdrawal of the bronchoscope.

BRIEF DESCRIPTION OF THE DRAWINGS

[0015] Fig. 1 is a side view of an endobronchial blocking device according to an embodiment of the present invention;

[0016] Fig. 2 is a sectional view taken along line 2-2 of Fig. 1;

[0017] Fig. 3 is a sectional view of an alternative embodiment of the device shown in Fig. 2;

[0018] Fig. 4 is a profile view of the trachea of a patient with an endotracheal tube in place, illustrating the inventive endobronchial blocking device and a fiberoptic bronchoscope passing through the blocking device;
[0019] Fig. 5 is a profile view of the trachea of a patient as in Fig. 4, wherein the distal tip of the endobronchial blocking device is shown in a deflected condition; and

[0020] Fig. 6 is a profile view of the trachea of a patient as in Fig. 4, wherein the distal tip of the endobronchial blocking device is positioned in the right mainstem bronchus of the patient, and the bronchoscope has been withdrawn.

DETAILED DESCRIPTION OF THE DRAWINGS AND THE PRESENTLY PREFERRED EMBODIMENTS

[0021] For purposes of promoting an understanding of the present invention, reference will now be made to the embodiments illustrated in the drawings, and specific language will be used to describe the same. It is nevertheless to be understood that no limitation of the scope of the invention is thereby intended, the proper scope of the invention being indicated by the claims appended below and the equivalents thereof. The figures are not all drawn to the same scale to avoid obscuring the details of the finer structures. The following detailed description of the preferred embodiments will make clear the preferred arrangement, size relationships and manner of using the components shown herein.

[0022] The present invention relates to an endobronchial blocking device. In the following discussion, the terms "proximal" and "distal" will be used to describe the opposing axial ends of the blocking device, as well as the axial ends of various component features. The term "proximal" is used in its conventional sense to refer to the end of the device (or component thereof) that is closest to the operator during use of the device. The term "distal" is used in its conventional sense to refer to the end of the device (or component thereof) that is initially inserted into the patient, or that is closest to the patient.

[0023] The endobronchial blocking device of the present invention has a large central lumen to allow passage of a bronchoscope therethrough, and a distal end portion that has greater flexibility than the proximal end portion. An inflatable balloon is wrapped around the distal end portion for achieving isolation of ventilation in either the left or right mainstem bronchus upon insertion of the blocking device. The flexibility of the distal end portion of the device allows the
tip-deflecting ability of the bronchoscope to be utilized to guide the blocking device into position in the selected mainstem bronchus. Once the blocking device is in position and the balloon is inflated, the bronchoscope can be removed, and ventilation as well as suction can be performed through the central lumen in well-known fashion.

[0024] One embodiment of the inventive device 10 is illustrated in Figs. 1 and 2. The device comprises an elongated polymeric tube 11. Preferably, tube 11 has a length of about 50-75 cm, although those skilled in the art will appreciate that longer, or shorter, tubes may be appropriate in some circumstances. Tube 11 includes a relatively long proximal portion 12 and a shorter distal portion 14. In a preferred embodiment, tube 11 has a length of about 65 cm, wherein proximal portion 12 has a length of about 50 cm, and distal portion 14 has a length of about 15 cm. One or more sideports 30 may be provided at the distal end of tube 11 for additional ventilation.

[0025] A conventional bifurcated fitting 21 is affixed to the proximal end of tube 11. Bifurcated fitting 21 includes branched portions 22, 24. Branched portion 22 is engaged with a conventional luer fitting 23 or similar apparatus for connecting the endobronchial blocking device 10 to, e.g., a ventilation apparatus (not shown). Branched portion 24 communicates, via inflation tube 26, with a conventional inflation assembly. In the embodiment shown, the inflation assembly comprises pilot balloon 38 and one-way valve 40. The inflation assembly receives an inflation fluid through end 41 and provides the inflation fluid for use in inflating a blocker balloon 16.

[0026] Inflatable blocker balloon 16 is provided at tube distal portion 14. Balloon 16 may have any conventional shape for blocker balloons. Balloon 16 is a high volume, low pressure balloon that is designed to accommodate up to about 20 ml of air. The amount of air required in a balloon to occlude the bronchus varies among individuals, but typically 5 to 20 ml is required, and more typically, about 5 to 8 ml. Balloon 16 is formed from conventional materials used for blocker balloons, such as silicone.
[0027] In the embodiment of Figs. 1 and 2, tube 11 includes two lumens 18, 20. Smaller diameter lumen 18 comprises the balloon inflation lumen. This lumen communicates in well-known fashion with the inflation assembly, and is used for transmission of an inflation fluid from the inflation assembly to the interior of the balloon 16 via one or more inflation ports 19 formed in tube 11. Larger diameter lumen 20 comprises the main lumen. Lumen 20 has an inner diameter that is at least large enough to accommodate a pediatric bronchoscope. In most cases, the inner diameter of this lumen is between about 3 mm and 6 mm, preferably between about 4.5 and 5 mm, and most preferably, about 4.7 mm. The outer diameter of tube 11 is sized to enable the tube to fit through a standard single lumen endotracheal tube 60, and yet leave sufficient room for ventilation between tube 11 and endotracheal tube 60. Preferably, the flexibility of tube 11 is comparable to that of commercially available airway exchange catheters, such as catheters available from Cook Incorporated, of Bloomington, Indiana.

[0028] Proximal and distal catheter portions 12, 14 of tube 11 are formed of well-known materials suitable for such use, preferably semi-rigid polymers such as polyethylene, polyurethane or polyvinyl. To enhance visibility, it is preferred to use a transparent or semi-transparent polymeric material. Radiopaque polyethylene is a particularly preferred polymeric material. The durometer of distal tip portion 14 is less than the durometer of the proximal portion, resulting in a distal tip portion that is softer and more flexible than the proximal portion. Both the proximal and distal portions may be formed of the same base polymer, or of different polymers.

[0029] The lower durometer distal tube portion 14 is bonded or adhered to the distal end of proximal portion 12 by conventional means, such as thermal bonding or adhesion. Attachment of distal tip portions to elongated medical devices is well known in the art, and the skilled artisan can readily determine an acceptable attachment mechanism without undue experimentation. To enhance bonding between the proximal and distal portions, it is preferred to use the same, or a similar, polymer for each of the respective sections in known fashion, which sections differ mainly in durometer, as described. As one possible alternative to
bonding, the catheter can be extruded, and the durometer of the respective portions can be altered during a continuous extrusion operation by known procedures.

[0030] An alternative embodiment of a tube for the endobronchial blocking device is shown in Fig. 3. In this embodiment, rather than utilizing a single elongated tube 11, two elongated tube members 44, 46 are affixed along adjoining longitudinal edges by any known, medically acceptable, affixation technique. In the embodiment shown, smaller diameter tube 44 includes inflation lumen 45, and larger diameter tube 46 includes main lumen 47.

[0031] As stated, the inventive endobronchial blocking device can be placed through a standard endotracheal tube (ETT). For best results, it is preferred that a large-diameter ETT be used, such as an ETT having a diameter between about 7 and 9 mm.

[0032] In use, a conventional small diameter fiberoptic bronchoscope, such as a pediatric bronchoscope, is inserted through main lumen 20 of the endobronchial blocking device 10 of Figs. 1 and 2 to visualize and aid in the placement of the device. The bronchoscope has a conventional tip-deflecting capability that enables it to be maneuvered for proper placement in either the left or right mainstem bronchus. The soft durometer distal portion 14 of tube 11 has sufficient flexibility such that the distal tip can be easily flexed when the tip-deflecting capability of the bronchoscope is activated. The tip-deflecting feature of the bronchoscope enables the operator to selectively direct, or "steer", the distal end of the blocking device into either the right or left mainstem bronchus. Once the blocking device is in position in the selected mainstem bronchus, the lung may be blocked by inflating the balloon that is positioned at the distal end of the blocking device.

[0033] Operation of the inventive endobronchial blocker in conjunction with a fiberoptic bronchoscope will now be described in greater detail, with particular reference to Figs. 4-6. An endotracheal tube 60 is initially positioned in the trachea 62 in conventional fashion, and is maintained in position by inflatable balloon 64. With the blocker balloon 16 fully deflated, the distal end of endobronchial blocking device 10 is inserted into the lumen of endotracheal tube
60. A conventional fiberoptic bronchoscope 66 having a deflectable, or "steerable", distal tip portion is then passed through main lumen 20 of the endobronchial blocking device. Preferably, the distal tip of bronchoscope 60 extends a few centimeters beyond the distal end of the endobronchial blocking device, as shown in Fig. 4. At this point, the carina should be visible through the bronchoscope.

[0034] To facilitate guidance into the desired right or left main bronchus, the distal tip of the bronchoscope is steered toward the desired bronchus in conventional fashion. Since the distal portion 14 of the endobronchial blocking device is formed of a low durometer, flexible material, the deflection of the distal end of the bronchoscope causes flexible distal portion 14 to deflect in the same direction as that of the bronchoscope. The blocking device and the bronchoscope are advanced into the selected mainstem bronchus 68 (in this case the right bronchus), as shown in Fig. 5. In most cases, a 10° to 45° deflection of the tip will be sufficient to enable the blocker to be directed into the selected bronchus.

[0035] The distal portion 14 of the endobronchial blocker is then advanced to just below the distal end of fiberoptic bronchoscope 66, such that visualization of the blocker balloon and tip may be maintained. Under bronchoscopic vision, proper positioning of the blocker in the bronchus is confirmed, and the blocker balloon 16 is inflated via the pilot balloon assembly as described. When fully inflated, the balloon should fill the entire endobronchial lumen to be blocked as shown in Fig. 6, and not herniate into the mainstem trachea. Following inflation of the balloon, the position of the endobronchial blocker should be inspected using the fiberoptic bronchoscope. Upon confirmation of proper placement and inflation, the bronchoscope is withdrawn.

[0036] Once the endobronchial blocker 10 is properly positioned in the right mainstem bronchus 68, ventilation is prevented from reaching lung areas distal to the inflated balloon. The main endobronchial blocker lumen 20 allows communication from the sealed lung segment to the proximal port. Fluid can thereafter be added, or removed, from the sealed lung segment.
[0037] The components of the inventive tip-deflecting endobronchial blocker are made from conventional medical-grade materials of the type that are commonly used in such devices. Those skilled in the art may readily determine acceptable compositions for these components without undue experimentation.

[0038] The inventive endobronchial blocking device has several advantages when compared to double lumen endotracheal tubes (DLT), or other isolation devices such as the Univent tube. For example, the inventive blocking device can be easily placed through a standard single-lumen ETT. The Univent and the DLT have much larger outer diameters and can be very difficult to place compared to a single ETT. In addition, the balloon in the inventive blocking device is a low pressure balloon. As a result, it is less traumatic to the bronchus and is better able to maintain its positioning. Furthermore, the inventive blocking device is easy to position, and in the event that it must be re-positioned, the positioning operation can be easily repeated. Easy placement through a single lumen tube makes the device very useful in difficult airway cases.

[0039] While this invention has been particularly shown and described with reference to preferred embodiments thereof, it will be understood by those skilled in the art that various changes in form and details may be made therein without departing from the spirit and scope of the invention. Those skilled in the art may recognize or be able to ascertain using no more than routine experimentation, many equivalents to the specific embodiments of the invention described specifically herein, which equivalents are intended to be encompassed in the scope of the invention.
WHAT IS CLAIMED IS:

1. An endobronchial blocking device for use in blocking a selected mainstem bronchus under visualization of a tip-deflectable bronchoscope, comprising:
   an elongated member having a plurality of lumens therein, the elongated member having a proximal portion and a distal portion, the proximal portion having a first durometer and the distal portion having a second durometer, the first durometer being greater than the second durometer;
   an inflatable blocker balloon disposed about said distal portion of the elongated member;
   a first one of said lumens having a diameter sufficient for receiving said bronchoscope, and a second one of said lumens communicating with an interior of said balloon to accomplish inflation, wherein the distal portion of said elongated member is deflectable responsive to a deflection of the tip of said bronchoscope for positioning said elongated member at a desired site in the selected mainstem bronchus.

2. The blocking device of claim 1, wherein the diameter of said first lumen is between about 3 and 6 mm.

3. The blocking device of claim 2, wherein the diameter of said first lumen is about 4.7 mm.

4. The blocking device of claim 1, wherein said elongated member has a length of about 50 to 75 cm.

5. The blocking device of claim 4, wherein said elongated member has a length of about 65 cm.

6. The blocking device of claim 5, wherein said proximal portion has a length of about 50 cm and said distal portion has a length of about 15 cm.

7. The blocking device of claim 6, wherein the balloon has an inflation capacity of between about 5 and 20 ml.

8. The blocking device of claim 7, wherein said inflation capacity is between about 5 and 8 ml.
9. The blocking device of claim 1, wherein said elongated member comprises a polymer selected from the group consisting of polyurethane, polyethylene and polyvinyl.

10. The blocking device of claim 9, wherein said proximal portion and said distal portion of said elongated member both comprise the same base polymer.

11. The blocking device of claim 1, wherein the elongated member comprises radiopaque polyethylene.

12. The blocking device of claim 1, wherein said proximal portion and said distal portion are joined by thermal bonding.

13. The blocking device of claim 1, wherein said proximal portion and said distal portion are formed by continuous extrusion.

14. The blocking device of claim 1, wherein said elongated member comprises a generally cylindrical tubular member.

15. The blocking device of claim 1, wherein said elongated member comprises two adjoining tubular members, a first one of said adjoining tubular members having said first lumen therein, and a second one of said adjoining tubular member having said second lumen therein.

16. The blocking device of claim 15, wherein said first tubular member has an inner diameter of between about 3 and 6 mm.

17. A method for positioning an endobronchial blocker in a selected mainstem bronchus of a patient under visualization from a tip-deflectable bronchoscope, comprising:

positioning an endotracheal tube in the trachea of a patient, said endotracheal tube having a lumen therethrough;

inserting a distal end of the endobronchial blocker into the lumen of the endotracheal tube, said endobronchial blocker comprising an elongated member having a proximal portion and a distal portion, and having a plurality of lumens therein, the proximal portion having a first durometer and the distal portion having a second durometer, wherein the first durometer is greater than the second durometer, and having an inflatable blocker balloon disposed about the distal portion of the elongated member, a first one of said lumens being sized for
receiving said bronchoscope and a second one of said lumens communicating with
an interior of said balloon to accomplish inflation;

inserting the distal end of said bronchoscope into said first lumen of said
endobronchial blocker, and advancing said bronchoscope such that a distal end
portion of said bronchoscope extends distally at least as far as said endobronchial
blocker distal end;

deflecting said distal portion of said bronchoscope such that said
bronchoscope is aligned for entry into said selected mainstem bronchus, said
deflecting causing corresponding deflection of said elongated body distal portion;

advancing said respective distal ends of said bronchoscope and said
endobronchial blocker such that said blocker distal end is positioned within said
selected mainstem bronchus; and

inflating said balloon such that said inflated balloon blocks the mainstem
bronchus.

18. The method of claim 17, further comprising the steps of confirming
placement of said endobronchial blocker through said bronchoscope, and
withdrawing said bronchoscope.

19. The method of claim 17, wherein the diameter of said first lumen is
between about 3 and 6 mm.

20. The method of claim 17, wherein the elongated member comprises
radiopaque polyethylene.
**INTERNATIONAL SEARCH REPORT**

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61M16/04

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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<td>US 5 904 648 A (ARNDT ET AL) 18 May 1999 (1999-05-18) column 4, line 15 - line 26 figures</td>
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<td>WO 01/02042 A (PULMONX) 11 January 2001 (2001-01-11) page 17, line 31 - page 8, line 7 page 12, line 10 - line 20; figures</td>
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<td>EP 0 841 071 A (BRAIN, ARCHIBALD IAN JEREMY) 13 May 1998 (1998-05-13) column 4, line 47 - column 5, line 1</td>
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**X** Further documents are listed in the continuation of box C. **X** Patent family members are listed in annex.

* Special categories of cited documents:
- **"X"** document defining the general state of the art which is not considered to be of particular relevance
- **"Y"** earlier document but published on or after the international filing date
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- **"R"** document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- **"S"** document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
- **"F"** document member of the same patent family

Date of the actual completion of the international search: 9 May 2005

Date of mailing of the international search report: 19/05/2005

Name and mailing address of the ISA

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**INTERNATIONAL SEARCH REPORT**

**Box II  Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)**

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. **X** Claims Nos.: 17-20 because they relate to subject matter not required to be searched by this Authority, namely:
   - Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. □ Claims Nos.; because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. □ Claims Nos.; because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

**Box III  Observations where unity of invention is lacking (Continuation of item 3 of first sheet)**

This International Searching Authority found multiple inventions in this international application, as follows:

1. □ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. □ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. □ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.: 

4. □ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.: 

**Remark on Protest**

□ The additional search fees were accompanied by the applicant's protest.

□ No protest accompanied the payment of additional search fees.

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