(19)日本国特許庁(JP)　(12)公表特許公報(A)　(11)特許出願公表番号
特表2004-512893
(P2004-512893A)
(43)公表日　平成16年4月30日(2004.4.30)

(51)Int.Cl.[7]	F I		テーマコード（参考）
A61B 17/24	A61B 17/24		4C060
A61B 17/00	A61B 17/00	320	4C167
A61M 29/02	A61M 29/02		

審査請求 未請求　予備審査請求 有　（全 121 頁）

(21)出願番号　特願2002-540629(P2002-540629)
(86)(22)出願日　平成13年10月26日(2001.10.26)
(85)翻訳文提出日　平成15年4月28日(2003.4.28)
(86)国際出願番号　PCT/US2001/051092
(87)国際公開番号　WO2002/038038
(87)国際公開日　平成14年5月16日(2002.5.16)
(31)優先権主張番号　09/699,302
(32)優先日　平成12年10月27日(2000.10.27)
(33)優先権主張国　米国(US)

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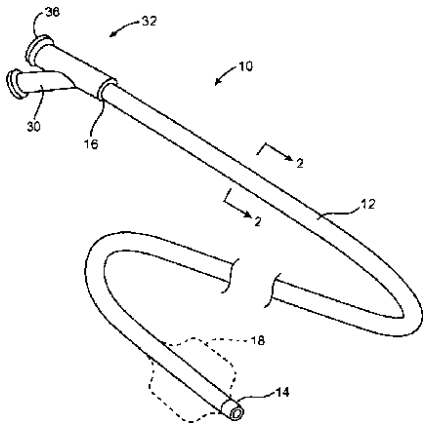
(54)【発明の名称】肺組織セグメントの閉塞および吸引のための方法およびデバイス

(57)【要約】
最小限に侵襲性である、肺組織セグメントを閉塞および吸引するための方法およびデバイスが提供され、装置は口を通じて導入され、肺の他の領域から標的肺組織セグメントを分離することに依存する。分離は、標的肺組織セグメントへと導く肺経路（１５２）において閉塞デバイス（１５０）を展開することによって達成される。いったん閉塞デバイスが定位置に固定されると、セグメントは、デバイスを通じて吸引され得る。このことは、多数の方法によって達成され得、吸引カテーテル（１０）と、閉塞デバイスの入口ポートに連結することおよびそのポートを通じた吸引を包含する。あるいは、呼吸周期の呼気の間に、分離した肺組織から気体の流出を可能にするが、吸気の間の空気の流入を防止する弁をポートに提供する。閉塞デバイスは、移植物として残って、分離を維持し、そして必要に応じて吸引を可能にするか、あるいは、任意の時点で取り除かれ得る。



【特許請求の範囲】
【請求項１】
肺組織セグメントからの気体の閉塞および放出のためのデバイスであって、
肺経路内において展開可能である、膨張可能な構造物と、
該膨張可能な構造物に関し、該構造物を通る一方の方向において気流を遮断し、かつ、該構造物を通る他方の方向において気流を許容する手段と、
を備える、デバイス。
【請求項２】
前記遮断する手段は、弁を備える、請求項１に記載のデバイス。
【請求項３】
前記弁は、呼気に対して開き、かつ、吸気に対して閉ったままであるように偏っている、請求項２に記載のデバイス。
【請求項４】
前記弁は、吸引カテーテルによって印加される吸引減圧に対して開くように偏っている、請求項２に記載のデバイス。
【請求項５】
吸引カテーテルに選択的に連結するためのポートをさらに備える、請求項４に記載のデバイス。
【請求項６】
前記遮断する手段は自己封止隔膜を備え、該隔膜を通って空気が引かれるように吸引カテーテルにおける貫通要素が選択的に該隔膜を通って貫通され得る、請求項４に記載のデバイス。
【請求項７】
前記膨張可能な構造物は、超弾性の、形状記憶のまたはスプリングテンパーされたワイヤを備え、該膨張可能な構造物は自己膨張する、請求項１～６のいずれか１項に記載のデバイス。
【請求項８】
前記膨張可能な構造物は、コイルを備える、請求項７に記載のデバイス。
【請求項９】
前記膨張可能な構造物は半径方向のセグメントおよび長手方向のセグメントを備え、該半径方向のセグメントは前記デバイスが膨張することを可能にし、該長手方向のセグメントは肺経路に対して静止する、請求項７に記載のデバイス。
【請求項１０】
肺組織セグメントへの肺経路を閉塞するためのシステムであって、該システムは：
近位端、遠位端および少なくとも１つのそれらを通る内腔を有するアクセスカテーテルと、
請求項１～１０のいずれか１項に記載の閉塞物であって、前記閉塞デバイスは、該アクセスカテーテルによって導入可能である、閉塞物と、
を備える、システム。
【請求項１１】
前記閉塞デバイスは、その遠位端から展開するために、前記アクセスカテーテルの内腔内に収容可能である、請求項１０に記載のシステム。
【請求項１２】
前記閉塞デバイスは、その遠位端付近の前記アクセスカテーテルに取り付け可能である、請求項１０に記載のシステム。
【請求項１３】
以下：
肺経路内において展開可能な閉塞デバイスと、
肺容量減少のための方法に従って使用するための指示書とを備え、該方法は、
肺経路において閉塞デバイスを肺組織セグメントへと展開する工程と、

該肺セグメントを少なくとも部分的に破壊するように該展開した閉塞デバイスを通って該セグメントを吸引する工程と、
を包含する、
キット。
【請求項１４】
近位端、遠位端および少なくとも１つのそれらを通る内腔を有するアクセスカテーテルをさらに備える、請求項１３に記載のキット。
【発明の詳細な説明】
【０００１】
（関連出願の相互参照）
本願の開示は、同日出願に係る、同時係属中の０９／６９９，３１３号に関連し、その開示全体は、本明細書において参考として援用される。
【０００２】
（発明の背景）
１．発明の分野
本発明は、概して、医療の方法、システムおよびキットに関する。より詳細には、本発明は、肺組織の分離したセグメントを吸引することによって肺容量の減少を行うための方法および装置に関する。
【０００３】
慢性閉塞性肺疾患は、約１６００万人、すなわち米国の人口の約６％に罹患する深刻な医療上の問題である。この群における具体的な疾患としては、慢性気管支炎、喘息性気管支炎、および気腫が挙げられる。多数の治療的介入が使用され、そして提唱されているが、いずれも完全に有効というわけではなく、しかも慢性閉塞性肺疾患は、米国における最も多い死因のうち第四位のままとなっている。従って、処置および治療の改善ならびに代替の処置および治療は、顕著に有利である。
【０００４】
本発明にとって特に興味深いことに、慢性閉塞性肺疾患のいくつかの形態に罹患する患者における肺機能が、有効肺容量を減少させることによって、代表的には、肺の疾患部分を切除することによって、改善され得る。肺の疾患部分の切除は、肺の非罹患領域の進展を促進すること、および肺に入るが血液に酸素を移入し得ない、吸入された空気の部分を減少させることの両方を行う。肺の減少は、従来は、開胸で、または胸腔鏡手順において行われている。これらの手順では、肺は、代表的に一体型の切断ブレードを有するステープリングデバイスを用いて切除される。
【０００５】
従来の肺減少手術は、多くの症例において有効であるが、胸腔鏡手順が使用されるときでさえ、患者に対して有意に外傷性である。そのような手順は、しばしば、健康な肺組織の意図しない切除を生じ、そしてしばしば肺における穿孔または他の不連続性を残し、これは、残りの肺からの空気の漏れを生じる。技術的に首尾よく終わった手順でさえ、呼吸不全、肺炎および死を生じ得る。さらに、多くの高齢患者および易感染性患者は、これらの手順に対して候補となり得ない。これらの理由から、上記欠点の少なくともいくつかを克服する、肺容量減少を行うための、改善された方法、システムおよびキットを提供することが所望される。
【０００６】
（２．背景技術の説明）
ＷＯ９９／０１０７６号および対応する米国特許第５，９５７，９１９号は、組織において熱エネルギーを加えてコラーゲンを収縮させることによって肺組織のサイズを減少させるデバイス及び方法を記載する。１つの実施形態において、空気が肺における小気胞から取り出されて小気胞のサイズが減少され得る。ついで小気胞への空気経路は、例えば、加熱により封止されて、小気胞のサイズが固定され得る。ＷＯ９８／４８７０６号は、肺空気経路において配置して肺組織の領域を孤立させるためのプラグ様のデバイスを記載する

。ここでは、空気は、栓をする前に組織から取り出されない。ＷＯ９８／４９１９１号は、呼吸器窮迫症候群を処置するための肺洗浄における界面活性剤の使用を記載する。米国特許第５，９２５０，０６０号もまた、興味深くあり得る。

【０００７】

肺へのアクセス、診断および処置に関する特許および出願としては、以下が挙げられる：米国特許第５，９５７，９４９号；米国特許第５，８４０，０６４号；米国特許第５，８３０，２２２号；米国特許第５，７５２，９２１号；米国特許第５，７０７，３５２号；米国特許第５，６８２，８８０号；米国特許第５，６６０，１７５号；米国特許第５，６５３，２３１号；米国特許第５，６４５，５１９号；米国特許第５，６４２，７３０号；米国特許第５，５９８，８４０号；米国特許第５，４９９，６２５号；米国特許第５，４７７，８５１号；米国特許第５，３６１，７５３号；米国特許第５，３３１，９４７号；米国特許第５，３０９，９０３号；米国特許第５，２８５，７７８号；米国特許第５，１４６，９１６号；米国特許第５，１４３，０６２号；米国特許第５，０５６，５２９号；米国特許第４，９７６，７１０号；米国特許第４，９５５，３７５号；米国特許第４，９６１，７３８号；米国特許第４，９５８，９３２号；米国特許第４，９４９，７１６号；米国特許第４，８９６，９４１号；米国特許第４，８６２，８７４号；米国特許第４，８５０，３７１号；米国特許第４，８４６，１５３号；米国特許第４，８１９，６６４号；米国特許第４，７８４，１３３号；米国特許第４，７４２，８１９号；米国特許第４，７１６，８９６号；米国特許第４，５６７，８８２号；米国特許第４，４５３，５４５号；米国特許第４，４６８，２１６号；米国特許第４，３２７，７２１号；米国特許第４，３２７，７２０号；米国特許第４，０４１，９３６号；米国特許第３，９１３，５６８号；米国特許第３，８６６，５９９号；米国特許第３，７７６，２２２号；米国特許第３，６７７，２６２号；米国特許第３，６６９，０９８号；米国特許第３，５４２，０２６号；米国特許第３，４９８，２８６号；米国特許第３，３２２，１２６号；ＷＯ　９５／３３５０６およびＷＯ　９２／１０９７１。

【０００８】

肺容量減少手術は、以下を含む多くの刊行物において記載されている：　Ｂｅｃｋｅｒ　ｅｔ　ａｌ．（１９９８）Ａｍ．Ｊ．Ｒｅｓｐｉｒ．Ｃｒｉｔ．Ｃａｒｅ　Ｍｅｄ．１５７：１５９３－１５９９；Ｃｒｉｎｅｒ　ｅｔ　ａｌ．（１９９８）Ａｍ．Ｓ．Ｒｅｓｐｉｒ．Ｃｒｉｔ．Ｃａｒｅ　Ｍｅｄ．１５７：１５７８－１５８５；Ｋｏｔｌｏｆｆ　ｅｔ　ａｌ．（１９９８）Ｃｈｅｓｔ　１１３：８９０－８９５；およびＯｊｏ　ｅｔ　ａｌ．（１９９７）Ｃｈｅｓｔ　１１２：１４９４－１５００。

【０００９】

肺閉塞を取り除くためのムコリチック剤の使用は、Ｓｃｌａｆａｎｉ　（１９９９）ＡＡＲＣ　Ｔｉｍｅｓ，　Ｊａｎｕａｒｙ，　６９－９７に記載されている。難治性無気肺に罹患する肺セグメントを再膨張するためのバルーンカフ形状の気管支ファイバースコープは、Ｈａｒａｄａ　ｅｔ　ａｌ．　（１９８３）Ｃｈｅｓｔ　８４：７２５－７２８に記載されている。

【００１０】

（発明の要旨）

本発明は、慢性閉塞性肺疾患、または肺セグメントの分離もしくは肺容量の減少が所望される他の状態に罹患する患者において肺容量減少を実施するための、改善された方法、システム、デバイスおよびキットを提供する。本発明は、同様に、気管支胸膜瘻の処置に適切である。この方法は、最小限に侵襲性であり、装置は口を通じて（気管内に）導入される。この方法は、標的肺組織セグメントを肺の他の領域から分離することに依存する。分離は、肺経路における閉塞デバイスを標的肺組織セグメントへと展開することによって達成される。いったん閉塞デバイスが定位置に配置されると、そのセグメントは、デバイスを通じて吸引される。これは、多数の方法により達成され得、これには、吸引カテーテルを、閉塞デバイス上の入口ポートに連結すること、およびそのポートを通じて吸引することが含まれる。あるいは、呼吸周期の呼気の間に、分離した肺組織から気体の流出を可能

にするが、吸気の間の空気の流入を防止する弁をポートに提供することによって達成され得る。さらに、多数の他の方法が使用され得る。閉塞デバイスは、移植物（インプラント）として残って、分離を維持し、そして必要に応じて続いての吸引を可能にすることができるか、あるいは、そのデバイスは、任意の時点で取り除かれ得る。同様に、このデバイスは、一定の期間にわたって生分解し得る。

【００１１】

閉塞デバイスは、肺経路における送達、展開および固定を可能とするために種々の形態をとり得る。送達は、一般に、最小限に侵襲性のデバイス（例えば、可撓性気管支鏡またはアクセスカテーテル）の使用によって実施される。可撓性気管支鏡は、その遠位端の付近に配置される膨張可能なカフを有するシースとともに利用され得る。このすべての記載は、本発明の譲渡人に譲渡される、同時係属中の出願（代理人整理番号０１７５３４－００１３００）において提供され、これはすべての目的で参考として援用される。そのようなシースを用いる場合、気管支鏡は、シース内の内腔へと導入されて次いで肺経路へ導入されるアセンブリを形成する。次いで、このカフを膨張させて経路を閉塞させ得る。同様に、操縦型であり得るかまたは関節構造をとり得るアクセスカテーテルが使用され得、これは、遠位端付近に膨張可能なバルーンカフを備え得、これには、バルーン膨張、ガイドワイヤ上でのトラッキングおよび光学画像化などのための多数の内腔が含まれ得る。閉塞デバイスは、代表的に、このアクセスカテーテル、気管支鏡、シースまたは適切なデバイスの内腔内に収容され、そのカテーテルの遠位先端の付近に取り付けられるか、または標的肺組織セグメントへと導く所望の肺経路に任意の方法で輸送される。従って、閉塞デバイスは、そのような送達のために適切な大きさにされなければならず、そして代表的に、展開の際に膨張して肺経路内に固定するように設計される。本明細書において以下、本発明は、アクセスカテーテルを伴って使用することに関連して記載されるが、任意の適切なデバイスが使用され得ることが理解され得る。

【００１２】

本発明の第一の局面において、閉塞デバイスは、肺経路において膨張しそしてそれによりそのデバイスを固定する構造支持体を備える。そのような支持体は、種々の膨張技術のための多数の構成を含み得る。例えば、この構造支持体は、閉塞デバイスを、円錐、ロッド状、円柱または送達のための他の形状において、巻き、回転させ、曲げ、まっすぐにしまたは折り曲げることができる。ついで、いったん所望の位置に配置されると、その閉塞デバイスは解放され得、そして膨張されて、経路においてデバイスを固定し得る。そのような膨張は、例えば、圧縮された構造が形成前の膨張された位置へと放たれるかのように、助けなしでなされ得る。あるいは、そのような膨張は、膨張可能なバルーンまたはカフの使用を伴うような補助ありで行われ得る。いくつかの場合において、バルーン部材または膨張可能な部材は、閉塞デバイスに取り込まれ得、そして経路を閉塞させるために膨張したままであり得る。これは、構造支持体または膨張可能なバルーンと組み合わせて提供され得、あるいは、類似のデバイスが、そのような支持体なしに使用され得る。

【００１３】

この構造支持体は、任意の型のワイヤ（特に、超弾性の、形状記憶のまたはスプリングテンパーされたワイヤ）あるいは任意の型のポリマーまたは適切な材料から構成され得る。このバルーンまたは膨張可能な部材は、そのような目的のために適切な、任意の、可撓性で、重合性の材料から構成され得る。この部材は、所望に応じて気体または液体で膨張され得るか、あるいはその部材は、膨張泡または類似の材料で膨張され得る。同様に、接着剤を用いて膨張または注入され得る。そのような接着剤は、その部材を膨張し得、および／またはその部材を堅くして破壊の可能性を減少させ得る。さらに、その接着剤は、肺経路の壁へとデバイスを接着して固定の程度を増加させるさらなる役割を果たしてもよい。さらに、このデバイスは、抗生物質薬剤（例えば、硝酸銀）または肺経路への薬剤の送達のための類似の薬剤の中に包埋またはそれでコーティングされてもよい。そのような送達は、任意の適用手段によって行われ得る。

【００１４】

構造支持体が存在する場合、そのような支持体は、種々の設計を包含し得る。第一の実施形態において、構造支持体は、半径方向のセグメントおよび長手方向のセグメントを備える。この半径方向のセグメントは、膨張してその経路を充填する。この長手方向のセグメントは、経路の壁に対して静止してそのデバイスを固定するのを助ける。第二の実施形態において、その構造支持体は、膨張して経路を充填するメッシュを備える。第三の実施形態において、この構造支持体は、螺旋またはスパイラルに巻かれたワイヤを備える。このワイヤもまた、膨張して経路の壁と接触し、そしてデバイスを固定する。これらの実施形態の各々において、この構造支持体は、薄ポリマーフィルムから構成される袋、連続発泡体もしくは独立発泡体開放されているかもしくは閉鎖されている気泡ガラス（ｃｅｌｌ ｆｏａｍ）または他の適切な材料と接続されるかまたはその中に密閉されて、肺経路の壁に対する封止およびそのデバイスを通る気流の閉塞を提供し得る。この袋の材料にはまた、接着剤、シーラントまたは他の材料が注入されて、気道の閉塞を改善し、そしておそらく気道壁への接着を改善し得る。

【００１５】

本発明の第二の局面において、閉塞デバイスは、さらに、そのデバイスを通って吸引するためのポートを備え得る。これは、後の時点で破壊された（ｃｏｌｌａｐｓｅｄ）肺セグメント（例えば、感染の症例において）へのアクセスを可能にし得る。代表的には、閉塞デバイスは、入口ポートを有し、この入口ポートは、そのデバイスの近位端の付近に配置され、分離された肺組織セグメントを取り除く。従って、そのようなポートは、吸引カテーテルのような最小限に侵襲性デバイスによってアクセス可能である。このようなデバイスは、気管支経路を通じて進行し得る。必要に応じて、出口ポートが閉塞デバイスの遠位端の付近に配置され得る。このポートは、多数の目的のための種々の設計を包含し得る。

【００１６】

第一の実施形態において、そのポートは、自己封止隔膜を供える。そのような隔膜は、中実（ｓｏｌｉｄ）膜または予備切断された膜を備え得る。そのポートを通じた吸引は、その遠位端においてアクセスチューブまたは貫通する部材を有する吸引カテーテルの使用によって達成され得る。そのようなカテーテルは、それ自体でまたはアクセスカテーテルの使用により閉鎖デバイスの部位へと進行し得る。この隔膜は、中実膜を通じて穿孔されるかまたは予備切断された膜の切断部分を通じて通過されるかのいずれかで、そのアクセスチューブにより貫通され得る。閉塞デバイスの設計に依存して、入口ポートおよび必要に応じて出口ポートは、この様式において貫通され得る。吸引は、そのアクセスチューブおよび吸引カテーテルを通じて達成されて、分離された肺組織セグメントおよび経路から、気体および／または液体を吸引し得る。必要に応じて、吸引の前に、１００％酸素、ヘリウム－酸素混合物または低分子量気体での、肺セグメントの洗浄が、アクセスチューブを通じてそのような気体を導入すること（例えば、高周波ジェット換気プロセスによる）によって実施され得る。この場合において、吸引は、導入された気体および任意の残りの気体の両方を取り除く。同様に、液体ペルフルオロカーボンまたは特定の薬物（例えば、抗生物質、レチノイン酸およびヒアルロン酸）は、吸引の前に導入され得る。ほとんどの場合、吸引は、肺セグメントを少なくとも部分的に破壊する。吸引カテーテルをポートから取り出すときに、隔膜が自己封止し得、あるいは、隔膜は、後のアクセスまたは恒常的な封止のために、シーラントまたは他の封止手段でさらに封止され得る。

【００１７】

自己封止隔膜が予備切断膜を備える場合、そのポートを通じた吸引は、代替的に、吸引カテーテルの閉塞デバイスへの連結によって達成され得る。連結は、その吸引カテーテルのポートへの係合または連結部材もしくは吸引カテーテルをポート上へスライドしてシールを形成することを包含し得る。いずれの場合においても、吸引カテーテルを通じた吸入は、気体および／または液体を膜における切断部を通じて通過させて、分離した肺組織セグメントおよび経路から吸引されることを可能にし得る。ここでも、これは、肺セグメントを少なくとも部分的に破壊する。同様に、吸引カテーテルをポートから取り除くとき、隔膜が自己封止し得るか、または隔膜が、後のアクセスまたは恒常的な封止のためのシーラ

ントまたは他の封止手段でさらに封止され得る。

【００１８】

第二の実施形態において、そのポートは、一方向弁を備える。そのような弁は、可撓性層によって覆われるポートを備え、この層は、少なくとも１つの接続点によってそのポートに付着する。この層がそのポートから移動すると、その弁を開き、そのポートに向けて移動するとその弁を閉じる。可撓性層が中実の場合、その層がそのポートから移動すると、気体が接続点の間、および可撓性層の端の周りを流れ得る。あるいは、この可撓性層は、その中に穴を有し得る。この場合において、そのポートはまた、その可撓性層における穴にそって整列されていない穴を有する仕切り（ｐａｒｔｉｔｉｏｎ）を備え得る。この層がそのポートから移動すると、気体がその仕切りにおけるその穴を通って流れ得、そしてその可撓性層における穴を通って外へ流れ得る。この層がその仕切りに対して移動するとき、その穴は、その弁を閉じながら覆われる。他の弁の設計としては、吹出しボール弁またはバイアス予備加重ダイアフラム弁（ｂｉａｓｅｄ　ｐｒｅ－ｌｏａｄｅｄ　ｄｉｐｈｒａｇｍ　ｖａｌｖｅ）が挙げられる。

【００１９】

一方向性弁を通じた吸引は、多数の方法によって達成され得る。同様に、そのポートは、吸引カテーテルまたは類似のデバイスを、気管支経路を通って閉塞デバイスの部位へと進行させることによってアクセスされ得る。これは、必要に応じて、アクセスカテーテルの使用によって達成され得る。この吸引カテーテルは、その弁の付近に配置され得るか、またはその弁に係合され得る。ここで、そのカテーテルを通じて適用される吸引または減圧によって、その弁が開く。その吸引カテーテルがその弁に係合していない場合、適切な吸引によって弁を開けることは、代表的には吸引カテーテルの遠位端である吸引点に対して近位にある経路を閉塞することによって達成され得る。このような閉塞は、吸引カテーテルの遠位端またはアクセスカテーテルに取り付けられたバルーンまたは閉塞デバイスを膨張させることによって達成され得る。いずれの場合においても、減圧によって、そのポートからその可撓性層を引き離すことができ、それによって、気体および／または液体が分離した肺セグメントから、弁を通って吸引カテーテルへと流れて出て行くことを可能にする。あるいは一方向性弁を通じた吸引は、呼吸の間に自然に達成され得る。呼気の間の圧変化によって、弁が開き得る。なぜなら、気体が分離した肺セグメントから流れて出るからである。吸気の間の逆の圧変化によって、弁が閉じ、分離したセグメントへ気体が流れるのを防ぐことができる。これは、時間に応じて末端のセグメントに捕捉される気体量を減少し得、したがって肺セグメントを少なくとも部分的に破壊し得る。同様に、一方向性弁を通じた吸引は、肺セグメントを取り出しそして弁から押し出すような肺への外的な機械的圧によって達成され得る。同様に、肺の跳ね返りの際の逆の圧変化によって弁が閉じ、気体が分離したセグメントへと流れ込むことを防止する。

【００２０】

本発明の第三の局面において、閉塞デバイスは、遮断デバイスを備える。この遮断デバイスは、肺経路において展開して気道を閉鎖する。そのような遮断デバイスは、これまでに記載した閉塞デバイスと類似の設計で構成され得る。なぜなら、それは、同様に送達され得、展開され得、そして肺経路内に固定され得るからである。したがって、遮断デバイスの実施形態は、代表的に膨張可能な支持構造物を含む。例えば、支持体構造の１つの実施形態において、その支持構造物はコイルを含む。第二の実施形態において、支持構造物は、メッシュを含む。同様に、その支持構造物は、ポリマー膜または袋へと連結または覆われ（入れられ）、肺経路壁に対する封止を提供し、そしてそのデバイスを通じた気流を閉塞する。代表的に、この遮断デバイスは、その末端肺セグメントが他の方法によって吸引された後、その経路に配置される。これは、肺セグメントの封止を取り、そして肺容量減少を維持する。あるいは、遮断デバイスは、末端肺セグメントが吸引される前に、経路内に配置され得る。この場合、肺セグメントに捕捉された気体は、時間とともに吸収され得、そして最終的に破壊される。これは、吸収無気肺として知られるプロセスである。このプロセスは、遮断デバイスを配置する前に、１００％酸素、ヘリウム酸素混合物または低

分子量ガスで肺セグメントを通気することによって増強され得る。このような増強は、肺セグメントの完全な破壊を促進し得る。いずれの場合においても、遮断デバイスは、必要に応じて、後に所望される場合に取り除かれ得る。

【００２１】

本発明の方法は、肺容量減少を達成するための閉塞デバイスの利用を包含する。上記のように、方法は、閉塞デバイスの標的肺組織セグメントへの肺経路における送達、展開および固定を包含する。末端肺組織セグメントの少なくとも部分的な破壊は、その経路において展開される閉塞デバイスを通ってそのセグメントを吸引することによって達成され得る。吸引は、閉塞デバイスにおけるポートを通じて、吸引カテーテルまたは類似のデバイスを使用することによって達成され得る。上記もされているように、そのポートは、一方向性弁を備え、吸引および最終的な肺容量減少は、呼吸周期における応答において、この弁の開閉によって達成され得る。さらに、本発明の方法は、以前に記載されるように、末端肺組織セグメントへ導かれる肺経路における、遮断デバイスの展開を包含する。

【００２２】

本発明のシステムは、本発明に関連して記載される任意の構成要素を含み得る。本発明のシステムの特定の実施形態は、上述のようなアクセスカテーテルおよび閉塞デバイスを備える。ここで、この閉塞デバイスは、そのアクセスカテーテルによって導入可能である。例えば、この閉塞デバイスは、そのアクセスカテーテルの遠位端から出て展開するために、そのアクセスカテーテルの内腔内に収容可能であり得るか、またはその閉塞デバイスは、その遠位端付近でそのアクセスカテーテルに取り付けられ得る。いずれの場合でも、その閉塞デバイスは、肺経路内で展開および固定され得る。

【００２３】

本発明の方法および装置は、そのような使用のために、１つ以上のキットにおいて提供され得る。このキットは、肺経路において展開可能な閉塞デバイスおよび使用のための指示書を備え得る。必要に応じて、そのようなキットは、本発明に関連して記載される他の任意のシステム構成要件および本発明に関連する他の任意の材料または物品をさらに備え得る。

【００２４】

本発明の他の目的および利点は、添付の図面とともに、以下の詳細な説明から明らかになる。

【００２５】

（詳細な実施形態の説明）

肺容積減少は、（通常、単一の肺経路を通って空気を受ける肺の葉領域または小葉領域内の）標的肺組織セグメント（すなわち、肺の肺胞領域へと空気を送達し、そしてそこから空気を受ける分岐する気管支のセグメント）を破壊することによって実施される。このように分離される肺組織セグメントは、まず分離され、そして次いで、標的肺組織セグメントから空気（または他の気体もしくは液体が存在し得る）の吸引により破壊される。肺組織は、非常に高い割合の無効容量を有し、したがって、内部気体の除去は、完全に膨張する（すなわち、通常の吸息圧で膨張する）ときに有する容量のほんの少しの割合にまで肺組織を減少させ得る。容量減少の例示および好ましい割合は、上記されている。

【００２６】

本発明の方法は、概して、肺の気管支への気管内での導入に適合されるアクセスカテーテルを用いて、標的肺組織セグメントをアクセスすることに依存する。例示のアクセスカテーテル１０は、図１および図２に例示され、そして遠位端１４、近位端１６およびそれらを通る少なくとも１つの内腔を有するカテーテル本体１２を備える。必要に応じて、このカテーテル１０は、膨張可能な閉塞バルーン１８を、その遠位端付近にさらに含む。この場合において、このカテーテルは、少なくとも２つの内腔、中央内腔２０およびバルーン膨張内腔２２を有する。図２に示されるように、このバルーン膨張内腔２２は、内側本体部材２４と、内側本体部材の周りに同軸に配置される外側本体部材２６とで規定される環状内腔であり得る。この内腔２２は、近位ハブ３２におけるポート３０を開き、そしてバ

ルーン１８の膨張を提供する。中央内腔２０は、ハブ３２におけるポート３６を開き、複数の機能（ガイドワイヤ上における必要に応じた導入、吸引、二次カテーテルの導入など）を提供する。

【００２７】

アクセスカテーテル１０の寸法および材料は、必要に応じてガイドワイヤおよび／または一次気管支管構造物を通じて、気管内導入および肺気管支または経路を通じた腔内への進行を可能にするように選択される（図４Ｂ下部に例示されるとおり）。適切な材料としては、特に、内側管状部材２４について、低密度ポリエチレン、高密度ポリエチレン、ポリアミド、ナイロン、ＰＴＦＥ、ＰＥＥＫなどが挙げられる。閉塞バルーンを含む、外側部材は、ポリウレタン、低密度ポリエチレン、ポリビニルアルコール、シリコーンゴム、ラテックスなどのような弾性材料から作製され得る。必要に応じて、外側管状部材２６の、膨張可能なバルーンの近位方向の部分は、そのバルーンの加圧の際に膨張しないように、より厚くされ得るかおよび／または補強され得る。アクセスカテーテル１０の例示的な寸法は、以下の表に示される。

【００２８】

【表１】

アクセスカテーテル寸法				
	例示		好適	
	内側管状部材	外側管状部材	内側管状部材	外側管状部材
外径（mm）	0.4～4	0.6～4.5	1～1.5	2～4
壁厚（mm）	0.05～0.25	0.5～0.25	0.1～0.2	0.15～0.25
長さ（mm）	50～150	同左	50～80	同左
バルーン長さ（mm）	5～50		10～20	
バルーン直径（mm）膨張	2～20		6～15	

このアクセスカテーテル１０は、多数の方法で改変され得る。これらのうちのいくつかは、図３Ａ～図３Ｆに例示される。例えば、内側同軸管構造および外側同軸管構造の代わりに、カテーテルは、図３Ａに示されるように、環状の主要内腔３２および三日月状形状の膨張内腔３４を有するカテーテル本体３０を有する単一押し出し物であり得る。あるいは、カテーテル本体４０は、３つの内腔（すなわち、ガイドワイヤを受け、吸引を適用し、および／または二次カテーテルを送達するための一次内腔４２）を有する単一押し出し物として形成され得る。第二の内腔４４は、閉塞バルーンを膨張するために提供され得る。第三の内腔４６は、代替のガイドワイヤまたは吸引内腔として提供され得る。主要管状本体５２を含むカテーテル本体５０は、図３Ｃに示されるように、バルーン膨張のために適切な内腔５６を規定するために、その上に融着される外側層５４を有する。一次内腔５８は、主要管状部材５２内に形成される。わずかに異なる代替として、カテーテル本体６０は、一次管状部材６２および二次管状部材６４から形成され得る。ここで、その管状部材（複数）は、外側部材６６（例えば、加熱収縮によって適用される層）によって一緒に保持される。一次管状部材６２は、主要内腔６８を提供し、他方、二次管６４は、二次内腔７０を提供する。この二次内腔７０は、代表的にバルーン膨張のために使用され、他方、一次内腔６８は、アクセスカテーテルの他のすべての機能のために使用され得る。

【００２９】
必要に応じて、本発明におけるアクセスカテーテルは、光学画像化能を伴って提供され得る。図３Ｅに示されるように、カテーテル本体８０は、代表的には、従来の押し出しプロセスによって、４つの内腔を備えるように形成され得る。内腔８２は、ガイドワイヤ上をたどる経路に適切である。内腔８４および内腔８６は両方とも、照明のために光ファイバ８８を含む。内腔９０は、光波ガイドまたは画像ファイバ９２を有する。内腔８２は、代表的にガイドワイヤが引き抜かれた後に洗浄および吸引のために使用され得る。バルーン膨張は、残っている空間ならびに光ファイバ８８を取り囲む内腔８４および内腔８６を通じて行われ得る。第二のカテーテル本体１００は、多数の分離管の同軸配置物として形成される。外側管１０２は、別個のガイドワイヤ管１０４を含み、このガイドワイヤ管は、ガイドワイヤの上をたどる導入ならびにガイドワイヤが取り出された後の潅流および吸引を可能にする内腔１０６を規定する。第二の内部管状部材１１０は、光画像化ファイバ１１２を含み、複数の光ファイバ１１２は、外側管状部材内の残りの空間１１４内を通過する。カテーテル構造８０およびカテーテル構造１００の両方において、前方画像化は、光ファイバによる照射およびカテーテルの遠位端におけるレンズを通じて画像を検出することによって行われ得る。この画像は、従来のカソード光線または他の型の画像スクリーン上に提示され得る。特に、以下に記載されるように、前方画像化は、ユーザーが、分岐気管支を通じて所望の経路を通ってカテーテルを進行させるためのガイドワイヤを選択的に配置することを可能にする。

【００３０】
通常、分岐気管支を通じたガイドワイヤの位置づけは、アクセスカテーテルの画像化構成要素を通じて見ながら操作される。このようにして、そのアクセスカテーテルは、ガイドワイヤおよびアクセスカテーテルを代替的に進行させることによってそれに沿って「インチ目盛り」が付けられ得る。アクセスカテーテルに画像化を提供することの代わりに、位置づけは、蛍光透視法によってのみなされ得る。さらなる代替として、操縦型画像化ガイドワイヤ３００（図４Ａ～４Ｃ）が使用され得る。ガイドワイヤ３００は、偏向尖端３０２を備え、この尖端は、押／引リボン３０４を用いて単一の平面上において偏向され得る。通常、この尖端は、ばね３０６を備えることによって偏向が容易になる。操縦可能性に加えて、ガイドワイヤ３００は、光画像化波ガイド３１０および照明光ファイバ３１２を備える。これらは、図４Ｃの断面図において最もよく見られる。従って、ガイドワイヤ３００は、分岐気管支を通じて操縦されて、それ自体のインサイチュ画像化能を用いて標的組織セグメントに到達し得る。いったん、ガイドワイヤ３００が定位置にくると、アクセスカテーテルはまた、標的肺組織セグメントへと導入され得る。そのガイドワイヤが画像化能力を有することから、アクセスカテーテルは、そのような画像を取り込む必要はない。これは、利点であり得る。なぜなら、これは、アクセス内腔がより大きなサイズで作製されることを可能にし、そのカテーテルは光波ガイドはなんら有する必要がないからである。

【００３１】
今度は図５Ａを参照すると、カテーテル１０は、患者の気管Ｔを通じて肺Ｌ内の肺組織セグメント（特に、罹患領域ＤＲ）へと進行し得る。気管Ｔを通じた進行は、比較的単純であり、そして必要に応じて、気管内チューブおよび／またはガイドワイヤを用いて分岐気管支を通じて進行経路が選択される。気管内チューブは、薄壁設計を有し得、ここで、内径は、標準的な気管内チューブにおけるものよりも大きい。標準的な気管内チューブは、７．０ｍｍ内径および１０ｍｍ外径を有する。薄壁設計は、９．０ｍｍ内径および１０ｍｍ外径を有し、より大きな内径により、適切な換気を提供しつつより大きな装置の挿入が可能になる。操縦は、図３Ｅおよび図３Ｆにおいて例示される画像化アクセスカテーテルを用いたリアルタイムの画像化のもとで行われ得る。必要に応じて、アクセスカテーテル１０は、米国特許第５，２８５，７７８号（本願の譲受人に実施許諾されている）において記載されるような、可視化気管を通じて導入され得る。図５Ｂにおいて示されるように、可視化気管内チューブ１２０は、閉塞カフ１２２を備える。このカフは、それぞれ、左

気管支ＬＢおよび右気管支ＲＢの分岐のちょうど上にある気管内で膨張され得る。可視化気管内チューブ１２０は、前方を見るための光学系（代表的に、照明ファイバおよび画像化ファイバ）を備え、左気管支ＬＢと右気管支ＲＢとの間の主要分岐を直接見ることを可能にする。従って、アクセスカテーテル１０の初期の配置は、気管内チューブ１２０および必要に応じてアクセスカテーテル１０自体を可視化する可視化のもとで行われ得る。アクセスカテーテルが気管内チューブまたは類似のデバイスを使用するかまたは使用することなく位置づけられ得る。そのようなデバイスが使用されるとき、それは、多数の形態をとり得、そして多数の位置に位置づけされ得る。例えば、気管内チューブまたはデバイスは、図５Ａに示されるように位置づけされ得るか、またはそれは、「一肺換気」を達成するように位置づけされ得る。一肺換気では、矯正手順に関与しない肺の側が適切に換気される。同様に、アクセスカテーテルは、挿管なしに局所麻酔のもとで位置づけられ得る。いずれの場合においても、特に図５Ａを再び参照すると、アクセスカテーテル１０は、その遠位端１４が気管支または罹患領域ＤＲへ直接導かれる肺経路における領域に達するまで進行される。

【００３２】

いったんアクセスカテーテル１０の遠位端１４が肺経路内の所望の位置に位置づけされると、閉塞デバイスは、経路内で展開され得る。その閉塞デバイスの展開または送達の方法は、多数の因子、特に閉塞デバイス自体の設計に依存する。代表的に、その閉塞デバイスは、アクセスカテーテル１０、またはアクセスカテーテル１０を通じて通過され得るカテーテル内に収容され得る。図６において示されるように、閉塞デバイス１５０は、アクセスカテーテル１０の内部腔内で圧縮または破壊され得る。示される閉塞デバイス１５０は、利用され得る多くの設計のうちのひとつである。次いで、閉塞デバイス１５０は、矢印の方向に、肺経路１５２へとカテーテル１０の遠位端１４から押し出され得る。そのデバイス１５０は、自己膨張する場合（例えば、張力または形状記憶による）、そのデバイス１５０は、それ自体が経路１５２において膨張および固定する。そのデバイス１５０が自己膨張しない場合、それは、アクセスカテーテル１０によって提供されるバルーンまたは他の機構、カテーテルまたはアクセスカテーテル１０によって送達されるデバイス、あるいは別のデバイスの使用によって膨張され得る。同様に、閉塞デバイス１５０は、アクセスカテーテル１０（示さず）または送達カテーテルの上に、取り付けられるかまたはクリンピングされ得、そして所望の位置へと送達され得る。次いで、挿入の間にシースがそのデバイス１５０の上に配置され得る。そのデバイス１５０の展開は、シースが引き抜かれること、およびそのデバイス１５０が自己膨張するようにさせることまたはそのデバイス１５０をバルーンまたは他の機構の使用によって膨張させることによって達成され得る。

【００３３】

閉塞デバイス１５０の種々の実施形態が提供される。まず、閉塞デバイス１５０の多数の実施形態は、経路１５２においてデバイス１５０を固定するように膨張する構造支持体を含んで構成される。図７Ａを参照すると、支持体１５４は、半径方向セグメント１６０および長手方向セグメント１６２を含んで構成され得る。半径方向セグメント１６０は、デバイス１５０が膨張して経路１５２を充填することを可能にし、そして長手方向セグメント１６２は経路１５２の壁に対して静止してデバイス１５０の固定を補助する。支持体１５４は、例えば、図７Ａに示されるように個別であり得るか、または図７Ｂに示されるように、互いに接続され得る。さらに、支持体１５４は、図７Ａに示されるように、デバイス１５０の近位端１６４および遠位端１６６に沿って連続し得るか、または支持体１５４は、図７Ｂに示されるように、そのような端１６４および１６６において存在しなくてもよい。

【００３４】

図８～１１を参照すると、支持体１５４は、メッシュ１７０または類似のインターロック構造物を含んで構成され得る。図８に示されるように、メッシュ１７０は、円柱状へと巻かれるかまたはロールされて、送達カテーテルまたはアクセスカテーテルの内腔内に適合させ得るか、またはそのような送達カテーテルまたはアクセスカテーテルの端部に取り付

けられ得る。いずれの場合においても、デバイス１５０は、肺経路１５２内で解放され得、そこで、そのメッシュ１７０が膨張し、解かれ、そして／またはロールが解かれ、経路１５２が充填される。そのような解放は、自己膨張を可能にし得るか、またはメッシュ１７０を膨張する機構的手段の使用を包含し得る。膨張したデバイス１５０は、図９において示されるようにほぼ円柱状で、図１０に示されるように単一または二重の円錐形状で、経路１５２を充填し得るか、あるいは、図１１に示される例である、他の種々の形状を形成し得る。

【００３５】

図１２を今度は参照すると、支持体１５４は、螺旋に巻かれるかまたはスパイラルに巻かれるワイヤを含んで構成される螺旋またはスパイラル１７１であり得る。スパイラル１７１は、多数の方法で圧縮されて、送達カテーテルの内腔内でまたは遠位端においてスパイラル１７１を充填し得る。例えば、スパイラル１７１は、腕時計のスプリングと同様に強固に巻かれて、スプリングの螺旋の断面を減少し得、そしてスプリング張力を提供し得る。スパイラル１７１が解放されると、コイル１７３が膨張して、経路１５２の壁に接触し、そしてデバイス１５０を固定する。

【００３６】

上記の実施形態のいずれにおいても、支持体１５４は、構造支持体１５４を通じた気体または液体の流れを防ぐ材料に結合され得るか、覆われ得るか、コーティングされ得るかまたは含浸され得、それにより、閉塞を提供する。さらに、この材料は、肺経路中への放出のための抗生物質薬剤を含有し得る。閉塞材料の例としては、薄ポリマーフィルム１５６（例えば、構造支持体１５４の間のウェビング）を含み得る。この薄フィルムを使用して、肺経路１５２の表面に対して封止させ得る。そのような設計は、図７Ａ～図７Ｂ、１０および１２に示される。同様に、構造支持体１５４は、接着剤またはシーラントで充填され得る。この接着剤またはシーラントは、構造支持体部材同士を互いに接着し、そしてデバイス１５０を通じた気体または液体の流れを防止する。これは、構造支持体部材が比較的互いに近いコイルまたはメッシュ設計において特に有用である。あるいは、図９および図１１に示されるように、支持体１５４は、薄ポリマー、フォームまたは他の材料を含んで構成される袋１５８中に入れられ得る。支持体１５４の袋１５８における膨張は、経路１５２の壁に対して袋１５８を圧迫し、シールが形成される。図９において、袋１５８は、袋１５８と支持体構造１５４との間を識別するための例示的目的のために、巻かれた支持体構造１５４の端を越えて伸ばされている。しかし、代表的には、支持体構造１５４は、袋１５８を充填する。袋１５８の存在はまた、支持体１５４を通じた気体または液体の流れを防止し、それによって、閉塞を提供する。構造支持体は、種々の設計を含み得、種々の長さおよび形状のデバイス１５０を形成し得ることが理解され得る。あるいは、袋１５８は、構造支持体１５４なしに利用され得る。この袋は、膨張して種々の方法によって経路を充填し得、そして接着剤または他の材料を染み込ませるによって定位置に保持され得る。このように染み込ませることによって、袋を強化または支持して、肺経路の閉塞を提供し得る。

【００３７】

さらにおよび図７Ａ、７Ｂ、９、１１～１３にも示されるように、閉塞デバイス１５０の多数の実施形態は、入口ポート１７２および出口ポート１７４を含み、この入口ポート１７２は、近位端１６４の付近に配置され、そして出口ポート１７４は遠位端１６６の付近に配置される。そのようなポート１７２および１７４は、任意の大きさまたは形状であり得るが、代表的には円状であるかまたは楕円形であり、そしてしばしば内腔へのアクセス可能性を容易にするために、経路５１２の中心付近に配置される。いくつかのデバイス１５０は、図１３に示されるように、近位端１６４付近に入口ポート１７２のみを備え得る。この場合、遠位端１６６は膨張して、肺経路１５２の壁と接触し、そしてデバイス１５０を固定する。従って、閉塞デバイス１５０は、円錐の先端において入口ポート１７２を有する円錐形状を有するようである。閉塞デバイス１５０が同心の配置を取ることを確実にするために、デバイス１５０は、デバイス１５０が占める経路の内径の少なくとも１．

０～１．５倍の長さにわたり、経路１５２の壁と接触すべきである。

【００３８】

入口ポート１７２、出口ポート１７４またはそれらの両方は、膜または隔膜１７６を含み得、これらは、ポートの開口部を覆う。隔膜１７６は、代表的に、自己封止する。１つの型の自己封止隔膜１７６は、図１４Ａに示されるように、中実膜１７８を含む。他の型は、図１４Ｂおよび図１４Ｃに示されるように、隔膜１７６が切断部１８０またはスリットを備える予備切断膜を含む。そのような切断部１８０は、以下に記載されるようにアクセスチューブまたは貫通要素によって隔膜１７６を通じた貫通を容易にし、他方でその貫通要素が取り出されるとき隔膜を通じた流れを防止することを可能とし得る。

【００３９】

閉鎖デバイス１５０が肺組織セグメントへと導かれる肺経路１５２において展開および固定された後、そのデバイス１５０は、続いての気流から経路１５２を閉塞する移植物として残留し得る。気流は、空気および／または他の任意の気体（例えば、二酸化炭素）もしくは気体の組み合わせを含み得る。しかし、配置直後またはその後任意の時点で、デバイス１５０の上記実施形態は、閉塞デバイス１５０を通じた肺組織セグメントを吸引するようにアクセスされ得る。これは、肺容量減少のための方法の一部として、そのセグメントが少なくとも部分的に破壊する原因となる。閉塞デバイス１５０を通じた吸引は、種々の方法によって達成され得る。例えば、図１５を参照すると、吸引は、貫通要素、針またはアクセスチューブ２００をまず、入口ポート１７２の隔膜１７６を通じて挿入することによって達成され得る。そのような挿入のためのそのアクセスチューブ２００の位置づけは、任意の方法によって達成され得るが、アクセスチューブ２００は、代表的に、アクセスチューブ２００またはアクセスチューブ２００を有するカテーテルを、アクセスカテーテル１０内の内腔を通じて、遠位端１４から通過して出てくるまで挿入することによって位置づけされる。アクセスカテーテル１０においてバルーン１８を膨張させることによって、肺経路１５２におけるカテーテルの遠位端１４を中心付けすることができる。入口ポート１７２が同様に中心付けされる場合、アクセスチューブ２００は、カテーテル１０から直接出て、入口ポート１７２の隔膜１７６を通じて通過され得る。

【００４０】

隔膜１７６が中実膜１７８である場合、アクセスチューブ２００は、膜１７８を穿刺または穿孔するに十分鋭利であり得る。隔膜１７６が切断部１８０またはスリットを有する場合、アクセスチューブ２００は、切断部１８０を通じて押され得る。いずれの場合でも、膜または隔膜１７６は、アクセスチューブ２００の周りを封止する。閉塞デバイス１５０がまた、出口ポート１７４を有する場合、アクセスチューブ２００は、必要に応じて、入口ポート１７２および出口ポート１７４の両方を通って通過し得る。いったんアクセスチューブ２００が挿入されると、気体および／または液体は、アクセスチューブ２００は肺組織セグメントおよび関連する肺経路から吸引され得る。必要に応じて、吸引の前に、１００％酸素、ヘリウム酸素混合物または低分子量気体の肺セグメント洗浄は、アクセスチューブ２００を通じたそのような気体の導入によって行われ得る。この場合、吸引は、導入された気体および任意の残りの気体の両方を取り除く。同様に、液体ペルフルオロカーボンまたは特定の薬物（例えば、抗生物質）が、吸引の前に導入され得る。これは、例えば、感染の場合などにおいて、破壊された肺セグメントに後の時点でアクセスすること可能にし得る。ほとんどの場合、吸引は、以前に記載されるように、肺セグメントを少なくとも部分的に破壊する。次いでアクセスチューブ２００は、取り出され得る。次いで、入口ポート１７２および／または出口ポート１７４の隔膜１７６は、穿刺部位を閉鎖することまたは切断部を閉鎖することのいずれかによって、自動的に封止する。必要に応じて、それらのポートは、シーラントまたは熱源もしくは高周波源の使用によってさらに封止され得る。

【００４１】

図１６および図１７を参照すると、閉塞デバイス１５０を通じた吸引は、閉塞デバイス１５０を吸引チューブまたは吸引カテーテル２０２に接触させること、および気体または液

体をそのデバイス１５０を通じて吸引することによって達成され得る。図１６に示されるように、吸引カテーテル２０２の遠位端２０４は、入口ポート１７２に対して保持され得る。そのような接触のための吸引カテーテル２０２の位置づけは、任意の方法によって達成され得るが、カテーテル２０２は、代表的に、上記されるアクセスチューブに類似の様式で位置づけされる。吸引カテーテル２０２をポート１７２に対して保持することによって、シールが作出され得、そして気体および／または液体が肺組織セグメントから、デバイス１５０を通じて吸引され得る。この場合、入口ポート１７２および出口ポート１７４は、存在する場合、中実膜１７８によって覆われてはならない。切断部１８０が存在する場合、気体または液体は、吸引圧に起因して、そのポートを通じて流れ得る。図１７に示されるように、吸引カテーテル２０２の遠位端２０４は、シールを形成するように、入口ポート１７２にわたってスライドし得る。次いで、気体および／または液体はまた、類似の様式でデバイス１５０を通じて吸引され得る。ついで、吸引カテーテル２０２は取り出され得る。次いで、入口ポート１７２および／または出口ポート１７４の隔膜１７６は、代表的に切断部を閉じることによって自動的に封止する。必要に応じて、そのポートは、シーラントあるいは熱源または高周波源の使用によってさらに封止され得る。

【００４２】

図１８Ａ～図１８Ｃを参照すると、閉塞デバイス１５０は、吸引カテーテル２１０に接続されながら、展開、固定およびそれを通じて吸引され得る。この場合、アクセスカテーテル１０は、所望の位置において肺経路１５３内に位置付けされる。カテーテル１０がその遠位端１４の付近において膨張可能な閉塞バルーン１８を有する場合、そのバルーン１８は膨張して、経路１５２内にカテーテル１０を固定および中心付けされ得る。しかし、この工程は任意である。ついで、図１８Ａに示されるように、閉塞デバイス１５０を有する吸引カテーテル２１０は、内腔を通じてアクセスカテーテル１０に導入される。図１８Ｂに示されるように、吸引カテーテル２１０は、その閉塞デバイス１５０がアクセスカテーテル１０の遠位端１４から出現し、肺経路１５２内で展開するように進行する。経路１５２内で閉塞デバイス１５０を膨張および固定することは、例えば、自己膨張することか、またはバルーンの助けを借りて膨張することによって達成され得る。次いで、デバイス１５０によって分離された肺組織セグメントは、デバイス１５０および付着される吸引カテーテル２１０を通じて吸引される。そのような吸引は、空気、気体または液体を、そのセグメントおよび肺経路１５２から取り除いて、肺セグメントを少なくとも部分的に破壊し得る。ついで、図１５Ｃに示されるように、閉塞デバイス１５０は、吸引カテーテル２１０から脱離し、そして経路１５２の後ろに残る。閉塞デバイス１５０の近位端１６４は、入口ポート１７２を備え得る。この入り口ポートは、後の時点で分離された肺組織セグメントへと続いてアクセスすることを可能とする。あるいは、近位端１６４は、封止された末端を備え得、ここで、閉塞デバイス１５０は、続いてアクセスされなくてもよく、そして末端肺組織セグメントの長期の分離を提供し得る。

【００４３】

上記の方法は、吸引カテーテル２１０を使用しなくても同様に達成され得ることが理解され得る。この場合、閉塞デバイス１５０は、アクセスカテーテル１０に付着したままで、アクセスカテーテル１０によって直接運搬され得、そして展開され得る。閉塞デバイス１５０およびアクセスカテーテル１０を通じて吸引が達成されて、分離された肺組織セグメントおよび経路１５２から気体を取り除くことができる。ついで、閉塞デバイス１５０は、アクセスカテーテル１０から脱離し得、そして続きのアクセスまたは単純な閉塞のために、経路１５２に残されたままであってもよい。

【００４４】

この点で、記載されるように、すべてのカテーテルおよび装置は、患者から取り出され得、そして閉塞デバイス１５０は、その固定された位置に残ったままでもよい。閉塞デバイス１５０は、肺経路１５２を本質的に閉塞し、そして分離された肺組織セグメントまたは罹患領域ＤＲへと空気または気体の中への流れまたは外への流れを防止する。これは、肺組織セグメントの所望のレベルの破壊を維持し、肺容量減少を達成するのに有効であり得

る。しかし、任意の点において、肺組織セグメントは、上記の工程を反復することによって、再アクセスおよび／または再吸引され得る。さらに、任意の点において、閉塞デバイス１５０は、膨張構造物の破壊または他の手段によるかのいずれかにより、肺経路１５２から取り除かれ得る。

【００４５】

閉塞デバイス１５０のさらなる実施形態は、一方向性弁を含んで構成される。この弁は、アクセスの際に作動され得るか、または呼吸に応答して作動し得る。例えば、その弁が肺経路に位置づけされるとき、その弁は、吸引カテーテルまたは結合部材をその弁に係合することによってアクセスされ得る。次いで、吸引カテーテルまたは結合部材による吸引によって、弁が開き、気体および／または液体が分離した肺セグメントから取り除かれる。あるいは、その弁は、呼吸に応答して自動的に開き得る。その弁は、呼気の間に開いて、肺セグメントからの気体の外への流れを可能にし得、そして吸気の間の閉鎖によって、肺セグメントへの気体の流れ込みを防止することができる。いずれの場合においても、一方向性弁は、多数の形態を採り得る。

【００４６】

そのような一方向性弁のひとつの実施形態は、図１９Ａ～図１９Ｃに例示される。この実施形態において、図１９Ａに正面図が示される一方向性弁２３０は、ポート２３２および可撓性層２３３を含んで構成され、この可撓性層は、ポート２３２に対して、少なくとも１つの接続点２３４によって付着される。示されるように、可撓性層２３３は、ポート２３２の正面表面に、４つの対称な接続点２３４において、付着され得る。好ましい実施形態において、層２３３の周縁２３６は、ポート２３２の開口部（ダッシュ線によって示される）の外側に位置づけされる。これは、その弁が閉鎖位置にあるときに所望の封止を提供する。

【００４７】

図１９Ｂおよび図１９Ｃに示される側面図では、異なる段階の呼吸周期の間の弁２３０を示す。呼気の間、図１９Ｂに示されるように弁２３０が開く。ここでは、呼気は、矢印で示される。弁２３０が位置づけされる肺経路から出る気体は、示されるように、ポート２３２の表面から外向きに逃げるように層２３３を膨張させるような力を可撓性層２３３の裏側に付与する。このことによって、接続点２３４の間の空間を通じて気体が流れることを可能にする。吸気の間、図１９Ｃに示されるように、弁２３０が閉まる。ここで、吸気は、矢印によって示される。肺経路に入る空気は、示されるように、ポート２３２の表面に対して層２３３が封止するような力を可撓性層２３３の正面側に適用する。このことによって、気体が弁２３０を通じて流れることを防止する。

【００４８】

一方向性弁２３０は、閉塞デバイス１５０の他の型について以前に記載される方法と類似する方法によって、肺経路１５２に位置づけされ得る。図２０に示されるように、弁２３０は、経路１５２に位置づけされ得、その結果、ポート２３２の外側の周囲は経路１５２の壁に接触する。このようにして、弁２３０は、本質的に経路腔の大きさであり、そして気体の流出の可能性について、最大面積を提供する。弁２３０は、その開放状態で示され、気体の流れは、分離される肺組織セグメントから、弁を通って、患者の気道から出るように移動する。図２１に示されるように、弁２３０は、代替的に、構造支持体１５４に付着され得るかまたはその一部であり得る。この構造支持体は、経路１５２においてデバイス１５０を固定するように半径方向に膨張する。そのような支持体１５４は、以前に記載される支持体に類似する。弁２３０はまた、その開放状態で示される。弁２３０は、任意の大きさまたは形状であり得、そして以前に記載される入口ポートおよび／または出口ポートのいずれかの代用となり得る。

【００４９】

一方向性弁の別の実施形態は、図２２Ａ～図２２Ｂに例示される。この実施形態において、弁２３０は、以前の実施形態におけるように、ポート２３２および可撓性層２３３を含んで構成される。しかし、ここでは、可撓性層２３３は、その層を通じて一連の穴２５０

を有する。さらに、弁２３０は、区切り２５２を含んで構成され、この区切りはまた、穴２５０を有する。この穴２５０は、層２３３および区切り２５２の全部または一部にわたり、どのような大きさ、形状または構成のものでもよい。区切り２５２は、図２２Ａに例示され、そして矢印で示されるように、ポート２３２を覆い、そして層２３３は、区切り２５２にわたって位置づけされ、その結果穴２５０は、実質的に整列されず、そしてそれゆえ遮断される。図２２Ｂに例示されるアセンブルした弁は、閉じた位置において任意の通り穴２５０を有しない。層２３３における穴２５０は、下にある区切り２５２によって遮断される。同様に、区切り２５２における穴２５０は、上にある層２３３によって遮断される。層２３３は、区切り２５２および／またはポート２３２に、その周囲に沿って付着する。その付着は、連続的な付着であってもよく、またはそれらの間の空間との不連続の接続点を有していてもよい。

【００５０】

図２３Ｂおよび図２３Ｃに示される側面図は、呼吸周期の異なる段階の間の弁２３０を示す。呼気の間、図２３Ｂに示されるように弁２３０が開く。ここでは、呼気は矢印で示される。弁２３０が位置づけされる肺経路を通じて出る気体は、区切り２５２における穴２５０を通じて通過し、そして可撓性層２３３の裏側に力を付与する。これは、示されるように、区切り２５２から外向けに出るように層２３３を膨張させる。これは、層２３３における穴２５０を通じて気体が流れることを可能にする。吸気の間、図２３Ｃに示されるように弁２３０は閉じる。ここでは、吸気は矢印で示される。肺経路に入る空気は、示されるように、区切り２５２の表面に対して、層２３３が封止させるようにする力を可撓性層２３３の前面に付与する。このことによって、気体が弁２３０を通じて流れることを防ぐ。一方向性弁２３０のこの実施形態は、図２０および図２１に特に示されるように、閉塞デバイス１５０の他の型について以前に記載される方法に類似する方法によって、肺経路１５２に位置づけされ得る。

【００５１】

上記の一方向性弁は、呼吸周期の異なる段階の間に作動するように示されるが、弁は、追加でまたは代替的に手動で作動され得る。図２０～２１に示されるような肺経路において位置づけされる弁は、吸引カテーテルと弁とを連結することによってアクセスされ得る。連結は、吸引カテーテル、適切なカテーテルまたは連結部材と弁とを係合することを包含し得る。いくつかの場合において、図２１に示されるように、特に、弁２３０が、肺経路における腔よりも直径が短いポート２３２を含む場合、吸引カテーテルまたは連結部材の遠位端は、ポートにわたりスライドしてシールを形成させることができる。このことは、弁つきでない閉塞デバイスの入口ポート１７２の回りの吸引カテーテル２０２の封止に関して図１７において以前に示された。この場合において弁が存在する場合、吸引カテーテルを通じた吸引によって、弁が開き、そして気体および／または液体が肺組織セグメントから取り出される。記載される一方向性弁２３０を用いて、吸引の吸引力は、可撓性層２３３を、ポート２３２または区切り２５２から外に向けて取り出されて弁が開く。

【００５２】

閉塞デバイス１５０のさらなる実施形態は、分離される肺組織セグメントの吸引から達成され得るポートがない遮断デバイス２８０を含んで構成される。遮断デバイス２８０が、肺組織セグメントへと導く肺経路１５２内で展開および固定された後、デバイス２８０は、続きの気流から経路１５２を閉塞する移植物として残留されるべきである。入口ポート１７２および／または出口ポート１７４を有する閉塞デバイス１５０の以前に記載される実施形態は類似の様式で利用され得るが、遮断デバイス２８０は、そのデバイスを通じた肺組織セグメントの吸引のために後にアクセスされなくてもよい。そのような遮断デバイス２８０の例は、図２４および図２５に例示される。

【００５３】

以前の閉塞デバイスと同様に、遮断デバイス２８０は、アクセスカテーテル１０内に収容され得るか、または、アクセスカテーテル１０を通じて通過され得るカテーテル内に収容され得る。図２４に示されるように、閉塞デバイス１５０は、アクセスカテーテル１０の

内部腔内で圧縮または破壊され得る。示される遮断デバイス２８０は、利用され得る多くの設計のうちのひとつである。次いで、遮断デバイス２８０は、矢印の方向でカテーテル１０の遠位端１４から肺経路１５２へと押し出され得る。デバイス２８０は、張力または形状記憶によって自己膨張性であるべきであり、その結果、それは、経路１５２において膨張し、そしてそれ自体を固定する。

【００５４】

図２５を参照すると、遮断デバイス２８０の１つの実施形態は、コイル２８２を含む。コイル２８２は、任意の型のワイヤ（特に、超弾性または形状記憶のワイヤ）、ポリマーまたは適切な材料を含んで構成され得る。コイル２８２における張力は、デバイス２８０を膨張させて経路１５２を充填し、そして経路１５２の壁に対して静止してデバイス２８０を固定することを可能にする。さらに、コイル２８２は、薄ポリマーフィルム２８４に連結されて（例えば、コイルの間のウェビング）、肺経路１５２の表面に対して封止することができる。そのようなフィルム２８４によって、気体または液体がコイルを通じて流れることを防止し、それによって、閉塞を提供する。あるいは、図２５に示されるように、コイル２８２は、袋２８６に覆われ得る。袋２８６内でのコイル２８２の膨張は、袋２８６を経路１５２の壁に対して押し、シールを形成する。このことはまた、矢印に示されるようなコイル２８２を通じた気体または液体の流れを、防止し、それによって閉塞を提供する。同様に、図２６に示されるように、遮断デバイス２８０の別の実施形態は、メッシュ２８３を含む。メッシュ２８３は、任意の型のワイヤ（特に、超弾性または形状記憶のワイヤ）、ポリマーまたは適切な材料を含んで構成され得る。メッシュ２８３における張力は、デバイス２８０が膨張して、経路１５２を充填し、そしてデバイス２８０に経路１５２の壁に対して静止することを可能にする。さらに、メッシュ２８３は、薄ポリマーフィルム２８４に接続されて（メッシュの格子の間のウェビングなど）、肺経路１５２の表面に対して封止し得る。このようなフィルム２８４は、気体または液体がメッシュを通じて流れることを防ぎ、それによって閉塞を提供する。

【００５５】

図２７を今度は参照すると、遮断デバイス２８０の別の実施形態は、示されるように、肺経路１５２へと押し込まれるように設計されたとげの形態の構造３０４を含む。そのような構造物３０４は、中実材料、膨張可能なバルーン材料または遮断機能を提供するに適切な任意の材料を含んで構成され得る。構造物３０４は、押し込まれる前、間または後に膨張して、肺経路において充分な固定を提供し得る。同様に、構造物３０４は、押し込みの前、間または後に、接着剤またはシーラントにしみこませるかまたは注入して、経路１５２を通じた液体または気体の流れに対する固定または抵抗もまた改良することができる。

【００５６】

図２８を参照すると、遮断デバイス２８０の別の実施形態は、膨張バルーンを備える。そのようなバルーンは、多数の形態をとり得る。例えば、バルーンは、種々の形態（例えば、丸、円柱、円錐、犬の骨型、または多数切片型など）を採ることができる。あるいは、一連の異なるまたは互いに連結したバルーンが利用され得る。さらに、バルーンの表面は、例えば、肺経路内のバルーンの固定を改善するように波型にされるかまたはテクスチャード加工されることによって増強され得る。図２８は、円柱型バルーン３００を、テクスチャード摩擦バンド３０２とともに示す。このテクスチャード摩擦バンド３０２は、そのバルーン３００が示されるように膨張するとき、肺経路１５２の壁に接触する。

【００５７】

そのようなバルーンは、多数の材料（生理食塩水、気体、適切な液体、膨張フォーム、および接着剤などを含む）を用いて膨張され得ることが理解され得る。さらに、多層バルーン３１０は、図２９に示されるように利用され得る。これは、バルーン３１０の外側層３１４と内側層３１６との間の接着剤３１２または適切な材料の注射を可能にする。そのような接着剤３１２は、閉塞デバイス２８０において硬化されたシェルを提供して、閉塞能を改善し得る。示されるように、バルーン３１０は、内側層３１６内で、フォーム３１８または他の材料を用いて膨張され得る。同様に、図３０に示されるように、遮断デバイス

２８０の外側層３１４は、穴、孔、スリットまたは開口部３２０を含み得る。このことによって、接着剤３１２が外側層３１４から多層バルーン３１０の外側表面へと出現することを可能にする。バルーン３１０が肺経路１５２内で膨張する場合、バルーン３１０の外側層３１４は、経路１５２の壁に対して圧迫し、そして接着剤３１２は、それが接触する壁と結合する。そのような接着は、遮断デバイス２８０の固定および閉塞能を改善するように設計される。

【００５８】

上記の遮断デバイスは、抗生物質薬剤（例えば、硝酸銀）を浸され得るか、コーティングされ得るかまたは他の方法で送達され得る。そのような取り込みは、肺経路への薬剤の送達に適切な任意の手段によってであり得る。特に、バルーン３１０の外側層と内側層との間に抗生物質薬剤を注射することを可能にする多層バルーンが提供され得る。以前に記載され、そして図３０に示されるように、遮断デバイス２８０の外側層３１４は、穴、孔、スリットまたは開口部３２０を含み得、これらは、薬剤が、外側層３１４を通って多層バルーン３１０の外側表面へと出現することを可能にする。したがって、薬剤は、壁および／または肺経路へと送達され得る。

【００５９】

遮断デバイス２８０は、種々の長さおよび形状を有する種々の設計を含み得ることがさらに理解され得る。さらに遮断デバイス２８０として使用するために例示される設計の多くはまた、閉塞デバイス１５０の以前に例示された実施形態に関して記載されるように使用するための吸引ポートに対して適合され得る。例えば、隔膜１７６を有するそのようなポート１７２は、図３０に示される。そのポートがアクセスされない場合、そのデバイスは、単に、遮断デバイス２８０として供するのみである。従って、いくつかの場合において、遮断デバイス２８０と閉塞デバイス１５０とは、同義である。

【００６０】

図３１を今度は参照すると、本発明に従うキット４００は、少なくとも１つの閉塞デバイスまたは遮断デバイス５００および使用のための指示書ＩＦＵを備える。必要に応じて、そのキットは、上記の他の任意のシステム構成要素（例えば、カテーテル１０、ガイドワイヤ４０２、アクセスチューブ２００、吸引カテーテル２０２または他の要請要素）をさらに含み得る。使用のための指示書ＩＦＵは、上記のように任意の方法を記載し、そしてすべてのキット構成要素は、通常、１つのパウチ４５０または他の従来の医療デバイス包装物に一緒に包装される。通常、患者において手順を実施するにおいて使用されるこれらのキット構成要素は、そのキット内で滅菌され、そして滅菌のまま維持される。必要に応じて、別個のパウチ、バッグ、トレイ、または他の包装は、より大きな包装で提供され得る。ここでは、より小さなパックは、別個にあけられ得、そして別個に滅菌様式で構成要素を維持し得る。

【００６１】

上記は本発明の好ましい実施形態の完全な記載であるが、種々の代替、改変および等価物が使用され得る。従って、上記記載は、本発明の範囲を限定すると解釈されるべきではなく、本発明の範囲は、添付の特許請求の範囲によって定義される。

【図面の簡単な説明】

【図１】

図１は、本発明の方法、システムおよびキットにおいて有用なアクセスカテーテルの斜視図である。

【図２】

図２は、図１に対して線２に沿って取った断面図である。

【図３Ａ】

図３Ａは、図１のアクセスカテーテルの代替の断面図を例示する。

【図３Ｂ】

図３Ｂは、図１のアクセスカテーテルの代替の断面図を例示する。

【図３Ｃ】

図３Ｃは、図１のアクセスカテーテルの代替の断面図を例示する。
【図３Ｄ】
図３Ｄは、図１のアクセスカテーテルの代替の断面図を例示する。
【図３Ｅ】
図３Ｅは、図１のアクセスカテーテルの代替の断面図を例示する。
【図３Ｆ】
図３Ｆは、図１のアクセスカテーテルの代替の断面図を例示する。
【図４Ａ】
図４Ａは、本発明の方法において使用されるアクセスカテーテルの位置づけを容易にするために使用され得る、操縦型画像化ガイドワイヤを例示する。
【図４Ｂ】
図４Ｂは、本発明の方法において使用されるアクセスカテーテルの位置づけを容易にするために使用され得る、操縦型画像化ガイドワイヤを例示する。
【図４Ｃ】
図４Ｃは、本発明の方法において使用されるアクセスカテーテルの位置づけを容易にするために使用され得る、操縦型画像化ガイドワイヤを例示する。
【図５Ａ】
図５Ａは、本発明の方法に従って、標的肺組織セグメントへアクセスするための、図１のアクセスカテーテルの使用を例示する。
【図５Ｂ】
図５Ｂは、本発明の方法に従って、標的組織セグメントにアクセスするための、図１のアクセスカテーテルを伴った可視化気管支管の使用を例示する。
【図６】
図６は、閉塞デバイスの展開または送達の方法を例示する。
【図７Ａ】
図７Ａは、とりわけ、半径方向構造支持体および長手方向の構造支持体を有する、閉塞デバイスの実施形態の斜視図である。
【図７Ｂ】
図７Ｂは、とりわけ、半径方向構造支持体および長手方向の構造支持体を有する、閉塞デバイスの実施形態の斜視図である。
【図８】
図８は、肺経路において放たれる前の、まかれた構成の閉塞デバイスの実施形態の斜視図である。
【図９】
図９は、可撓性袋内において膨張した状態の巻かれた円柱状の閉塞デバイスの実施形態の斜視図である。
【図１０】
図１０は、二重円錐形状の閉塞デバイスの実施形態を例示する。
【図１１】
図１１は、とりわけ、ポリマー膜によって覆われるメッシュ構造支持体を有する閉塞デバイスの実施形態の斜視図である。
【図１２】
図１２は、とりわけ、螺旋状構造支持体を有する閉塞デバイスの実施形態の斜視図である。
【図１３】
図１３は、円錐の先端において、入口ポートを伴う円錐形状を有する閉塞デバイスの実施形態の斜視図である。
【図１４Ａ】
図１４Ａは、本発明の自己封止隔膜の実施形態を例示する。
【図１４Ｂ】

図１４Ｂは、本発明の自己封止隔膜の実施形態を例示する。
【図１４Ｃ】
図１４Ｃは、本発明の自己封止隔膜の実施形態を例示する。
【図１５】
図１５は、入口ポートの隔膜を通じてアクセスチューブを挿入することによって、閉塞デバイスを通じて吸引する方法を例示する。
【図１６】
図１６は、入口ポートへ吸引カテーテルを接触させることによって、閉塞デバイスを通じて吸引する方法を例示する。
【図１７】
図１７は、入口ポートにわたって、吸引カテーテルの遠位端をスライドさせることによって閉塞デバイスを通じて吸引する方法を例示する。
【図１８Ａ】
図１８Ａは、閉塞デバイスを通じて展開、固定および吸引し、他方でそのようなデバイスが吸引カテーテルに接続される方法を例示する。
【図１８Ｂ】
図１８Ｂは、閉塞デバイスを通じて展開、固定および吸引し、他方でそのようなデバイスが吸引カテーテルに接続される方法を例示する。
【図１８Ｃ】
図１８Ｃは、閉塞デバイスを通じて展開、固定および吸引し、他方でそのようなデバイスが吸引カテーテルに接続される方法を例示する。
【図１９Ａ】
図１９Ａは、本発明の一方向性弁の実施形態の正面図である。
【図１９Ｂ】
図１９Ｂは、種々の段階の手術における図１９Ａの一方向性弁の斜視図である。
【図１９Ｃ】
図１９Ｃは、種々の段階の手術における図１９Ａの一方向性弁の斜視図である。
【図２０】
図２０は、本発明の一方向性弁の実施形態の肺経路における位置づけを例示する。
【図２１】
図２１は、本発明の一方向性弁の実施形態の肺経路における位置づけを例示する。
【図２２Ａ】
図２２Ａは、本発明の一方向性弁の実施形態の正面図である。
【図２２Ｂ】
図２２Ｂは、本発明の一方向性弁の実施形態の正面図である。
【図２３Ａ】
図２３Ａ～図２３Ｂは、種々の段階の手術における、図２１Ａ～図２１Ｂの一方向性弁の斜視図である。
【図２３Ｂ】
図２３Ａ～図２３Ｂは、種々の段階の手術における、図２１Ａ～図２１Ｂの一方向性弁の斜視図である。
【図２４】
図２４は、遮断デバイスの展開または送達の方法を例示する。
【図２５】
図２５は、ポリマー膜に覆われるコイルを含む、遮断デバイスの実施形態を例示する。
【図２６】
図２６は、ポリマー膜に結合されるメッシュを含む、遮断デバイスの実施形態を例示する。
【図２７】
図２７は、とげ（ｂａｒｂ）の形態の構造物を含む、遮断デバイスの実施形態を例示する

。
【図２８】
図２８は、テクスチャード加工の摩擦バンドを伴う、円柱形状のバルーンを有する遮断デバイスの実施形態を例示する。
【図２９】
図２９は、バルーンの外層と内層との間に接着材料を有する、多層バルーンを含む、遮断デバイスの実施形態を示す。
【図３０】
図３０は、図２９の遮断デバイスに類似する遮断デバイスの実施形態を示す。
これは、接着材料が滲み出得る外層において開口部を含む。
【図３１】
図３１は、本発明の原理に従って構築されるキットを例示する。

【国際公開パンフレット】

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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
16 May 2002 (16.05.2002)

PCT

(10) International Publication Number
WO 02/38038 A2

(51) International Patent Classification[7]: A61B

(21) International Application Number: PCT/US01/51092

(22) International Filing Date: 26 October 2001 (26.10.2001)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
09/699,302 27 October 2000 (27.10.2000) US

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(81) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, 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, NO, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW.

(84) Designated States (regional): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF,

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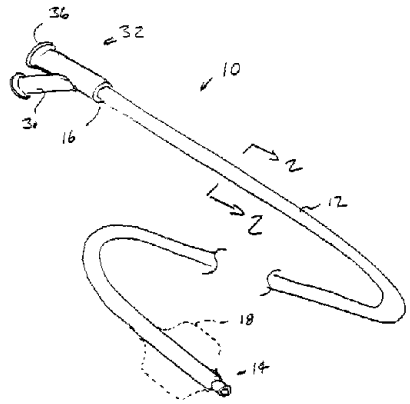
(54) Title: METHODS AND DEVICES FOR OBSTRUCTING AND ASPIRATING LUNG TISSUE SEGMENTS



(57) Abstract: The present invention provides improved methods, systems, devices and kits for performing lung volume reduction in patients suffering from chronic obstructive pulmonary disease or other conditions where isolation of a lung segment or reduction of lung volume is desired. The methods are minimally invasive with instruments being introduced through the mouth (endotracheally) and rely on isolating the target lung tissue segment from other regions of the lung. Isolation is achieved by deploying an obstructive device in a lung passageway leading to the target lung tissue segment. Once the obstructive device is anchored in place, the segment can be aspirated through the device. This may be achieved by a number of methods, including coupling an aspiration catheter to an inlet port on the obstruction device and aspirating through the port. Or, providing the port with a valve which allows outflow of gas from the isolated lung tissue segment during expiration of the respiratory cycle but prevents inflow of air during inspiration. In addition, a number of other methods may be used. The obstructive device may remain as an implant, to maintain isolation and optionally allow subsequent aspiration, or the device may be removed at any time.

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CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

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Published:

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

METHODS AND DEVICES FOR OBSTRUCTING AND ASPIRATING LUNG TISSUE SEGMENTS

CROSS-REFERENCES TO RELATED APPLICATIONS

The disclosure of this application is related to copending application no. 09/699,313, filed on the same day, the full disclosure of which is incorporated herein by reference.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates generally to medical methods, systems, and kits. More particularly, the present invention relates to methods and apparatus for effecting lung volume reduction by aspirating isolated segments of lung tissue.

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.

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 reduction is conventionally performed in open chest or thoracoscopic procedures where the lung is resected, typically using stapling devices having integral cutting blades.

While effective in many cases, conventional lung 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. For these reasons, it would be

desirable to provide improved methods, systems, and kits for performing lung volume reduction which overcome at least some of the shortcomings noted above.

2. Description of the Background Art

WO 99/01076 and corresponding U.S. Patent No. 5,957,919 describes devices and methods for reducing the size of lung tissue by applying heat energy to shrink collagen in the tissue. In one embodiment, air may be removed from a bleb in the lung to reduce its size. Air passages to the bleb may then be sealed, e.g., by heating, to fix the size of the bleb. WO 98/48706 describes a plug-like device for placement in a lung air passage to isolate a region of lung tissue, where air is not removed from the tissue prior to plugging. WO 98/49191 describes the use of surfactants in lung lavage for treating respiratory distress syndrome. U.S. Patent No. 5,925,060 may also be of interest.

Patents and applications relating to lung access, diagnosis, and treatment include U.S. Patent Nos. 5,957,949; 5,840,064; 5,830,222; 5,752,921; 5,707,352; 5,682,880; 5,660,175; 5,653,231; 5,645,519; 5,642,730; 5,598,840; 5,499,625; 5,477,851; 5,361,753; 5,331,947; 5,309,903; 5,285,778; 5,146,916; 5,143,062; 5,056,529; 4,976,710; 4,955,375; 4,961,738; 4,958,932; 4,949,716; 4,896,941; 4,862,874; 4,850,371; 4,846,153; 4,819,664; 4,784,133; 4,742,819; 4,716,896; 4,567,882; 4,453,545; 4,468,216; 4,327,721; 4,327,720; 4,041,936; 3,913,568 3,866,599; 3,776,222; 3,677,262; 3,669,098; 3,542,026; 3,498,286; 3,322,126; WO 95/33506, and WO 92/10971.

Lung volume reduction surgery is described in many publications, including Becker et al. (1998) Am. J. Respir. Crit. Care Med. 157:1593-1599; Criner et al. (1998) Am. J. Respir. Crit. Care Med. 157:1578-1585; Kotloff et al. (1998) Chest 113:890-895; and Ojo et al. (1997) Chest 112:1494-1500.

The use of mucolytic agents for clearing lung obstructions is described in Sclafani (1999) AARC Times, January, 69-97. Use of a balloon-cuffed bronchofiberscope to reinflate a lung segment suffering from refractory atelectasis is described in Harada et al. (1983) Chest 84:725-728.

SUMMARY OF THE INVENTION

The present invention provides improved methods, systems, devices and kits for performing lung volume reduction in patients suffering from chronic obstructive pulmonary disease or other conditions where isolation of a lung segment or reduction of lung volume is desired. The present invention is likewise suitable for the treatment of

bronchopleural fistula. The methods are minimally invasive with instruments being introduced through the mouth (endotracheally) and rely on isolating the target lung tissue segment from other regions of the lung. Isolation is achieved by deploying an obstructive device in a lung passageway leading to the target lung tissue segment. Once the obstructive device is anchored in place, the segment can be aspirated through the device. This may be achieved by a number of methods, including coupling an aspiration catheter to an inlet port on the obstruction device and aspirating through the port. Or, providing the port with a valve which allows outflow of gas from the isolated lung tissue segment during expiration of the respiratory cycle but prevents inflow of air during inspiration. In addition, a number of other methods may be used. The obstructive device may remain as an implant, to maintain isolation and optionally allow subsequent aspiration, or the device may be removed at any time. Likewise, the device may biodegrade over a period of time.

The obstruction device may take a variety of forms to allow delivery, deployment and anchoring in a lung passageway. Delivery is commonly performed with the use of a minimally invasive device, such as a flexible bronchoscope or an access catheter. The flexible bronchoscope may be utilized with a sheath having an inflatable cuff disposed near its distal end, a full description of which is provided in co-pending application [Attorney Docket No. 017534-001300], assigned to the assignee of the present invention and incorporated by reference for all purposes. When using such a sheath, the scope is introduced into a lumen in the sheath to form an assembly which is then introduced to the lung passageway. The cuff may then be inflated to occlude the passageway. Similarly, an access catheter may be used which may be steerable or articulating, may include an inflatable balloon cuff near its distal end and may include a number of lumens for balloon inflation, tracking over a guidewire, and optical imaging, to name a few. The obstruction device is typically housed within a lumen of the access catheter, bronchoscope, sheath or suitable device, mounted near the distal tip of the catheter or carried by any method to the desired lung passageway leading to the target lung tissue segment. Therefore, the obstruction device must be sized appropriately for such delivery and is typically designed to expand upon deployment to anchor within the lung passageway. Hereinafter the present invention is depicted in relation to use with an access catheter, however it may be appreciated that any suitable device may be used.

In a first aspect of the present invention, the obstruction device comprises a structural support which expands and thereby anchors the device in the lung passageway. Such supports may comprise a number of configurations for a variety of

expansion techniques. For example, the structural supports may allow the obstruction device to coil, roll, bend, straighten or fold in a cone, rod, cylinder or other shape for delivery. Then, once positioned in a desired location, the obstruction device may be released and expanded to anchor the device in the passageway. Such expansion may be unaided, such as in the release of a compressed structure to a pre-formed expanded position. Or, such expansion may be aided, such as with the use of an inflatable balloon or cuff. In some cases, a balloon or inflatable member may be incorporated into the obstruction device and may remain inflated to occlude the passageway. This may be provided in combination with structural supports or an inflatable balloon or similar device may be used without such support.

The structural supports may be comprised of any type of wire, particularly superelastic, shape-memory or spring tempered wire, or any type of polymer or a suitable material. The balloon or inflatable member may be comprised of any flexible, polymeric material suitable for such a purpose. The member may be inflated with gas or liquid as desired, or it may be inflated with an expanding foam or similar material. Likewise, it may be inflated or injected with an adhesive. Such an adhesive may expand the member and/or rigidify the member to reduce the likelihood of collapse. Further, the adhesive may additionally serve to bond the device to the walls of the lung passageway to increase anchorage. In addition, the device may be impregnated or coated with an antibiotic agent, such as silver nitrate, or similar agent for delivery of the agent to the lung passageway. Such delivery may occur by any applicable means.

When structural supports are present, such supports may comprise a variety of designs. In a first embodiment, the structural supports comprise radial segments which expand to fill the passageway and longitudinal segments which rest against the walls of the passageway to help anchor the device. In a second embodiment, the structural supports comprise a mesh which expands to fill the passageway. In a third embodiment, the structural supports comprise a helically or spirally wound wire which also expands to contact the walls of the passageway and anchor the device. In each of these embodiments, the structural support may be connected with or encapsulated in a sack comprised of a thin polymeric film, open or closed cell foam or other suitable material to provide a seal against walls of the lung passageway and obstruct airflow through the device. The sack material may also be infused with an adhesive, sealant or other material to improve obstruction of the airway and possibly improve adhesion to the airway walls.

In a second aspect of the present invention, the obstruction device may further comprise ports for aspiration through the device. This may allow access to the collapsed lung segment at a later time, for example, in the case of an infection. Typically, the obstruction device will have an inlet port located near the proximal end of the device, away from the isolated lung tissue segment. Such a port is thus accessible by minimally invasive devices, such as an aspiration catheter, which may be advanced through the bronchial passageways. Optionally, an outlet port may be located near the distal end of the obstruction device. The ports may comprise a variety of designs for a number of purposes.

In a first embodiment, the port comprises a self-sealing septum. Such a septum may comprise a solid membrane or a pre-cut membrane. Aspiration through the port may be achieved with the use of an aspiration catheter having an access tube or penetrating element at its distal end. Such a catheter may be advanced to the site of the obstruction device itself or with the use of an access catheter. The septum may be penetrated, either pierced through a solid membrane or passed through the cuts of a pre-cut membrane, by the access tube. Depending on the design of the obstruction device, the inlet port and optionally the outlet port may be penetrated in this fashion. Aspiration may be achieved through the access tube and aspiration catheter to withdraw gases and/or liquids from the isolated lung tissue segment and passageway. Optionally, prior to aspiration, a 100% oxygen, Helium-Oxygen mixture or low molecular weight gas washout of the lung segment may be performed by introducing such gas through the access tube, such as by a high frequency jet ventilation process. In this case, aspiration would remove both the introduced gas and any remaining gas. Similarly, liquid perfluorocarbon or certain drugs, such as antibiotics, retinoic acid and hyaluronic acid, may be introduced prior to aspiration. In most cases, aspiration will at least partially collapse the lung segment. Upon removal of the aspiration catheter from the port, the septum may self-seal or it may be further sealed with a sealant or other sealing means for later access or permanent closure.

When the self-sealing septum comprises a pre-cut membrane, aspiration through the port may alternatively be achieved by coupling an aspiration catheter to the obstructive device. Coupling may comprise engaging the aspiration catheter to the port or sliding a coupling member or the aspiration catheter over the port to form a seal. In either case, suction through the aspiration catheter may allow gases and/or liquids to pass through the cuts in the membrane to be withdrawn from the isolated lung tissue segment

and passageway. Again, this will at least partially collapse the lung segment. Likewise, upon removal of the aspiration catheter from the port, the septum may self-seal or it may be further sealed with a sealant or other sealing means for later access or permanent closure.

In a second embodiment, the port comprises a unidirectional valve. Such a valve may comprise a port covered by a flexible layer which is attached to the port by at least one point of connection. Movement of the layer away from the port opens the valve and movement against the port closes the valve. Wherein the flexible layer is solid, movement of the layer away from the port allows gas to flow between the points of connection and around the edges of the flexible layer. Alternatively, the flexible layer may have holes therethrough. In this case, the port may also comprise a partition having holes which are not aligned with the holes in the flexible layer. Movement of the layer away from the port allows gas to flow through the holes in the partition and out through the holes in the flexible layer. When the layer moves against the partition, the holes will be covered closing the valve. Other valve designs include a spring-loaded ball valve or a biased pre-loaded diaphragm valve.

Aspiration through a unidirectional valve may be achieved by a number of methods. Again, the port may be accessed by advancing an aspiration catheter or similar device through the bronchial passageways to the site of the obstruction device. This may optionally be achieved with the use of an access catheter. The aspiration catheter may be placed near the valve or engaged to the valve, wherein suction or vacuum applied through the catheter opens the valve. If the aspiration catheter is not engaged to the valve, adequate suction to open the valve may be achieved by occluding the passageway proximal to the point of suction which is typically the distal end of the aspiration catheter. Such occlusion may be achieved by inflating a balloon or occlusion device mounted on the distal end of the aspiration catheter or mounted on an access catheter. In either case, the vacuum may draw the flexible layer away from the port, allowing gases and/or liquids to flow out from the isolated lung segment, through the valve and into the aspiration catheter. Alternatively, aspiration through a unidirectional valve may be achieved naturally during respiration. Pressure changes may open the valve during expiration as gases flow out from the isolated lung segment. Reverse pressure changes, during inspiration, may close the valve preventing gases from flowing into the isolated segment. This may reduce the amount of gas trapped in the terminal segment over time and thus at least partially collapse the lung segment. Similarly, aspiration through the unidirectional

valve may be achieved by external mechanical pressure on the lung to force out of the lung segment and through the valve. Again, reverse pressure changes upon recoil of the lung would close the valve preventing gases from flowing into the isolated segment.

In a third aspect of the present invention, the obstruction device may comprise a blockage device which is deployed in a lung passageway to close the airway. Such a blockage device may be of similar design as previously described obstruction devices as it may be similarly delivered, deployed and anchored within a lung passageway. Thus, embodiments of the blockage device typically comprise expandable support structures. For example, in one embodiment the support structure comprises a coil. And, in a second embodiment, the support structure comprises a mesh. Again, the support structures may be connected to or encased in a polymer film or sack to provide a seal against the walls of the lung passageway and obstruct airflow through the device. Typically the blockage device will be placed in the passageway after the terminal lung segment has been aspirated by other methods. This will seal off the lung segment and maintain lung volume reduction. Alternatively, the blockage device may be placed in the passageway before the terminal lung segment has been aspirated. In this case, air trapped in the lung segment may be absorbed over time and would eventually collapse, a process known as absorption atelectasis. This process may be enhanced by insufflating the lung segment with 100% oxygen, a Helium-Oxygen mixture or low molecular weight gas prior to placing the blockage device. Such enhancement may promote complete collapse of the lung segment. In any case, the blockage device may optionally be later removed if it is so desired.

Methods of the present invention include the utilization of an obstruction device to achieve lung volume reduction. As described above, methods include delivery, deployment and anchoring of an obstruction device in a lung passageway leading to a target lung tissue segment. At least partial collapse of the terminal lung tissue segment may be achieved by aspirating the segment through the obstruction device deployed in the passageway. Aspiration may be accomplished with the use of an aspiration catheter or similar device through a port on the obstruction device. Also described above, when the port comprises a unidirectional valve, aspiration and eventual lung volume reduction may be accomplished by the opening and closing of the valve in response the respiratory cycle. In addition, methods of the present invention include deployment of a blockage device in a lung passageway leading to a terminal lung tissue segment, as previously described.

Systems of the present invention may include any of the components described in relation to the present invention. A particular embodiment of a system of the present invention comprises an access catheter and an obstruction device, as described above, wherein the obstruction device is introduceable by the access catheter. For example, the obstruction device may be houseable within a lumen of the access catheter for deployment out the distal end of the catheter, or the obstruction device may be mountable on the access catheter near its distal end. In either case, the obstruction device may be deployed and anchored within a lung passageway.

The methods and apparatuses of the present invention may be provided in one or more kits for such use. The kits may comprise an obstruction device deployable within a lung passageway and instructions for use. Optionally, such kits may further include any of the other system components described in relation to the present invention and any other materials or items relevant to the present invention.

Other objects and advantages of the present invention will become apparent from the detailed description to follow, together with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a perspective illustration of an access catheter useful in the methods, systems, and kits of the present invention.

Fig. 2 is a cross-sectional view taken along line 2 to a Fig. 1.

Figs. 3A-3F illustrate alternative cross-sectional views of the access catheter of Fig. 1.

Figs. 4A-4C illustrate a steerable imaging guidewire which may be used to facilitate positioning of the access catheter used in the methods of the present invention.

Fig. 5A illustrates use of the access catheter of Fig. 1 for accessing a target lung tissue segment according the to the methods of the present invention.

Fig. 5B illustrates use of a visualizing tracheal tube with the access catheter of Fig. 1 for accessing a target tissue segment according the to the methods of the present invention.

Fig. 6 illustrates a method of deployment or delivery of an obstructive device.

Figs. 7A-7B are perspective views of embodiments of obstructive devices having, among other features, radial and longitudinal structural supports.

Fig. 8 is a perspective view of an embodiment of an obstructive device in a rolled configuration prior to release in a lung passageway.

Fig. 9 is a perspective view of an embodiment of a rolled, cylindrical shaped obstructive device in an expanded state within a flexible sack.

Fig. 10 illustrates an embodiment of a double conical shaped obstructive device.

Fig. 11 is a perspective view of an embodiment of an obstructive device having, among other features, a mesh structural support encased by a polymer film.

Fig. 12 is a perspective view of an embodiment of an obstructive device having, among other features, a spiral structural support.

Fig. 13 is a perspective view of an embodiment of an obstructive device having a cone shape with an inlet port at the apex of the cone.

Figs. 14A-14C illustrate embodiments of self-sealing septums of the present invention.

Fig. 15 illustrates a method of aspirating through an obstructive device by inserting an access tube through a septum of an inlet port.

Fig. 16 illustrates a method of aspirating through an obstructive device by contacting an aspiration catheter to an inlet port.

Fig. 17 illustrates a method of aspirating through an obstructive device by sliding the distal end of an aspiration catheter over an inlet port.

Figs. 18A-18C illustrate a method of deploying, anchoring and aspirating through an obstruction device while such a device is connected to an aspiration catheter.

Fig. 19A is a front view of an embodiment of a unidirectional valve of the present invention. Figs. 19B-19C are perspective views of the unidirectional valve of Fig. 19A in various stages of operation.

Figs. 20-21 illustrate positioning of embodiments of unidirectional valves of the present invention in a lung passageway.

Figs. 22A-22B are front views of an embodiment of a unidirectional valve of the present invention.

Figs. 23A-23B are perspective views of the unidirectional valve of Figs. 21A-21B in various stages of operation.

Fig. 24 illustrates a method of deployment or delivery of a blockage device.

Fig. 25 illustrates an embodiment of a blockage device comprising a coil encased in a polymer film.

Fig. 26 illustrates an embodiment of a blockage device comprising a mesh connected to a polymer film.

Fig. 27 illustrates an embodiment of a blockage device comprising a barb-shaped structure.

Fig. 28 illustrates an embodiment of a blockage device having a cylindrical-type balloon with textured friction bands.

Fig. 29 depicts an embodiment of a blockage device comprising a multi-layer balloon which has an adhesive material between an outer layer and an inner layer of the balloon.

Fig. 30 illustrates an embodiment of a blockage device which is similar to that of Fig. 29, including openings in the outer layer through which adhesive may seep.

Fig. 31 illustrates a kit constructed in accordance with the principles of the present invention.

DESCRIPTION OF THE SPECIFIC EMBODIMENTS

Lung volume reduction is performed by collapsing a target lung tissue segment, usually within lobar or sub-lobular regions of the lung which receive air through a single lung passage, i.e., segment of the branching bronchus which deliver to and receive air from the alveolar regions of the lung. Such isolated lung tissue segments are first isolated and then collapsed by aspiration of the air (or other gases or liquids which may be present) from the target lung tissue segment. Lung tissue has a very high percentage of void volume, so removal of internal gases can reduce the lung tissue to a small percentage of the volume which it has when fully inflated, i.e. inflated at normal inspiratory pressures. The exemplary and preferred percentages for the volume reduction are set forth above.

The methods of the present invention will generally rely on accessing the target lung tissue segment using an access catheter adapted to be introduced endotracheally into the bronchus of the lung. An exemplary access catheter 10 is illustrated in Figs. 1 and 2 and comprises a catheter body 12 having a distal end 14, a proximal end 16, and at least one lumen therethrough. Optionally, the catheter 10 further comprises an inflatable occlusion balloon 18 near its distal end. In this case, the catheter will have at least two lumens, a central lumen 20 and a balloon inflation lumen 22. As

shown in Fig. 2, the balloon inflation lumen 22 may be an annular lumen defined by inner body member 24 and outer body member 26 which is coaxially disposed about the inner body member. The lumen 22 opens to port 30 on a proximal hub 32 and provides for inflation of balloon 18. The central lumen 20 opens to port 36 on hub 32 and provides for multiple functions, including optional introduction over a guidewire, aspiration, introduction of secondary catheters, and the like.

The dimensions and materials of access catheter 10 are selected to permit endotracheal introduction and intraluminal advancement through the lung bronchus or passageway, optionally over a guidewire and/or through a primary tracheal tube structure (as illustrated in Fig. 4B below). Suitable materials include low and high density polyethylenes, polyamides, nylons, PTFE, PEEK, and the like, particularly for the inner tubular member 24. The outer member, including the occlusion balloon, can be made from elastomeric materials, such as polyurethane, low density polyethylene, polyvinylchloride, silicone rubber, latex, and the like. Optionally, portions of the outer tubular member 26 proximal to the inflatable balloon can be made thicker and/or reinforced so that they do not dilate upon pressurization of the balloon. Exemplary dimensions for the access catheter 10 are set forth in the table below.

ACCESS CATHETER DIMENSIONS				
	Exemplary		Preferred	
	Inner Tubular Member	Outer Tubular Member	Inner Tubular Member	Outer Tubular Member
Outer Diameter (mm)	0.4-4	0.6-4.5	1-1.5	2-4
Wall Thickness (mm)	0.05-0.25	0.5-0.25	0.1-0.2	0.15-0.25
Length (cm)	50-150	same	50-80	same
Balloon Length (mm)	5-50		10-20	
Balloon Diameter (mm) (inflated)	2-20		6-15	

The access catheter 10 may be modified in a number of ways, some of which are illustrated in Figs. 3A-3F. For example, instead of an inner and outer coaxial tube construction, the catheter can be a single extrusion having a catheter body 30 with a circular main lumen 32 and a crescent-shaped inflation lumen 34, as illustrated in Fig. 3A. Alternatively, catheter body 40 may be formed as a single extrusion having

three lumens, i.e., a primary lumen 42 for receiving a guidewire, applying aspiration, and/or delivering secondary catheters. A second lumen 44 can be provided for inflating the occlusion balloon, and a third lumen 46 can be provided as an alternative guidewire or aspiration lumen. Catheter body 50 comprising a main tubular body 52 having an outer layer 54 fused thereover to define a lumen 56 suitable for balloon inflation as shown in Fig. 3C. A primary lumen 58 is formed within the main tubular member 52. As a slight alternative, catheter body 60 can be formed from a primary tubular member 62, and a secondary tubular member 64, where the tubular members are held together by an outer member 66, such as a layer which is applied by heat shrinking. The primary tubular member 62 provides the main lumen 68 while secondary tube 64 provides a secondary lumen 70. The secondary lumen 70 will typically be used for balloon inflation, while the primary lumen 68 can be used for all other functions of the access catheter.

Optionally, the access catheter in the present invention can be provided with optical imaging capability. As shown in Fig. 3E, catheter body 80 can be formed to include four lumens, typically by conventional extrusion processes. Lumen 82 is suitable for passage over a guidewire. Lumens 84 and 86 both contain light fibers 88 for illumination. Lumen 90 carries an optical wave guide or image fiber 92. Lumen 82 can be used for irrigation and aspiration, typically after the guidewire is withdrawn. Balloon inflation can be effected through the space remaining and lumens 84 and 86 surrounding the light fibers 88. A second catheter body 100 is formed as a coaxial arrangement of a number separate tubes. Outer tube 102 contains a separate guidewire tube 104 defining lumen 106 which permits introduction over a guidewire as well as perfusion and aspiration after the guidewire is removed. Second inner tubular member 110 will carry an optical image fiber 112 and a plurality of light fibers 112 are passed within the remaining space 114 within the outer tubular member. In both catheter constructions 80 and 100, forward imaging can be effected by illuminating through the light fibers and detecting an image through a lens at the distal end of the catheter. The image can be displayed on conventional cathode-ray or other types of imaging screens. In particular, as described below, forward imaging permits a user to selectively place the guidewire for advancing the catheters through a desired route through the branching bronchus.

Usually, positioning of a guidewire through the branching bronchus will be manipulated while viewing through the imaging components of the access catheter. In this way, the access catheter can be "inched" along by alternately advancing the guidewire and the access catheter. As an alternative to providing the access catheter with

imaging, positioning could be done solely by fluoroscopy. As a further alternative, a steerable, imaging guidewire 300 (Figs. 4A-4C) could be used. The guidewire 300 includes a deflectable tip 302 which can be deflected in a single plane using push/pull ribbon 304. Usually, the tip will comprise a spring 306 to facilitate deflection. In addition to steerability, the guidewire 300 will include an optical imaging wave guide 310 and illuminating optical fibers 312, as best seen in cross-sectional view of Fig. 4C. Thus, the guidewire 300 can be steered through the branching bronchus to reach the target tissue segment using its own *in situ* imaging capability. Once the guidewire 300 is in place, an access catheter can be introduced to the target lung tissue segment as well. Since the guidewire has imaging capability, the access catheter need not incorporate such imaging. This can be an advantage since it permits the access lumen to be made larger since the catheter need not carry any optical wave guides.

Referring now to Fig. 5A, a catheter 10 can be advanced to a lung tissue segment, specifically a diseased region DR, within a lung L through a patient's trachea T. Advancement through the trachea T is relatively simple and will optionally employ an endotracheal tube and/or a guidewire to select the advancement route through the branching bronchus. The endotracheal tube may have a thin-walled design wherein the inner diameter is larger than in standard endotracheal tubes. Standard endotracheal tubes have a 7.0 mm ID with a 10 mm OD. The thin-walled design would have a 9.0 mm ID with a 10 mm OD; the larger ID allows the insertion of a larger instrument while providing adequate ventilation. Steering can be effected under real time imaging using the imaging access catheters illustrated in Figs. 3E and 3F. Optionally, the access catheter 10 may be introduced through a visualizing tracheal tube, such as that described in U.S. Patent No. 5,285,778, licensed to the assignee of the present application. As shown in Fig. 5B, the visualizing endotracheal tube 120 includes an occlusion cuff 122 which may be inflated within the trachea just above the branch of the left bronchus and right bronchus LB and RB, respectively. The visualizing endotracheal tube 120 includes a forward-viewing optical system, typically including both illumination fibers and an image fiber to permit direct viewing of the main branch between the left bronchus LB and right bronchus RB. Thus, initial placement of the access catheter 10 can be made under visualization of the visualizing endotracheal tube 120 and optionally the access catheter 10 itself. It may be appreciated that the access catheter may be positioned with or without the use of a trachea tube or similar device. When such a device is used, it may take a number of forms and may be positioned in a number of locations. For example, the

trachea tube or device may be positioned as shown in Fig. 5A, or it may be positioned to achieve "one lung ventilation" wherein the side of the lung not involved in the corrective procedure will be properly ventilated. Likewise, the access catheter may be positioned under local anesthesia without intubation. In any case, referring again in particular to Fig. 5A, the access catheter 10 is advanced until its distal end 14 reaches a region in the bronchus or lung passageway which leads directly into the diseased region DR.

Once the distal end 14 of the access catheter 10 is positioned in a desired location within the lung passageway, an obstructive device may be deployed in the passageway. The method of deployment or delivery of the obstructive device is dependent on a number of factors, particularly the design of the obstructive device itself. Typically, the obstructive device is housed within the access catheter 10 or within a catheter that may be passed through the access catheter 10. As depicted in Fig. 6, the obstructive device 150 may be compressed or collapsed within an interior lumen of the access catheter 10. The obstructive device 150 depicted is one of many designs which may be utilized. The obstructive device 150 may then be pushed out of the distal end 14 of the catheter 10, in the direction of the arrow, into the lung passageway 152. If the device 150 is self-expanding, for example by tension or shape-memory, the device 150 will expand and anchor itself in the passageway 152. If the device 150 is not self-expanding, it may be expanded with the use of a balloon or other mechanism provided by the access catheter 10, a catheter or device delivered through the access catheter 10, or another device. Similarly, the obstructive device 150 may be mounted or crimped over the access catheter 10 (not shown) or a delivery catheter and delivered to the desired location. A sheath may then be placed over the device 150 during insertion. Deployment of the device 150 may be achieved by withdrawing the sheath and allowing the device 150 to self-expand or expanding the device 150 with the use of a balloon or other mechanism.

A variety of embodiments of obstructive devices 150 are provided. To begin, a number of embodiments of the obstructive device 150 are comprised of structural supports which expand to anchor the device 150 in the passageway 152. Referring to Fig. 7A, the supports 154 may be comprised of radial segments 160 and longitudinal segments 162. The radial segments 160 allow the device 150 to expand to fill the passageway 152 and the longitudinal segments 162 rest against the walls of the passageway 152 to help anchor the device 150. The supports 154 may be individual, as shown in Fig. 7A, or may be connected to one another, as shown in Fig. 7B, for example.

In addition, the supports 154 may continue along a proximal end 164 and distal end 166 of the device 150, as shown in Fig. 7A, or the supports 154 may not be present at such ends 164, 166, as shown in Fig. 7B.

Referring to Figs. 8-11, the supports 154 may be comprised of a mesh 170 or similar interlocking structure. As shown in Fig. 8, the mesh 170 may be coiled or rolled into a cylindrical shape to fit within an inner lumen of a delivery or access catheter or to be mounted on the end of a such a delivery or access catheter. In either case, the device 150 may be released within the lung passageway 152 where the mesh 170 expands, uncoils and/or unrolls to fill the passageway 152. Such release may allow self-expansion or may involve the use of mechanical means to expand the mesh 170. The expanded device 150 may fill the passageway 152 in a generally cylindrical shape, as shown in Fig. 9, in single or double conical shape, as shown in Fig. 10, or it may form a variety of other shapes, an example of which is shown in Fig. 11.

Referring now to Fig. 12, the supports 154 may be a helix or spiral 171 comprised of helically wound or spiral wound wire. The spiral 171 may be compressed in a number of ways to load the spiral 171 within a lumen or on a distal end of a delivery catheter. For example, the spiral 171 may be wound tightly, similar to a watch spring, to reduce the cross-section of the spiral and provide spring tension. Upon release of the spiral 171, the coils 173 expand to contact the walls of the passageway 152 and anchor the device 150.

In any of the above embodiments, the supports 154 may be connected to, encapsulated in, coated or impregnated with a material to prevent flow of gases or liquids through the structural supports 154, thereby providing an obstruction. In addition, the material may include an antibiotic agent for release into the lung passageway. Examples of obstructive materials include a thin polymer film 156, such as webbing between the structural supports 154, which may be used to seal against the surface of the lung passageway 152. Such a design is depicted in Figs. 7A-7B, 10 and 12. Similarly, the structural supports 154 may be filled with an adhesive or sealant which will adhere the structural support members together and prevent flow or gasses or liquids through the device 150. This is particularly useful in coiled or mesh designs in where the structural support members are relatively close together. Alternatively, as shown in Fig. 9 and Fig. 11, the supports 154 may be encased in a sack 158 comprised of a thin polymer, foam or other material. Expansion of the supports 154 within the sack 158 presses the sack 158 against the walls of the passageway 152 forming a seal. In Fig. 9, the sack 158 has been

extended beyond the ends of the rolled support structure 154 for illustration purposes to differentiate between the sack 158 and support structure 154. However, typically, the support structure 154 will fill the sack 158. Again, the presence of the sack 158 prevents flow of gases or liquids through the supports 154, thereby providing an obstruction. It may be appreciated that the structural supports may comprise a variety of designs, creating devices 150 of various lengths and shapes. Alternatively, the sack 158 may be utilized without structural supports 154. The sack may expand to fill the passageway by a variety of methods and may be held in position by impregnation with an adhesive or other material. Such impregnation may rigidify or support the sack to provide obstruction of the lung passageway.

In addition and also shown in Figs. 7A, 7B, 9, 11-13, a number of embodiments of the obstructive device 150 include an inlet port 172, located near the proximal end 164, and an outlet port 174, located near the distal end 166. Such ports 172, 174 may be of any size or shape but are typically round or oval and are often located near the center of the passageway 512 lumen for ease of accessibility. Some devices 150 may only include an inlet port 172 near the proximal end 164, as shown in Fig. 13. In this case, the distal end 166 is expanded to contact the walls of the lung passageway 152 and anchor the device 150. Thus, the obstruction device 150 appears to have a cone shape with the inlet port 172 at the apex of the cone. To ensure concentric placement of the obstruction device 150, the device 150 should contact the walls of the passageway 152 for a length of at least 1.0 to 1.5 times the internal diameter of the passageway that the device 150 occupies.

The inlet port 172, outlet port 174 or both may comprise a membrane or septum 176 covering the opening of the port. The septum 176 will typically be self-sealing. One type of self-sealing septum 176 comprises a solid membrane 178, illustrated in Fig. 14A. Other types comprise pre-cut membranes in which the septum 176 includes cuts 180 or slits, as shown in Figs. 14B and 14C. Such cuts 180 may allow ease of penetration through the septum 176 by an access tube or penetrating element, as will be later described, while preventing flow through the septum when the penetrating element is removed.

After the obstruction device 150 is deployed and anchored within a lung passageway 152 leading to a lung tissue segment, the device 150 may be left as an implant to obstruct the passageway 152 from subsequent airflow. Airflow may include air and/or any other gas or combination of gases, such as carbon dioxide. However,

immediately after placement or at any time thereafter, the above described embodiments of the device 150 may be accessed to aspirate the lung tissue segment through the obstructive device 150. This will cause the segment to at least partially collapse as part of a method for lung volume reduction. Aspirating through the obstructive device 150 may be accomplished by a variety of methods. For example, referring to Fig. 15, aspiration may be achieved by first inserting a penetration element, needle or access tube 200 through the septum 176 of the inlet port 172. Positioning of the access tube 200 for such insertion may be achieved by any method, however, the access tube 200 is typically positioned by inserting the access tube 200, or a catheter carrying the access tube 200, through a lumen in the access catheter 10 until it passes out of the distal end 14. Inflating the balloon 18 on the access catheter 10 may center the distal end 14 of the catheter in the lung passageway 152. If the inlet port 172 is similarly centered, the access tube 200 may be passed directly out of the catheter 10 and through the septum 176 of the inlet port 172.

If the septum 176 is a solid membrane 178, the access tube 200 may be sharp enough to puncture or pierce the membrane 178. If the septum 176 has cuts 180 or slits, the access tube 200 may be pushed through the cuts 180. In either case, the membrane or septum 176 will seal around the access tube 200. If the obstruction device 150 also has an outlet port 174, the access tube 200 may optionally be passed through both the inlet and outlet ports 172, 174. Once the access tube 200 is inserted, gases and/or liquids may be aspirated through the access tube 200 from the lung tissue segment and associated lung passageways. Optionally, prior to aspiration, a 100% oxygen, Helium-Oxygen mixture or low molecular weight gas washout of the lung segment may be performed by introducing such gas through the access tube 200. In this case, aspiration would removed both the introduced gas and any remaining gas. Similarly, liquid perfluorocarbon or certain drugs, such as antibiotics, may be introduced prior to aspiration. This may allow access to the collapsed lung segment at a later time, for example, in the case of an infection. In most cases, aspiration will at least partially collapse the lung segment, as previously described. The access tube 200 may then be withdrawn. The septum 176 of the inlet port 172 and/or outlet port 174 will then automatically seal, either by closing of the puncture site or by closure of the cuts. Optionally, the ports may be additionally sealed with a sealant or by use of a heat source or radiofrequency source.

Referring to Figs. 16 and 17, aspiration through the obstructive device 150 may be achieved by contacting the obstructive device 150 with a suction tube or

aspiration catheter 202 and aspirating gas or liquids through the device 150. As shown in Fig. 16, the distal end 204 of the aspiration catheter 202 may be held against the inlet port 172. Positioning of the aspiration catheter 202 for such contact may be achieved by any method, however the catheter 202 is typically positioned in a manner similar to the access tube described above. By holding the aspiration catheter 202 against the port 172, a seal may be created and gases and/or liquids may be aspirated from the lung tissue segment through the device 150. In this case, the inlet port 172 and the outlet port 174, if present, must not be covered by a solid membrane 178. If cuts 180 are present, the gas or liquid may flow through the port due to the pressure of the suction. As shown in Fig. 17, the distal end 204 of the aspiration catheter 202 may be slid over the inlet port 172 to form a seal. Again, gases and/or liquids may then be aspirated through the device 150 in a similar manner. The aspiration catheter 202 may then be withdrawn. The septum 176 of the inlet port 172 and/or outlet port 174 will then automatically seal, typically by closure of the cuts. Optionally, the ports may be additionally sealed with a sealant or by use of a heat source or radiofrequency source.

Referring to Figs. 18A-18C, the obstruction device 150 may be deployed, anchored and aspirated therethrough while connected to an aspiration catheter 210. In this case, the access catheter 10 is positioned within the lung passageway 152 at a desired location. If the catheter 10 has an inflatable occlusion balloon 18 near its distal end 14, the balloon 18 may be inflated to secure and center the catheter 10 within the passageway 152; however, this step is optional. As shown in Fig. 18A, an aspiration catheter 210 carrying an obstruction device 150 is then introduced through a lumen in the access catheter 10. As shown in Fig. 18B, the aspiration catheter 210 is advanced so that the obstruction device 150 emerges from the distal end 14 of the access catheter 10 and deploys within the lung passageway 152. Expansion and anchoring of the obstruction device 150 within the passageway 152 may be achieved by self-expansion or by expansion with the aid of a balloon, for example. The lung tissue segment isolated by the device 150 is then aspirated through the device 150 and the attached aspiration catheter 210. Such aspiration may remove air, gases, or liquids from the segment and lung passageway 152 to at least partially collapse the lung segment. As shown in Fig. 15C, the obstruction device 150 is then detached from the aspiration catheter 210 and left behind in the passageway 152. The proximal end 164 of the obstruction device 150 may comprise an inlet port 172 which would allow subsequent access to the isolated lung tissue segment at a later time. Alternatively, the proximal end 164 may comprise a sealed

end, wherein the obstruction device 150 may not be subsequently accessed and may provide long-term isolation of the terminal lung tissue segment.

It may be appreciated that the above described method may be similarly achieved without the use of an aspiration catheter 210. In this case, the obstruction device 150 may be carried directly by the access catheter 10 and may be deployed while remaining attached to the access catheter 10. Aspiration may be achieved through the obstruction device 150 and the access catheter 10 to remove gases from the isolated lung tissue segment and passageway 152. The obstructive device 150 may then be detached from the access catheter 10 and left behind in the passageway 152 for subsequent access or simple occlusion.

At this point, all catheters and instruments may be withdrawn from the patient and the obstruction device 150 may remain in its anchored position, as described. The obstruction device 150 will essentially occlude the lung passageway 152 and prevent the inflow or outflow of air or gases to the isolated lung tissue segment or diseased region DR. This may be effective in maintaining the desired level of collapse of the lung tissue segment to achieve lung volume reduction. However, at any point, the lung tissue segment may be reaccessed and/or reaspirated by repeating the steps described above. In addition, at any point, the obstruction device 150 may be removed from the lung passageway 152, either by collapse of the expandable structure or by other means.

Additional embodiments of the obstructive device 150 are comprised of a unidirectional valve. The valve may be operated upon access or it may operate in response to respiration. For example, when the valve is positioned in the lung passageway, the valve may be accessed by engaging an aspiration catheter or a coupling member to the valve. Aspiration through the aspiration catheter or coupling member then opens the valve to remove gases and/or liquids from the isolated lung segment. Alternatively, the valve may open automatically in response to respiration. The valve may open during expiration to allow outflow of gas from the lung segment and the close during inspiration to prevent inflow of gas to the lung segment. In either case, the unidirectional valves may take a number of forms.

One embodiment of such a unidirectional valve is illustrated in Figs. 19A-19C. In this embodiment, the unidirectional valve 230, front-view shown in Fig. 19A, is comprised of a port 232 and a flexible layer 233 which is attached to the port 232 by at least one point of connection 234. As shown, the flexible layer 233 may be attached to the front surface of the port 232 at four symmetrical points of connection 234. In

preferred embodiments, edges 236 of the layer 233 are positioned outside of the opening of the port 232 (indicated by dashed lines). This provides a desired seal when the valve is in the closed position.

Side-views shown in Figs. 19B and 19C depict the valve 230 during different stages of the respiratory cycle. During expiration, the valve 230 opens, as depicted in Fig. 19B. Here, expiration of gases is illustrated by arrows. Gases exiting through the lung passageway, within which the valve 230 is positioned, apply force to the backside of the flexible layer 233 causing the layer 233 to expand outwardly away from the surface of the port 232 as shown. This allows the gases to flow through the spaces between the points of connection 234. During inspiration, the valve 230 closes, as depicted in Fig. 19C. Here, inspiration of air is illustrated by an arrow. Air entering the lung passageway applies force to the front side of the flexible layer 233 causing the layer 233 to seal against the surface of the port 232 as shown. This prevents gases from flowing through the valve 230.

Unidirectional valves 230 may be positioned in the lung passageway 152 by methods similar to those previously described for other types of obstruction devices 150. As shown in Fig. 20, the valve 230 may be positioned in the passageway 152 so that the outside perimeter of the port 232 contacts the walls of the passageway 152. In this way, the valve 230 is essentially the size of the passageway lumen and provides the maximum area for potential flow-through of gas. The valve 230 is depicted in its open state, with gas flow traveling from an isolated lung tissue segment, through the valve and out of the patient's airways. As shown in Fig. 21, the valve 230 may alternatively be attached to or part of structural supports 154 which expand radially to anchor the device 150 in the passageway 152. Such supports 154 are similar to those previously described. Again, the valve 230 is depicted in its open state. It may be appreciated that the valve 230 may be of any size or shape and may substituted for any of the inlet and/or outlet ports previously described.

Another embodiment of a unidirectional valve is illustrated in Figs. 22A-22B. In this embodiment, the valve 230 is comprised of a port 232 and a flexible layer 233 as in the previous embodiment. However, here the flexible layer 233 has a series of holes 250 through the layer. In addition, the valve 230 is comprised of a partition 252 which also has holes 250. The holes 250 may be of any size, shape or arrangement throughout the entire or a portion of the layer 233 and partition 252. The partition 252 covers the port 232 and the layer 233 is positioned over the partition 252, as

illustrated in Fig. 22A and depicted by arrows, so that the holes 250 are substantially misaligned and therefore blocked. The assembled valve, illustrated in Fig. 22B, does not have any through holes 250 in the closed position. The holes 250 in the layer 233 are blocked by the underlying partition 252. Likewise, the holes 250 in the partition 252 are blocked by the overlying layer 233. The layer 233 is attached to the partition 252 and/or port 232 along its perimeter; it may be a continuous attachment or may have discrete points of connection with spaces therebetween.

Side-views shown in Figs. 23B and 23C depict the valve 230 during different stages of the respiratory cycle. During expiration, the valve 230 opens, as depicted in Fig. 23B. Here, expiration of gases is illustrated by arrows. Gases exiting through the lung passageway, within which the valve 230 is positioned, pass through the holes 250 in the partition 252 and apply force to the backside of the flexible layer 233. This causes the layer 233 to expand outwardly away from the partition 252 as shown. This allows the gases to flow through the holes 250 in the layer 233. During inspiration, the valve 230 closes, as depicted in Fig. 23C. Here, inspiration of air is illustrated by an arrow. Air entering the lung passageway applies force to the front side of the flexible layer 233 causing the layer 233 to seal against the surface of the partition 252 as shown. This prevents gases from flowing through the valve 230. This embodiment of a unidirectional valve 230 may be positioned in a lung passageway 152 by methods similar to those previously described for other types of obstruction devices 150, particularly as shown in Figs. 20 and 21.

Although the unidirectional valves described above are shown as operating during different stages of the respiratory cycle, the valves may additionally or alternatively be operated manually. Valves positioned in a lung passageway, as depicted in Figs 20-21, may be accessed by coupling an aspiration catheter to the valve. Coupling may comprise engaging the aspiration catheter, a suitable catheter or a coupling member to the valve. In some cases, particularly when the valve 230 comprises a port 232 which is smaller in diameter than the lumen of the lung passageway, as depicted in Fig. 21, the distal end of the aspiration catheter or coupling member may be slid over the port to form a seal. This was previously depicted in Fig. 17 in relation to sealing of the aspiration catheter 202 around an inlet port 172 of a non-valved obstruction device. When a valve is present in this case, aspiration through the aspiration catheter will open the valve and draw gases and/or liquids from the lung tissue segment. With the described unidirectional

valves 230, the suction force of the aspiration will draw the flexible layer 233 away from the port 232 or the partition 252 to open the valve.

Further embodiments of the obstructive device 150 are comprised of a blockage device 280 having no ports through which aspiration of the isolated lung tissue segment may be achieved. After the blockage device 280 is deployed and anchored within a lung passageway 152 leading to a lung tissue segment, the device 280 is to be left as an implant to obstruct the passageway 152 from subsequent airflow. Although the previously described embodiments of obstructive devices 150 having inlet and/or outlet ports 172, 174 may be utilized in a similar manner, the blockage device 280 may not be later accessed to aspirate the lung tissue segment through the device. An example of such a blockage device 280 is illustrated in Figs. 24 and 25.

As with the previous obstructive devices, the blockage device 280 may be housed within the access catheter 10 or within a catheter that may be passed through the access catheter 10. As depicted in Fig. 24, the obstructive device 150 may be compressed or collapsed within an interior lumen of the access catheter 10. The blockage device 280 depicted is one of many designs which may be utilized. The blockage device 280 may then be pushed out of the distal end 14 of the catheter 10, in the direction of the arrow, into the lung passageway 152. The device 280 is to be self-expanding by tension or shape-memory so that it will expand and anchor itself in the passageway 152.

Referring to Fig. 25, one embodiment of the blockage device 280 comprises a coil 282. The coil 282 may be comprised of any type of wire, particularly superelastic or shape-memory wire, polymer or suitable material. The tension in the coil 282 allows the device 280 to expand to fill the passageway 152 and rest against the walls of the passageway 152 to anchor the device 280. In addition, the coil 282 may be connected to a thin polymer film 284, such as webbing between the coils, to seal against the surface of the lung passageway 152. Such a film 284 prevents flow of gases or liquids through the coils, thereby providing an obstruction. Alternatively, as depicted in Fig. 25, the coil 282 may be encased in a sack 286. Expansion of the coil 282 within the sack 286 presses the sack 286 against the walls of the passageway 152 forming a seal. Again, this prevents flow of gases or liquids, depicted by arrows, through the coil 282, thereby providing an obstruction. Similarly, as depicted in Fig. 26, another embodiment of the blockage device 280 comprises a mesh 283. The mesh 283 may be comprised of any type of wire, particularly superelastic or shape-memory wire, polymer or suitable material. The tension in the mesh 283 allows the device 280 to expand to fill the passageway 152

and rest against the walls of the passageway 152 to anchor the device 280. In addition, the mesh 283 may be connected to a thin polymer film 284, such as webbing between the lattice of the mesh, to seal against the surface of the lung passageway 152. Such a film 284 prevents flow of gases or liquids through the mesh, thereby providing an obstruction.

Referring now to Fig. 27, another embodiment of the blockage device 280 comprises a barb-shaped structure 304 designed to be wedged into a lung passageway 152 as shown. Such a structure 304 may be comprised of a solid material, an inflatable balloon material, or any material suitable to provide a blockage function. The structure 304 may be inflated before, during or after wedging to provide sufficient anchoring in the lung passageway. Similarly, the structure 304 may be impregnated or infused with an adhesive or sealant before, during or after wedging to also improve anchoring or resistance to flow of liquids or gasses through the passageway 152.

Referring to Fig. 28, another embodiment of the blockage device 280 comprises an inflated balloon. Such a balloon may take a number of forms. For example, the balloon may have take a variety of shapes, such as round, cylindrical, conical, dogboned, or multi-sectional, to name a few. Or, a series of distinct or interconnected balloons may be utilized. Further, the surface of the balloon may be enhanced by, for example, corrugation or texturing to improve anchoring of the balloon within the lung passageway. Fig 28 illustrates a cylindrical-type balloon 300 with textured friction bands 302 which contact the walls of the lung passageway 152 when the balloon 300 is inflated as shown.

It may be appreciated that such balloons may be inflated with an number of materials, including saline, gas, suitable liquids, expanding foam, and adhesive, to name a few. Further, a multi-layer balloon 310 may be utilized, as shown in Fig. 29, which allows the injection of adhesive 312 or suitable material between an outer layer 314 and an inner layer 316 of the balloon 310. Such adhesive 312 may provide a hardened shell on the obstruction device 280 to improve its obstruction abilities. As shown, the balloon 310 may be inflated within the inner layer 316 with a foam 318 or other material. Similarly, as shown in Fig. 30, the outer layer 314 of the blockage device 280 may contain holes, pores, slits or openings 320 which allow the adhesive 312 to emerge through the outer layer 314 to the outside surface of the multi-layer balloon 310. When the balloon 310 is inflated within a lung passageway 152, the outer layer 314 of the balloon 310 will press against the walls of the passageway 152 and the adhesive 312 will

bond with the walls in which it contacts. Such adhesion is designed to improve anchorage and obstructive abilities of the blockage device 280.

It may also be appreciated that the above described blockage devices may be impregnated, coated or otherwise deliver an antibiotic agent, such as silver nitrate. Such incorporation may be by any means appropriate for delivery of the agent to the lung passageway. In particular, a multi-layer balloon may be provided which allows the injection of an antibiotic agent between an outer layer and an inner layer of the balloon 310. As previously described and depicted in Fig. 30, the outer layer 314 of the blockage device 280 may contain holes, pores, slits or openings 320 which allow the agent to emerge through the outer layer 314 to the outside surface of the multi-layer balloon 310. Thus, the agent may be delivered to the walls and/or the lung passageway.

It may further be appreciated that the blockage device 280 may comprise a variety of designs having various lengths and shapes. In addition, many of the designs illustrated for use as a blockage device 280 may also be adapted with an aspiration port for use as described in relation to the previously illustrated embodiments of obstruction devices 150. For example, such a port 172 having a septum 176 is shown in Fig. 30. If the port is not accessed, the device simply serves as a blockage device 280. Thus, in some cases, blockage devices 280 and obstructive devices 150 are synonymous.

Referring now to Fig. 31, kits 400 according to the present invention comprise at least an obstruction or blockage device 500 and instructions for use IFU. Optionally, the kits may further include any of the other system components described above, such as an access catheter 10, guidewire 402, access tube 200, aspiration catheter 202 or other components. The instructions for use IFU will set forth any of the methods as described above, and all kit components will usually be packaged together in a pouch 480 or other conventional medical device packaging. Usually, those kit components which will be used in performing the procedure on the patient will be sterilized and maintained sterilely within the kit. Optionally, separate pouches, bags, trays, or other packaging may be provided within a larger package, where the smaller packs may be opened separately and separately maintain the components in a sterile fashion.

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 device for obstructing and bleeding gas from a lung tissue segment, said device comprising:

an expandable structure which is deployable within a lung passageway; and

means for the expandable structure for blocking airflow in one direction therethrough and permitting airflow in the other direction therethrough.

2. A device as in claim 1, wherein the blocking means comprises a valve.

3. A device as in claim 2, wherein the valve is biased to open in response to expiration and remain closed in response to inspiration.

4. A device as in claim 2, wherein the valve is biased to open in response to an aspiration vacuum applied by an aspiration catheter.

5. A device as in claim 4, further comprising a port for selectively coupling to an aspiration catheter.

6. A device as in claim 4, wherein the blocking means comprises a self-sealing septum, wherein a penetrating element on an aspiration catheter can be selectively penetrated through the septum to draw air therethrough.

7. A device as in any of the preceeding claims, wherein the expandable structure comprises superelastic, shape-memory or spring tempered wire so that the expandable structure is self-expanding.

8. A device as in claim 7, wherein the expandable structure comprises a coil.

9. A device as in claim 7, wherein the expandable structure comprises radial segments which allow the device to expand and longitudinal segments which rest against the lung passageway.

10. A system for obstructing a lung passageway to a lung tissue segment, said system comprising:

an access catheter having a proximal end, a distal end, and at least one lumen extending therethrough, and

an obstruction as in any of claims 1-10, wherein the obstruction device is introduceable by the access catheter.

11. A system as in claim 10, wherein the obstruction device is houseable within a lumen of the access catheter for deployment out of its distal end.

12. A system as in claim 10, wherein the obstruction device is mountable on the access catheter near its distal end.

13. A kit comprising:

an obstruction device deployable within a lung passageway; and

instructions for use according to a method of lung volume reduction comprising:

deploying an obstructive device in a lung passageway to a lung tissue segment; and

aspirating the segment through the deployed obstructive device to at least partially collapse the lung segment.

14. A kit as in claim 13, further comprising an access catheter having a proximal end, a distal end, and at least one lumen extending therethrough.

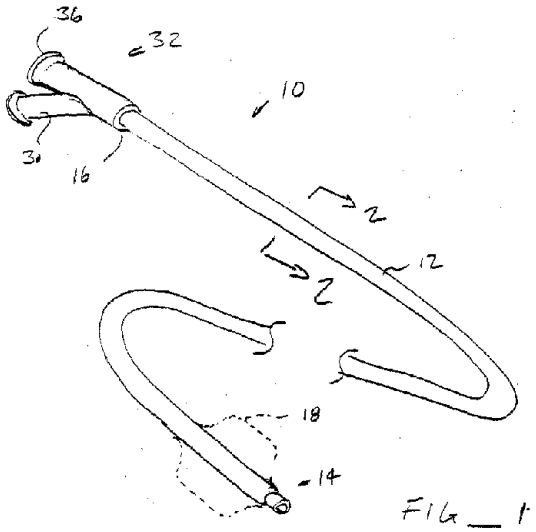


FIG_ 1

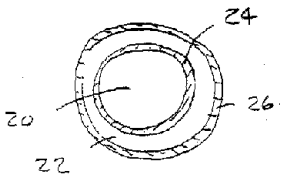


FIG_ 2

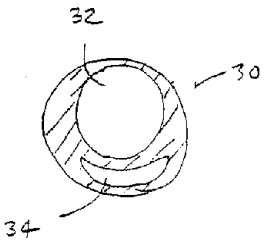


FIG-3A

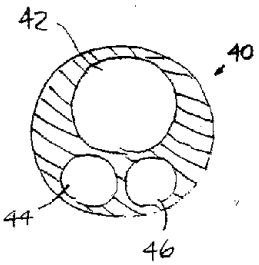


FIG-3B

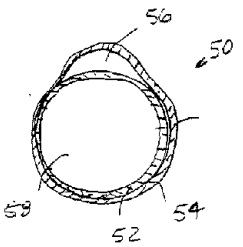


FIG-3C

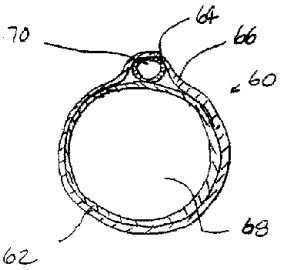


FIG-3D

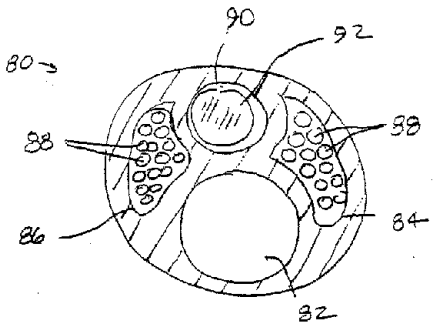


FIG-3E

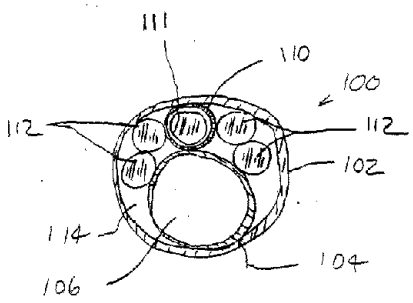


FIG-3F

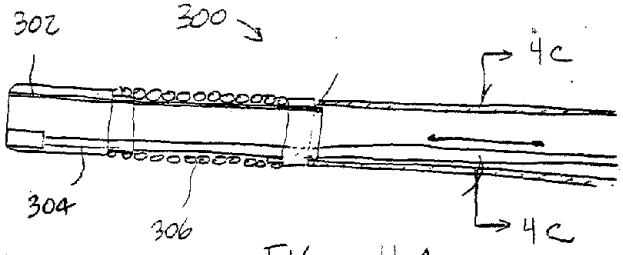


FIG- 4A

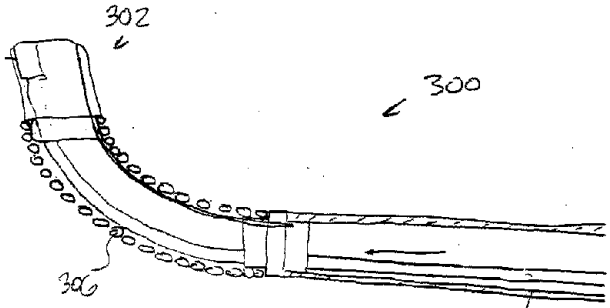


FIG- 4B

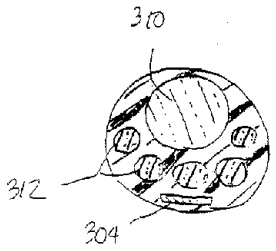
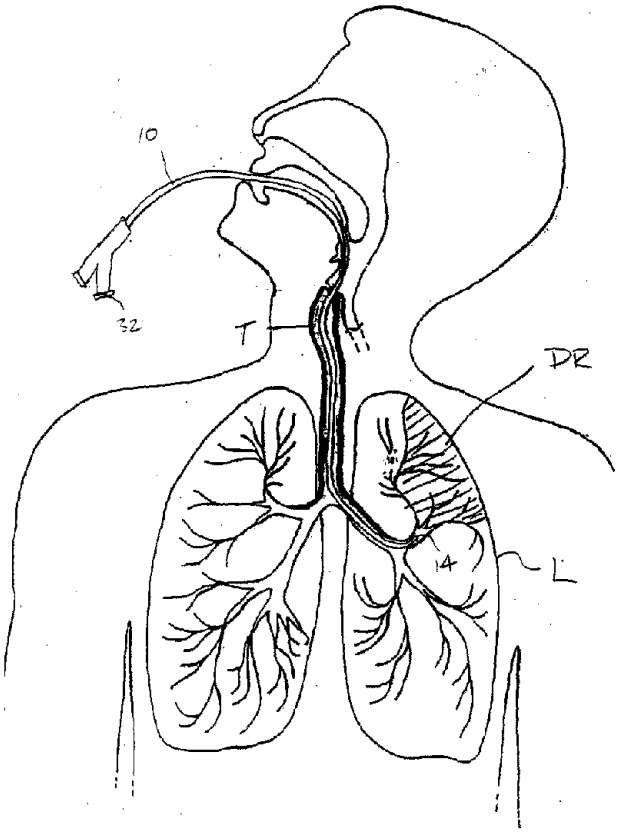


FIG- 4C



FIG— 5A

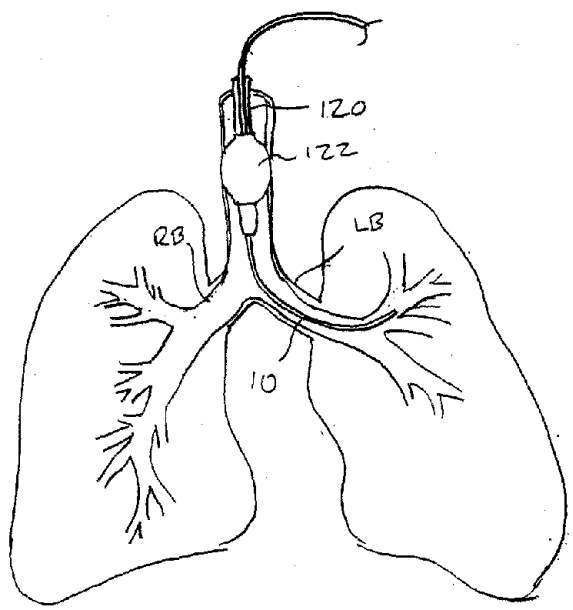


FIG-5B

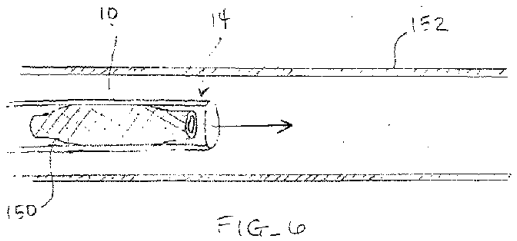


FIG_6

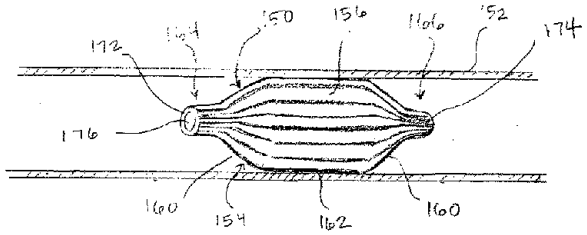


FIG_7A

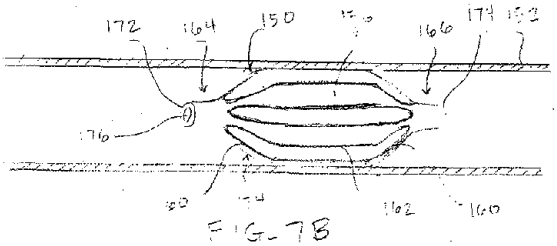


FIG_7B

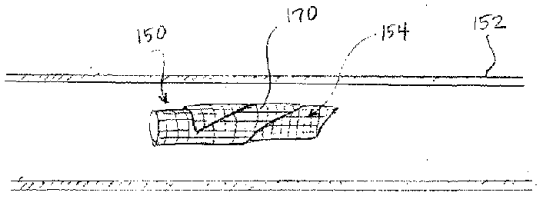


FIG_8

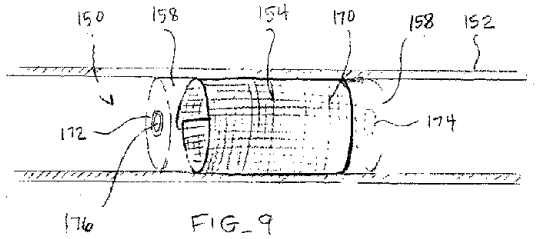


FIG_9

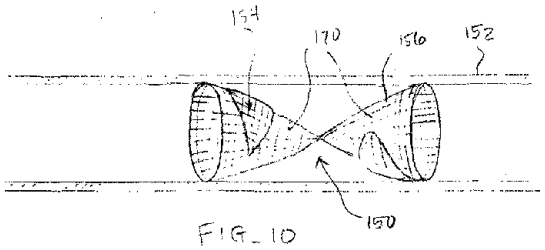


FIG_10

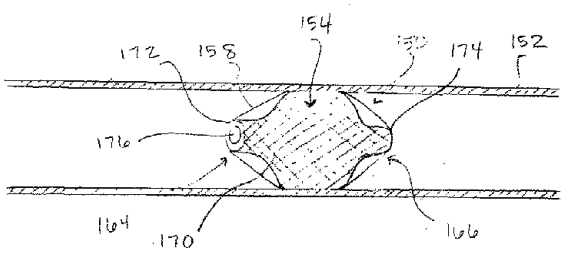

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FIG_11

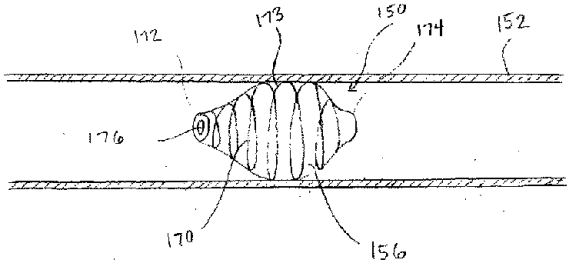
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FIG_12

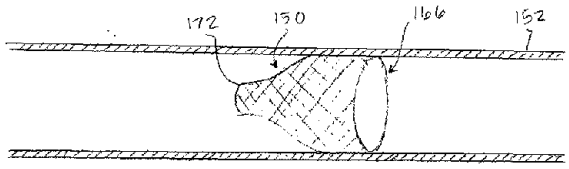


FIG_13

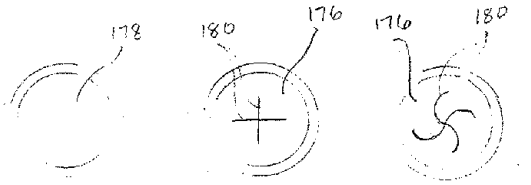


FIG_14A FIG_14B FIG_14C

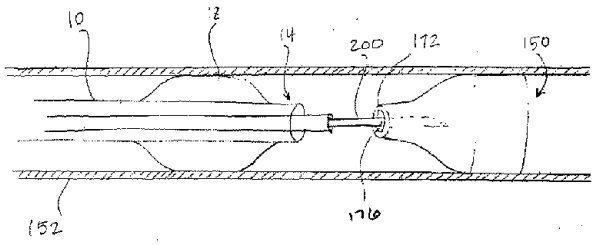


FIG_15

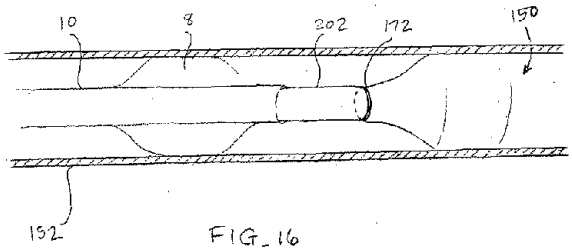


FIG_16

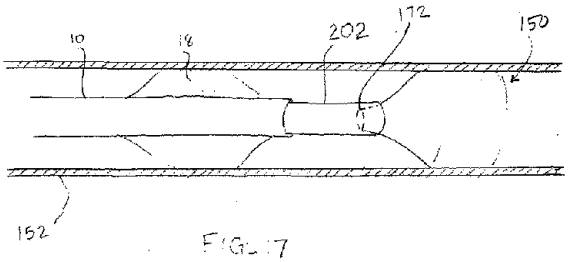


FIG_17

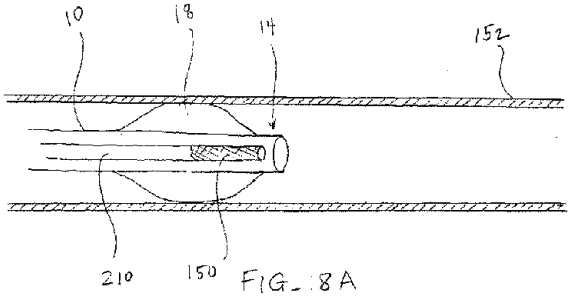


FIG_18A

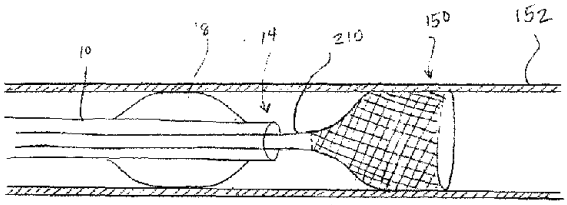


FIG_18B

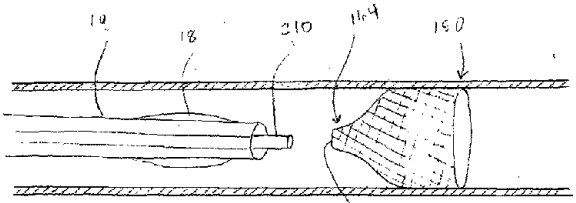


FIG_18C

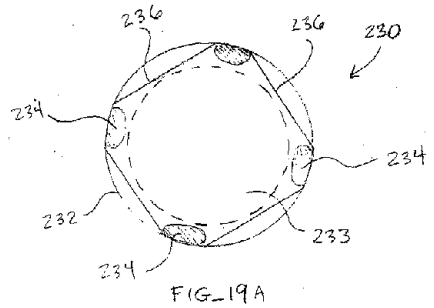


FIG_19A

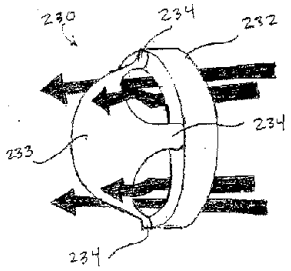


FIG_19B

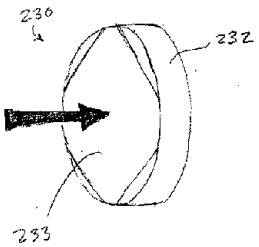


FIG_19C

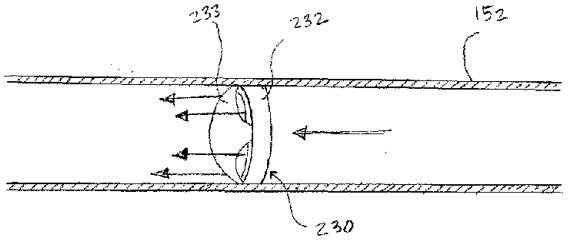


FIG. 20

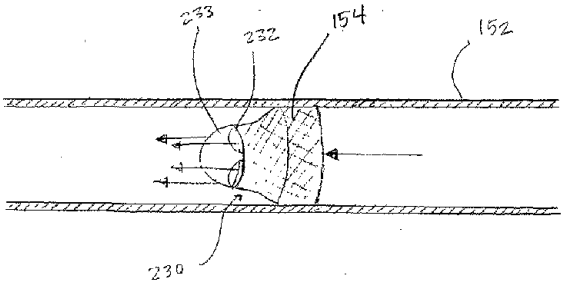


FIG. 21

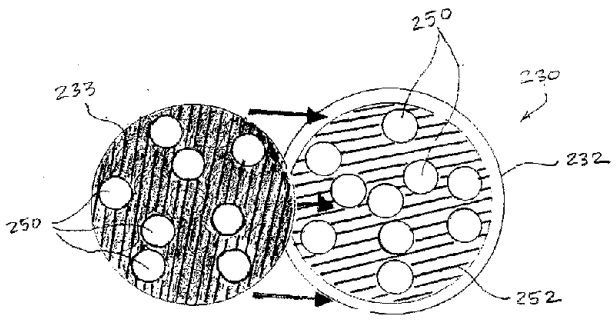


FIG_22A

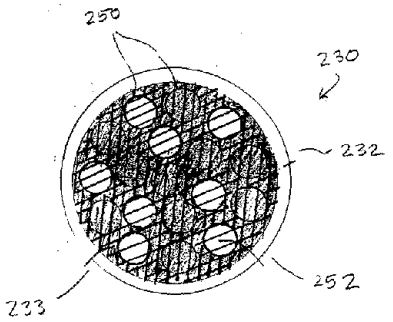


FIG_22B

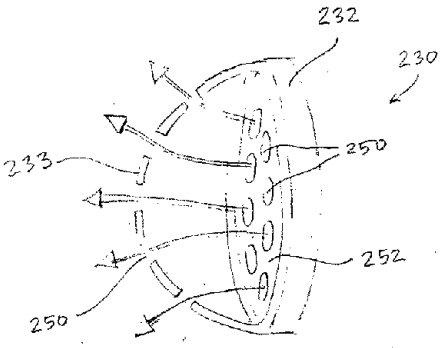


FIG_23A

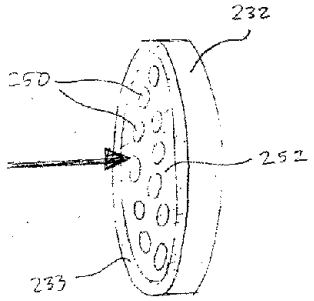


FIG_23B

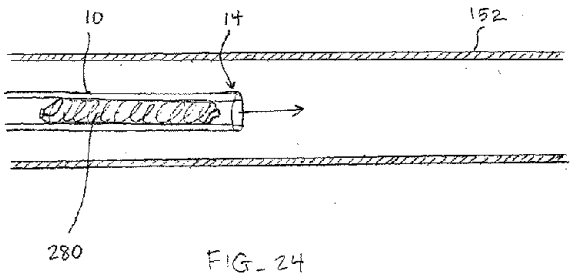


FIG_24

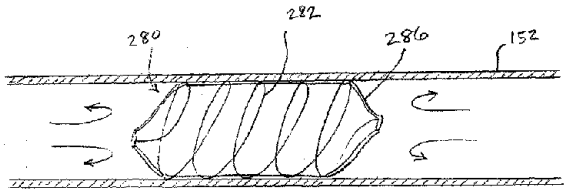


FIG_25

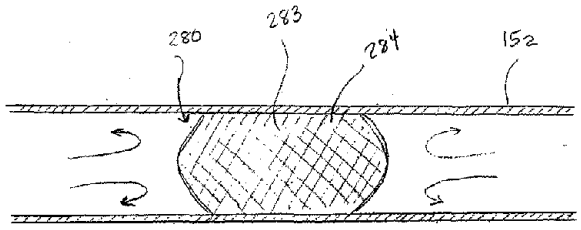


FIG_26

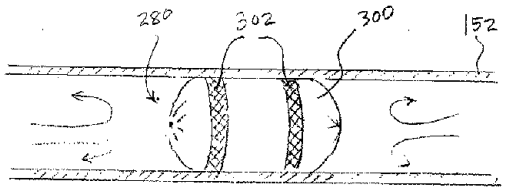


FIG_28

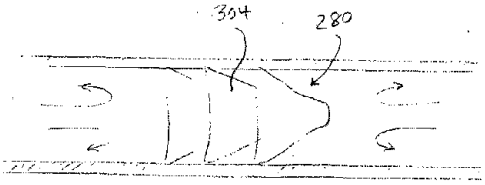


FIG_27

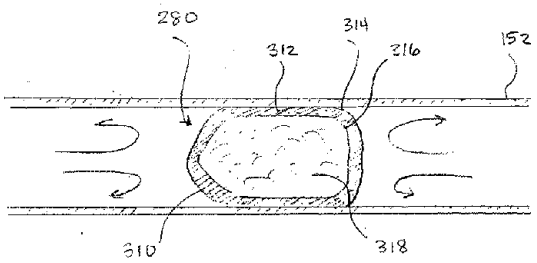


FIG_29

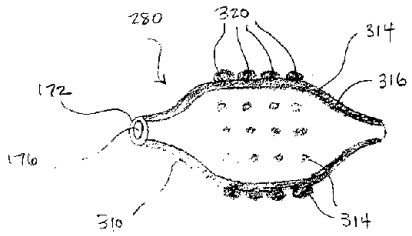


FIG_30

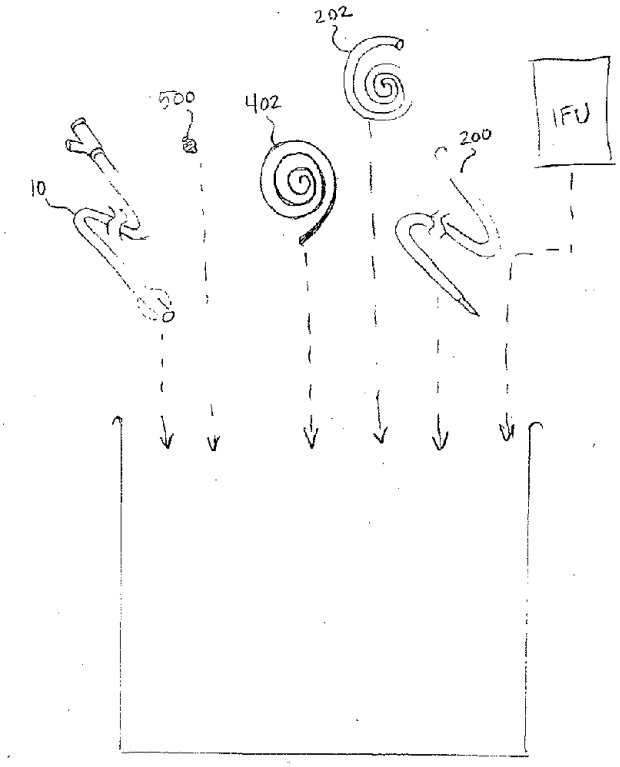


FIG-31

【国際公開パンフレット（コレクトバージョン）】

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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
16 May 2002 (16.05.2002)

PCT

(10) International Publication Number
WO 02/038038 A3

(51) International Patent Classification⁷: A61M 5/20

(21) International Application Number: PCT/US01/51092

(22) International Filing Date: 26 October 2001 (26.10.2001)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
09/699,302 27 October 2000 (27.10.2000) US

(71) Applicant: **PULMONX** [US/US]; 1049 Elwell Court, Palo Alto, CA 94303 (US).

(72) Inventors: **SOLTESZ, Peter, P.**; 4972 Miramar Avenue, San Jose, CA 95129 (US). **KOTMEL, Robert, E.**; 116 Bloomfield Road, Burlingame, CA 94010 (US). **WONDKA, Tony**; 2700 Del Medio Court, Mountain View, CA 94040 (US). **REILLY, Michael, P.**; 906 Parkview Avenue, Atherton, CA 94027 (US). **BUCH, Wally S.**; 178 Glenwood Avenue, Atherton, CA 94027 (US).

(74) Agents: **HESLIN, James, M.** et al.; Townsend and Townsend and Crew LLP, Two Embarcadero Center, Eight Floor, San Francisco, CA 94111 (US).

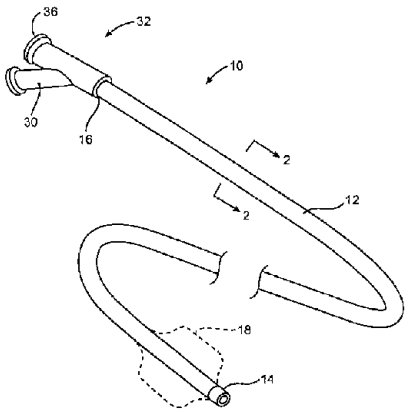
(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT,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

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

Published:
— *with international search report*

[Continued on next page]

(54) Title: METHODS AND DEVICES FOR OBSTRUCTING AND ASPIRATING LUNG TISSUE SEGMENTS



(57) Abstract: Methods and devices for obstructing and aspirating lung tissue segments minimally invasive with instruments being introduced through the mouth and rely on isolating the target lung tissue segments from other regions of the lung. Isolation is achieved by deploying an obstructive device (150) in a lung passageway (152) leading to the target lung tissue segment. Once the obstructive device is anchored in place, the segment can be aspirated through the device. This may be achieved by a number of methods, including coupling an aspiration catheter (10) to an inlet port on the obstruction device and aspirating through the port. Or, providing the port with a valve which allows outflow of gas from the isolated lung tissue segment during expiration of the respiratory cycle but prevents inflow of air during inspiration. The obstructive device may remain as an implant, to maintain isolation and optionally allow subsequent aspiration, or the device may be removed at any time.

WO 02/038038 A3

WO 02/038038 A3

(88) Date of publication of the international search report:
8 May 2003

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.

【国際公開パンフレット（コレクトバージョン）】

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CORRECTED VERSION

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PCT

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(74) Agents: HESLIN, James, M. et al.; Townsend and Townsend and Crew LLP, Two Embarcadero Center, Eight Floor, San Francisco, CA 94111 (US).

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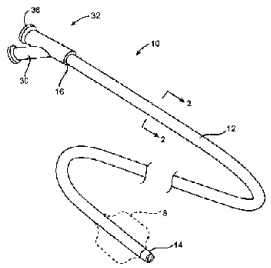
(84) Designated States (regional): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML,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

Published:
— with international search report

[Continued on next page]

(54) Title: METHODS AND DEVICES FOR OBSTRUCTING AND ASPIRATING LUNG TISSUE SEGMENTS



(57) Abstract: Methods and devices for obstructing and aspirating lung tissue segments minimally invasive with instruments being introduced through the mouth and rely on isolating the target lung tissue segments from other regions of the lung. Isolation is achieved by deploying an obstructive device (150) in a lung passageway (152) leading to the target lung tissue segment. Once the obstructive device is anchored in place, the segment can be aspirated through the device. This may be achieved by a number of methods, including coupling an aspiration catheter (10) to an inlet port on the obstruction device and aspirating through the port. Or, providing the port with a valve which allows outflow of gas from the isolated lung tissue segment during expiration of the respiratory cycle but prevents inflow of air during inspiration. The obstructive device may remain as an implant, to maintain isolation and optionally allow subsequent aspiration, or the device may be removed at any time.

WO 02/038038 A3

WO 02/038038 A3

(88) **Date of publication of the international search report:**
8 May 2003

(48) **Date of publication of this corrected version:**
12 September 2003

(15) **Information about Correction:**
see PCT Gazette No. 37/2003 of 12 September 2003, Section II

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.

METHODS AND DEVICES FOR OBSTRUCTING AND ASPIRATING LUNG TISSUE SEGMENTS

CROSS-REFERENCES TO RELATED APPLICATIONS

The disclosure of this application is related to copending application no. 09/699,313, filed on the same day, the full disclosure of which is incorporated herein by reference.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates generally to medical methods, systems, and kits. More particularly, the present invention relates to methods and apparatus for effecting lung volume reduction by aspirating isolated segments of lung tissue.

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.

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 reduction is conventionally performed in open chest or thoracoscopic procedures where the lung is resected, typically using stapling devices having integral cutting blades.

While effective in many cases, conventional lung 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. For these reasons, it would be

desirable to provide improved methods, systems, and kits for performing lung volume reduction which overcome at least some of the shortcomings noted above.

2. Description of the Background Art

WO 99/01076 and corresponding U.S. Patent No. 5,957,919 describes devices and methods for reducing the size of lung tissue by applying heat energy to shrink collagen in the tissue. In one embodiment, air may be removed from a bleb in the lung to reduce its size. Air passages to the bleb may then be sealed, e.g., by heating, to fix the size of the bleb. WO 98/48706 describes a plug-like device for placement in a lung air passage to isolate a region of lung tissue, where air is not removed from the tissue prior to plugging. WO 98/49191 describes the use of surfactants in lung lavage for treating respiratory distress syndrome. U.S. Patent No. 5,925,060 may also be of interest.

Patents and applications relating to lung access, diagnosis, and treatment include U.S. Patent Nos. 5,957,949; 5,840,064; 5,830,222; 5,752,921; 5,707,352; 5,682,880; 5,660,175; 5,653,231; 5,645,519; 5,642,730; 5,598,840; 5,499,625; 5,477,851; 5,361,753; 5,331,947; 5,309,903; 5,285,778; 5,146,916; 5,143,062; 5,056,529; 4,976,710; 4,955,375; 4,961,738; 4,958,932; 4,949,716; 4,896,941; 4,862,874; 4,850,371; 4,846,153; 4,819,664; 4,784,133; 4,742,819; 4,716,896; 4,567,882; 4,453,545; 4,468,216; 4,327,721; 4,327,720; 4,041,936; 3,913,568 3,866,599; 3,776,222; 3,677,262; 3,669,098; 3,542,026; 3,498,286; 3,322,126; WO 95/33506, and WO 92/10971.

Lung volume reduction surgery is described in many publications, including Becker et al. (1998) Am. J. Respir. Crit. Care Med. 157:1593-1599; Criner et al. (1998) Am. J. Respir. Crit. Care Med. 157:1578-1585; Kotloff et al. (1998) Chest 113:890-895; and Ojo et al. (1997) Chest 112:1494-1500.

The use of mucolytic agents for clearing lung obstructions is described in Sclafani (1999) AARC Times, January, 69-97. Use of a balloon-cuffed bronchofiberscope to reinflate a lung segment suffering from refractory atelectasis is described in Harada et al. (1983) Chest 84:725-728.

SUMMARY OF THE INVENTION

The present invention provides improved methods, systems, devices and kits for performing lung volume reduction in patients suffering from chronic obstructive pulmonary disease or other conditions where isolation of a lung segment or reduction of lung volume is desired. The present invention is likewise suitable for the treatment of

bronchopleural fistula. The methods are minimally invasive with instruments being introduced through the mouth (endotracheally) and rely on isolating the target lung tissue segment from other regions of the lung. Isolation is achieved by deploying an obstructive device in a lung passageway leading to the target lung tissue segment. Once the obstructive device is anchored in place, the segment can be aspirated through the device. This may be achieved by a number of methods, including coupling an aspiration catheter to an inlet port on the obstruction device and aspirating through the port. Or, providing the port with a valve which allows outflow of gas from the isolated lung tissue segment during expiration of the respiratory cycle but prevents inflow of air during inspiration. In addition, a number of other methods may be used. The obstructive device may remain as an implant, to maintain isolation and optionally allow subsequent aspiration, or the device may be removed at any time. Likewise, the device may biodegrade over a period of time.

The obstruction device may take a variety of forms to allow delivery, deployment and anchoring in a lung passageway. Delivery is commonly performed with the use of a minimally invasive device, such as a flexible bronchoscope or an access catheter. The flexible bronchoscope may be utilized with a sheath having an inflatable cuff disposed near its distal end, a full description of which is provided in co-pending application [Attorney Docket No. 017534-001300], assigned to the assignee of the present invention and incorporated by reference for all purposes. When using such a sheath, the scope is introduced into a lumen in the sheath to form an assembly which is then introduced to the lung passageway. The cuff may then be inflated to occlude the passageway. Similarly, an access catheter may be used which may be steerable or articulating, may include an inflatable balloon cuff near its distal end and may include a number of lumens for balloon inflation, tracking over a guidewire, and optical imaging, to name a few. The obstruction device is typically housed within a lumen of the access catheter, bronchoscope, sheath or suitable device, mounted near the distal tip of the catheter or carried by any method to the desired lung passageway leading to the target lung tissue segment. Therefore, the obstruction device must be sized appropriately for such delivery and is typically designed to expand upon deployment to anchor within the lung passageway. Hereinafter the present invention is depicted in relation to use with an access catheter, however it may be appreciated that any suitable device may be used.

In a first aspect of the present invention, the obstruction device comprises a structural support which expands and thereby anchors the device in the lung passageway. Such supports may comprise a number of configurations for a variety of

expansion techniques. For example, the structural supports may allow the obstruction device to coil, roll, bend, straighten or fold in a cone, rod, cylinder or other shape for delivery. Then, once positioned in a desired location, the obstruction device may be released and expanded to anchor the device in the passageway. Such expansion may be unaided, such as in the release of a compressed structure to a pre-formed expanded position. Or, such expansion may be aided, such as with the use of an inflatable balloon or cuff. In some cases, a balloon or inflatable member may be incorporated into the obstruction device and may remain inflated to occlude the passageway. This may be provided in combination with structural supports or an inflatable balloon or similar device may be used without such support.

The structural supports may be comprised of any type of wire, particularly superelastic, shape-memory or spring tempered wire, or any type of polymer or a suitable material. The balloon or inflatable member may be comprised of any flexible, polymeric material suitable for such a purpose. The member may be inflated with gas or liquid as desired, or it may be inflated with an expanding foam or similar material. Likewise, it may be inflated or injected with an adhesive. Such an adhesive may expand the member and/or rigidify the member to reduce the likelihood of collapse. Further, the adhesive may additionally serve to bond the device to the walls of the lung passageway to increase anchorage. In addition, the device may be impregnated or coated with an antibiotic agent, such as silver nitrate, or similar agent for delivery of the agent to the lung passageway. Such delivery may occur by any applicable means.

When structural supports are present, such supports may comprise a variety of designs. In a first embodiment, the structural supports comprise radial segments which expand to fill the passageway and longitudinal segments which rest against the walls of the passageway to help anchor the device. In a second embodiment, the structural supports comprise a mesh which expands to fill the passageway. In a third embodiment, the structural supports comprise a helically or spirally wound wire which also expands to contact the walls of the passageway and anchor the device. In each of these embodiments, the structural support may be connected with or encapsulated in a sack comprised of a thin polymeric film, open or closed cell foam or other suitable material to provide a seal against walls of the lung passageway and obstruct airflow through the device. The sack material may also be infused with an adhesive, sealant or other material to improve obstruction of the airway and possibly improve adhesion to the airway walls.

In a second aspect of the present invention, the obstruction device may further comprise ports for aspiration through the device. This may allow access to the collapsed lung segment at a later time, for example, in the case of an infection. Typically, the obstruction device will have an inlet port located near the proximal end of the device, away from the isolated lung tissue segment. Such a port is thus accessible by minimally invasive devices, such as an aspiration catheter, which may be advanced through the bronchial passageways. Optionally, an outlet port may be located near the distal end of the obstruction device. The ports may comprise a variety of designs for a number of purposes.

In a first embodiment, the port comprises a self-sealing septum. Such a septum may comprise a solid membrane or a pre-cut membrane. Aspiration through the port may be achieved with the use of an aspiration catheter having an access tube or penetrating element at its distal end. Such a catheter may be advanced to the site of the obstruction device itself or with the use of an access catheter. The septum may be penetrated, either pierced through a solid membrane or passed through the cuts of a pre-cut membrane, by the access tube. Depending on the design of the obstruction device, the inlet port and optionally the outlet port may be penetrated in this fashion. Aspiration may be achieved through the access tube and aspiration catheter to withdraw gases and/or liquids from the isolated lung tissue segment and passageway. Optionally, prior to aspiration, a 100% oxygen, Helium-Oxygen mixture or low molecular weight gas washout of the lung segment may be performed by introducing such gas through the access tube, such as by a high frequency jet ventilation process. In this case, aspiration would remove both the introduced gas and any remaining gas. Similarly, liquid perfluorocarbon or certain drugs, such as antibiotics, retinoic acid and hyaluronic acid, may be introduced prior to aspiration. In most cases, aspiration will at least partially collapse the lung segment. Upon removal of the aspiration catheter from the port, the septum may self-seal or it may be further sealed with a sealant or other sealing means for later access or permanent closure.

When the self-sealing septum comprises a pre-cut membrane, aspiration through the port may alternatively be achieved by coupling an aspiration catheter to the obstructive device. Coupling may comprise engaging the aspiration catheter to the port or sliding a coupling member or the aspiration catheter over the port to form a seal. In either case, suction through the aspiration catheter may allow gases and/or liquids to pass through the cuts in the membrane to be withdrawn from the isolated lung tissue segment

and passageway. Again, this will at least partially collapse the lung segment. Likewise, upon removal of the aspiration catheter from the port, the septum may self-seal or it may be further sealed with a sealant or other sealing means for later access or permanent closure.

In a second embodiment, the port comprises a unidirectional valve. Such a valve may comprise a port covered by a flexible layer which is attached to the port by at least one point of connection. Movement of the layer away from the port opens the valve and movement against the port closes the valve. Wherein the flexible layer is solid, movement of the layer away from the port allows gas to flow between the points of connection and around the edges of the flexible layer. Alternatively, the flexible layer may have holes therethrough. In this case, the port may also comprise a partition having holes which are not aligned with the holes in the flexible layer. Movement of the layer away from the port allows gas to flow through the holes in the partition and out through the holes in the flexible layer. When the layer moves against the partition, the holes will be covered closing the valve. Other valve designs include a spring-loaded ball valve or a biased pre-loaded diaphragm valve.

Aspiration through a unidirectional valve may be achieved by a number of methods. Again, the port may be accessed by advancing an aspiration catheter or similar device through the bronchial passageways to the site of the obstruction device. This may optionally be achieved with the use of an access catheter. The aspiration catheter may be placed near the valve or engaged to the valve, wherein suction or vacuum applied through the catheter opens the valve. If the aspiration catheter is not engaged to the valve, adequate suction to open the valve may be achieved by occluding the passageway proximal to the point of suction which is typically the distal end of the aspiration catheter. Such occlusion may be achieved by inflating a balloon or occlusion device mounted on the distal end of the aspiration catheter or mounted on an access catheter. In either case, the vacuum may draw the flexible layer away from the port, allowing gases and/or liquids to flow out from the isolated lung segment, through the valve and into the aspiration catheter. Alternatively, aspiration through a unidirectional valve may be achieved naturally during respiration. Pressure changes may open the valve during expiration as gases flow out from the isolated lung segment. Reverse pressure changes, during inspiration, may close the valve preventing gases from flowing into the isolated segment. This may reduce the amount of gas trapped in the terminal segment over time and thus at least partially collapse the lung segment. Similarly, aspiration through the unidirectional

valve may be achieved by external mechanical pressure on the lung to force out of the lung segment and through the valve. Again, reverse pressure changes upon recoil of the lung would close the valve preventing gases from flowing into the isolated segment.

In a third aspect of the present invention, the obstruction device may comprise a blockage device which is deployed in a lung passageway to close the airway. Such a blockage device may be of similar design as previously described obstruction devices as it may be similarly delivered, deployed and anchored within a lung passageway. Thus, embodiments of the blockage device typically comprise expandable support structures. For example, in one embodiment the support structure comprises a coil. And, in a second embodiment, the support structure comprises a mesh. Again, the support structures may be connected to or encased in a polymer film or sack to provide a seal against the walls of the lung passageway and obstruct airflow through the device. Typically the blockage device will be placed in the passageway after the terminal lung segment has been aspirated by other methods. This will seal off the lung segment and maintain lung volume reduction. Alternatively, the blockage device may be placed in the passageway before the terminal lung segment has been aspirated. In this case, air trapped in the lung segment may be absorbed over time and would eventually collapse, a process known as absorption atelectasis. This process may be enhanced by insufflating the lung segment with 100% oxygen, a Helium-Oxygen mixture or low molecular weight gas prior to placing the blockage device. Such enhancement may promote complete collapse of the lung segment. In any case, the blockage device may optionally be later removed if it is so desired.

Methods of the present invention include the utilization of an obstruction device to achieve lung volume reduction. As described above, methods include delivery, deployment and anchoring of an obstruction device in a lung passageway leading to a target lung tissue segment. At least partial collapse of the terminal lung tissue segment may be achieved by aspirating the segment through the obstruction device deployed in the passageway. Aspiration may be accomplished with the use of an aspiration catheter or similar device through a port on the obstruction device. Also described above, when the port comprises a unidirectional valve, aspiration and eventual lung volume reduction may be accomplished by the opening and closing of the valve in response the respiratory cycle. In addition, methods of the present invention include deployment of a blockage device in a lung passageway leading to a terminal lung tissue segment, as previously described.

Systems of the present invention may include any of the components described in relation to the present invention. A particular embodiment of a system of the present invention comprises an access catheter and an obstruction device, as described above, wherein the obstruction device is introduceable by the access catheter. For example, the obstruction device may be houseable within a lumen of the access catheter for deployment out the distal end of the catheter, or the obstruction device may be mountable on the access catheter near its distal end. In either case, the obstruction device may be deployed and anchored within a lung passageway.

The methods and apparatuses of the present invention may be provided in one or more kits for such use. The kits may comprise an obstruction device deployable within a lung passageway and instructions for use. Optionally, such kits may further include any of the other system components described in relation to the present invention and any other materials or items relevant to the present invention.

Other objects and advantages of the present invention will become apparent from the detailed description to follow, together with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a perspective illustration of an access catheter useful in the methods, systems, and kits of the present invention.

Fig. 2 is a cross-sectional view taken along line 2 to a Fig. 1.

Figs. 3A-3F illustrate alternative cross-sectional views of the access catheter of Fig. 1.

Figs. 4A-4C illustrate a steerable imaging guidewire which may be used to facilitate positioning of the access catheter used in the methods of the present invention.

Fig. 5A illustrates use of the access catheter of Fig. 1 for accessing a target lung tissue segment according the to the methods of the present invention.

Fig. 5B illustrates use of a visualizing tracheal tube with the access catheter of Fig. 1 for accessing a target tissue segment according the to the methods of the present invention.

Fig. 6 illustrates a method of deployment or delivery of an obstructive device.

Figs. 7A-7B are perspective views of embodiments of obstructive devices having, among other features, radial and longitudinal structural supports.

Fig. 8 is a perspective view of an embodiment of an obstructive device in a rolled configuration prior to release in a lung passageway.

Fig. 9 is a perspective view of an embodiment of a rolled, cylindrical shaped obstructive device in an expanded state within a flexible sack.

Fig. 10 illustrates an embodiment of a double conical shaped obstructive device.

Fig. 11 is a perspective view of an embodiment of an obstructive device having, among other features, a mesh structural support encased by a polymer film.

Fig. 12 is a perspective view of an embodiment of an obstructive device having, among other features, a spiral structural support.

Fig. 13 is a perspective view of an embodiment of an obstructive device having a cone shape with an inlet port at the apex of the cone.

Figs. 14A-14C illustrate embodiments of self-sealing septums of the present invention.

Fig. 15 illustrates a method of aspirating through an obstructive device by inserting an access tube through a septum of an inlet port.

Fig. 16 illustrates a method of aspirating through an obstructive device by contacting an aspiration catheter to an inlet port.

Fig. 17 illustrates a method of aspirating through an obstructive device by sliding the distal end of an aspiration catheter over an inlet port.

Figs. 18A-18C illustrate a method of deploying, anchoring and aspirating through an obstruction device while such a device is connected to an aspiration catheter.

Fig. 19A is a front view of an embodiment of a unidirectional valve of the present invention. Figs. 19B-19C are perspective views of the unidirectional valve of Fig. 19A in various stages of operation.

Figs. 20-21 illustrate positioning of embodiments of unidirectional valves of the present invention in a lung passageway.

Figs. 22A-22B are front views of an embodiment of a unidirectional valve of the present invention.

Figs. 23A-23B are perspective views of the unidirectional valve of Figs. 21A-21B in various stages of operation.

Fig. 24 illustrates a method of deployment or delivery of a blockage device.

Fig. 25 illustrates an embodiment of a blockage device comprising a coil encased in a polymer film.

Fig. 26 illustrates an embodiment of a blockage device comprising a mesh connected to a polymer film.

Fig. 27 illustrates an embodiment of a blockage device comprising a barb-shaped structure.

Fig. 28 illustrates an embodiment of a blockage device having a cylindrical-type balloon with textured friction bands.

Fig. 29 depicts an embodiment of a blockage device comprising a multi-layer balloon which has an adhesive material between an outer layer and an inner layer of the balloon.

Fig. 30 illustrates an embodiment of a blockage device which is similar to that of Fig. 29, including openings in the outer layer through which adhesive may seep.

Fig. 31 illustrates a kit constructed in accordance with the principles of the present invention.

DESCRIPTION OF THE SPECIFIC EMBODIMENTS

Lung volume reduction is performed by collapsing a target lung tissue segment, usually within lobar or sub-lobular regions of the lung which receive air through a single lung passage, i.e., segment of the branching bronchus which deliver to and receive air from the alveolar regions of the lung. Such isolated lung tissue segments are first isolated and then collapsed by aspiration of the air (or other gases or liquids which may be present) from the target lung tissue segment. Lung tissue has a very high percentage of void volume, so removal of internal gases can reduce the lung tissue to a small percentage of the volume which it has when fully inflated, i.e. inflated at normal inspiratory pressures. The exemplary and preferred percentages for the volume reduction are set forth above.

The methods of the present invention will generally rely on accessing the target lung tissue segment using an access catheter adapted to be introduced endotracheally into the bronchus of the lung. An exemplary access catheter 10 is illustrated in Figs. 1 and 2 and comprises a catheter body 12 having a distal end 14, a proximal end 16, and at least one lumen therethrough. Optionally, the catheter 10 further comprises an inflatable occlusion balloon 18 near its distal end. In this case, the catheter will have at least two lumens, a central lumen 20 and a balloon inflation lumen 22. As

shown in Fig. 2, the balloon inflation lumen 22 may be an annular lumen defined by inner body member 24 and outer body member 26 which is coaxially disposed about the inner body member. The lumen 22 opens to port 30 on a proximal hub 32 and provides for inflation of balloon 18. The central lumen 20 opens to port 36 on hub 32 and provides for multiple functions, including optional introduction over a guidewire, aspiration, introduction of secondary catheters, and the like.

The dimensions and materials of access catheter 10 are selected to permit endotracheal introduction and intraluminal advancement through the lung bronchus or passageway, optionally over a guidewire and/or through a primary tracheal tube structure (as illustrated in Fig. 4B below). Suitable materials include low and high density polyethylenes, polyamides, nylons, PTFE, PEEK, and the like, particularly for the inner tubular member 24. The outer member, including the occlusion balloon, can be made from elastomeric materials, such as polyurethane, low density polyethylene, polyvinylchloride, silicone rubber, latex, and the like. Optionally, portions of the outer tubular member 26 proximal to the inflatable balloon can be made thicker and/or reinforced so that they do not dilate upon pressurization of the balloon. Exemplary dimensions for the access catheter 10 are set forth in the table below.

ACCESS CATHETER DIMENSIONS

	Exemplary		Preferred	
	Inner Tubular Member	**Outer Tubular Member**	**Inner Tubular Member**	**Outer Tubular Member**
Outer Diameter (mm)	0.4-4	0.6-4.5	1-1.5	2-4
Wall Thickness (mm)	0.05-0.25	0.5-0.25	**0.1-0.2**	**0.15-0.25**
Length (cm)	50-150	same	50-80	same
Balloon Length (mm)	5-50		10-20	
Balloon Diameter (mm) (inflated)	2-20		6-15	

The access catheter 10 may be modified in a number of ways, some of which are illustrated in Figs. 3A-3F. For example, instead of an inner and outer coaxial tube construction, the catheter can be a single extrusion having a catheter body 30 with a circular main lumen 32 and a crescent-shaped inflation lumen 34, as illustrated in Fig. 3A. Alternatively, catheter body 40 may be formed as a single extrusion having

three lumens, i.e., a primary lumen 42 for receiving a guidewire, applying aspiration, and/or delivering secondary catheters. A second lumen 44 can be provided for inflating the occlusion balloon, and a third lumen 46 can be provided as an alternative guidewire or aspiration lumen. Catheter body 50 comprising a main tubular body 52 having an outer layer 54 fused thereover to define a lumen 56 suitable for balloon inflation as shown in Fig. 3C. A primary lumen 58 is formed within the main tubular member 52. As a slight alternative, catheter body 60 can be formed from a primary tubular member 62, and a secondary tubular member 64, where the tubular members are held together by an outer member 66, such as a layer which is applied by heat shrinking. The primary tubular member 62 provides the main lumen 68 while secondary tube 64 provides a secondary lumen 70. The secondary lumen 70 will typically be used for balloon inflation, while the primary lumen 68 can be used for all other functions of the access catheter.

Optionally, the access catheter in the present invention can be provided with optical imaging capability. As shown in Fig. 3E, catheter body 80 can be formed to include four lumens, typically by conventional extrusion processes. Lumen 82 is suitable for passage over a guidewire. Lumens 84 and 86 both contain light fibers 88 for illumination. Lumen 90 carries an optical wave guide or image fiber 92. Lumen 82 can be used for irrigation and aspiration, typically after the guidewire is withdrawn. Balloon inflation can be effected through the space remaining and lumens 84 and 86 surrounding the light fibers 88. A second catheter body 100 is formed as a coaxial arrangement of a number separate tubes. Outer tube 102 contains a separate guidewire tube 104 defining lumen 106 which permits introduction over a guidewire as well as perfusion and aspiration after the guidewire is removed. Second inner tubular member 110 will carry an optical image fiber 112 and a plurality of light fibers 112 are passed within the remaining space 114 within the outer tubular member. In both catheter constructions 80 and 100, forward imaging can be effected by illuminating through the light fibers and detecting an image through a lens at the distal end of the catheter. The image can be displayed on conventional cathode-ray or other types of imaging screens. In particular, as described below, forward imaging permits a user to selectively place the guidewire for advancing the catheters through a desired route through the branching bronchus.

Usually, positioning of a guidewire through the branching bronchus will be manipulated while viewing through the imaging components of the access catheter. In this way, the access catheter can be "inched" along by alternately advancing the guidewire and the access catheter. As an alternative to providing the access catheter with

imaging, positioning could be done solely by fluoroscopy. As a further alternative, a steerable, imaging guidewire 300 (Figs. 4A-4C) could be used. The guidewire 300 includes a deflectable tip 302 which can be deflected in a single plane using push/pull ribbon 304. Usually, the tip will comprise a spring 306 to facilitate deflection. In addition to steerability, the guidewire 300 will include an optical imaging wave guide 310 and illuminating optical fibers 312, as best seen in cross-sectional view of Fig. 4C. Thus, the guidewire 300 can be steered through the branching bronchus to reach the target tissue segment using its own *in situ* imaging capability. Once the guidewire 300 is in place, an access catheter can be introduced to the target lung tissue segment as well. Since the guidewire has imaging capability, the access catheter need not incorporate such imaging. This can be an advantage since it permits the access lumen to be made larger since the catheter need not carry any optical wave guides.

Referring now to Fig. 5A, a catheter 10 can be advanced to a lung tissue segment, specifically a diseased region DR, within a lung L through a patient's trachea T. Advancement through the trachea T is relatively simple and will optionally employ an endotracheal tube and/or a guidewire to select the advancement route through the branching bronchus. The endotracheal tube may have a thin-walled design wherein the inner diameter is larger than in standard endotracheal tubes. Standard endotracheal tubes have a 7.0 mm ID with a 10 mm OD. The thin-walled design would have a 9.0 mm ID with a 10 mm OD; the larger ID allows the insertion of a larger instrument while providing adequate ventilation. Steering can be effected under real time imaging using the imaging access catheters illustrated in Figs. 3E and 3F. Optionally, the access catheter 10 may be introduced through a visualizing tracheal tube, such as that described in U.S. Patent No. 5,285,778, licensed to the assignee of the present application. As shown in Fig. 5B, the visualizing endotracheal tube 120 includes an occlusion cuff 122 which may be inflated within the trachea just above the branch of the left bronchus and right bronchus LB and RB, respectively. The visualizing endotracheal tube 120 includes a forward-viewing optical system, typically including both illumination fibers and an image fiber to permit direct viewing of the main branch between the left bronchus LB and right bronchus RB. Thus, initial placement of the access catheter 10 can be made under visualization of the visualizing endotracheal tube 120 and optionally the access catheter 10 itself. It may be appreciated that the access catheter may be positioned with or without the use of a trachea tube or similar device. When such a device is used, it may take a number of forms and may be positioned in a number of locations. For example, the

trachea tube or device may be positioned as shown in Fig. 5A, or it may be positioned to achieve "one lung ventilation" wherein the side of the lung not involved in the corrective procedure will be properly ventilated. Likewise, the access catheter may be positioned under local anesthesia without intubation. In any case, referring again in particular to Fig. 5A, the access catheter 10 is advanced until its distal end 14 reaches a region in the bronchus or lung passageway which leads directly into the diseased region DR.

Once the distal end 14 of the access catheter 10 is positioned in a desired location within the lung passageway, an obstructive device may be deployed in the passageway. The method of deployment or delivery of the obstructive device is dependent on a number of factors, particularly the design of the obstructive device itself. Typically, the obstructive device is housed within the access catheter 10 or within a catheter that may be passed through the access catheter 10. As depicted in Fig. 6, the obstructive device 150 may be compressed or collapsed within an interior lumen of the access catheter 10. The obstructive device 150 depicted is one of many designs which may be utilized. The obstructive device 150 may then be pushed out of the distal end 14 of the catheter 10, in the direction of the arrow, into the lung passageway 152. If the device 150 is self-expanding, for example by tension or shape-memory, the device 150 will expand and anchor itself in the passageway 152. If the device 150 is not self-expanding, it may be expanded with the use of a balloon or other mechanism provided by the access catheter 10, a catheter or device delivered through the access catheter 10, or another device. Similarly, the obstructive device 150 may be mounted or crimped over the access catheter 10 (not shown) or a delivery catheter and delivered to the desired location. A sheath may then be placed over the device 150 during insertion. Deployment of the device 150 may be achieved by withdrawing the sheath and allowing the device 150 to self-expand or expanding the device 150 with the use of a balloon or other mechanism.

A variety of embodiments of obstructive devices 150 are provided. To begin, a number of embodiments of the obstructive device 150 are comprised of structural supports which expand to anchor the device 150 in the passageway 152. Referring to Fig. 7A, the supports 154 may be comprised of radial segments 160 and longitudinal segments 162. The radial segments 160 allow the device 150 to expand to fill the passageway 152 and the longitudinal segments 162 rest against the walls of the passageway 152 to help anchor the device 150. The supports 154 may be individual, as shown in Fig. 7A, or may be connected to one another, as shown in Fig. 7B, for example.

In addition, the supports 154 may continue along a proximal end 164 and distal end 166 of the device 150, as shown in Fig. 7A, or the supports 154 may not be present at such ends 164, 166, as shown in Fig. 7B.

Referring to Figs. 8-11, the supports 154 may be comprised of a mesh 170 or similar interlocking structure. As shown in Fig. 8, the mesh 170 may be coiled or rolled into a cylindrical shape to fit within an inner lumen of a delivery or access catheter or to be mounted on the end of a such a delivery or access catheter. In either case, the device 150 may be released within the lung passageway 152 where the mesh 170 expands, uncoils and/or unrolls to fill the passageway 152. Such release may allow self-expansion or may involve the use of mechanical means to expand the mesh 170. The expanded device 150 may fill the passageway 152 in a generally cylindrical shape, as shown in Fig. 9, in single or double conical shape, as shown in Fig. 10, or it may form a variety of other shapes, an example of which is shown in Fig. 11.

Referring now to Fig. 12, the supports 154 may be a helix or spiral 171 comprised of helically wound or spiral wound wire. The spiral 171 may be compressed in a number of ways to load the spiral 171 within a lumen or on a distal end of a delivery catheter. For example, the spiral 171 may be wound tightly, similar to a watch spring, to reduce the cross-section of the spiral and provide spring tension. Upon release of the spiral 171, the coils 173 expand to contact the walls of the passageway 152 and anchor the device 150.

In any of the above embodiments, the supports 154 may be connected to, encapsulated in, coated or impregnated with a material to prevent flow of gases or liquids through the structural supports 154, thereby providing an obstruction. In addition, the material may include an antibiotic agent for release into the lung passageway. Examples of obstructive materials include a thin polymer film 156, such as webbing between the structural supports 154, which may be used to seal against the surface of the lung passageway 152. Such a design is depicted in Figs. 7A-7B, 10 and 12. Similarly, the structural supports 154 may be filled with an adhesive or sealant which will adhere the structural support members together and prevent flow or gasses or liquids through the device 150. This is particularly useful in coiled or mesh designs in where the structural support members are relatively close together. Alternatively, as shown in Fig. 9 and Fig. 11, the supports 154 may be encased in a sack 158 comprised of a thin polymer, foam or other material. Expansion of the supports 154 within the sack 158 presses the sack 158 against the walls of the passageway 152 forming a seal. In Fig. 9, the sack 158 has been

extended beyond the ends of the rolled support structure 154 for illustration purposes to differentiate between the sack 158 and support structure 154. However, typically, the support structure 154 will fill the sack 158. Again, the presence of the sack 158 prevents flow of gases or liquids through the supports 154, thereby providing an obstruction. It may be appreciated that the structural supports may comprise a variety of designs, creating devices 150 of various lengths and shapes. Alternatively, the sack 158 may be utilized without structural supports 154. The sack may expand to fill the passageway by a variety of methods and may be held in position by impregnation with an adhesive or other material. Such impregnation may rigidify or support the sack to provide obstruction of the lung passageway.

In addition and also shown in Figs. 7A, 7B, 9, 11-13, a number of embodiments of the obstructive device 150 include an inlet port 172, located near the proximal end 164, and an outlet port 174, located near the distal end 166. Such ports 172, 174 may be of any size or shape but are typically round or oval and are often located near the center of the passageway 512 lumen for ease of accessibility. Some devices 150 may only include an inlet port 172 near the proximal end 164, as shown in Fig. 13. In this case, the distal end 166 is expanded to contact the walls of the lung passageway 152 and anchor the device 150. Thus, the obstruction device 150 appears to have a cone shape with the inlet port 172 at the apex of the cone. To ensure concentric placement of the obstruction device 150, the device 150 should contact the walls of the passageway 152 for a length of at least 1.0 to 1.5 times the internal diameter of the passageway that the device 150 occupies.

The inlet port 172, outlet port 174 or both may comprise a membrane or septum 176 covering the opening of the port. The septum 176 will typically be self-sealing. One type of self-sealing septum 176 comprises a solid membrane 178, illustrated in Fig. 14A. Other types comprise pre-cut membranes in which the septum 176 includes cuts 180 or slits, as shown in Figs. 14B and 14C. Such cuts 180 may allow ease of penetration through the septum 176 by an access tube or penetrating element, as will be later described, while preventing flow through the septum when the penetrating element is removed.

After the obstruction device 150 is deployed and anchored within a lung passageway 152 leading to a lung tissue segment, the device 150 may be left as an implant to obstruct the passageway 152 from subsequent airflow. Airflow may include air and/or any other gas or combination of gases, such as carbon dioxide. However,

immediately after placement or at any time thereafter, the above described embodiments of the device 150 may be accessed to aspirate the lung tissue segment through the obstructive device 150. This will cause the segment to at least partially collapse as part of a method for lung volume reduction. Aspirating through the obstructive device 150 may be accomplished by a variety of methods. For example, referring to Fig. 15, aspiration may be achieved by first inserting a penetration element, needle or access tube 200 through the septum 176 of the inlet port 172. Positioning of the access tube 200 for such insertion may be achieved by any method, however, the access tube 200 is typically positioned by inserting the access tube 200, or a catheter carrying the access tube 200, through a lumen in the access catheter 10 until it passes out of the distal end 14. Inflating the balloon 18 on the access catheter 10 may center the distal end 14 of the catheter in the lung passageway 152. If the inlet port 172 is similarly centered, the access tube 200 may be passed directly out of the catheter 10 and through the septum 176 of the inlet port 172.

If the septum 176 is a solid membrane 178, the access tube 200 may be sharp enough to puncture or pierce the membrane 178. If the septum 176 has cuts 180 or slits, the access tube 200 may be pushed through the cuts 180. In either case, the membrane or septum 176 will seal around the access tube 200. If the obstruction device 150 also has an outlet port 174, the access tube 200 may optionally be passed through both the inlet and outlet ports 172, 174. Once the access tube 200 is inserted, gases and/or liquids may be aspirated through the access tube 200 from the lung tissue segment and associated lung passageways. Optionally, prior to aspiration, a 100% oxygen, Helium-Oxygen mixture or low molecular weight gas washout of the lung segment may be performed by introducing such gas through the access tube 200. In this case, aspiration would removed both the introduced gas and any remaining gas. Similarly, liquid perfluorocarbon or certain drugs, such as antibiotics, may be introduced prior to aspiration. This may allow access to the collapsed lung segment at a later time, for example, in the case of an infection. In most cases, aspiration will at least partially collapse the lung segment, as previously described. The access tube 200 may then be withdrawn. The septum 176 of the inlet port 172 and/or outlet port 174 will then automatically seal, either by closing of the puncture site or by closure of the cuts. Optionally, the ports may be additionally sealed with a sealant or by use of a heat source or radiofrequency source.

Referring to Figs. 16 and 17, aspiration through the obstructive device 150 may be achieved by contacting the obstructive device 150 with a suction tube or

aspiration catheter 202 and aspirating gas or liquids through the device 150. As shown in Fig. 16, the distal end 204 of the aspiration catheter 202 may be held against the inlet port 172. Positioning of the aspiration catheter 202 for such contact may be achieved by any method, however the catheter 202 is typically positioned in a manner similar to the access tube described above. By holding the aspiration catheter 202 against the port 172, a seal may be created and gases and/or liquids may be aspirated from the lung tissue segment through the device 150. In this case, the inlet port 172 and the outlet port 174, if present, must not be covered by a solid membrane 178. If cuts 180 are present, the gas or liquid may flow through the port due to the pressure of the suction. As shown in Fig. 17, the distal end 204 of the aspiration catheter 202 may be slid over the inlet port 172 to form a seal. Again, gases and/or liquids may then be aspirated through the device 150 in a similar manner. The aspiration catheter 202 may then be withdrawn. The septum 176 of the inlet port 172 and/or outlet port 174 will then automatically seal, typically by closure of the cuts. Optionally, the ports may be additionally sealed with a sealant or by use of a heat source or radiofrequency source.

Referring to Figs. 18A-18C, the obstruction device 150 may be deployed, anchored and aspirated therethrough while connected to an aspiration catheter 210. In this case, the access catheter 10 is positioned within the lung passageway 152 at a desired location. If the catheter 10 has an inflatable occlusion balloon 18 near its distal end 14, the balloon 18 may be inflated to secure and center the catheter 10 within the passageway 152; however, this step is optional. As shown in Fig. 18A, an aspiration catheter 210 carrying an obstruction device 150 is then introduced through a lumen in the access catheter 10. As shown in Fig. 18B, the aspiration catheter 210 is advanced so that the obstruction device 150 emerges from the distal end 14 of the access catheter 10 and deploys within the lung passageway 152. Expansion and anchoring of the obstruction device 150 within the passageway 152 may be achieved by self-expansion or by expansion with the aid of a balloon, for example. The lung tissue segment isolated by the device 150 is then aspirated through the device 150 and the attached aspiration catheter 210. Such aspiration may remove air, gases, or liquids from the segment and lung passageway 152 to at least partially collapse the lung segment. As shown in Fig. 15C, the obstruction device 150 is then detached from the aspiration catheter 210 and left behind in the passageway 152. The proximal end 164 of the obstruction device 150 may comprise an inlet port 172 which would allow subsequent access to the isolated lung tissue segment at a later time. Alternatively, the proximal end 164 may comprise a sealed

end, wherein the obstruction device 150 may not be subsequently accessed and may provide long-term isolation of the terminal lung tissue segment.

It may be appreciated that the above described method may be similarly achieved without the use of an aspiration catheter 210. In this case, the obstruction device 150 may be carried directly by the access catheter 10 and may be deployed while remaining attached to the access catheter 10. Aspiration may be achieved through the obstruction device 150 and the access catheter 10 to remove gases from the isolated lung tissue segment and passageway 152. The obstructive device 150 may then be detached from the access catheter 10 and left behind in the passageway 152 for subsequent access or simple occlusion.

At this point, all catheters and instruments may be withdrawn from the patient and the obstruction device 150 may remain in its anchored position, as described. The obstruction device 150 will essentially occlude the lung passageway 152 and prevent the inflow or outflow of air or gases to the isolated lung tissue segment or diseased region DR. This may be effective in maintaining the desired level of collapse of the lung tissue segment to achieve lung volume reduction. However, at any point, the lung tissue segment may be reaccessed and/or reaspirated by repeating the steps described above. In addition, at any point, the obstruction device 150 may be removed from the lung passageway 152, either by collapse of the expandable structure or by other means.

Additional embodiments of the obstructive device 150 are comprised of a unidirectional valve. The valve may be operated upon access or it may operate in response to respiration. For example, when the valve is positioned in the lung passageway, the valve may be accessed by engaging an aspiration catheter or a coupling member to the valve. Aspiration through the aspiration catheter or coupling member then opens the valve to remove gases and/or liquids from the isolated lung segment. Alternatively, the valve may open automatically in response to respiration. The valve may open during expiration to allow outflow of gas from the lung segment and the close during inspiration to prevent inflow of gas to the lung segment. In either case, the unidirectional valves may take a number of forms.

One embodiment of such a unidirectional valve is illustrated in Figs. 19A-19C. In this embodiment, the unidirectional valve 230, front-view shown in Fig. 19A, is comprised of a port 232 and a flexible layer 233 which is attached to the port 232 by at least one point of connection 234. As shown, the flexible layer 233 may be attached to the front surface of the port 232 at four symmetrical points of connection 234. In

preferred embodiments, edges 236 of the layer 233 are positioned outside of the opening of the port 232 (indicated by dashed lines). This provides a desired seal when the valve is in the closed position.

Side-views shown in Figs. 19B and 19C depict the valve 230 during different stages of the respiratory cycle. During expiration, the valve 230 opens, as depicted in Fig. 19B. Here, expiration of gases is illustrated by arrows. Gases exiting through the lung passageway, within which the valve 230 is positioned, apply force to the backside of the flexible layer 233 causing the layer 233 to expand outwardly away from the surface of the port 232 as shown. This allows the gases to flow through the spaces between the points of connection 234. During inspiration, the valve 230 closes, as depicted in Fig. 19C. Here, inspiration of air is illustrated by an arrow. Air entering the lung passageway applies force to the front side of the flexible layer 233 causing the layer 233 to seal against the surface of the port 232 as shown. This prevents gases from flowing through the valve 230.

Unidirectional valves 230 may be positioned in the lung passageway 152 by methods similar to those previously described for other types of obstruction devices 150. As shown in Fig. 20, the valve 230 may be positioned in the passageway 152 so that the outside perimeter of the port 232 contacts the walls of the passageway 152. In this way, the valve 230 is essentially the size of the passageway lumen and provides the maximum area for potential flow-through of gas. The valve 230 is depicted in its open state, with gas flow traveling from an isolated lung tissue segment, through the valve and out of the patient's airways. As shown in Fig. 21, the valve 230 may alternatively be attached to or part of structural supports 154 which expand radially to anchor the device 150 in the passageway 152. Such supports 154 are similar to those previously described. Again, the valve 230 is depicted in its open state. It may be appreciated that the valve 230 may be of any size or shape and may substituted for any of the inlet and/or outlet ports previously described.

Another embodiment of a unidirectional valve is illustrated in Figs. 22A-22B. In this embodiment, the valve 230 is comprised of a port 232 and a flexible layer 233 as in the previous embodiment. However, here the flexible layer 233 has a series of holes 250 through the layer. In addition, the valve 230 is comprised of a partition 252 which also has holes 250. The holes 250 may be of any size, shape or arrangement throughout the entire or a portion of the layer 233 and partition 252. The partition 252 covers the port 232 and the layer 233 is positioned over the partition 252, as

illustrated in Fig. 22A and depicted by arrows, so that the holes 250 are substantially misaligned and therefore blocked. The assembled valve, illustrated in Fig. 22B, does not have any through holes 250 in the closed position. The holes 250 in the layer 233 are blocked by the underlying partition 252. Likewise, the holes 250 in the partition 252 are blocked by the overlying layer 233. The layer 233 is attached to the partition 252 and/or port 232 along its perimeter; it may be a continuous attachment or may have discrete points of connection with spaces therebetween.

Side-views shown in Figs. 23B and 23C depict the valve 230 during different stages of the respiratory cycle. During expiration, the valve 230 opens, as depicted in Fig. 23B. Here, expiration of gases is illustrated by arrows. Gases exiting through the lung passageway, within which the valve 230 is positioned, pass through the holes 250 in the partition 252 and apply force to the backside of the flexible layer 233. This causes the layer 233 to expand outwardly away from the partition 252 as shown. This allows the gases to flow through the holes 250 in the layer 233. During inspiration, the valve 230 closes, as depicted in Fig. 23C. Here, inspiration of air is illustrated by an arrow. Air entering the lung passageway applies force to the front side of the flexible layer 233 causing the layer 233 to seal against the surface of the partition 252 as shown. This prevents gases from flowing through the valve 230. This embodiment of a unidirectional valve 230 may be positioned in a lung passageway 152 by methods similar to those previously described for other types of obstruction devices 150, particularly as shown in Figs. 20 and 21.

Although the unidirectional valves described above are shown as operating during different stages of the respiratory cycle, the valves may additionally or alternatively be operated manually. Valves positioned in a lung passageway, as depicted in Figs 20-21, may be accessed by coupling an aspiration catheter to the valve. Coupling may comprise engaging the aspiration catheter, a suitable catheter or a coupling member to the valve. In some cases, particularly when the valve 230 comprises a port 232 which is smaller in diameter than the lumen of the lung passageway, as depicted in Fig. 21, the distal end of the aspiration catheter or coupling member may be slid over the port to form a seal. This was previously depicted in Fig. 17 in relation to sealing of the aspiration catheter 202 around an inlet port 172 of a non-valved obstruction device. When a valve is present in this case, aspiration through the aspiration catheter will open the valve and draw gases and/or liquids from the lung tissue segment. With the described unidirectional

valves 230, the suction force of the aspiration will draw the flexible layer 233 away from the port 232 or the partition 252 to open the valve.

Further embodiments of the obstructive device 150 are comprised of a blockage device 280 having no ports through which aspiration of the isolated lung tissue segment may be achieved. After the blockage device 280 is deployed and anchored within a lung passageway 152 leading to a lung tissue segment, the device 280 is to be left as an implant to obstruct the passageway 152 from subsequent airflow. Although the previously described embodiments of obstructive devices 150 having inlet and/or outlet ports 172, 174 may be utilized in a similar manner, the blockage device 280 may not be later accessed to aspirate the lung tissue segment through the device. An example of such a blockage device 280 is illustrated in Figs. 24 and 25.

As with the previous obstructive devices, the blockage device 280 may be housed within the access catheter 10 or within a catheter that may be passed through the access catheter 10. As depicted in Fig. 24, the obstructive device 150 may be compressed or collapsed within an interior lumen of the access catheter 10. The blockage device 280 depicted is one of many designs which may be utilized. The blockage device 280 may then be pushed out of the distal end 14 of the catheter 10, in the direction of the arrow, into the lung passageway 152. The device 280 is to be self-expanding by tension or shape-memory so that it will expand and anchor itself in the passageway 152.

Referring to Fig. 25, one embodiment of the blockage device 280 comprises a coil 282. The coil 282 may be comprised of any type of wire, particularly superelastic or shape-memory wire, polymer or suitable material. The tension in the coil 282 allows the device 280 to expand to fill the passageway 152 and rest against the walls of the passageway 152 to anchor the device 280. In addition, the coil 282 may be connected to a thin polymer film 284, such as webbing between the coils, to seal against the surface of the lung passageway 152. Such a film 284 prevents flow of gases or liquids through the coils, thereby providing an obstruction. Alternatively, as depicted in Fig. 25, the coil 282 may be encased in a sack 286. Expansion of the coil 282 within the sack 286 presses the sack 286 against the walls of the passageway 152 forming a seal. Again, this prevents flow of gases or liquids, depicted by arrows, through the coil 282, thereby providing an obstruction. Similarly, as depicted in Fig. 26, another embodiment of the blockage device 280 comprises a mesh 283. The mesh 283 may be comprised of any type of wire, particularly superelastic or shape-memory wire, polymer or suitable material. The tension in the mesh 283 allows the device 280 to expand to fill the passageway 152

and rest against the walls of the passageway 152 to anchor the device 280. In addition, the mesh 283 may be connected to a thin polymer film 284, such as webbing between the lattice of the mesh, to seal against the surface of the lung passageway 152. Such a film 284 prevents flow of gases or liquids through the mesh, thereby providing an obstruction.

Referring now to Fig. 27, another embodiment of the blockage device 280 comprises a barb-shaped structure 304 designed to be wedged into a lung passageway 152 as shown. Such a structure 304 may be comprised of a solid material, an inflatable balloon material, or any material suitable to provide a blockage function. The structure 304 may be inflated before, during or after wedging to provide sufficient anchoring in the lung passageway. Similarly, the structure 304 may be impregnated or infused with an adhesive or sealant before, during or after wedging to also improve anchoring or resistance to flow of liquids or gasses through the passageway 152.

Referring to Fig. 28, another embodiment of the blockage device 280 comprises an inflated balloon. Such a balloon may take a number of forms. For example, the balloon may have take a variety of shapes, such as round, cylindrical, conical, dogboned, or multi-sectional, to name a few. Or, a series of distinct or interconnected balloons may be utilized. Further, the surface of the balloon may be enhanced by, for example, corrugation or texturing to improve anchoring of the balloon within the lung passageway. Fig 28 illustrates a cylindrical-type balloon 300 with textured friction bands 302 which contact the walls of the lung passageway 152 when the balloon 300 is inflated as shown.

It may be appreciated that such balloons may be inflated with an number of materials, including saline, gas, suitable liquids, expanding foam, and adhesive, to name a few. Further, a multi-layer balloon 310 may be utilized, as shown in Fig. 29, which allows the injection of adhesive 312 or suitable material between an outer layer 314 and an inner layer 316 of the balloon 310. Such adhesive 312 may provide a hardened shell on the obstruction device 280 to improve its obstruction abilities. As shown, the balloon 310 may be inflated within the inner layer 316 with a foam 318 or other material. Similarly, as shown in Fig. 30, the outer layer 314 of the blockage device 280 may contain holes, pores, slits or openings 320 which allow the adhesive 312 to emerge through the outer layer 314 to the outside surface of the multi-layer balloon 310. When the balloon 310 is inflated within a lung passageway 152, the outer layer 314 of the balloon 310 will press against the walls of the passageway 152 and the adhesive 312 will

bond with the walls in which it contacts. Such adhesion is designed to improve anchorage and obstructive abilities of the blockage device 280.

It may also be appreciated that the above described blockage devices may be impregnated, coated or otherwise deliver an antibiotic agent, such as silver nitrate. Such incorporation may be by any means appropriate for delivery of the agent to the lung passageway. In particular, a multi-layer balloon may be provided which allows the injection of an antibiotic agent between an outer layer and an inner layer of the balloon 310. As previously described and depicted in Fig. 30, the outer layer 314 of the blockage device 280 may contain holes, pores, slits or openings 320 which allow the agent to emerge through the outer layer 314 to the outside surface of the multi-layer balloon 310. Thus, the agent may be delivered to the walls and/or the lung passageway.

It may further be appreciated that the blockage device 280 may comprise a variety of designs having various lengths and shapes. In addition, many of the designs illustrated for use as a blockage device 280 may also be adapted with an aspiration port for use as described in relation to the previously illustrated embodiments of obstruction devices 150. For example, such a port 172 having a septum 176 is shown in Fig. 30. If the port is not accessed, the device simply serves as a blockage device 280. Thus, in some cases, blockage devices 280 and obstructive devices 150 are synonymous.

Referring now to Fig. 31, kits 400 according to the present invention comprise at least an obstruction or blockage device 500 and instructions for use IFU. Optionally, the kits may further include any of the other system components described above, such as an access catheter 10, guidewire 402, access tube 200, aspiration catheter 202 or other components. The instructions for use IFU will set forth any of the methods as described above, and all kit components will usually be packaged together in a pouch 450 or other conventional medical device packaging. Usually, those kit components which will be used in performing the procedure on the patient will be sterilized and maintained sterilely within the kit. Optionally, separate pouches, bags, trays, or other packaging may be provided within a larger package, where the smaller packs may be opened separately and separately maintain the components in a sterile fashion.

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 device for obstructing and bleeding gas from a lung tissue segment, said device comprising:

an expandable structure which is deployable within a lung passageway; and

means for the expandable structure for blocking airflow in one direction therethrough and permitting airflow in the other direction therethrough.

2. A device as in claim 1, wherein the blocking means comprises a valve.

3. A device as in claim 2, wherein the valve is biased to open in response to expiration and remain closed in response to inspiration.

4. A device as in claim 2, wherein the valve is biased to open in response to an aspiration vacuum applied by an aspiration catheter.

5. A device as in claim 4, further comprising a port for selectively coupling to an aspiration catheter.

6. A device as in claim 4, wherein the blocking means comprises a self-sealing septum, wherein a penetrating element on an aspiration catheter can be selectively penetrated through the septum to draw air therethrough.

7. A device as in any of the preceeding claims, wherein the expandable structure comprises superelastic, shape-memory or spring tempered wire so that the expandable structure is self-expanding.

8. A device as in claim 7, wherein the expandable structure comprises a coil.

9. A device as in claim 7, wherein the expandable structure comprises radial segments which allow the device to expand and longitudinal segments which rest against the lung passageway.

10. A system for obstructing a lung passageway to a lung tissue segment, said system comprising:

an access catheter having a proximal end, a distal end, and at least one lumen extending therethrough, and

an obstruction as in any of claims 1-10, wherein the obstruction device is introduceable by the access catheter.

11. A system as in claim 10, wherein the obstruction device is houseable within a lumen of the access catheter for deployment out of its distal end.

12. A system as in claim 10, wherein the obstruction device is mountable on the access catheter near its distal end.

13. A kit comprising:

an obstruction device deployable within a lung passageway; and

instructions for use according to a method of lung volume reduction comprising:

deploying an obstructive device in a lung passageway to a lung tissue segment; and

aspirating the segment through the deployed obstructive device to at least partially collapse the lung segment.

14. A kit as in claim 13, further comprising an access catheter having a proximal end, a distal end, and at least one lumen extending therethrough.

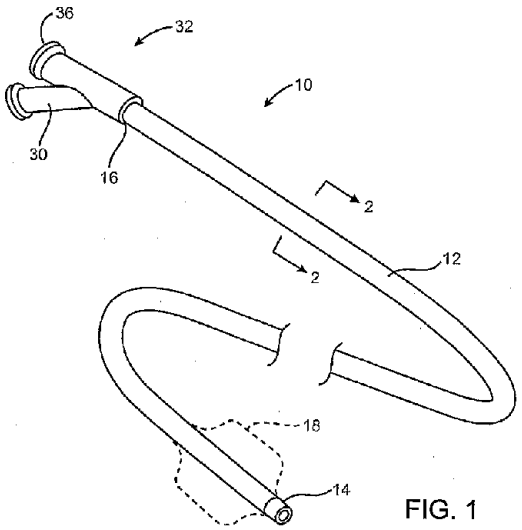


FIG. 1

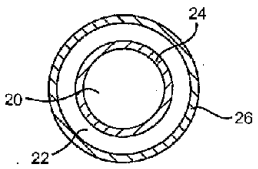


FIG. 2

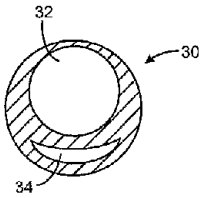


FIG. 3A

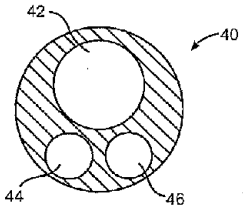


FIG. 3B

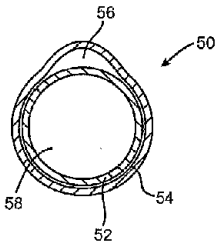


FIG. 3C

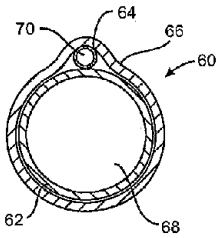


FIG. 3D

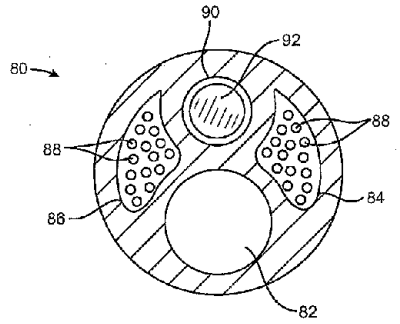


FIG. 3E

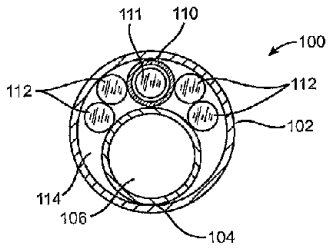


FIG. 3F

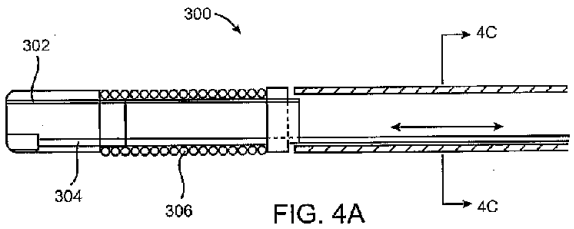


FIG. 4A

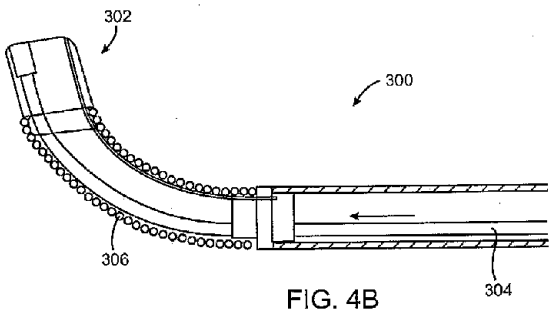


FIG. 4B

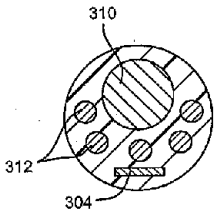


FIG. 4C

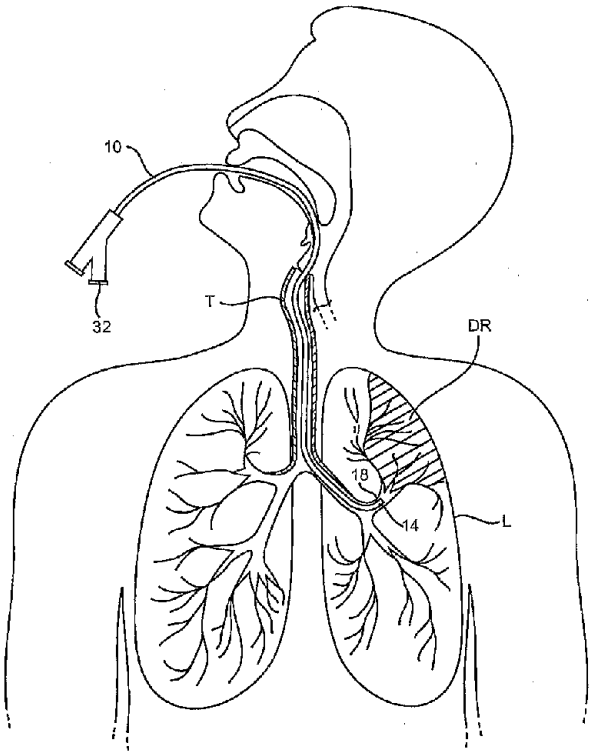


FIG. 5A

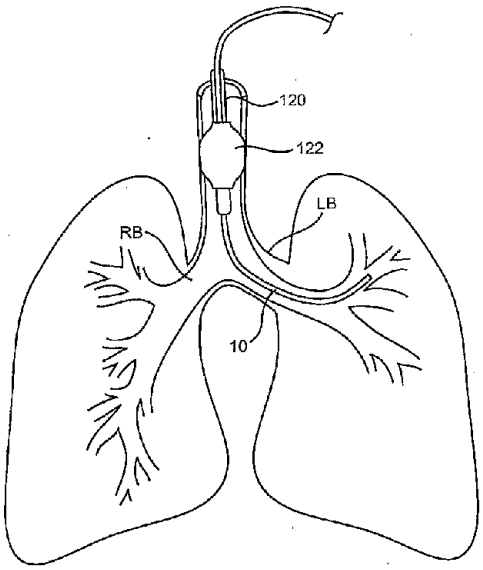


FIG. 5B

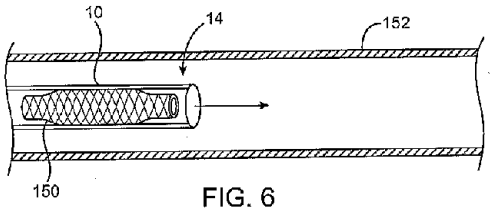


FIG. 6

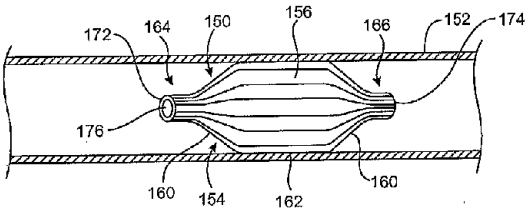


FIG. 7A

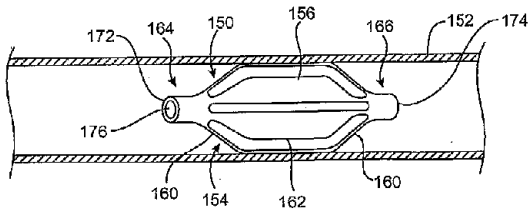


FIG. 7B

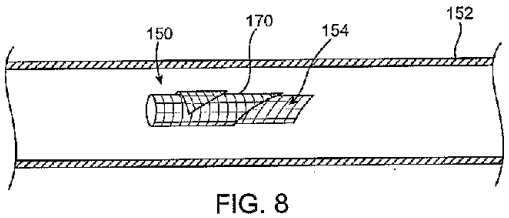


FIG. 8

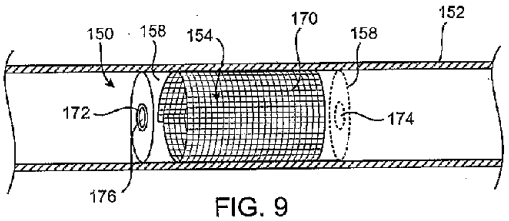


FIG. 9

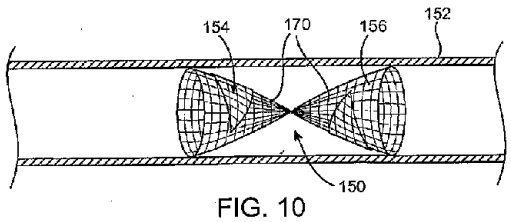


FIG. 10

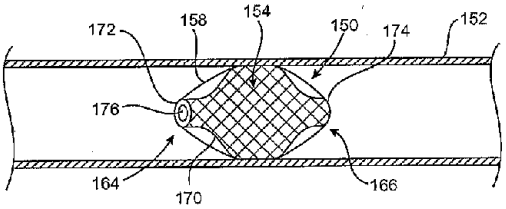

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FIG. 11

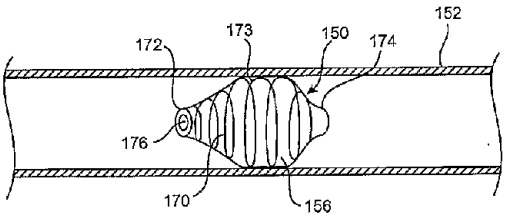
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FIG. 12

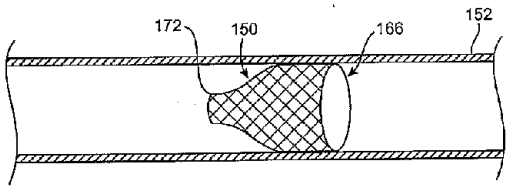


FIG. 13

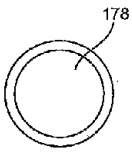


FIG. 14A

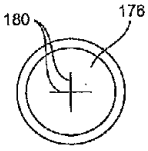


FIG. 14B

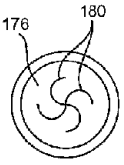


FIG. 14C

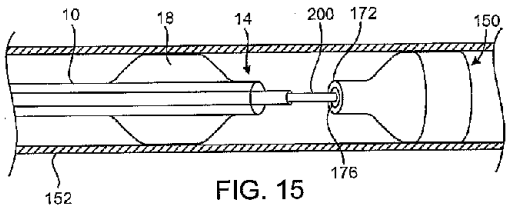


FIG. 15

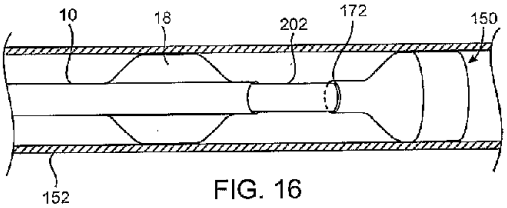


FIG. 16

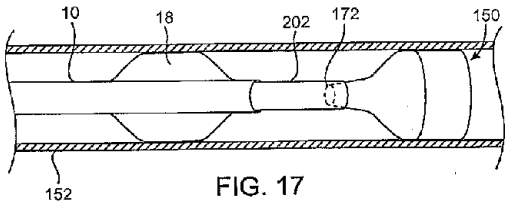


FIG. 17

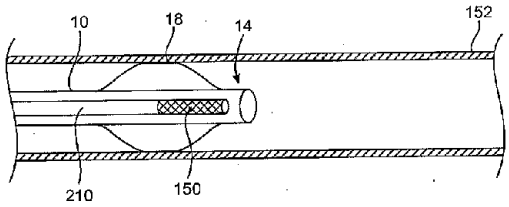


FIG. 18A

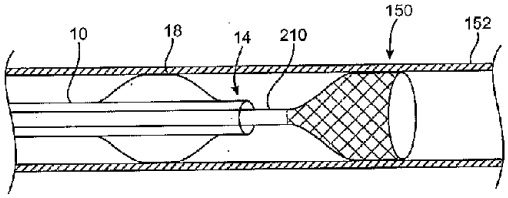


FIG. 18B

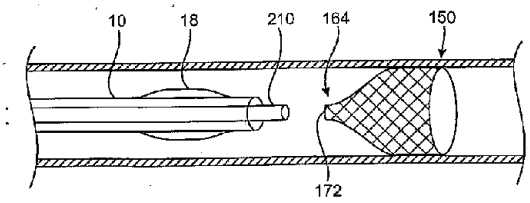


FIG. 18C

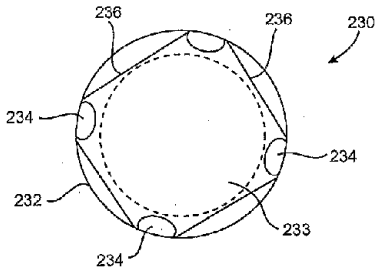


FIG. 19A

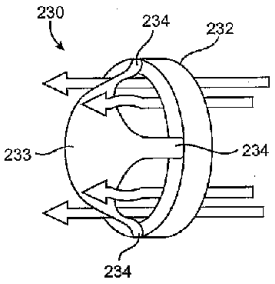


FIG. 19B

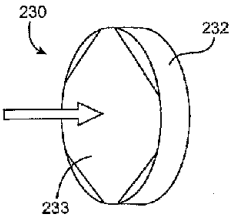


FIG. 19C

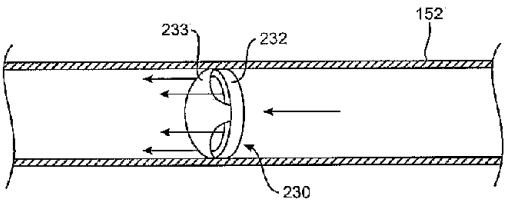


FIG. 20

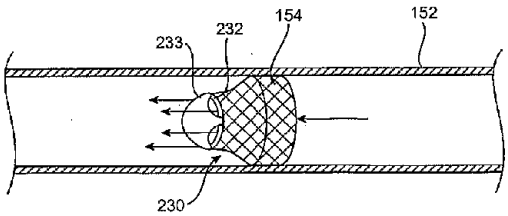


FIG. 21

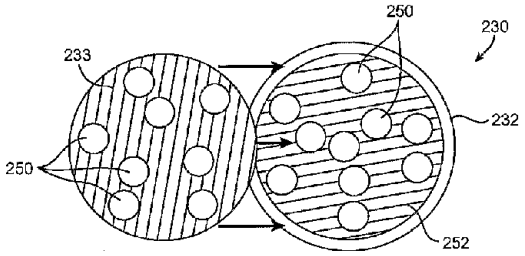


FIG. 22A

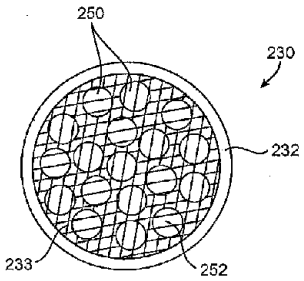


FIG. 22B

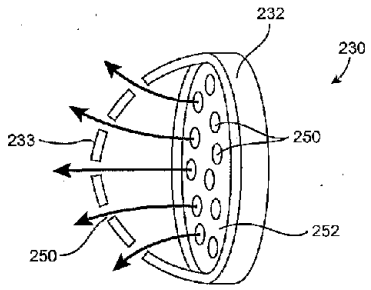


FIG. 23A

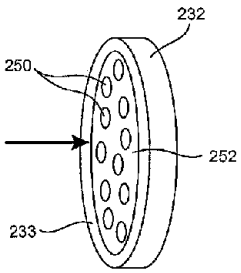


FIG. 23B

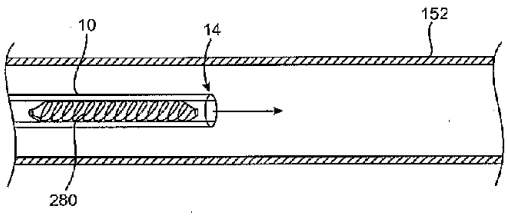
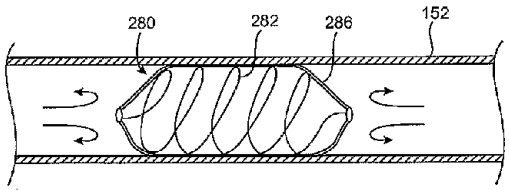


FIG. 24



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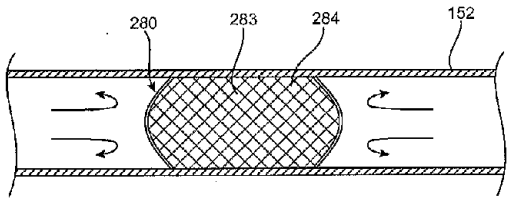

FIG. 26

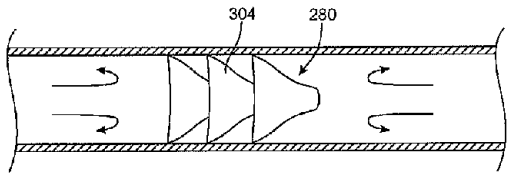

FIG. 27

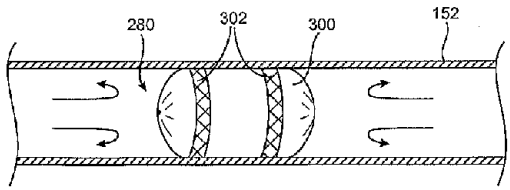

FIG. 28

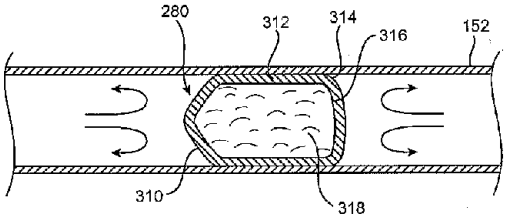

FIG. 29

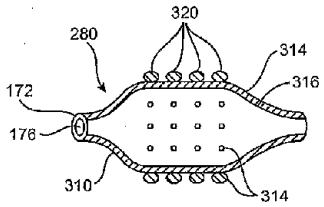

FIG. 30

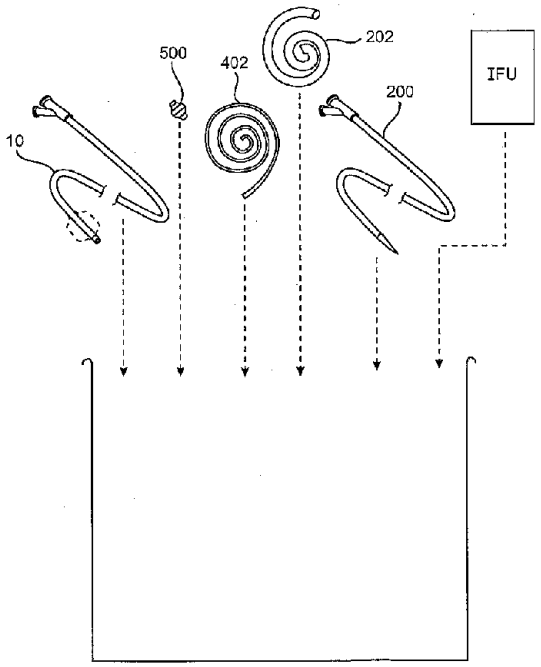

FIG. 31

【国際調査報告】

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US01/51092

A. CLASSIFICATION OF SUBJECT MATTER
IPC(7) : A61M 5/20
US CL : 604/516
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)
U.S. : 604/516; 600/37; 606/108, 232

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 practicable, search terms used)
EAST

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X,P	US 6,293,951 B1 (ALFERNESS et al) 25 September 2001 (25.09.2001), Claims 1-23	1-12
X,P	US 6,287,290 B1 (PERKINS et al) 11 September 2001 (11.09.2001), Claims 25-34	13-14

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" 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

"Y" 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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
03 July 2002 (03.07.2002)	30 AUG 2002
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703)305-3230	Authorized officer Teresa Walberg Telephone No. 703-308-0861

Form PCT/ISA/210 (second sheet) (July 1998)

フロントページの続き

(81)指定国 AP(GH,GM,KE,LS,MW,MZ,SD,SL,SZ,TZ,UG,ZW),EA(AM,AZ,BY,KG,KZ,MD,RU,TJ,TM),EP(AT,BE,CH,CY,DE,DK,ES,FI,FR,GB,GR,IE,IT,LU,MC,NL,PT,SE,TR),OA(BF,BJ,CF,CG,CI,CM,GA,GN,GQ,GW,ML,MR,NE,SN,TD,TG),AE,AG,AL,AM,AT,AU,AZ,BA,BB,BG,BR,BY,BZ,CA,CH,CN,CO,CR,CU,CZ,DE,DK,DM,DZ,EC,EE,ES,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,NO,NZ,OM,PH,PL,PT,RO,RU,SD,SE,SG,SI,SK,SL,TJ,TM,TR,TT,TZ,UA,UG,UZ,VN,YU,ZA,ZW

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Ｆターム(参考) 4C060 DD48 MM25
4C167 AA43 AA44 AA53 AA54 AA56 BB33 CC21 GG32 GG33