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(54) **SEAL ANCHOR WITH NON-PARALLEL LUMENS**

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(51) **Int. Cl.**

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A61M 13/00	(2006.01)
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A61B 17/00	(2006.01)

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

CPC ***A61M 13/003*** (2013.01); ***A61B 17/3423*** (2013.01); ***A61B 17/3462*** (2013.01); *A61B 17/3498* (2013.01); *A61B 2017/3429* (2013.01); *A61B 2017/3445* (2013.01); *A61B 2017/3466* (2013.01); *A61B 2017/3492* (2013.01); ***A61B 17/0218*** (2013.01); *A61B 2017/00238* (2013.01); *A61M 2202/02* (2013.01)

(58) **Field of Classification Search**

CPC A61B 17/3423

USPC 600/201–235, 245, 246

See application file for complete search history.

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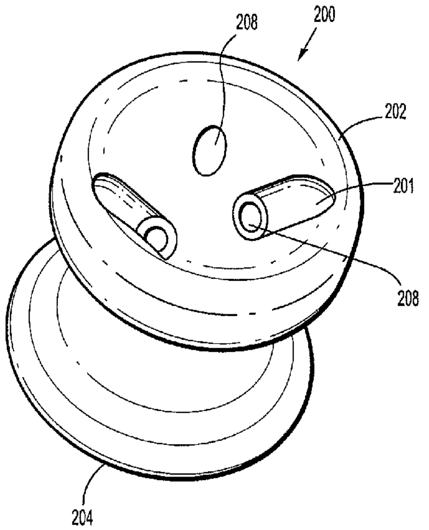
(57) **ABSTRACT**

A seal anchor member defines a housing defining a longitudinal axis, the housing having leading and trailing ends, and including a plurality of lumens extending between the leading and trailing ends, each lumen being adapted for substantially sealed reception of an object therein and defining a longitudinal axis, wherein at least two of the lumens define longitudinal axes that are non-parallel to facilitate angled, at-rest placement of multiple instruments within the seal anchor member.

19 Claims, 4 Drawing Sheets



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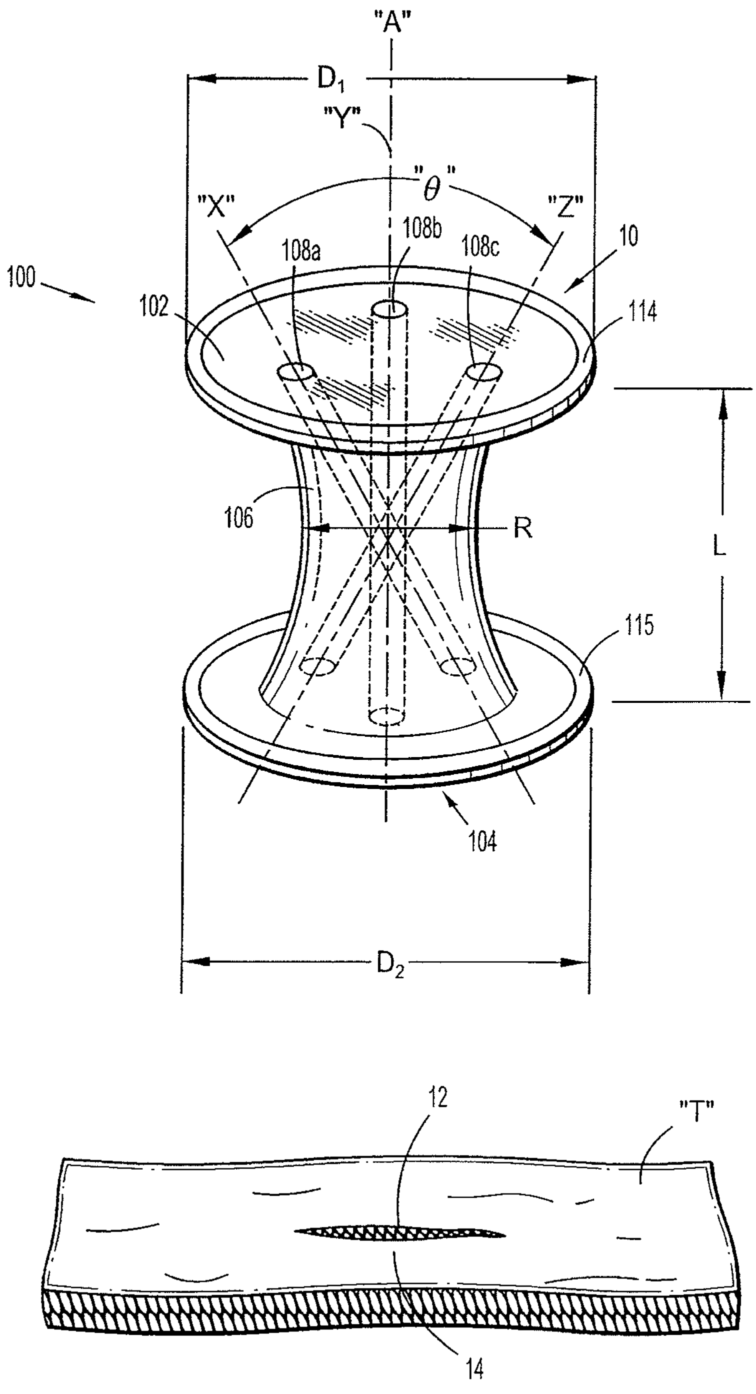

FIG. 1

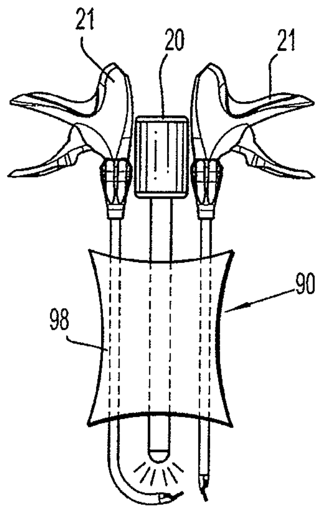

FIG. 2A

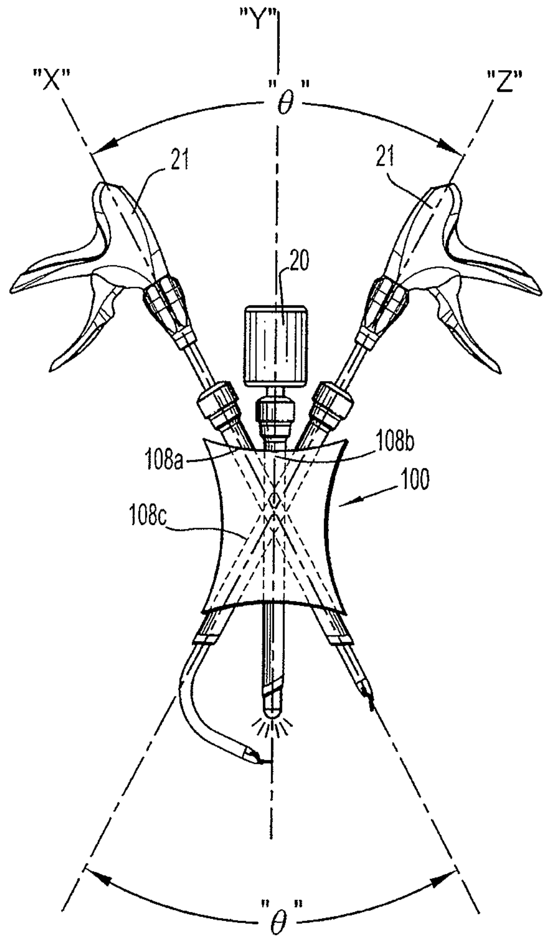

FIG. 2B

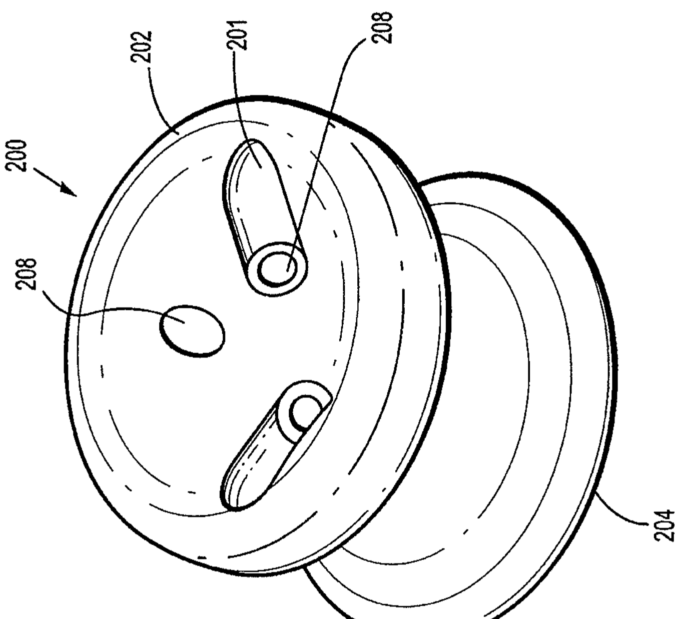

FIG. 3

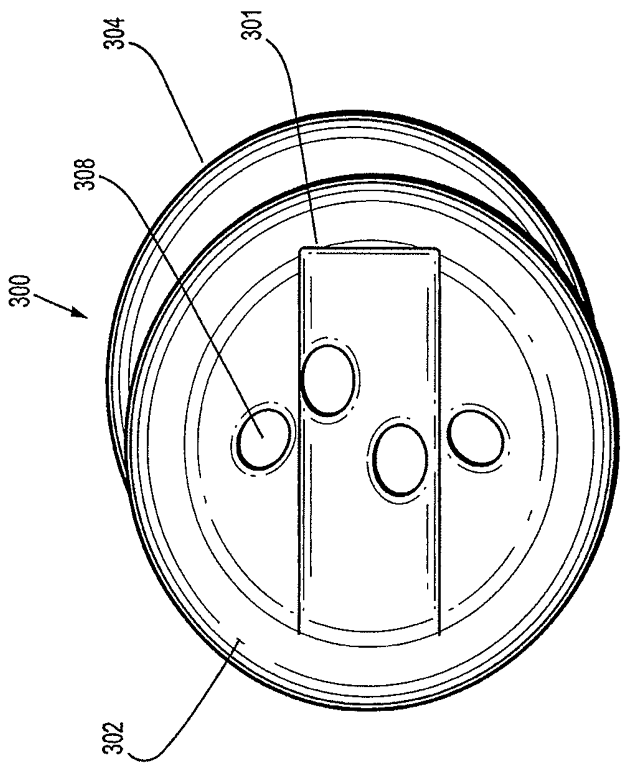

FIG. 4

SEAL ANCHOR WITH NON-PARALLEL LUMENS

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. patent application Ser. No. 13/891,717 filed May 10, 2013, which is a continuation of U.S. patent application Ser. No. 12/887,847 filed Sep. 22, 2010, which claims benefit of U.S. Provisional Application No. 61/247,654 filed Oct. 1, 2009, and the disclosures of each of the above-identified applications are hereby incorporated by reference in their entirety.

BACKGROUND

1. Technical Field

The present disclosure relates to a seal for use in a surgical procedure. More particularly, the present disclosure relates to a seal anchor member adapted for insertion into an incision in tissue and including a plurality of non-parallel lumens adapted for the sealed reception of one or more surgical objects such that a substantially fluid-tight seal is formed with both the tissue and the surgical object or objects.

2. Background of the Related Art

Today, many surgical procedures are performed through small incisions in the skin, as compared to the larger incisions typically required in traditional procedures, in an effort to reduce both trauma to the patient and recovery time. Generally, such procedures are referred to as "endoscopic", unless performed on the patient's abdomen, in which case the procedure is referred to as "laparoscopic". Throughout the present disclosure, the term "minimally invasive" should be understood to encompass both endoscopic and laparoscopic procedures.

During a typical minimally invasive procedure, surgical objects, such as surgical access devices (e.g., trocar and cannula assemblies) or endoscopes, are inserted into the patient's body through an incision in tissue. In general, prior to the introduction of the surgical object or instrument into the patient's body, insufflation gasses are used to enlarge the area surrounding the target surgical site to create a larger, more accessible work area. Accordingly, the maintenance of a substantially fluid-tight seal is desirable so as to prevent the escape of the insufflation gases and the deflation or collapse of the enlarged surgical site.

To this end, various valves and seals are used during the course of minimally invasive procedures and are widely known in the art. Various seals have been developed including lumens for the reception of surgical instruments. Depending upon the needs of a particular surgical procedure, instruments may need to be angled with respect to one another for extended periods of time. Holding the instruments at angles with respect to one another and/or overcoming the internal biases of the seal anchor member through which the instruments are inserted may fatigue the surgeon and/or breach the fluid-tight barrier between the seal anchor member and surrounding tissue.

Accordingly, a continuing need exists for new seal anchor members that can be inserted directly into the incision in tissue and that can accommodate a variety of surgical objects or instruments while maintaining the integrity of an insufflated workspace.

SUMMARY

Disclosed herein is a seal anchor member including a housing including leading and trailing ends, and one or more

lumens extending therethrough. Each of the lumens is adapted for receiving a surgical instrument in a substantially sealed reception. The one or more lumens are angled with respect to a longitudinal axis of the housing. At least two of the lumens define axes that are non-parallel with respect to one another. In an embodiment, the housing may include a plurality of lumens, e.g., three lumens, in which one of the lumens is parallel with respect to the longitudinal axis and the other two lumens are non-parallel with respect to each other and the longitudinal axis. As described herein, the lumens, while defining axes that are intersecting, do not cross each other since the lumens are laterally spaced apart, e.g., the axes, not the lumens, are intersecting when the housing is viewed in a side cross-sectional view. This arrangement of the lumens facilitates the simultaneous, non-parallel placement of multiple surgical objects or instruments within the seal anchor member. However, in other embodiments, the lumens may be intersecting.

Furthermore, the lumens may define openings at the leading end that are radially spaced apart about the trailing end. Alternatively, the lumens may define openings at the leading end that are spaced along a diameter of the trailing end. The openings defined by the lumens may be staggered about an axis of the trailing end or may be positioned along a diameter but offset from that diameter. Alternatively, the openings defined by the lumens may be positioned on a chord or a diameter of the trailing end.

The housing may be formed from a compressible material to facilitate adjusting the angles between instruments inserted within the lumens and with respect to the longitudinal axis of the housing. In the absence of a force, e.g, a radial force, upon the instruments inserted within the lumens, the lumens are angled, i.e., non-parallel, with respect to each other. During use, the angles of the lumens are adjustable by applying a force.

The leading end may include a groove, cut-out, or recess that is positioned adjacent to the proximal end of at least one of the lumens. The groove is configured and adapted to facilitate the insertion of the instrument into the lumen by stabilizing the instrument and leading the instrument into the lumen. The groove may be generally arcuate. The groove may narrow from the proximal end to the distal end of the groove. The groove may extend radially outward from the proximal end of the at least one lumen.

Furthermore, the housing of the seal anchor may be adapted to transition between a first compressed condition to facilitate at least partial insertion of the seal anchor member within a tissue tract, and a second expanded condition to facilitate securing of the seal anchor member within the tissue tract and in substantial sealed relation with tissue surfaces defining the tissue tract. In an embodiment, the housing may be formed from a compressible material or from a foam material. In an embodiment, the foam material may be at least partially constituted of a material selected from the group consisting of polyisoprene, urethane, and silicone. In another embodiment, the housing may be formed from a gel material.

The housing may also define a substantially arcuate configuration. The housing may define a substantially hour glass shape. Furthermore, the lumens may define openings at the leading end that are radially spaced apart about the trailing end. Alternatively, the lumens may define openings at the leading end that are spaced along a diameter of the trailing end. The openings defined by the lumens may be staggered about an axis of the trailing end or may be positioned along a diameter but offset from that diameter. Alternatively, the openings defined by the lumens may be positioned on a chord or a diameter of the trailing end.

These and other features of the apparatus disclosed herein will become more readily apparent to those skilled in the art from the following detailed description of various embodiments of the present disclosure.

BRIEF DESCRIPTION OF THE DRAWINGS

Various embodiments of the present disclosure are described hereinbelow with references to the drawings, wherein:

FIG. **1** is a front perspective view of a seal anchor in accordance with the present disclosure shown relative to tissue;

FIG. **2**A is a front perspective view of a seal anchor member having lumens therein that are parallel to one another;

FIG. **2**B is a front perspective view of the seal anchor of FIG. **1** shown with medical instruments inserted therein;

FIG. **3** is another embodiment of a seal anchor in accordance with the present disclosure; and

FIG. **4** is a yet another embodiment of a seal anchor in accordance with the present disclosure.

DETAILED DESCRIPTION OF THE EMBODIMENTS

In the drawings and in the description which follows, in which like references numerals identify similar or identical elements, the term "proximal" will refer to the end of the apparatus which is closest to the clinician during use, while the term "distal" will refer to the end which is furthest from the clinician, as is traditional and known in the art. A seal anchor for use in a surgical procedure is shown and described in U.S. Pat. Pub. 2009-0093752, the entire contents of which are hereby incorporated by reference. The seal anchor member may be used during a minimally invasive procedure in which the seal anchor is inserted into an incision. Alternatively, the seal anchor may be used through a naturally occurring opening (e.g., anus or vagina) or any incision in a patient's skin.

The use and function of seal anchor member **100** will be discussed during the course of a typical minimally invasive procedure. Initially, the peritoneal cavity (not shown) is insufflated with a suitable biocompatible gas such as, e.g., CO_2 gas, such that the cavity wall is raised and lifted away from the internal organs and tissue housed therein, providing greater access thereto. The insufflation may be performed with an insufflation needle or similar device, as is conventional in the art. Either prior or subsequent to insufflation, a tissue tract **12** is created in tissue "T", the dimensions of which may be varied dependent upon the nature of the procedure.

A seal anchor **100** will now be described with reference to FIGS. **1** and **2**. The seal anchor **100** defines a longitudinal axis "A" and has respective trailing (or proximal) and leading (or distal) ends **102**, **104** and an intermediate portion **106** disposed between the trailing and leading ends **102**, **104**. Seal anchor member **100** includes one or more lumens (or ports) **108***a*, **108***b*, **108***c* disposed between the trailing and leading ends **102**, **104** that define corresponding longitudinal axes "X", "Y", "Z". As seen in FIG. **1**, the axes "X", "Y", "Z" defined by the lumens **108***a*, **108***b*, **108***c*, respectively, are non-parallel with respect to one another. To facilitate the simultaneous placement of instruments into each of the lumens **108***a*, **108***b*, **108***c*, the lumens **108***a-c* do not cross one another. The lumens **108***a-c* are laterally spaced apart such that, although the lumens **108***a-c* are angled with respect to one another, the lumens **108***a-c* do not intersect one another. In other embodiments, however, lumens may be arranged to cross one another. In contrast to seal anchor **100**, a seal anchor **90** having parallel, non-intersecting lumens **98** is illustrated in FIG. **2**A.

As seen in FIG. **2**B, the lumens **108***a-c* are adapted to receive instrumentation therein in a substantially sealed manner. The lumens **108***a-c* are adapted to inhibit the escape of insufflation gasses within a body cavity with or without instrumentation being inserted therein. Accordingly, the lumens **108***a-c* have diameters that are adapted to contract in the absence of a surgical instrument inserted therein and are adapted to expand to accommodate instrumentation in a substantially sealed manner.

As shown in FIG. **2**B, the instrumentation inserted within the lumens **108** may include, but are not limited to, a camera **20** that may be inserted within one of the lumens **108** and a pair of surgical instruments **21** that are inserted into two of the other lumens **108**. Since the axes "X" and "Z" of the two lumens **108***a*, **108***c*, through which the pair of surgical instruments **21** are inserted, cross one another, the distance between the distal ends of the surgical instruments **21** is greater than it would be if the axes "X", "Z" were parallel to one another. Since the lumens **108***a*, **108***c* define non-parallel axes, manipulation of the surgical instruments **21** is facilitated since there is a lesser probability of the instruments **21** interfering with each other's use. Furthermore, since the at-rest state for the lumens **108***a-c* is at angles with respect to one another, surgeon fatigue is reduced for those procedures necessitating such positioning for an extended duration of time. Adjustment of the angles of the lumens with respect to one another is facilitated by overcoming the internal biasing force of the seal anchor member **100** by applying a radial force to the surgical instrumentation placed within the lumens **108***a-c*.

As previously discussed, FIG. **2**A illustrates a seal anchor **90** including lumens **98** that are parallel to one another. Inserted within lumens **98** are surgical instruments **21** and camera **20**. As seen in FIG. **2**A, the parallel configuration of the lumens **98** hinder camera **20** in obtaining a clear view of the surgical site. It will be appreciated that the non-parallel, intersecting configuration of the lumens **108***a-c* of seal anchor **100** facilitate obtaining a lesser obstructed field of view than would be obtainable using seal anchor **90**. In particular, as shown in FIG. **2**B, axes "X" and "Z" define an angle "θ" therebetween. The greater the value of angle "θ", the lesser the probability of surgical instruments **21** obstructing the view of camera **20**. Moreover, the greater the angle "θ", the lesser the probability of interference between instruments **21** during the procedure. In addition, the greater the angle "θ", the greater the number of internal structures included within the surgical field and within reach of instruments **21**.

Proximal end **102** of seal anchor member defines a first diameter D_1 and distal end **104** defines a second diameter D_2. In one embodiment of seal anchor member **100**, the respective first and second diameters D_1, D_2 of the proximal and distal ends **102**, **104** are substantially equivalent, as seen in FIG. **1**, although an embodiment of seal anchor member **100** in which diameters D_1, D_2 are different is also within the scope of the present disclosure. As depicted in FIG. **1**, proximal and distal ends **102**, **104** define substantially planar surfaces. However, embodiments are also contemplated herein in which either or both of proximal and distal ends **102**, **104**, respectively, define surfaces that are substantially arcuate to assist in the insertion of seal anchor member **100** within a tissue tract **12** defined by tissue surfaces **14** and formed in tissue "T", e.g., an incision, as discussed in further detail below.

Intermediate portion **106** defines a radial dimension "R" and extends longitudinally between proximal and distal ends

102, 104, respectively, to define an axial dimension or length "L". The radial dimension "R" of intermediate portion 106 varies along the axial dimension, or length, "L" thereof. Accordingly, seal anchor member 100 defines a cross-sectional dimension that varies along its length "L", which facilitates the anchoring of seal anchor member 100 within tissue "T", as discussed in further detail below. However, an embodiment of seal anchor member 100 in which the radial dimension "R" remains substantially uniform along the axial dimension "L" thereof is also within the scope of the present disclosure.

The radial dimension "R" of intermediate portion 106 is appreciably less than the respective diameters D_1, D_2 of proximal and distal ends 102, 104 such that seal anchor member 100 defines an "hour-glass" shape or configuration to assist in anchoring seal anchor member 100 within tissue "T", as discussed in further detail below. However, in an alternate embodiment, the radial dimension "R" of intermediate portion 106 may be substantially equivalent to the respective diameters D_1, D_2 of proximal and distal ends 102, 104. In cross section, intermediate portion 106 may exhibit any suitable configuration, e.g., substantially circular, oval or oblong.

The seal anchor 100 may be adapted to transition from an expanded condition to a compressed condition so as to facilitate the insertion and securement thereof within tissue tract 12 in tissue "T". In the expanded condition, seal anchor 100 is at rest and the respective radial dimensions D_1, D_2 of the proximal and distal ends 102, 104 of seal anchor 100, as well as the radial dimension R of the intermediate portion 106 are such that the seal anchor 100 cannot be inserted within tissue tract 12. However, the seal anchor 100 may transition to a compressed condition such that proximal and distal ends 102, 104, as well as intermediate portion 106 are dimensioned for insertion into tissue tract 12.

To facilitate the transition between an expanded and a compressed condition, the seal anchor 100 may be formed from a compressible material having an internal biasing force such that the seal anchor 100 will transition back to an expanded condition upon insertion of the seal anchor 100 within tissue tract 12, thereby ensuring a seal between the seal anchor 100 and the tissue tract 12. Seal anchor 100 may be formed from a shape memory material, a foam material, or a gel material, or the like, but may also be formed from other materials. In an embodiment, the seal anchor 100 may be formed from a material selected from the group consisting of polyisoprene, urethane, and silicone.

Positioning members 114, 115 of the trailing and leading ends 102, 104, respectively, may engage the walls defining the body cavity of the tissue tract 12 to facilitate securement of seal anchor member 100 within the body tissue. For example, positioning member 114 at leading end 104 may engage the internal peritoneal wall and positioning member 114 adjacent trailing end 102 may engage the outer epidermal tissue adjacent the incision 12 within tissue "T". In another embodiment of seal anchor member 100, one or more additional positioning members 114 may be associated with intermediate portion 106.

The use and function of seal anchor member 100 will be discussed during the course of a typical minimally invasive procedure. Initially, the peritoneal cavity (not shown) is insufflated with a suitable biocompatible gas such as, e.g., CO_2 gas, such that the cavity wall is raised and lifted away from the internal organs and tissue housed therein, providing greater access thereto. The insufflation may be performed with an insufflation needle or similar device, as is conventional in the art. Either prior or subsequent to insufflation, a tissue tract 12 is created in tissue "T", the dimensions of which may be varied dependent upon the nature of the procedure.

Different embodiments of seal anchors will be described with reference to FIGS. 2 and 3. Seal anchors 200, 300 are substantially similar to seal anchor 100, except in the configuration of lumens and further include structures to stabilize instrumentation inserted within the lumens. Both seal anchor 200 and seal anchor 300, shown in FIGS. 2 and 3, include lumens defining intersecting axes. Seal anchor 200 includes a trailing end 202 and a distal end 204. A plurality of lumens 208 is disposed between the trailing and leading ends 202, 204. Lumens 208 define openings in the trailing end 202 that are radially positioned along the trailing end 202. A cut-out or groove 201 in the leading end extending outward from at least one lumen 208 facilitates stabilization of instrumentation inserted within the lumen 208.

In an alternative embodiment, a seal anchor 300 including plurality of lumens disposed between leading and trailing ends 302, 304 is shown in FIG. 4. A cut-out or groove 301 in an arcuate or half-cylindrical configuration is disposed in the trailing end. At least one lumen 308 is disposed within the groove 301. Groove 301 is adapted to facilitate stabilization of instrumentation inserted within the at least one of the lumens 308 that is disposed within the area defined by the groove 301.

Although the illustrative embodiments of the present disclosure have been described herein with reference to the accompanying drawings, the above description, disclosure, and figures should not be construed as limiting, but merely as exemplifications of particular embodiments. It is to be understood, therefore, that the disclosure is not limited to those precise embodiments, and that various other changes and modifications may be effected therein by one skilled in the art without departing from the scope or spirit of the disclosure.

What is claimed is:

1. A surgical device comprising:

a flexible seal anchor member defining a longitudinal axis and comprising an arcuate distal surface, an arcuate proximal surface, and an intermediate portion extending therebetween, wherein the intermediate portion has a proximal section that tapers inwardly in a distal direction and a distal section that tapers outwardly in the distal direction;

the seal anchor member further comprising a protruding portion disposed along a periphery of each of the arcuate proximal surface and the arcuate distal surface;

the seal anchor member defining at least a first lumen, a second lumen and a third lumen extending from the arcuate proximal surface and through the intermediate portion to the arcuate distal surface, wherein the first lumen is parallel relative to the longitudinal axis of the seal anchor member and the second and third lumen are non-parallel relative to the longitudinal axis of the seal anchor member; and

wherein at least one of the arcuate proximal surface or the arcuate distal surface defines first and second cutouts, the entire first cutout extending linearly outward from the second lumen in a first direction and the entire second cutout extending linearly outward from the third lumen in a second direction.

2. The surgical device of claim 1, wherein the anchor seal member comprises at least one of a pliable, compressible and a shape memory material.

3. The surgical device of claim 1, wherein at least one of the arcuate proximal surface or the arcuate distal surface is concave.

4. The surgical device of claim **1**, wherein at least one of a relative position or shape of at least a portion of at least one of the first, second, or third lumen is adjustable by a force exerted by a surgical instrument.

5. The surgical device of claim **1**, wherein the seal anchor member is adapted to transition between a first condition in which at least a portion of the seal anchor member is insertable within an opening in a body of a patient, and a second condition in which at least a portion of the seal anchor member is in substantial sealing relation with tissue surfaces defining the opening.

6. The surgical device of claim **1**, wherein at least one of the first or second cutouts is configured to facilitate stabilization of a surgical instrument.

7. The surgical device of claim **1**, wherein at least a portion of at least one of first lumen, second lumen, or third lumen is configured for sealed reception of a surgical instrument.

8. The surgical device of claim **1**, wherein the seal anchor member is configured for insertion into an opening during a laparoscopic surgical procedure, and wherein at least one of the first lumen, second lumen, or third lumen is configured to inhibit escape of insufflation gases from within a body cavity.

9. The surgical device of claim **1**, further comprising an insufflation tube positioned within at least one of the first lumen, second lumen, or third lumen.

10. A surgical device comprising:

a flexible seal anchor member defining a longitudinal axis and comprising a first surface, a second surface and a body extending therebetween;

the seal anchor member defining at least a first port, a second port and a third port extending from the first surface and through the seal anchor member to the second surface, wherein at least a portion of at least one of the first port, second port, or third port is transitionable between a closed configuration to an open configuration upon introduction of an instrument;

wherein at least one of the first or second surfaces defines first and second cutouts, the entire first cutout extending linearly outward from the second port in a first direction and the entire second cutout extending linearly outward from the third port in a second direction; and

an insufflation tube positionable within at least one of the first port, the second port, and the third port.

11. The surgical device of claim **10**, wherein the first port is parallel to the longitudinal axis and the second and third ports are each nonparallel to the longitudinal axis.

12. The surgical device of claim **10**, wherein the first surface is the same shape and size as the second surface and, at least one of the first or second surfaces includes a protruding edge extending about its circumference.

13. The surgical device of claim **10**, wherein the first cutout and a portion of the second port defines an elliptical shape.

14. The surgical device of claim **10**, wherein the first and second surfaces are arcuate.

15. The surgical device of claim **10**, wherein the anchor seal member comprises at least one of a pliable, compressible and a shape memory material.

16. The surgical device of claim **10**, wherein at least one of a shape or a position of at least part of at least one of the first, second or third ports is adjustable by a force exerted by the introduction of the instrument.

17. The surgical device of claim **10**, wherein a cross section of the body taken perpendicular to the longitudinal axis and at the midpoint between the first and second surfaces has a smaller area than the area of either the first surface or the second surface.

18. The surgical device of claim **17**, wherein the body has a proximal section that tapers inwardly in a distal direction and a distal section that tapers outwardly in the distal direction.

19. The surgical device of claim **10**, wherein the first and second cutouts are configured to lead the instrument into the respective second and third ports.

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[标]申请(专利权)人(译)	柯惠有限合伙公司		
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摘要(译)

密封锚定构件限定了限定纵向轴线的壳体，壳体具有前端和尾端，并且包括在前端和后端之间延伸的多个腔，每个腔适于基本上密封接收其中的物体并限定纵向。轴，其中至少两个内腔限定不平行的纵向轴线，以便于多个器械在密封锚定构件内成角度的，静止放置。