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Hopper et al.

(10) **Patent No.: US 7,235,064 B2**
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(54) **METHOD AND APPARATUS FOR ANCHORING LAPAROSCOPIC INSTRUMENTS**

(75) Inventors: **Phillip K. Hopper**, San Carlos, CA (US); **Tim J. Kovac**, Los Gatos, CA (US); **Edmund J. Roschak**, Belmont, CA (US); **Wilson Eng**, San Jose, CA (US)

(73) Assignee: **Sherwood Services AG**, Schaffhausen (CH)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 16 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **10/373,487**

(22) Filed: **Feb. 25, 2003**

(65) **Prior Publication Data**

US 2003/0139758 A1 Jul. 24, 2003

Related U.S. Application Data

(60) Continuation of application No. 08/447,794, filed on May 23, 1995, now Pat. No. 6,524,283, which is a division of application No. 08/320,042, filed on Oct. 7, 1994, now Pat. No. 5,697,946.

(51) **Int. Cl.**
A61M 5/00 (2006.01)

(52) **U.S. Cl.** **604/264**; 606/108; 606/185

(58) **Field of Classification Search** 606/184, 606/185, 190–198, 1, 167, 108, 213; 604/96.01–109, 604/164.01, 164.04, 164.1, 264; 600/201, 600/204, 207, 210; 128/207.14–207.18
See application file for complete search history.

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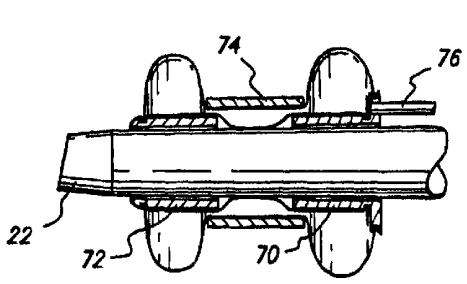
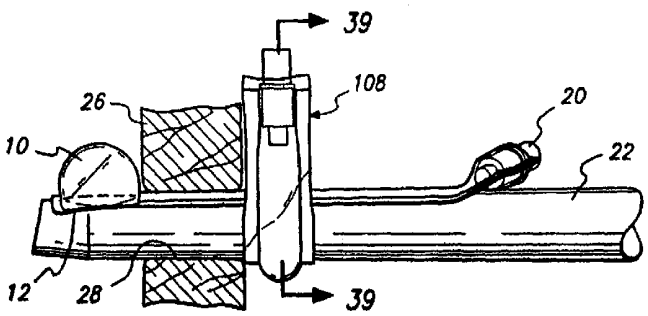
Primary Examiner—Glenn K. Dawson

(57) **ABSTRACT**

A balloon anchor provides for the anchoring of a surgical instrument, such as conventional trocar sheath, within a puncture opening formed by a trocar. When used on a trocar sheath, the anchor is secured to the smooth outer surface of the sheath for extension through the puncture opening as the trocar within the sheath forms the opening. Adhesive or mechanical means are provided to secure the balloon the instrument. No modification to the structure of the instrument is required. Once in place within the opening, the balloon is inflated to the interior of the tissue to anchor the instrument in place. Certain embodiments also provide for inflation of the balloon within and/or to the exterior of the opening.

10 Claims, 11 Drawing Sheets





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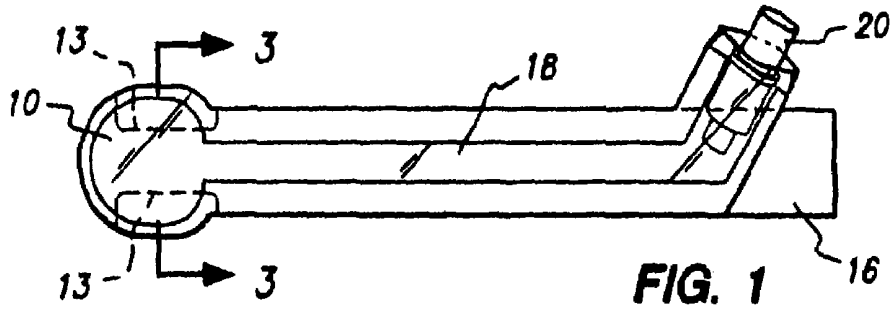
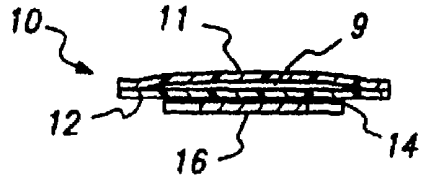


FIG. 1

FIG. 2



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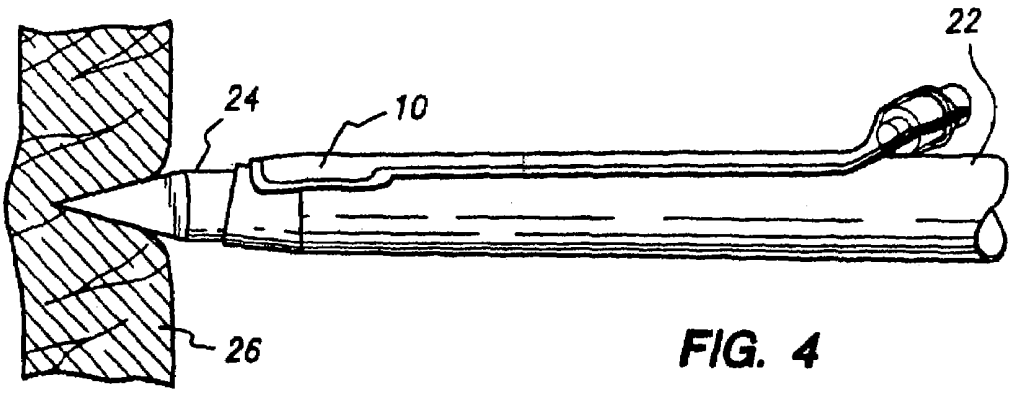

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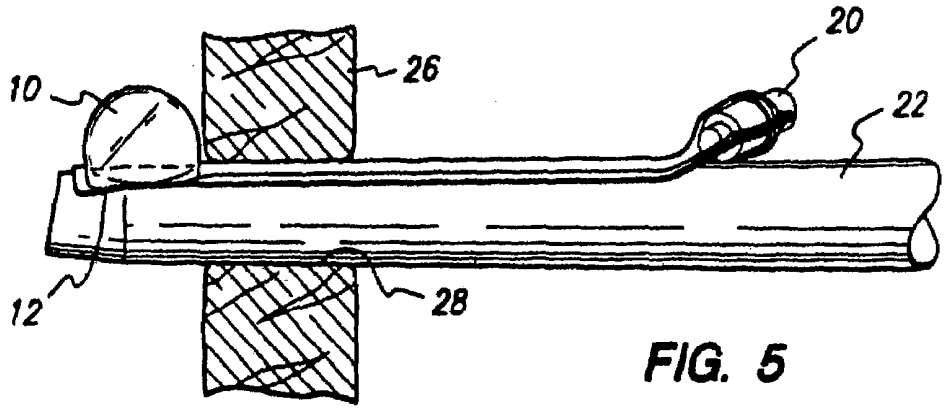

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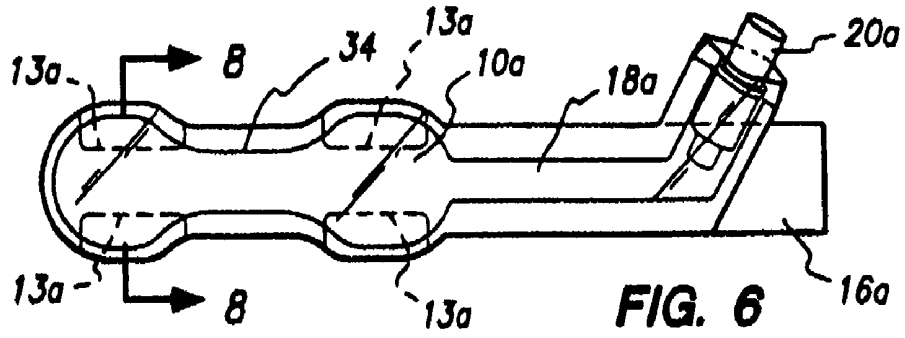

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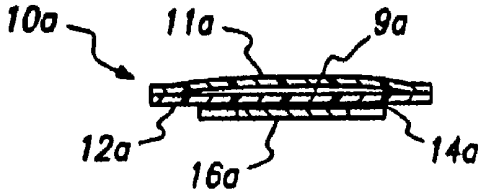

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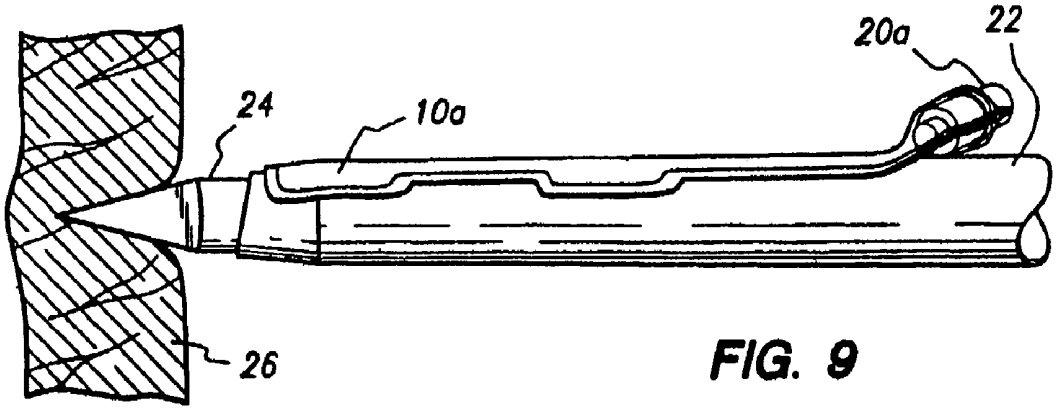

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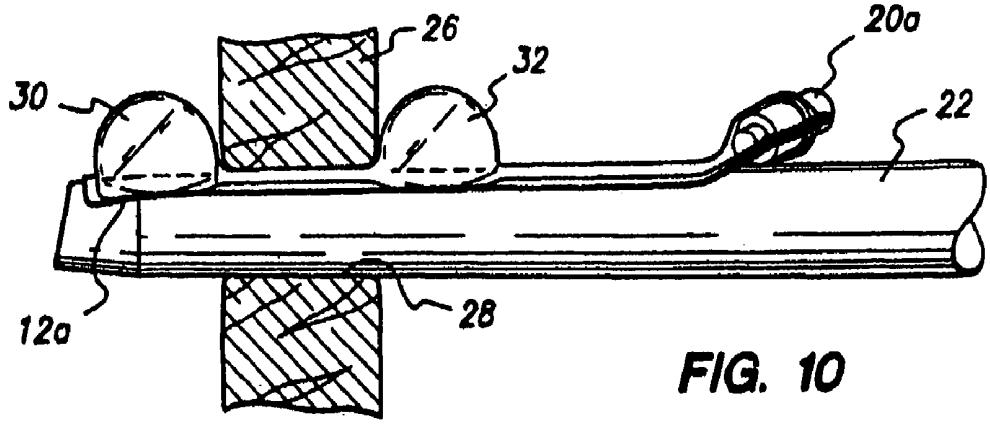

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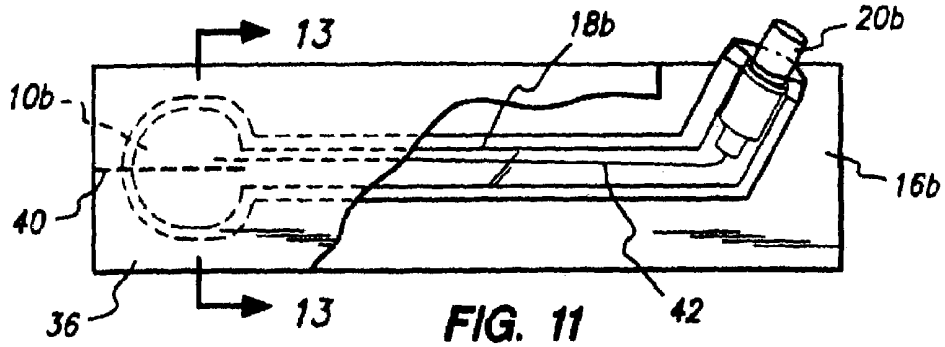

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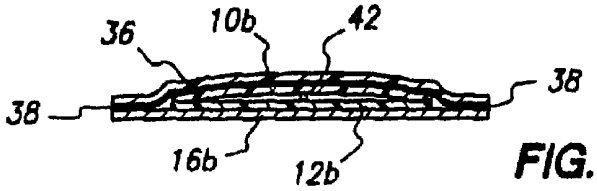

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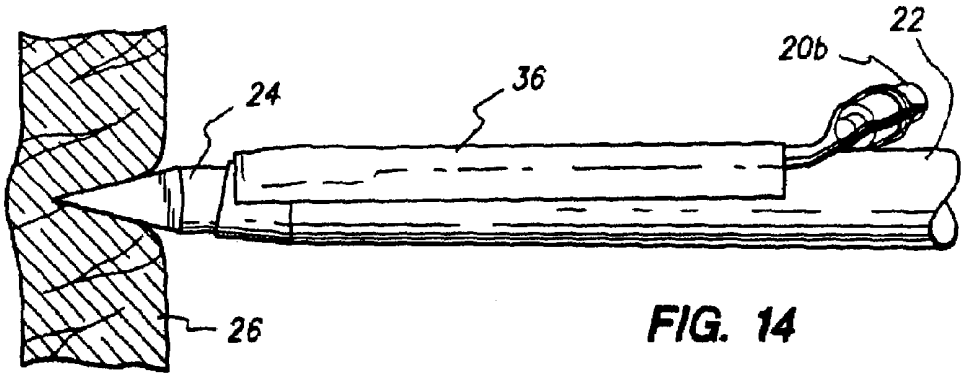

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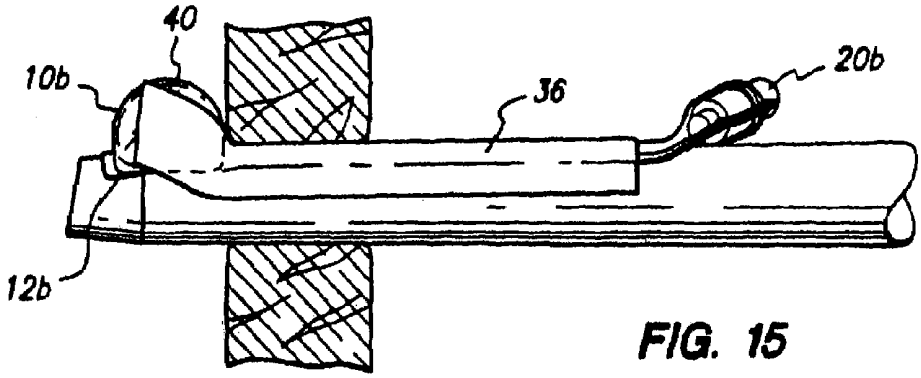

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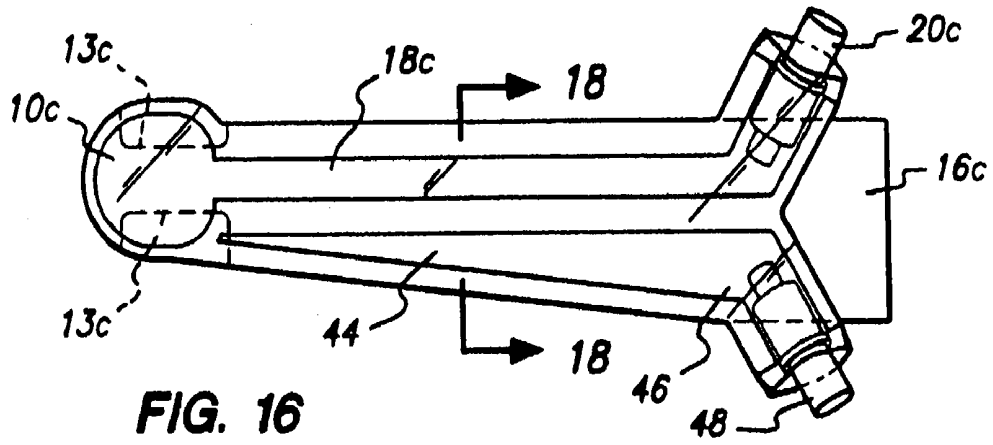

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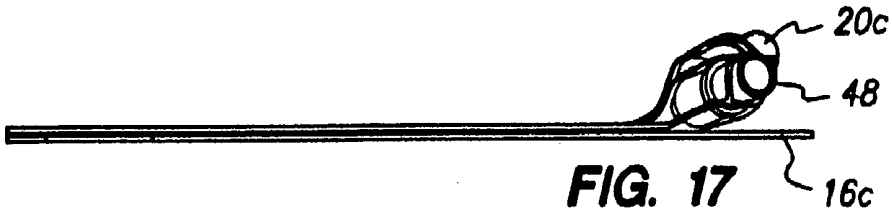

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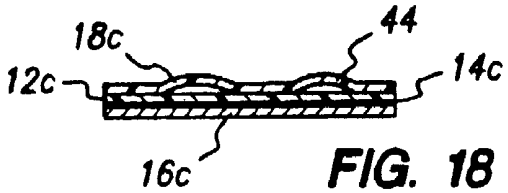

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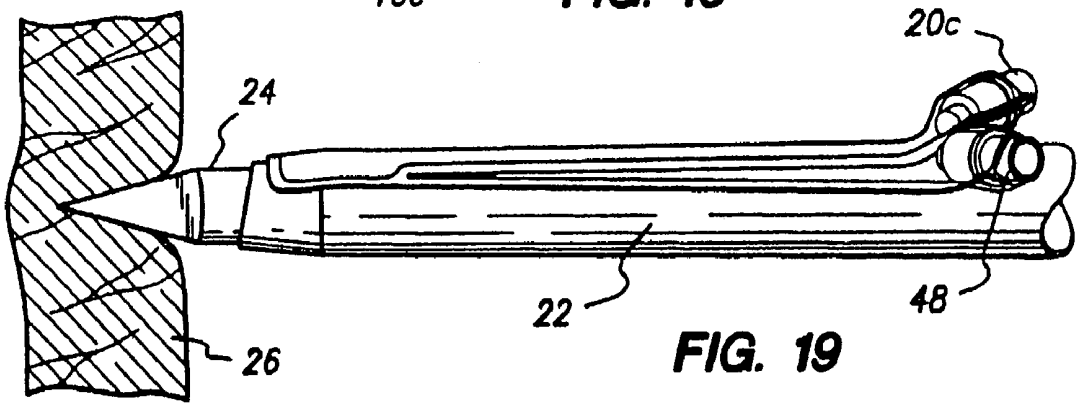

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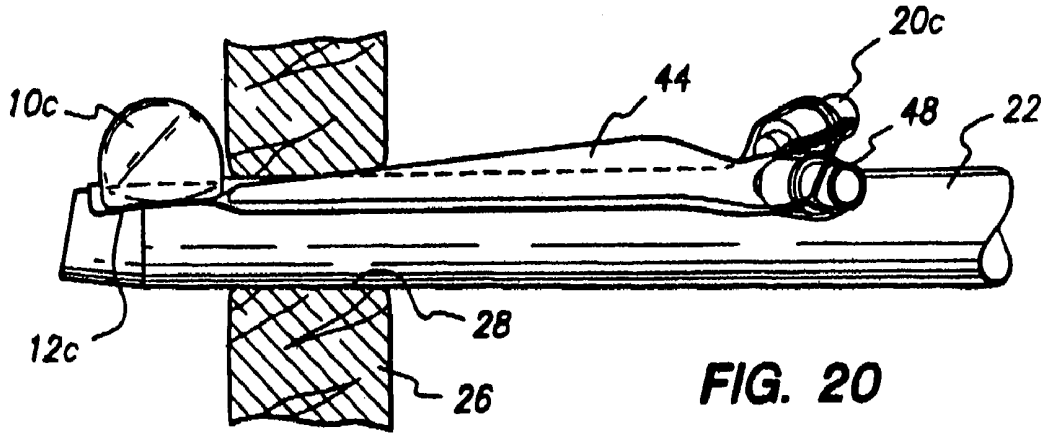

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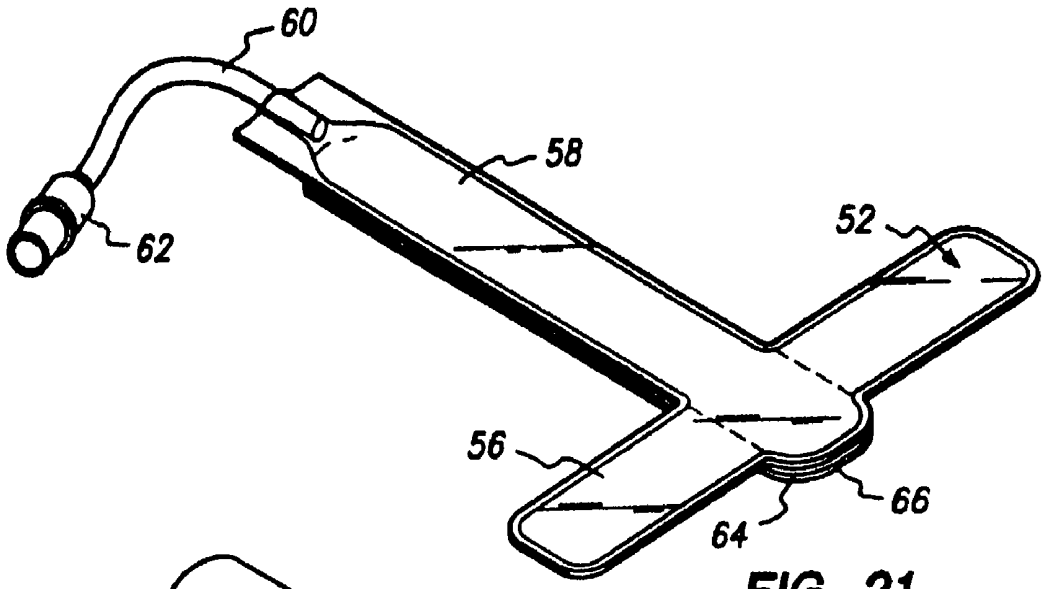

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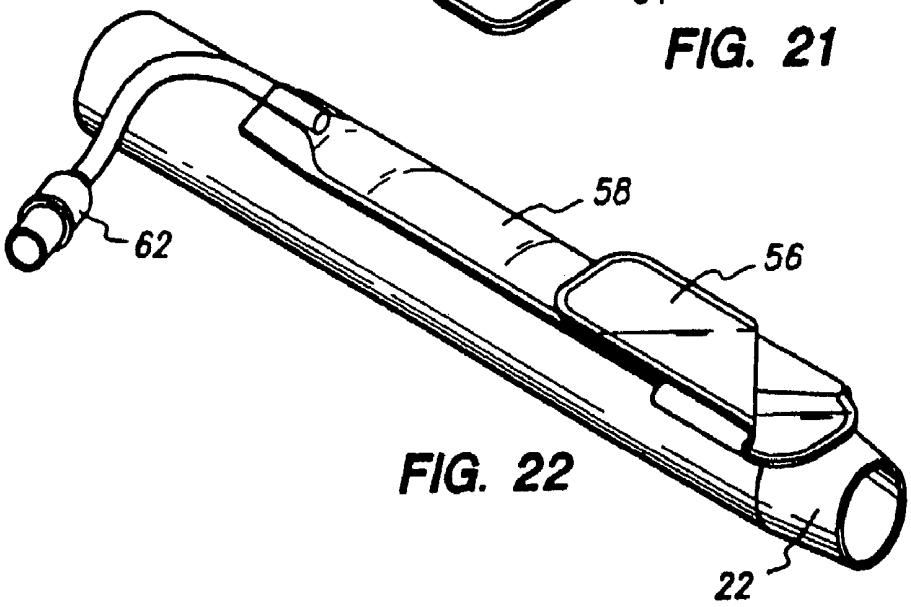

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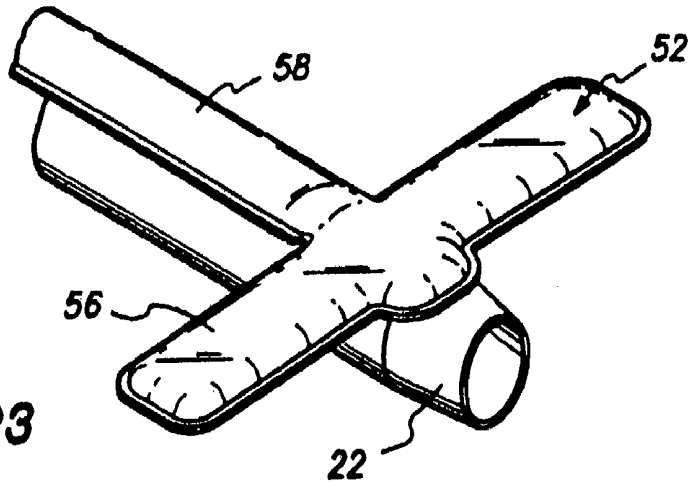

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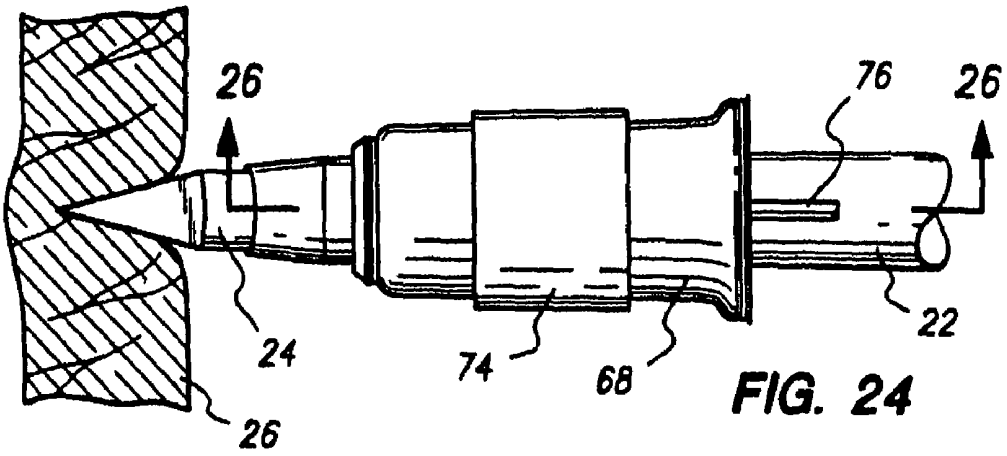

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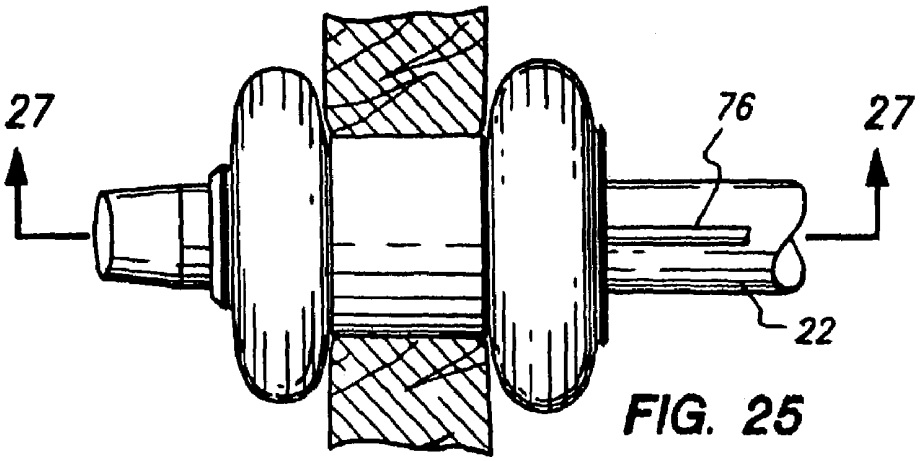

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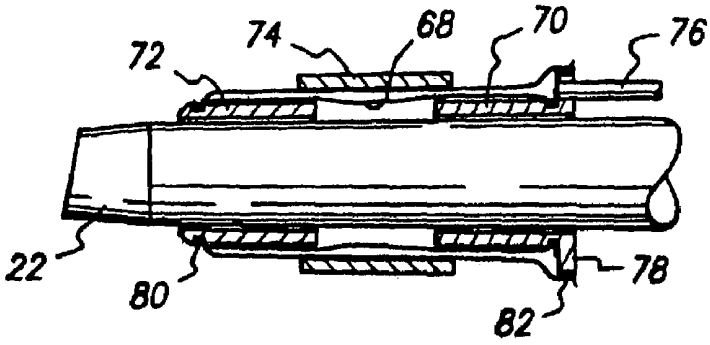

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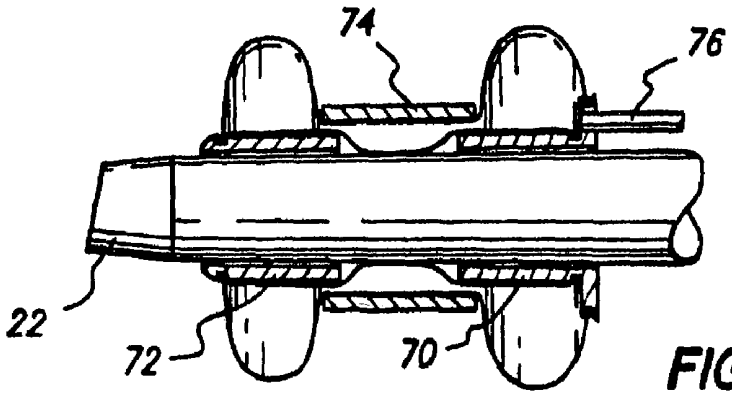

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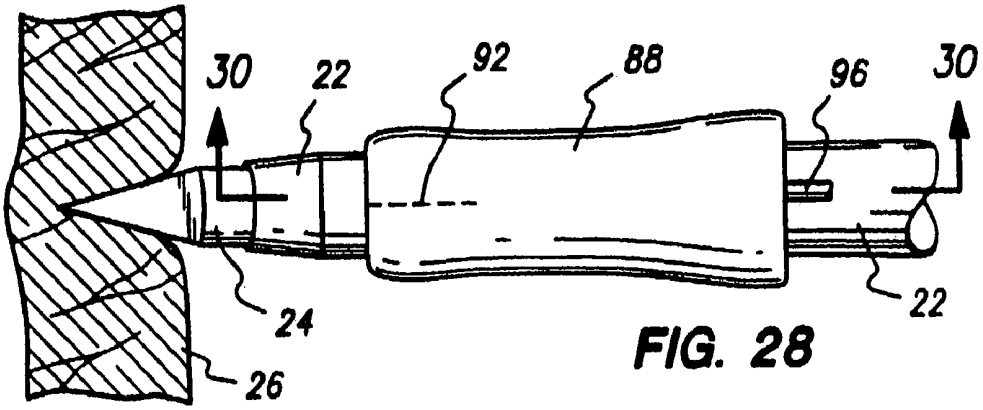

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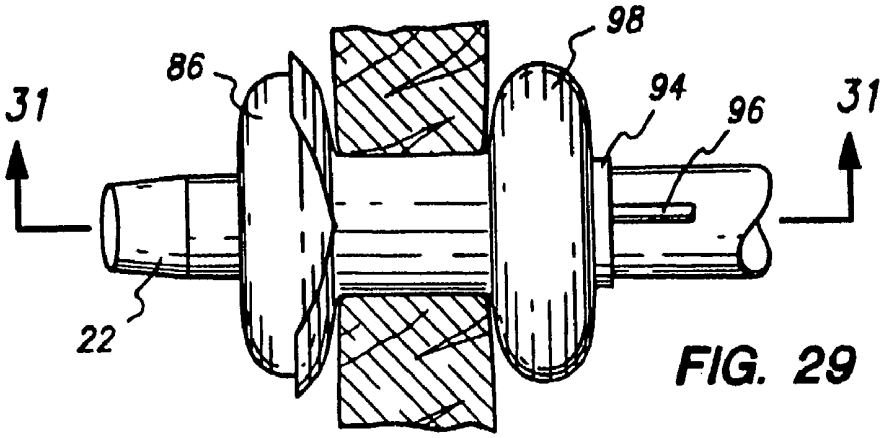

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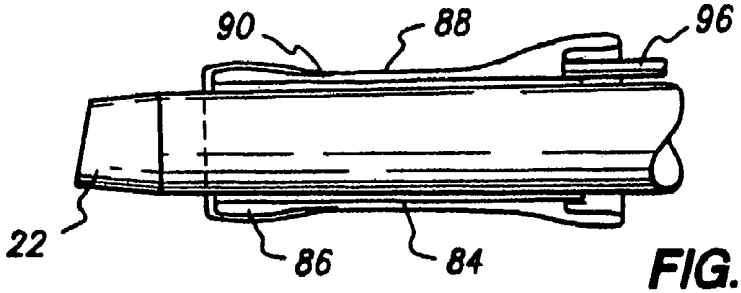

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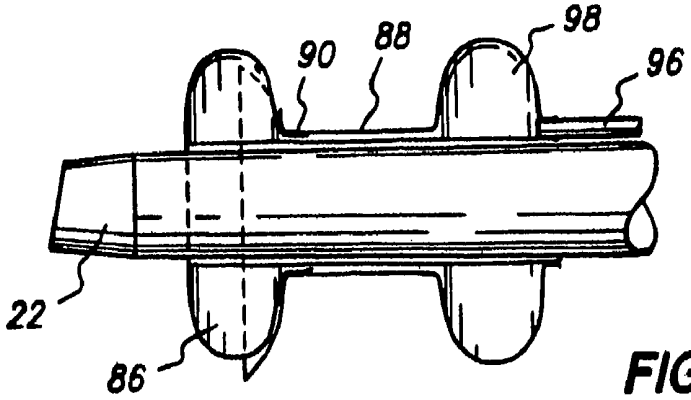

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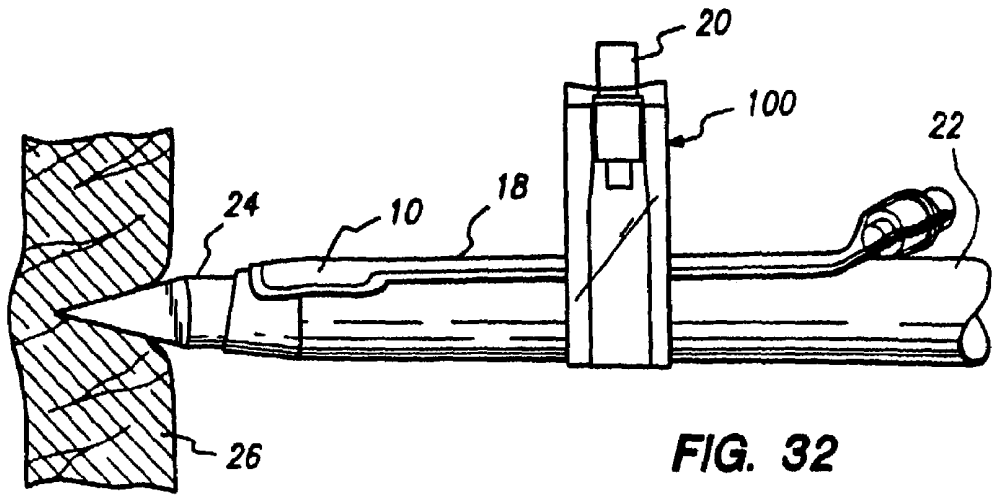

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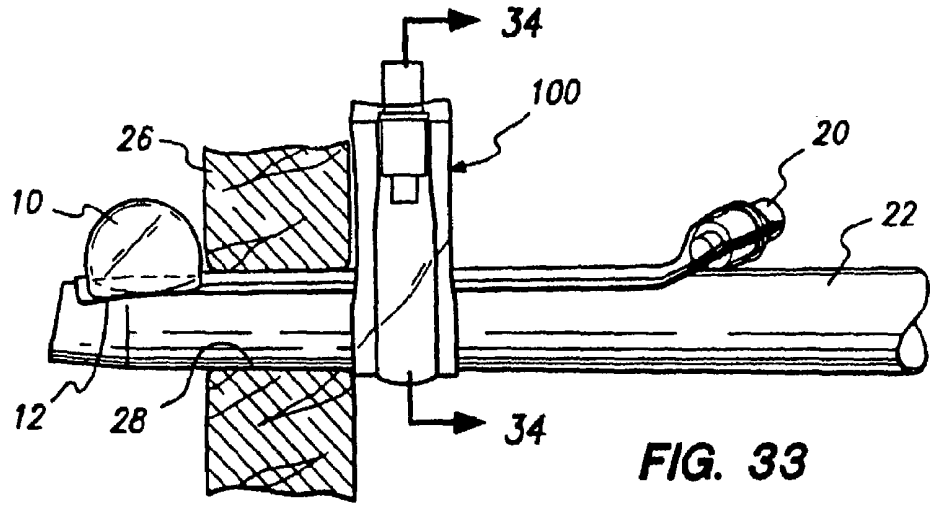

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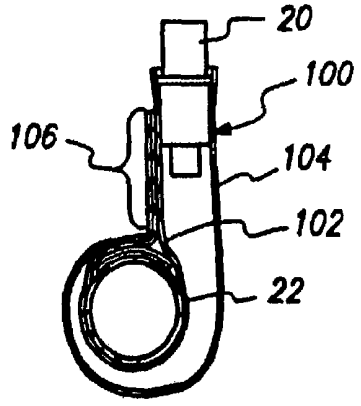

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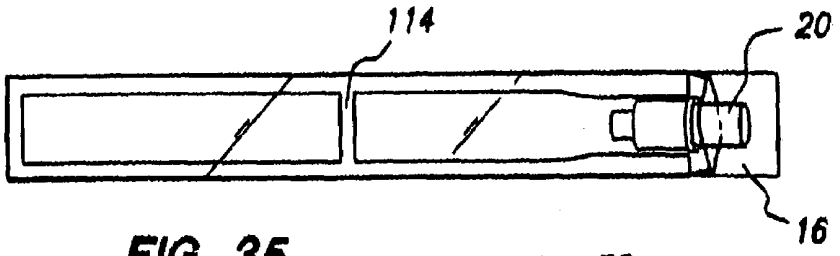

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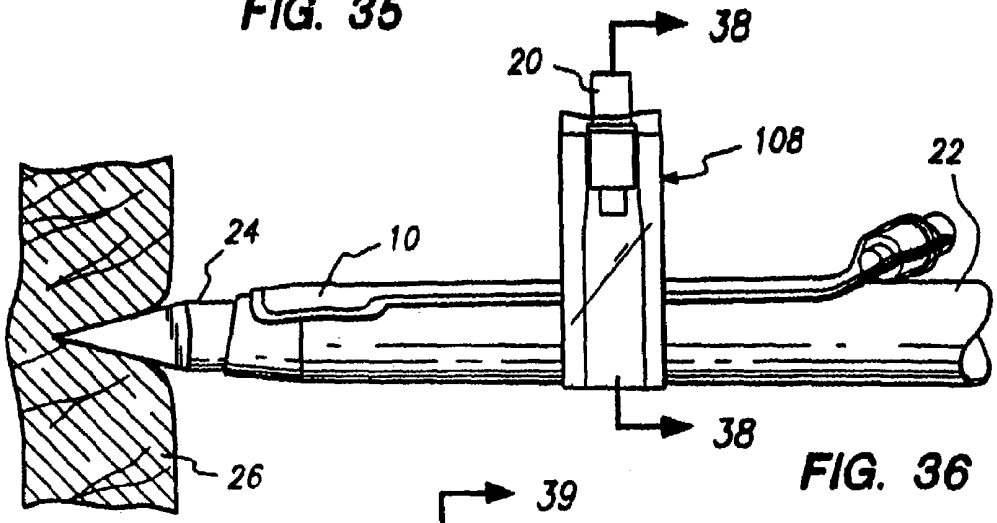

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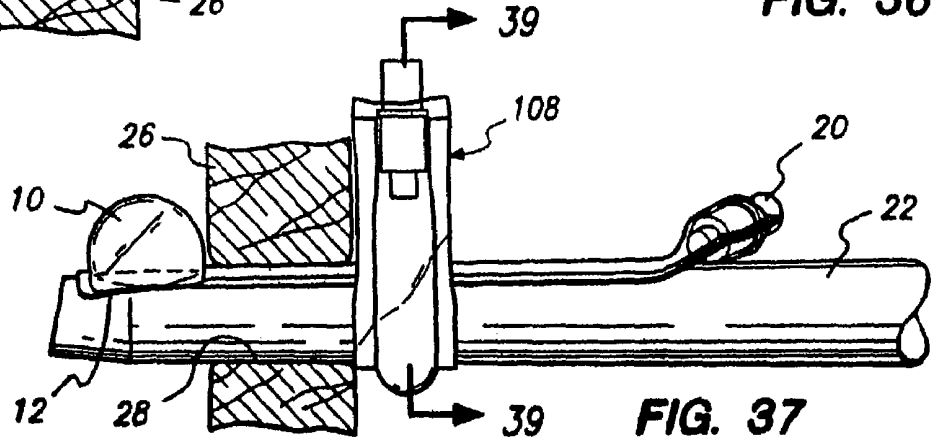

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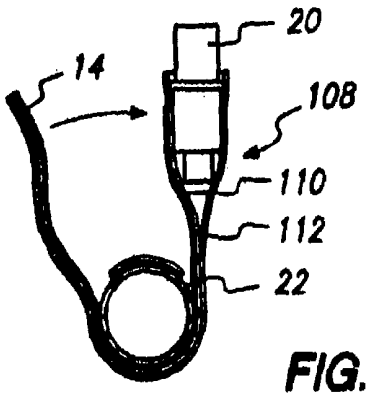

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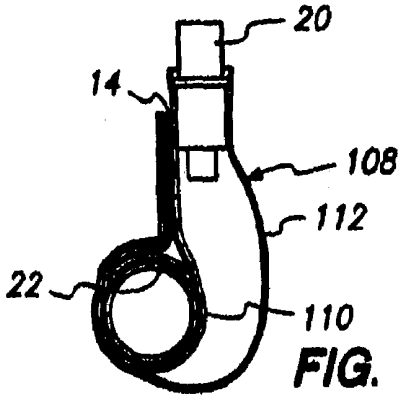

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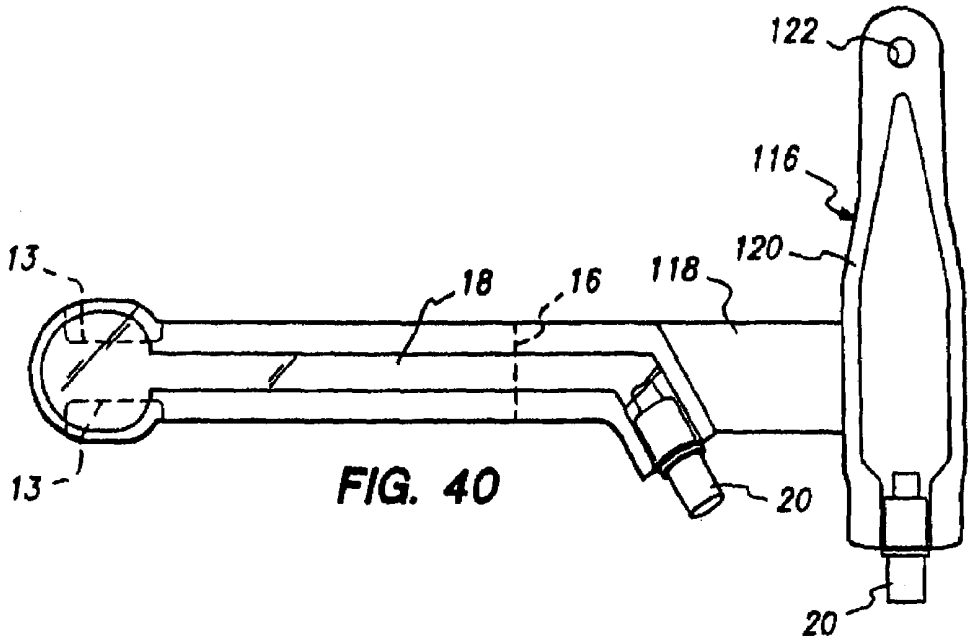
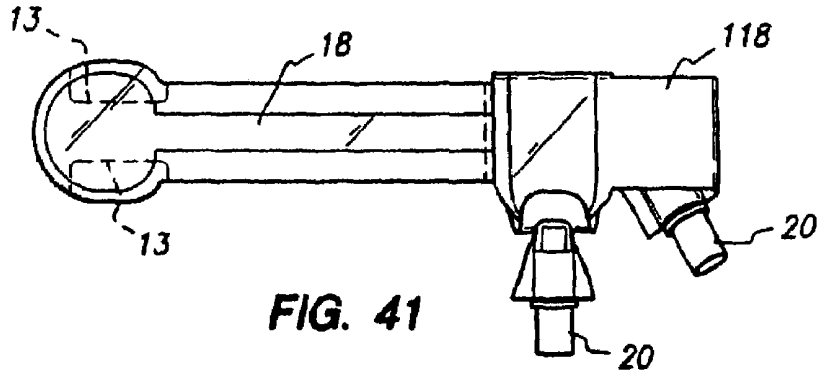


FIG. 40



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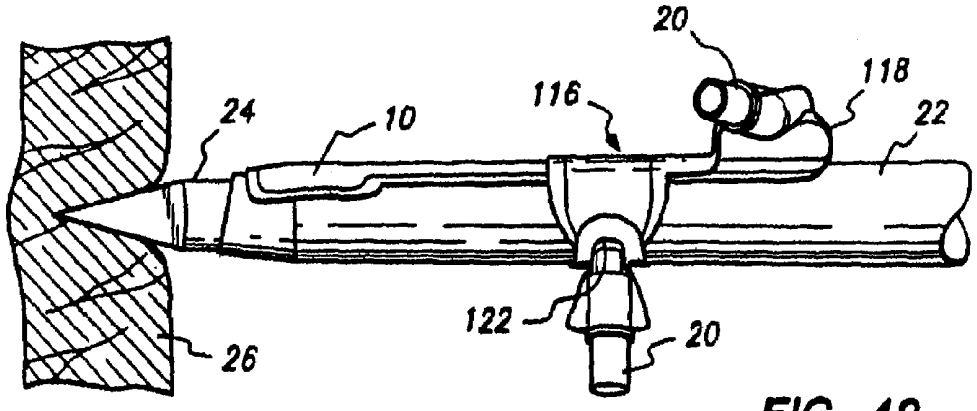

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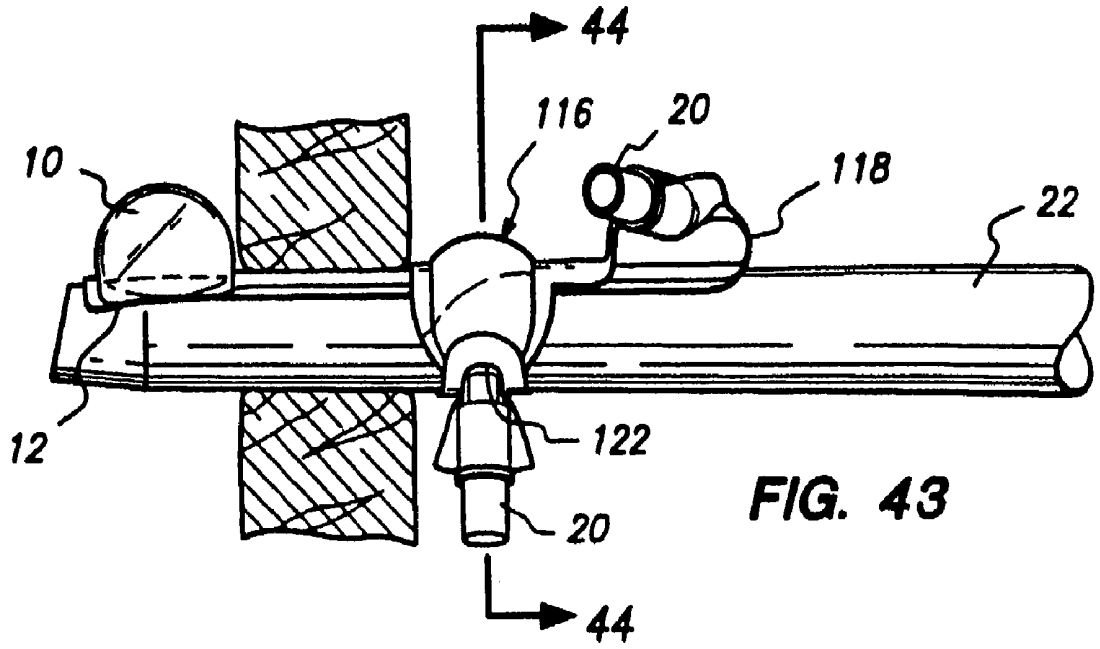

FIG. 43

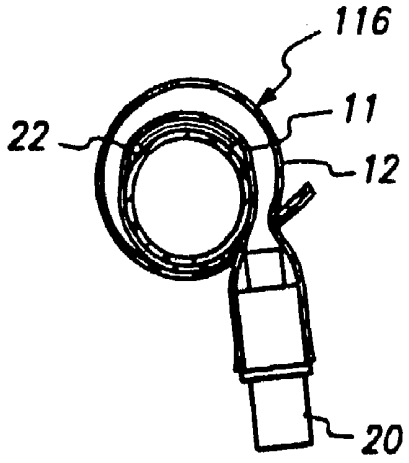

FIG. 44

METHOD AND APPARATUS FOR ANCHORING LAPAROSCOPIC INSTRUMENTS

CROSS-REFERENCE TO RELATED APPLICATIONS

The present application is a continuation of and claims the benefit of priority to U.S. patent application Ser. No. 08/447,794 filed on May 23, 1995 now U.S. Pat. No. 6,524,283, which is a Divisional Application of and claims the benefit of priority to application Ser. No. 08/320,042 now U.S. Pat. No. 5,697,946 filed on Oct. 7, 1994, the entire contents of which are incorporated herein by reference.

BACKGROUND OF THE INVENTION

The present invention relates to an improved anchor for securing laparoscopic instruments within puncture opening during surgery. In its more specific aspects, the invention is concerned with a balloon anchor adapted to be secured to the outside surface of virtually any laparoscopic instrument, without the necessity of modifying the structure of the instrument.

Laparoscopic surgery provides a minimally invasive approach to a wide variety of surgical procedures in, for example, the abdominal and thoracic cavities. In a minimally invasive approach, small incisions are made to provide access for instruments needed to perform surgery. The instruments, such as trocars, endoscopes, clip appliers, cautery devices and other tools, are commonly inserted through these small incisions using cannulas which are adapted to provide a pressure seal when using pneumoperitoneum. It is desirable to secure or anchor these cannulas into position in the incision to allow easy insertion and withdrawal of instruments through the cannula without corresponding movement of the cannula. Likewise, it is sometimes desirable to secure or anchor an instrument itself in an incision and prevent unwanted distal or proximal movement of the instrument.

Prior anchors for laparoscopic instruments have employed threaded sleeves adapted to be secured to the instruments and screwed into a laparoscopic puncture opening to secure the instrument in place. An anchor of this type is found in U.S. Patent No. 5,217,441. Such anchors require a specific size for each size of instrument, since the sleeve must be of a configuration complemental to that of the instrument. The screw threads also must be twisted into place and are relatively traumatic.

The prior art also teaches adhesive anchors, sometimes called "grippers," for securing laparoscopic instruments in place within puncture openings. Such anchors employ a tubular boss configured to snugly engage the instrument and a flexible disk carried by the boss for adhesion to the outside surface of the punctured tissue. The boss must be specifically configured to match the configuration of the instrument being anchored. Blood emitting from the puncture opening often intrudes between the disk and the tissue so as to destroy the integrity of the anchor during surgery.

The prior art also teaches the provision of specially constructed laparoscopic cannula provided with inflatable balloons to anchor the cannula in place within a puncture opening. A cannula of this type may be seen in U.S. Pat. No. 5,002,557. Such cannula are expensive to fabricate and must be especially configured to match the instrument with which they are used.

It is also old in the art to anchor drainage catheters with balloons incorporated into the catheter. One well-known catheter of this type used for urinary drainage is the "Foley" catheter. In such catheters, the balloon and the conduit provided for its inflation is integrally molded into the catheter.

SUMMARY OF THE INVENTION

The present invention is an improvement over the prior art in that it provides a universal balloon anchor which may be secured to the outside of a laparoscopic instrument and inflated to anchor the instrument in place within a puncture opening. The balloon is configured so as to have a low profile generally contiguous with the outside surface of the instrument to facilitate its low insertion force placement and removal, without significant trauma to the tissue defining a small laparoscopic opening.

In its broadest aspects, the anchoring system of the invention provides a low profile balloon adapted to be engaged with the outside surface of a laparoscopic instrument. In the preferred embodiments, the balloon is adhesively secured to the instrument. Certain embodiments also employ mechanical structure to constrain the balloon and hold it in place. Conduit means for inflating the balloon is also secured externally of the instrument being anchored.

In the method of the invention, the balloon is secured to the outer surface of an instrument to be anchored with the balloon in a deflated low profile configuration essentially contiguous with the outer surface of the instrument. The instrument is then extended through the puncture opening within which it is to be anchored so as to dispose at least a portion of the balloon to the inside of the opening. The balloon is then inflated to anchor the instrument.

A principal object of the invention is to provide a universal anchor which may be secured to virtually any instrument used for laparoscopic surgery to anchor the instrument within a puncture opening.

Another and related object is to provide such an anchor which is inexpensive and may be used with a minimum of trauma to the punctured tissue.

Yet another object of the invention is to provide such an anchor which can accommodate puncture openings formed in tissues of different wall thicknesses.

Still another object of the invention is to provide such an anchor which may form a seal around the puncture.

Still another and more specific object of the invention is to provide such an anchor which may lock the instrument against movement either into or out of a puncture opening.

A further object of the invention is to provide such an anchor which may be used for both gasless- and gas-(insufflation) type laparoscopic surgery.

Another object of the invention is to provide such an anchor which may be located anywhere along the length of a laparoscopic instrument and which can be used in multiples, if desired.

Yet a further object of the invention is to provide such an anchor which is ideally suited for one-time use and does not have such bulk as to create undue disposal problems.

The foregoing and other objects will become more apparent when viewed in light of the following detailed description and accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a plan of a first embodiment of the anchor, employing a balloon provided with an adhesive backing wherein a shielding strip is temporarily disposed over the backing;

FIG. **2** is an elevational view of the anchor shown in FIG. **1**;

FIG. **3** is a cross-sectional view of the anchor shown in FIG. **1**, taken on the plane designated by line **3**—**3**;

FIG. **4** is an elevational view of the FIG. **1** anchor in place on a trocar sheath, with the balloon of the anchor in a deflated condition and a trocar extended through the sheath in the process of forming a puncture opening in a tissue layer;

FIG. **5** is an elevational view similar to that of FIG. **4**, showing the sheath fully extended through the puncture opening, with the balloon inflated and the trocar removed from the sheath;

FIG. **6** is a plan view of a second embodiment of the anchor, employing a balloon of an elongate generally hour-glass-shaped configuration provided with an adhesive backing wherein a shielding strip is temporarily disposed over the backing;

FIG. **7** is an elevational view of the anchor shown in FIG. **6**;

FIG. **8** is an cross-sectional view of the anchor shown in FIG. **6**, taken on the plane designated by line **8**—**8**;

FIG. **9** is an elevational view of the FIG. **6** anchor in place on a trocar sheath with the balloon of the anchor in a deflated condition and a trocar extended through the sheath in the process of forming a puncture opening in a tissue layer;

FIG. **10** is an elevational view similar to FIG. **9**, showing the sheath fully extended through the puncture opening, with the balloon inflated and the trocar removed from the sheath;

FIG. **11** is a plan view of a third embodiment of the anchor, employing a balloon having a securing patch disposed thereover wherein the patch is provided with an adhesive backing and a shielding strip is temporarily disposed over the backing;

FIG. **12** is an elevational view of the anchor shown in FIG. **11**;

FIG. **13** is a cross-sectional view of the anchor shown in FIG. **11**, taken on the plane designated by line **13**—**13**;

FIG. **14** is an elevational view of the FIG. **11** anchor in place on a trocar sheath, with the balloon of the anchor in a deflated condition and a trocar extended through the sheath in the process of forming a puncture opening in a tissue layer;

FIG. **15** is an elevational view similar to that of FIG. **14**, showing the sheath fully extended through the puncture opening, with the balloon inflated and the trocar removed from the sheath;

FIG. **16** is a plan view of a fourth embodiment of the anchor employing a balloon, wherein the balloon has two separately inflatable chambers and an adhesive backing with a shielding strip temporarily disposed over the backing;

FIG. **17** is an elevational view of the anchor shown in FIG. **16**;

FIG. **18** is a cross-sectional view of the anchor shown in FIG. **16**, taken on the plane designated by line **18**—**18**;

FIG. **19** is an elevational view of the FIG. **16** anchor in place on a trocar sheath with the balloon of the anchor in a deflated condition and the trocar extended through the sheath in the process of forming a puncture opening in a tissue layer;

FIG. **20** is an elevational view similar to that of FIG. **19**, showing the sheath fully extended through the puncture opening, with both chambers of the balloon inflated and the trocar removed from the sheath;

FIG. **21** is a perspective view of a fifth embodiment of the anchor employing a balloon with an adhesive backing, wherein the balloon is elongate and extends across the backing;

FIG. **22** is a perspective view of the anchor shown in FIG. **21** adhesively secured to a trocar sheath, with the balloon in a deflated condition folded against the sheath;

FIG. **23** is a perspective view similar to that of FIG. **22**, showing the balloon inflated and extending transversely to either side of the sheath;

FIG. **24** is an elevational view of a sixth embodiment of the anchor in place on a trocar sheath, with the balloon of the anchor in a deflated condition and a trocar extended through the sheath in the process of forming a puncture opening in a tissue layer;

FIG. **25** is an elevational view similar to that of FIG. **24**, showing the sheath fully extended through the puncture opening, with the balloon inflated and the trocar removed from the sheath;

FIG. **26** is a cross-sectional view taken on the plane designated by line **26**—**26** of FIG. **24**;

FIG. **27** is a cross-sectional view taken on the plane designated by line **27**—**27** of FIG. **25**;

FIG. **28** is an elevational view of a seventh embodiment of the anchor in place on a trocar sheath, with the balloon of the anchor in a deflated condition and a trocar extended through the sheath in the process of forming a puncture opening in a tissue layer;

FIG. **29** is an elevational view similar to that of FIG. **28**, showing the sheath fully extended through the puncture opening, with the balloon inflated and the trocar removed from the sheath;

FIG. **30** is a cross-sectional view taken on the plane designated by line **30**—**30** of FIG. **28**;

FIG. **31** is a cross-sectional view taken on the plane designated by line **31**—**31** of FIG. **29**;

FIG. **32** is an elevational view of an eighth embodiment of the anchor in place on a trocar sheath with the balloon of the anchor in a deflated condition and a trocar extended through the sheath in the process of forming a puncture opening in a tissue layer;

FIG. **33** is an elevational view similar to that of FIG. **32**, showing the sheath fully extended through the puncture opening, with the balloons of the anchor inflated and the trocar removed from the sheath;

FIG. **34** is a cross-sectional view taken on the plane designated by line **34**—**34** of FIG. **33**;

FIG. **35** is a plan view of a flat balloon adapted to be wrapped around a trocar sheath to provide a generally angular balloon in a ninth embodiment of the anchor;

FIG. **36** is an elevational view of the ninth embodiment of the anchor in place on a trocar sheath, with the balloons of the anchor in a deflated condition and a trocar extending through the sheath in the process of forming a puncture opening in a tissue layer;

FIG. **37** is an elevational view similar to that of FIG. **36**, showing the sheath fully extended through the puncture opening, with the balloons inflated and the trocar removed from the sheath;

FIG. **38** is a cross-sectional view taken on the plane designated by line **38**—**38** of the FIG. **36**;

FIG. **39** is a cross-sectional view taken on the plane designated by line **39**—**39** of FIG. **37**;

FIG. **40** is a plan view of a tenth embodiment of the anchor employing a distal balloon corresponding generally to that of the first embodiment and a proximal balloon connected to the distal balloon by a web;

FIG. **41** is a plan view of the tenth embodiment anchor wherein the proximal balloon has been folded over and wrapped around the air passage leading to the distal balloon;

FIG. **42** is an elevational view of the tenth embodiment anchor in place on a trocar sheath, with the balloons of the anchor in a deflated condition and a trocar extending through the sheath in the process of forming a puncture opening in a tissue layer;

FIG. **43** is an elevational view similar to that of FIG. **42**, showing the sheath fully extended through the puncture opening, with the balloons inflated and the trocar removed from the sheath; and,

FIG. **44** is a cross-sectional view taken on the plane designated by line **44**—**44** of FIG. **43**.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

First Embodiment

As shown in FIGS. **1**–**3**, this embodiment comprises an elastomeric balloon **10** having a first film layer **11** of elastic or semi-elastic material, and a second film layer **12** of elastic, semi-elastic or inelastic material. Second film layer **12** is ideally very flexible so that it can easily confirm to the outside surface of an instrument such as a trocar sheath. Preferably, first film layer **11** and second film layer **12** are made of material suitable for medical applications having a good strength to thickness ratio. Thinner materials facilitate lower deflated profiles and thus lower incision insertion forces. First film layer **11** can be made of urethane or other appropriate film. A semi-elastic PS-8010 polyurethane film, referred to as PS-8010, manufactured by Deerfield Urethane of Deerfield, Mass. is suitable. Second film layer **12** is preferably a flexible inelastic material, such as polyester. A suitable material is Rexham 705517 manufactured by Rexham Industrial, Inc. of Matthews, N.C. Alternatively, first and second film layers **11**, **12** can be made of the same elastic or semi-elastic material if desired. A contact adhesive **14** is adhered to the undersurface of second layer **12** and covered by a removable paper or plastic shielding strip **16**. Contact adhesive **14** and corresponding shielding strip **16** are cut-away at portions **13** to facilitate unrestrained expansion of the balloon upon inflation. An inflation tube **18** is integrally formed by bonding first and second film layers **11**, **12** together. A check valve or stop cock **20** is secured to the proximal end of the tube **18** for purposes of introducing inflation fluid (liquid or gas) into the tube **18**.

In the embodiment illustrated, the balloon **10** is formed by peripherally bonding first layer **11** and second layer **12** together thereby creating a sealed inflatable chamber **9** therebetween. An alternative construction for the balloon would be to fabricate the balloon as a closed elastomeric envelope with contact adhesive applied directly one side of the envelope. With such a construction, a removable paper or plastic shielding strip would also be provided over the adhesive. In use, the balloon of such a construction would be adhered directly to an instrument with the contact adhesive. The surface of the instrument would serve as the inelastic backing restraining the balloon from elongation upon inflation.

FIG. **4** illustrates the first embodiment balloon attached to the smooth outer surface of an instrument, in this case a conventional trocar sheath **22**. As there shown, the shielding strip **16** has been removed from the adhesive **14** and the second film layer **12** is adhered to the sheath by the adhesive. In the deflated condition shown in FIG. **4**, the balloon **10** and tube **18** have a low profile essentially contiguous with the outside surface of the sheath **22**.

FIG. **4** also shows a sharp tipped trocar **24** extending through the sheath **22** and into piercing engagement with a layer of living tissue **26** such as an abdominal wall. The sheath **22** is telescopically received on the trocar **24** and moves with the trocar through the tissue **26**.

FIG. **5** shows the sheath **22** extended fully through a puncture opening **28** which has been formed by the trocar **24**, with the trocar removed from the sheath. As shown in FIG. **5**, the balloon **12** has been inflated to the interior of the tissue to anchor the sheath distally against removal from the puncture. With the sheath so anchored, other instruments can be passed therethrough for diagnostic or surgical purposes and withdrawn from the sheath without unwanted proximal movement of the sheath. Upon completion of the procedure, the balloon **12** is deflated to return to the condition shown in FIG. **4** and the sheath may be removed from the incision with a minimum of trauma.

Second Embodiment

This embodiment is illustrated in FIGS. **6**–**10** and is similar to the first embodiment, with the exception that the balloon **10***a* is of an elongate hourglass-shaped configuration. Parts of the second embodiment corresponding to those of the first embodiment are designated by like numerals followed by the letter a, as follows: elastic balloon **10***a*; first layer **11***a*; second layer **12***a*; chamber **9***a*; adhesive cut-away portions **13***a*; contact adhesive **14***a*; shielding strip **16***a*; inflation tube **18***a*; and check valve or stop cock **20***a*.

The second embodiment balloon is applied and used in the same way as that of the first embodiment. As seen in FIG. **9**, the balloon is adhered to the outside surface of a trocar sheath **22** so as to extend longitudinally of the sheath. The hourglass shape of the balloon **10***a* provides distal and proximal portions **30** and **32**, respectively. Upon extension of the sheath **22** through the tissue as shown in FIG. **10**, these portions are disposed to either side of the tissue **26** to anchor the sheath **22** against movement distally into or proximally out of the opening **28** through which the sheath extends. The necked-down portion of the balloon **10***a*, designated **34**, does not significantly expand upon inflation of the portions **30** and **32**. Constraint of the portion **34** is provided both by its reduced dimension, as compared to the portions **30** and **32**, and its adherence to the second film layer **12***a*.

Like the first embodiment balloon, when in the deflated condition the balloon **10***a* assumes a low profile configuration essentially contiguous with the outside surface of the sheath **12**. This minimizes trauma to the tissue both during insertion and removal of the sheath.

Third Embodiment

As shown in FIGS. **11**–**15**, the third embodiment is similar to that of the first embodiment, with the exception that the balloon, designated **10***b*, is a closed elastomeric envelope having top and bottom surfaces; and the backing strip is a patch **36** adhered to and extending over the balloon. The patch **36** is provided with contact adhesive **38** to either side of the balloon **10***b*. A removable paper or plastic shielding strip **16***b* extends across the balloon **10***b* and over the adhesive **38**. Inflation tube **18***b* for the third embodiment is

contiguous with the balloon **10***b* and also adhered beneath the patch **36**. Contact adhesive **38** on the patch **36** is disposed to either side of the tube **18***b* and covered by the removable shielding strip **16***b*. A check valve or stop cock **20***b* is secured in the proximal end of the inflation tube **18***b*.

In use, the shielding strip **16***b* is removed from the adhesive **38** and the balloon assembly is secured directly to the outside surface of the instrument with which it is used by the patch **36**. FIG. **14** shows the balloon so applied to a trocar sheath **22** having a trocar **24** extended therethrough. The adhesive **38** to either side of the balloon lob and inflation tube **18***b* adheres directly to the smooth outside surface of the trocar sheath **22**. A perforated tear line **40** is formed in the patch **36** over the balloon **10***b*.

Once secured in place as shown in FIG. **14**, the third embodiment balloon **10***b* is extended through the tissue **26** in the same manner as the first embodiment balloon. After being extended fully through the tissue as shown in FIG. **40**, the balloon is inflated to the inside of the tissue. Such inflation functions to tear the patch **36** along the frangible tear line **40**. Upon completion of the surgical procedure or as otherwise desired, the balloon may be deflated to return to its condition closely contiguous to the sheath so that the sheath may be removed with a minimum of trauma.

The third embodiment sheath shown in FIGS. **11**–**15** is provided with a thin spacer string **42** between the inner and outer sides of the balloon **10***b*. Ideally, this string extends over the full length of the balloon **10***b* and inflation tube **18***b* so as to prevent the sides of the balloon and tube from fully closing against one another when the balloon is in the deflated condition. The space provided by the string provides a fluid passage and facilitates inflation of the balloon with a minimum of pressure. Although the string is only shown in the third embodiment, it should be understood that it might be applied to any of the embodiments discussed herein.

Fourth Embodiment

As shown in FIGS. **16**–**20**, the fourth embodiment corresponds to the first embodiment, with the addition that it is provided with a second balloon **44** of an elongate-divergent configuration. The balloon **44**, as may be seen in FIG. **16**, diverges from the distal balloon, designated **10***c*. The balloons **10***c* and **44** provide separate inflation chambers. A separate inflation tube **46** having a check valve or stop cock **48** is provided for inflation of the balloon **44**. The elements of the fourth embodiment corresponding to those of the first embodiment are designated by like numerals, followed by the letter c, as follows: balloon **10***c*; first film layer **12***c*; second film layer **12***c*; adhesive cut-away portions **13***c*; contact adhesive **14***c*; shielding strip **16***c*; inflation tube **18***c*; and, check valve or stop cock **20***c*.

The fourth embodiment anchor is applied to an instrument and surgically inserted in the same manner as the first embodiment anchor. Such an application may be seen in FIG. **19** wherein the fourth embodiment anchor is shown attached to the smooth outside surface of the trocar sheath **22** having a sharp tipped trocar **24** extended therethrough into piercing engagement with a layer of living tissue **26**. Once extended through the tissue as shown in FIG. **20***a*, the balloon **10***c* is first inflated to the interior of the tissue to anchor the sheath against removal in the proximal direction. The second balloon **44** is then inflated to anchor the sheath against movement interiorally of the tissue in the distal direction relative to the user. The elongate tapered configuration of the balloon **44** accommodates tissue of virtually any thickness and can also serve to form a seal between the interior of the puncture **28** and the sheath **22**. Upon completion of the surgical procedure, both balloons are deflated and the sheath is removed, with a minimum of trauma.

Fifth Embodiment

The balloon of this embodiment, as shown in FIGS. **21**–**23**, is of a generally T-shaped configuration and fabricated of superimposed sheets of flexible inelastic film. The commercially available film known as Rexham 705517 has been found suitable.

FIG. **21** shows the fifth embodiment anchor in deflated condition as it would be supplied for use with any desired surgical instrument. The anchor comprises a balloon **52** fabricated of superimposed peripherally connected sheets of elastic, semi-elastic or inelastic flexible film. Preferably, semi-elastic urethane material is used. The balloon has an elongate transverse section **56** and a longitudinally extending section **58**. An inflation tube **60** having a check valve or stop cock **62** is secured in fluid communication with the section **58**. A contact adhesive layer is secured to and extends over the section **58**. A removable shielding strip **66** is disposed over the adhesive **64**. As shown, the adhesive **64** is adhered directly to the balloon **52**.

The fifth embodiment anchor is adhered to the outside surface of an instrument and used in essentially the same manner as the first embodiment anchor. FIG. **22** shows the anchor secured to a trocar sheath **22**. As there shown, the shielding strip **66** has been removed from the adhesive and the section **58** has been adhered longitudinally of the sheath with the adhesive **64**. While FIG. **22** shows the ends of the transverse balloon section **56** folded over the section **58**, it should be understood that these ends are not adhered to the sheath. The folded over condition is simply for purposes of reducing the profile of the balloon during insertion.

FIG. **23** shows the balloon as it would appear after inserted into place through a puncture and inflated. Such insertion would be carried out in essentially the same manner shown in FIGS. **4** and **5**. Once in place with the transverse section **56** to the interior of the pierced tissue, inflation of the anchor functions to expand the transverse section transversely of the trocar sheath **22**, thus securely anchoring the sheath against removal from the puncture opening. Upon completion of the surgical procedure, the balloon is deflated and may collapse against the sheath upon removal, with a minimum of trauma.

Sixth Embodiment

The sixth embodiment anchor is of an elongate toroidal configuration and adapted to be slipped over and around a surgical instrument, without need for an adhesive. As shown in FIGS. **24**–**27**, this embodiment comprises: an elongate toroidal elastic balloon **68**; spaced proximal and distal rings **70** and **72**, respectively, disposed within the balloon **68**; an intermediate ring **74** disposed around the balloon between the proximal and distal rings; and, an inflation tube **76** communicating with the interior of the balloon through a flange **78** on the ring **70**. As shown, the balloon **68** is fabricated of a sleeve folded over upon itself with one end of the sleeve tied to the ring **72** by a cord **80** and the other end of the sleeve tied to the outside of the flange **78** by a cord **82**.

In use, the sixth embodiment anchor is simply slipped over the instrument to which it is applied. In the exemplary embodiment illustrated, the instrument comprises a trocar

sheath **22**. As shown in FIG. **24**, the balloon is deflated and a sharp tipped trocar **24** extends through the sheath **22** into piercing engagement with a layer of living tissue **26**. Once fully extended through the tissue, the balloon **68** is inflated as shown in FIG. **25** to expand to either side of the tissue. As so expanded, the balloon forms donut-shaped barriers to either side of the tissue. Expansion of the balloon within the thickness of the tissue is prevented by the ring **74**. The space between the rings **72** and **70** permits the interior wall of the balloon to expand into gripping engagement with the sheath, as shown in FIG. **27**. Thus, the sheath is anchored against movement into or out of the pierced tissue. Upon completion of the surgical procedure, the balloon is deflated and returns to the condition shown in FIG. **26**, thus permitting removal of the anchor with a minimum of trauma.

To maintain the orientation of the rings in the sixth embodiment, one or more thin ribs may be provided between the proximal and distal rings **70** and **72**. These ribs (not illustrated) are so proportioned and spaced so as not to interfere with inward expansion of the balloon into gripping engagement with the sheath, as shown in FIG. **27**. The outer intermediate ring **74** may be adhered to the outside surface of the balloon **68** to prevent its displacement along the balloon.

Seventh Embodiment

The seventh embodiment anchor is similar to that of the sixth embodiment in that it employs an elongate toroidal balloon adapted to be received around the instrument to be anchored. In the case of the seventh embodiment, however, the balloon is preferably fabricated so that the distal portion of the balloon is elastomeric and the proximal portion is inelastic. FIG. **30** shows such a construction wherein an inner elastomeric sleeve **84** is folded upon itself to provide a distal balloon section **86**. An inelastic sleeve **88** is extended over the sleeve **84**. The inelastic sleeve **84** is circumferentially welded to the folded over end of the inner sleeve **84** at a weld line **90**. From the weld line to the distal end of the inelastic sleeve a perforated tear line **92** is provided to permit the sleeve to break upon expansion of the distal balloon section **86**. The proximal end of the outer inelastic sleeve **88** is folded upon itself and circumferentially sealed to a flange member **94** by a tie. An inflation tube **96** extends through the flange member **94** into fluid communication with the interior of the balloon formed by the sleeves **84** and **88**.

In use, the seventh embodiment anchor is slipped around the instrument to be anchored. As shown in FIG. **28**, the instrument comprises a trocar sheath **22** having a sharp tipped trocar **24** extending therethrough in the process of piercing an opening in a layer of living tissue **26**. The trocar is pushed fully through the tissue, together with the anchor. Once in place, as shown in FIG. **29**, the trocar is removed and the balloon is inflated. Inflation functions to form toroidal balloon sections to either side of the tissue and to interiorally expand the balloon into gripping engagement with the sheath. Thus, the sheath is anchored against movement into or out of the tissue.

It will be appreciated that upon expansion of the distal balloon section **86** the inelastic sleeve tears along the tear line **92**. That portion of the sleeve **88** within the tissue remains intact and functions to constrain the balloon. The proximal end of the balloon, designated **98**, expands to a toroidal configuration by unfolding the folded over portions of the sleeve **88** (see FIG. **30**). Upon completion of the surgical procedure, the balloon is deflated, thus permitting the anchor to be removed with a minimum of trauma.

Eighth Embodiment

This embodiment is illustrated in FIGS. **32**–**34** and corresponds to the first embodiment, with the addition that it is provided with a toroidal balloon assembly **100** adapted to be slidably received around the balloon **10** and its air passage **18**. Elements of the eighth embodiment corresponding to those of the first embodiment are designated by like numerals. The purpose of the torodial balloon assembly **100** is to provide an anchor "ring" which can be freely moved along a trocar sheath or other instrument to which the balloon **10** is adhered to provide a skin-side anchor which may be adjusted to accommodate the thickness of the tissue (e.g., abdominal wall) through which the sheath is extended. Initially, the balloon assembly is in a deflated condition and freely movable along the sheath. Upon being adjusted to the desired position (see FIG. **33**), the assembly is inflated, thus causing its inner diameter to decrease into secure gripping engagement with the sheath.

Ideally, the balloon assembly **100** is fabricated with an elastic or semi-elastic inner film layer **102** and an elastic or semi-elastic outer film layer **104** which are peripherally RF welded together. The materials for these layers may be the same as those suggested for the balloon of the first embodiment. A check valve or stop cock **20** is sealingly secured in the open end of the balloon assembly **100**.

The inner construction of the toroidal balloon assembly **100** is illustrated in FIG. **34**. As there seen, the assembly is elongate and wrapped upon itself to form a toroidal configuration. The proximal and distal ends of the elongate balloon are adhered or welded together at area **106**. The trocar sheath **22** is shown slidably received within the toroid provided by the assembly.

In use of the eighth embodiment, the balloon **10** would be secured to the sheath in a manner identical to that described with respect to the first embodiment. The toroidal balloon assembly **100** would then be slid over the sheath in a deflated condition. Then the sheath would be passed through the tissue **26** and anchored against removal by inflation of the balloon **10**, as shown in FIG. **29**. The deflated toroidal assembly **100** would then be adjusted along the length of the sheath to engage the outside of the tissue and then inflated, as shown in FIG. **33**. The latter inflation functions to expand the assembly **100** into gripping engagement with the sheath and anchor the sheath against movement distally relative to the tissue.

Ninth Embodiment

This embodiment is shown in FIGS. **35**–**39** and is similar to the eighth embodiment in that it is used with the distal balloon **10** of the first embodiment and provides a skin-side anchor. It differs from the eighth embodiment only in the construction of the skin-side anchor assembly, designated **108**. Elements of the ninth embodiment corresponding to those of the first embodiment are designated by like numerals.

The anchor assembly **108** is similar to the assembly **100** in that it is fabricated of an elastic or semi-elastic inner film layer **110** and an inelastic or semi-elastic outer film layer **112** peripherally RF welded together to provide a balloon. In the case of the assembly **108**, however, a weld line **114** is formed to extend across the assembly intermediate its length so that the balloon only extends over approximately one-half of the length of the assembly (see FIG. **35**). Also, in the case of the ninth embodiment, the distal and proximal ends of the assembly are not welded together, but rather are provided

with contact adhesive **14** whereby they may be selectively secured together after being wrapped around an instrument. A check valve or stock cock **20** is sealingly received in the open end of the balloon provided by the assembly **108**.

FIGS. **38** and **39** show how the assembly **108** is placed around the trocar sheath **22**. In FIG. **38**, the assembly is being wrapped around the sheath. In FIG. **39**, the distal and proximal ends of the assembly have been secured together by the adhesive **14** and the balloon has been inflated to expand the assembly into gripping engagement with the sheath.

In use, the ninth embodiment anchor is passed through a tissue layer in the same manner as the first embodiment anchor and the distal balloon **10** is then inflated, as seen in FIG. **37**. Then the assembly **108** is slid along the sheath **22** into engagement with the outside surface of the tissue. Once so engaged, the assembly is inflated to securely engage the assembly with the outside surface of the sheath and anchor the sheath against distal movement relative to the tissue.

FIG. **36** shows the assembly **108** in place around the sheath prior to extension of the sheath through the tissue layer **26**. As an alternative, the assembly could be wrapped around the sheath after it has been extended through the tissue. Such a procedure is possible because the assembly is capable of being wrapped around the sheath after it is in place within a layer of body tissue.

Tenth Embodiment

This embodiment is shown in FIGS. **40–44** and also incorporates the distal balloon of the first embodiment. In the case of the tenth embodiment, however, a skin-side anchor assembly **116** is connected in transverse relationship to the inflation tube **18** by a flexible web **118**. Elements of the tenth embodiment corresponding to those of the first embodiment are designated by like numerals.

The assembly **116** and web **118** are fabricated from continuations of the film layers forming the balloon **10** and the tube **18**. These layers are peripherally welded together at a weld line **120** extending around the assembly **116**. One end of the assembly **116** is open and sealingly receives a check valve or stock cock **20**. An aperture **122** proportioned for receipt over the distal end of the valve **20** is formed in the end of the assembly **116** opposite that which receives the valve.

To prepare the tenth embodiment for use, the web **118** is folded over the tube **18** to dispose the first elastic film layer **11** of the assembly in opposition to the tube **18**. Then the assembly is wrapped around the inflation tube **118** to engage the aperture **122** over the distal end of the valve **20**, as shown in FIG. **41**. With the assembly **116** so prepared, the generally toroidal balloon provided by the anchor may be slipped over an instrument, such as a trocar sheath, with which it is used. Initially, the shielding strip **16** would be left in place as the anchor is so positioned. Once the balloon **10** is positioned as desired, its distal end would be lifted and the shielding strip would be removed. Then the balloon **10** and the inflation tube **18** would be pressed into secure adhered relationship with the outside of the instrument, as shown in FIG. **42**.

With the tenth embodiment anchor in place on a trocar sheath as shown in FIG. **42** and the balloons in deflated condition, the sheath is initially passed through a tissue layer and anchored with the distal balloon **10** in same manner as the first embodiment. Once so in place, the assembly **116** is slid along the sheath into engagement with the outside of the tissue, as shown in FIG. **43**, and inflated. The flexibility of the web **118** facilitates such adjustment. Inflation of the assembly **116** serves to secure the assembly against movement relative to the sheath and anchor the sheath against distal movement.

CONCLUSION

From the foregoing description, it is believed apparent that the present invention enables the attainment of the objects initially set forth herein. In particular, it provides an anchor which may be readily applied to any surgical instrument without modification of the instrument and which may be used with a minimum of trauma to the patient. While all embodiments serve as effective anchors, the tenth embodiment is considered the preferred embodiment because of its ease of manufacture from two layers of film material and the secure anchor which it provides against both proximal and distal movement. It should be understood, however, that the invention is not intended to be limited to the specifics of the illustrated embodiments, but rather is defined by the accompanying claims.

What is claimed as the invention is:

1. In combination with a trocar sheath, an improved anchoring system, comprising:

a balloon system operatively securable to an outer surface of the trocar sheath, the balloon system having a low profile when in a contracted non-inflated condition closely adjacent the outer surface of the trocar sheath and an anchoring profile when in an expanded inflated condition extending laterally asymmetrically from the trocar sheath; the balloon system including:

a self-contained balloon adapted to be secured along an outside surface of the instrument such that when the balloon system is in the anchoring profile the balloon extends in a laterally asymmetrical direction;

a conduit for selectively inflating a balloon portion of the balloon system, the conduit including a portion extending proximally along the outer surface of the trocar sheath; and

securing structure to selectively engage at least the self-contained balloon and the outer surface of the trocar sheath upon inflation thereof to thereby anchor the trocar sheath against distal movement relative to a tissue through which the trocar sheath extends.

2. In combination with a trocar sheath, an improved anchoring system, comprising:

an elongate toroidal balloon operatively engageable with an outer surface of the trocar sheath, the balloon having a low profile when in a contracted non-inflated condition closely adjacent the outer surface of the trocar sheath and an anchoring profile when in an expanded inflated condition extending radially outward from the trocar sheath;

a conduit for selectively inflating the balloon, the conduit including a portion extending proximally along the outer surface of the trocar sheath;

at least one ring interposed between the balloon and the trocar sheath; and

securing structure configured and adapted to allow a central portion of the balloon to press against the trocar sheath for anchoring of the balloon to the trocar sheath and to allow a distal end and a proximal end of the balloon to radially expand upon inflation of the balloon.

3. The anchoring system according to claim **2**, wherein the securing structure includes a ring disposed around the balloon between the proximal end and the distal end thereof, wherein the ring prevents expansion of the balloon within a thickness thereof.

4. The system according to claim 2, wherein the securing structure includes an inelastic sleeve disposed over the balloon, wherein the inelastic sleeve is circumferentially secured to the balloon along a weld line, the inelastic sleeve including a perforated tear line extending from the weld line to a distal end thereof.

5. In combination with a trocar sheath, an improved anchoring system, comprising:

a self-contained asymmetrically expandable balloon system operatively coupled to an outer surface of the trocar sheath, the balloon system having a low profile when in a contracted non-inflated condition which is closely adjacent the outer surface of the trocar sheath and an anchoring profile when in an expanded inflated condition extending laterally asymmetrically from the trocar sheath; and

an inflatable toroidal balloon system operatively engageable with the expandable balloon and the trocar sheath, the inflatable toroidal balloon system including:

an elongate tubular body having a distal end and a proximal end, the tubular body defining an inflatable chamber, wherein the distal end and the proximal end are securable to one another to define an aperture of the toroidal balloon system; and

a conduit in fluid engagement with one of the proximal and distal ends of the tubular body for delivering a fluid to the inflatable chamber of the tubular body.

6. In combination with a trocar sheath, an improved anchoring system, comprising:

an elongate toroidal balloon operatively engageable with an outer surface of the trocar sheath, the balloon having a low profile when in a contracted non-inflated condition closely adjacent the outer surface of the trocar sheath and an anchoring profile when in an expanded inflated condition extending radially outward from the trocar sheath;

a conduit for selectively inflating the balloon, the conduit including a portion extending proximally along the outer surface of the trocar sheath;

at least one ring interposed between the balloon and the trocar sheath; and

securing structure configured and adapted to allow a central portion of the balloon to press against the trocar sheath for anchoring of the balloon to the trocar sheath and to allow a distal end and a proximal end of the balloon to radially expand upon inflation of the balloon, wherein the securing structure includes a ring disposed around the balloon between the proximal end and the distal end thereof, wherein the ring prevents expansion of the balloon within a thickness thereof.

7. In combination with a trocar sheath, an improved anchoring system, comprising:

an elongate toroidal balloon operatively engageable with an outer surface of the trocar sheath, the balloon having a low profile when in a contracted non-inflated condition closely adjacent the outer surface of the trocar sheath and an anchoring profile when in an expanded inflated condition extending radially outward from the trocar sheath;

a conduit for selectively inflating the balloon, the conduit including a portion extending proximally along the outer surface of the trocar sheath; and

securing structure configured and adapted to allow a central portion of the balloon to press against the trocar sheath for anchoring of the balloon to the trocar sheath and to allow a distal end and a proximal end of the balloon to radially expand upon inflation of the balloon, wherein the securing structure includes an inelastic sleeve disposed over the balloon, wherein the inelastic sleeve is circumferentially secured to the balloon along a weld line, the inelastic sleeve including a perforated tear line extending from the weld line to a distal end thereof.

8. In combination with a trocar sheath having a longitudinal axis and a circumference, an improved anchoring system, comprising:

a self-contained asymmetric balloon system operatively secured to an outer surface of the trocar sheath, the balloon system including a balloon portion having an elongate shape extending along the longitudinal axis of the trocar sheath, the balloon portion having a low profile when in a contracted non-inflated condition closely adjacent the outer surface of the trocar sheath and an anchoring profile when in an expanded inflated condition extending laterally away from the longitudinal axis of the trocar sheath, the balloon portion extending on a portion of the circumference of the trocar sheath; the balloon system further including:

a conduit for selectively inflating the balloon portion of the balloon system, the conduit including a portion extending proximally along the outer surface of the trocar sheath; and

securing structure to selectively engage at least the self-contained balloon system and the outer surface of the trocar sheath upon inflation thereof to thereby anchor the trocar sheath against distal movement relative to a tissue through which the trocar sheath extends.

9. In combination with a trocar sheath, an improved anchoring system, comparing:

an elongate toroidal balloon operatively engageable with an outer surface of the trocar sheath, the balloon having a low profile when in a contracted non-inflated condition closely adjacent the outer surface of the trocar sheath and an anchoring profile when in an expanded inflated condition extending radially outward from the trocar sheath, the balloon having a length, wherein a portion of the length of said balloon is in contact with an outer surface of said trocar sheath;

a conduit for selectively inflating the balloon, the conduit including a portion extending proximally along the outer surface of the trocar sheath;

at least one ring interposed between the balloon and the trocar sheath; and

securing structure configured and adapted to allow a portion of the length of the balloon to press against the trocar sheath for anchoring of the balloon to the trocar sheath and to allow another portion of the balloon to radially expand upon inflation of the balloon.

10. The anchoring system according to claim 9, wherein said portion of the length of the balloon is a middle portion.

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专利名称(译)	用于锚固腹腔镜器械的方法和设备		
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申请(专利权)人(译)	料斗PHILLIP K. 科瓦奇TIM J. ROSCHAK埃德蒙 ENG WILSON		
当前申请(专利权)人(译)	COVIDIEN AG		
[标]发明人	HOPPER PHILLIP K KOVAC TIM J ROSCHAK EDMUND J ENG WILSON		
发明人	HOPPER, PHILLIP K. KOVAC, TIM J. ROSCHAK, EDMUND J. ENG, WILSON		
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摘要(译)

球囊锚固件用于将外科器械（例如传统的套管针护套）锚固在由套管针形成的穿刺开口内。当在套管针护套上使用时，当护套内的套管针形成开口时，锚固件固定到护套的光滑外表面以穿过穿刺开口延伸。提供粘合剂或机械装置以将气球固定到器械上。不需要修改仪器的结构。一旦在开口内就位，将球囊充气到组织内部以将器械固定在适当位置。某些实施例还提供球囊在开口内和/或外部的膨胀。