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(54) **ACCESS PORT FOR LAPAROSCOPIC SURGERY**

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(52) **U.S. Cl.** **606/108**

(57) **ABSTRACT**

An access port for use in laparoscopic surgery is disclosed. The port includes a duct having a one-way valve and a tubular seal. The one-way valve has opposed surfaces that co-apt in response to internal pressure within the duct. The tubular seal has an inner layer with a low friction coefficient surrounded by an outer elastic layer that biases the inner layer into sealing engagement with a surgical tool inserted through the duct. The one-way valve seals the duct in the absence of a tool extending through the duct. The low friction coefficient of the inner layer facilitates insertion and removal of the tool through the duct. The port has a distal end insertable into a pressurized cavity, and a proximal end that extends from the cavity and provides access thereto.

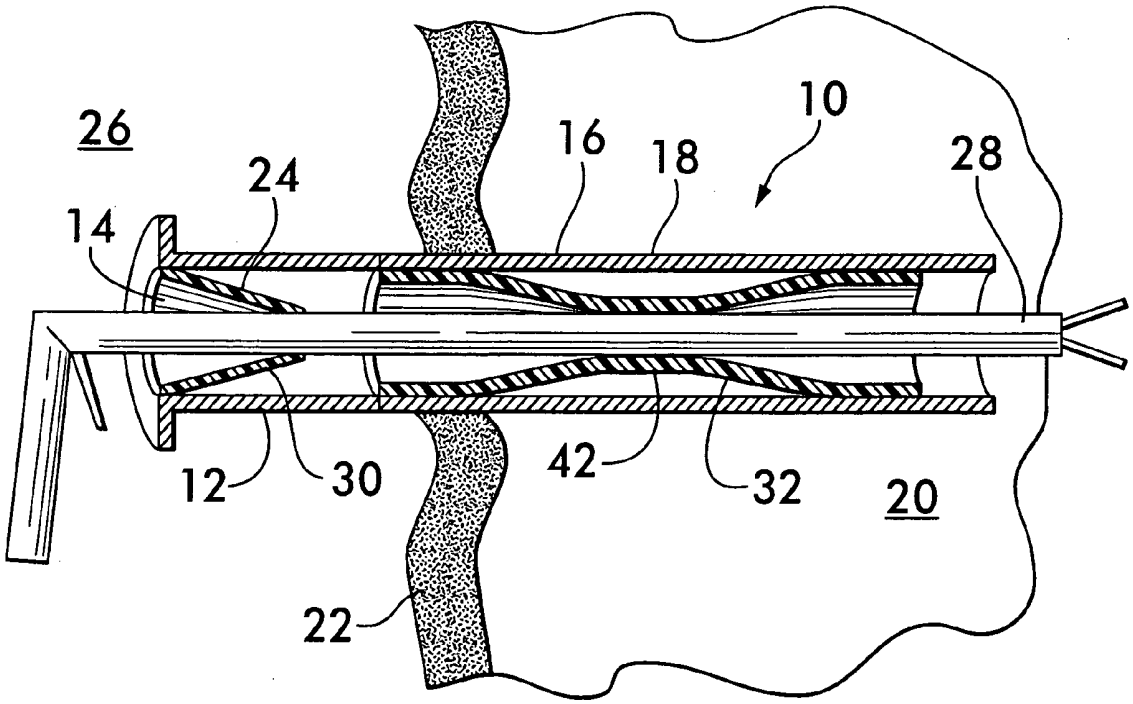


FIG.1

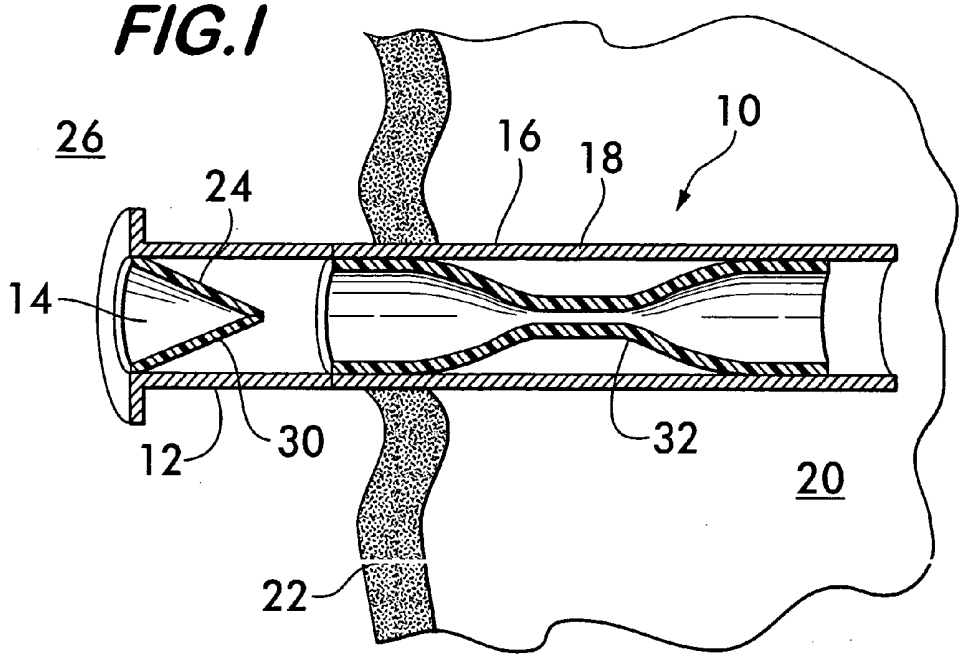


FIG.2

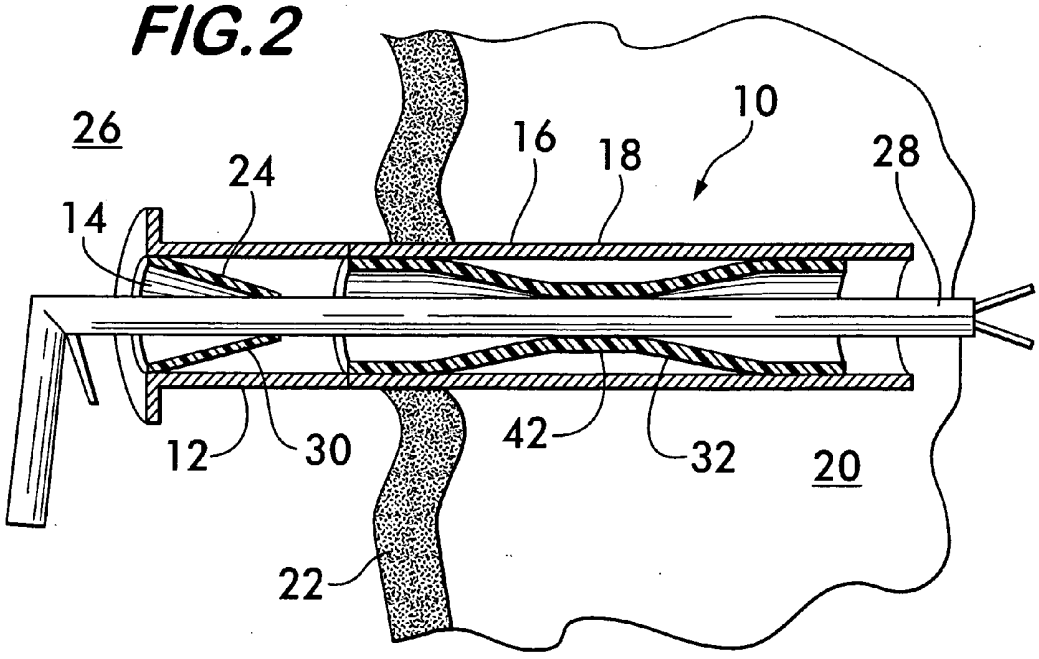
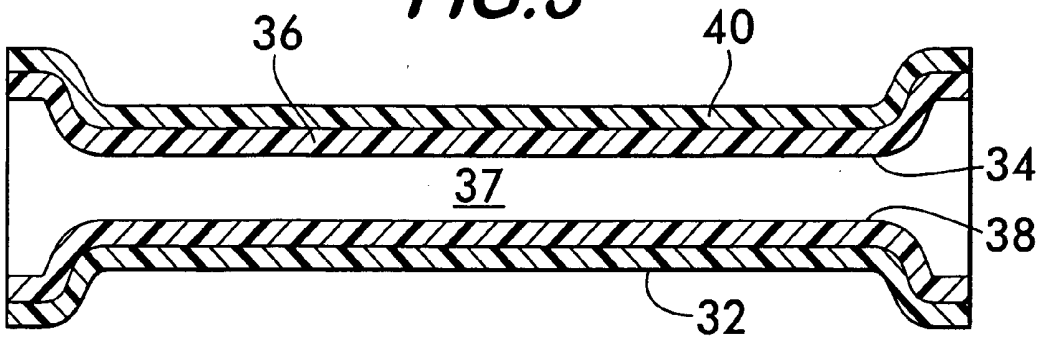


FIG.3



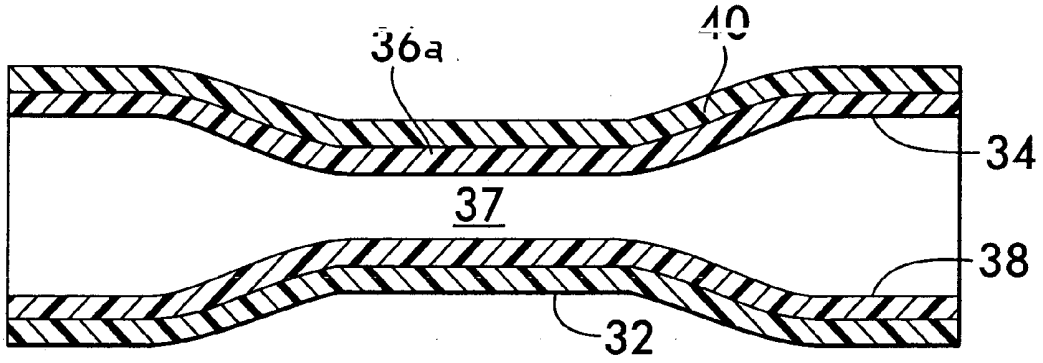


FIG.4

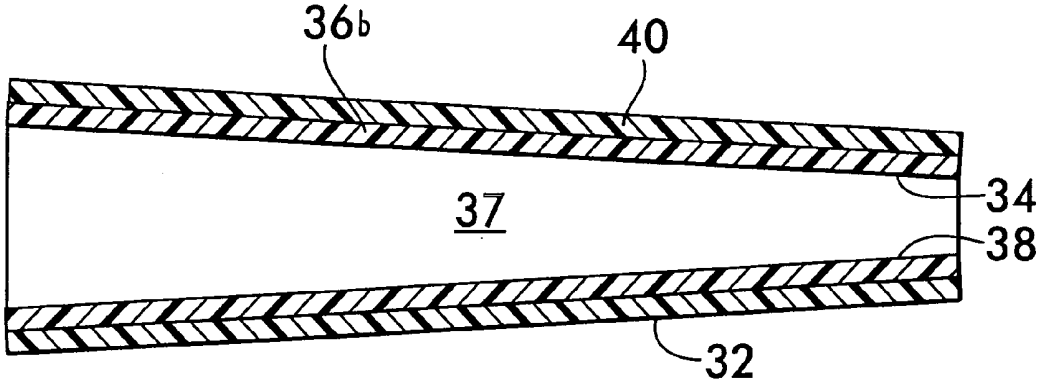


FIG.5

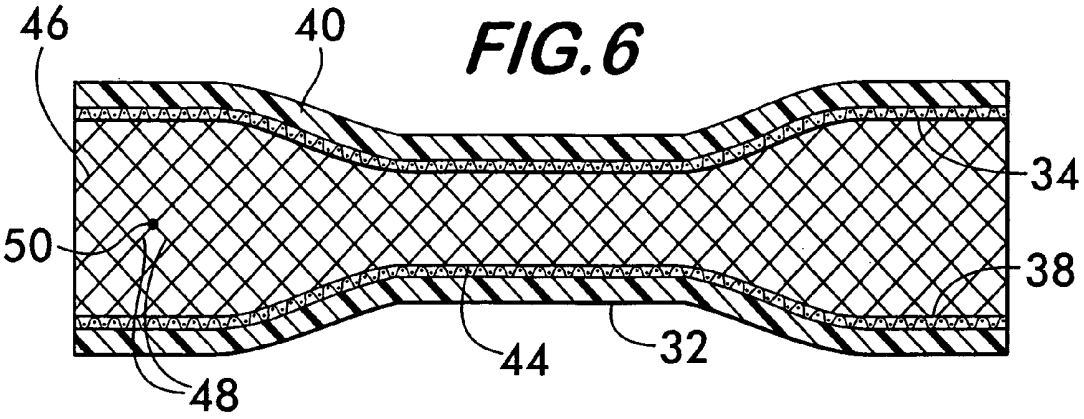


FIG.6

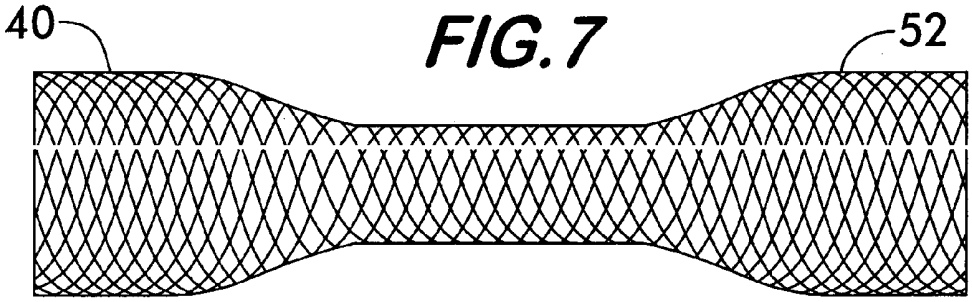


FIG.7

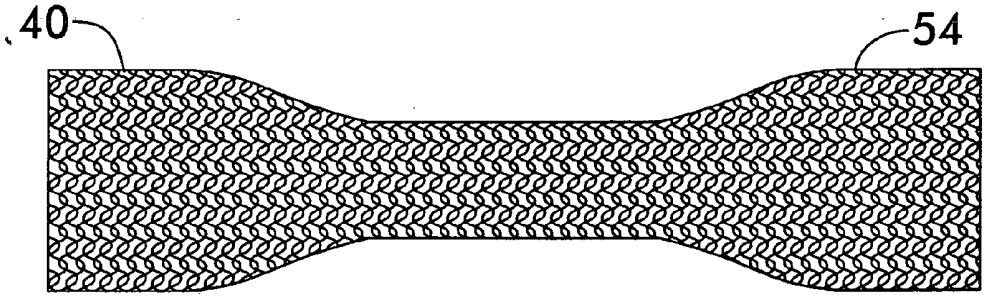


FIG.8

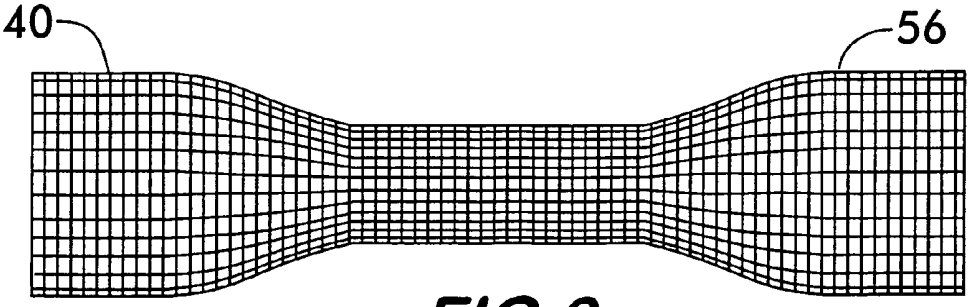


FIG.9

FIG. 10

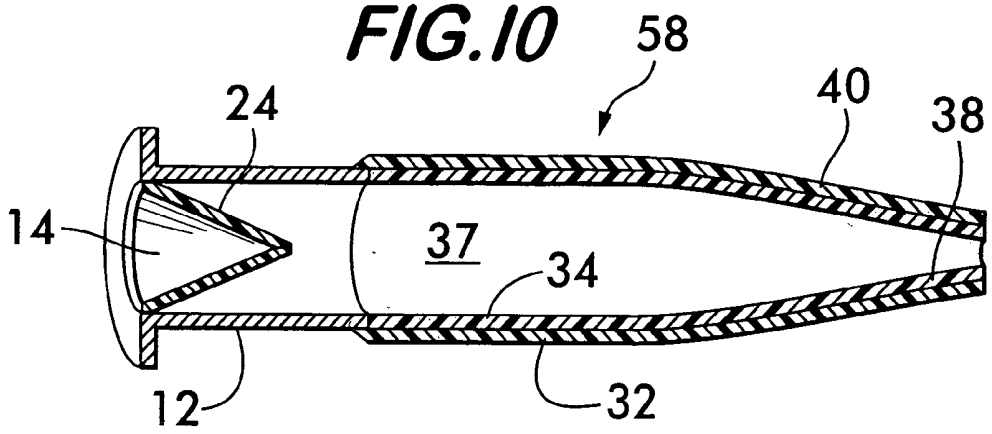


FIG. 11

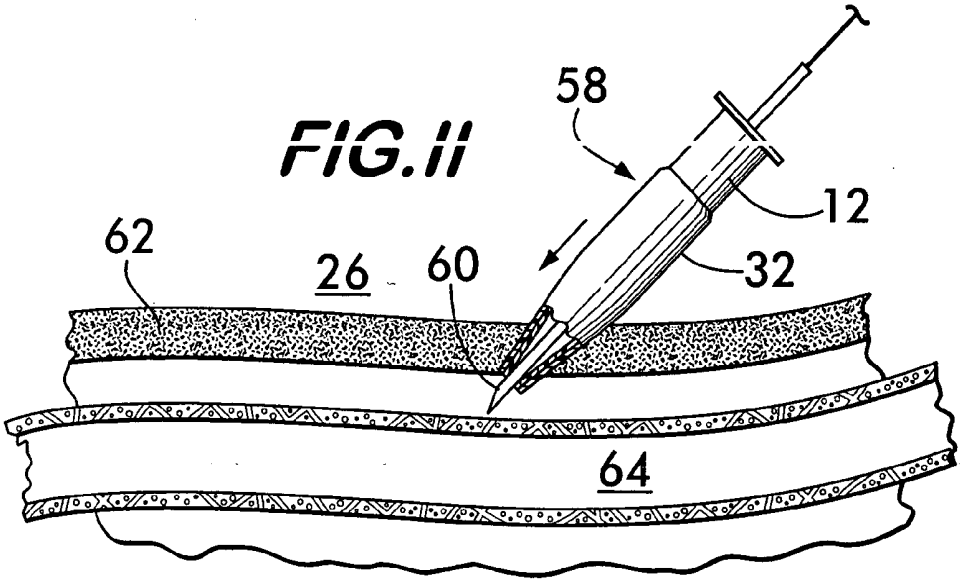


FIG. 12

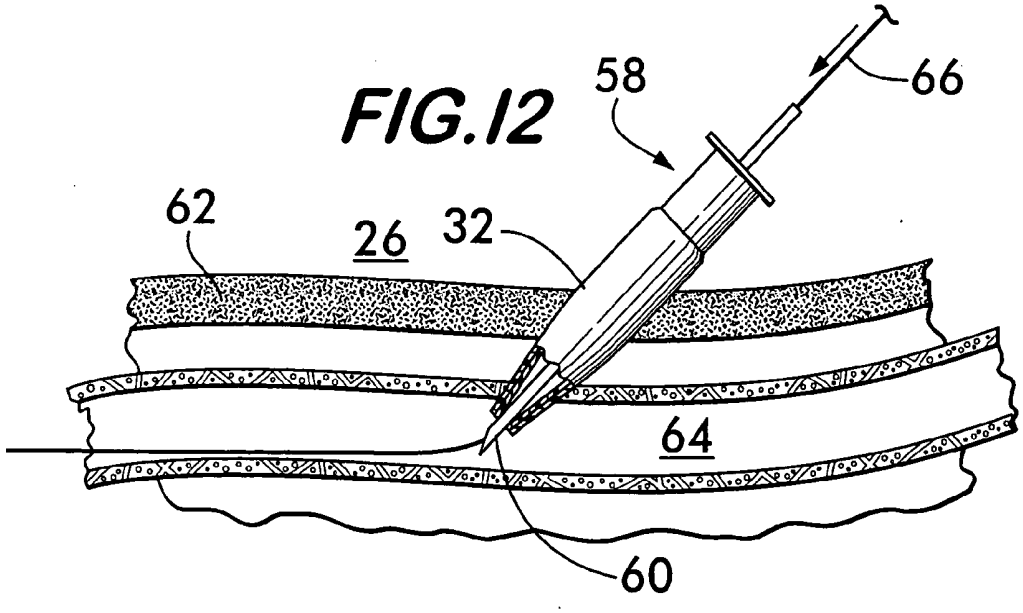


FIG.13

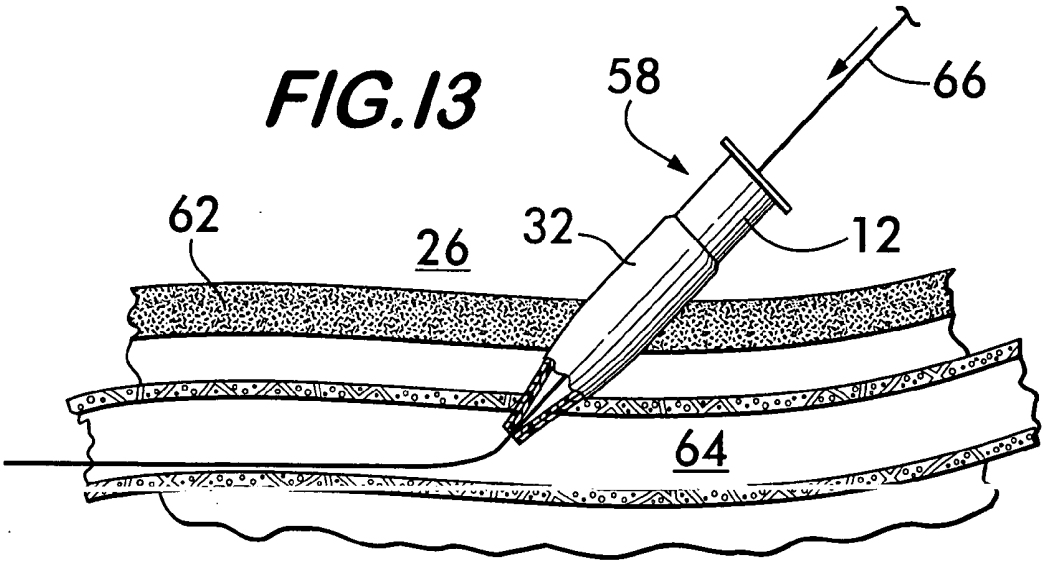
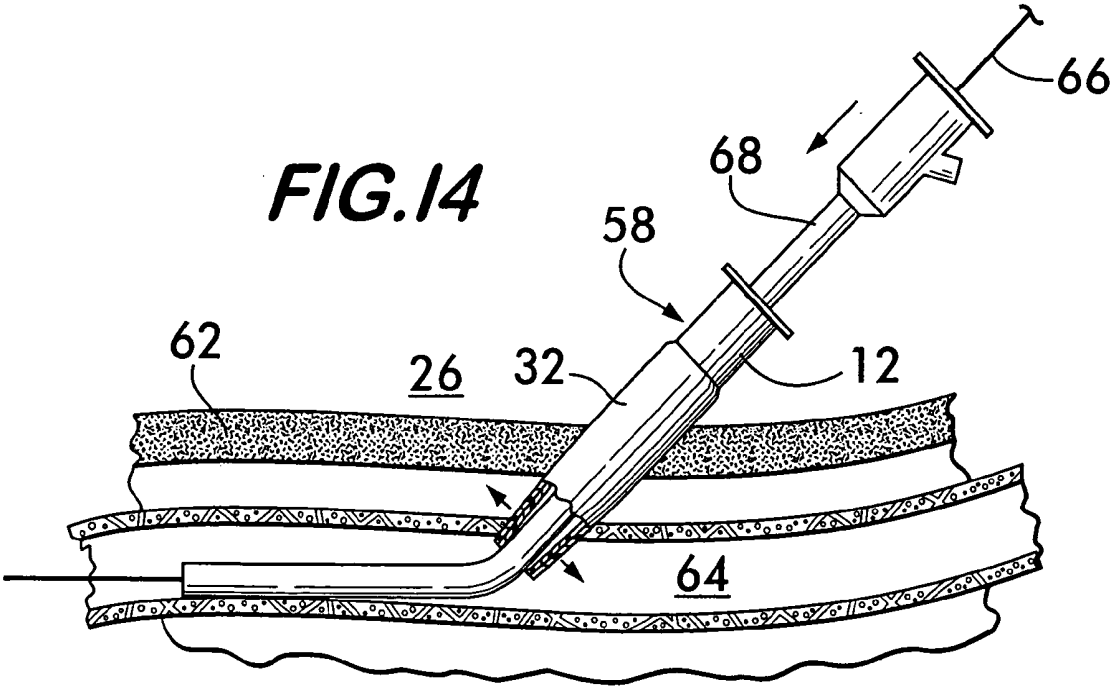


FIG.14



ACCESS PORT FOR LAPAROSCOPIC SURGERY

FIELD OF THE INVENTION

[0001] The invention concerns an access port having a flexible resilient tube with an inner surface which substantially conforms to an outer surface of an item inserted through the port to provides a fluid-tight seal between the tube and the item.

BACKGROUND OF THE INVENTION

[0002] Various medical procedures require that sealing access ports be provided for the introduction and removal of surgical tools, guide wires, catheters or other items into the cavity or vessel being operated upon. A sealing access port is necessary when the procedure is carried out in a region of higher pressure within the body which must be maintained at that pressure without allowing significant leakage. For example, in a laparoscopic procedure within the abdomen, carbon dioxide gas is pumped into the abdomen to form an expanded or enlarged cavity within which the procedure may be carried out. As various tools are inserted and removed through the access ports, it is advantageous that the ports seal substantially fluid-tight to maintain the gas pressure within the cavity and keep it inflated.

[0003] Similarly, a sealing access port, more properly called an "introducer", is advantageous when catheters and guide wires are being inserted within a pressurized vessel, such as an artery of the vascular system, to prevent blood from leaking out as the items are introduced and removed.

[0004] Access ports currently provide a seal that prevents leakage when there is no tool inserted through the port. However, when a tool or other item is inserted through the port and manipulated, the seals as currently configured cannot maintain sufficient integrity to prevent significant leakage. It would be advantageous to provide an access port or an introducer that provides an adequate fluid-tight seal under all conditions of use, i.e., when a tool or other device is absent from the port, as well as when a tool or item extends through the port into the cavity or vessel which is the subject of the procedure.

SUMMARY OF THE INVENTION

[0005] The invention concerns an access port useable to perform procedures within a pressurized environment, for example, within a body cavity during laparoscopic surgery or within a vascular vessel. The access port permits insertion of a tool into the pressurized environment while substantially maintaining pressure therein. The access port comprises an elongated duct. A plurality of flexible, resilient opposed surfaces are positioned within the duct. The opposed surfaces cooperate with one another when subjected to internal pressure within the duct to form a substantially fluid-tight one-way valve. The opposed surfaces are flexibly deformable to permit the tool to be inserted through the duct and into the pressurized environment.

[0006] A flexible, resilient tube is in fluid communication with the duct. The tube is radially inwardly biased so as to be engageable with the tool and form a substantially fluid-tight seal therearound when the tool is inserted through the duct and the tube. In one embodiment, particularly suited for use in laparoscopic surgery, the tube is positioned within the duct and the duct has a distal end insertable through an opening in the living tissue surrounding the pressurized body cavity. The duct has an outer surface that forms a seal with the living tissue. A proximal end of the duct extends outwardly from the cavity to receive the tool.

[0007] In another embodiment, suitable for procedures in vascular vessels, the tube is attached to the duct in end to end relationship.

[0008] Preferably, the tube comprises an inner layer having a low coefficient of friction. The inner layer interfaces with the tool and facilitates insertion of the tool therethrough. An outer elastic layer surrounds the inner layer. The outer elastic layer provides the radially inward biasing that enables the tube to form a substantially fluid-tight seal around the tool.

[0009] The tube may have one of a number of different profile shapes, for example, the tube may be substantially cylindrical in profile, have a substantially hourglass-shaped profile or a tapered profile.

BRIEF DESCRIPTION OF THE DRAWINGS

[0010] **FIGS. 1 and 2** are longitudinal sectional views of an access port according to the invention;

[0011] **FIG. 3** is a longitudinal sectional view of a component of an access port, the component having a substantially cylindrical profile;

[0012] **FIG. 4** is a longitudinal sectional view of a component of an access port, the component having a substantially hourglass shaped profile;

[0013] **FIG. 5** is a longitudinal sectional view of a component of an access port, the component having a substantially tapered profile;

[0014] **FIG. 6** is a longitudinal section view of a component of an access port according to the invention;

[0015] **FIGS. 7-9** are side views of a component of an access port according to the invention illustrating, respectively, braided, knitted, and woven embodiments thereof;

[0016] **FIG. 10** is a longitudinal sectional view of an embodiment of an access port according to the invention; and

[0017] **FIGS. 11-14** illustrate the use of the access port shown in **FIG. 10** in a procedure within a vascular vessel.

DETAILED DESCRIPTION OF THE EMBODIMENTS

[0018] **FIG. 1** shows a sealing access port **10** according to the invention useable in laparoscopic surgical procedures. Access port **10** comprises an elongated duct **12** surrounding and defining a bore **14**. Duct **12** preferably has a substantially rigid sidewall **16** that allows the access port **10** to be inserted into a body cavity **20** through an opening in a muscular tissue wall **22** and maintain the patency of the access port **10** against the muscle pressure during the laparoscopic procedure. The outer surface **18** of the sidewall **16** forms a seal with the living tissue **22** to maintain a higher pressure within the body cavity **20** as described below.

[0019] A one-way valve **24** is positioned within the duct **12**, preferably at a proximal end that extends outwardly from

the cavity **20**. One-way valve **24** is designed to close substantially fluid-tight in response to a pressure differential between the body cavity **20** and the ambient **26**. The differential pressure results when the cavity-is pressurized with gas to provide an enlarged space to perform the surgical procedure. As shown in **FIG. 2**, the one-way valve **24** also allows surgical tools **28** to extend through the duct **12** and into the body cavity **20**. Thus, it is advantageous that the one-way valve **24** comprise resilient, flexible opposed surfaces **30**, preferably in the form of a duckbill. As shown in **FIG. 1**, due to their duckbill shape and flexibility, the opposed surfaces **30** cooperate with one another, for example by co-apting, when subjected to the increased pressure within the body cavity **10** and provide a substantially fluid-tight seal preventing leakage to the ambient **26** through the duct **12**. However, the opposed surfaces **30**, being flexible, deform readily to allow the tool **28** to pass through the duct **12** and into the body cavity **20**. Because they are resilient, the opposed surfaces **30** co-apt again upon removal of the tool **28** to effect the seal.

[**0020**] When tool **28** extends through one-way valve **24**, it is not always possible for the valve to maintain a fluid-tight seal against the tool. This is especially true when the tool is manipulated to perform the procedure, the manipulations, usually consisting of angular displacements of the tool within the access port **10**, cause the opposed surfaces **30** to separate and allow leakage from the pressurized body cavity **20** to the ambient **26**. To prevent such leakage when tool **28** extends though the access port **10**, a tubular seal **32** is installed within bore **14**, preferably in a distal portion of the duct **12**.

[**0021**] Tubular seal **32** is shown in detail in **FIG. 3** and preferably comprises two layers. An inner layer **34**, in this example having the shape of an elongated cylinder **36**, surrounds and defines a central space **37** for receiving the tool **28**. Inner layer **34** has a pliant, lubricious inner surface **38** that interfaces with the tool **28** to form a substantially fluid-tight seal preventing unacceptable leakage. The lubricious inner surface **38** has a low coefficient of friction that allows the tool **28** to pass easily through the tubular seal **32** with little friction. An outer elastic layer **40** surrounds the inner layer **34**. Elastic layer **40** provides radial biasing that forces the inner surface **38** of inner layer **34** into sealing engagement with the tool **28**. Together, the two layers **34** and **40** are radially expandable and contractible to accommodate tools **28** of various diameters and shapes. As readily observable in **FIG. 2**, the tubular seal **32** preferably interfaces with the tool **28** over a predetermined engagement length **42**. Thus, its effectiveness as a seal is not adversely affected by motion of the tool **28** during the surgical procedure, the tubular seal **32** being flexible and following the motions of the tool while maintaining sealing contact between its inner surface **38** and the tool **28** over at least a portion of its engagement length **42**. Although the tube is flexible in bending, radially compliant and resilient, it is advantageous that it also resist lengthwise stretching, i.e., it is preferred that the tube **32** be axially stiff.

[**0022**] Preferably, the inner layer **34** of tubular seal **32** is formed from expanded polytetrafluoroethylene (PTFE) and the outer elastic layer comprises an elastic membrane formed from elastic material such as rubber, polyurethane or silicone. Expanded PTFE is preferred because it provides the pliant, lubricious inner surface **38** having a low coefficient of friction as well as the desired mechanical properties of axial stiffness and radial compliance. Other polymers such as nylon, polyethylene, polypropylene and polyester are also feasible for inner layer **34**.

[**0023**] The tubular seal **32** is formed by expanding a PTFE tube plastically beyond its yield point so that it takes a permanent set at a predetermined enlarged diameter, forming the inner layer **34**. The expanded PTFE tube is then worked to compress it radially back down close to its original (smaller) diameter. Because of its plastic expansion, the expanded PTFE tube has lost its resilient, elastic qualities and will readily expand and contract radially between the smaller and larger diameters, but it will not of itself return to either diameter. The outer elastic layer **40** is positioned surrounding the inner layer **34** and resiliently biases the inner layer radially inwardly toward its smaller diameter. This combination of elastic and low friction layers allows the tubular seal **32** to provide a lubricious inner surface **38** that expands and contracts radially to accommodate the tool **28** while maintaining the inner surface in sealing contact with the tool. It is possible to tailor the radial biasing force to a predetermined value by choice of material with different elastic properties (i.e., types of urethane, silicone or other materials) as well as by adjusting the durometer and thickness of the elastic biasing layer **40** on the inner layer **34**.

[**0024**] As shown in **FIGS. 3-5**, the tubular seal **32** may have a wide variety of shapes ranging from the substantially cylindrical shape **36** (**FIG. 3**) to the hour glass shape **36***a* (**FIG. 4**) or the tapered shape **36***b* (**FIG. 5**) as well as others. These shapes are formed by first expanding a PTFE tube to make expanded PTFE and then inserting one or more mandrels into it. The expanded PTFE tube is then compressed radially so that it takes on the shape of the mandrel, and the outer elastic biasing layer is applied to the outer surface of the tube. Upon curing, the elastic biasing layer holds the tube in the preferred shape dictated by the mandrels, which are then removed. Application of the outer elastic biasing layer may be effected by dipping, spraying or injection molding as well as other procedures.

[**0025**] **FIG. 6** illustrates an alternate embodiment of the tubular seal **32** wherein the inner layer **34** comprises a tube **44** formed from a lattice **46** of elongated members **48** joined to one another at intersection points **50**. When made from PTFE or other lubricious polymers, lattice **46** provides an inner lubricious surface **38** as well as a structure that is radially expandable and contractible (but still longitudinally stiff) to accommodate tools of various sizes. Such a tube may be formed, for example, by starting with a solid tube and forming slots, slits or removing the interstitial material between the lattice members. With this procedure, the full panoply of stent manufacturing techniques may be utilized, as the tube resembles a stent in its physical behavior of radial compliance and axial stiffness. The slots, slits and removed material may have predetermined shapes as is known in stent manufacturing to imbue the tube with specific physical characteristics such as axial stiffness, radial compliance, bending stiffness and the like, all controllable by the shape and spacing of the openings in the tube. Cutting may be effected by laser, cutting blades, or a particular pattern of lattice may be molded. It is also possible to braid elongated members together and fuse them to one another at the intersection points.

[0026] The elastic outer biasing layer **40** surrounds the lattice **46** and forces it into engagement with the tool as described above for the previous examples. Biasing layer **40** in this case however, also performs the sealing function since the lattice **46** is a substantially open network in order to achieve the desired radial expansion and contraction characteristics. Once again, elastic flexible coatings or membranes such as rubber, polyurethane and silicone are preferred for the biasing layer **40**.

[0027] Outer biasing layer **40** may also have alternate embodiments as illustrated in **FIGS. 7-9**. **FIG. 7** shows a braided sleeve **52** that may be positioned surrounding an inner layer to form a multi-layer tubular seal. Similarly, **FIG. 8** shows a knitted sleeve **54** and **FIG. 9** shows a woven sleeve **56**, either of which may surround an inner layer having a low friction surface to form a biased tubular seal. Preferably, the sleeves **52**, **54** and **56** are formed from interlaced elastic filamentary members that allow them to expand and contract radially while biasing the inner layer sealingly against a tool. Elastic fibers such as lycra, hytrel and other synthetic polymers are preferred.

[0028] **FIG. 10** shows an access port **58**, also known as an introducer, which is preferred for use in vascular procedures. Introducer **58** is similar to access port **10** in that it has a duct **12** surrounding a bore **14** and a one-way valve **24** positioned within the bore **14** of the duct. A tubular seal **32** is attached to the duct in fluid communication with the bore **14**. Preferably the tubular seal **32** has an inner layer **34** in the form of a tube having a lubricious inner surface **38**, and an outer elastic biasing layer **40** surrounding the inner layer. Missing is the distal portion of duct **12** which is not used for vascular procedures.

[0029] **FIGS. 11-14** show the introducer **58** in operation. A needle **60** is positioned within the bore **14** of the duct **12**, the needle **60** extending through the central space **37** of the tubular seal **32**. The elastic layer **40** biases the inner layer **34** against the needle **60** and forms a fluid-tight seal. The needle **60** with the introducer **58** is inserted through tissue **62** and into a blood vessel **64**. The seal between the inner layer **34** and the needle **60** substantially prevents blood from escaping through the introducer to the ambient **26**.

[0030] As shown in **FIG. 12**, a guide wire **66** may then be inserted into the vessel **64** through the needle **60**. Next, as shown in **FIG. 13** the needle is removed. Blood from the vessel **64** is prevented from leaking from the introducer **58** to the ambient by the one-way valve **24** positioned within the proximal portion of duct **12**. As shown in **FIG. 14** the introducer is used to insert items, such as catheter **68** into the vessel. The tubular seal **32** expands radially and sealingly engages catheter **68** and prevents any blood flow through the introducer **58** to the ambient **26**.

[0031] Access ports according to the invention permit procedures to be performed within a pressurized environment while substantially maintaining the pressure through the use of multiple seals which cooperate to allow tools to be inserted and removed to and from the environment without significant leakage through the access port.

What is claimed is:

1. An access port useable for laparoscopic surgery within a pressurized body cavity surrounded by living tissue, said access port permitting insertion of a surgical tool into said cavity while maintaining pressure therein, said access port comprising:

an elongated duct having a distal end insertable through an opening in said tissue into said cavity, and a proximal end extending outwardly therefrom, said duct having an outer surface forming a seal with said living tissue;

a plurality of flexible, resilient opposed surfaces positioned within said duct, said opposed surfaces cooperating with one another when subjected to internal pressure within said duct to form a substantially fluid-tight one-way valve, said opposed surfaces being flexibly deformable to permit said tool to be inserted through said duct and into said cavity; and

a flexible, resilient tube positioned within said duct, said tube being radially inwardly biased so as to be engageable with said tool and form a substantially fluid-tight seal therearound when said tool is inserted through said duct.

2. An access port according to claim 1, wherein said tube has a predetermined engagement length over which it engages said tool.

3. An access port according to claim 1, wherein said opposed surfaces are positioned at said proximal end of said duct.

4. An access port according to claim 1, wherein said tube comprises an inner layer having a low coefficient of friction, said inner layer interfacing with said tool and facilitating insertion of said tool therethrough, an outer elastic layer surrounding said inner layer, said outer elastic layer providing said radially inward biasing.

5. An access port according to claim 4, wherein said inner layer comprises a material selected from the group consisting of expanded polytetrafluoroethylene, polypropylene, polyester and nylon.

6. An access port according to claim 4, wherein said outer elastic layer comprises an elastic membrane selected from the group consisting of rubber, polyurethane and silicone.

7. An access port according to claim 4, wherein said outer layer comprises a plurality of interlaced elastic filamentary members.

8. An access port according to claim 7, wherein said filamentary members are interlaced by a technique selected from the group consisting of braiding, weaving and knitting.

9. An access port according to claim 4, wherein said inner layer comprises a lattice of interconnected elongated members, and said outer elastic layer comprises an elastic membrane surrounding said inner layer.

10. An access port according to claim 1, wherein said tube has a substantially cylindrical profile.

11. An access port according to claim 1, wherein said tube has a substantially hourglass-shaped profile.

12. An access port according to claim 1, wherein said tube has a tapered profile.

13. An access port useable for procedures within a vascular vessel, said access port permitting insertion of a tool into said vessel while maintaining pressure therein, said access port comprising:

an elongated duct;

a plurality of flexible, resilient opposed surfaces positioned within said duct, said opposed surfaces cooper-

ating with one another when subjected to internal pressure within said duct to form a substantially fluid-tight one-way valve, said opposed surfaces being flexibly deformable to permit said tool to be inserted through said duct and into said vessel; and

a flexible, resilient tube extending from an end of said duct, said tube being radially inwardly biased so as to be engageable with said tool and form a substantially fluid-tight seal therearound when said tool is inserted through said duct and into said vessel.

14. An access port according to claim 13, wherein said tube has a predetermined engagement length over which it engages said tool.

15. An access port according to claim 13, wherein said tube comprises an inner layer having a low coefficient of friction, said inner layer interfacing with said tool and facilitating insertion of said tool therethrough, an outer elastic layer surrounding said inner layer, said outer elastic layer providing said radially inward biasing.

16. An access port according to claim 15, wherein said inner layer comprises a material selected from the group consisting of expanded polytetrafluoroethylene, polypropylene, polyester and nylon.

17. An access port according to claim 15, wherein said outer elastic layer comprises an elastic membrane selected from the group consisting of rubber, polyurethane, and silicone.

18. An access port according to claim 15, wherein said outer elastic layer comprises a plurality of interlaced elastic filamentary members.

19. An access port according to claim 18, wherein said filamentary members are interlaced by a technique selected from the group consisting of braiding, weaving and knitting.

20. An access port according to claim 15, wherein said inner layer comprises a lattice of interconnected elongated members.

21. An access port according to claim 20, wherein said outer elastic layer comprises an elastic membrane surrounding said inner layer.

22. An access port according to claim 13, wherein said tube has a substantially cylindrical profile.

23. An access port according to claim 13, wherein said tube has a tapered profile.

24. An access port useable to perform procedures within a pressurized environment, said access port permitting insertion of a tool into said environment while maintaining pressure therein, said access port comprising:

an elongated duct;

a plurality of flexible, resilient opposed surfaces positioned within said duct, said opposed surfaces cooperating with one another when subjected to internal pressure within said duct to form a substantially fluid-tight one-way valve, said opposed surfaces being flexibly deformable to permit said tool to be inserted through said duct and into said environment; and

a flexible, resilient tube in fluid communication with said duct, said tube being radially inwardly biased so as to be engageable with said tool and form a substantially fluid-tight seal therearound when said tool is inserted through said duct and said tube.

25. An access port according to claim 24, wherein said tube is positioned within said duct.

26. An access port according to claim 25, wherein said tube has a predetermined engagement length over which it engages said tool.

27. An access port according to claim 24, wherein said tube is attached to said duct in end-to-end relationship.

28. An access port according to claim 24, wherein said tube comprises an inner layer having a low coefficient of friction, said inner layer interfacing with said tool and facilitating insertion of said tool therethrough, an outer elastic layer surrounding said inner layer, said outer elastic layer providing said radially inward biasing.

* * * * *

专利名称(译)	腹腔镜手术的进入端口		
公开(公告)号	US20050277946A1	公开(公告)日	2005-12-15
申请号	US11/152434	申请日	2005-06-14
[标]申请(专利权)人(译)	医疗弦截		
申请(专利权)人(译)	医疗弦截，LLC		
当前申请(专利权)人(译)	STOUT医疗集团LP		
[标]发明人	GREENHALGH E SKOTT		
发明人	GREENHALGH, E. SKOTT		
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优先权	60/579614 2004-06-15 US		
外部链接	Espacenet USPTO		

摘要(译)

公开了一种用于腹腔镜手术的进入端口。该端口包括具有单向阀和管状密封件的管道。单向阀具有相对的表面，其响应于管道内的内部压力而共同适应。管状密封件具有内层，该内层具有由外弹性层围绕的低摩擦系数，外弹性层将内层偏置成与插入管道的外科工具密封接合。在没有延伸通过管道的工具的情况下，单向阀密封管道。内层的低摩擦系数便于通过管道插入和移除工具。该端口具有可插入加压腔中的远端，以及从腔延伸并提供通向其的入口的近端。