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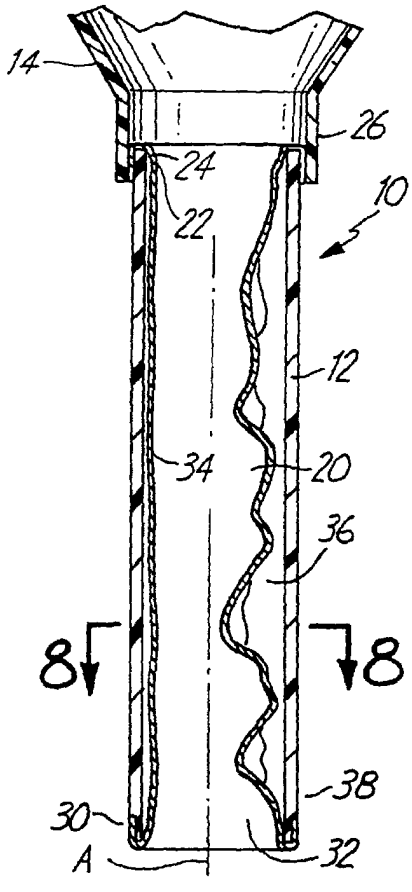
[Continued on next page]

(54) Title: LAPAROSCOPIC ACCESS TOOL WITH GAS SEAL



(57) Abstract: A laparoscopic access apparatus (10) enabling the removal of tissue (T) or other debris from a surgical site. A catheter (12) having a longitudinal access is provided with a flexible internal sleeve (20) having distal (28) and proximal (22) ends. The sleeve (20) forms an inner channel (32) through which laparoscopic surgical instruments (16) may be passed. The sleeve (20) is mounted with axial tautness along one side (34) of the catheter (12), it is provided with a loose, baggy portion elsewhere in the catheter (12) defining an inflatable cavity (36) between the catheter (12) and sleeve (20). A gas port (38) is positioned to enable gas under pressure from a body cavity to enter the inflatable cavity (36) adjacent the distal end thereof to thereby collapse the sleeve and seal the channel (32).

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Laparoscopic Access Tool with Gas Seal

Field of the Invention

The invention relates to apparatus useful in laparoscopic surgery, and particularly to a device enabling tissue to be withdrawn from a body cavity using laparoscopic surgical tools while maintaining gas pressure within the body cavity.

Background of the Invention

Laparoscopic surgery commonly requires that one or more small openings be made through the tissues of a patient to enable the insertion of laparoscopic surgical instruments. Commonly, the body cavity (the abdomen, the knee capsule, etc.) in which laparoscopic surgery is to be performed is first inflated with a gas such as CO_2 to provide an open, inflated area within which the surgical instruments may be manipulated. A catheter may be provided through the tissue wall bounding the body cavity, and it is through the catheter that the surgical instruments are introduced into the body cavity.

Because the body cavity is pressurized, there is a tendency for the pressurizing gas within the body cavity to escape outwardly through the catheter, thereby deflating the cavity. To counter this problem, a number of devices have been proposed to provide a pressure seal within the catheter, but yet enable laparoscopic instruments to be passed inwardly and outwardly of the body cavity through the catheter. One such seal is shown in Mollenauer, et al., U.S. Patent 5,634,937. Another is shown in published UK Patent Application GB 2 275 420 (Gaunt, et al.), and yet another is shown in PCT International Publication No. WO 94/22357 (Yoon). The sealing devices described in the above references by and large relate to inflatable, donut-like devices, through the center of which laparoscopic instruments may be passed.

Although those portions of laparoscopic instruments that are introduced through a cannula into a body cavity are routinely fairly uniform in size, and thus can be introduced and withdrawn from the catheter with some ease, a problem arises when instruments with diameters much larger or smaller that usual are to be introduced into the body cavity, or particularly when pieces of tissue are severed within the body cavity and are to be withdrawn through the catheter without significant loss of pressure in the body cavity. Particularly in the latter case, the tissue sample may not easily fit through the gas seal that is provided, and in this instance, the tissue sample may in fact have to be painstakingly

severed into small pieces in order to be successfully removed. If a large tissue sample is removed with some force, then the seal mechanism may be damaged, resulting in a loss of pressure within the body cavity with easily foreseeable medical problems.

It would be desirable to provide a laparoscopic access apparatus that would maintain a seal against the escape of gas from within a body cavity, that would enable large tissue samples to be withdrawn through the catheter without damage to the pressure seal, and that would also adapt to a variety of instrument sizes and configurations that are to be passed into and out of the catheter.

Brief Description of the Invention

I have found that a suitable gas seal may be made from a film of generally tubular flexible material carried in laparoscopic access catheter, the film at one side of the catheter being stretched tautly, and the film elsewhere in the catheter remaining baggy and loose. The outer surface of the baggy film portion defines, with the catheter walls, an inflatable cavity between the catheter and the sleeve, and the inner surface of the sleeve defines a channel leading through the catheter. The sleeve is joined at its distal and proximal ends to the catheter adjacent its distal and proximal ends.

The taut configuration of the flexible sleeve on one side of the catheter, together with the loose, baggy nature of the sleeve elsewhere in the catheter and the sealing of the sleeve at its ends to the catheter, enable the baggy portion of the sleeve to readily deform toward the catheter walls without ripping or tearing to allow passage through the channel of large objects such as tissue specimens from within a body cavity within which laparoscopic surgery occurs. The apparatus includes a gas port positioned to enable gas under pressure from within the body cavity to enter the cavity between the sleeve and catheter to thereby collapse the sleeve and seal the channel defined by the sleeve.

In its sealed configuration, the sleeve will readily accept the passage of laparoscopic instruments passed through the catheter into the body cavity, the sleeve collapsing onto and conforming to the instruments to maintain the gas seal. As large tissue specimens are removed through the catheter, the sleeve will similarly collapse about the tissue specimen, such that as the specimen is drawn

outwardly, the channel within the sleeve will enlarge to accept the specimen, the sleeve collapsing against itself beneath the specimen as the specimen passes to thereby maintain the gas seal.

Thus, in one embodiment, the invention provides a laparoscopic access apparatus enabling the removal of tissue or other debris from a surgical site. The apparatus comprises a catheter having a longitudinal axis. A flexible sleeve having distal and proximal ends is carried within the catheter, the sleeve forming an inner channel through which laparoscopic surgical instruments may be passed. The sleeve is mounted with axial tautness along one side of the catheter, and has a loose, baggy portion elsewhere in the catheter defining an inflatable cavity between the catheter and sleeve. The apparatus includes a gas port positioned to enable gas under pressure to enter the cavity adjacent to the distal end of the sleeve to thereby collapse the sleeve and seal the channel.

Brief Description of the Drawing

Figure 1 is a perspective view of an apparatus of the invention;

Figure 2 is a perspective view of a flexible sleeve used in the apparatus in Figure 1;

Figure 3 is a perspective view of the sleeve in Figure 2, showing a loose, baggy feature of the sleeve;

Figure 4 is a broken-away, cross-sectional view of an apparatus of the invention;

Figure 5 is a broken-away side view of an apparatus of the invention, showing a gas access port;

Figure 6 is a view similar to that of Figure 5 but showing a different gas access port;

Figure 7 is a broken-away, cross-sectional view of an apparatus showing a modification of gas access ports;

Figure 8 is a cross-sectional view taken along line 8-8 of Figure 4 and showing the flexible sleeve in an open configuration;

Figure 9 is a view similar to that of Figure 8 but showing the flexible sleeve in a sealed configuration;

Figure 10 is a view similar to that of Figures 8 and 9, but showing the flexible sleeve in a sealed, collapsed position about the shaft of a laparoscopic instrument;

Figure 11 is a broken-away view, in partial cross-section, showing a step in the removal of a tissue specimen through the apparatus, and further showing a gas supply system;

Figure 12 is a view similar to that of Figure 11, showing another step in the tissue removal procedure; and

Figure 13 is a broken-away, cross-sectional view of the structure designated 13 in Figure 1.

Brief Description of the Preferred Embodiment

Referring first to Figure 1, the laparoscopic access apparatus of the invention is labeled generally as 10 and includes an elongated catheter 12 which desirably is rigid and which may be made from any suitable material such as a metal or plastic material. At its outer, or proximal end, the catheter may have mounted to it a cup shaped or funnel shaped entrance portion 14 for the purpose of enabling laparoscopic tools to be easily introduced by a surgeon into the catheter from outside the body cavity. A laparoscopic tool is typified in Figure 1 as a forceps 16, the forceps having jaws 18 illustrated as clamping to an enlarged tissue specimen "T" that is to be removed through the catheter. As shown, the tissue specimen approaches the size of the catheter 12.

The catheter 12 is shown perhaps best in Figure 4. The catheter is tubular, and commonly is made of a rigid plastic material such as polyethylene, polycarbonate or polysulfone. A funnel shaped portion 14 is illustrated as being carried at the top (the proximal end) of the catheter, and serves simply to direct laparoscopic tools into the catheter. Within the catheter is a flexible sleeve 20, of generally tubular design, the sleeve having a proximal end portion 22 that is doubled back over the proximal mouth 24 of the catheter. In the depicted embodiment, the funnel shaped portion 14 has a lower, generally cylindrical neck section 26 that fits tightly over the double-backed portion of the sleeve 20 to secure the proximal end of the sleeve to the proximal end of the catheter. An

adhesive or cement can be employed as desired to secure the cylindrical neck 26 and doubled-back portion of the sleeve to the proximal end of the catheter.

Referring to Figure 2, a section of sleeve is depicted having its proximal end 22 at generally right angles to its length, but having its bottom or distal end 28 portion cut at a sharp angle to its length, e.g., at an angle of about 40 degrees to the length of the sheath. When the distal end 28 of the sheath is raised so as to be substantially at right angles to the length of the sheath, as shown in Figure 3, the sheath itself becomes loose and baggy.

The distal end 28 of the sheath is similarly doubled back about the distal mouth of the catheter, as shown in Figure 4, and is there attached to the catheter by any appropriate means, a surrounding plastic band 30 being typified in the drawing. An adhesive may be used in place of the band, or in combination with the band, to secure the distal end of the sheath peripherally to the distal end of the catheter. Details of a preferred attachment of the distal end of the sheath to the catheter is shown in Figure 13. The distal end of the catheter terminates in a short section 15 of reduced diameter and receives the doubled-back portion of the sheath. Band 30 is then received over the doubled back portion of the sheath, the band having an outer diameter that is equivalent to the outer diameter of the catheter proximally of the section 30. In this manner, the catheter and band, as a unit, present a smooth outer surface of uniform diameter to enable the catheter to be received through a tissue wall and into a body cavity.

Sheath 20 is made of a very flexible material, and polyurethane films have given good results. In the preferred embodiment, the film is elastic, although non-elastic films may also be used. The film is in any event sufficiently limp as to readily conform to the shape of the solid object in which it is brought into contact. Sheath 20 itself defines a channel 32 extending within the catheter, and the inner surface of the sheath that faces that the channel is slippery. Slipperiness may be attained either by choosing a sheath material that is normally quite slippery, or by treating the inner surface of the sheath with a material that confers slipperiness. For example, the sheath may be of polyurethane to which a thin film of a fluorocarbon polymer such as poly (tetrefluoroethylene) is bonded, or the sheath may be coated with a hydrophilic material which, when wet, becomes slippery. If

desired, a lubricating agent such as a fine biocompatable powder or a lubricating liquid such as a jelly may be applied to the inner surface of the sheath to increase its slipperiness.

Desirably, the sheath has an outer diameter which is somewhat greater than the inner diameter of the catheter, and this, coupled with the baggy nature of the sleeve discussed above, results in the sleeve retaining a baggy configuration within the catheter as shown in Figure 4. Although bagginess may be obtained by the method described above, other methods may be used to provide bagginess as well. For example, the sleeve may be formed about a mandrel configured to provide the desired baggy configuration. As another example, the sleeve, after having been formed, may simply be stretched in certain areas to provide the desired configuration, the sleeve in this situation desirably being stretchy but not elastic, so that it retains its stretched-out configuration.

As shown best in Figure 4, one side of the sleeve 34 is pulled taut between its attachments to the catheter. This side of the sheath is the short side shown in Figure 2. "Taut" as used herein reflects the fact that the side 34 of the sheath does not loosely bag out into the interior of the catheter, but rather maintains a position at or fairly close to the side wall of the catheter. The portion 34 of the sheath need not be actually tight or under axial tension. If desired, the side 34 of the sheath may be actually adhered to the confronting surface of the catheter, as by welding or through the use of an adhesive.

It will be noted in Figure 4 that the baggy portion of the sheath 20 defines, with the confronting wall of the catheter, an inflatable cavity 36. A gas port is provided to enable gas from within the body cavity to enter the inflatable space 36 and to collapse the sheath inwardly. A suitable port is shown at 38 in Figures 4 and 5 as being formed through the thickness of the catheter wall adjacent the distal end of the catheter; that is, just above the band 30. A variety of gas entry ports can be employed. Figure 6 shows a generally U-shaped slot 42 formed in the distal end 40 of the catheter, the slot extending proximally of the band 30 far enough so that its proximal portion is open to gas from the body cavity. In Figure 7, the distal end portion 28 of the sheath is provided with axially extending cuts or slots 44, the slots forming ports through which gas can enter the cavity 36. If

desired, the distal end of the sheath can be thus cut or slotted around its periphery to form a plurality of distally extending fingers 46, each finger then being secured to the catheter adjacent its distal end.

Figure 8 is a cross-sectional view taken along line 8-8 of Figure 4, and shows the sheath 20 in an open position loosely bounding the channel 32. Once the catheter has been deployed with its distal end portion within a pressurized body cavity, gas under pressure is received through the gas port 38 to inflate the cavity 36, causing the inner walls of the catheter to collapse upon each other to seal the channel 32. This configuration is illustrated in Figure 9. If the shaft of a laparoscopic instrument, such as the forceps shown in Figures 1, 11 and 12, extends through the channel 32, then the inner walls of the sheath collapse about the shaft as shown in Figure 10, again sealing the channel 32. Inasmuch as the inner surface of the sheath is quite slippery, as discussed above, the gas seal is maintained as the laparoscopic tool is moved proximally or distally or otherwise maneuvered within the sheath as may be necessary during laparoscopic surgery. It will be understood that the sheath is sufficiently baggy as to enable it, when the cavity 36 is inflated, to completely collapse towards the center of the catheter and thereby seal the channel 32.

Figures 11 and 12 show steps in a procedure in which a large tissue specimen T is withdrawn through an access apparatus of the invention. In Figure 11, the catheter 12 is shown in place with its distal end within the body cavity and its proximal end extending outwardly of the body cavity. For ease of visualization, a layer of skin and muscle, representing a wall of a body cavity, is shown generally as S in Figure 11. Placement of the access catheter through the wall involves the use of a sharpened, solid trocar (not shown) that is inserted within the channel 32 with its sharpened end projecting distally. The body cavity is inflated by means of a suitable needle and gas delivery tubing in a known fashion, and the trocar pierces the layer of skin and muscle S, carrying with it the distal end of the catheter. The trocar (not shown) is then removed, the sheath collapsing as typified in Figure 9 to seal the channel 32, as described above.

If desired, the catheter may be provided with a gas transport system, as shown at 48 in Figure 11, comprising a valved gas tube 50 communicating with

the catheter adjacent its proximal end. Within the catheter, a peripheral shoulder 52 extends inwardly slightly from the catheter walls to define a circumferential gas channel 54, the shoulder restraining the sheath from collapsing outwardly against the walls of the catheter at this location. Gas from the delivery tube thus may flow distally within the inflatable cavity 36, and thence through the gas port 38 and into the body cavity. The gas tube 50 may also be used to depressurize the proximal end of the inflatable cavity as a very large tissue section is being withdrawn through the catheter, and also may serve to depressurize the body cavity when it is appropriate to do this in a surgical procedure.

In Figures 11 and 12, the cannula is shown rotated 90 degrees in a clockwise direction from the positions shown in Figures 4, 8, 9 and 10. In Figure 11, as part of a laparoscopic surgical procedure, a large tissue sample T has been severed from the body within the body cavity and is shown grasped by the jaws 18 of a forceps. The tissue sample must now be withdrawn by the forceps proximally through the channel 32 without significant loss of pressurizing gas within the body cavity. In Figure 11, it will be seen that the inner walls of the sheath have collapsed against the shaft 46 of the forceps due to inflation of the space 36 between the walls of the catheter and the sheath. As the forceps is withdrawn proximally, the walls of the sheath yield as needed to accept and enfold the tissue sample T, as shown in Figure 12, such that as the tissue sample proceeds proximally through the channel 32, the walls of the sheath close distally behind the tissue sample to maintain the gas seal.

While several forms of the invention have been shown and described, other forms will be apparent to those skilled in the art. The embodiment shown on the drawings and described above are merely for illustrative purposes and are not intended to limit the scope of the invention, which is defined by the claims which follow.

I claim:

1. Laparoscopic access apparatus enabling the removal of tissue or other debris from a surgical site, comprising a catheter having a longitudinal axis, a flexible sleeve having distal and proximal ends and carried within the catheter, the sleeve forming an inner channel through which laparoscopic surgical instruments may be passed, the sleeve being mounted with axial tautness along one side of the catheter and having a loose, baggy portion defining an inflatable cavity between the catheter and sleeve, the apparatus including a gas port positioned to enable gas under pressure to enter said cavity adjacent said distal end to thereby collapse said sleeve and seal said channel.

2. The apparatus of claim 1 wherein the portion of the sleeve mounted with axial tautness is adhered to the catheter.

3. The apparatus of claim 1 wherein the proximal end of the sheath is sealed about its periphery to the periphery of the catheter adjacent its proximal end .

4. The apparatus of claim 1 or claim 3 wherein the distal end of the sheath is mounted to the periphery of the catheter adjacent its distal end.

5. The apparatus of claim 4 wherein said port comprises an aperture through said catheter adjacent the distal end of the catheter.

6. The apparatus of claim 4 wherein said port comprises an aperture formed through said sheath adjacent the distal end of the catheter.

7. The apparatus of claim 1 wherein said sheath is formed of a non-elastic material.

8. The apparatus of claim 1 wherein said sheath is formed of an elastic material.

9. The apparatus of claim 1 wherein said sheath has an inner surface facing the channel, and including a slippery coating carried by said inner surface.

10. The apparatus of claim 9 wherein said slippery coating is a lubricating liquid.

11. The apparatus of claim 9 wherein said slippery coating is a lubricating powder

12. The apparatus of claim 9 wherein said slippery coating comprises a film of a fluorocarbon polymer.

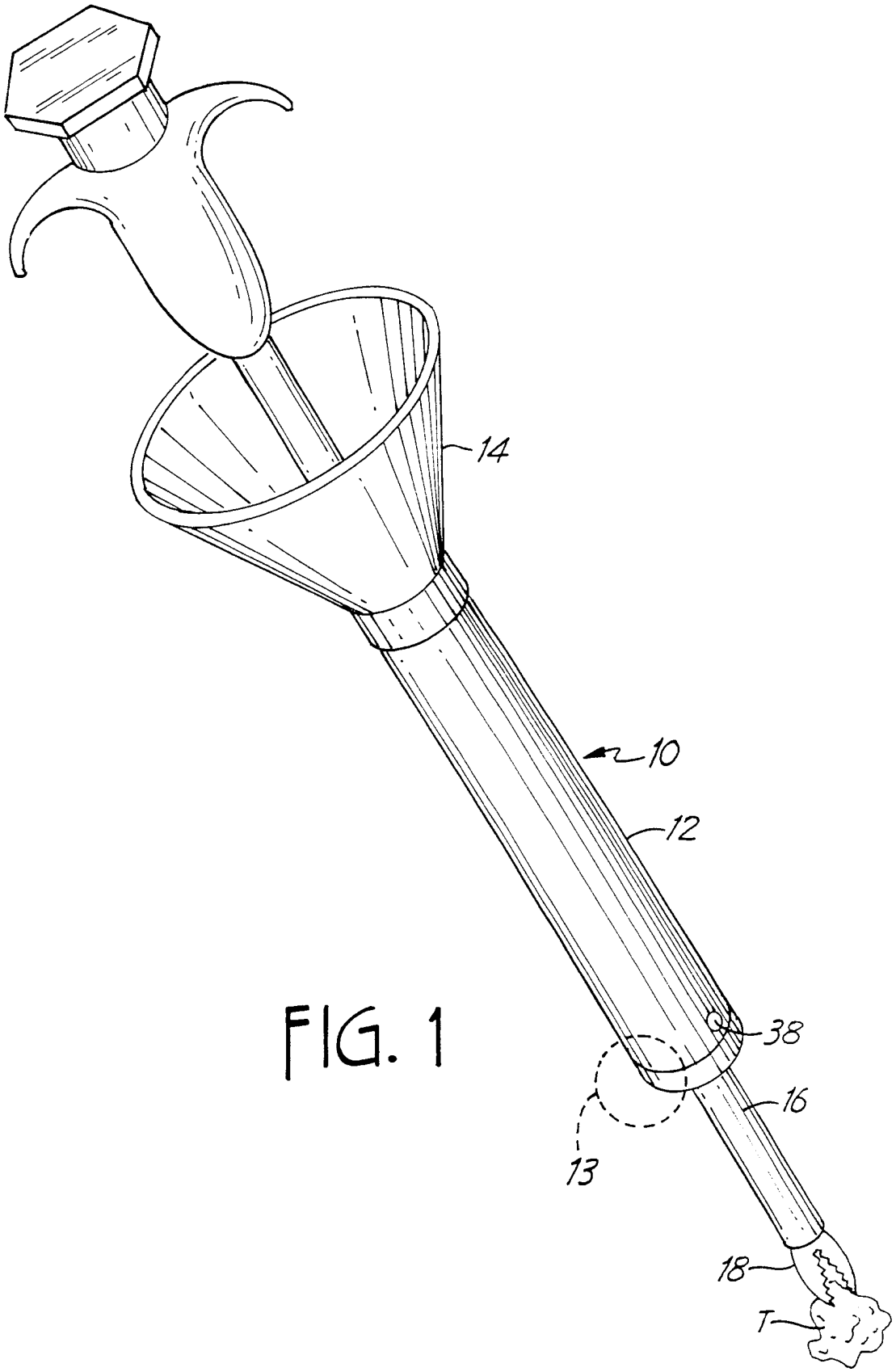

FIG. 1

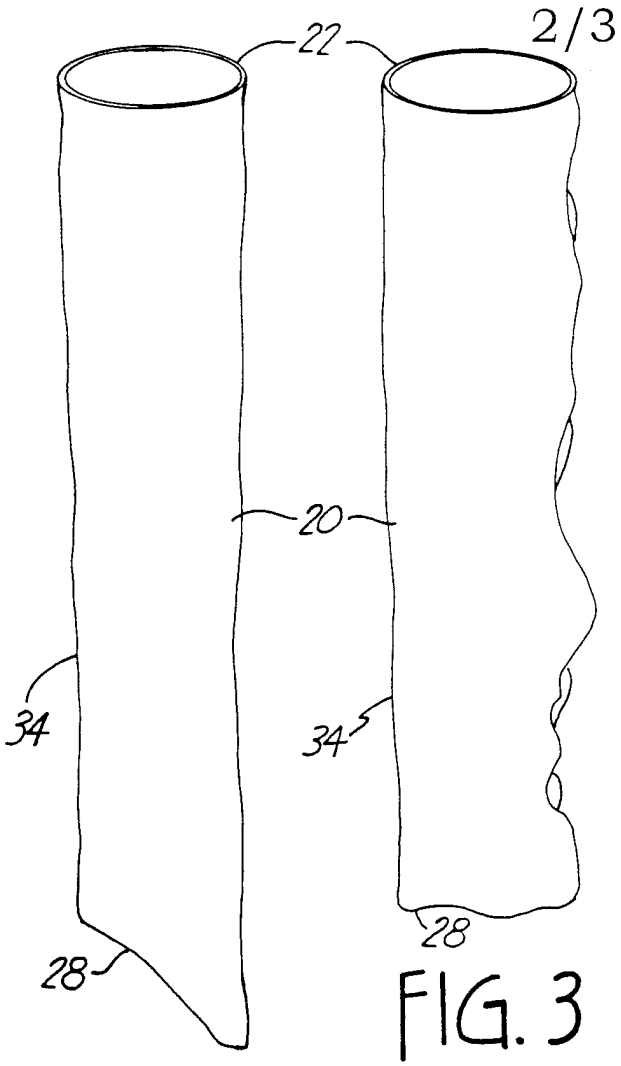

FIG. 2

FIG. 3

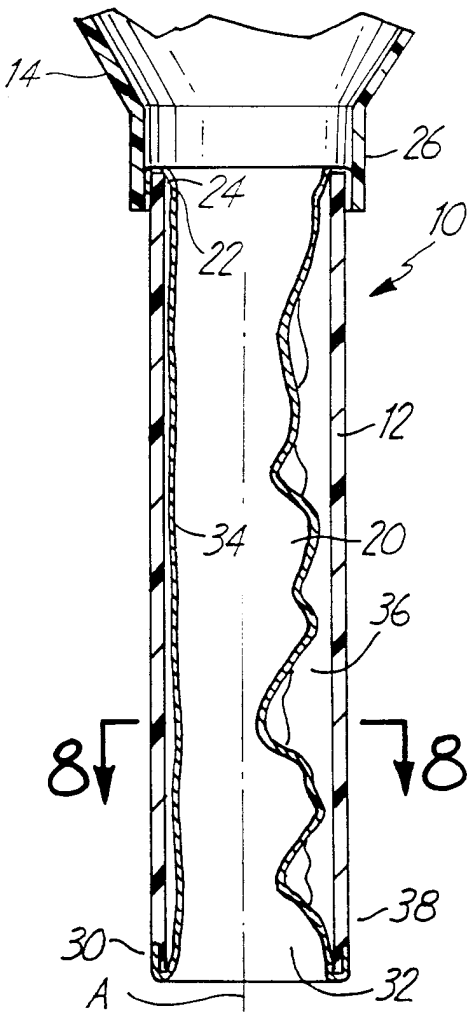

FIG. 4

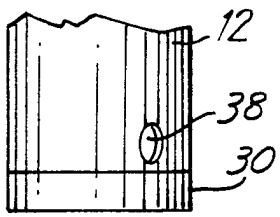

FIG. 5

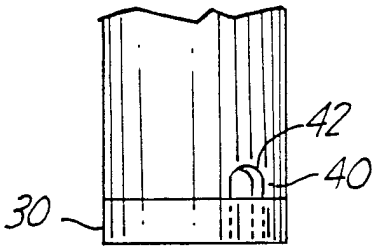

FIG. 6

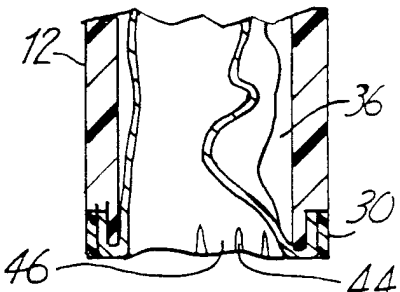

FIG. 7

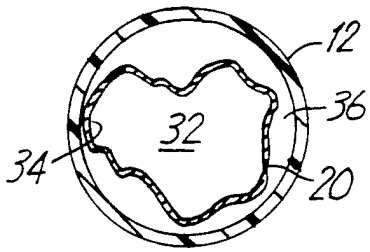

FIG. 8

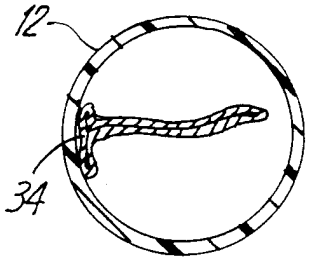

FIG. 9

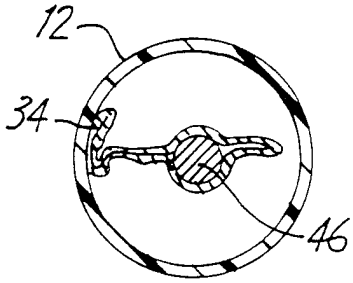

FIG. 10

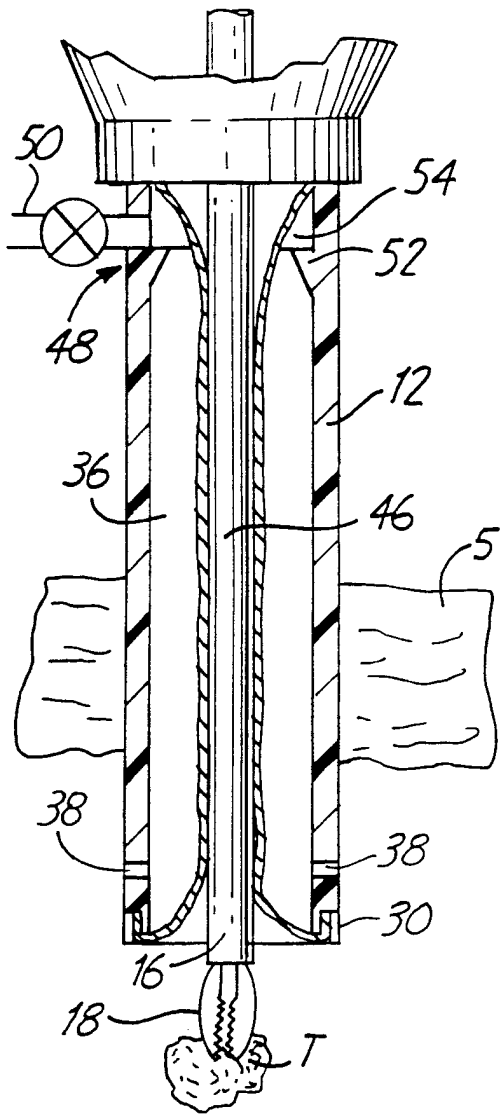

FIG. 11

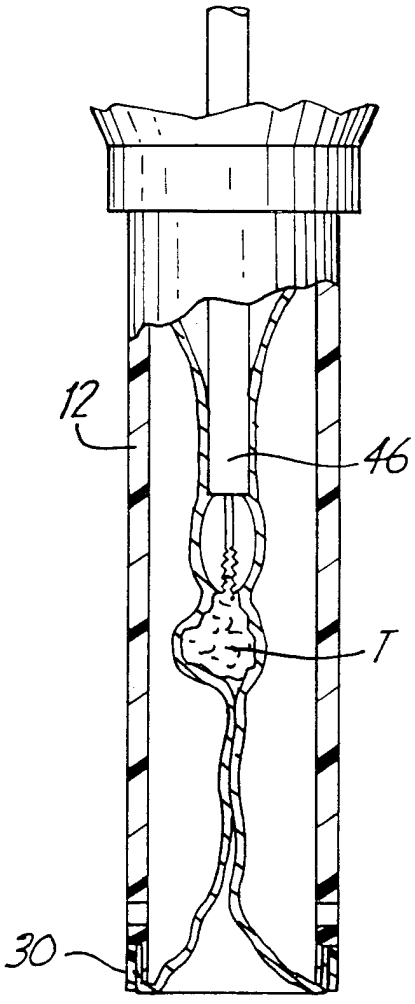

FIG. 12

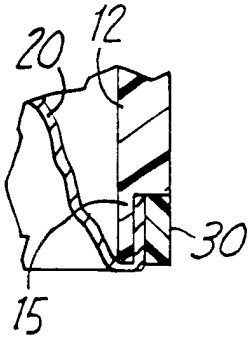

FIG. 13

INTERNATIONAL SEARCH REPORT

Intern ıal Application No
PCT/US 01/01561

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B17/34

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

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

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 99 29242 A (PHILLIPS PLASTICS CORPORATION) 17 June 1999 (1999-06-17) cited in the application the whole document	1-12
A	US 5 634 911 A (HERMANN ET AL.) 3 June 1997 (1997-06-03) column 6, line 8 -column 8, line 10; figures	1
A	US 5 967 970 A (COWAN ET AL.) 19 October 1999 (1999-10-19) abstract; figures	
A	WO 98 48724 A (UNIVERSITY OF MASSACHUSETTS ET AL.) 5 November 1998 (1998-11-05) abstract; figures page 19, line 22 -page 20, paragraph 7	

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
23 April 2001	03/05/2001

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Giménez Burgos, R

1

INTERNATIONAL SEARCH REPORT

Information on patent family members

Intern ıal Application No
PCT/US 01/01561

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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		EP 0981302 A	01-03-2000
		JP 2000501978 T	22-02-2000
		US 6142936 A	07-11-2000

专利名称(译)	腹腔镜进气工具，带气封		
公开(公告)号	EP1248572A1	公开(公告)日	2002-10-16
申请号	EP2001942531	申请日	2001-01-16
申请(专利权)人(译)	PHILLIPS塑料制品公司		
当前申请(专利权)人(译)	爱惜康内镜手术，INC.		
[标]发明人	PETERSON FRANCIS C		
发明人	PETERSON, FRANCIS, C.		
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外部链接	Espacenet		

摘要(译)

一种腹腔镜进入装置（10），其能够从手术部位移除组织（T）或其他碎屑。具有纵向入口的导管（12）设置有具有远端（28）和近端（22）端部的柔性内部套管（20）。套管（20）形成内部通道（32），腹腔镜手术器械（16）可以穿过该内部通道。套管（20）沿导管（12）的一侧（34）轴向拉紧安装，在导管（12）的其他地方设置有松散的袋状部分，在导管之间限定可充气腔（36）（12）和套管（20）。气体端口（38）定位成使得来自体腔的压力下的气体能够进入邻近其远端的可充气腔（36），从而使套管收缩并密封通道（32）。