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(54) HAND ASSISTED LAPAROSCOPIC DEVICE

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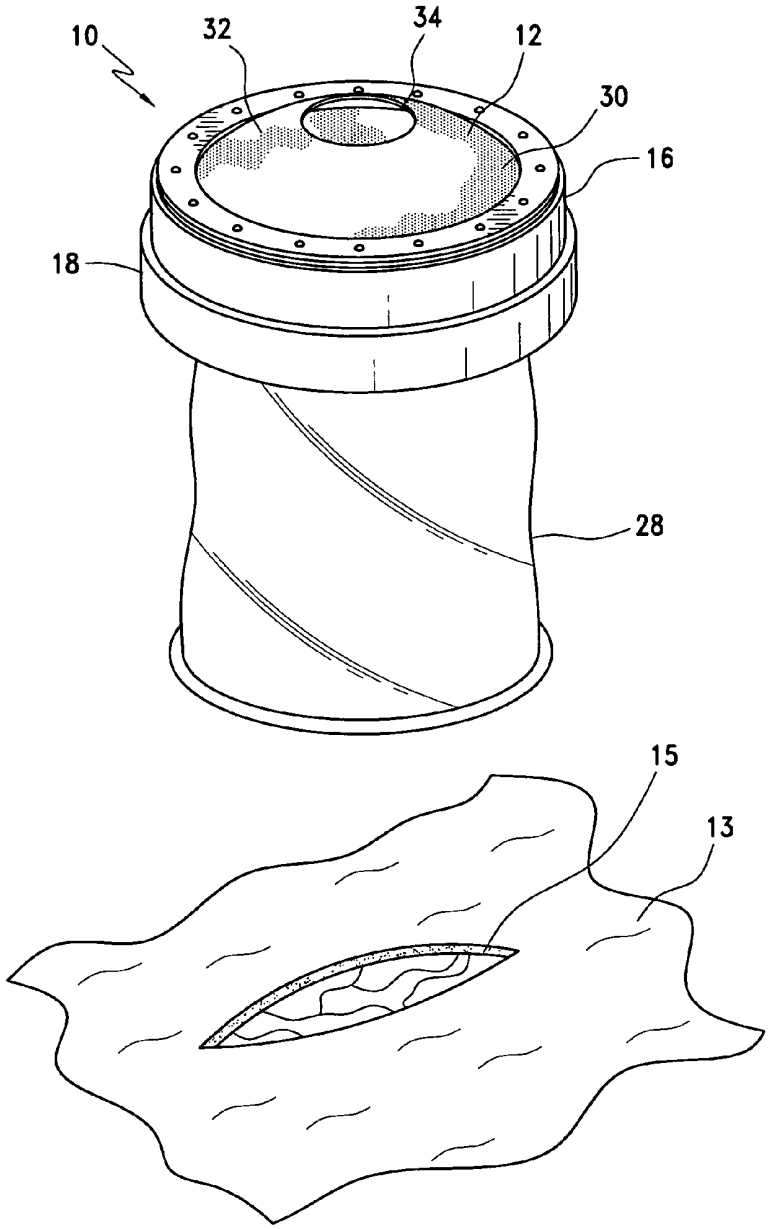
(57) **ABSTRACT**

A hand assisted laparoscopic seal apparatus includes an outer seal, an inner seal and a housing supporting the outer seal relative to the inner seal, wherein one of the outer seal or the inner seal is shaped and dimensioned for engaging and sealing around an arm of a medical practitioner and the other seal is shaped and dimensioned for sealing a body cavity from an external environment.



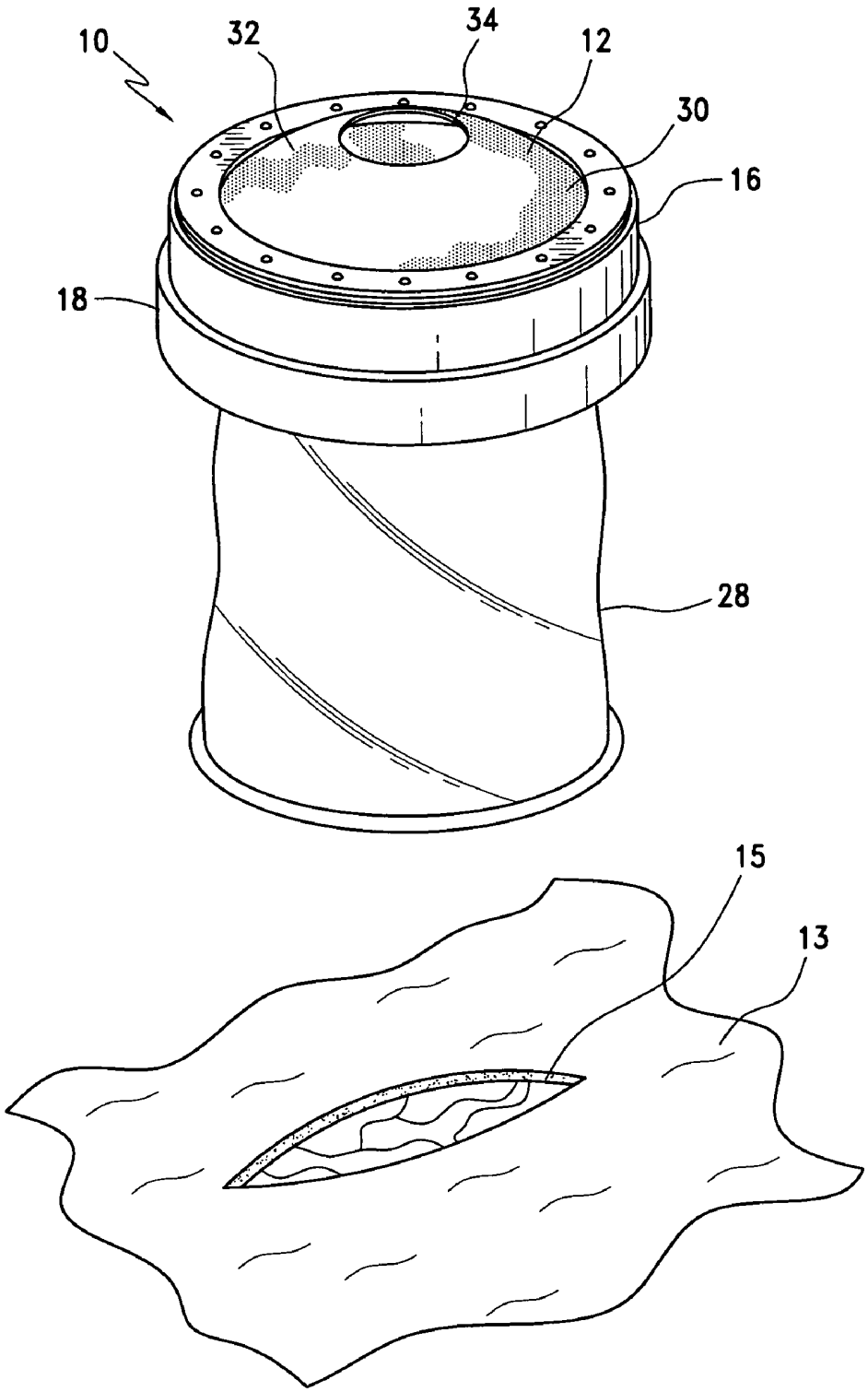


FIG. 1

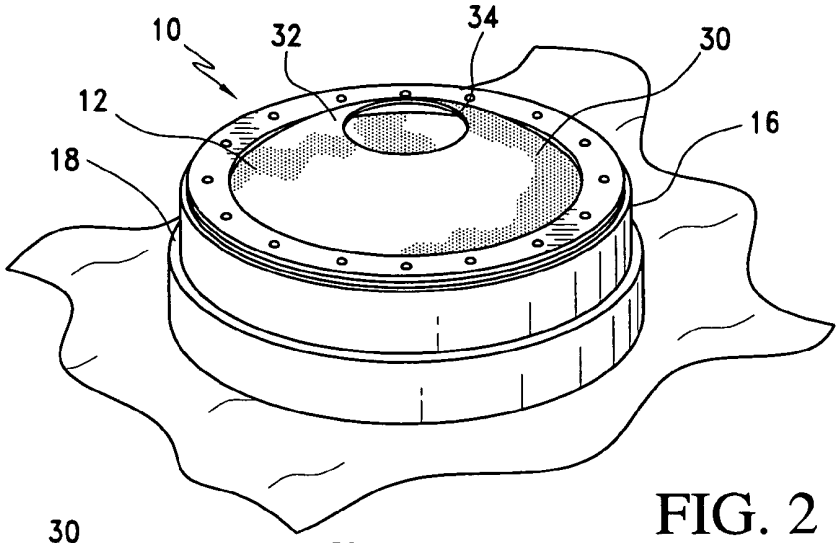


FIG. 2

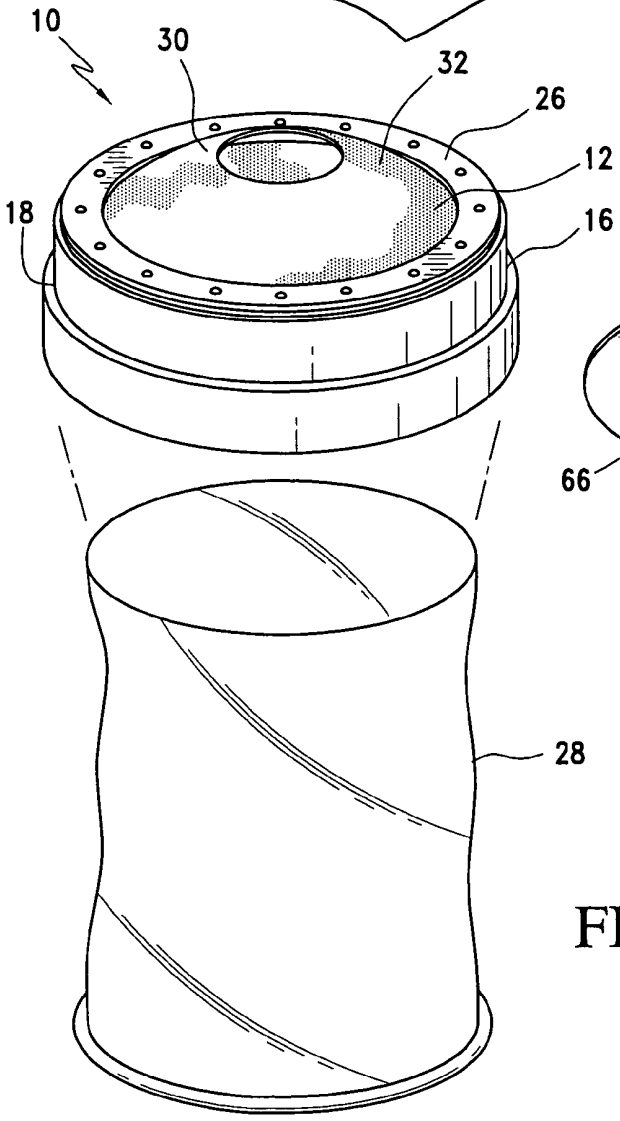


FIG. 4

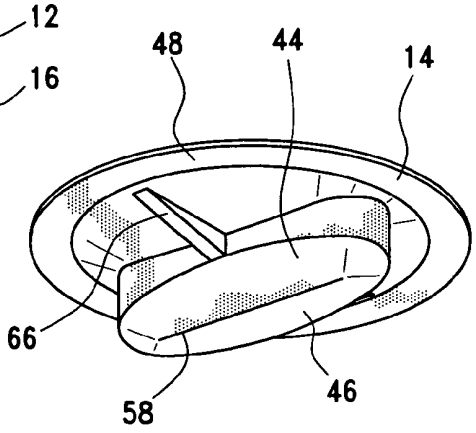
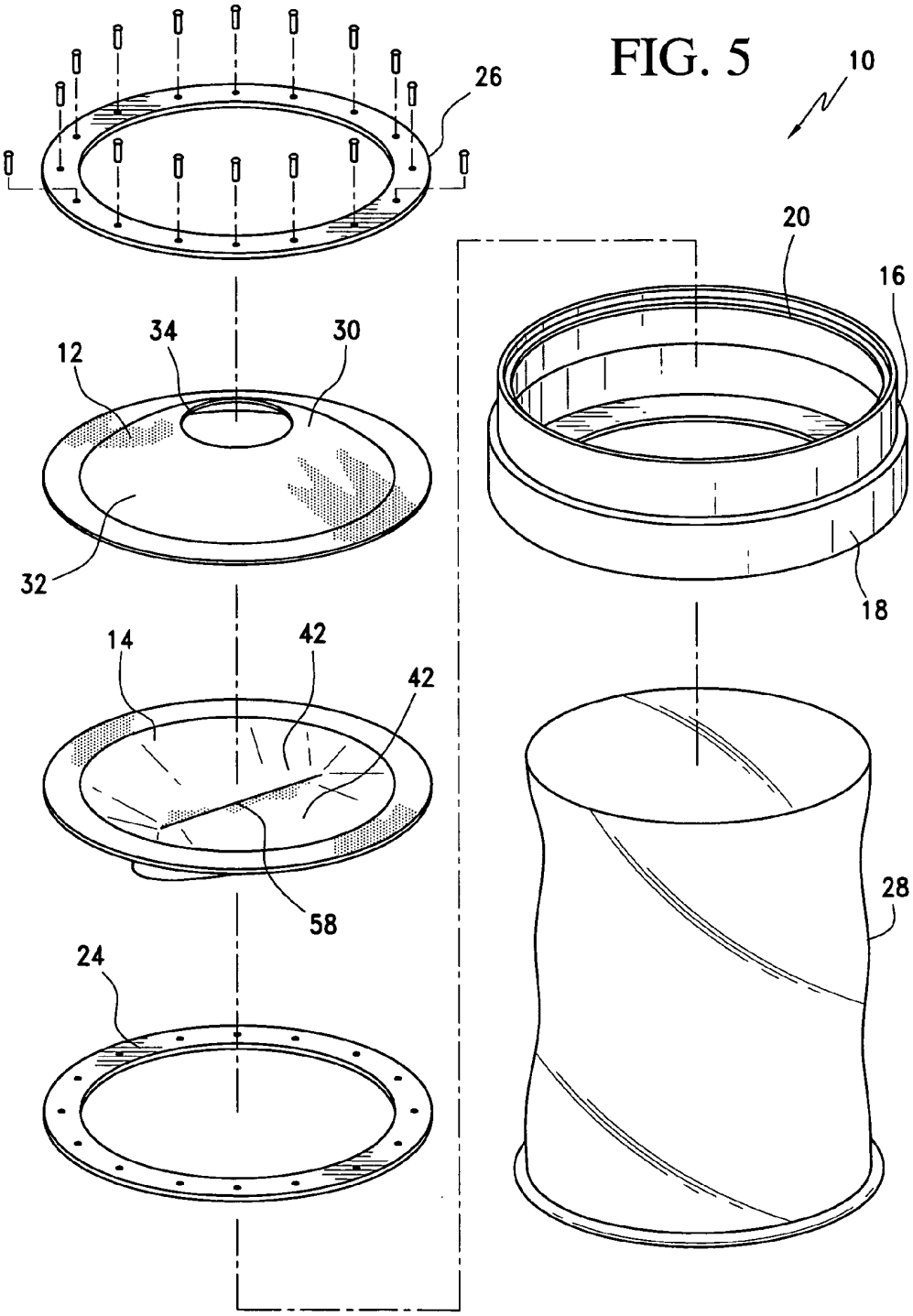


FIG. 3

FIG. 5



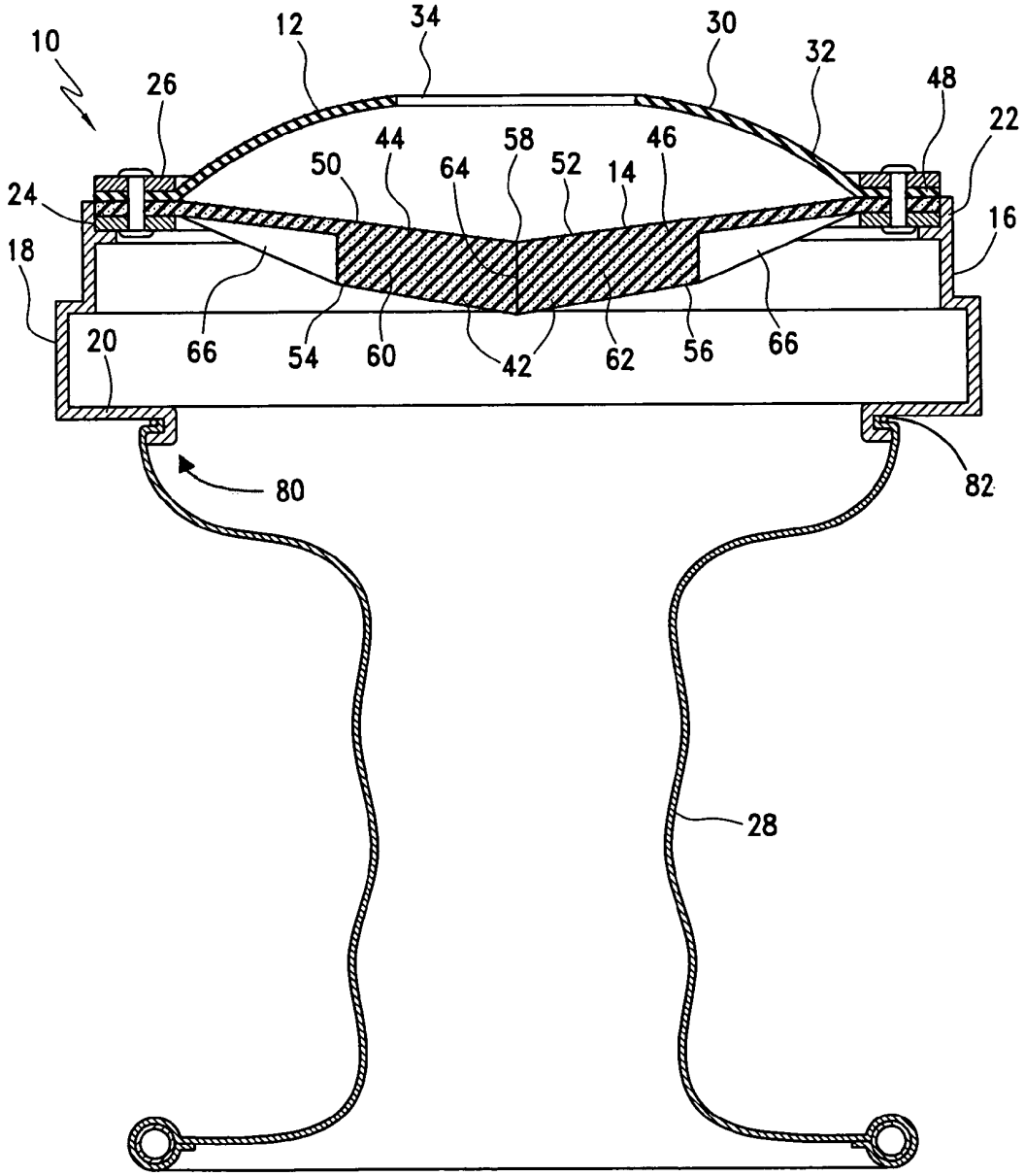

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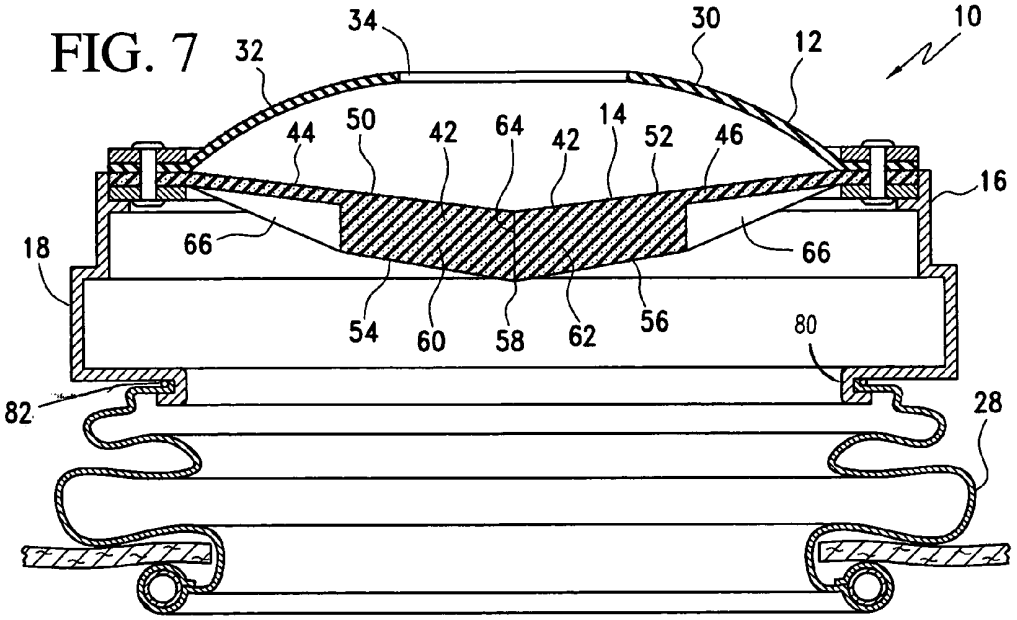
FIG. 6

FIG. 7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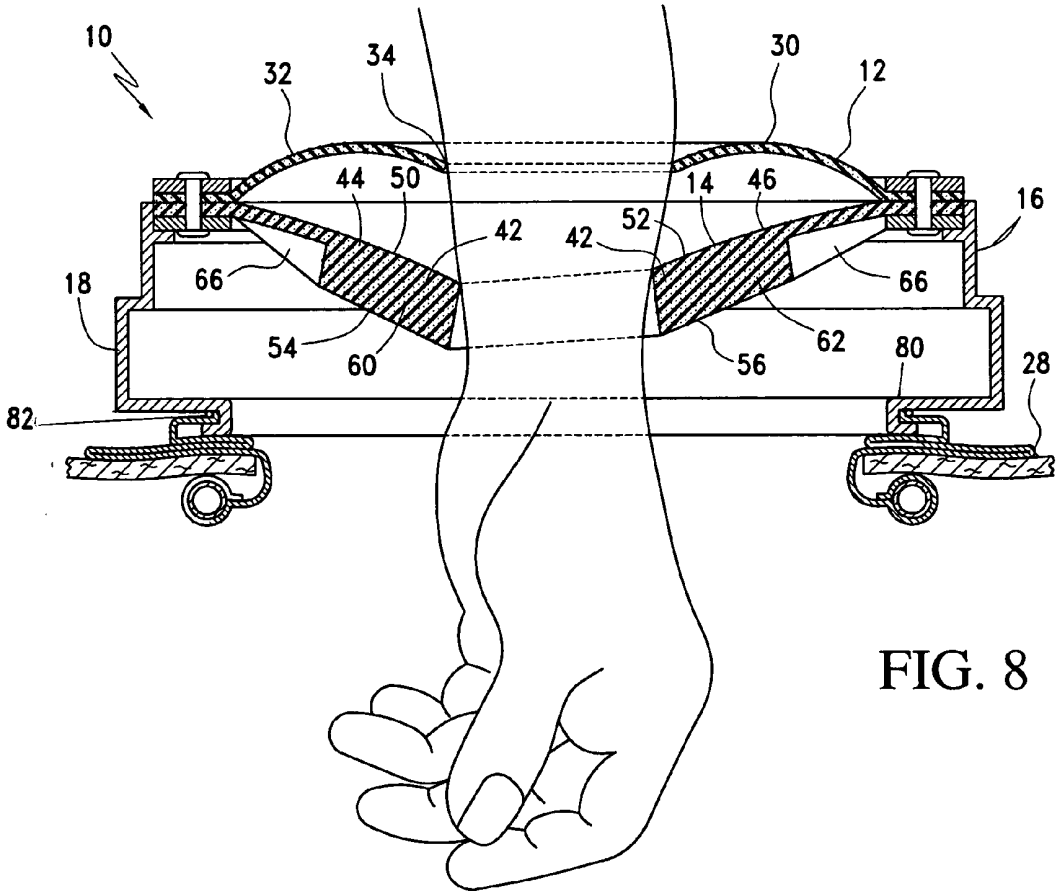
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FIG. 8

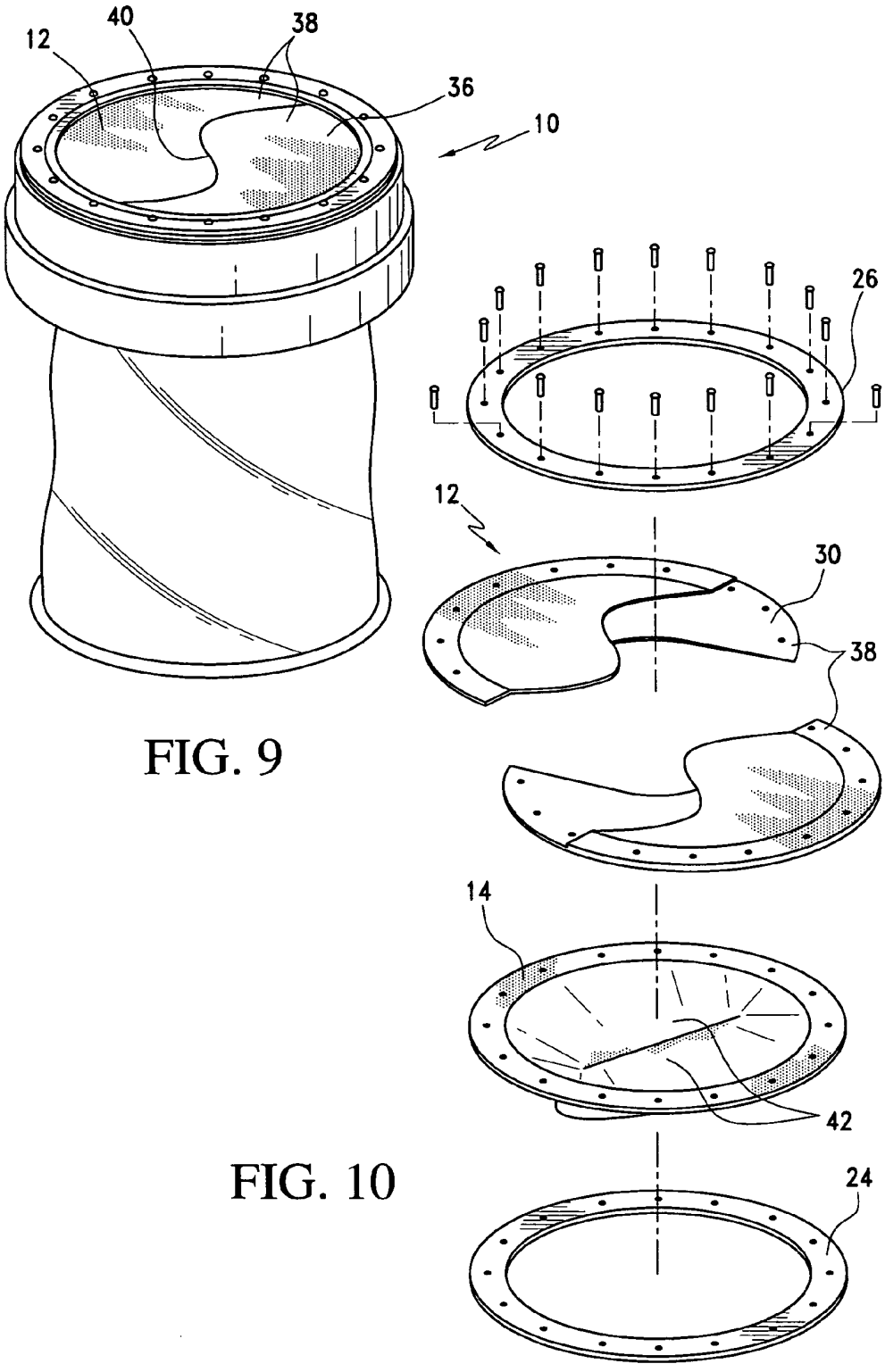
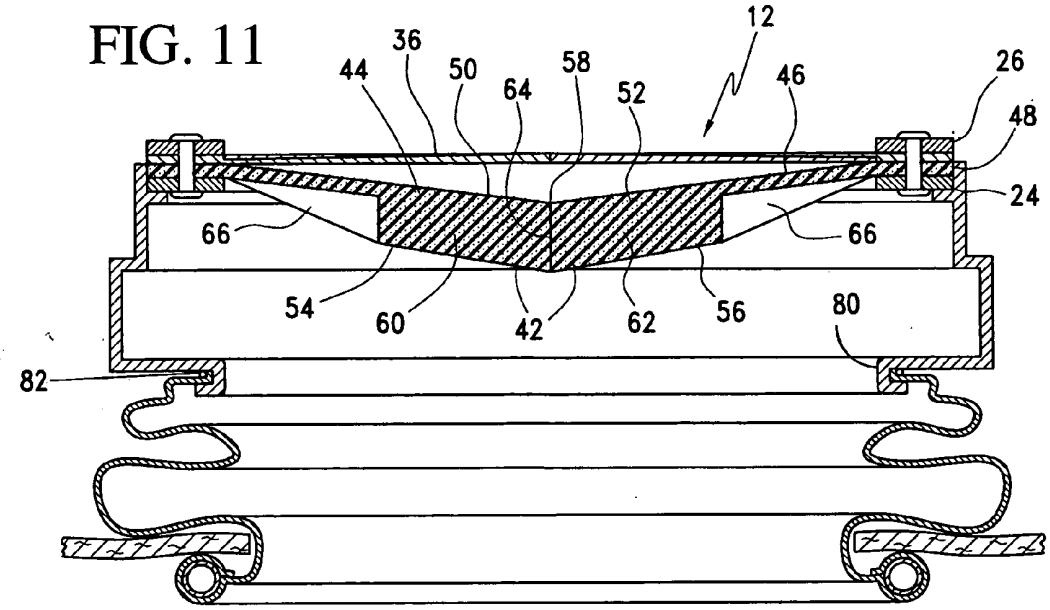


FIG. 9

FIG. 10

FIG. 11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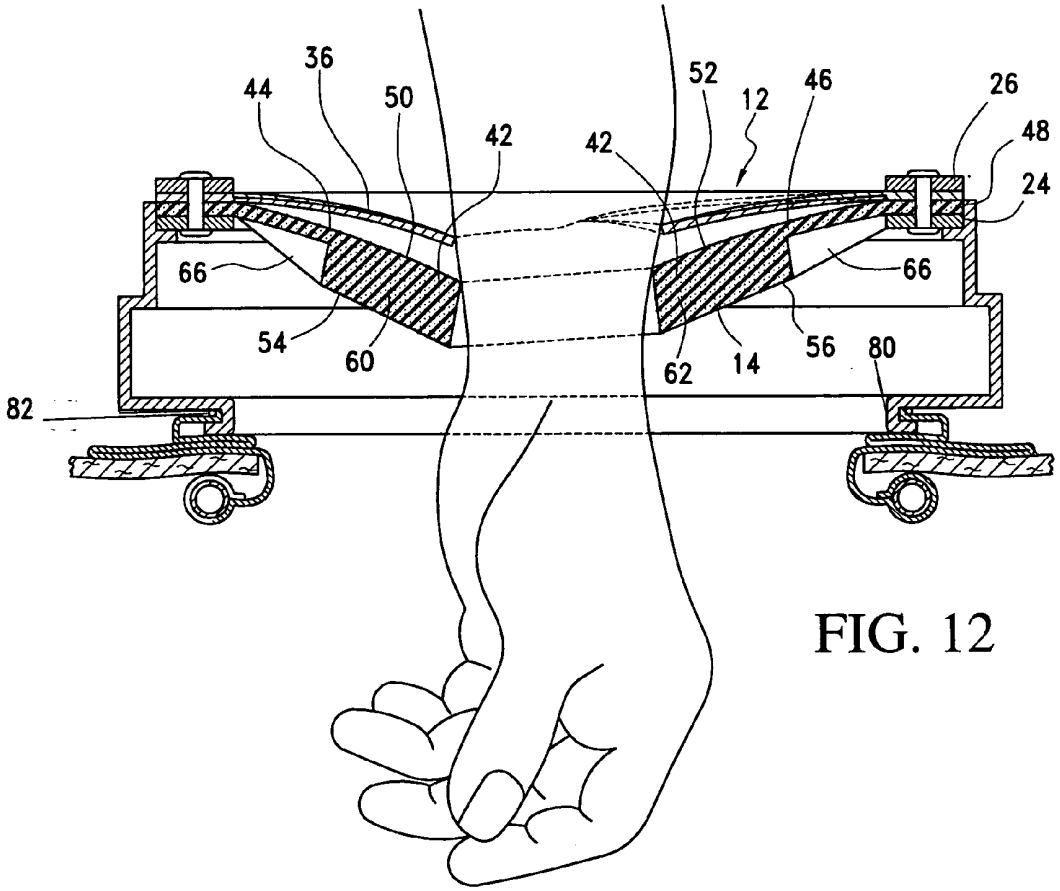
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FIG. 12

HAND ASSISTED LAPAROSCOPIC DEVICE

BACKGROUND OF THE INVENTION

[0001] 1. Field of the Invention

[0002] The invention relates to laparoscopic devices. In particular, the invention relates to a laparoscopic seal assembly permitting the use of hands in assisting during laparoscopic procedures.

[0003] 2. Description of the Prior Art

[0004] During laparoscopic procedures, it is often desirable for the surgeon to place his or her hand within the patient in a manner manipulating the instruments positioned within the patient. When this occurs, it is desirable to separate the external environment from the internal portion of the patient. For example, when hand assisted laparoscopic procedures are performed within the abdominal cavity, it is desirable to perform hand exchanges with minimal loss of abdominal pressure.

[0005] As such, a need exists for skin mountable seals permitting hand assisted laparoscopic procedures without fear that the abdominal pressure will be compromised. The present invention provides such an apparatus.

SUMMARY OF THE INVENTION

[0006] It is, therefore, an object of the present invention to provide a hand assisted laparoscopic seal apparatus. The apparatus includes a first seal, a second seal and a housing supporting the first seal relative to the second seal. One of the first seal or the second seal is shaped and dimensioned for engaging and sealing around an arm of a medical practitioner and the other seal is shaped and dimensioned for sealing a body cavity from an external environment.

[0007] It is also an object of the present invention to provide a seal apparatus wherein the first seal is a lip seal having a central opening.

[0008] It is also another object of the present invention to provide a seal apparatus wherein the second seal is a duckbill seal.

[0009] It is also a further object of the present invention to provide a seal apparatus wherein the first seal is an outer seal and the second seal is an inner seal.

[0010] It is another object of the present invention to provide a seal apparatus wherein the lip seal includes a flexible annular membrane with the central opening formed therein.

[0011] It is a further object of the present invention to provide a seal apparatus wherein the central opening is approximately 2.00 inches or less.

[0012] It is yet a further object of the present invention to provide a seal apparatus wherein the central opening ranges between approximately 1.25 inches to approximately 1.5 inches.

[0013] It is still another object of the present invention to provide a seal apparatus wherein the first seal is an overlapping seal having a central opening.

[0014] It is also an object of the present invention to provide a seal apparatus wherein the second seal includes first and second seal bodies, each of the first and second seal bodies include an upper surface and a lower surface, and the respective first and second seal bodies includes a thickened section adjacent a meeting point of the first and second seal bodies.

[0015] It is another object of the present invention to provide a seal apparatus wherein the thickness of the first and second seal bodies is approximately 0.540 inch along the thickened section.

[0016] It is a further object of the present invention to provide a seal apparatus wherein the first and second seal bodies are approximately less than 0.10 inch thick along a remainder thereof.

[0017] It is also an object of the present invention to provide a seal apparatus including a seal and a housing supporting the seal, wherein the seal is composed of open cell foam impregnated with silicone.

[0018] It is still another object of the present invention to provide a seal apparatus wherein the seal is manufactured by casting the open cell foam within a mold and then pouring silicone therein to produce seal bodies exhibiting softness and durability.

[0019] It is yet a further object of the present invention to provide a seal apparatus wherein the open cell foam is polyurethane, urethane-ether or polyolefin.

[0020] Other objects and advantages of the present invention will become apparent from the following detailed description when viewed in conjunction with the accompanying drawings, which set forth certain embodiments of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

[0021] FIG. **1** is a perspective view of the present seal apparatus adjacent an incision in accordance with a preferred embodiment of the present invention.

[0022] FIG. **2** is a perspective view of the seal apparatus shown in FIG. **1** mounted at a predetermined tissue location.

[0023] FIG. **3** is a bottom perspective view of the inner seal of the seal apparatus shown with reference to FIG. **1**.

[0024] FIG. **4** is a partially exploded view of the seal apparatus shown in FIG. **1**.

[0025] FIG. **5** is an exploded view of the seal apparatus shown in FIG. **1**.

[0026] FIG. **6** is a cross sectional view of the seal apparatus shown in FIG. **1**.

[0027] FIGS. **7** and **8** are cross sectional views showing use of the seal apparatus shown in FIG. **1**.

[0028] FIG. **9** is a perspective view of the present seal apparatus in accordance with an alternate embodiment of the present invention.

[0029] FIG. **10** is an exploded view of the seal apparatus shown in FIG. **9**.

[0030] FIGS. **11** and **12** are cross sectional views showing use of the seal apparatus shown in FIG. **9**.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0031] The detailed embodiments of the present invention are disclosed herein. It should be understood, however, that the disclosed embodiments are merely exemplary of the invention, which may be embodied in various forms. Therefore, the details disclosed herein are not to be interpreted as limiting, but merely as the basis for teaching one skilled in the art how to make and/or use the invention.

[0032] Referring to FIGS. **1** to **12**, a seal apparatus **10** for permitting hand assisted laparoscopic procedures is disclosed. The seal apparatus **10** generally employs a two-seal design to ensure abdominal pressure is not compromised

during hand exchanges while hand assisted laparoscopic procedures are performed. As such, the seal apparatus **10** includes an outer seal **12** and an inner seal **14**. Although a two-seal design is disclosed in accordance with a preferred embodiment of the present invention, those skilled in the art will appreciate the concepts underlying the present invention may be applied to apparatuses employing additional seal layers without departing from the spirit of the present invention.

[0033] The outer seal **12** is shaped and dimensioned to create a gas tight barrier around the surgeon's wrist when inserted through the seal apparatus **10**, while the inner seal **14** is shaped and dimensioned to create a gas tight barrier between the interior abdominal space and the external environment when a hand is not inserted through the seal apparatus **10**.

[0034] Referring to the various figures, both the inner seal **14** and the outer seal **12** are positioned within a housing **16**. In accordance with a preferred embodiment, the housing **16** is made of polyurethane, polycarbonate, and soft elastomers, such as, EPDM (Ethylene Propylene Dimonomer) and SANTOPRENE (that is, a thermoplastic elastomer), although those skilled in the art will appreciate a variety of materials may be used without departing from the spirit of the present invention. The housing **16** preferably supports the outer and inner seals **12**, **14** in a concentric manner, although noncentric constructions may be employed without departing from the spirit of the present invention. More particularly, the housing **16** includes an annular base member **18**. The annular base member **18** includes an inwardly directed rim **20** and a circumferentially extending outer border **22**. Positioned along the inner rim **20** is a lower gasket member **24** upon which is placed the inner seal **14**. Positioned directly upon the inner seal **14** is the outer seal **12**, and an upper closure gasket **26** is positioned thereabove. The upper closure gasket **26** is secured to the outer seal **12**, inner seal **14** and lower gasket member **24** in a manner securing all components of the present apparatus together. In accordance with a preferred embodiment, the various components are held together using mechanical attachment structures, such as, press fit rivets, adhesive, welds, or other suitable securing mechanism known to those skilled in the art.

[0035] The housing **16** is secured to the skin of an individual by first creating an incision and positioning the housing **16** adjacent the incision. Thereafter, a retractor (or wound protector) **28**, which is coupled to the housing **16** at housing end **80** by an O-ring **82**, is inserted into the body cavity. The skirt **29** of the retractor **28** is then drawn about the lower end of the housing **16** with the skin therebetween. As such, the housing **16** is securely supported on the skin with the retractor **28** resiliently holding the skin therebetween. Although a fixed length retractor is disclosed in accordance with a preferred embodiment of the present invention, it is contemplated adjustable retractors may be used without departing from the spirit of the present invention. For example, an adjustable retractor may be employed which allows for one to "roll-up" the free end of the retractor, or otherwise adjust the length of the retractor, for proper positioning of the present seal apparatus relative to an incision.

[0036] More particularly, and in accordance with one technique for the performance of hand assisted laparoscopic procedures, the surgical site is prepared in accordance with conventional standard hospital procedures, making sure the skin is clean and dry. Thereafter, a template is placed over the incision site and an incision line is marked upon the template using a sterile skin marker. As those skilled in the art will appreciate, the glove size dictates the size of the incision. For example, if the surgeon's glove size is 7, a 7 cm incision is usually appropriate. Thereafter, an incision is made along the marked incision line. The incision size is thereafter verified by inserting the surgeon's hand into the abdomen prior to attaching the present seal apparatus **10**. If the incision is too small, the incision is extended as required on each end to maintain the central position of the incision relative to the placement of the present seal apparatus **10**. Thereafter, the retractor **28** is inserted through the incision. Using one's fingers, the retractor **28** is seated evenly under the peritoneum and the area is swept to ensure that tissue is not trapped between the retractor **28** and the abdominal cavity. Thereafter, the housing **16** is pulled down into contact with the skin with the patient's tissue between the retractor **28** and the housing **16**.

[0037] In accordance with a preferred embodiment, it is contemplated the outer seal **12** may be constructed with either a lip seal design or an overlapping seal design (respectively see FIGS. **1-8** and **9-12**, where similar numerals are used for similar elements). However, and as those skilled in the art will certainly appreciate, other similar seal constructions, for example, an iris seal, may be employed without departing from the spirit of the present invention.

[0038] Where a lip seal **30** is employed, the lip seal **30** is shaped and dimensioned to seal about the surgeon's wrist thereby creating a gas tight barrier thereabout when inserted through the seal apparatus **10**. With this in mind, the lip seal **30** includes a flexible annular membrane **32** with a central opening **34**. In accordance with a preferred embodiment, the central opening **34** is approximately 2.0 inches or less, and more preferably between approximately 1.25 inches to approximately 1.5 inches. The size is chosen to comfortably accommodate a wide range of wrist and forearm sizes ensuring that most doctors will be readily able to insert their hand and wrist/forearm through the central opening **34** while allowing the central opening **34** to return to its unstressed configuration wrapped about the wrist of the doctor. The lip seal **30** is manufactured of a material allowing for the creation of contact pressure about the wrist sufficient to form a gas tight barrier without undue pressure upon the user's wrist. As such, it is contemplated the lip seal **30** will be composed of polyisoprene, urethane, neoprene, silicone, or similar materials offering desirable resilience and comfort.

[0039] Where an overlapping seal **36** is contemplated, the overlapping seal **36** is composed of multiple seal members **38** positioned about the central opening **40** in a manner creating an opening as the various seal members are pushed downwardly as one's hand is pushed therethrough. As those skilled in the art will appreciate, the various seal members **38** making up the overlapping seal **36** are shaped and dimensioned in a manner allowing them to be coupled together to create an annular space similar to the lip seal **30**. However, because multiple seal members **38** are used in the construction of an overlapping seal **36**, and the seal members **38** are fixedly coupled along the peripheral edge of the overlapping seal **36**, the central opening **40** readily flexes to permit passage of a hand therethrough. As such, the overlapping seal **36** will open as a surgeon forces his wrist through the present seal apparatus **10** and the resiliency of the various seal members **38** will close upon the surgeon's

wrist as he passes through the outer seal **12**. With this in mind, and as with the lip seal construction, the overlapping seal **36** will be composed of polyisoprene, urethane, neoprene, silicone or similar materials offering desirable resilience and comfort.

[0040] While both a lip seal **30** and an overlapping seal **36** are contemplated in accordance with preferred embodiments of the present invention, it is contemplated an overlapping seal **36** will offer advantages over the lip seal **30**. In particular, the contact pressure on the surgeon's wrist will be less when an overlapping seal **36** is utilized (although the gas tight barrier will be equivalent). In addition, an overlapping seal **36** will permit adjustment of the opening size to accommodate various wrist sizes and instrument sealing.

[0041] Although a lip seal and an overlapping seal are disclosed above in accordance with a preferred embodiment, those skilled in the art will appreciate various seal designs may be employed without departing from the spirit of the present invention. For example, an iris seal may be employed. In addition, it is contemplated layered seal designs may be employed within the spirit of the present invention. Specifically, a layered design might employ multiple overlapping seals as discussed above placed upon each other with their opening (and seal members) angularly offset to enhance the seals' ability to create a barrier when an individual's hand is passed therethrough.

[0042] With regard to the inner seal **14**, it is preferably a duckbill seal design. Generally, the duckbill inner seal **14** includes a pair of opposed valve members **42** which open and close in much the same manner a duck opens and closes its bill. In accordance with a preferred embodiment of the present invention, the duckbill inner seal **14** includes first and second seal bodies **44**, **46** extending from a circumferential flange member **48** shaped and dimensioned for mounting within the housing **16**. Each of the first and second seal bodies **44**, **46** includes an upper surface **50**, **52** and a lower surface **54**, **56**. The upper surface **50**, **52** is substantially smooth and consistently flat as it extends from the perimeter of the inner seal **14** to the central slit **58** where the first and second seal bodies **44**, **46** meet. As will be discussed below, the lower surfaces **54**, **56** of the respective first and second seal bodies **44**, **46** include a thickened section **60**, **62** adjacent the meeting point of the first and second seal bodies **44**, **46**.

[0043] The first and second seal bodies **44**, **46** are mounted within the housing **16** for movement as a surgeon's hand and/or an instrument is passed therethrough. With this in mind, the proximal end of each of the first and second seal bodies **44**, **46** is coupled to the housing **16** via the circumferential flange member **48**, while the distal ends of the first and second seal bodies **44**, **46** intersect to define an abutment face **64**. The abutment face **64** is generally positioned within the center of the housing **16**, and in line with the outer seal **12**, to permit the passage of a hand and/or instrument therethrough. In the absence of the passage of a hand and/or instrument therethrough, the abutment face **64** is closed via the resilience of the first and second seal bodies **44**, **46** as they are biased under the pressure generated from the body cavity in which the present seal apparatus **10** is positioned, for example, biased under the pressure from the abdominal insufflation gas pressure. This pressure causes the duckbill inner seal **14** to move to a closed position with the distal ends of the first and second seal bodies **44**, **46** in contact.

[0044] As briefly mentioned above, the first and second seal bodies **44**, **46** are formed with a thickened section **60**, **62** adjacent the abutment face **64**. In particular, the thickness of the first and second seal bodies **44**, **46** is approximately 0.540 inch thick along the abutment face **64**, while the remainder of the first and second seal bodies **44**, **46** is preferably less than approximately 0.1 inch thick, and more preferably approximately 0.080 inch thick. Each of the first and second seal bodies **44**, **46** is further provided with a plurality of radially extending reinforcement ribs **66** extending between the distal end of the seal bodies **44**, **46** and the thickened section **60**, **62** adjacent the abutment face **64**.

[0045] In accordance with a preferred embodiment of the present invention, the inner seal is constructed to offer a soft yet durable construction. With this in mind, and in accordance with a preferred embodiment, the seal bodies are composed of open cell foam, for example, polyurethane, urethane-ether or polyolefin, impregnated with silicone. The seal bodies are manufactured by casting the open cell foam within a mold and then pouring silicone therein to produce seal bodies which exhibit desirable softness with durability as one passes his or her hand therethrough. As those skilled in the art will appreciate, the thickened sections **60**, **62** of the first and second seal bodies **44**, **46** are manufactured from silicone (or other elastomer materials, such as, urethane) reinforced with polyurethane foam while the remainder of the seal bodies **44**, **46** is composed of silicone (or other elastomer materials, such as, urethane). In particular, the first and second seal bodies **44**, **46** are made entirely from silicone and the thickened sections **60**, **62** thereof are reinforced with polyurethane open cell foam. In addition, it is contemplated the duckbill portion may include fabric or open cell lattice structure as a reinforcement. This will provide durability while maintaining flexibility. As with the open cell foam employed in accordance with a preferred embodiment, the silicone (or other elastomer) can be combined with the reinforcement to fill the lattice structure or spaces.

[0046] In accordance with a preferred embodiment, the wall angle of the upper surface **50**, **52** of the first and second seal bodies **44**, **46** is maintained at an angle of approximately 30 degrees to approximately 45 degrees so as to balance the ease of passage through the inner seal **14** with the seal's ability to fully close when not in use.

[0047] It is further contemplated forces between the duckbill seal and a hand and/or instrument passing therethrough may be further minimized by adjusting wall thickness, rib geometry, surface coatings and material properties.

[0048] The positioning of the lip or overlapping seal as the outer seal and the duckbill seal as the inner seal is disclosed in accordance with a preferred embodiment. However, those skilled in the art will certainly appreciate the seal types may be reversed without adversely affecting the functionality of the present seal apparatus.

[0049] While the preferred embodiments have been shown and described, it will be understood that there is no intent to limit the invention by such disclosure, but rather, is intended to cover all modifications and alternate constructions falling within the spirit and scope of the invention.

1. A hand assisted laparoscopic seal apparatus, comprising:

a first seal;

a second seal; and

a housing supporting the first seal relative to the second seal;

wherein one of the first seal or the second seal is shaped and dimensioned for engaging and sealing around an arm of a medical practitioner and the other seal is shaped and dimensioned for sealing a body cavity from an external environment.

2. The seal apparatus according to claim **1**, wherein the first seal is a lip seal having a central opening.

3. The seal apparatus according to claim **2**, wherein the second seal is a duckbill seal.

4. The seal apparatus according to claim **3**, wherein the first seal is an outer seal and the second seal is an inner seal.

5. The seal apparatus according to claim **2**, wherein the lip seal includes a flexible annular membrane with the central opening formed therein.

6. The seal apparatus according to claim **5**, wherein the central opening is approximately 2.00 inches or less.

7. The seal apparatus according to claim **5**, wherein the central opening ranges between approximately 1.25 inches to approximately 1.5 inches.

8. The seal apparatus according to claim **1**, wherein the first seal is an overlapping seal having a central opening.

9. The seal apparatus according to claim **8**, wherein the second seal is a duckbill seal.

10. The seal apparatus according to claim **9**, wherein the first seal is an outer seal and the second seal is an inner seal.

11. The seal apparatus according to claim **1**, wherein the second seal is a duckbill seal.

12. The seal apparatus according to claim **11**, wherein the second seal includes first and second seal bodies, each of the first and second seal bodies includes an upper surface and a lower surface, and the respective first and second seal bodies include a thickened section adjacent a meeting point of the first and second seal bodies.

13. The seal apparatus according to claim **12**, wherein the thickness of the first and second seal bodies is approximately 0.540 inch along the thickened section.

14. The seal apparatus according to claim **13**, wherein the first and second seal bodies are approximately less than 0.10 inch thick along a remainder thereof.

15. A hand assisted laparoscopic seal apparatus, comprising:

a seal and a housing supporting the seal, wherein the seal is composed of open cell foam impregnated with silicone.

16. The seal apparatus according to claim **15**, wherein the seal is manufactured by casting the open cell foam within a mold and then pouring silicone therein to produce seal bodies exhibiting softness and durability.

17. The seal apparatus according to claim **16**, wherein the open cell foam is polyurethane, urethane-ether or polyolefin.

18. The seal apparatus according to claim **17**, wherein the seal is a duckbill seal.

19. The seal apparatus according to claim **18**, wherein the seal includes first and second seal bodies, each of the first and second seal bodies includes an upper surface and a lower surface, and wherein the respective first and second seal bodies include a thickened section adjacent a meeting point of the first and second seal bodies.

20. The seal apparatus according to claim **19**, wherein the thickness of the first and second seal bodies is approximately 0.540 inch along the thickened section.

* * * * *

专利名称(译)	手助腹腔镜设备		
公开(公告)号	US20080011307A1	公开(公告)日	2008-01-17
申请号	US11/484846	申请日	2006-07-12
[标]申请(专利权)人(译)	BECKMAN ANDREW t 克罗宁MICHAEL Đ		
申请(专利权)人(译)	BECKMAN ANDREW t 克罗宁MICHAEL Đ		
当前申请(专利权)人(译)	BECKMAN ANDREW t 克罗宁MICHAEL Đ		
[标]发明人	BECKMAN ANDREW T CRONIN MICHAEL D		
发明人	BECKMAN, ANDREW T. CRONIN, MICHAEL D.		
IPC分类号	A61B19/08		
CPC分类号	A61B17/02 A61B17/3423 A61B2017/0084 A61B17/3498 A61B2017/00526 A61B17/3431		
外部链接	Espacenet USPTO		

摘要(译)

一种手助腹腔镜密封装置，包括外密封件，内密封件和相对于内密封件支撑外密封件的壳体，其中外密封件或内密封件中的一个的形状和尺寸适于接合和密封围绕臂的臂。医疗从业者和另一个密封件的形状和尺寸适于将体腔与外部环境密封。