



US007878974B2

(12) **United States Patent**
Brustad et al.

(10) **Patent No.:** **US 7,878,974 B2**
(45) **Date of Patent:** **Feb. 1, 2011**

(54) **HAND ACCESS LAPAROSCOPIC DEVICE**
(75) Inventors: **John R Brustad**, Dana Point, CA (US);
Jeremy J Albrecht, Rancho Santa
Margarita, CA (US); **Nabil Hilal**,
Laguna Niguel, CA (US); **Gary M**
Johnson, Mission Viejo, CA (US);
Charles C Hart, Summerville, SC (US)

(73) Assignee: **Applied Medical Resources**
Corporation, Rancho Santa Margarita,
CA (US)

(*) Notice: Subject to any disclaimer, the term of this
patent is extended or adjusted under 35
U.S.C. 154(b) by 0 days.

(21) Appl. No.: **12/815,986**

(22) Filed: **Jun. 15, 2010**

(65) **Prior Publication Data**
US 2010/0249527 A1 Sep. 30, 2010

Related U.S. Application Data
(63) Continuation of application No. 11/548,955, filed on
Oct. 12, 2006, now Pat. No. 7,736,306.

(60) Provisional application No. 60/726,826, filed on Oct.
14, 2006, provisional application No. 60/745,730,
filed on Apr. 26, 2006, provisional application No.
60/803,346, filed on May 26, 2006, provisional appli-
cation No. 60/803,965, filed on Jun. 5, 2006, provi-
sional application No. 60/828,089, filed on Oct. 4,
2006.

(51) **Int. Cl.**
A61B 1/32 (2006.01)

(52) **U.S. Cl.** **600/208; 600/233**

(58) **Field of Classification Search** **606/108,**
606/206, 208; 600/201-246

See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

558,364 A	4/1896	Doolittle
1,810,466 A	6/1931	Deutsch
2,305,289 A	12/1942	Coburg
2,478,586 A	8/1949	Krapp

(Continued)

FOREIGN PATENT DOCUMENTS

EP	1 125 552	8/2001
----	-----------	--------

(Continued)

OTHER PUBLICATIONS

Neil Sheehan, Supplemental Expert Report of Neil Sheehan, Re: U S
Patent No. 5,741,298, United States District Court for the Central
District of California, Civil Action No. SACV 03-1322 JVS, Aug. 9,
2005.

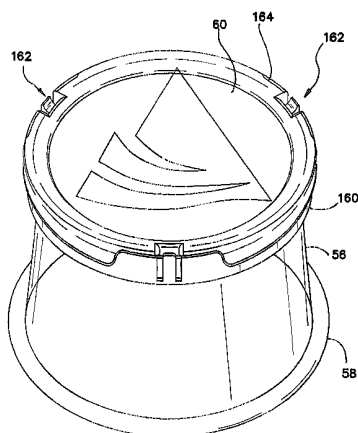
(Continued)

Primary Examiner—Eduardo C Robert
Assistant Examiner—Christina Negrelli
(74) *Attorney, Agent, or Firm*—Pui Tong Ho

(57) **ABSTRACT**

The invention relates to a hand access laparoscopy device having a gelcap, a retainer, a sleeve and a retention ring. The gelcap includes gel that is bonded to a cap. The cap includes an inner cylindrical wall to which the gel is bonded, thereby providing a sealing area between the device and the wound in a body wall. By securing the gel to the inner cylindrical wall, the thickness of the gel and corresponding cap is minimized along with the overall footprint of the device. With the gel thickness reduced and able to be substantially flush, the “doming” phenomenon produced by insufflation of a patient’s abdomen is reduced.

17 Claims, 16 Drawing Sheets



U.S. PATENT DOCUMENTS					
			5,435,943 A	7/1995	Adams et al.
			5,437,683 A	8/1995	Neumann et al.
2,812,758 A	11/1957	Blumenschein	5,441,486 A	8/1995	Yoon
2,835,253 A	5/1958	Borgeson	5,460,616 A	10/1995	Weinstein et al.
2,853,075 A	9/1958	Hoffman et al.	5,476,475 A	12/1995	Gadberry
3,039,468 A	6/1962	Price	5,480,410 A	1/1996	Cuschieri et al.
3,111,943 A	11/1963	Orndorff	5,486,426 A	1/1996	McGee et al.
3,195,934 A	7/1965	Parrish	5,492,304 A	2/1996	Smith et al.
3,244,169 A	4/1966	Baxter	5,496,280 A	3/1996	Vandenbroek et al.
3,332,417 A	7/1967	Blanford et al.	5,503,112 A	4/1996	Luhman et al.
3,347,226 A	10/1967	Harrower	5,514,133 A	5/1996	Golub et al.
3,347,227 A	10/1967	Harrower	5,518,278 A	5/1996	Sampson
3,397,692 A	8/1968	Creager, Jr. et al.	5,522,791 A	6/1996	Leyva
3,402,710 A	9/1968	Paleschuck	5,524,644 A	6/1996	Crook
3,416,520 A	12/1968	Creager, Jr.	5,531,758 A	7/1996	Uschold et al.
3,447,533 A	6/1969	Spicer	5,545,179 A	8/1996	Williamson, IV
3,523,534 A	8/1970	Nolan	5,562,677 A	10/1996	Hildwein et al.
3,717,151 A	2/1973	Collett	5,603,702 A	2/1997	Smith et al.
3,831,583 A	8/1974	Edmunds, Jr. et al.	5,628,732 A	5/1997	Antoon, Jr. et al.
3,841,332 A	10/1974	Treacle	5,632,284 A	5/1997	Graether
3,850,172 A	11/1974	Cazalis	5,634,936 A	6/1997	Linden et al.
3,856,021 A	12/1974	McIntosh	5,634,937 A	6/1997	Mollenauer et al.
3,860,274 A	1/1975	Ledstrom et al.	5,636,645 A	6/1997	Ou
4,024,872 A	5/1977	Muldoon	5,640,977 A	6/1997	Leahy et al.
4,043,328 A	8/1977	Cawood, Jr. et al.	5,649,550 A	7/1997	Crook
4,069,913 A	1/1978	Harrigan	5,653,705 A	8/1997	de la Torre et al.
4,083,370 A	4/1978	Taylor	5,672,168 A	9/1997	de la Torre et al.
4,188,945 A	2/1980	Wenander	5,681,341 A	10/1997	Lunsford et al.
4,217,664 A	8/1980	Faso	5,709,664 A	1/1998	Vandenbroek et al.
4,222,126 A	9/1980	Boretos et al.	5,720,730 A	2/1998	Blake, III
4,254,973 A	3/1981	Benjamin	5,728,103 A	3/1998	Picha et al.
4,338,937 A	7/1982	Lerman	5,741,298 A	4/1998	MacLeod
4,367,728 A	1/1983	Mutke	5,753,150 A	5/1998	Martin et al.
4,454,873 A	6/1984	Laufenberg et al.	5,782,817 A	7/1998	Franzel et al.
4,475,548 A	10/1984	Muto	5,788,676 A	8/1998	Yoon
4,550,713 A	11/1985	Hyman	5,792,119 A	8/1998	Marx
4,553,537 A	11/1985	Rosenberg	5,795,290 A	8/1998	Bridges
4,691,942 A	9/1987	Ford	5,803,919 A	9/1998	Hart et al.
4,755,170 A	7/1988	Golden	5,803,921 A	9/1998	Bonadio
4,777,943 A	10/1988	Chvapil	5,810,721 A	9/1998	Mueller et al.
4,798,594 A	1/1989	Hillstead	5,813,409 A	9/1998	Leahy et al.
4,802,694 A	2/1989	Vargo	5,814,026 A	9/1998	Yoon
4,842,931 A	6/1989	Zook	5,832,925 A	11/1998	Rothrum
4,856,502 A	8/1989	Ersfeld et al.	5,841,298 A	11/1998	Huang
4,863,438 A	9/1989	Gauderer et al.	5,853,395 A	12/1998	Crook et al.
4,889,107 A	12/1989	Kaufman	5,865,729 A	2/1999	Meehan et al.
4,895,565 A	1/1990	Hillstead	5,865,807 A	2/1999	Blake, III
4,903,710 A	2/1990	Jessamine et al.	5,895,377 A	4/1999	Smith et al.
4,911,974 A	3/1990	Shimizu et al.	5,899,208 A	5/1999	Bonadio
4,926,882 A	5/1990	Lawrence	5,904,703 A	5/1999	Gilson
4,950,223 A	8/1990	Silvanov	5,906,577 A	5/1999	Beane et al.
4,984,564 A	1/1991	Yuen	5,919,476 A	7/1999	Fischer et al.
4,991,593 A	2/1991	LeVahn	5,947,922 A	9/1999	MacLeod
4,998,538 A	3/1991	Charowsky et al.	5,951,588 A	9/1999	Moening
5,009,224 A	4/1991	Cole	5,964,781 A	10/1999	Mollenauer et al.
5,015,228 A	5/1991	Columbus et al.	5,980,806 A	11/1999	Ohmi et al.
5,037,379 A	8/1991	Clayman et al.	5,989,233 A	11/1999	Yoon
5,082,005 A	1/1992	Kaldany	5,993,471 A	11/1999	Riza et al.
5,178,162 A	1/1993	Bose	5,993,485 A	11/1999	Beckers
5,192,301 A	3/1993	Kamiya et al.	5,997,515 A	12/1999	de la Torre et al.
5,207,656 A	5/1993	Kranys	6,010,494 A	1/2000	Schafer et al.
5,213,114 A	5/1993	Bailey, Jr.	6,024,736 A	2/2000	de la Torre et al.
5,299,582 A	4/1994	Potts	6,025,067 A	2/2000	Fay
5,316,541 A	5/1994	Fischer	6,033,426 A	3/2000	Kaji
5,350,364 A	9/1994	Stephens et al.	6,033,428 A	3/2000	Sardella
5,353,786 A	10/1994	Wilk	6,035,559 A	3/2000	Freed et al.
5,366,478 A	11/1994	Brinkerhoff et al.	6,045,535 A	4/2000	Ben Nun
5,368,545 A	11/1994	Schaller et al.	6,093,358 A	7/2000	Schiewe et al.
5,380,288 A	1/1995	Hart et al.	6,142,936 A	11/2000	Beane et al.
5,389,080 A	2/1995	Yoon	6,149,642 A	11/2000	Gerhart et al.
5,389,081 A	2/1995	Castro	6,162,172 A	12/2000	Cosgrove et al.
5,407,433 A	4/1995	Loomas	6,254,533 B1	7/2001	Fadem et al.
5,429,609 A	7/1995	Yoon	6,254,534 B1	7/2001	Butler et al.

6,325,384 B1	12/2001	Berry, Sr. et al.	2006/0149306 A1	7/2006	Hart et al.
6,375,877 B2	4/2002	Lauf et al.	2006/0161050 A1	7/2006	Butler et al.
6,382,211 B1	5/2002	Crook			
6,383,162 B1	5/2002	Sugarbaker			
6,406,499 B1	6/2002	Kania			
6,413,244 B1	7/2002	Bestetti et al.	IE	930649	9/1993
6,413,458 B1	7/2002	Pearce	IE	930650	9/1993
6,440,063 B1	8/2002	Beane et al.	IE	S940150	2/1994
6,450,983 B1	9/2002	Rambo	IE	S940613	8/1994
6,482,181 B1	11/2002	Racenet et al.	IE	S940960	12/1994
6,485,435 B1	11/2002	Bakal	IE	S950055	1/1995
6,533,734 B1	3/2003	Corley, III et al.	IE	S950266	4/1995
6,551,344 B2	4/2003	Thill	IE	S960196	8/1997
6,579,281 B2	6/2003	Palmer et al.	IE	S970810	11/1997
6,582,364 B2	6/2003	Butler et al.	IE	990218	11/2000
6,589,167 B1	7/2003	Shimomura et al.	IE	990219	11/2000
6,589,211 B1	7/2003	MacLeod	IE	990220	11/2000
6,613,952 B2	9/2003	Rambo	IE	990660	2/2001
6,623,426 B2	9/2003	Bonadio et al.	IE	990795	3/2001
6,702,787 B2	3/2004	Racenet et al.	JP	11-290327	10/1999
6,723,044 B2	4/2004	Pulford et al.	JP	2002-28163	1/2002
6,814,078 B2	11/2004	Crook	JP	02003 235879 A	8/2003
6,846,287 B2	1/2005	Bonadio et al.	WO	WO95/07056	3/1995
6,866,861 B1	3/2005	Luhman	WO	WO95/22289	8/1995
6,895,965 B2	5/2005	Scarberry et al.	WO	WO 95/24864	9/1995
6,902,541 B2	6/2005	McNally et al.	WO	WO 95/27468	10/1995
6,908,430 B2	6/2005	Caldwell et al.	WO	WO 99/25268	5/1999
6,939,296 B2	9/2005	Ewers et al.	WO	WO00/32116	6/2000
6,945,932 B1	9/2005	Caldwell et al.	WO	WO00/54675	9/2000
6,958,037 B2	10/2005	Ewers et al.	WO	WO00/54676	9/2000
6,972,026 B1	12/2005	Caldwell et al.	WO	WO00/54677	9/2000
6,997,909 B2	2/2006	Goldberg	WO	WO01/08581	2/2001
7,033,319 B2	4/2006	Pulford et al.	WO	WO02/34108	5/2002
7,052,454 B2	5/2006	Taylor	WO	WO03/032819	4/2003
7,081,089 B2	7/2006	Bonadio et al.	WO	WO03/034908	5/2003
2001/0037053 A1	11/2001	Bonadio et al.	WO	WO03/061480	7/2003
2002/0002324 A1	1/2002	McManus	WO	WO 2004/075730	9/2004
2002/0010388 A1	1/2002	Taylor et al.	WO	WO 2004/075741	9/2004
2002/0038077 A1	3/2002	de la Torre et al.	WO	WO 2004/075930	9/2004
2002/0072762 A1	6/2002	Bonadio et al.	WO	WO 2005/034766	4/2005
2003/0040711 A1	2/2003	Racenet et al.			
2003/0139756 A1	7/2003	Brustad			
2003/0187376 A1	10/2003	Rambo			
2003/0192553 A1	10/2003	Rambo			
2003/0225392 A1	12/2003	McMichael et al.			
2004/0015185 A1	1/2004	Ewers et al.			
2004/0049100 A1	3/2004	Butler et al.			
2004/0073090 A1	4/2004	Butler et al.			
2004/0092796 A1	5/2004	Butler et al.			
2004/0106942 A1	6/2004	Taylor et al.			
2004/0127772 A1	7/2004	Ewers et al.			
2004/0154624 A1	8/2004	Bonadio et al.			
2004/0167559 A1	8/2004	Taylor et al.			
2004/0173218 A1	9/2004	Yamada et al.			
2004/0254426 A1	12/2004	Wenchell			
2004/0267096 A1	12/2004	Caldwell et al.			
2005/0020884 A1	1/2005	Hart et al.			
2005/0033246 A1	2/2005	Ahlberg et al.			
2005/0059865 A1	3/2005	Kahle et al.			
2005/0090717 A1	4/2005	Bonadio et al.			
2005/0148823 A1	7/2005	Vaugh et al.			
2005/0155611 A1	7/2005	Vaugh et al.			
2005/0197537 A1	9/2005	Bonadio et al.			
2005/0222582 A1	10/2005	Wenchell			
2005/0241647 A1	11/2005	Nguyen et al.			
2005/0267419 A1	12/2005	Smith			
2005/0283050 A1	12/2005	Gundlapalli et al.			
2005/0288558 A1	12/2005	Ewers et al.			
2006/0030755 A1	2/2006	Ewers et al.			
2006/0047284 A1	3/2006	Gresham			
2006/0052669 A1	3/2006	Hart			
2006/0084842 A1	4/2006	Hart et al.			
2006/0129165 A1	6/2006	Edoga et al.			

FOREIGN PATENT DOCUMENTS

IE	930649	9/1993
IE	930650	9/1993
IE	S940150	2/1994
IE	S940613	8/1994
IE	S940960	12/1994
IE	S950055	1/1995
IE	S950266	4/1995
IE	S960196	8/1997
IE	S970810	11/1997
IE	990218	11/2000
IE	990219	11/2000
IE	990220	11/2000
IE	990660	2/2001
IE	990795	3/2001
JP	11-290327	10/1999
JP	2002-28163	1/2002
JP	02003 235879 A	8/2003
WO	WO95/07056	3/1995
WO	WO95/22289	8/1995
WO	WO 95/24864	9/1995
WO	WO 95/27468	10/1995
WO	WO 99/25268	5/1999
WO	WO00/32116	6/2000
WO	WO00/54675	9/2000
WO	WO00/54676	9/2000
WO	WO00/54677	9/2000
WO	WO01/08581	2/2001
WO	WO02/34108	5/2002
WO	WO03/032819	4/2003
WO	WO03/034908	5/2003
WO	WO03/061480	7/2003
WO	WO 2004/075730	9/2004
WO	WO 2004/075741	9/2004
WO	WO 2004/075930	9/2004
WO	WO 2005/034766	4/2005

OTHER PUBLICATIONS

Dexterity Protractor Instruction Manual by Dexterity Surgical, Inc. Horigane, et al, Technical Note: Development of a Duodenoal Cannula for Sheep, Journal of Animal Science, Apr. 1992, vol. 70, Issue 4, pp. 1216-1219.

Horigane, et al, Silicone Rumen Cannula with a Soft Cylindrical Part and a Hard Flange, Journal of Dairy Science, Nov. 1989 vol. 72, No. 11, pp. 3230-3232.

McSweeney, Cannulation of the Rumen in Cattle and Buffaloes, Australian Veterinary Journal, Aug. 1989, vol. 66, No. 8, pp. 266-268.

Yamazaki et al, Diurnal Changes in the Composition of Abomasal Digesta in Fasted and Fed Sheep, The Tohoku Journal of Agricultural Research, Mar. 1987, vol. 37, No. 3-4, pp. 49-58.

European Patent Office; International Search Report and The Written Opinion of the International Searching Authority for International Application No. PCT/US2006/040154, maile.

European Patent Office, International Search Report and The Written Opinion of the International Searching Authority for PCT Application No. PCT/US2006/039800 mailed Apr. 16.

Co-Pending U.S. Appl. No. 10/381,220, filed Mar. 20, 2003; Title: Surgical Access Apparatus and Method.

Co-Pending U.S. Appl. No. 10/516,198, filed Nov. 30, 2004; Title: Wound Retractor.

Co-Pending U.S. Appl. No. 10/927,551, filed Aug. 25, 2004; Title: Surgical Access System.

Co-Pending U.S. Appl. No. 11/244,647, filed Oct. 5, 2005; Title: Surgical Access Apparatus and Method.

Co-Pending U.S. Appl. No. 11/245,709, filed Oct. 7, 2005; Title: Surgical Access System.

Co-Pending U.S. Appl. No. 11/330,661, filed Jan. 12, 2006; Title: Sealed Surgical Access Device.

Co-Pending U.S. Appl. No. 11/548,746, filed Oct. 12, 2006; Title: Method of Making a Hand Access Laparoscopic Device.

Co-Pending U.S. Appl. No. 11/548,758, filed Oct. 12, 2006; Title: Split Hoop Wound Retractor With Gel Pad.

Co-Pending U.S. Appl. No. 11/548,765, filed Oct. 12, 2006; Title: Split Hoop Wound Retractor.

Co-Pending U.S. Appl. No. 11/548,767, filed Oct. 12, 2006; Title: Circular Surgical Retractor.

Co-Pending U.S. Appl. No. 11/548,781, filed Oct. 12, 2006; Title: Wound Retractor With Gel Cap.

Co-Pending U.S. Appl. No. 11/755,305, filed May 30, 2007; Title: Wound Retraction Apparatus and Method.

Co-Pending U.S. Appl. No. 11/564,409, filed Nov. 29, 2006; Title: Surgical Instrument Access Device.

The International Bureau of WIPO, International Preliminary Report on Patentability for International Application No. PCT/US2006/039800 dated Apr. 16, 2008.

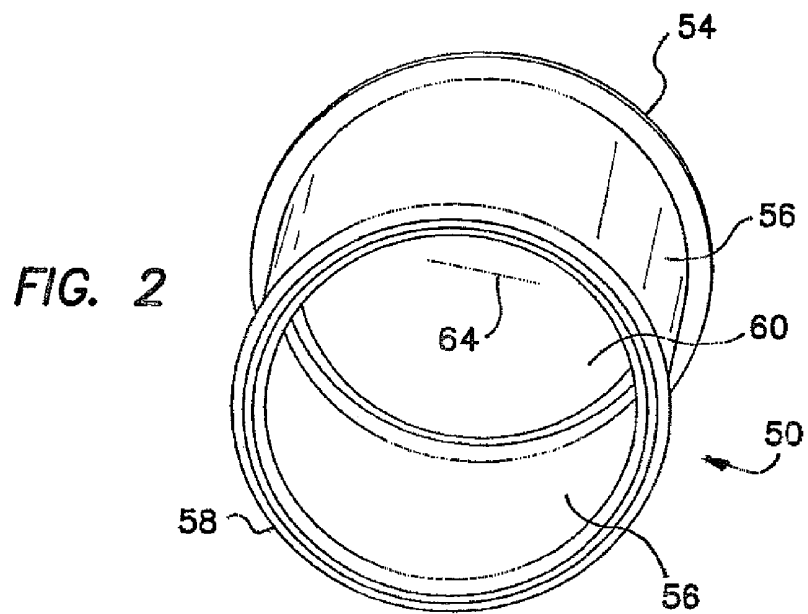
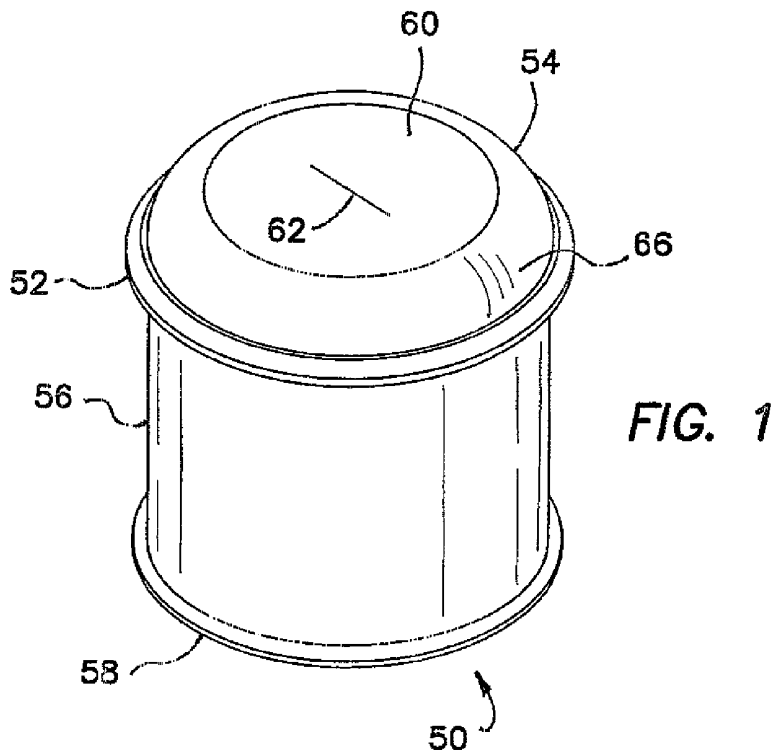
Declaration of John R. Brustad Under 37 C.F.R. 1.132, dated Dec. 10, 2009.

“Applied GelPort™ Advanced Access Device” product sales brochure dated 2001.

“Cap Ring” production drawing dated Jan. 19, 2001.

“Gelport® Laparoscopic Hand Access System” product sales brochure dated 2005.

“Cap Ring Medium” production drawing dated Aug. 16, 2005.



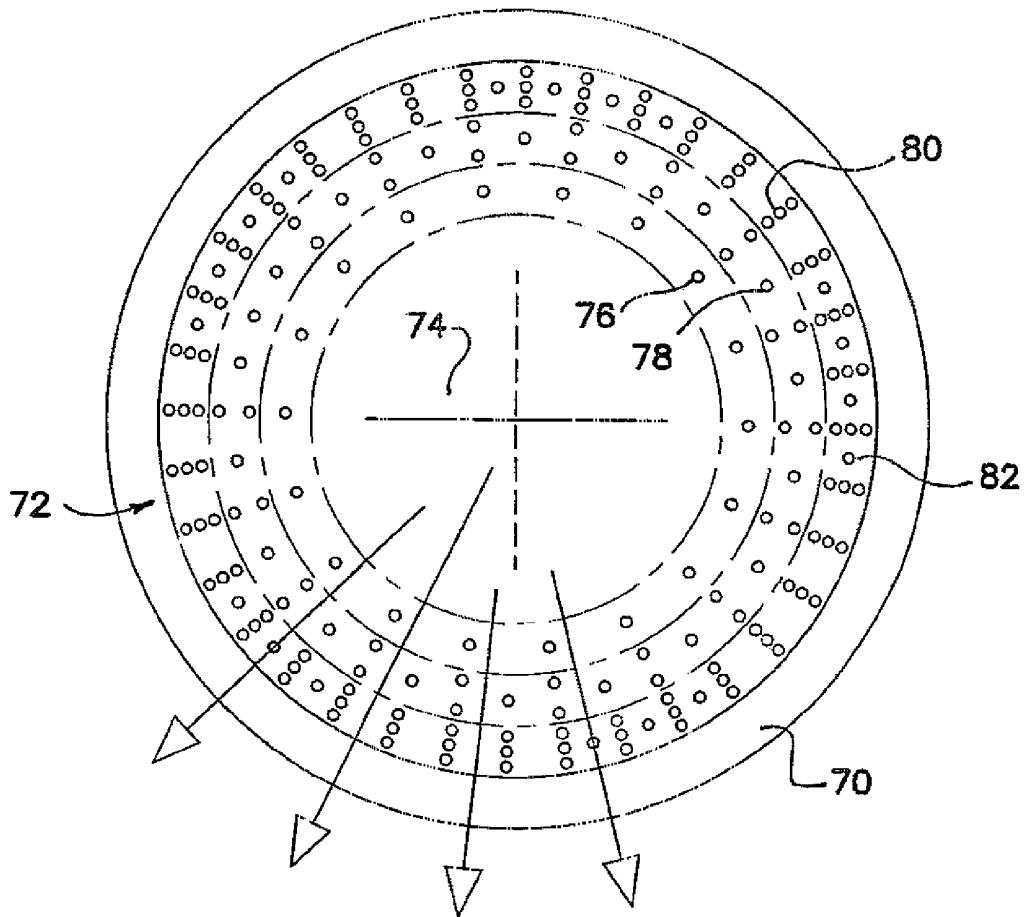


FIG. 3

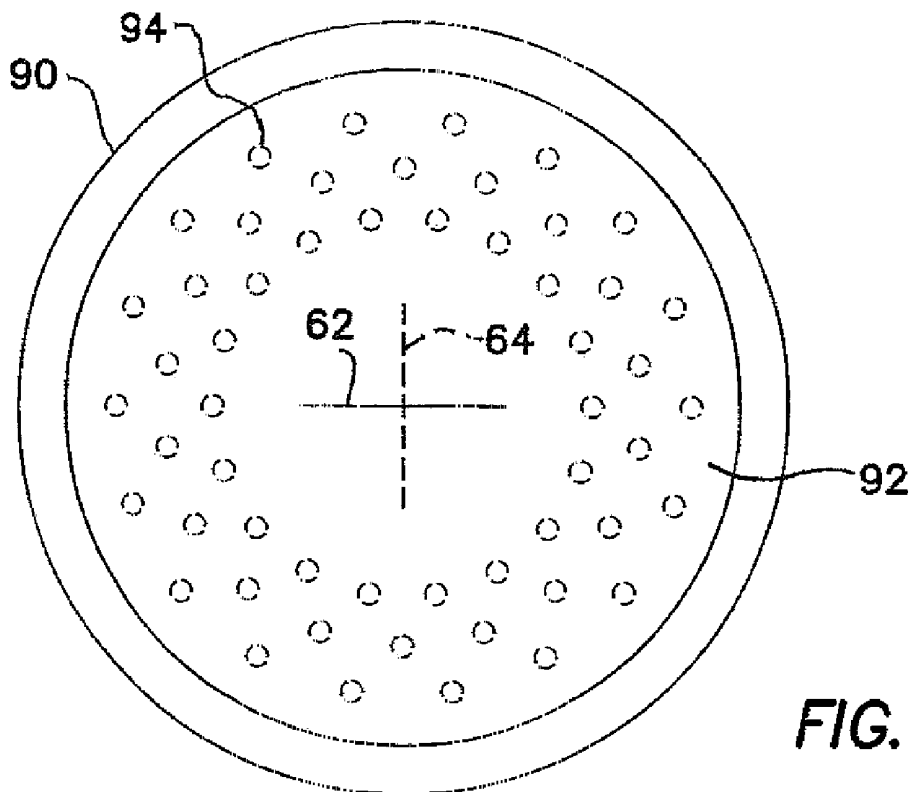
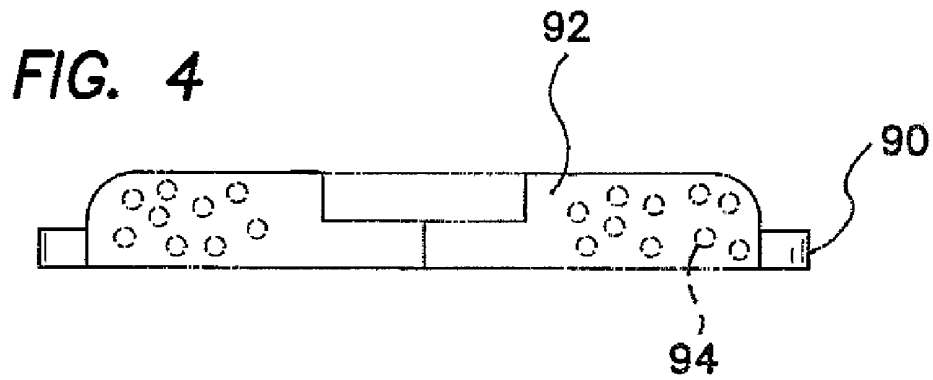


FIG. 6

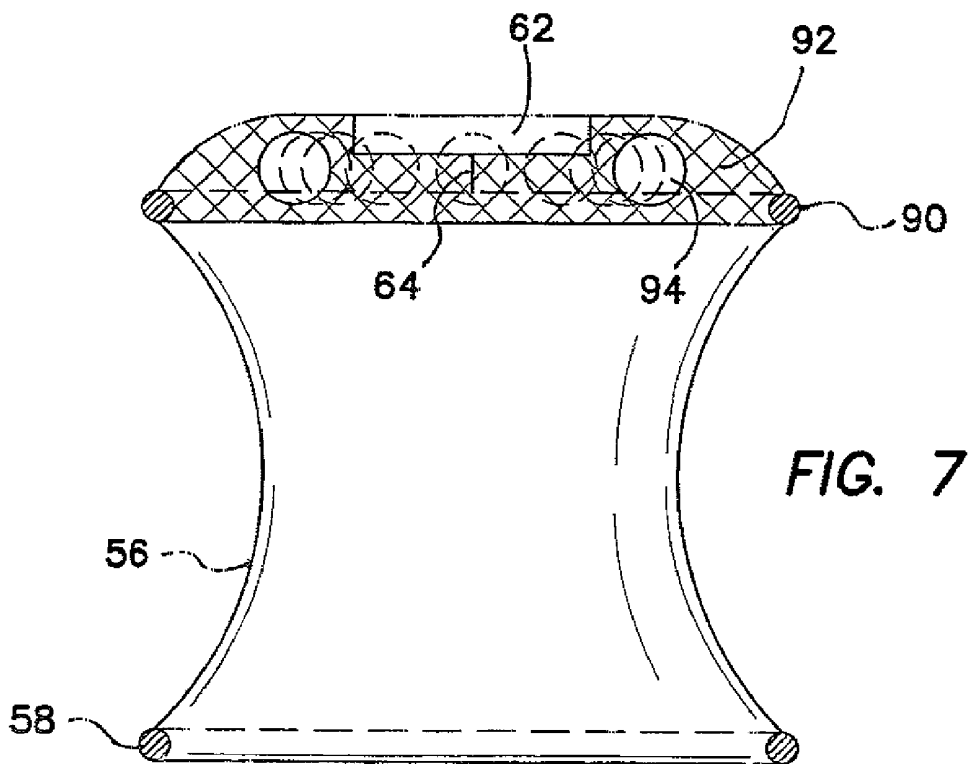
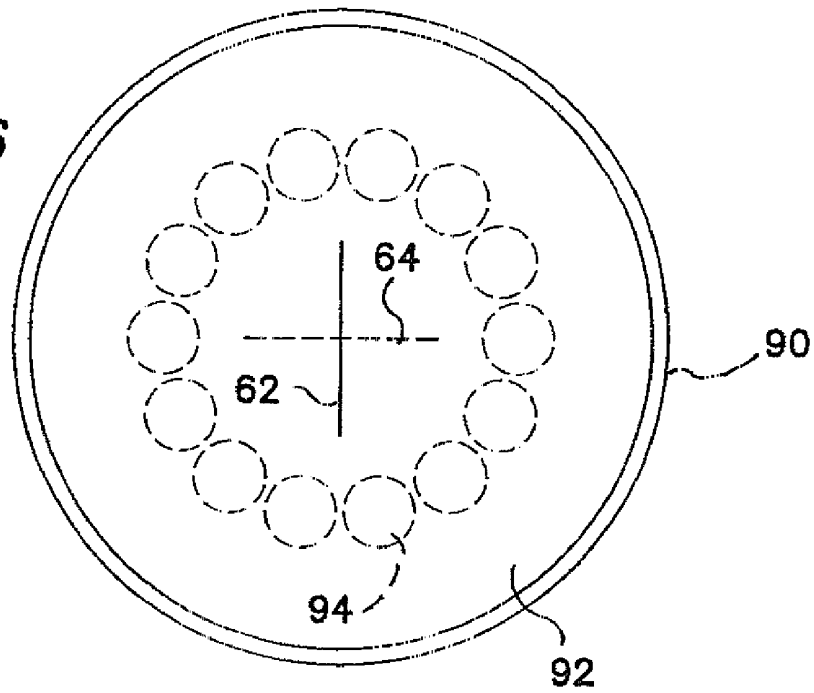
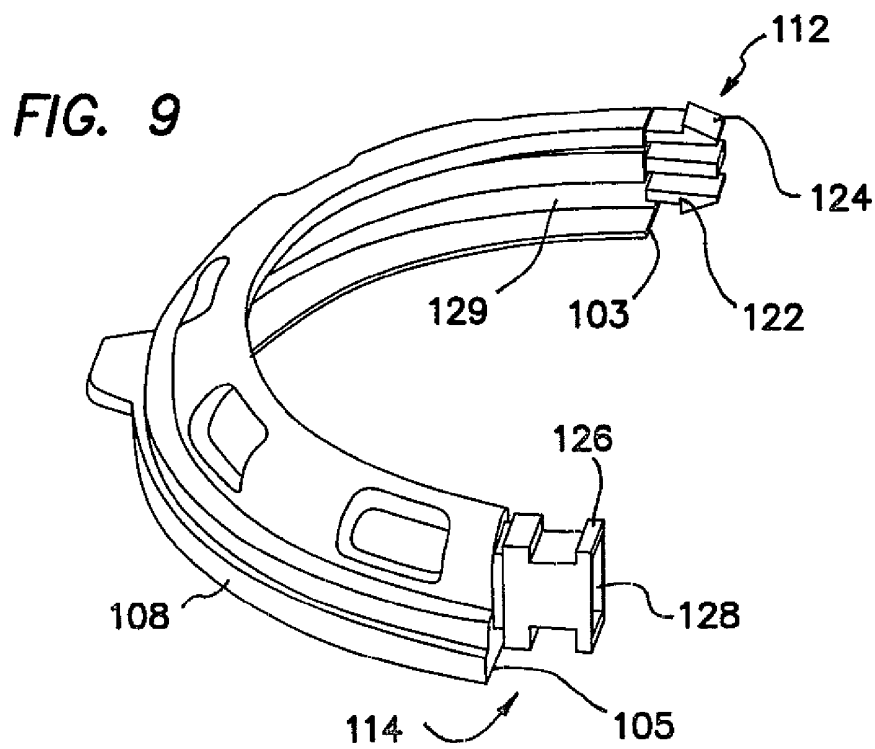
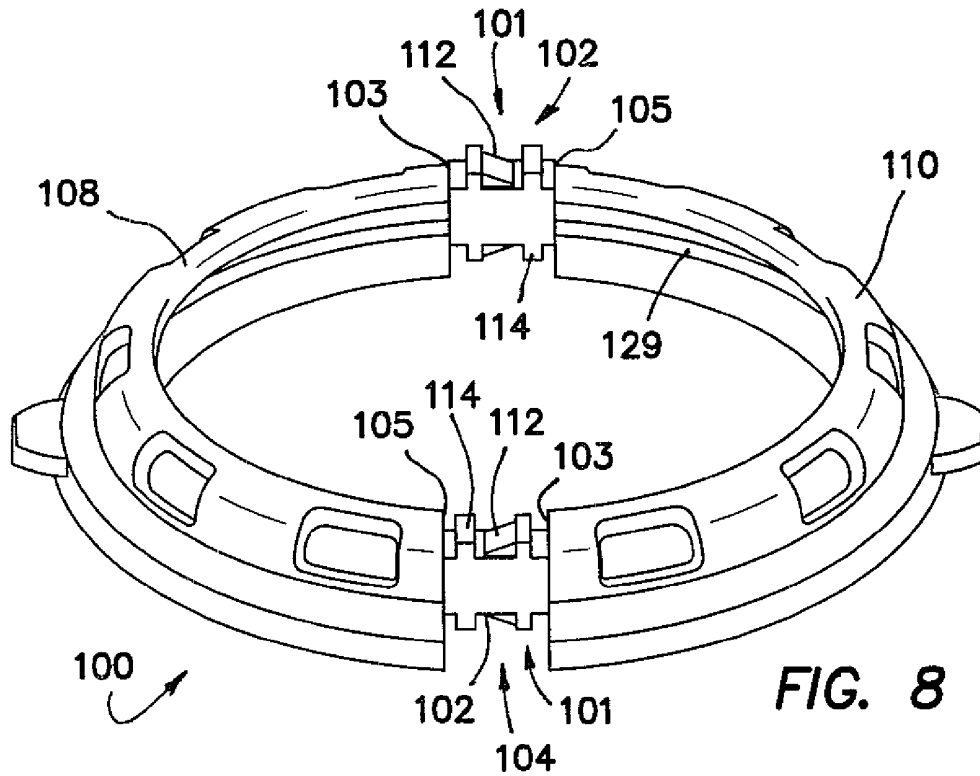
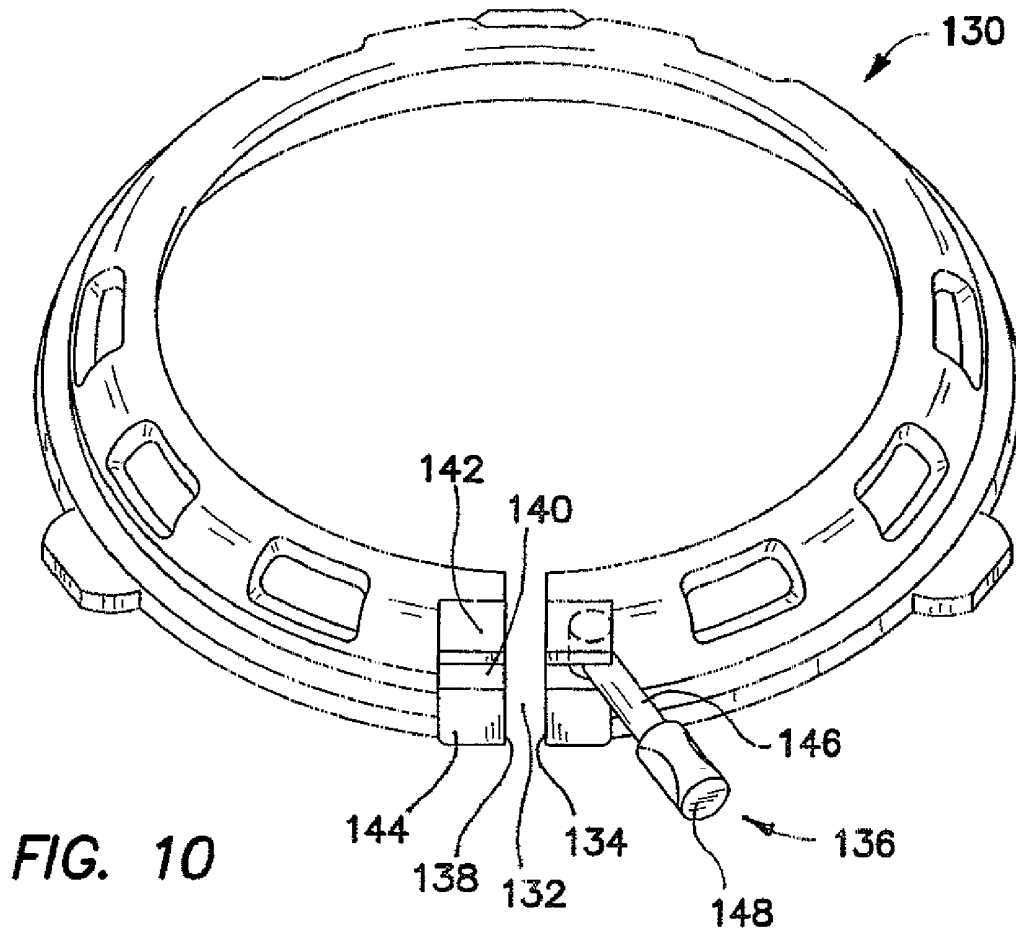
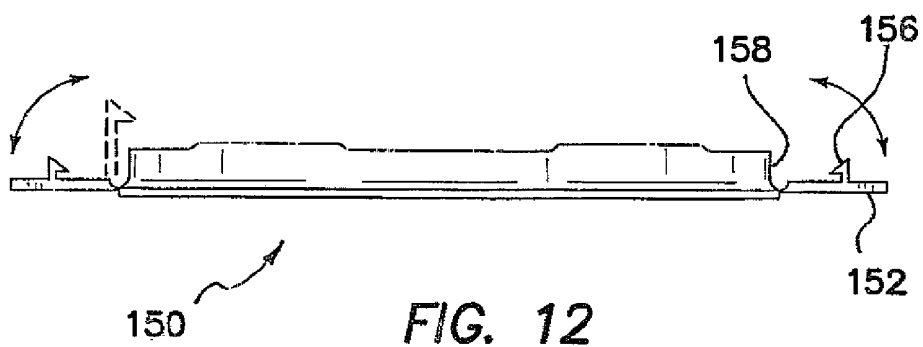
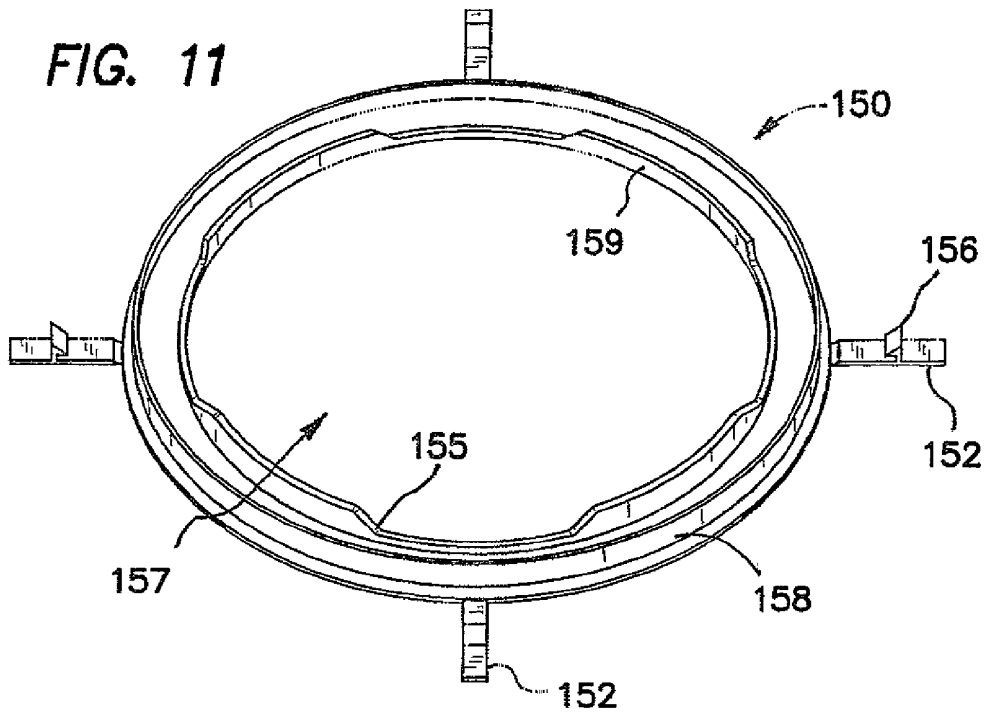


FIG. 7







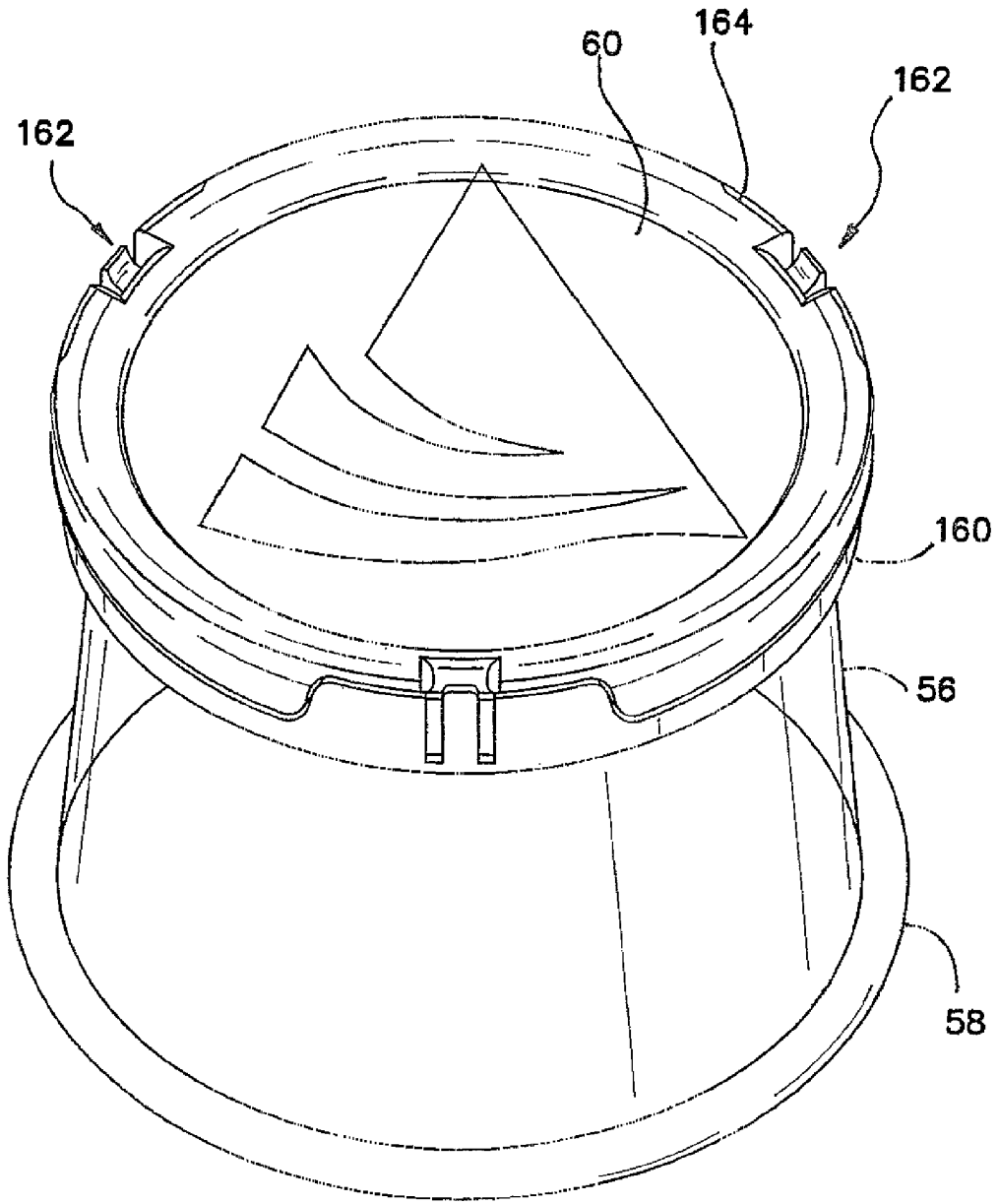


FIG. 13

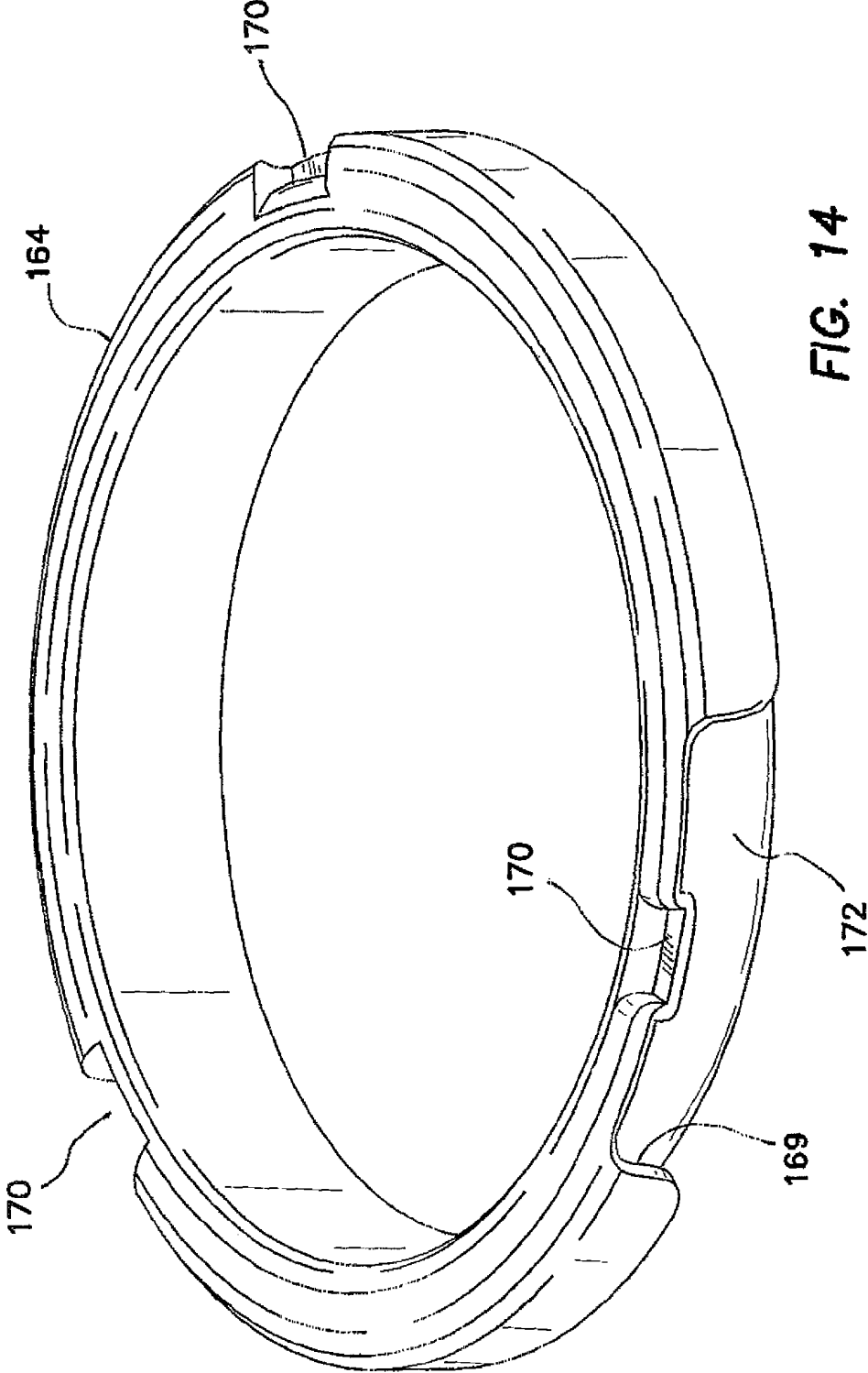


FIG. 14

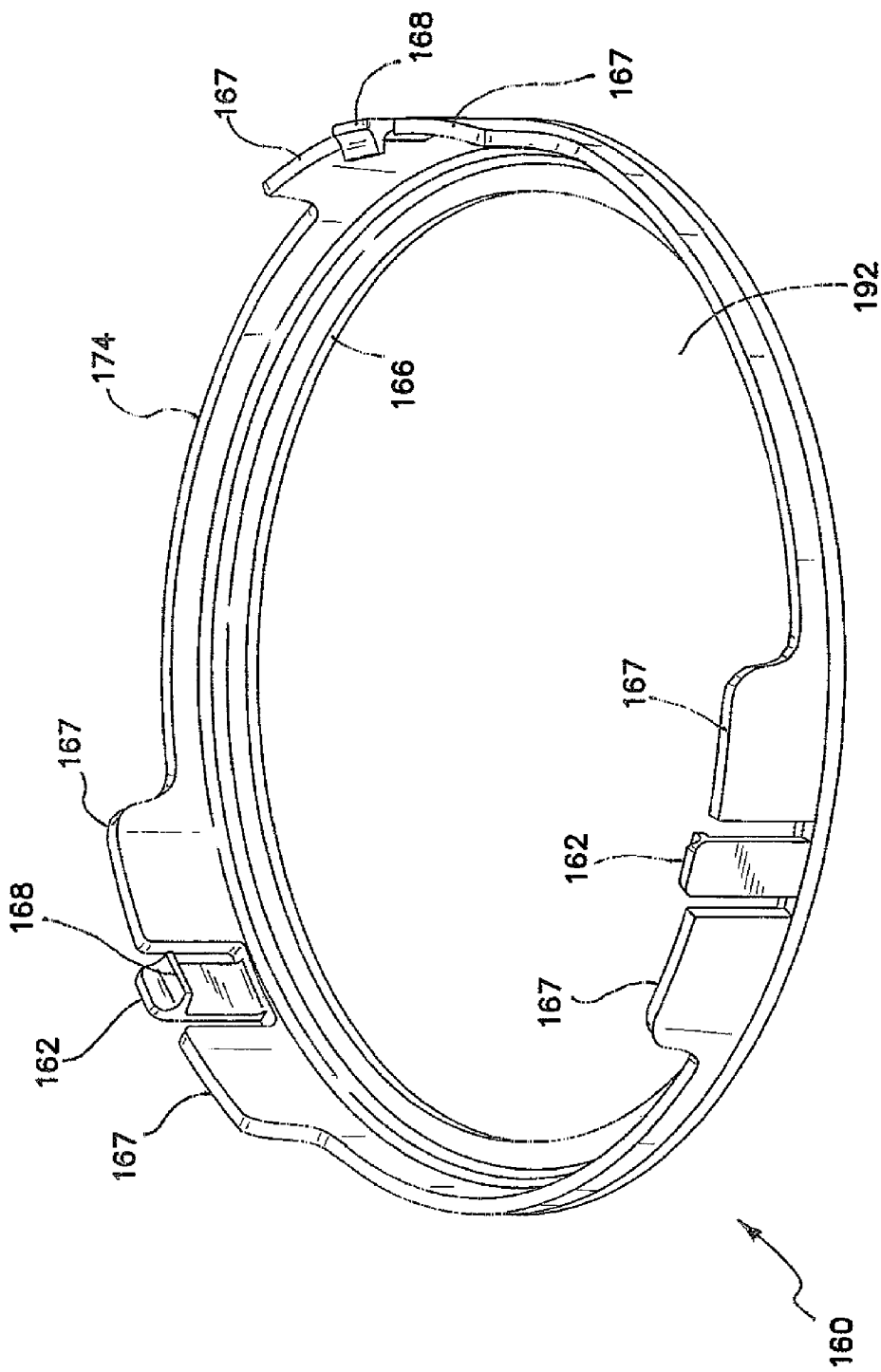


FIG. 15

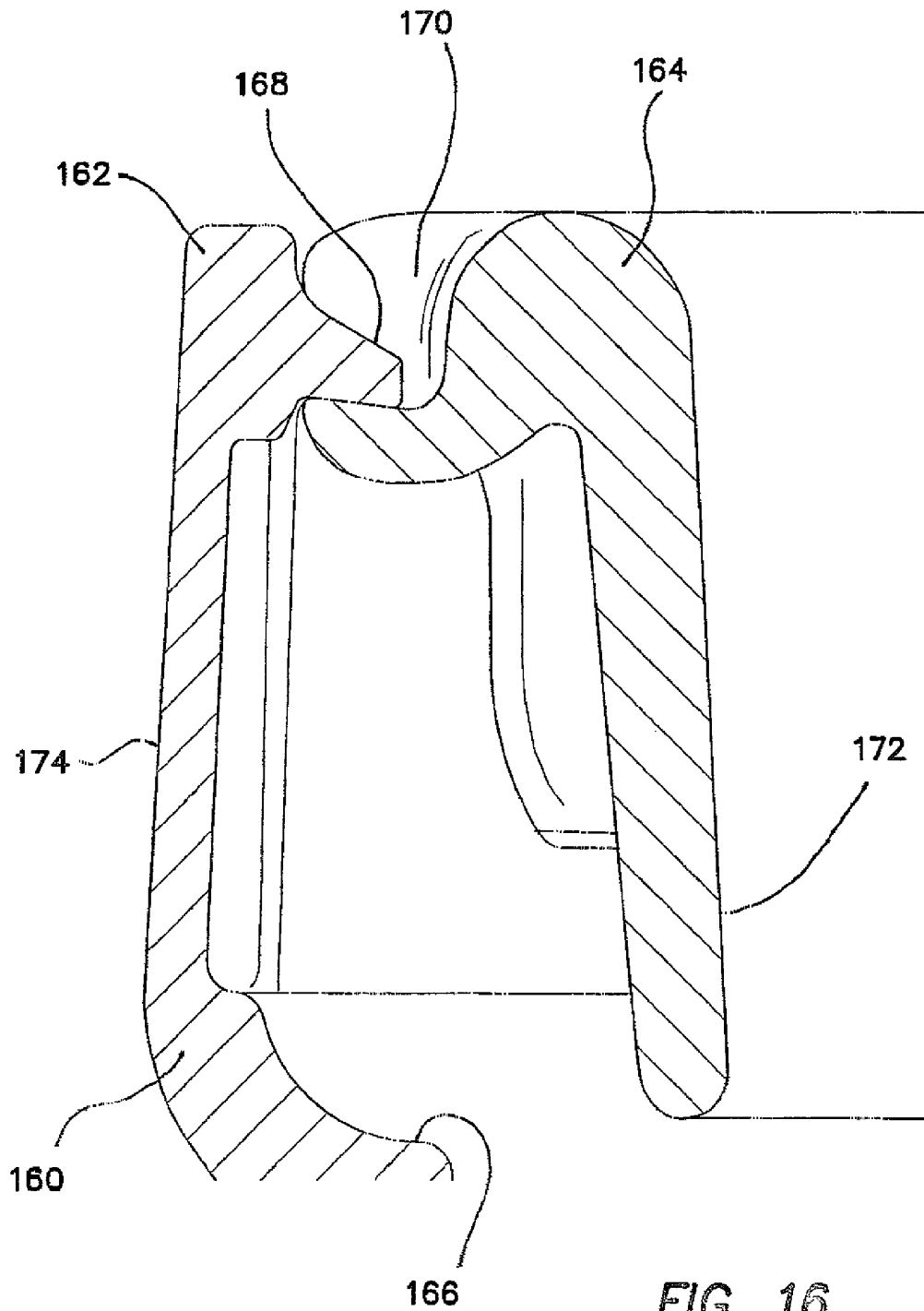
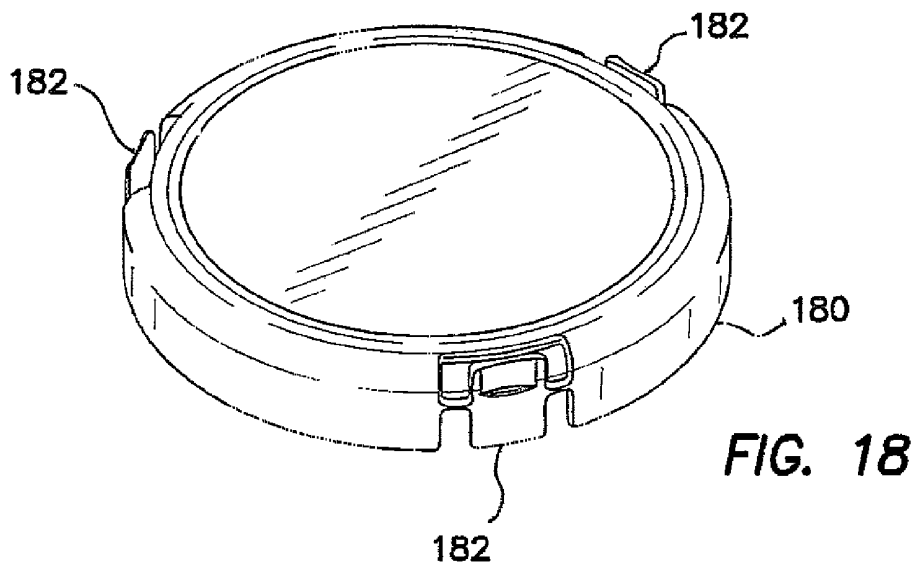
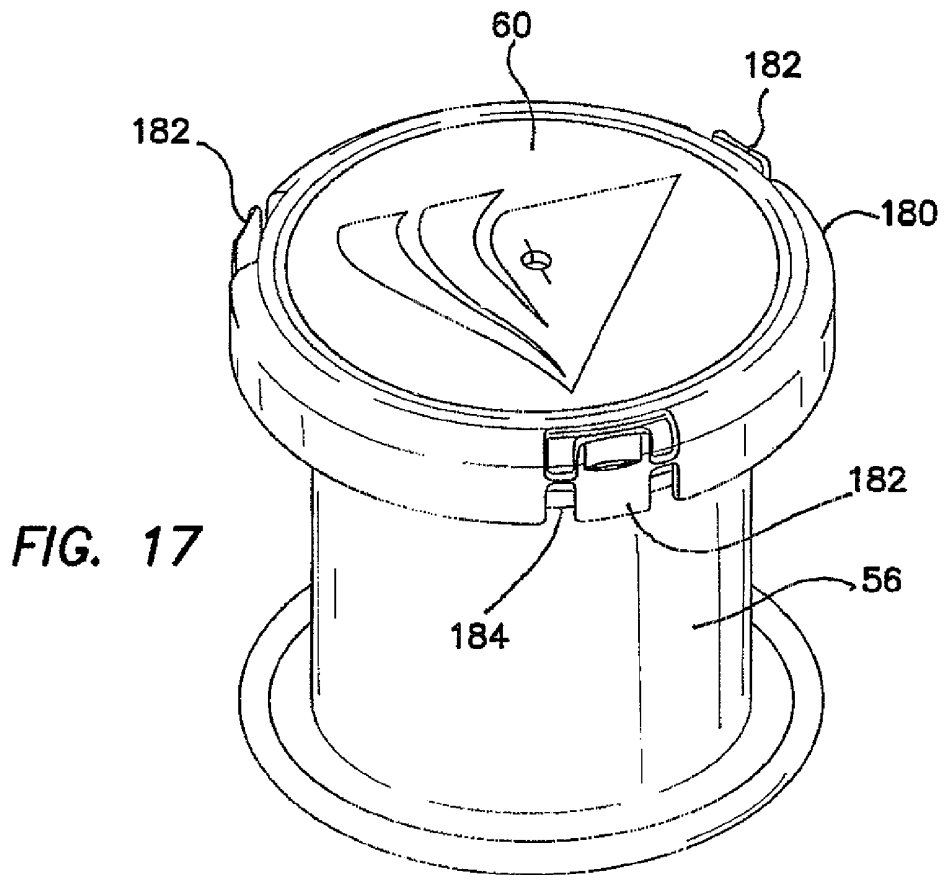


FIG. 16



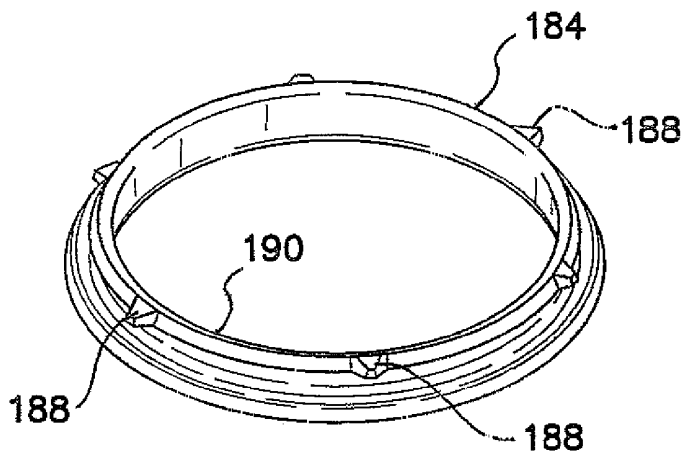


FIG. 19

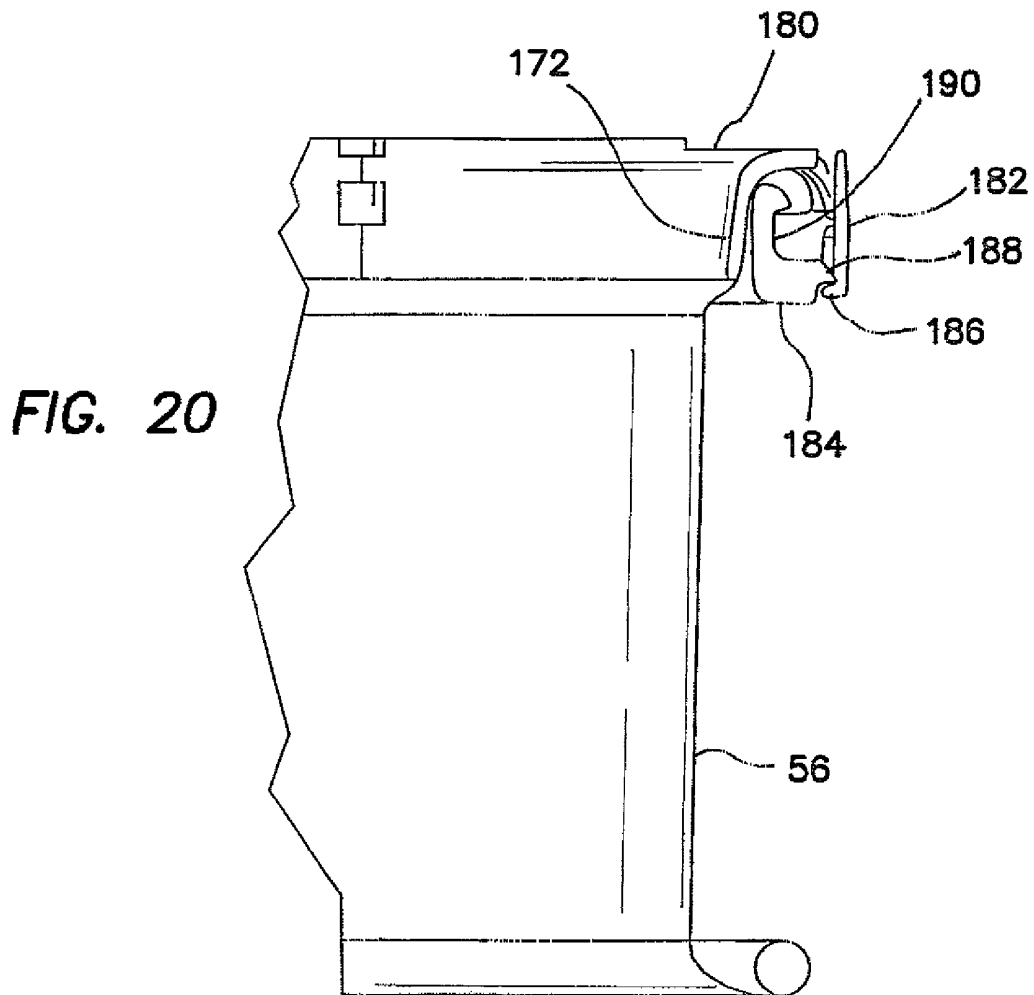


FIG. 20

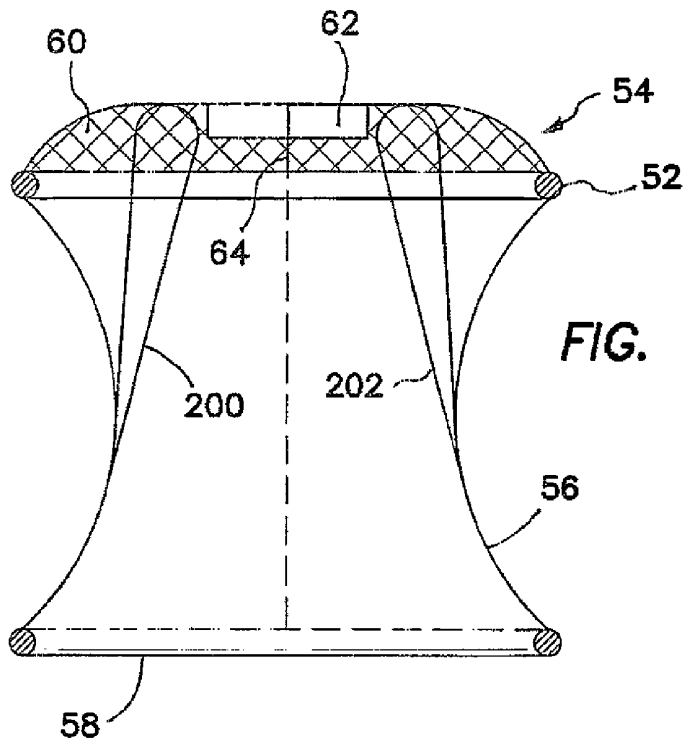


FIG. 21

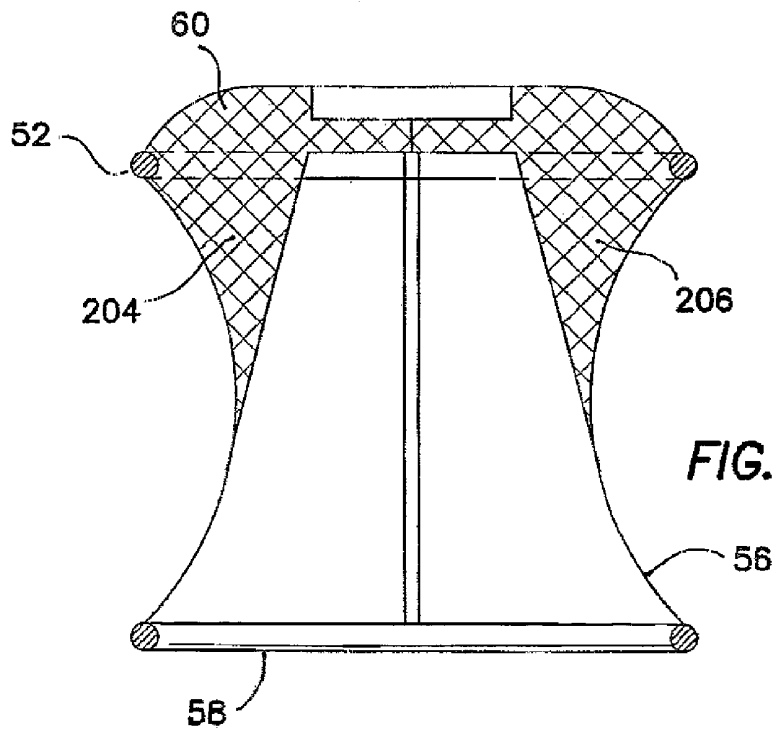


FIG. 22

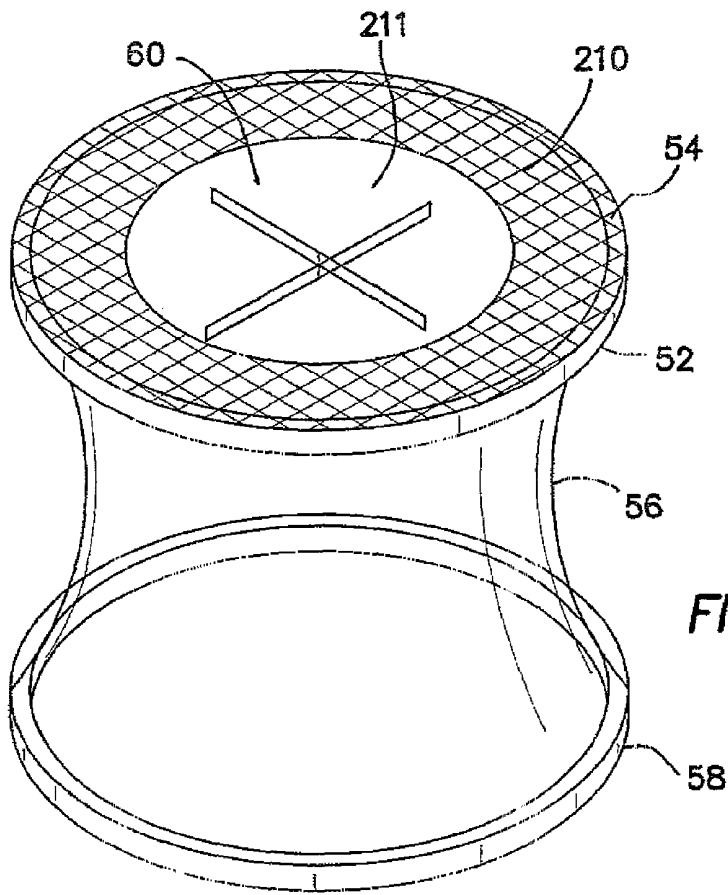


FIG. 23

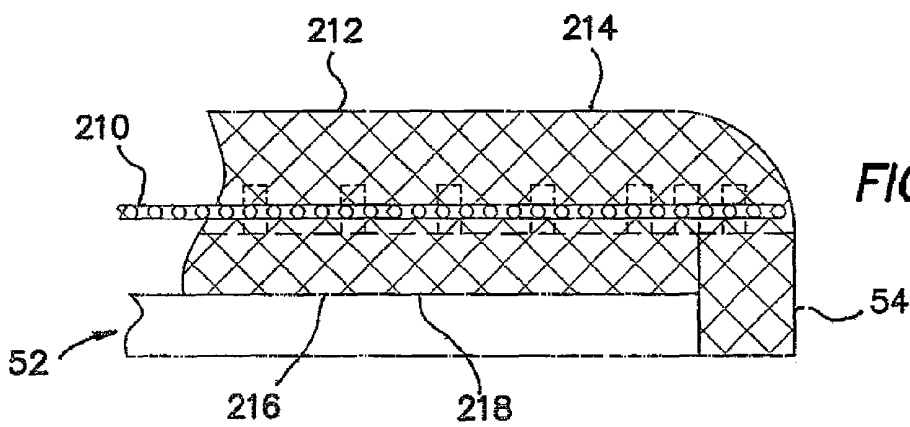


FIG. 24

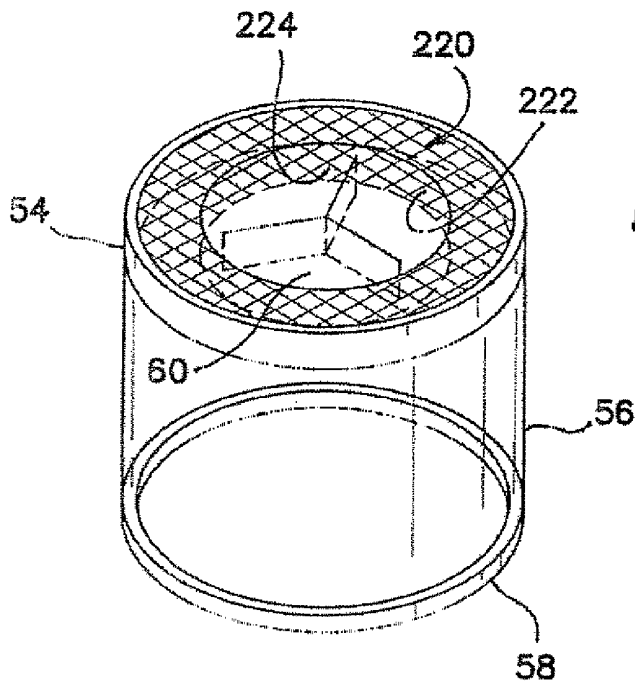


FIG. 25

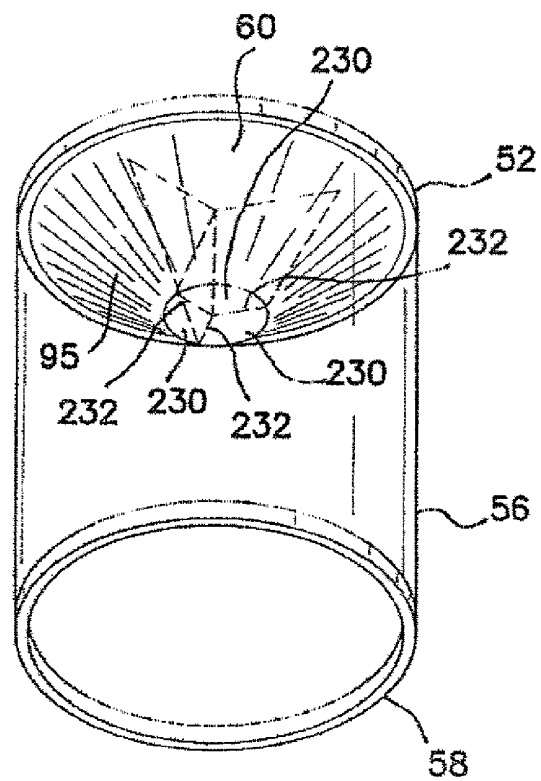


FIG. 26

HAND ACCESS LAPAROSCOPIC DEVICE

CROSS REFERENCE TO RELATED APPLICATIONS

This application is a divisional of U.S. application Ser. No. 11/548,955, filed Oct. 12, 2006, now U.S. Pat. No. 7,736,306, which claims the benefit of U.S. application Ser. No. 60/726,826, filed Oct. 14, 2005, of which the entire disclosures are incorporated by reference herein.

BACKGROUND OF THE INVENTION

This invention relates substantially to devices and other apparatuses facilitating sealed access with surgical instruments, such as a surgeon's hand, across a body wall and into a body cavity.

In several areas of surgery there exists a need to have mechanisms or devices that can seal a body cavity or space, and yet permit the introduction of surgical instruments such as guidewires, endoscopes, and even the hand of a surgeon. Typical of these areas of surgery is laparoscopic surgery that relies on surgical instruments inserted through the abdominal wall to reach an operative site within the abdominal cavity. In order to increase space around the operative site within the cavity, insufflation gases are typically introduced to inflate the cavity and elevate the abdominal wall. This pressurizing of the abdominal cavity is referred to as pneumoperitoneum. In this context, the need to seal the body cavity or space arises from the need to maintain the pneumoperitoneum even when instruments are present.

Trocars have been commonly used to provide instrument access in laparoscopic surgeries. These trocars have included elaborate seal structures having zero seals that prevent escape of the gases in the absence of instruments, and instrument seals that prevent escape of the gases in the presence of instruments. Unfortunately, the instrument seals have been able to accommodate only a narrow range of instrument diameters. Multiple seal pairs had to be provided where wider ranges were desired.

Some instruments, such as the hand of the surgeon, have been too large for trocar access. Under these circumstances, hand-assisted laparoscopic seals have been provided. Such devices have been large, cumbersome, and largely ineffective in providing the required sealing mechanism. Other access devices, such as Touhy-Borst seals, have been used, but only for very small diameter access such as that required by a guidewire.

Each of the prior devices suffers from drawbacks that make the device difficult or cumbersome to use. For example, a Touhy-Borst seal requires two hands to use and does not form a seal when a guidewire or other device is about to be introduced. Present trocar seals and hand-assisted seals require two valves, one forming an instrument seal in the presence of the instrument, and the other forming a zero seal in the absence of the instrument. For example, in hand-assisted devices, elaborate mechanisms have been required to seal around the surgeon's arm. When the arm is removed, a separate zero seal has been required to prevent the escape of blood or insufflation gases.

SUMMARY

The invention is directed to a surgical access device that is adapted for disposition relative to an incision in a body wall. The access device facilitates insertion of an instrument there-through as well as maintenance of a sealing relationship with

the instrument. The surgical access device includes a cap that is substantially annular and has an opening therethrough. The surgical access device also includes a gel pad that is coupled to the cap and adapted for insertion of the instrument there-through. The gel pad covers and seals the entire opening of the cap. The surgical access device further includes a retainer that is substantially annular and adapted for placement against the body wall. Additionally, the surgical access device includes coupling means that are adapted for coupling the cap and the retainer together. The retainer is configured to be coupled to a proximal portion of an elongate sleeve that is adapted to extend through the incision. The retainer is also adapted, together with the elongate sleeve, to retract the incision.

In one aspect, the cap includes at least one gap along the annular perimeter of the cap. The at least one gap creates at least one first end and at least one second end of the cap. The at least one gap facilitates a transition in the cap from a first, larger periphery to a second, smaller periphery. In another aspect, the surgical access device also includes means for maintaining the periphery of the cap at the second, smaller periphery. In another aspect, when the cap is at the first, larger periphery, the retainer may be inserted into or removed from the opening of the cap, and the retainer may be fixedly coupled to the cap by first, transitioning the perimeter of the cap to the second, smaller periphery with the retainer positioned within the opening of the cap, and second, maintaining the periphery of the cap at the second, smaller periphery with the maintaining means. In one aspect, the maintaining means includes a squeeze release buckle fitting configured to couple the at least one first end of the cap to the at least one second end of the cap. The squeeze release buckle fitting includes a first, barbed portion that extends from the at least one first end of the cap and a second, receiver portion that extends from the at least one second end of the cap. The barbed portion and the receiver portion of the squeeze release buckle fitting are configured to engage each other in a mating relationship. In another aspect, the barbed portion of the squeeze release buckle fitting includes a plurality of arms, two of which are resilient and have projections extending therefrom. The receiver portion of the squeeze release buckle fitting has corresponding sidewalls for engaging the projections of the barbed portion, thereby causing the two arms to slide into a channel defined by the receiver and to flex away from each other as the projections clear the ends of the sidewalls and into a fully engaged state. In another aspect, the cap includes at least a first gap and a second gap. The first and second gaps create first and second arc portions of the annular cap, each of which includes first and second ends. The first end of the first arc portion corresponds with the second end of the second arc portion and the second end of the first arc portion corresponds with the first end of the second arc portion. The first end of each of the first and second arc portions has a barbed portion of the squeeze release buckle fitting extending therefrom and the second end of each of the first and second arc portions has a corresponding receiver portion of the squeeze release buckle fitting extending therefrom. In another aspect, the maintaining means includes a latch that is pivotally coupled proximate the first end of the cap and a latch receiver that is positioned proximate the second end of the cap. In another aspect, the latch receiver includes a channel that is defined by substantially parallel channel walls. The channel is configured to releasably receive the latch. In another aspect, the latch includes a shaft that has an enlarged head positioned at the non-hinged end of the latch. The perimeter of the enlarged head is larger than the perimeter of the shaft. The head of the latch is configured to engage the channel and to be held in the

channel. The width of the channel is smaller than the head of the latch. The channel walls are resilient such that the walls flex away from each other during receipt of the head of the latch. In another aspect, the coupling means include at least one latch that is pivotally coupled to the retainer. The at least one latch is configured to engage the cap. The at least one latch includes a projection that extends substantially orthogonally from the at least one latch and is configured to engage the cap. The cap includes at least one engagement portion for receiving the projection on the at least one latch. In another aspect, the at least one latch is coupled to the retainer with a live hinge. In another aspect, the at least one latch includes a plurality of latches that are spaced along the periphery of the retainer. In another aspect, in a first position the at least one latch extends substantially laterally from the periphery of the retainer in a substantially planar relationship with the retainer. After placing the cap on the retainer, the at least one latch is rotated toward the cap to a second position in which the latch engages the cap to couple the retainer to the cap. In another aspect, the retainer includes at least one resilient snap for releasably coupling the retainer to the cap. The at least one snap extends from the outer periphery of the retainer in a substantially perpendicular direction from a substantially planar, annular surface of the retainer. Each of the at least one snaps has a projection extending substantially perpendicular and radially inwardly from the snap. The at least one snap is configured to deflect radially outwardly to slide over a corresponding lip portion of the cap when the cap and retainer are brought together in a mating relationship. The at least one snap is configured to return toward a neutral position after the projection on the at least one snap passes the lip portion of the cap such that the projection of the at least one snap engages a receiver portion of the cap. In another aspect, the planar, annular surface of the retainer is configured to secure the sleeve to the retainer. In another aspect, the retainer includes a sidewall portion adjacent to each of the at least one snaps and on either side of each of the at least one snaps. The cap includes openings disposed along the edges of the cap for receiving the sidewall portions of the retainer. In another aspect, the cap includes at least one snap for releasably coupling the cap to the retainer. The at least one snap extends perpendicularly from the periphery of the cap. The at least one snap is configured to engage with a corresponding lip portion of the retainer. Each of the at least one snaps has a projection extending substantially perpendicular and radially inward from the snap. The at least one snap is configured to deflect radially outwardly such that the projection on the at least one snap slides over the corresponding lip portion of the retainer when the cap and retainer are brought together in a mating relationship. The at least one snap is configured to return toward a neutral position after the projection on the at least one snap passes the lip portion of the retainer such that the projection of the at least one snap engages a lip portion of the retainer. In another aspect, the cap includes an inner cylindrical wall and the gel pad being coupled to the inner cylindrical wall. In another aspect, the gel pad is bonded to the inner cylindrical wall. In another aspect, the gel pad is molded to the cap. In another aspect, the surgical access device also includes a resilient fabric integrated on a surface of the gel pad and coupled to the periphery of the cap. In another aspect, the surgical access device also includes a first fabric integrated on a first surface of the gel pad and coupled to the periphery of the cap, and a second fabric integrated on a second, opposite surface of the gel pad and coupled to the cap. In another aspect, the surgical access device also includes a first fabric coupled to the periphery of the cap and a second fabric coupled to the cap a distance from the first fabric. The space

between the first fabric and the second fabric defines a cavity. The gel pad is positioned within the cavity between the first and second fabric. In another aspect, the gel pad includes multi-cusped lobes. Adjacent lobes are configured to seal upon one another. In another aspect, the gel pad includes at least two concentric regions of differing resiliency. The at least two concentric regions include a first, central region having first resiliency and a second, outer region having less resiliency than the first region. In another aspect, the gel pad has more than two concentric regions having differing resiliency with the resiliency of each region decreasing in relation to the increase in distance from the first, central region. In another aspect, the gel pad includes gas-filled pockets arranged substantially around the center of the gel pad. In another aspect, the gel pad includes gas-filled pockets dispersed randomly throughout a region beyond the center of the gel pad.

These and other features of the invention will become more apparent with a discussion of the various embodiments in reference to the associated drawings.

DESCRIPTION OF THE DRAWINGS

FIG. 1 depicts a top perspective view of a hand access laparoscopic device of the present invention;

FIG. 2 depicts a bottom perspective view of the hand access laparoscopic device of FIG. 1;

FIG. 3 depicts a plan view of a gelcap with a gel pad having regions of varying firmness;

FIG. 4 depicts a side view of a gelcap with gel having gas-filled pockets disbursed therein;

FIG. 5 depicts a plan view of a gelcap with gel having gas-filled pockets disbursed therein;

FIG. 6 depicts a plan view of a gelcap with gel having gas-filled pockets disbursed therein;

FIG. 7 depicts a side view of a hand access laparoscopic device including a gelcap with gel having gas-filled pockets disbursed therein;

FIG. 8 depicts a top perspective view of a multiple-piece cap having squeeze release buckle connectors molded into the ends of the pieces forming the cap;

FIG. 9 depicts a top perspective view of one of the pieces of the cap having a male squeeze release buckle connector fitting at one end and a female squeeze release buckle connector fitting at the other end;

FIG. 10 depicts a top perspective view of a cap having a latch pivotally coupled on one side of the cap and a groove for accepting the latch on the other side of the cap;

FIG. 11 depicts a top perspective view of a cap having latches for releasable coupling the cap to a retainer;

FIG. 12 depicts a side view of the cap of FIG. 11;

FIG. 13 depicts a top perspective view of a hand access laparoscopic device of the present invention including a cap and a retainer, the retainer having a plurality of snaps for releasably coupling the retainer to the cap;

FIG. 14 depicts a top perspective view of the cap of FIG. 13;

FIG. 15 depicts a top perspective view of the retainer of FIG. 13;

FIG. 16 depicts a section view depicting the interaction between the cap and the retainer of FIG. 13;

FIG. 17 depicts a top perspective view of a hand access laparoscopic device of the present invention including a cap and a retainer, the cap having a plurality of snaps for releasably coupling the cap to the retainer;

FIG. 18 depicts a top perspective view of the cap of FIG. 17;

FIG. 19 depicts a top perspective view of the retainer of FIG. 17;

FIG. 20 depicts a section view depicting the interaction between the cap and the retainer of FIG. 17;

FIG. 21 depicts a side view of a hand access laparoscopic device having a gelcap, a retainer, a sleeve and a retention ring, with a plurality of stabilizers in the form of strings or tethers extending from the retention ring to the gelcap;

FIG. 22 depicts a side view of a hand access laparoscopic device having a gelcap, a retainer, a sleeve and a retention ring, with a plurality of stabilizers in the form of gussets or webs extending from the retention ring to the gelcap;

FIG. 23 depicts a top perspective view of a hand access laparoscopic device having a gelcap, a retainer, a sleeve and a retention ring, with a fabric integrated on the surface of the gel pad;

FIG. 24 depicts a partial side view of the hand access laparoscopic device of FIG. 23;

FIG. 25 depicts a top perspective view of a hand access laparoscopic device having a gelcap, a retainer, a sleeve and a retention ring, the gelcap having a cavity defined by fabric with the gel pad housed within the cavity; and

FIG. 26 depicts a bottom perspective view of a hand access laparoscopic device having a gelcap, a retainer, a sleeve and a retention ring, with the gel pad having multi-cusped lobes that seal upon one another.

DESCRIPTION

In FIGS. 1 and 2, a surgical hand access device 50 according to one aspect of the present invention is shown. The device includes a retainer 52 and a cap 54. The cap 54 and the retainer 52 are both substantially annular and both include an opening therethrough. The retainer 52 is adapted to be placed against a body wall. The retainer 52, in one aspect, is rigid and is associated with and/or capable of being coupled to an elongate sleeve 56. The surgical hand access device 50 is adapted for disposition relative to an incision in a body wall. The surgical hand access device 50 also facilitates insertion of an instrument through the access device and maintenance of a sealing relationship with the instrument.

In one aspect, the elongate sleeve 56 extends through an incision to a point where an attached retention ring 58 contacts the interior portions of the body cavity and provides tension between the retainer 52 outside the body cavity and the retention ring. The retainer 52 in one aspect also supports or otherwise enables a portion of the elongate sleeve 56 to remain outside of the body cavity. Additionally, the retainer 52, retention ring 58 and elongate sleeve 56 together allow the incision to be retracted and isolated during a surgical procedure. In one aspect, the elongate sleeve 56 and aspects thereof is a wound retractor type device such as described in U.S. patent application Ser. No. 10/516,198, filed Nov. 30, 2004, the disclosure of which is hereby incorporated by reference as if set forth in full herein.

As shown, the retainer 52 and retention ring 58 are circular, but as one skilled in the art would appreciate, they may be of different shapes and sizes. The retainer 52 in one aspect may be either rigid, flexible or a combination of both. The retention ring 58 may be flexible to facilitate insertion into the body cavity. As will be described in more detail, the access device 50 includes coupling means that are adapted for coupling the cap 54 and the retainer 52 together.

A gel pad 60 may be coupled to, attached to, formed or integrated with the cap 54 so that a gas-tight conduit is formed between the cap and the sleeve 56. The gel pad 60 covers and seals the entire opening in the cap 54. In one aspect, the gel

pad includes a plurality of intersecting dead-end slits 62, 64 that form an access portion or passage through the gel pad 60. Unlike foam rubber or other similar types of elastic materials, the gel pad 60 provides a gas tight seal around a variety of shapes and sizes of hands or instruments inserted there-through.

In one aspect, the gel material from which the gel pad 60 is made is an elastomeric gel. Some such gels have been described in U.S. patent application Ser. No. 10/381,220, filed Mar. 20, 2003, the disclosure of which is hereby incorporated by reference as if set forth in full herein. The gel can be prepared by mixing a triblock copolymer with a solvent for the midblocks. The endblocks are typically thermoplastic materials such as styrene and the midblocks are thermoset elastomers such as isoprene or butadiene, e.g., Styrene-Ethylene-Butylene-Styrene (SEBS). In one aspect, the solvent used is mineral oil. Upon heating this mixture or slurry, the midblocks are dissolved into the mineral oil and a network of the insoluble endblocks forms. The resulting network has enhanced elastomeric properties over the parent copolymer. In one aspect, the triblock copolymer used is KRATON G1651, which has a styrene to rubber ratio of 33/67. Once formed, the gel is substantially permanent and, by the nature of the endblocks, processable as thermoplastic elastomers henceforward. The mixture or slurry has a minimum temperature at which it becomes a gel, i.e., the minimum gelling temperature (MGT). This temperature, in one aspect, corresponds to the glass transition temperature of the thermoplastic endblock plus a few degrees. For example, the MGT for the mixture of KRATON G1651 and mineral oil is about 120° C. When the slurry reaches the MGT and the transformation to a gel state takes place, the gel becomes more transparent, thereby providing means for visually confirming when the transformation of the slurry to the gel state is substantially complete and that the gel may be cooled. In addition to triblocks, there are also diblock versions of the materials that may be used where Styrene is present at only one end of the formula, for example, Styrene-Ethylene/Butylene (SEB).

For a given mass of slurry to form into a complete gel, the entire mass of the slurry is heated to the MGT and remains heated at the MGT for sufficient time for the end blocks to form a matrix of interconnections. The slurry will continue to form into gel at temperatures above the MGT until the slurry/gel reaches temperatures at which the components within the slurry/gel begin to decompose or oxidize. For example, when the slurry/gel is heated at temperatures above 250° C., the mineral oil in the slurry/gel will begin to be volatile and oxidize. Oxidizing may cause the gel to turn brown and become oily.

The speed at which a given volume of slurry forms a gel is dependant on the speed with which the entire mass of slurry reaches the MGT. Also, with the application of temperatures higher than the MGT, this speed is further enhanced as the end block networks distribute and form more rapidly.

The various base formulas may also be alloyed with one another to achieve a variety of intermediate properties. For example, KRATON G1701X is a 70% SEB 30% SEBS mixture with an overall Styrene to rubber ratio of 28/72. It can be appreciated that an almost infinite number of combinations, alloys, and Styrene to rubber ratios can be formulated, each capable of providing advantages to a particular embodiment of the invention. These advantages will typically include low durometer, high elongation, and good tear strength.

It is contemplated that the gel material may also include silicone, soft urethanes and even harder plastics that might provide the desired sealing qualities with the addition of a foaming agent. The silicone material may be of the types

currently used for electronic encapsulation. The harder plastics may include PVC, Isoprene, KRATON neat, and other KRATON/oil mixtures. In the KRATON/oil mixture, oils such as vegetable oils, petroleum oils and silicone oils may be substituted for the mineral oil.

Any of the gel materials contemplated could be modified to achieve different properties such as enhanced lubricity, appearance, and wound protection. Additives may be incorporated directly into the gel or applied as a surface treatment. Other compounds may be added to the gel to modify its physical properties or to assist in subsequent modification of the surface by providing bonding sites or a surface charge. Additionally, oil based colorants may be added to the slurry to create gels of different colors.

In one aspect, the mixture/slurry used with the various embodiments of the caps that are described herein are composed of about 90% by weight of mineral oil and about 10% by weight of KRATON G1651. From a thermodynamic standpoint, this mixture behaves similar to mineral oil. Mineral oil has a considerable heat capacity and, therefore, at about 130° C. it can take 3 or 4 hours to heat a pound of the slurry sufficiently to form a homogeneous gel. Once formed, the gel can be cooled as quickly as practical with no apparent deleterious effects on the gel. This cooling, in one aspect, is accomplished with cold-water immersion. In another aspect, the gel may be air-cooled. Those familiar with the art will recognize that other cooling techniques that are well known in the art may be employed and are contemplated as within the scope of the present invention.

Many of the properties of the KRATON/oil mixture will vary with adjustments in the weight ratio of the components. In general, the greater the percentage of mineral oil the less firm the mixture; the greater the percentage of KRATON, the more firm the mixture. If the resultant gel is too soft it can lead to excessive tenting or doming of the gelcap during surgery when a patient's abdominal cavity is insufflated. Excessive tenting or doming may cause the slits **62**, **64** to open, providing a leak path. Additionally, if the gel is too soft it might not provide an adequate seal. However, the gel should be sufficiently soft to be comfortable for the surgeon while simultaneously providing good sealing both in the presence of an instrument and in the absence of an instrument.

If the slurry is permitted to sit for a prolonged period of time, the copolymer, such as KRATON, and the solvent, such as mineral oil, may separate. The slurry may be mixed, such as with high shear blades, to make the slurry more homogeneous. However, mixing the slurry may introduce or add air to the slurry. To remove air from the slurry, the slurry may be degassed. In one aspect, the slurry may be degassed in a vacuum, such as within a vacuum chamber. In one aspect, the applied vacuum may be 0.79 meters (29.9 inches) of mercury, or about 1.0 atmosphere. The slurry may be stirred while the slurry is under vacuum to facilitate removal of the air. During degassing within a vacuum, the slurry typically expands, then bubbles, and then reduces in volume. The vacuum may be discontinued when the bubbling substantially ceases. Degassing the slurry in a vacuum chamber reduces the volume of the slurry by about 10%. Degassing the slurry helps reduce the potential of the finished gel to oxidize.

Degassing the slurry tends to make the resultant gel firmer. A degassed slurry composed of about 91.6% by weight of mineral oil and about 84% by weight of KRATON G1651, an eleven-to-one ratio, results in a gel having about the same firmness as a gel made from a slurry that is not degassed and that is composed of about 90% by weight of mineral oil and about 10% by weight of KRATON G1651, a nine-to-one ratio.

Mineral oil is of a lighter density than KRATON and the two components will separate after mixing, with the lighter mineral oil rising to the top of the container. This separation may occur when attempting to form static slurry into gel over a period of several hours. The separation can cause the resulting gel to have a higher concentration of mineral oil at the top and a lower concentration at the bottom, e.g., a non-homogeneous gel. The speed of separation is a function of the depth or head height of the slurry being heated. The mass of slurry combined with the head height, the temperature at which the gel sets and the speed with which the energy can be transferred to the gel, factor into the determination or result of homogeneous gel versus a non-homogeneous gel.

One aspect of a cap **70** in accordance with the present invention is illustrated in FIG. **3** with a gel pad **72** that differs in texture in specific regions **74-80**. For example, in one aspect, the gel pad **72** has a soft occlusive first, central sealing region **74**, a second region **76** less resilient than the first region, a third region **78** less resilient than the second region, a fourth region **80** less resilient than the third region, and so-on. More particularly, the gel pad **72** may include more than two concentric regions having differing resiliency with the resiliency of each region decreasing in relation to the increase in distance from the first, central region **74**. The progressively less resilient or pliable regions allow positive attachment of the gel pad **72** to a support structure, such as the cap **70**, while preserving the desirable occlusive properties of a softer more resilient material at, or about, the central portion of the gel pad.

In one aspect, the gel pad **72** has gradient concentric portions **74-80** in which the gel pad is centrifugally molded or formed. During gel formation, the slurry is mixed in a centrifuge. By rotating the slurry while forming the gel pad **72**, density separation is created in which denser triblocks of the slurry migrate towards the circumference of the container holding the spinning slurry and the mineral oil increases in concentration towards the center. In this manner, a firmer gel is formed on the exterior of the finished part and a softer gel is formed in the central portion of the finished part, which is useful in hand access seals for laparoscopic surgery.

In one aspect, a long flat rectangular part is used instead of a thin circular part. There are three conventional axes of rotation associated with the rectangular part. The first axis is through the center of the part normal to the long and short axes of the part. Rotation about the first axis induces a higher density gel at the ends of the part as will rotating the gel about the short midpoint of the rectangle. However, rotation about the long axis of the rectangle creates higher density gel along the long edges of the rectangle. The rotation can be altered during processing, as in the case of rotational molding, in which the part is rotated about multiple axes during processing. The axis of rotation does not have to intersect a centroid of the part or even be within the part itself.

A reverse texture layout of the gel pad **70** can be achieved by selecting lighter density triblocks and higher density mineral oils. Other components can be added as well, based on the desired effect, including additives such as colorants, inert filler material, different oils, different triblock or diblock copolymers, polymers, plasticizers, decorative items, etc.

In one aspect, heavy plastic components **82** are provided with the gel pad **72** or slurry and gravitate toward outer regions of the gel away from the center, leaving the central region **74** with a particular proportion of plastic material and oil. The outer regions **76-80** of the gel pad **72** are denser and contain more heavy plastic material than the central region

74. When the particular gradient proportions for the gel pad 72 are achieved, rotation is slowed and the gel pad is allowed to cool.

In one aspect, a non-homogenous gel pad with soft gel on one side and a firmer gel on the other is accomplished with density separation over time commensurate with the timing of the energy input into the gel which can vary with the direction of gravity.

In FIGS. 4-7, a cap 90 includes a gel pad 92 with a plurality of gas-filled pockets 94. The pockets 94 may be formed by the presence of lightweight foam or balloons, or by casting or molding the gel around spheres or solid objects of other shapes that are removed after the gel pad 92 has cured. The foam, balloons, spheres or other shapes may be inserted into the mold cavity either prior to or after filling the mold cavity with the slurry. In one aspect, the arrangement of gas-pockets 94 substantially around the center of the gel pad 92 reduces the weight of the gel pad and resistance to the passage of a surgeon's hand or instruments while retaining occlusive properties. An alternative aspect of the gel pad 92 contemplates a more random dispersion of gas pockets 94 throughout the region beyond the center of the gel pad, which reduces the overall weight of the gel pad.

The gel pad or gelcap in various aspects of the present invention may be gamma sterilized. The relative or comparative simplicity of qualifying the sterilization process, for example of gamma versus ethylene oxide, of the gel pad and the device with the gel pad is desirable. However, under gamma sterilization large bubbles can form in the gel pad causing potential cosmetic or aesthetic issues in the sterilized devices. The bubbles are more than 99% room air, so removal of the dissolved air in the slurry is performed prior to forming the slurry into gel. For example, the slurry may be degassed via vacuum, as described above, and turned into gel by heat. Bubbles may still form in the gel during gamma sterilization but disappear in a period of about 24 to 72 hours. In one aspect, the percentage of dissolved gas in the mineral oil at room temperature is about 10%. The removal of the air in the gel has an additional effect of making the gel firmer. This however is counterbalanced by the softening effect on the gel caused by gamma radiation during gamma sterilization.

If the gel pad is to be gamma sterilized, the gel may include about 90% mineral oil by weight and about 10% KRATON by weight. As stated above, degassing the slurry has the effect of making the gel firmer. However, the gamma radiation softens the gel to substantially the same firmness as a gel having about 90% mineral oil by weight and about 10% KRATON by weight that is not degassed and gamma sterilized.

In one aspect, cyanoacrylate, e.g., SUPERGLUE or KRAZY GLUE, may be used to bond or otherwise couple or attach the gel pad 60 to the cap 54. The glue may attach to either the rubber or styrene component of the tri-block and the bond is frequently stronger than the gel material itself. In another aspect, a solvent may be used to dissolve the plastics in the cap and the polystyrene in the gel. The solution of solvent is applied to the gel pad and cap in either a spray or dip form. In effect, the solution melts both the plastic of the cap as well as the polystyrene in the gel pad to allow a chemical bond to form between the two, which remains when the solvent evaporates.

Polyethylene can be dissolved in mineral oil and then applied to the gel pad. The mineral oil will not evaporate but will over time absorb into the gel pad and impart a polyethylene layer on the gel pad that may have some beneficial properties.

In one aspect, the gel pad 60 is cast into a DYNAFLEX or KRATON polymer support structure, e.g., the cap 54. By

using KRATON polymer or a similar material in the cap, ring adhesion between the gel pad 60 and the cap 54 can be achieved. The polystyrene in the gel is identified as achieving adhesion with polyphenylene oxide (PPO), polystyrene and other polymers.

In the casting process the gel pad 60 and the cap 54 are heated to a temperature above about 130° C. and held at that temperature for several hours, e.g., about 3 to 4 hours. The temperature used is not sufficient to deform the cap 54.

The cap 54, in one aspect, includes a polymer, e.g., polyethylene (PE). In one aspect, the polyethylene is a low density polyethylene (LDPE) or high density polyethylene (HDPE), or ultra high molecular weight polyethylene (UHMWPE). In one aspect, the cap 54 may be made of a polymer, such as polycarbonate and may be fabricated by methods including injection molding.

The gel includes mineral oil. PE has a higher molecular weight than mineral oil. PE is dissolved by mineral oil at high temperatures. As such, as the PE and the mineral oil in the gel pad 60 intermix as both are heated to and held at temperatures above about 130° C., a bond between the PE and gel pad is formed.

In one aspect, the cap 54 includes polycarbonate. The polycarbonate of the cap 54 does not form bonds with the gel pad 60 at 130° C. However, by raising the temperature to about 150° C. for a few minutes during casting, bonding occurs between the gel pad 60 and the cap 54. As such, heating the gel pad 60 and cap 54 to temperatures at which both the polystyrene of the gel and the polycarbonate are simultaneously beyond their melt points allow bonds to form between the gel pad and the cap. Alternatively, the gel pad 60 and cap 54 may be heated to near or at the glass transition temperature of the polycarbonate cap to form the bond between the gel pad and the cap.

Referring to FIGS. 8-10, the cap 100, 130 includes at least one gap 101, 132 along the annular perimeter of the cap. The at least one gap 101, 132 creates at least one first end 103, 134 and at least one second end 105, 138 of the cap 100, 130. The gap 101, 132 facilitates a transition in the cap from a first, larger periphery to a second, smaller periphery. As will be discussed in more detail below, the cap 100, 130 includes means for maintaining the cap at the second, smaller periphery. When the cap 100, 130 is set at the first, larger periphery, the retainer 52 (FIG. 1) may be inserted into or removed from the opening of the cap. The retainer 52 (FIG. 1) may be fixedly coupled to the cap 100, 130 by transitioning the perimeter of the cap to the second, smaller periphery while the retainer is positioned within the opening of the cap, and maintaining the periphery of the cap at the second, smaller periphery with the maintaining means.

Referring to FIGS. 8-9, the cap 100 incorporates squeeze release buckles 102 molded into or otherwise coupled to the cap. The cap 100 includes a first arc 108 and a second arc 110, the first and second arcs being separated by first and second gaps 101. The first arc 108 has a first barbed portion 112 extending from a first end and adapted to be inserted in a snap fit mating relationship with a second, receiver portion 114 extending from a second end of the second arc 110, thereby coupling the at least one first end 103 of the cap 100 to the at least one second end 105 of the cap. Another barbed portion 112 may extend from the first end of the second arc 110, which is operationally inserted in a snap fit mating relationship with another receiver portion 114 extending from the second end 105 of the first arc 108. In another aspect, the first arc 108 has a barbed portion 112 on each end of the arc with the second arc 110 having corresponding receiver portions 114 on each end of the second arc.

With the first and second arcs **108**, **110** placed adjacent to each other, such that the first end **103** of the first arc corresponds with the second end **105** of the second arc and the second end **105** of the first arc corresponds with the first end **103** of the second arc, and prior to being snapped together, the arcs define a first, larger periphery to allow placement of a retainer **52** (FIG. 1) between the two arcs. The barbed portions **112** engage with corresponding receivers **114** coupling the arcs together. Each barbed portion has a plurality of resilient arms **122**, two of which have projections **124** extending therefrom. Each receiver **114** has corresponding sidewalls **126** for engaging projections **124** from the barbed portion, which causes the arms **122** to flex towards each other as the arms slide into a channel **128** defined by the receiver. As the projections **124** clear the ends of the sidewalls **126**, the arms **122** are allowed to flex away from each other. Engagement or contact between the edges of the projections **124** with edges of the end of the sidewall **126** prevents the arcs **108**, **110** from being detached from each other. By coupling the two arcs **108**, **110** together, the delimited circumference is reduced to a second, smaller periphery to capture or hold the retainer **52** (FIG. 1). Flexing the arms **122** toward each other allows the barbed portions **112** to disengage from the sidewalls of the corresponding receiver **114** and to slide out from the receiver, thereby allowing the arcs **108**, **110** to separate and detach from the retainer **52** (FIG. 1).

Although not shown, additional barbed portions and receiver snap engagements may be included in each arc to assist in the coupling between the cap **100** and the retainer **52** (FIG. 1) or allow for other size and shape configurations of the cap and/or retainer. In one aspect, the cap **100** includes a single gap **101** and a single barbed portion **112** and receiver portion **114** is provided. In one aspect the cap **100** having the single barbed portion **112** and receiver portion **114** may be provided with a hinge or pivot on another portion of the arc.

Referring now to FIG. 10, a cap **130** has a gap or opening **132** along a portion of the periphery of the cap. A latch **136** is hinged or pivotally coupled to the cap proximate a first end **134** of the opening **132** of the cap **130**. Proximate a second, opposite end **138** of the opening **132**, a latch receiver, such as an aperture or channel **140** defined by substantially parallel channel walls **142**, **144**, is configured to releasably receive the latch **136**. The latch **136** has a shaft **146** coupled to the cap **130** on one end and an enlarged or bulbous head **148** having a perimeter or diameter larger than the perimeter or diameter of the shaft on the non-hinged end of the latch. The head **148** of the latch **136** is configured to be graspable and the latch swung so that the head may engage and be held in the channel **140** defined by the channel walls **142**, **144**. The width of the channel **140** is smaller than the diameter of the head **148** of the latch **136** and the channel walls **142**, **144** are resilient such that the walls flex away from each other during receipt of the head of the latch. Alternatively, or additionally, portions of the head **148** may compress so that the head may be received and held in the channel **140**. In one aspect, one or more projections extend from one or both channel walls **142**, **144** and engage notches in the head **148**, or vice versa, to secure the latch **136** to the channel **140**.

In this manner, with the latch **136** open or not engaged with the channel **140**, the initial periphery of the cap **130** allows simple placement of the retainer **52** (FIG. 1) within the periphery of the cap. Actuating the latch **136** closes the cap **130** and reduces the size of the periphery delimited by the cap, thereby securing the cap to the retainer **52** (FIG. 1).

Referring back to FIGS. 8-10, with the cap **100**, **130** being separable or otherwise disjointed, placement of the respective retainer **52** (FIG. 1) within the inner periphery of the cap is

eased. Subsequent joining or recoupling of the cap together secures the retainer and cap to each other. As such, one skilled in the art would recognize that other types of couplings or engagements may be used to couple or join separate portions of the cap and/or the retainer together to close or delimit a periphery to encase or otherwise secure the cap and the retainer together and vice versa. In one aspect, the retainer, or both the retainer and the cap, are separable, having couplings and/or engagements to recouple the separate portions together to secure the cap and retainer to each other.

In FIGS. 11-12, the retainer **150** has one or more latches **152** to releasably couple the retainer to a cap **54** (FIGS. 1 and 2). In one aspect, a plurality of latches **152** is spaced along the periphery of the retainer **150**. The latches **152** are hinged or pivotally coupled to the retainer **150** and are spaced along the periphery of the retainer. In one aspect, each of the latches is coupled to the retainer **150** with a live hinge. In a first position, the latches **152** extend laterally from the periphery of the retainer **150** in a substantially planar relationship with the retainer. Each latch **152** has a projection **156** extending substantially orthogonally from the latch. After placing or fitting the cap **54** on the retainer **150** and/or vice versa, the latches **152** are actuated to couple the cap and retainer together. In particular, the latches **152** are rotated toward the cap to a second position in which the latches engage a portion or edge of the cap **54** to couple the retainer to the cap. In one aspect, the engagement portion of the cap **54** is an opening, aperture, notch, step, projection or other similar type of receiver or engagement to secure the projection of the latch **152** to the cap.

In one aspect, one or more of the latches **152** has notches or openings for receiving corresponding projections or protrusions extending laterally from the cap **54** to couple the retainer **150** to the cap. Additionally or alternatively, although not shown, the cap may have one or more latches hinged along the periphery of the cap for engagement with portions or edges of the retainer to releasably couple the cap and retainer together.

Referring now to FIGS. 13-16, the retainer **160** has one or more resilient snaps **162** for releasably coupling the retainer and a cap **164** together. The snaps **162** extend from the outer periphery or edge of the retainer **160** in a substantially perpendicular direction from a substantially planar, annular surface **166** of the retainer. The planar, annular surface **166** of the retainer **160** secures the sleeve **56** (FIGS. 1 and 2) to the retainer. In one aspect, the surface **166** has projections or hooks to catch and secure the sleeve **56** to the retainer **160** under tension. The edge of the retainer **160** is also slightly raised to assist in the holding of the sleeve **56** and the handling of the retainer.

Multiple snaps **162** may be spaced along the periphery of the retainer **160**. In one aspect, portions of the edge of the retainer **160** adjacent to each snap are elevated, thereby forming sidewall portions **167** on either side of each snap. The sidewall portions **167** protect the snaps **162** and strengthen or bolster the coupling between the retainer **160** and the cap **164** once coupled together. Additionally, the sidewall portions **167** facilitate handling and coupling the retainer **160** to the cap **164**. Corresponding openings or cutouts **169** are disposed along the edges of the cap **164** to receive the sidewall portions **167** of the retainer **160**.

Each snap **162** also has a projection **168** extending substantially perpendicular and radially inwardly from the snap. After placing or fitting a cap **164** on the retainer **160** and/or vice versa, both are squeezed together. The snaps **162** are configured to flex or deflect radially outwardly to slide over a corresponding receiver portion **170**, such as a lip portion or an

edge, of the cap **164** when the cap and retainer are brought together in a mating relationship. The snaps **162** are also configured to return toward a neutral position after the projection **168** on the snaps pass the receiver portion **170** of the cap **164** such that the projection of the snaps engages the receiver portion **170** of the cap. The receiver portion **170** in one aspect has an opening, aperture, notch, step, projection or other similar type of receiver or engagement means to secure the projection **168** of the snap **162** to the cap **164**. Alternatively, one or more of the snaps **162** have notches or openings (not shown) for receiving corresponding projections or protrusions (not shown) extending from the cap to secure the snaps of the retainer **160** to the cap **164**. The cap **164** and retainer **160** may each be made via injection molding. Additionally, the cap **164** and retainer **160** may each be made of a polycarbonate material.

In one aspect, as shown in FIGS. **17-20**, a cap **180** has one or more snaps **182** for releasably coupling the cap to a retainer **184**. The snaps **182** extend perpendicularly from the periphery of the cap **180** for engagement with portions **188**, such as corresponding lip portions, and/or edges of the retainer **184**. Each snap **182** has a projection **186** extending substantially perpendicular and radially inwardly from the snap. After placing or fitting the cap **180** on the retainer **184**, both are squeezed together. The snaps **182** flex or deflect radially outwardly to slide over the lip or edge **188** of the retainer **184** when the cap **180** and retainer are brought together in a mating relationship, thereby securing the cap, retainer and sleeve **56** disposed therebetween. Each snap **182** is configured to return toward a neutral position after the projection **186** on the snap passes the lip portion **188** of the retainer **184** such that the projection of the snap engages the lip portion of the retainer.

Referring now to FIGS. **1-20**, the retainers and caps previously described in one aspect are rigid, thereby providing manufacturing benefits as well as easing the assembly of the device. In one aspect, the caps **54**, **70**, **90**, **100**, **130**, **164**, **180** also incorporate an inner cylindrical wall **172** (see FIG. **14**) to which the gel pad **60** is bonded or otherwise coupled or attached to the cap. In this manner, the gel pad **60** attaches to a "skeleton" inside the sleeve **56** and provides a sealing area between the device and the wound, incision and/or body cavity. The coupling or intersection of the sleeve, cap and retainer together also provides another sealing area between the device and the body.

By securing the gel pad **60** to the inner cylindrical wall **172**, the thickness of the gel pad and corresponding cap **54**, **70**, **90**, **100**, **130**, **164**, **180** is minimized along with the overall footprint of the device. A reduced thickness and overall size of the device provides a lighter device and allows for easier hand exchanges. With the gel pad thickness reduced and the gel pad being able to be substantially flush or recessed in the cap, the "doming" phenomena produced by gas pressure exerted on the body and device during insufflation is also reduced.

In various aspects (FIGS. **11-20**) in accordance with the present invention, the retainer **150**, **160** has a raised edge **158**, **174** disposed around the outer periphery of the retainer. A raised edge **159**, **190**, in one aspect, is also disposed around the inner periphery of the retainer **150**, **184**. The inner periphery defines an opening **157**, **192** through which the sleeve extends. The outer raised edge **158**, **174** assists in maintaining or securing the releasable coupling between the cap and the retainer. In one aspect, a groove **129** (FIG. **8**) extends along the circumference of the cap for receiving the outer raised edge to further enhance the coupling between the cap and retainer. Similarly, the inner raised edge assists in maintaining or securing the releasable coupling between the retainer

and the sleeve. The inner raised edge also facilitates the seal between the inner cylindrical wall and/or gel pad, the sleeve and the retainer. In one aspect, notches or spaced valleys or openings **155** (FIG. **11**) are disposed along the inner raised edge **159**, which facilitates the engagement of the inner cylindrical wall and/or gel pad with the retainer by reducing binding between the components.

Several of the above-described attachments could be modified to integrate the retainer or a retainer like component directly into a sleeve to which the cap is releasably coupled. Similarly, the cap may be integrated directly into the retainer and/or sleeve creating a non-releasable coupling between the components.

In one aspect, casting the gel pad **60** into the cap **54** to form a gelcap **66** includes placing the cap into a mold cavity of a casting mold. The mold cavity may include support for the annular walls of the cap **54**. The mold may be made of aluminum, copper, brass, or other mold material having good heat dissipation properties. However, those familiar with the art will recognize that other mold materials having lower heat dissipation properties will produce acceptable parts and these are contemplated as within the scope of the present invention as well.

The mold cavity having the cap **54** is filled with the slurry such that the slurry is in contact with the cap. To facilitate filling voids in the mold cavity with the slurry, the slurry may be preheated, for example, to about 52° C. (125° F.). Preheating the slurry to a temperature below the MGT reduces the viscosity of the slurry and allows the slurry to flow more easily. As stated above, the slurry may have been degassed in a vacuum. The slurry may be degassed again within the mold after the mold cavity is filled to remove air that may have been introduced during the filling of the mold cavity and to facilitate flow of the slurry into voids in the mold. Heat is applied to the mold having the cap **54** and the slurry, such as in an oven, until the slurry attains a temperature of about 150° C. As stated above, the slurry turns into gel at about 120° C., however, at about 150° C., the gel can bond to a polycarbonate cap **54**. Depending on the material used to fabricate the cap **54**, bonding may take place at temperatures other than about 150° C. If the cap **54** is fabricated of a material having a lower melting point than 120° C., then the gel pad **60**, such as a gel slug **60**, may be molded separately and then bonded to the cap. The slits **62**, **64** may be molded into the gel pad **60** through the use of an insert in the form of the slit in the mold.

Once the temperature of the gel pad **60** reaches about 150° C., the gelcap **66** may be cooled, such as by air-cooling, cold-water immersion, or other cooling means that are well known in the art. At 150° C. the gel pad is soft and if it were distorted during cooling it would set with the distortion included. To reduce the likelihood of distorting the gel pad **60**, the gelcap **66** may be cooled within the mold. Cooling times may vary based on parameters including size and configuration of the mold, quantity of gel, temperature and quantity of cooling medium, cooling medium properties and the mold material. As an example, the cooling time may be about two (2) hours if cooling in air and about fifteen (15) minutes if cooling in water. Whether cooling with air or water, the final properties of the gel are substantially the same. The gelcap **66** is typically cooled to about ambient room temperature, but may be cooled to lower temperatures. If the gelcap **66** is cooled to the freezing point of the gel, about 0° C., then the gel will freeze and become hard. This may be beneficial for other means of coupling the gel pad **60** to the cap **54**, such as with a secondary operation. The gelcap **66** may be removed from the mold at any time after the gel has set.

When removed from the mold, the gel pad **60** typically has a tacky surface. The gelcap **66** may be coated with a powder, such as cornstarch, to substantially reduce or eliminate the tackiness of the cured gel pad **60**.

As stated above, in another aspect, the gel pad **60** may be molded separately from the cap **54** and coupled to the cap **54** by a secondary operation, such as by bonding. In one aspect, the gel pad **60** may be molded into a gel slug **60** having an outer perimeter smaller than the inner cylindrical wall of the cap **54** and to a height higher than the height of the cap. Since the gel pad **60** is being molded separate from the cap **54**, the slurry only needs to be heated until it reaches about 120° C. and completes the transformation from slurry into gel and the gel becomes substantially transparent. The gel slug **60** may then be placed within the inner cylindrical wall of the cap **54**. The gel slug **60** may be cooled and/or frozen prior to placing it within the inner cylindrical wall of the cap **54**. The gel slug **60** may be coupled to the cap **54** through compression molding with the gel slug being compressed longitudinally so that the outer perimeter of the gel slug expands and compresses against the inner cylindrical wall of the cap. The gel slug **60** and cap **54** are heated to a sufficient temperature for the polystyrene of the gel and the polymer of the cap to form bonds between the gel and the cap. Molding the gel slug **60** separately from the cap **54** and heat bonding the gel slug to the cap at a later time is especially useful when the cap is made of a material that has a lower melting temperature than the MGT. In such situations, the gel slug **60** can be molded first and heat bonded to the cap **54** without melting the cap.

In reference to FIGS. **21-22**, a cap **54** has the gel pad **60** attached, formed or integrated with the cap and is capable of being coupled to the retainer **52** which is capable of being coupled to the sleeve **56**. In one aspect, the elongate sleeve **56** extends through an incision and is attached to a retention ring **58** that contacts the interior portions of the body cavity and provides tension between the retainer **52** outside the body cavity and the deformable retention ring. A plurality of stabilizers **200-206** extends from the retention ring **58** to the gel pad **60**.

In one aspect, the stabilizers **200-206** are sized and configured to prevent excessive bulging of the gel pad **60** in response to the elevated body-cavity pressure. The stabilizers **200, 202**, in one aspect, include a plurality of strings or tethers that extend from the retention ring **58** and subsequently through or into the gel pad **60**. The stabilizers **204, 206** include a plurality of contiguous gel based gussets or webs that extend between the retention ring **58** and the gel pad **60**.

With reference to FIGS. **23-24**, a cap **54** has a woven or knitted fabric **210** that is stretchable and/or resilient. The fabric **210** is integrated into or attached onto the surface **211** of the gel pad **60** and coupled to the periphery of the cap **54**. The fabric **210** provides support to counteract the “doming” or “bowing” of the gel pad **60** or cap **54** under the influence of the internal inflation gas pressure associated with the inflation of the body cavity. In one aspect, a first fabric **212** can be integrated on a first surface **214** of the gel pad **60** and coupled to the periphery of the cap **54** and a second fabric **216** can be integrated on a second, opposite surface **218** and coupled to the cap. In this manner, counteracting support is provided in both directions to minimize uncontrolled deformation of the gel pad as a hand or instrument is placed through or withdrawn.

In FIG. **25**, a first fabric **220** is coupled to the periphery of the cap **54** and a second fabric **222** is coupled to the cap a distance from the first fabric. A cavity **224** is defined by the space between the first fabric **220** and the second fabric **222**. The gel pad **60** may be inserted into the cavity **224** or other-

wise held within the cavity. The gel pad **60** may be processed alone and formed to a preferred shape and size and firmness prior to coupling to the cap **54**. The temperatures commonly required to process SEBS may substantially deform associated plastic structures. Therefore, separate processing and subsequent assembly may be useful for constructing a cap with the gel pad.

Referring to FIG. **26**, the gel pad **60** has multi-cusped lobes **230** that seal upon one another. The channel **232** through which a surgeon's hand or instruments may be inserted through is formed between individual lobes of the gel pad **60**.

Accordingly, the present invention provides a hand access device and methods thereof. Although this invention has been described in certain specific embodiments, many additional modifications and variations would be apparent to those skilled in the art. It is therefore to be understood that this invention may be practiced otherwise than specifically described, including various changes in the size, shape and materials, without departing from the scope and spirit of the present invention. Thus, embodiments of the present invention should be considered in all respects as illustrative and not restrictive. The scope of the present invention is to be determined by the appended claims and their equivalents rather than the foregoing description.

What is claimed is:

1. A surgical access device comprising:

a retractor comprising a proximal end; a distal end; a retention ring at the distal end of the retractor, wherein the retention ring is deformably insertable through an opening into a body cavity; and an elongate sleeve extending proximally from the retention ring;

a gelcap couplable with the proximal end of the retractor, the gelcap comprising an annular cap ring defining a central opening; and a gel pad sealing the central opening and secured to the cap ring, wherein a periphery of the annular cap ring comprises a gap defining a first end of the cap ring and a second end of the cap ring;

a latch pivotably coupled to the annular cap ring towards the first end of the cap ring;

a latch receiver disposed on the cap ring towards the second end of the cap ring dimensioned to releasably receive the latch; and

an access channel extending from a proximal end of the access device to a distal end of the access device, and through the gel pad and the cap ring of the gel pad, through the elongate sleeve, and through the retention ring,

wherein

in a first state in which the latch is not engaged with the latch receiver, the cap ring has a first diameter,

in a second state in which the latch is engaged with the latch receiver, the cap ring has a second diameter smaller than the first diameter, and

in the second state, the gel cap is coupled to the retractor.

2. The surgical access device of claim 1, wherein the latch comprises a shaft comprising a first end pivotably coupled to the first end of the cap ring, and a second end comprising an enlarged head.

3. The surgical access device of claim 2, wherein portions of the enlarged head are compressible.

4. The surgical access device of claim 1, wherein the latch comprises at least one projection that engages a corresponding notch in the latch receiver.

5. The surgical access device of claim 1, wherein the latch receiver comprises parallel walls defining a channel.

6. The surgical access device of claim 5, wherein the parallel walls flex away from each other when engaging the latch.

17

7. The surgical access device of claim 5, wherein the parallel walls comprises at least one projection that engages a corresponding notch in the latch.

8. The surgical access device of claim 1, wherein the cap ring comprises an inner, cylindrical wall.

9. The surgical access device of claim 1, wherein the gel pad is adhesively secured to the cap ring.

10. The surgical access device of claim 1, wherein the gel pad is mechanically secured to the cap ring.

11. The surgical access device of claim 10, wherein the cap ring comprises a wall comprising a plurality of apertures through which portions of the gel pad extend, mechanically securing the gel pad to the cap ring.

12. The surgical access device of claim 1, wherein the gel pad is solvent welded to the cap ring.

13. The surgical access device of claim 1, wherein the gel pad comprises an elastomeric gel.

18

14. The surgical access device of claim 13, wherein the elastomeric gel comprises a diblock or triblock copolymer, and mineral oil.

15. The surgical access device of claim 1, wherein the gel pad comprises an access portion comprising a plurality of dead-end slits through which the access channel extends.

16. The surgical access device of claim 1, wherein the cap ring comprises at least one of polymer, polyethylene, low density polyethylene, high density polyethylene, ultra high molecular weight polyethylene, and polycarbonate.

17. The surgical access device of claim 1, further comprising an annular retainer couplable to the proximal end of the elongate sleeve, positionable in the cap ring in the first state, and couplable to the cap ring in the second state.

* * * * *

专利名称(译)	手进入腹腔镜装置		
公开(公告)号	US7878974	公开(公告)日	2011-02-01
申请号	US12/815986	申请日	2010-06-15
[标]申请(专利权)人(译)	应用医疗资源		
申请(专利权)人(译)	应用医疗资源CORPORATION		
当前申请(专利权)人(译)	应用医疗资源CORPORATION		
[标]发明人	BRUSTAD JOHN R ALBRECHT JEREMY J HILAL NABIL JOHNSON GARY M HART CHARLES C		
发明人	BRUSTAD, JOHN R ALBRECHT, JEREMY J HILAL, NABIL JOHNSON, GARY M HART, CHARLES C		
IPC分类号	A61B1/32		
CPC分类号	A61B17/02 A61B17/0293 A61B17/3423 A61B17/3431 A61B17/3462 A61B17/3498 A61B19/38 A61B17/3439 A61B2019/0203 A61B2017/00477 A61B2017/00526 A61B2017/3419 A61B2019/0202 A61B17/3496 A61B17/0218 A61B90/40 A61B2017/0225 A61B2017/0287 A61B2017/347 A61B2050/005 A61B2050/0051		
代理机构(译)	HO, 背塘		
优先权	60/726826 2005-10-14 US 60/803965 2006-06-05 US 60/745730 2006-04-26 US 60/828089 2006-10-04 US 60/803346 2006-05-26 US		
其他公开文献	US20100249527A1		
外部链接	Espacenet USPTO		

摘要(译)

本发明涉及一种手动进入腹腔镜检查装置，其具有软胶囊，保持器，套管和保持环。gelcap包括与帽结合的凝胶。帽包括内圆柱形壁，凝胶结合到该内圆柱形壁上，从而在装置和体壁中的伤口之间提供密封区域。通过将凝胶固定到内圆柱壁上，凝胶和相应帽的厚度随着装置的整体占地面积而最小化。随着凝胶厚度减小并且能够基本上齐平，通过吹入患者腹部产生的“隆起”现象减少。

