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(54) **SURGICAL ACCESS SYSTEM**

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(71) Applicant: **Applied Medical Resources Corporation**, Rancho Santa Margarita, CA (US)

See application file for complete search history.

(72) Inventors: **Edward D. Pingleton**, Rancho Santa Margarita, CA (US); **Charles C. Hart**, Rancho Santa Margarita, CA (US)

(56) **References Cited**

U.S. PATENT DOCUMENTS

558,364 A 4/1896 Doolittle
1,157,202 A 10/1915 Bates et al.

(Continued)

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

FOREIGN PATENT DOCUMENTS

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DE 26 05 148 A1 8/1977
DE 33 36 279 C2 1/1986

(Continued)

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OTHER PUBLICATIONS

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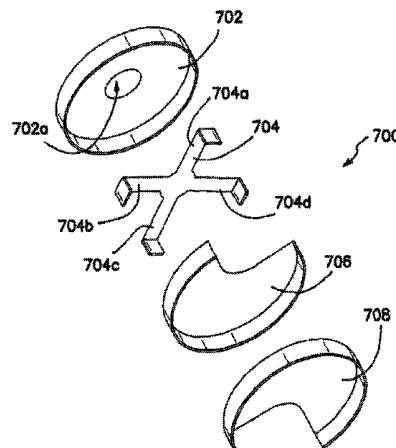
(74) *Attorney, Agent, or Firm* — Patrick Y. Ikehara

(57)

ABSTRACT

The invention is directed to a surgical access system that provides access to a surgical area while maintaining pneumoperitoneum during laparoscopic surgery. The access system comprises a sheath retractor adapted to dilate a wound stretchable to a desired diameter and a detachable seal adapted to be removable from the sheath retractor. In another aspect, the detachable seal comprising a valve including a plurality of overlapping sheets defining an access channel that extends into communication with the incision in the patient. Each of the overlapping sheets includes a portion of the perimeter that is not fixed to the inner diameter of the ring, which provide open edges defining the access channel.

7 Claims, 22 Drawing Sheets



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continuation of application No. 10/927,551, filed on Aug. 25, 2004, now abandoned, which is a continuation of application No. PCT/US2004/005484, filed on Feb. 25, 2004, and a continuation of application No. PCT/US2004/005487, filed on Feb. 25, 2004, and a continuation of application No. PCT/US2004/005361, filed on Feb. 24, 2004.

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(56) **References Cited**

U.S. PATENT DOCUMENTS

1,598,284 A	8/1926	Kinney	4,083,370 A	4/1978	Taylor
1,690,995 A	11/1928	Pratt	4,096,853 A	6/1978	Weigand
1,180,466 A	6/1931	Deutsch	4,112,932 A	9/1978	Chiulli
1,810,466 A	6/1931	Deutsch	4,117,847 A	10/1978	Clayton
2,219,564 A	10/1940	Reyniers	4,130,113 A	12/1978	Graham
2,305,289 A	12/1942	Coburg	4,177,814 A	12/1979	Knepshield et al.
2,478,586 A	8/1949	Krapp	4,183,357 A	1/1980	Bentley et al.
2,669,991 A	2/1954	Curutchet	4,187,849 A	2/1980	Stim
2,695,608 A	11/1954	Gibbon	4,188,945 A	2/1980	Wenander
2,812,758 A	11/1957	Blumenschein	4,217,664 A	8/1980	Faso
2,835,253 A	5/1958	Borgeson	4,222,126 A	9/1980	Boretos et al.
2,853,075 A	9/1958	Hoffman et al.	4,228,792 A	10/1980	Rhys-Davies
3,039,468 A	6/1962	Price	4,239,036 A	12/1980	Krieger
3,057,350 A	10/1962	Cowley	4,240,411 A	12/1980	Hosono
3,111,943 A	11/1963	Orndorff	4,253,201 A	3/1981	Ross et al.
3,195,934 A	7/1965	Parrish	4,254,973 A	3/1981	Banjamin
3,244,169 A	4/1966	Baxter	4,306,562 A	12/1981	Osborne
3,253,594 A	5/1966	Matthews et al.	4,321,915 A	3/1982	Leighton
3,313,299 A	4/1967	Spademan	4,331,138 A	5/1982	Jessen
3,329,390 A	7/1967	Hulsey	4,338,934 A	7/1982	Spademan
3,332,417 A	7/1967	Blanford et al.	4,338,937 A	7/1982	Lerman
3,347,226 A	10/1967	Harrover	4,367,728 A	1/1983	Mutke
3,347,227 A	10/1967	Harrover	4,369,284 A	1/1983	Chen
3,397,692 A	8/1968	Creager, Jr. et al.	4,399,816 A	8/1983	Spangler
3,402,710 A	9/1968	Paleschuck	4,402,683 A	9/1983	Kopman
3,416,520 A	12/1968	Creager, Jr.	4,411,659 A	10/1983	Jensen et al.
3,447,533 A	6/1969	Spicer	4,421,296 A	12/1983	Stephens
3,522,800 A	8/1970	Lesser	4,424,833 A	1/1984	Spector et al.
3,523,534 A	8/1970	Nolan	4,428,364 A	1/1984	Bartolo
3,570,475 A	3/1971	Weinstein	4,430,081 A	2/1984	Timmermans
3,656,485 A	4/1972	Robertson	4,434,791 A	3/1984	Darnell
3,685,786 A	8/1972	Woodson	4,436,519 A	3/1984	O'Neill
3,717,151 A	2/1973	Collett	4,454,873 A	6/1984	Laufenberg et al.
3,717,883 A	2/1973	Mosher	4,473,067 A	9/1984	Schiff
3,729,006 A	4/1973	Wilder et al.	4,475,548 A	10/1984	Muto
3,729,027 A	4/1973	Bare	4,485,490 A	12/1984	Akers et al.
3,782,370 A	1/1974	McDonald	4,488,877 A	12/1984	Klein
3,797,478 A	3/1974	Walsh et al.	4,543,088 A	9/1985	Bootman et al.
3,799,166 A	3/1974	Marsan	4,550,713 A	11/1985	Hyman
3,807,393 A	4/1974	McDonald	4,553,537 A	11/1985	Rosenberg
3,828,764 A	8/1974	Jones	4,555,242 A	11/1985	Saudagar
3,831,583 A	8/1974	Edmunds et al.	4,556,996 A	12/1985	Wallace
3,841,332 A	10/1974	Treacle	4,601,710 A	7/1986	Moll
3,850,172 A	11/1974	Cazalis	4,610,665 A	9/1986	Matsumoto et al.
3,853,126 A	12/1974	Schulte	4,626,245 A	12/1986	Weinstein
3,853,127 A	12/1974	Spademan	4,634,424 A	1/1987	O'Boyle
3,856,021 A	12/1974	McIntosh	4,634,432 A	1/1987	Kocak
3,860,274 A	1/1975	Ledstrom et al.	4,644,951 A	2/1987	Bays
3,861,416 A	1/1975	Wichterle	4,649,904 A	3/1987	Krauter
3,907,389 A	9/1975	Cox et al.	4,653,476 A	3/1987	Bonnet
3,915,171 A	10/1975	Shermeta	4,654,030 A	3/1987	Moll et al.
3,965,890 A	6/1976	Gauthier	4,655,752 A	4/1987	Honkanen et al.
3,970,089 A	7/1976	Saice	4,673,393 A	6/1987	Suzuki et al.
3,996,623 A	12/1976	Kaster	4,673,394 A	6/1987	Fenton
4,000,739 A	1/1977	Stevens	4,691,942 A	9/1987	Ford
4,016,884 A	4/1977	Kwan-Gett	4,714,749 A	12/1987	Hughes et al.
4,024,872 A	5/1977	Muldoon	4,738,666 A	4/1988	Fuqua
4,030,500 A	6/1977	Ronnquist	4,755,170 A	7/1988	Golden
4,043,328 A	8/1977	Cawood, Jr. et al.	4,760,933 A	8/1988	Christner et al.
4,069,913 A	1/1978	Harrigan	4,776,843 A	10/1988	Martinez et al.
			4,777,943 A	10/1988	Chvapil
			4,784,646 A	11/1988	Feingold
			4,796,629 A	1/1989	Grayzel
			4,798,594 A	1/1989	Hillstead
			4,802,694 A	2/1989	Vargo
			4,808,168 A	2/1989	Warring
			4,809,679 A	3/1989	Shimonaka et al.
			4,828,554 A	5/1989	Griffin
			4,842,931 A	6/1989	Zook
			4,848,575 A	7/1989	Nakamura et al.
			4,856,502 A	8/1989	Ersfeld et al.
			4,863,430 A	9/1989	Klyce et al.
			4,863,438 A	9/1989	Gauderer et al.
			4,889,107 A	12/1989	Kaufman
			4,895,565 A	1/1990	Hillstead
			4,897,081 A	1/1990	Poirier
			4,903,710 A	2/1990	Jessamine et al.
			4,911,974 A	3/1990	Shimizu et al.
			4,915,132 A	4/1990	Hodge et al.

(56)

References Cited

U.S. PATENT DOCUMENTS

4,926,882	A	5/1990	Lawrence	5,300,036	A	4/1994	Mueller et al.
4,929,235	A	5/1990	Merry et al.	5,308,336	A	5/1994	Hart et al.
4,944,732	A	7/1990	Russo	5,309,896	A	5/1994	Moll et al.
4,950,222	A	8/1990	Scott et al.	5,312,391	A	5/1994	Wilk
4,950,223	A	8/1990	Silvanov	5,314,417	A	5/1994	Stephens et al.
4,984,564	A	1/1991	Yuen	5,316,541	A	5/1994	Fischer
4,991,593	A	2/1991	LeVahn	5,320,611	A	6/1994	Bonutti et al.
4,998,538	A	3/1991	Charowsky et al.	5,330,437	A	7/1994	Durman
5,000,745	A	3/1991	Guest et al.	5,330,486	A	7/1994	Wilk
5,009,224	A	4/1991	Cole	5,330,497	A	7/1994	Freitas et al.
5,015,228	A	5/1991	Columbus et al.	5,331,975	A	7/1994	Bonutti
5,019,101	A	5/1991	Purkait et al.	5,334,143	A	8/1994	Carroll
5,026,366	A	6/1991	Leckrone	5,334,646	A	8/1994	Chen
5,037,379	A	8/1991	Clayman et al.	5,336,192	A	8/1994	Palestrant
5,041,095	A	8/1991	Littrell	5,336,708	A	8/1994	Chen
5,045,070	A	9/1991	Grodecki et al.	5,338,313	A	8/1994	Mollenauer et al.
5,071,411	A	12/1991	Hillstead	5,342,315	A	8/1994	Rowe et al.
5,073,169	A	12/1991	Raiken	5,342,385	A	8/1994	Norelli et al.
5,074,878	A	12/1991	Bark et al.	5,350,364	A	9/1994	Stephens et al.
5,082,005	A	1/1992	Kaldany	5,353,786	A	10/1994	Wilk
5,086,763	A	2/1992	Hathman	5,354,280	A	10/1994	Haber et al.
5,092,846	A	3/1992	Nishijima et al.	5,360,417	A	11/1994	Gravener et al.
5,104,389	A	4/1992	Deem	5,364,345	A	11/1994	Lowery et al.
5,125,396	A	6/1992	Ray	5,364,372	A	11/1994	Danks et al.
5,125,897	A	6/1992	Quinn et al.	5,366,446	A	11/1994	Tal et al.
5,127,626	A	7/1992	Hilal et al.	5,366,478	A	11/1994	Brinkerhoff et al.
5,129,885	A	7/1992	Green et al.	5,368,545	A	11/1994	Schaller et al.
5,141,498	A	8/1992	Christian	5,375,588	A	12/1994	Yoon
5,149,327	A	9/1992	Oshiyama	5,380,288	A	1/1995	Hart et al.
5,156,617	A	10/1992	Reid	5,383,861	A	1/1995	Hempel et al.
5,158,553	A	10/1992	Berry et al.	5,385,552	A	1/1995	Haber et al.
5,159,921	A	11/1992	Hoover	5,385,553	A	1/1995	Hart et al.
5,161,773	A	11/1992	Tower	5,385,560	A	1/1995	Wulf
5,167,636	A	12/1992	Clement	5,389,080	A	2/1995	Yoon
5,167,637	A	12/1992	Okada et al.	5,389,081	A	2/1995	Castro
5,176,648	A	1/1993	Holmes et al.	5,391,153	A	2/1995	Haber et al.
5,176,662	A	1/1993	Bartholomew et al.	5,391,156	A	2/1995	Hildwein et al.
5,176,697	A	1/1993	Hasson et al.	5,395,367	A	3/1995	Wilk
5,178,162	A	1/1993	Bose	5,403,264	A	4/1995	Wohlert et al.
5,180,365	A	1/1993	Ensminger et al.	5,403,336	A	4/1995	Kieturakis et al.
5,183,471	A	2/1993	Wilk	5,407,433	A	4/1995	Loomas
5,188,595	A	2/1993	Jacobi	5,411,483	A	5/1995	Loomas
5,188,607	A	2/1993	Wu	5,413,571	A	5/1995	Katsaros et al.
5,192,301	A	3/1993	Kamiya et al.	5,423,848	A	6/1995	Washizuka et al.
5,197,955	A	3/1993	Stephens et al.	5,429,609	A	7/1995	Yoon
5,207,656	A	5/1993	Kranys	5,431,676	A	7/1995	Durdal et al.
5,209,737	A	5/1993	Rirchart et al.	5,437,683	A	8/1995	Neumann et al.
5,211,370	A	5/1993	Powers	5,439,455	A	8/1995	Kieturakis et al.
5,211,633	A	5/1993	Stouder, Jr.	5,441,486	A	8/1995	Yoon
5,213,114	A	5/1993	Bailey, Jr.	5,443,452	A	8/1995	Hart et al.
5,226,879	A *	7/1993	Ensminger et al. 604/288.03	5,456,284	A	10/1995	Ryan et al.
5,226,890	A	7/1993	Ianniruberto et al.	5,460,170	A	10/1995	Hammerslag
5,234,455	A	8/1993	Mulhollan	5,460,616	A	10/1995	Weinstein et al.
5,241,968	A	9/1993	Slater	5,468,248	A	11/1995	Chin et al.
5,242,400	A	9/1993	Blake, III et al.	5,476,475	A	12/1995	Gadberry
5,242,409	A	9/1993	Buelna	5,480,410	A	1/1996	Cuschieri et al.
5,242,412	A	9/1993	Blake, III et al.	5,486,426	A	1/1996	McGee et al.
5,242,415	A	9/1993	Kantrowitz et al.	5,490,843	A	2/1996	Hildwein et al.
5,248,304	A	9/1993	Vigdorchik et al.	5,492,304	A	2/1996	Smith et al.
5,256,150	A	10/1993	Quiachon et al.	5,496,280	A	3/1996	Vandenbroek et al.
5,257,973	A	11/1993	Villasuso	5,503,112	A	4/1996	Luhman et al.
5,257,975	A	11/1993	Foshee	5,507,758	A	4/1996	Thomason et al.
5,259,366	A	11/1993	Reydel et al.	5,508,334	A	4/1996	Chen
5,261,883	A	11/1993	Hood et al.	5,511,564	A	4/1996	Wilk
5,262,468	A	11/1993	Chen	5,514,109	A	5/1996	Mollenauer et al.
5,263,922	A	11/1993	Sova et al.	5,514,133	A	5/1996	Golub et al.
5,269,763	A	12/1993	Boehmer et al.	5,514,153	A	5/1996	Bonutti
5,269,772	A	12/1993	Wilk	5,518,278	A	5/1996	Sampson
5,273,449	A	12/1993	Mattis et al.	5,520,632	A	5/1996	Leveen
5,273,545	A	12/1993	Hunt et al.	5,522,791	A	6/1996	Leyva
5,279,575	A	1/1994	Sugarbaker	5,522,824	A	6/1996	Ashby
5,290,310	A	3/1994	Makower et al.	5,524,644	A	6/1996	Crook
5,299,582	A	4/1994	Potts	5,526,536	A	6/1996	Cartmill
5,300,034	A	4/1994	Behnke	5,531,758	A	7/1996	Uschold et al.
5,300,035	A	4/1994	Clement	5,538,509	A	7/1996	Dunlap et al.
				5,540,648	A	7/1996	Yoon
				5,540,711	A	7/1996	Kieturakis et al.
				5,545,150	A	8/1996	Danks et al.
				5,545,179	A	8/1996	Williamson, IV

(56)

References Cited

U.S. PATENT DOCUMENTS

5,549,563 A	8/1996	Kronner	5,820,600 A	10/1998	Carlson et al.
5,549,637 A	8/1996	Crainich	5,830,191 A	11/1998	Hildwein et al.
5,554,124 A	9/1996	Alvarado	5,832,925 A	11/1998	Rothrum
5,562,632 A	10/1996	Davila et al.	5,836,871 A	11/1998	Wallace et al.
5,562,677 A	10/1996	Hildwein et al.	5,841,298 A	11/1998	Huang
5,562,688 A	10/1996	Riza	5,842,971 A	12/1998	Yoon
5,571,115 A	11/1996	Nicholas	5,848,992 A	12/1998	Hart et al.
5,571,137 A	11/1996	Marlow et al.	5,853,395 A	12/1998	Crook et al.
5,575,799 A	11/1996	Bolanos et al.	5,853,417 A	12/1998	Fogarty et al.
5,577,993 A	11/1996	Zhu et al.	5,857,461 A	1/1999	Levitsky et al.
5,578,048 A	11/1996	Pasqualucci et al.	5,860,995 A	1/1999	Berkelaar
5,580,344 A	12/1996	Hasson	5,865,728 A	2/1999	Moll et al.
5,584,850 A	12/1996	Hart et al.	5,865,729 A	2/1999	Meehan et al.
5,601,579 A	2/1997	Semertzides	5,865,807 A	2/1999	Blake, III
5,601,581 A	2/1997	Fogarty et al.	5,865,817 A	2/1999	Moenning et al.
5,603,702 A	2/1997	Smith et al.	5,871,474 A	2/1999	Hermann et al.
5,607,443 A	3/1997	Kieturakis et al.	5,876,413 A	3/1999	Fogarty et al.
5,620,415 A	4/1997	Lucey et al.	5,879,368 A	3/1999	Hoskin et al.
5,620,420 A	4/1997	Kriesel	5,882,344 A	3/1999	Stouder, Jr.
5,628,732 A	5/1997	Antoon, Jr. et al.	5,884,639 A	3/1999	Chen
5,632,284 A	5/1997	Graether	5,894,843 A	4/1999	Benetti et al.
5,632,979 A	5/1997	Goldberg et al.	5,895,377 A	4/1999	Smith et al.
5,634,911 A	6/1997	Hermann et al.	5,899,208 A	5/1999	Bonadio
5,634,936 A	6/1997	Linden et al.	5,899,913 A	5/1999	Fogarty et al.
5,634,937 A	6/1997	Mollenauer et al.	5,904,703 A	5/1999	Gilson
5,636,645 A	6/1997	Ou	5,906,577 A	5/1999	Beane et al.
5,640,977 A	6/1997	Leahy et al.	5,913,847 A	6/1999	Yoon
5,643,301 A	7/1997	Mollenauer	5,916,198 A	6/1999	Dillow
5,649,550 A	7/1997	Crook	5,916,232 A	6/1999	Hart
5,651,771 A	7/1997	Tangherlini et al.	5,919,476 A	7/1999	Fischer et al.
5,653,705 A	8/1997	de la Torre et al.	5,931,832 A	8/1999	Jensen
5,657,963 A	8/1997	Hinchliffe et al.	5,947,922 A	9/1999	MacLeod
5,658,272 A	8/1997	Hasson	5,951,467 A	9/1999	Picha et al.
5,658,306 A	8/1997	Kieturakis	5,951,588 A	9/1999	Moenning
5,662,615 A	9/1997	Blake, III	5,957,888 A	9/1999	Hinchiffe et al.
5,672,168 A	9/1997	de la Torre et al.	5,957,913 A	9/1999	de la Torre et al.
5,681,341 A	10/1997	Lunsford et al.	5,962,572 A	10/1999	Chen
5,683,378 A	11/1997	Christy	5,964,781 A	10/1999	Mollenauer et al.
5,685,854 A	11/1997	Green et al.	5,976,174 A	11/1999	Ruiz
5,685,857 A	11/1997	Negus et al.	5,989,232 A	11/1999	Yoon
5,697,914 A	12/1997	Brimhall	5,989,233 A	11/1999	Yoon
5,707,703 A	1/1998	Rothrum et al.	5,989,266 A	11/1999	Foster
5,709,664 A	1/1998	Vandenbroek et al.	5,993,471 A	11/1999	Riza et al.
5,713,858 A	2/1998	Heruth et al.	5,993,485 A	11/1999	Beckers
5,713,869 A	2/1998	Morejon	5,994,450 A	11/1999	Pearce
5,720,730 A	2/1998	Blake, III	5,997,515 A	12/1999	de la Torre et al.
5,725,536 A	3/1998	Oberlin et al.	6,004,303 A	12/1999	Peterson
5,728,103 A	3/1998	Picha et al.	6,010,494 A	1/2000	Schafer et al.
5,730,748 A	3/1998	Fogarty et al.	6,017,355 A	1/2000	Hessel et al.
5,735,791 A	4/1998	Alexander et al.	6,018,094 A	1/2000	Fox
5,738,628 A	4/1998	Sierocuk et al.	6,024,736 A	2/2000	de la Torre et al.
5,741,234 A	4/1998	Aboul-Hosn	6,025,067 A	2/2000	Fay
5,741,298 A	4/1998	MacLeod	6,033,426 A	3/2000	Kaji
5,743,884 A	4/1998	Hasson et al.	6,033,428 A	3/2000	Sardella
5,749,882 A	5/1998	Hart et al.	6,035,559 A	3/2000	Freed et al.
5,755,660 A	5/1998	Tyagi	6,042,573 A	3/2000	Lucey
5,760,117 A	6/1998	Chen	6,045,535 A	4/2000	Nun
5,769,783 A	6/1998	Fowler	6,048,309 A	4/2000	Flom et al.
5,782,812 A	7/1998	Hart et al.	6,050,871 A	4/2000	Chen
5,782,817 A	7/1998	Franzel et al.	6,053,934 A	4/2000	Andrews et al.
5,782,859 A	7/1998	Nicholas et al.	6,059,816 A	5/2000	Moenning
5,788,676 A	8/1998	Yoon	6,066,117 A	5/2000	Fox et al.
5,792,119 A	8/1998	Marx	6,068,639 A	5/2000	Fogarty et al.
5,795,290 A	8/1998	Bridges	6,076,560 A	6/2000	Stahle et al.
5,803,919 A	9/1998	Hart et al.	6,077,288 A	6/2000	Shimomura
5,803,921 A	9/1998	Bonadio	6,086,603 A	7/2000	Termin et al.
5,803,923 A	9/1998	Singh-Derewa et al.	6,090,043 A	7/2000	Austin et al.
5,807,350 A	9/1998	Diaz	6,099,506 A	8/2000	Macoviak et al.
5,810,712 A	9/1998	Dunn	6,110,154 A	8/2000	Shimomura et al.
5,810,721 A	9/1998	Mueller et al.	6,123,689 A	9/2000	To et al.
5,813,409 A	9/1998	Leahy et al.	6,142,935 A	11/2000	Flom et al.
5,814,026 A	9/1998	Yoon	6,142,936 A	11/2000	Beane et al.
5,817,062 A	10/1998	Flom et al.	6,149,642 A	11/2000	Gerhart et al.
5,819,375 A	10/1998	Kastner	6,150,608 A	11/2000	Wambeke et al.
5,820,555 A	10/1998	Watkins, III et al.	6,159,182 A	12/2000	Davis
			6,162,172 A	12/2000	Cosgrove et al.
			6,162,196 A	12/2000	Hart et al.
			6,162,206 A	12/2000	Bindokas
			6,163,949 A	12/2000	Neuenschwander

(56)

References Cited

U.S. PATENT DOCUMENTS

6,164,279	A	12/2000	Tweedle	6,796,940	B2	9/2004	Bonadio et al.
6,171,282	B1	1/2001	Ragsdale	6,797,765	B2	9/2004	Pearce
6,183,486	B1	2/2001	Snow et al.	6,800,084	B2	10/2004	Davison et al.
6,197,002	B1	3/2001	Peterson	6,811,546	B1	11/2004	Callas et al.
6,217,555	B1	4/2001	Hart et al.	6,814,078	B2	11/2004	Crook
6,217,590	B1	4/2001	Levinson	6,814,700	B1	11/2004	Mueller et al.
6,224,612	B1	5/2001	Bates et al.	6,817,974	B2	11/2004	Cooper et al.
6,228,063	B1	5/2001	Aboul-Hosn	6,830,578	B2	12/2004	O'Heeron et al.
6,238,373	B1	5/2001	de la Torre et al.	6,837,893	B2	1/2005	Miller
6,241,768	B1	6/2001	Agarwal et al.	6,840,946	B2	1/2005	Fogarty et al.
6,254,533	B1	7/2001	Fadem et al.	6,840,951	B2	1/2005	de la Torre et al.
6,254,534	B1	7/2001	Butler et al.	6,846,287	B2	1/2005	Bonadio et al.
6,258,065	B1	7/2001	Dennis et al.	6,860,463	B2	3/2005	Hartley
6,264,604	B1	7/2001	Kieturakis et al.	6,863,674	B2	3/2005	Kasahara et al.
6,267,751	B1	7/2001	Mangosong	6,866,861	B1	3/2005	Luhman
6,276,661	B1	8/2001	Laird	6,867,253	B1	3/2005	Chen
6,287,280	B1	9/2001	Lampropoulos et al.	6,869,393	B2	3/2005	Butler
6,315,770	B1	11/2001	de la Torre et al.	6,878,110	B2	4/2005	Yang et al.
6,319,246	B1	11/2001	de la Torre et al.	6,884,253	B1	4/2005	McFarlane
6,322,541	B2	11/2001	West	6,890,295	B2	5/2005	Michels et al.
6,325,384	B1	12/2001	Berry, Sr. et al.	6,895,965	B2	5/2005	Scarberry et al.
6,346,074	B1	2/2002	Roth	6,902,541	B2	6/2005	McNally et al.
6,371,968	B1	4/2002	Kogasaka et al.	6,902,569	B2	6/2005	Parmer et al.
6,382,211	B1	5/2002	Crook	6,908,430	B2	6/2005	Caldwell et al.
6,383,162	B1	5/2002	Sugarbaker	6,909,220	B2	6/2005	Chen
6,391,043	B1	5/2002	Moll et al.	6,913,609	B2	7/2005	Yencho et al.
6,413,244	B1	7/2002	Bestetti et al.	6,916,310	B2	7/2005	Sommerich
6,413,458	B1	7/2002	Pearce	6,916,331	B2	7/2005	Mollenauer et al.
6,420,475	B1	7/2002	Chen	6,929,637	B2	8/2005	Gonzalez et al.
6,423,036	B1	7/2002	Van Huizen	6,936,037	B2	8/2005	Bubb et al.
6,440,061	B1	8/2002	Wenner et al.	6,939,296	B2	9/2005	Ewers et al.
6,440,063	B1	8/2002	Beane et al.	6,945,932	B1	9/2005	Caldwell et al.
6,443,957	B1	9/2002	Addis	6,958,037	B2	10/2005	Ewers et al.
6,447,489	B1	9/2002	Peterson	6,972,026	B1	12/2005	Caldwell et al.
6,450,983	B1	9/2002	Rambo	6,979,324	B2	12/2005	Bybordi et al.
6,454,783	B1	9/2002	Piskun	6,991,602	B2	1/2006	Nakazawa et al.
6,464,686	B1	10/2002	O'Hara et al.	6,997,909	B2	2/2006	Goldberg
6,468,292	B1	10/2002	Mollenauer et al.	7,001,397	B2	2/2006	Davison et al.
6,482,181	B1	11/2002	Racenet et al.	7,008,377	B2	3/2006	Beane et al.
6,485,435	B1	11/2002	Bakal	7,014,628	B2	3/2006	Bousquet
6,485,467	B1	11/2002	Crook et al.	7,033,319	B2	4/2006	Pulford et al.
6,488,620	B1	12/2002	Segermark et al.	7,052,454	B2	5/2006	Taylor
6,488,692	B1	12/2002	Spence et al.	7,056,304	B2	6/2006	Bacher et al.
6,494,893	B2	12/2002	Dubrul et al.	7,056,321	B2	6/2006	Pagliuca et al.
6,527,787	B1	3/2003	Fogarty et al.	7,067,583	B2	6/2006	Chen
6,533,734	B1	3/2003	Corley, III et al.	7,077,852	B2	7/2006	Fogarty et al.
6,551,270	B1	4/2003	Bimbo et al.	7,081,089	B2	7/2006	Bonadio et al.
6,551,276	B1	4/2003	Mann et al.	7,083,626	B2	8/2006	Hart et al.
6,551,344	B2	4/2003	Thill	7,093,599	B2	8/2006	Chen
6,552,109	B1	4/2003	Chen	7,100,614	B2	9/2006	Stevens et al.
6,554,793	B1	4/2003	Pauker et al.	7,101,353	B2	9/2006	Lui et al.
6,558,371	B2	5/2003	Dorn	7,105,009	B2	9/2006	Johnson
6,569,120	B1	5/2003	Green	7,105,607	B2	9/2006	Chen
6,578,577	B2	6/2003	Bonadio et al.	7,112,185	B2	9/2006	Hart et al.
6,579,281	B2	6/2003	Palmer et al.	7,118,528	B1	10/2006	Piskun
6,582,364	B2	6/2003	Butler et al.	7,134,929	B2	11/2006	Chen
6,589,167	B1	7/2003	Shimomura et al.	7,153,261	B2	12/2006	Wenchell
6,589,211	B1	7/2003	MacLeod	7,163,510	B2	1/2007	Kahle et al.
6,607,504	B2	8/2003	Haarala et al.	7,192,436	B2	3/2007	Sing et al.
6,613,952	B2	9/2003	Rambo	7,193,002	B2	3/2007	Chen
6,623,426	B2	9/2003	Bonadio et al.	7,195,590	B2	3/2007	Butler et al.
6,627,275	B1	9/2003	Chen	7,214,185	B1	5/2007	Rosney et al.
6,663,598	B1	12/2003	Carrillo et al.	7,217,277	B2	5/2007	Parihar et al.
6,669,674	B1	12/2003	Macoviak et al.	7,222,380	B2	5/2007	Chen
6,676,639	B1	1/2004	Ternström	7,223,257	B2	5/2007	Shubayev et al.
6,702,787	B2	3/2004	Racenet et al.	7,223,278	B2	5/2007	Davison et al.
6,705,989	B2	3/2004	Cuschieri et al.	7,226,484	B2	6/2007	Chen
6,706,050	B1	3/2004	Giannadakis	7,235,062	B2	6/2007	Brustad
6,714,298	B2	3/2004	Ryer	7,235,084	B2	6/2007	Skakoon et al.
6,716,201	B2	4/2004	Blanco	7,238,154	B2	7/2007	Ewers et al.
6,723,044	B2	4/2004	Pulford et al.	7,244,244	B2	7/2007	Racenet et al.
6,723,088	B2	4/2004	Gaskill, III et al.	7,276,075	B1	10/2007	Callas et al.
6,725,080	B2	4/2004	Melkent et al.	7,290,367	B2	11/2007	Chen
6,793,621	B2	9/2004	Butler et al.	7,294,103	B2	11/2007	Bertolero et al.
6,794,440	B2	9/2004	Chen	7,297,106	B2	11/2007	Yamada et al.
				7,300,399	B2	11/2007	Bonadio et al.
				7,316,699	B2	1/2008	McFarlane
				7,331,940	B2	2/2008	Sommerich
				7,338,473	B2	3/2008	Campbell et al.

(56)

References Cited

U.S. PATENT DOCUMENTS

7,344,546	B2	3/2008	Wulfman et al.	2004/0072942	A1	4/2004	Chen
7,344,547	B2	3/2008	Piskun	2004/0073090	A1	4/2004	Butler
7,344,568	B2	3/2008	Chen	2004/0092795	A1	5/2004	Bonadio et al.
7,377,898	B2	5/2008	Ewers et al.	2004/0092796	A1	5/2004	Butler et al.
7,390,317	B2	6/2008	Taylor et al.	2004/0093018	A1	5/2004	Johnson
7,393,322	B2	7/2008	Wenchell	2004/0097793	A1	5/2004	Butler et al.
7,412,977	B2	8/2008	Fields et al.	2004/0106942	A1	6/2004	Taylor et al.
7,445,597	B2	11/2008	Butler et al.	2004/0111061	A1	6/2004	Curran
7,473,221	B2	1/2009	Ewers et al.	2004/0127772	A1	7/2004	Ewers et al.
7,481,765	B2	1/2009	Ewers et al.	2004/0138529	A1	7/2004	Wiltshire et al.
7,537,564	B2	5/2009	Bonadio et al.	2004/0143158	A1	7/2004	Hart et al.
7,540,839	B2	6/2009	Butler et al.	2004/0154624	A1	8/2004	Bonadio et al.
7,559,893	B2	7/2009	Bonadio et al.	2004/0167559	A1	8/2004	Taylor et al.
7,578,832	B2	8/2009	Johnson	2004/0173218	A1	9/2004	Yamada et al.
7,645,232	B2	1/2010	Shluzas	2004/0215063	A1	10/2004	Bonadio et al.
7,650,887	B2	1/2010	Nguyen et al.	2004/0230161	A1	11/2004	Zeiner
7,661,164	B2	2/2010	Chen	2004/0243144	A1	12/2004	Bonadio et al.
7,704,207	B2	4/2010	Albrecht et al.	2004/0249248	A1	12/2004	Bonadio et al.
7,717,847	B2	5/2010	Smith	2004/0254426	A1	12/2004	Wenchell
7,727,146	B2	6/2010	Albrecht et al.	2004/0260244	A1	12/2004	Piechowicz et al.
7,727,255	B2	6/2010	Taylor et al.	2004/0267096	A1	12/2004	Caldwell et al.
7,736,306	B2	6/2010	Brustad et al.	2005/0020884	A1	1/2005	Hart et al.
7,749,415	B2	7/2010	Brustad et al.	2005/0033246	A1	2/2005	Ahlbert et al.
7,753,901	B2	7/2010	Piskun et al.	2005/0059865	A1	3/2005	Kahle et al.
7,758,500	B2	7/2010	Boyd et al.	2005/0065475	A1	3/2005	Hart et al.
7,766,824	B2	8/2010	Jensen et al.	2005/0065543	A1	3/2005	Kahle et al.
7,811,251	B2	10/2010	Wenchell et al.	2005/0080319	A1	4/2005	Dinkler, II et al.
7,815,567	B2	10/2010	Albrecht et al.	2005/0090713	A1	4/2005	Gonzales et al.
7,837,612	B2	11/2010	Gill et al.	2005/0090716	A1	4/2005	Bonadio et al.
7,841,765	B2	11/2010	Keller	2005/0090717	A1	4/2005	Bonadio et al.
7,850,667	B2	12/2010	Gresham	2005/0096695	A1	5/2005	Olich
7,867,164	B2	1/2011	Butler et al.	2005/0131349	A1	6/2005	Albrecht et al.
7,878,974	B2	2/2011	Brustad et al.	2005/0148823	A1	7/2005	Vaugh et al.
7,883,461	B2	2/2011	Albrecht et al.	2005/0155611	A1	7/2005	Vaugh et al.
7,892,172	B2	2/2011	Albrecht et al.	2005/0159647	A1	7/2005	Hart et al.
7,896,889	B2	3/2011	Mazzocchi et al.	2005/0192483	A1	9/2005	Bonadio et al.
7,909,760	B2	3/2011	Albrecht et al.	2005/0192598	A1	9/2005	Johnson et al.
7,913,697	B2	3/2011	Nguyen et al.	2005/0197537	A1	9/2005	Bonadio et al.
7,930,782	B2	4/2011	Chen	2005/0203346	A1	9/2005	Bonadio et al.
7,998,068	B2	8/2011	Bonadio et al.	2005/0209510	A1	9/2005	Bonadio et al.
8,021,296	B2	9/2011	Bonadio	2005/0222582	A1	10/2005	Wenchell
8,317,690	B2	11/2012	Ransden	2005/0240082	A1	10/2005	Bonadio et al.
RE44,380	E	7/2013	de la Torre et al.	2005/0241647	A1	11/2005	Nguyen
8,574,153	B2	11/2013	Richard	2005/0251124	A1	11/2005	Zvulonni et al.
RE44,790	E	3/2014	de la Torre et al.	2005/0261720	A1	11/2005	Caldwell et al.
2001/0037053	A1	11/2001	Bonadio et al.	2005/0267419	A1	12/2005	Smith
2001/0047188	A1	11/2001	Bonadio et al.	2005/0277946	A1	12/2005	Greenhalgh
2002/0002324	A1	1/2002	McManus	2005/0283050	A1	12/2005	Gundlapalli et al.
2002/0010389	A1	1/2002	Butler et al.	2005/0288558	A1	12/2005	Ewers et al.
2002/0013542	A1	1/2002	Bonadio et al.	2005/0288634	A1	12/2005	O'Heeron et al.
2002/0016607	A1	2/2002	Bonadio et al.	2006/0020164	A1	1/2006	Butler et al.
2002/0026230	A1	2/2002	Moll et al.	2006/0020241	A1	1/2006	Piskun et al.
2002/0038077	A1	3/2002	de la Torre et al.	2006/0030755	A1	2/2006	Ewers et al.
2002/0072762	A1	6/2002	Bonadio et al.	2006/0041270	A1	2/2006	Lenker
2002/0111536	A1	8/2002	Cuschieri et al.	2006/0047284	A1	3/2006	Gresham
2003/0004253	A1	1/2003	Chen	2006/0047293	A1	3/2006	Haberland et al.
2003/0014076	A1	1/2003	Mollenauer et al.	2006/0052669	A1	3/2006	Hart
2003/0028179	A1	2/2003	Piskun	2006/0084842	A1	4/2006	Hart et al.
2003/0040711	A1	2/2003	Racenet et al.	2006/0106402	A1	5/2006	McLucas
2003/0078478	A1	4/2003	Bonadio et al.	2006/0129165	A1	6/2006	Edoga et al.
2003/0139756	A1	7/2003	Brustad	2006/0149137	A1	7/2006	Pingleton et al.
2003/0167040	A1	9/2003	Bacher et al.	2006/0149306	A1	7/2006	Hart et al.
2003/0187376	A1	10/2003	Rambo	2006/0161049	A1	7/2006	Beane et al.
2003/0192553	A1	10/2003	Rambo	2006/0161050	A1	7/2006	Butler et al.
2003/0225392	A1	12/2003	McMichael et al.	2006/0241651	A1	10/2006	Wilk
2003/0236505	A1	12/2003	Bonadio et al.	2006/0247498	A1	11/2006	Bonadio et al.
2003/0236549	A1	12/2003	Bonadio et al.	2006/0247499	A1	11/2006	Butler et al.
2004/0015185	A1	1/2004	Ewers et al.	2006/0247500	A1	11/2006	Voegele et al.
2004/0024363	A1	2/2004	Goldberg	2006/0247516	A1	11/2006	Hess et al.
2004/0049099	A1	3/2004	Ewers et al.	2006/0247586	A1	11/2006	Voegele et al.
2004/0049100	A1	3/2004	Butler	2006/0247673	A1	11/2006	Voegele et al.
2004/0054353	A1	3/2004	Taylor	2006/0247678	A1	11/2006	Weisenburgh, II et al.
2004/0063833	A1	4/2004	Chen	2006/0258899	A1	11/2006	Gill et al.
2004/0068232	A1	4/2004	Hart et al.	2006/0264706	A1	11/2006	Piskun
2004/0070187	A1	4/2004	Chen	2006/0270911	A1	11/2006	Voegele et al.
				2007/0004968	A1	1/2007	Bonadio et al.
				2007/0049966	A1	3/2007	Bonadio et al.
				2007/0088202	A1	4/2007	Albrecht et al.
				2007/0088204	A1	4/2007	Albrecht

(56)

References Cited

U.S. PATENT DOCUMENTS

2007/0093695 A1 4/2007 Bonadio et al.
 2007/0118175 A1 5/2007 Butler et al.
 2007/0149859 A1 6/2007 Albrecht
 2007/0151566 A1 7/2007 Kahle et al.
 2007/0156023 A1 7/2007 Frasier et al.
 2007/0185387 A1 8/2007 Albrecht et al.
 2007/0203398 A1 8/2007 Bonadio et al.
 2007/0208312 A1 9/2007 Norton et al.
 2007/0255219 A1 11/2007 Vaugh et al.
 2007/0270752 A1 11/2007 Labombard
 2007/0299387 A1 12/2007 Williams et al.
 2008/0027476 A1 1/2008 Piskun
 2008/0048011 A1 2/2008 Weller
 2008/0097162 A1 4/2008 Bonadio et al.
 2008/0097163 A1 4/2008 Butler et al.
 2008/0200767 A1 8/2008 Ewers et al.
 2008/0255519 A1 10/2008 Piskun et al.
 2008/0281161 A1 11/2008 Albrecht et al.
 2008/0281162 A1 11/2008 Albrecht et al.
 2009/0012477 A1 1/2009 Norton et al.
 2009/0036745 A1 2/2009 Bonadio et al.
 2009/0069837 A1 3/2009 Bonadio et al.
 2009/0093683 A1 4/2009 Richard et al.
 2009/0093752 A1 4/2009 Richard et al.
 2009/0131754 A1 5/2009 Ewers et al.
 2009/0137879 A1 5/2009 Ewers et al.
 2009/0149714 A1 6/2009 Bonadio
 2009/0182279 A1 7/2009 Wenchell et al.
 2009/0182282 A1 7/2009 Okihisa
 2009/0187079 A1 7/2009 Albrecht et al.
 2009/0227843 A1 9/2009 Smith et al.
 2009/0292176 A1 11/2009 Bonadio et al.
 2009/0326330 A1 12/2009 Bonadio et al.
 2010/0063362 A1 3/2010 Bonadio et al.
 2010/0063364 A1 3/2010 Bonadio et al.
 2010/0081880 A1 4/2010 Widenhouse et al.
 2010/0081881 A1 4/2010 Murray et al.
 2010/0081995 A1 4/2010 Widenhouse et al.
 2010/0100043 A1 4/2010 Racenet
 2010/0113882 A1 5/2010 Widenhouse et al.
 2010/0217087 A1 8/2010 Bonadio et al.
 2010/0228091 A1 9/2010 Widenhouse et al.
 2010/0228092 A1 9/2010 Ortiz et al.
 2010/0228094 A1 9/2010 Ortiz et al.
 2010/0240960 A1 9/2010 Richard
 2010/0249523 A1 9/2010 Spiegel et al.
 2010/0249524 A1 9/2010 Ransden et al.
 2010/0249525 A1 9/2010 Shelton, IV et al.
 2010/0249694 A1 9/2010 Choi et al.
 2010/0261972 A1 10/2010 Widenhouse et al.
 2010/0261975 A1 10/2010 Huey et al.
 2010/0286484 A1 11/2010 Stellon et al.
 2010/0298646 A1 11/2010 Stellon et al.
 2011/0021877 A1 1/2011 Fortier et al.
 2011/0028891 A1 2/2011 Okoniewski
 2011/0034935 A1 2/2011 Kleyman
 2011/0034946 A1 2/2011 Kleyman
 2011/0034947 A1 2/2011 Kleyman
 2011/0071462 A1 3/2011 Ewers et al.
 2011/0071463 A1 3/2011 Ewers et al.
 2012/0095297 A1 4/2012 Dang et al.

FOREIGN PATENT DOCUMENTS

DE 37 39 532 12/1988
 DE 37 37 121 5/1989
 DE 296 00 939 6/1996
 DE 19828099 12/1999
 EP 0 113 520 7/1984
 EP 0 142 262 5/1985
 EP 0 517 248 12/1992
 EP 0 537 768 4/1993
 EP 0 807 416 11/1997
 EP 0 849 517 6/1998

EP 0950376 10/1999
 EP 1 118 657 7/2001
 EP 1 125 552 8/2001
 EP 1 312 318 5/2003
 EP 1 407 715 4/2004
 EP 2 044 889 4/2009
 EP 2 272 450 A2 1/2011
 EP 2 340 792 7/2011
 FR 1456623 9/1966
 GB 1151993 5/1969
 GB 1355611 6/1974
 GB 1372491 10/1974
 GB 1379772 1/1975
 GB 1400808 7/1975
 GB 1407023 9/1975
 GB 1482857 8/1977
 GB 1496696 12/1977
 GB 2071502 9/1981
 GB 2255019 10/1992
 GB 2275420 8/1994
 GB 2298906 9/1996
 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 S75368 8/1997
 IE S960196 8/1997
 IE S970810 11/1997
 IE 991010 7/2000
 IE 990218 11/2000
 IE 990219 11/2000
 IE 990220 11/2000
 IE 990660 2/2001
 IE 990795 3/2001
 JP 10-108868 4/1998
 JP 11-290327 10/1999
 JP 2001-61850 3/2001
 JP 2002-28163 1/2002
 JP 02003 235879 A 8/2003
 JP 2004-195037 7/2004
 RU 1342485 1/1997
 WO WO 86/06272 11/1986
 WO WO 86/06316 11/1986
 WO WO 92/11880 7/1992
 WO WO 92/21292 12/1992
 WO WO 93/05740 4/1993
 WO WO 93/14801 8/1993
 WO WO 94/04067 3/1994
 WO WO 94/22357 10/1994
 WO WO 95/05207 2/1995
 WO WO 95/07056 3/1995
 WO WO 95/22289 8/1995
 WO WO 95/24864 9/1995
 WO WO 95/27445 10/1995
 WO WO 95/27468 10/1995
 WO WO 96/36283 11/1996
 WO WO 97/11642 4/1997
 WO WO 97/32514 9/1997
 WO WO 97/32515 9/1997
 WO WO 97/42889 11/1997
 WO WO 98/19853 5/1998
 WO WO 98/35614 8/1998
 WO WO 98/48724 11/1998
 WO WO 99/03416 1/1999
 WO WO 99/15068 4/1999
 WO WO 99/16368 4/1999
 WO WO 99/22804 5/1999
 WO WO 99/25268 5/1999
 WO WO 99/29250 6/1999
 WO WO 00/32116 6/2000
 WO WO 00/32117 6/2000
 WO WO 00/32119 6/2000
 WO WO 00/32120 6/2000
 WO WO 00/35356 6/2000
 WO WO 00/54675 9/2000
 WO WO 00/54676 9/2000

(56) **References Cited**

FOREIGN PATENT DOCUMENTS

WO	WO 00/54677	9/2000
WO	WO 01/08563	2/2001
WO	WO 01/08581	2/2001
WO	WO 01/26558	4/2001
WO	WO 01/26559	4/2001
WO	WO 01/45568	6/2001
WO	WO 01/49363	7/2001
WO	WO 01/91652	12/2001
WO	WO 02/07611	1/2002
WO	WO 02/17800	3/2002
WO	WO 02/34108	5/2002
WO	WO 03/011153	2/2003
WO	WO 03/011551	2/2003
WO	WO 03/026512	4/2003
WO	WO 03/032819	4/2003
WO	WO 03/034908	5/2003
WO	WO 03/061480	7/2003
WO	WO 03/077726	9/2003
WO	WO 03/103548	12/2003
WO	WO 2004/026153	4/2004
WO	WO 2004/030547	4/2004
WO	WO 2004/075730	9/2004
WO	WO 2004/075741	9/2004
WO	WO 2004/075930	9/2004
WO	WO 2005/009257	2/2005
WO	WO 2005/034766	4/2005
WO	WO 2005/089661	9/2005
WO	WO 2006/040748	4/2006
WO	WO 2006/059318	6/2006
WO	WO 2006/100658	9/2006
WO	WO 2007/044849	4/2007
WO	WO 2008/015566	2/2008
WO	WO 2008/093313	8/2008
WO	WO 2008/121294	10/2008
WO	WO 2010/045253	4/2010
WO	WO 2010/082722	7/2010
WO	WO 2010/104259	9/2010

OTHER PUBLICATIONS

U.S. Appl. No. 10/802,125, filed Mar. 15, 2004; Title: Surgical Guide Valve, now abandoned.

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

U.S. Appl. No. 10/695,295, filed Oct. 28, 2003; Title: Surgical Gel Seal.

U.S. Appl. No. 11/132,741, filed May 18, 2005; Title: Gas-Tight Seal Accommodating Surgical Instruments With a Wide Range of Diameters.

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

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

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

U.S. Appl. No. 12/108,400, filed Apr. 23, 2008; Title: Wound Retractor Apparatus and Method.

U.S. Appl. No. 12/119,371, filed May 12, 2008; Title: Surgical Retractor With Gel Pad.

U.S. Appl. No. 12/119,414, filed May 12, 2008; Title: Surgical Retractor.

U.S. Appl. No. 12/358,080, filed Jan. 22, 2009; Title: Surgical Instrument Access Device.

U.S. Appl. No. 12/360,634, filed Jan. 27, 2009; Title: Surgical Access Apparatus and Method.

U.S. Appl. No. 12/360,710, filed Jan. 27, 2009; Title: Surgical Access Apparatus and Method.

U.S. Appl. No. 12/578,422, filed Oct. 13, 2009; Title: Single Port Access System.

U.S. Appl. No. 12/905,932, filed Oct. 15, 2010; Title: Split Hoop Wound Retractor.

U.S. Appl. No. 12/960,449, filed Dec. 3, 2010; Title: Surgical Access Apparatus and Method.

U.S. Appl. No. 12/960,458, filed Dec. 3, 2010; Title: Surgical Access Apparatus and Method.

U.S. Appl. No. 13/006,727, filed Jan. 14, 2011; Title: Hand Access Laparoscopic Device.

U.S. Appl. No. 13/008,728, filed Jan. 18, 2011; Title: Wound Retractor With Gel Cap.

U.S. Appl. No. 13/023,334, filed Feb. 8, 2011; Title: Circular Surgical Retractor.

U.S. Appl. No. 13/031,892, filed Feb. 22, 2011; Title: Wound Retractor.

U.S. Appl. No. 13/050,042, filed Mar. 17, 2011; Title: Split Hoop Wound Retractor With Gel Pad.

U.S. Appl. No. 10/446,365, filed May 28, 2003; Title: Screw-Type Seal With Inflatable Membrane.

U.S. Appl. No. 12/004,439, filed Dec. 20, 2007; Title: Skin Seal.

U.S. Appl. No. 12/004,441, filed Dec. 20, 2007; Title: Screw-Type Skin Seal With Inflatable Membrane.

U.S. Appl. No. 12/607,667, filed Oct. 28, 2009; Title: Screw-Type Skin Seal With Inflatable Membrane.

U.S. Appl. No. 10/965,217, filed Oct. 15, 2004; Title: Surgical Sealing Device.

U.S. Appl. No. 10/981,730, filed Nov. 5, 2004; Title: Surgical Sealing Device.

U.S. Appl. No. 11/246,909, filed Oct. 11, 2005; Title: Instrument Access Device.

U.S. Appl. No. 11/291,089, filed Dec. 1, 2005; Title: A Surgical Sealing Device.

U.S. Appl. No. 11/486,383, filed Jul. 14, 2006; Title: Wound Retractor.

U.S. Appl. No. 11/785,752, filed Apr. 19, 2007; Title: Instrument Access Device.

U.S. Appl. No. 12/244,024, filed Oct. 2, 2008; Title: Seal Anchor for Use in Surgical Procedures.

U.S. Appl. No. 12/578,832, filed Oct. 14, 2009; Title: Flexible Access Device for Use in Surgical Procedure.

U.S. Appl. No. 12/706,043, filed Feb. 16, 2010; Title: Flexible Port Seal.

U.S. Appl. No. 12/719,341, filed Mar. 8, 2010; Title: Foam Port and Introducer Assembly.

U.S. Appl. No. 10/895,546, filed Jul. 21, 2004; Title: Laparoscopic Instrument and Cannula Assembly and Related Surgical Method.

U.S. Appl. No. 10/913,565, filed Aug. 5, 2004; Title: Surgical Device With Tack-Free Gel and Method of Manufacture.
Dexterity Protractor Instruction Manual by Dexterity Surgical, Inc., dated 1999.

European Patent Office, European Search Report for European Application No. EP 10 18 4681, entitled "Wound Retraction Apparatus and Method", dated Nov. 22, 2010.

European Patent Office, European Search Report for European Application No. EP 10 18 4608, entitled "Wound Retraction Apparatus and Method", dated Nov. 22, 2010.

European Patent Office, European Search Report for European Application No. EP 10 18 4648, entitled "Wound Retraction Apparatus and Method", dated Nov. 22, 2010.

European Patent Office, European Search Report for European Application No. EP 10 18 4731, entitled "Wound Retraction Apparatus and Method", dated Nov. 22, 2010.

European Patent Office, European Search Report for European Application No. EP 10 18 4661, entitled "Wound Retraction Apparatus and Method", dated Nov. 22, 2010.

European Patent Office, European Search Report for European Application No. EP 10 18 4677, entitled "Wound Retraction Apparatus and Method", dated Nov. 22, 2010.

European Patent Office, European Search Report for European Application No. EP 10 18 9325, entitled "Split Hoop Wound Retractor", dated Dec. 14, 2010.

European Patent Office, European Search Report for European Application No. EP 10 18 9327, entitled "Split Hoop Wound Retractor", dated Dec. 14, 2010.

(56)

References Cited

OTHER PUBLICATIONS

European Patent Office, European Search Report for European Application No. EP 10 18 9328, entitled "Split Hoop Wound Retractor", dated Dec. 15, 2010.

European Patent Office, European Search Report for European Application No. EP 04 00 2888, entitled "Hand Access Port Device", dated Sep. 10, 2004.

European Patent Office, European Search Report for European Application No. EP 04 00 2889, entitled "Hand Access Port Device", dated Sep. 13, 2004.

European Patent Office, International Search Report and the Written Opinion of the International Searching Authority for International Application No. PCT/US2006/040154, mailed Jan. 30, 2007.

European Patent Office, International Search Report and the Written Opinion of the International Searching Authority for International Application No. PCT/US2006/040073, mailed Jan. 26, 2007.

European Patent Office, International Search Report and the Written Opinion of the International Searching Authority for International Application No. PCT/US2006/039905, mailed Jan. 17, 2007.

European Patent Office, International Search Report and the Written Opinion of the International Searching Authority for International Application No. PCT/US2006/039883, mailed Jan. 31, 2007.

European Patent Office, International Search Report and the Written Opinion of the International Searching Authority for International Application No. PCT/US2006/039800, mailed Apr. 16, 2007.

European Patent Office, International Search Report and the Written Opinion of the International Searching Authority for International Application No. PCT/US2006/039799, mailed Mar. 27, 2007.

European Patent Office, European Search Report for European Application No. EP 08253236 dated Feb. 10, 2009.

Horigame, 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.

Horigame, et al., Technical Note: Development of Duodenoal Cannula for Sheep, *Journal of Animal Science*, Apr. 1992, vol. 70, Issue 4, pp. 1216-1219.

International Searching Authority/US, International Search Report and the Written Opinion of the International Searching Authority for International Application No. PCT/US04/05484, mailed on Nov. 12, 2004.

International Searching Authority/US, International Search Report and the Written Opinion of the International Searching Authority for International Application No. PCT/US01/29682, mailed on Jun. 14, 2002.

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

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

Office Action in co-pending U.S. Appl. No. 12/360,634, dated Jan. 24, 2011 in 12 pages.

Office Action in co-pending U.S. Appl. No. 12/360,710, dated Jan. 24, 2011 in 12 pages.

Technical Note: Development of Duodenal Cannula for Sheep, Faculty of Agriculture and School of Medicine Tohoku University, Sendai 981, Japan, dated 1992.

The International Bureau of WIPO, International Preliminary Report on Patentability for International Application No. PCT/US2004/028250, dated Aug. 29, 2006.

The International Bureau of WIPO, International Preliminary Report on Patentability for International Application No. PCT/US2006/039799, dated Apr. 16, 2008.

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

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.

Kagaya, "Laparoscopic cholecystectomy via two ports, using the Twin-Port" system, *J. Hepatobiliary Pancreat Surg* (2001) 8:76-80, dated Feb. 20, 2001.

Declaration of John R. Brustad dated Dec. 10, 2009, submitted in U.S. Appl. No. 11/548,955, including Appendices A-D regarding product sales brochures and production drawings from 2001 and 2005.

International Search Report and Written Opinion for PCT/IE2005/000113, mailed on Feb. 22, 2006.

International Searching Authority-US, International Search Report and Written Opinion of the International Searching Authority for International Application No. PCT/US04/25511, mailed Nov. 7, 2007.

International Bureau of WIPO, International Report on Patentability for International Application No. PCT/US04/25511, mailed Dec. 6, 2007.

International Search Report and Written Opinion for PCT/IE2007/000050 mailed on Aug. 13, 2007.

The International Searching Authority, The International Search Report and Written Opinion of the International Searching Authority for International Application No. PCT/US08/63445, mailed Sep. 29, 2008.

The International Searching Authority, The International Search Report and Written Opinion of the International Searching Authority for International Application No. PCT/US08/63463 mailed Sep. 10, 2008.

The International Bureau of WIPO, International Preliminary Report on Patentability for International Application No. PCT/US2008/063463, entitled "Surgical Retractor", dated Nov. 17, 2009.

The International Bureau of WIPO, International Preliminary Report on Patentability for International Application No. PCT/US08/63445, entitled "Surgical Retractor with Gel Pad", dated Nov. 17, 2009.

International Searching Authority—European Patent Office, The International Search Report and Written Opinion for International Application No. PCT/US2011/054266, mailed Feb. 9, 2012.

European Patent Office, European Search Report for European Patent No. 11172709.5, dated Aug. 16, 2011.

European Patent Office, European Search Report for European Patent No. 11172706.1, dated Aug. 16, 2011.

European Patent Office, European Search Report for European Patent No. 12151288, dated Feb. 10, 2012.

European Patent Office, European Search Report for European Patent No. 08755332, dated Apr. 18, 2012.

European Patent Office, Supplementary European Search Report for European Patent Application No. 08755322, dated Apr. 18, 2012.

European Patent Office, Supplementary European Search Report for European Patent Application No. 08755336, dated Jun. 15, 2012.

Harold W. Harrower, M.D., Isolation of Incisions into Body Cavities, *The American Journal of Surgery*, vol. 116, pp. 824-826, Dec. 1968.

International Searching Authority—European Patent Office, The International Search Report and Written Opinion for International Application No. PCT/US2013/037213, mailed Jul. 3, 2013.

* cited by examiner

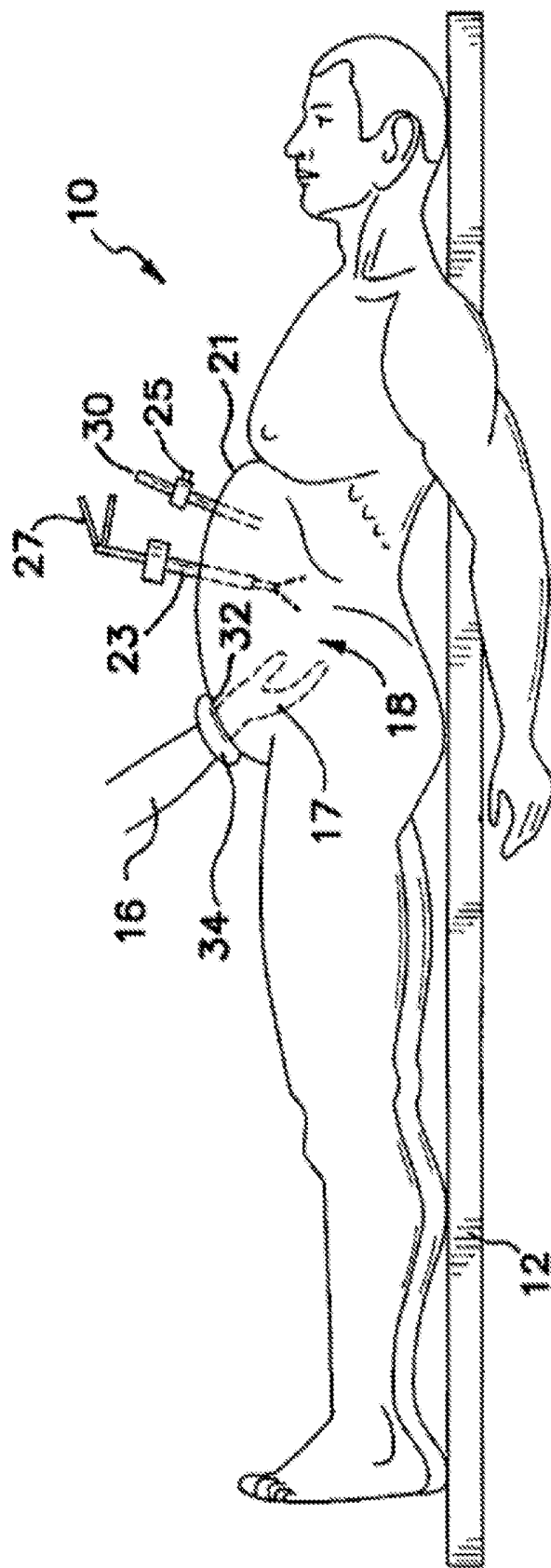
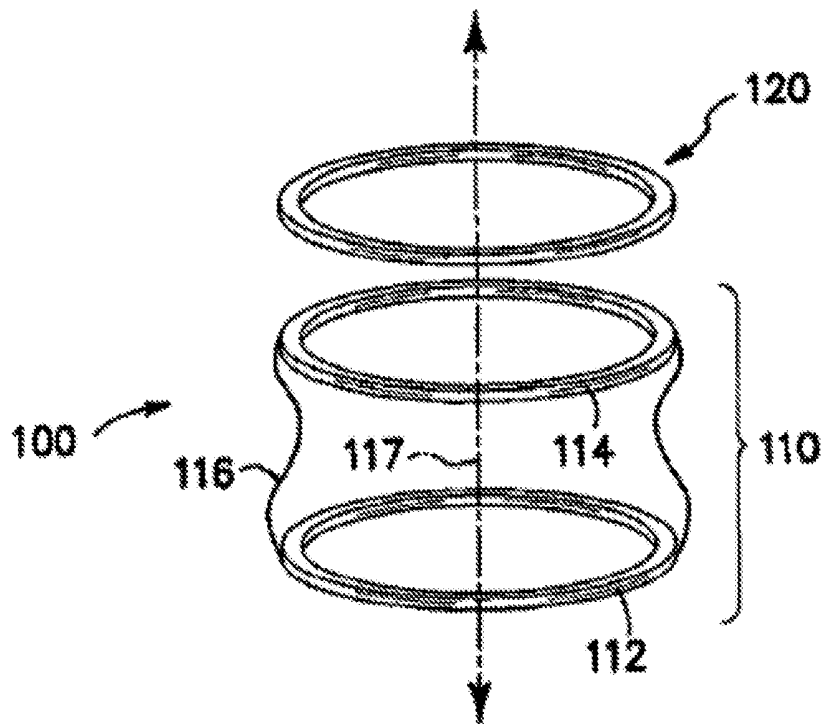
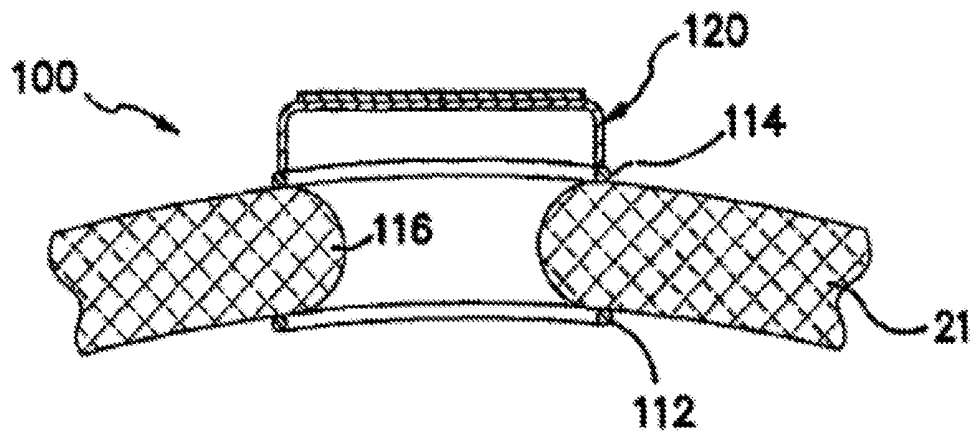


FIG. 1

**FIG. 2A****FIG. 2B**

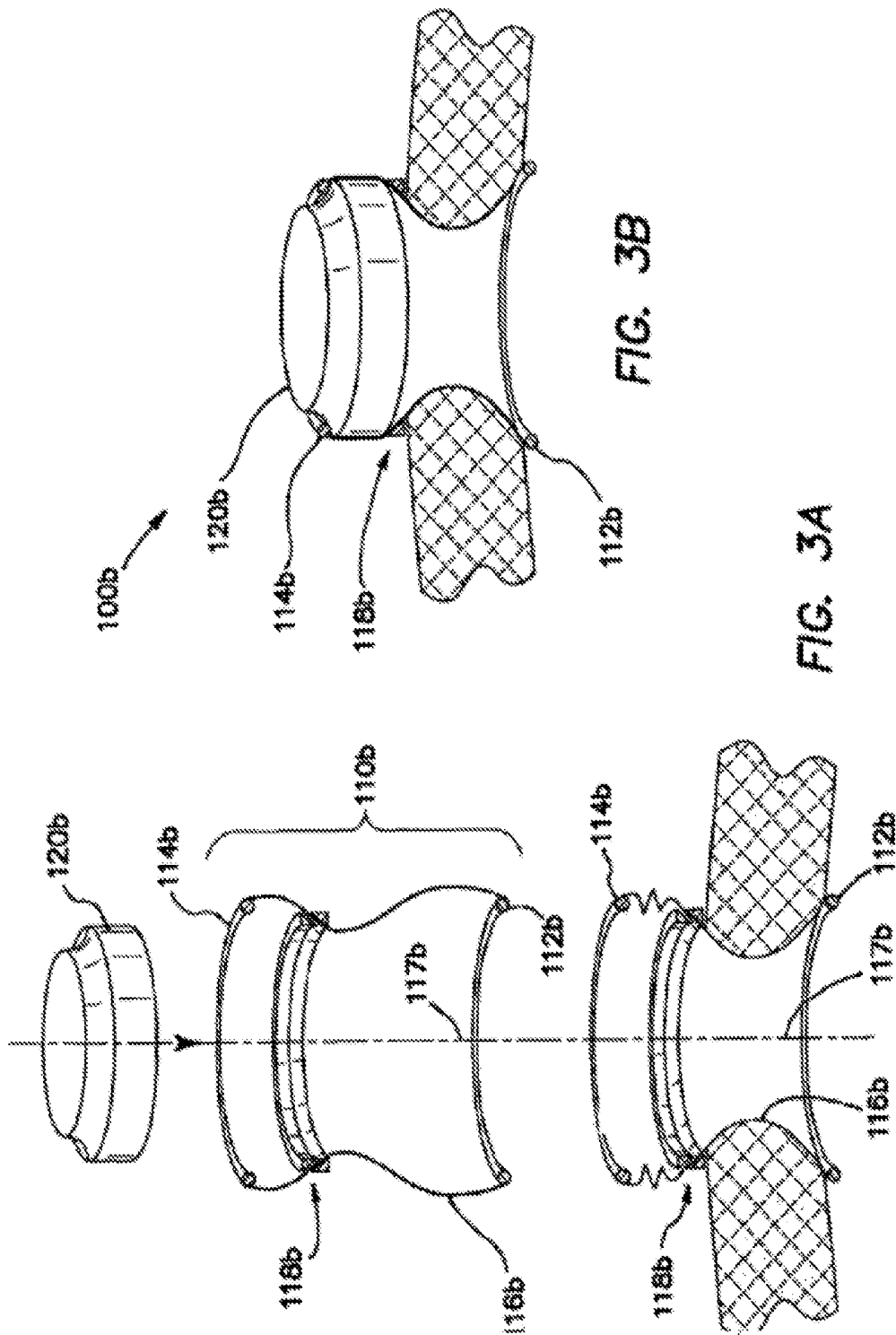


FIG. 3B

FIG. 3A

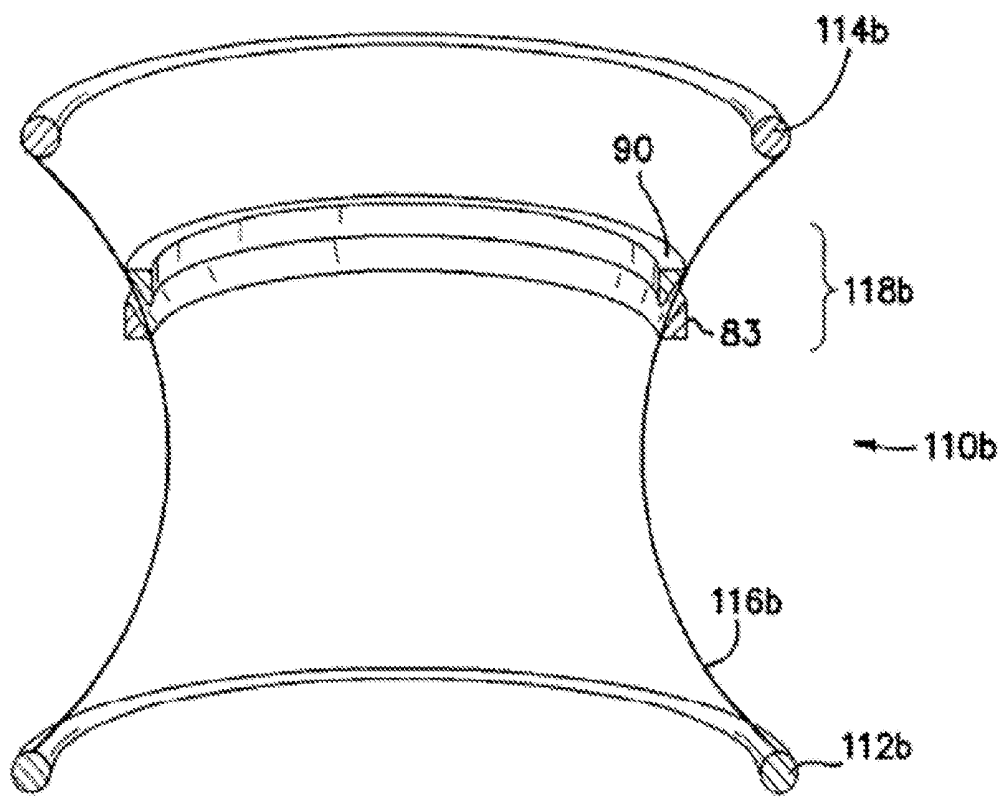


FIG. 3C

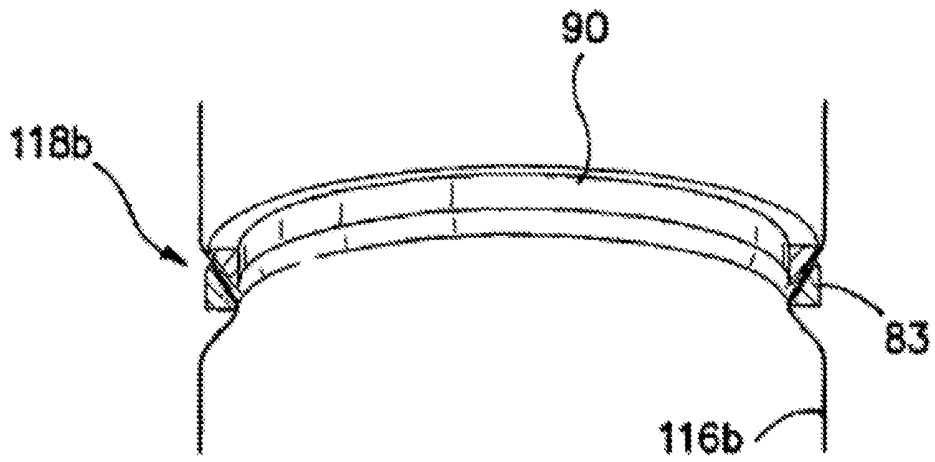


FIG. 3D

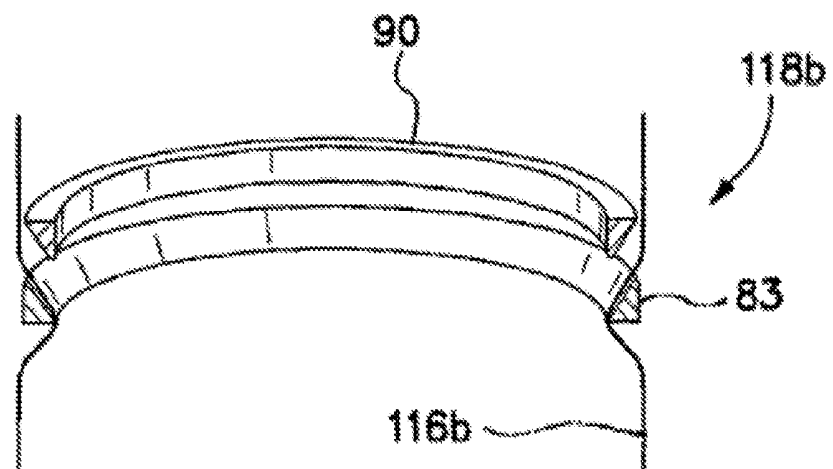


FIG. 3E

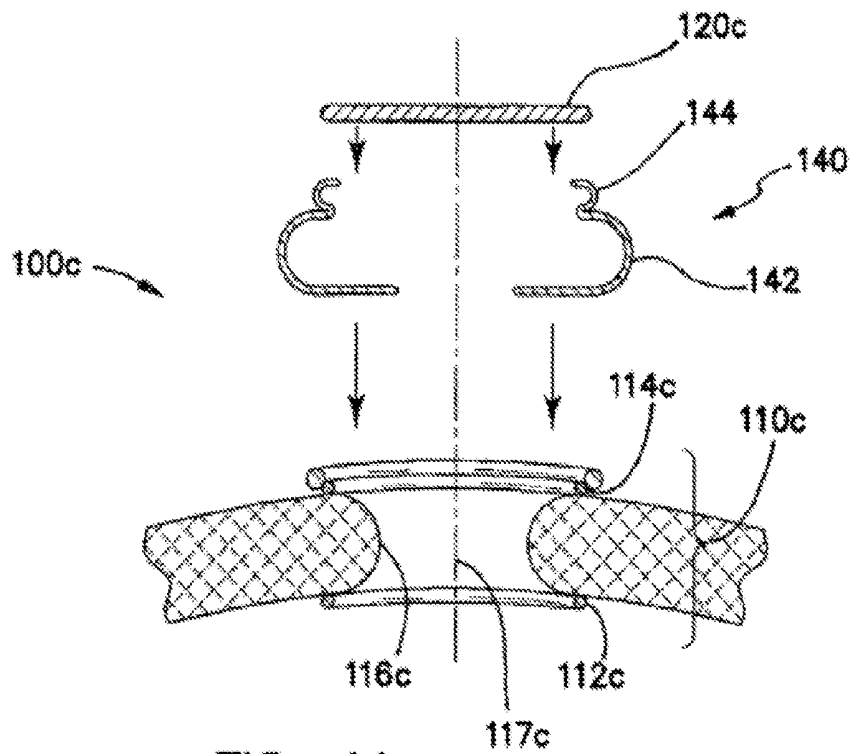


FIG. 4A

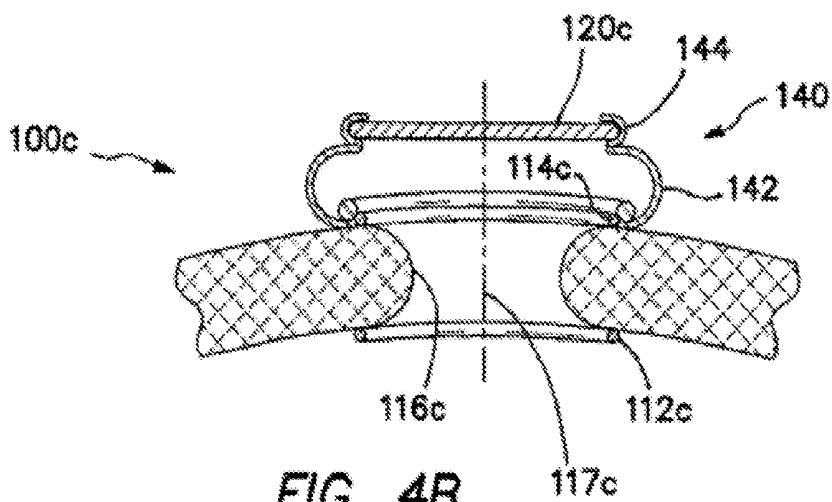
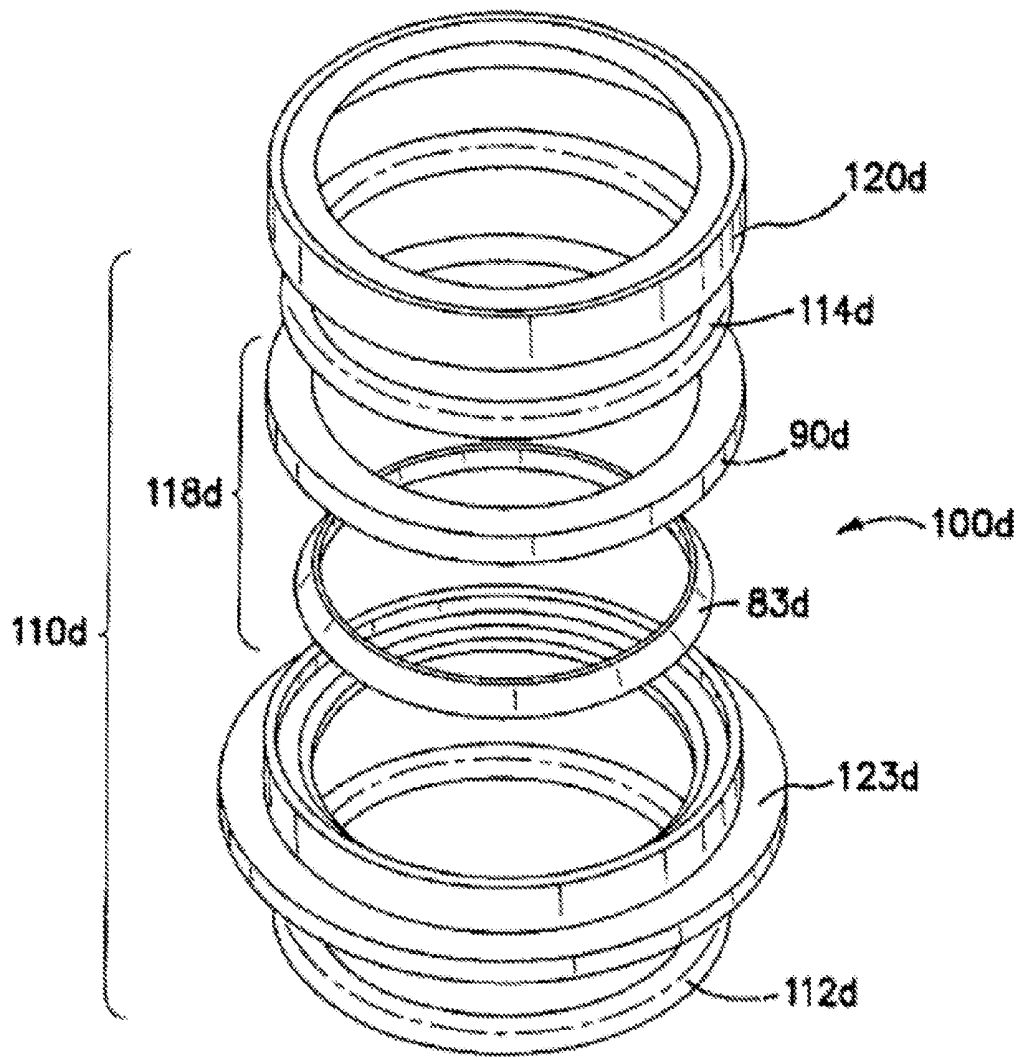
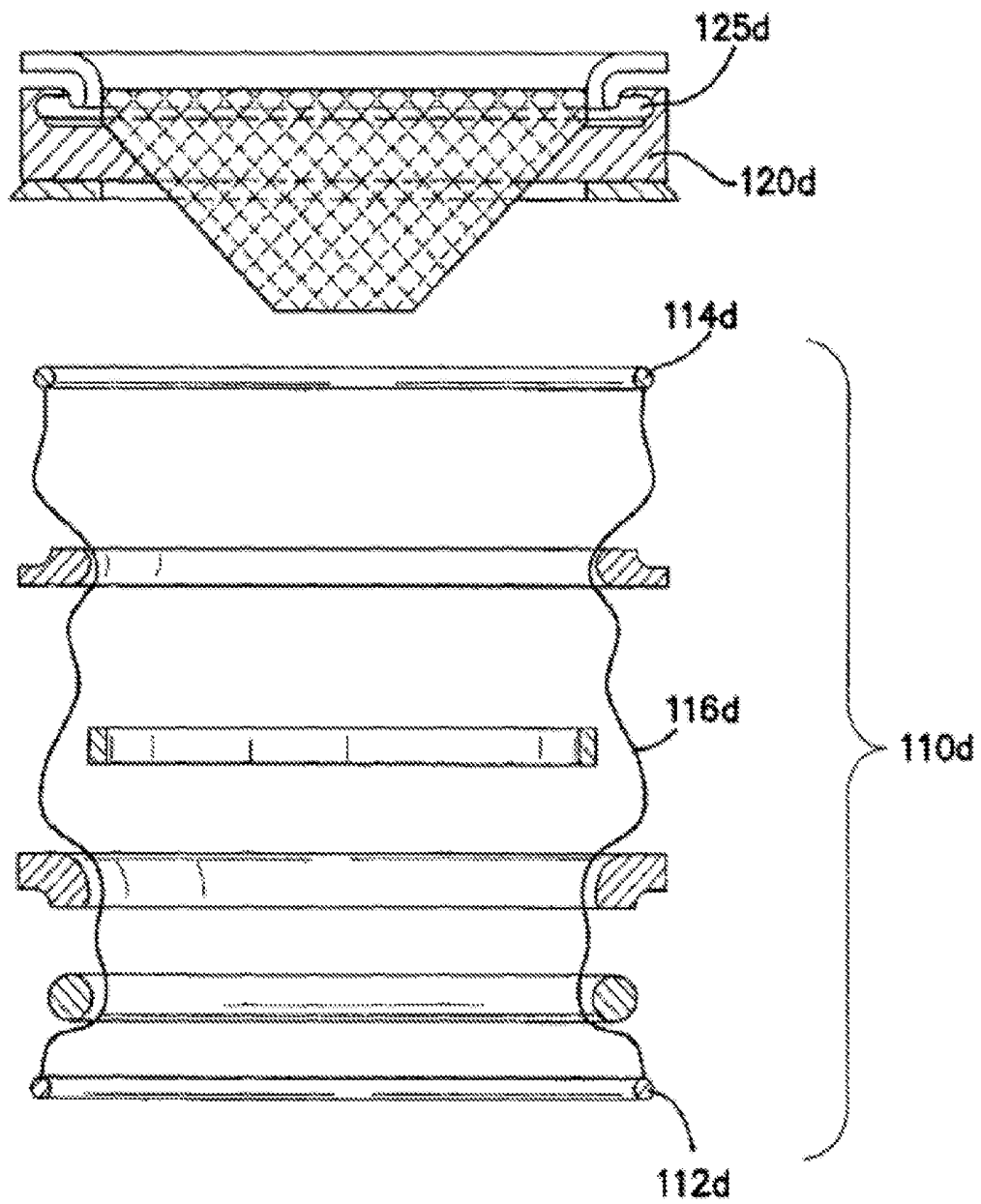


FIG. 4B

**FIG. 5A**

**FIG. 5B**

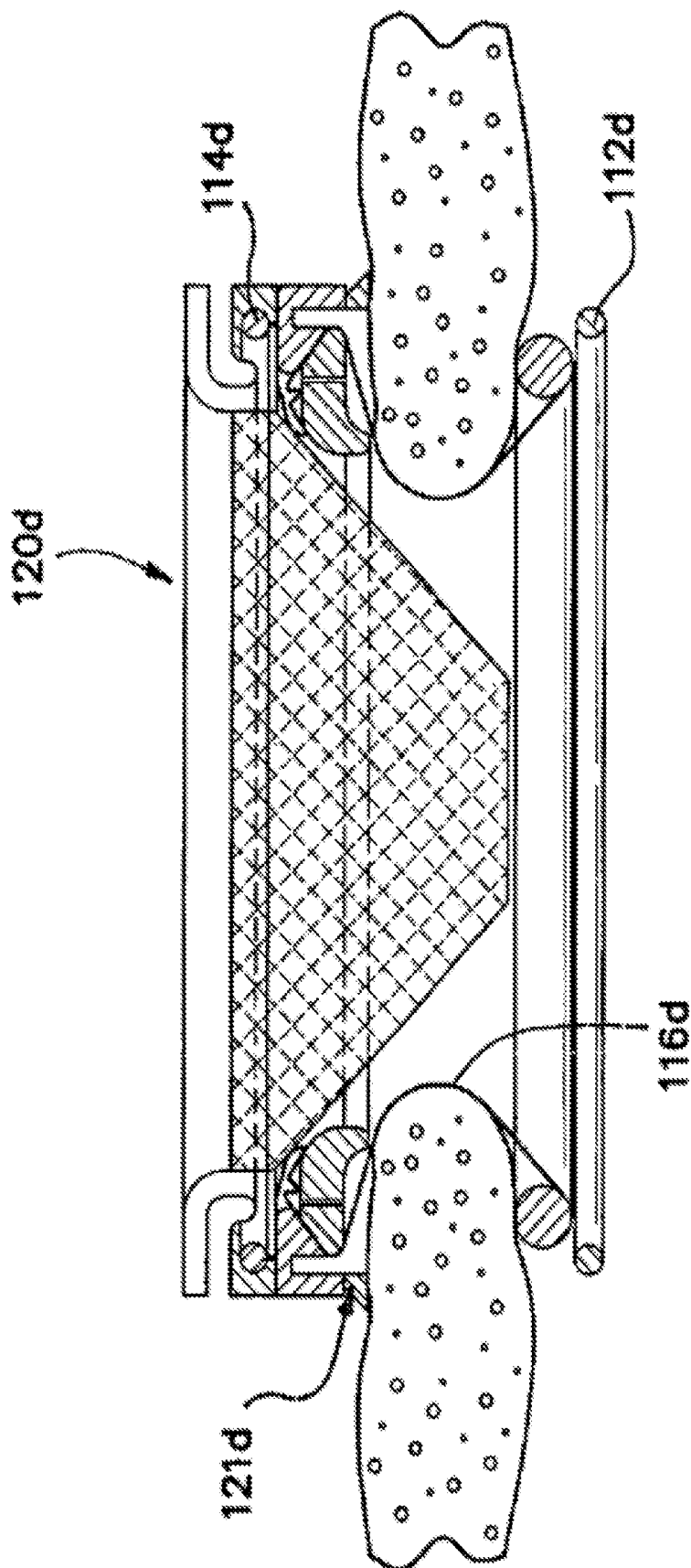


FIG. 5C

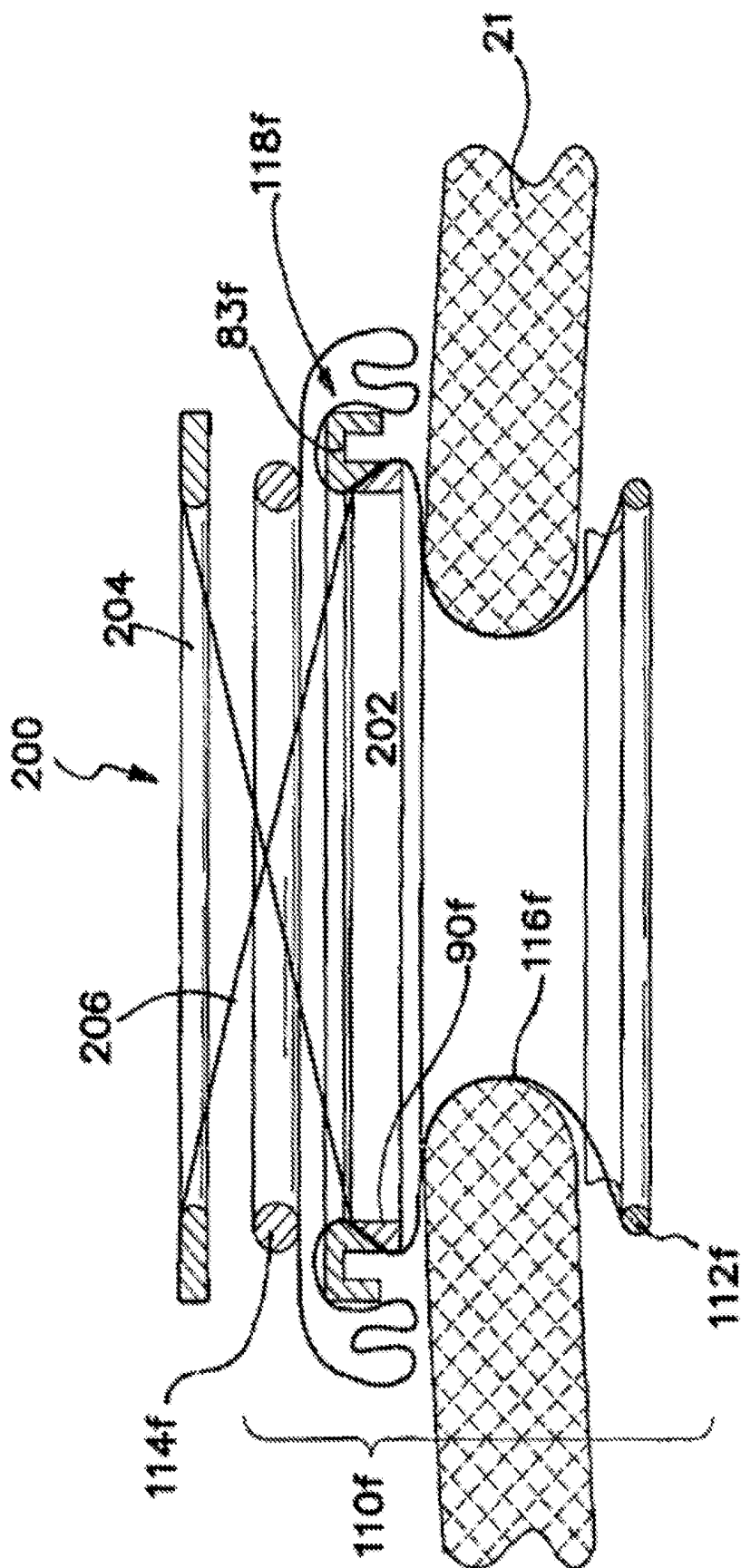
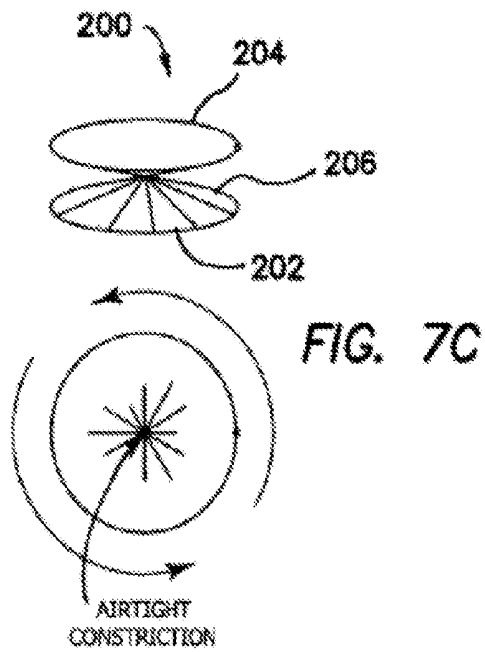
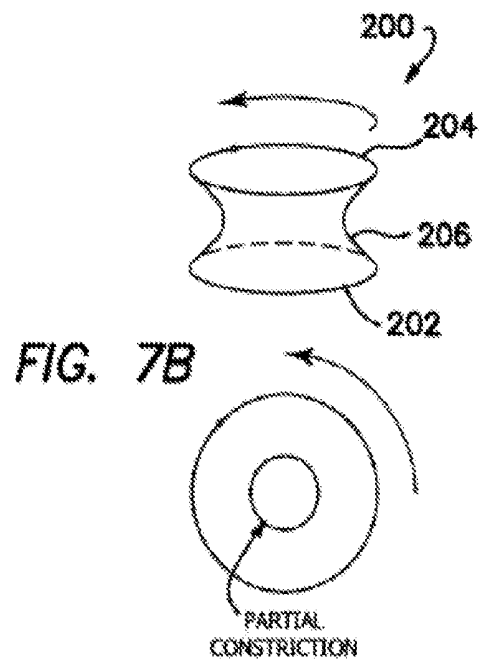
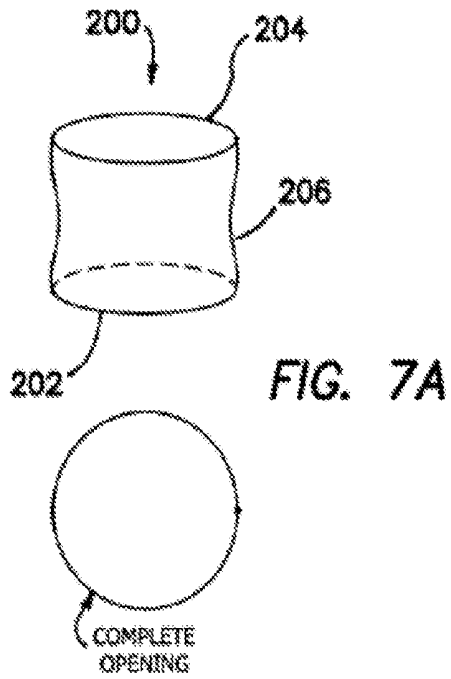
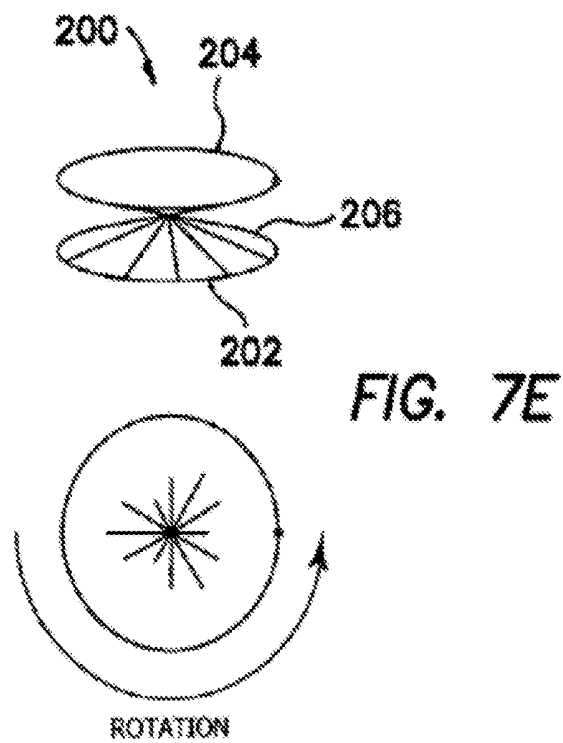
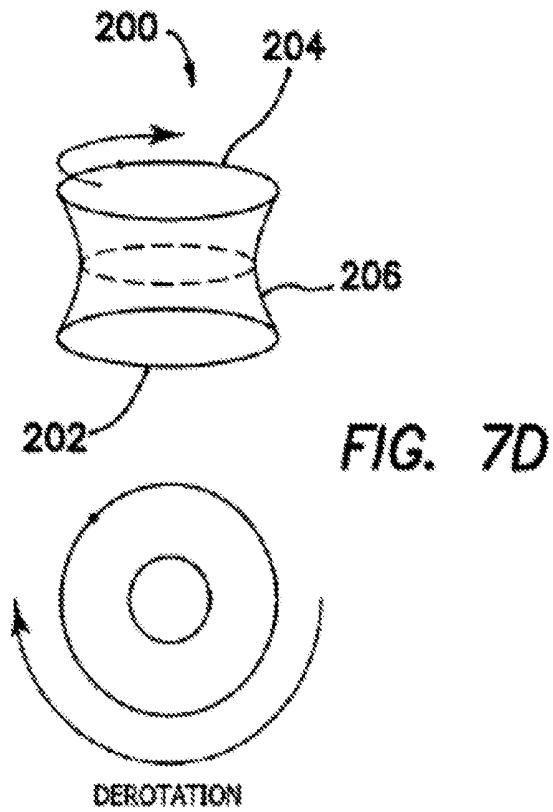
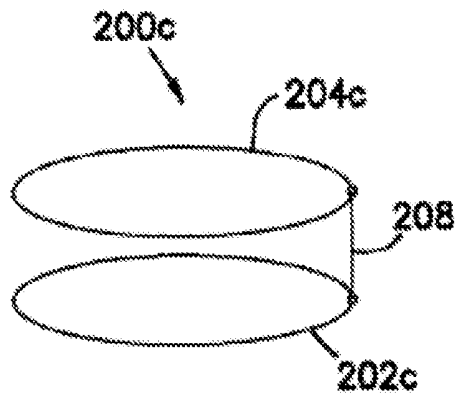
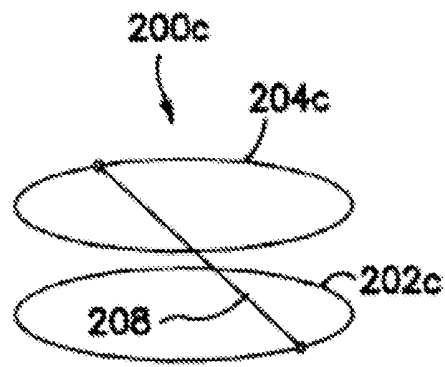
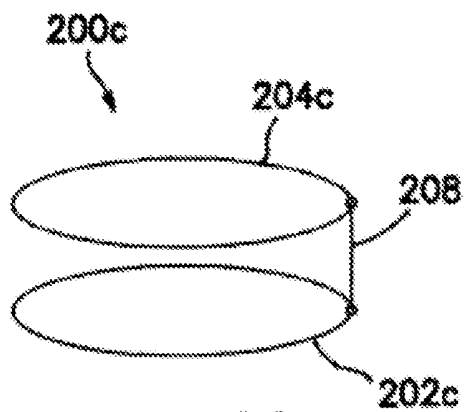
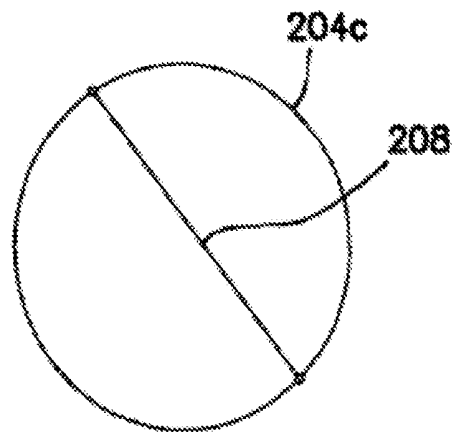
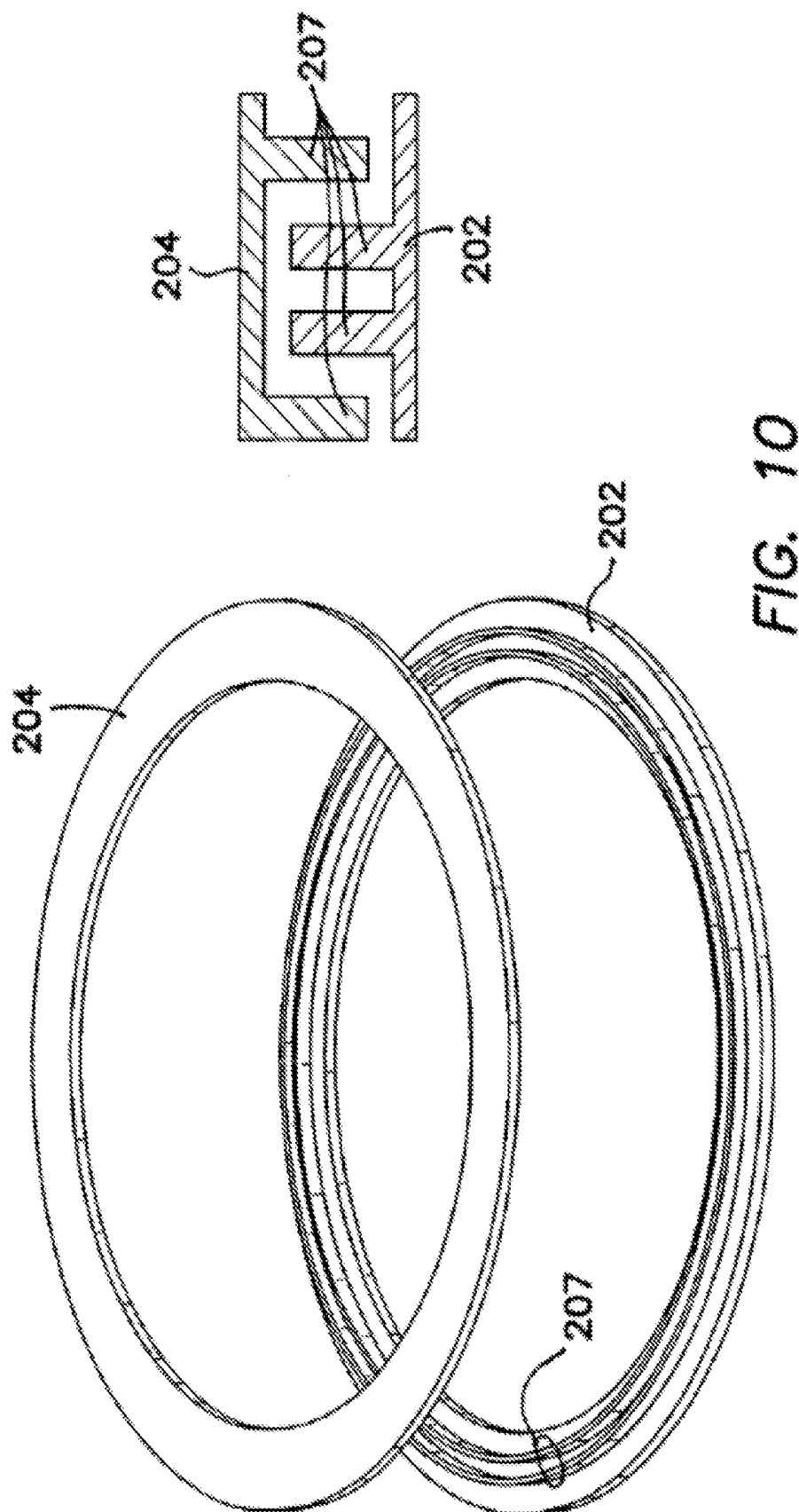


FIG. 6





**FIG. 8A****FIG. 8B****FIG. 8C****FIG. 9**



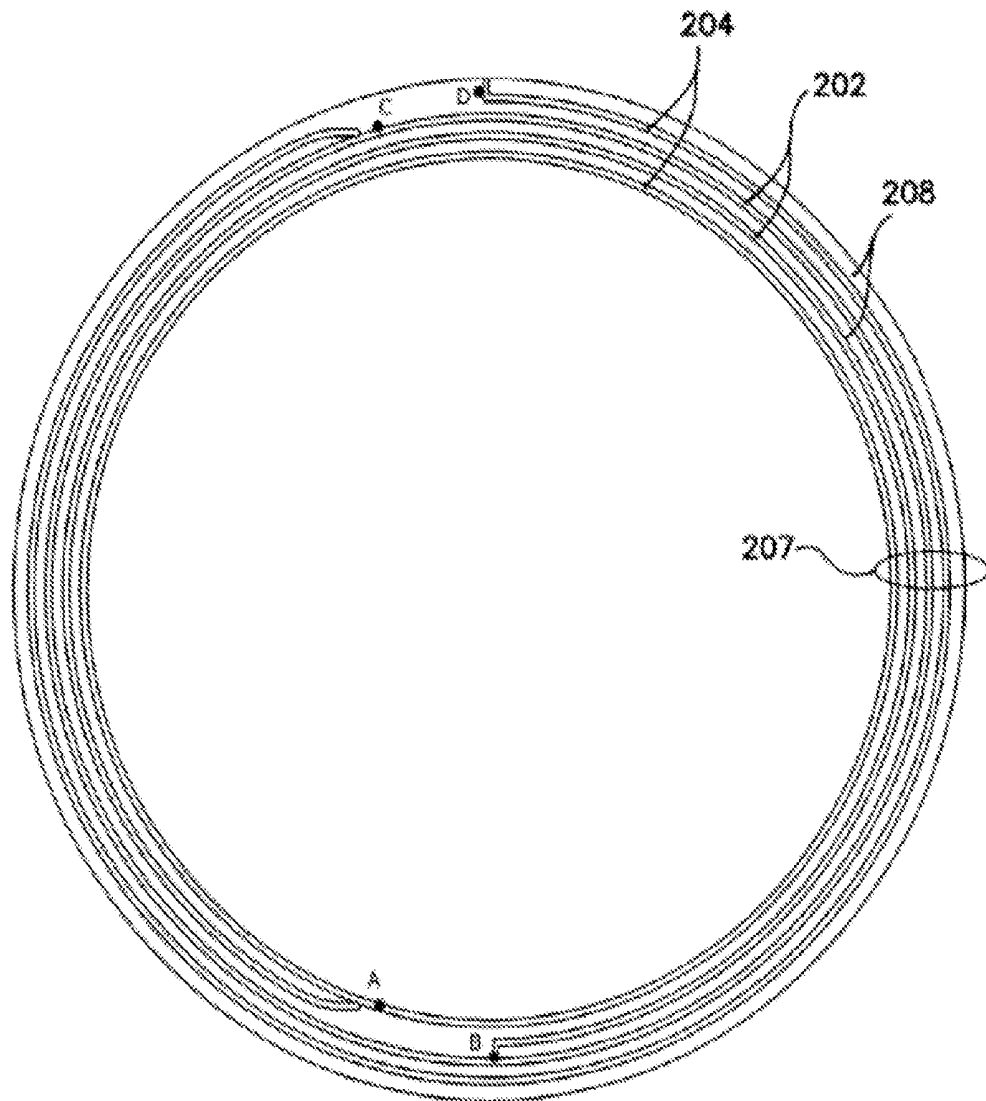


FIG. 11A

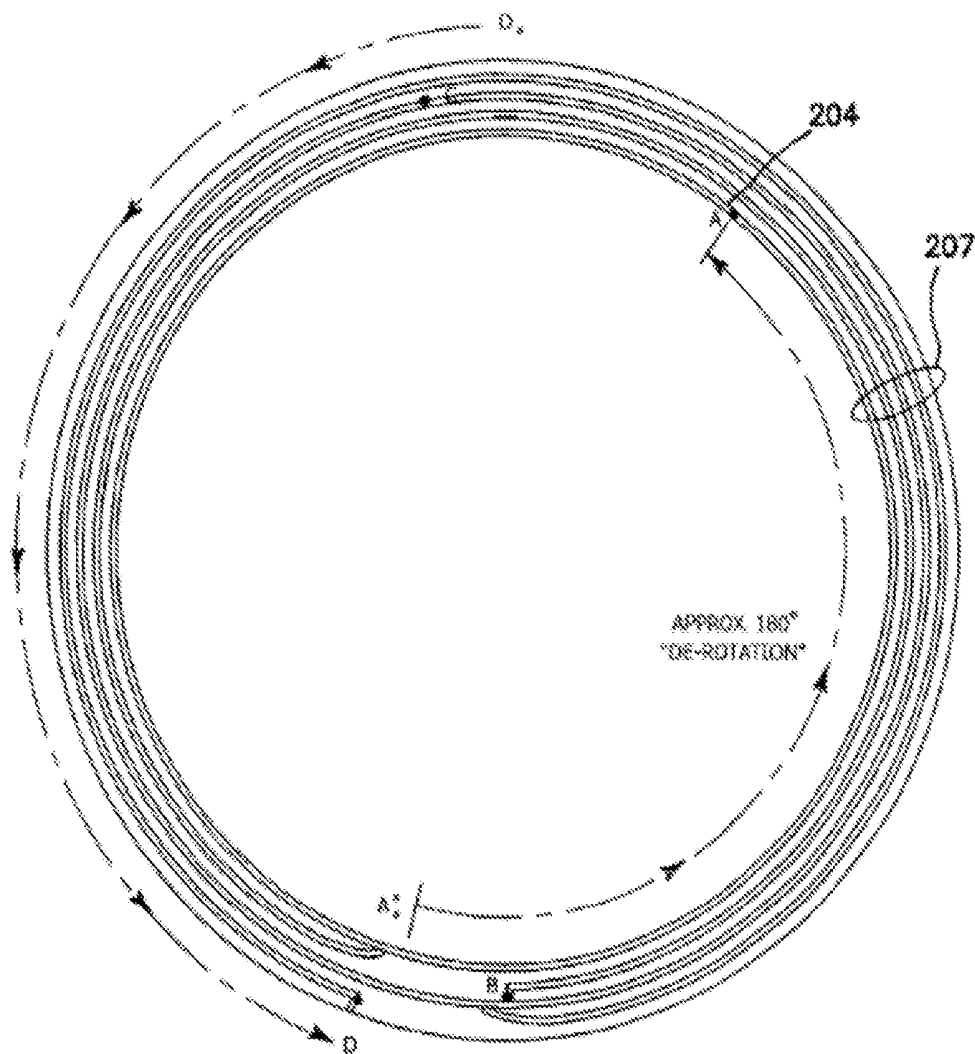


FIG. 11B

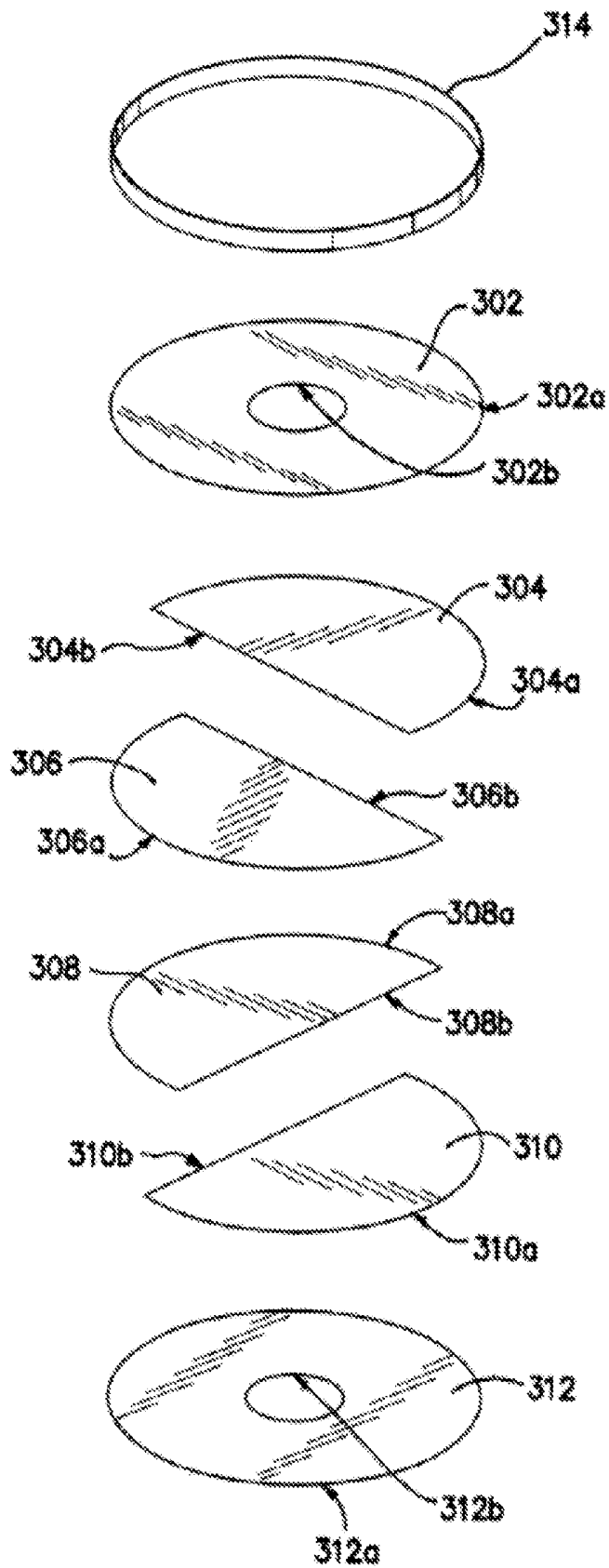
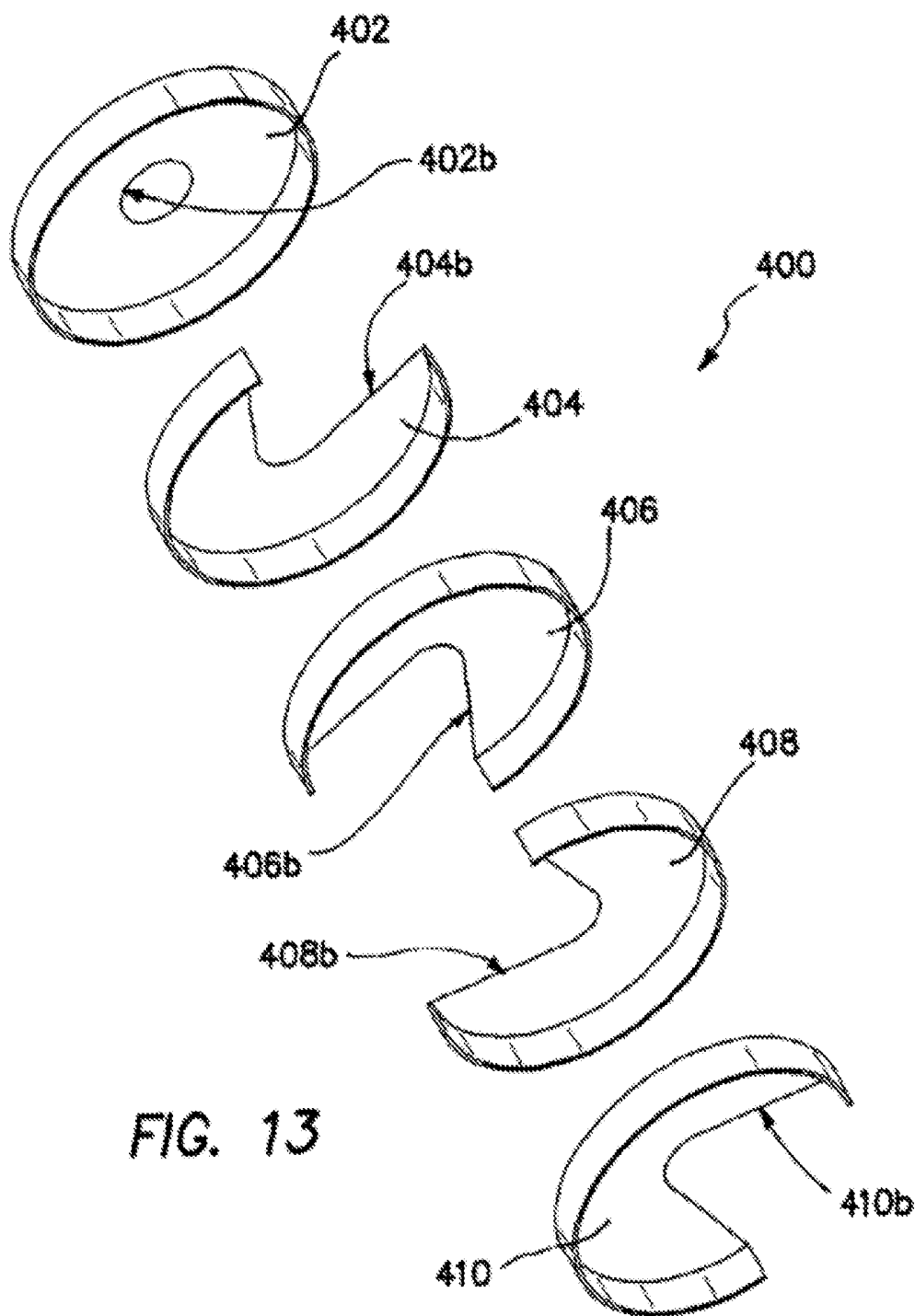


FIG. 12



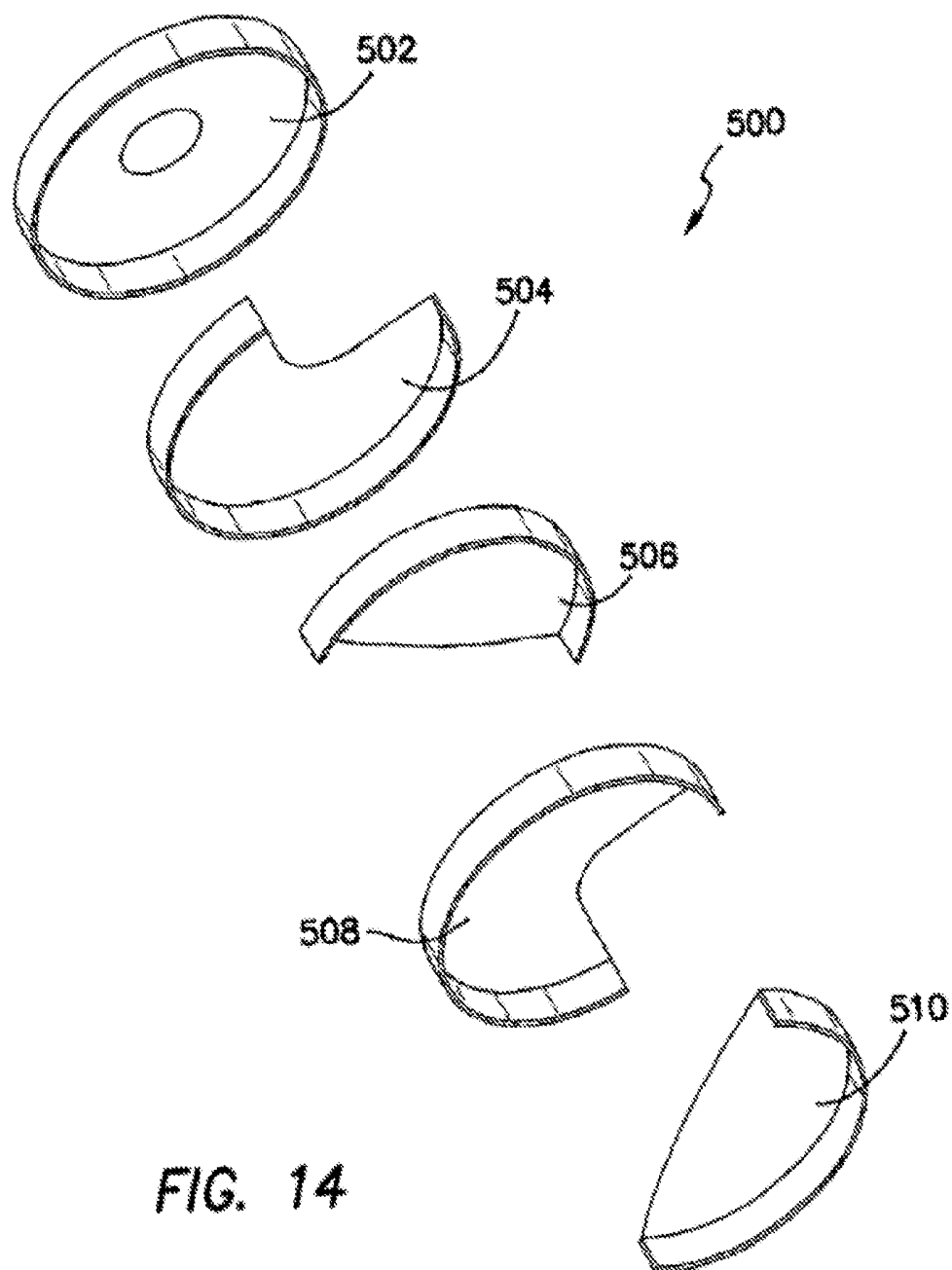
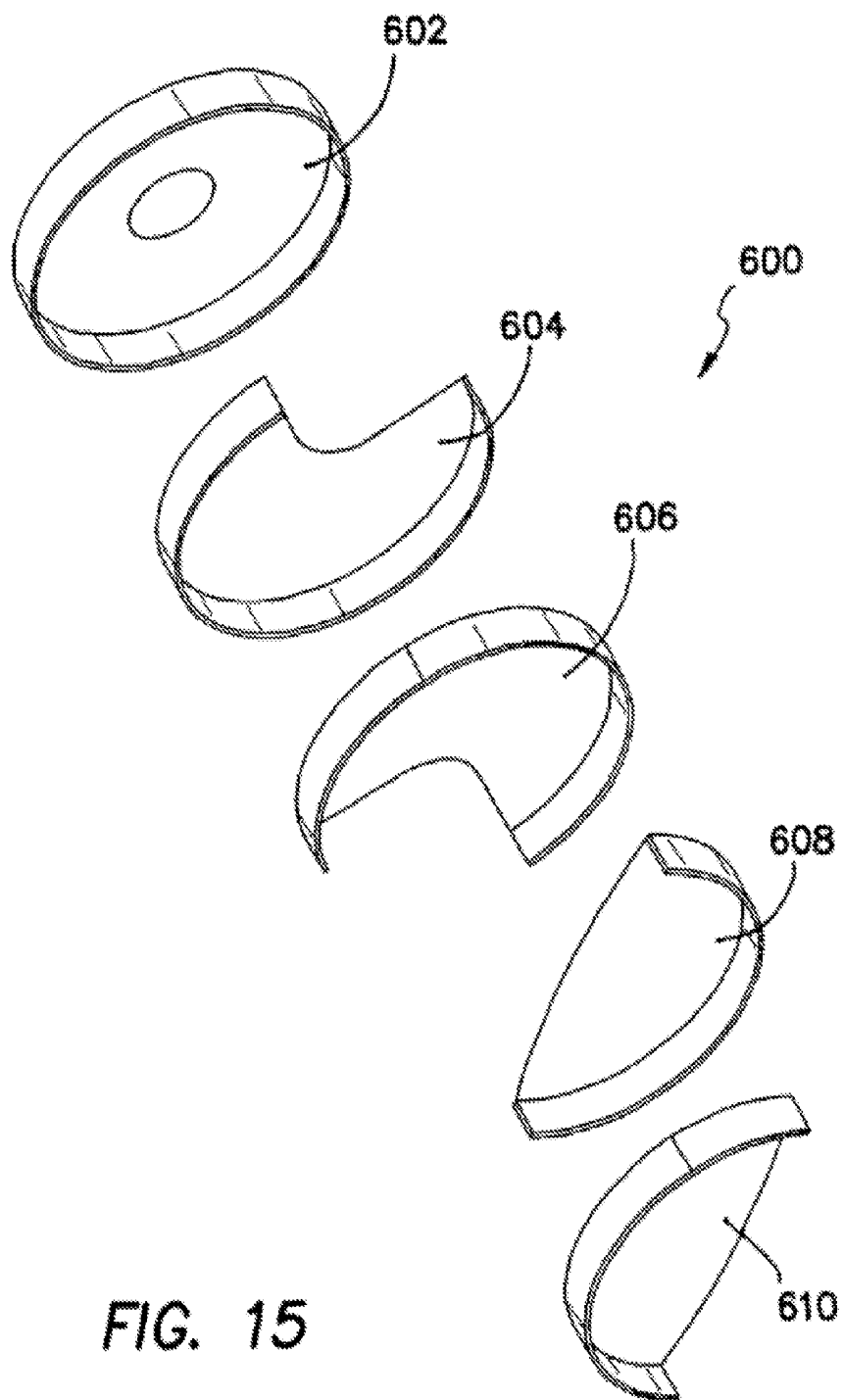
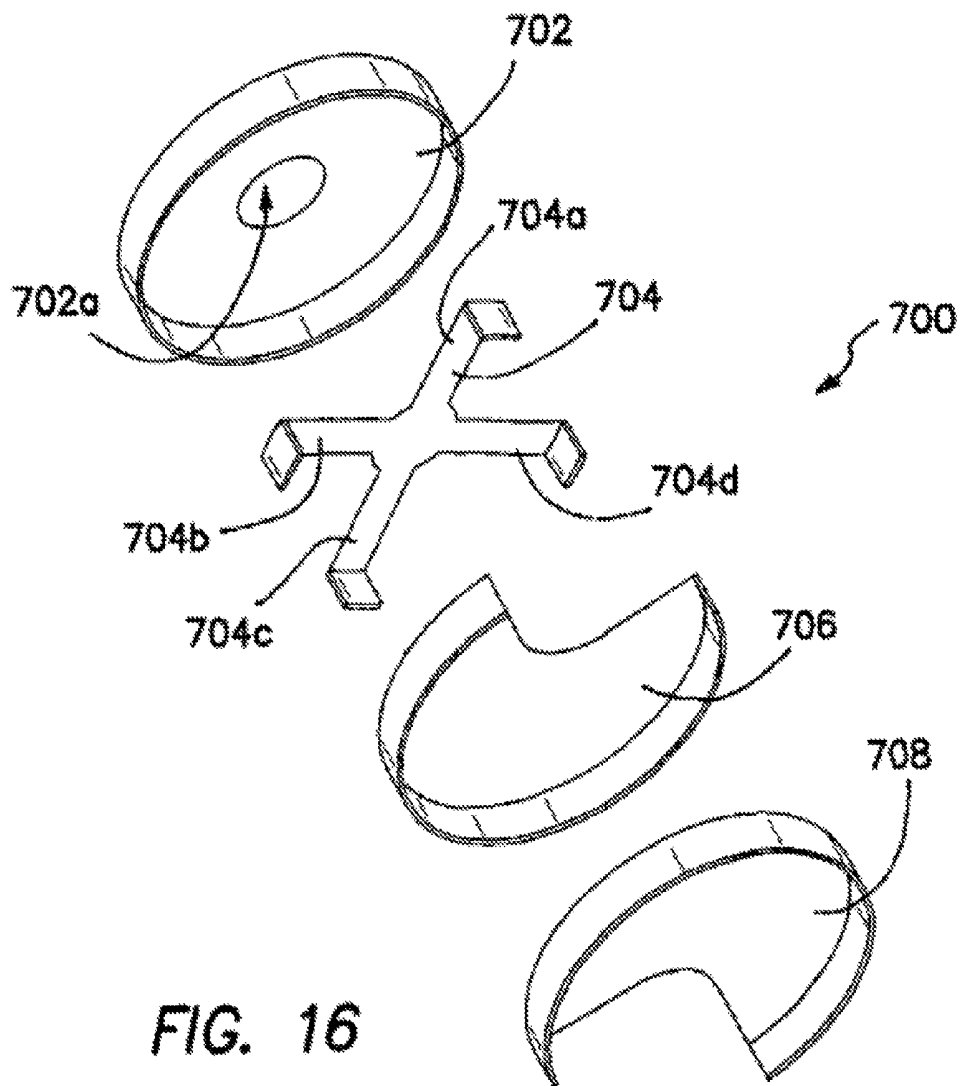
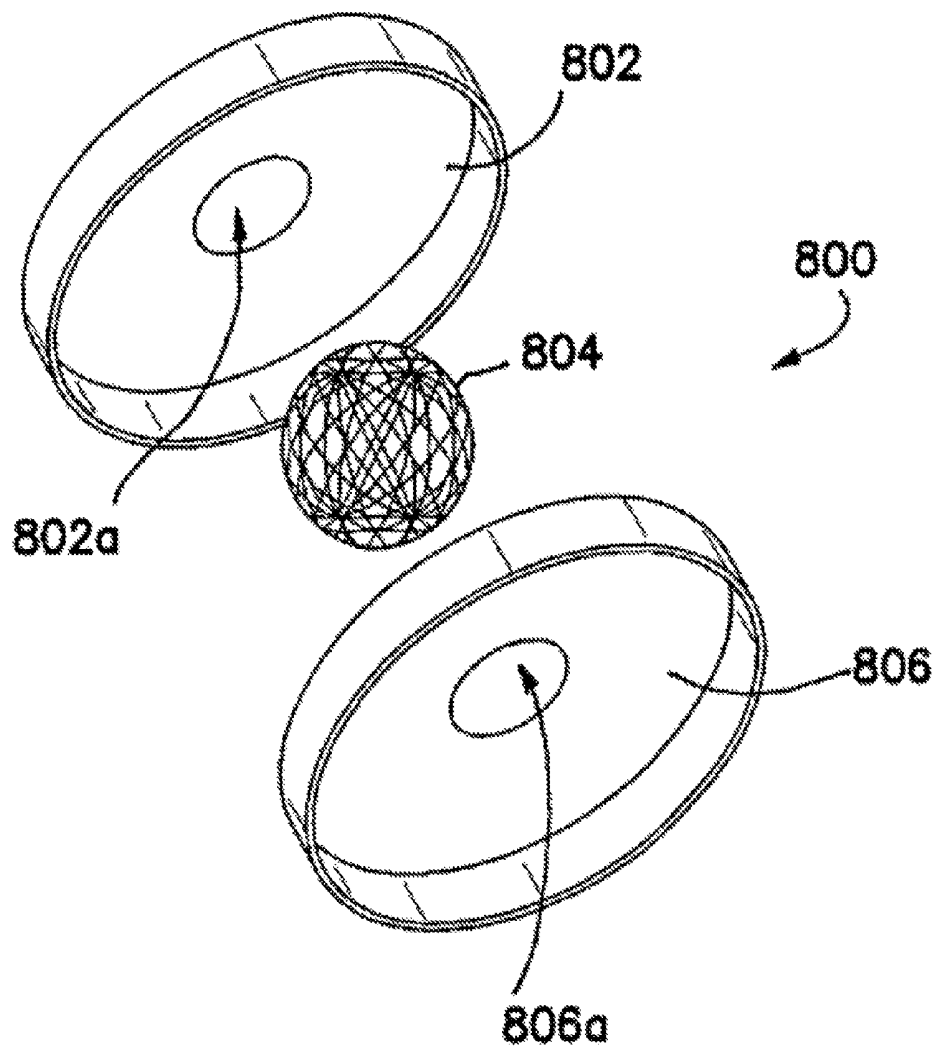


FIG. 14





**FIG. 17**

SURGICAL ACCESS SYSTEM

CROSS-REFERENCE TO RELATED APPLICATIONS

This is a continuation of U.S. patent application Ser. No. 13/105,179, filed May 11, 2011, which is a continuation of U.S. patent application Ser. No. 11/245,709, filed Oct. 7, 2005, now U.S. Pat. No. 7,951,076, which is a continuation of U.S. patent application Ser. No. 10/927,551, filed Aug. 25, 2004, which is a continuation of (1) PCT application Serial No. PCT/US2004/005484, entitled "Sealed Surgical Access Device," filed on Feb. 25, 2004, (2) PCT application Serial No. PCT/US2004/005487, entitled "Wound Retractor for Use in Hand-Assisted Laparoscopic Surgery," filed on Feb. 25, 2004, and (3) PCT application Serial No. PCT/US2004/005361, entitled "Apparatus and Method for Illuminating a Peritoneal Cavity During Laparoscopic Surgery," filed on Feb. 24, 2004, all of which claim priority to (4) provisional application Ser. No. 60/449,857, filed on Feb. 25, 2003, entitled "Hand-Assisted Laparoscopy Apparatus and Method," all of which are fully incorporated herein by reference in their entireties.

BACKGROUND

This invention generally relates to surgical access systems that facilitate sealed access across a body wall and into a body cavity during a laparoscopic surgical procedure.

During laparoscopic surgery, it is desirable to inflate the abdominal cavity in order to increase the volume of the working space. This is accomplished with an insufflation gas which must be maintained at a pressure sufficient to inflate the abdomen. Maintaining the pressure of the insufflation gas is difficult when it is also desirable to insert instrumentation through the abdominal wall. If a surgeon is interested in inserting his or her hand in a hand-assisted laparoscopic procedure, the maintenance of insufflation pressure is even more difficult. Currently, several devices exist that accomplish this surgical need although they suffer from drawbacks such as difficult placement and cumbersome use. For example, these hand-assisted devices require elaborate mechanisms such as inflatable cuffs and adhesives to seal around a surgeon's wrist or forearm to maintain the insufflation gases. As such, there is a need for a special seal formed around the wrist or forearm of a surgeon to prevent the escape of insufflation gases. Moreover, it is desirable that the wound be retracted, protected and fixed while maintaining the insufflation seal.

SUMMARY

The invention is directed to a hand access system that provides hand access to a surgical area while maintaining pneumoperitoneum during laparoscopic surgery. The hand access system comprises a sheath retractor adapted to dilate a wound stretchable to a desired diameter, the sheath retractor includes a first ring being adapted for disposition interiorly of the wound, a second ring being adapted for disposition exteriorly of the wound, and a sheath being disposed in a generally cylindrical form between the first ring and the second ring and operable to exert a radial retraction force on the wound. The hand access system further comprises a detachable hand seal adapted to be attached and detached from the second ring of the sheath retractor. In particular, the hand seal can be detached from the sheath retractor to convert the hand access system from laparoscopic surgery to open surgery. In one aspect, the first ring, second ring and sheath are formed from

an elastomeric material, and the hand seal is formed of a gel material and includes a slit providing an instrument seal in the presence of an instrument or hand and a zero seal in the absence of the instrument or hand. The gel material includes, for example, a thermoplastic base such as Kraton® and an oil. The resulting elastomer has excellent tear strength, elongation greater than 1,000 percent, a very low durometer or hardness, and biocompatibility. It is appreciated that the first ring has a first diameter and the second ring has a second diameter, and the first and second diameters are greater than the desired diameter of the wound.

In another aspect, the sheath retractor further comprises a third ring disposed circumferentially of the sheath and moveable between a plurality of positions between the first ring and the second ring, each of the positions being associated with a different retraction force, the third ring being adapted for disposition exteriorly of the wound. The sheath retractor may further comprise means for retaining the third ring at one of the plurality of positions in order to provide the desired radial retraction force associated with that position. The retaining means may comprise a fourth ring adapted to interlock with the third ring to fix the sheath at the desired position. The retaining means may include a wedge disposed between the third ring and the fourth ring.

In yet another aspect of the invention, the hand access system may further comprise an adapter having a first adapter cavity for releasably attaching to a ring of the retractor sheath and a second adapter cavity for releasably attaching to the hand seal. The first adapter cavity has a first diameter and the second adapter cavity has a second diameter.

In other aspects of the invention, the hand seal may include a cavity to receive the second ring of the sheath retractor, the hand seal may further comprise a latch on an inner diameter for latching the third ring, and the third ring may comprise at least a hook to latch the hand seal as the hand seal is attached to the sheath retractor. To facilitate sealing of the peritoneum, a conformable gasket may be provided that may be attached to the first ring or to the sheath of the sheath retractor, or the conformable gasket may float unattached to the sheath and interiorly of the wound.

In another aspect of the invention, the hand access system may comprise a detachable iris seal in place of the hand seal that is adapted to be attached and detached from the sheath retractor. The iris seal comprises a first iris ring, a second iris ring coaxially attached to the first iris ring, and a cylindrical elastic member connected to the first and second iris rings and having an opening. With this aspect, the first and second iris rings operate to rotate relative to one another in either direction to open or close the opening of the cylindrical elastic member. More specifically, the first and second iris rings may be rotated in opposite directions to create an airtight constriction in the middle of the elastic member. After rotation, at least one of the first and second iris rings may be de-rotated to loosen or enlarge the constriction of the elastic member.

Each of the iris rings may comprise a plurality of tracks to allow the iris rings to be relatively rotated at predetermined angles. In yet another aspect, the iris seal may further comprise a spring connecting the first and second iris rings to further facilitate a complete opening, a partial constriction or an airtight constriction of the opening of the elastic member. The spring operates to automatically pull and rotate the iris rings after de-rotation. In particular, as an object is withdrawn from the iris seal, the spring contracts and causes the sheath constriction to tighten automatically. The spring may be formed from an elastomeric material. It is appreciated that the amount the spring stretches and contracts is determined by the length of the spring. Each of the iris springs may comprise

a hollow frame and a plurality of interlocking tracks. The interlocking tracks operate to encase the spring to prevent the spring from crossing into an instrument or hand passage area within the iris rings. The interlocking tracks also operate to open and close the seal at predetermined angles.

In another aspect of the invention, there is disclosed a surgical access device adapted for disposition relative to an incision in a patient comprising a valve including a plurality of overlapping sheets defining an access channel, and a ring having an inner diameter for holding the valve by fixing each of the overlapping sheets along a portion of the perimeter, the access channel extends into communication with the incision in the patient. With this aspect, each of the overlapping sheets includes a portion of the perimeter that is not fixed to the inner diameter of the ring. It is appreciated that the non-fixed portions provide open edges defining the access channel. In one aspect, the open edges slightly overlap for about 0.25" at the center of the ring. The hand access device may further comprise a septum seal formed at the proximal end and at the distal end of the ring, the septum seal having a hole formed at the center of the seal. It is further appreciated that the open edges of the non-fixed portions may have different shapes including at least one of a straight edge, concave, convex and a cross-configuration.

In yet another aspect of the invention, there is disclosed a surgical access device adapted for disposition relative to an incision in a patient comprising a plurality of septum layers each having a hole at the center of the septum layer and a first diameter, a ball sandwiched between the septum layers and having a second diameter greater than the first diameter, and a ring having an inner diameter for affixing the plurality of septum layers along the perimeter. In another aspect, a surgical access device facilitating a sealing relationship with an instrument or an arm of a surgeon extending through the device and into an incision in a patient is disclosed, the access device comprising a valve structure including a plurality of overlapping sheets defining an access channel, the valve in a first state forming a zero seal in the absence of the instrument or the arm of the surgeon extending through the valve structure, the valve in a second state forming an instrument seal in the presence of the instrument or the arm of the surgeon extending through the valve structure, and the access channel extends into communication with the incision in the patient.

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

BRIEF DESCRIPTION OF THE DRAWINGS

The accompanying drawings, which are included in and constitute a part of this specification, illustrate the embodiments of the invention and, together with the description, explain the features and principles of the invention. In the drawings:

FIG. 1 is a perspective view showing a patient prone on an operating table with his abdomen insufflated and with instrument access provided by trocar and the access device of the present invention;

FIGS. 2A and 2B illustrate a perspective view and a cross-sectional view, respectively, of a hand access system in accordance with a first embodiment of the invention;

FIGS. 3A-3E illustrate axial perspective views and cross-sectional views of a hand access system in accordance with another embodiment of the invention including a one-way mechanism;

FIGS. 4A and 4B illustrate cross-sectional views of a hand access system in accordance with another embodiment of the invention including an adapter;

FIGS. 5A-5C illustrate an axial perspective view and cross-sectional views of a hand access system in accordance with another embodiment of the invention including a conformable gasket;

FIG. 6 illustrates a cross-sectional view of a hand access system in accordance with another embodiment of the invention including an iris seal;

FIGS. 7A-7E illustrate the rotation of the iris seal rings of the invention to create an airtight constriction in the middle of the sheath;

FIGS. 8A-8C illustrate side views of another embodiment of the iris seal including a spring connecting the two rings;

FIG. 9 illustrates a top view of FIG. 8B;

FIGS. 10 and 11A-B illustrate perspective and top views of rings of an iris seal having interlocking tracks in accordance with another embodiment of the invention;

FIG. 12 illustrates a perspective view of a hand-assisted laparoscopic seal formed by overlapping sheets of elastomeric material in accordance with another embodiment of the invention;

FIG. 13 illustrates a perspective view of a hand-assisted laparoscopic seal formed by differently shaped overlapping sheets of elastomeric material in accordance with another embodiment of the invention;

FIGS. 14 and 15 illustrate perspective views of a hand-assisted laparoscopic seal formed by overlapping sheets of elastomeric material having concave and convex configurations;

FIG. 16 illustrates a perspective view of a hand-assisted laparoscopic seal formed by overlapping sheets of elastomeric material including a central patch supported by spokes in accordance with another embodiment of the invention; and

FIG. 17 illustrates a perspective view of a hand-assisted laparoscopic seal formed by two septum layers sandwiching a ball in accordance with another embodiment of the invention.

DETAILED DESCRIPTION

Referring to FIG. 1, there is shown a typical abdominal surgery on a patient 10 in a prone position on an operating table 12. FIG. 1 further illustrates a surgeon having an arm 16 and a hand 17 performing the surgery. In the illustrated example, the operative procedure is performed within an abdominal cavity 18 with instrument access provided through an abdominal wall 21. In this type of operation, commonly referred to as laparoscopic surgery, trocars 23 and 25 are commonly used to provide minimally invasive access through the abdominal wall 21 for instruments such as a grasper 27 and an endoscope 30. In addition, it is desirable that the surgeon be able to insert his/her hand 17 through the abdominal wall 21 and into the abdominal cavity 18. The insertion of the hand 17 provides the surgeon with direct access to various elements of the anatomy.

In order to accommodate the hand 17 and arm 16 of the surgeon, a small incision 32 is typically created in the abdominal wall 21. An access device 34 of the present invention can be provided to further facilitate this access by the hand 17 of the surgeon. Particularly in the case of laparoscopic surgery, it is advantageous to insufflate the abdominal cavity 18 with a gas, such as carbon dioxide, in order to elevate the abdominal wall 21 and thereby increase the volume of the working space within the cavity 18. Maintenance of this insufflation pressure, commonly referred to as pneu-

moperitoneum, is particularly difficult where access is desired across the abdominal wall 21, for example, through the trocars 23, 25, as well as the access device 34. For this reason, a substantial effort has been directed to providing such access devices with sealing characteristics both in the presence of instruments and in the absence of instruments, such as the grasper 27, scope 30 and hand 17.

Were it not for the desire to maintain the pneumoperitoneum, there would be no need for the trocars 23, 25 or the access device 34. That is, one would merely cut an incision in the abdominal wall 21 and insert the instrument directly through the incision. However, without appropriate valves or seals, the insufflation gases would merely escape through the incision 32. This would be particularly detrimental in the case of the incision 32 which must be sufficiently large to accept the hand 17 of the surgeon. Thus, the access device 34 operates to form with the incision 32 to provide an access or working channel, and to provide a valve or other sealing structure across the working channel in order to maintain the pneumoperitoneum.

Referring to FIGS. 2A and 2B, there are shown a perspective view and a cross-sectional view, respectively, of a hand access system 100 of the invention. The hand access system 100 provides hand access to a surgical area such as the abdominal cavity 18 while maintaining pneumoperitoneum during laparoscopic surgery. The hand access system 100 comprises a sheath retractor 110 including a peritoneal ring 112, a proximal ring 114, and a sheath 116 extending along an axis 117 connecting the peritoneal ring 112 and the proximal ring 114. The sheath 116 has a generally cylindrical configuration that may be retracted to protect an incision within a body cavity such as the abdominal wall 21. The peritoneal ring 112 and proximal ring 114 are disposed in respective planes which extend radially of the axis 117. The hand access system 100 further comprises a detachable hand seal 120 that is operably attachable and detachable to the proximal ring 114 of the sheath retractor 110 as illustrated in FIG. 2B to permit insufflation. It is appreciated that the hand seal 120 can be separated from the sheath retractor 110 to allow removal of large organs or to provide open access to the abdominal cavity 18. Stated another way, the hand seal 120 can be removed at any time to allow conversion from laparoscopic surgery to open surgery.

It is further appreciated that wound retraction in accordance with the present invention allows a surgeon to easily locate the sheath retractor 110 and to provide a base for the hand seal 120. The sheath retractor 110 operates to remove the tissue pressure from the wrist during hand-assisted laparoscopic surgery. The sheath retractor 110 further protects tissue at the wound site, for example, from abrasion, bacteria or other contaminated organs, such as donor kidneys to be removed with minimal risk or damage. The sheath retractor 110 also opens the wound providing greater access to the operative site for instruments, such as the hand of the surgeon. In particular, the sheath protector 110 includes the sheath 116 having elastomeric properties that separate the two rings 112, 114. During surgery, the peritoneal ring 112 is placed interiorly of the abdominal wall 21 and the proximal ring 114 is placed exteriorly of the abdominal wall 21 and is then stretched beyond its natural state. The diameters of the rings 112, 114 are greater than that of the wound site so as to provide sufficient footing and tension between the rings 112, 114. This tension is created by the elastic material that has been stretched and retained at a distance greater than its natural state. It will be appreciated that in other embodiments, the sheath 116 can be formed of a non-elastic sheathing material. In a similar manner, the rings 112, 114 may be

provided with a rigid configuration or alternatively may be formed of an elastomeric material.

Referring to FIGS. 3A and 3B, there are shown perspective views of a hand access system 100b where elements of structure similar to those previously described are designated by the same reference numeral followed by the lower case letter "b" in accordance with another embodiment of the invention. The sheath retractor 110b comprises a peritoneal ring 112b, a proximal ring 114b, a sheath 116b extending along an axis 117b connecting the peritoneal ring 112b and the proximal ring 114b, and a one-way mechanism 118b (a cylindrical plug) that is placed to extend above the incision. More specifically, the one-way mechanism 118b is placed between the peritoneal ring 112b and the proximal ring 114b. The hand access system 100b further comprises a "plug" hand seal 120b that is operably attached to the proximal ring 114b of the sheath retractor 110b. The hand seal 120b can be made of a soft gel material including a slit providing an instrument seal in the presence of an instrument or hand and a zero seal in the absence of an instrument or hand. The gel material includes, for example, a thermoplastic base such as Kraton® and an oil. The resulting elastomer has excellent tear strength, elongation greater than 1,000 percent, a very low durometer or hardness, and biocompatibility.

Referring to FIGS. 3C-3E, there are shown axial perspective views of an exemplary embodiment of the one-way mechanism 118b of the invention. Specifically, the one-way mechanism 118b comprises two complimentary interlocking rings 83 and 90. The proximal ring 114b can be disposed outwardly of the sheath 116b and the locking ring 90 can be disposed inwardly of the sheath 116b. These two rings 114b and 90 function to clamp the sheath 116b so that the ring 83 is maintained in a fixed position by the locking ring 90. The interlocking rings 83, 90 of FIG. 3C provide for simple operation of the sheath retractor 110b. These interlocking rings 83, 90 can be pushed down so that they rest on the outer surface of the abdominal wall 21. As the sheath 116b is drawn upwardly to achieve the proper degree of tension, it is easily moved between the interlocking rings 83, 90. However, any tendency of this sheath 116b to move back into the wound site will tighten the interlocking relationship of the rings 83, 90. Thus, the desired degree of tension is maintained on the sheath 116b until it is again pulled to release the locking ring 90 from the ring 83.

The one-way characteristics of the interlocking rings 83, 90 are further illustrated in the progressive views of FIGS. 3D and 3E. With reference to these figures, it can be seen that retraction is maintained by preventing the sheath 116b from pulling back into the wound by means of the one-way operation of the interlocking rings 83, 90. The sheath 116b slides easily through the interlocking rings 83, 90 in the upper direction, but is prevented from sliding through the rings 83, 90 in the downward direction. In order to disengage or separate the interlocking rings 83, 90, one needs only re-tension the sheath 116b by pulling it proximally thereby unlocking the rings 83 and 90. This enables the ring 83 to be removed from the sheath 116b in order to remove the retractor 116b from the wound site.

In another aspect of the invention, FIGS. 4A and 4B illustrate axial perspective views of a hand access system 100c comprising a sheath retractor 110c, an adapter 140 and a detachable hand seal 120c. The sheath retractor 110c includes a peritoneal ring 112c, a proximal ring 114c, and a sheath 116c extending along an axis 117c connecting the peritoneal ring 112c and the proximal ring 114c. The adapter 140 comprises a first or lower ring 142 for attaching to the proximal ring 114c of the sheath retractor 110c, and a second or upper

ring **144** for attaching to the detachable hand seal **120c**. FIG. 4B illustrates the hand access system **100c** with the sheath retractor **110c**, the adapter **140** and the hand seal **120c** installed. More specifically, the adapter **140** is first attached to the proximal ring **114c** of the sheath retractor **110c**. In turn, the hand seal **120c** may be attached and detached from the upper ring **144** of the adapter **140** as needed.

It is appreciated that the proximal ring **114c** may further include a movable ring, which together with the proximal ring **114c**, may be used to press down on the adapter **140** against the abdomen, for example, to secure it and form an airtight connection. It is further appreciated that the upper ring **144** may have a diameter that is greater than, equal to or less than the diameter of the lower ring **142**. In another aspect of the invention, the adapter **140** may further comprise grooves to snap in a self-closing iris seal to gain pneumoperitoneum.

FIGS. 5A-5C illustrate perspective and cross-sectional views of a hand access system **100d** in accordance with yet another embodiment of the invention where elements of structure similar to those previously described are designated by the same reference numeral followed by the lower case letter "d". The hand access system **100d** comprises a sheath retractor **110d** and a hand seal **120d** operably attached to the sheath retractor **110d**. The sheath retractor **110d** includes a peritoneal ring **112d**, a proximal ring **114d**, a sheath (not shown) connecting the peritoneal ring **112d** and the proximal ring **114d**, and a one-way mechanism **118d** comprising a plurality of interlocking rings **83d**, **90d**. The hand seal **120d** operably attaches to the proximal ring **114d** of the sheath retractor **110d**. The hand seal **120d** may be formed of a soft gel material and includes a small slit to allow passage of a hand or a surgical instrument during surgery. Referring to FIG. 5B, there is shown a cross-sectional view of the hand seal **120d** having a cavity **125d** inside the gel to receive the proximal ring **114d** of the sheath retractor **110d**. Referring to FIG. 5C, the hand seal **120d** may further comprise a latch **121d** on an inner diameter for latching the one-way mechanism **118d**. The access sheath material may be placed inside or outside of the hand seal **120d** after attachment of the hand seal **120d** and the seal retractor **110d**.

In another aspect, the one-way mechanism **118d** may include hooks to latch the hand seal **120d** as the seal **120d** is pressed down on the open end of the sheath. As explained above, the hand seal **120d** includes a small slit in the gel that will not allow air to pass with the absence of an instrument or hand, but the slit will stretch and the gel will compress to allow objects to pass through with little loss of pneumoperitoneum. Compression of the gel onto the proximal ring **114d** of the sheath retractor **110d** creates an airtight connection. The sheath retractor **110d**, as illustrated in FIG. 5A, may further include a conformable gasket **123d** to facilitate sealing of the peritoneum. The conformable gasket **123d** on the peritoneum ensures an airtight seal inside the incision as opposed to outside the incision. The gasket **123d** can be attached to the peritoneal ring **112d** or the sheath **116d**, or it can float unattached to the sheath. The floating gasket **123d** is less likely to crease or bunch (a path for air leaks) as the abdominal wall **21**, sheath **116d** and peritoneal ring **112d** distort as the sheath **116d** is pulled up into the incision. Without the need for sealing externally on the skin surface, the conformable gasket **123d** is not susceptible to air leaks from irregularities on the skin, such as scars or folds. Furthermore, the conformable gasket **123d** protects the abdominal wall **21** from potential traumatic pressure or abrasion by the peritoneal ring **112d**.

In all of the above embodiments of the invention, the ability to attach and detach the hand seal from the sheath retractor allows larger objects to pass unfettered through the incision.

In addition, the invention is easy to use, it provides increased comfort for the surgeon, and is less traumatic to tissue being passed through the incision. For example, the latching or interlocking feature of the hand seal and the adapter with the sheath retractor makes it fast and simple to use compared to other methods that may involve inflatable cuffs or adhesives. Adhesives often require time to cure and inflation with pumps also creates delay.

In another aspect of the invention, the hand access system may comprise a sheath retractor and an iris seal directly connected to the sheath retractor to form a continuous, seamless sheath. Referring to FIG. 6, there is shown a hand access system in accordance with another embodiment of the invention including an iris seal **200**. The iris seal **200** comprises a first ring **202**, a second ring **204** coaxially attachable to the first ring **202**, and a cylindrical elastic member **206** connected to the first and second rings **202**, **204** and having an opening. The first and second rings **202**, **204** operate to rotate relative to one another in either direction to open or close the opening of the cylindrical elastic member **206**. In particular, the seal **200** operates like the iris aperture of a camera, except that the iris seal **200** is made of a thin film sheath or elastic member **206**. A ring **202**, **204** is attached to each end of the sheath or elastic sheath **206**. Referring to FIGS. 7A-7C, the rings **202**, **204** are rotated in opposite directions to create an airtight constriction in the middle of the sheath or elastic member **206**. The constriction is maintained as long as the rotation is not undone (termed de-rotation). The sheath or elastic member **206** can be made of an elastic material, which allows objects small in diameter relative to the rings **202**, **204** to pass easily through the constriction without the need for de-rotation. However, objects with large diameters may require de-rotation to loosen or enlarge the constriction in the sheath as illustrated in FIG. 7D. Once an object is withdrawn, the rings **202**, **204** must rotate back to create the airtight constriction as illustrated in FIG. 7E. In another aspect, the rings **202**, **204** may include a plurality of tracks **207** such that they may be relatively rotated to open or close the opening at predetermined angles as further discussed below and illustrated in FIG. 10. More specifically, the sectional area of the opening changes in response to the predetermined angle rotation of the rings.

Referring back to FIG. 6, the iris seal **200** may be attached to a sheath retractor **110f** having a peritoneal ring **112f**, a proximal ring **114f**, a sheath **116f** connecting the peritoneal ring **112f** and the proximal ring **114f**, and a one-way mechanism **118f** (comprising a plurality of interlocking rings **83f**, **90f**). A feature of the iris seal **200** is its constriction can be dilated as wide as the retracted incision and, as such, it may not be necessary for it to be detached from the sheath retractor **110f**. In this case, the iris seal **200** can be made a permanent part of one of the interlocking rings of the one-way mechanism **118f**. Thus, the self-closing iris seal **200** and sheath retractor **110f** combination allows pneumoperitoneum to be regained more quickly without having to detach and reattach a seal as with previous methods. In another aspect, an iris seal can be easily removed when constructed as part of a two-ring design in the form of a wedge clamp similar to that shown in FIGS. 3C-3E. Pulling up on a sheath pushes or un-wedges the seal out of the sheath retractor.

It is appreciated that other hand seals can be used and interchanged as contemplated by the concept of the invention. For example, the iris seal of the invention may further include a spring **208** connecting the first and second rings **202**, **204** to further facilitate the opening and closing of the opening of the cylindrical elastic member **206**. More particularly, one or more springs **208** may be used to connect the first and second

rings **202**, **204** to provide a complete opening, a partial constriction or an airtight constriction of the iris seal. Referring to FIGS. **8A-8C**, there are shown perspective views of the iris seal **200c** of the invention further comprising the spring **208** connecting the first and second rings **202c**, **204c**. FIG. **9** is a top view of the iris seal **200c** of FIG. **8B**.

As illustrated in FIGS. **8** and **9**, as the rings **202c**, **204c** are rotated relative to one another, the spring **208** expands and contracts causing opening and constriction of the seal. More specifically, the spring **208** can be used to pull and rotate the rings **202c**, **204c** automatically after de-rotation, for example. The ends of the spring **208** are connected to the rings **202c**, **204c** in a manner such that de-rotation causes the spring **208** to stretch as illustrated in FIGS. **8A** and **8B**. Afterwards, the spring **208** contracts and causes the sheath constriction to tighten automatically as large objects are withdrawn (FIG. **8C**). The amount the spring **208** stretches and contracts is determined by the length of the spring **208**—typically larger objects require longer springs. Longer springs, however, may crossover the area within the rings **202c**, **204c** and interfere with the passage of objects as illustrated in FIG. **9**. To limit interference and to accommodate large objects, longer springs can be housed partially within a series of interlocking tracks **207** of hollow frame rings **202d**, **204d** as illustrated in FIGS. **10** and **11A-B**. In particular, the interlocking tracks **207** on the rings can encase longer springs so they do not cross into the passage area. The interlocking tracks **207** also operate to open and close the seal at predetermined angles. FIG. **11A** illustrates an axial cross-sectional view of the seal with the springs contracted and the iris closed, and FIG. **11B** illustrates an axial cross-sectional view of the seal with the springs expanded and the iris opened.

An advantage of rotational adjustment, versus fixed rings, is that a wider range of object sizes can easily pass through the iris seal. A self-closing mechanism of the invention has the advantage of hands-free adjustment. In comparison to other self-closing methods that involve gears and springs that are connected to stationary components external to the iris seal, the spring(s) of the present invention are connected to and contained within the rings, which are integral to the iris seal. With the self-closing mechanism built in, the iris seal is portable and can be more easily adapted to a wide range of access ports, wound retractors and the like.

In another aspect of the invention, a hand-assisted laparoscopy seal **300** is formed by overlapping several sheets **302**, **304**, **306**, **308**, **310**, **312** of elastomeric material as illustrated, for example, in FIG. **12**. Each of these sheets **302**, **304**, **306**, **308**, **310**, **312** is fixed along a portion of its perimeter to the circumference of a semi-rigid or rigid ring (not shown). As a result, each of the sheets **302-312** has at least a portion **302a**, **304a**, **306a**, **308a**, **310a**, **312a** of its perimeter fixed to the ring and a portion **302b**, **304b**, **306b**, **308b**, **310b**, **312b** not fixed to the ring. These non-fixed portions **302b-312b** provide open edges within the area of the ring. The sheets **302-312** are laid on top of one another and are rotated so that open edges extend along different planes. These open edges slightly overlap, such as approximately one-quarter inch, at the center of the ring to prevent leakage of the insufflation gas. During operation, an instrument or hand of the surgeon is introduced through the center of the ring forcing the open edges to part, but also causing the open edges to form a sealing structure around the forearm or wrist.

It is appreciated that in the above aspect, the overlapping sheets **302**, **312** may comprise two septum sheets having their full perimeters fixed to the ring and a hole formed at the center of the septum sheets. Referring to FIG. **13**, there is shown

another aspect of the invention where the open edges **404b**, **406b**, **408b**, **410b** have different shapes, which when laid on top of one another, tend to form overlapping sections of a circle. It is appreciated that the concept of the invention contemplates any number of overlapping sheets of any material and of any shape. In one simple embodiment, for example, the invention contemplates two semi-circular sheets having slightly straight overlapping edges.

In another aspect, FIGS. **14** and **15** show how the open edges can be provided with concave or convex configurations. The sheets or layers having convex open edges **506**, **510**, **608**, **610** tend to flex more while the sheets or layers having concave edges **504**, **508**, **604**, **606** tend to give more support. The septum sheets or layers **502**, **602** provide the most support. Other shapes can be used for the layers as illustrated in the embodiment of FIG. **16** where one of the layers includes a central patch **704** supported by spokes **704a**, **704b**, **704c**, **704d** which extend to the ring. The central patch **704** is large enough to cover the hole **702a** in the septum layer **702**. In the embodiment of FIG. **17**, two septum layers **802**, **806** sandwich a ball **804** which is movable within the confines of the ring. The ball **804** has a diameter greater than the holes **802a**, **806a** in the septum layers **802**, **806**, respectively.

It will be understood that many other modifications can be made to the various disclosed embodiments without departing from the spirit and scope of the invention. For these reasons, the above description should not be construed as limiting the invention, but should be interpreted as merely exemplary of the disclosed embodiments.

The invention claimed is:

1. A surgical access device comprising:

a valve structure comprising:

a plurality of septum layers; and

a ring having an inner diameter for affixing the plurality of septum layers along their perimeter;

wherein the plurality of septum layers includes a first septum layer having a hole at a center of the first septum layer;

wherein the plurality of septum layers comprises a second septum layer comprising a central patch supported by a plurality of spokes extending from the central patch, the central patch being large enough to cover the hole of the first septum layer;

wherein the valve structure in a first state forming a zero seal in the absence of the instrument or the arm of the surgeon extending through the valve structure, the valve structure in a second state forming an instrument seal in the presence of the instrument or the arm of the surgeon extending through the valve structure and into a patient.

2. The surgical access device of claim 1 wherein the plurality of septum layers includes a third septum layer having an open edge and a fourth septum layer having an open edge.

3. The surgical access device of claim 2 wherein the open edges of the third septum layer and the fourth septum layer slightly overlap at a center of the ring.

4. The surgical access device of claim 2 wherein the open edges of the third septum layer and the fourth septum layer have a concave configuration.

5. The surgical access device of claim 4 wherein the ring is rigid.

6. The surgical access device of claim 4 wherein the second septum layer and the third septum layer are disposed between the first septum layer and the fourth septum layer.

7. The surgical access device of claim 4 wherein the plurality of septum layers are made of elastomeric material.

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摘要(译)

本发明涉及一种外科进入系统，其在腹腔镜手术期间提供进入手术区域同时维持气腹。进入系统包括适于将可伸展至所需直径的伤口扩张的鞘牵开器和适于可从鞘牵开器移除的可拆卸密封件。在另一方面，所述可拆卸密封件包括阀，所述阀包括限定进入通道的多个重叠片，所述进入通道延伸成与患者的切口连通。每个重叠的片材包括不固定到环的内径的周边的一部分，其提供限定进入通道的开口边缘。

