



US010064649B2

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

(10) **Patent No.:** **US 10,064,649 B2**
(45) **Date of Patent:** **Sep. 4, 2018**

(54) **PLEATED SEAL FOR SURGICAL HAND OR INSTRUMENT ACCESS**

(71) Applicant: **Covidien LP**, Mansfield, MA (US)

(72) Inventors: **Kevin Golebieski**, Prospect, CT (US);
Greg Furnish, Louisville, KY (US);
Benjamin Morris, Jeffersonville, IN (US); **Wayne Johnson**, Louisville, KY (US)

(73) Assignee: **Covidien LP**, Mansfield, MA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 41 days.

(21) Appl. No.: **14/740,353**

(22) Filed: **Jun. 16, 2015**

(65) **Prior Publication Data**

US 2016/0000420 A1 Jan. 7, 2016

Related U.S. Application Data

(60) Provisional application No. 62/021,298, filed on Jul. 7, 2014.

(51) **Int. Cl.**
A61B 1/32 (2006.01)
A61B 17/34 (2006.01)
A61B 17/02 (2006.01)

(52) **U.S. Cl.**
CPC **A61B 17/3423** (2013.01); **A61B 17/0293** (2013.01); **A61B 17/3498** (2013.01); **A61B 2017/3435** (2013.01)

(58) **Field of Classification Search**

CPC **A61B 17/3423**; **A61B 2017/3425**–**2017/3429**; **A61B 2017/00265**
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

2,468,985 A	5/1949	Krotz
3,402,710 A	9/1968	Paleschuck
3,495,586 A	2/1970	Regenbogen
3,674,007 A	7/1972	Freis
4,016,884 A	4/1977	Kwan-Gett
4,112,932 A	9/1978	Chiulli
4,183,357 A	1/1980	Bentley et al.

(Continued)

FOREIGN PATENT DOCUMENTS

CA	2702419 A1	11/2010
EP	0226026 A2	6/1987

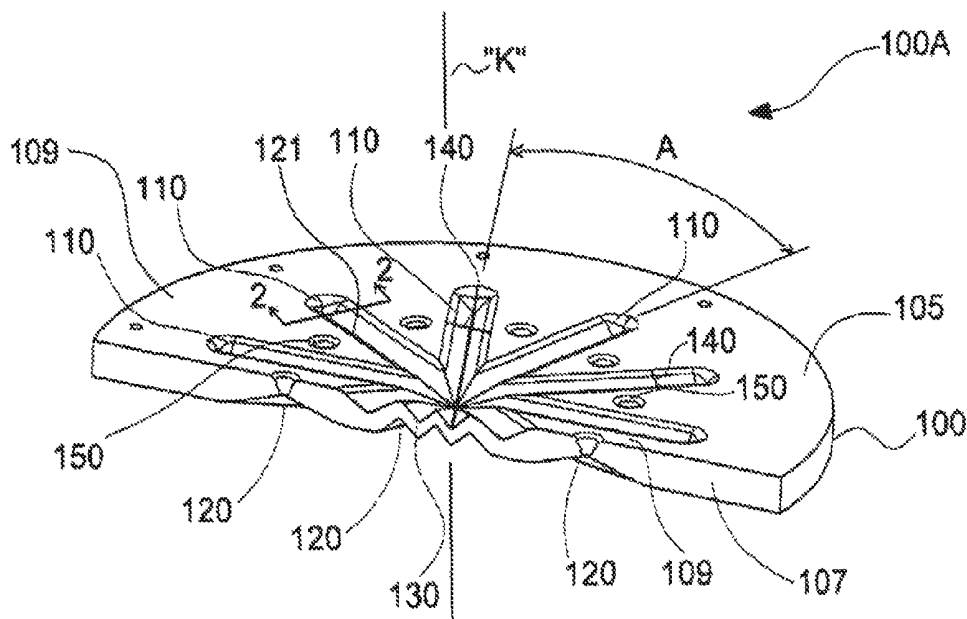
(Continued)

Primary Examiner — Jacqueline Johanas

(57) **ABSTRACT**

A surgical access assembly for a surgical instrument and/or a surgeon's hand, the assembly including a housing, such as a wound retractor, and a seal body mounted to the housing. The seal body may have a pleated configuration when viewed in cross-section. The seal body may have a first surface and a second surface, the first surface having a plurality of radially-extending first channels and the second surface having a plurality of radially-extending second channels, the plurality of first channels being offset from the plurality of second channels. The seal body may define a substantially centrally disposed opening for reception of a hand/arm or instrument. In addition, the seal body may define one or more additional openings for simultaneous reception of an instrument and a hand.

19 Claims, 8 Drawing Sheets



(56)

References Cited

U.S. PATENT DOCUMENTS

4,356,826 A	11/1982	Kubota	5,653,705 A	8/1997	de la Torre et al.
4,402,683 A	9/1983	Kopman	5,656,013 A	8/1997	Yoon
D276,937 S	12/1984	Griggs	5,672,168 A	9/1997	de la Torre et al.
4,653,476 A	3/1987	Bonnet	5,683,378 A	11/1997	Christy
4,737,148 A	4/1988	Blake	5,685,857 A	11/1997	Negus et al.
4,863,430 A	9/1989	Klyce et al.	5,697,946 A	12/1997	Hopper et al.
4,863,438 A	9/1989	Gauderer et al.	5,709,675 A	1/1998	Williams
4,984,564 A	1/1991	Yuen	5,713,858 A	2/1998	Heruth et al.
5,002,557 A	3/1991	Hasson	5,713,869 A	2/1998	Morejon
5,073,169 A	12/1991	Raiken	5,722,962 A	3/1998	Garcia
5,082,005 A	1/1992	Kaldany	5,728,103 A	3/1998	Picha et al.
5,122,122 A	6/1992	Allgood	5,730,748 A	3/1998	Fogarty et al.
5,159,921 A	11/1992	Hoover	5,735,791 A	4/1998	Alexander, Jr. et al.
5,176,697 A	1/1993	Hasson et al.	5,741,298 A	4/1998	MacLeod
5,183,471 A	2/1993	Wilk	5,752,970 A	5/1998	Yoon
5,192,301 A	3/1993	Kamiya et al.	5,782,817 A	7/1998	Franzel et al.
5,197,955 A	3/1993	Stephens et al.	5,795,290 A	8/1998	Bridges
5,209,754 A	5/1993	Ahluwalia	5,803,921 A	9/1998	Bonadio
5,217,466 A	6/1993	Hasson	5,810,712 A	9/1998	Dunn
5,242,409 A	9/1993	Buelna	5,813,409 A	9/1998	Leahy et al.
5,242,415 A	9/1993	Kantrowitz et al.	5,830,191 A	11/1998	Hildwein et al.
5,257,973 A	11/1993	Villasuso	5,836,871 A	11/1998	Wallace et al.
5,257,975 A	11/1993	Foshee	5,836,913 A	11/1998	Orth et al.
5,269,772 A	12/1993	Wilk	5,840,077 A	11/1998	Rowden et al.
5,290,249 A	3/1994	Foster et al.	5,842,971 A	12/1998	Yoon
5,312,391 A	5/1994	Wilk	5,848,992 A	12/1998	Hart et al.
5,312,417 A	5/1994	Wilk	5,853,417 A	12/1998	Fogarty et al.
5,314,417 A	5/1994	Stephens et al.	5,857,461 A	1/1999	Levitsky et al.
5,318,516 A	6/1994	Cosmescu	5,865,817 A	2/1999	Moenning et al.
5,330,486 A	7/1994	Wilk	5,871,474 A	2/1999	Hermann et al.
5,334,143 A	8/1994	Carroll	5,876,413 A	3/1999	Fogarty et al.
5,336,169 A	8/1994	Divilio et al.	5,894,843 A	4/1999	Benetti et al.
5,336,203 A	8/1994	Goldhardt et al.	5,899,208 A	5/1999	Bonadio
5,337,937 A	8/1994	Remiszewski et al.	5,899,913 A	5/1999	Fogarty et al.
5,342,385 A *	8/1994	Norelli A61B 17/02	5,904,703 A	5/1999	Gilson
		604/104	5,906,577 A	5/1999	Beane et al.
5,345,927 A	9/1994	Bonutti	5,914,415 A	6/1999	Tago
5,350,364 A	9/1994	Stephens et al.	5,916,198 A	6/1999	Dillow
5,360,417 A	11/1994	Gravener et al.	5,941,898 A	8/1999	Moenning et al.
5,366,478 A	11/1994	Brinkerhoff et al.	5,951,588 A	9/1999	Moenning
5,375,588 A	12/1994	Yoon	5,957,913 A	9/1999	de la Torre et al.
5,391,156 A	2/1995	Hildwein et al.	5,964,781 A	10/1999	Mollenauer et al.
5,394,863 A	3/1995	Sanford et al.	5,976,174 A	11/1999	Ruiz
5,395,367 A	3/1995	Wilk	5,997,515 A	12/1999	de la Torre et al.
5,437,683 A	8/1995	Neumann et al.	6,017,355 A	1/2000	Hessel et al.
5,443,452 A *	8/1995	Hart A61B 17/3498	6,018,094 A	1/2000	Fox
		137/849	6,024,736 A	2/2000	de la Torre et al.
5,443,453 A	8/1995	Walker et al.	6,030,402 A	2/2000	Thompson et al.
5,445,615 A	8/1995	Yoon	6,033,426 A	3/2000	Kaji
5,451,222 A	9/1995	De Maagd et al.	6,033,428 A	3/2000	Sardella
5,460,170 A	10/1995	Hammerslag	6,042,573 A	3/2000	Lucey
5,464,409 A	11/1995	Mohajer	6,048,309 A	4/2000	Flom et al.
5,480,410 A	1/1996	Cuschieri et al.	6,059,816 A	5/2000	Moenning
5,490,843 A	2/1996	Hildwein et al.	6,068,639 A	5/2000	Fogarty et al.
5,507,758 A	4/1996	Thomason et al.	6,077,288 A	6/2000	Shimomura et al.
5,511,564 A	4/1996	Wilk	6,086,603 A	7/2000	Termin et al.
5,514,133 A	5/1996	Golub et al.	6,099,506 A	8/2000	Macoviak et al.
5,514,153 A	5/1996	Bonutti	6,110,154 A	8/2000	Shimomura et al.
5,520,698 A	5/1996	Koh	6,142,936 A	11/2000	Beane et al.
5,522,791 A	6/1996	Leyva	6,156,006 A	12/2000	Brosens et al.
5,524,644 A	6/1996	Crook	6,162,196 A	12/2000	Hart et al.
5,540,648 A	7/1996	Yoon	6,171,282 B1	1/2001	Ragsdale
5,545,150 A	8/1996	Danks et al.	6,197,002 B1	3/2001	Peterson
5,545,179 A	8/1996	Williamson, IV	6,217,555 B1	4/2001	Hart et al.
5,556,385 A	9/1996	Andersen	6,228,063 B1	5/2001	Aboul-Hosn
5,556,387 A	9/1996	Mollenauer et al.	6,234,958 B1	5/2001	Snoke et al.
5,569,159 A	10/1996	Anderson et al.	6,238,373 B1	5/2001	de la Torre et al.
5,577,993 A	11/1996	Zhu et al.	6,241,768 B1	6/2001	Agarwal et al.
5,601,581 A	2/1997	Fogarty et al.	6,251,119 B1	6/2001	Addis
5,624,399 A	4/1997	Ackerman	6,254,534 B1	7/2001	Butler et al.
5,634,911 A	6/1997	Hermann et al.	6,264,604 B1	7/2001	Kieturakis et al.
5,634,937 A	6/1997	Mollenauer et al.	6,276,661 B1	8/2001	Laird
5,643,285 A	7/1997	Rowden et al.	6,293,952 B1	9/2001	Brosens et al.
5,649,550 A	7/1997	Crook	6,315,770 B1	11/2001	de la Torre et al.
5,651,771 A	7/1997	Tangherlini et al.	6,319,246 B1	11/2001	de la Torre et al.
			6,328,720 B1	12/2001	McNally et al.
			6,329,637 B1	12/2001	Hembree et al.
			6,371,968 B1	4/2002	Kogasaka et al.
			6,382,211 B1	5/2002	Crook

(56)

References Cited

U.S. PATENT DOCUMENTS

6,423,036 B1	7/2002	Van Huizen	7,104,981 B2	9/2006	Elkins et al.
6,440,061 B1	8/2002	Wenner et al.	7,153,261 B2	12/2006	Wenchell
6,440,063 B1	8/2002	Beane et al.	7,160,309 B2	1/2007	Voss
6,443,957 B1	9/2002	Addis	7,163,510 B2	1/2007	Kahle et al.
6,447,489 B1	9/2002	Peterson	7,192,436 B2	3/2007	Sing et al.
6,450,983 B1	9/2002	Rambo	7,195,590 B2	3/2007	Butler et al.
6,454,783 B1	9/2002	Piskun	7,201,725 B1	4/2007	Cragg et al.
6,464,686 B1	10/2002	O'Hara et al.	7,214,185 B1	5/2007	Rosney et al.
6,468,292 B1	10/2002	Mollenauer et al.	7,217,277 B2	5/2007	Parihar et al.
6,485,410 B1	11/2002	Loy	7,223,257 B2	5/2007	Shubayev et al.
6,488,620 B1	12/2002	Segermark et al.	7,223,278 B2	5/2007	Davison et al.
6,488,692 B1	12/2002	Spence et al.	7,235,064 B2	6/2007	Hopper et al.
6,524,283 B1	2/2003	Hopper et al.	7,235,084 B2	6/2007	Skakoon et al.
6,527,787 B1	3/2003	Fogarty et al.	D545,967 S	7/2007	Joyce et al.
6,544,210 B1	4/2003	Trudel et al.	7,238,154 B2	7/2007	Ewers et al.
6,551,270 B1	4/2003	Bimbo et al.	7,258,712 B2	8/2007	Schultz et al.
6,558,371 B2	5/2003	Dorn	7,276,075 B1	10/2007	Callas et al.
6,562,022 B2	5/2003	Hoste et al.	7,294,103 B2	11/2007	Bertolero et al.
6,572,631 B1	6/2003	McCartney	7,300,399 B2	11/2007	Bonadio et al.
6,578,577 B2	6/2003	Bonadio et al.	7,316,699 B2	1/2008	McFarlane
6,582,364 B2	6/2003	Butler et al.	7,331,940 B2	2/2008	Sommerich
6,589,167 B1	7/2003	Shimomura et al.	7,344,547 B2	3/2008	Piskun
6,589,316 B1	7/2003	Schultz et al.	7,377,898 B2	5/2008	Ewers et al.
6,592,543 B1	7/2003	Worrich et al.	7,390,322 B2	6/2008	McGuckin, Jr. et al.
6,610,031 B1 *	8/2003	Chin A61M 39/045 604/167.04	7,393,322 B2	7/2008	Wenchell
6,613,952 B2	9/2003	Rambo	7,412,977 B2	8/2008	Fields et al.
6,623,426 B2	9/2003	Bonadio et al.	7,440,661 B2	10/2008	Kobayashi
6,669,674 B1	12/2003	Macoviak et al.	7,445,597 B2	11/2008	Butler et al.
6,676,639 B1	1/2004	Ternstrom	7,452,363 B2	11/2008	Ortiz
6,684,405 B2	2/2004	Lezdey	7,473,221 B2	1/2009	Ewers et al.
6,706,050 B1	3/2004	Giannadakis	7,481,765 B2	1/2009	Ewers et al.
6,716,201 B2	4/2004	Blanco	7,493,703 B2	2/2009	Kim et al.
6,718,628 B2	4/2004	Munshi	7,513,361 B1	4/2009	Mills, Jr.
6,723,044 B2	4/2004	Pulford et al.	7,513,461 B2	4/2009	Reutenauer et al.
6,723,088 B2	4/2004	Gaskill, III et al.	7,520,876 B2	4/2009	Ressemann et al.
6,725,080 B2	4/2004	Melkent et al.	7,537,564 B2	5/2009	Bonadio et al.
6,800,084 B2	10/2004	Davison et al.	7,540,839 B2	6/2009	Butler et al.
6,811,546 B1	11/2004	Callas et al.	7,559,893 B2	7/2009	Bonadio et al.
6,814,078 B2	11/2004	Crook	7,608,082 B2	10/2009	Cuevas et al.
6,830,578 B2	12/2004	O'Heeron et al.	7,625,361 B2	12/2009	Suzuki et al.
6,837,893 B2	1/2005	Miller	7,645,232 B2	1/2010	Shluzas
6,840,946 B2	1/2005	Fogarty et al.	7,650,887 B2	1/2010	Nguyen et al.
6,840,951 B2	1/2005	de la Torre et al.	7,704,207 B2	4/2010	Albrecht et al.
6,846,287 B2	1/2005	Bonadio et al.	7,717,846 B2	5/2010	Zirps et al.
6,863,674 B2	3/2005	Kasahara et al.	7,717,847 B2	5/2010	Smith
6,878,110 B2	4/2005	Yang et al.	7,721,742 B2	5/2010	Kalloor et al.
6,884,253 B1	4/2005	McFarlane	7,727,146 B2	6/2010	Albrecht et al.
6,890,295 B2	5/2005	Michels et al.	7,730,629 B2	6/2010	Kim
6,913,609 B2	7/2005	Yencho et al.	7,736,306 B2	6/2010	Brustad et al.
6,916,310 B2	7/2005	Sommerich	7,753,901 B2	7/2010	Piskun et al.
6,916,331 B2	7/2005	Mollenauer et al.	7,758,500 B2	7/2010	Boyd et al.
6,929,637 B2	8/2005	Gonzalez et al.	7,762,995 B2	7/2010	Eversull et al.
6,939,296 B2	9/2005	Ewers et al.	7,766,824 B2	8/2010	Jensen et al.
6,942,633 B2	9/2005	Odland	7,787,963 B2	8/2010	Geistert et al.
6,945,932 B1	9/2005	Caldwell et al.	7,789,861 B2 *	9/2010	Franer A61B 17/3462 604/167.01
6,958,037 B2	10/2005	Ewers et al.	7,798,898 B2	9/2010	Luciano, Jr. et al.
6,972,026 B1	12/2005	Caldwell et al.	7,798,998 B2	9/2010	Thompson et al.
6,981,966 B2 *	1/2006	Green A61B 17/34 604/167.01	7,811,251 B2	10/2010	Wenchell et al.
6,986,752 B2	1/2006	McGuckin, Jr. et al.	7,815,567 B2	10/2010	Albrecht et al.
6,991,602 B2	1/2006	Nakazawa et al.	7,837,612 B2	11/2010	Gill et al.
6,997,909 B2	2/2006	Goldberg	7,846,123 B2	12/2010	Vassiliades et al.
7,001,397 B2	2/2006	Davison et al.	7,850,600 B1	12/2010	Piskun
7,008,377 B2	3/2006	Beane et al.	7,850,667 B2	12/2010	Gresham
7,011,645 B2	3/2006	McGuckin, Jr. et al.	7,867,164 B2	1/2011	Butler et al.
7,014,628 B2	3/2006	Bousquet	7,896,889 B2	3/2011	Mazzocchi et al.
7,033,319 B2	4/2006	Pulford et al.	7,905,829 B2	3/2011	Nishimura et al.
7,052,454 B2	5/2006	Taylor	7,909,760 B2	3/2011	Albrecht et al.
7,056,321 B2	6/2006	Pagliuca et al.	7,951,076 B2	5/2011	Hart et al.
7,077,852 B2	7/2006	Fogarty et al.	7,955,257 B2	6/2011	Frasier et al.
7,081,089 B2	7/2006	Bonadio et al.	7,955,313 B2	6/2011	Boismier
7,083,626 B2	8/2006	Hart et al.	7,988,671 B2 *	8/2011	Albrecht A61B 17/3462 604/167.01
7,100,614 B2	9/2006	Stevens et al.	7,998,068 B2	8/2011	Bonadio et al.
7,101,353 B2	9/2006	Lui et al.	8,021,296 B2	9/2011	Bonadio et al.
			8,025,670 B2	9/2011	Sharp et al.
			8,038,652 B2	10/2011	Morrison et al.
			8,066,673 B2	11/2011	Hart et al.
			8,079,986 B2	12/2011	Taylor et al.

(56)	References Cited		2005/0288634 A1 *	12/2005	O'Heeron	A61B 17/3462 604/167.06
	U.S. PATENT DOCUMENTS		2006/0071432 A1	4/2006	Staudner	
			2006/0129165 A1	6/2006	Edoga et al.	
8,092,430 B2	1/2012	Richard et al.	2006/0149137 A1	7/2006	Pingleton et al.	
8,105,234 B2	1/2012	Ewers et al.	2006/0149306 A1	7/2006	Hart et al.	
8,157,786 B2	4/2012	Miller et al.	2006/0161049 A1	7/2006	Beane et al.	
8,157,817 B2	4/2012	Bonadio et al.	2006/0161050 A1	7/2006	Butler et al.	
8,187,177 B2	5/2012	Kahle et al.	2006/0212063 A1	9/2006	Wilk	
8,187,178 B2	5/2012	Bonadio et al.	2006/0220325 A1 *	10/2006	McFarlane	A61B 17/3462 277/607
8,226,553 B2	7/2012	Shelton, IV et al.	2006/0224161 A1	10/2006	Bhattacharyya	
8,251,900 B2	8/2012	Ortiz et al.	2006/0241651 A1	10/2006	Wilk	
8,257,252 B2	9/2012	Kleyman	2006/0247500 A1	11/2006	Voegel et al.	
8,257,317 B2 *	9/2012	Albrecht	2006/0247516 A1	11/2006	Hess et al.	
		A61B 17/3462 604/167.06	2006/0247586 A1	11/2006	Voegel et al.	
8,282,547 B2 *	10/2012	Jensen	2006/0247673 A1	11/2006	Voegel et al.	
		A61B 17/3423 600/208	2006/0247678 A1	11/2006	Weisenburgh et al.	
8,308,639 B2 *	11/2012	Albrecht	2006/0270911 A1	11/2006	Voegel et al.	
		A61B 17/02 600/206	2007/0118175 A1	5/2007	Butler et al.	
8,317,690 B2	11/2012	Ransden et al.	2007/0203398 A1	8/2007	Bonadio et al.	
8,323,184 B2	12/2012	Spiegel et al.	2007/0208312 A1	9/2007	Norton et al.	
8,328,761 B2	12/2012	Widenhouse et al.	2007/0255218 A1 *	11/2007	Franer	A61B 17/3462 604/167.02
8,343,047 B2	1/2013	Albrecht et al.	2007/0270654 A1	11/2007	Pignato et al.	
8,388,526 B2	3/2013	Ewers et al.	2007/0270882 A1	11/2007	Hjelle et al.	
8,394,018 B2	3/2013	Piskun	2008/0027476 A1	1/2008	Piskun	
8,414,485 B2	4/2013	Richard et al.	2008/0048011 A1	2/2008	Weller	
8,465,494 B2	6/2013	Butler et al.	2008/0097162 A1	4/2008	Bonadio et al.	
8,480,683 B2	7/2013	Fowler et al.	2008/0097332 A1	4/2008	Greenhalgh et al.	
8,550,992 B2	10/2013	Kleyman	2008/0146883 A1 *	6/2008	Kistler	A61B 17/3423 600/207
8,574,153 B2	11/2013	Richard	2008/0161826 A1	7/2008	Guiraudon	
8,597,251 B2 *	12/2013	Albrecht	2008/0194973 A1	8/2008	Imam	
		A61B 17/3462 604/167.01	2008/0255519 A1	10/2008	Piskun et al.	
8,641,610 B2	2/2014	Okoniewski et al.	2008/0319261 A1	12/2008	Lucini et al.	
8,668,641 B2	3/2014	Smith	2009/0012477 A1	1/2009	Norton et al.	
8,684,918 B2	4/2014	Stopek	2009/0036738 A1	2/2009	Cuschieri et al.	
8,696,557 B2	4/2014	Fischvogt	2009/0093752 A1	4/2009	Richard et al.	
8,727,974 B2	5/2014	Kasvikis	2009/0093850 A1	4/2009	Richard	
8,728,037 B2 *	5/2014	Franer	2009/0105635 A1	4/2009	Bettuchi et al.	
		A61B 17/3462 604/167.01	2009/0131751 A1	5/2009	Spivey et al.	
8,764,647 B2	7/2014	Kleyman	2009/0182279 A1	7/2009	Wenchell et al.	
D712,033 S	8/2014	Richard et al.	2009/0182288 A1	7/2009	Spenciner	
D712,034 S	8/2014	Richard et al.	2009/0204067 A1	8/2009	Abu-Halawa	
8,795,164 B2	8/2014	Stopek	2009/0227843 A1	9/2009	Smith et al.	
9,017,254 B2 *	4/2015	Brustad	2009/0299292 A1	12/2009	Renaux	
		A61B 17/02 600/206	2009/0326330 A1	12/2009	Bonadio et al.	
D736,921 S	8/2015	Richard et al.	2009/0326332 A1	12/2009	Carter	
9,149,294 B2 *	10/2015	Webb	2010/0063452 A1	3/2010	Edelman et al.	
9,314,269 B2 *	4/2016	Webb	2010/0100043 A1	4/2010	Racenet	
9,398,924 B2 *	7/2016	Webb	2010/0113886 A1	5/2010	Piskun et al.	
		A61B 17/3421	2010/0228094 A1	9/2010	Ortiz et al.	
2001/0037053 A1	11/2001	Bonadio et al.	2010/0240960 A1	9/2010	Richard	
2002/0055714 A1	5/2002	Rothschild	2010/0249516 A1	9/2010	Shelton, IV et al.	
2003/0014076 A1	1/2003	Mollenauer et al.	2010/0261975 A1	10/2010	Huey et al.	
2003/0093104 A1	5/2003	Bonner et al.	2010/0280326 A1	11/2010	Hess et al.	
2003/0212383 A1	11/2003	Cote et al.	2010/0286484 A1	11/2010	Stellon et al.	
2004/0059297 A1	3/2004	Racenet et al.	2010/0286506 A1	11/2010	Ransden et al.	
2004/0092795 A1	5/2004	Bonadio et al.	2010/0298646 A1	11/2010	Stellon et al.	
2004/0102804 A1	5/2004	Chin	2011/0009704 A1	1/2011	Marczyk et al.	
2004/0111061 A1	6/2004	Curran	2011/0021877 A1	1/2011	Fortier et al.	
2004/0127772 A1 *	7/2004	Ewers	2011/0028891 A1	2/2011	Okoniewski	
		A61B 1/06 600/212	2011/0054257 A1	3/2011	Stopek	
2004/0138529 A1	7/2004	Wiltshire et al.	2011/0054258 A1	3/2011	O'Keefe et al.	
2004/0204734 A1	10/2004	Wagner et al.	2011/0054260 A1	3/2011	Albrecht et al.	
2004/0267096 A1	12/2004	Caldwell et al.	2011/0082341 A1	4/2011	Kleyman et al.	
2005/0020884 A1	1/2005	Hart et al.	2011/0082343 A1	4/2011	Okoniewski	
2005/0070935 A1	3/2005	Ortiz	2011/0082346 A1	4/2011	Stopek	
2005/0096695 A1	5/2005	Olich	2011/0118553 A1	5/2011	Stopek	
2005/0119525 A1	6/2005	Takemoto	2011/0124968 A1	5/2011	Kleyman	
2005/0137459 A1	6/2005	Chin et al.	2011/0124969 A1	5/2011	Stopek	
2005/0148823 A1	7/2005	Vaugh et al.	2011/0124970 A1	5/2011	Kleyman	
2005/0192483 A1	9/2005	Bonadio et al.	2011/0125186 A1	5/2011	Fowler et al.	
2005/0203346 A1	9/2005	Bonadio et al.	2011/0166423 A1	7/2011	Farascioni et al.	
2005/0203467 A1 *	9/2005	O'Heeron	2011/0251463 A1	10/2011	Kleyman	
		A61B 17/3498 604/249	2011/0251464 A1	10/2011	Kleyman	
2005/0209608 A1	9/2005	O'Heeron	2011/0251465 A1	10/2011	Kleyman	
2005/0245876 A1	11/2005	Khosravi et al.	2011/0251466 A1	10/2011	Kleyman et al.	
2005/0251092 A1	11/2005	Howell et al.				
2005/0277946 A1	12/2005	Greenhalgh				

(56)	References Cited			EP	0807416	A2	11/1997
	U.S. PATENT DOCUMENTS			EP	0950376	A1	10/1999
				EP	1188415	A2	3/2002
				EP	1312318	A1	5/2003
2011/0251560	A1 *	10/2011	Albrecht A61B 17/3462	EP	1774918	A1	4/2007
			604/167.01	EP	1932485	A1	6/2008
2011/0313250	A1	12/2011	Kleyman	EP	2044889	A1	4/2009
2012/0004613	A1 *	1/2012	Franer A61B 17/3462	EP	2044897	A1	4/2009
			604/167.03	EP	2095781	A2	9/2009
2012/0059640	A1	3/2012	Roy et al.	EP	2098182	A2	9/2009
2012/0130177	A1	5/2012	Davis	EP	2181657	A2	5/2010
2012/0130179	A1	5/2012	Rockrohr	EP	2226025	A1	9/2010
2012/0130181	A1	5/2012	Davis	EP	2229900	A1	9/2010
2012/0130182	A1	5/2012	Rodrigues, Jr. et al.	EP	2238924	A1	10/2010
2012/0130183	A1	5/2012	Barnes	EP	2238925	A1	10/2010
2012/0130184	A1	5/2012	Richard	EP	2238933	A1	10/2010
2012/0130185	A1	5/2012	Pribanic	EP	2248478	A1	11/2010
2012/0130186	A1	5/2012	Stopek et al.	EP	2248482	A1	11/2010
2012/0130187	A1	5/2012	Okoniewski	EP	2253283	A1	11/2010
2012/0130188	A1	5/2012	Okoniewski	EP	2272450	A2	1/2011
2012/0130190	A1	5/2012	Kasvikis	EP	2277464	A1	1/2011
2012/0130191	A1	5/2012	Pribanic	EP	2292165		3/2011
2012/0149987	A1	6/2012	Richard et al.	EP	2343019		7/2011
2012/0157777	A1	6/2012	Okoniewski	GB	2469083		4/2009
2012/0157779	A1	6/2012	Fischvogt	WO	84/01512		4/1984
2012/0157780	A1	6/2012	Okoniewski et al.	WO	93/14801		8/1993
2012/0157781	A1	6/2012	Kleyman	WO	94/04067		3/1994
2012/0157782	A1	6/2012	Alfieri	WO	96/10963		4/1996
2012/0157783	A1	6/2012	Okoniewski et al.	WO	96/36283		11/1996
2012/0157784	A1	6/2012	Kleyman et al.	WO	97/33520		9/1997
2012/0157785	A1	6/2012	Kleyman	WO	97/42889	A1	11/1997
2012/0157786	A1	6/2012	Pribanic	WO	99/16368		4/1999
2012/0190931	A1	7/2012	Stopek	WO	99/22804		5/1999
2012/0190932	A1	7/2012	Okoniewski	WO	00/32116		6/2000
2012/0190933	A1	7/2012	Kleyman	WO	00/32120		6/2000
2012/0209077	A1	8/2012	Racenet	WO	01/08581		2/2001
2012/0245425	A1	9/2012	Okoniewski	WO	01/49363		7/2001
2012/0253134	A1	10/2012	Smith	WO	02/07611		1/2002
2012/0316501	A1 *	12/2012	Albrecht A61B 17/3462	WO	03/034908	A2	5/2003
			604/167.03	WO	03/071926		9/2003
2013/0178708	A1	7/2013	Malkowski et al.	WO	2004/043275		5/2004
2013/0184646	A1	7/2013	Richard et al.	WO	2004/054456		7/2004
2013/0225931	A1	8/2013	Cruz et al.	WO	2004/075741	A2	9/2004
2013/0245373	A1	9/2013	Okoniewski	WO	2004/075930		9/2004
2013/0253277	A1	9/2013	Smith	WO	2005/058409		6/2005
2013/0253278	A1	9/2013	Smith	WO	2006/019723		2/2006
2013/0274559	A1	10/2013	Fowler et al.	WO	2006/100658	A2	9/2006
2013/0310651	A1	11/2013	Alfieri	WO	2006/110733		10/2006
2014/0039268	A1	2/2014	Richard	WO	2007/018458		2/2007
2014/0051933	A1	2/2014	Okoniewski	WO	2007/095703		8/2007
2014/0121466	A1	5/2014	Okoniewski et al.	WO	2007/143200		12/2007
2014/0142392	A1	5/2014	Smith	WO	2008/015566	A2	2/2008
2014/0171745	A1	6/2014	Stopek	WO	2008/042005		4/2008
2014/0316338	A1 *	10/2014	Franer A61B 17/3462	WO	2008/077080		6/2008
			604/167.03	WO	2008/093313		8/2008
2015/0038796	A1	2/2015	Okoniewski	WO	2008/103151		8/2008
				WO	2008/121294	A1	10/2008
				WO	2009/036343		3/2009
				WO	2010/141409		12/2010
	FOREIGN PATENT DOCUMENTS						
EP	0538060	A1	4/1993				
EP	630660	A1	12/1994				

* cited by examiner

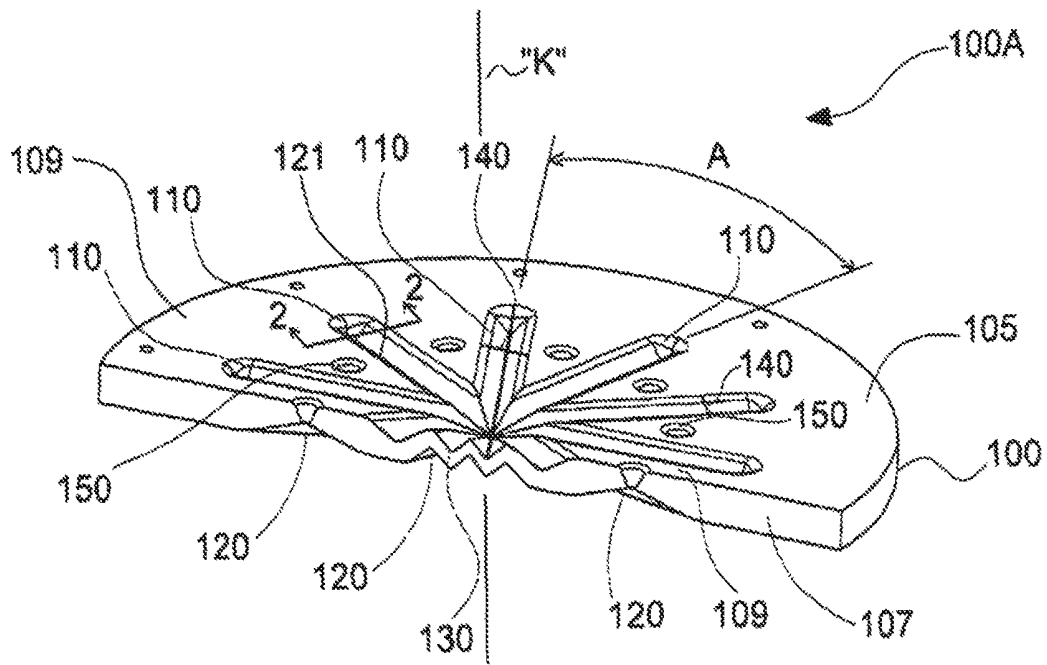


FIG. 1

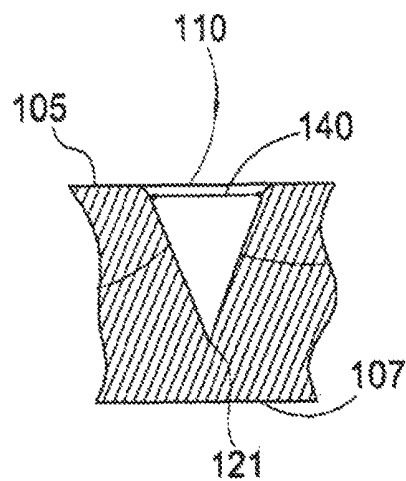


FIG. 2

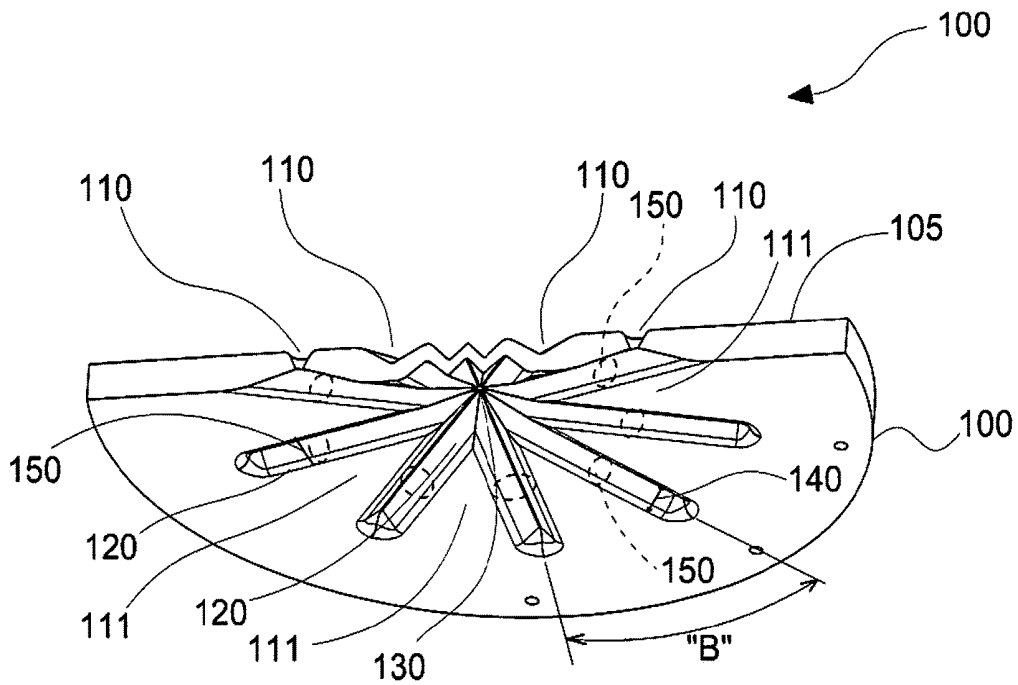


FIG. 3

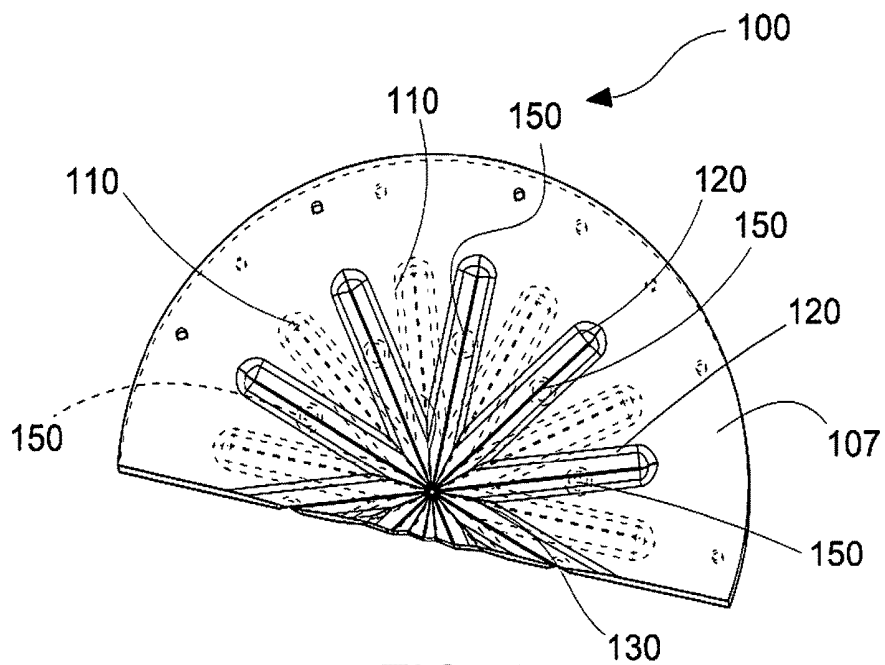


FIG. 4

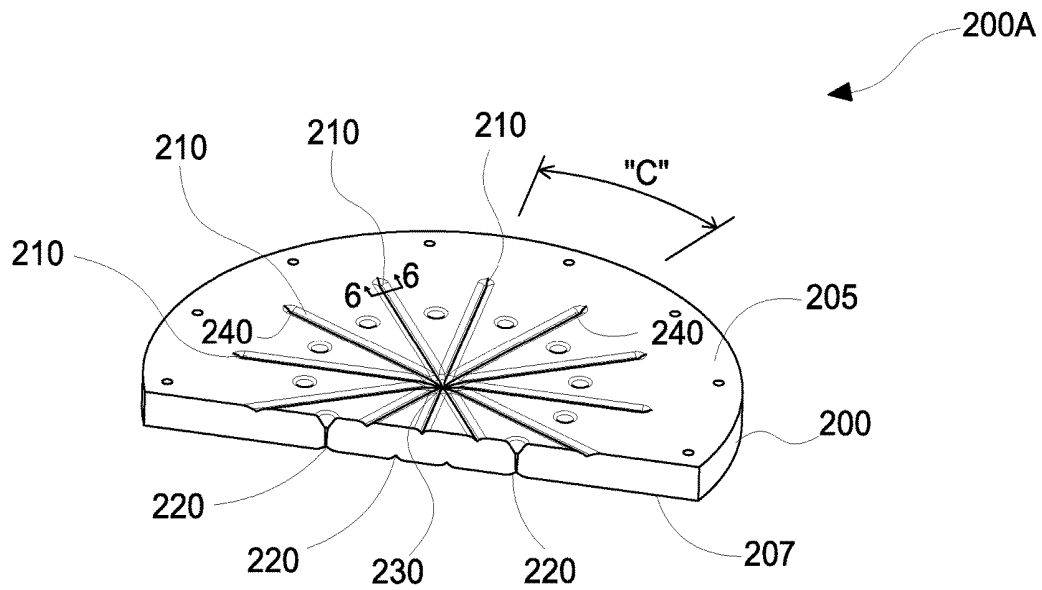


FIG. 5

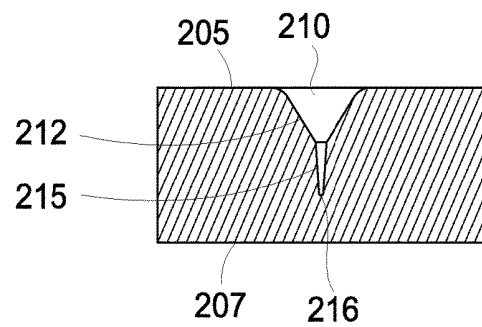


FIG. 6

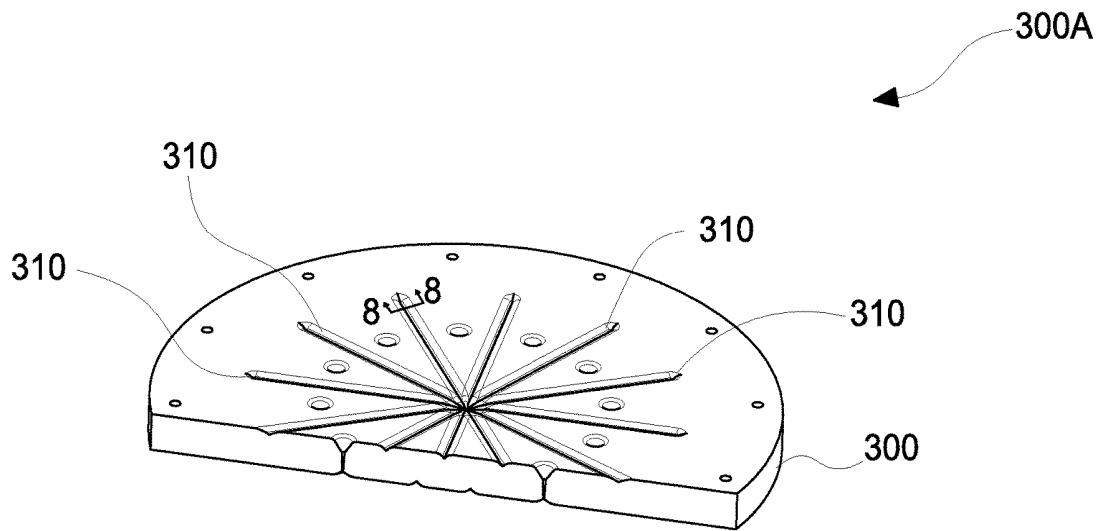


FIG. 7

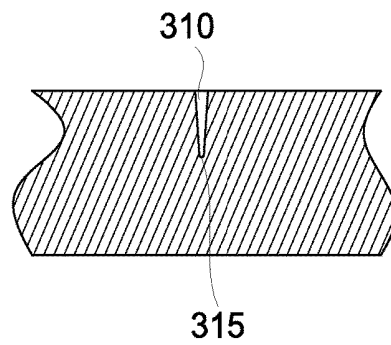


FIG. 8

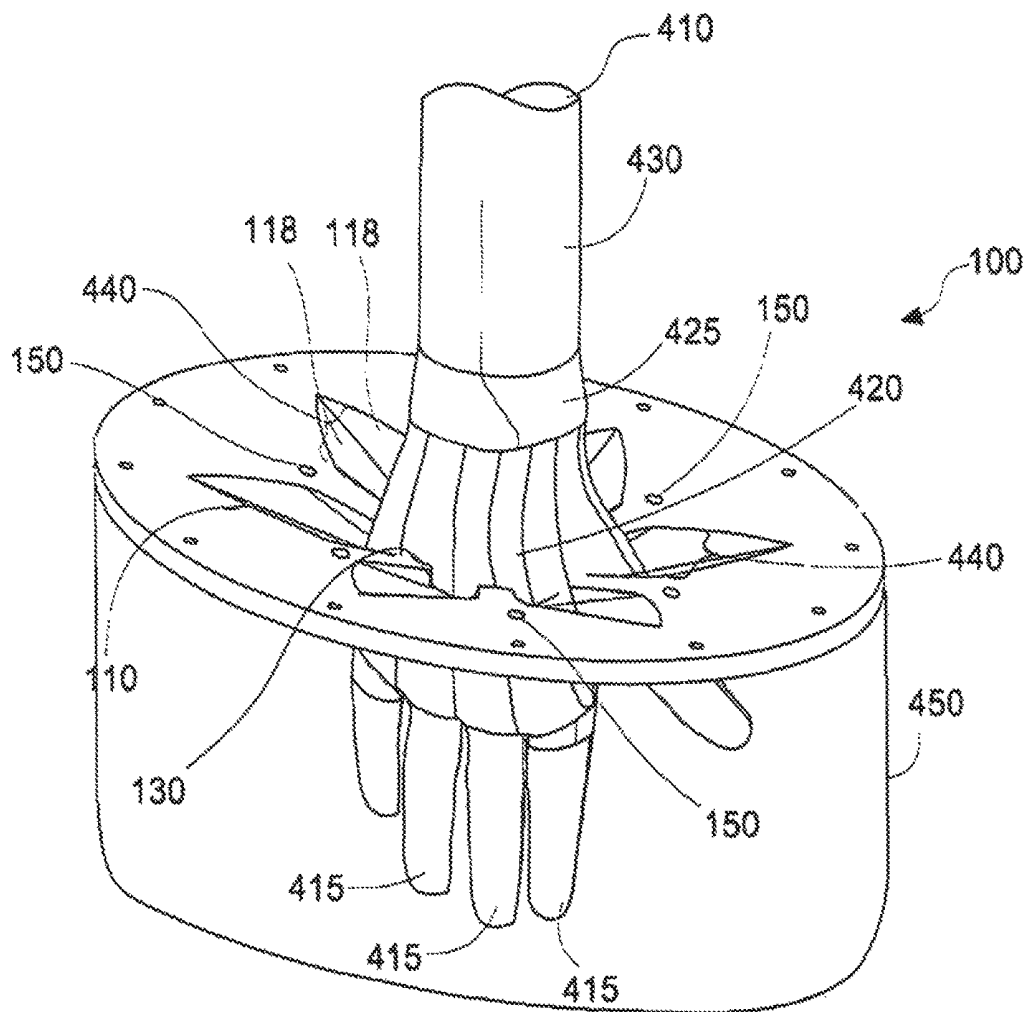


FIG. 9

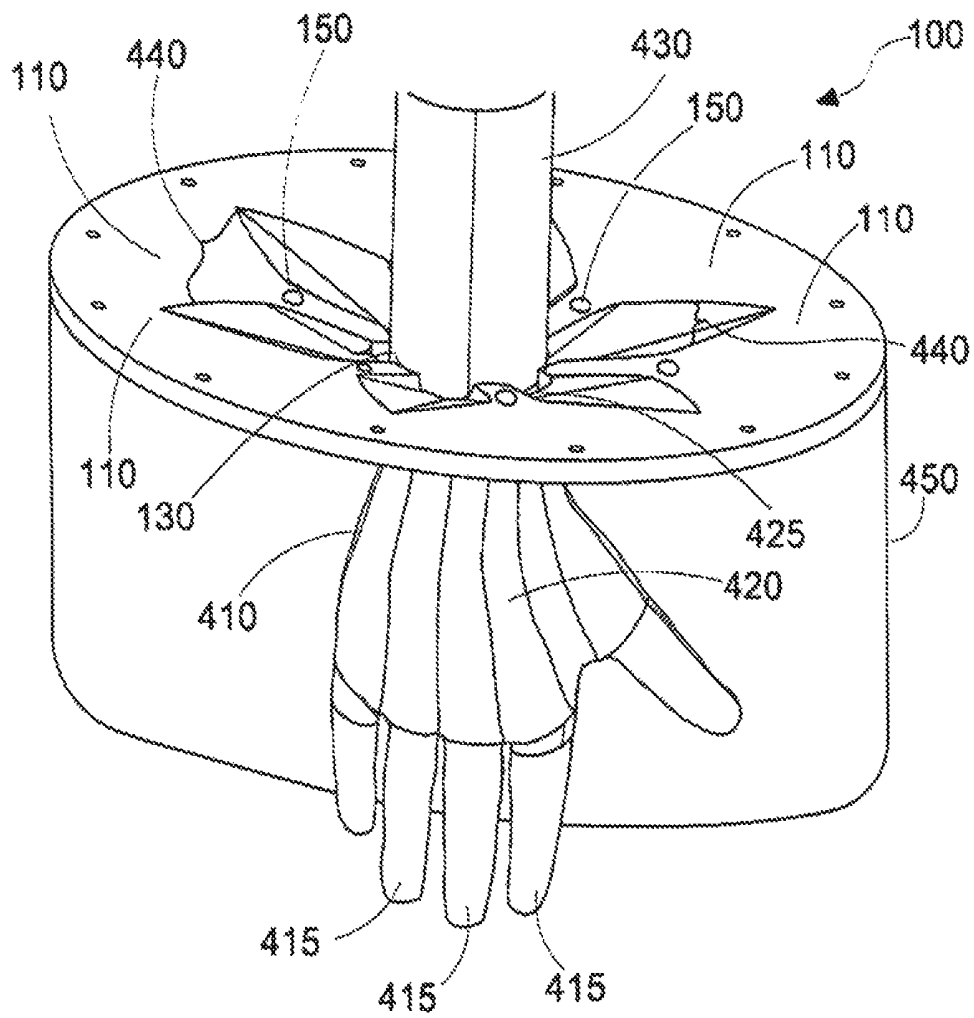


FIG. 10

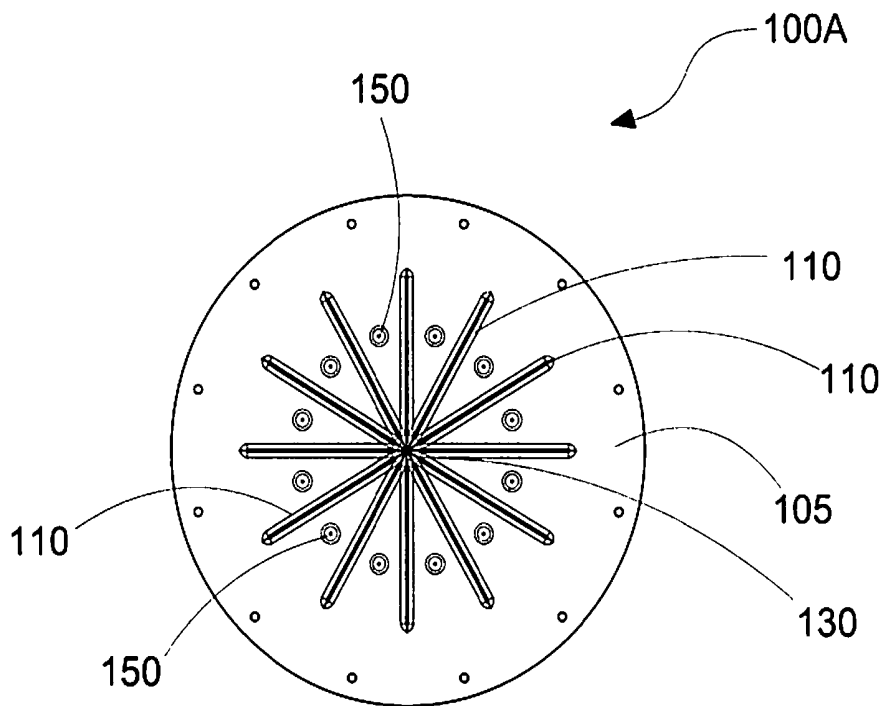


FIG. 11

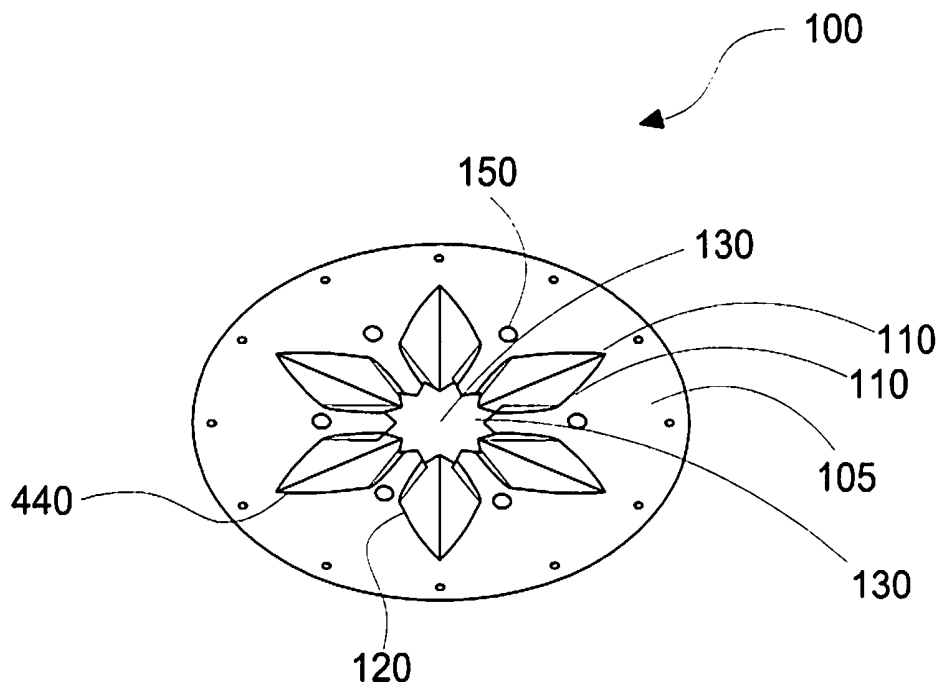


FIG. 12

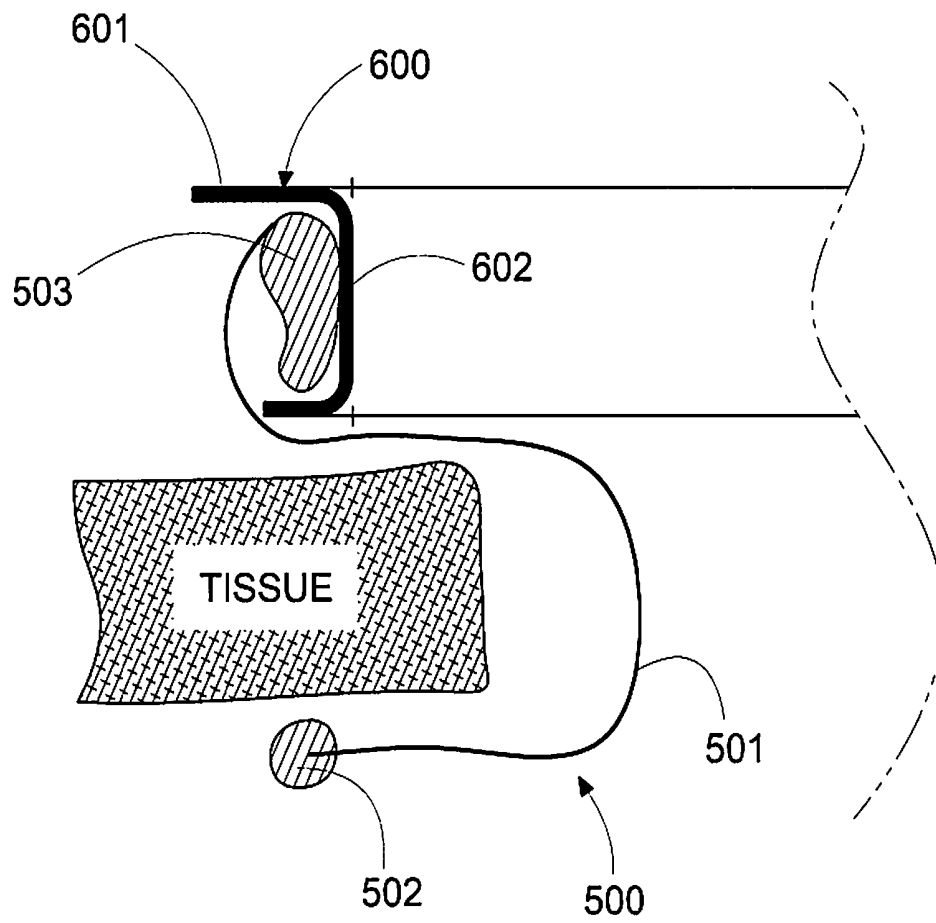


FIG. 13

1

PLEATED SEAL FOR SURGICAL HAND OR INSTRUMENT ACCESS

CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims the benefit of and priority to U.S. Provisional Patent Application No. 62/021,298, filed Jul. 7, 2014, the entire disclosure of which is incorporated by reference herein.

TECHNICAL FIELD

The present application is directed to devices for providing sealed access of a hand or instrument plugs for use in surgical procedures and, more particularly, to access surgical site seal covers or plugs that improve a surgical seal while providing greater flexibility.

SUMMARY

The present disclosure, according to various embodiments thereof, relates to a hand or instrument access assembly comprising a housing and a seal body mounted to the housing, the seal body having a first surface and a second surface, the seal body defining a substantially centrally disposed opening therethrough, wherein the first surface has a plurality of radially-extending first channels and the second surface has a plurality of radially-extending second channels, the plurality of first channels being offset from the plurality of second channels.

The plurality of first channels may have a first width and the plurality of second channels may have a second width, the first width being equal to the second width or the first width being different than the second width. The plurality of first channels and the plurality of second channels may each form a star-shaped configuration. The plurality of first channels and the plurality of second channels may extend partially along the radius of the seal. One end of each of the plurality of first channels and one end of each of the plurality of second channels may converge at the opening.

In various embodiments, when a hand or an instrument is inserted through the opening, the plurality of first channels and the plurality of second channels deform in an accordion-like manner to accommodate the hand or the instrument. The seal may be formed of foam, e.g., a monolithic piece of foam.

The housing may be a wound retractor. The wound retractor may include a distal ring for positioning through an incision for placement inside a body wall and against an interior surface of a body wall, a proximal ring for positioning outside of the body wall and a flexible sleeve connecting the distal and proximal rings, the sleeve configured to be rolled around the proximal ring so as to shorten the length of the sleeve and thereby generate a retraction force to retract the incision. In addition, the housing may also include a stiffening ring that assists with maintaining the proximal ring in a circular shape, the seal mounting directly to the stiffening ring.

The opening may be closed in a rest position so as to prevent the escape of insufflation gas therethrough when no hand or instrument is inserted. The seal body may also have one or more additional openings for sealed reception of an instrument therethrough. At least a portion of the one or more additional openings may be molded so as to be closed until reception of an instrument therethrough tears the material to fully form the opening. At least a portion of the

2

one or more additional openings may include a pre-formed slit that, in a rest position, is closed.

The present disclosure, according to various embodiments thereof, may also relate to a hand access assembly for performing a laparoscopic surgical procedure, the assembly comprising a housing, and a seal body mounted to the housing and defining an opening therethrough for reception of a hand, the seal body having a pleated configuration. The pleated configuration may include a plurality of first and second channels positioned on opposite sides of the seal body, and may be offset relative to each other. The plurality of first channels may have a first width and the plurality of second channels have a second width, the first width being equal to the second width or the first width being different than the second width. The plurality of first channels and the plurality of second channels may each form a star-shaped configuration. The plurality of first channels and the plurality of second channels may extend partially along the radius of the seal. One end of each of the plurality of first channels and one end of each of the plurality of second channels may converge at the opening.

In various embodiments, when a hand or an instrument is inserted through the opening, the plurality of first channels and the plurality of second channels deform in an accordion-like manner to accommodate the hand or the instrument. The seal may be formed of foam, e.g., a monolithic piece of foam.

The housing may be a wound retractor. The wound retractor may include a distal ring for positioning through an incision for placement inside a body wall and against an interior surface of a body wall, a proximal ring for positioning outside of the body wall and a flexible sleeve connecting the distal and proximal rings, the sleeve configured to be rolled around the proximal ring so as to shorten the length of the sleeve and thereby generate a retraction force to retract the incision. In addition, the housing may also include a stiffening ring that assists with maintaining the proximal ring in a circular shape, the seal mounting directly to the stiffening ring.

The opening may be closed in a rest position so as to prevent the escape of insufflation gas therethrough when no hand or instrument is inserted. The seal body may also have one or more additional openings for sealed reception of an instrument therethrough. At least a portion of the one or more additional openings may be molded so as to be closed until reception of an instrument therethrough tears the material to fully form the opening. At least a portion of the one or more additional openings may include a pre-formed slit that, in a rest position, is closed.

The present disclosure, according to various embodiments thereof, may also relate to a hand or surgical instrument access assembly comprising a wound retractor, wherein the wound retractor includes a distal ring for positioning through an incision for placement inside a body wall and against an interior surface of a body wall, a proximal ring for positioning outside of the body wall and a flexible sleeve connecting the distal and proximal rings, the sleeve configured to be rolled around the proximal ring so as to shorten the length of the sleeve and thereby generate a retraction force to retract the incision; a stiffening ring for maintaining the proximal ring in a circular shape; and a seal body mounted to the stiffening ring, the seal body defining an opening therethrough for reception of a surgical instrument or hand, wherein the seal body has a pleated configuration.

The pleated configuration may include a plurality of first and second channels positioned on opposite sides of the seal body, and may be offset relative to each other. The plurality

3

of first channels may have a first width and the plurality of second channels have a second width, the first width being equal to the second width or the first width being different than the second width. The plurality of first channels and the plurality of second channels may each form a star-shaped configuration. The plurality of first channels and the plurality of second channels may extend partially along the radius of the seal. One end of each of the plurality of first channels and one end of each of the plurality of second channels may converge at the opening.

In various embodiments, when a hand or an instrument is inserted through the opening, the plurality of first channels and the plurality of second channels deform in an accordion-like manner to accommodate the hand or the instrument. The seal may be formed of foam, e.g., a monolithic piece of foam.

The housing may be a wound retractor. The wound retractor may include a distal ring for positioning through an incision for placement inside a body wall and against an interior surface of a body wall, a proximal ring for positioning outside of the body wall and a flexible sleeve connecting the distal and proximal rings, the sleeve configured to be rolled around the proximal ring so as to shorten the length of the sleeve and thereby generate a retraction force to retract the incision. In addition, the housing may also include a stiffening ring that assists with maintaining the proximal ring in a circular shape, the seal mounting directly to the stiffening ring.

The opening may be closed in a rest position so as to prevent the escape of insufflation gas therethrough when no hand or instrument is inserted. The seal body may also have one or more additional openings for sealed reception of an instrument therethrough. At least a portion of the one or more additional openings may be molded so as to be closed until reception of an instrument therethrough tears the material to fully form the opening. At least a portion of the one or more additional openings may include a pre-formed slit that, in a rest position, is closed.

Further scope of applicability of the present disclosure will become apparent from the detailed description given hereinafter. However, it should be understood that the detailed description and specific examples, while indicating illustrative embodiments of the present disclosure, are given by way of illustration only, since various changes and modifications within the spirit and scope of the present disclosure will become apparent to those skilled in the art from this detailed description.

BRIEF DESCRIPTION OF THE DRAWINGS

The accompanying drawings, which are incorporated in and constitute a part of this specification, illustrate embodiments of the present disclosure and, together with the detailed description of the embodiments given below, serve to explain the principles of the disclosure:

FIG. 1 is a perspective view in partial cross-section of a hand or instrument access surgical site seal cover or plug according to one exemplary embodiment of the present disclosure, including a pleated seal having a plurality of first and second channels on respective first top and second bottom sides of the pleated seal;

FIG. 2 is an enlarged cross-sectional view taken along the lines 2-2 of FIG. 1 illustrating the configuration of the first and second channels;

FIG. 3 is a perspective view in partial cross-section illustrating the second side of the pleated seal and the second channels;

4

FIG. 4 is a top plan view of the pleated seal illustrating the radial displacement of the first and second channels with the second channels being shown in phantom;

FIG. 5 is a perspective view in partial cross-section of a hand or instrument access surgical site seal cover or plug according to another exemplary embodiment of the present disclosure;

FIG. 6 is an enlarged cross-sectional view taken along the lines 6-6 of FIG. 5 illustrating the configuration of the first and second channels of FIG. 5;

FIG. 7 is a perspective view in partial cross-section of a hand or instrument access surgical site seal cover or plug according to another exemplary embodiment of the present disclosure;

FIG. 8 is an enlarged cross-sectional view taken along the lines 8-8 of FIG. 7 illustrating the configuration of the first and second channels of FIG. 7;

FIGS. 9-10 are perspective views illustrating introduction of a patient's arm through the pleated seal body;

FIGS. 11-12 are top plan views of the seal in closed and open positions respectively; and

FIG. 13 is a side partial cross-sectional view of a wound retractor having a stiffening ring to which the laparoscopic sealing covers or plugs may be mounted, according to various embodiments of the present invention.

DETAILED DESCRIPTION

Particular embodiments of the present disclosure will be described herein with reference to the accompanying drawings. As shown in the drawings and as described throughout the following description, and as is traditional when referring to relative positioning on an object, the term "proximal" refers to the end of the laparoscopic sealing cover or plug that is closer to the user and the term "distal" refers to the end of the laparoscopic sealing cover or plug that is further from the user.

The laparoscopic sealing covers or plugs of the present disclosure, according to various embodiments thereof, include sealable openings that receive various types of instrumentation or objects (e.g., a hand of a user) while maintaining a fluid tight seal about the instrumentation or hand to prevent the loss of insufflation pressure within a laparoscopic surgical site. In addition, the laparoscopic sealing covers or plugs of the present disclosure, according to various embodiments thereof, maintain insufflation pressure within a laparoscopic surgical site when no instrumentation or objects are introduced, the sealable openings thereby providing a zero seal. The laparoscopic sealing covers or plugs accommodate angular manipulation of the hand, arm or a surgical instrument. The sealable openings may prevent the escape of insufflation gas from the body cavity, as well as prevent the entry of undesirable foreign matter into the body cavity. Examples of instrumentation include trocars, clip applicators, graspers, dissectors, retractors, staplers, laser probes, photographic devices, endoscopes and laparoscopes, tubes, and the like.

The present disclosure relates to various embodiments of hand/or instrument access surgical site seal covers or plugs that enable sealed access to a surgical site with either a surgeon's hand and/or one or more instruments.

A surgical site may include an opening or incision in a patient or a natural orifice through which a surgical procedure may be performed.

FIGS. 1-4 illustrate an exemplary embodiment of the present invention. The laparoscopic sealing cover or plug may be mounted to a housing, such as a wound retractor or

5

a separate stiffening ring used in combination with a wound refractor. The laparoscopic sealing cover or plug 100A includes a seal body 100 defining a central longitudinal axis “k” and a central seal passage or opening 130 in general longitudinal alignment with the central longitudinal axis “k”. The seal body 100 has a first top (e.g., proximal) side or surface 105 and an opposed second bottom (e.g., distal) side or surface 107. The laparoscopic sealing cover or plug 100 has a plurality of first grooves or channels 110 disposed on the top surface 105 and a plurality of second grooves or channels 120 disposed on the bottom surface 107. The first and second channels 110, 120 do not extend fully through the seal body 100 but rather extend partially from there-through. The plurality of second channels 120 are more clearly depicted in FIG. 3, which is a bottom view of the laparoscopic sealing cover or plug 100A. The laparoscopic sealing cover or plug 100A is illustrated as being flat, although it may have a domed or other suitable shape. A plurality of different materials may be used to form or construct the laparoscopic sealing cover or plug 100A, as discussed below in further detail.

Each of the first and second channels 110, 120 may be generally V-shaped, as best depicted in FIG. 2, or U-shaped, having a first width or dimension 140 at or near the exterior surface of the laparoscopic sealing cover or plug, the first width or dimension 140 gradually decreasing toward the interior of the seal body 100 and terminating at a bottom surface 121. The first and second channels 110, 120 may be substantially identical in their respective cross-sectional shapes or dimensions, or, in the alternative, may have different cross-sectional shapes or dimensions. Referring to the embodiment shown herein, the V-shape of the second channels 120 is inverted relative to the V-shape of the first channel 110 due to their arrangement on the opposite side of surface of the laparoscopic sealing cover or plug 100A. In an embodiment, the top surface 105 has ten channels (see FIG. 1) and the bottom surface 107 also has 10 channels (see FIG. 3). However, any number of channels may be located on either the top or bottom surfaces 105, 107, such as, for example, 5 through 20 channels per side. In the embodiment shown, the first and second channels 110, 120 do not extend fully to the outer perimeter of the laparoscopic sealing cover or plug 100A (or along the entire radius of the laparoscopic sealing cover or plug 100A). Instead, the first and second channels 110, 120 extend about $\frac{3}{4}$ of the radius of the laparoscopic sealing cover or plug 100A. The first and second channels 110, 120 each extend radially outwardly relative to the longitudinal axis “k”, and may or may not be coterminous with the central seal passage 130. The first and second channels 110, 120 form star-shaped configurations on the top surface 105 and the bottom surface 107, respectively. As illustrated, the plurality of first channels 110 are arranged in a circumferential manner and the plurality of second channels 120 are also arranged in a circumferential manner. The plurality of first channels 110 may form a first pattern on the top surface 105 and the plurality of second channels 120 may form a second pattern on the bottom surface 107. In the exemplary embodiments described herein, the first and second patterns are similar.

Adjacent first channels 110 are separated by wedge segments 109 of the seal body 100 (FIG. 1) and adjacent second channels 120 are separated by wedge segments 111 of the seal body 100 (FIG. 3). This arrangement of alternating channels and wedge segments, offset on opposite sides of the laparoscopic sealing cover or plug 100A, provides an undulating or corrugated structure in cross-section so as to form pleats, such structure increasing the structural integrity of

6

the laparoscopic sealing cover or plug 100A while enabling the laparoscopic sealing cover or plug 100A to accommodate stretching and deformation during passage of an instrument or a clinician’s hand and arm.

In an embodiment, the first channels 110 are equidistantly spaced relative to each other at a first predefined angular displacement “A” and the second channels 120 are equidistantly spaced relative to each other at a second predefined angular displacement “B.” In an embodiment having the same number of first and second channels 110, 120, the first and second predefined angular displacements “A”, “B” may be substantially equal. For example, in an embodiment having ten first and second channels 110, 120 on the top and bottom surfaces 105, 107, the angular displacement “A”, “B” is about 36 degrees. In other embodiments, the first and second channels 110, 120 may have varying angular displacements. Furthermore, while the first and second channels 110, 120 are each straight in the embodiments shown and described herein, in still other embodiments, the first and second channels 110, 120 may define a shape other than straight, e.g., curved, angled, etc.

With reference to FIG. 4, the first and second channels 110, 120 may be angularly offset or displaced with respect to each other. In FIG. 4, the second channels 120 are depicted in phantom. In an embodiment, the second channels 120 are angularly offset to bisect adjacent first channels 110, e.g., the second channels 120 are arranged along the midline separating adjacent first channels 110, e.g., along the midline of the wedge segment 109. The first channels 110 are angularly offset to bisect adjacent second channels 120, e.g., the first channels 110 are arranged along the midline separating adjacent second channels 120, e.g., along the midline of the wedge segment 111. This arrangement adds to the structural integrity of the seal body 100 by ensuring that the thickness beneath each of the first channels 110 and above each of the second channels 120 is sufficient to withstand stretching of the seal body during passage of the arm or hand of the clinician without the laparoscopic sealing cover or plug 100A inadvertently tearing.

Referring to FIG. 1, opening 130 is shown adjacent the center of top surface 105. In the embodiment shown, the opening 130 is configured to receive a hand and/or arm of a user (e.g., a surgeon). In addition, FIG. 1 illustrates a plurality of additional openings 150 (although any number of such openings, e.g., one or more, may be employed). Openings 150 are located on the top surface of the laparoscopic sealing cover or plug 100A and advantageously are positioned such that their uppermost portion (the portion that is co-planar with the top surface of the laparoscopic sealing cover or plug 100A) is located in a respective wedge section of the top surface, and such that their lowermost portion (the portion that is co-planar with the bottom surface of the laparoscopic sealing cover or plug 100A) is located in a respective channel 120 of the bottom surface. In an embodiment, the openings 150 taper from the top surface of the laparoscopic sealing cover or plug 100A to the bottom surface of the laparoscopic sealing cover or plug 100A. In this manner, the openings 150 have a relatively large diameter at the top surface, allowing a surgeon to easily locate and place an instrument therethrough, and a relatively small diameter at the bottom surface, providing for an improved seal. In an embodiment, the openings 150 may, in a rest position of the laparoscopic sealing cover or plug 100A, be open. Alternatively, in other embodiments, the openings 150 may, in a rest position of the laparoscopic sealing cover or plug 100A, be closed so as to provide a zero seal when an instrument is not present therethrough. In such an embodi-

ment, the laparoscopic sealing cover or plug **100A** may be molded such that the material that forms the lowermost portion of the openings **150** forms a thin barrier that prevents passage of insufflation gases, the thin barrier being puncturable by an instrument inserted therethrough. Alternatively, the laparoscopic sealing cover or plug **100A** may be molded such that the material that forms the lowermost portion of the openings **150** has a pre-formed hole or slit therethrough, the hole or slit being pressed closed during use so as to prevent passage of insufflation gases. Any number of openings **150** may be employed, so as to enable simultaneous sealed access of both a hand/arm (through the opening **130**) and an instrument (through the openings **150**).

The laparoscopic sealing cover or plug **100A** may be constructed of rigid materials or alternatively made from a disposable, pliable, compressible, and/or flexible type material, for example, but not limited to, a suitable foam material having sufficient compliance to form a seal about one or more surgical objects. In one embodiment, the foam may be at least partially constituted of polyisoprene, urethane, or silicone, or the like. Moreover, the laparoscopic sealing cover or plug **100A** may be formed of a medical grade plastic or medical grade foam or, e.g., latex, silicone rubber, Mylar®, polyethylene, polyurethane, a flexible polymeric material, or a composite material, such as a polyethylene and nylon composite, or any other resilient material suitable for the intended purpose of permitting insertion and manipulation, e.g., off-axis manipulation, of a surgical instrument or clinician's hand.

FIG. **5** illustrates a top view of a laparoscopic sealing cover or plug **200**, according to another exemplary embodiment of the present disclosure. The laparoscopic sealing cover or plug **200** is generally similar to the seal **100** described with reference to FIGS. **1-4**, except that the plurality of first channels **210** and the plurality of second channels **220** are twelve in number. Thus, the first channels **210** may be angularly displaced at an angle "C" of about 30 degrees. Similarly, the second channels **220** may be angularly displaced at an angle "D" of about 30 degrees. Other symmetrical and non-symmetrical arrangements are envisioned as well. In addition, similar to the embodiment of FIGS. **1-4**, the first and second channels **210**, **220** are radially offset with respect to each other, e.g., when viewing the laparoscopic sealing cover or plug **200** in plan view, to bisect adjacent first and second channels **210**, **220** as discussed hereinabove.

As best depicted in FIG. **6**, the first and second channels **210**, **220** may each define cross-sectional dimensions that differ at varying depths thereof. For example, the first and second channels **210**, **220** each define a first, relatively wider V-shaped segment **212** adjacent the respective top and bottom surfaces of the seal **200** and a second, relatively narrower segment **215** extending therefrom farther into the interior of the laparoscopic sealing cover or plug **200** so as to provide still further flexibility of the laparoscopic sealing cover or plug **100A**. The second, relatively narrower segment **215** may, in a rest position of the laparoscopic sealing cover or plug **200**, be slightly V-shaped or may be closed and converge to bottom **216**.

FIG. **7** illustrates a top perspective view of a laparoscopic sealing cover or plug **300A**, according to another exemplary embodiment of the present disclosure. The laparoscopic sealing cover or plug **300A** is similar to the embodiments previously described hereinabove—however, in this embodiment, the channels **310** define a slight taper or elongate V-shape, e.g., almost substantially linear in configuration, and terminating at an apex **315** such that, in a rest

position, they are nearly closed (the channels, in other embodiments, may be completely closed, e.g., the opposing side walls that define the channels may touch each other when the laparoscopic sealing cover or plug **300A** is in a rest position). These different channel configurations may further increase the flexibility and structural integrity of the laparoscopic sealing cover or plug **300A**.

FIGS. **9-10** illustrate an arm **410** extending through the laparoscopic sealing cover or plug, e.g., the laparoscopic sealing cover or plug **200A** of FIGS. **5-6** having the opening **230**. FIG. **9** depicts the fingers and palm of a hand of the clinician initially introduced within the opening **230**. As the fingers pass through the opening **230**, the opening **230** stretches in, e.g., an accordion-like manner as facilitated by the pleated configuration provided by the first and second channels **210**, **220**. For example, the channels **210**, **220** expand to accommodate passage of the hand, and may also contract once the hand passes through the seal opening **230** to maintain the seal about the arm. FIG. **10** illustrates the seal opening **230** expanded to accommodate the arm of the clinician. It is noted that FIGS. **9-10** further illustrate schematically a housing **450**, which may be a wound retractor or a wound retractor in combination with a proximal stiffening ring. It is contemplated that the laparoscopic sealing cover or plug **100A** is selectively attachable/detachable to a housing **450** in order to form a hand or instrument access assembly.

In operation, as illustrated in FIGS. **9-10**, as the user (e.g., a surgeon) inserts his/her fingers **415**, palm **420**, wrist **425**, and forearm **430** through the opening **130** of the seal **200**, the seal **200** deforms in an accordion-like manner. The deformation may be an expansion/contraction of the individual channels **210**, **220** as various portions of the arm **410** are inserted through the opening **230** of the seal **200**. The expansion/contraction action occurs to the first surface **218** of each channel **110**. Thus, the width of each channel **210** is expanded to accommodate the arm **410**. The channels **110** on the top surface **205** expand and/or flex in order to enable the central opening to more easily accommodate the hand **420** and maintain a secure sealing relationship between the hand **420** and the opening **230**. The channels **220** on the bottom surface **207** may likewise expand and/or flex when the hand **420** is accommodated in the opening **230**. The off-centered or offset relationship between the plurality of first channels **210** and the plurality of second channels **220** allows for the creation of an accordion-like deformation **440** of the seal **200** as an object (e.g., an arm **410**) is inserted through the opening **230**.

FIGS. **11-12** illustrate such accordion-like deformation **440**. FIG. **11** is a top view **500A** of the laparoscopic sealing cover or plug **200** in a closed, rest configuration. FIG. **12** is a top view **500B** of the laparoscopic sealing cover or plug **200** in a biased configuration. Each of the plurality of channels **210** is deformed to a biased or expanded condition due to the insertion of an object (e.g., an arm **410**, not shown) in opening **230**. This deformation **440** is characterized as an accordion-like deformation due to the expansion/contraction of channels **210**, **220**.

This pleated or undulating cross-sectional arrangement may incorporate any number of channels on the top and bottom surfaces of the seal to create a plurality of different patterns thereon. By off-centering the channels of the top surface from the channels of the bottom surface, the probability of tearing the seal is reduced and the laparoscopic sealing cover or plug has improved flexibility to accommodate passage and movement of an instrument and/or hand/arm.

As set forth above, the laparoscopic sealing cover or plug may be mounted to a housing, such as a wound retractor or a separate stiffening ring used in combination with a wound retractor. FIG. 13 is a side partial cross-sectional view of a wound retractor having a stiffening ring to which the laparoscopic sealing covers or plugs may be mounted, according to various embodiments of the present invention. For example, FIG. 13 illustrates a wound retractor 500 that includes a distal ring 502 for positioning through an incision for placement inside a body wall and against an interior surface of a body wall, a proximal ring 503 for positioning outside of the body wall and a flexible sleeve 501 connecting the distal and proximal rings 502, 503, the sleeve 501 configured to be rolled around the proximal ring 503 so as to shorten the length of the sleeve 501 and thereby generate a refraction force to retract the incision. FIG. 13 also illustrates a stiffening ring 600 that assists with maintaining the proximal ring 503 in a circular shape. In various embodiments, the laparoscopic sealing covers or plugs may be selectively mounted directly to the stiffening ring 600 so as to be attached and/or detached as desired by the user. In various embodiments, the seal body may engage, e.g., by friction-fit or any other method of engagement, a radial inward-facing surface 602 of the stiffening ring 600 such that a compression force creates a seal between the stiffening ring 600 and the seal body. Additionally or alternatively, the seal body may engage, e.g., by friction-fit or any other method of engagement, an upper flange 601 of the stiffening ring 600 such that a seal between the stiffening ring 600 and the seal body is created at this location.

While several embodiments of the disclosure have been shown in the drawings, it is not intended that the disclosure be limited thereto, as it is intended that the disclosure be as broad in scope as the art will allow and that the specification be read likewise. Therefore, the above description should not be construed as limiting, but merely as examples of particular embodiments. Those skilled in the art will envision other modifications within the scope and spirit of the claims appended hereto.

Persons skilled in the art will understand that the various covers or plugs, and corresponding methods of use described herein, and shown in the accompanying drawings, constitute non-limiting, exemplary embodiments of the present disclosure, and that additional components and features may be added to any of the embodiments discussed herein above without departing from the scope of the present disclosure.

Additionally, persons skilled in the art will understand that the elements and features shown or described in connection with one exemplary embodiment may be combined with those of another embodiment without departing from the scope of the present disclosure, and will appreciate further features and advantages of the presently disclosed subject matter based on the above-described embodiments and the claims. Accordingly, the present disclosure is not limited by what has been particularly shown and described.

What is claimed is:

1. A hand or instrument access assembly comprising:
a housing; and

a seal body mounted to the housing, the seal body having a first proximal surface and a second distal surface opposing the first proximal surface, the seal body defining a substantially centrally disposed opening extending through the first proximal surface and the second distal surface, and second openings for sealed reception of an instrument therethrough;

the first proximal surface having a plurality of first channels extending radially outwardly from the substantially centrally disposed opening and coterminous therewith and the second distal surface having a plurality of second channels extending radially outwardly from the substantially centrally disposed opening and coterminous therewith, the plurality of first channels being radially offset relative to the plurality of second channels, wherein the plurality of first and second channels are separate and distinctly formed from one another, at least one of the second openings being positioned in between at least two of the first channels of the plurality of first channels.

2. The hand or instrument access assembly according to claim 1, wherein the plurality of first channels have a first width and the plurality of second channels have a second width, the first width being equal to the second width.

3. The hand or instrument access assembly according to claim 1, wherein the plurality of first channels have a first width and the plurality of second channels have a second width, the first width being different than the second width.

4. The hand or instrument access assembly according to claim 1, wherein the plurality of first channels and the plurality of second channels each form a star-shaped configuration.

5. The hand or instrument access assembly according to claim 1, wherein the plurality of first channels and the plurality of second channels are configured to deform in an accordion-like manner to accommodate a hand or an instrument introduced therein.

6. The hand or instrument access assembly according to claim 1, wherein the seal body is formed of foam.

7. The hand or instrument access assembly according to claim 6, wherein the seal body is formed of a monolithic piece of foam.

8. The hand or instrument access assembly according to claim 1, wherein the housing is a wound retractor.

9. The hand or instrument access assembly according to claim 8, wherein the wound retractor includes a distal ring for positioning through an incision for placement inside a body wall and against an interior surface of the body wall, a proximal ring for positioning outside of the body wall and a flexible sleeve connecting the distal and proximal rings, the sleeve configured to be rolled around the proximal ring so as to shorten the length of the sleeve and thereby generate a retraction force to retract the incision.

10. The hand or instrument access assembly according to claim 9, wherein the housing further comprises a stiffening ring that assists with maintaining the proximal ring in a circular shape, the seal body mounted directly to the stiffening ring.

11. The hand or instrument access assembly according to claim 1, wherein the substantially centrally disposed opening is closed in a rest position and configured to inhibit the escape of insufflation gas therethrough when no hand or instrument is inserted.

12. The hand or instrument access assembly according to claim 1, wherein at least a portion of one of the second openings is molded so as to be closed until reception of the instrument therethrough, which tears the material to fully form the opening.

13. The hand or instrument access assembly according to claim 1, wherein at least a portion of one of the second openings includes a pre-formed slit that, in a rest position, is closed.

11

14. The hand or instrument access assembly according to claim 1, wherein each of the first and second channels are partially configured to be normally closed to inhibit passage of fluids therethrough.

15. A hand access assembly for performing a laparoscopic surgical procedure, the assembly comprising:

a seal body defining a central longitudinal axis and having a first proximal surface and a second distal surface, and defining a first opening extending through the first proximal surface and the second distal surface for reception of a hand, and a second opening for sealed reception of an instrument therethrough, the seal body having a plurality of first channels within the first proximal surface and extending radially outwardly relative to the opening and a plurality of second channels within the second distal surface and extending radially outwardly relative to the opening, the plurality of first and second channels being radially offset with respect to each other and the longitudinal axis, wherein

12

the plurality of first and second channels are separate and distinctly formed from one another, the second opening interposed between two first channels of the plurality of first channels.

16. The hand access assembly according to claim 15, wherein the first channels and the second channels each terminate within the seal body.

17. The hand access assembly according to claim 16, wherein each of the first and second channels have portions configured to be normally closed to inhibit passage of fluids therethrough.

18. The hand access assembly according to claim 15, wherein the second opening is molded so as to be closed until reception of the instrument therethrough, which tears the material to fully form the opening.

19. The hand access assembly according to claim 15, wherein the second opening includes a pre-formed slit that, in a rest position, is closed.

* * * * *

专利名称(译)	用于手术或仪器通道的折叠式密封		
公开(公告)号	US10064649	公开(公告)日	2018-09-04
申请号	US14/740353	申请日	2015-06-16
[标]申请(专利权)人(译)	柯惠有限合伙公司		
申请(专利权)人(译)	COVIDIEN LP		
当前申请(专利权)人(译)	COVIDIEN LP		
[标]发明人	GOLEBIESKI KEVIN FURNISH GREG MORRIS BENJAMIN JOHNSON WAYNE		
发明人	GOLEBIESKI, KEVIN FURNISH, GREG MORRIS, BENJAMIN JOHNSON, WAYNE		
IPC分类号	A61B1/32 A61B17/34 A61B17/02		
CPC分类号	A61B17/3423 A61B17/3498 A61B17/0293 A61B2017/3435		
审查员(译)	JOHANAS, 杰奎琳		
优先权	62/021298 2014-07-07 US		
其他公开文献	US20160000420A1		
外部链接	Espacenet		

摘要(译)

一种用于外科器械和/或外科医生的手的外科进入组件，该组件包括壳体，例如伤口牵开器，以及安装到壳体的密封体。当在横截面中观察时，密封体可以具有褶皱构造。密封体可以具有第一表面和第二表面，第一表面具有多个径向延伸的第一通道，第二表面具有多个径向延伸的第二通道，多个第一通道偏离多个第二通道。第二频道。密封体可以限定基本上居中设置的开口，用于接收手/臂或器械。另外，密封体可以限定一个或多个附加开口，用于同时接收器械和手。

