

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

(10) **Patent No.:** **US 12,357,209 B2**

(45) **Date of Patent:** ***Jul. 15, 2025**

(54) **BLOOD SAMPLE OPTIMIZATION DEVICE**

(71) Applicant: **Kurin, Inc.**, San Diego, CA (US)

(72) Inventors: **Bobby E. Rogers**, Park City, UT (US); **Gino Kang**, Irvine, CA (US); **John Detloff**, San Diego, CA (US)

(73) Assignee: **Kurin, Inc.**, San Diego, CA (US)

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

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **18/494,622**

(22) Filed: **Oct. 25, 2023**

(65) **Prior Publication Data**
US 2024/0252079 A1 Aug. 1, 2024

Related U.S. Application Data

(63) Continuation of application No. 18/113,710, filed on Feb. 24, 2023, now Pat. No. 11,832,944, which is a (Continued)

(51) **Int. Cl.**
A61B 5/00 (2006.01)
A61B 5/15 (2006.01)
(Continued)

(52) **U.S. Cl.**
CPC **A61B 5/150992** (2013.01); **A61B 5/15003** (2013.01); **A61B 5/150213** (2013.01);
(Continued)

(58) **Field of Classification Search**
CPC A61B 5/150992; A61B 5/15003; A61B 5/150213; A61B 5/150221;
(Continued)

(56) **References Cited**

U.S. PATENT DOCUMENTS

3,382,865 A 5/1968 Worrall, Jr.
3,494,352 A 2/1970 Russo
(Continued)

FOREIGN PATENT DOCUMENTS

CA 2993646 2/2017
CN 1717280 1/2006
(Continued)

OTHER PUBLICATIONS

Office Action (Non-Final Rejection) dated Sep. 24, 2024 for U.S. Appl. No. 18/783,173 ; (pp. 1-62).
(Continued)

Primary Examiner — May A Abouelela
(74) *Attorney, Agent, or Firm* — Pillsbury Winthrop Shaw Pittman LLP

(57) **ABSTRACT**
Blood sample optimization systems and methods are described that reduce or eliminate contaminants in collected blood samples, which in turn reduces or eliminates false positive readings in blood cultures or other testing of collected blood samples. A blood sample optimization system can include a blood sequestration device located between a patient needle and a sample needle. The blood sequestration device can include a sequestration chamber for sequestering an initial, potentially contaminated aliquot of blood, and may further include a sampling channel that bypasses the sequestration chamber to convey likely uncontaminated blood between the patient needle and the sample needle after the initial aliquot of blood is sequestered in the sequestration chamber.

30 Claims, 50 Drawing Sheets

1

Magnolia, Ex. 1025

US 12,357,209 B2

Page 2

Related U.S. Application Data

continuation of application No. 17/538,990, filed on Nov. 30, 2021, now Pat. No. 11,963,769, which is a continuation of application No. 16/208,559, filed on Dec. 4, 2018, now Pat. No. 11,185,266, which is a continuation of application No. 15/994,559, filed on May 31, 2018, now Pat. No. 10,143,412, which is a continuation of application No. 15/140,448, filed on Apr. 27, 2016, now Pat. No. 10,010,282.

- (60) Provisional application No. 62/318,194, filed on Apr. 4, 2016, provisional application No. 62/238,636, filed on Oct. 7, 2015, provisional application No. 62/196,797, filed on Jul. 24, 2015.

(51) Int. Cl.

A61B 5/153 (2006.01)
A61B 5/154 (2006.01)
A61M 39/04 (2006.01)
A61M 39/06 (2006.01)
A61M 39/02 (2006.01)

(52) U.S. Cl.

CPC .. *A61B 5/150221* (2013.01); *A61B 5/150389* (2013.01); *A61B 5/150473* (2013.01); *A61B 5/150572* (2013.01); *A61B 5/153* (2013.01); *A61B 5/154* (2013.01); *A61M 39/04* (2013.01); *A61M 39/0693* (2013.01); *A61M 2039/0202* (2013.01); *A61M 2039/0633* (2013.01); *A61M 2039/068* (2013.01)

(58) Field of Classification Search

CPC *A61B 5/150389*; *A61B 5/150473*; *A61B 5/150572*; *A61B 5/153*; *A61B 5/154*; *A61B 5/150251*; *A61M 39/04*; *A61M 39/0693*; *A61M 2039/0202*; *A61M 2039/0633*; *A61M 2039/068*

See application file for complete search history.

(56) References Cited

U.S. PATENT DOCUMENTS

3,604,410 A 9/1971 Whitacre
3,648,684 A 3/1972 Barnwell
3,741,197 A * 6/1973 Sanz *A61B 5/150267*
600/583
3,817,240 A * 6/1974 Ayres *A61B 5/150221*
600/584
3,835,835 A 9/1974 Thompson
3,848,579 A 11/1974 Villa
3,848,581 A 11/1974 Cinqualbre
3,859,998 A 1/1975 Thomas
3,874,367 A * 4/1975 Ayres *A61B 5/15003*
600/577
3,886,930 A * 6/1975 Ryan *A61B 5/150351*
600/584
3,945,380 A 3/1976 Dabney
4,056,101 A 11/1977 Geissler
4,057,050 A * 11/1977 Sarstedt *A61B 5/150351*
604/125
4,106,497 A * 8/1978 Percarpio *A61B 5/150389*
600/579
4,150,089 A 4/1979 Linet
4,154,229 A * 5/1979 Nugent *A61B 5/154*
600/577
4,193,400 A 3/1980 Loveless
4,207,870 A * 6/1980 Eldridge *A61B 5/150732*
604/167.03
4,257,416 A 3/1981 Prager
4,312,362 A 1/1982 Kaufman
4,349,035 A 9/1982 Thomas

4,373,535 A 2/1983 Martell
4,412,548 A * 11/1983 Hoch *A61B 5/150213*
600/577
4,416,290 A 11/1983 Lutkowski
4,416,291 A 11/1983 Kaufman
4,436,098 A * 3/1984 Kaufman *A61B 5/1545*
604/199
4,444,203 A * 4/1984 Engelman *A61B 5/150496*
600/576
4,673,386 A 6/1987 Gordon
4,690,154 A 9/1987 Woodford
4,813,433 A 3/1989 Downey
4,904,240 A 2/1990 Hoover
4,980,297 A 12/1990 Haynes
5,045,185 A 9/1991 Ohnaka
5,097,842 A 3/1992 Bonn
5,100,394 A 3/1992 Dudar
5,135,489 A 8/1992 Jepson
5,147,329 A 9/1992 Brannon
5,200,325 A 4/1993 Blatt
5,222,502 A * 6/1993 Kurose *A61B 5/150732*
600/584
5,401,262 A 3/1995 Karwoski
5,417,673 A 5/1995 Gordon
5,431,811 A 7/1995 Tusini
5,432,084 A 7/1995 Brubaker
5,439,450 A 8/1995 Haedt
5,518,005 A 5/1996 Brannon
5,520,193 A * 5/1996 Suzuki *A61B 5/1545*
604/126
5,632,906 A 5/1997 Ishida
5,691,486 A 11/1997 Behringer
5,749,857 A * 5/1998 Cuppy *A61M 25/0606*
604/161
5,772,608 A 6/1998 Dhas
5,811,658 A 9/1998 Van Driel
5,865,803 A 2/1999 Major
5,873,841 A 2/1999 Brannon
5,972,294 A 10/1999 Smith
5,980,830 A 11/1999 Savage
6,013,037 A 1/2000 Brannon
6,106,509 A 8/2000 Loubser
6,126,643 A 10/2000 Vaillancouert
6,187,347 B1 2/2001 Patterson
6,224,561 B1 5/2001 Swendson
6,398,743 B1 * 6/2002 Halseth *A61B 5/15003*
604/164.12
6,506,182 B2 1/2003 Estabrook
6,569,117 B1 * 5/2003 Ziv *A61M 39/02*
604/246
6,599,474 B2 7/2003 Evtodienko
6,626,884 B1 9/2003 Dillon
6,638,252 B2 10/2003 Moulton
6,695,004 B1 2/2004 Raybuck
6,733,433 B1 5/2004 Fell
6,736,783 B2 5/2004 Blake
6,843,775 B2 1/2005 Hyun
6,860,871 B2 3/2005 Kuracina
6,905,483 B2 6/2005 Newby
6,913,580 B2 7/2005 Stone
6,945,948 B2 9/2005 Bainbridge
7,052,603 B2 5/2006 Schick
7,055,401 B2 6/2006 Prybella
7,241,281 B2 7/2007 Coelho
7,306,736 B2 12/2007 Collins
7,461,671 B2 12/2008 Ehwald
7,479,131 B2 1/2009 Mathias
7,666,166 B1 2/2010 Emmert
8,070,725 B2 12/2011 Christensen
8,197,420 B2 * 6/2012 Patton *A61B 10/0045*
600/573
8,349,254 B2 1/2013 Hoshino
8,377,040 B2 2/2013 Burkholz
8,523,826 B2 * 9/2013 Layton, Jr. *A61M 39/16*
604/533
8,535,241 B2 * 9/2013 Bullington *A61B 5/150251*
604/249

US 12,357,209 B2

Page 3

(56)

References Cited

U.S. PATENT DOCUMENTS

8,540,663 B2 * 9/2013 Davey A61M 25/0029
604/93.01
8,568,371 B2 * 10/2013 Siopes A61M 39/06
251/903
8,574,203 B2 11/2013 Stout
8,603,009 B2 * 12/2013 Tan A61B 5/150251
600/573
8,827,958 B2 9/2014 Bierman
8,864,684 B2 * 10/2014 Bullington A61B 10/0048
600/576
9,022,950 B2 * 5/2015 Bullington A61B 5/153
600/576
9,022,951 B2 * 5/2015 Bullington A61B 5/150992
600/576
9,060,724 B2 * 6/2015 Bullington A61B 5/150221
9,138,572 B2 * 9/2015 Zeytoonian A61M 39/26
9,155,495 B2 * 10/2015 Bullington A61B 5/150389
9,204,864 B2 * 12/2015 Bullington A61B 10/0096
9,764,891 B1 9/2017 Aviles
9,820,682 B2 11/2017 Rogers
9,877,675 B2 * 1/2018 Baid A61B 5/150389
10,010,282 B2 7/2018 Rogers
10,143,412 B2 12/2018 Rogers
10,265,007 B2 4/2019 Bullington
10,299,713 B2 5/2019 Patton
10,596,315 B2 3/2020 Bullington
10,624,977 B2 4/2020 Bullington
10,827,964 B2 11/2020 Rogers
10,881,343 B2 1/2021 Bullington
11,185,266 B2 11/2021 Rogers
11,213,232 B2 1/2022 Ivošević
11,234,626 B2 2/2022 Bullington
11,259,727 B2 3/2022 Bullington
11,311,219 B2 4/2022 Rogers
11,395,612 B2 7/2022 Bullington
11,419,531 B2 8/2022 Bullington
11,439,332 B2 9/2022 Bullington
11,589,843 B2 2/2023 Bullington
11,612,340 B2 3/2023 Bullington
11,653,863 B2 5/2023 Bullington
11,660,030 B2 5/2023 Bullington
11,737,693 B2 8/2023 Bullington
11,786,155 B2 10/2023 Bullington
11,789,017 B2 10/2023 Bullington
2001/0044615 A1 11/2001 Amano
2002/0004647 A1 * 1/2002 Leong A61B 5/15003
604/168.01
2003/0082074 A1 5/2003 Jurik
2003/0105414 A1 * 6/2003 Leong A61B 5/15003
600/576
2003/0185707 A1 10/2003 Iwaki
2003/0208151 A1 11/2003 Kraus
2004/0054333 A1 * 3/2004 Theeuwes A61M 5/14276
604/248
2004/0073171 A1 * 4/2004 Rogers A61M 39/26
604/164.13
2004/0112808 A1 6/2004 Takagi
2004/0116830 A1 6/2004 Trudeau
2004/0147855 A1 * 7/2004 Marsden A61B 5/150496
600/576
2005/0004524 A1 * 1/2005 Newby A61B 5/150648
604/164.08
2005/0005635 A1 1/2005 Le Metais
2005/0007524 A1 1/2005 Luo
2005/0161112 A1 7/2005 Ehwald
2005/0240161 A1 * 10/2005 Crawford A61B 5/150816
604/264
2005/0245885 A1 11/2005 Brown
2005/0273019 A1 12/2005 Conway
2006/0009713 A1 1/2006 Flaherty
2007/0031283 A1 2/2007 Davis
2007/0083162 A1 * 4/2007 O'Reagan A61M 39/26
604/167.03

2007/0088279 A1 * 4/2007 Shue A61M 25/0693
604/168.01
2007/0119508 A1 5/2007 West
2008/0086085 A1 * 4/2008 Brown A61B 5/150389
604/122
2008/0145933 A1 * 6/2008 Patton A61B 10/0051
435/379
2008/0167577 A1 * 7/2008 Weillbacher A61B 5/1545
600/576
2008/0319346 A1 * 12/2008 Crawford A61B 5/150656
600/576
2009/0227953 A1 9/2009 Tan
2009/0299253 A1 12/2009 Hursey
2010/0010372 A1 * 1/2010 Brown A61B 5/15003
600/573
2010/0057004 A1 * 3/2010 Christensen A61M 25/0606
604/122
2011/0306899 A1 12/2011 Brown
2012/0016266 A1 * 1/2012 Burkholz A61B 5/150992
600/581
2013/0116599 A1 5/2013 Bullington
2013/0158506 A1 6/2013 Harris
2013/0317391 A1 * 11/2013 Bullington A61B 5/15003
600/578
2014/0039348 A1 2/2014 Bullington
2014/0073990 A1 3/2014 Holmes
2014/0107564 A1 4/2014 Bullington
2014/0112841 A1 4/2014 Schoen
2014/0155781 A1 6/2014 Bullington
2014/0155782 A1 6/2014 Bullington
2014/0163419 A1 6/2014 Bullington
2014/0276578 A1 9/2014 Bullington
2014/0309558 A1 10/2014 Fletcher
2014/0323911 A1 10/2014 Sloan
2015/0246352 A1 9/2015 Bullington
2015/0314105 A1 11/2015 Gasparian
2015/0342510 A1 12/2015 Bullington
2015/0351678 A1 12/2015 Bullington
2015/0359473 A1 12/2015 Garrett
2016/0008579 A1 * 1/2016 Burkholz A61M 5/158
604/164.08
2016/0017488 A1 1/2016 Kobayashi
2016/0073937 A1 3/2016 Burkholz
2016/0174888 A1 * 6/2016 Berthier A61B 5/150503
600/573
2016/0262677 A1 9/2016 Ebetsberger
2016/0325085 A1 * 11/2016 Chelak F16K 7/20
2016/0361006 A1 12/2016 Bullington
2017/0020427 A1 1/2017 Rogers
2017/0020428 A1 1/2017 Rogers
2017/0065733 A1 3/2017 Bullington
2018/0140240 A1 5/2018 Bullington
2018/0177445 A1 6/2018 Rogers
2018/0271425 A1 9/2018 Rogers
2018/0297303 A1 10/2018 Sekiguchi
2018/0353117 A1 12/2018 Bullington
2019/0159711 A1 5/2019 Rogers
2019/0175087 A1 6/2019 Bullington
2019/0365303 A1 12/2019 Bullington
2020/0289039 A1 9/2020 Bullington
2021/0145336 A1 5/2021 Rogers
2021/0275068 A1 9/2021 Miazga
2022/0151525 A1 5/2022 Bullington
2022/0151527 A1 5/2022 Bullington
2022/0160271 A1 5/2022 Ivošević
2022/0304600 A1 9/2022 Hammer
2022/0304664 A1 9/2022 Hammer

FOREIGN PATENT DOCUMENTS

CN 104107054 10/2014
CN 104981203 10/2015
DE 7203008 5/1972
DE 2541494 3/1977
DE 29913417 12/2000
DE 10038026 2/2001
DE 10134913 2/2003
DE 10134913 C2 6/2003

(56)

References Cited

FOREIGN PATENT DOCUMENTS

DE	10243129	4/2004
EP	0448795	2/1991
EP	0448795 A2	10/1991
EP	1665986	6/2006
EP	2593169 A1	5/2013
EP	3324845 A1	5/2018
EP	3562397 A1	11/2019
EP	3622890 A1	3/2020
GB	1378602 A	12/1974
JP	S5643474	10/1981
JP	S5789869	6/1982
JP	S5825146 A	2/1983
JP	S5867238 A	4/1983
JP	H02224742	9/1990
JP	H08257018	10/1996
JP	H09504726 A	5/1997
JP	2001000424	1/2001
JP	2005349196	12/2005
JP	2009131273 A	6/2009
JP	2012016496 A	1/2012
JP	2013240628	12/2013
JP	5643474	12/2014
JP	5789869 B2	10/2015
JP	5825146 B2	12/2015
JP	5867238 B2	2/2016
JP	2016504075	2/2016
JP	2019534792 A	12/2019
JP	2020000340 A	1/2020
JP	6643474 B2	2/2020
JP	6734490	8/2020
WO	199216144	10/1992
WO	9605875 A1	2/1996
WO	1996005875	2/1996
WO	2007033319 A1	3/2007
WO	2008101025	8/2008
WO	2010062734 A1	6/2010
WO	2011162772 A1	12/2011
WO	2013082301 A1	6/2013
WO	2013181352 A1	12/2013
WO	2014058945	4/2014
WO	2015150742	10/2015
WO	2017019552 A1	2/2017
WO	2018125929 A1	7/2018
WO	2019055487 A1	3/2019
WO	2019232196 A1	12/2019

OTHER PUBLICATIONS

Office Action (Non-Final Rejection) dated Sep. 17, 2024 for U.S. Appl. No. 17/893,079 ; (pp. 1-50).

Office Action (Non-Final Rejection) dated Sep. 23, 2024 for U.S. Appl. No. 17/730,118 ; (pp. 1-73).

Office Action (Non-Final Rejection) dated Sep. 17, 2024 for U.S. Appl. No. 18/783,088 ; (pp. 1-60).

Office Action (Notice of Deficiencies) dated Oct. 14, 2023 for IL App No. 309380 (pp. 1-7).

Office Action (Non-Final Rejection) mailed Nov. 29, 2022 for Application No. 2021-214177, pp. 1-3.

Notice of Allowance mailed Jun. 20, 2023; 6 pages.

Office Action (Non-Final Rejection) mailed Nov. 4, 2022 for U.S. Appl. No. 17/094,692, pp. 1-50.

Notice of Allowance mailed Apr. 20, 2023; 36 pages.

Office Action (Non-Final Rejection) mailed Aug. 4, 2022 for U.S. Appl. No. 16/819,033, pp. 1-35.

Notice of Allowance mailed Nov. 28, 2022; 9 pages.

Notice of Allowance mailed Jul. 4, 2024; 9 pages.

Office Action mailed May 21, 2024; 6 pages.

European Patent Office, Examination Report for European Patent Application 20781928.5, dated Jul. 31, 2024, pp. 1-6.

International Search Report and Written Opinion dated Nov. 5, 2015, for PCT application No. PCT/US2015/035870. 6 pages.

International Search Report and Written Opinion dated Jul. 16, 2020 for PCT application No. PCT/US2020/026276. 9 pages.

Bullington, et al., Systems and Methods for Sample Collection with Reduced Hemolysis, Exhibit H in U.S. Appl. No. 62/517,681, dated Jun. 9, 2017, 131 pages.

International Search Report and Written Opinion dated Jun. 19, 2020, for PCT application No. PCTUS2020/023617. 12 pages.

International Search Report/Written Opinion for PCT/US17/68569 dated Apr. 25, 2018. 9 pages.

International Search Report and Written Opinion for PCT/US16/43709, Dated Oct. 19, 2016. 13 pages.

Retractable Techs., Inc. v. Becton Dickinson & Co., CA No. 2:07-CV-250, Claim Construction Order (E.D. Tex., Jan. 20, 2009). 20 pages.

Hillyer, Christopher D., et al. "Bacterial Contamination of Blood Components: Risks, Strategies and Regulation," *Hematology*, 2003, pp. 575-589.

De Korte, Dirk, et al. "Diversion of first blood volume results in a reduction of bacterial contamination for whole-blood collections." *Vox sanguinis* 83.1 (2002): 13-16.

Brecher, Mark E., et al. "Bacterial contamination of blood components." *Clinical microbiology reviews* 18.1 (2005): 195-204.

Van Zundert, Adrien. "New closed IV catheter system." *Acta Anaesthesiologica Belgica* 56.3 (2005): 283-285.

Hall, Keri K., et al. "Updated review of blood culture contamination." *Clinical microbiology reviews* 19.4 (2006): 788-802.

Li, Yiwen, et al. "Direct labeling and visualization of blood vessels with lipophilic carbocyanine dye Dil." *Nature protocols* 3.11 (2008): 1703-1708.

Page, Catherine, et al. "Blood conservation devices in critical care: a narrative review." *Annals of intensive care* 3 (2013): 1-6.

Abbott Point of Care, Cartridge and Test Information, Art: 714258-010; Rev. Date: Aug. 15, 2016, 1-6 pages.

Zimmon, David S. et al. "Effect of portal venous blood flow diversion on portal pressure." *The Journal of Clinical Investigation* 65.6 (1980): 1388-1397.

Patton, Richard G., et al. "Innovation for reducing blood culture contamination: initial specimen diversion technique." *Journal of clinical microbiology* 48.12 (2010): 4501-4503.

Tang, Menglin, et al. "Closed blood conservation device for reducing catheter-related infections in children after cardiac surgery." *Critical Care Nurse* 34.5 (2014): 53-60.

Ernst, Dennis J. et al. "NCCLS simplifies the order of draw: a brief history." *MLO: medical laboratory observer* 36.5 (2004): 1-5 pages.

Gottlieb, T. "Hazards of bacterial contamination of blood products." *Anaesthesia and intensive care* 21.1 (1993): 20-23.

Norberg, Alonna, et al. "Contamination rates of blood cultures obtained by dedicated phlebotomy vs intravenous catheter." *Jama* 289.6 (2003): 726-729.

Quilici, Nathalie, et al. "Differential quantitative blood cultures in the diagnosis of catheter-related sepsis in intensive care units." *Clinical infectious diseases* 25.5 (1997): 1066-1070.

Napolitano, Marcello, et al. "Quality control of bacterial contamination of blood components: the feasibility of diversion system testing." *Blood Transfus* 2 (2004): 231-232.

De Korte, Dirk, et al. "Effects of skin disinfection method, deviation bag, and bacterial screening on clinical safety of platelet transfusions in the Netherlands." *Transfusion* 46.3 (2006): 476-485.

Liumbruno, Giancarlo Maria, et al. "Reduction of the risk of bacterial contamination of blood components through diversion of the first part of the donation of blood and blood components." *Blood Transfusion* 7.2 (2009): 86.

NCCLS. Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard—Fifth Edition. H3-A5, vol. 23, No. 32. Replaces H3-A4; vol. 18, No. 7. 1-52 pages. <http://demo.nextlab.ir/Organization/Documents/CLSI-Standards/CLSI-H3-A5.aspx>.

Challiner, A., et al. "Venous/arterial blood management protection system." *Anaesthesia* 47.2 (1992): 169-169.

Murphy, Michael F. "Better Blood Transfusion." *Journal of the Intensive Care Society* 4.3 (2003): 78-80.

Palavecino, Elizabeth L., et al. "Detecting bacterial contamination in platelet products." *Clinical laboratory* 52.9-10 (2006): 443-456.

(56)

References Cited

OTHER PUBLICATIONS

Sheppard, Chelsea A., et al. "Bacterial contamination of platelets for transfusion: recent advances and issues." *Laboratory Medicine* 36.12 (2005): 767-770.

Shulman, Gerald. "Quality of processed blood for autotransfusion." *Journal of Extracorporeal Technology* 32.1 (2000): 11-19.

Weinbaum, Fredric I., et al. "Doing it right the first time: quality improvement and the contaminant blood culture." *Journal of Clinical Microbiology* 35.3 (1997): 563-565.

Weinstein, Melvin P. "Blood culture contamination: persisting problems and partial progress." *Journal of clinical microbiology* 41.6 (2003): 2275-2278.

Weinstein, Melvin P., et al. "The clinical significance of positive blood cultures in the 1990s: a prospective comprehensive evaluation of the microbiology, epidemiology, and outcome of bacteremia and fungemia in adults." *Clinical Infectious Diseases* 24.4 (1997): 584-602.

Weinstein, Melvin P. "Current blood culture methods and systems: clinical concepts, technology, and interpretation of results." *Clinical infectious diseases* 23.1 (1996): 40-46.

Closed IV, BD Saf-T-Intima. "Catheter System, Becton, Dickinson and Company, Brochure." Retrieved from the Internet (Aug. 23, 2019). 4 pages.

Perez, P., et al. "Multivariate analysis of determinants of bacterial contamination of whole-blood donations." *Vox Sanguinis* 82.2 (2002): 55-60.

McDonald, Carl P. "Interventions implemented to reduce the risk of transmission of bacteria by transfusion in the English National Blood Service." *Transfusion Medicine and Hemotherapy* 38.4 (2011): 255-258.

Lifesciences, Edwards. "Conservation. Safety. Simplicity. Edwards VAMP and VAMP Jr. Systems." (2002). 4 pages.

Sheppard, et al., Bacterial Contamination of Platelets for Transfusion: Recent Advances and Issues, *Labmedicine*, vol. 36, No. 12, Dec. 2005 ("Sheppard 2005").

BD Diagnostics, "Venous Blood Collection, BD Vacutainer Passive Shielding Blood Collection Needle" literature (2005) 2 pages.

Barnard, Dorothy R., et al. "Fibronectin (cold insoluble globulin) in the neonate," *The Journal of Pediatrics*, vol. 102, Issue 3, Mar. 1983, pp. 453-455.

Mayer, G.A. "A Method for the Reliable Determination of Clotting Time in Whole Blood," *Canadian Medical Association Journal*, Jun. 15, 1955, vol. 72, pp. 927-929.

Ziegler, R., et al. "Controlled Clinical Laboratory Comparison of Two Supplemented Aerobic and Anaerobic Media Used in Automated Blood Culture Systems to Detect Bloodstream Infections," *Journal of Clinical Microbiology*, Mar. 1998, p. 657-661.

Pall Medical, "Leukotrap Filtration Systems for Whole Blood Derived Platelets, Leukotrap RC PL and Leukotrap PL Systems" literature, (2005) 8 pages.

Meissner, George F., et al., "The Standard Clotting Time, A Method Based on the Use of Whole Venous Blood in Capillary Tubes," *The American Journal of Clinical Pathology*, vol. 39, No. 3., pp. 321-323, Mar. 1963.

U.S. Appl. No. 62/845,767, filed May 9, 2019, Brewer Michael.

JP Office Action mailed Feb. 27, 2024; 11 pages.

Notice of Allowance mailed Jan. 17, 2024; 16 pages.

Office Action (Notice of Section 18) dated Dec. 20, 2023 for IL App No. 309380 (pp. 1-5).

Examination Report dated Sep. 28, 2023, for European Patent Application No. 22181212.6. 5 pages.

JP Notice of Allowance mailed Jun. 20, 2023; 6 pages.

Office Action (Non-Final Rejection) dated Oct. 4, 2023 for U.S. Appl. No. 17/538,990 (pp. 1-47).

Notice of Allowance mailed Sep. 14, 2023; 90 pages.

Notice of Allowance mailed Sep. 8, 2023; 35 page.

Office Action (Final Rejection) dated Aug. 25, 2023 for U.S. Appl. No. 18/113,710 (pp. 1-50).

Japanese Patent Office, Notice of Reasons for Rejection for JP Application No. JP 2020-118498 date Aug. 10, 2021.

Japanese Patent Office, Notice of Reasons for Rejection dated Jun. 15, 2021, Application No. JP 2019-534792, 6 pages.

Japanese Patent Office, Notice of Reasons for Rejection, Japanese patent application No. JP2018-523384, dated Jul. 23, 2019, 5 pages.

European Patent Office; Communication pursuant to Article 94(3) EPC, dated Oct. 31, 2018; 11 pages.

Examination Report No. 1 dated Apr. 29, 2020, for Australian Patent Application No. 2016297849. 3 pages.

European Patent Application No. EP19200766.4 extended European Search Report dated Dec. 2, 2019, 11 pages.

European Patent Office, Extended European Search Report for European Patent Application 20197213.0-1132, dated Dec. 9, 2020, 6 pages.

Communication Under Rule 71(3) EPC dated Apr. 22, 2020 for EP application No. 17840467.9. 125 pages.

Office Action (Non-Final Rejection) dated Jan. 25, 2024 for IL App. 302893 (pp. 1-3).

Office Action (Non-Final Rejection) dated Apr. 25, 2023 for U.S. Appl. No. 16/838,017 (pp. 1-20).

Office Action (Final Rejection) dated Jan. 29, 2024 for U.S. Appl. No. 16/838,017 (pp. 1-44).

"Membrane Definition & Meaning," Merriam-Webster, Merriam-Webster, Apr. 22, 2009, www.merriam-webster.com/dictionary/membrane. (Year: 2009).

Office Action (Advisory Action) dated Feb. 9, 2024 for U.S. Appl. No. 16/838,017 (pp. 1-6).

Office Action (Non-Final Rejection) dated Apr. 16, 2024 for U.S. Appl. No. 16/838,017 (pp. 1-19).

Office Action (Non-Final Rejection) dated May 21, 2024 for IL App. 286812 (pp. 1-3).

First Office Action (Non-Final Rejection) dated Jan. 16, 2024 for JP App. 2021-558648 (pp. 1-6).

First Office Action (Non-Final Rejection) dated Sep. 27, 2023 for CN App. 202080000666.0 (pp. 1-11).

Second Office Action (Non-Final Rejection) dated Apr. 28, 2024 for CN App. 202080000666.0 (pp. 1-11).

European Patent Office, Extended European Search Report for European Patent Application 21818838.1-1122, dated Apr. 22, 2024, 11 pages.

European Patent Office, Extended European Search Report for European Patent Application 23155927.9-1122, dated Jul. 26, 2023, pp. 1-8.

Office Action (Non-Final Rejection) mailed Oct. 4, 2023 for U.S. Appl. No. 17/538,900 (1-47).

First Office Action (Non-Final Rejection) dated Aug. 3, 2023 for CN Application No. 202010300942.7. 21 pages.

Office Action (Non-Final Rejection) dated Feb. 21, 2023 for U.S. Appl. No. 17/893,079, pp. 1-32.

Office Action (Final Rejection) dated Jul. 19, 2023 for U.S. Appl. No. 17/893,079, pp. 1-21.

Advisory Action dated Sep. 29, 2023 for U.S. Appl. No. 17/893,079, pp. 1-24.

European Patent Office, Extended European Search Report for European Patent Application 20781928.5-1122 dated Oct. 28, 2022, pp. 1-10.

Rule 70(a) Communication for European Application No. 20781928.5-1122 dated Nov. 15, 2022, 1 page.

International Search Report and Written Opinion dated Mar. 19, 2020 for PCT application No. PCT/US2020/023617. pages.

International Search Report and Written Opinion dated Sep. 28, 2021 for PCT application No. PCT/US2021/035294. 7 pages.

European Patent Office, Extended European Search Report for European Patent Application 22181212.6-1122 dated Oct. 24, 2022, pp. 1-10.

Australian Patent Office, Australian Examination Report No. 1 for Application No. 2021120 622 dated Mar. 18, 2022, 3 pages.

Notice of Allowance mailed Mar. 1, 2023; 3 pages.

First Office Action dated Nov. 24, 2021 for IL Application No. 286030, pp. 1-3.

Notice of Allowance mailed Jan. 29, 2023; 87 pages.

Office Action (Non-Final Rejection) dated Aug. 10, 2021 for Japanese Application No. 2020-118498, pp. 1-7.

(56)

References Cited

OTHER PUBLICATIONS

Office Action (Non-Final Rejection) dated Mar. 28, 2022 for Japanese Application No. 2020-118498, pp. 1-3.

Office Action (Non-Final Rejection) dated Sep. 1, 2022 for Japanese Application No. 2020-118498, pp. 1-4.

Notice of Allowance mailed Apr. 4, 2023; 6 pages.

Rule 71(3) Communication and Text for Grant mailed Aug. 31, 2022 for European Application No. 19200766.4-1122. 189 pages.

Office Action (Non-Final Rejection) mailed Jan. 21, 2022 for Israeli Application No. 267684. 3 pages.

Notice of Allowance mailed Feb. 14, 2023; 122 pages.

* cited by examiner

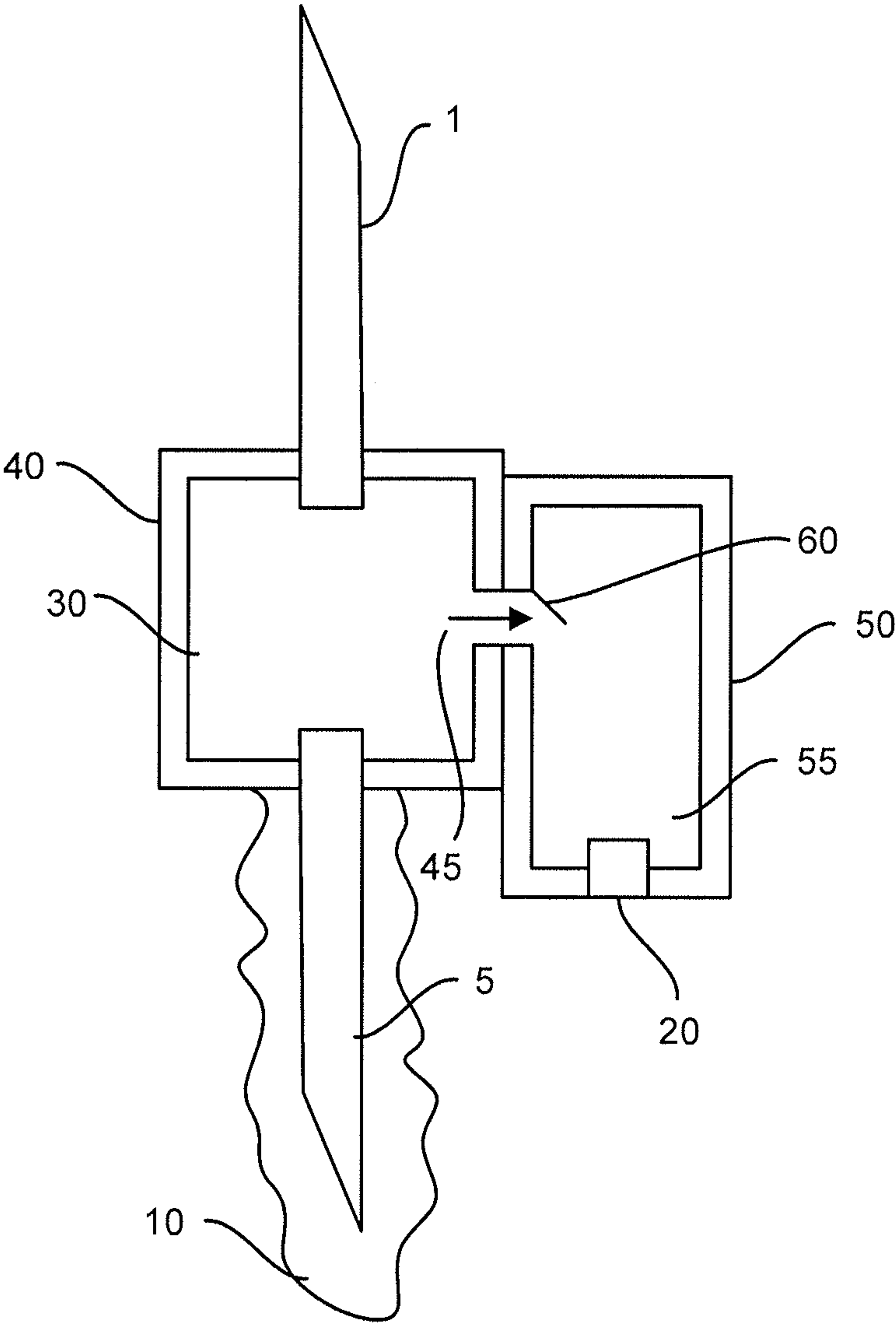


FIG. 1

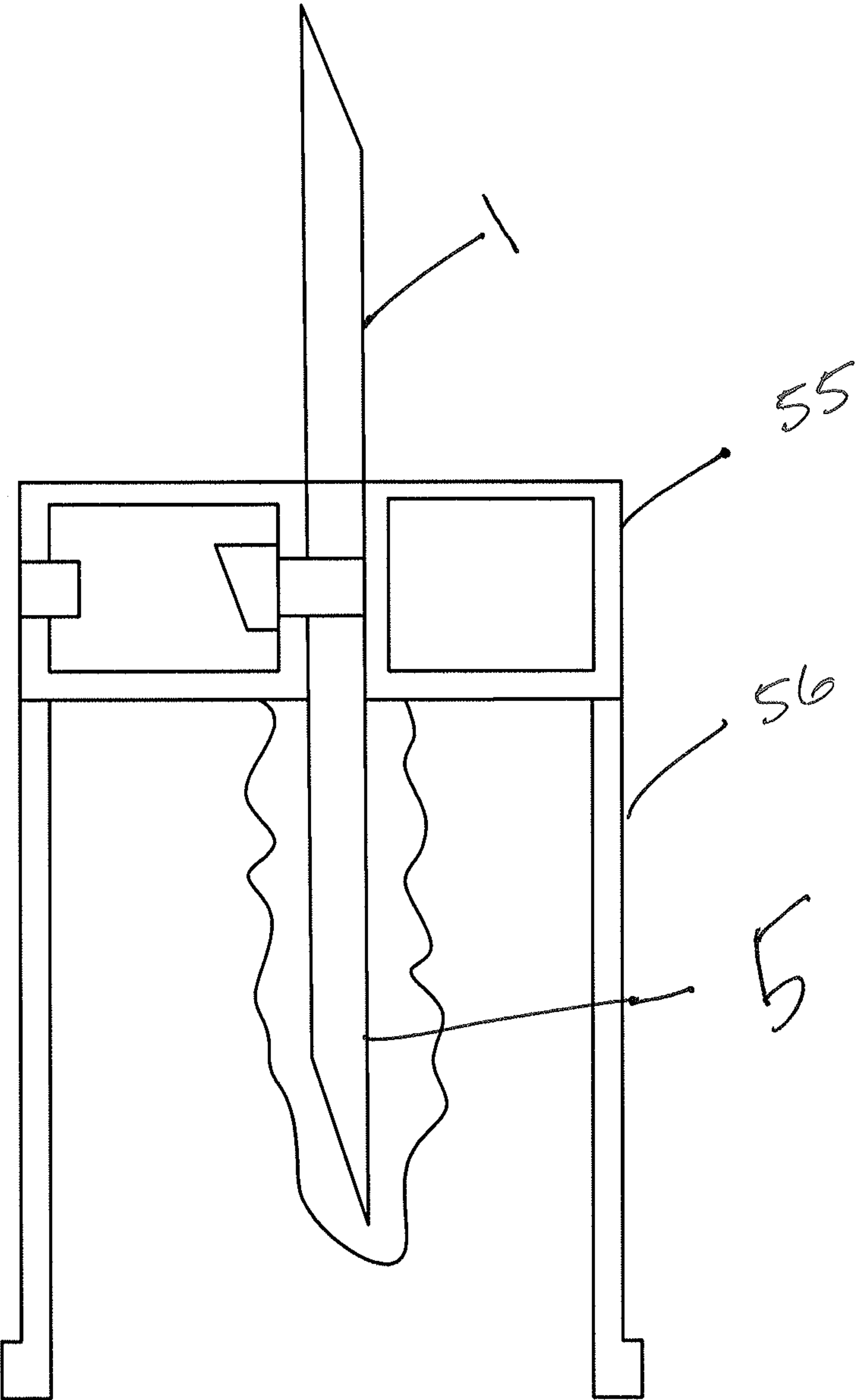


FIG. 2

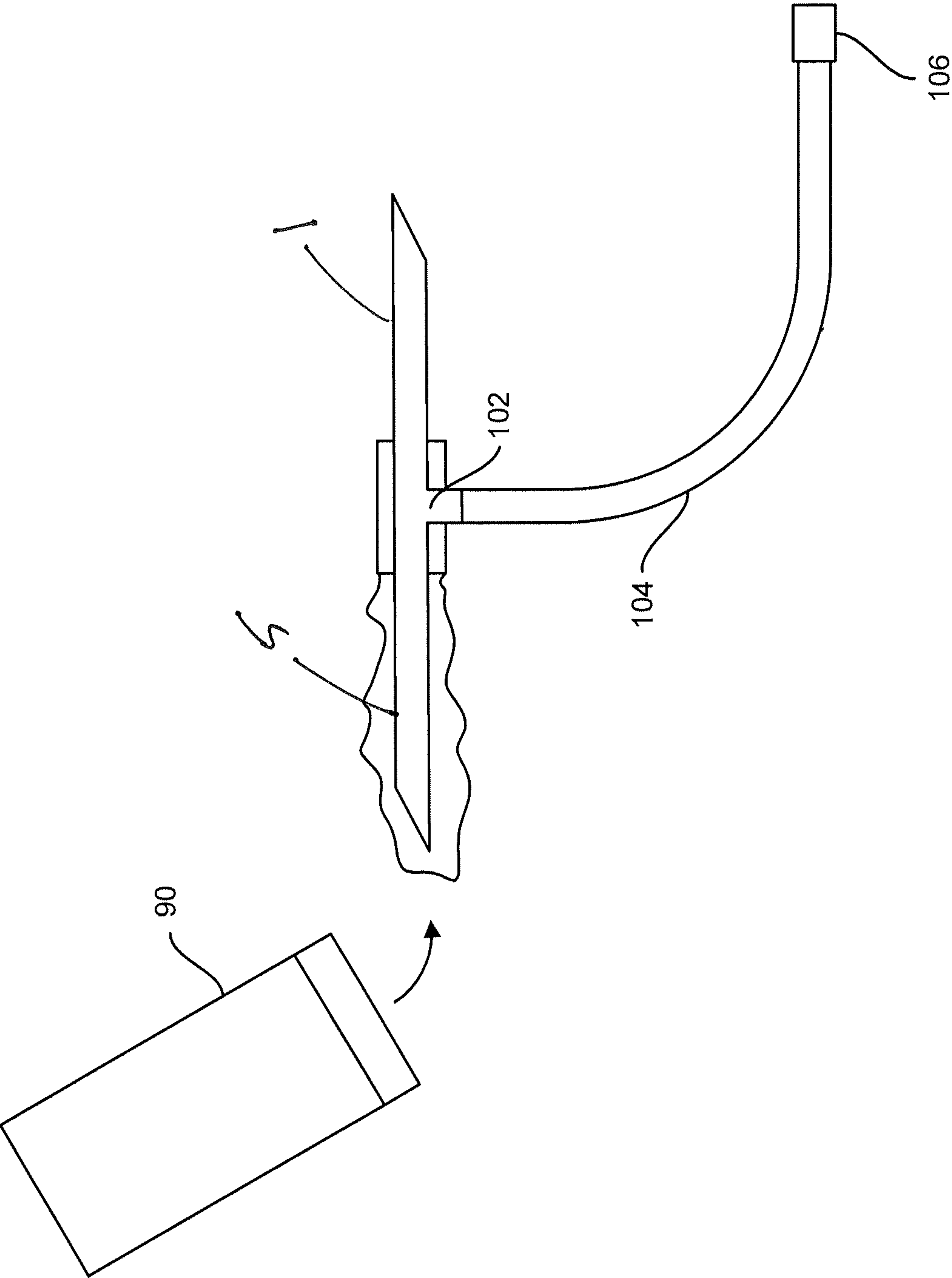


FIG. 3

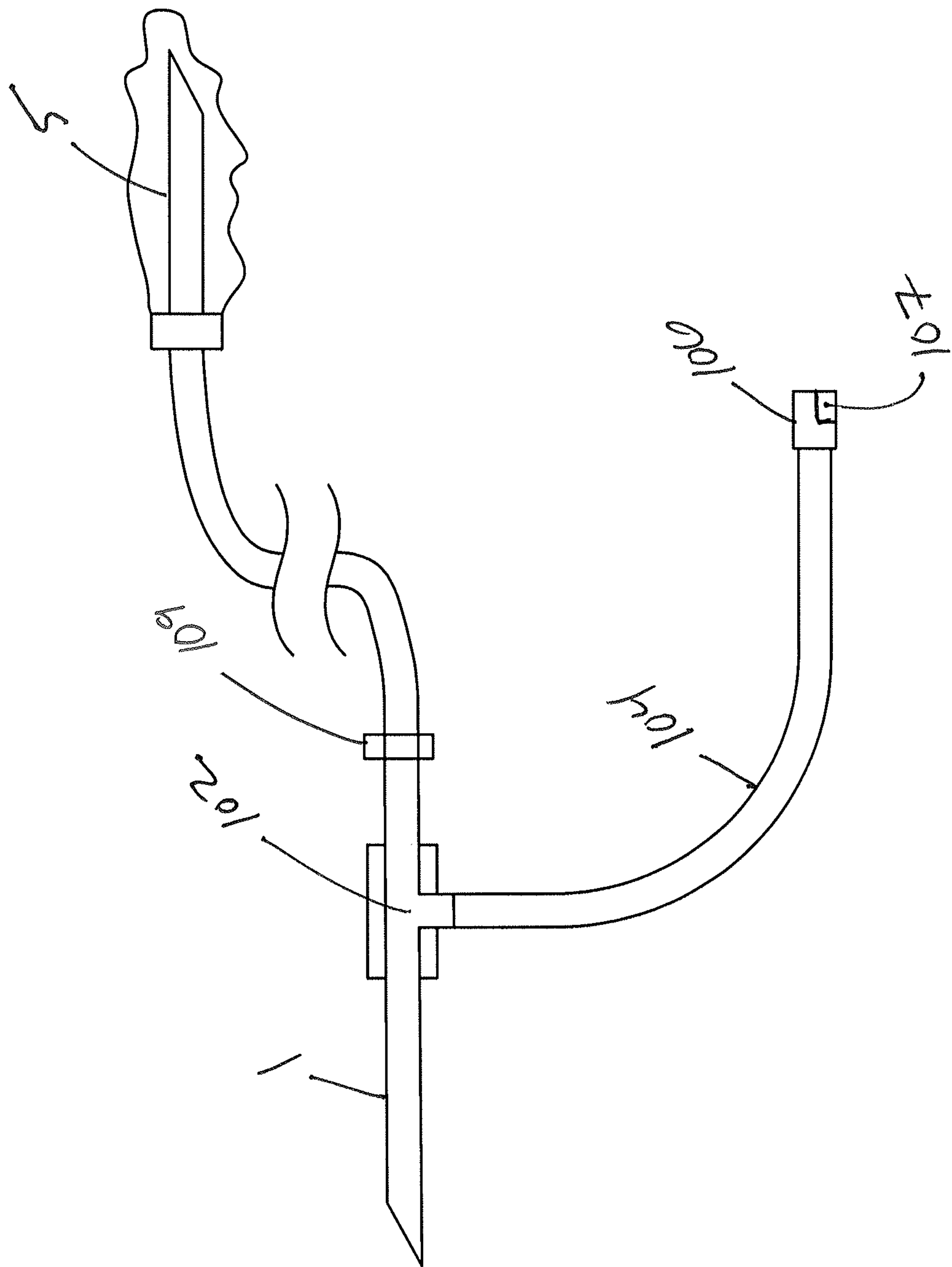


FIG. 4

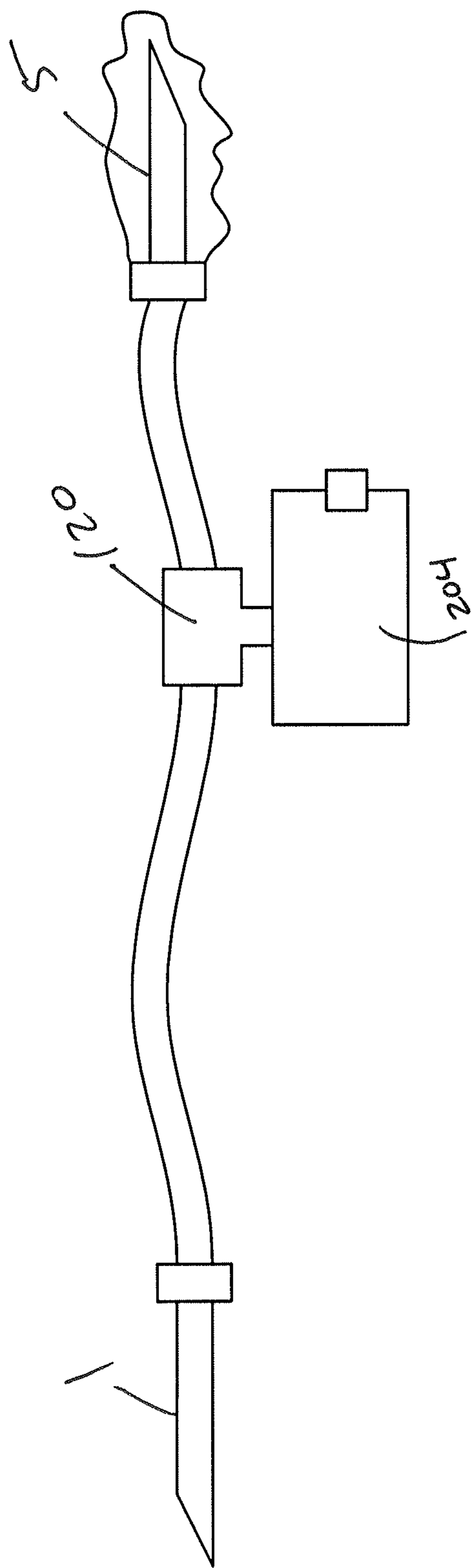


FIG. 5

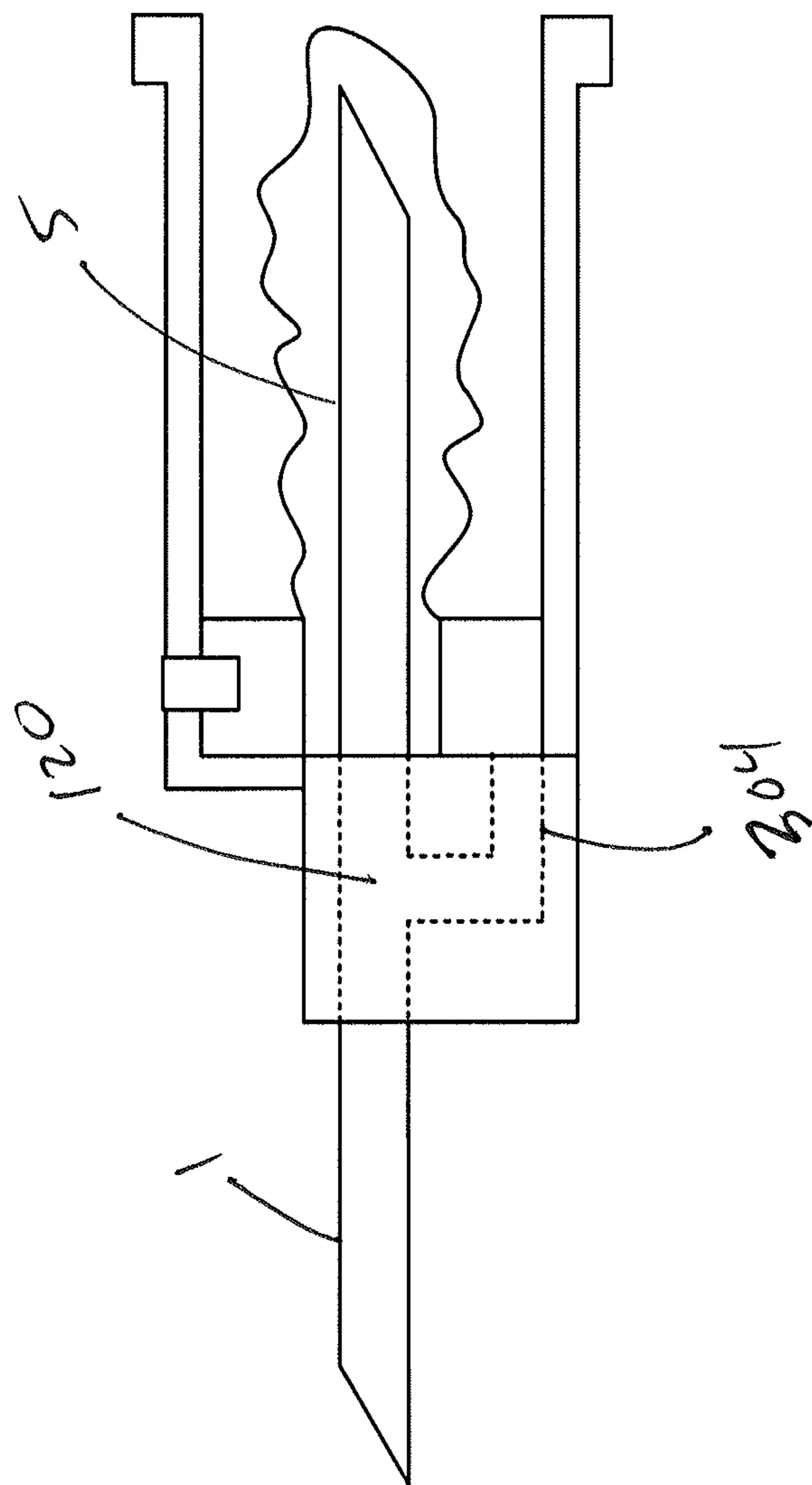


FIG. 6

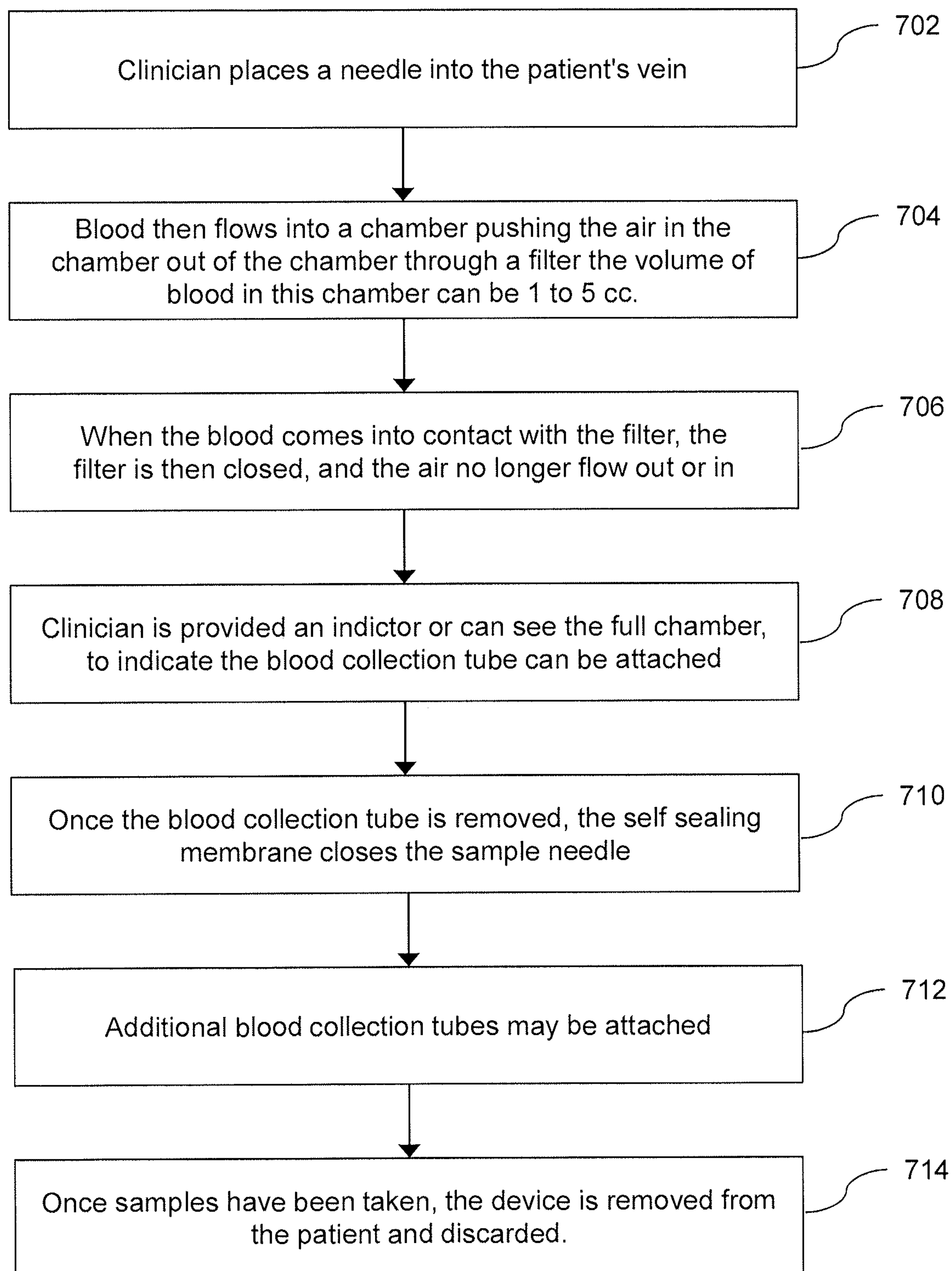


FIG. 7

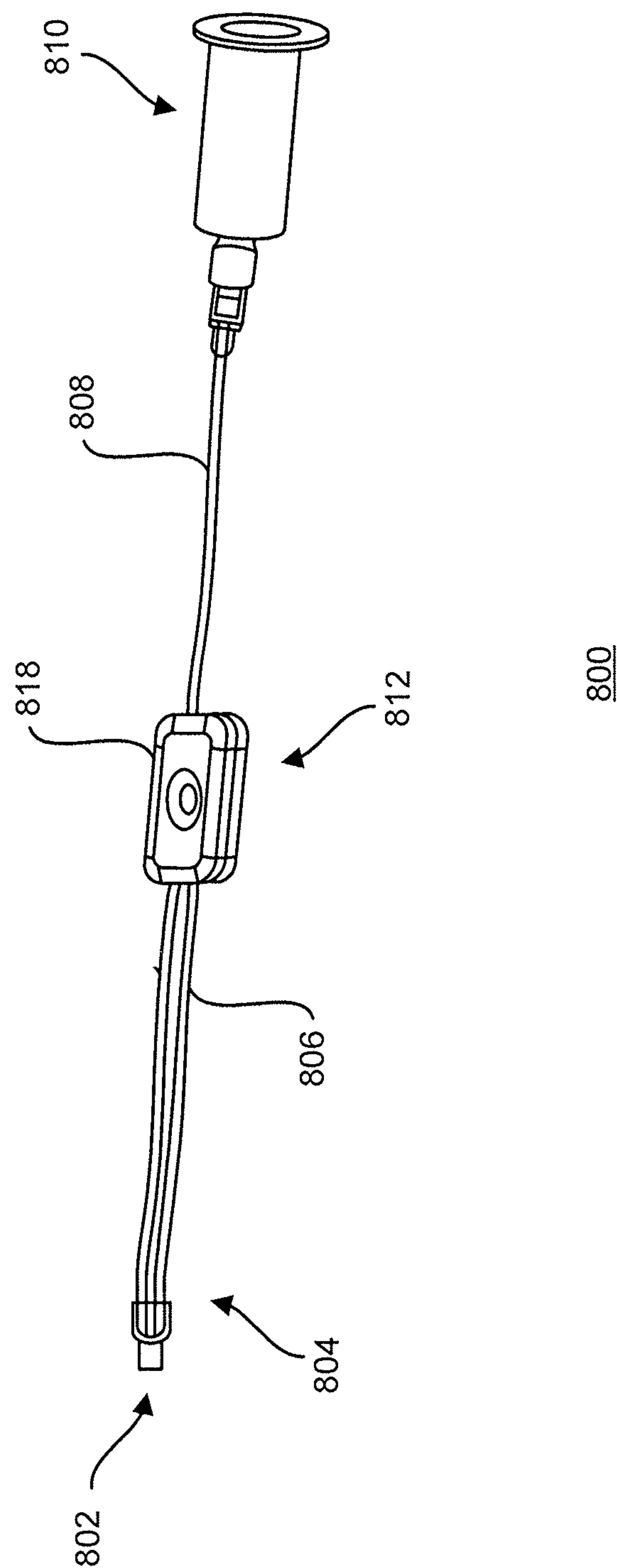


FIG. 8A

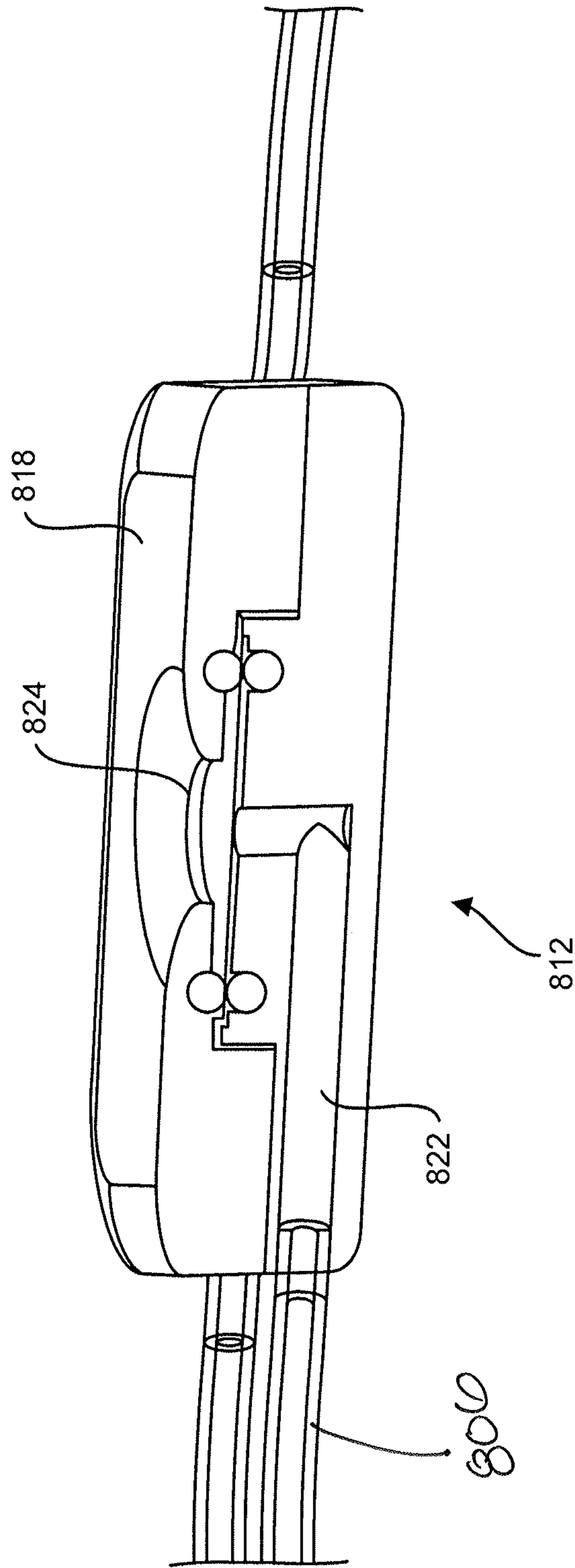


FIG. 8B

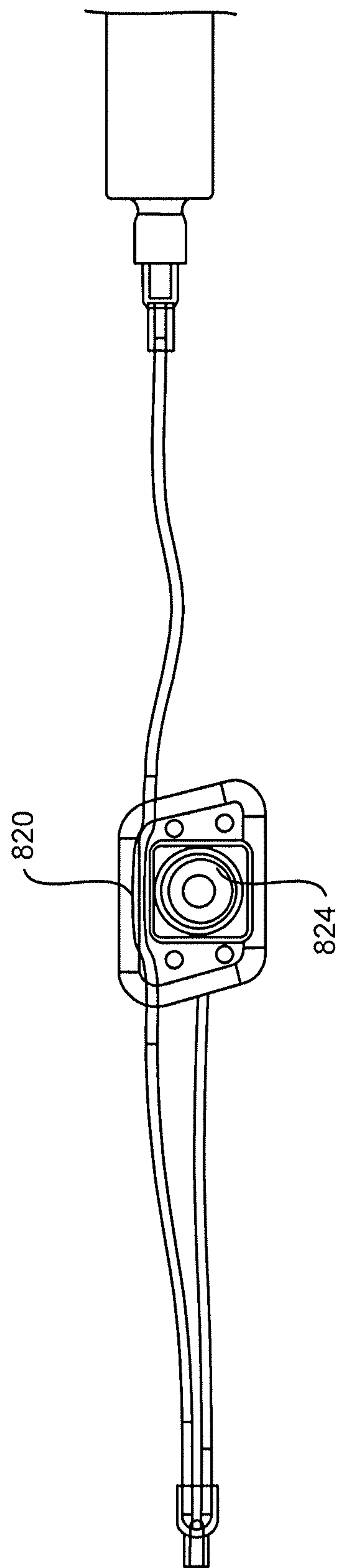


FIG. 8C

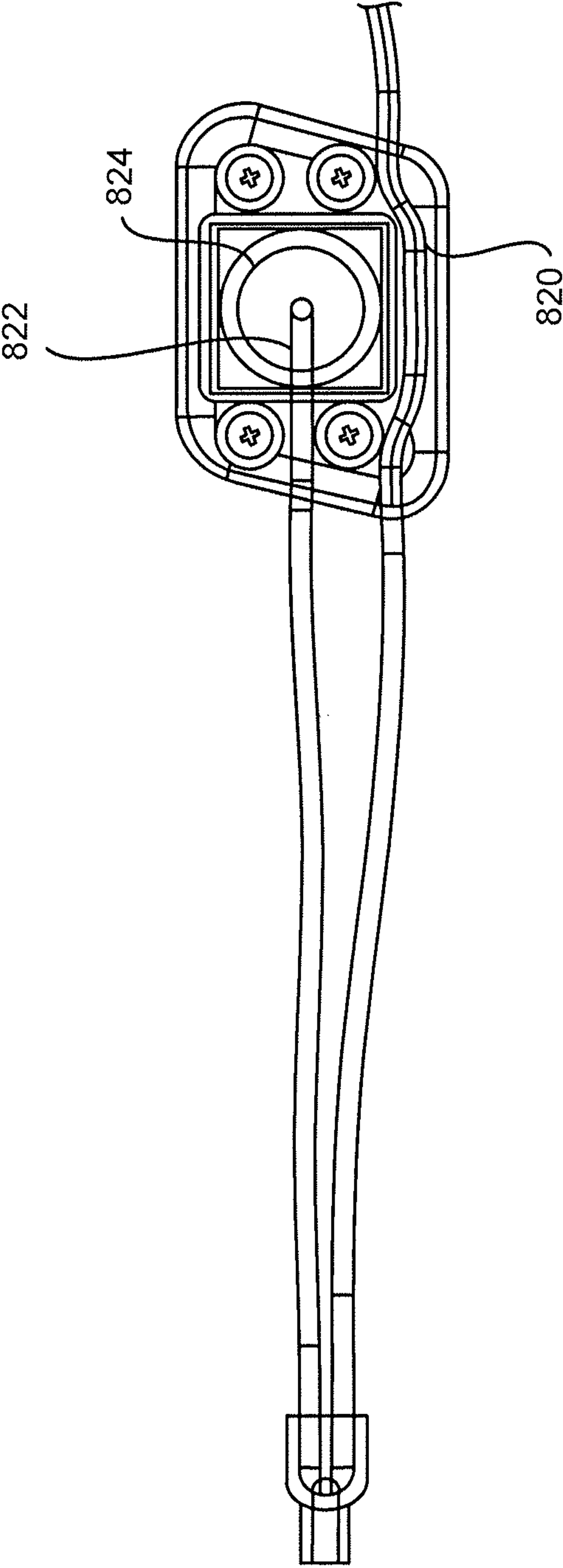


FIG. 8D

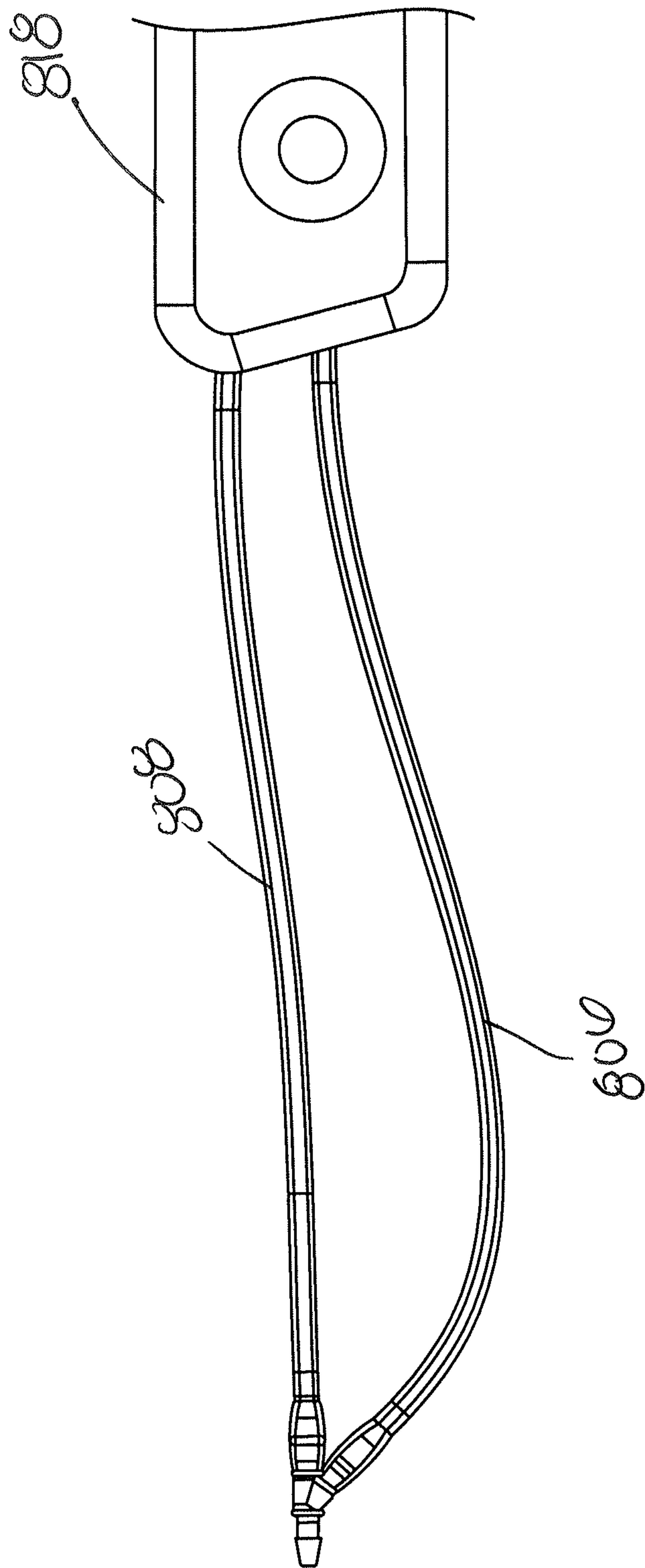


FIG. 8E

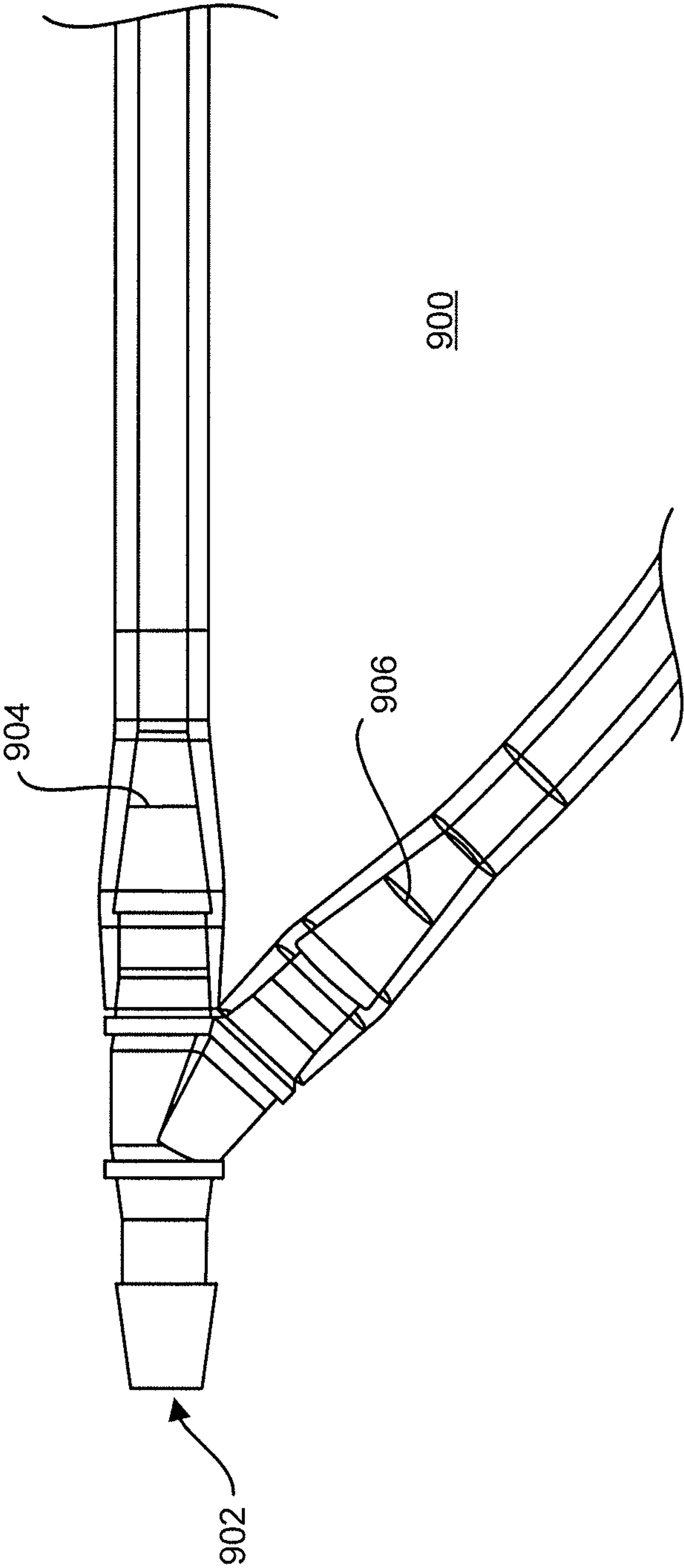


FIG. 9

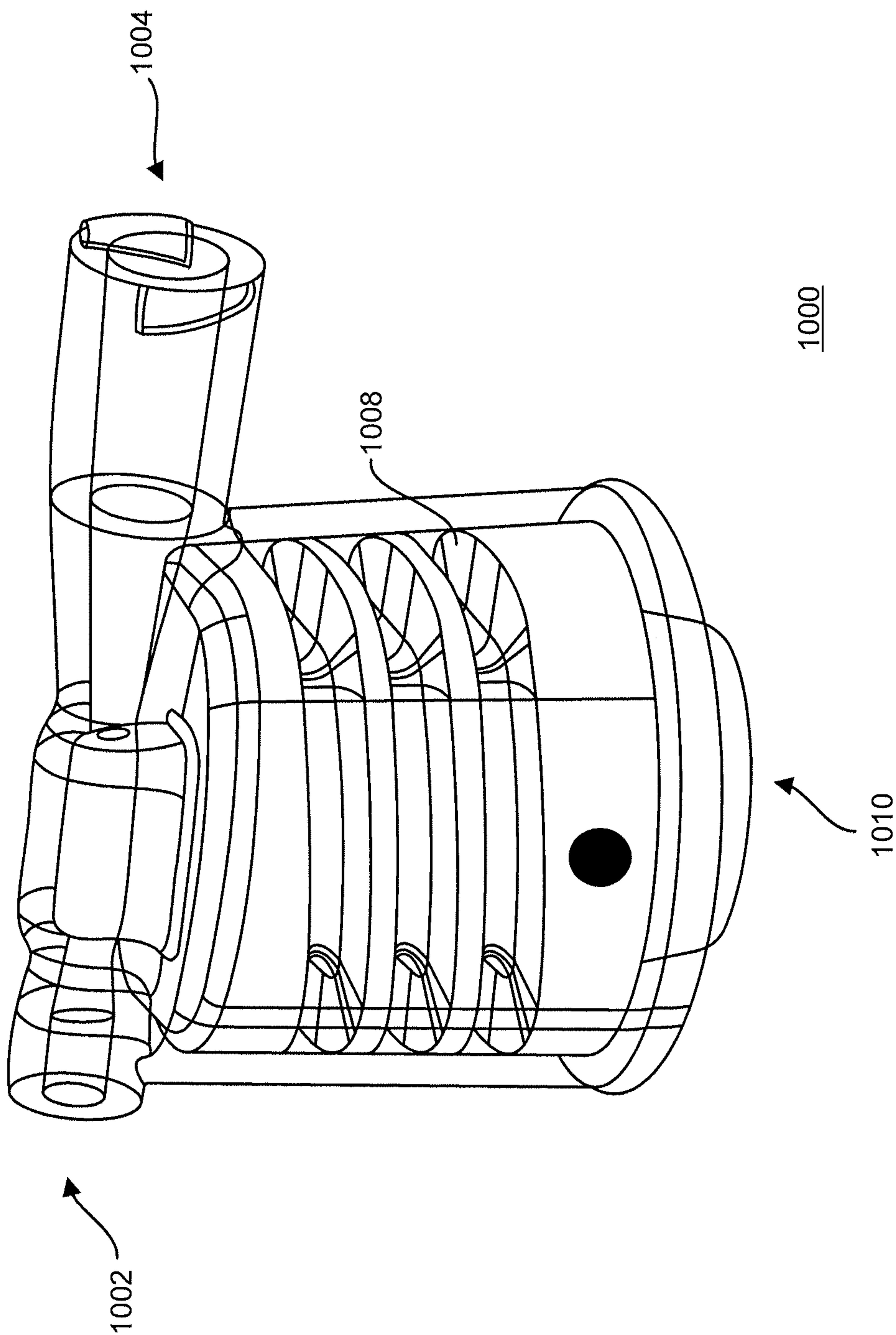


FIG. 10A

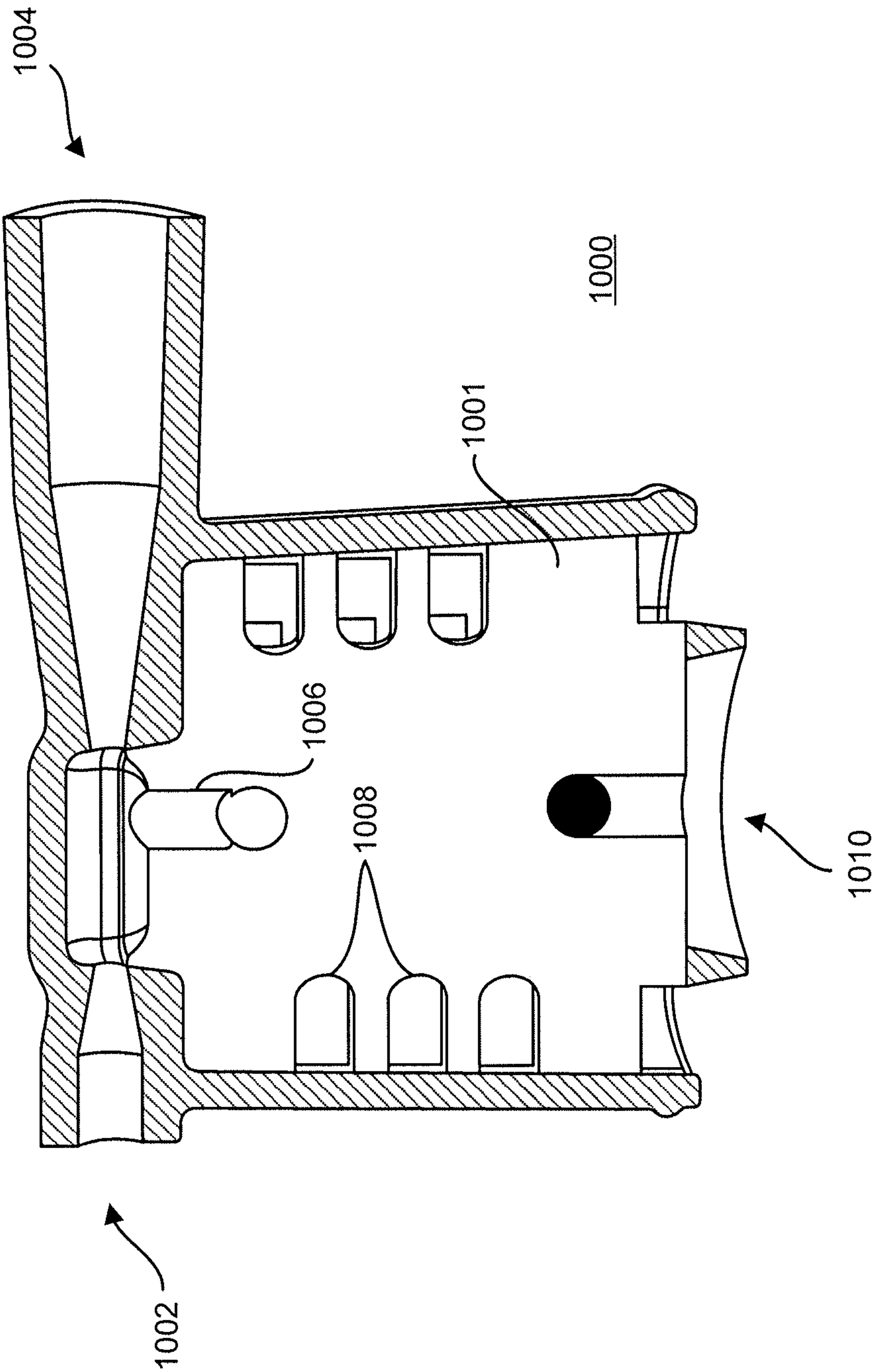


FIG. 10B

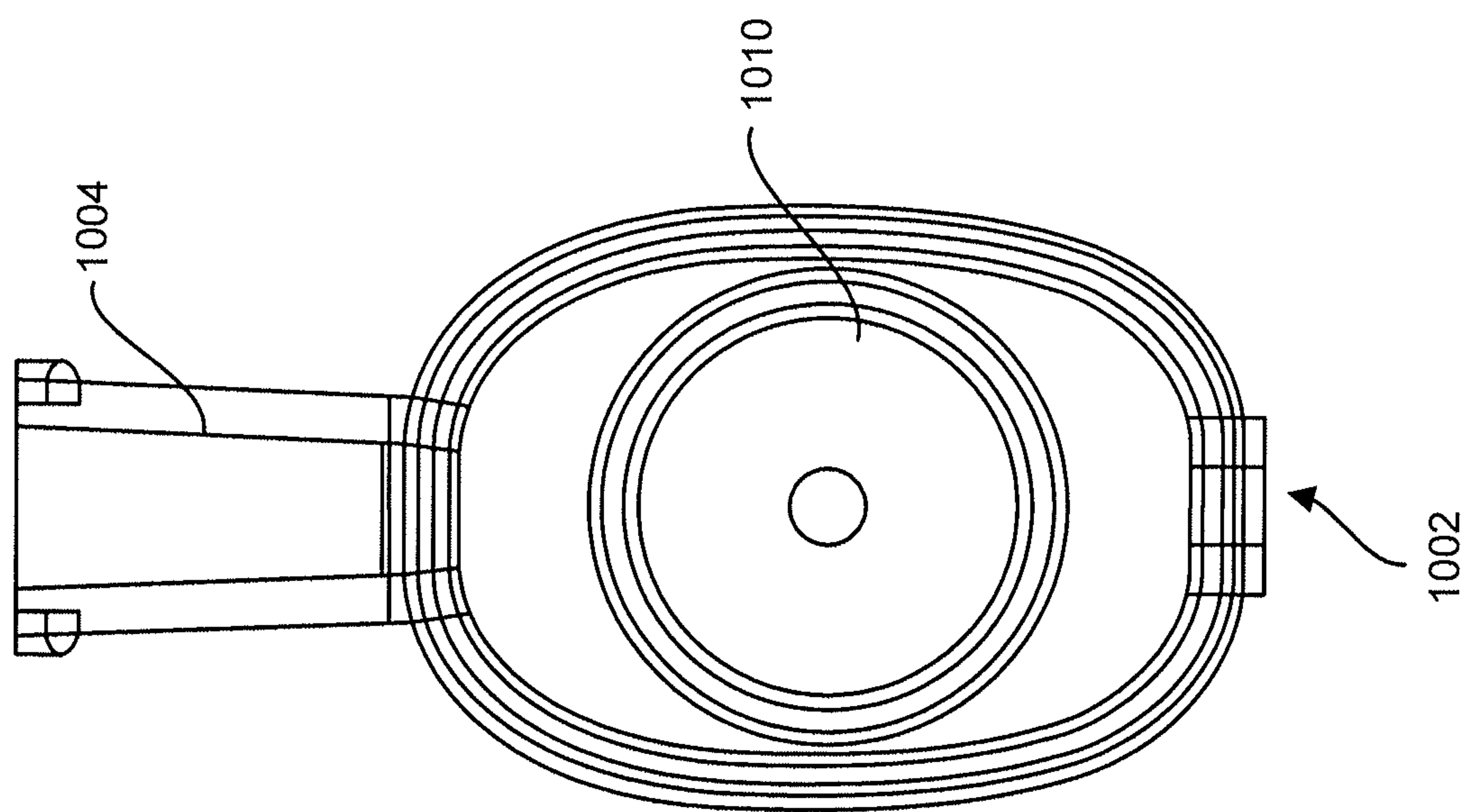


FIG. 10C

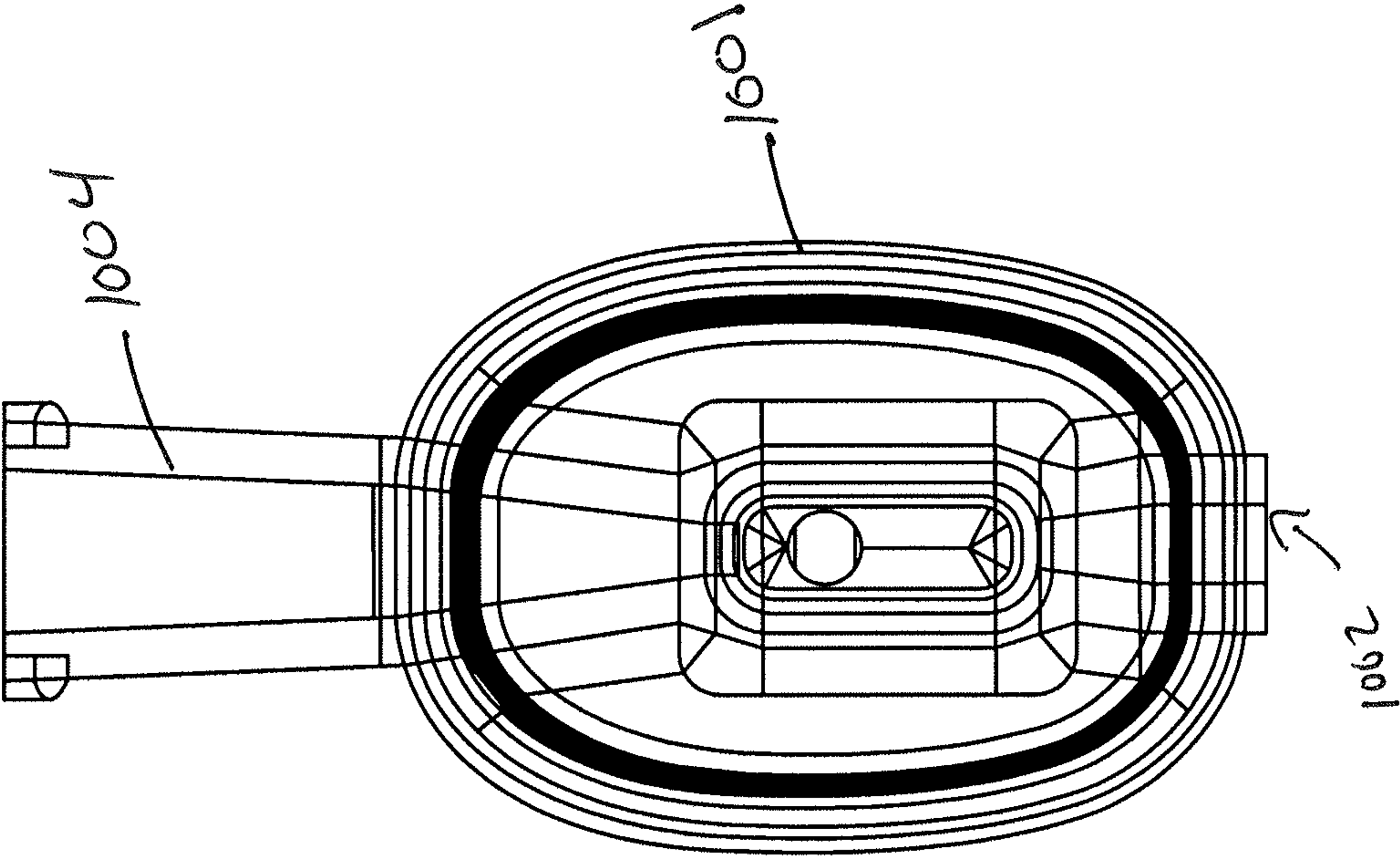


FIG. 10D

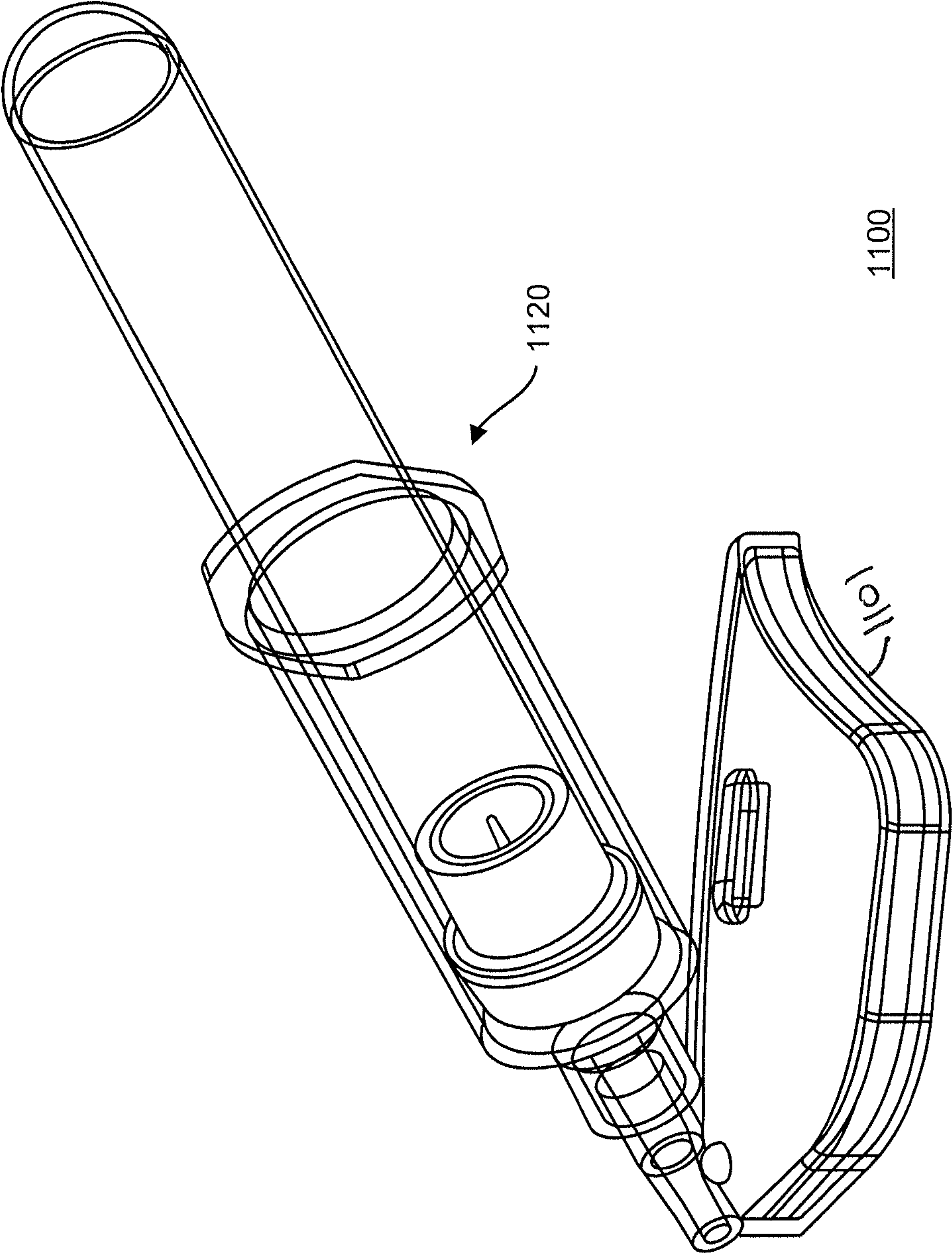


FIG. 11A

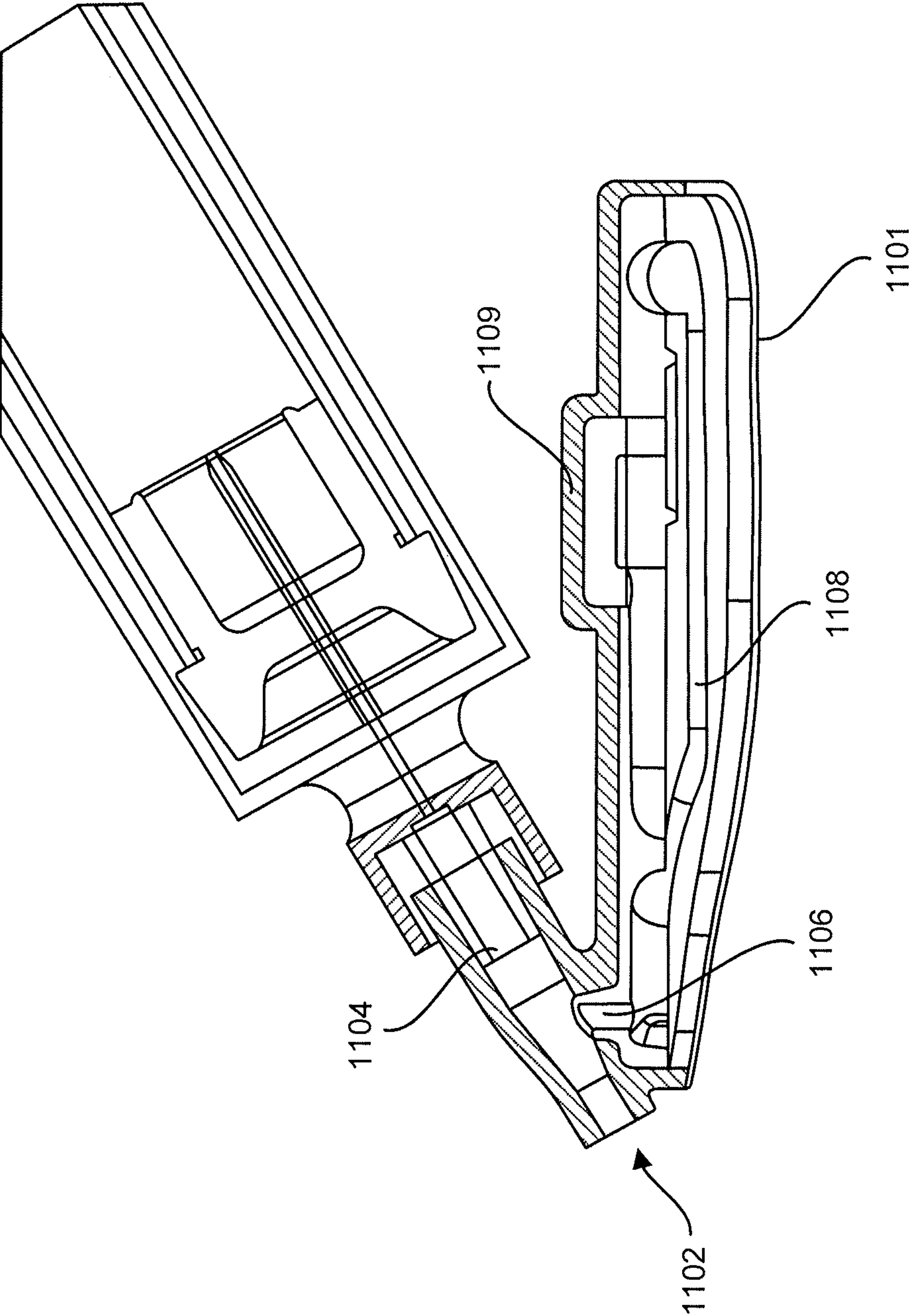


FIG. 11B

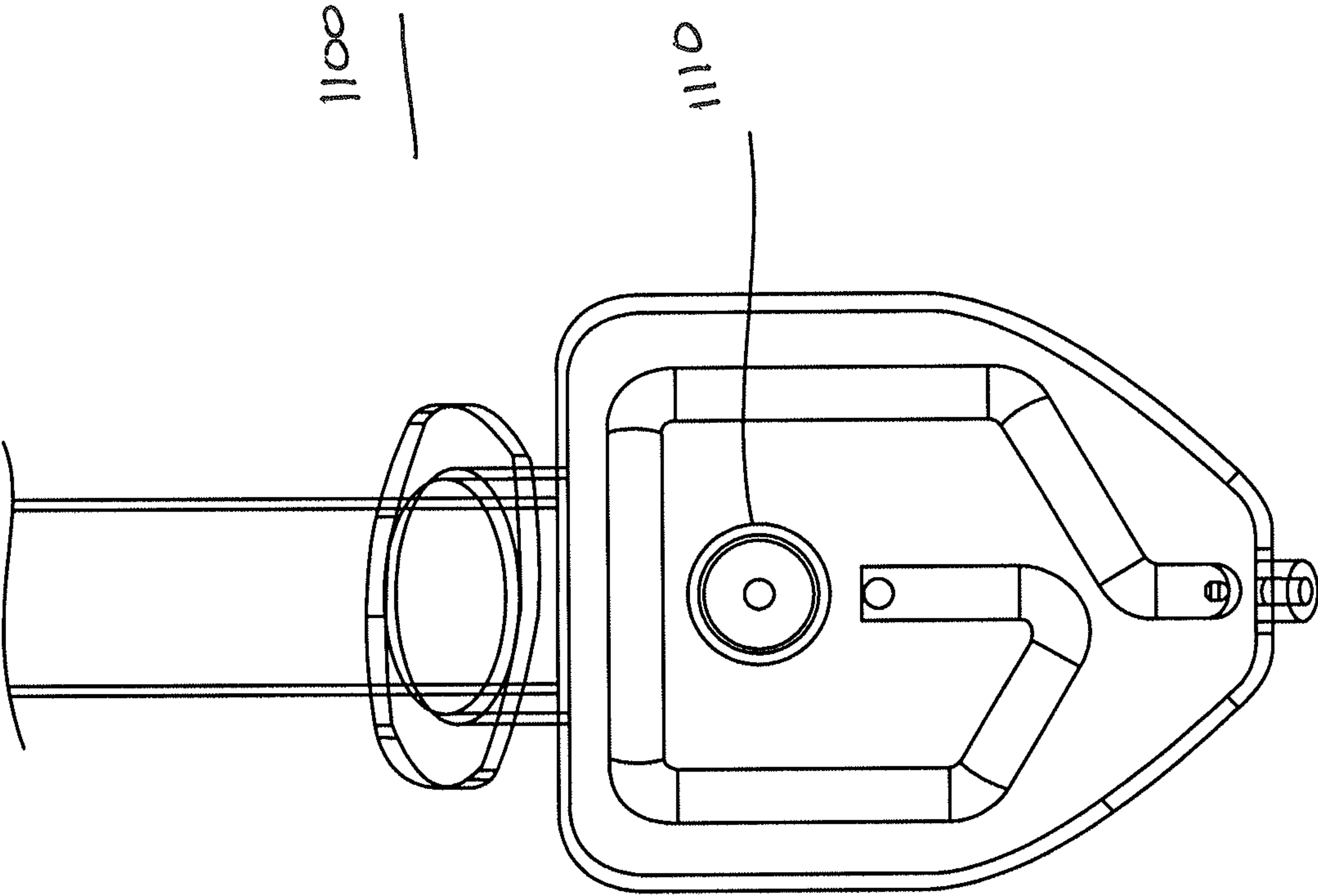


FIG. 11C

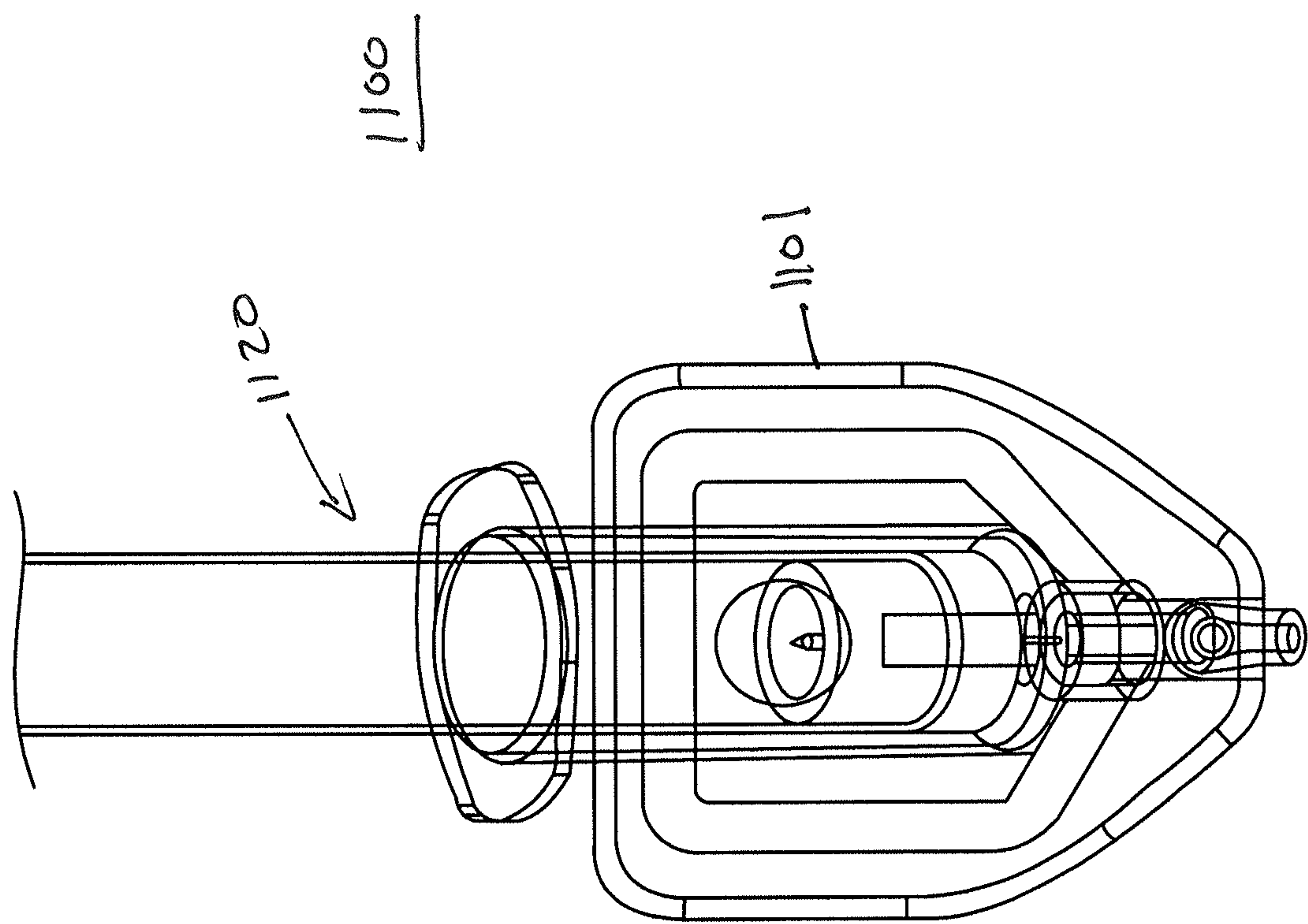


FIG. 11D

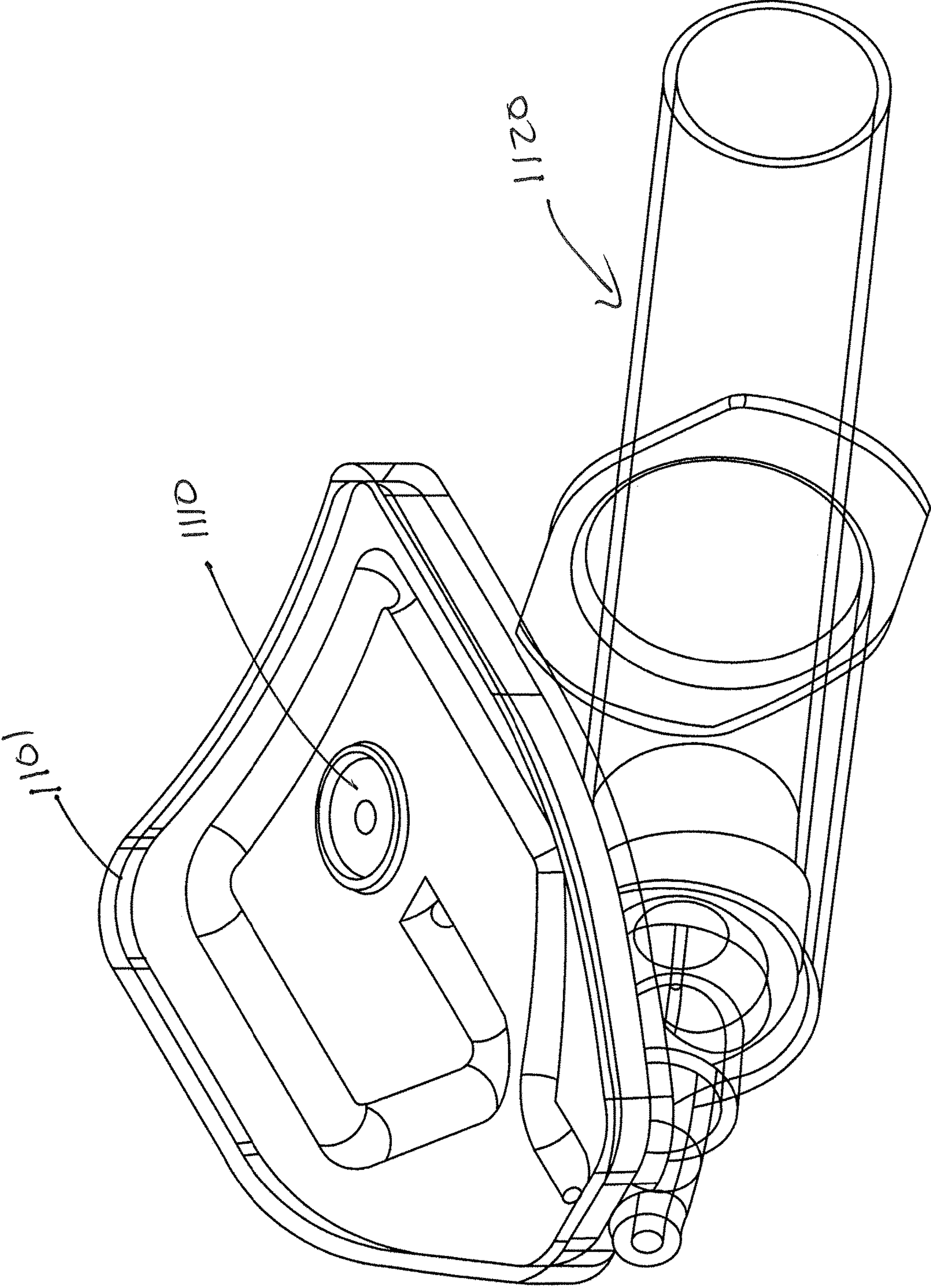


FIG. 11E

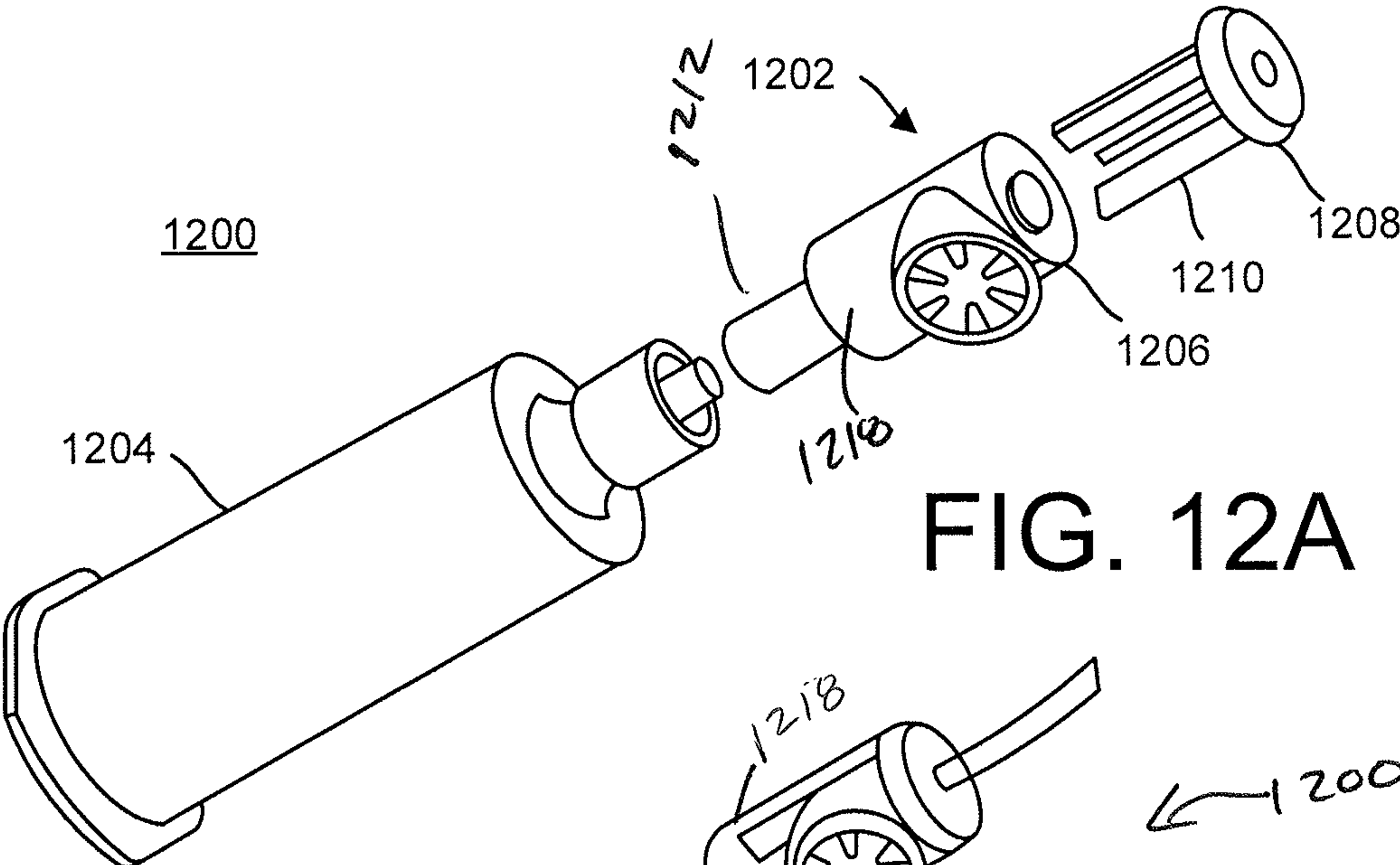


FIG. 12A

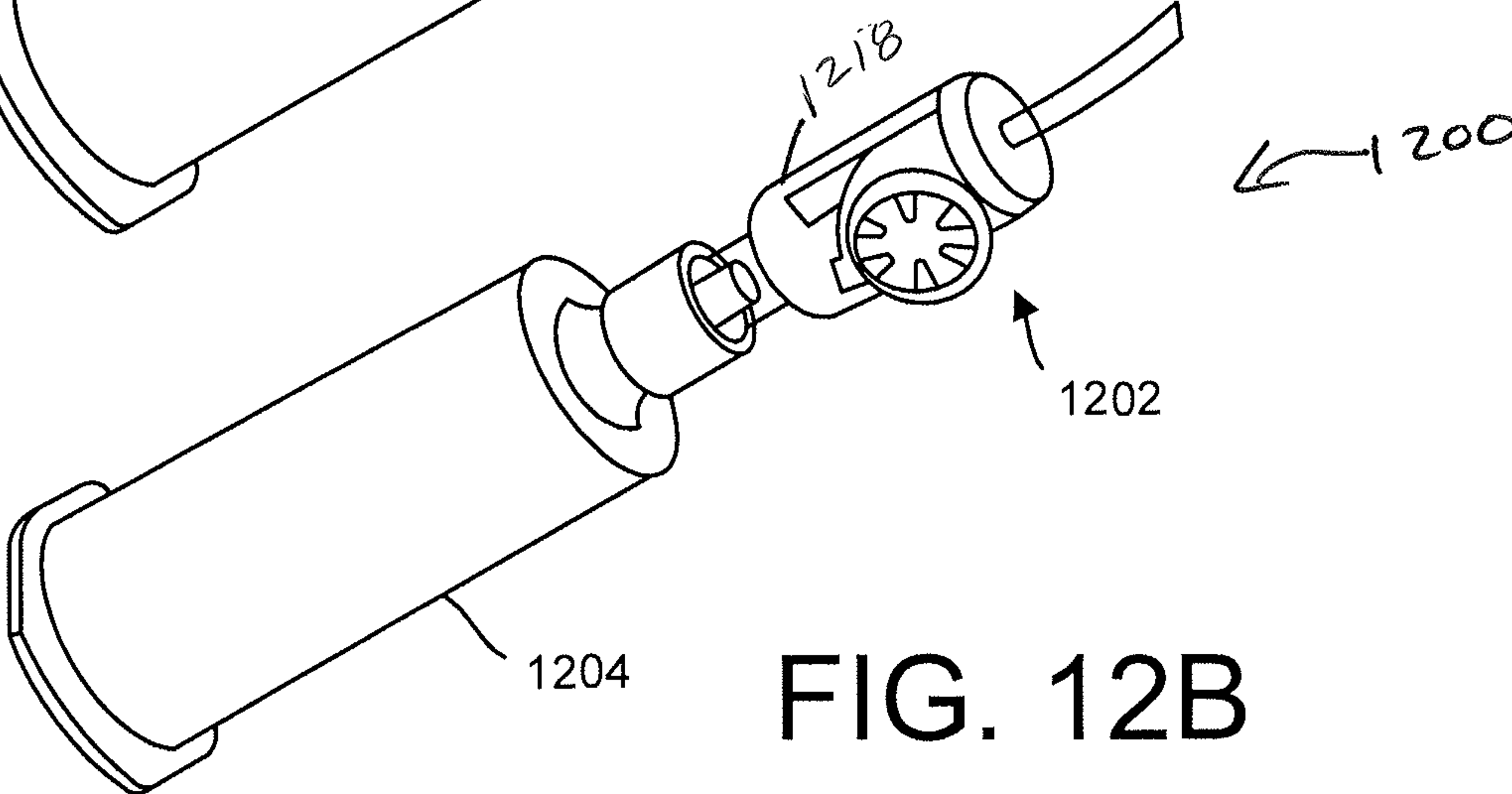


FIG. 12B

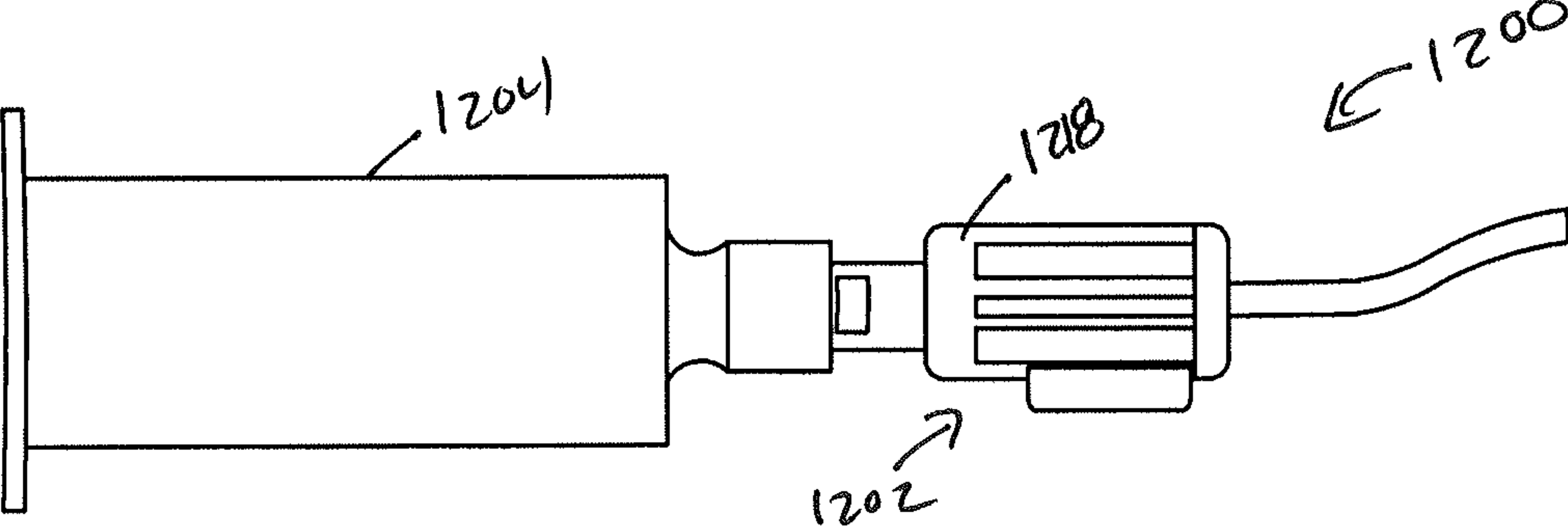


FIG. 12C

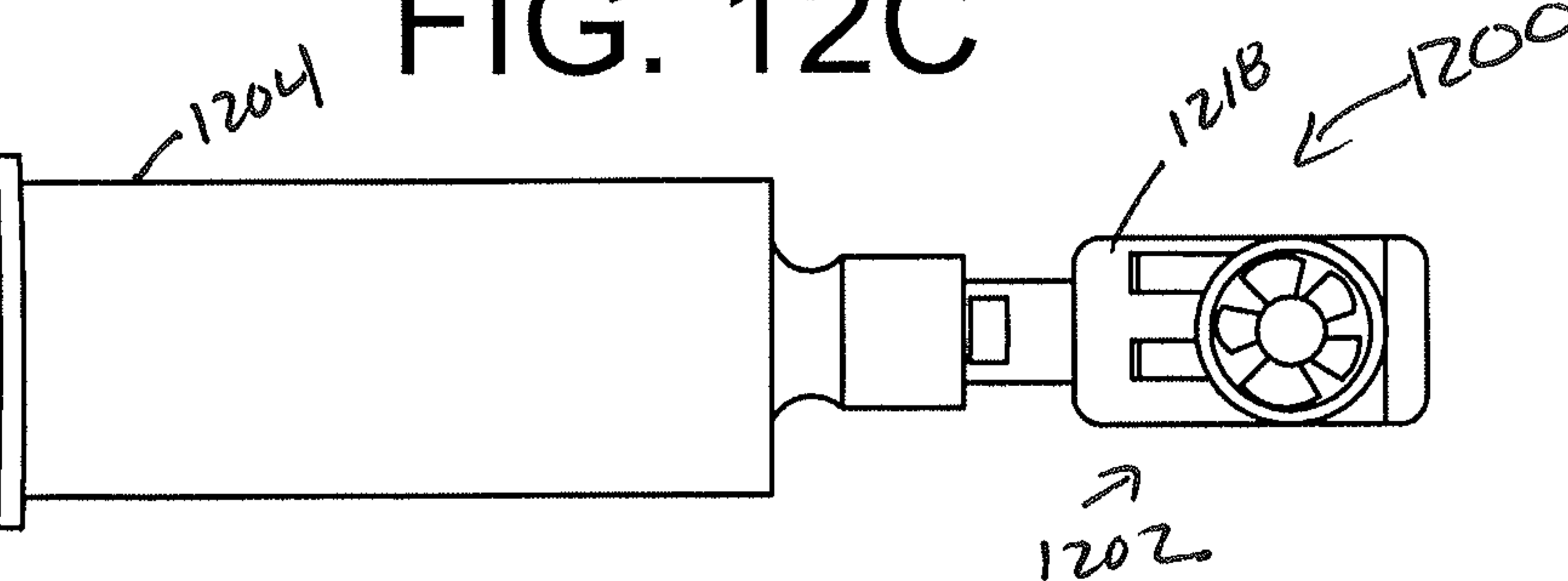


FIG. 12D

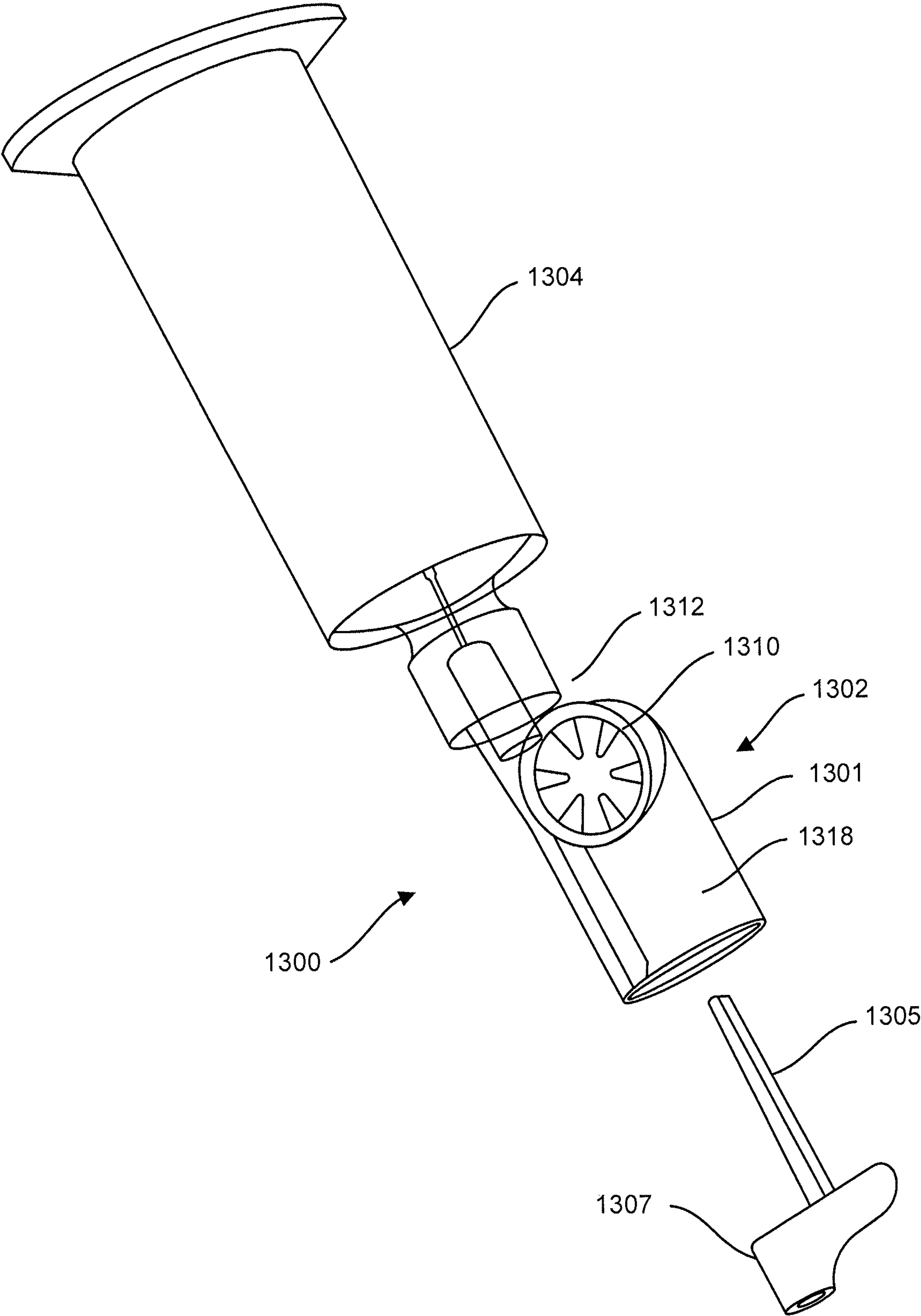


FIG. 13A

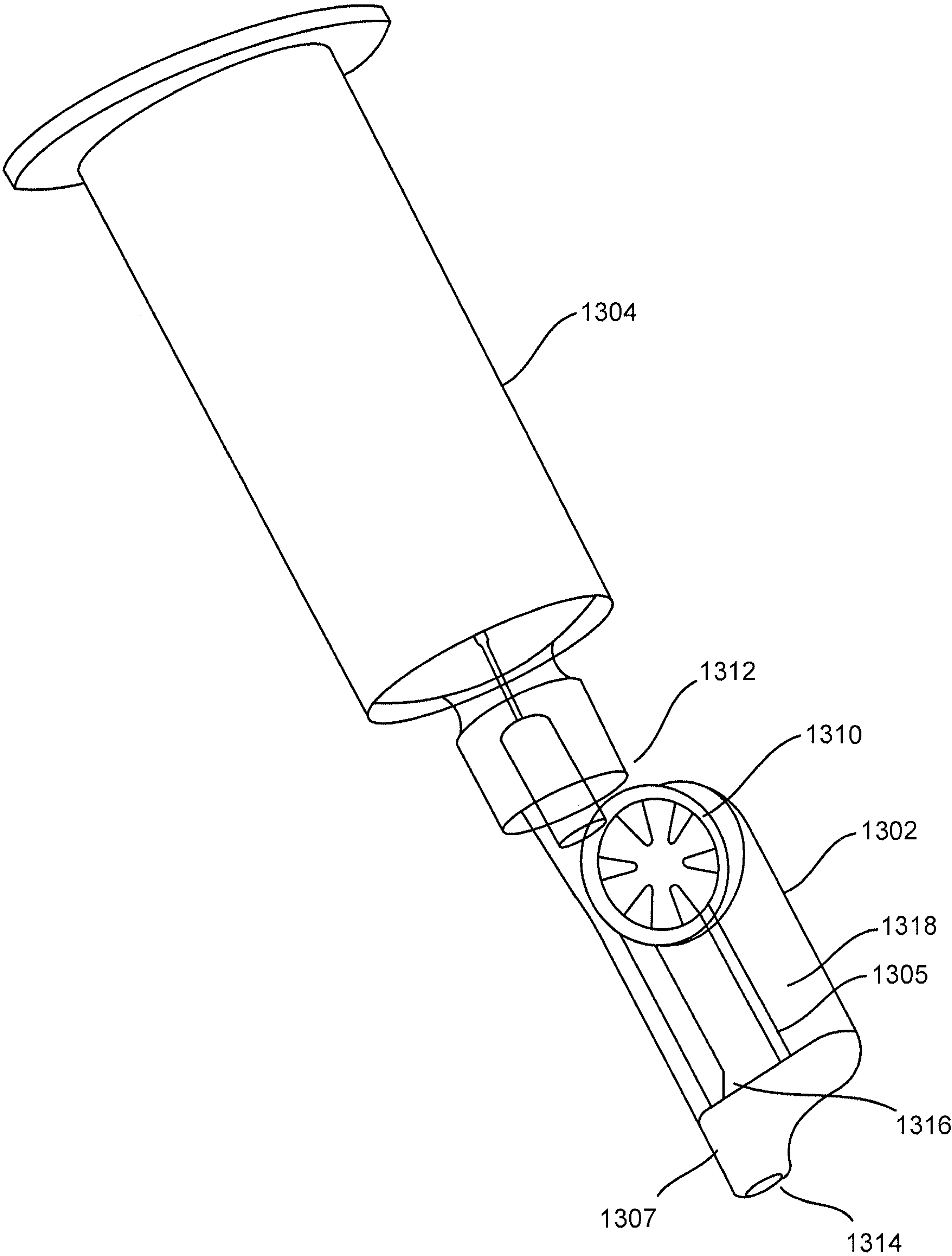


FIG. 13B

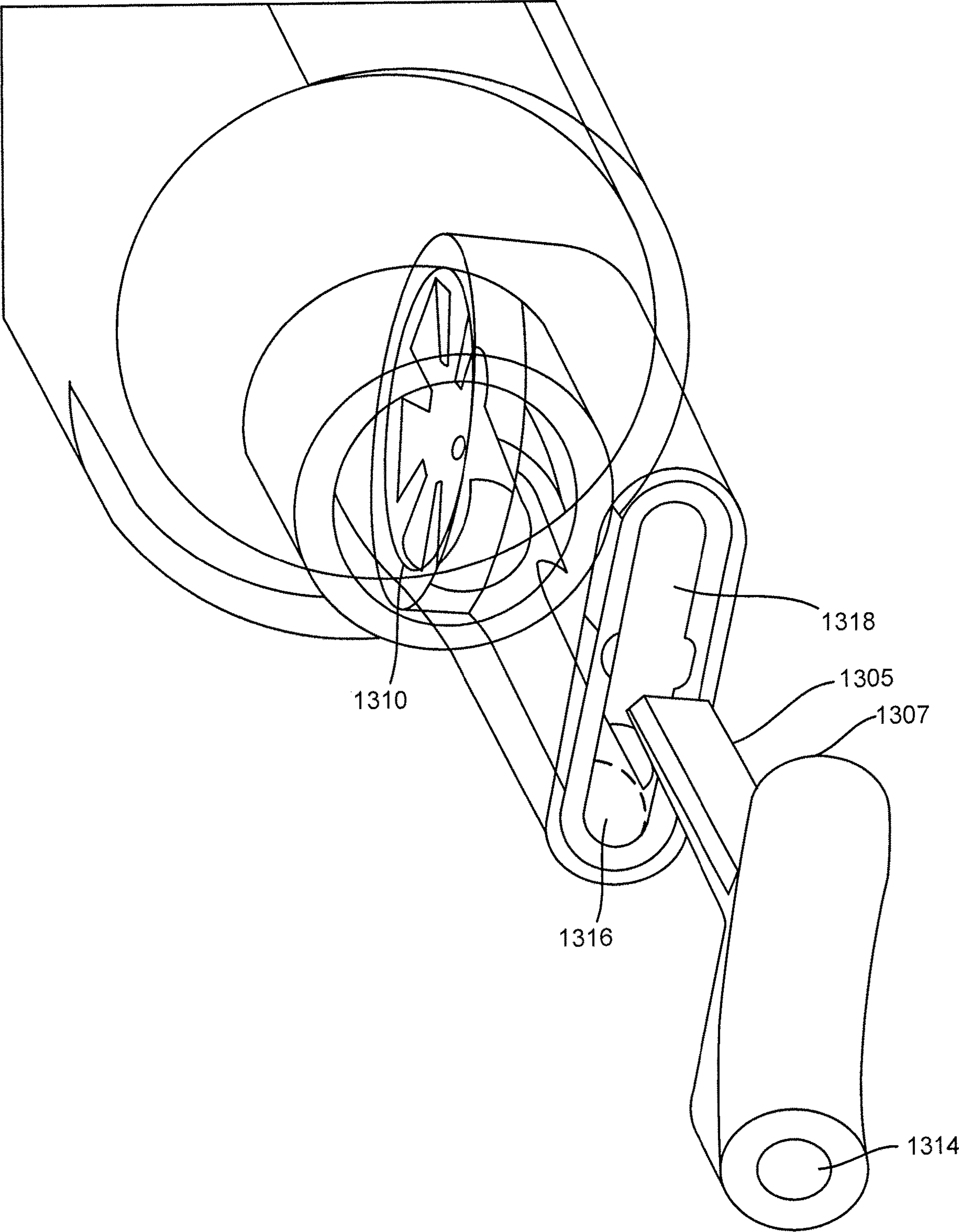


FIG. 13C

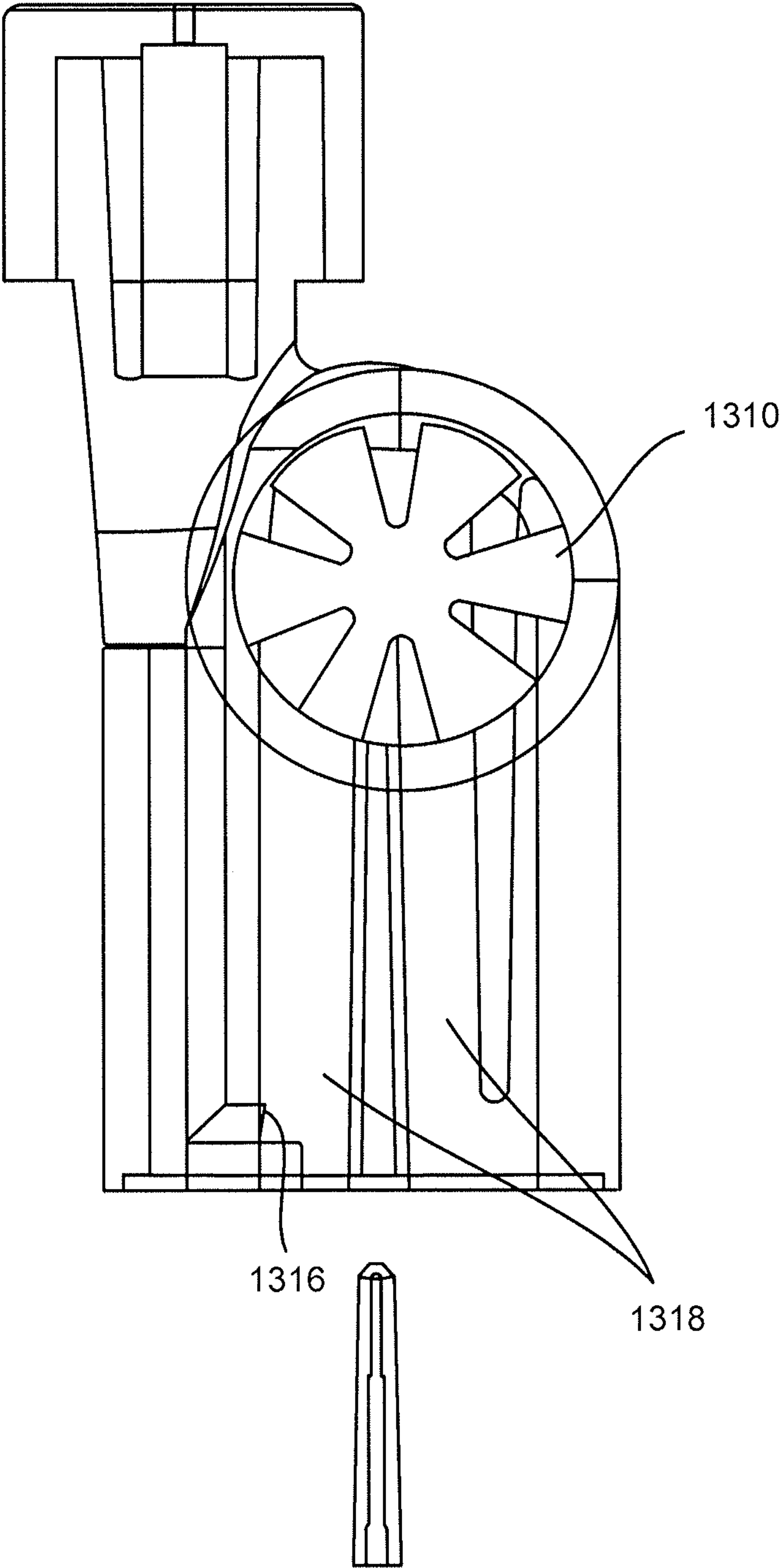


FIG. 13D

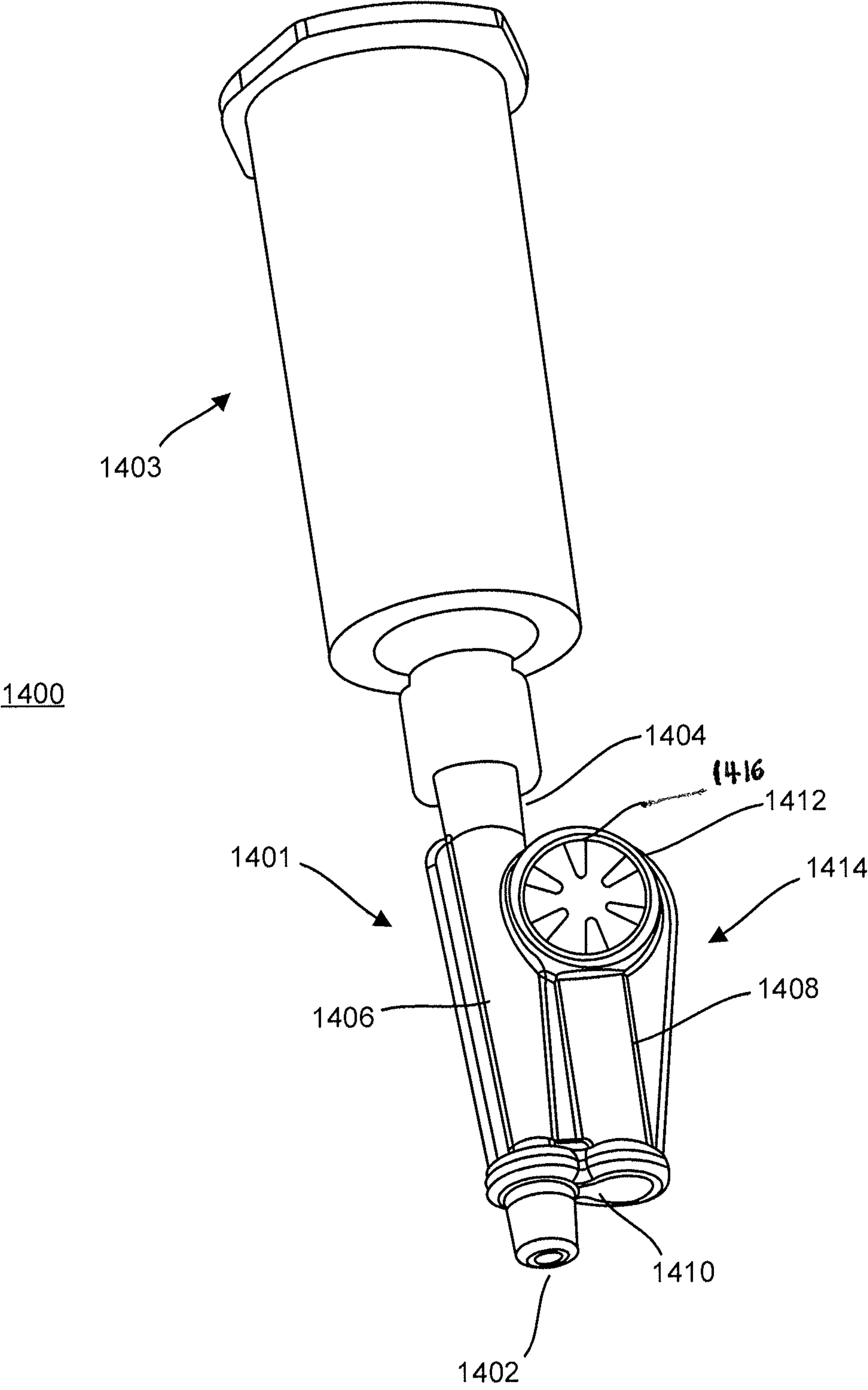


FIG. 14A

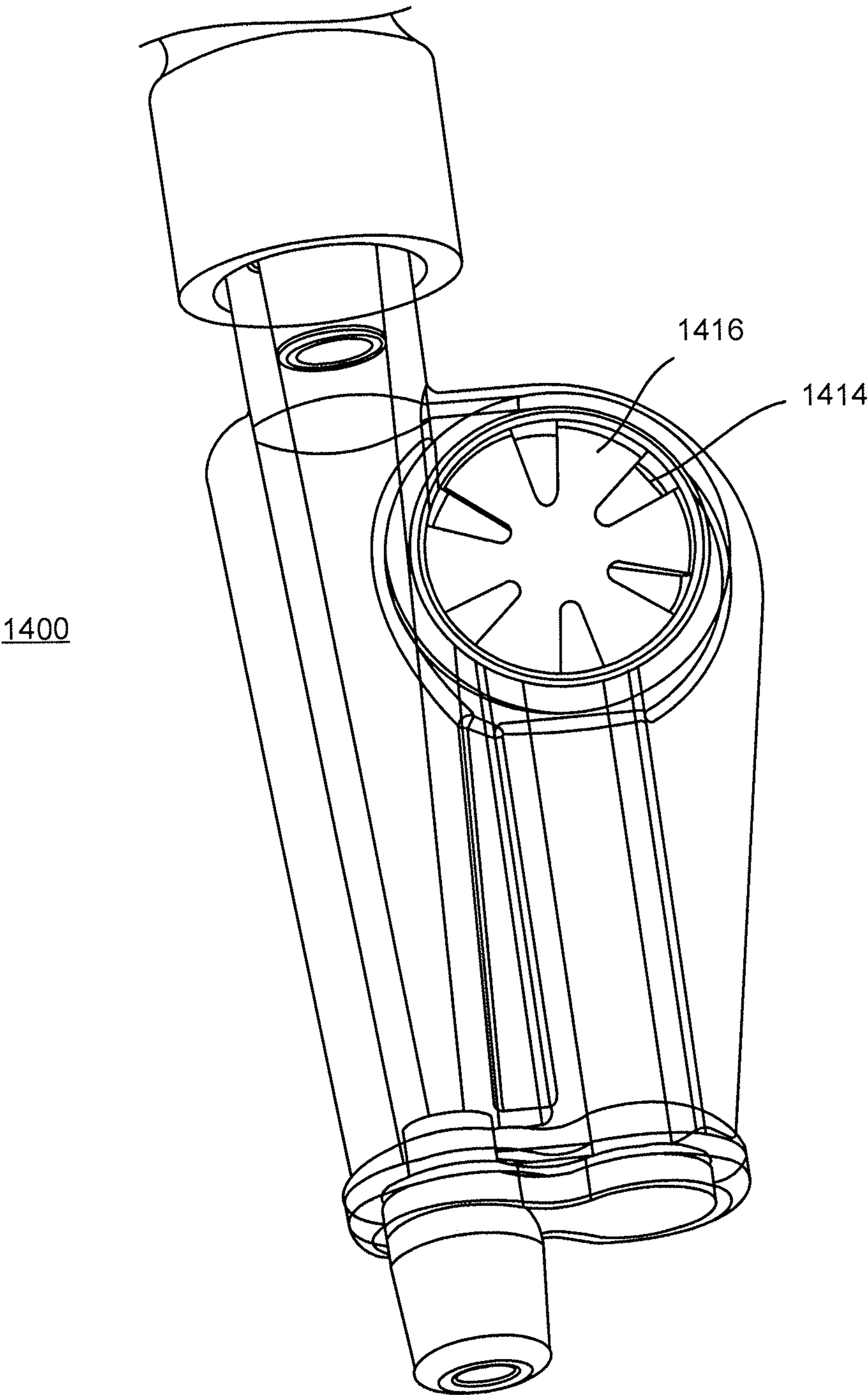


FIG. 14B

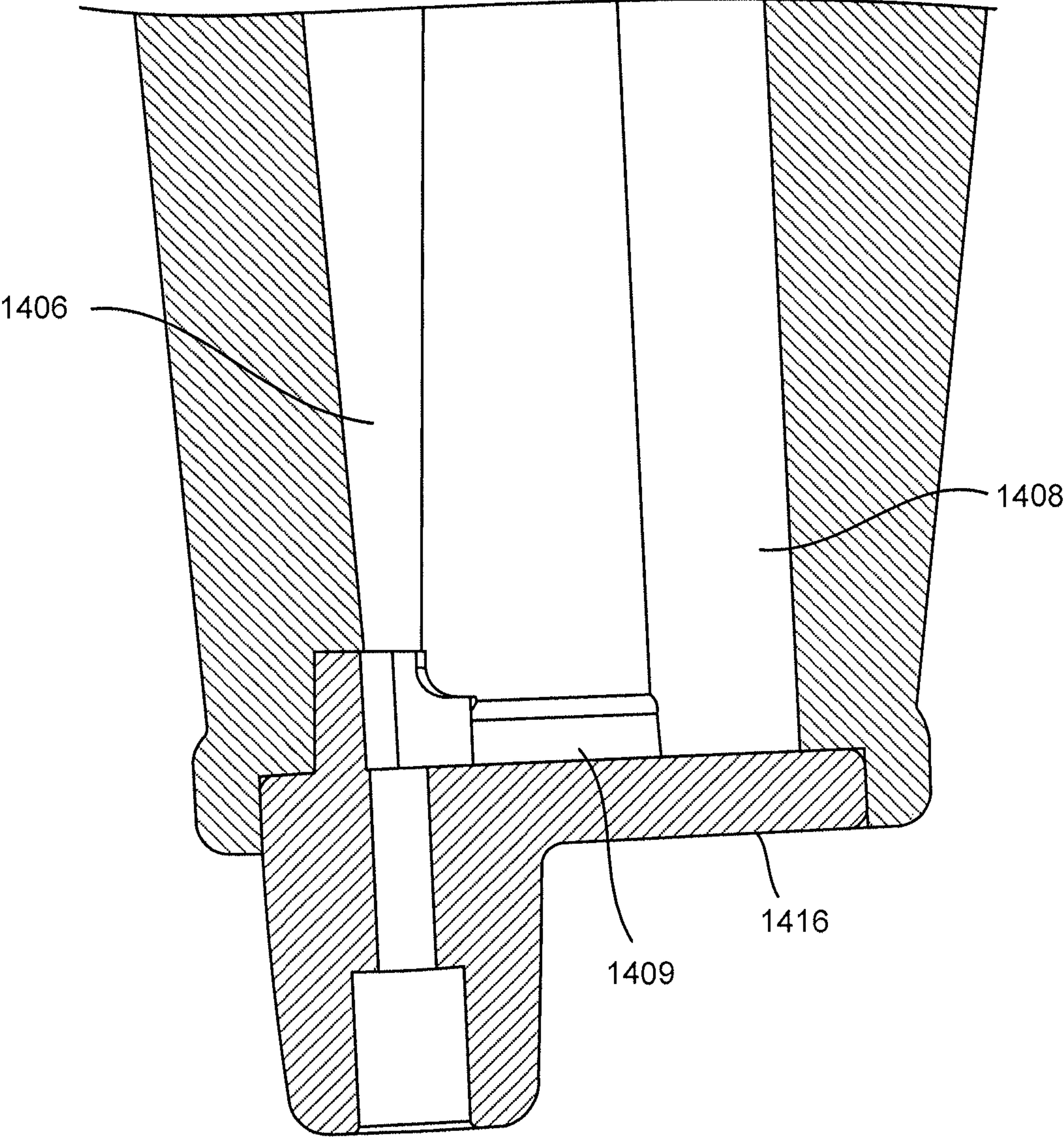


FIG. 14C

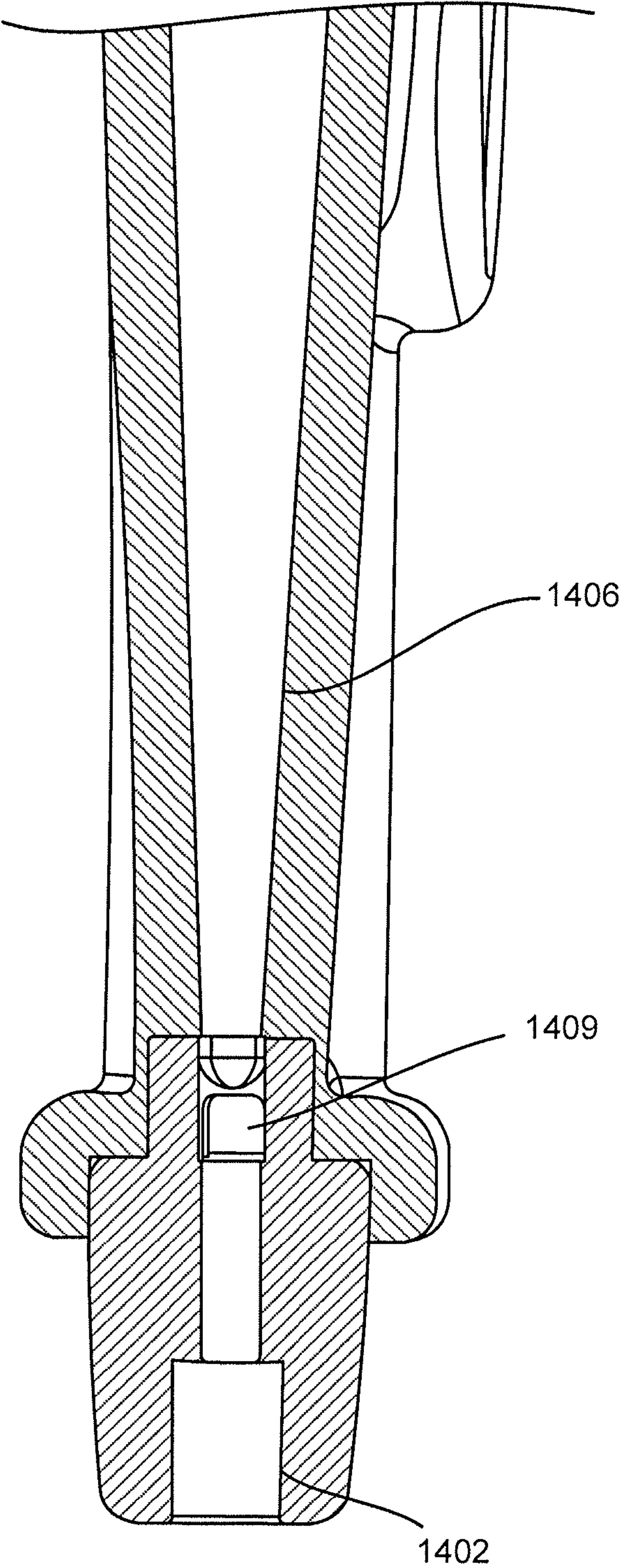


FIG. 14D

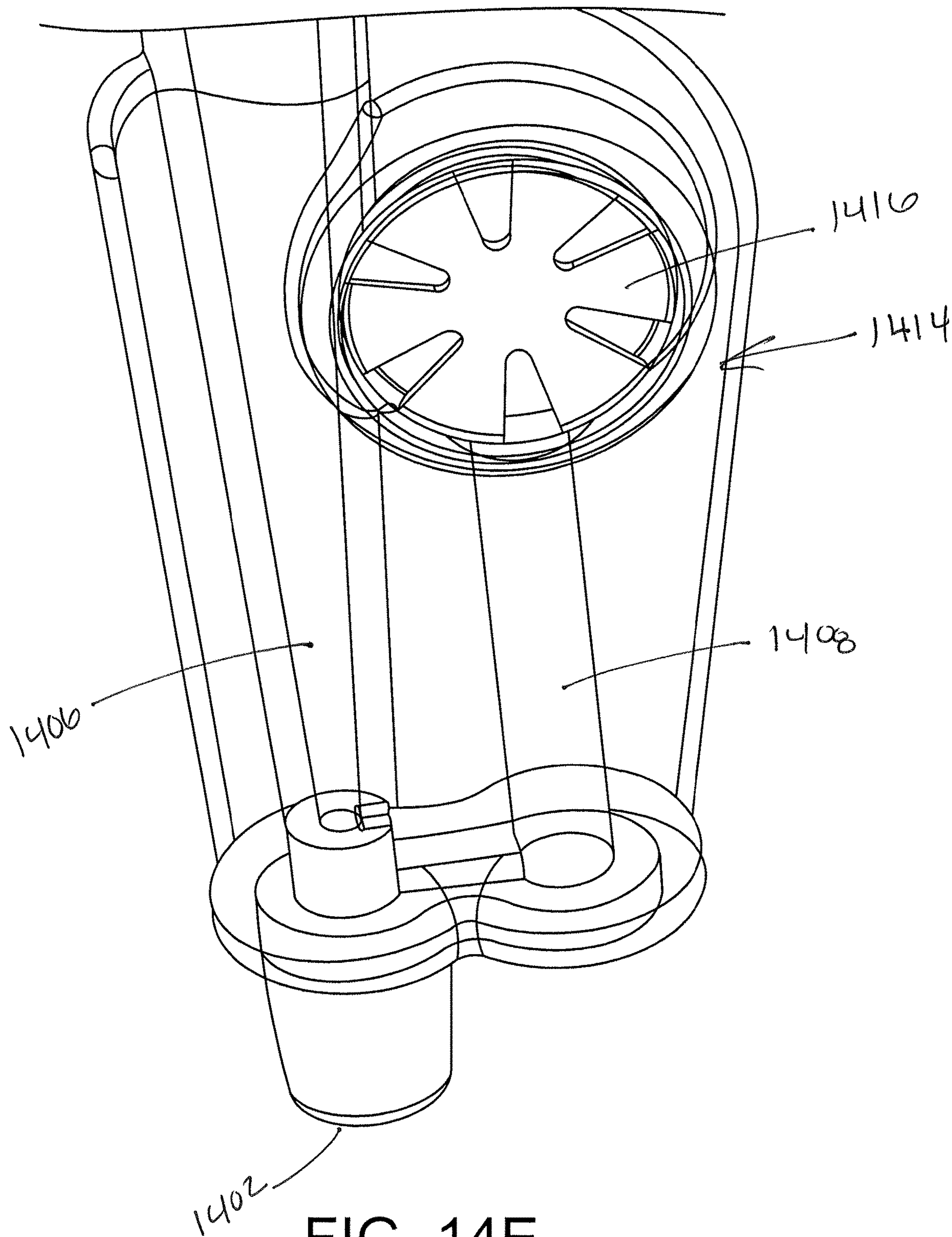


FIG. 14E

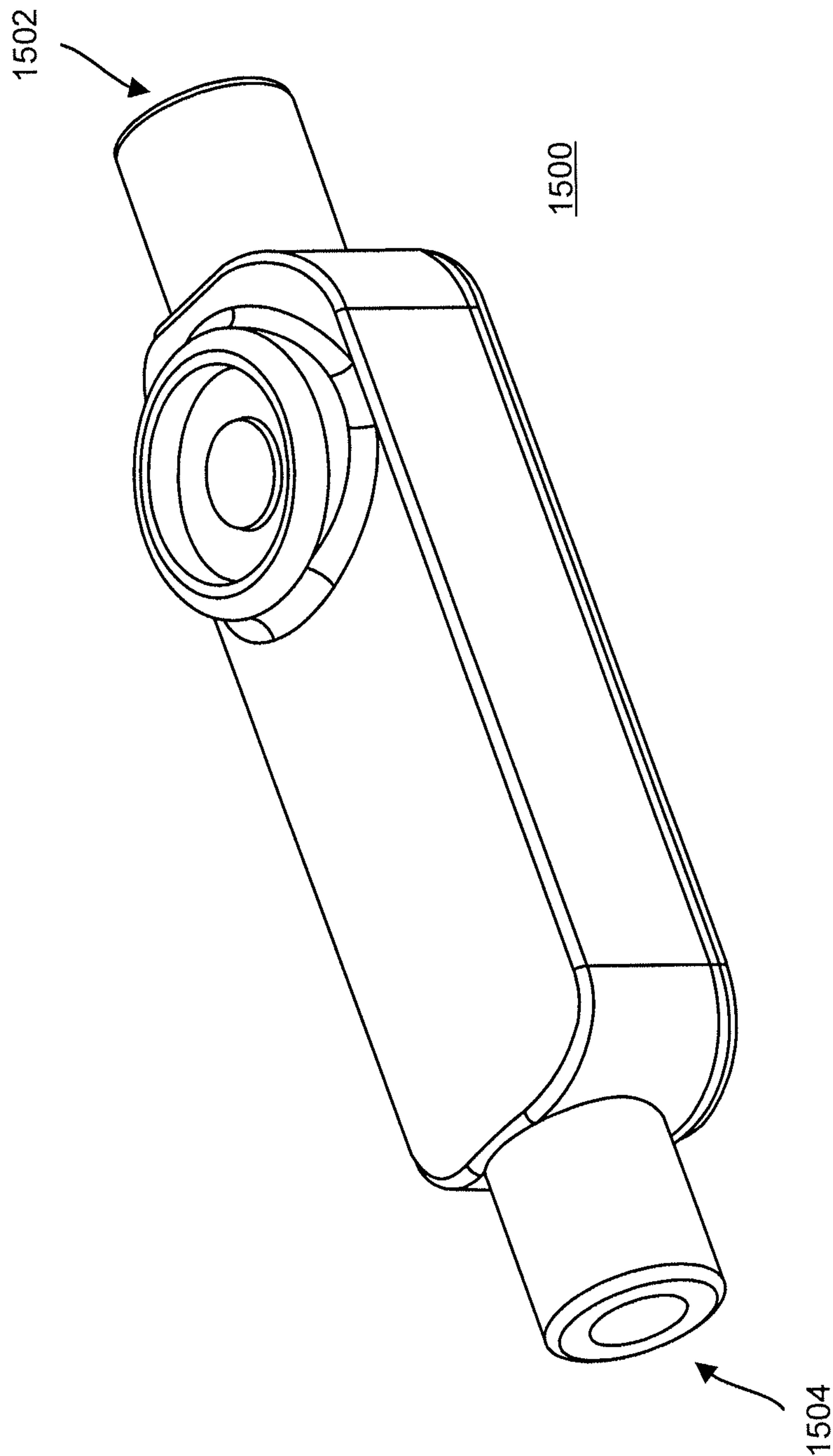


FIG. 15A

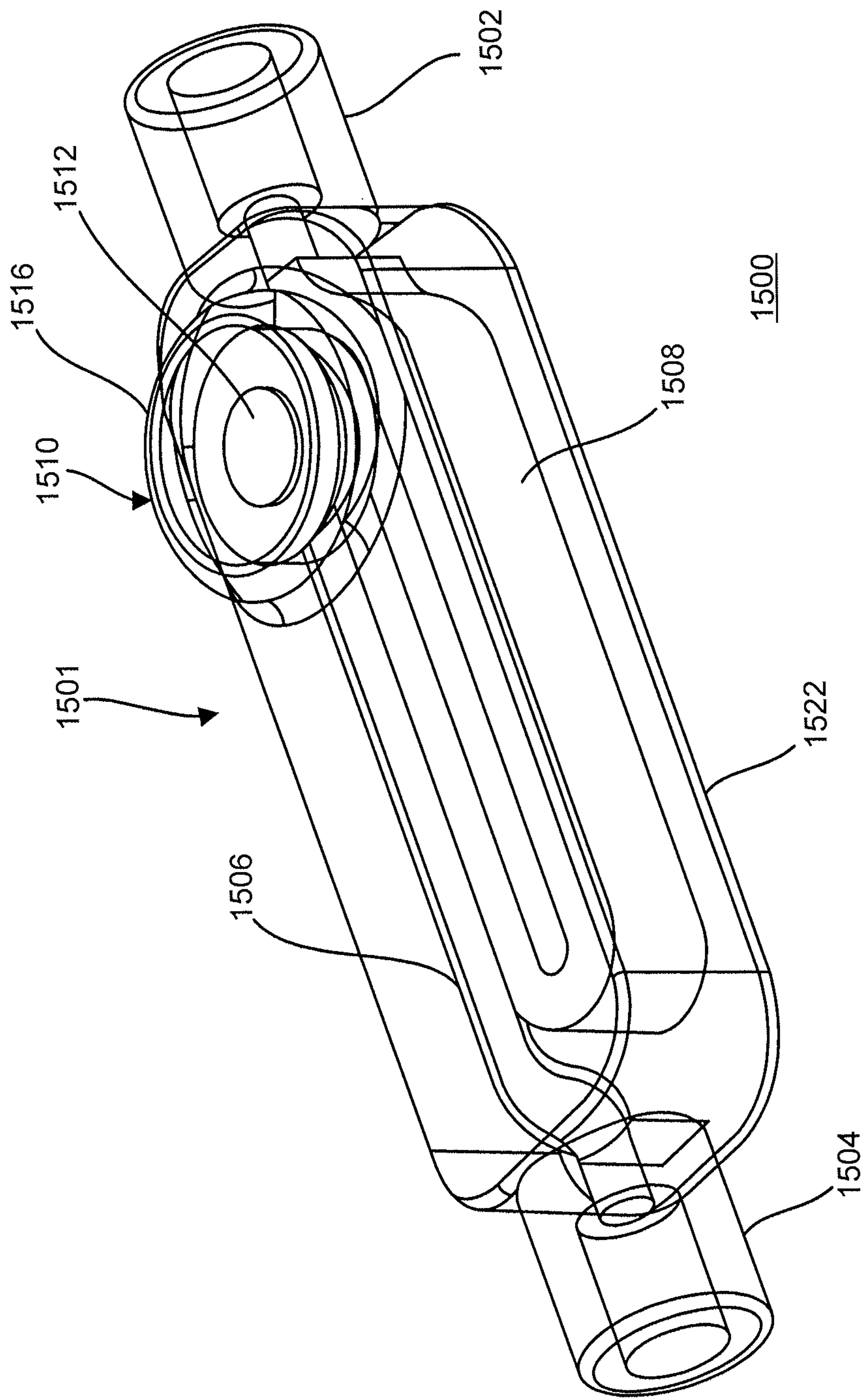


FIG. 15B

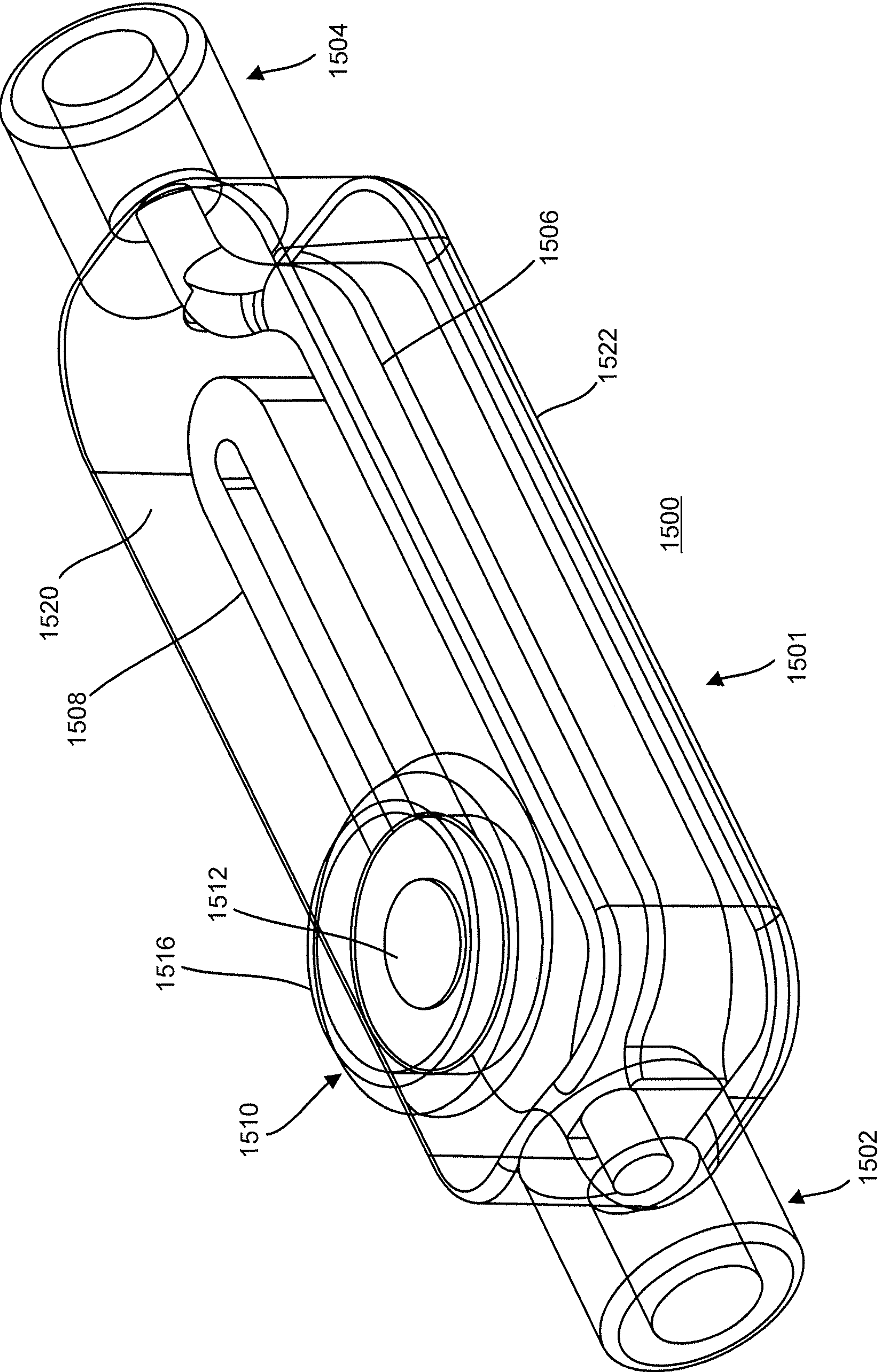


FIG. 15C

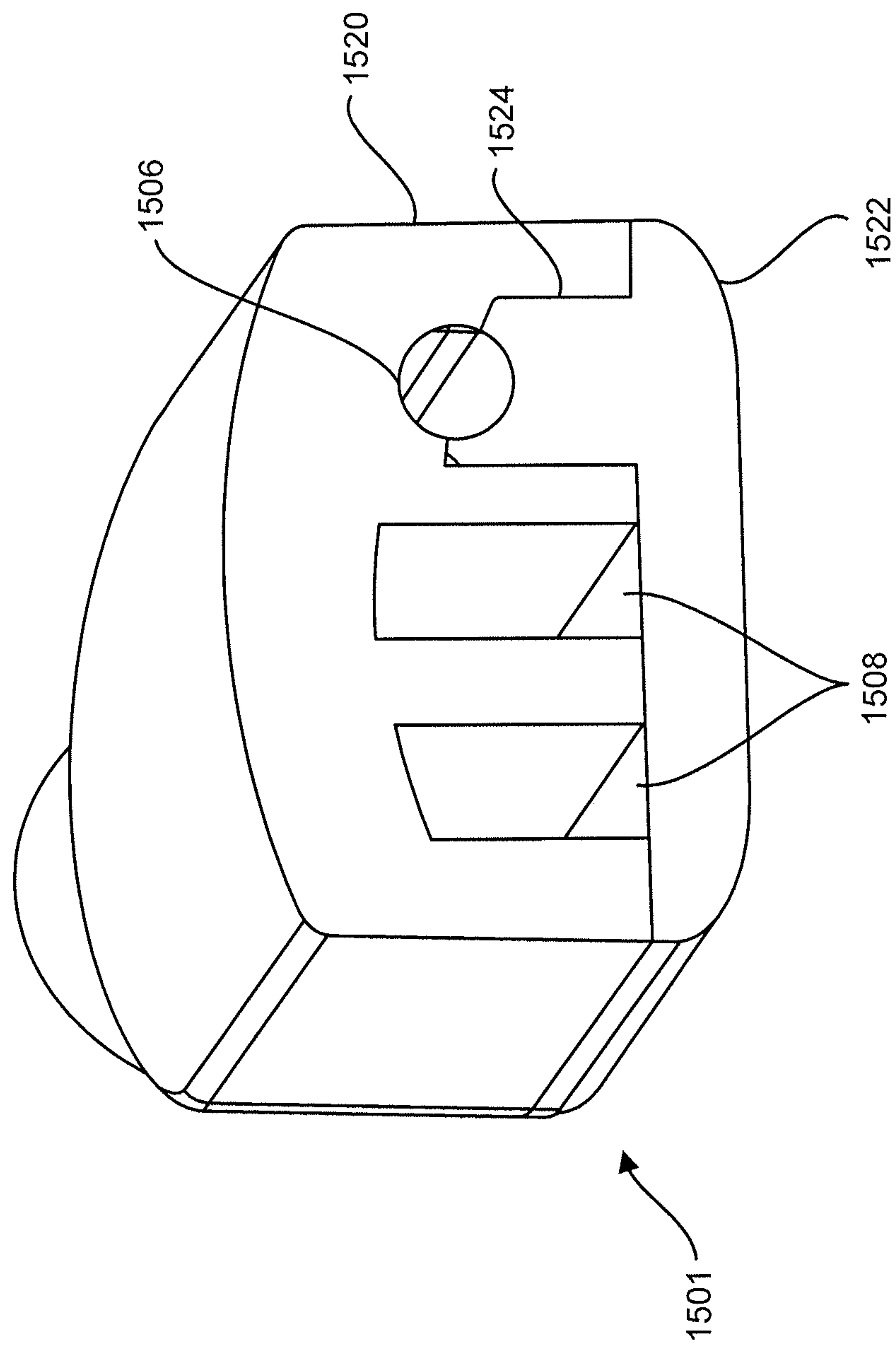


FIG. 15D

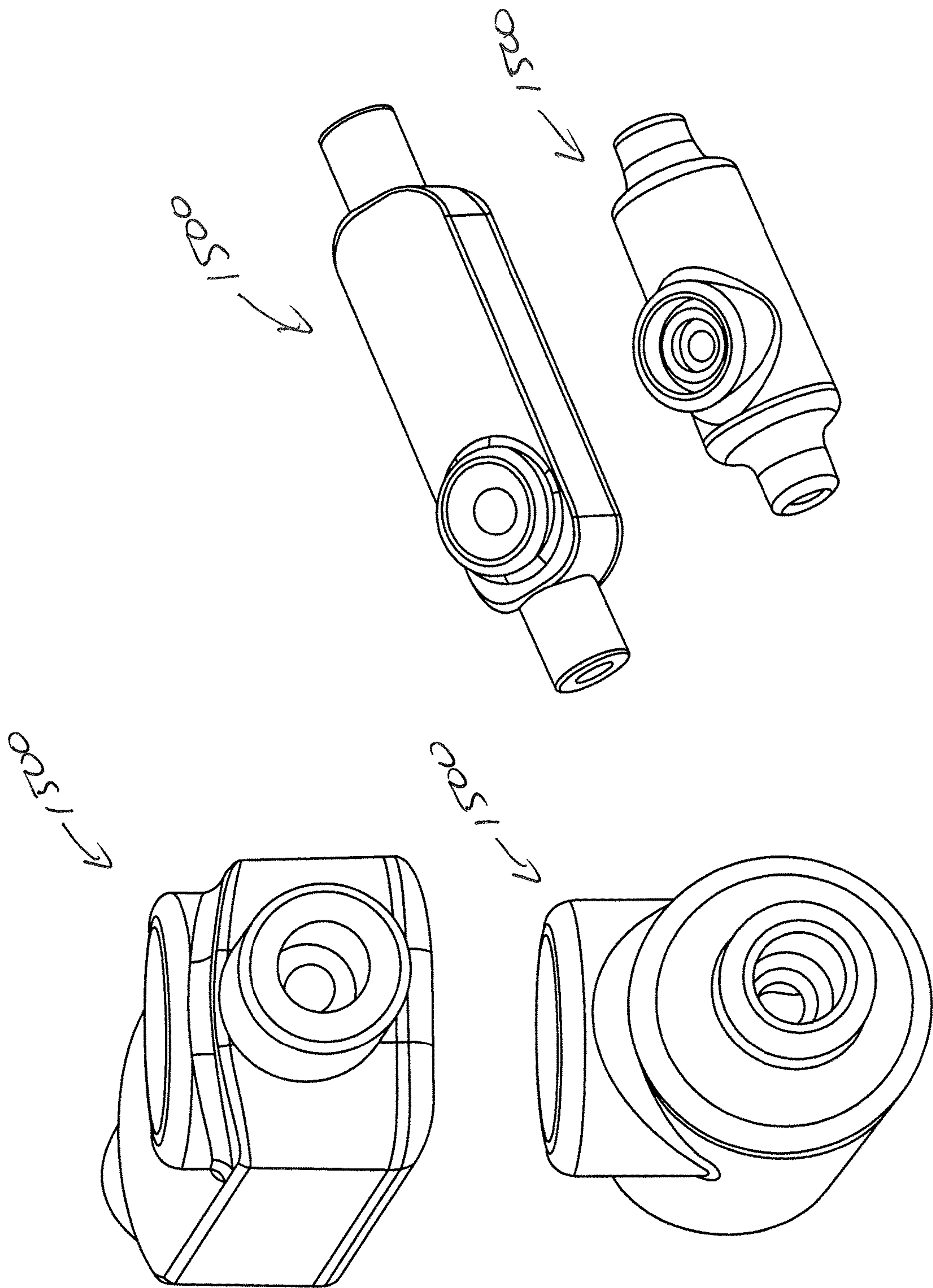


FIG. 15F

FIG. 15E

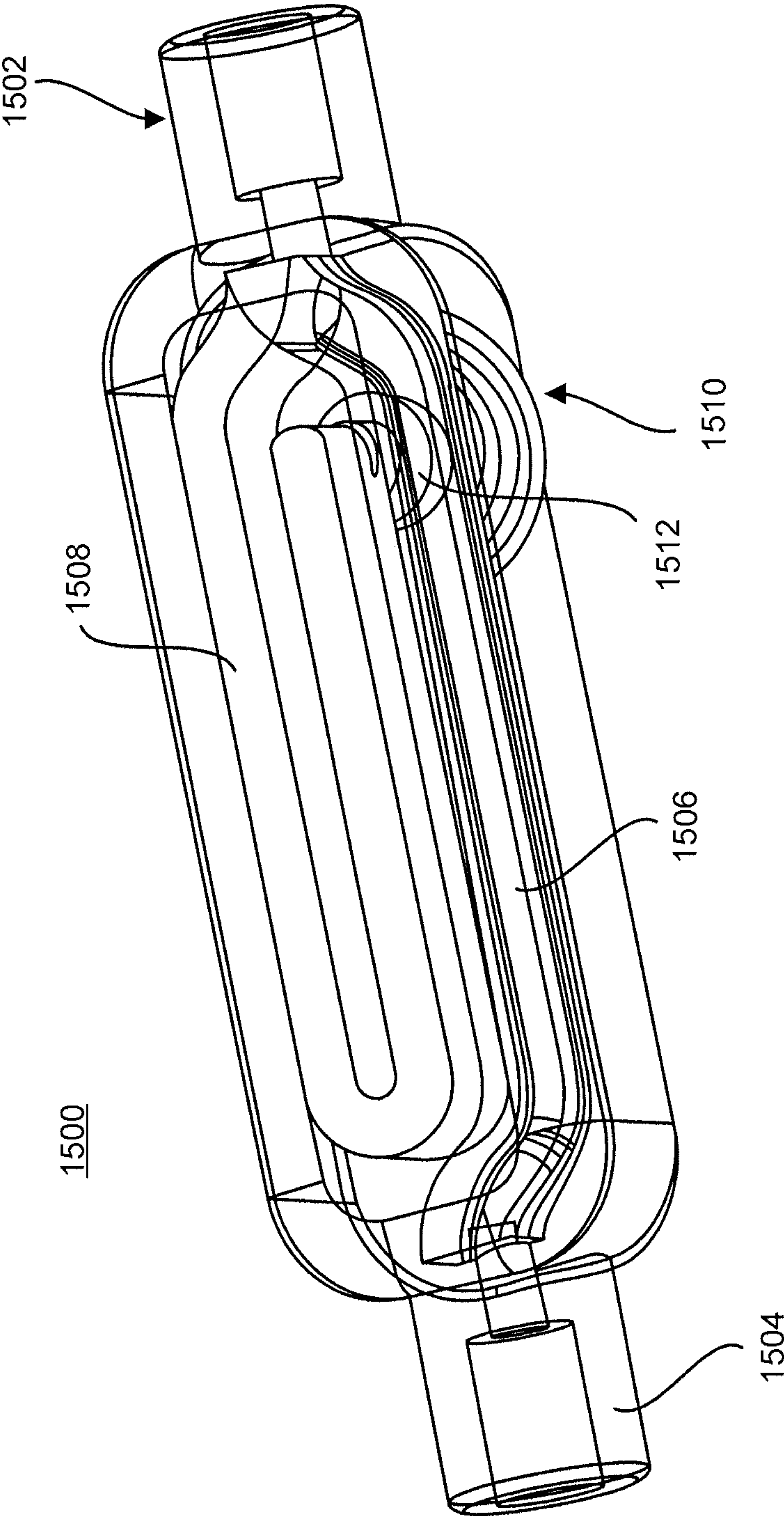


FIG. 15G

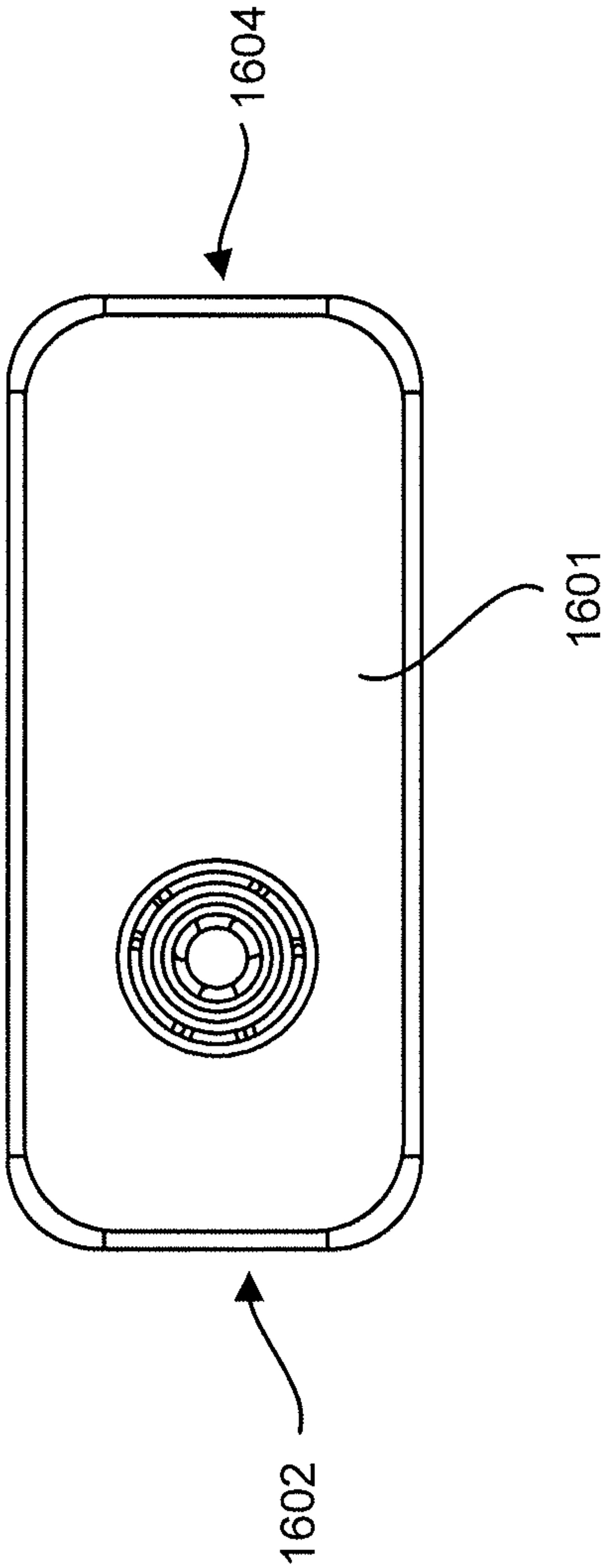


FIG. 16A

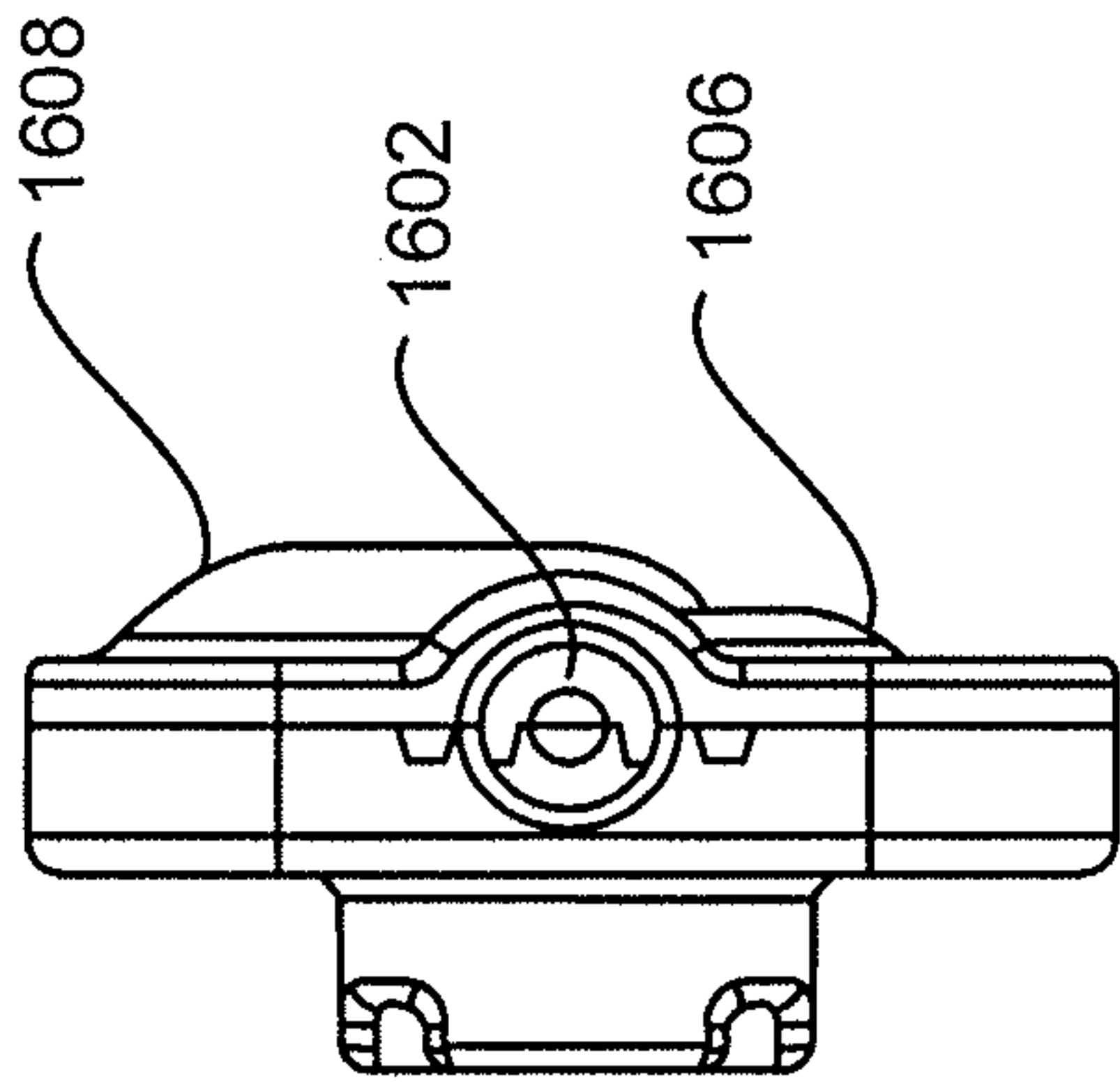


FIG. 16C

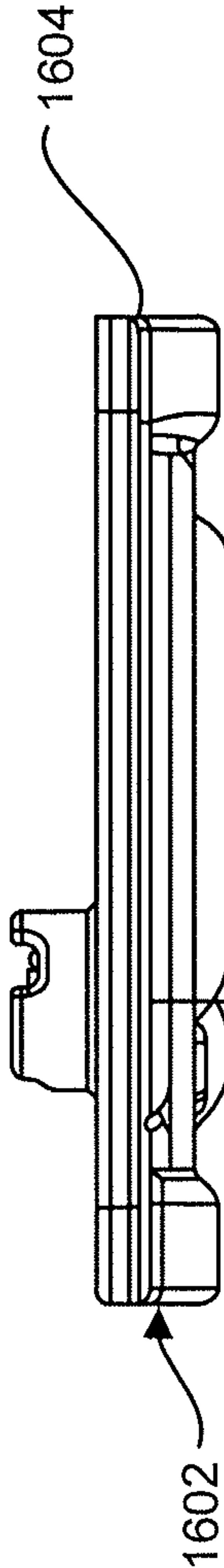


FIG. 16B

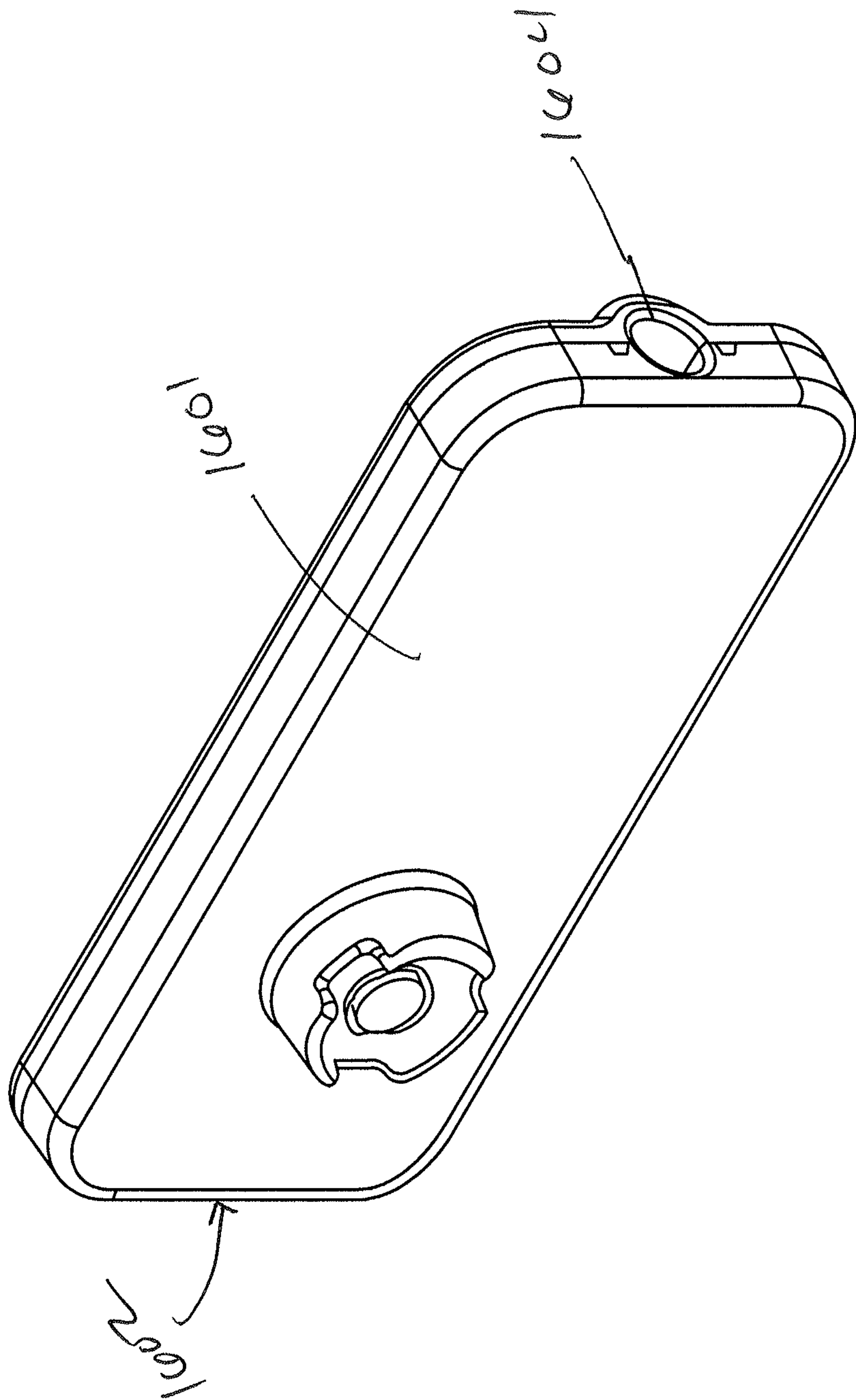


FIG. 16D

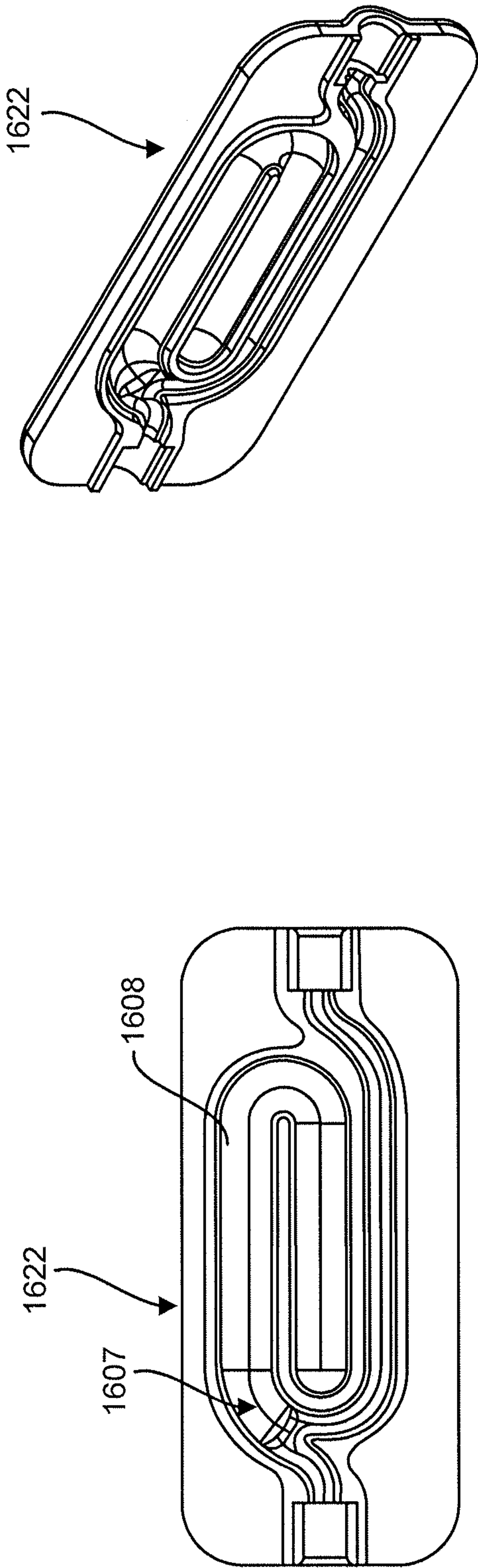


FIG. 17A

FIG. 17B

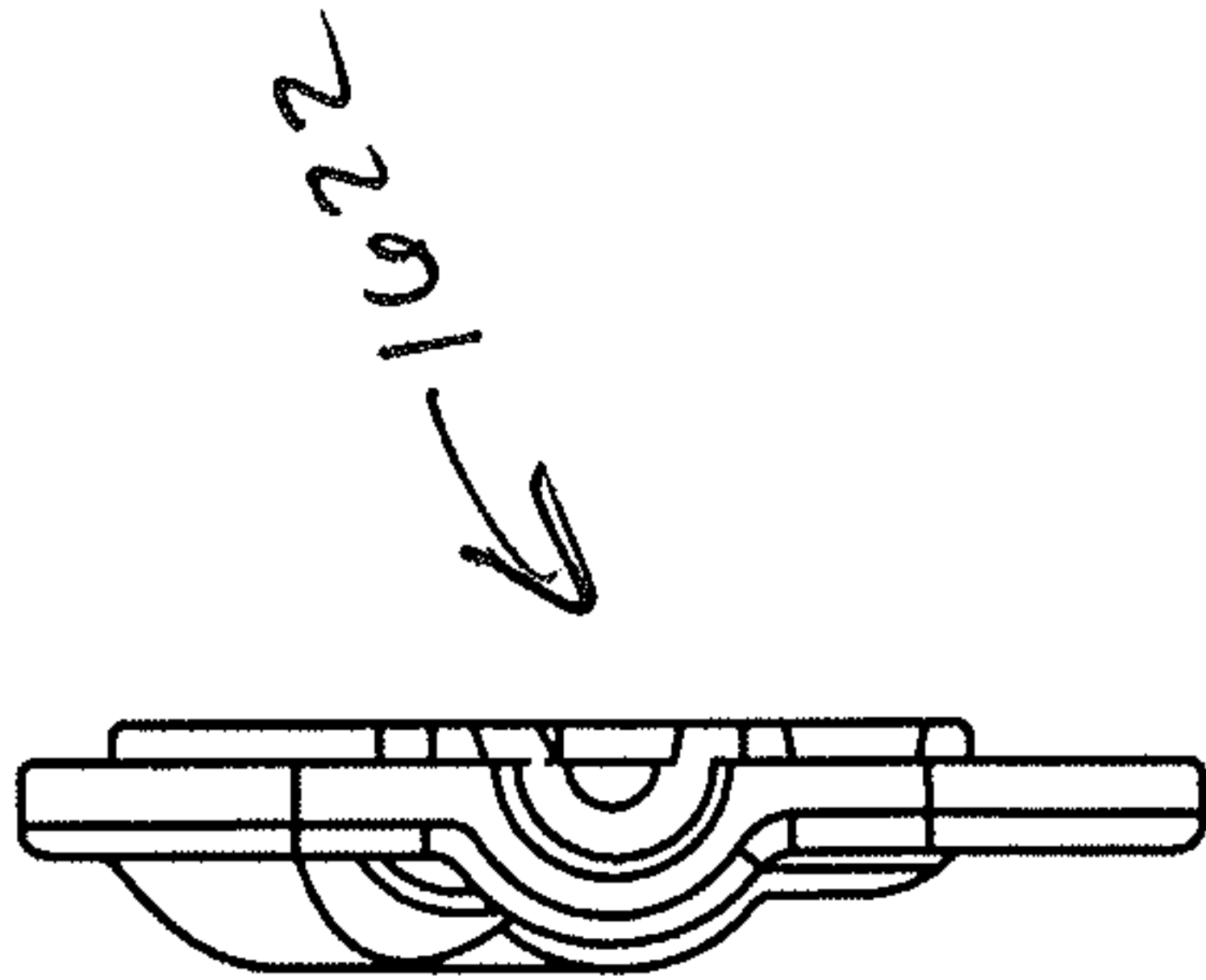


FIG. 17C

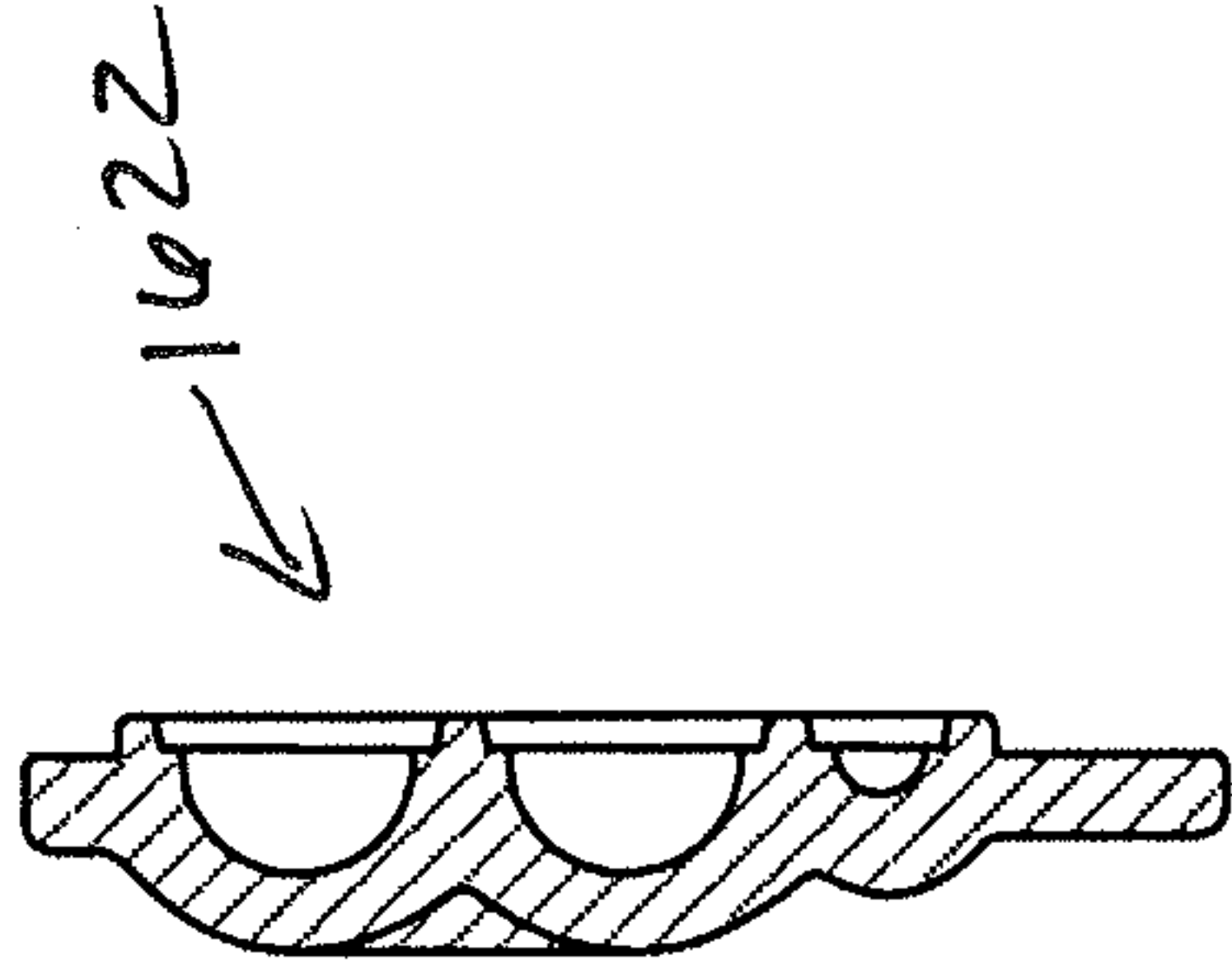


FIG. 17D

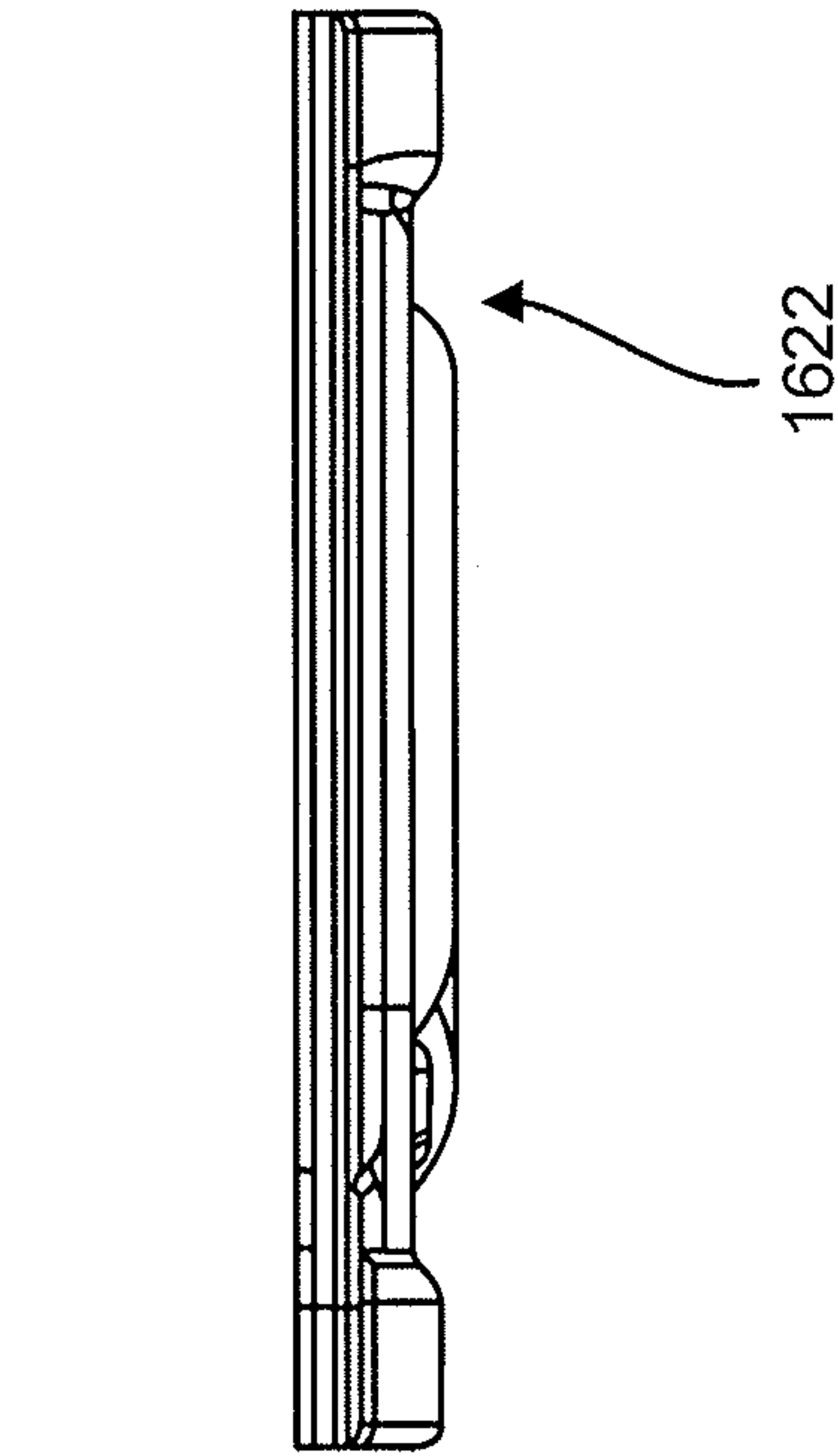


FIG. 17E

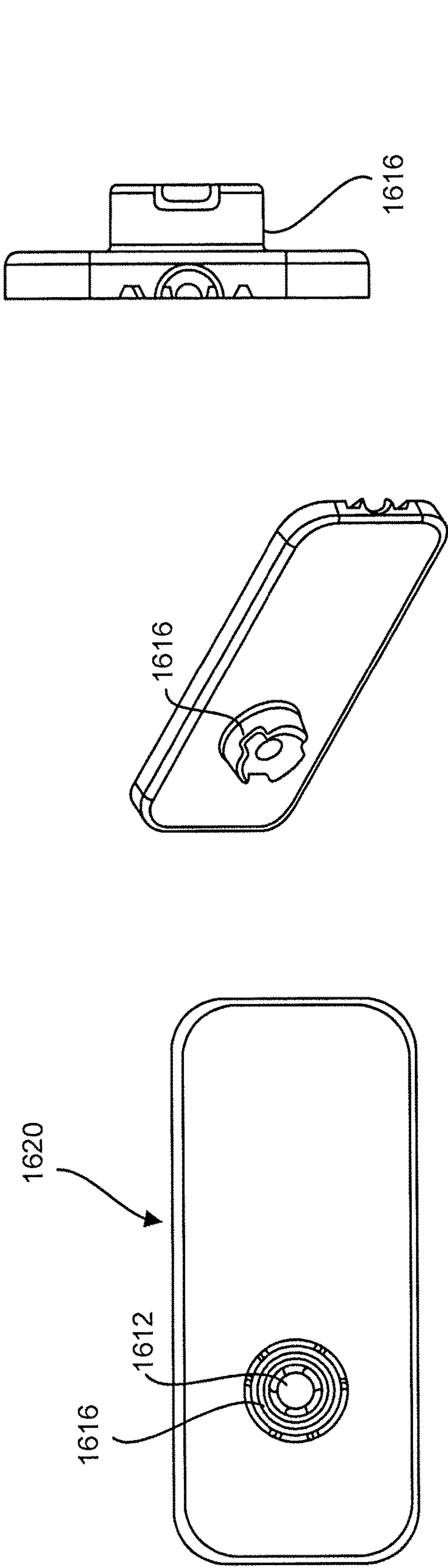


FIG. 18A

FIG. 18B

FIG. 18C

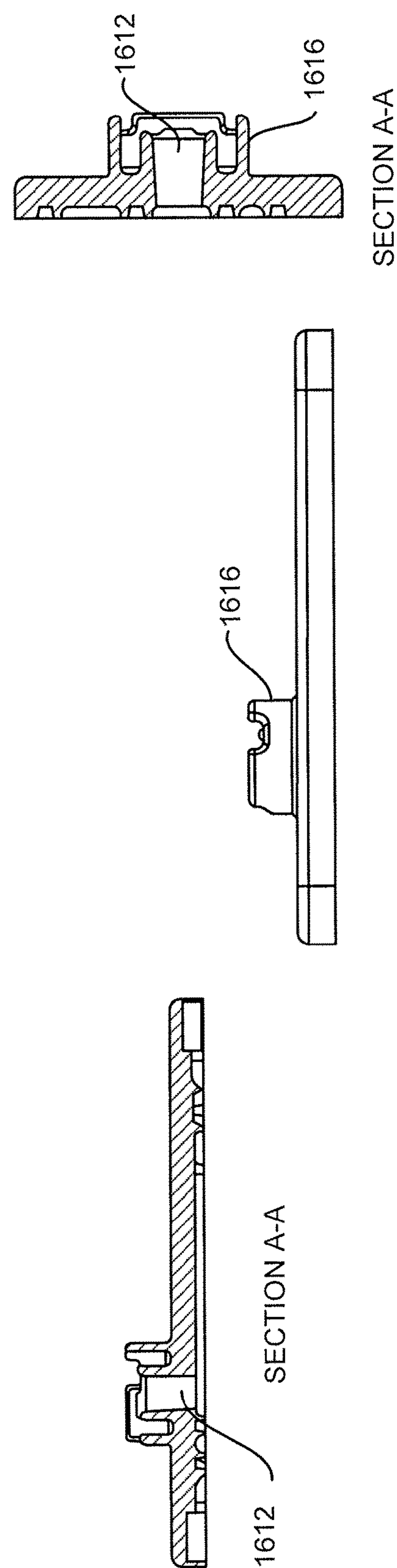


FIG. 18D

FIG. 18E

FIG. 18F

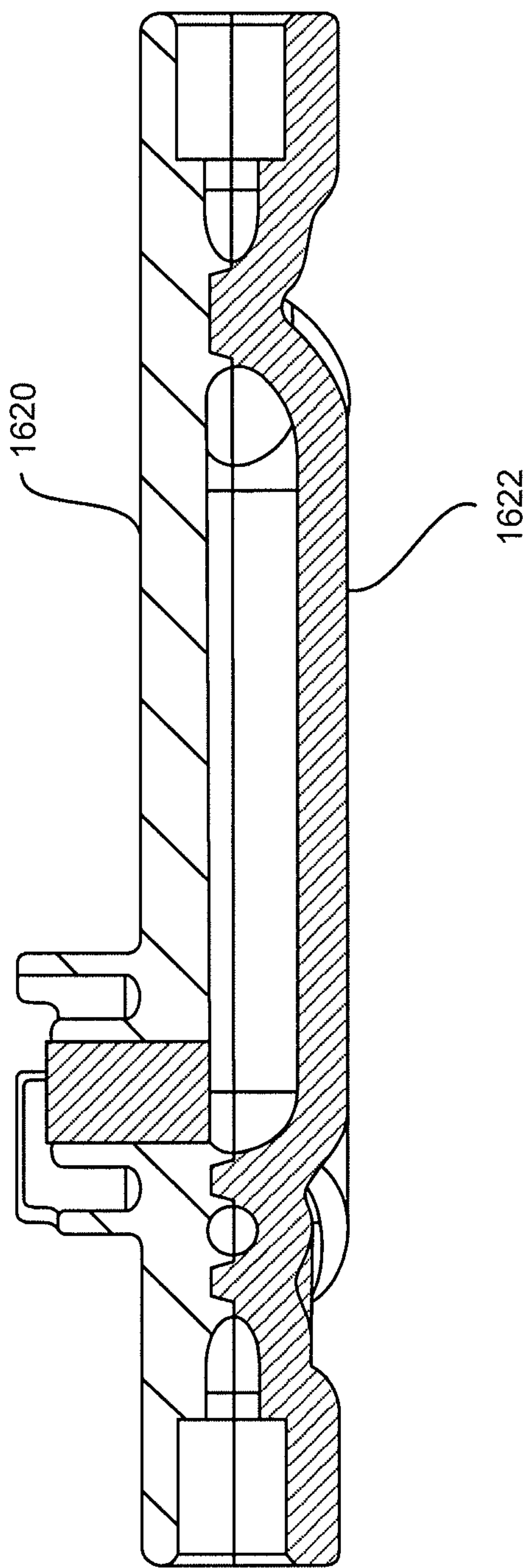


FIG. 19A

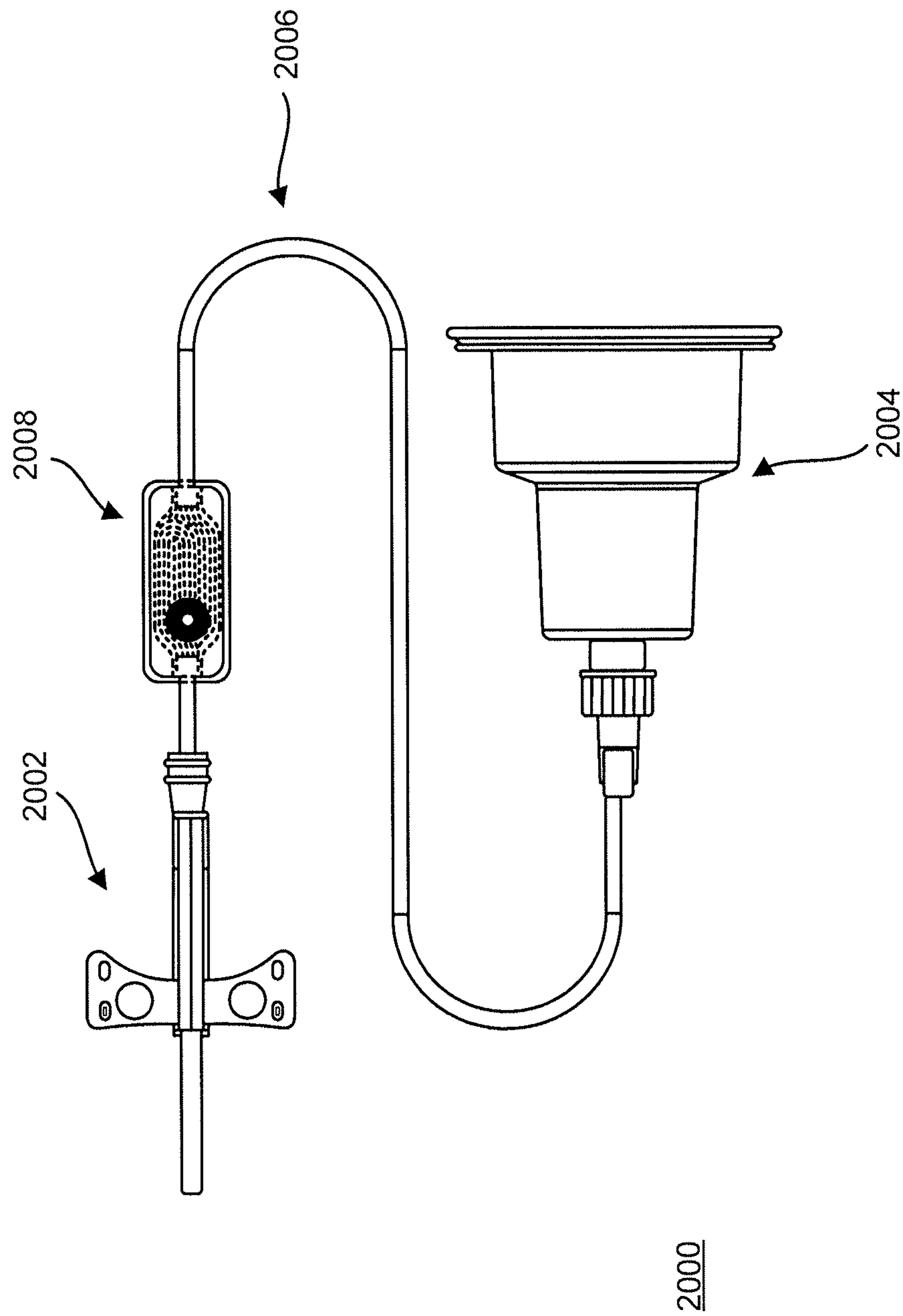


FIG. 20

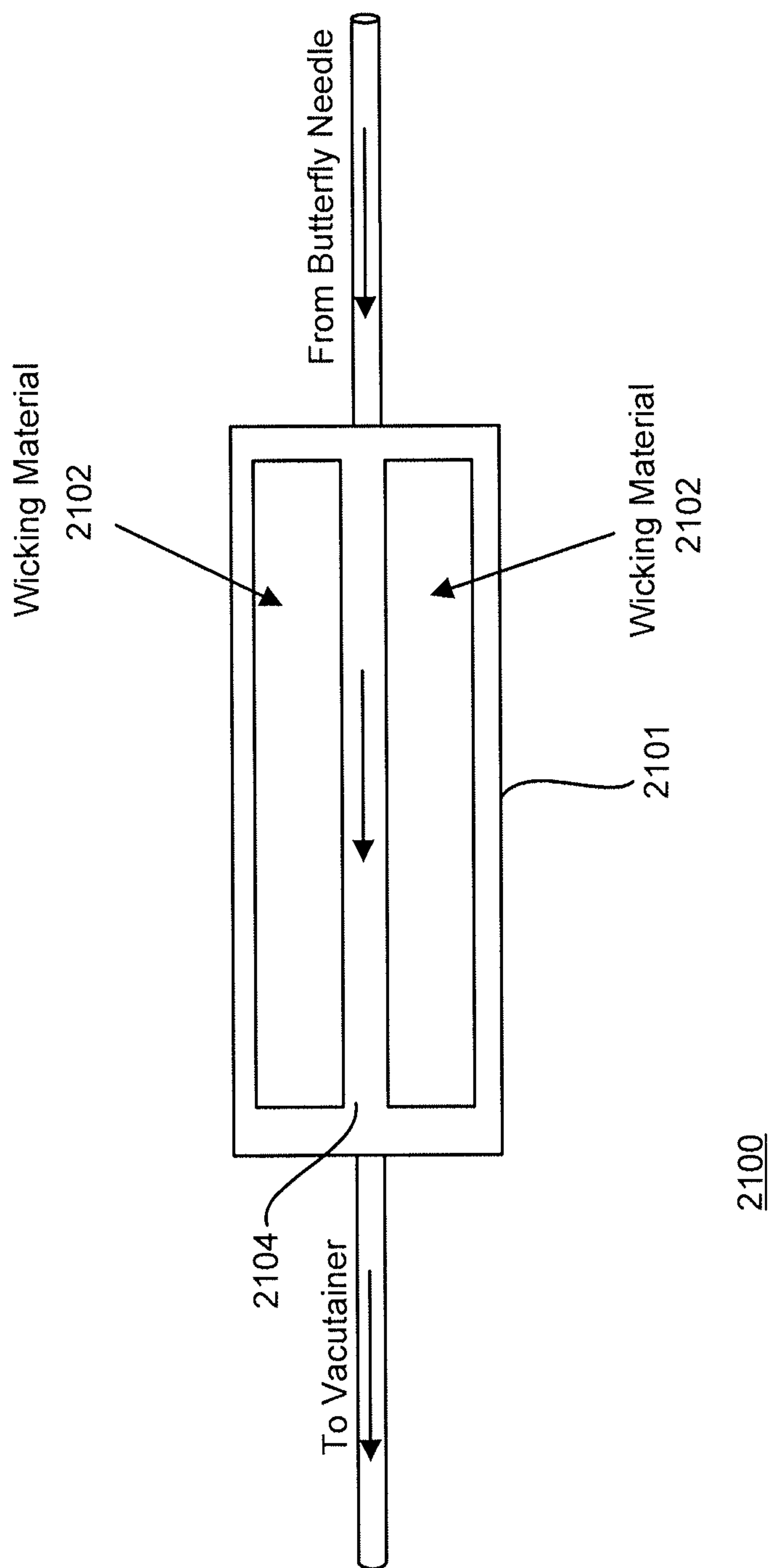


FIG. 21

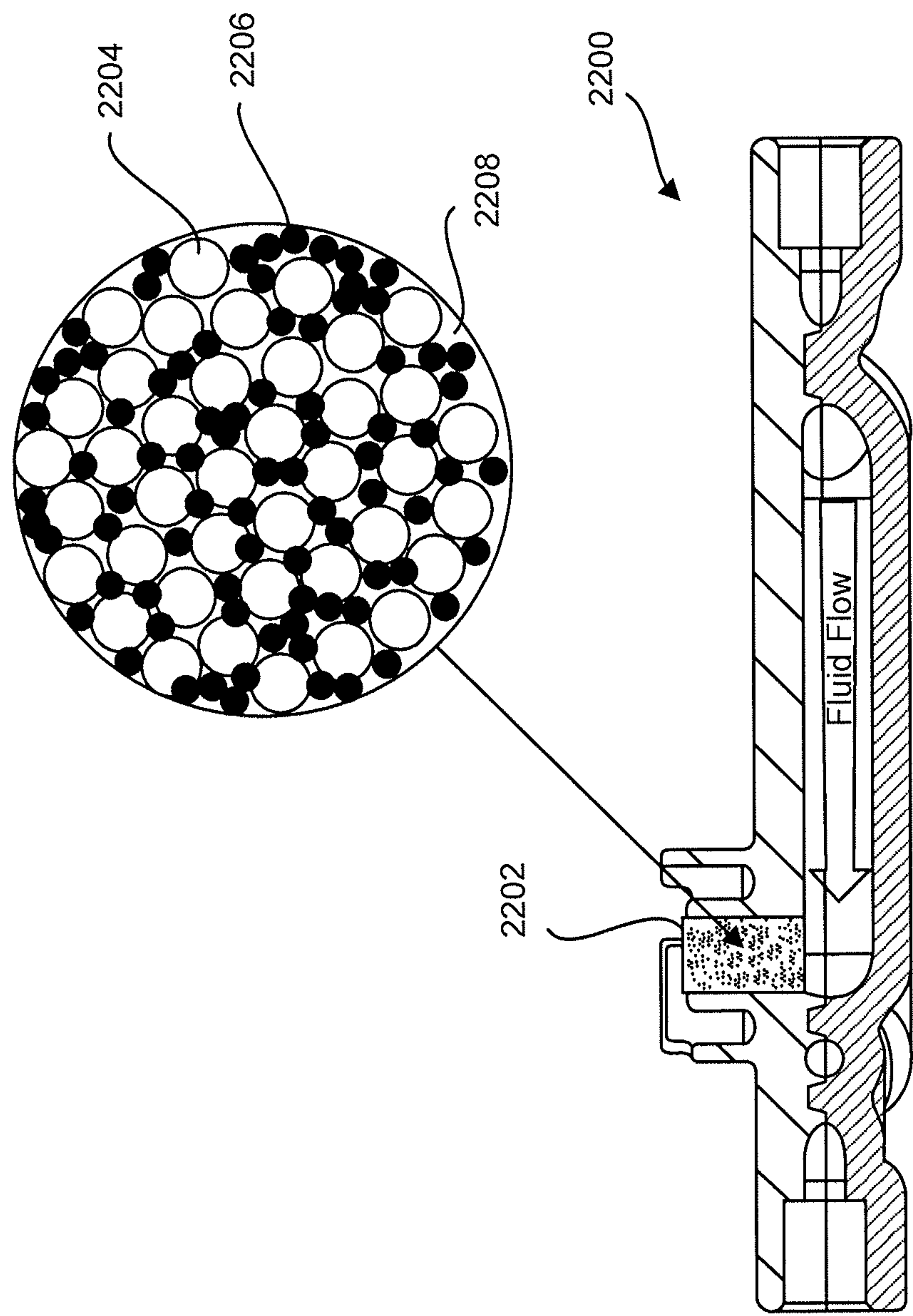


FIG. 22A

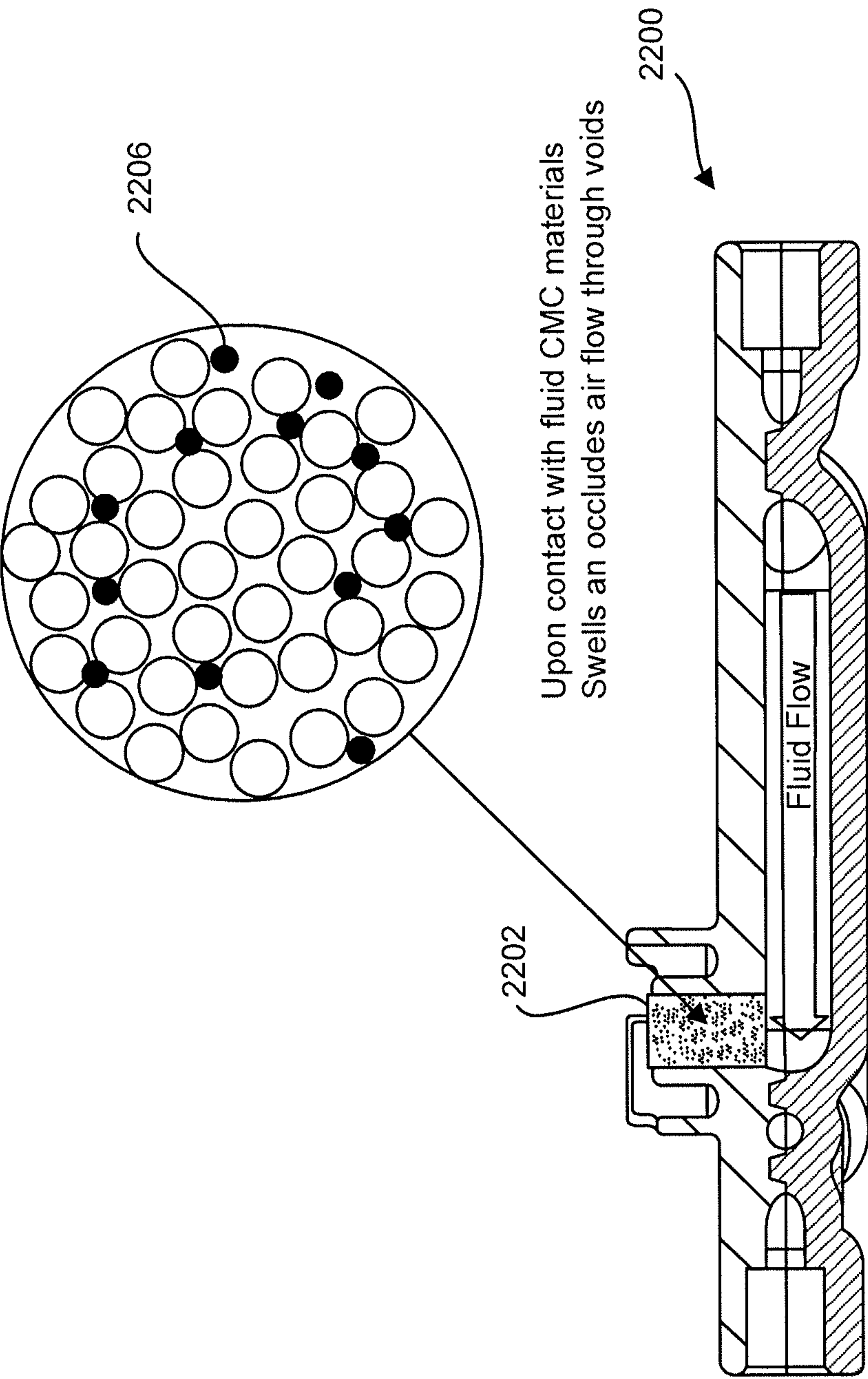


FIG. 22B

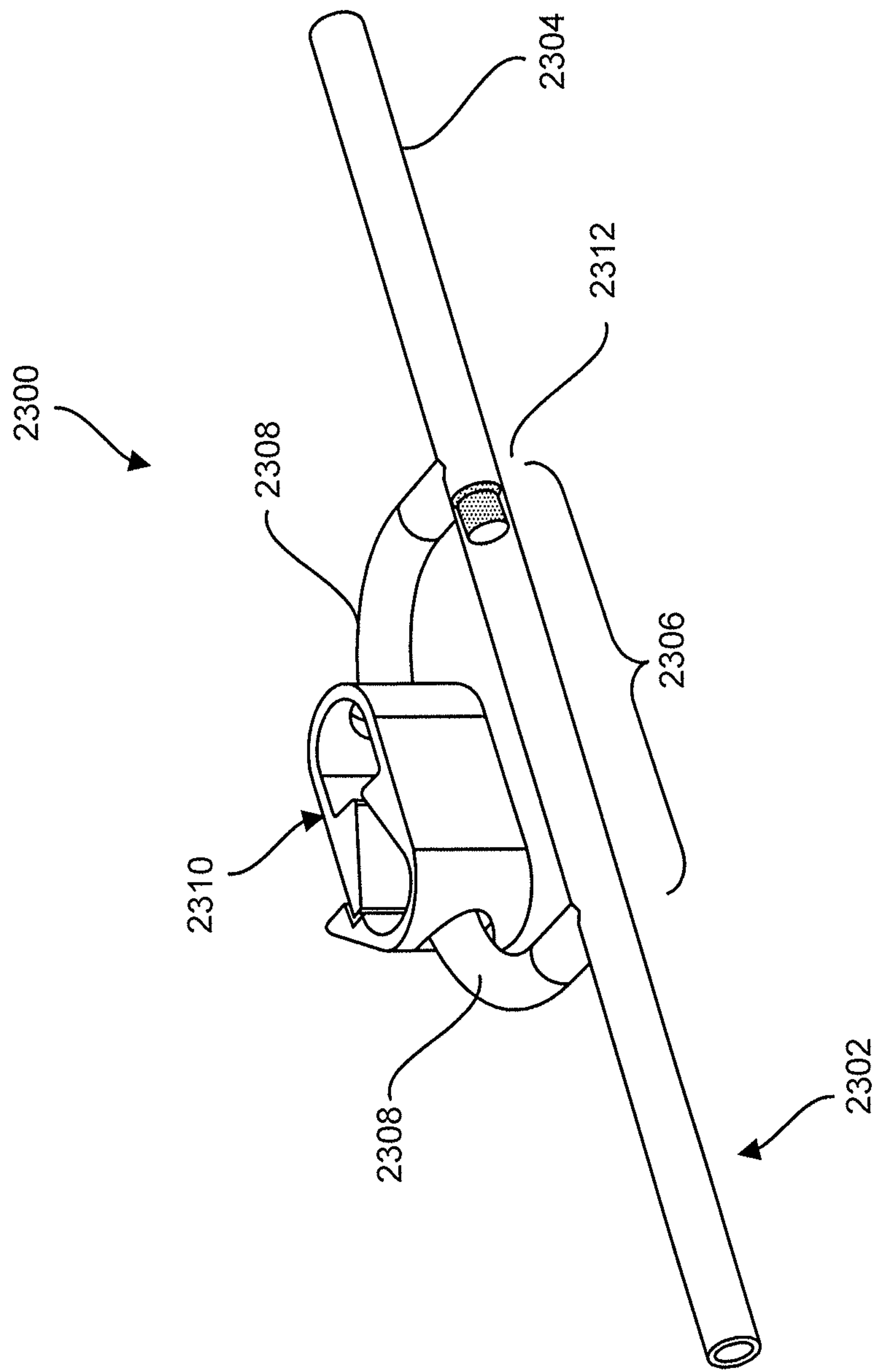


FIG. 23A

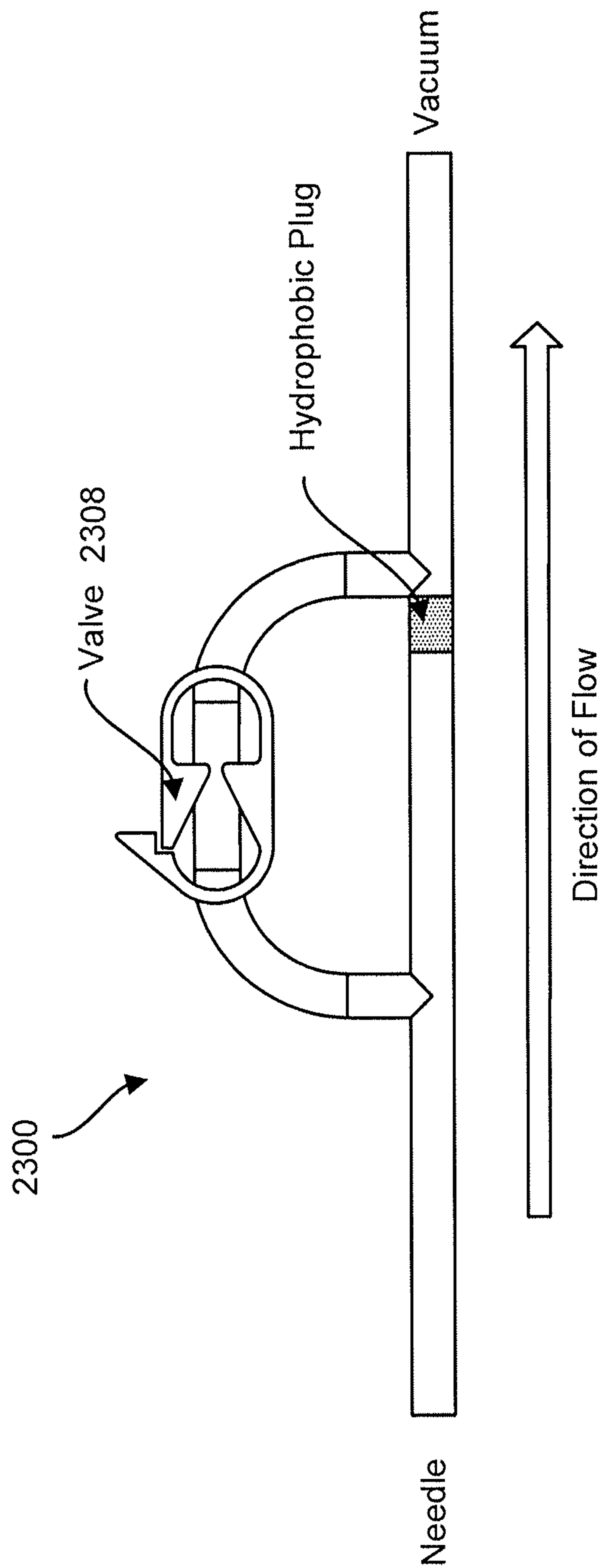


FIG. 23B

BLOOD SAMPLE OPTIMIZATION DEVICE**CROSS-REFERENCE TO RELATED APPLICATIONS**

This application is a Continuation of U.S. application Ser. No. 18/113,710 filed Feb. 24, 2023, entitled “BLOOD SAMPLE OPTIMIZATION DEVICE,” which is a continuation of U.S. application Ser. No. 17/538,990 filed Nov. 11, 2021, entitled “BLOOD SAMPLE OPTIMIZATION DEVICE,” which is a continuation of U.S. application Ser. No. 16/208,559 filed Dec. 4, 2018, entitled “BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD,” now U.S. Pat. No. 11,185,266, issued Nov. 30, 2021, which is a Continuation of U.S. application Ser. No. 15/994,559, filed on May 31, 2018 and titled “BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD,” now U.S. Pat. No. 10,143,412, issued Dec. 4, 2018; which is a Continuation of U.S. application Ser. No. 15/140,448, filed on Apr. 27, 2016, now U.S. Pat. No. 10,010,282 issued Jul. 3, 2018, which claims the benefit of U.S. Provisional Application Ser. No. 62/196,797, filed on Jul. 24, 2015 and titled “BLOOD CULTURE IMPROVEMENT SYSTEM AND METHOD”; U.S. Provisional Application Ser. No. 62/238,636, filed on Oct. 7, 2015 and titled “BLOOD SEQUESTRATION SYSTEM FOR NON-CONTAMINATED BLOOD SAMPLING”; and U.S. Provisional Application Ser. No. 62/318,194, filed on Apr. 4, 2016 and titled “BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD,” the disclosures of which are incorporated by reference in their entirety.

BACKGROUND

Bacteraemia is the presence of microorganisms in the blood. Sepsis, on the other hand, is bacteraemia in the presence of clinical symptoms and signs such as fever, tachycardia, tachypnea and hypotension. Bacteraemia and sepsis are associated with a high mortality and an increased incidence and duration of hospital stay and associated costs. Many bacteraemias, sepsis, fungaemias and other pathogens actually occur within a hospital or other healthcare settings with catheters and venipunctures being a source of contamination as potential carriers of these pathogens.

Blood cultures are the standard test used to detect microbial pathogens related to bacteraemia and sepsis in a patient's blood. The term blood culture refers to a single venipuncture, either from a peripheral site or central or arterial line, with the blood inoculated into one or more blood culture bottles or containers. One bottle is considered a blood culture where two or more are considered a set. Multiple sets may be obtained from multiple venipunctures and are associated with different sites on the patient.

These methods allow for microbial identification and susceptibility testing to be performed, which is a critical component to managing sepsis, however the lack of rapid results and decreased sensitivity for fastidious pathogens has led to the development of improved systems and adjunctive molecular or proteomic testing.

Collection of blood samples for conducting blood cultures is a critical component of modern patient care and can either positively affect the patient outcome by providing an accurate diagnosis, or can adversely affect the outcome by

prolonging unnecessary antimicrobial therapy, the length of hospital stays, and increasing costs.

One outcome of collection of blood cultures is contamination. Blood culture contamination can lead to a false positive culture result and/or significant increase in health-care related costs. Sources of blood culture contamination include improper skin antisepsis, improper collection tube disinfection, and contamination of the initial blood draw which may then skew results.

Blood culture collection kits generally consist of a “butterfly” set, infusion set, or other type of venipuncture device as offered by companies like BD, Smiths, B. Braun and others, and aerobic and anaerobic blood culture bottles. Various different bottles are also available depending on the test requirements. These bottles are specifically designed to optimize recovery of both aerobic and anaerobic organisms. In conventional kits, a bottle used is known generally as a “Vacutainer,” which is a blood collection tube formed of a sterile glass or plastic tube with a closure that is evacuated to create a vacuum inside the tube to facilitate the draw of a predetermined volume of liquid such as blood.

False positive blood cultures are typically a result of poor sampling techniques. They cause the use of antibiotics when not needed, increasing hospital costs and patient anxiety. Blood cultures are drawn from a needlestick into the skin, and then a Vacutainer is attached to capture a sample of blood. Contamination may occur from improper or incomplete disinfection of the skin area in and around the puncture site. It may also occur from the coring of the skin by the needle during insertion, with the cored skin cells and any associated contamination being pulled into the sample.

Blood flow through a hypodermic needle is laminar, and as such, a velocity gradient can be developed over the flow tube as a pressure drop is applied to the hypodermic needle. Either forceful aspiration of blood, or using a very small hypodermic needle, can cause lysis and a release of potassium from the red blood cells, thereby rendering the blood samples abnormal.

In other instances, some patients have delicate veins that can collapse under a pressure drop or vacuum, particularly as applied by a syringe's plunger that is drawn too quickly for the patient's condition. Since such condition is impossible to know beforehand, such vein collapses are a risk and very difficult to control.

Various strategies have been implemented to decrease blood culture contamination rates, e.g. training staff with regard to aseptic collection technique, feedback with regard to contamination rates and implementation of blood culture collection kits. Although skin antisepsis can reduce the burden of contamination, 20% or more of skin organisms are located deep within the dermis and are unaffected by antisepsis. Changing needles before bottle inoculation is not advisable as it increases the risk to acquire needle stick injuries without decreasing contamination rates.

Some conventional systems and techniques for reducing blood culture contamination include discarding the initial aliquot of blood taken from central venous catheters, venipunctures, and other vascular access systems. However, these systems require the user to mechanically manipulate an intravascular device, or require a complex series of steps that are difficult to ensure being followed.

SUMMARY

This document presents systems and methods for reducing blood culture contamination, lysing of cells, and vein collapse. In some implementations, a system and method

3

can eliminate user variability in disinfection, and also eliminate the risk of skin cells getting into the blood culture sample. The systems and methods disclosed herein do not require a change in existing clinical processes, other than to potentially indicate when a vacutainer or other blood collection device (i.e., syringe) should be attached for drawing contaminant-free blood samples.

In some implementations of the systems and methods disclosed herein the withdrawal of blood is accomplished passively by use of the patient's own blood pressure, thereby reducing the risk of vein collapse and eliminating any additional user steps over current practice. The systems and methods can be applied to accommodate short-path direct stick or butterfly venipuncture systems. They can also be used with samples drawn through a catheter.

In one aspect, a blood sequestration device is presented. The blood sequestration device includes an inlet port and an outlet port. The blood sequestration device further includes a sequestration chamber connected with the inlet port, the sequestration chamber having a vent comprising an air permeable blood barrier. The blood sequestration device further includes a sampling channel having a proximal end connected with the inlet port and a distal end connected with the outlet port.

In another aspect, a blood sequestration device connected with a blood sampling pathway is described. The blood sampling pathway has a patient needle and a sample collection device. The blood sequestration device includes an inlet port connected with the patient needle, and a sequestration chamber connected with the inlet port, the sequestration chamber having a vent comprising an air permeable blood barrier. The blood sequestration device further includes a sampling channel having a proximal end connected with the inlet port, and an outlet port connected with a distal end of the sampling channel and with the sample collection device.

In yet another aspect, a blood sequestration device connected with a blood sampling system is described. The blood sampling system includes a patient needle for accessing a blood sample from a patient, and a sample needle that is sealed and adapted for receiving an evacuated blood collection tube. The blood sequestration device includes an inlet port connected with the patient needle to receive the blood sample from the patient. The blood sequestration device further includes a sequestration chamber connected with the inlet port and having a vent comprising an air permeable blood barrier, the sequestration chamber for receiving and sequestering a first portion of the blood sample prior to the sample needle being unsealed by the evacuated blood collection tube. The blood sequestration device further includes a sampling channel having a proximal end connected with the inlet port, the sampling channel for conveying a subsequent portion of the blood sample once the sample needle is unsealed by the evacuated blood collection tube. The blood sequestration device further includes an outlet port connected with a distal end of the sampling channel for conveying the subsequent portion of the blood sample to the sample needle.

In yet another aspect, a blood sample optimization system is disclosed and described. The blood sample optimization system includes a blood sampling system for accessing and acquiring one or more samples of a patient's blood, and a blood sequestration device for receiving and sequestering a first portion of the one or more samples of the patient's blood which might be contaminated by a venipuncture process and which could result in a false positive identification of a pathogen in the patient's blood.

4

The blood sampling system includes a patient needle configured for a venipuncture of a patient to access a sample of blood of a patient, a blood sampling pathway connected with the patient needle for conveying the sample of blood, and a sample needle configured for receiving an evacuated blood collection container to collect and contain a subsequent portion of the sample of blood.

In yet another aspect, a blood sequestration device is disclosed and described. In some implementations, the blood sequestration device can include an inlet port, an outlet port connected with the inlet port, and a sequestration chamber connected with the inlet port. The sequestration chamber can have a vent comprising an air permeable blood barrier.

The blood sequestration device is connected along the blood sampling pathway between the patient needle and the sample needle, and includes an inlet port for receiving the sample of blood. The blood sequestration device further includes a sequestration chamber connected with the inlet port for receiving a first amount of the sample of blood, the sequestration chamber having a vent comprising an air permeable blood barrier for sequestering at least a first portion of the first amount of the sample of blood. The blood sequestration device may further include a sampling channel having a proximal end connected with the inlet port, the sampling channel conveying a subsequent amount of the sample of blood to the evacuated blood collection container upon the sequestration chamber sequestering at least the first portion of the first amount of the sample of blood. The blood sequestration device further includes an outlet port connected with a distal end of the sampling channel, the outlet port for outputting the subsequent amount of the sample of blood.

The details of one or more embodiments are set forth in the accompanying drawings and the description below. Other features and advantages will be apparent from the description and drawings, and from the claims.

BRIEF DESCRIPTION OF THE DRAWINGS

These and other aspects will now be described in detail with reference to the following drawings.

FIG. 1 illustrates a blood sample optimization system.

FIG. 2 illustrates a blood sample optimization system in accordance with an alternative implementation.

FIG. 3 illustrates a blood sample optimization system in accordance with another alternative implementation.

FIG. 4 illustrates a blood sample optimization system in accordance with another alternative implementation.

FIG. 5 illustrates a blood sample optimization system in accordance with another alternative implementation.

FIG. 6 illustrates a blood sample optimization system in accordance with an alternative implementation.

FIG. 7 is a flowchart of a method for optimizing a quality of a blood culture.

FIGS. 8A-8E illustrate a blood sequestration system for non-contaminated blood sampling, in accordance with some implementations.

FIG. 9 illustrates a pathway splitter for use in a blood sequestrations system.

FIGS. 10A-10D illustrate a blood sequestration system for non-contaminated blood sampling, in accordance with alternative implementations.

FIGS. 11A-11E illustrate a blood sequestration system for non-contaminated blood sampling, in accordance with other alternative implementations.

5

FIGS. 12A-12D illustrate a blood sample optimization system including a blood sequestration device in accordance with yet other alternative implementations.

FIGS. 13A-13D illustrate a blood sample optimization system 1300 in accordance with yet another alternative implementations.

FIGS. 14A-14E illustrate yet another implementation of a blood sampling system to sequester contaminants of an initial aliquot or sample to reduce false positives in blood cultures or tests performed on a patient's blood sample.

FIGS. 15A-15G illustrate a blood sequestration device and method of using the same, in accordance with yet another implementation.

FIGS. 16A-16D illustrate a blood sequestration device in accordance with yet another implementation.

FIGS. 17A-17E illustrate a bottom member of a housing for a blood sequestration device.

FIGS. 18A-18F illustrate a top member of a housing for a blood sequestration device.

FIGS. 19A and 19B illustrate a blood sequestration device having a top member mated with a bottom member.

FIG. 20 shows a blood sample optimization system including a blood sequestration device.

FIG. 21 illustrates a non-vented blood sequestration device using a wicking material chamber.

FIGS. 22A and 22B illustrate a material makeup of a filter for sequestering blood in a sequestration chamber of a blood sequestration device.

FIGS. 23A and 23B illustrate another implementation of a blood sequestration device that uses a vacuum force from a blood collection device.

Like reference symbols in the various drawings indicate like elements.

DETAILED DESCRIPTION

This document describes blood sample optimization systems and methods for reducing or eliminating contaminants in collected blood samples, which in turn reduces or eliminates false positive readings in blood cultures or other testing of collected blood samples. In some implementations, a blood sample optimization system includes a patient needle for vascular access to a patient's bloodstream, a sample needle for providing a blood sample to a blood collection container, such as an evacuated blood collection container or tube like a Vacutainer™ or the like, or other sampling device, and a blood sequestration device located between the patient needle and the sample needle. The blood sequestration device includes a sequestration chamber for sequestering an initial, potentially contaminated aliquot of blood, and may further include a sampling channel that bypasses the sequestration chamber to convey likely uncontaminated blood between the patient needle and the sample needle after the initial aliquot of blood is sequestered in the sequestration chamber.

FIG. 1 illustrates a blood sample optimization system in accordance with some implementations. The system includes a patient needle 1 to puncture the skin of a patient to access the patient's vein and blood therein. The system further includes a sample needle (i.e., a resealably closed needle for use with Vacutainers™ or the like) 5, which may be contained within and initially sealed by a resealable boot 10, a Luer activated valve, or another collection interface or device. The resealable boot 10 can be pushed aside or around the sample needle 5 by application of a Vacutainer™ bottle (not shown) for drawing the patient's blood. The system can further include a low volume chamber 30 that leads to the

6

sample needle 5, but also includes an orifice or one or more channels 45 that lead to a sequestration chamber 55 formed by a housing 50.

The sequestration chamber 55 is a chamber, channel, pathway, lock, or other structure for receiving and holding a first aliquot of the patient's blood, which may be in a predetermined or measured amount, depending on a volume of the sequestration chamber 55. The first draw of blood typically contains or is more susceptible to containing organisms that cause bacteraemia and sepsis or other pathogens than subsequent blood draws. The sequestration chamber 55 can be a vessel encased in a solid housing, formed in or defined by the housing itself, or can be implemented as tubing or a lumen. The sequestration chamber 55, regardless how formed and implemented, may have a predetermined volume. In some implementations, the predetermined volume may be based on a volume of the patient needle, i.e. ranging from less than the volume of the patient needle to any volume up to or greater than 20 times or more of the volume of the patient needle. The predetermined volume of the sequestration chamber 55 may also be established to economize or minimize an amount of blood to be sequestered and disposed of.

The sequestration chamber 55 can be formed, contained or housed in a chamber housing 50, and can be made of plastic, rubber, steel, aluminum or other suitable material. For example, the sequestration chamber 55 could be formed of flexible tubing or other elastomeric materials. The sequestration chamber 55 further includes an air permeable blood barrier 20 that allows air to exit the sequestration chamber 55. As used herein the term "air permeable blood barrier" means an air permeable but substantially blood impermeable substance, material, or structure. Examples may include hydrophobic membranes and coatings, a hydrophilic membrane or coating combined with a hydrophobic membrane or coating, mesh, a filter, a mechanical valve, antimicrobial material, or any other means of allowing air to be displaced from the sequestration chamber 55 as it is filled with blood. In various exemplary embodiments, an air permeable blood barrier may be formed by one or more materials that allow air to pass through until contacted by a liquid, such material then becomes completely or partially sealed to prevent or inhibit the passage of air and/or liquid. In other words, prior to contact with liquid, the material forms a barrier that is air permeable. After contact with a liquid, the material substantially or completely prevents the further passage of air and/or liquid.

The orifice or channel 45 can be any desired length, cross-sectional shape or size, and/or can be formed to depart from the low volume chamber 30 at any desired angle or orientation. The orifice or channel 45 may also include a one-way flap or valve 60 that maintains an initial aliquot of blood sample within the sequestration chamber 55. In some specific implementations, the orifice or channel 45 can include a "duck bill" or flapper valve 60, or the like, for one-way flow of blood from low volume chamber 30 to the sequestration chamber 55. The air permeable blood barrier 20 can also be constructed of a material that allows air to exit but then seals upon contact with blood, thereby not allowing external air to enter sequestration chamber 55. This sealing would eliminate the need for a valve.

Valve 60 can be any type of valve or closing mechanism. Chamber 30 is designed to hold virtually no residual blood, and can be designed to be adapted to hold or allow pass-through of a particular volume or rate of blood into sequestration chamber 55. Likewise, sequestration chamber 55 may also include any type of coating, such as an anti-

7

microbial coating, or a coating that aids identification and/or diagnosis of components of the first, sequestered blood draw.

Housing **50** and **40** can be formed of any suitable material, including plastic, such as acrylonitrile butadiene styrene (ABS) or other thermoplastic or polymeric material, rubber, steel, or aluminum. The air permeable blood barrier **20** can include a color-providing substance, or other signaling mechanism, that is activated upon contact with blood from the initial blood draw, or when air displacement is stopped, or any combination of events with blood in the sequestration chamber **55**. The air permeable barrier may also include an outer layer such as a hydrophobic membrane or cover that inhibits or prevents the inadvertent or premature sealing of the filter by an external fluid source, splash etc. Sequestration chamber **55** can also be translucent or clear to enable a user to visually confirm the chamber is filled.

FIG. **2** illustrates a blood sample optimization system in accordance with some alternative implementations. In the implementation shown in FIG. **2**, a sequestration chamber **55**, or waste chamber, surrounds the patient needle **1**, with an open-ended cuff or housing connected with the waste chamber and encircling the sample needle housing base and housing. The patient needle **1** and sample needle **5** are connected together by a boot **56**, which forms a continuous blood draw channel therethrough. The boot **56** includes a single orifice or channel leading from the blood draw channel into sequestration chamber **55**. The device can include more than one single orifice or channel, in other implementations. Each orifice or channel can include a one-way valve, and can be sized and adapted for predetermined amount of blood flow.

The sequestration chamber **55** includes an air permeable blood barrier. The filter can further include a sensor or indicator to sense and/or indicate, respectively, when a predetermined volume of blood has been collected in the sequestration chamber **55**. That indication will alert a user to attach an evacuated blood collection tube or bottle, such as a Vacutainer™ to the sample needle **5**. The housing for the sequestration chamber **55** can be any size or shape, and can include any type of material to define an interior space or volume therein. The interior space is initially filled only with air, but can also be coated with an agent or substance, such as a decontaminate, solidifying agent, or the like. Once evacuated blood collection tube is attached to the sample needle **5**, blood will flow automatically into the patient needle **1**, through the blood draw channel and sample needle **5**, and into the bottle. The sample needle **5** is covered by a resealable boot, coating or membrane that seals the sample needle when a blood collection bottle is not attached thereon or thereto.

FIG. **3** illustrates a blood sample optimization system in accordance with some alternative implementations. In the implementation shown, a sample needle **5** is surrounded by a resealable boot or membrane, and is further connected with a patient needle **1**. A blood flow channel is formed through the sample needle and the patient needle. The connection between the sample needle and patient needle includes a “T” or “Y” connector **102**, which includes a channel, port or aperture leading out from the main blood flow channel to a sequestration chamber **104**.

The T or Y connector **102** may include a flap or one-way valve, and have an opening that is sized and adapted for a predetermined rate of flow of blood. The sequestration chamber **104** can be formed from tubing, or be formed by a solid housing, and is initially filled with air. The sequestration chamber **104** will receive blood that flows out of a

8

patient automatically, i.e. under pressure from the patient's own blood pressure. The sequestration chamber **104** includes an air permeable blood barrier **106**, preferably at the distal end of tubing that forms the sequestration chamber **104**, and which is connected at the proximal end to the T or Y connector **102**. The T or Y connector **102** can branch off at any desired angle for most efficient blood flow, and can be formed so as to minimize an interface between the aperture and channel and the main blood flow channel, so as to minimize or eliminate mixing of the initial aliquot of blood with main blood draw samples.

In some alternative implementations, the sample needle may be affixed to a tubing of any length, as shown in FIG. **4**, connecting at its opposite end to the T or Y connector **102**. The sequestration chamber **104** can be any shape or volume so long as it will contain a predetermined amount of blood sample in the initial aliquot. The T or Y connector **102** may also include an opening or channel that is parallel to the main blood flow channel. The air permeable blood barrier may further include an indicator **107** or other mechanism to indicate when a predetermined amount of blood has been collected in the sequestration chamber, or when air being expelled reaches a certain threshold, i.e. to zero. The tubing can also include a clip **109** that can be used to pinch off and prevent fluid flow therethrough.

Once the air permeable blood barrier and primary chamber are sealed the initial aliquot of blood is trapped in the sequestration chamber **104**, an evacuated blood collection tube, such as a Vacutainer™ bottle may be attached to the sample needle **5** to obtain the sample. The blood collection tube can be removed, and the sample needle **5** will be resealed. Any number of follow-on blood collection tubes can then be attached for further blood draws or samples. Upon completion of all blood draws, the system can be discarded, with the initial aliquot of blood remaining trapped in the sequestration chamber **104**.

FIG. **5** illustrates a blood sample optimization system in accordance with some alternative implementations. In the implementation shown, a sample needle **5** is connected with a patient needle by tubing. A “T” or “Y” connector **120** is added along the tubing at any desired location, and includes an aperture, port or channel leading to a sequestration chamber **204**, substantially as described above.

FIG. **6** illustrates a blood sample optimization system in accordance with some alternative implementations, in which a sequestration chamber **304**, formed as a primary collection channel, receives an initial aliquot of blood, and is provided adjacent to the blood sampling channel. The sequestration chamber **304** can encircle the blood sampling channel, the patient needle **1**, and/or the sample needle **5**. The primary collection channel can include a T or Y connector **120**, or other type of aperture or channel. The sequestration chamber **304** includes an air permeable blood barrier, which can also include an indicator of being contacted by a fluid such as blood, as described above.

In some implementations, either the patient needle **1** or the sample needle **5**, or both, can be replaced by a Luer lock male or female connector. However, in various implementations, the connector at a sample needle end of the blood sample optimization system is initially sealed to permit the diversion of the initial aliquot of blood to the sequestration chamber, which is pressured at ambient air pressure and includes the air outlet of the air permeable blood barrier. In this way, the system passively and automatically uses a patient's own blood pressure to overcome the ambient air pressure of the sequestration chamber to push out air

through the air permeable blood barrier and displace air in the sequestration chamber with blood.

FIG. 7 is a flowchart of an exemplary method for optimizing the quality of a blood culture. At 702, a clinician places a needle into a patient's vein. At 704, blood then flows into a sequestration chamber, pushing the air in the sequestration chamber out of the sequestration chamber through an air permeable blood barrier. In some implementations, the volume of the sequestration chamber is less than 0.1 to more than 5 cubic centimeters (cc's), or more. The sequestration chamber is sized and adapted to collect a first portion of a blood sample, which is more prone to contamination than secondary and other subsequent portion of the blood sample or subsequent draws. Since the sequestration chamber has an air-permeable blood barrier through which air can be displaced by blood pushed from the patient's vein, such blood will naturally and automatically flow into the sequestration chamber before it is drawn into or otherwise enters into a Vacutainer or other bottle for receiving and storing a blood sample.

When the sequestration chamber fills, the blood will gather at or otherwise make contact with the air permeable blood barrier, which will inhibit or prevent blood from passing therethrough. At 706, when the blood comes into contact with the entire internal surface area of the air permeable blood barrier, the air permeable blood barrier is then closed and air no longer flows out or in. At 708, the clinician may be provided an indicator or can see the full chamber, to indicate the evacuated blood collection tube, such as a Vacutainer™ can be attached. The indicator can include visibility into the primary chamber to see whether it is full, the blood barrier changing color, for example, or other indicator. The fill time of the sequestration chamber may be substantially instantaneous, so such indicator, if present, may be only that the sequestration chamber is filled.

Prior to an evacuated blood collection tube being attached, communication between the needle, sampling channel, and the sequestration chamber is restricted by the sealing of the sequestration chamber blood barrier thereby not permitting air to reenter the system through the sequestration. Sealing the communication path could also be accomplished with a mechanical twist or other movement, a small orifice or tortuous pathway, eliminating the need for a separate valve or mechanical movement or operation by the clinician. At 710, once the evacuated blood collection tube is removed, the self-sealing membrane closes the sample needle, and at 712, additional subsequent evacuated blood collection tubes may be attached. Once samples have been taken, at 714 the device is removed from the patient and discarded.

FIGS. 8A-8E illustrate an exemplary blood sample optimization system 800 for non-contaminated blood sampling, in accordance with some implementations. The blood sample optimization system 800 includes an inlet port 802 that can be connected to tubing, a patient needle (or both), or other vascular or venous access device, and a pathway splitter 804 having a first outlet to a sequestration chamber tubing 806 and a second outlet to sample collection tubing 808. One or both of the sequestration chamber tubing 806 and the sample collection tubing 808 can be formed of tubing. In some implementations, the sequestration chamber tubing 806 is sized so as to contain a particular volume of initial blood sample. The sample collection tubing 808 will receive a blood sample once the sequestration chamber tubing 806 is filled. The sample collection tubing 808 can be connected to a Vacutainer™ base or housing 810, or other blood sample collection device.

The blood sequestration system 800 further includes a blood sequestration device 812 which, as shown in more detail in FIGS. 8B-8D, includes a housing 818 that includes a sampling channel 820 defining a pathway for the non-contaminated sample collection tubing 808 or connected at either end to the non-contaminated sample collection tubing 808. The sampling channel 820 can be curved through the housing 818 so as to better affix and stabilize the housing 818 at a location along the non-contaminated sample collection tubing 808.

The blood sequestration device 812 further includes a sequestration chamber 822 connected with the sequestration chamber tubing 806 or other chamber. The sequestration chamber 822 terminates at an air permeable blood barrier 824. The air permeable blood barrier 824 can also include a coloring agent that turns a different color upon full contact with blood, as an indicator that the regular collection of blood samples (i.e. the non-contaminated blood samples) can be initiated. Other indicators may be used, such as a small light, a sound generation mechanism, or the like. In some implementations, the air permeable blood barrier is positioned at a right angle from the direction of sequestration chamber 822, but can be positioned at any distance or orientation in order to conserve space and materials used for the housing 818. The housing 818 and its contents can be formed of any rigid or semi-rigid material or set of materials.

FIG. 9 illustrates a pathway splitter 900 for use in a blood sequestrations system, such as those shown in FIGS. 8A-8E, for example. The pathway splitter 900 includes an inlet port 902, a main line outlet port 904, and a sequestration channel outlet port 906. The inlet port 902 can be connected to main tubing that is in turn connected to a patient needle system, or directly to a patient needle. The main line outlet port 904 can be connected to main line tubing to a blood sampling system, such as a vacutainer base or housing, or directly to such blood sampling system. The sequestration channel outlet port 906 can be connected to sequestration tubing for receiving and sequestering a first sample of blood, up to a measured amount or predetermined threshold. Alternatively, the sequestration channel outlet port 906 can be connected to a sequestration chamber. The sequestration channel outlet port 906 is preferably 20-70 degrees angled from the main line outlet port 904, which in turn is preferably in-line with the inlet port 902. Once the predetermined amount of initial blood sample is sequestered in the sequestration tubing or chamber, in accordance with mechanisms and techniques described herein, follow-on blood samples will flow into the inlet port 902 and directly out the main line outlet port 904, without impedance.

FIGS. 10A-10D illustrate a blood sequestration device 1000 in accordance with alternative implementations. The blood sequestration device 1000 includes an inlet port 1002, a main outlet port 1004, and a sequestration channel port 1006. The inlet port 1002 can be connected to a patient needle or related tubing. The main outlet port 1004 can be connected to a blood sample collection device such as a Vacutainer, associated tubing, or a Luer activated valve, or the like. The sequestration channel port 1006 splits off from the main outlet port 1004 to a sequestration chamber 1008. In some implementations, the sequestration chamber 1008 is formed as a helical channel within a housing or other container 1001.

The sequestration chamber 1008 is connected at the distal end to an air permeable blood barrier 1010, substantially as described above. Air in the sequestration chamber 1008 is displaced through the air permeable blood barrier 1010 by an initial aliquot of blood that is guided into the sequestra-

11

tion channel port **1006**. Once the sequestration chamber **1008** is filled, further blood draws through the main outlet port **1004** can be accomplished, where these samples will be non-contaminated.

FIGS. **11A-11E** illustrate a blood sequestration device **1100** in accordance with other alternative implementations. The blood sequestration device **1100** includes an inlet port **1102**, similar to the inlet ports described above, a main outlet port **1104**, and a sequestration channel port **1106** that splits off from the main outlet port **1104** and inlet port **1102**. The sequestration channel port is connected to a sequestration chamber **1108**. In the implementation shown in FIGS. **11A-11E**, the blood sequestration device includes a base member **1101** having a channel therein, which functions as the sequestration chamber **1108**. The channel can be formed as a tortuous path through the base member **1101**, which is in turn shaped and formed to rest on a limb of a patient.

A portion of the sequestration chamber **1108** can protrude from the base member or near a top surface of the base member, just before exiting to an air permeable blood barrier **1110**, to serve as a blood sequestration indicator **1109**. The indicator **1109** can be formed of a clear material, or a material that changes color when in contact with blood.

In some implementations, the blood sequestration device **1100** can include a blood sampling device **1120** such as a normally closed needle, Vacutainer™ shield or other collection device. The blood sampling device **1120** can be manufactured and sold with the blood sequestration device **1100** for efficiency and convenience, so that a first aliquot of blood that may be contaminated by a patient needle insertion process can be sequestered. Thereafter, the blood sampling device **1120** can draw non-contaminated blood samples to reduce the risk of false positive testing and ensure a non-contaminated sample.

FIGS. **12A-12D** illustrate a blood sample optimization system **1200** in accordance with yet other alternative implementations. The system **1200** includes a blood sequestration device **1202** for attaching to a blood sampling device **1204**, such as a Vacutainer™ or other collection and sampling device. The blood sequestration device **1202** is configured and arranged to receive, prior to a Vacutainer™ container or vial being attached to a collection needle of the blood sampling device **1204**, a first aliquot or amount of blood, and sequester that first aliquot or amount in a sequestration channel of the blood sequestration device **1202**.

In some implementations, the blood sequestration device **1202** can include an inlet port **1212**, a main outlet port, and a sequestration channel port. The inlet port **1212** can be connected to a patient needle or related tubing. The main outlet port **1214** can be connected to a normally closed needle or device to enable connection with an evacuated blood collection container or other collection device such as a Vacutainer™, associated tubing, luer connectors, syringe, a Luer activated valve, or the like. The sequestration channel port splits off from the main outlet port to a sequestration chamber **1218**.

In some implementations, the sequestration chamber **1218** is formed as a channel within the body of a sequestration device **1202**. The sequestration chamber **1218** can be a winding channel, such as a U-shaped channel, an S-shaped channel, a helical channel, or any other winding channel. The sequestration device **1202** can include a housing or other containing body, and one or more channels formed therein. As shown in FIGS. **12A** and **12B**, the sequestration device **1202** includes a main body **1206** and a cap **1208**. The main body **1206** is formed with one or more cavities or channels, which are further formed with one or more arms

12

1210 that extend from the cap **1208**, and which abut the cavities or channels in the main body **1206** to form the primary collection port and main outlet port.

FIGS. **13A-13D** illustrate a blood sample optimization system **1300** in accordance with yet other alternative implementations. The system **1300** includes a blood sequestration device **1302** for attaching to a blood sampling device **1304**, such as a Vacutainer or other bodily fluid collection and sampling device. The blood sequestration device **1302** is configured and arranged to receive, prior to a Vacutainer container or vial being attached to a collection needle of the blood sampling device **1304**, a first aliquot or amount of blood, and to sequester that first aliquot or amount of blood or other bodily fluid in a sequestration channel of the blood sequestration device **1302**.

The blood sequestration device **1302** includes a housing **1301** having an inlet port **1314**, a main outlet port **1312**, and a sequestration channel port **1316**. The inlet port **1314** can be connected to a patient needle or associated tubing. The main outlet port **1312** can be connected to a normally closed needle or device to enable connection with an evacuated blood collection container or other collection device such as a Vacutainer™, associated tubing, luer connectors, syringe, a Luer activated valve, or the like. The sequestration channel port **1316** splits off from the main inlet port **1314** to a sequestration chamber **1318**.

In the implementation shown in FIGS. **13A-D**, the sequestration chamber **1318** is formed as a cavity or chamber within housing **1301** or formed by walls that define housing **1301**. The sequestration chamber **1318** can be a winding channel, such as a U-shaped channel, an S-shaped channel, a helical channel, or any other winding channel, that is defined by the cooperation and connection of housing **1301** with cap **1307** which cap **1307** can include a protrusion **1305** that provides one or more walls or directors for the winding channel in the sequestration chamber **1318**. The protrusion **1305** from the cap **1307** can be straight or curved, and may have various channels, apertures or grooves embedded therein, and can extend from the cap **1307** any angle or orientation. When the cap **1307** is connected with the housing **1301** to complete the formation of the sequestration chamber **1318**, the protrusion **1305** forms at least part of the winding channel to sequester a first aliquot or amount of blood or other bodily fluid in a sequestration channel formed in the sequestration chamber **1318** and by the winding channel.

The sequestration chamber **1318** includes an air permeable blood barrier **1310**, substantially as described above. Air in the sequestration chamber **1318** is displaced through the air permeable blood barrier **1310** by an initial aliquot of blood that is provided into the sequestration chamber **1318** by the blood pressure of the patient. Once the sequestration chamber **1318** is filled and the air in the sequestration chamber **1318** displaced, the blood pressure of the patient will be insufficient to drive or provide further blood into the blood sequestration device **1302**, and in particular the outlet port **1312**, until a force such as a vacuum or other pressure, such as provided by the blood sample collection device like Vacutainer is provided to draw out a next aliquot or amount of blood or bodily fluid. Further blood draws through the main outlet port **1312** can be accomplished, where these samples will be non-contaminated since any contaminants would be sequestered in the sequestration chamber **1318** with the first aliquot of blood.

FIGS. **14A-14E** illustrate yet another implementation of a blood sampling system **1400** to sequester contaminants of an initial aliquot or sample to reduce false positives in blood

13

cultures or tests performed on a patient's blood sample. The blood sampling system **1400** includes a blood sequestration device **1401** that can be connected between a blood sample collection device **1403** and a patient needle (not shown). The blood sample collection device **1403** can be a Vacutainer or the like. The blood sequestration device **1401** includes an inlet port **1402** that can be connected with a patient needle that is inserted into a patient's vascular system for access to and withdrawing of a blood sample. The inlet port **1402** may also be connected with tubing or other conduit that is in turn connected with the patient needle.

The inlet port **1402** defines an opening into the blood sequestration device **1401**, which opening can be the same cross sectional dimensions as tubing or other conduit connected with the patient needle or the patient needle itself. For instance, the opening can be circular with a diameter of approximately 0.045 inches, but can have a diameter of between 0.01 inches or less to 0.2 inches or more. The blood sequestration device **1401** further includes an outlet port **1404**, which defines an opening out of the blood sequestration device **1401** and to the blood sample collection device **1403**. The outlet port **1404** may also be connected with tubing or other conduit that is in turn connected with the blood sequestration device **1403**. The outlet port **1404** can further include a connector device such as a threaded cap, a Luer connector (male or female), a non threaded interference or glue joint fitting for attachment of various devices including but not limited to tubing, or the like.

The blood sequestration device **1401** further includes a sampling channel **1406** between the inlet port **1402** and the outlet port **1404**, and which functions as a blood sample pathway once a first aliquot of blood has been sequestered. The sampling channel **1406** can be any sized, shaped or configured channel, or conduit. In some implementations, the sampling channel **1406** has a substantially similar cross sectional area as the opening of the inlet port **1402**. In other implementations, the sampling channel **1406** can gradually widen from the inlet port **1402** to the outlet port **1404**.

The blood sequestration device **1401** further includes a sequestration chamber **1408** that is connected to and split off or diverted from the sampling channel **1406** at any point between the inlet port **1402** and the outlet port **1404**, but preferably from a proximal end of the sampling channel **1406** near the inlet port **1402**. The sequestration chamber **1408** is at first maintained at atmospheric pressure, and includes an air outlet **1412** at or near a distal end of the sequestration chamber **1408** opposite the diversion point from the sampling channel **1406**. The air outlet **1412** includes an air permeable blood barrier **1412**. As shown in FIG. **14B**, the air permeable blood barrier **1412** can be overlaid with a protective cover **1416**. The protective cover **1416** can be sized and configured to inhibit a user from touching the air permeable blood barrier **1412** with their finger or other external implement, while still allowing air to exit the air permeable blood barrier **1412** as the air is displaced from the sequestration chamber **1408** by blood being forced into the sequestration chamber **1408** by a patient's own blood pressure. In addition the protective cover **1416** can be constructed to inhibit or prevent accidental exposure of the air permeable blood barrier to environmental fluids or splashes. This can be accomplished in a variety of mechanical ways including but not limited to the addition of a hydrophobic membrane to the protective cover.

As shown in FIGS. **14C** and **14D**, the sampling channel **1406** can be cylindrical or frusto-conical in shape, going from a smaller diameter to a larger diameter, to minimize a potential to lyse red blood cells. Likewise, the sampling

14

channel **1406** is formed with a minimal amount of or no sharp turns or edges, which can also lyse red blood cells. The sampling channel **1406** splits off to the sequestration chamber **1408** near the inlet port **1402** via a diversion pathway **1409**. The diversion pathway **1409** can have any cross-sectional shape or size, but is preferably similar to the cross-sectional shape of at least part of the inlet port **1402**.

In some implementations, the sampling channel **1406** and the sequestration chamber **1408** are formed by grooves, channels, locks or other pathways formed in housing **1414**. The housing **1414** can be made of plastic, metal or other rigid or semi-rigid material. The housing **1414** can have a bottom member that sealably mates with a top member. One or both of the bottom member and the top member can include the sampling channel **1406** and the sequestration chamber **1408**, as well as the diversion pathway **1409**, the inlet port **1402**, and the outlet port **1404**. In some other implementations, one or more of the diversion pathway **1409**, the inlet port **1402**, and/or the outlet port **1404** can be at least partially formed by a cap member that is connected to either end of the housing **1414**. In some implementations, the top member and the bottom member, as well as the cap member(s), can be coupled together by laser welding, heat sealing, gluing, snapping, screwing, bolting, or the like. In other implementations, some or all of the interior surface of the diversion pathway **1409** and/or sequestration chamber **1408** can be coated or loaded with an agent or substance, such as a decontaminate, solidifying agent, or the like. For instance, a solidifying agent can be provided at the diversion pathway **1409** such that when the sequestration chamber **1408** is filled and the initial aliquot of blood backs up to the diversion pathway **1409**, that last amount of sequestered blood could solidify, creating a barrier between the sequestration chamber **1408** and the sampling channel **1406**.

FIGS. **15A-15G** illustrate a blood sequestration device **1500**. The blood sequestration device **1500** can be connected to a normally closed needle or device to enable connection with an evacuated blood collection container or other collection device such as a Vacutainer™, associated tubing, luer connectors, syringe, a Luer activated valve, or the like.

The blood sequestration device **1500** includes an inlet port **1502** that can be connected with a patient needle that is inserted into a patient's vascular system for access to and withdrawing of a blood sample. The inlet port **1502** may also be connected with tubing or other conduit that is in turn connected with the patient needle. The inlet port **1502** defines an opening into the blood sequestration device **1500**, which opening may be the same cross sectional dimensions as tubing or other conduit connected with the patient needle or the patient needle itself. For instance, the opening can be circular with a diameter of approximately 0.045 inches, but can have a diameter of between 0.01 inches or less to 0.2 inches or more.

The inlet port **1502** can also include a sealing or fluid-tight connector or connection, such as threading or Luer fitting, or the like. In some implementations, tubing or other conduit associated with the patient needle can be integral with the inlet port **1502**, such as by co-molding, gluing, laser weld, or thermally bonding the parts together. In this manner, the blood sequestration device **1500** can be fabricated and sold with the patient needle as a single unit, eliminating the need for connecting the patient needle to the blood sequestration device **1500** at the time of blood draw or sampling.

The blood sequestration device **1500** further includes an outlet port **1504**, which defines an opening out of the blood sequestration device **1500** and to the blood sample collection device. The outlet port **1504** may also be connected with

15

tubing or other conduit that is in turn connected with the blood sequestration device, and may also include a sealing or fluid-tight connector or connection, such as threading or Luer fitting, or the like. Accordingly, as discussed above, the blood sequestration device **1500** can be fabricated and sold with the patient needle and/or tubing and the blood sample collection device as a single unit, eliminating the need for connecting the patient needle and the blood sample collection device to the blood sequestration device **1500** at the time of blood draw or sampling.

The blood sequestration device **1500** further includes a sampling channel **1506** between the inlet port **1502** and the outlet port **1504**, and which functions as a blood sample pathway once a first aliquot of blood has been sequestered. The sampling channel **1506** can be any sized, shaped or configured channel or conduit. In some implementations, the sampling channel **1506** has a substantially similar cross sectional area as the opening of the inlet port **1502**. In other implementations, the sampling channel **1506** can gradually widen from the inlet port **1502** to the outlet port **1504**.

The blood sequestration device **1500** further includes a sequestration chamber **1508** that is connected to and split off or diverted from the sampling channel **1506** at any point between the inlet port **1502** and the outlet port **1504**, but preferably from a proximal end of the sampling channel **1506** near the inlet port **1502**. In some implementations, the diversion includes a Y-shaped junction. The sequestration chamber **1508** is preferably maintained at atmospheric pressure, and includes a vent **1510** at or near a distal end of the sequestration chamber **1508**. The vent **1510** includes an air permeable blood barrier **1512**. FIG. **15C** illustrates the blood sequestration device **1500** with the sequestration chamber **1508** filled with a first aliquot or sample of blood from the patient.

The air permeable blood barrier **1512** can be covered with a protective cover **1516**. The protective cover **1516** can be sized and configured to inhibit a user from touching the air permeable blood barrier **1512** with their finger or other external implement, while still allowing air to exit the air permeable blood barrier **1512** as the air is displaced from the sequestration chamber **1508** by blood being forced into the sequestration chamber **1508** by a patient's own blood pressure. The protective cover **1516** can be constructed to inhibit or prevent accidental exposure of the filter to environmental fluids or splashes. This can be accomplished in a variety of mechanical ways including but not limited to the addition of a hydrophobic membrane to the protective cover.

FIG. **15B** is a perspective view of the blood sequestration device **1500** from the outlet port **1504** and top side of a housing **1501** of the blood sequestration device **1500** that includes the vent **1510**, and illustrating an initial aliquot of blood filling sequestration chamber **1508** while the sampling channel **1506** is empty, before a sample collection device is activated. FIG. **15G** is a perspective view of the blood sequestration device **1500** from the outlet port **1504** and bottom side of the housing **1501** of the blood sequestration device **1500**, and illustrating the initial aliquot of blood filling sequestration chamber **1508** while the sampling channel **1506** is empty, before the sample collection device is activated. FIG. **15C** is another perspective view of the blood sequestration device **1500** from the inlet port **1502** and top side of a housing **1501** of the blood sequestration device **1500** that includes the vent **1510**, and illustrating blood now being drawn through sampling channel **1506** while the sequestered blood remains substantially in the sequestration chamber **1508**.

16

FIG. **15D** is a cross section of the blood sequestration device **1500** in accordance with some implementations, showing the housing **1501** that defines the sampling channel **1506** and the sequestration chamber **1508**. FIGS. **15E** and **15F** illustrate various form factors of a housing for a blood sequestration device, in accordance with one or more implementations described herein.

The sequestration chamber **1508** can have a larger cross-sectional area than the sampling channel **1506**, and the cross-sectional area and length can be configured for a predetermined or specific volume of blood to be sequestered or locked. The sampling channel **1506** can be sized to be compatible with tubing for either or both of the patient needle tubing or the blood collection device tubing.

The housing **1501** can be formed of multiple parts or a single, unitary part. In some implementations, and as illustrated in FIG. **15D**, the housing **1501** includes a top member **1520** and a bottom member **1522** that are mated together, one or both of which having grooves, channels, locks, conduits or other pathways pre-formed therein, such as by an injection molding process or by etching, cutting, drilling, etc. The top member **1520** can be connected with the bottom member **1522** by any mating or connection mechanism, such as by laser welding, thermal bonding, ultrasonic welding, gluing, using screws, rivets, bolts, or the like, or by other mating mechanisms such as latches, grooves, tongues, pins, flanges, or the like.

In some implementations, such as shown in FIG. **15D**, the top member **1520** can include the grooves, channels, locks, conduits or other pathways, while the bottom member **1522** can include a protrusion **1524** that is sized and adapted to fit into at least one of the grooves, channels, locks or other pathways of the top member **1520**. The protrusion **1524** can provide a surface feature, such as a partial groove or channel, for instance, to complete the formation of either the sampling channel **1506** and/or the sequestration chamber **1508**. In some implementations, the protrusion **1524** can be formed with one or more angled sides or surfaces for a tighter fit within the corresponding groove, channel, lock or other pathway. In yet other implementations, both the top member **1520** and the bottom member can include grooves, channels, locks or other pathways, as well as one or more protrusions **1524**.

In some implementations, the sampling channel **1506** and the sequestration chamber **1508** are formed by grooves, channels, locks or other pathways formed in housing **1501**. The housing **1501** can be made of any suitable material, including rubber, plastic, metal or other material. The housing **1501** can be formed of a clear or translucent material, or of an opaque or non-translucent material. In other implementations, the housing **1501** can be mostly opaque or non-translucent, while the housing surface directly adjacent to the sampling channel **1506** and/or the sequestration chamber **1508** is clear or translucent, giving a practitioner a visual cue or sign that the sequestration chamber **1508** is first filled to the extent necessary or desired, and/or then a visual cue or sign that the sequestered blood remains sequestered while a clean sample of blood is drawn through the sampling channel **1506**. Other visual cues or signs of the sequestration can include, without limitation: the air permeable blood barrier **1512** turning a different color upon contact, saturation, or partial saturation with blood; a color-coded tab or indicator at any point along or adjacent to the sequestration chamber; an audible signal; a vibratory signal; or other signal.

After a venipuncture by a patient needle of a patient (not shown), which could gather a number of pathogens from the

17

patient's skin, a first amount of the patient's blood with those pathogens will make its way into the input port **1502** blood sequestration device **1500** and flow into the sequestration chamber **1508** by following the path of least resistance, as the patient's own blood pressure overcomes the atmospheric pressure in the sequestration chamber **1508** to displace air therein through the air permeable blood barrier **1512**. The patient's blood pressure will not be sufficient to overcome the air pressure that builds up in the sealed sampling channel **1506**. Eventually, the sequestration chamber **1508**, which has a predetermined volume, is filled with blood that displaces air through the air permeable blood barrier **1512**. Once the blood hits the air permeable blood barrier, the blood interacts with the air permeable blood barrier **1512** material to completely or partially seal the vent **1510**. A signal or indication may be provided that the practitioner can now utilize the Vacutainer capsule or other blood sample collection device to acquire a next amount of the patient's blood for sampling. The blood in the sequestration chamber **1508** is now effectively sequestered in the sequestration chamber.

Upon filling the blood sequestration pathway **1508** but prior to use of the Vacutainer or other blood sample collection device, the patient's blood pressure may drive compression of the air in the sampling channel **1506**, possibly resulting in a small amount of blood moving past the diversion point to the sequestration chamber **1508** and into the sampling channel **1506**, queuing up the uncontaminated blood to be drawn through the sampling channel **1506**.

FIGS. **16-19** illustrate yet another implementation of a blood sequestration device. FIGS. **16A-16D** illustrate a blood sequestration device **1600** that can be connected between a blood sample collection device, such as an evacuated blood collection container like a Vacutainer™ (not shown), and a patient needle (not shown) and/or associated tubing. FIG. **17** illustrates a bottom member of the blood sequestration device, and FIG. **18** illustrates a top member of the blood sequestration device, which top member and bottom member can be mated together to form an input port, and output port, a sequestration chamber and a sampling channel, as explained more fully below. FIGS. **19A** and **B** show the top member and bottom member mated together. It should be understood that FIGS. **16-19** illustrate one exemplary manner of constructing a blood sequestration device as described herein, and other forms of construction are possible.

Referring to FIGS. **16A-D**, the blood sequestration device **1600** includes an inlet port **1602** that can be connected with a patient needle that is inserted into a patient's vascular system for access to and withdrawing of a blood sample. The inlet port **1602** may also be connected with tubing or other conduit that is in turn connected with the patient needle. The inlet port **1602** defines an opening into the blood sequestration device **1600**, which opening can be the same cross sectional dimensions as tubing or other conduit connected with the patient needle or the patient needle itself. For instance, the opening can be circular with a diameter of approximately 0.045 inches, but can have a diameter of between 0.01 inches or less to 0.2 inches or more.

The inlet port **1602** can also include a sealing or fluid-tight connector or connection, such as threading or Luer fitting, or the like. In some implementations, tubing or other conduit associated with the patient needle can be integral with the inlet port **1602**, such as by co-molding, gluing, laser weld, or thermally bonding the parts together. In this manner, the blood sequestration device **1600** can be fabricated and sold with the patient needle and/or tubing as a single unit,

18

eliminating the need for connecting the patient needle to the blood sequestration device **1600** at the time of blood draw or sampling.

The blood sequestration device **1600** further includes an outlet port **1604**, which defines an opening out of the blood sequestration device **1600** and to the blood sample collection device. The outlet port **1604** may also be connected with tubing or other conduit that is in turn connected with the blood sequestration device, and may also include a sealing or fluid-tight connector or connection, such as threading or Luer fitting, or the like. Accordingly, as discussed above, the blood sequestration device **1600** can be fabricated and sold with the patient needle and/or tubing and the blood sample collection device as a single unit, eliminating the need for connecting the patient needle and the blood sample collection device to the blood sequestration device **1600** at the time of blood draw or sampling.

The blood sequestration device **1600** further includes a sampling channel **1606** between the inlet port **1602** and the outlet port **1604**, and a sequestration chamber **1608** that is connected to and split off or diverted from the sampling channel **1606** at any point between the inlet port **1602** and the outlet port **1604**. The sampling channel **1606** functions as a blood sampling pathway once a first aliquot of blood has been sequestered in the sequestration chamber **1608**. The sampling channel **1606** can be any sized, shaped or configured channel, or conduit. In some implementations, the sampling channel **1606** has a substantially similar cross sectional area as the opening of the inlet port **1602**. In other implementations, the sampling channel **1606** can gradually widen from the inlet port **1602** to the outlet port **1604**. The sequestration chamber **1608** may have a larger cross section to form a big reservoir toward the sequestration channel path so that the blood will want to enter the reservoir first versus entering a smaller diameter on the sampling channel **1606**, as is shown more fully in FIGS. **17** and **19**.

In some exemplary implementations, the diversion between the sampling channel **1606** and the sequestration chamber **1608** is by diverter junction **1607**. Diverter junction **1607** may be a substantially Y-shaped, T-shaped, or U-shaped. In some preferred exemplary implementations, and as shown in FIG. **17A-17B**, the diverter junction **1607** is configured such that the flow out of the inlet port **1602** is preferentially directed toward the sequestration chamber **1608**. The sequestration chamber **1608** may also include or form a curve or ramp to direct the initial blood flow toward and into the sequestration chamber **1608**.

The sequestration chamber **1608** is preferably maintained at atmospheric pressure, and includes a vent **1610** at or near a distal end of the sequestration chamber **1608**. The vent **1610** may include an air permeable blood barrier **1612** as described above.

The blood sequestration device **1600** can include a housing **1601** that can be formed of multiple parts or a single, unitary part. In some implementations, and as illustrated in FIGS. **17A-17E** and FIGS. **18A-18F**, the housing **1601** includes a top member **1620** and a bottom member **1622** that are mated together. The blood sequestration device **1600** can also include a gasket or other sealing member (not shown) so that when the top member **1620** is mechanically attached with the bottom member **1622**, the interface between the two is sealed by the gasket or sealing member. The FIGS. **17A-17E** illustrate a bottom member **1622** of a housing for a blood sequestration device **1600**. The bottom member **1622** can include grooves, channels, locks, conduits or other pathways pre-formed therein, such as by an injection mold-

19

ing process or by etching, cutting, drilling, etc., to form the sampling channel **1606**, the sequestration chamber **1608**, and diverter junction **1607**.

The sequestration chamber **1608** may have a larger cross section than the sampling channel **1606** so that the blood will preferentially move into the sequestration chamber first versus entering a smaller diameter on the sampling channel **1606**.

FIGS. **18A-18F** illustrate the top member **1620**, which can be connected with the bottom member **1622** by any mating or connection mechanism, such as by laser welding, thermal bonding, gluing, using screws, rivets, bolts, or the like, or by other mating mechanisms such as latches, grooves, tongues, pins, flanges, or the like. The top member **1620** can include some or all of the grooves, channels, locks, conduits or other pathways to form the sampling channel **1606**, the sequestration chamber **1608**, and the diverter junction **1607**. In yet other implementations, both the top member **1620** and the bottom member **1622** can include the grooves, channels, locks or other pathways.

In some implementations, the sampling channel **1606** and the sequestration chamber **1608** are formed by grooves, channels, locks or other pathways formed in housing **1601**. The housing **1601** can be made of rubber, plastic, metal or any other suitable material. The housing **1601** can be formed of a clear or translucent material, or of an opaque or non-translucent material. In other implementations, the housing **1601** can be mostly opaque or non-translucent, while the housing surface directly adjacent to the sampling channel **1606** and/or the sequestration chamber **1608** may be clear or translucent, giving a practitioner a visual cue or sign that the sequestration chamber **1608** is first filled to the extent necessary or desired, and/or then a visual cue or sign that the sequestered blood remains sequestered while a clean sample of blood is drawn through the sampling channel **1606**. Other visual cues or signs of the sequestration can include, without limitation: the air permeable blood barrier **1612** turning a different color upon contact, saturation, or partial saturation with blood; a color-coded tab or indicator at any point along or adjacent to the sequestration chamber; an audible signal; a vibratory signal; or other signal.

As shown in FIGS. **18A-18F**, the air permeable blood barrier **1612** can be covered with, or surrounded by, a protective member **1616**. The protective member **1616** can be sized and configured to inhibit a user from touching the air permeable blood barrier **1612** with their finger or other external implement, while still allowing air to exit the air permeable blood barrier **1612** as the air is displaced from the sequestration chamber **1608**. In some implementations, the protective member **1616** includes a protrusion that extends up from a top surface of the top member **1620** and around the air permeable blood barrier **1612**. The protective cover **1616** can be constructed to inhibit or prevent accidental exposure of the filter to environmental fluids or splashes. This can be accomplished in a variety of mechanical ways including but not limited to the addition of a hydrophobic membrane to the protective cover.

In use, the blood sequestration device **1600** includes a sampling channel **1606** and a sequestration chamber **1608**. Both pathways are initially air-filled at atmospheric pressure, but the sampling channel **1606** is directed to an output port **1604** that will be initially sealed by a Vacutainer or other such sealed blood sampling device, and the sequestration chamber **1608** terminates at a vent **1610** to atmosphere that includes an air permeable blood barrier **1612**.

After a venipuncture by a patient needle of a patient (not shown), which could gather a number of pathogens from the

20

patient's skin, a first amount of the patient's blood with those pathogens will pass through input port **1602** of blood sequestration device **1600**. This initial volume of potentially contaminated blood will preferentially flow into the sequestration chamber **1608** by finding the path of least resistance. The patient's own blood pressure overcomes the atmospheric pressure in the vented sequestration chamber **1608** to displace air therein through the air permeable blood barrier **1612**, but is not sufficient to overcome the air pressure that builds up in the sealed sampling channel **1606**. In various exemplary embodiments, the sequestration chamber **1608** and sampling channel **1606** can be configured such that the force generated by the patient's blood pressure is sufficient to overcome any effect of gravity, regardless of the blood sequestration device's orientation.

Eventually, the sequestration chamber **1608** fills with blood that displaces air through the air permeable blood barrier **1612**. Once the blood contacts the air permeable blood barrier **1612** material to completely or partially seal the vent **1610**. A signal or indication may be provided that the practitioner can now utilize the Vacutainer or other blood sampling device.

Upon filling the blood sequestration pathway **1608** but prior to use of the Vacutainer or other blood sample collection device, the patient's blood pressure may drive compression of the air in the sampling channel **1606**, possibly resulting in a small amount of blood moving past the diversion point into the sampling channel **1606**, queuing up the uncontaminated blood to be drawn through the sampling channel **1606**.

FIG. **19A** is a side view, and FIG. **19B** is a cross-sectional view, of the blood sequestration device **1600**, illustrating the top member **1620** mated with the bottom member **1622**.

FIG. **20** shows a blood sample optimization system **2000** that includes a patient needle **2002** for vascular access to a patient's bloodstream, a blood sample collection device **2004** to facilitate the collecting of one or more blood samples, and a conduit **2006** providing a fluid connection between the patient needle **2002** and the blood sample collection device **2004**. In some implementations, the blood sample collection device **2004** includes a protective shield that includes a sealed collection needle on which a sealed vacuum-loaded container is placed, which, once pierced by the collection needle, draws in a blood sample under vacuum pressure or force through the conduit **2006** from the patient needle **2002**.

The blood sample optimization system **2000** further includes a blood sequestration device **2008**, located at any point on the conduit **2006** between the patient needle **2002** and the blood sample collection device **2004** as described herein.

FIG. **21** illustrates a non-vented blood sequestration device **2100** using a wicking material chamber. The blood sequestration device **2100** includes a housing **2101** that has a sampling channel **2104** that is at least partially surrounded or abutted by a sequestration chamber **2102** that is filled with a wicking material. An initial aliquot of blood is drawn in from the patient needle into the sampling channel **2104** where it is immediately wicked into the wicking material of the sequestration chamber **2102**. The wicking material and/or sequestration chamber **2102** is sized and adapted to receive and hold a predetermined amount of blood, such that follow-on or later blood draws pass by the wicking material and flow straight through the sampling channel **2104** to a

21

sampling device such as a Vacutainer. The wicking material can include a substance such as a solidifier, a decontaminate, or other additive.

As described herein, an air permeable blood barrier may be created using a wide variety of different structures and materials. As shown in FIGS. 22A and B, an air permeable blood barrier **2202** of a blood sequestration device **2200** can include a polymer bead matrix **2204**, in which at least some beads are treated to make them hydrophilic. The air permeable blood barrier **2202** further includes a self-sealing material **2206**, such as carboxymethyl cellulose (CMC) or cellulose gum, or other sealing material. The air permeable blood barrier **2202** can further include voids **2208** that permit air flow before contact or during partial contact with a fluid such as blood. As shown in FIG. 22B, contact with a fluid causes the self-sealing material **2206** to swell and close off the voids **2208**, occluding air flow through the voids **2208** and creating a complete or partial seal.

FIGS. 23A and B illustrate yet another implementation of a blood sequestration device **2300**, having an inlet port **2302** to connect with a patient needle, an outlet port **2304** to connect with a blood sample collection device, a sequestration chamber **2306**, and a sampling channel **2308** that bypasses the sequestration chamber **2306** once the sequestration chamber is filled to an initial aliquot of potentially contaminated blood to be sequestered. The sequestration chamber **2306** includes a hydrophobic plug **2312** at a distal end of the sequestration chamber **2306** that is farthest from the inlet port **2302**. A vacuum or other drawing force applied from the outlet port **2304**, such as from a Vacutainer or the like, draws in blood into the inlet port **2302** and directly into the sequestration chamber **2306**, where the initial aliquot of blood will contact the hydrophobic plug **2312** and cause the initial aliquot of blood to back up into the sequestration chamber **2306** and be sequestered there. A small amount of blood may make its way into the sampling channel **2308**, which is initially closed off by valve **2308**. Upon release of the valve **2308**, and under further force of the vacuum or other force, follow-on amounts of blood will flow into inlet port **2302**, bypass the sequestration chamber **2306**, and flow into and through sampling channel **2308** toward the outlet port **2304** and to the collection device.

The sampling channel **2308** can have any suitable geometry and can be formed of plastic tubing or any other suitable material. Valve **2308** can be a clip or other enclosing device to pinch, shunt, bend or otherwise close off the sampling channel before the initial aliquot of blood is sequestered in the sequestration chamber **2306**.

Although a variety of embodiments have been described in detail above, other modifications are possible. Other embodiments may be within the scope of the following claims.

The invention claimed is:

1. A device comprising:

- an inlet port configured for receiving a blood sample;
- an outlet port;
- a chamber connected to the inlet port and being configured to collect a first portion of the blood sample, the chamber having a blood impermeable membrane configured to facilitate the chamber collecting the first portion of the blood sample;
- a housing, separate from the blood impermeable membrane; and
- a sampling channel connected with the inlet port and configured to convey a subsequent portion of the blood sample to the outlet port.

22

2. The device in accordance with claim **1**, wherein the blood impermeable membrane is configured to cause the first portion of the blood sample to back up into the chamber following application of a drawing force applied from the outlet port.

3. The device in accordance with claim **1**, wherein the device is configured such that, when a drawing force is applied at the outlet port, the first portion of the blood sample is drawn into the chamber to contact a material that is blood impermeable.

4. The device in accordance with claim **1**, further comprising a valve configured to initially close off the sampling channel.

5. The device in accordance with claim **1**, further comprising a valve configured to initially close off the sampling channel until the first portion of the blood sample is in the chamber.

6. The device in accordance with claim **1**, further comprising a valve that is configured to initially close off the sampling channel until the first portion of the blood sample is in the chamber and is further configured such that, upon release, the subsequent portion of the blood sample will bypass the chamber and flow through the sampling channel toward the outlet port.

7. The device in accordance with claim **4**, wherein the valve is configured to pinch, shunt, bend or otherwise close off the sampling channel before the first portion of the blood sample is collected in the chamber.

8. The device in accordance with claim **1**, wherein the housing defines the inlet port, the sampling channel, and the outlet port.

9. The device in accordance with claim **1**, further comprising a patient needle and a sample collection device.

10. The device in accordance with claim **1**, the chamber having a volume configured to be sufficient to collect the first portion of the blood sample that is more prone to contamination and also to minimize an amount of blood to be sequestered.

11. The device in accordance with claim **1**, wherein the chamber has a volume of less than 1.5 cubic centimeters.

12. A device comprising:

- an inlet port configured for receiving blood;
- an outlet port;
- a chamber connected to the inlet port and being configured to collect a first portion of the blood, the chamber comprising a flexible blood impermeable membrane that allows the chamber to collect the first portion of the blood; and
- a sampling channel connected with the inlet port and configured to convey a subsequent portion of the blood to the outlet port.

13. The device in accordance with claim **12**, wherein the flexible blood impermeable membrane is configured to cause the first portion of the blood to back up into the chamber following application of a drawing force applied from the outlet port.

14. The device in accordance with claim **12**, wherein the device is configured such that, when a drawing force is applied at the outlet port, the first portion of the blood is drawn into the chamber to contact a material that is blood impermeable.

15. The device in accordance with claim **12**, further comprising a valve configured to initially close off the sampling channel.

23

16. The device in accordance with claim 12, further comprising a valve configured to initially close off the sampling channel until the first portion of the blood is in the chamber.

17. The device in accordance with claim 12, further comprising a valve that is configured to initially close off the sampling channel until the first portion of the blood is in the chamber and is further configured such that, upon release, the subsequent portion of the blood will bypass the chamber and flow through the sampling channel toward the outlet port.

18. The device in accordance with claim 15, wherein the valve is configured to pinch, shunt, bend or otherwise close off the sampling channel before the first portion of the blood is collected in the chamber.

19. The device in accordance with claim 12, further comprising a patient needle and a sample collection device.

20. The device in accordance with claim 12, the chamber having a volume configured to be sufficient to collect the first portion of the blood that is more prone to contamination and also to minimize an amount of blood to be sequestered.

21. A device comprising:

an inlet port configured for receiving blood;

an outlet port;

a chamber connected to the inlet port, the chamber having a blood impermeable membrane and being configured to collect a first portion of the blood; and

a sampling channel connected with the inlet port and configured to convey a subsequent portion of the blood to the outlet port.

22. The device in accordance with claim 21, wherein the blood impermeable membrane is configured to cause the first portion of the blood to back up into the chamber following application of a drawing force applied from the outlet port.

24

23. The device in accordance with claim 21, wherein the device is configured such that, when a drawing force is applied at the outlet port, the first portion of the blood is drawn into the chamber to contact a material that is blood impermeable.

24. The device in accordance with claim 21, further comprising a valve configured to initially close off the sampling channel.

25. The device in accordance with claim 21, further comprising a valve configured to initially close off the sampling channel until the first portion of the blood is in the chamber.

26. The device in accordance with claim 21, further comprising a valve that is configured to initially close off the sampling channel until the first portion of the blood is in the chamber and is further configured such that, upon release, the subsequent portion of the blood will bypass the chamber and flow through the sampling channel toward the outlet port.

27. The device in accordance with claim 24, wherein the valve is configured to pinch, shunt, bend or otherwise close off the sampling channel before the first portion of the blood is collected in the chamber.

28. The device in accordance with claim 21, further comprising a patient needle and a sample collection device.

29. The device in accordance with claim 21, the chamber having a volume configured to be sufficient to collect the first portion of the blood that is more prone to contamination and also to minimize an amount of blood to be sequestered.

30. The device in accordance with claim 21, wherein the chamber has a volume of less than 1.5 cubic centimeters.

* * * * *