

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

(10) **Patent No.:** **US 12,011,367 B2**
(45) **Date of Patent:** ***Jun. 18, 2024**

(54) **EXPANDABLE INTERVERTEBRAL DEVICE**

(71) Applicant: **Moskowitz Family LLC**, Rockville,
MD (US)

(72) Inventors: **Ahmnon D. Moskowitz**, Rockville,
MD (US); **Mosheh T. Moskowitz**,
Rockville, MD (US); **Pablo A. Valdivia**
Y. Alvarado, Cambridge, MA (US);
Eric Sugalski, Arlington, MA (US);
Nathan C. Moskowitz, Rockville, MD
(US); **David Schoon**, Rockville, MD
(US)

(73) Assignee: **Moskowitz Family LLC**, Rockville,
MD (US)

(*) Notice: Subject to any disclaimer, the term of this
patent is extended or adjusted under 35
U.S.C. 154(b) by 204 days.

This patent is subject to a terminal dis-
claimer.

(21) Appl. No.: **17/408,068**

(22) Filed: **Aug. 20, 2021**

(65) **Prior Publication Data**

US 2022/0039963 A1 Feb. 10, 2022

Related U.S. Application Data

(63) Continuation of application No. 16/587,993, filed on
Sep. 30, 2019, now Pat. No. 11,096,797, which is a
(Continued)

(51) **Int. Cl.**
A61F 2/44 (2006.01)
A61B 17/064 (2006.01)
(Continued)

(52) **U.S. Cl.**
CPC **A61F 2/447** (2013.01); **A61B 17/0642**
(2013.01); **A61B 17/064** (2013.01);
(Continued)

(58) **Field of Classification Search**

CPC .. A61F 2/442; A61F 2/4425; A61F 2002/443;
A61F 2002/4455

(Continued)

(56) **References Cited**

U.S. PATENT DOCUMENTS

2,360,942 A 10/1944 Ellerstein
4,064,881 A 12/1977 Meredith

(Continued)

FOREIGN PATENT DOCUMENTS

FR 2727003 5/1996
WO WO 2004093749 11/2004
WO WO 2006091503 8/2006

OTHER PUBLICATIONS

Grob, et al. "Clinical Experience With the Dynesys Semirigid
Fixation System for the Lumbar Spine," Spine, vol. 30, No. 3, 2005,
pp. 324-331.

(Continued)

Primary Examiner — Eduardo C Robert

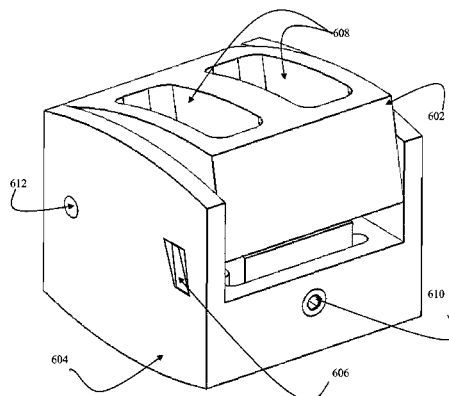
Assistant Examiner — Christina Negrelli-rodriguez

(74) *Attorney, Agent, or Firm* — Fish & Richardson P.C.

(57) **ABSTRACT**

A unique, universal Zero-Profile Expandable Intervertebral
Spacer (ZP-EIS) device for fusion and distraction through-
out the entire spine is provided which can be inserted via
anterior, anterolateral, lateral, far lateral or posterior surgical
approaches dependent on the need and preference. Multiple
ZP-EIS embodiments each with unique mechanisms of
calibrated expansion are provided. Two of these embodi-
ments incorporate bi-directional fixing transvertebral
(BDFT) screws and five other embodiments do not incor-
porate BDFT screws. A tool for implantation into the
intervertebral device and calibrated device expansion is also
disclosed.

21 Claims, 38 Drawing Sheets



600

Related U.S. Application Data

continuation of application No. 16/025,667, filed on Jul. 2, 2018, now Pat. No. 10,426,633, which is a continuation of application No. 15/820,232, filed on Nov. 21, 2017, now Pat. No. 10,016,284, which is a continuation of application No. 14/063,197, filed on Oct. 25, 2013, now Pat. No. 9,848,993, which is a continuation-in-part of application No. 13/741,361, filed on Jan. 14, 2013, now Pat. No. 9,301,854, and a continuation-in-part of application No. 13/210,150, filed on Aug. 15, 2011, now Pat. No. 9,867,719, and a continuation-in-part of application No. 13/210,157, filed on Aug. 15, 2011, now Pat. No. 9,889,022, and a continuation-in-part of application No. 13/210,168, filed on Aug. 15, 2011, now Pat. No. 9,907,674, and a continuation-in-part of application No. 13/210,162, filed on Aug. 15, 2011, now Pat. No. 9,895,238, said application No. 13/741,361 is a continuation of application No. 13/108,982, filed on May 16, 2011, now Pat. No. 9,005,293, said application No. 13/210,150 is a continuation of application No. 13/108,982, filed on May 16, 2011, now Pat. No. 9,005,293, said application No. 13/210,157 is a continuation of application No. 13/108,982, filed on May 16, 2011, now Pat. No. 9,005,293, said application No. 13/210,162 is a continuation of application No. 13/108,982, filed on May 16, 2011, now Pat. No. 9,005,293, said application No. 13/210,168 is a continuation of application No. 13/108,982, filed on May 16, 2011, now Pat. No. 9,005,293, said application No. 13/210,162 is a continuation of application No. 13/084,543, filed on Apr. 11, 2011, now Pat. No. 8,353,913, said application No. 13/741,361 is a continuation of application No. 13/084,543, filed on Apr. 11, 2011, now Pat. No. 8,353,913, said application No. 13/210,157 is a continuation of application No. 13/084,543, filed on Apr. 11, 2011, now Pat. No. 8,353,913, said application No. 13/210,168 is a continuation of application No. 13/084,543, filed on Apr. 11, 2011, now Pat. No. 8,353,913, said application No. 13/210,150 is a continuation of application No. 13/084,543, filed on Apr. 11, 2011, now Pat. No. 8,353,913, said application No. 13/108,982 is a continuation of application No. 11/842,855, filed on Aug. 21, 2007, now Pat. No. 7,942,903, said application No. 13/084,543 is a continuation of application No. 11/842,855, filed on Aug. 21, 2007, now Pat. No. 7,942,903, which is a continuation-in-part of application No. 11/536,815, filed on Sep. 29, 2006, now Pat. No. 7,846,188, which is a continuation-in-part of application No. 11/208,644, filed on Aug. 23, 2005, now Pat. No. 7,704,279.

- (60) Provisional application No. 61/801,783, filed on Mar. 15, 2013, provisional application No. 61/718,707, filed on Oct. 25, 2012, provisional application No. 60/670,231, filed on Apr. 12, 2005.

(51) Int. Cl.

A61B 17/70 (2006.01)
A61F 2/46 (2006.01)
A61B 17/02 (2006.01)
A61B 17/86 (2006.01)
A61B 17/88 (2006.01)
A61B 17/92 (2006.01)
A61F 2/28 (2006.01)
A61F 2/30 (2006.01)

(52) U.S. Cl.

CPC *A61F 2/4611* (2013.01); *A61B 2017/0256* (2013.01); *A61B 17/86* (2013.01); *A61B 17/8875* (2013.01); *A61B 2017/922* (2013.01); *A61F 2002/2835* (2013.01); *A61F 2002/30261* (2013.01); *A61F 2002/30266* (2013.01); *A61F 2002/30281* (2013.01); *A61F 2002/30387* (2013.01); *A61F 2002/30448* (2013.01); *A61F 2002/30471* (2013.01); *A61F 2002/30495* (2013.01); *A61F 2002/30507* (2013.01); *A61F 2002/30525* (2013.01); *A61F 2002/30538* (2013.01); *A61F 2002/3055* (2013.01); *A61F 2002/30556* (2013.01); *A61F 2002/30579* (2013.01); *A61F 2002/30593* (2013.01); *A61F 2002/30604* (2013.01); *A61F 2002/30772* (2013.01); *A61F 2002/30878* (2013.01); *A61F 2002/448* (2013.01); *A61F 2002/4627* (2013.01); *A61F 2002/4681* (2013.01); *A61F 2002/4687* (2013.01); *A61F 2220/0025* (2013.01); *A61F 2220/005* (2013.01); *A61F 2230/0015* (2013.01); *A61F 2250/0007* (2013.01)

(58) Field of Classification Search

USPC 623/17.11–17.16; 606/246–249
 See application file for complete search history.

(56)**References Cited****U.S. PATENT DOCUMENTS**

4,554,914 A	11/1985	Kapp	
4,599,086 A	7/1986	Doty	
4,636,217 A	1/1987	Ogilvie	
4,904,261 A	2/1990	Dove	
4,960,420 A	10/1990	Goble	
4,997,432 A	3/1991	Keller	
5,005,749 A	4/1991	Aranyi	
5,062,850 A	11/1991	Macmillan	
5,123,926 A	6/1992	Pisharodi	
5,290,312 A	3/1994	Kojimoto	
5,405,391 A	4/1995	Henderson	
5,413,583 A	5/1995	Wohlers	
5,454,819 A	10/1995	Knoepfler	
5,514,180 A	5/1996	Heggeness	
5,653,763 A	8/1997	Errico	
5,658,336 A	8/1997	Pisharodi	
5,660,188 A	8/1997	Groiso	
5,665,122 A	9/1997	Kambin	
5,667,472 A	9/1997	Finn	
5,713,912 A	2/1998	Porter	
5,782,832 A	7/1998	Larsen	
5,865,848 A	2/1999	Baker	
5,888,223 A	3/1999	Bray, Jr.	
5,916,224 A	6/1999	Esplin	
5,951,574 A	9/1999	Stefanchik	
5,960,522 A	10/1999	Boe	
5,968,054 A	10/1999	Yeatts	
5,976,136 A	11/1999	Bailey	
5,980,522 A	11/1999	Koros	
6,102,950 A *	8/2000	Vaccaro	 A61F 2/4637 606/247
6,126,689 A	10/2000	Brett	
6,190,414 B1	2/2001	Young	
6,193,757 B1	2/2001	Foley	
6,224,602 B1	5/2001	Hayes	
6,235,034 B1	5/2001	Bray, Jr.	
6,299,642 B1	10/2001	Chan	
6,322,562 B1	11/2001	Wolter	
6,342,074 B1	1/2002	Simpson	
6,368,350 B1	4/2002	Erickson	
6,368,351 B1	4/2002	Glenn	
6,375,682 B1	4/2002	Fleischman	
6,419,705 B1	4/2002	Glenn	

US 12,011,367 B2

Page 3

(56)

References Cited

U.S. PATENT DOCUMENTS

6,419,704 B1	7/2002	Ferree	7,942,903 B2	5/2011	Moskowitz
6,432,106 B1	8/2002	Fraser	7,959,675 B2	6/2011	Gately
6,454,807 B1	9/2002	Jackson	7,972,363 B2	7/2011	Moskowitz
6,458,159 B1	10/2002	Thalgott	7,985,255 B2	7/2011	Bray
6,491,724 B1	12/2002	Ferree	8,029,512 B2	10/2011	Paltzer
6,527,804 B1	3/2003	Gauchet	8,034,060 B2	10/2011	Keren
6,533,818 B1	3/2003	Weber	8,043,376 B2	10/2011	Falahee et al.
6,558,423 B1	5/2003	Michelson	8,062,375 B2	11/2011	Glerum
6,572,653 B1	6/2003	Simonson	8,105,358 B2	1/2012	Phan
6,579,318 B2	6/2003	Varga	8,105,367 B2	1/2012	Austin
6,582,468 B1	6/2003	Gauchet	8,105,382 B2	1/2012	Olmos
6,613,055 B2	9/2003	Di Emidio	8,114,162 B1	2/2012	Bradley
6,629,998 B1	10/2003	Lin	8,123,810 B2	2/2012	Gordon
6,641,614 B1	11/2003	Wagner	8,133,232 B2	3/2012	Levy
6,655,243 B2	12/2003	Anderson	8,137,405 B2	3/2012	Kostuik
6,716,247 B2	4/2004	Michelson	8,167,949 B2	5/2012	Tyber
6,719,794 B2	4/2004	Gerber	8,187,332 B2	5/2012	McLuen
6,723,126 B1	4/2004	Berry	8,267,939 B2	9/2012	Cipoletti
6,733,532 B1	5/2004	Gauchet	8,268,000 B2	9/2012	Waugh
6,764,491 B2	7/2004	Frey	8,273,127 B2	9/2012	Jones
6,770,094 B2	8/2004	Fehling	8,328,872 B2	12/2012	Duffield
6,824,564 B2	11/2004	Crozet	8,382,842 B2	2/2013	Greenhalgh
6,835,206 B2	12/2004	Jackson	8,394,145 B2	3/2013	Weiman
6,852,117 B2	2/2005	Orlowski	8,398,713 B2	3/2013	Weiman
6,890,355 B2	5/2005	Michelson	8,403,986 B2	3/2013	Michelson
6,904,308 B2	6/2005	Frisch	8,403,990 B2	3/2013	Dryer
6,953,477 B2	10/2005	Berry	8,414,651 B2	4/2013	Tyber
6,955,671 B2	10/2005	Uchikubo	8,419,797 B2	4/2013	Biedermann
6,955,691 B2	10/2005	Ayyanathan	8,425,607 B2	4/2013	Waugh
6,962,606 B2	11/2005	Michelson	8,435,298 B2	5/2013	Weiman
6,972,019 B2	12/2005	Michelson	8,491,659 B2	7/2013	Weiman
6,974,480 B2	12/2005	Messerli	8,496,706 B2	7/2013	Ragab
7,030,904 B2	4/2006	Adair	8,518,120 B2	8/2013	Glerum
7,033,394 B2	4/2006	Michelson	8,523,944 B2	9/2013	Jimenez
7,037,258 B2	5/2006	Chatenever	8,535,380 B2	9/2013	Greenhalgh
7,044,971 B2	5/2006	Suddaby	8,540,774 B2	9/2013	Kueenzi
7,070,598 B2	7/2006	Lim	8,556,979 B2	10/2013	Glerum
7,077,864 B2	7/2006	Byrd	8,568,481 B2	10/2013	Olmos
7,087,055 B2	8/2006	Lim	8,353,913 B2	11/2013	Moskowitz
7,097,615 B2	8/2006	Banik	8,603,170 B2	12/2013	Cipoletti
7,118,579 B2	10/2006	Michelson	8,613,761 B2	12/2013	Lindemann
7,135,043 B2	11/2006	Nakahara	8,628,577 B1	1/2014	Jimenez
7,211,112 B2	5/2007	Baynham	8,628,578 B2	1/2014	Miller
7,214,243 B2	5/2007	Taylor	8,632,595 B2	1/2014	Weiman
7,232,464 B2	6/2007	Mathieu	8,663,329 B2	3/2014	Ernst
7,238,203 B2	7/2007	Bagga	8,679,183 B2	3/2014	Glerum
7,320,555 B2	1/2008	Chang	8,685,095 B2	4/2014	Miller
7,326,248 B2	2/2008	Michelson	8,685,098 B2	4/2014	Glerum
7,410,501 B2	8/2008	Michelson	8,709,086 B2	4/2014	Glerum
7,442,209 B2	10/2008	Michelson	8,721,723 B2	5/2014	Hansell
7,442,299 B2	10/2008	Lee	8,728,165 B2	5/2014	Parry
7,445,636 B2	11/2008	Michelson	8,778,025 B2	7/2014	Ragab
7,615,059 B2	11/2009	Watschke	8,790,405 B2	7/2014	Biedermann
7,618,456 B2	11/2009	Mathieu	8,795,366 B2	8/2014	Varela
7,628,816 B2	12/2009	Magerl	8,845,731 B2	9/2014	Weiman
7,655,027 B2	2/2010	Michelson	8,845,732 B2	9/2014	Weiman
7,655,046 B2	2/2010	Dryer	8,845,734 B2	9/2014	Weiman
7,704,279 B2	4/2010	Moskowitz	8,888,853 B2	11/2014	Glerum
7,722,674 B1	5/2010	Grotz	8,888,854 B2	11/2014	Glerum
7,727,246 B2	6/2010	Sixto	8,894,711 B2	11/2014	Varela
7,753,958 B2	7/2010	Gordon	8,894,712 B2	11/2014	Varela
7,763,078 B2	7/2010	Peterman	8,926,704 B2	1/2015	Glerum
7,776,047 B2	8/2010	Fanger	8,940,049 B1	1/2015	Jimenez
7,776,093 B2	8/2010	Wolek	9,034,045 B2	5/2015	Davenport
7,799,081 B2	9/2010	Mckinley	9,039,771 B2	5/2015	Glerum
7,803,162 B2	9/2010	Marnay	9,119,730 B2	9/2015	Glerum
D626,233 S	10/2010	Cipoletti	9,198,772 B2	12/2015	Weiman
7,828,849 B2	11/2010	Lim	9,445,919 B2	9/2016	Palmatier
7,846,185 B2	12/2010	Carls	9,848,993 B2	12/2017	Moskowitz
7,846,207 B2	12/2010	Lechmann	10,016,284 B2 *	7/2018	Moskowitz A61B 17/0642
7,850,733 B2	12/2010	Baynham	10,426,633 B2 *	10/2019	Moskowitz A61F 2/4611
7,862,616 B2	1/2011	Lechmann	2002/0068976 A1	6/2002	Jackson
7,875,078 B2	1/2011	Wysocki	2002/0068977 A1	6/2002	Jackson
7,887,591 B2	2/2011	Aebi	2002/0143338 A1	10/2002	Orbay
7,909,869 B2	3/2011	Gordon	2003/0130737 A1	7/2003	McGahan
			2004/0010315 A1	1/2004	Song
			2004/0087947 A1	5/2004	Lim
			2004/0088054 A1	5/2004	Berry
			2004/0177531 A1	9/2004	Dibenedetto

(56)

References Cited

U.S. PATENT DOCUMENTS

2004/0186569 A1 9/2004 Berry
 2004/0193272 A1 9/2004 Zubok
 2004/0220571 A1 11/2004 Assaker
 2004/0249466 A1 12/2004 Liu
 2004/0254644 A1 12/2004 Taylor
 2005/0027362 A1 2/2005 Williams
 2005/0049590 A1 3/2005 Alleyne
 2005/0113916 A1 5/2005 Branch
 2005/0113917 A1 5/2005 Chae
 2005/0177235 A1 8/2005 Baynham
 2005/0216084 A1 9/2005 Fleischman
 2005/0256576 A1 11/2005 Moskowitz
 2005/0261769 A1 11/2005 Moskowitz
 2005/0273170 A1 12/2005 Navarro
 2005/0273171 A1 12/2005 Gordon
 2005/0278026 A1 12/2005 Gordon
 2006/0155285 A1 7/2006 Anderson
 2006/0206207 A1 9/2006 Dryer
 2006/0241621 A1 10/2006 Moskowitz
 2006/0241643 A1 10/2006 Lim
 2006/0241770 A1 10/2006 Rhoda
 2006/0247778 A1 11/2006 Ferree
 2007/0049943 A1 3/2007 Moskowitz
 2007/0167678 A1 7/2007 Moskowitz
 2007/0198089 A1 8/2007 Moskowitz
 2007/0213820 A1 9/2007 Magerl
 2007/0250167 A1 10/2007 Bray
 2007/0250172 A1 10/2007 Moskowitz
 2007/0270968 A1 11/2007 Baynham
 2007/0276498 A1 11/2007 Aebi
 2008/0033440 A1 2/2008 Moskowitz
 2008/0058938 A1 3/2008 Mujwid
 2008/0177307 A1 7/2008 Moskowitz
 2008/0183293 A1 7/2008 Parry
 2008/0249569 A1 10/2008 Waugh
 2008/0249575 A1 10/2008 Waugh
 2008/0249625 A1 10/2008 Waugh
 2008/0281424 A1 11/2008 Parry
 2008/0281425 A1 11/2008 Thalgott
 2009/0030520 A1 1/2009 Biederman
 2009/0080997 A1 3/2009 Johnson
 2009/0105830 A1 4/2009 Jones
 2009/0105831 A1 4/2009 Jones
 2009/0112271 A1 4/2009 Moskowitz
 2009/0112319 A1 4/2009 O'Neil
 2009/0171461 A1 7/2009 Conner
 2009/0182430 A1 7/2009 Tyber
 2009/0187218 A1 7/2009 Schaffhausen
 2009/0210062 A1 8/2009 Thalgott
 2009/0224023 A1 9/2009 Moskowitz
 2009/0234455 A1 9/2009 Moskowitz
 2009/0292361 A1 11/2009 Lopez
 2009/0299478 A1 12/2009 Carls
 2010/0057208 A1 3/2010 Dryer
 2010/0145460 A1 6/2010 McDonough
 2010/0168862 A1 7/2010 Edie
 2010/0204795 A1 8/2010 Greenhalgh
 2010/0286780 A1 11/2010 Dryer
 2010/0292796 A1 11/2010 Greenhalgh
 2010/0305704 A1 12/2010 Messerli
 2010/0318189 A1 12/2010 Edie
 2010/0324606 A1 12/2010 Moskowitz
 2011/0015742 A1 1/2011 Hong
 2011/0029082 A1 2/2011 Hall
 2011/0054621 A1 3/2011 Lim
 2011/0093074 A1 4/2011 Glerum
 2011/0125269 A1 5/2011 Moskowitz
 2011/0137349 A1 6/2011 Moskowitz
 2011/0172721 A1 7/2011 Frigg
 2011/0172774 A1 7/2011 Varela

2011/0178600 A1 7/2011 Moskowitz
 2011/0208312 A1 8/2011 Moskowitz
 2011/0288646 A1 11/2011 Moskowitz
 2011/0295327 A1 12/2011 Moskowitz
 2011/0295371 A1 12/2011 Moskowitz
 2011/0307011 A1 12/2011 Moskowitz
 2011/0319935 A1 12/2011 Moskowitz
 2011/0319997 A1 * 12/2011 Glerum A61F 2/442
 623/17.11
 2012/0010714 A1 1/2012 Moskowitz
 2012/0035729 A1 2/2012 Glerum
 2012/0109319 A1 5/2012 Perisic
 2012/0150304 A1 6/2012 Glerum
 2012/0150305 A1 6/2012 Glerum
 2012/0158146 A1 6/2012 Glerum
 2012/0158147 A1 6/2012 Glerum
 2012/0158148 A1 6/2012 Glerum
 2012/0271419 A1 10/2012 Marik
 2012/0271423 A1 10/2012 Wallenstein
 2012/0277865 A1 11/2012 Trieu
 2012/0277870 A1 11/2012 Wolters
 2012/0323330 A1 12/2012 Kueenzi
 2012/0330419 A1 12/2012 Moskowitz
 2013/0018468 A1 1/2013 Moskowitz
 2013/0018469 A1 1/2013 Moskowitz
 2013/0018470 A1 1/2013 Moskowitz
 2013/0023991 A1 1/2013 Moskowitz
 2013/0023992 A1 1/2013 Moskowitz
 2013/0053962 A1 2/2013 Moskowitz
 2013/0060339 A1 3/2013 Duffield
 2013/0073044 A1 3/2013 Gamache
 2013/0144388 A1 6/2013 Emery
 2013/0158663 A1 6/2013 Miller
 2013/0158664 A1 6/2013 Palmatier
 2013/0173002 A1 7/2013 Moskowitz
 2013/0211526 A1 8/2013 Alheidt
 2013/0282017 A1 10/2013 Moskowitz
 2014/0088714 A1 3/2014 Miller
 2014/0121774 A1 5/2014 Glerum
 2014/0249628 A1 9/2014 Weiman
 2014/0249629 A1 9/2014 Moskowitz
 2014/0324171 A1 10/2014 Glerum
 2015/0025637 A1 1/2015 Moskowitz
 2015/0105824 A1 4/2015 Moskowitz
 2015/0148847 A1 5/2015 Moskowitz
 2016/0374830 A1 12/2016 Moskowitz
 2017/0252178 A1 9/2017 Moskowitz
 2018/0078383 A1 3/2018 Moskowitz
 2018/0318103 A1 11/2018 Moskowitz

OTHER PUBLICATIONS

Guyer, et al., "Intervertebral Disc Prostheses," Spine, vol. 28, No. 15S, Supp. To Aug. 1, 2003, pp. S15-S23.
 International Search Report and Written Opinion of the International Searching Authority, dated Dec. 3, 2007, International Application No. PCT/US 07/05005.
 International Search Report and Written Opinion of the International Searching Authority, dated Jul. 9, 2008, International Application No. PCT/US2007021013.
 International Search Report and Written Opinion of the International Searching Authority, dated May 21, 2008, International Application No. PCT/US2007/021015.
 Traynelis, "Prosthetics and Biologics: The Wave of the Future," Clinical Neurosurgery, vol. 50, Proceedings of the Congress of Neurological Surgeons, Philadelphia, PA 2002, Chapter 9, pp. 207-219.
 Wai, et al., "Disk Replacement Arthroplasties: Can the Success of Hip and Knee Replacements be Repeated in the Spine?," Seminars in Spine Surgery, vol. 15, No. 4 Dec. 2003, pp. 473-482.

* cited by examiner

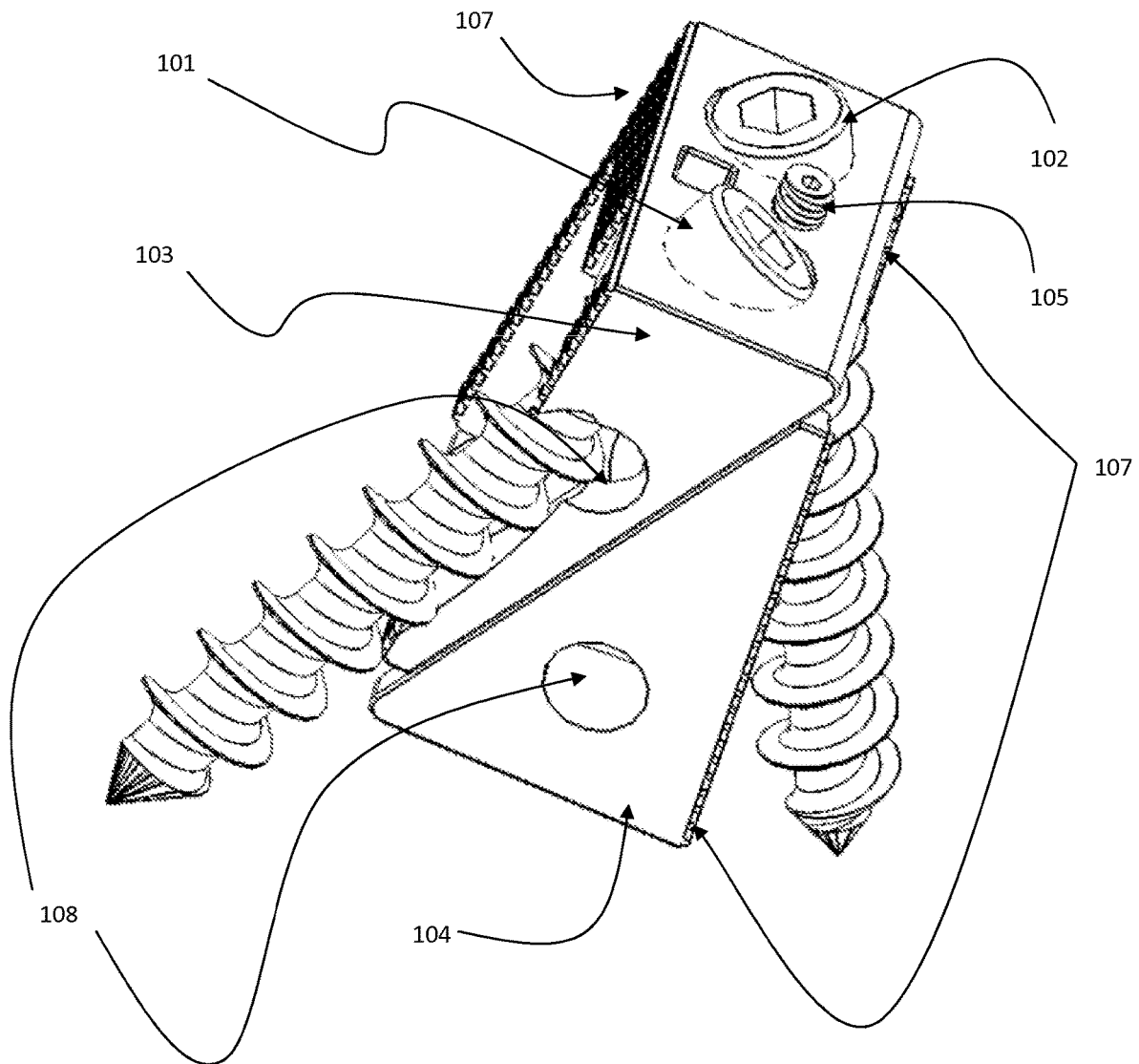


Fig. 1A

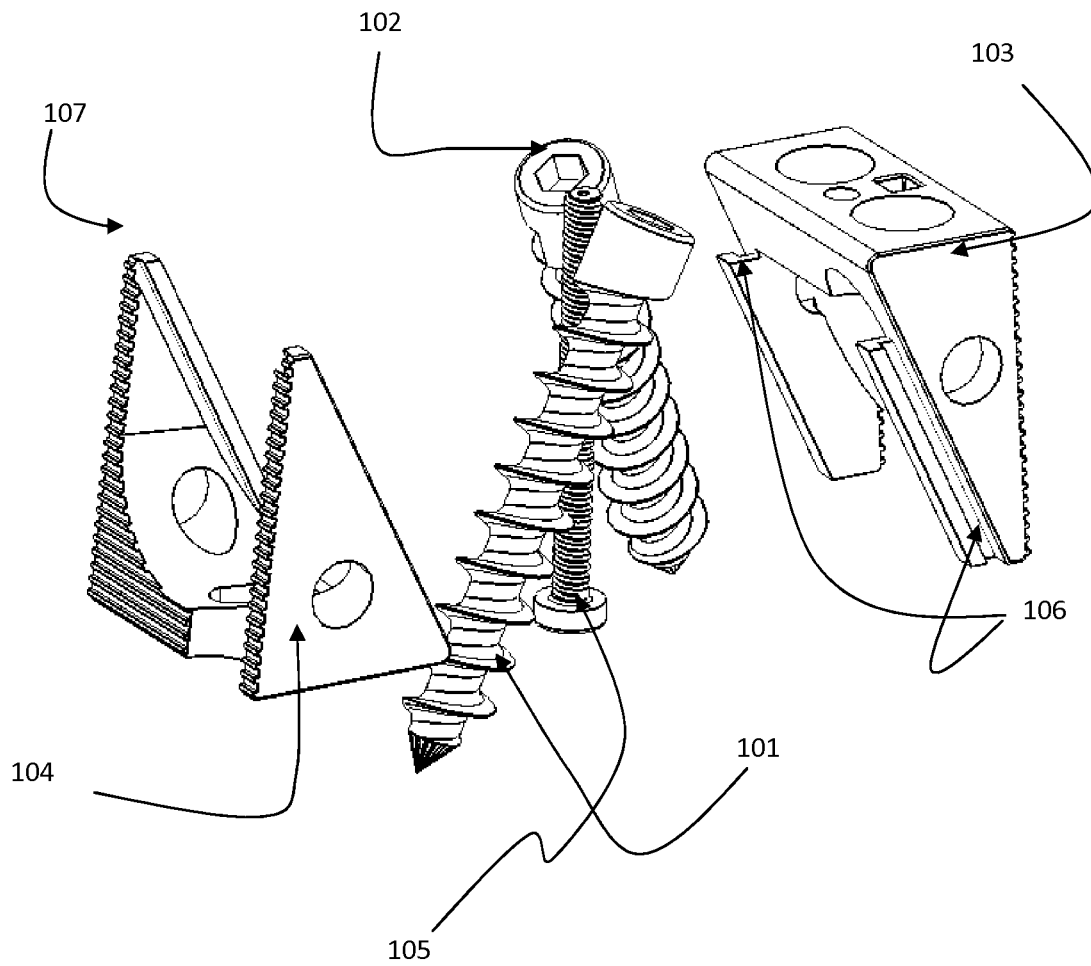


Fig. 1B

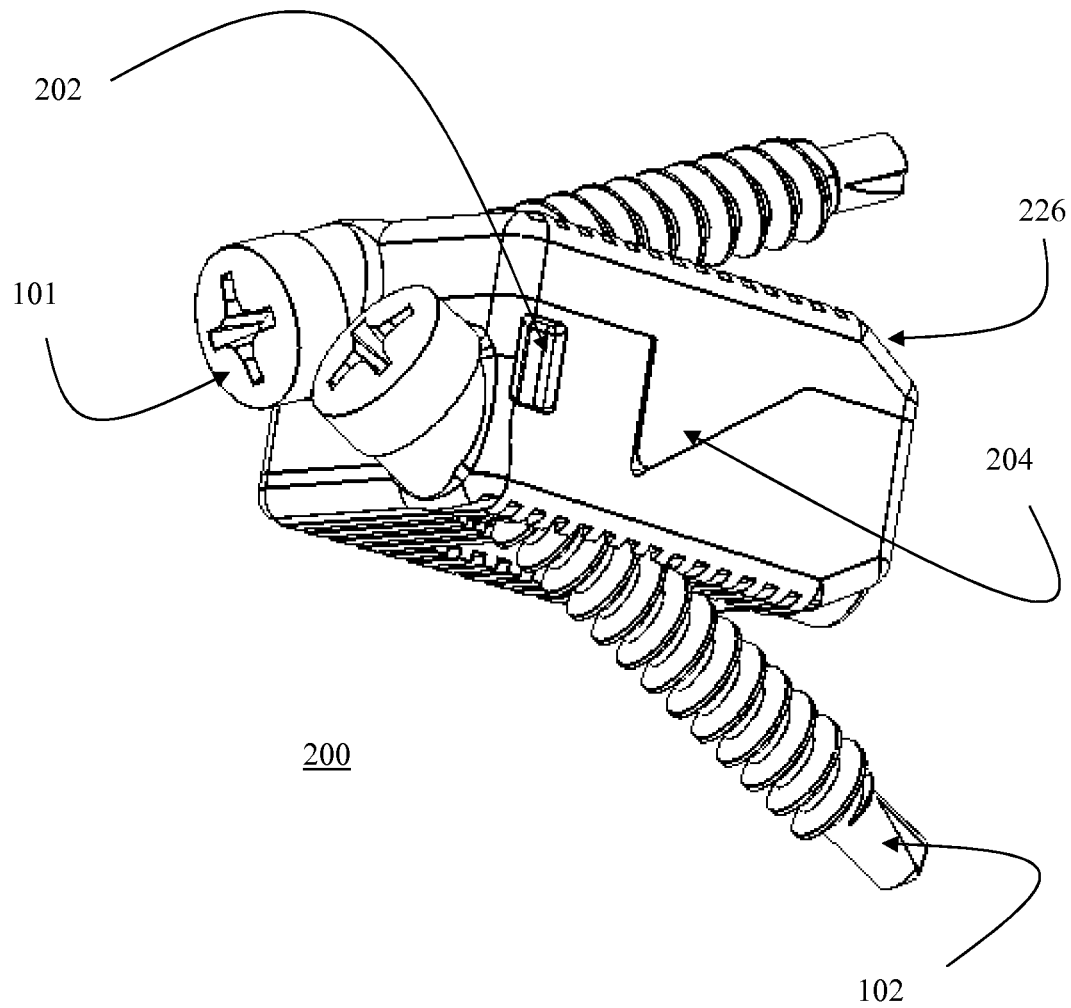


Fig. 2A

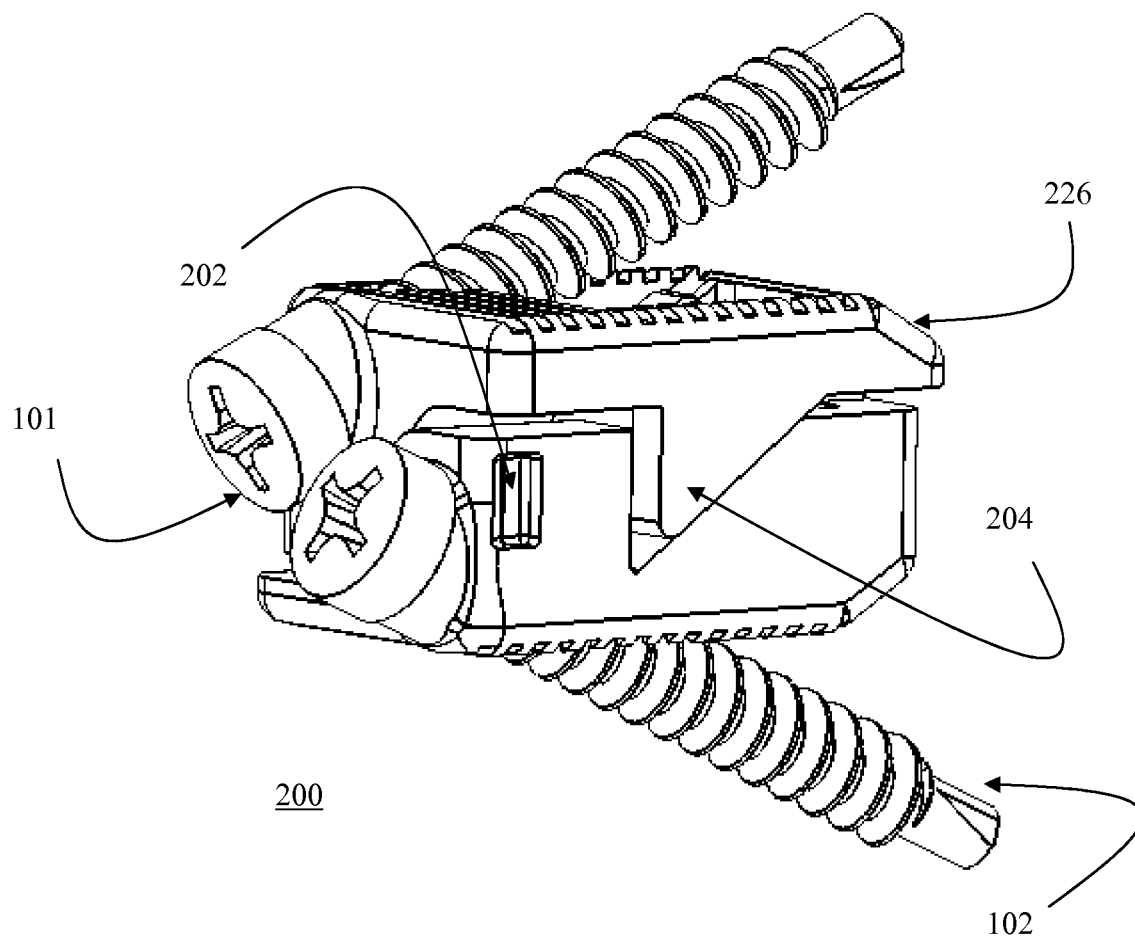


Fig. 2B

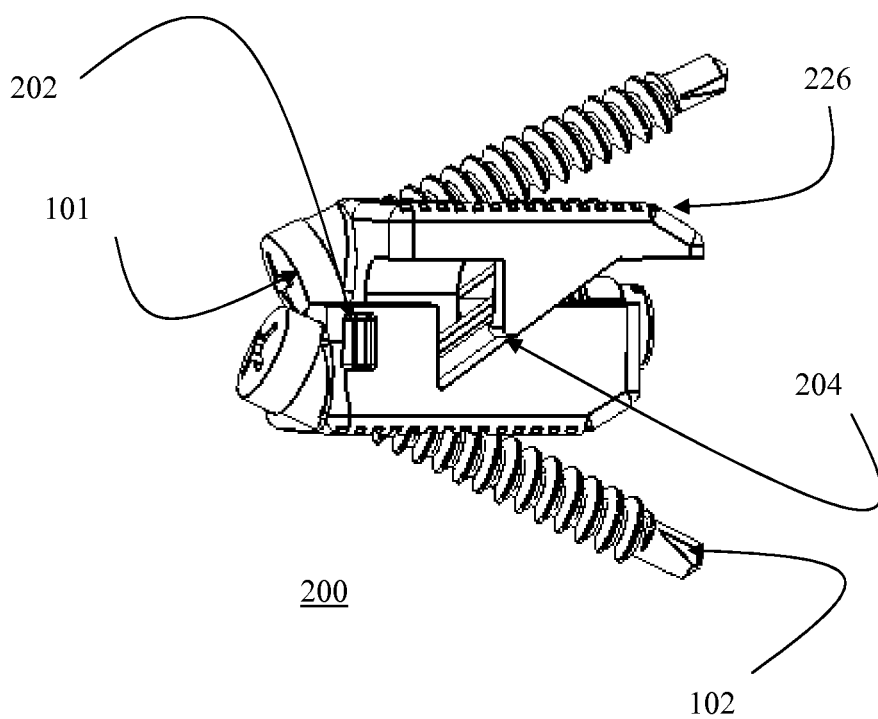


Fig. 2C

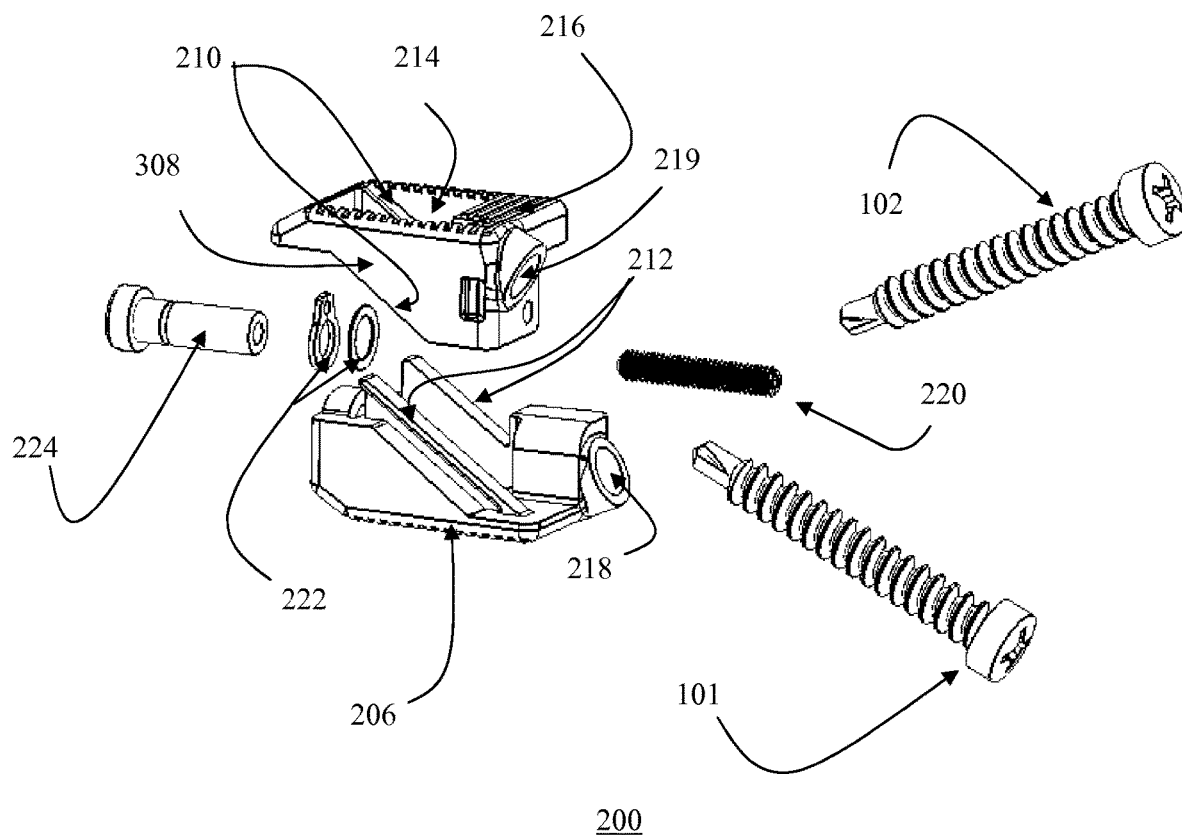


Fig. 2D

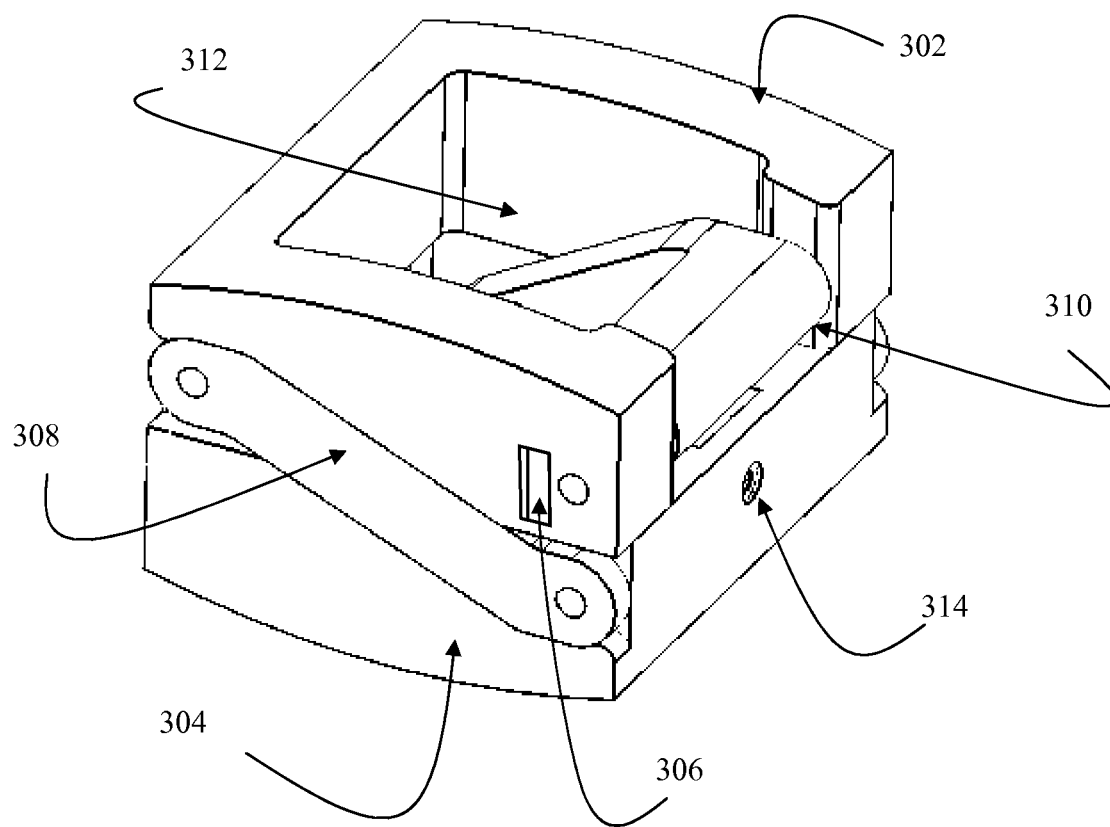


Fig. 3A

300

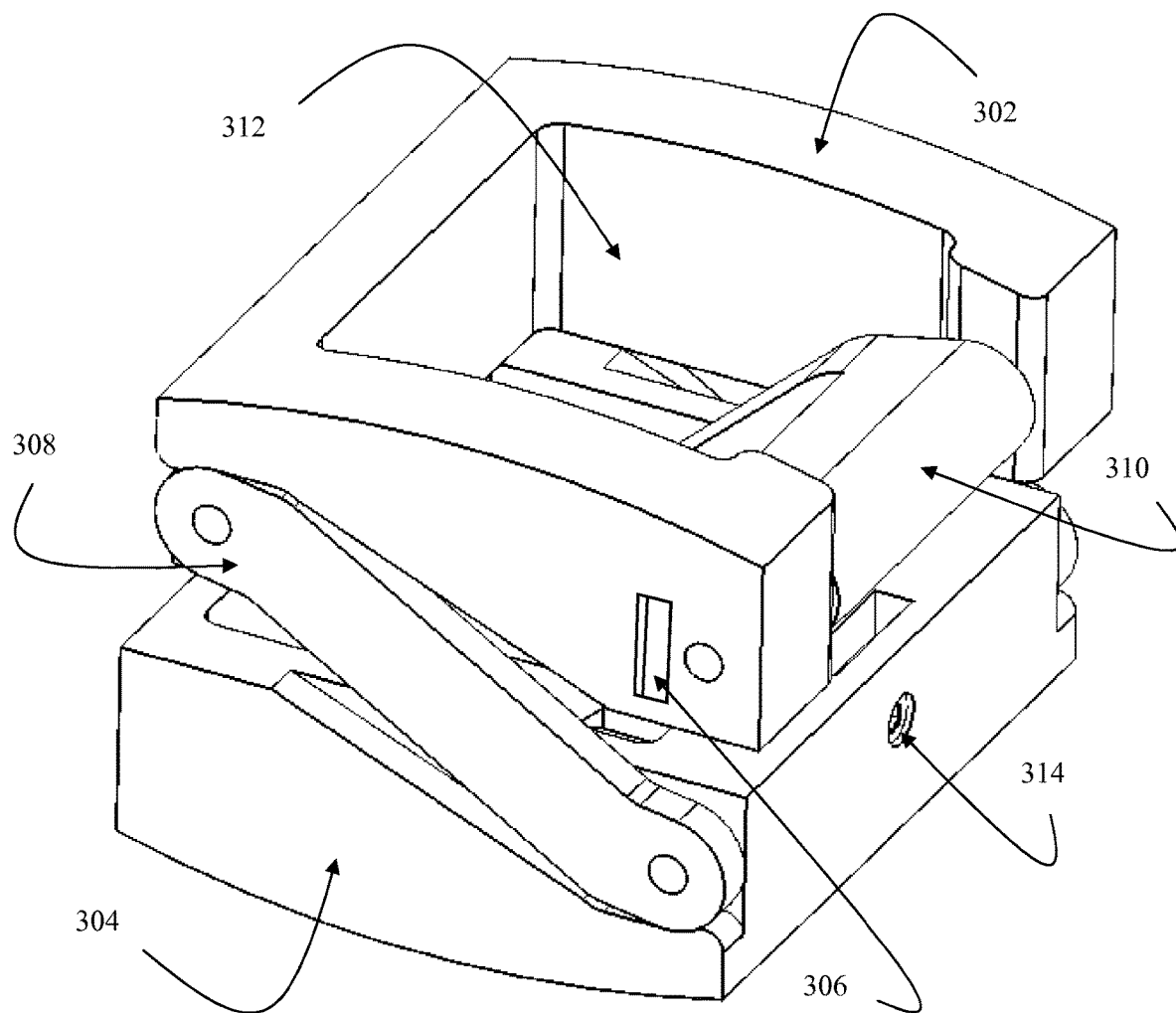


Fig. 3B

300

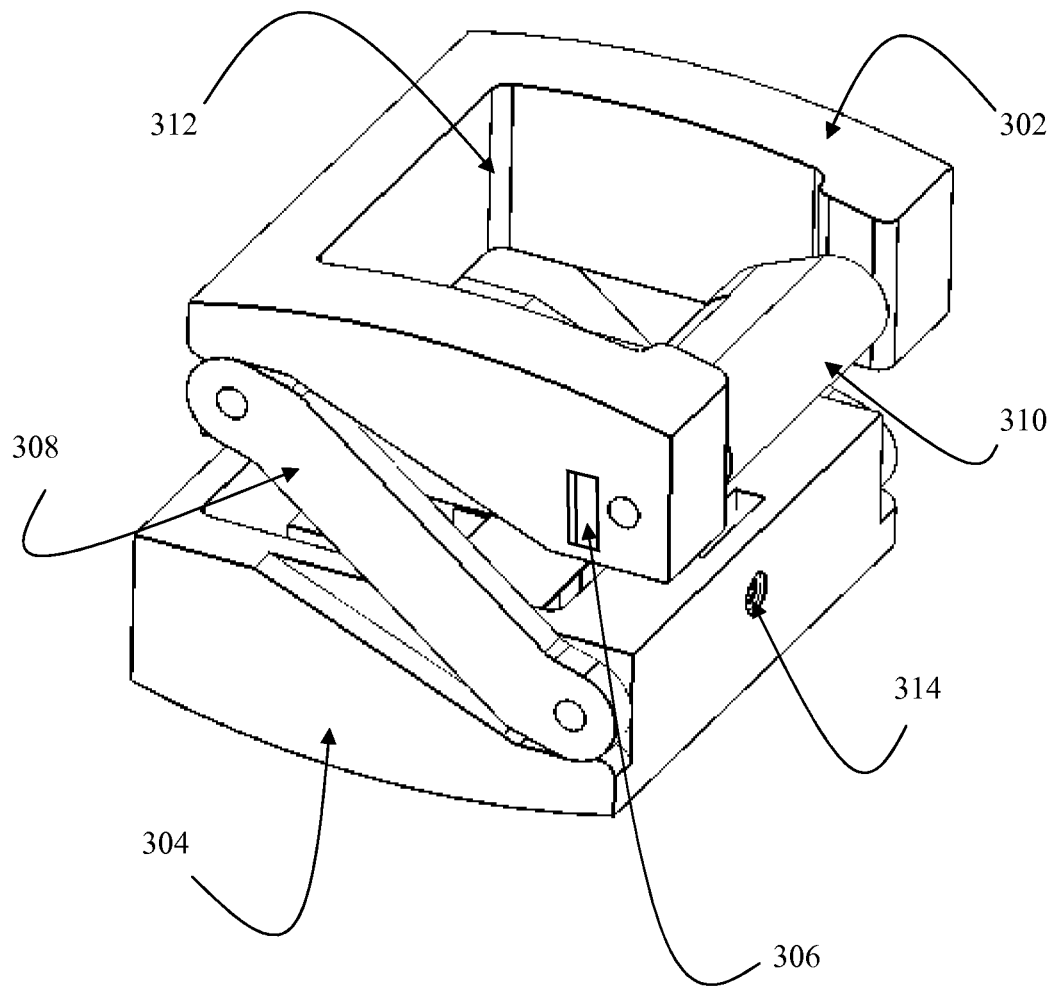


Fig. 3C

400

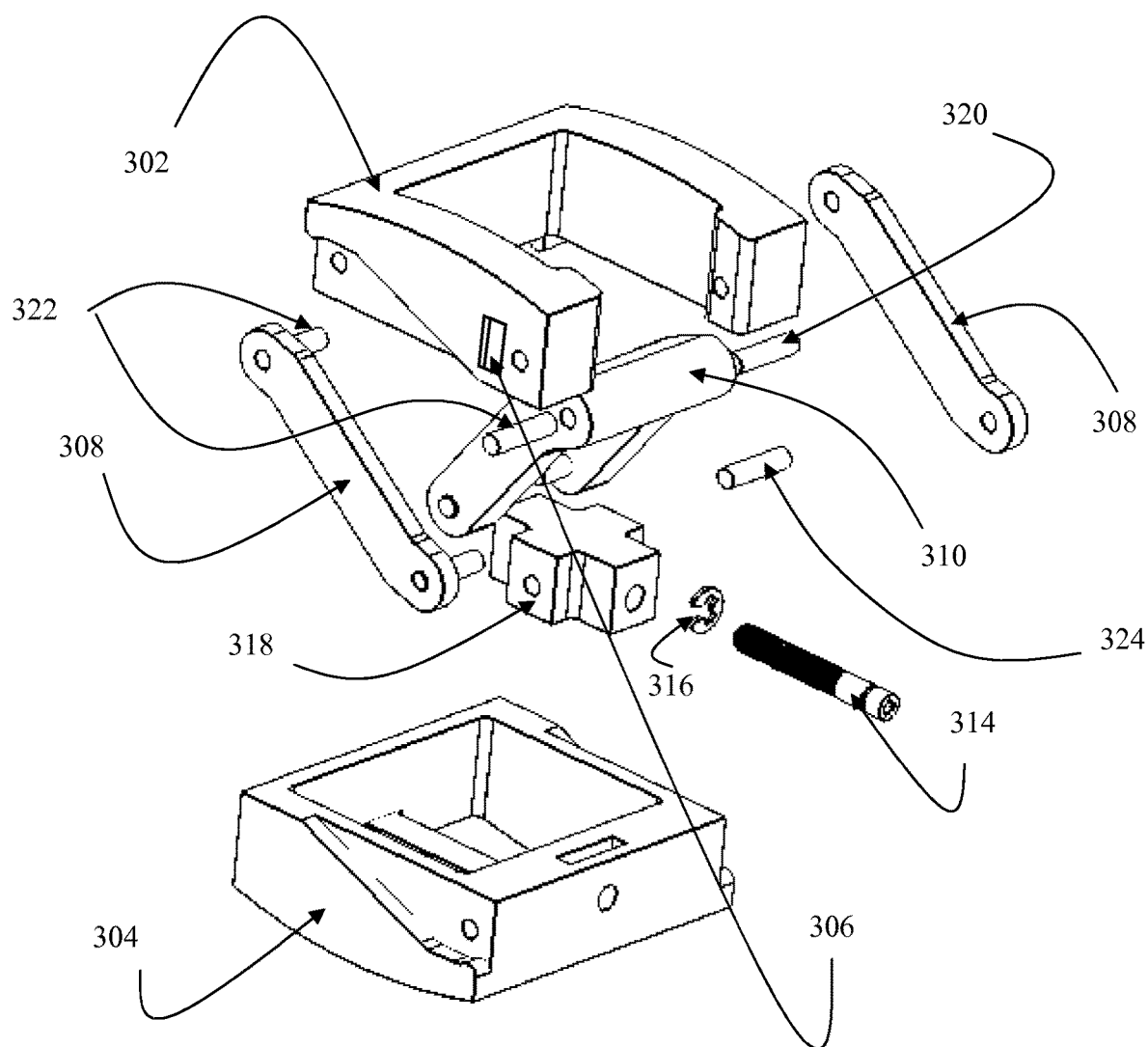


Fig. 3D

300

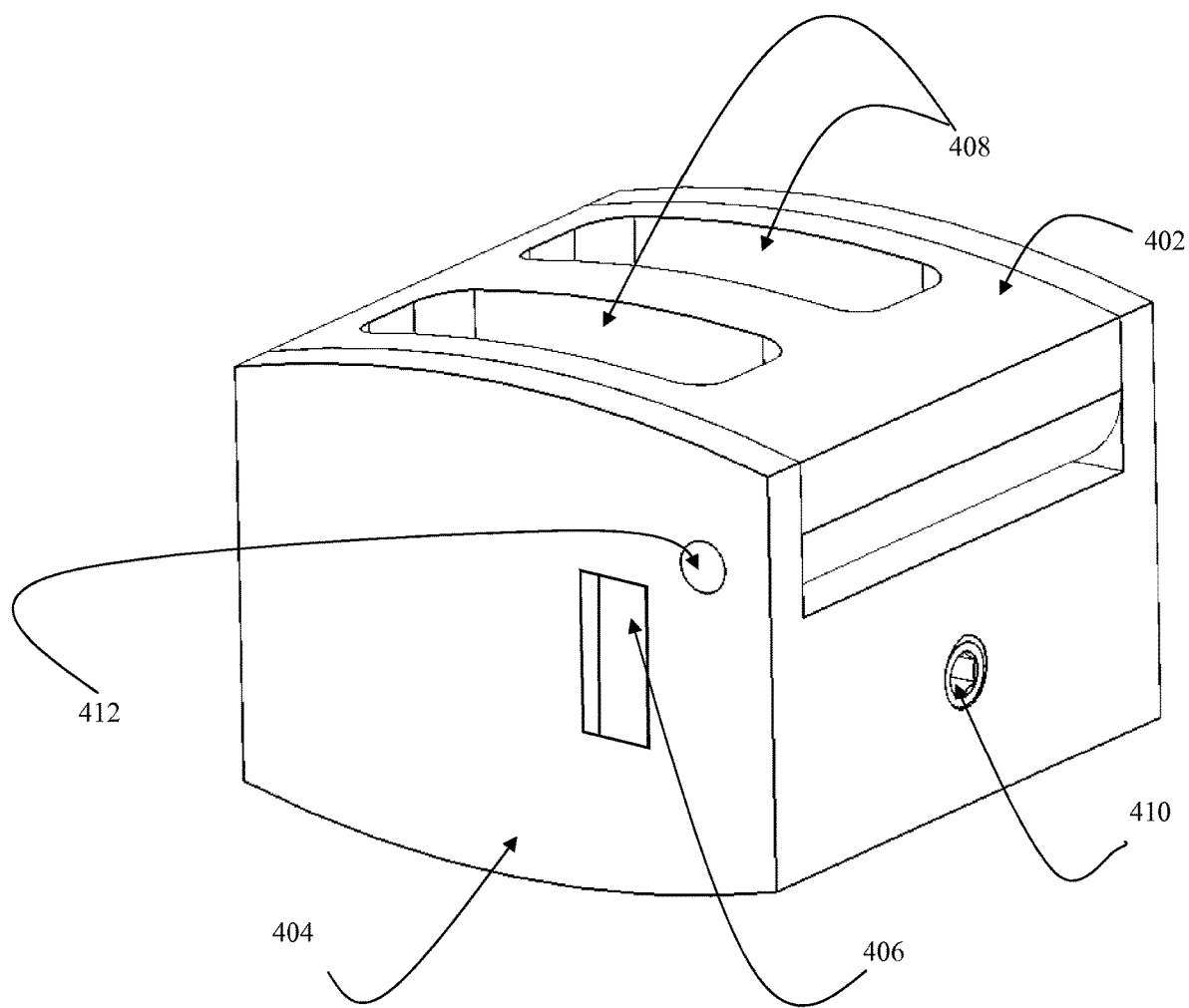


Fig. 4A

400

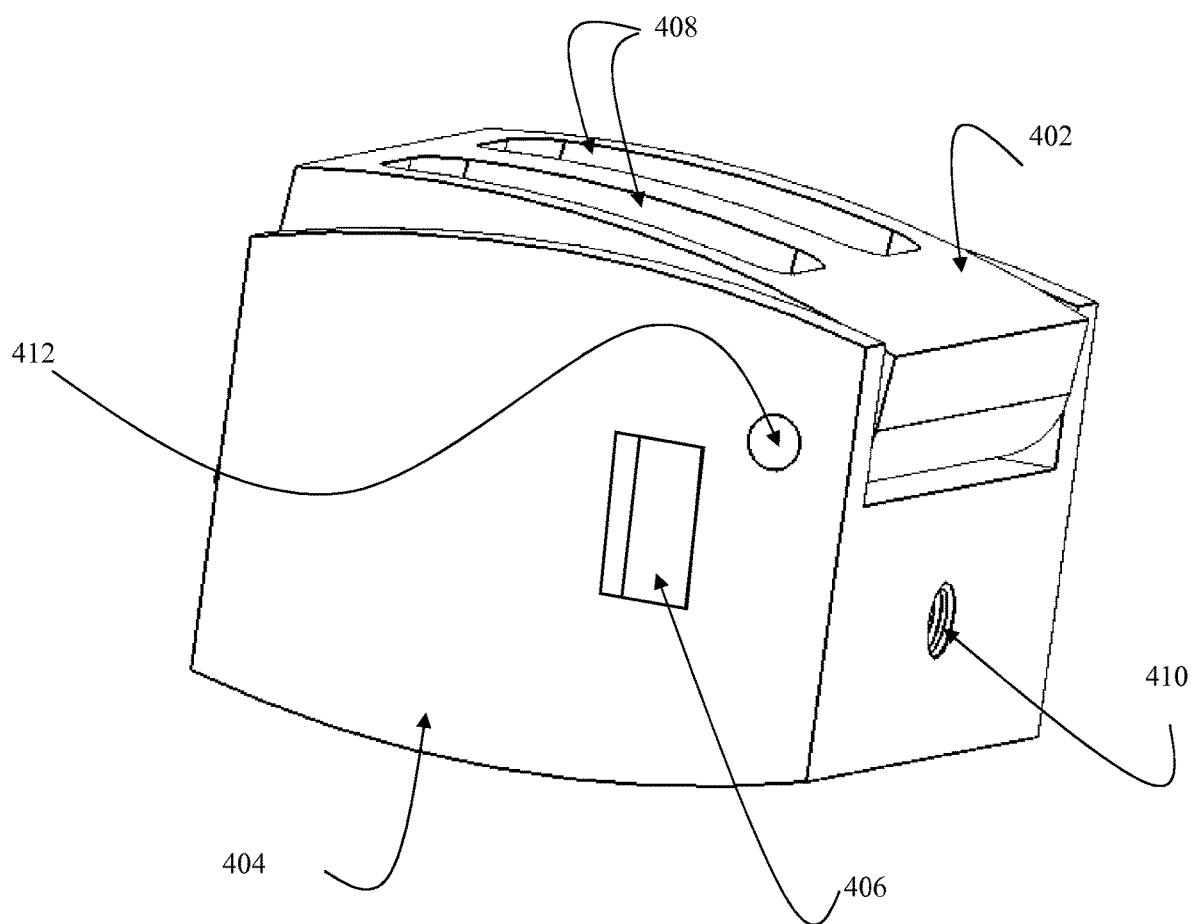
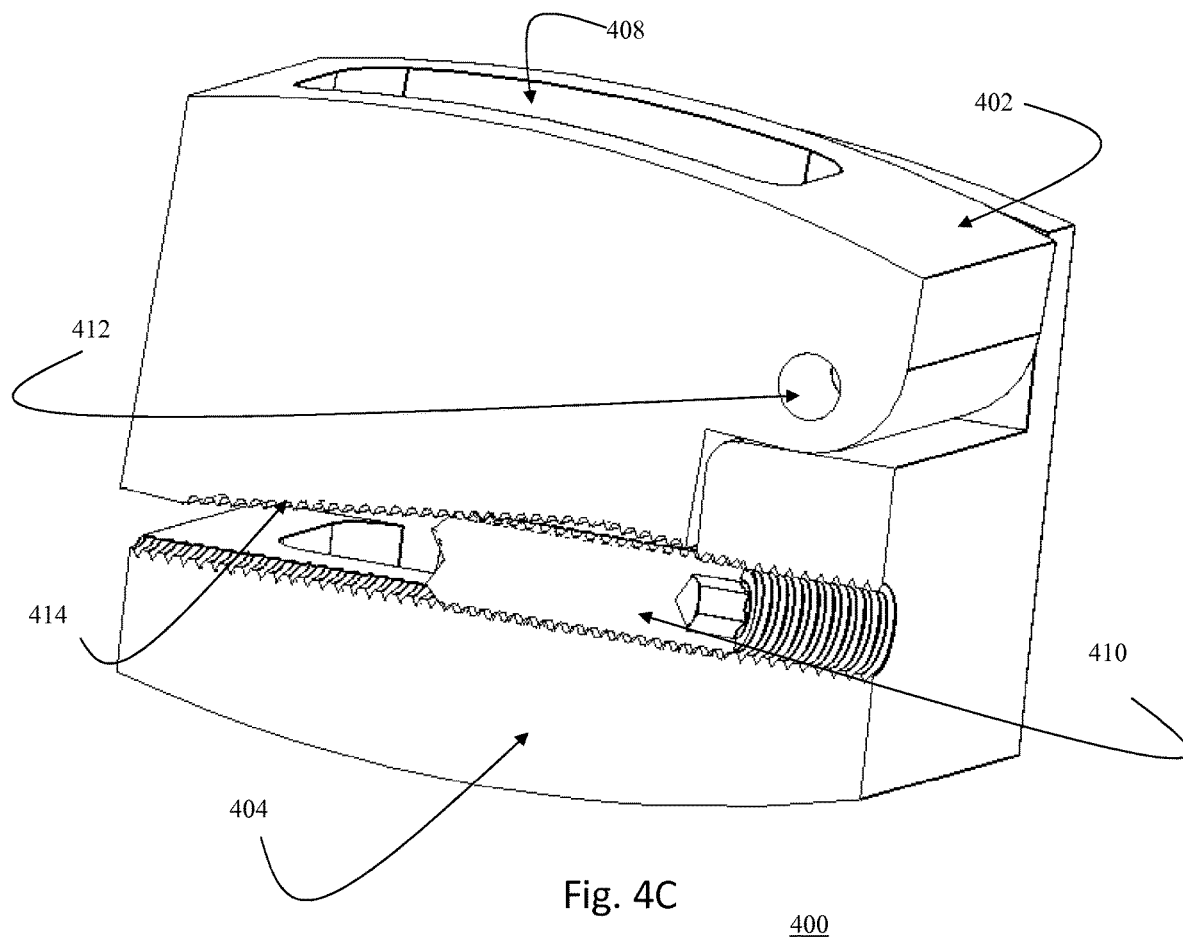


Fig. 4B

400



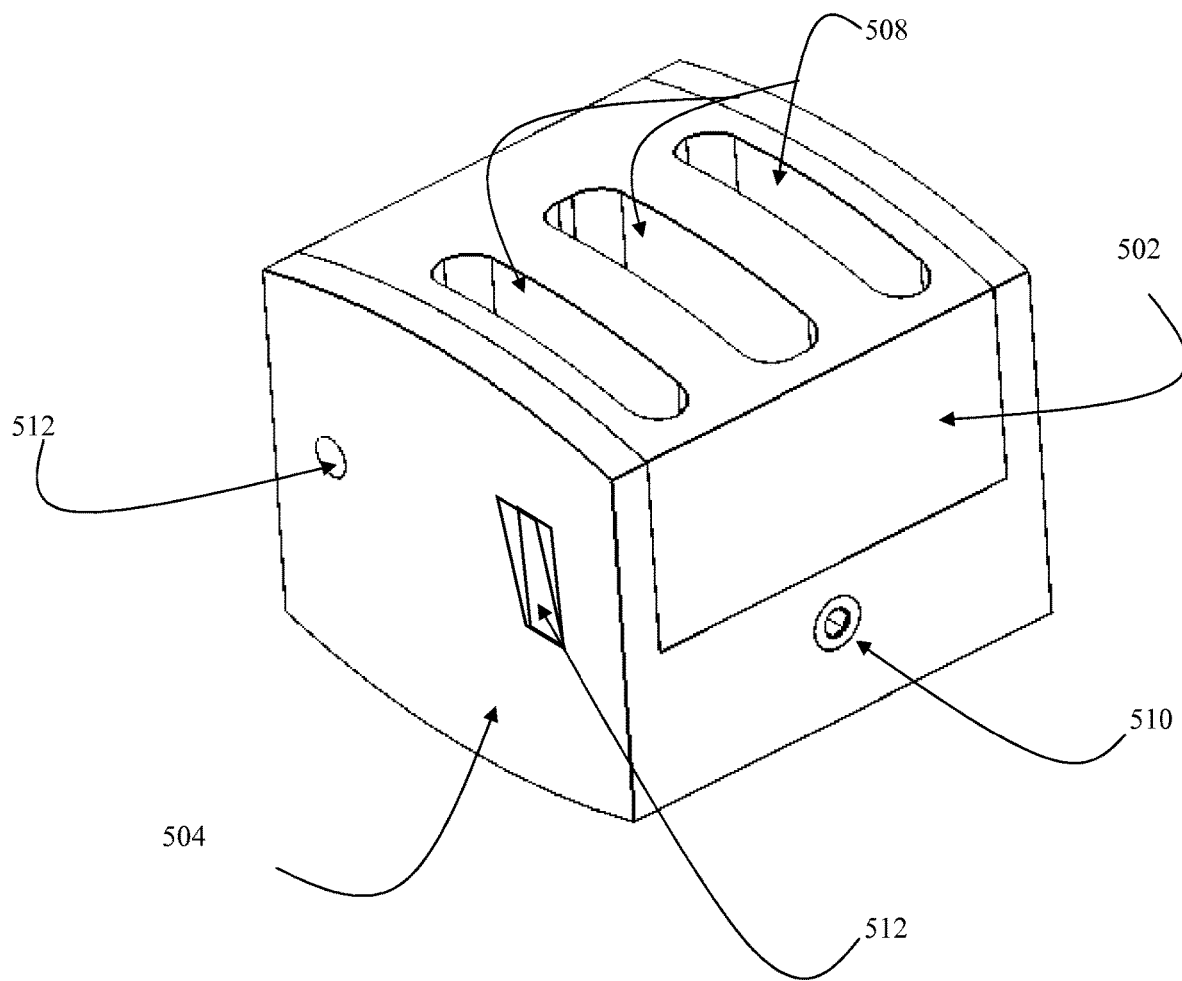
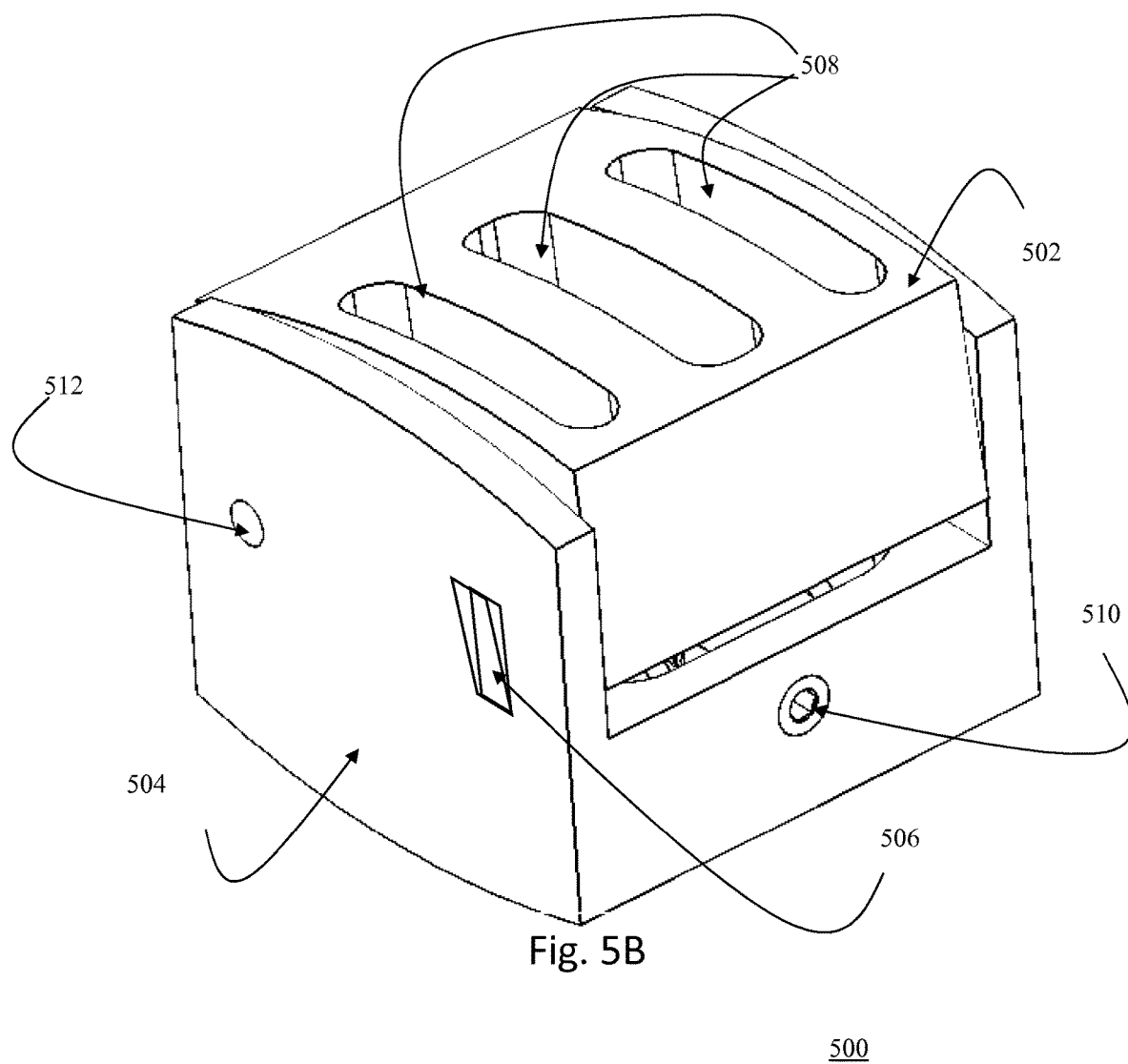


Fig. 5A

500



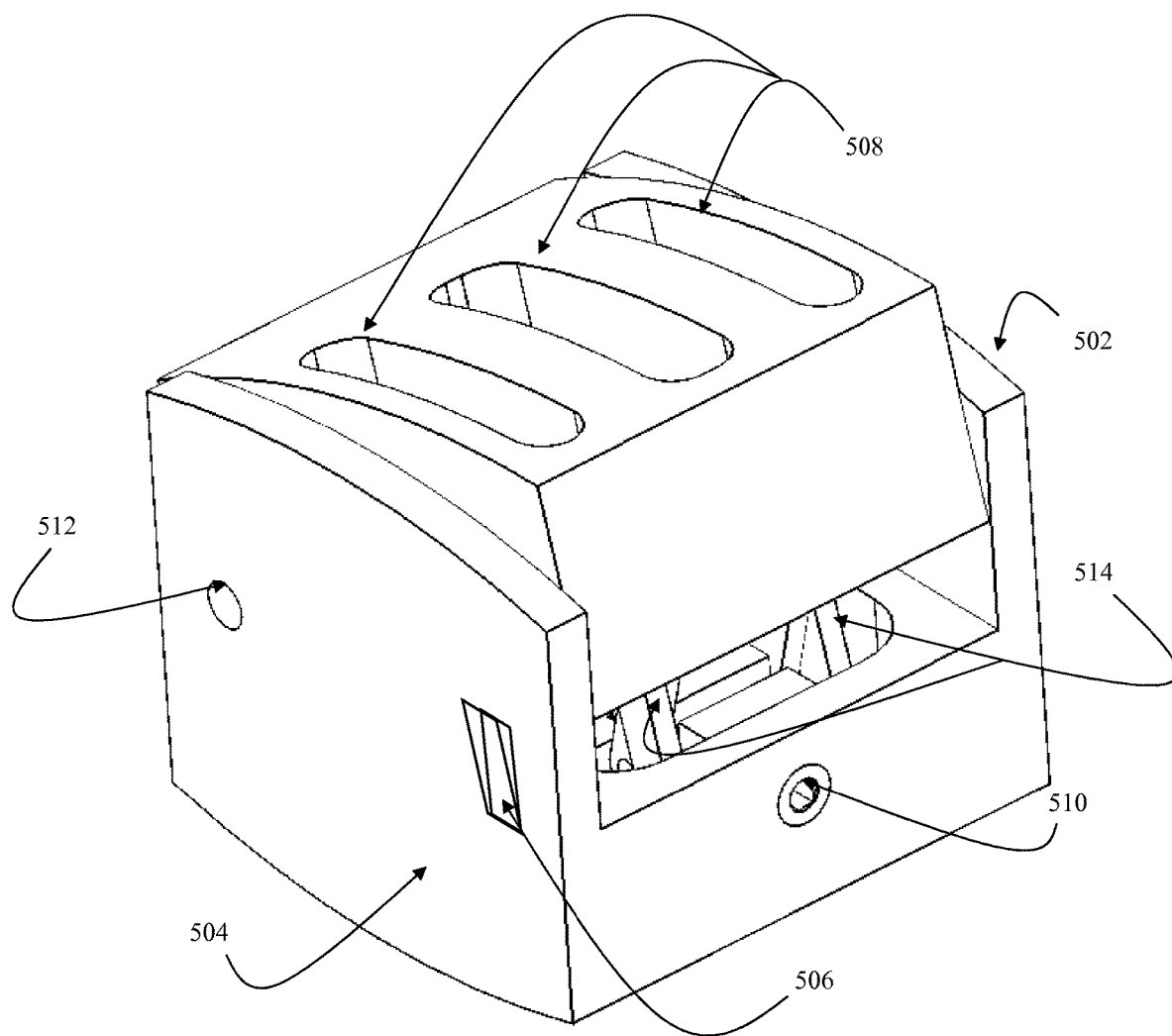


Fig. 5C

500

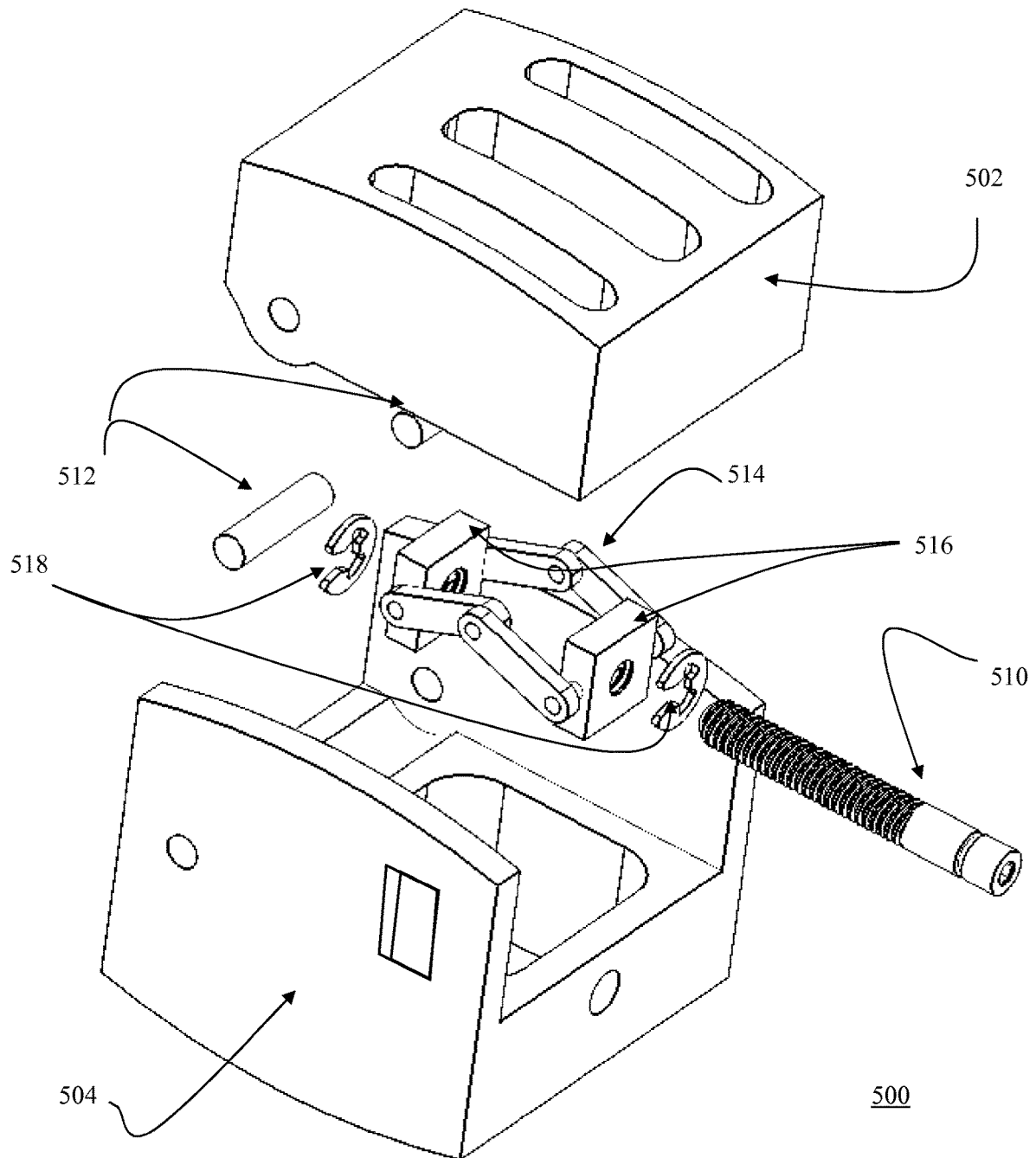


Fig. 5D

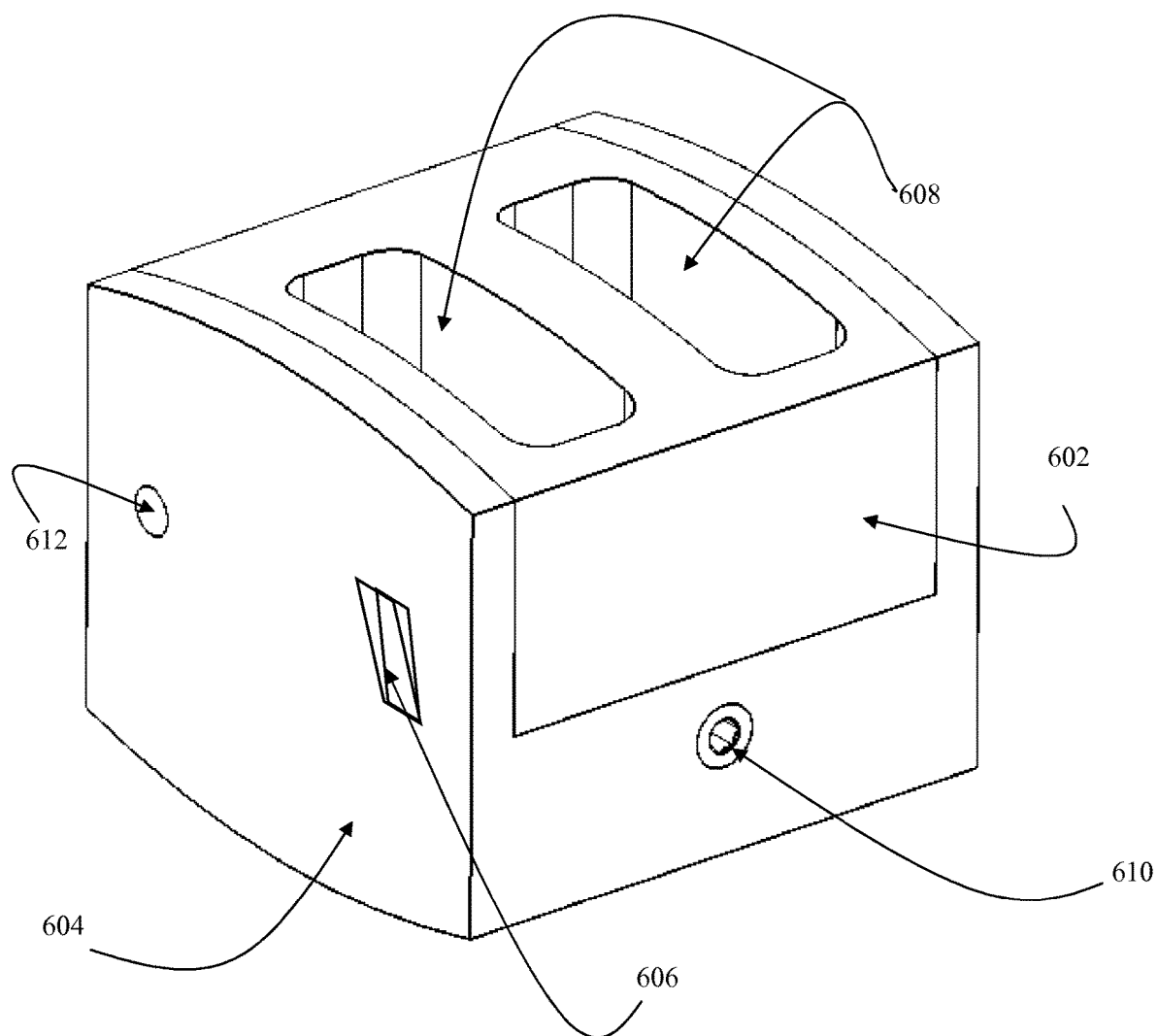


Fig. 6A

600

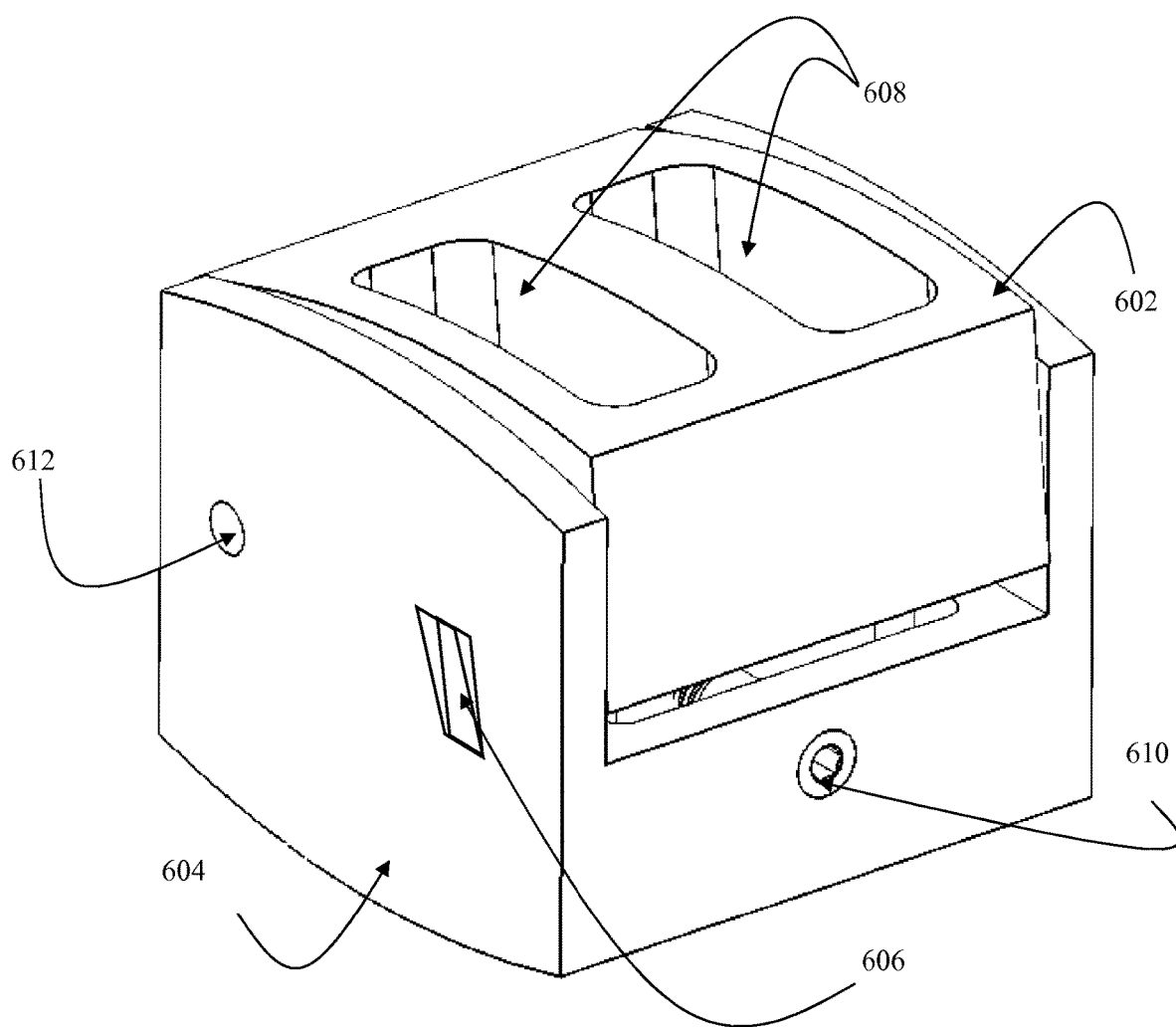


Fig. 6B

600

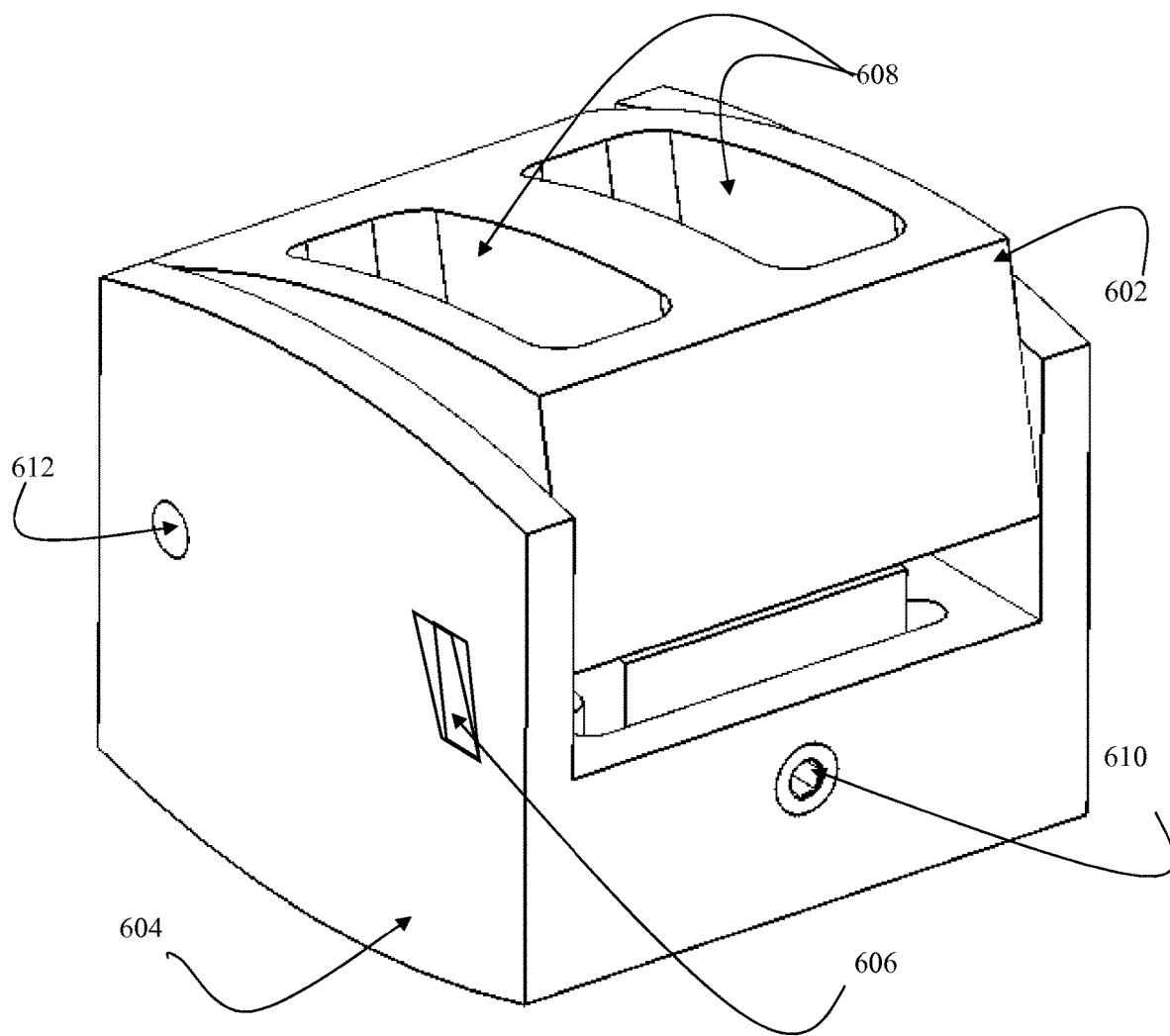


Fig. 6C

600

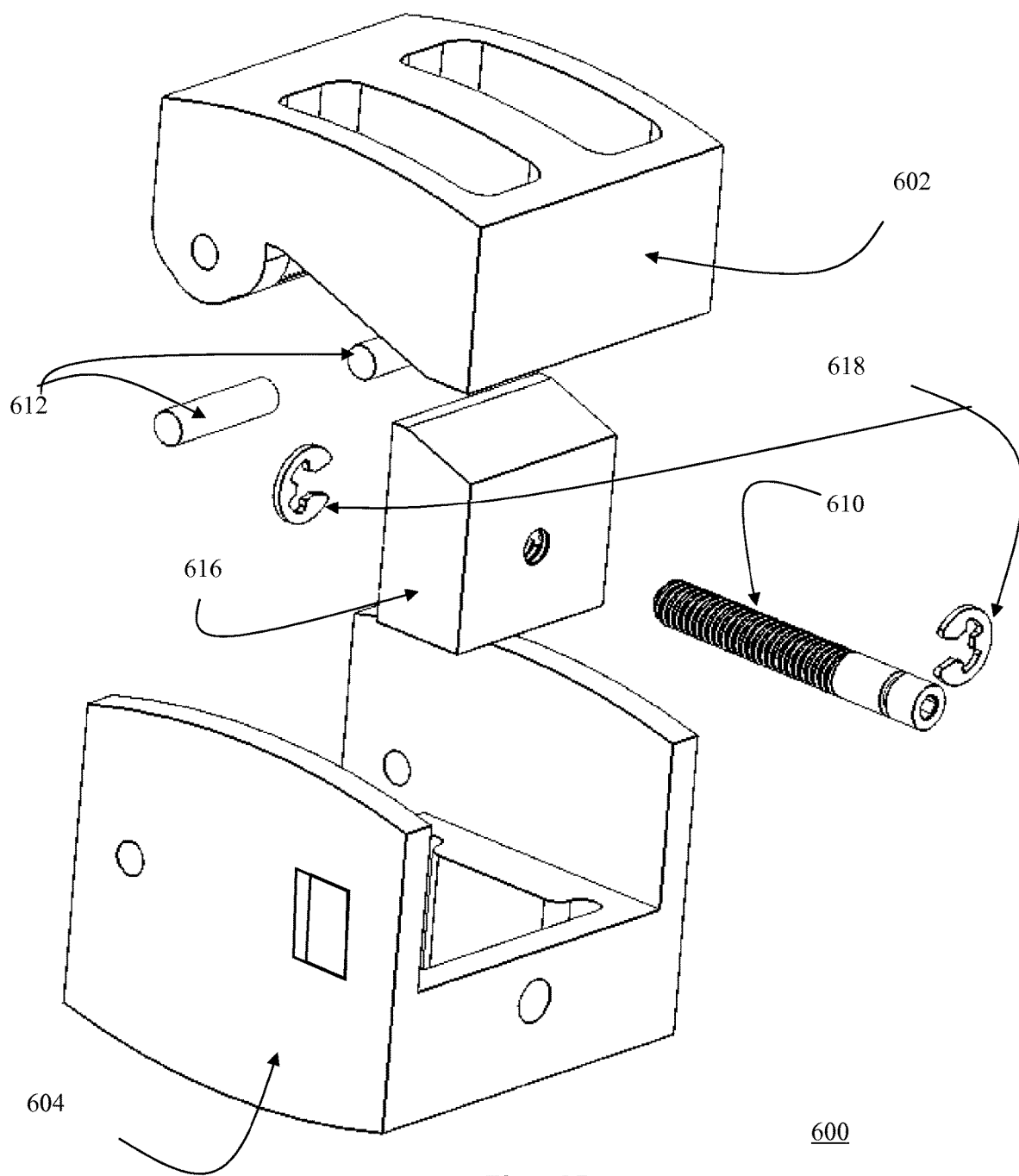


Fig. 6D

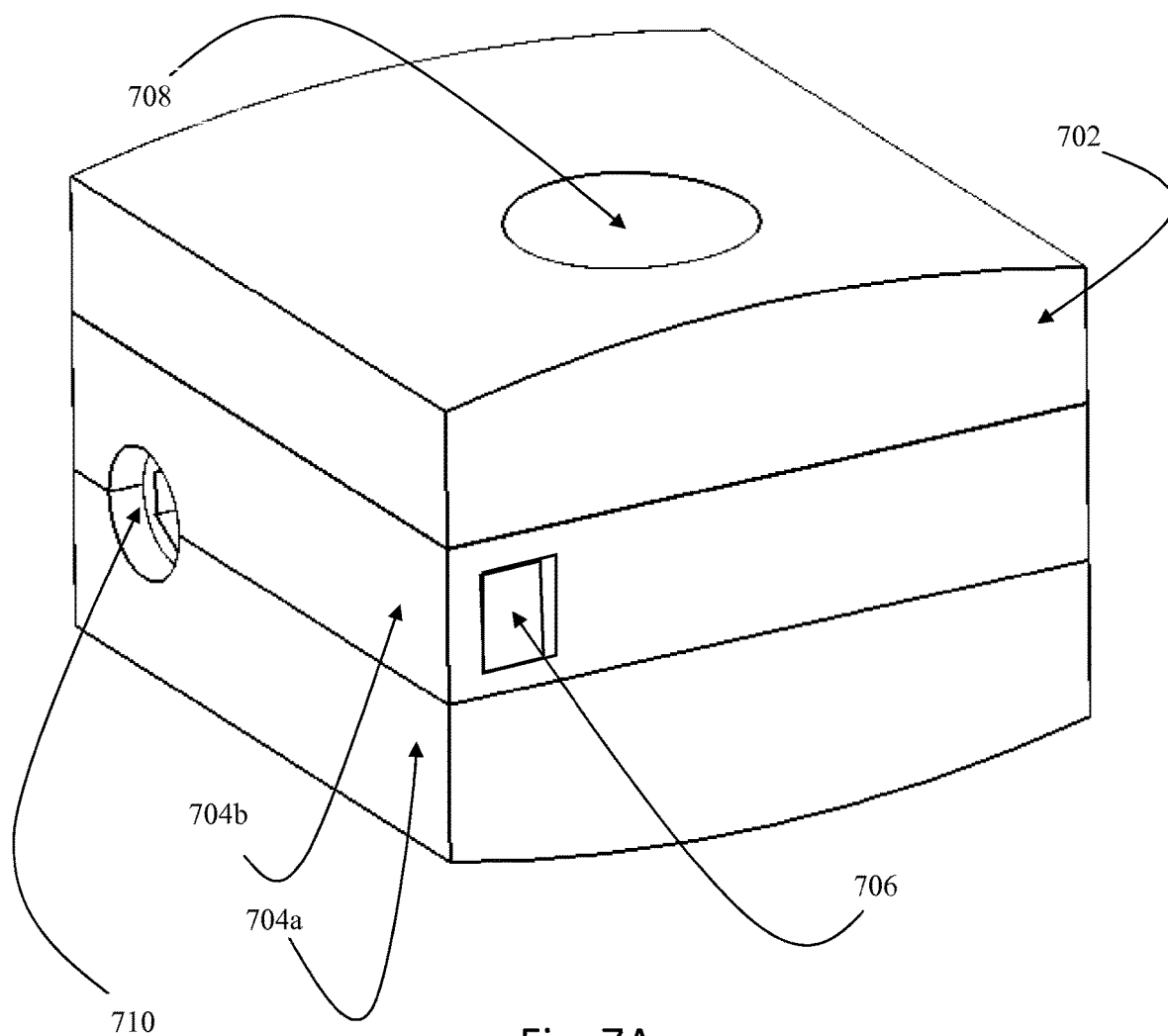


Fig. 7A

700

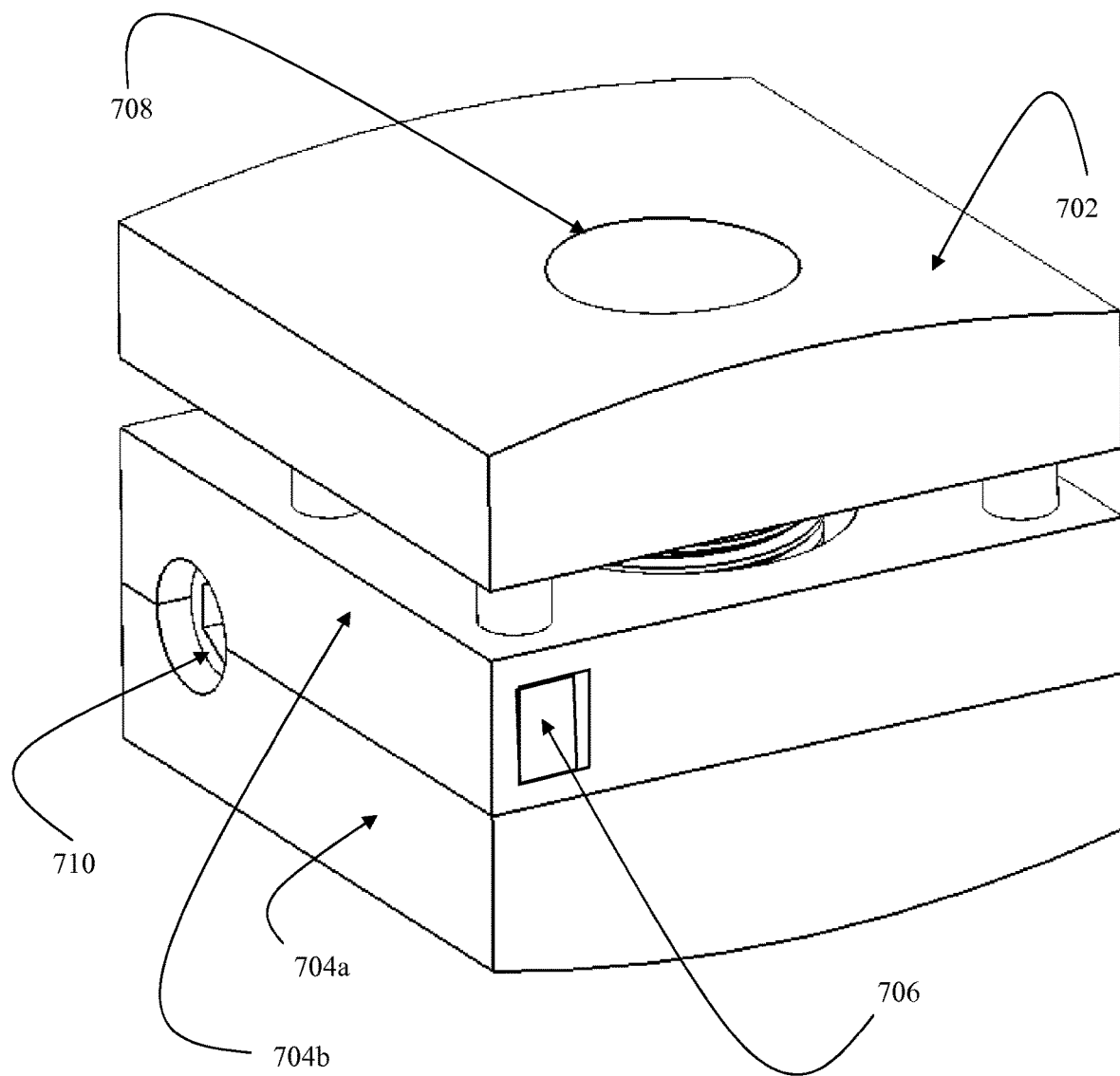
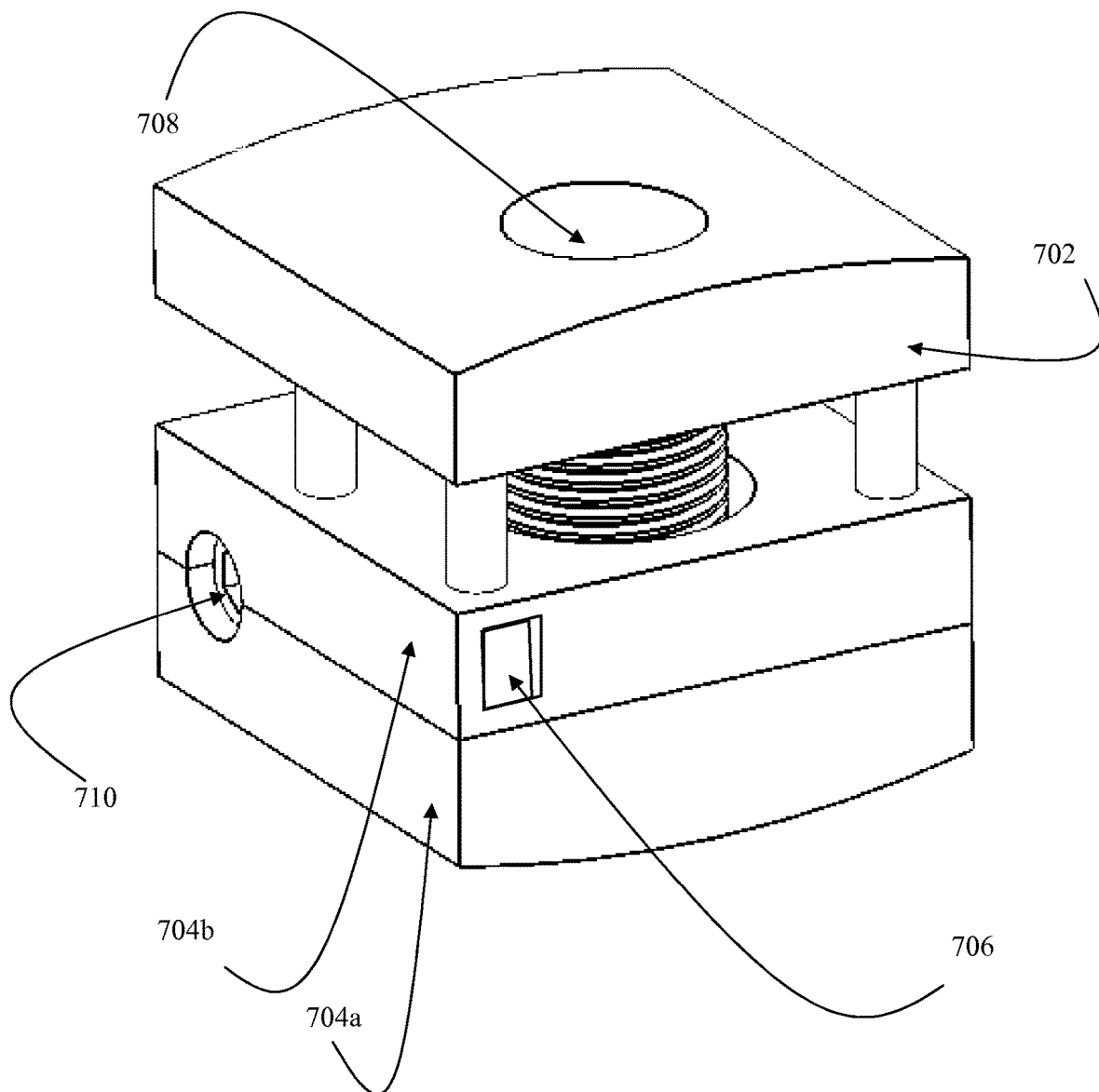


Fig. 7B

700



700

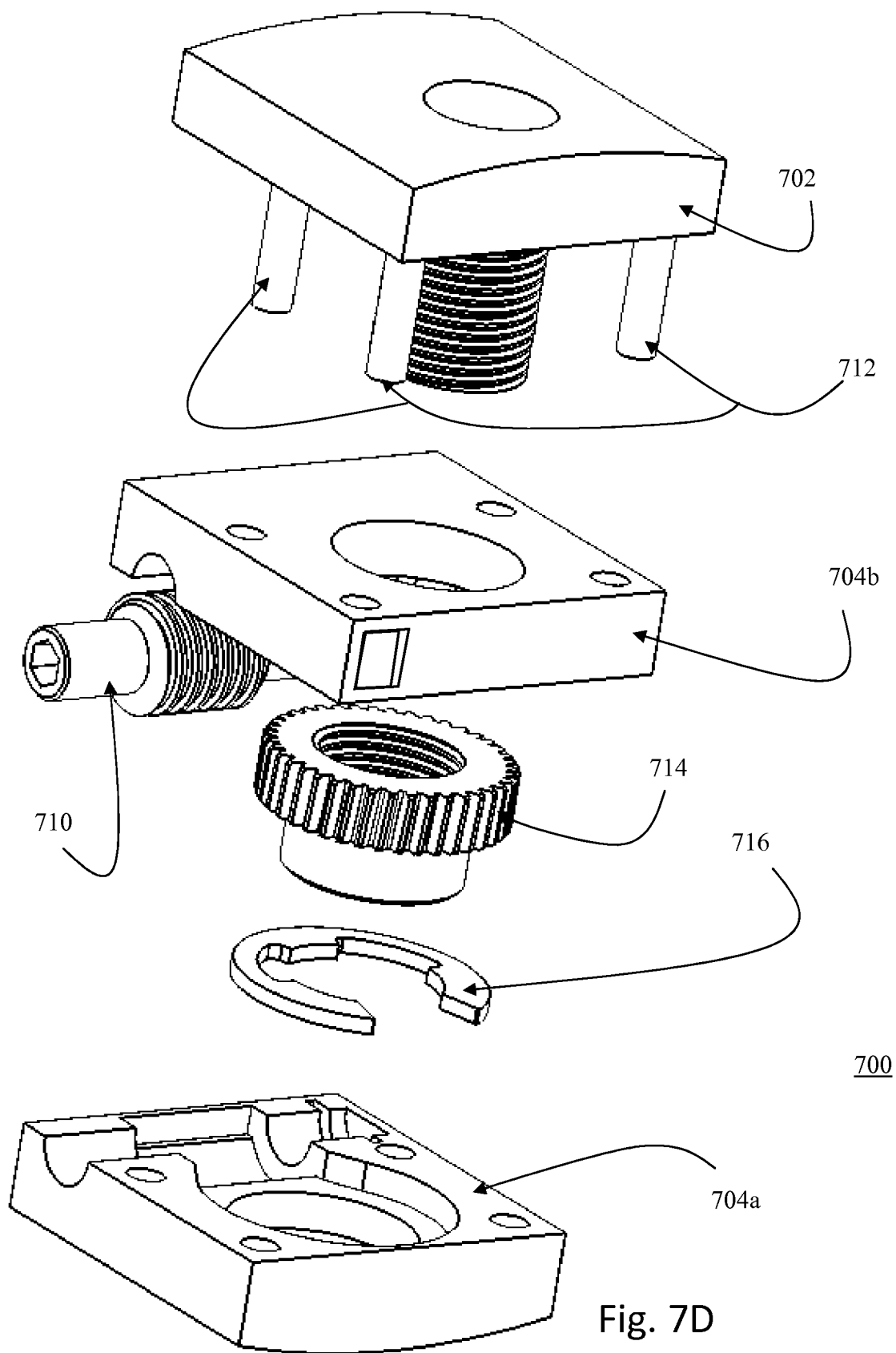


Fig. 7D

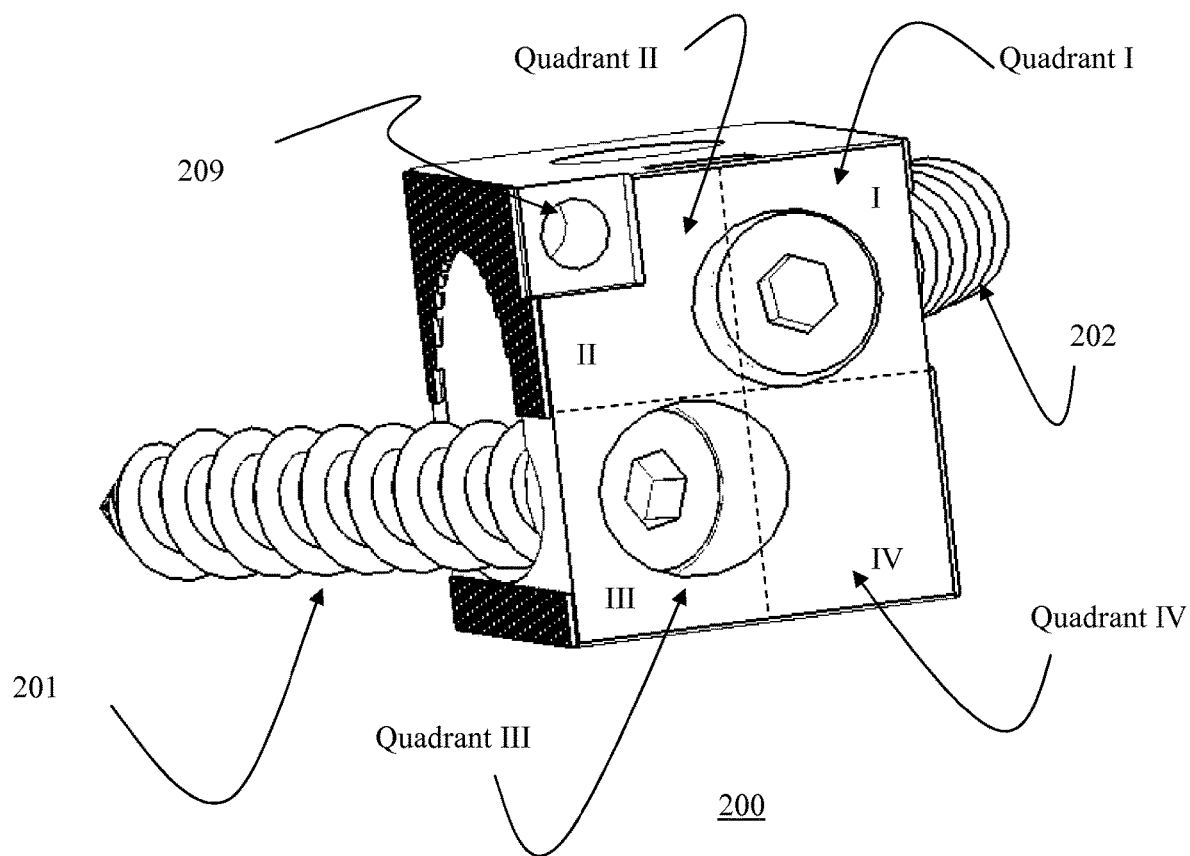


Fig. 7E(i)

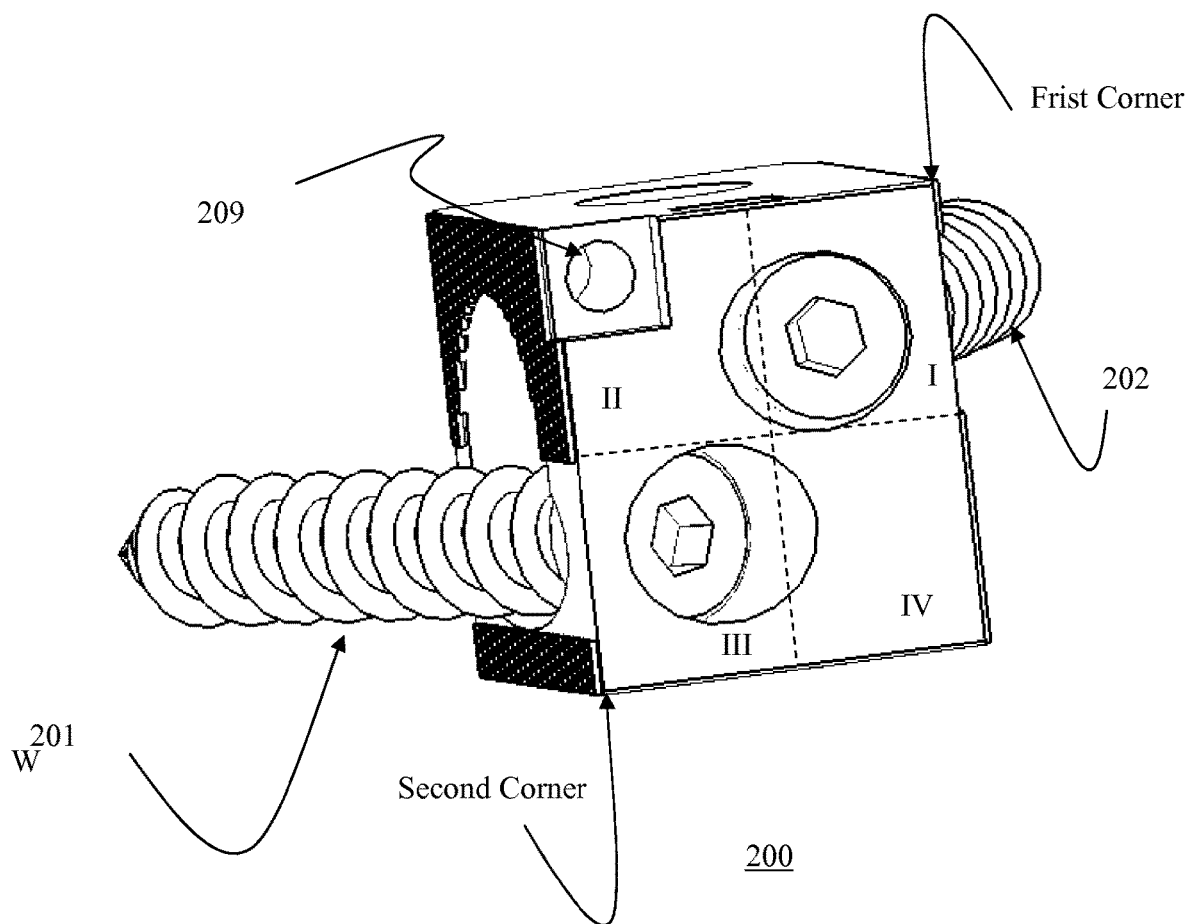


Fig. 7E(ii)

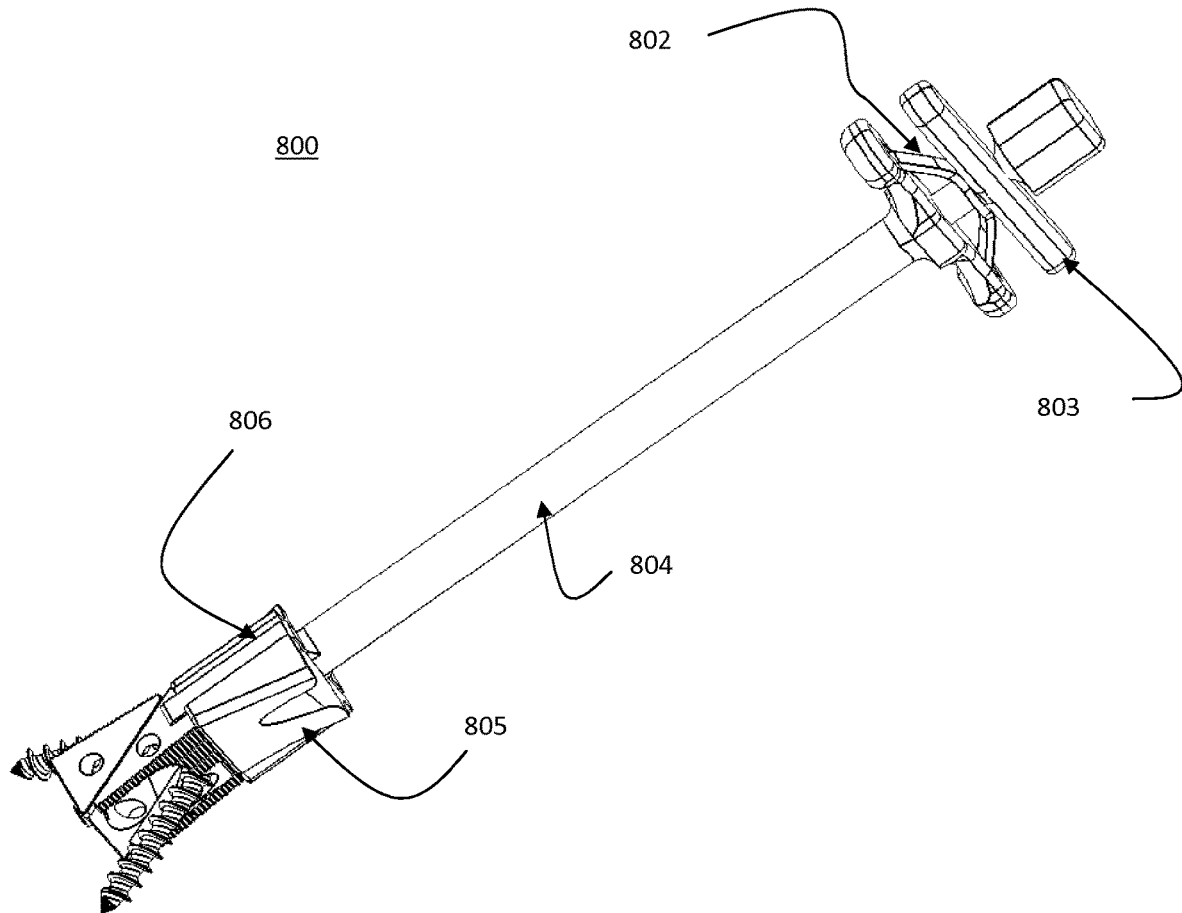


Fig. 8A

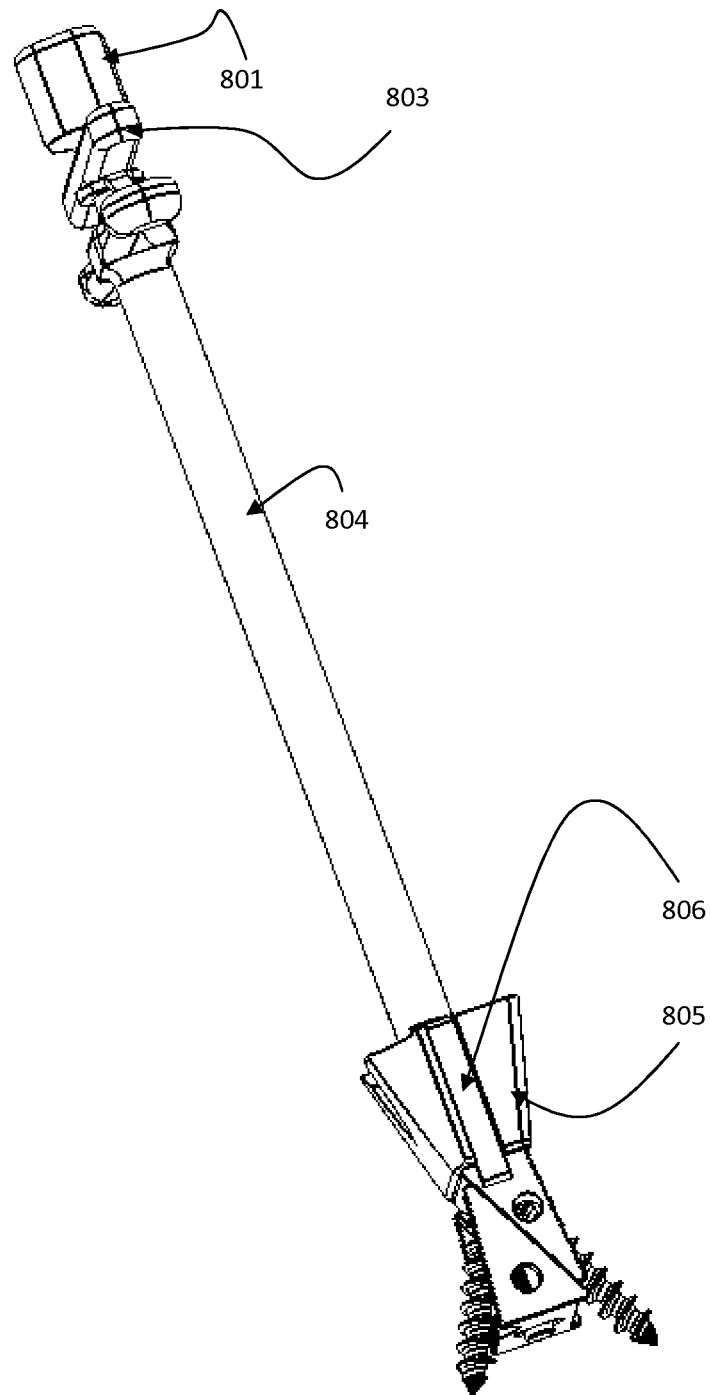


Fig. 8B

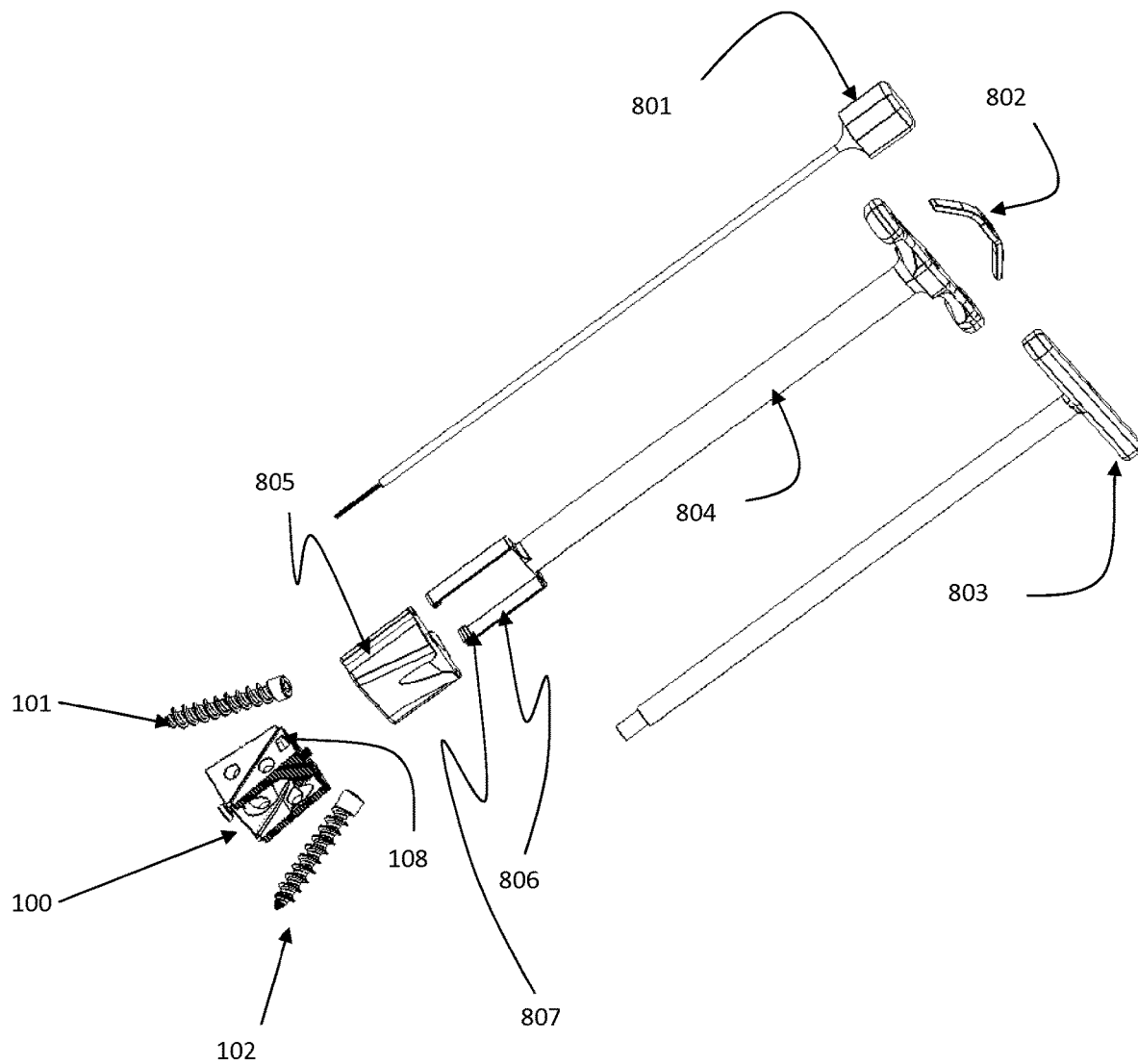


Fig. 8C

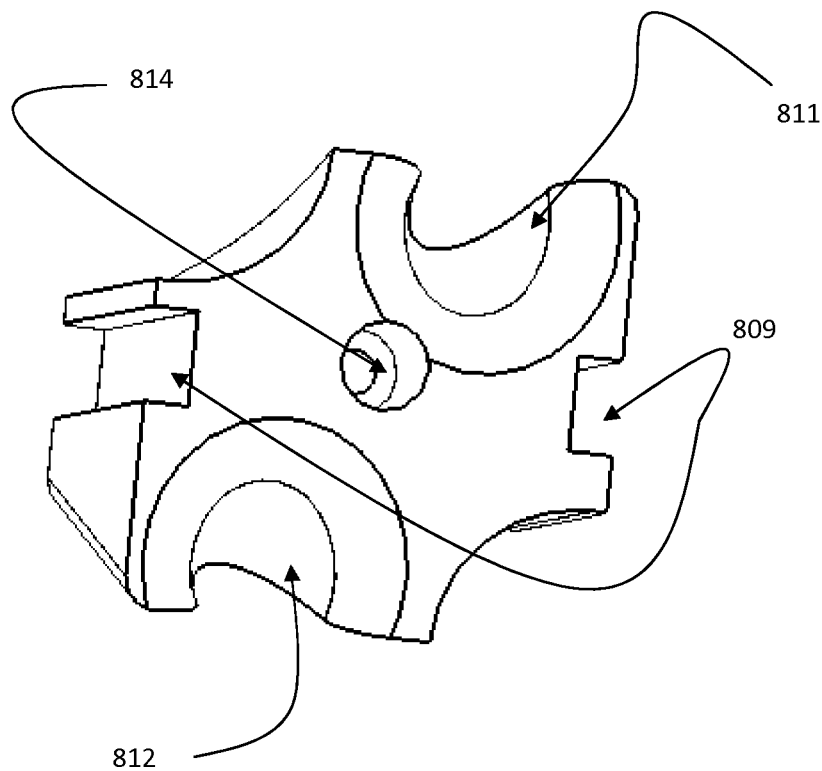


Fig. 8D(i)

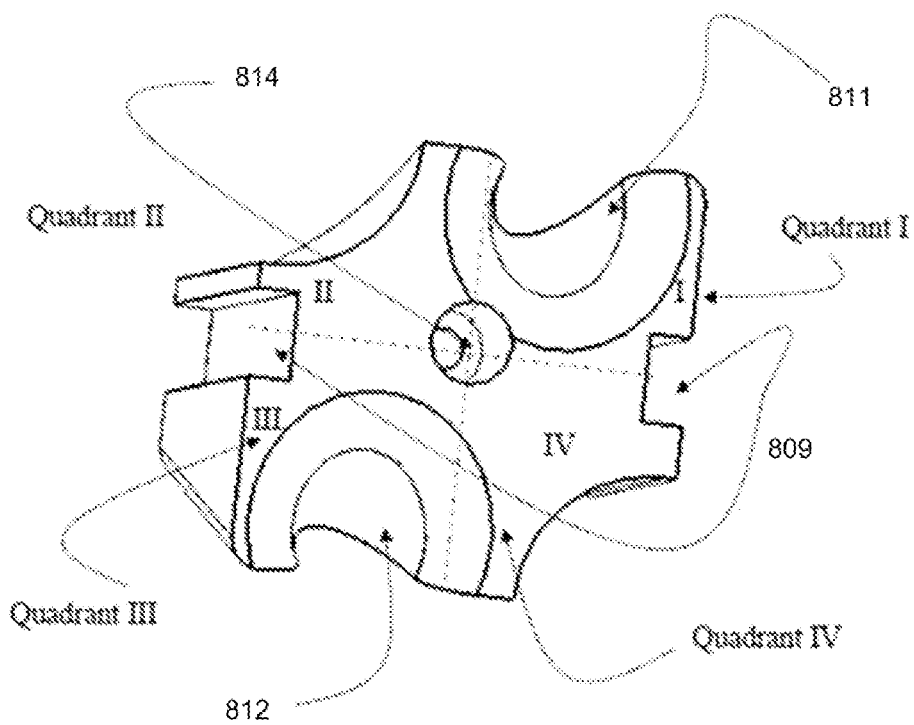


Fig. 8D(ii)

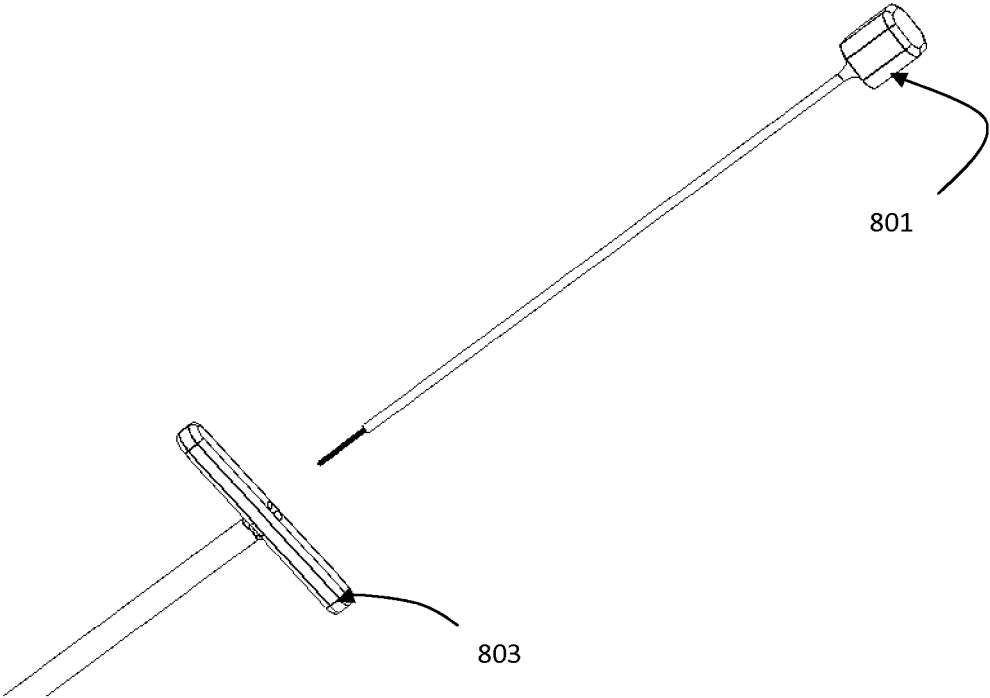


Fig. 8E

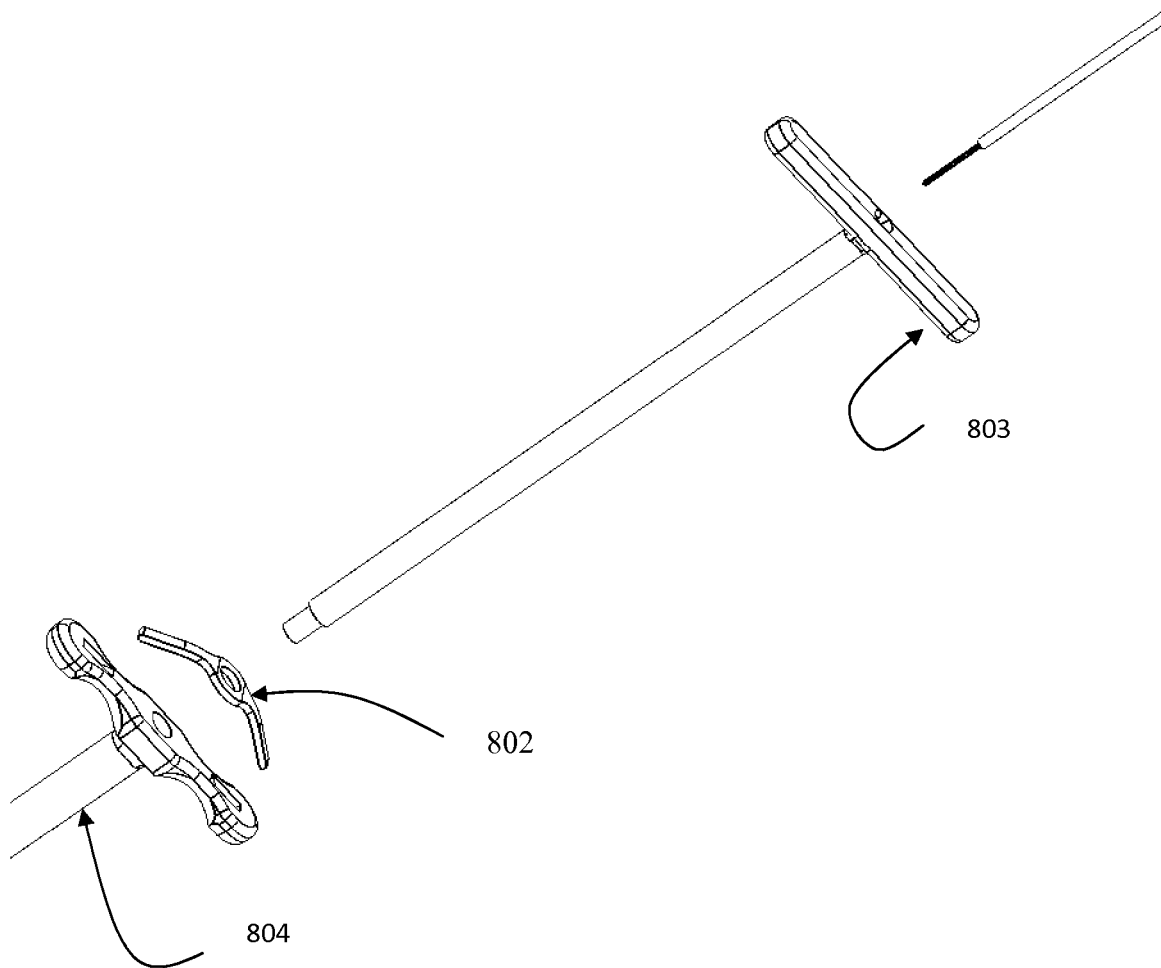


Fig. 8F

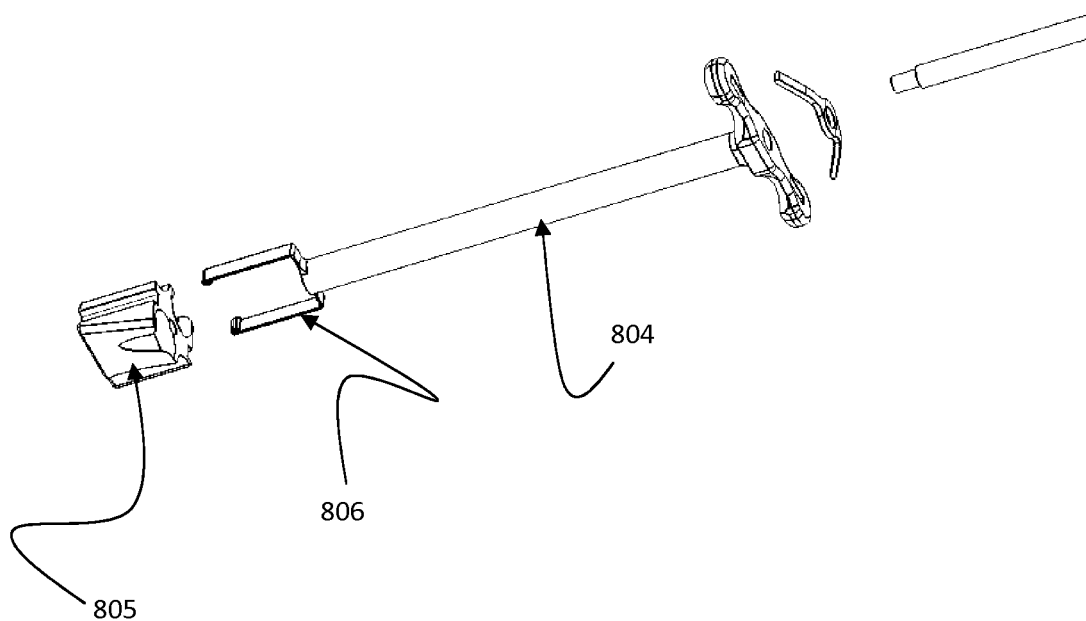


Fig. 8G

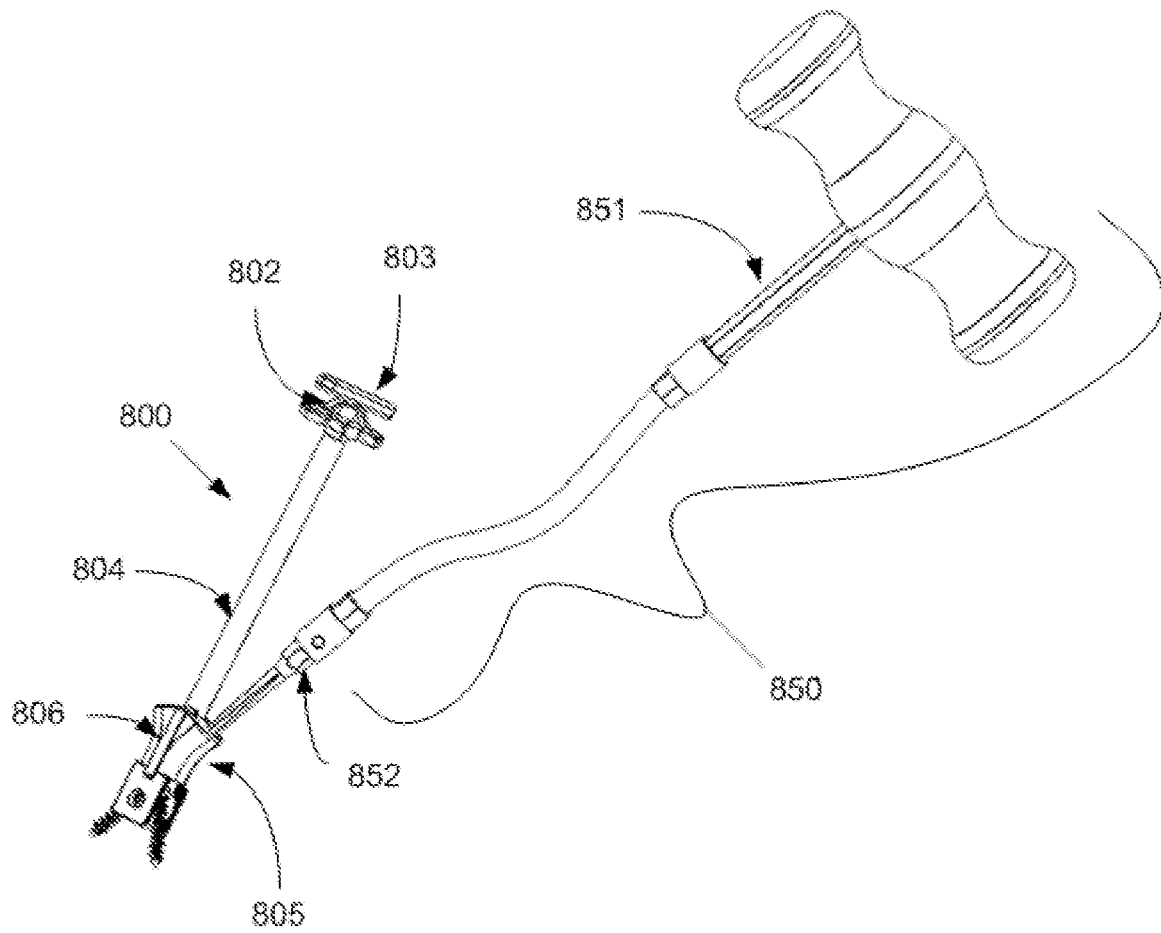


Fig. 8H

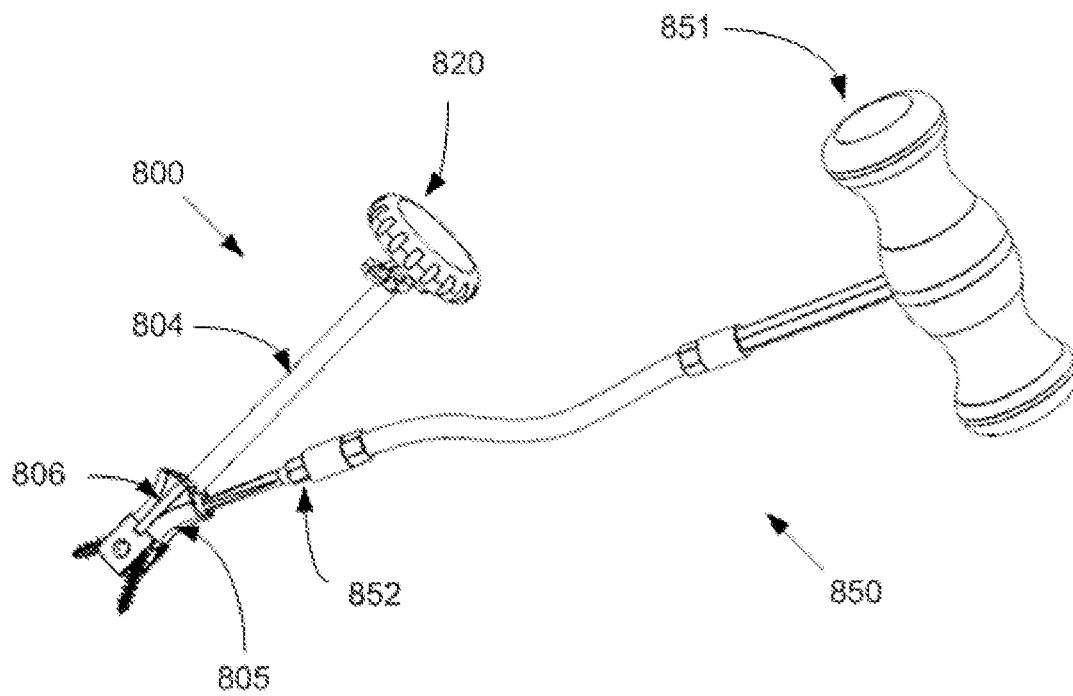


Fig. 8I

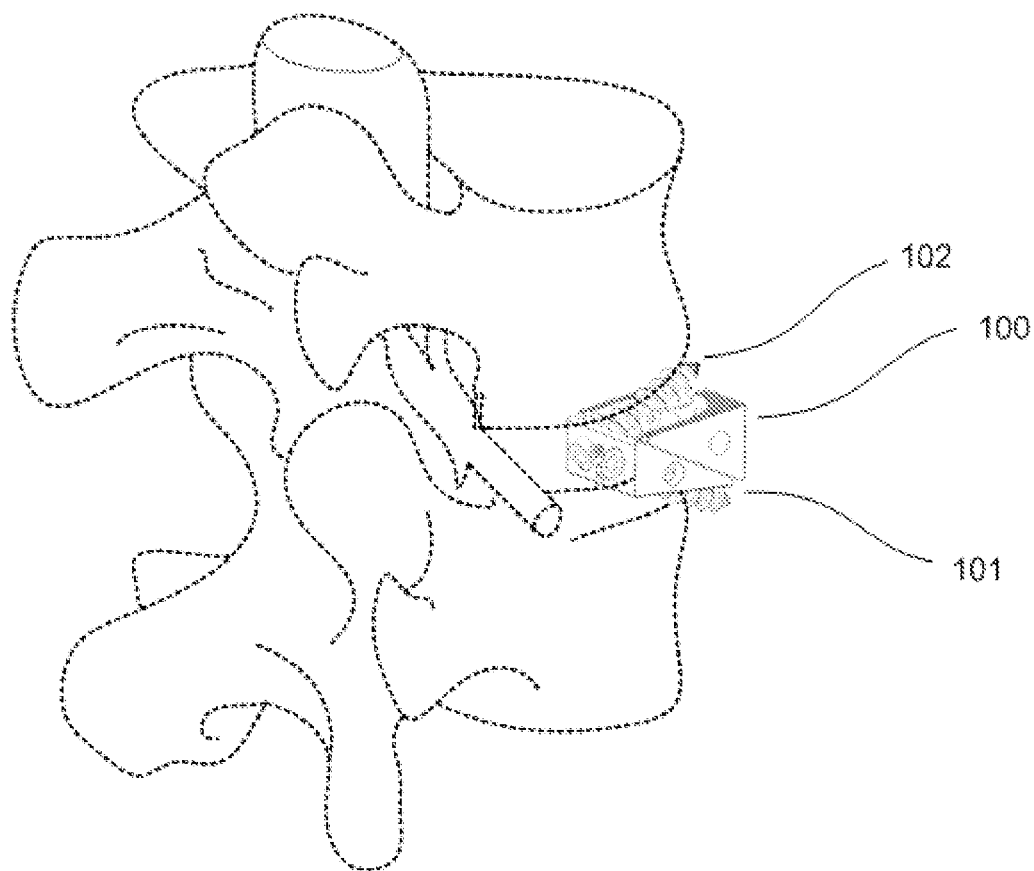


Fig. 8J

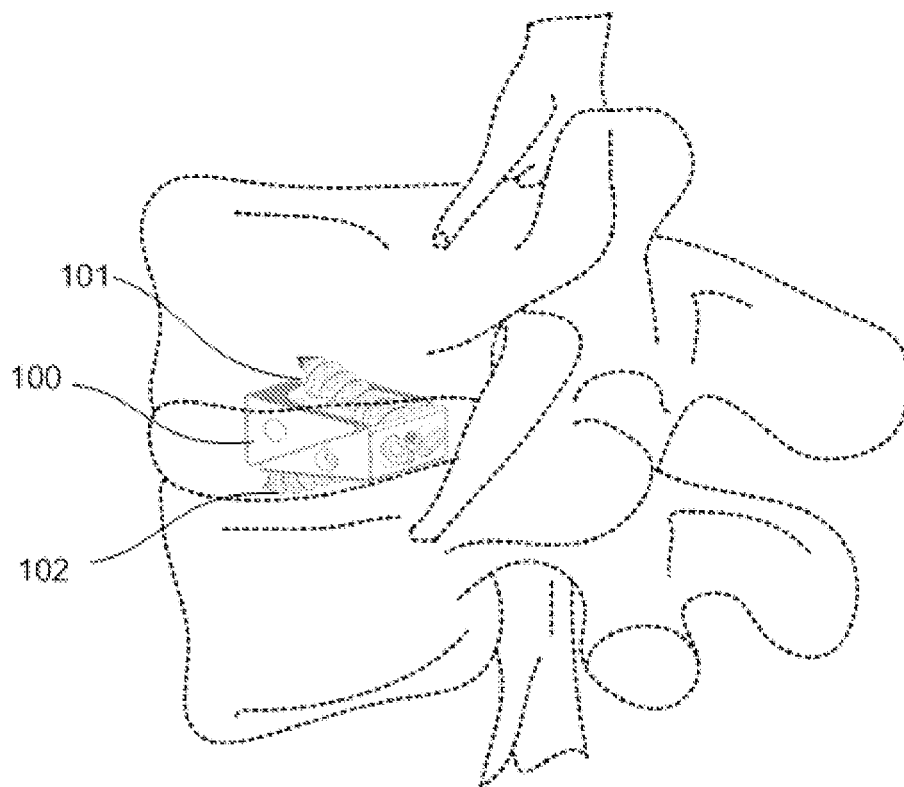


Fig. 8K

EXPANDABLE INTERVERTEBRAL DEVICE**CROSS-REFERENCE TO RELATED APPLICATIONS**

This application is a Continuation Application of application Ser. No. 16/587,993, filed on Sep. 30, 2019, now U.S. Pat. No. 11,096,797, which is a continuation application of application Ser. No. 16/025,667, filed on Jul. 2, 2018, now U.S. Pat. No. 10,426,633, which is a Continuation Application of application Ser. No. 15/820,232, filed on Nov. 21, 2017, now U.S. Pat. No. 10,016,284 issued Jul. 10, 2018, which is a Continuation Application of application Ser. No. 14/063,197, filed on Oct. 25, 2013, which is a Continuation-in-part Application of application Ser. No. 13/210,150, filed Aug. 15, 2011, now U.S. Pat. No. 9,867,719 issued Jan. 16, 2018, and a Continuation-in-part Application of application Ser. No. 13/210,157, filed Aug. 15, 2011, now U.S. Pat. No. 9,889,022 issued Feb. 13, 2018, and a Continuation-in-part Application of application Ser. No. 13/210,162, filed Aug. 15, 2011, now U.S. Pat. No. 9,895,238 issued Feb. 20, 2018 and a Continuation-in-part Application of application Ser. No. 13/210,168, filed Aug. 15, 2011, now U.S. Pat. No. 9,907,674 issued Mar. 6, 2018, and a Continuation-in-part Application of application Ser. No. 13/741,361, filed on Jan. 14, 2013, now U.S. Pat. No. 9,301,854 issued Apr. 5, 2016.

Ser. No. 14/063,197, filed on Oct. 25, 2013, claims priority under U.S.C. § 119(e) of U.S. provisional application Nos. 61/801,783, filed Mar. 15, 2013 and 61/718,707, filed Oct. 25, 2012.

Ser. No. 13/210,150, filed Aug. 15, 2011, is a Continuation of application Ser. No. 13/084,543, filed Apr. 11, 2011, now U.S. Pat. No. 8,353,913 issued on Jan. 15, 2013, and is a Continuation of Ser. No. 13/108,982, filed May 16, 2011, now U.S. Pat. No. 9,005,293 issued Apr. 14, 2015.

Ser. No. 13/210,157, filed Aug. 15, 2011, is a Continuation of application Ser. No. 13/084,543, filed Apr. 11, 2011, now U.S. Pat. No. 8,353,913 issued on Jan. 15, 2013, and is a Continuation of Ser. No. 13/108,982, filed May 16, 2011, now U.S. Pat. No. 9,005,293 issued Apr. 14, 2015.

Ser. No. 13/210,162, filed Aug. 15, 2011, is a Continuation of application Ser. No. 13/084,543, filed Apr. 11, 2011, now U.S. Pat. No. 8,353,913 issued on Jan. 15, 2013, and is a Continuation of Ser. No. 13/108,982, filed May 16, 2011, now U.S. Pat. No. 9,005,293 issued Apr. 14, 2015.

Ser. No. 13/210,168, filed Aug. 15, 2011, is a Continuation of application Ser. No. 13/084,543, filed Apr. 11, 2011, now U.S. Pat. No. 8,353,913 issued on Jan. 15, 2013, and is a Continuation of Ser. No. 13/108,982, filed May 16, 2011, now U.S. Pat. No. 9,005,293 issued Apr. 14, 2015.

Ser. No. 13/741,361, filed Jan. 14, 2013, is a Continuation of application Ser. No. 13/084,543, filed Apr. 11, 2011, now U.S. Pat. No. 8,353,913 issued on Jan. 15, 2013, and is a Continuation of Ser. No. 13/108,982, filed May 16, 2011, now U.S. Pat. No. 9,005,293 issued Apr. 14, 2015.

Ser. No. 13/084,543, filed Apr. 11, 2011, is a Continuation of application Ser. No. 11/842,855, filed Aug. 21, 2007, now U.S. Pat. No. 7,942,903 issued May 17, 2011.

Ser. No. 13/108,982, filed May 16, 2011, is a Continuation of application Ser. No. 11/842,855, filed Aug. 21, 2007, now U.S. Pat. No. 7,942,903 issued May 17, 2011, which is a Continuation-in-part of application Ser. No. 11/536,815, filed Sep. 29, 2006, now U.S. Pat. No. 7,846,188 issued Dec. 7, 2010, which is a Continuation-in-part of application Ser. No. 11/208,644, filed Aug. 23, 2005, now U.S. Pat. No. 7,704,279 issued Apr. 27, 2010, which claims priority under 35 U.S.C. § 119(e) of U.S. provisional application No.

60/670,231, filed on Apr. 12, 2005; the entire contents of all the above identified patent applications are hereby incorporated by reference.

FIELD OF DISCLOSURE

The present invention relates to unique, universal Zero-Profile Expandable Intervertebral Spacer (ZP-EIS) devices for fusion and distraction throughout the entire spine which can be inserted via anterior, anterolateral, lateral, far lateral or posterior surgical approaches dependent on the need and preference. Multiple ZP-EIS embodiments each with unique mechanisms of calibrated expansion are presented. Two of these embodiments incorporate bi-directional fixating trans-vertebral (BDFT) screws and five other embodiments do not incorporate BDFT screws. A universal tool for their intervertebral placement and device expansion is also described.

The ZP-EIS embodiments with incorporated BDFT screws can be used as stand-alone intervertebral devices. These exemplary embodiments combine the dual functions of intervertebral calibrated expandable distraction, and segmental vertebral body spinal fusion. These embodiments can include bone cavities which can be filled with bone fusion material(s) to promote segmental spinal fusion.

The calibrated ZP-EIS embodiments without incorporated BDFT screws can also be used as stand-alone devices for calibrated intervertebral expansion and segmental vertebral body fusion. The exemplary devices can include bone cavities which can be filled with bone fusion material. If desirable, the exemplary devices can be supplemented with other forms of screw stabilization.

The exemplary ZP-EIS embodiments, especially those with incorporated BDFT screws, may obviate the need for supplemental pedicle screw fixation in many situations. The exemplary embodiments allow nuanced, fine-tuned incremental and calibrated distraction of the disc space to allow nerve root decompression in a minimally invasive and safe manner, as well as promoting segmental spinal fusion.

In the related applications in the Cross-Reference to Related Applications, Applicants first introduced the terminology “zero-profile” relating to spinal fusion devices. Applicants also have described zero-profile non-expandable and expandable stand-alone intervertebral spinal fusion device embodiments with incorporated BDFT screws. As described in greater detail below, exemplary embodiments of advanced ZP-EIS devices with BDFT screws are provided which have an improved contoured body with tapered edges to more precisely insert into and conform to the biconcave disc space. The present application also provides exemplary embodiments of more advanced ZP-EIS devices without accompanying BDFT screws each with very unique calibrated expandable mechanisms allowing minimally invasive intervertebral expansion, vertebral body distraction and segmental spinal fusion. An exemplary embodiment of a universal tool also is described that can be adapted to implant one or more (e.g., all) of the intervertebral device embodiments herein described into the intervertebral space, and mechanically expand them.

BACKGROUND

The history and evolution of instrumented spinal fusion in the entire human spine has been reviewed in Applicants' copending applications set forth in the Cross-Reference to Related Applications (for example in U.S. Ser. No. 11/536,815, filed on Sep. 29, 2006, and Ser. No. 11/208,644, filed on Aug. 23, 2005). Currently, the majority of spinal fusion

techniques are typically supplemented with posterior pedicle screw placement and/or anterior (or lateral) plating. Complications of pedicle screw placement in the spine may include duration of procedure, significant tissue dissection and muscle retraction, misplaced screws with neural and/or vascular injury, excessive blood loss, need for transfusions, prolonged recovery, incomplete return to work, and excess rigidity leading to adjacent segmental disease requiring further fusions and re-operations. Recent advances in pedicle screw fixation including minimally invasive and image-guided technology, and the development of flexible rods, imperfectly may address some but not all of these issues.

Anterior/and or lateral plating because of the plates' elevated profiles can be complicated by esophageal, or major vascular injury. The zero-profile devices described herein with reference to the exemplary embodiments avoid these complications.

Current non-expandable intervertebral spacers must be manufactured with different heights, and the most appropriate sized spacer is selected for insertion. In these situations, the vertebral bodies are forcefully distracted to allow placement of an imperfectly fitting spacer. These are most often supplemented with pedicle screw and/or plate fixation.

SUMMARY

The exemplary embodiments described herein can allow a more precisely tailored complimentary fit between spacer and disc space, allowing the spacer to expand gradually in a calibrated manner, and to incrementally achieve the precise fit and degree of distraction desirable. Thus, the process according to the present invention can be more individualized for every patient and apply less forceful disruption to the intervertebral space thereby improving safety and enhancing effectiveness of the placement of intervertebral spacers. The exemplary embodiments are zero-profile, and thus, do not damage or indent overlying soft tissue or vascular structures further decreasing morbidity.

Herein described are exemplary embodiments of multiple ZP-EIS devices which combine in a single construct the dual functions of calibrated expandable intervertebral spacer distraction maintaining disc space height, and simultaneous segmental vertebral body spinal fusion.

To achieve safe, effective zero-profile and minimally invasive segmental spinal fusion, the exemplary embodiments of the present invention use of novel zero-profile calibrated expandable spacer (ZP-EIS) devices with or without BDFT screws which can be strategically inserted into the intervertebral disc space via anterior, antero-lateral, lateral, far lateral or posterior surgical approaches.

In Applicants' applications set forth in the Cross-Reference to Related Applications, exemplary embodiments are directed to expanding intervertebral spacers which incorporated BDFT screws. One of these embodiments includes two sliding triangular bases to house two screws driven in two opposing directions which can be expanded in two simultaneous directions, height and depth, by turning a built-in screw adjuster. This was facilitated by a combined external drill/screw guide/cage expander to further enhance trajectory precision and to simultaneously expand the screw box in height and depth to custom-fit the individual disc space height. Applicants' copending applications set forth in the Cross-Reference to Related Applications further describe an exemplary embodiment of a universal tool and the adaptability of the tool, for example, to exemplary embodiments

of sliding boxes, as well as to the exemplary embodiments described herein, including those with and without BDFT screws.

The evolved zero-profile expandable intervertebral spacer (ZP-EIS) embodiments with incorporated BDFT screws presented herein are more finely tapered and contoured to more easily allow insertion and conformation to the biconcave disc space.

The exemplary embodiments of ZP-EIS devices without incorporated BDFT screws described herein have the ability to incrementally and uniformly separate and distract the vertebral bodies. Each embodiment has a very unique mechanically designed mechanism of incremental expansion. The devices are all designed with cavities for bone fusion giving the surgeon the option to use these as stand-alone fusion/spacer devices or as supplemental devices if other screw fixation is deemed necessary. These innovations represent a continued evolution of our concept of zero-profile calibrated expandable intervertebral distraction/fusion spacers described in Applicants' applications, for example, as set forth in the Cross-Reference to Related Applications.

In the exemplary ZP-EIS embodiments with incorporated BDFT screws, a rostral-directed screw is passed through one built-in screw guide of the device which then is inserted and screwed into the superior vertebral body. Next, a caudally directed screw is passed through an adjacent built-in screw guide, which then is inserted and screwed into the inferior vertebral body. One of many novel features of this design is the built-in prescribed angles of the integral screw guides which allow the transvertebral penetration into the vertebral bodies. This is a truly amazing feat accomplished particularly in the posterior or lateral/far lateral lumbar spine considering the small anatomically restricted work zone within which to work, which is very narrowly prescribed by obtuse angulations between screw and intervertebral bone surfaces, and by nerve root, facet joint and pedicle. Applicants' applications set forth in the Cross-Reference to Related Applications included an angled screw driver specifically designed to fit these devices if a straight screw driver impedes screw placement. Hence, these external tools can provide the means in any circumstance to accomplish precision screw trajectory.

The exemplary zero-profile embodiments of the present invention can provide enhanced individualized intervertebral conformation, and multiple methods of finely calibrating intervertebral expansion, and vertebral body distraction further reducing morbidity and enabling more minimally invasive surgical methods of vertebral body distraction and segmental fusion compared to Applicants' applications set forth in the Cross-Reference to Related Applications.

The exemplary embodiments of box casings can include perforations to allow bone packing for fusion. These exemplary devices can prevent subsidence. In an exemplary embodiment, both the inside of the denuded intervertebral space, and the devices can be packed with autologous or allograft bone, BMP, DBX or similar osteoconductive material.

The zero-profile EIS embodiments, in particular those with incorporated BDFT screws, can provide as strong or stronger segmental fusion as pedicle screws without the complications arising from pedicle screw placement which include screw misplacement with potential nerve and/or vascular injury, violation of healthy facets, possible pedicle destruction, blood loss, and overly rigid fusions. In the case of the posterior Lumbar spine by placing screws across the intervertebral space from vertebral body to vertebral body,

5

engaging anterior and middle spinal columns, and not the vertebral bodies via the transpedicular route, the healthy facet joints, if they exist, are preserved. Because the exemplary techniques accomplish both anterior and middle column fusion, without rigidly fixating the posterior column, the exemplary embodiments in essence create a flexible fusion. This exemplary devices therefore can provide a flexible fusion device because the preserved posterior facet joints retain their function achieving at least a modicum of mobility and hence a less rigid (i.e. a flexible) fusion.

The very advantage of transpedicular screws which facilitate a strong solid fusion by rigidly engaging all three spinal columns is the same mechanical mechanism whereby complete inflexibility of all columns is incurred thereby leading to increasing rostral and caudal segmental stress which leads to an increased rate of re-operation.

Transvertebral fusion also leads to far less muscle retraction, blood loss, and significant reduction in operating room (O.R.) time. Thus, the complication of pedicular screw pull-out and hence high re-operation rate associated with the conventional flexible fusion pedicle screws/rods is obviated.

Although the exemplary embodiments can be supplemented with transpedicular screws, there would be no absolute need for supplemental pedicle screw fixation with these operative techniques. The expandable spacers without BDFT screws can be supplemented with other screw stabilization if desired.

Because the exemplary embodiments are zero-profile, these devices also obviate the morbidity involved with profiled anterior or lateral plating. Multi-level fusions can be performed with all of the exemplary embodiments described herein.

Currently failed anterior lumbar arthroplasties are salvaged by combined anterior and posterior fusions. The exemplary ZP-EIS embodiments with incorporated BDFT screws could be utilized as a one-step salvage operation for failed/extruded anteriorly placed lumbar artificial discs obviating the above salvage procedure which has far greater morbidity.

BRIEF DESCRIPTION OF DRAWINGS

These and other aspects and features of embodiments of the present invention will be better understood after a reading of the following detailed description, together with the attached drawings, wherein:

FIGS. 1A-1B illustrate an exemplary embodiment (Embodiment I) of a non-tapered sliding base ZP-EIS device with incorporated BDFT screws in sagittal-oblique (FIG. 1A), and exploded (FIG. 1B) views.

FIGS. 2A-2D illustrate an exemplary embodiment (Embodiment II) of a tapered sliding base ZP-EIS device with incorporated BDFT screws in closed (FIG. 2A), semi-expanded (FIG. 2B), and fully expanded (FIG. 2C) positions, and in an exploded view (FIG. 2D).

FIGS. 3A-3D illustrate an exemplary embodiment (Embodiment III) of a scissors jack driven ZP-EIS device without incorporated BDFT screws in closed (FIG. 3A), semi-expanded (FIG. 3B), and fully expanded (FIG. 3C) positions, and in exploded view (FIG. 3D).

FIGS. 4A-4C illustrate an exemplary embodiment (Embodiment IV) of a tapered thread driven ZP-EIS device without incorporated BDFT screws in closed (FIG. 4A), semi-expanded/fully expanded positions (FIG. 4B), and in cross-sectional view (FIG. 4C).

FIGS. 5A-5D illustrate an exemplary embodiment (Embodiment V) of a dry anchor driven ZP-EIS device without

6

incorporated BDFT screws in closed (FIG. 5A), semi-expanded (FIG. 5B), and fully expanded (FIG. 5C) positions, and in an exploded view (FIG. 5D).

FIGS. 6A-6D illustrate an exemplary embodiment (Embodiment VI) of a modified wedge driven ZP-EIS device without incorporated BDFT screws in closed (FIG. 6A), semi-expanded (FIG. 6B), and fully expanded (FIG. 6C) positions, and in an exploded view (FIG. 6D).

FIGS. 7A-7D illustrate an exemplary embodiment (Embodiment VII) of a worm drive ZP-EIS device without incorporated BDFT screws in closed (FIG. 7A), semi-expanded (FIG. 7B), and fully expanded (FIG. 7C) positions, and in an exploded view (FIG. 7D).

FIG. 7C illustrates a top, perspective view of an intervertebral cage construct according to an exemplary embodiment of the invention.

FIG. 7D illustrates a top, perspective, exploded view of a positioning tool/screw guide/box expander according to an exemplary embodiment.

FIG. 7E illustrates a superior oblique perspective view of the positioning tool/drill guide/box expander component according to an exemplary embodiment.

FIGS. 8A-8C illustrate a positioning tool/screw guide/box expander in oblique perspective (FIG. 8A), lateral (FIG. 8B), and exploded (FIG. 8C) views according to an exemplary embodiment, which is shown coupled to the exemplary non-tapered sliding base ZP-EIS device illustrated in FIGS. 1A-1B.

FIGS. 8D(i) and 8D(ii) illustrate superior oblique perspective views of the positioning tool/drill guide/box expander component, according to an exemplary embodiment, which may be optionally used for the exemplary embodiments illustrated in FIGS. 1A-1B and 2A-2D.

FIGS. 8E-8G illustrate sequential steps Step I (FIG. 8E), step II (FIG. 8F), and step III (FIG. 8G)) of the positioning tool/screw guide/box expander assembly according to an exemplary embodiment.

FIGS. 8H-8I illustrate three-dimensional views of positioning tools, according to exemplary embodiments, for impaction and placement of two transvertebral screws, for example, of the exemplary embodiments illustrated in FIGS. 1A-1B and 2A-2D.

FIGS. 8J-8K illustrate the insertion of expandable Lumbar bi-directional screw box with two BDFT screws into the Lumbar spine in oblique (FIG. 8J) and lateral (FIG. 8K) views.

DETAILED DESCRIPTION OF THE INVENTION

The present invention now is described more fully hereinafter with reference to the accompanying drawings, in which embodiments of the invention are shown. This invention may, however, be embodied in many different forms and should not be construed as limited to the embodiments set forth herein; rather, these embodiments are provided so that this disclosure will be thorough and complete, and will fully convey the scope of the invention to those skilled in the art.

1. The Medical Device

Referring now to the drawings, FIGS. 1A-8K illustrate exemplary embodiments of ZP-EIS devices that can solve the above described problems and others in the spine by insertion of the ZP-EIS devices into the denuded intervertebral disc space according to the features illustrated in the exemplary embodiments (I-VII).

7

FIGS. 1A-1B illustrate three-dimensional views of a ZP-EIS device **100** according to embodiment I, with two BDFT screws **101**, **102**.

The expandable ZP-EIS device **100** includes of top and bottom triangular sliding bases **103**, **104** (FIGS. 1A-1B). The superior and inferior segments of the height/depth adjusting screw **105** are integrated and connected to the two separate top and bottom triangular bases **103**, **104**, respectively. By turning this adjusting (rotation) screw **105** back and forth, i.e. clock-wise, and counter clockwise, the sliding rails **106** of the top triangular base **103** (FIGS. 1A-1B) slide up and down the rail inserts **107** on the bottom triangular base **104** (FIGS. 1A-1B). This action will simultaneously alter the intervertebral height and depth of the device **100** allowing individualized custom fitting of the ZPEIS device **100** conforming to the dimensions of the disc space.

A transvertebral screw **101** penetrates the top base **103**, and a transvertebral screw **102** traverses the bottom base **104** of the screw box (device **100**). The two screws **101**, **102** traverse the screw box **100** in opposing directions, bi-directionally. The external edges of the triangular bases **103**, **104** in contact with vertebral body surfaces can include ridges **107**, which facilitates the ZP-EIS device **100** incorporation into and fusion with the superior and inferior vertebral bodies (FIGS. 1A-1B). Both top and bottom ZP-EIS bases **103**, **104** can be perforated with holes **108** to allow bone placement for fusion. In an exemplary embodiment, the entire construct, furthermore, can be hollow to allow filling with bone filling material. Hence, the exemplary device functions as both an intervertebral bone fusion spacer and bi-directional transvertebral screw fusion device.

FIGS. 2A-D illustrate a ZP-EIS device **200** according to exemplary embodiment II. This exemplary device **200** incorporates BDFT screws and employs a fusion wedge mechanism of expansion.

The device **200** includes a contoured top **208** and bottom **206** housing which have tapered edges and are coupled to each other by a diagonal dovetail interface **204** which constrains the components **208**, **206** to translate linearly relative to each other. The linear translation causes a vertical separation of the top **208** and bottom **206** housing surfaces which are parallel to each other. The position is secured and adjusted by a threaded rotation screw **220** coupled to a nut **224** and a retaining ring **222** and passed through the top **208** and bottom **206** housing pieces. As the threaded rotation screw **220** is rotated further into the nut **224**, the housing pieces **208**, **206** expand vertically.

By turning this adjusting (rotation) screw **220** back and forth i.e. clock-wise, and counter clockwise, the sliding rails **210** of the top housing piece **208** slide up and down the rail inserts **212** on the bottom housing piece **206**. This action will simultaneously alter the intervertebral height and depth of the device **200** allowing individualized custom fitting of the ZP-EIS conforming to the dimensions of the disc space. A transvertebral screw **101** penetrates the top housing piece **208**, and a transvertebral screw **102** traverses the bottom housing piece **206** of the device **200**. The two screws **101**, **102** traverse the device **200** in opposing directions, bi-directionally. The external edges of the housing pieces in contact with vertebral body surfaces include ridges **216**. This facilitates the ZP-EIS device **200** incorporation into and fusion with the superior and inferior vertebral bodies (FIGS. 2A-D). Both top and bottom ZP-EIS housing bases **208**, **206** are perforated with holes **214** to allow bone placement for fusion. The entire device **200**, furthermore, can be hollow to allow bone filling. Hence, the exemplary device **200** func-

8

tions as both an intervertebral bone fusion spacer and bi-directional transvertebral screw fusion device.

The device **200** can include a tapered edge **226** (shown for example in FIGS. 2A-2B), which allows easier introduction and insertion of the device **200** into the disc space.

FIGS. 3A-3D illustrate a ZP-EIS device **300** according to exemplary embodiment III, which employs a scissor jack expansion mechanism.

In this embodiment the top **302** and bottom **304** housing are attached by one internal linkage arm **310**, and two external linkage arms **308**. The device **300** can include indentations **306** on each lateral side close to the top of the device **300** to mate with the prongs of the universal tool (for example, as described in FIGS. 8A-8I) to assist in grasping, inserting and impacting the device **300**. A lead screw or rotation screw **314** is mounted in the bottom housing **304** and secured in place with a retaining ring **316**. When the lead (rotation) screw **314** is rotated by an external tool (for example, as described in FIGS. 8A-8I), the screw **314** causes the linear displacement of the separation block **318** which is hinged to the internal linkage **310**. The horizontal motion of the separation block causes the top **302** and bottom **304** housing pieces to separate vertically. The separation distance depends on the amount of rotation of the lead (rotation) screw **314**, and is limited by the freedom of the separation block **318** to move within the bottom housing **304**. The exemplary embodiment can include a plurality of pins, such as eight pins **320**, **322**, **324**, to secure the external linkage arms **308** to the top **302** and bottom **304** housing units and to the separation block **318**. The top housing **302** and bottom housing **304** can include one or more cavities **312** for bone incorporation/fusion.

FIGS. 4A-4C illustrate a ZP-EIS device **400** according to exemplary embodiment IV, which employs a tapered thread mechanism of expansion.

The exemplary device **400** can include a top housing **402** and bottom housing **404**, which can be attached by one or more pins, such as two pins **412**, which allow rotation of the top housing **402** and bottom housing **404** relative to each other about the axis of the pins **412**. The top housing **402** and/o bottom housing **404** can include indentations **406** on their lateral sides close to the top of the device **400** to mate with the prongs of a tool or universal tool (e.g., prongs **806** in FIGS. 8A-8I) to assist in grasping, inserting and impacting the device **400**. The bottom housing **404** can include a mount for the rotation screw **410** (FIG. 4C), which can control the relative angular orientation of the two housing pieces **402**, **404**. When the screw **410** is rotated by an external tool (e.g. as shown in FIGS. 8A-8I), the screw **410** engages the internal teeth/ridges **414** of the top housing **402** and acts as a wedge to rotate the top housing **402** away from the bottom housing **404**. More particularly, the device **400** can include a sloped ridge **414**, as exemplary illustrated in FIG. 4C. When the rotating screw **410** advances, the top housing **402** rotates further and further away from the bottom housing **404**. The device **400** can include one or more bone cavities in the top housing **402** and bottom housing **404** for bone fusion.

FIGS. 5A-5D illustrate exemplary embodiments of a ZP-EIS device according to embodiment V, which employs an anchor mechanism of expansion.

The top housing **502** and bottom housing **504** can be coupled or attached by one or more pins, such as two pins **512**, which allow rotation of the top housing **502** and bottom housing **504** relative to each other about the axis of the pins **512**. The top housing **502** and/or the bottom housing **504** can include indentations **506** on their lateral sides close to the top

9

of the device **500** to mate with the prongs of a tool or universal tool (e.g. see FIGS. **8A-8I**) to assist in grasping, inserting and impacting the device **500**. The bottom housing **504** can include, for example, a mount for the lead (rotation) screw **510**, which can control the relative angular orientation of the two housing pieces **502**, **504**. The lead (rotation) screw **510** can be secured with one or more retaining rings, such as two retaining rings **518**. When the screw **510** is rotated by an external tool (not illustrated) (e.g., such as the tool shown in FIGS. **8A-8I**), the screw **510** causes lateral motion of a translation nut **516**, which is attached to two linkage bars **514** to a second nut **516** fixed to the bottom housing. A plurality of pins, such as six pins **512**, can secure the linkage bars or arms **514** to each other and to translation nuts **516**. When the translation nuts **516** move, the linkage bars or arms **514** extend outside of the bottom housing **504**, pushing against the top housing **502**. Alternatively, in other embodiments, the linkage bars or arms **514** can be replaced by a solid material such as spring steel which can bend to produce the same effect. The device **500** can include one or more bone cavities that can be incorporated into the top housing **502** and the bottom housing **504** for bone fusion.

FIGS. **6A-6D** illustrate exemplary embodiments of a ZP-EIS device **600** according to embodiment VI which employs a modified wedge expansion mechanism.

The device **600** includes a top housing **602** and a bottom housing **604** that can be attached or coupled by one or more pins, such as two pins **612**, which allow rotation of the top housing **602** and the bottom housing **604** relative to each other about the axis of the pins **612**. The top housing **602** and/or the bottom housing **604** can include indentations **606** on their lateral sides close to the top of the device **600** to mate with the prongs of a tool, such as prongs **806** of the universal tool shown in FIGS. **8A-8I**, to assist in grasping, inserting and impacting the device **600**. The bottom housing **604** can include a mount for the lead (rotation) screw **610**, which can control the relative angular orientation of the two housing pieces **602**, **604**. The lead (rotation) screw **610** can be secured with one or more retaining rings, such as two retaining rings **618**. When the screw **610** is rotated by an external tool (e.g., the tool shown in FIGS. **8A-8I**), the screw **610** causes lateral motion of a wedge-shaped translation nut **616**. The nut **616** engages an inner tapered surface of the top housing **602** and forces the top housing piece **602** to rotate away from the bottom housing **604**. The device **600** can include one or more bone cavities **608** incorporated into the top housing **602** and/or bottom housing **604** for bone fusion.

FIGS. **7A-7D** illustrate exemplary embodiments of a ZP-EIS device **700** according to embodiment VII, which employs a worm drive (gear) mechanism.

According to the invention, the device **700** includes a worm drive design that allows a user to rotate a worm gear/drive **712** with an external tool (FIG. **8**) to control the translation of the top housing **702** relative to the bottom housing **704a**, **704b**. The worm gear drive **712** engages a spur gear mount **714** which has internal threading for engaging a corresponding part, such as a threaded stud of bolt **720**, to couple the spur gear mount **714** to the top housing **702**. The top housing **702** can include a plurality of pins, such as four pins **712**, which extend into the bottom housing **704a**, **704b**. These pins **712** prevent the top housing **702** from rotating with the spur gear **714**, and constrain the spur gear **714** to translate linearly. The bottom housing **704** can include two halves **704a**, **704b** to secure the worm drive **710** and spur mount **714** in place. A worm retaining ring and a spur retaining ring **716** also can be used to secure the worm gear drive **710** and the spur gear mount **714**. The device **700**

10

can include one or more bone cavities **708** that are incorporated into the top housing **702** and/or bottom housing **704a**, **704b** for bone fusion. The top housing **702** and/or bottom housing **704a**, **704b** can include one or more indentations **706** on its lateral sides close to the top of the device **700** to mate with prongs of a tool, such as prongs **806** of the universal tool **800** in FIGS. **8A-8I**, to assist in grasping, inserting and impacting the device **700**.

FIGS. **8A-8C** illustrate three-dimensional views of exemplary embodiments of the external drill/screw guide-box expander universal tool **800** which can be used to assist in both screw trajectory and box expansion of an expandable device, such as the exemplary embodiments of devices illustrated in embodiments I and II, and for device expansion of the devices illustrated in embodiments III-VII. The same universal tool **800** can be utilized for all the exemplary embodiments illustrated in embodiments I-VII. In some embodiments, the external drill/screw guide **850** may not be needed or used for embodiments II-VII. The prongs **806** can be inserted into the indentations (e.g., **202**, **306**, **406**, **506**, **606**, **706**) of the sides of the devices (e.g., **100**, **200**, **300**, **400**, **500**, **600**, **700**) according to one or all of the exemplary embodiments illustrated in embodiments I-VII, and implant the device into the intervertebral space. Once implanted and impacted, an Allen key (e.g., as shown in FIG. **8**) can be used to expand the device (e.g., **100**, **200**, **300**, **400**, **500**, **600**, **700**) by turning the adjustment (rotation) screw (e.g., **105**, **220**, **314**, **410**, **510**, **610**, **710**).

The exemplary tool can include, among other things, an Allen key **801**, a spring **802**, a handle **803**, a gripper **804** and a screw guide **805**. The Allen key **801**, when inserted in the insertion **814** and turned, can turn the rotation screws (e.g., **105**, **220**, **314**, **410**, **510**, **610**, **710**) of one or all of the exemplary embodiments I-VII. The gripper **804** includes gripper prongs **806**, which insert into grooves **509** of the screw guide **805** and the screw box indentations (e.g., **202**) in the exemplary embodiment illustrated in embodiment I (as shown in FIGS. **8A-8D**), as well as in similar indentations (e.g., **306**, **406**, **506**, **606**, **706**) of devices (e.g., **100**, **200**, **300**, **400**, **500**, **600**, **700**) illustrated in embodiments II-VII (not shown).

As shown in FIG. **8C**, each longitudinal end of the screw box **100** can include a slot or indentation **108** formed adjacent to an edge of an upper surface of the screw box **100** for engaging a protuberant extension of a tool, such as the protuberant extension **807** of the tool **800**.

FIG. **8D** illustrates a superior oblique view of the screw guide **805** demonstrating insertions **809** for gripper prong **086**, built-in trajectory guides **811**, **812** for insertion of screws **101** and **102**, and the Allen key **801**. This exemplary embodiment can be limited, for example, to use with the devices of embodiments I and II, which includes BDFT screws.

FIGS. **8E-8G** illustrate three-dimensional views of the sequential steps necessary for the external guide assembly. FIG. **8E** illustrates the insertion of the Allen key **801** into the handle **803**. FIG. **5F** illustrates the insertion of the handle **803** through the spring **802** and gripper **804**. FIG. **8G** illustrates insertion of the gripper **804** into the screw guide **805**. The gripper prongs **806** can include medially oriented male protuberant extensions **807** that engage the slot or indentation of a device, such as indentation **108** of device **100**, thereby perfectly aligning the prongs **805** of the tool **800** with the device (e.g., **100**, **200**, **300**, **400**, **500**, **600**, **700**). This exemplary embodiment can be limited, for example, to use with the devices of embodiments I and II.

11

FIG. 8H illustrates a three-dimensional view of another exemplary embodiment of a positioning tool **800** for impaction and placement of two transvertebral screws **201**, **202** for example, for use with the exemplary embodiments I and II.

With reference again to FIGS. 8A-8K, the screw guide **805** can include insertions **809** for receiving the griper prong **806**, built-in trajectory guides **811**, **812** for insertion of screws **101** and **102**, and the Allen key **801**.

The driver assembly **850** can include a screw driver **851**, a flexible shaft **852** and a square recess bit **853**. This exemplary device can facilitate turning the screws **101**, **102** into the bone. The flexible shaft **852** can facilitate the avoidance of spinous processes which might hinder the screw driving if the shaft **852** were straight. The positioning tool **800** can have a rectangular handle, as shown for example in Embodiment I, or a circular handle, as exemplary shown in Embodiment II. This exemplary embodiment can serve to position a screw box within the intervertebral space, and screws **101**, **102** within the screw box or device. Once positioned, the screw box or device (e.g., **100**, **200**, **300**, **400**, **500**, **600**, **700**) can be impacted by tapping the handle **803** with a mallet (not shown). The griper handle **803** inserts into the screw guide and the screw box or device (e.g., **100**, **200**, **300**, **400**, **500**, **600**, **700**), which maintains alignment.

2. The Surgical Method

Exemplary embodiments of a surgical method for utilizing the exemplary devices described herein, will now be described. The procedures can be performed open, micro-scopical, closed tubular or endoscopic. Fluoroscopic guidance can be used with any of these procedures.

An exemplary embodiment of a ZP-EIS device, as illustrated in embodiments (I-VII), can be inserted into the intervertebral space (for example as shown in FIGS. 8J and 8K) after an adequate discectomy is performed in any disc space throughout the entire spine upon their exposure anteriorly, antero-laterally, laterally, far laterally or posteriorly.

For exemplary embodiments I-II of the ZP-EIS devices can be inserted into the disc space by a tool or universal tool, such as the universal tool **800** in FIGS. 8A-8I. In operation, the grab prongs of tool **800** can attach to the insets or indentations (e.g., **202**, **306**, **406**, **506**, **606**, **706**) on the side of the devices. Once in the disc space, the rotation screw (e.g., **105**, **220**, **314**, **410**, **510**, **610**, **710**) of each embodiment is turned by rotating the Allen key **801** of the tool **800** to expand the device (e.g., **100**, **200**, **300**, **400**, **500**, **600**, **700**) to the desirable disc height achieving the desirable intervertebral distraction deemed necessary for the individual patient and disc space. Once this is achieved, BDFT screws **101**, **102** are inserted and screwed into the vertebral body above and below securing the device (e.g., **100**, **200**, **300**, **400**, **500**, **600**, **700**) to the vertebral bodies with screws **101**, **102**. Prior to implantation of the device (e.g., **100**, **200**, **300**, **400**, **500**, **600**, **700**), the bone cavities of each device can be filled with any type of bone fusion material.

For the exemplary embodiments III-VII, the ZP-EIS device (e.g., **100**, **200**, **300**, **400**, **500**, **600**, **700**) can be inserted into the disc space by the same universal tool, such as tool **800**. The grab prongs **806** of the tool **800** attach to the insets or indentations (e.g., **202**, **306**, **406**, **506**, **606**, **706**) on the side of the devices (e.g., **100**, **200**, **300**, **400**, **500**, **600**, **700**) on the side of the devices (e.g., **100**, **200**, **300**, **400**, **500**, **600**, **700**). Once in the disc space, the rotation screw (e.g., **105**, **220**, **314**, **410**, **510**, **610**, **710**) is turned by rotating the Allen key **801** of the tool **800** expanding the device (e.g., **100**, **200**, **300**, **400**, **500**, **600**, **700**) to the desirable disc height achieving the desirable intervertebral distraction

12

deemed necessary for the individual patient and disc space. Prior to implantation of the device (e.g., **100**, **200**, **300**, **400**, **500**, **600**, **700**) the bone cavities of each device (e.g., **100**, **200**, **300**, **400**, **500**, **600**, **700**) can be filled with any type of bone fusion material.

The exemplary embodiments of the present invention may provide effective and safe techniques that overcome the problems associated with current transpedicular and/or plated fusion technology employed for many degenerative stable and unstable spine diseases. These exemplary embodiments may replace much pedicle screw-based and plated based instrumentation in many but not all degenerative spine conditions.

The speed and simplicity of the surgical implantation of the exemplary embodiments of the ZP-EIS devices far exceeds that of conventional pedicle screw technology. Furthermore, the exemplary embodiments of zero-profile devices can provide markedly significantly decreased risk of misguided screw placement, and hence decreased risk of neural and vascular injury, and blood loss. The exemplary embodiments can provide decreased recovery and back to work time. The exemplary embodiments of devices may lead to similar if not equal fusion with significantly less morbidity, and hence overall make the exemplary devices a major advance in the evolution of spinal instrumented technology leading to advances in the care of the spinal patient.

According to the exemplary embodiments, such as the embodiments in embodiments I and II, an intervertebral fusion device is provided that uses a threaded rod mechanism located at the peripheral of the box to control expansion of the device. The device can include a cavity within the walls for placement of bone material for fusion.

In another embodiment, an intervertebral fusion device can include a threaded rod which can obstruct (inhibit) expansion of the device when it is not being turned. The threaded rod can be disposed at the front anterior part of the box or device.

In yet another embodiment, an intervertebral fusion device can include a threaded rod, which exerts a clamping force to expand the device until the device properly accommodates the dimensions of the intervertebral disc space and distracts the space based on individual anatomy and surgical judgment. The device can include a cavity for bone in-between the walls of the box.

In another embodiment, an expandable intervertebral fusion device can include indentations on its sides to accommodate a placement tool.

In another embodiment, an expandable intervertebral fusion device can be adjusted by using a threaded rod as a wedge to pivot components within the device. The threaded rod can be accessible from the front anterior of the box or device.

In another embodiment, an expandable fusion device can include a threaded rod to expand a spacer. The threaded rod can be used as a wedge to mechanically separate the pieces. The threaded rod can be accessible from the front anterior of the box or device.

In another embodiment, an expandable fusion device can include wedge components which translate relative to each other along a contact. The degree of expansion can be determined by an adjustment rod located at the peripheral of the box or device.

In another embodiment, an expandable fusion device includes components which are mechanically linked together. The expansion of the device is controlled by the user via an adjustment rod coupled to a mechanical trans-

13

mission that causes mechanical components within the device to separate. The threaded rod is accessible from the front anterior of the box or device.

In another embodiment, an expandable fusion device can be provided wherein the position of the device is secured and adjusted by a threaded rod that is mechanically linked to housing pieces. When the threaded rod is rotated, the threaded rod forces the pieces to separate.

In another embodiment, an intervertebral fusion device is provided wherein the two internal screw guides are in the top housing unit.

In another embodiment, an intervertebral fusion expansive device is provided wherein the center of the two internal screw guides could be in quadrants I and III or II and IV.

In another embodiment, an expandable fusion device can be provided that uses a threaded rod (rotation screw) to expand the device using a metal driver as the wedge to mechanically separate the pieces.

In another embodiment, an expandable fusion device can be adjusted by using a threaded rod (rotation screw) as a wedge to offset the opposing cages.

In another embodiment, an expandable intervertebral fusion device can be provided wherein its position is secured and adjusted by a threaded rod (rotation screw) coupled to a nut and passed through the top and bottom housing pieces. As the threaded rod is rotated further into the nut, the pieces separate.

In another embodiment, an expandable intervertebral fusion device can include a tapered edge to allow contoured insertion into the disc space.

In another embodiment, an intervertebral fusion device can be provided wherein the internal screw guides for screw insertion within the device are diagonal to each other within the xyz plane.

In another embodiment, an intervertebral fusion device wherein the internal screw guides can be adjacent and somewhat diagonal to each other within the xyz plane.

In another embodiment, an intervertebral fusion device can be provided wherein the majority each of the 2 screw holes can be in quadrant I and III or II and IV within the xyz plane.

In another embodiment, an intervertebral fusion device can be provided wherein the screw guides can have approximately the same xy coordinates and have different z coordinates or vice versa.

In another embodiment, an intervertebral fusion device can be provided wherein the center of the two internal screw guides could be in quadrants I and III or II and IV within the xyz plane.

In another embodiment, an intervertebral fusion device can be provided wherein one screw guide is in the top housing unit, and another screw guide is in the bottom housing unit.

In another embodiment, an intervertebral fusion device can be provided that uses a threaded rod (rotation screw) to engage a moveable component which engages a linkage to expand the device.

In another embodiment, an intervertebral fusion device can be provided that uses a threaded rod (rotation screw) to engage a wedge which engages its attaching linkages to expand the device.

In another embodiment, an expandable fusion device can be provided that can be adjusted using a threaded rod (rotation screw) coupled to a scissor-jack linkage.

In another embodiment, an expandable fusion device can be held together with fastener (s). These fasteners constrain the box to one degree of freedom. Part of the mechanism

14

contains a mount for the rotation screw, which can control the movement of the pieces. As the screw is turned, it engages the teeth of the mechanism and acts as a wedge to rotate the pieces away from each other.

In another embodiment, an expandable fusion device adjusted by using a threaded rod (rotation screw) can be used as a wedge to offset the opposing cage surfaces.

In another embodiment, an expandable fusion device can be provided that uses a threaded rod (rotation screw) to expand the device using a metal driver as the wedge to mechanically separate the pieces.

In another embodiment, an expandable fusion device can be provided that can be adjusted by a threaded rod (rotation screw) coupled to a nut which translates to deform an elastomeric material used to force the expansion of the device.

In another embodiment, an expandable fusion device can be provided that has a threaded rod (rotation screw) that engages a wedge to control the expansion of the device.

In another embodiment, an expandable fusion device can be provided that can be contained by fasteners and retaining rings.

In another embodiment, an expandable fusion device can be provided that can be adjusted by a threaded rod (rotation screw) coupled to a wedge that can move the opposing cage surfaces.

In another embodiment, an expandable fusion device can be provided that uses a worm drive to turn a gear that acts as a wedge to expand the device.

In another embodiment, an expandable fusion device can be provided that includes fasteners and retaining rings containing and constraining the device pieces.

In another embodiment, an expandable fusion device can be provided that can be adjusted by a worm gear coupled to an internally threaded spur gear which, upon rotation, linearly advances a threaded component.

In another embodiment, a tool includes a handle, a gripper cooperating with the handle and having a plurality of prongs, a screw guide held in place the plurality of prongs, for controlling the direction of self-drilling screws that are screwed into the vertebral bodies, and an Allen key which expands expandable intervertebral devices.

The present invention has been described herein in terms of several preferred embodiments. However, modifications and additions to these embodiments will become apparent to those of ordinary skill in the art upon a reading of the foregoing description. It is intended that all such modifications and additions comprise a part of the present invention to the extent that they fall within the scope of the several claims appended hereto.

We claim:

1. An expandable intervertebral device comprising:

a first body extending from a first end to a second end and having a first length between the first end and the second end, wherein the first body has first and second end portions positioned at the first and second ends, respectively, and has first and second side portions extending between the first and second end portions, wherein the first body has a first vertebral body engagement surface and has a first interior surface positioned on an opposite side of the first body than the first vertebral body engagement surface, the first interior surface includes at least one angled housing surface protruding from the first interior surface;

a second body extending from a third end to a fourth end and having a second length between the third end and the fourth end, the second length being greater than the

15

- first length, wherein the second body has third and fourth end portions positioned at the third and fourth ends, respectively, and has third and fourth side portions extending between the third and fourth end portions, wherein the second body has a second vertebral body engagement surface and has a second interior surface positioned on an opposite side of the second body than the second vertebral body engagement surface;
- a wedge having an angled wedge surface, wherein the wedge is positioned between the first body and the second body with the angled wedge surface facing the first interior surface of the first body and the at least one angled housing surface of the first body is positioned to engage the angled wedge surface of the wedge, wherein the wedge is configured to slide within a space defined by the first body and second body in a direction toward the second and fourth ends of the first body and second body from a first wedge position in which the first body and the second body are in a substantially closed position to a second wedge position whereby the angled wedge surface presses against the first interior surface of the first body to move the first body relative to the second body from a compressed configuration to an expanded configuration, whereby the wedge remains axially confined within the space defined by the first body and second body in the compressed and expanded configurations; and
- a cavity defined within the expandable intervertebral device, the cavity configured to be filled with bone fusion materials; and
- wherein the second end portion of the first body is smaller than the fourth end portion of the second body such that the second end portion of the first body is positionable between the third and fourth side portions of the second body at the fourth end of the second body in the compressed configuration.
2. The expandable intervertebral device of claim 1, wherein the first body and second body are hingedly connected such that the first body can pivot with respect to the second body so as to move the first end of the first body away from the third end of the second body.
3. The expandable intervertebral device of claim 1, wherein movement of the first body relative to the second body toward the expanded configuration of the expandable intervertebral device increases a volume of the cavity.
4. The expandable intervertebral device of claim 1, further comprising:
- wherein the wedge is actuated in response to a rotation of a threaded screw; and
- wherein the rotation of the threaded screw results in axial movement of the wedge within the space defined by the first body and the second body such that the at least one angled housing surface of the first body engages the angled wedge surface of the wedge to move the first body relative to the second body from the compressed configuration to the expanded configuration.
5. The expandable intervertebral device of claim 4, wherein the rotation of the threaded screw in a first direction actuates movement of the first body relative to the second body so as to expand the expandable intervertebral device vertically.
6. The expandable intervertebral device of claim 5, wherein the expandable intervertebral device further comprises indentations on opposing sides for engaging a positioning tool.

16

7. The expandable intervertebral device of claim 1, wherein the second interior surface is substantially parallel with the second vertebral body engagement surface such that the wedge is configured to move along a path parallel to the second vertebral body engagement surface when the wedge slides within the space against the second interior surface.
8. An expandable intervertebral device comprising:
- a first body extending from a first end to a second end, wherein the first body has first and second end portions positioned at the first and second ends, respectively, and has first and second side portions extending between the first and second end portions, wherein the first body has a first vertebral body engagement surface and has a first interior surface positioned on an opposite side of the first body than the first vertebral body engagement surface, the first vertebral body engagement surface comprising a plurality of ridges for interfacing with a vertebral body surface, the first interior surface includes at least one angled housing surface protruding from the first interior surface;
- a second body extending from a third end to a fourth end, wherein the second body has third and fourth end portions positioned at the third and fourth ends, respectively, and has third and fourth side portions extending between the third and fourth end portions, wherein the second body has a second vertebral body engagement surface and has a second interior surface positioned on an opposite side of the second body than the second vertebral body engagement surface, the first body configured to fit between the third and fourth side portions in a compressed configuration of the expandable intervertebral device; and
- a wedge having an angled wedge surface, wherein the wedge is positioned between the first body and the second body with the angled wedge surface facing the first interior surface of the first body and the at least one angled housing surface of the first body is positioned to engage the angled wedge surface of the wedge, wherein the wedge is configured to slide within a space defined by the first body and second body in a direction toward the second and fourth ends of the first body and second body from a first wedge position in which the first body and the second body are in a substantially closed position to a second wedge position whereby the angled wedge surface presses against the first interior surface of the first body to move the first body relative to the second body from a compressed configuration to an expanded configuration without moving the second body, whereby the wedge remains axially confined within the space defined by the first body and second body in the compressed and expanded configurations.
9. The expandable intervertebral device of claim 8, wherein in the expanded configuration of the expandable intervertebral device the plurality of ridges on the first vertebral body engagement surface are configured to be in contact with the vertebral body surface.
10. The expandable intervertebral device of claim 8, further comprising a locking mechanism for retaining the expandable intervertebral device in the expanded configuration.
11. The expandable intervertebral device of claim 10, further comprising means to promote segmental spinal fusion.
12. The expandable intervertebral device of claim 8, wherein the first body defines first and second bone cavities extending through the first vertebral body engagement surface with a wall of the first body at least partially separating

17

the first and second bone cavities and wherein the first and second side portions of the first body have respective first and second outer side surfaces, wherein the third and fourth side portions of the second body have respective third and fourth inner side surfaces, and wherein the first body is positioned at least partially inside the second body with the first and second outer side surfaces positioned inward of and adjacent to the third and fourth inner side surfaces of the third and fourth side portions in the compressed configuration.

13. The expandable intervertebral device of claim 8, wherein the second interior surface is substantially parallel with the second vertebral body engagement surface such that the wedge is configured to move along a path parallel to the second vertebral body engagement surface when the wedge slides within the space against the second interior surface.

14. A system comprising:

the expandable intervertebral device of claim 6; and
a tool comprising:

an elongate shaft;

first and second prongs that are sized and positioned such that the first and second prongs engage the indentations on opposing sides of the expandable intervertebral device when the tool engages the expandable intervertebral device; and

a screwdriver sized and configured for operating the threaded screw.

15. The system of claim 14, wherein the screwdriver comprises an elongate member configured to extend within the elongate shaft of the tool.

16. The system of claim 14, the tool further comprising a handle positioned at a proximal end of the elongate shaft.

17. An expandable intervertebral device comprising:

a first body extending from a first end to a second end, wherein the first body has first and second end portions positioned at the first and second ends, respectively, and has first and second side portions extending between the first and second end portions, wherein the first body has a first vertebral body engagement surface having a first plurality of ridges formed therein and has a first interior surface positioned on an opposite side of the first body than the first vertebral body engagement surface;

a second body extending from a third end to a fourth end, wherein the second body has third and fourth end portions positioned at the third and fourth ends, respectively, and has third and fourth side portions extending between the third and fourth end portions, wherein the second body has a second vertebral body engagement surface having a second plurality of ridges formed therein and has a second interior surface positioned on an opposite side of the second body than the second vertebral body engagement surface, wherein the first body is aligned with the second body such that the first end of the first body is axially aligned with the third end of the second body and the second end of the first body is axially aligned with the fourth end of the second body, wherein the first end portion of the first body and the third end portion of the second body are hingedly

18

interconnected such that the first body can pivot with respect to the second body so as to move the second end portion of the first body away from the fourth end portion of the second body; and

a wedge extending from a fifth end to a sixth end and having an angled wedge surface extending along at least a portion of a distance between the fifth end and the sixth end, wherein the wedge is positioned between the first body and the second body with the angled wedge surface facing the first interior surface of the first body, wherein the first interior surface of the first body has an angled housing surface shaped to engage the angled wedge surface of the wedge, wherein the wedge is configured to slide within a space defined by the first body and second body in a direction toward the second and fourth ends of the first body and second body from a first wedge position that allows the first body and second body to pivot to a position that is substantially closed to a second wedge position whereby the angled wedge surface presses against the first interior surface of the first body to hingedly open the first body with respect to the second body whereby the wedge remains axially confined within the space defined by the first body and second body in the first and second wedge positions.

18. The expandable intervertebral device of claim 17, wherein a first length of the first body from the first end to the second end is substantially equal to a second length of the second body from the third end to the fourth end, and wherein the second end portion of the first body is smaller than the fourth end portion of the second body such that the second end portion of the first body is positionable between the third and fourth side portions of the second body at the fourth end of the second body.

19. The expandable intervertebral device of claim 18, wherein the first body defines a first bone material receiving area between the first and second end portions and the first and second side portions, and the second body defines a second bone material receiving area between the third and fourth end portions and the third and fourth side portions, and wherein the first bone material receiving area is coupled to the second bone material receiving area when the wedge is in the second wedge position.

20. The expandable intervertebral device of claim 19, wherein a distance from the fifth end to the sixth end of the wedge is less than a distance from the first end to the second end of the first body and is less than a distance from the third end to the fourth end of the second body.

21. A method of operating the expandable intervertebral device of claim 17, the method comprising:

inserting the expandable intervertebral device in a target surgical location between two vertebrae of a human patient; and

turning a rotation screw to actuate a movement of the wedge to pivot the first body away from the second body while the device is positioned between the vertebrae of the human patient.

* * * * *