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(12) **United States Patent**
Abdou

(10) **Patent No.: US 8,172,855 B2**
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(54) **DEVICES AND METHODS FOR INTER-VERTEBRAL ORTHOPEDIC DEVICE PLACEMENT**

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(22) Filed: **Nov. 23, 2005**

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Related U.S. Application Data

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(51) **Int. Cl.**
A61B 17/70 (2006.01)
A61B 17/58 (2006.01)
A61B 17/60 (2006.01)

(52) **U.S. Cl.** .... **606/99**; 606/90; 606/86 A; 606/249

(58) **Field of Classification Search** .... 606/86 A, 606/90, 97, 246–249; 623/17.11–17.16
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

2,248,054 A 7/1941 Becker
3,090,386 A 5/1963 Babcock
3,659,595 A 5/1972 Haboush
4,037,592 A 7/1977 Kronner
4,289,123 A 9/1981 Dunn
4,569,662 A 2/1986 Dragan
4,580,563 A 4/1986 Gross
4,722,331 A 2/1988 Fox
4,790,303 A 12/1988 Steffee
4,899,761 A 2/1990 Brown et al.
4,903,692 A 2/1990 Reese
4,932,975 A 6/1990 Main et al.
5,002,576 A 3/1991 Fuhrmann et al.
5,133,717 A 7/1992 Chopin
5,254,118 A 10/1993 Mirkovic
5,275,601 A 1/1994 Goglewski et al.
5,330,468 A 7/1994 Burkhart
5,334,205 A 8/1994 Cain
5,354,292 A 10/1994 Braeuer et al.
5,360,429 A 11/1994 Jeanson et al.
5,456,714 A 10/1995 Owen
5,484,440 A 1/1996 Allard

(Continued)

FOREIGN PATENT DOCUMENTS

DE 10035182 2/2002

(Continued)

OTHER PUBLICATIONS

Derwent WPI Acc No. 2002-155861/200221 for German Patent No. DE 10035182 (item AG).

(Continued)

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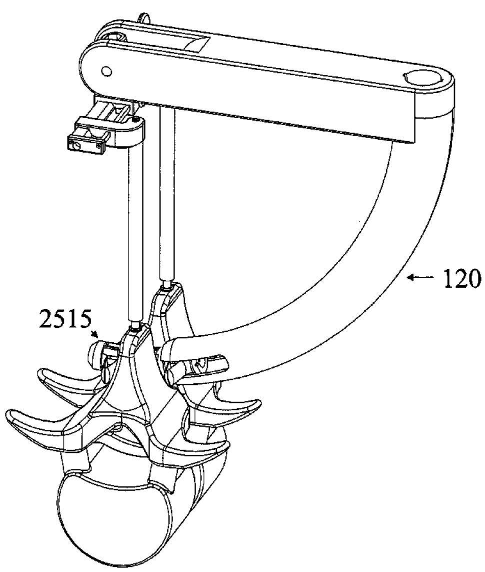
(57) **ABSTRACT**

The disclosure relates to devices and methods for implantation of an orthopedic device between skeletal segments using limited surgical dissection. The implanted devices are used to adjust and maintain the spatial relationship(s) of adjacent bones. Depending on the implant design, the motion between the skeletal segments may be increased, limited, modified, or completely immobilized.

42 Claims, 54 Drawing Sheets



U.S. PATENT DOCUMENTS

5,531,747	A	7/1996	Ray	
5,545,164	A	8/1996	Howland	
5,558,674	A	9/1996	Heggeness et al.	
5,569,248	A	10/1996	Mathews	
5,609,634	A	3/1997	Voydeville	
5,616,142	A	4/1997	Yuan et al.	
5,645,599	A	7/1997	Samani	
5,672,176	A	9/1997	Biedermann et al.	
5,681,312	A	10/1997	Yuan et al.	
5,928,139	A	7/1999	Koros et al.	
5,928,233	A	7/1999	Apfelbaum et al.	
5,971,987	A	10/1999	Huxel et al.	
5,976,146	A	11/1999	Ogawa et al.	
5,993,449	A	11/1999	Schlapfer et al.	
6,039,761	A	3/2000	Li et al.	
6,059,786	A	5/2000	Jackson	
6,086,589	A	7/2000	Kuslich	
6,090,113	A	7/2000	Le Couedic et al.	
6,117,135	A	9/2000	Schlapfer et al.	
6,123,707	A	9/2000	Wagner	
6,139,549	A	10/2000	Keller	
6,159,244	A	12/2000	Suddaby et al.	
6,193,757	B1	2/2001	Foley et al.	
6,306,136	B1	10/2001	Baccelli	
6,309,391	B1	10/2001	Crandell et al.	
6,312,431	B1	11/2001	Asfora	
6,319,002	B1	11/2001	Pond	
6,319,257	B1	11/2001	Carignan et al.	
6,331,179	B1	12/2001	Freid et al.	
6,332,882	B1	12/2001	Zucherman et al.	
6,355,038	B1	3/2002	Pisharodi	
6,402,752	B2	6/2002	Schaffler-Wachter et al.	
6,419,676	B1	7/2002	Zucherman et al.	
6,419,677	B2	7/2002	Zucherman et al.	
6,428,576	B1	8/2002	Haldimann	
6,432,140	B1	8/2002	Lin	
6,440,133	B1	8/2002	Beale et al.	
6,451,019	B1	9/2002	Zucherman et al.	
6,451,020	B1	9/2002	Zucherman et al.	
6,478,800	B1	11/2002	Fraser et al.	
6,508,839	B1	1/2003	Lambrecht et al.	
6,514,256	B2	2/2003	Zucherman et al.	
6,524,315	B1	2/2003	Selvitelli et al.	
6,530,929	B1 *	3/2003	Justis et al.	606/103
6,547,790	B2	4/2003	Harckey, III et al.	
6,558,386	B1	5/2003	Cragg	
6,558,390	B2	5/2003	Cragg	
6,599,294	B2 *	7/2003	Fuss et al.	606/99
6,599,295	B1	7/2003	Tornier et al.	
6,645,207	B2	11/2003	Dixon et al.	
6,663,631	B2	12/2003	Kuntz et al.	
6,695,842	B2	2/2004	Zucherman et al.	
6,699,246	B2	3/2004	Zucherman et al.	
6,699,247	B2	3/2004	Zucherman et al.	
6,716,212	B1	4/2004	Pickens	
6,730,126	B2	5/2004	Boehm, Jr. et al.	
6,733,534	B2	5/2004	Sherman	
6,739,068	B1	5/2004	Rinner	
6,740,087	B2	5/2004	Knox	
6,740,090	B1	5/2004	Cragg et al.	
6,746,449	B2	6/2004	Jones et al.	
6,749,614	B2	6/2004	Teitelbaum et al.	
6,755,841	B2	6/2004	Fraser et al.	
6,761,720	B1	7/2004	Senegas	
6,783,547	B2	8/2004	Castro	
6,790,210	B1	9/2004	Cragg et al.	
6,805,697	B1	10/2004	Helm et al.	
6,821,277	B2	11/2004	Teitelbaum	
6,830,571	B2	12/2004	Lenke et al.	
6,875,211	B2	4/2005	Nichols et al.	
6,884,243	B2	4/2005	Sellers	
6,899,716	B2	5/2005	Cragg	
6,921,403	B2	7/2005	Cragg et al.	
6,945,975	B2	9/2005	Dalton et al.	
7,008,422	B2	3/2006	Foley et al.	
7,011,658	B2	3/2006	Young	
7,011,660	B2 *	3/2006	Sherman et al.	606/86 A
7,014,633	B2	3/2006	Cragg	
7,060,066	B2	6/2006	Zhao et al.	
7,087,058	B2	8/2006	Cragg	
7,118,579	B2 *	10/2006	Michelson	606/99
7,118,580	B1	10/2006	Beyersdorff et al.	
7,153,281	B2 *	12/2006	Holmes	600/594
7,160,300	B2	1/2007	Jackson	
7,232,463	B2	6/2007	Falahee	
7,338,527	B2	3/2008	Blatt et al.	
7,455,685	B2 *	11/2008	Justis	606/246
7,572,276	B2 *	8/2009	Lim et al.	606/246
7,585,316	B2 *	9/2009	Trieu	606/279
2001/0012938	A1 *	8/2001	Zucherman et al.	606/61
2001/0021850	A1	9/2001	Zucherman et al.	
2001/0031965	A1	10/2001	Zucherman et al.	
2002/0016595	A1	2/2002	Michelson	
2002/0045904	A1	4/2002	Fuss et al.	
2002/0049444	A1	4/2002	Knox	
2002/0055741	A1	5/2002	Schlapfer et al.	
2002/0099386	A1	7/2002	Beger et al.	
2002/0143328	A1	10/2002	Shluzas et al.	
2002/0161368	A1	10/2002	Foley et al.	
2002/0183755	A1	12/2002	Michelson et al.	
2002/0188296	A1	12/2002	Michelson	
2003/0018389	A1	1/2003	Castro et al.	
2003/0040746	A1	2/2003	Mitchell et al.	
2003/0060826	A1	3/2003	Foley et al.	
2003/0074005	A1	4/2003	Roth et al.	
2003/0078583	A1	4/2003	Biedermann et al.	
2003/0153913	A1	8/2003	Altarac	
2003/0187436	A1	10/2003	Bolger et al.	
2003/0229347	A1 *	12/2003	Sherman et al.	606/61
2003/0236472	A1	12/2003	Van Hoeck et al.	
2004/0012938	A1 *	1/2004	Sylvester et al.	361/794
2004/0018228	A1	1/2004	Fischell et al.	
2004/0030346	A1	2/2004	Frey et al.	
2004/0044412	A1	3/2004	Lambrecht et al.	
2004/0073216	A1	4/2004	Lieberman	
2004/0133207	A1	7/2004	Abdou	
2004/0138671	A1	7/2004	Zander et al.	
2004/0153070	A1	8/2004	Barker et al.	
2004/0167625	A1 *	8/2004	Beyar et al.	623/11.11
2004/0204712	A1	10/2004	Kolb et al.	
2004/0204713	A1	10/2004	Abdou	
2005/0004573	A1	1/2005	Abdou	
2005/0010227	A1	1/2005	Paul	
2005/0021029	A1	1/2005	Trieu et al.	
2005/0021031	A1 *	1/2005	Foley et al.	606/61
2005/0021040	A1 *	1/2005	Bertagnoli	606/90
2005/0055031	A1	3/2005	Lim et al.	
2005/0085813	A1	4/2005	Spitler et al.	
2005/0119747	A1	6/2005	Fabris et al.	
2005/0126576	A1	6/2005	Ferree	
2005/0131406	A1	6/2005	Reiley et al.	
2005/0131421	A1	6/2005	Anderson et al.	
2005/0154389	A1	7/2005	Selover et al.	
2005/0165398	A1	7/2005	Reiley	
2005/0171540	A1	8/2005	Lim et al.	
2005/0177163	A1	8/2005	Abdou	
2005/0192589	A1	9/2005	Raymond	
2005/0197660	A1 *	9/2005	Haid et al.	606/61
2005/0203512	A1 *	9/2005	Hawkins et al.	606/61
2005/0203533	A1 *	9/2005	Ferguson et al.	606/90
2005/0203624	A1	9/2005	Serhan	
2005/0209694	A1	9/2005	Loeb	
2005/0215999	A1	9/2005	Birkmeyer et al.	
2005/0234449	A1	10/2005	Aferzon	
2005/0234451	A1	10/2005	Markworth	
2005/0245928	A1	11/2005	Colleran	
2005/0261768	A1 *	11/2005	Trieu	623/17.11
2005/0273120	A1	12/2005	Abdou	
2005/0283153	A1	12/2005	Polyner	
2005/0288669	A1	12/2005	Abdou	
2006/0052870	A1	3/2006	Ferree	
2006/0074488	A1	4/2006	Abdou	
2006/0084986	A1	4/2006	Grinberg et al.	
2006/0084988	A1	4/2006	Kim	
2006/0111728	A1	5/2006	Abdon	
2006/0142761	A1	6/2006	Landry et al.	
2006/0149238	A1	7/2006	Sherman et al.	

2006/0149278	A1	7/2006	Abdon
2006/0167454	A1	7/2006	Ludwig et al.
2006/0184247	A1	8/2006	Edidin et al.
2006/0195102	A1*	8/2006	Malandain 606/72
2006/0200135	A1	9/2006	Sherman et al.
2006/0217710	A1	9/2006	Abdou
2006/0229614	A1	10/2006	Foley et al.
2006/0229615	A1	10/2006	Abdou
2006/0235532	A1	10/2006	Meunier et al.
2006/0247630	A1	11/2006	Lott et al.
2006/0247634	A1	11/2006	Warner et al.
2006/0264942	A1	11/2006	Lim et al.
2006/0276803	A1	12/2006	Salerni
2007/0032790	A1	2/2007	Aschmann et al.
2007/0093828	A1	4/2007	Abdon
2007/0093829	A1	4/2007	Abdon
2007/0106383	A1	5/2007	Abdon
2007/0123884	A1	5/2007	Abdou
2007/0151116	A1*	7/2007	Malandain 33/512
2007/0173831	A1	7/2007	Abdon
2007/0173842	A1	7/2007	Abdon
2007/0185367	A1	8/2007	Abdon
2007/0185489	A1	8/2007	Abdon
2007/0191958	A1	8/2007	Abdon
2007/0198090	A1	8/2007	Abdon
2007/0233083	A1	10/2007	Abdon
2007/0233251	A1	10/2007	Abdon
2007/0282448	A1	12/2007	Abdon
2008/0027438	A1	1/2008	Abdon
2008/0039843	A1	2/2008	Abdon
2008/0045963	A1	2/2008	Abdon
2008/0058810	A1	3/2008	Abdon
2008/0243186	A1	10/2008	Abdon
2008/0281358	A1	11/2008	Abdon
2008/0281359	A1	11/2008	Abdon
2010/0016906	A1	1/2010	Abdon
2010/0069929	A1	3/2010	Abdon
2010/0069965	A1	3/2010	Abdon
2010/0076448	A1	3/2010	Abdon
2010/0087858	A1	4/2010	Abdon
2010/0087869	A1	4/2010	Abdon
2010/0087878	A1	4/2010	Abdon
2010/0087923	A1	4/2010	Abdon
2010/0106250	A1	4/2010	Abdon
2010/0121384	A1	5/2010	Abdon

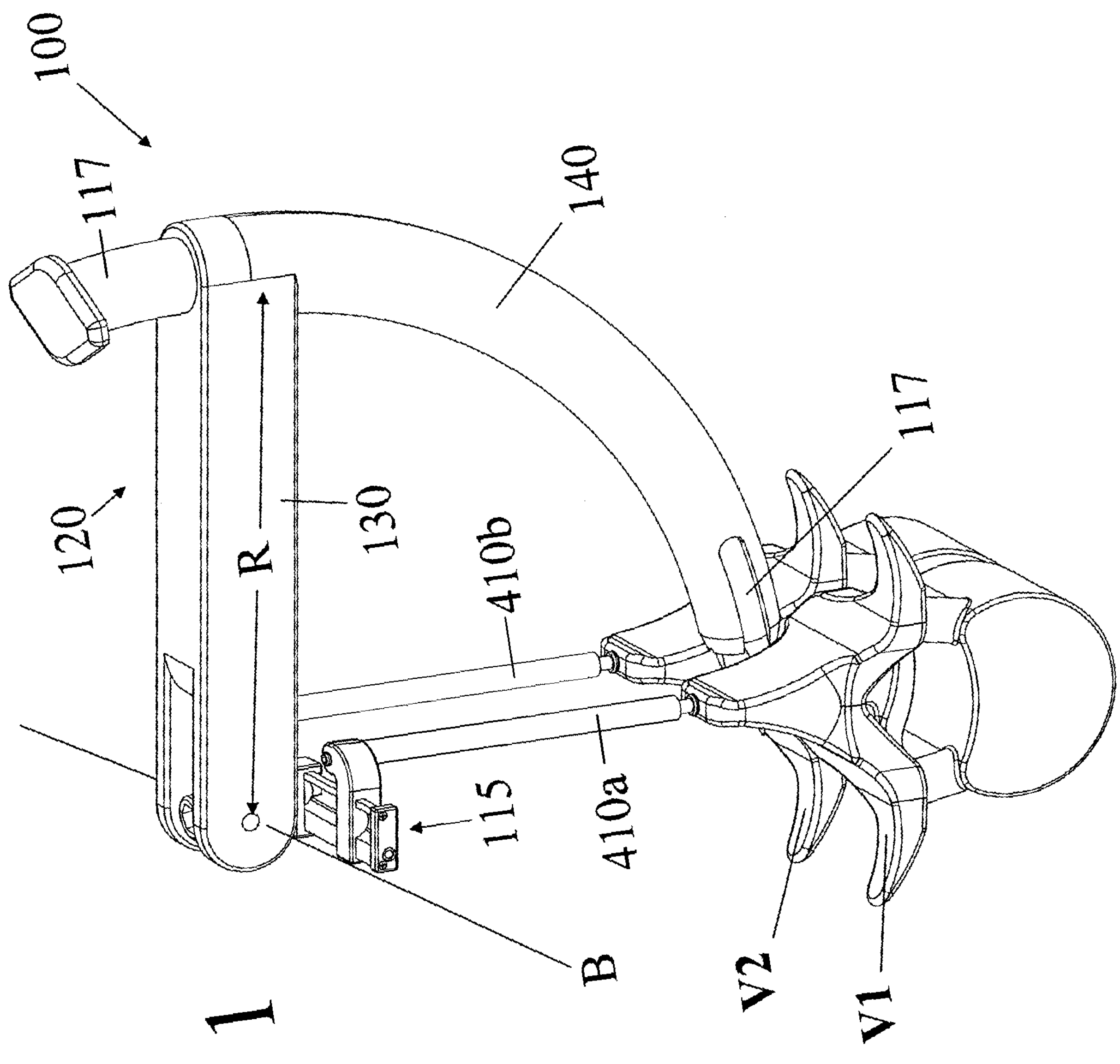
FOREIGN PATENT DOCUMENTS

EP	077159	4/1983
EP	0611116	8/1994
EP	1180348	2/2002
EP	1442715	8/2004
FR	2781359	1/2000
FR	2856271	12/2004
WO	2004/032726	4/2004
WO	WO 2004/032726	4/2004
WO	2004/062482	7/2004
WO	WO 2004/062482	7/2004
WO	2004/093702	11/2004
WO	WO 2004/093702	11/2004
WO	WO 2005/077288	8/2005
WO	WO 2005/122922	12/2005
WO	WO 2006/041963	4/2006
WO	WO 2006/058221	6/2006
WO	WO 2006/089292	8/2006
WO	WO 2006/096756	9/2006
WO	WO 2007/041648	4/2007
WO	WO 2007/044705	4/2007
WO	WO 2007/044836	4/2007
WO	WO 2007/056516	5/2007
WO	WO 2007/059207	5/2007
WO	WO 2008/106140	2/2008

OTHER PUBLICATIONS

U.S. Appl. No. 11/739,053, filed Apr. 23, 2007.
U.S. Appl. No. 11/888,754, filed Aug. 1, 2007.
U.S. Appl. No. 12/690,824, filed Jan. 20, 2010.
U.S. Appl. No. 12/727,641, filed Mar. 19, 2010.
U.S. Appl. No. 12/758,531, filed Apr. 12, 2010.
U.S. Appl. No. 12/767,573, filed Apr. 26, 2010.
U.S. Appl. No. 12/779,839, filed May 13, 2010.
U.S. Appl. No. 12/789,435, filed May 27, 2010.
U.S. Appl. No. 12/790,754, filed May 28, 2010.
U.S. Appl. No. 12/790,713, filed May 28, 2010.
Derwent English Language Abstract WPI Acc. No. 2002-155861-200221 for German Patent No. DE10035182 (Item DE).
Derwent English Abstract for French Patent Publication FR 2781359, published Jan. 28, 2000, entitled: "Osteosynthesis frame for spinal surgery has rod with clamps to hold cross bars with anchor screws". Accession No. 9867555.
Derwent English Abstract for French Patent Publication FR 2856271, published Dec. 24, 2004, Osteo-synthesis vertebral column plate, has connection head integrated with plate and movable in three directions of space so as to adapt itself to connection rod, and including opening to facilitate introduction of rod. Accession No. 14694557.

* cited by examiner



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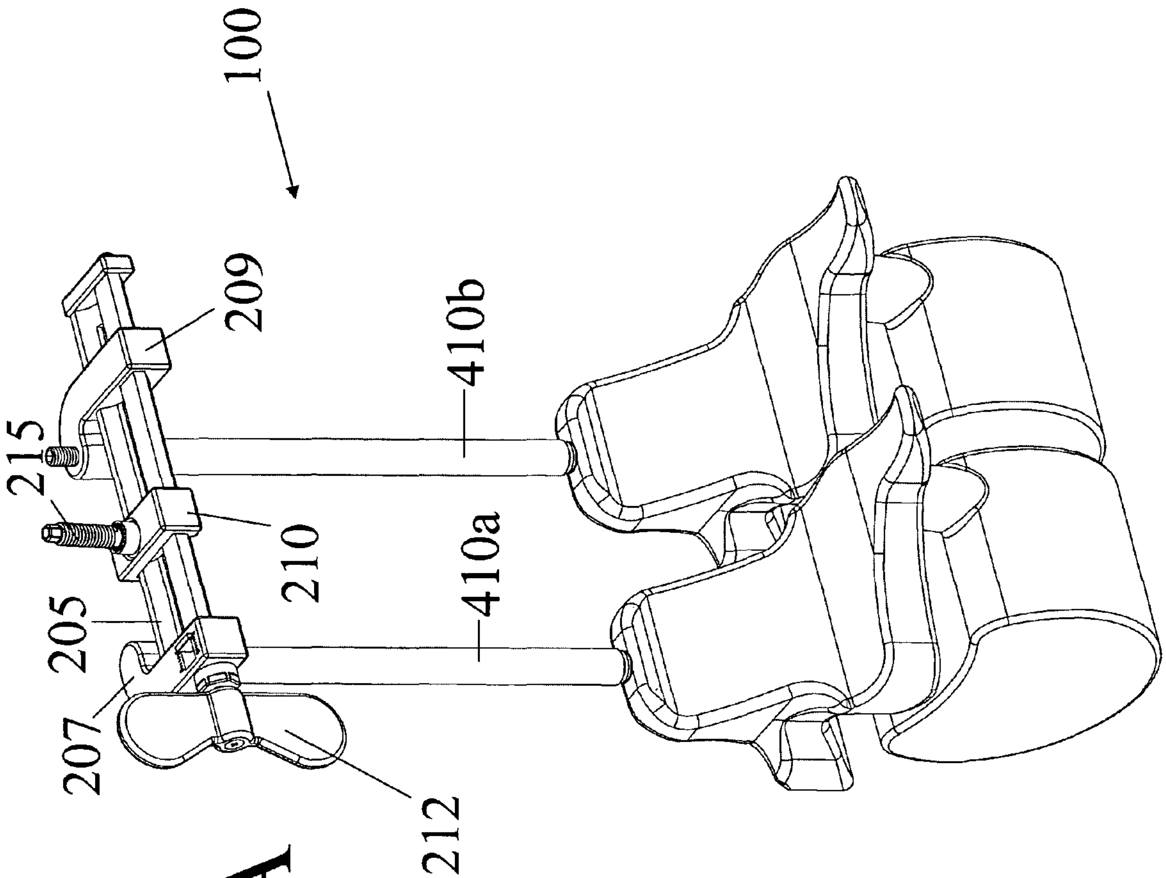

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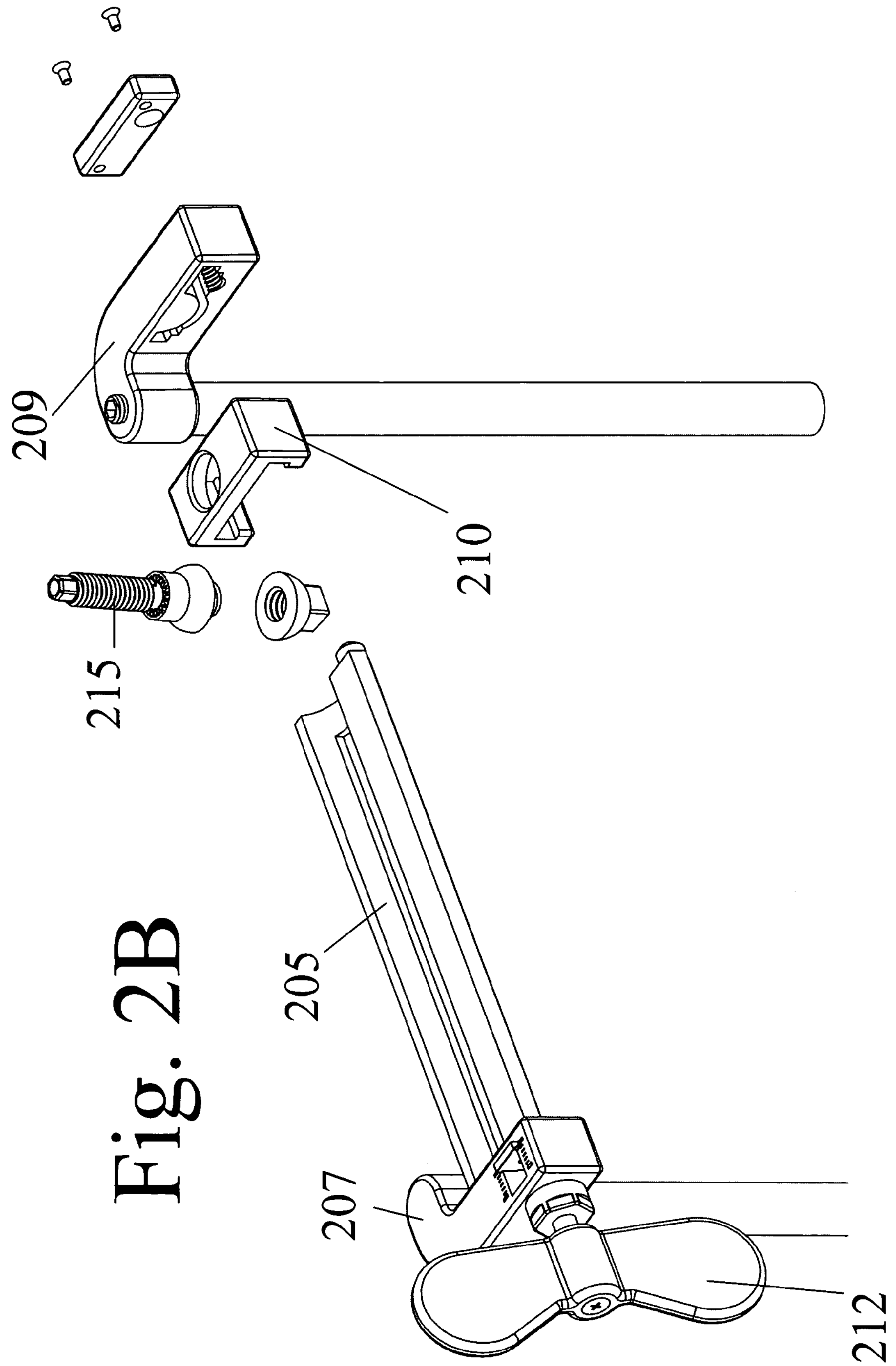

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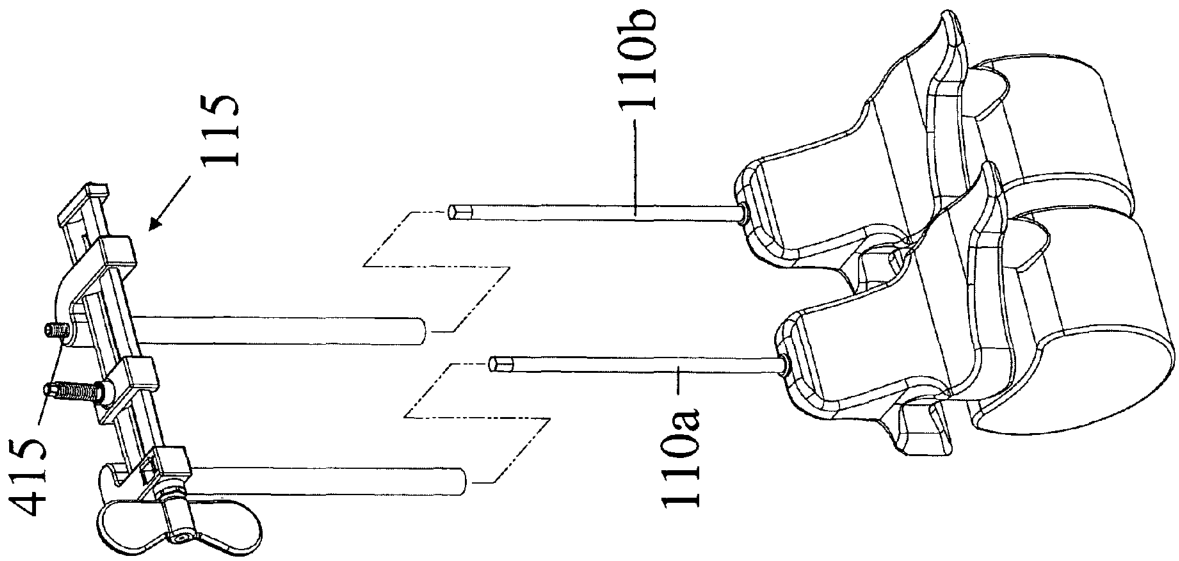

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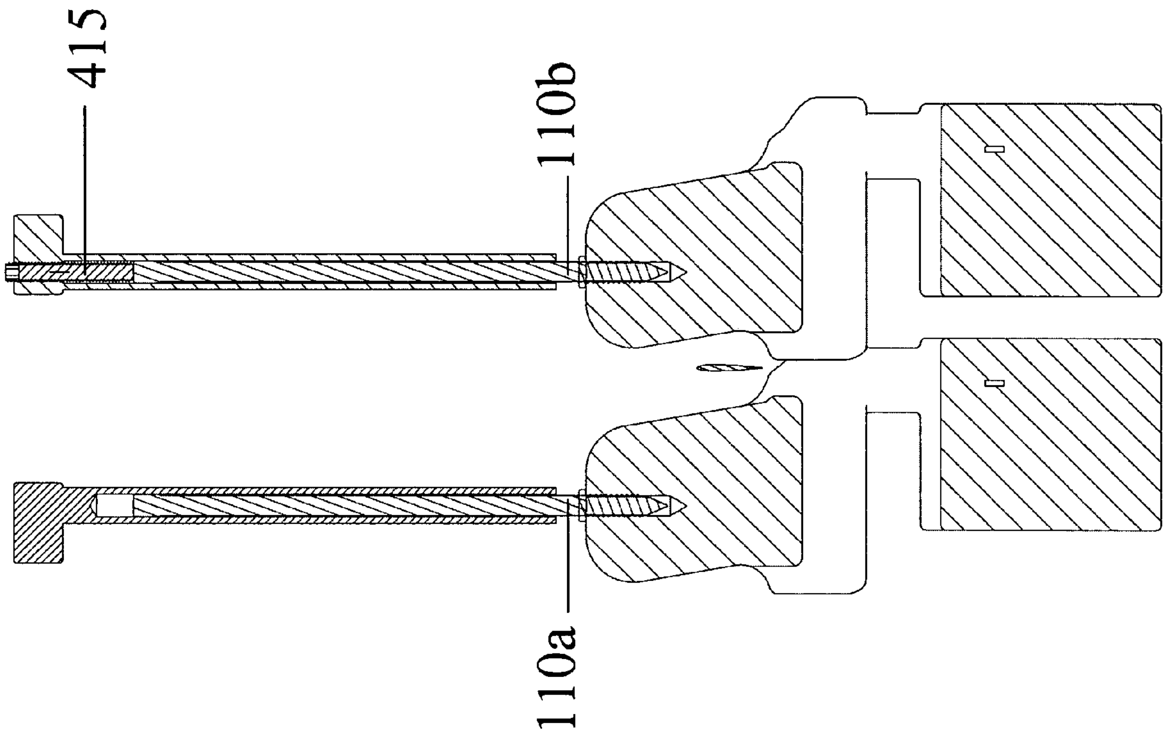


Fig. 4

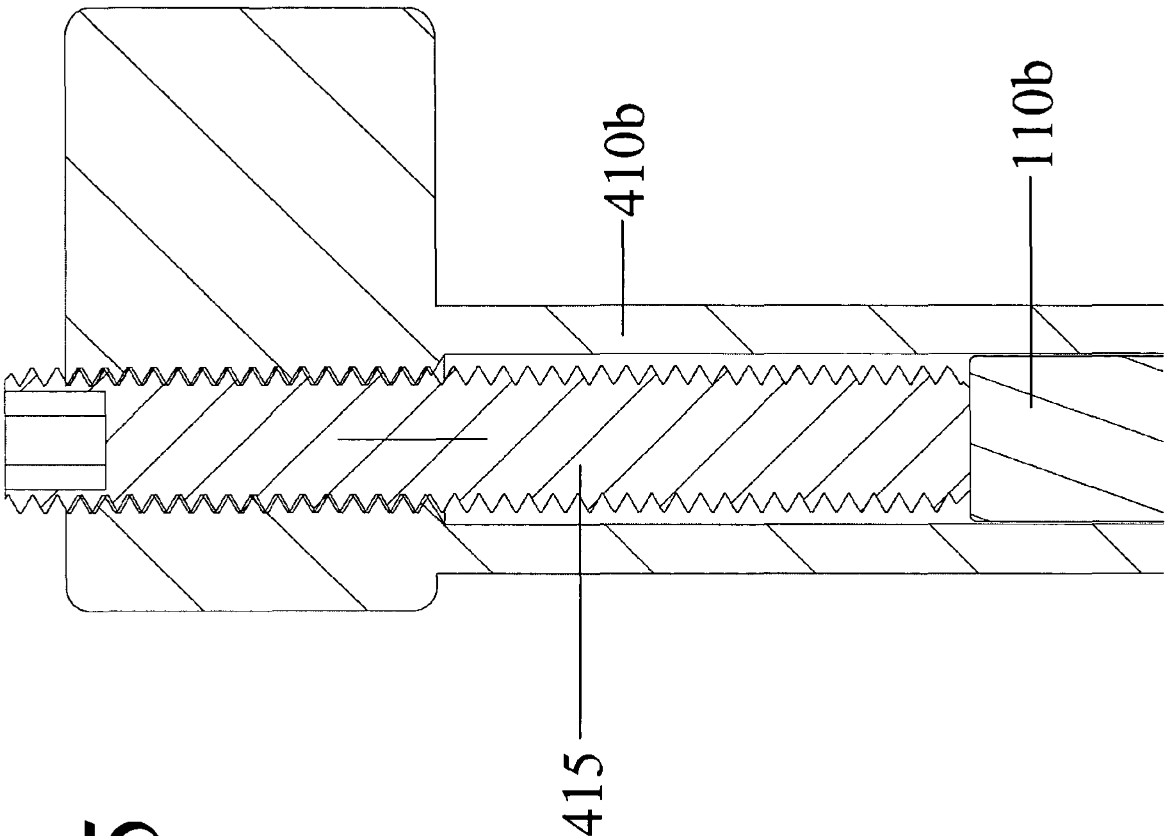
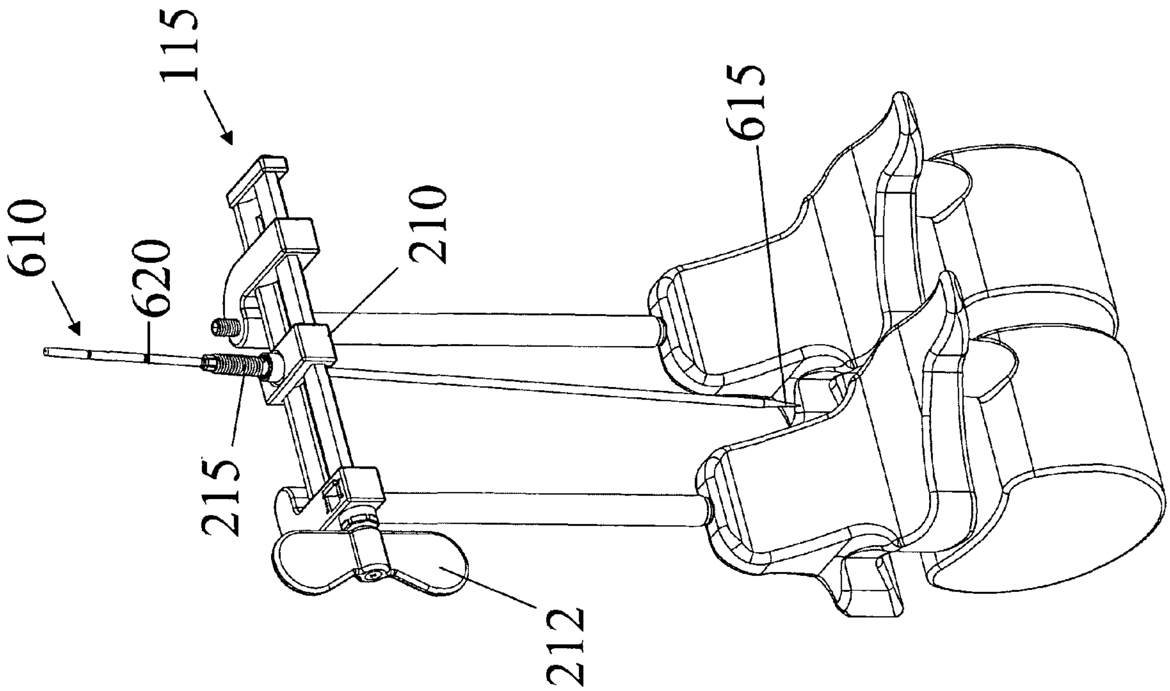


Fig. 5



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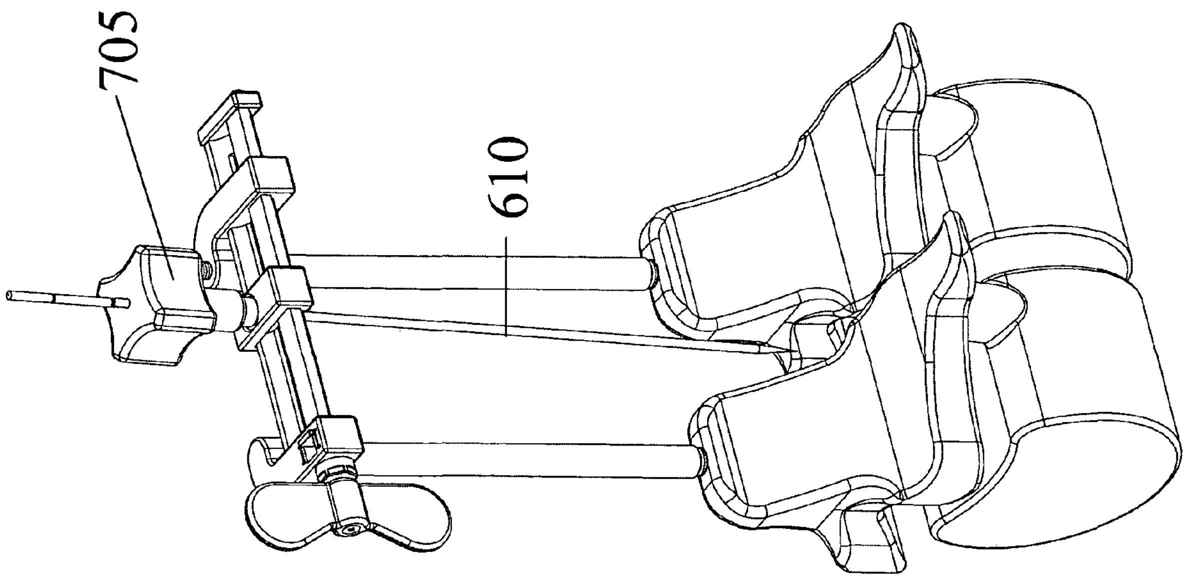

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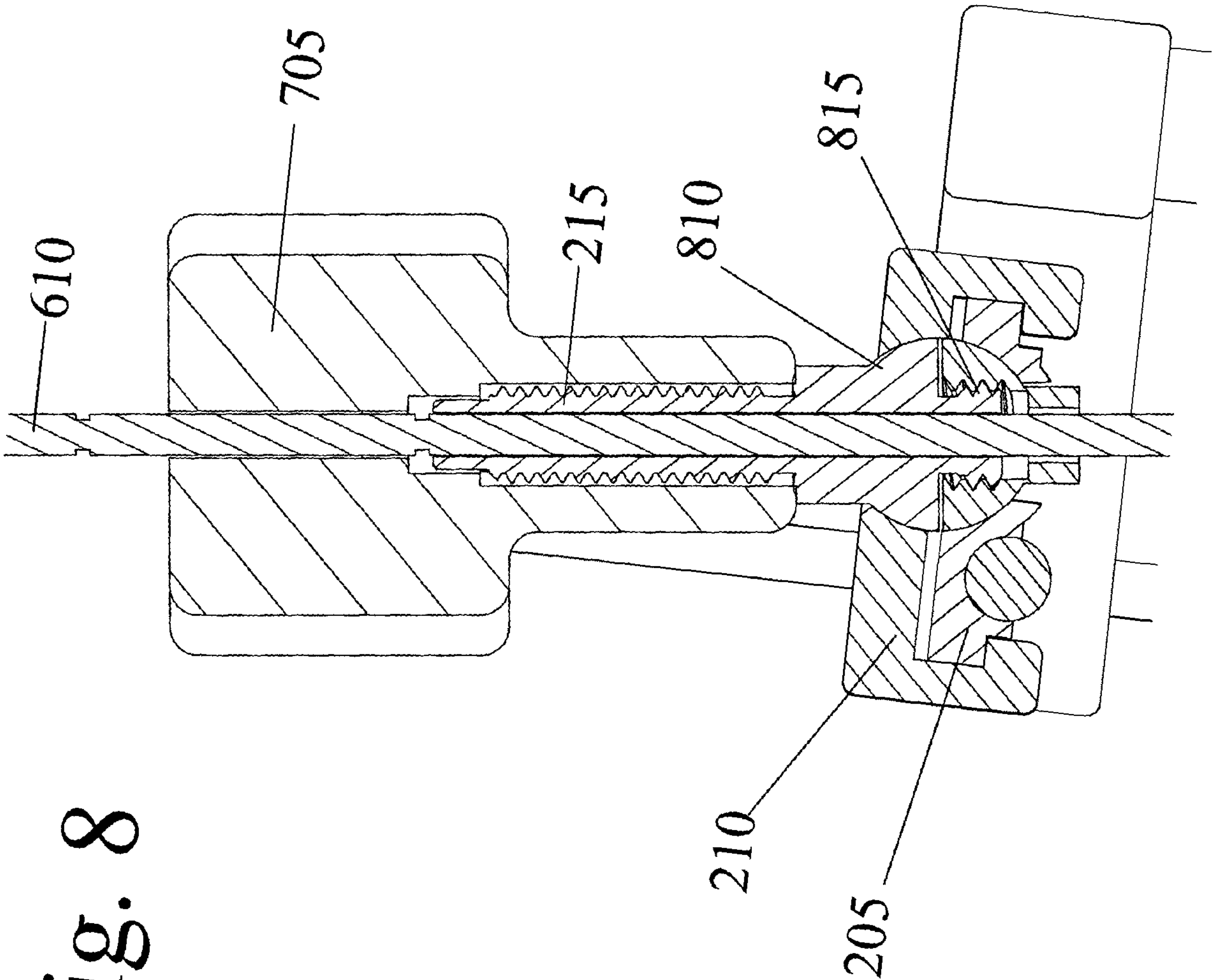

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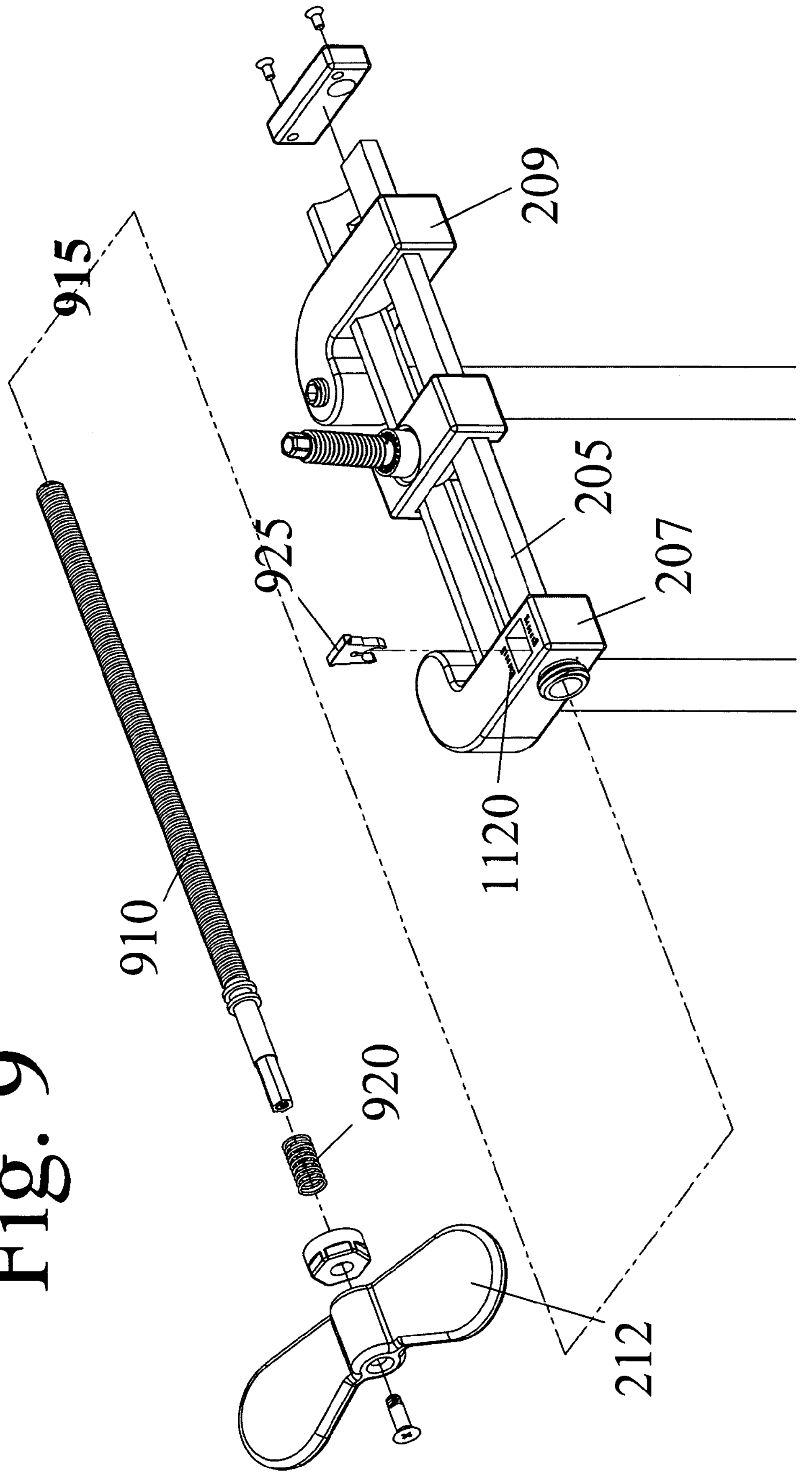

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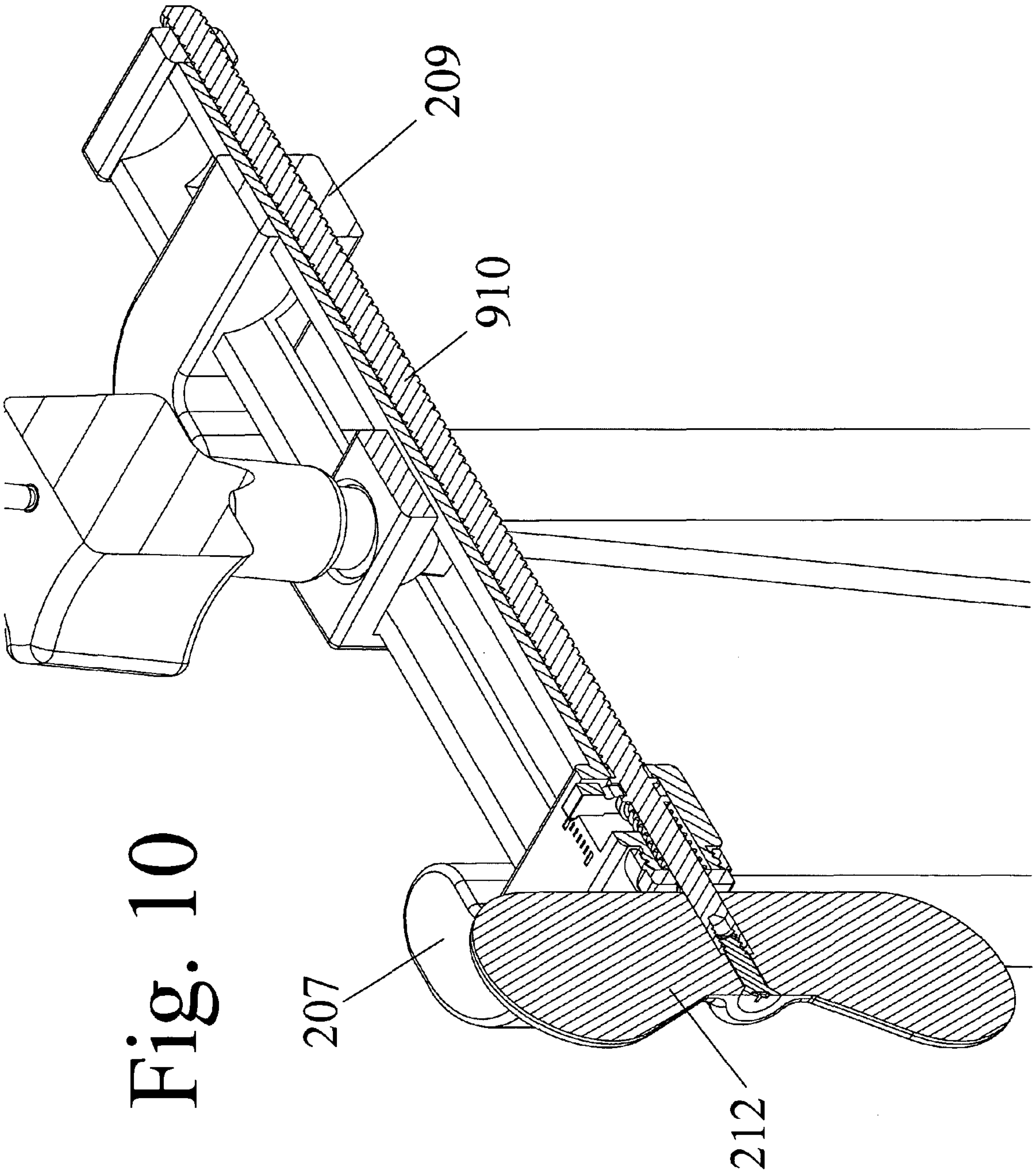
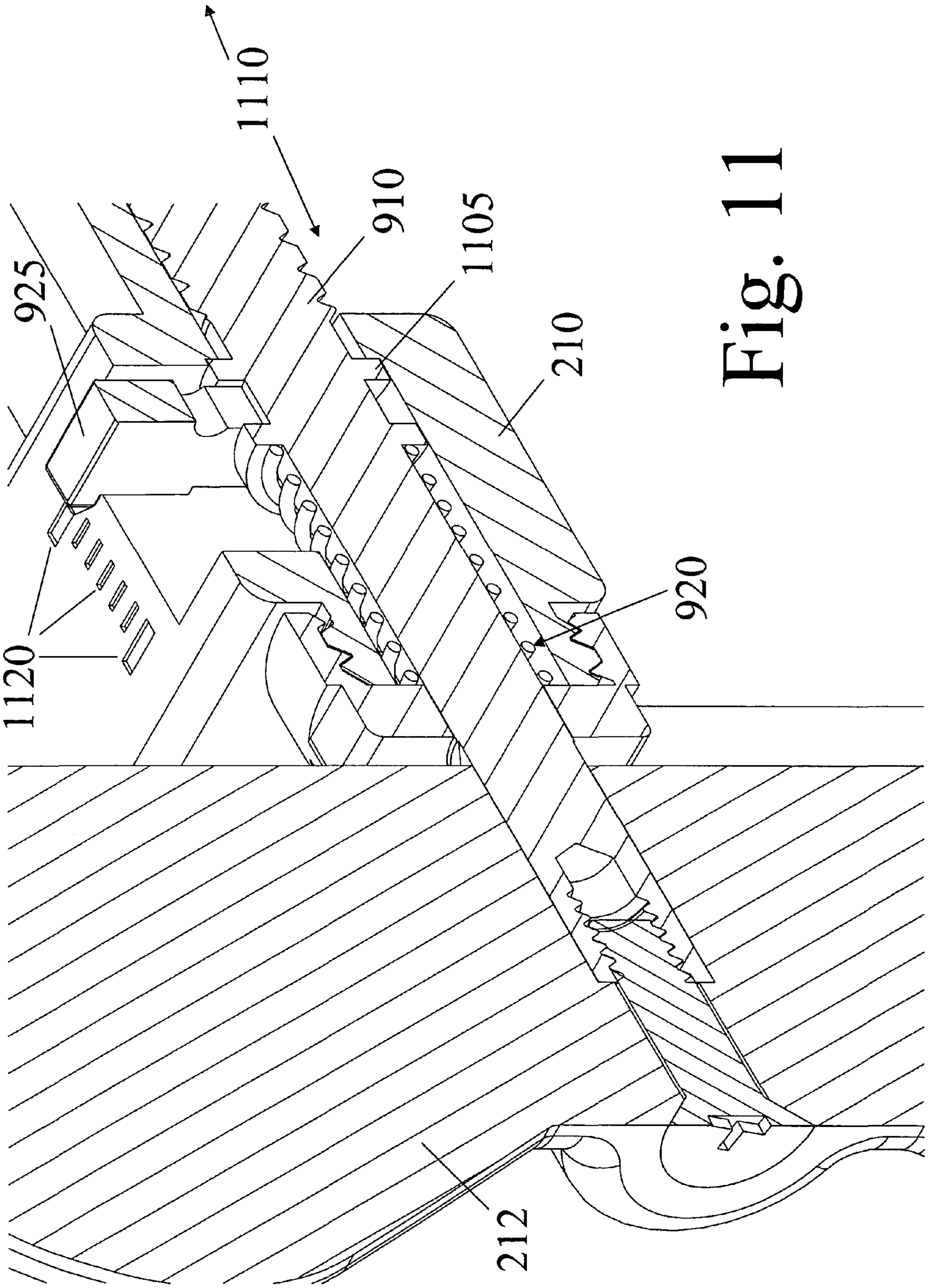


Fig. 10



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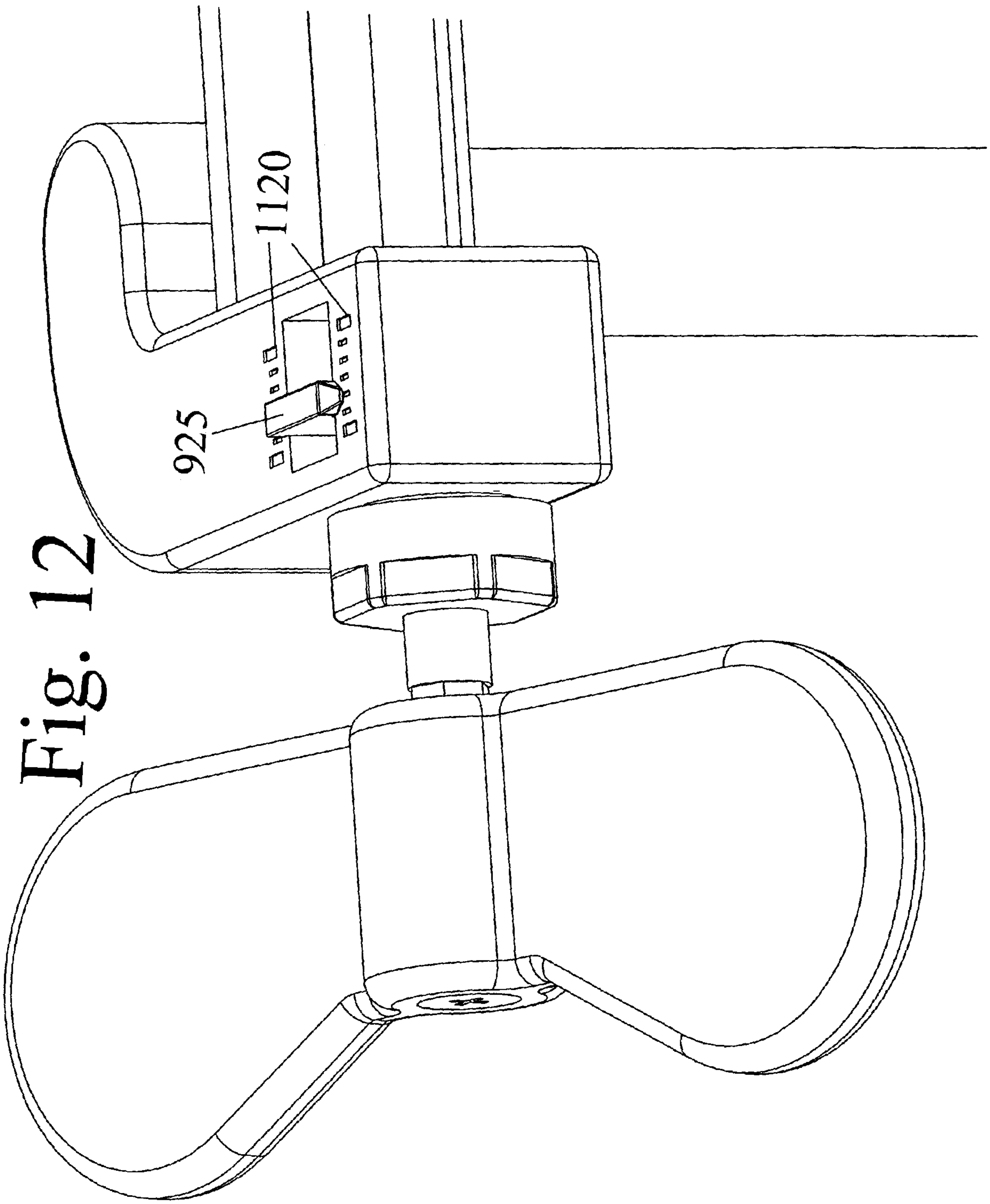

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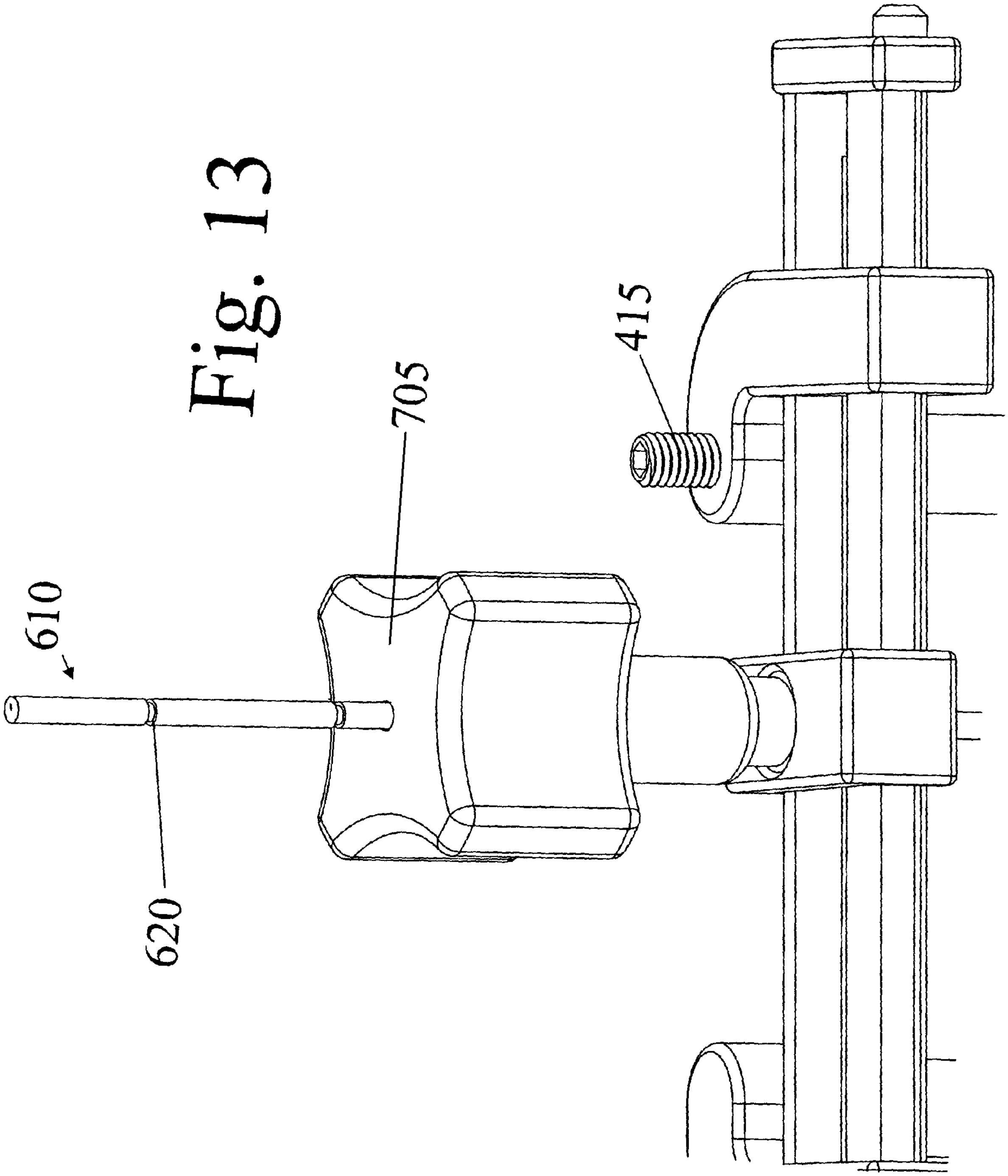

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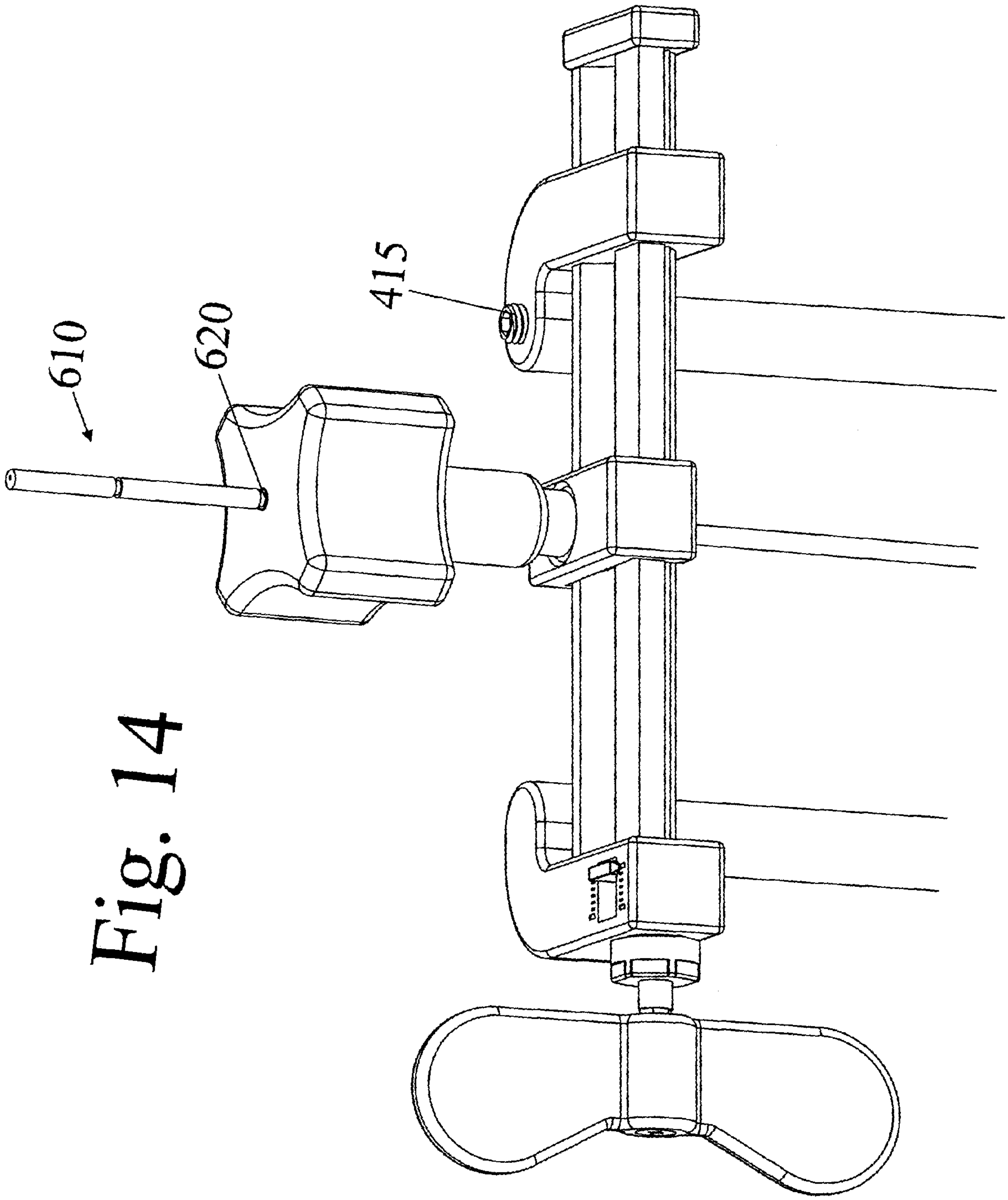

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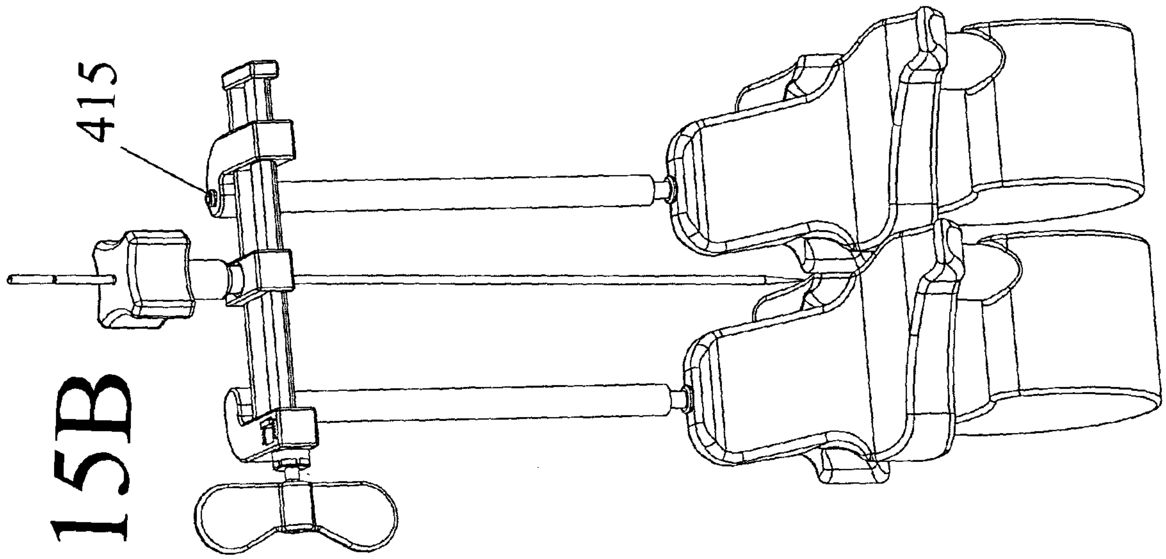


Fig. 15B

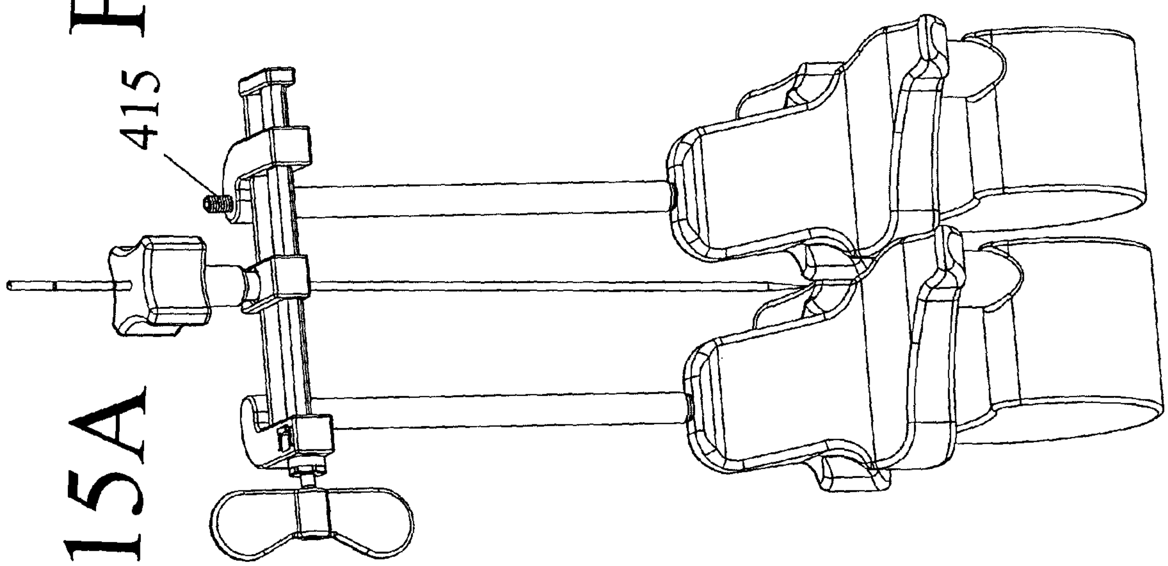


Fig 15A

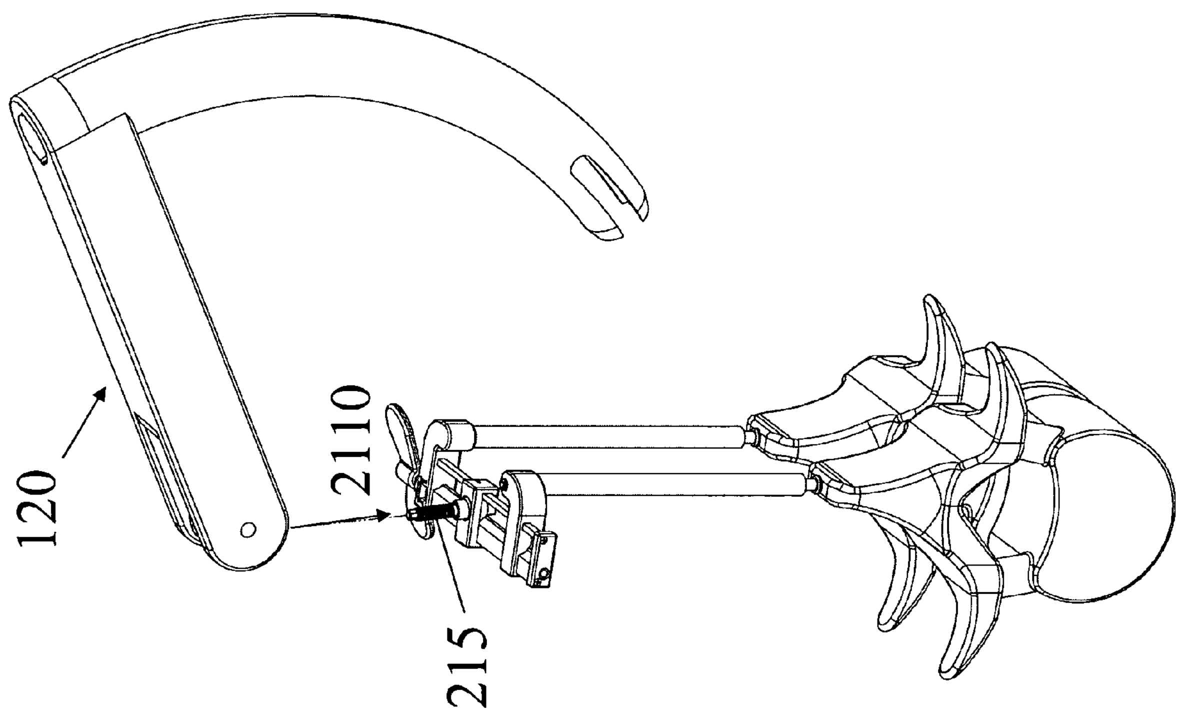


Fig. 16

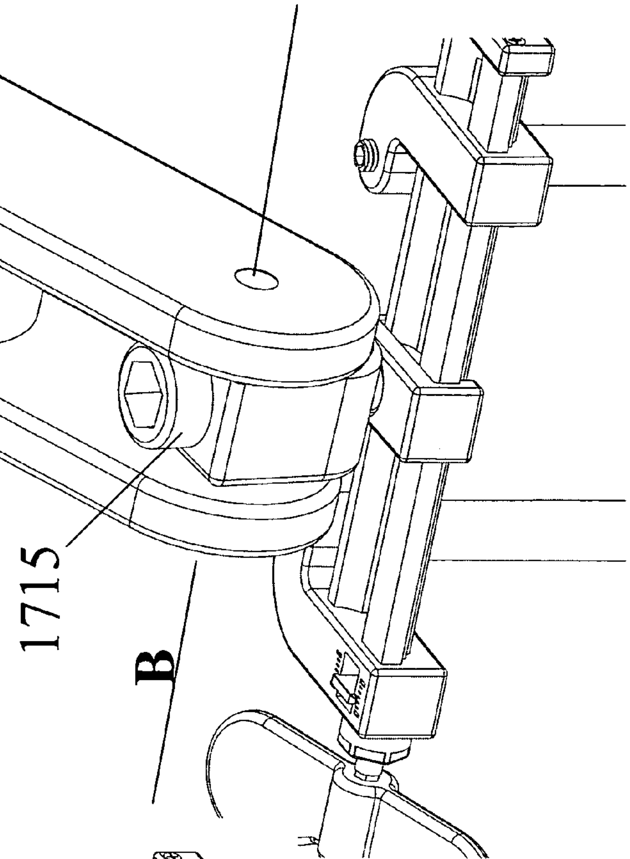


Fig. 17B

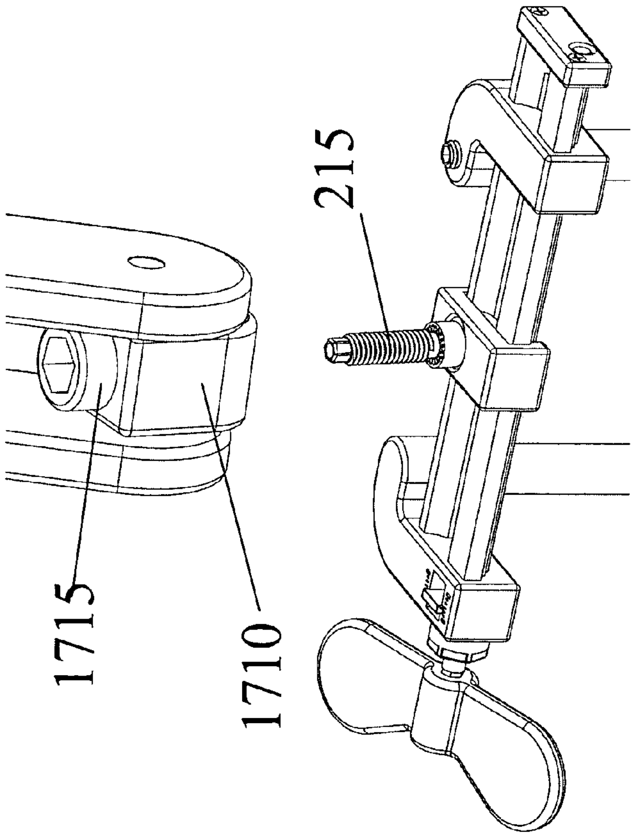


Fig. 17A

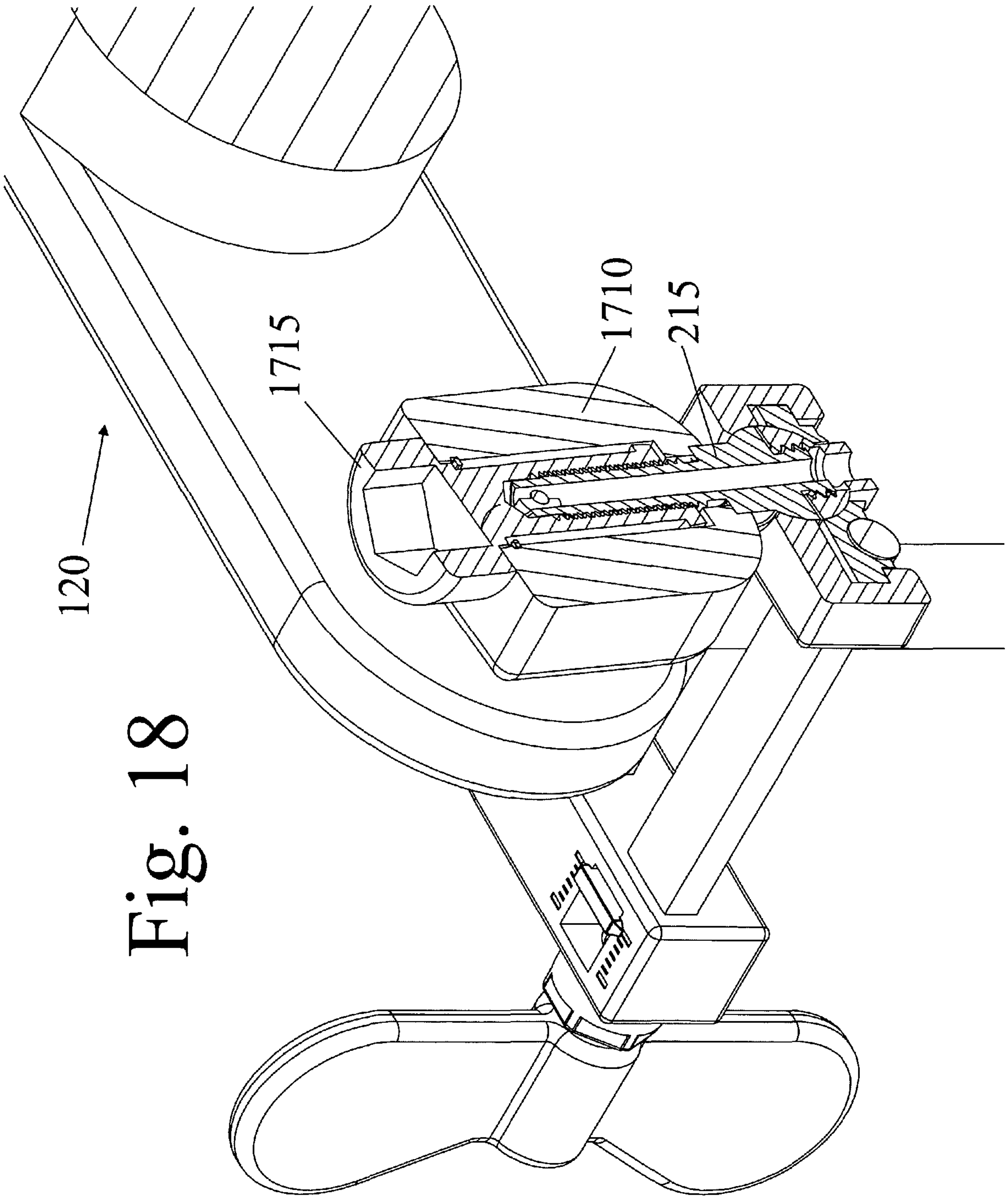


Fig. 18

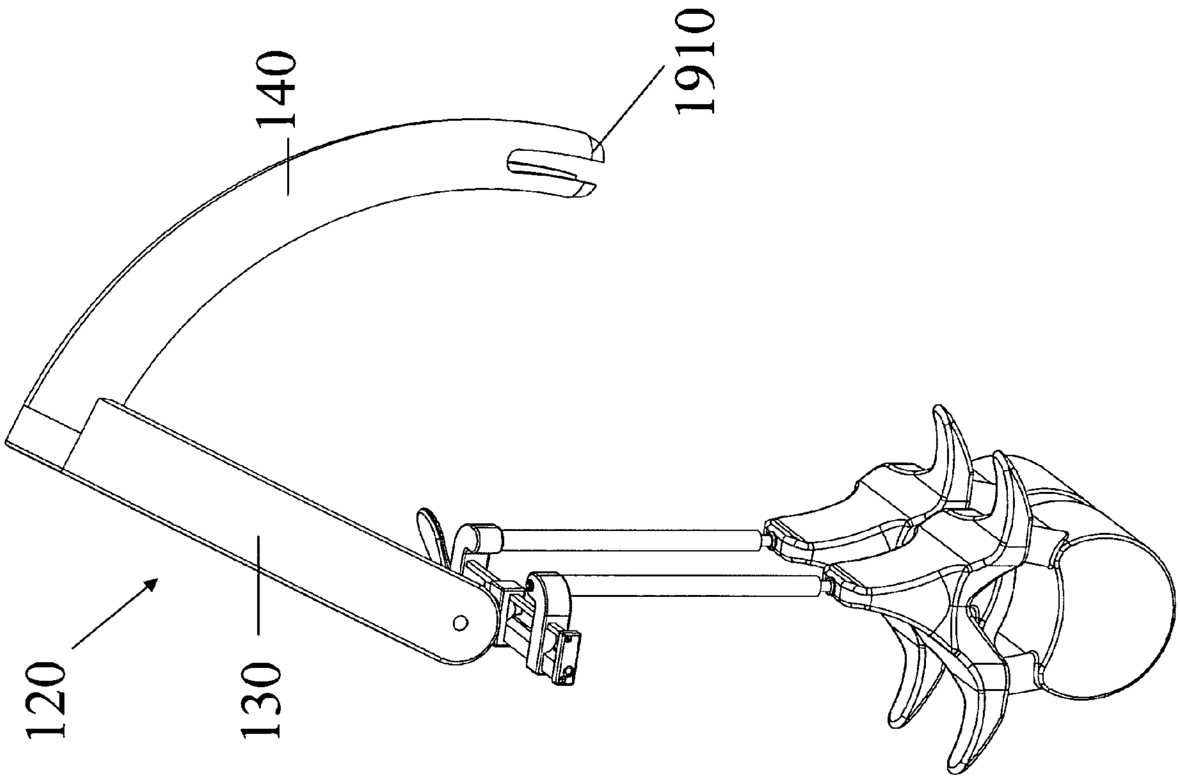


Fig. 19

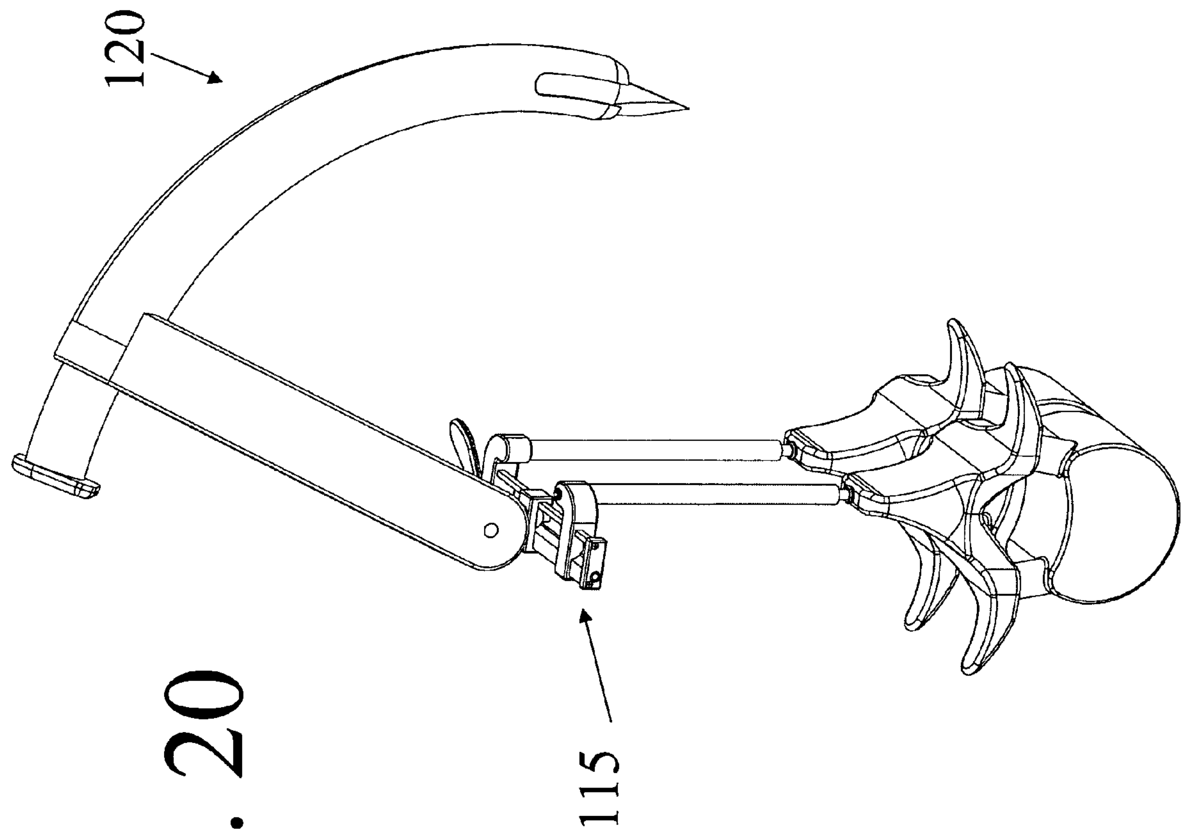


Fig. 20

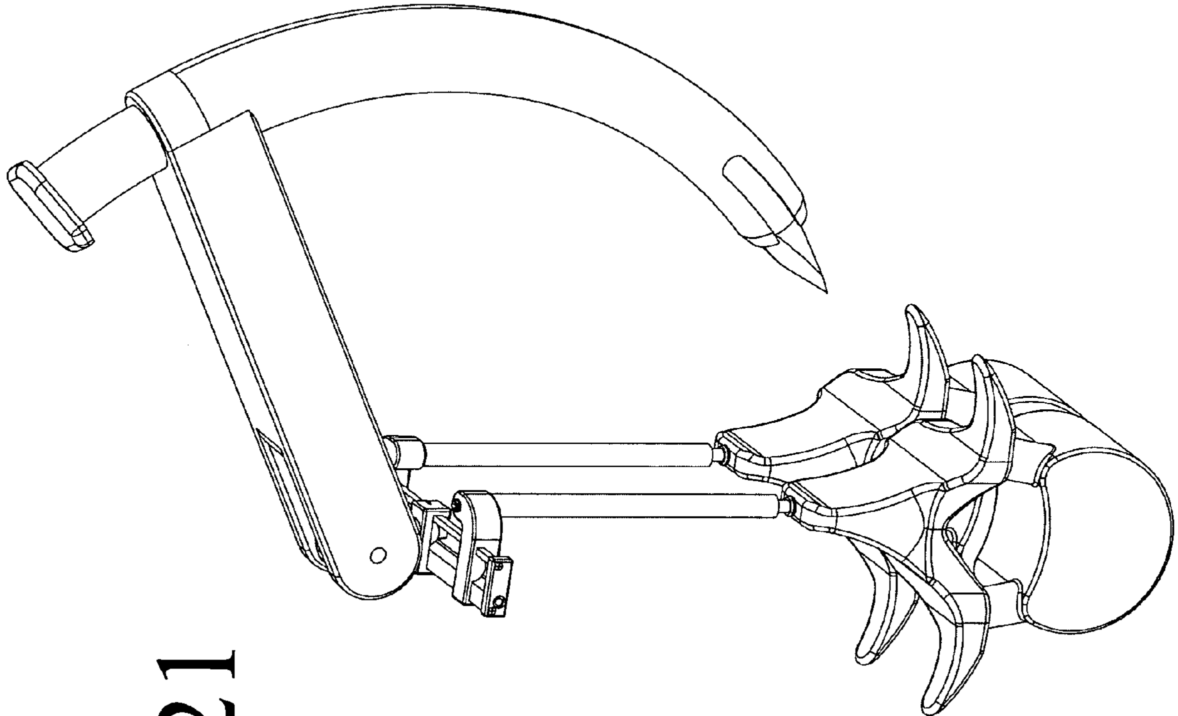


Fig. 21

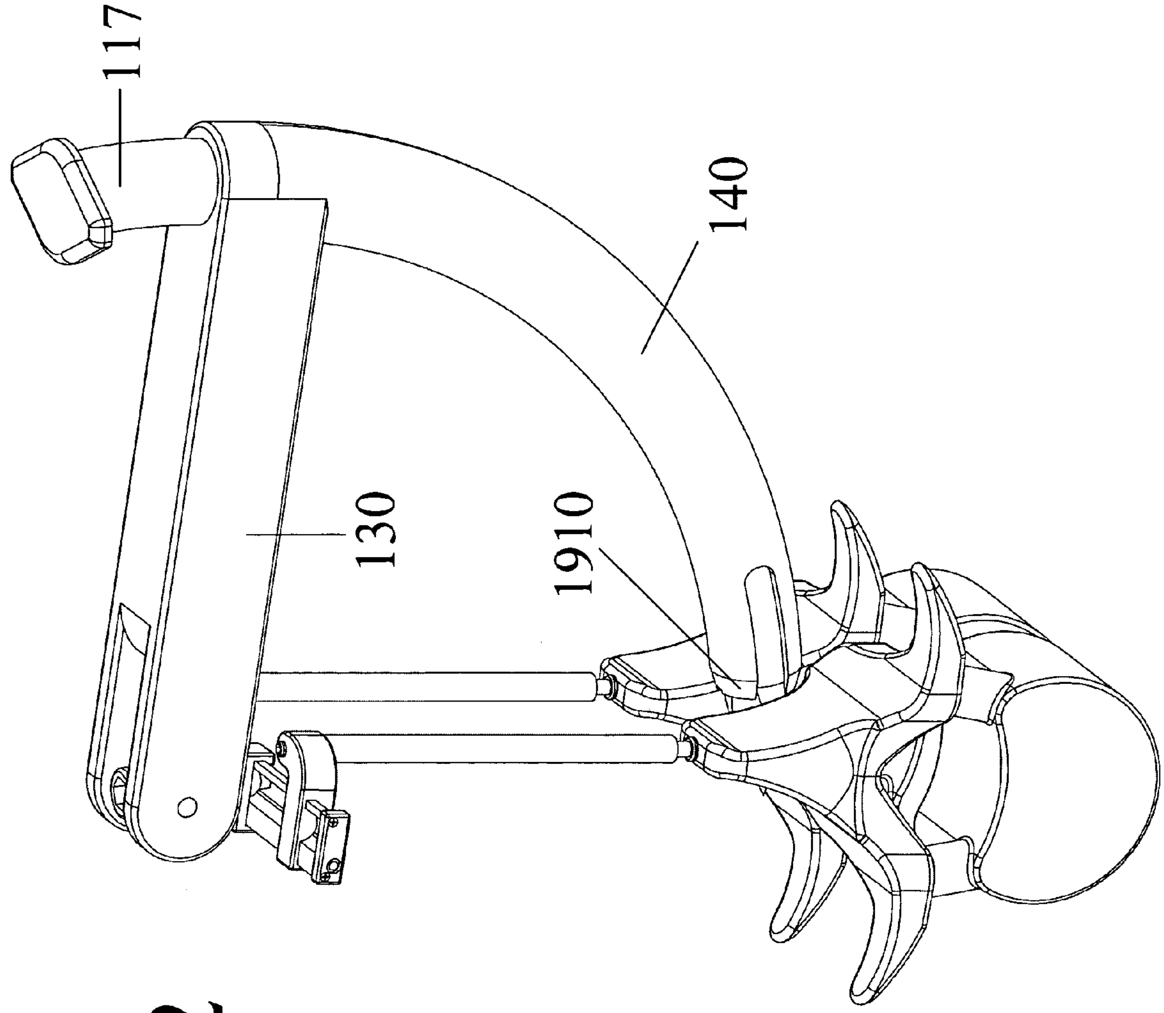


Fig. 22

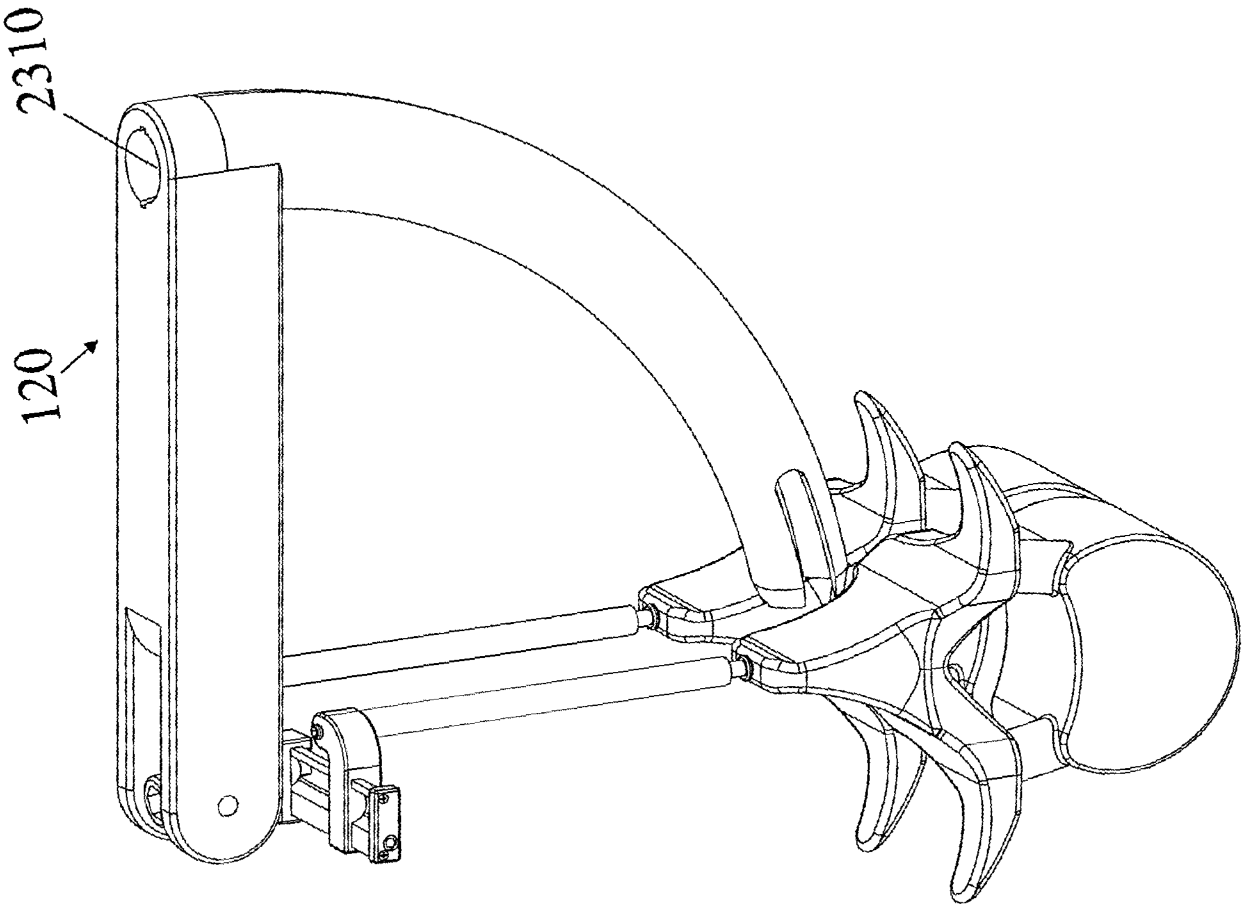


Fig. 23

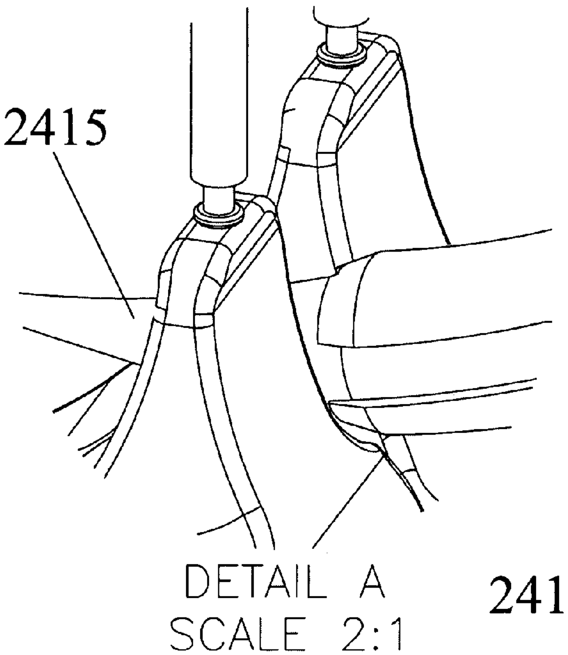


Fig. 24C

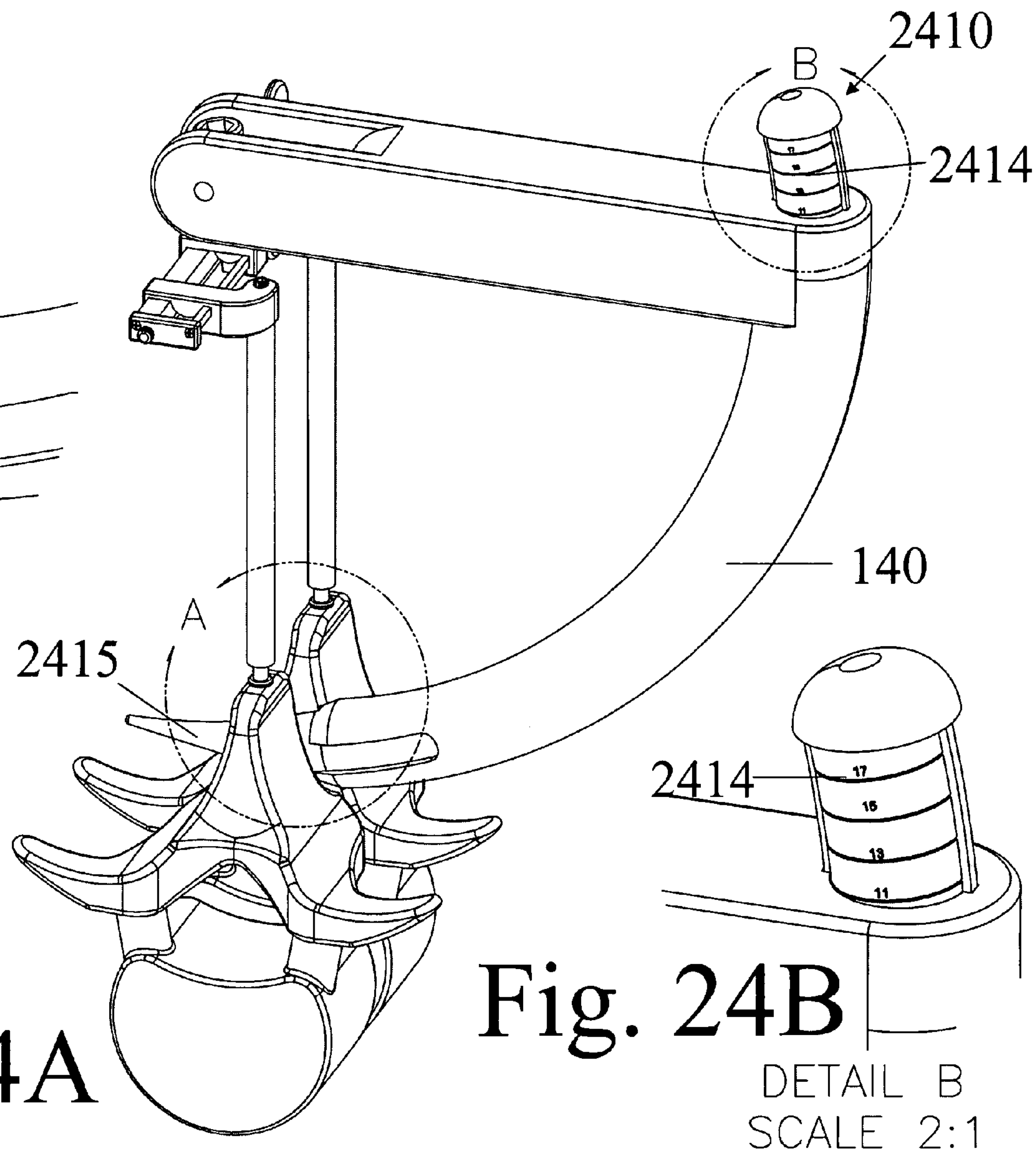


Fig. 24A

Fig. 24B

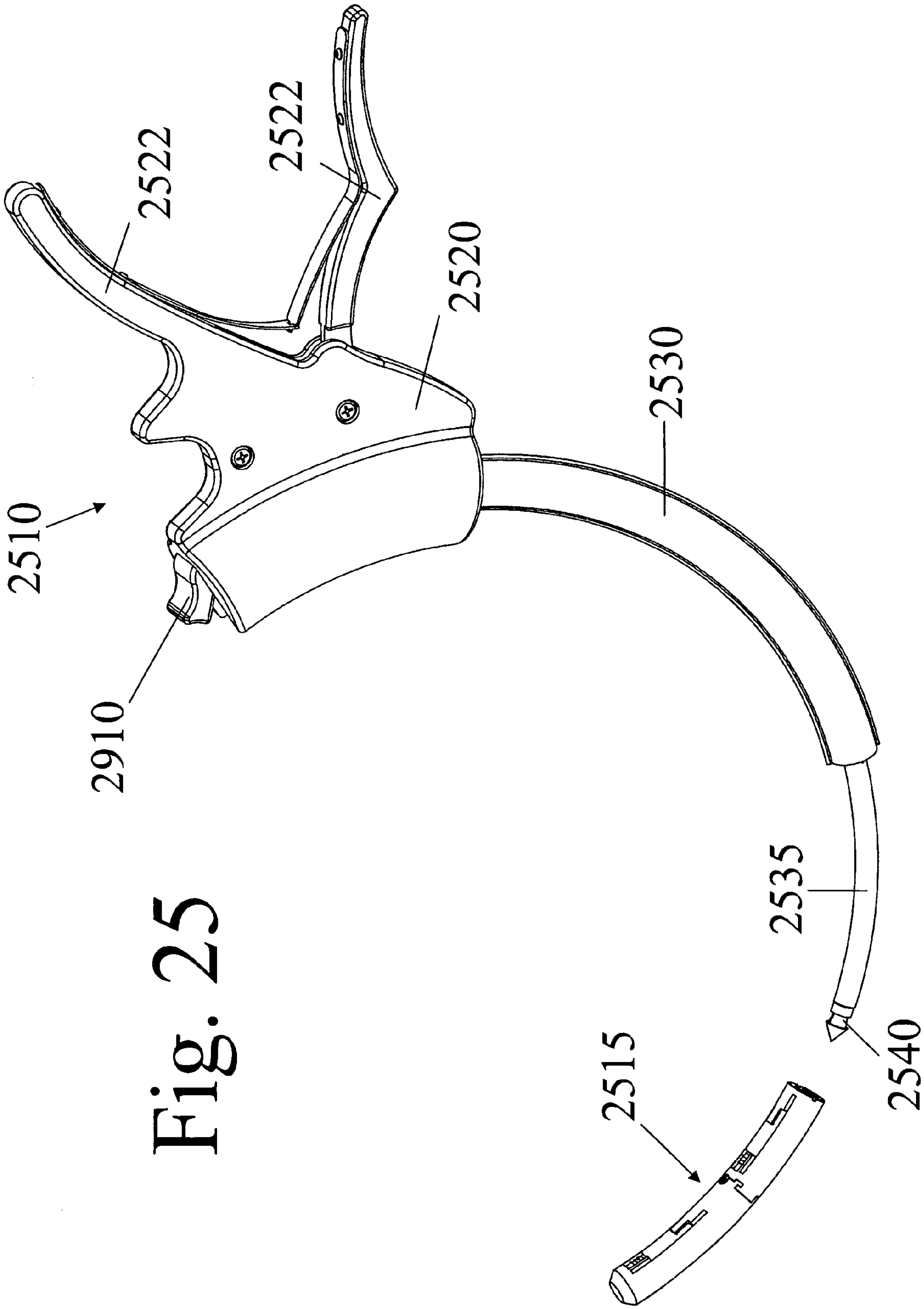


Fig. 25

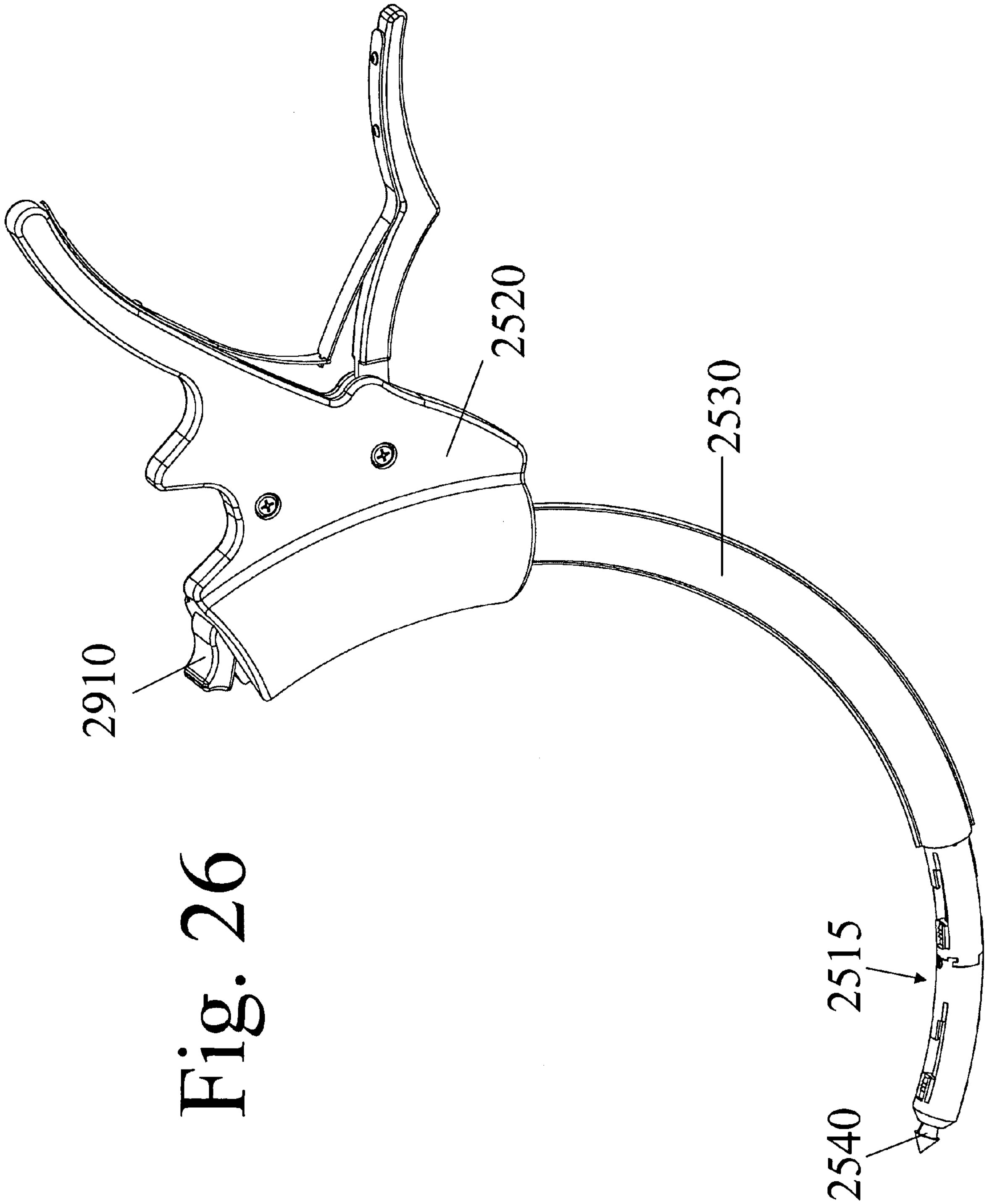


Fig. 26

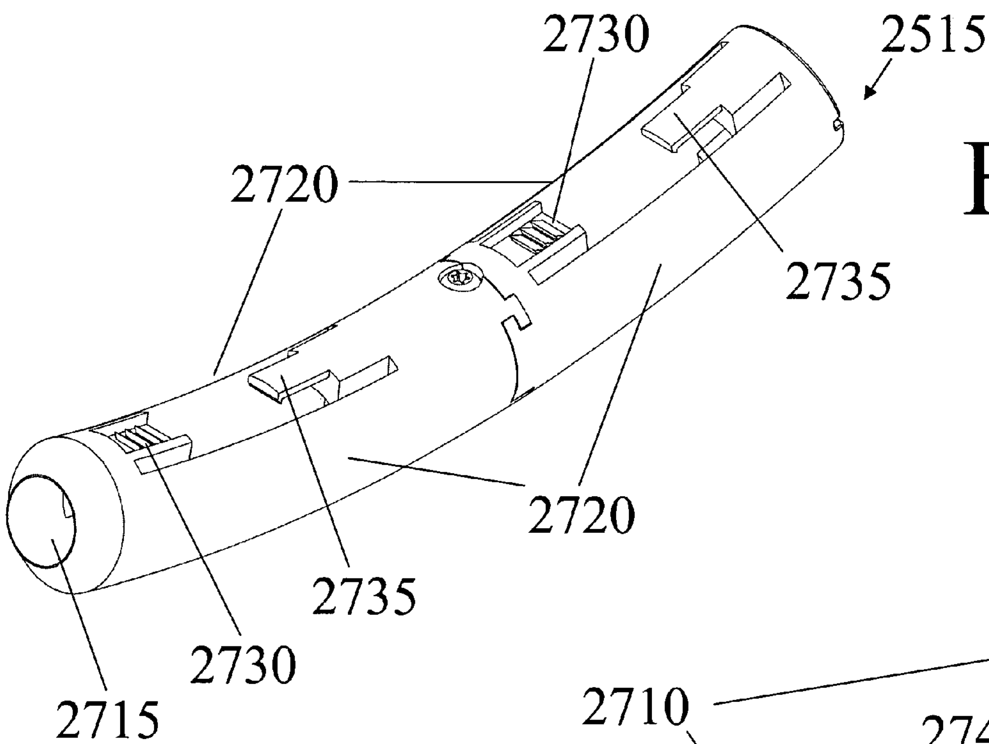


Fig. 27A

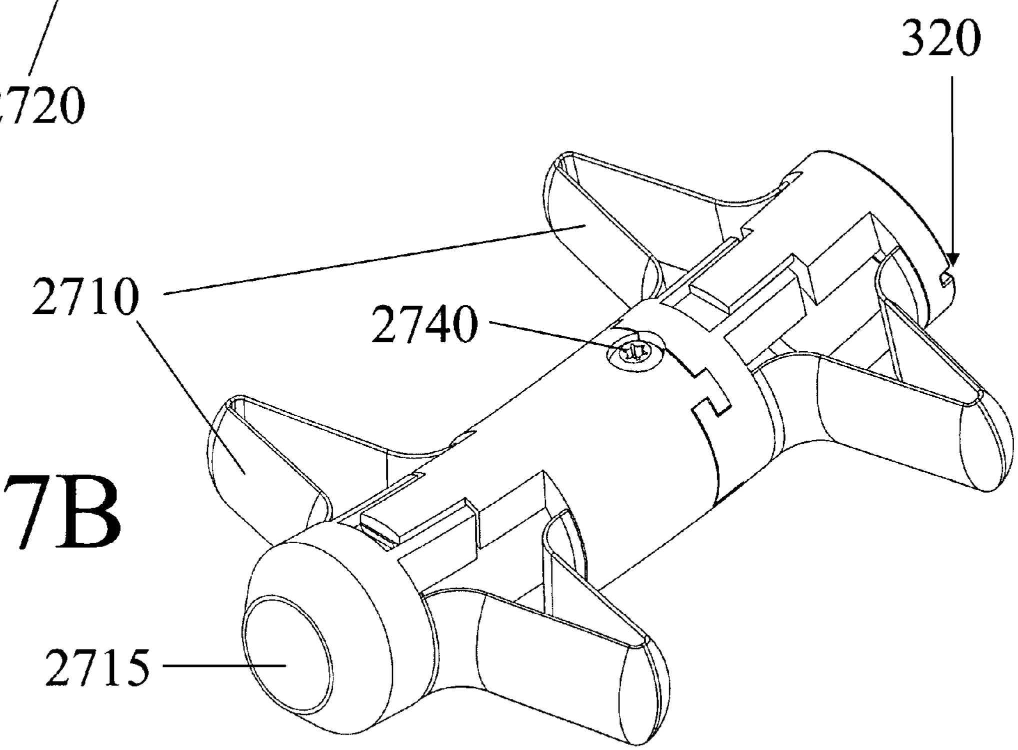
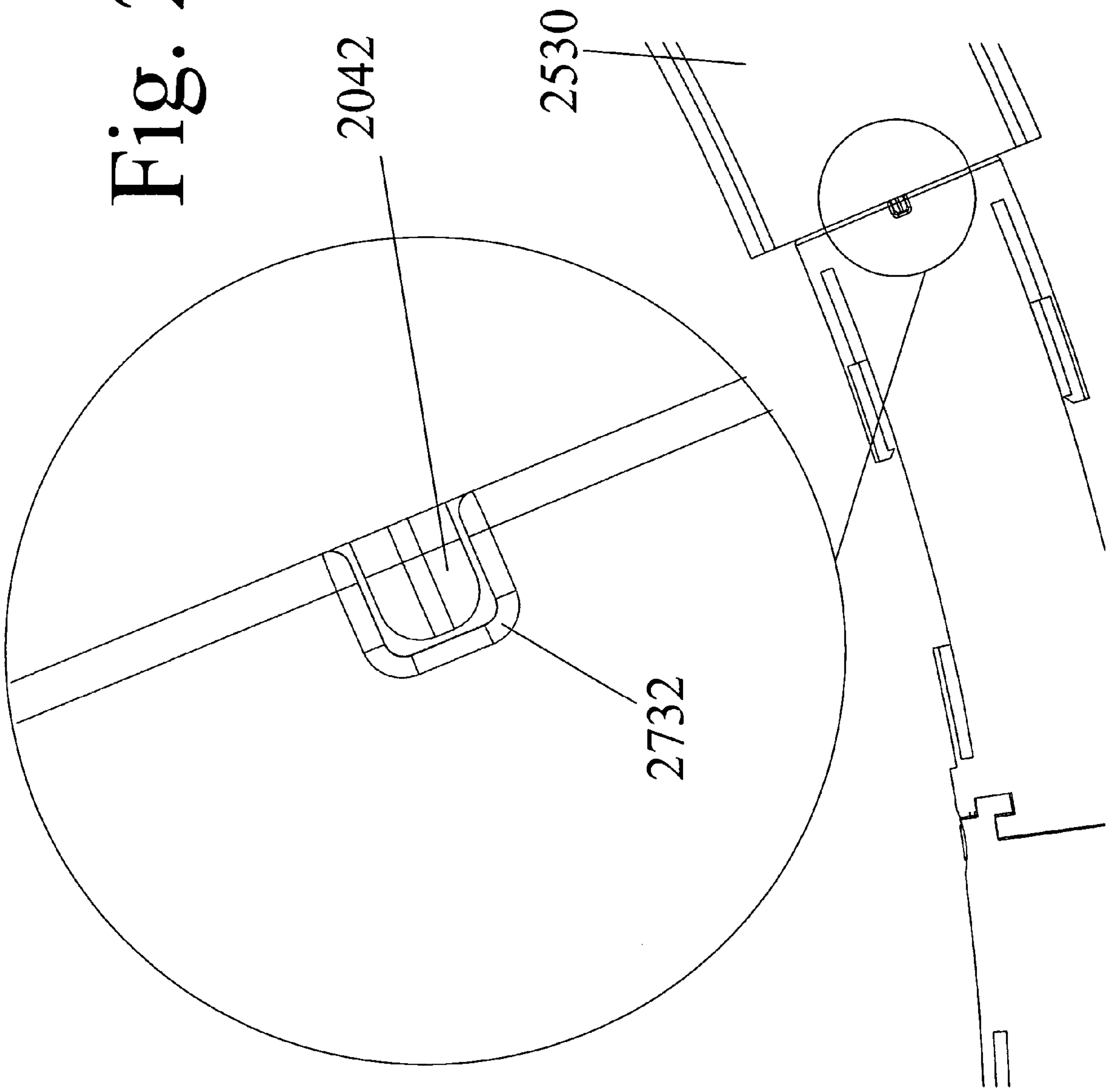


Fig. 27B

Fig. 28



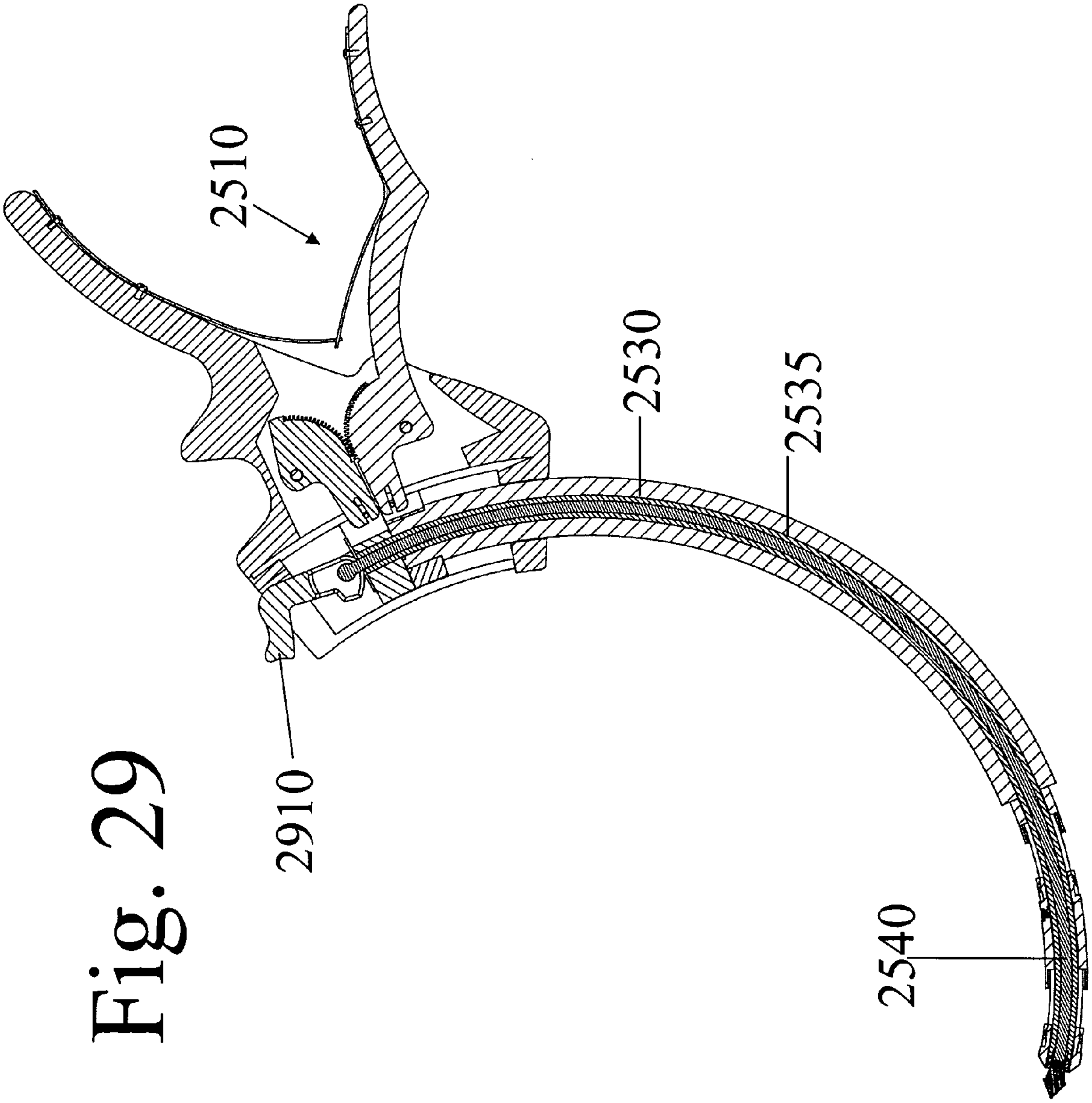


Fig. 29

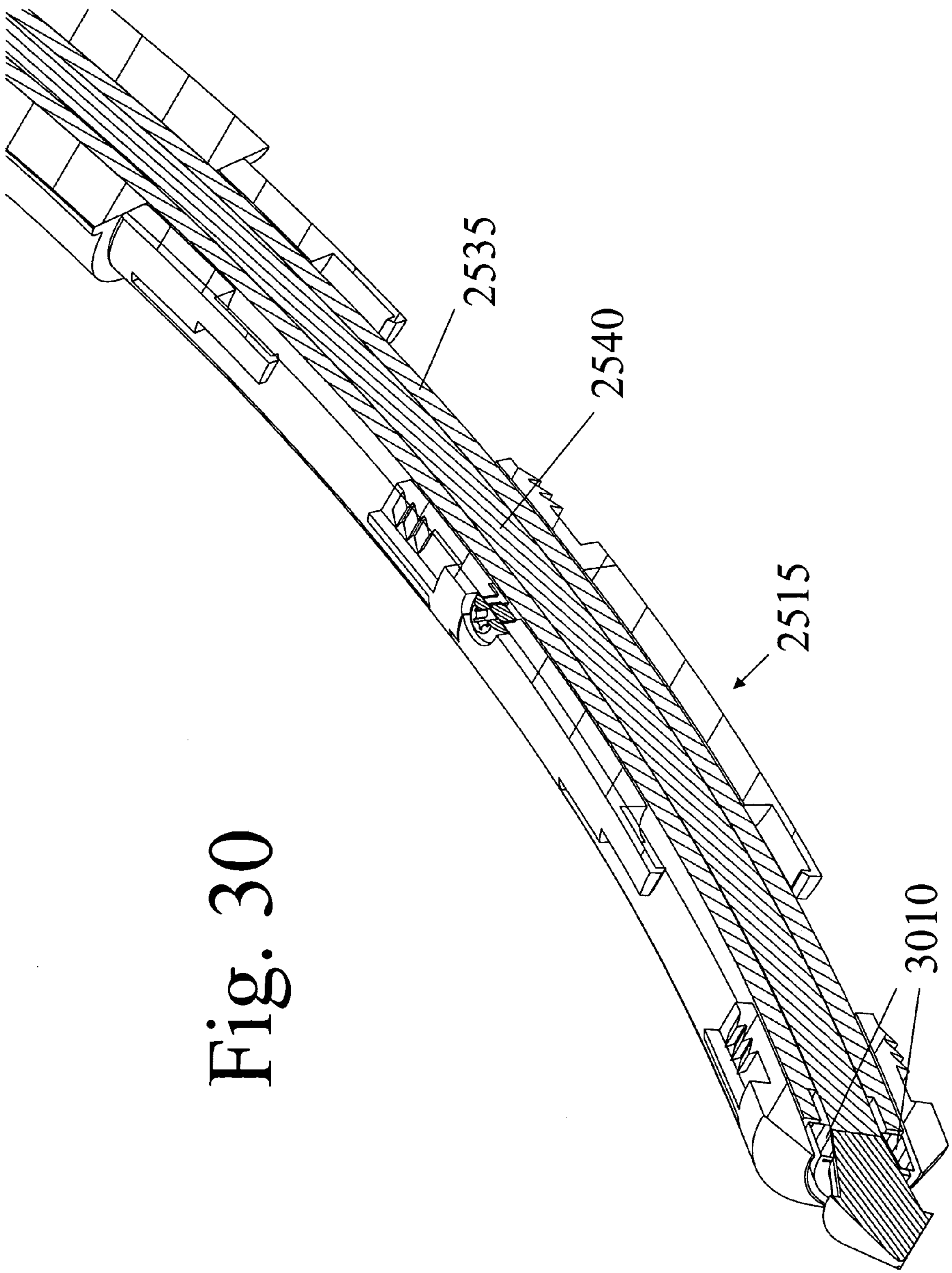


Fig. 30

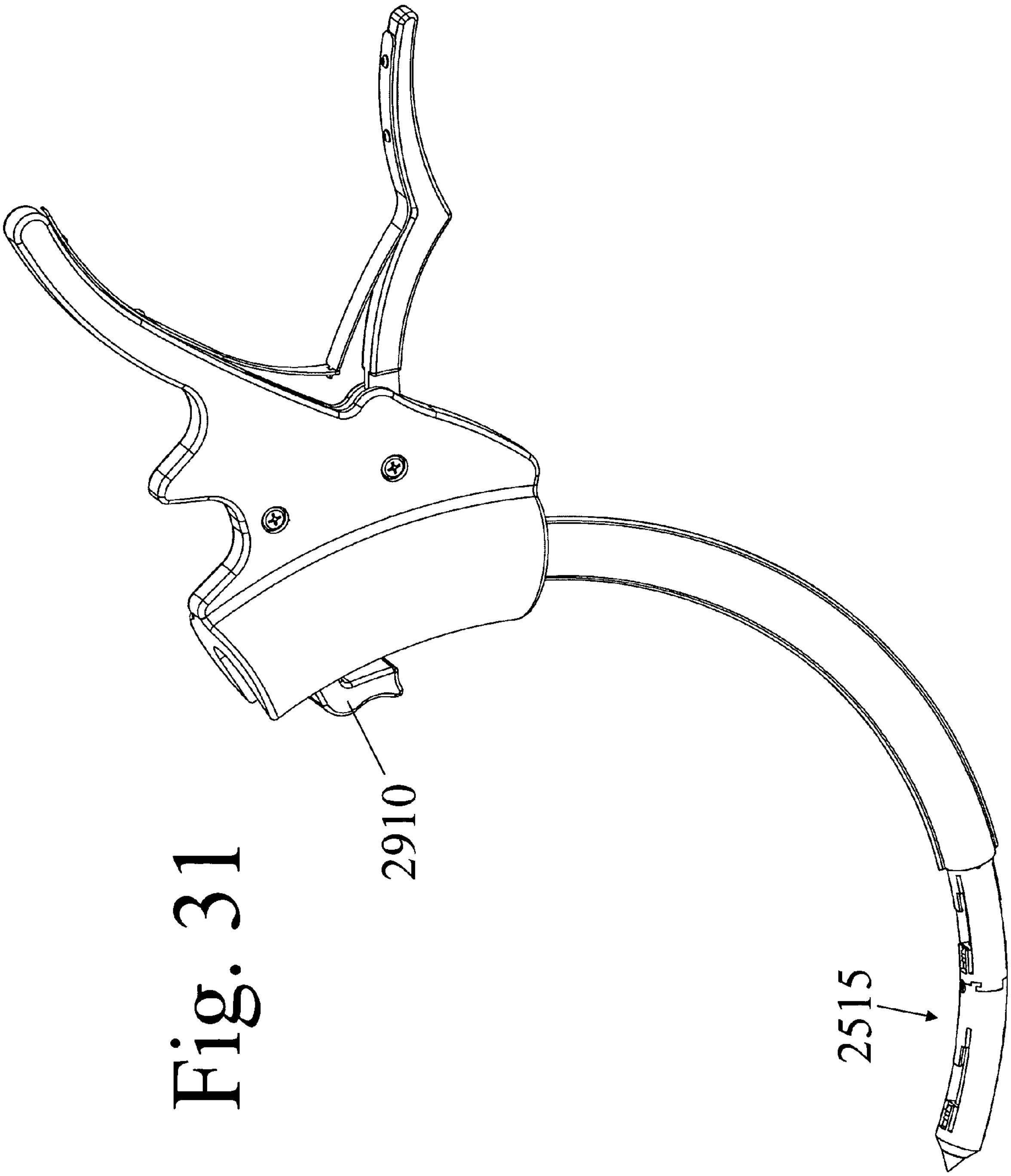


Fig. 31

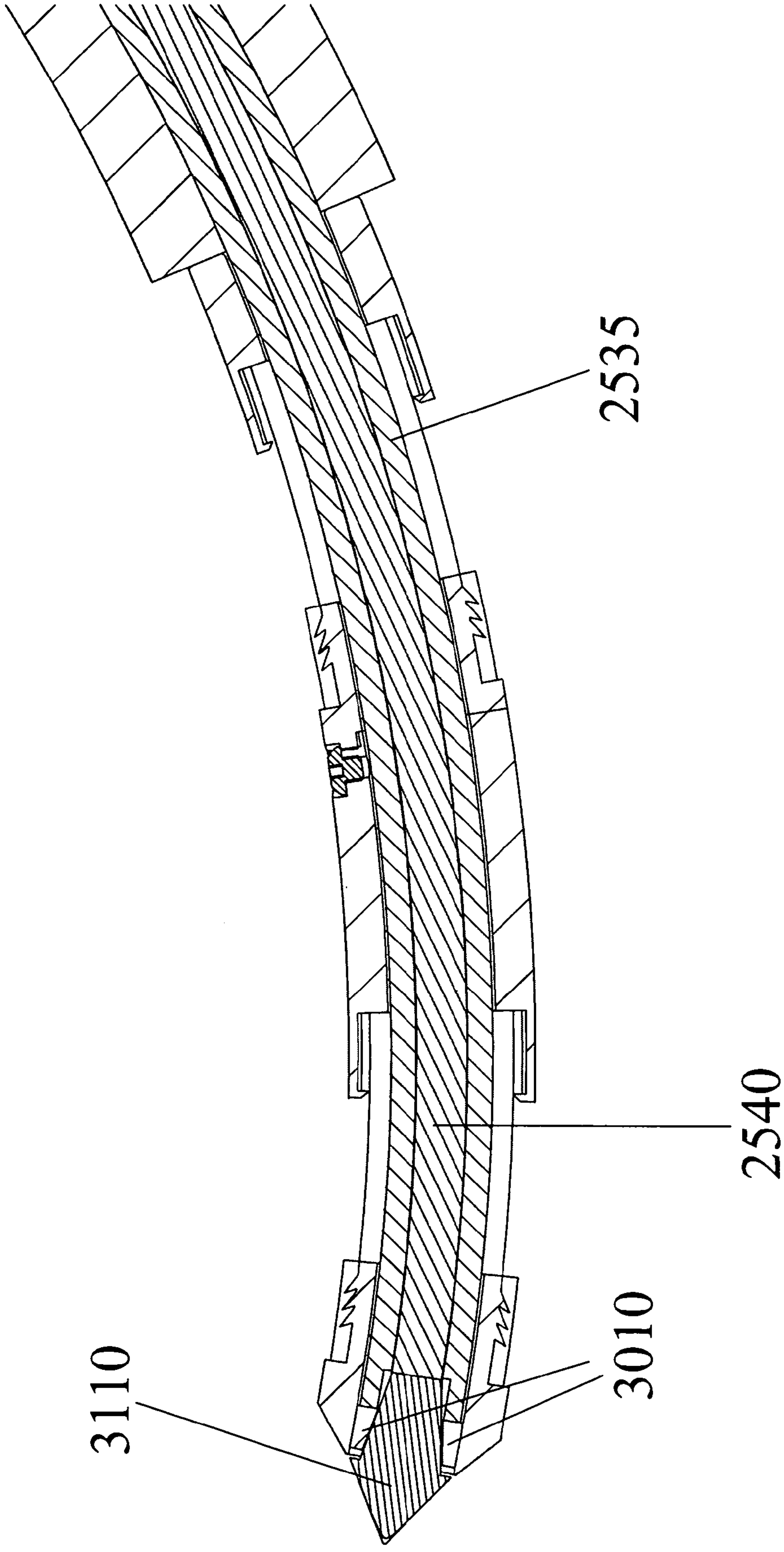


Fig. 32

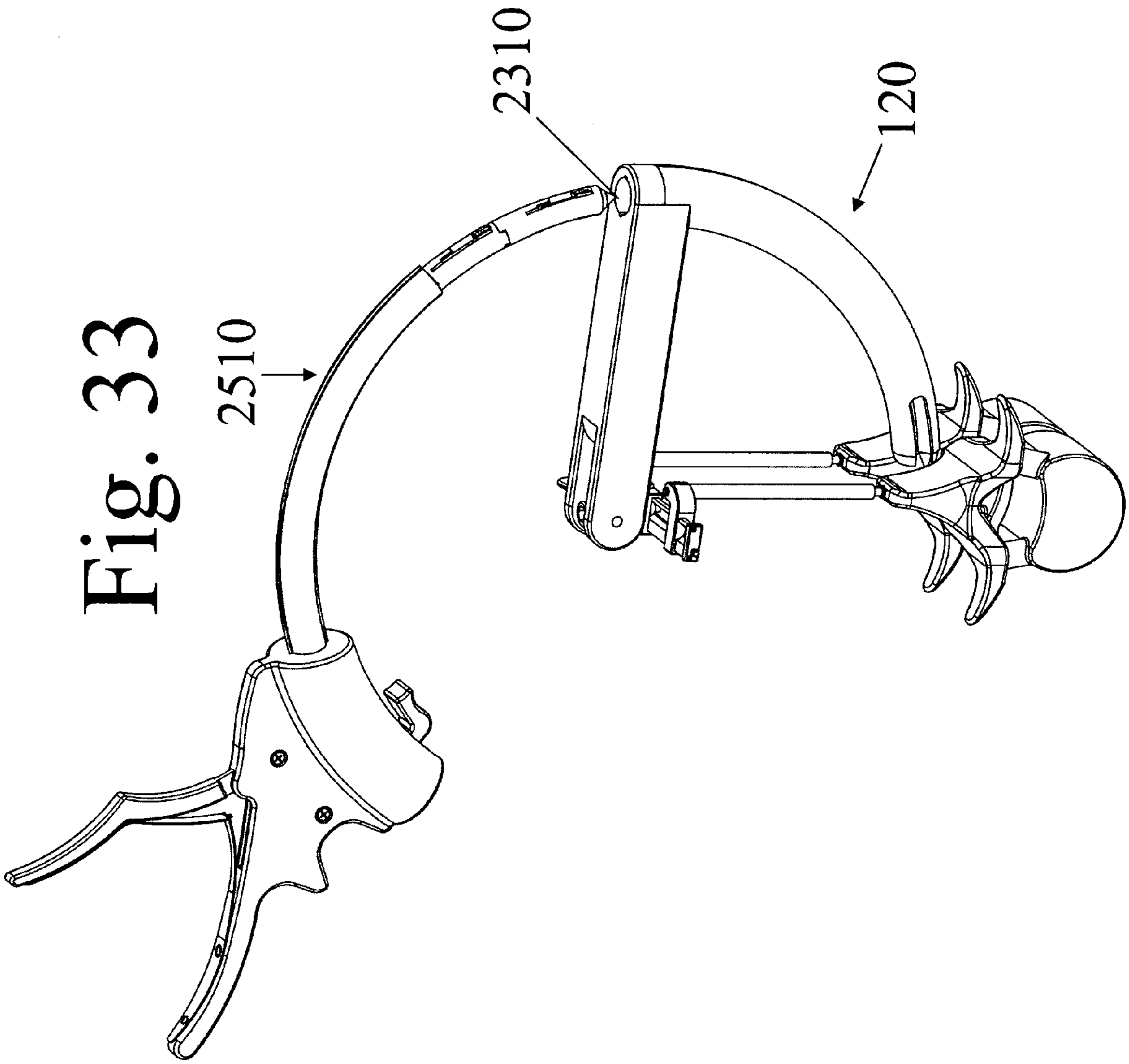


Fig. 33

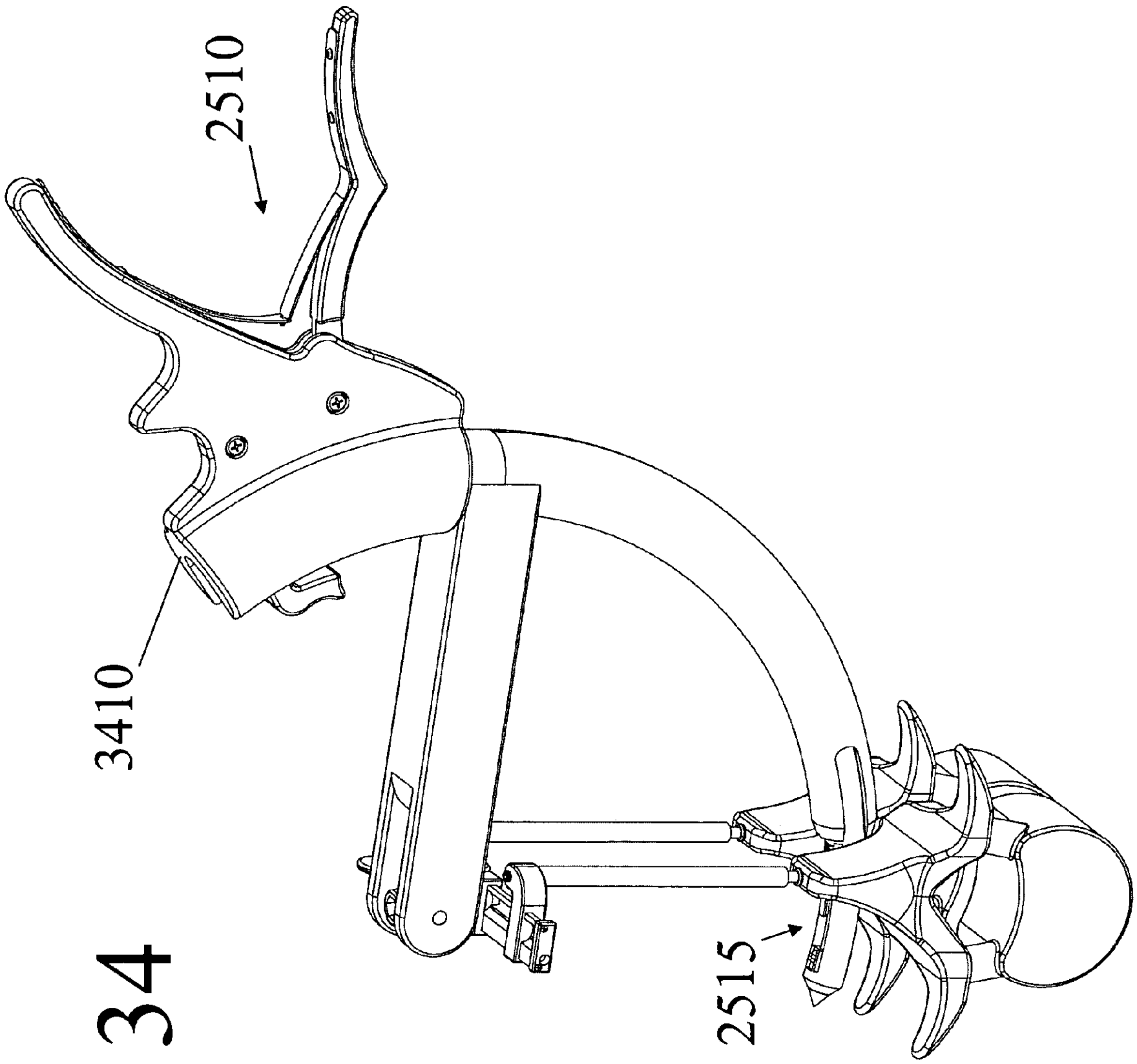


Fig. 34

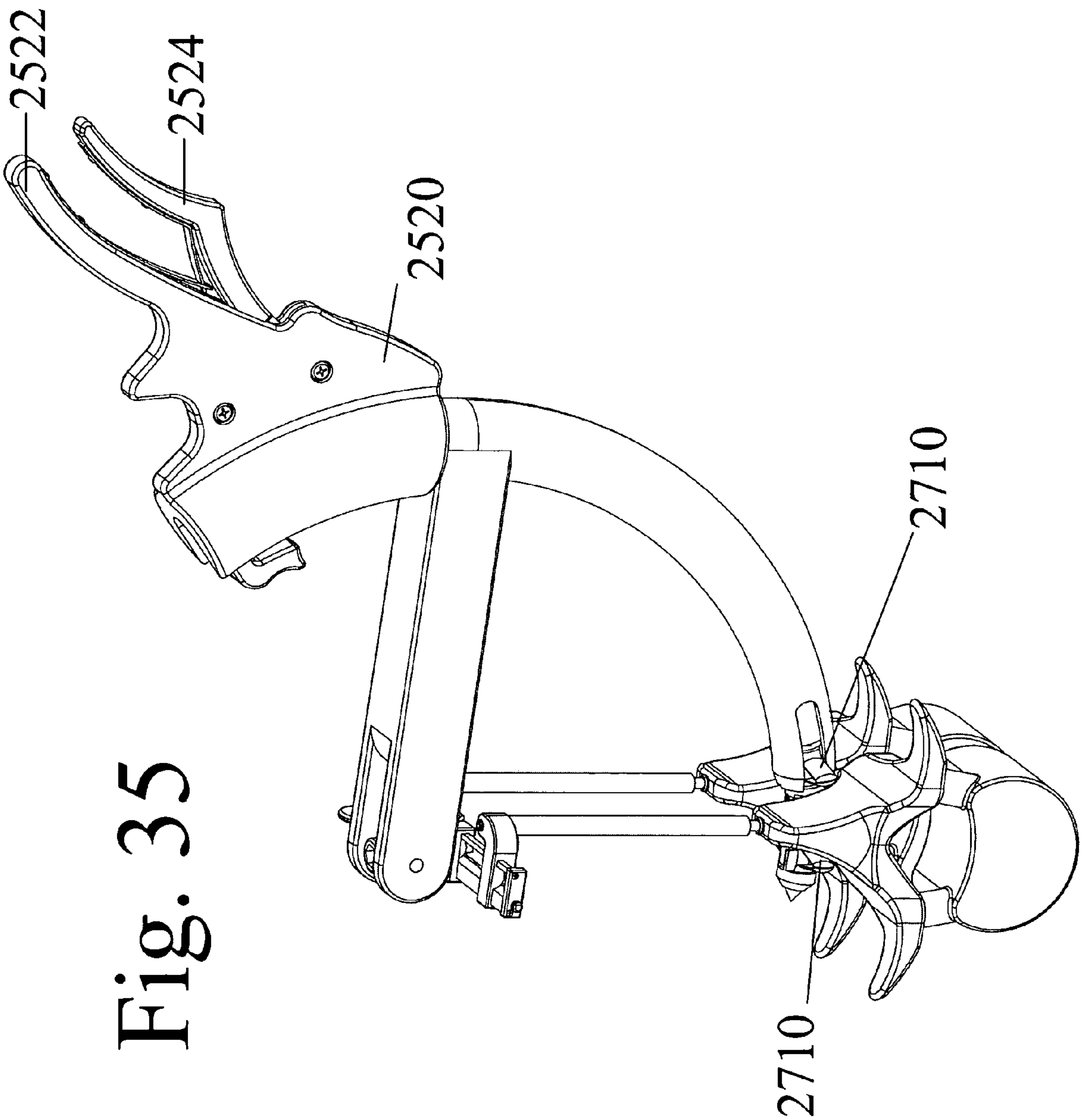


Fig. 35

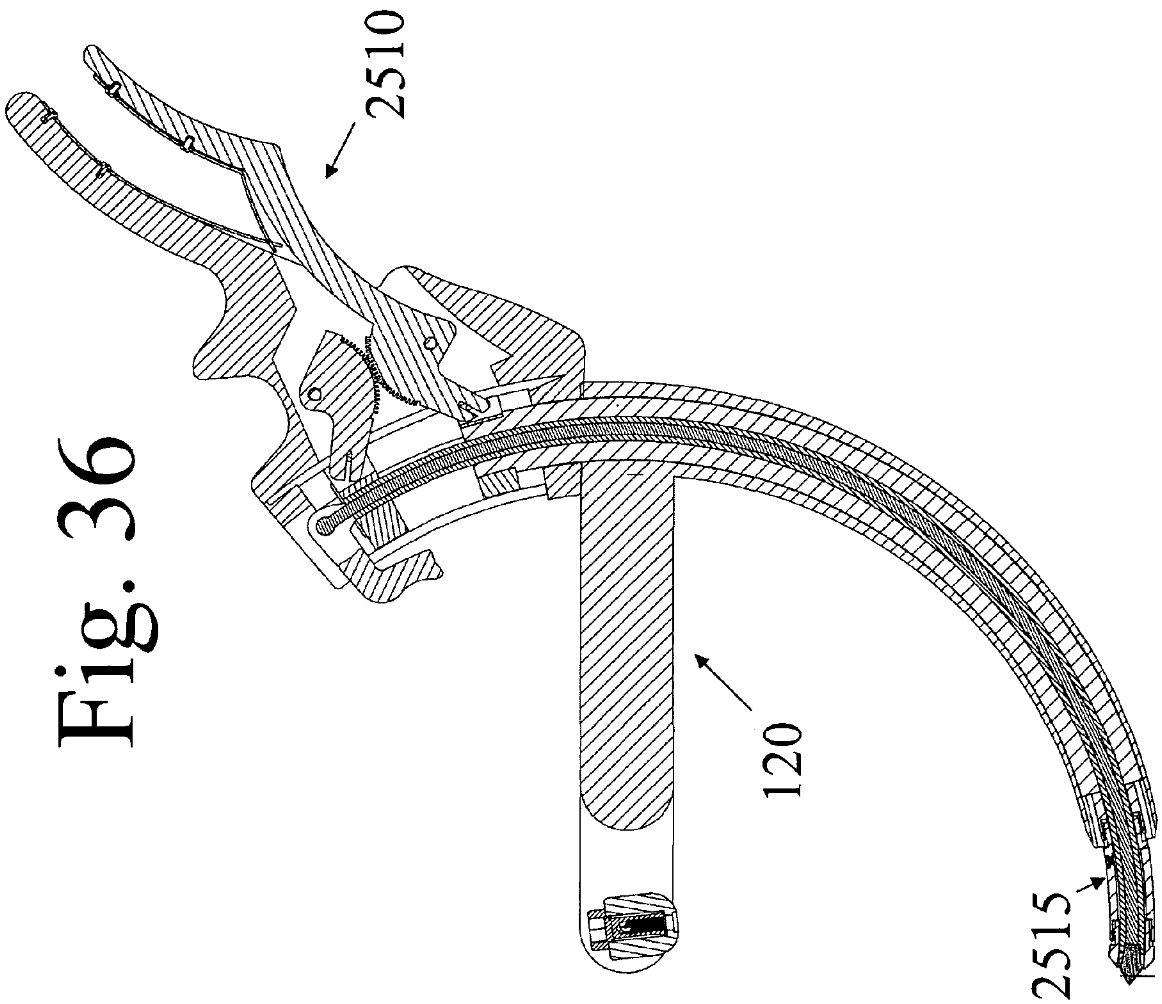


Fig. 36

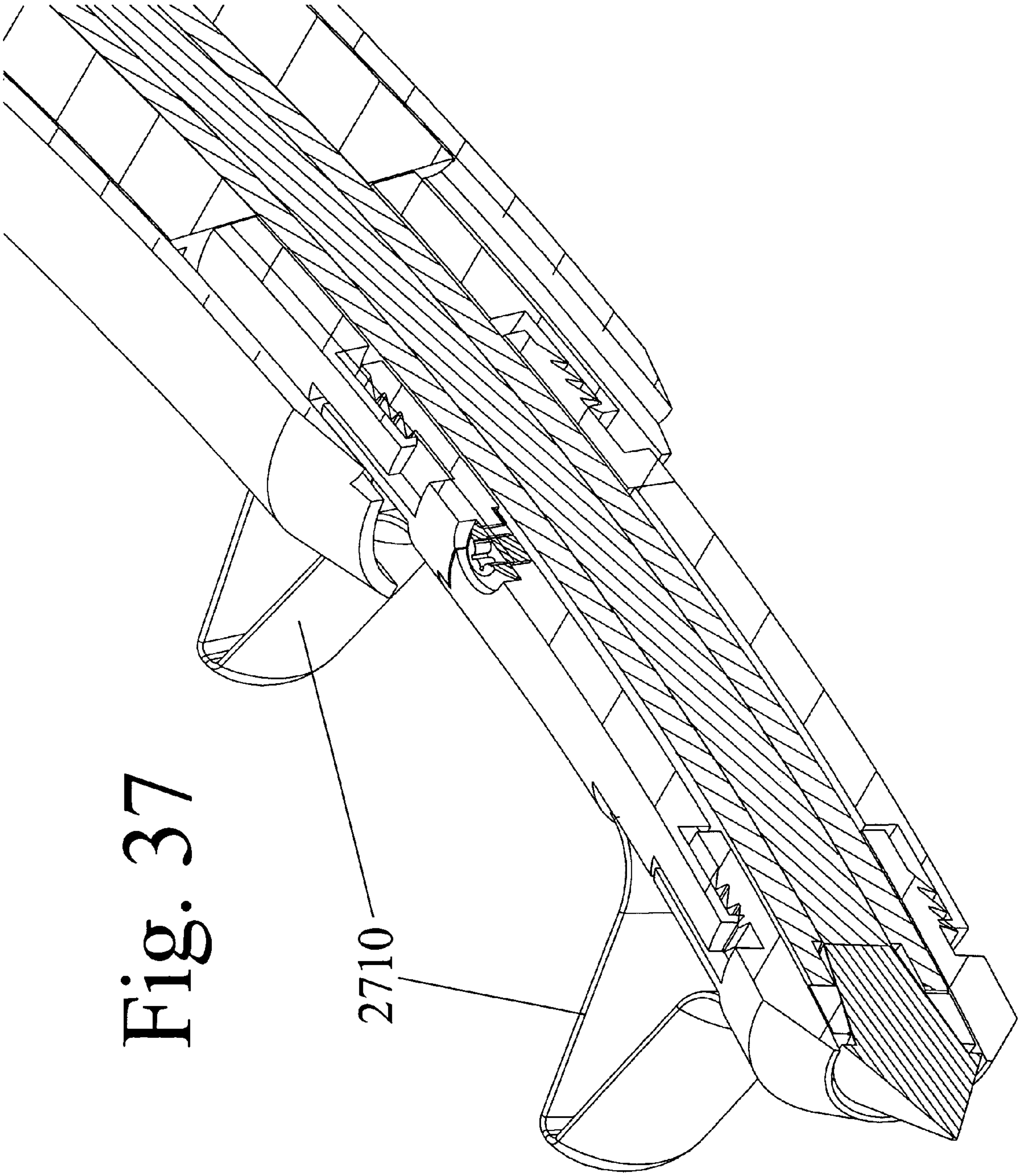


Fig. 37

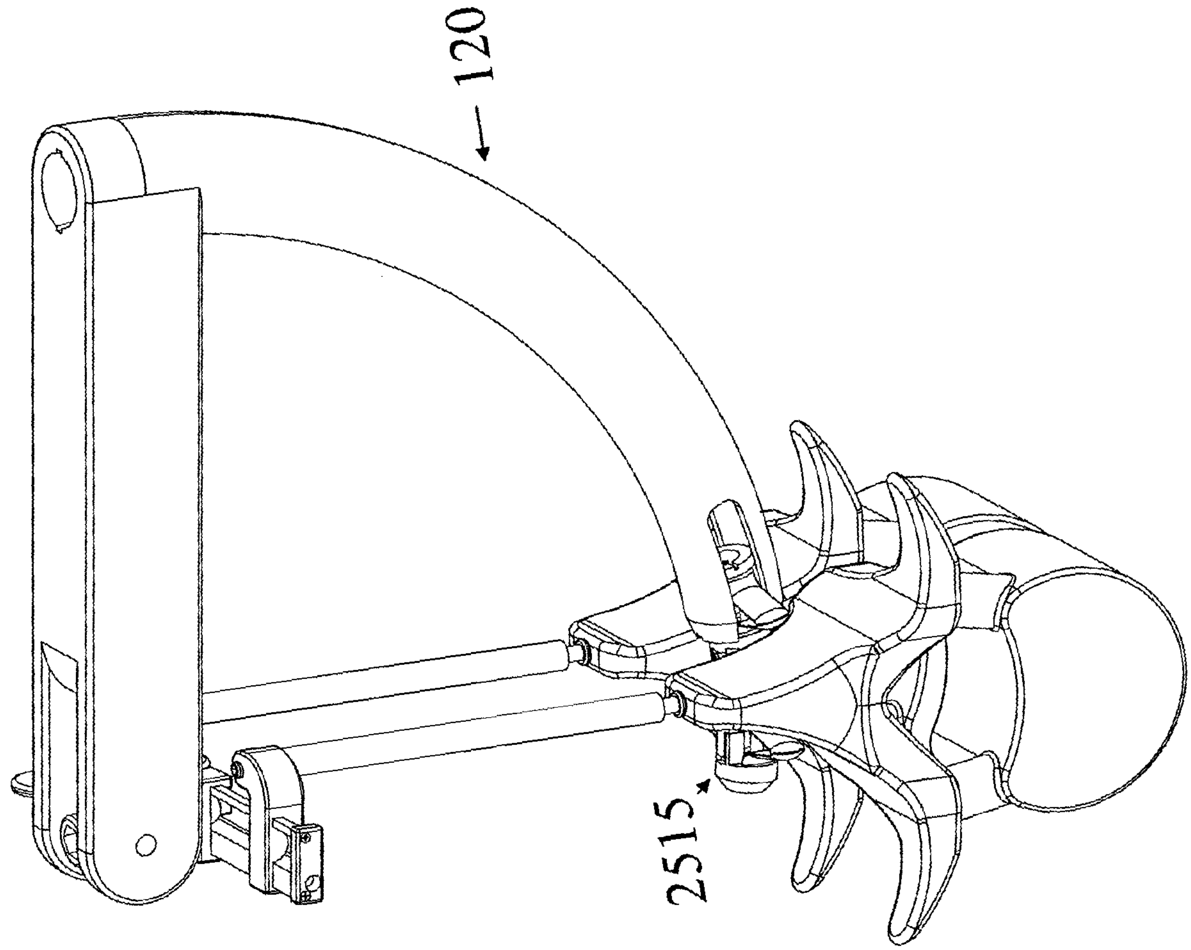


Fig. 38

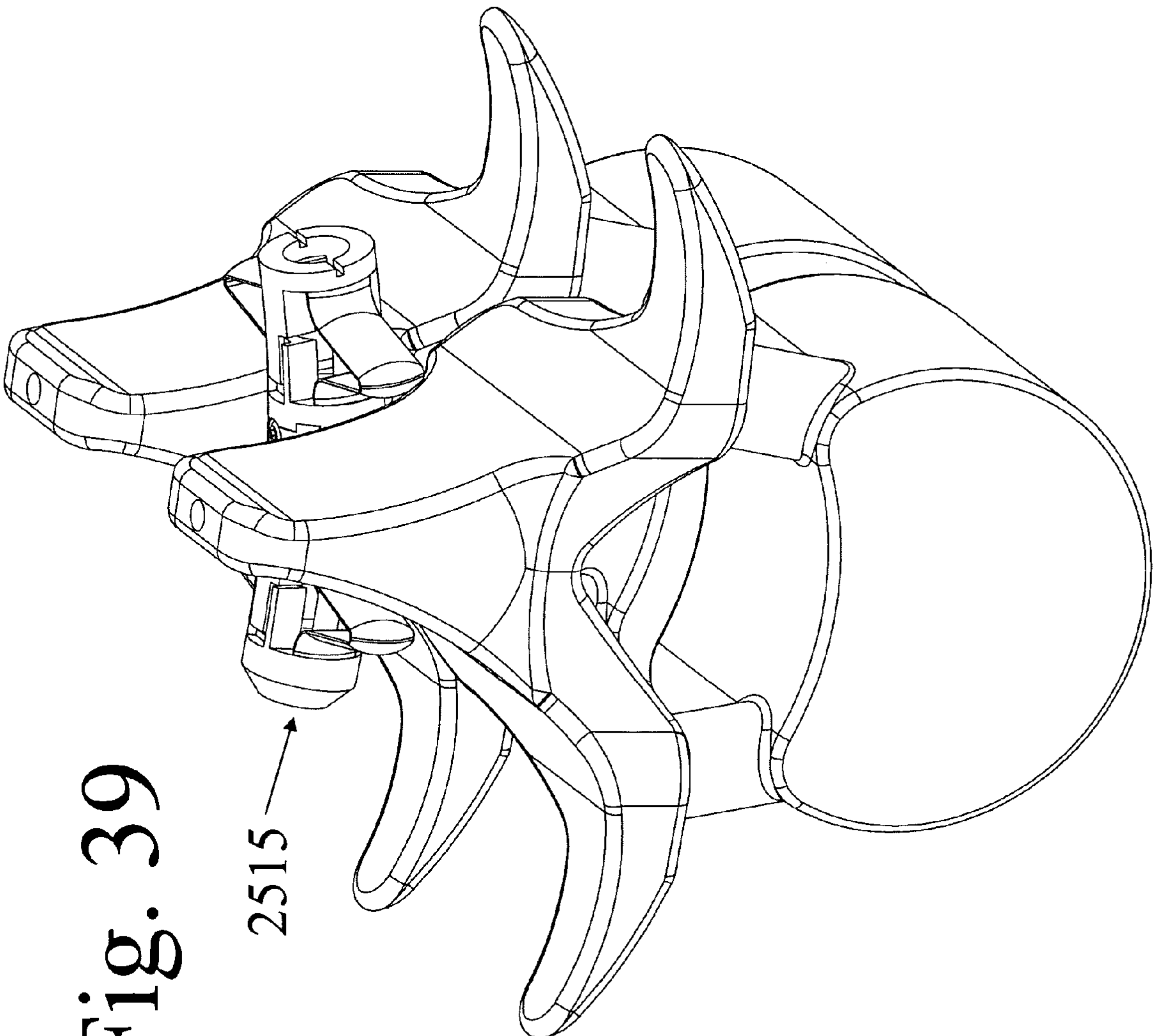


Fig. 39

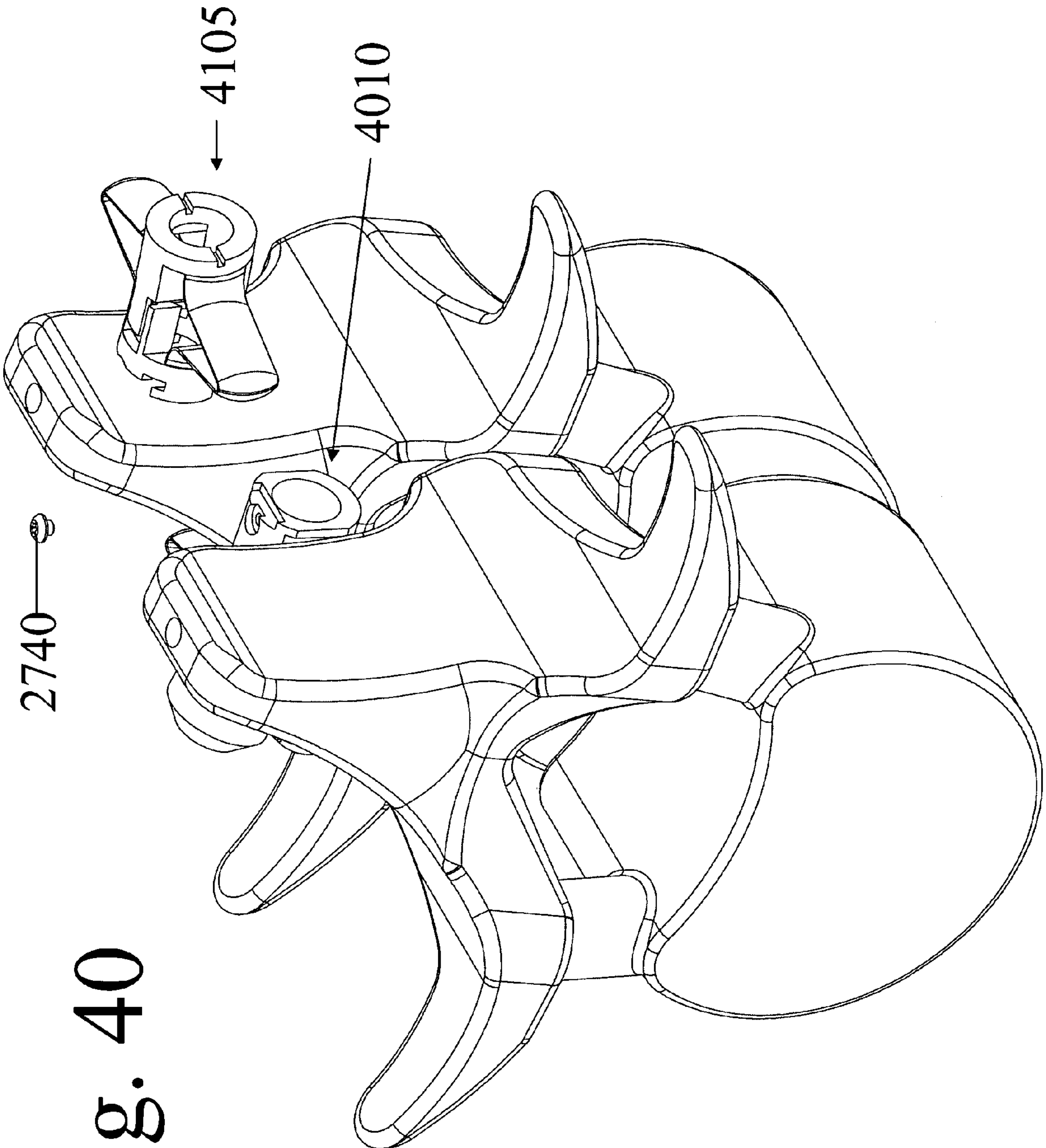


Fig. 40

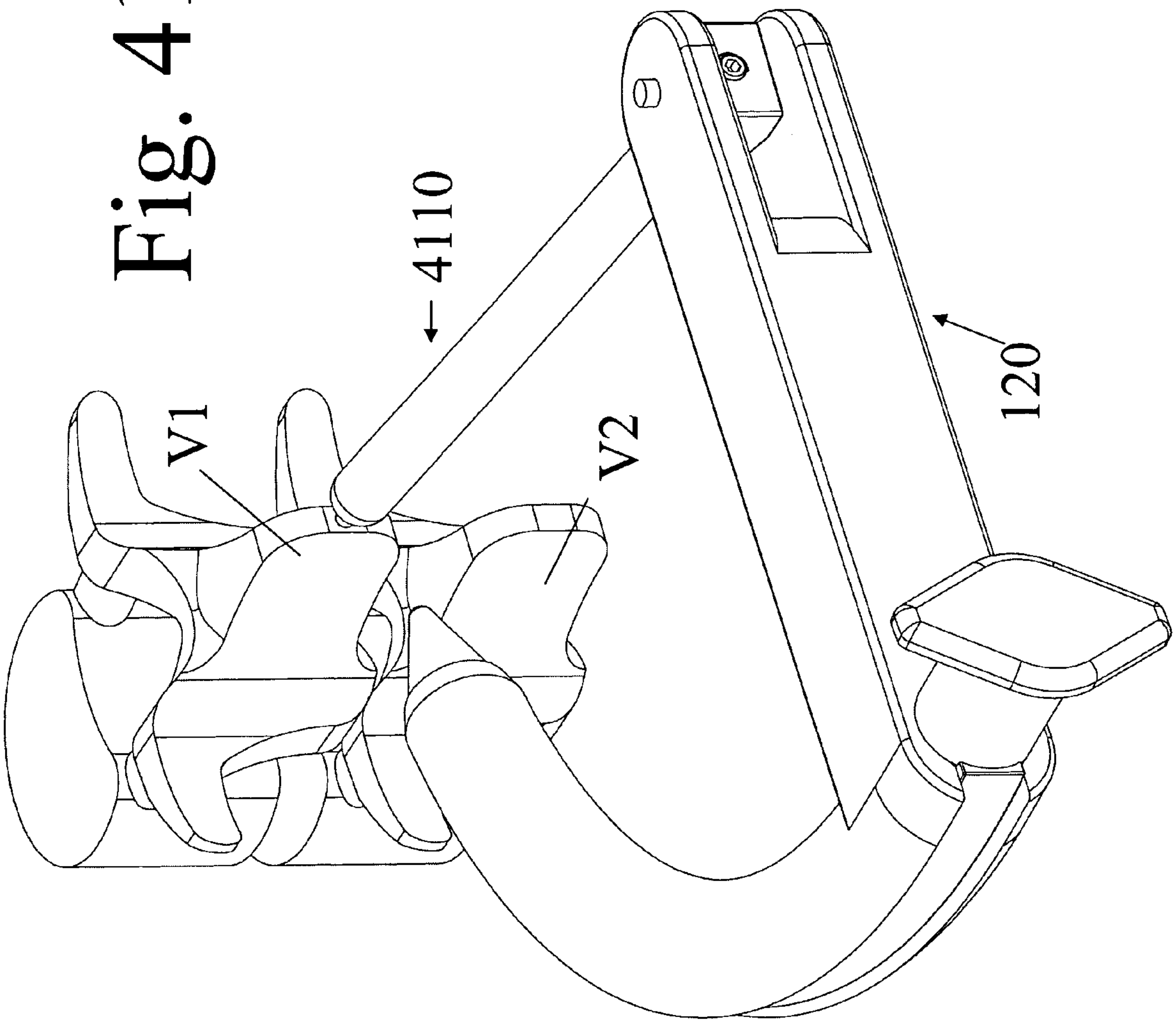


Fig. 41

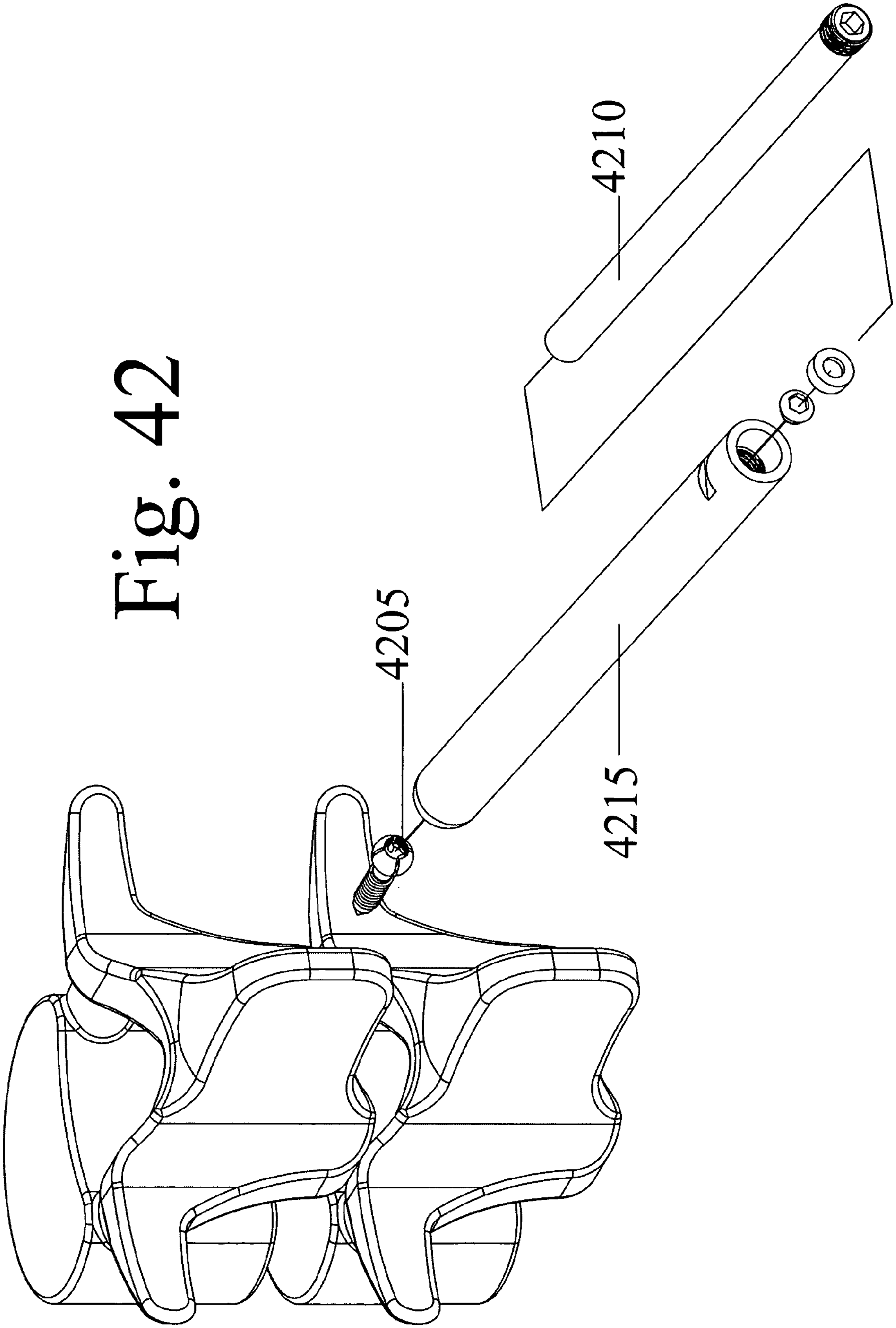
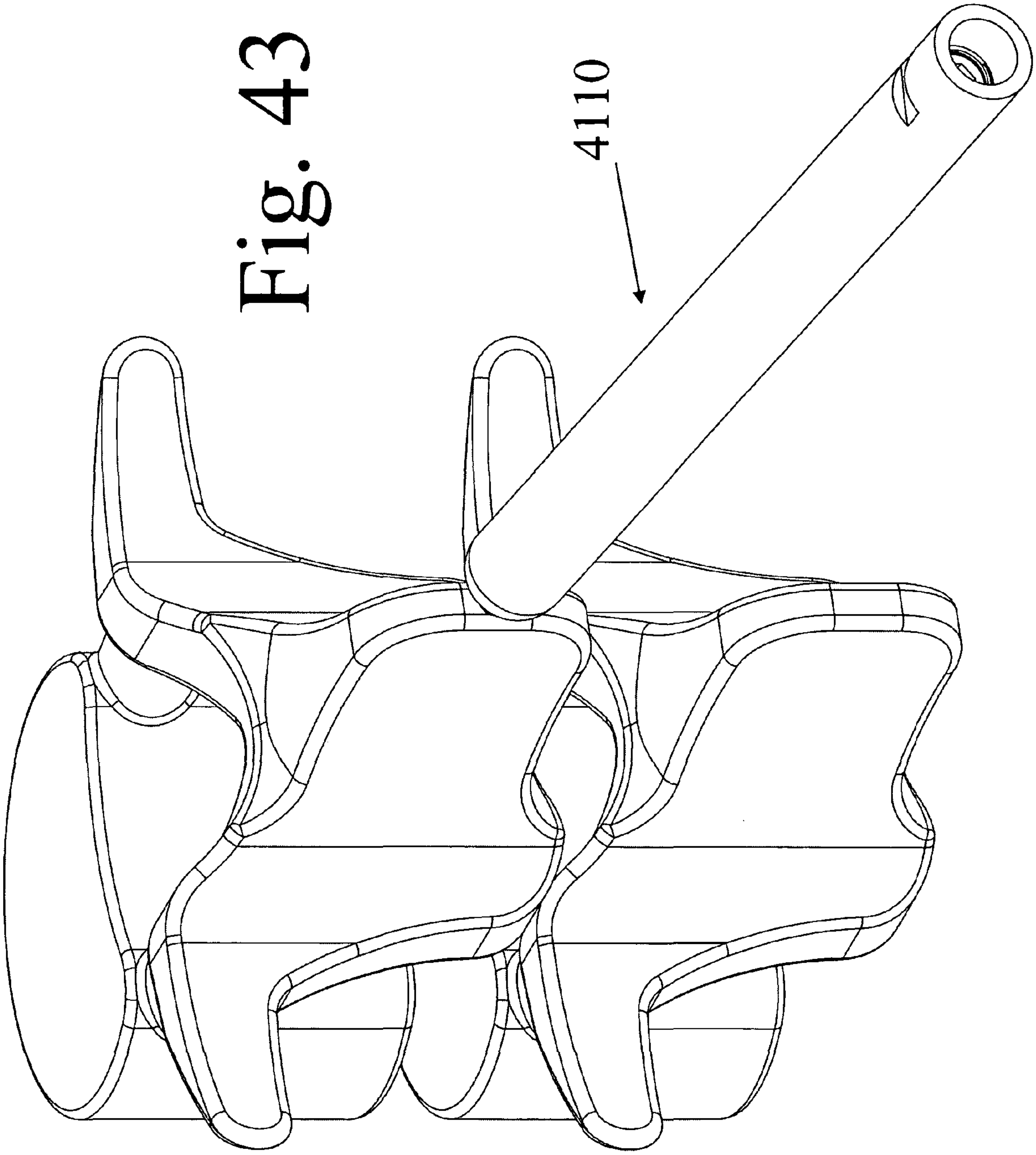


Fig. 42

Fig. 43



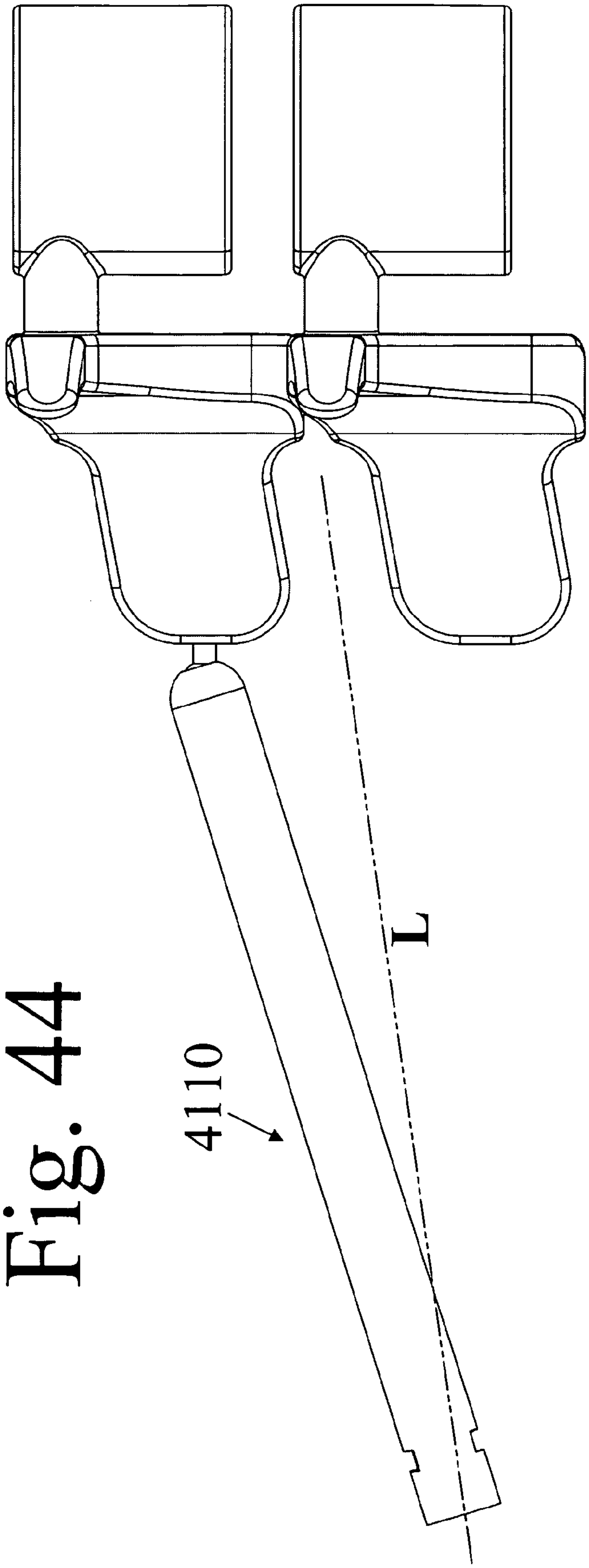


Fig. 44

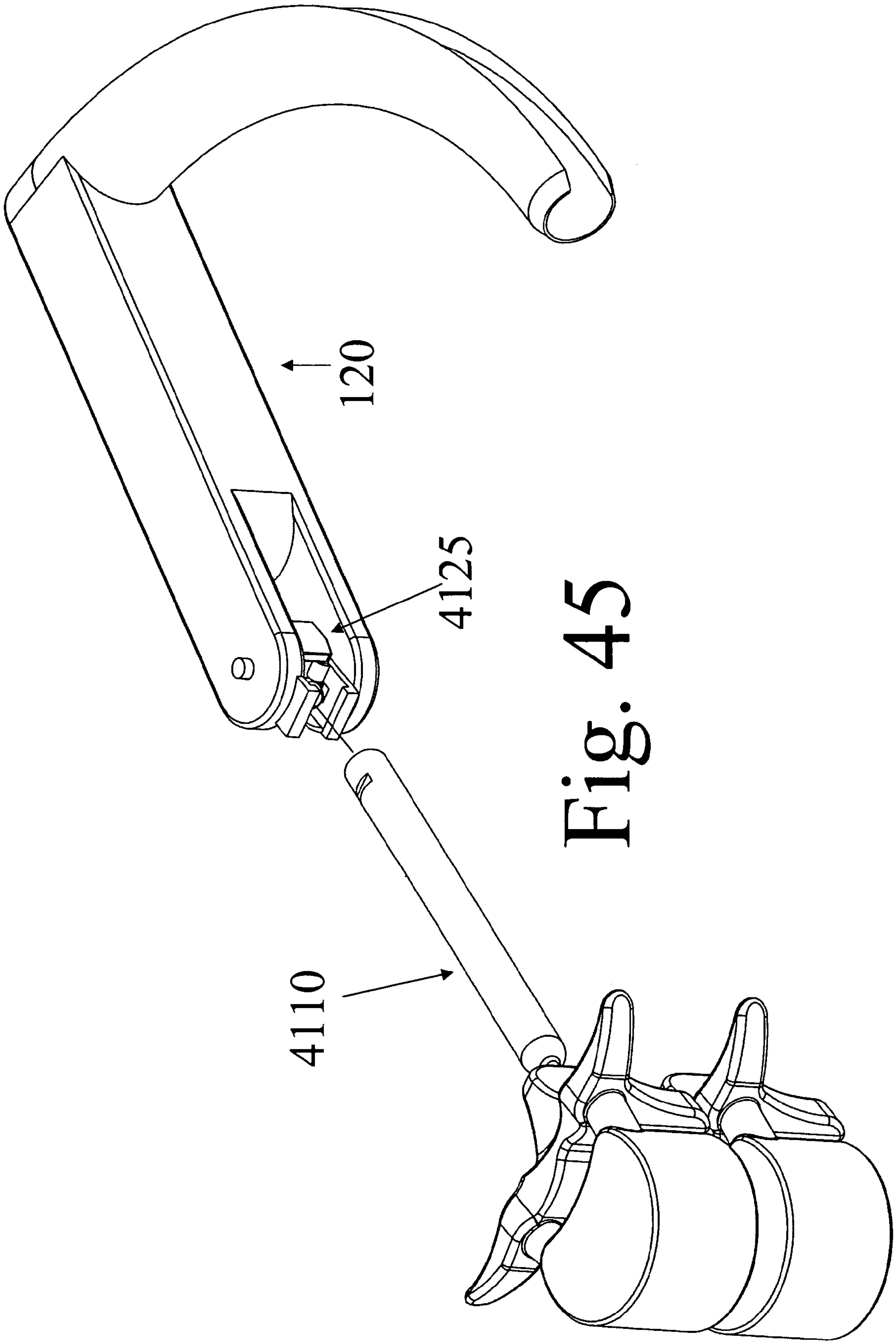


Fig. 45

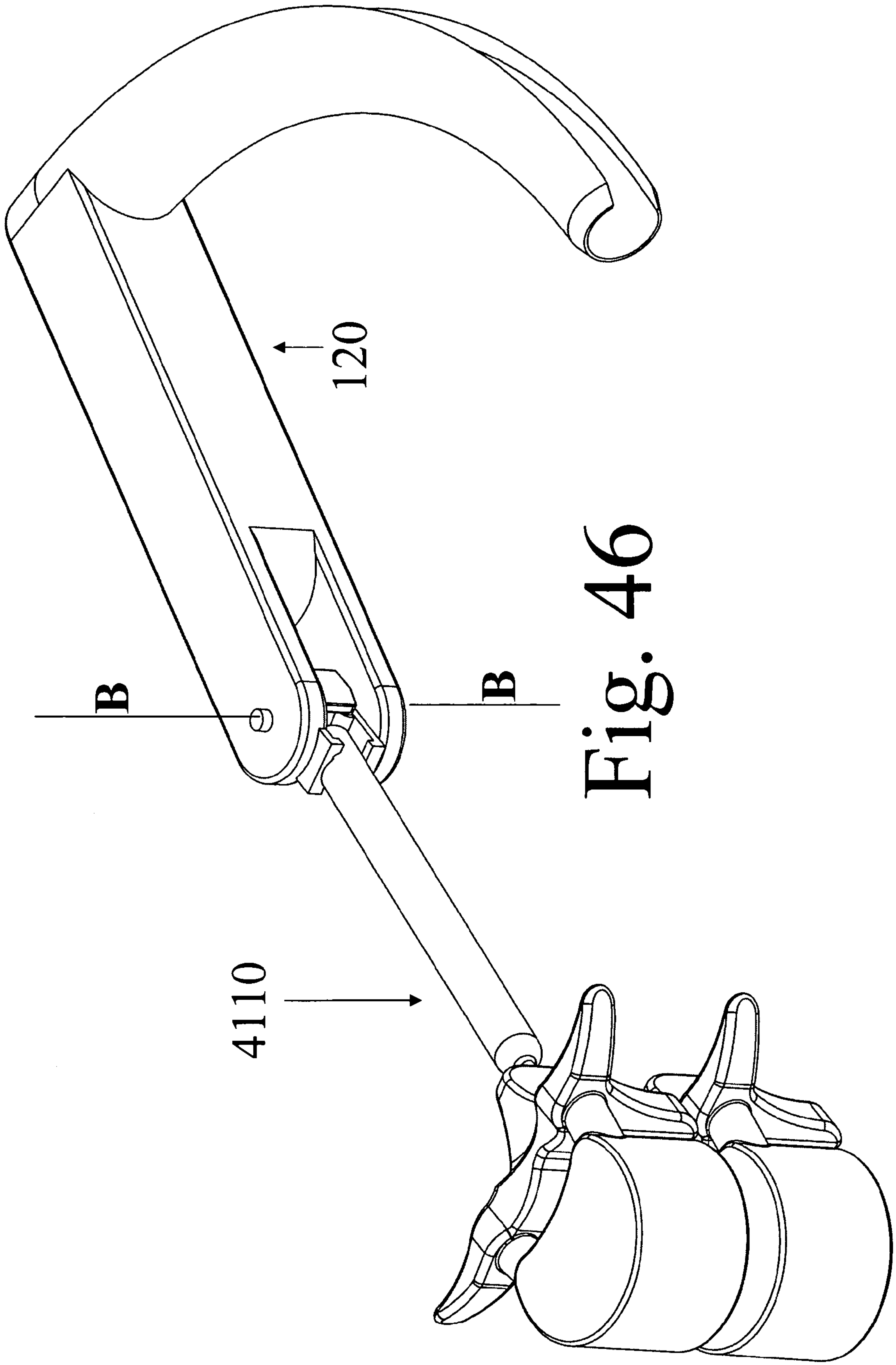


Fig. 46

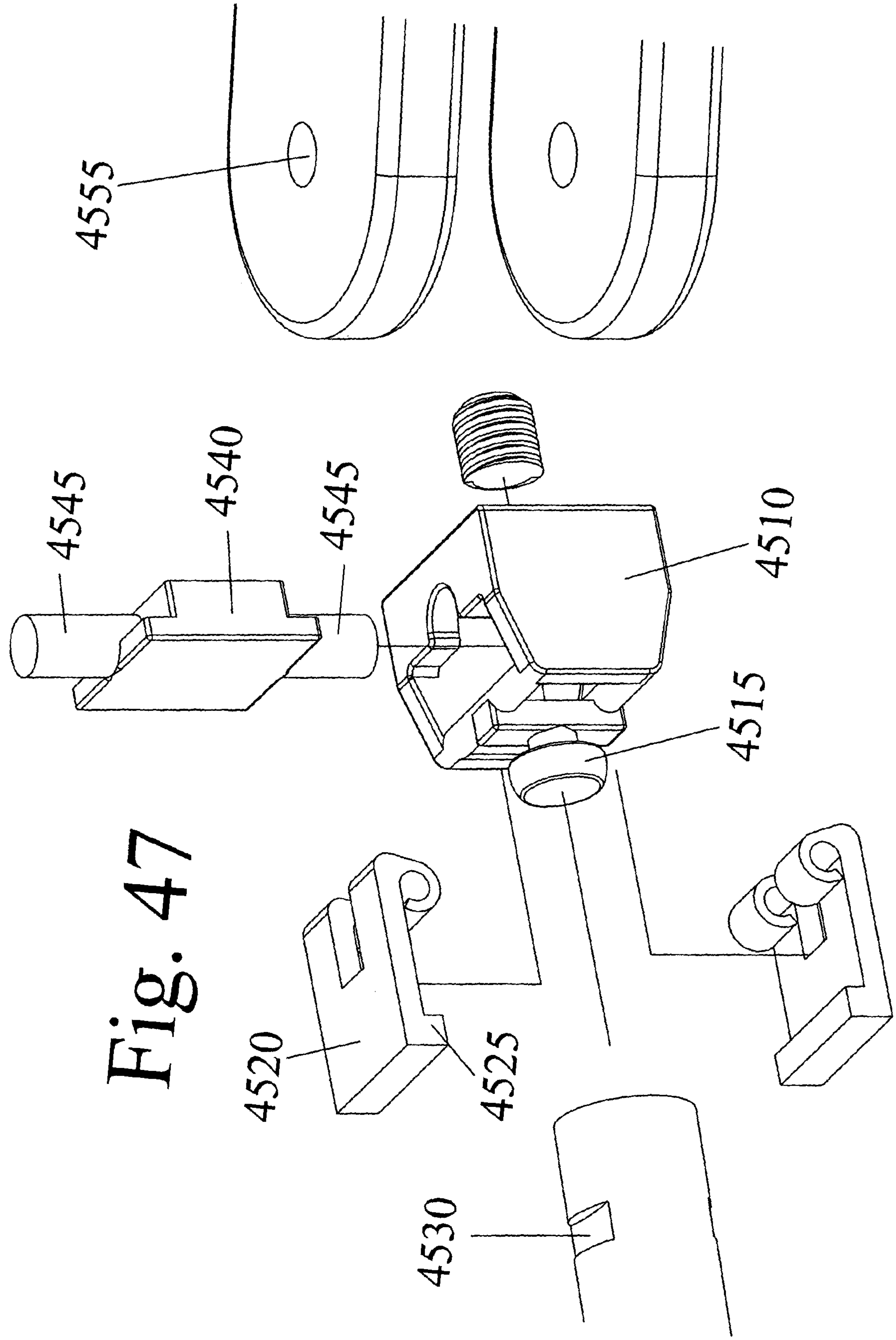


Fig. 47

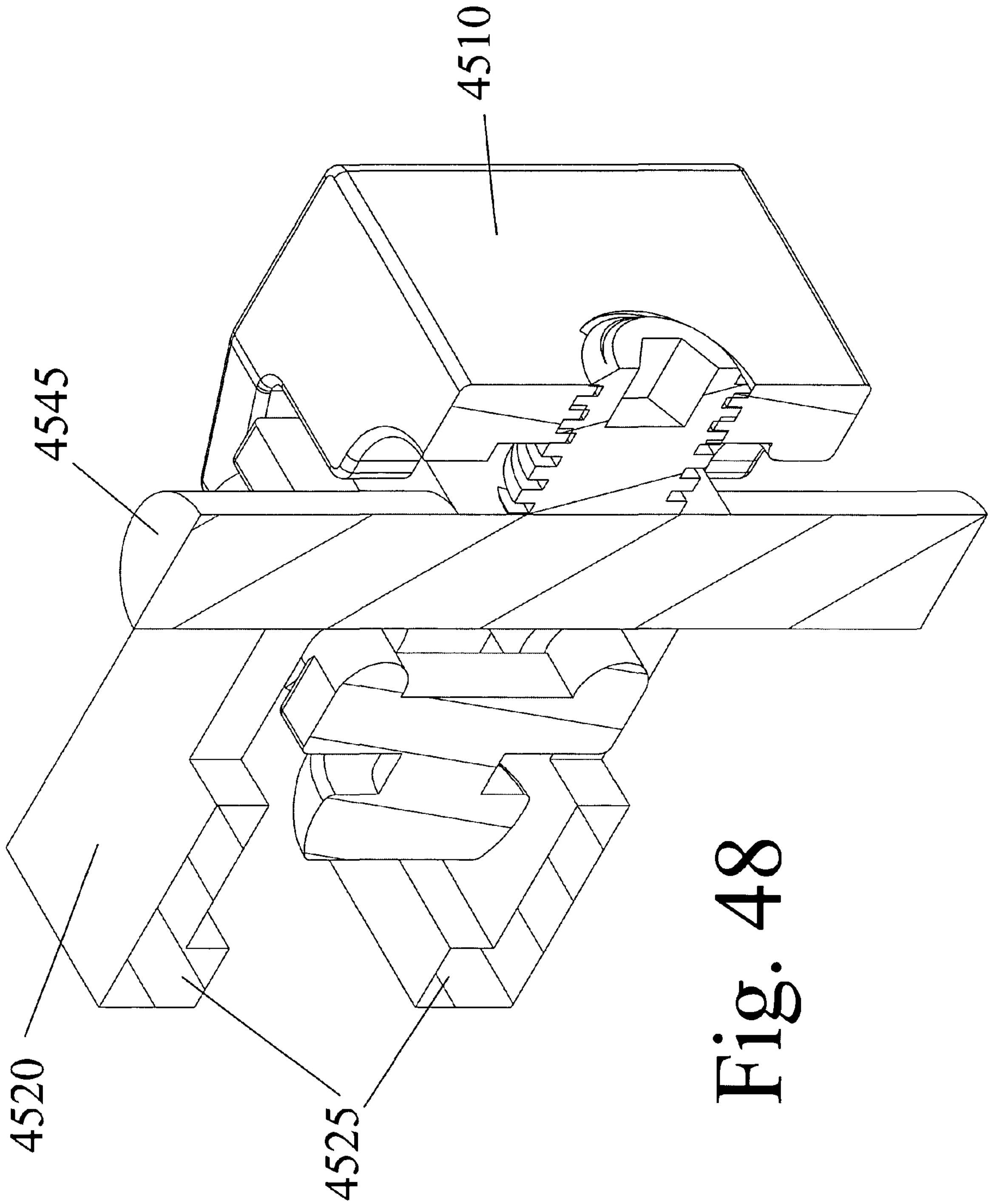


Fig. 48

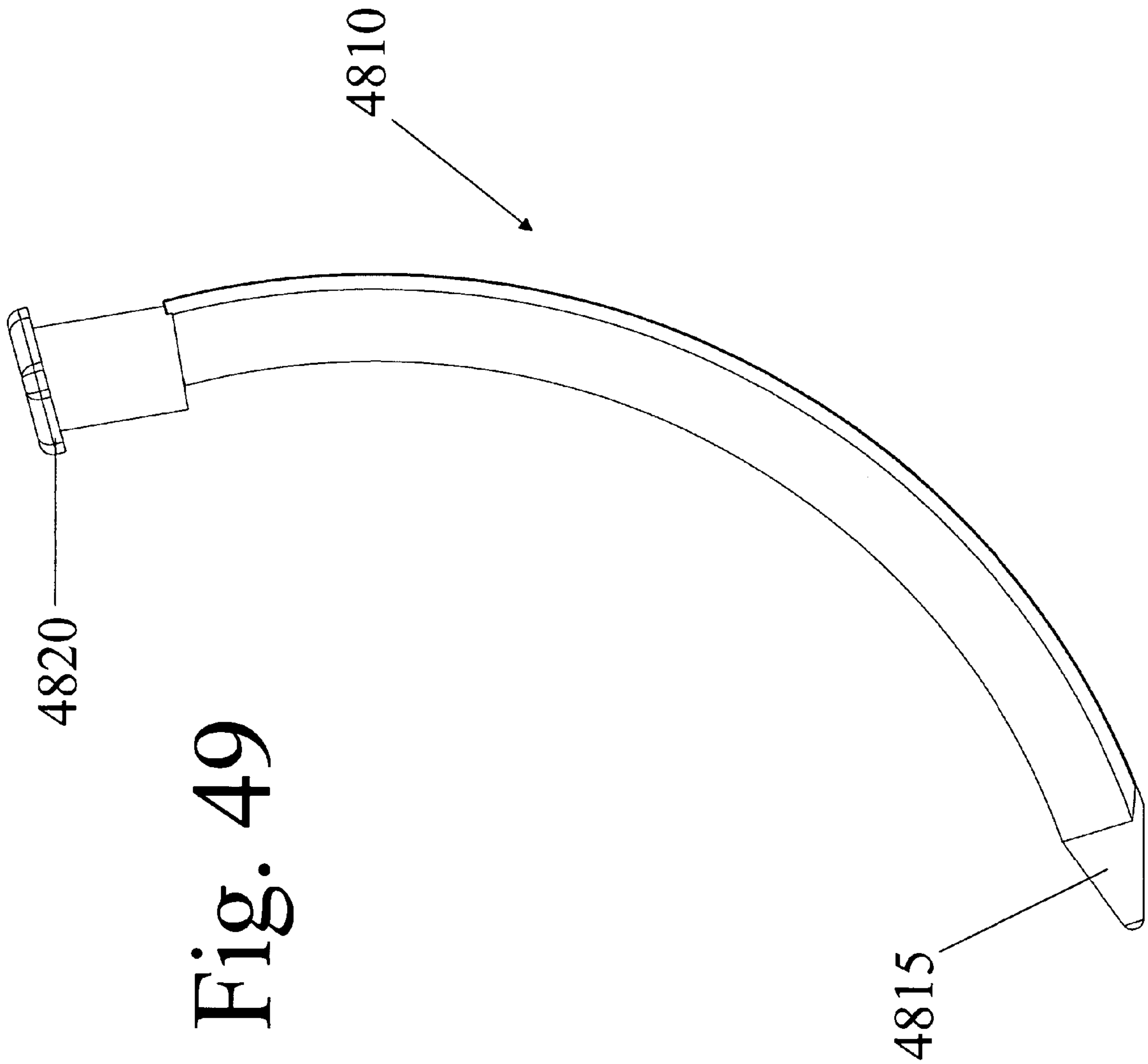


Fig. 49

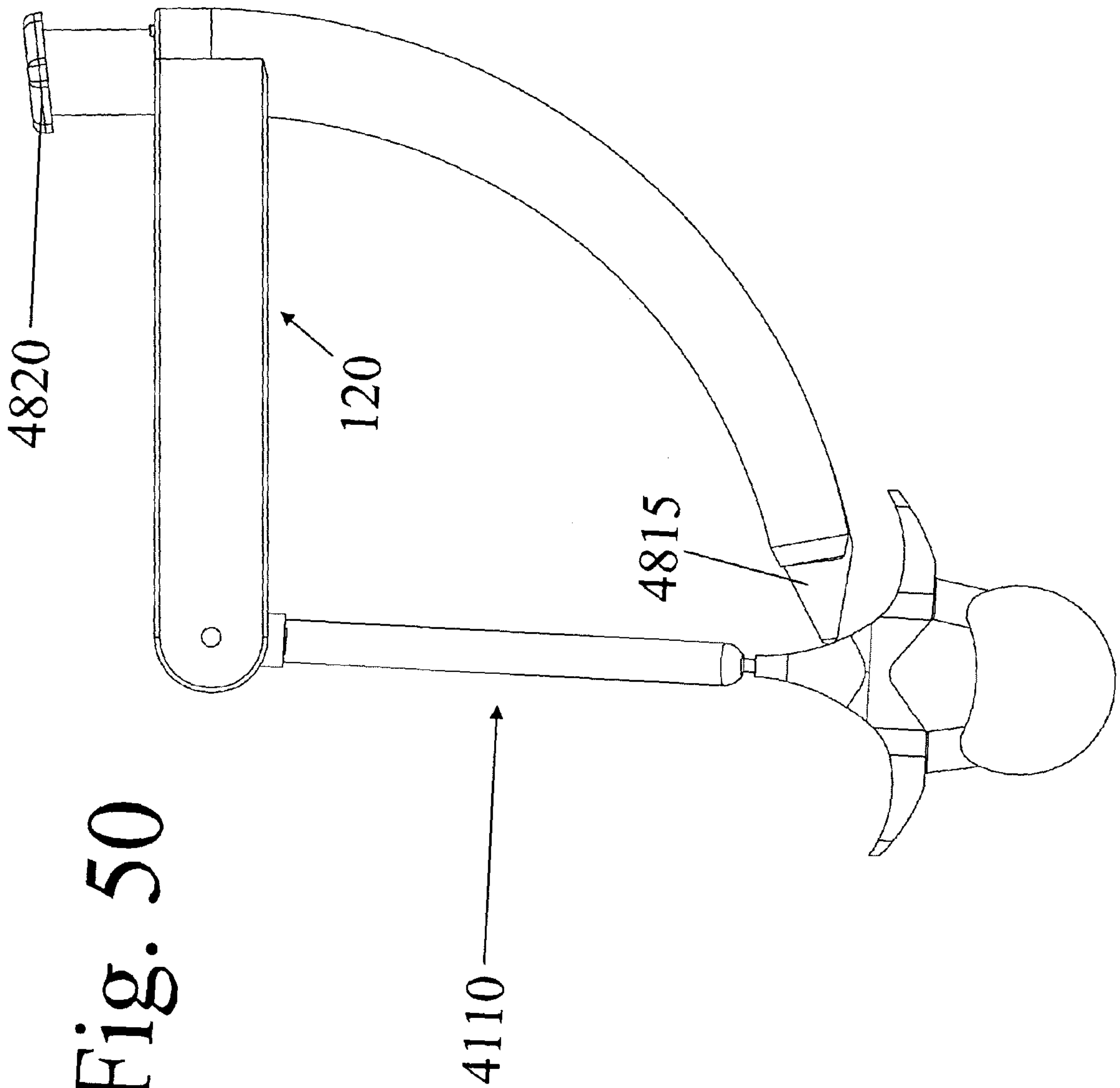


Fig. 50

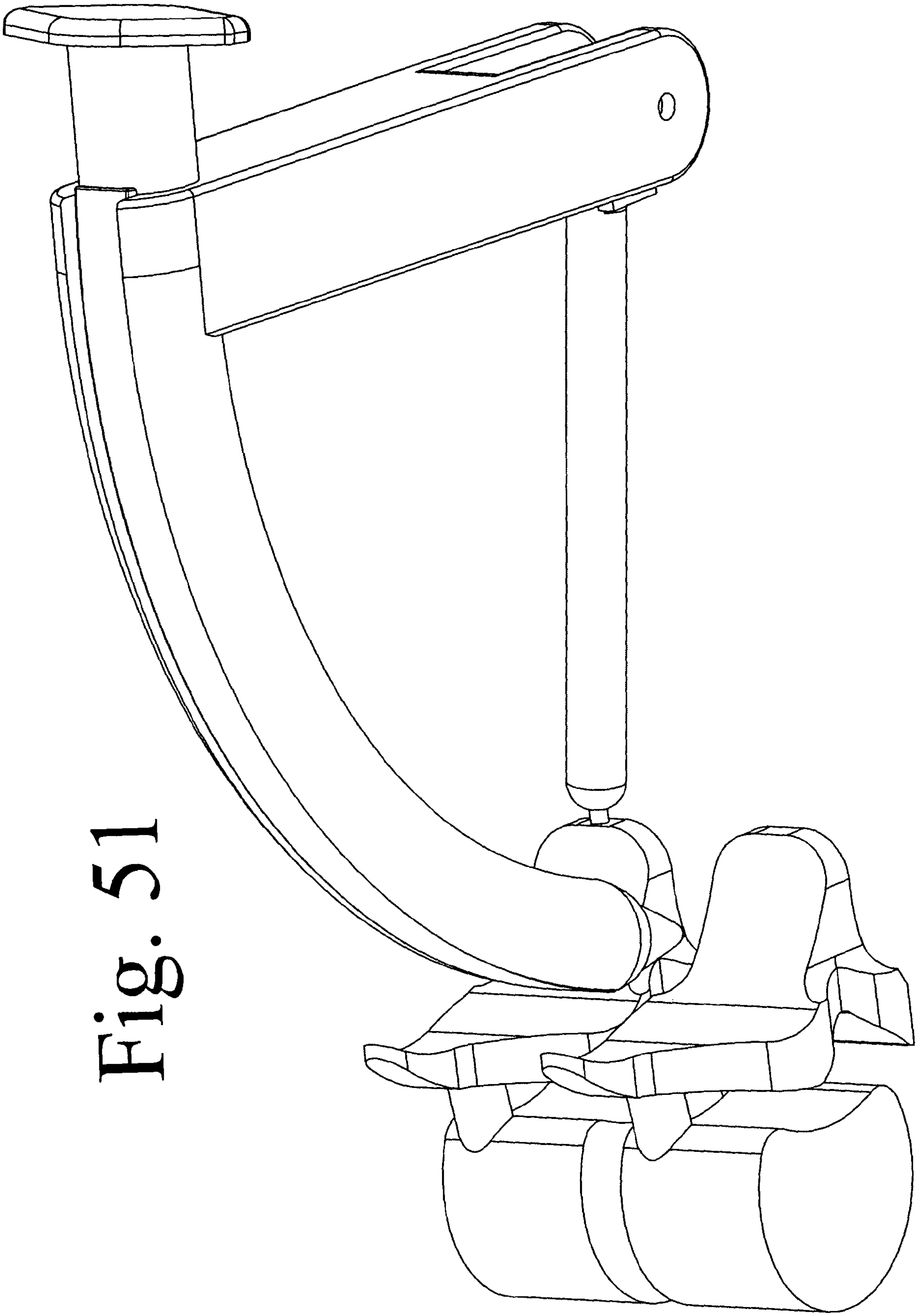


Fig. 51

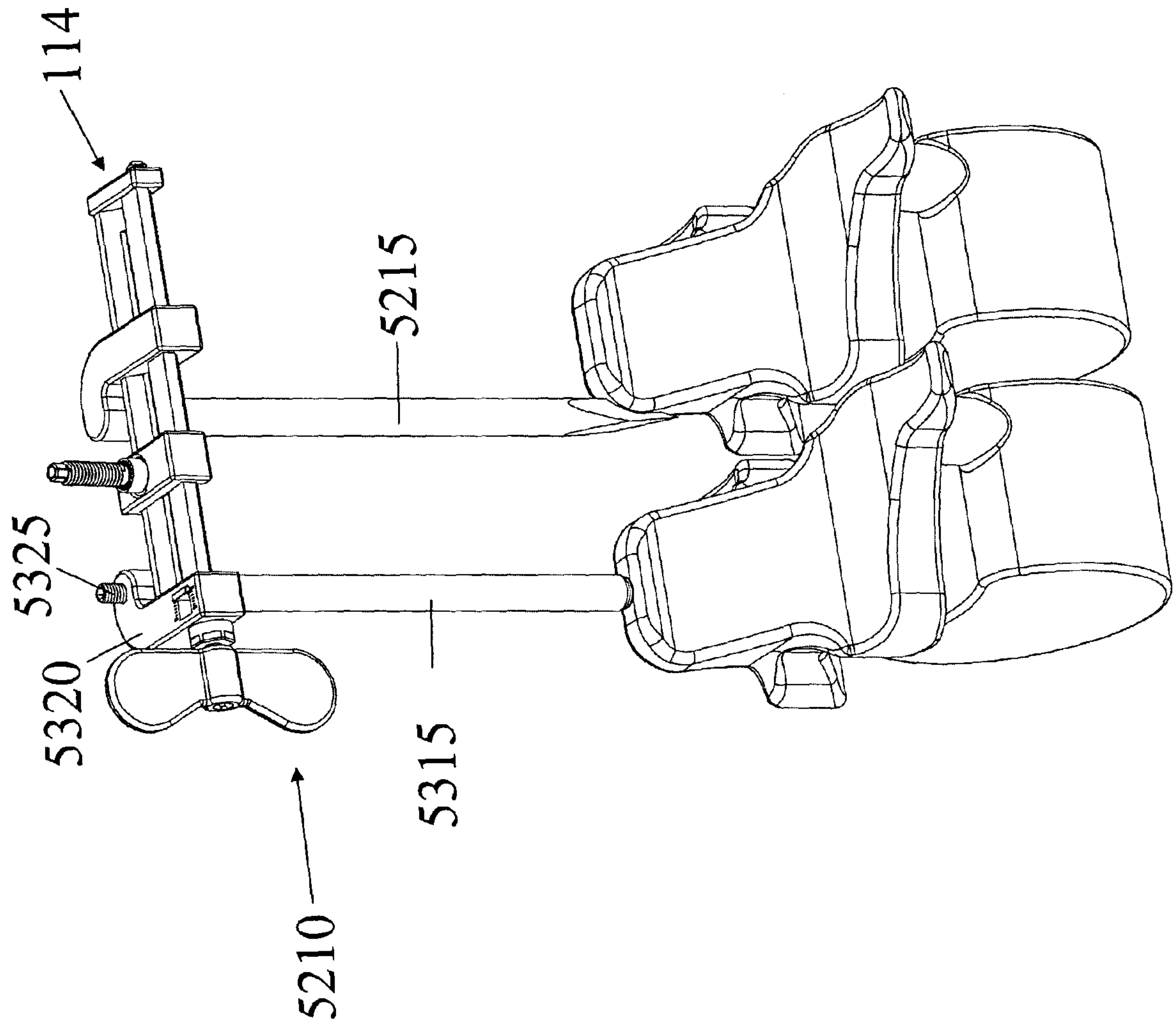
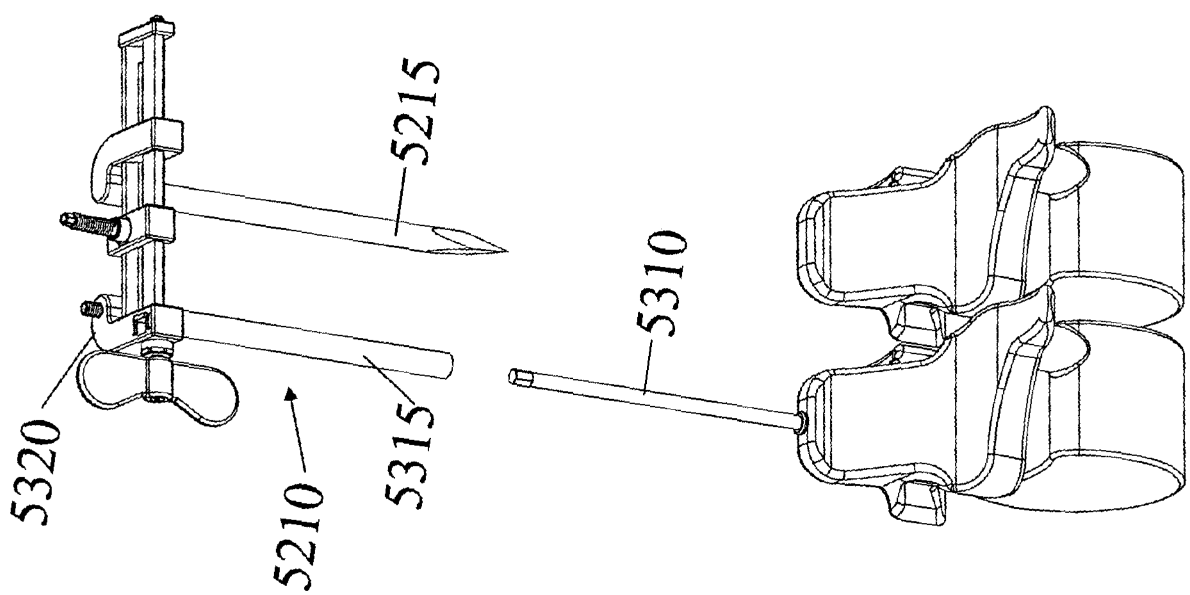


Fig. 52

Fig. 53



DEVICES AND METHODS FOR INTER-VERTEBRAL ORTHOPEDIC DEVICE PLACEMENT

REFERENCE TO PRIORITY DOCUMENT

This application claims priority of U.S. Provisional Patent Application Ser. No. 60/631,213, filed Nov. 24, 2004 and U.S. Provisional Patent Application Ser. No. 60/713,235, filed Aug. 31, 2005. Priority of the aforementioned filing dates is hereby claimed, and the disclosures of the Provisional Patent Applications are hereby incorporated by reference in their entirety.

BACKGROUND

The disclosure relates to devices and methods for implantation of an orthopedic device between skeletal segments using limited surgical dissection. The implanted devices are used to adjust and maintain the spatial relationship(s) of adjacent bones. Depending on the implant design, the motion between the skeletal segments may be increased, limited, modified, or completely immobilized.

Progressive constriction of the central canal within the spinal column is a predictable consequence of aging. As the spinal canal narrows, the nerve elements that reside within it become progressively more crowded. Eventually, the canal dimensions become sufficiently small so as to significantly compress the nerve elements and produce pain, weakness, sensory changes, clumsiness and other manifestation of nervous system dysfunction.

Constriction of the canal within the lumbar spine is termed lumbar stenosis. This condition is very common in the elderly and causes a significant proportion of the low back pain, lower extremity pain, lower extremity weakness, limitation of mobility and the high disability rates that afflict this age group. The traditional treatment for this condition has been the surgical removal of the bone and ligamentous structures that constrict the spinal canal. Despite advances in surgical technique, spinal decompression surgery can be an extensive operation with risks of complication from the actual surgical procedure and the general anesthetic that is required to perform it. Since many of these elderly patients are in frail health, the risk of developing significant peri-operative medical problems remains high. In addition, the traditional treatment of surgical resection of spinal structures may relieve the neural compression but lead to spinal instability in a substantial minority of patients. That is, removal of the spinal elements that compress the nerves may cause the spinal elements themselves to move in an abnormal fashion relative to one another and produce pain. Should it develop, instability would require additional and even more extensive surgery in order to re-establish spinal stability. Because of these and other issues, elderly patients with lumbar stenosis must often choose between living the remaining years in significant pain or enduring the potential life-threatening complications of open spinal decompression surgery.

Recently, lumbar stenosis has been treated by the distraction—instead of resection—of those tissues that compress the spinal canal. In this approach, an implantable device is placed between the spinous processes of the vertebral bodies at the stenotic level in order to limit the extent of bone contact during spinal extension. Since encroachment upon the nerve elements occurs most commonly and severely in extension, this treatment strategy produces an effective increase in the size of the spinal canal by limiting the amount of spinal extension. In effect, distraction of the spinous processes changes the local bony anatomy and decompresses the nerves by placing the distracted spinal segment into slight flexion.

A number of devices that utilize this strategy have been disclosed. U.S. Pat. Nos. 6,451,020; 6,695,842; 5,609,634; 5,645,599; 6,451,019; 6,761,720; 6,332,882; 6,419,676; 6,514,256; 6,699,246 and other illustrate various spinous process distractors. Unfortunately, the placement of each device requires exposure of the spinous processes and the posterior aspect of the spinal column. Thus, these operations still present a significant risk of peri-operative complications in this frail patient population.

It would be desirable to design an improved method for the placement of an orthopedic device between the spinous processes of adjacent spinal segments. A workable method of percutaneous delivery would reduce the surgical risks of these procedures and significantly increase the usefulness of these spinous process distractors. This application discloses a device for the percutaneous placement of inter-spinous process implants. The method of use provides a reliable approach that maximizes the likelihood of optimal device placement and obviates the need for open surgery.

SUMMARY

Disclosed are devices and methods that can accurately place an orthopedic device between adjacent spinous processes. The devices and methods employs a percutaneous approach and constitutes the least invasive method of delivery system yet devised. Also disclosed are various instruments for implant placement and the implant itself.

Pursuant to a procedure, a patient is placed on his side or in the prone position. The hips and knees are flexed and the procedure is performed under x-ray guidance. The level of interest is identified radiographically and bone screws are percutaneously inserted into the spinous processes of the upper and lower vertebras of the stenotic level. A distractor is placed onto the two screws and a needle is placed through the distractor platform and guided into the space between the spinous processes under X-ray guidance. The tip of the needle is guided into the exact position where the implant needs to be placed. The needle is marked so that the distance from the needle tip to the center of rotation of the insertion device (discussed below) can be measured. The platform is then immobilized relative to the rest of the distractor and the spinous processes of the stenotic level are gently distracted. In order to gauge the extent of distraction and better standardize the procedure, a measure of the force of distraction is displayed by the distraction device. The localizing needle is removed.

A curvilinear device is attached to the platform. The device has a guide arm that rotates about a central point so as to form an arc. Since the distance from the guide arm's center of rotation to the tip of the localizing needle is known, a guide arm of radius equal to that distance will necessarily form an arc that contains the needle point on its circumference. A trocar with a knife-like tip is placed through the central channel in order to divide tissue before the advancing guide arm. The guide arm is them rotated through the skin and underlying tissue until the distal end of the guide arm abuts the side of the ligament between the spinous processes at the stenotic level. Using this method, a curvilinear path is created to the point marked by the needle tip in a completely percutaneous manner and without any open surgical tissue dissection.

The trocar is removed from the guide arm's central canal. The central canal is then used to deliver the implant to the desired point between the spinous processes. Alternatively, a solid guide arm may be used with the implant attached to the tip.

The placement system described herein provides an easy and reliable way of placing an orthopedic device within the inter-spinous ligament. Using this method, the implant can be placed rapidly, precisely, with a few small skin incisions and the absolute minimum amount of tissue dissection. It permits minimally invasive device placement using only local anesthesia into those afflicted patients who are least able to withstand the stress of open surgical intervention.

In one aspect, there is disclosed a distractor instrument, comprising: a first distractor member that engages at a distal end to a first skeletal segment; a second distractor member that engages at a distal to a second skeletal segment; a distractor device mounted to proximal ends of the first and second distractor members; and a distraction actuator attached to the distractor device, wherein the distraction actuator is actuated to apply a distraction force to the first and second distractor members to distract the first and second skeletal segments relative to one another.

In another aspect, there is disclosed a distractor instrument, comprising first and second distraction members that each engage a respective skeletal segment, wherein the distraction members can be distracted to cause distraction of the skeletal segments.

In another aspect, there is disclosed a method of distracting a pair of spinous processes, comprising using one or more distractor elements to engage the spinous processes to apply a distraction force to the spinous processes.

In another aspect, there is disclosed a minimally-invasive surgical procedure, comprising localizing a surgical point of interest using a localizing needle that points to the point of interest; and placing an implant at the point of interest using the localizing needle as a guide.

In another aspect, there is disclosed a minimally-invasive surgical procedure, comprising localizing a surgical point of interest using an x-ray to identify the point of interest; relating the point of interest to a delivery apparatus; and delivering an implant to the point of interest using an inserter device that pivots about a central axis such that the inserter device travels along a curvilinear path that contains the localized point of interest.

In another aspect, there is disclosed a skeletal implant holder, comprising a hand-operated handle assembly; and a holder assembly attached to the handle assembly. The holder assembly is configured to be removably attached to an implant, wherein the handle assembly can be actuated to secure the implant to the holder assembly and to detach the implant from the holder assembly, and wherein the holder assembly is configured to apply a first force to the implant in a first direction and a second force to the implant in a second direction opposite the first direction when the handle assembly is actuated.

In another aspect, there is disclosed an implant for implanting between a pair of skeletal segments, comprising a first segment; at least one wing attached to the first segment, the wing movable between a collapsed configuration and an expanded configuration wherein the wing can engage a skeletal segment as an anchor when in the expanded configuration; and a second segment removably attached to the first segment, wherein the second segment can be detached from the first segment to disengage the wing from the skeletal segment.

These and other features will become more apparent from the following description and the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** shows a perspective, assembled view of a distractor device **100** for implanting an orthopedic device between skeletal segments, such as between a first vertebral body V**1** and a second vertebral body V**2**.

FIG. **2**A shows a perspective view of the device with an insertion device detached.

FIG. **2**B shows an exploded view of a platform of the device.

FIG. **3** shows a perspective view of the device with the platform removed.

FIG. **4** shows a cross-sectional view of sheaths with screws positioned therein.

FIG. **5** shows an enlarged, cross-sectional view of the upper region of a sheath with a turn screw and a distraction screw a mounted therein.

FIG. **6** shows a perspective view of the device with a localizing needle coupled thereto.

FIG. **7** shows a perspective view of the device with a locking instrument coupled to the platform for locking and unlocking the localizing needle.

FIG. **8** shows a cross-sectional view of the locking instrument attached to the platform.

FIG. **9** shows a partial exploded view of the platform and shows an exemplary mechanism for effectuating distraction.

FIG. **10** shows a partial cross-sectional view of the platform in an assembled state.

FIG. **11** shows an enlarged cross-sectional view of the platform in the region of a force pointer that provides a measure of distraction force provided to vertebral bodies.

FIG. **12** shows an enlarged view of the pointer and corresponding markings on the platform.

FIG. **13** shows an enlarged view of the locking mechanism and localizing needle.

FIG. **14** shows the platform with the locking mechanism and localizing needle coupled thereto.

FIG. **15**A shows the device with the platform positioned before it had been moved by a turn screw.

FIG. **15**B shows the platform after movement.

FIG. **16** is a perspective view of the device showing how the insertion device is pivotably attached to the platform.

FIGS. **17**A and **17**B show enlarged views of the attachment member of the insertion device being lowered onto the attachment screw of the platform.

FIG. **18** shows a cross-sectional view of the attachment member attached to the attachment screw.

FIG. **19** shows the device including the pivotably mounted insertion device attached to a pair of vertebral bodies.

FIGS. **20**-**22** sequentially illustrate how the insertion device swings toward the target location where the implant is to be positioned.

FIG. **23** shows the device with a trocar member removed.

FIGS. **24**A, **24**B, and **24**C show an exemplary sizing device for determining the appropriate size of an implant.

FIGS. **25** and **26** shows an implant holder device that can be used to hold an implant and install the implant via the internal shaft in the installer device.

FIGS. **27**A and **27**B show the implant with extendable wings in an undeployed (FIG. **27**A) and a deployed state (FIG. **27**B).

FIG. **28** shows an enlarged view of a portion of the implant coupled to the holder device.

FIG. **29** shows a cross-sectional view of the implant attached to the holder.

FIG. **30** shows a close-up view of the implant attached to the holder.

FIG. **31** shows the implant locked onto the holder with a handle in a locked position.

FIG. **32** shows a close-up, cross-sectional view of the implant end of the holder.

FIG. **33** shows the holder and attached implant just prior to insertion into the internal shaft of the curved portion.

FIG. **34** shows the device with the holder and implant in a ready-to-deploy state.

FIG. **35** shows the device with the holder and implant in a deployed state.

FIG. **36** shows a cross-sectional view of the deployed holder and implant.

FIG. **37** shows a close-up view of the implant coupled to the holder.

FIG. **38** shows the implant deployed between the vertebral bodies and the holder removed from the device.

FIG. **39** shows the implant deployed between the vertebral bodies after the inserter device has been rotated out of the soft tissue and the device and distraction screws have been removed.

FIG. **40** shows how a screw may be removed and the implant disassembled.

FIG. **41** shows another embodiment of a device with a swinging or pivoting installer device.

FIG. **42** shows a mounting post in an exploded state.

FIG. **43** shows the mounting post attached to a vertebral body.

FIG. **44** shows a free end of the post a positioned along a line L parallel to the inter-spinous space.

FIG. **45** shows the insertion device prior to attachment to the post.

FIG. **46** shows the insertion device attached to the post.

FIG. **47** shows an exploded view of an attachment device for attaching the insertion device to the post.

FIG. **48** shows a cross-sectional view of the attachment device.

FIG. **49** shows a side view of a plunger that couples into the insertion device.

FIG. **50** shows a side view of the device with the plunger positioned inside the curved portion of the insertion device.

FIG. **51** shows a perspective view of the insertion device with a tapered end contacting the lateral side of the inter-spinous space.

FIG. **52** shows a perspective view of another embodiment of a distractor device coupled to vertebral bodies.

FIG. **53** shows another perspective view of the distractor device of FIG. **52**.

DETAILED DESCRIPTION

Disclosed are methods and devices for implanting a device (such as an orthopedic device) between skeletal segments (such as vertebrae), using limited surgical dissection. The implanted devices are used to adjust and maintain the spatial relationship(s) of adjacent bones.

FIG. **1** shows a perspective, assembled view of a distractor device **100** for implanting an orthopedic device between skeletal segments, such as between a first vertebral body V**1** and a second vertebral body V**2**. For clarity of illustration, the vertebral bodies are represented schematically and those skilled in the art will appreciate that actual vertebral bodies include anatomical details not shown in FIG. **1**. Moreover, although described in the context of being used with vertebrae, it should be appreciated the device **100** and associated methods can also be used with other skeletal segments.

The device **100** generally includes a pair of anchors that include elongate distraction screws **110***a* and **110***b* (collectively screws **110**), a platform **115**, and an insertion device **120** that is pivotably attached to the platform **115** via an attachment member. A curvilinear trocar **117** is removably mounted in a hollow shaft of the insertion device **120**. Each of the distraction screws **110** is attached at a distal end to a respective vertebral body. In this regard, the distal end of each screw can include a structure for attaching to the vertebral body, such as a threaded shank. The proximal ends of the distraction screws **110** are attached to the platform **115**. The screws **110** are axially positioned within sheaths that surround the screws and extend downwardly from the platform **115**, as described below with reference to FIGS. **3-4**.

The insertion device **120** is pivotably attached to the platform **115** such that the insertion device **120** can pivot about an axis B. The insertion device **120** includes a connecting arm **130** that extends outwardly from the platform **115**, and a curved portion **140** that curves toward the vertebral bodies from an outward tip of arm **130**. Arm **130** has a length R that corresponds to a radius of curvature of the curved portion **140**. Thus, when the insertion device **120** pivots about the axis B, the curved member **140** moves along a curved or arced pathway of radius R. The curved portion **140** can include an internal guide shaft that extends through the curved portion **140** along the entire length of the curved portion **140**. The guide shaft is sized and shaped to slidably receive the trocar **117**. The radius of curvature of the curved portion **140** can vary. As described in detail below, the curved portion **140** acts as a guide for guiding an implant device to a position between the vertebral bodies

FIG. **2**A shows a perspective view of the device **100** with the insertion device **120** detached. The platform **115** includes a rail **205** that extends between the screws **110** along a direction generally parallel to the axis of the spine. As mentioned, each screw **110** extends upwardly from a respective vertebral body and attaches at a proximal end to the platform **115**. The screw **110***a* attaches to a member **207** that is fixedly attached to the rail **205**. The screw **100***b* attaches to a member **209** that is slidably attached to the rail **205**. A distraction actuator, such as a thumb screw **212**, can be actuated (such as rotated) to distract the screws **110** (and the attached vertebral bodies) relative to one another, as described below.

With reference still to FIG. **2**A, a mount **210** is slidably attached to the platform **115** such that the mount **210** can slide along the length of the rail **205**, although the position of the mount **210** can be locked relative to the platform **115**, as described below. The mount **210** includes a hollow-shafted attachment screw **215** that can be used to removably attach the insertion device **120** to the platform **115**. The attachment screw **215** can also be used to attach a localizing needle (described below) to the device **100**. FIG. **2**B shows an exploded view of the platform **115**.

FIG. **3** shows a perspective view of the device **100** with the platform **115** removed from the screws **110**. As mentioned above, the screws **110***a* and **110***b* are axially positioned within corresponding sheaths **410***a* and **410***b*, respectively. FIG. **4** shows a cross-sectional view of the sheaths **410** with the screws **110** positioned therein. For clarity of illustration, the platform **115** is not shown in FIG. **4**. Each sheath **410** has a hollow, internal shaft that is sized to slidably receive a respective screw **110**. The internal shaft of the sheath **410***a* terminates at an upward end while the internal shaft of the sheath **410***b* extends entirely through the sheath **410** to form a hole in the upper end of the sheath **410***b*.

With reference to FIGS. **3** and **4**, a vertical adjustment actuator, such as a turn screw **415**, is positioned in the shaft of the sheath **410***b* above the screw **110***b*. The vertical adjustment actuator is actuated to adjust the vertical position of the platform **115** relative to the vertebral bodies. It should be appreciated that use of terms such as vertical, upward, downward, etc. are with reference to the figures and are not intended to limit actual use.

An exemplary configuration for such vertical adjustment is now described. An upper region of the turn screw **415** protrudes upwardly out of the platform **1115**, as best seen in FIG. **3**. FIG. **5** shows an enlarged, cross-sectional view of the upper region of the sheath **410***b* with the turn screw **415** and distraction screw **110***b* mounted therein. The turn screw **415** has outer threads that mate with threads on the inner shaft of the sheath **410***b*. A lower edge of the turn screw **415** abuts an upper edge of the distraction screw **110***b*. When the turn screw **415** is rotated, the lower edge of the screw **415** moves downwardly or upwardly depending on the direction of rotation. The abutment of the turn screw **415** with the distraction screw **110***b* causes the sheath **410***b* (and the attached platform **115**) to rise or drop relative to distraction screw **110***b* and the vertical bodies when the turn screw **415** is rotated. In this manner, the vertical position of the platform **415** can be adjusted by rotating the turn screw **415**.

FIG. **6** shows a perspective view of the device **100** with a localizing needle **610** coupled thereto. As mentioned, the localizing needle **610** can be inserted through the attachment screw **215**. The localizing needle **610** has a length such that a distal tip **615** of the needle **610** can be positioned at or substantially near a target location where an implant is to be placed. The localizing needle **610** includes one or more hatch markings **620**. Each hatch marking **620** indicates the distance from the distal tip **615** of the localizing needle **610** to the hatch marking for purposes of selecting an appropriately-sized insertion device **120** for delivering an implant to the location identified by the distal tip **615**, as described more fully below.

The localizing needle **610** can be locked or unlocked relative to the platform **115**. When unlocked, the position and orientation of the localizing needle **610** can be adjusted relative to the platform **115**. For example, the localizing needle **610** can rotate or pivot to adjust the orientation of the axis of the localizing needle **610**. The localizing needle **610** can also slide relative to the rail **205** of the platform **115** by sliding the mount **210** and attachment screw **215** along the rail **205**. When locked, the position and orientation of the localizing needle **610** relative to the platform **115** is fixed.

FIG. **7** shows a perspective view of the device **100** with a locking instrument **705** coupled to the platform **115** for locking and unlocking the localizing needle. The locking instrument **705** is configured to tighten onto the attachment screw **215** (FIG. **6**) for locking of the localizing needle **610**. When the locking instrument tightens onto the attachment screw **215**, the localizing needle locks.

This is described in more detail with reference to FIG. **8**, which shows a cross-sectional view of the locking instrument **705** attached to the platform **115** via threads that mate with threads on the locking screw **215**. The locking screw **215** has an expandable, spherically-shaped head **810** that is positioned within a socket collectively formed by the mount **210** and the rail **205**. When the locking instrument **705** is not tightened onto the attachment screw **215**, the spherical head **810** is of a size that permits the head **810** to rotate within the socket. In addition, the mount **210** and attachment screw **215** can slide along the rail **205** when the locking instrument **705** is untightened.

However, when the locking instrument **705** is tightened, a threaded protrusion **815** causes the head **810** to expand within the socket. Specifically, the head **810** includes an upper half-sphere that contains a threaded protrusion **815**, which engages a complimentary threaded bore within a lower half-sphere. The threads are arranged so that clockwise rotation of the upper half-sphere causes the two half-spheres to separate from one another. Since the two half-spheres are housed in an enclosed space, clock-wise rotation of the locking instrument causes the half-spheres to separate and become frictionally locked relative to the rail **205** and the mount **210**. In this way, the mount **210** and attached needle **610** are locked in position relative to the platform **115**.

As mentioned above with reference to FIG. **2**A, the device **100** includes a distraction actuator, such as a thumb screw **212**, that is actuated (such as by being rotated) to distract the screws **110** (and the attached vertebral bodies) relative to one another. FIG. **9** shows a partial exploded view of the platform **115** and shows an exemplary mechanism for effectuating distraction. The thumb screw **212** attaches to an elongate, threaded lead screw **910** that can be axially inserted into one of the rails **205**, as represented by the dashed line **915**. A biasing member, such as a spring **920**, mounts onto the lead screw **910**. A pointer **925** also mounts onto the lead screw **910** for providing a measure of distraction force provided to vertebral bodies, as described more fully below. As mentioned, the member **207** is fixedly mounted to the rails **205**, while the member **209** is slidably mounted on the rails **205**.

FIG. **10** shows a partial cross-sectional view of the platform **115** in an assembled state. The lead screw **910** engages threads within the rail **205** and also engages threads within the slidable member **209**. When the thumbscrew **212** is rotated, the attached lead screw **910** also rotates and moves inward or outward relative to the member **207**, which causes the slidable member **209** to move toward or away from the member **207** depending on the direction of rotation. In this manner, the vertebral bodies, which are attached to the members **207**, **209** via the distraction screws **110** (FIG. **2**A) and the sheaths **410**, can be distracted.

FIG. **11** shows an enlarged cross-sectional view of the platform **115** in the region of the force pointer **910** that provides a measure of distraction force provided to vertebral bodies. The spring **920** is mounted on the lead screw **910** in between an internal wall of the member and a flange **1105** on the lead screw **910**. As the lead screw **910** moves along the direction **1110** in response to rotation of the thumbscrew **212**, the spring **920** compresses or expands depending on the direction of movement of the lead screw **910**. As lead screw **910** turns and members **207 209** are moved apart, pointer **925** will move relative to marking **1120** in manner directly related to the force of distraction. That is, the pointer **925** moves with the lead screw **910** and moves relative to markings **1120** wherein the position of the pointer is proportional to the spring force of the spring **920** as the spring expands and contracts. In other words, as the distraction screws **110** and attached vertebral bodies are distracted, the pointer **925** moves relative to the markings **1120** to provide an indication as to force of distraction. The configuration of the hatch markings **1120** can vary. The hatch markings **126** may provide an actual measure of the distraction force in a recognized physical unit or simply give an arbitrary number, letter, or designation to which the operator would distract the vertebral bodies. FIG. **12** shows an enlarged view of the pointer **925** and the markings **1120** on the platform.

There is now described a method of use for the device **100**. The patient is first placed in a position suitable for the procedure. For example, the patient is placed on his side or in the prone position. The hips and knees are flexed and the procedure is performed under x-ray guidance. The vertebral bodies at the diseased level(s) are identified radiographically and the bone screws **110** are percutaneously inserted into the spinous processes of the upper and lower vertebras. The device **100** is then coupled to the distraction screws **110** by sliding the sheaths **410** over the distraction screws, as shown in FIG. **3**. For clarity of illustration, certain anatomical details, such as the patient's skin, are not shown in FIG. **3** and in some other figures.

As shown in FIG. **6**, the localizing needle **610** is placed through the platform **115** and percutaneously guided into the inter-spinous space at the stenotic level. Under X-ray guidance, the needle's distal tip **615** is advanced until it lies where the operating surgeon wishes to place the implant. At this stage, the localizing needle **610** is in the unlocked state so that the surgeon can adjust the position and orientation of the needle. Once the surgeon has located the distal tip **615** so that it lies at a target location where the operating surgeon wishes to place the implant, the locking instrument **705** is locked onto the device, as shown in FIG. **7**.

As discussed and as shown in FIG. **13**, the localizing needle **610** has one or more hatch markings **620** that indicate the distance from the distal tip **615** to the radial center of rotation of the guide arm. That distance can be illustrated at each hatch mark on the needle **610**, although the distance is not shown in FIG. **13** for simplicity of illustration. After the needle's distal tip **615** is placed in the desired position, the position of the needle's hatch marks relative to the top of the locking instrument **705** is noted. The distractor device **100** is then moved upwards (or downward) by manipulating the turn screw **415** until the hatch mark immediately above the locking instrument **705** rests immediately adjacent the top of the instrument **705**, as shown in FIG. **14**. FIG. **15**A shows the device with the platform **115** positioned before it had been moved by the turn screw **112** while FIG. **15**B shows the platform **115** after movement. Note that the bottom portion of the distractor platform has displaced upward relative to the distraction bone screws.

At this stage of the procedure, the localizing needle **610** is locked in place with the marking **620** on the needle providing an indication as to the radius of rotation of the insertion member **120** to be mounted to the platform **115**. With the needle and platform locked, the vertebral bodies are then distracted. This is accomplished by turning the thumb screw **212** which, in turn, moves the lead screw **910** and distracts the member **207** relative to the member **209** in the manner described above. As mentioned, the pointer **925** in combination with the markings **925** provide an actual measure of the distraction force in a recognized physical unit or provide an arbitrary number, letter, or designation to which the operator would distract the vertebral bodies.

At this stage of the procedure, the localizing needle **610** is fixed in place, the platform **115** is locked in position, and the vertebral bodies are distracted with the distraction force indicated by the pointer **925**. A swing arm is selected with a radius R equivalent to the number, letter or designation of the hatch mark on the localizing needle **610** (the hatch mark **620** at the level of the top of locking instrument). Thus, when the insertion device **120** is pivoted about the axis B (FIG. **1**), the curved portion **140** moves along a pathway that intersects the target location defined by the distal tip of the localizing needle **610**.

FIG. **16** is a perspective view of the device showing how the insertion device **120** is pivotably attached to the platform **115**. The insertion device **120** includes an attachment member **1710** (FIGS. **17**A and **17**B) that removably mates with the attachment screw **215** by lowering the attachment member **2210** onto the attachment screw **215**, as represented by the arrow **2110** in FIG. **16**.

FIGS. **17**A and **17**B show enlarged views of the attachment member **1710** of the insertion device **120** being lowered onto the attachment screw **215** of the platform **115**. FIG. **18** shows a cross-sectional view of the attachment member **1710** attached to the attachment screw **215**. The attachment member **1710** includes an attachment screw **1715** that has a threaded bore that mates with a shank of the attachment screw **215**. Once attached, the insertion device **120** can pivot about the axis B.

At this stage of the procedure, the device **110** including the pivotably mounted insertion device **120** is attached to the pair of vertebral bodies, as shown in FIG. **19**. The insertion device **120** is positioned such that a distal tip **1910** of the curved portion **140** is positioned above the level of the patient's skin. For clarity of illustration, the skin is not illustrated in FIG. **19**.

FIG. **19** shows the insertion device **120** prior to insertion of the trocar **117** into the internal shaft of the curved portion **140**. FIG. **20** shows the device **100** with the trocar **117** positioned within the curved portion **140** of the insertion device **120**. The trocar has a handle on one end and a sharp, knife-like tip **2010** at an opposite end.

FIGS. **20-22** sequentially illustrate how the insertion device **120** swings toward the target location where the implant is to be positioned. As mentioned, as the insertion device **120** pivots, the distal end **1910** of the curved portion **140** moves along a curvilinear pathway that intersects the target location. In FIG. **20**, the tocar **117** is slid into the internal shaft of the curved portion **140**. The handle of the trocar **117** is then pushed toward the skin so that the distal end **1910** swings toward the skin along a pathway D. The sharp, knife-like tip of the trocar **117** cuts through the skin and soft tissue as the insertion device **120** swings toward the skin. The trocar **117** and the curved portion **140** are then forced through the skin and soft tissue as illustrated in FIGS. **21** and **22** until the distal tip **1910** of the curved portion **140** abuts the side of the spinous processes of the vertebral bodies. Since the swinging insertion device **120** rotates about the locked platform **115** and arm **130** has a radius equivalent to the distance between the center of rotation and the needle tip, the curved portion **140** will necessarily travel along an arc that intersects the position of the needle tip. As shown in FIG. **23**, the trocar **117** is then removed leaving the central shaft **2310** of the curved portion **140** of the insertion device free as a conduit for implant placement.

In the next step, the appropriate size of the implant is determined, wherein the appropriate size is based upon the size of the space between the two spinous processes. FIGS. **24**A, **24**B, and **24**C show an exemplary sizing device **2410** for determining the appropriate size of an implant. The sizing device **2410** is an elongate rod that is sized to be positioned within the shaft **2310** of the curved portion **140**. A proximal end of the sizing device **2410** has hatch marks **2414**. A distal end **2415** of the sizing device has a gradually reducing diameter. As the sizing device **2410** is advanced further into the curved portion and into the space between the spinous processes, the distal end **2415** of the sizing device **2410** begins to distract the spinous processes and thereby unload the distractor.

Distraction of the spinous processes can be easily recognized by movement of pointer **925** (FIG. **12**) relative to hatch marks **1120**. That is, as the sizing device **2410** is advanced, the pointer **925** will indicate that less force is borne by the distraction screws **110**. Once the sizing device **2410** is advanced sufficiently to unload the distraction screws, the implant size is noted on hatch markings **2414** on the sizing device **2410**. For illustration, this size is shown as "11" in FIG. **24**B. It should be appreciated that this number may provide an actual measure of the implant size in a recognized physical unit or simply give an arbitrary designation by which the implants are labeled. With the implant size determined, the sizing device **2410** is removed and the appropriate implant is selected.

FIGS. **25** and **26** show an implant holder device **2510** that can be used to hold an implant **2515** and install the implant via the internal shaft in the curved portion **140** of the install device **120**. The holder device **2510** includes a handle assembly **2520** having a pair of arms **2522** and **2524**. A curved member **2530** extends outwardly from the handle assembly **2520**. The curved member **2530** is coupled to a member **2535** and a member **2540**, which are movable relative to one another in response to actuation of the handles **2522**, **2524**. The members **2530**, **2535**, and **2540** collectively form a holder element that holds and secures the implant **2515**. The implant **2515** has a curvilinear shape and mounts onto the members **2535** and **2540**, as shown in FIG. **26** and described below.

FIGS. **27**A and **27**B show the implant **2515** with extendable wings **2710** in an undeployed (FIG. **27**A) and a deployed state (FIG. **27**B). The implant **2515** has an internal bore **2715**. The wings **2710** are formed of foldable arms **2720**. The implant **2515** also includes ratchets **2730** that are engageable by protrusions **2735**. An indentation **2732** is located along a proximal edge of the implant **2515**. When the implant **2515** is positioned within the space between the spinous processes, the implant **2515** is collapsed along its length, which causes the arms **2720** to fold outward and form the wings **2710**. The protrusions **2735** engage the ratchets **2730** to lock the implant in the deployed state.

The implant **2515** mounts onto the holder **2510** by sliding the members **2535**, **2540** through the bore **2715** in the implant **2515** such that the implant **2515** is positioned over the members **2535**, **254**, as shown in FIG. **26**. When the implant **2515** is mounted as such, a protrusion **2810** on the distal edge of the member **2530** engages the indentation **2732** on the proximal edge of the implant **2515**, as shown in FIG. **28**. The engagement prevents the implant **2515** from rotating when mounted on the members **2530**, **2540**.

FIG. **29** shows a cross-sectional view of the implant attached to the holder. FIG. **30** shows a close-up view of the implant attached to the holder. The members **2535** and **2540** of the holder **2510** are both positioned within the central bore **2715** and engage the head of the implant. A handle **2910** on the assembly **2520** is actuated to cause the member **2540** to move back relative to the member **2535** and expand a split ring **3010**. As the split ring **3010** expands, the ring **3010** wedges against the internal wall of the bore **2715** and thereby lock the implant **2515** onto the implant holder **2510**. The locking mechanism at the head of the implant and the prevention of rotation (by engagement of protrusion **2810** and indentation **2732** as shown in FIG. **28**) effectively immobilize the implant **2515** relative to the holder **2510**.

FIG. **31** shows the implant **2515** locked onto the holder **2510** with the handle **2910** in a locked position. FIG. **32** shows a close-up, cross-sectional view of the implant end of the holder **2510**. Note that the split ring **310** now abuts the inside of the bore **2715** and a conical head **3110** of the member **2540** is situated at the distal tip of the implant **2515**.

At this stage of the procedure, the implant **2515** is locked onto the holder **2510** pursuant to the above-described process. The holder **2510** and the attached implant **2515** can now be inserted into the internal shaft of the curved member **140** of the insertion device **120**. FIG. **33** shows the holder **2510** and attached implant **2515** just prior to insertion into the internal shaft **2310** of the curved portion **140**. The holder **2510** and attached implant **2515** are slid through the internal shaft **2310** until the implant protrudes out of the curved portion and is positioned between the spinous processes, as shown in FIG. **34**. If needed, a mallet may be used to apply force to surface **3410** of the implant holder **2510** in order to position the implant between the spinous processes.

The handles **2522** and **2524** of the implant holder **2510** are then actuated, which causes the ends of members **2530** and **2535** to move towards one another. The actuation of the handles **2522** and **2524** causes the implant to deform such that the wings **2710** are deployed, as shown in FIG. **35**.

FIG. **36** shows a cross-sectional view of the deployed holder and implant. FIG. **37** shows a close-up view of the implant coupled to the holder **2510**. The handle **2524** and **2522** are connected to a mechanism that causes the members **2530** and **2535** to move when the handles are actuated. The movement causes the implant wings to deploy. Note that the implant's ratchet locking mechanism (the ratchets **2730** and protrusions **2735**) is now locked and keeps the implant in the deployed position. At this stage, the handle **2910** can be unlocked and the implant holder **2510** removed form the central channel of the curved portion **140** of the installer device **120**. FIG. **38** shows the implant **2515** deployed between the vertebral bodies and the holder removed from the device **100**. FIG. **39** shows the implant **2515** deployed between the vertebral bodies after the inserter device **120** has been rotated out of the soft tissue and the device **100** and distraction screws have been removed.

With reference again to FIG. **27**, the implant **2515** includes a screw **2740** that secures a first portion of the implant to a second portion of the implant. When the screw **2740** is in place, the first portion and second portion are secured to one another. When the screw **2740** is removed, the first portion and second portion detach from one another. The implant **2515** can advantageously be disassembled by removing the screw **2740**. If open surgery is required at a future date, the implant **2515** can be disassembled and completely removed—making the implantation procedure completely reversible. FIG. **40** shows how the screw **2740** may be removed and the implant divided into subunits comprised of a first portion **4010** and a second portion **4015**. This permits the removal of each subunit without removal of the interspinous ligament.

FIG. **41** shows another embodiment of a device with a swinging or pivoting installer device **120** having a structure similar to the installer device **120** described above. Thus, like reference numerals refer to like structures. In this embodiment, the installer device **120** mounts at the proximal end of a single mounting post **4110** that attaches at a distal end to the spinous process of a vertebral body V**1** or V**2**.

FIG. **42** shows the mounting post **4110** in an exploded state. The mounting post **4110** includes a screw **4205** with a shank that screws into the spinal process. A two-piece post portion couples to the screw **4205**. The post portion has an internal member **4210** positionable inside an external member **4215**. The internal member **4210** and the external member **4215** are coupled to one another to form the elongate mounting post **4110**, as shown in FIG. **43**.

Under X-ray guidance, the screw **4205** of the post **4110** is percutaneously attached onto the spinous process through a small skin incision. The internal member **4210** of the post **4110** is configured to lock to the screw **4205** while the screw **4205** is being driven into bone. In this way, rotation of the outer member **4215** causes advancement of the screw into the spinous process. The internal member **4210** is then unlocked and the external member **4215** is moved in the long axis of the spine until the free end of the post **4110** rests along a line L parallel to the inter-spinous space, as shown in FIG. **44**. The inter-spinous space is easily identified on X-rays. After this is performed, the internal member **4215** is locked, which immobilizes the post **4110** relative to the screw **4205**.

After the post-screw is appropriately positioned, the installer device **120** is attached onto the proximal end of the post **4110** as shown in FIGS. **45** and **46**. An attachment member **4125** pivotably attaches the insertion member **120** to the proximal end of the post **4110**. The attachment member **4125** is configured to permit the insertion member **120** to pivot about a pivot axis B (shown in FIG. **46**).

FIG. **47** shows an enlarged, exploded view of the attachment member **4125** positioned adjacent an attachment region of the insertion device **120**. FIG. **48** shows a perspective, cross-sectional, assembled view of the attachment member **4125**. The attachment member **4125** includes a main body **4510** having a rounded protrusion **4515** that can be positioned inside the proximal end of the post **4110**. A pair of side walls **4520** having inwardly extending teeth **4525** are positioned on opposite sides of the main body **4510**. As mentioned, the structural configuration of the attachment member **4125** can vary and is not limited to the embodiment described herein.

With reference to FIG. **47**, the attachment member **4125** is attached to the post **4110 115** by inserting the rounded protrusion **4515** into the proximal end of the post **4110**. The two side walls **4520** are positioned on either side of the post **4110** such that each tooth **4525** engages a corresponding slot **4530** on the post **4110**. In this manner, the attachment member **4125** is attached to the post **4110**.

With reference to FIGS. **47** and **48**, a pivot rod member **4540** is positionable inside the main body **4510**. The pivot rod member **4540** includes a pivot rod **4545** that protrude outwardly from opposed sides of the main body **4510** when the pivot rod member **540** is positioned inside the main body **4510**. The pivot rod **4545** can be inserted into a pair of apertures **4555** (FIG. **47**) on the insertion device **120** to pivotably couple the insertion device **120** to the post **4110** via the attachment member **4125**. The pivot rod **545** defines the pivot axis B (FIG. **46**) for pivoting of the insertion device **120**.

FIG. **49** shows a side view of an elongate plunger **4810** that slidably fits within a guide shaft inside the curved portion **140** of the insertion device **120**. The plunger **4810** has a tapered tip **4815** on a distal end and a handle **4820** on a proximal end. When the plunger **4810** is fully positioned in the guide shaft, the handle **4820** protrudes out of one end of the guide shaft and the tapered tip **4815** protrudes out of the opposite end of the guide shaft. FIG. **50** shows a side view of the device with the plunger **4810** positioned inside the curved portion **140** of the insertion device **120**.

With the insertion device **110** attached to the post **4110**, the handle **4820** of the plunger **4810** is then used to push curved portion **140** toward the skin. As the tip **4815** abuts the skin, a small incision is made and the curved portion is then rotated further until the tapered end **4815** contacts the lateral side of the inter-spinous space, as shown in FIG. **50** and FIG. **51**.

The plunger **4810** is removed and an orthopedic device can then be placed into the inter-spinous space through the guide shaft comprised of open curvilinear central bore of the curved portion **140**. In this way, a device can be precisely delivered into the inter-spinous space with minimal tissue dissection. This method will provide a minimally invasive way of implanting orthopedic devices into this space.

In other embodiments, one or more anchors may be placed into the inter-spinous ligament, lateral to the inter-spinous space, into the pedicles or any other suitable anchor point. The insertion device is then attached and rotated onto the lateral aspect of the inter-spinal space. Lastly, the curved portion **140** of the insertion device **120** may be designed without a central bore for implant insertion. Instead, the implant is attached to the tip of the curved portion **140** and delivered by rotation of the curved portion. Once in place, the implant is detached from the insertion device **120**.

FIGS. **52** and **53** shows another embodiment of a distractor device **5210** that is similar to the distractor device **100** described above. In this embodiment, the distractor device **5210** is attached to a pair of distractor members **5315** and **5215** that engage the first and second vertebral bodies. The distractor member **5215** is an elongate rod having a sharpened distal end for penetrating the skin. As shown in FIG. **53**, the distal end does not penetrate the vertebral body but rather engages the vertebral body by abutting a side of the vertebral body.

It should be appreciated that the distractor members can engage the vertebral bodies in various ways. For example, the distractor members can be anchors with shanks that actually penetrate into the vertebral bodies. The distractor members can also be clamps that clamp onto the vertebral bodies or can simply by shaped to abut a portion of the vertebral body to purchase onto the vertebral body for distraction purposes. In addition, one of the distractor members can engage a first vertebral body in one manner (such as by penetrating the vertebral body) and the other distractor member can engage a vertebral body in another manner, such as by simply abutting or clamping onto the vertebral body. Alternately, both distractor members can simply abut a respective vertebral body without any penetration of the vertebral bodies by the distractor members.

As shown in FIG. **53**, the distractor member **5215** has a structural configuration wherein an anchor **5310** anchors into the respective vertebral body. The anchor **5310** fits into a sheath **5315** that extends downward from a member **5320** on a platform **114**. A vertical adjustment actuator **5325** is located on the member **5320** for adjusting the vertical position of the platform **114** in the manner described above with reference to the previous embodiment.

Although embodiments of various methods and devices are described herein in detail with reference to certain versions, it should be appreciated that other versions, embodiments, methods of use, and combinations thereof are also possible. Therefore the spirit and scope of the appended claims should not be limited to the description of the embodiments contained herein.

What is claimed is:

1. A method for the placement of an orthopedic implant into a interspinous space between the spinous process of a first vertebral bone and the spinous process of a second vertebral bone of a subject, wherein the first and second vertebral bones are immediately adjacent spinal levels, comprising:

visualizing the spinous process of the first vertebral bone using radiographic imaging;

visualizing the spinous process of the second vertebral bone using radiographic imaging;

forming a pathway through skin and soft tissue that are adjacent to the spinous processes of the first and second vertebral bones, wherein a distal region of the pathway abuts the target inter-spinous space between the spinous processes of the first and second vertebral bones;

passing a percutaneous implant sizing instrument into the inter-spinous space such that a distal region of the sizing instrument abuts each of the spinous processes of the first and second vertebral bones and such that a proximal region of the sizing instrument is positioned outside of the body cavity of the subject, and wherein the proximal region of the instrument provides an indicia of the size of the implant to be selected;

distracting the spinous processes of the first and second vertebral bones with the distal region of the sizing instrument until the sizing instrument imparts a desired amount of distraction force onto the spinous processes and the spinous processes are separated by a separation distance;

reading the indicia on the proximal region of the sizing instrument, wherein the indicia provides an indication of an appropriate implant size to be positioned in the interspinous space and wherein the indicia is at least partially based on the separation distance produced by the distraction force imparted to the spinous processes by the sizing instrument;

selecting an orthopedic implant based on the indicia;

advancing the selected implant through the formed pathway of the skin and soft tissue and into the target interspinous space.

2. A method as in claim **1**, wherein the method is minimally invasive.

3. A method as in claim **1**, wherein the implant is affixed to an implant holder prior to insertion between the spinous processes of the first and second vertebral bones.

4. A method as in claim **3**, wherein the implant holder includes a locking mechanism that can rigidly affix the implant onto the holder.

5. A method as in claim **3**, wherein the implant holder is used to advance the implant into the space between the spinous processes of the first and second vertebral bones.

6. A method for the delivery of an orthopedic implant onto a target location within a spinal column of a subject, comprising:

identifying the target location using an imaging technique;

positioning an implant insertion assembly in proximity to the target location, wherein the implant insertion assembly comprises:

an implant insertion member having an elongated curvilinear body and an internal bore, wherein at least a segment of the internal bore extends from a proximal opening to a distal opening along a curvilinear trajectory, and wherein the internal bore is sized to permit advancement of the implant through the internal bore;

a fixation member, having a first segment that attaches onto a proximal segment of the implant insertion member and a second segment that attaches onto a first surface, wherein, after attachment, the fixation member limits movement of the implant insertion member relative to the target location in at least one plane;

advancing the orthopedic implant through the internal bore of the implant insertion member and onto the target location.

7. A method as in claim **6**, wherein the implant placement procedure is performed using radiographic imaging.

8. A method as in claim **6**, wherein the implant placement procedure is minimally invasive.

9. A method as in claim **6**, wherein the implant insertion member is advanced onto the target location through a skin incision and wherein at least a portion of the same incision is used to advance the implant into the subject.

10. A method as in claim **6**, wherein at least a segment of the insertion member is retained outside of the body cavity of the subject during implant placement.

11. A method as in claim **6**, wherein at least a segment of the fixation member is retained outside of the subject during implant placement.

12. A method as in claim **6**, wherein the implant is affixed to an implant holder prior to insertion into the internal bore of the insertion member.

13. A method as in claim **12**, wherein the implant holder includes a locking mechanism that is adapted to retain the implant onto the holder.

14. A method as in claim **12**, wherein the implant holder is used to advance the implant through the internal bore of the insertion member.

15. A method as in claim **12**, wherein the implant holder extends along an axis from a proximal segment adapted to be held by an operator to a distal segment that is affixed to the implant, and wherein at least a segment of the axis follows a curvilinear trajectory.

16. A method as in claim **12**, wherein the implant is detached from the implant holder after the implant is positioned at the target location.

17. A method as in claim **6**, wherein an implant sizing device is used to determine the size of the required implant prior to implant placement at the target location.

18. A method as in claim **17**, wherein the sizing instrument extends along an axis from a proximal segment to a distal segment and wherein at least a segment of the axis follows a curvilinear trajectory.

19. A method as in claim **6**, wherein the implant insertion member is advanced from a skin incision site to the spinal column with at least one internal member positioned within the internal bore of the insertion member.

20. A method as in claim **19**, wherein the internal member extends from a proximal end to a distal end along an axis and for a first distance, and wherein the distal end is tapered.

21. A method as in claim **19**, wherein the internal member, when positioned within the internal bore of the implant insertion member, prevents the advancement of the implant though the internal bore.

22. A method as in claim **19**, wherein the internal member extends from a proximal aspect to a distal aspect in a curvilinear trajectory.

23. A method as in claim **20**, wherein the first distance of the internal member is greater than the distance from the proximal opening to the distal opening of the internal bore of the implant insertion member.

24. A method as in claim **6**, wherein the fixation member is comprised of more than one segment.

25. A method as in claim **6**, wherein the fixation member is comprised of at least a first and a second segment that cooperatively articulate.

26. A method as in claim **25**, wherein the first segment and the second segment of the fixation member from a ball and socket articulation.

27. A method as in claim **6**, wherein the fixation member contains at least one deployable locking mechanism that is adapted to transition from a first state to a second state, wherein, in the first state, at least two segments of the fixation member are movable relative to one another, and wherein, in the second state, the said segments of the fixation member are rigidly affixed to one another.

28. A method to target and access a spinal segment of a subject, comprising:

identifying a target location within the spinal segment, wherein the target location is in proximity to a first vertebral bone;

positioning at least a first member of a targeting apparatus in proximity to the first vertebral bone, the targeting apparatus being comprised of:

the first member;

a second member being comprised of at least one base segment that is attached to a pivot member, wherein the pivot member is adapted to rotate relative to the base segment about a pivot axis, wherein the pivot member has an elongated arm that extends from the pivot axis to a distal segment, wherein the distal segment of the elongated arm contains at least one bore that is adapted to receive a curvilinear member, wherein the curvilinear member extends from a proximal end to a distal tip;

the first member being movably coupled to the second member, wherein a distance adjustment feature is adapted to adjust a distance between the first and the second members, wherein advancement of the adjustment feature in a first direction increases and retains the increased distance between the pivot axis of the second member and the target location, and wherein advancement of the adjustment feature in a second direction decreases and retains the decreased distance between the pivot axis and the target location;

using a pointer member to localize the target location on an imaging modality, wherein the pointer member extends form a proximal segment to a distal end, wherein the proximal segment contains an attachment region that is adapted to couple with the second member, and wherein the attachment region is a first distance from the distal end;

coupling the attachment region of the pointer member to the second member and

actuating the adjustment feature of the targeting apparatus, wherein, after manipulation of the adjustment feature, the distal end of the pointer member is positioned at the target location on the imaging modality;

rotating the pivot member about the pivot axis and advancing the distal tip of the curvilinear member from a skin entry site to the target location within the subject.

29. A method as in claim **28**, wherein the subject is in the prone position for performance of the targeting procedure.

30. A method as in claim **28**, wherein the first member is positioned in proximity to the spinous process of the first bone.

31. A method as in claim **30**, wherein the first member is positioned in proximity to the spinous process of the first bone using a percutaneous technique.

32. A method as in claim **28**, wherein the first member is positioned using radiographic guidance.

33. A method as in claim **28**, wherein the adjustment feature of the targeting apparatus is adapted to movably adjust the location of the pivot axis relative to the first vertebral bone.

34. A method as in claim **28**, wherein the adjustment feature of the targeting apparatus adjusts the distance between the first and the second members using a threaded member.

35. A method as in claim **28**, wherein the pointer member is adapted to be immobilized relative to the second member in at least one plane.

36. A method as in claim **28**, wherein the elongated arm of the pivot member extends a first distance from the pivot axis to the bore that is adapted to receive the curvilinear member, wherein the first distance of elongated arm is substantially equal to the first distance of the pointer member.

37. A method as in claim **28**, wherein the advancing curvilinear member of the targeting apparatus produces a curvilinear corridor within the subject from the skin entry site to the target location.

38. A method as in claim **37**, wherein an orthopedic implant is advanced to the target location at least partially through the curvilinear corridor produced by the targeting apparatus.

39. A method as in claim **38**, wherein the implant, when positioned at the target location, functions as a spacer that is adapted to separate at least a segment of the first vertebral bone from a segment of an adjacent vertebral bone.

40. A method as in claim **38**, wherein the orthopedic implant extends from a proximal end to a distal end along a central axis, and wherein at least a segment of the implant extends along the central axis in a curvilinear trajectory.

41. A method as in claim **38**, wherein the orthopedic implant, when positioned at the target location, is aligned with a proximal segment on a first side of a vertebral midline and a distal segment positioned contra-lateral to the first side, and wherein the vertebral midline is defined by a mid-sagittal plane that is used to divide the vertebral bone into right and left halves.

42. A method as in claim **28**, wherein the distal tip of the curvilinear member is adapted to separate tissue ahead of the rotating pivot member.

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