

# (19) United States (12) Reissued Patent Fraser et al.

# (10) Patent Number: US RE45,639 E (45) Date of Reissued Patent: Aug. 4, 2015

(54) MEDICAL INSTALLATION TOOL

(71) Applicant: **DePuy Synthes Products, LLC**, Raynham, MA (US)

(72) Inventors: Robert D. Fraser, Adelaide (AU);
Alexander Grinberg, Newton, MA
(US); John D. Malone, Franklin, MA
(US); Bradley Moore, West Vancouver
(CA); Michael J. O'Neil, West
Barnstable, MA (US); Mark C. Boomer,
Phoenix, AZ (US)

**References Cited** 

(56)

DE

DE

U.S. PATENT DOCUMENTS

3,409,013 A 11/1968 Berry 3,486,505 A \* 12/1969 Morrison ...... 606/90

(Continued)

#### FOREIGN PATENT DOCUMENTS

20001611 U //1000

- (73) Assignee: DePuy Synthes Products, Inc.,Raynham, MA (US)
- (21) Appl. No.: 14/172,631
- (22) Filed: Feb. 4, 2014

#### **Related U.S. Patent Documents**

Reissue of:

(64)	Patent No.:	6,755,841
	Issued:	Jun. 29, 2004
	Appl. No.:	10/011,264
	Filed:	Dec. 7, 2001

U.S. Applications:

(63) Continuation-in-part of application No. 09/566,514, filed on May 8, 2000, now Pat. No. 6,478,800, which is an application for the reissue of Pat. No. Re. 43,317, which is an application for the reissue of Pat. No.

29901011	U	4/1222
29901611	U1	4/1999

(Continued)

#### OTHER PUBLICATIONS

[No Author Listed] Metronic, "Parallel Tissue Offerings," (2004). (Continued)

Primary Examiner — Nicholas Woodall
(74) Attorney, Agent, or Firm — Nutter McClennen & Fish
LLP

#### (57) **ABSTRACT**

An installation tool that is useful for the efficient and effective placement of an article, such as an artificial disc, between adjacent vertebral bodies is provided. The installation tool can be provided as a kit having modular components which allow the surgeon to select from among a variety of components to assemble an installation tool that is optimized for its intended use. The installation tool of the invention generally includes a pair of opposed levers, each of which has a proximal handle portion and a distal portion. A fulcrum is disposed between the two levers to enable proper operation of the tool. The tool further includes a pusher block that is positioned between the two levers and is selectively movable between an initial location distal of the fulcrum and a final location adjacent the distal end of the levers. The pusher block includes a proximal end, a distal end, and a bore extending at least partially therethrough. A pusher rod, which facilitates movement of a pusher block, has a distal end extending into the bore in the pusher block and a proximal, handle end.

#### 6,755,841.

(51)	Int. Cl.	
	A61B 17/58	(2006.01)
	A61F 2/46	(2006.01)
(52)	U.S. Cl.	
	CPC	
(58)	Field of Classificat	tion Search
	CPC	A61F 2/4611
	USPC	
	See application file	for complete search history.

#### 16 Claims, 19 Drawing Sheets



# US RE45,639 E Page 2

(56)		Referen	ces Cited	6,083,225 6,083,228			Winslow et al. Michelson	
	U.S. 1	PATENT	DOCUMENTS	6,085,228			Michelson	
				6,113,602				606/61
4,034	4,746 A	7/1977	Williams	6,117,174				
/	7,576 A			/ /			Shrivastava et al. Michelson et al.	
	/	1/1983		· · · · ·			Yonemura et al.	
,	4,184 A 5 374 A *		Oretorp Jacobson 606/61	/ /			Schoedinger, III et al.	
	0,287 A		Decker				Urbahns et al	606/86
/	0,613 A			6,159,244			•	<u>cocioo</u>
,	5,202 A		Williams	6,168,601 6,197,033			Martini Haid, Jr. et al.	606/90
	2,287 A			6,200,322			Branch et al.	
/	7,020 A 8.161 A *	10/1989 2/1990	Grundei 606/105	6,261,296			Aebi et al.	
	7,432 A	3/1991		6,267,763		7/2001		
	5,247 A		Michelson	6,277,122			McGahan Carianan at al	606/00
/	9,081 A			6,436,119			Carignan et al Erb et al.	000/99
	2,373 A *		Hayes et al 128/69 Michelson	/ /			Ralph et al.	
/	5,104 A			, ,			Fraser et al	606/99
,	,		Michelson	6,520,967			Cauthen	
/	2,130 A	6/1992		6,551,316			Rinner et al. Roud et al	
			Dolgin et al.	6,575,981 6,582,437			Boyd et al. Dorchak et al.	
,	3,112 A 4,128 A	5/1993	Niwa et al. Mesa	6,589,247			McGahan et al.	
,	2,329 A	3/1994		6,599,291			Foley et al.	
	4,119 A		Balaban et al.	6,599,294			Fuss et al.	
,	5,309 A		Wagner et al.	6,648,888				
,	4,477 A		Marnay	6,663,638			Burkus et al. Ralph	
	3,337 A 3,843 A	4/1995 6/1995		6,712,825			Aebi et al.	
	/		Moskovich	6,719,760			Dorchak et al.	
	1,672 A		Cote et al.	6,743,234	B2	6/2004	Burkus et al.	
	3,514 A	8/1995		· · · ·			Fraser et al.	
,	1,804 A	1/1996		6,814,737			Cauthen	
,	4,437 A 5,340 A		Michelson Abidin et al.				Beyersdorff et al.	
,	5,732 A		Michelson	RE43,317 RE44,835			Fraser et al. Fraser et al.	
	/		Shackelford, Sr. et al.	2001/0029377			Aebi et al.	
	2,736 A		• • • • • • • • • • • • • • • • • • •	2001/0031968			Dorchak et al.	
,	2		Abidin et al.	2001/0031969	A1	10/2001	Aebi et al.	
/	/	10/1996	Bertagnoli	2002/0116009			Fraser et al.	
	9,351 A		Haber et al.	2002/0123754			Holmes et al.	
· · · · · · · · · · · · · · · · · · ·	0,454 A		Pierce et al.	2002/0143343		10/2002		
/	5,597 A	7/1997	I	2002/0198532 2003/0069586			Michelson Errico et al.	
· · · · · ·	5,099 A 3,407 A		Pilo et al. Jolly et al	2003/0078590			Errico et al.	
/	/		Jolly et al. Wagner et al.	2003/0149438			Nichols et al.	
,	0,751 A		Jackson	2003/0212404	A1	11/2003	Dorchak et al.	
5,722	2,977 A	3/1998	Wilhelmy	2003/0225416	A1	12/2003	Bonvallet et al.	
,	,		Dillon et al.	2004/0039397				
/	1,253 A 2,968 A		Michelson Jolly et al	2004/0078079		4/2004		
,	5,252 A		Jolly et al. Henry et al.	2004/0102790 2004/0106927			Ralph et al. Ruffner et al.	
/	9,724 A		-	2004/0100927			Trieu et al.	
/	2,830 A			2004/0167535			Errico et al.	
r	2,162 A		-	2004/0167536			Errico et al.	
	7,909 A 0.438 A *		Tuke et al 606/90	2004/0172037			Dorchak	
	7,309 A			2004/0225295			Zubok et al.	
			Herbert et al.	2005/0010213			Stad et al.	
/	/		Winslow et al.	2005/0027300 2005/0043741			Hawkins et al. Michelson	
/	/		Tokuhashi et al. Beckers et al.	2005/0075644			DiPoto et al.	
/	9,901 A			2005/0119665				
	8,432 A	6/1999		2005/0143747	A1	6/2005	Zubok et al.	
5,935	5,151 A *	8/1999	Broughton et al 606/241	2005/0159756		7/2005	-	
/	/		Koros et al. $606/100$	2005/0165408	A1	7/2005	Puno et al.	
/	/		Schroder et al 606/100 Magee et al.	TT /	ידיתר			
	•		Castro et al.	FC	JKEIG	IN PATE	NT DOCUMENTS	
,	,		Strome et al.	DE	20014	5078 U	11/1999	
	/		Flumene et al.	DE DE		5078 U1		
,	2,582 A	3/2000		DE		2549 U		
	3,088 A		Winslow	DE	20012	2549 U1	10/2000	
,	5,174 A			EP		938 A1	12/1998	
0,080	J,133 A *	0/2000	Michelson 606/61	EP	0880	)938	12/1998	

	6,267,763	B1	7/2001	Castro	
	6,277,122		8/2001	McGahan	
	6,319,257		11/2001	Carignan et al 606	5/
	6,436,119	B1		Erb et al.	
	6,440,142	B1	8/2002	Ralph et al.	
	6,478,800	B1 *	11/2002	Fraser et al 606	5/
	6,520,967	B1	2/2003	Cauthen	
	6,551,316	B1	4/2003	Rinner et al.	
	6,575,981	B1	6/2003	Boyd et al.	
	6,582,437	B2	6/2003	Dorchak et al.	
	6,589,247		7/2003	McGahan et al.	
	6,599,291	B1	7/2003	Foley et al.	
	6,599,294	B2	7/2003	Fuss et al.	
	6,648,888		11/2003	Shluzas	
	6,648,895		11/2003	Burkus et al.	
	6,663,638	B2	12/2003	Ralph	
	6,712,825	B2	3/2004	Aebi et al.	
	6,719,760	B2	4/2004	Dorchak et al.	
	6,743,234	B2	6/2004	Burkus et al.	
	6,755,841	B2	6/2004	Fraser et al.	
	6,814,737	B2	11/2004	Cauthen	
	7,118,580	B1	10/2006	Beyersdorff et al.	
	RE43,317	Е		Fraser et al.	
	RE44,835		4/2014	Fraser et al.	
)()	1/0029377			Aebi et al.	
~~~					

#### Page 3

#### **References Cited** (56) FOREIGN PATENT DOCUMENTS EP 1 153 582 A2 11/2001 WO 0074605 A1 12/2000 WO WO 00/74605 12/2000 OTHER PUBLICATIONS

[No Author Listed] Metronic Sofamor Danek, "Catalyst Anterior Instrument Set," pp. 1-10 (2004).

Capasso, G. Velotti A. and Auzino, G., "Mechanical Behavior of Two Types of Vertebral Distractors Submitted to Compression-Flexion Tests," Ital J. Orthop Traumatol. 13(1):121-6 (1987).

Demetropoulas, C.K., Truumees, E., Herkowitz, H.N. and Yang, K.H., "Development and calivration of a load sensing cervical distractor capable of withstanding autoclave sterilization," Med Eng Phys. 27(4):343-6 (2005).

Rutsky, V.V. and Valkav, A.N., "Designing a dynamic spinal distractor," Med Tekh. 4:29-32 (1995).

[No Author Listed] Depuy Motech., "Keystone Graft Instruments Anterior Cervical Technique," Technical Manual. 1998, 16 pages. [No Author Listed] FRA Space Instruments. For anterior lumbar fusion (ALIF) using straight anterior or anterolateral approach. Synthes Spine, 1998, 15 pages.

\* cited by examiner

## **U.S. Patent** Aug. 4, 2015 Sheet 1 of 19 US RE45,639 E





## **U.S. Patent** Aug. 4, 2015 Sheet 2 of 19 US RE45,639 E



## **U.S. Patent** Aug. 4, 2015 Sheet 3 of 19 US RE45,639 E





## **U.S. Patent** Aug. 4, 2015 Sheet 4 of 19 US RE45,639 E





## **U.S. Patent** Aug. 4, 2015 Sheet 5 of 19 US RE45,639 E



## **U.S. Patent** Aug. 4, 2015 Sheet 6 of 19 US RE45,639 E



# FIG. 4



# FIG. 5

## **U.S. Patent** Aug. 4, 2015 Sheet 7 of 19 US RE45,639 E



## **U.S. Patent** Aug. 4, 2015 Sheet 8 of 19 US RE45,639 E



## U.S. Patent Aug. 4, 2015 Sheet 9 of 19 US RE45,639 E





## U.S. Patent Aug. 4, 2015 Sheet 10 of 19 US RE45,639 E



10b

## U.S. Patent Aug. 4, 2015 Sheet 11 of 19 US RE45,639 E



FIG. 8A



# FIG. 8B

## U.S. Patent Aug. 4, 2015 Sheet 12 of 19 US RE45,639 E





# FIG. 8D

## U.S. Patent Aug. 4, 2015 Sheet 13 of 19 US RE45,639 E



## U.S. Patent Aug. 4, 2015 Sheet 14 of 19 US RE45,639 E



je j 



## U.S. Patent Aug. 4, 2015 Sheet 15 of 19 US RE45,639 E







#### U.S. Patent US RE45,639 E Aug. 4, 2015 **Sheet 16 of 19**





## **U.S. Patent** Aug. 4, 2015 Sheet 17 of 19 US RE45,639 E



## U.S. Patent Aug. 4, 2015 Sheet 18 of 19 US RE45,639 E







## **U.S. Patent** Aug. 4, 2015 Sheet 19 of 19 US RE45,639 E



## **MEDICAL INSTALLATION TOOL**

Matter enclosed in heavy brackets [] appears in the original patent but forms no part of this reissue specifica-5 tion; matter printed in italics indicates the additions made by reissue; a claim printed with strikethrough indicates that the claim was canceled, disclaimed, or held invalid by a prior post-patent action or proceeding.

#### **CROSS-REFERENCE TO RELATED** APPLICATIONS

#### 2

ing spinal implants. The intervertebral space is first distracted and a hollow sleeve having teeth at one end is then driven into the vertebrae that are adjacent the disc space. A drill is then passed through the hollow sleeve, removing the disc and the bone in preparation for receiving the spinal implant, which is then inserted through the sleeve.

Despite existing tools and technologies, there remains a need to provide a device to facilitate the proper and convenient insertion of an object, such as a disc prosthesis, between <sup>10</sup> adjacent vertebral bodies while minimizing the risk of further injury to the patient.

#### SUMMARY OF THE INVENTION

[This application] More than one reissue application has been filed for the reissue of U.S. Pat. No. 6,755,841. This 15 application is a continuation reissue of U.S. patent application Ser. No. 13/331,675, filed on Dec. 20, 2011, now U.S. Pat. No. Re. 44,835, which is a continuation reissue of U.S. patent application Ser. No. 11/397,887, filed on Mar. 29, 2006, now U.S. Pat. No. Re. 43,317, which is a reissue of U.S. patent 20 application Ser. No. 10/011,264, filed on Dec. 7, 2001, now U.S. Pat. No. 6,755,841, which is a continuation-in-part of U.S. patent application Ser. No. 09/566,514, filed on May 8, 2000, now U.S. Pat. No. 6,478,800 entitled "Medical Installation Tool," the entire contents of each of which is hereby 25 expressly incorporated herein by reference.

#### BACKGROUND OF THE INVENTION

The invention relates to a tool for inserting prostheses 30 within the body, and more particularly to tools for inserting prostheses, such as artificial discs and cages, within an intervertebral space.

Spinal surgery involves many challenges as the long-term health and mobility of the patient often depends on the sur- 35 geon's technique and precision. One type of spinal surgery involves the removal of the natural disc tissue that is located between adjacent vertebral bodies. Procedures are known in which the natural, damaged disc tissue is replaced with an interbody cage or fusion device, or with a disc prosthesis. The insertion of an article, such as an artificial disc prosthesis, presents the surgeon with several challenges. The adjacent vertebral bodies collapse upon each other once the natural disc tissue is removed. These bodies must be separated to an extent sufficient to enable the placement of the prosthesis. 45 However, if the vertebral bodies are separated, or distracted, to beyond a certain degree, further injury can occur. The disc prosthesis must also be properly positioned between the adjacent vertebral bodies. Over-insertion, or under-insertion of the prosthesis can lead to pain, postural problems and/or 50 limited mobility or freedom of movement. Specialized tools have been developed to facilitate the placement of devices, such as disc prosthesis, between adjacent vertebral bodies of a patient's spine. Among the known tools for performing such procedures are separate spinal distractors and insertion devices. The use of separate tools to distract the vertebral bodies and insert a disc prosthesis or graft can prove cumbersome. Further, the use of some distractors can cause over-distraction of the vertebral bodies. Exemplary devices for installing prosthesis and/or grafts 60 prosthesis. between vertebral bodies are disclosed in U.S. Pat. Nos. 5,431,658 and 5,505,732. U.S. Pat. No. 5,431,658 discloses a facilitator device for the insertion of bone grafts between two adjacent vertebrae. The disclosed tool has two flat, tong-like guides that distract the vertebrae as a screw-type inserter 65 forces the graft between the distracted vertebrae. U.S. Pat. No. 5,505,732 discloses an apparatus and a method of insert-

The present invention provides a device useful for implanting prostheses, such as artificial spinal discs and cages, within a patient in a safe and efficient manner. The installation tool of the invention generally includes a pair of opposed levers, each of which has a proximal handle portion and a distal portion. A fulcrum is disposed between the two levers to enable proper operation of the tool. The tool further includes a pusher block that is positioned between the two levers and is selectively movable between an initial location distal of the fulcrum and a final location adjacent the distal end of the levers. The pusher block includes a proximal end, a distal end, and a bore extending at least partially therethrough. A pusher rod, which facilitates movement of a pusher block, has a distal end extending into the bore in the pusher block and a proximal, handle end.

The pusher rod and/or pusher block can be adapted to mate to a variety of prosthesis devices. In one embodiment, the pusher block can include a blind bore and a distal end of the pusher rod can mate with the blind bore in the pusher block. The pusher block can thus include a distally facing surface having surface features adapted to conform to or mate with complementary surface features on a prosthesis. In another embodiment, the bore can extend entirely through the pusher block to allow a distal end of the pusher rod to extend through the bore in the pusher block. The pusher rod can thus include 40 a distal tip that is effective to mate to a prosthesis. In yet another embodiment, the rod can include a first externally threaded distal portion and a second externally threaded distal portion. The second distal portion is positioned proximal to the first distal portion, and has a diameter greater than a diameter of the first distal portion. The bore of the pusher block can include a threaded proximal opening, a distal opening, and a chamber formed therebetween. The proximal opening is threadingly matable with the second distal portion of the rod to allow the second distal portion of the rod to be threadingly inserted through the proximal opening and positioned within the chamber. The diameter of the distal opening of the pusher block should be less than the diameter of the proximal opening of the pusher block to prevent the second threaded portion of the rod from extending through the distal opening in the pusher block. The threaded second distal portion is preferably freely rotatable within the chamber of the pusher block. The threaded first distal portion of the rod extends through the distal opening in the pusher block and includes a distal tip which is adapted to mate to a In other aspects of the invention the bore extends entirely through the pusher block and a distal tip of the pusher rod is adapted to extend through the bore in the pusher block. The distal tip of the pusher rod is further adapted to mate to a grasping element effective to releasably engage a prosthesis. The grasping element can include an elongate proximal portion with a bore formed therein and a distal portion that is

effective to releasably engage a prosthesis. The proximal portion has an outer diameter that is adapted to fit within the bore of the distal end of the pusher block. The distal portion of the grasping can include opposed first and second components that are movable between a first, open position, and a 5 second, closed position that is effective to engage a prosthesis. In use, the distal end of the rod threadingly engages the bore of the grasping element. Rotation of the rod in a first direction is effective to cause the elongate proximal portion of the grasping element to move proximally within the bore of 10 the pusher block, thereby moving the first and second components to the second, closed position. Rotation of the rod in a second, opposed direction is effective to cause the elongate proximal portion of the grasping element to move distally out of the bore of the pusher block and move the first and second 15 components to the first, open position. The first and second components can optionally include at least one surface feature effective to engage a prosthesis. In yet another embodiment, a medical device installation kit can be provided having a pair of opposed levers, a fulcrum 20 disposed between the levers for allowing pivotal movement of the levers with respect to each other, and a plurality of prosthesis installation assemblies. Each assembly is adapted to be slidably disposed between the levers and movable between a first, proximal position and a second, distal portion. A handle 25 portion can be provided on each assembly for moving the prosthesis installation assembly between the first and second positions. Each assembly further includes a distal prosthesis effecting element adapted to place a prosthesis between adjacent bone structures. 30 In one embodiment, one of the prosthesis installation assemblies includes a pusher block having a proximal end, a distal end, and a bore extending therethrough, a pusher rod slidably disposed between the levers and extending through the bore in the pusher block, and a grasping element effective 35 to releasably engage a prosthesis. In another embodiment, one of the prosthesis installation assemblies includes a pusher rod having a proximal handle portion and a distal portion having a distal tip adapted to positively engage a prosthesis. A pusher block can be provided having a bore extending there- 40 through and adapted to receive a distal portion of the pusher rod. In yet another embodiment, one of the prosthesis installation assemblies can include a pusher rod having an externally threaded first distal portion and an externally threaded second distal portion. The second distal portion has a diam- 45 eter greater than the first distal portion, and is positioned proximal to the first distal portion. The assembly further includes a pusher block having a bore extending entirely therethrough having a threaded proximal opening that is threadingly matable with the second distal portion of the rod, 50 and a distal opening having a diameter less than the diameter of the second distal portion of the rod. A chamber having a diameter greater than the diameter of the second distal portion of the pusher rod is disposed between the first and second openings of the pusher block. In other aspects, one of the 55 prosthesis installation assemblies can include a pusher block having a bore extending therethrough, a pusher rod extending through the bore in the pusher block, and a plurality of connector elements having a proximal portion adapted to mate to a distal tip of the pusher rod, and a distal portion adapted to 60 mate to a prosthesis. The installation tool of the invention can be used in the following manner. Once the natural, damaged disc tissue is removed from a patient and the area is prepared to receive an artificial prosthesis, such as an artificial disc, the artificial disc 65 is loaded between the levers of the installation tool so that a posterior side of the disc abuts a distal end of the pusher block.

The distal tip of the levers is then positioned between the vertebral bodies such that the outwardly facing surfaces of each lever contacts opposed vertebral bodies. Once this position is achieved, the pusher rod is advanced distally, causing the pusher block and the artificial disc to likewise move distally along the inner surfaces of the levers. As the artificial disc and the pusher rod move distally, or forward, the levers separate and also cause vertical separation of the adjacent vertebral bodies. To achieve the proper position of the artificial disc, the distal facing surfaces of the pusher block should contact the vertebral bodies. Once such contact is achieved between the distal facing surfaces of the pusher block and the vertebral bodies, the artificial disc is properly positioned. This tool thus enables the proper positioning of the artificial disc between the vertebral bodies, without over-insertion or under-insertion of the artificial disc, while minimizing the degree of distraction of the vertebrae. To remove the tool, a slaphammer or similar device can be used to apply a proximally directed force to the tool to extract the blade tips without removing the implant.

#### BRIEF DESCRIPTION OF THE DRAWINGS

The invention will be more fully understood from the following detailed description taken in conjunction with the accompanying drawings, in which:

FIG. 1 is a perspective view of an installation tool according to the present invention;

FIG. 2 is a side, elevation view of the tool shown in FIG. 1; FIG. 3 is a top view of the tool shown in FIG. 1;

FIG. 3A is a perspective view of an installation tool having curved distal blade tips according to another embodiment of the present invention;

FIG. **3**B is a side view illustration of another embodiment of an installation tool according to the present invention;

FIG. 4 is a sectional view of the tool shown in FIG. 2, at line 4-4;

FIG. **5** is a top view of a portion of the tool shown in FIG. 2, at line 5-5;

FIG. 6 is an exploded view of a proximal portion of the tool shown in FIG. 1;

FIG. 7 is an exploded view of a portion of the tool shown in FIG. 1;

FIG. 7A is an enlarged view of another embodiment of a pusher block of the tool shown in FIGS. 1-3B;

FIG. 8 is a side view of a portion of a medical installation tool according to yet another embodiment;

FIGS. 8A-8D illustrate, sequentially, the operation of the installation tool according to the present invention during the installation of an artificial disc;

FIG. 9 is a side-elevation view of one embodiment of an installation tool according to the present invention in an initial, unlocked position;

FIG. 10 is a side view of the installation tool of FIG. 9 in a final, locked position;

FIG. 11 is a sectional view of the tool shown in FIG. 9, at line 11-11;

FIG. 12 is perspective view of a pusher block useful with the tool of the present invention;

FIG. 13 is a perspective view of a further embodiment of an installation tool according to the present invention; FIG. 14 is an exploded, perspective view of a portion of the installation tool shown in FIG. 13; FIG. 15A is a side, elevation view of a portion of the distal end of the installation tool of FIG. 13 in a first position; FIG. **15**B is a side, elevation view of a portion of the distal

end of the installation tool of FIG. 13 in a second position;

### 5

FIG. **16** is an exploded side, perspective view of one embodiment of a connector element for use with a medical installation tool;

FIG. **17** is an exploded perspective view of a slaphammer instrument for use with a medical installation tool of the <sup>5</sup> present invention;

FIG. **18** is a side view illustration of a portion of a pusher rod for use with a medical installation tool according to the present invention;

FIG. **19**A is a cross-sectional side view of a pusher block component of the medical installation tool shown in FIG. **8**; and

FIG. **19**B is a plan view of the proximal end of the pusher block of FIG. **19**A.

#### 6

The proximal portion 12B of each lever may include an indented region 28 for receiving the fulcrum 16. As shown in FIGS. 1 and 6, the indented region 28 is in the form of a substantially rectangular cut-out formed on both sides of levers 12B, 14B. This indented region 28 enables the levers to conveniently seat the fulcrum 16, as described below. The recessed region 28 is preferably formed slightly proximally of the shoulder 26. In one embodiment the distal portion of the recessed region 28 begins approximately 10 to 100 mm proximally of shoulder 26. The recessed region 28 generally has a length in the range of about 10 to 40 mm and is recessed by about 1 to 40 mm.

The proximal region of each lever 12B, 14B may also include a bore 30A, 30B which is adapted to seat a bolt 32 that 15 enables control of the spacing between levers so that the pusher block accurately engages the metal portion of the artificial disc. As shown in FIG. 6, bolt 32 includes a head 34 and shaft 35 having a threaded region 36. Preferably, internal threads **36** are formed within bore **30**A. The distal portion of each lever 12A, 14A features side surfaces 46, 48, outwardly facing surfaces 38, 40 (illustrated as top and bottom surfaces in FIG. 6, respectively), and inwardly facing surfaces 42, 44 upon which the artificial disc 24 can ride during an installation procedure. The outwardly and inwardly facing surfaces of the lever preferably are substantially smooth. The inwardly facing surfaces 42, 44 can, however, include surface features effective to mate to complementary surface features formed on the implant. For example, each lever 12, 14 can include a rail (not shown) formed in the inwardly facing surface 42, 44 that is effective to be slidably disposed within a corresponding groove or channel formed in the implant. As a result of the surface features formed on the inwardly facing surfaces 42, 44 of the levers 12, 14, the width  $(W_d)$  of the distal portion of each lever can be substantially the same as or even greater than the width  $(W_n)$  of the proximal

#### DETAILED DESCRIPTION OF THE DRAWINGS

The present invention provides an installation tool that is useful for the efficient and effective placement of an article, such as an artificial disc or cage, between adjacent vertebral bodies. The installation tool can be provided as a kit having modular components which allow the surgeon to select from among a variety of components to assemble an installation tool that is optimized for its intended use. Although the invention is described primarily with reference to being used to install an artificial disc between adjacent vertebral bodies, it is understood that the installation tool of the invention can be used to place other elements between vertebral bodies, or in other locations within a patient's body. Exemplary elements 30 that can be placed between vertebral bodies include, but are not limited to interbody cages, fulsion devices, spacers, grafts, and the like.

As shown in FIGS. 1-3B, the installation tool 10 of the invention includes opposed levers 12, 14, each having a distal 35 portion 12A, 14A and a proximal, handle portion 12B, 14B. Disposed between the levers 12, 14 is a fulcrum 16 and pusher block 18, which is disposed distally of the fulcrum 16. The pusher block 18 includes a bore extending at least partially therethrough and it is selectively movable from an initial 40 position distal of the fulcrum 16 to a final location adjacent a distal end of the levers. A pusher rod 20, which facilitates selective movement of the pusher block, has a proximal handle end 20B and a distal end 20A extending into the bore in the pusher block. Although not part of the invention, a 45 prosthesis, such as an artificial disc 24, is positioned between the levers, distal of the pusher block 18. Preferably the levers 12 and 14 are elongate elements that are mirror images of each other. There is no absolute top or bottom of the tool 10 since it is possible to use either surface 50 as a "top" surface. For ease of reference, however, levers will sometimes be described herein with reference to an illustrated orientation. For example, lever 12, and components thereof, may sometimes be referred to as the top, upper, or superior lever while lever 14 may sometimes be referred to as the 55 bottom, lower, or inferior lever.

With further reference to FIGS. 1-3B, the levers 12, 14

portion of each lever.

The distal portions 12A, 14A of the levers 12, 14 can also have blade tips 50A, 50B formed at the distal ends of the levers. The blade tips are sized and configured to facilitate their placement between vertebral bodies 201, 202. The outwardly facing surfaces 52A, 52B of blade tips may be configured to have surfaces that are beveled or radiused. In one embodiment illustrated in FIG. 3A, the blade tips 12<sub>c</sub>C, 14<sub>c</sub>C can be substantially curved or angled in a superior or inferior direction to facilitate placement of the blade tips  $12_{c}C$ ,  $14_{c}C$ between adjacent vertebrae. In the illustrated embodiment, the distal tip of the rod  $20_{c}$  includes a spring 2 which allows the distal portion of the rod  $20_c$  to conform or bend to the shape of the curved blade tips 50A, 50B. The proximal end 4 of the spring 2 can be threadingly mated to or otherwise attached to the distal end of the rod  $20_c$ , and the end 6 of the spring 4 can be attached to the proximal end of the pusher block 18. Preferably, the pusher block 18. includes a protrusion adapted to extend into the bore in the spring 4 to mate the pusher block  $18_{c}$  to the spring 4.

The thickness of the levers, measured at the blade tips when the tool is closed, as shown in FIG. 1, can be considerably less than the thickness of the levers measured near the fulcrum between outwardly facing surfaces **38**, **40** when the tool is in the closed position. Preferably, the thickness measured at the blade tips is in the range of about 0.5 to 2 mm. A portion of each lever **12A**, **14A**, disposed adjacent a proximal end of the blade tips **50A**, **50B**, can include a stop surface **54**. The stop surface **54**, which is substantially vertically oriented and distally facing, is adapted to abut a vertebral body during a surgical procedure for installing an element, such as an artificial disc, between adjacent vertebral bodies. The stop sur-

include distal 12A, 14A and proximal 12B, 14B ends. The proximal end 12B, 14B of each lever may be of a shape that facilitates convenient grasping and handling of the tool. The 60 proximal end of each lever may comprise approximately one-half of the length of each lever. In one embodiment, a shoulder 26 marks the end of the proximal portion of the tool and the beginning of the distal portion of the tool. As shown in FIGS. 1 and 3, the proximal portion of each lever preferably has a 65 width  $(W_p)$  that is greater than the width  $(W_d)$  of the distal portion of each lever.

#### 7

face 54 may assume a variety of configurations. In one embodiment, shown in FIGS. 2 and 8A-9, the stop surface has a substantially concave profile when viewed in the vertical plane.

As shown in FIGS. 6-7 the side surfaces of the distal 5 portions 12A, 14A of the levers 12, 14 may have opposed rails 56, 58, with a recessed track 60 disposed therebetween. The formation of such recessed tracks 60 within the distal side walls of levers 12, 14 causes these elements to have a profile that, as shown in FIGS. 4 and 7, is substantially I-shaped or 10 T-shaped. The rails 56, 58 and track 60, as discussed below, can be effective to facilitate smooth and efficient movement of the pusher block.

One of ordinary skill in the art will appreciate that the size and shape of the levers may vary. Generally, however, the 15 overall length of the levers is about 200 to 400 mm, with proximal portion 12B, 14B (proximal end to shoulder 26) having a length of about 100 to 300 mm and the distal portion 12A, 14A (shoulder 26 to blade tips) having a length of about 100 to 300 mm. In one embodiment, illustrated in FIGS. 1-3 and 6, the fulcrum 16 is substantially a block-like object having substantially vertical side walls 62. The upper and lower surfaces 64, 66 of fulcrum 16 include recesses or grooves 68, each of which is defined by a base wall 70, 72 and opposed inner side 25 walls 74. A core section 78 lies between the base walls 70 and 72. The core section 78 preferably includes a central bore 80 to allow passage of pusher rod therethrough. In an exemplary embodiment each base wall 70, 72 includes a mounting post 82. As shown in FIG. 6, a biasing element 84', such as a coil 30 spring, may be placed upon each of mounting posts 82 and the mounting posts, in turn, positioned within the bores 31A, 31B of levers 12, 14.

#### 8

other. In use, proximal movement of the pusher block  $18_a$  is effective to cause the blade tips 50A, 50B to move to the closed position, and to cause the proximal portion of the levers 12, 14 to be fully disposed within the recesses 68 (FIG. 6) of the fulcrum 16. Once the pusher block 18 is positioned just distal to the fulcrum 16, the levers 12, 14 are in effect locked in the closed position.

Referring back to FIG. 7, the core section 91 of the pusher block 18 is disposed between upper and lower base walls 90 and includes a proximally facing wall 96 and a distally facing wall 97. In one embodiment, the height of the core section 91 is less than the height of the prosthesis to be installed, thus enabling inwardly facing surfaces 42, 44 of levers 12, 14 to contact the prosthesis. Alternatively, as shown in FIG. 8, the core section 91 can have a height h<sub>c</sub> that is slightly greater than the height of the prosthesis  $24_{h}$  to prevent the prosthesis  $24_{h}$  from contacting the inwardly facing surface 42, 44 of each lever  $12_b$ ,  $14_b$ . Thus, the prosthesis  $24_b$  is spaced apart from the levers  $12_b$ ,  $14_b$  when mated to the pusher block  $18_b$ or pusher rod  $20_{h}$ . The distally facing wall of the pusher block 18 can have a shape which conforms to the shape of a prosthesis. In an exemplary embodiment, several pusher blocks 18, 18,  $18_{a}$ ,  $18_{b}$  can be provided, each having a different size and/or shape that is optimized for use with a particular prosthesis or patient. As noted above, a pusher rod 20 may be utilized to actuate pusher block 18. The pusher rod 20 is preferably an elongate, cylindrical member having a proximal end **20**B and a distal end 20A. The rod is adapted to be positioned between the proximal ends 12B, 14B of the levers 12, 14 so that it extends into or through the bore 80 in fulcrum 16. The rod 20 can be adapted to mate to the pusher block 18 such that forward and rearward movement of the pusher rod will directly move the pusher block. Alternatively, the pusher block 18 can include a bore extending entirely therethrough, and the rod 20 can be

The fulcrum **16** may assume virtually any size and shape that is able to render it effective to separate a substantially 35

intermediate portion of levers while allowing the proximal, handle portion 12B, 14B to be closed together and result in the opening or separation of the distal portion 12A, 14A. Generally, the height of the vertical side walls 62 is in the range of about 20 to 70 mm while the height of the core 40 section 78 (shown in FIG. 7) is in the range of about 5 to 30 mm. The length of the core section 78 may be about 5 to 40 mm.

One of ordinary skill in the art will further appreciate that the fulcrum may take on a variety of other shapes, sizes and 45 mounting configurations. The embodiment described above is intended to represent one exemplary fulcrum design and mounting configuration.

The bolt **32**, as noted above, can be used to adjust the height/spacing of the levers. One of bores **30A**, **30B**, has 50 internal threads **37** that mate with threaded portion **36** of bolt **32**. Tightening or loosening of the bolt will result in increasing or decreasing the spacing/distance between the levers.

The pusher block 18, as illustrated in FIG. 7, may be in the form of a substantially block-like object having vertical side 55 walls 84 that define upper and lower recesses 86, 88 wherein each recess is defined by a base wall 90 and opposed inwardly facing side walls 92. Each inwardly facing side wall 92 preferably includes a guide post 94 that is matable within recessed tracks 60 formed in the distal portion of levers 12A, 14A. 60 In another embodiment, shown in FIG. 7A, each inwardly facing side wall 92' of pusher block 18<sub>a</sub> includes a rail 95 extending from the proximal end to the distal end of the pusher block 18<sub>a</sub>. Each rail 95 forms a groove or track 97 that is matable with rail 56 or rail 58 of each lever 12, 14. The rail 65 95 and track 97 of top and bottom sides of the pusher block 18<sub>a</sub> limit movement of the levers 12, 14 with respect to each

disposed through the bore to mate directly to a prosthesis, or to mate to a connector element which, in turn, mates to a prosthesis.

The pusher rod 20 can optionally include a stop feature to prevent the levers 12, 14 from being removed from the recessed formed in the pusher block. As shown in FIGS. 3A and 3B, the rod 20,  $20_c$  can include a stop surface 17 which abuts the proximal opening of the bore 80 in the fulcrum 16, thereby preventing proximal movement of the levers 12, 14 and fulcrum 16. The stop surface 17 can be formed by a change in diameter of the pusher rod 20,  $20_c$ , such that the proximal portion of the rod has a diameter greater than the distal portion of the rod 20,  $20_c$ , and greater than the bore in the pusher block 18. Alternatively, the stop surface 17 can be formed from an annular flange or similar protruding structure.

The pusher block 18 and pusher rod 20 can include a variety of features, e.g. connector elements, for joining the block 18 to the rod 20, or for mating the rod 20 and/or the block 18 to a prosthesis 24. By way of non-limiting example, FIG. 7 illustrates one embodiment in which the proximal end of the pusher block 18 facing wall includes a blind bore 98 having internal threads 100. The threads are adapted to mate with complimentary threads 102 formed on a distal end 20A of the pusher rod 20, thereby allowing the pusher rod 20 to 60 positively engage the pusher block 18. The distal facing wall 97 of the pusher block may include a recessed region 104 that is adapted to nest artificial disc 24. As illustrated, the recessed region 104 has dimensions that enable the artificial disc to fit loosely therein. One of ordinary skill in the art will appreciate that the recessed area should have dimensions slightly greater than the dimensions of the disc so as to avoid a frictional fit that may inhibit free release of the disc from the tool. FIG. 12

#### 9

illustrates one embodiment of a recessed region 104 having a contact wall 106 that has a generally arcuate shape. Preferably, contact wall 106 is substantially concave and well suited to maintaining contact over a substantial surface area of a generally curved (convex) posterior surface of an artificial 5 disc 24.

FIGS. 8, and 18-19B illustrate another embodiment of a connector element for joining the pusher rod  $20_b$  to the pusher block  $18_{h}$ , and optionally to a prosthesis  $24_{h}$ . As shown in FIGS. 19A and 19B, the pusher block  $18_b$  includes a bore 401 10 having a proximal opening 406, a distal opening 405, and a chamber 408 extending therebetween. The proximal and distal openings 406, 405 preferably each have substantially the same diameter, and preferably each have a diameter less than the diameter of the chamber 408. As shown in FIG. 19B, the 15 proximal opening 406 includes a threaded region 403 which mates to a corresponding threaded region **411** formed on the rod  $20_{h}$  (FIG. 18). The proximal opening 406 can, however, include a variety of engagement elements such as, for example, an o-ring which mates to a corresponding groove 20 formed on the rod  $20_{b}$ . The distal opening 405 does not include threads, and thus is effective to prevent the threaded portion of the rod  $20_{h}$  from being threaded through the distal opening 405. The proximal opening 406 can also include a tapered portion 409 for abutting a corresponding tapered 25 portion 410 formed on the rod  $20_{b}$ . FIG. 18 illustrates a pusher rod  $20_{h}$  that is suitable for use with the embodiment of pusher block  $18_{h}$  shown in FIGS. **19**A and **19**B. Pusher rod  $20_{b}$  includes a distal tip **413**, a connector segment 412 extending proximally from the distal 30 tip 413, and an annular flange 411 having a distal end 418 integral with the connector segment 412 and a proximal end 416 mated to the rod 20. The proximal and distal ends 416, 418 can be tapered to facilitate insertion and removal of the rod  $20_{h}$  from the pusher block 18. The distal tip 413 of the rod 35  $20_{h}$  can mate to a prosthesis, and thus can include an engagement element. As shown in FIG. 18, the distal tip 413 is threaded **415** to mate with corresponding threads formed in a bore in a prosthesis. In use, the rod  $20_{h}$  is inserted into the proximal opening 406 40 of the pusher block 18. The distal tip 413 and connector segment 412 can be inserted through the bore until the threaded annular flange 411 engages the threaded region 403 of the pusher block  $18_{h}$ . The flange 411 can then be rotated and thus threaded through the bore 403 to position the flange 45 **411** in the chamber **408**. Further distal movement of the rod  $20_{h}$  will insert the distal tip 413 and a substantial portion of the connector rod 412 through the distal opening 405 of the pusher block  $18_{h}$ . The lack of threads, and the size differential, in the distal opening 405 will, however, prevent the 50 annular flange **411** from exiting the chamber. Once the annular flange 411 is positioned in the chamber, the rod  $20_{h}$  is free to rotate. The rod  $20_{h}$  can then be rotated to positively engage a prosthesis, or to detach the rod from a prosthesis. In an exemplary embodiment, the threads formed on the annular 55 flange **411** are oriented in a direction opposite to the threads 415 formed on the distal tip 413. This allows the rod  $20_{h}$  to be detached from a prosthesis without allowing the rod  $20_{h}$  to be threadingly removed through the proximal opening **406**. A person having ordinary skill in the art will appreciate that 60 the annular flange 411, and the distal tip 413 can employ a variety of engagement elements other than threads. For example, other locking elements include snap-fit engagements, frictional engagements, bayonet-type locks, leur locks, or any other type of connector. FIG. 16 illustrates another embodiment of a connector

#### 10

As shown, a grasper element **500** is provided for grasping a prosthesis 600. The grasper 500 includes a proximal portion 502 and a distal portion 504. The proximal portion 502 is elongate, having a substantially cylindrical cross-section with an outer diameter d, and a bore 506 extending therethrough along the longitudinal axis 1 of the instrument. The bore 506 is adapted to matingly engage the distal end 20A of the rod 20, and thus can include internal threads that threadingly receive the threaded distal end 20A of the rod 20. A person having ordinary skill in the art will appreciate that a variety of alternative engagement mechanisms can be provided for mating the grasper 500 to the rod 20. The outer diameter d of the cylindrical proximal portion 502 should be less than the diameter of the bore  $\mathbf{80}_d$  in the pusher block  $\mathbf{18}_d$  to allow the proximal portion 502 to be inserted into the bore  $80_d$ . The proximal portion 502 preferably includes a tapered region 505 which increases toward the distal portion 504. The distal portion 504 of the grasper 500 is oriented to extend in a direction substantially transverse to the longitudinal axis 1 of the instrument and includes first and second wing-like components 508, 509, each positioned on opposed sides of the longitudinal axis 1, and separated from one another by a gap 513. The first and second components 508, **509** are not attached to each other, but include a proximally extending portion 510, 511 which mates to the proximal portion 502. The proximally extending portions 510, 511 taper inwardly toward the proximal portion 502. As a result, the grasper 500 incrementally increases in diameter d toward the distal portion 504 of the grasper 500. In an exemplary embodiment, the gap 513 allows the first and second components 508, 509 to be pinched together. The first and second components 508, 509 each include a distally facing wall 520, 521. The walls 520, 521 can have a shape that conforms to the shape of a prosthesis, and preferably the walls are slightly concave to fit around a substantially cylindrical or disc-shaped prosthesis 600, as shown. Each component 508, 509 can include a protruding element 515, 516 disposed on the distally facing wall 520, 521 that is effective to engage a prosthesis 600. The protruding elements 515, 516 can be, for example, triangle-shaped, diamond shaped, or hook-like members which, when placed into openings 518 formed in the prosthesis 600, are effective to engage the prosthesis 600. In use, the grasper 500 is inserted into the bore  $80_{A}$  in the pusher block  $18_{\mathcal{A}}$  and it is mated to the rod 20. The protruding elements 515, 516 are inserted into the openings 518 formed in the prosthesis 600, and the rod 20 is rotated to engage the grasper 600, thereby moving the grasper 600 proximally. As the grasper 600 is pulled in a proximal direction by the rod 20, the tapered portion of the grasper 500 is pulled into bore  $80_{d}$ , thereby causing the first and second components 508, 509 to be pinched together. As a result, the protruding elements 515, 516 grasp and retain the prosthesis 600. The prosthesis 600 can then be positioned between adjacent vertebrae and, once positioned, the rod 20 can be rotated in the opposite direction to release the grasper 500, thereby allowing the first and second components 508, 509 to return to their separated state, thus releasing the prosthesis 600. In an exemplary embodiment, the pusher block  $18_{A}$ includes a recessed region 19 formed in each of the side walls of the pusher block  $18_d$  to allow the grasper 500 to be inserted into the bore  $80_d$ . The first and second components 508, 509, when mated to the pusher block  $18_d$ , sit within the recessed <sup>65</sup> region 19. The rod 20 preferably includes a stop surface (not shown) to prevent further insertion of the rod 20 through the bore  $80_d$  in the pusher block  $18_d$ . The stop surface should be

element for joining the pusher block  $18_d$  to a prosthesis 600.

### 11

positioned to allow a distal portion of the rod 20 to extend through the bore  $80_{d}$  to engage the grasper 500.

The depth of insertion of the cage 600 between the vertebral bodies is dependent on the length of the grasper 500 and the depth of the recessed portion 19. For example, the length 5of the grasper 500 and the depth of the recessed portion 19 can be substantially the same such that the distal end of the pusher block is aligned with the distal end of the grasper. In use, the distal ends of the pusher block and the grasper align with the outer edge of the adjacent vertebrae. As a result, the implanted <sup>10</sup> disc is substantially aligned with the outer edge of the adjacent vertebrae. Alternatively, the grasper 500 can have a length greater than the depth of the recessed portion 19 such that the depth of insertion of the disc is substantially equal to 15the different between the length of the grasper 500 and the depth of the recessed portion 19. FIGS. 9 and 10 illustrate an alternative embodiment in which installation tool 10' includes a locking mechanism 108 in the proximal, handle portion 12B', 14B' of levers 12', 14'. 20 The locking mechanism, which may comprise a latch and groove, simply secures the proximal handle portion of levers in a desired position and prevents complete separation of these elements. FIG. 9 illustrates the tool 10' in a position in which the proximal portion 12B', 14B' of the levers is open or 25 unactuated. The locking mechanism 108 prevents further opening or separation of the proximal portions 12B', 14B' of the levers. However, as shown in FIG. 10, the locking mechanism still allows the handles 12B', 14B' to be actuated or closed together in order to operate the tool and install a 30 prosthesis, such as artificial disc 24. One benefit of the locking mechanism 108 is that the disc is less likely to become inadvertently dislodged from the tool during pre-surgical installation manipulation of the tool.

#### 12

**308** permits the blade tip length to be adjusted by varying the relative positions of components 307, 308.

As shown in FIGS. 13 and 14 tool 300 includes a junction box 309 which houses and secures the components 307, 308. A portion 307A of the stop member component 307, which mates with the inner surface of the cover 320 of the junction box 309, includes a series of grooves 310 separated by raised ridges **311**. Similarly, the abutting, inner surface of the cover 320 of the junction box 309 includes grooves and ridges 310, 311 as well. As further illustrated, the cover 320 is secured to levers 312, 314 by suitable fasteners, such as screws 322. Biasing elements, such as compression springs (not shown) are preferably used to bias the junction box to a position such that the grooves and ridges 310, 311 of the cover 320 and the stop member component 307 mate with and remain firmly secured to one another. As shown in FIG. 14, suitable indicia 325 may be present on the stop member component 307 to indicate the position of the stop member component 307 with respect to the blade member component. Although FIG. 14 only illustrates, in detail, the configuration of lever 12, it is understood that the same construction is used for lever 14. The result of this selective adjustability is shown in FIGS. **15**A and **15**B, in which the blade tip length is greater in FIG. **15**A than in FIG. **15**B. FIGS. 1 and 8A-8D sequentially illustrate the use of tool 10 for the installation of an artificial disc 24. The tool is first assembled as shown in FIG. 1, and with pusher block 18 positioned in its initial position such that its proximally facing wall 96 abuts shoulder 26, the posterior surface 27 of the disc is placed against the distal facing wall 97 of the pusher block. With the handles 12B, 14B in the open position and the blade tips 50A, B closed, the blade tips are wedged between adjacent vertebral bodies 201, 202 to effect slight separation The blade tips **50**A, B should be fully inserted between the vertebral bodies, as shown in FIG. 8A, so as to enable the vertebral stop surface 54 to abut the posterior side 204 of the vertebral bodies 201, 202. The pusher rod 20 is then pushed forward, causing distal movement of the pusher block 18 and artificial disc 24. The forward or distal movement of pusher block 18 and the artificial disc 24 also causes further separation of the blade tips 50A, B and thus further separation of the vertebral bodies 201, 202 as shown in FIG. 8B. Advancement of the pusher block 18 and the artificial disc 24 continues until, as shown in FIG. 8C, the disc is properly installed between adjacent vertebral bodies. FIGS. 8B and 8C illustrate that at all times separation of the vertebral bodies is only effected to the extent necessary to insert the disc. Excessive distraction or separation of the vertebral bodies does not occur because the separation of vertebral bodies is caused by the height of the pusher block. The installation tool of the present invention can also be provided as a kit having modular components which allow the 55 surgeon to select from among a variety of components to assemble an installation tool that is optimized for its intended use. The kit preferably includes several different rods, pusher blocks, and connectors elements, such as grasper 500, each adapted to be used with a particular implant. For example, the kit can include three types of pusher blocks, each adapted to mate with a particular prosthesis. As shown in FIG. 16, the pusher block  $18_{d}$  can be used in combination with grasper 500 to insert a cage-type spacing prosthesis. Alternatively, as shown in FIG. 1, pusher block 18 can be provided for inserting an artificial disc. A person having ordinary skill in the art will appreciate that the installation tool can include a variety of components having a combination of different features.

FIG. 13 illustrates an embodiment of the invention in 35 between at least the anterior portions of the vertebral bodies.

which installation tool **300** includes a plurality protrusions **302**, **304** formed on proximal or handle portions **312**B, **314**B of levers 312, 314. Preferably, the protrusions 302, 304 are formed on lateral surfaces of the handle portions. In an exemplary embodiment two protrusions are formed on each of the 40 top and bottom levers 312, 314. Although illustrated as being substantially cylindrical in shape, it is understood that protrusions 302, 304 may take virtually any shape. Referring back to FIG. 3B, for example, the proximal end 12B, 14B of the handles 12, 14 can have a T-shape. The T-shape, or the 45 protrusions, may be useful to facilitate extraction of the blade tips 350A, 350B using a tool such a slaphammer 800 or a slap fork (shown in FIG. 17) The slap hammer 800 is positioned around the levers 12, 14, and slid proximally to apply a proximally directed force to the T-shaped handles, or to the 50 protrusions 302, 304. The dimensions of T-shaped handles or the protrusions 302, 304 may vary within a wide range. Generally, however, the T-shaped handles or protrusions 302, 304 extend from the lateral surfaces of levers 312, 314 by a distance of about 3 mm to 50 mm.

Although T-shaped handles and protrusions 302, 304 are illustrated, one of ordinary skill in the art will readily appreciate that the handles can have a variety of configurations for allowing use of a slap hammer with the instrument. With reference to FIGS. 13-15B, the installation tool 300 60 may also include a feature which permits selective adjustment of blade tip length (i.e., the distance between the distal end 306 of blade tips 350A, B and stop surface 354). In such an embodiment the distal portion of each of the levers 312A, **314**A has a stop member component **307** and a blade member 65 component 308, which are longitudinally separable with respect to each other. The separability of components 307 and

10

#### 13

Moreover, the components can be adapted for use with particular types of prosthesis, or for use with other components.

One of ordinary skill in the art will appreciate further features and advantages of the invention based on the abovedescribed embodiments. Accordingly, the invention is not to 5 be limited by what has been particularly shown and described, except as indicated by the appended claims. All publication and references cited herein are expressly incorporated herein by reference in their entity.

What is claimed is:

**1**. A medical device installation kit, comprising: a pair of opposed levers, each lever having a proximal handle portion and a distal portion;

#### 14

diameter of the first distal portion and being positioned proximal to the first distal portion;

- a pusher block having a bore extending entirely therethrough having a threaded proximal opening that is threadingly matable with the second distal portion of the rod, and a distal opening having a diameter less than the diameter of the second distal portion of the rod; and a chamber disposed between the proximal and distal openings and having a diameter greater than the diameter of the second distal portion of the rod.] **[8**. The medical device installation kit of claim **7**, wherein the rod is freely rotatable when the second distal portion is
- disposed within the chamber of the pusher block.]
- a fulcrum disposed between the opposed levers for allowing pivotal movement of the levers with respect to each 15 other; and
- a plurality of prosthesis installation assemblies adapted to be slidably disposed between the levers and slidably coupled to the fulcrum such that each prosthesis installation assembly is movable between a first, proximal 20 position and a second, distal position, each assembly including a handle portion effective to move the prosthesis installation assembly between the first and second positions, and a distal prosthesis effecting element adapted to place a prosthesis between adjacent bone 25 structures.
- **[2**. The medical device installation kit of claim 1, wherein one of the prosthesis installation assemblies comprises: a pusher block having a proximal end, a distal end, and a bore extending therethrough; 30
  - a pusher rod slidably disposed between the levers and extending through the bore in the pusher block; and a grasping element effective to releasably engage a prosthesis.
  - **3**. The medical device installation kit of claim **2**, wherein 35

**[9**. The medical device installation kit of claim **8**, wherein the first distal portion of the rod is adapted to positively engage a prosthesis.

**10**. The medical device installation kit of claim 1, wherein one of the prosthesis installation assemblies comprises:

- a pusher block having a proximal end, a distal end, and a bore extending therethrough, the pusher block being slidably disposed between the levers;
- a pusher rod having a proximal, handle portion and a distal portion extending through the bore in the pusher block; and
- a plurality of connector elements having a proximal portion adapted to mate to a distal tip of the pusher rod and a distal portion adapted to mate to a prosthesis. **11**. A medical device installation tool, comprising: a pair of opposed levers, each having a proximal, handle portion and a distal portion;
  - a fulcrum disposed between the two levers and including an opening extending therethrough;
- a pusher block having a proximal end, a distal end, and a bore extending at least partially therethrough, the pusher

the grasping element has an elongate proximal portion adapted to fit within the bore of the distal end of the pusher block, and a distal portion having opposed first and second components which are movable between a first, open position, and a second, closed position that is effective to engage 40 a prosthesis.

**[4**. The medical device installation kit of claim **3**, wherein a distal end of the rod threadingly engages the bore of the pusher block and wherein rotation of the rod in a first direction is effective to cause the elongate proximal portion of the 45 grasping element to move proximally within the bore of the pusher block and move the first and second components to the second, closed position while rotation of the rod in a second direction is effective to cause the elongate proximal portion of the grasping element to move distally out of the bore of the 50 pusher block and move the first and second components to the first, open position.

**5**. The medical device installation kit of claim 1, wherein one of the prosthesis installation assemblies comprises a pusher rod having a proximal handle portion, and distal por-55 tion having a distal tip adapted to positively engage a prosthesis.

block being positioned between the two levers and slidably moveable between an initial location distal of the fulcrum and a final location adjacent a distal end of the levers; and

a pusher rod having a proximal, handle end, and a distal end, the pusher rod being slidably disposed through the fulcrum and the distal end of the pusher rod extending into the bore in the pusher block.

[12. The medical device installation tool of claim 11, wherein the bore is a blind bore and the distal end of the pusher rod mates with the blind bore in the pusher block.

[13. The medical devise installation tool of claim 11, wherein each lever includes a surface feature disposed between the proximal and distal portions thereof, the surface feature being effective to slidably mate to a complementary surface feature formed in a prosthesis.]

[14. The medical device installation tool of claim 11, wherein the bore extends entirely through the pusher block and the distal end of the pusher rod has a distal tip that is adapted to extend through the bore in the pusher block and that is effective to mate to a prosthesis.

[15. The medical device installation tool of claim 14, wherein the pusher block has a height effective to separate the levers from a prosthesis such that, when the pusher rod is mated to a prosthesis, the levers are spaced apart from the prosthesis. **[16**. The medical device installation tool of claim **14**, wherein the rod includes an externally threaded first distal portion and an externally threaded second distal portion, the second distal portion having a diameter greater than a diameter of the first distal portion and being positioned proximal to the first distal portion.

**[6**. The medical device installation kit of claim **5**, wherein the prosthesis installation assembly further includes a pusher block having a proximal end, a distal end, and a bore extend- 60 ing therethrough, the distal portion of the pusher rod extending through the bore in the pusher block.]

**[7**. The medical device installation kit of claim 1, wherein one of the prosthesis installation assemblies comprises: a pusher rod having an externally threaded first distal por- 65 tion and an externally threaded second distal portion, the second distal portion having a diameter greater than a

5

### 15

**[17**. The medical device installation tool of claim 16, wherein:

- the bore of the pusher block includes a threaded proximal opening that is threadingly matable with the second distal portion of the rod;
- a distal opening of the pusher block having a diameter less than the diameter of the second distal portion of the rod; and
- a chamber disposed between the proximal and distal openings, the chamber having a diameter greater than the <sup>10</sup> diameter of the second distal portion of the rod.]

[18. The medical device installation tool of claim 17, wherein the rod is freely rotatable when the second distal portion is disposed within the chamber of the pusher block. [19. The medical device installation tool of claim 17, wherein the threaded first distal portion of the rod is threaded in a direction opposite to the direction of the threads of the threaded second distal portion. **[20**. The medical device installation tool of claim **11**, 20 wherein the bore extends entirely through the pusher block and a distal tip of the pusher rod is adapted to extend through the bore in the pusher block, the distal tip of the pusher rod being further adapted to mate to a grasping element effective to releasably engage a prosthesis. [21. The medical device installation tool of claim 20, further comprising a grasping element that has an elongate proximal portion with a bore formed therein and a distal portion that is effective to releasably engage a prosthesis, the proximal portion having an outer diameter that is adapted to <sup>30</sup> fit within the bore of the distal end of the pusher block.] [22. The medical device installation tool of claim 21, wherein the distal portion of the grasping element includes opposed first and second components that are movable 35 between a first, open position, and a second, closed position that is effective to engage a prosthesis. [23. The medical device installation tool of claim 22, wherein the distal end of the rod threadingly engages the bore of the grasping element, and wherein rotation of the rod in a  $_{40}$ first direction is effective to cause the elongate proximal portion of the grasping element to move proximally within the bore of the pusher block and move the first and second components to the second, closed position while rotation of the rod in a second direction is effective to cause the elongate 45 proximal portion of the grasping element to move distally out of the bore of the pusher block and move the first and second components to the first, open position. [24. The medical device installation tool of claim 23, wherein the first and second components each include at least 50 *lever*. one surface feature effective to engage a prosthesis.] **[25**. The medical installation tool of claim **11**, wherein the bore extends entirely through the pusher block and a distal tip of the pusher rod is adapted to extend through the bore in the pusher block, the distal tip of the pusher rod being further 55 adapted to positively engage a prosthesis.

#### 16

[28. The medical device installation tool of claim 11, wherein the pusher rod includes a stop member effective to limit advancement of the pusher rod through the opening in the fulcrum.]

[29. The medical device installation tool of claim 11, wherein the distal portion of each lever includes a curve tip.] 30. A method of installing an implant, comprising: inserting distal tips of a pair of opposed levers between adjacent vertebral bodies, the distal tips being movable relative to one another between a closed position and an open position; and

advancing a pusher rod disposed between the pair of opposed levers distally to advance a pusher block distally and to move an implant engaged by the pusher block from an initial proximal location to a final location adjacent to the distal tips and between the adjacent vertebral bodies, the pusher block being coupled to a distal end of the pusher rod and disposed between the pair of opposed levers, and the pusher block having projections that slide within respective tracks formed in the pair of opposed levers as the pusher block is advanced distally. 31. The method of claim 30, wherein advancing the pusher block causes the distal tips to move to an open position and to 25 *distract the adjacent vertebral bodies.* 32. The method of claim 30, wherein inserting the distal tips comprises advancing the distal tips distally between the adjacent vertebral bodies until stop surfaces of the distal tips abut the adjacent vertebral bodies. 33. The method of claim 30, wherein inserting the distal tips effects a separation of the adjacent vertebral bodies. 34. A method of installing an implant, comprising: inserting distal tips of a pair of opposed levers between adjacent vertebral bodies, the pair of opposed levers being coupled to one another adjacent a proximal end thereof and being movable at a distal end thereof between a closed position and an open position; and advancing an implant having first and second surface features formed thereon by sliding the and first and second surface features along complementary surface features formed on inwardly facing surfaces of the opposed levers, the implant being engaged and advanced by a pusher component positioned between the pair of opposed levers such that projections of the pusher component slide in engagement with the opposed levers to maintain alignment between the pusher component and the opposed levers. 35. The method of claim 34, wherein the surface feature on each lever extends between the proximal and distal ends of the

[26. The medical device installation tool of claim 11,

36. The method of claim 34, wherein the surface feature on each lever comprises a rail, and the first and second surface features on the implant comprise first and second channels formed in the implant.

37. The method of claim 34, further comprising moving the levers from the closed position to the open position to distract the adjacent vertebral bodies by moving the pusher component distally towards the distal ends of the opposed levers.
38. The method of claim 34, wherein the projections comprise a plurality of posts extending from the pusher block, each post being complementary to a track formed in each lever such that the post is configured to slide along the track to facilitate movement of the pusher block with respect to the opposed levers.
39. The method of claim 34, wherein inserting the distal tips comprises advancing the distal tips distally between the adjacent vertebral bodies until stop features of the distal tips

wherein the pusher block has upper and lower recesses, each adapted to seat one of the levers, each of the upper and lower recesses including opposed, substantially vertical walls separated by a substantially horizontal base wall, the vertical walls each including a rail extending between the proximal and distal ends of the pusher block and effective to retain the levers.]

[27. The medical device installation tool of claim 11, 65 wherein the handle portion of each lever is substantially T-shaped.]

#### 17

engage the adjacent vertebral bodies to stop further distal movement of the opposed levers.

40. The method of claim 34, wherein inserting the distal tips effects a separation of the adjacent vertebral bodies. 41. A method of installing an implant, comprising: inserting a distal tip of a first lever and a distal tip of a second lever between adjacent vertebral bodies, the first lever having proximal and distal ends and a first rail formed thereon, the second lever having proximal and distal ends and a second rail formed thereon and being 10 coupled to the first lever at a location proximal to the distal tips of the first and second levers; and sliding a pusher block disposed between the first and second levers and engaged with an implant towards the distal tips of the first and second levers to advance the 15 implant distally relative to the first and second levers such that the first and second rails slide within first and second grooves formed in opposed surfaces of the implant.

#### 18

42. The method of claim 41, wherein sliding the pusher block comprises sliding a first post of the pusher block along a first track formed in the first lever and sliding a second post of the pusher block along a second track formed in the second lever to move the pusher block with respect to the first and second levers.

43. The method of claim 41, wherein advancing the pusher block causes the distal tips to move to an open position and to distract the adjacent vertebral bodies.

44. The method of claim 41, wherein inserting the distal tips comprises advancing the distal tips distally between the adjacent vertebral bodies until stop surfaces of the distal tips abut the adjacent vertebral bodies.

45. The method of claim 41, wherein inserting the distal tips effects a separation of the adjacent vertebral bodies.

\* \* \* \* \*

## UNITED STATES PATENT AND TRADEMARK OFFICE **CERTIFICATE OF CORRECTION**

: RE45,639 E PATENT NO. APPLICATION NO. DATED INVENTOR(S)

: 14/172631 : August 4, 2015 : Fraser et al.

Page 1 of 1

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

#### In the Specification

#### Column 1, beginning at Line 11, replace the heading "CROSS-REFERENCE TO RELATED APPLICATIONS" and the paragraph thereunder, with the following:

Notice: More than one reissue application has been filed for the reissue of U.S. Patent No. 6,755,841. The reissue applications are U.S. Reissue Patent Application Serial No. 14/800,411, filed on July 15, 2015, now U.S. Reissue Patent No. RE46,410 E, issued May 23, 2017, which is a continuation reissue application of U.S. Reissue Patent Application Serial No. 14/172,631 (the present application), filed on February 4, 2014, now U.S. Reissue Patent No. RE45,639 E, issued August 4, 2015, which is a continuation reissue application of U.S. Reissue Patent Application Serial No. 13/331,675, filed on December 20, 2011, now U.S. Reissue Patent No. RE44,835 E, issued April 8, 2014, which is a continuation reissue application of U.S. Reissue Patent Application Serial No. 11/397,887, filed on March 29, 2006, now U.S. Reissue Patent No. RE43,317 E, issued April 17, 2012.

#### CROSS-REFERENCE TO RELATED APPLICATIONS

U.S. Patent Application Serial No. 10/011,264, filed December 7, 2001, now U.S. Patent No. 6,755,841, issued June 29, 2004, is a continuation-in-part of U.S. Patent Application Serial No. 09/566,514, filed May 8, 2000, now U.S. Patent No. 6,478,800, issued November 12, 2002, entitled "Medical Installation Tool," the entire contents of each of which is hereby expressly incorporated *herein by reference.* 

> Signed and Sealed this Twelfth Day of June, 2018

Andrei Jana

#### Andrei Iancu Director of the United States Patent and Trademark Office