FISH.
FISH & RICHARDSON

Street Address
Fish & Richardson P.C.
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July 2, 2018

Attorney Docket No.: 46440-0020003

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Presented for filing is a new continuation patent application for prioritized examination of:

Inventor(s): AHMNON D. MOSKOWITZ, MOSHEH T. MOSKOWITZ, PABLO A. VALDIVIA Y. ALVARADO, ERIC SUGALSKI AND NATHAN C. MOSKOWITZ

Title: ZERO-PROFILE EXPANDABLE INTERVERTEBRAL SPACER DEVICES FOR DISTRACTION AND SPINAL FUSION AND A UNIVERSAL TOOL FOR THEIR PLACEMENT AND EXPANSION

Enclosed are the following papers, including those required to receive a filing date under 37 CFR 1.53(b):

	Pages
Specification	29
Claims	1
Abstract	1
Declaration	5
Drawing(s)	38

Enclosures:

— Application Data Sheet, 12 pages.
— Power of Attorney, 2 pages.
— Certification and Request for Prioritized Examination (Track I), 1 page

The applicant claims small entity status under 37 CFR 1.27.

Basic Filing Fee $75

Search Fee			$330
Examination Fee			$380
Publication fee			$0
Track I processing fee			$70
Track I prioritized examination fee			$2000
Total Claims 1	over 20	**0 x $50**	$0
Independent Claims 1	over 3	**0 x $230**	$0
Fee for Multiple Dependent claims			$0
Application size fee for each 50 pages over 100 Total Sheets: 69x .75 - 100/50 = 0x			$0
Total Filing fee			$2855

The total filing fee is being paid concurrently on the Electronic Filing System (EFS) by deposit account authorization. Apply any other required fees or any credits to Deposit Account No. 06-1050, referencing the attorney docket number shown above.

I hereby authorize the USPTO to communicate in response to email communications from the undersigned and practitioners under Customer No. 26191 in accordance with 37 CFR 1.33 and 37 CFR 1.34 concerning any subject matter of this application via email. I understand that a copy of these communications will be made of record in the application file. (MPEP 502.03).

If this application is considered to be incomplete, or if a telephone conference would otherwise be helpful, call the undersigned at (612) 337-2538.

Send all correspondence to:

26191
Customer Number

Respectfully submitted,

/Stuart A. Nelson/

Stuart A. Nelson

Registration No. 63,947
Enclosures
SWN/aur
61713119.doc

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	46440-0020003
	Application Number	
Title of Invention	ZERO-PROFILE EXPANDABLE INTERVERTEBRAL SPACER DEVICES FOR DISTRACTION AND SPINAL FUSION AND A UNIVERSAL TOOL FOR THEIR PLACEMENT AND EXPANSION	

The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76.
This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application.

Secrecy Order 37 CFR 5.2:

☐ Portions or all of the application associated with this Application Data Sheet may fall under a Secrecy Order pursuant to 37 CFR 5.2 (Paper filers only. Applications that fall under Secrecy Order may not be filed electronically.)

Inventor Information:

Inventor 1 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Ahmnon	D.	Moskowitz	

Residence Information (Select One) • US Residency ○ Non US Residency ○ Active US Military Service

City	State/Province	Country of Residence
Rockville	MD	US

Mailing Address of Inventor:

Address 1	212 North Adams St.
Address 2	
City	Rockville
State/Province	MD
Postal Code	20850
Country	US

Inventor 2 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Mosheh	T.	Moskowitz	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	State/Province	Country of Residence
Rockville	MD	US

Mailing Address of Inventor:

Address 1	212 North Adams St.
Address 2	
City	Rockville
State/Province	MD
Postal Code	20850
Country	US

Inventor 3 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Pablo	A. Valdivia Y.	Alvarado	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	46440-0020003
	Application Number	
Title of Invention	ZERO-PROFILE EXPANDABLE INTERVERTEBRAL SPACER DEVICES FOR DISTRACTION AND SPINAL FUSION AND A UNIVERSAL TOOL FOR THEIR PLACEMENT AND EXPANSION	

City	Cambridge	State/Province	MA	Country of Residence	US

Mailing Address of Inventor:

Address 1	13 Lancaster St. #2		
Address 2			
City	Cambridge	State/Province	MA
Postal Code	02139	Country	US

Inventor 4 — Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Eric		Sugalski	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	Arlington	State/Province	MA	Country of Residence	US

Mailing Address of Inventor:

Address 1	128 Blossom Street		
Address 2			
City	Arlington	State/Province	MA
Postal Code	02474	Country	US

Inventor 5 — Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Nathan	C.	Moskowitz	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	Rockville	State/Province	MD	Country of Residence	US

Mailing Address of Inventor:

Address 1	212 North Adams Street		
Address 2			
City	Rockville	State/Province	MD
Postal Code	20850	Country	US

All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the **Add** button. — Add

Correspondence Information:

Enter either Customer Number or complete the Correspondence Information section below.
For further information see 37 CFR 1.33(a).

☐ **An Address is being provided for the correspondence Information of this application.**

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	46440-0020003
	Application Number	
Title of Invention	ZERO-PROFILE EXPANDABLE INTERVERTEBRAL SPACER DEVICES FOR DISTRACTION AND SPINAL FUSION AND A UNIVERSAL TOOL FOR THEIR PLACEMENT AND EXPANSION	

Customer Number	26191		
Email Address	apsi@fr.com	Add Email	Remove Email

Application Information:

Title of the Invention	ZERO-PROFILE EXPANDABLE INTERVERTEBRAL SPACER DEVICES FOR DISTRACTION AND SPINAL FUSION AND A UNIVERSAL TOOL FOR THEIR PLACEMENT AND EXPANSION		
Attorney Docket Number	46440-0020003	**Small Entity Status Claimed**	☒
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)	38	**Suggested Figure for Publication (if any)**	

Filing By Reference:

Only complete this section when filing an application by reference under 35 U.S.C. 111(c) and 37 CFR 1.57(a). Do not complete this section if application papers including a specification and any drawings are being filed. Any domestic benefit or foreign priority information must be provided in the appropriate section(s) below (i.e., "Domestic Benefit/National Stage Information" and "Foreign Priority Information").

For the purposes of a filing date under 37 CFR 1.53(b), the description and any drawings of the present application are replaced by this reference to the previously filed application, subject to conditions and requirements of 37 CFR 1.57(a).

Application number of the previously filed application	Filing date (YYYY-MM-DD)	Intellectual Property Authority or Country

Publication Information:

☐ Request Early Publication (Fee required at time of Request 37 CFR 1.219)

☐ **Request Not to Publish.** I hereby request that the attached application not be published under 35 U.S.C. 122(b) and certify that the invention disclosed in the attached application **has not and will not** be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing.

Representative Information:

Representative information **should** be provided for all practitioners having a power of attorney in the application. Providing this information in the Application Data Sheet does not constitute a power of attorney in the application (see 37 CFR 1.32).
Either enter Customer Number or complete the Representative Name section below. If both sections are completed the customer Number will be used for the Representative Information during processing.

Please Select One:	● Customer Number	US Patent Practitioner	○ Limited Recognition (37 CFR 11.9)
Customer Number	26191		

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	46440-0020003
	Application Number	
Title of Invention	ZERO-PROFILE EXPANDABLE INTERVERTEBRAL SPACER DEVICES FOR DISTRACTION AND SPINAL FUSION AND A UNIVERSAL TOOL FOR THEIR PLACEMENT AND EXPANSION	

Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, 365(c), or 386(c) or indicate National Stage entry from a PCT application. Providing benefit claim information in the Application Data Sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78.
When referring to the current application, please leave the "Application Number" field blank.

Prior Application Status	Pending				Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)		
	Continuation of	15820232	2017-11-21		
Prior Application Status	Patented				Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
15820232	Continuation of	14063197	2013-10-25	9848993	2017-12-26
Prior Application Status	Expired				Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)		
14063197	Claims benefit of provisional	61801783	2013-03-15		
Prior Application Status	Expired				Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)		
14063197	Claims benefit of provisional	61718707	2012-10-25		
Prior Application Status	Patented				Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
14063197	Continuation in part of	13210150	2011-08-15	9867719	2018-01-16
Prior Application Status	Patented				Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
14063197	Continuation in part of	13210157	2011-08-15	9889022	2018-02-13
Prior Application Status	Patented				Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
14063197	Continuation in part of	13210162	2011-08-15	9895238	2018-02-20
Prior Application Status	Patented				Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
14063197	Continuation in part of	13210168	2011-08-15	9907674	2018-03-06

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	46440-0020003
	Application Number	
Title of Invention	ZERO-PROFILE EXPANDABLE INTERVERTEBRAL SPACER DEVICES FOR DISTRACTION AND SPINAL FUSION AND A UNIVERSAL TOOL FOR THEIR PLACEMENT AND EXPANSION	

Prior Application Status	Patented				Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
14063197	Continuation in part of	13741361	2013-01-14	9301854	2016-04-05
Prior Application Status	Patented				Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
13210150	Continuation of	13084543	2011-04-11	8353913	2013-01-15
Prior Application Status	Patented				Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
13210150	Continuation of	13108982	2011-05-16	9005293	2015-04-14
Prior Application Status	Patented				Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
13210157	Continuation of	13084543	2011-04-11	8353913	2013-01-15
Prior Application Status	Patented				Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
13210157	Continuation of	13108982	2011-05-16	9005293	2015-04-14
Prior Application Status	Patented				Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
13210162	Continuation of	13084543	2011-04-11	8353913	2013-01-15
Prior Application Status	Patented				Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
13210162	Continuation of	13108982	2011-05-16	9005293	2015-04-14
Prior Application Status	Patented				Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
13210168	Continuation of	13084543	2011-04-11	8353913	2013-01-15
Prior Application Status	Patented				Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
13210168	Continuation of	13108982	2011-05-16	9005293	2015-04-14
Prior Application Status	Patented				Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
13741361	Continuation of	13084543	2011-04-11	8353913	2013-01-15

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	46440-0020003
	Application Number	
Title of Invention	ZERO-PROFILE EXPANDABLE INTERVERTEBRAL SPACER DEVICES FOR DISTRACTION AND SPINAL FUSION AND A UNIVERSAL TOOL FOR THEIR PLACEMENT AND EXPANSION	

Prior Application Status	Patented			Remove	
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
13741361	Continuation of	13108982	2011-05-16	9005293	2015-04-14
Prior Application Status	Patented			Remove	
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
13084543	Continuation of	11842855	2007-08-21	7942903	2011-05-17
Prior Application Status	Patented			Remove	
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
13108982	Continuation of	11842855	2007-08-21	7942903	2011-05-17
Prior Application Status	Patented			Remove	
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
11842855	Continuation in part of	11536815	2006-09-29	7846188	2010-12-07
Prior Application Status	Abandoned			Remove	
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)		
11536815	Continuation in part of	11208644	2005-08-23		
Prior Application Status	Expired			Remove	
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)		
11208644	Claims benefit of provisional	60670231	2005-04-12		
Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the **Add** button.				Add	

Foreign Priority Information:

This section allows for the applicant to claim priority to a foreign application. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55. When priority is claimed to a foreign application that is eligible for retrieval under the priority document exchange program (PDX)[i] the information will be used by the Office to automatically attempt retrieval pursuant to 37 CFR 1.55(i)(1) and (2). Under the PDX program, applicant bears the ultimate responsibility for ensuring that a copy of the foreign application is received by the Office from the participating foreign intellectual property office, or a certified copy of the foreign priority application is filed, within the time period specified in 37 CFR 1.55(g)(1).

Remove

Application Number	Country[i]	Filing Date (YYYY-MM-DD)	Access Code[i] (if applicable)

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	46440-0020003
	Application Number	
Title of Invention	ZERO-PROFILE EXPANDABLE INTERVERTEBRAL SPACER DEVICES FOR DISTRACTION AND SPINAL FUSION AND A UNIVERSAL TOOL FOR THEIR PLACEMENT AND EXPANSION	

Additional Foreign Priority Data may be generated within this form by selecting the **Add** button. Add

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications

☐ This application (1) claims priority to or the benefit of an application filed before March 16, 2013 and (2) also contains, or contained at any time, a claim to a claimed invention that has an effective filing date on or after March 16, 2013.
NOTE: By providing this statement under 37 CFR 1.55 or 1.78, this application, with a filing date on or after March 16, 2013, will be examined under the first inventor to file provisions of the AIA.

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	46440-0020003
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Title of Invention	ZERO-PROFILE EXPANDABLE INTERVERTEBRAL SPACER DEVICES FOR DISTRACTION AND SPINAL FUSION AND A UNIVERSAL TOOL FOR THEIR PLACEMENT AND EXPANSION	

Authorization or Opt-Out of Authorization to Permit Access:

When this Application Data Sheet is properly signed and filed with the application, applicant has provided written authority to permit a participating foreign intellectual property (IP) office access to the instant application-as-filed (see paragraph A in subsection 1 below) and the European Patent Office (EPO) access to any search results from the instant application (see paragraph B in subsection 1 below).

Should applicant choose not to provide an authorization identified in subsection 1 below, applicant **must opt-out** of the authorization by checking the corresponding box A or B or both in subsection 2 below.

NOTE: This section of the Application Data Sheet is **ONLY** reviewed and processed with the **INITIAL** filing of an application. After the initial filing of an application, an Application Data Sheet cannot be used to provide or rescind authorization for access by a foreign IP office(s). Instead, Form PTO/SB/39 or PTO/SB/69 must be used as appropriate.

1. Authorization to Permit Access by a Foreign Intellectual Property Office(s)

A. Priority Document Exchange (PDX) - Unless box A in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the European Patent Office (EPO), the Japan Patent Office (JPO), the Korean Intellectual Property Office (KIPO), the State Intellectual Property Office of the People's Republic of China (SIPO), the World Intellectual Property Organization (WIPO), and any other foreign intellectual property office participating with the USPTO in a bilateral or multilateral priority document exchange agreement in which a foreign application claiming priority to the instant patent application is filed, access to: (1) the instant patent application-as-filed and its related bibliographic data, (2) any foreign or domestic application to which priority or benefit is claimed by the instant application and its related bibliographic data, and (3) the date of filing of this Authorization. See 37 CFR 1.14(h)(1).

B. Search Results from U.S. Application to EPO - Unless box B in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the EPO access to the bibliographic data and search results from the instant patent application when a European patent application claiming priority to the instant patent application is filed. See 37 CFR 1.14(h)(2).

The applicant is reminded that the EPO's Rule 141(1) EPC (European Patent Convention) requires applicants to submit a copy of search results from the instant application without delay in a European patent application that claims priority to the instant application.

2. Opt-Out of Authorizations to Permit Access by a Foreign Intellectual Property Office(s)

☐ A. Applicant **DOES NOT** authorize the USPTO to permit a participating foreign IP office access to the instant application-as-filed. If this box is checked, the USPTO will not be providing a participating foreign IP office with any documents and information identified in subsection 1A above.

☐ B. Applicant **DOES NOT** authorize the USPTO to transmit to the EPO any search results from the instant patent application. If this box is checked, the USPTO will not be providing the EPO with search results from the instant application.

NOTE: Once the application has published or is otherwise publicly available, the USPTO may provide access to the application in accordance with 37 CFR 1.14.

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	Application Number	
Title of Invention	ZERO-PROFILE EXPANDABLE INTERVERTEBRAL SPACER DEVICES FOR DISTRACTION AND SPINAL FUSION AND A UNIVERSAL TOOL FOR THEIR PLACEMENT AND EXPANSION	

Applicant Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

Applicant 1 Remove

If the applicant is the inventor (or the remaining joint inventor or inventors under 37 CFR 1.45), this section should not be completed. The information to be provided in this section is the name and address of the legal representative who is the applicant under 37 CFR 1.43; or the name and address of the assignee, person to whom the inventor is under an obligation to assign the invention, or person who otherwise shows sufficient proprietary interest in the matter who is the applicant under 37 CFR 1.46. If the applicant is an applicant under 37 CFR 1.46 (assignee, person to whom the inventor is obligated to assign, or person who otherwise shows sufficient proprietary interest) together with one or more joint inventors, then the joint inventor or inventors who are also the applicant should be identified in this section.

Clear

● Assignee	Legal Representative under 35 U.S.C. 117	Joint Inventor
Person to whom the inventor is obligated to assign.	Person who shows sufficient proprietary interest	

If applicant is the legal representative, indicate the authority to file the patent application, the inventor is:

Name of the Deceased or Legally Incapacitated Inventor:

If the Applicant is an Organization check here. ☒

Organization Name	Moskowitz Family LLC		
Mailing Address Information For Applicant:			
Address 1	212 North Adams Street		
Address 2			
City	Rockville	**State/Province**	MD
Country	US	Postal Code	20850
Phone Number		Fax Number	
Email Address			

Additional Applicant Data may be generated within this form by selecting the Add button. Add

Assignee Information including Non-Applicant Assignee Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	46440-0020003
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Title of Invention	ZERO-PROFILE EXPANDABLE INTERVERTEBRAL SPACER DEVICES FOR DISTRACTION AND SPINAL FUSION AND A UNIVERSAL TOOL FOR THEIR PLACEMENT AND EXPANSION	

Assignee 1

Complete this section if assignee information, including non-applicant assignee information, is desired to be included on the patent application publication. An assignee-applicant identified in the "Applicant Information" section will appear on the patent application publication as an applicant. For an assignee-applicant, complete this section only if identification as an assignee is also desired on the patent application publication.

Remove

If the Assignee or Non-Applicant Assignee is an Organization check here. ☐

Prefix	**Given Name**	Middle Name	**Family Name**	Suffix

Mailing Address Information For Assignee including Non-Applicant Assignee:

Address 1			
Address 2			
City		**State/Province**	
Country i		Postal Code	
Phone Number		Fax Number	
Email Address			

Additional Assignee or Non-Applicant Assignee Data may be generated within this form by selecting the Add button. Add

Signature:

Remove

NOTE: This Application Data Sheet must be signed in accordance with 37 CFR 1.33(b). **However, if this Application Data Sheet is submitted with the INITIAL filing of the application and either box A or B is not checked in subsection 2 of the "Authorization or Opt-Out of Authorization to Permit Access" section, then this form must also be signed in accordance with 37 CFR 1.14(c).**

This Application Data Sheet **must** be signed by a patent practitioner if one or more of the applicants is a **juristic entity** (e.g., corporation or association). If the applicant is two or more joint inventors, this form must be signed by a patent practitioner, **all** joint inventors who are the applicant, or one or more joint inventor-applicants who have been given power of attorney (e.g., see USPTO Form PTO/AIA/81) on behalf of **all** joint inventor-applicants.

See 37 CFR 1.4(d) for the manner of making signatures and certifications.

Signature	/Stuart A. Nelson/			Date (YYYY-MM-DD)	2018-07-02
First Name	Stuart A.	Last Name	Nelson	Registration Number	63,947

Additional Signature may be generated within this form by selecting the Add button. Add

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	46440-0020003
	Application Number	
Title of Invention	ZERO-PROFILE EXPANDABLE INTERVERTEBRAL SPACER DEVICES FOR DISTRACTION AND SPINAL FUSION AND A UNIVERSAL TOOL FOR THEIR PLACEMENT AND EXPANSION	

This collection of information is required by 37 CFR 1.76. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 23 minutes to complete, including gathering, preparing, and submitting the completed application data sheet form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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3 A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

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7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

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TRANSMITTAL FOR POWER OF ATTORNEY TO ONE OR MORE REGISTERED PRACTITIONERS

Application Number	To Be Assigned
Filing Date	Herewith
First Named Inventor	Ahmnon D. Moskowitz
Title	ZERO-PROFILE EXPANDABLE INTERVERTEBRAL SPACER DEVICES FOR DISTRACTION AND SPINAL FUSION AND A UNIVERSAL TOOL FOR THEIR PLACEMENT AND EXPANSION
Art Unit	Unknown
Examiner Name	Unknown
Attorney Docket Number	46440-0020003

SIGNATURE of Applicant or Patent Practitioner

Signature	/Stuart A. Nelson/	Date (Optional)	7/2/2018
Name	Stuart A. Nelson	Registration Number	63,947
Title (if Applicant is a juristic entity)			
Applicant Name (if Applicant is a juristic entity)			

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications. If more than one applicant, use multiple forms.

☐ *Total of _____ forms are submitted.

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POWER OF ATTORNEY BY APPLICANT

I hereby revoke all previous powers of attorney given in the application identified in either the attached transmittal letter or the boxes below.

Application Number	Filing Date

(Note: The boxes above may be left blank if information is provided on the Transmittal.)

☒ I hereby appoint the Patent Practitioner(s) associated with the following Customer Number as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the application referenced in the attached transmittal letter, which may be an application filed after the date of this power of attorney, or identified above:

26191

OR

☐ I hereby appoint Practitioner(s) named in the attached list as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the patent application referenced in the attached transmittal letter, which may be an application filed after the date of this power of attorney, or identified above.

Please recognize or change the correspondence address for the application identified in the attached transmittal letter to:

☐ The address associated with the above-mentioned Customer Number

OR

☒ The address associated with Customer Number: **26191**

OR

Firm or Individual Name					
Address					
City		State		Zip	
Country					
Telephone		Email			

I am the Applicant (if the Applicant is a juristic entity, list the Applicant name in the box):

Moskowitz Family LLC

☐ Inventor or Joint Inventor (title not required below)

☐ Legal Representative of a Deceased or Legally Incapacitated Inventor (title not required below)

☒ Assignee or Person to Whom the Inventor is Under an Obligation to Assign (provide signer's title if applicant is a juristic entity)

☐ Person Who Otherwise Shows Sufficient Proprietary Interest (e.g., a petition under 37 CFR 1.46(b)(2) was granted in the application or is concurrently being filed with this document) (provide signer's title if applicant is a juristic entity)

SIGNATURE of Applicant for Patent

The undersigned (whose title is supplied below) is authorized to act on behalf of the applicant (e.g., where the applicant is a juristic entity).

Signature	Nathan C. Moskowitz	Date (Optional)	7/17/16
Name	Nathan C. Moskowitz		
Title	Manager, Moskowitz Family LLC		

NOTE: Signature - This form must be signed by the applicant in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. If more than one applicant, use multiple forms.

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Attorney Docket No.: 45335-0020001

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DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

Title of Invention	ZERO-PROFILE EXPANDABLE INTERVERTEBRAL SPACER DEVICES FOR DISTRACTION AND SPINAL FUSION AND A UNIVERSAL TOOL FOR THEIR PLACEMENT AND EXPANSION

As the below named inventor, I hereby declare that:

This declaration is directed to:

[ ] The attached application, or

[X] United States application or PCT international application number 14/063,197

filed on October 25, 2013.

The above-identified application was made or authorized to be made by me.

I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

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LEGAL NAME OF INVENTOR

Inventor: Ahmnon D. Moskowitz Date (Optional): 9/25/17

Signature:

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

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LEGAL NAME OF INVENTOR

Inventor: Mosheh T. Moskowitz Date (Optional): 11/24/13

Signature:

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

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LEGAL NAME OF INVENTOR

Inventor: Pablo A. Valdivia y Alvarado Date (Optional): OCT-10-2017

Signature:

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

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LEGAL NAME OF INVENTOR

Inventor: Eric Sugalski Date (Optional): 09 / 27 / 2017

Signature: _____

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

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LEGAL NAME OF INVENTOR

Inventor: Nathan C. Moskowitz Date (Optional): 9/25/17

Signature: Nathan C. Moskowitz

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

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ZERO-PROFILE EXPANDABLE INTERVERTEBRAL SPACER DEVICES FOR DISTRACTION AND SPINAL FUSION AND A UNIVERSAL TOOL FOR THEIR PLACEMENT AND EXPANSION

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is a Continuation-in-part Application of each of co-pending application Serial No. 13/210,150, filed on August 15, 2011, co-pending application Serial No. 13/210,157, filed on August 15, 2011, co-pending application Serial No. 13/210,162, filed on August 15, 2011, co-pending application Serial No. 13/210,168, filed on August 15, 2011, co-pending application Serial No. 13/741,361, filed on January 14, 2013, each of which is a Continuation Application of application Serial No. 13,084,543, filed on April 11, 2011, now U.S. Patent No. 8,353,913 issued on January 15, 2013, which is a Divisional Application of application Serial No. 11/842,855, filed on August 21, 2007, now U.S. Patent No. 7,942,903 issued on May 17, 2011, and a Continuation Application of application Serial No. 13,108,982, filed on May 16, 2011, which also is a Continuation Application of application Serial No. 11/842,855, filed on August 21, 2007, now U.S. Patent No. 7,942,903 issued on May 17, 2011, which is a Continuation-In-Part Application of application Serial No. 11/536,815, filed on September, 29, 2006, now U.S. Patent No. 7,846,188 issued on December 7, 2010, which is a Continuation-In-Part Application of application Serial No. 11/208,644, filed on August 23, 2005, now U.S. Patent No. 7,704,279 issued on April 27, 2010, for which priority is claimed under 35 U.S.C. §120; and this application also claims priority under 35 U.S.C. § 119(e) of U.S. provisional application No. 61/801,783, filed on March 15,

2013, U.S. provisional application No. 61/718,707, filed on October 25, 2012, and U.S. provisional application No. 60/670,231, filed on April 12, 2005; the entire contents of all the above identified patent applications are hereby incorporated by reference.

[0002] U.S. Patent Application Serial Nos. 13/084,543, filed on April 11, 2011 (Attorney Docket No. 3003/0105PUS2), 11/842,855, filed on August 21, 2007 (Attorney Docket No. 3003/0105PUS1), 11/536,815, filed on September 29, 2006 (Attorney Docket No. 3003/0104PUS2), and 11/208,644, filed on August 23, 2005 (Attorney Docket No. 3003/0104PUS1), each claim the benefit of priority under 35 U.S.C. § 119(e) of U.S. Provisional Application No. 60/670,231, filed on April 12, 2005 (Attorney Docket No. 3003/0102PR01), and this application hereby incorporates the claim of priority to this provisional application under 35 U.S.C. § 119(e) from the aforementioned intermediate applications (for which priority of each intermediate application is claimed under 35 U.S.C. § 120); and the entire contents of all of the above identified patent applications are hereby incorporated by reference in their entirety.

FIELD OF DISCLOSURE

[0003] The present invention relates to unique, universal Zero-Profile Expandable Intervertebral Spacer (ZP-EIS) devices for fusion and distraction throughout the entire spine which can be inserted via anterior, anterolateral, lateral, far lateral or posterior surgical approaches dependent on the need and preference. Multiple ZP-EIS embodiments each with unique mechanisms of calibrated expansion are presented. Two of these embodiments incorporate bi-directional fixating transvertebral (BDFT) screws

and five other embodiments do not incorporate BDFT screws. A universal tool for their intervertebral placement and device expansion is also described.

[0004] The ZP-EIS embodiments with incorporated BDFT screws can be used as stand-alone intervertebral devices. These exemplary embodiments combine the dual functions of intervertebral calibrated expandable distraction, and segmental vertebral body spinal fusion. These embodiments can include bone cavities which can be filled with bone fusion material(s) to promote segmental spinal fusion.

[0005] The calibrated ZP-EIS embodiments without incorporated BDFT screws can also be used as stand-alone devices for calibrated intervertebral expansion and segmental vertebral body fusion. The exemplary devices can include bone cavities which can be filled with bone fusion material. If desirable, the exemplary devices can be supplemented with other forms of screw stabilization.

[0006] The exemplary ZP-EIS embodiments, especially those with incorporated BDFT screws, may obviate the need for supplemental pedicle screw fixation in many situations. The exemplary embodiments allow nuanced, fine-tuned incremental and calibrated distraction of the disc space to allow nerve root decompression in a minimally invasive and safe manner, as well as promoting segmental spinal fusion.

[0007] In the related applications in the Cross-Reference to Related Applications, Applicants first introduced the terminology "zero-profile" relating to spinal fusion devices. Applicants also have described zero-profile non-expandable and expandable stand-alone intervertebral spinal fusion device embodiments with incorporated BDFT screws. As described in greater detail below, exemplary embodiments of advanced ZP-EIS devices with BDFT screws are provided which have an improved contoured body

with tapered edges to more precisely insert into and conform to the biconcave disc space. The present application also provides exemplary embodiments of more advanced ZP-EIS devices without accompanying BDFT screws each with very unique calibrated expandable mechanisms allowing minimally invasive intervertebral expansion, vertebral body distraction and segmental spinal fusion. An exemplary embodiment of a universal tool also is described that can be adapted to implant one or more (e.g., all) of the intervertebral device embodiments herein described into the intervertebral space, and mechanically expand them.

BACKGROUND

[0008] The history and evolution of instrumented spinal fusion in the entire human spine has been reviewed in Applicants' copending applications set forth in the Cross-Reference to Related Applications (for example in U.S. Serial No. 11/536,815, filed on September, 29, 2006, and Serial No. 11/208,644, filed on August 23, 2005). Currently, the majority of spinal fusion techniques are typically supplemented with posterior pedicle screw placement and/or anterior (or lateral) plating. Complications of pedicle screw placement in the spine may include duration of procedure, significant tissue dissection and muscle retraction, misplaced screws with neural and/or vascular injury, excessive blood loss, need for transfusions, prolonged recovery, incomplete return to work, and excess rigidity leading to adjacent segmental disease requiring further fusions and re-operations. Recent advances in pedicle screw fixation including minimally invasive and image-guided technology, and the development of flexible rods, imperfectly may address some but not all of these issues.

[0009] Anterior/and or lateral plating because of the plates' elevated profiles can be complicated by esophageal, or major vascular injury. The zero-profile devices described herein with reference to the exemplary embodiments avoid these complications.

[0010] Current non-expandable intervertebral spacers must be manufactured with different heights, and the most appropriate sized spacer is selected for insertion. In these situations, the vertebral bodies are forcefully distracted to allow placement of an imperfectly fitting spacer. These are most often supplemented with pedicle screw and/or or plate fixation.

SUMMARY

[0011] The exemplary embodiments described herein can allow a more precisely tailored complimentary fit between spacer and disc space, allowing the spacer to expand gradually in a calibrated manner, and to incrementally achieve the precise fit and degree of distraction desirable. Thus, the process according to the present invention can be more individualized for every patient and apply less forceful disruption to the intervertebral space thereby improving safety and enhancing effectiveness of the placement of intervertebral spacers. The exemplary embodiments are zero-profile, and thus, do not damage or indent overlying soft tissue or vascular structures further decreasing morbidity.

[0012] Herein described are exemplary embodiments of multiple ZP-EIS devices which combine in a single construct the dual functions of calibrated expandable

intervertebral spacer distraction maintaining disc space height, and simultaneous segmental vertebral body spinal fusion.

[0013] To achieve safe, effective zero-profile and minimally invasive segmental spinal fusion, the exemplary embodiments of the present invention use of novel zero-profile calibrated expandable spacer (ZP-EIS) devices with or without BDFT screws which can be strategically inserted into the intervertebral disc space via anterior, anterio-lateral, lateral, far lateral or posterior surgical approaches.

[0014] In Applicants' applications set forth in the Cross-Reference to Related Applications, exemplary embodiments are directed to expanding intervertebral spacers which incorporated BDFT screws. One of these embodiments includes two sliding triangular bases to house two screws driven in two opposing directions which can be expanded in two simultaneous directions, height and depth, by turning a built-in screw adjuster. This was facilitated by a combined external drill/screw guide/cage expander to further enhance trajectory precision and to simultaneously expand the screw box in height and depth to custom-fit the individual disc space height. Applicants' copending applications set forth in the Cross-Reference to Related Applications further describe an exemplary embodiment of a universal tool and the adaptability of the tool, for example, to exemplary embodiments of sliding boxes, as well as to the exemplary embodiments described herein, including those with and without BDFT screws.

[0015] The evolved zero-profile expandable intervertebral spacer (ZP-EIS) embodiments with incorporated BDFT screws presented herein are more finely tapered and contoured to more easily allow insertion and conformation to the biconcave disc space.

[0016] The exemplary embodiments of ZP-EIS devices without incorporated BDFT screws described herein have the ability to incrementally and uniformly separate and distract the vertebral bodies. Each embodiment has a very unique mechanically designed mechanism of incremental expansion. The devices are all designed with cavities for bone fusion giving the surgeon the option to use these as stand-alone fusion/spacer devices or as supplemental devices if other screw fixation is deemed necessary. These innovations represent a continued evolution of our concept of zero-profile calibrated expandable intervertebral distraction/fusion spacers described in Applicants' applications, for example, as set forth in the Cross-Reference to Related Applications.

[0017] In the exemplary ZP-EIS embodiments with incorporated BDFT screws, a rostral-directed screw is passed through one built-in screw guide of the device which then is inserted and screwed into the superior vertebral body. Next, a caudally directed screw is passed through an adjacent built-in screw guide, which then is inserted and screwed into the inferior vertebral body. One of many novels features of this design is the built-in prescribed angles of the integral screw guides which allow the transvertebral penetration into the vertebral bodies. This is a truly amazing feat accomplished particularly in the posterior or lateral/far lateral lumbar spine considering the small anatomically restricted work zone within which to work, which is very narrowly prescribed by obtuse angulations between screw and intervertebral bone surfaces, and by nerve root, facet joint and pedicle. Applicants' applications set forth in the Cross-Reference to Related Applications included an angled screw driver specifically designed to fit these devices if

a straight screw driver impedes screw placement. Hence, these external tools can provide the means in any circumstance to accomplish precision screw trajectory.

[0018] The exemplary zero-profile embodiments of the present invention can provide enhanced individualized intervertebral conformation, and multiple methods of finely calibrating intervertebral expansion, and vertebral body distraction further reducing morbidity and enabling more minimally invasive surgical methods of vertebral body distraction and segmental fusion compared to Applicants' applications set forth in the Cross-Reference to Related Applications.

[0019] The exemplary embodiments of box casings can include perforations to allow bone packing for fusion. These exemplary devices can prevent subsidence. In an exemplary embodiment, both the inside of the denuded intervertebral space, and the devices can be packed with autologous or allograft bone, BMP, DBX or similar osteoconductive material.

[0020] The zero-profile EIS embodiments, in particular those with incorporated BDFT screws, can provide as strong or stronger segmental fusion as pedicle screws without the complications arising from pedicle screw placement which include screw misplacement with potential nerve and/or vascular injury, violation of healthy facets, possible pedicle destruction, blood loss, and overly rigid fusions. In the case of the posterior Lumbar spine by placing screws across the intervertebral space from vertebral body to vertebral body, engaging anterior and middle spinal columns, and not the vertebral bodies via the transpediclar route, the healthy facet joints, if they exist, are preserved. Because the exemplary techniques accomplish both anterior and middle column fusion, without rigidly fixating the posterior column, the exemplary embodiments

in essence create a flexible fusion. This exemplary devices therefore can provide a flexible fusion device because the preserved posterior facet joints retain their function achieving at least a modicum of mobility and hence a less rigid (i.e. a flexible) fusion.

[0021] The very advantage of transpedicular screws which facilitate a strong solid fusion by rigidly engaging all three spinal columns is the same mechanical mechanism whereby complete inflexibility of all columns is incurred thereby leading to increasing rostral and caudal segmental stress which leads to an increased rate of re-operation.

[0022] Transvertebral fusion also leads to far less muscle retraction, blood loss, and significant reduction in operating room (O.R.) time. Thus, the complication of pedicular screw pull-out and hence high re-operation rate associated with the conventional flexible fusion pedicle screws/rods is obviated.

[0023] Although the exemplary embodiments can be supplemented with transpedicular screws, there would be no absolute need for supplemental pedicle screw fixation with these operative techniques. The expandable spacers without BDFT screws can be supplemented with other screw stabilization if desired.

[0024] Because the exemplary embodiments are zero-profile, these devices also obviate the morbidity involved with profiled anterior or lateral plating. Multi-level fusions can be performed with all of the exemplary embodiments described herein.

[0025] Currently failed anterior lumbar arthroplasties are salvaged by combined anterior and posterior fusions. The exemplary ZP-EIS embodiments with incorporated BDFT screws could be utilized as a one-step salvage operation for failed/extruded anteriorly placed lumbar artificial discs obviating the above salvage procedure which has far greater morbidity.

BRIEF DESCRIPTION OF DRAWINGS

[0026] These and other aspects and features of embodiments of the present invention will be better understood after a reading of the following detailed description, together with the attached drawings, wherein:

[0027] FIGS. 1A-1B illustrate an exemplary embodiment (Embodiment I) of a non-tapered sliding base ZP-EIS device with incorporated BDFT screws in sagittal-oblique (FIG. 1A), and exploded (FIG. 1B) views.

[0028] FIGS. 2A-2D illustrate an exemplary embodiment (Embodiment II) of a tapered sliding base ZP-EIS device with incorporated BDFT screws in closed (FIG. 2A), semi-expanded (FIG. 2B), and fully expanded (FIG. 2C) positions, and in an exploded view (FIG. 2D).

[0029] FIGS. 3A-3D illustrate an exemplary embodiment (Embodiment III) of a scissors jack driven ZP-EIS device without incorporated BDFT screws in closed (FIG. 3A), semi- expanded (FIG. 3B), and fully expanded (FIG.3C) positions, and in exploded view (FIG. 3D).

[0030] FIGS. 4A-4C illustrate an exemplary embodiment (Embodiment IV) of a tapered thread driven ZP-EIS device without incorporated BDFT screws in closed (FIG. 4A), semi-expanded/fully expanded positions (FIG. 4B), and in cross-sectional view (FIG. 4C).

[0031] FIGS. 5A-5D illustrate an exemplary embodiment (Embodiment V) of a dry anchor driven ZP-EIS device without incorporated BDFT screws in closed (FIG. 5A),

semi- expanded (FIG. 5B), and fully expanded (FIG. 5C) positions, and in an exploded view (FIG. 5D).

[0032] FIGS. 6A-6D illustrate an exemplary embodiment (Embodiment VI) of a modified wedge driven ZP-EIS device without incorporated BDFT screws in closed (FIG. 6A), semi-expanded (FIG. 6B), and fully expanded (FIG. 6C) positions, and in an exploded view (FIG. 6D).

[0033] FIGS. 7A-7D illustrate an exemplary embodiment (Embodiment VII) of a worm drive ZP-EIS device without incorporated BDFT screws in closed (FIG. 7A), semi-expanded (FIG. 7B), and fully expanded (FIG. 7C) positions, and in an exploded view (FIG. 7D).

[0034] FIGS. 7E(i) and 7E(ii) illustrate top, perspective views of an intervertebral cage construct according to an exemplary embodiment of the invention.

[0035] FIG. 8A-8C illustrate a positioning tool/screw guide/box expander in oblique perspective (FIG. 8A), lateral (FIG. 8B), and exploded (FIG. 8C) views according to an exemplary embodiment, which is shown coupled to the exemplary non-tapered sliding base ZP-EIS device illustrated in FIGS. 1A-1B.

[0036] FIG. 8D(i) and 8D(ii) illustrate superior oblique perspective views of the positioning tool/drill guide/box expander component, according to an exemplary embodiment, which may be optionally used for the exemplary embodiments illustrated in FIGS. 1A-1B and 2A-2D.

[0037] FIGS. 8E-8G illustrate sequential steps (I-III: Step I (FIG. 8E), step II (FIG. 8F), and step III (FIG. 8G)) of the positioning tool/screw guide/box expander assembly according to an exemplary embodiment.

[0038] FIGS. 8H-8I illustrate three-dimensional views of positioning tools, according to exemplary embodiments, for impaction and placement of two transvertebral screws, for example, of the exemplary embodiments illustrated in FIGS. 1A-1B and 2A-2D.

[0039] FIGS. 8J-8K illustrate the insertion of expandable Lumbar bi-directional screw box with two BDFT screws into the Lumbar spine in oblique (FIG. 8J) and lateral (FIG. 8K) views.

DETAILED DESCRIPTION OF THE INVENTION

[0040] The present invention now is described more fully hereinafter with reference to the accompanying drawings, in which embodiments of the invention are shown. This invention may, however, be embodied in many different forms and should not be construed as limited to the embodiments set forth herein; rather, these embodiments are provided so that this disclosure will be thorough and complete, and will fully convey the scope of the invention to those skilled in the art.

1. THE MEDICAL DEVICE

[0041] Referring now to the drawings, Figures 1A-8K illustrate exemplary embodiments of ZP-EIS devices that can solve the above described problems and others in the spine by insertion of the ZP-EIS devices into the denuded intervertebral disc space according to the features illustrated in the exemplary embodiments (I-VII).

[0042] FIGS. 1A-1B illustrate three-dimensional views of a ZP-EIS device 100 according to embodiment I, with two BDFT screws 101, 102.

[0043] The expandable ZP-EIS device 100 includes of top and bottom triangular sliding bases 103, 104 (FIGS. 1A-1B). The superior and inferior segments of the height/depth adjusting screw 105 are integrated and connected to the two separate top and bottom triangular bases 103, 104, respectively. By turning this adjusting (rotation) screw 105 back and forth, i.e. clock-wise, and counter clockwise, the sliding rails 106 of the top triangular base 103 (FIGS. 1A-1B) slide up and down the rail inserts 107 on the bottom triangular base 104 (FIGS. 1A-1B). This action will simultaneously alter the intervertebral height and depth of the device 100 allowing individualized custom fitting of the ZPEIS device 100 conforming to the dimensions of the disc space.

[0044] A transvertebral screw 101 penetrates the top base 103, and a transvertebral screw 102 traverses the bottom base 104 of the screw box (device 100). The two screws 101, 102 traverse the screw box 100 in opposing directions, bi-directionally. The external edges of the triangular bases 103, 104 in contact with vertebral body surfaces can include ridges 107, which facilitates the ZP-EIS device 100 incorporation into and fusion with the superior and inferior vertebral bodies (FIGS. 1A-1B). Both top and bottom ZP-EIS bases 103, 104 can be perforated with holes 108 to allow bone placement for fusion. In an exemplary embodiment, the entire construct, furthermore, can be hollow to allow filling with bone filling material. Hence, the exemplary device functions as both an intervertebral bone fusion spacer and bi-directional transvertebral screw fusion device.

[0045] FIGS. 2A-2D illustrate a ZP-EIS device 200 according to exemplary embodiment II. This exemplary device 200 incorporates BDFT screws and employs a fusion wedge mechanism of expansion.

[0046] The device 200 includes a contoured top 208 and bottom 206 housing which have tapered edges and are coupled to each other by a diagonal dovetail interface 204 which constrains the components 208, 206 to translate linearly relative to each other. The linear translation causes a vertical separation of the top 208 and bottom 206 housing surfaces which are parallel to each other. The position is secured and adjusted by a threaded rotation screw 220 coupled to a nut 224 and a retaining ring 222 and passed through the top 208 and bottom 206 housing pieces. As the threaded rotation screw 220 is rotated further into the nut 224, the housing pieces 208, 206 expand vertically.

[0047] By turning this adjusting (rotation) screw 220 back and forth i.e. clock-wise, and counter clockwise, the sliding rails 210 of the top housing piece 208 slide up and down the rail inserts 212 on the bottom housing piece 206. This action will simultaneously alter the intervertebral height and depth of the device 200 allowing individualized custom fitting of the ZP-EIS conforming to the dimensions of the disc space. A transvertebral screw 101 penetrates the top housing piece 208, and a transvertebral screw 102 traverses the bottom housing piece 206 of the device 200. The two screws 101, 102 traverse the device 200 in opposing directions, bi-directionally. The external edges of the housing pieces in contact with vertebral body surfaces include ridges 216. This facilitates the ZP-EIS device 200 incorporation into and fusion with the superior and inferior vertebral bodies (FIGS. 2A-2D). Both top and bottom ZP-EIS housing bases 208, 206 are perforated with holes 214 to allow bone placement for fusion. The entire device 200, furthermore, can be hollow to allow bone filling. Hence, the exemplary device 200 functions as both an intervertebral bone fusion spacer and bi-directional transvertebral screw fusion device.

[0048] The device 200 can include a tapered edge 226 (shown for example in FIGS. 2A-2B), which allows easier introduction and insertion of the device 200 into the disc space.

[0049] FIGS. 3A-3D illustrate a ZP-EIS device 300 according to exemplary embodiment III, which employs a scissor jack expansion mechanism.

[0050] In this embodiment the top 302 and bottom 304 housing are attached by one internal linkage arm 310, and two external linkage arms 308. The device 300 can include indentations 306 on each lateral side close to the top of the device 300 to mate with the prongs of the universal tool (for example, as described in FIGS. 8A-8I) to assist in grasping, inserting and impacting the device 300. A lead screw or rotation screw 314 is mounted in the bottom housing 304 and secured in place with a retaining ring 316. When the lead (rotation) screw 314 is rotated by an external tool (for example, as described in FIGS. 8A-8I), the screw 314 causes the linear displacement of the separation block 318 which is hinged to the internal linkage 310. The horizontal motion of the separation block causes the top 302 and bottom 304 housing pieces to separate vertically. The separation distance depends on the amount of rotation of the lead (rotation) screw 314, and is limited by the freedom of the separation block 318 to move within the bottom housing 304. The exemplary embodiment can include a plurality of pins, such as eight pins 320, 322, 324, to secure the external linkage arms 308 to the top 302 and bottom 304 housing units and to the separation block 318. The top housing 302 and bottom housing 304 can include one or more cavities 312 for bone incorporation/fusion.

[0051] FIGS. 4A-4C illustrate a ZP-EIS device 400 according to exemplary embodiment IV, which employs a tapered thread mechanism of expansion.

[0052] The exemplary device 400 can include a top housing 402 and bottom housing 404, which can be attached by one or more pins, such as two pins 412, which allow rotation of the top housing 402 and bottom housing 404 relative to each other about the axis of the pins 412. The top housing 402 and/o bottom housing 404 can include indentations 406 on their lateral sides close to the top of the device 400 to mate with the prongs of a tool or universal tool (e.g., prongs 806 in FIGS. 8A-8I) to assist in grasping, inserting and impacting the device 400. The bottom housing 404 can include a mount for the rotation screw 410 (FIG. 4C), which can control the relative angular orientation of the two housing pieces 402, 404. When the screw 410 is rotated by an external tool (e.g. as shown in FIGS. 8A-8I), the screw 410 engages the internal teeth/ridges 414 of the top housing 402 and acts as a wedge to rotate the top housing 402 away from the bottom housing 404. More particularly, the device 400 can include a sloped ridge 414, as exemplary illustrated in FIG. 4C. When the rotating screw 410 advances, the top housing 402 rotates further and further away from the bottom housing 404. The device 400 can include one or more bone cavities in the top housing 402 and bottom housing 404 for bone fusion.

[0053] FIGS. 5A-5D illustrate exemplary embodiments of a ZP-EIS device according to embodiment V, which employs an anchor mechanism of expansion.

[0054] The top housing 502 and bottom housing 504 can be coupled or attached by one or more pins, such as two pins 512, which allow rotation of the top housing 502 and bottom housing 504 relative to each other about the axis of the pins 512. The top housing 502 and/or the bottom housing 504 can include indentations 506 on their lateral sides close to the top of the device 500 to mate with the prongs of a tool or universal tool

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

[0055] FIGS. 6A-6D illustrate exemplary embodiments of a ZP-EIS device 600 according to embodiment VI which employs a modified wedge expansion mechanism.

[0056] The device 600 includes a top housing 602 and a bottom housing 604 that can be attached or coupled by one or more pins, such as two pins 612, which allow rotation of the top housing 602 and the bottom housing 604 relative to each other about the axis of the pins 612. The top housing 602 and/or the bottom housing 604 can include indentations 606 on their lateral sides close to the top of the device 600 to mate with the prongs of a tool, such as prongs 806 of the universal tool shown in FIGS. 8A-8I, to assist in grasping, inserting and impacting the device 600. The bottom housing 604 can

include a mount for the lead (rotation) screw 610, which can control the relative angular orientation of the two housing pieces 602, 604. The lead (rotation) screw 610 can be secured with one or more retaining rings, such as two retaining rings 618. When the screw 610 is rotated by an external tool (e.g., the tool shown in FIGS. 8A-8I), the screw 610 causes lateral motion of a wedge-shaped translation nut 616. The nut 616 engages an inner tapered surface of the top housing 602 and forces the top housing piece 602 to rotate away from the bottom housing 604. The device 600 can include one or more bone cavities 608 incorporated into the top housing 602 and/or bottom housing 604 for bone fusion.

[0057] FIGS. 7A-7D illustrate exemplary embodiments of a ZP-EIS device 700 according to embodiment VII, which employs a worm drive (gear) mechanism.

[0058] According to the invention, the device 700 includes a worm drive design that allows a user to rotate a worm gear/drive 712 with an external tool (FIG. 8) to control the translation of the top housing 702 relative to the bottom housing 704a, 704b. The worm gear drive 712 engages a spur gear mount 714 which has internal threading for engaging a corresponding part, such as a threaded stud of bolt 720, to couple the spur gear mount 714 to the top housing 702. The top housing 702 can include a plurality of pins, such as four pins 712, which extend into the bottom housing 704a, 704b. These pins 712 prevent the top housing 702 from rotating with the spur gear 714, and constrain the spur gear 714 to translate linearly. The bottom housing 704 can include two halves 704a, 704b to secure the worm drive 710 and spur mount 714 in place. A worm retaining ring and a spur retaining ring 716 also can be used to secure the worm gear drive 710 and the spur gear mount 714. The device 700 can include one or more bone cavities 708 that

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

[0059] FIGS. 8A-8C illustrate three-dimensional views of exemplary embodiments of the external drill/screw guide-box expander universal tool 800 which can be used to assist in both screw trajectory and box expansion of an expandible device, such as the exemplary embodiments of devices illustrated in embodiments I and II, and for device expansion of the devices illustrated in embodiments III - VII. The same universal tool 800 can be utilized for all the exemplary embodiments illustrated in embodiments I-VII. In some embodiments, the external drill/screw guide 850 may not be needed or used for embodiments II-VII. The prongs 806 can be inserted into the indentations (e.g., 202, 306, 406, 506, 606, 706) of the sides of the devices (e.g., 100, 200, 300, 400, 500, 600, 700) according to one or all of the exemplary embodiments illustrated in embodiments I-VII, and implant the device into the intervertebral space. Once implanted and impacted, an Allen key (e.g., as shown in FIG. 8) can be used to expand the device (e.g., 100, 200, 300, 400, 500, 600, 700) by turning the adjustment (rotation) screw (e.g., 105, 220, 314, 410, 510, 610, 710).

[0060] The exemplary tool can include, among other things, an Allen key 801, a spring 802, a handle 803, a griper 804 and a screw guide 805. The Allen key 801, when inserted in the insertion 814 and turned, can turn the rotation screws (e.g., 105, 220, 314, 410, 510, 610, 710) of one or all of the exemplary embodiments I-VII. The griper 804

includes griper prongs 806, which insert into grooves 509 of the screw guide 805 and the screw box indentations (e.g., 202) in the exemplary embodiment illustrated in embodiment I (as shown in FIGS 8A-8D), as well as in similar indentations (e.g., 306, 406, 506, 606, 706) of devices (e.g., 100, 200, 300, 400, 500, 600, 700) illustrated in embodiments II-VII (not shown).

[0061] As shown in FIG. 8C, each longitudinal end of the screw box 100 can include a slot or indentation 108 formed adjacent to an edge of an upper surface of the screw box 100 for engaging a protuberant extension of a tool, such as the protuberant extension 807 of the tool 800.

[0062] FIG. 8D illustrates a superior oblique view of the screw guide 805 demonstrating insertions 809 for griper prong 086, built-in trajectory guides 811, 812 for insertion of screws 101 and 102, and the Allen key 801. This exemplary embodiment can be limited, for example, to use with the devices of embodiments I and II, which includes BDFT screws.

[0063] FIGS. 8E-8G illustrate three-dimensional views of the sequential steps necessary for the external guide assembly. FIG. 8E illustrates the insertion of the Allen key 801 into the handle 803. FIG. 5F illustrates the insertion of the handle 803 through the spring 802 and griper 804. FIG. 8G illustrates insertion of the griper 804 into the screw guide 805. The griper prongs 806 can include medially oriented male protuberant extensions 807 that engage the slot or indentation of a device, such as indentation 108 of device 100, thereby perfectly aligning the prongs 805 of the tool 800 with the device (e.g., 100, 200, 300, 400, 500, 600, 700). This exemplary embodiment can be limited, for example, to use with the devices of embodiments I and II.

[0064] FIG. 8H illustrates a three-dimensional view of another exemplary embodiment of a positioning tool 800 for impaction and placement of two transvertebral screws 201, 202 for example, for use with the exemplary embodiments I and II.

[0065] With reference again to FIGS. 8A-8K, the screw guide 805 can include insertions 809 for receiving the griper prong 806, built-in trajectory guides 811, 812 for insertion of screws 101 and 102, and the Allen key 801.

[0066] The driver assembly 850 can include a screw driver 851, a flexible shaft 852 and a square recess bit 853. This exemplary device can facilitate turning the screws 101, 102 into the bone. The flexible shaft 852 can facilitate the avoidance of spinous processes which might hinder the screw driving if the shaft 852 were straight. The positioning tool 800 can have a rectangular handle, as shown for example in Embodiment I, or a circular handle, as exemplary shown in Embodiment II. This exemplary embodiment can serve to position a screw box within the intervertebral space, and screws 101, 102 within the screw box or device. Once positioned, the screw box or device (e.g., 100, 200, 300, 400, 500, 600, 700) can be impacted by tapping the handle 803 with a mallet (not shown). The griper handle 803 inserts into the screw guide and the screw box or device (e.g., 100, 200, 300, 400, 500, 600, 700), which maintains alignment.

2. THE SURGICAL METHOD

[0067] Exemplary embodiments of a surgical method for utilizing the exemplary devices described herein, will now be described. The procedures can be performed open, microscopic, closed tubular or endoscopic. Fluoroscopic guidance can be used with any of these procedures.

[0068] An exemplary embodiment of a ZP-EIS device, as illustrated in embodiments (I-VII), can be inserted into the intervertebral space (for example as shown in FIGS. 8J and 8K) after an adequate discectomy is performed in any disc space throughout the entire spine upon their exposure anteriorly, anterio-laterally, laterally, far laterally or posteriorly.

[0069] For exemplary embodiments I-II of the ZP-EIS devices can be inserted into the disc space by a tool or universal tool, such as the universal tool 800 in FIGS. 8A-8I. In operation, the grab prongs of tool 800 can attach to the insets or indentations (e.g., 202, 306, 406, 506, 606, 706) on the side of the devices. Once in the disc space, the rotation screw (e.g., 105, 220, 314, 410, 510, 610, 710) of each embodiment is turned by rotating the Allen key 801 of the tool 800 to expand the device (e.g., 100, 200, 300, 400, 500, 600, 700) to the desirable disc height achieving the desirable intervertebral distraction deemed necessary for the individual patient and disc space. Once this is achieved, BDFT screws 101, 102 are inserted and screwed into the vertebral body above and below securing the device (e.g., 100, 200, 300, 400, 500, 600, 700) to the vertebral bodies with screws 101, 102. Prior to implantation of the device (e.g., 100, 200, 300, 400, 500, 600, 700), the bone cavities of each device can be filled with any type of bone fusion material.

[0070] For the exemplary embodiments III-VII, the ZP-EIS device (e.g., 100, 200, 300, 400, 500, 600, 700) can be inserted into the disc space by the same universal tool, such as tool 800. The grabs prongs 806 of the tool 800 attach to the insets or indentations (e.g., 202, 306, 406, 506, 606, 706) on the side of the devices (e.g., 100, 200, 300, 400, 500, 600, 700) on the side of the devices (e.g., 100, 200, 300, 400, 500, 600,

700). Once in the disc space, the rotation screw (e.g., 105, 220, 314, 410, 510, 610, 710) is turned by rotating the Allen key 801 of the tool 800 expanding the device (e.g., 100, 200, 300, 400, 500, 600, 700) to the desirable disc height achieving the desirable intervertebral distraction deemed necessary for the individual patient and disc space. Prior to implantation of the device (e.g., 100, 200, 300, 400, 500, 600, 700)the bone cavities of each device (e.g., 100, 200, 300, 400, 500, 600, 700) can be filled with any type of bone fusion material.

[0071] The exemplary embodiments of the present invention may provide effective and safe techniques that overcome the problems associated with current transpedicular and/or plated fusion technology employed for many degenerative stable and unstable spine diseases. These exemplary embodiments may replace much pedicle screw-based and plated based instrumentation in many but not all degenerative spine conditions.

[0072] The speed and simplicity of the surgical implantation of the exemplary embodiments of the ZP-EIS devices far exceeds that of conventional pedicle screw technology. Furthermore, the exemplary embodiments of zero-profile devices can provide markedly significantly decreased risk of misguided screw placement, and hence decreased risk of neural and vascular injury, and blood loss. The exemplary embodiments can provide decreased recovery and back to work time. The exemplary embodiments of devices may lead to similar if not equal fusion with significantly less morbidity, and hence overall make the exemplary devices a major advance in the evolution of spinal instrumented technology leading to advances in the care of the spinal patient.

[0073] According to the exemplary embodiments, such as the embodiments in embodiments I and II, an intervertebral fusion device is provided that uses a threaded rod mechanism located at the peripheral of the box to control expansion of the device. The device can include a cavity within the walls for placement of bone material for fusion.

[0074] In another embodiment, an intervertebral fusion device can include a threaded rod which can obstruct (inhibit) expansion of the device when it is not being turned. The threaded rod can be disposed at the front anterior part of the box or device.

[0075] In yet another embodiment, an intervertebral fusion device can include a threaded rod, which exerts a clamping force to expand the device until the device properly accommodates the dimensions of the intervertebral disc space and distracts the space based on individual anatomy and surgical judgment. The device can include a cavity for bone in-between the walls of the box.

[0076] In another embodiment, an expandable intervertebral fusion device can includes indentations on its sides to accommodate a placement tool.

[0077] In another embodiment, an expandable intervertebral fusion device can be adjusted by using a threaded rod as a wedge to pivot components within the device. The threaded rod can be accessible from the front anterior of the box or device.

[0078] In another embodiment, an expandable fusion device can include a threaded rod to expand a spacer. The threaded rod can be used as a wedge to mechanically separate the pieces. The threaded rod can be accessible from the front anterior of the box or device.

[0079] In another embodiment, an expandable fusion device can include wedge components which translate relative to each other along a contact. The degree of

expansion can be determined by an adjustment rod located at the peripheral of the box or device.

[0080] In another embodiment, an expandable fusion device includes components which are mechanically linked together. The expansion of the device is controlled by the user via an adjustment rod coupled to a mechanical transmission that causes mechanical components within the device to separate. The threaded rod is accessible from the front anterior of the box or device.

[0081] In another embodiment, an expandable fusion device can be provide wherein the position of the device is secured and adjusted by a threaded rod that is mechanically linked to housing pieces. When the threaded rod is rotated, the threaded rod forces the pieces to separate.

[0082] In another embodiment, an intervertebral fusion device is provide wherein the two internal screw guides are in the top housing unit.

[0083] In another embodiment, an intervertebral fusion expansile device is provided wherein the center of the two internal screw guides could be in quadrants I and III or II and IV.

[0084] In another embodiment, an expandable fusion device can be provided that uses a threaded rod (rotation screw) to expand the device using a metal driver as the wedge to mechanically separate the pieces.

[0085] In another embodiment, an expandable fusion device can be adjusted by using a threaded rod (rotation screw) as a wedge to offset the opposing cages.

[0086] In another embodiment, an expandable intervertebral fusion device can be provided wherein its position is secured and adjusted by a threaded rod (rotation screw)

coupled to a nut and passed through the top and bottom housing pieces. As the threaded rod is rotated further into the nut, the pieces separate.

[0087] In another embodiment, an expandable intervertebral fusion device can include a tapered edge to allow contoured insertion into the disc space.

[0088] In another embodiment, an intervertebral fusion device can be provided wherein the internal screw guides for screw insertion within the device are diagonal to each other within the xyz plane.

[0089] In another embodiment, an intervertebral fusion device wherein the internal screw guides can be adjacent and somewhat diagonal to each other within the xyz plane.

[0090] In another embodiment, an intervertebral fusion device can be provided wherein the majority each of the 2 screw holes can be in quadrant I and III or II and IV within the xyz plane.

[0091] In another embodiment, an intervertebral fusion device can be provided wherein the screw guides can have approximately the same xy coordinates and have different z coordinates or vice versa.

[0092] In another embodiment, an intervertebral fusion device can be provided wherein the center of the two internal screw guides could be in quadrants I and III or II and IV within the xyz plane.

[0093] In another embodiment, an intervertebral fusion device can be provided wherein one screw guide is in the top housing unit, and another screw guide is in the bottom housing unit.

[0094] In another embodiment, an intervertebral fusion device can be provided that uses a threaded rod (rotation screw) to engage a moveable component which engages a linkage to expand the device.

[0095] In another embodiment, an intervertebral fusion device can be provided that uses a threaded rod (rotation screw) to engage a wedge which engages its attaching linkages to expand the device.

[0096] In another embodiment, an expandable fusion device can be provided that can be adjusted using a threaded rod (rotation screw) coupled to a scissor-jack linkage.

[0097] In another embodiment, an expandable fusion device can be held together with fastener (s). These fasteners constrain the box to one degree of freedom. Part of the mechanism contains a mount for the rotation screw, which can control the movement of the pieces. As the screw is turned, it engages the teeth of the mechanism and acts as a wedge to rotate the pieces away from each other.

[0098] In another embodiment, an expandable fusion device adjusted by using a threaded rod (rotation screw) can be used as a wedge to offset the opposing cage surfaces.

[0099] In another embodiment, an expandable fusion device can be provided that uses a threaded rod (rotation screw) to expand the device using a metal driver as the wedge to mechanically separate the pieces.

[00100] In another embodiment, an expandable fusion device can be provided that can be adjusted by a threaded rod (rotation screw) coupled to a nut which translates to deform an elastomeric material used to force the expansion of the device.

[00101] In another embodiment, an expandable fusion device can be provided that has a threaded rod (rotation screw) that engages a wedge to control the expansion of the device.

[00102] In another embodiment, an expandable fusion device can be provided that can be contained by fasteners and retaining rings.

[00103] In another embodiment, an expandable fusion device can be provided that can be adjusted by a threaded rod (rotation screw) coupled to a wedge that can move the opposing cage surfaces.

[00104] In another embodiment, an expandable fusion device can be provided that uses a worm drive to turn a gear that acts as a wedge to expand the device.

[00105] In another embodiment, an expandable fusion device can be provided that includes fasteners and retaining rings containing and constraining the device pieces.

[00106] In another embodiment, an expandable fusion device can be provided that can be adjusted by a worm gear coupled to an internally threaded spur gear which, upon rotation, linearly advances a threaded component.

[00107] In another embodiment, a tool includes a handle, a gripper cooperating with the handle and having a plurality of prongs, a screw guide held in place the plurality of prongs, for controlling the direction of self-drilling screws that are screwed into the vertebral bodies, and an Allen key which expands expandable intervertebral devices.

[00108] The present invention has been described herein in terms of several preferred embodiments. However, modifications and additions to these embodiments will become apparent to those of ordinary skill in the art upon a reading of the foregoing description. It is intended that all such modifications and additions comprise a part of the

present invention to the extent that they fall within the scope of the several claims appended hereto.

We claim:

1. An expandible intervertebral fusion device comprising:

a first movable portion;

a second movable portion; and

a mechanism that moves the first movable portion and the second movable portion with respect to each other to expand a dimension of the expandible intervertebral fusion device.

ABSTRACT

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

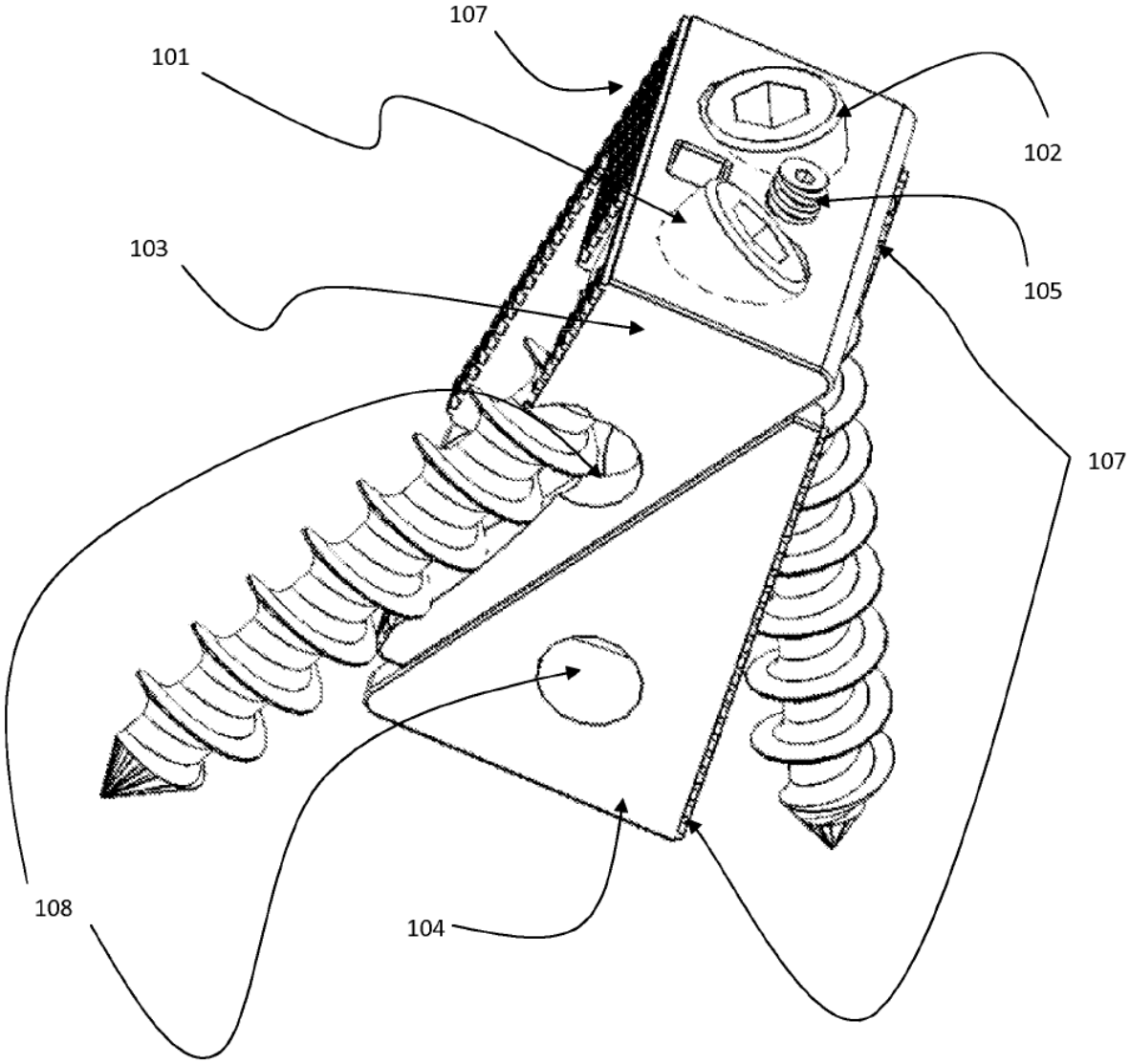


Fig. 1A

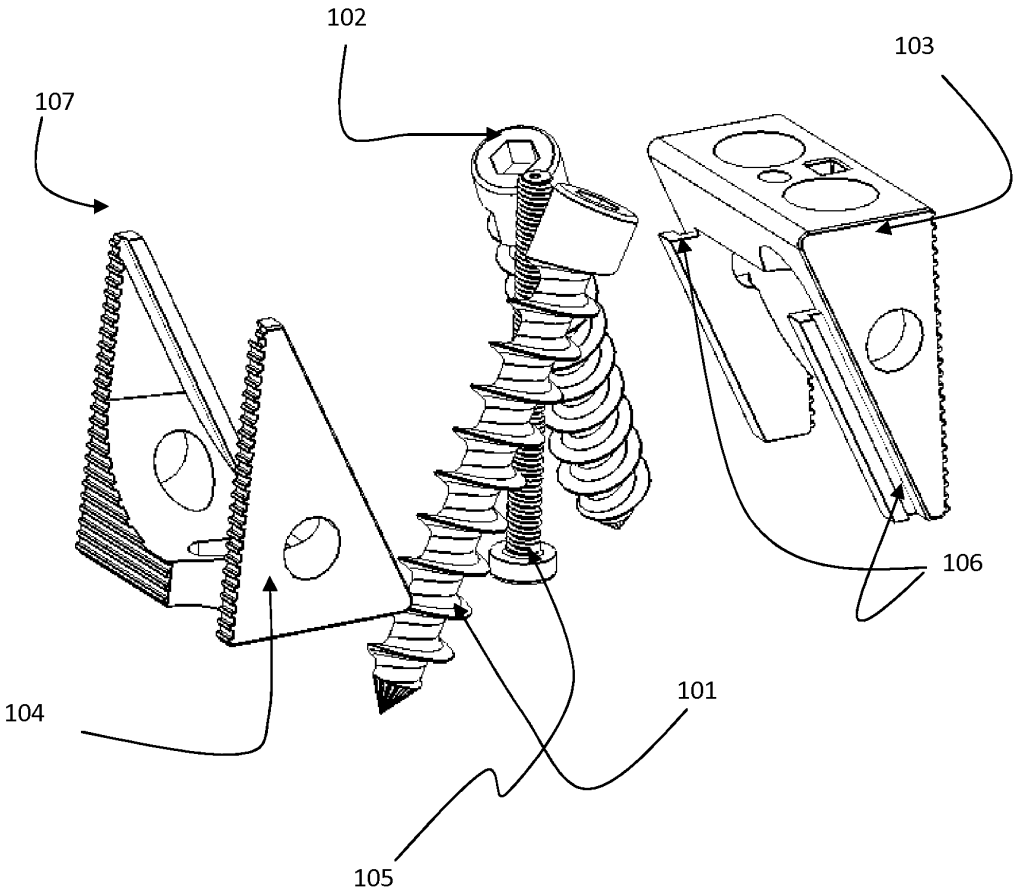


Fig. 1B

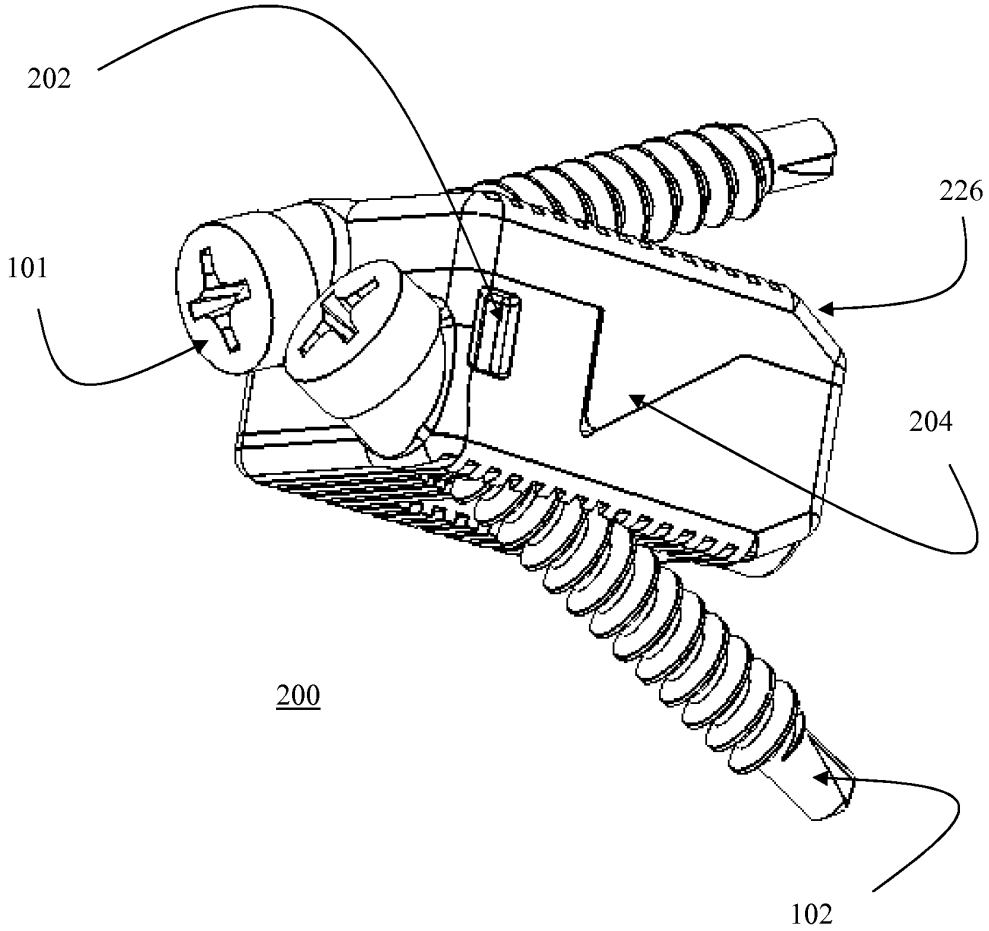


Fig. 2A

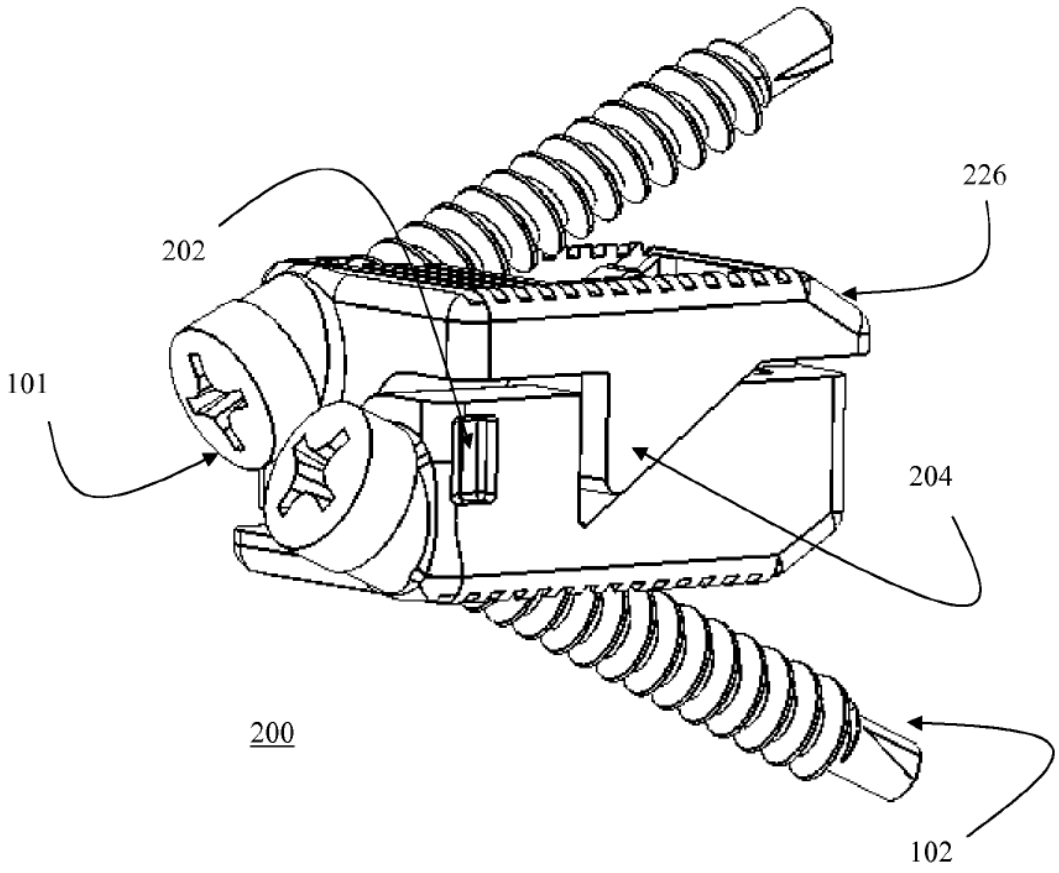


Fig. 2B

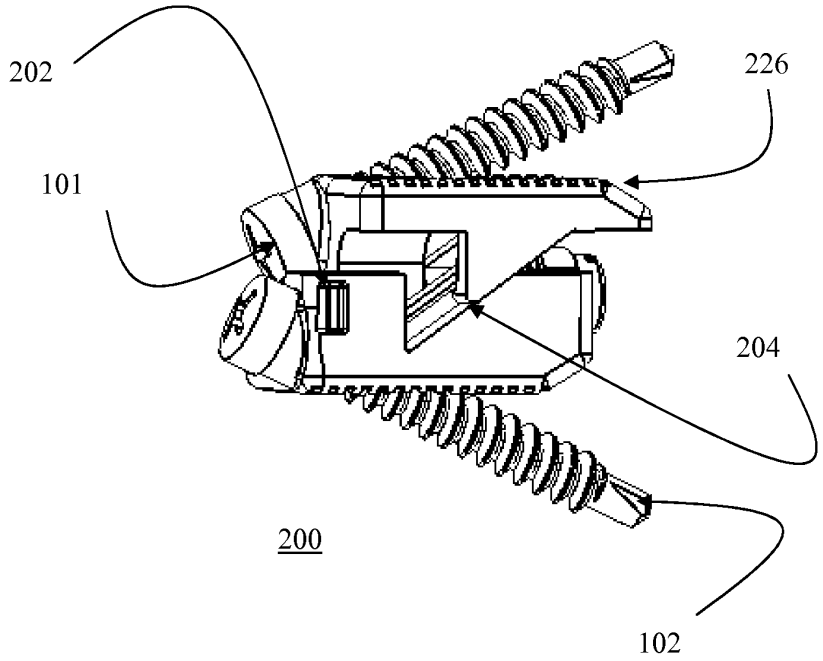


Fig. 2C

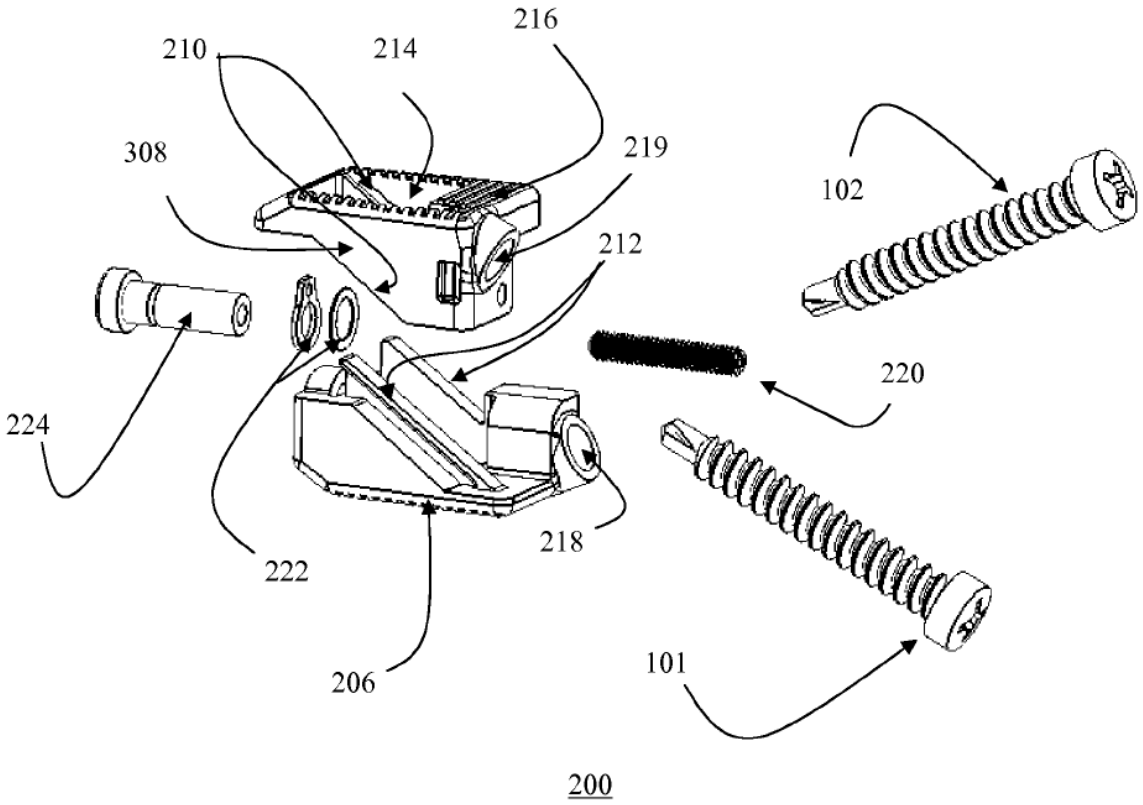


Fig. 2D

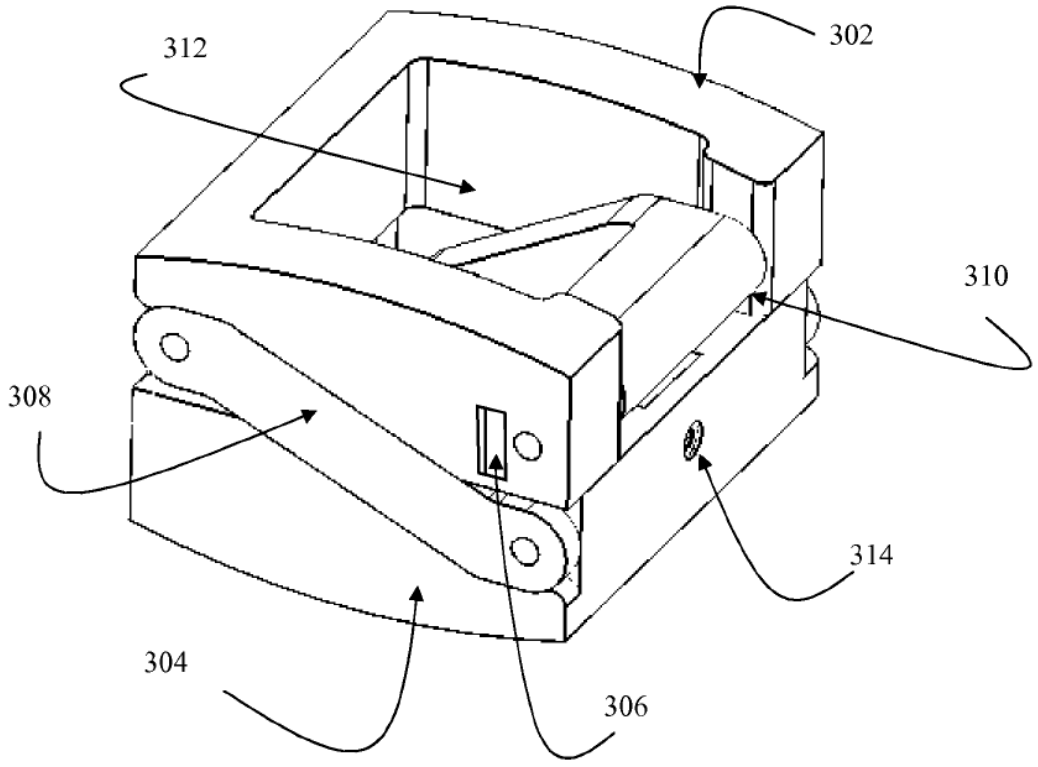


Fig. 3A

300

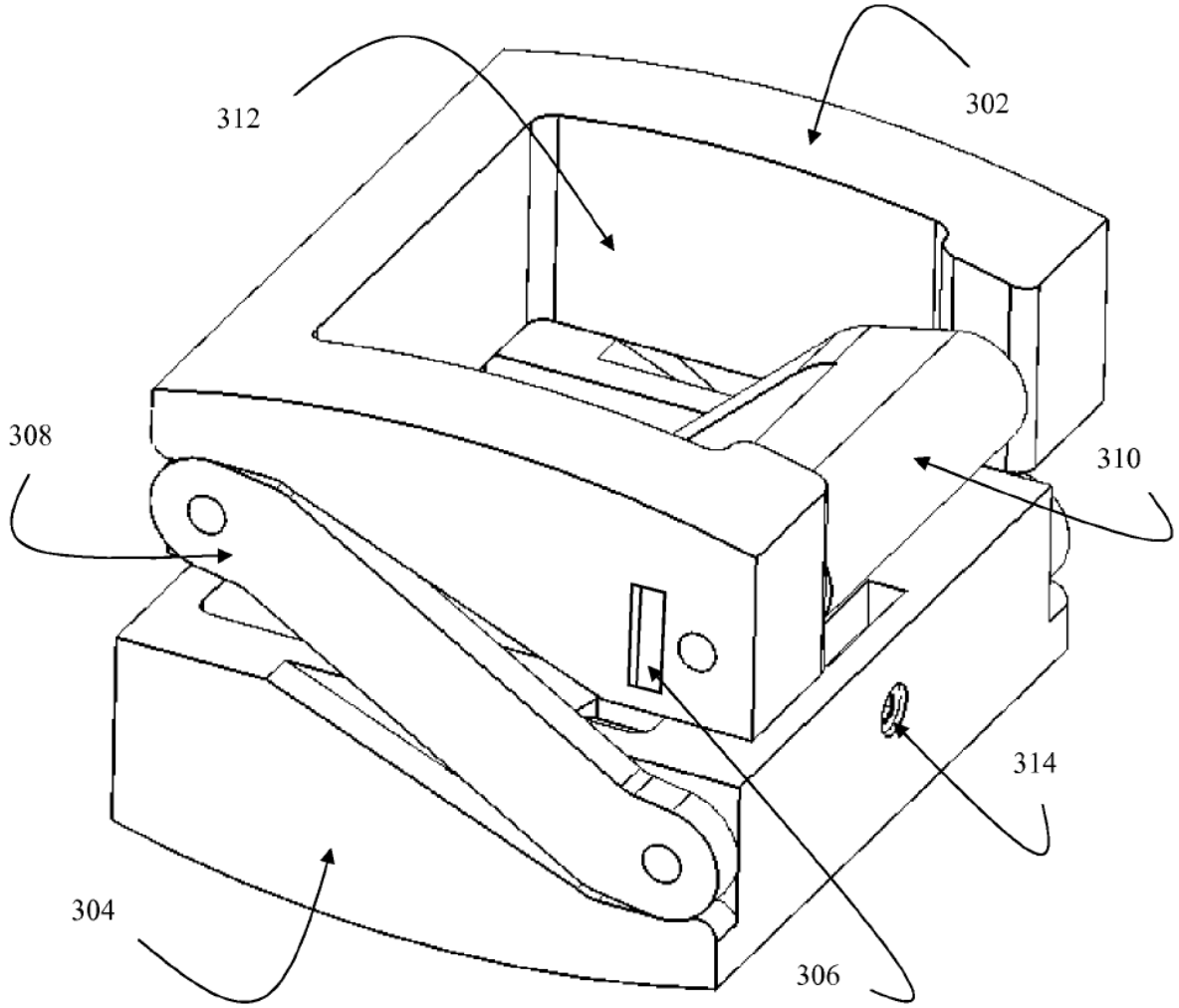


Fig. 3B

300

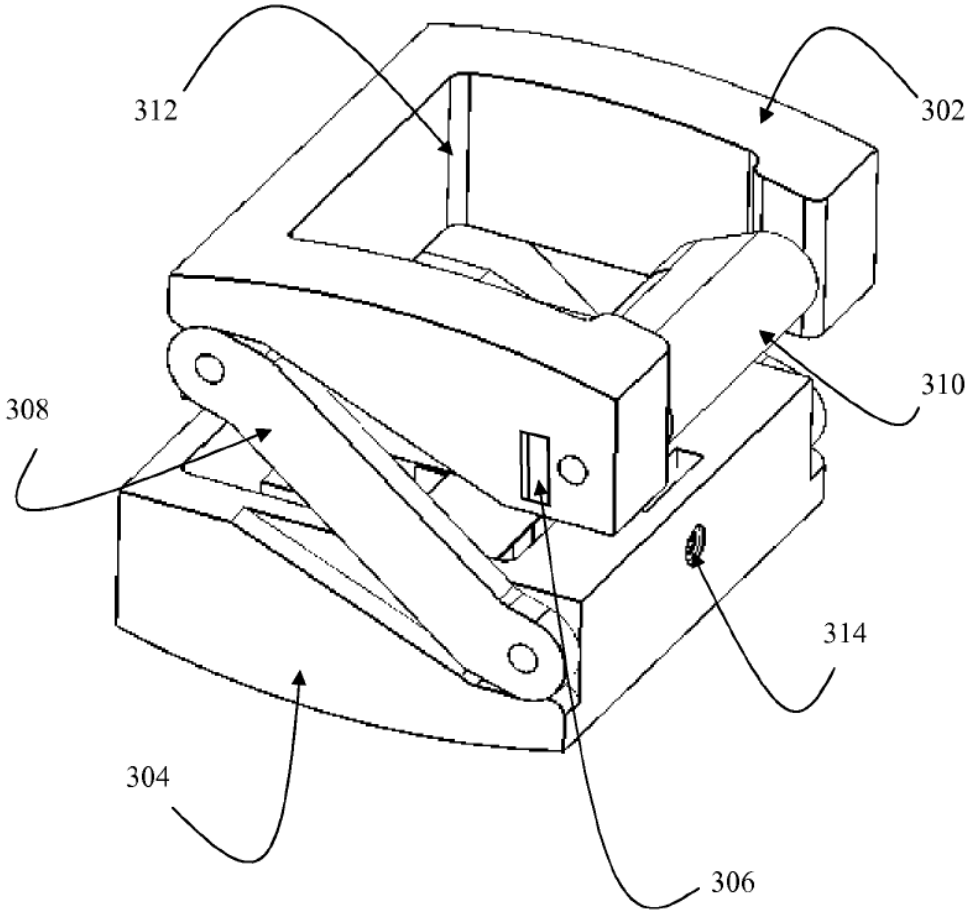


Fig. 3C

400

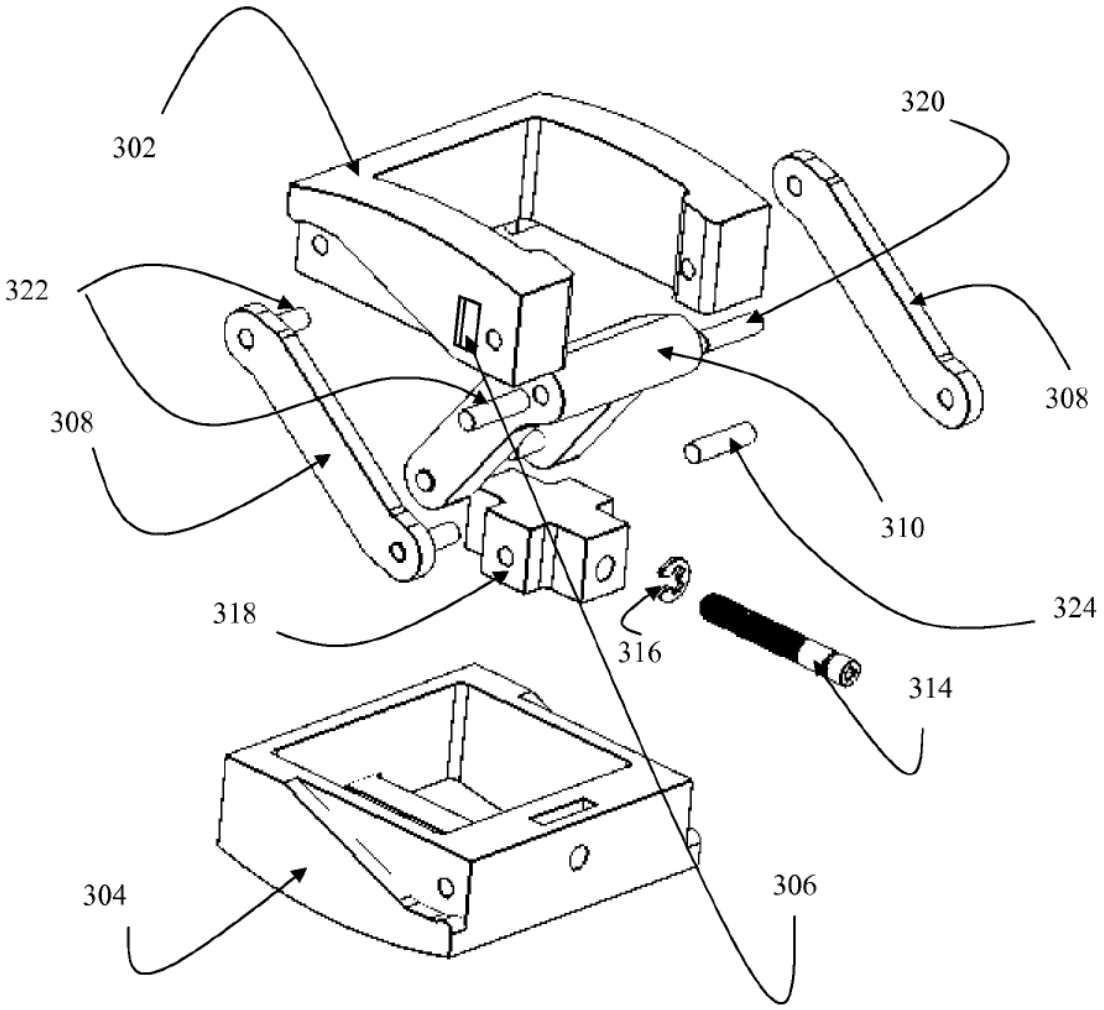


Fig. 3D

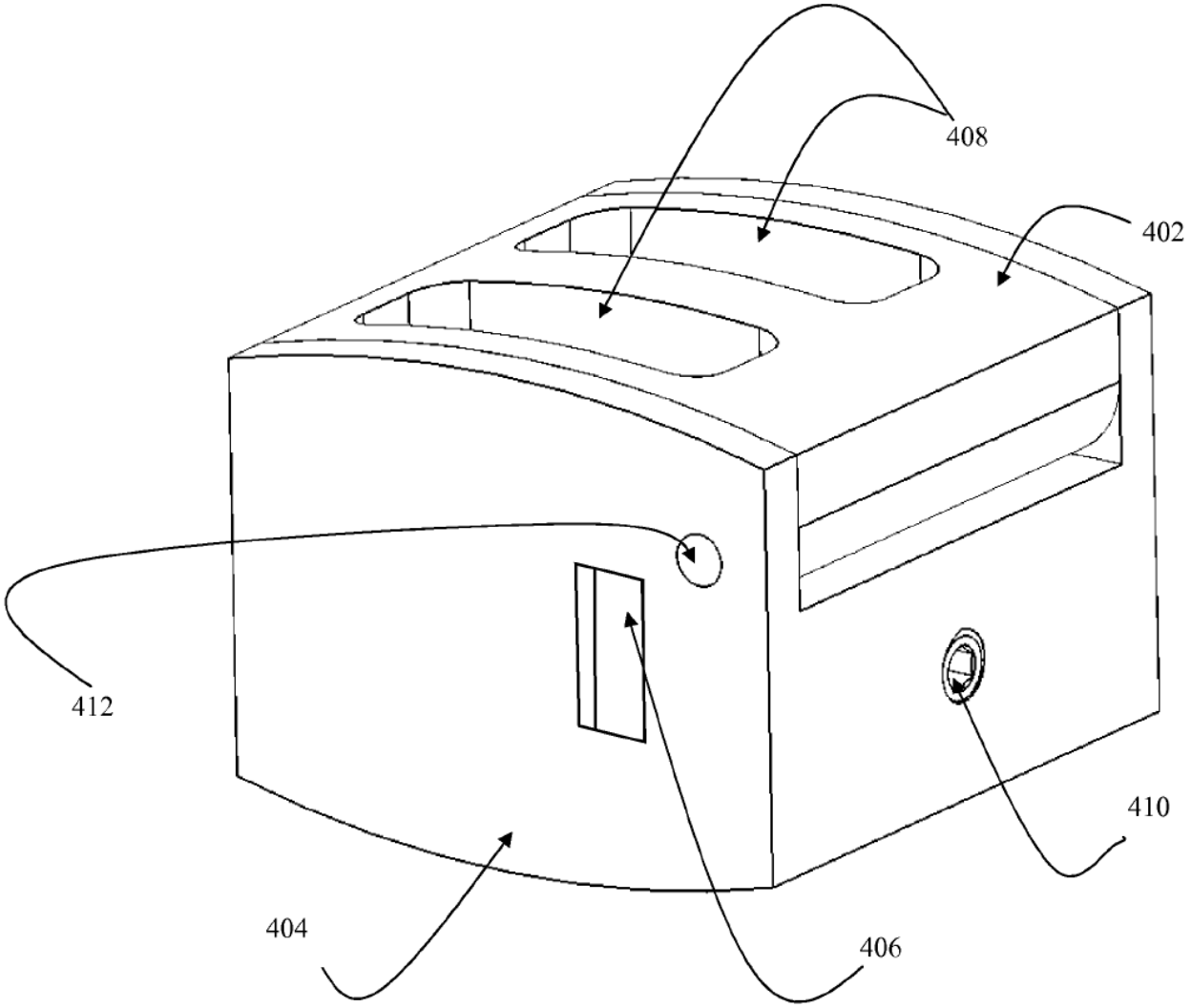


Fig. 4A

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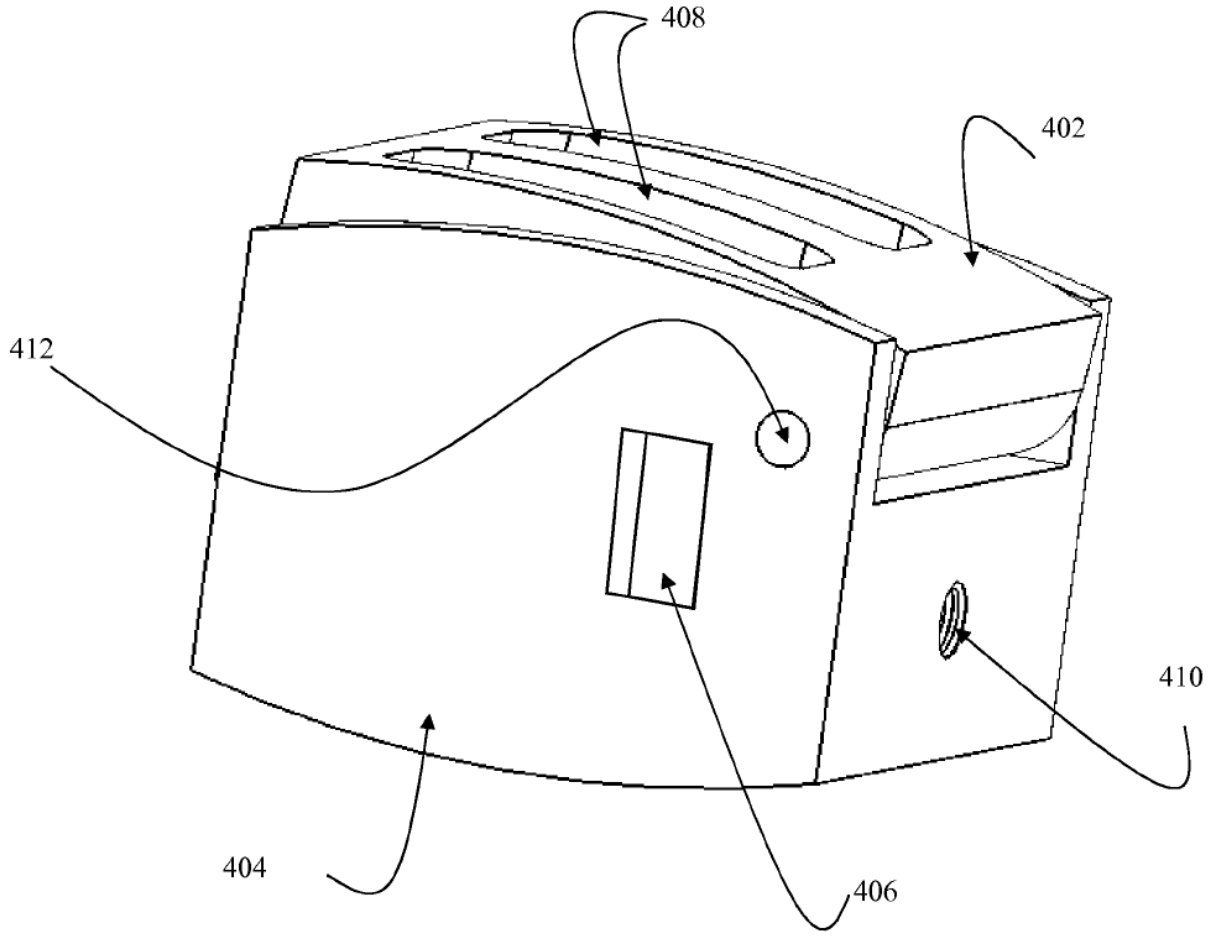


Fig. 4B

400

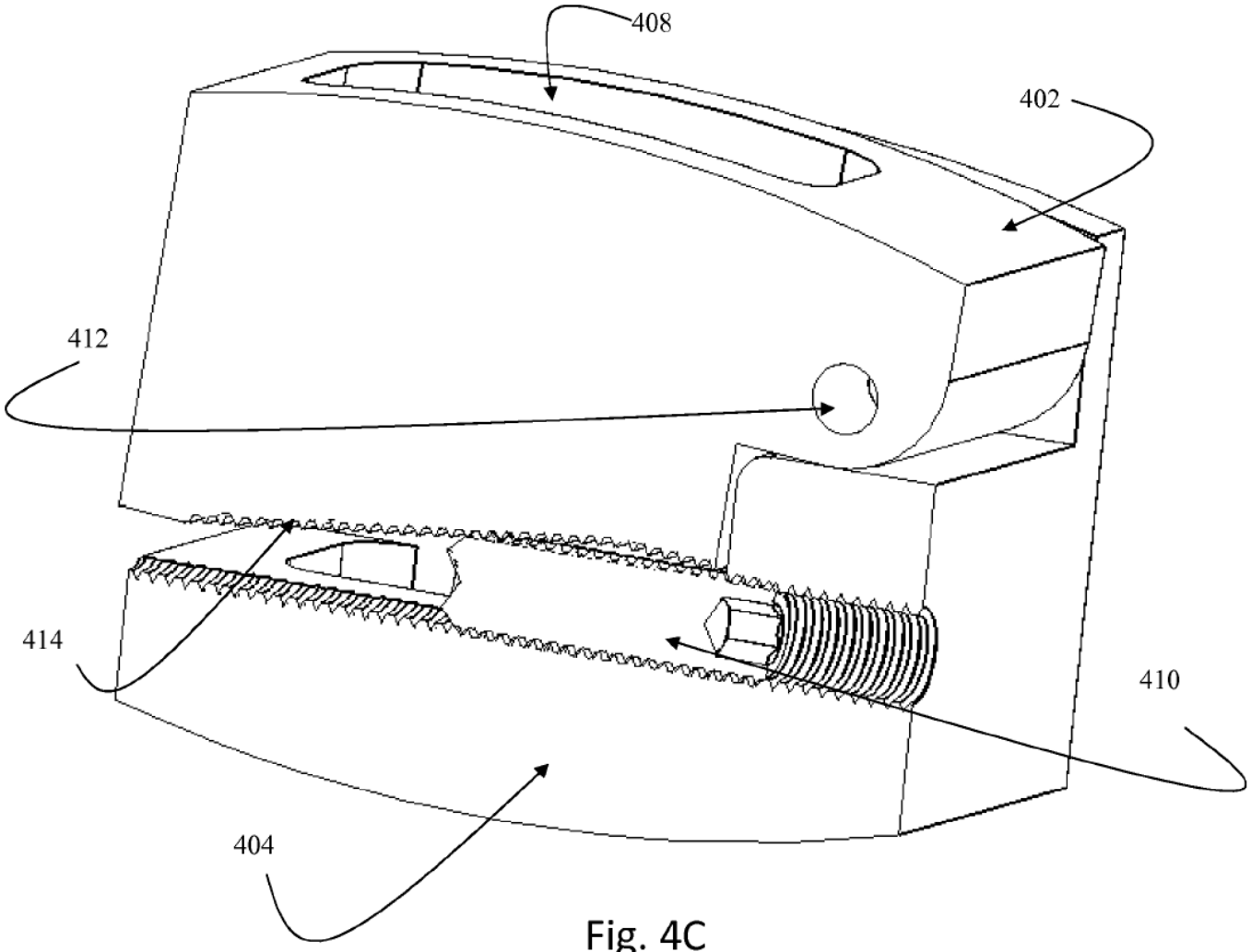


Fig. 4C

400

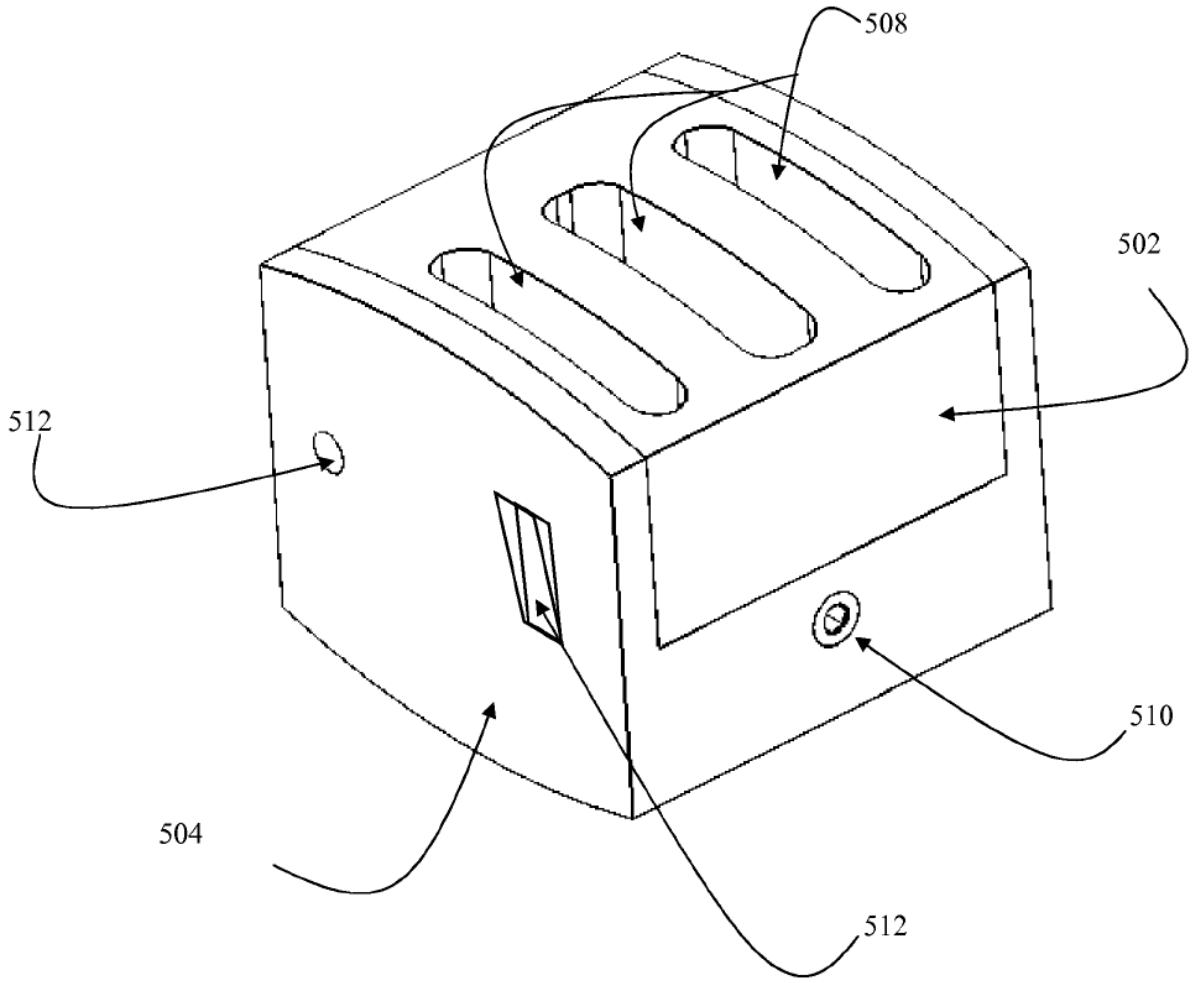


Fig. 5A

500

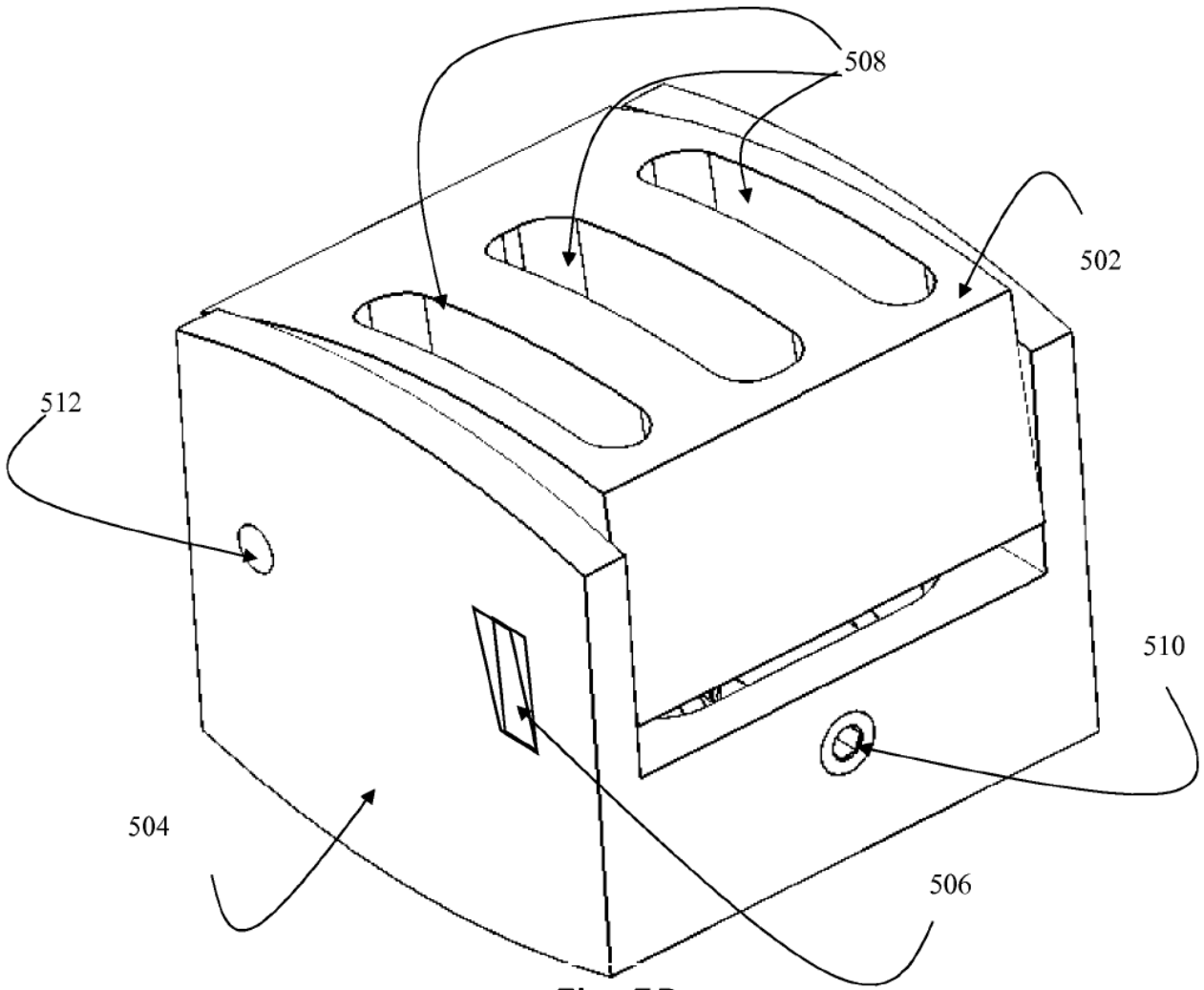


Fig. 5B

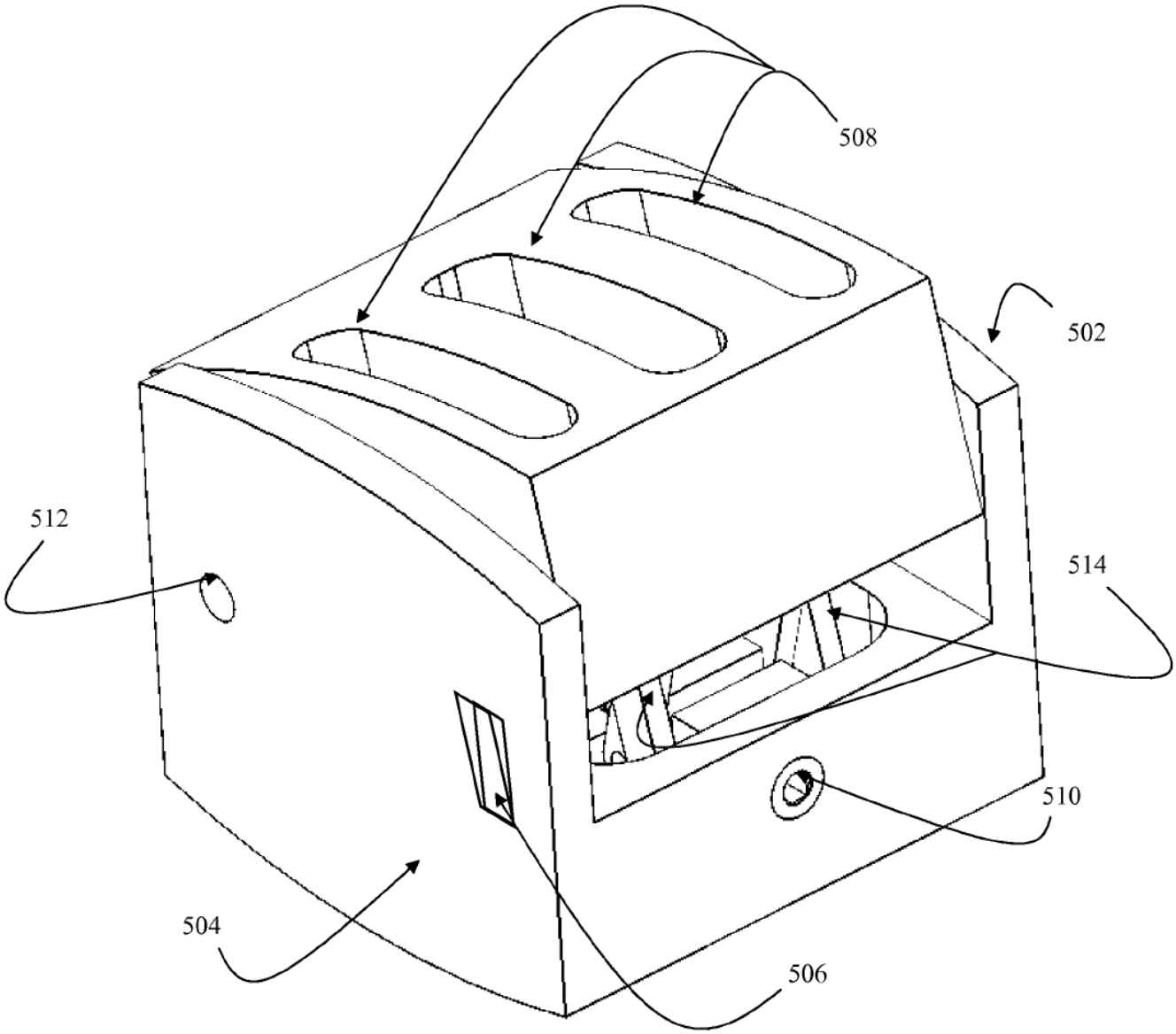


Fig. 5C

500

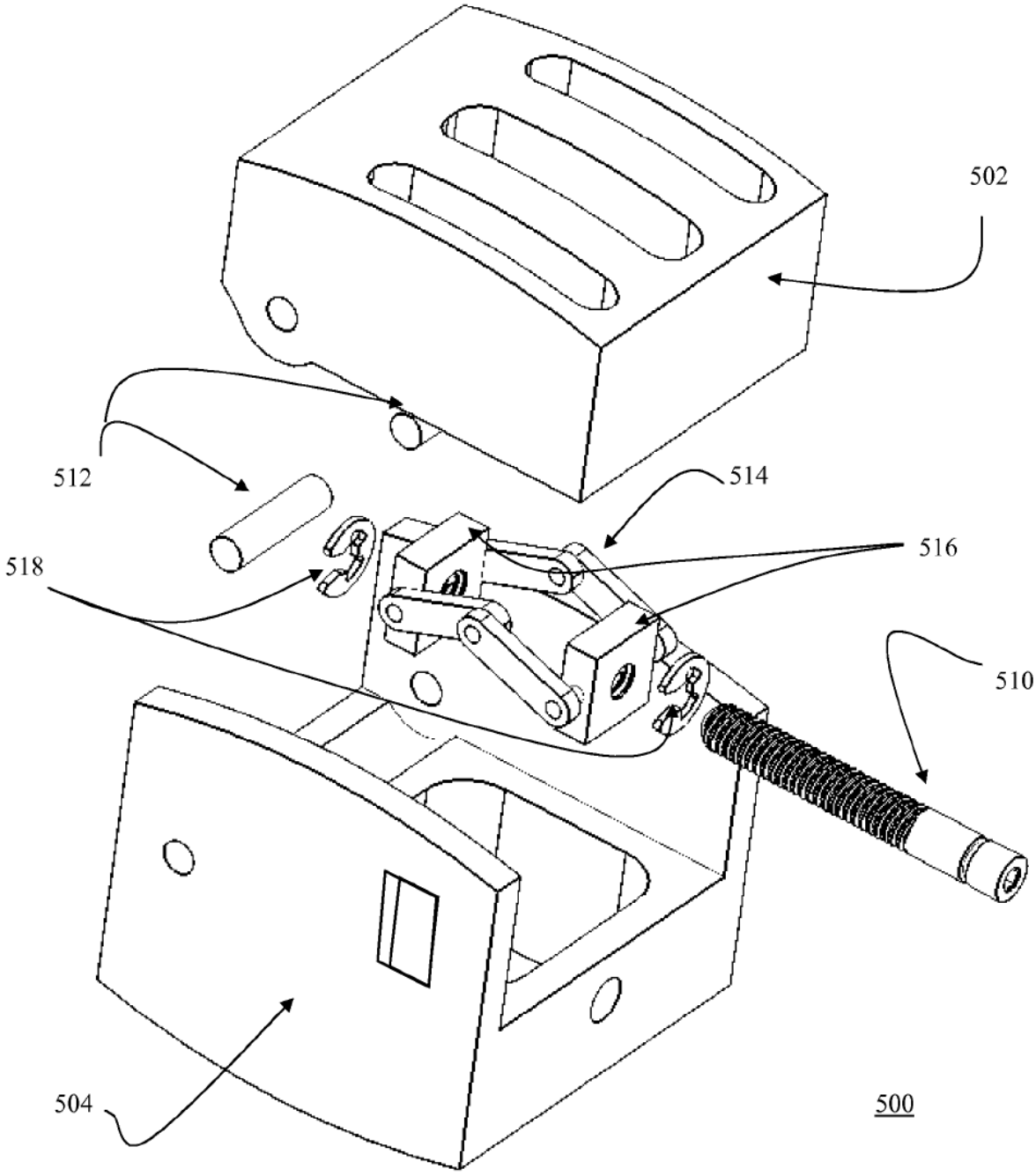


Fig. 5D

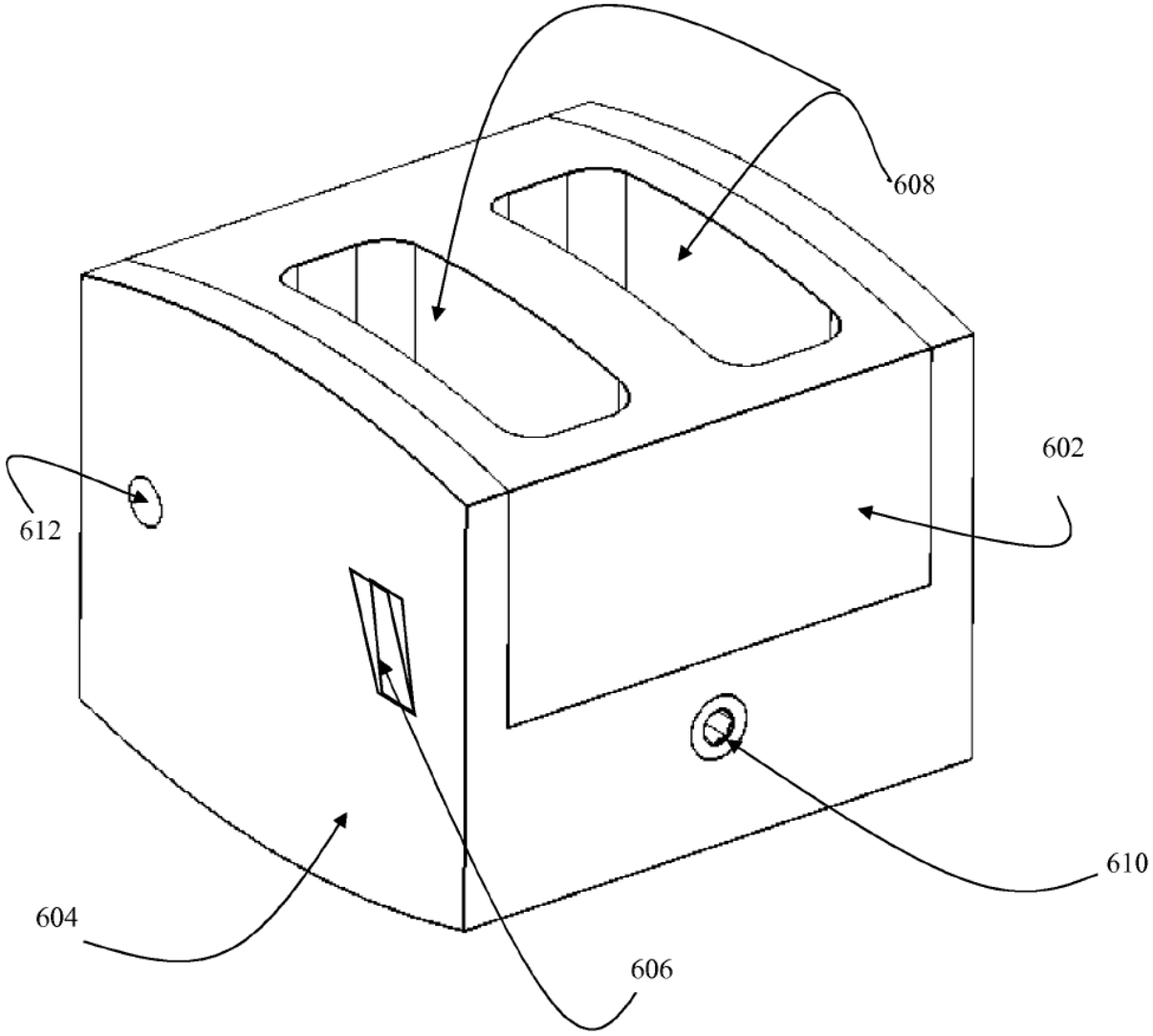


Fig. 6A

600

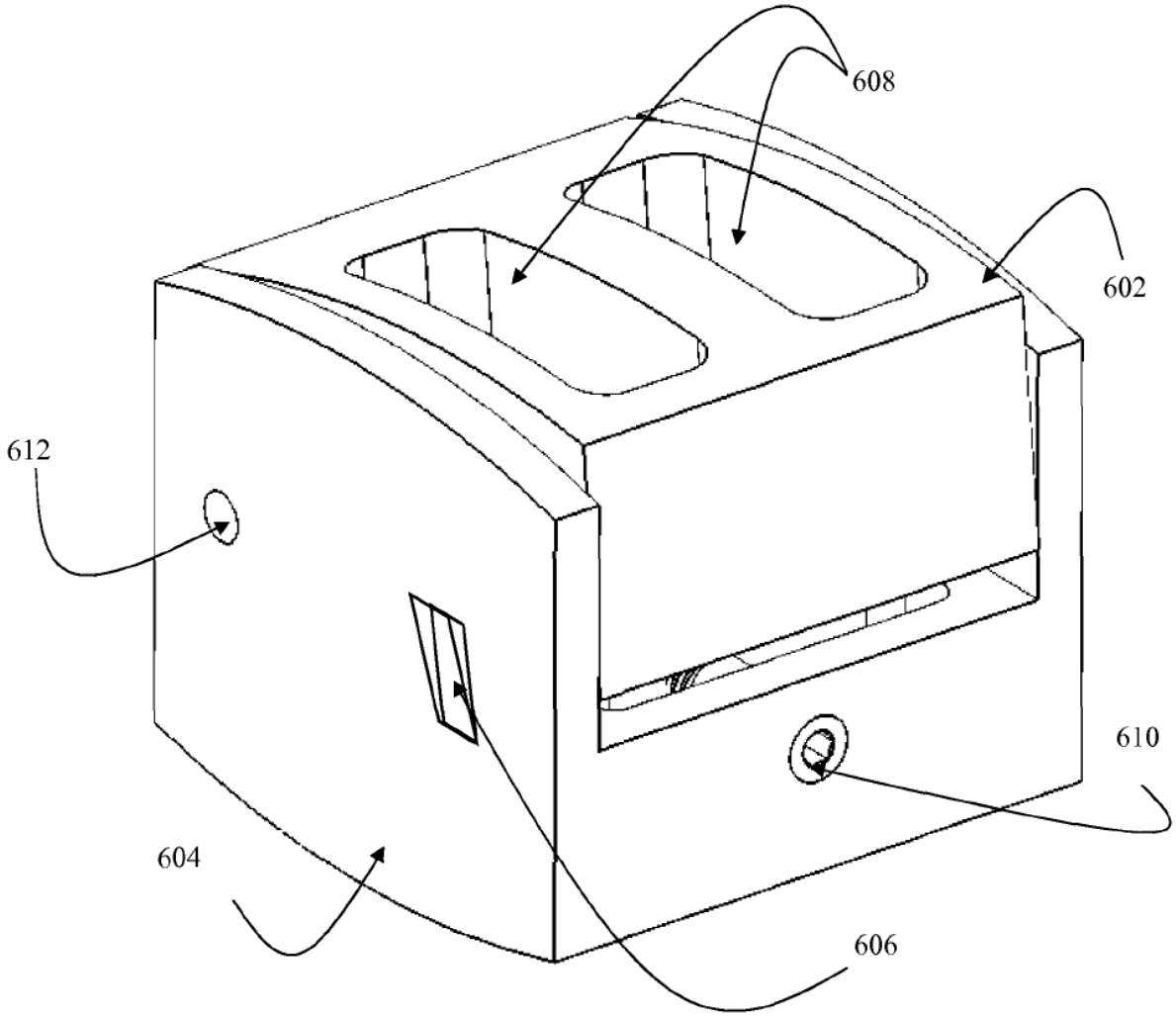


Fig. 6B

600

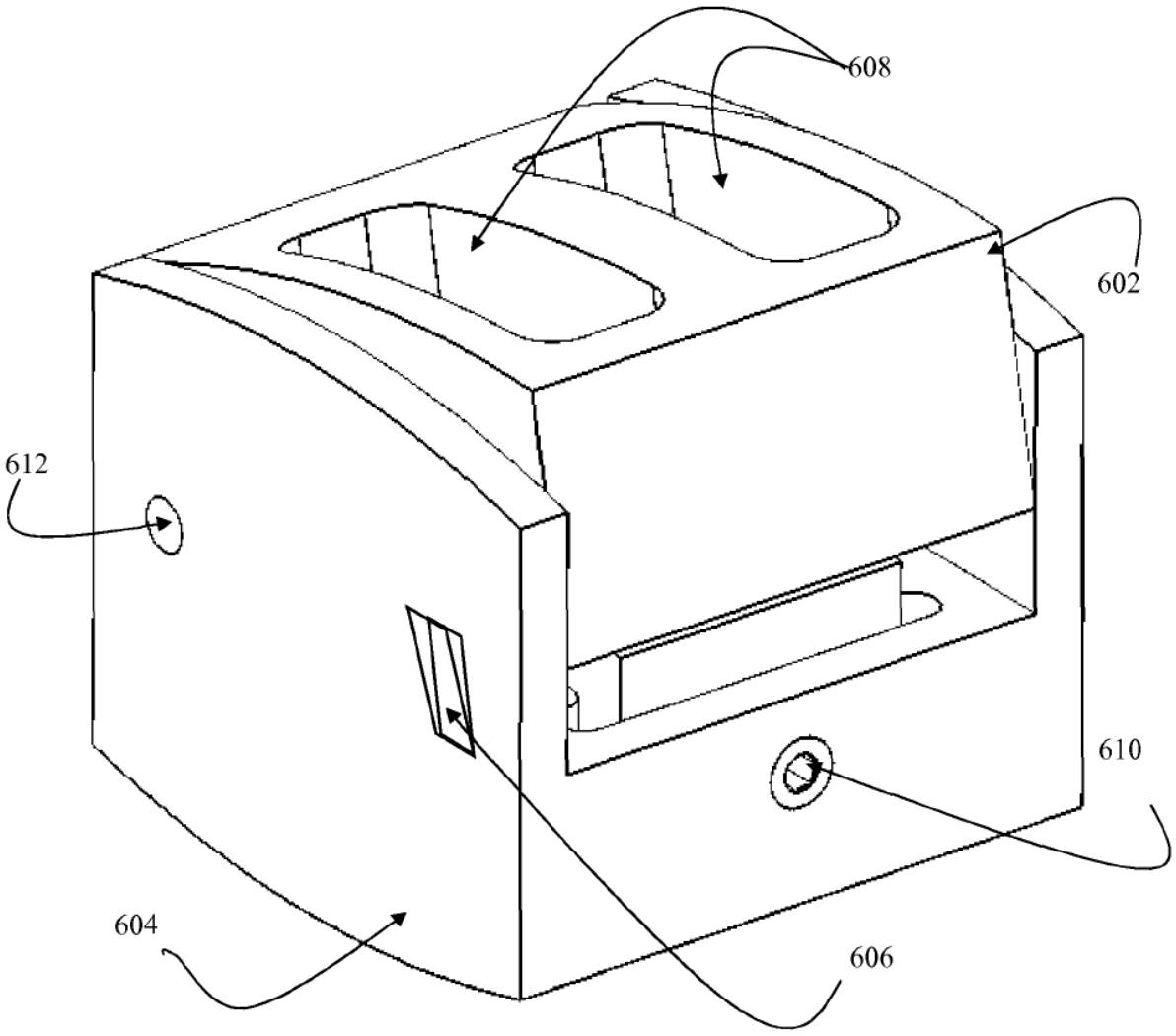


Fig. 6C

600

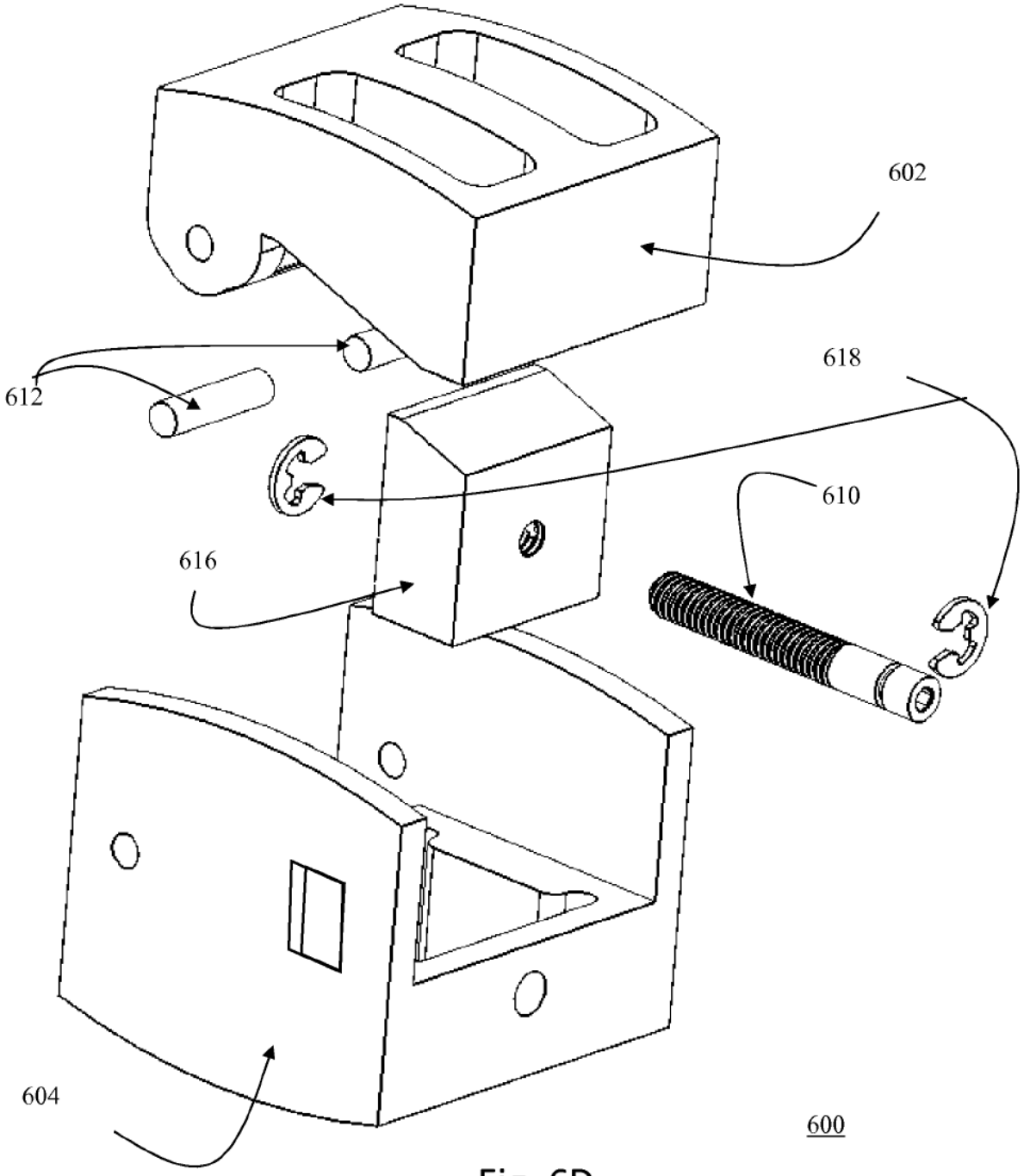


Fig. 6D

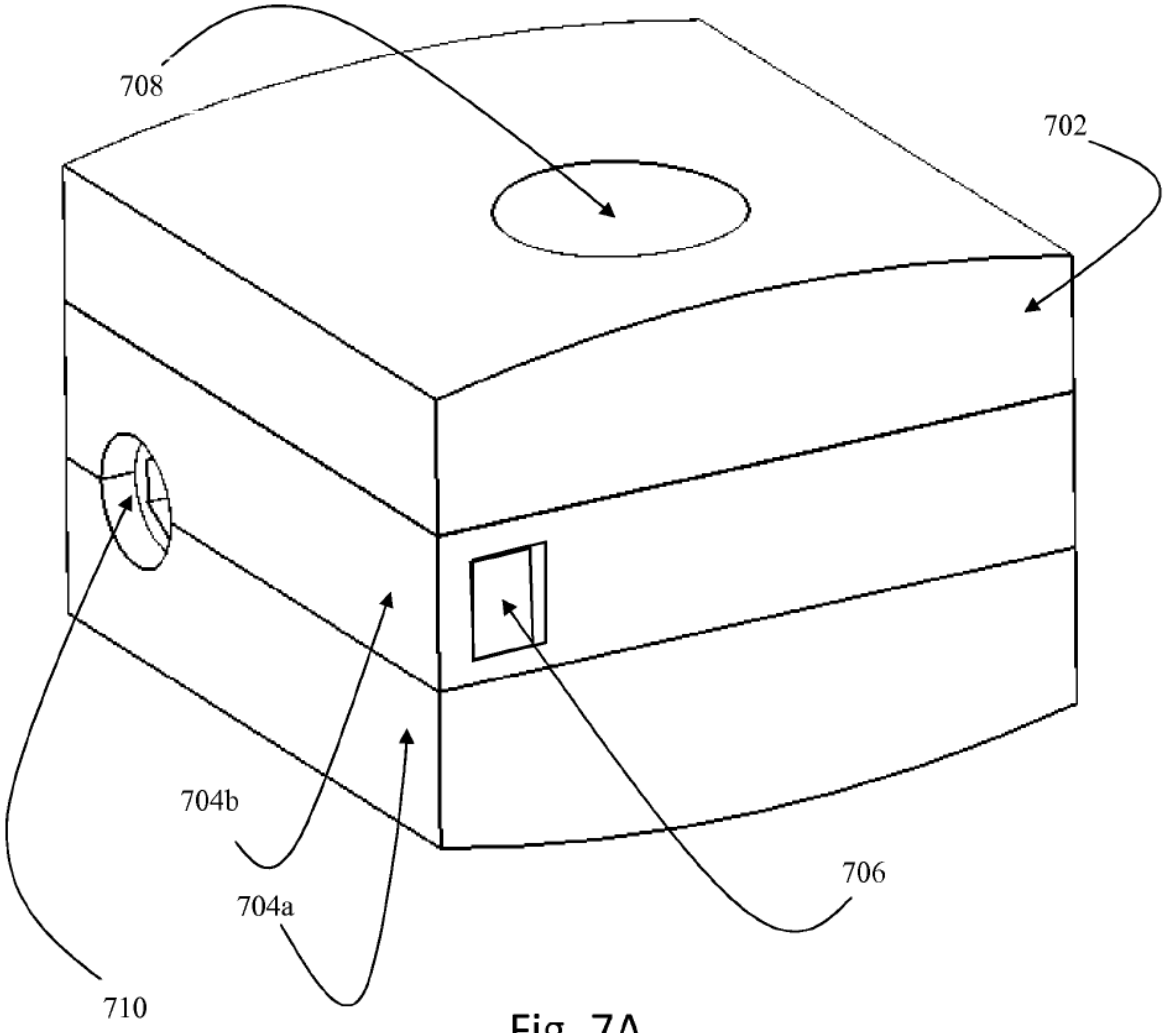


Fig. 7A

700

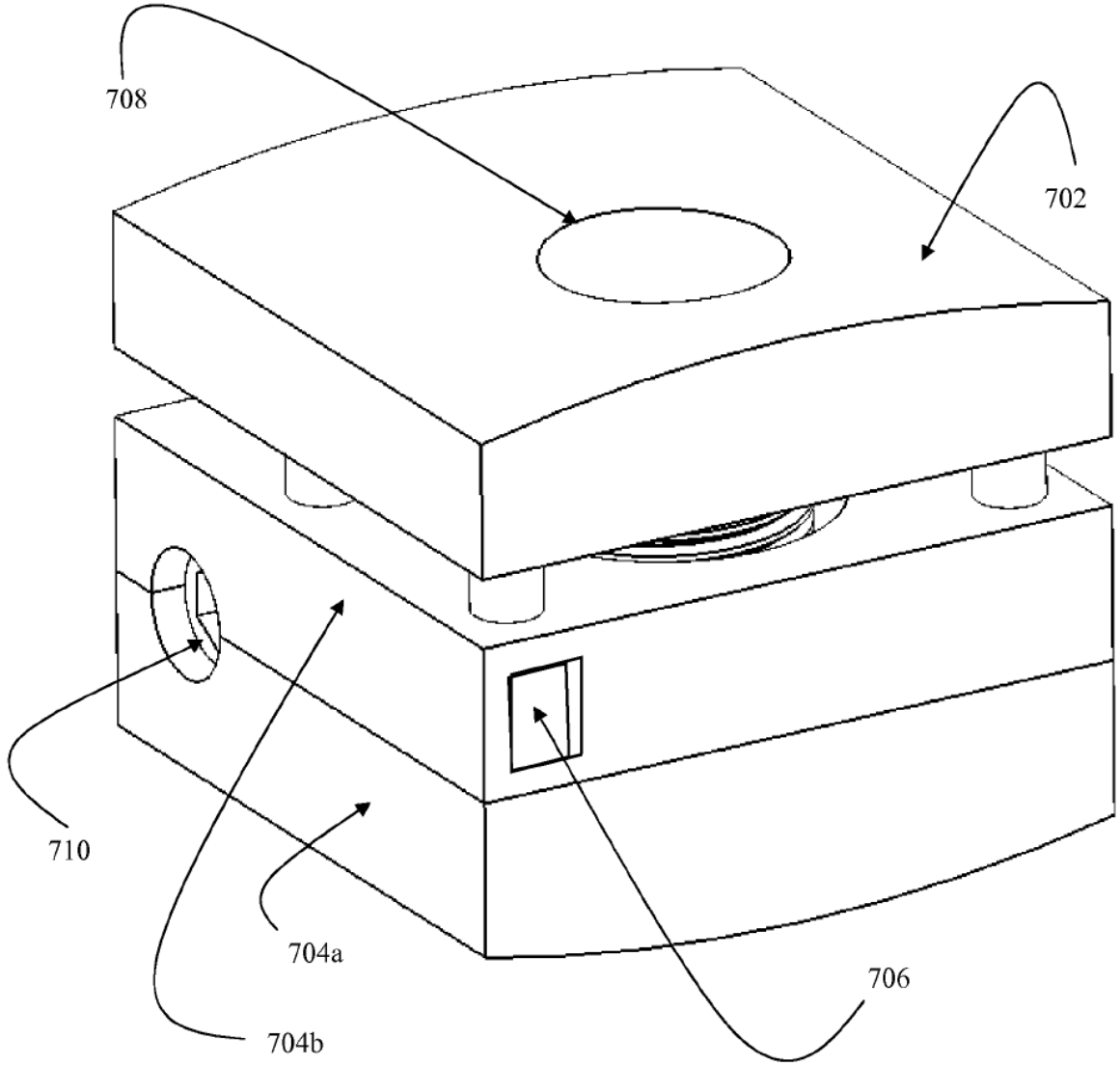


Fig. 7B 700

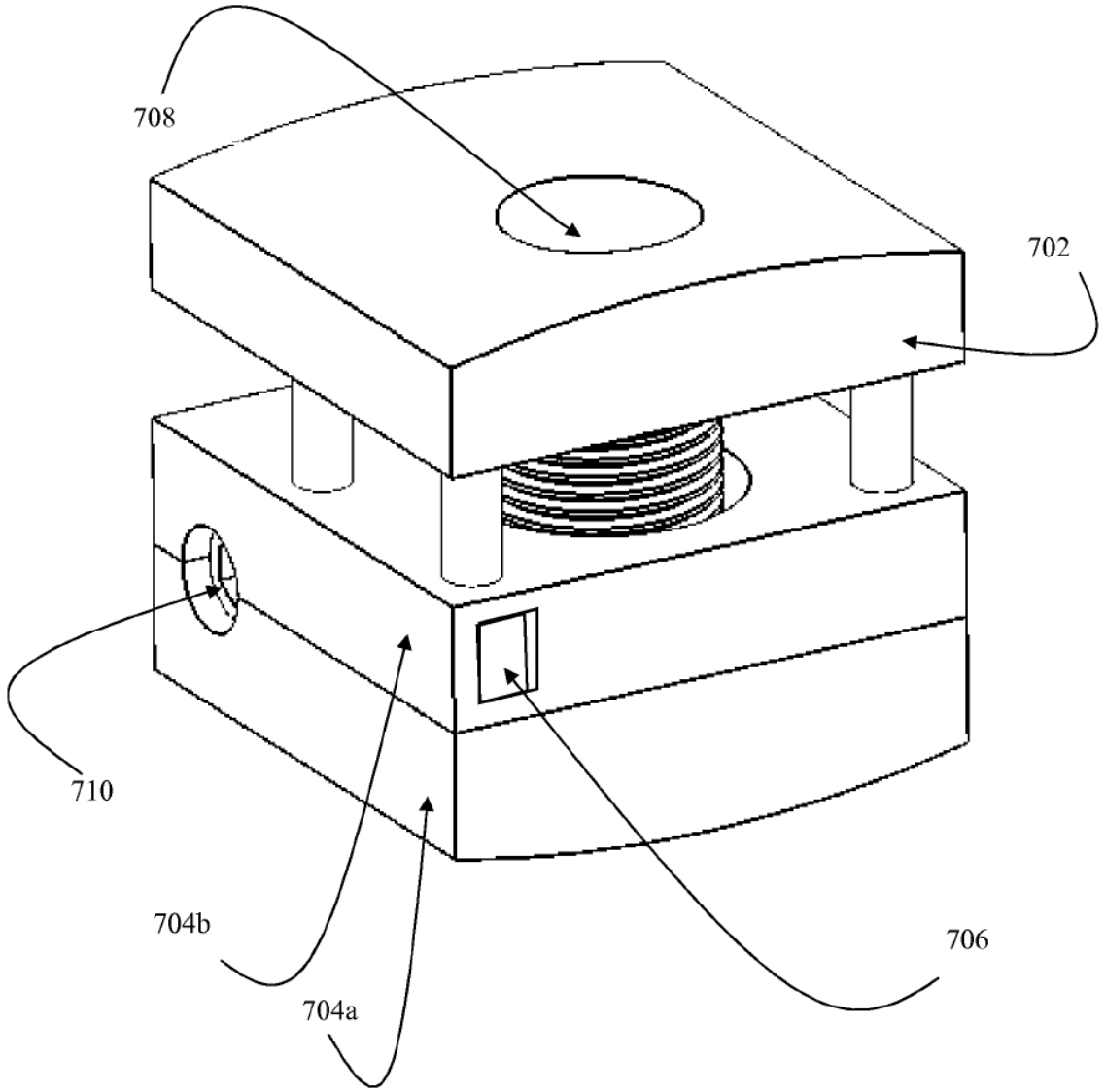


Fig. 7C

700

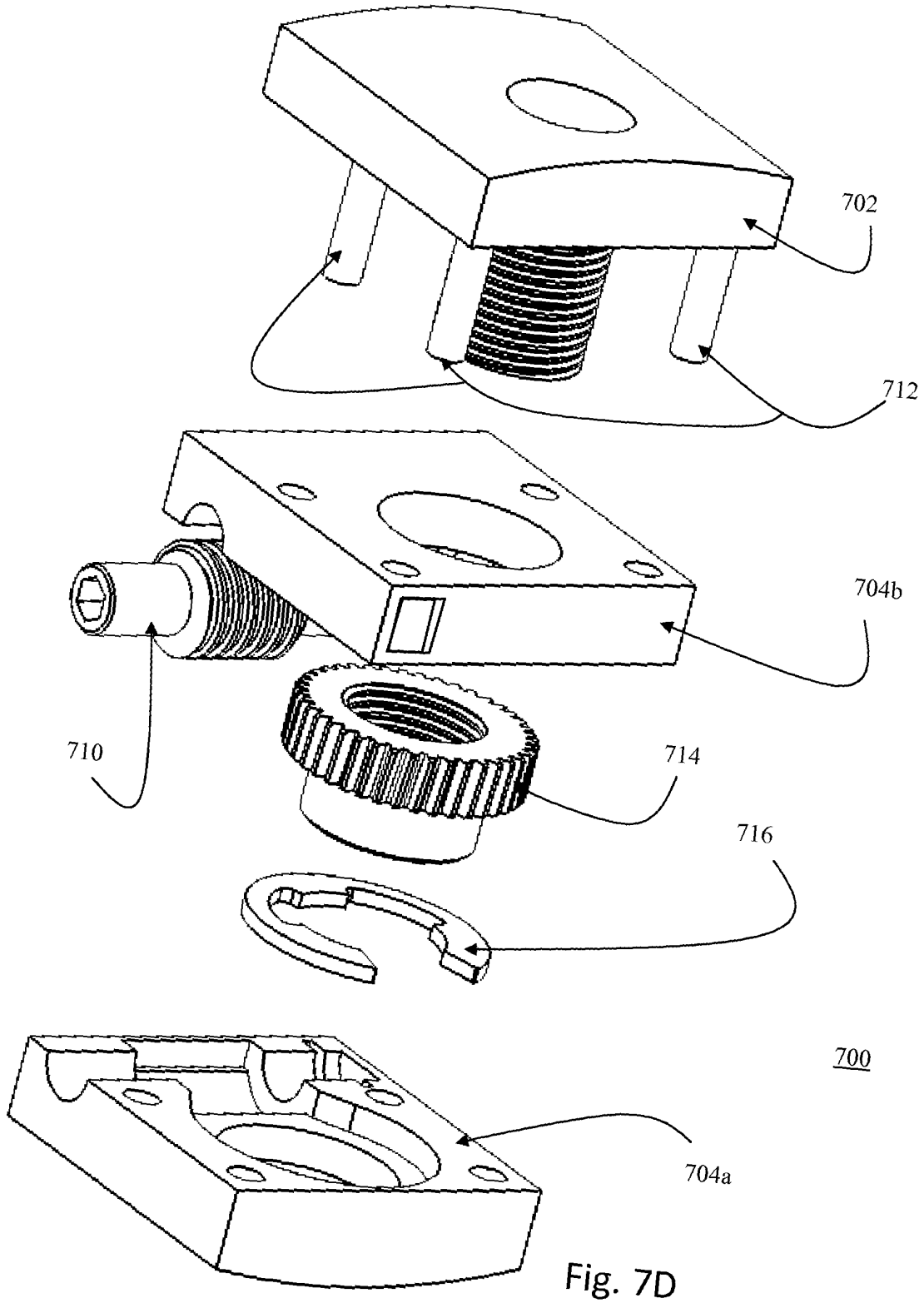


Fig. 7D

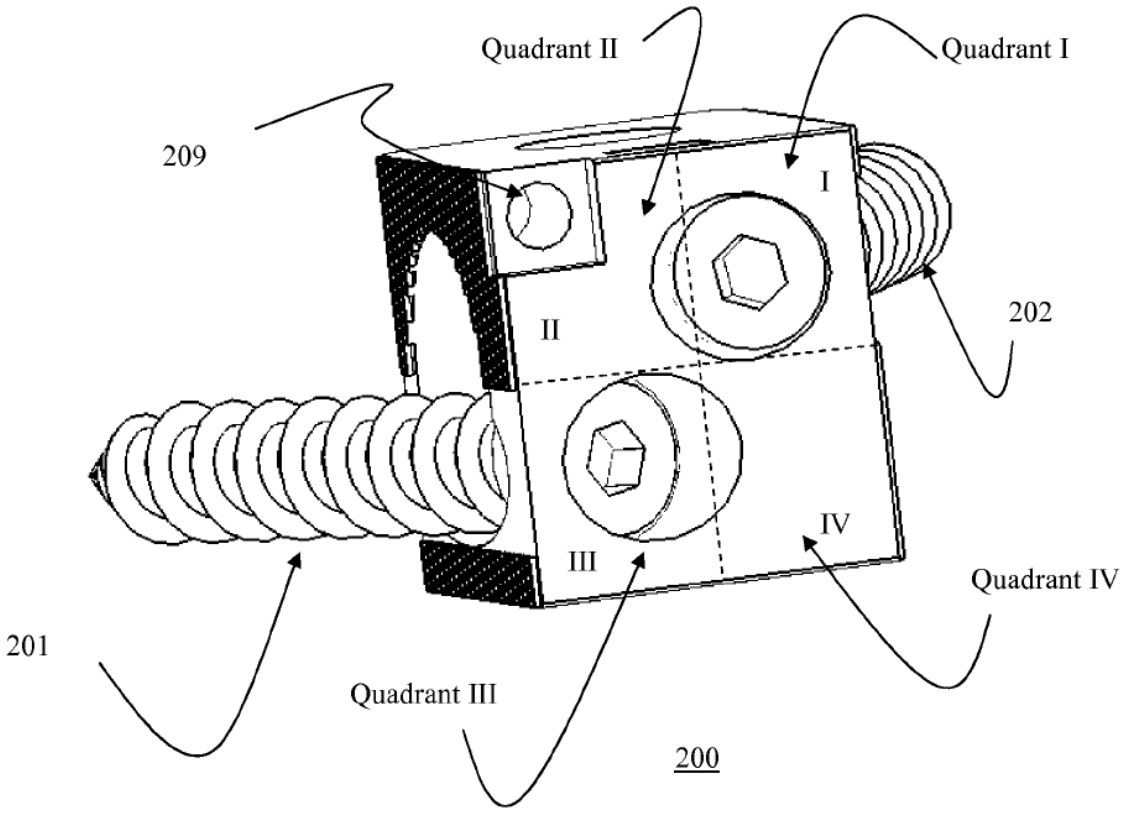

Quadrant II
Quadrant I
209
I
II
202
IV
III
Quadrant IV
201
Quadrant III
200

Fig. 7E(i)

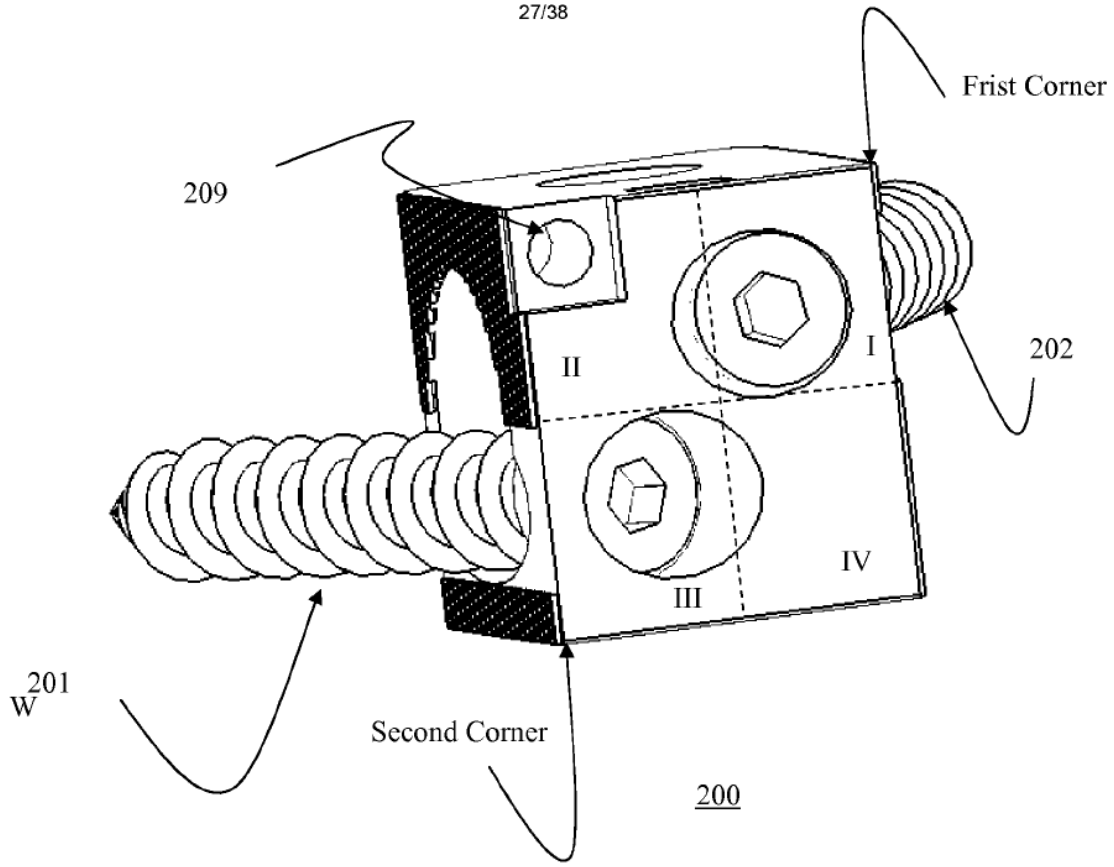


Fig. 7E(ii)

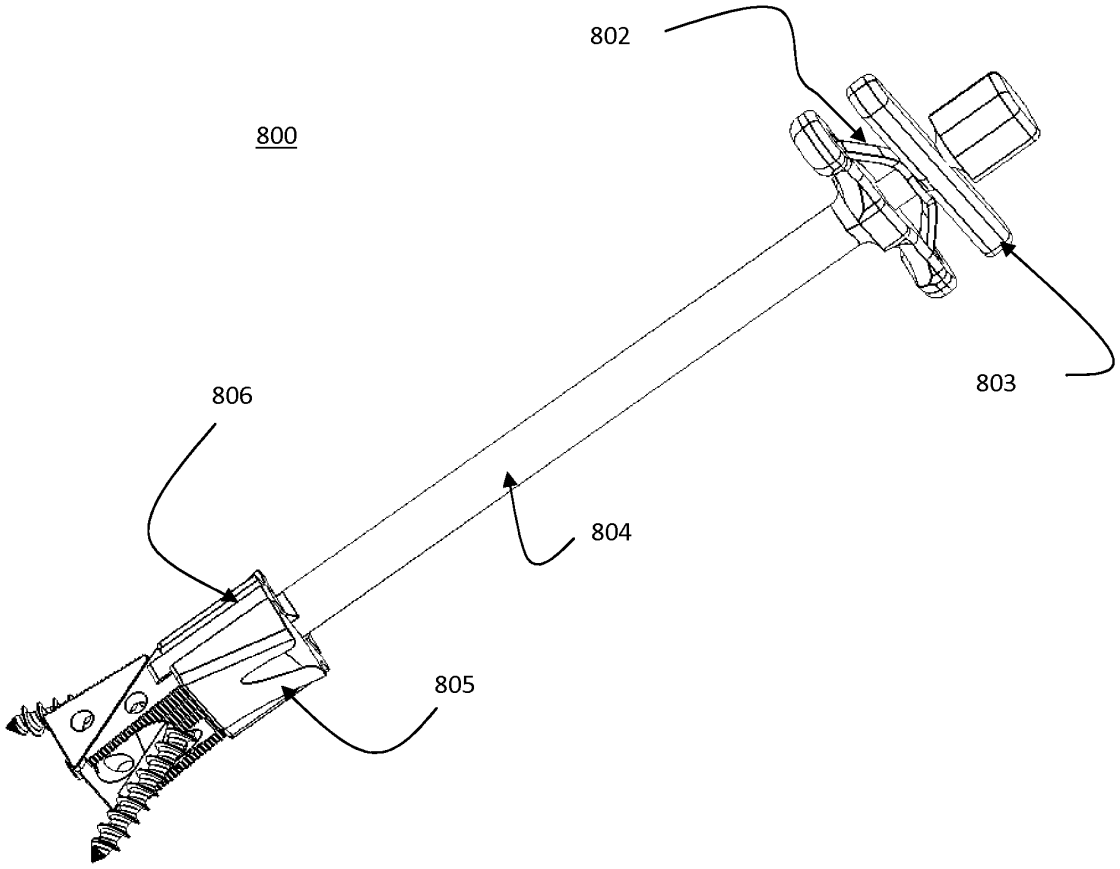


Fig. 8A

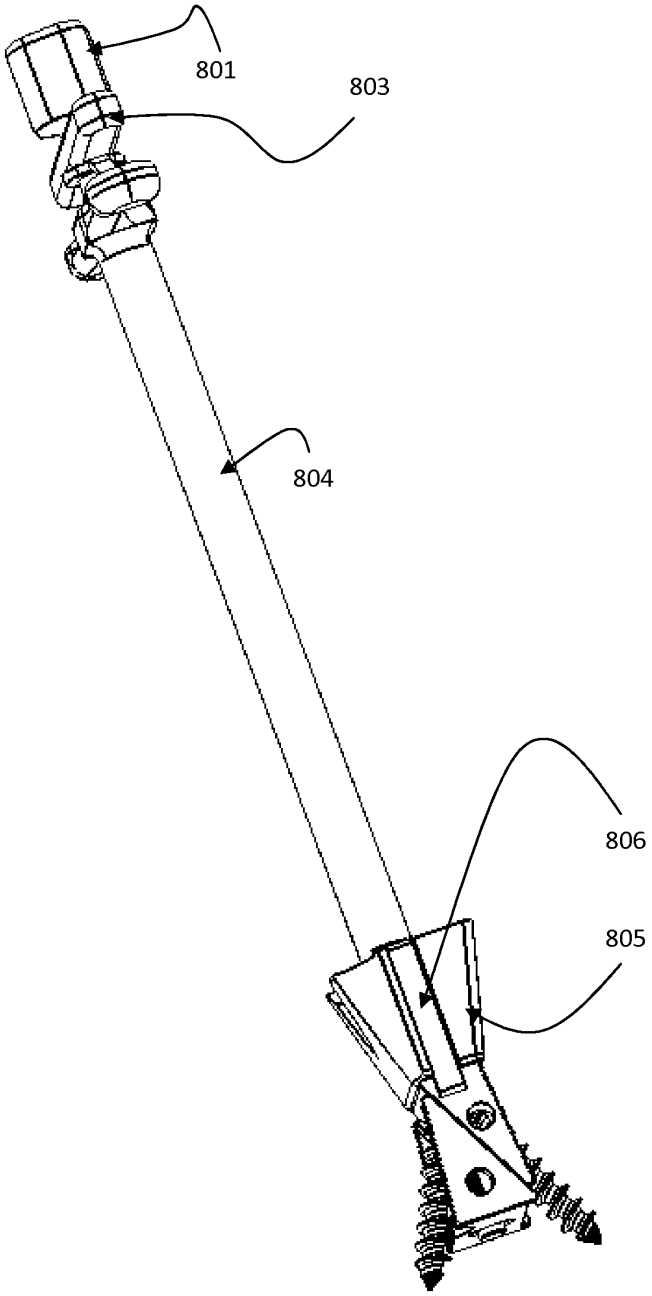


Fig. 8B

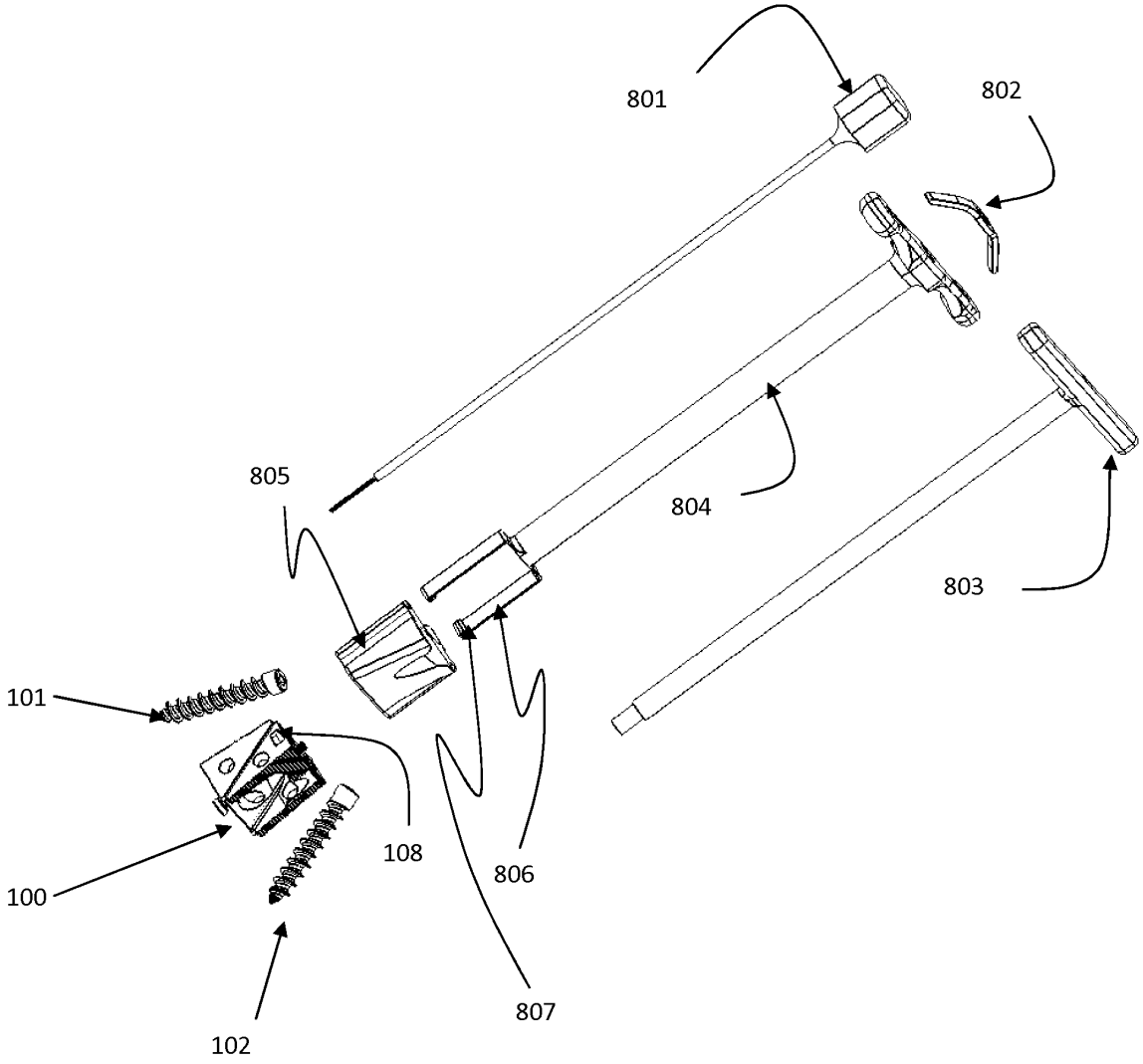


Fig. 8C

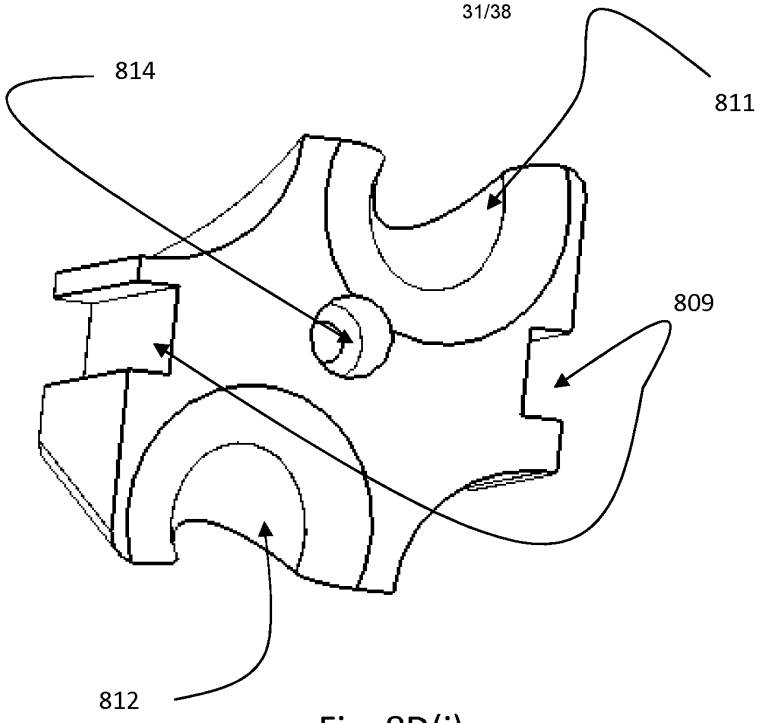


Fig. 8D(i)

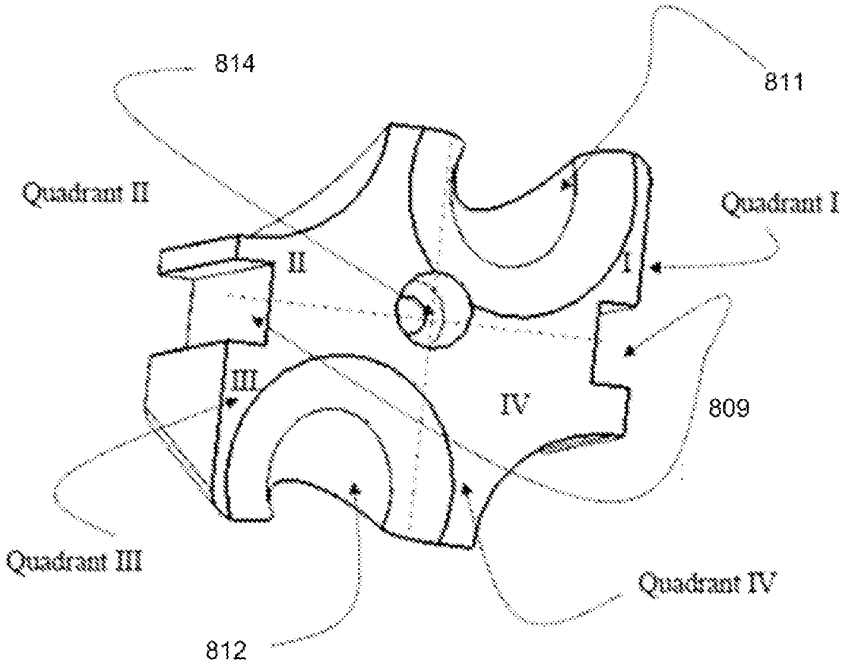


Fig. 8D(ii)

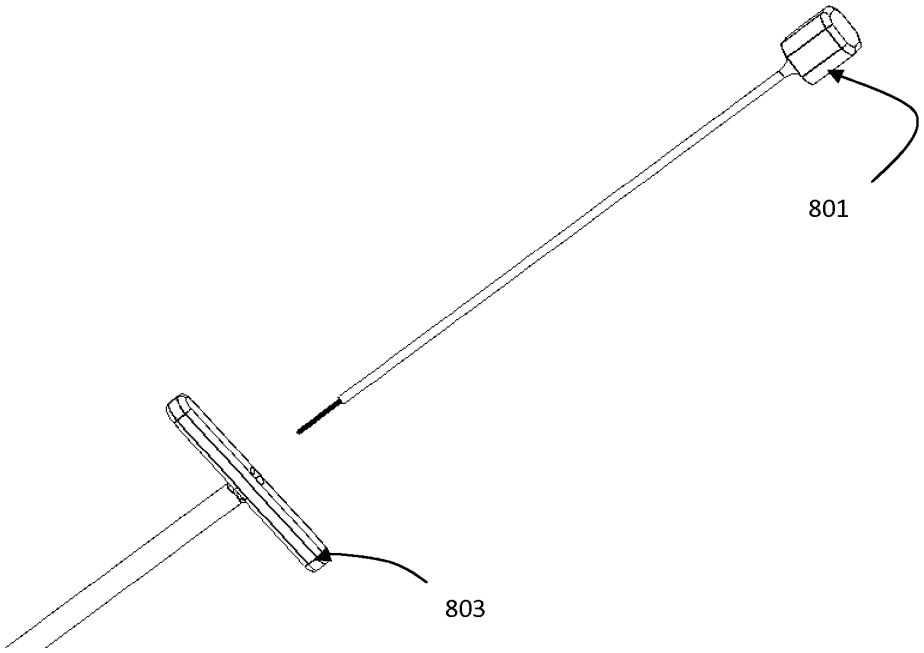


Fig. 8E

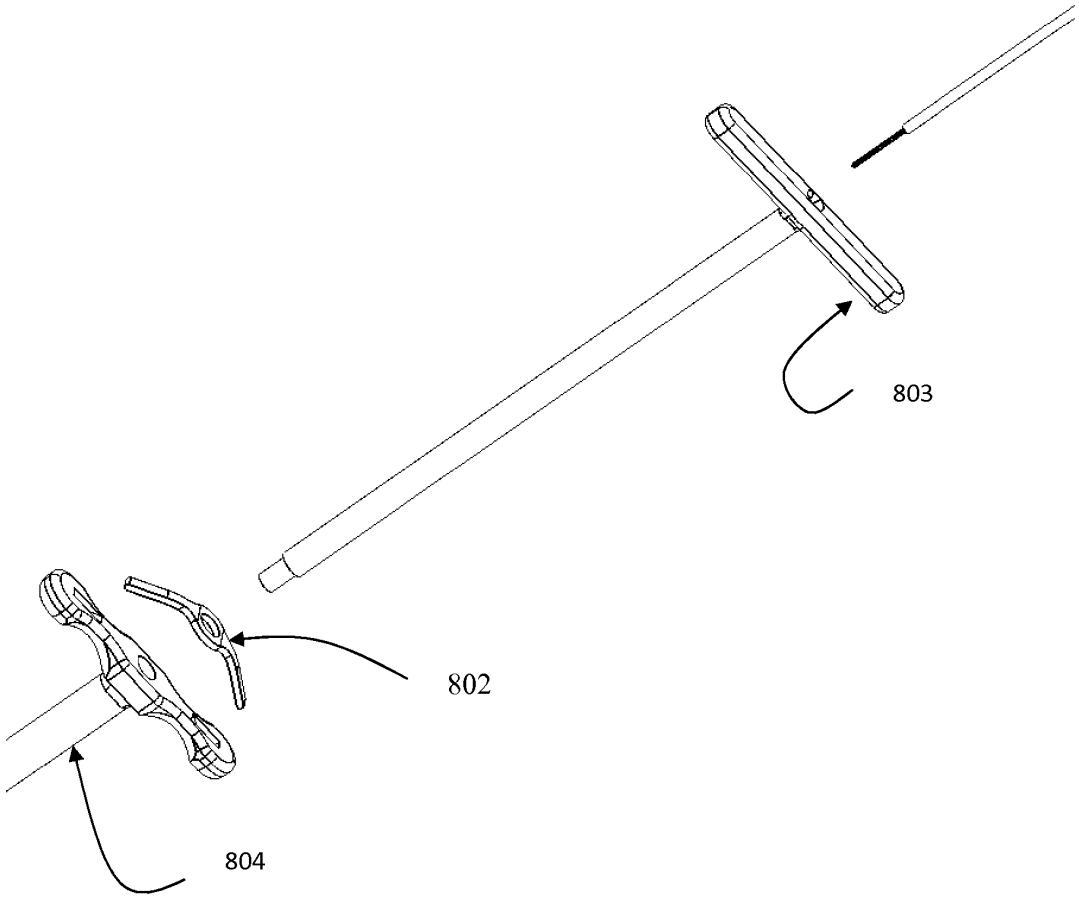


Fig. 8F

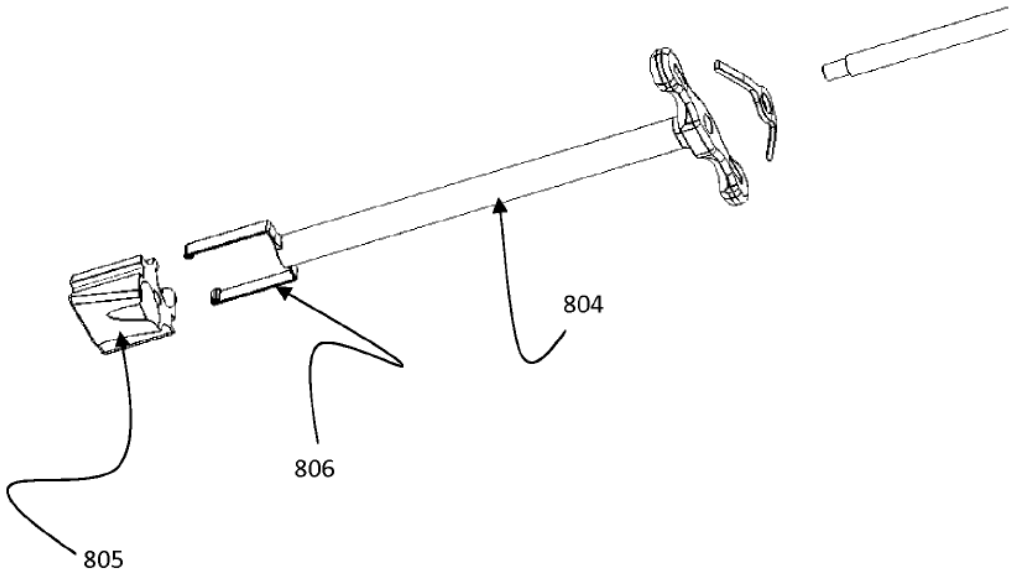


Fig. 8G

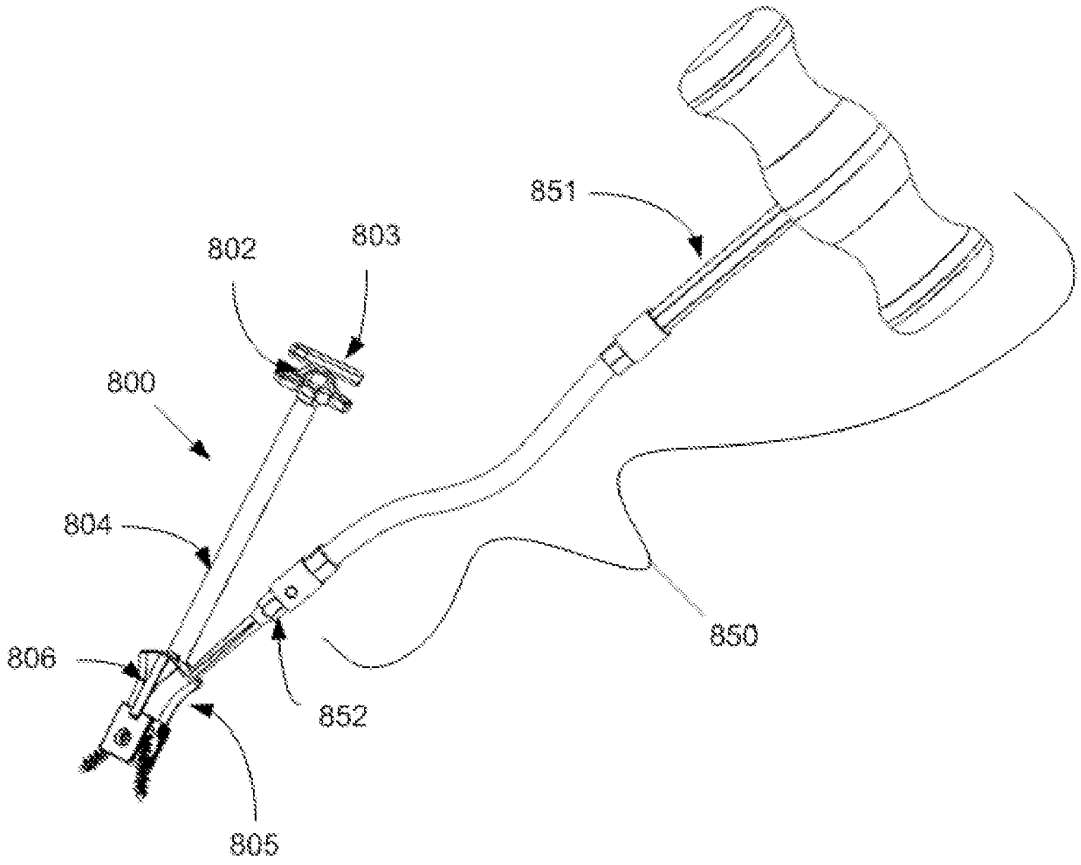


Fig. 8H

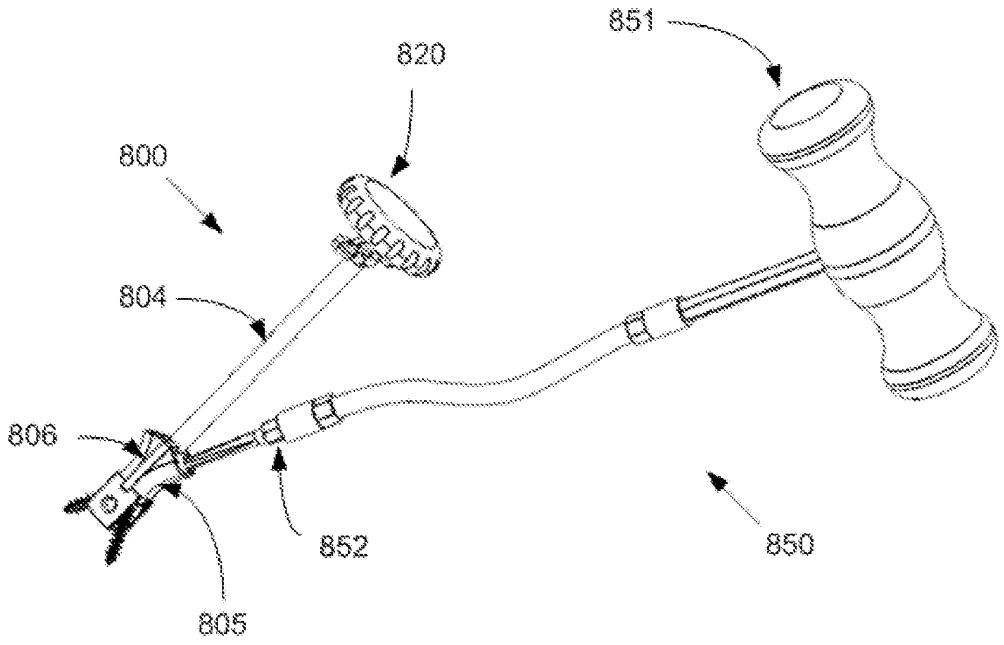


Fig. 8I

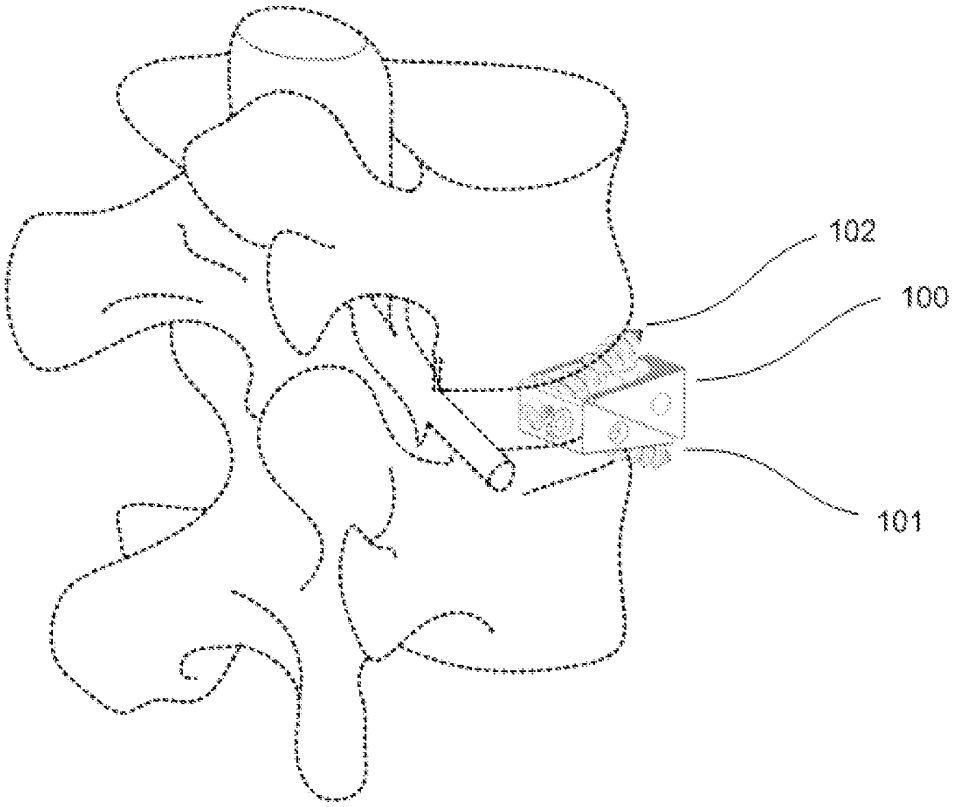


Fig. 8J

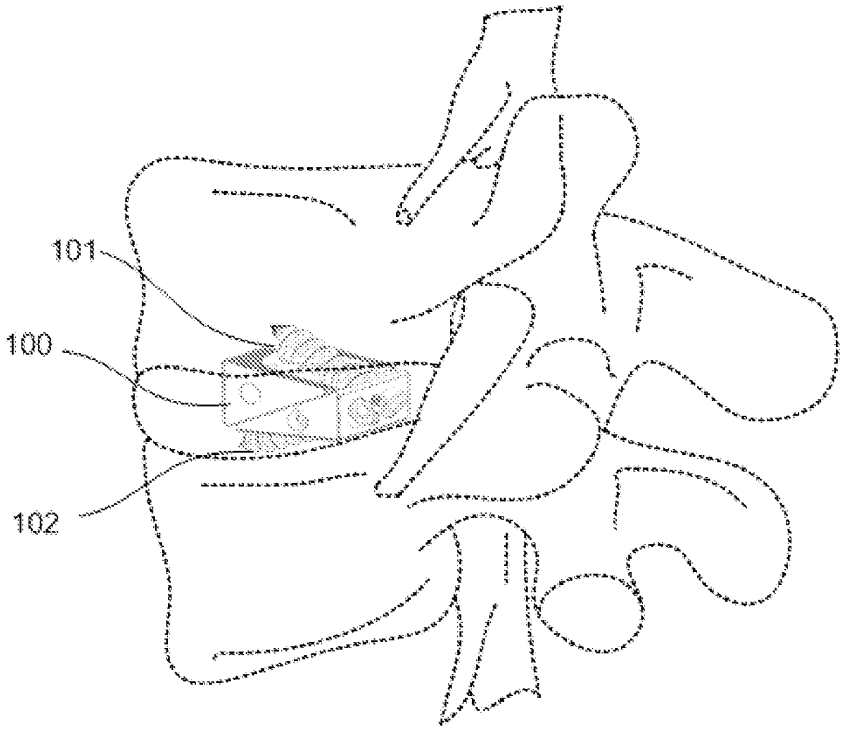


Fig. 8K

Electronic Patent Application Fee Transmittal	
Application Number:	
Filing Date:	
Title of Invention:	ZERO-PROFILE EXPANDABLE INTERVERTEBRAL SPACER DEVICES FOR DISTRACTION AND SPINAL FUSION AND A UNIVERSAL TOOL FOR THEIR PLACEMENT AND EXPANSION
First Named Inventor/Applicant Name:	Ahmnon D. Moskowitz
Filer:	Stuart A. Nelson/Abby Remer
Attorney Docket Number:	46440-0020003
Filed as Small Entity	
Filing Fees for Track I Prioritized Examination - Nonprovisional Application under 35 USC 111(a)	

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
UTILITY FILING FEE (ELECTRONIC FILING)	4011	1	75	75
UTILITY SEARCH FEE	2111	1	330	330
UTILITY EXAMINATION FEE	2311	1	380	380
REQUEST FOR PRIORITIZED EXAMINATION	2817	1	2000	2000
Pages:				
Claims:				
Miscellaneous-Filing:				
PROCESSING FEE, EXCEPT PROV. APPLS.	2830	1	70	70

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
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Electronic Acknowledgement Receipt	
EFS ID:	33069808
Application Number:	16025667
International Application Number:	
Confirmation Number:	5655
Title of Invention:	ZERO-PROFILE EXPANDABLE INTERVERTEBRAL SPACER DEVICES FOR DISTRACTION AND SPINAL FUSION AND A UNIVERSAL TOOL FOR THEIR PLACEMENT AND EXPANSION
First Named Inventor/Applicant Name:	Ahmnon D. Moskowitz
Customer Number:	26191
Filer:	Stuart A. Nelson/Geri O'Connor
Filer Authorized By:	Stuart A. Nelson
Attorney Docket Number:	46440-0020003
Receipt Date:	02-JUL-2018
Filing Date:	
Time Stamp:	17:12:32
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	$2855
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Authorized User	
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	TrackOne Request	Track1.pdf	143106 06f1a31f908c10336b4f32e508c67afbac59af1c	no	1
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Information:					
2	Transmittal of New Application	PapTrans.pdf	112448 2c08bc4992ede94e734772185d4dc9d552abdf9d	no	3
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3	Application Data Sheet	ADS.pdf	1824391 1a90695813a9e2ee6ae44c8a2692a1466511caad	no	12
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4	Power of Attorney	POA.pdf	756557 06b9c4644881c80818baef20d8d576cc3cc782cd	no	2
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	Specification		1	29	
	Claims		30	30	
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Warnings:					
Information:					
7	Drawings-only black and white line drawings	Drawings.pdf	1901571 fc3f1f22cf7ec04ec33ae238d1ee49f21609f87c	no	38
Warnings:					
Information:					
8	Fee Worksheet (SB06)	fee-info.pdf	38666 4b2d8da15a0f96723a8689268a22a7139af23667	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	13675634		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Doc Code: TRACK1.REQ
Document Description: TrackOne Request

PTO/AIA/424 (03-14)

CERTIFICATION AND REQUEST FOR PRIORITIZED EXAMINATION UNDER 37 CFR 1.102(e) (Page 1 of 1)

First Named Inventor:	Ahmnon D. Moskowitz	Non provisional Application Number (if known):	
Title of Invention:	ZERO-PROFILE EXPANDABLE INTERVERTEBRAL SPACER DEVICES FOR DISTRACTION AND SPINAL FUSION AND A UNIVERSAL TOOL FOR THEIR PLACEMENT AND EXPANSION		

APPLICANT HEREBY CERTIFIES THE FOLLOWING AND REQUESTS PRIORITIZED EXAMINATION FOR THE ABOVE-IDENTIFIED APPLICATION.

1. The processing fee set forth in 37 CFR 1.17(i)(1), the prioritized examination fee set forth in 37 CFR 1.17(c), and if not already paid, the publication fee set forth in 37 CFR 1.18(d) have been filed with the request. The basic filing fee, search fee, and examination fee are filed with the request or have been already been paid. I understand that any required excess claims fees or application size fee must be paid for the application.

2. I understand that the application may not contain, or be amended to contain, more than four independent claims, more than thirty total claims, or any multiple dependent claims.

3. The applicable box is checked below:

I. ☒ Original Application (Track One) - Prioritized Examination under § 1.102(e)(1)

i. (a) The application is an original non provisional utility application filed under 35 U.S.C. 111(a). This certification and request is being filed with the utility application via EFS-Web.

---OR---

(b) The application is an original non provisional plant application filed under 35 U.S.C. 111(a). This certification and request is being filed with the plant application in paper.

ii. An executed inventor's oath or declaration under 37 CFR 1.63 or 37 CFR 1.64 for each inventor, **or** the application data sheet meeting the conditions specified in 37 CFR 1.53(f)(3)(i) is filed with the application.

II. ☐ Request for Continued Examination - Prioritized Examination under § 1.102(e)(2)

i. A request for continued examination has been filed with, or prior to, this form.
ii. If the application is a utility application, this certification and request is being filed via EFS-Web.
iii. The application is an original non provisional utility application filed under 35 U.S.C. 111(a), or is a national stage entry under 35 U.S.C. 371.
iv. This certification and request is being filed prior to the mailing of a first Office action responsive to the request for continued examination.
v. No prior request for continued examination has been granted prioritized examination status under 37 CFR 1.102(e)(2).

Signature /Stuart A. Nelson/	Date 7/2/2018
Name (Print/Typed) Stuart A. Nelson	Practitioner Registration Number 63,947

Note: *This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications. Submit multiple forms if more than one signature is required.**

☐ *Total of _____ forms are submitted.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor	:	Ahmnon D. Moskowitz	Art Unit	:	Unknown
Application No.	:	16/025,667	Examiner	:	Unknown
Filed	:	July 2, 2018	Conf. No.	:	5655
Title	:	ZERO-PROFILE EXPANDABLE INTERVERTEBRAL SPACER DEVICES FOR DISTRACTION AND SPINAL FUSION AND A UNIVERSAL TOOL FOR THEIR PLACEMENT AND EXPANSION			

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PRELIMINARY AMENDMENT

Prior to examination, please amend the application as indicated on the following pages.

Amendments to the Specification:

Please replace the paragraphs beginning after the title with the following paragraphs:

[0001] This application is a Continuation Application of application Serial No. 15/820,232, filed on November 21, 2017, now U.S. Patent No. 10,016,284 issued July 10, 2018, which is a Continuation Application of application Serial No. 14/063,197, filed on October 25, 2013, which is a Continuation-in-part Application of co-pending application Serial No. 13/210,150, filed August 15, 2011, now U.S. Patent No. 9,867,719 issued January 16, 2018, and a Continuation-in-part Application of co-pending application Serial No. 13/210,157, filed August 15, 2011, now U.S. Patent No. 9,889,022 issued February 13, 2018, and a Continuation-in-part Application of co-pending application Serial No. 13/210,162, filed August 15, 2011, now U.S. Patent No. 9,895,238 issued February 20, 2018 and a Continuation-in-part Application of co-pending application Serial No. 13/210,168, filed August 15, 2011, now U.S. Patent No. 9,907,674 issued March 6, 2018, and a Continuation-in-part Application of application Serial No. 13/741,361, filed on January 14, 2013, now U.S. Patent No. 9,301,854 issued April 5, 2016.

[0002] Serial No. 14/063,197, filed on October 25, 2013, claims priority under U.S.C. § 119(e) of U.S. provisional application Nos. 61/801,783, filed March 15, 2013 and 61/718,707, filed October 25, 2012.

[0003] Serial No. 13/210,150, filed August 15, 2011, is a Continuation of application Serial No. 13/084,543, filed April 11, 2011, now U.S. Patent No. 8,353,913 issued on January 15, 2013, and is a Continuation of 13/108,982, filed May 16, 2011, now U.S. Patent No. 9,005,293 issued April 14, 2015.

[0004] Serial No. 13/210,157, filed August 15, 2011, is a Continuation of application Serial No. 13/084,543, filed April 11, 2011, now U.S. Patent No. 8,353,913 issued on January 15, 2013, and is a Continuation of 13/108,982, filed May 16, 2011, now U.S. Patent No. 9,005,293 issued April 14, 2015.

[0005] Serial No. 13/210,162, filed August 15, 2011, is a Continuation of application Serial No. 13/084,543, filed April 11, 2011, now U.S. Patent No. 8,353,913 issued on January 15, 2013, and is a Continuation of 13/108,982, filed May 16, 2011, now U.S. Patent No. 9,005,293 issued April 14, 2015.

[0006] Serial No. 13/210,168, filed August 15, 2011, is a Continuation of application Serial No. 13/084,543, filed April 11, 2011, now U.S. Patent No. 8,353,913 issued on January 15, 2013, and is a Continuation of 13/108,982, filed May 16, 2011, now U.S. Patent No. 9,005,293 issued April 14, 2015.

[0007] Serial No. 13/741,361, filed January 14, 2013, is a Continuation of application Serial No. 13/084,543, filed April 11, 2011, now U.S. Patent No. 8,353,913 issued on January 15, 2013, and is a Continuation of 13/108,982, filed May 16, 2011, now U.S. Patent No. 9,005,293 issued April 14, 2015.

[0008] Serial No. 13/084,543, filed April 11, 2011, is a Continuation of application Serial No. 11/842,855, filed August 21, 2007, now U.S. Patent No. 7,942,903 issued May 17, 2011.

[0009] Serial No. 13/108,982, filed May 16, 2011, is a Continuation of application Serial No. 11/842,855, filed August 21, 2007, now U.S. Patent No. 7,942,903 issued May 17, 2011, which is a Continuation-in-part of application Serial No. 11/536,815, filed September 29, 2006, now U.S. Patent No. 7,846,188 issued December 7, 2010, which is a Continuation-in-part of application Serial No.11/208,644, filed August 23, 2005, now U.S. Patent No. 7,704,279 issued April 27, 2010, which claims priority under 35 U.S.C. § 119(e) of U.S. provisional application No. 60/670,231, filed on April 12, 2005; the entire contents of all the above identified patent applications are hereby incorporated by reference.

Amendments to the Claims:

This listing of claims replaces all prior versions and listings of claims in the application:

Listing of Claims:

1. (Currently Amended) An ~~expandible~~ expandable intervertebral fusion device comprising:

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

a second movable portion extending from a third end to a fourth end, wherein the second movable portion has third and fourth end portions positioned at the third and fourth ends, respectively, and has third and fourth side portions extending between the third and fourth end portions, wherein the second movable portion has a second vertebral body engagement surface and has a second interior surface positioned on an opposite side of the second movable portion than the second vertebral body engagement surface, wherein the first movable portion is aligned with the second movable portion such that the first end of the first movable portion is axially aligned with the third end of the second movable portion and the second end of the first movable portion is axially aligned with the fourth end of the second movable portion, wherein the first end portion of the first movable portion is hingedly connected to the third end portion of the second movable portion such that the first movable portion can pivot with respect to the second movable portion so as to move the second end portion of the first movable portion

away from the fourth end portion of the second movable portion, wherein the second movable portion defines a slot in the fourth end portion between the third and fourth side portions that is sized to receive the second end portion of the first movable portion such that the second end of the first movable portion and the fourth end of the second movable portion are axially aligned; and

a mechanism that pivotably moves the first movable portion and the second movable portion with respect to each other to expand a dimension of the ~~expandible~~ expandable intervertebral fusion device, wherein the mechanism comprises:

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

a rotation screw operably connected to the wedge and to the second movable portion, wherein rotation of the rotation screw moves the wedge in an axially translating direction with respect to the first movable portion and the second movable portion within the space defined between the first and second movable portions from the first wedge position to the second wedge position.

2. (New) The device of claim 1, wherein the first movable portion defines a first bone material receiving area between the first and second end portions and the first and second side portions, wherein the second movable portion defines a second bone material receiving area between the third and fourth end portions and the third and fourth side portions, and wherein the first bone material receiving area is aligned with the second bone material receiving area and sized such that a path between the first and second bone material receiving areas is only partially blocked by the wedge.

3. (New) The device of claim 1, and further comprising means for retaining the rotation screw to the second movable portion.

4. (New) The device of claim 1, and further comprising means for mating the second movable portion with prongs of a tool.

5. (New) The device of claim 1, wherein the wedge comprises a threaded hole that engages with a threaded surface around a circumferential perimeter of the rotation screw.

6. (New) The device of claim 1, and further comprising first and second retaining rings connected to the rotation screw so as to retain the rotation screw in place when the rotation screw rotates.

7. (New) The device of claim 1, wherein the third and fourth side portions define first and second indentations that extend into but not through the third and fourth side portions and that are configured to be grabbed by an insertion tool.

8. (New) A system comprising the device of claim 7, wherein the system further comprises:

means for gripping and inserting the device.

9. (New) The system of claim 8, and further comprising:

means for turning the rotation screw with respect to the second movable portion and the wedge.

10. (New) The device of claim 1, and further comprising:

means for pivotably attaching the first movable portion to the second movable portion.

11. (New) The device of claim 1, wherein the first movable portion has a thickness that varies between the first end and the second end such that the first interior surface comprises a curved portion and a straight portion.

12. (New) The device of claim 1, wherein the wedge comprises opposing first and second side surfaces with first and second substantially flat portions, wherein the angled wedge surface extends between the first and second side surfaces and is substantially flat across the angled wedge surface from the first side surface to the second side surface.

13. (New) A method of operating the device of claim 1, the method comprising:

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

turning the rotation screw to drive the wedge against the first movable portion to push and pivot the first movable portion away from the second movable portion while the device is positioned between the vertebrae of the human patient.

14. (New) An expandable interbody device comprising:

a top housing extending from a first end to a second end, wherein the top housing has first and second end portions positioned at the first and second ends, respectively, and has first and second side portions extending between the first and second end portions, wherein the top housing has a first vertebral body engagement surface that is at least partially convex and has a first interior surface positioned on an opposite side of the top housing than the first vertebral body engagement surface, wherein the top housing defines at least one first bone material receiving area extending through the top housing between the first and second end portions and the first and second side portions;

a bottom housing extending from a third end to a fourth end, wherein the bottom housing has third and fourth end portions positioned at the third and fourth ends, respectively, and has third and fourth side portions extending between the third and fourth end portions, wherein the bottom housing has a second vertebral body engagement surface that is at least partially convex and has a second interior surface positioned on an opposite side of the bottom housing than the second vertebral body engagement surface, wherein the bottom housing defines at least one second bone material receiving area extending through the bottom housing between the third and fourth end portions and the third and fourth side portions, wherein the top housing is aligned with the bottom housing such that the first end of the top housing is axially aligned with the third end of the bottom housing and the second end of the top housing is axially aligned with the fourth end of the bottom housing, wherein the first end portion of the top housing and the third end portion of the bottom housing are hingedly interconnected such that the top housing can pivot with respect to the bottom housing so as to move the second end portion of the top housing away from the fourth end portion of the bottom housing, wherein a first length of the top housing from the first end to the second end is substantially equal to a second length of the bottom housing from the third end to the fourth end, and wherein the second end portion of the top housing is

smaller than the fourth end portion of the bottom housing such that the fourth end portion of the top housing is positionable between the third and fourth side portions of the bottom housing at the fourth end of the bottom housing;

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

a rotation screw operably connected to the wedge and to the bottom housing, wherein rotation of the rotation screw moves the wedge in an axially translating direction with respect to the top housing and the bottom housing within the space defined by the first and bottom housings from the first wedge position to the second wedge position.

15. (New) The device of claim 14, wherein the first end portion of the top housing and the third end portion of the bottom housing are hingedly interconnected via at least two pins.

16. (New) The device of claim 14, wherein the top housing has a thickness that varies between the first end and the second end such that the first interior surface comprises a curved portion and a straight portion.

17. (New) The device of claim 14, and further comprising means for attaching the first end portion of the top housing to the third end portion of the bottom housing.

18. (New) A method of operating the device of claim 14, the method comprising:

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

turning the rotation screw to drive the wedge to pivot the top housing away from the bottom housing while the device is positioned between the vertebrae of the human patient.

19. (New) An expandable interbody device comprising:

a first housing extending from a first end to a second end, wherein the first housing has first and second end portions positioned at the first and second ends, respectively, and has first and second side portions extending between the first and second end portions, wherein the first housing has a first vertebral body engagement surface and has a first interior surface positioned on an opposite side of the first housing than the first vertebral body engagement surface, wherein the first housing defines a first bone material receiving area between the first and second end portions and the first and second side portions;

a second housing extending from a third end to a fourth end, wherein the second housing has third and fourth end portions positioned at the third and fourth ends, respectively, and has third and fourth side portions extending between the third and fourth end portions, wherein the second housing has a second vertebral body engagement surface and has a second interior surface positioned on an opposite side of the second housing than the second vertebral body engagement surface, wherein the second housing defines a second bone material receiving area

between the third and fourth end portions and the third and fourth side portions, wherein the third and fourth side portions define first and second indentations configured to be grabbed by an insertion tool, wherein the first housing is aligned with the second housing such that the first end of the first housing is axially aligned with the third end of the second housing and the second end of the first housing is axially aligned with the fourth end of the second housing, wherein the first end portion of the first housing is hingedly connected to the third end portion of the second housing such that the first housing can pivot with respect to the second housing so as to move the second end portion of the first housing away from the fourth end portion of the second housing, wherein the second housing defines a slot in the fourth end portion between the third and fourth side portions that is sized to receive the second end portion of the first housing such that the second end of the first housing and the fourth end of the second housing are axially aligned;

a wedge extending from a fifth end to a sixth end with an angled wedge surface extending along a portion of a distance between the fifth end and the sixth end and with first and second opposing side surfaces on opposite sides of the angled wedge surface, wherein the wedge is positioned between the first housing and the second housing with the angled wedge surface facing the first interior surface of the first housing, wherein the first interior surface of the first housing has an angled housing surface shaped to engage the angled wedge surface of the wedge, wherein a distance from the fifth end to the sixth end of the wedge is less than a distance from the first end to the second end of the first housing and is less than a distance from the third end to the fourth end of the second housing, wherein the wedge is configured to slide within a spaced defined between the first and second housings in a direction toward the second and fourth ends of the first and second housings from a first wedge position that allows the first and second housings to pivot to a housing position that is substantially closed to a second wedge position whereby the angled wedge surface presses against the first interior surface of the first housing to hingedly open the first housing with respect to the second housing whereby the

wedge remains axially confined within the space defined between the first and second housings in the first and second wedge positions; and

a rotation screw operably connected to the wedge and to the second housing, wherein rotation of the rotation screw moves the wedge in an axially translating direction with respect to the first housing and the second housing within the space defined between the first and second housings from the first wedge position to the second wedge position.

20. (New) A system comprising the device of claim 19, wherein the device further comprises means for attaching the first end of the first housing to the third end of the second housing and wherein the system further comprises:

means for gripping and inserting the device; and

means for turning the rotation screw with respect to the second movable portion and the wedge.

REMARKS

Claim 1 is currently pending. With this Preliminary Amendment, claim 1 is amended without prejudice and claims 2-20 are added. Support for these amendments can be found throughout the specification, including, but not limited to, Figures 6A-6D and the corresponding text.

Applicant asks that all claims be examined in view of the amendments. No fees are believed to be due. Please apply any necessary charges or credits to Deposit Account 06-1050, referencing the above attorney docket number.

Respectfully submitted,

Date: 7/17/2018

/Stuart A. Nelson/
Stuart A. Nelson
Reg. No. 63,947

Customer Number 26191
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Facsimile: (877) 769-7945

61718453.doc

Electronic Acknowledgement Receipt	
EFS ID:	33197307
Application Number:	16025667
International Application Number:	
Confirmation Number:	5655
Title of Invention:	ZERO-PROFILE EXPANDABLE INTERVERTEBRAL SPACER DEVICES FOR DISTRACTION AND SPINAL FUSION AND A UNIVERSAL TOOL FOR THEIR PLACEMENT AND EXPANSION
First Named Inventor/Applicant Name:	Ahmnon D. Moskowitz
Customer Number:	26191
Filer:	Stuart A. Nelson/Abby Remer
Filer Authorized By:	Stuart A. Nelson
Attorney Docket Number:	46440-0020003
Receipt Date:	17-JUL-2018
Filing Date:	
Time Stamp:	11:54:23
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		Prelim.pdf	97193 609dcdca3326113a87a3a363596e53c9840 1abf4	yes	13

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Preliminary Amendment	1	1
	Specification	2	3
	Claims	4	12
	Applicant Arguments/Remarks Made in an Amendment	13	13
Warnings:			
Information:			
	Total Files Size (in bytes):	97193	

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New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.
National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.
New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor	:	Ahmnon D. Moskowitz	Art Unit	:	Unknown
Application No.	:	16/025,667	Examiner	:	Unknown
Filed	:	July 2, 2018	Conf. No.	:	5655
Title	:	ZERO-PROFILE EXPANDABLE INTERVERTEBRAL SPACER DEVICES FOR DISTRACTION AND SPINAL FUSION AND A UNIVERSAL TOOL FOR THEIR PLACEMENT AND EXPANSION			

MAIL STOP AMENDMENT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Please consider the documents listed on the disclosure form submitted with this statement. Copies of the documents are being submitted with this statement to the extent required under 37 C.F.R. § 1.98(a)(2). A copy of a communication from a foreign patent office in a counterpart application is also being submitted.

This statement is being filed within three months of the filing date of the application.

Apply any necessary charges or credits applicable under 37 C.F.R. § 1.17(p) to deposit account 06-1050, referencing the above attorney docket number.

Please contact the undersigned if there are any questions regarding this statement.

Respectfully submitted,

Date: 7/20/2018

/Stuart A. Nelson/
Stuart A. Nelson
Reg. No. 63,947

Customer Number 26191
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Substitute Disclosure Form	U.S. Department of Commerce Patent and Trademark Office	Attorney Docket No. 46440-0020003	Application No. 16/025,667
Information Disclosure Statement by Applicant (Use several sheets if necessary)		Applicant Moskowitz Family LLC	
(37 CFR §1.98(b))		Filing Date July 2, 2018	Group Art Unit

U.S. Patent Documents							
Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	1.	2360942	1944-10-24	ELLERSTEIN			
	2.	4064881	1977-12-27	Meredith			
	3.	4554914	1985-11-26	Kapp et al.			
	4.	4599086	1986-07-08	DOTY			
	5.	4636217	1987-01-13	Ogilvie et al.			
	6.	4904261	1990-02-27	Dove et al.			
	7.	4960420	1990-10-02	Goble et al.			
	8.	4997432	1991-03-05	Keller			
	9.	5005749	1991-04-09	Aranyi			
	10.	5062850	1991-11-05	MACMILLAN et al.			
	11.	5123926	1992-06-23	Pisharodi			
	12.	5290312	1994-03-01	KOJIMOTO et al.			
	13.	5405391	1995-04-11	Henderson et al.			
	14.	5413583	1995-05-09	Wohlers			
	15.	5454819	1995-10-03	Knoepfler			
	16.	5514180	1996-05-07	Heggeness et al.			
	17.	5660188	1997-08-26	Groiso			
	18.	5667472	1997-09-07	Finn et al.			
	19.	5713912	1998-02-03	Porter			
	20.	5782832	1998-07-21	Larsen et al.			
	21.	5865848	1999-02-02	Baker			
	22.	5888223	1999-03-30	Bray, Jr.			
	23.	5916224	1999-06-29	Esplin			
	24.	5951574	1999-09-14	Stefanchik et al.			
	25.	5960522	1999-10-05	Boe			
	26.	5968054	1999-10-19	Yeatts et al.			

Examiner Signature	Date Considered

EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Substitute Disclosure Form

Substitute Disclosure Form	U.S. Department of Commerce Patent and Trademark Office	Attorney Docket No. 46440-0020003	Application No. 16/025,667
Information Disclosure Statement by Applicant (Use several sheets if necessary) (37 CFR §1.98(b))		Applicant Moskowitz Family LLC	
		Filing Date July 2, 2018	Group Art Unit

U.S. Patent Documents

Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
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Information Disclosure Statement by Applicant (Use several sheets if necessary) (37 CFR §1.98(b))	46440-0020003	16/025,667
	Applicant: Moskowitz Family LLC	
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	72.	6953477	2005-10-11	BERRY			
	73.	6955671	2005-10-18	Uchikubo			
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	75.	20050256576	11/17/2005	Moskowitz et al.			
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EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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Substitute Disclosure Form	U.S. Department of Commerce Patent and Trademark Office	Attorney Docket No. 46440-0020003	Application No. 16/025,667
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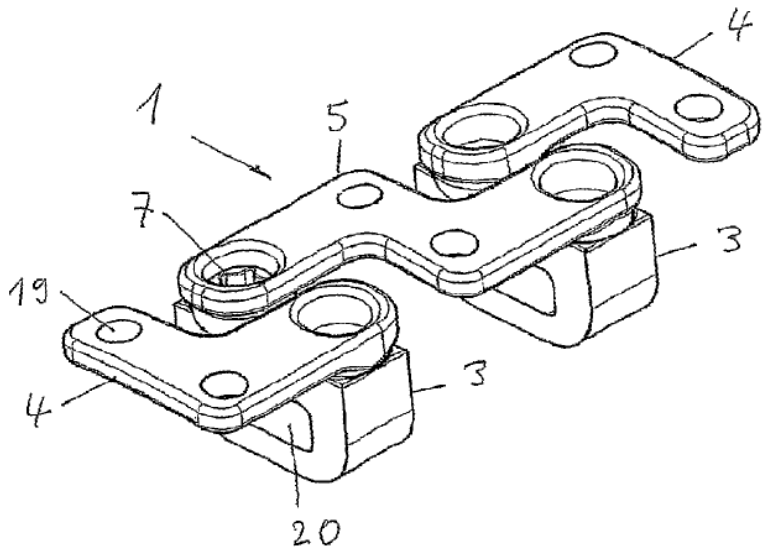
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[Fortsetzung auf der nächsten Seite]

(54) Title: SPONDYLODESIS DEVICE

(54) Bezeichnung: VORRICHTUNG FÜR DIE SPONDYLODESE



(57) Abstract: Disclosed is a device comprising at least one intervertebral implant (3) and at least one plate (4, 5) that is to be connected to the intervertebral implant (3) and an adjacent spine (21-23). The intervertebral implant (3) is connected to at least two spaced-apart plates (4, 5). One end of both plates (4, 5) respectively forms a fixable joint along with the intervertebral implant (3). Preferably, at least one of the plates (5, 4) is embodied in a Z-shaped or L-shaped manner. The inventive device provides for great adaptability to the anatomic characteristics of the spinal column and a modular structure while the number of parts is kept small.

[Fortsetzung auf der nächsten Seite]

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(84) Bestimmungsstaaten *(soweit nicht anders angegeben, für jede verfügbare regionale Schutzrechtsart)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), eurasisches (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), europäisches (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Veröffentlicht:
— *mit internationalem Recherchenbericht*

Zur Erklärung der Zweibuchstaben-Codes und der anderen Abkürzungen wird auf die Erklärungen ("Guidance Notes on Codes and Abbreviations") am Anfang jeder regulären Ausgabe der PCT-Gazette verwiesen.

(57) Zusammenfassung: Die Vorrichtung weist wenigstens ein Intervertebralimplantat (3) und wenigstens eine Platte (4,5) auf, die mit dem Intervertebralimplantat (3) und einem benachbarten Wirbel (21-23) zu verbinden ist. Das Intervertebralimplantat (3) ist mit wenigstens zwei im Abstand zueinander angeordneten Platten (4,5) verbunden. Beide Platten (4,5) bilden jeweils an einem Ende mit dem Intervertebralimplantat (3) ein fixierbares Gelenk. Vorzugsweise ist wenigstens eine der Platten (5,4) Z-förmig oder L-förmig ausgebildet. Die Vorrichtung ermöglicht eine hohe Anpassungsfähigkeit an die anatomischen Gegebenheiten der Wirbelsäule und bei kleinerer Teilezahl einen modularen Aufbau.

Vorrichtung für die Spondylodese

Die Erfindung betrifft eine Vorrichtung für die Spondylodese und insbesondere für die vordere interkorporelle Spondylodese an der Halswirbelsäule, mit wenigstens einem Intervertebralimplantat, und mit wenigstens einer Verbindungsplatte, die mit dem Intervertebralimplantat und einem benachbarten Wirbel zu verbinden ist.

Als Spondylodese wird die chirurgische Versteifung oder Verblockung eines Abschnittes der Wirbelsäule verstanden. Hierzu wird nach der klassischen Methode Knochen- oder Knochenersatzmaterial verwendet, welches zwischen die Wirbelkörper eingesetzt wird, sogenannte interkorporelle Spondylodese, oder über die hinteren Wirbelelemente angelagert wird, sogenannte dorsale Spondylodese. Hierdurch entsteht mit der Zeit eine knöcherne Brücke, welche die Wirbel verbindet, so dass sie sich nicht mehr gegeneinander bewegen können. Damit eine Verknöcherung stattfinden kann, ist es erforderlich, dass der betreffende Abschnitt der Wirbelsäule ruhiggestellt wird. Letzteres geschieht durch geeignete Implantate. Diese können mit dem Intervertebralimplantat verbunden oder von diesem unabhängig angebracht werden.

Mit konservativen Behandlungsmassnahmen nicht beeinflussbare Schmerzen, Rückenmark- oder Nervenwurzelkompressionen sowie Fehlstellungen sind Indikationen für Spondylodesen. Schmerzen können prinzipiell von allen krankhaft veränderten Strukturen der Wirbelsäule ausgehen. Für die Entwicklung von Rückenmark- oder Nervenwurzelkompressionen sind Verengungen des Wirbelkanals

oder der Zwischenwirbellöcher verantwortlich. Mit einem chirurgischen Eingriff werden die pathologischen Veränderungen beseitigt und die Stabilität der Wirbelsäule durch die Spondylodese wieder hergestellt.

Weil bei der interkorporellen Spondylodese immer Bandscheiben ausgeräumt werden und dies die Stabilität der Wirbelsäule beeinträchtigt, ist diese immer wieder herzustellen. Dies kann beispielsweise mit druckfesten Knochenspänen geschehen, die man vom Patienten entnimmt, sogenannte autogene Knochenspäne, und zwischen den Wirbelkörpern einsetzt. Da die Belastbarkeit solcher Späne oft unsicher und ihre Verfügbarkeit begrenzt ist, und zudem die durch eine Spanentnahme verursachte Morbidität erheblich sein kann, benutzt man anstelle von autogenen Knochenspänen zunehmend aus körperfremden Materialien hergestellte Intervertebralimplantate, auch „Cages" genannt.

Ein Intervertebralimplantat funktioniert als druckaufnehmender Platzhalter, welcher die Spondylodese stabilisiert, die Einstellung der Wirbelkörper zueinander sichert und gewährleistet, dass sich zwischen den benachbarten Wirbelkörpern eine solide Knochenbrücke bildet. In die Intervertebralimplantate eingefülltes und/oder um sie herum angelagertes Knochen- oder Knochenersatzmaterial bilden eine Matrix für eine Knochenneubildung. Für den Ossifikationsprozess spielt die Stabilität der Spondylodese eine entscheidende Rolle. Innerhalb der Spondylodese stattfindende Bewegungen verzögern oder verhindern deren knöcherne Konsolidierung.

Im Stand der Technik sind zahlreiche Intervertebralimplantate bekannt geworden, die mit einer Platte mit Wirbeln verbunden werden.

So zeigt beispielsweise die US 6,235,059 B eine Vorrichtung mit einem Intervertebralimplantat, mit dem zwei Wirbel aneinander stabilisiert werden können. Am Intervertebralimplantat ist eine zweiarmige Platte befestigt, die starr oder schwenkbar mit dem Intervertebralimplantat verbunden ist. Jeder Arm besitzt eine Durchgangsbohrung, durch die eine Knochenschraube in den entsprechenden Wirbelkörper einschraubbar ist. Eine Anpassung an die jeweiligen anatomischen Gegebenheiten und insbesondere an die sagittale Krümmung ist hier sehr beschränkt. Das Intervertebralimplantat kann nur mit den benachbarten Wirbeln verbunden werden.

Die WO 00/24343 offenbart eine Vorrichtung mit einem Intervertebralimplantat, das am Umfang Windungen besitzt und ähnlich einer Schraube zwischen die Wirbel eingeschraubt werden kann. An einem vorderen Ende des Intervertebralimplantates ist eine flügelförmige zweiarmige Platte befestigt. Die Befestigung ist hier so ausgeführt, dass die Platte zur Anpassung an die anatomischen Gegebenheiten bewegbar ist. Die beiden Arme der Platte weisen jeweils ein Langloch für die Aufnahme einer Knochenschraube auf. Auch bei dieser Vorrichtung kann das Intervertebralimplantat nur mit den benachbarten Wirbeln verbunden werden. Die Anpassbarkeit an die anatomischen Gegebenheiten ist sehr beschränkt.

Die FR 2 727 005 offenbart eine Vorrichtung mit mehreren Intervertebralimplantaten, die mit einem gemeinsamen Band miteinander verbunden werden. Das Band weist Löcher zur Befestigung des Bandes und jeweils ein Intervertebralimplantat und Löcher zur Aufnahme einer Knochenschraube auf. Mit dieser Vorrichtung können zwar mehrere Intervertebralimplantate miteinander verbunden werden, die Anpassbarkeit an die anatomischen Gegebenheiten ist auch hier jedoch sehr beschränkt. Um eine solche Anpassbarkeit zu gewährleisten, müssten hier entsprechend unterschiedliche

Bänder zur Verfügung stehen. Die Abstände zwischen den Intervertebralimplantaten ist vorgegeben.

Die EP 0 179 695 A offenbart ein Intervertebralimplantat, an dem Ösen angeformt sind, mit denen das Implantat an benachbarten Wirbeln festschraubbar ist. Auch hier ist die Anpassbarkeit an anatomische Gegebenheiten sehr beschränkt. Insbesondere ist es hier in der Regel nicht möglich, die Knochenschrauben an der geeigneten Stelle in den Wirbelkörper einzusetzen. Es können auch hier nur zwei Wirbel mit einem Intervertebralimplantat verbunden werden.

Die US 5,360,430 offenbart ein Intervertebralimplantat, welches einen Wirbel ganz oder teilweise ersetzt, welches mit Platten an den oberen resp. unteren Wirbeln befestigt wird und welches zwischen diesen Wirbeln eine gewisse ungefederte oder gefederte Beweglichkeit erlaubt.

Die S 5,443,515 offenbart ebenfalls ein Implantat, welches einen Wirbelkörper ersetzen soll. Es ist aus Tantalschaum hergestellt.

Die Stabilisierung von Intervertebralimplantaten mit herkömmlichen Platten erfordert somit wegen der grossen individuellen und krankheitsbedingten anatomischen Variabilität insbesondere der Halswirbelsäule ein grosses Sortiment verschieden langer Platten mit unterschiedlichen Lochabständen. Die Länge der Platten richtet sich dabei nach der Position der oberen und unteren Endlöcher. Wenn bei mehrsegmentalen Spondylodesen die Platten nur an die Endwirbel befestigt werden, besteht die Gefahr, dass die Platten an einem Endwirbel ausreissen. Es ist deshalb ratsam, die Platten auch an die zwischen den Endwirbeln liegenden Wirbelkörper mit Schrauben zu fixieren. Die bei herkömmlichen Platten dafür vorgesehenen Schraubenlöcher liegen aber nicht immer genau so, dass die betreffenden Schrauben gut in die zwischen

den Endwirbeln liegenden Wirbelkörper eingesetzt werden können. Zudem kann bei verschiedenen Plattentypen nur jeweils eine Schraube im Wirbelkörper befestigt werden.

Der Erfindung liegt die Aufgabe zugrunde, eine Vorrichtung der genannten Art zu schaffen, die optimaler an die jeweiligen anatomischen Gegebenheiten anpassbar ist.

Die Aufgabe ist bei einer gattungsgemässen Vorrichtung dadurch gelöst, dass das Intervertebralimplantat mit zwei im Abstand zueinander angeordneten Platten verbunden ist, wobei die beiden Platten jeweils an einem Ende mit dem Intervertebralimplantat ein fixierbares Gelenk bilden. Die beiden mit dem Intervertebralimplantat verbundenen Platten können unabhängig voneinander in mehreren Freiheitsgraden bewegt und in einer gewünschten Endstellung winkelstabil fixiert werden. Ein wesentlicher Vorteil der erfindungsgemässen Vorrichtung besteht darin, dass auch Mehretagenspondylodesen hergestellt werden können, wobei benachbarte Intervertebralimplantate direkt miteinander verbunden werden können. Dadurch ergibt sich eine besonders hohe Stabilität und damit Sicherheit. Die Intervertebralimplantate bilden somit mit den Platten eine besonders stabile Einheit. Es können auch unterschiedlich grosse Intervertebralimplantate kombiniert und mit unterschiedlichen Platten untereinander winkelstabil verbunden werden. Insbesondere ist eine Anpassung an unterschiedliche Krümmungen der Wirbelsäule und an unterschiedliche Abstände zwischen Intervertebralimplantaten und Wirbeln möglich. Die Erfindung eignet sich insbesondere für Platten, die plastisch nicht deformierbar sind, und beispielsweise aus Titan oder einem Verbundwerkstoff bestehen.

Die Vorrichtung eignet sich insbesondere für die Spondylodese an der Halswirbelsäule. Hier empfiehlt es sich, die Spondylodese mit an die Vorderfläche der Halswirbelkörper fixierten Platten

abzusichern. Es ist insbesondere ein Modularsystem möglich, das sowohl in der Herstellung als auch in der Praxis vorteilhaft ist. Die Anpassbarkeit ist mit einem überraschend kleinen Sortiment aus Einzelteilen möglich.

Nach einer Weiterbildung der Erfindung ist vorgesehen, dass wenigstens eine Platte Z-förmig oder L-förmig ausgebildet ist. Mit solchen Platten ist eine besonders hohe Anpassbarkeit und ein besonders stabiler Verbund möglich. Z-förmige Platten eignen sich insbesondere zum Verbinden benachbarter Intervertebralimplantate und damit zur Stabilisierung von drei Wirbeln. Solche Z-förmige Platten können in einem mittleren Bereich beispielsweise mit zwei Knochenschrauben verankert werden. L-förmige Platten ermöglichen ebenfalls eine Befestigung solcher Platten mit zwei Knochenschrauben. Auf dieselbe Art können auch mehr als drei Wirbel resp. mehr als zwei Intervertebralimplantate untereinander verbunden werden. Als Implantatbrücken eignen sich auch gerade Platten, welche durch fixierbare Gelenke an die Intervertebralimplantate und Knochenschrauben an den zwischen Intervertebralimplantaten liegenden Wirbelkörper befestigt werden. Denkbar ist auch eine Ausführung, bei welcher zwei Intervertebralimplantate nicht direkt durch eine sie verbindende Platte (Implantatbrücke) aneinander fixiert werden, sondern indirekt über den zwischen den beiden Intervertebralimplantaten liegenden Wirbelkörper. Für diesen Fall sind kurze Platten vorgesehen, welche durch fixierbare Gelenke an das jeweilige Intervertebralimplantat und mit Knochenschrauben an den Wirbelkörper befestigt werden, wobei dann die am oberen Intervertebralimplantat angebrachte Platte nach unten und die am unteren Intervertebralimplantat angebrachte Platte nach oben gerichtet ist, sodass die Plattenenden mit den Knochenschrauben am Zwischenwirbel nebeneinander liegen. Somit ist dann jedes der beiden Intervertebralimplantate mit durch eine Platte und mindestens eine Knochenschraube mit dem Zwischenwirbel verbunden.

Die Erfindung betrifft auch einen Bausatz zur Herstellung einer Vorrichtung gemäss Anspruch 1.

Ausführungsbeispiele der Erfindung werden nachfolgend anhand der Zeichnungen näher erläutert. Es zeigen:

Fig. 1 schematisch eine räumliche Ansicht einer erfindungsgemässen Vorrichtung,

Fig. 2 eine weitere Ansicht der erfindungsgemässen Vorrichtung gemäss Fig. 1,

Fig. 3 einen Schnitt entlang der Linie III - III der Fig. 2,

Fig. 4 eine weitere Ansicht der erfindungsgemässen Vorrichtung gemäss Fig. 1,

Fig. 5 eine weitere Ansicht der erfindungsgemässen Vorrichtung gemäss Fig. 1,

Fig. 6 eine räumliche Ansicht einer Variante der erfindungsgemässen Vorrichtung,

Fig. 7 eine räumliche Ansicht einer Variante der erfindungsgemässen Vorrichtung,

Fig. 8 eine räumliche Ansicht einer geraden Platte mit einem Gelenk,

Fig. 9 eine räumliche Ansicht einer geraden Platte mit zwei Gelenken, und

Fig. 10-15 schematisch Ansichten eines Abschnittes einer Wirbelsäule mit jeweils einer erfindungsgemässen Vorrichtung, welche Wirbel miteinander verbindet.

Die in den Fig. 1 bis 4 gezeigte Vorrichtung 1 weist zwei Intervertebralimplantate 3 auf, die gemäss den Fig. 10 und 11 jeweils in den Bandscheibenraum benachbarter Wirbel 21 und 22 bzw. 22 und 23 einer Wirbelsäule 24 eingesetzt sind. Die Wirbel 21 bis 23 sind hier insbesondere Wirbel der Halswirbelsäule, wobei mit 26 die Vorderfläche der Halswirbelsäule bezeichnet ist. In der

Fig. 10 liegen links vor der Vorderfläche hier nicht gezeigte Speiseröhre und grosse Blutgefässe.

Die beiden Intervertebralimplantate 3 bestehen aus Metall, insbesondere Titan oder einem geeigneten Kunststoff und sind interkorporelle und druckaufnehmende Körper. Sie weisen jeweils eine nach aussen offene Ausnehmung 20 auf, die zur Aufnahme von Knochen oder Knochenersatzmaterial dient. Die Ausnehmungen 20 werden vom Knochen des Patienten durchwachsen, so dass sich eine knöcherne Brücke zwischen den benachbarten Wirbeln 21 und 22 bzw. 22 und 23 bildet. Die Wirbel 21, 22 und 23 können damit fest miteinander verbunden werden.

Die beiden Intervertebralimplantate 3 sind mit einer Z-förmigen Platte 5 fest miteinander verbunden. Diese Platte 5 weist gemäss Fig. 2 zwei Arme 5a und 5b sowie einen quer zu diesen verlaufenden mittleren Bereich 5c auf. Die beiden Arme 5a und 5b sind vorzugsweise gleich ausgebildet, so dass die Platte 5 bezüglich eines mittleren Punktes P drehsymmetrisch ist. Die beiden Arme 5a weisen jeweils an einem freien Ende eine halbkugelförmige Vertiefung 27 auf, durch die mittig eine Durchgangsöffnung 17 hindurch geht. Diese halbkugelförmigen Vertiefungen 27 und die

Durchgangsöffnungen 17 nehmen jeweils eine Kugelkopfschraube 7 auf, die mit einem Gewindeschaft 12 in eine Bohrung 13 eines Intervertebralimplantates 3 eingeschraubt ist. Die Kugelkopfschrauben 7 weisen jeweils einen Kopf 9 mit einem Werkzeugangriff 8 und einer ebenfalls halbkugelförmigen Unterseite 10 auf. Zwischen dem Schaft 12 und dem Kopf 9 ist ein Hals 11 angeordnet, dessen Durchmesser kleiner ist als derjenige des Schaftes 12 und der Durchgangsöffnung 28. Die halbkugelförmige Unterseite 10 liegt an der halbkugelförmigen Vertiefung 27 an. Sind die beiden Schrauben 12 fest in das jeweilige Intervertebralimplantat 3 eingeschraubt, so ist die Platte 5 an ihren beiden freien Enden fest am jeweiligen Intervertebralimplantat 3 durch Klemmung fixiert. Die Klemmflächen werden durch eine halbkugelförmige Fläche 15 und eine ebenfalls halbkugelförmige Fläche 14 des entsprechenden Intervertebralimplantates 3 gebildet. Sind die beiden Kugelkopfschrauben 7 nicht vollständig eingeschraubt, so bilden die beiden Verbindungen der Platte 5 zu den Intervertebralimplantaten 3 jeweils eine Art Kugelgelenk, die jeweils an beiden Befestigungspunkten Bewegungen in mehreren Freiheitsgraden ermöglichen.

Die Platte 5 und die beiden Intervertebralimplantate 3 können somit gegeneinander bewegt werden und in jeder gewünschten Position können diese Teile durch Festziehen der Schrauben 7 winkelstabil miteinander verbunden werden. Nach dem Festziehen der Kugelkopfschrauben 7 bilden die beiden Intervertebralimplantate 3 und die Z-förmige Platte 5 eine stabile Einheit. Nötigenfalls können die Schrauben 7 jederzeit gelöst und damit wieder der bewegliche Zustand hergestellt werden.

An den beiden Intervertebralimplantaten 3 ist jeweils eine weitere Platte 4 angeordnet, die vorzugsweise L- bzw. winkelförmig ausgebildet sind. Diese Platten 4 weisen jeweils zwei Arme 4a und 4b auf, die gleich oder unterschiedlich sein können. Der

Arm 4a weist an seiner Unterseite einen kugelförmigen Gelenkteil 18 mit einer kugelförmigen Innenfläche 16 und einer ebenfalls halbkugelförmigen Aussenfläche 15 auf. Der Gelenkteil 18 weist eine Durchgangsöffnung 17 auf. Der Gelenkteil 18 sitzt in einer halbkugelförmigen Vertiefung 14 des entsprechenden Intervertebralimplantates 3. Um die Platte 4 am entsprechenden Intervertebralimplantat 3 zu befestigen, wird gleich wie zur Befestigung der Z-förmigen Platte 5 in den Gelenkteil 18 von oben eine Kugelkopfschraube 7 eingesetzt und in die Bohrung 13 des entsprechenden Intervertebralimplantates 3 eingeschraubt. In den Fig. 1 - 3 sind diese Schrauben 7 aus zeichnerischen Gründen nicht eingezeichnet. Vor dem Festziehen der Schraube 7 kann die entsprechende Platte 4 aufgrund der kugelgelenkartigen Verbindung bewegt und an die anatomischen Gegebenheiten angepasst werden. Ist die optimale Position erreicht, so werden die entsprechenden Schrauben 7 angezogen und damit die Platten 4 winkelstabil bezüglich des entsprechenden Intervertebralimplantates 3 fixiert.

Die beiden Platten 4 weisen im Arm 4b jeweils zwei im Abstand zueinander angeordnete Durchgangsöffnung 19 auf, die jeweils zur Aufnahme einer Knochenschraube 25 dienen, wie dies in Fig. 7 schematisch dargestellt ist. Solche Knochenschrauben 25 sind an sich bekannt. Die Verbindung kann mit einer Schraube gemäss der WO 01/30251 winkelstabil oder alternativ auch beweglich sein. Mit diesen Schrauben 25 werden die beiden Platten 4 im entsprechenden Wirbelkörper 21 bzw. 23 befestigt. Diese Knochenschrauben 25 sollten möglichst in der Mitte des entsprechenden Wirbelkörpers 21 bzw. 23 liegen. Andernfalls könnte ihr Halt beeinträchtigt werden. Diese Schrauben sollten ferner nicht in eine gesunde Bandscheibe eindringen und zudem sollten die Arme 4b nicht eine gesunde Bandscheibe berühren. Dies würde zu Zerstörungen bzw. Degenerationen der betreffenden Bandscheiben führen. Aufgrund der Einstellbarkeit der Platten 4 ist es nun möglich,

diese so auszurichten, dass die Schrauben wie oben erläutert in geeigneten Positionen in die Wirbelkörper 21 bzw. 23 eingeschraubt werden können. Ebenfalls kann damit vermieden werden, dass die Arme 4b eine Bandscheibe berühren.

Die genannte Einstellbarkeit der Platten 4 lassen sich diese an die unterschiedlichen Krümmungen und Formen der Vorderfläche 26 der Halswirbelsäule anpassen. Dies ist auch dann möglich, wenn Intervertebralimplantate 3 wie gewünscht nicht an der Vorderseite 26 vorstehen. Die Intervertebralimplantate 3 dürfen an der Vorderfläche 26 nicht vorstehen, da sie dadurch Verletzungen der vor der Halswirbelsäule 24 angeordneter Gebilde und insbesondere der Speiseröhre und grosser Blutgefässe verursachen könnten.

Die beiden Platten 4 verbinden somit bei festgezogenen Kugelkopfschrauben 7 jeweils ein Intervertebralimplantat 3 winkelstabil mit einem Wirbelkörper 21 und 22 bzw. 22 und 23. Die Platte 5 verbindet die beiden Intervertebralimplantate 3 winkelstabil miteinander. Zudem weist die Platte 5 im mittleren und quer verlaufen Bereich 5c zwei Durchgangsöffnungen 6 auf, welche jeweils eine Knochenschraube 25 aufnehmen, die in den mittleren Wirbelkörper 22 eingeschraubt sind und mit denen dadurch die Platte 5 an diesem mittleren Wirbel 22 verankert wird. Auch hier ist eine winkelstabile oder bewegliche Verbindung zwischen Platte 4 und Knochenschraube 25 möglich.

Die beiden Platten 4 und die Platte 5 können gemäss den Fig. 4 und 5 in einer Ebene liegen. Aufgrund der genannten Gelenkverbindungen ist eine solche ebene Anordnung jedoch nicht zwingend. So können die beiden Platten 4 gemäss den Doppelpfeilen 29 der Fig. 4 unabhängig voneinander in einen vergleichsweise grossen Bereich nach oben und nach unten verschwenkt werden. Diese beiden Platten 4 können auch unabhängig voneinander gemäss den Doppelpfeilen 29 bis 31 der Fig. 2, 4, 5 und 6 verschwenkt werden.

Aufgrund der kugelgelenkartigen Verbindungen sind hier aber auch noch andere Bewegungen bzw. Freiheitsgrade möglich. So steht insbesondere die in Fig. 5 mit dem Doppelpfeil 31 angedeutete Schwenkbewegung zur Verfügung. Jede mögliche Position ist durch Festziehen der entsprechenden Kugelkopfschraube 7 fixierbar. Damit ist wie oben erläutert eine optimale Anpassung an die jeweiligen anatomischen Gegebenheiten möglich.

Die Fig. 6 zeigt eine erfindungsgemässe Vorrichtung 2, die lediglich ein Intervertebralimplantat 3 sowie zwei L- bzw. winkelförmige Platten 4 aufweist. Die Platten 4 sind wie bereits oben erläutert jeweils mit einer Kugelkopfschraube 7 am Intervertebralimplantat 3 befestigt. Die Verbindung ist wie oben erläutert kugelgelenkartig. Die beiden Platten 4 können ebenfalls wie oben erläutert vor dem Festziehen der beiden Schrauben 7 bewegt werden. In der Fig. 6 ist lediglich eine der beiden Kugelkopfschrauben 7 gezeigt. Die beiden Platten 4 sind in der gezeigten Ausführung gleich ausgebildet. Die Platten 4 können jedoch auch unterschiedlich sein, beispielsweise unterschiedlich lang sein. Sie müssen nicht zwingend L- bzw. winkelförmig sein, sondern können auch gerade längliche Platten sein. Dies gilt auch für die Platten 4 der Vorrichtung 1. Die Vorrichtung 2 dient zum Verbinden von zwei benachbarten Wirbeln 21 und 22 bzw. 22 und 23. Selbstverständlich können an einer Wirbelsäule 24 mehrere solche Vorrichtungen 2 angebracht werden. Die entsprechenden Intervertebralimplantate 3 sind dann jedoch nur über zwischenliegende Wirbel miteinander verbunden. Eine direkte Verbindung wie bei der Vorrichtung 1 ist damit hier nicht vorhanden.

Die Platten 4 und 5 sowie die Intervertebralimplantate 3 sind vorzugsweise aus einem geeigneten Kunststoff, beispielsweise aus einem faserverstärkten Kunststoff hergestellt. Solche Kunststoffe sind an sich bekannt und haben den wesentlichen Vorteil, dass sie für Röntgenstrahlen durchlässig sind. Mit solchen Materia-

lien können auch sehr stabile Platten 4 und 5 hergestellt werden, die zudem sehr biegesteif sind. Damit ist es möglich, Bewegungen innerhalb der Spondylodese und damit das Risiko einer mitunter folgenschweren sekundären Implantatdislokation zu mindern. Grundsätzlich können die Platten 4 und 5 aber auch aus einem anderen Werkstoff, beispielsweise auch aus Titan hergestellt werden.

Möglich ist auch eine hier nicht gezeigte Vorrichtung mit mehr als zwei Intervertebralimplantaten 3, die mit einer entsprechenden Anzahl von Z-förmigen Platten 5 direkt miteinander verbunden sind. Beispielsweise kann eine solche Vorrichtung drei Intervertebralimplantate 3 aufweisen, die mit zwei Z-förmigen Platten 5 miteinander verbunden sind. An den beiden äusseren Intervertebralimplantaten ist dann jeweils noch eine L-förmige Platte 4 befestigt.

Die Figur 7 zeigt eine Ausführung einer erfindungsgemässen Vorrichtung, welche zwei L-förmigen Platten 4 und eine gerade Platte 32 aufweist. Die lange Platte 32 ist an ihren Enden jeweils mit einer Kugelkopfschraube 7 mit einem Intervertebralimplantat 3 verbunden. Die Verbindungen zu den Intervertebralimplantaten 3 sind Gelenke, die polyaxial beweglich und durch Festziehen der Schrauben 7 fixierbar sind. Die Ausbildung der langen und geraden Platte 32 ergibt sich auch aus der Fig. 9.

Die Figur 8 zeigt zudem eine vergleichsweise kurze Platte 33, die eine Kugelkopfschraube 7 und eine Knochenschraube 25 aufnehmen kann und die insbesondere gemäss Fig. 13 verwendbar ist.

Nachfolgend wird ein Verfahren zur Versteifung eines Abschnittes einer Wirbelsäule mit der erfindungsgemässen Vorrichtung näher erläutert.

Nach einer entsprechenden Freilegung des zu versteifenden Abschnittes der Wirbelsäule wird die befallene Bandscheibe ausgeräumt. Mit einem geeigneten Instrument wird der ausgeräumte Bandscheibenraum erweitert bzw. vergrössert. Nun wird ein passendes Intervertebralimplantat 3 ausgewählt und in den ausgeräumten Bandscheibenraum eingesetzt, wo es zwischen den benachbarten Wirbeln verklemmt. Gegebenenfalls wird eine weitere Bandscheide ausgeräumt und entsprechend ein weiteres Intervertebralimplantat 3 eingesetzt.

Nun werden Abstände zwischen dem Intervertebralimplantat 3 bzw. den Intervertebralimplantaten 3 und geeigneten Positionen für die Knochenschrauben ermittelt. Bei zwei Intervertebralimplantaten 3 wird auch der Abstand zwischen diesen gemessen. Entsprechend diesen Abständen werden passende Platten 4 und gegebenenfalls 5 gewählt und diese lose am Intervertebralimplantat 3 bzw. an den Intervertebralimplantaten fixiert. Die Platten 4 werden so gewählt, dass sie benachbarte Bandscheiben nicht berühren, wie dies in den Figuren 7 und 8 ersichtlich ist. Die lose fixierten Platten 4 und 5 werden an die Wirbel angelegt und mit Knochenschrauben 25 fixiert. Nun werden die Platten 4 und gegebenenfalls 5 durch Festziehen der Schrauben 7 fest mit dem Intervertebralimplantat 3 bzw. Intervertebralimplantaten verbunden.

Die Figuren 10 und 11 zeigen drei Wirbel 21 bis 23, die mit einer erfindungsgemässen Vorrichtung miteinander verbunden sind. Die Platte 5 verbindet wie ersichtlich zwei Intervertebralimplantate 3 miteinander und ist zudem mit Knochenschrauben 25 mit dem Wirbel 22 verbunden. Werden lediglich zwei Wirbel miteinander verbunden, wird die Vorrichtung 2 gemäss Figur 6 verwendet, bei der eine Z-förmige Platte 5 nicht vorgesehen ist.

Die Fig. 11-15 zeigen fünf von den denkbaren Ausführungsmöglich-

keiten der erfindungsgemässen Vorrichtung, mit welchen zwei oder mehr Wirbel miteinander verbunden werden können. In den Fig. 11 bis 15 ist die Halswirbelsäule von vorne zu sehen und in der Fig. 10 von der Seite.

Die Fig. 14 zeigt eine Verbindung von zwei Wirbeln mit Hilfe von zwei L-förmigen Platten 4 und einem Intervertebralimplantat 3. Die L-Platten 4 sind mit je zwei Knochenschrauben 25 an die Wirbelkörper und je einer Kugelkopfschraube 7 an das Intervertebralimplantat 3 befestigt.

Die Fig. 11 zeigt eine Verbindung von drei Wirbeln 21-23. Die Intervertebralimplantate 3 sind durch eine Implantatbrücke direkt miteinander verbunden. Sie besteht in diesem Fall aus einer Z-förmigen Platte 5. Die Z-Platte 5 wird durch zwei Knochenschrauben 25 an den Körper des mittleren Wirbels 22 befestigt.

Die Fig. 10 zeigt eine Ansicht einer Halswirbelsäule von der Seite mit der den Halswirbelkörpern vorne anliegenden erfindungsgemässen Vorrichtung gemäss Fig. 11.

Die Fig. 12 zeigt eine Verbindung von vier Wirbelkörpern, wobei gerade Platten 32 die Implantatbrücke zu den Intervertebralimplantaten 3 bilden. Jede gerade Platte 32 ist mit einer Knochenschraube 25 an den unter der betreffenden Platte 32 liegenden Wirbelkörpern befestigt.

Bei dem Ausführungsbeispiel gemäss Fig. 13 werden drei Intervertebralimplantate 3 nicht direkt durch Implantatbrücken miteinander verbunden, sondern indirekt über den jeweils zwischen zwei Intervertebralimplantaten 3 liegenden Wirbelkörpern, indem kurze Platten 33 an die Intervertebralimplantate 3 und die zwischen ihnen liegenden Wirbelkörper befestigt werden.

Die Fig. 15 zeigt eine Verbindung von vier Wirbeln, wobei wiederum Z-Platten 5 die Implantatbrücken zu Intervertebralimplantaten 3 bilden. Die Z-Platten 5 werden mit je zwei Knochenschrauben 25 an dem unter der jeweiligen Platte befindlichen Wirbelkörper befestigt. Die Verbindung zum oberen und unteren Wirbel erfolgt wie in Fig. 14 beschrieben. Die Verbindung wird in diesem Fall ausschliesslich mit Z-Platten 5 hergestellt.

Ein wesentlicher Vorteil der Erfindung ist, dass das erfindungsgemässe Implantat dank der gelenkigen Cage-Plattenverbindungen einem Sortiment verschieden langer Platten und verschieden grosser (hoher) Intervertebralimplantate den individuell zuweilen sehr unterschiedlichen anatomischen Gegebenheiten, insbesondere der vorderen Oberfläche der Halswirbelsäule, genau angepasst werden kann. Diese kann eben, mehr oder weniger konvex oder sogar konkav oder von Wirbel zu Wirbel wechselnd konvex oder konkav sein. Die Halswirbelsäule kann von vorne gesehen auch etwas krumm oder um die Längsachse etwas verdreht sein. Das alles ist dank der freien Beweglichkeit der Platten ausgleichbar.

Bei der vorliegenden Erfindung geht es insbesondere nicht nur um stabile Verbindungen der Implantate untereinander sowie um ebenso stabile Verbindungen zwischen den Endwirbeln des mit Hilfe der Vorrichtung verblockten Abschnitts der Wirbelsäule, sondern vor allem um die vollständige Anpassbarkeit der Vorrichtung an die jeweiligen anatomischen Gegebenheiten (Krümmungen, Grössenverhältnisse, Unebenheiten). Diese Anpassbarkeit ist besonders an der Halswirbelsäule von grosser Bedeutung, weil die Implantate von der Vorderfläche der Halswirbelsäule nicht vorragen dürfen. Sie dürfen nicht dicker als 2 mm bis höchstens 3 mm sein und müssen den Wirbelkörpern gut anliegen. Anderenfalls besteht die Gefahr, dass eine schwere Komplikation auftreten kann, wenn z.B. der Vorderfläche der Halswirbelsäule eng anliegende Gebilde wie Speiseröhre und Blutgefässe mit der Zeit arrodiert werden.

Unsere Vorrichtung zeichnet sich durch ein niedriges Profil aus, d.h. durch eine niedrige Bauhöhe.

Die Anpassbarkeit der erfindungsgemässen Vorrichtung beruht insbesondere auf

- den blockierbaren Kugelgelenken mit je drei Freiheitsgraden
- einem Sortiment verschieden langer Platten (sowohl L- und Z-Platten)
- einem Sortiment verschieden grosser Intervertebralimplantate.

Bezugzeichenliste

1	Vorrichtung	14	Fläche
2	Vorrichtung	15	Fläche
3	Intervertebralimplantat	17	Durchgangsöffnung
4	Platte	18	Gelenkteil
4a	Arm	19	Durchgangsöffnung
4b	Arm	21-23	Wirbel
5	Platte	24	Halswirbelsäule
5a	Arme	25	Knochenschraube
5b	Arme	26	Vorderfläche
5c	mittlerer Bereich	27	Vertiefung
6	Durchgangsöffnung	28	Durchgangsöffnung
7	Kugelkopfschraube	29-31	Doppelpfeile
8	Werkzeugangriff	32	gerade Platten
9	Kopf	33	kurze Platte
10	Unterseite	P	mittlerer Punkt
11	Hals		
12	Gewindeschaft		
13	Bohrung		

Patentansprüche

1. Vorrichtung für die Spondylodese und insbesondere für die vordere interkorporelle Spondylodese an der Halswirbelsäule, mit wenigstens einem Intervertebralimplantat (3) und mit wenigstens einer Platte (4,5), die mit dem Intervertebralimplantat (3) und einem benachbarten Wirbel (21-23) zu verbinden ist, dadurch gekennzeichnet, dass das Intervertebralimplantat (3) mit wenigstens zwei im Abstand zueinander angeordneten Platten (4,5) verbunden ist, wobei die beiden Platten (4,5) jeweils an einem Ende mit dem Intervertebralimplantat (3) ein fixierbares Gelenk bilden.

2. Vorrichtung nach Anspruch 1, dadurch gekennzeichnet, dass wenigstens eine der Platten (5, 4) Z-förmig, I-förmig oder L-förmig ausgebildet ist.

3. Vorrichtung nach Anspruch 1 oder 2, dadurch gekennzeichnet, dass wenigstens eine Platte (5) in einem mittleren und quer zur Längsachse der Wirbelsäule (24) verlaufenden Bereich (5c) wenigstens einen Durchgang (6) für eine Knochenschraube (25) aufweist, derart, dass diese Platte (5) mit einem Wirbel (22) verbindbar ist.

4. Vorrichtung nach Anspruch 3, dadurch gekennzeichnet, dass der genannte Bereich (5c) zwei im Abstand zueinander angeordnete Durchgänge (6) für jeweils eine Knochenschraube (25) aufweist.

5. Vorrichtung nach einem der Ansprüche 1 - 4, dadurch gekennzeichnet, dass wenigstens eine Platte (4,5) an wenigstens einem Ende einen halbkugelförmigen und vorstehenden Gelenkteil (18) aufweist, der einen Durchgang (17) für eine Befestigungsschraube (7) aufweist und der in eine halbkugelförmige Vertiefung (14) eines Intervertebralimplantates (3) eingreift, derart, dass ein Kugelgelenk gebildet wird.

6. Vorrichtung nach Anspruch 5, dadurch gekennzeichnet, dass wenigstens zwei Platten (4,5) jeweils über ein polyaxiales Gelenk, insbesondere ein Kugelgelenk mit einem Intervertebralimplantat (3) verbunden sind.

7. Vorrichtung nach einem der Ansprüche 1 - 6, dadurch gekennzeichnet, dass wenigstens zwei L-förmige Platten (4) mit einem Intervertebralimplantat (3) verbunden sind.

8. Vorrichtung nach Anspruch 7, dadurch gekennzeichnet, dass die beiden Platten (4) jeweils in einem quer zur Längsrichtung der Wirbelsäule (24) verlaufenden Arm (4b) wenigstens zwei im Abstand zueinander angeordnete Durchgänge (19) zur Aufnahme jeweils einer Knochenschraube (25) aufweisen.

9. Vorrichtung nach einem der Ansprüche 1 - 8, dadurch gekennzeichnet, dass zwei Intervertebralimplantate (3) mit einer Z-förmigen Platte (5) miteinander verbunden sind.

10. Vorrichtung nach einem der Ansprüche 1 - 9, dadurch gekennzeichnet, dass zwei Intervertebralimplantate (3) vorgesehen sind, die mit einer Z-förmigen Platte (5) miteinander verbunden sind und an denen jeweils eine L-förmige oder I-förmige Platte (4) befestigt ist, wobei sämtliche Verbindungen zwischen den Platten (4,5) und den Intervertebra-

limplantaten (3) als polyaxiale Gelenke, insbesondere Kugelgelenke ausgebildet sind.

11. Vorrichtung nach einem der Ansprüche 1 - 10, dadurch gekennzeichnet, dass wenigstens eine Platte (4,5) und/oder ein Intervertebralimplantat (3) aus einem röntgendurchlässigen Werkstoff hergestellt ist bzw. sind.

12. Vorrichtung nach einem der Ansprüche 1 - 11, dadurch gekennzeichnet, dass sie für eine Spondylodese der Halswirbelsäule vorgesehen ist.

13. Bausatz zur Herstellung einer Vorrichtung nach einem der Ansprüche 1 - 12, mit wenigstens einem Intervertebralimplantat (3) und wenigstens einer Platte (4,5) zum Verbinden des Intervertebralimplantates (3) mit wenigstens einem Wirbel (21-23), dadurch gekennzeichnet, dass wenigstens eine Platte (4) L-förmig und wenigstens eine Platte (5) Z-förmig ausgebildet ist und dass wenigstens ein Intervertebralimplantat (3) im Abstand zueinander zwei Bohrungen (13) zur Aufnahme jeweils einer Befestigungsschraube (7) aufweist.

14. Bausatz nach Anspruch 13, dadurch gekennzeichnet, dass das Intervertebralimplantat (3) und die Platten (4,5) jeweils mindestens ein Gelenkteil (18) zum Bilden eines Kugelgelen kes aufweisen.

15. Bausatz nach Anspruch 13 oder 14, dadurch gekennzeichnet, dass das Intervertebralimplantat (3) und die Platten (4,5) aus einem röntgendurchlässigen Werkstoff hergestellt sind.

16. Bausatz nach einem der Ansprüche 13 - 15, gekennzeichnet durch mehrere Knochenschrauben (25) und mehrere Befestigungsschrauben (7).

17. Bausatz nach Anspruch 16, dadurch gekennzeichnet, dass die Befestigungsschrauben Kugelkopfschrauben sind, die einen Schraubenkopf (8) aufweisen, der an seiner Unterseite im Wesentlichen halbkugelförmig ausgebildet ist.

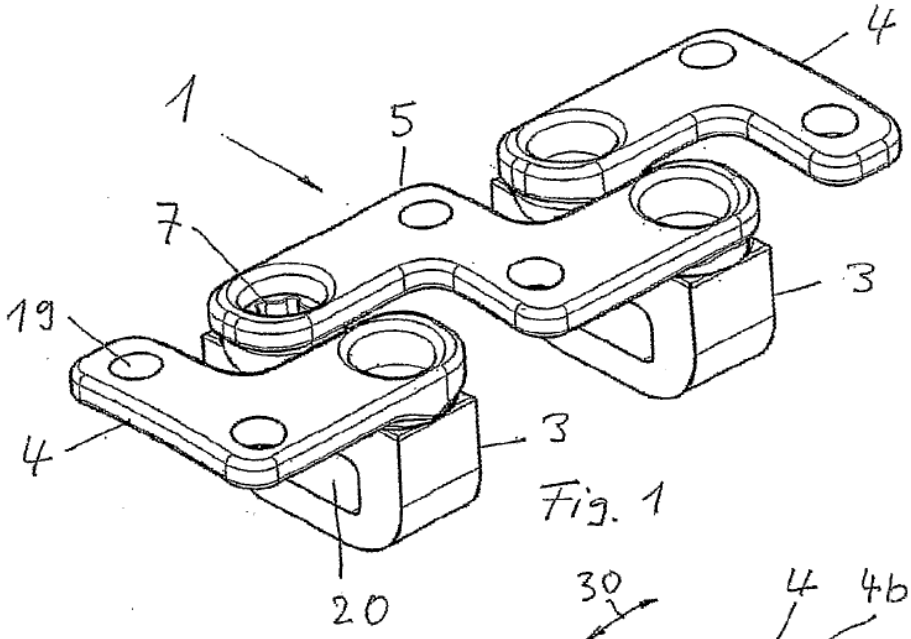


Fig. 1

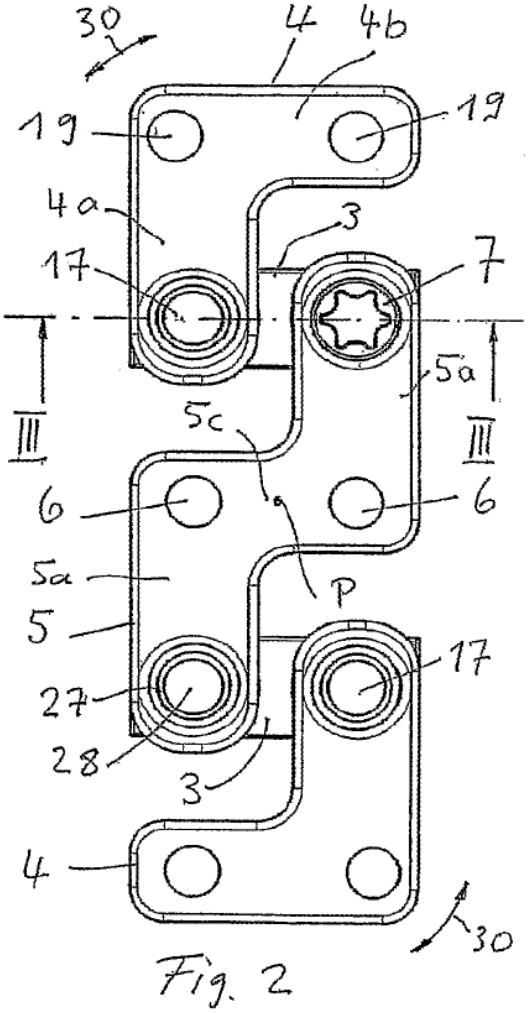


Fig. 2

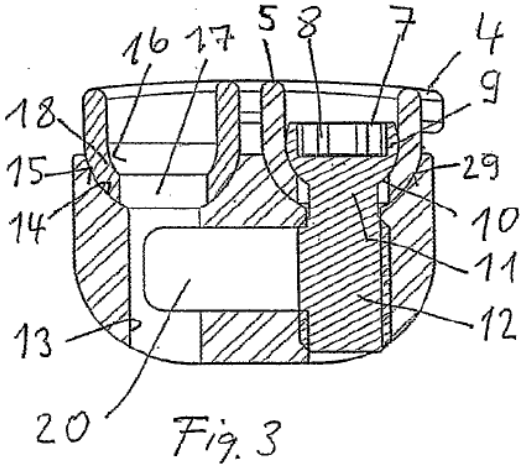


Fig. 3

ERSATZBLATT (REGEL 26)

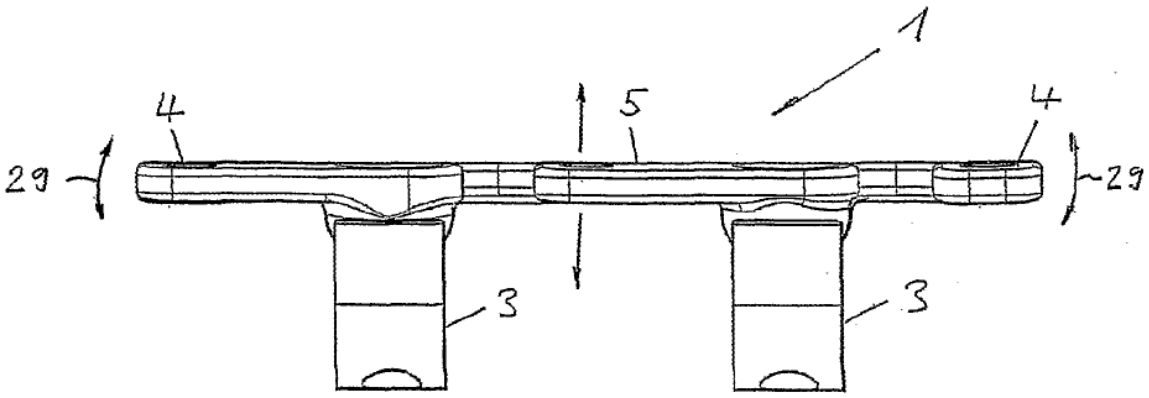


Fig. 4

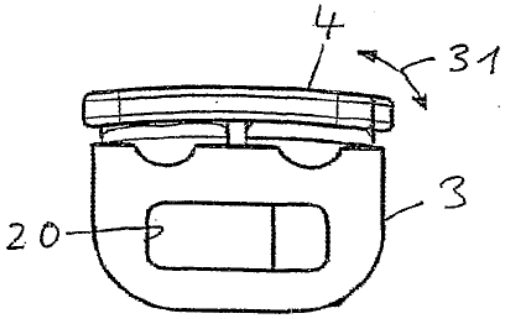


Fig. 5

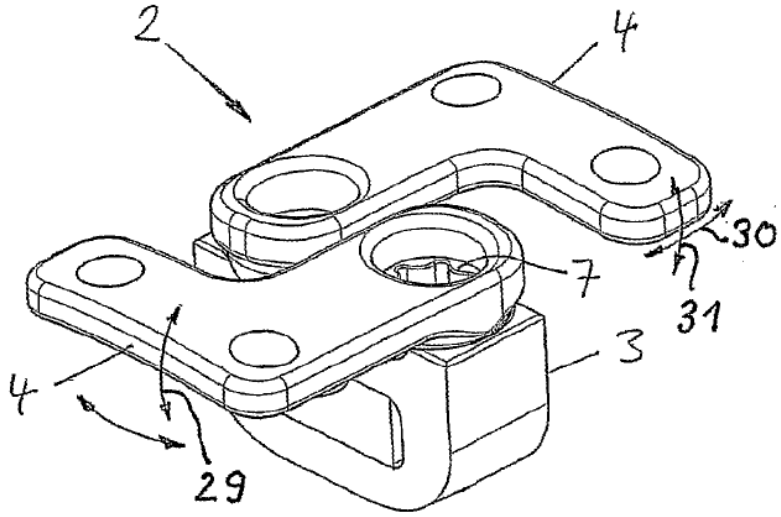


Fig. 6

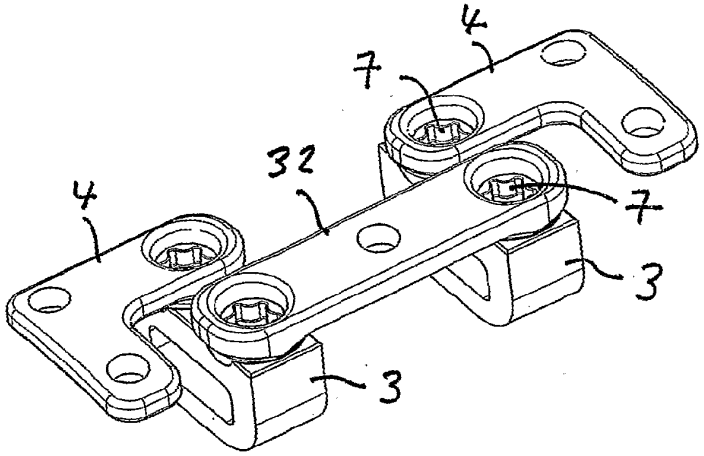


Fig. 7

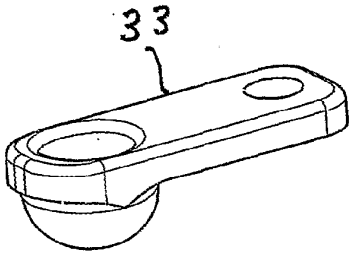


Fig. 8

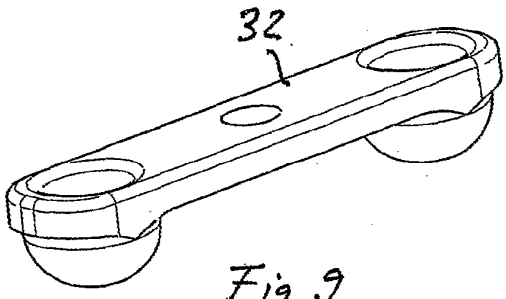


Fig. 9

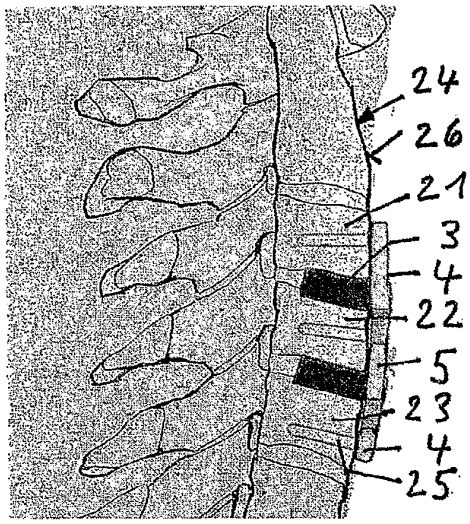


Fig. 10

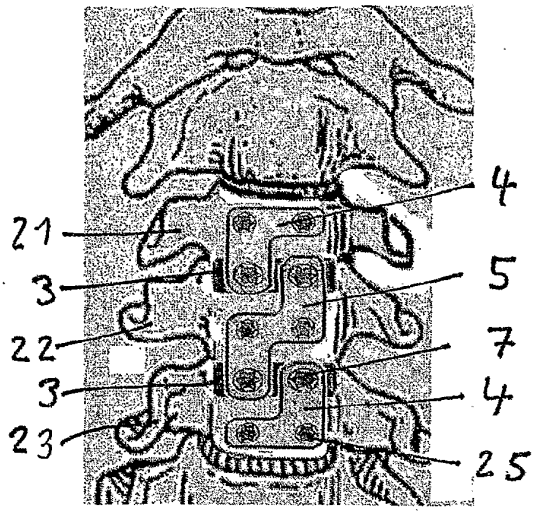


Fig. 11

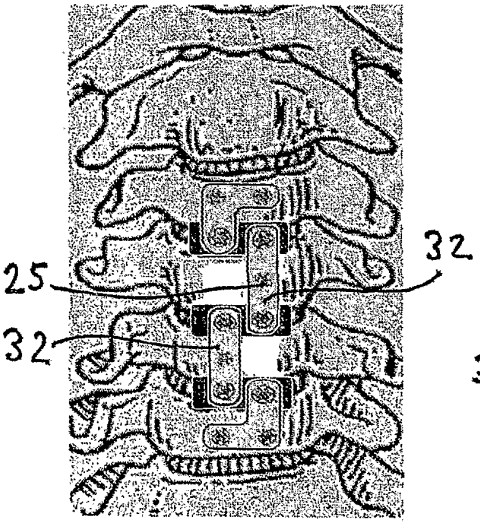


Fig. 12

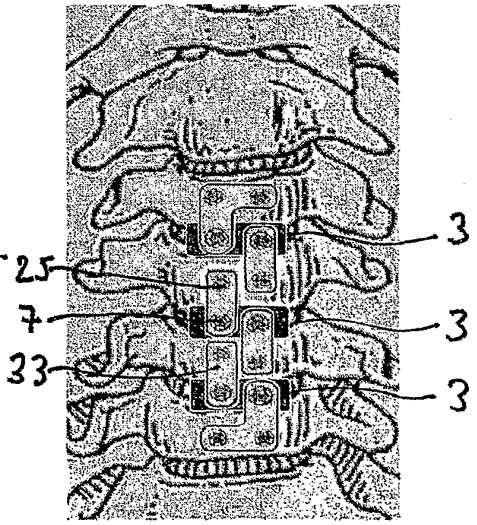


Fig. 13

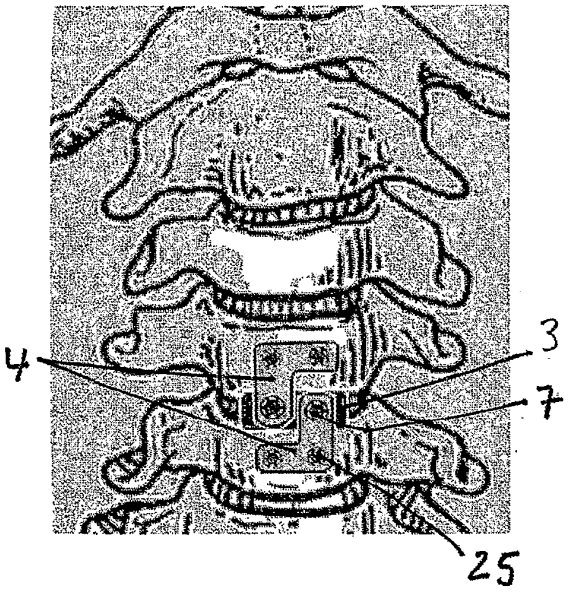


Fig. 14

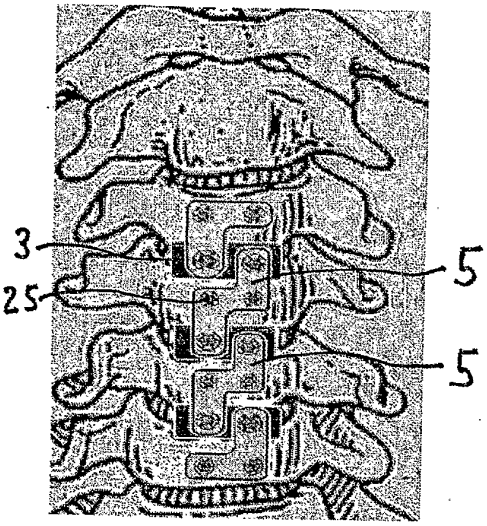


Fig. 15

INTERNATIONAL SEARCH REPORT

ɔnal Application No
PCT/CH2004/000244

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/44 A61F2/46

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 360 430 A (LIN CHIH-I) 1 November 1994 (1994-11-01) cited in the application claim 1; figures 1,2A-2H,2L-3	1,2,7, 11,12
Y		8
A		13,16

X	US 5 443 515 A (COHEN ROBERT C ET AL) 22 August 1995 (1995-08-22) cited in the application figures 1-5 column 7, line 12 - line 48	1,2,7, 11,12
A		13,16

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[X] Further documents are listed in the continuation of box C.

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Date of the actual completion of the international search	Date of mailing of the international search report
30 July 2004	09/08/2004

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Stach, R

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INTERNATIONAL SEARCH REPORT

nal Application No
PCT/CH2004/000244

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 00/22998 A (JACKSON ROGER P) 27 April 2000 (2000-04-27) figures 12,13	8
A		1-4,7,9, 13
A	US 6 156 037 A (LEHUEC JEAN-CHARLES ET AL) 5 December 2000 (2000-12-05) claim 1; figures 2-6,13-16 column 3, line 51 - column 4, line 14	1,5,13, 14
A	US 6 306 136 B1 (BACCELLI CHRISTIAN) 23 October 2001 (2001-10-23) figures 3,7,8	1,2,7,8, 13
A	US 2001/007072 A1 (AEBI MAX ET AL) 5 July 2001 (2001-07-05) figures 3,4 paragraph '0029!	1,5,6, 13,14
A	GB 1 243 353 A (LUMB WILLIAM) 18 August 1971 (1971-08-18) figures 5,7 page 2, line 91 - line 124 page 3, line 50 - line 105	1,2,10, 11
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INTERNATIONALER RECHERCHENBERICHT

nales Aktenzeichen
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A. KLASSIFIZIERUNG DES ANMELDUNGSGEGENSTANDES
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Nach der Internationalen Patentklassifikation (IPK) oder nach der nationalen Klassifikation und der IPK

B. RECHERCHIERTE GEBIETE

Recherchierter Mindestprüfstoff (Klassifikationssystem und Klassifikationssymbole)
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Recherchierte aber nicht zum Mindestprüfstoff gehörende Veröffentlichungen, soweit diese unter die recherchierten Gebiete fallen

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C. ALS WESENTLICH ANGESEHENE UNTERLAGEN

Kategorie°	Bezeichnung der Veröffentlichung, soweit erforderlich unter Angabe der in Betracht kommenden Teile	Betr. Anspruch Nr.
X	US 5 360 430 A (LIN CHIH-I) 1. November 1994 (1994-11-01) in der Anmeldung erwähnt Anspruch 1; Abbildungen 1,2A-2H,2L-3	1,2,7, 11,12
Y		8
A		13,16
X	US 5 443 515 A (COHEN ROBERT C ET AL) 22. August 1995 (1995-08-22) in der Anmeldung erwähnt Abbildungen 1-5 Spalte 7, Zeile 12 - Zeile 48	1,2,7, 11,12
A		13,16

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[X] Weitere Veröffentlichungen sind der Fortsetzung von Feld C zu entnehmen

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° Besondere Kategorien von angegebenen Veröffentlichungen :
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Internales Aktenzeichen
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C.(Fortsetzung) ALS WESENTLICH ANGESEHENE UNTERLAGEN

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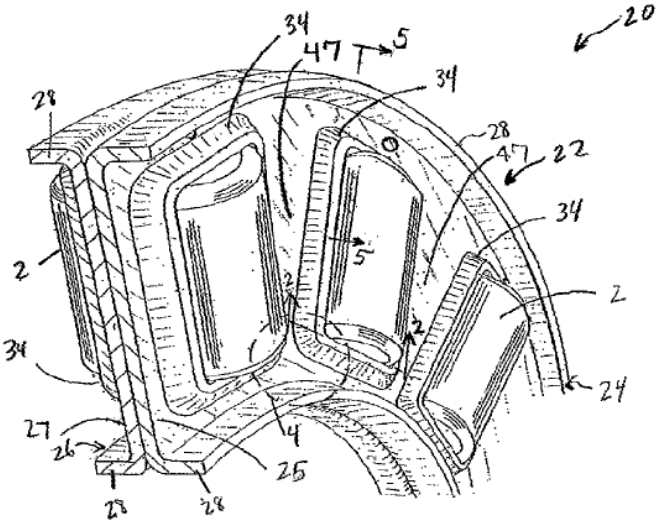
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[Continued on next page]

(54) Title: THRUST BEARING ASSEMBLY



(57) Abstract: A thrust bearing assembly (20) generally includes a cage (22) and a plurality of rolling elements (2). The cage (22) has first and second cage halves (24,26) with each cage half having a respective radial segment (25,27) with a plurality of circumferentially spaced openings (30,32). Each opening has an opening perimeter. The cage halves (24,26) are interconnected with portions of the radial segments (25,27) circumferentially between the plurality of openings (30,32) abutting along a given plane and the respective openings (30,32) aligned to defined rolling element pockets. The rolling elements (2) are positioned in the rolling element pockets such that a centerline of each rolling element (2) lies in or in proximity to the given plane (P). A flange (34) extends along at least a portion of each opening perimeter to retain the rolling elements (2) within a respective one of the rolling element pockets.

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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

THRUST BEARING ASSEMBLY

CROSS REFERENCE TO OTHER APPLICATIONS

[0001] This application claims priority under 35 U.S.C. sec. 119 to provisional patent application no. 60/654,916, filed on Feb. 22, 2005, the entire contents of which is hereby incorporated by reference.

FIELD OF THE INVENTION

[0002] The present invention relates to a thrust bearing assembly and in particular to a needle roller thrust bearing assembly.

BACKGROUND OF THE INVENTION

[0003] Referring to Figs. 11 and 12, an example of a prior art needle roller thrust bearing 1 is shown. The bearing 1 includes a plurality of cylindrical rolling elements 2 arranged radially from a center of rotation. The rolling elements 2 are retained and guided by a bearing cage 3, which forms the primary structure of the bearing 1.

[0004] There are several types of construction currently used to produce metallic needle roller bearing cages 3. Figs. 13 and 14 show a thrust bearing 1A with a cage 3A that is constructed of two halves 4. Each half 4 has rectangular window openings 5 which are slightly smaller in width than the diameter of the rolling elements 2. Each cage half 4 also has circumferential flanges 6 which are directed inwardly towards the opposite member. When joined together, these two cage halves 4 form a box which provides structural integrity for the assembly, along with guidance for the rolling elements 2 and their retention in both directions.

[0005] A prior art thrust bearing 1B with a cage 3B having another construction is shown in Figs. 15 and 16. In this construction, the cage 3B is formed from a single piece of metal into a shape which, along with specially shaped openings, retains and guides the rolling elements 2. In cross-section, this type of cage 3B has a shape similar to that of the Greek letter sigma (Σ).

[0006] Another thrust bearing 1C having a cage 3C of yet another construction is shown in Figs. 17 and 18. Here, the cage 3C has a material thickness close to the diameter of

the rolling elements 2 and has rectangular openings 5 to accept the rolling elements 2. Retention is provided by staking 7 or otherwise forming the cage face near the openings 5 so that these are made smaller than the diameter of the rolling element 2.

SUMMARY OF THE INVENTION

[0007] In one embodiment, a thrust bearing assembly includes a cage and a plurality of rolling elements. The cage has first and second cage halves with each cage half having a respective radial segment with a plurality of circumferentially spaced openings. Each opening has an opening perimeter. The cage halves are interconnected with portions of the radial segments circumferentially between the plurality of openings abutting along a given plane and the respective openings aligned to define rolling element pockets. The rolling elements are positioned in the rolling element pockets such that a centerline of each rolling element lies in or in proximity to the given plane. A flange extends along at least a portion of each opening perimeter to retain the rolling elements within a respective one of the rolling element pockets. The flange may include a smooth rolled surface adjacent to each rolling element.

[0008] In another embodiment, a thrust bearing assembly includes a cage and a plurality of rolling elements. The cage has first and second cage halves with each cage half having a respective radial segment with a plurality of openings. Each opening has an opening perimeter and the cage halves are interconnected with portions of the radial segments abutting along a given plane. The respective openings are aligned to define rolling element pockets. The rolling elements are positioned in the rolling element pockets such that a centerline of each rolling element lies in or in proximity to the given plane. A flange extends along the entire perimeter of each respective opening to guide and retain the rolling elements within a respective one of the rolling element pockets.

BRIEF DESCRIPTION OF THE DRAWINGS

[0009] Fig. 1 is a partial isometric view of a needle roller thrust bearing assembly that is a first embodiment of the present invention;

[0010] Fig. 2 is a cross-sectional view along the line 2-2 in Fig. 1;

[0011] Fig. 3 is a cross-sectional view similar to Fig. 2 showing another embodiment of a thrust bearing assembly;

[0012] Fig. 4 is an exploded view of a portion of the cage as indicated by the circle 4 in Fig. 1 with the rolling elements removed for clarity;

[0013] Fig. 5 is a cross-sectional view along the lines 5-5 in Fig. 1;

[0014] Figs. 6-8 are cross-sectional views similar to Fig. 5 illustrating other embodiments of a thrust bearing assembly;

[0015] Fig. 9 is a cross-sectional view illustrating the needle roller thrust bearing assembly of Fig. 1 positioned between a pair of bearing surfaces;

[0016] Fig. 10 is a cross-sectional view similar to Fig. 9 showing another embodiment of a thrust bearing assembly;

[0017] Fig. 11 is a cross-sectional view along line 11-11 in Fig. 12;

[0018] Fig. 12 is a front elevation view of a prior art thrust bearing;

[0019] Fig. 13 is a partial cross-sectional view of an alternative prior art thrust bearing;

[0020] Fig. 14 is a partial isometric view of the cage of the thrust bearing of Fig. 13;

[0021] Fig. 15 is an isometric view of a cage of another prior art thrust bearing;

[0022] Fig. 16 is a partial cross-sectional view of the alternative thrust bearing using the cage of Fig. 15;

[0023] Fig. 17 is an isometric view of yet another alternative prior art thrust bearing;

[0024] Fig. 18 is a cross-sectional view along the line 18-18 in Fig. 17;

[0025] Fig. 19 is a cross-sectional view along the line 19-19 in Fig. 13; and

[0026] Fig. 20 is an exploded view of a portion of the cage as indicated by the circle 20 in Fig. 14.

DETAILED DESCRIPTION

[0027] The present invention will be described with reference to the accompanying drawing figures wherein like numbers represent like elements throughout. Certain terminology, for example, "top", "bottom", "right", "left", "front", "frontward", "forward", "back", "rear" and "rearward", is used in the following description for relative descriptive clarity only and is not intended to be limiting.

[0028] Referring to Figs. 1 and 2, a needle roller thrust bearing assembly 20 that is a first embodiment of the present invention is shown. The thrust bearing assembly 20 includes a cage 22 supporting a plurality of preferably cylindrical rolling elements 2 arranged radially from a center of rotation (not shown). The cage 22 comprises two cage halves 24, 26. Each cage half 24, 26 includes a radially extending segment 25, 27 respectively with circumferentially spaced openings 30, 32 respectively. Each radially extending segment 25, 27 includes portions 47, 48 circumferentially between the plurality of openings 30, 32.

[0029] The openings 30, 32 are preferably generally rectangular and configured to receive the rolling elements 2. The cage halves 24, 26 are interconnected with the openings 30, 32 radially and circumferentially aligned and with at least portions such as portions 47, 48 of the radially extending segments 25, 27 abutting one another along a plane P. The centerline of each of the rolling elements 2 lies in or in proximity to the plane P. In this embodiment, circumferential flanges 28 are provided at the inner and outer diameters of the radial portions 25, 27 to provide a piloting surface for the thrust bearing assembly 20 and to provide additional structural rigidity for the cage 22.

[0030] Each opening 30, 32 has a flange 34 about at least a portion of or the entire opening perimeter. Each flange 34 extends outwardly from the plane P. The flanges 34 are formed in such a way as to guide and retain the rolling elements 2. An advantage of this design over the prior art cage 3 constructions is that any portion of the cage 22 of the present invention that contacts the rolling elements 2 has a smooth rolled and formed surface. In contradistinction, as shown in Fig. 19, the surfaces that contact the rolling elements 2 of the cage 3A are pierced such that the opening 5 is defined by rough pierced surfaces 10 which can interfere with proper lubrication and also lead to wear.

[0031] Fig. 2 illustrates how the configuration of the thrust bearing assembly 20 allows an effective lubricant film to be developed. Specifically, lubricant can be captured in the

generally triangular area defined between the rolling element 2 and the two abutting cage halves 24, 26. The abutting portions 47 and 48 close off the triangular area between the flanges 34 and prevent the lubricant from escaping circumferentially from adjacent the rolling element 2. Lubricant that either splashes into or is carried by adhesion to the rolling element 2 into this generally triangular area will tend to accumulate in this area and help promote a hydrodynamic lubricant film between the rolling element 2 and the surfaces 35 of the flanges 34. The smooth, generally convex surfaces 35 of the flanges 34 will minimize the "scraping" of lubricant off the rolling element 2 and will help maintain the presence of lubricant in the generally triangular area adjacent the rolling element 2. The smooth surfaces 35 also minimize direct contact between the rolling elements 2 and the cage 22, thereby reducing friction and wear.

[0032] Another form of the flange construction for rolling element openings 30, 32 is shown in Fig. 3. In this case, the cage halves 24A, 26A still abut on the plane P extending along or approximately along the centerline of the rolling elements 2, however, the flanges 34A along the length of the rolling elements 2 are divided into separate tabs 37. These tabs 37 are formed to present a smooth, generally conforming surface to the rolling elements, which is a variation of the smooth, generally convex surfaces 35 shown in Fig. 2. However, the tabs 37 are directed towards the opposite side of the rolling elements 2 rather than the closest side. In order to secure retention of the rolling elements in both directions, the tabs 37 are arranged so as to alternate on a portion of the perimeter such as along the length of the rolling elements 2. This sturdier construction allows a greater length of flange 34A. This additional length allows for greater flexibility in the shape of the flange 34A and is particularly useful for bearing assembly 20 with rolling elements having smaller diameters and that have tighter space restrictions for the cage 22.

[0033] In addition to improved wear and lubrication, another advantage of the cage 22 of thrust bearing assembly 20 is the substantially greater strength it provides compared to existing types of cage construction. This is particularly important in those areas with high concentrations of stress, such as the corners of the cage openings. Figure 20 shows a portion of a prior art cage 3A, taken near the inner diameter. It can be seen that the corners 13 of the cage openings 5 must be at right angles and relatively sharp to clear the rolling elements. The trapezoidal shape of the cage bars 14 between the openings 5 exacerbates this situation in the prior art designs because there is minimal cage material to resist stresses caused by radial and

torsional loads on the cage. Referring to Fig. 4, the flanges 34 of the thrust bearing assembly 20 includes a continuous surface at the corners 31 of the generally rectangular openings 30, 32. This structure can increase the cage strength in two ways. First, the flanges 34 provide additional material all around the openings 30 for the rolling elements 2. In the areas of high stress, such as corners 31 near the inner diameter, the flanges 34 can as much as double the amount of material available to resist these stresses. The cage openings 30 are further strengthened by the actual shape of the flanges 34. The flanges 34 are designed in such a way that the stresses are directed away from the corners 31 of the openings 30. The combination of additional material and optimized stress flow results in cage strength that is several times greater than that of the prior art constructions.

[0034] There are several possible ways to interconnect the two cage halves 24, 26 to form the rigid cage 22. Using the embodiment of the sealed bearing assembly 20 as shown in Figure 3, the rolling elements 3 can be snapped past the tabs 37 to join the cage halves 24A, 26A and form a unitary thrust bearing assembly 20.

[0035] Several additional examples of interconnecting the cage halves 24, 26 are shown in Figs. 5-8, however, other methods may also be utilized. Referring to Fig. 5, the cage halves 24, 26 are spot welded 40 at various points along the abutting radial portions 25 and 27. Fig. 6 illustrates a mechanical joint 42 created by partially piercing the radial portions 25, 27 and locking the two halves 24, 26 together. Referring to Fig. 7, a circumferential band 44 is secured to the inner and/or outer diameters of the cage halves 24, 26 about the inner or outer flanges 28 to secure the halves 24, 26 together. In the embodiment shown in Fig. 8, one of the cage halves 26B does not have a flange, but instead terminates in the radial portion 27. The other cage half 24B has a flange 46 extending from the radial portion 25 that extends toward and wraps around the radial portion 27. While the flange 46 is illustrated as being along the cage outer diameter, it is also possible to provide the flange 46 along the cage inner diameter.

[0036] Another advantage of the current invention is that various combinations of differently sized circumferential flanges 28 at the inner and outer diameter of the cage 22 can be used to control lubricant flow within the bearing assembly 20. In some cases it is desirable to restrict or partially restrict the lubrication flow, while in other cases it is desirable to allow as much flow as possible. For example, Fig. 9 shows the thrust bearing assembly 20 of Fig. 1 positioned between two structures 50 and 52. As can be seen, the inner and outer

diameter circumferential flanges 28 restrict the radial oil flow past the bearing assembly 20. Fig. 10 shows another embodiment thrust bearing assembly 20C positioned between structures 50, 52. The thrust bearing assembly 20C includes a cage 22C with interconnected halves 24C and 26C. Both halves 24C and 26C are without flanges which thereby allows more oil flow past the bearing assembly 20C. Other designs could incorporate partial or shorter flanges 28 to partially restrict flow.

[0037] The present invention addresses the essential requirements of a thrust bearing cage, namely, structure, guidance and retention, in a manner than greatly improves both the strength, rigidity, lubrication advantages, and the efficiency of the bearing assembly. Further, a low profile of the bearing assembly can be achieved.

[0038] Various features and advantages of the invention are set forth in the following claims.

CLAIMS

What is claimed is:

1. A thrust bearing assembly comprising:

a cage having first and second cage halves, each cage half having a respective radial segment with a plurality of circumferentially spaced openings, each opening having an opening perimeter, the cage halves being interconnected with portions of the radial segments circumferentially between the plurality of openings abutting along a given plane and the respective openings aligned to defined rolling element pockets;

a plurality of rolling elements positioned in the rolling element pockets such that a centerline of each rolling element lies in or in proximity to the given plane; and

a flange extending along at least a portion of each opening perimeter to retain the rolling elements within a respective one of the rolling element pockets.

2. The thrust bearing assembly of claim 1, wherein the centerline of each rolling element lies in the given plane.

3. The thrust bearing assembly of claim 1, wherein each flange extends along the entire perimeter of a respective opening.

4. The thrust bearing assembly of claim 1, wherein the openings are generally rectangular.

5. The thrust bearing assembly of claim 4, wherein each flange includes a continuous surface at corners of the generally rectangular openings.

6. The thrust bearing assembly of claim 1, wherein each flange is formed as a plurality of tabs, and tabs from one cage half alternate with tabs of the other cage half on at least a portion of a respective opening perimeter.

7. The thrust bearing assembly of claim 1, wherein at least one cage half includes a flange along an outer radius, the flange extending away from the given plane.

8. The thrust bearing assembly of claim 1, wherein at least one cage half includes a flange along an inner radius, the flange extending away from the given plane.

9. The thrust bearing assembly of claim 1, wherein the cage halves are joined together by one of spot welding, a mechanical joint, a circumferentially extending clamping band, and a portion of one cage half overlapping and clamping a portion of the other cage half.

10. The thrust bearing assembly of claim 1, wherein the cage halves are identical.

11. A thrust bearing assembly comprising:

a cage having first and second cage halves, each cage half having a respective radial segment with a plurality of openings, each opening having an opening perimeter, the cage halves being interconnected with respective openings of the halves being aligned to define rolling element pockets and with portions of the radial segments abutting along a given plane;

a plurality of rolling elements positioned in the rolling element pockets such that a centerline of each rolling element lies in or in proximity to the given plane; and

a flange extending along the entire perimeter of each opening to guide and retain the rolling elements within a respective one of the rolling element pockets.

12. The thrust bearing assembly of claim 11, wherein the centerline of each rolling element lies in the given plane.

13. The thrust bearing of claim 11, wherein the flange includes a smooth curved surface adjacent the rolling element.

14. The thrust bearing assembly of claim 11, wherein the openings are generally rectangular, and each flange includes a continuous surface at corners of the generally rectangular openings.

15. The thrust bearing assembly of claim 11, wherein each flange is formed as a plurality of tabs, and tabs from one cage half alternate with tabs of the other cage half on at least a portion of a respective opening perimeter.

16. The thrust bearing assembly of claim 11, wherein each cage half includes a flange along an outer radius, the flange extending away from the given plane.

17. The thrust bearing assembly of claim 11, wherein each cage half includes a flange along an inner radius, the flange extending away from the given plane.

18. The thrust bearing assembly of claim 11, wherein the cage halves are joined together by one of spot welding, a mechanical joint, a circumferentially extending clamping band, and a portion of one cage half overlapping and clamping a portion of the other cage half.

19. A thrust bearing assembly comprising:

a cage having first and second cage halves, each cage half having a plurality of circumferentially spaced openings and radial portions circumferentially between the plurality of openings, each opening having an opening perimeter, the cage halves being interconnected with the openings of respective halves being aligned to define rolling element pockets and with the radial portions abutting along a given plane;

a plurality of rolling elements positioned in the rolling element pockets such that a centerline of each rolling element lies in or in proximity to the given plane; and

a flange extending along the entire perimeter of each opening to guide and retain the rolling elements within a respective one of the rolling element pockets.

20. The thrust bearing assembly of claim 19, wherein each flange is formed as a plurality of tabs, and tabs from one cage half alternate with tabs of the other cage half on at least a portion of a respective opening perimeter.

Fig. 1

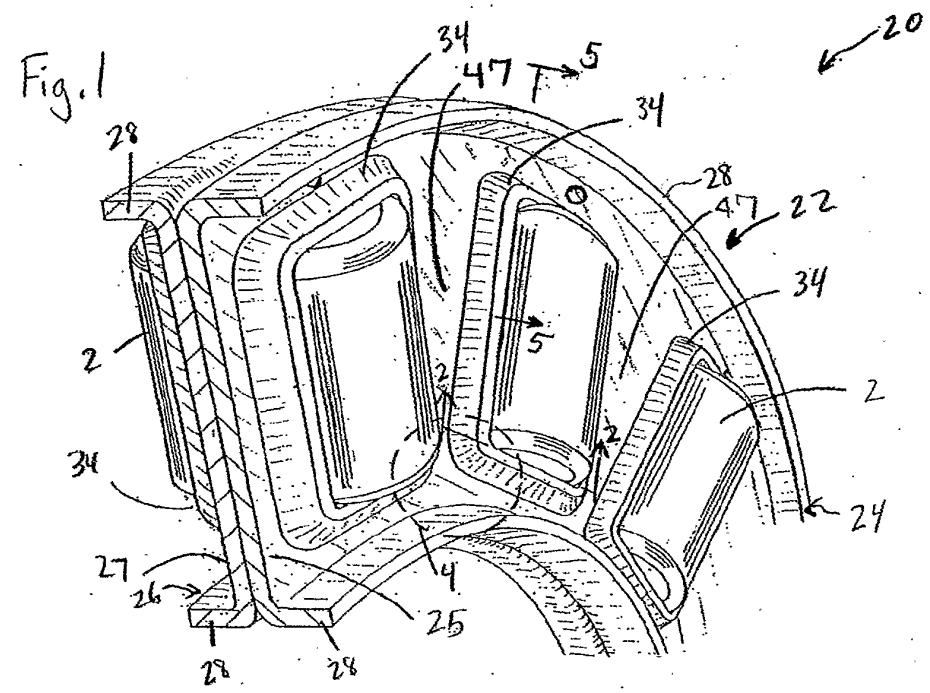


Fig. 2

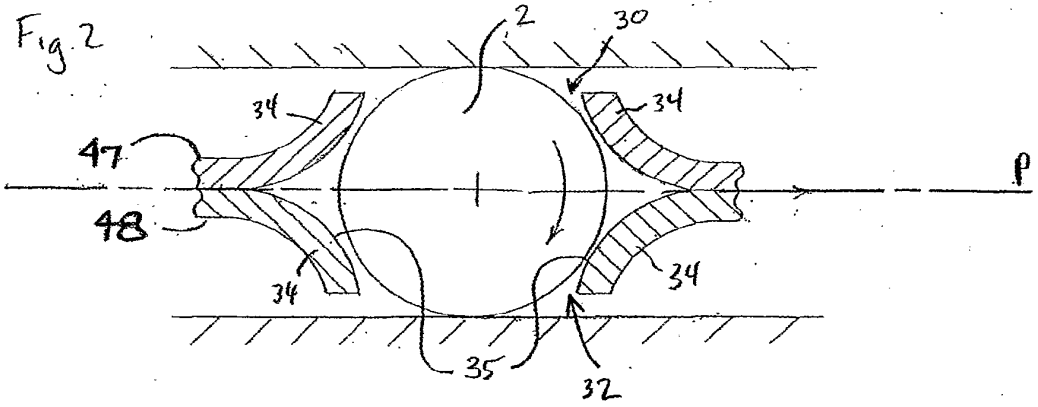


Fig. 3

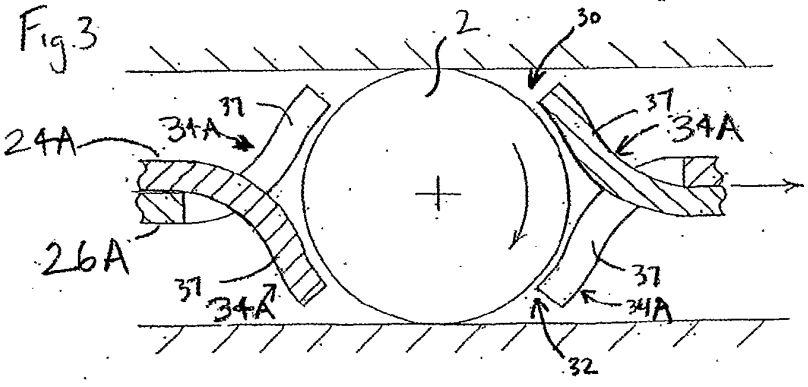
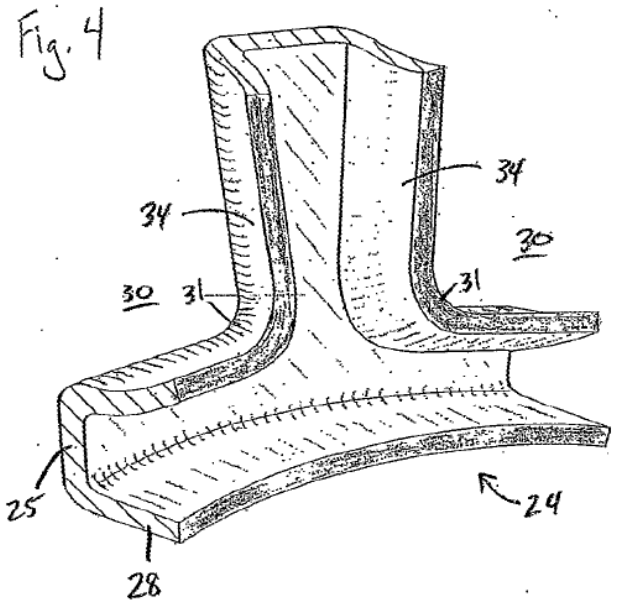


Fig. 4



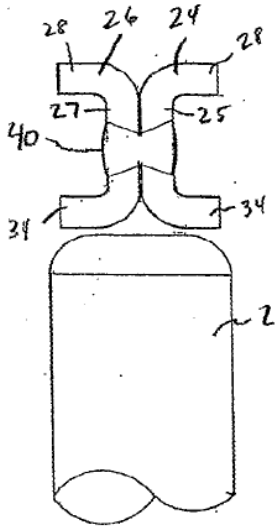


Fig. 5

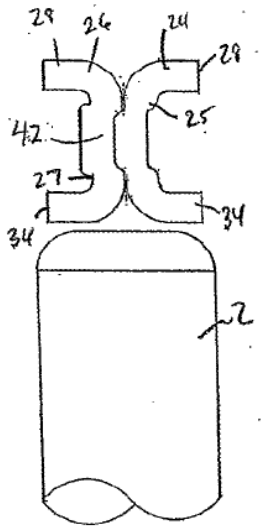


Fig. 6

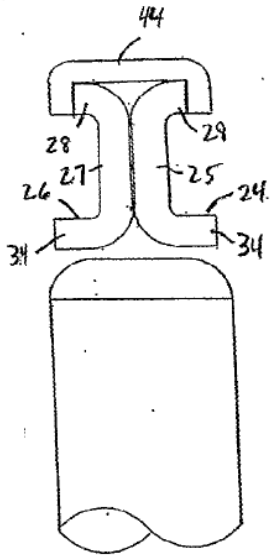


Fig. 7

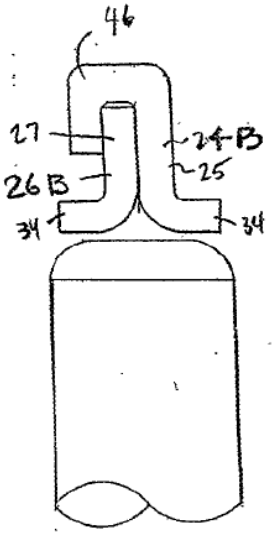


Fig. 8

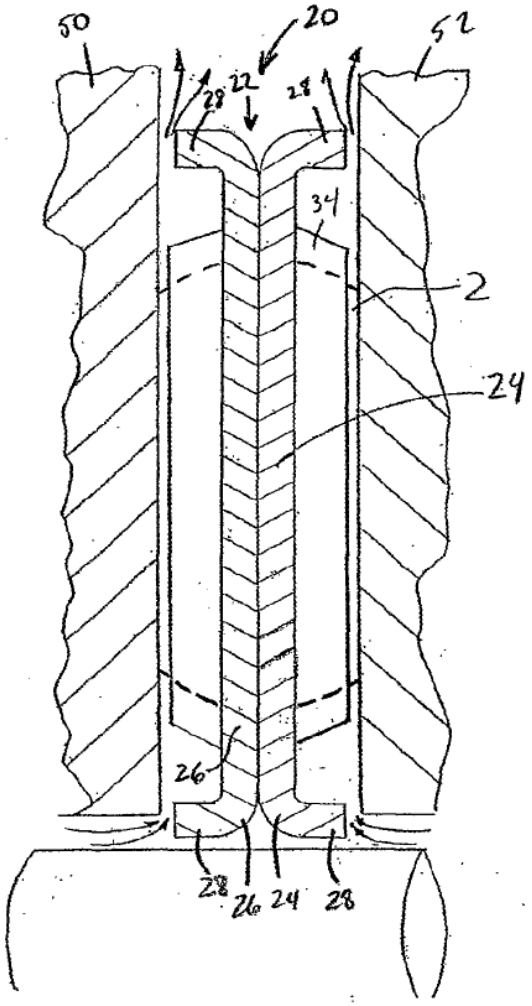


Fig. 9

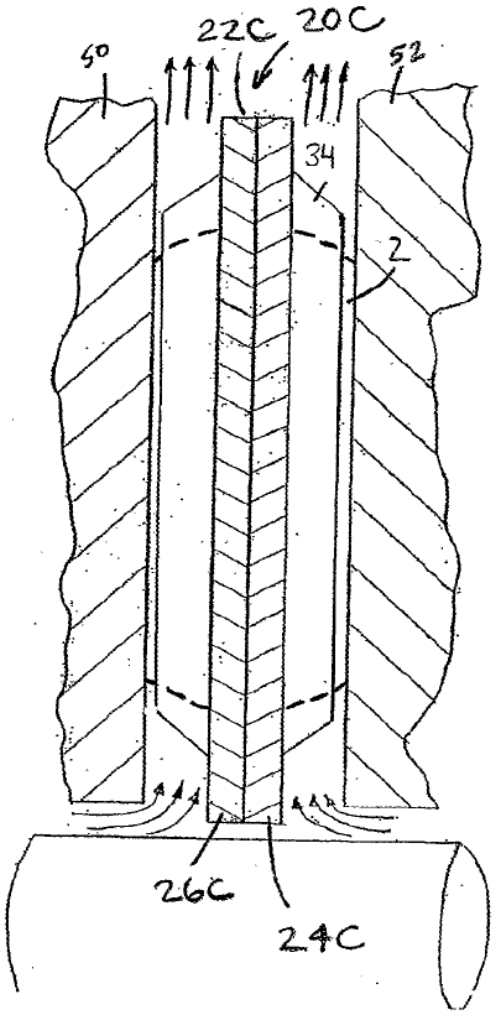


Fig. 10

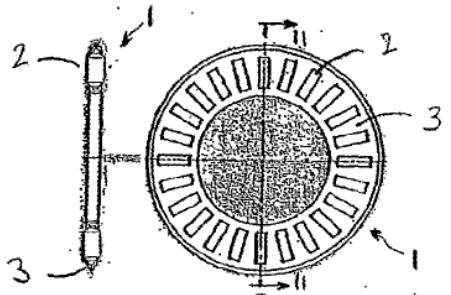


Fig. 11 (Prior Art)

Fig. 12 (Prior Art)

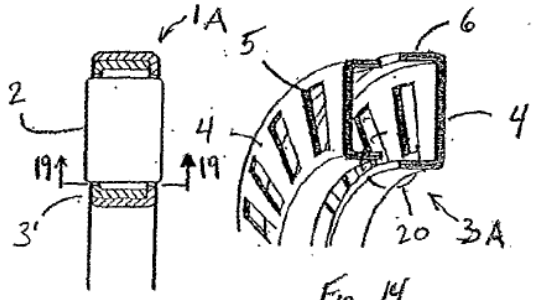


Fig. 13 (Prior Art)

Fig. 14 (Prior Art)

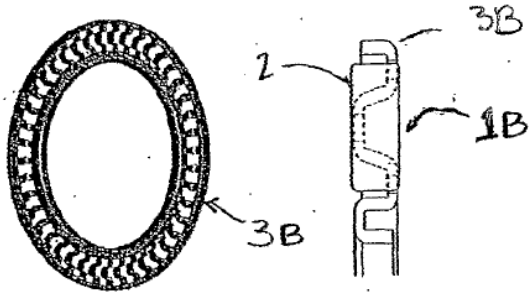


Fig. 15 (Prior Art)

Fig. 16 (Prior Art)

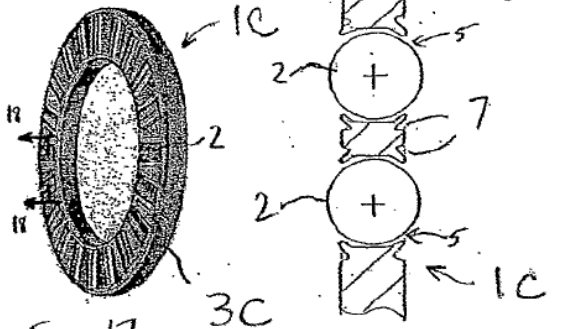


Fig. 17 (Prior Art)

Fig. 18 (Prior Art)

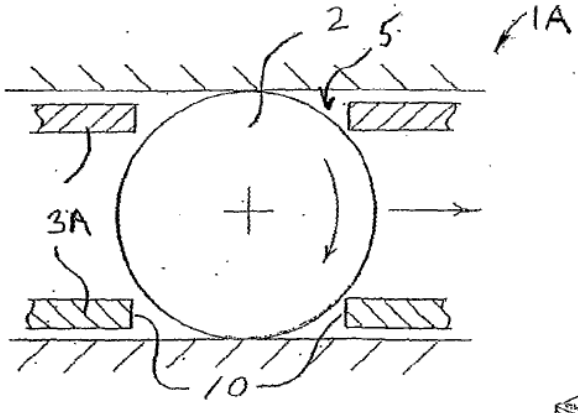


Fig. 19 (Prior Art)

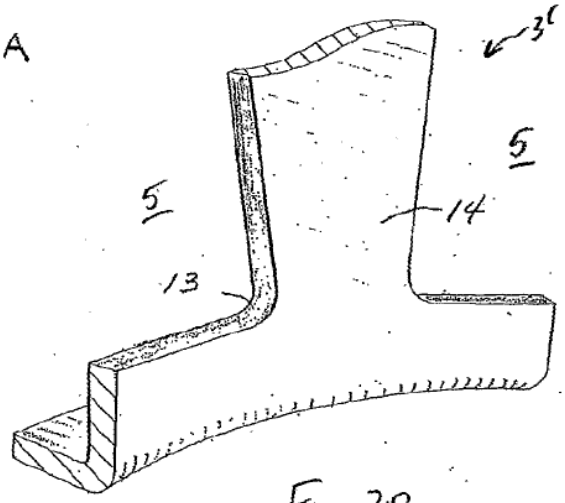


Fig. 20 (Prior Art)

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2006/005789

A. CLASSIFICATION OF SUBJECT MATTER
INV. F16C33/54 F16C19/30

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
F16C

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	FR 2 242 595 A (SKF INDUSTRIAL TRADING DEV CY BV,NL; SKF INDUSTRIAL TRADING DEV CY BV) 28 March 1975 (1975-03-28) page 3, line 5 - line 11; figures 5-7	1-5, 9-14,18, 19
X	US 2 978 282 A (FISHER WALTER) 4 April 1961 (1961-04-04) the. whole document	1,2,4, 7-10
X	US 1 353 044 A (KEIPER HENRY B) 14 September 1920 (1920-09-14) page 1, line 59 - page 2, line 36; figures 1-4	1-3,7-9, 11-13, 16-19
X A	US 1 734 222 A (MARLES HENRY) 5 November 1929 (1929-11-05) page 1, line 31 - line 83; figures 1-4	1,2,4, 7-10 6

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[X] Further documents are listed in the continuation of Box C. [X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier document but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
15 June 2006	30/06/2006

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Axelsson, T

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INTERNATIONAL SEARCH REPORT

International application No
PCT/US2006/005789

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	DE 21 14 697 A1 (INDUSTRIWERK SCHAEFFLER OHG) 12 October 1972 (1972-10-12) page 3; figures	1,6

Form PCT/ISA/210 (continuation of second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2006/005789

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
FR 2242595	A	28-03-1975	NONE	
US 2978282	A	04-04-1961	NONE	
US 1353044	A	14-09-1920	NONE	
US 1734222	A	05-11-1929	NONE	
DE 2114697	A1	12-10-1972	NONE	

Espacenet

Bibliographic data: FR2727003 (A1) — 1996-05-24

Lumbar-sacral vertebrae anterior stabiliser

Inventor(s): TISSERAND PHILIPPE ± (TISSERAND PHILIPPE)

Applicant(s): EUROS SA [FR] ± (EUROS SA)

Classification: - international: ***A61F2/44;*** *A61B17/86; A61F2/00; A61F2/28; A61F2/30;* (IPC1-7): A61B17/70; A61F2/44
- cooperative: **A61F2/442; A61F2/4455;** A61B17/86; A61F2/30965; A61F2002/2835; A61F2002/30112; A61F2002/30153; A61F2002/30271; A61F2002/30777; A61F2002/30782; A61F2002/30785; A61F2002/30787; A61F2002/30789; A61F2002/30794; A61F2002/30904; A61F2002/4475; A61F2230/0004; A61F2230/0019; A61F2230/0082; A61F2310/00023

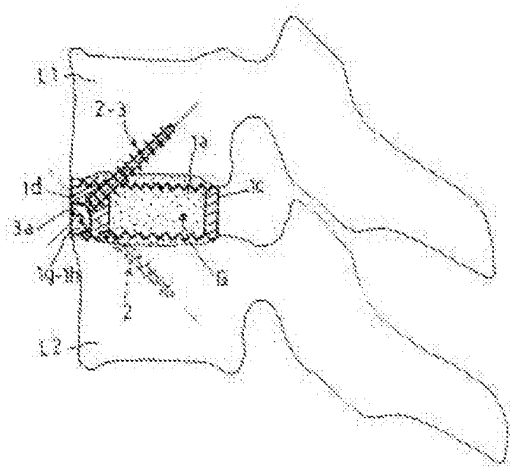
Application number: FR19940014067 19941118

Priority number(s): FR19940014067 19941118

Also published as: FR2727003 (B1)

Abstract of FR2727003 (A1)

The stabiliser consists of an insert designed to fit between two vertebrae (L1,L2) to maintain the spacing between them and receive spongy grafts, permitting their intersomatic fusion. The insert has holes (1g,1h) for fixings (2,3) which engage with the adjacent vertebrae and are angled at 90 deg to one another. The inset is three-dimensional and hollow, generally rectangular and shaped to conform to the anatomy of the adjacent vertebrae. It has a concave posterior surface (1c) and a rounded anterior surface (1d), with the anterior surface having a greater height than the posterior one to conform to the lumbar-sacral lordosis. Its upper and lower surfaces are grooved to ensure primary stability. The insert can be made from titanium or a polymer reinforced with carbon fibres.



(19) RÉPUBLIQUE FRANÇAISE

INSTITUT NATIONAL
DE LA PROPRIÉTÉ INDUSTRIELLE

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(21) N° d'enregistrement national : **94 14067**

(51) Int Cl⁶ : A 61 F 2/44, A 61 B 17/70

(12) DEMANDE DE BREVET D'INVENTION A1

(22) **Date de dépôt** : 18.11.94.

(30) **Priorité** :

(43) **Date de la mise à disposition du public de la demande :** 24.05.96 Bulletin 96/21.

(56) **Liste des documents cités dans le rapport de recherche préliminaire :** *Se reporter à la fin du présent fascicule.*

(60) **Références à d'autres documents nationaux apparentés :**

(71) **Demandeur(s) :** *EUROS SA SOCIETE ANONYME* — FR.

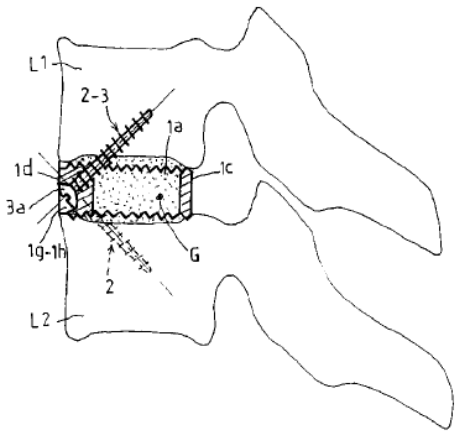
(72) **Inventeur(s) :** TISSERAND PHILIPPE.

(73) **Titulaire(s) :**

(74) **Mandataire :** CABINET LAURENT ET CHARRAS.

(54) DISPOSITIF DE STABILISATION ANTERIEURE DU RACHIS LOMBO-SACRE.

(57) Le dispositif comprend un élément (1) apte à maintenir l'écartement entre les corps vertébraux (L1) (L2) du rachis lombaire tout en étant agencé pour recevoir des greffons spongieux et permettre leur fusion intersomatique, ledit élément (1) présentant des trous orientés (1g) (1h) pour le passage d'organes de fixation (2) et (3) coopérant avec les corps vertébraux sus et sous jacents.



FR 2 727 003 - A1

Dispositif de stabilisation antérieure du rachis lombo-sacré.

L'invention se rattache au secteur technique des implants rachidiens.

Le problème que se propose de résoudre l'invention, est de stabiliser les vertèbres lombaires et la charnière lombo-sacrée, par voie antérieure.

Pour assurer une telle stabilisation, il est connu d'utiliser des implants sous forme de plateaux, destinés à être inserrés entre les corps vertébraux. Le plateau n'est pas fixé mais est simplement impacté entre les deux corps vertébraux. Le plateau peut être conformé pour recevoir un greffon. Cette solution n'est cependant pas satisfaisante, étant donné qu'il peut y avoir des risques d'expulsion du greffon, en cas d'instabilité et de déplacement du plateau, qui n'est pas fixé.

L'invention s'est fixée pour but de remédier à ces inconvénients, de manière simple, sûre, efficace et rationnelle.

Le problème que se propose de résoudre l'invention, est d'apporter une stabilité des vertèbres lombaires concernées, au moyen d'un ensemble prothétique, en évitant tout risque d'expulsion de cet ensemble prothétique, et en tenant compte du fait qu'au niveau lombaire, il peut y avoir des risques vasculaires, étant donné que les vertèbres sont relativement proches des vaisseaux.

Pour résoudre un tel problème, il a été conçu et mis au point un dispositif de stabilisation antérieure du rachis lombo-sacré, qui comprend un élément apte à maintenir l'écartement entre les corps vertébraux du rachis lombaire tout en étant agencé pour recevoir des

greffons spongieux et permettre leur fusion intersomatique, ledit élément présentant des trous orientés pour le passage et l'intégration d'organes de fixation coopérant avec les corps vertébraux sus et sous jacents.

Pour résoudre le problème posé d'intégrer les organes de fixation et pour permettre auxdits organes d'être implantés dans l'os cortico-spongieux des corps vertébraux, les trous constituent des chambrages internes formés à partir de la face antérieure de l'élément, l'un des chambrages étant dirigés vers le bas tandis que l'autre est dirigé vers le haut, en étant orienté l'un par rapport à l'autre, selon un angle d'environ 90°.

Pour résoudre le problème posé d'éviter l'écrasement, tout en ayant pour objectif de permettre la fusion intersomatique des greffons, l'élément est constitué par une structure volumétrique creuse de forme générale rectangulaire profilée pour correspondre à l'anatomie des corps vertébraux concernés.L'élément présente un bord postérieur concave en arrière et un bord antérieur arrondi pour épouser la face antérieure du corps vertébral.

Pour résoudre le problème posé de respecter la lordose lombo-sacrée, la hauteur de la face antérieure est supérieure à la hauteur de la face postérieure pour respecter la lordose lombo-sacrée.

Les faces supérieure et inférieure de l'élément sont crantées pour faciliter la stabilité primaire.

L'invention est exposée, ci-après plus en détail à l'aide des dessins annexés, dans lesquels :

La figure 1 est une vue en perspective du dispositif selon

l'invention.

La figure 2 est une vue en plan du dispositif.

La figure 3 est une vue en coupe montrant la fixation du dispositif entre deux plateaux des vertèbres lombaires.

Comme le montre la figure 1, le dispositif comprend un élément (1) apte à maintenir l'écartement entre deux corps vertébraux (L1) et (L2) de la partie lombaire du rachis, y compris de la charnière lombo-sacrée. Cet élément (1) est agencé pour recevoir des greffons spongieux (G) et permettre leur fusion intersomatique. Les greffons sont avantageusement prélevés sur la crête iliaque ou dans l'extrémité supérieure du tibia.

L'élément (1) est constitué par une structure volumétrique creuse de forme générale rectangulaire profilée, pour correspondre à l'anatomie des corps vertébraux (L1) (L2). Notamment, l'élément (1) présente un bord postérieur (1c) concave en arrière et un bord antérieur arrondi (1d). La hauteur de la face antérieure est supérieure à la hauteur de la face postérieure.

En outre, l'élément (1) présente deux ouvertures débouchantes et séparées (1a) (1b), recevant chacune les greffons spongieux. On n'exclut pas de pratiquer dans l'épaisseur de l'élément (1), une seule ouverture débouchante, ou plus de deux ouvertures.

Suivant une caractéristique importante de l'invention, l'élément (1) présente des trous orientés (1g) (1h), pour le passage et l'intégration d'organes de fixation (2) et (3), coopérant avec les corps vertébraux (L1) et (L2) sus et sous jacents audit élément (1). Comme le

montre notamment la figure 3, les trous (1g) et (1h) constituent des chambrages internes établis à partir de la face antérieure (1d), à proximité des bords transversaux de l'élément (1). Le chambrage (1g) est orienté vers le haut, tandis que le chambrage (1h) est orienté vers le bas. Les deux chambrages (1g) et (1h) sont décalés angulairement d'environ 90°.

En conséquence, après introduction des vis (2) et (3), l'une d'entre elles (2) sera dirigée vers le bas, tandis que l'autre (3) sera dirigée vers le haut. A noter que ces vis sont orientées d'un angle de très sensiblement 45°, pour s'implanter dans l'os cortico-spongieux, des corps vertébraux (L1) (L2).

Les têtes (2a) et (3a) des vis (2) et (3) sont noyées dans le chambrage, en appui dans le fond de ce dernier, et ne débordent pas de la face antérieure (1d).

Les faces supérieure (1i) et inférieure (1j) sont crantées pour faciliter la stabilité primaire. L'élément (1) est exécuté en titane ou polymère renforcé de fibre de carbonne.

A noter que l'élément (1) est réalisé selon essentiellement trois tailles, à savoir :

- une petite taille correspondant à une largeur de l'ordre de 20mm et à une longueur de l'ordre de 30mm,
- une taille moyenne correspondant à une largeur de l'ordre de 25mm et à une longueur de l'ordre de 35mm,
- une grande taille correspondant à une largeur de l'ordre de 30mm et à une longueur de l'ordre de 40mm.

A noter également que l'on distingue deux types d'éléments (1), selon qu'il concerne l'étage lombo-sacré L5-S1 ou les étages supérieures. A l'étage lombo-sacré, on utilise un élément dont l'obliquité

est plus accentuée, c'est-à-dire dont la hauteur de la face antérieure est nettement supérieure à celle de la face postérieure.

Trois types d'implants sont disponibles pour l'étage L5-S1, dont les hauteurs antérieures sont respectivement de 10mm, 12mm et 14mm, tandis que les hauteurs postérieures 8mm, 10mm et 12mm. Pour les étages supérieurs L4, L5 et suivants, les hauteurs antérieure sont respectivement de 9mm, 11mm et 13mm, tandis que les hauteurs postérieures sont de 8mm, 10mm et 12mm.

On indique ci-après, le mode opératoire de mise en place du dispositif selon l'invention.

Après ablation du disque intervertébral réalisée par une voie antérieure, la distraction vertébrale permet de récupérer la hauteur intervertébrale souhaitée. Cette distraction peut être réalisée par une traction appliquée sur le crâne et est permise par la résection la plus large possible de tout le tissu discal jusqu'au niveau du ligament vertébral postérieur qui peut être également réséqué. Un distracteur intersomatique peut compléter l'espacement intervertébral, la hauteur de l'élément (1) étant calculée d'après des fantômes et après essai de la bonne taille de l'élément. L'élément (1) est rempli de greffons spongieux et est disposé dans l'espace intervertébral considéré (L1) (L2) par exemple. L'élément (1) est ensuite solidarisé aux vertèbres sus et sous jacentes au moyen des vis (2) et (3), qui coopèrent dans l'os cortico-spongieux des corps vertébraux.

Un contrôle radioscopique per-opératoire est nécessaire pour s'assurer de la bonne position du dispositif.

Ce dispositif est particulièrement bien adapté pour stabiliser un segment mobile du rachis lombaire ou lombosacré et s'adresse essentillement soit à la charnière lombosacrée soit aux vertèbres sus-

jacentes, notamment au niveau des espaces L3-L4 et L4-L5.

Les avantages ressortent bien de la description, en particulier on souligne et on rappelle que l'emploi des vis d'ostéosynthèse permet une stabilisation primaire, et permet d'éviter toute mobilisation des greffons spongieux, pendant le délai nécessaire à la repousse osseuse.

REVENDICATIONS

-1- Dispositif de stabilisation antérieure du rachis lombosacré, caractérisé en ce qu'il comprend un élément (1) apte à maintenir l'écartement entre les corps vertébraux (L1) (L2) du rachis lombaire tout en étant agencé pour recevoir des greffons spongieux et permettre leur fusion intersomatique, ledit élément (1) présentant des trous orientés (1g) (1h) pour le passage d'organes de fixation (2) et (3) coopérant avec les corps vertébraux sus et sous jacents.

-2-Dispositif selon la revendication 1, caractérisé en ce que les trous (1g) (1h) constituent des chambrages internes formés à partir de la face antérieure (1d) de l'élément (1), l'un des chambrages étant dirigé vers le bas tandis que l'autre est dirigé vers le haut, en étant orientés l'un par rapport à l'autre, selon un angle d'environ 90°.

-3- Dispositif selon la revendication 1, caractérisé en ce que l'élément (1) est constitué par une structure volumétrique creuse de forme générale rectangulaire profilée pour correspondre à l'anatomie des corps vertébraux concernés.

-4- Dispositif selon la revendication 1, caractérisé en ce que l'élément présente un bord postérieur (1c) concave en arrière et un bord antérieur arrondi (1d) pour épouser la face antérieure du corps vertébral.

-5- Dispositif selon la revendication 1, caractérisé en ce que la hauteur de la face antérieure (1d) est supérieure à la hauteur de la face postérieure (1c) pour respecter la lordose lombosacrée.

-6- Dispositif selon la revendication 1, caractérisé en ce que les faces

supérieure (1i) et inférieure (1j) de l'élément (1) sont crantées pour faciliter la stabilité primaire.

-7- Dispositif selon la revendication 1, caractérisé en ce que l'élément (1) présente deux ouvertures débouchantes séparées (1a) (1b) pour recevoir les greffons spongieux.

-8- Dispositif selon la revendication 1, caractérisé en ce que l'élément (1) est réalisé en titane ou en polymère renforcé en fibres de carbone.

1/2

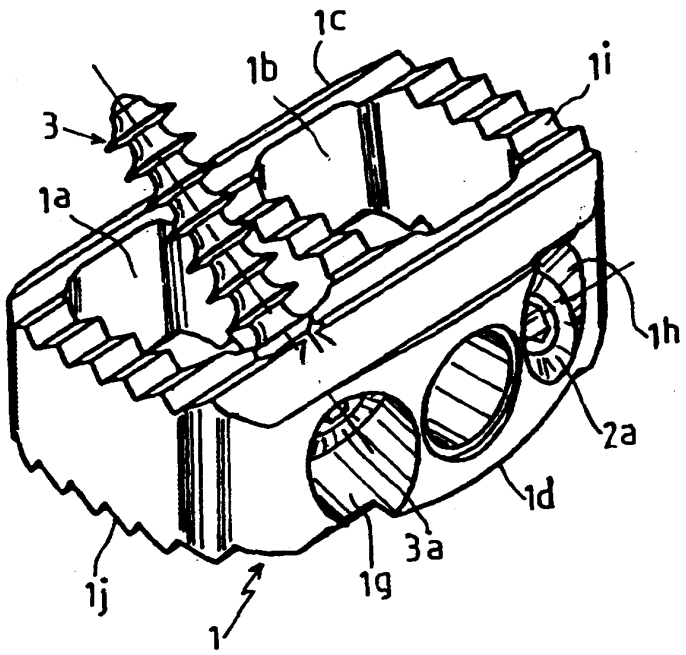


FIG.1

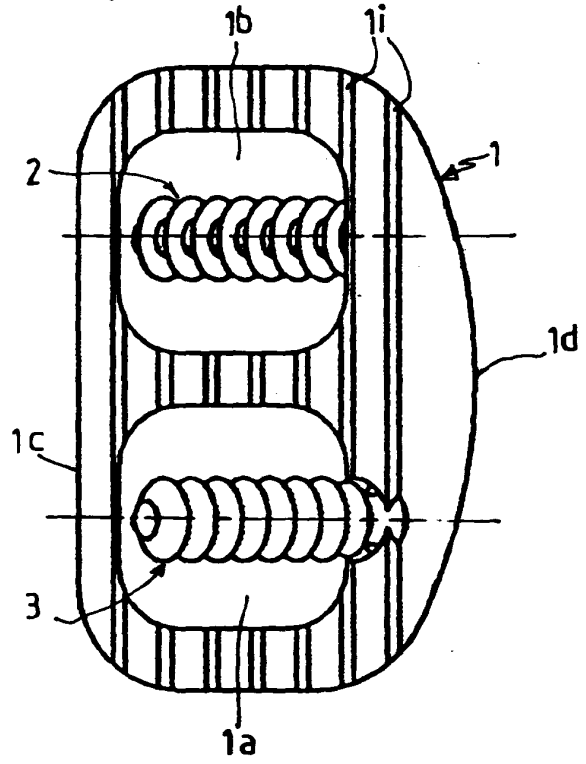
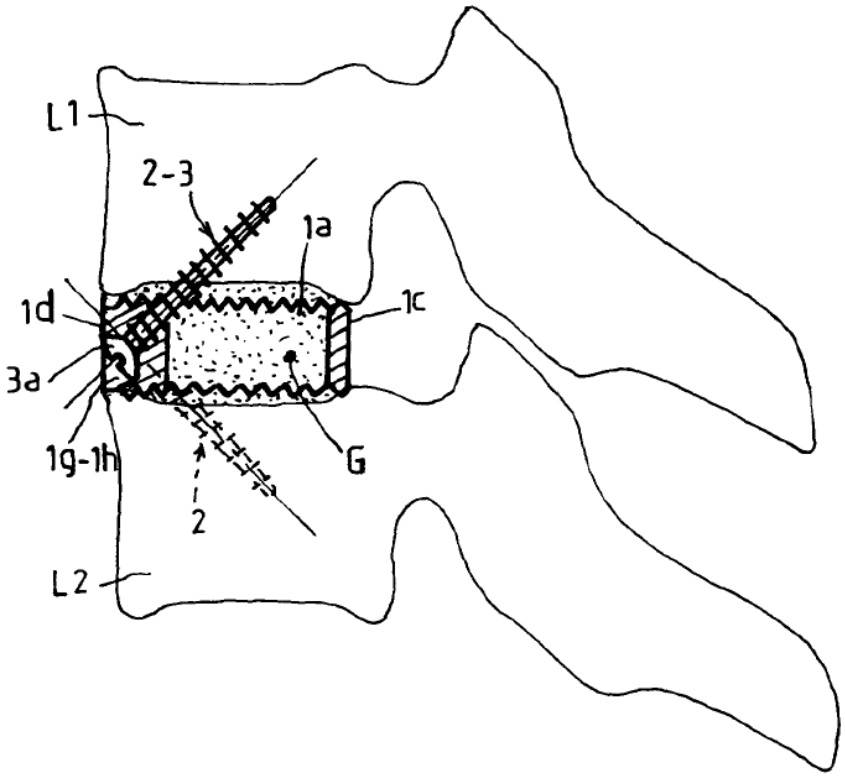


FIG.2

FIG. 3



REPUBLIQUE FRANÇAISE

2727003

N° d'enregistrement national

INSTITUT NATIONAL de la PROPRIETE INDUSTRIELLE

RAPPORT DE RECHERCHE PRELIMINAIRE

établi sur la base des dernières revendications déposées avant le commencement de la recherche

FA 507769
FR 9414067

DOCUMENTS CONSIDERES COMME PERTINENTS		Revendications concernées de la demande examinée
Catégorie	Citation du document avec indication, en cas de besoin, des parties pertinentes	
X	WO-A-94 18913 (HENDERSON FRASER C ;HENDERSON REBECCA SASSCER (US); NEWMAN JOHN W) 1 Septembre 1994 * page 8, alinéa 1 - page 9, alinéa 1; figures * * abrégé *	1,3
Y		5-7
A		2

Y	FR-A-2 703 580 (ROBERT GILLES) 14 Octobre 1994 * abrégé; revendication 6; figures *	5-7
A		1,3,8

A	WO-A-94 05235 (BRANTIGAN JOHN W) 17 Mars 1994 * abrégé; figures *	1,3,6-8

A	EP-A-0 298 233 (SULZER AG) 11 Janvier 1989 * colonne 2, ligne 14 - ligne 17; revendications; figures * * abrégé *	1,4,5,8

A	US-A-5 180 381 (AUST GILBERT M ET AL) 19 Janvier 1993 * abrégé; figure 2 *	1,2

DOMAINES TECHNIQUES RECHERCHES (Int.Cl.6)
A61F A61B

Date d'achèvement de la recherche	Examinateur
19 Juillet 1995	Neumann, E

CATEGORIE DES DOCUMENTS CITES

X : particulièrement pertinent à lui seul
Y : particulièrement pertinent en combinaison avec un autre document de la même catégorie
A : pertinent à l'encontre d'au moins une revendication ou arrière-plan technologique général
O : divulgation non-écrite
P : document intercalaire

T : théorie ou principe à la base de l'invention
E : document de brevet bénéficiant d'une date antérieure à la date de dépôt et qui n'a été publié qu'à cette date de dépôt ou qu'à une date postérieure.
D : cité dans la demande
L : cité pour d'autres raisons

& : membre de la même famille, document correspondant

1

EPO FORM 1503 03.82 (P04C13)

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DEC 6 2007
MG-IP Law, PLLC

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To: Richard McGrath
McGrath, Geissler, Olds & Richardson, PLLC
P.O. Box 1364
Fairfax, Virginia 22038

CFT 12/6/07
due: 2/3/08

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT AND THE WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

	Date of mailing *(day month year)* 03 DEC 2007
Applicant's or agent's file reference 3003/101 PWO2	**FOR FURTHER ACTION** See paragraphs 1 and 4 below
International application No. PCT/US 07/05005	International filing date *(day month year)* 28 February 2007 (28.02.2007)
Applicant MOSKOWITZ, Nathan	

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

Filing of amendments and statement under Article 19:
The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes 1211 Geneva 20, Switzerland, Facsimile No.: +41 22 740 14 35

For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. ☐ **With regard to the protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Reminders**

Shortly after the expiration of **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90*bis*.1 and 90*bis*.3, respectively, before the completion of the technical preparations for international publication.

The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase **until 30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months.

See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the ISA/US	Authorized officer:
Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/220 (January 2004) *(See notes on accompanying sheet)*

From the INTERNATIONAL BUREAU

PCT

FIRST NOTICE INFORMING THE APPLICANT OF THE COMMUNICATION OF THE INTERNATIONAL APPLICATION (TO DESIGNATED OFFICES WHICH DO NOT APPLY THE 30 MONTH TIME LIMIT UNDER ARTICLE 22(1))

(PCT Rule 47.1(c))

To:

MCGRATH, Richard
McGrath, Geissler, Olds & Richardson, PLLC
P.O. Box 1364
Fairfax, Virginia 22038
ETATS-UNIS D'AMERIQUE

Date of mailing *(day/month/year)* 22 November 2007 (22.11.2007)	
Applicant's or agent's file reference 3003/101PWO2	**IMPORTANT NOTICE**

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US2007/005005	28 February 2007 (28.02.2007)	04 April 2006 (04.04.2006)

Applicant: MOSKOWITZ, Nathan et al

1. **ATTENTION**: For any designated Office(s), for which the time limit under Article 22(1), as in force from 1 April 2002 (30 months from the priority date), **does apply**, please see Form PCT/IB/308(Second and Supplementary Notice) (to be issued promptly after the expiration of 28 months from the priority date).

2. Notice is hereby given that the following designated Office(s), for which the time limit under Article 22(1), as in force from 1 April 2002, **does not apply**, has/have requested that the communication of the international application, as provided for in Article 20, be effected under Rule 93*bis*.1. The International Bureau has effected that communication on the date indicated below:
15 November 2007 (15.11.2007)

   None

   In accordance with Rule 47.1(c-*bis*)(i), those Offices will accept the present notice as conclusive evidence that the communication of the international application has duly taken place on the date of mailing indicated above and no copy of the international application is required to be furnished by the applicant to the designated Office(s).

3. The following designated Offices, for which the time limit under Article 22(1), as in force from 1 April 2002, **does not apply**, have not requested, as at the time of mailing of the present notice, that the communication of the international application be effected under Rule 93*bis*.1 :

   CH, LU, TZ, UG

   In accordance with Rule 47.1(c-*bis*)(ii), those Offices accept the present notice as conclusive evidence that the Contracting State for which that Office acts as a designated Office does not require the furnishing, under Article 22, by the applicant of a copy of the international application.

4. **TIME LIMITS for entry into the national phase**

   For the designated Office(s) listed above, and unless a demand for international preliminary examination has been filed before the expiration of **19 months** from the priority date (see Article 39(1)), the applicable time limit for entering the national phase will, **subject to what is said in the following paragraph,** be **20 MONTHS** from the priority date.

   In practice, **time limits other than the 20-month time limit** will continue to apply, for various periods of time, in respect of certain of the designated Offices listed above. For **regular updates on the applicable time limits** (20 or 21 months, or other time limit), Office by Office, refer to the *PCT Gazette*, the *PCT Newsletter* and the *PCT Applicant's Guide*, Volume II, National Chapters, all available from WIPO's Internet site, at http://www.wipo.int/pct/en/index.html.

   It is the applicant's **sole responsibility** to monitor all these time limits.

RECEIVED

DEC 3 2007

CF3 12/4/07
CIA

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No. +41 22 338 82 70

Authorized officer: MG-IP Law, PLLC
Beate Giffo-Schmitt CF3

e-mail: pt03.pct@wipo.int

Form PCT/IB/308(First Notice) (January 2004)

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To: Richard McGrath
McGrath, Geissler, Olds & Richardson, PLLC
P.O. Box 1364
Fairfax, Virginia 22038

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT AND THE WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

	Date of mailing *(day month year)* 03 DEC 2007
Applicant's or agent's file reference 3003/101 PWO2	**FOR FURTHER ACTION** See paragraphs 1 and 4 below
International application No. PCT/US 07/05005	International filing date *(day month year)* 28 February 2007 (28.02.2007)
Applicant MOSKOWITZ, Nathan	

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

   Filing of amendments and statement under Article 19:
   The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

   When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

   Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes 1211 Geneva 20, Switzerland, Facsimile No.: +41 22 740 14 35

   For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. ☐ **With regard to the protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

   ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

   ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Reminders**

   Shortly after the expiration of **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90*bis*.1 and 90*bis*.3, respectively, before the completion of the technical preparations for international publication.

   The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

   Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase **until 30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

   In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months.

   See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/220 (January 2004) *(See notes on accompanying sheet)*

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 3003/101 PWO2	**FOR FURTHER ACTION**	see Form PCT/ISA/220 as well as, where applicable, item 5 below.
International application No. PCT/US 07/05005	International filing date *(day/month/year)* 28 February 2007 (28.02.2007)	(Earliest) Priority Date *(day/month/year)* 04 April 2006 (04.04.2006)
Applicant MOSKOWITZ, Nathan		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 2 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

a. With regard to the **language**, the international search was carried out on the basis of:

☒ the international application in the language in which it was filed.

☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

b. ☐ This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6*bis*(a)).

c. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☐ **Certain claims were found unsearchable** (see Box No. II).

3. ☐ **Unity of invention is lacking** (see Box No. III).

4. With regard to the **title**,

☐ the text is approved as submitted by the applicant.

☒ the text has been established by this Authority to read as follows:

ARTIFICIAL DISC FOR POSTERIOR PLACEMENT IN THE LUMBAR SPINE

5. With regard to the **abstract**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the **drawings**,

a. the figure of the **drawings** to be published with the abstract is Figure No. 17A

☐ as suggested by the applicant.

☐ as selected by this Authority, because the applicant failed to suggest a figure.

☒ as selected by this Authority, because this figure better characterizes the invention.

b. ☐ none of the figures is to be published with the abstract.

Form PCT/ISA/210 (first sheet) (April 2007)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 07/05005

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61F 2/44 (2007.01)
USPC - 623/17.15
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
USPC: 623/17.15

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
USPC: All classes (text search--see keywords)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PubWEST (PGPB, USPT, EPAB, JPAB), Google Scholar, Google Patents
Keywords: Expand, expansible, frame, scaffold, structure, implant, prosthetic, disc, vertebrae, spine, bifunctional, screw, worm, nut, sliding, tray, plate, lateral, thread, oblique, spike, tooth, conical

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2005/0278026 A1 (GORDON et al.) 15 December 2005 (15.12.2005) para [0148], [0163], [0253], [0259], [0262]; Fig 40, 41, 47a, 50a, 50b	16 and 21-23
Y	US 2005/0216084 A1 (FLEISCHMANN et al.) 29 September 2005 (29.09.2005) Fig 1a, 3a	3-4
Y	US 2005/0027362 A1 (WILLIAMS et al.) 03 February 2005 (03.02.2005) para [0062], [0066], [0067]; Fig 5c, 5e	10, 17, 19 and 20
Y	US 2005/0049590 A1 (ALLEYNE et al.) 03 March 2005 (03.03.2005) para [0033]; Fig 5b, 9b, 10a	1-10
Y	US 2004/0254644 A1 (TAYLOR) 16 December 2004 (16.12.2004) para [0071]; Fig 1, 8	1-10
X -- Y	US 4,997,432 A (KELLER) 05 March 1991 (05.03.1991) col 1, ln 19-29; col 4, ln 59 to col 5, ln 39; col 5, ln 58 to col 6, ln 2; Fig 1-3, 5, 7	11-15 and 18 --- 1-10, 16, 17 and 19-23

☐ Further documents are listed in the continuation of Box C. ☐

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
03 October 2007 (03.10.2007)	03 DEC 2007
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (April 2007)

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To: Richard McGrath
McGrath, Geissler, Olds & Richardson, PLLC
P.O. Box 1364
Fairfax, Virginia 22038

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)*	03 DEC 2007
Applicant's or agent's file reference 3003/101 PWO2	**FOR FURTHER ACTION** See paragraph 2 below

International application No.	International filing date *(day month year)*	Priority date *(day month year)*
PCT/US 07/05005	28 February 2007 (28.02.2007)	04 April 2006 (04.04.2006)

International Patent Classification (IPC) or both national classification and IPC
IPC(8) - A61F 2/44 (2007.01)
USPC - 623/17.15

Applicant MOSKOWITZ, Nathan

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability, citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/US	Date of completion of this opinion	Authorized officer:
Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	03 October 2007 (03.10.2007)	Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/237 (cover sheet) (April 2007)

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 07/05005

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:

   ☒ the international application in the language in which it was filed.

   ☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a))

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of:

   a. type of material

      ☐ a sequence listing

      ☐ table(s) related to the sequence listing

   b. format of material

      ☐ on paper

      ☐ in electronic form

   c. time of filing/furnishing

      ☐ contained in the international application as filed

      ☐ filed together with the international application in electronic form

      ☐ furnished subsequently to this Authority for the purposes of search

4. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 07/05005

Box No. V **Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	1-10, 14-17 and 19-23	YES
	Claims	11-13 and 18	NO
Inventive step (IS)	Claims	None	YES
	Claims	1-23	NO
Industrial applicability (IA)	Claims	1-23	YES
	Claims	None	NO

2. Citations and explanations:

Claims 11-13 and 18 lack novelty under PCT Article 33(2) as being anticipated by US 4,997,432 A (Keller).

As pertaining to claim 11, Keller teaches a disc comprising:
a pair of substantially parallel plates 3, that move apart along a first axis, in order to occupy a space defined by vertebral endplates 1 (col 4, ln 54-59; Fig 1);
an expansion device 9, that moves the pair of plates 3 along the first axis (col 5, ln 3-39; Fig 2);
a core 4, disposed between the pair of plates 3, that permits the vertebral endplates to move relative to one another (col 4, ln 67 to col 5, ln 2; Fig 1); and
a limiter 7 which prevents the core 4 from being extruded from between the substantially parallel plates 3 (col 4, ln 67 to col 5, ln 1; Fig 1).

As pertaining to claim 12, Keller teaches the above disc of claim 11. Keller also teaches a disc wherein the limiter 7 includes a substantially ring shaped member having a raised edge, and the core 4 is disposed within said limiter (Fig 1).

As pertaining to claim 13, Keller teaches the above disc of claim 12. Keller also teaches a disc wherein the limiter 3 includes a second substantially ring shaped member, said first and second substantially ring shaped members include raised barriers that prevent the extrusion of the core 4 (Fig 1).

As pertaining to claim 18, Keller teaches the above disc of claim 11. Keller also teaches a disc wherein the limiter 3 includes a ring shaped member having raised edges that surround said core 4 (Fig 1).

Claims 14 and 15 lack an inventive step under PCT Article 33(3) as being obvious over Keller.

As pertaining to claim 14, Keller teaches the above disc of claim 13. Keller also teaches a disc wherein at least one of the substantially ring shaped members fits into a groove formed in the core (Fig 1). Keller also teaches a disc wherein the plates slide with respect to each other (col 1, ln 19-29). While Keller does not expressly show rotation of the plates, it would have been obvious to one of ordinary skill in the art that a set of circular plates placed around a circular core with no rotational limiters would allow the plates to rotate with respect to each other.

As pertaining to claim 15, Keller teaches the above disc of claim 14. Keller also teaches a disc wherein the core 4 includes an ellipsoidal shaped member having superior and inferior domes, and the groove is formed in the exterior periphery of the core (Fig 1).

Claims 16 and 21-23 lack an inventive step under PCT Article 33(3) as being obvious over Keller in view of US 2005/0278026 A1 to GORDON et al. (hereinafter 'Gordon').

As pertaining to claim 16, Keller teaches the above disc of claim 15. Gordon also teaches a disc wherein the substantially parallel plates include alignment holes 182 (para [0163]). It would have been obvious for one of ordinary skill in the art to combine these references as both teach replacement discs, with Gordon teaching a disc which may allow disc rotation but will not allow rotation beyond a certain point, preventing over-rotation of the spine.

---Continued in Supplemental Box---

Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**
Continuation of:
Box V, Sect. 2

As pertaining to claim 21, Keller teaches a tool comprising:
a pair of manipulators 10 and 11 each having a cradle for each of said plates 3 (col 5, ln 29-39; Fig 2, 3),
wherein the manipulators force the spikes 6 of said plates into the vertebral end plates 1 (col 4, ln 59-64; Fig 1, 5); and
wherein the tool is used to insert the pair of plates, disposed in the cradles of the separators, between a pair vertebral endplates (col 6, ln 29-50).
Keller does not show alignment members, a wedge separator, or posterior insertion.
Gordon teaches a tool comprising:
a pair of manipulators each having a cradle 716 for a plate 488 and an insert 470, said cradles including threaded alignment members 726 (Fig 40, 41, 47a); and
a wedge separator 778 disposed between a pair of manipulators 780 and 782 (para [0253]; Fig 50a, 50b);
wherein the tool is used to posteriorly insert the pair of plates, disposed in the cradles of the separators, between a pair vertebral endplates (para [0253], [0259], [0262]);
wherein said wedge separator is used to separate said pair of plates (para [0253], [0262]).
While Gordon does not show that the alignment members cooperate with the first alignment members of the plates, it would have been obvious to one of ordinary skill in the art that the alignment members would have to cooperate with the first alignment members in order to expand the plate assembly of claim 10, as the assembly of claim 10 is expanded by means of the first alignment member (see claims 1 and 10).

As pertaining to claim 22, Keller and Gordon teach the above tool of claim 21. Gordon also teaches a tool wherein the separator 778 is actuated by a push/pull rod 782 (para [0253]; Fig 50a, 50b). While Gordon does not show that the rod includes digit inserts for operator of the tool, it would have been obvious to one of ordinary skill in the art that such a modification would allow for more precise maneuvering of the tool.

As pertaining to claim 23, Keller and Gordon teach the above tool of claim 22. Keller also teaches a tool wherein a separator 4 is attached to a manipulator 23 (col 5, ln 58 to col 6, ln 2; Fig 7). While Keller does not show that the separator is attached by a transmission linkage, it does teach that the cradle manipulators 10 and 11 may be interconnected by a linkage 12 (Fig 2). It would have been obvious to one of ordinary skill in the art that the separator mechanism might be attached to a manipulator by a transmission linkage in order to reduce the complexity of the procedure and reduce the size of the incision needed to insert the required tools.

Claims 17, 19 and 20 lack an inventive step under PCT Article 33(3) as being obvious over Keller in view of US 2005/0027362 A1 to WILLIAMS et al. (hereinafter 'Williams').

As pertaining to claim 17, Keller teaches the above disc of claim 11. Keller also teaches a disc wherein the substantially parallel plates contain an array of spikes 6 (col 4, ln 59-64; Fig 1, 5). Williams teaches a disc wherein the substantially parallel plates contain an array of spikes, said spikes including conical and angled spikes (para [0062], [0067]; Fig 5c, 5e). While Williams does not show pyramidal spikes, it does teach square spikes, which are very similar in form and function to pyramidal spikes. It would have been obvious to one of ordinary skill in the art that the conical spike should be central, as it will be subjected to varying forces from all angles. It would have been obvious to one of ordinary skill in the art that the pyramidal spikes should be on the edge, as the forces on them will tend to come perpendicular and parallel to the edge. It would have been obvious to one of ordinary skill in the art that the angled spikes should be between the pyramidal pikes and the center, as the forces on them will tend to come from the closer edge of the implant.
It would have been obvious for one of ordinary skill in the art to combine these references as both teach replacement discs, with Keller teaching a disc with securing spikes and Williams teaching the specific configuration of said spikes.

As pertaining to claim 19, Keller teaches the above disc of claim 18. Williams teaches a disc wherein the disc may be constructed of radiolucent or traditional materials (para [0066]). While Williams does not specifically show that radiopaque materials are used in the ring-shaped member, it would have been obvious to one of ordinary skill in the art that such a composition would allow for radiographic identification of the disc and easier placement of the core while not obscuring the vertebral endplates.

As pertaining to claim 20, Keller and Williams teach the above disc of claim 19. Keller teaches a disc wherein the core 4 includes superior and inferior domes (Fig 1).

---Continued in Supplemental Box---

Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**
Continuation of:
Box V, Sect. 2

Claims 1, 2 and 5-9 lack an inventive step under PCT Article 33(3) as being obvious over Keller in view of US 2004/0254644 A1 (TAYLOR) and US 2005/0049590 A1 to ALLEYNE et al. (hereinafter 'Alleyne').

As pertaining to claim 1, Keller teaches a disc comprising:
a pair of substantially parallel plates 3, that move apart along a first axis, in order to occupy a space defined by vertebral endplates 1 (col 4, ln 54-59; Fig 1);
a core 4, disposed between the pair of plates 3, that permits the vertebral endplates to move relative to one another (col 4, ln 67 to col 5, ln 2; Fig 1); and
a limiter 7 which prevents the core 4 from being extruded from between the substantially parallel plates 3 (col 4, ln 67 to col 5, ln 1; Fig 1).
Keller does not teach plate expansion or multi-axial expansion.
Taylor teaches a disc comprising at least one pair of substantially parallel plates 12 and 14 which occupy a space defined by vertebral endplates, each of said parallel plates including a first plate 12 or 14 and a second extending plate 18 that moves along a horizontal axis (para [0044], [0053]; Fig 1). While Taylor does not show that the second plates slide, it would have been obvious to one of ordinary skill in the art that the plates slide with regards to the extending wedge 97 and that the hinges 22 could be replaced with sliding track members similar to the wedge track 95 (para [0071]; Fig 1, 8).
Alleyne teaches an expansion device that expands a fixation member 112 and 126 along horizontal or vertical axes, respectively, with respect to the fixation driver 120 (Fig 9b, 10a). While Alleyne does not show in these embodiments that the members are moved along both axes in the same device, it does teach that the device may be expanded both horizontally and vertically (para [0033]). It would have been obvious to one of ordinary skill in the art that the two mechanisms could be combined for fixation along two axes to provide a more secure fixation along four planes rather than two.
It would have been obvious for one of ordinary skill in the art to combine these references as all teach spinal replacement systems, with Keller teaching the basic disc system, Taylor teaching a method of expanding plates to accommodate larger vertebrae, and Alleyne teaching a system which can expand the system along two axes.

As pertaining to claim 2, Keller, Taylor, and Alleyne teach the above disc of claim 1. Keller also teaches a disc wherein the limiter 7 includes a substantially ring shaped member having a raised edge, and the core 4 is disposed within said limiter (Fig 1).

As pertaining to claim 5, Keller, Taylor, and Alleyne teach the above disc of claim 1. Alleyne also teaches an expansion device wherein the expansion device includes a plurality of threaded worm gears that expand a fixation member 112 or 126 along horizontal or vertical axes, respectively, with respect to the fixation driver 104 or 120 (Fig 9b, 10a). While Alleyne does not show that the members are moved along both axes in the same device, it would have been obvious to one of ordinary skill in the art that the two mechanisms would be combined to provide for fixation in two axes to provide a more secure fixation along four planes rather than two. It would also have been obvious to one of ordinary skill in the art that a screw could be substituted for the threaded worm gear.

As pertaining to claim 6, Keller, Taylor, and Alleyne teach the above disc of claim 5. Alleyne also teaches an expansion device wherein the expansion device further includes a plurality of adjustment screws 126 and slotted worm nuts 122 and 124 that cooperate with the threaded worm gear 120 (Fig 10a).

As pertaining to claim 7, Keller, Taylor, and Alleyne teach the above disc of claim 6. Alleyne also teaches an expansion device wherein the threaded worm gears 120 include threads which cooperate with the slots on the worm nuts 122 and 124, said worm nuts being internally threaded and cooperating with threads disposed on the adjustment screws 126 (Fig 10a). Alleyne also teaches a device wherein the driving screw 31 includes threads which cooperate with openings disposed on a first plate 30 (Fig 5b).

As pertaining to claim 8, Keller, Taylor, and Alleyne teach the above disc of claim 7. While Alleyne does not show that the expansion device is removed upon completion of the expansion, Alleyne.s device does not use a mobile core (Fig 9b, 10a). It would have been obvious to one of ordinary skill in the art that in order for a flexion-permitting core to be introduced and properly used, the expansion device would have to be removed.

As pertaining to claim 9, Keller, Taylor, and Alleyne teach the above disc of claim 8. Keller also teaches a disc which further includes a trough 7 disposed in the center of the parallel plates 3 which receives the core 4 (Fig 1).

Claims 3 and 4 lack an inventive step under PCT Article 33(3) as being obvious over Keller in view of Taylor, in further view of Alleyne, and still in view of US 2005/0216084 A1 to FLEISCHMANN et al. (hereinafter 'Fleischmann').

As pertaining to claim 3, Keller, Taylor, and Alleyne teach the above disc of claim 2. Fleischmann teaches a disc wherein the limiter includes two substantially ring shaped members 10b, wherein the core includes a pair of flanges 20 at the top and bottom of the core, and wherein the flanges of the core are ensconced within the two ring shaped members of said limiter (Fig 1a, 3a). It would have been obvious for one of ordinary skill in the art to combine these references as Keller teaches a disc with a core and Fleischmann teaches a way of securing such a core.

As pertaining to claim 4, Keller, Taylor, Alleyne, and Fleischmann teach the above disc of claim 3. Keller also teaches a disc which further includes a trough 7 disposed in the center of the parallel plates 3 which receives the core 4 (Fig 1).

---Continued in Supplemental Box---

NOTES TO FORM PCT/ISA/220 (continued)

The letter must indicate the differences between the claims as filed and the claims as amended. It must, in particular, indicate, in connection with each claim appearing in the international application (it being understood that identical indications concerning several claims may be grouped), whether

(i) the claim is unchanged;
(ii) the claim is cancelled;
(iii) the claim is new;
(iv) the claim replaces one or more claims as filed;
(v) the claim is the result of the division of a claim as filed.

The following examples illustrate the manner in which amendments must be explained in the accompanying letter:

1. [Where originally there were 48 claims and after amendment of some claims there are 51]:
"Claims 1 to 29, 31, 32, 34, 35, 37 to 48 replaced by amended claims bearing the same numbers, claims 30, 33 and 36 unchanged; new claims 49 to 51 added."

2. [Where originally there were 15 claims and after amendment of all claims there are 11]:
"Claims 1 to 15 replaced by amended claims 1 to 11."

3. [Where originally there were 14 claims and the amendments consist in cancelling some claims and in adding new claims]:
"Claims 1 to 6 and 14 unchanged; claims 7 to 13 cancelled; new claims 15, 16 and 17 added." or
"Claims 7 to 13 cancelled; new claims 15, 16 and 17 added; all other claims unchanged."

4. [Where various kinds of amendments are made]:
"Claims 1-10 unchanged; claims 11 to 13, 18 and 19 cancelled; claims 14, 15 and 16 replaced by amended claim 14; claim 17 subdivided into amended claims 15, 16 and 17; new claims 20 and 21 added."

"Statement under Article 19(1)" (Rule 46.4)

The amendments may be accompanied by a statement explaining the amendments and indicating any impact that such amendments might have on the description and the drawings (which cannot be amended under Article 19(1)).

The statement will be published with the international application and the amended claims.

It must be in the language in which the international application is to be published.

It must be brief, not exceeding 500 words if in English or if translated into English.

It should not be confused with and does not replace the letter indicating the differences between the claims as filed and as amended. It must be filed on a separate sheet and must be identified as such by a heading, preferably by using the words "Statement under Article 19(1)."

It may not contain any disparaging comments on the international search report or the relevance of citations contained in that report. Reference to citations, relevant to a given claim, contained in the international search report may be made only in connection with an amendment of that claim.

Consequence if a demand for international preliminary examination has already been filed

If, at the time of filing any amendments and any accompanying statement, under Article 19, a demand for international preliminary examination has already been submitted, the applicant must preferably, at the time of filing the amendments (and any statement) with the International Bureau, also file with the International Preliminary Examining Authority a copy of such amendments (and of any statement) and, where required, a translation of such amendments for the procedure before that Authority (see Rules 55.3(a) and 62.2, first sentence). For further information, see the Notes to the demand form (PCT/IPEA/401).

If a demand for international preliminary examination is made, the written opinion of the International Searching Authority will, except in certain cases where the International Preliminary Examining Authority did not act as International Searching Authority and where it has notified the International Bureau under Rule 66.1*bis*(b), be considered to be a written opinion of the International Preliminary Examining Authority. If a demand is made, the applicant may submit to the International Preliminary Examining Authority a reply to the written opinion together, where appropriate, with amendments before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later (Rule 43*bis*.1(c)).

Consequence with regard to translation of the international application for entry into the national phase

The applicant's attention is drawn to the fact that, upon entry into the national phase, a translation of the claims as amended under Article 19 may have to be furnished to the designated/elected Offices, instead of, or in addition to, the translation of the claims as filed.

For further details on the requirements of each designated/elected Office, see the *PCT Applicant's Guide*, Volume II.

RECEIVED
MAY 23 2008
MG-IP LAW, PLLC

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To: Matthew T. Shanley
McGrath Geissler Olds & Richardson, PPLC
PO Box 1364
Fairfax, Virginia 22082

RECEIVED
CF 5/23/08
NG

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT AND THE WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

	Date of mailing *(day/month/year)*
Applicant's or agent's file reference 30030104PW02	**FOR FURTHER ACTION** See paragraphs 1 and 4 below
International application No. PCT/US2007/021015	International filing date *(day/month/year)* 01 October 2007
Applicant MOSKOWITZ, Nathan	

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

   Filing of amendments and statement under Article 19:
   The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

   When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

   Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes 1211 Geneva 20, Switzerland, Facsimile No.: +41 22 740 14 35

   For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. ☐ **With regard to the protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

   ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

   ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Reminders**

   Shortly after the expiration of **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90*bis*.1 and 90*bis*.3, respectively, before the completion of the technical preparations for international publication.

   The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

   Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase **until 30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

   In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months.

   See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Blaine R. Copenheaver Telephone No. 571-272-7774

Form PCT/ISA/220 (January 2004) *(See notes on accompanying sheet)*

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To: Matthew T. Shanley
McGrath Geissler Olds & Richardson, PPLC
PO Box 1364
Fairfax, Virginia 22082

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT AND THE WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

	Date of mailing *(day/month/year)* 21 MAY 2008
Applicant's or agent's file reference 30030104PW02	**FOR FURTHER ACTION** See paragraphs 1 and 4 below
International application No. PCT/US2007/021015	International filing date *(day/month/year)* 01 October 2007
Applicant MOSKOWITZ, Nathan	

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

   Filing of amendments and statement under Article 19:
   The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

   When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

   Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes 1211 Geneva 20, Switzerland, Facsimile No.: +41 22 740 14 35

   For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. ☐ **With regard to the protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

   ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

   ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Reminders**

   Shortly after the expiration of **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90*bis*.1 and 90*bis*.3, respectively, before the completion of the technical preparations for international publication.

   The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

   Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase **until 30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

   In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months.

   See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Blaine R. Copenheaver Telephone No. 571-272-7774

Form PCT/ISA/220 (January 2004) *(See notes on accompanying sheet)*

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 30030104PW02	**FOR FURTHER ACTION**	see Form PCT/ISA/220 as well as, where applicable, item 5 below.
International application No. PCT/US2007/021015	International filing date *(day/month/year)* 01 October 2007	(Earliest) Priority Date *(day/month/year)* 29 September 2006
Applicant MOSKOWITZ, Nathan		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 4 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

   a. With regard to the **language**, the international search was carried out on the basis of:

   ☒ the international application in the language in which it was filed

   ☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))

   b. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☐ **Certain claims were found unsearchable** (see Box No. II)

3. ☒ **Unity of invention is lacking** (see Box No. III)

4. With regard to the **title**,

   ☒ the text is approved as submitted by the applicant

   ☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

   ☐ the text is approved as submitted by the applicant

   ☒ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority

6. With regard to the **drawings**,

   a. the figure of the **drawings** to be published with the abstract is Figure No. 1A

   ☐ as suggested by the applicant

   ☒ as selected by this Authority, because the applicant failed to suggest a figure

   ☐ as selected by this Authority, because this figure better characterizes the invention

   b. ☐ none of the figures is to be published with the abstract

Form PCT/ISA/210 (first sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2007/021015

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:
Group I, claims 1-14, drawn to a self-drilling screw apparatus comprising a drive mechanism including a gear disposed between the first and second screw members for driving first and second screw members from a gear box.
Group II, claims 15-17, drawn to a staple for joining facets comprising a second rotatable segment having a plurality of bone piercing elements disposed on serrated surfaces.
Group III, claims 18-21, drawn to a stapling apparatus comprising a pair of grip handles disposed at a first end of a cylinder.

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-14

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

Box No. IV Text of the abstract (Continuation of item 5 of the first sheet)

An apparatus and method for joining members together using a self-drilling screw apparatus or stapling apparatus are disclosed. The screw apparatus includes a worm drive screw, a spur gear and superior and inferior screws which turn simultaneously. A rotating mechanism drives the first and second screw members in opposite directions and causes the screw members to embed themselves in the members to be joined. The screw apparatus can be used to join members such as bones, portions of the spinal column, vertebral bodies, wood, building materials, metals, masonry, or plastics. A device employing two screws can be combined with a capping mini-plate. A device employing three screws can be combined in enclosures. The stapling apparatus includes handles, transmission linkages, a drive rod a fulcrum and a cylinder. The staple has superior and inferior segments with serrated interfaces, a teethed unidirectional locking mechanism and four facet piercing elements.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2007/021015

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61F 2/44 (2008.04)
USPC - 623/17
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC(8) - A61F 2/44 (2008.04)
USPC - 623/17

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PatBase

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 4,636,217 A (OGILVIE et al) 13 January 1987 (13.01.1987) entire document	1-8, 11 --- 9-10, 12-14
Y	US 2002/0143338 A1 (ORBAY et al) 03 October 2002 (03.10.2002) entire document	10
Y	WO 2004/093749 A1 (MAGERL et al) 04 November 2004 (04.11.2004) entire document	9-10
Y	WO 2006/091503 A1 (SHATTUCK et al) 31 August 2006 (31.08.2006) entire document	12-14

☐ Further documents are listed in the continuation of Box C. ☐

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
05 May 2008	21 MAY 2008
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (April 2005)

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To: Matthew T. Shanley
McGrath Geissler Olds & Richardson, PPLC
PO Box 1364
Fairfax, Virginia 22082

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)* 21 MAY 2008

Applicant's or agent's file reference	FOR FURTHER ACTION
30030104PW02	See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US2007/021015	01 October 2007	29 September 2006

International Patent Classification (IPC) or both national classification and IPC
IPC(8) - A61F 2/44 (2008.04)
USPC - 623/17

Applicant MOSKOWITZ, Nathan

1. This opinion contains indications relating to the following items:

- [X] Box No. I Basis of the opinion
- [ ] Box No. II Priority
- [ ] Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- [X] Box No. IV Lack of unity of invention
- [X] Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- [ ] Box No. VI Certain documents cited
- [ ] Box No. VII Certain defects in the international application
- [ ] Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/US	Date of completion of this opinion	Authorized officer:
Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	05 May 2008	Blaine Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/237 (cover sheet) (April 2007)

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2007/021015

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:

   ☒ the international application in the language in which it was filed.

   ☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a))

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of:

   a. type of material

      ☐ a sequence listing

      ☐ table(s) related to the sequence listing

   b. format of material

      ☐ on paper

      ☐ in electronic form

   c. time of filing/furnishing

      ☐ contained in the international application as filed

      ☐ filed together with the international application in electronic form

      ☐ furnished subsequently to this Authority for the purposes of search

4. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2007/021015

Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees the applicant has, within the appicable time limit:

   ☐ paid additional fees

   ☐ paid additional fees under protest and, where applicable, the protest fee

   ☐ paid additional fees under protest but the applicable protest fee was not paid

   ☒ not paid additional fees

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is

   ☐ complied with

   ☒ not complied with for the following reasons:

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I, claims 1-14, drawn to a self-drilling screw apparatus comprising a drive mechanism including a gear disposed between the first and second screw members for driving first and second screw members from a gear box.
Group II, claims 15-17, drawn to a staple for joining facets comprising a second rotatable segment having a plurality of bone piercing elements disposed on serrated surfaces.
Group III, claims 18-21, drawn to a stapling apparatus comprising a pair of grip handles disposed at a first end of a cylinder.

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the special technical feature of Group I, a self-drilling screw apparatus comprising a drive mechanism including a gear disposed between the first and second screw members for driving first and second screw members from a gear box, is not present in Groups II and/or III; the special technical feature of Group II, a staple for joining facets comprising a second rotatable segment having a plurality of bone piercing elements disposed on serrated surfaces, is not present in Groups I and/or III; the special technical feature of Group III, a stapling apparatus comprising a pair of grip handles disposed at a first end of a cylinder, is not present in Groups I and/or II.

Since none of the special technical features of the Group I, Group II or Group III inventions is found in more than one of the inventions, unity of invention is lacking.

4. Consequently, this opinion has been established in respect of the following parts of the international application:

   ☐ all parts

   ☒ the parts relating to claims Nos. 1-14

Form PCT/ISA/237 (Box No. IV) (April 2007)

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2007/021015

Box No. V **Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	8-14	YES
	Claims	1-7	NO
Inventive step (IS)	Claims	None	YES
	Claims	1-14	NO
Industrial applicability (IA)	Claims	1-14	YES
	Claims	None	NO

2. Citations and explanations:

Claims 1-7 lack novelty under PCT Article 33(2) as being anticipated by Ogilvie et al.

Regarding claim 1, Ogilvie et al. disclose a self-drilling screw apparatus, which comprises: a gear box (Assembly of Fig. 5); a first screw member (Fig. 4, first screw on right side) having a tapered end (Fig. 4, item 32) and a threaded body (Fig. 4, item 31 and 33) disposed within the gear box (Fig. 4); a second screw member (Fig. 4, third screw from right side) having a tapered end (Fig. 4, item 32) and a threaded body (Fig. 4, item 31 and 33) disposed within the gear box (Fig. 4), the second screw member being axially offset from the first screw member (Fig. 4); and a drive mechanism (Assembly of Fig. 5), including a gear (Fig. 5, item 33 and 40) disposed between the first and second screw members (Fig. 5), for driving the first and second screw members from the gear box (The insert body is provided with a drive mechanism which will drive the retaining screws upon rotation of the drive mechanism. This drive mechanism comprises drive gears having a drive connection accessible from the exterior of the insert body after the insert has been placed into the void. A drive wrench is coupled to the drive connection and moved to rotate the drive gears, which will rotate the self-tapping, bone penetrating retaining screws so that they will be driven outwardly from the opposite end surfaces of the implanted insert body, col. 2, lines 13-23).

Regarding claim 2, Ogilvie et al. disclose that as applied to claim 1 wherein the gear box includes an aperture (Fig. 1, item 45; Fig. 4, item 46) which provides access to a wormed drive screw (Fig. 5, item 40-21; Fig. 6 and Fig. 5).

Regarding claim 3, Ogilvie et al. disclose that as applied to claim 1 wherein the drive mechanism wherein the gear is a spur gear (Fig. 5, item 33) which is driven by a wormed drive screw (Fig. 5, item 40-42) and which rotates the first and second screw members (The insert body is provided with a drive mechanism which will drive the retaining screws upon rotation of the drive mechanism. This drive mechanism comprises drive gears having a drive connection accessible from the exterior of the insert body after the insert has been placed into the void. A drive wrench is coupled to the drive connection and moved to rotate the drive gears, which will rotate the self-tapping, bone penetrating retaining screws so that they will be driven outwardly from the opposite end surfaces of the implanted insert body, col. 2, lines 13-23).

Regarding claim 4, Ogilvie et al. disclose that as applied to claim 3 wherein the wormed drive screw includes an accessible head (Fig. 6, item 57 and 58) that is rotated in order to drive the first and second screw members from the gear box (Fig. 5; The insert body is provided with a drive mechanism which will drive the retaining screws upon rotation of the drive mechanism. This drive mechanism comprises drive gears having a drive connection accessible from the exterior of the insert body after the insert has been placed into the void. A drive wrench is coupled to the drive connection and moved to rotate the drive gears, which will rotate the self-tapping, bone penetrating retaining screws so that they will be driven outwardly from the opposite end surfaces of the implanted insert body, col. 2, lines 13-23).

Regarding claim 5, Ogilvie et al. disclose that as applied to claim 3 wherein the first and second screw members include internal threading (Fig. 4, item 26B and 26C) and spindles (Fig. 4, item 30A; the screw shanks 30A are positioned in the interior threads of the bores 25 and 26 and the screw threads clear the thread sections 25C and 26C, col. 5, lines 41-43).

Regarding claim 6, Ogilvie et al. disclose that as applied to claim 3 wherein the wormed drive screw includes a spindle (Fig. 5, item 54).

Regarding claim 7, Ogilvie et al. disclose that as applied to claim 4 wherein the accessible head is rotated by a screw driver (The opposite ends of the worm shaft 40 are provided with internal polygonal openings indicated at 57 and 58, respectively, to receive suitable drive key wrenches, (such as Allen wrenches for a hex-shaped socket) for rotating the worm shafts from the exterior of the insert body 20, col. 4, lines 61-66)

Claims 8 and 11 lack an inventive step under PCT Article 33(3) as being obvious over Ogilvie et al.

Regarding claim 8, Ogilvie et al. disclose that as applied to claim 1. Ogilvie et al. does not teach further including: at least a second gear box; a third screw member having a tapered end and a threaded body disposed within the second gear box; a fourth screw member having a tapered end and a threaded body disposed within the second gear box, the fourth screw member being axially offset from the third screw member; and a second drive mechanism, including a gear disposed between the third and fourth screw members, for driving the third and fourth screw members from the second gear box. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use at least a second gear box; a third screw member having a tapered end and a threaded body disposed within the second gear box; a fourth screw member having a tapered end and a threaded body disposed within the second gear box, the fourth screw member being axially offset from the third screw member; and a second drive mechanism, including a gear disposed between the third and fourth screw members, for driving the third and fourth screw members from the second gear box for the purpose of providing extra support in the spine, since a mere duplication of essential working parts of device involves only routine skill in the art.

(Continued in Supplemental Box)

Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**
Continuation of:
Box V

Regarding claim 11, Ogilvie et al. disclose that as applied to claim 8. Ogilvie et al. does not teach further including: at least a third gear box; a fifth screw member having a tapered end and a threaded body disposed within the third gear box; a sixth screw member having a tapered end and a threaded body disposed within the third gear box, the sixth screw member being axially offset from the fifth screw member; and a third drive mechanism, including a gear disposed between the fifth and sixth screw members for driving the fifth and sixth screw members from the third gear box. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use at least a third gear box; a fifth screw member having a tapered end and a threaded body disposed within the third gear box; a sixth screw member having a tapered end and a threaded body disposed within the third gear box, the sixth screw member being axially offset from the fifth screw member; and a third drive mechanism, including a gear disposed between the fifth and sixth screw members for driving the fifth and sixth screw members from the third gear box for the purpose of providing extra support in the spine, since a mere duplication of essential working parts of device involves only routine skill in the art.

Claim 9 lacks an inventive step under PCT Article 33(3) as being obvious over Ogilvie et al. in view of Mageri et al.
Regarding claim 9, Ogilvie et al. disclose that as applied to claim 8. Ogilvie et al. do not teach which further includes a plate for joining the first and second gear boxes together. Mageri et al. teach a plate (Fig. 1, item 5) for joining the first and second devices together (Fig. 1, item 5 joins leftmost item 3 to rightmost item 3). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the plate as taught by Mageri et al. with the invention of Ogilvie et al. for the purpose of joining two of the implants together.

Claim 10 lacks an inventive step under PCT Article 33(3) as being obvious over Ogilvie et al. in view of Mageri et al. in further view of Orbay et al.
Regarding claim 10, Ogilvie et al. and Mageri et al. disclose that as applied to claim 9. Neither Ogilvie et al. or Mageri et al. teach wherein the plate includes screw caps. Orbay et al. teach screw caps (paragraph [0012]). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the screw caps as taught by Orbay et al. with the invention of Ogilvie et al. for the purpose of preventing the screw from backing out.

Claims 12-14 lack an inventive step under PCT Article 33(3) as being obvious over Ogilvie et al.in view of Shattuck et al.
Regarding claim 12, Ogilvie et al. disclose that as applied to claim 11. Ogilvie et al. do not teach wherein the gear boxes are aligned in a predetermined pattern and a first enclosure is disposed above the gear boxes and a second enclosure is disposed below the gear boxes. Shattuck et al. teach wherein the boxes are aligned in a predetermined pattern (Fig. 1 and Fig. 12 show the boxes aligned in a circular pattern) and a first enclosure (Fig. 1, item 28 on the right side of item 2) is disposed above the boxes (Fig. 1) and a second enclosure (Fig. 1, item 28 on the right side of item 2) is disposed below the boxes (Fig. 1). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the enclosure as taught by Shattuck et al. with the invention of Ogilvie et al. for the purpose of maintaining an aligned orientation for the gear boxes.
Regarding claim 13, Ogilvie et al. and Shattuck et al. disclose that as applied to claim 12. Neither Ogilvie et al. or Shattuck et al. teach wherein the gear boxes are aligned in a triangular pattern. It would have been obvious to one of ordinary skill in the art at the time the invention was made to align the gear boxes in a triangular pattern for the purpose of allowing evenly distributed pressure for motion, since a change in shape of an element involves only routine skill in the art.
Regarding claim 14, Ogilvie et al. and Shattuck et al. disclose that as applied to claim 13. Ogilvie et al. do not teach wherein the first and second enclosures include slots for bone fusion material. Shattuck et al. teach wherein the first and second enclosures include slots (Fig. 4, slotted channel surrounded by item 28, 25 and 31). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the slots as taught by Shattuck et al. with the invention of Ogilvie et al. for the purpose of allowing bone fusion/growth.

Claims 1-14 meets the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

NOTES TO FORM PCT/ISA/220 (continued)

The letter must indicate the differences between the claims as filed and the claims as amended. It must, in particular, indicate, in connection with each claim appearing in the international application (it being understood that identical indications concerning several claims may be grouped), whether

(i) the claim is unchanged;
(ii) the claim is cancelled;
(iii) the claim is new;
(iv) the claim replaces one or more claims as filed;
(v) the claim is the result of the division of a claim as filed.

The following examples illustrate the manner in which amendments must be explained in the accompanying letter:

1. [Where originally there were 48 claims and after amendment of some claims there are 51]:
"Claims 1 to 29, 31, 32, 34, 35, 37 to 48 replaced by amended claims bearing the same numbers, claims 30, 33 and 36 unchanged; new claims 49 to 51 added."
2. [Where originally there were 15 claims and after amendment of all claims there are 11]:
"Claims 1 to 15 replaced by amended claims 1 to 11."
3. [Where originally there were 14 claims and the amendments consist in cancelling some claims and in adding new claims]:
"Claims 1 to 6 and 14 unchanged; claims 7 to 13 cancelled; new claims 15, 16 and 17 added." or
"Claims 7 to 13 cancelled; new claims 15, 16 and 17 added; all other claims unchanged."
4. [Where various kinds of amendments are made]:
"Claims 1-10 unchanged; claims 11 to 13, 18 and 19 cancelled; claims 14, 15 and 16 replaced by amended claim 14; claim 17 subdivided into amended claims 15, 16 and 17; new claims 20 and 21 added."

"Statement under Article 19(1)" (Rule 46.4)

The amendments may be accompanied by a statement explaining the amendments and indicating any impact that such amendments might have on the description and the drawings (which cannot be amended under Article 19(1)).

The statement will be published with the international application and the amended claims.

It must be in the language in which the international application is to be published.

It must be brief, not exceeding 500 words if in English or if translated into English.

It should not be confused with and does not replace the letter indicating the differences between the claims as filed and as amended. It must be filed on a separate sheet and must be identified as such by a heading, preferably by using the words "Statement under Article 19(1)."

It may not contain any disparaging comments on the international search report or the relevance of citations contained in that report. Reference to citations, relevant to a given claim, contained in the international search report may be made only in connection with an amendment of that claim.

Consequence if a demand for international preliminary examination has already been filed

If, at the time of filing any amendments and any accompanying statement, under Article 19, a demand for international preliminary examination has already been submitted, the applicant must preferably, at the time of filing the amendments (and any statement) with the International Bureau, also file with the International Preliminary Examining Authority a copy of such amendments (and of any statement) and, where required, a translation of such amendments for the procedure before that Authority (see Rules 55.3(a) and 62.2, first sentence). For further information, see the Notes to the demand form (PCT/IPEA/401).

If a demand for international preliminary examination is made, the written opinion of the International Searching Authority will, except in certain cases where the International Preliminary Examining Authority did not act as International Searching Authority and where it has notified the International Bureau under Rule 66.1*bis*(b), be considered to be a written opinion of the International Preliminary Examining Authority. If a demand is made, the applicant may submit to the International Preliminary Examining Authority a reply to the written opinion together, where appropriate, with amendments before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later (Rule 43*bis*.1(c)).

Consequence with regard to translation of the international application for entry into the national phase

The applicant's attention is drawn to the fact that, upon entry into the national phase, a translation of the claims as amended under Article 19 may have to be furnished to the designated/elected Offices, instead of, or in addition to, the translation of the claims as filed.

For further details on the requirements of each designated/elected Office, see the *PCT Applicant's Guide*, Volume II.

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To: MATTHEW T. SHANLEY
McGrath Geissler Olds & Richardson, PLLC
PO Box 1364
Fairfax, Virginia 22082

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT AND THE WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

	Date of mailing *(day/month/year)* 09 JUL 2008
Applicant's or agent's file reference 30030105pwo1	**FOR FURTHER ACTION** See paragraphs 1 and 4 below
International application No. PCT/US2007/021013	International filing date *(day/month/year)* 01 October 2007
Applicant MOSKOWITZ, Ahmnon D.	

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

   Filing of amendments and statement under Article 19:
   The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

   When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

   Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes 1211 Geneva 20, Switzerland, Facsimile No.: +41 22 740 14 35

   For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. ☐ **With regard to the protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

   ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

   ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Reminders**

   Shortly after the expiration of **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90*bis*.1 and 90*bis*.3, respectively, before the completion of the technical preparations for international publication.

   The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

   Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase **until 30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

   In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months.

   See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Blaine R. Copenheaver Telephone No. 571-272-7774

RECEIVED
JUL 10 2008
ENTERED
DUE: 8/9/08

Form PCT/ISA/220 (January 2004) *(See notes on accompanying sheet)*

MG-IP Law, PLLC

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To: MATTHEW T. SHANLEY
McGrath Geissler Olds & Richardson, PLLC
PO Box 1364
Fairfax, Virginia 22082

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT AND THE WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

	Date of mailing *(day/month/year)* 09 JUL 2008
Applicant's or agent's file reference 30030105pwo1	**FOR FURTHER ACTION** See paragraphs 1 and 4 below
International application No. PCT/US2007/021013	International filing date *(day/month/year)* 01 October 2007
Applicant MOSKOWITZ, Ahmnon D.	

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

   Filing of amendments and statement under Article 19:
   The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

   When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

   Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes 1211 Geneva 20, Switzerland, Facsimile No.: +41 22 740 14 35

   For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. ☐ **With regard to the protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

   ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

   ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Reminders**

   Shortly after the expiration of **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90*bis*.1 and 90*bis*.3, respectively, before the completion of the technical preparations for international publication.

   The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

   Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase **until 30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

   In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months.

   See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Blaine R. Copenheaver Telephone No. 571-272-7774

Form PCT/ISA/220 (January 2004) *(See notes on accompanying sheet)*

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 30030105pwo1	**FOR FURTHER ACTION**	see Form PCT/ISA/220 as well as, where applicable, item 5 below.
International application No. PCT/US2007/021013	International filing date *(day/month/year)* 01 October 2007	(Earliest) Priority Date *(day/month/year)* 29 September 2006
Applicant MOSKOWITZ, Ahmnon D.		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 3 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

   a. With regard to the **language**, the international search was carried out on the basis of:

   ☒ the international application in the language in which it was filed

   ☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))

   b. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☐ **Certain claims were found unsearchable** (see Box No. II)

3. ☒ **Unity of invention is lacking** (see Box No. III)

4. With regard to the **title**,

   ☒ the text is approved as submitted by the applicant

   ☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

   ☒ the text is approved as submitted by the applicant

   ☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority

6. With regard to the **drawings**,

   a. the figure of the **drawings** to be published with the abstract is Figure No. 1A

   ☒ as suggested by the applicant

   ☐ as selected by this Authority, because the applicant failed to suggest a figure

   ☐ as selected by this Authority, because this figure better characterizes the invention

   b. ☐ none of the figures is to be published with the abstract

Form PCT/ISA/210 (first sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2007/021013

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:
Group I, claims 1-15 and 24, drawn to a self drilling bone fusion screw apparatus comprising a first box and first and second screw members.
Group II, claims 16-17 and 25, drawn to a tool assembly comprising a gripper and screw guide held in place by the plurality of prongs.
Group III, claims 18-22, drawn to a cervical facet staple and impaction tool comprising an insertion member disposed on the top surface of the curved staple base.
Group IV, claim 23, drawn to a lumbar facet staple comprising a pair of rotating arms and a ratchet attached to one of the rotating arms.

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-15, 24

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2007/021013

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61F 2/44 (2008.04)
USPC - 623/17.11
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC(8) - A61F 2/44 (2008.04)
USPC - 17.11

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
USPTO EAST System (US, USPG-PUB, EPO, DERWENT), PatBase

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,290,312 A (KOJIMOTO et al) 01 March 1994 (01.03.1994) entire document	1, 2
Y		3-15, 24
Y	US 2005/0177235 A1 (BAYNHAM et al) 11 August 2005 (11.08.2005) entire document	6-9
Y	US 2002/0068977 A1 (JACKSON) 06 June 2002 (06.06.2002) entire document	10-15, 24

☐ Further documents are listed in the continuation of Box C. ☐

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
25 June 2008	09 JUL 2008
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (April 2005)

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To: MATTHEW T. SHANLEY
McGrath Geissler Olds & Richardson, PLLC
PO Box 1364
Fairfax, Virginia 22082

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)*	09 JUL 2008

Applicant's or agent's file reference	FOR FURTHER ACTION
30030105pwo1	See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US2007/021013	01 October 2007	29 September 2006

International Patent Classification (IPC) or both national classification and IPC
IPC(8) - A61F2/44 (2008.01)
USPC - 17.11

Applicant MOSKOWITZ, Ahmnon D.

1. This opinion contains indications relating to the following items:

- [X] Box No. I Basis of the opinion
- [ ] Box No. II Priority
- [ ] Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- [X] Box No. IV Lack of unity of invention
- [X] Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- [ ] Box No. VI Certain documents cited
- [ ] Box No. VII Certain defects in the international application
- [ ] Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/US	Date of completion of this opinion	Authorized officer:
Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	25/June/2008	Blaine Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/237 (cover sheet) (April 2007)

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2007/021013

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:

   ☒ the international application in the language in which it was filed.

   ☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a))

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of:

   a. type of material

      ☐ a sequence listing

      ☐ table(s) related to the sequence listing

   b. format of material

      ☐ on paper

      ☐ in electronic form

   c. time of filing/furnishing

      ☐ contained in the international application as filed

      ☐ filed together with the international application in electronic form

      ☐ furnished subsequently to this Authority for the purposes of search

4. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2007/021013

Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees the applicant has, within the appicable time limit:

   ☐ paid additional fees

   ☐ paid additional fees under protest and, where applicable, the protest fee

   ☐ paid additional fees under protest but the applicable protest fee was not paid

   ☒ not paid additional fees

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is

   ☐ complied with

   ☒ not complied with for the following reasons:

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I, claims 1-15 and 24, drawn to a self drilling bone fusion screw apparatus comprising a first box and first and second screw members.
Group II, claims 16-17 and 25, drawn to a tool assembly comprising a gripper and screw guide held in place by the plurality of prongs.
Group III, claims 18-22, drawn to a cervical facet staple and impaction tool comprising an insertion member disposed on the top surface of the curved staple base.
Group IV, claim 23, drawn to a lumbar facet staple comprising a pair of rotating arms and a ratchet attached to one of the rotating arms.

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the special technical feature of Group I, a self drilling bone fusion screw apparatus comprising a first box and first and second screw members, is not present in Groups II, III and/or IV; the special technical feature of Group II, a tool assembly comprising a gripper and screw guide held in place by the plurality of prongs, is not present in Groups I, III and/or IV; the special technical feature of Group III, a cervical facet staple and impaction tool comprising an insertion member disposed on the top surface of the curved staple base, is not present in Groups I, II and/or IV; the special technical feature of Group IV, a lumbar facet staple comprising a pair of rotating arms and a ratchet attached to one of the rotating arms, is not present in Groups I, II and/or III.

Since none of the special technical features of the Group I, Group II, Group III or Group IV inventions is found in more than one of the inventions, unity of invention is lacking.

4. Consequently, this opinion has been established in respect of the following parts of the international application:

   ☐ all parts

   ☒ the parts relating to claims Nos. 1-15, 24

Form PCT/ISA/237 (Box No. IV) (April 2007)

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2007/021013

Box No. V **Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	3-15, 24	YES
	Claims	1, 2	NO
Inventive step (IS)	Claims	None.	YES
	Claims	1-15, 24	NO
Industrial applicability (IA)	Claims	1-15, 24	YES
	Claims	None	NO

2. Citations and explanations:

Claims 1 and 2 lack novelty under PCT Article 33(2) as being anticipated by Kojimoto et al.
Regarding claim 1, Kojimoto et al. discloses a self-drilling bone fusion screw apparatus, which comprises: a first sliding box (fig. 2, 18); a second sliding box (fig. 2, 20), positioned relative to the first sliding box; a first screw member having a tapered end and a threaded body disposed within the first sliding box (fig. 2, 70); a second screw member having a tapered end and a threaded body disposed within the second sliding box (fig. 2, 78); and an adjuster for adjusting the height of the sliding boxes (fig. 2, 88; col. 6, lines 60-66 wherein screw 88 engages both the first and second sliding boxes to fix movement of the second box axially within the first box when screwed in).
Regarding claim 2, Kojimoto et al. discloses the self-drilling bone fusion screw apparatus according to claim 1 wherein the first and second screw members are medially aligned (fig. 2, 70 and 78).

Claims 3-5 lack an inventive step under PCT Article 33(3) as being obvious over Kojimoto et al.
Regarding claims 3-5, Kojimoto et al. discloses the self-drilling bone fusion screw apparatus according to claim 1. Kojimoto et al. does not disclose [claim 3] wherein at least one of the first and second screw members is laterally aligned; [claim 4] the self-drilling bone fusion screw apparatus according to claim 3 wherein both the first and second screw members are laterally aligned; and [claim 5] wherein one of the first and second screw members is laterally aligned and the other screw member is laterally aligned. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to change or allow differentiation in the orientation of the screw members in order to give the fusion cage added stability, since the provision of adjustability, where needed, involves only routine skill in the art.

Claims 6-9 lack an inventive step under PCT Article 33(3) as being obvious over Kojimoto et al in view of Baynham et al.
Regarding claims 6-9, Kojimoto et al. discloses the self-drilling bone fusion screw apparatus according to claim 1. Kojimoto et al. does not disclose [claim 6] wherein the first and second sliding boxes are substantially triangularly shaped; [claim 7] wherein the triangularly shaped first and second sliding boxes include a sliding rail and ridged surfaces; [claim 8] wherein the triangularly shaped first and second sliding boxes include holes for bone grafts and [claim 9] wherein the adjuster includes a screw. However, Baynham et al. discloses a spinal fusion device which consists of two substantially triangular sections which are adjustable (fig. 1, 12 and 14) using a screw (fig. 1, 40). Baynham et al. additionally discloses a hole in the device for promoting bone ingrowth (paragraph 0021) and wherein the triangularly shaped first and second sliding boxes include a sliding rail (formed by walls 35 and 36 about which flange 26 slides in and enages (paragraph 0021) and ridged surface (ridges 15-18; see figs. 1 and 3). It would have been obvious to one skilled in the art at the time of the invention to incorporate the triangular shaped device further including an adjusting screw, sliding rail, ridged surfaces and holes for bone grafts taught by Baynham et al. into the spinal prosthetic disclosed by Kojimoto et al. in order to provide an adjustable height fusion cage that remains secure in the intervertebral space and also promotes bone growth.

Claims 10-12 lack an inventive step under PCT Article 33(3) as being obvious over Kojimoto et al in view of Jackson.
Regarding claim 10, Kojimoto et al. discloses a self-drilling bone fusion screw apparatus, which comprises: a box (fig. 2, 18); a first screw member and a second member having a tapered end and a threaded body disposed at least partially within the box (fig. 2, 68 and 70). Kojimoto et al. does not disclose where the first and second screw members are laterally aligned; however it would have been obvious to one of ordinary skill in the art at the time the invention was made to change or allow differentiation in the orientation of the screw members in order to give the fusion cage added stability, since the provision of adjustability, where needed, involves only routine skill in the art. Kojimoto et al. further does not disclose a plurality of ridges disposed on along side of the box. However, Jackson discloses an anterior variable expandable fusion cage which includes ridges (fig. 1, 15). It would have been obvious to one skilled in the art at the time of the invention to include ridges as taught by Jackson to the device disclosed by Kojimoto et al. in order to increase the gripping ability of the device to the adjacent bone.
Regarding claims 11 and 12, Kojimoto et al. in view of Jackson disclose the self-drilling bone fusion screw apparatus according to claim 10. Kojimoto et al. does not disclose [claim 11] where the device further includes bone graft holes or [claim 12] which is attachable to a second self-drilling fusion screw apparatus via a plate. However, Jackson discloses side windows (paragraph 0046) and a plate to add a second screw device (paragraph 0050). It would have been obvious to one skilled in the art at the time of the invention to incorporate bone graft holes and a connector plate as taught by Jackson to the fusion device disclosed by Kojimoto et al. in order to promote bone ingrowth as well as allow the addition of a second fusion device for added stability.

See Supplemental Box.

Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**
Continuation of:
Box No. V

Claims 13-15 and 24 lack an inventive step under PCT Article 33(3) as being obvious over Jackson in view of Kojimoto et al.

Regarding claim 13, Jackson discloses a bone fusion apparatus, which comprises: a first box; a second box (fig. 10, 5); and an attachment member for engaging the first and second boxes (fig. 14, 80). Jackson does not disclose a first screw member having a tapered end and a threaded body disposed at least partially within the first box and laterally aligned with the first box; a second screw member having a tapered end and a threaded body disposed at least partially within the second box and laterally aligned with the second box. However, Kojimoto et al. discloses an artificial vertebral body that includes first and second screw members (fig. 2, 70 and 78). It would have been obvious to one skilled in the art at the time of the invention to include multiple screws as taught by Kojimoto et al. to the fusion devices as disclosed by Jackson in order to further secure the boxes into the intervertebral space.

Regarding claims 14, 15 and 24, Jackson in view of Kojimoto et al. disclose the self-drilling bone fusion screw apparatus according to claim 13, [claim 14] further including bone graft holes (paragraph 0046), [claim 15] wherein the plate is joined to the first and second boxes by a plurality of screws (paragraph 0050) and [claim 24] wherein the attachment member for engaging the first and second boxes comprises a plate or a circumferential cage defining at least one recess, the first and the second boxes being positioned within the recess of the circumferential cage (fig. 13, 80 and fig. 18, 180).

Claim 1-15 and 24 the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

NOTES TO FORM PCT/ISA/220

These Notes are intended to give the basic instructions concerning the filing of amendments under Article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the *PCT Applicant's Guide*, a publication of WIPO.

In these Notes, "Article," "Rule" and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions, respectively.

INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report and the written opinion of the International Searching Authority, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only (see *PCT Applicant's Guide*, Volume I/A, Annexes B1 and B2).

The attention of the applicant is drawn to the fact that amendments to the claims under Article 19 are not allowed where the International Searching Authority has declared, under Article 17(2), that no international search report would be established (see *PCT Applicant's Guide*, Volume I/A, paragraph 296).

What parts of the international application may be amended ?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Preliminary Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

When ? Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

Where not to file the amendments ?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

How ? Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Section 205(b)).

The amendments must be made in the language in which the international application is to be published.

What documents must/may accompany the amendments ?

Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.

Electronic Acknowledgement Receipt

EFS ID:	33238235
Application Number:	16025667
International Application Number:	
Confirmation Number:	5655
Title of Invention:	ZERO-PROFILE EXPANDABLE INTERVERTEBRAL SPACER DEVICES FOR DISTRACTION AND SPINAL FUSION AND A UNIVERSAL TOOL FOR THEIR PLACEMENT AND EXPANSION
First Named Inventor/Applicant Name:	Ahmnon D. Moskowitz
Customer Number:	26191
Filer:	Stuart A. Nelson/Melissa Andersen
Filer Authorized By:	Stuart A. Nelson
Attorney Docket Number:	46440-0020003
Receipt Date:	20-JUL-2018
Filing Date:	
Time Stamp:	13:08:29
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	Transmittal.pdf	71726 0f2014dfba937e5ed920eab5da8148bf0736f715	no	1

Warnings:

Information:					
This is not an USPTO supplied IDS fillable form					
2	Non Patent Literature	PTO-1449.pdf	193415 9ab547a473debf8fbe6081f3cd6b3905231fa050	no	13
Warnings:					
Information:					
3	Foreign Reference	WO2004093749.pdf	8060108 a1cab22f6415aada187d3b5a0607113e57144029	no	35
Warnings:					
Information:					
4	Foreign Reference	WO2006091503.pdf	4256674 afdfdde07b037d12ec859ba138441fd3078ea9f6	no	20
Warnings:					
Information:					
5	Foreign Reference	FR2727003.pdf	1532286 0aa11efa6354403787574 2106ecef4a047ae5caa	no	14
Warnings:					
Information:					
6	Non Patent Literature	Traynelis.pdf	1935154 fcb99c1a6f52a84ade29b7921aaf7334ae2eaf1e	no	8
Warnings:					
Information:					
7	Non Patent Literature	Wai.pdf	1892725 49c5a4f89243b628b858548f143e4e1ba29e882a	no	10
Warnings:					
Information:					
8	Non Patent Literature	Guyer.pdf	2292941 30fe3d2eaf55ec30e258cd488b5ff925c76c86cb	no	10
Warnings:					
Information:					

9	Non Patent Literature	Grob.pdf	1793707 dbe18385ce9ec6e48612e4e95f9e16dfa1a2d5d3	no	8
Warnings:					
Information:					
10	Non Patent Literature	ISR_12-3-2007.pdf	1631466 6224b2c21d9f6a3a8dc571a723d08b88af5b0d1f	no	11
Warnings:					
Information:					
11	Non Patent Literature	ISR_5-21-2008.pdf	5407617 c405f1655824fb598a18b00978e8c24fbf727dd7	no	12
Warnings:					
Information:					
12	Non Patent Literature	ISR_7-9-2008.pdf	4981490 c66e241190165e40674c381bbffd626f8b20f7be	no	11
Warnings:					
Information:					
		Total Files Size (in bytes):	34049309		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number: 16/025,667

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY FEE($)
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	75		N/A	
SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	330		N/A	
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	380		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	20 minus 20 =	*	x 50 =	0.00	OR		
INDEPENDENT CLAIMS (37 CFR 1.16(h))	3 minus 3 =	*	x 230 =	0.00			
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			0.00			
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				0.00			
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	785		TOTAL	

APPLICATION AS AMENDED - PART II

AMENDMENT A

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY ADDITIONAL FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE($)
Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
Application Size Fee (37 CFR 1.16(s))									
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
					TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

AMENDMENT B

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY ADDITIONAL FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE($)
Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
Application Size Fee (37 CFR 1.16(s))									
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
					TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest found in the appropriate box in column 1.

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APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
16/025,667	07/02/2018	2827	785	46440-0020003	20	3

CONFIRMATION NO. 5655

FILING RECEIPT

26191
FISH & RICHARDSON P.C. (TC)
PO BOX 1022
MINNEAPOLIS, MN 55440-1022



Date Mailed: 08/03/2018

Receipt is acknowledged of this non-provisional patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please submit a written request for a Filing Receipt Correction. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections**

Inventor(s)

Ahmnon D. Moskowitz, Rockville, MD;
Mosheh T. Moskowitz, Rockville, MD;
Pablo A. Valdivia Y. Alvarado, Cambridge, MA;
Eric Sugalski, Arlington, MA;
Nathan C. Moskowitz, Rockville, MD;

Applicant(s)

Moskowitz Family LLC, Rockville, MD;

Power of Attorney: The patent practitioners associated with Customer Number 26191

Domestic Priority data as claimed by applicant

This application is a CON of 15/820,232 11/21/2017 PAT 10016284
which is a CON of 14/063,197 10/25/2013 PAT 9848993
which claims benefit of 61/801,783 03/15/2013
and claims benefit of 61/718,707 10/25/2012
and is a CIP of 13/210,150 08/15/2011 PAT 9867719
and is a CIP of 13/210,157 08/15/2011 PAT 9889022
and is a CIP of 13/210,162 08/15/2011 PAT 9895238
and is a CIP of 13/210,168 08/15/2011 PAT 9907674
and is a CIP of 13/741,361 01/14/2013 PAT 9301854
and said 13/210,150 08/15/2011
is a CON of 13/084,543 04/11/2011 PAT 8353913
and is a CON of 13/108,982 05/16/2011 PAT 9005293
and said 13/210,157 08/15/2011
is a CON of 13/084,543 04/11/2011 PAT 8353913
and is a CON of 13/108,982 05/16/2011 PAT 9005293

and said 13/210,162 08/15/2011
is a CON of 13/084,543 04/11/2011 PAT 8353913
and is a CON of 13/108,982 05/16/2011 PAT 9005293
and said 13/210,168 08/15/2011
is a CON of 13/084,543 04/11/2011 PAT 8353913
and is a CON of 13/108,982 05/16/2011 PAT 9005293
and said 13/741,361 01/14/2013
is a CON of 13/084,543 04/11/2011 PAT 8353913
and is a CON of 13/108,982 05/16/2011 PAT 9005293
and said 13/084,543 04/11/2011
is a CON of 11/842,855 08/21/2007 PAT 7942903
and said 13/108,982 05/16/2011
is a CON of 11/842,855 08/21/2007 PAT 7942903
which is a CIP of 11/536,815 09/29/2006 PAT 7846188
which is a CIP of 11/208,644 08/23/2005 PAT 7704279
which claims benefit of 60/670,231 04/12/2005

Foreign Applications for which priority is claimed (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see http://www.uspto.gov for more information.) - None.
Foreign application information must be provided in an Application Data Sheet in order to constitute a claim to foreign priority. See 37 CFR 1.55 and 1.76.

Permission to Access Application via Priority Document Exchange: Yes

Permission to Access Search Results: Yes

Applicant may provide or rescind an authorization for access using Form PTO/SB/39 or Form PTO/SB/69 as appropriate.

If Required, Foreign Filing License Granted: 08/01/2018
The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 16/025,667**
Projected Publication Date: 11/08/2018
Non-Publication Request: No
Early Publication Request: No
** **SMALL ENTITY** **
Title

ZERO-PROFILE EXPANDABLE INTERVERTEBRAL SPACER DEVICES FOR DISTRACTION AND SPINAL FUSION AND A UNIVERSAL TOOL FOR THEIR PLACEMENT AND EXPANSION

Preliminary Class

365

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: No

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international

application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at http://www.uspto.gov/web/offices/pac/doc/general/index.html.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, http://www.stopfakes.gov. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4258).

LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

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security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign AssetsControl, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/025,667	07/02/2018	Ahmnon D. Moskowitz	46440-0020003	5655

26191 7590 08/27/2018
FISH & RICHARDSON P.C. (TC)
PO BOX 1022
MINNEAPOLIS, MN 55440-1022
UNITED STATES OF AMERICA

EXAMINER	
ROBERT, EDUARDO C	

ART UNIT	PAPER NUMBER
3733	

NOTIFICATION DATE	DELIVERY MODE
08/27/2018	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

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Commissioner for Patents
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Doc Code:
TRACK1.GRANT

Decision Granting Request for Prioritized Examination (Track I or After RCE)	Application No.: 16/025,667

1. THE REQUEST FILED July 2, 2018 IS **GRANTED.**

The above-identified application has met the requirements for prioritized examination
A. ☒ for an original nonprovisional application (Track I).
B. ☐ for an application undergoing continued examination (RCE).

2. **The above-identified application will undergo prioritized examination.** The application will be accorded special status throughout its entire course of prosecution until one of the following occurs:

A. filing a **petition for extension of time** to extend the time period for filing a reply;
B. filing an **amendment to amend the application to contain more than four independent claims, more than thirty total claims**, or a multiple dependent claim;
C. filing a **request for continued examination**;
D. filing a notice of appeal;
E. filing a request for suspension of action;
F. mailing of a notice of allowance;
G. mailing of a final Office action;
H. completion of examination as defined in 37 CFR 41.102; or
I. abandonment of the application.

Telephone inquiries with regard to this decision should be directed to Cheryl Gibson-Baylor at (571)272-3213, Office of Petitions. In his/her absence, calls may be directed to Brian W. Brown, (571)272-5338.

Cheryl Gibson-Baylor
/Cheryl Gibson-Baylor/
[*Signature*]

Petitions Paralegal Specialist
(Title)

U.S. Patent and Trademark Office
PTO-2298 (Rev. 02-2012)

Office of Petitions: Routing Sheet



Application No. 16025667

This application is being forwarded to your office for further processing. A decision has been rendered on a petition filed in this application, as indicated below. For details of this decision, please see the document PET.OP.DEC filed on the same date as this document.

- [X] **GRANTED**
- [ ] **DISMISSED**
- [ ] **DENIED**

Office of Petitions: Decision Count Sheet

Mailing Month 8

Application No. 16025667

16025667

For US serial numbers: enter number only, no slashes or commas. Ex: 10123456
For PCT: enter "51+single digit of year of filing+last 5 numbers", Ex. for PCT/US05/12345, enter 51512345

Deciding Official: GIBSON-BAYLOR, CHERYL

Count (1) - Palm Credit 16025667

Decision: GRANT

FINANCE WORK NEEDED
☐ Select Check Box for YES

GRANT

Decision Type: 643 - Track One request

643

Notes:

Count (2)

Decision: n/a

FINANCE WORK NEEDED
☐ Select Check Box for YES

Decision Type: NONE

Notes:

Count (3)

Decision: n/a

FINANCE WORK NEEDED
☐ Select Check Box for YES

Decision Type: NONE

Notes:

Initials of Approving Official (if required)

If more than 3 decisions, attach 2nd count sheet & mark this box ☐

Printed on: 8/14/2018

Office of Petitions Internal Document - Ver. 5.0

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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
16/025,667	07/02/2018	Ahmnon D. Moskowitz	46440-0020003

CONFIRMATION NO. 5655

PUBLICATION NOTICE

26191
FISH & RICHARDSON P.C. (TC)
PO BOX 1022
MINNEAPOLIS, MN 55440-1022



Title:ZERO-PROFILE EXPANDABLE INTERVERTEBRAL SPACER DEVICES FOR DISTRACTION AND SPINAL FUSION AND A UNIVERSAL TOOL FOR THEIR PLACEMENT AND EXPANSION

Publication No.US-2018-0318103-A1
Publication Date:11/08/2018

NOTICE OF PUBLICATION OF APPLICATION

The above-identified application will be electronically published as a patent application publication pursuant to 37 CFR 1.211, et seq. The patent application publication number and publication date are set forth above.

The publication may be accessed through the USPTO's publically available Searchable Databases via the Internet at www.uspto.gov. The direct link to access the publication is currently http://www.uspto.gov/patft/.

The publication process established by the Office does not provide for mailing a copy of the publication to applicant. A copy of the publication may be obtained from the Office upon payment of the appropriate fee set forth in 37 CFR 1.19(a)(1). Orders for copies of patent application publications are handled by the USPTO's Public Records Division. The Public Records Division can be reached by telephone at (571) 272-3150 or (800) 972-6382, by facsimile at (571) 273-3250, by mail addressed to the United States Patent and Trademark Office, Public Records Division, Alexandria, VA 22313-1450 or via the Internet.

In addition, information on the status of the application, including the mailing date of Office actions and the dates of receipt of correspondence filed in the Office, may also be accessed via the Internet through the Patent Electronic Business Center at www.uspto.gov using the public side of the Patent Application Information and Retrieval (PAIR) system. The direct link to access this status information is currently https://portal.uspto.gov/pair/PublicPair. Prior to publication, such status information is confidential and may only be obtained by applicant using the private side of PAIR.

Further assistance in electronically accessing the publication, or about PAIR, is available by calling the Patent Electronic Business Center at 1-866-217-9197.

Office of Data Managment, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/025,667	07/02/2018	Ahmnon D. Moskowitz	46440-0020003	5655

26191 7590 11/14/2018

FISH & RICHARDSON P.C. (TC)
PO BOX 1022
MINNEAPOLIS, MN 55440-1022
UNITED STATES OF AMERICA

EXAMINER	
NEGRELLIRODRIGUE, CHRISTINA	

ART UNIT	PAPER NUMBER
3773	

NOTIFICATION DATE	DELIVERY MODE
11/14/2018	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary	Application No. 16/025,667	Applicant(s) MOSKOWITZ ET AL.	
	Examiner CHRISTINA NEGRELLI	Art Unit 3773	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07/17/2018*.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5)☒ Claim(s) *1-20* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1-20* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☒ The drawing(s) filed on *07/02/2018* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☒ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

4) ☐ Other: _____.

DETAILED ACTION

Claim Objections

Claims 1, 14 and 19 are objected to because of the following informalities: Claim 1, line 43, claim 14, line 42, and claim 19, line 41 recite, in part, "wherein the wedge is configured to slide within a spaced...". The phrase "spaced" should be changed to "space". Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of pre-AIA 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-14 and 16-20 rejected under pre-AIA 35 U.S.C. 102(b) as being anticipated by Vaccaro (U.S. Patent No.6,102,950).

Regarding claim 1, Vaccaro discloses an expandable intervertebral fusion device comprising: a first movable portion (rigid upper member 22) extending from a first end to a second end (see annotated Figure 2 below), wherein the first movable portion has first and second end portions (spines 50) positioned at the first and second ends, respectively, and has first and second side portions extending between the first and second end portions (Figure 2), wherein the first movable portion has a first vertebral body engagement surface (22a) and has a first interior surface positioned on an opposite side of the first movable portion than the first vertebral body engagement surface (22b); a second movable portion (rigid lower member 24) extending

from a third end to a fourth end (see annotated Figure 2 below), wherein the second movable portion has third and fourth end portions (spines 50) positioned at the third and fourth ends, respectively, and has third and fourth side portions extending between the third and fourth end portions (Figure 2), wherein the second movable portion has a second vertebral body engagement surface (24a) and has a second interior surface positioned on an opposite side of the second movable portion than the second vertebral body engagement surface (24b), wherein the first movable portion is aligned with the second movable portion such that the first end of the first movable portion is axially aligned with the third end of the second movable portion and the second end of the first movable portion is axially aligned with the fourth end of the second movable portion (Figures 4-6), wherein the first end portion of the first movable portion is hingedly connected to the third end portion of the second movable portion (resilient web 60) such that the first movable portion can pivot with respect to the second movable portion so as to move the second end portion of the first movable portion away from the fourth end portion of the second movable portion (Figure 7), wherein the second movable portion defines a slot (passages 26) in the fourth end portion between the third and fourth side portions that is sized to receive the second end portion of the first movable portion (spines 50) such that the second end of the first movable portion and the fourth end of the second movable portion are axially aligned (Figures 4-6); and a mechanism that pivotably moves the first movable portion and the second movable portion with respect to each other to expand a dimension of the expandable intervertebral fusion device, wherein the mechanism comprises: a wedge (40) extending from a fifth end to a sixth end (see annotated Figure 2 below) and having an angled wedge surface extending along at least a portion of a distance between the fifth end and the sixth end (recessed

ramp 46), wherein the wedge is positioned between the first movable portion and the second movable portion with the angled wedge surface facing the first interior surface of the first movable portion (Figure 7), wherein the first interior surface of the first movable portion has an angled movable portion surface shaped to engage the angled wedge surface of the wedge (spines 50), wherein a distance from the fifth end to the sixth end of the wedge is less than a distance from the first end to the second end of the first movable portion and is less than a distance from the third end to the fourth end of the second movable portion (Figure 7), wherein the wedge is configured to slide within a spaced defined between the first and second movable portions in a direction toward the second and fourth ends of the first and second movable portions from a first wedge position that allows the first and second movable portions to pivot to a device position that is substantially closed to a second wedge position whereby the angled wedge surface presses against the first interior surface of the first movable portion to hingedly open the first movable portion with respect to the second movable portion whereby the wedge remains axially confined within the space defined by the first and second movable portions in the first and second wedge positions (see Figure 7); and a rotation screw operably connected to the wedge (contraction mechanism 30) and to the second movable portion (at threaded aperture 34), wherein rotation of the rotation screw moves the wedge in an axially translating direction with respect to the first movable portion and the second movable portion within the space defined between the first and second movable portions (gap 70) from the first wedge position to the second wedge position (col.7, ll.65-67 and col.8, ll.1-23).

Regarding claim 2, Vaccaro further discloses wherein the first movable portion defines a first bone material receiving area between the first and second end portions and the first and

second side portions, wherein the second movable portion defines a second bone material receiving area between the third and fourth end portions and the third and fourth side portions, and wherein the first bone material receiving area is aligned with the second bone material receiving area and sized such that a path between the first and second bone material receiving areas is only partially blocked by the wedge (see passages 26 on upper and lower members 22 and 24).

Regarding claim 3, Vaccaro further discloses a means for retaining the rotation screw to the second movable portion (via threadless seat 38).

Regarding claim 4, Vaccaro further discloses a means for mating the second movable portion with prongs of a tool (via passages 26).

Regarding claim 5, Vaccaro further discloses wherein the wedge comprises a threaded hole that engages with a threaded surface around a circumferential perimeter of the rotation screw (Figure 2).

Regarding claim 6, Vaccaro further discloses first and second retaining rings connected to the rotation screw (threaded portion 82 on screw 30 and threads 35 in aperture 36) so as to retain the rotation screw in place when the rotation screw rotates.

Regarding claims 7-9, Vaccaro further discloses wherein the third and fourth side portions define first and second indentations that extend into but not through the third and fourth side portions and that are configured to be grabbed by an insertion tool (through holes 26 closest to the side portions). Vaccaro further discloses a means for gripping and inserting the device (through holes 26 closest to the side portions). Vaccaro further discloses a means for turning the rotation screw with respect to the second movable portion and the wedge (see tool T in Figure 1).

Regarding claim 10, Vaccaro further discloses a means for pivotably attaching (via resilient web 60) the first movable portion to the second movable portion (col.5, ll.46-58).

Regarding claim 11, Vaccaro further discloses wherein the first movable portion has a thickness that varies between the first end and the second end such that the first interior surface comprises a curved portion and a straight portion (Figure 6).

Regarding claim 12, Vaccaro further discloses wherein the wedge comprises opposing first and second side surfaces with first and second substantially flat portions (Figure 3), wherein the angled wedge surface extends between the first and second side surfaces and is substantially flat across the angled wedge surface from the first side surface to the second side surface (see recessed ramps 46 in Figure 3).

Regarding claim 13, Vaccaro further discloses a method of operating the device of claim 1, the method comprising: inserting the device in a target surgical location between two vertebrae of a human patient (Figure 1); and turning the rotation screw to drive the wedge against the first movable portion to push and pivot the first movable portion away from the second movable portion while the device is positioned between the vertebrae of the human patient (col.7, ll.29-67 and col.8, ll.1-23).

Regarding claim 14, Vaccaro discloses an expandable interbody device comprising: a top housing (rigid upper member 22) extending from a first end to a second end (see annotated Figure 2 below), wherein the top housing has first and second end portions positioned at the first and second ends, respectively, and has first and second side portions extending between the first and second end portions (Figure 2), wherein the top housing has a first vertebral body engagement surface (22a) that is at least partially convex (Figures 5 and 6) and has a first interior

surface positioned on an opposite side of the top housing than the first vertebral body engagement surface (22b), wherein the top housing defines at least one first bone material receiving area extending through the top housing between the first and second end portions and the first and second side portions (passages 26); a bottom housing (lower member 24) extending from a third end to a fourth end (see annotated Figure 2 below), wherein the bottom housing has third and fourth end portions positioned at the third and fourth ends, respectively, and has third and fourth side portions extending between the third and fourth end portions (Figure 2), wherein the bottom housing has a second vertebral body engagement surface (24a) that is at least partially convex (Figures 5 and 6) and has a second interior surface positioned on an opposite side of the bottom housing than the second vertebral body engagement surface (24b), wherein the bottom housing defines at least one second bone material receiving area extending through the bottom housing between the third and fourth end portions and the third and fourth side portions (passages 26), wherein the top housing is aligned with the bottom housing such that the first end of the top housing is axially aligned with the third end of the bottom housing and the second end of the top housing is axially aligned with the fourth end of the bottom housing (Figures 5 and 6), wherein the first end portion of the top housing and the third end portion of the bottom housing are hingedly interconnected (via web 60) such that the top housing can pivot with respect to the bottom housing so as to move the second end portion of the top housing away from the fourth end portion of the bottom housing (Figure 7), wherein a first length of the top housing from the first end to the second end is substantially equal to a second length of the bottom housing from the third end to the fourth end (Figures 5 and 6), and wherein the second end portion of the top housing is smaller than the fourth end portion of the bottom housing such

that the fourth end portion of the top housing is positionable between the third and fourth side portions of the bottom housing at the fourth end of the bottom housing (Figures 5 and 6); a wedge (40) extending from a fifth end to a sixth end and having an angled wedge surface extending along at least a portion of a distance between the fifth end and the sixth end (recessed ramp 46), wherein the wedge is positioned between the top housing and the bottom housing with the angled wedge surface facing the first interior surface of the top housing (Figure 7), wherein the first interior surface of the top housing has an angled housing surface shaped to engage the angled wedge surface of the wedge (bottom surface of spines 50), wherein a distance from the fifth end to the sixth end of the wedge is less than a distance from the first end to the second end of the top housing and is less than a distance from the third end to the fourth end of the bottom housing (Figure 7), wherein the wedge is configured to slide within a space defined by the top and bottom housings (gap 70) in a direction toward the second and fourth ends of the top and bottom housings from a first wedge position that allows the top and bottom housings to pivot to a housing position that is substantially closed to a second wedge position whereby the angled wedge surface presses against the first interior surface of the top housing to hingedly open the top housing with respect to the bottom housing whereby the wedge remains axially confined within the space defined by the top and bottom housings in the first and second wedge positions (see Figure 7); and a rotation screw (contraction mechanism 30) operably connected to the wedge (through tunnel 36) and to the bottom housing (through threaded aperture 34), wherein rotation of the rotation screw moves the wedge in an axially translating direction with respect to the top housing and the bottom housing within the space defined by the first and bottom housings from the first wedge position to the second wedge position (col.7, ll.65-67 and col.8, ll.1-23).

Regarding claim 16, Vaccaro further discloses wherein the top housing has a thickness that varies between the first end and the second end such that the first interior surfaces comprises a curved portion and a straight portion (Figures 5 and 6).

Regarding claim 17, Vaccaro further discloses a means for attaching (via web 60) the first end portion of the top housing to the third end portion of the bottom housing (col.5, ll.46-58).

Regarding claim 18, Vaccaro further discloses a method of operating the device of claim 14, the method comprising: inserting the device in a target surgical location between two vertebra of a human patient (Figure 1); and turning the rotation screw to drive the wedge to pivot the top housing away from the bottom housing while the device is positioned between the vertebrae of the human patient (col.7, ll.29-67 and col.8, ll.1-23).

Regarding claim 19, Vaccaro also discloses an expandable interbody device comprising: a first housing (rigid upper member 22) extending from a first end to a second end (see annotated Figure 2 below), wherein the first housing has first and second end portions positioned at the first and second ends, respectively, and has first and second side portions extending between the first and second end portions (Figure 2), wherein the first housing has a first vertebral body engagement surface (22a) and has a first interior surface positioned on an opposite side of the first housing than the first vertebral body engagement surface (22b), wherein the first housing defines a first bone material receiving area between the first and second end portions and the first and second side portions (through passages 26); a second housing (lower member 24) extending from a third end to a fourth end (see annotated Figure 2 below), wherein the second housing has third and fourth end portions positioned at the third and fourth ends, respectively, and has third

and fourth side portions extending between the third and fourth end portions (Figure 2), wherein the second housing has a second vertebral body engagement surface (24a) and has a second interior surface positioned on an opposite side of the second housing than the second vertebral body engagement surface (24b), wherein the second housing defines a second bone material receiving area between the third and fourth end portions and the third and fourth side portions (through passages 26), wherein the third and fourth side portions define first and second indentations configured to be grabbed by an insertion tool (passages 26 closer to the side portions), wherein the first housing is aligned with the second housing such that the first end of the first housing is axially aligned with the third end of the second housing and the second end of the first housing is axially aligned with the fourth end of the second housing (Figures 5 and 6), wherein the first end portion of the first housing is hingedly connected to the third end portion of the second housing (at web 60) such that the first housing can pivot with respect to the second housing so as to move the second end portion of the first housing away from the fourth end portion of the second housing (Figure 7), wherein the second housing defines a slot in the fourth end portion between the third and fourth side portions that is sized to receive the second end portion of the first housing (spines 50 are identical on both upper and lower members 22 and 24, and thus are sized to receive each other as they flex inward or outward) such that he second end of the first housing and the fourth end of the second housing are axially aligned (Figures 5 and 6); a wedge (40) extending from a fifth end to a sixth end (see annotated Figure 2 below) with an angled wedge surface extending along a portion of a distance between the fifth end and the sixth end(recessed ramp 46) and with first and second opposing side surfaces on opposite sides of the angled wedge surface (Figure 2), wherein the wedge is positioned between the first housing and

the second housing with the angled wedge surface facing the first interior surface of the first housing (Figure 7), wherein the first interior surface of the first housing has an angled housing surface shaped to engage the angled wedge surface of the wedge (bottom sides of spines 50), wherein a distance from the fifth end to the sixth end of the wedge is less than a distance from the first end to the second end of the first housing and is less than a distance from the third end to the fourth end of the second housing (Figure 7), wherein the wedge is configured to slide within a space defined between the first and second housings (70) in a direction toward the second and fourth ends of the first and second housings from a first wedge position that allows the first and second housings to pivot to a housing position that is substantially closed to a second wedge position whereby the angled wedge surface presses against the first interior surface of the first housing to hingedly open the first housing with respect to the second housing whereby the wedge remains axially confined within the space defined between the first and second housings in the first and second wedge positions (Figure 7); and a rotation screw (30) operably connected to the wedge and to the second housing, wherein rotation of the rotation screw moves the wedge in an axially translating direction with respect to the first housing and the second housing within the space defined between the first and second housings from the first wedge position to the second wedge position (col.7, ll.65-67 and col.8, ll.1-23).

Regarding claim 20, Vaccaro further discloses a means for attaching (via web 60) the first end of the first housing to the third end of the second housing (col.5, ll.46-58) and wherein the system further comprises: means for gripping and inserting the device (passages 26 closer to the side portions are configured to be grabbed by an insertion tool); and means for turning the rotation screw with respect to the second movable portion and the wedge (see tool T in Figure 1).

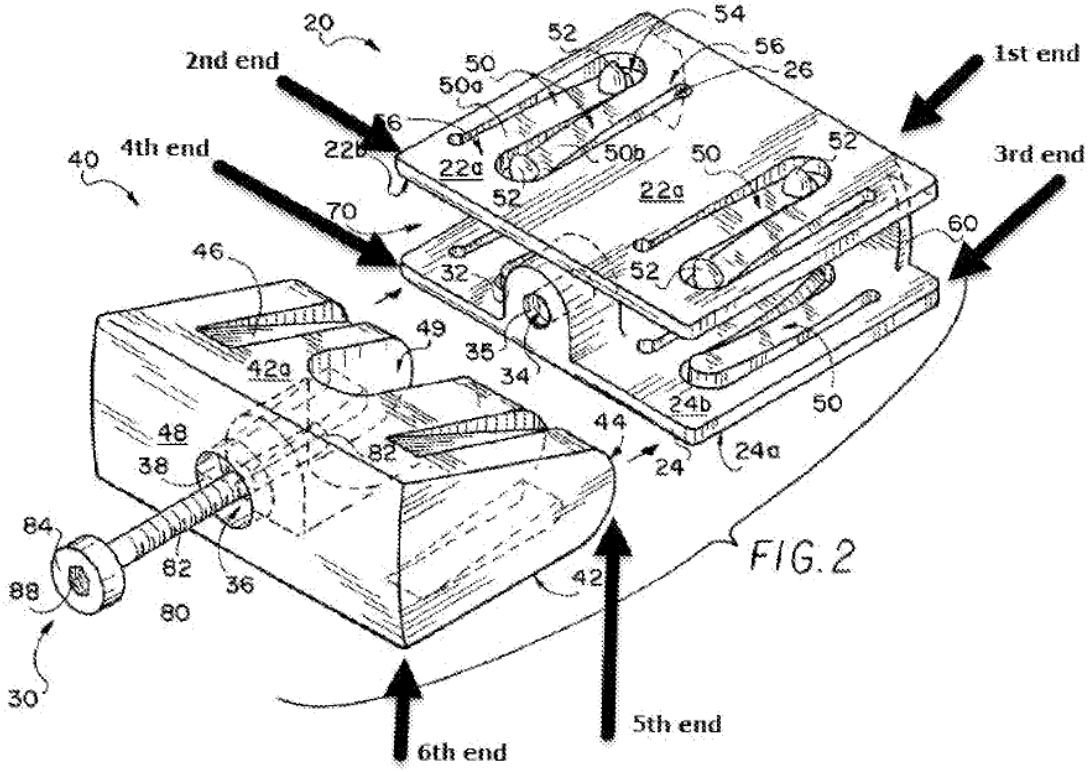


FIG. 2

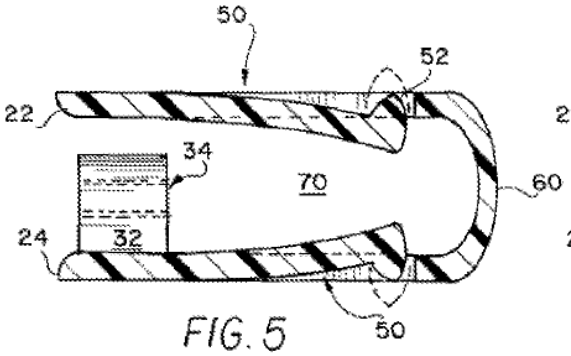


FIG. 5

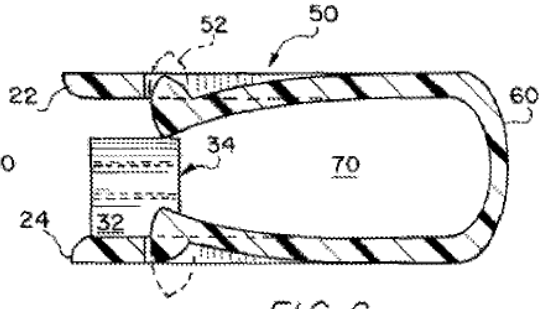


FIG. 6

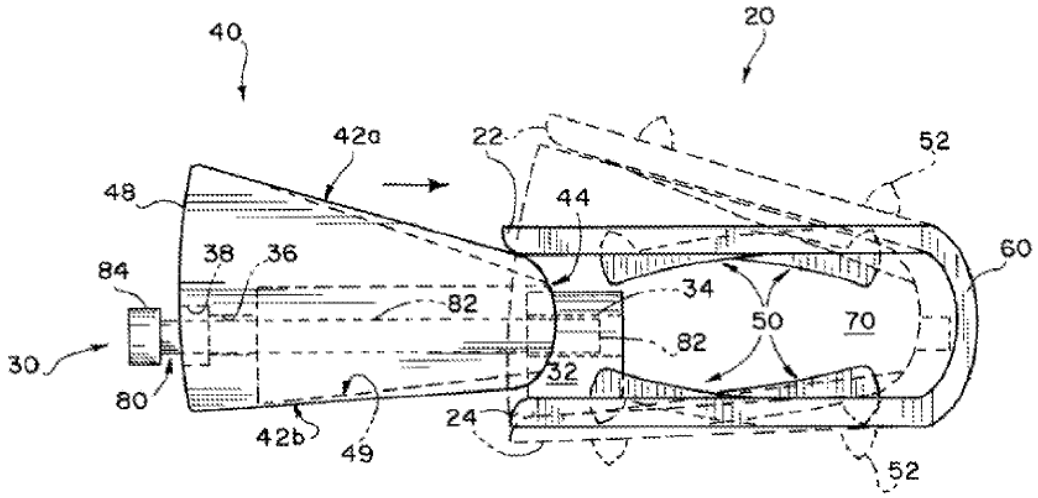


FIG. 7

Claim Rejections - 35 USC § 103

The following is a quotation of pre-AIA 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 15 is rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Vaccaro (U.S. Patent No.6,102,950) in view of Suddaby (U.S. Patent No.7,044,971 B2).

Regarding claim 15, Vaccaro discloses the claimed invention, as discussed above, except for w herein the first end portion of the top housing and the third end portion of the bottom housing are hingedly interconnected via at least two pins. However, Suddaby discloses hingedly connecting a first end portion of a top housing and a third end portion of a bottom housing with

at least two pins (see hinge pins 20 in Figure 1). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the connection between Vaccaro's upper and lower members to be interconnected via two pins, as taught by Suddaby, since hinge pins are a common means of joining members together.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christina Negrelli whose telephone number is (571)270-7389. The examiner can normally be reached on Monday-Friday, between 8:00am to 4:00pm. If attempts to reach the examiner by telephone are unsuccessful, ***please contact*** **the examiner's supervisor, Eduardo Robert,** ***at*** **(571) 272-4719**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/CHRISTINA NEGRELLI/

Examiner, Art Unit 3733

/JULIANNA N HARVEY/

Primary Examiner, Art Unit 3773

Notice of References Cited	Application/Control No. 16/025,667	Applicant(s)/Patent Under Reexamination MOSKOWITZ ET AL.	
	Examiner CHRISTINA NEGRELLI	Art Unit 3773	Page 1 of 1

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*	B	US-7,044,971 B2	05-2006	Suddaby; Loubert	A61F2/28	623/17.11
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	D	US-				
	E	US-				
	F	US-				
	G	US-				
	H	US-				
	I	US-				
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	K	US-				
	L	US-				
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	Examiner	Art Unit
	CHRISTINA NEGRELLIRODRIGUE	3773

CPC- SEARCHED		
Symbol	Date	Examiner
A61F2/442, A61F2/4425, A61F2002/443, A61F2/4455	11/7/2018	CN

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner
606	246-249	11/7/2018	CN
623	17.11-17.16	11/7/2018	CN

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SEARCH NOTES		
Search Notes	Date	Examiner
Inventor Name Search	11/7/2018	CN
EAST Search History	11/7/2018	CN

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner

/CHRISTINA NEGRELLIRODRIGUE/ Examiner.Art Unit 3773	/JULIANNA N HARVEY/ Primary Examiner, Art Unit 3773

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CONFIRMATION NO. 5655

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16/025,667	07/02/2018 RULE	623	3773	46440-0020003

APPLICANTS
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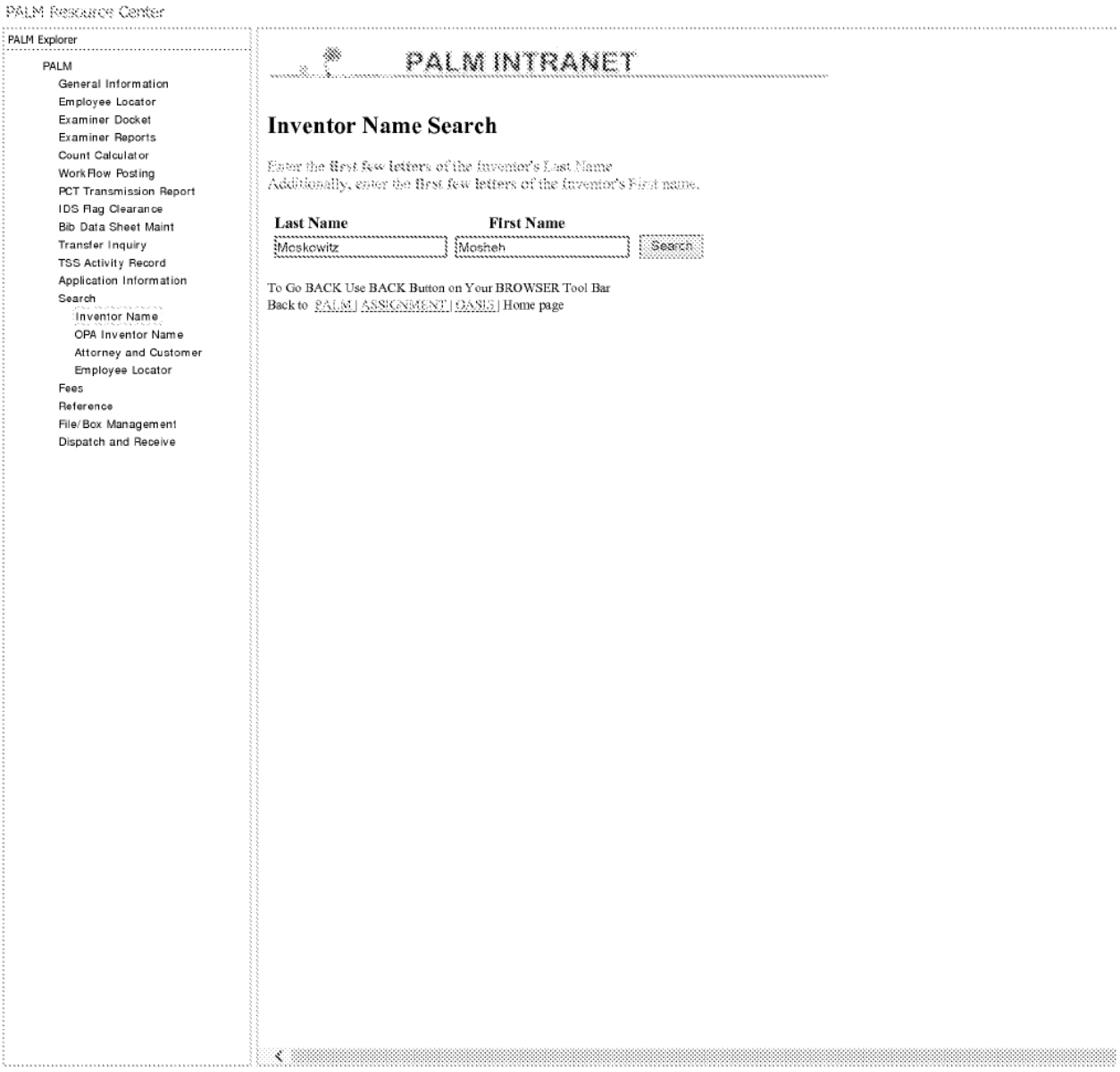
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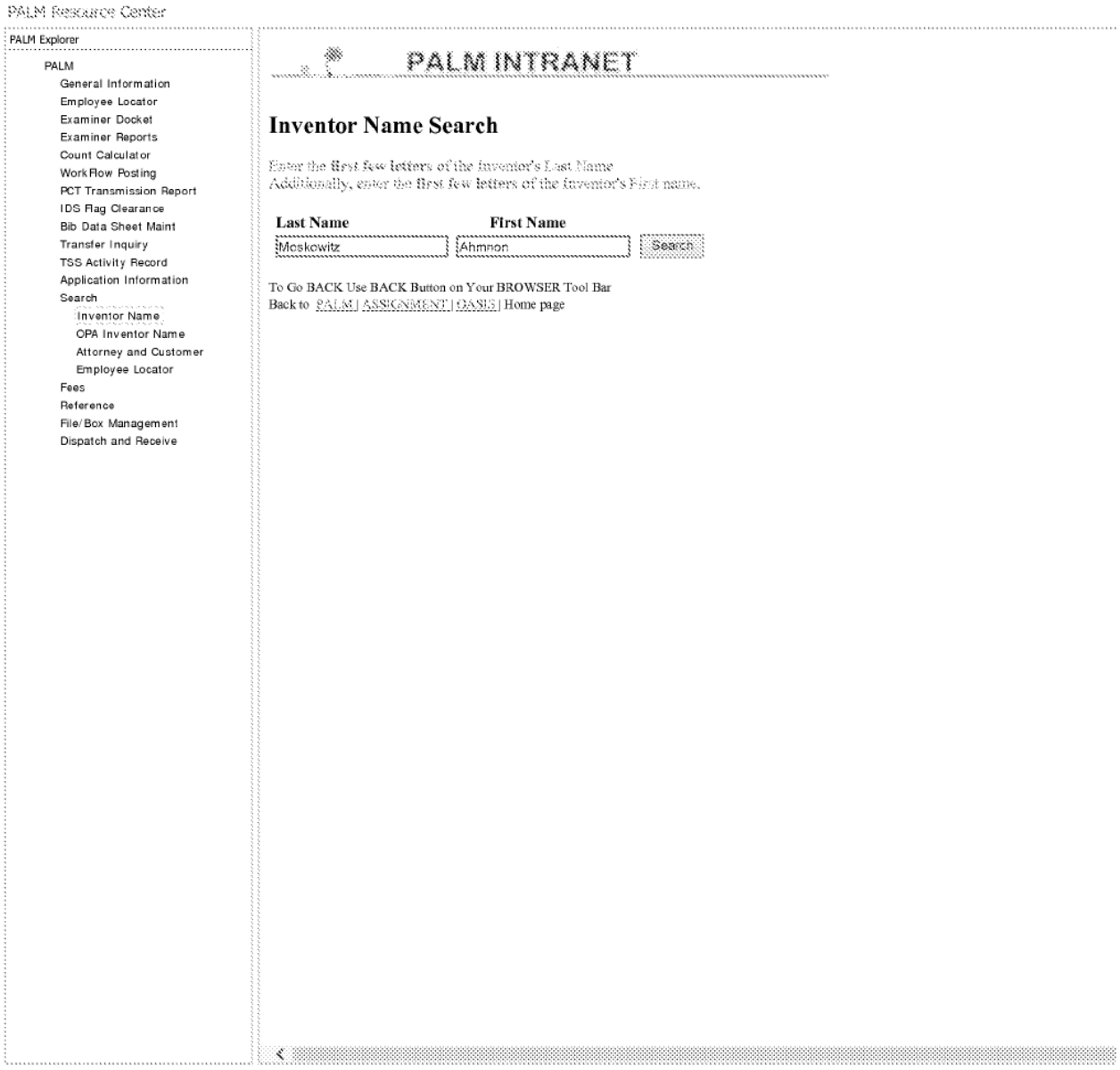
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which claims benefit of 60/670,231 04/12/2005

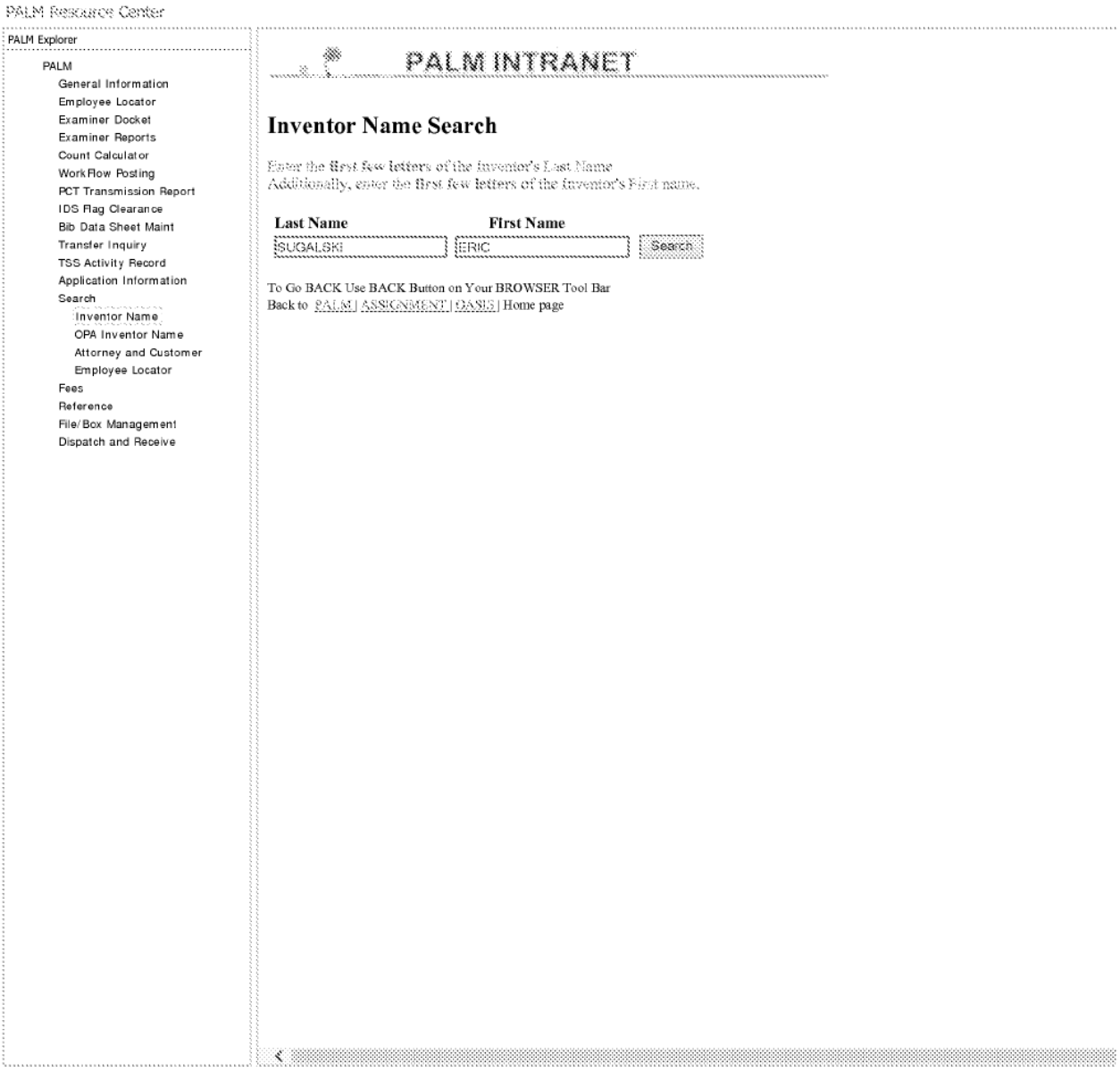
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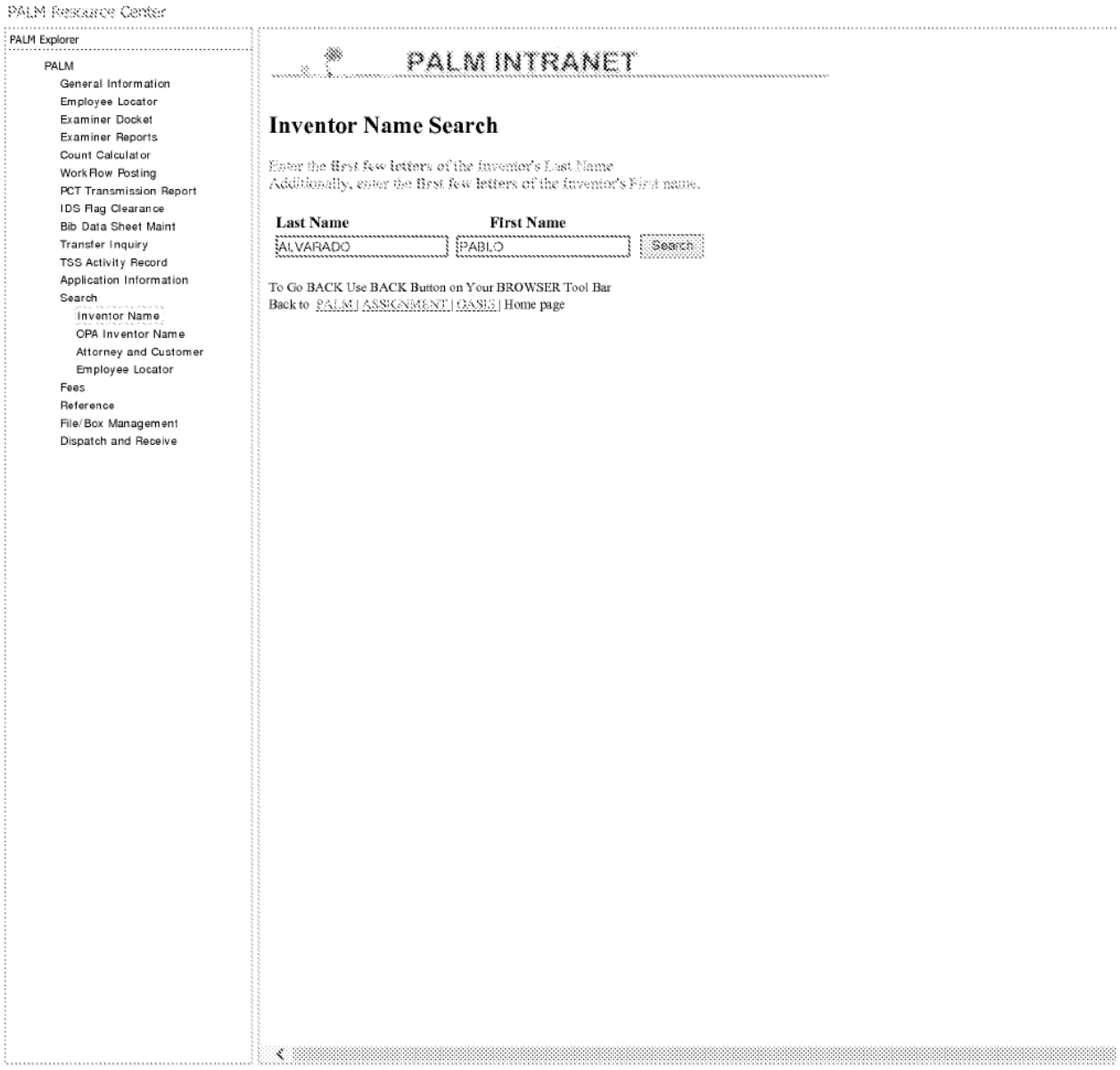
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EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L2	195	(MOSKOWITZ NEAR2 AHMNON).in. or (MOSKOWITZ NEAR2 MOSHEH).in. or (MOSKOWITZ NEAR2 MATHAN).in. or (ALVARADO NEAR2 PABLO).in. or (SUGALSKI NEAR2 ERIC).in.	US-PGPUB; USPAT; USOCR	OR	ON	2018/11/07 22:19
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S19	713	606/249.ccls.	US-PGPUB; USPAT; USOCR	OR	OFF	2018/11/07 16:09
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11/7/2018 10:23:49 PM
C:\Users\cnegrelli\Documents\EAST\Workspaces\16025667.wsp

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16025667	MOSKOWITZ ET AL.
	Examiner	**Art Unit**
	CHRISTINA NEGRELLIRODRIGUE	3773

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	11/07/2018								
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	2	✓								
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	18	✓								
	19	✓								
	20	✓								

Substitute Disclosure Form / U.S. Department of Commerce Patent and Trademark Office	Attorney Docket No.	Application No.
Information Disclosure Statement by Applicant (Use several sheets if necessary) (37 CFR §1.98(b))	46440-0020003	16/025,667
	Applicant: Moskowitz Family LLC	
	Filing Date: July 2, 2018	Group Art Unit

U.S. Patent Documents

Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	1.	2360942	1944-10-24	ELLERSTEIN			
	2.	4064881	1977-12-27	Meredith			
	3.	4554914	1985-11-26	Kapp et al.			
	4.	4599086	1986-07-08	DOTY			
	5.	4636217	1987-01-13	Ogilvie et al.			
	6.	4904261	1990-02-27	Dove et al.			
	7.	4960420	1990-10-02	Goble et al.			
	8.	4997432	1991-03-05	Keller			
	9.	5005749	1991-04-09	Aranyi			
	10.	5062850	1991-11-05	MACMILLAN et al.			
	11.	5123926	1992-06-23	Pisharodi			
	12.	5290312	1994-03-01	KOJIMOTO et al.			
	13.	5405391	1995-04-11	Henderson et al.			
	14.	5413583	1995-05-09	Wohlers			
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	17.	5660188	1997-08-26	Groiso			
	18.	5667472	1997-09-07	Finn et al.			
	19.	5713912	1998-02-03	Porter			
	20.	5782832	1998-07-21	Larsen et al.			
	21.	5865848	1999-02-02	Baker			
	22.	5888223	1999-03-30	Bray, Jr.			
	23.	5916224	1999-06-29	Esplin			
	24.	5951574	1999-09-14	Stefanchik et al.			
	25.	5960522	1999-10-05	Boe			
	26.	5968054	1999-10-19	Yeatts et al.			

Examiner Signature	Date Considered
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EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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U.S. Patent Documents

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	27.	5976136	1999-11-02	Bailey et al.			
	28.	6126689	2000-10-03	Brett			
	29.	6224602	5/1/2001	Hayes			
	30.	6235034	5/22/2001	Bray			
	31.	6322562	11/27/2001	Wolter			
	32.	6342074	2002-01-29	Simpson			
	33.	6368350	2002-04-09	Erickson et al.			
	34.	6375682	2002-04-23	Fleischmann et al.			
	35.	20020068977	2002-06-06	JACKSON			
	36.	6419704	2002-07-16	Ferree			
	37.	6432106	2002-08-13	Fraser			
	38.	6454807	09-2002	Jackson			
	39.	6458159	2002-10-01	Thalgott			
	40.	20020143338	2002-10-03	ORBAYet al.			
	41.	6527804	2003-03-04	Gauchet et al.			
	42.	6533818	2003-03-18	Weber et al.			
	43.	6558423	2003-05-06	Michelson			
	44.	6572653	2003-06-03	Simonson			
	45.	6579318	2003-06-17	Varga et al.			
	46.	6582468	2003-06-24	Gauchet			
	47.	20030130737	2003-07-10	MCGAHAN et al.			
	48.	6613055	2003-09-02	Di Emidio			
	49.	6629998	2003-10-07	Lin			
	50.	6641614	2003-11-04	Wagner et al.			
	51.	6655243	2003-12-02	Anderson et al.			
	52.	6716247	4/6/2004	Michelson			

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	Filing Date: July 2, 2018	Group Art Unit

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	54.	6723126	2004-04-20	Berry			
	55.	20040088054	2004-05-06	Berry			
	56.	6733532	2004-05-11	Gauchet et al.			
	57.	6764491	2004-07-20	Frey et al.			
	58.	6770094	2004-08-03	Fehling et al.			
	59.	20040177531	2004-09-16	DiBenedetto et al.			
	60.	20040186569	9/23/2004	Berry			
	61.	20040193272	2004-09-30	Zubok et al.			
	62.	20040220571	2004-11-04	Assaker et al.			
	63.	6824564	2004-11-30	Crozet			
	64.	20040254644	2004-12-16	Taylor			
	65.	20050027362	2005-02-03	Williams et al.			
	66.	6852117	2005-02-08	Orlowski			
	67.	20050049590	2005-03-03	Alleyne et al.			
	68.	6890355	5/10/2005	Michelson			
	69.	6904308	2005-06-07	Frisch et al.			
	70.	20050177235	2005-08-11	BAYNHAM et al.			
	71.	20050216084	2005-09-29	Fleischmann			
	72.	6953477	2005-10-11	BERRY			
	73.	6955671	2005-10-18	Uchikubo			
	74.	6962606	2005-11-08	MICHELSON			
	75.	20050256576	11/17/2005	Moskowitz et al.			
	76.	20050261769	11/24/2005	Moskowitz et al.			
	77.	6972019	2005-12-06	Michelson			
	78.	20050273170	2005-12-08	Navarro et al.			

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	Applicant: Moskowitz Family LLC	
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	79.	6974480	2005-12-13	Messerli et al.			
	80.	20050278026	2005-12-15	Gordon, et al.			
	81.	7030904	2006-04-18	Adair et al.			
	82.	7033394	2006-04-25	Michelson			
	83.	7037258	2006-05-02	Chatenever et al.			
	84.	20060155285	2006-07-13	Anderson			
	85.	7077864	2006-07-18	Byrd et al.			
	86.	7097615	2006-08-29	Banik et al.			
	87.	20060241621	10/26/2006	Moskowitz et al.			
	88.	7135043	2006-11-14	NAKAHARA et al.			
	89.	2007/0049943	3/1/2007	Moskowitz et al.			
	90.	7211112	2007-05-01	Baynham et al.			
	91.	7232464	2007-06-19	Mathieu et al.			
	92.	7238203	2007-07-03	Bagga et al.			
	93.	20070167678	7/19/2007	Moskowitz et al.			
	94.	20070198089	8/23/2007	Moskowitz et al.			
	95.	20070213820	2007-09-13	MAGERL et al			
	96.	20070250167	2007-10-25	BRAY et al.			
	97.	2007/0250172	10/25/2007	Moskowitz et al.			
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	99.	7326248	2008-02-05	Michelson			
	100.	2008/0033440	2/7/2008	Moskowitz et al.			
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	103.	20080249575	2008-10-09	Waugh et al.			
	104.	20080249569	2008-10-09	Waugh et al.			

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Substitute Disclosure Form / U.S. Department of Commerce Patent and Trademark Office	Attorney Docket No.	Application No.
Information Disclosure Statement by Applicant (Use several sheets if necessary) (37 CFR §1.98(b))	46440-0020003	16/025,667
	Applicant: Moskowitz Family LLC	
	Filing Date: July 2, 2018	Group Art Unit

U.S. Patent Documents

Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	105.	20080249625	2008-10-09	Waugh et al.			
	106.	7442299	2008-10-28	Lee et al.			
	107.	7442209	2008-10-28	Michelson			
	108.	20080281425	2008-11-13	THALGOTT et al.			
	109.	20080281424	11/13/2008	Parry et al.			
	110.	20090030520	2009-01-29	BIEDERMANN et al.			
	111.	20090080997	2009-03-26	JOHNSON			
	112.	20090105831	2009-04-23	Jones et al.			
	113.	20090105830	2009-04-23	Jones et al.			
	114.	20090105831	4/23/2009	Jones et al.			
	115.	20090112271	4/30/2009	Moskowitz et al.			
	116.	20090182430	2009-07-16	TYBER et al.			
	117.	20090187218	2009-07-23	Schaffhausen			
	118.	20090210062	2009-08-20	THALGOTT et al.			
	119.	2009/0224023	9/10/2009	Moskowitz et al.			
	120.	2009/0234455	9/17/2009	Moskowitz et al.			
	121.	7615059	2009-11-10	Watschke et al.			
	122.	7618456	2009-11-17	Mathieu et al.			
	123.	7628816	2009-12-08	Magerl et al.			
	124.	7704279	2010-04-27	MOSKOWITZ et al.			
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	126.	20100145460	2010-06-10	McDonough et al.			
	127.	7776093	2010-08-17	Wolek et al.			
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	129.	7799081	09-2010	McKinley			
	130.	7803162	2010-09-28	MARNAY et al.			

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U.S. Patent Documents

Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
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	132.	20100305704	2010-12-02	Messerli et al.			
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	134.	2010/0324606	12/23/2010	Moskowitz et al.			
	135.	7862616	2011-01-04	Lechmann et al.			
	136.	7887591	2011-02-15	Aebi et al.			
	137.	7942903	2011-05-17	MOSKOWITZ et al.			
	138.	2011/0125269	5/26/2011	Moskowitz et al.			
	139.	2011/0137349	6/9/2011	Moskowitz et al.			
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	141.	7972363	2011-07-05	Moskowitz et al.			
	142.	2011/0178600	7/21/2011	Moskowitz et al.			
	143.	7985255	2011-07-26	BRAY et al.			
	144.	20110208312	8/25/2011	Moskowitz et al.			
	145.	8029512	2011-10-04	Paltzer			
	146.	8034060	2011-10-11	Keren et al.			
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	151.	2011/0319935	12/29/2011	Moskowitz et al.			
	152.	2012/0010714	1/12/2012	Moskowitz et al.			
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	154.	8114162	2012-02-14	BRADLEY			
	155.	8137405	2012-03-20	KOSTUIK et al.			
	156.	8167949	2012-05-01	TYBER et al.			

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	158.	8273127	2012-09-25	Jones et al.			
	159.	20120271423	2012-10-25	Wallenstein et al.			
	160.	20120277870	2012-11-01	Wolters et al.			
	161.	8328872	2012-12-11	Duffield et al.			
	162.	20120323330	2012-12-20	Kueenzi et al.			
	163.	2012/0330419	12/27/2012	Moskowitz et al.			
	164.	8353913	2013-01-15	Moskowitz et al.			
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	167.	2013/0018470	1/17/2013	Moskowitz et al.			
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	170.	2013/0053962	2/28/2013	Moskowitz et al.			
	171.	20130060339	2013-03-07	Duffield et al.			
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	173.	8403986	2013-03-26	Michelson			
	174.	8414651	2013-04-09	TYBER et al.			
	175.	8419797	2013-04-16	Biedermann et al.			
	176.	8425607	2013-04-23	Waugh et al.			
	177.	20130173002	7/4/2013	Moskowitz et al.			
	178.	8535380	09-2013	Greenhalgh			
	179.	8540774	2013-09-24	KUEENZI et al.			
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	181.	8613761	2013-12-24	Lindemann et al.			
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	184.	2014/0249629	9/4/2014	Moskowitz et al.			
	185.	2015/0025637	1/22/2015	Moskowitz et al.			
	186.	2015/0105824	4/16/2015	Moskowitz et al.			
	187.	2015/0148847	5/28/2015	Moskowitz et al.			
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	198.	20120271419	10/25/2012	Marik			
	199.	20120277865	11/1/2012	Trieu et al.			
	200.	20130158663	6/20/2013	Miller et al.			
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	203.	8398713	3/19/2013	Weiman			
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	207.	8845731	9/30/2014	Weiman			
	208.	8845732	9/30/2014	Weiman			

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	215.	8888853	11/18/2014	Glerum et al.			
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	236.	7214243	5/8/2007	Taylor et al.			
	237.	7320555	1/22/2008	Chang et al.			
	238.	7410501	8/12/2008	Michelson			
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	241.	7655046	2/2/2010	Dryer et al.			
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	245.	7828849	11/9/2010	Lim			
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	255.	8187332	5/29/2012	McLuen			
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	260.	8523944	9/3/2013	Jimenez et al.			

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	270.	8940049	1/27/2015	Jimenez et al.			
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	272.	9119730	9/1/2015	Glerum et al.			
	273.	20020068976	6/6/2002	Jackson			
	274.	20040010315	1/15/2004	Song			
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	284.	20090112319	4/30/2009	O'Neil et al.			
	285.	20090171461	7/2/2009	Conner et al.			
	286.	20090292361	11/26/2009	Lopez et al.			

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	288.	20100057208	3/4/2010	Dryer et al.			
	289.	20100204795	8/12/2010	Greenhalgh			
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	291.	20100286783	12/24/2010	Ueda			
	292.	20100292796	11/18/2010	Greenhalgh et al.			
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	294.	20110029082	2/3/2011	Hall			
	295.	20110054621	3/3/2011	Lim			
	296.	20110093074	4/21/2011	Glerum et al.			
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	307.	20140121774	5/1/2014	Glerum et al.			
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	311.	9,445,919	9/2016	Palmatier			

Foreign Patent Documents or Published Foreign Patent Applications

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Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation Yes	Translation No
	312.	WO 2004/093749	2004-11-04	WO			English Abstract	
	313.	WO 2006/091503	2006-08-31	WO				
	314.	2727003	1996-05-24	FR			English Abstract	

Other Documents (include Author, Title, Date, and Place of Publication)		
Examiner Initial	Desig. ID	Document
	315.	Vincent C. TRAYNELIS, "Prosthetics and Biologics: The Wave of the Future," CLINICAL NEUROSURGERY, Volume 50, Proceedings of the Congress of Neurological Surgeons, Philadelphia, PA 2002, Chapter 9, pages 207-219
	316.	E.K. WAI et al., "Disk Replacement Arthroplasties: Can The Success of Hip and Knee Replacements be Repeated in the Spine?," Seminars in Spine Surgery, Vol. 15, No. 4 (December) 2003, pp 473-482
	317.	Richard D. GUYER et al., "Intervertebral Disc Prostheses," SPINE JOURNAL, Volume 28, Number 15S, Supp. To 8/1/03, pages S15-S23
	318.	DIETER GROB et al.. "Clinical Experience With the Dynesys Semirigid Fixation System for the Lumbar Spine," SPINE, Vol. 30, No. 3, 2005, pp. 324-331
	319.	International Search Report (ISR) and Written Opinion of the International Searching Authority, 03 December 2007, International Application No. PCT/US 07/05005
	320.	International Search Report (ISR) and Written Opinion of the International Searching Authority, 21 May 2008, International Application No. PCT/US2007/021015
	321.	International Search Report (ISR) and Written Opinion of the International Searching Authority, 09 July 2008, International Application No. PCT/US2007021013

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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 16/025,667	Filing Date 07/02/2018	☐ To be Mailed

ENTITY: ☐ LARGE ☑ SMALL ☐ MICRO

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA		RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A		N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A		N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*		x $50 =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*		x $230 =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).				
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))					
* If the difference in column 1 is less than zero, enter "0" in column 2.				TOTAL	

APPLICATION AS AMENDED - PART II

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT	01/29/2019	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 20	Minus	** 20	= 0		x $50 =	0
	Independent (37 CFR 1.16(h))	* 3	Minus	*** 3	= 0		x $230 =	0
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	0

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=		x $0 =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=		x $0 =	
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.	LIE
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".	/ANTJUAN M RIVERA/
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This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor	:	Ahmnon D. Moskowitz	Art Unit	:	3773
Application No.	:	16/025,667	Examiner	:	Christina Negrellirodrigue
Filed	:	July 2, 2018	Conf. No.	:	5655
Title	:	ZERO-PROFILE EXPANDABLE INTERVERTEBRAL SPACER DEVICES FOR DISTRACTION AND SPINAL FUSION AND A UNIVERSAL TOOL FOR THEIR PLACEMENT AND EXPANSION			

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REPLY TO ACTION OF NOVEMBER 14, 2018

Please consider the following reply.

Amendments to Claims:

1. (Currently Amended) An expandable intervertebral fusion device comprising:

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

a second movable portion extending from a third end to a fourth end, wherein the second movable portion has third and fourth end portions positioned at the third and fourth ends, respectively, and has third and fourth side portions extending between the third and fourth end portions, wherein the second movable portion has a second vertebral body engagement surface and has a second interior surface positioned on an opposite side of the second movable portion than the second vertebral body engagement surface, wherein the first movable portion is aligned with the second movable portion such that the first end of the first movable portion is axially aligned with the third end of the second movable portion and the second end of the first movable portion is axially aligned with the fourth end of the second movable portion, wherein the first end portion of the first movable portion is hingedly connected to the third end portion of the second movable portion such that the first movable portion can pivot with respect to the second movable portion so as to move the second end portion of the first movable portion away from the fourth end portion of the second movable portion, wherein the second movable portion defines a slot in the fourth end portion between the third and fourth side portions that is sized to receive the second end portion of the first movable portion such that the second end of the first movable portion and the fourth end of the second movable portion are axially aligned; and

a mechanism that pivotably moves the first movable portion and the second movable portion with respect to each other to expand a dimension of the expandable intervertebral fusion device, wherein the mechanism comprises:

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

a rotation screw operably connected to the wedge and to the second movable portion, wherein rotation of the rotation screw moves the wedge in an axially translating direction with respect to the first movable portion and the second movable portion within the space defined between the first and second movable portions from the first wedge position to the second wedge position.

2. (Previously Presented) The device of claim 1, wherein the first movable portion defines a first bone material receiving area between the first and second end portions and the first and second side portions, wherein the second movable portion defines a second bone material receiving area between the third and fourth end portions and the third and fourth side portions, and wherein the first bone material receiving area is aligned with the second bone material receiving area and sized such that a path between the first and second bone material receiving areas is only partially blocked by the wedge.

3. (Previously Presented) The device of claim 1, and further comprising means for retaining the rotation screw to the second movable portion.

4. (Previously Presented) The device of claim 1, and further comprising means for mating the second movable portion with prongs of a tool.

5. (Previously Presented) The device of claim 1, wherein the wedge comprises a threaded hole that engages with a threaded surface around a circumferential perimeter of the rotation screw.

6. (Previously Presented) The device of claim 1, and further comprising first and second retaining rings connected to the rotation screw so as to retain the rotation screw in place when the rotation screw rotates.

7. (Previously Presented) The device of claim 1, wherein the third and fourth side portions define first and second indentations that extend into but not through the third and fourth side portions and that are configured to be grabbed by an insertion tool.

8. (Previously Presented) A system comprising the device of claim 7, wherein the system further comprises:

means for gripping and inserting the device.

9. (Previously Presented) The system of claim 8, and further comprising:

means for turning the rotation screw with respect to the second movable portion and the wedge.

10. (Previously Presented) The device of claim 1, and further comprising:

means for pivotably attaching the first movable portion to the second movable portion.

11. (Previously Presented) The device of claim 1, wherein the first movable portion has a thickness that varies between the first end and the second end such that the first interior surface comprises a curved portion and a straight portion.

12. (Previously Presented) The device of claim 1, wherein the wedge comprises opposing first and second side surfaces with first and second substantially flat portions, wherein the angled wedge surface extends between the first and second side surfaces and is substantially flat across the angled wedge surface from the first side surface to the second side surface.

13. (Previously Presented) A method of operating the device of claim 1, the method comprising:

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

turning the rotation screw to drive the wedge against the first movable portion to push and pivot the first movable portion away from the second movable portion while the device is positioned between the vertebrae of the human patient.

14. (Currently Amended) An expandable interbody device comprising:

a top housing extending from a first end to a second end, wherein the top housing has first and second end portions positioned at the first and second ends, respectively, and has first and second side portions extending between the first and second end portions, wherein the top housing has a first vertebral body engagement surface

that is at least partially convex and has a first interior surface positioned on an opposite side of the top housing than the first vertebral body engagement surface, wherein the top housing defines at least one first bone material receiving area extending through the top housing between the first and second end portions and the first and second side portions;

a bottom housing extending from a third end to a fourth end, wherein the bottom housing has third and fourth end portions positioned at the third and fourth ends, respectively, and has third and fourth side portions extending between the third and fourth end portions, wherein the bottom housing has a second vertebral body engagement surface that is at least partially convex and has a second interior surface positioned on an opposite side of the bottom housing than the second vertebral body engagement surface, wherein the bottom housing defines at least one second bone material receiving area extending through the bottom housing between the third and fourth end portions and the third and fourth side portions, wherein the top housing is aligned with the bottom housing such that the first end of the top housing is axially aligned with the third end of the bottom housing and the second end of the top housing is axially aligned with the fourth end of the bottom housing, wherein the first end portion of the top housing and the third end portion of the bottom housing are hingedly interconnected such that the top housing can pivot with respect to the bottom housing so as to move the second end portion of the top housing away from the fourth end portion of the bottom housing, wherein a first length of the top housing from the first end to the second end is substantially equal to a second length of the bottom housing from the third end to the fourth end, and wherein the second end portion of the top housing is smaller than the fourth end portion of the bottom housing such that the ~~fourth~~ second end portion of the top housing is positionable between the third and fourth side portions of the bottom housing at the fourth end of the bottom housing;

a wedge extending from a fifth end to a sixth end and having an angled wedge surface extending along at least a portion of a distance between the fifth end and the sixth end, wherein the wedge is positioned between the top housing and the bottom

housing with the angled wedge surface facing the first interior surface of the top housing, wherein the first interior surface of the top housing has an angled housing surface shaped to engage the angled wedge surface of the wedge, wherein a distance from the fifth end to the sixth end of the wedge is less than a distance from the first end to the second end of the top housing and is less than a distance from the third end to the fourth end of the bottom housing, wherein the wedge is configured to slide within a ~~spaced~~ space defined by the top and bottom housings in a direction toward the second and fourth ends of the top and bottom housings from a first wedge position that allows the top and bottom housings to pivot to a housing position that is substantially closed to a second wedge position whereby the angled wedge surface presses against the first interior surface of the top housing to hingedly open the top housing with respect to the bottom housing whereby the wedge remains axially confined within the space defined by the top and bottom housings in the first and second wedge positions; and

a rotation screw operably connected to the wedge and to the bottom housing, wherein rotation of the rotation screw moves the wedge in an axially translating direction with respect to the top housing and the bottom housing within the space defined by the first and bottom housings from the first wedge position to the second wedge position.

15. (Previously Presented) The device of claim 14, wherein the first end portion of the top housing and the third end portion of the bottom housing are hingedly interconnected via at least two pins.

16. (Previously Presented) The device of claim 14, wherein the top housing has a thickness that varies between the first end and the second end such that the first interior surface comprises a curved portion and a straight portion.

17. (Previously Presented) The device of claim 14, and further comprising means for attaching the first end portion of the top housing to the third end portion of the bottom housing.

18. (Previously Presented) A method of operating the device of claim 14, the method comprising:

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

turning the rotation screw to drive the wedge to pivot the top housing away from the bottom housing while the device is positioned between the vertebrae of the human patient.

19. (Currently Amended) An expandable interbody device comprising:

a first housing extending from a first end to a second end, wherein the first housing has first and second end portions positioned at the first and second ends, respectively, and has first and second side portions extending between the first and second end portions, wherein the first housing has a first vertebral body engagement surface and has a first interior surface positioned on an opposite side of the first housing than the first vertebral body engagement surface, wherein the first housing defines a first bone material receiving area between the first and second end portions and the first and second side portions;

a second housing extending from a third end to a fourth end, wherein the second housing has third and fourth end portions positioned at the third and fourth ends, respectively, and has third and fourth side portions extending between the third and fourth end portions, wherein the second housing has a second vertebral body engagement surface and has a second interior surface positioned on an opposite side of the second housing than the second vertebral body engagement surface, wherein the second housing defines a second bone material receiving area between the third and fourth end portions and the third and fourth side portions, wherein the third and fourth side portions define first and second indentations configured to be grabbed by an insertion tool, wherein the first housing is aligned with the second housing such that the first end of the first housing is axially aligned with the third end of the second housing and the second end of the first

housing is axially aligned with the fourth end of the second housing, wherein the first end portion of the first housing is hingedly connected to the third end portion of the second housing such that the first housing can pivot with respect to the second housing so as to move the second end portion of the first housing away from the fourth end portion of the second housing, wherein the second housing defines a slot in the fourth end portion between the third and fourth side portions that is sized to receive the second end portion of the first housing such that the second end of the first housing and the fourth end of the second housing are axially aligned;

a wedge extending from a fifth end to a sixth end with an angled wedge surface extending along a portion of a distance between the fifth end and the sixth end and with first and second opposing side surfaces on opposite sides of the angled wedge surface, wherein the wedge is positioned between the first housing and the second housing with the angled wedge surface facing the first interior surface of the first housing, wherein the first interior surface of the first housing has an angled housing surface shaped to engage the angled wedge surface of the wedge, wherein a distance from the fifth end to the sixth end of the wedge is less than a distance from the first end to the second end of the first housing and is less than a distance from the third end to the fourth end of the second housing, wherein the wedge is configured to slide within a ~~spaced~~ space defined between the first and second housings in a direction toward the second and fourth ends of the first and second housings from a first wedge position that allows the first and second housings to pivot to a housing position that is substantially closed to a second wedge position whereby the angled wedge surface presses against the first interior surface of the first housing to hingedly open the first housing with respect to the second housing whereby the wedge remains axially confined within the space defined between the first and second housings in the first and second wedge positions; and

a rotation screw operably connected to the wedge and to the second housing, wherein rotation of the rotation screw moves the wedge in an axially translating direction with respect to the first housing and the second housing within the space defined

between the first and second housings from the first wedge position to the second wedge position.

20. (Previously Presented) A system comprising the device of claim 19, wherein the device further comprises means for attaching the first end of the first housing to the third end of the second housing and wherein the system further comprises:

means for gripping and inserting the device; and

means for turning the rotation screw with respect to the second movable portion and the wedge.

REMARKS

Claims 1-20 are pending, with claims 1, 14, and 19 being independent. With this response, claims 1, 14, and 19 have been amended to correct scrivener's errors.

Claim Objections

Claims 1, 14, and 19 were objected to for using the word "spaced" rather than "space." With this amendment, claims 1, 14, and 19 have been amended to replace the word "spaced" with "space." Accordingly, Applicant respectfully requests that this objection be withdrawn.

Claim Rejections – 35 USC § 102 and 103

Claims 1-14 and 16-20 were rejected under pre-AIA 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,102,950 (Vaccaro). Claim 15 was rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,102,950 (Vaccaro) in view of U.S. Patent No. 7,044,971 (Suddaby). Applicant respectfully contends that the claims include a number of features not present in the cited references, and accordingly, request that this rejection be withdrawn.

Claim 1 requires "the second movable portion defines a **slot** in the fourth end portion between the third and fourth side portions that is sized to receive the second end portion of the first movable portion such that the second end of the first movable portion and the fourth end of the second movable portion are axially aligned." One example of the claimed arrangement is shown below in Figure 6C of the present application. The following Figure 6C has been annotated to show (generally) the fourth end portion colored green, the third side portion colored purple, the fourth side portion colored orange, and the second end portion blue.[1] As can be seen, the second movable portion defines a slot in the fourth end portion (green) between the third and fourth side portions (purple and orange), as claimed. Vaccaro has no second movable portion defining a slot as claimed.

[1] Has been added to Figure 6C to show, generally, the location of claimed features in the example shown in Figure 6C for illustration purposes. The color is not intended to limit the claims beyond the language present in the claims.

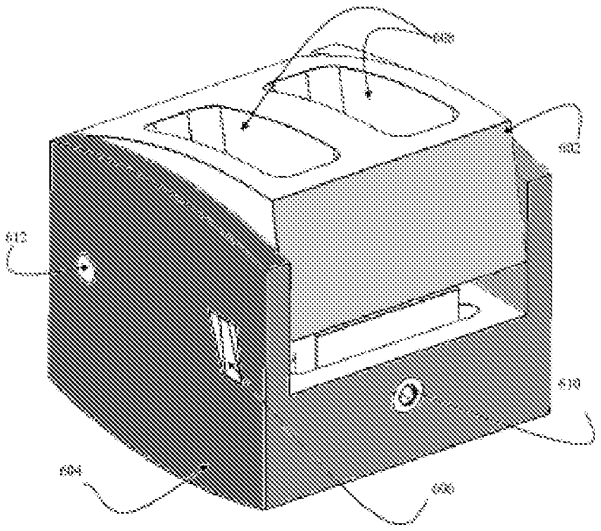


Fig. 6C

Claim 1 also requires: "the wedge is configured to **slide** within a space defined between the first and second movable portions **in a direction toward the second and fourth ends** of the first and second movable portions **from a first wedge position** that allows the first and second movable portions to pivot to a device position that is substantially closed **to a second wedge position** whereby the angled wedge surface presses against the first interior surface of the first movable portion **to hingedly open** the first movable portion with respect to the second movable portion." As shown in the version of Vaccaro's Figure 2 that is annotated on page 12 of the Office Action, Vaccaro does not have a wedge that is configured to slide in a direction toward the second and fourth ends to hingedly open the first movable portion with respect to the second movable portion, particularly as claimed.

Claim 1 also requires "the wedge remains **axially confined within** the space defined by the first and second movable portions in the first and second wedge positions." As shown in the version of Vaccaro's Figure 2 that is annotated on page 12 of the Office Action, Vaccaro does not have a wedge that remains axially confined within the space as claimed.

Accordingly, claim 1 and all claims depending therefrom are patentable over the cited reference for at least these reasons. Moreover, the claims depending from claim 1 include further features that further distinguish over the cited reference.

For example, claim 5 requires "the wedge comprises a threaded hole that engages with a threaded surface around a circumferential perimeter of the rotation screw." Vaccaro does not disclose a wedge with the claimed threaded hole. On the contrary, Vaccaro says "However, the wedge body includes a **threadless** seat 38 for receiving the head portion 84. This seat 38 permits free rotation of the head portion 84 within the wedge body 40 and therefore permits the threaded portion 82 to advance the wedge body 40 towards the cage component 20 as the shaft 80 is turned while the threaded portion 82 is engaged to lobe 32." Vaccaro, 7:48-64 (emphasis added).

Claim 7 requires "the third and fourth side portions define first and second indentations that extend into but not through the third and fourth side portions and that are configured to be grabbed by an insertion tool." Vaccaro discloses no such indentations. Vaccaro's "through passage 26" is not an indentation that extend into but not through the third or fourth side portions and that is configured to be grabbed by an insertion tool.

Claim 8 requires "means for gripping and inserting the device." Vaccaro includes no such means. The office action identifies tool T in Figure 1 of Vaccaro, but does not show how tool T is alleged to meet this claim element.

Claim 14 requires "the second end portion of the top housing is smaller than the fourth end portion of the bottom housing such that the second end portion of the top housing is positionable between the third and fourth side portions of the bottom housing at the fourth end of the bottom housing." This feature is not taught by Vaccaro. For example, Figure 6C of the present application is reproduced below to show one example of a device where the second end portion (colored blue) is smaller than the fourth end portion (colored green) such that the second end portion (colored blue) is positionable between the third and fourth side portions (purple and orange). Vaccaro, on the other hand, does not disclose the claimed relationship.

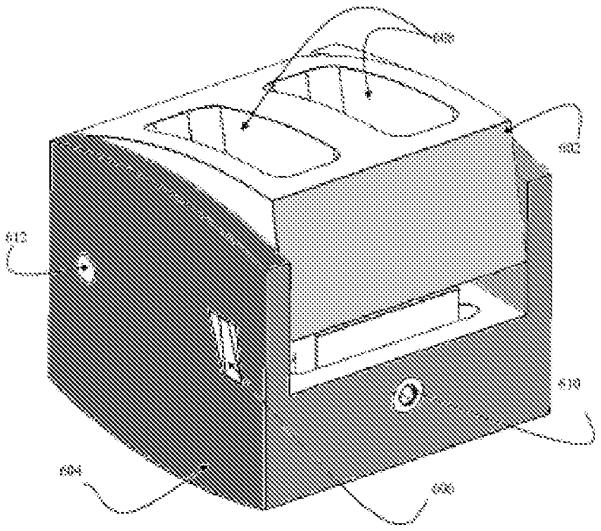


Fig. 6C

Claim 14 also requires "the wedge is configured to **slide** within a space defined by the top and bottom housings **in a direction toward the second and fourth ends** of the top and bottom housings **from a first wedge position** that allows the top and bottom housings to pivot to a housing position that is substantially closed **to a second wedge position** whereby the angled wedge surface presses against the first interior surface of the top housing **to hingedly open** the top housing with respect to the bottom housing." As shown in the version of Vaccaro's Figure 2 that is annotated on page 12 of the Office Action, Vaccaro does not have a wedge that is configured to slide in a direction toward the second and fourth ends to hingedly open the top housing with respect to the bottom housing, particularly as claimed.

Claim 14 also requires "the wedge remains axially confined within the space defined by the top and bottom housings in the first and second wedge positions." As shown in the version of Vaccaro's Figure 2 that is annotated on page 12 of the Office Action, Vaccaro does not have a wedge that remains axially confined within the space as claimed.

Accordingly, claim 14 and all claims depending therefrom are patentable over the cited reference for at least these reasons. Moreover, the claims depending from claim 14 include further features that further distinguish over the cited reference.

Claim 19 requires "the third and fourth side portions define first and second indentations configured to be grabbed by an insertion tool." Vaccaro discloses no such indentations. Vaccaro's "through passage 26" is not an indentation defined by one of the third and fourth side portions that is configured to be grabbed by an insertion tool.

Claim 19 also requires "the second housing defines a slot in the fourth end portion between the third and fourth side portions that is sized to receive the second end portion of the first housing such that the second end of the first housing and the fourth end of the second housing are axially aligned. Vaccaro discloses no such slot sized to receive the second end portion of the first housing as claimed.

Claim 19 also requires "the wedge is configured to **slide** within a space defined between the first and second housings **in a direction toward the second and fourth ends** of the first and second housings **from a first wedge position** that allows the first and second housings to pivot to a housing position that is substantially closed **to a second wedge position** whereby the angled wedge surface presses against the first interior surface of the first housing **to hingedly open** the first housing with respect to the second housing. Vaccaro discloses no wedge configured to slide in a direction toward the second and fourth ends to hingedly open the first housing with respect to the second housing as claimed.

Claim 19 also requires "the wedge remains **axially confined within** the space defined between the first and second housings in the first and second wedge positions." Vaccaro discloses no wedge that remains axially confined as claimed.

Accordingly, claim 19 is patentable over the cited references for at least these reasons. Claim 20, which depends therefrom, is also patentable over the cited references for at least these reasons in addition to the additional features claimed therein.

Request for Reconsideration

The Applicant respectfully requests prompt consideration and a Notice of Allowance. In the event that no Notice of Allowance will be provided in the next communication, Applicant requests that the Examiner telephone the undersigned attorney (612-337-2538) prior to the next communication so that prosecution on the merits may be expedited. It is believed that all of the pending claims have been addressed. However, the absence of a reply to a specific rejection,

issue or comment does not signify agreement with or concession of that rejection, issue or comment. In addition, because the arguments made above may not be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed. Nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendments herein do not signify concession of unpatentability of any claims prior to this amendment. Applicant hereby specifically reserves the right to prosecute the previously presented subject matter in a continuing application. Also, Applicant expressly reserves the right to prosecute claims of different or broader scope in a continuing application. The Patent Office should infer no (i) adoption of a position with respect to patentability, (ii) change in the Applicant's position with respect to any claim or subject matter of the invention, or (iii) acquiescence in any way to any position taken by the Office Action, based on the amendments made herein.

Apply any necessary charges or credits to Deposit Account 06-1050, referencing the above attorney docket number.

Respectfully submitted,

Date: 1/29/2019

/Stuart A. Nelson/
Stuart A. Nelson
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100020564.doc

Electronic Acknowledgement Receipt	
EFS ID:	34992735
Application Number:	16025667
International Application Number:	
Confirmation Number:	5655
Title of Invention:	ZERO-PROFILE EXPANDABLE INTERVERTEBRAL SPACER DEVICES FOR DISTRACTION AND SPINAL FUSION AND A UNIVERSAL TOOL FOR THEIR PLACEMENT AND EXPANSION
First Named Inventor/Applicant Name:	Ahmnon D. Moskowitz
Customer Number:	26191
Filer:	Stuart A. Nelson/Abby Remer
Filer Authorized By:	Stuart A. Nelson
Attorney Docket Number:	46440-0020003
Receipt Date:	29-JAN-2019
Filing Date:	02-JUL-2018
Time Stamp:	13:58:28
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		Response.pdf	127704 9293edf6e84360c292f5fb2feaa7f1da7c7f1350	yes	16

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Amendment/Req. Reconsideration-After Non-Final Reject	1	1
	Claims	2	10
	Applicant Arguments/Remarks Made in an Amendment	11	16
Warnings:			
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If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.
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MINNEAPOLIS, MN 55440-1022

EXAMINER	
NEGRELLIRODRIGUE, CHRISTINA	
ART UNIT	PAPER NUMBER
3773	

DATE MAILED: 05/30/2019

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/025,667	07/02/2018	Ahmnon D. Moskowitz	46440-0020003	5655

TITLE OF INVENTION: ZERO-PROFILE EXPANDABLE INTERVERTEBRAL SPACER DEVICES FOR DISTRACTION AND SPINAL FUSION AND A UNIVERSAL TOOL FOR THEIR PLACEMENT AND EXPANSION

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$500	$0.00	$0.00	$500	08/30/2019

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

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If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Maintenance fees are due in utility patents issuing on applications filed on or after Dec. 12, 1980. It is patentee's responsibility to ensure timely payment of maintenance fees when due. More information is available at www.uspto.gov/PatentMaintenanceFees.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), by mail or fax, or via EFS-Web.

By mail, send to: Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

By fax, send to: (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

26191 7590 05/30/2019
FISH & RICHARDSON P.C. (TC)
PO BOX 1022
MINNEAPOLIS, MN 55440-1022

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being transmitted to the USPTO via EFS-Web or by facsimile to (571) 273-2885, on the date below.

(Typed or printed name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/025,667	07/02/2018	Ahmnon D. Moskowitz	46440-0020003	5655

TITLE OF INVENTION: ZERO-PROFILE EXPANDABLE INTERVERTEBRAL SPACER DEVICES FOR DISTRACTION AND SPINAL FUSION AND A UNIVERSAL TOOL FOR THEIR PLACEMENT AND EXPANSION

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$500	$0.00	$0.00	$500	08/30/2019

EXAMINER	ART UNIT	CLASS-SUBCLASS
NEGRELLIRODRIGUE, CHRISTINA	3773	623-017150

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

❑ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

❑ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-09 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 _____
2 _____
3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ❑ Individual ❑ Corporation or other private group entity ❑ Government

4a. Fees submitted: ❑ Issue Fee ❑ Publication Fee (if required) ❑ Advance Order - # of Copies _____

4b. Method of Payment: *(Please first reapply any previously paid fee shown above)*

❑ Electronic Payment via EFS-Web ❑ Enclosed check ❑ Non-electronic payment by credit card (Attach form PTO-2038)

❑ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. _____

5. **Change in Entity Status** (from status indicated above)

❑ Applicant certifying micro entity status. See 37 CFR 1.29

❑ Applicant asserting small entity status. See 37 CFR 1.27

❑ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.
NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.
NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/025,667	07/02/2018	Ahmnon D. Moskowitz	46440-0020003	5655

26191 7590 05/30/2019
FISH & RICHARDSON P.C. (TC)
PO BOX 1022
MINNEAPOLIS, MN 55440-1022

EXAMINER	
NEGRELLIRODRIGUE, CHRISTINA	
ART UNIT	PAPER NUMBER
3773	

DATE MAILED: 05/30/2019

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Notice of Allowability	Application No. 16/025,667	Applicant(s) Moskowitz et al.	
	Examiner CHRISTINA NEGRELLI-RODRIGUEZ	Art Unit 3773	AIA (FITF) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☑ This communication is responsive to Applicant's Arguments and Amendments to the Claimed filed on 01/29/2019.
   ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

3. ☑ The allowed claim(s) is/are 1-20 . As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see **http://www.uspto.gov/patents/init_events/pph/index.jsp** or send an inquiry to **PPHfeedback@uspto.gov.**

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

   Certified copies:

   a) ☐ All b) ☐ Some *c) ☐ None of the:

   1. ☐ Certified copies of the priority documents have been received.
   2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
   3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____ .

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file areply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____ .

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☑ Notice of References Cited (PTO-892)
2. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____.
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material _____.
4. ☐ Interview Summary (PTO-413), Paper No./Mail Date. _____.
5. ☐ Examiner's Amendment/Comment
6. ☑ Examiner's Statement of Reasons for Allowance
7. ☐ Other _____.

/CHRISTINA NEGRELLIRODRIGUEZ/ Examiner, Art Unit 3773	/JULIANNA N HARVEY/ Primary Examiner, Art Unit 3773

REASONS FOR ALLOWANCE

The following is an examiner's statement of reasons for allowance:

Claims 1-20 in the instant application have not been rejected using prior art because no references, or reasonable combination thereof, could be found to disclose, or suggest an expandable intervertebral fusion device comprising: a first movable portion extending from a first end to a second end, wherein the first movable portion has first and second end portions positioned at the first and second ends, respectively, and has first and second side portions extending between the first and second end portions, wherein the first movable portion has a first vertebral body engagement surface and has a first interior surface positioned on an opposite side of the first movable portion than the first vertebral body engagement surface; a second movable portion extending from a third end to a fourth end, wherein the second movable portion has third and fourth end portions positioned at the third and fourth ends, respectively, and has third and fourth side portions extending between the third and fourth end portions, wherein the second movable portion has a second vertebral body engagement surface and has a second interior surface positioned on an opposite side of the second movable portion than the second vertebral body engagement surface, wherein the first movable portion is aligned with the second movable portion such that the first end of the first movable portion is axially aligned with the third end of the second movable portion and the second end of the first movable portion is axially aligned with the fourth end of the second movable portion, wherein the first end portion of the first movable portion is hingedly connected to the third end portion of the second movable portion such that the first movable portion can pivot with respect to the second movable portion so as to move the second end portion of the first movable portion away from the fourth end portion of the second movable portion, wherein the second movable portion defines a slot in the fourth end

portion between the third and fourth side portions that is sized to receive the second end portion of the first movable portion such that the second end of the first movable portion and the fourth end of the second movable portion are axially aligned; and a mechanism that pivotably moves the first movable portion and the second movable portion with respect to each other to expand a dimension of the expandable intervertebral fusion device, wherein the mechanism comprises: a wedge extending from a fifth end to a sixth end and having an angled wedge surface extending along at least a portion of a distance between the fifth end and the sixth end, wherein the wedge is positioned between the first movable portion and the second movable portion with the angled wedge surface facing the first interior surface of the first movable portion, wherein the first interior surface of the first movable portion has an angled movable portion surface shaped to engage the angled wedge surface of the wedge, wherein a distance from the fifth end to the sixth end of the wedge is less than a distance from the first end to the second end of the first movable portion and is less than a distance from the third end to the fourth end of the second movable portion, wherein the wedge is configured to slide within a spaced space defined between the first and second movable portions in a direction toward the second and fourth ends of the first and second movable portions from a first wedge position that allows the first and second movable portions to pivot to a device position that is substantially closed to a second wedge position whereby the angled wedge surface presses against the first interior surface of the first movable portion to hingedly open the first movable portion with respect to the second movable portion whereby the wedge remains axially confined within the space defined by the first and second movable portions in the first and second wedge positions; and a rotation screw operably connected to the wedge and to the second movable portion, wherein rotation of the rotation screw moves the wedge in an axially translating direction with respect to the first movable

portion and the second movable portion within the space defined between the first and second movable portions from the first wedge position to the second wedge position.

Furthermore, no references, or reasonable combination thereof, could be found to disclose, or suggest an expandable interbody device comprising: a top housing extending from a first end to a second end, wherein the top housing has first and second end portions positioned at the first and second ends, respectively, and has first and second side portions extending between the first and second end portions, wherein the top housing has a first vertebral body engagement surface that is at least partially convex and has a first interior surface positioned on an opposite side of the top housing than the first vertebral body engagement surface, wherein the top housing defines at least one first bone material receiving area extending through the top housing between the first and second end portions and the first and second side portions; a bottom housing extending from a third end to a fourth end, wherein the bottom housing has third and fourth end portions positioned at the third and fourth ends, respectively, and has third and fourth side portions extending between the third and fourth end portions, wherein the bottom housing has a second vertebral body engagement surface that is at least partially convex and has a second interior surface positioned on an opposite side of the bottom housing than the second vertebral body engagement surface, wherein the bottom housing defines at least one second bone material receiving area extending through the bottom housing between the third and fourth end portions and the third and fourth side portions, wherein the top housing is aligned with the bottom housing such that the first end of the top housing is axially aligned with the third end of the bottom housing and the second end of the top housing is axially aligned with the fourth end of the bottom housing, wherein the first end portion of the top housing and the third end portion of the bottom housing are hingedly interconnected such that the top housing can pivot with respect

to the bottom housing so as to move the second end portion of the top housing away from the fourth end portion of the bottom housing, wherein a first length of the top housing from the first end to the second end is substantially equal to a second length of the bottom housing from the third end to the fourth end, and wherein the second end portion of the top housing is smaller than the fourth end portion of the bottom housing such that the fourth second end portion of the top housing is positionable between the third and fourth side portions of the bottom housing at the fourth end of the bottom housing; a wedge extending from a fifth end to a sixth end and having an angled wedge surface extending along at least a portion of a distance between the fifth end and the sixth end, wherein the wedge is positioned between the top housing and the bottom housing with the angled wedge surface facing the first interior surface of the top housing, wherein the first interior surface of the top housing has an angled housing surface shaped to engage the angled wedge surface of the wedge, wherein a distance from the fifth end to the sixth end of the wedge is less than a distance from the first end to the second end of the top housing and is less than a distance from the third end to the fourth end of the bottom housing, wherein the wedge is configured to slide within a spaced space defined by the top and bottom housings in a direction toward the second and fourth ends of the top and bottom housings from a first wedge position that allows the top and bottom housings to pivot to a housing position that is substantially closed to a second wedge position whereby the angled wedge surface presses against the first interior surface of the top housing to hingedly open the top housing with respect to the bottom housing whereby the wedge remains axially confined within the space defined by the top and bottom housings in the first and second wedge positions; and a rotation screw operably connected to the wedge and to the bottom housing, wherein rotation of the rotation screw moves the wedge in an axially translating direction with respect to the top housing and the

bottom housing within the space defined by the first and bottom housings from the first wedge position to the second wedge position.

Furthermore, no references, or reasonable combination thereof, could be found to disclose, or suggest an expandable interbody device comprising: a first housing extending from a first end to a second end, wherein the first housing has first and second end portions positioned at the first and second ends, respectively, and has first and second side portions extending between the first and second end portions, wherein the first housing has a first vertebral body engagement surface and has a first interior surface positioned on an opposite side of the first housing than the first vertebral body engagement surface, wherein the first housing defines a first bone material receiving area between the first and second end portions and the first and second side portions; a second housing extending from a third end to a fourth end, wherein the second housing has third and fourth end portions positioned at the third and fourth ends, respectively, and has third and fourth side portions extending between the third and fourth end portions, wherein the second housing has a second vertebral body engagement surface and has a second interior surface positioned on an opposite side of the second housing than the second vertebral body engagement surface, wherein the second housing defines a second bone material receiving area between the third and fourth end portions and the third and fourth side portions, wherein the third and fourth side portions define first and second indentations configured to be grabbed by an insertion tool, wherein the first housing is aligned with the second housing such that the first end of the first housing is axially aligned with the third end of the second housing and the second end of the first housing is axially aligned with the fourth end of the second housing, wherein the first end portion of the first housing is hingedly connected to the third end portion of the second housing such that the first housing can pivot with respect to the second housing so as to move the second

end portion of the first housing away from the fourth end portion of the second housing, wherein the second housing defines a slot in the fourth end portion between the third and fourth side portions that is sized to receive the second end portion of the first housing such that the second end of the first housing and the fourth end of the second housing are axially aligned; a wedge extending from a fifth end to a sixth end with an angled wedge surface extending along a portion of a distance between the fifth end and the sixth end and with first and second opposing side surfaces on opposite sides of the angled wedge surface, wherein the wedge is positioned between the first housing and the second housing with the angled wedge surface facing the first interior surface of the first housing, wherein the first interior surface of the first housing has an angled housing surface shaped to engage the angled wedge surface of the wedge, wherein a distance from the fifth end to the sixth end of the wedge is less than a distance from the first end to the second end of the first housing and is less than a distance from the third end to the fourth end of the second housing, wherein the wedge is configured to slide within a spaced space defined between the first and second housings in a direction toward the second and fourth ends of the first and second housings from a first wedge position that allows the first and second housings to pivot to a housing position that is substantially closed to a second wedge position whereby the angled wedge surface presses against the first interior surface of the first housing to hingedly open the first housing with respect to the second housing whereby the wedge remains axially confined within the space defined between the first and second housings in the first and second wedge positions; and a rotation screw operably connected to the wedge and to the second housing, wherein rotation of the rotation screw moves the wedge in an axially translating direction with respect to the first housing and the second housing within the space defined

between the first and second housings from the first wedge position to the second wedge position.

Applicant's arguments, filed 01/29/2019, with respect to the rejection of claims 1-20 under pre-AIA 35 U.S.C. 102(b) as being anticipated by Vaccaro, have been fully considered and are persuasive.

Vaccaro fails to disclose "wherein the second movable portion defines a slot in the fourth end portion between the third and fourth side portions that is sized to receive the second end portion of the first movable portion such that the second end of the first movable portion and the fourth end of the second movable portion are axially aligned". Vaccaro's rigid lower member 24 comprises a through passage 26 which is not sized to receive spines 50 of rigid upper member 22. Instead, spines 50 are configured to be received by recessed ramp 46 of wedge body 40.

Furthermore, Vaccaro fails to disclose "wherein the wedge remains axially confined within the space defined by the first and second movable portion in the first and second wedge positions." Instead, Vaccaro's wedge body 40 slides freely in coacting positions, representing a pre-insertion state in solid lines wherein the wedge component is substantially external to the cage component, and, a post-insertion state shown in phantom lines wherein the wedge component is substantially fully housed within the cage component (see Figure 7 of Vaccaro).

Furthermore, Vaccaro fails to disclose "wherein the second end portion of the top housing is smaller than the fourth end portion of the bottom housing such that the second end portion of the top housing is positionable between the third and fourth side portions of the bottom housing at the fourth end of the bottom housing". The end portions Vaccaro's rigid

upper and lower members 22, 24 are the same size and thus the second end portion of member 22 is not positionable between the third and fourth side portions of member 24.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christina Negrelli whose telephone number is (571)270-7389. The examiner can normally be reached on Monday-Friday, between 8:00am to 4:00pm. If attempts to reach the examiner by telephone are unsuccessful, ***please contact*** **the examiner's supervisor, Eduardo Robert,** ***at*** **(571) 272-4719**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/CHRISTINA NEGRELLI/

Examiner, Art Unit 3773

/JULIANNA N HARVEY/
Primary Examiner, Art Unit 3773

Notice of References Cited	Application/Control No. 16/025,667	Applicant(s)/Patent Under Reexamination Moskowitz et al.	
	Examiner CHRISTINA NEGRELLI-RODRIGUEZ	Art Unit 3773	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
*	A	US-6102950-A	08-2000	Vaccaro; Alex	A61F2/4611	606/247
	B					
	C					
	D					
	E					
	F					
	G					
	H					
	I					
	J					
	K					
	L					
	M					

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	CPC Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/025,667	Moskowitz et al.
	Examiner	Art Unit
	CHRISTINA NEGRELLI-RODRIGUEZ	3773

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

CLAIMS

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	11/07/2018	05/21/2019							
1	1	✓	=							
2	2	✓	=							
3	3	✓	=							
4	4	✓	=							
5	5	✓	=							
6	6	✓	=							
7	7	✓	=							
8	8	✓	=							
9	9	✓	=							
10	10	✓	=							
11	11	✓	=							
12	12	✓	=							
13	13	✓	=							
14	14	✓	=							
15	15	✓	=							
16	16	✓	=							
17	17	✓	=							
18	18	✓	=							
19	19	✓	=							
20	20	✓	=							

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/025,667	Moskowitz et al.
	Examiner	**Art Unit**
	CHRISTINA NEGRELLI-RODRIGUEZ	3773

CPC						
Symbol					**Type**	**Version**
A61F	/	2	/	447	F	2013-01-01
A61B	/	17	/	0642	I	2013-01-01
A61F	/	2	/	4611	I	2013-01-01
A61B	/	17	/	7064	I	2013-01-01
A61B	/	17	/	86	A	2013-01-01
A61B	/	2017	/	922	A	2013-01-01
A61F	/	2002	/	2835	A	2013-01-01
A61F	/	2002	/	30387	A	2013-01-01
A61F	/	2002	/	30448	A	2013-01-01
A61F	/	2002	/	30507	A	2013-01-01
A61F	/	2002	/	3055	A	2013-01-01
A61F	/	2002	/	30579	A	2013-01-01
A61F	/	2002	/	30604	A	2013-01-01
A61F	/	2002	/	30772	A	2013-01-01
A61F	/	2002	/	30878	A	2013-01-01
A61F	/	2002	/	4475	A	2013-01-01
A61F	/	2002	/	448	A	2013-01-01
A61F	/	2002	/	4627	A	2013-01-01
A61F	/	2002	/	4681	A	2013-01-01
A61F	/	2002	/	4687	A	2013-01-01
A61F	/	2220	/	0025	A	2013-01-01
A61F	/	2220	/	005	A	2013-01-01
A61F	/	2230	/	0015	A	2013-01-01
A61F	/	2250	/	0007	A	2013-01-01
A61B	/	17	/	8875	A	2013-01-01
A61B	/	2017	/	0256	A	2013-01-01
A61F	/	2002	/	30261	A	2013-01-01
A61F	/	2002	/	30266	A	2013-01-01
A61F	/	2002	/	30281	A	2013-01-01
A61F	/	2002	/	30471	A	2013-01-01
A61F	/	2002	/	30497	A	2013-01-01

/CHRISTINA NEGRELLIRODRIGUEZ/ Examiner, Art Unit 3773	21 May 2019	**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	20	
/JULIANNA N HARVEY/ Primary Examiner, Art Unit 3773	22 May 2019	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	6C

U.S. Patent and Trademark Office — Part of Paper No.: 20190521

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/025,667	Moskowitz et al.
	Examiner	**Art Unit**
	CHRISTINA NEGRELLI-RODRIGUEZ	3773

CPC						
Symbol					**Type**	**Version**
A61F	/	2002	/	30525	A	2013-01-01
A61F	/	2002	/	30538	A	2013-01-01
A61F	/	2002	/	30556	A	2013-01-01

CPC Combination Sets							
Symbol					**Type**	**Set**	**Ranking**	**Version**
	/		/					

/CHRISTINA NEGRELLIRODRIGUEZ/ Examiner, Art Unit 3773	21 May 2019	**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	20	
/JULIANNA N HARVEY/ Primary Examiner, Art Unit 3773	22 May 2019	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	6C

U.S. Patent and Trademark Office — Part of Paper No.: 20190521

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/025,667	Moskowitz et al.
	Examiner	Art Unit
	CHRISTINA NEGRELLI-RODRIGUEZ	3773

INTERNATIONAL CLASSIFICATION					
CLAIMED					
A61F	/	2	/	44	

NON-CLAIMED					
	/		/		

US ORIGINAL CLASSIFICATION	
CLASS	SUBCLASS

CROSS REFERENCES(S)						
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)					

/CHRISTINA NEGRELLIRODRIGUEZ/ Examiner, Art Unit 3773	21 May 2019	Total Claims Allowed:	
(Assistant Examiner)	(Date)	20	
/JULIANNA N HARVEY/ Primary Examiner, Art Unit 3773	22 May 2019	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	6C

U.S. Patent and Trademark Office — Part of Paper No.: 20190521

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/025,667	Moskowitz et al.
	Examiner	**Art Unit**
	CHRISTINA NEGRELLI-RODRIGUEZ	3773

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIMS

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
1	1	10	10	19	19										
2	2	11	11	20	20										
3	3	12	12												
4	4	13	13												
5	5	14	14												
6	6	15	15												
7	7	16	16												
8	8	17	17												
9	9	18	18												

/CHRISTINA NEGRELLIRODRIGUEZ/ Examiner, Art Unit 3773	21 May 2019	**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	20	
/JULIANNA N HARVEY/ Primary Examiner, Art Unit 3773	22 May 2019	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	6C

U.S. Patent and Trademark Office Part of Paper No.: 20190521

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/025,667	Moskowitz et al.
	Examiner	Art Unit
	CHRISTINA NEGRELLI-RODRIGUEZ	3773

CPC - Searched*		
Symbol	Date	Examiner
A61F2/442, A61F2/4425, A61F2002/443, A61F2/4455	11/7/2018	CN
A61F2/442, A61F2/4425, A61F2002/443, A61F2/4455	05/21/2019	CN

CPC Combination Sets - Searched*		
Symbol	Date	Examiner

US Classification - Searched*			
Class	Subclass	Date	Examiner
606	246-249	11/7/2018	CN
623	17.11-17.16	11/7/2018	CN

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	Date	Examiner
Inventor Name Search	11/7/2018	CN
EAST Search History	11/7/2018	CN
Updated EAST Search History	05/21/2019	CN
Updated Inventor Name Search	05/21/2019	CN
International Issue Classification Search - A61F2/44	05/21/2019	CN
Interference Search History Printout	05/21/2019	CN

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner
	Interference Search History Printout	05/21/2019	CN

/JULIANNA N HARVEY/ Primary Examiner, Art Unit 3773	/CHRISTINA NEGRELLIRODRIGUEZ/ Examiner, Art Unit 3773

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/025,667	Moskowitz et al.
	Examiner	Art Unit
	CHRISTINA NEGRELLI-RODRIGUEZ	3773

/JULIANNA N HARVEY/ Primary Examiner, Art Unit 3773	/CHRISTINA NEGRELLIRODRIGUEZ/ Examiner, Art Unit 3773

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L194	1	"6102950".pn.	US-PGPUB; USPAT; USOCR	OR	ON	2019/05/21 12:36
L195	10834	A61F2/442.cpc. or A61F2/4425.cpc. or A61F2002/443.cpc. or A61F2/4455.cpc.	US-PGPUB; USPAT; USOCR	OR	ON	2019/05/21 12:40
L197	399	L195 and @pd>"20181107"	US-PGPUB; USPAT; USOCR	OR	ON	2019/05/21 12:40
L198	217	(MOSKOWITZ NEAR2 AHMNON).in. or (MOSKOWITZ NEAR2 MOSHEH).in. or (MOSKOWITZ NEAR2 MATHAN).in. or (ALVARADO NEAR2 PABLO).in. or (SUGALSKI NEAR2 ERIC).in.	US-PGPUB; USPAT; USOCR	OR	ON	2019/05/21 12:42
L199	15	(MOSKOWITZ FAMILY).as.	US-PGPUB; USPAT; USOCR	ADJ	ON	2019/05/21 12:42
L200	0	A61F2/44/.IPC.NOT-US.	US-PGPUB; USPAT; USOCR	ADJ	ON	2019/05/21 12:54

5/21/2019 1:39:45 PM
C:\Users\cnegrelli\Documents\EAST\Workspaces\16025667.wsp

EAST Search History

EAST Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L202	1	(second movable portion) AND (sixth end) AND (rotation screw).clm.	US-PGPUB	ADJ	ON	2019/05/21 13:12
L221	0	(angled wedge surface facing the first interior surface of the first housing) AND (sixth end) AND (rotation screw).clm.	US-PGPUB	ADJ	ON	2019/05/21 13:31

5/ 21/ 2019 1:39:54 PM
C:\ Users\ cnegrelli\ Documents\ EAST\ Workspaces\ 16025667.wsp

Electronic Patent Application Fee Transmittal

Application Number:	16025667
Filing Date:	02-Jul-2018
Title of Invention:	ZERO-PROFILE EXPANDABLE INTERVERTEBRAL SPACER DEVICES FOR DISTRACTION AND SPINAL FUSION AND A UNIVERSAL TOOL FOR THEIR PLACEMENT AND EXPANSION
First Named Inventor/Applicant Name:	Ahmnon D. Moskowitz
Filer:	Stuart A. Nelson/Abby Remer
Attorney Docket Number:	46440-0020003

Filed as Small Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
UTILITY APPL ISSUE FEE	2501	1	500	500

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**500**

Electronic Acknowledgement Receipt	
EFS ID:	36951400
Application Number:	16025667
International Application Number:	
Confirmation Number:	5655
Title of Invention:	ZERO-PROFILE EXPANDABLE INTERVERTEBRAL SPACER DEVICES FOR DISTRACTION AND SPINAL FUSION AND A UNIVERSAL TOOL FOR THEIR PLACEMENT AND EXPANSION
First Named Inventor/Applicant Name:	Ahmnon D. Moskowitz
Customer Number:	26191
Filer:	Stuart A. Nelson/Abby Remer
Filer Authorized By:	Stuart A. Nelson
Attorney Docket Number:	46440-0020003
Receipt Date:	22-AUG-2019
Filing Date:	02-JUL-2018
Time Stamp:	14:34:40
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	$500
RAM confirmation Number	E20198LE34578424
Deposit Account	
Authorized User	
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Issue Fee Payment (PTO-85B)	IssueFee.pdf	171638 6a83d5dacb7ad6872b41920e65abd3afab88ba68	no	3
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	30606 5be941ec69e0c7859bb5e52feb557448ae89da59	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	202244		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.
National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.
New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor	:	Ahmnon D. Moskowitz	Art Unit	:	3773
			Examiner	:	Christina Negrellirodrigue
Application No.	:	16/025,667			
Filed	:	July 2, 2018	Confirmation No.	:	5655
			Notice of Allowance Date: May 30, 2019		
Title	:	ZERO-PROFILE EXPANDABLE INTERVERTEBRAL SPACER DEVICES FOR DISTRACTION AND SPINAL FUSION AND A UNIVERSAL TOOL FOR THEIR PLACEMENT AND EXPANSION			

MAIL STOP ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REPLY TO NOTICE OF ALLOWANCE

In response to the Notice of Allowance dated May 30, 2019, enclosed is a completed Part B - Fee(s) Transmittal.

The issue fee is being paid with this reply on the Electronic Filing System. Apply those fees and any other necessary charges or credits to Deposit Account 06-1050, referencing the above attorney docket number.

COMMENTS ON EXAMINER'S REASONS FOR ALLOWANCE

It is recognized that in accordance with M.P.E.P. § 1302.14, the Examiner's reasons for allowance need not set forth all of the details as to why the claims are allowed. In the above-referenced application, it is not conceded that the Examiner's stated reasons for allowance are the only reasons for which the claims are allowable. The Examiner's reasons for allowance indicate that particular claim elements are not disclosed or suggested by the prior art of record, yet the claims may be patentable for other reasons as well, including the inventive combination of all of the recited claim elements. It is not conceded that the specific limitations identified by the Examiner are necessary to distinguish the art of record or to satisfy the requirements of 35 U.S.C. § 112. Moreover, the Examiner does not assert, and it would not be conceded, that the Examiner's reasons have any bearing on the patentability of claims in any other applications directed to the disclosed subject matter.

In addition, each dependent claim stands on its own and may be allowable on its own merits. In particular, each dependent claim may be allowable on the basis of a combination of

some of the features recited in the dependent claim and its base claim(s), which combination of features may not include all of the limitations identified in the Examiner's reasons for allowance.

Respectfully submitted,

Date: 8/22/2019

/Stuart A. Nelson/
Stuart A. Nelson
Reg. No. 63,947

Customer Number 26191
Fish & Richardson P.C.
Telephone: (612) 337-2538
Facsimile: (877) 769-7945

62028789.doc

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), by mail or fax, or via EFS-Web

By mail, send to: Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22314-1450

By fax, send to: (571) 273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

26191 7590 05/30/2019

FISH & RICHARDSON P.C.
P.O. BOX 1022
MINNEAPOLIS, MN 55440-1022

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being transmitted to the USPTO via EFS-Web or by facsimile to (571) 273-2885, on the date below.

(Typed or printed name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/025,667	07/02/2018	Ahmnon D. Moskowitz	46440-0020003	5655

TITLE OF INVENTION: ZERO-PROFILE EXPANDABLE INTERVERTEBRAL SPACER DEVICES FOR DISTRACTION AND SPINAL FUSION AND A UNIVERSAL TOOL FOR THEIR PLACEMENT AND EXPANSION

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$500	$0		$500	08/30/2019

EXAMINER	ART UNIT	CLASS-SUBCLASS
NEGRELLIRODRIGUE, CHRISTINA	3773	623-017150

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

[ ] Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

[ ] "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-09 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,

(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 Fish & Richardson P.C.
2
3

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE: Moskowitz Family LLC

(B) RESIDENCE: (CITY and STATE OR COUNTRY): Rockville, MD

Please check the appropriate assignee category or categories (will not be printed on the patent): [ ] Individual [X] Corporation or other private group entity [ ] Government

4a. Fees Submitted: [X] Issue Fee [ ] Publication Fee (if required) [ ] Advance Order - # of Copies

4b. Method of Payment (*Please first reapply any previously paid fee shown above*):

[ ] Electronic Payment via EFS-Web [ ] Enclosed check [ ] Non-electronic payment by credit card (Attach form PTO-2038)

[X] The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account No. 06-1050

5. **Change of Entity Status** (from status indicated above)

[ ] Applicant certifying micro entity status. See 37 CFR 1.29 — **NOTE**: Absent a valid Certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

[ ] Applicant asserting small entity status. See 37 CFR 1.27. — **NOTE**: If the application was previously under micro entity status, checking this box will be taken as a notification of loss of entitlement to micro entity status.

[ ] Applicant changing to regular undiscounted fee status. — **NOTE**: Checking this box will be taken as a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature /Stuart A. Nelson/ Date 8/22/2019

Typed or printed name Stuart A. Nelson Registration No. 63,947

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/025,667	10/01/2019	10426633	46440-0020003	5655

26191 7590 09/11/2019

FISH & RICHARDSON P.C. (TC)
PO BOX 1022
MINNEAPOLIS, MN 55440-1022

ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment is 1 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Application Assistance Unit (AAU) of the Office of Data Management (ODM) at (571)-272-4200.

APPLICANT(s) (Please see PAIR WEB site http://pair.uspto.gov for additional applicants):

Moskowitz Family LLC, Rockville, MD;
Ahmnon D. Moskowitz, Rockville, MD;
Mosheh T. Moskowitz, Rockville, MD;
Pablo A. Valdivia Y. Alvarado, Cambridge, MA;
Eric Sugalski, Arlington, MA;
Nathan C. Moskowitz, Rockville, MD;

The United States represents the largest, most dynamic marketplace in the world and is an unparalleled location for business investment, innovation, and commercialization of new technologies. The USA offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to encourage and facilitate business investment. To learn more about why the USA is the best country in the world to develop technology, manufacture products, and grow your business, visit SelectUSA.gov.

IR103 (Rev. 10/09)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor	:	Ahmnon D. Moskowitz	Art Unit	:	3773
Patent No.	:	10,426,633	Examiner	:	Christina Negrellirodrigue
Issue Date	:	October 1, 2019			
Application No.	:	16/025,667	Conf. No.	:	5655
Filed	:	July 2, 2018			
Title	:	ZERO-PROFILE EXPANDABLE INTERVERTEBRAL SPACER DEVICES FOR DISTRACTION AND SPINAL FUSION AND A UNIVERSAL TOOL FOR THEIR PLACEMENT AND EXPANSION			

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REQUEST TO CORRECT INVENTORSHIP OF PATENT UNDER 37 C.F.R. § 1.324

Applicant respectfully requests that the inventorship of the above-referenced utility patent be corrected pursuant to 37 C.F.R. § 1.324 to add the name of the following inventor(s):

David Schoon

Statements from all inventors and the assignee, agreeing to the change of inventorship are enclosed.

Payment of the required fee set forth in § 1.20(b) is being made at this time, apply any other charges or credits to Deposit Account No. 06-1050, referencing the above attorney docket number.

Respectfully submitted,

Date: 8/31/2021

/Stuart A. Nelson/
Stuart A. Nelson
Reg. No. 63,947

Customer Number 26191
Fish & Richardson P.C.
Telephone: (612) 337-2538
Facsimile: (877) 769-7945

62230524.doc

PTO/AIA/96 (08-12)
Approved for use through 01/31/2013. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

STATEMENT UNDER 37 CFR 3.73(c)

Applicant/Patent Owner: MOSKOWITZ FAMILY LLC

Application No./Patent No.: 16/025,667 Filed/Issue Date: July 2, 2018

Titled: ZERO-PROFILE EXPANDABLE INTERVERTEBRAL SPACER DEVICES FOR DISTRACTION AND SPINAL FUSION AND A UNIVERSAL TOOL FOR THEIR PLACEMENT AND EXPANSION

MOSKOWITZ FAMILY LLC, a Limited Liability Corporation

(Name of Assignee) (Type of Assignee, e.g., corporation, partnership, university, government agency, etc.)

states that, for the patent application/patent identified above, it is (choose **one** of the option 1, 2, 3 or 4 below):

1. ☒ The assignee of the entire right, title, and interest.

2. ☐ An assignee of less than the entire right, title and interest (check applicable box):

☐ The extent (by percentage) of its ownership interest is _____. Additional Statement(s) by the owners holding the balance of the interest must be submitted to account for 100% of the ownership interest.

☐ There are unspecified percentages of ownership. The other parties, including inventors, who together own the entire right, title and interest are:

Additional Statement(s) by the owner(s) holding the balance of the interest must be submitted to account for the entire right, title, and interest.

3. ☐ The assignee of an undivided interest in the entirety (a complete assignment from one of the joint inventors was made). The other parties, including inventors, who together own the entire right, title, and interest are:

Additional Statement(s) by the owner(s) holding the balance of the interest must be submitted to account for the entire right, title, and interest.

4. ☐ The recipient, via a court proceeding or the like (e.g., bankruptcy, probate), of an undivided interest in the entirety (a complete transfer of ownership interest was made). The certified document(s) showing the transfer is attached.

The interest identified in option 1, 2 or 3 above (not option 4) is evidenced by either (choose **one** of the options A or B below):

A. ☐ An assignment from the inventor(s) of the patent application/patent identified above. The assignment was recorded in the United States Patent and Trademark Office at Reel _____, Frame _____, or for which a copy thereof is attached.

B. ☒ A chain of title from the inventor(s), of the patent application/patent identified above, to the current assignee as follows:

1. From: SUGALSKI, ERIC To: MOSKOWITZ, NATHAN C.
The document was recorded in the United States Patent and Trademark Office at
Reel 048237, Frame 0758, or for which a copy thereof is attached.

2. From: ALVARADO, PABLO A. VALDIVIA Y To: MOSKOWITZ, NATHAN C.
The document was recorded in the United States Patent and Trademark Office at
Reel 048237, Frame 0710, or for which a copy thereof is attached.

This collection of information is required by 37 CFR 3.73(b). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Approved for use through 01/31/2013. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

STATEMENT UNDER 37 CFR 3.73(c)

3. From: MOSKOWITZ, MOSHEH T. To: MOSKOWITZ, NATHAN C.
The document was recorded in the United States Patent and Trademark Office at
Reel 048260, Frame 0654, or for which a copy thereof is attached.

4. From: MOSKOWITZ, AHMNON D. To: MOSKOWITZ, NATHAN C.
The document was recorded in the United States Patent and Trademark Office at
Reel 048260, Frame 0595, or for which a copy thereof is attached.

5. From: MOSKOWITZ, NATHAN C. To: MOSKOWITZ FAMILY LLC
The document was recorded in the United States Patent and Trademark Office at
Reel 048237, Frame 0270, or for which a copy thereof is attached.

6. From: SCHOON, DAVID To: MOSKOWITZ FAMILY LLC
The document was recorded in the United States Patent and Trademark Office at
Reel 057014, Frame 0629, or for which a copy thereof is attached.

☐ Additional documents in the chain of title are listed on a supplemental sheet(s).

☒ As required by 37 CFR 3.73(c)(1)(i), the documentary evidence of the chain of title from the original owner to the assignee was, or concurrently is being, submitted for recordation pursuant to 37 CFR 3.11.

[NOTE: A separate copy *(i.e.,* a true copy of the original assignment document(s)) must be submitted to Assignment Division in accordance with 37 CFR Part 3, to record the assignment in the records of the USPTO. See MPEP 302.08]

The undersigned (whose title is supplied below) is authorized to act on behalf of the assignee.

/Stuart A. Nelson/	8/31/2021
Signature	Date
Stuart A. Nelson	63,947
Printed or Typed Name	Title or Registration Number

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor	:	Ahmnon D. Moskowitz	Art Unit	:	3773
Patent No.	:	10,426,633	Examiner	:	Christina Negrellirodrigue
Issue Date	:	October 1, 2019			
Application No.	:	16/025,667	Conf. No.	:	5655
Filed	:	July 2, 2018			
Title	:	ZERO-PROFILE EXPANDABLE INTERVERTEBRAL SPACER DEVICES FOR DISTRACTION AND SPINAL FUSION AND A UNIVERSAL TOOL FOR THEIR PLACEMENT AND EXPANSION			

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REQUEST TO CORRECT INVENTORSHIP - INVENTOR'S DECLARATION

Ahmnon D. Moskowitz, Mosheh T. Moskowitz, Pablo A. Valdivia Y. Alvarado, Eric Sugalski, Nathan C. Moskowitz and David Schoon each hereby declare:

1. That he is an original inventor of the above-identified patent.

2. That he either agrees that David Schoon should be added as an inventor or that he has no disagreement with adding David Schoon as an inventor.

Date: 1/23/20

Ahmaon D. Moskowitz

Date: 1/23/20

Mosheh T. Moskowitz

Date: 8/30/21

Pablo A. Valdivia Y. Alvarado

Date: 01 / 23 / 2020

Eric Sugalski

Date: 1/23/20

Nathan C. Moskowitz

Date: 1/23/20

David Schoon

Fish & Richardson P.C.
3200 RBC Plaza
60 South Sixth Street
Minneapolis, MN 55402
Telephone: (612) 337-2538
Facsimile: (877) 769-7945

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor	:	Ahmnon D. Moskowitz	Art Unit	:	3773
Patent No.	:	10,426,633	Examiner	:	Christina Negrellirodrigue
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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REQUEST TO CORRECT INVENTORSHIP - COMPANY OFFICER'S DECLARATION

As an officer of the concern to which the noted application has been assigned, I hereby consent to the correction of inventorship of this patent by adding David Schoon.

Respectfully submitted,

Date: 7/15/21

MOSKOWITZ FAMILY LLC
Name:
Title:

Fish & Richardson P.C.
3200 RBC Plaza
60 South Sixth Street
Minneapolis, MN 55402
Telephone: (612) 337-2538
Facsimile: (877) 769-7945

PTO/AIA/01 (06-12)
Approved for use through 01/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number

DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

Title of Invention	ZERO-PROFILE EXPANDABLE INTERVERTEBRAL SPACER DEVICES FOR DISTRACTION AND SPINAL FUSION AND A UNIVERSAL TOOL FOR THEIR PLACEMENT AND EXPANSION

As the below named inventor, I hereby declare that:

This declaration is directed to:

☐ The attached application, or

☒ United States application or PCT international application number 14/063,197

filed on 10/25/2013.

The above-identified application was made or authorized to be made by me.

I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

WARNING:

Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.

LEGAL NAME OF INVENTOR

Inventor: David SCHOON Date (Optional): 4/1/2015

Signature: _____

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 1 minute to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Electronic Patent Application Fee Transmittal

Application Number:	16025667
Filing Date:	02-Jul-2018
Title of Invention:	ZERO-PROFILE EXPANDABLE INTERVERTEBRAL SPACER DEVICES FOR DISTRACTION AND SPINAL FUSION AND A UNIVERSAL TOOL FOR THEIR PLACEMENT AND EXPANSION
First Named Inventor/Applicant Name:	Ahmnon D. Moskowitz
Filer:	Stuart A. Nelson/Emily Whitcomb
Attorney Docket Number:	46440-0020003

Filed as Small Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
CERTIFICATE OF CORRECTION	2811	1	160	160

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**160**

Electronic Acknowledgement Receipt	
EFS ID:	43651808
Application Number:	16025667
International Application Number:	
Confirmation Number:	5655
Title of Invention:	ZERO-PROFILE EXPANDABLE INTERVERTEBRAL SPACER DEVICES FOR DISTRACTION AND SPINAL FUSION AND A UNIVERSAL TOOL FOR THEIR PLACEMENT AND EXPANSION
First Named Inventor/Applicant Name:	Ahmnon D. Moskowitz
Customer Number:	26191
Filer:	Stuart A. Nelson/Emily Whitcomb
Filer Authorized By:	Stuart A. Nelson
Attorney Docket Number:	46440-0020003
Receipt Date:	31-AUG-2021
Filing Date:	02-JUL-2018
Time Stamp:	16:44:25
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	$160
RAM confirmation Number	E20218UG45220569
Deposit Account	
Authorized User	
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Request under Rule 48 correcting inventorship	RequestoCorrectInventorship.PDF	40906 5b73a9e635a69e78bf6de4a8398facaadcdb076f	no	1
Warnings:					
Information:					
2	Assignee showing of ownership per 37 CFR 3.73	Statement373C.PDF	85714 f3fb6b49dffd9b19248a765815b93238953db92b	no	2
Warnings:					
Information:					
3	Oath or Declaration filed	003SignedDec.pdf	222938 8c2684e8348e6c8db29874d0c201c3ff24a569e8	no	2
Warnings:					
Information:					
4	Oath or Declaration filed	003OfficerDec.pdf	368941 3abba547a11ab5c344a73b6c6d99b9e66578d110	no	1
Warnings:					
Information:					
5	Oath or Declaration filed	SchoonDec.pdf	1425286 de86decff2d77c6734b0aa1eac90eede6ecbd0f0	no	1
Warnings:					
Information:					
6	Fee Worksheet (SB06)	fee-info.pdf	38376 a948cfd38f8dfcb82c41cac78e7048e7da451cb9	no	2
Warnings:					
Information:					

Total Files Size (in bytes):	2182161

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/025,667	07/02/2018	Ahmnon D. Moskowitz	46440-0020003	5655

26191 7590 11/29/2021

FISH & RICHARDSON P.C. (TC)
PO BOX 1022
MINNEAPOLIS, MN 55440-1022

EXAMINER	
NEGRELLIRODRIGUEZ, CHRISTINA	

ART UNIT	PAPER NUMBER
3773	

NOTIFICATION DATE	DELIVERY MODE
11/29/2021	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

PTOL-90A (Rev. 04/07)

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

Patent No.: 10426633
Issue Date: 10/01/2019
Appl. No.: 16/025,667
Filed: 07/02/2018

PART (A) RESPONSE FOR CERTIFICATES OF CORRECTION

This is a decision on the Certificate of Correction request filed ____.

The request for issuance of Certificate of Correction for the above-identified correction(s) under the provisions of 37 CFR 1.322 and/or 1.323 is hereby:

(Check one)
☐ Approved ☐ Approved in Part ☐ Denied

Comments: ____

PART (B) PETITION UNDER 37 CFR 1.324 OR 37 CFR 1.48

☑ This is a decision on the petition filed 31 August 2021 to correct inventorship under 37 CFR 1.324.

☐ This is a decision on the request under 37 CFR 1.48, petition filed ____. In view of the fact that the patent has already issued, the request under 37 CFR 1.48 has been treated as a petition to correct inventorship under 37 CFR 1.324.

The petition is hereby: ☑ Granted ☐ Dismissed

Comment: ____

The patented filed is being forwarded to Certificate of Corrections Branch for issuance of a certificate naming only the actual inventor or inventors.

/EDUARDO C ROBERT/
Supervisory Patent Examiner, Art Unit 3773
Technology Center 3700
Phone: (571)272-4719

Certificates of Correction Branch email: CustomerServiceCoC@uspto.gov CoC Central Phone Number: (703) 756-1814

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

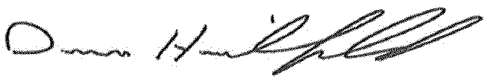
PATENT NO. : 10,426,633 B2
APPLICATION NO. : 16/025667
DATED : October 1, 2019
INVENTOR(S) : Moskowitz et al.

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

On the Title Page

Item (72) Inventor is corrected to read:
--Ahmnon D. Moskowitz, Rockville, MD (US);
Mosheh T. Moskowitz, Rockville, MD (US);
Pablo A. Valdivia Y. Alvarado, Cambridge, MA (US);
Eric Sugalski, Arlington, MA (US);
Nathan C. Moskowitz, Rockville, MD (US);
David Schoon, Somerville, Massachusetts (US)--.

Signed and Sealed this
Fourteenth Day of December, 2021



Drew Hirshfeld
Performing the Functions and Duties of the
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office