

UTILITY PATENT APPLICATION TRANSMITTAL <i>(Only for new nonprovisional applications under 37 CFR 1.53(b))</i>	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 30%;">Attorney Docket No.</td> <td>3003/0107PUS18</td> </tr> <tr> <td>First Named Inventor</td> <td>Ahmnon D. MOSKOWITZ et al.</td> </tr> <tr> <td>Title</td> <td>BI-DIRECTIONAL FIXATING/LOCKING TRANSVERTEBRAL...</td> </tr> <tr> <td>Express Mail Label No.</td> <td>eFiled</td> </tr> </table>	Attorney Docket No.	3003/0107PUS18	First Named Inventor	Ahmnon D. MOSKOWITZ et al.	Title	BI-DIRECTIONAL FIXATING/LOCKING TRANSVERTEBRAL...	Express Mail Label No.	eFiled
Attorney Docket No.	3003/0107PUS18								
First Named Inventor	Ahmnon D. MOSKOWITZ et al.								
Title	BI-DIRECTIONAL FIXATING/LOCKING TRANSVERTEBRAL...								
Express Mail Label No.	eFiled								

APPLICATION ELEMENTS <i>See MPEP chapter 600 concerning utility patent application contents.</i>	Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450
1. ☐ Fee Transmittal Form (PTO/SB/17 or equivalent) 2. ☒ Applicant asserts small entity status. See 37 CFR 1.27 3. ☐ Applicant certifies micro entity status. See 37 CFR 1.29. Applicant must attach form PTO/SB/15A or B or equivalent. 4. ☒ Specification [Total Pages <u>34</u>] Both the claims and abstract must start on a new page. (See MPEP § 608.01(a) for information on the preferred arrangement) 5. ☒ Drawing(s) (35 U.S.C. 113) [Total Sheets <u>40</u>] 6. Inventor's Oath or Declaration [Total Pages _____] (including substitute statements under 37 CFR 1.64 and assignments serving as an oath or declaration under 37 CFR 1.63(e)) a. ☐ Newly executed (original or copy) b. ☐ A copy from a prior application (37 CFR 1.63(d)) 7. ☒ Application Data Sheet * See note below. See 37 CFR 1.76 (PTO/AIA/14 or equivalent) 8. CD-ROM or CD-R in duplicate, large table, or Computer Program (Appendix) ☐ Landscape Table on CD 9. Nucleotide and/or Amino Acid Sequence Submission (if applicable, items a. – c. are required) a. ☐ Computer Readable Form (CRF) b. ☐ Specification Sequence Listing on: i. ☐ CD-ROM or CD-R (2 copies); or ii. ☐ Paper c. ☐ Statements verifying identity of above copies	ACCOMPANYING APPLICATION PAPERS 10. ☐ Assignment Papers (cover sheet & document(s)) Name of Assignee _____ 11. ☐ 37 CFR 3.73(c) Statement ☐ Power of Attorney (when there is an assignee) 12. ☐ English Translation Document (if applicable) 13. ☐ Information Disclosure Statement (PTO/SB/08 or PTO-1449) ☐ Copies of citations attached 14. ☐ Preliminary Amendment 15. ☐ Return Receipt Postcard (MPEP § 503) (Should be specifically itemized) 16. ☐ Certified Copy of Priority Document(s) (if foreign priority is claimed) 17. ☐ Nonpublication Request Under 35 U.S.C. 122(b)(2)(B)(i). Applicant must attach form PTO/SB/35 or equivalent. 18. ☐ Other: _____ _____ _____ _____

***Note:** (1) Benefit claims under 37 CFR 1.78 and foreign priority claims under 1.55 **must** be included in an Application Data Sheet (ADS).
 (2) For applications filed under 35 U.S.C. 111, the application must contain an ADS specifying the applicant if the applicant is an assignee, person to whom the inventor is under an obligation to assign, or person who otherwise shows sufficient proprietary interest in the matter. See 37 CFR 1.46(b).

19. CORRESPONDENCE ADDRESS					
☒ The address associated with Customer Number: <u>87409</u> OR ☐ Correspondence address below					
Name					
Address					
City	State		Zip Code		
Country	Telephone		Email		
Signature	/John J. Dresch/		Date	April 18, 2017	
Name (Print/Type)	John J. Dresch		Registration No. (Attorney/Agent)	46,672	

This collection of information is required by 37 CFR 1.53(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.

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.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	3003/0107PUS18
		Application Number	
Title of Invention	BI-DIRECTIONAL FIXATING/LOCKING TRANSVERTEBRAL BODY SCREW/INTERVERTEBRAL CAGE STAND-ALONE CONSTRUCTS HAVING A CENTRAL SCREW LOCKING LEVER, AND PLIERS AND DEVICES FOR SPINAL FUSION		
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.)
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Inventor Information:

Inventor	1				Remove	
Legal Name						
Prefix	Given Name	Middle Name	Family Name	Suffix		
	Ahmnnon	D.	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			
Inventor	2				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			
Inventor	3				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						

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City	Rockville	State/Province	MD	Country of Residence	US
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Mailing Address of Inventor:

Address 1	212 North Adams Street				
Address 2					
City	Rockville	State/Province	MD		
Postal Code	20850	Country	US		
Inventor	4				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

City	Cambridge	State/Province	MA	Country of Residence	US
------	-----------	----------------	----	----------------------	----

Mailing Address of Inventor:

Address 1	65R Otis Street #1				
Address 2					
City	Cambridge	State/Province	MA		
Postal Code	02141	Country	US		

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

Customer Number	87409		
Email Address	mailroom@dreschiplaw.com	Add Email	Remove Email
Email Address	jdresch@dreschiplaw.com	Add Email	Remove Email

Application Information:

Title of the Invention	BI-DIRECTIONAL FIXATING/LOCKING TRANSVERTEBRAL BODY SCREW/INTERVERTEBRAL CAGE STAND-ALONE CONSTRUCTS HAVING A CENTRAL SCREW LOCKING LEVER, AND PLIERS AND DEVICES FOR SPINAL FUSION		
Attorney Docket Number	3003/0107PUS18	Small Entity Status Claimed	☒
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)	40	Suggested Figure for Publication (if any)	1A

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	3003/0107PUS18
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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	☐	Limited Recognition (37 CFR 11.9)
Customer Number	87409		

Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, or 365(c) or indicate National Stage entry from a PCT application. Providing this 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 blank.

Prior Application Status	Pending	Remove			
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)		
	Continuation of	14257650	2014-04-21		
Prior Application Status	Patented	Remove			
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
14257650	Division of	12471340	2009-05-22	8734516	2014-05-27
Prior Application Status	Patented	Remove			
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
12471340	Continuation in part of	12054335	2008-03-24	7972363	2011-07-05
Prior Application Status	Patented	Remove			
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
12054335	Continuation in part of	11842855	2007-08-21	7942903	2011-05-17
Prior Application Status	Patented	Remove			

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Application Data Sheet 37 CFR 1.76		Attorney Docket Number		3003/0107PUS18	
		Application Number			
Title of Invention	BI-DIRECTIONAL FIXATING/LOCKING TRANSVERTEBRAL BODY SCREW/INTERVERTEBRAL CAGE STAND-ALONE CONSTRUCTS HAVING A CENTRAL SCREW LOCKING LEVER, AND PLIERS AND DEVICES FOR SPINAL FUSION				

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		Patented ▾	Remove		
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
11536815	Continuation in part of ▾	11208644	2005-08-23	7704279	2010-04-27
Prior Application Status		Expired ▾	Remove		
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)		
14257650	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(d). When priority is claimed to a foreign application that is eligible for retrieval under the priority document exchange program (PDX)¹ the information will be used by the Office to automatically attempt retrieval pursuant to 37 CFR 1.55(h)(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 ^j (if applicable)
Remove			
Application Number	Country ⁱ	Filing Date (YYYY-MM-DD)	Access Code ^j (if applicable)
Additional Foreign Priority Data may be generated within this form by selecting the Add button.			
Add			

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	3003/0107PUS18
		Application Number	
Title of Invention	BI-DIRECTIONAL FIXATING/LOCKING TRANSVERTEBRAL BODY SCREW/INTERVERTEBRAL CAGE STAND-ALONE CONSTRUCTS HAVING A CENTRAL SCREW LOCKING LEVER, AND PLIERS AND DEVICES FOR SPINAL FUSION		

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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Authorization to Permit Access:

☒ Authorization to Permit Access to the Instant Application by the Participating Offices If 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 World Intellectual Property Office (WIPO), and any other intellectual property offices in which a foreign application claiming priority to the instant patent application is filed access to the instant patent application. See 37 CFR 1.14(c) and (h). This box should not be checked if the applicant does not wish the EPO, JPO, KIPO, WIPO, or other intellectual property office in which a foreign application claiming priority to the instant patent application is filed to have access to the instant patent application. In accordance with 37 CFR 1.14(h)(3), access will be provided to a copy of the instant patent application with respect to: 1) the instant patent application-as-filed; 2) any foreign application to which the instant patent application claims priority under 35 U.S.C. 119(a)-(d) if a copy of the foreign application that satisfies the certified copy requirement of 37 CFR 1.55 has been filed in the instant patent application; and 3) any U.S. application-as-filed from which benefit is sought in the instant patent application. In accordance with 37 CFR 1.14(c), access may be provided to information concerning the date of filing this Authorization.
--

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.
--

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	3003/0107PUS18
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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. ☐			

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

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If the Assignee or Non-Applicant Assignee is an Organization check here. ☐				
Prefix	Given Name	Middle Name	Family Name	Suffix
Dr. ☐	Nathan	C.	Moskowitz	☐
Mailing Address Information For Assignee including Non-Applicant Assignee:				
Address 1	212 North Adams Street			
Address 2				
City	Rockville	State/Province	MD	
Country ⁱ	US	Postal Code	20850	
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:

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications.					
Signature	/John J. Dresch/			Date (YYYY-MM-DD)	2017-04-18
First Name	John	Last Name	Dresch	Registration Number	46672
Additional Signature may be generated within this form by selecting the Add button. Add					

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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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 the Freedom of Information Act requires disclosure of these records.
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 inspections 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.

**BI-DIRECTIONAL FIXATING/LOCKING TRANSVERTEBRAL
BODY SCREW/INTERVERTEBRAL CAGE STAND-ALONE
CONSTRUCTS HAVING A CENTRAL SCREW LOCKING LEVER,
AND PLIERS AND DEVICES FOR SPINAL FUSION**

[0001] This application is a Continuation of 14/257,650 filed April 21, 2014, which is a Divisional Application of 12/471,340 filed May 22, 2009, now U.S. Patent No. 8,734,516 issued May 27, 2014, which is a Continuation-In-Part Application of Application Serial No. 12/054,335 filed on March 24, 2008, now U.S. Patent No. 7,972,363 issued July 5, 2011, which is a Continuation-In-Part of Application Serial No. 11/842,855, filed on 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 on 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 on August 23, 2005, now U.S. Patent No. 7,704,279 issued April 27, 2010, and this application also 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 of the above identified patent applications are hereby incorporated by reference in their entirety.

[0002] This application is related to applicants' U.S. Patent No. 8,257,370 issued September 4, 2012, titled "POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT STAPLES, STAPLING GUNS, AND DEVICES FOR SPINAL FUSION", Attorney Docket No. 3003/0107PUS3, which is incorporated herein by reference.

Field of Disclosure

[0003] The present invention relates to a unique universal bi-directional screw (BDS) system, and in particular its application to the spine, also referred to as bi-directional fixating transvertebral (BDFT) screw/cage constructs which can be used as stand-alone intervertebral devices which combine the dual functions of an intervertebral spacer that can be filled with bone fusion material(s), as well as a bi-directional transvertebral bone fixating/fusion screw apparatus. In the posterior lumbosacral and thoracic spine, intervertebral cage/BDFT screw constructs can be used as stand-alone devices obviating the need for pedicle screw fixation in many but not all cases. In the anterior cervical,

thoracic and lumbosacral spine, intervertebral cage/BDFT screw constructs can be used as stand-alone devices obviating the need for anterior or lateral (thoracic) spinal plating, and/or supplemental posterior pedicle screw fixation.

[0004] The present invention also relates to percutaneous stand-alone or supplemental posterior cervical, thoracic and lumbosacral calibrated intrerarticulating joint staple guns and staples which may obviate and/or lessen the need for posterior supplemental pedicle screw fixation.

Background

[0005] The history and evolution of instrumented spinal fusion in the entire human spine has been reviewed in related applications Serial No. 12/054,335 filed on March 24, 2008, Serial No. 11/842,855, filed on August 21, 2007, Serial No. 11/536,815 filed on September 29, 2006, and Serial No. 11/208,644 filed on August 23, 2005, the contents of which are hereby incorporated by reference in their entirety. Conventionally, the majority of posterior cervical and almost all posterior thoracic and lumbosacral fusion surgical techniques are typically supplemented with pedicle screw placement. Conventionally, the majority of anterior cervical spinal fusions, and many antero-lateral thoracic, and anterior or antero-lateral lumbosacral fusions are supplemented with anterior or anterior-lateral spinal plating, and very often, in particular in the thoracic and lumbosacral spine, are supplemented with posterior pedicle screw instrumentation.

[0006] Complications of pedicle screw placement in cervical, thoracic and lumbosacral spine 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 excessive rigidity leading to adjacent segmental disease requiring further fusions and re-operations. Recent advances in pedicle screw fixation including minimally invasive, and stereotactic CT image-guided technology, and the development of flexible rods, imperfectly address some but not all of these issues.

[0007] Complications of anterior plating in the cervical spine include potential plate, and/or screw esophageal compression, and misplaced screws leading to neurovascular injury. Complications of anterior plating in the anterior lumbar spine include potential devastating injury to the major vessels due to chronic vascular erosion of the major vessels, or acute vascular injuries due to partial or complete plate and/or screw back out.

Furthermore, for re-do surgeries, plate removal can be arduous, with potential complications of prolonged esophageal retraction, vascular injury and screw breakage. Recent advances including diminishing the plate width and/or profile, and absorbable plates, imperfectly address some but not all of these issues.

[0008] Complications of all conventional spinal anterior intervertebral device constructs are their potential for extrusion in the absence of plating. Hence, they are supplemented with anterior plating to prevent extrusion. Complications of posterior lumbosacral intervertebral device construct in the presence or absence of supplemental pedicle screw fixation is device extrusion, and potential nerve root injuries related to retraction.

SUMMARY

[0009] Herein described are multiple device embodiments which combine in a single stand-alone construct the dual functions of: a) an intervertebral cage spacer which can be filled with bone fusion material maintaining disc height, and, b) a bi-directional fixating/fusion transvertebral body screw apparatus. These embodiments are described for posterior and anterior lumbar (and antero-lateral thoracic) intervertebral placement, and anterior cervical intervertebral placement. The present invention recognizes the aforementioned problems with conventional apparatus and solves these problems by, among other things, improving upon the designs illustrated in the aforementioned related applications. The present application provides an advanced and novel bi-directional fixating transvertebral (BDFT) screw/cage apparatus having, for example, more advanced screw locking embodiments that prevent screw pull-out or back-out.

[0010] The exemplary embodiments of a bi-directional fixating transvertebral (BDFT) screw/cage apparatus provide as strong or stronger segmental fusion as pedicle screws without the complications arising from pedicle screw placement, which include misplacement with potential nerve and/or vascular injury, violation of healthy facets, possible pedicle destruction, blood loss, and overly rigid fusions. 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 transpedicular route thereby excluding the posterior spinal column, then healthy facet joints, if they exist, are preserved. Because the present invention accomplishes both anterior and middle column fusion, without rigidly fixating the posterior column, the present invention in essence creates a flexible fusion.

[0011] The present invention recognizes that 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.

[0012] Transvertebral fusion also leads to far less muscle retraction, blood loss and significant reduction in O.R. time. Thus, the complication of pedicle screw pull out, and hence high re-operation rate associated with the current embodiment of flexible fusion pedicle screws/rods is obviated. The lumbosacral intervertebral cage/BDFT screw constructs can be introduced via posterior lateral, transforaminal or anterior interbody fusion approaches/surgical techniques. Although one can opt to supplement these constructs with transpedicular screws there would be no absolute need for supplemental pedicle screw fixation with these operative techniques.

[0013] The anterior placement of a bi-directional fixating transvertebral (BDFT) screw/cage apparatus according to the embodiments of the present invention into the cervical and lumbar spine obviates the need for supplemental anterior cervical or anterior lumbar plating. The sole purpose of these plates is to prevent intervertebral device extrusion. This function is completely obviated and replaced by the dual functioning bi-directional fixating transvertebral (BDFT) screw/cage apparatus, according to the present invention. The obvious advantage of this is a significant savings in operative time, and prevention of injuries associated with plating, in particular esophageal, large and small vessel injuries, and spinal cord nerve root injuries.

[0014] Because the embodiments of the bi-directional fixating transvertebral (BDFT) screw/cage apparatus engage a small percentage of the rostral and caudal vertebral body surface area, multi-level fusions can be performed with these devices.

[0015] The aforementioned related applications described a novel calibrated lumbar/thoracic stapling device which staples the inferior articulating facet of the superior spinal segment to the superior articulating facet of the inferior vertebral segment unilaterally or bilaterally, which may minimize motion until interbody fusion occurs. The present invention presents an evolved and lumbar staple gun which is far more user friendly than previously described embodiments by incorporating a new release mechanism, as described in the aforementioned related applications. This new change simplifies the earlier design, and facilitates easier insertion and removal of the

staple decreasing the risk of the staple becoming loose or falling off during an operation. The exemplary staple gun thus makes posterior lumbar facet stapling far more amenable for percutaneous fluoroscopically guided surgical stapling.

[0016] The aforementioned related applications introduced a novel posterior cervical facet stapling device which staples the inferior articulating facet of the superior cervical segment with the superior articulating facet of the inferior cervical segment either unilaterally or bilaterally. The advantage of cervical facet staples is speed and safety. The risks of cervical facet pedicle screw fixation, which include nerve root and vertebral artery injuries, are completely obviated by the use of the embodiments of the present invention. Thus, cervical facet staples achieve the same function of cervical pedicle screws without the risks.

[0017] Placement of different embodiments of the cervical facet staples which include those with two or four prongs, along unilateral and/or bilateral facet joints in a modular manner, lead to different degrees of calibrated joint motion hence introducing the novel concept of calibrated cervical fusion. In the related applications, cervical facet embodiments of a highly evolved cervical staple gun for the two and four pronged cervical staples were introduced. The staple gun included a built-in trigger, trigger spring, spring hook, and return spring polyethylene cushion that improved the strength, ease and speed of staple bone penetration. In this application, the embodiments can provide more simplified and economically efficient staple guns which are very user friendly and further enhances the application of the cervical staple gun also making posterior cervical facet stapling more amenable to a non-invasive, percutaneous surgical procedure.

[0018] Conventionally, failed anterior lumbar arthroplasties are salvaged by combined anterior and posterior fusions. Intervertebral cage/BDFT screw constructs may be utilized as a one-step salvage mechanism for failed/extruded anteriorly placed lumbar artificial discs obviating the need for supplemental posterior pedicle screws and/or anterior lumbar plating thereby significantly reducing and/or eliminating co-morbidities associated with these other salvage procedures.

[0019] Likewise, anterior cervical intervertebral cage/BDFT screw construct placement can be used to salvage failed anterior cervical arthroplasties, and re-do fusions without having to supplement with cervical anterior plates, thereby reducing the morbidity of this procedure.

[0020] In addition, if a patient develops a discogenic problem necessitating anterior cervical discectomy and fusion at a level above or below a previously fused and plated segment, the present invention reduces or eliminates the need to remove the prior plate in order to place a new superior plate, because the function of the plate is replaced by the dual functioning intervertebral cervical construct, thereby reducing the operating room time and surgical morbidity of this procedure.

[0021] Furthermore, because of the orientation and length of the BDFT screws within the intervertebral cage/BDFT constructs, multiple level fusions can be easily performed. Posterior cervical and lumbar stapling can also be performed for multiple levels.

[0022] For example, an exemplary embodiment is directed to an intervertebral cage spacer and bi-directional fixating/fusion transvertebral body screw/cage apparatus, a posterior lumbar facet staple and a staple gun for a posterior lumbar facet staple, and a staple gun for a posterior cervical facet joint staple are provided. The apparatus includes an intervertebral cage for maintaining disc height. The intervertebral cage includes a first internal screw guide and a second internal screw guide. The apparatus further includes a first screw member having a tapered end and a threaded body disposed within the intervertebral cage, a second screw member having a tapered end and a threaded body disposed within the intervertebral cage, The device includes a novel mechanism involving a separate screw locking bracket with hooks that insert into a prefabricated insertion site within the sides of the intervertebral cage which when press-fit onto the cage prevents the screw members from pulling-out of the internal screw guides. A specifically designed set of pliers is illustrated which can be used to insert the locking brackets. The tips have stops so that the brackets can be more easily held. It also has a limiting screw to limit the amount the pliers close to prevent over-pressing the locking brackets. It also has a leaf spring that preloads the pliers. These applicators can also apply gentle pressure on the brackets flexure grips (side tabs) to slightly deform (open) the bracket hooks, thus easily removing the bracket if necessary intra-operatively or in the future.

[0023] Another exemplary embodiment is directed to a staple gun for a posterior lumbar facet joint staple gun, including a handle having a first grip and a second grip, a cylinder body having a first end for receiving the posterior lumbar facet joint staple and a second end adjacent to the handle, a connector that connects the cylinder body to the handle, a puller, an independent puller tip and a return spring. This embodiment is more user

friendly making the staple gun easier to load, easier to use, and prevents the staple from falling off during any portion of the surgery.

[0024] Yet another exemplary embodiment is directed to a staple gun for a posterior cervical facet joint staple, including a handle, a retaining spring, a central plunger and a tip. The device can be used with a hammer to apply two or four pronged posterior cervical staples to impact them into the facets. A central button releases the staple from the spring allowing the staple gun to be reloaded.

[0025] Another exemplary embodiment is directed to a method of inserting a bi-directional fixating transvertebral (BDFT) screw/cage apparatus between a first vertebral body and a second vertebral body. The method includes measuring a dimension of a disc space between the first vertebral body and the second vertebral body, determining that the disc space is a posterior lumbar disc space, an anterior lumbar disc space, or an anterior cervical disc space, selecting an intervertebral cage based on the measured dimension of the disc space and based on the determination of the disc space being the posterior lumbar disc space, the anterior lumbar disc space, or the anterior cervical disc space, inserting the selected intervertebral cage into a midline of the disc space until the selected intervertebral cage is flush or countersunk relative to the first vertebral body and the second vertebral body, inserting a first screw member into a first internal screw guide of the selected intervertebral cage, inserting a second screw member into a second internal screw guide of the selected intervertebral cage, screwing the first screw member and the second screw member into the first vertebral body and the second vertebral body respectively, confirming a position and placement of the intervertebral cage relative to the first vertebral body and the second vertebral body, and locking the first screw member and the second screw member in a final position by embedding a portion of the first screw member and the second screw member into a screw locking mechanism of the selected intervertebral cage.

[0026] Once the surgeon is satisfied with the position and placement of the cage, the screws can then be locked in their final positions. Then a screw locking bracket is applied with the special plier tool on top of the cage allowing the bracket hooks to snap into the cage inserts. If the surgeon changes his mind intra-operatively, or if in a future date the construct needs to be removed, the surgeon presses on the side tabs with a pliers embodiment to slightly deform (open) the bracket hooks and can then easily remove the locking bracket. Multiple level placements can be performed including two, three or more levels if necessary.

BRIEF DESCRIPTION OF THE DRAWINGS

- [0027] The accompanying drawings are presented to aid in the description of embodiments of the invention and are provided solely for illustration of the embodiments and not limitation thereof.
- [0028] Figures 1A-E illustrate an embodiment of an anterior cervical intervertebral cage/BDFT screw construct with a central screw locking lever in top (Fig 1A), bottom isometric (Fig 1B), side (Fig. 1C), isometric front (Fig. 1D), isometric bottom, and isometric fully exploded with visualized internalized angled screw guides (Fig 1E) views.
- [0029] Figures 2A-D illustrate an embodiment of an intervertebral cage/BDFT screw construct with screw locking bracket in top (Fig 2A), bottom isometric (Fig 2B), side isometric (Fig 2C), top isometric fully explodes with visualized internal screw guides (Fig 2D), and bottom isometric fully exploded with visualized bracket hooks and flexion grips (Fig 2E) views.
- [0030] Figures 3A-F illustrate an embodiment of an anterior lumbar intervertebral cage/BDFT screw construct with screw locking bracket in top (Fig 3A), bottom (Fig 3B), front (Fig 3C), side (Fig 3D), isometric top fully exploded with visualized internalized angled screw guides (Fig. 2E), and isometric fully exploded with visualized bracket hooks and flexion grips (Figure 3F) views.
- [0031] Figures 4A-F illustrate an embodiment of a posterior lumbar intervertebral cage/BDFT construct with screw locking bracket in top (Fig 4A), front (Fig.4B), side (Fig. 4C), isometric (Fig. 4D), isometric fully exploded with visualized internalized angled screw guides (Fig 4E), and isometric fully exploded with visualized bracket hooks and flexion grips (Fig. 4F) views.
- [0032] Figure 5 illustrates a pliers embodiment which applies the locking bracket to and also removes it from the intervertebral cage /BDFT constructs.
- [0033] Figures 6A-D illustrate an embodiment of a Lumbar facet joint staple gun in side view (Fig 6A), exploded (Fig. 6B) and cross-sectional (Fig. 6C) and front-on (Fig 6D) view.
- [0034] Figures 7A-E illustrate an embodiment of a posterior cervical facet staple gun in side view (Fig.7A), oblique (Fig. 7B), exploded (Fig.7C), cross-sectional (Fig. 7D), and front-on (Fig 7E) views.

- [0035] Figures 8A-E illustrate another embodiment of a posterior cervical facet staple gun in side view (Fig. 8A), oblique (Fig. 8B), exploded (Fig. 8C), cross-sectional (Fig. 8D), and front-on (Fig. 8E) views.
- [0036] Figures 9A-B illustrate an embodiment of a posterior lumbar facet staple, flexure spring embodiment in side isometric (Fig. 9A) and exploded (Fig. 9B) views.
- [0037] Figures 10A-C illustrate an embodiment of a posterior lumbar facet staple, torsional spring embodiment in side isometric (Fig. 10A), bottom isometric (Fig. 10B), and exploded (Fig. 10C) views.

DETAILED DESCRIPTION

- [0038] Aspects of the invention are disclosed in the following description and related drawings directed to specific embodiments of the invention. Alternate embodiments may be devised without departing from the scope of the invention. Additionally, well-known elements of the invention will not be described in detail or will be omitted so as not to obscure the relevant details of the invention.
- [0039] The word “exemplary” is used herein to mean “serving as an example, instance, or illustration.” Any embodiment described herein as “exemplary” is not necessarily to be construed as preferred or advantageous over other embodiments. Likewise, the term “embodiments of the invention” does not require that all embodiments of the invention include the discussed feature, advantage or mode of operation.
- [0040] With reference to FIGS. 1A-10C, exemplary embodiments of the invention will now be described.
- [0041] 1. The Medical Device
- [0042] Referring to FIGS. 1-5, the above described problems of the conventional art can be solved in the cervical, thoracic and lumbosacral spines by insertion into the denuded intervertebral disc space multiple embodiments of a bi-directional fixating transvertebral (BDFT) screw/cage apparatus.
- [0043] For example, Figures 1A-E illustrate three-dimensional views of an embodiment of an anterior cervical intervertebral cage/BDFT construct 10. In this embodiment, the cage is elliptically contoured (Fig 1C; side view) to fit into the bi-concave cervical disc space. The embodiment includes two screws 12, 14. A first screw 12 is oriented rostrally (superiorly) and a second screw 14 is oriented caudally (inferiorly). The cage 10 can include a cavity 16 for bone product placement. The cage 10 includes two built in internalized screw/drill guides 18, 20, one for each screw 12, 14 which orient the

screws bi-directionally in opposite directions. One of ordinary skill in the art will recognize that the internalized screw/drill guides 18, 20 can have different degrees of angulation and/or different positions within the cage 10. The built in tunnels of the screw guides 18, 20 provide an important advantage of ensuring that only one prescribed angled trajectory is possible for transvertebral screw placement. Embodiments of the intervertebral cages 10 can be designed with internalized screw/drill guides 18, 20 with different angles and/or different positions within the cage 10. The angle and size of the screws 12, 14 make them amenable to single or multi-level placement. The superior and inferior surfaces or edges of the lumbar cage 10 can include ridges 22 to facilitate integration and fusion with superior and inferior vertebral bodies.

[0044] The embodiment also includes a central screw locking lever 24 which is inserted in between left and right internalized screw/drill/guides 18, 20 into the top center of the construct 10 (Fig 1E). The central screw locking lever 24 can be manufactured from a variety of materials, such as titanium. After the screws 12, 14 are fully turned into the construct 10, the screw locking lever handle 26 which is initially oriented vertically, is rotated ninety degrees so that the handle 26 covers and locks both left and right screws 12, 14 thereby preventing back-out And pull-out. The locking mechanism 24 can be reused for a number of cycles. This locking mechanism 24 is an additional evolutionary embodiment not described in the aforementioned related applications.

[0045] For example, an aspect of the invention is directed to bi-directional fixating transvertebral (BDFT) screw/cage 10 apparatus, comprising an intervertebral cage 10 for maintaining disc height, the intervertebral cage 10 including a first internal screw guide 18 and a second internal screw guide 20, a first screw member 12 having a tapered end and a threaded body disposed within the intervertebral cage 10, a second screw member 14 having a tapered end and a threaded body disposed within the intervertebral cage 10, wherein each of the first internal screw guide 18 and the second internal screw guide 20 are angled to orient the first screw member 12 and the second screw member 14 bi-directionally in opposite directions, wherein the first internal screw guide 18 and the second internal screw guide 20 are aligned along a longitudinal axis of the intervertebral cage 10, and a central screw locking lever 24 coupled to the intervertebral cage 10, wherein the central screw locking lever 24 prevents the first screw member 12 and the second screw member 14 from pulling-out of the first internal screw guide 18 and the second internal screw guide 20.

[0046] The central screw locking lever 24 can be rotatably coupled to the intervertebral cage 10. The central screw locking lever 24 can include a handle portion 26, and a stem portion 28 extending from a lower side of the handle portion 26, the stem portion 28 being substantially perpendicular to the lower side of the handle portion 26. The central screw locking lever 24 can be rotatable about an axis of the stem portion 28.

[0047] The central screw locking lever 24 can be rotatable between an unlocked position in which the handle portion 26 is transverse to the longitudinal axis of the intervertebral cage 10, and a locked position in which the handle portion 26 extends along the longitudinal axis of the intervertebral cage 10.

[0048] The first screw member 12 and the second screw member 14 are exposed when the handle portion 26 is in the unlocked position, and the handle portion 26 of the central screw locking lever 24 covers and locks the first screw member 12 and the second screw member 14 in the intervertebral cage 10 when the handle portion 26 is in the locked position. The central screw locking lever can be a T-shaped screw locking lever 24. A top face of the intervertebral cage 10 can include an opening for engaging the central screw locking member 24. The opening 29 can be formed between the first internal screw guide 18 and the second internal screw guide 20. The central screw locking lever 24 can include a first threaded portion and the opening 29 can include a corresponding second threaded portion, and wherein the central screw locking lever 24 is threaded into the opening 29 of the intervertebral cage 10 by engaging the first threaded portion of the central screw locking lever 24 with the second threaded portion of the opening. The central screw locking lever 24 can be press-fit into the opening 29 of the intervertebral cage 10. The central screw locking lever 24 can be made of titanium.

[0049] Figures 2A-E depict another screw locking mechanism for anterior cervical cage/BDFT constructs. This locking mechanism is a screw locking horizontal bracket 30 which snaps on to the top of the construct 10 once the screws 12, 14 have been maximally turned thereby preventing screw pull-out or back-out. The screw locking bracket 30 is designed with left and right bracket hooks 34. They are inserted into hook insertion slots 36 which are prefabricated on the left and right sides of the cage construct 10 to precisely snugly fit the bracket hooks 34. Once the bracket hooks 34 are inserted into the cage insertion slots 36, the bracket 30 cannot be dislodged. In order to remove the bracket 30; if it becomes necessary to remove the cage 10 at some future time, flexion grips (side tabs) 32 have been designed on the bracket 30. The locking

bracket 30 can be applied to the construct 10 with the specially designed pliers (exemplarily described with reference to Figure 5) which press fit the bracket 30 onto the cage 10 thereby locking the screws 12, 14. In order to remove the bracket 30, the user needs only to press on the side tabs 32 with the pliers (Fig 5) to slightly deform (open) the bracket hooks 34, and thereby easily remove the bracket 30.

[0050] The novel embodiments of the present invention are quite unique and different from all other conventional locking mechanisms used for other types of anterior cervical plates. No other conventional anterior cervical intervertebral cage/BDFT screw constructs are known.

[0051] For example, an exemplary aspect of the invention is directed to a central screw locking lever 24 can include a screw locking horizontal bracket 30. The screw locking horizontal bracket 30 can be press fit on a top of the intervertebral cage 10 and covers and locks the first screw member 12 and the second screw member 14 in the intervertebral cage 10. The screw locking horizontal bracket 30 can include a cover portion extending in a direction of the longitudinal axis of the intervertebral cage 10 and substantially parallel to a top face of the intervertebral cage 10, the cover portion covering and locking the first screw member 12 and the second screw member 14 in the intervertebral cage 10, and side tabs 32 on each end of the cover portion, wherein the side tabs 32 extend in a direction perpendicular to the cover portion along the sides of the intervertebral cage 10. The side tabs 32 include bracket hooks 34 extending from the side tabs 32 toward the sides of the intervertebral cage 10 and in a direction of the longitudinal axis of the intervertebral cage 10. The intervertebral cage 10 can include one or more slots 36 for lockingly engaging a part of the screw locking horizontal bracket 30. The sides of the intervertebral cage 10 include hook insertion slots 36, and wherein the bracket hooks 34 engage the hook insertion slots 36. The bracket hooks 34 lockingly engage the hook insertion slots 36. The side tabs 32 of the screw locking horizontal bracket 30 include bracket flexion grips. The screw locking horizontal bracket 30 can be deformable. The screw locking horizontal bracket 30 can be deformable under pressure applied to the bracket flexion grips. The bracket hooks 34 include flexible bracket hooks.

[0052] Figures 3A-F illustrate three-dimensional views of an embodiment of an anterior lumbar intervertebral cage/BDFT construct. In this embodiment, the cage 10 is larger than the cervical cage and is also elliptically contoured to fit into the bi-concave lumbar disc space (Figure 3D; side view). The cage 10 includes four (4) horizontally aligned

internalized screw guides 18, 19, 20, 21 for four (4) screws 12, 13, 14, 15. The two lateral (left and right) screws are oriented inferiorly, and the two middle screws are oriented superiorly. In the embodiment, the orientations of the four screw guides 18, 19, 20, 21 (and screws 12, 13, 14, 15) are selected because of their symmetry and inherent stability. The cage 10 can include a large cavity 16 for bone product placement. The cage 10 includes four built-in internalized screw/drill guides 18, 19, 20, 21, one for each screw. Other embodiments of the intervertebral cage 10 can be designed with internalized screw/drill guides 18, 19, 20, 21 with different angles and/or different positions within the cage 10. The angle and size of the screws make them amenable to single or multi-level placement. The superior and inferior surfaces or edges of the cage 110 can include ridges 22 to facilitate integration and fusion with superior and inferior vertebral bodies. In this embodiment, there are no compartmental divisions in the cavity 16 for bone product placement to maximize the quantity of bone for fusion.

[0053] Figures 3A-F depicts a screw locking embodiment for anterior thoracic and Lumbosacral cage/BDFT constructs. This locking mechanism is a screw locking horizontal bracket 30 which snaps on to the top of the construct once the four screws 12, 13, 14, 15 have been maximally turned thereby preventing screw pull-out or back-out of all four screws 12, 13, 14, 15 simultaneously. The screw locking bracket 30 is designed with left and right bracket hooks 34. They are inserted using the specially designed pliers (Figure 5) into hook insertion slots 36 which are prefabricated on the left and right sides of the cage construct to precisely snugly fit the bracket hooks 34. Once the bracket hooks 34 are inserted into the cage insertion slots 36, the bracket 30 cannot be dislodged. In order to remove the bracket 30; if it might become necessary to remove the cage 10 at some future time, flexion grips (side tabs) 32 have been designed on the bracket 30. The locking bracket 30 is the press fit by the pliers (Fig 5) onto the cage 10 in order to lock the screws 12, 13, 14, 15. In order to remove the bracket 30, the user needs only to press on the side tabs 32 with the pliers (Fig 5) to slightly deform (open) the bracket hooks thereby easily removing the bracket 30.

[0054] Another identical locking mechanism embodiment which includes a central rotating locking lever mechanism as designed for the cervical cage. BDFT constructs can likewise be designed for the anterior thoracic and lumbosacral cage/BDFT constructs. These novel locking mechanisms also are quite unique and different from

all other conventional locking mechanisms used for other types of anterior lumbar cages.

[0055] Another patent which mentions anterior placed lumbar implants with perforating screws includes US Patent 4,904,261 (John Dove, Philip H. Hardcastle, John K. Davis and Brian King). The '261 patent discloses a horseshoe implant having a plurality of cylindrical holes with smooth inner surfaces and comprise only one stop for the heads of the bone screws to be inserted into them. The placement of five cylindrical holes is oriented within the cage in a non-symmetric manner.

[0056] In comparison, the embodiments of the present invention differ in many substantial ways from the conventional devices. For example, the present invention provides a symmetric orientation of the screw holes, as well as completely novel and unique screw locking mechanism (e.g., 24, 30, etc.). The present invention also describes an angulation/trajectory (e.g., a preferred angulation/trajectory) for preventing pull-out or back-out of the screws that would make placement of all screws in a manner which would lead to maximum stability of the construct within the vertebral space, and obviate the need for external drill guides, and surgeon trajectory angulation guess work.

[0057] In another patent US 7, 232,464 B2 (Claude Mathieu and Christopher Marden John Cain) multiple embodiments of lumbar intervertebral implants are presented which include one with internally threaded bore holes, another embodiment with a front plate mounted at the front surface of the implant, and another embodiment with the front plate displaceably configured to move vertically relative to the implant. In addition, the disclosed preferred borehole axes are 35-55 degrees. The '464 patent has four screw perforations that are not aligned four in a row. Two of the screw holes are laterally placed on the left, one on top of each other, the top one with a superior trajectory, and the bottom with an inferior trajectory. Likewise, two perforations are placed on the right, one on top of each other, the top one with a superior trajectory and the bottom one with an inferior trajectory. The disclosed screw locking mechanism is a screw with an external thread matching the internal borehole thread, or spiral springs.

[0058] In comparison, the anterior lumbar construct of the present invention differs in many substantial ways from the conventional devices. The present invention includes a single cage construct with four (4) internalized drill guides 18, 19, 20, 21 arranged horizontally in a row. The middle two screws are oriented superiorly, and the lateral left and right screws are oriented inferiorly. This symmetric alignment of screws and orientations within the superior and inferior vertebral bodies (e.g., two middle

superiorly projecting screws, and two laterally projecting inferior screws) make the fixation to the superior and inferior vertebral bodies much more symmetric and thus more stable. In an embodiment of the present invention, the cage includes a screw guide having a predetermined trajectory (e.g., a preferred trajectory of 25 degrees) that makes placement of all screws equally facile, more amenable to multi-level placement, and diminishes the need for external drill guides. Furthermore, the exemplary screw locking mechanisms are unique and differ substantially from the conventional approach of matching screw/cage threads or spiral springs.

[0059] Figures 4A-F illustrate three-dimensional views of an embodiment of a posterior lumbar intervertebral cage/BDFT construct. In this embodiment, the screws perforate and orient in opposing superior and inferior directions. The cage 10 can include a cavity 16 for bone product placement. The top and bottom portions of the cage 10 are elliptically contoured to naturally fit into the bi-concave intervertebral disc space (Fig 4C; side view). The cage 10 includes built-in internalized screw/drill guides 18, 19 having a predetermined angled trajectory. One of the guides is angled rostrally (superiorly) (e.g., guide) and the other caudally (inferiorly) (e.g., guide). The intervertebral cages can be designed with internalized screw/drill guides 18, 19 with different angles and/or different positions within the cage 10. The angle and size of the screws 12, 14 make them amenable to single or multi-level placement. The superior and inferior surfaces or edges can include ridges 22 to facilitate integration and fusion with superior and inferior vertebral bodies. One of these constructs is placed posteriorly into the intervertebral space on the left side, and the other on the right side.

[0060] The cage 10 includes a screw locking mechanism for posterior lumbosacral cage/BDFT constructs. This locking mechanism is a screw locking horizontal bracket 30 which snaps on to the top of the construct once the screws have been maximally turned thereby preventing screw pull-out or back-out. The screw locking bracket 30 is designed with left and right bracket hooks 34. They are inserted into hook insertion slots 36 which are prefabricated on the left and right sides of the cage construct to precisely snugly fit the bracket hooks 34. Once the bracket hooks 34 are inserted into the cage insertion slots 36 using the specially designed pliers (Fig 5), the bracket 30 cannot be dislodged. In order to remove the bracket 30; if it becomes necessary to remove the cage 10 at some future time, flexion grips (side tabs) 32 have been designed on the bracket 30. The locking bracket 30 can be press fit onto the cage 10 using the pliers (Fig 5) thereby locking the screws 12, 14. In order to remove the bracket 30, the user needs

only to press on the side tabs 32 with the pliers (Fig 5) to slightly deform (open) the bracket hooks 34, and thereby easily remove the bracket 30.

[0061] The screw locking bracket 30 can be manufactured from a variety of materials, such as titanium. It can be reused for a number of cycles.

[0062] As illustrated in FIG. 5, a pliers device 40 for inserting and removing the locking mechanism can include a first arm rotatably coupled to a second arm; wherein each of the first arm and the second arm includes a handle portion on a first end; wherein the first arm includes an upper plier tip 42 and the second arm includes a lower plier tip 44, and wherein the first arm and the second arm engage the central screw locking lever 30. The upper plier tip 42 and the lower plier tip 44 each include a stop 46 configured to engage the bracket flexion grips 32. The pliers 40 can include a leaf spring 48 between the first arm and the second arm, wherein the leaf spring 48 biases the first handle portion away from the second handle portion. The pliers 40 can include a limiter 50 and limiting screw 52.

[0063] In an aspect of the pliers device 40 for inserting and removing a bi-directional fixating transvertebral (BDFT) screw/cage apparatus, the pliers device comprises a first arm rotatably coupled to a second arm; wherein each of the first arm and the second arm includes a handle portion on a first end; wherein the first arm includes an upper plier tip 42 and the second arm includes a lower plier tip 44, wherein the first arm and the second arm engage the bracket flexion grips 32, wherein the upper plier tip 42 and the lower plier tip 44 each include a stop 46 configured to engage the bracket flexion grips 32, and a leaf spring 48 between the first arm and the second arm, wherein the leaf spring 48 biases the first hand portion away from the second handle portion.

[0064] Another identical locking mechanism embodiment which includes a central rotating locking lever mechanism as designed for the cervical, thoracic and lumbosacral cage/BDFT constructs can likewise be designed for the posterior lumbosacral cage/BDFT constructs.

[0065] The exemplary embodiments of these locking mechanisms are another evolutionary embodiment not illustrated in the aforementioned related applications. The novel locking mechanisms are also quite unique and different from other conventional locking mechanisms used for other known cervical and lumbar anterior or posterior plate screws. No other conventional posterior lumbar intervertebral cage BDFT/screw constructs are known.

[0066] Figures 6A-6D illustrate an embodiment of a lumbar facet joint staple gun.

[0067] Features of lumbar facet joint staple guns have been thoroughly described in the aforementioned related applications, the relevant portions of which are hereby incorporated by reference in their entirety. The exemplary staple gun 400 is an evolutionary advanced version compared to the conventional designs. The changes incorporated herein facilitate easier insertion and removal of the staple 700 compared to our prior design. An improved feature of the staple gun is the design of an independent puller tip which can be swung open when the stapler is at its maximum open position.

[0068] The figures illustrate the staple gun 400 which includes two upper and lower grips 404, 406, upper and lower bars 408, 410, a cylinder 418, a puller 414, a puller tip 402, a connector 418, a return spring 420, and pins 422.

[0069] In our previous design the user might have to force the staple hinge to fit into the loops (puller), and once the staple 700 was closed the user had to pry the staple hinge from the loops. To address this problem, one of the loops was made as an independent part which can be swung open when the stapler is at its maximum open position.

[0070] The following is the mechanism of its action: The user opens the stapler handles to their maximum. This forces the puller part 414 to stick out from the cylinder part 412. In that configuration, the puller tip 402 can be opened, and the user can insert the staple 700, and close the puller tip 402 (no force required). As the user closes the staple handles, the puller part 414 retracts into the cylinder part 412 which prevents the puller tip part 402 from opening. Thus there is no risk of the staple 700 becoming loose or falling off during surgery. Once the staple 700 has been closed, and is locked, the user can open once more the staple handles to their max to force the puller part out, and in that configuration, the puller tip 402 can be opened, and the staple 700 can be released. The release mechanism doesn't have a spring. The puller tip 402 can simply be opened only when the center shaft (puller) is extended completely. When the puller 414 is retracted (during stapling) the release (puller tip) is constrained by the surrounding geometry i.e. it cannot move. The main advantage of this mechanism is its simplicity. The spring 420 is for the return. The spring 420 pushes the puller out, so after the user staples, by pressing the handles together and pulling the center shaft in (puller), the spring 420 will force the puller 414 out and swing the handles open to reset the stapler.

[0071] For example, an aspect of the invention can include a staple gun for a lumbar facet joint staple includes a handle having an upper bar 408 and a lower bar 410, each of the upper bar 408 and the lower bar 410 having a first and a free end, a hollow cylinder 412 body having a first end for receiving the lumbar facet joint staple and a second end

adjacent to the handle, a connector 418 having a first end coupled to the hollow cylinder 412 body and a second end coupled to the handle such that the first end of each of the upper bar 408 and the lower bar 410 can be pivotably coupled to the connector 418, a puller 414 disposed in and extending through the hollow cylinder 412 body, wherein the puller 414 has a first end for receiving the lumbar facet joint staple and a second end adjacent to the handle, the second end of the puller 414 being coupled to the handle, and a puller tip 402 coupled to the first end of the puller 414, wherein the handle can be moveable from a closed position to an open position, a distance between the free end of the upper bar 408 and the free end of the lower bar 410 in the closed position being less than a distance between the free end of the upper bar 408 and the free end of the lower bar 410 in the open position, wherein the first end of the puller 414 and at least a part of the puller tip 402 are disposed inside the first end of the hollow cylinder 412 body when the handle is in the closed position, and wherein the first end of the puller 414 and at least a part of the puller tip 402 extend outside the first end of the hollow cylinder 412 body when the handle is in the open.

[0072] The puller tip 402 can be moveable between an open position and a closed position when the handle in the open position, and wherein the puller tip 402 is locked in the closed position by the first end of the hollow cylinder 412 body when the handle in the closed position. The puller tip 402 can include a first loop part and a second loop part, the first loop part and the second loop part for grasping sides of the lumbar facet joint staple, wherein the first loop part is movable with respect to the second loop part in a direction transverse to a longitudinal axis of the puller 414. The staple gun can include a spring return mechanism that biases the handle in the open position. The handle can include a linkage coupling the puller 414 to each of the upper bar 408 and the lower bar 410.

[0073] Features of cervical facet joint staples have been thoroughly described in the aforementioned related applications, the relevant portions of which are hereby incorporated by reference in their entirety.

[0074] As shown in Figures 7A through 8E, an exemplary posterior cervical facet joint staple 702 includes a staple body extending along a longitudinal axis. The body includes a plurality of prongs extending from a lower surface of the staple body. The lower surface of the staple body also includes a groove for engaging or fitting into the spring supports of a staple gun (e.g., a cervical staple gun, as described in more detail

below). The groove extends along an axis that is perpendicular to the longitudinal axis of the staple body. The groove is disposed at a center point along the longitudinal axis.

[0075] Figures 7 and 8 illustrate a four-prong embodiment. The cervical staple gun embodiments can also be used for a two pronged staple embodiment.

[0076] More particularly, the lumbar staple has top and bottom claws which come together. The top part of the staple, beneath from where the staple prongs come out, has on either side, a circular protuberance with a hole in the center. A pin goes through this hole and through a hole in the lower staple claw thus connecting these two components which pivot around the pin to open and close the jaw of the staple. The protuberances on both sides of the staple can be fit snugly into the puller tip 402 of the staple gun.

[0077] Exemplary aspects of a staple are illustrated in Figures 9A-B and 10A-C.

[0078] Figures 9A-B illustrate an embodiment of a posterior lumbar facet staple having a flexure spring. Figures 10A-C illustrate an embodiment of a lumbar facet staple having a torsional spring. Features of a lumbar facet staple have been thoroughly described in the aforementioned related applications, the relevant portions of which are hereby incorporated by reference herein in their entirety. The embodiments illustrated in the related applications included a ratchet. The staple could be incrementally closed with increased ratcheting over increasing number of spurs. The present invention provides two evolved embodiments, which are superior to conventional designs in that the closing mechanisms can withstand much greater force (Newtons) than a small external ratchet. Other improvements will be described below.

[0079] Figures 9A-B illustrate an embodiment of a posterior lumbar facet staple 500 having a flexure spring 530. As shown in Figures 9A-B, the features of the staple 500 include top claws 510 and bottom claws 520 with ridges 570 to help incorporate and fuse with bone. A staple pin (pivot) 560 connects the top claws 510 and bottom claws 520. The staple 500 includes four fastener pins (prongs) 580, 582, 584, 586, two per top claw 510 or bottom claw 520. Ratchet teeth 540 are molded onto the lower claw 520, and a spring loaded ratchet pawl 530 pivots on the claw, and locks the staple 500 in position. As the staple 500 closes, the ratchet 540 works in standard fashion. When a force is applied to open the staple 500, the ratchet 540 locks up, but the ratchet pawl (e.g., the flexure spring) 530 acts as a spring due to its curvature. So depending on the material used for the ratchet spring, the ratchet spring 530 can deform more or less, thereby providing different degrees of resistance. The ratchet mechanism 540 limits the opening force of the staple 500 by a force proportional to the stiffness of the flexure

spring 530 (e.g., ratchet pawl). The force can be tailored by making the pawl from different materials or varying the dimension of the flexure spring on the pawl. This embodiment can achieve significant rigidity (stiffness).

[0080] Figures 10A-C illustrate an embodiment of a posterior lumbar facet staple 600 having a torsional spring 630. Figures 10A-C illustrate features of the staple 600, which include top claws 610 and bottom claws 620 with ridges 670 to help incorporate and fuse with bone. A staple pin (pivot) 660 joins the upper claw 610 and lower claw 620 of the staple 600. The staple 600 includes four fastener pins (prongs) 682, 684, 686, 688, two per top claw 610 or bottom claw 620 of the staple 600. The features of the staple 600 include a torsional spring 630, a brake 680, and a pivot spring pin 640. As the staple 600 closes, the ratchet works in standard fashion. When the staple 600 is open, the spring does not interfere with the motion. Once the staple 600 is closed there is a ratchet mechanism (brake) 680 that engages with the spring 630. At that point, the force required to open the staple 600 will depend on the stiffness of the spring 630. Having staple models with different types of springs (e.g., soft, hard, etc.) allows the tailoring of different staples to the needs of a given patient. The embodiments of the present invention have less compliance than the conventional devices.

[0081] The staple gun embodiments illustrated in Figures 7 and 8 provide improved features over those previously described in our prior applications. The advantages of both these embodiments are their economic efficiency of design, their simplicity and their amenability to percutaneous surgical approaches.

[0082] Figures 7A-E illustrate an embodiment of a posterior cervical facet staple gun.

[0083] The internal mechanism includes a handle 802, a central staple plunger 804, a tip 806, and a retaining spring 808. A staple 702 is held in place at the tip 806 of the staple guide by a retaining spring 808. The device can be used with a hammer to apply a staple 702 (either two or four pronged). The spring 808 holding the staples 702 in place is a bi-staple spring that is opened to release a staple by pressing the center button (central plunger) of the handle 802. Pressing the central button opens up the spring 808, and the staple gun can then be reloaded with another staple 702.

[0084] Figures 8A-E illustrate another embodiment of a posterior cervical facet staple gun. The internal mechanism includes a handle 902, a plunger 910, and two mirror retaining springs 908, 909. The staple 702 is held in place at the tip of the staple guide by the retaining springs 908, 909. The device can be used with a hammer to impact the

staple (either two or four pronged). A center button can be pressed to release the staple when needed. The staple gun can then be reloaded with another staple.

[0085] 2. SURGICAL METHOD

[0086] Exemplary surgical steps for practicing one or more of the forgoing embodiments will now be described.

[0087] Anterior cervical spine placement of the intervertebral cage/BDFT screw construct (Figures 1-2) can be implanted via previously described techniques for anterior cervical discectomy and fusion. Some but not all of these techniques include, open, microscopic, closed endoscopic or tubular. Fluoroscopic or any other form of visualized guidance can be used for this procedure.

[0088] After the adequate induction of anesthesia the patient is placed in a supine position. An incision is made overlying the intended disc space or spaces, and the anterior spine is exposed. A discectomy is performed and the endplates exposed. The disc height is measured and an anterior cervical intervertebral cage of the appropriate disc height, width and depth is selected. The central cavity is packed with bone fusion material, autologous bone graft, allograft, alone or in combination with any commercially available bone fusion promoting product. The cage is then inserted into the midline of the anterior disc space routinely until it is flush or countersunk relative to the vertebral body above and below. The BDFT screws are then inserted into the internalized rostrally (superiorly) and caudally (inferiorly) angled screw guides. A drill with or without a drill guide can be used to prepare for screw placement. This is not absolutely necessary. Because the cage has internalized screw guides, self-drilling/self-tapping screws of the appropriately selected lengths can be directly screwed into the vertebral bodies once placed into the internalized drill-guided angled tunnels. The cage's screw guides, which have internalized tunnels, direct the screws into the superior and inferior vertebral bodies in the predetermined angle of the internalized tunnels. There is no other angled trajectory other than that which is built into the internalized screw guide/tunnel of the cage that the screw can be oriented in. Hence, there is no absolute need for fluoroscopic guidance.

[0089] Once the surgeon is satisfied with the position and placement of the cage, the BDFT screws can then be locked into their final positions. In the embodiment in figure 1, the patient rotates the central locking screw lever from the midline vertical position, ninety degrees; so that the locking lever handles lock the screws into position preventing screw pull-out. . If the surgeon changes his mind intra-operatively or if in a

future date the construct needs to be removed, the screw locking lever is rotated another ninety degrees, unblocking access to the screws, and the screws can be backed out. The locking mechanism has several cycles of use, and thus screws once backed out, can be re-screwed and re-locked. Multiple level placements can be performed including two, three or more levels if necessary.

[0090] For the embodiment illustrated in Figure 2, once the surgeon is satisfied with the position and placement of the cage, the BDFT screws can then be locked in their final positions. Then a screw locking bracket is gently placed on top of the cage with the pliers (Fig 5) allowing the bracket hooks to snap into the cage inserts. The plier tips have stops so that the brackets could be more easily held. It has a limiting screw that limits the amount the pliers close to prevent over-pressing the locking brackets. It also has a leaf spring that serves to pre-load the pliers. If the surgeon changes his mind intra-operatively, or if in a future date the construct needs to be removed, the surgeon presses on the side tabs with the pliers (Figure 5) to slightly deform (open) the bracket hooks and easily remove it. The locking mechanism has several cycles of use, and thus screws once backed out, can be re-screwed and re-locked. Multiple level placements can be performed including two, three or more levels if necessary.

[0091] Anterior or anteriolateral placement of thoracic or lumbar spine intervertebral cage/BDFT screw constructs (Figure 3) can be implanted via previously described surgical techniques for anterior lumbar discectomy, and transthoracic, anterior-lateral thoracic discectomy. Some but not all of these techniques include, open, microscopic, closed endoscopic or tubular. Fluoroscopic or any other form of visualized guidance can be used for this procedure.

[0092] After the adequate induction of anesthesia and after the anterior spine is exposed a discectomy is performed and the endplates exposed. The disc height is measured and an anterior lumbar (or thoracic) intervertebral cage of the appropriate disc height, width and depth is selected. The central cavity is packed with bone fusion material, autologous bone graft, allograft, alone or in combination with any commercially available bone fusion promoting product. The cage is then inserted into the midline of the anterior disc space routinely until it is flush or countersunk relative to the vertebral body above and below. The four BDFT screws are then inserted into the two middle internalized rostrally (superiorly) and two lateral, caudally (inferiorly) angled screw guides. A drill with or without a drill guide can be used to prepare for screw placement. This is not absolutely necessary. Because the cage has internalized screw guides, self-drilling/self-

tapping screws of the appropriately selected lengths can be directly screwed into the vertebral bodies once placed into the internalized drill-guided angled tunnels. The cage's internalized guides, which have internalized tunnels, direct the screws into the superior and inferior vertebral bodies in the predetermined angle of the internalized tunnels. There is no other angled trajectory other than that which is built into the internalized screw guide/tunnel of the cage that the screw can be oriented in. Hence there is no absolute need for fluoroscopic guidance.

[0093] Once the surgeon is satisfied with the position and placement of the cage, the BDFT screws can then be locked in their final positions. Then a screw locking bracket is gently placed on top of the cage with the pliers (Fig 5) allowing the bracket hooks to snap into the cage inserts. If the surgeon changes his mind intra-operatively, or if in a future date the construct needs to be removed, the surgeon presses on the side tabs with pliers (Figure 5) to slightly deform (open) the bracket hooks and can then easily remove the locking bracket. The locking bracket has several cycles of use, and thus screws once backed out, can be re-screwed and re-locked. Multiple level placements can be performed including two, three or more levels if necessary.

[0094] Implantation of the posterior lumbar intervertebral cage/BDFT screw constructs (Figure 4) can be performed via previously described posterior lumbar interbody fusion (PLIF) or posterior transforaminal lumbar interbody fusion (TLIF) procedures. The procedures can be performed open, microscopic, closed tubular or endoscopic techniques. Fluoroscopic guidance can be used with any of these procedures.

[0095] After the adequate induction of anesthesia, the patient is placed in the prone position. A midline incision is made for a PLIF procedure, and one or two parallel paramedian incisions or a midline incision is made for the TLIF procedure. For the PLIF procedure, a unilateral or bilateral facet sparing hemi-laminotomy is created to introduce the posterior lumbar construct into the disc space after a discectomy is performed and the space adequately prepared.

[0096] For the TLIF procedure, after unilateral or bilateral dissection and drilling of the inferior articulating surface and the medial superior articulating facet the far lateral disc space is entered and a circumferential discectomy is performed. The disc space is prepared and the endplates exposed.

[0097] The disc height is measured and a posterior lumbar intervertebral cage/BDFT screw construct (Figure 4) of the appropriate disc height, width and depth is selected. The central cavity is packed with bone fusion material, autologous bone graft, allograft,

alone or in combination with any commercially available bone fusion promoting product. Then one construct is placed on either right or left sides, or one construct each is placed into left and right sides. The constructs are inserted such they are flush or countersunk relative to the superior and inferior vertebral bodies. In addition to the central cavities that are packed with bone product, the intervertebral space in between the constructs can also be packed with bone product for fusion.

[0098] The BDFT screws are then inserted into internalized rostrally (superiorly) and caudally (inferiorly) angled screw guides. A drill with or without a drill guide can be used to prepare for screw placement. This is not absolutely necessary. Because the cage has internalized screw guides, self-drilling/self-tapping screws of the appropriately selected lengths can be directly screwed into the vertebral bodies once placed into the internalized drill-guided angled tunnels. The cage's internalized guides, which have internalized tunnels, direct the screws into the superior and inferior vertebral bodies in the predetermined angle of the internalized tunnels. There is no other angled trajectory other than that which is built into the internalized screw guide/tunnel of the cage that the screw can be oriented in. Hence, unlike posterior placement of pedicle screws there is no absolute need for fluoroscopic or expensive and cumbersome, frameless stereotactic CT guidance.

[0099] Once the surgeon is satisfied with the position and placement of the cage, the BDFT screws can then be locked in their final positions. Then a screw locking bracket is gently placed on top of the cage with the pliers (Fig 5) allowing the bracket hooks to snap into the cage inserts. If the surgeon changes his mind intra-operatively, or if in a future date the construct needs to be removed, the surgeon presses on the side tabs with pliers (Figure 5) to slightly deform (open) the bracket hooks and can then easily remove the locking bracket. The locking bracket has several cycles of use, and thus screws once backed out, can be re-screwed and re-locked. Multiple level placements can be performed including two, three or more levels if necessary.

[00100] The surgical placement of the lumbar facet staples via a posterior facet lumbar staple gun (Figure 6) is described in the aforementioned related applications. The surgical procedure for these staple embodiments with this staple gun embodiment is identical to that which has been previously described. The evolutionary advantages of these embodiments are explained above.

[00101] For posterior placement of the cervical facet staples using the cervical facet staple gun embodiments (Figures 7- 8), after the adequate induction of anesthesia the

patient is flipped prone and his head and neck secured. A single midline or two paramedian incisions are made for unilateral or bilateral or multilevel placement of cervical staples. Ultimately the facet joint is exposed. Alternatively and preferably this can be performed percutaneously under fluoroscopic guidance with IV sedation. The cervical staple, two or four pronged is loaded either into the two or four pronged staple gun, is placed on the two articulating cervical facets, and then stapled into the joint using the staple gun. To achieve modular calibrated fusion, different combinations and permutations of cervical facet staples can be inserted ranging from a single unilateral two pronged staple providing a high degree of flexibility to a total of four bilaterally placed four pronged cervical staples leading to the highest degree of rigidity per cervical posterior joint. Additional bone may or may not be placed in the vicinity to facilitate permanent and solid fusion. These simplified and economically efficient cervical staple guns make this procedure amenable to percutaneous, precise staple placement, as well as contoured staple-bone integration.

[00102] The present inventions may provide effective and safe techniques that overcome the problems associated with current transpedicular based cervical, thoracic and lumbar fusion technology, as well as anterior cervical, thoracic and lumbar plating technology, and for many degenerative stable and unstable spinal diseases. These inventions could replace much pedicle screw, and anterior plating based instrumentation in many but not all degenerative spine conditions.

[00103] The speed and simplicity of placement of posterior cervical and lumbar facet staples, placement of anterior and posterior lumbar intervertebral cage/BDFT screw constructs, and placement of anterior cervical cage/BDFT screw constructs far exceeds that of current pedicle screw and anterior spinal plating technology. Furthermore, these devices have markedly significantly decreased risk of misguided screw placement and hence decreased risk of neurovascular injury, and blood loss. In the cervical and lumbar spines, intervertebral cage/BDFT screw constructs and facet staples could be applied modularly in different combinations to achieve different degrees of rigidity (flexibility). Furthermore, the posterior cervical and lumbar staple technology is amenable to short same-day procedures performed under local/IV anesthesia with a rapid recovery time. The lumbar and cervical intervertebral cage/BDFT screw constructs all would have decreased recovery time, and more rapid return to work time compared to pedicle screw, and plating technology. These devices with great probability lead to similar if not equal fusion rates, with substantially less morbidity, and hence, overall, make them a major

advance in the evolution of spinal instrumented technology leading to advances in the compassionate care of the spinal patient.

[00104] For example, an aspect of the invention is directed to a method of inserting a bi-directional fixating transvertebral (BDFT) screw/cage apparatus between a first vertebral body and a second vertebral body, the method including inserting an intervertebral cage into a midline of a disc space between the first vertebral body and the second vertebral body until the intervertebral cage is one of flush and countersunk relative to the first vertebral body and the second vertebral body, inserting a first screw member into a first internal screw guide of the selected intervertebral cage, inserting a second screw member into a second internal screw guide of the selected intervertebral cage, screwing the first screw member and the second screw member into the first vertebral body and the second vertebral body respectively, and locking the first screw member and the second screw member in the intervertebral cage using a central screw locking lever coupled to the intervertebral cage, wherein the central screw locking lever prevents the first screw member and the second screw from pulling-out of the first internal screw guide and the second internal screw guide.

[00105] The central screw locking lever is rotatably coupled to the intervertebral cage, and the locking the first screw member and the second screw member in the intervertebral cage includes unlocking the first screw member and the second screw member, wherein the unlocking includes rotating the central screw locking lever with respect to the intervertebral cage from the locked position in which the central screw locking lever covers and locks the first screw member and the second screw member in the intervertebral cage to the unlocked position in which the first screw member and the second screw member are exposed.

[00106] The central screw locking lever includes a screw locking horizontal bracket, and wherein the locking includes press fitting the screw locking horizontal bracket on a top of the intervertebral cage such that the screw locking horizontal bracket covers and locks the first screw member and the second screw member in the intervertebral cage. The method can further include unlocking the first screw member and the second screw member, wherein the intervertebral cage includes hook insertion slots, wherein the screw locking horizontal bracket includes a cover portion extending in a direction of a longitudinal axis of the intervertebral cage and substantially parallel to a top face of the intervertebral cage, the cover portion covering and locking the first screw member and the second screw member in the intervertebral cage, side tabs on each end of the cover

portion, wherein the side tabs extend in a direction perpendicular to the cover portion along the sides of the intervertebral cage, and wherein the side tabs include bracket hooks extending from the side tabs and lockingly engaging the hook insertion slots of the intervertebral cage, and bracket flexion grips for deforming the screw locking horizontal bracket, wherein the unlocking includes applying pressure to the bracket flexion grips to deform the screw locking horizontal bracket such that the side tabs of the screw locking bracket move away from the intervertebral cage and release the bracket hooks of the screw locking horizontal bracket from the hook insertion slots of the intervertebral cage.

[00107] While the foregoing disclosure shows illustrative embodiments of the invention, it should be noted that various changes and modifications could be made herein without departing from the scope of the invention as defined by the appended claims. The functions, steps and/or actions of the method claims in accordance with the embodiments of the invention described herein need not be performed in any particular order. Furthermore, although elements of the invention may be described or claimed in the singular, the plural is contemplated unless limitation to the singular is explicitly stated.

CLAIMS

WHAT IS CLAIMED IS:

1. A bi-directional fixating transvertebral (BDFT) screw/cage apparatus, comprising:
 - an intervertebral cage for maintaining disc height, the intervertebral cage including a first internal screw guide and a second internal screw guide;
 - a first screw member having a tapered end and a threaded body disposed within the intervertebral cage;
 - a second screw member having a tapered end and a threaded body disposed within the intervertebral cage;
 - wherein each of the first internal screw guide and the second internal screw guide are angled to orient the first screw member and the second screw member bi-directionally in opposite directions, wherein the first internal screw guide and the second internal screw guide are aligned along a longitudinal axis of the intervertebral cage; and
 - a central screw locking lever coupled to the intervertebral cage, wherein the central screw locking lever prevents the first screw member and the second screw member from pulling-out of the first internal screw guide and the second internal screw guide.
2. The apparatus according to claim 1, wherein the central screw locking lever is rotatably coupled to the intervertebral cage.
3. The apparatus according to claim 2, wherein the central screw locking lever includes:
 - a handle portion; and
 - a stem portion extending from a lower side of the handle portion, the stem portion being substantially perpendicular to the lower side of the handle portion.
4. The apparatus according to claim 3, wherein the central screw locking lever is rotatable about an axis of the stem portion.

5. The apparatus according to claim 3, wherein the central screw locking lever is rotatable between:
 - an unlocked position in which the handle portion is transverse to the longitudinal axis of the intervertebral cage, and
 - a locked position in which the handle portion extends along the longitudinal axis of the intervertebral cage.
6. The apparatus according to claim 5,
 - wherein the first screw member and the second screw member are exposed when the handle portion is in the unlocked position, and
 - wherein the handle portion of the central screw locking lever covers and locks the first screw member and the second screw member in the intervertebral cage when the handle portion is in the locked position.
7. The apparatus according to claim 2, wherein the central screw locking lever is a T-shaped screw locking lever.
8. The apparatus according to claim 2, wherein a top face of the intervertebral cage includes an opening for engaging the central screw locking member.
9. The apparatus according to claim 8, wherein the opening is formed between the first internal screw guide and the second internal screw guide
10. The apparatus according to claim 8, wherein the central screw locking lever includes a first threaded portion and the opening includes a corresponding second threaded portion, and
 - wherein the central screw locking lever is threaded into the opening of the intervertebral cage by engaging the first threaded portion of the central screw locking lever with the second threaded portion of the opening.
11. The apparatus according to claim 9, wherein the central screw locking lever is press-fit into the opening of the intervertebral cage.

12. The apparatus according to claim 1, wherein the central screw locking lever includes a screw locking horizontal bracket.
13. The apparatus according to claim 12, wherein the screw locking horizontal bracket is press fit on a top of the intervertebral cage and covers and locks the first screw member and the second screw member in the intervertebral cage.
14. The apparatus according to claim 12, wherein the screw locking horizontal bracket includes:
 - a cover portion extending in a direction of the longitudinal axis of the intervertebral cage and substantially parallel to a top face of the intervertebral cage, the cover portion covering and locking the first screw member and the second screw member in the intervertebral cage; and
 - side tabs on each end of the cover portion,
 - wherein the side tabs extend in a direction perpendicular to the cover portion along the sides of the intervertebral cage.
15. The apparatus according to claim 14, wherein the side tabs include bracket hooks extending from the side tabs toward the sides of the intervertebral cage and in a direction of the longitudinal axis of the intervertebral cage.
16. The apparatus according to claim 12, wherein the intervertebral cage includes one or more slots for lockingly engaging a part of the screw locking horizontal bracket.
17. The apparatus according to claim 15, wherein the sides of the intervertebral cage include hook insertion slots, and
 - wherein the bracket hooks engage the hook insertion slots.
18. The apparatus according to claim 17, wherein the bracket hooks lockingly engage the hook insertion slots.
19. The apparatus according to claim 14, wherein the side tabs of the screw locking horizontal bracket include bracket flexion grips.

20. The apparatus according to claim 12, wherein the screw locking horizontal bracket is deformable.
21. The apparatus according to claim 19, wherein the screw locking horizontal bracket is deformable under pressure applied to the bracket flexion grips.
22. The apparatus according to claim 15, wherein the bracket hooks include flexible bracket hooks.
23. A pliers device for inserting and removing the apparatus according to claim 1, wherein the pliers device comprises:
 - a first arm rotatably coupled to a second arm;
 - wherein each of the first arm and the second arm includes a handle portion on a first end;
 - wherein the first arm includes an upper plier tip and the second arm includes a lower plier tip, and
 - wherein the first arm and the second arm engage the central screw locking lever.
24. The pliers device according to claim 23, wherein the upper plier tip and the lower plier tip each include a stop configured to engage the bracket flexion grips.
25. The pliers device according to claim 23, comprising:
 - a leaf spring between the first arm and the second arm, wherein the leaf spring biases the first handle portion away from the second handle portion.
26. A pliers device for inserting and removing a bi-directional fixating transvertebral (BDFT) screw/cage apparatus, wherein the pliers device comprises:
 - a first arm rotatably coupled to a second arm;
 - wherein each of the first arm and the second arm includes a handle portion on a first end;
 - wherein the first arm includes an upper plier tip and the second arm includes a lower plier tip,
 - wherein the first arm and the second arm engage the bracket flexion grips,

wherein the upper plier tip and the lower plier tip each include a stop configured to engage the bracket flexion grips, and

a leaf spring between the first arm and the second arm, wherein the leaf spring biases the first hand portion away from the second handle portion.

27. A method of inserting a bi-directional fixating transvertebral (BDFT) screw/cage apparatus between a first vertebral body and a second vertebral body, the method including:

inserting an intervertebral cage into a midline of a disc space between the first vertebral body and the second vertebral body until the intervertebral cage is one of flush and countersunk relative to the first vertebral body and the second vertebral body;

inserting a first screw member into a first internal screw guide of the selected intervertebral cage;

inserting a second screw member into a second internal screw guide of the selected intervertebral cage;

screwing the first screw member and the second screw member into the first vertebral body and the second vertebral body respectively; and

locking the first screw member and the second screw member in the intervertebral cage using a central screw locking lever coupled to the intervertebral cage, wherein the central screw locking lever prevents the first screw member and the second screw from pulling-out of the first internal screw guide and the second internal screw guide.

28. The method according to claim 27, wherein the central screw locking lever is rotatably coupled to the intervertebral cage, and

wherein said locking the first screw member and the second screw member in the intervertebral cage includes

29. The method according to claim 28, further comprising:

unlocking the first screw member and the second screw member,

wherein said unlocking includes:

rotating the central screw locking lever with respect to the intervertebral cage from the locked position in which the central screw locking lever covers and locks the first screw member and the second screw member in the

intervertebral cage to the unlocked position in which the first screw member and the second screw member are exposed.

30. The method according to claim 27, wherein the central screw locking lever includes a screw locking horizontal bracket, and
wherein the locking includes press fitting the screw locking horizontal bracket on a top of the intervertebral cage such that the screw locking horizontal bracket covers and locks the first screw member and the second screw member in the intervertebral cage.
31. The method according to claim 30, further comprising:
unlocking the first screw member and the second screw member,
wherein the intervertebral cage includes hook insertion slots,
wherein the screw locking horizontal bracket includes:
a cover portion extending in a direction of a longitudinal axis of the intervertebral cage and substantially parallel to a top face of the intervertebral cage, the cover portion covering and locking the first screw member and the second screw member in the intervertebral cage;
side tabs on each end of the cover portion,
wherein the side tabs extend in a direction perpendicular to the cover portion along the sides of the intervertebral cage, and
wherein the side tabs include bracket hooks extending from the side tabs and lockingly engaging the hook insertion slots of the intervertebral cage, and bracket flexion grips for deforming the screw locking horizontal bracket,
wherein said unlocking includes:
applying pressure to the bracket flexion grips to deform the screw locking horizontal bracket such that the side tabs of the screw locking bracket move away from the intervertebral cage and release the bracket hooks of the screw locking horizontal bracket from the hook insertion slots of the intervertebral cage.

ABSTRACT

A bi-directional fixating transvertebral (BDFT) screw/cage apparatus including an intervertebral cage for maintaining disc height, and a method of inserting the same is provided. The intervertebral cage includes a first internal screw guide and a second internal screw guide, a first screw member and a second screw member, and a central screw locking lever coupled to the intervertebral cage, wherein the central screw locking lever prevents the first screw member and the second screw from pulling-out of the first internal screw guide and the second internal screw guide. The central screw locking lever includes a rotatable handle and stem portion, or a screw locking horizontal bracket. A pliers device for inserting and removing the bi-directional fixating transvertebral (BDFT) screw/cage apparatus, a posterior cervical and lumbar facet joint staple, and a staple gun for a posterior cervical and lumbar facet joint staple also are provided.

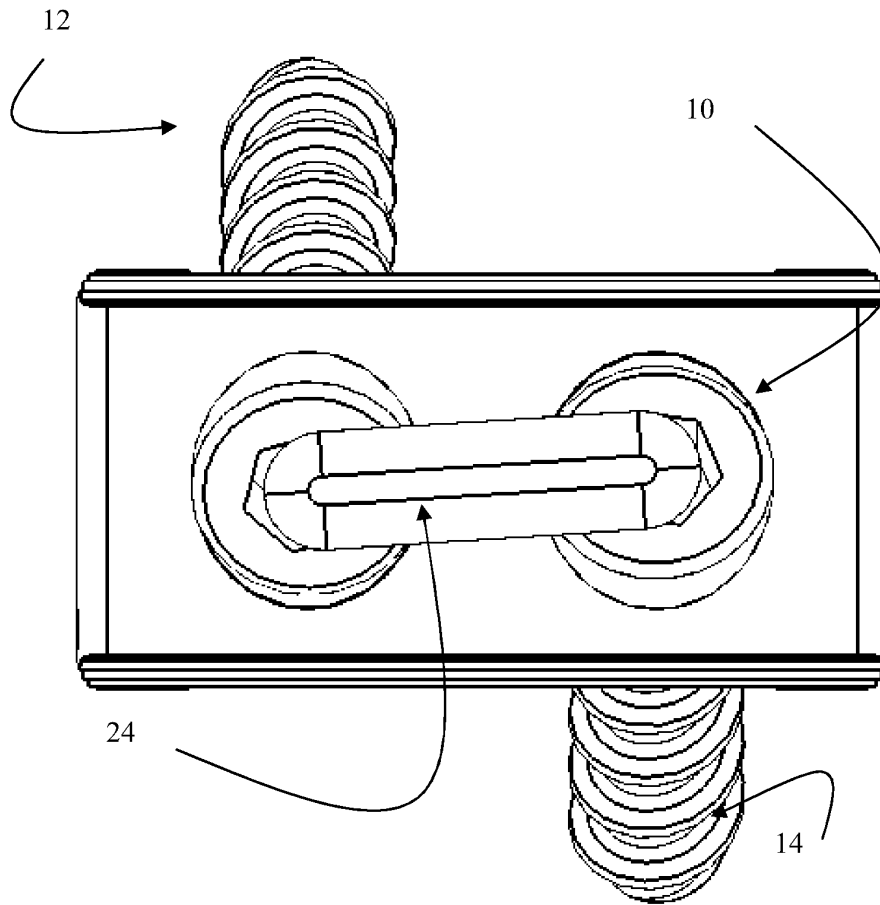


FIGURE 1(A)

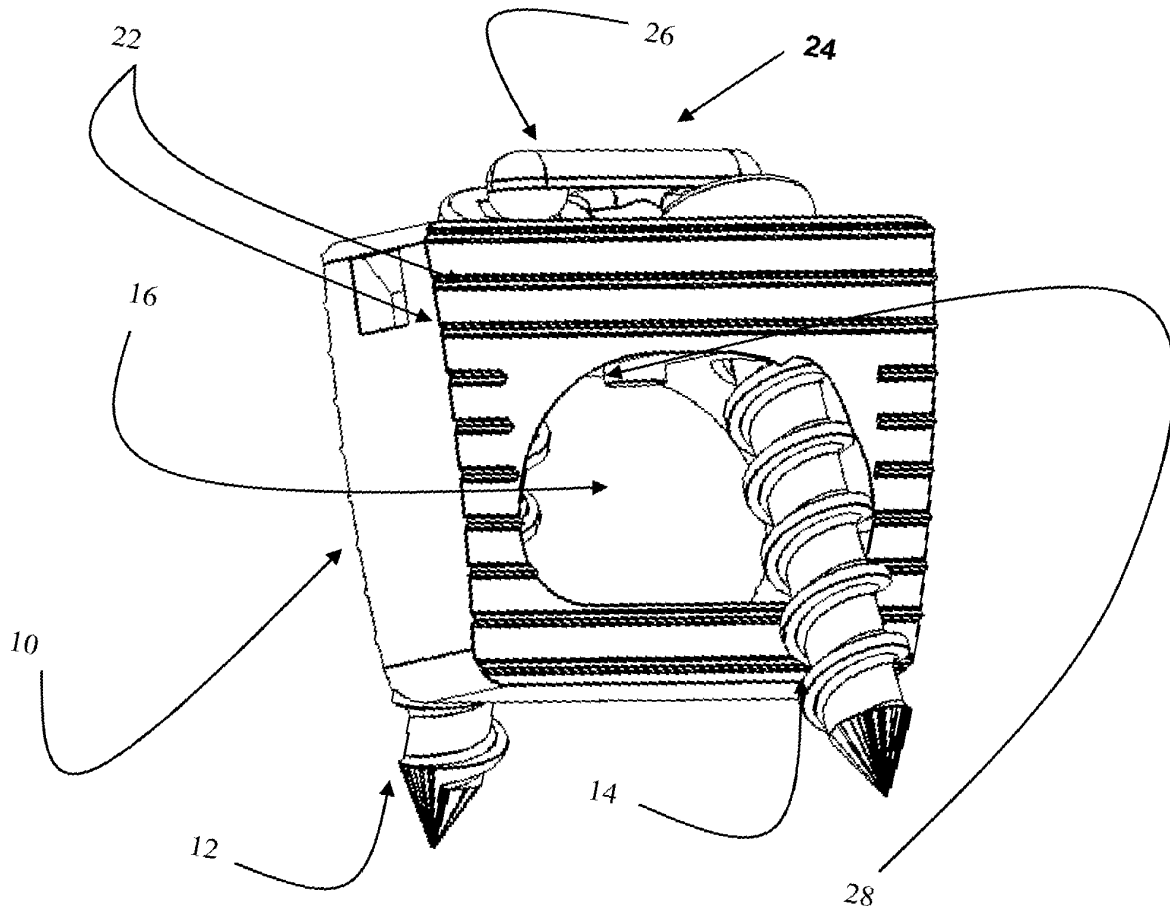


FIGURE 1(B)

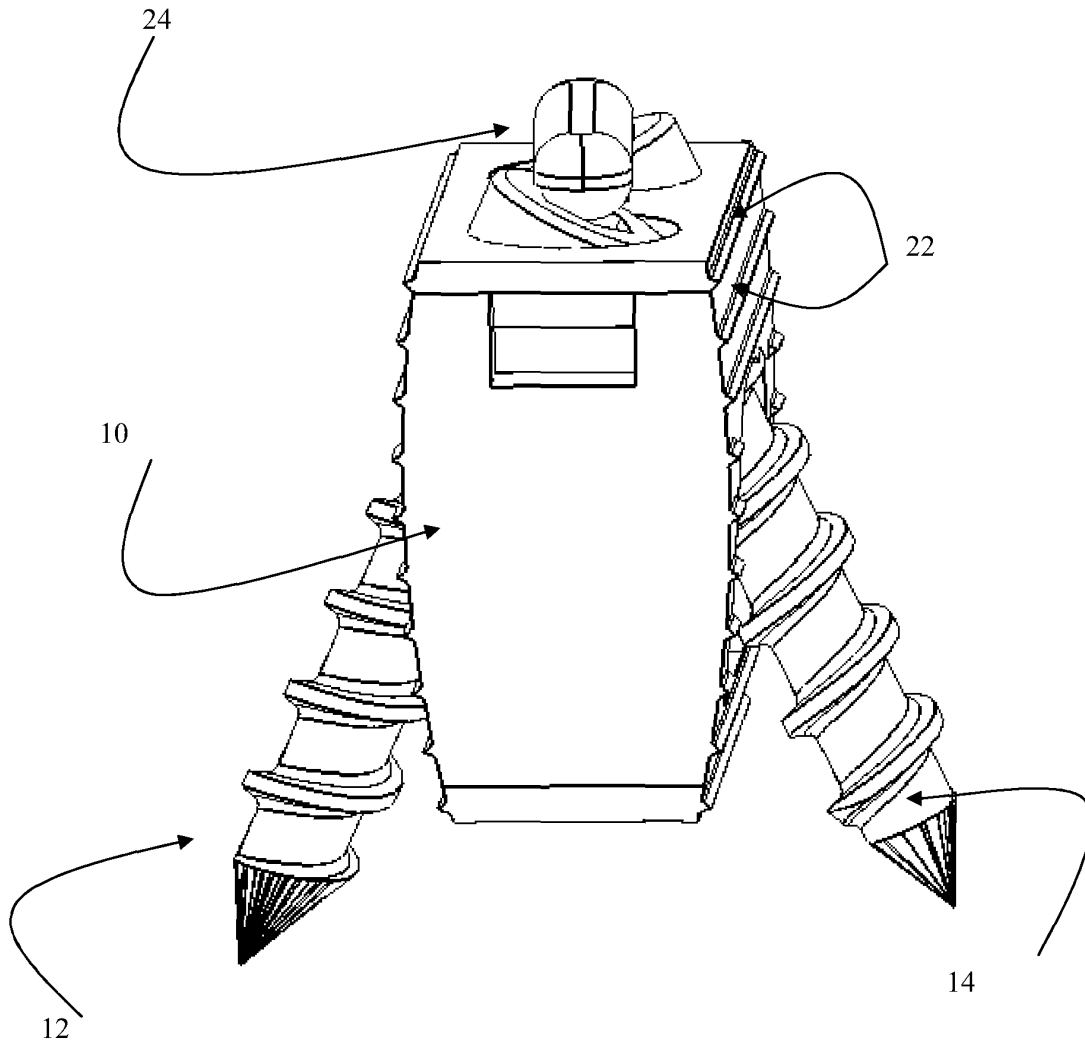


FIGURE 1(C)

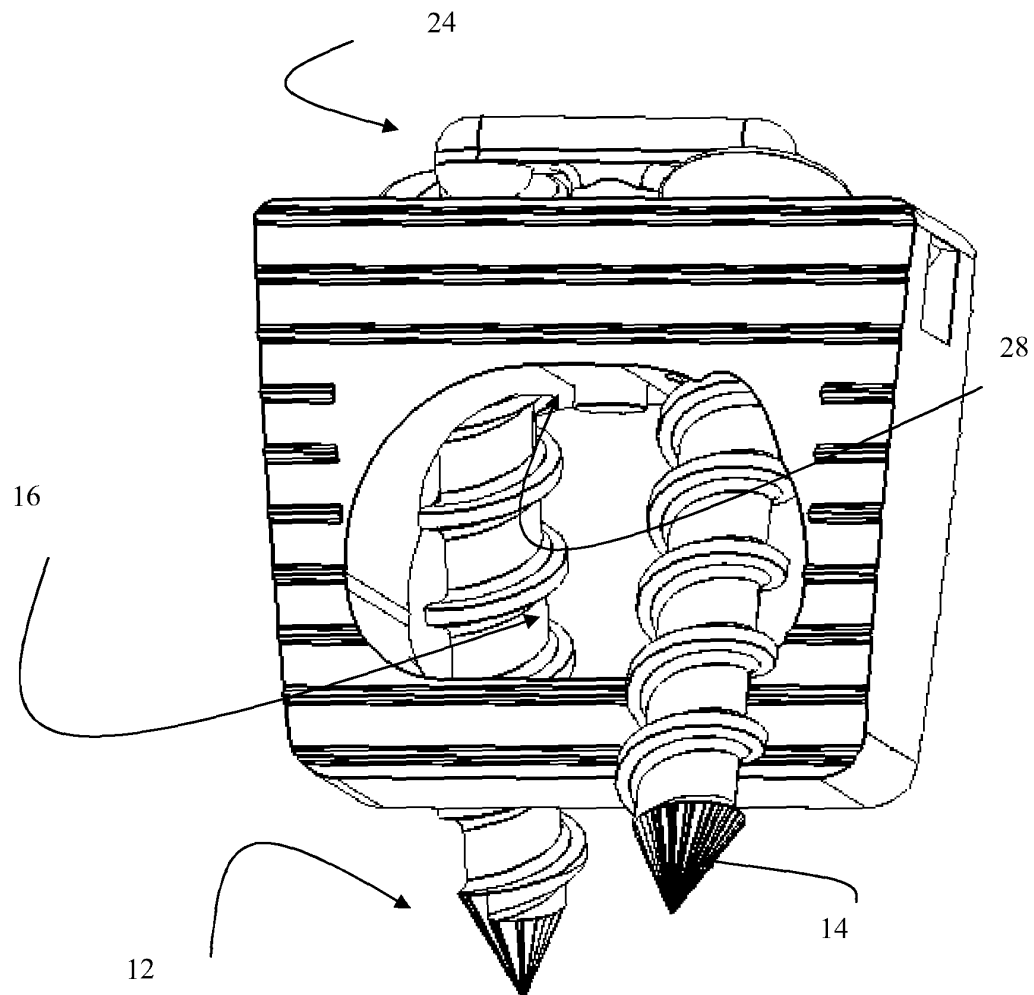


FIGURE 1(D)

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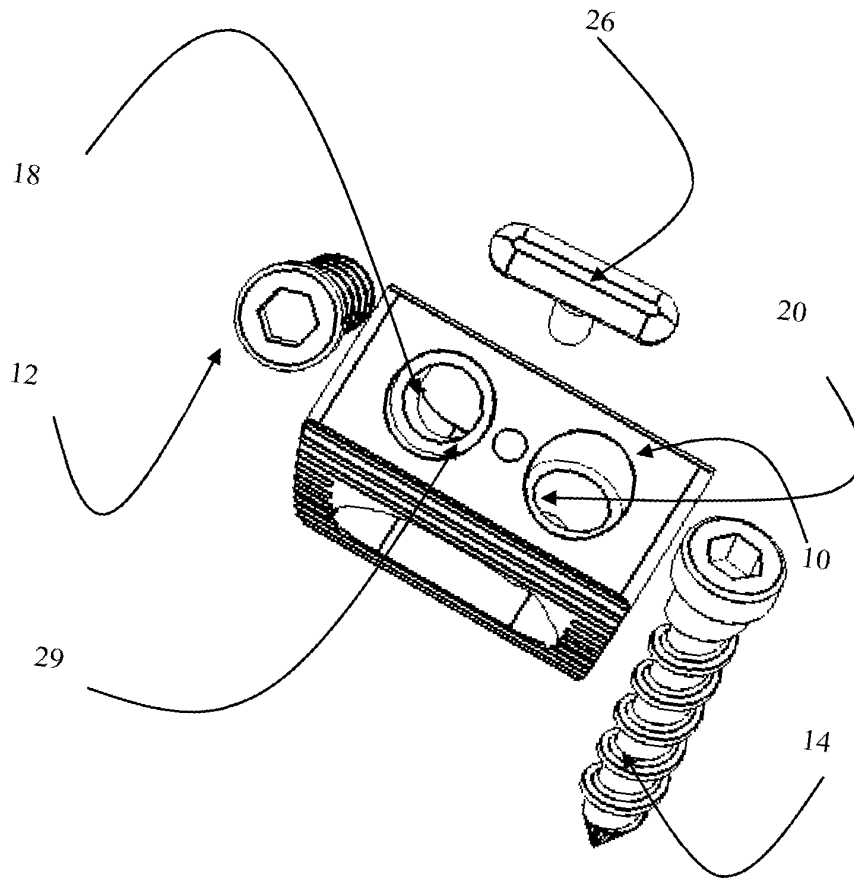


FIGURE 1(E)

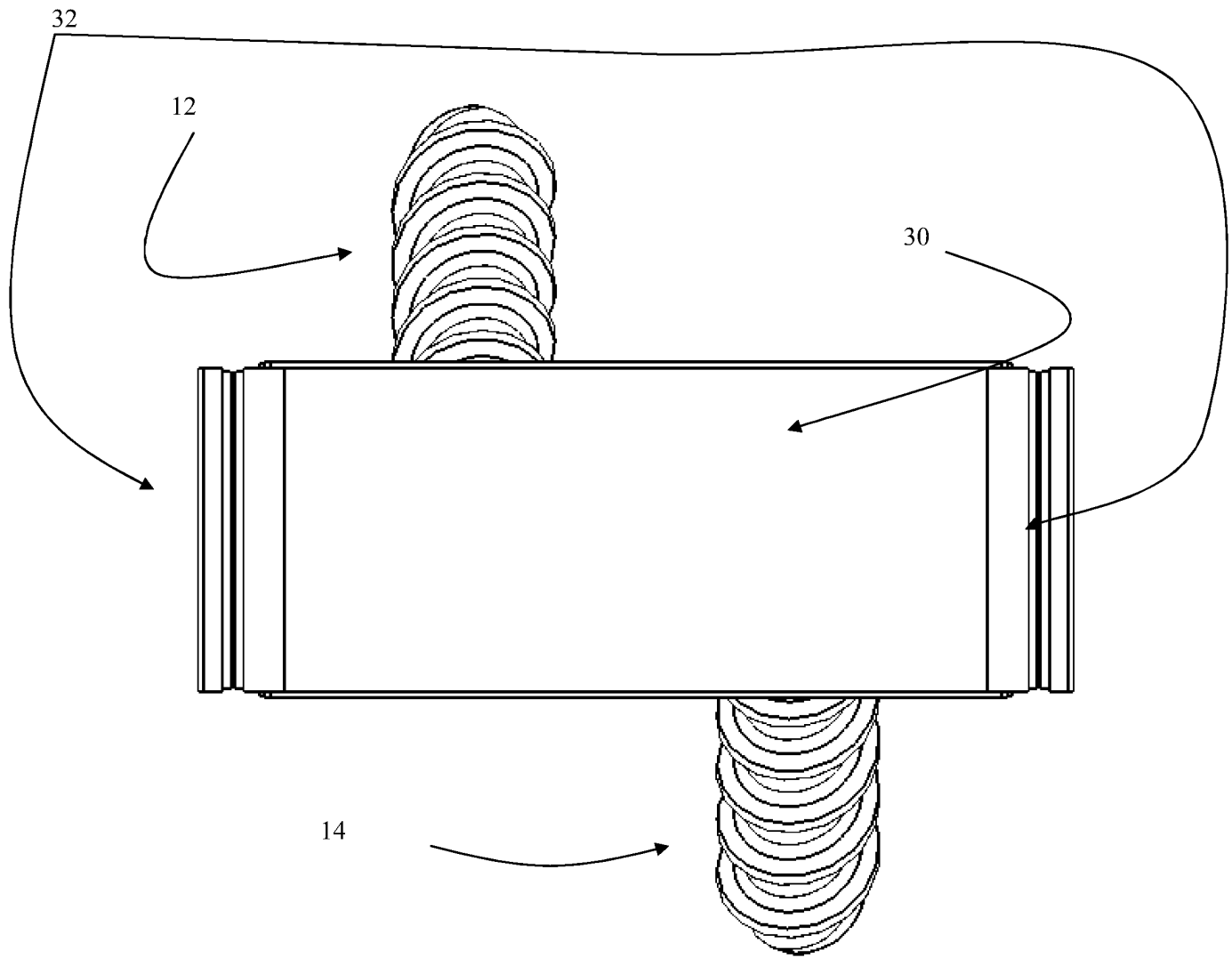


FIGURE 2(A)

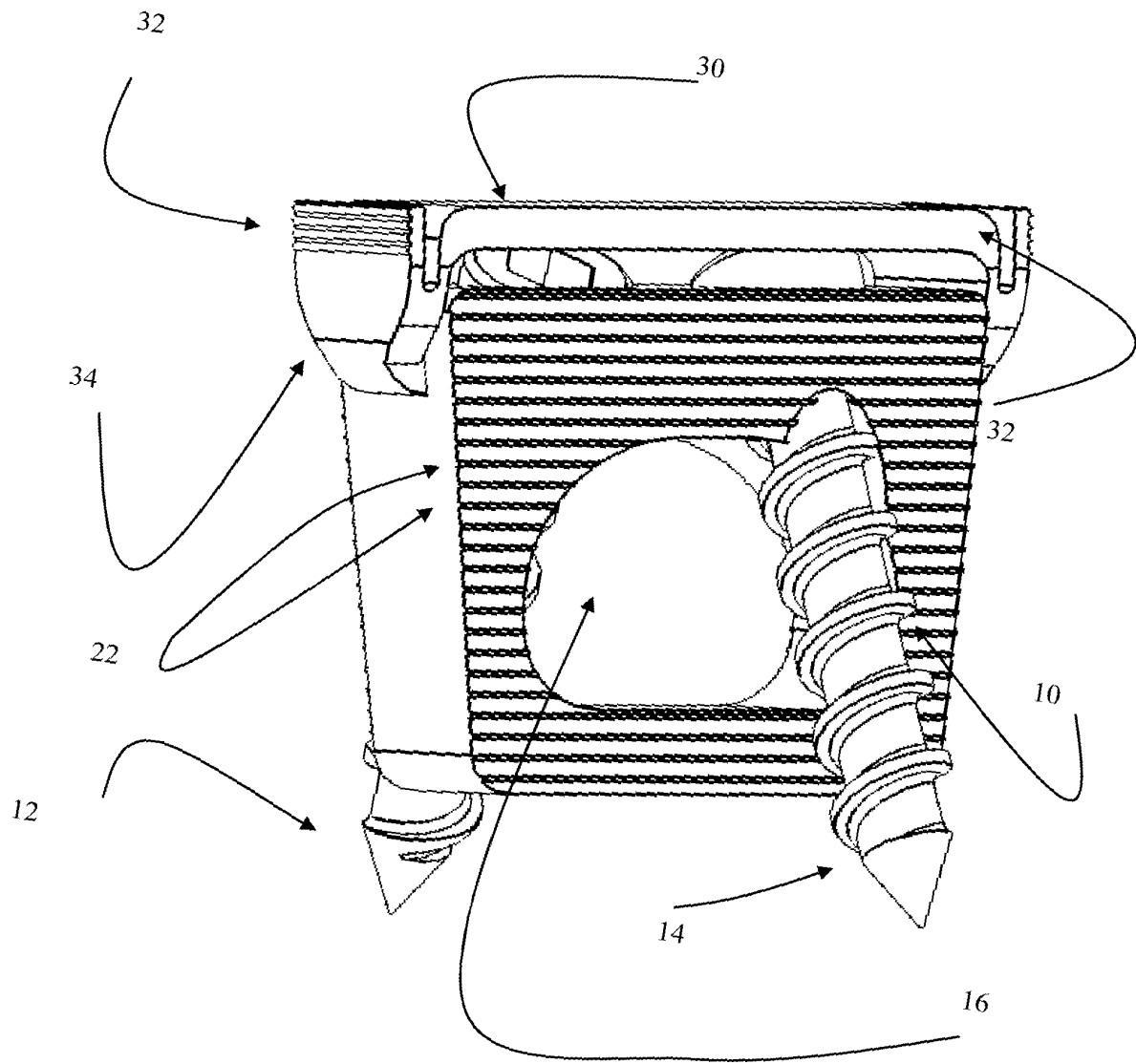


FIGURE 2(B)

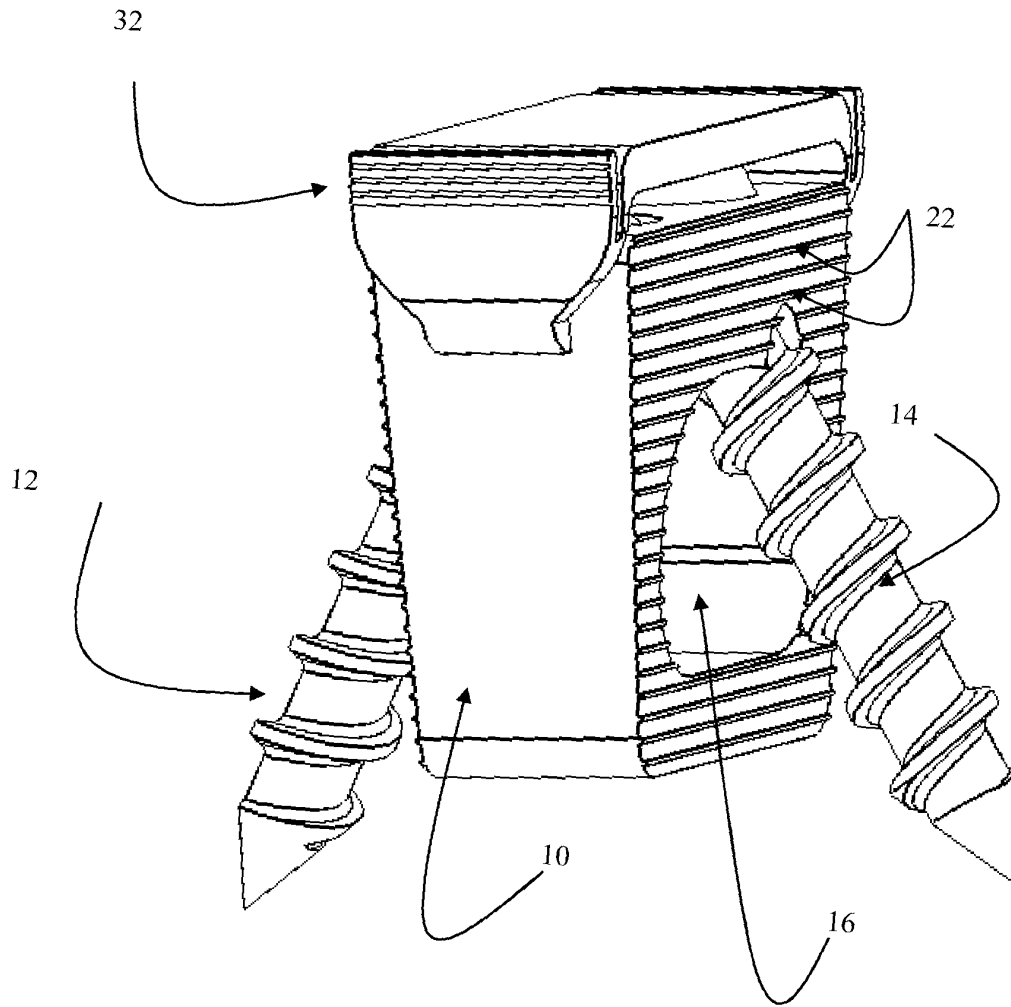


FIGURE 2(C)

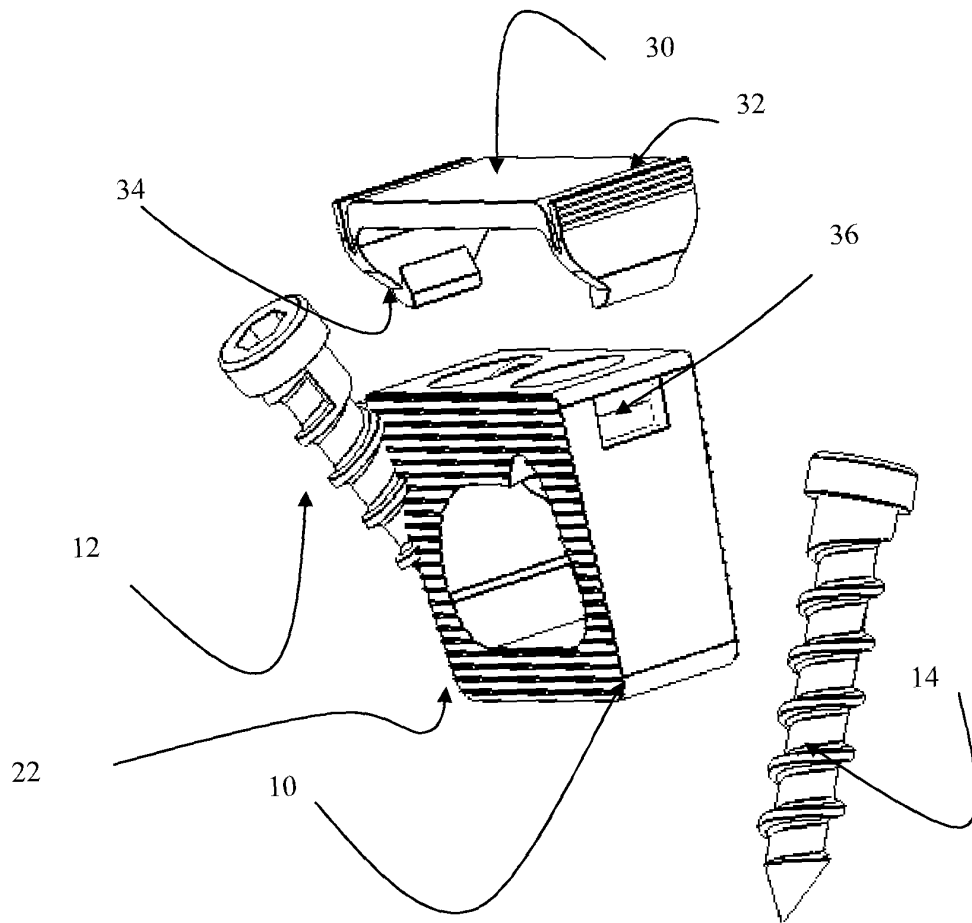


FIGURE 2(D)

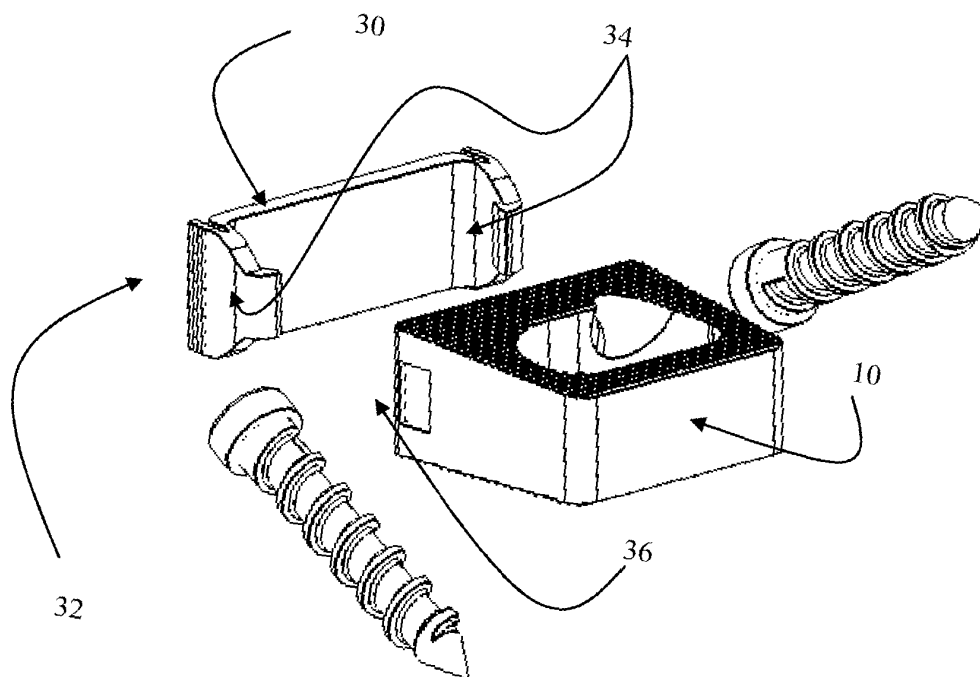


FIGURE 2(E)

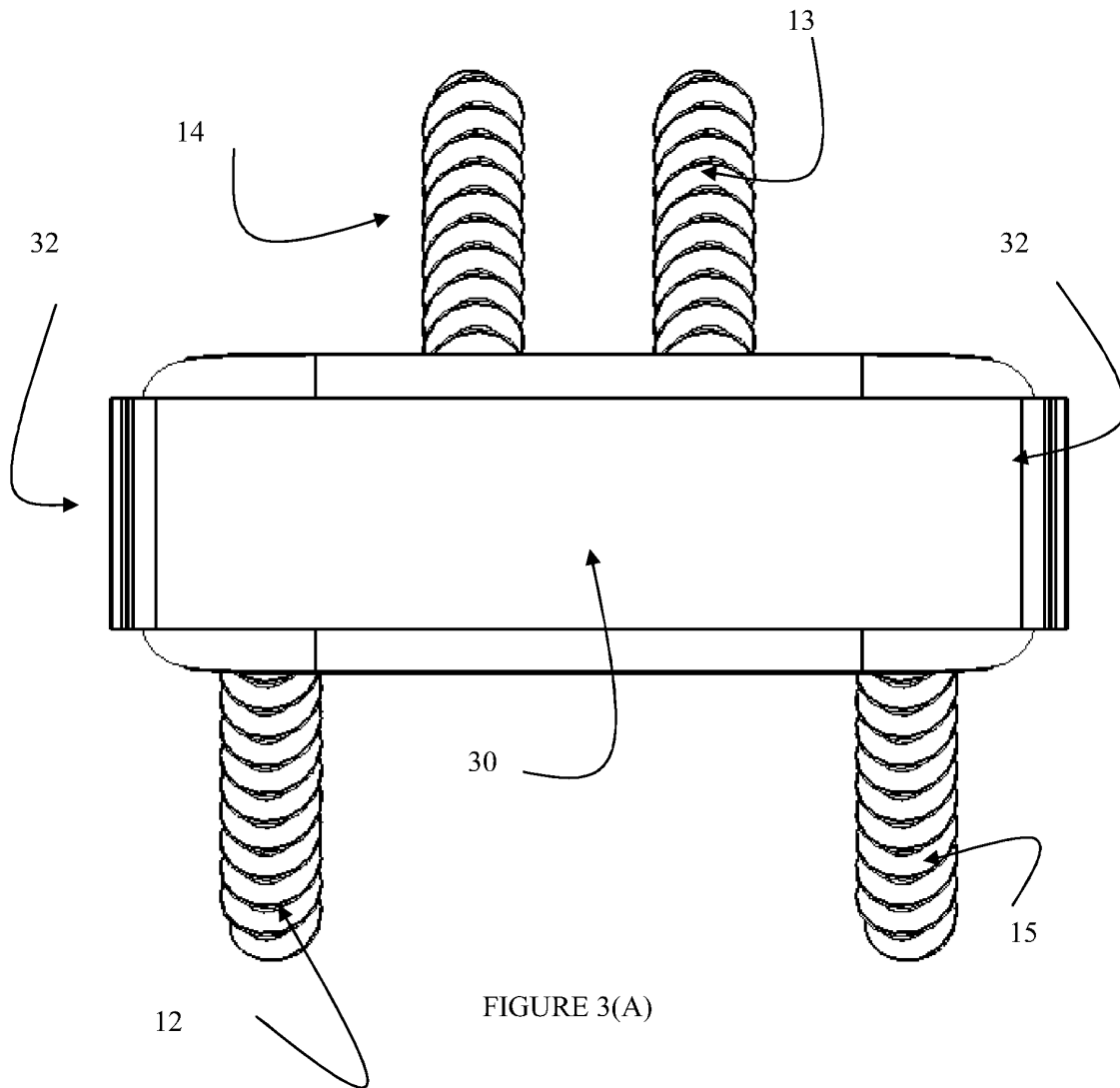


FIGURE 3(A)

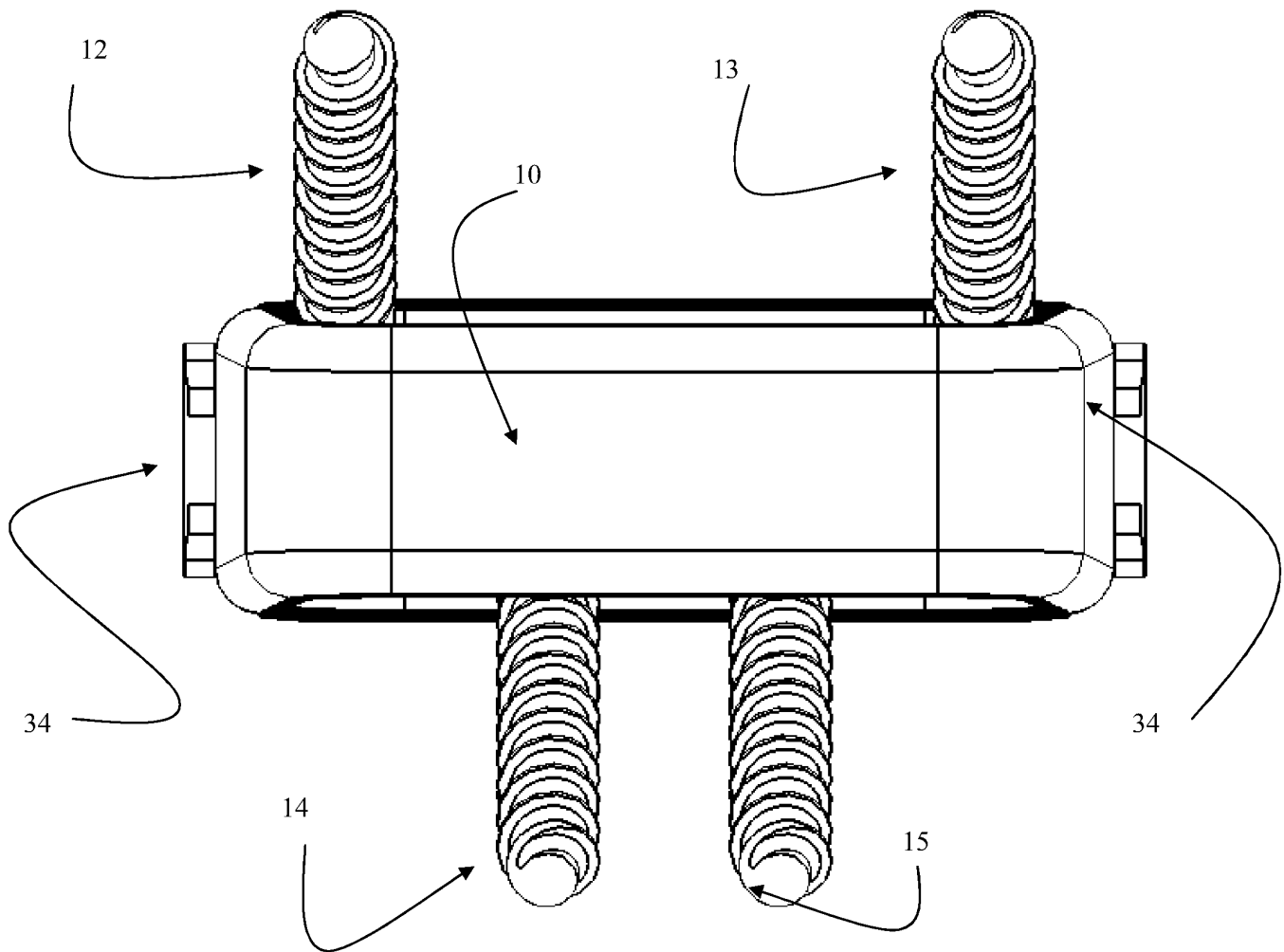


FIGURE 3(B)

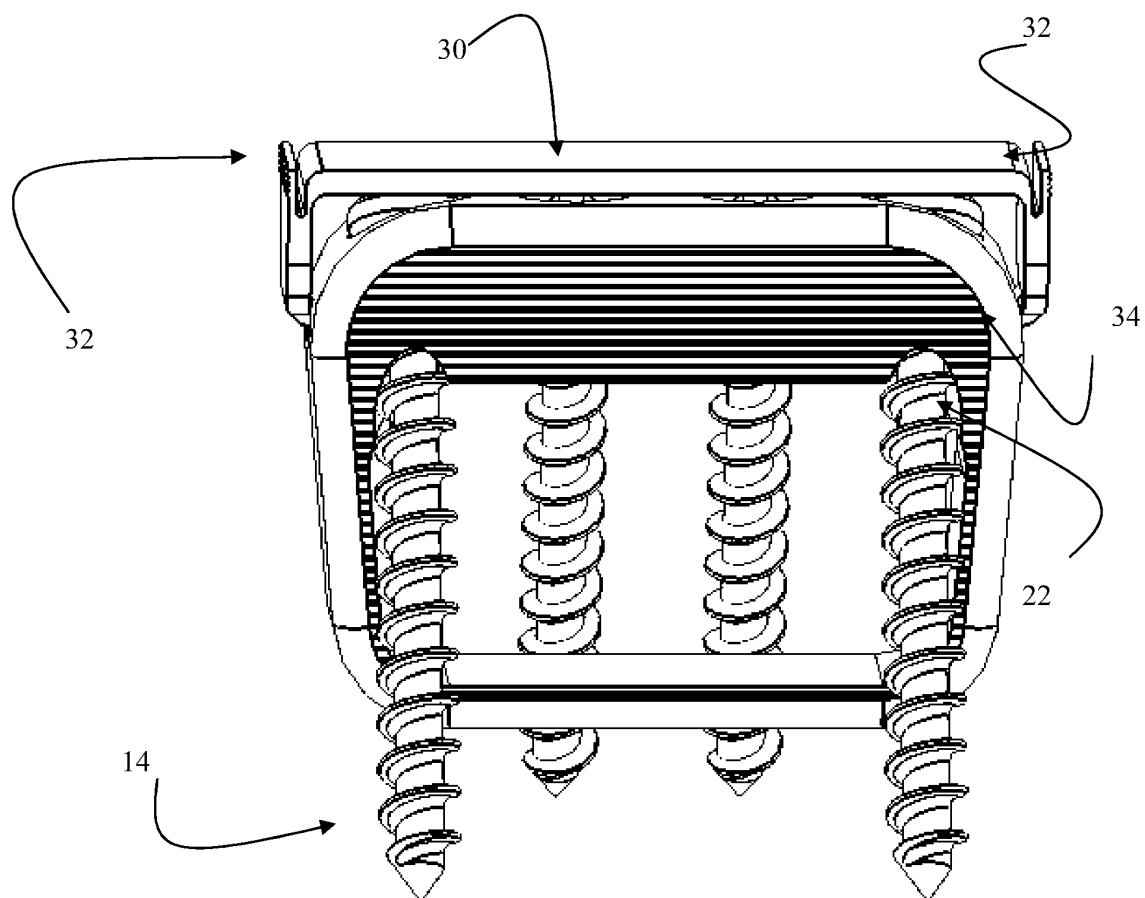


FIGURE 3(C)

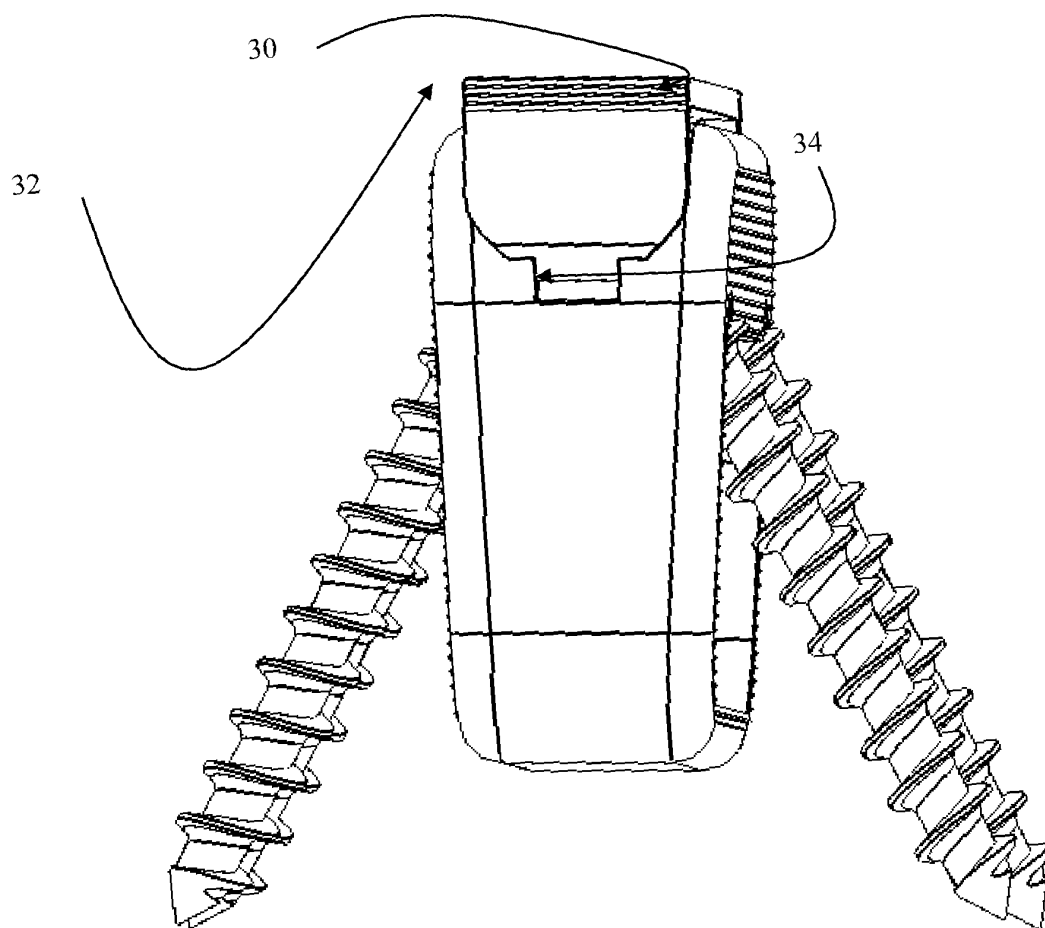


FIGURE 3(D)

15 / 40

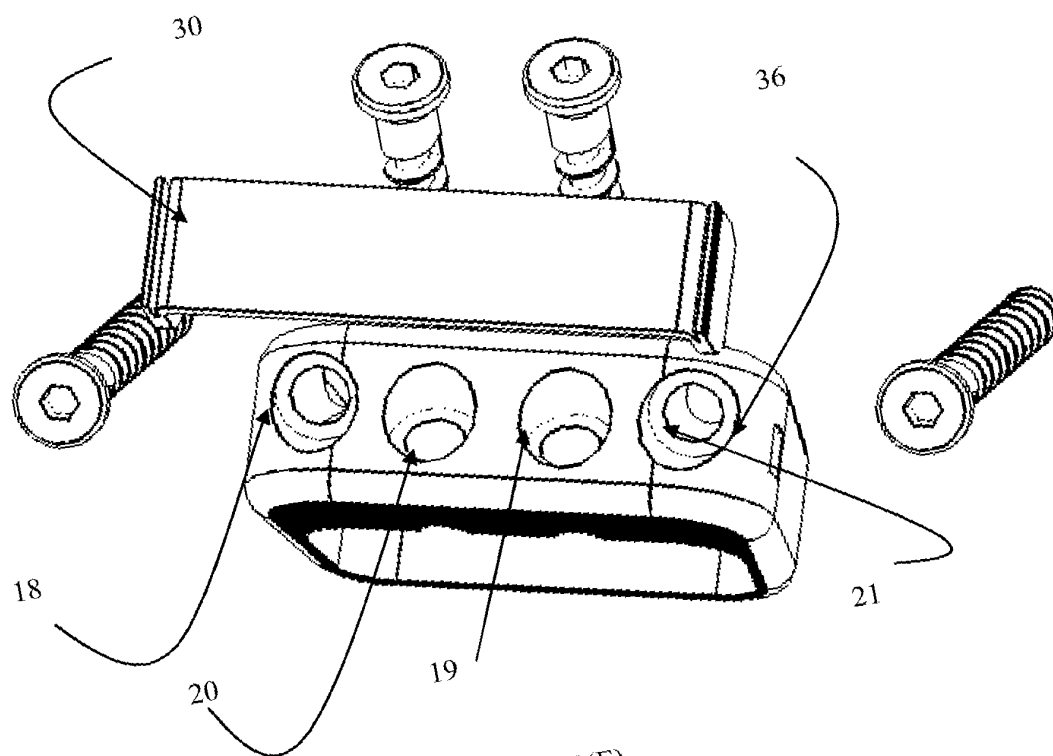


FIGURE 3(E)

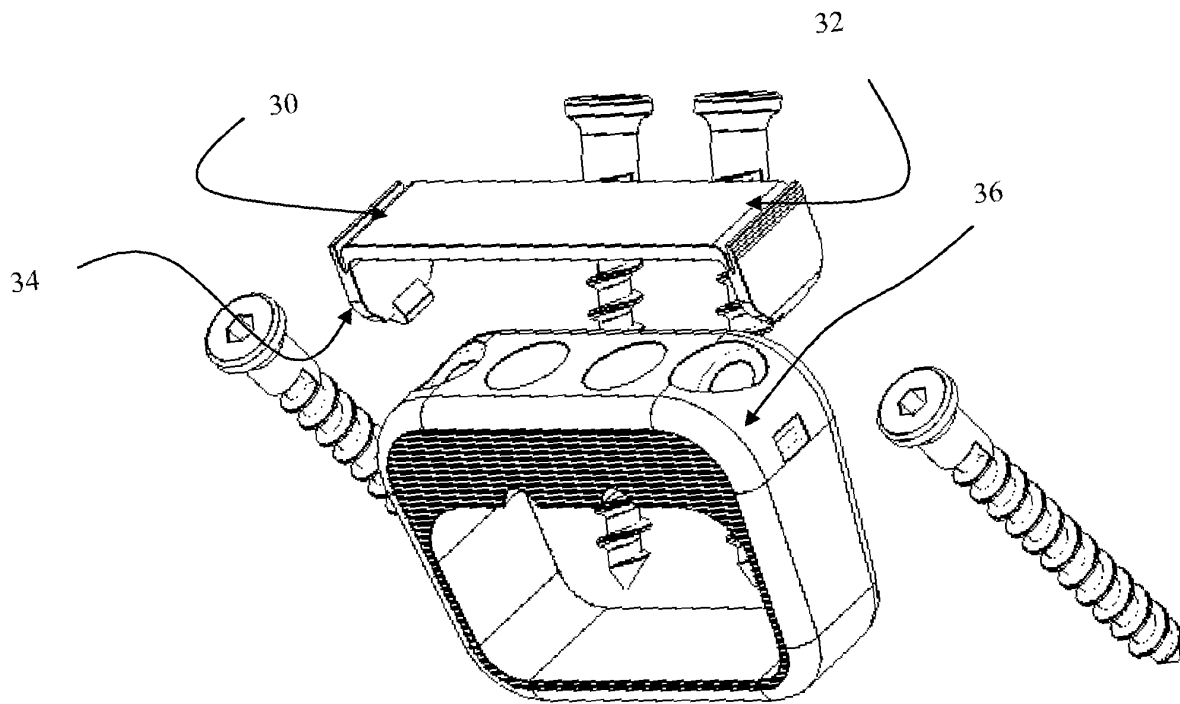


FIGURE 3(F)

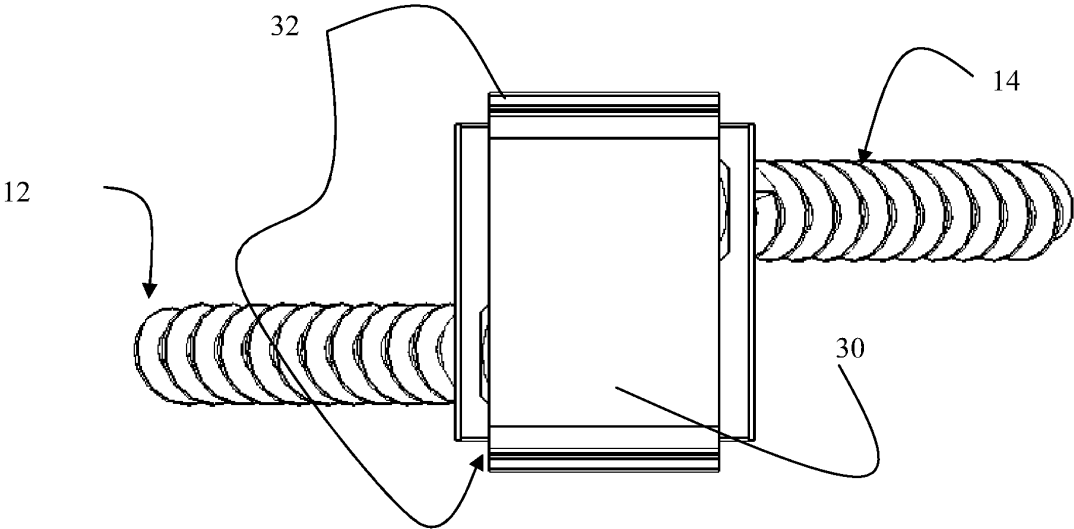


FIGURE 4(A)

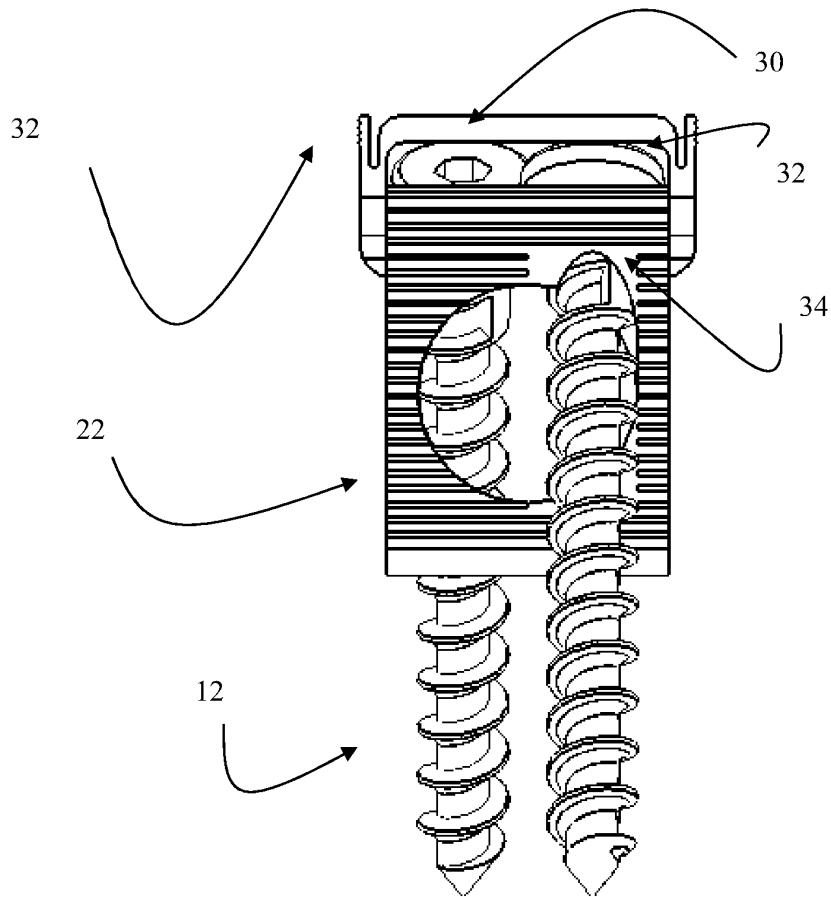


FIGURE 4(B)

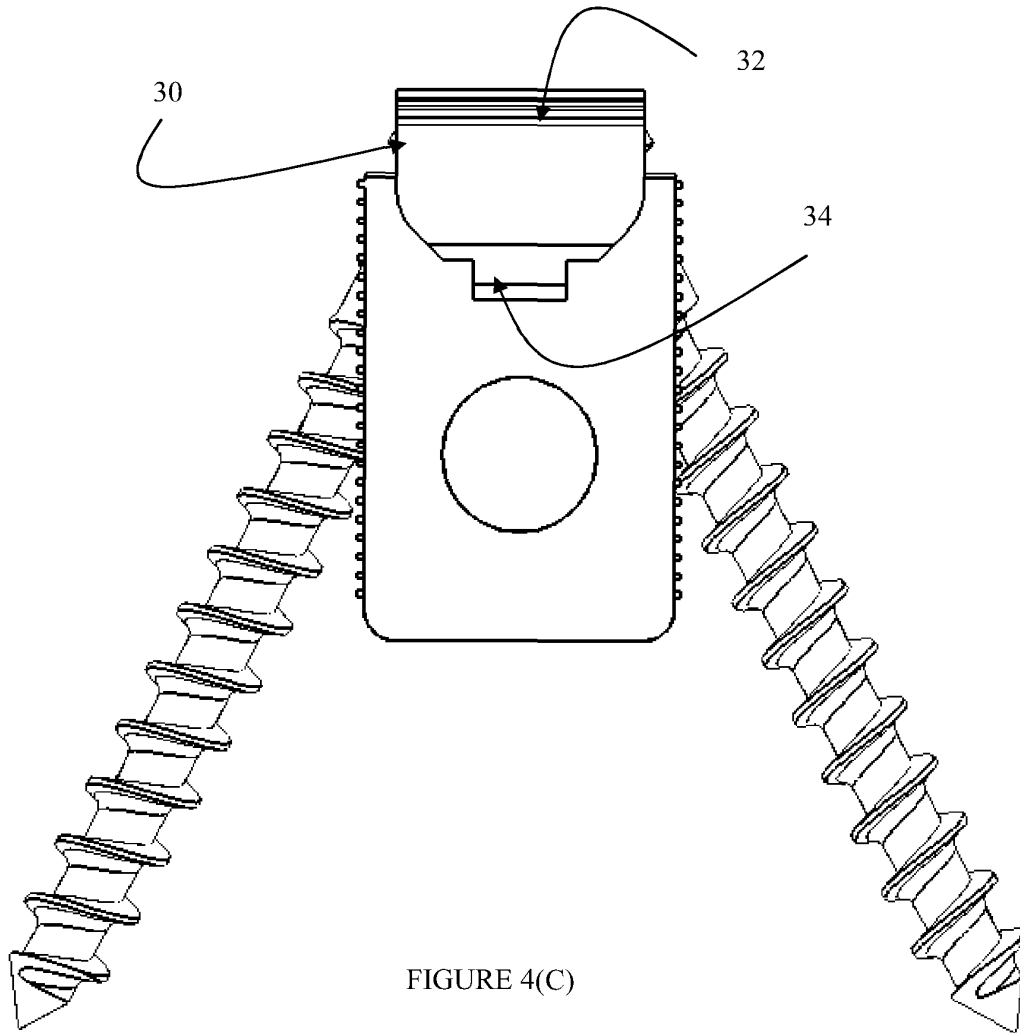


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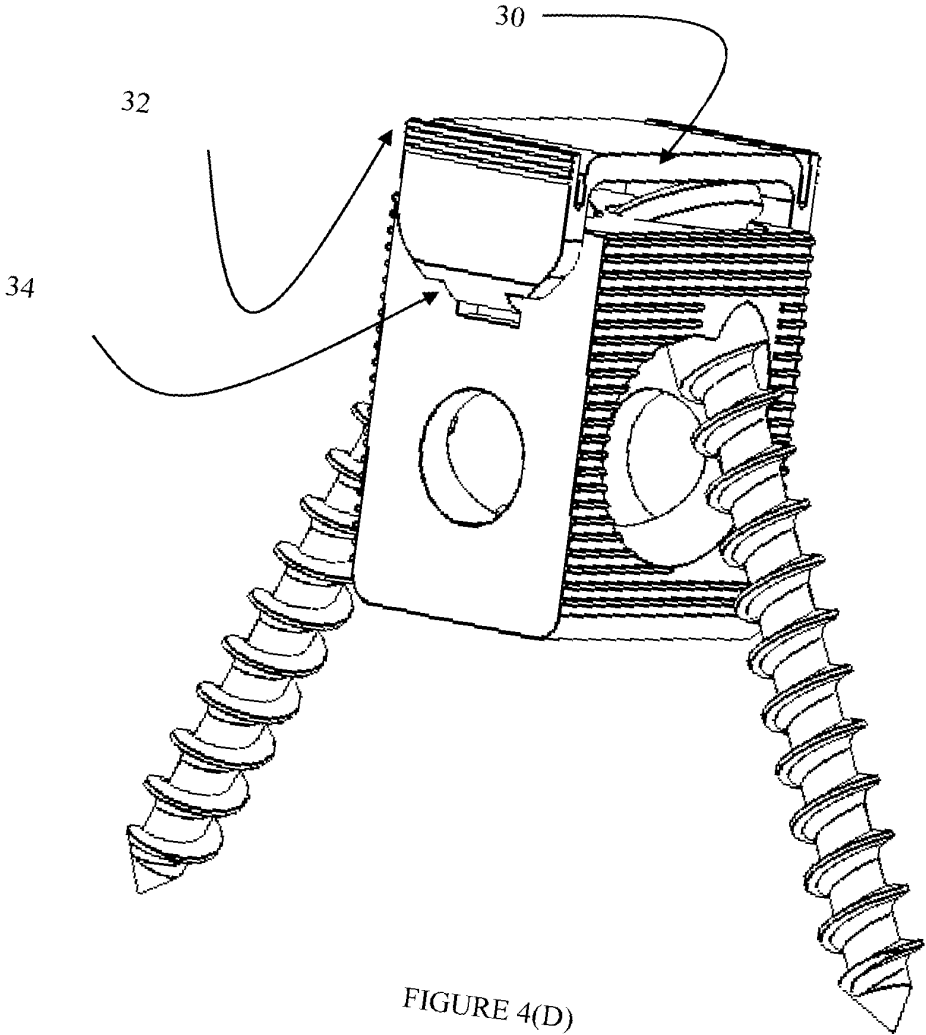


FIGURE 4(D)

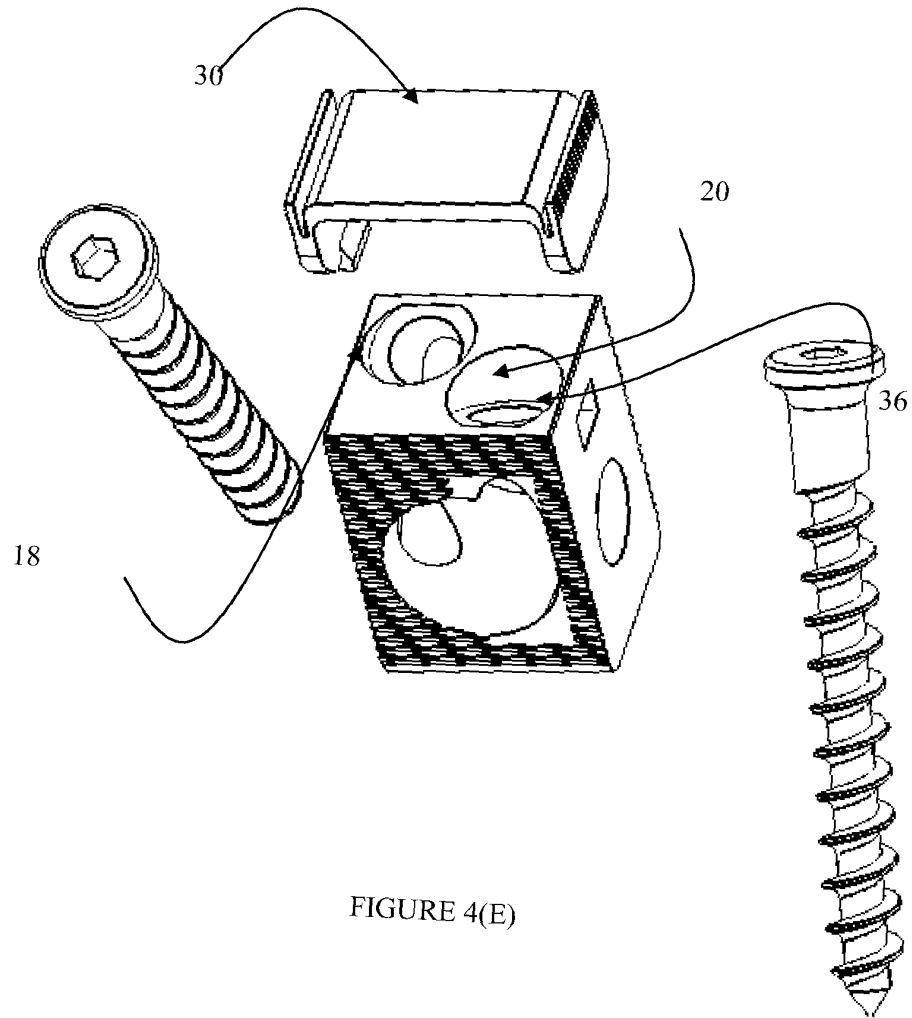


FIGURE 4(E)

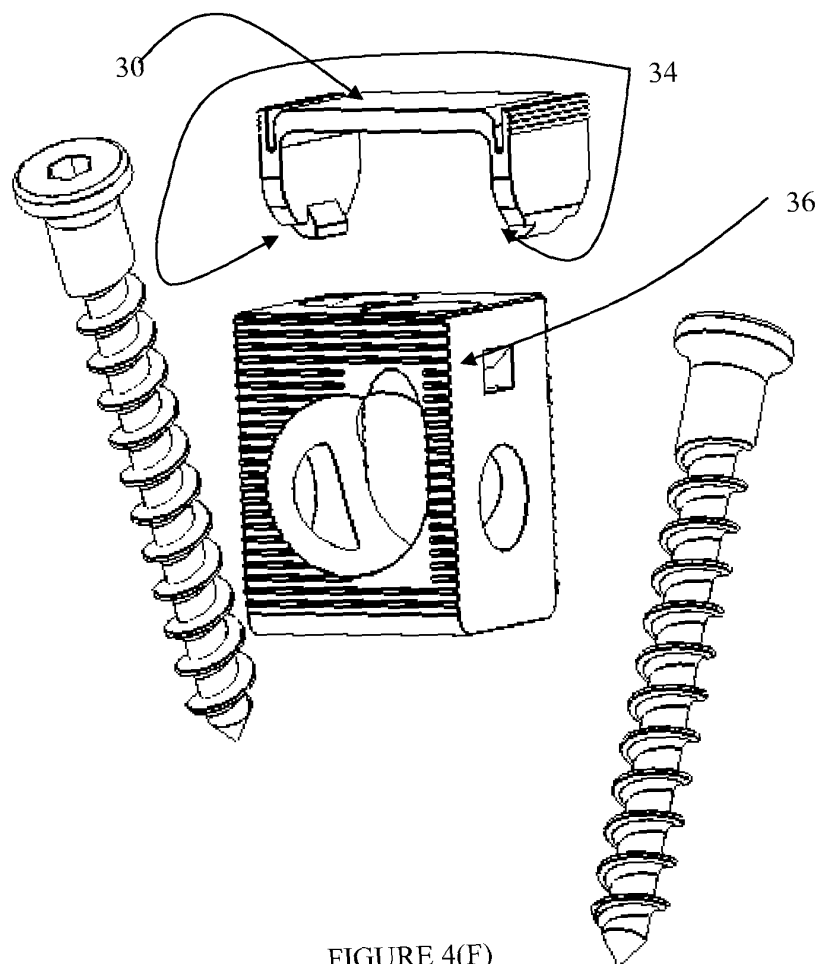


FIGURE 4(F)

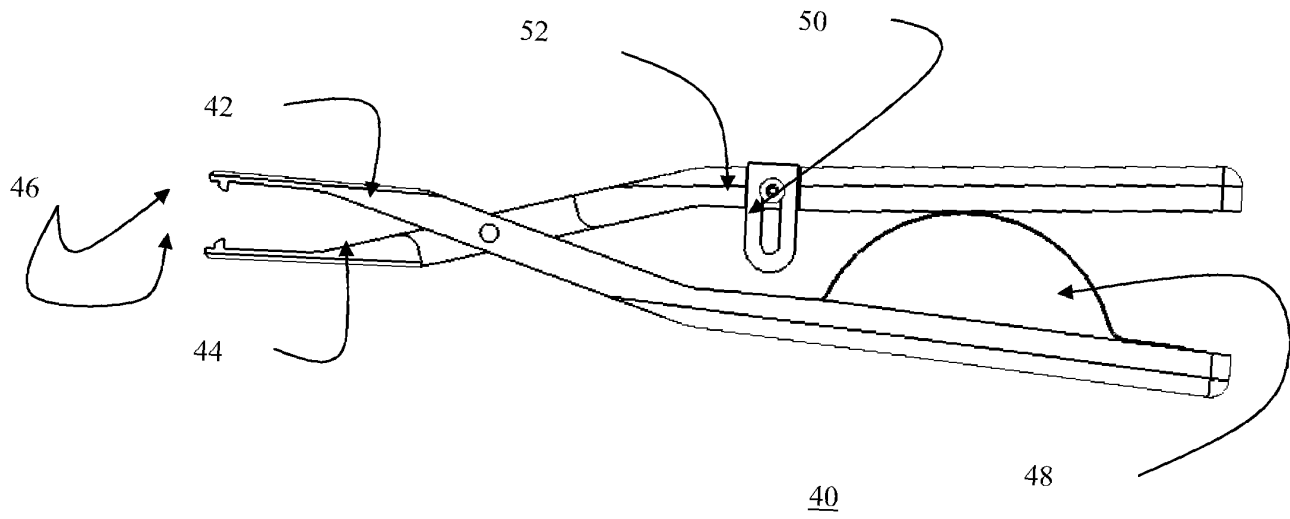


FIGURE 5

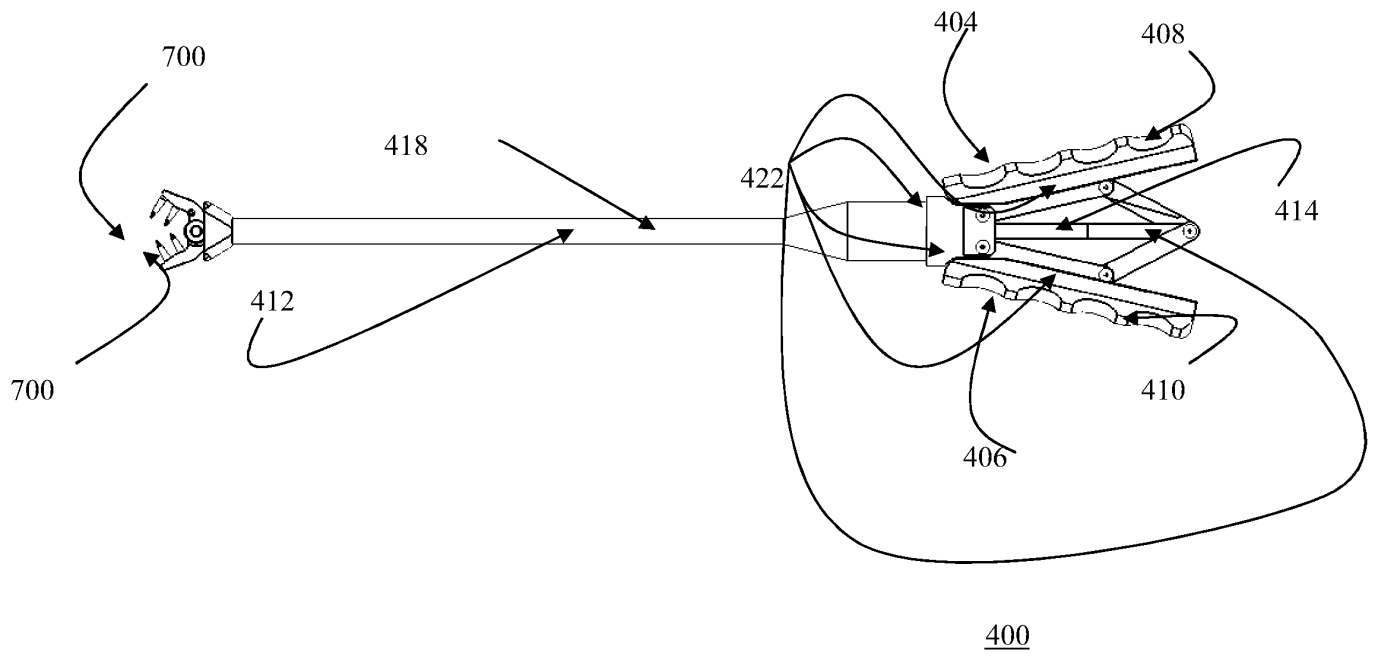


FIGURE 6(A)

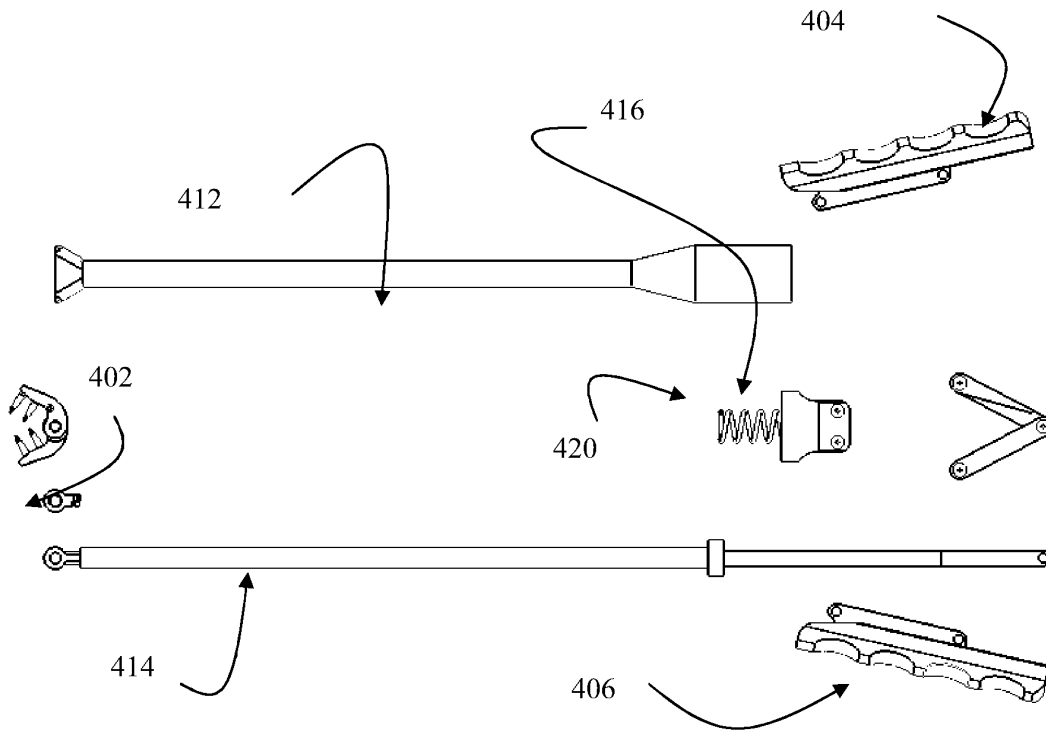


FIGURE 6(B)

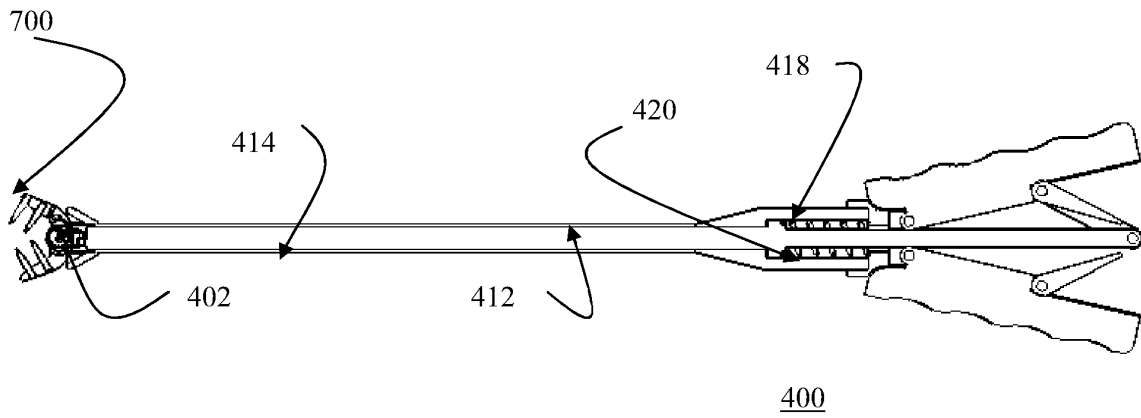


FIGURE 6(C)

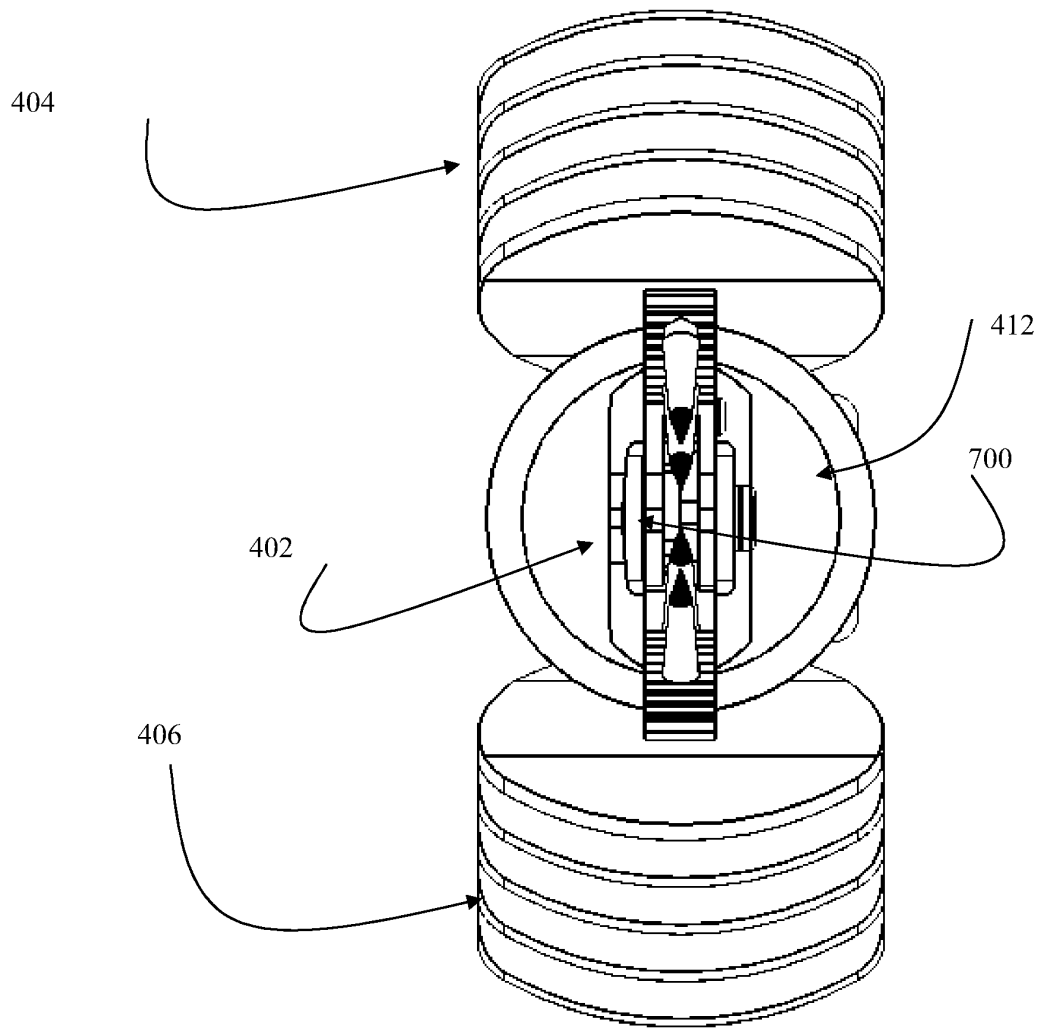


FIGURE 6(D)

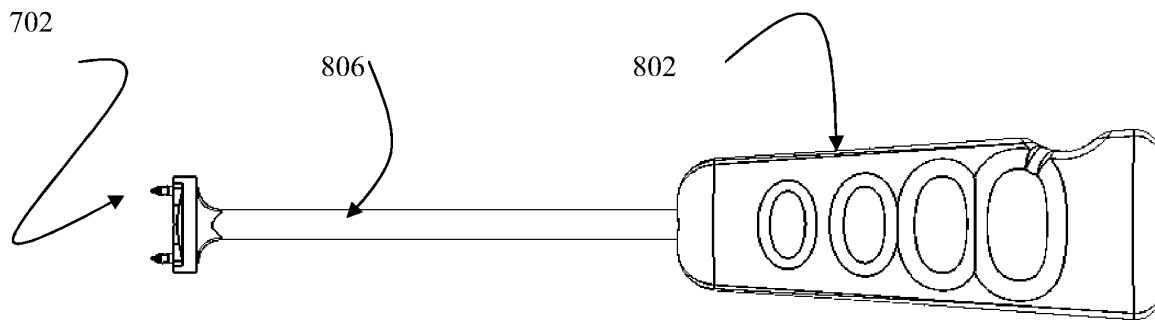


FIGURE 7(A)

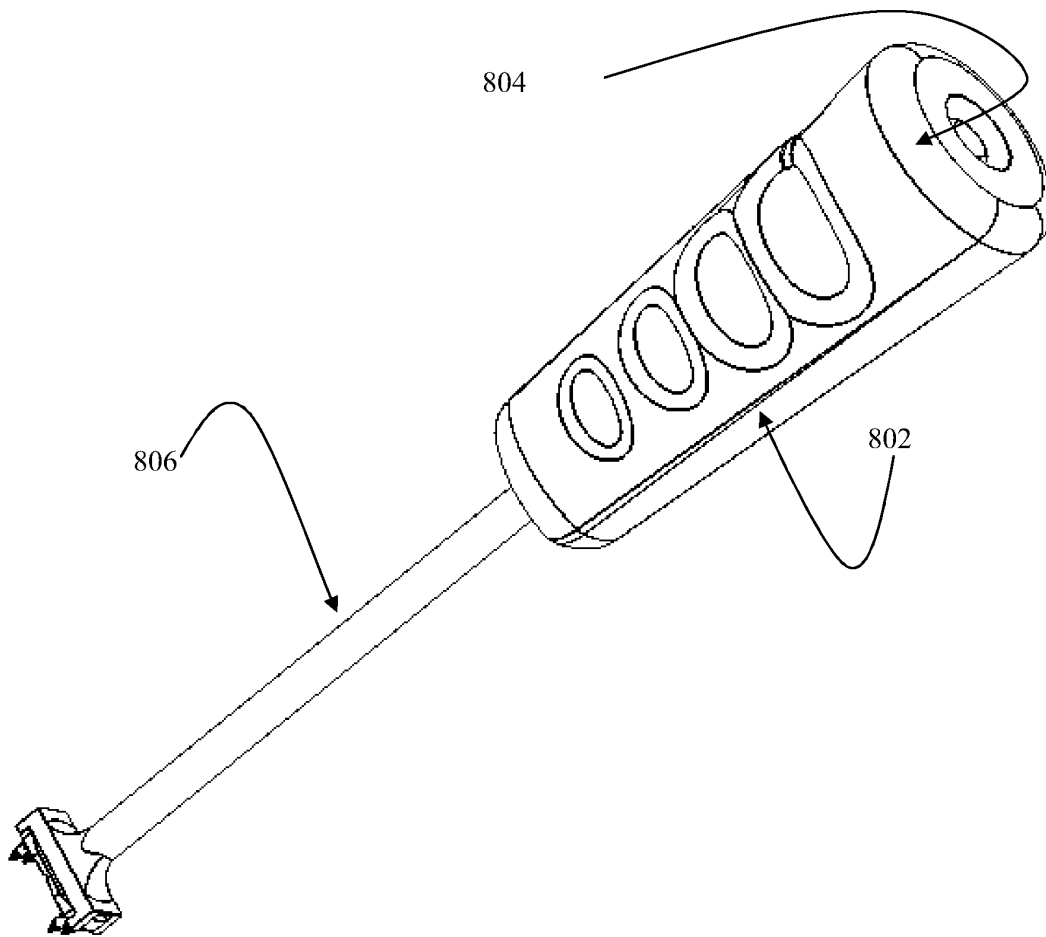
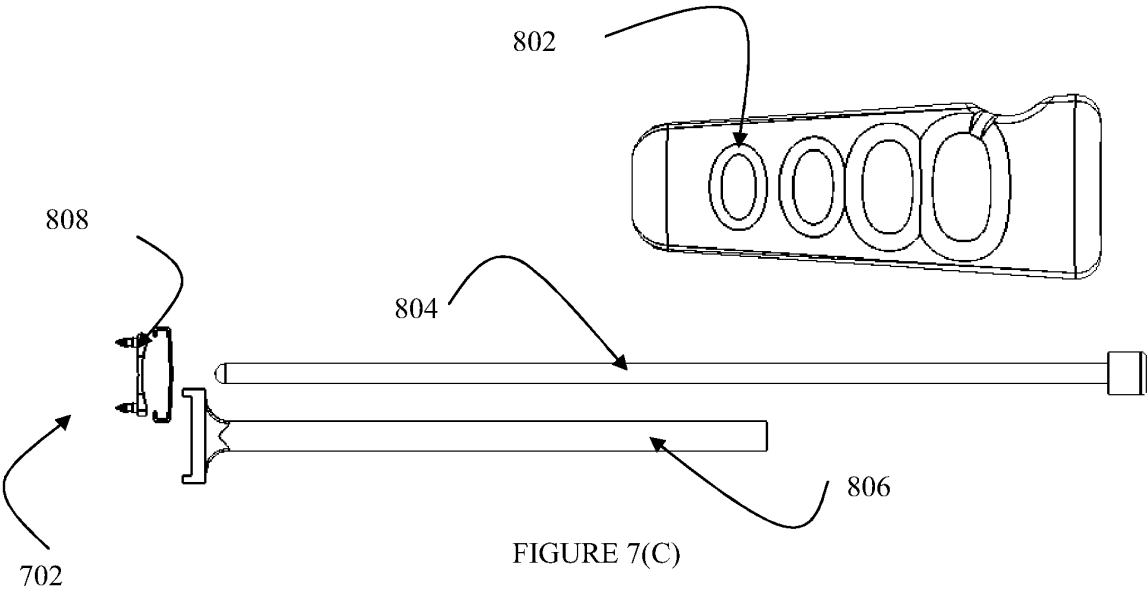


FIGURE 7(B)



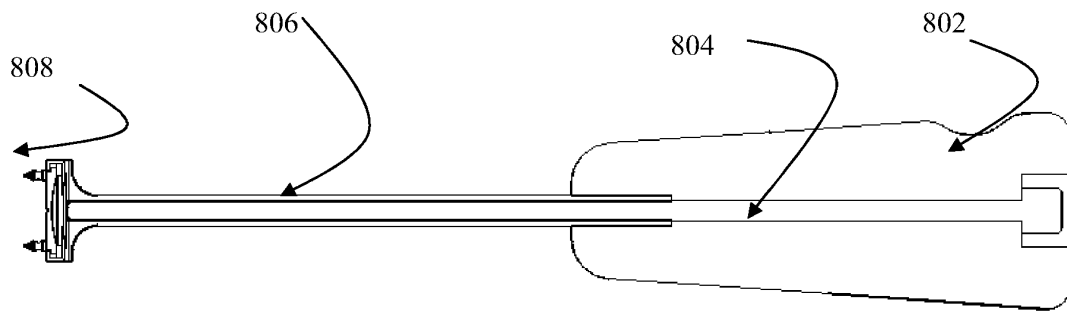


FIGURE 7(D)

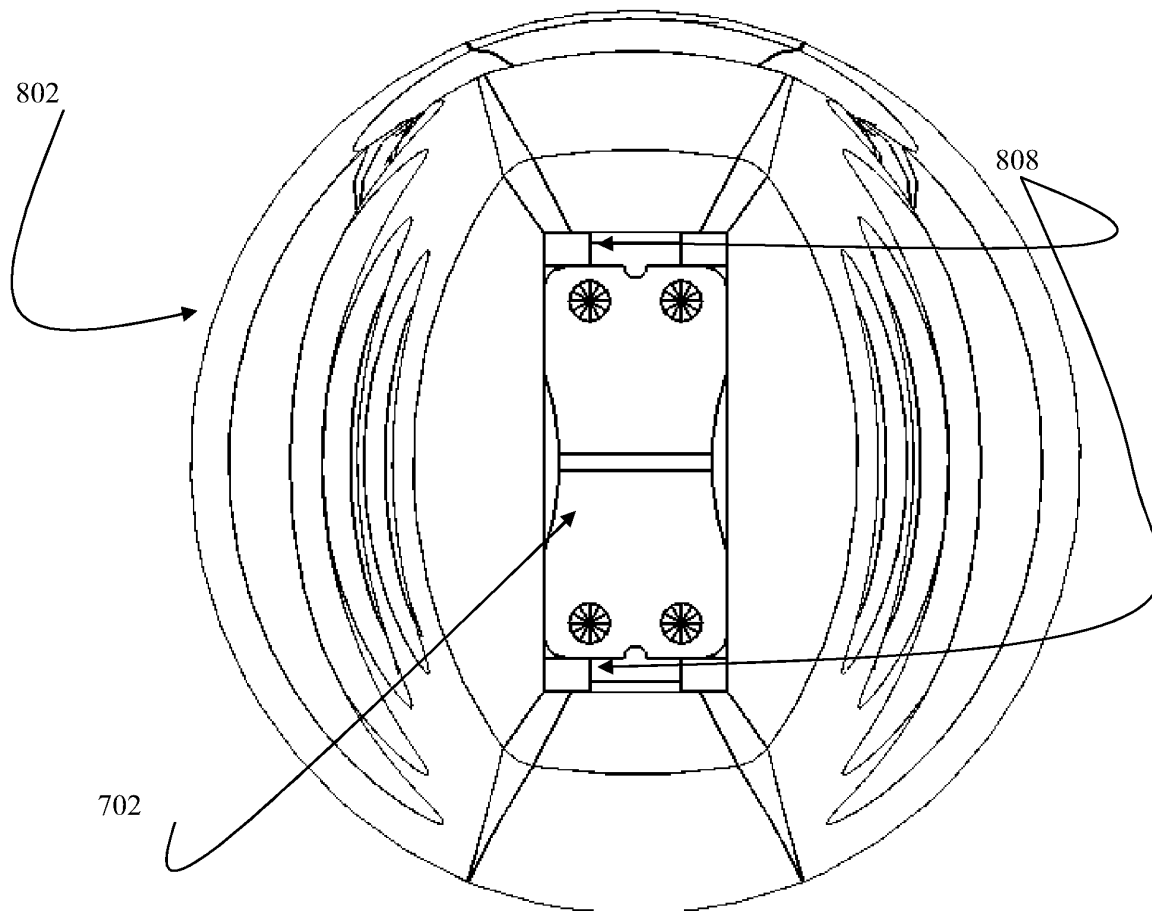


FIGURE 7(E)

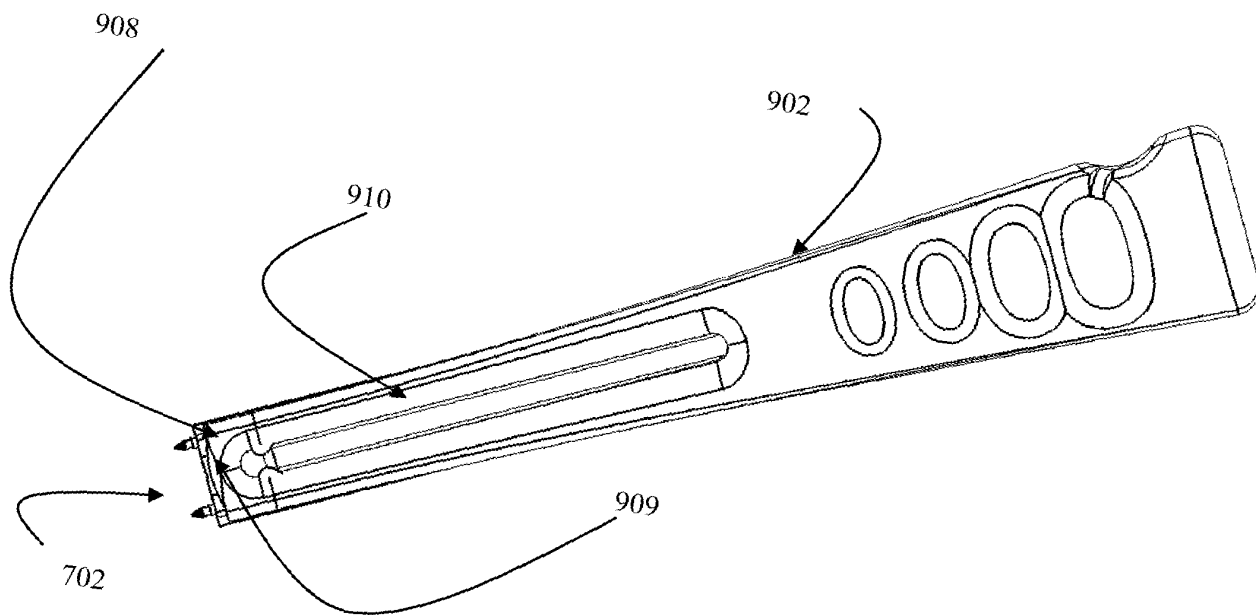


FIGURE 8(A)

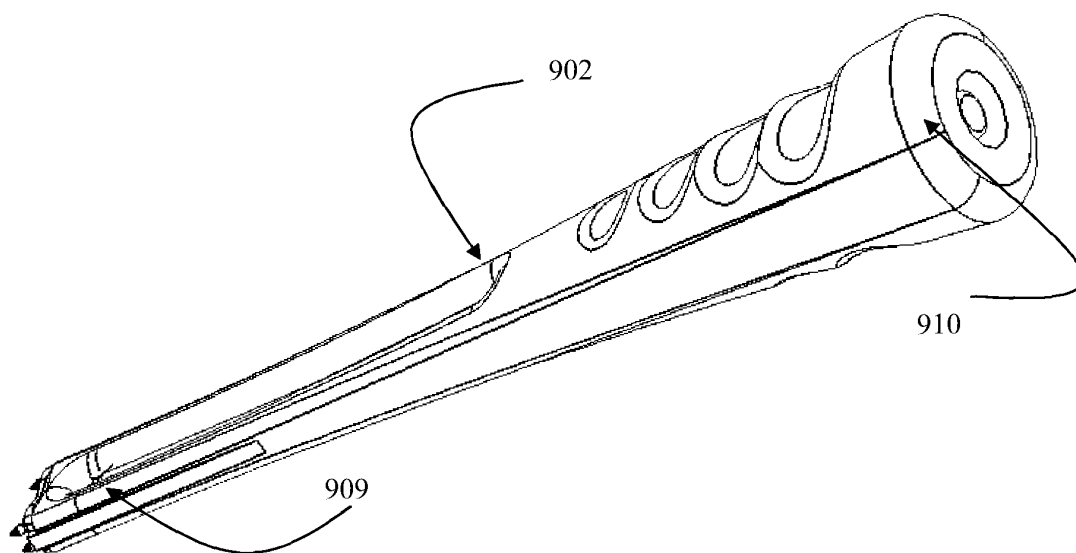


FIGURE 8(B)

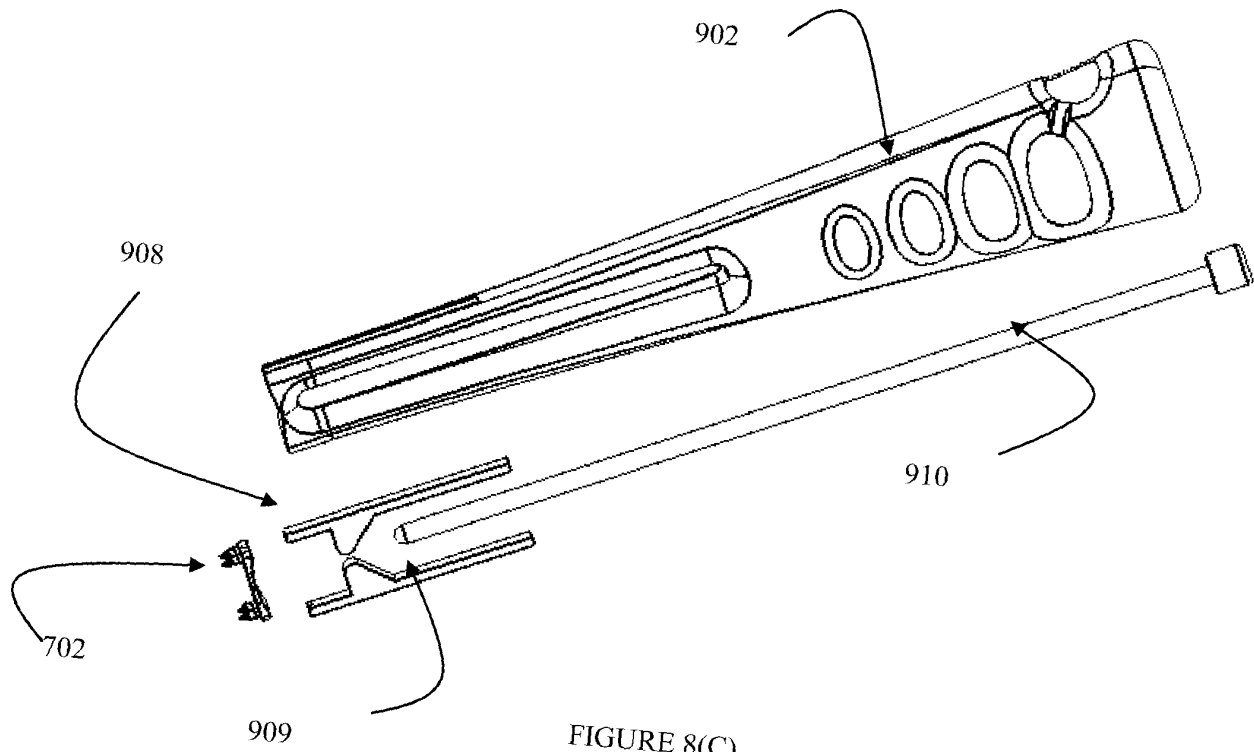
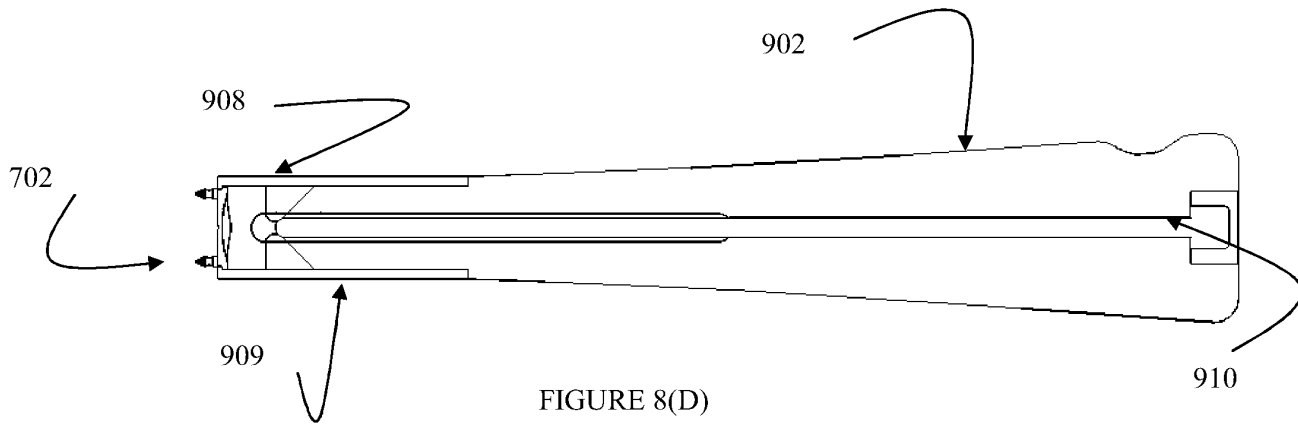


FIGURE 8(C)



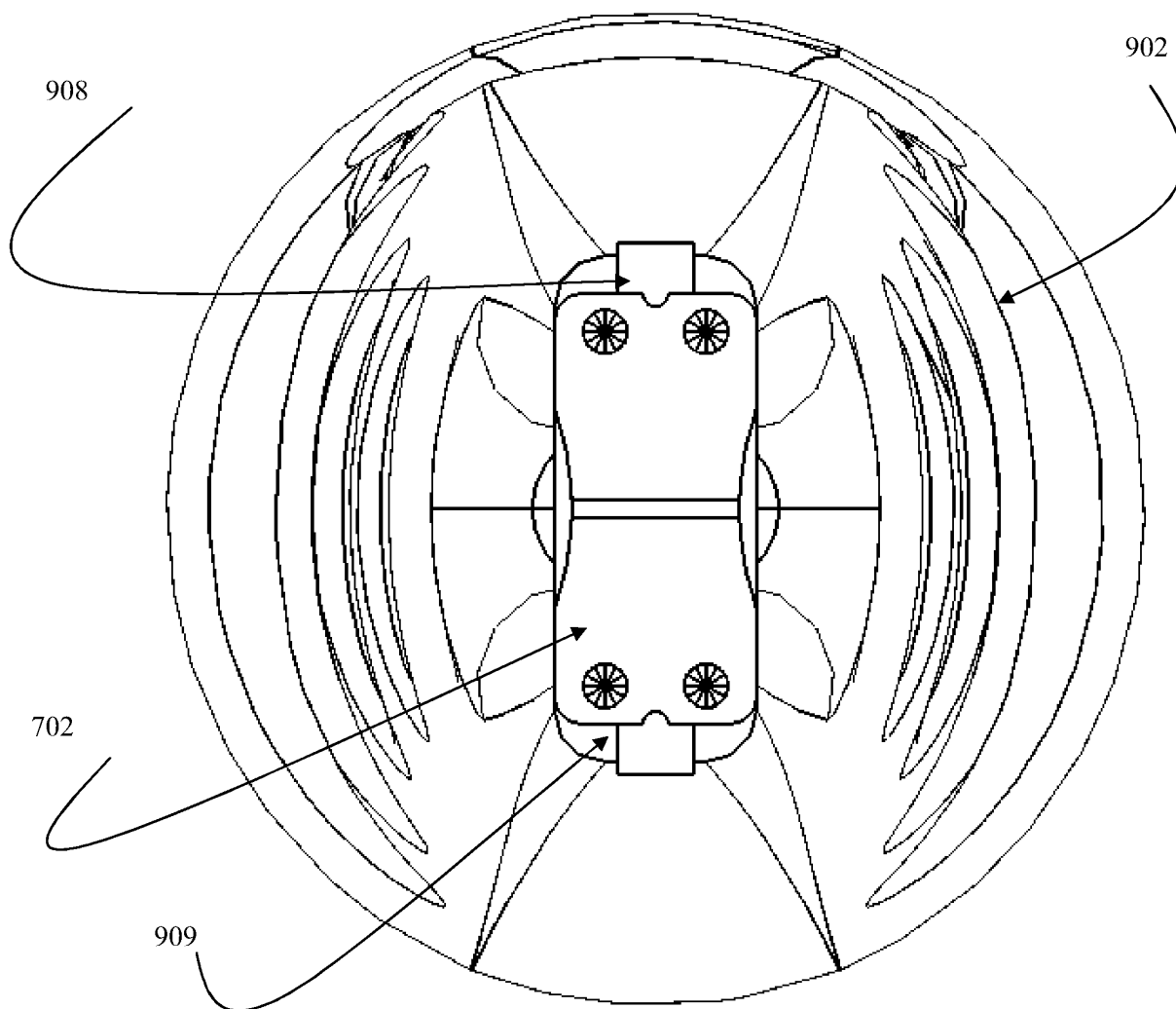


FIGURE 8(E)

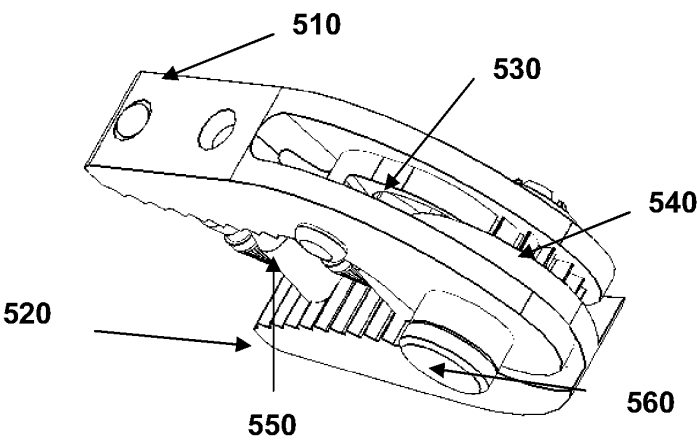


FIGURE 9A

500

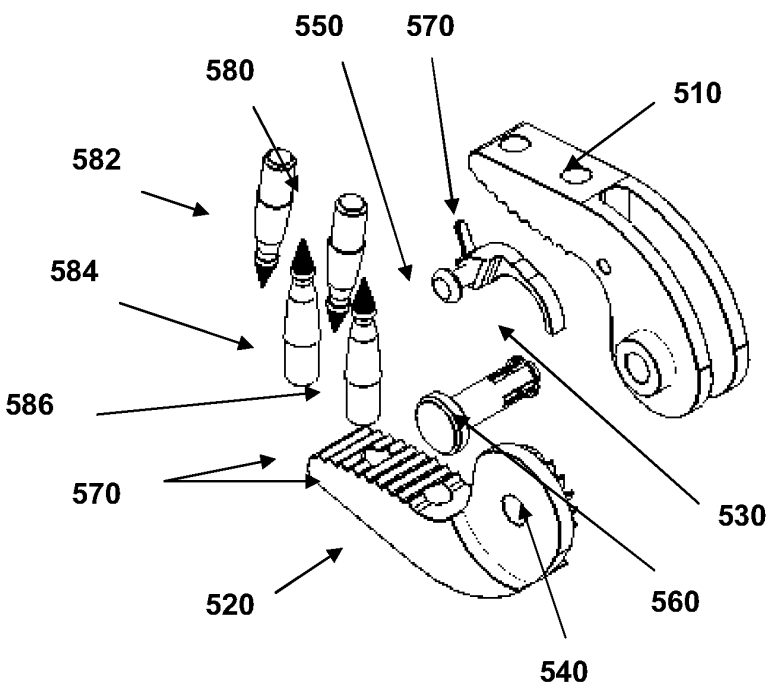
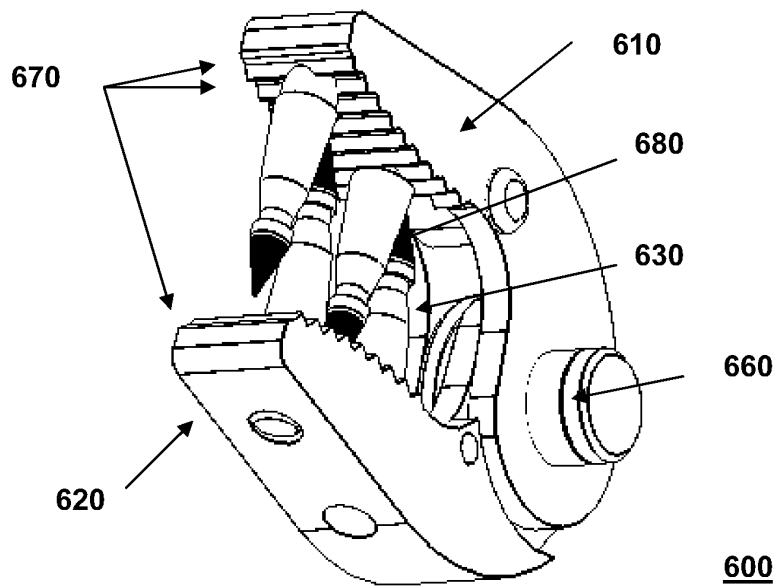
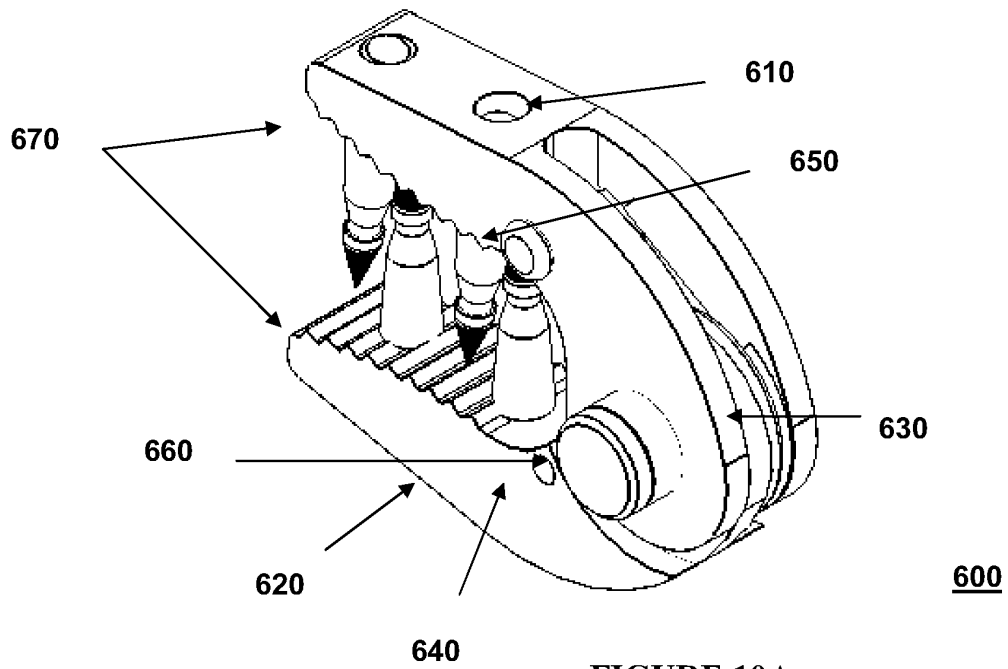


FIGURE 9B

500



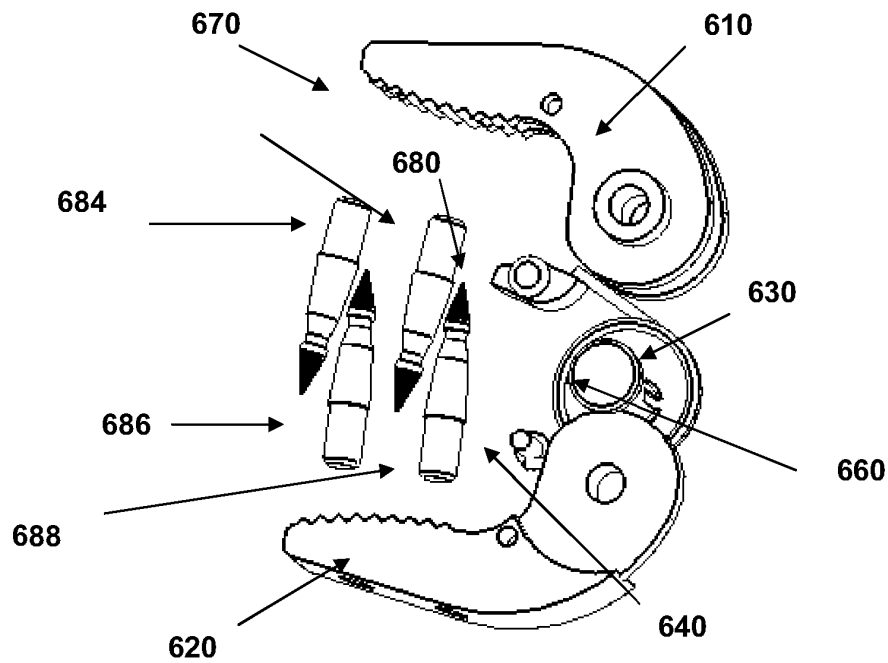


FIGURE 10C

Electronic Acknowledgement Receipt	
EFS ID:	28953543
Application Number:	15490107
International Application Number:	
Confirmation Number:	5831
Title of Invention:	BI-DIRECTIONAL FIXATING/LOCKING TRANSVERTEBRAL BODY SCREW/ INTERVERTEBRAL CAGE STAND-ALONE CONSTRUCTS HAVING A CENTRAL SCREW LOCKING LEVER, AND PLIERS AND DEVICES FOR SPINAL FUSION
First Named Inventor/Applicant Name:	Nathan C. Moskowitz
Customer Number:	87409
Filer:	John Jeremy Dresch
Filer Authorized By:	
Attorney Docket Number:	3003/0107PUS18
Receipt Date:	18-APR-2017
Filing Date:	
Time Stamp:	14:07:32
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	Transmittal of New Application	3003-0107PUS18_Utility_Application_Form.pdf	275897 e5fa5f26c31b391eafc73f92103875598104d ba9	no	2
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Information:					
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3		3003-0107PUS18_Application.pdf	283826 d393a78c392df21e1aa8d51d435348d5504 506ff	yes	34
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	Document Description		Start	End	
	Specification		1	27	
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4	Drawings-only black and white line drawings	3003-0107PUS18_Drawings.pdf	550374 fc4db56e95b17d3c57194c1c0cbb8f2a7099 ac11	no	40
Warnings:					
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Total Files Size (in bytes):			2390068		
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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
15/490,107	04/18/2017	3733	0.00	3003/0107PUS18	31	3

CONFIRMATION NO. 5831

FILING RECEIPT



0000000090878070

87409
Dresch IP Law, PLLC
P.O. Box 650903
Potomac Falls, VA 20165

Date Mailed: 04/27/2017

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)

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Mosheh T. MOSKOWITZ, Rockville, MD;
Pablo A. Valdivia Y. ALVARADO, Cambridge, MA;

Applicant(s)

Dr. Nathan C. Moskowitz, Rockville, MD

Assignment For Published Patent Application

Dr. Nathan C. Moskowitz, Rockville, MD

Power of Attorney: None

Domestic Priority data as claimed by applicant

This application is a CON of 14/257,650 04/21/2014 PAT 9622875
which is a DIV of 12/471,340 05/22/2009 PAT 8734516
which is a CIP of 12/054,335 03/24/2008 PAT 7972363
which is a CIP 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
and said 14/257,650 04/21/2014
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: No

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The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 15/490,107**

Projected Publication Date: To Be Determined - pending completion of Missing Parts

Non-Publication Request: No

Early Publication Request: No

**** SMALL ENTITY ****

Title

BI-DIRECTIONAL FIXATING/LOCKING TRANSVERTEBRAL BODY SCREW/INTERVERTEBRAL CAGE STAND-ALONE CONSTRUCTS HAVING A CENTRAL SCREW LOCKING LEVER, AND PLIERS AND DEVICES FOR SPINAL FUSION

Preliminary Class

623

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: No

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page 2 of 4

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>.

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The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national 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 Assets Control, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

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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 U.S. offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to promote and facilitate business investment. SelectUSA provides information assistance to the international investor community; serves as an ombudsman for existing and potential investors; advocates on behalf of U.S. cities, states, and regions competing for global investment; and counsels U.S. economic development organizations on investment attraction best practices. To learn more about why the United States is the best country in the world to develop technology, manufacture products, deliver services, and grow your business, visit <http://www.SelectUSA.gov> or call +1-202-482-6800.

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875						Application or Docket Number 15/490,107			
APPLICATION AS FILED - PART I									
(Column 1)		(Column 2)		SMALL ENTITY		OTHER THAN SMALL ENTITY			
FOR	NUMBER FILED	NUMBER EXTRA	RATE(\$)	FEE(\$)		RATE(\$)	FEE(\$)		
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	70		N/A			
SEARCH FEE (37 CFR 1.16(k), (l), or (m))	N/A	N/A	N/A	300		N/A			
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	360		N/A			
TOTAL CLAIMS (37 CFR 1.16(i))	31	minus 20 = * 11	x 40 =	440					
INDEPENDENT CLAIMS (37 CFR 1.16(h))	3	minus 3 = *	x 210 =	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					
			TOTAL	1170	TOTAL				
* If the difference in column 1 is less than zero, enter "0" in column 2.									
APPLICATION AS AMENDED - PART II									
(Column 1)		(Column 2)		(Column 3)		SMALL ENTITY		OTHER THAN SMALL ENTITY	
AMENDMENT A	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE(\$)	ADDITIONAL FEE(\$)		RATE(\$)	ADDITIONAL FEE(\$)	
	Total (37 CFR 1.16(i))	*	Minus **	=	x =		x =		
	Independent (37 CFR 1.16(h))	*	Minus ***	=	x =		x =		
	Application Size Fee (37 CFR 1.16(s))								
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))								
			TOTAL ADD'L FEE			TOTAL ADD'L FEE			
AMENDMENT B	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE(\$)	ADDITIONAL FEE(\$)		RATE(\$)	ADDITIONAL FEE(\$)	
	Total (37 CFR 1.16(i))	*	Minus **	=	x =		x =		
	Independent (37 CFR 1.16(h))	*	Minus ***	=	x =		x =		
	Application Size Fee (37 CFR 1.16(s))								
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))								
			TOTAL ADD'L FEE			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.									



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 NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
15/490,107	04/18/2017	Ahmnnon D. MOSKOWITZ	3003/0107PUS18

CONFIRMATION NO. 5831

FORMALITIES LETTER



0C00000090878071

Date Mailed: 04/27/2017

87409
Dresch IP Law, PLLC
P.O. Box 650903
Potomac Falls, VA 20165

NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION

FILED UNDER 37 CFR 1.53(b)

Filing Date Granted

Items Required To Avoid Abandonment:

An application number and filing date have been accorded to this application. The item(s) indicated below, however, are missing. Applicant is given **TWO MONTHS** from the date of this Notice within which to file all required items below to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

- The statutory basic filing fee is missing.
- The application search fee must be submitted.
- The application examination fee must be submitted.
- Additional claim fees of \$ **440** as a small entity, including any required multiple dependent claim fee, are required. Applicant must submit the additional claim fees or cancel the additional claims for which fees are due.
- Surcharge as set forth in 37 CFR 1.16(f) must be submitted.

The surcharge is due for any one of:

- late submission of the basic filing fee, search fee, or examination fee,
- late submission of inventor's oath or declaration,
- filing an application that does not contain at least one claim on filing, or
- submission of an application filed by reference to a previously filed application.

SUMMARY OF FEES DUE:

The fee(s) required within **TWO MONTHS** from the date of this Notice to avoid abandonment is/are itemized below. Small entity discount is in effect. If applicant is qualified for micro entity status, an acceptable Certification of Micro Entity Status must be submitted to establish micro entity status. (See 37 CFR 1.29 and forms PTO/SB/15A and 15B.)

- \$ **70** basic filing fee.
- \$ **70** surcharge.
- \$ **300** search fee.
- \$ **360** examination fee.
- \$ **440** for **11** total claims over 20.

- \$(0) previous unapplied payment amount.
- \$ 1240 TOTAL FEE BALANCE DUE.

Items Required To Avoid Processing Delays:

Applicant is notified that the above-identified application contains the deficiencies noted below. No period for reply is set forth in this notice for correction of these deficiencies. However, if a deficiency relates to the inventor's oath or declaration, the applicant must file an oath or declaration in compliance with 37 CFR 1.63, or a substitute statement in compliance with 37 CFR 1.64, executed by or with respect to each actual inventor no later than the expiration of the time period set in the "Notice of Allowability" to avoid abandonment. See 37 CFR 1.53(f).

- A properly executed inventor's oath or declaration has not been received for the following inventor(s):
Ahmnon D. MOSKOWITZ
Nathan C. MOSKOWITZ
Mosheh T. MOSKOWITZ
Pablo A. Valdivia Y. ALVARADO

Replies must be received in the USPTO within the set time period or must include a proper Certificate of Mailing or Transmission under 37 CFR 1.8 with a mailing or transmission date within the set time period. For more information and a suggested format, see Form PTO/SB/92 and MPEP 512.

Replies should be mailed to:

Mail Stop Missing Parts
Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

Registered users of EFS-Web may alternatively submit their reply to this notice via EFS-Web, including a copy of this Notice and selecting the document description "Applicant response to Pre-Exam Formalities Notice".
<https://sportal.uspto.gov/authenticate/AuthenticateUserLocalEPF.html>

For more information about EFS-Web please call the USPTO Electronic Business Center at 1-866-217-9197 or visit our website at <http://www.uspto.gov/ebc>.

If you are not using EFS-Web to submit your reply, you must include a copy of this notice.

Questions about the contents of this notice and the requirements it sets forth should be directed to the Office of Data Management, Application Assistance Unit, at (571) 272-4000 or (571) 272-4200 or 1-888-786-0101.

/ygizaw/

TRANSMITTAL FOR POWER OF ATTORNEY TO ONE OR MORE REGISTERED PRACTITIONERS

Application Number	15/490,107		
Filing Date	April 18, 2017		
First Named Inventor	Ahmnon D. Moskowitz		
Title	BI-DIRECTIONAL FIXATING/LOCKING TRANSVERTEBRAL BODY SCREW/INTERVERTEBRAL CAGE STAND-ALONE CONSTRUCTS HAVING A CENTRAL SCREW LOCKING LEVER, AND PLIERS AND DEVICES FOR SPINAL FUSION		
Art Unit			
Examiner Name			
Attorney Docket Number	45335-0012004		
SIGNATURE of Applicant or Patent Practitioner			
Signature	/Michael T. Hawkins/	Date (Optional)	July 25, 2017
Name	Michael T. Hawkins	Registration Number	57,867
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.			

61538671.doc

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

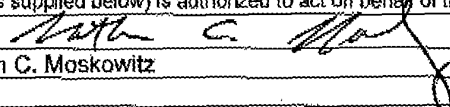
Firm or Individual Name			
Address			
City	State	Zip	
Country			
Telephone	Email		

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

- ☐ 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		Date (Optional)	2/20/17
Name	Nathan C. Moskowitz		
Title			

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.

- ☐ *Total of _____ forms are submitted.

61531511.doc

Electronic Acknowledgement Receipt	
EFS ID:	29886084
Application Number:	15490107
International Application Number:	
Confirmation Number:	5831
Title of Invention:	BI-DIRECTIONAL FIXATING/LOCKING TRANSVERTEBRAL BODY SCREW/ INTERVERTEBRAL CAGE STAND-ALONE CONSTRUCTS HAVING A CENTRAL SCREW LOCKING LEVER, AND PLIERS AND DEVICES FOR SPINAL FUSION
First Named Inventor/Applicant Name:	Ahmnon D. MOSKOWITZ
Customer Number:	87409
Filer:	Michael T. Hawkins/Abby Remer
Filer Authorized By:	Michael T. Hawkins
Attorney Docket Number:	3003/0107PUS18
Receipt Date:	25-JUL-2017
Filing Date:	18-APR-2017
Time Stamp:	16:24:46
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	Power of Attorney	POA.pdf	365728 eb549900df531e968ef43377ce3c0487e96561e0	no	2
Warnings:					

Information:	
Total Files Size (in bytes):	365728
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. <u>New Applications Under 35 U.S.C. 111</u> 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. <u>National Stage of an International Application under 35 U.S.C. 371</u> 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. <u>New International Application Filed with the USPTO as a Receiving Office</u> 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
Serial No. : 15/490,107 Examiner : Unknown
Filed : April 18, 2017
Title : BI-DIRECTIONAL FIXATING/LOCKING TRANSVERTEBRAL
BODY SCREW/INTERVERTEBRAL CAGE STAND-ALONE
CONSTRUCTS HAVING A CENTRAL SCREW LOCKING
LEVER, AND PLIERS AND DEVICES FOR SPINAL FUSION

MAIL STOP AMENDMENT

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

INFORMATION DISCLOSURE STATEMENT

Please consider the references listed on the enclosed PTO-1449 Form. Cited U.S. patents and patent application publications will be provided on request.

Under 35 USC §120, this application relies on the earlier filing date of application serial number 14/257,650, filed on April 21, 2014. The references corresponding to Desig. ID Nos. 82-132 have not been considered in the prior application. All other references listed on the PTO-1449 Form were submitted to and/or cited by the Office in the prior application, and so copies of those references are not provided in this application.

This statement is being filed within three months of the filing date of the application or before the receipt of a first action on the merits.

Apply any necessary charges or credits to deposit account 06-1050, referencing the above attorney docket number.

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

First Named Inventor : Ahmnon D. Moskowitz
Serial No. : 15/490,107
Filed : April 18, 2017
Page : 2 of 2

Attorney Docket: 45335-0012004

Respectfully submitted,

Date: 10/6/2017

/Stuart A. Nelson/

Stuart A. Nelson

Reg. No. 63,947

Customer Number
Fish & Richardson P.C.
Telephone: (612) 337-2538
Facsimile: (877) 769-7945

61573439.doc

Substitute Disclosure Form U.S. Department of Commerce Patent and Trademark Office Information Disclosure Statement by Applicant (Use several sheets if necessary) (37 CFR §1.98(b))	Attorney Docket No. 45335-0012004	Application No. 15/490,107
	Applicant Moskowitz et al.	
	Filing Date April 18, 2017	Group Art Unit

U.S. Patent Documents							
Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	1.	5123926	1992-06-23	Pisharodi			
	2.	5514180	1996-05-07	Heggeness et al.			
	3.	6368350	2002-04-09	Erickson et al.			
	4.	6419704	2002-07-16	Ferree			
	5.	6458159	2002-10-01	Thalgott			
	6.	6527804	2003-03-04	Gauchet et al.			
	7.	6533818	2003-03-18	Weber et al.			
	8.	6579318	2003-06-17	Varga et al.			
	9.	6582468	2003-06-24	Gauchet			
	10.	6719794	2004-04-13	Gerber			
	11.	6733532	2004-05-11	Gauchet et al.			
	12.	6764491	2004-07-20	Frey et al.			
	13.	6770094	2004-08-03	Fehling et al.			
	14.	6572653	2003-06-03	Simonson			
	15.	5782832	1998-07-21	Larsen et al.			
	16.	6641614	2003-11-04	Wagner et al.			
	17.	6126689	2000-10-03	Brett			
	18.	6375682	2002-04-23	Fleischmann et al.			
	19.	6723126	2004-04-20	Berry			
	20.	5667472	1997-09-07	Finn et al.			
	21.	6955671	2005-10-18	Uchikubo			
	22.	7037258	2006-05-02	Chatenever et al.			
	23.	6904308	2005-06-07	Frisch et al.			
	24.	7097615	2006-08-29	Banik et al.			
	25.	7030904	2006-04-18	Adair et al.			
	26.	4997432	1991-03-05	Keller			

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 Information Disclosure Statement by Applicant (Use several sheets if necessary) (37 CFR §1.98(b))	Attorney Docket No. 45335-0012004	Application No. 15/490,107
	Applicant Moskowitz et al.	
	Filing Date April 18, 2017	Group Art Unit

U.S. Patent Documents							
Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	27.	5960522	1999-10-05	Boc			
	28.	5660188	1997-08-26	Groiso			
	29.	4960420	1990-10-02	Goble et al.			
	30.	4636217	1987-01-13	Ogilvie et al.			
	31.	4554914	1985-11-26	Kapp et al.			
	32.	6953477	2005-10-11	BERRY			
	33.	4599086	1986-07-08	DOTY			
	34.	5062850	1991-11-05	MACMILLAN et al.			
	35.	5290312	1994-03-01	KOJIMOTO et al.			
	36.	5865848	1999-02-02	Baker			
	37.	6972019	2005-12-06	Michelson			
	38.	6629998	2003-10-07	Lin			
	39.	7211112	2007-05-01	Baynham et al.			
	40.	5405391	1995-04-11	Henderson et al.			
	41.	6824564	2004-11-30	Crozet			
	42.	7442209	2008-10-28	Michelson			
	43.	6342074	2002-01-29	Simpson			
	44.	6558423	2003-05-06	Michelson			
	45.	6432106	2002-08-13	Fraser			
	46.	7326248	2008-02-05	Michelson			
	47.	7033394	2006-04-25	Michelson			
	48.	5888223	1999-03-30	Bray, Jr.			
	49.	7862616	2011-01-04	Lechmann et al.			
	50.	8403986	2013-03-26	Michelson			
	51.	8328872	2012-12-11	Duffield et al.			
	52.	5005749	1991-04-09	Aranyi			

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 Information Disclosure Statement by Applicant (Use several sheets if necessary) (37 CFR §1.98(b))	Attorney Docket No. 45335-0012004	Application No. 15/490,107
	Applicant Moskowitz et al.	
	Filing Date April 18, 2017	Group Art Unit

U.S. Patent Documents							
Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	53.	5413583	1995-05-09	Wohlers			
	54.	5454819	1995-10-03	Knoepfner			
	55.	5951574	1999-09-14	Stefanchik et al.			
	56.	7615059	2009-11-10	Watschke et al.			
	57.	6613055	2003-09-02	Di Emidio			
	58.	8034060	2011-10-11	Keren et al.			
	59.	20040088054	2004-05-06	Berry			
	60.	20050273170	2005-12-08	Navarro et al.			
	61.	20040177531	2004-09-16	DiBenedetto et al.			
	62.	20050278026	2005-12-15	Gordon, et al.			
	63.	20050216084	2005-09-29	Fleischmann			
	64.	20050027362	2005-02-03	Williams et al.			
	65.	20050049590	2005-03-03	Alleyne et al.			
	66.	20040254644	2004-12-16	Taylor			
	67.	20020143338	2002-10-03	ORBAY et al.			
	68.	20050177235	2005-08-11	BAYNHAM et al.			
	69.	20020068977	2002-06-06	JACKSON			
	70.	20070213820	2007-09-13	MAGERL et al			
	71.	20100145460	2010-06-10	McDonough et al.			
	72.	20090105831	2009-04-23	Jones et al.			
	73.	8,734,516	5/2014	Moskowitz			
	74.	7985255	2011-07-26	Bray et al.			
	75.	6962606	2005-11-08	Michelson			
	76.	7238203	2007-07-03	Bagga et al.			
	77.	7232464	2007-06-19	Mathieu et al.			
	78.	8790405	2014-07-29	Biedermann 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 Information Disclosure Statement by Applicant (Use several sheets if necessary) (37 CFR §1.98(b))	Attorney Docket No. 45335-0012004	Application No. 15/490,107
	Applicant Moskowitz et al.	
	Filing Date April 18, 2017	Group Art Unit

U.S. Patent Documents							
Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	79.	8268000	2012-09-18	Waugh et al.			
	80.	7135043	2006-11-14	Akahara et al.			
	81.	4904261	1990-02-27	Dove et al.			
	82.	7442209	10/28/2008	Michelson			
	83.	2009/0105831	4/23/2009	Jones et al.			
	84.	6235034	5/22/2001	Bray			
	85.	6224602	5/1/2001	Hayes			
	86.	6890355	5/10/2005	Michelson			
	87.	6629998	10/7/2003	Lin			
	88.	6322562	11/27/2001	Wolter			
	89.	2008/0281424	11/13/2008	Parry et al.			
	90.	7211112	5/1/2007	Baynham et al.			
	91.	6454807	9/24/2002	Jackson			
	92.	6716247	4/6/2004	Michelson			
	93.	2004/0186569	9/23/2004	Berry			
	94.	7776047	8/17/2010	Fanger et al.			
	95.	20050256576	11/17/2005	Moskowitz et al.			
	96.	20050261769	11/24/2005	Moskowitz et al.			
	97.	20070198089	8/23/2007	Moskowitz et al.			
	98.	20110288646	11/24/2011	Moskowitz et al.			
	99.	20070167678	7/19/2007	Moskowitz et al.			
	100.	20130173002	7/4/2013	Moskowitz et al.			
	101.	20060241621	10/26/2006	Moskowitz et al.			
	102.	20090112271	4/30/2009	Moskowitz et al.			
	103.	20110208312	8/25/2011	Moskowitz et al.			
	104.	2007/0250172	10/25/2007	Moskowitz 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 Information Disclosure Statement by Applicant (Use several sheets if necessary) (37 CFR §1.98(b))	Attorney Docket No. 45335-0012004	Application No. 15/490,107
	Applicant Moskowitz et al.	
	Filing Date April 18, 2017	Group Art Unit

U.S. Patent Documents							
Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	105.	2011/0178600	7/21/2011	Moskowitz et al.			
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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

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	Applicant Moskowitz et al.	
	Filing Date April 18, 2017	Group Art Unit

U.S. Patent Documents							
Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	131.	2013/0023992	1/24/2013	Moskowitz et al.			
	132.	2013/0018470	1/17/2013	Moskowitz et al.			

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Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation	
							Yes	No
	133.	2004093749	2004-11-04	WO				
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Examiner Initial	Desig. ID	Document
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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

Electronic Acknowledgement Receipt	
EFS ID:	30592597
Application Number:	15490107
International Application Number:	
Confirmation Number:	5831
Title of Invention:	BI-DIRECTIONAL FIXATING/LOCKING TRANSVERTEBRAL BODY SCREW/ INTERVERTEBRAL CAGE STAND-ALONE CONSTRUCTS HAVING A CENTRAL SCREW LOCKING LEVER, AND PLIERS AND DEVICES FOR SPINAL FUSION
First Named Inventor/Applicant Name:	Ahmnon D. MOSKOWITZ
Customer Number:	87409
Filer:	Stuart A. Nelson/Melissa Andersen
Filer Authorized By:	Stuart A. Nelson
Attorney Docket Number:	3003/0107PUS18
Receipt Date:	06-OCT-2017
Filing Date:	18-APR-2017
Time Stamp:	17:19:08
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	72390 297241e9d8a6359878397d5e1068733e2d efd2a7	no	2
Warnings:					

Information:					
This is not an USPTO supplied IDS fillable form					
2	Information Disclosure Statement (IDS) Form (SB08)	PTO-1449.pdf	153028	no	6
			e322ae87ec0d73ec74fb6b003e855d82d88c5f29		
Warnings:					
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Total Files Size (in bytes):				225418	
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. <u>New Applications Under 35 U.S.C. 111</u> 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. <u>National Stage of an International Application under 35 U.S.C. 371</u> 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. <u>New International Application Filed with the USPTO as a Receiving Office</u> 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.					

TRANSMITTAL FOR POWER OF ATTORNEY TO ONE OR MORE REGISTERED PRACTITIONERS

Application Number	15/490,107		
Filing Date	April 18, 2017		
First Named Inventor	Ahmnon D. Moskowitz		
Title	BI-DIRECTIONAL FIXATING/LOCKING TRANSVERTEBRAL BODY SCREW/INTERVERTEBRAL CAGE STAND-ALONE CONSTRUCTS HAVING A CENTRAL SCREW LOCKING LEVER, AND PLIERS AND DEVICES FOR SPINAL FUSION		
Art Unit			
Examiner Name			
Attorney Docket Number	45335-0012004		
SIGNATURE of Applicant or Patent Practitioner			
Signature	/Stuart A. Nelson/	Date (Optional)	9/23/2017
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

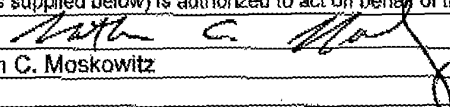
Firm or Individual Name			
Address			
City	State	Zip	
Country			
Telephone	Email		

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

- ☐ 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		Date (Optional)	2/20/17
Name	Nathan C. Moskowitz		
Title			

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.

- ☐ *Total of _____ forms are submitted.

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Electronic Acknowledgement Receipt	
EFS ID:	30726453
Application Number:	15490107
International Application Number:	
Confirmation Number:	5831
Title of Invention:	BI-DIRECTIONAL FIXATING/LOCKING TRANSVERTEBRAL BODY SCREW/ INTERVERTEBRAL CAGE STAND-ALONE CONSTRUCTS HAVING A CENTRAL SCREW LOCKING LEVER, AND PLIERS AND DEVICES FOR SPINAL FUSION
First Named Inventor/Applicant Name:	Ahmnon D. MOSKOWITZ
Customer Number:	87409
Filer:	Stuart A. Nelson/Abby Remer
Filer Authorized By:	Stuart A. Nelson
Attorney Docket Number:	3003/0107PUS18
Receipt Date:	23-OCT-2017
Filing Date:	18-APR-2017
Time Stamp:	12:08:22
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	Power of Attorney	POA_12004.pdf	365679	no	2
			caaa64f87f9c2d74b455c14de6a2d4b13e205034		
Warnings:					

Information:	
Total Files Size (in bytes):	365679
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. <u>New Applications Under 35 U.S.C. 111</u> 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. <u>National Stage of an International Application under 35 U.S.C. 371</u> 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. <u>New International Application Filed with the USPTO as a Receiving Office</u> 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
Serial No. : 15/490,107 Examiner : Unknown
Filed : April 18, 2017 Conf. No. : 5831

Title : BI-DIRECTIONAL FIXATING/LOCKING TRANSVERTEBRAL
BODY SCREW/INTERVERTEBRAL CAGE STAND-ALONE
CONSTRUCTS HAVING A CENTRAL SCREW LOCKING
LEVER, AND PLIERS AND DEVICES FOR SPINAL FUSION

MAIL STOP MISSING PARTS

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

REPLY TO NOTICE TO FILE MISSING PARTS OF APPLICATION

In response to the Notice to File Missing Parts of Application under 37 CFR §1.53(b) dated April 27, 2017, applicant claims small entity status (see 37 CFR §1.27) and submits herewith the following:

- ☒ Payment of the basic filing fee of \$70;
- ☒ Payment of the search fee of \$300;
- ☒ Payment of the examination fee of \$360; and
- ☒ Payment of the surcharge of \$70 for late filing of the basic filing fee and/or declaration.

The fees in the amount of \$1,900 (\$800 for the filing fees and \$1,100 for the extension of time) are being paid with this reply on the Electronic Filing System. Apply any necessary charges or credits to Deposit Account 06-1050, referencing the above attorney docket number.

Respectfully submitted,

Date: 10/26/2017

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

Customer Number
Fish & Richardson P.C.
Telephone: (612) 337-2538
Facsimile: (877) 769-7945

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor :	Ahmnon D. Moskowitz	Art Unit :	Unknown
Serial No. :	15/490,107	Examiner :	Unknown
Filed :	April 18, 2017	Conf. No. :	5831
Title :	BI-DIRECTIONAL FIXATING/LOCKING TRANSVERTEBRAL BODY SCREW/INTERVERTEBRAL CAGE STAND-ALONE CONSTRUCTS HAVING A CENTRAL SCREW LOCKING LEVER, AND PLIERS AND DEVICES FOR SPINAL FUSION		

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 Claims:

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

Listing of Claims:

1-31 (Cancelled)

32. (New) A intervertebral combination internal screw guide and fixation apparatus configured to be inserted into a disc space between a first vertebral body and a second vertebral body and to provide fusion of the first vertebral body to the second vertebral body via biological bone fusion and screw fusion, the apparatus comprising:

an intervertebral cage including:

a top wall, a bottom wall, and two sidewalls defining an open space capable of receiving bone filling for the biological bone fusion;

an internal screw guide having a screw entrance portion and an internal bore portion, wherein the screw entrance portion is larger than and coaxial with the internal bore and is formed at least partially in the top surface of the top wall as viewed from the top, wherein the internal bore portion has an entry opening formed only in a top surface of the top wall as viewed from the top and has an exit opening formed at least partially in a bottom surface of the top wall and at least partially in a side surface of the top wall;

a second internal screw guide having a second screw entrance portion and a second internal bore portion, wherein the second screw entrance portion is larger than and coaxial with the second internal bore and is formed at least partially in the top surface of the top wall as viewed from the top, wherein the second internal bore portion has a second entry opening formed only in the top surface of the top wall as viewed from the top and has a second exit opening formed at least partially in the bottom surface of the top wall and at least partially in a second side surface of the top wall, and wherein the internal screw

guide and the second internal screw guide are angled to orient a first screw member and a second member screw bi-directionally in opposite directions;
a first slot on a first outer side of a first sidewall of the two sidewalls;
a second slot on a second outer side of a second sidewall of the two sidewalls, wherein the second slot is positioned opposite of the first slot;

wherein the first slot is positioned along a first centerline axis that bisects the first side wall and is positioned nearer a top of the intervertebral cage than a bottom of the intervertebral cage,

wherein the second slot is positioned along a second centerline axis that bisects the second side wall and is positioned nearer the top of the intervertebral cage than the bottom of the intervertebral cage,

wherein the side surface and the second side surface of the top wall are patterned with a plurality of surface features to create rough side surfaces, wherein at least some of the plurality of surface features are positioned on the side surface between the top wall and the exit opening, and

wherein the top wall, the bottom wall, and the sidewalls are integrally formed and the open space for receiving bone graft material extends continuously from an inner surface of the first sidewall to an inner surface of the second sidewall and extends continuously from an inner surface of the top wall to an inner surface of the bottom wall;

a first screw having a first screw head and a first screw threaded portion, wherein the first screw is sized to be positioned in the internal screw guide with the first screw head in the screw entrance portion;

a second screw having a second screw head and a second screw threaded portion, wherein the second screw is sized to be positioned in the second internal screw guide with the second screw head in the second screw entrance portion; and

a screw locking bracket having a first end portion sized and positioned to be inserted in the first slot, a second end portion sized and positioned to be inserted in the second slot and a central portion extending between the first end portion and the second end portion, wherein when the screw locking bracket is connected to the intervertebral

cage with the first end portion in the first slot and the second end portion in the second slot, the central portion partially blocks the screw entrance portion and the second screw entrance portion so as to retain the first and second screws in the internal screw guide and the second internal screw guide while leaving at least a portion of the screw entrance portion and the second screw entrance portion at least partially exposed.

33. (New) The apparatus of claim 32, wherein the screw locking bracket contacts both the first and second screw heads when the screw locking bracket is connect to the intervertebral cage.

34. (New) The apparatus of claim 32, wherein the screw locking bracket comprises a first hook at the first end portion that is sized to fit in the first slot and a second hook at the second end portion that is sized to fit in the second slot.

35. (New) The apparatus of claim 32, wherein the first end portion and the second end portion extend in a direction that is substantially perpendicular to the central portion.

36. (New) The apparatus of claim 32, wherein the plurality of surface features on the side surface and the second side surface are patterned all the way next to the top surface of the top wall so as to be adjacent the top surface of the top wall.

37. (New) The apparatus of claim 32, and further comprising means for fusing superior and inferior vertebral bodies in conjunction with the intervertebral cage.

38. (New) The apparatus of claim 32, wherein the intervertebral cage is sized and configured for use in a patient's lumbar spine, the apparatus further comprising means for fusing superior and inferior lumbar vertebral bodies in conjunction with the intervertebral cage.

39. (New) The apparatus of claim 32, wherein at least some of the plurality of surface features are positioned on the second side surface between the top wall and the second exit opening.

40. (New) The apparatus of claim 32, wherein the screw locking bracket comprises a first hook at the first end portion that curves inward to engage the first slot and a second hook at the second end portion that curves inward to engage the second slot.

41. (New) The apparatus of claim 32, wherein the screw locking bracket comprises means to slightly open the screw locking bracket.

42. (New) A intervertebral combination internal screw guide and fixation apparatus configured to be inserted into a disc space between a first vertebral body and a second vertebral body and to provide fusion of the first vertebral body to the second vertebral body via biological bone fusion and screw fusion, the apparatus comprising:

an intervertebral cage including:

a top wall, a bottom wall, and two sidewalls defining an open space capable of receiving bone filling for the biological bone fusion;

an internal screw guide having a screw entrance portion and an internal bore portion, wherein the screw entrance portion is larger than and coaxial with the internal bore and is formed at least partially in the top surface of the top wall as viewed from the top, wherein the internal bore portion has an entry opening formed only in a top surface of the top wall as viewed from the top and has an exit opening formed at least partially in a bottom surface of the top wall and at least partially in a side surface of the top wall;

a second internal screw guide having a second screw entrance portion and a second internal bore portion, wherein the second screw entrance portion is larger than and coaxial with the second internal bore and is formed at least partially in the top surface of the top wall as viewed from the top, wherein the second internal bore portion has a second entry opening formed only in the top surface of the top wall as viewed from the top and has a second exit opening formed at least partially in the bottom surface of the top wall and at least partially in a second side surface of the top wall, and wherein the internal screw guide and the second internal screw guide are angled to orient a first screw

member and a second member screw bi-directionally in opposite directions;

a first slot extending at least partially into a first sidewall of the two sidewalls;

a second slot extending at least partially into a second sidewall of the two sidewalls, wherein the second slot is positioned opposite of the first slot;

wherein the first slot is positioned along a first centerline axis that bisects the first side wall and is positioned nearer a top of the intervertebral cage than a bottom of the intervertebral cage,

wherein the second slot is positioned along a second centerline axis that bisects the second side wall and is positioned nearer the top of the intervertebral cage than the bottom of the intervertebral cage,

wherein the side surface and the second side surface of the top wall are patterned with a plurality of surface features to create rough side surfaces, wherein at least some of the plurality of surface features are positioned on the side surface between the top wall and the exit opening, and

wherein the top wall, the bottom wall, and the sidewalls are integrally formed;

a first screw having a first screw head and a first screw threaded portion, wherein the first screw is sized to be positioned in the internal screw guide with the first screw head in the screw entrance portion;

a second screw having a second screw head and a second screw threaded portion, wherein the second screw is sized to be positioned in the second internal screw guide with the second screw head in the second screw entrance portion; and

a screw locking bracket having a first end portion sized and positioned to be inserted in the first slot, a second end portion sized and positioned to be inserted in the second slot and a central portion extending between the first end portion and the second end portion, wherein when the screw locking bracket is connected to the intervertebral cage with the first end portion in the first slot and the second end portion in the second slot, the central portion partially blocks the screw entrance portion and the second screw entrance portion so as to retain the first and second screws in the internal screw guide and

the second internal screw guide while leaving at least a portion of the screw entrance portion and the second screw entrance portion at least partially exposed.

43. (New) The apparatus of claim 32, wherein the plurality of surface features on the side surface and the second side surface are patterned all the way next to the top surface of the top wall so as to be adjacent the top surface of the top wall.

44. (New) The apparatus of claim 32, and further comprising means for fusing superior and inferior vertebral bodies in conjunction with the intervertebral cage.

45. (New) The apparatus of claim 32, wherein the intervertebral cage is sized and configured for use in a patient's lumbar spine, the apparatus further comprising means for fusing superior and inferior lumbar vertebral bodies in conjunction with the intervertebral cage.

46. (New) The apparatus of claim 32, wherein at least some of the plurality of surface features are positioned on the second side surface between the top wall and the second exit opening.

47. (New) The apparatus of claim 32, wherein the screw locking bracket comprises means to slightly deform the screw locking bracket to remove the screw locking bracket from the intervertebral cage.

48. (New) The apparatus of claim 47, wherein the means comprises a flexion portion of the screw locking bracket.

49. (New) The apparatus of claim 32, wherein the screw locking bracket contacts both the first and second screw heads when the screw locking bracket is connect to the intervertebral cage.

50. (New) The apparatus of claim 32, wherein the screw locking bracket comprises a first hook at the first end portion that is sized to fit in the first slot and a second hook at the second end

portion that is sized to fit in the second slot.

51. (New) A method of inserting a bi-directional fixating transvertebral (BDFT) screw/cage apparatus between a first vertebral body and a second vertebral body, the method including:

inserting an intervertebral cage into a midline of a disc space between the first vertebral body and the second vertebral body until the intervertebral cage is one of flush and countersunk relative to the first vertebral body and the second vertebral body, wherein the intervertebral cage includes:

a top wall, a bottom wall, and two sidewalls defining an open space capable of receiving bone filling for the biological bone fusion;

an internal screw guide having a screw entrance portion and an internal bore portion, wherein the screw entrance portion is larger than and coaxial with the internal bore and is formed at least partially in the top surface of the top wall as viewed from the top, wherein the internal bore portion has an entry opening formed only in a top surface of the top wall as viewed from the top and has an exit opening formed at least partially in a bottom surface of the top wall and at least partially in a side surface of the top wall;

a second internal screw guide having a second screw entrance portion and a second internal bore portion, wherein the second screw entrance portion is larger than and coaxial with the second internal bore and is formed at least partially in the top surface of the top wall as viewed from the top, wherein the second internal bore portion has a second entry opening formed only in the top surface of the top wall as viewed from the top and has a second exit opening formed at least partially in the bottom surface of the top wall and at least partially in a second side surface of the top wall, and wherein the internal screw guide and the second internal screw guide are angled to orient a first screw member and a second member screw bi-directionally in opposite directions;

a first slot extending at least partially into a first sidewall of the two sidewalls;

a second slot extending at least partially into a second sidewall of the two

sidewalls, wherein the second slot is positioned opposite of the first slot;

wherein the first slot is positioned along a first centerline axis that bisects the first side wall and is positioned nearer a top of the intervertebral cage than a bottom of the intervertebral cage,

wherein the second slot is positioned along a second centerline axis that bisects the second side wall and is positioned nearer the top of the intervertebral cage than the bottom of the intervertebral cage,

wherein the side surface and the second side surface of the top wall are patterned with a plurality of surface features to create rough side surfaces, wherein at least some of the plurality of surface features are positioned on the side surface between the top wall and the exit opening, and

wherein the top wall, the bottom wall, and the sidewalls are integrally formed; and

inserting a first screw into the internal screw guide of the intervertebral cage;

inserting a second screw into the second internal screw guide of the intervertebral cage;

screwing the first screw and the second screw into the first vertebral body and the second vertebral body respectively; and

locking the first screw and the second screw in the intervertebral cage using a screw locking bracket coupled to the intervertebral cage by positioning a first end portion of the screw locking bracket in the first slot, a second end portion of the screw locking bracket in the second slot and a central portion of the screw locking bracket extending between the first end portion and the second end portion across at least part of the top surface of the top wall such that the central portion partially blocks the screw entrance portion and the second screw entrance portion so as to retain the first and second screws in the internal screw guide and the second internal screw guide while leaving at least a portion of the screw entrance portion and the second screw entrance portion at least partially exposed.

First Named Inventor : Ahmnon D. Moskowitz
Serial No. : 15/490,107
Filed : April 18, 2017
Page : 10 of 10

Attorney Docket: 45335-0012004

REMARKS

With this amendment, claims 1-31 are cancelled and claims 32-51 are added. Support for the amendments can be found throughout the specification, including in Figures 2(A)-5 and the accompanying text. Applicant asks that all claims be examined in view of the amendment to the claims.

Please apply any necessary charges or credits to Deposit Account 06-1050, referencing the above attorney docket number.

Respectfully submitted,

Date: 10/26/2017

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

Customer Number
Fish & Richardson P.C.
Telephone: (612) 337-2538
Facsimile: (877) 769-7945

61582722.doc

Electronic Patent Application Fee Transmittal				
Application Number:		15490107		
Filing Date:		18-Apr-2017		
Title of Invention:		BI-DIRECTIONAL FIXATING/LOCKING TRANSVERTEBRAL BODY SCREW/ INTERVERTEBRAL CAGE STAND-ALONE CONSTRUCTS HAVING A CENTRAL SCREW LOCKING LEVER, AND PLIERS AND DEVICES FOR SPINAL FUSION		
First Named Inventor/Applicant Name:		Ahmnon D. MOSKOWITZ		
Filer:		Stuart A. Nelson/Amanda Petersen		
Attorney Docket Number:		3003/0107PUS18		
Filed as Small Entity				
Filing Fees for Utility under 35 USC 111(a)				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
UTILITY FILING FEE (ELECTRONIC FILING)	4011	1	70	70
UTILITY SEARCH FEE	2111	1	300	300
UTILITY EXAMINATION FEE	2311	1	360	360
Pages:				
Claims:				
Miscellaneous-Filing:				
LATE FILING FEE FOR OATH OR DECLARATION	2051	1	70	70
Petition:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Extension - 4 months with \$0 paid	2254	1	1100	1100
Miscellaneous:				
Total in USD (\$)				1900

Electronic Acknowledgement Receipt	
EFS ID:	30766698
Application Number:	15490107
International Application Number:	
Confirmation Number:	5831
Title of Invention:	BI-DIRECTIONAL FIXATING/LOCKING TRANSVERTEBRAL BODY SCREW/ INTERVERTEBRAL CAGE STAND-ALONE CONSTRUCTS HAVING A CENTRAL SCREW LOCKING LEVER, AND PLIERS AND DEVICES FOR SPINAL FUSION
First Named Inventor/Applicant Name:	Ahmnon D. MOSKOWITZ
Customer Number:	87409
Filer:	Stuart A. Nelson/Amanda Petersen
Filer Authorized By:	Stuart A. Nelson
Attorney Docket Number:	3003/0107PUS18
Receipt Date:	26-OCT-2017
Filing Date:	18-APR-2017
Time Stamp:	11:34:07
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	\$1900
RAM confirmation Number	102617INTEFSW00012558061050
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	Applicant Response to Pre-Exam Formalities Notice	Reply.pdf	79610	no	1
			1e4d63a0530674a58811ea78bad3ea2924ca8d9a		
Warnings:					
Information:					
2		PA.pdf	90520	yes	10
			986d9670dc69beb79957dfd64d3a79819a755050		
	Multipart Description/PDF files in .zip description				
	Document Description	Start	End		
	Preliminary Amendment	1	1		
	Claims	2	9		
	Applicant Arguments/Remarks Made in an Amendment	10	10		
Warnings:					
Information:					
3	Fee Worksheet (SB06)	fee-info.pdf	39359	no	2
			9144f69914cf9df86ba3aca4b687426a14613dcd		
Warnings:					
Information:					
Total Files Size (in bytes):			209489		

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.

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.

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 15/490,107	Filing Date 04/18/2017	☐ To be Mailed
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ENTITY: ☐ LARGE ☒ SMALL ☐ MICRO

APPLICATION AS FILED – PART I

FOR	NUMBER FILED (Column 1)	NUMBER EXTRA (Column 2)	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), (j), 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 \$ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X \$ =	
☐ 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

AMENDMENT	10/26/2017	CLAIMS REMAINING AFTER AMENDMENT	MINUS	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)
	Total (37 CFR 1.16(i))	* 20	Minus	** 20	= 0	x \$40 =	0
	Independent (37 CFR 1.16(h))	* 3	Minus	*** 3	= 0	x \$210 =	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

AMENDMENT	(Column 1)	CLAIMS REMAINING AFTER AMENDMENT	MINUS	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)
	Total (37 CFR 1.16(i))	*	Minus	**	=	X \$ =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X \$ =	
	☐ 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.

** 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 number found in the appropriate box in column 1.

LIE
KIM DOWNING

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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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
15/490,107	04/18/2017	Ahmnnon D. MOSKOWITZ	3003/0107PUS18

CONFIRMATION NO. 5831

POA ACCEPTANCE LETTER



OC000000095078052

87409
Dresch IP Law, PLLC
P.O. Box 650903
Potomac Falls, VA 20165

Date Mailed: 10/30/2017

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 10/23/2017.

The Power of Attorney in this application is accepted. Correspondence in this application will be mailed to the above address as provided by 37 CFR 1.33.

Questions about the contents of this notice and the requirements it sets forth should be directed to the Office of Data Management, Application Assistance Unit, at (571) 272-4000 or (571) 272-4200 or 1-888-786-0101.

/agizaw/



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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
15/490,107	04/18/2017	3733	800	3003/0107PUS18	20	3

CONFIRMATION NO. 5831

UPDATED FILING RECEIPT



0000000093077965

87409
Dresch IP Law, PLLC
P.O. Box 650903
Potomac Falls, VA 20165

Date Mailed: 10/30/2017

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)

Ahmnnon D. MOSKOWITZ, Rockville, MD;
Nathan C. MOSKOWITZ, Rockville, MD;
Mosheh T. MOSKOWITZ, Rockville, MD;
Pablo A. Valdivia Y. ALVARADO, Cambridge, MA;

Applicant(s)

Dr. Nathan C. Moskowitz, Rockville, MD

Assignment For Published Patent Application

Dr. Nathan C. Moskowitz, 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 14/257,650 04/21/2014 PAT 9622875
which is a DIV of 12/471,340 05/22/2009 PAT 8734516
which is a CIP of 12/054,335 03/24/2008 PAT 7972363
which is a CIP 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
and said 14/257,650 04/21/2014
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: No

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: 04/24/2017

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 15/490,107**

Projected Publication Date: 02/08/2018

Non-Publication Request: No

Early Publication Request: No

**** SMALL ENTITY ****

Title

BI-DIRECTIONAL FIXATING/LOCKING TRANSVERTEBRAL BODY SCREW/INTERVERTEBRAL CAGE STAND-ALONE CONSTRUCTS HAVING A CENTRAL SCREW LOCKING LEVER, AND PLIERS AND DEVICES FOR SPINAL FUSION

Preliminary Class

623

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

page 2 of 4

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).

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Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
15/490,107	04/18/2017	Ahmnon D. MOSKOWITZ	3003/0107PUS18

CONFIRMATION NO. 5831

INFORMAL NOTICE



Date Mailed: 10/30/2017

87409
Dresch IP Law, PLLC
P.O. Box 650903
Potomac Falls, VA 20165

INFORMATIONAL NOTICE TO APPLICANT

Applicant is notified that the above-identified application contains the deficiencies noted below. No period for reply is set forth in this notice for correction of these deficiencies. However, if a deficiency relates to the inventor's oath or declaration, the applicant must file an oath or declaration in compliance with 37 CFR 1.63, or a substitute statement in compliance with 37 CFR 1.64, executed by or with respect to each actual inventor no later than the expiration of the time period set in the "Notice of Allowability" to avoid abandonment. See 37 CFR 1.53(f).

The item(s) indicated below are also required and should be submitted with any reply to this notice to avoid further processing delays.

- A properly executed inventor's oath or declaration has not been received for the following inventor(s):
Ahmnon D. MOSKOWITZ
Nathan C. MOSKOWITZ
Mosheh T. MOSKOWITZ
Pablo A. Valdivia Y. ALVARADO

Questions about the contents of this notice and the requirements it sets forth should be directed to the Office of Data Management, Application Assistance Unit, at (571) 272-4000 or (571) 272-4200 or 1-888-786-0101.

/agizaw/

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875						Application or Docket Number 15/490,107				
APPLICATION AS FILED - PART I										
(Column 1)		(Column 2)		SMALL ENTITY		OTHER THAN SMALL ENTITY				
FOR	NUMBER FILED	NUMBER EXTRA	RATE(\$)	FEE(\$)		RATE(\$)	FEE(\$)			
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	70		N/A				
SEARCH FEE (37 CFR 1.16(k), (l), or (m))	N/A	N/A	N/A	300		N/A				
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	360		N/A				
TOTAL CLAIMS (37 CFR 1.16(i))	20	minus 20 = *	x 40 =	0.00						
INDEPENDENT CLAIMS (37 CFR 1.16(h))	3	minus 3 = *	x 210 =	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	730		TOTAL				
APPLICATION AS AMENDED - PART II										
(Column 1)		(Column 2)		(Column 3)		SMALL ENTITY		OTHER THAN SMALL ENTITY		
AMENDMENT A		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE(\$)	ADDITIONAL FEE(\$)		RATE(\$)	ADDITIONAL FEE(\$)
	Total (37 CFR 1.16(i))	*	Minus	**	=	x	=		x	=
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x	=		x	=
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))									
						TOTAL ADD'L FEE			TOTAL ADD'L FEE	
AMENDMENT B		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE(\$)	ADDITIONAL FEE(\$)		RATE(\$)	ADDITIONAL FEE(\$)
	Total (37 CFR 1.16(i))	*	Minus	**	=	x	=		x	=
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x	=		x	=
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))									
						TOTAL ADD'L FEE			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	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
15/490,107	04/18/2017	Ahmnon D. MOSKOWITZ	3003/0107PUS18

CONFIRMATION NO. 5831

PUBLICATION NOTICE



OC0000009727488

87409
Dresch IP Law, PLLC
P.O. Box 650903
Potomac Falls, VA 20165

Title:BI-DIRECTIONAL FIXATING/LOCKING TRANSVERTEBRAL BODY SCREW/INTERVERTEBRAL CAGE STAND-ALONE CONSTRUCTS HAVING A CENTRAL SCREW LOCKING LEVER, AND PLIERS AND DEVICES FOR SPINAL FUSION

Publication No.US-2018-0036134-A1

Publication Date:02/08/2018

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.

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CHANGE OF CORRESPONDENCE ADDRESS *Application*

Address to:
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Application Number	15/490,107
Filing Date	April 18, 2017
First Named Inventor	Ahmnon D. Moskowitz
Art Unit	
Examiner Name	
Attorney Docket Number	45335-0012004

Please change the Correspondence Address for the above-identified patent application to:

☒ The address associated with
Customer Number:

26191

OR

☐ Firm or
Individual Name

Address

City

State

Zip

Country

Telephone

Email

This form cannot be used to change the data associated with a Customer Number. To change the data associated with an existing Customer Number use "Request for Customer Number Data Change" (PTO/SB/124).

I am the:

- ☐ Applicant
- ☒ Attorney or agent of record. Registration Number 63,947.
- ☐ Registered practitioner named in the application transmittal papers who acts in a representative capacity under 37 CFR 1.34. See 37 CFR 1.33(a)(1). Registration Number ____.

Signature /Stuart A. Nelson/

Typed or Printed
Name Stuart A. Nelson

Date 2/9/2018

Telephone: (612) 337-2538

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, see below*.

☐ *Total of _____ forms are submitted.

This collection of information is required by 37 CFR 1.33. 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 3 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.

Electronic Acknowledgement Receipt	
EFS ID:	31752526
Application Number:	15490107
International Application Number:	
Confirmation Number:	5831
Title of Invention:	BI-DIRECTIONAL FIXATING/LOCKING TRANSVERTEBRAL BODY SCREW/ INTERVERTEBRAL CAGE STAND-ALONE CONSTRUCTS HAVING A CENTRAL SCREW LOCKING LEVER, AND PLIERS AND DEVICES FOR SPINAL FUSION
First Named Inventor/Applicant Name:	Ahmnon D. MOSKOWITZ
Customer Number:	87409
Filer:	Stuart A. Nelson/Abby Remer
Filer Authorized By:	Stuart A. Nelson
Attorney Docket Number:	3003/0107PUS18
Receipt Date:	09-FEB-2018
Filing Date:	18-APR-2017
Time Stamp:	15:20:09
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no				
File Listing:					
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1	Change of Address	changeofcorrespondence.pdf	106001 8fcf5dc6fe320213bd9c359256b2c350cc7481f4	no	1
Warnings:					

Information:	
Total Files Size (in bytes):	106001
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. <u>New Applications Under 35 U.S.C. 111</u> 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. <u>National Stage of an International Application under 35 U.S.C. 371</u> 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. <u>New International Application Filed with the USPTO as a Receiving Office</u> 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.	

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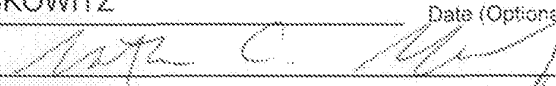
**DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN
APPLICATION DATA SHEET (37 CFR 1.76)**

Title of Invention	
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 <u>14/257,650</u> filed on <u>04/21/2014</u> 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: <u>Ahmnnon D. MOSKOWITZ</u> Date (Optional): _____ Signature: <u><i>Ahmnnon D. Moskowitz</i></u> 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.

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

Title of Invention	
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 <u>14/257,650</u> filed on <u>04/21/2014</u> 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-2036 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-2036 submitted for payment purposes are not retained in the application file and therefore are not publicly available.	
LEGAL NAME OF INVENTOR	
Inventor:	<u>Nathan C. MOSKOWITZ</u> Date (Optional): _____
Signature:	<u></u>
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.

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

Title of Invention	BI-DIRECTIONAL FIXATING/LOCKING TRANSVERTEBRAL BODY SCREW/INTERVERTEBRAL CAGE STAND-ALONE CONSTRUCTS HAVING A CENTRAL SCREW LOCKING LEVER, AND PLIERS AND DEVICES FOR SPINAL
-------------------------------	---

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 14/257,650
filed on 04/21/2014

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

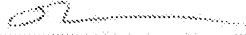
I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

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: Mosheh T. MOSKOWITZ Date (Optional): 8/13/16
Signature: 

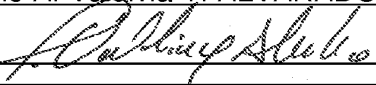
Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

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If you need assistance in completing the form, call 1-800-PTO-8199 and select option 2.

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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	BI-DIRECTIONAL FIXATING/LOCKING TRANSVERTEBRAL BODY SCREW/INTERVERTEBRAL CAGE STAND-ALONE CONSTRUCTS HAVING A CENTRAL SCREW LOCKING LEVER, AND PLIERS AND DEVICES FOR SPINAL FUSION
As the below named inventor, I hereby declare that: This declaration ☐ The attached application, or is directed to: ☒ United States application or PCT international application number <u>14/257,650</u> filed on <u>04/21/2014</u>. The above-identified application was authorized to be made by me. I believe that I am the 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: <u>Pablo A. Valdivia Y. ALVARADO</u> Date (Optional) : <u>4/29/2015</u> Signature: <u></u> 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 Acknowledgement Receipt	
EFS ID:	32369034
Application Number:	15490107
International Application Number:	
Confirmation Number:	5831
Title of Invention:	BI-DIRECTIONAL FIXATING/LOCKING TRANSVERTEBRAL BODY SCREW/ INTERVERTEBRAL CAGE STAND-ALONE CONSTRUCTS HAVING A CENTRAL SCREW LOCKING LEVER, AND PLIERS AND DEVICES FOR SPINAL FUSION
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:	3003/0107PUS18
Receipt Date:	18-APR-2018
Filing Date:	18-APR-2017
Time Stamp:	10:01:46
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	Oath or Declaration filed	Declarations.pdf	426418 166dd759a297d9b537f7695de8a9e25b53841ad3	no	4
Warnings:					

Information:	
Total Files Size (in bytes):	426418
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. <u>New Applications Under 35 U.S.C. 111</u> 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. <u>National Stage of an International Application under 35 U.S.C. 371</u> 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. <u>New International Application Filed with the USPTO as a Receiving Office</u> 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.	



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/490,107	04/18/2017	Ahmnnon D. MOSKOWITZ	3003/0107PUS18	5831

26191 7590 05/16/2018
FISH & RICHARDSON P.C. (TC)
PO BOX 1022
MINNEAPOLIS, MN 55440-1022

EXAMINER

PHILOGENE, PEDRO

ART UNIT	PAPER NUMBER
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3733

NOTIFICATION DATE	DELIVERY MODE
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05/16/2018

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. 15/490,107	Applicant(s) MOSKOWITZ ET AL.	
	Examiner PEDRO PHILOGENE	Art Unit 3733	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 10/26/17.
☐ 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) 32-51 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) 32-51 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 ____ 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) | 3) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) ☒ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)
Paper No(s)/Mail Date <u>10/6/17</u> . | 4) ☐ Other: ____. |

The present application is being examined under the pre-AIA first to invent provisions.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112(a):

(a) IN GENERAL.—The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.

The following is a quotation of the first paragraph of pre-AIA 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 32-51 are rejected under 35 U.S.C. 112(a) or 35 U.S.C. 112 (pre-AIA), first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant fails to disclose a locking bracket “such that the central portion partially blocks the screw entrance portion and the second screw entrance portion so as to retain the first and second screws in the internal screw guide and the second internal screw guide while leaving at least a portion of the screw entrance portion and the second screw entrance portion at least partially exposed”.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on nonstatutory double patenting provided the reference application or patent either is shown to be commonly owned with the examined application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. See MPEP § 717.02 for applications subject to examination under the first inventor to file provisions of the AIA as explained in MPEP § 2159. See MPEP §§ 706.02(l)(1) - 706.02(l)(3) for applications not subject to examination under the first inventor to file provisions of the AIA. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO Internet website contains terminal disclaimer forms which may be used. Please visit www.uspto.gov/patent/patents-forms. The filing date of the application

in which the form is filed determines what form (e.g., PTO/SB/25, PTO/SB/26, PTO/AIA/25, or PTO/AIA/26) should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp.

Claims 32-51 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-47 of U.S. Patent No. 9,895,238 in view of Moskowitz et al. (9,622,875).

It is noted that Moskowitz '238 discloses all the limitations, except for locking bracket inserted in the first and second slots of the intervertebral cage wherein the central portion of the locking bracket extending between the first end portion and the second end portion across at least part of the top surface of the top wall such that the central portion blocks the screw entrance portion and the second screw entrance portion so as to retain the first and second screws in the internal screw guide and the second internal screw guide, As claimed by applicant. However, in a similar art, Moskowitz '875 provides the evidences of the use of a locking bracket inserted in the first and second slots of the intervertebral cage wherein the central portion of the locking bracket extending between the first end portion and the second end portion across at least part of the top surface of the top wall such that the central portion blocks the screw entrance portion and the second screw entrance portion so as to retain the first and

second screws in the internal screw guide and the second internal screw guide to prevent the screws from backing out.

Therefore, given the teaching of Moskowitz '875, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Moskowitz '238, as taught by Moskowitz '875, by incorporating a locking bracket in the device to prevent the screw from backing out.

Claims 32-51 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-70 of U.S. Patent No. 9,889,022 in view of Moskowitz et al. (9,622,875).

It is noted that Moskowitz '022 discloses all the limitations, except for locking bracket inserted in the first and second slots of the intervertebral cage wherein the central portion of the locking bracket extending between the first end portion and the second end portion across at least part of the top surface of the top wall such that the central portion blocks the screw entrance portion and the second screw entrance portion so as to retain the first and second screws in the internal screw guide and the second internal screw guide, As claimed by applicant. However, in a similar art, Moskowitz '875 provides the evidences of the use of a locking bracket inserted in the first and second slots of the intervertebral cage wherein the central portion of the locking bracket extending between the first end portion and the second end portion across at least part of the top surface of the top wall such that the central portion blocks the screw entrance portion and the second screw entrance portion so as to retain the first and

second screws in the internal screw guide and the second internal screw guide to prevent the screws from backing out.

Therefore, given the teaching of Moskowitz '875, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Moskowitz '022, as taught by Moskowitz '875, by incorporating a locking bracket in the device to prevent the screw from backing out.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, "the locking bracket partially blocks the screw entrance portion and the second screw entrance portion so as to retain the first and second screws in the internal screw guide and the second internal screw guide while leaving at least a portion of the screw entrance portion and the second screw entrance portion at least partially exposed" must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for

consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

7,238,203	7-2007	Bagga et al.
7,862,616	1-2011	Lechmann et al.
8,328,872	12-2012	Duffield et al.
6,629,998	10-2003	Lin
2010/0145460	6-2010	McDonough et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PEDRO PHILOGENE whose telephone number is (571)272-4716. The examiner can normally be reached on Monday to Friday 8:00 AM to 4:30 PM.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at <http://www.uspto.gov/interviewpractice>.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (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.

/PEDRO PHILOGENE/
Primary Examiner, Art Unit 3733
May 11, 2018

Notice of References Cited	Application/Control No. 15/490,107	Applicant(s)/Patent Under Reexamination MOSKOWITZ ET AL.	
	Examiner PEDRO PHILOGENE	Art Unit 3733	Page 1 of 1

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*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
*	A	US-6,629,998 B1	10-2003	Lin; Chih-I	A61F2/447	623/17.11
*	B	US-8,328,872 B2	12-2012	Duffield; William E.	A61F2/447	623/17.16
*	C	US-7,862,616 B2	01-2011	Lechmann; Beat	A61B17/86	623/17.11
*	D	US-7,238,203 B2	07-2007	Bagga; Charanpreet	A61F2/4455	623/17.11
*	E	US-9,889,022 B2	02-2018	Moskowitz; Ahmnon D.	A61F2/4611	1/1
*	F	US-9,895,238 B2	02-2018	Moskowitz; Ahmnon D.	A61F2/4611	1/1
*	G	US-9,622,875 B2	04-2017	Moskowitz; Ahmnon D.	A61F2/442	1/1
*	H	US-2010/0145460 A1	06-2010	McDonough; William P.	A61B17/1728	623/17.16
	I	US-				
	J	US-				
	K	US-				
	L	US-				
	M	US-				

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*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	CPC Classification
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	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.

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	1	"20180036134"	US-PGPUB; USPAT	OR	OFF	2018/05/11 09:32
L2	1	moskowitz near ahmnon.in. & intervertebral near cage & internal near screw near guide & internal near bore & slot & patterned & surface near features & screw & locking near bracket	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2018/05/11 10:26
L3	1	moskowitz near nathan.in. & intervertebral near cage & internal near screw near guide & internal near bore & slot & patterned & surface near features & screw & locking near bracket	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2018/05/11 10:26
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L5	0	pablo near valdivia.in. & intervertebral near cage & internal near screw near guide & internal near bore & slot & patterned & surface near features & screw & locking near bracket	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2018/05/11 10:27
L6	1	intervertebral near cage & internal near screw near guide & internal near bore & slot & patterned & surface near features & screw & locking near bracket	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2018/05/11 10:27
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L14	87	intervertebral near (cage or implant or apparatus or spacer) & screw near guide & bore & lock\$4	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2018/05/11 11:23
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L16	85	14 AND ((A61B17/0642 OR A61B17/068 OR A61B17/7064 OR A61B17/7074 OR A61B17/8042 OR A61B17/809 OR A61B17/86 OR A61B2017/0641 OR A61B2017/0647 OR A61B2017/0648 OR A61B2017/922 OR A61F2002/2835 OR A61F2002/30331 OR A61F2002/30383 OR A61F2002/30476 OR A61F2002/305 OR A61F2002/30517 OR A61F2002/30604 OR A61F2002/30772 OR A61F2002/30787 OR A61F2002/30879 OR A61F2002/448 OR A61F2002/4622 OR A61F2002/4641 OR A61F2220/0025 OR A61F2220/0033 OR A61F2220/0041 OR A61F2/442 OR A61F2/447 OR A61F2/4637).CPC. OR (1/1 or 623/17.11-17.16).CCLS. OR (A61B17/064 OR A61B17/068 OR A61B17/70 OR A61B17/80 OR A61B17/86 OR A61B17/92 OR A61F2/28 OR A61F2/30 OR A61F2/44 OR A61F2/46).IPC.)	US-PGPUB; OR USPAT		OFF	2018/05/11 11:25
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5/ 11/ 2018 11:28:27 AM

<i>Index of Claims</i> 	Application/Control No. 15490107	Applicant(s)/Patent Under Reexamination MOSKOWITZ ET AL.
	Examiner PEDRO PHILOGENE	Art Unit 3733

✓	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	05/11/2018																																					
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<i>Index of Claims</i> 	Application/Control No. 15490107	Applicant(s)/Patent Under Reexamination MOSKOWITZ ET AL.
	Examiner PEDRO PHILOGENE	Art Unit 3733

✓	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	05/11/2018								
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Search Notes 	Application/Control No. 15490107	Applicant(s)/Patent Under Reexamination MOSKOWITZ ET AL.
	Examiner PEDRO PHILOGENE	Art Unit 3733

CPC- SEARCHED		
Symbol	Date	Examiner
A61F2/442,447,4637; A61B17/0642,068,7064,7074,809,8042,86	5/11/2018	/P.P./
A61B2017/0641,0647,0648,922,		
A61F2002/2835,30331,30383,30476,305,30517,30604,307723278730879,448,4622,4641		
A61F2220/0025,0033,0041		

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner
623	17.11-17.16	5/11/2018	/P.P./

* 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
EAST search enclosed	5/11/2018	/P.P./

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner

	/PEDRO PHILOGENE/ Primary Examiner.Art Unit 3733
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Substitute Disclosure Form U.S. Department of Commerce Patent and Trademark Office Information Disclosure Statement by Applicant (Use several sheets if necessary) (37 CFR §1.98(b))	Attorney Docket No. 45335-0012004	Application No. 15/490,107
	Applicant Moskowitz et al.	
	Filing Date April 18, 2017	Group Art Unit

U.S. Patent Documents							
Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	1.	5123926	1992-06-23	Pisharodi			
	2.	5514180	1996-05-07	Heggeness et al.			
	3.	6368350	2002-04-09	Erickson et al.			
	4.	6419704	2002-07-16	Ferree			
	5.	6458159	2002-10-01	Thalgott			
	6.	6527804	2003-03-04	Gauchet et al.			
	7.	6533818	2003-03-18	Weber et al.			
	8.	6579318	2003-06-17	Varga et al.			
	9.	6582468	2003-06-24	Gauchet			
	10.	6719794	2004-04-13	Gerber			
	11.	6733532	2004-05-11	Gauchet et al.			
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	25.	7030904	2006-04-18	Adair et al.			
	26.	4997432	1991-03-05	Keller			

Examiner Signature /PEDRO PHILOGENE/	Date Considered 05/11/2018
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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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /P.P/

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	Applicant Moskowitz et al.	
	Filing Date April 18, 2017	Group Art Unit

U.S. Patent Documents							
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	28.	5660188	1997-08-26	Groiso			
	29.	4960420	1990-10-02	Goble et al.			
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	33.	4599086	1986-07-08	DOTY			
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	52.	5005749	1991-04-09	Aranyi			

Examiner Signature /PEDRO PHILOGENE/	Date Considered 05/11/2018
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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	Applicant Moskowitz et al.	
	Filing Date April 18, 2017	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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Examiner Signature /PEDRO PHILOGENE/	Date Considered 05/11/2018
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

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /P.P/

Substitute Disclosure Form U.S. Department of Commerce Patent and Trademark Office Information Disclosure Statement by Applicant (Use several sheets if necessary) (37 CFR §1.98(b))	Attorney Docket No. 45335-0012004	Application No. 15/490,107
	Applicant Moskowitz et al.	
	Filing Date April 18, 2017	Group Art Unit

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	Applicant Moskowitz et al.	
	Filing Date April 18, 2017	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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	Applicant Moskowitz et al.	
	Filing Date April 18, 2017	Group Art Unit

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Bibliographic Data

Application No: 15/490,107

Foreign Priority claimed: ☐ Yes ☒ No

35 USC 119 (a-d) conditions met: ☐ Yes ☒ No ☐ Met After Allowance

Verified and Acknowledged: /PEDRO PHILOGENE/

Examiner's Signature

Initials

Title:

BI-DIRECTIONAL FIXATING/LOCKING TRANSVERTEBRAL
BODY SCREW/INTERVERTEBRAL CAGE STAND-ALONE
CONSTRUCTS HAVING A CENTRAL SCREW LOCKING LEVER,
AND PLIERS AND DEVICES FOR SPINAL FUSION

FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
04/18/2017	623	3733	3003/0107PUS18
RULE			

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CONTINUING DATA

This application is a CON of 14257650 04/21/2014 PAT 9622875

14257650 is a DIV of 12471340 05/22/2009 PAT 8734516

12471340 is a CIP of 12054335 03/24/2008 PAT 7972363

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FOREIGN APPLICATIONS

IF REQUIRED, FOREIGN LICENSE GRANTED**

04/24/2017

** SMALL ENTITY **

STATE OR COUNTRY

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UNITED STATES

FILING FEE RECEIVED

\$1,900

First Named Inventor : Ahmnon D. Moskowitz
Application No. : 15/490,107
Filed : April 18, 2017
Page : 13 of 16

Attorney Docket: 46440-0012004

REMARKS

Claims 32-64 are pending, with claims 32, 42, and 51 being independent. With this amendment, claims 52-64 are new.

Examiner Interview

On May 23, 2018, an examiner interview was conducted between Examiner Pedro Philogene for the USPTO and Stuart A. Nelson for the applicant. During the interview, the parties discussed the §112 rejection and the drawings objections. During the interview, the both parties agreed that the identified claim language was shown in the figures, including for example Figures 4A-4F. Applicant agreed to amend the specification to recite what is shown in the figures regarding the identified claim language.

Claim Rejections – 35 USC § 112

Claims 32-51 are rejected under 35 U.S.C. 112(a) or 35 U.S.C. 112 (pre-AIA), first paragraph as failing to comply with the enablement requirement as certain claim language was identified as not sufficiently described in the specification.

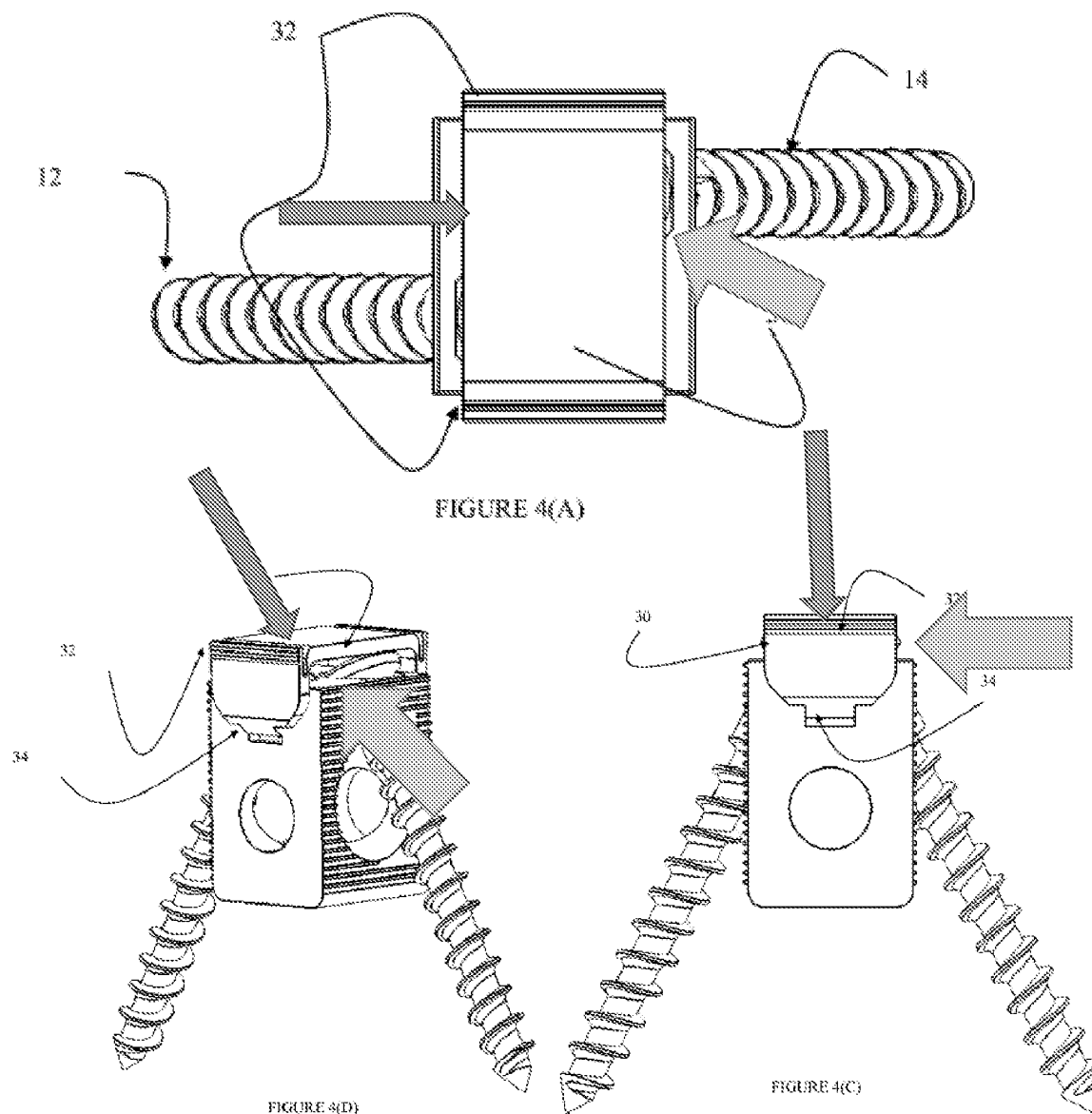
Without conceding the merits of the rejection but to further prosecution, paragraph [0060] has been amended to address this rejection. Support for this amendment can be found in the original specification, including for example Figures 4A-4F. As agreed during the 5/23/2018 examiner interview, the claims are enabled by the specification at least as amended.

Drawings

The drawings were objected to under 37 CFR 1.83(a) for allegedly failing to show every feature of the invention specified in the claims.

As discussed and agreed during the 5/23/2018 examiner interview, the drawings show "the locking bracket partially blocks the screw entrance portion and the second screw entrance portion so as to retain the first and second screws in the internal screw guide and the second internal screw guide while leaving at least a portion of the screw entrance portion and the second

screw entrance portion at least partially exposed", for example, at Figures 4A-4F. *See*, for example, Figures 4A, 4C, and 4D which are reproduced below and annotated with arrows.



Claim Rejections – Double Patenting

First Named Inventor : Ahmnon D. Moskowitz
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Claims 32-51 were rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-47 of U.S. Patent No. 9,895,238 in view of Moskowitz et al. (9,622,875). Claims 32-51 were rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-70 of U.S. Patent No. 9,889,022 in view of Moskowitz et al. (9,622,875).

Without conceding the merits of the rejection but to further prosecution, a terminal disclaimer is filed herewith to obviate the rejection.

New Claims

With this amendment, new claims 52-64 have been added. Claims 52-64 depend from independent claims 31, 41, and 51, and consequently, are patentable for at least the same reasons as for their base claims as well as for the additional features recited therein. Support for these amendments can be found throughout the original specification, including the text and figures (such as Figures 4A-4F and the corresponding text). Note that many of the new dependent method claims 56-64 recite subject matter similar to the dependent apparatus claims.

Accordingly, all claims are now in condition for allowance.

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

First Named Inventor : Ahmnon D. Moskowitz
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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: 5/24/2018

/Stuart A. Nelson/

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List of claims (replacing prior versions).

1-31 (Cancelled)

32. (Previously Presented) A intervertebral combination internal screw guide and fixation apparatus configured to be inserted into a disc space between a first vertebral body and a second vertebral body and to provide fusion of the first vertebral body to the second vertebral body via biological bone fusion and screw fusion, the apparatus comprising:

an intervertebral cage including:

a top wall, a bottom wall, and two sidewalls defining an open space capable of receiving bone filling for the biological bone fusion;

an internal screw guide having a screw entrance portion and an internal bore portion, wherein the screw entrance portion is larger than and coaxial with the internal bore and is formed at least partially in the top surface of the top wall as viewed from the top, wherein the internal bore portion has an entry opening formed only in a top surface of the top wall as viewed from the top and has an exit opening formed at least partially in a bottom surface of the top wall and at least partially in a side surface of the top wall;

a second internal screw guide having a second screw entrance portion and a second internal bore portion, wherein the second screw entrance portion is larger than and coaxial with the second internal bore and is formed at least partially in the top surface of the top wall as viewed from the top, wherein the second internal bore portion has a second entry opening formed only in the top surface of the top wall as viewed from the top and has a second exit opening formed at least partially in the bottom surface of the top wall and at least partially in a second side surface of the top wall, and wherein the internal screw guide and the second internal screw guide are angled to orient a first screw

member and a second member screw bi-directionally in opposite directions;
a first slot on a first outer side of a first sidewall of the two sidewalls;
a second slot on a second outer side of a second sidewall of the two
sidewalls, wherein the second slot is positioned opposite of the first slot;

wherein the first slot is positioned along a first centerline axis that bisects
the first side wall and is positioned nearer a top of the intervertebral cage than a
bottom of the intervertebral cage,

wherein the second slot is positioned along a second centerline axis that
bisects the second side wall and is positioned nearer the top of the intervertebral
cage than the bottom of the intervertebral cage,

wherein the side surface and the second side surface of the top wall are
patterned with a plurality of surface features to create rough side surfaces,
wherein at least some of the plurality of surface features are positioned on the side
surface between the top wall and the exit opening, and

wherein the top wall, the bottom wall, and the sidewalls are integrally
formed and the open space for receiving bone graft material extends continuously
from an inner surface of the first sidewall to an inner surface of the second
sidewall and extends continuously from an inner surface of the top wall to an
inner surface of the bottom wall;

a first screw having a first screw head and a first screw threaded portion, wherein
the first screw is sized to be positioned in the internal screw guide with the first screw
head in the screw entrance portion;

a second screw having a seconds screw head and a seconds screw threaded
portion, wherein the second screw is sized to be positioned in the second internal screw
guide with the second screw head in the second screw entrance portion; and

a screw locking bracket having a first end portion sized and positioned to be
inserted in the first slot, a second end portion sized and positioned to be inserted in the
second slot and a central portion extending between the first end portion and the second
end portion, wherein when the screw locking bracket is connected to the intervertebral
cage with the first end portion in the first slot and the second end portion in the second

slot, the central portion partially blocks the screw entrance portion and the second screw entrance portion so as to retain the first and second screws in the internal screw guide and the second internal screw guide while leaving at least a portion of the screw entrance portion and the second screw entrance portion at least partially exposed.

33. (Previously Presented) The apparatus of claim 32, wherein the screw locking bracket contacts both the first and second screw heads when the screw locking bracket is connect to the intervertebral cage.

34. (Previously Presented) The apparatus of claim 32, wherein the screw locking bracket comprises a first hook at the first end portion that is sized to fit in the first slot and a second hook at the second end portion that is sized to fit in the second slot.

35. (Previously Presented) The apparatus of claim 32, wherein the first end portion and the second end portion extend in a direction that is substantially perpendicular to the central portion.

36. (Previously Presented) The apparatus of claim 32, wherein the plurality of surface features on the side surface and the second side surface are patterned all the way next to the top surface of the top wall so as to be adjacent the top surface of the top wall.

37. (Previously Presented) The apparatus of claim 32, and further comprising means for fusing superior and inferior vertebral bodies in conjunction with the intervertebral cage.

38. (Previously Presented) The apparatus of claim 32, wherein the intervertebral cage is sized and configured for use in a patient's lumbar spine, the apparatus further comprising means for fusing superior and inferior lumbar vertebral bodies in conjunction with the intervertebral cage.

39. (Previously Presented) The apparatus of claim 32, wherein at least some of the plurality of surface features are positioned on the second side surface between the top wall and the second exit opening.

40. (Previously Presented) The apparatus of claim 32, wherein the screw locking bracket comprises a first hook at the first end portion that curves inward to engage the first slot and a second hook at the second end portion that curves inward to engage the second slot.

41. (Previously Presented) The apparatus of claim 32, wherein the screw locking bracket comprises means to slightly open the screw locking bracket.

42. (Previously Presented) A intervertebral combination internal screw guide and fixation apparatus configured to be inserted into a disc space between a first vertebral body and a second vertebral body and to provide fusion of the first vertebral body to the second vertebral body via biological bone fusion and screw fusion, the apparatus comprising:

an intervertebral cage including:

a top wall, a bottom wall, and two sidewalls defining an open space capable of receiving bone filling for the biological bone fusion;

an internal screw guide having a screw entrance portion and an internal bore portion, wherein the screw entrance portion is larger than and coaxial with the internal bore and is formed at least partially in the top surface of the top wall as viewed from the top, wherein the internal bore portion has an entry opening formed only in a top surface of the top wall as viewed from the top and has an exit opening formed at least partially in a bottom surface of the top wall and at least partially in a side surface of the top wall;

a second internal screw guide having a second screw entrance portion and a second internal bore portion, wherein the second screw entrance portion is larger than and coaxial with the second internal bore and is formed at least partially in the top surface of the top wall as viewed from the top, wherein the second internal bore portion has a second entry opening formed only in the top surface of the top wall as viewed from the top and has a second exit opening formed at least partially in the bottom surface of the top wall and at least partially in a second side surface of the top wall, and wherein the internal screw

guide and the second internal screw guide are angled to orient a first screw member and a second member screw bi-directionally in opposite directions;
a first slot extending at least partially into a first sidewall of the two sidewalls;

a second slot extending at least partially into a second sidewall of the two sidewalls, wherein the second slot is positioned opposite of the first slot;

wherein the first slot is positioned along a first centerline axis that bisects the first side wall and is positioned nearer a top of the intervertebral cage than a bottom of the intervertebral cage,

wherein the second slot is positioned along a second centerline axis that bisects the second side wall and is positioned nearer the top of the intervertebral cage than the bottom of the intervertebral cage,

wherein the side surface and the second side surface of the top wall are patterned with a plurality of surface features to create rough side surfaces, wherein at least some of the plurality of surface features are positioned on the side surface between the top wall and the exit opening, and

wherein the top wall, the bottom wall, and the sidewalls are integrally formed;

a first screw having a first screw head and a first screw threaded portion, wherein the first screw is sized to be positioned in the internal screw guide with the first screw head in the screw entrance portion;

a second screw having a second screw head and a second screw threaded portion, wherein the second screw is sized to be positioned in the second internal screw guide with the second screw head in the second screw entrance portion; and

a screw locking bracket having a first end portion sized and positioned to be inserted in the first slot, a second end portion sized and positioned to be inserted in the second slot and a central portion extending between the first end portion and the second end portion, wherein when the screw locking bracket is connected to the intervertebral cage with the first end portion in the first slot and the second end portion in the second slot, the central portion partially blocks the screw entrance portion and the second screw

entrance portion so as to retain the first and second screws in the internal screw guide and the second internal screw guide while leaving at least a portion of the screw entrance portion and the second screw entrance portion at least partially exposed.

43. (Previously Presented) The apparatus of claim 32, wherein the plurality of surface features on the side surface and the second side surface are patterned all the way next to the top surface of the top wall so as to be adjacent the top surface of the top wall.

44. (Previously Presented) The apparatus of claim 32, and further comprising means for fusing superior and inferior vertebral bodies in conjunction with the intervertebral cage.

45. (Previously Presented) The apparatus of claim 32, wherein the intervertebral cage is sized and configured for use in a patient's lumbar spine, the apparatus further comprising means for fusing superior and inferior lumbar vertebral bodies in conjunction with the intervertebral cage.

46. (Previously Presented) The apparatus of claim 32, wherein at least some of the plurality of surface features are positioned on the second side surface between the top wall and the second exit opening.

47. (Previously Presented) The apparatus of claim 32, wherein the screw locking bracket comprises means to slightly deform the screw locking bracket to remove the screw locking bracket from the intervertebral cage.

48. (Previously Presented) The apparatus of claim 47, wherein the means comprises a flexion portion of the screw locking bracket.

49. (Previously Presented) The apparatus of claim 32, wherein the screw locking bracket contacts both the first and second screw heads when the screw locking bracket is connect to the intervertebral cage.

50. (Previously Presented) The apparatus of claim 32, wherein the screw locking bracket comprises a first hook at the first end portion that is sized to fit in the first slot and a second hook at the second end portion that is sized to fit in the second slot.

51. (Previously Presented) A method of inserting a bi-directional fixating transvertebral (BDFT) screw/cage apparatus between a first vertebral body and a second vertebral body, the method including:

inserting an intervertebral cage into a midline of a disc space between the first vertebral body and the second vertebral body until the intervertebral cage is one of flush and countersunk relative to the first vertebral body and the second vertebral body, wherein the intervertebral cage includes:

a top wall, a bottom wall, and two sidewalls defining an open space capable of receiving bone filling for the biological bone fusion;

an internal screw guide having a screw entrance portion and an internal bore portion, wherein the screw entrance portion is larger than and coaxial with the internal bore and is formed at least partially in the top surface of the top wall as viewed from the top, wherein the internal bore portion has an entry opening formed only in a top surface of the top wall as viewed from the top and has an exit opening formed at least partially in a bottom surface of the top wall and at least partially in a side surface of the top wall;

a second internal screw guide having a second screw entrance portion and a second internal bore portion, wherein the second screw entrance portion is larger than and coaxial with the second internal bore and is formed at least partially in the top surface of the top wall as viewed from the top, wherein the second internal bore portion has a second entry opening formed only in the top surface of the top wall as viewed from the top and has a second exit opening formed at least partially in the bottom surface of the top wall and at least partially in a second side surface of the top wall, and wherein the internal screw guide and the second internal screw guide are angled to orient a first screw

member and a second member screw bi-directionally in opposite directions;

a first slot extending at least partially into a first sidewall of the two sidewalls;

a second slot extending at least partially into a second sidewall of the two sidewalls, wherein the second slot is positioned opposite of the first slot;

wherein the first slot is positioned along a first centerline axis that bisects the first side wall and is positioned nearer a top of the intervertebral cage than a bottom of the intervertebral cage,

wherein the second slot is positioned along a second centerline axis that bisects the second side wall and is positioned nearer the top of the intervertebral cage than the bottom of the intervertebral cage,

wherein the side surface and the second side surface of the top wall are patterned with a plurality of surface features to create rough side surfaces, wherein at least some of the plurality of surface features are positioned on the side surface between the top wall and the exit opening, and

wherein the top wall, the bottom wall, and the sidewalls are integrally formed; and

inserting a first screw into the internal screw guide of the intervertebral cage;

inserting a second screw into the second internal screw guide of the intervertebral cage;

screwing the first screw and the second screw into the first vertebral body and the second vertebral body respectively; and

locking the first screw and the second screw in the intervertebral cage using a screw locking bracket coupled to the intervertebral cage by positioning a first end portion of the screw locking bracket in the first slot, a second end portion of the screw locking bracket in the second slot and a central portion of the screw locking bracket extending between the first end portion and the second end portion across at least part of the top surface of the top wall such that the central portion partially blocks the screw entrance portion and the second screw entrance portion so as to retain the first and second screws in the internal screw guide and the second internal screw guide while leaving at least a portion of the screw entrance portion and the second screw entrance portion at least partially exposed.

52. (New) The apparatus of claim 42, wherein the screw locking bracket comprises titanium.

53. (New) The apparatus of claim 32, wherein the screw locking bracket is configured to be press fit to the intervertebral cage.

54. (New) The apparatus of claim 42, wherein the screw locking bracket is configured to be press fit to the intervertebral cage.

55. (New) The apparatus of claim 42, wherein the screw locking bracket is configured to be removed from the intervertebral cage by pressing the screw locking bracket to deform the screw locking bracket and then removing the screw locking bracket from the intervertebral cage.

56. (New) The method of claim 51, and further comprising press fitting the screw locking bracket to the intervertebral cage.

57. (New) The method of claim 51, and further comprising removing the screw locking bracket from the intervertebral cage by first pressing the screw locking bracket to deform the screw locking bracket and then removing the screw locking bracket from the intervertebral cage.

58. (New) The method of claim 51, wherein the screw locking bracket comprises titanium.

59. (New) The method of claim 51, wherein the plurality of surface features on the side surface and the second side surface are patterned all the way next to the top surface of the top wall so as to be adjacent the top surface of the top wall.

60. (New) The method of claim 51, wherein at least some of the plurality of surface features are positioned on the second side surface between the top wall and the second exit opening.

61. (New) The method of claim 51, wherein the screw locking bracket comprises means to

slightly deform the screw locking bracket to remove the screw locking bracket from the intervertebral cage.

62. (New) The method of claim 61, wherein the means comprises a flexion portion of the screw locking bracket.

63. (New) The method of claim 51, and further comprising contacting both the first and second screw heads with the screw locking bracket when the screw locking bracket is connected to the intervertebral cage.

64. (New) The method of claim 51, wherein the screw locking bracket comprises a first hook at the first end portion that is sized to fit in the first slot and a second hook at the second end portion that is sized to fit in the second slot.

Amendments to the Specification:

Please replace the original paragraph [0060] with the following amended paragraph:

[0060] The cage 10 includes a screw locking mechanism for posterior lumbosacral cage/BDFT constructs. This locking mechanism is a screw locking horizontal bracket 30 which snaps on to the top of the construct once the screws have been maximally turned thereby preventing screw pull-out or back-out. As shown in Figures 4A-F, a central portion of the screw locking horizontal bracket 30 partially blocks the screw entrance portions of the internalized screw/drill guides 20 so as to retain the screws 12 while leaving at least a portion of the screw entrance portions of the internalized screw/drill guides 20 at least partially exposed. The screw locking bracket 30 is designed with left and right bracket hooks 34. They are inserted into hook insertion slots 36 which are prefabricated on the left and right sides of the cage construct to precisely snugly fit the bracket hooks 34. Once the bracket hooks 34 are inserted into the cage insertion slots 36 using the specially designed pliers (Fig 5), the bracket 30 cannot be dislodged. In order to remove the bracket 30; if it becomes necessary to remove the cage 10 at some future time, flexion grips (side tabs) 32 have been designed on the bracket 30. The locking bracket 30 can be press fit onto the cage 10 using the pliers (Fig 5) thereby locking the screws 12, 14. In order to remove the bracket 30, the user needs only to press on the side tabs 32 with the pliers (Fig 5) to slightly deform (open) the bracket hooks 34, and thereby easily remove the bracket 30.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor : Ahmnon D. Moskowitz Art Unit : 3733
Application No. : 15/490,107 Examiner : Pedro Philogene
Filed : April 18, 2017
Title : BI-DIRECTIONAL FIXATING/LOCKING TRANSVERTEBRAL
BODY SCREW/INTERVERTEBRAL CAGE STAND-ALONE
CONSTRUCTS HAVING A CENTRAL SCREW LOCKING
LEVER, AND PLIERS AND DEVICES FOR SPINAL FUSION

Mail Stop Amendment

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

REPLY TO ACTION OF MAY 16, 2018

Please consider the following reply.

Electronic Patent Application Fee Transmittal				
Application Number:		15490107		
Filing Date:		18-Apr-2017		
Title of Invention:		BI-DIRECTIONAL FIXATING/LOCKING TRANSVERTEBRAL BODY SCREW/ INTERVERTEBRAL CAGE STAND-ALONE CONSTRUCTS HAVING A CENTRAL SCREW LOCKING LEVER, AND PLIERS AND DEVICES FOR SPINAL FUSION		
First Named Inventor/Applicant Name:		Ahmnon D. MOSKOWITZ		
Filer:		Stuart A. Nelson/Abby Remer		
Attorney Docket Number:		3003/0107PUS18		
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:				
CLAIMS IN EXCESS OF 20	2202	2	50	100
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Extension-of-Time:				
Miscellaneous:				
Total in USD (\$)				100

Electronic Acknowledgement Receipt	
EFS ID:	32719782
Application Number:	15490107
International Application Number:	
Confirmation Number:	5831
Title of Invention:	BI-DIRECTIONAL FIXATING/LOCKING TRANSVERTEBRAL BODY SCREW/ INTERVERTEBRAL CAGE STAND-ALONE CONSTRUCTS HAVING A CENTRAL SCREW LOCKING LEVER, AND PLIERS AND DEVICES FOR SPINAL FUSION
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:	3003/0107PUS18
Receipt Date:	24-MAY-2018
Filing Date:	18-APR-2017
Time Stamp:	16:42:15
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	\$100
RAM confirmation Number	052518INTEFSW00003475061050
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		Response.pdf	187031	yes	16
			35efdc9cfd607d776573a1adcb31e5b100687b65		
	Multipart Description/PDF files in .zip description				
	Document Description		Start	End	
	Amendment/Req. Reconsideration-After Non-Final Reject		13	16	
	Claims		3	12	
	Specification		2	2	
	Amendment/Req. Reconsideration-After Non-Final Reject		1	1	
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	30751	no	2
			92b0b080d9bc036098ed251f10115b1e37ad217f		
Warnings:					
Information:					
Total Files Size (in bytes):			217782		

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: DIST.E.FILE Document Description: Electronic Terminal Disclaimer - Filed		PTO/SB/26 U.S. Patent and Trademark Office Department of Commerce	
Electronic Petition Request	TERMINAL DISCLAIMER TO OBTAIN A DOUBLE PATENTING REJECTION OVER A "PRIOR" PATENT		
Application Number	15490107		
Filing Date	18-Apr-2017		
First Named Inventor	Dr. Nathan Moskowitz		
Attorney Docket Number	3003/0107PUS18		
Title of Invention	BI-DIRECTIONAL FIXATING/LOCKING TRANSVERTEBRAL BODY SCREW/INTERVERTEBRAL CAGE STAND-ALONE CONSTRUCTS HAVING A CENTRAL SCREW LOCKING LEVER, AND PLIERS AND DEVICES FOR SPINAL FUSION		
☒ Filing of terminal disclaimer does not obviate requirement for response under 37 CFR 1.111 to outstanding Office Action ☒ This electronic Terminal Disclaimer is not being used for a Joint Research Agreement.			
Owner		Percent Interest	
Nathan C. Moskowitz		100%	
The owner(s) with percent interest listed above in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term of prior patent number(s) 9895238 9889022 as the term of said prior patent is presently shortened by any terminal disclaimer. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the prior patent are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns. In making the above disclaimer, the owner does not disclaim the terminal part of the term of any patent granted on the instant application that would extend to the expiration date of the full statutory term of the prior patent, "as the term of said prior patent is presently shortened by any terminal disclaimer," in the event that said prior patent later: - expires for failure to pay a maintenance fee; - is held unenforceable; - is found invalid by a court of competent jurisdiction; - is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321; - has all claims canceled by a reexamination certificate; - is reissued; or - is in any manner terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer.			

- ☒ Terminal disclaimer fee under 37 CFR 1.20(d) is included with Electronic Terminal Disclaimer request.
- ☐ I certify, in accordance with 37 CFR 1.4(d)(4), that the terminal disclaimer fee under 37 CFR 1.20(d) required for this terminal disclaimer has already been paid in the above-identified application.

Applicant claims the following fee status:

- ☒ Small Entity
- ☐ Micro Entity
- ☐ Regular Undiscounted

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

THIS PORTION MUST BE COMPLETED BY THE SIGNATORY OR SIGNATORIES

I certify, in accordance with 37 CFR 1.4(d)(4) that I am:

- ☒ An attorney or agent registered to practice before the Patent and Trademark Office who is of record in this application
- Registration Number 63947
- ☐ A sole inventor
- ☐ A joint inventor; I certify that I am authorized to sign this submission on behalf of all of the inventors as evidenced by the power of attorney in the application
- ☐ A joint inventor; all of whom are signing this request

Signature	/Stuart A. Nelson/
Name	Stuart A. Nelson

*Statement under 37 CFR 3.73(b) is required if terminal disclaimer is signed by the assignee (owner).
Form PTO/SB/96 may be used for making this certification. See MPEP § 324.

Electronic Patent Application Fee Transmittal				
Application Number:		15490107		
Filing Date:		18-Apr-2017		
Title of Invention:		BI-DIRECTIONAL FIXATING/LOCKING TRANSVERTEBRAL BODY SCREW/ INTERVERTEBRAL CAGE STAND-ALONE CONSTRUCTS HAVING A CENTRAL SCREW LOCKING LEVER, AND PLIERS AND DEVICES FOR SPINAL FUSION		
First Named Inventor/Applicant Name:		Dr. Nathan C. Moskowitz		
Filer:		Stuart A. Nelson		
Attorney Docket Number:		3003/0107PUS18		
Filed as Small Entity				
Filing Fees for Utility under 35 USC 111(a)				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
STATUTORY OR TERMINAL DISCLAIMER	2814	1	160	160
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Extension-of-Time:				
Miscellaneous:				
Total in USD (\$)				160

Doc Code: DISQ.E.FILE

Document Description: Electronic Terminal Disclaimer – Approved

Application No.: 15490107

Filing Date: 18-Apr-2017

Applicant/Patent under Reexamination: Moskowitz

Electronic Terminal Disclaimer filed on May 24, 2018

☒ APPROVED

This patent is subject to a terminal disclaimer

☐ DISAPPROVED

Approved/Disapproved by: Electronic Terminal Disclaimer automatically approved by EFS-Web

U.S. Patent and Trademark Office

Electronic Acknowledgement Receipt	
EFS ID:	32717325
Application Number:	15490107
International Application Number:	
Confirmation Number:	5831
Title of Invention:	BI-DIRECTIONAL FIXATING/LOCKING TRANSVERTEBRAL BODY SCREW/ INTERVERTEBRAL CAGE STAND-ALONE CONSTRUCTS HAVING A CENTRAL SCREW LOCKING LEVER, AND PLIERS AND DEVICES FOR SPINAL FUSION
First Named Inventor/Applicant Name:	Dr. Nathan C. Moskowitz
Customer Number:	26191
Filer:	Stuart A. Nelson
Filer Authorized By:	
Attorney Docket Number:	3003/0107PUS18
Receipt Date:	24-MAY-2018
Filing Date:	18-APR-2017
Time Stamp:	17:01:20
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	052518INTEFSW00007077061050
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	Terminal Disclaimer-Filed (Electronic)	eTerminal-Disclaimer.pdf	33776	no	2
			ba67d4a0a8ed358386c4cf6b7cec0a62b2a34753		
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	31042	no	2
			46dcaedfbecba827b5e28a479859c38b2a429f0		
Warnings:					
Information:					
Total Files Size (in bytes):			64818		
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. <u>New Applications Under 35 U.S.C. 111</u> 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. <u>National Stage of an International Application under 35 U.S.C. 371</u> 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. <u>New International Application Filed with the USPTO as a Receiving Office</u> 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.					

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.

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 15/490,107	Filing Date 04/18/2017	☐ To be Mailed
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ENTITY: ☐ LARGE ☒ SMALL ☐ MICRO

APPLICATION AS FILED – PART I

(Column 1) (Column 2)

FOR	NUMBER FILED	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), (j), 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 \$ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X \$ =	
☐ 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))				
			TOTAL	

* If the difference in column 1 is less than zero, enter "0" in column 2.

APPLICATION AS AMENDED – PART II

(Column 1) (Column 2) (Column 3)

AMENDMENT	05/24/2018	CLAIMS REMAINING AFTER AMENDMENT	MINUS	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)
	Total (37 CFR 1.16(i))	* 33	Minus	** 31	= 2	X \$50 =	100
	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	100

(Column 1) (Column 2) (Column 3)

AMENDMENT	CLAIMS REMAINING AFTER AMENDMENT	MINUS	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)
	Total (37 CFR 1.16(i))	*	Minus	**	X \$ =	
	Independent (37 CFR 1.16(h))	*	Minus	***	X \$ =	
	☐ 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.

** 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 number found in the appropriate box in column 1.

SLIE
RANELL D. GRAY

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.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/490,107	04/18/2017	Ahmnnon D. MOSKOWITZ	3003/0107PUS18	5831

26191 7590 05/30/2018
FISH & RICHARDSON P.C. (TC)
PO BOX 1022
MINNEAPOLIS, MN 55440-1022

EXAMINER

PHILOGENE, PEDRO

ART UNIT	PAPER NUMBER
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3733

NOTIFICATION DATE	DELIVERY MODE
-------------------	---------------

05/30/2018

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

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews

Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.



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NOTICE OF ALLOWANCE AND FEE(S) DUE

26191 7590 07/20/2018
FISH & RICHARDSON P.C. (TC)
PO BOX 1022
MINNEAPOLIS, MN 55440-1022
UNITED STATES OF AMERICA

EXAMINER

PHILOGENE, PEDRO

ART UNIT

PAPER NUMBER

3733

DATE MAILED: 07/20/2018

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/490,107	04/18/2017	Ahmnnon D. MOSKOWITZ	3003/0107PUS18	5831

TITLE OF INVENTION: BI-DIRECTIONAL FIXATING/LOCKING TRANSVERTEBRAL BODY SCREW/INTERVERTEBRAL CAGE
STAND-ALONE CONSTRUCTS HAVING A CENTRAL SCREW LOCKING LEVER, AND PLIERS AND DEVICES FOR SPINAL FUSION

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	\$500	\$0	\$0	\$500	10/22/2018

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.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

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), to: Mail Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (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 07/20/2018
FISH & RICHARDSON P.C. (TC)
PO BOX 1022
MINNEAPOLIS, MN 55440-1022
UNITED STATES OF AMERICA

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 facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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15/490,107 04/18/2017 Ahmnon D. MOSKOWITZ 3003/0107PUS18 5831

TITLE OF INVENTION: BI-DIRECTIONAL FIXATING/LOCKING TRANSVERTEBRAL BODY SCREW/INTERVERTEBRAL CAGE STAND-ALONE CONSTRUCTS HAVING A CENTRAL SCREW LOCKING LEVER, AND PLIERS AND DEVICES FOR SPINAL FUSION

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	\$500	\$0	\$0	\$500	10/22/2018

EXAMINER	ART UNIT	CLASS-SUBCLASS
PHIOLOGENE, PEDRO	3733	623-017160

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 03-02 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, 1 _____
- (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. 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 has been filed for recordation as set forth in 37 CFR 3.11. 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. The following fee(s) are submitted:

- ☐ Issue Fee
- ☐ Publication Fee (No small entity discount permitted)
- ☐ Advance Order - # of Copies _____

4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above)

- ☐ A check is enclosed.
- ☐ Payment by credit card. Form PTO-2038 is attached.
- ☐ The director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

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.
15/490,107	04/18/2017	Ahmnon D. MOSKOWITZ	3003/0107PUS18	5831

26191 7590 07/20/2018
FISH & RICHARDSON P.C. (TC)
PO BOX 1022
MINNEAPOLIS, MN 55440-1022
UNITED STATES OF AMERICA

EXAMINER

PHILOGENE, PEDRO

ART UNIT	PAPER NUMBER
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3733

DATE MAILED: 07/20/2018

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 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, 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. 15/490,107	Applicant(s) MOSKOWITZ ET AL.	
	Examiner PEDRO PHILOGENE	Art Unit 3733	AIA (First Inventor to File) 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 amendment filed 5/24/18.
☐ 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 32-64. 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 a reply 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 _____.	
/PEDRO PHILOGENE/ Primary Examiner, Art Unit 3733	

The present application is being examined under the pre-AIA first to invent provisions.

REASONS FOR ALLOWANCE

The following is an examiner's statement of reasons for allowance: the prior art fails to disclose or reasonably teach an intervertebral cage including an internal screw guide, wherein the internal bore portion has a an entry opening formed only in a top surface of the top wall as viewed from the top and has an exit opening formed at least partially in a bottom surface of the top wall and at least partially in a side surface of the top wall. Thus the examiner has allowed claims 32-64.

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."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PEDRO PHILOGENE whose telephone number is (571)272-4716. The examiner can normally be reached on Monday to Friday 8:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (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.

/PEDRO PHILOGENE/
Primary Examiner, Art Unit 3733

Search Notes 	Application/Control No. 15490107	Applicant(s)/Patent Under Reexamination MOSKOWITZ ET AL.
	Examiner PEDRO PHILOGENE	Art Unit 3733

CPC- SEARCHED		
Symbol	Date	Examiner
A61F2/442,447,4637; A61B17/0642,068,7064,7074,809,8042,86	6/6/2018	/P.P./
A61B2017/0641,0647,0648,922,		
A61F2002/2835,30331,30383,30476,305,30517,30604,307723278730879,448,4622,4641		
A61F2220/0025,0033,0041		

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner
623	17.11-17.16	6/27/2018	/P.P./

* 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
EAST search enclosed	6/27/2018	/P.P./

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner
623	17.16	6/27/2018	/P.P./

	/PEDRO PHILOGENE/ Primary Examiner.Art Unit 3733
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INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner
Interference Search History Printout		6/27/2018	/P.P./

	/PEDRO PHILOGENE/ Primary Examiner, Art Unit 3733
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<i>Index of Claims</i> 	Application/Control No. 15490107	Applicant(s)/Patent Under Reexamination MOSKOWITZ ET AL.
	Examiner PEDRO PHILOGENE	Art Unit 3733

✓	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	05/11/2018	06/27/2018						
	1	-	-						
	2	-	-						
	3	-	-						
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	28	-	-						
	29	-	-						
	30	-	-						
	31	-	-						
1	32	✓	=						
2	33	✓	=						
3	34	✓	=						
4	35	✓	=						
5	36	✓	=						

<i>Index of Claims</i> 	Application/Control No. 15490107	Applicant(s)/Patent Under Reexamination MOSKOWITZ ET AL.
	Examiner PEDRO PHILOGENE	Art Unit 3733

✓	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	05/11/2018	06/27/2018																																				
6	37	✓	=																																				
7	38	✓	=																																				
8	39	✓	=																																				
9	40	✓	=																																				
10	41	✓	=																																				
12	42	✓	=																																				
13	43	✓	=																																				
14	44	✓	=																																				
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31	62		=																																				
32	63		=																																				
33	64		=																																				

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	88	intervertebral near (cage or implant or apparatus or spacer) & screw near guide & bore & lock\$4	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2018/06/27 11:34
L2	10	intervertebral near (cage or implant or apparatus or spacer) & screw near guide & bore & lock\$4 near bracket	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2018/06/27 11:35
L4	1	"20180036134"	US-PGPUB; USPAT	OR	OFF	2018/06/27 11:37
L5	1	4 AND ((A61B17/0642 OR A61B17/068 OR A61B17/7064 OR A61B17/7074 OR A61B17/8042 OR A61B17/809 OR A61B17/86 OR A61B2017/0641 OR A61B2017/0647 OR A61B2017/0648 OR A61B2017/922 OR A61F2002/2835 OR A61F2002/30331 OR A61F2002/30383 OR A61F2002/30476 OR A61F2002/305 OR A61F2002/30517 OR A61F2002/30604 OR A61F2002/30772 OR A61F2002/30787 OR A61F2002/30879 OR A61F2002/448 OR A61F2002/4622 OR A61F2002/4641 OR A61F2220/0025 OR A61F2220/0033 OR A61F2220/0041 OR A61F2/442 OR A61F2/447 OR A61F2/4637 OR H05K999/99).CPC. OR (1/1 or 623/17.11-17.16).CCLS. OR (A61B17/064 OR A61B17/068 OR A61B17/70 OR A61B17/80 OR A61B17/86 OR A61B17/92 OR A61F2/28 OR A61F2/30 OR A61F2/44 OR A61F2/46).IPC.)	US-PGPUB; USPAT	OR	OFF	2018/06/27 11:38
L6	86	1 AND ((A61B17/0642 OR A61B17/068 OR A61B17/7064 OR A61B17/7074 OR A61B17/8042 OR A61B17/809 OR A61B17/86 OR A61B2017/0641 OR A61B2017/0647 OR A61B2017/0648 OR A61B2017/922 OR A61F2002/2835 OR A61F2002/30331 OR A61F2002/30383 OR A61F2002/30476 OR A61F2002/305 OR A61F2002/30517 OR A61F2002/30604 OR A61F2002/30772 OR A61F2002/30787 OR A61F2002/30879 OR A61F2002/448 OR A61F2002/4622 OR A61F2002/4641 OR A61F2220/0025 OR A61F2220/0033 OR A61F2220/0041 OR A61F2/442 OR A61F2/447 OR A61F2/4637 OR	US-PGPUB; USPAT	OR	OFF	2018/06/27 11:39

EAST Search History

		H05K999/99).CPC. OR (1/1 or 623/17.11-17.16).CCLS. OR (A61B17/064 OR A61B17/068 OR A61B17/70 OR A61B17/80 OR A61B17/86 OR A61B17/92 OR A61F2/28 OR A61F2/30 OR A61F2/44 OR A61F2/46).IPC.)				
L8	283	A61B017/064.ipc.	FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2018/06/27 11:42
L9	423	A61B017/068.ipc.	FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2018/06/27 11:42
L10	1461	A61B017/70.ipc.	FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2018/06/27 11:42
L11	427	A61B017/80.ipc.	FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2018/06/27 11:42
L12	293	A61B017/86.ipc.	FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2018/06/27 11:42

EAST Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L3	1	intervertebral near (cage or implant or apparatus or spacer) & screw near guide & bore & lock\$4 near bracket.clm.	USPAT	OR	ON	2018/06/27 11:36
L7	4530	(623/17.16).CCLS.	US- PGPUB; USPAT	OR	OFF	2018/06/27 11:41

6/27/2018 11:43:18 AM

Issue Classification 	Application/Control No. 15490107	Applicant(s)/Patent Under Reexamination MOSKOWITZ ET AL.	
	Examiner PEDRO PHILOGENE	Art Unit 3733	

CPC					
Symbol				Type	Version
A61F	2		442	F	2013-01-01
A61B	17		0642	I	2013-01-01
A61B	17		7064	I	2013-01-01
A61B	17		8042	A	2013-01-01
A61B	17		809	I	2013-01-01
A61B	17		86	A	2013-01-01
A61B	2017		0641	A	2013-01-01
A61B	2017		0647	A	2013-01-01
A61B	2017		0648	A	2013-01-01
A61B	2017		922	A	2013-01-01
A61F	2		447	I	2013-01-01
A61F	2002		2835	A	2013-01-01
A61F	2002		30476	A	2013-01-01
A61F	2002		30772	A	2013-01-01
A61F	2002		30787	A	2013-01-01
A61F	2002		448	A	2013-01-01
A61F	2220		0025	A	2013-01-01
A61B	17		068	I	2013-01-01
A61F	2		4637	I	2013-01-01
A61F	2002		30331	A	2013-01-01
A61F	2002		30383	A	2013-01-01
A61F	2002		305	A	2013-01-01
A61F	2002		30517	A	2013-01-01
A61F	2002		30604	A	2013-01-01
A61F	2002		30879	A	2013-01-01
A61F	2002		4622	A	2013-01-01
A61F	2002		4641	A	2013-01-01
A61F	2220		0033	A	2013-01-01
A61B	17		7074	I	2013-01-01
A61F	2220		0041	A	2013-01-01

NONE		Total Claims Allowed:	
		33	
(Assistant Examiner) /PEDRO PHILOGENE/ Primary Examiner.Art Unit 3733 (Primary Examiner)	(Date) 06/27/2018 (Date)	O.G. Print Claim(s)	O.G. Print Figure
		1	1

Issue Classification 	Application/Control No. 15490107	Applicant(s)/Patent Under Reexamination MOSKOWITZ ET AL.
	Examiner PEDRO PHILOGENE	Art Unit 3733

CPC Combination Sets				
Symbol	Type	Set	Ranking	Version

NONE	Total Claims Allowed: 33	
(Assistant Examiner)	(Date)	
/PEDRO PHILOGENE/ Primary Examiner.Art Unit 3733	06/27/2018	O.G. Print Claim(s) 1
(Primary Examiner)	(Date)	O.G. Print Figure 1

Issue Classification 	Application/Control No. 15490107	Applicant(s)/Patent Under Reexamination MOSKOWITZ ET AL.
	Examiner PEDRO PHILOGENE	Art Unit 3733

US ORIGINAL CLASSIFICATION						INTERNATIONAL CLASSIFICATION										
CLASS			SUBCLASS			CLAIMED					NON-CLAIMED					
623			17.16			A	6	1	B	17 / 064 (2006.0)						
CROSS REFERENCE(S)						A	6	1	B	17 / 068 (2006.0)						
						A	6	1	B	17 / 70 (2006.0)						
						A	6	1	B	17 / 80 (2006.0)						
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)					A	6	1	B	17 / 80 (2006.0)						
						A	6	1	F	2 / 44 (2006.0)						
						A	6	1	F	2 / 46 (2006.0)						
						A	6	1	F	2 / 28 (2006.0)						
						A	6	1	F	2 / 30 (2006.0)						
						A	6	1	B	17 / 86 (2006.01.01)						

NONE		Total Claims Allowed:	
		33	
(Assistant Examiner)	(Date)		
/PEDRO PHILOGENE/ Primary Examiner.Art Unit 3733	06/27/2018	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	1

Issue Classification 	Application/Control No. 15490107	Applicant(s)/Patent Under Reexamination MOSKOWITZ ET AL.
	Examiner PEDRO PHILOGENE	Art Unit 3733

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☒ T.D. ☐ R.1.47															
Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
	1		17	2	33	19	49								
	2		18	3	34	20	50								
	3		19	4	35	24	51								
	4		20	5	36	21	52								
	5		21	6	37	11	53								
	6		22	7	38	22	54								
	7		23	8	39	23	55								
	8		24	9	40	25	56								
	9		25	10	41	26	57								
	10		26	12	42	27	58								
	11		27	13	43	28	59								
	12		28	14	44	29	60								
	13		29	15	45	30	61								
	14		30	16	46	31	62								
	15		31	17	47	32	63								
	16	1	32	18	48	33	64								

NONE (Assistant Examiner) _____ (Date) _____		Total Claims Allowed: 33	
/PEDRO PHILOGENE/ Primary Examiner.Art Unit 3733 (Primary Examiner) _____ (Date) _____		O.G. Print Claim(s) 1	O.G. Print Figure 1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor : Ahmnon D. Art Unit : 3733
Moskowitz Examiner : Pedro Philogene
Application No. : 15/490,107 Confirmation No. : 5831
Filed : April 18, 2017 Notice of Allowance Date: July 20, 2018

Title : BI-DIRECTIONAL FIXATING/LOCKING TRANSVERTEBRAL
BODY SCREW/INTERVERTEBRAL CAGE STAND-ALONE
CONSTRUCTS HAVING A CENTRAL SCREW LOCKING
LEVER, AND PLIERS AND DEVICES FOR SPINAL FUSION

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 July 20, 2018, enclosed is a completed Part B - Fee(s) Transmittal.

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.

First Named Inventor : Ahmnon D. Moskowitz
Application No. : 15/490,107
Filed : April 18, 2017
Page : 2 of 2

Attorney Docket: 46440-0012004

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.

Respectfully submitted,

Date: 8/2/2018

/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

61730568.doc

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22314-1450
or Fax (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 07/20/2018

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, EFS-Web transmitted, or facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/490,107	04/18/2017	Ahmnon D. Moskowitz	46440-0012004	5831

TITLE OF INVENTION: BI-DIRECTIONAL FIXATING/LOCKING TRANSVERTEBRAL BODY SCREW/INTERVERTEBRAL CAGE STAND-ALONE CONSTRUCTS HAVING A CENTRAL SCREW LOCKING LEVER, AND PLIERS AND DEVICES FOR SPINAL FUSION

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	10/22/2018

EXAMINER	ART UNIT	CLASS-SUBCLASS
PHIOLOGENE, PEDRO	3733	623-017160

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 03-02 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, 1 Fish & Richardson P.C.
- (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. 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 has been filed for recordation as set forth in 37 CFR 3.11. 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 categories (will not be printed on the patent): ☐ Individual ☒ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

- ☒ Issue Fee
- ☐ Publication Fee (No small entity discount permitted)
- ☐ Advance Order - # of Copies _____

4b. Payment of Fee(s): (**Please first reapply any previously paid fee shown above**)

- ☐ A check is enclosed.
- ☐ Payment by credit card. Form PTO-2038 is attached.
- ☒ The Director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number 06-1050 (enclose an extra copy of this form).

5. **Change of 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 form 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 /Stuart A. Nelson/

Date 8/2/2018

Typed or printed name Stuart A. Nelson

Registration No. 63,947

PTOL-85 Part B (06-17). Approved for use through 1/31/2020

OMB 0651-0033

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

61730569.doc

Electronic Patent Application Fee Transmittal				
Application Number:		15490107		
Filing Date:		18-Apr-2017		
Title of Invention:		BI-DIRECTIONAL FIXATING/LOCKING TRANSVERTEBRAL BODY SCREW/ INTERVERTEBRAL CAGE STAND-ALONE CONSTRUCTS HAVING A CENTRAL SCREW LOCKING LEVER, AND PLIERS AND DEVICES FOR SPINAL FUSION		
First Named Inventor/Applicant Name:		Ahmnon D. MOSKOWITZ		
Filer:		Stuart A. Nelson/Abby Remer		
Attorney Docket Number:		3003/0107PUS18		
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:	33359076
Application Number:	15490107
International Application Number:	
Confirmation Number:	5831
Title of Invention:	BI-DIRECTIONAL FIXATING/LOCKING TRANSVERTEBRAL BODY SCREW/ INTERVERTEBRAL CAGE STAND-ALONE CONSTRUCTS HAVING A CENTRAL SCREW LOCKING LEVER, AND PLIERS AND DEVICES FOR SPINAL FUSION
First Named Inventor/Applicant Name:	Ahmnon D. MOSKOWITZ
Customer Number:	26191
Filer:	Stuart A. Nelson/Janell Nelson
Filer Authorized By:	Stuart A. Nelson
Attorney Docket Number:	3003/0107PUS18
Receipt Date:	02-AUG-2018
Filing Date:	18-APR-2017
Time Stamp:	16:09:53
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	080318INTEFSW00002700061050
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	172944	no	3
			a6b337acc4a741157d5e54cb7ea82e2da5d41138		
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	30753	no	2
			3344e666abc742af3c9e14086d95c7e2be3ff801		
Warnings:					
Information:					
Total Files Size (in bytes):			203697		
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. <u>New Applications Under 35 U.S.C. 111</u> 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. <u>National Stage of an International Application under 35 U.S.C. 371</u> 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. <u>New International Application Filed with the USPTO as a Receiving Office</u> 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
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Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/490,107	09/04/2018	10064738	3003/0107PUS18	5831

26191 7590 08/21/2018
FISH & RICHARDSON P.C. (TC)
PO BOX 1022
MINNEAPOLIS, MN 55440-1022
UNITED STATES OF AMERICA

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 0 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):

Ahmnon D. MOSKOWITZ, Rockville, MD;
Dr. Nathan C. Moskowitz, Rockville, MD
Nathan C. MOSKOWITZ, Rockville, MD;
Mosheh T. MOSKOWITZ, Rockville, MD;
Pablo A. Valdivia Y. ALVARADO, Cambridge, MA;

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor : Ahmnon D. Moskowitz Art Unit : 3733
Patent No. : 10,064,738 Examiner : Pedro Philogene
Issue Date : September 4, 2018 Conf. No. :
Serial No. : 15/490,107
Filed : April 18, 2017
Title : BI-DIRECTIONAL FIXATING/LOCKING TRANSVERTEBRAL BODY
SCREW/INTERVERTEBRAL CAGE STAND-ALONE CONSTRUCTS
HAVING A CENTRAL SCREW LOCKING LEVER, AND PLIERS AND
DEVICES FOR SPINAL FUSION

Attention Certificate of Corrections Branch
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REQUEST FOR CERTIFICATE OF CORRECTION

Please issue a certificate of correction in accordance with the attached form.

One or more of the errors to be corrected were made by applicant. The fee of \$150 is being paid with this request.

Apply any other necessary charges or credits to Deposit Account 06-1050, referencing the above attorney docket number.

Respectfully submitted,

Date: 10/2/2018

/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

61762571.doc

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

Page 1 of 1

PATENT NO. : 10,064,738

APPLICATION NO.: 15/490,107

ISSUE DATE : September 4, 2018

INVENTOR(S) : Ahmnon D. Moskowitz, Nathan C. Moskowitz, Mosheh T. Moskowitz and Pablo A. Valdivia Y. Alvarado

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

Column 21; Line 9 (Claims): In Claim 1, delete "seconds" and insert - - second - -, therefor.

Column 21; Line 10 (Claims): In Claim 1, delete "seconds" and insert - - second - -, therefor.

Column 22; Line 61 (Claims): In Claim 12, delete "seconds" and insert - - second - -, therefor.

Column 22; Line 62 (Claims): In Claim 12, delete "seconds" and insert - - second - -, therefor.

MAILING ADDRESS OF SENDER (Please do not use customer number below):

Fish & Richardson P.C.
P.O. Box 1022
Minneapolis, MN 55440-1022

This collection of information is required by 37 CFR 1.322, 1.323, and 1.324. 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 1.0 hour 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: Attention Certificate of Corrections Branch, 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 selection option2.

Electronic Patent Application Fee Transmittal				
Application Number:		15490107		
Filing Date:		18-Apr-2017		
Title of Invention:		BI-DIRECTIONAL FIXATING/LOCKING TRANSVERTEBRAL BODY SCREW/ INTERVERTEBRAL CAGE STAND-ALONE CONSTRUCTS HAVING A CENTRAL SCREW LOCKING LEVER, AND PLIERS AND DEVICES FOR SPINAL FUSION		
First Named Inventor/Applicant Name:		Ahmnon D. MOSKOWITZ		
Filer:		Stuart A. Nelson/Abby Remer		
Attorney Docket Number:		3003/0107PUS18		
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	150	150

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Extension-of-Time:				
Miscellaneous:				
Total in USD (\$)				150

Electronic Acknowledgement Receipt	
EFS ID:	33897675
Application Number:	15490107
International Application Number:	
Confirmation Number:	5831
Title of Invention:	BI-DIRECTIONAL FIXATING/LOCKING TRANSVERTEBRAL BODY SCREW/ INTERVERTEBRAL CAGE STAND-ALONE CONSTRUCTS HAVING A CENTRAL SCREW LOCKING LEVER, AND PLIERS AND DEVICES FOR SPINAL FUSION
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:	3003/0107PUS18
Receipt Date:	02-OCT-2018
Filing Date:	18-APR-2017
Time Stamp:	16:43:41
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	\$150
RAM confirmation Number	100318INTEFSW00003924061050
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 for Certificate of Correction	COC.pdf	131003	no	2
			7ce6a65837dc72ae80971a56cbc606c3c4856edb		
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	30752	no	2
			6cd4ef40a6bdf9db7728da6df8f9be0075a06cc9		
Warnings:					
Information:					
Total Files Size (in bytes):			161755		
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UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 10,064,738 B2
APPLICATION NO. : 15/490107
DATED : September 4, 2018
INVENTOR(S) : Ahmnon D. Moskowitz et al.

Page 1 of 1

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

In the Claims

Column 21; Line 9: In Claim 1, delete “seconds” and insert -- second --, therefor.

Column 21; Line 10: In Claim 1, delete “seconds” and insert -- second --, therefor.

Column 22; Line 61: In Claim 12, delete “seconds” and insert -- second --, therefor.

Column 22; Line 62: In Claim 12, delete “seconds” and insert -- second --, therefor.

Signed and Sealed this
Sixth Day of November, 2018



Andrei Iancu
Director of the United States Patent and Trademark Office