FISH.
FISH & RICHARDSON

Street Address
Fish & Richardson P.C.
3200 RBC Plaza
60 South Sixth Street
Minneapolis, MN 55402

Mail Address
P.O. Box 1022
Minneapolis, MN 55440-1022

612 335 5070 main
877 769 7945 fax

February 20, 2019

Attorney Docket No.: 46440-0009015

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

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

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

Title: BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION

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

	Pages
Specification	27
Claims	2
Abstract	1
Declaration	4
Drawing(s)	38

Enclosures:

— Application Data Sheet, 10 pages.
— Information disclosure statement, 2 pages.
PTO-1449, 9 pages.
— Power of Attorney, 2 pages.
— Certification and Request for Prioritized Examination (Track I), 2 pages

The applicant claims small entity status under 37 CFR 1.27.

Basic Filing Fee	$75
Search Fee	$330
Examination Fee	$380

MEDTRONIC EXHIBIT 1049
Medtronic, Inc. v. Moskowitz Family LLC
IPR2026-00163

Publication fee			$0
Track I processing fee			$70
Track I prioritized examination fee			$2000
Total Claims 14	over 20	**0 x $50**	$0
Independent Claims 3	over 3	**0 x $230**	$0
Fee for Multiple Dependent claims			$0
Application size fee for each 50 pages over 100 Total Sheets: 68 x .75 - 100/50 = 0 x			$0
Total Filing fee			$2855

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

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

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

Send all correspondence to:

26191
Customer Number

Respectfully submitted,

/Stuart A. Nelson/

Stuart A. Nelson
Registration No. 63,947

Enclosures

SWN/aur
100022485.doc

TRANSMITTAL FOR POWER OF ATTORNEY TO ONE OR MORE REGISTERED PRACTITIONERS

Application Number	To Be Assigned
Filing Date	Herewith
First Named Inventor	Ahmnon D. Moskowitz
Title	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION
Art Unit	Unknown
Examiner Name	Unknown
Attorney Docket Number	46440-0009015

SIGNATURE of Applicant or Patent Practitioner

Signature	/Stuart A. Nelson/	Date (Optional)	2/20/2019
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.

100022472.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):

Moskowitz Family LLC

☐ Inventor or Joint Inventor (title not required below)

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

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

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

SIGNATURE of Applicant for Patent

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

Signature	Nathan C. Moskowitz	Date (Optional)	9/17/18
Name	Nathan C. Moskowitz		
Title	Manager, Moskowitz Family LLC		

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

☐ *Total of _____ forms are submitted.

61666868.doc

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	46440-0009015
	Application Number	
Title of Invention	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING 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.)

Inventor Information:

Inventor 1 Remove

Legal Name

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

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

City	State/Province	Country of Residence
Rockville	MD	US

Mailing Address of Inventor:

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

Inventor 2 Remove

Legal Name

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

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

City	State/Province	Country of Residence
Cambridge	MA	US

Mailing Address of Inventor:

Address 1	13 Lancaster St. #2
Address 2	
City	Cambridge
State/Province	MA
Postal Code	02139
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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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	46440-0009015
	Application Number	
Title of Invention	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION	

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 4 Remove

Legal Name

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

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

City	Rockville	State/Province	MD	Country of Residence	US

Mailing Address of Inventor:

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

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

Correspondence Information:

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

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

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

Application Information:

Title of the Invention	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION		
Attorney Docket Number	46440-0009015	Small Entity Status Claimed	☒
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)	38	Suggested Figure for Publication (if any)	

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	46440-0009015
	Application Number	
Title of Invention	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION	

Filing By Reference:

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

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

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

Publication Information:

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

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

Representative Information:

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

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

Domestic Benefit/National Stage Information:

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

Prior Application Status	Pending		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
	Continuation of	15894471	2018-02-12

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	46440-0009015
	Application Number	
Title of Invention	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION	

Prior Application Status	Patented	Remove

Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
15894471	Continuation of	13210157	2011-08-15	9889022	2018-02-23

Prior Application Status	Patented	Remove

Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
13210157	Continuation of	13108982	2011-05-16	9005293	2015-04-14

Prior Application Status	Patented	Remove

Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
13210157	Continuation of	13084543	2011-04-11	8353913	2013-01-15

Prior Application Status	Patented	Remove

Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
13084543	Continuation of	11842855	2007-08-21	7942903	2011-05-17

Prior Application Status	Patented	Remove

Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
13108982	Continuation of	11842855	2007-08-21	7942903	2011-05-17

Prior Application Status	Patented	Remove

Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
11842855	Continuation in part of	11536815	2006-09-29	7846188	2010-12-07

Prior Application Status	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 or 371(c) Date (YYYY-MM-DD)
11208644	Claims benefit of provisional	60670231	2005-04-12

Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the **Add** button. Add

Foreign Priority Information:

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	46440-0009015
	Application Number	
Title of Invention	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION	

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

Remove

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

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

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

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

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	46440-0009015
	Application Number	
Title of Invention	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION	

Authorization or Opt-Out of Authorization to Permit Access:

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

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

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

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

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

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

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

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

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

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

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

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	46440-0009015
	Application Number	
Title of Invention	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION	

Applicant Information:

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

Applicant 1 — Remove

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

Clear

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

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

Name of the Deceased or Legally Incapacitated Inventor:

If the Applicant is an Organization check here. ☒

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

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

Assignee Information including Non-Applicant Assignee Information:

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

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	46440-0009015
	Application Number	
Title of Invention	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION	

Assignee 1

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

Remove

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

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

Mailing Address Information For Assignee including Non-Applicant Assignee:

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

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

Signature:

Remove

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

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

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

Signature	/Stuart A. Nelson/			Date (YYYY-MM-DD)	2019-02-20
First Name	Stuart A.	Last Name	Nelson	Registration Number	63,947

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

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	46440-0009015
	Application Number	
Title of Invention	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION	

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.**

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 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 CooperationTreaty.

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.

Electronic Patent Application Fee Transmittal	
Application Number:	
Filing Date:	
Title of Invention:	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION
First Named Inventor/Applicant Name:	Ahmnon D. Moskowitz
Filer:	Stuart A. Nelson/Abby Remer
Attorney Docket Number:	46440-0009015
Filed as Small Entity	
Filing Fees for **Track I Prioritized Examination - Nonprovisional Application under 35 USC 111(a)**	

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

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
		Total in USD ($)		**2855**

Electronic Acknowledgement Receipt	
EFS ID:	35202633
Application Number:	16280684
International Application Number:	
Confirmation Number:	1247
Title of Invention:	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION
First Named Inventor/Applicant Name:	Ahmnon D. Moskowitz
Customer Number:	26191
Filer:	Stuart A. Nelson/Nicholas Halverson
Filer Authorized By:	Stuart A. Nelson
Attorney Docket Number:	46440-0009015
Receipt Date:	20-FEB-2019
Filing Date:	
Time Stamp:	16:35:46
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	$2855
RAM confirmation Number	022119INTEFSW00002806061050
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	TrackOne Request	Track1Req.pdf	153013 a23967864f9ad94b1a57ce1e707e66ba42a009fd	no	2
Warnings:					
Information:					
2	Information Disclosure Statement (IDS) Form (SB08)	1449Doc.pdf	171691 04b936f9e7aba466a4a38222f173972f37d9ea33	no	9
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
3		Application.pdf	1684759 95348bdf9bed59f0fc556296592fd46fa6376e82	yes	30

Multipart Description/PDF files in .zip description		
Document Description	**Start**	**End**
Specification	1	27
Claims	28	29
Abstract	30	30

Warnings:					
Information:					
4	Oath or Declaration filed	Declarations.pdf	4510683 8b0cbc6175e2529631a9c3944c279ea721d7254a	no	4
Warnings:					
Information:					

5	Drawings-only black and white line drawings	Drawings.pdf	1837085 7da758557a5c794ef314ad11ca7af1843fa2d806	no	38
Warnings:					
Information:					
6	Information Disclosure Statement (IDS) Form (SB08)	IDSTrans.pdf	54819 8ddb638d912abeb9444d2adcc18e800ff663902b	no	2
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
7	Transmittal of New Application	PapTrans.pdf	102933 5a392c0db23bb31459ba4ca9c7d42da60cf69390	no	2
Warnings:					
Information:					
8	Power of Attorney	POA.pdf	756011 c2333783548b6712682f7a881e2be52a03b448a5	no	2
Warnings:					
Information:					
9	Application Data Sheet	ADS.pdf	1256891 925e3f67ea0fcc9e2f9156199233c721026c7a60	no	10
Warnings:					
Information:					
10	Fee Worksheet (SB06)	fee-info.pdf	38962 5d74e0f620b38d8fe4b4a60d7d0dbfb0244a8b58	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	10566847		

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

New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

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

Doc Code: TRACK1.REQ
Document Description: TrackOne Request

PTO/AIA/424 (03-14)

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

First Named Inventor:	Ahmnon D. Moskowitz	Non provisional Application Number (if known):	
Title of Invention:	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION		

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

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

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

3. The applicable box is checked below:

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

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

---OR---

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

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

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

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

Signature /Stuart A. Nelson/	Date 2/20/2019
Name (Print/Typed) Stuart A. Nelson	Practitioner Registration Number 63,947

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

☐ *Total of _____ forms are submitted.

100022479.doc

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.
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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.

Substitute Disclosure Form	U.S. Department of Commerce Patent and Trademark Office	Attorney Docket No. 46440-0009015	Application No. To Be Assigned
Information Disclosure Statement by Applicant (Use several sheets if necessary)		Applicant Moskowitz Family LLC	
(37 CFR §1.98(b))		Filing Date Herewith	Group Art Unit Unknown

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

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		Filing Date Herewith	Group Art Unit Unknown

U.S. Patent Documents

Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	27.	5960522	10/5/1999	Boe			
	28.	5660188	8/26/1997	Groiso			
	29.	4960420	10/2/1990	Goble et al.			
	30.	4636217	1/13/1987	Ogilvie et al.			
	31.	4554914	11/26/1985	Kapp et al.			
	32.	6953477	10/11/2005	Berry			
	33.	4599086	7/8/1986	Doty			
	34.	5062850	11/5/1991	MacMillan et al.			
	35.	5290312	3/1/1994	Kojimoto et al.			
	36.	5865848	2/2/1999	Baker			
	37.	6972019	12/6/2005	Michelson			
	38.	6629998	10/7/2003	Lin			
	39.	7211112	5/1/2007	Baynham et al.			
	40.	5405391	4/11/1995	Henderson et al.			
	41.	6824564	11/30/2004	Crozet			
	42.	7442209	10/28/2008	Michelson			
	43.	6342074	1/29/2002	Simpson			
	44.	6558423	5/6/2003	Michelson			
	45.	6432106	8/13/2002	Fraser			
	46.	7326248	2/5/2008	Michelson			
	47.	7033394	4/25/2006	Michelson			
	48.	5888223	3/30/1999	Bray, Jr.			
	49.	7862616	1/4/2011	Lechmann et al.			
	50.	8403986	3/26/2013	Michelson			
	51.	8328872	12/11/2012	Duffield et al.			
	52.	5005749	4/9/1991	Aranyi			

Examiner Signature	Date Considered

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		Filing Date Herewith	Group Art Unit Unknown

U.S. Patent Documents

Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	53.	5413583	5/9/1995	Wohlers			
	54.	5454819	10/3/1995	Knoepfter			
	55.	5951574	9/14/1999	Stefanchik et al.			
	56.	7615059	11/10/2009	Watschke et al.			
	57.	6613055	9/2/2003	Di Emidio			
	58.	8034060	10/11/2011	Keren et al.			
	59.	4064881	12/27/1977	Meredith			
	60.	5713912	2/3/1998	Porter			
	61.	5976136	11/2/1999	Bailey et al.			
	62.	6852117	2/8/2005	Orlowski			
	63.	5916224	6/29/1999	Esplin			
	64.	7727246	6/1/2010	Sixto et al.			
	65.	5968054	10/19/1999	Yeatts et al.			
	66.	7238203	7/3/2007	Bagga et al.			
	67.	7077864	7/18/2006	Byrd et al.			
	68.	6655243	12/2/2003	Anderson et al.			
	69.	4904261	2/27/1990	Dove et al.			
	70.	7875076	1/25/2011	Mathieu et al.			
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	72.	7846207	12/7/2010	Lechmann et al.			
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	74.	7887591	2/15/2011	Aebi et al.			
	75.	7959675	6/14/2011	Gately			
	76.	7972363	7/5/2011	Moskowitz et al.			
	77.	7442299	10/28/2008	Lee et al.			
	78.	20040088054	5/6/2004	Berry			

Examiner Signature	Date Considered

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		Filing Date Herewith	Group Art Unit Unknown

U.S. Patent Documents

Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	79.	20050273170	12/8/2005	Navarro et al.			
	80.	20040177531	9/16/2004	DiBenedetto et al.			
	81.	20050278026	12/15/2005	Gordon, et al.			
	82.	20050216084	9/29/2005	Fleischmann			
	83.	20050027362	2/3/2005	Williams et al.			
	84.	20050049590	3/3/2005	Alleyne et al.			
	85.	20040254644	12/16/2004	Taylor			
	86.	20020143338	10/3/2002	Orbay et al.			
	87.	20050177235	8/11/2005	Baynham et al.			
	88.	20020068977	6/6/2002	Jackson			
	89.	20070213820	9/13/2007	Magerl et al			
	90.	20100145460	6/10/2010	McDonough et al.			
	91.	20090105831	4/23/2009	Jones et al.			
	92.	20100305704	12/2/2010	Messerli et al.			
	93.	8,353,913	Jan-13	Moskowitz et al.			
	94.	8,029,512	Oct-11	Paltzer			
	95.	7776093	Aug-10	Wolek			
	96.	7628816	Dec-09	Mageri et al.			
	97.	8425607	Apr-13	Waugh et al.			
	98.	6974480	12/13/2005	Messerli et al.			
	99.	8105367	1/31/2012	Austin et al.			
	100.	8273127	9/25/2012	Jones et al.			
	101.	7135043	11/14/2006	Nakahara et al.			
	102.	2360942	10/24/1944	Ellerstein et al.			
	103.	7704279	4/27/2010	Moskowitz et al.			
	104.	7803162	9/28/2010	Marnay et al.			

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Information Disclosure Statement by Applicant (Use several sheets if necessary)		Applicant Moskowitz Family LLC	
(37 CFR §1.98(b))		Filing Date Herewith	Group Art Unit Unknown

U.S. Patent Documents

Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	105.	7942903	5/17/2011	Moskowitz et al.			
	106.	8114162	2/14/2012	Bradley			
	107.	8137405	3/20/2012	Kostuik et al.			
	108.	8167949	5/1/2012	Tyber et al.			
	109.	8414651	4/9/2013	Tyber et al.			
	110.	8540774	9/24/2013	Kueenzi et al.			
	111.	8419797	4/6/2013	Biedermann et al.			
	112.	8613761	12/24/2013	Lindermann et al.			
	113.	20080249575	10/9/2008	Waugh et al.			
	114.	20080183293	7/31/2008	Parry et al.			
	115.	20040220571	11/4/2004	Assaker et al.			
	116.	20030130737	7/10/2003	McGahan et al.			
	117.	20070250167	10/25/2007	Bray et al.			
	118.	20070276498	11/29/2007	Aebi et al.			
	119.	20080249569	10/9/2008	Waugh et al.			
	120.	20080249625	10/9/2008	Waugh et al.			
	121.	20080281425	11/13/2008	Thalgott et al.			
	122.	20090030520	1/29/2009	Biedermann et al.			
	123.	20090080997	3/26/2009	Johnson			
	124.	20090182430	7/16/2009	Tyber et al.			
	125.	20090210062	8/20/2009	Thalgott et al.			
	126.	20060155285	7/13/2006	Anderson et al.			
	127.	20090105830	4/23/2009	Jones et al.			
	128.	20120271423	10/25/2012	Wallenstein et al.			
	129.	20120277870	11/1/2012	Wolters et al.			
	130.	20120323330	12/20/2012	Kueenzi et al.			

Examiner Signature	Date Considered

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		Filing Date Herewith	Group Art Unit Unknown

U.S. Patent Documents

Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	131.	20130060339	3/7/2013	Duffield et al.			
	132.	20040193272	9/30/2004	Zubok et al.			
	133.	20090187218	7/23/2009	Schaffhausen et al.			
	134.	8728165	5/20/2014	Parry et al.			
	135.	20130073044	3/21/2013	Gamache			
	136.	8790405	7/29/2014	BIEDERMANN et al.			
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Substitute Disclosure Form

Substitute Disclosure Form	U.S. Department of Commerce Patent and Trademark Office	Attorney Docket No. 46440-0009015	Application No. To Be Assigned
Information Disclosure Statement by Applicant (Use several sheets if necessary) (37 CFR §1.98(b))		Applicant Moskowitz Family LLC	
		Filing Date Herewith	Group Art Unit Unknown

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BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION

[0001] This application is a Continuation-In-Part Application of copending application Serial No. 11/536,815, filed on September, 29, 2006, which is a Continuation-In-Part Application of copending application Serial No. 11/208,644, filed on August 23, 2005 for which priority is claimed under 35, U.S.C. §120; and this application also claims priority under 35 U.S.C. § 119(e) of U.S. provisional application No. 60/670,231, filed on April 12, 2005; the entire contents of all the above identified patent applications are hereby incorporated by reference.

Field of Invention

[0002] The present invention relates to a unique universal bidirectional screw (BDS) system, and in particular its application to the spine, also referred to as bi-directional fixating transvertebral (BDFT) screws which can be used as a stand-alone intervertebral device which combines the dual functions of an intervertebral spacer which can be filled with bone fusion material(s), as well as a transvertebral bone fusion screw apparatus. In the posterior lumbosacral and thoracic spine, BDFT screw/box constructs can be used independently or supplemented with a novel horizontal mini-plate which prevents upward bone graft intrusion into the thecal sac and nerves. In the anterior lumbosacral spine BDFT screw box constructs can be inserted into and supplemented by a circumferential cage. These posteriorly and anteriorly placed stand-alone

intervertebral body fusion constructs may obviate the need for supplemental pedicle screw fixation.

[0003] The present invention also relates to stand-alone or supplemental posterior cervical and lumbar calibrated inter-articular joint stapling devices which may obviate and/or lessen the need for supplemental pedicle screw fixation.

Description of the Relevant Art

[0004] The history and evolution of instrumented spinal fusion in the entire human spine has been reviewed in our two prior copending applications Serial No. 11/536,815, filed on September, 29, 2006, and Serial No. 11/208,644, filed on August 23, 2005, the related contents of which are hereby incorporated by reference. Currently the majority of posterior cervical and almost all anterior and posterior lumbosacral and thoracic fusion techniques are typically supplemented with pedicle screw placement. Complications of pedicle screw placement in cervical, thoracic and lumbar 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 excess rigidity leading to adjacent segmental disease requiring further fusions and re-operations. Recent advances in pedicle screw fixation including minimally invasive and image-guided technology, and the development of flexible rods, imperfectly address some but not all of these issues.

[0005] Complications of all current spinal interbody fusion devices is their lack of coverage of the majority of the cross- sectional area of the vertebral endplates, and their lack of adequate, if any capacity to penetrate bone, and hence the heightened risk of implant extrusion. Furthermore the bone and biological bone fusion agents which are packed into the intervertebral space can easily blossom and grow upward into the thecal sac causing neural compression, in the absence of a physical barrier between the fusing growing bone, and the thecal sac.

Summary

[0006] Herein we describe multiple device embodiments which combine in a single construct the dual functions of an intervertebral spacer maintaining disc space height, and transvertebral body fusion screws.

[0007] We also introduce an entirely novel horizontal mini-plate capping off the intervertebral space capable of functioning as a physical barrier preventing upward bone intrusion and/or compression of the ventral thecal sac, and traversing and exciting nerve roots.

[0008] Furthermore, we present an advanced mechanism in calibrated posterior facet joint stapling compared to our previous designs illustrated in our co-pending patents. We also introduce the entirely novel concept of posterior cervical facet staples to obviate and/or diminish the need for posterior cervical pedicle screw instrumented fusion. Using combinations and permutations of different embodiments of cervical facet staples in a modular manner advances

[0009] To achieve safe, effective and minimally invasive segmental spinal fusion, applicants propose the use of novel bi-directional fixating transvertebral (BDFT) screws which can be strategically inserted via anterior or posterior surgical spinal approaches into the anterior and middle columns of the interverterbral disc space. In our previous applications these bi-directional screws employed turning a wormed driving screw which turns a spur gear which in turn simultaneously turns a rostral oriented screw into the cephalad vertebral body, and a caudal directed screw into the caudal vertebral body. The vertebral bodies above and below the disc space by virtue of their engagement and penetration by the BDFT screws are thus linked, interlocked, and eventually biologically fused with placement of intervertebral bone agents.

[0010] In this current application one or more of the described embodiments may eliminate the intervening wormed driving screws and gears required by previous designs, e.g., a gearless screw box is achieved. We have designed a screw box to be placed inter-vertebrally, either unilaterally or bilaterally, in particular, posteriorly between vertebral bodies. The housing screw box incorporates built-in screw and/or drill guides which allow the direct placement and insertion of two self drilling screws which are driven in two opposing directions into superior and inferior vertebral bodies, respectively. One screw within the screw box is angled superiorly, and the other screw in the screw box is angled inferiorly.

[0011] In yet another embodiment, in addition to these features we designed an

expanding screw box with sliding triangular bases to house two screws driven in two opposing directions which can be expanded in two simultaneous directions , height and depth, by turning a built-in screw adjuster. This is accomplished by a combined positioning tool/screw guide/cage expander to further enhance trajectory precision and to simultaneously expand the screw box in height and depth to custom-fit the individual disc space height. This embodiment has two sub-embodiments; one has two laterally oriented BDFT screws, and the other has a lateral and a medial oriented BDFT screw. These innovations represent a continued evolution of our concept of expandable fusion cages described in our previous co-pending patents.

[0012] In yet another embodiment we designed a screw box which houses only one, instead of two screws. Each box allows the placement of one superior or inferior directed screw on one side (left or right) , and the contra lateral screw box device allows placement of an inferior or superior oriented screw which goes in the opposite direction of the contra lateral device. In totality these two separate single screw boxes fuse the superior and inferior vertebrae. The potential advantage of this embodiment is that it diminishes the width of the screw box in cases where it might be favorable to have less nerve root retraction with a smaller width device.

[0013] In all screw-box embodiments, a rostral-directed screw is passed through one built-in screw guide of the device which then is inserted and screwed into the superior vertebral body. Then a caudaly directed screw is passed through an adjacent built-in screw guide which then is inserted and screwed into the inferior

vertebral body. The novelty of this design is the built-in prescribed angles of the integral screw guides which allow the posterior transvertebral penetration into the vertebral bodies. This is a truly amazing feat accomplished in the posterior lumbar spine considering the small anatomically restricted work zone within which to work, which is very narrowly prescribed by obtuse angulations between screw and intervertebral bone surfaces, and by nerve root, facet joint and pedicle. We have also designed a positioning tool for the placement of the non-expandable screw boxes which has a screwdriver with a flexible shaft specifically designed to fit these devices if a straight screw driver impedes screw placement. Hence these external tools provide the means in any circumstance to accomplish precision screw trajectory. The embodiments described herein compared to our previous co-pending patent designs, streamline and ease production of bi-directionally oriented transvertebral screws, and allows placement of longer and wider screws with greater bone penetration to provide yet a sturdier fusion construct. The designs are also easily modifiable for anterior placement into the cervical spine. The expandable embodiment of the screw box can also be enlarged and modified to be suitable for cervical, thoracic and lumber vertebral body replacements.

[0014] The box casings have multiple perforations to allow both screw traversal and horizontal bone packing preventing upward vertical migration of bone. The boxes prevent subsidence. Both the inside of the denuded intervertebral space, and the screw boxes can be packed with autologous or allograft bone, BMP, DBX or similar osteoconductive material. Posteriorly or anteriorly in the lumbar

[0015] It is believed that BDFT- screw constructs provide as strong or stronger segmental fusion as pedicle screws without the complications arising from pedicle screw placement which include screw misplacement with potential nerve and/or vascular injury, violation of healthy facets, possible pedicle destruction, blood loss, and overly rigid fusions. By placing screws across the intervertebral space from vertebral body to vertebral body, engaging anterior and middle spinal columns, and not the vertebral bodies via the transpediclar route, the healthy facet joints, if they exist, are preserved. Because this technique accomplishes both anterior and middle column fusion, without rigidly fixating the posterior column, it in essence creates a flexible fusion. This device therefore is a flexible fusion device because the preserved posterior facet joints retain their function achieving at least a modicum of mobility and hence a less rigid (i.e. a flexible) fusion.

[0016] 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.

[0017] Transvertebral fusion also leads to far less muscle retraction, blood loss, and significant reduction in O.R. time. Thus the complication of pedicular screw pull-out and hence high re-operation rate associated with the current embodiment of flexible fusion pedicle screws/rods is obviated. The lumbosacral screw box embodiments and BDFT screws can be introduced via posterior lateral, transforaminal or anterior interbody fusion approaches /techniques. Although one can opt to supplement these screws with transpedicular screws there would be no absolute need for supplemental pedicle screw fixation with these operative techniques.

[0018] BDFT screw constructs outlined here can also be combined with novel zero-profile horizontal cervical and, lumbar/thoracic mini-plates. Likewise one or two of these devices can be inserted anteriorly with or without circumferential cage supplementation.

[0019] Because the BDFT screws engage a small percentage of the rostral and caudal vertebral body surface area, multi-level fusions can be performed with these devices.

[0020] Previous improvements included a novel calibrated lumbar /thoracic facet stapling device which staples the inferior articulating facet of the superior segment to the superior articulating facet of the caudal vertebral segment unilaterally or bilaterally, which may minimize motion until interbody fusion occurs. In the present patent application we introduce a new design of the staple enhancing its calibrating capability.

[0021] In this patent application we also introduce 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 caudal vertebral segment unilaterally or bilaterally.

[0022] 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. Thus they thereby achieve the same function of pedicle screws without the risks.

[0023] Placement of different embodiments of the cervical facet staples along unilateral and/or bilateral facet joints in a modular manner, lead to differing degrees of calibrated motion joint motion hence introducing for the first time the concept of calibrated cervical fusion.

[0024] Currently failed anterior lumbar arthroplasties are salvaged by combined anterior and posterior fusions. BDFT screw constructs could be utilized as a one-step salvage operation for failed/extruded anteriorly placed lumbar artificial discs obviating the above salvage procedure which has far greater morbidity.

[0025] For example, in one general aspect, a self-drilling bone fusion screw apparatus includes a first sliding box, a second sliding box, positioned relative to the first sliding box, a first screw member having a tapered end and a threaded body disposed within the first sliding box, a second screw member having a tapered end and a threaded body disposed within the second sliding box, and an adjuster for adjusting the height of the sliding boxes.

[0026] Implementations of this aspect may include one or more of the following features. For example, the first and second screw members may be medially aligned. At least one of the first and second screw members may be laterally aligned. The first and second screw members are laterally aligned. One of the first and second screw members is laterally aligned and the other screw member is laterally aligned. The first and second sliding boxes may be substantially triangularly shaped. The triangularly shaped first and second sliding boxes may include a sliding rail and ridged surfaces. The triangularly shaped first and second sliding boxes may include holes for bone grafts. The adjuster may include a screw.

[0027] In another general aspect, a self-drilling bone fusion screw apparatus includes a box, a first screw member having a tapered end and a threaded body disposed at least partially within the box and laterally aligned with the box, a second screw member having a tapered end and a threaded body disposed at least partially within the box and laterally aligned with the box, and a plurality of ridges disposed on along the sides of the box.

[0028] Implementations of this aspect may include one or more of the following features. For example, the apparatus may include bone graft holes. The apparatus may be attachable to a second self-drilling fusion screw apparatus via a plate.

[0029] In another general aspect, a self-drilling bone fusion screw apparatus may include a first box, a first screw member having a tapered end and a threaded body disposed at least partially within the first box and laterally aligned

with the first box, a second box, a second screw member having a tapered end and a threaded body disposed at least partially within the second box and laterally aligned with the second box, and an attachment member for engaging the first and second boxes.

[0030] Implementations of this aspect may include one or more of the following features. For example, the self-drilling bone fusion screw apparatus may include bone graft holes. The plate may be directly joined to the first and second boxes by a plurality of screws. The attachment member for engaging the first and second boxes may include a plate or the attachment member may include a circumferential cage defining at least one recess. The first and the second boxes may be positioned within or securely held within the recess of the circumferential cage, e.g, with an interference fit.

[0031] In another general aspect, a tool assembly for manipulating a self-drilling bone fusion screw apparatus includes a handle, a gripper cooperating with the handle and having a plurality of prongs, a screw guide, held in place the plurality of prongs, for controlling the direction of self-drilling screws that are screwed into a vertebral body.

[0032] Implementations of this aspect may include one or more of the following features. For example, the tool assembly for manipulating a self-drilling bone fusion screw apparatus may include a key for controlling an adjustment device which controls the height of the self-drilling bone fusion screw apparatus. The tool assembly according to claim may include a driver assembly. The driver assembly may include a handle, a drive bit portion, and a flexible drive shaft

extending between the handle and the drive bit portion for manipulating a screw of an expandable or non-expandable screw box. The assembly may include one or more of an expandable screw box and/or a non-expandable screw box. The boxes may include one or more screws. The screw boxes may be joined by or include an attachment member, such as a plate and/or a circumferential cage.

[0033] In another general aspect, a cervical facet staple includes a curved staple base, at least two prongs attached to the bottom surface of the curved staple base, and an insertion member disposed on the top surface of the curved staple base.

[0034] Implementations of this aspect may include one or more of the following features. For example, the staple may include at least four prongs attached to the bottom surface of the curved staple base. The insertion member may include a threaded insert.

[0035] In another general aspect, an impaction tool for a cervical facet staple includes a handle, a stem attached to the handle, a plurality of wings for contacting the cervical facet staple, and an insertion member for coupling the cervical facet staple to the impaction tool.

[0036] Implementations of this aspect may include one or more of the following features. For example, the handle may include a flattened portion that can be struck by a mallet.

[0037] In another general aspect, a lumbar facet staple includes a pair of rotating arms, at least two prongs attached to the inner surfaces of the rotating

arms, a plurality of spurs attached to one of the rotating arms, and a ratchet attached to one of the rotating arms. The rotating arms and prongs are rotated to a closed position to staple a lumbar facet joint.

BRIEF DESCRIPTION OF DRAWINGS

[0038] Figures 1A-D illustrate the Lumbar intervertebral screw box with one lateral oriented BDFT screw and one medially oriented two BDFT screw (Embodiment IA) in sagittal-oblique (Figure 1A), superior perspective(Figure 1B), inferior perspective (Figure 1C) and exploded (Figure 1D) views.

[0039] Figure 1E illustrates the lumbar intervertebral expandable screw box with two lateral oriented BDFT screws (Embodiment IB; sagittal-oblique view).

[0040] Figures 2A-C illustrate the Lumbar intervertebral non-expandable screw box with two BDFT screws (Embodiment II) in lateral (Figure 2A), oblique (Figure2B), and superior perspective (Figure 2C) views.

[0041] Figure 3 illustrates a superior oblique perspective view of left and right lumbar intervertebral non-expandable screw boxes with one BDFT screw (Embodiment III).

[0042] Figures 4A-B illustrate the horizontal intervertebral zero-profile mini-plate prior to insertion (Figure 4A), and after insertion (Figure 4B) into two non-expandable lumbar intervertebral screw boxes with two BDFT screws.

[0043] Figure 4C illustrates two non-expandable lumbar intervertebral screw

boxes with two screws within a large circumferential cage for anterior placement into the lumbar spine

[0044] Figures 5A-C illustrate t positioning tool / screw guide/box expander in oblique perspective (Figure 5A), lateral (Figure 5B), and exploded (Figure 5C) views.

[0045] Figure 5D illustrates a superior oblique perspective view of the positioning tool/drill guide/box expander component.

[0046] Figures E-G illustrate the sequential steps (I-III) of the positioning tooll/screw guide/box expander assembly. Step I (Figure5E), step II (Figure 5F), and step III (Figure 5G).

[0047] Figures 5H-I illustrate the positioning tool for impaction and placement of the non-expandable screw box with two transvertebral screws. Embodiment I has a rectangular positioning handle (Figure 5H), and embodiment II has a circular positioning handle (Figure 5I)

[0048] Figures 6A-B illustrate the insertion of expandable Lumbar bi-directional screw box with two BDFT screws into the Lumbar spine in oblique (Figure 6A) and lateral (Figure 6B) views.

[0049] Figures7A-B illustrate the cervical facet staple (Embodiment I) in lateral (Figure 7A) and oblique (Figure 7B) views.

[0050] Figures 8-C illustrate the cervical facet staple (Embodiment II) in oblique (Figure 8A), superior perspective (Figure 8B) and inferior-oblique (Figure 8C)

views.

[0051] Figure 9A illustrates the two-pronged cervical facet staple inserter/impactor (Embodiment I).

[0052] Figure 9B illustrates the two-pronged cervical facet staple inserter/impactor inserted into the staple (Embodiment I).

[0053] Figure 10A illustrates the four pronged cervical facet staple impactor (Embodiment II).

[0054] Figure 10B illustrates the four pronged cervical facet staple impactor inserted into the cervical facet staple (Embodiment II).

[0055] Figure 10C illustrates an inferior-oblique perspective view of the four – pronged cervical facet staple impactor (Embodiment II).

[0056] Figure 11A illustrates placement of two-pronged cervical facet staples in a three-dimensional cervical spine.

[0057] Figure 11B illustrates placement of four-pronged cervical facet staples in a three-dimensional cervical spine.

[0058] Figure 11C illustrates modular placement of two and four pronged cervical facet staples in a three-dimensional cervical spine to achieve differing calibrated degrees of flexibility.

[0059] Figures 12 A-B illustrate the Lumbar facet joint staple with a calibrated ratcheting mechanism in opened (Figure A) and closed (Figure B) positions.

DETAILED DESCRIPTION OF THE INVENTION

1. THE MEDICAL DEVICE

[0060] Referring to Figures 1-6, the above described problem can be solved in the thoracic and lumbar spine by insertion into the denuded intervertebral disc space multiple embodiments of screw box constructs with BDFT screws.

[0061] Figures 1A-D illustrate three-dimensional views of the Lumbar intervertebral expandable screw box 100 with two BDFT screws 101, 102; one lateral and one medially oriented (Embodiment IA). Figure 1E illustrates a sagittal-oblique view of the lumbar intervertebral expandable screw box 120 with two lateral oriented BDFT screws 121, 122 (Embodiment IB).

[0062] The expandable box 100 consists of top and bottom triangular sliding bases 103, 104 (Figures 1-D). The superior and inferior segments of the height/depth adjusting screw 105 are integrated and connected to the two separate top and bottom triangular bases 103, 104, respectively. By turning this adjusting screw 105 back and forth i.e. clock-wise, and counter clockwise, the sliding rails 106 of the top triangular base 103 (Figure 1D) slide up and down the rail inserts 107 on the bottom triangular base 104 (Figure 1D). This action will simultaneously alter the intervertebral height and depth of the screw box 100 allowing individualized custom fitting of the screw box 100 conforming to the dimensions of the disc space.

[0063] Transvertebral screw 101 penetrates the top base 103, and transvertebral screw 102 traverses the bottom base 104 of the screw box 100. The two screws 101, 102 traverse the screw box 100 in opposing directions, bi-

directionally (whether they are lateral or medially oriented). The external edges of the triangular bases 103, 104 in contact with vertebral body surfaces include ridges 107. This facilitates the screw box's 100 incorporation into and fusion with the superior and inferior vertebral bodies (Figures 1A-E). Both top and bottom screw box bases 103, 104 are perforated with holes 108 to allow bone placement for fusion. The entire construct, furthermore, is hollow to allow bone filling. Hence this device functions as both an intervertebral bone fusion spacer and bi-directional transvertebral screw fusion device.

[0064] Figures 2A-C illustrate three-dimensional views of the Lumbar intervertebral non-expandable screw box 200 with two BDFT screws 201, 202 (Embodiment II). Screws 201 and 202 perforate and orient in opposing, superior and inferior directions. There are holes 208 and hollow spaces allowing packaging with bone. There are also holes which allow the traversal of screws. The superior and inferior edges include ridges 207 to facilitate integration and fusion with superior and inferior vertebral bodies. The expandable screw box 200 may include a screw insert 209 to attach a horizontal mini-plate (not shown). The self-contained internalized drill guides are at a 25 degree angle. The screw boxes can be designed with the internalized drill guides with different angles and/or different positions within the box.

[0065] Figure 3 illustrates a three-dimensional view of left and right lumbar intervertebral non-expandable screw boxes 300a, 300b with one BDFT screw 301 or 302 (Embodiment III). It is roughly half the width of Embodiments I and II. Screw 301 is inserted into screw box 300a (left) and screw 302 is inserted into

screw box 300b (right). There are holes 308 and hollow spaces allowing packing of bone to achieve biological fusion. The combined effect of one superior oriented and one inferior oriented screw fuses the superior and inferior vertebral bodies with small constructs. This also enables placement of larger dimension screws compared to embodiments I and II.

[0066] Figures 4A and B illustrate three-dimensional views of the horizontal intervertebral zero profile mini-plate 400 with two non-expandable lumbar intervertebral screw boxes 300a, 300b housing two BDFT screws 301, 302. Figure 4A illustrates the perforations 401 within the plate 400 through which small plate securing screws 310 will be inserted to connect it to the built-in screw holes of the screw box 300a, 300b (Figure 4B). The horizontal mini-plate 400 together with the top surfaces of left and right screw boxes 300a, 300b provide a physical barrier between the underlying bone placed beneath it (not illustrated), and the thecal sac and nerve roots above it (not illustrated).

[0067] Figure 4C illustrates two screw boxes 300c, 300d within a circumferential cage 420 (2 in 1) construct which is designed for anterior placement into the lumbar spine. There are slots 308a, 308b for bone graft placement, both outside and inside the boxes. The circumferential cage 420 has perforations 401a for the placement of transvertebral screws (not shown).

[0068] Figures 5A-C illustrate three-dimensional views of the external drill /screw guide -box expander 500 which assists in screw trajectory and box expansion (embodiments IA-B). For embodiments II and III, the same instrument is utilized; however, an expanding Allen key component is not used.

[0069] The key components of this device include an Allen key 501, a spring 502, a handle 503, a griper 504 and a screw guide 505. The Allen key 501 when inserted in the insertion 514 and turned, turns the screw adjuster (Figure 5C) which in turn regulates top and bottom triangular screw box base sliding, and hence box 200 width and depth. The griper 504 has griper prongs 506 which insert into grooves of the screw guide 505 and the screw box 200 (Figures 5A-D) thus perfectly aligning them.

[0070] Figure 5D illustrates a superior oblique view of the screw guide 505 demonstrating insertions 509 for griper prong 506, built-in trajectory guides 511, 512 for insertions of screws 101 and 102, and the Allen key 501.

[0071] Figures 5E-G illustrate three–dimensional views of the sequential steps necessary for the external guide assembly. Figure 5E illustrates the insertion of the Allen key 501 into the handle 503. Figure 5F illustrates the insertion of the handle 503 through the spring 502 and griper 504. Figure 5G illustrates insertion of the griper 504 into the screw guide 505.

[0072] Figures 5H-I illustrate three-dimensional views of a positioning tool 500a for impaction and placement of two transvertebral screws 201, 202 in the non-expandable screw box 200. The driver assembly 550 consists of a screw driver 551, a flexible shaft 552 and a square recess bit 553. This facilitates turning the screws 201, 202 into the bone. The flexible shaft 552 facilitates the avoidance of spinous processes which might hinder the screw driving if the shaft 552 were straight. The positioning tool 500a can have a rectangular handle, Embodiment I (Figure5H), or a circular handle, Embodiment II (Figure 5I). This serves to

position the screw box within the intervertebral space, and screws 201, 202 within the screw box. Once positioned, the screw box can be impacted by tapping the handle with a mallet (not shown). The positioning tool's 500a griper handle inserts into the screw guide and the box, which maintains alignment.

[0073] Figure 6A illustrates a three-dimensional view of insertion of the construct (Embodiment I) into the lumbar intervertebral disc space.

[0074] Figure 6B illustrates a three dimensional lateral view of insertion of the construct (Embodiment I) into the disc space with short screws. Placement with longer screws would capture more bone.

[0075] Figures 7Aand B illustrate three-dimensional views of the two-pronged cervical facet staple 700 (Embodiment I). There is a staple base 701 which is contoured to align with the curved surface of the cervical facet joints. There is a superior impactor threaded insert 702. An impactor can be screwed into this insert 702 and then impacted with a mallet. The two spikes 703, 704 perforate the inferior and superior facets of the superior and inferior vertebral bodies hence leading to cervical facet joint fusion. The spikes can be designed with ridges and/ or fishhooks to facilitate irreversible extraction.

[0076] Figures 8A-C illustrate three-dimensional views of the four-pronged cervical facet staple 800 (Embodiment II). Likewise it has a staple base 805 contoured specifically for the surface of the facet joint. It also has an impactor insert 806. The insertion of a device with four prongs 801-804 instead of two prongs further limits the degrees of motion of the joint hence making the fusion more rigid.

[0077] Figures 9 A-B illustrate a three-dimensional view of the two-pronged cervical staple impactor 900. It has a handle 901, a stem 902, and a screw insert 903 which can be screwed into the threaded staple insert. The impactor has two wings 904 which keep the staple base edges in place facilitating staple impaction. The handle 901of the impactor 900 is broad in order to allow impaction by a mallet.

[0078] Figures 10A -C illustrate three-dimensional views of the four-pronged cervical staple impactor 1000 (Embodiment II). It has the same features as the two-pronged impactor 900, except its wings 1004 are broader accommodating the broader staple base. The impactor 1000 also includes a handle 1001, a stem 1002, and an impact screw 1003.

[0079] Figure 11A illustrates a three-dimensional view of placement of the two pronged cervical facet staple 700 into a cervical spine model having vertebral body 1103 and lamina 1104. One staple 700 is perched on the joint 1101 prior to impaction. The other staple 700 is impacted.

[0080] Figure 11B illustrates a three-dimensional view of placement of the four pronged cervical facet staple 800 into a cervical spine pre and post impaction.

[0081] Figure 11C illustrates the concept of modularity and incremental diminution of movement of the joint by the modular placement of different combinations and permutations of varying numbers of two and four pronged cervical facet staples 700, 800. If one wishes to have the most flexible (least rigid) fusion, one would place a unilateral two pronged staple 700. One can increase i.e. calibrate increasing degrees of rigidity by increasing the number of

prongs penetrating the facet joints bilaterally. In Figure 11C each facet joint is fused using a total number of six prongs. One side this is accomplished by using three two pronged staples 700, and on the other side using one four pronged staple 800 and one two pronged staple 700. These two embodiments can be mixed and matched unilaterally or bilaterally to vary the degree of rigidity and conversely flexibility of fusion. The most flexible fusion at one level would be accomplished by one staple 700 (2 prongs). The highest level of rigidity would be achieved by placing two four pronged staples 800 on both sides totaling sixteen prongs. Intermediate degrees of relative joint motion can be modulated by insertion into the cervical facet joints staples in two-four prong increments from 2-16. Each additional prong further limits the degree of facet joint motion hence increasing rigidity, and conversely decreasing flexibility. Thus the novel modular use of these embodiments heralds an era of flexible cervical spine fusion.

[0082] Figures 12 A - B illustrate a lumbar facet joint staple 1200 in open and closed positions and having staple prongs 1203. This lumbar facet staple has been thoroughly described in our previous co-pending patent applications, Serial No. 11/536,815, filed on September, 29, 2006, and Serial No. 11/208,644, filed on August 23, 2005, the relevant portion of each of which is hereby incorporated by reference hereinafter. The new improvement of this device includes a ratchet 1201. The staple 1200 can be incrementally closed with increased ratcheting over increasing number of spurs 1202. This achieves increasing calibrated levels of lumbar facet joint fusion, and conversely diminishing joint flexibility. This new designs further enhances the capacity to achieve flexible fusions in the lumbar

spine.

2. THE SURGICAL METHOD

[0083] Exemplary surgical steps for practicing one or more of the foregoing embodiments will now be described.

[0084] The posterior lumbar spine implantation of all the screw box 100, 200, 300 embodiments, with BDFT screws, and horizontal mini-plate 400 can be implanted 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. Fluoroscopic guidance can be used with any of these procedures.

[0085] After 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, a unilateral or bilateral facet sparing hemi-laminotomy is created to introduce screw box 100, 200, 300 embodiments I-III into the disc space, after it is adequately prepared.

[0086] 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.

[0087] Then one screw box 100, 200, 300 of either embodiments I-III is placed

on either right, left or both sides. Then another screw box of embodiments 100, 200, 300 I-III is placed on the contralateral side. For embodiment I the external screw guide 505/ box expander is attached to the screw box (Figures 5A-H). First the Allen key 501 is screwed until the box conforms perfectly to the height and depth of the space. Then a pilot hole can be drilled or an awl can start a pilot hole in the vertebral bodies. Then a transvertebral screw is screwed into the vertebral body via the built- in box screw guides 505. For difficult angles, an angled screw driver can be employed.

[0088] For embodiments II-III the same method is used for placing screws, except the Allen key 501 is not utilized in the absence of plate expansion.

[0089] If bilateral constructs have been inserted, bone is packed into the intervertebral space, as well as within the device. Then the horizontal intervertebral zero profile mini-plate 400 is slid beneath the thecal sac and is secured to both left and right screw boxes with small mini-plate screws 210 (Figures 4A-B). This prevents bone intrusion into the thecal sac and hence possible nerve root compression.

[0090] Figures 6A and B illustrate the process of insertion and final placement of the construct into the lumbar spine. The mini- plates 400 can come in different horizontal lengths and widths to accommodate different intra and inter -patient disc space diameters. The BDFT screws can come in different widths, lengths and thread designs.

[0091] The anterior thoracic and lumbar spine implantation of one, two or three screw box constructs 100, 200, 300 and BDFT screws can be performed in a

similar manner to the posterior application. Likewise, a horizontal mini-plate 400 can be used to cap two or three screw box constructs 100, 200, 300 (one placed midline deeply, one placed left and one placed right, forming a triangulation). Alternatively two screw box constructs may be placed into a circumferential ring for anterior placement. Anterior placement of these devices can be performed into the L4/5 and L5/S1 spaces on the supine anesthetized patient via previously described open microscopic or endoscopic techniques. Once the disc space is exposed and discectomy and space preparation are performed, placement of one, two or three screw box embodiments 100, 200, 300 (I-III) or a 2 in I construct can be placed. The screw placement is facilitated by the internal screw guides, and different positioning tools ((Figure 5). A right angled screw driver and/or ratchet could alternatively be employed A capping mini-plate 400 may be applied if desirable. The mechanism of screw placement and mini-plate 400 attachment are identical to what was described above.

[0092] The posterior placement of screw box constructs 100, 200, 300 alone or combined with horizontal mini-plates 400 into the thoracic spine can be performed via previously described transpedicular approaches; open or endoscopic. The anterior placement into the thoracic spine can be accomplished via a trans-thoracic approach. Once the disc space is exposed via either approach, any combination of the above mention Embodiments (I-III) can be inserted. Engagement of the devices is identical to what was mentioned above.

[0093] For posterior placement of cervical facet staple 700, 800 embodiments, after adequate induction of anesthesia the patient is flipped prone and his head

and neck secured. A single midline or two para-median incisions are made for unilateral or bilateral or multilevel placement of staples. Ultimately the facet joint is exposed. Alternatively and preferably this can be performed percutaneously under fluoroscopic guidance with intravenous sedation. The staple 700, 800 (Embodiments I or II) is loaded into the impactor 900, 1000. The staple 700, 800 is placed on the two articulating cervical facets, and then impacted into the joint. To achieve modular calibrated fusion different combinations and permutations of cervical facet stales 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 staples 800 (16 prongs) leading to the highest degree of rigidity. Additional bone may or may not be placed in its vicinity to facilitate permanent and solid fusion. This procedure can be performed open, closed, percutaneously, tubulary, endoscopically or microscopically. Figures 11 A-C illustrates placement of the staples 700, 800 in the cervical spine.

[0094] We have previously described surgical placement of the lumbar facet joint staple in our two co-pending patents. The surgical procedure for this device is identical to that which has been previously mentioned.

[0095] The present inventions may provide effective and safe techniques that overcome the problems associated with current transpedicular based cervical, thoracic and lumbar fusion technology, and for many degenerative stable and unstable spine disease. These inventions could replace much pedicle screw-based instrumentation in many but not all degenerative spine conditions.

[0096] The speed and simplicity of placement of cervical and lumbar facet

staples, and placement of Lumbar screw box –BDFT constructs far exceeds that of current pedicle screw technology. Furthermore, these devices have markedly significantly decreased risk of misguided screw placement, and hence decreased risk of neural and vascular injury, and blood loss. In the lumbar spine BDFT screw constructs and facet staples could be applied modularly in different combinations to achieve different degrees of rigidity (flexibility). Patients having these devices would have decreased recovery and back to work time. These devices most likely lead to similar if not equal fusion with significantly less morbidity, and hence overall make them a major advance in the evolution of spinal instrumented technology leading to advances in the care of the spinal patient.

[0097] Another major novelty and advance is the introduction of simple and safe modular calibrated cervical flexible fusion. To our knowledge neither a similar device nor a similar mathematical concept of modular joint flexibility/fusion calibration has been postulated for the cervical spine or for any other articulating joint.

[0098] To our knowledge there have not been any previously described similar posterior lumbar and thoracic combined spacer and screw constructs. These devices can similarly be modified to stabilize bone fractures throughout the entire body. To our knowledge the description of zero to subzero profile anterior or posterior horizontal spinal plates which traverse the diameter of the disc space has not been previously described.

We claim:

1. A self-drilling bone fusion screw apparatus, which comprises:

a first sliding box;

a second sliding box, positioned relative to the first sliding box;

a first screw member having a tapered end and a threaded body disposed within the first sliding box;

a second screw member having a tapered end and a threaded body disposed within the second sliding box,; and

an adjuster for adjusting the height of the sliding boxes.

2. The self-drilling bone fusion screw apparatus according to claim 1 wherein the first and second screw members are medially aligned.

3. The self-drilling bone fusion screw apparatus according to claim 1 wherein at least one of the first and second screw members is laterally aligned.

4. The self-drilling bone fusion screw apparatus according to claim 3 wherein both the first and second screw members are laterally aligned.

5. The self-drilling bone fusion screw apparatus according to claim 1 wherein one of the first and second screw members is laterally aligned and the other screw member is laterally aligned.

6. The self-drilling bone fusion screw apparatus according to claim 1 wherein the first and second sliding boxes are substantially triangularly shaped.

7. The self-drilling bone fusion screw apparatus according to claim 6 wherein the triangularly shaped first and second sliding boxes include a sliding rail and ridged surfaces.

8. The self-drilling bone fusion screw apparatus according to claim 7 wherein the triangularly shaped first and second sliding boxes include holes for bone grafts.

9. The self-drilling bone fusion screw apparatus according to claim 8 wherein the adjuster includes a screw.

10. A self-drilling bone fusion screw apparatus, which comprises:

a box;

a first screw member having a tapered end and a threaded body disposed at least partially within the box and laterally aligned with the box;

a second screw member having a tapered end and a threaded body disposed at least partially within the box and laterally aligned with the box; and

a plurality of ridges disposed on along the sides of the box.

11. The self-drilling bone fusion screw apparatus according to claim 10 which further includes bone graft holes.

12. The self-drilling bone fusion screw apparatus according to claim 11 which is attachable to a second self-drilling fusion screw apparatus via a plate.

13. A tool assembly for manipulating a self-drilling bone fusion screw apparatus, which comprises:

a handle;

a gripper cooperating with the handle and having a plurality of prongs;

a screw guide, held in place the plurality of prongs, for controlling the direction of self-drilling screws that are screwed into a vertebral body.

14. The tool assembly for manipulating a self-drilling bone fusion screw apparatus, according to claim 13, which further includes a key for controlling an adjustment device which controls the height of the self-drilling bone fusion screw apparatus.

ABSTRACT OF THE DISCLOSURE

A self-drilling bone fusion screw apparatus is disclosed which includes at least first and second sliding boxes. A first screw member having a tapered end and a threaded body is disposed within the first sliding box, and a second screw member having a tapered end and a threaded body disposed within the second sliding box. An adjuster adjusts the height of the sliding boxes. The screw members are screwed into vertebral bodies in order to fuse the vertebral bodies together. A plurality of the self-drilling bone fusion screw apparatuses may be attached together and/or integrated via a plate or cage. Also disclosed is a cervical facet staple that includes a curved staple base and at least two prongs attached to the bottom surface of the curved staple base. .

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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 TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION

As the below named inventor, I hereby declare that:

This declaration is directed to:

[ ] The attached application, or

[X] United States application or PCT international application number 15/894,471

filed on February 12, 2018.

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.

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LEGAL NAME OF INVENTOR

Inventor: Ahmnon D. Moskowitz Date (Optional) :

Signature:

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LEGAL NAME OF INVENTOR

Inventor: Pablo A. Valdivia Y. Alvarado Date (Optional): 30/5/2018

Signature:

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LEGAL NAME OF INVENTOR

Inventor: Mosheh T. Moskowitz Date (Optional): 5/11/18

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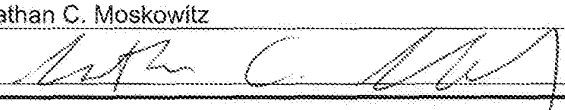
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Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card 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: Nathan C. Moskowitz Date (Optional): 5/11/18

Signature: 

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

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 1 minute to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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

61683172.doc

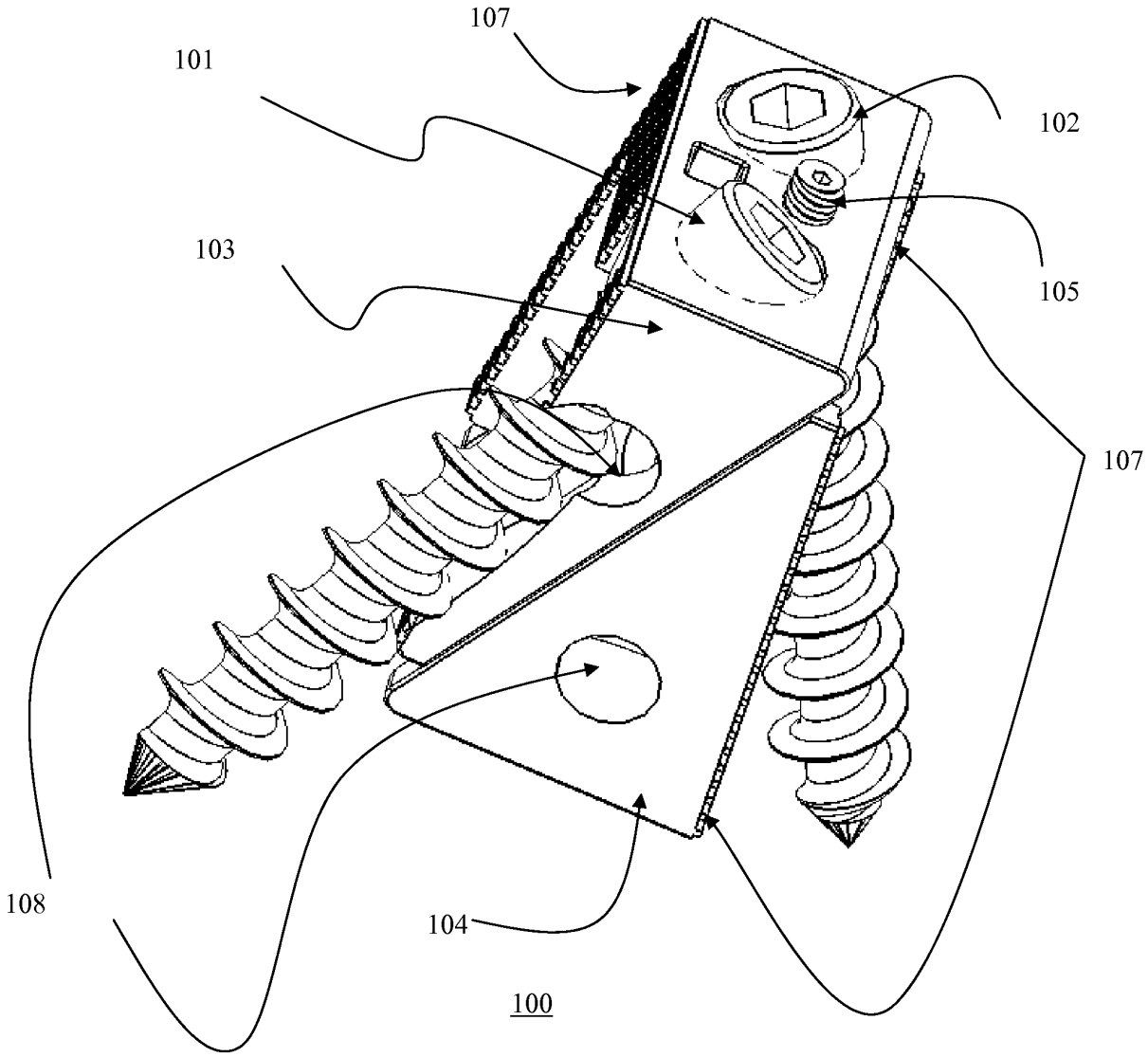


Fig. 1A

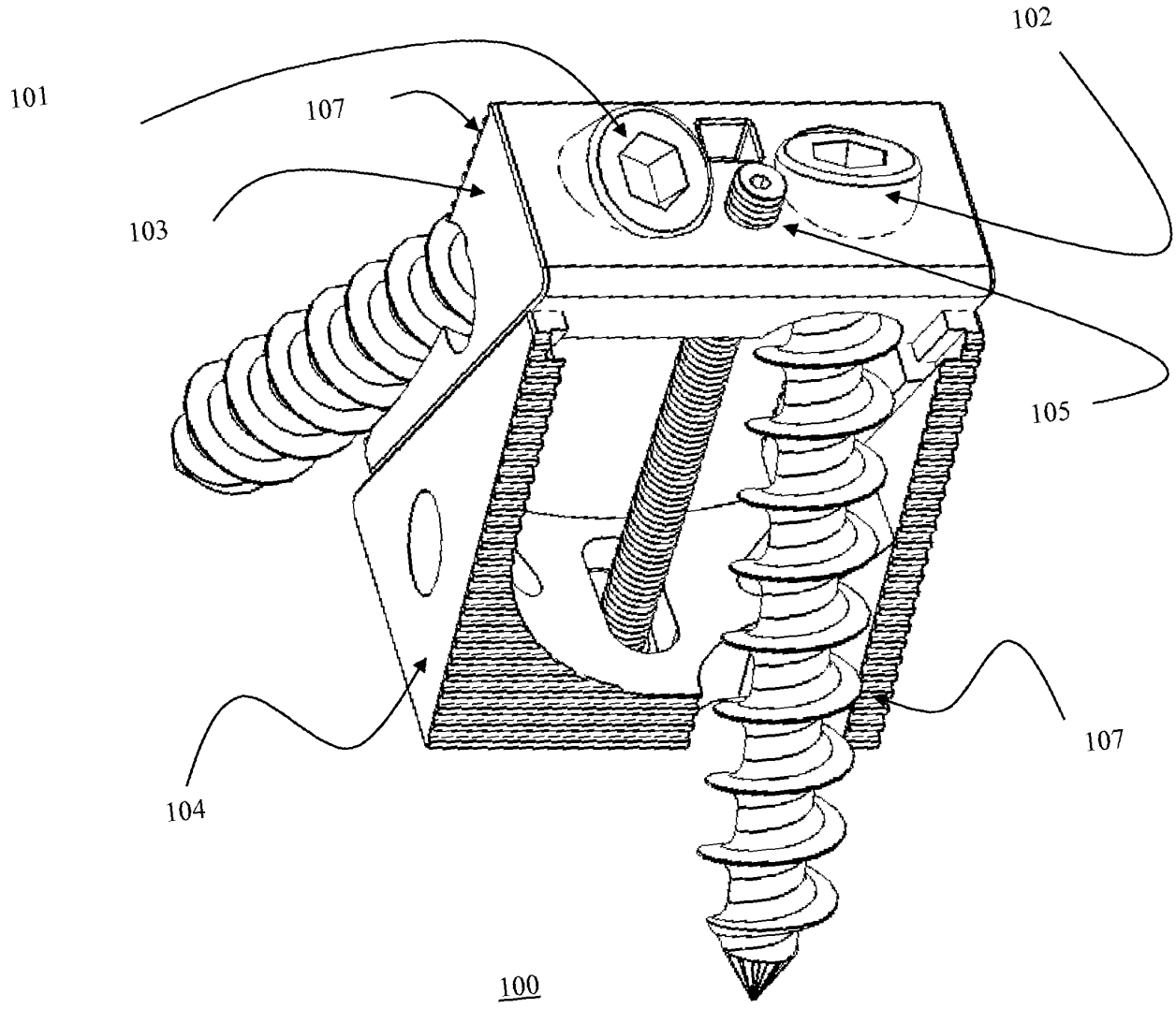


Fig. 1B

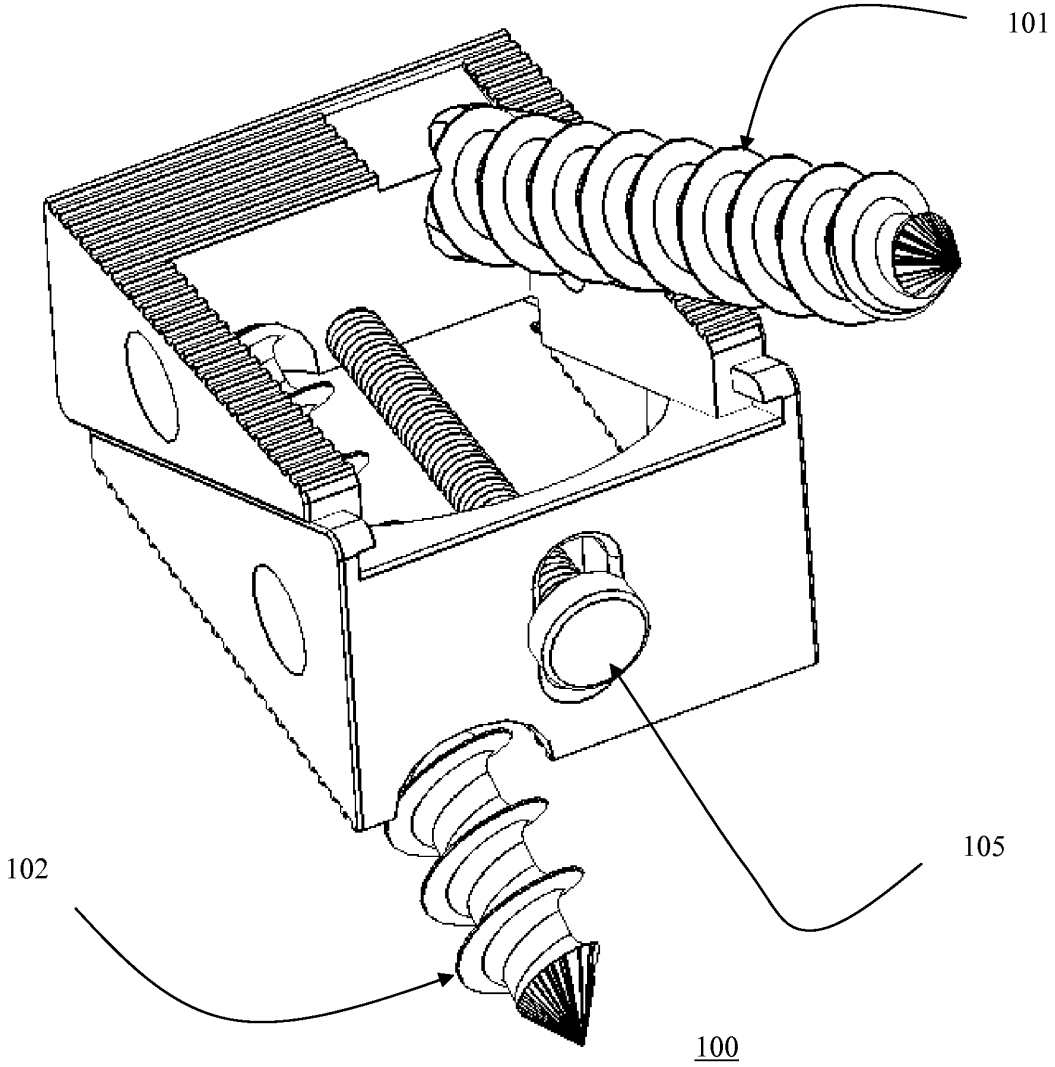


Fig. 1C

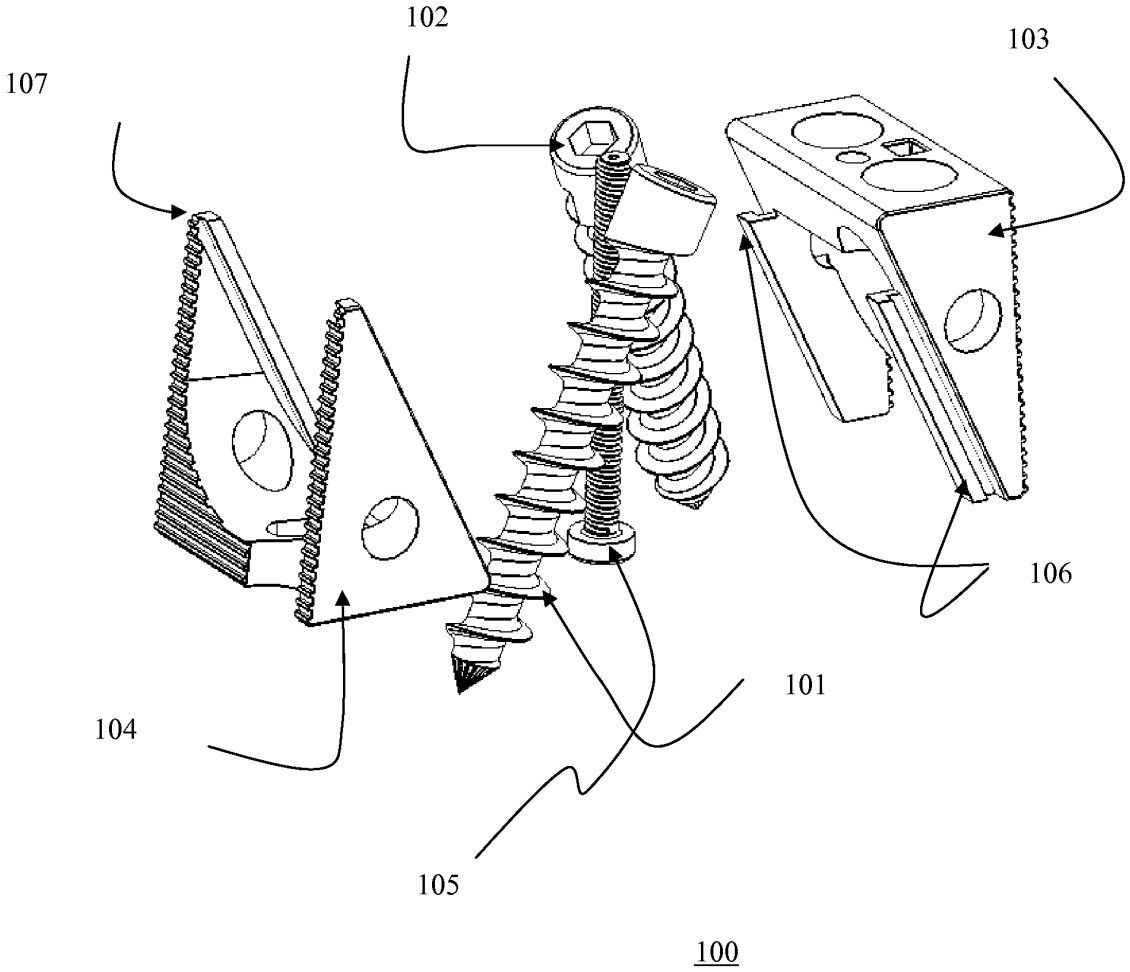


Fig. 1D

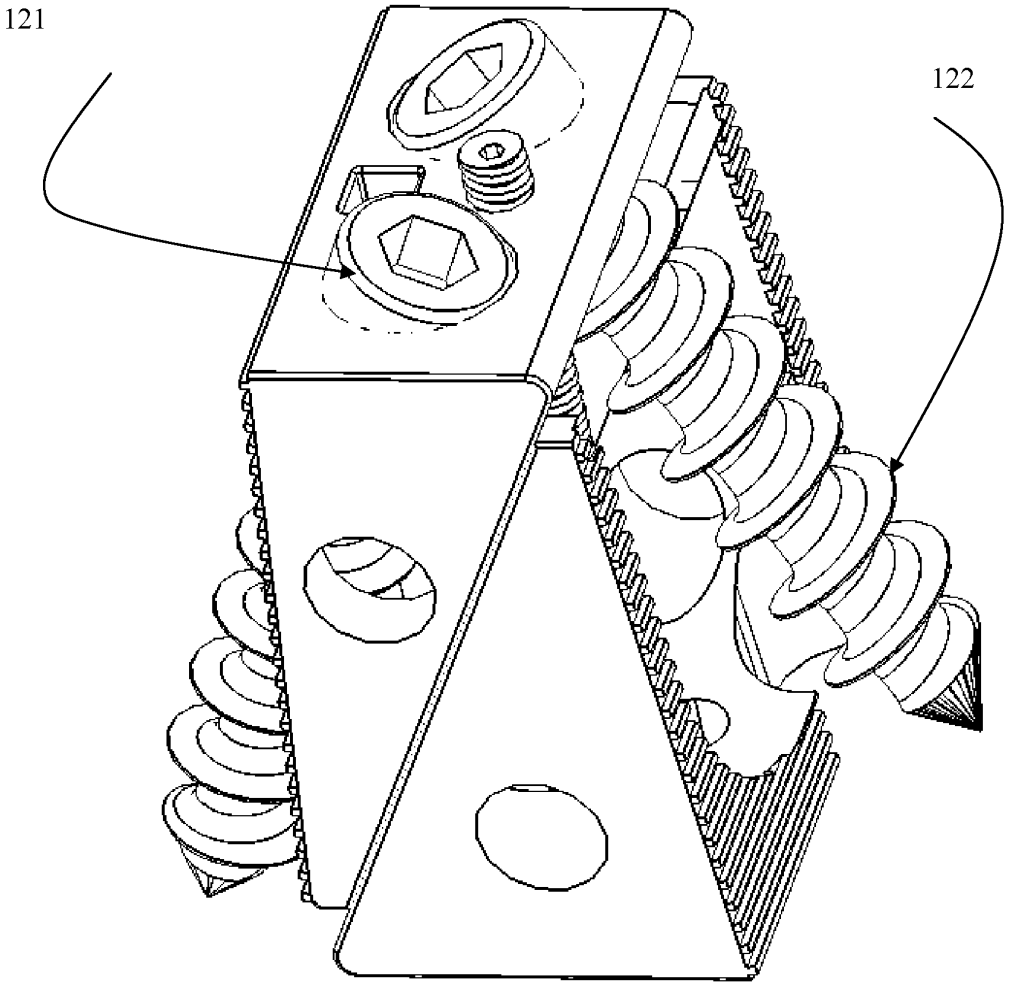


Fig. 1E

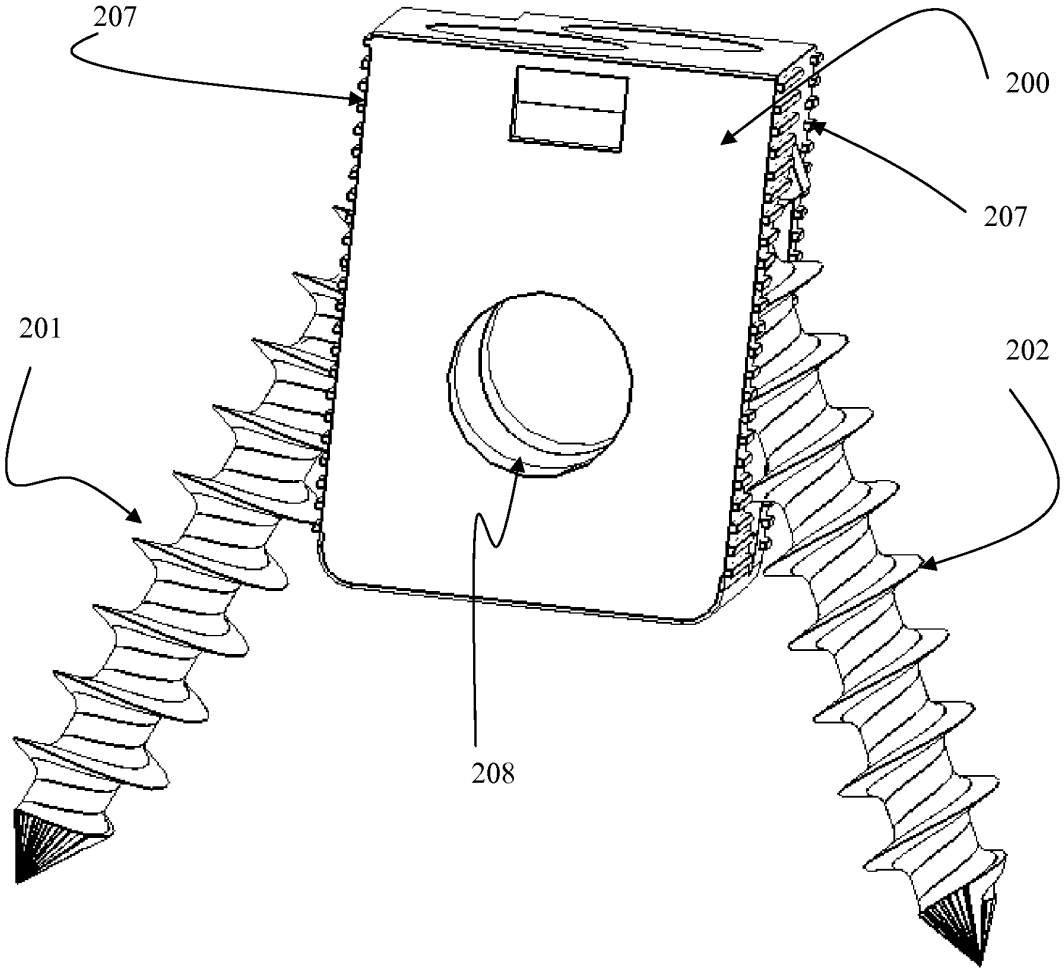


Fig. 2A

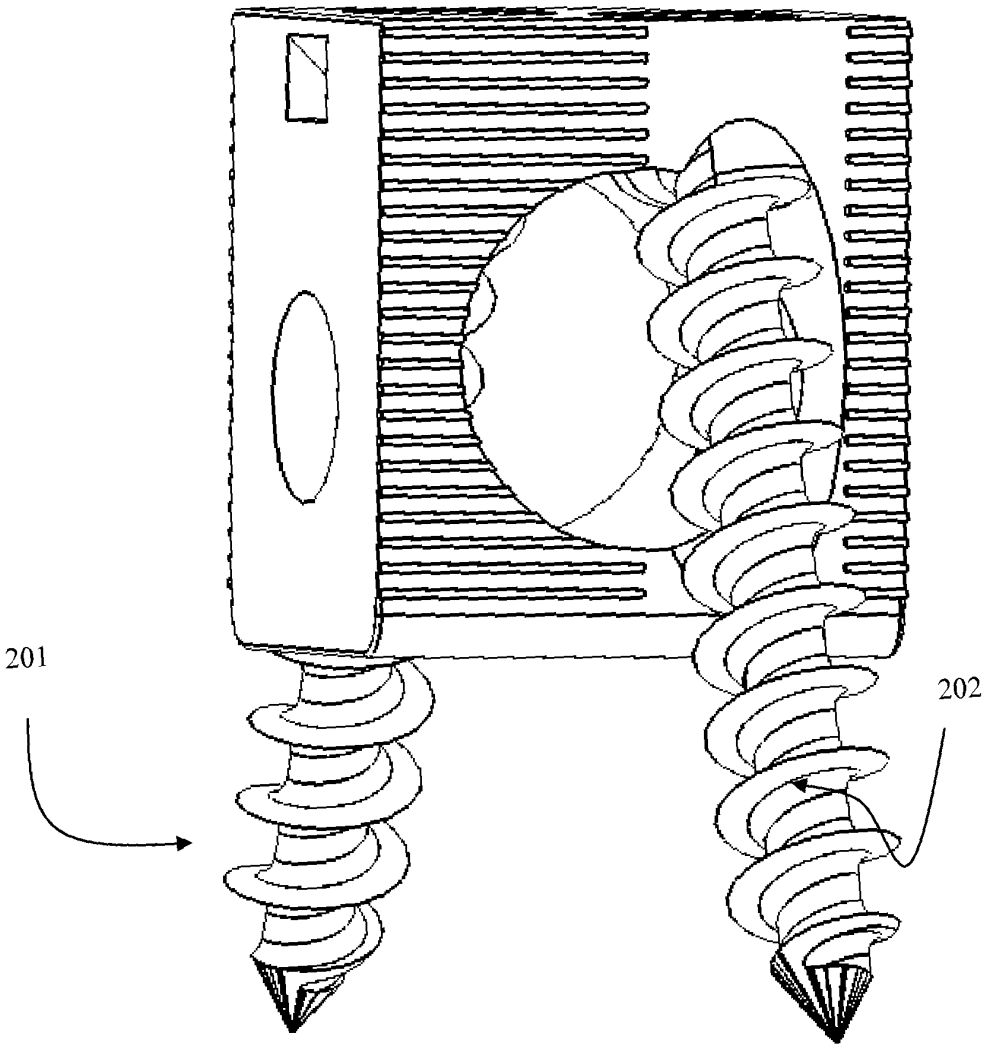


Fig. 2B

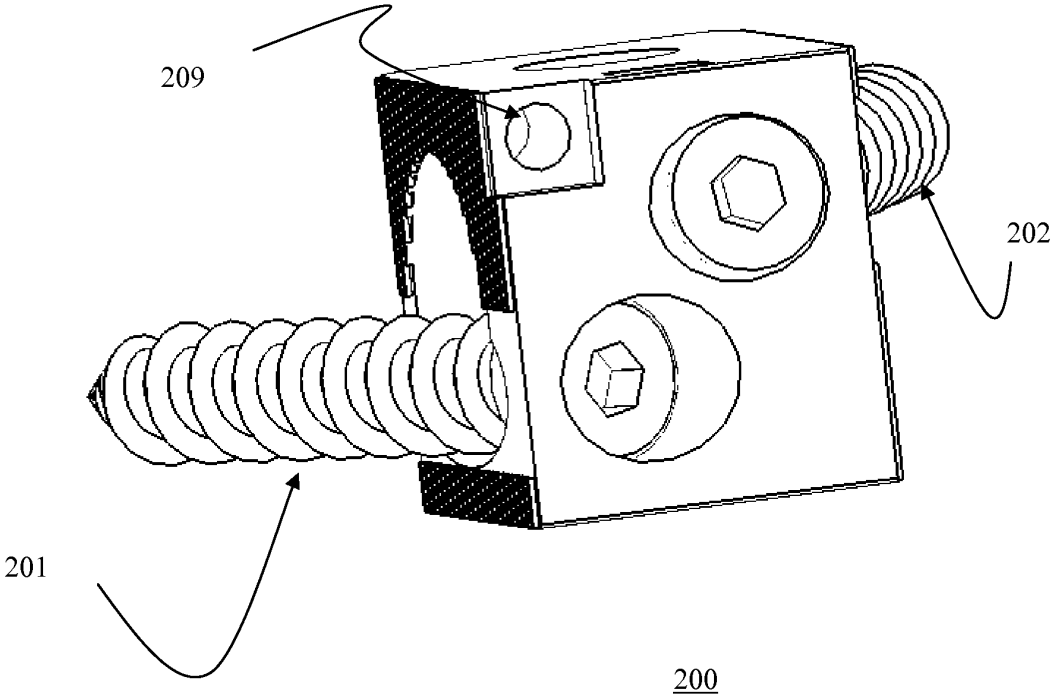


Fig. 2C

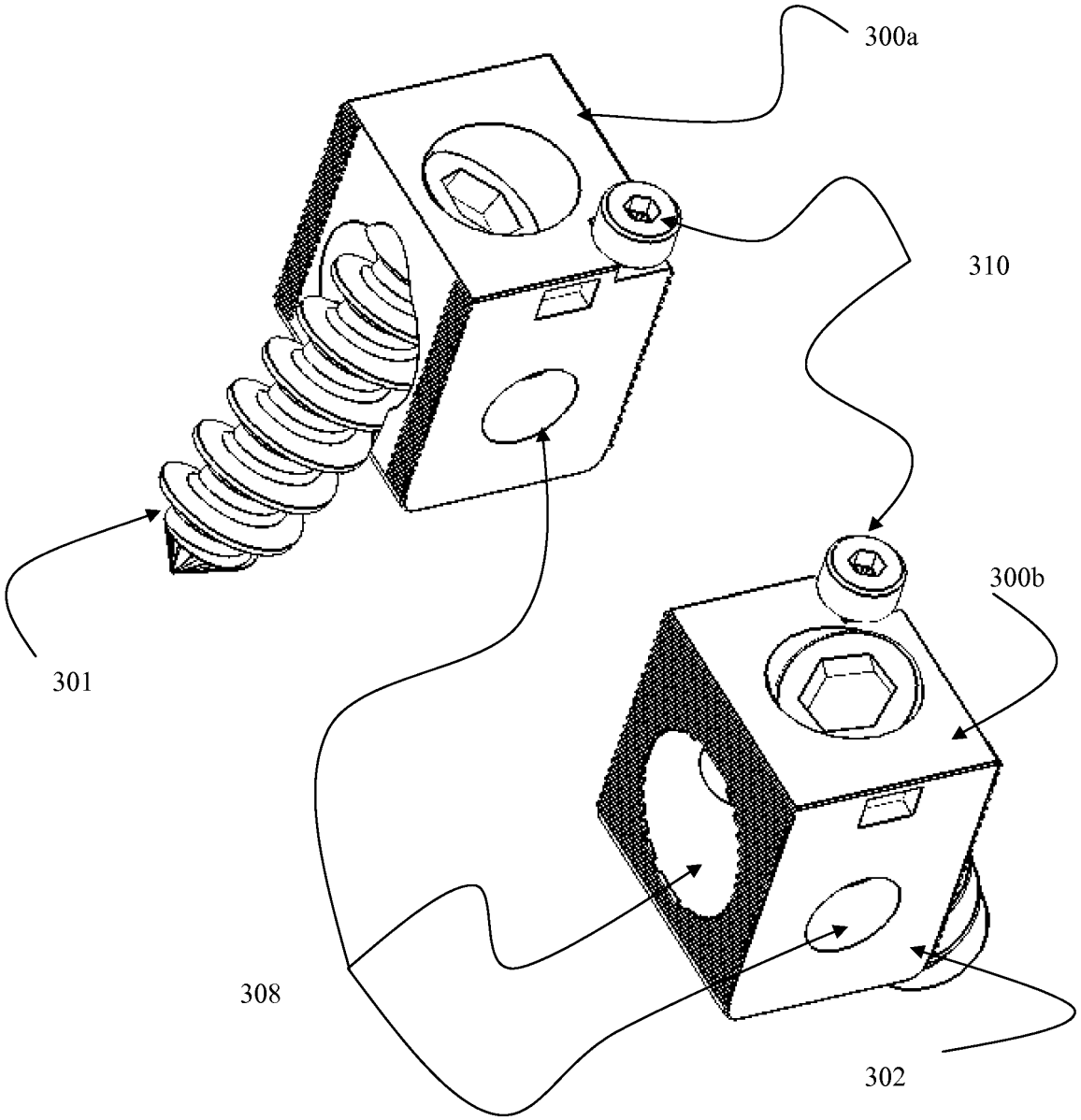


Fig. 3

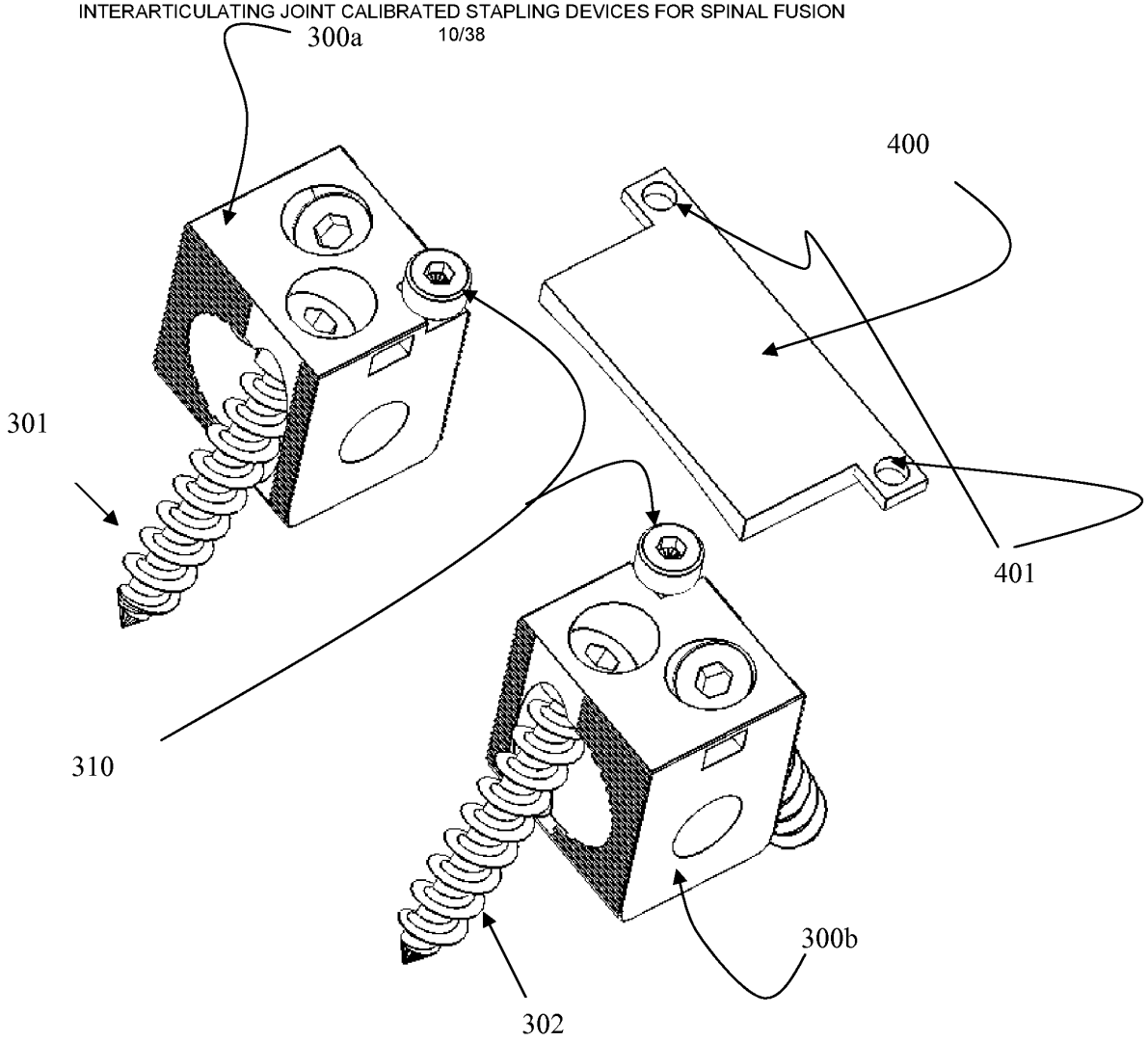


Fig. 4A

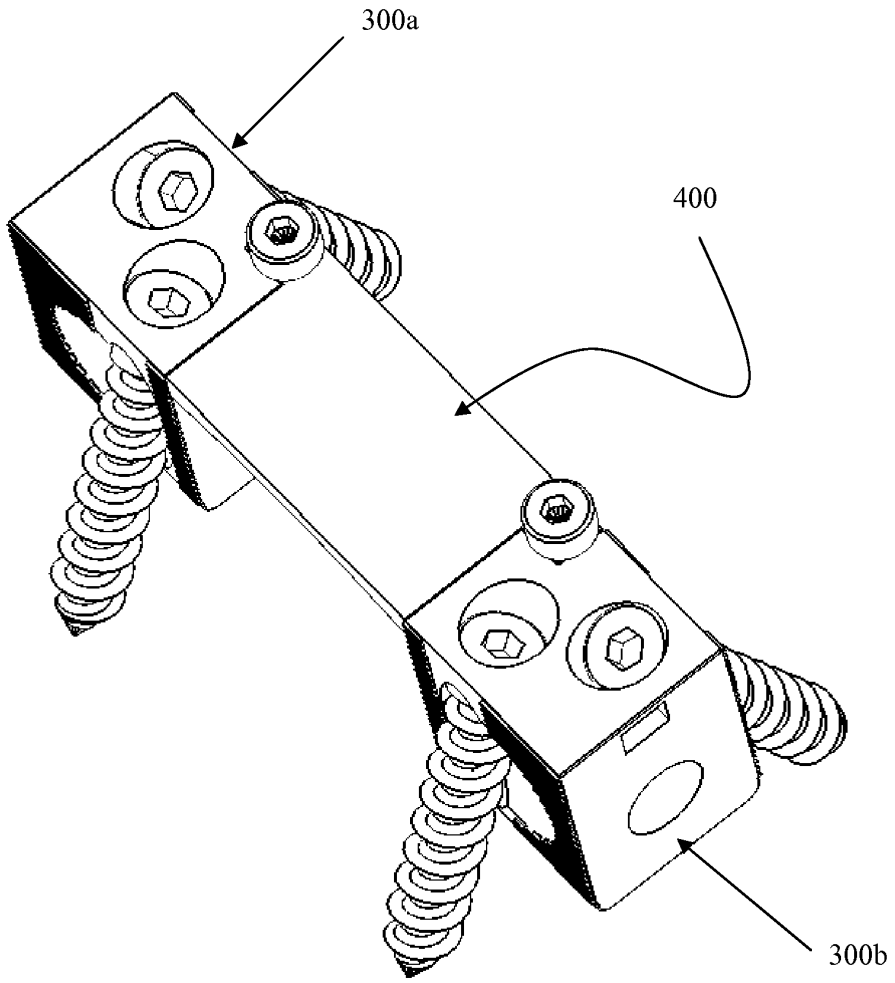


Fig. 4B

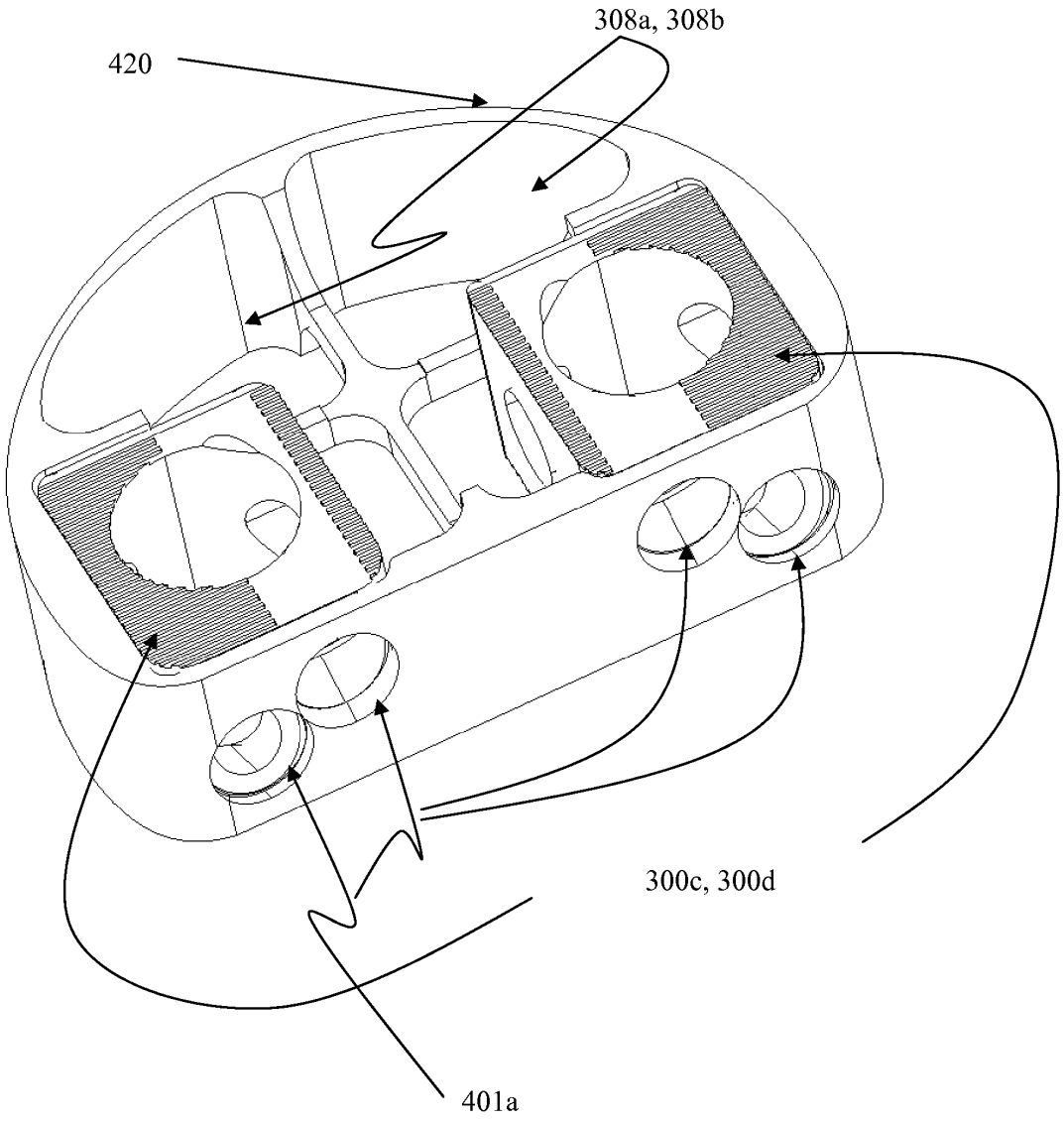


FIG. 4C

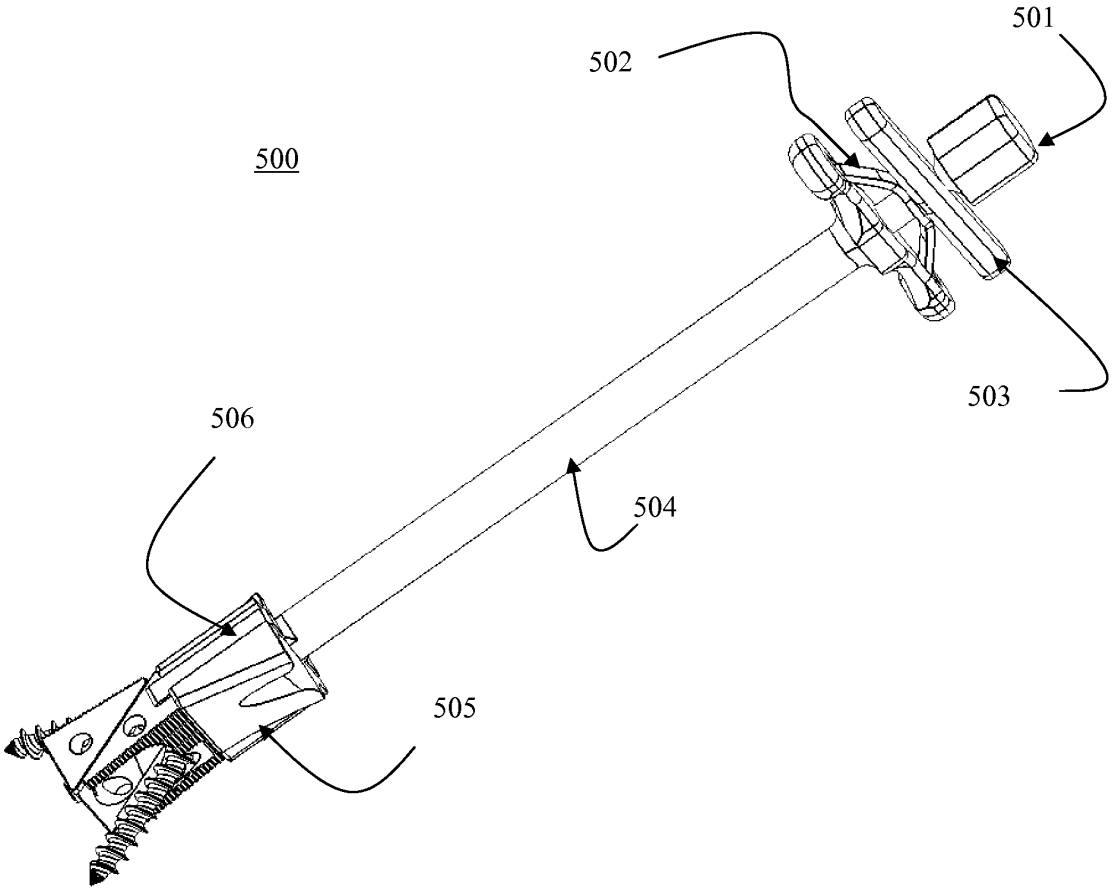


Fig. 5A

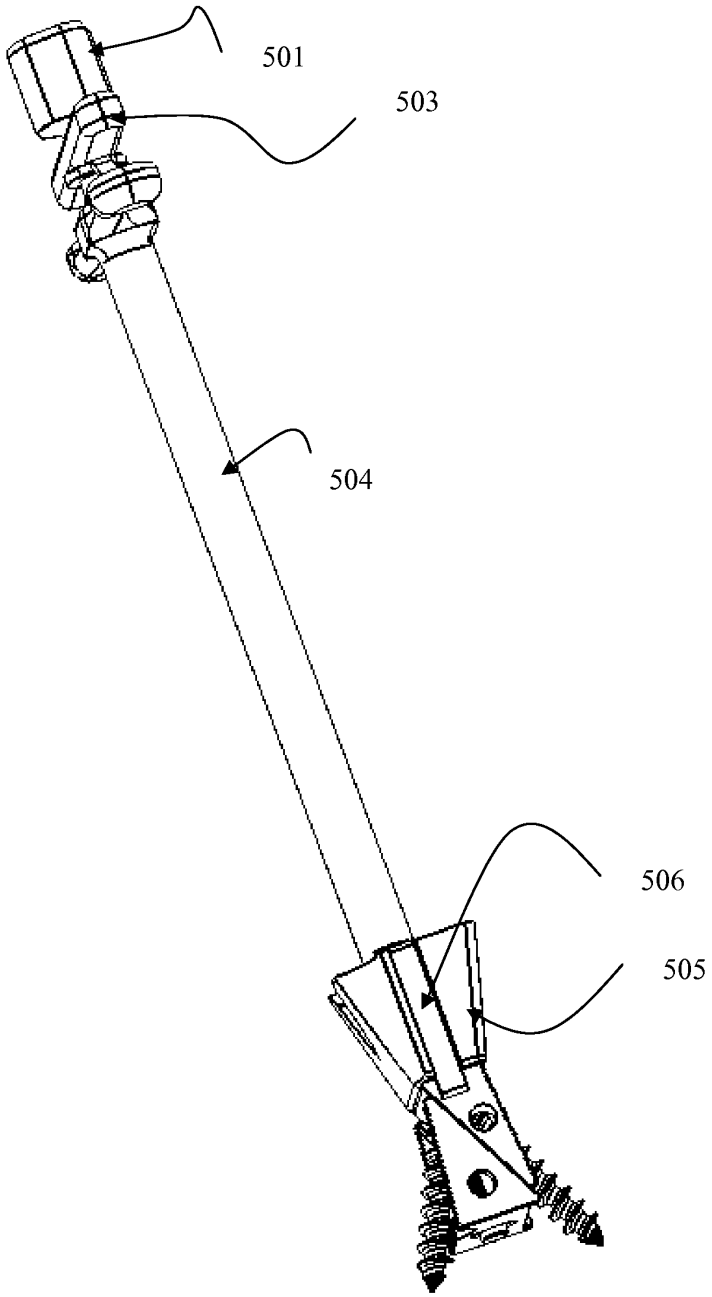


Fig. 5B

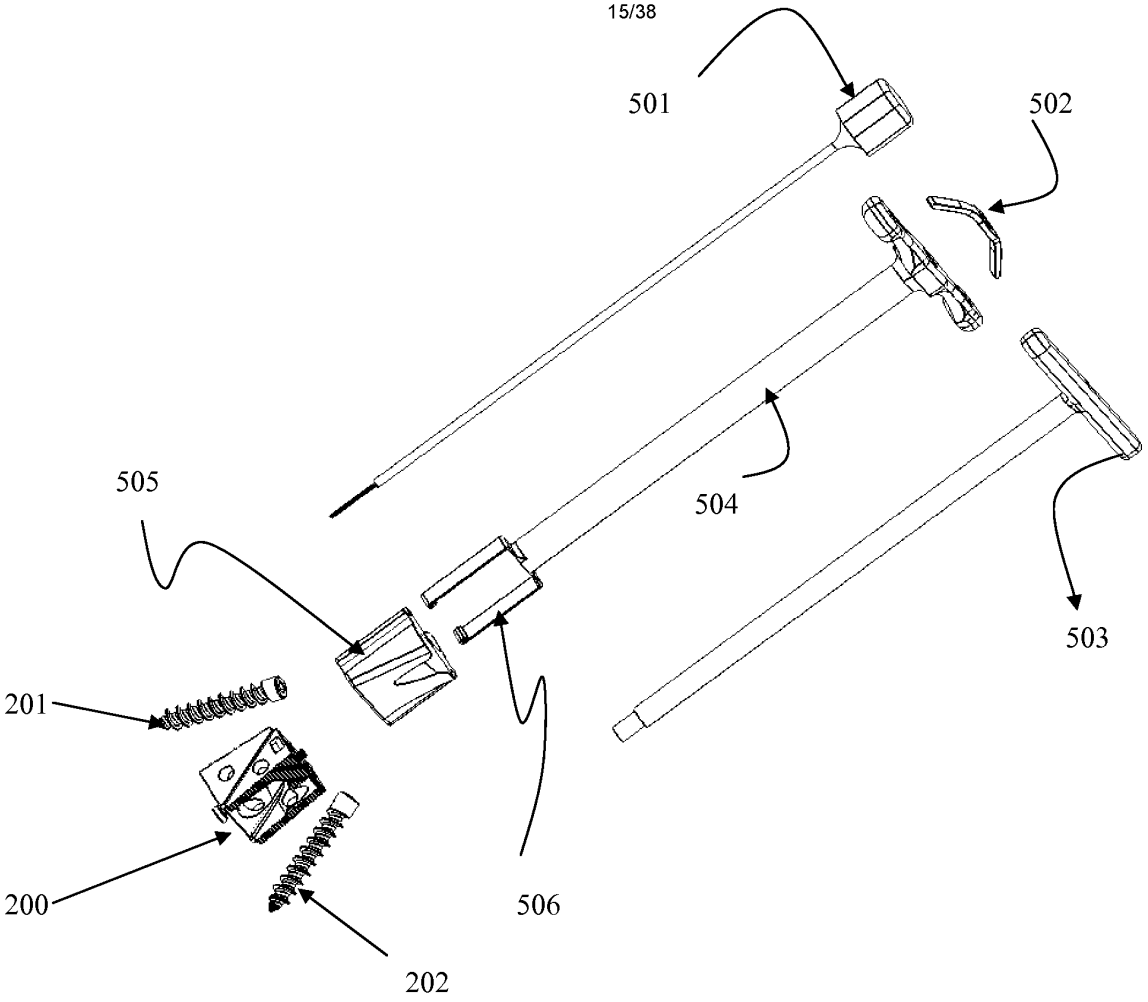


Fig. 5C

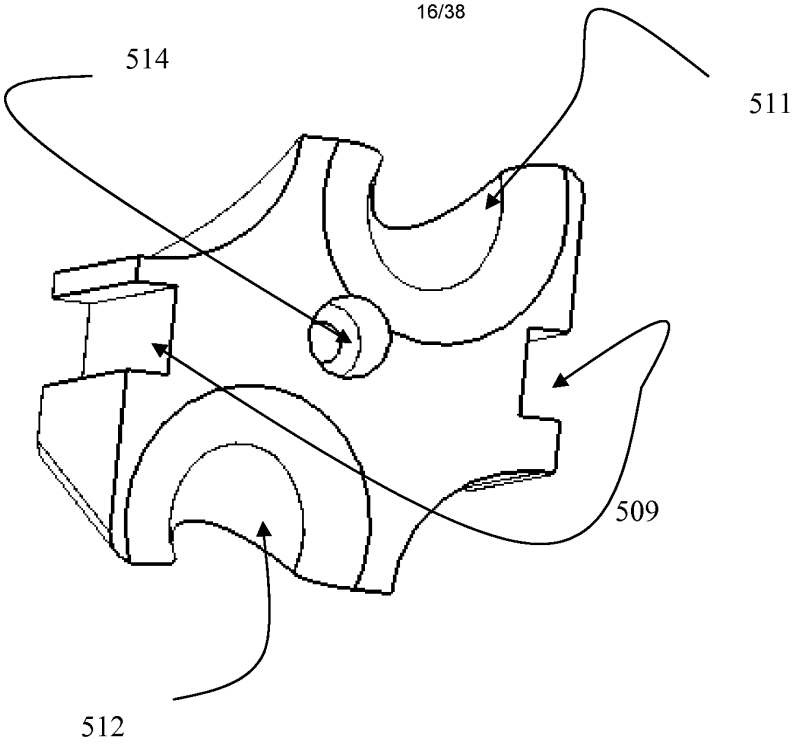


Fig. 5D

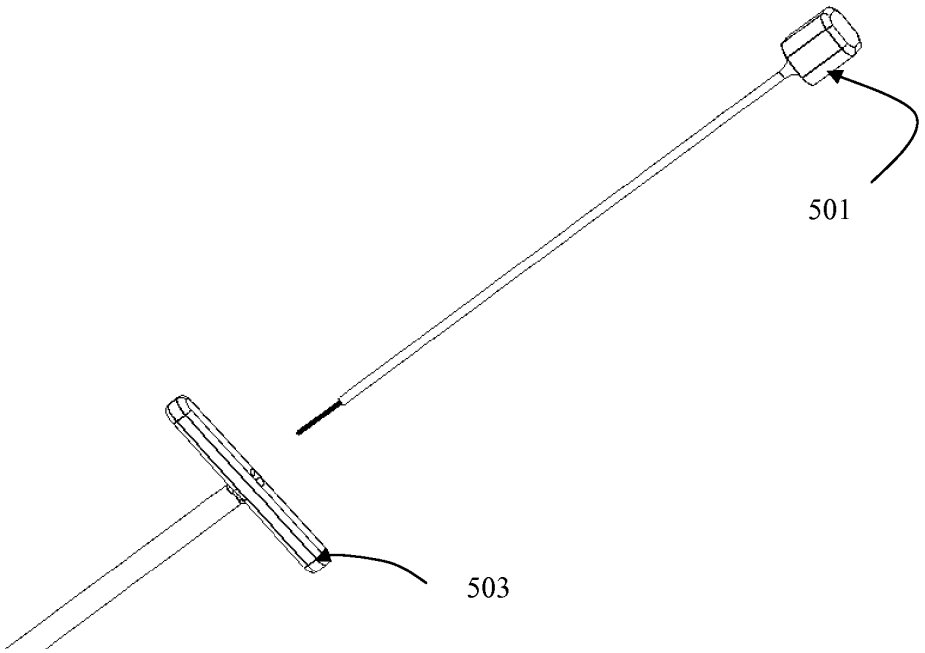


Fig. 5E

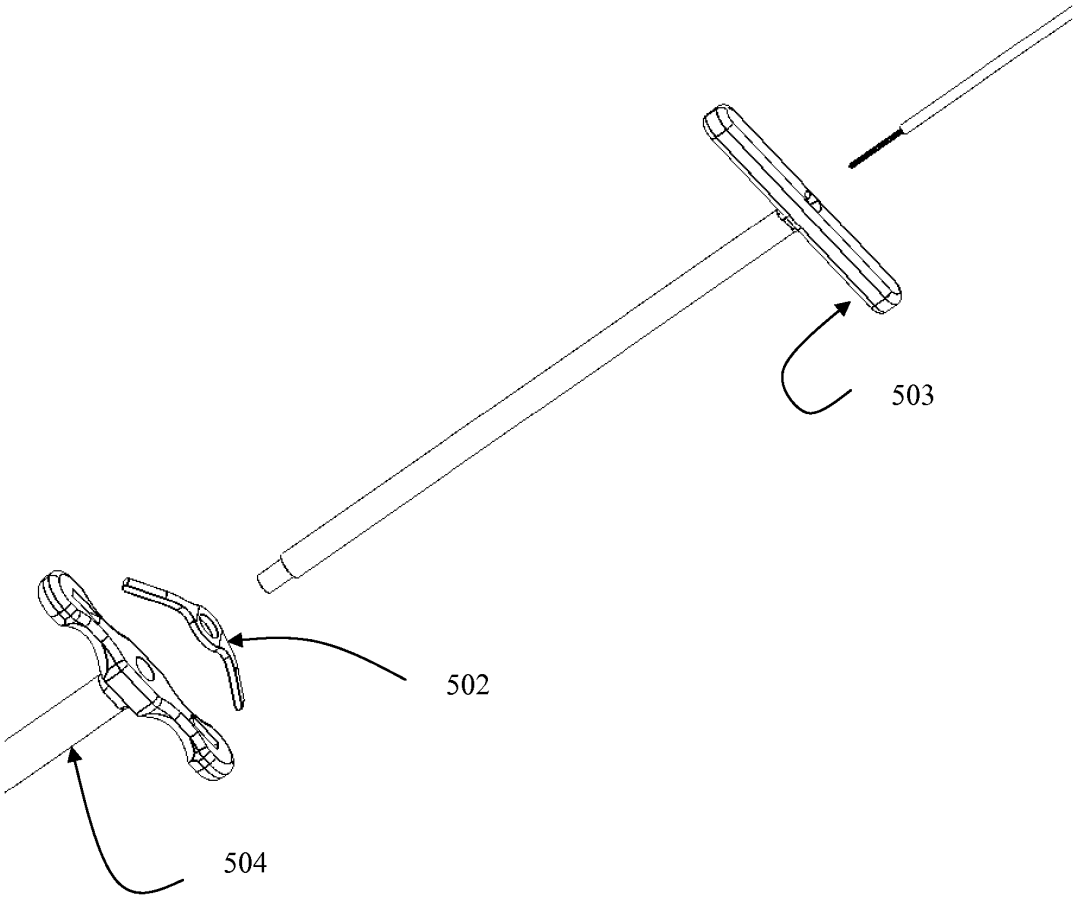


Fig. 5F

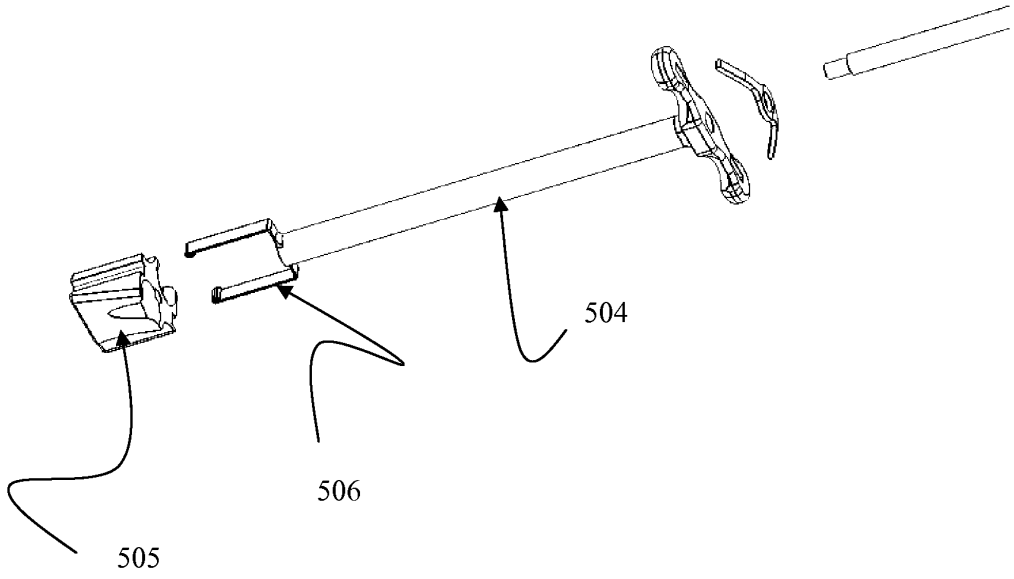


Fig. 5G

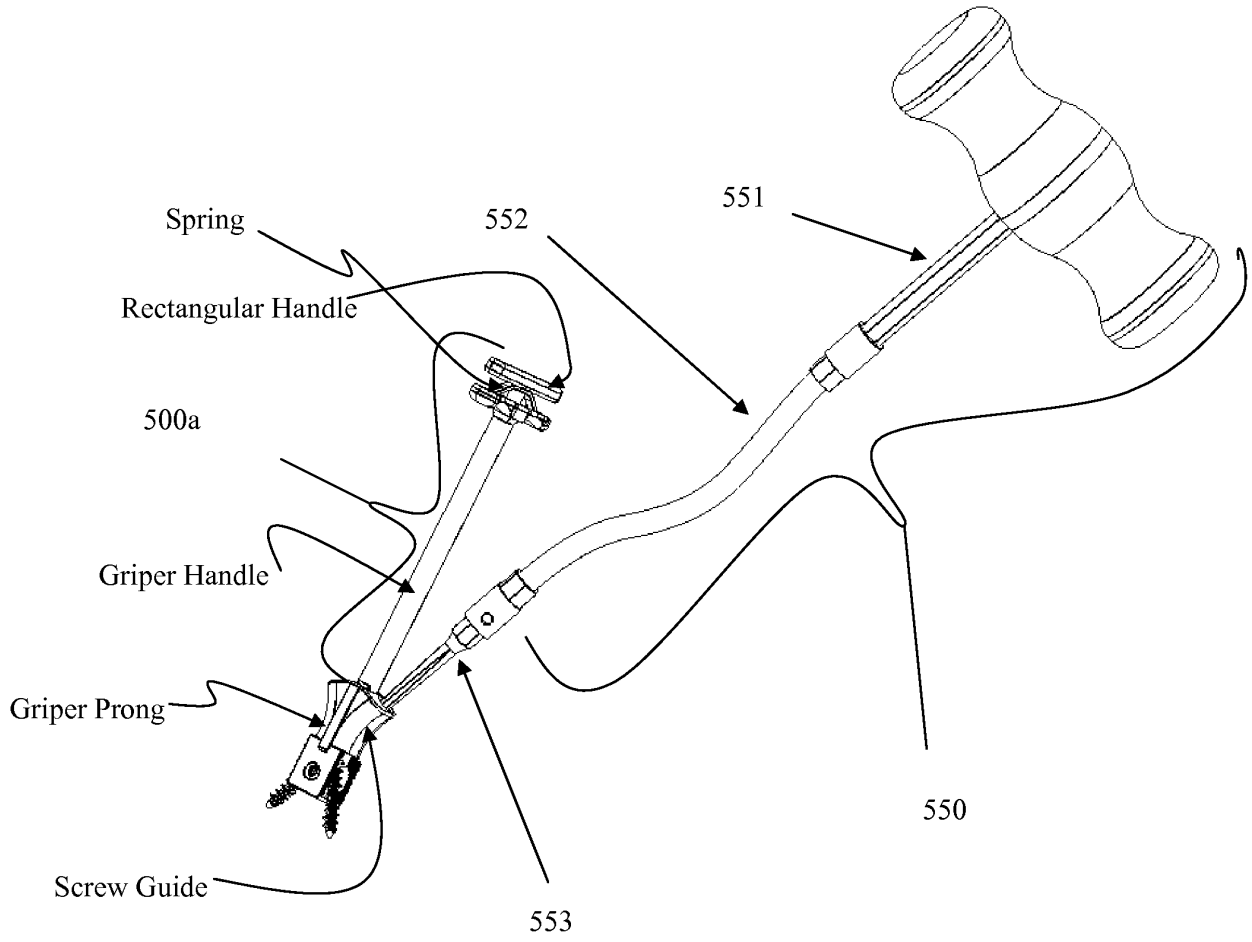

Spring
552
551
Rectangular Handle
500a
Griper Handle
Griper Prong
550
Screw Guide
553

FIG. 5H

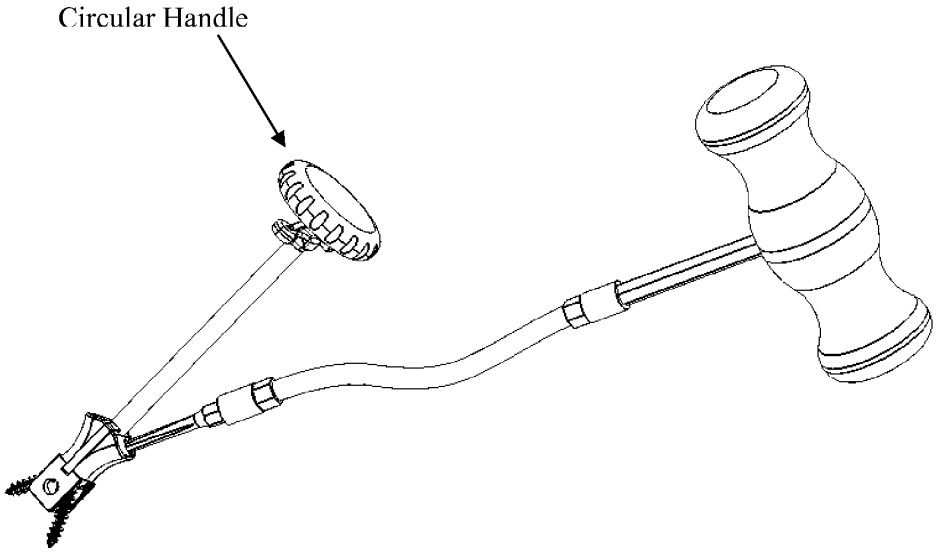


FIG. 5I

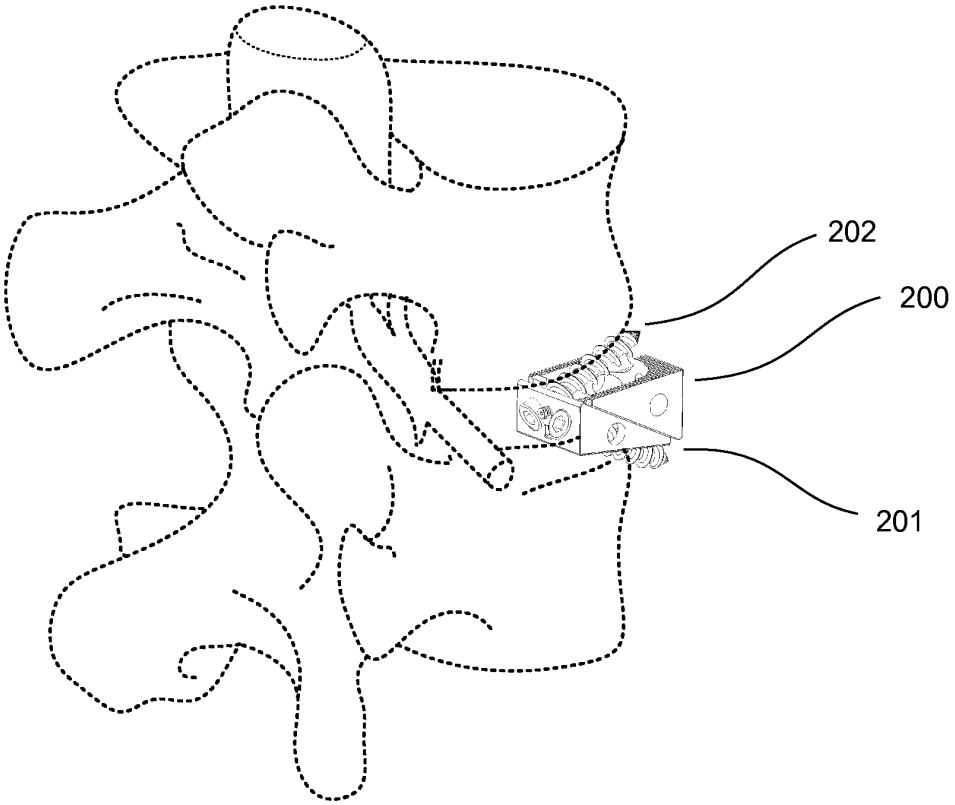


Fig. 6A

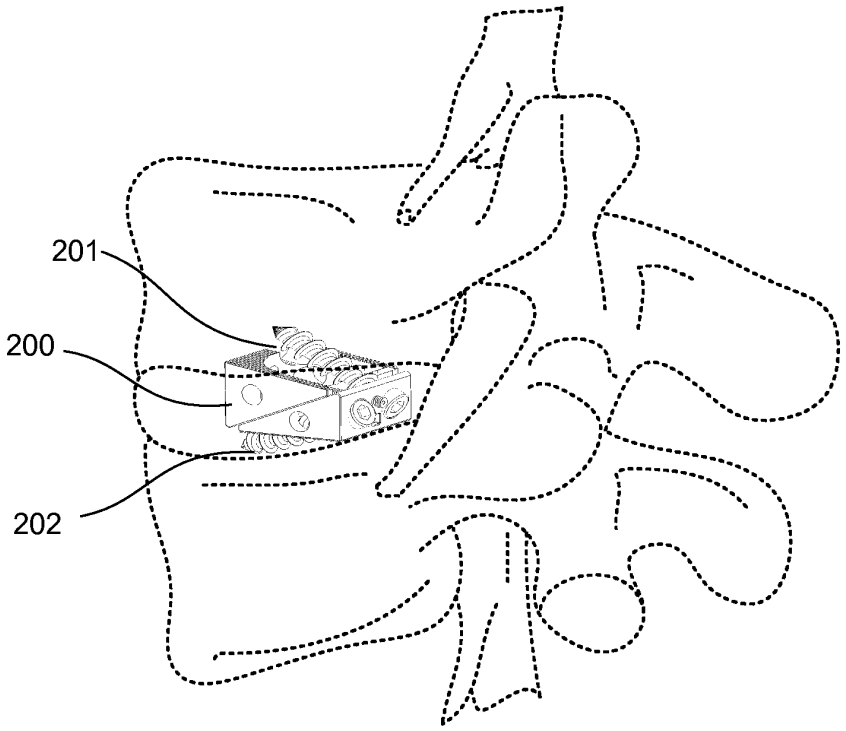


Fig. 6B

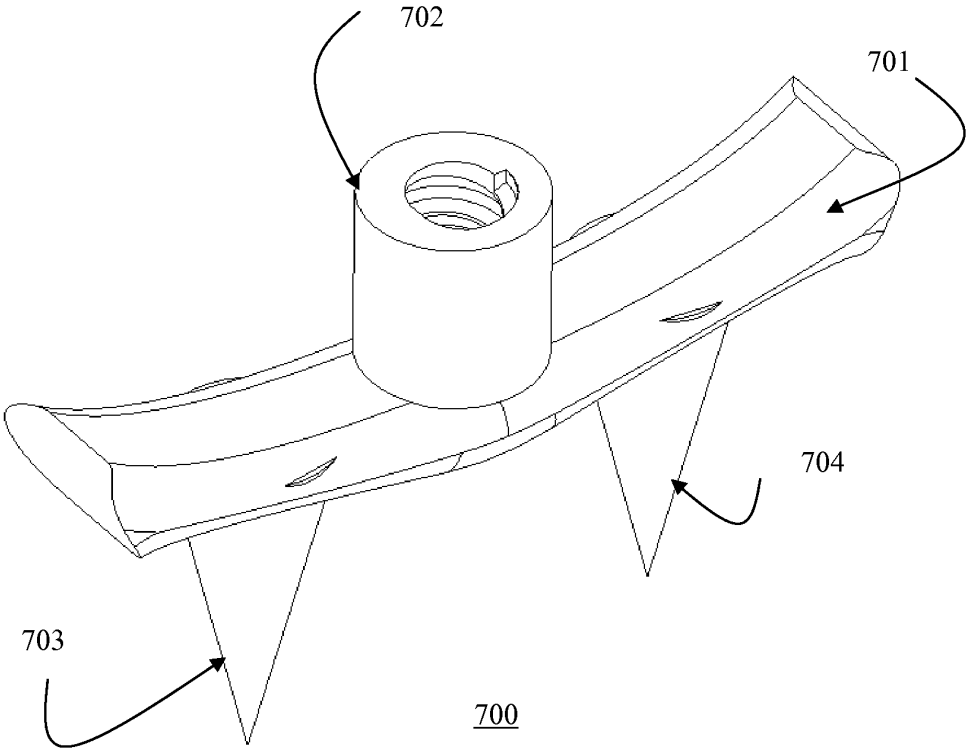
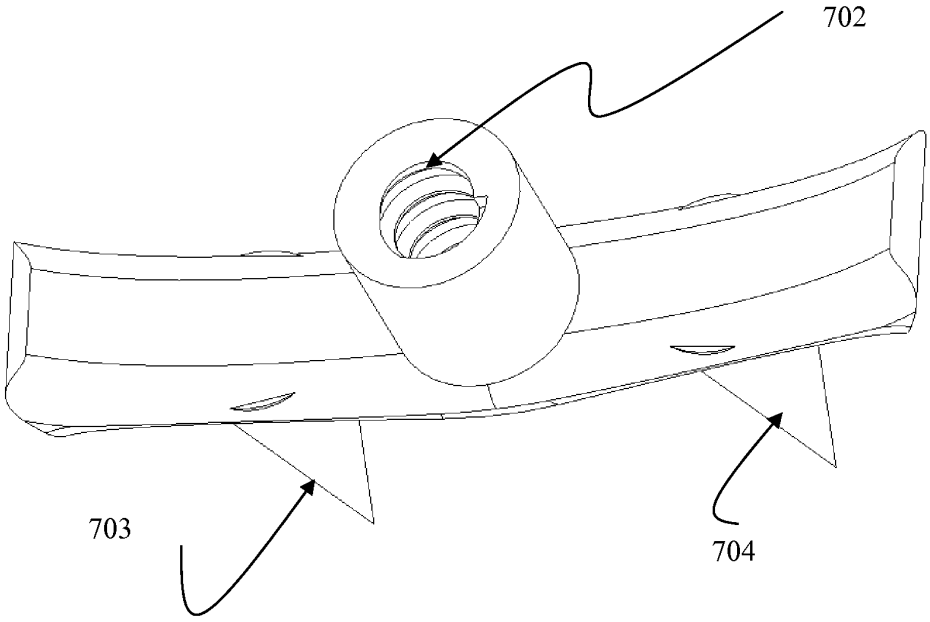
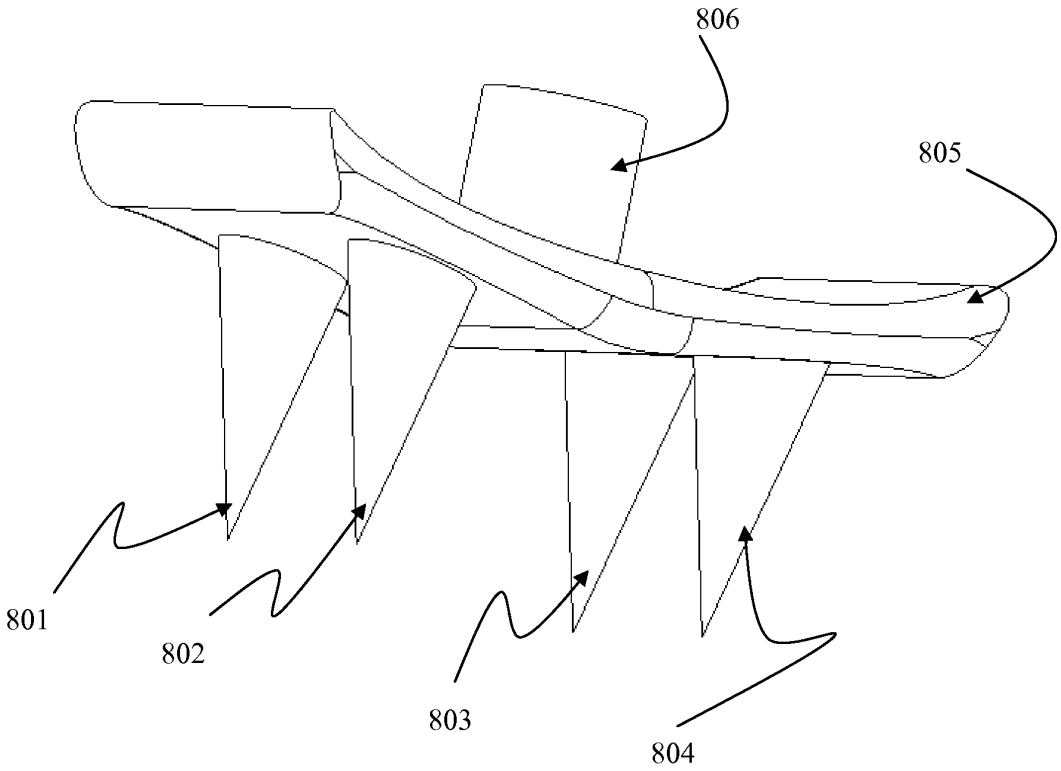


Fig. 7A



700

Fig. 7B



800

Fig. 8A

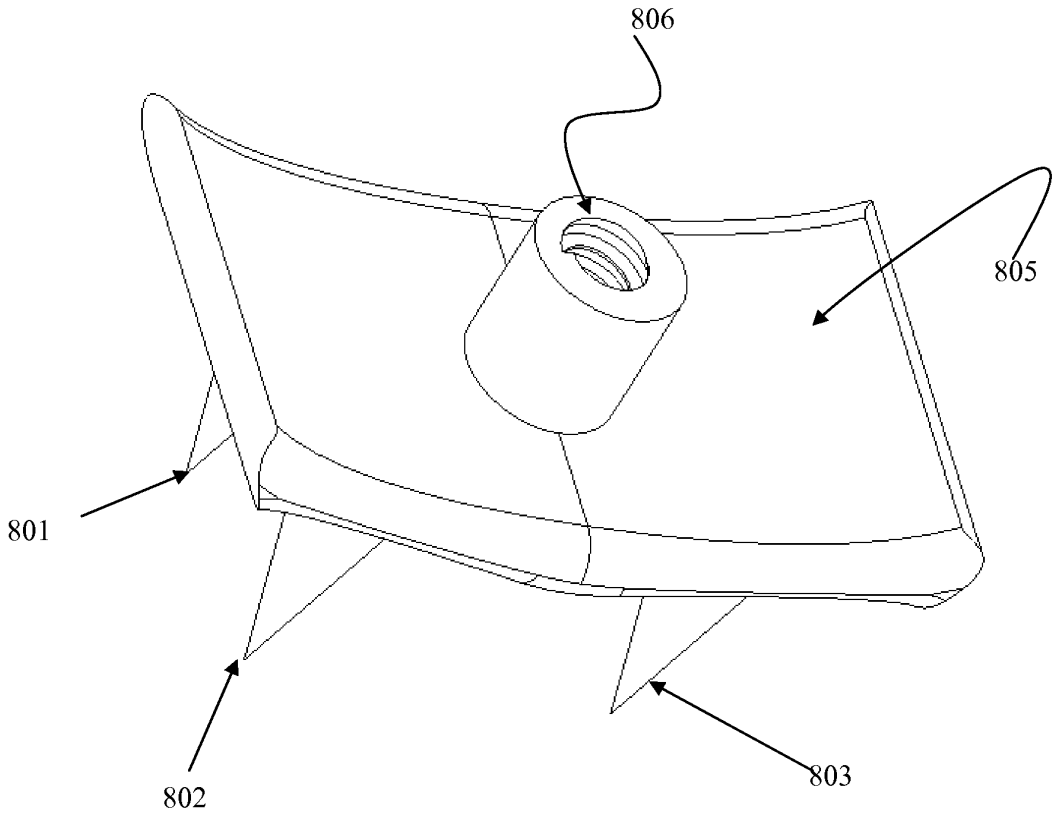
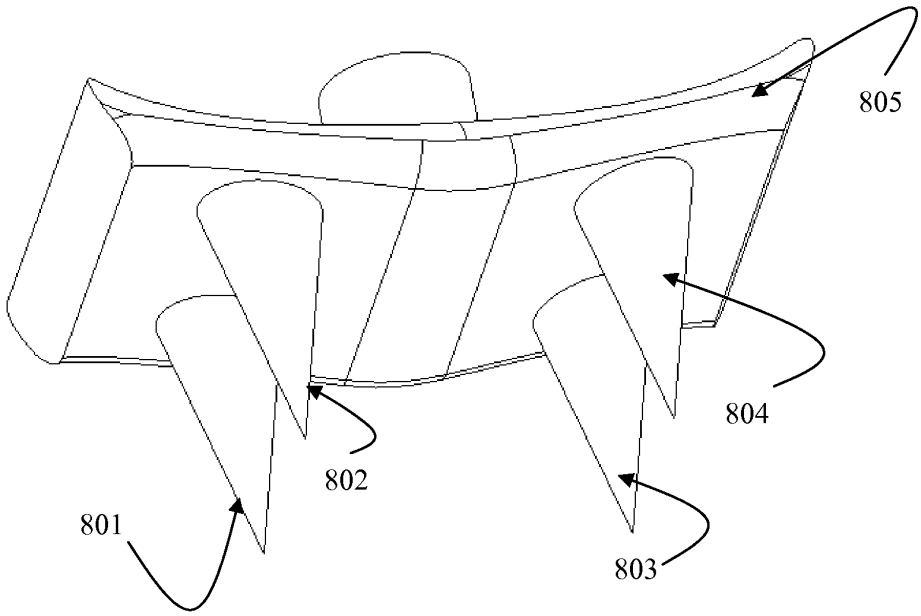


Fig. 8B



800

Fig. 8C

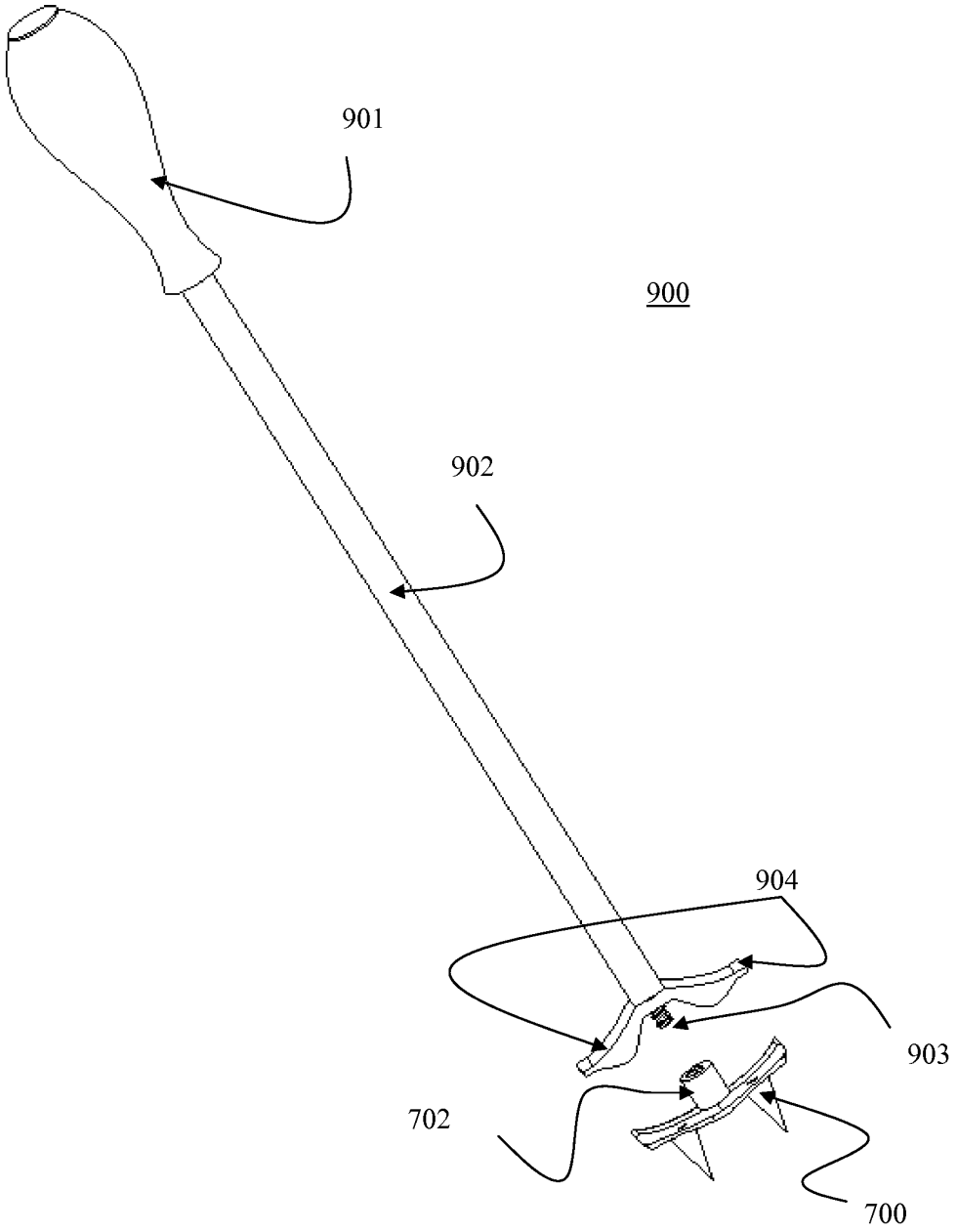


Fig. 9A

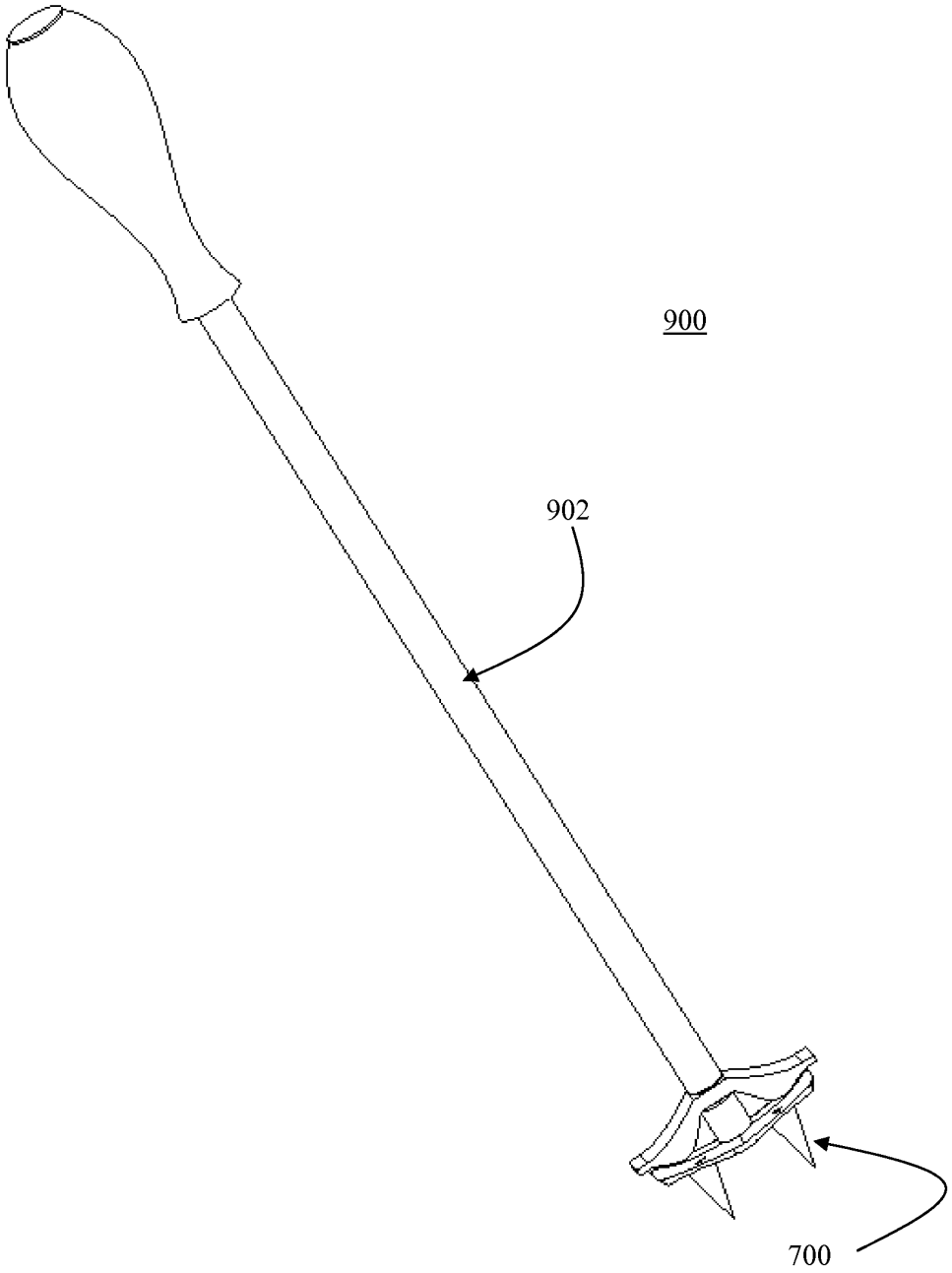


Fig. 9B

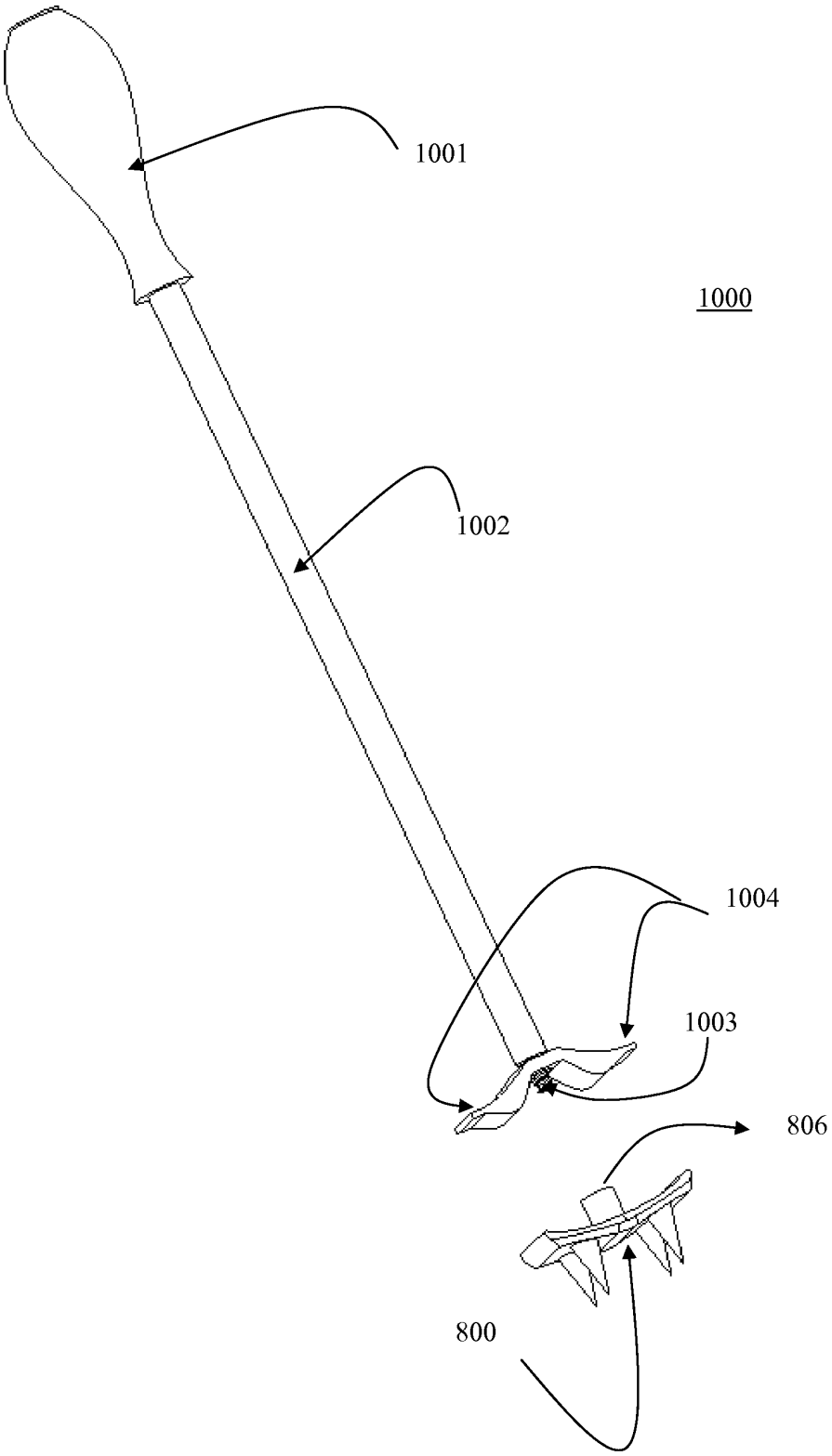


Fig. 10A

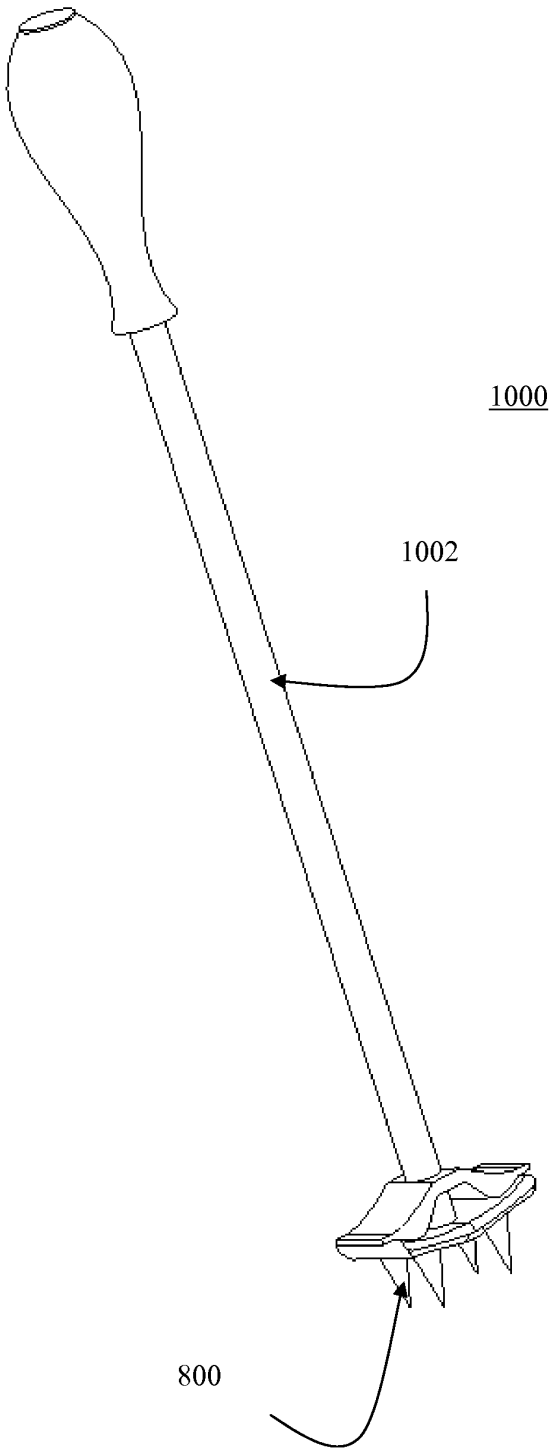


Fig. 10B

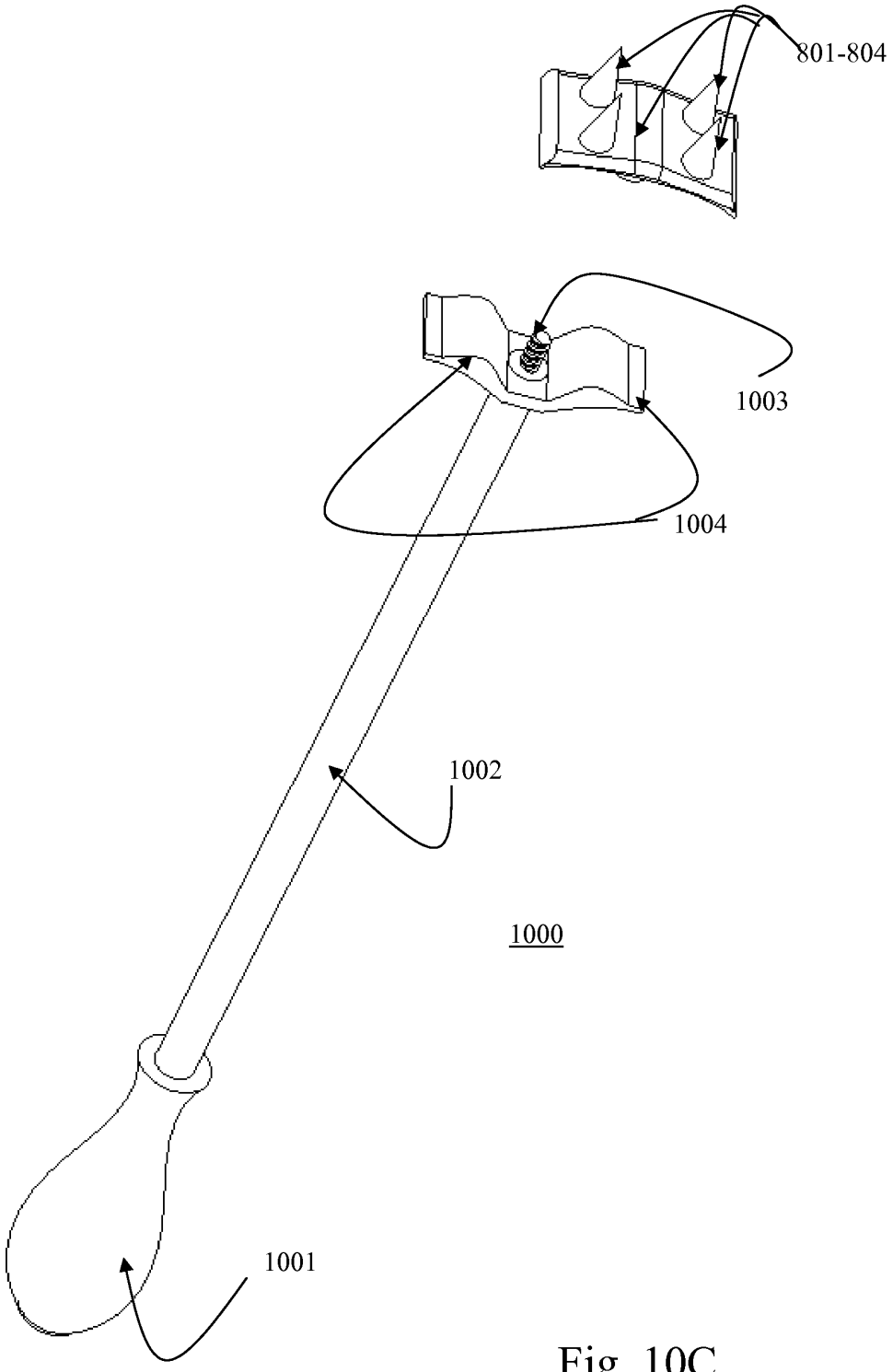


Fig. 10C

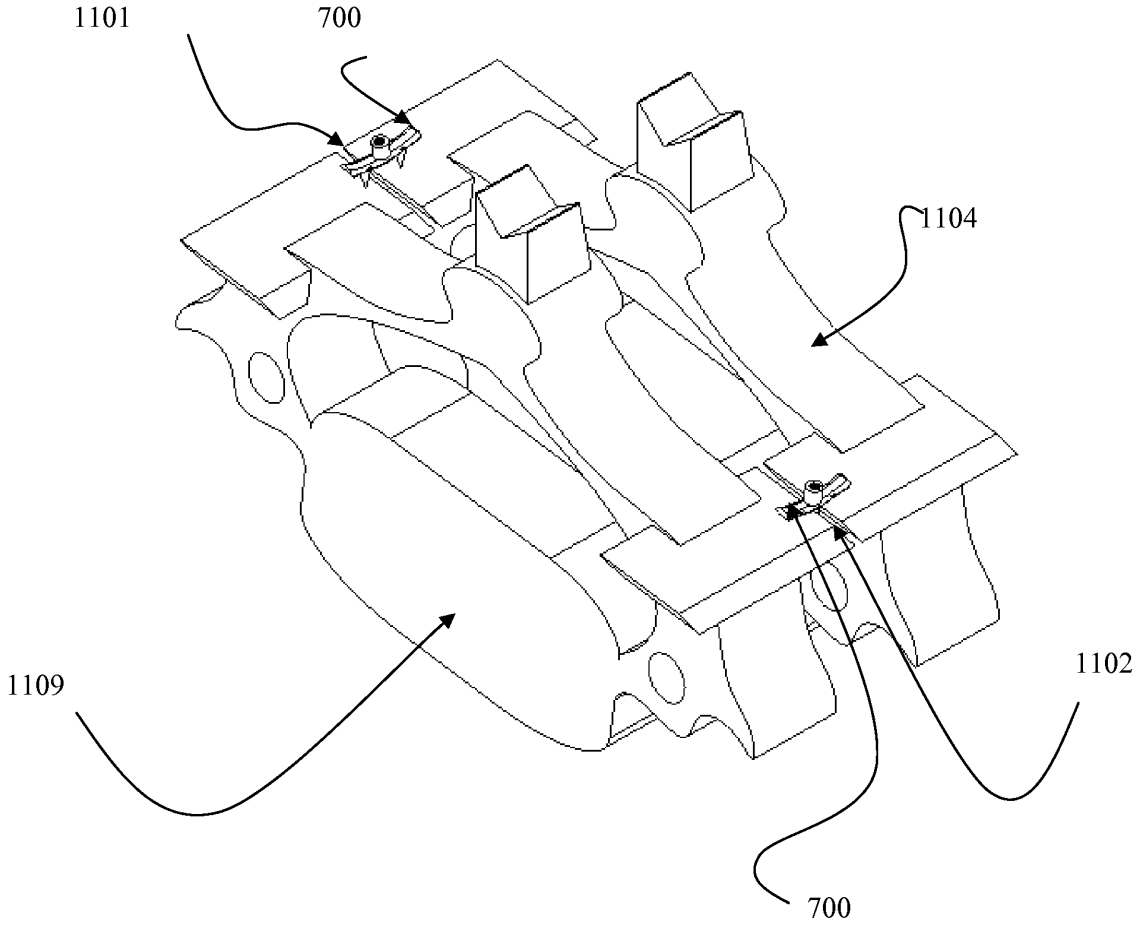


Fig. 11A

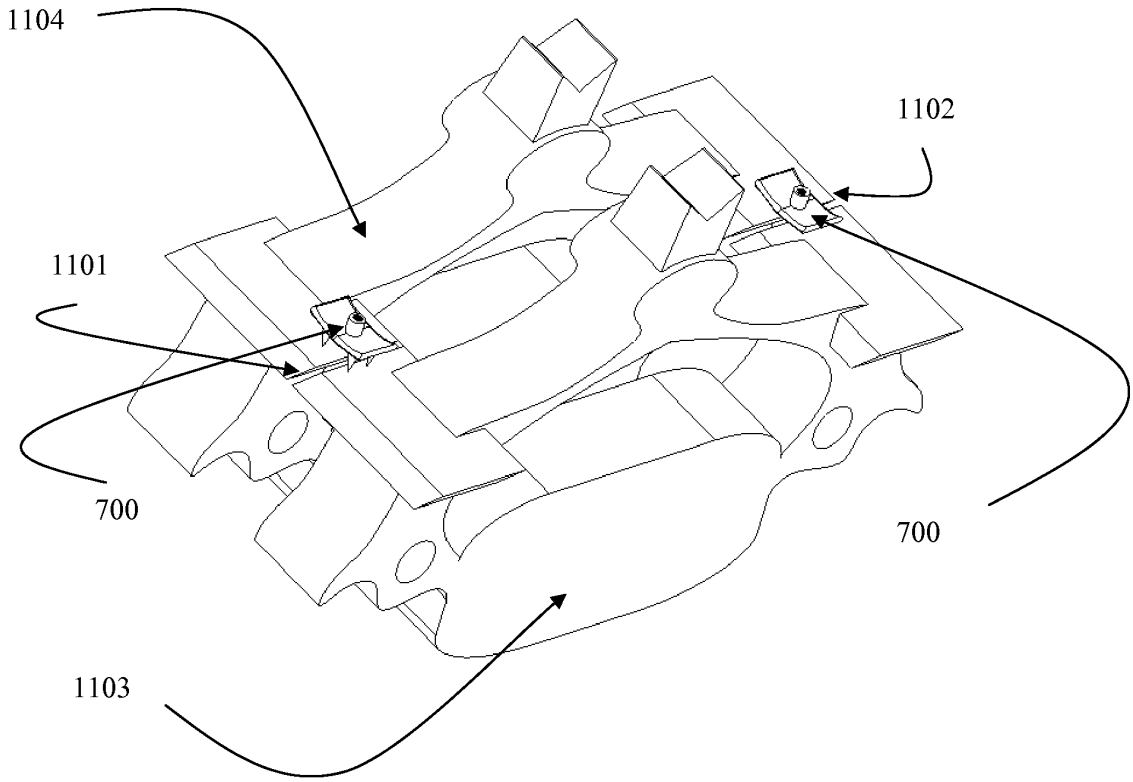


Fig. 11B

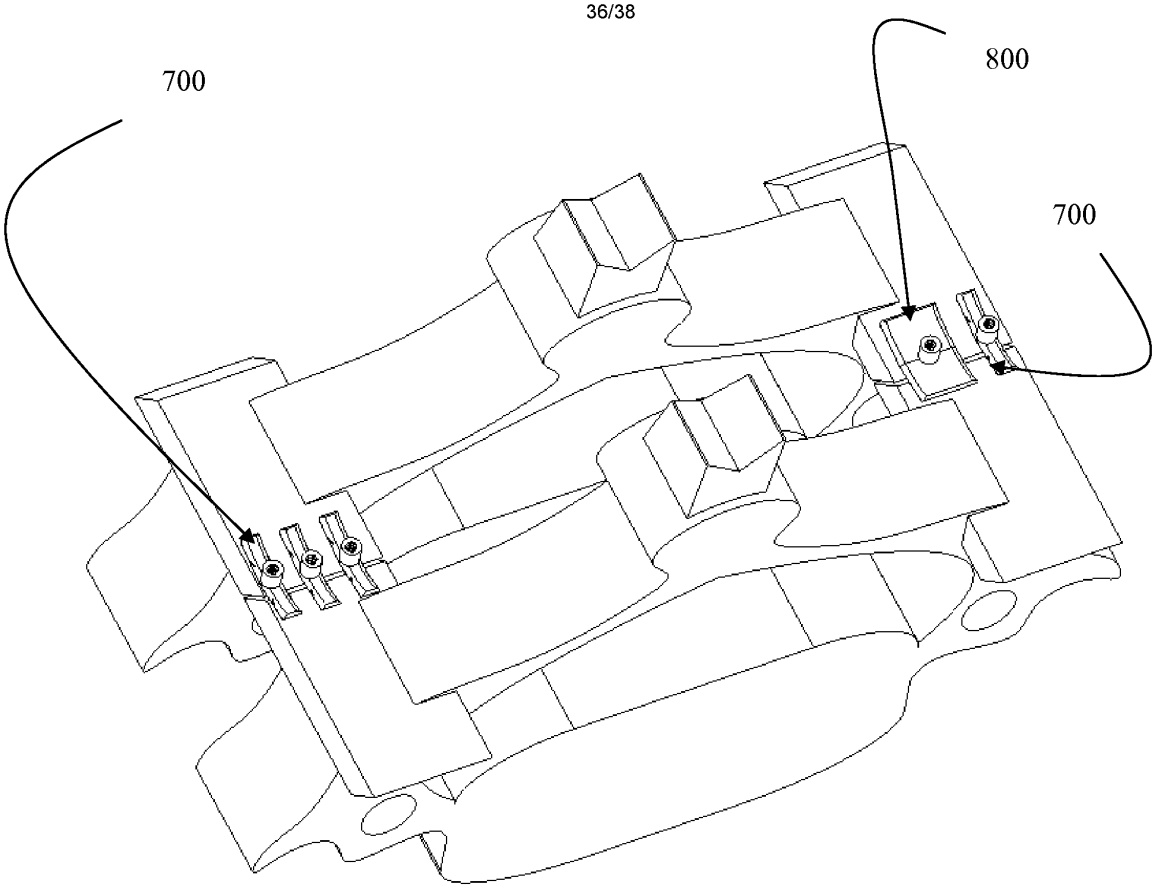


Fig. 11C

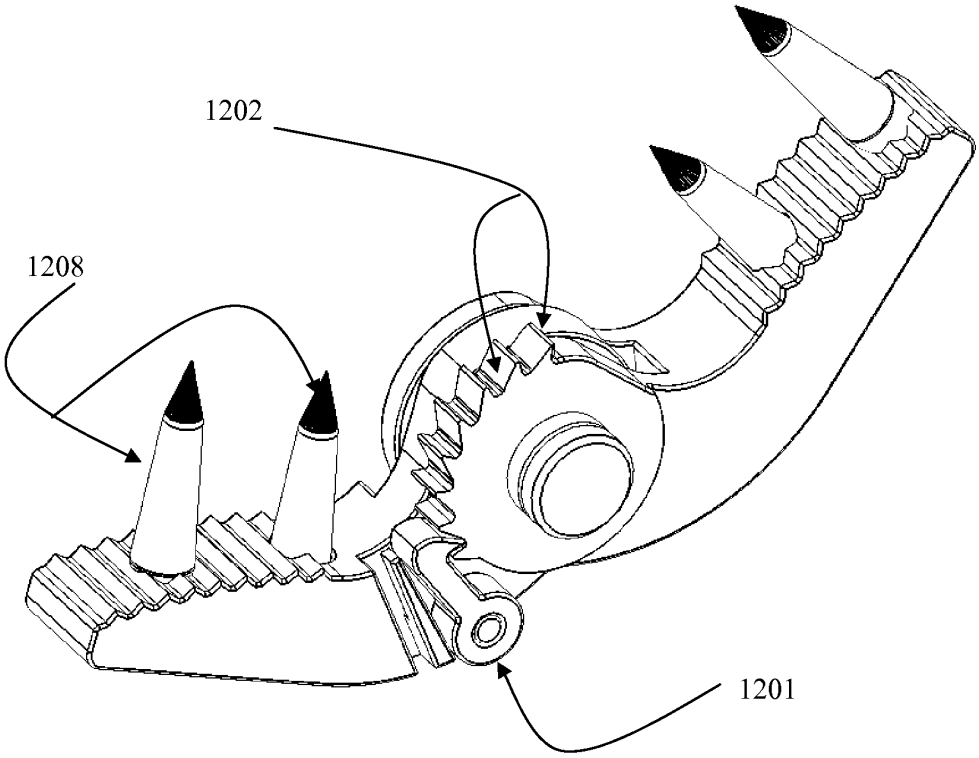


Fig. 12A

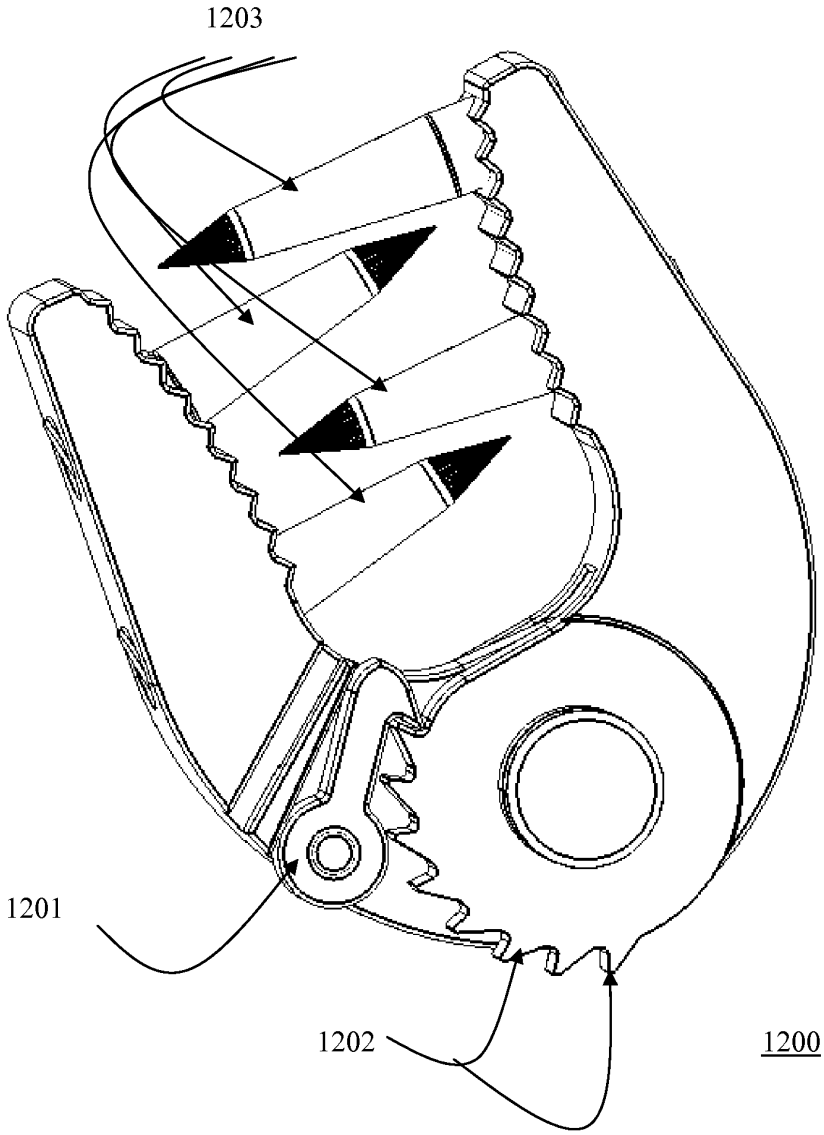


Fig. 12B

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor	:	Ahmnon D. Moskowitz	Art Unit	:	Unknown
Application No.	:	To Be Assigned	Examiner	:	Unknown
Filed	:	Herewith			
Title	:	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION			

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

INFORMATION DISCLOSURE STATEMENT

Please consider the documents listed on the disclosure form submitted with this statement. Copies of the documents are being submitted with this statement to the extent required under 37 C.F.R. § 1.98(a)(2).

Under 35 U.S.C. § 120, this application relies on the earlier filing date of application number 16/018,354, filed on 6/26/2018. The documents corresponding to Desig. ID Nos. 196-199, and 209 have not been submitted to and/or cited by the Office in the prior application. All other listed documents were submitted to and/or cited by the Office in the prior application, and so copies of those documents are not provided in this application.

This statement is being filed with the application.

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

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

Respectfully submitted,

Date: 2/20/2019 /Stuart A. Nelson/

Stuart A. Nelson
Reg. No. 63,947

Customer Number 26191
Fish & Richardson P.C.
Telephone: (612) 337-2538
Facsimile: (877) 769-7945

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APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
16/280,684	02/20/2019	3775	785	46440-0009015	14	3

CONFIRMATION NO. 1247

26191
FISH & RICHARDSON P.C. (TC)
PO BOX 1022
MINNEAPOLIS, MN 55440-1022

FILING RECEIPT

OC000000108410728

Date Mailed: 03/08/2019

Receipt is acknowledged of this non-provisional patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please submit a written request for a Filing Receipt Correction. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections**

Inventor(s)

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

Applicant(s)

Moskowitz Family LLC, Rockville, MD;

Power of Attorney: The patent practitioners associated with Customer Number 26191

Domestic Priority data as claimed by applicant

This application is a CON of 15/894,471 02/12/2018
which is a CON of 13/210,157 08/15/2011 PAT 9889022
which is a CON of 13/108,982 05/16/2011 PAT 9005293
and is a CON of 13/084,543 04/11/2011 PAT 8353913
which is a CON of 11/842,855 08/21/2007 PAT 7942903
and said 13/108,982 05/16/2011
is a CON of 11/842,855 08/21/2007 PAT 7942903
which is a CIP of 11/536,815 09/29/2006 PAT 7846188
which is a CIP of 11/208,644 08/23/2005 PAT 7704279
which claims benefit of 60/670,231 04/12/2005

Foreign Applications for which priority is claimed (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see http://www.uspto.gov for more information.) - None.
Foreign application information must be provided in an Application Data Sheet in order to constitute a claim to foreign priority. See 37 CFR 1.55 and 1.76.

Permission to Access Application via Priority Document Exchange: Yes

Permission to Access Search Results: Yes

Applicant may provide or rescind an authorization for access using Form PTO/SB/39 or Form PTO/SB/69 as appropriate.

If Required, Foreign Filing License Granted: 03/07/2019

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 16/280,684**

Projected Publication Date: 06/13/2019

Non-Publication Request: No

Early Publication Request: No
**** SMALL ENTITY ****
Title

BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION

Preliminary Class

606

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

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign

patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at http://www.uspto.gov/web/offices/pac/doc/general/index.html.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, http://www.stopfakes.gov. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4258).

LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

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The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

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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 AssetsControl, 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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PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number: 16/280,684

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY FEE($)
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	75		N/A	
SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	330		N/A	
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	380		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	14 minus 20 =	*	x 50 =	0.00	OR		
INDEPENDENT CLAIMS (37 CFR 1.16(h))	3 minus 3 =	*	x 230 =	0.00			
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			0.00			
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				0.00			
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	785		TOTAL	

APPLICATION AS AMENDED - PART II

AMENDMENT A

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY ADDITIONAL FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE($)
Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
Application Size Fee (37 CFR 1.16(s))									
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
					TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

AMENDMENT B

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE($)	ADDITIONAL FEE($)	OR	RATE($)	ADDITIONAL FEE($)
Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
Application Size Fee (37 CFR 1.16(s))									
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
					TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".
The "Highest Number Previously Paid For" (Total or Independent) is the highest found in the appropriate box in column 1.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
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P.O. Box 1450
Alexandria, Virginia 22313-1450
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/280,684	02/20/2019	Ahmnon D. Moskowitz	46440-0009015	1247

26191 7590 03/12/2019
FISH & RICHARDSON P.C. (TC)
PO BOX 1022
MINNEAPOLIS, MN 55440-1022

EXAMINER	

ART UNIT	PAPER NUMBER
3773	

NOTIFICATION DATE	DELIVERY MODE
03/12/2019	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

Decision Granting Request for Prioritized Examination (Track I)	**Application No.** 16/280,684	**Applicant(s)** Moskowitz et al.	
	Examiner BRIAN W BROWN	**Art Unit** OPET	**AIA (First Inventor to File) Status** No

1. THE REQUEST FILED 20 February 2019 IS **GRANTED** .

The above-identified application has met the requirements for prioritized examination

A. ☑ for an original nonprovisional application (Track I).
B. ☐ for an application undergoing continued examination (RCE).

2. **The above-identified application will undergo prioritized examination**. The application will be accorded special status throughout its entire course of prosecution until one of the following occurs:

A. filing a **petition for extension of time** to extend the time period for filing a reply;

B. filing an **amendment to amend the application to contain more than four independent claims, more than thirty total claims** , or a multiple dependent claim;

C. filing a **request for continued examination** ;

D. filing a notice of appeal;

E. filing a request for suspension of action;

F. mailing of a notice of allowance;

G. mailing of a final Office action;

H. completion of examination as defined in 37 CFR 41.102; or

I. abandonment of the application.

Telephone inquiries with regard to this decision should be directed to BRIAN BROWN at (571)272-5338.

In his/her absence, calls may be directed to Petition Help Desk at (571) 272-3282.

/BRIAN W BROWN/ Petitions Examiner, OPET	

UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/280,684	02/20/2019	Ahmnon D. Moskowitz	46440-0009015	1247

26191 7590 03/19/2019

FISH & RICHARDSON P.C. (TC)
PO BOX 1022
MINNEAPOLIS, MN 55440-1022

EXAMINER	
PHILOGENE, PEDRO	

ART UNIT	PAPER NUMBER
3773	

NOTIFICATION DATE	DELIVERY MODE
03/19/2019	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary	**Application No.** 16/280,684	**Applicant(s)** Moskowitz et al.	
	Examiner PEDRO PHILOGENE	**Art Unit** 3773	**AIA (FITF) 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 2 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 2/20/19.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL.** 2b) ☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 1-14 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) _____ is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☑ Claim(s) 1-14 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)

2) ☐ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

Notice of Pre-AIA or AIA Status

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

DETAILED ACTION

Election/Restriction

This application contains claims directed to the following patentably distinct species:

FIGS. 1A-1E relating to a claims 1-9.

FIGS 2A-2E relating to claims 10-12.

FIGS. 5A-5C relating to claims 13-14.

The species are independent or distinct because species I claims first and second sliding boxes and an adjuster; species II claims a box and a plurality of ridges; species III claims a tool assembly. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, or a single grouping of patentably indistinct species, for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claim is generic.

There is a search and/or examination burden for the patentably distinct species as set forth above because at least the following reason(s) apply: the species or groupings of patentably indistinct species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search strategies or search queries).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species or grouping of patentably indistinct species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species or grouping of patentably indistinct species.

Should applicant traverse on the ground that the species, or groupings of patentably indistinct species from which election is required, are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing them to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 or pre-AIA 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

A telephone call was made to Nelson Stuart on 3/14/19 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be corrected in compliance with 37 CFR 1.48(a) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. A request to correct inventorship under 37 CFR 1.48(a) must be accompanied by an application data sheet in accordance with 37 CFR 1.76 that identifies each inventor by his or her legal name and by the processing fee required under 37 CFR 1.17(i).

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 M-F 8:00-4:00PM.

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, **Robert Eduardo** 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 3773
March 14, 2019

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/280,684	Moskowitz et al.
	Examiner	Art Unit
	PEDRO PHILOGENE	3773

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

CLAIMS											
☐ Claims renumbered in the same order as presented by applicant					☐ CPA		☐ T.D.		☐ R.1.47		
CLAIM		DATE									
Final	Original	03/14/2019									
	1	÷									
	2	÷									
	3	÷									
	4	÷									
	5	÷									
	6	÷									
	7	÷									
	8	÷									
	9	÷									
	10	÷									
	11	÷									
	12	÷									
	13	÷									
	14	÷									

Bibliographic Data

Application No: 16/280,684

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 TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION

FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
02/20/2019	623	3773	46440-0009015
RULE			

APPLICANTS

Moskowitz Family LLC, Rockville, MD, UNITED STATES

INVENTORS

Ahmnon D. Moskowitz Rockville, MD, UNITED STATES

Pablo A. Valdivia Y. Alvarado Cambridge, MA, UNITED STATES

Mosheh T. Moskowitz Rockville, MD, UNITED STATES

Nathan C. Moskowitz Rockville, MD, UNITED STATES

CONTINUING DATA

This application is a CON of 15894471 02/12/2018

15894471 is a CON of 13210157 08/15/2011 PAT 9889022

13210157 is a CON of 13108982 05/16/2011 PAT 9005293

13210157 is a CON of 13084543 04/11/2011 PAT 8353913

13084543 is a CON of 11842855 08/21/2007 PAT 7942903

13108982 is a CON of 11842855 08/21/2007 PAT 7942903

11842855 is a CIP of 11536815 09/29/2006 PAT 7846188

11536815 is a CIP of 11208644 08/23/2005 PAT 7704279

11208644 has PRO of 60670231 04/12/2005

FOREIGN APPLICATIONS

IF REQUIRED, FOREIGN LICENSE GRANTED**

03/07/2019

**** SMALL ENTITY ****

STATE OR COUNTRY

UNITED STATES

ADDRESS

FISH & RICHARDSON P.C. (TC)
PO BOX 1022
MINNEAPOLIS, MN 55440-1022
UNITED STATES

FILING FEE RECEIVED

$2,855

Electronic Acknowledgement Receipt	
EFS ID:	35920824
Application Number:	16280684
International Application Number:	
Confirmation Number:	1247
Title of Invention:	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION
First Named Inventor/Applicant Name:	Ahmnon D. Moskowitz
Customer Number:	26191
Filer:	Stuart A. Nelson/Kathy Bell
Filer Authorized By:	Stuart A. Nelson
Attorney Docket Number:	46440-0009015
Receipt Date:	06-MAY-2019
Filing Date:	20-FEB-2019
Time Stamp:	08:34:18
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Response to Election / Restriction Filed	46440-0009015_RR.pdf	98787 c6f55060305ffccb1b691a6c3ce77dfd2a11f2f2	no	10
Warnings:					

Information:	
Total Files Size (in bytes):	98787

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

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

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor	:	Ahmnon D. Moskowitz	Art Unit	:	3773
Application No.	:	16/280,684	Examiner	:	Pedro Philogene
Filed	:	February 20, 2019	Conf. No.	:	1247
Title	:	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION			

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

AMENDMENT AND RESPONSE TO RESTRICTION REQUIREMENT DATED

MARCH 19, 2019

Amendments to the Specification:

Please replace paragraph [0008] with the following amended paragraph:

[0008] Furthermore, we present an advanced mechanism in calibrated posterior facet joint stapling compared to our previous designs illustrated in our co-pending patents. We also introduce the entirely novel concept of posterior cervical facet staples to obviate and/or diminish the need for posterior cervical pedicle screw instrumented fusion. Using combinations and permutations of different embodiments of cervical facet staples in a modular manner advances the concept of flexible fusion in the cervical spine.

Please replace paragraph [0014] with the following amended paragraph:

[0014] The box casings have multiple perforations to allow both screw traversal and horizontal bone packing preventing upward vertical migration of bone. The boxes prevent subsidence. Both the inside of the denuded intervertebral space, and the screw boxes can be packed with autologous or allograft bone, BMP, DBX or similar osteoconductive material. Posteriorly or anteriorly in the lumbar spine, these screws can be capped with a horizontal mini-plate which will prevent bony growth into the thecal sac and nerves. We refer to this as a two-in-one device, i.e. two screw boxes/BDFT screws combined with one horizontal mini-plate. This is an entirely novel concept in posterior lumbar spinal surgery. In yet another embodiment two BDFT screw boxes can be combined with a circumferential cage (also 2 in 1) to be placed anteriorly into the lumbar spine.

Amendments to Claims:
Listing of Claims.

1-12 (Cancelled)

13. (Currently Amended) A system comprising:

a tool assembly ~~for manipulating a self-drilling bone fusion screw apparatus,~~ which comprises:

a first tool having a first proximal end and a first distal end with a first handle[[;]] and a gripper, the gripper being positioned at the first distal end, cooperating with the first handle, and having ~~a plurality of~~ first and second engagement prongs~~; a screw guide, held in place the plurality of prongs, for controlling the direction of self-drilling screws that are screwed into a vertebral body~~ positioned at the first distal end, wherein the first tool defines an adjusting tool passage through the first tool; and

a second adjusting tool having a second proximal end and a second distal end with a second handle positioned at the second proximal end, a screw engagement portion positioned at the second distal end, and a shaft extending from the second handle to the screw engagement portion, wherein the shaft of the second adjusting tool is sized with a smaller diameter than that of the adjusting tool passage such that the second adjusting tool can extend through the adjusting tool passage of the first tool; and

an expandable spinal implant sized and configured to be implanted in a human spine, the expandable spinal implant comprising a first expandable spinal implant structure, a second expandable spinal implant structure, and an adjusting screw having a screw head and a threaded portion, wherein the expandable spinal implant is configured to expand the first expandable spinal implant structure with respect to the second expandable spinal implant structure in response to turning of the adjusting screw, wherein the expandable spinal implant defines first and second

tool engagement indentations sized and configured for receiving the first and second engagement prongs of the first tool, wherein the adjusting screw is positioned within the expandable spinal implant in a screw location such that the second adjusting tool can extend through the adjusting tool passage of the first tool to engage the screw head of the adjusting screw while the first and second engagement prongs of the first tool are engaged with the first and second tool engagement indentations of the expandable spinal implant.

14. (Currently Amended) The system of claim 13, wherein the screw engagement portion of the second adjusting tool comprises ~~tool assembly for manipulating a self-drilling bone fusion screw apparatus, according to claim 13, which further includes~~ a key for engaging the head of the adjusting screw to turn the adjusting screw and controlling ~~an adjustment device which controls the~~ height of the expandable spinal implant ~~self-drilling bone fusion screw apparatus~~.

15. (New) The system of claim 13, wherein the expandable spinal implant defines a longitudinal axis, wherein the first and second expandable spinal implant structures have first and second angled wedge surfaces that engage one another, wherein the adjusting screw is connected to the second expandable spinal implant structure so as to move the second expandable spinal implant structure along the longitudinal axis and slide the first angled wedge surface with respect to the second angled wedge surface to push the first expandable spinal implant structure in a direction that is substantially away from the longitudinal axis of the expandable spinal implant.

16. (New) The system of claim 13, wherein the first expandable spinal implant structure defines a first angled wedge portion that comprises a first inwardly-facing rail and a second inwardly-facing rail, wherein a first inwardly-facing slot is defined at a location adjacent the first inwardly-facing rail, wherein a second inwardly-facing slot is defined at a location adjacent the second inwardly-facing rail, wherein the second expandable spinal implant structure defines a second angled wedge portion that comprises a first outwardly-facing rail and a second outwardly-facing rail that faces outwardly in a direction opposite that of the first outwardly-facing rail, wherein a first outwardly-facing slot is defined at a location adjacent the first

outwardly-facing rail, wherein a second outwardly-facing slot is defined at a location adjacent the second outwardly-facing rail, wherein the first expandable spinal implant structure is slidably-engaged with the second expandable spinal implant structure such that the first angled wedge portion engages the second angled wedge portion with the first inwardly-facing rail of the first expandable spinal implant structure positioned in the first outwardly-facing slot of the second expandable spinal implant structure, the second inwardly-facing rail of the first expandable spinal implant structure positioned in the second outwardly facing slot of the second expandable spinal implant structure, the first outwardly-facing rail of the second expandable spinal implant structure positioned in the first inwardly-facing slot of the first expandable spinal implant structure, and the second outwardly-facing rail of the second expandable spinal implant structure positioned in the second inwardly-facing slot of the first expandable spinal implant structure.

17. (New) The system of claim 13, and further comprising first and second anchors, wherein the expandable spinal implant comprises first and second anchor guides angled to guide the first and second anchors bidirectionally into first and second vertebral bodies.

18. (New) The system of claim 17, wherein the first tool defines third and fourth screw guides configured to align with the first and second screw guides of the expandable spinal implant when the first and second engagement prongs are engaged with the first and second tool engagement indentations so as to guide the first and second anchors through the third and fourth screw guides into the first and second screw guides.

19. (New) A method of using the system of claim 13, the method comprising:

connecting the first tool to the expandable spinal implant with the first and second engagement prongs engaged with the first and second tool engagement indentations;

implanting the expandable spinal implant into a disc space in the human spine via the first tool;

extending the second adjusting tool through the first tool to engage the adjusting screw of

the expandable spinal implant; and

expanding the expandable spinal implant by turning the second adjusting tool to turn the adjusting screw of the expandable spinal implant.

20. (New) A system comprising:

a tool assembly comprising:

a first tool having a first proximal end, a first distal end, and a first elongate body between the first proximal end and the first distal end, wherein the first tool defines a first tool axis from the first proximal end to the first distal end, wherein the first tool includes first and second engagement prongs positioned at the first distal end on opposite sides of the first tool axis, wherein the first tool defines an adjusting tool passage through the first tool;

a second adjusting tool having a second proximal end and a second distal end, wherein the second adjusting tool includes a second handle positioned at the second proximal end, a screw engagement portion positioned at the second distal end, and a shaft extending from the second handle to the screw engagement portion, wherein the shaft of the second adjusting tool is sized with a smaller diameter than that of the adjusting tool passage such that the second adjusting tool can extend through the adjusting tool passage of the first tool; and

an expandable spinal implant sized and configured to be implanted in a human spine, the expandable spinal implant comprising a first expandable spinal implant structure defining a first engagement surface sized and configured to engage a first vertebral body, a second expandable spinal implant structure defining a second engagement surface sized and configured to engage a second vertebral body, and an adjusting screw having a screw head and a threaded shaft, wherein the expandable spinal implant is configured to expand the first expandable spinal implant structure with respect to the second expandable spinal implant structure in response to turning of the adjusting screw, wherein the expandable spinal implant

defines first and second tool engagement indentations sized and configured for receiving the first and second engagement prongs of the first tool, wherein the adjusting screw is positioned within the expandable spinal implant in a screw location such that the second adjusting tool can extend through the adjusting tool passage of the first tool to engage the screw head of the adjusting screw while the first and second engagement prongs of the first tool are engaged with the first and second tool engagement indentations of the expandable spinal implant.

21. (New) The system of claim 20, wherein the expandable spinal implant includes ridges on each of the first and second engagement surfaces, wherein the first indentation extends into a first side of the first expandable spinal implant structure, wherein the second indentation extends into a second side of the expandable spinal implant structure.

22. (New) The system of claim 20, wherein the expandable spinal implant comprises first and second angled wedge surfaces, wherein rotation of the adjustment screw by the second adjusting tool drives relative motion of the first angled wedge surface with respect to the second angled wedge surface to expand the expandable spinal implant.

23. (New) The system of claim 20, wherein the first expandable spinal implant structure defines an end gap between the first and second opposing side surfaces at a first end of the first vertebral body engagement surface, wherein the first vertebral body engagement surface comprises a plurality of ridges extending from the first vertebral body engagement surface, wherein at least some of the ridges are positioned on the first vertebral body engagement surface on opposite sides of the end gap.

24. (New) The system of claim 20, and further comprising first and second anchors, wherein the expandable spinal implant comprises first and second anchor guides angled to guide the first and second anchors bidirectionally into the first and second vertebral bodies.

25. (New) The system of claim 20, wherein the first tool defines third and fourth screw guides

configured to align with the first and second screw guides of the expandable spinal implant so as to guide the first and second anchors through the third and fourth screw guides into the first and second screw guides when the first and second engagement prongs are engaged with the first and second tool engagement indentations.

26. (New) The system of claim 20, wherein the first tool comprises a first handle positioned proximate the first proximal end and extending in a direction that is substantially perpendicular to the first proximal axis, wherein the second handle of the second adjusting tool is substantially circular when viewed along the first proximal axis when the second adjusting tool is positioned in the adjusting tool passage.

27. (New) The system of claim 20, wherein the first expandable spinal implant structure and the first engagement surface move with respect to the second expandable spinal implant structure and the second engagement surface at least partially along a direction of the first tool axis when the second adjusting tool turns the adjusting screw.

28. (New) The system of claim 20, wherein the expandable spinal implant has a proximal end, a distal end, and first and second sides, wherein screw head of the adjusting screw is positioned at the proximal end of the expandable spinal implant, wherein the first and second tool indentations are positioned on the first and second sides proximate to the proximal end.

29. (New) The system of claim 28, wherein the expandable spinal implant defines a proximal screw hole at the proximal end of the expandable spinal implant and a distal screw hole at the distal end of the expandable spinal implant and wherein the adjusting screw extends through both the proximal and the distal screw holes.

30. (New) The system of claim 20, wherein the first tool indentation extends into a first side of the expandable spinal implant with a first substantially rectangular shape as viewed from a direction perpendicular to the first side and the second tool indentation extends into a second side of the expandable spinal implant with a second substantially rectangular shape as viewed from a

direction perpendicular to the second side.

31. (New) The system of claim 20, wherein a distal end of the adjusting screw has a distal diameter, wherein the head of the adjusting screw has a head diameter, and wherein the distal diameter is larger than the head diameter.

32. (New) A method of using the system of claim 20, the method comprising:

connecting the first tool to the expandable spinal implant with the first and second engagement prongs engaged with the first and second tool engagement indentations;

implanting the expandable spinal implant into a disc space in the human spine via the first tool;

extending the second adjusting tool through the first tool to engage the adjusting screw of the expandable spinal implant; and

expanding the expandable spinal implant by turning the second adjusting tool to turn the adjusting screw of the expandable spinal implant.

REPLY TO RESTRICTION REQUIREMENT

With this amendment, claims 1-12 are cancelled, claims 13-14 are amended, and claims 15-32 are added.

In response to the restriction requirement made in the action dated 3/19/2019, the third identified species corresponding to Figures 5A-5C (as well as Figures 5D-5I) and claims 13-14 (as well as new claims 15-32) is elected for examination. The election is made without traverse.

Please apply any necessary charges or credits to Deposit Account No. 06-1050, referencing the above attorney docket number.

Respectfully submitted,

Date: 5/6/2019

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

Customer Number 26191
Fish & Richardson P.C.
Telephone: (612) 337-2538
Facsimile: (877) 769-7945

100025238.doc

Substitute Disclosure Form	U.S. Department of Commerce Patent and Trademark Office	Attorney Docket No. 46440-0009015	Application No. 16/280,684
Information Disclosure Statement by Applicant (Use several sheets if necessary) (37 CFR §1.98(b))		Applicant Moskowitz Family LLC	
		Filing Date February 20, 2019	Group Art Unit 3773

U.S. Patent Documents

Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	1.	2004/0162558	8/19/2004	Hegde			
	2.	2006/0058876	3/2006	Laurence			
	3.	2006/0217713	9/28/2006	Serhan			
	4.	2007/0191850	8/16/2007	Kim			
	5.	2008/0249575	10/1/2008	Waugh			
	6.	2010/0100138	4/22/2010	Reynolds			
	7.	4,505,273	3/19/1985	Braun			
	8.	5,352,229	10/4/1994	Goble			
	9.	5,662,655	9/2/1997	Laboureau			
	10.	5,865,848	2/1/1999	Baker			
	11.	6,325,805	12/4/2001	Ogilvie			
	12.	6,746,450	6/8/2004	Wall			
	13.	8,167,949	5/1/2012	Tyber			
	14.	9,895,238	2/20/2018	Moskowitz et al.			
	15.	9,907,674	3/6/2018	Moskowitz			
	16.	10,238,505	3/26/2019	Moskowitz et al.			

Foreign Patent Documents or Published Foreign Patent Applications

Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation Yes	Translation No

Other Documents (include Author, Title, Date, and Place of Publication)

Examiner Initial	Desig. ID	Document

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:	35921047
Application Number:	16280684
International Application Number:	
Confirmation Number:	1247
Title of Invention:	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION
First Named Inventor/Applicant Name:	Ahmnon D. Moskowitz
Customer Number:	26191
Filer:	Stuart A. Nelson/Richard Welsh
Filer Authorized By:	Stuart A. Nelson
Attorney Docket Number:	46440-0009015
Receipt Date:	06-MAY-2019
Filing Date:	20-FEB-2019
Time Stamp:	09:21:00
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 Letter	Transmittal_0009015.pdf	73913 471ce29e9c0dc0f644928607b9e8c7b3351b8f52	no	1

Warnings:

Information:					
2	Information Disclosure Statement (IDS) Form (SB08)	1449_0009015.pdf	127291 39f91afd981ceaaf30227f3d0a6f270e69d94134	no	1
Warnings:					
Information:					
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			Total Files Size (in bytes):	201204	

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

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

New International Application Filed with the USPTO as a Receiving Office

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

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor	:	Ahmnon D. Moskowitz	Art Unit	:	3773
Application No.	:	16/280,684	Examiner	:	Pedro Philogene
Filed	:	February 20, 2019	Conf. No.	:	1247
Title	:	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION			

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

INFORMATION DISCLOSURE STATEMENT

Please consider the documents listed on the disclosure form submitted with this statement. Copies of the documents are being submitted with this statement to the extent required under 37 C.F.R. § 1.98(a)(2).

This statement is being filed before the receipt of a first action on the merits.

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

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

Respectfully submitted,

Date: 5/6/2019

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

Customer Number 26191
Fish & Richardson P.C.
Telephone: (612) 337-2538
Facsimile: (877) 769-7945

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PTO/SB/06 (09-11)
Approved for use through 1/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 16/280,684	Filing Date 02/20/2019	☐ To be Mailed

ENTITY: ☐ LARGE ☑ SMALL ☐ MICRO

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA		RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A		N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A		N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*		x $50 =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*		x $230 =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).				
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))					
* If the difference in column 1 is less than zero, enter "0" in column 2.				TOTAL	

APPLICATION AS AMENDED - PART II

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT	05/06/2019	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 22	Minus	** 20	= 2		x $50 =	100
	Independent (37 CFR 1.16(h))	* 4	Minus	*** 3	= 1		x $230 =	230
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	330

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=		x $0 =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=		x $0 =	
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.	
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".	/LISA R EPPS/
*** 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.	

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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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 16/280,684	Filing Date 02/20/2019	☐ To be Mailed

ENTITY: ☐ LARGE ☑ SMALL ☐ MICRO

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA		RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A		N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A		N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*		x $50 =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*		x $230 =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).				
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))					
* If the difference in column 1 is less than zero, enter "0" in column 2.				TOTAL	

APPLICATION AS AMENDED - PART II

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT	05/07/2019	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 22	Minus	** 22	= 0		x $50 =	0
	Independent (37 CFR 1.16(h))	* 4	Minus	*** 4	= 0		x $230 =	0
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	0

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=		x $0 =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=		x $0 =	
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.	SLIE
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".	/MONIQUE BENJAMIN/
*** 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.	

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.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor	:	Ahmnon D. Moskowitz	Art Unit	:	3773
Application No.	:	16/280,684	Examiner	:	Pedro Philogene
Filed	:	February 20, 2019	Conf. No.	:	1247
Title	:	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION			

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

SUPPLEMENTAL AMENDMENT

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

Electronic Patent Application Fee Transmittal

Application Number:	16280684
Filing Date:	20-Feb-2019
Title of Invention:	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION
First Named Inventor/Applicant Name:	Ahmnon D. Moskowitz
Filer:	Stuart A. Nelson/Anne Roy
Attorney Docket Number:	46440-0009015

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
INDEPENDENT CLAIMS IN EXCESS OF 3	2201	1	230	230
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**330**

Electronic Acknowledgement Receipt	
EFS ID:	35944767
Application Number:	16280684
International Application Number:	
Confirmation Number:	1247
Title of Invention:	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION
First Named Inventor/Applicant Name:	Ahmnon D. Moskowitz
Customer Number:	26191
Filer:	Stuart A. Nelson/Anne Roy
Filer Authorized By:	Stuart A. Nelson
Attorney Docket Number:	46440-0009015
Receipt Date:	07-MAY-2019
Filing Date:	20-FEB-2019
Time Stamp:	17:34:48
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	$330
RAM confirmation Number	050819INTEFSW00004967061050
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		46440amend.pdf	95503 c9412f79778be31ec51f3e7bea742cad8f58077e	yes	12
	Multipart Description/PDF files in .zip description				
	Document Description		**Start**	**End**	
	Applicant Arguments/Remarks Made in an Amendment		12	12	
	Claims		2	11	
	Supplemental Response or Supplemental Amendment		1	1	
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	32299 055f7e77bd540b65682750a14889311ea669029a	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	127802		

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

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.

REMARKS

With this amendment, claims 18, 20, and 31 are amended to correct clarity and antecedent issues. Claims 33-34 are added. Applicant asks that all claims be examined in view of the amendment to the claims.

The fees in the amount of $330 for excess claim fees are being paid with this reply on the Electronic Filing System. In addition, please apply any other necessary charges or credits to Deposit Account 06-1050, referencing the above attorney docket number.

Respectfully submitted,

Date: 5/7/2019

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

Customer Number 26191
Fish & Richardson P.C.
Telephone: (612) 337-2538
Facsimile: (877) 769-7945

61908431.doc

Amendments to the Claims:

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

Listing of Claims:

1-12 (Cancelled)

13. (Previously Presented) A system comprising:

a tool assembly which comprises:

a first tool having a first proximal end and a first distal end with a first handle and a gripper, the gripper being positioned at the first distal end, cooperating with the first handle, and having first and second engagement prongs positioned at the first distal end, wherein the first tool defines an adjusting tool passage through the first tool; and

a second adjusting tool having a second proximal end and a second distal end with a second handle positioned at the second proximal end, a screw engagement portion positioned at the second distal end, and a shaft extending from the second handle to the screw engagement portion, wherein the shaft of the second adjusting tool is sized with a smaller diameter than that of the adjusting tool passage such that the second adjusting tool can extend through the adjusting tool passage of the first tool; and

an expandable spinal implant sized and configured to be implanted in a human spine, the expandable spinal implant comprising a first expandable spinal implant structure, a second expandable spinal implant structure, and an adjusting screw having a screw head and a threaded portion, wherein the expandable spinal implant is configured to expand the first expandable spinal implant structure with respect to the second expandable spinal implant structure in response to turning of the

adjusting screw, wherein the expandable spinal implant defines first and second tool engagement indentations sized and configured for receiving the first and second engagement prongs of the first tool, wherein the adjusting screw is positioned within the expandable spinal implant in a screw location such that the second adjusting tool can extend through the adjusting tool passage of the first tool to engage the screw head of the adjusting screw while the first and second engagement prongs of the first tool are engaged with the first and second tool engagement indentations of the expandable spinal implant.

14. (Previously Presented) The system of claim 13, wherein the screw engagement portion of the second adjusting tool comprises a key for engaging the head of the adjusting screw to turn the adjusting screw and controlling height of the expandable spinal implant.

15. (Previously Presented) The system of claim 13, wherein the expandable spinal implant defines a longitudinal axis, wherein the first and second expandable spinal implant structures have first and second angled wedge surfaces that engage one another, wherein the adjusting screw is connected to the second expandable spinal implant structure so as to move the second expandable spinal implant structure along the longitudinal axis and slide the first angled wedge surface with respect to the second angled wedge surface to push the first expandable spinal implant structure in a direction that is substantially away from the longitudinal axis of the expandable spinal implant.

16. (Previously Presented) The system of claim 13, wherein the first expandable spinal implant structure defines a first angled wedge portion that comprises a first inwardly-facing rail and a second inwardly-facing rail, wherein a first inwardly-facing slot is defined at a location adjacent the first inwardly-facing rail, wherein a second inwardly-facing slot is defined at a location adjacent the second inwardly-facing rail, wherein the second expandable spinal implant structure defines a second angled wedge portion that comprises a first outwardly-facing rail and a second outwardly-facing rail that faces outwardly in a direction opposite that of the first outwardly-facing rail, wherein a first outwardly-facing slot is defined at a location adjacent the first

outwardly-facing rail, wherein a second outwardly-facing slot is defined at a location adjacent the second outwardly-facing rail, wherein the first expandable spinal implant structure is slidably-engaged with the second expandable spinal implant structure such that the first angled wedge portion engages the second angled wedge portion with the first inwardly-facing rail of the first expandable spinal implant structure positioned in the first outwardly-facing slot of the second expandable spinal implant structure, the second inwardly-facing rail of the first expandable spinal implant structure positioned in the second outwardly facing slot of the second expandable spinal implant structure, the first outwardly-facing rail of the second expandable spinal implant structure positioned in the first inwardly-facing slot of the first expandable spinal implant structure, and the second outwardly-facing rail of the second expandable spinal implant structure positioned in the second inwardly-facing slot of the first expandable spinal implant structure.

17. (Previously Presented) The system of claim 13, and further comprising first and second anchors, wherein the expandable spinal implant comprises first and second anchor guides angled to guide the first and second anchors bidirectionally into first and second vertebral bodies.

18. (Currently Amended) The system of claim 17, wherein the first tool defines third and fourth anchor [[screw]] guides configured to align with the first and second anchor [[screw]] guides of the expandable spinal implant when the first and second engagement prongs are engaged with the first and second tool engagement indentations so as to guide the first and second anchors through the third and fourth anchor [[screw]] guides into the first and second anchor [[screw]] guides.

19. (Previously Presented) A method of using the system of claim 13, the method comprising:

connecting the first tool to the expandable spinal implant with the first and second engagement prongs engaged with the first and second tool engagement indentations;

implanting the expandable spinal implant into a disc space in the human spine via the first tool;

extending the second adjusting tool through the first tool to engage the adjusting screw of the expandable spinal implant; and

expanding the expandable spinal implant by turning the second adjusting tool to turn the adjusting screw of the expandable spinal implant.

20. (Currently Amended) A system comprising:

a tool assembly comprising:

a first tool having a first proximal end, a first distal end, and a first elongate body between the first proximal end and the first distal end, wherein the first tool defines a first tool axis from the first proximal end to the first distal end, wherein the first tool includes first and second engagement prongs positioned at the first distal end on opposite sides of the first tool axis, wherein the first tool defines an adjusting tool passage through the first tool; and

a second adjusting tool having a second proximal end and a second distal end, wherein the second adjusting tool includes a second handle positioned at the second proximal end, a screw engagement portion positioned at the second distal end, and a shaft extending from the second handle to the screw engagement portion, wherein the shaft of the second adjusting tool is sized with a smaller diameter than that of the adjusting tool passage such that the second adjusting tool can extend through the adjusting tool passage of the first tool; and

an expandable spinal implant sized and configured to be implanted in a human spine, the expandable spinal implant comprising a first expandable spinal implant structure defining a first engagement surface sized and configured to engage a first vertebral body, a second expandable spinal implant structure defining a second engagement surface sized and configured to engage a second vertebral body, and an adjusting screw having a screw head and a threaded shaft, wherein the expandable spinal implant is configured to expand the first expandable spinal implant structure with respect to the second expandable spinal implant structure in

response to turning of the adjusting screw, wherein the expandable spinal implant defines first and second tool engagement indentations sized and configured for receiving the first and second engagement prongs of the first tool, wherein the adjusting screw is positioned within the expandable spinal implant in a screw location such that the second adjusting tool can extend through the adjusting tool passage of the first tool to engage the screw head of the adjusting screw while the first and second engagement prongs of the first tool are engaged with the first and second tool engagement indentations of the expandable spinal implant.

21. (Previously Presented) The system of claim 20, wherein the expandable spinal implant includes ridges on each of the first and second engagement surfaces, wherein the first indentation extends into a first side of the first expandable spinal implant structure, wherein the second indentation extends into a second side of the expandable spinal implant structure.

22. (Previously Presented) The system of claim 20, wherein the expandable spinal implant comprises first and second angled wedge surfaces, wherein rotation of the adjustment screw by the second adjusting tool drives relative motion of the first angled wedge surface with respect to the second angled wedge surface to expand the expandable spinal implant.

23. (Previously Presented) The system of claim 20, wherein the first expandable spinal implant structure defines an end gap between the first and second opposing side surfaces at a first end of the first vertebral body engagement surface, wherein the first vertebral body engagement surface comprises a plurality of ridges extending from the first vertebral body engagement surface, wherein at least some of the ridges are positioned on the first vertebral body engagement surface on opposite sides of the end gap.

24. (Previously Presented) The system of claim 20, and further comprising first and second anchors, wherein the expandable spinal implant comprises first and second anchor guides angled to guide the first and second anchors bidirectionally into the first and second vertebral bodies, wherein the first tool defines third and fourth anchor guides configured to align with the first and

second anchor guides of the expandable spinal implant so as to guide the first and second anchors through the third and fourth anchor guides into the first and second anchor guides when the first and second engagement prongs are engaged with the first and second tool engagement indentations.

25. (Previously Presented) The system of claim 20, wherein a distal end of the adjusting screw has a distal diameter, wherein the head of the adjusting screw has a head diameter, and wherein the distal diameter is larger than the head diameter.

26. (Previously Presented) The system of claim 20, wherein the first tool comprises a first handle positioned proximate the first proximal end and extending in a direction that is substantially perpendicular to the first proximal axis, wherein the second handle of the second adjusting tool is substantially circular when viewed along the first proximal axis when the second adjusting tool is positioned in the adjusting tool passage.

27. (Previously Presented) The system of claim 20, wherein the first expandable spinal implant structure and the first engagement surface move with respect to the second expandable spinal implant structure and the second engagement surface at least partially along a direction of the first tool axis when the second adjusting tool turns the adjusting screw.

28. (Previously Presented) The system of claim 20, wherein the expandable spinal implant has a proximal end, a distal end, and first and second sides, wherein the screw head of the adjusting screw is positioned at the proximal end of the expandable spinal implant, wherein the first and second tool indentations are positioned on the first and second sides proximate to the proximal end, wherein the expandable spinal implant defines a proximal screw hole at the proximal end of the expandable spinal implant and a distal screw hole at the distal end of the expandable spinal implant and wherein the adjusting screw extends through both the proximal and the distal screw holes.

29. (Previously Presented) The system of claim 20, wherein the first tool indentation extends into

a first side of the expandable spinal implant with a first substantially rectangular shape as viewed from a direction perpendicular to the first side and the second tool indentation extends into a second side of the expandable spinal implant with a second substantially rectangular shape as viewed from a direction perpendicular to the second side.

30. (Previously Presented) A method of using the system of claim 20, the method comprising:

connecting the first tool to the expandable spinal implant with the first and second engagement prongs engaged with the first and second tool engagement indentations;

implanting the expandable spinal implant into a disc space in the human spine via the first tool;

extending the second adjusting tool through the first tool to engage the adjusting screw of the expandable spinal implant; and

expanding the expandable spinal implant by turning the second adjusting tool to turn the adjusting screw of the expandable spinal implant.

31. (Currently Amended) A system comprising:

a tool assembly comprising:

a first tool having a first proximal end, a first distal end, and a first elongate body between the first proximal end and the first distal end, wherein the first tool defines a first tool axis from the first proximal end to the first distal end, wherein the first tool includes a gripper having one or more engagement prongs positioned at the first distal end axially offset from the first tool axis, wherein the first tool defines an adjusting tool passage through the first tool; and

a second adjusting tool having a second proximal end and a second distal end, wherein the second adjusting tool includes a screw engagement portion positioned at the second distal end and a shaft extending from the second proximal end to the screw engagement portion, wherein the shaft of the second adjusting tool is sized with a smaller diameter than that of the

adjusting tool passage such that the second adjusting tool can extend through and turn within the adjusting tool passage of the first tool; and

an expandable spinal implant sized and configured to be implanted in a human spine, the expandable spinal implant comprising a first expandable spinal implant structure defining a first engagement surface sized and configured to engage a first vertebral body, a second expandable spinal implant structure defining a second engagement surface sized and configured to engage a second vertebral body, and an adjusting screw having a screw engagement portion and a threaded portion, wherein the expandable spinal implant is configured to expand the first expandable spinal implant structure with respect to the second expandable spinal implant structure in response to turning of the adjusting screw, wherein the expandable spinal implant defines one or more tool engagement indentations sized and configured for engaging with the gripper of the first tool, wherein the adjusting screw is positioned within the expandable spinal implant in a screw location such that the second adjusting tool can extend through the adjusting tool passage of the first tool to engage the screw engagement portion of the adjusting screw one or more engagement prongs of the first tool are engaged with the one or more engagement indentations of the expandable spinal implant, wherein at least one of the one or more engagement indentations of the expandable spinal implant is positioned on one or more side surfaces of the expandable spinal implant such that the one or more engagement prongs of the gripper is positioned on the one or more side surfaces of the expandable spinal implant when the first tool is engages with the expandable spinal implant.

32. (Previously Presented) The system of claim 31, wherein the expandable spinal implant comprises a substantially cylindrical side hole extending through a side of the expandable spinal implant into an interior cavity of the expandable spinal implant and is sized and configured to allow for bone placement through the side hole into the interior cavity, wherein the expandable spinal implant comprises an angled wedge portion having rails and slots configured to allow for relative movement and expansion of the expandable spinal implant during expansion of the

expandable spinal implant.

33. (New) A system comprising:

a tool assembly comprising:

a first tool having a first proximal end, a first distal end, and a first elongate body between the first proximal end and the first distal end, wherein the first tool defines a first tool axis from the first proximal end to the first distal end, wherein the first tool includes a gripper having one or more engagement prongs positioned at the first distal end axially offset from the first tool axis, wherein the first tool defines an adjusting tool passage through the first tool; and

a second adjusting tool having a second proximal end and a second distal end, wherein the second adjusting tool includes a screw engagement portion positioned at the second distal end and a shaft extending from the second proximal end to the screw engagement portion, wherein the shaft of the second adjusting tool is sized with a smaller diameter than that of the adjusting tool passage such that the second adjusting tool can extend through and turn within the adjusting tool passage of the first tool; and

an expandable spinal implant sized and configured to be implanted in a human spine, the expandable spinal implant comprising a first expandable spinal implant structure defining a first engagement surface sized and configured to engage a first vertebral body, a second expandable spinal implant structure defining a second engagement surface sized and configured to engage a second vertebral body, and an adjusting screw having a screw engagement portion and a threaded portion, wherein the expandable spinal implant is configured to expand the first expandable spinal implant structure with respect to the second expandable spinal implant structure in response to turning of the adjusting screw, wherein the expandable spinal implant defines one or more tool engagement indentations sized and configured for engaging with the gripper of the first tool, wherein the adjusting screw is positioned within the expandable spinal implant in a screw

location such that the second adjusting tool can extend through the adjusting tool passage of the first tool to engage the screw engagement portion of the adjusting screw one or more engagement prongs of the first tool are engaged with the one or more engagement indentations of the expandable spinal implant, wherein at least one of the one or more engagement indentations of the expandable spinal implant is positioned on one or more side surfaces of the expandable spinal implant such that the one or more engagement prongs of the gripper is positioned on the one or more side surfaces of the expandable spinal implant when the first tool is engages with the expandable spinal implant.

34. (New) The system of claim 32, wherein the expandable spinal implant comprises a substantially cylindrical side hole extending through a side of the expandable spinal implant into an interior cavity of the expandable spinal implant and is sized and configured to allow for bone placement through the side hole into the interior cavity, wherein the expandable spinal implant comprises an angled wedge portion having rails and slots configured to allow for relative movement and expansion of the expandable spinal implant during expansion of the expandable spinal implant.

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www.uspto.gov

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
16/280,684	02/20/2019	Ahmnon D. Moskowitz	46440-0009015

CONFIRMATION NO. 1247

26191
FISH & RICHARDSON P.C. (TC)
PO BOX 1022
MINNEAPOLIS, MN 55440-1022

PUBLICATION NOTICE

OC000000108892449

Title:BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION

Publication No.US-2019-0175361-A1
Publication Date:06/13/2019

NOTICE OF PUBLICATION OF APPLICATION

The above-identified application will be electronically published as a patent application publication pursuant to 37 CFR 1.211, et seq. The patent application publication number and publication date are set forth above.

The publication may be accessed through the USPTO's publically available Searchable Databases via the Internet at www.uspto.gov. The direct link to access the publication is currently http://www.uspto.gov/patft/.

The publication process established by the Office does not provide for mailing a copy of the publication to applicant. A copy of the publication may be obtained from the Office upon payment of the appropriate fee set forth in 37 CFR 1.19(a)(1). Orders for copies of patent application publications are handled by the USPTO's Public Records Division. The Public Records Division can be reached by telephone at (571) 272-3150 or (800) 972-6382, by facsimile at (571) 273-3250, by mail addressed to the United States Patent and Trademark Office, Public Records Division, Alexandria, VA 22313-1450 or via the Internet.

In addition, information on the status of the application, including the mailing date of Office actions and the dates of receipt of correspondence filed in the Office, may also be accessed via the Internet through the Patent Electronic Business Center at www.uspto.gov using the public side of the Patent Application Information and Retrieval (PAIR) system. The direct link to access this status information is currently https://portal.uspto.gov/pair/PublicPair. Prior to publication, such status information is confidential and may only be obtained by applicant using the private side of PAIR.

Further assistance in electronically accessing the publication, or about PAIR, is available by calling the Patent Electronic Business Center at 1-866-217-9197.

Office of Data Managment, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/280,684	02/20/2019	Ahmnon D. Moskowitz	46440-0009015	1247

26191 7590 07/16/2019

FISH & RICHARDSON P.C. (TC)
PO BOX 1022
MINNEAPOLIS, MN 55440-1022

EXAMINER	
PHILOGENE, PEDRO	

ART UNIT	PAPER NUMBER
3773	

NOTIFICATION DATE	DELIVERY MODE
07/16/2019	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary	Application No. 16/280,684	Applicant(s) Moskowitz et al.	
	Examiner PEDRO PHILOGENE	Art Unit 3773	AIA (FITF) 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 5/7/19.

☐ 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) 13-34 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) 13-34 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)

2) ☑ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

Notice of Pre-AIA or AIA Status

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

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 13-34 rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-26 of U.S. Patent No. 10,307,268. Although the claims at issue are not identical, they are not patentably distinct from each other because it is clear that all the elements of claims of the application are to be found in claims of the patent. The difference between claims of the application and claims of the patent lies in the fact that the patent claims include many more elements and are thus much more specific. Thus the invention of claims of the patent is in effect a “species” of the “generic” invention of claims of the application. It has been held that the generic invention is “anticipated” by the “species”. See in re Goodman, 29 USPQ2d 2010 (Fed. Cir. 1993). Since claims of the application are anticipated by claims of the patent, then they are not patentably distinct.

Conclusion

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

2007/0270968	11-2007	Baynham et al.
2009/0058876	3-2006	McKinley
7,211,112	5-2007	Baynham et al.
8,328,851	12-2012	Currqn 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 M-F 8:00-4:00PM.

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, **Robert, Eduardo** 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 3773
July 11, 2019

Notice of References Cited	Application/Control No. 16/280,684	Applicant(s)/Patent Under Reexamination Moskowitz et al.	
	Examiner PEDRO PHILOGENE	Art Unit 3773	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
*	A	US-8328851-B2	12-2012	Curran; Matthew	A61F2/4425	606/279
*	B	US-7211112-B2	05-2007	Baynham; Bret O.	A61F2/447	623/17.11
*	C	US-20060058876-A1	03-2006	McKinley; Laurence M.	A61F2/4455	623/17.11
*	D	US-20070270968-A1	11-2007	Baynham; Bret O.	A61F2/447	623/17.11
*	E	US-10307268-B2	06-2019	Moskowitz; Ahmnon D.	A61B17/0642	1/1
	F					
	G					
	H					
	I					
	J					
	K					
	L					
	M					

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	CPC Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/280,684	Moskowitz et al.
	Examiner	Art Unit
	PEDRO PHILOGENE	3773

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

CLAIMS

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	03/14/2019	07/11/2019							
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	34		✓							

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/280,684	Moskowitz et al.
	Examiner	Art Unit
	PEDRO PHILOGENE	3773

CPC - Searched*		
Symbol	Date	Examiner
A61F2/4611,4465,447; A61B17/0642,7064,809,8635,8875,8894,92,0644,1757,86	07/11/2019	/P.P./
A61B2017/00407,0641,0648,922,		
A61F2002/2835,30133,30387,30448,30507,3055,30579,30604,30772,30878,30879,30904,4475,448,4627,4681,4687		
A61F2220/0025,005; A61F2230/0015; A61F2250/0007		

CPC Combination Sets - Searched*		
Symbol	Date	Examiner

US Classification - Searched*			
Class	Subclass	Date	Examiner
623	17.11-17.16	07/11/2019	/P.P./
606	246-289,300-308,86A,99,96,100		
227	175.1, 176.1		

* 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	07/11/2019	/P.P./

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner

Substitute Disclosure Form	U.S. Department of Commerce Patent and Trademark Office	Attorney Docket No. 46440-0009015	Application No. To Be Assigned
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(37 CFR §1.98(b))		Filing Date Herewith	Group Art Unit Unknown

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		Filing Date Herewith	Group Art Unit Unknown

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EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	0	((ahmnon or mosheh or nathan) near moskowitz or pablo near valdivia near alvarado).in. & tool near assembly & handle and prong & gripper & adjusting near tool & expandable near spinal near implant & adjusting near screw & indentation & structure	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2019/07/11 09:32
L2	153	((ahmnon or mosheh or nathan) near moskowitz or pablo near valdivia near alvarado).in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2019/07/11 09:33
L3	0	((ahmnon or mosheh or nathan) near moskowitz or pablo near valdivia near alvarado).in. & tool near assembly & expandable near spinal near implant & adjusting near screw	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2019/07/11 09:35
L4	0	((ahmnon or mosheh or nathan) near moskowitz or pablo near valdivia near alvarado).in. & tool & expandable near spinal near implant & adjusting near screw	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2019/07/11 09:40
L5	0	"20190175361" & tool & expandable near spinal near implant & adjusting near screw	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2019/07/11 09:43
L6	0	((ahmnon or mosheh or nathan) near moskowitz or pablo near valdivia near alvarado).in. & expandable near spinal near implant	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2019/07/11 09:44
L7	24	((ahmnon or mosheh or nathan) near moskowitz or pablo near valdivia near alvarado).in. & tool near assembly and screw near box	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2019/07/11 09:49
L8	1	("7942903").PN.	USPAT;	OR	OFF	2019/07/11

			USOCR			10:44
L9	211	("10238505" | "20040162558" | "20060058876" | "20060217713" | "20070191850" | "20080249575" | "20100100138" | "4505273" | "5352229" | "5662655" | "5865848" | "6325805" | "6746450" | "8167949" | "9895238" | "9907674" | "20020068977" | "20020143338" | "20030130737" | "20040088054" | "20040177531" | "20040186482" | "20040186569" | "20040193272" | "20040220571" | "20040254644" | "20050027362" | "20050049590" | "20050177235" | "20050216084" | "20050256576" | "20050261769" | "20050273170" | "20050278026" | "20060155285" | "20060241621" | "20070049943" | "20070167678" | "20070198089" | "20070213820" | "20070250167" | "20070250172" | "20070270968" | "20070276498" | "20080033440" | "20080177307" | "20080183293" | "20080249569" | "20080249625" | "20080281424" | "20080281425" | "20090030520" | "20090080997" | "20090105830" | "20090105831" | "20090112271" | "20090182430" | "20090187218" | "20090210062" | "20090224023" | "20090234455" | "20100145460" | "20100211176" | "20100305704" | "20100324606" | "20110125269" | "20110137349" | "20110178600" | "20110208312" | "20110288646" | "20110295327" | "20110295371" | "20110307011" | "20110319935" | "20120010714" | "20120271423" | "20120277870" | "20120323330" | "20120330419" | "20130018468" | "20130018469" | "20130018470" | "20130023991" | "20130023992" | "20130053962" | "20130060339" | "20130073044" | "20130173002" | "20130282017" | "20140249629" | "20150025637" | "20150105824" | "20150148847" | "20160374830" | "20170252178" | "20180311052" | "2360942" | "4064881" | "4554914" | "4599086" | "4636217" | "4904261" | "4960420" | "4997432" | "5005749" | "5062850" | "5123926" | "5290312" | "5405391" | "5413583" | "5454819" | "5514180" | "5609635" | "5660188" | "5665122" | "5667472" | "5713912" | "5782832" | "5888223" | "5916224" | "5951574" | "5960522" | "5968054" | "5976136" | "6126689" | "6224602" | "6235034" | "6322562" | "6342074" | "6368350" | "6375682" | "6419704" | "6432106" | "6454807" | "6458159" | "6527804" | "6533818" | "6558423" | "6562074" | "6572653" | "6579318" | "6582468" | "6613055" | "6629998" | "6641614" | "6655243" |	US-PGPUB; USPAT	OR	OFF	2019/07/11 10:51

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L10	2512	insert$4 near (device or tool or instrument) & expandable near (implant or cage or spacer)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2019/07/11 11:03
L11	2	"20190175361"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2019/07/11 11:05
L12	2	11 AND ((A61B17/7064 OR A61B17/0642 OR A61B17/809 OR A61B17/8875 OR A61B17/0644 OR A61B17/1757 OR A61B17/8042 OR A61B17/86 OR A61B17/8635 OR A61B17/8894 OR A61B17/92 OR A61B2017/00407 OR A61B2017/0641 OR A61B2017/0648 OR A61B2017/922 OR A61B17/0643 OR A61B17/068 OR A61B17/0682 OR A61B17/70 OR A61B17/7001 OR A61B17/7004 OR A61B17/7011 OR A61B17/7023 OR A61B17/7047 OR A61B17/7065 OR A61B17/707 OR A61B17/7074 OR A61B17/8047 OR A61B17/8605 OR A61B17/8625 OR A61B17/8685 OR A61B2017/0256 OR A61B2017/0647 OR A61F2/447 OR A61F2/4611 OR A61F2002/2835 OR A61F2002/30133 OR A61F2002/30387 OR A61F2002/30448 OR A61F2002/30507 OR A61F2002/3055 OR A61F2002/30579 OR A61F2002/30604 OR A61F2002/30772 OR A61F2002/30878 OR A61F2002/30879 OR A61F2002/30904 OR A61F2002/4475 OR A61F2002/448 OR A61F2002/4627 OR A61F2002/4681 OR A61F2002/4687 OR A61F2220/0025 OR A61F2220/005 OR	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2019/07/11 11:07

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7/ 11/ 2019 11:29:27 AM

Substitute Disclosure Form	U.S. Department of Commerce Patent and Trademark Office	Attorney Docket No. 46440-0009015	Application No. 16/280,684
Information Disclosure Statement by Applicant (Use several sheets if necessary) (37 CFR §1.98(b))		Applicant Moskowitz Family LLC	
		Filing Date February 20, 2019	Group Art Unit 3773

U.S. Patent Documents

Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	1.	2004/0162558	8/19/2004	Hegde			
	2.	2006/0058876	3/2006	Laurence			
	3.	2006/0217713	9/28/2006	Serhan			
	4.	2007/0191850	8/16/2007	Kim			
	5.	2008/0249575	10/1/2008	Waugh			
	6.	2010/0100138	4/22/2010	Reynolds			
	7.	4,505,273	3/19/1985	Braun			
	8.	5,352,229	10/4/1994	Goble			
	9.	5,662,655	9/2/1997	Laboureau			
	10.	5,865,848	2/1/1999	Baker			
	11.	6,325,805	12/4/2001	Ogilvie			
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	13.	8,167,949	5/1/2012	Tyber			
	14.	9,895,238	2/20/2018	Moskowitz et al.			
	15.	9,907,674	3/6/2018	Moskowitz			
	16.	10,238,505	3/26/2019	Moskowitz et al.			

Foreign Patent Documents or Published Foreign Patent Applications

Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation Yes	Translation No

Other Documents (include Author, Title, Date, and Place of Publication)

Examiner Initial	Desig. ID	Document

Examiner Signature	Date Considered
/PEDRO PHILOGENE/	07/11/2019

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/

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor	:	Ahmnon D. Moskowitz	Art Unit	:	3773
Application No.	:	16/280,684	Examiner	:	Pedro Philogene
Filed	:	February 20, 2019	Conf. No.	:	1247
Title	:	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION			

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

REPLY TO ACTION OF JULY 16, 2019

Please consider the following reply.

Electronic Acknowledgement Receipt	
EFS ID:	36597936
Application Number:	16280684
International Application Number:	
Confirmation Number:	1247
Title of Invention:	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING 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:	46440-0009015
Receipt Date:	16-JUL-2019
Filing Date:	20-FEB-2019
Time Stamp:	14:52:31
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		Response.pdf	109294 1c70a85817aa4a8a11c3ceb0b8771cc1222acccd	yes	15

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Applicant Arguments/Remarks Made in an Amendment	14	15
	Claims	4	13
	Abstract	3	3
	Specification	2	2
	Amendment/Req. Reconsideration-After Non-Final Reject	1	1
Warnings:			
Information:			
	Total Files Size (in bytes):	109294	

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.

REMARKS

Claims 13-34 are pending, with claims 13,20, 31, and 33 being independent. With this amendment claim 31 is amended for clarity. Claim 35 is added. The title and abstract have been amended to describe the claimed subject matter.

Double Patenting

Claims 13-34 were rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-26 of U.S. Patent No. 10,307,268.

Without conceding the merits of the rejection but to further prosecution, a terminal disclaimer is filed herewith to obviate this rejection. In view of the terminal disclaimer, Applicant respectfully requests that this rejection be withdrawn.

Request for Reconsideration

The Applicant respectfully requests prompt consideration and a Notice of Allowance. In the event that no Notice of Allowance will be provided in the next communication, Applicant requests that the Examiner telephone the undersigned attorney (612-337-2538) prior to the next communication so that prosecution on the merits may be expedited. It is believed that all of the pending claims have been addressed. However, the absence of a reply to a specific rejection, issue or comment does not signify agreement with or concession of that rejection, issue or comment. In addition, because the arguments made above may not be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed. Nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendments herein do not signify concession of unpatentability of any claims prior to this amendment. Applicant hereby specifically reserves the right to prosecute the previously presented subject matter in a continuing application. Also, Applicant expressly reserves the right to prosecute claims of different or broader scope in a continuing application. The Patent Office should infer no (i) adoption of a position with respect to patentability, (ii) change in the Applicant's position with

respect to any claim or subject matter of the invention, or (iii) acquiescence in any way to any position taken by the Office Action, based on the amendments made herein.

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

Respectfully submitted,

Date: 7/16/2019

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

Customer Number 26191
Fish & Richardson P.C.
Telephone: (612) 337-2538
Facsimile: (877) 769-7945

62006668.doc

Amendments to Claims:
Listing of Claims.

1-12 (Cancelled)

13. (Previously Presented) A system comprising:

a tool assembly which comprises:

a first tool having a first proximal end and a first distal end with a first handle and a gripper, the gripper being positioned at the first distal end, cooperating with the first handle, and having first and second engagement prongs positioned at the first distal end, wherein the first tool defines an adjusting tool passage through the first tool; and

a second adjusting tool having a second proximal end and a second distal end with a second handle positioned at the second proximal end, a screw engagement portion positioned at the second distal end, and a shaft extending from the second handle to the screw engagement portion, wherein the shaft of the second adjusting tool is sized with a smaller diameter than that of the adjusting tool passage such that the second adjusting tool can extend through the adjusting tool passage of the first tool; and

an expandable spinal implant sized and configured to be implanted in a human spine, the expandable spinal implant comprising a first expandable spinal implant structure, a second expandable spinal implant structure, and an adjusting screw having a screw head and a threaded portion, wherein the expandable spinal implant is configured to expand the first expandable spinal implant structure with respect to the second expandable spinal implant structure in response to turning of the adjusting screw, wherein the expandable spinal implant defines first and second tool engagement indentations sized and configured for receiving the first and second engagement prongs of the first tool, wherein the adjusting screw is positioned within the expandable spinal implant in a screw location such that the

second adjusting tool can extend through the adjusting tool passage of the first tool to engage the screw head of the adjusting screw while the first and second engagement prongs of the first tool are engaged with the first and second tool engagement indentations of the expandable spinal implant.

14. (Previously Presented) The system of claim 13, wherein the screw engagement portion of the second adjusting tool comprises a key for engaging the head of the adjusting screw to turn the adjusting screw and controlling height of the expandable spinal implant.

15. (Previously Presented) The system of claim 13, wherein the expandable spinal implant defines a longitudinal axis, wherein the first and second expandable spinal implant structures have first and second angled wedge surfaces that engage one another, wherein the adjusting screw is connected to the second expandable spinal implant structure so as to move the second expandable spinal implant structure along the longitudinal axis and slide the first angled wedge surface with respect to the second angled wedge surface to push the first expandable spinal implant structure in a direction that is substantially away from the longitudinal axis of the expandable spinal implant.

16. (Previously Presented) The system of claim 13, wherein the first expandable spinal implant structure defines a first angled wedge portion that comprises a first inwardly-facing rail and a second inwardly-facing rail, wherein a first inwardly-facing slot is defined at a location adjacent the first inwardly-facing rail, wherein a second inwardly-facing slot is defined at a location adjacent the second inwardly-facing rail, wherein the second expandable spinal implant structure defines a second angled wedge portion that comprises a first outwardly-facing rail and a second outwardly-facing rail that faces outwardly in a direction opposite that of the first outwardly-facing rail, wherein a first outwardly-facing slot is defined at a location adjacent the first outwardly-facing rail, wherein a second outwardly-facing slot is defined at a location adjacent the second outwardly-facing rail, wherein the first expandable spinal implant structure is slidably-engaged with the second expandable spinal implant structure such that the first angled wedge portion engages the second angled wedge portion with the first inwardly-facing rail of the

first expandable spinal implant structure positioned in the first outwardly-facing slot of the second expandable spinal implant structure, the second inwardly-facing rail of the first expandable spinal implant structure positioned in the second outwardly facing slot of the second expandable spinal implant structure, the first outwardly-facing rail of the second expandable spinal implant structure positioned in the first inwardly-facing slot of the first expandable spinal implant structure, and the second outwardly-facing rail of the second expandable spinal implant structure positioned in the second inwardly-facing slot of the first expandable spinal implant structure.

17. (Previously Presented) The system of claim 13, and further comprising first and second anchors, wherein the expandable spinal implant comprises first and second anchor guides angled to guide the first and second anchors bidirectionally into first and second vertebral bodies.

18. (Previously Presented) The system of claim 17, wherein the first tool defines third and fourth anchor guides configured to align with the first and second anchor guides of the expandable spinal implant when the first and second engagement prongs are engaged with the first and second tool engagement indentations so as to guide the first and second anchors through the third and fourth anchor guides into the first and second anchor guides.

19. (Previously Presented) A method of using the system of claim 13, the method comprising:

connecting the first tool to the expandable spinal implant with the first and second engagement prongs engaged with the first and second tool engagement indentations;

implanting the expandable spinal implant into a disc space in the human spine via the first tool;

extending the second adjusting tool through the first tool to engage the adjusting screw of the expandable spinal implant; and

expanding the expandable spinal implant by turning the second adjusting tool to turn the adjusting screw of the expandable spinal implant.

20. (Previously Presented) A system comprising:

a tool assembly comprising:

a first tool having a first proximal end, a first distal end, and a first elongate body between the first proximal end and the first distal end, wherein the first tool defines a first tool axis from the first proximal end to the first distal end, wherein the first tool includes first and second engagement prongs positioned at the first distal end on opposite sides of the first tool axis, wherein the first tool defines an adjusting tool passage through the first tool; and

a second adjusting tool having a second proximal end and a second distal end, wherein the second adjusting tool includes a second handle positioned at the second proximal end, a screw engagement portion positioned at the second distal end, and a shaft extending from the second handle to the screw engagement portion, wherein the shaft of the second adjusting tool is sized with a smaller diameter than that of the adjusting tool passage such that the second adjusting tool can extend through the adjusting tool passage of the first tool; and

an expandable spinal implant sized and configured to be implanted in a human spine, the expandable spinal implant comprising a first expandable spinal implant structure defining a first engagement surface sized and configured to engage a first vertebral body, a second expandable spinal implant structure defining a second engagement surface sized and configured to engage a second vertebral body, and an adjusting screw having a screw head and a threaded shaft, wherein the expandable spinal implant is configured to expand the first expandable spinal implant structure with respect to the second expandable spinal implant structure in response to turning of the adjusting screw, wherein the expandable spinal implant defines first and second tool engagement indentations sized and configured for receiving the first and second engagement prongs of the first tool, wherein the adjusting screw is positioned within the expandable spinal implant in a screw location such that the second adjusting tool can extend through the adjusting tool

passage of the first tool to engage the screw head of the adjusting screw while the first and second engagement prongs of the first tool are engaged with the first and second tool engagement indentations of the expandable spinal implant.

21. (Previously Presented) The system of claim 20, wherein the expandable spinal implant includes ridges on each of the first and second engagement surfaces, wherein the first indentation extends into a first side of the first expandable spinal implant structure, wherein the second indentation extends into a second side of the expandable spinal implant structure.

22. (Previously Presented) The system of claim 20, wherein the expandable spinal implant comprises first and second angled wedge surfaces, wherein rotation of the adjustment screw by the second adjusting tool drives relative motion of the first angled wedge surface with respect to the second angled wedge surface to expand the expandable spinal implant.

23. (Previously Presented) The system of claim 20, wherein the first expandable spinal implant structure defines an end gap between the first and second opposing side surfaces at a first end of the first vertebral body engagement surface, wherein the first vertebral body engagement surface comprises a plurality of ridges extending from the first vertebral body engagement surface, wherein at least some of the ridges are positioned on the first vertebral body engagement surface on opposite sides of the end gap.

24. (Previously Presented) The system of claim 20, and further comprising first and second anchors, wherein the expandable spinal implant comprises first and second anchor guides angled to guide the first and second anchors bidirectionally into the first and second vertebral bodies, wherein the first tool defines third and fourth anchor guides configured to align with the first and second anchor guides of the expandable spinal implant so as to guide the first and second anchors through the third and fourth anchor guides into the first and second anchor guides when the first and second engagement prongs are engaged with the first and second tool engagement indentations.

25. (Previously Presented) The system of claim 20, wherein a distal end of the adjusting screw has a distal diameter, wherein the head of the adjusting screw has a head diameter, and wherein the distal diameter is larger than the head diameter.

26. (Previously Presented) The system of claim 20, wherein the first tool comprises a first handle positioned proximate the first proximal end and extending in a direction that is substantially perpendicular to the first proximal axis, wherein the second handle of the second adjusting tool is substantially circular when viewed along the first proximal axis when the second adjusting tool is positioned in the adjusting tool passage.

27. (Previously Presented) The system of claim 20, wherein the first expandable spinal implant structure and the first engagement surface move with respect to the second expandable spinal implant structure and the second engagement surface at least partially along a direction of the first tool axis when the second adjusting tool turns the adjusting screw.

28. (Previously Presented) The system of claim 20, wherein the expandable spinal implant has a proximal end, a distal end, and first and second sides, wherein the screw head of the adjusting screw is positioned at the proximal end of the expandable spinal implant, wherein the first and second tool indentations are positioned on the first and second sides proximate to the proximal end, wherein the expandable spinal implant defines a proximal screw hole at the proximal end of the expandable spinal implant and a distal screw hole at the distal end of the expandable spinal implant and wherein the adjusting screw extends through both the proximal and the distal screw holes.

29. (Previously Presented) The system of claim 20, wherein the first tool indentation extends into a first side of the expandable spinal implant with a first substantially rectangular shape as viewed from a direction perpendicular to the first side and the second tool indentation extends into a second side of the expandable spinal implant with a second substantially rectangular shape as viewed from a direction perpendicular to the second side.

30. (Previously Presented) A method of using the system of claim 20, the method comprising:

connecting the first tool to the expandable spinal implant with the first and second engagement prongs engaged with the first and second tool engagement indentations;

implanting the expandable spinal implant into a disc space in the human spine via the first tool;

extending the second adjusting tool through the first tool to engage the adjusting screw of the expandable spinal implant; and

expanding the expandable spinal implant by turning the second adjusting tool to turn the adjusting screw of the expandable spinal implant.

31. (Currently Amended) A system comprising:

a tool assembly comprising:

a first tool having a first proximal end, a first distal end, and a first elongate body between the first proximal end and the first distal end, wherein the first tool defines a first tool axis from the first proximal end to the first distal end, wherein the first tool includes a gripper having one or more engagement prongs positioned at the first distal end axially offset from the first tool axis, wherein the first tool defines an adjusting tool passage through the first tool; and

a second adjusting tool having a second proximal end and a second distal end, wherein the second adjusting tool includes a screw engagement portion positioned at the second distal end and a shaft extending from the second proximal end to the screw engagement portion, wherein the shaft of the second adjusting tool is sized with a smaller diameter than that of the adjusting tool passage such that the second adjusting tool can extend through and turn within the adjusting tool passage of the first tool; and

an expandable spinal implant sized and configured to be implanted in a human spine, the expandable spinal implant comprising a first expandable spinal implant structure defining a first engagement surface sized and configured to engage a first

vertebral body, a second expandable spinal implant structure defining a second engagement surface sized and configured to engage a second vertebral body, and an adjusting screw having a screw engagement portion and a threaded portion, wherein the expandable spinal implant is configured to expand the first expandable spinal implant structure with respect to the second expandable spinal implant structure in response to turning of the adjusting screw, wherein the expandable spinal implant defines one or more tool engagement indentations sized and configured for engaging with the gripper of the first tool, wherein the adjusting screw is positioned within the expandable spinal implant in a screw location such that the second adjusting tool can extend through the adjusting tool passage of the first tool to engage the screw engagement portion of the adjusting screw while one or more engagement prongs of the first tool are engaged with the one or more engagement indentations of the expandable spinal implant, wherein at least one of the one or more engagement indentations of the expandable spinal implant is positioned on one or more side surfaces of the expandable spinal implant such that the one or more engagement prongs of the gripper is positioned on the one or more side surfaces of the expandable spinal implant when the first tool is engages with the expandable spinal implant.

32. (Previously Presented) The system of claim 31, wherein the expandable spinal implant comprises a substantially cylindrical side hole extending through a side of the expandable spinal implant into an interior cavity of the expandable spinal implant and is sized and configured to allow for bone placement through the side hole into the interior cavity, wherein the expandable spinal implant comprises an angled wedge portion having rails and slots configured to allow for relative movement and expansion of the expandable spinal implant during expansion of the expandable spinal implant.

33. (Previously Presented) A system comprising:

a tool assembly comprising:

a first tool having a first proximal end, a first distal end, and a first elongate body between the first proximal end and the first distal end, wherein the first tool defines a first tool axis from the first proximal end to the first distal end, wherein the first tool includes a gripper having one or more engagement prongs positioned at the first distal end axially offset from the first tool axis, wherein the first tool defines an adjusting tool passage through the first tool; and

a second adjusting tool having a second proximal end and a second distal end, wherein the second adjusting tool includes a screw engagement portion positioned at the second distal end and a shaft extending from the second proximal end to the screw engagement portion, wherein the shaft of the second adjusting tool is sized with a smaller diameter than that of the adjusting tool passage such that the second adjusting tool can extend through and turn within the adjusting tool passage of the first tool; and

an expandable spinal implant sized and configured to be implanted in a human spine, the expandable spinal implant comprising a first expandable spinal implant structure defining a first engagement surface sized and configured to engage a first vertebral body, a second expandable spinal implant structure defining a second engagement surface sized and configured to engage a second vertebral body, and an adjusting screw having a screw engagement portion and a threaded portion, wherein the expandable spinal implant is configured to expand the first expandable spinal implant structure with respect to the second expandable spinal implant structure in response to turning of the adjusting screw, wherein the expandable spinal implant defines one or more tool engagement indentations sized and configured for engaging with the gripper of the first tool, wherein the adjusting screw is positioned within the expandable spinal implant in a screw location such that the second adjusting tool can extend through the adjusting tool passage of the first tool to engage the screw engagement portion of the adjusting screw one or more engagement prongs of the first tool are engaged with the one or more engagement indentations of the expandable spinal implant, wherein at

least one of the one or more engagement indentations of the expandable spinal implant is positioned on one or more side surfaces of the expandable spinal implant such that the one or more engagement prongs of the gripper is positioned on the one or more side surfaces of the expandable spinal implant when the first tool is engages with the expandable spinal implant.

34. (Previously Presented) The system of claim 32, wherein the expandable spinal implant comprises a substantially cylindrical side hole extending through a side of the expandable spinal implant into an interior cavity of the expandable spinal implant and is sized and configured to allow for bone placement through the side hole into the interior cavity, wherein the expandable spinal implant comprises an angled wedge portion having rails and slots configured to allow for relative movement and expansion of the expandable spinal implant during expansion of the expandable spinal implant.

35. (New) The system of claim 13, and further comprising bone graft material configured to be placed inside and outside of the expandable spinal implant.

Amendment to the Abstract:

Please delete previous abstract at page 30 and add the following new abstract:

A system includes a tool assembly and an expandable spinal implant. The tool assembly includes a first tool and a second adjusting tool. The first tool has first and second engagement prongs positioned at a first distal end and the first tool defines an adjusting tool passage. The second adjusting tool can extend through the adjusting tool passage of the first tool. The expandable spinal implant includes a first expandable spinal implant structure, a second expandable spinal implant structure, and an adjusting screw having a screw head and a threaded portion. The expandable spinal implant defines first and second tool engagement indentations. The adjusting screw is positioned within the expandable spinal implant such that the second adjusting tool can extend through the adjusting tool passage to engage the screw head while the first and second engagement prongs are engaged with the first and second tool engagement indentations.

Amendments to the Title:

Please replace the title with the following replacement title:

SYSTEM WITH TOOL ASSEMBLY AND EXPANDABLE SPINAL IMPLANT

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 OBVIATE A DOUBLE PATENTING REJECTION OVER A "PRIOR" PATENT**
Application Number	16280684
Filing Date	20-Feb-2019
First Named Inventor	Ahmnon Moskowitz
Attorney Docket Number	46440-0009015
Title of Invention	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING 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
Moskowitz Family LLC	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)

10307268

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:	16280684
Filing Date:	20-Feb-2019
Title of Invention:	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION
First Named Inventor/Applicant Name:	Ahmnon D. Moskowitz
Filer:	Stuart A. Nelson/Abby Remer
Attorney Docket Number:	46440-0009015
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.: 16280684

Filing Date: 20-Feb-2019

Applicant/Patent under Reexamination: Moskowitz

Electronic Terminal Disclaimer filed on July 16, 2019

☒ 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:	36596697
Application Number:	16280684
International Application Number:	
Confirmation Number:	1247
Title of Invention:	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING 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:	46440-0009015
Receipt Date:	16-JUL-2019
Filing Date:	20-FEB-2019
Time Stamp:	14:54:29
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	071719INTEFSW00001258061050
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	33672 77840fb5ef91ca88fa50b164a6c36a1159910b9f	no	2
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	30846 43b35b7a88155ac24973587aa1657a0cc458610d	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	64518		

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.

PTO/SB/06 (09-11)
Approved for use through 1/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 16/280,684	Filing Date 02/20/2019	☐ To be Mailed

ENTITY: ☐ LARGE ☑ SMALL ☐ MICRO

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA		RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A		N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A		N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*		x $50 =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*		x $230 =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).				
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))					
* If the difference in column 1 is less than zero, enter "0" in column 2.				TOTAL	

APPLICATION AS AMENDED - PART II

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT	07/16/2019	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 23	Minus	** 22	= 1		x $50 =	50
	Independent (37 CFR 1.16(h))	* 4	Minus	*** 4	= 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	50

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT	07/16/2019	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 23	Minus	** 22	= 1		x $50 =	50
	Independent (37 CFR 1.16(h))	* 4	Minus	*** 4	= 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	50

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.	LIE
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".	/GLORIA J NORRIS/
*** 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.	

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.

Substitute Disclosure Form	U.S. Department of Commerce Patent and Trademark Office	Attorney Docket No. 46440-0009015	Application No. 16/280,684
Information Disclosure Statement by Applicant (Use several sheets if necessary)		Applicant Moskowitz Family LLC	
(37 CFR §1.98(b))		Filing Date February 20, 2019	Group Art Unit 3773

U.S. Patent Documents

Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	1.	6,652,533	11/25/2003	O'Neil			
	2.	7,588,573	9/15/2009	Berry			
	3.	8,845,731	9/30/2014	Weiman			
	4.	9,333,095	5/10/2016	Beaurain et al			
	5.	9,393,130	7/19/2016	Suddaby & McClintock			
	6.	20040015315	1/22/2004	Kreider			
	7.	20110172774	7/14/2011	Varela			
	8.	20130211526	8/15/2013	Alheidt et al			

Foreign Patent Documents or Published Foreign Patent Applications

Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation Yes	Translation No

Other Documents (include Author, Title, Date, and Place of Publication)

Examiner Initial	Desig. ID	Document

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 Patent Application Fee Transmittal					
Application Number:	16280684				
Filing Date:	20-Feb-2019				
Title of Invention:	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION				
First Named Inventor/Applicant Name:	Ahmnon D. Moskowitz				
Filer:	Stuart A. Nelson/Richard Welsh				
Attorney Docket Number:	46440-0009015				
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:					
Extension-of-Time:					

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
SUBMISSION- INFORMATION DISCLOSURE STMT	2806	1	120	120
		Total in USD ($)		**120**

Electronic Acknowledgement Receipt	
EFS ID:	36601223
Application Number:	16280684
International Application Number:	
Confirmation Number:	1247
Title of Invention:	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION
First Named Inventor/Applicant Name:	Ahmnon D. Moskowitz
Customer Number:	26191
Filer:	Stuart A. Nelson/Richard Welsh
Filer Authorized By:	Stuart A. Nelson
Attorney Docket Number:	46440-0009015
Receipt Date:	16-JUL-2019
Filing Date:	20-FEB-2019
Time Stamp:	16:55:08
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	$120
RAM confirmation Number	071719INTEFSW00005780061050
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	Transmittal Letter	Transmittal_0009015.pdf	73135 0a2fe849468f823f7712b074aaa2e2f9602e7559	no	1
Warnings:					
Information:					
2	Information Disclosure Statement (IDS) Form (SB08)	1449_0009015.pdf	127248 f21a985e7a80ef5159d896d042281073b5f4d0a9	no	1
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
3	Fee Worksheet (SB06)	fee-info.pdf	30866 60e78b68e6e169386430615c526f8b92ed30ebc4	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	231249		

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New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

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

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor	:	Ahmnon D. Moskowitz	Art Unit	:	3773
Application No.	:	16/280,684	Examiner	:	Pedro Philogene
Filed	:	February 20, 2019	Conf. No.	:	1247
Title	:	SYSTEM WITH TOOL ASSEMBLY AND EXPANDABLE SPINAL IMPLANT			

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

INFORMATION DISCLOSURE STATEMENT

Cursor Please consider the documents listed on the disclosure form submitted with this statement. Copies of the documents are being submitted with this statement to the extent required under 37 C.F.R. § 1.98(a)(2).

This statement is being filed after a first action on the merits, but before receipt of a final action or a notice of allowance.

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

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

Respectfully submitted,

Date: 7/16/2019

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

Customer Number 26191
Fish & Richardson P.C.
Telephone: (612) 337-2538
Facsimile: (877) 769-7945

62008482.doc

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NOTICE OF ALLOWANCE AND FEE(S) DUE

26191 7590 08/30/2019
FISH & RICHARDSON P.C. (TC)
PO BOX 1022
MINNEAPOLIS, MN 55440-1022

EXAMINER	
PHILOGENE, PEDRO	
ART UNIT	PAPER NUMBER
3773	

DATE MAILED: 08/30/2019

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/280,684	02/20/2019	Ahmnon D. Moskowitz	46440-0009015	1247

TITLE OF INVENTION: BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING 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	$0.00	$0.00	$500	12/02/2019

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

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), by mail or fax, or via EFS-Web.

By mail, send to: Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

By fax, send to: (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

26191 7590 08/30/2019
FISH & RICHARDSON P.C. (TC)
PO BOX 1022
MINNEAPOLIS, MN 55440-1022

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being transmitted to the USPTO via EFS-Web or by facsimile to (571) 273-2885, on the date below.

(Typed or printed name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/280,684	02/20/2019	Ahmnon D. Moskowitz	46440-0009015	1247

TITLE OF INVENTION: BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING 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	$0.00	$0.00	$500	12/02/2019

EXAMINER	ART UNIT	CLASS-SUBCLASS
PHILOGENE, PEDRO	3773	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 03-09 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 _____
2 _____
3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ❑ Individual ❑ Corporation or other private group entity ❑ Government

4a. Fees submitted: ❑ Issue Fee ❑ Publication Fee (if required) ❑ Advance Order - # of Copies _____

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

❑ Electronic Payment via EFS-Web ❑ Enclosed check ❑ Non-electronic payment by credit card (Attach form PTO-2038)

❑ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. _____

5. **Change in Entity Status** (from status indicated above)

❑ Applicant certifying micro entity status. See 37 CFR 1.29

❑ Applicant asserting small entity status. See 37 CFR 1.27

❑ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.
NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.
NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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ART UNIT	PAPER NUMBER
3773	

DATE MAILED: 08/30/2019

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Notice of Allowability	Application No. 16/280,684	Applicant(s) Moskowitz et al.	
	Examiner PEDRO PHILOGENE	Art Unit 3773	AIA (FITF) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☑ This communication is responsive to applicant's amendment filed 7/16/19.
   ☐ 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 13-35 . 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 3773

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/280,684	Moskowitz et al.
	Examiner	Art Unit
	PEDRO PHILOGENE	3773

CPC - Searched*		
Symbol	**Date**	**Examiner**
A61F2/4611,4465,447; A61B17/0642,7064,809,8635,8875,8894,92,0644,1757,86	07/11/2019	/P.P./
A61B2017/00407,0641,0648,922,		
A61F2002/2835,30133,30387,30448,30507,3055,30579,30604,30772,30878,30879,30904,4475,448,4627,4681,4687		
A61F2220/0025,005; A61F2230/0015; A61F2250/0007		
updated search	08/23/2019	/P.P./

CPC Combination Sets - Searched*		
Symbol	**Date**	**Examiner**

US Classification - Searched*			
Class	**Subclass**	**Date**	**Examiner**
623	17.11-17.16	07/11/2019	/P.P./
606	246-289,300-308,86A,99,96,100		
227	175.1, 176.1		
updated search		08/23/2019	/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	07/11/2019	/P.P./
EAST search enclosed	08/23/2019	/P.P./

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/280,684	Moskowitz et al.
	Examiner	Art Unit
	PEDRO PHILOGENE	3773

Interference Search			
US Class/CPC Symbol	**US Subclass/CPC Group**	**Date**	**Examiner**
623	17.16	08/23/2019	/P.P./
Interference Search History Printout		08/23/2019	/P.P./

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/280,684	Moskowitz et al.
	Examiner	**Art Unit**
	PEDRO PHILOGENE	3773

CPC						
Symbol					**Type**	**Version**
A61F	/	2	/	4611	F	2013-01-01
A61B	/	17	/	0642	I	2013-01-01
A61B	/	17	/	7064	I	2013-01-01
A61B	/	17	/	809	I	2013-01-01
A61B	/	17	/	8894	I	2013-01-01
A61F	/	2	/	4465	I	2013-01-01
A61F	/	2	/	447	I	2013-01-01
A61B	/	17	/	8875	I	2013-01-01
A61B	/	17	/	8635	I	2013-01-01
A61B	/	17	/	92	I	2013-01-01
A61B	/	2017	/	00407	A	2013-01-01
A61F	/	2002	/	4687	A	2013-01-01
A61B	/	17	/	86	A	2013-01-01
A61B	/	2017	/	0641	A	2013-01-01
A61B	/	2017	/	0648	A	2013-01-01
A61B	/	2017	/	922	A	2013-01-01
A61F	/	2002	/	2835	A	2013-01-01
A61F	/	2002	/	30133	A	2013-01-01
A61F	/	2002	/	30387	A	2013-01-01
A61F	/	2002	/	30448	A	2013-01-01
A61F	/	2002	/	30507	A	2013-01-01
A61F	/	2002	/	3055	A	2013-01-01
A61F	/	2002	/	30579	A	2013-01-01
A61F	/	2002	/	30604	A	2013-01-01
A61F	/	2002	/	30772	A	2013-01-01
A61F	/	2002	/	30878	A	2013-01-01
A61F	/	2002	/	4475	A	2013-01-01
A61F	/	2002	/	448	A	2013-01-01
A61F	/	2002	/	4627	A	2013-01-01
A61F	/	2002	/	4681	A	2013-01-01
A61F	/	2220	/	0025	A	2013-01-01

NONE		**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	23	
/PEDRO PHILOGENE/ Primary Examiner, Art Unit 3773	23 August 2019	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	1B

U.S. Patent and Trademark Office — Part of Paper No.: 20190823

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/280,684	Moskowitz et al.
	Examiner	Art Unit
	PEDRO PHILOGENE	3773

CPC						
Symbol					Type	Version
A61F	/	2220	/	005	A	2013-01-01
A61F	/	2230	/	0015	A	2013-01-01
A61F	/	2250	/	0007	A	2013-01-01
A61B	/	17	/	0644	A	2013-01-01
A61B	/	17	/	1757	A	2013-01-01
A61F	/	2002	/	30879	A	2013-01-01
A61F	/	2002	/	30904	A	2013-01-01

CPC Combination Sets							
Symbol					Type	Set	Ranking	Version
	/		/					

NONE (Assistant Examiner)	(Date)	Total Claims Allowed: 23	
/PEDRO PHILOGENE/ Primary Examiner, Art Unit 3773 (Primary Examiner)	23 August 2019 (Date)	O.G. Print Claim(s) 1	O.G. Print Figure 1B

U.S. Patent and Trademark Office — Part of Paper No.: 20190823

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/280,684	Moskowitz et al.
	Examiner	**Art Unit**
	PEDRO PHILOGENE	3773

INTERNATIONAL CLASSIFICATION				
CLAIMED				
A61B	/	17	/	064
A61B	/	17	/	70
A61B	/	17	/	80
A61B	/	17	/	86
A61B	/	17	/	88
A61F	/	2	/	44
A61F	/	2	/	46
A61F	/	2	/	28
A61F	/	2	/	30

NON-CLAIMED				
	/		/	

US ORIGINAL CLASSIFICATION	
CLASS	**SUBCLASS**
623	17.16

CROSS REFERENCES(S)						
CLASS	**SUBCLASS (ONE SUBCLASS PER BLOCK)**					

NONE (Assistant Examiner)	(Date)	**Total Claims Allowed:** 23	
/PEDRO PHILOGENE/ Primary Examiner, Art Unit 3773 (Primary Examiner)	23 August 2019 (Date)	O.G. Print Claim(s) 1	O.G. Print Figure 1B

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	Examiner	Art Unit
	PEDRO PHILOGENE	3773

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☑ T.D. ☐ R.1.47

CLAIMS

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
	1		10	7	19	17	28								
	2		11	9	20	18	29								
	3		12	10	21	19	30								
	4	1	13	11	22	20	31								
	5	2	14	12	23	21	32								
	6	3	15	13	24	23	33								
	7	4	16	14	25	22	34								
	8	5	17	15	26	8	35								
	9	6	18	16	27										

NONE		Total Claims Allowed:	
(Assistant Examiner)	(Date)	23	
/PEDRO PHILOGENE/ Primary Examiner, Art Unit 3773	23 August 2019	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	1B

U.S. Patent and Trademark Office Part of Paper No.: 20190823

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/280,684	Moskowitz et al.
	Examiner	Art Unit
	PEDRO PHILOGENE	3773

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

CLAIMS

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☑ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	03/14/2019	07/11/2019	08/23/2019						
	1	÷	-	-						
	2	÷	-	-						
	3	÷	-	-						
	4	÷	-	-						
	5	÷	-	-						
	6	÷	-	-						
	7	÷	-	-						
	8	÷	-	-						
	9	÷	-	-						
	10	÷	-	-						
	11	÷	-	-						
	12	÷	-	-						
1	13	÷	✓	=						
2	14	÷	✓	=						
3	15		✓	=						
4	16		✓	=						
5	17		✓	=						
6	18		✓	=						
7	19		✓	=						
9	20		✓	=						
10	21		✓	=						
11	22		✓	=						
12	23		✓	=						
13	24		✓	=						
14	25		✓	=						
15	26		✓	=						
16	27		✓	=						
17	28		✓	=						
18	29		✓	=						
19	30		✓	=						
20	31		✓	=						
21	32		✓	=						
23	33		✓	=						
22	34		✓	=						
8	35			=						

Substitute Disclosure Form	U.S. Department of Commerce Patent and Trademark Office	Attorney Docket No. 46440-0009015	Application No. 16/280,684
Information Disclosure Statement by Applicant (Use several sheets if necessary) (37 CFR §1.98(b))		Applicant Moskowitz Family LLC	
		Filing Date February 20, 2019	Group Art Unit 3773

U.S. Patent Documents

Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	1.	6,652,533	11/25/2003	O'Neil			
	2.	7,588,573	9/15/2009	Berry			
	3.	8,845,731	9/30/2014	Weiman			
	4.	9,333,095	5/10/2016	Beaurain et al			
	5.	9,393,130	7/19/2016	Suddaby & McClintock			
	6.	20040015315	1/22/2004	Kreider			
	7.	20110172774	7/14/2011	Varela			
	8.	20130211526	8/15/2013	Alheidt et al			

Foreign Patent Documents or Published Foreign Patent Applications

Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation Yes	Translation No

Other Documents (include Author, Title, Date, and Place of Publication)

Examiner Initial	Desig. ID	Document

Examiner Signature	Date Considered
/PEDRO PHILOGENE/	08/23/2019

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/

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	1	"20190175361"	US-PGPUB; USPAT	OR	OFF	2019/08/23 09:24
L2	1	1 AND ((A61B17/0642 OR A61B17/0644 OR A61B17/1757 OR A61B17/7064 OR A61B17/809 OR A61B17/86 OR A61B17/8635 OR A61B17/8875 OR A61B17/8894 OR A61B17/92 OR A61B2017/00407 OR A61B2017/0641 OR A61B2017/0648 OR A61B2017/922 OR A61F2002/2835 OR A61F2002/30133 OR A61F2002/30387 OR A61F2002/30448 OR A61F2002/30507 OR A61F2002/3055 OR A61F2002/30579 OR A61F2002/30604 OR A61F2002/30772 OR A61F2002/30878 OR A61F2002/30879 OR A61F2002/30904 OR A61F2002/4475 OR A61F2002/448 OR A61F2002/4627 OR A61F2002/4681 OR A61F2002/4687 OR A61F2220/0025 OR A61F2220/005 OR A61F2230/0015 OR A61F2250/0007 OR A61F2/4465 OR A61F2/447 OR A61F2/4611).CPC. OR (1/1 or 606/86A,99,75,246-279,300-328,916 or 623/17.11-17.16 or 227/175.1,176.1).CCLS. OR (A61B17/064 OR A61B17/70 OR A61B17/80 OR A61B17/86 OR A61B17/88 OR A61B17/92 OR A61F2/44 OR A61F2/46).IPCR.)	US-PGPUB; USPAT	OR	OFF	2019/08/23 09:27
L3	0	tool near assembly & handle and prong & gripper & adjusting near tool & expandable near spinal near implant & adjusting near screw & indentation & structure	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2019/08/23 09:31
L5	2476	insert$4 near (device or tool or instrument) & expandable near (implant or cage or space)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2019/08/23 09:33
L7	1803	5 AND ((A61B17/0642 OR A61B17/0644 OR A61B17/1757 OR A61B17/7064 OR A61B17/809 OR A61B17/86 OR A61B17/8635 OR A61B17/8875 OR A61B17/8894 OR A61B17/92 OR A61B2017/00407 OR A61B2017/0641 OR A61B2017/0648 OR A61B2017/922 OR A61F2002/2835 OR A61F2002/30133 OR A61F2002/30387 OR A61F2002/30448 OR A61F2002/30507 OR A61F2002/3055 OR A61F2002/30579 OR A61F2002/30604 OR	US-PGPUB; USPAT	OR	OFF	2019/08/23 09:36

		A61F2002/30772 OR A61F2002/30878 OR A61F2002/30879 OR A61F2002/30904 OR A61F2002/4475 OR A61F2002/448 OR A61F2002/4627 OR A61F2002/4681 OR A61F2002/4687 OR A61F2220/0025 OR A61F2220/005 OR A61F2230/0015 OR A61F2250/0007 OR A61F2/4465 OR A61F2/447 OR A61F2/4611).CPC. OR (1/1 or 606/86A,99,75,246-279,300-328,916 or 623/17.11-17.16 or 227/175.1,176.1).CCLS. OR (A61B17/064 OR A61B17/70 OR A61B17/80 OR A61B17/86 OR A61B17/88 OR A61B17/92 OR A61F2/44 OR A61F2/46).ICPCR.)				
L8	4	(("6652533") or ("7588573") or ("8845731") or ("9333130")).PN.	USPAT; USOCR	OR	OFF	2019/08/23 09:46
L9	5	(("6652533") or ("7588573") or ("8845731") or ("9333095") or ("9393130")).PN.	USPAT; USOCR	OR	OFF	2019/08/23 09:47
L10	1	"20040015315"	US-PGPUB; USPAT	OR	OFF	2019/08/23 09:55
L11	4	"20110172774"	US-PGPUB; USPAT	OR	OFF	2019/08/23 09:55
L12	2	"20130211526"	US-PGPUB; USPAT	OR	OFF	2019/08/23 09:56
L14	287	A61B017/064.ipc.	FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2019/08/23 09:59
L15	1499	A61B017/70.ipc.	FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2019/08/23 09:59
L16	460	A61B017/80.ipc.	FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2019/08/23 09:59
L17	337	A61B017/86.ipc.	FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2019/08/23 09:59
L18	384	A61B017/88.ipc.	FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2019/08/23 10:00
L19	1732	A61F002/44.ipc.	FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2019/08/23 10:02
L20	1404	A61F002/46.ipc.	FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2019/08/23 10:02
L21	1562	A61F002/28.ipc.	FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2019/08/23 10:03
L22	1423	A61F002/30.ipc.	FPRS; EPO; JPO;	OR	OFF	2019/08/23 10:03

			DERWENT; IBM_TDB			

EAST Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L4	0	tool near assembly & handle and prong & gripper & adjusting near tool & expandable near spinal near implant & adjusting near screw & indentation & structure.clm.	USPAT	OR	ON	2019/08/23 09:31
L13	4529	(623/17.16).CCLS.	US-PGPUB; USPAT	OR	OFF	2019/08/23 09:58

8/23/2019 10:04:48 AM

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor	:	Ahmnon D. Moskowitz	Art Unit	:	3773
			Examiner	:	Pedro Philogene
Application No.	:	16/280,684	Confirmation No.	:	1247
Filed	:	February 20, 2019	Notice of Allowance Date: August 30, 2019		
Title	:	SYSTEM WITH TOOL ASSEMBLY AND EXPANDABLE SPINAL IMPLANT			

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

AMENDMENT AFTER ALLOWANCE
PURSUANT TO 37 C.F.R. §1.312

Please amend the application as indicated on the following pages. This amendment is being filed concurrently with the payment of the issue fee.

Amendments to the Specification:

Please replace the title with the following amended Title:

SYSTEM WITH TOOL ASSEMBLY AND EXPANDABLE SPINAL IMPLANT

Amendments to Claims:

Listing of Claims.

1-12. (Cancelled)

13. (Previously Presented) A system comprising:

a tool assembly which comprises:

a first tool having a first proximal end and a first distal end with a first handle and a gripper, the gripper being positioned at the first distal end, cooperating with the first handle, and having first and second engagement prongs positioned at the first distal end, wherein the first tool defines an adjusting tool passage through the first tool; and

a second adjusting tool having a second proximal end and a second distal end with a second handle positioned at the second proximal end, a screw engagement portion positioned at the second distal end, and a shaft extending from the second handle to the screw engagement portion, wherein the shaft of the second adjusting tool is sized with a smaller diameter than that of the adjusting tool passage such that the second adjusting tool can extend through the adjusting tool passage of the first tool; and

an expandable spinal implant sized and configured to be implanted in a human spine, the expandable spinal implant comprising a first expandable spinal implant structure, a second expandable spinal implant structure, and an adjusting screw having a screw head and a threaded portion, wherein the expandable spinal implant is configured to expand the first expandable spinal implant structure with respect to the second expandable spinal implant structure in response to turning of the adjusting screw, wherein the expandable spinal implant defines first and second tool engagement indentations sized and configured for receiving the first and second engagement prongs of the first tool, wherein the adjusting screw is positioned within the expandable spinal implant in a screw location such that the second adjusting tool

can extend through the adjusting tool passage of the first tool to engage the screw head of the adjusting screw while the first and second engagement prongs of the first tool are engaged with the first and second tool engagement indentations of the expandable spinal implant.

14. (Previously Presented) The system of claim 13, wherein the screw engagement portion of the second adjusting tool comprises a key for engaging the head of the adjusting screw to turn the adjusting screw and controlling height of the expandable spinal implant.

15. (Previously Presented) The system of claim 13, wherein the expandable spinal implant defines a longitudinal axis, wherein the first and second expandable spinal implant structures have first and second angled wedge surfaces that engage one another, wherein the adjusting screw is connected to the second expandable spinal implant structure so as to move the second expandable spinal implant structure along the longitudinal axis and slide the first angled wedge surface with respect to the second angled wedge surface to push the first expandable spinal implant structure in a direction that is substantially away from the longitudinal axis of the expandable spinal implant.

16. (Previously Presented) The system of claim 13, wherein the first expandable spinal implant structure defines a first angled wedge portion that comprises a first inwardly-facing rail and a second inwardly-facing rail, wherein a first inwardly-facing slot is defined at a location adjacent the first inwardly-facing rail, wherein a second inwardly-facing slot is defined at a location adjacent the second inwardly-facing rail, wherein the second expandable spinal implant structure defines a second angled wedge portion that comprises a first outwardly-facing rail and a second outwardly-facing rail that faces outwardly in a direction opposite that of the first outwardly-facing rail, wherein a first outwardly-facing slot is defined at a location adjacent the first outwardly-facing rail, wherein a second outwardly-facing slot is defined at a location adjacent the second outwardly-facing rail, wherein the first expandable spinal implant structure is slidably-engaged with the second expandable spinal implant structure such that the first angled wedge portion engages the second angled wedge portion with the first inwardly-facing rail of the first expandable spinal implant structure positioned in the first outwardly-facing slot of the second

expandable spinal implant structure, the second inwardly-facing rail of the first expandable spinal implant structure positioned in the second outwardly facing slot of the second expandable spinal implant structure, the first outwardly-facing rail of the second expandable spinal implant structure positioned in the first inwardly-facing slot of the first expandable spinal implant structure, and the second outwardly-facing rail of the second expandable spinal implant structure positioned in the second inwardly-facing slot of the first expandable spinal implant structure.

17. (Previously Presented) The system of claim 13, and further comprising first and second anchors, wherein the expandable spinal implant comprises first and second anchor guides angled to guide the first and second anchors bidirectionally into first and second vertebral bodies.

18. (Previously Presented) The system of claim 17, wherein the first tool defines third and fourth anchor guides configured to align with the first and second anchor guides of the expandable spinal implant when the first and second engagement prongs are engaged with the first and second tool engagement indentations so as to guide the first and second anchors through the third and fourth anchor guides into the first and second anchor guides.

19. (Previously Presented) A method of using the system of claim 13, the method comprising:

connecting the first tool to the expandable spinal implant with the first and second engagement prongs engaged with the first and second tool engagement indentations;

implanting the expandable spinal implant into a disc space in the human spine via the first tool;

extending the second adjusting tool through the first tool to engage the adjusting screw of the expandable spinal implant; and

expanding the expandable spinal implant by turning the second adjusting tool to turn the adjusting screw of the expandable spinal implant.

20. (Previously Presented) A system comprising:

a tool assembly comprising:

a first tool having a first proximal end, a first distal end, and a first elongate body between the first proximal end and the first distal end, wherein the first tool defines a first tool axis from the first proximal end to the first distal end, wherein the first tool includes first and second engagement prongs positioned at the first distal end on opposite sides of the first tool axis, wherein the first tool defines an adjusting tool passage through the first tool; and

a second adjusting tool having a second proximal end and a second distal end, wherein the second adjusting tool includes a second handle positioned at the second proximal end, a screw engagement portion positioned at the second distal end, and a shaft extending from the second handle to the screw engagement portion, wherein the shaft of the second adjusting tool is sized with a smaller diameter than that of the adjusting tool passage such that the second adjusting tool can extend through the adjusting tool passage of the first tool; and

an expandable spinal implant sized and configured to be implanted in a human spine, the expandable spinal implant comprising a first expandable spinal implant structure defining a first engagement surface sized and configured to engage a first vertebral body, a second expandable spinal implant structure defining a second engagement surface sized and configured to engage a second vertebral body, and an adjusting screw having a screw head and a threaded shaft, wherein the expandable spinal implant is configured to expand the first expandable spinal implant structure with respect to the second expandable spinal implant structure in response to turning of the adjusting screw, wherein the expandable spinal implant defines first and second tool engagement indentations sized and configured for receiving the first and second engagement prongs of the first tool, wherein the adjusting screw is positioned within the expandable spinal implant in a screw location such that the second adjusting tool can extend through the adjusting tool passage of the first tool to engage the screw head of the adjusting screw while the first and second engagement prongs of the first tool are engaged with the first and second tool

engagement indentations of the expandable spinal implant.

21. (Previously Presented) The system of claim 20, wherein the expandable spinal implant includes ridges on each of the first and second engagement surfaces, wherein the first indentation extends into a first side of the first expandable spinal implant structure, wherein the second indentation extends into a second side of the expandable spinal implant structure.

22. (Previously Presented) The system of claim 20, wherein the expandable spinal implant comprises first and second angled wedge surfaces, wherein rotation of the adjustment screw by the second adjusting tool drives relative motion of the first angled wedge surface with respect to the second angled wedge surface to expand the expandable spinal implant.

23. (Previously Presented) The system of claim 20, wherein the first expandable spinal implant structure defines an end gap between the first and second opposing side surfaces at a first end of the first vertebral body engagement surface, wherein the first vertebral body engagement surface comprises a plurality of ridges extending from the first vertebral body engagement surface, wherein at least some of the ridges are positioned on the first vertebral body engagement surface on opposite sides of the end gap.

24. (Previously Presented) The system of claim 20, and further comprising first and second anchors, wherein the expandable spinal implant comprises first and second anchor guides angled to guide the first and second anchors bidirectionally into the first and second vertebral bodies, wherein the first tool defines third and fourth anchor guides configured to align with the first and second anchor guides of the expandable spinal implant so as to guide the first and second anchors through the third and fourth anchor guides into the first and second anchor guides when the first and second engagement prongs are engaged with the first and second tool engagement indentations.

25. (Previously Presented) The system of claim 20, wherein a distal end of the adjusting screw has a distal diameter, wherein the head of the adjusting screw has a head diameter, and wherein

the distal diameter is larger than the head diameter.

26. (Previously Presented) The system of claim 20, wherein the first tool comprises a first handle positioned proximate the first proximal end and extending in a direction that is substantially perpendicular to the first proximal axis, wherein the second handle of the second adjusting tool is substantially circular when viewed along the first proximal axis when the second adjusting tool is positioned in the adjusting tool passage.

27. (Previously Presented) The system of claim 20, wherein the first expandable spinal implant structure and the first engagement surface move with respect to the second expandable spinal implant structure and the second engagement surface at least partially along a direction of the first tool axis when the second adjusting tool turns the adjusting screw.

28. (Previously Presented) The system of claim 20, wherein the expandable spinal implant has a proximal end, a distal end, and first and second sides, wherein the screw head of the adjusting screw is positioned at the proximal end of the expandable spinal implant, wherein the first and second tool indentations are positioned on the first and second sides proximate to the proximal end, wherein the expandable spinal implant defines a proximal screw hole at the proximal end of the expandable spinal implant and a distal screw hole at the distal end of the expandable spinal implant and wherein the adjusting screw extends through both the proximal and the distal screw holes.

29. (Previously Presented) The system of claim 20, wherein the first tool indentation extends into a first side of the expandable spinal implant with a first substantially rectangular shape as viewed from a direction perpendicular to the first side and the second tool indentation extends into a second side of the expandable spinal implant with a second substantially rectangular shape as viewed from a direction perpendicular to the second side.

30. (Previously Presented) A method of using the system of claim 20, the method comprising:

connecting the first tool to the expandable spinal implant with the first and second

engagement prongs engaged with the first and second tool engagement indentations;

implanting the expandable spinal implant into a disc space in the human spine via the first tool;

extending the second adjusting tool through the first tool to engage the adjusting screw of the expandable spinal implant; and

expanding the expandable spinal implant by turning the second adjusting tool to turn the adjusting screw of the expandable spinal implant.

31. (Previously Presented) A system comprising:

a tool assembly comprising:

a first tool having a first proximal end, a first distal end, and a first elongate body between the first proximal end and the first distal end, wherein the first tool defines a first tool axis from the first proximal end to the first distal end, wherein the first tool includes a gripper having one or more engagement prongs positioned at the first distal end axially offset from the first tool axis, wherein the first tool defines an adjusting tool passage through the first tool; and

a second adjusting tool having a second proximal end and a second distal end, wherein the second adjusting tool includes a screw engagement portion positioned at the second distal end and a shaft extending from the second proximal end to the screw engagement portion, wherein the shaft of the second adjusting tool is sized with a smaller diameter than that of the adjusting tool passage such that the second adjusting tool can extend through and turn within the adjusting tool passage of the first tool; and

an expandable spinal implant sized and configured to be implanted in a human spine, the expandable spinal implant comprising a first expandable spinal implant structure defining a first engagement surface sized and configured to engage a first vertebral body, a second expandable spinal implant structure defining a second engagement surface sized and configured to engage a second vertebral body, and an adjusting

screw having a screw engagement portion and a threaded portion, wherein the expandable spinal implant is configured to expand the first expandable spinal implant structure with respect to the second expandable spinal implant structure in response to turning of the adjusting screw, wherein the expandable spinal implant defines one or more tool engagement indentations sized and configured for engaging with the gripper of the first tool, wherein the adjusting screw is positioned within the expandable spinal implant in a screw location such that the second adjusting tool can extend through the adjusting tool passage of the first tool to engage the screw engagement portion of the adjusting screw while one or more engagement prongs of the first tool are engaged with the one or more engagement indentations of the expandable spinal implant, wherein at least one of the one or more engagement indentations of the expandable spinal implant is positioned on one or more side surfaces of the expandable spinal implant such that the one or more engagement prongs of the gripper is positioned on the one or more side surfaces of the expandable spinal implant when the first tool is engages with the expandable spinal implant.

32. (Previously Presented) The system of claim 31, wherein the expandable spinal implant comprises a substantially cylindrical side hole extending through a side of the expandable spinal implant into an interior cavity of the expandable spinal implant and is sized and configured to allow for bone placement through the side hole into the interior cavity, wherein the expandable spinal implant comprises an angled wedge portion having rails and slots configured to allow for relative movement and expansion of the expandable spinal implant during expansion of the expandable spinal implant.

33-34. (Cancelled)

35. (Previously Presented) The system of claim 13, and further comprising bone graft material configured to be placed inside and outside of the expandable spinal implant.

REMARKS

Claims 13-32 and 35 are pending, with claims 13, 20, and 31 being independent. With this amendment, claims 33-34 have been cancelled.

Applicant notes that the title was previously amended in a Reply filed on July 16, 2019. It appears that the amendment to the title has not yet been acknowledged by the US Patent Office. Applicant again amends the title with this amendment and requests that the USPTO acknowledge the new title so that it appears on the face of the patent when it issues.

No fees are believed due. Please apply any other necessary charges or credits to Deposit Account 06-1050, referencing the above attorney docket number.

Respectfully submitted,

Date: 8/30/2019

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

Customer Number 26191
Fish & Richardson P.C.
Telephone: (612) 337-2538
Facsimile: (877) 769-7945

12291252.doc

Electronic Patent Application Fee Transmittal

Application Number:	16280684
Filing Date:	20-Feb-2019
Title of Invention:	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION
First Named Inventor/Applicant Name:	Ahmnon D. Moskowitz
Filer:	Stuart A. Nelson/Kathy Bell
Attorney Docket Number:	46440-0009015

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:	37031357
Application Number:	16280684
International Application Number:	
Confirmation Number:	1247
Title of Invention:	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION
First Named Inventor/Applicant Name:	Ahmnon D. Moskowitz
Customer Number:	26191
Filer:	Stuart A. Nelson/Kathy Bell
Filer Authorized By:	Stuart A. Nelson
Attorney Docket Number:	46440-0009015
Receipt Date:	30-AUG-2019
Filing Date:	20-FEB-2019
Time Stamp:	13:08:34
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	E20198TD09037317
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	Post Allowance Communication - Incoming	Response.pdf	72166 1cf496d3233e04cc5e4dbc637298d510f38545ab	no	1
Warnings:					
Information:					
2	Issue Fee Payment (PTO-85B)	Issue_fee.pdf	162516 7765413236de71b4921ef2a74ec3c84dd9b764ec	no	1
Warnings:					
Information:					
3		312_Amendment.pdf	96525 ed05b5eb575bd3c15bf0fdf99cbd8c6b6012ebeb	yes	11

Multipart Description/PDF files in .zip description

Document Description	Start	End
Amendment after Notice of Allowance (Rule 312)	1	1
Specification	2	2
Claims	3	10
Applicant Arguments/Remarks Made in an Amendment	11	11

Warnings:					
Information:					
4	Fee Worksheet (SB06)	fee-info.pdf	30772 2877c63ab1d2900bbf9f060ccdee664b89e8c77e	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	361979		

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

New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

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

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor	:	Ahmnon D. Moskowitz	Art Unit	:	3773
			Examiner	:	Pedro Philogene
Application No.	:	16/280,684	Confirmation No.	:	1247
Filed	:	February 20, 2019	Notice of Allowance Date: August 30, 2019		
Title	:	SYSTEM WITH TOOL ASSEMBLY AND EXPANDABLE SPINAL IMPLANT			

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 August 30, 2019, enclosed is a completed Part B - Fee(s) Transmittal. Also enclosed is an Amendment After Allowance.

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: 8/30/2019

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

Customer Number 26191
Fish & Richardson P.C.
Telephone: (612) 337-2538
Facsimile: (877) 769-7945

12291248.doc

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), by mail or fax, or via EFS-Web

By mail, send to: Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22314-1450

By fax, send to: (571) 273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

26191 7590 08/30/2019

FISH & RICHARDSON P.C.
P.O. BOX 1022
MINNEAPOLIS, MN 55440-1022

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being transmitted to the USPTO via EFS-Web or by facsimile to (571) 273-2885, on the date below.

Kathy J. Bell	(Typed or printed name)
/Kathy J. Bell/	(Signature)
8/30/2019	(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/280,684	02/20/2019	Ahmnon D. Moskowitz	46440-0009015	1247

TITLE OF INVENTION: SYSTEM WITH TOOL ASSEMBLY AND EXPANDABLE SPINAL IMPLANT

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$500	$0	$0.00	$500	12/02/2019

EXAMINER	ART UNIT	CLASS-SUBCLASS
PHILOGENE, PEDRO	3773	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 03-09 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,

(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 Fish & Richardson P.C.
2
3

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE: Moskowitz Family LLC

(B) RESIDENCE: (CITY and STATE OR COUNTRY): Rockville, MD

Please check the appropriate assignee category or categories (will not be printed on the patent): [ ] Individual [X] Corporation or other private group entity [ ] Government

4a. Fees Submitted: [X] Issue Fee [ ] Publication Fee (if required) [ ] Advance Order - # of Copies

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

[ ] Electronic Payment via EFS-Web [ ] Enclosed check [ ] Non-electronic payment by credit card (Attach form PTO-2038)

[X] The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account No. 06-1050

5. **Change of Entity Status** (from status indicated above)

[ ] Applicant certifying micro entity status. See 37 CFR 1.29 — **NOTE**: Absent a valid Certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

[ ] Applicant asserting small entity status. See 37 CFR 1.27. — **NOTE**: If the application was previously under micro entity status, checking this box will be taken as a notification of loss of entitlement to micro entity status.

[ ] Applicant changing to regular undiscounted fee status. — **NOTE**: Checking this box will be taken as a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature /Stuart A. Nelson/ Date 8/30/2019

Typed or printed name Stuart A. Nelson Registration No. 63,947

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
16/280,684	02/20/2019	3773	1115	46440-0009015	14	3

CONFIRMATION NO. 1247

CORRECTED FILING RECEIPT

26191
FISH & RICHARDSON P.C. (TC)
PO BOX 1022
MINNEAPOLIS, MN 55440-1022

OC000000110890373

Date Mailed: 09/05/2019

Receipt is acknowledged of this non-provisional utility 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 FIRST INVENTOR, 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 corrected Filing Receipt, including a properly marked-up ADS showing the changes with strike-through for deletions and underlining for additions. If you received a "Notice to File Missing Parts" or other Notice requiring a response for this application, please submit any request for correction 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 provided that the request is grantable.

Inventor(s)

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

Applicant(s)

Moskowitz Family LLC, Rockville, MD;

Power of Attorney: The patent practitioners associated with Customer Number 26191

Domestic Priority data as claimed by applicant

This application is a CON of 15/894,471 02/12/2018 PAT 10390969
which is a CON of 13/210,157 08/15/2011 PAT 9889022
which is a CON of 13/108,982 05/16/2011 PAT 9005293
and is a CON of 13/084,543 04/11/2011 PAT 8353913
which is a CON of 11/842,855 08/21/2007 PAT 7942903
and said 13/108,982 05/16/2011
is a CON of 11/842,855 08/21/2007 PAT 7942903
which is a CIP of 11/536,815 09/29/2006 PAT 7846188
which is a CIP of 11/208,644 08/23/2005 PAT 7704279
which claims benefit of 60/670,231 04/12/2005

Foreign Applications for which priority is claimed (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see http://www.uspto.gov for more information.) - None.

Foreign application information must be provided in an Application Data Sheet in order to constitute a claim to foreign priority. See 37 CFR 1.55 and 1.76.

Permission to Access Application via Priority Document Exchange: Yes

Permission to Access Search Results: Yes

Applicant may provide or rescind an authorization for access using Form PTO/SB/39 or Form PTO/SB/69 as appropriate.

If Required, Foreign Filing License Granted: 03/07/2019
The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 16/280,684**
Projected Publication Date: Not Applicable
Non-Publication Request: No
Early Publication Request: No
**** SMALL ENTITY ****
Title

SYSTEM WITH TOOL ASSEMBLY AND EXPANDABLE SPINAL IMPLANT

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

patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at http://www.uspto.gov/web/offices/pac/doc/general/index.html.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, http://www.stopfakes.gov. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4258).

LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

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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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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/280,684	02/20/2019	Ahmnon D. Moskowitz	46440-0009015	1247

26191 7590 09/11/2019

FISH & RICHARDSON P.C. (TC)
PO BOX 1022
MINNEAPOLIS, MN 55440-1022

EXAMINER	
PHILOGENE, PEDRO	

ART UNIT	PAPER NUMBER
3773	

NOTIFICATION DATE	DELIVERY MODE
09/11/2019	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

Corrected ***Notice of Allowability***	**Application No.** 16/280,684	**Applicant(s)** Moskowitz et al.	
	Examiner PEDRO PHILOGENE	**Art Unit** 3773	**AIA (FITF) Status** No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☑ This communication is responsive to applicant's amendment filed 8/30/19.
   ☐ 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 13-32 and 35 . 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 3773

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/280,684	Moskowitz et al.
	Examiner	Art Unit
	PEDRO PHILOGENE	3773

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

CLAIMS

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☑ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	03/14/2019	07/11/2019	08/23/2019	09/06/2019					
	1	÷	-	-	-					
	2	÷	-	-	-					
	3	÷	-	-	-					
	4	÷	-	-	-					
	5	÷	-	-	-					
	6	÷	-	-	-					
	7	÷	-	-	-					
	8	÷	-	-	-					
	9	÷	-	-	-					
	10	÷	-	-	-					
	11	÷	-	-	-					
	12	÷	-	-	-					
1	13	÷	✓	=	=					
2	14	÷	✓	=	=					
3	15		✓	=	=					
4	16		✓	=	=					
5	17		✓	=	=					
6	18		✓	=	=					
7	19		✓	=	=					
9	20		✓	=	=					
10	21		✓	=	=					
11	22		✓	=	=					
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13	24		✓	=	=					
14	25		✓	=	=					
15	26		✓	=	=					
16	27		✓	=	=					
17	28		✓	=	=					
18	29		✓	=	=					
19	30		✓	=	=					
20	31		✓	=	=					
21	32		✓	=	=					
	33		✓	=	-					
	34		✓	=	-					
8	35			=	=					

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/280,684	Moskowitz et al.
	Examiner	Art Unit
	PEDRO PHILOGENE	3773

CPC						
Symbol					Type	Version
A61F	/	2	/	4611	F	2013-01-01
A61B	/	17	/	0642	I	2013-01-01
A61B	/	17	/	7064	I	2013-01-01
A61B	/	17	/	809	I	2013-01-01
A61B	/	17	/	8894	I	2013-01-01
A61F	/	2	/	4465	I	2013-01-01
A61F	/	2	/	447	I	2013-01-01
A61B	/	17	/	8875	I	2013-01-01
A61B	/	17	/	8635	I	2013-01-01
A61B	/	17	/	92	I	2013-01-01
A61B	/	2017	/	00407	A	2013-01-01
A61F	/	2002	/	4687	A	2013-01-01
A61B	/	17	/	86	A	2013-01-01
A61B	/	2017	/	0641	A	2013-01-01
A61B	/	2017	/	0648	A	2013-01-01
A61B	/	2017	/	922	A	2013-01-01
A61F	/	2002	/	2835	A	2013-01-01
A61F	/	2002	/	30133	A	2013-01-01
A61F	/	2002	/	30387	A	2013-01-01
A61F	/	2002	/	30448	A	2013-01-01
A61F	/	2002	/	30507	A	2013-01-01
A61F	/	2002	/	3055	A	2013-01-01
A61F	/	2002	/	30579	A	2013-01-01
A61F	/	2002	/	30604	A	2013-01-01
A61F	/	2002	/	30772	A	2013-01-01
A61F	/	2002	/	30878	A	2013-01-01
A61F	/	2002	/	4475	A	2013-01-01
A61F	/	2002	/	448	A	2013-01-01
A61F	/	2002	/	4627	A	2013-01-01
A61F	/	2002	/	4681	A	2013-01-01
A61F	/	2220	/	0025	A	2013-01-01

NONE		Total Claims Allowed:	
(Assistant Examiner)	(Date)	21	
/PEDRO PHILOGENE/ Primary Examiner, Art Unit 3773	06 September 2019	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	1B

U.S. Patent and Trademark Office — Part of Paper No.: 20190906

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/280,684	Moskowitz et al.
	Examiner	Art Unit
	PEDRO PHILOGENE	3773

CPC						
Symbol					Type	Version
A61F	/	2220	/	005	A	2013-01-01
A61F	/	2230	/	0015	A	2013-01-01
A61F	/	2250	/	0007	A	2013-01-01
A61B	/	17	/	0644	A	2013-01-01
A61B	/	17	/	1757	A	2013-01-01
A61F	/	2002	/	30879	A	2013-01-01
A61F	/	2002	/	30904	A	2013-01-01

CPC Combination Sets							
Symbol					Type	Set	Ranking	Version
	/		/					

NONE (Assistant Examiner)	(Date)	Total Claims Allowed: 21	
/PEDRO PHILOGENE/ Primary Examiner, Art Unit 3773 (Primary Examiner)	06 September 2019 (Date)	O.G. Print Claim(s) 1	O.G. Print Figure 1B

U.S. Patent and Trademark Office — Part of Paper No.: 20190906

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/280,684	Moskowitz et al.
	Examiner	**Art Unit**
	PEDRO PHILOGENE	3773

INTERNATIONAL CLASSIFICATION				
CLAIMED				
A61B	/	17	/	064
A61B	/	17	/	70
A61B	/	17	/	80
A61B	/	17	/	86
A61B	/	17	/	88
A61F	/	2	/	44
A61F	/	2	/	46
A61F	/	2	/	28
A61F	/	2	/	30

NON-CLAIMED				
	/		/	

US ORIGINAL CLASSIFICATION	
CLASS	**SUBCLASS**
623	17.16

CROSS REFERENCES(S)						
CLASS	**SUBCLASS (ONE SUBCLASS PER BLOCK)**					

NONE (Assistant Examiner)	(Date)	**Total Claims Allowed:** 21	
/PEDRO PHILOGENE/ Primary Examiner, Art Unit 3773 (Primary Examiner)	06 September 2019 (Date)	O.G. Print Claim(s) 1	O.G. Print Figure 1B

U.S. Patent and Trademark Office — Part of Paper No.: 20190906

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/280,684	Moskowitz et al.
	Examiner	Art Unit
	PEDRO PHILOGENE	3773

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☑ T.D. ☐ R.1.47

CLAIMS

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
	1		10	7	19	17	28								
	2		11	9	20	18	29								
	3		12	10	21	19	30								
	4	1	13	11	22	20	31								
	5	2	14	12	23	21	32								
	6	3	15	13	24		33								
	7	4	16	14	25		34								
	8	5	17	15	26	8	35								
	9	6	18	16	27										

NONE		Total Claims Allowed:	
(Assistant Examiner)	(Date)	21	
/PEDRO PHILOGENE/ Primary Examiner, Art Unit 3773	06 September 2019	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	1B

U.S. Patent and Trademark Office — Part of Paper No.: 20190906

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor	:	Ahmnon D. Moskowitz	Art Unit	:	3773
			Examiner	:	Pedro Philogene
Application No.	:	16/280,684	Confirmation No.	:	1247
Filed	:	February 20, 2019	Notice of Allowance Date: August 30, 2019		
Title	:	SYSTEM WITH TOOL ASSEMBLY AND EXPANDABLE SPINAL IMPLANT			

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

OK TO ENTER: /P.P/

AMENDMENT AFTER ALLOWANCE
PURSUANT TO 37 C.F.R. §1.312

Please amend the application as indicated on the following pages. This amendment is being filed concurrently with the payment of the issue fee.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor	:	Ahmnon D. Moskowitz	Art Unit	:	3773
Application No.	:	16/280,684	Examiner	:	Pedro Philogene
Filed	:	February 20, 2019	Conf. No.	:	1247
Title	:	SYSTEM WITH TOOL ASSEMBLY AND EXPANDABLE SPINAL IMPLANT			

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

REPLY TO NOTICE TO FILE CORRECTED APPLICATION PAPERS DATED SEPTEMBER 19, 2019

The applicant as a small entity submits:

☒ Substitute drawings (1 sheet) correcting Figure 1A in compliance with 37 CFR §1.84.

☒ A substitute specification in compliance with 37 CFR §1.52. The number "5" was added to the phrase "Figures 5E-G" in paragraph 0046. No new matter has been added.

The applicant understands that this perfects the application and no additional papers or filing fees are required.

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

Respectfully submitted,

Date: 9/19/2019

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

Customer Number 26191
Fish & Richardson P.C.
Telephone: (612) 337-2538
Facsimile: (877) 769-7945

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SYSTEM WITH TOOL ASSEMBLY AND EXPANDABLE SPINAL IMPLANT

[0001] This application is a Continuation-In-Part Application of copending application Serial No. 11/536,815, filed September, 29, 2006, which is a Continuation-In-Part Application of copending application Serial No. 11/208,644, filed August 23, 2005 for which priority is claimed under 35, U.S.C. §120; and this application also claims priority under 35 U.S.C. § 119(e) of U.S. provisional application No. 60/670,231, filed on April 12, 2005; the entire contents of all the above identified patent applications are hereby incorporated by reference.

Field of Invention

[0002] The present invention relates to a unique universal bidirectional screw (BDS) system, and in particular its application to the spine, also referred to as bi-directional fixating transvertebral (BDFT) screws which can be used as a stand-alone intervertebral device which combines the dual functions of an intervertebral spacer which can be filled with bone fusion material(s), as well as a transvertebral bone fusion screw apparatus. In the posterior lumbosacral and thoracic spine, BDFT screw/box constructs can be used independently or supplemented with a novel horizontal mini-plate which prevents upward bone graft intrusion into the thecal sac and nerves. In the anterior lumbosacral spine BDFT screw box constructs can be inserted into and supplemented by a circumferential cage. These posteriorly and anteriorly placed stand-alone intervertebral body fusion constructs may obviate the need for supplemental pedicle screw fixation.

[0003] The present invention also relates to stand-alone or supplemental

posterior cervical and lumbar calibrated inter-articular joint stapling devices which may obviate and/or lessen the need for supplemental pedicle screw fixation.

Description of the Relevant Art

[0004] The history and evolution of instrumented spinal fusion in the entire human spine has been reviewed in our two prior copending applications Serial No. 11/536,815, filed on September, 29, 2006, and Serial No. 11/208,644, filed on August 23, 2005, the related contents of which are hereby incorporated by reference. Currently the majority of posterior cervical and almost all anterior and posterior lumbosacral and thoracic fusion techniques are typically supplemented with pedicle screw placement. Complications of pedicle screw placement in cervical, thoracic and lumbar 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 excess rigidity leading to adjacent segmental disease requiring further fusions and re-operations. Recent advances in pedicle screw fixation including minimally invasive and image-guided technology, and the development of flexible rods, imperfectly address some but not all of these issues.

[0005] Complications of all current spinal interbody fusion devices is their lack of coverage of the majority of the cross- sectional area of the vertebral endplates, and their lack of adequate, if any capacity to penetrate bone, and hence the heightened risk of implant extrusion. Furthermore the bone and biological bone fusion agents which are packed into the intervertebral space can easily blossom

and grow upward into the thecal sac causing neural compression, in the absence of a physical barrier between the fusing growing bone, and the thecal sac.

Summary

[0006] Herein we describe multiple device embodiments which combine in a single construct the dual functions of an intervertebral spacer maintaining disc space height, and transvertebral body fusion screws.

[0007] We also introduce an entirely novel horizontal mini-plate capping off the intervertebral space capable of functioning as a physical barrier preventing upward bone intrusion and/or compression of the ventral thecal sac, and traversing and exciting nerve roots.

[0008] Furthermore, we present an advanced mechanism in calibrated posterior facet joint stapling compared to our previous designs illustrated in our co-pending patents. We also introduce the entirely novel concept of posterior cervical facet staples to obviate and/or diminish the need for posterior cervical pedicle screw instrumented fusion. Using combinations and permutations of different embodiments of cervical facet staples in a modular manner advances the concept of flexible fusion in the cervical spine.

[0009] To achieve safe, effective and minimally invasive segmental spinal fusion, applicants propose the use of novel bi-directional fixating transvertebral (BDFT) screws which can be strategically inserted via anterior or posterior surgical spinal approaches into the anterior and middle columns of the interverterbral disc space. In our previous applications these bi-directional screws employed turning a wormed driving screw which turns a spur gear which in turn

simultaneously turns a rostral oriented screw into the cephalad vertebral body, and a caudal directed screw into the caudal vertebral body. The vertebral bodies above and below the disc space by virtue of their engagement and penetration by the BDFT screws are thus linked, interlocked, and eventually biologically fused with placement of intervertebral bone agents.

[0010] In this current application one or more of the described embodiments may eliminate the intervening wormed driving screws and gears required by previous designs, e.g., a gearless screw box is achieved. We have designed a screw box to be placed inter-vertebrally, either unilaterally or bilaterally, in particular, posteriorly between vertebral bodies. The housing screw box incorporates built-in screw and/or drill guides which allow the direct placement and insertion of two self drilling screws which are driven in two opposing directions into superior and inferior vertebral bodies, respectively. One screw within the screw box is angled superiorly, and the other screw in the screw box is angled inferiorly.

[0011] In yet another embodiment, in addition to these features we designed an expanding screw box with sliding triangular bases to house two screws driven in two opposing directions which can be expanded in two simultaneous directions, height and depth, by turning a built-in screw adjuster. This is accomplished by a combined positioning tool/screw guide/cage expander to further enhance trajectory precision and to simultaneously expand the screw box in height and depth to custom-fit the individual disc space height. This embodiment has two sub-embodiments; one has two laterally oriented BDFT screws, and the other has a lateral and a medial oriented BDFT screw. These innovations represent a

continued evolution of our concept of expandable fusion cages described in our previous co-pending patents.

[0012] In yet another embodiment we designed a screw box which houses only one, instead of two screws. Each box allows the placement of one superior or inferior directed screw on one side (left or right) , and the contra lateral screw box device allows placement of an inferior or superior oriented screw which goes in the opposite direction of the contra lateral device. In totality these two separate single screw boxes fuse the superior and inferior vertebrae. The potential advantage of this embodiment is that it diminishes the width of the screw box in cases where it might be favorable to have less nerve root retraction with a smaller width device.

[0013] In all screw-box embodiments, a rostral-directed screw is passed through one built-in screw guide of the device which then is inserted and screwed into the superior vertebral body. Then a caudaly directed screw is passed through an adjacent built-in screw guide which then is inserted and screwed into the inferior vertebral body. The novelty of this design is the built-in prescribed angles of the integral screw guides which allow the posterior transvertebral penetration into the vertebral bodies. This is a truly amazing feat accomplished in the posterior lumbar spine considering the small anatomically restricted work zone within which to work, which is very narrowly prescribed by obtuse angulations between screw and intervertebral bone surfaces, and by nerve root, facet joint and pedicle. We have also designed a positioning tool for the placement of the non-expandable screw boxes which has a screwdriver with a flexible shaft specifically designed to fit these devices if a straight screw driver impedes screw placement. Hence these external tools provide the means in any circumstance to

accomplish precision screw trajectory. The embodiments described herein compared to our previous co-pending patent designs, streamline and ease production of bi-directionally oriented transvertebral screws, and allows placement of longer and wider screws with greater bone penetration to provide yet a sturdier fusion construct. The designs are also easily modifiable for anterior placement into the cervical spine. The expandable embodiment of the screw box can also be enlarged and modified to be suitable for cervical, thoracic and lumber vertebral body replacements.

[0014] The box casings have multiple perforations to allow both screw traversal and horizontal bone packing preventing upward vertical migration of bone. The boxes prevent subsidence. Both the inside of the denuded intervertebral space, and the screw boxes can be packed with autologous or allograft bone, BMP, DBX or similar osteoconductive material. Posteriorly or anteriorly in the lumbar spine, these screws can be capped with a horizontal mini-plate which will prevent bony growth into the thecal sac and nerves. We refer to this as a two-in-one device, i.e. two screw boxes/BDFT screws combined with one horizontal mini-plate. This is an entirely novel concept in posterior lumbar spinal surgery. In yet another embodiment two BDFT screw boxes can be combined with a circumferential cage (also 2 in 1) to be placed anteriorly into the lumbar spine.

[0015] It is believed that BDFT- screw constructs provide as strong or stronger segmental fusion as pedicle screws without the complications arising from pedicle screw placement which include screw misplacement with potential nerve and/or vascular injury, violation of healthy facets, possible pedicle destruction, blood loss, and overly rigid fusions. By placing screws across the intervertebral space from vertebral body to vertebral body, engaging anterior and middle spinal

columns, and not the vertebral bodies via the transpediclar route, the healthy facet joints, if they exist, are preserved. Because this technique accomplishes both anterior and middle column fusion, without rigidly fixating the posterior column, it in essence creates a flexible fusion. This device therefore is a flexible fusion device because the preserved posterior facet joints retain their function achieving at least a modicum of mobility and hence a less rigid (i.e. a flexible) fusion.

[0016] 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.

[0017] Transvertebral fusion also leads to far less muscle retraction, blood loss, and significant reduction in O.R. time. Thus the complication of pedicular screw pull-out and hence high re-operation rate associated with the current embodiment of flexible fusion pedicle screws/rods is obviated. The lumbosacral screw box embodiments and BDFT screws can be introduced via posterior lateral, transforaminal or anterior interbody fusion approaches /techniques. Although one can opt to supplement these screws with transpedicular screws there would be no absolute need for supplemental pedicle screw fixation with these operative techniques.

[0018] BDFT screw constructs outlined here can also be combined with novel zero-profile horizontal cervical and, lumbar/thoracic mini-plates. Likewise one or two of these devices can be inserted anteriorly with or without circumferential cage supplementation.

[0019] Because the BDFT screws engage a small percentage of the rostral and caudal vertebral body surface area, multi-level fusions can be performed with these devices.

[0020] Previous improvements included a novel calibrated lumbar /thoracic facet stapling device which staples the inferior articulating facet of the superior segment to the superior articulating facet of the caudal vertebral segment unilaterally or bilaterally, which may minimize motion until interbody fusion occurs. In the present patent application we introduce a new design of the staple enhancing its calibrating capability.

[0021] In this patent application we also introduce 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 caudal vertebral segment unilaterally or bilaterally.

[0022] 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. Thus they thereby achieve the same function of pedicle screws without the risks.

[0023] Placement of different embodiments of the cervical facet staples along unilateral and/or bilateral facet joints in a modular manner, lead to differing degrees of calibrated motion joint motion hence introducing for the first time the concept of calibrated cervical fusion.

[0024] Currently failed anterior lumbar arthroplasties are salvaged by combined anterior and posterior fusions. BDFT screw constructs could be utilized as a one-

step salvage operation for failed/extruded anteriorly placed lumbar artificial discs obviating the above salvage procedure which has far greater morbidity.

[0025] For example, in one general aspect, a self-drilling bone fusion screw apparatus includes a first sliding box, a second sliding box, positioned relative to the first sliding box, a first screw member having a tapered end and a threaded body disposed within the first sliding box, a second screw member having a tapered end and a threaded body disposed within the second sliding box, and an adjuster for adjusting the height of the sliding boxes.

[0026] Implementations of this aspect may include one or more of the following features. For example, the first and second screw members may be medially aligned. At least one of the first and second screw members may be laterally aligned. The first and second screw members are laterally aligned. One of the first and second screw members is laterally aligned and the other screw member is laterally aligned. The first and second sliding boxes may be substantially triangularly shaped. The triangularly shaped first and second sliding boxes may include a sliding rail and ridged surfaces. The triangularly shaped first and second sliding boxes may include holes for bone grafts. The adjuster may include a screw.

[0027] In another general aspect, a self-drilling bone fusion screw apparatus includes a box, a first screw member having a tapered end and a threaded body disposed at least partially within the box and laterally aligned with the box, a second screw member having a tapered end and a threaded body disposed at least partially within the box and laterally aligned with the box, and a plurality of ridges disposed on along the sides of the box.

[0028] Implementations of this aspect may include one or more of the following

features. For example, the apparatus may include bone graft holes. The apparatus may be attachable to a second self-drilling fusion screw apparatus via a plate.

[0029] In another general aspect, a self-drilling bone fusion screw apparatus may include a first box, a first screw member having a tapered end and a threaded body disposed at least partially within the first box and laterally aligned with the first box, a second box, a second screw member having a tapered end and a threaded body disposed at least partially within the second box and laterally aligned with the second box, and an attachment member for engaging the first and second boxes.

[0030] Implementations of this aspect may include one or more of the following features. For example, the self-drilling bone fusion screw apparatus may include bone graft holes. The plate may be directly joined to the first and second boxes by a plurality of screws. The attachment member for engaging the first and second boxes may include a plate or the attachment member may include a circumferential cage defining at least one recess. The first and the second boxes may be positioned within or securely held within the recess of the circumferential cage, e.g, with an interference fit.

[0031] In another general aspect, a tool assembly for manipulating a self-drilling bone fusion screw apparatus includes a handle, a gripper cooperating with the handle and having a plurality of prongs, a screw guide, held in place the plurality of prongs, for controlling the direction of self-drilling screws that are screwed into a vertebral body.

[0032] Implementations of this aspect may include one or more of the following

features. For example, the tool assembly for manipulating a self-drilling bone fusion screw apparatus may include a key for controlling an adjustment device which controls the height of the self-drilling bone fusion screw apparatus. The tool assembly according to claim may include a driver assembly. The driver assembly may include a handle, a drive bit portion, and a flexible drive shaft extending between the handle and the drive bit portion for manipulating a screw of an expandable or non-expandable screw box. The assembly may include one or more of an expandable screw box and/or a non-expandable screw box. The boxes may include one or more screws. The screw boxes may be joined by or include an attachment member, such as a plate and/or a circumferential cage.

[0033] In another general aspect, a cervical facet staple includes a curved staple base, at least two prongs attached to the bottom surface of the curved staple base, and an insertion member disposed on the top surface of the curved staple base.

[0034] Implementations of this aspect may include one or more of the following features. For example, the staple may include at least four prongs attached to the bottom surface of the curved staple base. The insertion member may include a threaded insert.

[0035] In another general aspect, an impaction tool for a cervical facet staple includes a handle, a stem attached to the handle, a plurality of wings for contacting the cervical facet staple, and an insertion member for coupling the cervical facet staple to the impaction tool.

[0036] Implementations of this aspect may include one or more of the following

features. For example, the handle may include a flattened portion that can be struck by a mallet.

[0037] In another general aspect, a lumbar facet staple includes a pair of rotating arms, at least two prongs attached to the inner surfaces of the rotating arms, a plurality of spurs attached to one of the rotating arms, and a ratchet attached to one of the rotating arms. The rotating arms and prongs are rotated to a closed position to staple a lumbar facet joint.

BRIEF DESCRIPTION OF DRAWINGS

[0038] Figures 1A-D illustrate the Lumbar intervertebral screw box with one lateral oriented BDFT screw and one medially oriented two BDFT screw (Embodiment IA) in sagittal-oblique (Figure 1A), superior perspective(Figure 1 B), inferior perspective (Figure 1C) and exploded (Figure 1D) views.

[0039] Figure 1 E illustrates the lumbar intervertebral expandable screw box with two lateral oriented BDFT screws (Embodiment IB; sagittal-oblique view).

[0040] Figures 2A-C illustrate the Lumbar intervertebral non-expandable screw box with two BDFT screws (Embodiment II) in lateral (Figure 2A), oblique (Figure2B), and superior perspective (Figure 2C) views.

[0041] Figure 3 illustrates a superior oblique perspective view of left and right lumbar intervertebral non-expandable screw boxes with one BDFT screw (Embodiment III).

[0042] Figures 4A-B illustrate the horizontal intervertebral zero-profile mini-plate prior to insertion (Figure 4A), and after insertion (Figure 4B) into two non-expandable lumbar intervertebral screw boxes with two BDFT screws.

[0043] Figure 4C illustrates two non-expandable lumbar intervertebral screw boxes with two screws within a large circumferential cage for anterior placement into the lumbar spine

[0044] Figures 5A-C illustrate t positioning tool / screw guide/box expander in oblique perspective (Figure 5A), lateral (Figure 5B), and exploded (Figure 5C) views.

[0045] Figure 5D illustrates a superior oblique perspective view of the positioning tool/drill guide/box expander component.

[0046] Figures 5E-G illustrate the sequential steps (I-III) of the positioning tooll/screw guide/box expander assembly. Step I (Figure5E), step II (Figure 5F), and step III (Figure 5G).

[0047] Figures 5H-I illustrate the positioning tool for impaction and placement of the non-expandable screw box with two transvertebral screws. Embodiment I has a rectangular positioning handle (Figure 5H), and embodiment II has a circular positioning handle (Figure 5I)

[0048] Figures 6A-B illustrate the insertion of expandable Lumbar bi-directional screw box with two BDFT screws into the Lumbar spine in oblique (Figure 6A) and lateral (Figure 6B) views.

[0049] Figures 7A-B illustrate the cervical facet staple (Embodiment I) in lateral

(Figure 7A) and oblique (Figure 7B) views.

[0050] Figures 8A-C illustrate the cervical facet staple (Embodiment II) in oblique (Figure 8A), superior perspective (Figure 8B) and inferior-oblique (Figure 8C) views.

[0051] Figure 9A illustrates the two-pronged cervical facet staple inserter/impactor (Embodiment I).

[0052] Figure 9B illustrates the two-pronged cervical facet staple inserter/impactor inserted into the staple (Embodiment I).

[0053] Figure 10A illustrates the four pronged cervical facet staple impactor (Embodiment II).

[0054] Figure 10B illustrates the four pronged cervical facet staple impactor inserted into the cervical facet staple (Embodiment II).

[0055] Figure 10C illustrates an inferior-oblique perspective view of the four – pronged cervical facet staple impactor (Embodiment II).

[0056] Figure 11 A illustrates placement of two-pronged cervical facet staples in a three-dimensional cervical spine.

[0057] Figure 11 B illustrates placement of four-pronged cervical facet staples in a three-dimensional cervical spine.

[0058] Figure 11C illustrates modular placement of two and four pronged cervical facet staples in a three-dimensional cervical spine to achieve differing calibrated degrees of flexibility.

[0059] Figures 12 A-B illustrate the Lumbar facet joint staple with a calibrated

ratcheting mechanism in opened (Figure A) and closed (Figure B) positions.

DETAILED DESCRIPTION OF THE INVENTION

1. THE MEDICAL DEVICE

[0060]Referring to Figures 1-6, the above described problem can be solved in the thoracic and lumbar spine by insertion into the denuded intervertebral disc space multiple embodiments of screw box constructs with BDFT screws.

[0061] Figures 1A-D illustrate three-dimensional views of the Lumbar intervertebral expandable screw box 100 with two BDFT screws 101, 102; one lateral and one medially oriented (Embodiment IA). Figure 1E illustrates a sagittal-oblique view of the lumbar intervertebral expandable screw box 120 with two lateral oriented BDFT screws 121, 122 (Embodiment IB).

[0062] The expandable box 100 consists of top and bottom triangular sliding bases 103, 104 (Figures 1-D). The superior and inferior segments of the height/depth adjusting screw 105 are integrated and connected to the two separate top and bottom triangular bases 103, 104, respectively. By turning this adjusting screw 105 back and forth i.e. clock-wise, and counter clockwise, the sliding rails 106 of the top triangular base 103 (Figure 1D) slide up and down the rail inserts 107 on the bottom triangular base 104 (Figure 1D). This action will simultaneously alter the intervertebral height and depth of the screw box 100 allowing individualized custom fitting of the screw box 100 conforming to the dimensions of the disc space.

[0063] Transvertebral screw 101 penetrates the top base 103, and transvertebral screw 102 traverses the bottom base 104 of the screw box 100. The two screws 101, 102 traverse the screw box 100 in opposing directions, bi-

directionally (whether they are lateral or medially oriented). The external edges of the triangular bases 103, 104 in contact with vertebral body surfaces include ridges 107. This facilitates the screw box's 100 incorporation into and fusion with the superior and inferior vertebral bodies (Figures 1A-E). Both top and bottom screw box bases 103, 104 are perforated with holes 108 to allow bone placement for fusion. The entire construct, furthermore, is hollow to allow bone filling. Hence this device functions as both an intervertebral bone fusion spacer and bidirectional transvertebral screw fusion device.

[0064] Figures 2A-C illustrate three-dimensional views of the Lumbar intervertebral non-expandable screw box 200 with two BDFT screws 201, 202 (Embodiment II). Screws 201 and 202 perforate and orient in opposing, superior and inferior directions. There are holes 208 and hollow spaces allowing packaging with bone. There are also holes which allow the traversal of screws. The superior and inferior edges include ridges 207 to facilitate integration and fusion with superior and inferior vertebral bodies. The expandable screw box 200 may include a screw insert 209 to attach a horizontal mini-plate (not shown). The self-contained internalized drill guides are at a 25 degree angle. The screw boxes can be designed with the internalized drill guides with different angles and/or different positions within the box.

[0065] Figure 3 illustrates a three-dimensional view of left and right lumbar intervertebral non-expandable screw boxes 300a, 300b with one BDFT screw 301 or 302 (Embodiment III). It is roughly half the width of Embodiments I and II. Screw 301 is inserted into screw box 300a (left) and screw 302 is inserted into

screw box 300b (right). There are holes 308 and hollow spaces allowing packing of bone to achieve biological fusion. The combined effect of one superior oriented and one inferior oriented screw fuses the superior and inferior vertebral bodies with small constructs. This also enables placement of larger dimension screws compared to embodiments I and II.

[0066] Figures 4A and B illustrate three-dimensional views of the horizontal intervertebral zero profile mini-plate 400 with two non-expandable lumbar intervertebral screw boxes 300a, 300b housing two BDFT screws 301, 302. Figure 4A illustrates the perforations 401 within the plate 400 through which small plate securing screws 310 will be inserted to connect it to the built-in screw holes of the screw box 300a, 300b (Figure 4B). The horizontal mini-plate 400 together with the top surfaces of left and right screw boxes 300a, 300b provide a physical barrier between the underlying bone placed beneath it (not illustrated), and the thecal sac and nerve roots above it (not illustrated).

[0067] Figure 4C illustrates two screw boxes 300c, 300d within a circumferential cage 420 (2 in 1) construct which is designed for anterior placement into the lumbar spine. There are slots 308a, 308b for bone graft placement, both outside and inside the boxes. The circumferential cage 420 has perforations 401a for the placement of transvertebral screws (not shown).

[0068] Figures 5A-C illustrate three-dimensional views of the external drill /screw guide -box expander 500 which assists in screw trajectory and box expansion (embodiments IA-B). For embodiments II and III, the same instrument is utilized; however, an expanding Allen key component is not used.

[0069] The key components of this device include an Allen key 501, a spring 502, a handle 503, a griper 504 and a screw guide 505. The Allen key 501 when inserted in the insertion 514 and turned, turns the screw adjuster (Figure 5C) which in turn regulates top and bottom triangular screw box base sliding, and hence box 200 width and depth. The griper 504 has griper prongs 506 which insert into grooves of the screw guide 505 and the screw box 200 (Figures 5A-D) thus perfectly aligning them.

[0070] Figure 5D illustrates a superior oblique view of the screw guide 505 demonstrating insertions 509 for griper prong 506, built-in trajectory guides 511, 512 for insertions of screws 101 and 102, and the Allen key 501.

[0071] Figures 5E-G illustrate three–dimensional views of the sequential steps necessary for the external guide assembly. Figure 5E illustrates the insertion of the Allen key 501 into the handle 503. Figure 5F illustrates the insertion of the handle 503 through the spring 502 and griper 504. Figure 5G illustrates insertion of the griper 504 into the screw guide 505.

[0072] Figures 5H-I illustrate three-dimensional views of a positioning tool 500a for impaction and placement of two transvertebral screws 201, 202 in the non-expandable screw box 200. The driver assembly 550 consists of a screw driver 551, a flexible shaft 552 and a square recess bit 553. This facilitates turning the screws 201, 202 into the bone. The flexible shaft 552 facilitates the avoidance of spinous processes which might hinder the screw driving if the shaft 552 were straight. The positioning tool 500a can have a rectangular handle, Embodiment I (Figure5H), or a circular handle, Embodiment II (Figure 5I). This serves to

position the screw box within the intervertebral space, and screws 201, 202 within the screw box. Once positioned, the screw box can be impacted by tapping the handle with a mallet (not shown). The positioning tool's 500a griper handle inserts into the screw guide and the box, which maintains alignment.

[0073] Figure 6A illustrates a three-dimensional view of insertion of the construct (Embodiment I) into the lumbar intervertebral disc space.

[0074] Figure 6B illustrates a three dimensional lateral view of insertion of the construct (Embodiment I) into the disc space with short screws. Placement with longer screws would capture more bone.

[0075] Figures 7Aand B illustrate three-dimensional views of the two-pronged cervical facet staple 700 (Embodiment I). There is a staple base 701 which is contoured to align with the curved surface of the cervical facet joints. There is a superior impactor threaded insert 702. An impactor can be screwed into this insert 702 and then impacted with a mallet. The two spikes 703, 704 perforate the inferior and superior facets of the superior and inferior vertebral bodies hence leading to cervical facet joint fusion. The spikes can be designed with ridges and/ or fishhooks to facilitate irreversible extraction.

[0076] Figures 8A-C illustrate three-dimensional views of the four-pronged cervical facet staple 800 (Embodiment II). Likewise it has a staple base 805 contoured specifically for the surface of the facet joint. It also has an impactor insert 806. The insertion of a device with four prongs 801-804 instead of two prongs further limits the degrees of motion of the joint hence making the fusion more rigid.

[0077] Figures 9 A-B illustrate a three-dimensional view of the two-pronged cervical staple impactor 900. It has a handle 901, a stem 902, and a screw insert 903 which can be screwed into the threaded staple insert. The impactor has two wings 904 which keep the staple base edges in place facilitating staple impaction. The handle 901of the impactor 900 is broad in order to allow impaction by a mallet.

[0078] Figures 10A -C illustrate three-dimensional views of the four-pronged cervical staple impactor 1000 (Embodiment II). It has the same features as the two-pronged impactor 900, except its wings 1004 are broader accommodating the broader staple base. The impactor 1000 also includes a handle 1001, a stem 1002, and an impact screw 1003.

[0079] Figure 11 A illustrates a three-dimensional view of placement of the two pronged cervical facet staple 700 into a cervical spine model having vertebral body 1103 and lamina 1104. One staple 700 is perched on the joint 1101 prior to impaction. The other staple 700 is impacted.

[0080] Figure 11 B illustrates a three-dimensional view of placement of the four pronged cervical facet staple 800 into a cervical spine pre and post impaction.

[0081] Figure 11C illustrates the concept of modularity and incremental diminution of movement of the joint by the modular placement of different combinations and permutations of varying numbers of two and four pronged cervical facet staples 700, 800. If one wishes to have the most flexible (least rigid) fusion, one would place a unilateral two pronged staple 700. One can increase i.e. calibrate increasing degrees of rigidity by increasing the number of

prongs penetrating the facet joints bilaterally. In Figure 11 C each facet joint is fused using a total number of six prongs. One side this is accomplished by using three two pronged staples 700, and on the other side using one four pronged staple 800 and one two pronged staple 700. These two embodiments can be mixed and matched unilaterally or bilaterally to vary the degree of rigidity and conversely flexibility of fusion. The most flexible fusion at one level would be accomplished by one staple 700 (2 prongs). The highest level of rigidity would be achieved by placing two four pronged staples 800 on both sides totaling sixteen prongs. Intermediate degrees of relative joint motion can be modulated by insertion into the cervical facet joints staples in two-four prong increments from 2-16. Each additional prong further limits the degree of facet joint motion hence increasing rigidity, and conversely decreasing flexibility. Thus the novel modular use of these embodiments heralds an era of flexible cervical spine fusion.

[0082] Figures 12 A - B illustrate a lumbar facet joint staple 1200 in open and closed positions and having staple prongs 1203. This lumbar facet staple has been thoroughly described in our previous co-pending patent applications, Serial No. 11/536,815, filed on September, 29, 2006, and Serial No. 11/208,644, filed on August 23, 2005, the relevant portion of each of which is hereby incorporated by reference hereinafter. The new improvement of this device includes a ratchet 1201. The staple 1200 can be incrementally closed with increased ratcheting over increasing number of spurs 1202. This achieves increasing calibrated levels of lumbar facet joint fusion, and conversely diminishing joint flexibility. This new designs further enhances the capacity to achieve flexible fusions in the lumbar

spine.

2. THE SURGICAL METHOD

[0083] Exemplary surgical steps for practicing one or more of the foregoing embodiments will now be described.

[0084] The posterior lumbar spine implantation of all the screw box 100, 200, 300 embodiments, with BDFT screws, and horizontal mini-plate 400 can be implanted 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. Fluoroscopic guidance can be used with any of these procedures.

[0085] After 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, a unilateral or bilateral facet sparing hemi-laminotomy is created to introduce screw box 100, 200, 300 embodiments I-III into the disc space, after it is adequately prepared.

[0086] 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.

[0087] Then one screw box 100, 200, 300 of either embodiments I-III is placed

on either right, left or both sides. Then another screw box of embodiments 100, 200, 300 I-III is placed on the contralateral side. For embodiment I the external screw guide 505/ box expander is attached to the screw box (Figures 5A-H). First the Allen key 501 is screwed until the box conforms perfectly to the height and depth of the space. Then a pilot hole can be drilled or an awl can start a pilot hole in the vertebral bodies. Then a transvertebral screw is screwed into the vertebral body via the built-in box screw guides 505. For difficult angles, an angled screw driver can be employed.

[0088] For embodiments II-III the same method is used for placing screws, except the Allen key 501 is not utilized in the absence of plate expansion.

[0089] If bilateral constructs have been inserted, bone is packed into the intervertebral space, as well as within the device. Then the horizontal intervertebral zero profile mini-plate 400 is slid beneath the thecal sac and is secured to both left and right screw boxes with small mini-plate screws 210 (Figures 4A-B). This prevents bone intrusion into the thecal sac and hence possible nerve root compression.

[0090] Figures 6A and B illustrate the process of insertion and final placement of the construct into the lumbar spine. The mini- plates 400 can come in different horizontal lengths and widths to accommodate different intra and inter -patient disc space diameters. The BDFT screws can come in different widths, lengths and thread designs.

[0091] The anterior thoracic and lumbar spine implantation of one, two or three screw box constructs 100, 200, 300 and BDFT screws can be performed in a

similar manner to the posterior application. Likewise, a horizontal mini-plate 400 can be used to cap two or three screw box constructs 100, 200, 300 (one placed midline deeply, one placed left and one placed right, forming a triangulation). Alternatively two screw box constructs may be placed into a circumferential ring for anterior placement. Anterior placement of these devices can be performed into the L4/5 and L5/S1 spaces on the supine anesthetized patient via previously described open microscopic or endoscopic techniques. Once the disc space is exposed and discectomy and space preparation are performed, placement of one, two or three screw box embodiments 100, 200, 300 (I-III) or a 2 in I construct can be placed. The screw placement is facilitated by the internal screw guides, and different positioning tools ((Figure 5). A right angled screw driver and/or ratchet could alternatively be employed A capping mini-plate 400 may be applied if desirable. The mechanism of screw placement and mini-plate 400 attachment are identical to what was described above.

[0092] The posterior placement of screw box constructs 100, 200, 300 alone or combined with horizontal mini-plates 400 into the thoracic spine can be performed via previously described transpedicular approaches; open or endoscopic. The anterior placement into the thoracic spine can be accomplished via a trans-thoracic approach. Once the disc space is exposed via either approach, any combination of the above mention Embodiments (I-III) can be inserted. Engagement of the devices is identical to what was mentioned above.

[0093] For posterior placement of cervical facet staple 700, 800 embodiments, after adequate induction of anesthesia the patient is flipped prone and his head

and neck secured. A single midline or two para-median incisions are made for unilateral or bilateral or multilevel placement of staples. Ultimately the facet joint is exposed. Alternatively and preferably this can be performed percutaneously under fluoroscopic guidance with intravenous sedation. The staple 700, 800 (Embodiments I or II) is loaded into the impactor 900, 1000. The staple 700, 800 is placed on the two articulating cervical facets, and then impacted into the joint. To achieve modular calibrated fusion different combinations and permutations of cervical facet stales 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 staples 800 (16 prongs) leading to the highest degree of rigidity. Additional bone may or may not be placed in its vicinity to facilitate permanent and solid fusion. This procedure can be performed open, closed, percutaneously, tubulary, endoscopically or microscopically. Figures 11 A-C illustrates placement of the staples 700, 800 in the cervical spine.

[0094] We have previously described surgical placement of the lumbar facet joint staple in our two co-pending patents. The surgical procedure for this device is identical to that which has been previously mentioned.

[0095] The present inventions may provide effective and safe techniques that overcome the problems associated with current transpedicular based cervical, thoracic and lumbar fusion technology, and for many degenerative stable and unstable spine disease. These inventions could replace much pedicle screw-based instrumentation in many but not all degenerative spine conditions.

[0096] The speed and simplicity of placement of cervical and lumbar facet

staples, and placement of Lumbar screw box –BDFT constructs far exceeds that of current pedicle screw technology. Furthermore, these devices have markedly significantly decreased risk of misguided screw placement, and hence decreased risk of neural and vascular injury, and blood loss. In the lumbar spine BDFT screw constructs and facet staples could be applied modularly in different combinations to achieve different degrees of rigidity (flexibility). Patients having these devices would have decreased recovery and back to work time. These devices most likely lead to similar if not equal fusion with significantly less morbidity, and hence overall make them a major advance in the evolution of spinal instrumented technology leading to advances in the care of the spinal patient.

[0097] Another major novelty and advance is the introduction of simple and safe modular calibrated cervical flexible fusion. To our knowledge neither a similar device nor a similar mathematical concept of modular joint flexibility/fusion calibration has been postulated for the cervical spine or for any other articulating joint.

[0098] To our knowledge there have not been any previously described similar posterior lumbar and thoracic combined spacer and screw constructs. These devices can similarly be modified to stabilize bone fractures throughout the entire body. To our knowledge the description of zero to subzero profile anterior or posterior horizontal spinal plates which traverse the diameter of the disc space has not been previously described.

SYSTEM WITH TOOL ASSEMBLY AND EXPANDABLE SPINAL IMPLANT

[0001] This application is a Continuation-In-Part Application of copending application Serial No. 11/536,815, filed September, 29, 2006, which is a Continuation-In-Part Application of copending application Serial No. 11/208,644, filed August 23, 2005 for which priority is claimed under 35, U.S.C. §120; and this application also claims priority under 35 U.S.C. § 119(e) of U.S. provisional application No. 60/670,231, filed on April 12, 2005; the entire contents of all the above identified patent applications are hereby incorporated by reference.

Field of Invention

[0002] The present invention relates to a unique universal bidirectional screw (BDS) system, and in particular its application to the spine, also referred to as bi-directional fixating transvertebral (BDFT) screws which can be used as a stand-alone intervertebral device which combines the dual functions of an intervertebral spacer which can be filled with bone fusion material(s), as well as a transvertebral bone fusion screw apparatus. In the posterior lumbosacral and thoracic spine, BDFT screw/box constructs can be used independently or supplemented with a novel horizontal mini-plate which prevents upward bone graft intrusion into the thecal sac and nerves. In the anterior lumbosacral spine BDFT screw box constructs can be inserted into and supplemented by a circumferential cage. These posteriorly and anteriorly placed stand-alone intervertebral body fusion constructs may obviate the need for supplemental pedicle screw fixation.

[0003] The present invention also relates to stand-alone or supplemental

posterior cervical and lumbar calibrated inter-articular joint stapling devices which may obviate and/or lessen the need for supplemental pedicle screw fixation.

Description of the Relevant Art

[0004] The history and evolution of instrumented spinal fusion in the entire human spine has been reviewed in our two prior copending applications Serial No. 11/536,815, filed on September, 29, 2006, and Serial No. 11/208,644, filed on August 23, 2005, the related contents of which are hereby incorporated by reference. Currently the majority of posterior cervical and almost all anterior and posterior lumbosacral and thoracic fusion techniques are typically supplemented with pedicle screw placement. Complications of pedicle screw placement in cervical, thoracic and lumbar 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 excess rigidity leading to adjacent segmental disease requiring further fusions and re-operations. Recent advances in pedicle screw fixation including minimally invasive and image-guided technology, and the development of flexible rods, imperfectly address some but not all of these issues.

[0005] Complications of all current spinal interbody fusion devices is their lack of coverage of the majority of the cross- sectional area of the vertebral endplates, and their lack of adequate, if any capacity to penetrate bone, and hence the heightened risk of implant extrusion. Furthermore the bone and biological bone fusion agents which are packed into the intervertebral space can easily blossom

and grow upward into the thecal sac causing neural compression, in the absence of a physical barrier between the fusing growing bone, and the thecal sac.

Summary

[0006] Herein we describe multiple device embodiments which combine in a single construct the dual functions of an intervertebral spacer maintaining disc space height, and transvertebral body fusion screws.

[0007] We also introduce an entirely novel horizontal mini-plate capping off the intervertebral space capable of functioning as a physical barrier preventing upward bone intrusion and/or compression of the ventral thecal sac, and traversing and exciting nerve roots.

[0008] Furthermore, we present an advanced mechanism in calibrated posterior facet joint stapling compared to our previous designs illustrated in our co-pending patents. We also introduce the entirely novel concept of posterior cervical facet staples to obviate and/or diminish the need for posterior cervical pedicle screw instrumented fusion. Using combinations and permutations of different embodiments of cervical facet staples in a modular manner advances the concept of flexible fusion in the cervical spine.

[0009] To achieve safe, effective and minimally invasive segmental spinal fusion, applicants propose the use of novel bi-directional fixating transvertebral (BDFT) screws which can be strategically inserted via anterior or posterior surgical spinal approaches into the anterior and middle columns of the interverterbral disc space. In our previous applications these bi-directional screws employed turning a wormed driving screw which turns a spur gear which in turn

simultaneously turns a rostral oriented screw into the cephalad vertebral body, and a caudal directed screw into the caudal vertebral body. The vertebral bodies above and below the disc space by virtue of their engagement and penetration by the BDFT screws are thus linked, interlocked, and eventually biologically fused with placement of intervertebral bone agents.

[0010] In this current application one or more of the described embodiments may eliminate the intervening wormed driving screws and gears required by previous designs, e.g., a gearless screw box is achieved. We have designed a screw box to be placed inter-vertebrally, either unilaterally or bilaterally, in particular, posteriorly between vertebral bodies. The housing screw box incorporates built-in screw and/or drill guides which allow the direct placement and insertion of two self drilling screws which are driven in two opposing directions into superior and inferior vertebral bodies, respectively. One screw within the screw box is angled superiorly, and the other screw in the screw box is angled inferiorly.

[0011] In yet another embodiment, in addition to these features we designed an expanding screw box with sliding triangular bases to house two screws driven in two opposing directions which can be expanded in two simultaneous directions, height and depth, by turning a built-in screw adjuster. This is accomplished by a combined positioning tool/screw guide/cage expander to further enhance trajectory precision and to simultaneously expand the screw box in height and depth to custom-fit the individual disc space height. This embodiment has two sub-embodiments; one has two laterally oriented BDFT screws, and the other has a lateral and a medial oriented BDFT screw. These innovations represent a

continued evolution of our concept of expandable fusion cages described in our previous co-pending patents.

[0012] In yet another embodiment we designed a screw box which houses only one, instead of two screws. Each box allows the placement of one superior or inferior directed screw on one side (left or right) , and the contra lateral screw box device allows placement of an inferior or superior oriented screw which goes in the opposite direction of the contra lateral device. In totality these two separate single screw boxes fuse the superior and inferior vertebrae. The potential advantage of this embodiment is that it diminishes the width of the screw box in cases where it might be favorable to have less nerve root retraction with a smaller width device.

[0013] In all screw-box embodiments, a rostral-directed screw is passed through one built-in screw guide of the device which then is inserted and screwed into the superior vertebral body. Then a caudaly directed screw is passed through an adjacent built-in screw guide which then is inserted and screwed into the inferior vertebral body. The novelty of this design is the built-in prescribed angles of the integral screw guides which allow the posterior transvertebral penetration into the vertebral bodies. This is a truly amazing feat accomplished in the posterior lumbar spine considering the small anatomically restricted work zone within which to work, which is very narrowly prescribed by obtuse angulations between screw and intervertebral bone surfaces, and by nerve root, facet joint and pedicle. We have also designed a positioning tool for the placement of the non-expandable screw boxes which has a screwdriver with a flexible shaft specifically designed to fit these devices if a straight screw driver impedes screw placement. Hence these external tools provide the means in any circumstance to

accomplish precision screw trajectory. The embodiments described herein compared to our previous co-pending patent designs, streamline and ease production of bi-directionally oriented transvertebral screws, and allows placement of longer and wider screws with greater bone penetration to provide yet a sturdier fusion construct. The designs are also easily modifiable for anterior placement into the cervical spine. The expandable embodiment of the screw box can also be enlarged and modified to be suitable for cervical, thoracic and lumber vertebral body replacements.

[0014] The box casings have multiple perforations to allow both screw traversal and horizontal bone packing preventing upward vertical migration of bone. The boxes prevent subsidence. Both the inside of the denuded intervertebral space, and the screw boxes can be packed with autologous or allograft bone, BMP, DBX or similar osteoconductive material. Posteriorly or anteriorly in the lumbar spine, these screws can be capped with a horizontal mini-plate which will prevent bony growth into the thecal sac and nerves. We refer to this as a two-in-one device, i.e. two screw boxes/BDFT screws combined with one horizontal mini-plate. This is an entirely novel concept in posterior lumbar spinal surgery. In yet another embodiment two BDFT screw boxes can be combined with a circumferential cage (also 2 in 1) to be placed anteriorly into the lumbar spine.

[0015] It is believed that BDFT- screw constructs provide as strong or stronger segmental fusion as pedicle screws without the complications arising from pedicle screw placement which include screw misplacement with potential nerve and/or vascular injury, violation of healthy facets, possible pedicle destruction, blood loss, and overly rigid fusions. By placing screws across the intervertebral space from vertebral body to vertebral body, engaging anterior and middle spinal

columns, and not the vertebral bodies via the transpediclar route, the healthy facet joints, if they exist, are preserved. Because this technique accomplishes both anterior and middle column fusion, without rigidly fixating the posterior column, it in essence creates a flexible fusion. This device therefore is a flexible fusion device because the preserved posterior facet joints retain their function achieving at least a modicum of mobility and hence a less rigid (i.e. a flexible) fusion.

[0016] 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.

[0017] Transvertebral fusion also leads to far less muscle retraction, blood loss, and significant reduction in O.R. time. Thus the complication of pedicular screw pull-out and hence high re-operation rate associated with the current embodiment of flexible fusion pedicle screws/rods is obviated. The lumbosacral screw box embodiments and BDFT screws can be introduced via posterior lateral, transforaminal or anterior interbody fusion approaches /techniques. Although one can opt to supplement these screws with transpedicular screws there would be no absolute need for supplemental pedicle screw fixation with these operative techniques.

[0018] BDFT screw constructs outlined here can also be combined with novel zero-profile horizontal cervical and, lumbar/thoracic mini-plates. Likewise one or two of these devices can be inserted anteriorly with or without circumferential cage supplementation.

[0019] Because the BDFT screws engage a small percentage of the rostral and caudal vertebral body surface area, multi-level fusions can be performed with these devices.

[0020] Previous improvements included a novel calibrated lumbar /thoracic facet stapling device which staples the inferior articulating facet of the superior segment to the superior articulating facet of the caudal vertebral segment unilaterally or bilaterally, which may minimize motion until interbody fusion occurs. In the present patent application we introduce a new design of the staple enhancing its calibrating capability.

[0021] In this patent application we also introduce 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 caudal vertebral segment unilaterally or bilaterally.

[0022] 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. Thus they thereby achieve the same function of pedicle screws without the risks.

[0023] Placement of different embodiments of the cervical facet staples along unilateral and/or bilateral facet joints in a modular manner, lead to differing degrees of calibrated motion joint motion hence introducing for the first time the concept of calibrated cervical fusion.

[0024] Currently failed anterior lumbar arthroplasties are salvaged by combined anterior and posterior fusions. BDFT screw constructs could be utilized as a one-

step salvage operation for failed/extruded anteriorly placed lumbar artificial discs obviating the above salvage procedure which has far greater morbidity.

[0025] For example, in one general aspect, a self-drilling bone fusion screw apparatus includes a first sliding box, a second sliding box, positioned relative to the first sliding box, a first screw member having a tapered end and a threaded body disposed within the first sliding box, a second screw member having a tapered end and a threaded body disposed within the second sliding box, and an adjuster for adjusting the height of the sliding boxes.

[0026] Implementations of this aspect may include one or more of the following features. For example, the first and second screw members may be medially aligned. At least one of the first and second screw members may be laterally aligned. The first and second screw members are laterally aligned. One of the first and second screw members is laterally aligned and the other screw member is laterally aligned. The first and second sliding boxes may be substantially triangularly shaped. The triangularly shaped first and second sliding boxes may include a sliding rail and ridged surfaces. The triangularly shaped first and second sliding boxes may include holes for bone grafts. The adjuster may include a screw.

[0027] In another general aspect, a self-drilling bone fusion screw apparatus includes a box, a first screw member having a tapered end and a threaded body disposed at least partially within the box and laterally aligned with the box, a second screw member having a tapered end and a threaded body disposed at least partially within the box and laterally aligned with the box, and a plurality of ridges disposed on along the sides of the box.

[0028] Implementations of this aspect may include one or more of the following

features. For example, the apparatus may include bone graft holes. The apparatus may be attachable to a second self-drilling fusion screw apparatus via a plate.

[0029] In another general aspect, a self-drilling bone fusion screw apparatus may include a first box, a first screw member having a tapered end and a threaded body disposed at least partially within the first box and laterally aligned with the first box, a second box, a second screw member having a tapered end and a threaded body disposed at least partially within the second box and laterally aligned with the second box, and an attachment member for engaging the first and second boxes.

[0030] Implementations of this aspect may include one or more of the following features. For example, the self-drilling bone fusion screw apparatus may include bone graft holes. The plate may be directly joined to the first and second boxes by a plurality of screws. The attachment member for engaging the first and second boxes may include a plate or the attachment member may include a circumferential cage defining at least one recess. The first and the second boxes may be positioned within or securely held within the recess of the circumferential cage, e.g, with an interference fit.

[0031] In another general aspect, a tool assembly for manipulating a self-drilling bone fusion screw apparatus includes a handle, a gripper cooperating with the handle and having a plurality of prongs, a screw guide, held in place the plurality of prongs, for controlling the direction of self-drilling screws that are screwed into a vertebral body.

[0032] Implementations of this aspect may include one or more of the following

features. For example, the tool assembly for manipulating a self-drilling bone fusion screw apparatus may include a key for controlling an adjustment device which controls the height of the self-drilling bone fusion screw apparatus. The tool assembly according to claim may include a driver assembly. The driver assembly may include a handle, a drive bit portion, and a flexible drive shaft extending between the handle and the drive bit portion for manipulating a screw of an expandable or non-expandable screw box. The assembly may include one or more of an expandable screw box and/or a non-expandable screw box. The boxes may include one or more screws. The screw boxes may be joined by or include an attachment member, such as a plate and/or a circumferential cage.

[0033] In another general aspect, a cervical facet staple includes a curved staple base, at least two prongs attached to the bottom surface of the curved staple base, and an insertion member disposed on the top surface of the curved staple base.

[0034] Implementations of this aspect may include one or more of the following features. For example, the staple may include at least four prongs attached to the bottom surface of the curved staple base. The insertion member may include a threaded insert.

[0035] In another general aspect, an impaction tool for a cervical facet staple includes a handle, a stem attached to the handle, a plurality of wings for contacting the cervical facet staple, and an insertion member for coupling the cervical facet staple to the impaction tool.

[0036] Implementations of this aspect may include one or more of the following

features. For example, the handle may include a flattened portion that can be struck by a mallet.

[0037] In another general aspect, a lumbar facet staple includes a pair of rotating arms, at least two prongs attached to the inner surfaces of the rotating arms, a plurality of spurs attached to one of the rotating arms, and a ratchet attached to one of the rotating arms. The rotating arms and prongs are rotated to a closed position to staple a lumbar facet joint.

BRIEF DESCRIPTION OF DRAWINGS

[0038] Figures 1A-D illustrate the Lumbar intervertebral screw box with one lateral oriented BDFT screw and one medially oriented two BDFT screw (Embodiment IA) in sagittal-oblique (Figure 1A), superior perspective(Figure 1 B), inferior perspective (Figure 1C) and exploded (Figure 1D) views.

[0039] Figure 1 E illustrates the lumbar intervertebral expandable screw box with two lateral oriented BDFT screws (Embodiment IB; sagittal-oblique view).

[0040] Figures 2A-C illustrate the Lumbar intervertebral non-expandable screw box with two BDFT screws (Embodiment II) in lateral (Figure 2A), oblique (Figure2B), and superior perspective (Figure 2C) views.

[0041] Figure 3 illustrates a superior oblique perspective view of left and right lumbar intervertebral non-expandable screw boxes with one BDFT screw (Embodiment III).

[0042] Figures 4A-B illustrate the horizontal intervertebral zero-profile mini-plate prior to insertion (Figure 4A), and after insertion (Figure 4B) into two non-expandable lumbar intervertebral screw boxes with two BDFT screws.

[0043] Figure 4C illustrates two non-expandable lumbar intervertebral screw boxes with two screws within a large circumferential cage for anterior placement into the lumbar spine

[0044] Figures 5A-C illustrate t positioning tool / screw guide/box expander in oblique perspective (Figure 5A), lateral (Figure 5B), and exploded (Figure 5C) views.

[0045] Figure 5D illustrates a superior oblique perspective view of the positioning tool/drill guide/box expander component.

[0046] Figures 5E-G illustrate the sequential steps (I-III) of the positioning tooll/screw guide/box expander assembly. Step I (Figure5E), step II (Figure 5F), and step III (Figure 5G).

[0047] Figures 5H-I illustrate the positioning tool for impaction and placement of the non-expandable screw box with two transvertebral screws. Embodiment I has a rectangular positioning handle (Figure 5H), and embodiment II has a circular positioning handle (Figure 5I)

[0048] Figures 6A-B illustrate the insertion of expandable Lumbar bi-directional screw box with two BDFT screws into the Lumbar spine in oblique (Figure 6A) and lateral (Figure 6B) views.

[0049] Figures_7A-B illustrate the cervical facet staple (Embodiment I) in lateral

(Figure 7A) and oblique (Figure 7B) views.

[0050] Figures 8A-C illustrate the cervical facet staple (Embodiment II) in oblique (Figure 8A), superior perspective (Figure 8B) and inferior-oblique (Figure 8C) views.

[0051] Figure 9A illustrates the two-pronged cervical facet staple inserter/impactor (Embodiment I).

[0052] Figure 9B illustrates the two-pronged cervical facet staple inserter/impactor inserted into the staple (Embodiment I).

[0053] Figure 10A illustrates the four pronged cervical facet staple impactor (Embodiment II).

[0054] Figure 10B illustrates the four pronged cervical facet staple impactor inserted into the cervical facet staple (Embodiment II).

[0055] Figure 10C illustrates an inferior-oblique perspective view of the four – pronged cervical facet staple impactor (Embodiment II).

[0056] Figure 11 ~~1~~A illustrates placement of two-pronged cervical facet staples in a three-dimensional cervical spine.

[0057] Figure 11 B illustrates placement of four-pronged cervical facet staples in a three-dimensional cervical spine.

[0058] Figure 11C illustrates modular placement of two and four pronged cervical facet staples in a three-dimensional cervical spine to achieve differing calibrated degrees of flexibility.

[0059] Figures 12 A-B illustrate the Lumbar facet joint staple with a calibrated

ratcheting mechanism in opened (Figure A) and closed (Figure B) positions.

DETAILED DESCRIPTION OF THE INVENTION

1. THE MEDICAL DEVICE

[0060]Referring to Figures 1-6, the above described problem can be solved in the thoracic and lumbar spine by insertion into the denuded intervertebral disc space multiple embodiments of screw box constructs with BDFT screws.

[0061] Figures 1A-D illustrate three-dimensional views of the Lumbar intervertebral expandable screw box 100 with two BDFT screws 101, 102; one lateral and one medially oriented (Embodiment IA). Figure 1E illustrates a sagittal-oblique view of the lumbar intervertebral expandable screw box 120 with two lateral oriented BDFT screws 121, 122 (Embodiment IB).

[0062] The expandable box 100 consists of top and bottom triangular sliding bases 103, 104 (Figures 1-D). The superior and inferior segments of the height/depth adjusting screw 105 are integrated and connected to the two separate top and bottom triangular bases 103, 104, respectively. By turning this adjusting screw 105 back and forth i.e. clock-wise, and counter clockwise, the sliding rails 106 of the top triangular base 103 (Figure 1D) slide up and down the rail inserts 107 on the bottom triangular base 104 (Figure 1D). This action will simultaneously alter the intervertebral height and depth of the screw box 100 allowing individualized custom fitting of the screw box 100 conforming to the dimensions of the disc space.

[0063] Transvertebral screw 101 penetrates the top base 103, and transvertebral screw 102 traverses the bottom base 104 of the screw box 100. The two screws 101, 102 traverse the screw box 100 in opposing directions, bi-

directionally (whether they are lateral or medially oriented). The external edges of the triangular bases 103, 104 in contact with vertebral body surfaces include ridges 107. This facilitates the screw box's 100 incorporation into and fusion with the superior and inferior vertebral bodies (Figures 1A-E). Both top and bottom screw box bases 103, 104 are perforated with holes 108 to allow bone placement for fusion. The entire construct, furthermore, is hollow to allow bone filling. Hence this device functions as both an intervertebral bone fusion spacer and bidirectional transvertebral screw fusion device.

[0064] Figures 2A-C illustrate three-dimensional views of the Lumbar intervertebral non-expandable screw box 200 with two BDFT screws 201, 202 (Embodiment II). Screws 201 and 202 perforate and orient in opposing, superior and inferior directions. There are holes 208 and hollow spaces allowing packaging with bone. There are also holes which allow the traversal of screws. The superior and inferior edges include ridges 207 to facilitate integration and fusion with superior and inferior vertebral bodies. The expandable screw box 200 may include a screw insert 209 to attach a horizontal mini-plate (not shown). The self-contained internalized drill guides are at a 25 degree angle. The screw boxes can be designed with the internalized drill guides with different angles and/or different positions within the box.

[0065] Figure 3 illustrates a three-dimensional view of left and right lumbar intervertebral non-expandable screw boxes 300a, 300b with one BDFT screw 301 or 302 (Embodiment III). It is roughly half the width of Embodiments I and II. Screw 301 is inserted into screw box 300a (left) and screw 302 is inserted into

screw box 300b (right). There are holes 308 and hollow spaces allowing packing of bone to achieve biological fusion. The combined effect of one superior oriented and one inferior oriented screw fuses the superior and inferior vertebral bodies with small constructs. This also enables placement of larger dimension screws compared to embodiments I and II.

[0066] Figures 4A and B illustrate three-dimensional views of the horizontal intervertebral zero profile mini-plate 400 with two non-expandable lumbar intervertebral screw boxes 300a, 300b housing two BDFT screws 301, 302. Figure 4A illustrates the perforations 401 within the plate 400 through which small plate securing screws 310 will be inserted to connect it to the built-in screw holes of the screw box 300a, 300b (Figure 4B). The horizontal mini-plate 400 together with the top surfaces of left and right screw boxes 300a, 300b provide a physical barrier between the underlying bone placed beneath it (not illustrated), and the thecal sac and nerve roots above it (not illustrated).

[0067] Figure 4C illustrates two screw boxes 300c, 300d within a circumferential cage 420 (2 in 1) construct which is designed for anterior placement into the lumbar spine. There are slots 308a, 308b for bone graft placement, both outside and inside the boxes. The circumferential cage 420 has perforations 401a for the placement of transvertebral screws (not shown).

[0068] Figures 5A-C illustrate three-dimensional views of the external drill /screw guide -box expander 500 which assists in screw trajectory and box expansion (embodiments IA-B). For embodiments II and III, the same instrument is utilized; however, an expanding Allen key component is not used.

[0069] The key components of this device include an Allen key 501, a spring 502, a handle 503, a griper 504 and a screw guide 505. The Allen key 501 when inserted in the insertion 514 and turned, turns the screw adjuster (Figure 5C) which in turn regulates top and bottom triangular screw box base sliding, and hence box 200 width and depth. The griper 504 has griper prongs 506 which insert into grooves of the screw guide 505 and the screw box 200 (Figures 5A-D) thus perfectly aligning them.

[0070] Figure 5D illustrates a superior oblique view of the screw guide 505 demonstrating insertions 509 for griper prong 506, built-in trajectory guides 511, 512 for insertions of screws 101 and 102, and the Allen key 501.

[0071] Figures 5E-G illustrate three–dimensional views of the sequential steps necessary for the external guide assembly. Figure 5E illustrates the insertion of the Allen key 501 into the handle 503. Figure 5F illustrates the insertion of the handle 503 through the spring 502 and griper 504. Figure 5G illustrates insertion of the griper 504 into the screw guide 505.

[0072] Figures 5H-I illustrate three-dimensional views of a positioning tool 500a for impaction and placement of two transvertebral screws 201, 202 in the non-expandable screw box 200. The driver assembly 550 consists of a screw driver 551, a flexible shaft 552 and a square recess bit 553. This facilitates turning the screws 201, 202 into the bone. The flexible shaft 552 facilitates the avoidance of spinous processes which might hinder the screw driving if the shaft 552 were straight. The positioning tool 500a can have a rectangular handle, Embodiment I (Figure5H), or a circular handle, Embodiment II (Figure 5I). This serves to

position the screw box within the intervertebral space, and screws 201, 202 within the screw box. Once positioned, the screw box can be impacted by tapping the handle with a mallet (not shown). The positioning tool's 500a griper handle inserts into the screw guide and the box, which maintains alignment.

[0073] Figure 6A illustrates a three-dimensional view of insertion of the construct (Embodiment I) into the lumbar intervertebral disc space.

[0074] Figure 6B illustrates a three dimensional lateral view of insertion of the construct (Embodiment I) into the disc space with short screws. Placement with longer screws would capture more bone.

[0075] Figures 7Aand B illustrate three-dimensional views of the two-pronged cervical facet staple 700 (Embodiment I). There is a staple base 701 which is contoured to align with the curved surface of the cervical facet joints. There is a superior impactor threaded insert 702. An impactor can be screwed into this insert 702 and then impacted with a mallet. The two spikes 703, 704 perforate the inferior and superior facets of the superior and inferior vertebral bodies hence leading to cervical facet joint fusion. The spikes can be designed with ridges and/ or fishhooks to facilitate irreversible extraction.

[0076] Figures 8A-C illustrate three-dimensional views of the four-pronged cervical facet staple 800 (Embodiment II). Likewise it has a staple base 805 contoured specifically for the surface of the facet joint. It also has an impactor insert 806. The insertion of a device with four prongs 801-804 instead of two prongs further limits the degrees of motion of the joint hence making the fusion more rigid.

[0077] Figures 9 A-B illustrate a three-dimensional view of the two-pronged cervical staple impactor 900. It has a handle 901, a stem 902, and a screw insert 903 which can be screwed into the threaded staple insert. The impactor has two wings 904 which keep the staple base edges in place facilitating staple impaction. The handle 901of the impactor 900 is broad in order to allow impaction by a mallet.

[0078] Figures 10A -C illustrate three-dimensional views of the four-pronged cervical staple impactor 1000 (Embodiment II). It has the same features as the two-pronged impactor 900, except its wings 1004 are broader accommodating the broader staple base. The impactor 1000 also includes a handle 1001, a stem 1002, and an impact screw 1003.

[0079] Figure 11 ~~1~~A illustrates a three-dimensional view of placement of the two pronged cervical facet staple 700 into a cervical spine model having vertebral body 1103 and lamina 1104. One staple 700 is perched on the joint 1101 prior to impaction. The other staple 700 is impacted.

[0080] Figure 11 B illustrates a three-dimensional view of placement of the four pronged cervical facet staple 800 into a cervical spine pre and post impaction.

[0081] Figure 11C illustrates the concept of modularity and incremental diminution of movement of the joint by the modular placement of different combinations and permutations of varying numbers of two and four pronged cervical facet staples 700, 800. If one wishes to have the most flexible (least rigid) fusion, one would place a unilateral two pronged staple 700. One can increase i.e. calibrate increasing degrees of rigidity by increasing the number of

prongs penetrating the facet joints bilaterally. In Figure 11 C each facet joint is fused using a total number of six prongs. One side this is accomplished by using three two pronged staples 700, and on the other side using one four pronged staple 800 and one two pronged staple 700. These two embodiments can be mixed and matched unilaterally or bilaterally to vary the degree of rigidity and conversely flexibility of fusion. The most flexible fusion at one level would be accomplished by one staple 700 (2 prongs). The highest level of rigidity would be achieved by placing two four pronged staples 800 on both sides totaling sixteen prongs. Intermediate degrees of relative joint motion can be modulated by insertion into the cervical facet joints staples in two-four prong increments from 2-16. Each additional prong further limits the degree of facet joint motion hence increasing rigidity, and conversely decreasing flexibility. Thus the novel modular use of these embodiments heralds an era of flexible cervical spine fusion.

[0082] Figures 12 A - B illustrate a lumbar facet joint staple 1200 in open and closed positions and having staple prongs 1203. This lumbar facet staple has been thoroughly described in our previous co-pending patent applications, Serial No. 11/536,815, filed on September, 29, 2006, and Serial No. 11/208,644, filed on August 23, 2005, the relevant portion of each of which is hereby incorporated by reference hereinafter. The new improvement of this device includes a ratchet 1201. The staple 1200 can be incrementally closed with increased ratcheting over increasing number of spurs 1202. This achieves increasing calibrated levels of lumbar facet joint fusion, and conversely diminishing joint flexibility. This new designs further enhances the capacity to achieve flexible fusions in the lumbar

spine.

2. THE SURGICAL METHOD

[0083] Exemplary surgical steps for practicing one or more of the foregoing embodiments will now be described.

[0084] The posterior lumbar spine implantation of all the screw box 100, 200, 300 embodiments, with BDFT screws, and horizontal mini-plate 400 can be implanted 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. Fluoroscopic guidance can be used with any of these procedures.

[0085] After 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, a unilateral or bilateral facet sparing hemi-laminotomy is created to introduce screw box 100, 200, 300 embodiments I-III into the disc space, after it is adequately prepared.

[0086] 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.

[0087] Then one screw box 100, 200, 300 of either embodiments I-III is placed

on either right, left or both sides. Then another screw box of embodiments 100, 200, 300 I-III is placed on the contralateral side. For embodiment I the external screw guide 505/ box expander is attached to the screw box (Figures 5A-H). First the Allen key 501 is screwed until the box conforms perfectly to the height and depth of the space. Then a pilot hole can be drilled or an awl can start a pilot hole in the vertebral bodies. Then a transvertebral screw is screwed into the vertebral body via the built-in box screw guides 505. For difficult angles, an angled screw driver can be employed.

[0088] For embodiments II-III the same method is used for placing screws, except the Allen key 501 is not utilized in the absence of plate expansion.

[0089] If bilateral constructs have been inserted, bone is packed into the intervertebral space, as well as within the device. Then the horizontal intervertebral zero profile mini-plate 400 is slid beneath the thecal sac and is secured to both left and right screw boxes with small mini-plate screws 210 (Figures 4A-B). This prevents bone intrusion into the thecal sac and hence possible nerve root compression.

[0090] Figures 6A and B illustrate the process of insertion and final placement of the construct into the lumbar spine. The mini- plates 400 can come in different horizontal lengths and widths to accommodate different intra and inter -patient disc space diameters. The BDFT screws can come in different widths, lengths and thread designs.

[0091] The anterior thoracic and lumbar spine implantation of one, two or three screw box constructs 100, 200, 300 and BDFT screws can be performed in a

similar manner to the posterior application. Likewise, a horizontal mini-plate 400 can be used to cap two or three screw box constructs 100, 200, 300 (one placed midline deeply, one placed left and one placed right, forming a triangulation). Alternatively two screw box constructs may be placed into a circumferential ring for anterior placement. Anterior placement of these devices can be performed into the L4/5 and L5/S1 spaces on the supine anesthetized patient via previously described open microscopic or endoscopic techniques. Once the disc space is exposed and discectomy and space preparation are performed, placement of one, two or three screw box embodiments 100, 200, 300 (I-III) or a 2 in I construct can be placed. The screw placement is facilitated by the internal screw guides, and different positioning tools ((Figure 5). A right angled screw driver and/or ratchet could alternatively be employed A capping mini-plate 400 may be applied if desirable. The mechanism of screw placement and mini-plate 400 attachment are identical to what was described above.

[0092] The posterior placement of screw box constructs 100, 200, 300 alone or combined with horizontal mini-plates 400 into the thoracic spine can be performed via previously described transpedicular approaches; open or endoscopic. The anterior placement into the thoracic spine can be accomplished via a trans-thoracic approach. Once the disc space is exposed via either approach, any combination of the above mention Embodiments (I-III) can be inserted. Engagement of the devices is identical to what was mentioned above.

[0093] For posterior placement of cervical facet staple 700, 800 embodiments, after adequate induction of anesthesia the patient is flipped prone and his head

and neck secured. A single midline or two para-median incisions are made for unilateral or bilateral or multilevel placement of staples. Ultimately the facet joint is exposed. Alternatively and preferably this can be performed percutaneously under fluoroscopic guidance with intravenous sedation. The staple 700, 800 (Embodiments I or II) is loaded into the impactor 900, 1000. The staple 700, 800 is placed on the two articulating cervical facets, and then impacted into the joint. To achieve modular calibrated fusion different combinations and permutations of cervical facet stales 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 staples 800 (16 prongs) leading to the highest degree of rigidity. Additional bone may or may not be placed in its vicinity to facilitate permanent and solid fusion. This procedure can be performed open, closed, percutaneously, tubulary, endoscopically or microscopically. Figures 11 A-C illustrates placement of the staples 700, 800 in the cervical spine.

[0094] We have previously described surgical placement of the lumbar facet joint staple in our two co-pending patents. The surgical procedure for this device is identical to that which has been previously mentioned.

[0095] The present inventions may provide effective and safe techniques that overcome the problems associated with current transpedicular based cervical, thoracic and lumbar fusion technology, and for many degenerative stable and unstable spine disease. These inventions could replace much pedicle screw-based instrumentation in many but not all degenerative spine conditions.

[0096] The speed and simplicity of placement of cervical and lumbar facet

staples, and placement of Lumbar screw box –BDFT constructs far exceeds that of current pedicle screw technology. Furthermore, these devices have markedly significantly decreased risk of misguided screw placement, and hence decreased risk of neural and vascular injury, and blood loss. In the lumbar spine BDFT screw constructs and facet staples could be applied modularly in different combinations to achieve different degrees of rigidity (flexibility). Patients having these devices would have decreased recovery and back to work time. These devices most likely lead to similar if not equal fusion with significantly less morbidity, and hence overall make them a major advance in the evolution of spinal instrumented technology leading to advances in the care of the spinal patient.

[0097] Another major novelty and advance is the introduction of simple and safe modular calibrated cervical flexible fusion. To our knowledge neither a similar device nor a similar mathematical concept of modular joint flexibility/fusion calibration has been postulated for the cervical spine or for any other articulating joint.

[0098] To our knowledge there have not been any previously described similar posterior lumbar and thoracic combined spacer and screw constructs. These devices can similarly be modified to stabilize bone fractures throughout the entire body. To our knowledge the description of zero to subzero profile anterior or posterior horizontal spinal plates which traverse the diameter of the disc space has not been previously described.

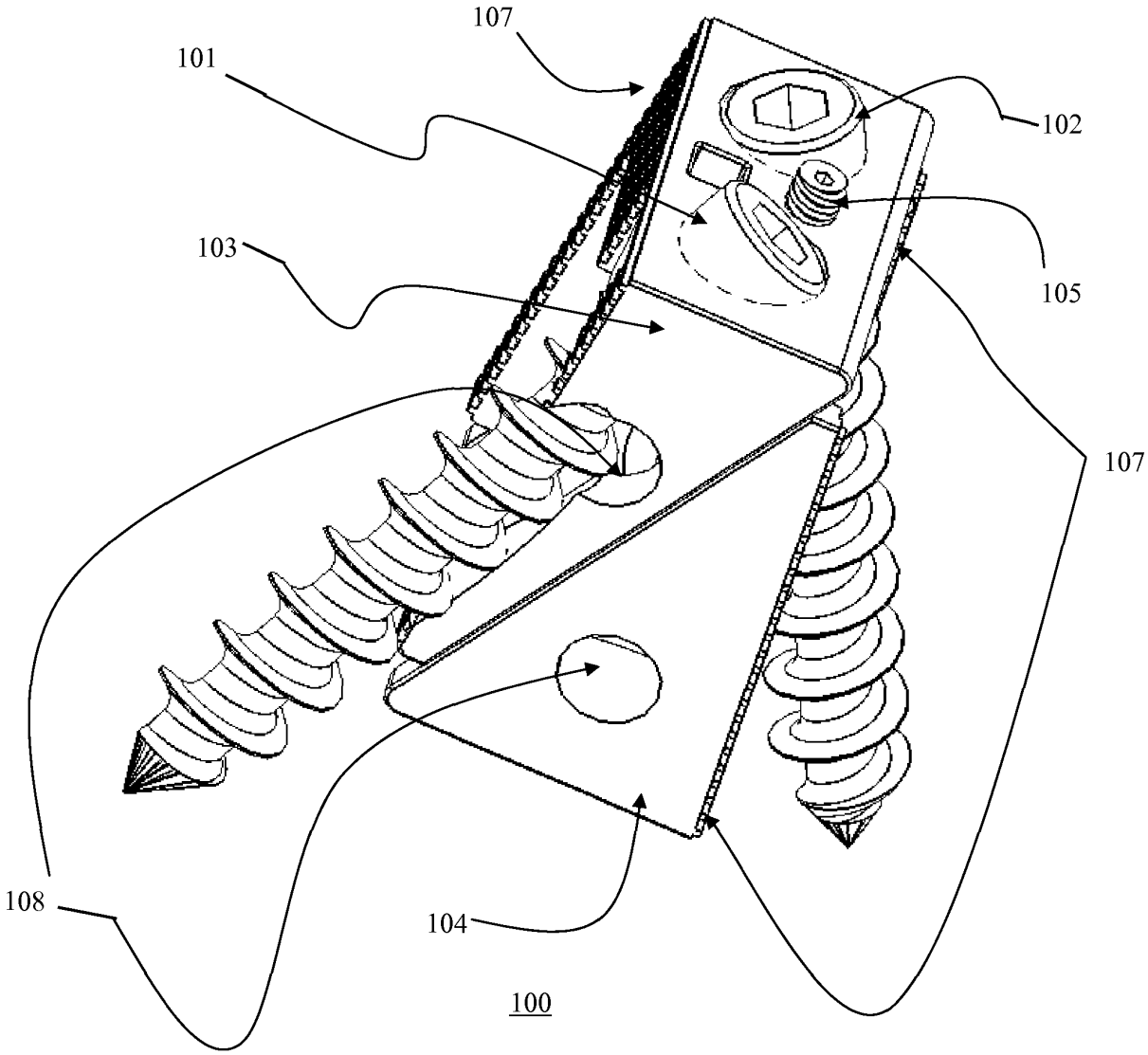


Fig. 1A

Electronic Acknowledgement Receipt

EFS ID:	37217071
Application Number:	16280684
International Application Number:	
Confirmation Number:	1247
Title of Invention:	SYSTEM WITH TOOL ASSEMBLY AND EXPANDABLE SPINAL IMPLANT
First Named Inventor/Applicant Name:	Ahmnon D. Moskowitz
Customer Number:	26191
Filer:	Stuart A. Nelson/Abby Remer
Filer Authorized By:	Stuart A. Nelson
Attorney Docket Number:	46440-0009015
Receipt Date:	19-SEP-2019
Filing Date:	20-FEB-2019
Time Stamp:	16:10:46
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	Miscellaneous Incoming Letter	Response.pdf	61889 dca9891da06d7983c05f6496d09d8d4591e4c848	no	1

Warnings:

Information:					
2	Specification	SubSpec.pdf	206509 a27eb38e7295fb538934b9b66dcb55a0d55eb094	no	27
Warnings:					
Information:					
3	Specification	MarkedUpSpec.pdf	206184 344cb6f73adb416ef33fabf8cdab0701efadf476	no	27
Warnings:					
Information:					
4	Drawings-only black and white line drawings	ReplacementFigure.pdf	1189852 ca63d4c6682758c56b9818f2d62d2ffbc68bf2c2	no	1
Warnings:					
Information:					
		Total Files Size (in bytes):	1664434		

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.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/280,684	02/20/2019	Ahmnon D. Moskowitz	46440-0009015	1247

26191 7590 09/19/2019
FISH & RICHARDSON P.C. (TC)
PO BOX 1022
MINNEAPOLIS, MN 55440-1022

EXAMINER	
PHILOGENE, PEDRO	

ART UNIT	PAPER NUMBER
3773	

NOTIFICATION DATE	DELIVERY MODE
09/19/2019	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

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Application No. : 16280684
Applicant : Moskowitz
Filing Date : 02/20/2019
Date Mailed : 09/19/2019

NOTICE TO FILE CORRECTED APPLICATION PAPERS

Notice of Allowance Mailed

This application has been accorded an Allowance Date and is being prepared for issuance. The application, however, is incomplete for the reasons below.

Applicant is given two (2) months from the mail date of this Notice within which to respond. This time period for reply is extendable under 37 CFR 1.136(a) for only TWO additional MONTHS.

The informalities requiring correction are indicated in the attachment(s). If the informality pertains to the abstract, specification (including claims) or drawings, the informality must be corrected with an amendment in compliance with 37 CFR 1.121 (or, if the application is a reissue application, 37 CFR 1.173). Such an amendment may be filed after payment of the issue fee if limited to correction of informalities noted herein. See Waiver of 37 CFR 1.312 for Documents Required by the Office of Patent Publication, 1280 Off. Gaz. Patent Office 918 (March 23, 2004). In addition, if the informality is not corrected until after payment of the issue fee, for purposes of 35 U.S.C. 154(b)(1)(iv), "all outstanding requirements" will be considered to have been satisfied when the informality has been corrected. A failure to respond within the above-identified time period will result in the application being ABANDONED.

See attachment(s).

A copy of this notice MUST be returned with the reply. Please address response to "Mail Stop Issue Fee, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450".

/Ashley Gerstlauer/
Publication Branch
Office of Data Management
(571) 272-4200

Application No. 16280684 **Drawings filed: 02/20/2019**

IDENTIFICATION OF DRAWING DEFICIENCIES

- [ ] There is a hole or the image thereof within the illustration. FIG(s)
- [ ] The illustration is penetrated or traversed by a solid or broken line that is not intended to be part of the drawing, such as a dark line caused by a flaw in the copying process. FIG(s)
- [ ] An ink stamp or the image thereof obscures part of the illustration. FIG(s)
- [ ] The drawing is marred by black smudges, obliterations, or fax/copier marks (for example, speckles or dots in a substantial portion of the drawing). FIG(s)
- [ ] Figure numbers are duplicated or missing. FIG(s)
- [ ] Drawing sheet or figure is missing. FIG(s)
- [ ] Numbers, letters, or reference characters in the drawing have been crossed out or are illegibly handwritten. FIG(s)
- [ ] The character of the lines, numbers, and letters is poor. FIG(s)
- [ ] The drawing's background shows that the original drawing was made on graph paper or other paper with a pattern or decoration. FIG(s)
- [ ] The FIG. number label is placed in a location that causes the drawing to be read upside down. FIG(s)
- [X] Data, a reference number, or part of the drawing is truncated or missing, or a lead line has no reference number. FIG(s) 1A
- [ ] The drawing and/or the FIG. label contain(s) foreign language. FIG(s)
- [ ] This utility application contains a photograph of a view that is capable of being illustrated as a line drawing. FIG(s)
- [ ] A petition under 37 CFR 1.84(a)(2) to accept color drawings has been granted, but the brief description of the drawings in the specification does not contain (or has not been amended to contain) the paragraph required by 37 CFR 1.84(a)(2)(iii).
- [ ] This reissue application contains added and/or amended drawings that are not labeled as “New” or “Amended” or “Canceled” as required by 37 CFR 1.173(b)(3). FIG(s)
- [ ] This Design reissue application contains a drawing that is labeled as “Canceled” but is not surrounded by brackets, or a drawing that is surrounded by brackets but is not labeled as “Canceled.” See 37 CFR 1.173(b)(3). FIG(s)
- [ ] OTHER:
- [ ] COMMENTS:

Application No. 16280684

IDENTIFICATION OF SPECIFICATION/DRAWING INCONSISTENCIES

☐ On Page of the specification there is a brief description of FIG. , but the drawings filed do not include a drawing with that designation. Applicant must respond either by supplying the omitted drawing or by amending the specification to remove all references to that drawing.

☒ The drawings filed 02/20/2019 include FIG. 5E-G, but the specification's brief description of the drawings does not describe a drawing with that designation. Applicant must respond either by amending the specification to add a brief description of that drawing or by correcting the drawings to remove the drawing in question.

☐ In the utility application, drawings are present in the application and are referred to in the detailed description of the invention, but the specification does not contain a brief description of the several views as required by 37 CFR 1.74 and 37 CFR 1.77(b)(9).

☐ The design application does not contain a description of the figure or figures of the drawing as required by 37 CFR 1.153(a) and 37 CFR 1.154(b)(4).

☐ In the plant application, the specification does not contain a brief description of the drawing as required by 37 CFR 1.163(c)(8).

☐ Page of the specification refers to FIG. , but no drawing with that designation is described in the brief description of the drawings and no drawing with that designation is present in the application. Applicant must respond either by amending the specification to remove all references to that drawing, or by supplying that drawing and amending the specification to add a brief description of it.

☐ In the reissue application, FIG. , is labeled as "New" but is not described in the reissue specification's brief description of the drawings. Applicant must respond by amending the reissue specification's brief description of the drawings to add a brief description of the new drawing.

☐ OTHER:

☐ COMMENTS:

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/280,684	02/20/2019	Ahmnon D. Moskowitz	46440-0009015	1247

26191 7590 09/25/2019
FISH & RICHARDSON P.C. (TC)
PO BOX 1022
MINNEAPOLIS, MN 55440-1022

EXAMINER	
PHILOGENE, PEDRO	

ART UNIT	PAPER NUMBER
3773	

NOTIFICATION DATE	DELIVERY MODE
09/25/2019	ELECTRONIC

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PATDOCTC@fr.com

Response to Rule 312 Communication	Application No. 16/280,684	Applicant(s)
	Examiner	Art Unit

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

1. ☒ The amendment filed on *19 September 2019* under 37 CFR 1.312 has been considered, and has been:

a) ☒ entered.

b) ☐ entered as directed to matters of form not affecting the scope of the invention.

c) ☐ disapproved because the amendment was filed after the payment of the issue fee.
Any amendment filed after the date the issue fee is paid must be accompanied by a petition under 37 CFR 1.313(c)(1) and the required fee to withdraw the application from issue.

d) ☐ disapproved. See explanation below.

e) ☐ entered in part. See explanation below.

Kimberly Payne

PUBLISHING DIVISION

Substitute Disclosure Form	U.S. Department of Commerce Patent and Trademark Office	Attorney Docket No. 46440-0009015	Application No. To Be Assigned
Information Disclosure Statement by Applicant (Use several sheets if necessary) (37 CFR §1.98(b))		Applicant Moskowitz Family LLC	
		Filing Date Herewith	Group Art Unit Unknown

U.S. Patent Documents

Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	131.	20130060339	3/7/2013	Duffield et al.			
	132.	20040193272	9/30/2004	Zubok et al.			
	133.	20090187218	7/23/2009	Schaffhausen et al.			
	134.	8728165	5/20/2014	Parry et al.			
	135.	20130073044	3/21/2013	Gamache			
	136.	8790405	7/29/2014	BIEDERMANN et al.			
	137.	8268000	9/18/2012	Waugh et al.			
	138.	7985255	7/26/2011	Bray et al.			
	139.	6962606	11/8/2005	Dove et al.			
	140.	6235034	5/22/2001	Bray			
	141.	6224602	5/1/2001	Hayes			
	142.	6890355	5/10/2005	Michelson			
	143.	6322562	11/27/2001	Wolter			
	144.	20080281424	11/13/2008	Parry et al.			
	145.	6454807	9/24/2002	Jackson			
	146.	6716247	4/6/2004	Michelson			
	147.	20040186569	9/23/2004	Berry			
	148.	7776047	8/17/2010	Fanger et al.			
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	150.	7758617	~~Jul-10~~ 7-2010	Lott et al.			
	151.	8328851	~~Dec-12~~ 12-2012	Curran			
	152.	8882813	11/11/2014	Jones et al.			
	153.	20050256576	11/17/2005	Moskowitz et al.			
	154.	20050261769	11/24/2005	Moskowitz et al.			
	155.	20070198089	8/23/2007	Moskowitz et al.			
	156.	20110288646	11/24/2011	Moskowitz et al.			

Change(s) applied to document, /H.J.L./ 9/4/2019

Examiner Signature	Date Considered
/PEDRO PHILOGENE/	07/11/2019

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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Substitute Disclosure Form	U.S. Department of Commerce Patent and Trademark Office	Attorney Docket No. 46440-0009015	Application No. To Be Assigned
Information Disclosure Statement by Applicant (Use several sheets if necessary)		Applicant Moskowitz Family LLC	
(37 CFR §1.98(b))		Filing Date Herewith	Group Art Unit Unknown

U.S. Patent Documents

Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	79.	20050273170	12/8/2005	Navarro et al.			
	80.	20040177531	9/16/2004	DiBenedetto et al.			
	81.	20050278026	12/15/2005	Gordon, et al.			
	82.	20050216084	9/29/2005	Fleischmann			
	83.	20050027362	2/3/2005	Williams et al.			
	84.	20050049590	3/3/2005	Alleyne et al.			
	85.	20040254644	12/16/2004	Taylor			
	86.	20020143338	10/3/2002	Orbay et al.			
	87.	20050177235	8/11/2005	Baynham et al.			
	88.	20020068977	6/6/2002	Jackson			
	89.	20070213820	9/13/2007	Magerl et al			
	90.	20100145460	6/10/2010	McDonough et al.			
	91.	20090105831	4/23/2009	Jones et al.			
	92.	20100305704	12/2/2010	Messerli et al.			
	93.	8,353,913	~~Jan-13~~ 1-2013	Moskowitz et al.			
	94.	8,029,512	~~Oct-11~~ 10-2011	Paltzer			
	95.	7776093	~~Aug-10~~ 8-2010	Wolek			
	96.	7628816	~~Dec-09~~ 12-2009	Mageri et al.			
	97.	8425607	~~Apr-13~~ 4-2013	Waugh et al.			
	98.	6974480	12/13/2005	Messerli et al.			
	99.	8105367	1/31/2012	Austin et al.			
	100.	8273127	9/25/2012	Jones et al.			
	101.	7135043	11/14/2006	Nakahara et al.			
	102.	2360942	10/24/1944	Ellerstein et al.			
	103.	7704279	4/27/2010	Moskowitz et al.			
	104.	7803162	9/28/2010	Marnay et al.			

Change (s) applied to document, /H.J.L/ 9/4/2019

Examiner Signature	Date Considered
/PEDRO PHILOGENE/	07/11/2019

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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APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/280,684	11/19/2019	10478319	46440-0009015	1247

26191 7590 10/30/2019

FISH & RICHARDSON P.C. (TC)
PO BOX 1022
MINNEAPOLIS, MN 55440-1022

ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment is 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;
Moskowitz Family LLC, Rockville, MD;
Pablo A. Valdivia Y. Alvarado, Cambridge, MA;
Mosheh T. Moskowitz, Rockville, MD;
Nathan C. Moskowitz, Rockville, MD;

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IR103 (Rev. 10/09)

AO 120 (Rev. 08/10)

TO:	REPORT ON THE FILING OR DETERMINATION OF AN ACTION REGARDING A PATENT OR TRADEMARK
Mail Stop 8 Director of the U.S. Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450	

In Compliance with 35 U.S.C. § 290 and/or 15 U.S.C. § 1116 you are hereby advised that a court action has been filed in the U.S: District Court Western District of Texas - Waco Division on the following

☐ Trademarks or ☑ Patents. (☐ the patent action involves 35 U.S.C. § 292.):

DOCKET NO.	DATE FILED	U.S. DISTRICT COURT
6:19-cv-672	11/20/2019	Western District of Texas - Waco Division

PLAINTIFF	DEFENDANT
MOSKOWITZ FAMILY LLC	GLOBUS MEDICAL, INC.

	PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1	SEE ATTACHED		
2	8,353,913		
3	9,889,022		
4	10,028,740		
5	10,076,367		

In the above—entitled case, the following patent(s)/ trademark(s) have been included:

DATE INCLUDED	INCLUDED BY ☐ Amendment ☐ Answer ☐ Cross Bill ☐ Other Pleading	
PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1 10,307,268		
2 10,251,643		
3 10,376,386		
4 10,478,319		
5		

In the above—entitled case, the following decision has been rendered or judgement issued:

DECISION/JUDGEMENT

CLERK	(BY) DEPUTY CLERK	DATE
Jeannette J. Clack		11/21/2019

Copy 1—Upon initiation of action, mail this copy to Director Copy 3—Upon termination of action, mail this copy to Director
Copy 2—Upon filing document adding patent(s), mail this copy to Director Copy 4—Case file copy

Trials@uspto.gov
571-272-7822

Paper 7
Entered: January 8, 2021

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

GLOBUS MEDICAL, INC.,
Petitioner,

v.

MOSKOWITZ FAMILY LLC,
Patent Owner.

IPR2020-01305
Patent 10,478,319 B2

Before MEREDITH C. PETRAVICK, NEIL T. POWELL, and JAMES J. MAYBERRY, *Administrative Patent Judges.*

MAYBERRY, *Administrative Patent Judge.*

DECISION
Denying Institution of *Inter Partes* Review
35 U.S.C. § 314

I. INTRODUCTION

A. Background and Summary

Globus Medical, Inc. ("Petitioner") filed a Petition ("Pet.") requesting *inter partes* review of claims 1–5, 7–9, 11, 12, 14, 15, and 18–21 (the "Challenged Claims") of U.S. Patent No. 10,478,319 B2 (Ex. 1001, "the

'319 patent"). Paper 1. Moskowitz Family LLC ("Patent Owner") filed a Preliminary Response ("Prelim. Resp.") to the Petition. Paper 6.

We have authority under 35 U.S.C. § 314 to determine whether to institute review. *See also* 37 C.F.R. § 42.4(a) (permitting the Board to institute trial on behalf of the Director). To institute an *inter partes* review, we must determine that the information presented in the Petition shows "a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a). For the reasons set forth below, upon considering the Petition, Preliminary Response, and evidence of record, we deny the Petition and do not institute an *inter partes* review.

B. Real Parties in Interest

Petitioner identifies itself as the real party-in-interest. Pet. 1. Petitioner states that "[n]o other party had access to the Petition, and no other party had any control over, or contributed to any funding of, the preparation or filing of the Petition." *Id.* at 1–2. Patent Owner identifies itself as the sole real party-in-interest. Paper 4, 2.

C. Related Matters

The parties identify *Moskowitz Family LLC v. Globus Medical Inc.*, Case No. 2:20-cv-03271 (E.D. Pa.), as a matter related to the '319 patent. Pet. 2; Paper 4, 2 ("Pending Litigation"). This case was transferred from the District Court for the Western District of Texas on July 6, 2020. *Id.*

Petitioner indicates that it filed *inter partes* review proceedings challenging five other patents asserted in the Pending Litigation. Pet. 2–3 (identifying U.S. Pat. Nos. 8,353,913; 9,889,022; 10,028,740; 10,251,643; and 10,307,268). Petitioner states that it filed, concurrent with the present Petition, a second petition challenging the same Challenged Claims of the

'319 patent. *Id.* at 3; *see* Paper 4, 2 (identifying IPR2020-01306 as the second proceeding).[1]

D. The '319 Patent

The '319 patent, titled "System with Tool Assembly and Expandable Spinal Implant," issued November 19, 2019, from an application filed February 20, 2019. Ex. 1001, codes (54), (45), (22). The '319 patent's earliest priority claim is to a provisional application (U.S. provisional no. 60/670,231), filed April 12, 2005. *Id.* at 1:4–13.

The '319 patent "relates to . . . bi-directional fixating transvertebral (BDFT) screws which can be used as a stand-alone intervertebral device which combines the dual functions of an intervertebral spacer which can be filled with bone fusion material(s), as well as a transvertebral bone fusion screw apparatus." *Id.* at 1:18–25. We reproduce Figures 1B and 1D from the '319 patent, below.

[1] Petitioner ranks the current Petition as the first of the two petitions we should consider. Pet. 4.

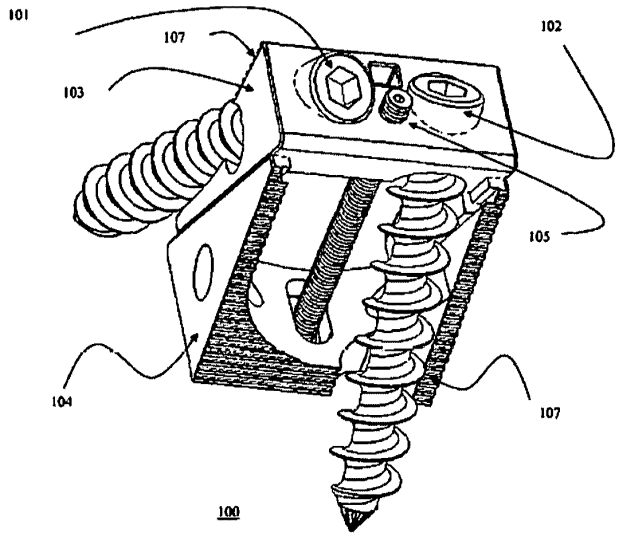


Fig. 1B

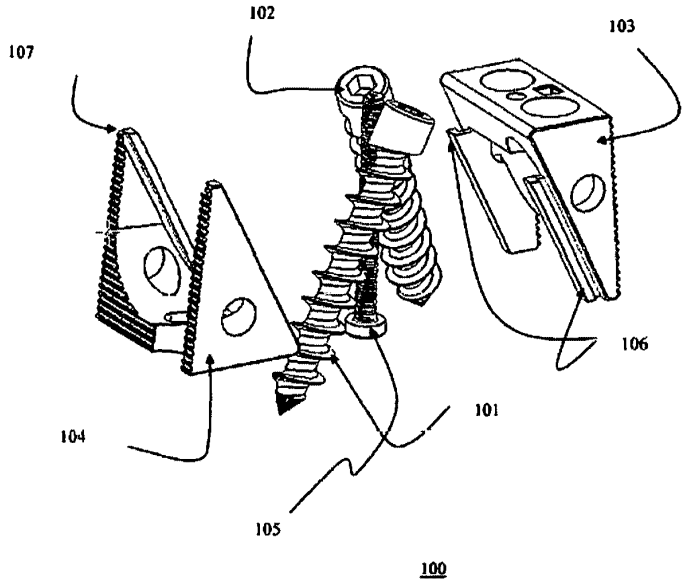


Fig. 1D

Figure 1B provides a superior perspective view of an expandable screw box and Figure 1D provides an exploded view of the same screw box. Ex. 1001,

6:31–35. Expandable box 100 includes two BDFT screws 101, 102, triangular sliding bases 103, 104, and adjustment screw 105. *Id.* at 7:42–53. The surfaces of triangular sliding bases 103, 104 that contact vertebral body surfaces include ridges 107 to facilitate fusion of the screw box with the vertebral bodies. *Id.* at 7:66–8:5. Triangular sliding bases 103, 104 are hollow and include holes to allow bone filling. *Id.* at 8:3–6.

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

Ex. 1001, 7:50–57.

We reproduce Figures 5A and 5C from the '319 patent, below.

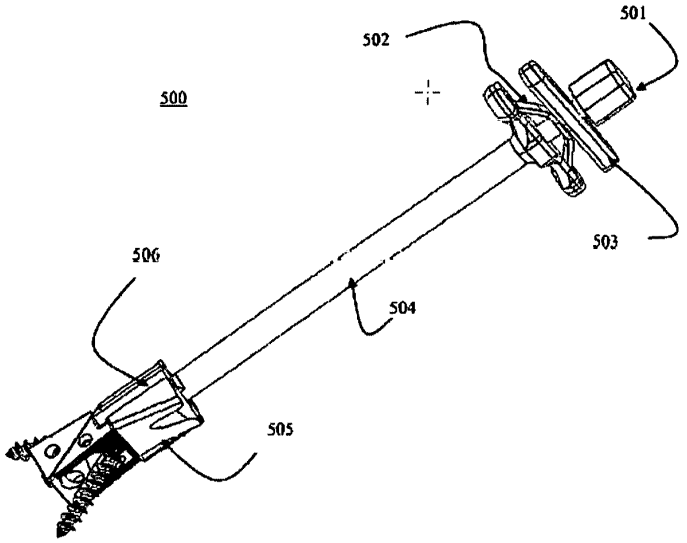


Fig. 5A

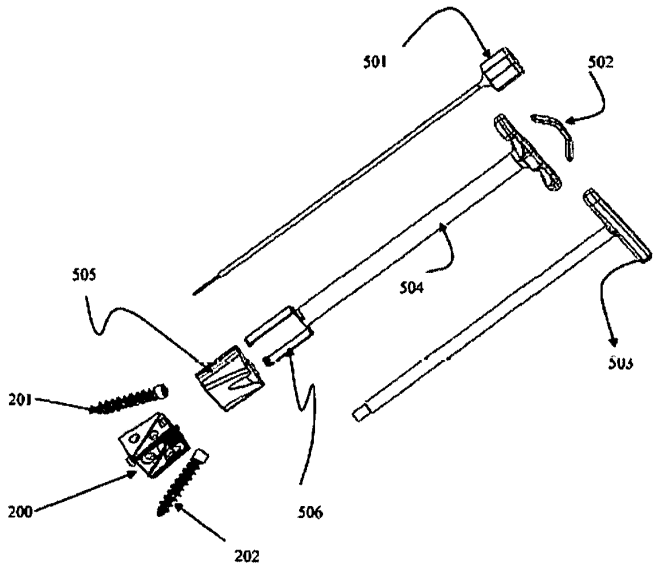


Fig. 5C

Figures 5A and 5C depict a positioning tool in oblique perspective and exploded views, respectively. Ex. 1001, 6:54–56. Tool 500 includes Allen key 501, handle 503, and gripper 504. *Id.* at 8:62–63. Gripper 504 includes a hollow passageway, into which Allen key 501 is inserted. *Id.* at 8:64–65.

Gripper 504 includes gripper prongs 506, which insert into grooves or indentations of a screw box to align Allen key 501 with the head of adjustment screw 105. Ex. 1001, 8:67–9:3. The surgeon uses the knob at one end of Allen key 501 to adjust the relative positioning of triangular sliding bases 103, 104 by turning adjustment screw 105. *Id.* at 8:64–67.

E. Illustrative Claims

Of the Challenged Claims, claims 1, 9, and 20 are independent. We reproduce claim 1, which is representative, below.

1. A system comprising:
a tool assembly which comprises:
a first tool having a first proximal end and a first distal end with a first handle and a gripper,

the gripper being positioned at the first distal end, cooperating with the first handle, and having first and second engagement prongs positioned at the first distal end,

wherein the first tool defines an adjusting tool passage through the first tool; and

a second adjusting tool having a second proximal end and a second distal end with a second handle positioned at the second proximal end, a screw engagement portion positioncd at the second distal end, and a shaft extending from the second handle to the screw engagement portion,

wherein the shaft of the second adjusting tool is sized with a smaller diameter than that of the adjusting tool passage such that the second adjusting tool can extend through the adjusting tool passage of the first tool; and

an expandable spinal implant sized and configured to be implanted in a human spine, the expandable spinal implant comprising a first expandable spinal implant structure, a second expandable spinal implant structure, and an adjusting screw having a screw head and a threaded portion,

wherein the expandable spinal implant is configured to expand the first expandable spinal implant structure with respect to the second expandable spinal implant structure in response to turning of the adjusting screw,

wherein the expandable spinal implant defines first and second tool engagement indentations sized and configured for receiving the first and second engagement prongs of the first tool,

wherein the adjusting screw is positioned within the expandable spinal implant in a screw location such that the second adjusting tool can extend through the adjusting tool passage of the first tool to engage the screw head of the adjusting screw while the first and second engagement prongs of the first tool are engaged with the first and second tool engagement indentations of the expandable spinal implant.

Ex. 1001, 12:64–13:36.

F. Prior Art and Asserted Grounds

Petitioner asserts that the Challenged Claims are unpatentable based on two grounds:

Claims Challenged	35 U.S.C. §	References/Basis
1–4, 7–9, 11, 12, 14, 15, 18–20	103(a)	Allen,[2] Baynham,[3] McLuen[4]
5, 21[5]	103(a)	Allen, Baynham, McLuen, Sutcliffe[6]

Petitioner relies on declaration testimony of Dr. Jorge A. Ochoa (Ex. 1003) in support of these grounds.

The following subsections provide a brief description of the asserted prior art references.

1. Allen

Allen, titled "Spinal Fixator," issued August 19, 1997. Ex. 1031, codes (54), (45). Allen is directed to "a contoured, adjustable spinal fixator for insertion between damaged or resected vertebrae." *Id.* at 1:6–7. We reproduce Allen's Figure 12, below.

[2] Allen, US 5,658,335, issued August 19, 1997 (Ex. 1031, "Allen").
[3] Baynham et al., US 2007/0270968 A1, published November 22, 2007 (Ex. 1029, "Baynham").
[4] McLuen, US 2006/0253201 A1, published November 9, 2006 (Ex. 1030, "McLuen").
[5] Petitioner includes claim 21 in its listing for and analysis of Ground 1. *See* Pet. 6, 65–67. Petitioner, however, relies on teachings from Sutcliffe in contending that claim 21 would have been obvious over the prior art. *See id.* at 66–67. So, we include claim 21 in Ground 2.
[6] Sutcliffe, US 2002/0143399 A1, published October 3, 2002 (Ex. 1032, "Sutcliffe").

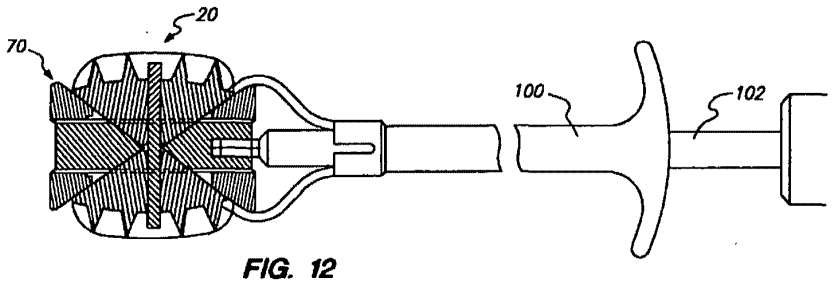


FIG. 12

Figure 12 depicts a "sectional view of [Allen's] spinal fixator . . . shown with [an] insertion tool." *Id.* at 3:48–50. Relevant to our Decision, hollow insertion tool 100 is used to insert spinal fixator 20 between two vertebrae. *Id.* at 5:18–20. As seen in Figure 12, two prongs on tool 100 grasp nut assembly 70. *Id.*; *id.* at Fig. 12. Tool 102, which ends in a hex configuration, is inserted through the hollow interior of tool 100 to engage aperture 60 (which is used to expand spinal fixator 20). *Id.* at 5:21–26.

2. Baynham

Baynham, titled "PLIF Opposing Wedge Ramp," published November 22, 2007. Ex. 1029, codes (54), (43). Baynham is directed to "implants . . . placed between vertebrae in the spine." *Id.* ¶ 3. We reproduce Baynham's Figure 1 below.

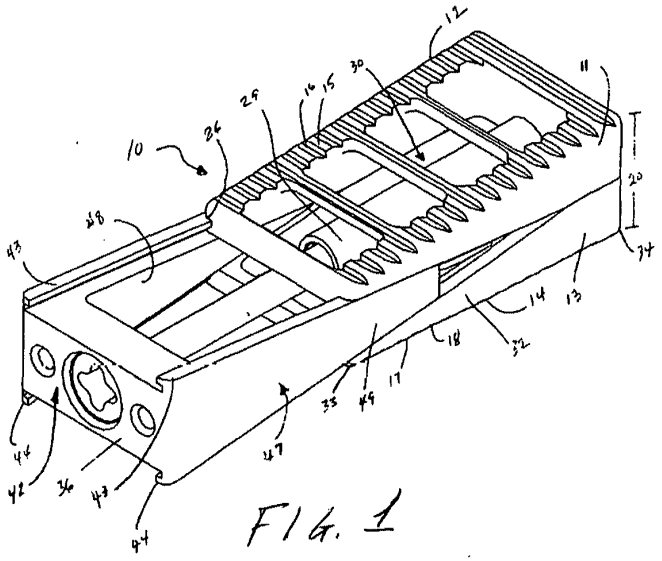


FIG. 1

Figure 1 depicts "a perspective of the spinal fusion implant of [Baynham's] invention." *Id.* ¶ 16. Spinal fusion device 10 includes upper section 11, with top surface 12, and lower section 13, with bottom surface 14. *Id.* ¶ 22. Top surface 12 and bottom surface 14 include lands and grooves 15, 16, 17, 18 forming a roughened surface to contact the end plates of vertebrae. *Id.*

Ramp or distractor 42 inserts between upper section 11 and lower section 13. Ex. 1029 ¶ 28. Distractor 42 includes a slot and rail configuration on which upper section 11 and lower section 13 move relative to distractor 42. *Id.* "[J]ack screw 67 is inserted through bore 61 engaging the threads in the tube 27. As the jack screw 67 is tightened, the ramp is drawn toward the leading end of the implant and the leading ends of the upper and lower sections slide apart along flanges 65 and 66." *Id.* at ¶ 29.

3. McLuen

McLuen, titled "Bone Fusion Device," published November 9, 2006. Ex. 1030, codes (54), (43). McLuen is directed to "bone fusion devices . . . for fusing vertebrae of the spine." *Id.* ¶ 2. We reproduce McLuen's Figure 16, below.

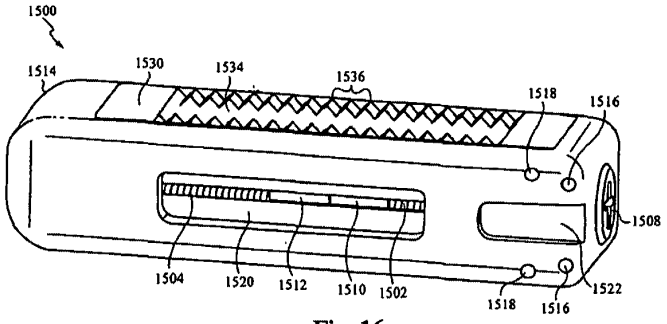


Fig. 16

Figure 16 depicts "a side perspective view of the bone fusion device in the preferred embodiment of" McLuen's invention. *Id.* ¶ 32. Relevant to this Decision, bone fusion device 1500 is expanded by using a screwdriver to turn positioning means 1508. *Id.* ¶ 76. McLuen provides that "[s]crew drivers unfortunately have the ability to slip out of place. When performing surgery near someone's spine, it is preferable to prevent or at least minimize the slipping ability." *Id.* Bone fusion device 1500 includes channels 1522 on each side of the device to receive a tool, which has attachments that fit within channels 1522. *Id.* In this way, the tool is secured to bone fusion device 1500 to prevent a screwdriver from slipping and injuring the patient when interfacing positioning means 1508. *Id.* at ¶ 78.

4. Sutcliffe

Sutcliffe, titled "Anchorable Vertebral Implant," published October 3, 2002. Ex. 1032, codes (54), (43). Sutcliffe is directed to "an implant used to replace . . . [a] vertebrae and/or intervertebral disk." *Id.* ¶ 2. We reproduce Sutcliffe's Figure 6, below.

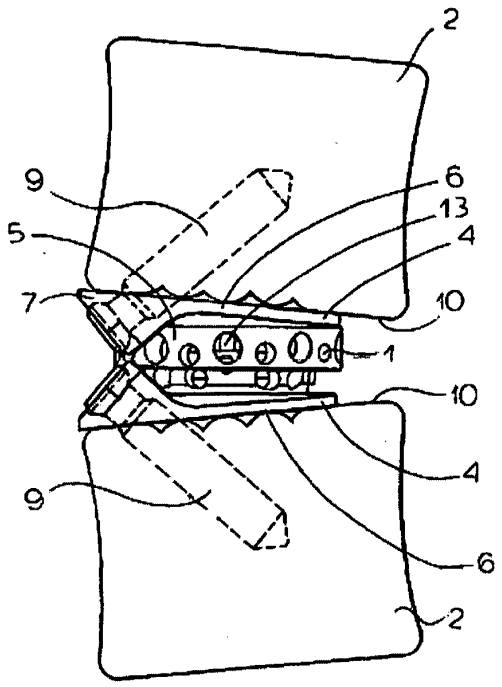


FIG.6

Figure 6 depicts an implant. *Id.* ¶ 21. Relevant to this Decision, Sutcliffe's implant includes through holes 13, "so that an interior [volume of the implant] can be packed with bone chips and so that bone growth through the implant 1 is possible." *Id.* ¶ 23. Also, Figure 6 illustrates cortical screws 9 extending through angled guides. *Id.* Fig. 6.

II. UNPATENTABILITY

A. Applicable Law

Petitioner's asserted grounds of unpatentability are based on obviousness under 35 U.S.C. § 103.

> Section 103(a) forbids issuance of a patent when "the differences between the subject matter sought to be patented and the prior art

> are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains."

KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations, including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) when available, objective evidence, such as commercial success, long felt but unsolved needs, and failure of others.[7] *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

"[O]bviousness must be determined in light of *all the facts*, and . . . a given course of action often has simultaneous advantages and disadvantages, and this does not necessarily obviate motivation to combine" teachings from multiple references. *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1165 (Fed. Cir. 2006) (emphasis added); *see also PAR Pharm., Inc. v. TWI Pharms., Inc.*, 773 F.3d 1186, 1196 (Fed. Cir. 2014) ("The presence or absence of a motivation to combine references in an obviousness determination is a pure question of fact." (quoting *Alza Corp. v. Mylan Labs., Inc.*, 464 F.3d 1286, 1289 (Fed.Cir.2006))).

B. Level of Ordinary Skill in the Art

The level of skill in the art is "a prism or lens" through which we view the prior art and the claimed invention. *Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001). Petitioner contends that a person having ordinary skill in the art "of the '319 patent would have a Bachelor's or equivalent degree in Mechanical Engineering or a related discipline (e.g.

[7] The Patent Owner does not direct us to any objective evidence of non-obviousness in the current record.

biomechanics or biomedical engineering), and at least five years of experience." Pet. 14 (referencing Ex. 1003 ¶¶ 26–30, Ex. 1004). Petitioner adds that "[t]he experience would consist of a) designing, developing, evaluating and/or using prosthetic devices, b) anatomy, physiology and biology of soft and calcified tissues including bone healing and fusion, and c) biomechanical and functional loading of orthopedic implants." *Id.* Petitioner contends, as an alternative, a person having ordinary skill in the art "could have an advanced degree in the technical disciplines provided above, or a Doctor of Medicine, and at least two years of experience in the subject areas provided above." *Id.*

Patent Owner does not contest Petitioner's contentions nor does Patent Owner offer its own level of ordinary skill.

Based on the current record, we adopt Petitioner's level of ordinary skill for this Decision. We determine, on the current record, that the proposed level of ordinary skill is commensurate with the '319 patent and prior art of record.

C. Claim Construction

In *inter partes* reviews, we interpret a claim "using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. 282(b)." 37 C.F.R. § 42.100(b) (2020). Under this standard, we construe the claim "in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent." *Id.*

Petitioner contends "that the claim terms [of the Challenged Claims] require no express construction and that they should be given their ordinary and customary meaning." Pet. 13. Petitioner then asserts that "[t]his is true for all limitations, except" the term "first expandable spinal implant

structure" / "second expandable spinal implant structure." *Id.* at 13–14. Petitioner contends that this term "should be construed in accordance with the intrinsic evidence and Petitioner offered the same constructions in the Pending Litigation." *Id.* at 13.

Petitioner proposes that we construe the term "first expandable spinal implant structure" / "second expandable spinal implant structure" to mean "a [first/second] implant structure comprising the [first/second] vertebral body engagement surface." Pet. 14. Neither Petitioner nor Dr. Ochoa identifies any supporting intrinsic or extrinsic evidence for the proposed construction. *See id.* at 13–14; *see also* Ex. 1003 ¶ 12 (stating that "I have been advised by Counsel that . . .[Petitioner] has proposed the . . . construction" presented above).

Patent Owner argues that Petitioner fails to meet its claim construction burden. Prelim. Resp. 9. Patent Owner argues that the Consolidated Trial Practice Guide requires a petitioner that proposes an express construction for a claim term to identify the intrinsic and extrinsic evidence that supports the proposed construction. *Id.* (citing Consolidated Trial Practice Guide 44, available at https://www.uspto.gov/TrialPracticeGuideConsolidated (Nov. 2019)).

We determine that we need not expressly construe any term of the Challenged Claims to resolve the parties' dispute. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) ("[W]e need only construe terms 'that are in controversy, and only to the extent necessary to resolve the controversy.'" (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999))).

We are not persuaded by Petitioner's proposed construction, as Petitioner fails to provide any supporting evidence for the construction. *See*

Consolidated Trial Practice Guide 44 ("If a petitioner believes that a claim term requires an express construction, the petitioner must include a statement identifying a proposed construction of the particular term *and where the intrinsic and/or extrinsic evidence supports that meaning.*" (emphasis added)). Accordingly, we apply the plain and ordinary meaning to the terms "first expandable spinal implant structure" and "second expandable spinal implant structure."

In summary, no claim terms require express constructions, and we apply the plain and ordinary meaning to the terms of the Challenged Claims.

D. Ground 1: Claims 1–4, 7–9, 11, 12, 14, 15, and 18–20 as Obvious Over Allen, Baynham, and McLuen

Petitioner contends that the combination of Allen, Baynham, and McLuen renders claims 1–4, 7–9, 11, 12, 14, 15, and 18–20 obvious.[8]

1. Independent claim 1

For independent claim 1, we first analyze Petitioner's contentions as to how the combination of Allen, Baynham, and McLuen discloses the subject matter recited in claim 1. Then we turn to Petitioner's reasons for combining the teachings of these three references.

a) Subject matter of claim 1

(1) Tool assembly limitations

Claim 1 recites, in relevant part, a "tool assembly" that comprises "a first tool" and "a second adjusting tool." Ex. 1001, 12:64–13:15 (the "tool assembly" limitations of claim 1). Specifically, claim 1 recites

> a first tool having a first proximal end and a first distal end with a first handle and a gripper, the gripper being positioned at the

[8] Petitioner also includes claim 21 in Ground 1. Pet. 6. We consider it in Ground 2, as Petitioner relies on Sutcliffe for certain teachings directed to that claim. *See id.* at 66.

> first distal end, cooperating with the first handle, and having first and second engagement prongs positioned at the first distal end, wherein the first tool defines an adjusting tool passage through the first tool.

Id. at 12:66–13:5 (the "first tool" limitation of claim 1). Claim 1 also recites

> a second adjusting tool having a second proximal end and a second distal end with a second handle positioned at the second proximal end, a screw engagement portion positioned at the second distal end, and a shaft extending from the second handle to the screw engagement portion, wherein the shaft of the second adjusting tool is sized with a smaller diameter than that of the adjusting tool passage such that the second adjusting tool can extend through the adjusting tool passage of the first tool.

Id. at 13:6–15 (the "second adjusting tool" limitation of claim 1).

Petitioner contends that Allen discloses the "first tool" and "second adjusting tool" limitations of claim 1. Pet. 21–24 (referencing Ex. 1031, 5:19–47, Fig. 12; Ex. 1003 ¶¶ 61–64). We reproduce Allen's Figure 12, below.

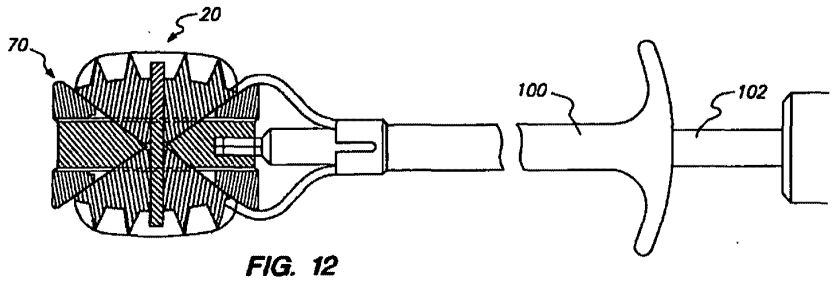


FIG. 12

Figure 12 depicts a "sectional view of [Allen's] spinal fixator . . . shown with [an] insertion tool." Ex. 1031, 3:48–50. Petitioner contends that insertion tool 100 corresponds to the first tool, which includes a handle at one end and a gripper having prongs at the other. Pet. 21. Petitioner contends that insertion tool 100 is hollow, defining the adjusting tool passage. *Id.* at 22; *see also* Ex. 1031, 5:18–20 ("A conventional, hollow

insertion tool 100 is used to gasp a nut assembly 70 to insert the retracted spinal fixator 20 between the two vertebrae bodies 4.").

Petitioner contends that tool 102 corresponds to the recited second adjusting tool, with a second handle at one end and a screw engagement portion at the other and a shaft extending between the handle and screw engagement portion. Pet. 22–23; *see also* Ex. 1031, 5:21–26 ("[T]ool 102 having a terminus defining a hex configuration is inserted through the insertion tool 100 to engage in aperture 60 in the core member 50. The tool 102 is used to rotate core member 50 to extend the crowns 90 outwardly . . . ."). Petitioner contends that tool 102 is sized to fit within the hollow passage of tool 100. Pet. 23–24; *see* Ex. 1031, 5:21–23.

We determine that Petitioner has made the requisite showing, at this stage of the proceeding, that Allen discloses the subject matter of the "tool assembly" limitations of claim 1. Patent Owner does not dispute these contentions at this time.

(2) First and second expandable spinal implant structures limitation

Claim 1 also recites "an expandable spinal implant sized and configured to be implanted in a human spine, the expandable spinal implant comprising a first expandable spinal implant structure, [and] a second expandable spinal implant structure." Ex. 1001, 13:16–19 (the "first and second expandable spinal implant structures" limitation of claim 1). Petitioner contends that Baynham teaches an expandable spinal implant satisfying the "first and second expandable spinal implant structures" limitation of claim 1. Pet. 24–25 (referencing Ex. 1029 ¶¶ 10, 22, 25, 26, 29, 30, Figs. 1–3; Ex. 1003 ¶ 67). Specifically, Petitioner contends that Baynam's device 10 includes upper section 11 (corresponding to the first

expandable spinal structure) and lower section 13 and distractor 42 (together corresponding to the second expandable spinal structure). *Id.* We reproduce Baynham's Figure 1 below.

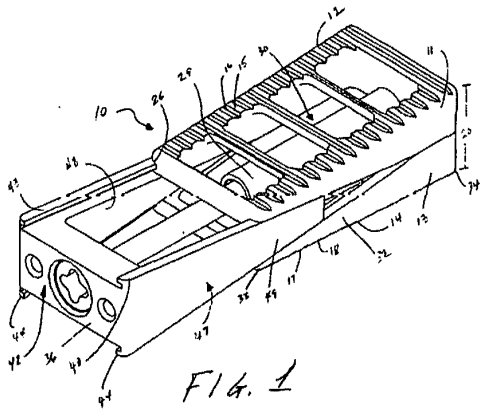


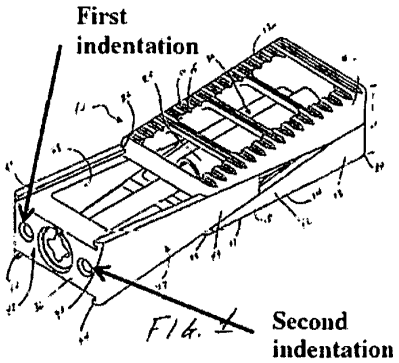
Figure 1 depicts "a perspective of the spinal fusion implant of [Baynham's] invention," showing upper section 11, lower section 13, and distractor 42. Ex. 1029 ¶¶ 16, 22, 23.

We determine that Petitioner has made the requisite showing, at this stage of the proceeding, that Baynham discloses the subject matter of the "first and second expandable spinal implant structures" limitation of claim 1. Patent Owner does not dispute these contentions directed to the subject matter of this limitation at this time.

(3) Tool engagement indentations limitation

Claim 1 also requires "the expandable spinal implant [to] define[] first and second tool engagement indentations sized and configured for receiving the first and second engagement prongs of the first tool." Ex. 1001, 13:25–28 (the "tool engagement indentations" limitation of claim 1). Petitioner contends that Baynham discloses an implant with first and second tool indentations. Pet. 26. Specifically, Petitioner contends that Bayhnam discloses holes in end wall 36 of distractor 42 positioned on either side of

countersink 63. *Id.* We reproduce Petitioner's annotated version of Baynham's Figure 1, below.



Pet. 27. This annotated figure identifies the structures Petitioner contends corresponds to the recited first and second tool engagement indentations. Petitioner acknowledges that Baynham does not expressly disclose the function of these structures, but contends that a person having ordinary skill in the art "would have understood that these indentations *could* function as tool engagement indentations." *Id.* (emphasis added) (referencing Ex. 1003 ¶ 69) (emphasis added).

Petitioner also contends that a person having ordinary skill in the art "would have understood that [Allen's tool] . . . *could* be used to insert and expand" Baynham's implant. Pet. 27 (emphasis added).

Petitioner contends that, to the extent that Allen's tool must interface with the outside surface of an implant, a person having ordinary skill in the art "would have understood that [Baynham's] implant *could* be modified as a matter of simple substitution to move the indentations from the end (36) to opposing side surfaces of the implant so that the first and second tool engagement indentations would be positioned at the proximal end of the implant." Pet. 27 (referencing Ex. 1003 ¶ 70). Petitioner restates its position as "placement and positioning of indentations for insertion tool

engagement at the proximal or trailing end of the implant is a predictable substitution that does not affect its function." *Id.*

Petitioner contends that McLuen discloses spinal implant 1500 having indentations 1522 on either side of the implant near an adjustment screw head. Pet. 27–28. We reproduce McLuen's Figure 16, below.

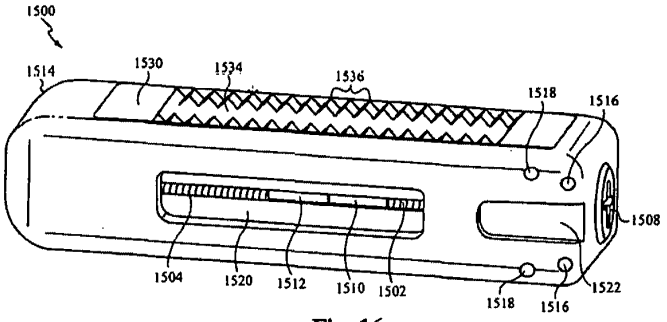


Fig. 16

Figure 16 depicts "a side perspective view of the bone fusion device in the preferred embodiment of" McLuen's invention. Ex. 1030 ¶ 32. Petitioner contends that McLuen teaches that, because of the risk of a screwdriver slipping when driving screw 1508 and injuring a patient, its implant includes channels 1522 on opposing sides of the implant to receive a tool. Pet. 28 (referencing Ex. 1030 ¶¶ 76, 77, Fig. 16; Ex. 1003 ¶ 71). Petitioner contends that:

> It would therefore have been obvious to a [person having ordinary skill in the art] to combine the teachings of Baynham with McLuen to substitute the indentations disclosed in Baynham for the indentations in McLuen, moving the indentations from either side of the countersink (63) to opposing sides at the proximal end of the implant to provide the disclosed advantage of prevention or minimization of screw driver slippage.

Id. Petitioner adds that "[t]his substitution would represent a design choice which would yield a predictable result with a reasonable expectation of success." *Id.* at 28–29 (referencing Ex. 1003 ¶ 72).

We understand Petitioner's position to be that it would have been obvious to modify Baynham's implant by including McLuen's indentations on the side of body 47 of distractor 42 rather than the indentations adjacent to countersink 63.

We determine that Petitioner has made the requisite showing, at this stage of the proceeding, that Baynham, as modified by McLuen, discloses the subject matter of the "tool engagement indentations" limitation of claim 1. Patent Owner does not dispute the contentions directed to the subject matter of this limitation at this time.

(4) Adjusting screw limitations

Claim 1 also recites "an adjusting screw having a screw head and a threaded portion." Ex. 1001, 13:20–21. Claim 1 requires "the expandable spinal implant [be] configured to expand the first expandable spinal implant structure with respect to the second expandable spinal implant structure in response to turning of the adjusting screw." *Id.* at 13:21–25. Claim 1 also requires

> the adjusting screw [be] positioned within the expandable spinal implant in a screw location such that the second adjusting tool can extend through the adjusting tool passage of the first tool to engage the screw head of the adjusting screw while the first and second engagement prongs of the first tool are engaged with the first and second tool engagement indentations of the expandable spinal implant.

Id. at 13:29–36 (the "adjusting screw" limitations of claim 1).

Petitioner contends that Baynham discloses the subject matter of the adjusting screw limitations of claim 1, identifying Baynham's jack screw 67. Pet 24, 25–26, 29–31 (referencing Ex. 1029 ¶¶ 28–30, Fig. 2; Ex. 1003 ¶¶ 67, 68, 73–75). Petitioner explains that "[t]he surgeon turns the jack screw (67) causing the upper and lower sections to move along the

complementary inclined plane to shorten the fusion device and increase the distance between the end plates of the adjacent vertebrae." *Id.* at 26. Petitioner adds that:

> Allen discloses the second adjusting tool (102) can extend through the adjusting tool passage of the first tool (100) to engage the screw head of the adjusting screw (67) while the first and second engagement prongs of the first tool (100) are engaged with the first and second tool engagement indentations of the expandable spinal implant. Allen discloses that following placement of the implant, the tool (102) having a terminus defining a hex configuration is inserted through the hollow insertion tool (100) to engage an adjusting screw.

Id. at 30 (referencing Ex. 1031, 5:19–28; Ex. 1003 ¶ 75).

We determine that Petitioner has made the requisite showing, at this stage of the proceeding, that Baynham, as modified by McLuen, discloses the subject matter of the "adjusting screw" limitations of claim 1. Patent Owner does not dispute the contentions directed to the subject matter of this limitation at this time.

b) Reasons to combine the teachings of Allen, Baynham, and McLuen

First, we address Petitioner's reasoning for combining the teachings of Allen's tool with Baynham's implant. Petitioner contends that a person having ordinary skill in the art would have understood that Allen's tool "is configured to interface with any number of expandable spinal implants" and that the tool "is of a typical design." Pet. 24. Petitioner concludes that Allen's tool "could be combined/used with the expandable spinal implant in Baynham or in McLuen." *Id.* (referencing Ex. 1003 ¶ 66). Petitioner adds that a person having ordinary skill in the art "would have understood that the inserter disclosed by Allen could be used to insert and expand" Baynham's implant.

Patent Owner argues that Petitioner's reasons to combine the teachings of Allen and Baynham rely on improper hindsight. Prelim. Resp. 12. Patent Owner argues that Petitioner's rationale amounts to nothing more than conclusory statements. *Id.* Patent Owner also argues that Petitioner's rationale fails to recognize that Allen already discloses an implant, so there would be no reason to modify Allen with Baynham's implant. *Id.* at 12–13.

Patent Owner also argues that Dr. Ochoa's testimony repeats, verbatim, the conclusory statements from the Petition and that Dr. Ochoa "fails to explain how or why a [person having ordinary skill in the art] would have 'understood' that Allen and Baynham could be combined." Prelim. Resp. 13–14. Patent Owner concludes that Petitioner's rationale to combine the teachings of Allen and Baynham, "at best, reduces to an assertion that the proposed combination ***could*** be made, without the requisite reasoning as to why a [person having ordinary skill in the art] ***would*** have been motivated to" make the proposed combination. *Id.* at 14.

We determine that Patent Owner's argument, at least in part, is persuasive of a deficiency in the Petition. As an initial point, we are not persuaded by the argument that Petitioner fails to recognize that Allen already has an implant. We understand Petitioner's position to be that a person having ordinary skill in the art would have employed Allen's tool to insert Baynham's implant (as modified by McLuen), given the typical nature of the tool. *See* Pet. 24. We do not read the Petition to propose using Baynham's insert because of some inadequacy with Allen's implant or otherwise as a substitute for Allen's implant.

We determine, however, that Petitioner fails to provide sufficient reasons, with rational underpinnings, to employ Allen's tool with Baynham's implant. As Patent Owner argues, Petitioner's bases its reasoning on the position that Allen's tool *could* be used for Baynham's implant, not that a person having ordinary skill in the art *would* have been motivated to use Allen's tool with Baynham's implant. *See* Prelim. Resp. 14; Pet. 24. Our reviewing court has stated that "obviousness concerns whether a skilled artisan not only *could have made* but *would have been motivated to make* the combinations or modifications of prior art to arrive at the claimed invention." *Belden Inc. v. Berk-Tek LLC*, 805 F.3d 1064, 1073 (Fed. Cir. 2015). The information in the Petition lacks such a rationale.

Even if we assume Petitioner's statements represent sufficient reasoning for combining Allen's tool with Baynham's implant, we determine that Petitioner fails to provide a rational underpinning of facts to support that reasoning. *See KSR Int'l Co.*, 550 U.S. at 418 (stating that, to facilitate the analysis of an obviousness position, the proponent should provide "some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness"). The only evidence Petitioner directs us to is testimony from Dr. Ochoa. *See* Pet. 24, 31. We determine, however, that this testimony is entitled to very little weight. Dr. Ochoa fails to provide any underlying support for the testimony. *See* Ex. 1003 ¶¶ 60–76 (providing analysis of claim 1 under Ground 1 and including numerous statements about what a person having ordinary skill would have known or understood without providing the basis for those statements). These unsupported statements are entitled to little or no weight. 37 C.F.R. 42.65(a)

("Expert testimony that does not disclose the underlying facts or data on which the opinion is based is entitled to little or no weight.").

We recognize that Petitioner characterizes Allen's tool as of a "typical design." Pet. 24. Petitioner also contends that tools such as Allen's "were in common use at the time" of the invention of claim 1 and that "[s]imilar devices were also used in arthroscopic and endoscopic surgery." *Id.* at 31 (referencing Ex. 1003 ¶ 76). Such general statements, without more, do not sufficiently support a finding that a person having ordinary skill in the art would have been motivated to employ Allen's tool with Baynham's implant. *See KSR Int'l Co.*, 550 U.S. at 418 ("[A] patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.").

We also recognize that Petitioner directs us to statements in McLuen that a surgeon would generally use a tool to insert a spinal implant. Pet. 28. McLuen discloses that:

> To secure the bone fusion device 1500 in place, a user generally utilizes an implement such as a screw driver to turn the positioning means 1508. Screw drivers unfortunately have the ability to slip out of place. When performing surgery near someone's spine, it is preferable to prevent or at least minimize the slipping ability. To do so, channels 1522 are implemented to receive a tool (not shown). The tool (not shown) has attachments that fit within the channels 1522 to secure the tool (not shown) in place.

Ex. 1030 ¶ 76. However, we do not read the Petition to rely on this teaching to support employing Allen's tool with Baynham's implant, but instead, the Petition relies on this teaching to support a modification directed to tool engagement indentations. *See* Pet. 27–29. Petitioner is the master of the Petition, and typically, the Board will not rely on a position not articulated in

a petition or otherwise fill gaps in a petition. *Cf. In re Magnum Oil Tools Int'l, Ltd.*, 829 F.3d 1364, 1381 (Fed. Cir. 2016) ("[T]he Board must base its decision on arguments that were advanced by a party, and to which the opposing party was given a chance to respond.").

Accordingly, Petitioner fails sufficiently to support its reasons to combine Allen's tool with Baynham's implant.

Now turning to reasons to modify Baynham with McLuen, we determine that the Petition suffers from the same problem as we discuss above. We acknowledge that McLuen expressly discloses the benefits of using a tool to prevent a screwdriver from slipping, as Petitioner contends. *See* Pet. 28. We determine, however, that, absent hindsight, Petitioner fails to provide sufficient reasoning as to why a person having ordinary skill in the art would have moved Baynham's indentations from end wall 36 to the sides of body 47 of distractor 42. For example, Petitioner fails to explain adequately why a tool (either a tool different from the one in Allen or a modified version of Allen's tool) could not have been used to interface the indentations on end wall 36, without having to modify Baynham's implant with McLuen's channels 1522.

Also, Petitioner's assertion that its proposed modification "represent[s] a design choice" fails to provide a sufficient reason, on the current record. Pet. 28–29. Petitioner does not adequately explain why the placement of Baynham's indentations on end wall 36 solves no stated problem or is not critical to implanting Baynham's device, such that moving the location is merely a matter of design choice. *See Ex Parte Spangler*, Appeal No. 2018-00300 (PTAB Feb. 20, 2019) (informative); *see also Polaris Indus., Inc. v. Arctic Cat, Inc.*, 882 F.3d 1056, 1069 n4. (Fed. Cir. 2018) ("The Board failed to consider that '[m]erely stating that a particular

placement of an element is a design choice does not make it obvious.' Instead, the [Petitioner] must explain why a person of ordinary skill in the art 'would have selected these components for combination in the manner claimed.'" (citations omitted); *cf. In re Kuhle,* 526 F.2d 553, 555 (CCPA 1975) ("Use of such a means of electrical connection in lieu of those used in the references solves *no stated problem* and would be an obvious matter of design choice within thc skill in the art." (emphasis added)). Said another way, we find no persuasive argument or credible supporting evidence to explain that the location of Baynham's indentations are not critical to how its device is implanted into the spine, such that their locations could be moved as a matter of design choice or why such a modification would have been motivated.

Finally, an underlying basis for Petitioner's position regarding modifying Baynham with McLuen's teachings of side indentations is that the two openings adjacent to countersink 63 on end wall 36 of Baynham's distractor 42 are tool indentations. *See* Pet. 26–27. Petitioner fails to provide any credible evidence that these openings are indeed tool indentations. *See id.*

c) Conclusion as to claim 1

For the reasons discussed above, we determine, on the current record, that Petitioner fails to provide the requisite reasoning, with rational underpinnings, for combining the teachings of Allen, Baynham, and McLuen. Accordingly, we determine that the information in the Petition does not demonstrate a reasonable likelihood that claim 1 is obvious over the combination of Allen, Baynham, and McLuen.

2. Independent claims 9 and 20

In contending that independent claims 9 and 20 are obvious over the combination of Allen, Baynham, and McLuen, Petitioner makes similar contentions, with respect to combining the teachings of Allen, Baynham, and McLuen, to the contentions we analyzed above for claim 1. *Compare* Pet. 41–46, 56–65 *with* Pet. 21–25. For the reasons discussed above in our analysis of claim 1, we determine, on the current record, that Petitioner fails to provide the requisite reasoning, with rational underpinnings, for combining the teachings of Allen, Baynham, and McLuen. Accordingly, we determine that the information in the Petition does not demonstrate a reasonable likelihood that claims 9 and 20 are obvious over the combination of Allen, Baynham, and McLuen.

3. Dependent claims 2–4, 7, 8, 11, 12, 14, 15, 18, and 19

We have reviewed Petitioner's contentions with respect to dependent claims 2–4, 7, 8, 11, 12, 14, 15, 18, and 19. *See* Pet. 31–41, 46–55. We discern nothing in the Petition directed to these claims that remedies the deficiencies we identify above with respect to independent claims 1 and 9, from which these claims depend. Accordingly, we determine that the information in the Petition does not demonstrate a reasonable likelihood that dependent claims 2–4, 7, 8, 11, 12, 14, 15, 18, and 19 are obvious over the combination of Allen, Baynham, and McLuen.

E. Ground 2: Claims 5 and 21 as Obvious Over Allen, Baynham, McLuen, and Sutcliffe

Petitioner contends that the combination of teachings from Allen, Baynham, McLuen, and Sutcliffe renders dependent claims 5 and 21 obvious. *See* Pet. 6 (providing Petitioner's asserted grounds), 65–67 (providing Petitioner's analysis of claim 21 and relying on Sutcliffe's

disclosure of side openings); 67–71 (providing Petitioner's analysis of claim 5).

We have reviewed Petitioner's contentions with respect to dependent claims 5 and 21. We discern nothing in the Petition directed to these claims that remedies the deficiencies we identify above with respect to independent claims 1 and 20, from which claims 5 and 21, respectfully, depend. Accordingly, we determine that the information in the Petition does not demonstrate a reasonable likelihood that dependent claims 5 and 21 are obvious over the combination of Allen, Baynham, McLuen, and Sutcliffe.

III. CONCLUSION

After considering all the evidence and arguments presently before us, we determine that the information in the Petition fails to shows a reasonable likelihood that Petitioner would prevail with respect to at least one of the claims challenged in the Petition. Accordingly, we do not institute an *inter partes* review.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that, pursuant to 35 U.S.C. § 314(a), the Petition is *denied.*

FOR PETITIONER:

George D. Moustakas
David P. Utykanski
HARNESS, DICKEY & PIERCE, P.L.C.
gdmoustakas@hdp.com
dutykanski@hdp.com

FOR PATENT OWNER:

Timothy W. Riffe
Joseph V. Colaianni
Indranil Mukerji
Brian J. Livedalen
Hyun Jin In
FISH & RICHARDSON P.C.
riffe@fr.com
colaianni@fr.com
mukerji@fr.com
bvl@fr.com
in@fr.com

Trials@uspto.gov
571-272-7822

Paper 7
Date: January 8, 2021

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

GLOBUS MEDICAL, INC.,
Petitioner,

v.

MOSKOWITZ FAMILY LLC,
Patent Owner.

IPR2020-01306
Patent 10,478,319 B2

Before MEREDITH C. PETRAVICK, NEIL T. POWELL, and JAMES J. MAYBERRY, *Administrative Patent Judges.*

MAYBERRY, *Administrative Patent Judge.*

DECISION
Denying Institution of *Inter Partes* Review
35 U.S.C. § 314

I. INTRODUCTION

A. Background and Summary

Globus Medical, Inc. ("Petitioner") filed a Petition ("Pet.") requesting *inter partes* review of claims 1–5, 7–9, 11, 12, 14, 15, and 18–21 (the "Challenged Claims") of U.S. Patent No. 10,478,319 B2 (Ex. 1001, the

"'319 patent"). Paper 1. Moskowitz Family LLC ("Patent Owner"), filed a Preliminary Response ("Prelim. Resp.") to the Petition. Paper 6.

We have authority under 35 U.S.C. § 314 to determine whether to institute review. *See also* 37 C.F.R. § 42.4(a) (permitting the Board to institute trial on behalf of the Director). To institute an *inter partes* review, we must determine that the information presented in the Petition shows "a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a). For the reasons set forth below, upon considering the Petition, Preliminary Response, and evidence of record, we deny the Petition and do not institute an *inter partes* review.

B. Real Parties in Interest

Petitioner identifies itself as the real party-in-interest. Pet. 1. Petitioner states that "[n]o other party had access to the Petition, and no other party had any control over, or contributed to any funding of, the preparation or filing of the Petition." *Id.* at 1–2. Patent Owner identifies itself as the sole real party-in-interest. Paper 4, 2.

C. Related Matters

The parties identify *Moskowitz Family LLC v. Globus Medical Inc.*, case no. 2:20-cv-03271 (E.D. Pa.) as a matter related to the '319 patent. Pet. 2; Paper 4, 2 ("Pending Litigation"). This case was transferred from the District Court for the Western District of Texas on July 6, 2020. *Id.*

Petitioner indicates that it filed *inter partes* review proceedings challenging five other patents asserted in the Pending Litigation. Pet. 2–3 (identifying U.S. Pat. Nos. 8,353,913; 9,889,022; 10,028,740; 10,251,643; and 10,307,268). Petitioner states that it filed, concurrent with the present Petition, "a first IPR petition" challenging the same Challenged Claims of

the '319 patent.[1] *Id.* at 3; *see* Paper 4, 2 (identifying IPR2020-01305 as the other proceeding, which challenges the '319 patent).

D. The '319 Patent

The '319 patent, titled "System with Tool Assembly and Expandable Spinal Implant," issued November 19, 2019, from an application filed February 20, 2019. Ex. 1001, codes (54), (45), (22). The '319 patent's earliest priority claim is to a provisional application (U.S. provisional no. 60/670,231), filed April 12, 2005. *Id.* at 1:4–13.

The '319 patent "relates to . . . bi-directional fixating transvertebral (BDFT) screws which can be used as a stand-alone intervertebral device which combines the dual functions of an intervertebral spacer which can be filled with bone fusion material(s), as well as a transvertebral bone fusion screw apparatus." *Id.* at 1:18–25. We reproduce Figures 1B and 1D from the '319 patent, below.

[1] Petitioner states that it "is also concurrently filing a first IPR petition for the *'268* patent to address the Challenged Claims." Pet. 3 (emphasis added). We regard this statement as containing a typographical error and that Petitioner meant the '319 patent.

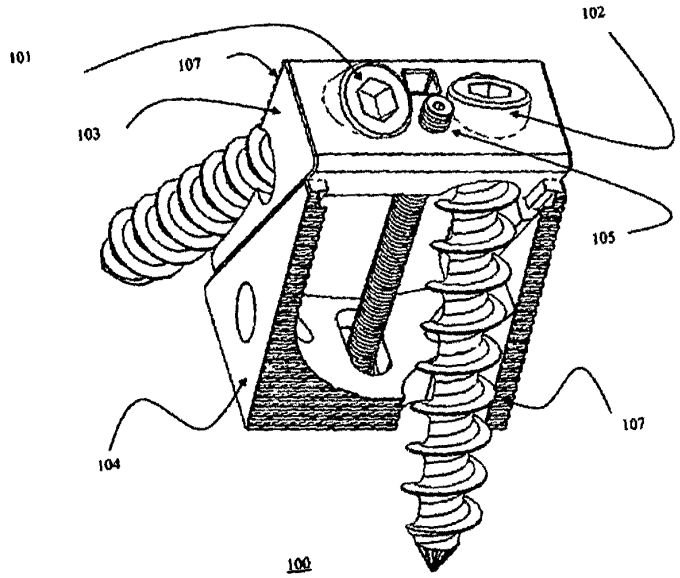


Fig. 1B

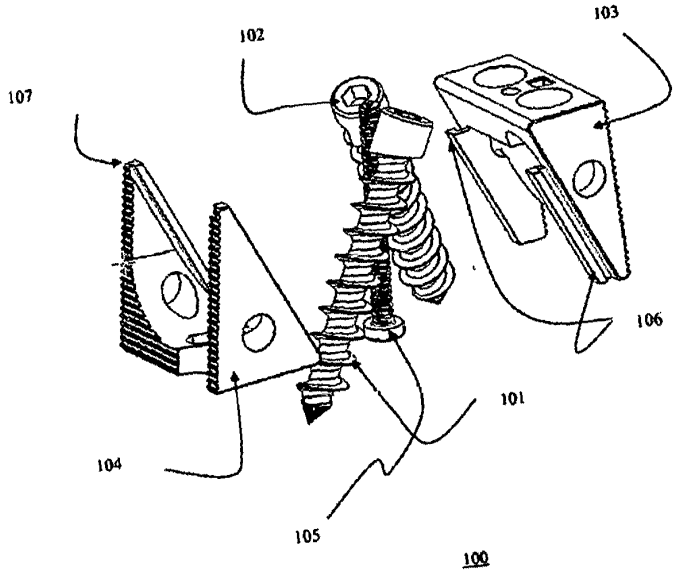


Fig. 1D

Figure 1B provides a superior perspective view of an expandable screw box and Figure 1D provides an exploded view of the same screw box. Ex. 1001, 6:31–35. Expandable box 100 includes two BDFT screws 101, 102, triangular sliding bases 103, 104, and adjustment screw 105. *Id.* at 7:42–53. The surfaces of triangular sliding bases 103, 104 that contact vertebral body surfaces include ridges 107 to facilitate fusion of the screw box with the vertebral bodies. *Id.* at 7:66–8:5. Triangular sliding bases 103, 104 are hollow and include holes to allow bone filling. *Id.* at 8:3–6.

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

Ex. 1001, 7:50–57.

We reproduce Figures 5A and 5C from the '319 patent, below.

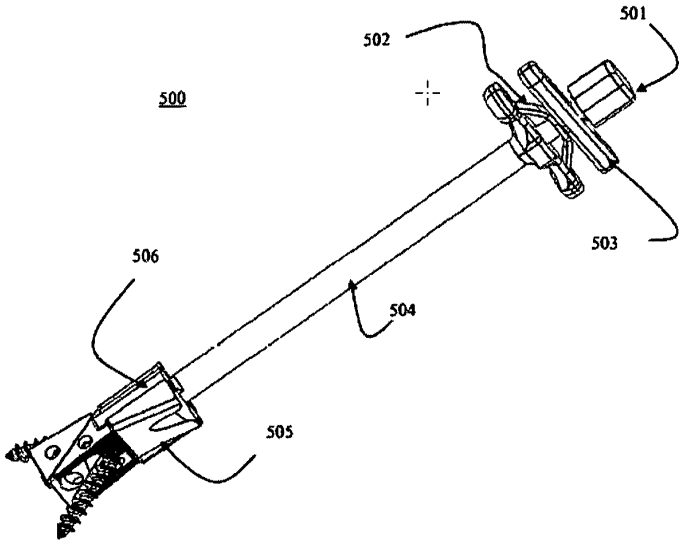


Fig. 5A

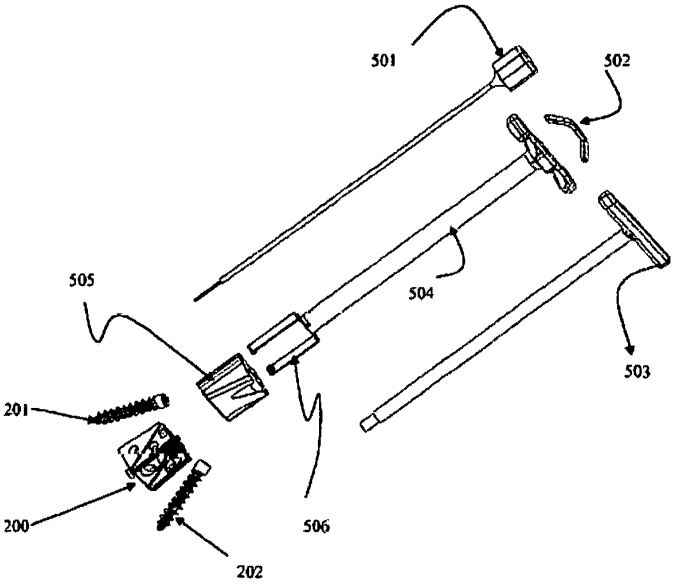


Fig. 5C

Figures 5A and 5C depict a positioning tool in oblique perspective and exploded views, respectively. Ex. 1001, 6:54–56. Tool 500 includes Allen

key 501, handle 503, and gripper 504. *Id.* at 8:62–63. Gripper 504 includes a hollow passageway, into which Allen key 501 is inserted. *Id.* at 8:64–65.

Gripper 504 includes gripper prongs 506, which insert into grooves or indentations of a screw box to align Allen key 501 with the head of adjustment screw 105. Ex. 1001, 8:67–9:3. The surgeon uses the knob at one end of Allen key 501 to adjust the relative positioning of triangular sliding bases 103, 104 by turning adjustment screw 105. *Id.* at 8:64–67.

E. Illustrative Claims

Of the Challenged Claims, claims 1, 9, and 20 are independent. We reproduce claim 1, which is representative, below.

> 1. A system comprising:
> a tool assembly which comprises:
> a first tool having a first proximal end and a first distal end with a first handle and a gripper,
> the gripper being positioned at the first distal end, cooperating with the first handle, and having first and second engagement prongs positioned at the first distal end,
> wherein the first tool defines an adjusting tool passage through the first tool; and
> a second adjusting tool having a second proximal end and a second distal end with a second handle positioned at the second proximal end, a screw engagement portion positioned at the second distal end, and a shaft extending from the second handle to the screw engagement portion,
> wherein the shaft of the second adjusting tool is sized with a smaller diameter than that of the adjusting tool passage such that the second adjusting tool can extend through the adjusting tool passage of the first tool; and
> an expandable spinal implant sized and configured to be implanted in a human spine, the expandable spinal implant comprising a first expandable spinal implant structure, a

second expandable spinal implant structure, and an adjusting screw having a screw head and a threaded portion,

wherein the expandable spinal implant is configured to expand the first expandable spinal implant structure with respect to the second expandable spinal implant structure in response to turning of the adjusting screw,

wherein the expandable spinal implant defines first and second tool engagement indentations sized and configured for receiving the first and second engagement prongs of the first tool,

wherein the adjusting screw is positioned within the expandable spinal implant in a screw location such that the second adjusting tool can extend through the adjusting tool passage of the first tool to engage the screw head of the adjusting screw while the first and second engagement prongs of the first tool are engaged with the first and second tool engagement indentations of the expandable spinal implant.

Ex. 1001, 12:64–13:36.

F. Prior Art and Asserted Grounds

Petitioner asserts that the Challenged Claims are unpatentable based on two grounds:

Claims Challenged	35 U.S.C. §	References/Basis
1–4, 7–9, 11, 12, 14, 15, 18–21	103(a)	Allen,[2] Chung,[3] McLuen[4]
5	103(a)	Allen, Chung, McLuen, Sutcliffe[5]

Petitioner relies on declaration testimony of Dr. Jorge A. Ochoa (Ex. 1003) in support of these grounds.

[2] Allen, US 5,658,335, issued August 19, 1997 (Ex. 1031, "Allen").
[3] Chung et al., KR 20-0290058, issued September 26, 2002 (Ex. 1033, "Chung"). Ex. 1033 also includes the Korean language version of Chung (Ex. 1033, 12–21) and an attestation of translation (Ex. 1033, 11).
[4] McLuen, US 2006/0253201 A1, published November 9, 2006 (Ex. 1030, "McLuen").
[5] Sutcliffe, US 2002/0143399 A1, published October 3, 2002 (Ex. 1032, "Sutcliffe").

The following subsections provide a brief description of the asserted prior art references.

1. Allen

Allen, titled "Spinal Fixator," issued August 19, 1997. Ex. 1031, codes (54), (45). Allen is directed to "a contoured, adjustable spinal fixator for insertion between damaged or resected vertebrae." *Id.* at 1:6–7. We reproduce Allen's Figure 12, below.

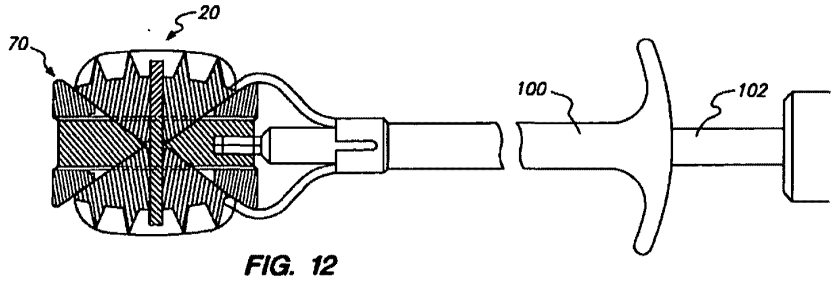


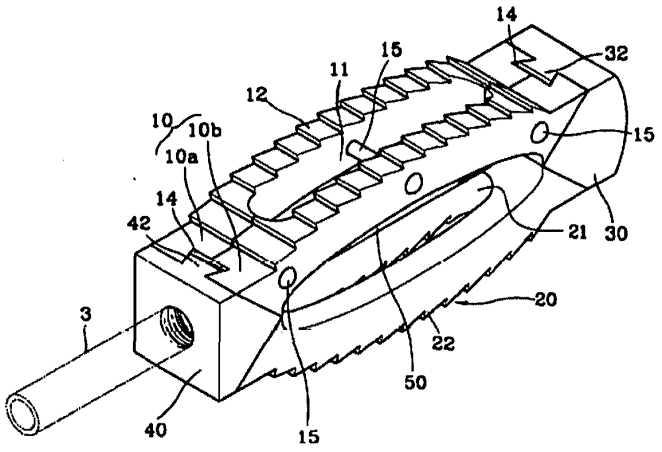
FIG. 12

Figure 12 depicts a "sectional view of [Allen's] spinal fixator . . . shown with [an] insertion tool." *Id.* at 3:48–50. Relevant to our Decision, hollow insertion tool 100 is used to insert spinal fixator 20 between two vertebrae. *Id.* at 5:18–20. As seen in Figure 12, two prongs on tool 100 grasp nut assembly 70. *Id.*; *id.* at Fig. 12. Tool 102, which ends in a hex configuration, is inserted through the hollow interior of tool 100 to engage aperture 60 (which is used to expand spinal fixator 20). *Id.* at 5:21–26.

2. Chung

Chung, titled "A Lumbar Holder," issued September 26, 2002. Ex. 1033, codes (54), (45). Chung is directed to "a lumbar holder that is inserted between the back bones consisting of the lumbar in order to fix the back bones robustly while freely adjusting the height in order to maintain the appropriate space according to the patient's state." *Id.* at 3. We reproduce Chung's Figures 1 and 3, below.

도면 1



도면 3

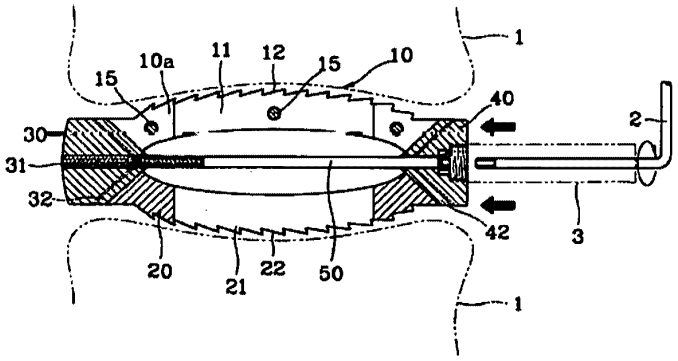


Figure 1 depicts "a combined perspective view drawing of [Chung's] lumber holder," and Figure 3 "illustrat[es] the state in which the lumbar holder . . . is inserted between back bones." *Id.* at 2. The lumbar holder includes opposed holder body 10 and holder body 20. *Id.* at 5.

Holder bodies 10, 20 are connected to wedges 30, 40 through dovetails 32, 40. Ex. 1033, 5, Fig. 2. Wedges 30, 40 act as separation devices that adjust the vertical space between holder bodies 10, 20. *Id.* at 5, Figs. 3, 4. Wedges 30, 40 include a hole that receives groove fastening screw 50. *Id.* at 6, Fig. 3. "[G]roove fastening screw (50) . . . is fastened

between. . . lead wedge (30) and the opposing wedge (40) to be tightened or loosened in order to adjust the space between" the wedges. *Id.* at 5.

Wrapper 3 is attached to penetrating hole 41 and the surgeon holds wrapper 3 to insert the lumbar holder between two back bones. Ex. 1033, 6. Wrench 2 is inserted into wrapper 3 and used to adjust groove fastening screw 50. *Id.*

3. McLuen

McLuen, titled "Bone Fusion Device," published November 9, 2006. Ex. 1030, codes (54), (43). McLuen is directed to "bone fusion devices . . . for fusing vertebrae of the spine." *Id.* ¶ 2. We reproduce McLuen's Figure 16, below.

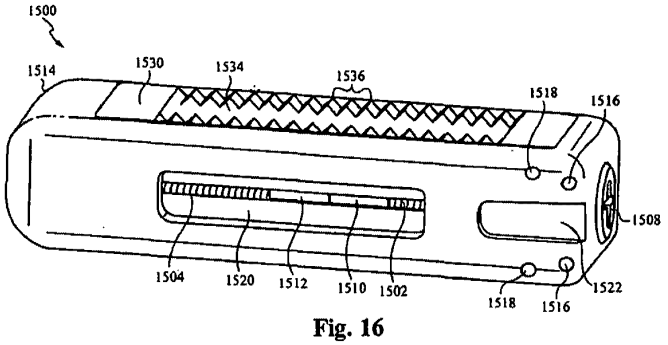


Fig. 16

Figure 16 depicts "a side perspective view of the bone fusion device in the preferred embodiment of" McLuen's invention. *Id.* ¶ 32. Relevant to this Decision, bone fusion device 1500 is expanded by using a screwdriver to turn positioning means 1508. *Id.* ¶ 76. McLuen provides that "[s]crew drivers unfortunately have the ability to slip out of place. When performing surgery near someone's spine, it is preferable to prevent or at least minimize the slipping ability." *Id.* Bone fusion device 1500 includes channels 1522 on each side of the device to receive a tool, which has attachments that fit within channels 1522. *Id.* In this way, the tool is secured to bone fusion

device 1500 to prevent a screwdriver from slipping and injuring the patient when interfacing positioning means 1508. *Id.* at ¶ 78.

4. Sutcliffe

Sutcliffe, titled "Anchorable Vertebral Implant," published October 3, 2002. Ex. 1032, codes (54), (43). Sutcliffe is directed to "an implant to replace . . . [a] vertebrae and/or intervertebral disk." *Id.* ¶ 2. We reproduce Sutcliffe's Figure 6, below.

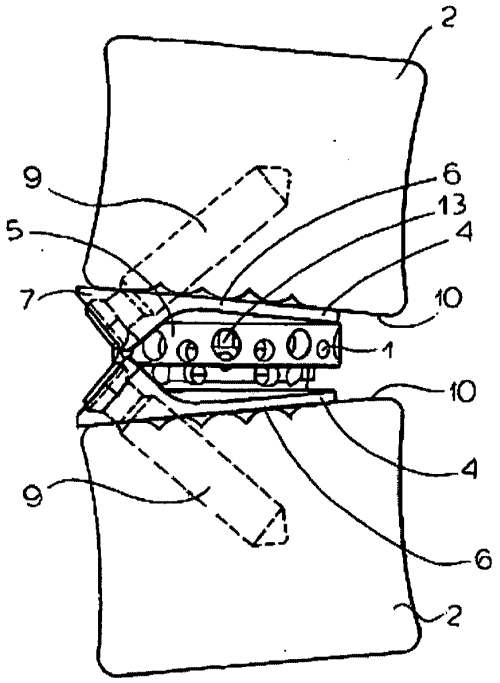


FIG.6

Figure 6 depicts an implant. *Id.* ¶ 21. Relevant to this Decision, Sutcliffe's implant includes through holes 13, "so that an interior [volume of the implant] can be packed with bone chips and so that bone growth through the

implant 1 is possible." *Id.* ¶ 23. Also, Figure 6 illustrates cortical screws 9 extending through angled guides. *Id.* Fig. 6.

II. DISCRETIONARY DENIAL

The Board has discretion not to institute an *inter partes* review. *See* 35 U.S.C. § 314(a) (authorizing institution of an *inter partes* review under particular circumstances, but not requiring institution under any circumstances); 37 C.F.R. § 42.108(a) (stating "the Board *may* authorize the review to proceed") (emphasis added); *Harmonic Inc. v. Avid Tech, Inc.*, 815 F.3d 1356, 1367 (Fed. Cir. 2016) (explaining that under § 314(a), "the PTO is permitted, but never compelled, to institute an IPR proceeding").

The Trial Practice Guide states that "[t]wo or more petitions filed against the same patent at or about the same time (e.g., before the first preliminary response by the patent owner) may place a substantial and unnecessary burden on the Board and the patent owner and could raise fairness, timing, and efficiency concerns." Consolidated Trial Practice Guide 59, available at https://www.uspto.gov/sites/default/files/documents/tpgnov.pdf (Nov. 21, 2019) ("Trial Practice Guide"). The Trial Practice Guide goes on to explain that "multiple petitions by a petitioner are not necessary in the vast majority of cases" and that "a substantial majority of patents have been challenged with a single petition." *Id.* The Trial Practice Guide "[n]onetheless . . . recognizes that there may be" rare "circumstances in which more than one petition may be necessary." *Id.* The Trial Practice Guide states that, in situations where, as here, a petitioner files multiple petitions challenging the same patent, "the petitioner should . . . identify: (1) a ranking of the petitions . . ., and (2) a succinct explanation of . . . why the Board should exercise its

discretion to institute additional petitions if it identifies one petition that satisfies petitioner's burden under 35 U.S.C. § 314(a)." Trial Practice Guide 59–60 (footnotes omitted).

As we indicated in the section above directed to Related Matters, Petitioner filed two petitions challenging the same claims of the '319 patent. Petitioner states that it filed two petitions as a contingency against us exercising our discretion under 35 U.S.C. § 325(d) to not institute the proceeding in IPR2020-01305. *See* IPR2020-01305, Paper 1 at 3–4. Petitioner states that "to the extent the Board declines to exercise its discretion under 35 U.S.C. § 325(d) and institutes the first petition (IPR2020-01305), Petitioner does not seek institution of this second petition (IPR2020-01306)." Pet. 3. Petitioner adds that "if the Board exercises its discretion to deny institution of the first petition under 35 U.S.C. § 325(d) or on the merits, then Petitioner seeks institution of this second petition." *Id.*

We entered, concurrent with entering this Decision, a decision in IPR2020-01305, denying institution on the merits.

Patent Owner argues that two petitions are not warranted and that we should deny institution of the present Petition, as it is ranked second by Petitioner. Prelim. Resp. 18–19. Patent Owner argues "that the instant Petition (IPR2020-01306) should not be instituted if the other petition (IPR2020-01305) is instituted." *Id.* at 19. Patent Owner argues that "[t]his case is typical, and thus undeserving of the burden imposed by instituting multiple" proceedings and that we should "decline Petitioner's request to depart from the normal practice of instituting no more than a single petition." *Id.*

Because we deny this Petition on its merits, we need not reach this issue.

III. UNPATENTABILITY

A. Applicable Law

Petitioner's asserted grounds of unpatentability are based on obviousness under 35 U.S.C. § 103.

> Section 103(a) forbids issuance of a patent when "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains."

KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations, including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) when available, objective evidence, such as commercial success, long felt but unsolved needs, and failure of others.[6] *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

"[O]bviousness must be determined in light of *all the facts*, and . . . a given course of action often has simultaneous advantages and disadvantages, and this does not necessarily obviate motivation to combine" teachings from multiple references. *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1165 (Fed. Cir. 2006) (emphasis added); *see also PAR Pharm., Inc. v. TWI Pharms., Inc.*, 773 F.3d 1186, 1196 (Fed. Cir. 2014) ("The presence or absence of a motivation to combine references in an obviousness determination is a pure question of fact.").

[6] The Patent Owner does not direct us to any objective evidence of non-obviousness in the current record.

B. Level of Ordinary Skill in the Art

The level of skill in the art is "a prism or lens" through which we view the prior art and the claimed invention. *Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001). Petitioner contends that a person having ordinary skill in the art "of the '319 patent would have a Bachelor's or equivalent degree in Mechanical Engineering or a related discipline (e.g. biomechanics or biomedical engineering), and at least five years of experience." Pet. 12–13 (referencing Ex. 1003 ¶¶ 28–30, Ex. 1004). Petitioner adds that "[t]he experience would consist of a) designing, developing, evaluating and/or using prosthetic devices, b) anatomy, physiology and biology of soft and calcified tissues including bone healing and fusion, and c) biomechanical and functional loading of orthopedic implants." *Id.* at 13. Petitioner contends, as an alternative, a person having ordinary skill in the art "could have an advanced degree in the technical disciplines provided above, or a Doctor of Medicine, and at least two years of experience in the subject areas provided above." *Id.*

Patent Owner does not contest Petitioner's contentions nor does Patent Owner offer its own level of ordinary skill.

Based on the current record, we adopt Petitioner's level of ordinary skill for this Decision. We determine, on the current record, that the proposed level of ordinary skill is commensurate with the '319 patent and prior art of record.

C. Claim Construction

In *inter partes* reviews, we interpret a claim "using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. 282(b)." *See* 37 C.F.R. § 42.100(b) (2020). Under this standard, we construe the claim "in accordance with the ordinary and

customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent." *Id.*

Petitioner contends "that the claim terms [of the Challenged Claims] require no express construction and that they should be given their ordinary and customary meaning." Pet. 12. Petitioner then asserts that "[t]his is true for all limitations, except" the term "first expandable spinal implant structure" / "second expandable spinal implant structure." *Id.* Petitioner contends that this term "should be construed in accordance with the intrinsic evidence and Petitioner offered the same constructions in the Pending Litigation." *Id.*

Petitioner proposes that we construe the term "first expandable spinal implant structure" / "second expandable spinal implant structure" to mean "a [first/second] implant structure comprising the [first/second] vertebral body engagement surface." Pet. 12. Neither Petitioner nor Dr. Ochoa identifies any supporting intrinsic or extrinsic evidence for the proposed construction. *See id.*; *see also* Ex. 1003 ¶ 12 (stating that "I have been advised by Counsel that . . . [Petitioner] has proposed the . . . construction" presented above).

Patent Owner argues that Petitioner fails to meet its claim construction burden. Prelim. Resp. 8–9. Patent Owner argues that the Consolidated Trial Practice Guide requires a petitioner that proposes an express construction for a claim term to identify the intrinsic and extrinsic evidence that supports the proposed construction. *Id.* at 9 (citing Consolidated Trial Practice Guide 44, available at https://www.uspto.gov/TrialPracticeGuideConsolidated (Nov. 2019)).

We determine that we need not expressly construe any term of the Challenged Claims to resolve the parties' dispute. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017)

("[W]e need only construe terms 'that are in controversy, and only to the extent necessary to resolve the controversy.'" (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999))).

We are not persuaded by Petitioner's proposed construction, as Petitioner fails to provide any supporting evidence for the construction. *See* Consolidated Trial Practice Guide 44 ("If a petitioner believes that a claim term requires an express construction, the petitioner must include a statement identifying a proposed construction of the particular term *and where the intrinsic and/or extrinsic evidence supports that meaning.*" (emphasis added)). Accordingly, we apply the plain and ordinary meaning to the terms "first expandable spinal implant structure" and "second expandable spinal implant structure."

In summary, no claim terms require express constructions and we apply the plain and ordinary meaning to the terms of the Challenged Claims.

D. Ground 1: Claims 1–4, 7–9, 11, 12, 14, 15, and 18–21 as Obvious Over Allen, Chung, and McLuen

Petitioner contends that the combination of Allen, Chung, and McLuen renders claims 1–4, 7–9, 11, 12, 14, 15, and 18–21 obvious.

1. Independent claim 1

For independent claim 1, we first analyze Patent Owner's argument about a deficiency in Chung's translation certification. We then turn to Petitioner's contentions as to how the combination of Allen, Chung, and McLuen discloses the subject matter recited in claim 1. Finally, we turn to Petitioner's reasons for combining the teachings of these three references.

a) Chung's translation certification

We address, as an initial matter, Patent Owner argument that Chung is not properly authenticated. Prelim. Resp. 12. Specifically, Patent Owner

argues that the translation certification for Chung does not satisfy the requirements of 37 C.F.R. §§ 1.68, 42.2. *Id.* Patent Owner also argues that the "certification is not signed by the linguist with personal knowledge of the accuracy of the translation." *Id.*

We do not agree with Patent Owner, on the current record, that the translation certification does not comport with our rules for an affidavit. The translation of Chung is accompanied by a statement that 1) identifies the affiant (Cierra Sharp, a Project Manager at Morningside IP), provides its statement of fact (that the attached translation of Chung from Korean to English "is an accurate representation of the documents received by this office") and an attestation that "[t]o the best of my knowledge, the aforementioned documents are a true, full and accurate translation of the specified documents." Ex. 1033, 11. The statement is signed and notarized, with the Notary Public stating that the statement was "[s]worn to before me this day April 28, 2020." *Id.*

Patent Owner directs us to the requirement in 37 C.F.R. § 1.68 that a declaration must include language regarding the penalty for making false statements, warnings that Patent Owner argues "are . . . imposed as safeguards to ensure credibility of the witness and maintain the integrity of the proceeding." Prelim. Resp. 12–13.

Our rules, however, allow a witness to provide *either* an affidavit *or* a declaration. 37 C.F.R. § 42.2 ("*Affidavit* means affidavit or declaration under § 1.68 of this chapter."). The requirements to which Patent Owner directs us are for a declaration, not an affidavit. *See* 37 C.F.R. § 1.68 ("Declaration in lieu of oath"). Patent Owner does not explain adequately why the certification fails to satisfy the requirements of an affidavit. *See, e.g.*, BLACK'S LAW DICTIONARY 36 (6th ed. (abridged) 1991) (defining

"affidavit" to be "[a] written . . . statement of fact, made voluntarily, and confirmed by the oath or affirmation of the party making it, taken before a person having authority to administer such oath or affirmation.").

Even if the certification is deficient, this failure is not fatal, as the Board routinely allows a Petitioner to correct such a declaration. *See, e.g.*, *Ascend Performance Materials Operations LLC v. Samsung Sdi Co., Ltd.*, IPR2020-00349, Paper 13 at 11 (PTAB. July 16, 2020) (requiring the petitioner in that proceeding to "refile any English-language translations of references with new declarations that satisfy the requirements of 37 C.F.R. §§ 42.63(b) and 42.2.").

Also, we determine Patent Owner's argument that the certification was not signed by the linguist with personal knowledge of the accuracy of the translation is unpersuasive of a deficiency on the current record. Although the certification uses the phrase "[t]o the best of my knowledge," suggesting that the affiant is making the statement on information and belief, this statement goes to the weight of the evidence. *Cf.* 37 C.F.R. § 1.68 (allowing, for a declaration filed in lieu of an oath, to be based on the declarant's own knowledge or on information and belief). Our rules require a translation, but do not require the certification to be signed by someone with personal knowledge of the translation. *See* 37 C.F.R. § 42.63(b) ("When a party relies on a document or is required to produce a document in a language other than English, a translation of the document into English and an affidavit attesting to the accuracy of the translation must be filed with the document.")

We note also that Patent Owner does not offer any argument or evidence that the translation is inaccurate, such that we should afford the translation little weight.

b) Subject matter of claim 1

(1) Tool assembly limitations

Claim 1 recites, in relevant part, a "tool assembly" that comprises "a first tool" and "a second adjusting tool." Ex. 1001, 12:64–13:15 (the "tool assembly" limitations of claim 1). Specifically, claim 1 recites

> a first tool having a first proximal end and a first distal end with a first handle and a gripper, the gripper being positioned at the first distal end, cooperating with the first handle, and having first and second engagement prongs positioned at the first distal end, wherein the first tool defines an adjusting tool passage through the first tool.

Id. at 12:66–13:5 (the "first tool" limitation of claim 1). Claim 1 also recites

> a second adjusting tool having a second proximal end and a second distal end with a second handle positioned at the second proximal end, a screw engagement portion positioned at the second distal end, and a shaft extending from the second handle to the screw engagement portion, wherein the shaft of the second adjusting tool is sized with a smaller diameter than that of the adjusting tool passage such that the second adjusting tool can extend through the adjusting tool passage of the first tool.

Id. at 13:6–15 (the "second adjusting tool" limitation of claim 1).

Petitioner contends that Allen discloses the "first tool" and "second adjusting tool" limitations of claim 1. Pet. 19–22 (referencing Ex. 1031, 5:19–47, Fig. 12; Ex. 1003 ¶¶ 136–138). We reproduce Allen's Figure 12, below.

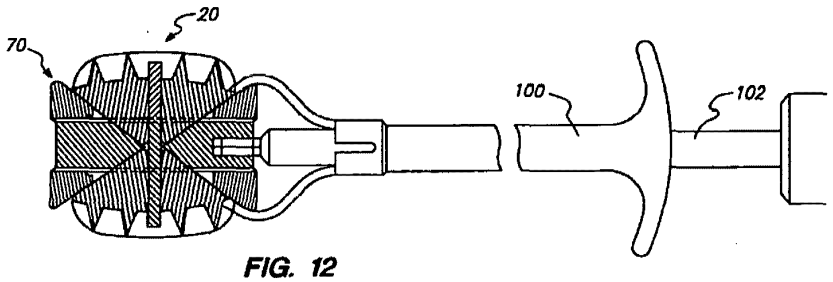


FIG. 12

Figure 12 depicts a "sectional view of [Allen's] spinal fixator . . . shown with [an] insertion tool." Ex. 1031, 3:48–50. Petitioner contends that insertion tool 100 corresponds to the first tool, which includes a handle at one end and a gripper having prongs at the other. Pet. 19–20. Petitioner contends that insertion tool 100 is hollow, defining the adjusting tool passage. *Id.* at 20–21; *see also* Ex. 1031, 5:18–20 ("A conventional, hollow insertion tool 100 is used to gasp a nut assembly 70 to insert the retracted spinal fixator 20 between the two vertebrae bodies 4.").

Petitioner contends that tool 102 corresponds to the recited second adjusting tool, with a second handle at one end and a screw engagement portion at the other and a shaft extending between the handle and screw engagement portion. Pet. 21–22; *see also* Ex. 1031, 5:21–26 ("[T]ool 102 having a terminus defining a hex configuration is inserted through the insertion tool 100 to engage in aperture 60 in the core member 50. The tool 102 is used to rotate core member 50 to extend the crowns 90 outwardly."). Petitioner contends that tool 102 is sized to fit within the hollow passage of tool 100. Pet. 22; *see* Ex. 1031, 5:21–23.

We determine that Petitioner has made the requisite showing, at this stage of the proceeding, that Allen discloses the subject matter of the "tool assembly" limitations of claim 1. Patent Owner does not dispute these contentions at this time.

(2) First and second expandable spinal implant structures limitation

Claim 1 also recites "an expandable spinal implant sized and configured to be implanted in a human spine, the expandable spinal implant comprising a first expandable spinal implant structure, [and] a second expandable spinal implant structure." Ex. 1001, 13:16–19 (the "first and

second expandable spinal implant structures" limitation of claim 1). Petitioner contends that Chung teaches an expandable spinal implant satisfying the "first and second expandable spinal implant structures" limitation of claim 1. Pet. 23–24 (referencing Ex. 1033, 5, Figs. 1–3; Ex. 1003 ¶¶ 143–144). Specifically, Petitioner contends that Chung's lumbar holder includes holder body 10 and lead wedge 30 (corresponding to the first expandable spinal implant structure) and opposing holder body 20 and wedge 40 (corresponding to the second expandable spinal implant structure). *Id.* at 23. We reproduce Chung's Figure 3 below.

도면 3

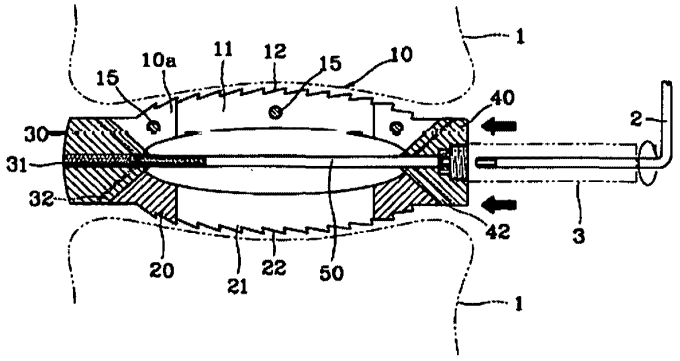


Figure 3 "illustrat[es] the state in which the lumbar holder . . . is inserted between back bones." *Id.* at 2.

We determine that Petitioner has made the requisite showing, at this stage of the proceeding, that Chung discloses the subject matter of the "first and second expandable spinal implant structures" limitation of claim 1. Patent Owner does not dispute these contentions directed to the subject matter of this limitation at this time.

(3) Tool engagement indentations limitation

Claim 1 also requires "the expandable spinal implant [to] define[] first and second tool engagement indentations sized and configured for receiving the first and second engagement prongs of the first tool." Ex. 1001, 13:25–28 (the "tool engagement indentations" limitation of claim 1). Petitioner contends that Chung discloses an implant with a tool engagement indentation. Pet. 25. Specifically, Petitioner contends that Chung discloses penetrating hole 41 (a "double raised spot structure") for receiving wrapper 3. *Id.*; *see id.*, Fig. 3 (reproduced above and showing wrapper 3 engaged with Chung's lumbar holder).

Petitioner also contends that a person having ordinary skill in the art "would have understood that [Allen's tool] . . . *could* be used to insert and expand" Chung's implant. Pet. 26 (emphasis added).

Petitioner contends that, to the extent that Allen's tool must interface with the outside surface of an implant, a person having ordinary skill in the art "would have understood that the Chung implant *could* be modified as a matter of simple substitution to move the double raised spot structure from the center of the proximal face to the opposing side surfaces of the implant." Pet. 26 (referencing Ex. 1003 ¶ 147). Petitioner restates its position as "placement and positioning of indentations for insertion tool engagement at the proximal or trailing end of the implant is a predictable substitution that does not affect its function." *Id.*

Petitioner contends that McLuen discloses spinal implant 1500 having indentations 1522 on either side of the implant near an adjustment screw head. Pet. 26–27. We reproduce McLuen's Figure 16, below.

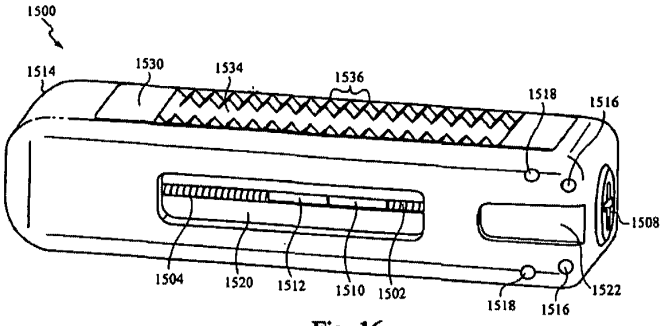


Fig. 16

Figure 16 depicts "a side perspective view of the bone fusion device in the preferred embodiment of" McLuen's invention. Ex. 1030 ¶ 32. Petitioner contends that McLuen teaches that, because of the risk of a screwdriver slipping when driving screw 1508 and injuring a patient, its implant includes channels 1522 on opposing sides of the implant to receive a tool. Pet. 27 (referencing Ex. 1030 ¶¶ 76, 77, Fig. 16; Ex. 1003 ¶ 147). Petitioner contends that

> It would therefore have been obvious to a [person having ordinary skill in the art] to combine the teachings of Chung with McLuen to substitute the "double raised spot structure" disclosed in Chung for the indentations in McLuen, moving the tool engagement to opposing sides at the proximal end of the implant to provide the disclosed advantage of prevention or minimization of screw driver slippage.

Id. Petitioner adds that "[t]his substitution would represent a design choice which would yield a predictable result with a reasonable expectation of success." *Id.* (referencing Ex. 1003 ¶ 149).

We understand Petitioner's position to be that it would have been obvious to modify Chung's's implant by including McLuen's indentations on the side of wedge 40.

We determine that Petitioner has made the requisite showing, at this stage of the proceeding, that Chung, as modified by McLuen, discloses the

subject matter of the "tool engagement indentations" limitation of claim 1. Patent Owner does not dispute the contentions directed to the subject matter of this limitation at this time.

(4) Adjusting screw limitations

Claim 1 also recites "an adjusting screw having a screw head and a threaded portion." Ex. 1001, 13:20–21. Claim 1 requires "the expandable spinal implant [be] configured to expand the first expandable spinal implant structure with respect to the second expandable spinal implant structure in response to turning of the adjusting screw." *Id.* at 13:21–25. Claim 1 also requires

> the adjusting screw [be] positioned within the expandable spinal implant in a screw location such that the second adjusting tool can extend through the adjusting tool passage of the first tool to engage the screw head of the adjusting screw while the first and second engagement prongs of the first tool are engaged with the first and second tool engagement indentations of the expandable spinal implant.

Id. at 13:29–36 (the "adjusting screw" limitations of claim 1).

Petitioner contends that Chung discloses the subject matter of the adjusting screw limitations of claim 1, identifying Chung's adjusting screw 50. Pet 23, 24, 27–30 (referencing Ex. 1033, 6, Figs. 3–4; Ex. 1003 ¶¶ 145, 150–154). Petitioner explains that Chung discloses that its implant "is configured to expand the first expandable spinal implant structure (10 and 30) with respect to the second expandable spinal implant structure (20 and 40) in response to turning of the adjusting screw (50)." *Id.* at 24. Petitioner adds that

> Allen discloses the second adjusting tool (102) can extend through the adjusting tool passage of the first tool (100) to engage the screw head of the adjusting screw (67) (sic, (50)) while the first and second engagement prongs of the first tool

> (100) are engaged with the first and second tool engagement indentations of the expandable spinal implant (20). Allen discloses that following placement of the implant, the tool (102) having a terminus defining a hex configuration is inserted through the hollow insertion tool (100) to engage an adjusting screw.

Id. at 29 (referencing Ex. 1031, 5:19–28; Ex. 1003 ¶ 152).

We determine that Petitioner has made the requisite showing, at this stage of the proceeding, that Chung, as modified by McLuen, discloses the subject matter of the "adjusting screw" limitations of claim 1. Patent Owner does not dispute the contentions directed to the subject matter of this limitation at this time.

c) Reasons to combine the teachings of Allen, Chung, and McLuen

First, we address Petitioner's reasoning for combining the teachings of Allen's tool with Chung's implant. Petitioner contends that a person having ordinary skill in the art would have understood that Allen's tool "is configured to interface with any number of expandable spinal implants" and that the tool "is of a typical design." Pet. 23. Petitioner concludes that Allen's tool "could be combined/used with the expandable spinal implant in Allen or in Chung." *Id.* (referencing Ex. 1003 ¶ 142). Petitioner contends that a person having ordinary skill in the art "would have understood that the inserter disclosed by Allen could be used to insert and expand the implant disclosed by Chung." *Id.* at 26.

Patent Owner argues that Petitioner's reasons to combine the teachings of Allen and Chung rely on improper hindsight. Prelim. Resp. 15. Patent Owner argues that Petitioner's rationale amounts to nothing more than conclusory statements. *Id.* Patent Owner also argues that Petitioner's

rationale fails to recognize that Allen already discloses an implant, so there would be no reason to modify Allen with Chung's implant. *Id.*

Patent Owner also argues that Dr. Ochoa's testimony repeats, verbatim, the conclusory statements from the Petition and that Dr. Ochoa "fails to explain how or why a [person having ordinary skill in the art] would have 'understood' that Allen and Chung could be combined." Prelim. Resp. 16–17. Patent Owner concludes that Petitioner's rationale to combine the teachings of Allen and Chung, "at best, reduces to an assertion that the proposed combination ***could*** be made, without the requisite reasoning as to why a [person having ordinary skill in the art] ***would*** have been motivated to" make the proposed combination. *Id.* at 17.

We determine that Patent Owner's argument, at least in part, is persuasive of a deficiency in the Petition. We determine that Petitioner fails to provide sufficient reasons, with rational underpinnings, to employ Allen's tool with Chung's implant. As Patent Owner argues, Petitioner bases its reasoning on the position that Allen's tool *could* be used for Chung's implant, not that a person having ordinary skill in the art *would* have been motivated to use Allen's tool with Chung's implant. *See* Prelim. Resp. 17; Pet. 23, 26. Our reviewing court has stated that "obviousness concerns whether a skilled artisan not only *could have made* but *would have been motivated to make* the combinations or modifications of prior art to arrive at the claimed invention." *Belden Inc. v. Berk-Tek LLC*, 805 F.3d 1064, 1073 (Fed. Cir. 2015). The information in the Petition lacks such a rationale.

Also, Petitioner fails to explain adequately why a person having ordinary skill in the art would have considered Allen's tool for Chung's implant, given that Chung has its own tool. The only apparent reason to employ Allen's tool is that claim 1 requires a tool with prongs, and Chung's

tool does not have prongs. As such, Petitioner's combination appears to be the product of hindsight rather than an obvious combination—something against which we must guard. *See St. Jude Med., Inc. v. Access Closure, Inc.*, 729 F.3d 1369, 1381 (Fed. Cir. 2013) ("Even under [the] 'expansive and flexible' obviousness analysis [of *KSR*], we must guard against 'hindsight bias' and '*ex post* reasoning.'" (citation omitted)).

Even if we assume Petitioner's statements represent sufficient reasoning for combining Allen's tool with Chung's implant, we determine that Petitioner fails to provide a rational underpinning of facts to support that reasoning. *See KSR Int'l Co.*, 550 U.S. at 418 (stating that, to facilitate the analysis of an obviousness position, the proponent should provide "some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness"). The only evidence Petitioner directs us to is testimony from Dr. Ochoa. *See* Pet. 23, 26. We determine, however, that this testimony is entitled to very little weight. Dr. Ochoa fails to provide any underlying support for the testimony. *See* Ex. 1003 ¶¶ 136–154 (providing analysis of claim 1 under Ground 1 and including numerous statements about what a person having ordinary skill would have known or understood without providing the basis for those statements). These unsupported statements are entitled to little or no weight. 37 C.F.R. 42.65(a) ("Expert testimony that does not disclose the underlying facts or data on which the opinion is based is entitled to little or no weight.").

We recognize that Petitioner characterizes Allen's tool as of a "typical design." Pet. 23. Petitioner also contends that tools such as Allen's "were in common use at the time" of the invention of claim 1 and that "[s]imilar devices were also used in arthroscopic and endoscopic surgery." *Id.* at 29–30 (referencing Ex. 1003 ¶ 153). Such general statements, without more, do

not sufficiently support a finding that a person having ordinary skill in the art would have been motivated to employ Allen's tool with Chung's implant. *See KSR Int'l Co.*, 550 U.S. at 418 ("[A] patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.").

We also recognize that Petitioner directs us to statements in McLuen that a surgeon would generally use a tool to insert a spinal implant. Pet. 26–27. McLuen discloses that

> To secure the bone fusion device 1500 in place, a user generally utilizes an implement such as a screw driver to turn the positioning means 1508. Screw drivers unfortunately have the ability to slip out of place. When performing surgery near someone's spine, it is preferable to prevent or at least minimize the slipping ability. To do so, channels 1522 are implemented to receive a tool (not shown). The tool (not shown) has attachments that fit within the channels 1522 to secure the tool (not shown) in place.

Ex. 1030 ¶ 76. Even in light of these statements, Petitioner's reasoning is insufficient. Chung includes wrapper 3, which is threaded into Chung's lumbar holder and into which is inserted wrench 2. As such, wrench 2 is not at risk to slip out of place. *See* Ex. 1033, Fig. 3 (showing wrench 2 inserted into wrapper 3).

Accordingly, Petitioner fails sufficiently to support its reasons to combine Allen's tool with Chung's implant.

Now turning to reasons to modify Chung with McLuen, we determine that the Petition suffers from the same problem as we discuss above. We acknowledge that McLuen expressly discloses the benefits of using a tool to prevent a screwdriver from slipping, as Petitioner contends. *See* Pet. 27. We determine, however, that, absent hindsight, Petitioner fails to provide

sufficient reasoning as to why a person having ordinary skill in the art would have added McLuen's indentations to Chung's lumbar holder. As discussed above, Chung discloses that wrapper 3 is threaded into penetrating hole 41 and then wrench 2 is inserted into wrapper 3 to turn groove fastening screw 50. Ex. 1033, 6, Fig. 3. As such, wrench 3 cannot slip and injure a patient. Instead, Petitioner's proposed modification appears motivated by the need to satisfy the tool engagement indcntations limitation of claim 1, that is, by hindsight.

Also, Petitioner's assertion that its proposed modification "represent[s] a design choice" fails to provide a sufficient reason, on the current record. Pet. 27. Petitioner does not adequately explain why its proposed modification, which eliminates wrapper 3 and adds tool indentations to wedge 40, is merely a matter of design choice. *See Ex Parte Spangler*, Appeal 2018-00300 (PTAB Feb. 20, 2019) (informative); *see also Polaris Indus., Inc. v. Arctic Cat, Inc.*, 882 F.3d 1056, 1069 n4. (Fed. Cir. 2018) ("The Board failed to consider that '[m]erely stating that a particular placement of an element is a design choice does not make it obvious.' Instead, the [Petitioner] must explain why a person of ordinary skill in the art 'would have selected these components for combination in the manner claimed.'"); *cf. In re Kuhle,* 526 F.2d 553, 555 (CCPA 1975) ("Use of such means of electrical connection in lieu of those used in the references solves *no stated problem* and would be an obvious matter of design choice within the skill in the art." (emphasis added)). Said another way, we find no persuasive argument or credible supporting evidence to explain that the use of wrapper 3 is not critical to how its device is implanted into the spine, such that it could be eliminated as a matter of design choice or why such a modification would have been motivated.

d) Conclusion as to claim 1

For the reasons discussed above, we determine, on the current record, that Petitioner fails to provide the requisite reasoning, with rational underpinnings, for combining the teachings of Allen, Chung, and McLuen. Accordingly, we determine that the information in the Petition does not demonstrate a reasonable likelihood that claim 1 is obvious over the combination of Allen, Chung, and McLuen.

2. Independent claims 9 and 20

In contending that independent claims 9 and 20 are obvious over the combination of Allen, Chung, and McLuen, Petitioner makes similar contentions, with respect to combining the teachings of Allen, Chung, and McLuen, to the contentions we analyzed above for claim 1. *Compare* Pet. 38–43, Pet. 51–61 *with* Pet. 19–30. For the reasons discussed above in our analysis of claim 1, we determine, on the current record, that Petitioner fails to provide the requisite reasoning, with rational underpinnings, for combining the teachings of Allen, Chung, and McLuen. Accordingly, we determine that the information in the Petition does not demonstrate a reasonable likelihood that claims 9 and 20 are obvious over the combination of Allen, Chung, and McLuen.

3. Dependent claims 2–4, 7, 8, 11, 12, 14, 15, 18, 19, and 21

We have reviewed Petitioner's contentions with respect to dependent claims 2–4, 7, 8, 11, 12, 14, 15, 18, 19, and 21. *See* Pet. 30–38, 43–51, 61–63. We discern nothing in the Petition directed to these claims that remedies the deficiencies we identify above with respect to independent claims 1, 9, and 20, from which these claims depend. Accordingly, we determine that the information in the Petition does not demonstrate a reasonable likelihood

that dependent claims 2–4, 7, 8, 11, 12, 14, 15, 18, 19, and 21 are obvious over the combination of Allen, Chung, and McLuen.

E. Ground 2: Claim 5 as Obvious Over Allen, Chung, McLuen, and Sutcliffe

Petitioner contends that the combination of teachings from Allen, Chung, McLuen, and Sutcliffe renders dependent claim 5 obvious. *See* Pet. 5, 63–65

We have reviewed Petitioner's contentions with respect to dependent claim 5. We discern nothing in the Petition directed to this claim that remedies the deficiencies we identify above with respect to independent claim 1, from which claim 5 depends. Accordingly, we determine that the information in the Petition does not demonstrate a reasonable likelihood that dependent claim 5 is obvious over the combination of Allen, Chung, McLuen, and Sutcliffe.

IV. CONCLUSION

After considering all the evidence and arguments presently before us, we determine that the information in the Petition fails to shows a reasonable likelihood that Petitioner would prevail with respect to at least one of the claims challenged in the Petition. Accordingly, we do not institute an *inter partes* review.

V. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that, pursuant to 35 U.S.C. § 314(a), the Petition is *denied.*

FOR PETITIONER:

George D. Moustakas
David P. Utykanski
HARNESS, DICKEY & PIERCE, P.L.C.
gdmoustakas@hdp.com
dutykanski@hdp.com

FOR PATENT OWNER:

Timothy W. Riffe
Joseph V. Colaianni
Indranil Mukerji
Brian J. Livedalen
Hyun Jin In
FISH & RICHARDSON P.C.
IPR43982-0006IP1@fr.com
PTABInbound@fr.com