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	46440-0009016

SIGNATURE of Applicant or Patent Practitioner

Signature	/Stuart A. Nelson/	Date (Optional)	1/16/2020
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.

62227236.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.

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	46440-0009016
	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	Rockville	State/Province	MD	Country of Residence	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	Cambridge	State/Province	MA	Country of Residence	US

Mailing Address of Inventor:

Address 1	13 Lancaster St. #2
Address 2	

City	Cambridge	State/Province	MA
Postal Code	02139	Country	US

Inventor 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	46440-0009016
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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	46440-0009016	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	46440-0009016
	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	15944117	2018-04-03

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	46440-0009016
	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	Pending	Remove

Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
15944117	Continuation of	15894471	2018-02-12

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	2018-02-13

Prior Application Status	Patented	Remove

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

Prior Application Status	Patented	Remove

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

Prior Application Status	Patented	Remove

Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
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	2006-09-26	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

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	46440-0009016
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Title of Invention	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION	

Foreign Priority Information:

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

Remove

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

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	46440-0009016
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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	46440-0009016
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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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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)	2020-01-16
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

PTO/AIA/14 (02-18)
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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.

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

January 16, 2020

Attorney Docket No.: 46440-0009016

Commissioner for Patents
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Alexandria, VA 22313-1450

Presented for filing is a new continuation patent application 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	4
Abstract	1
Declaration	4
Drawing(s)	38

Enclosures:

— Application Data Sheet, 10 pages.
— Power of Attorney, 2 pages.

The applicant claims small entity status under 37 CFR 1.27.

Basic Filing Fee			$75
Search Fee			$330
Examination Fee			$380
Total Claims 20	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: 70 x .75 - 100/50 = 0 x	$0
Total Filing fee	$785

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Send all correspondence to:

26191
Customer Number

Respectfully submitted,

/Stuart A. Nelson/

Stuart A. Nelson
Registration No. 63,947

Enclosures

SWN/euw
62227815.doc

Electronic Acknowledgement Receipt	
EFS ID:	38312757
Application Number:	16744755
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Confirmation Number:	5369
Title of Invention:	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION
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Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Drawings-only black and white line drawings	Drawings.pdf	2495188 44ba7b28ae5b64f77fa3b332130264863657790 5	no	38
Warnings:					

Information:					
2		Application.pdf	3108188 ce737c6fff74e269bdf8fba846550e12d818fa2f	yes	32
	Multipart Description/PDF files in .zip description				
	Document Description		**Start**	**End**	
	Abstract		32	32	
	Claims		28	31	
	Specification		1	27	
Warnings:					
Information:					
3	Oath or Declaration filed	Declaration.pdf	4510683 8b0cbc6175e2529631a9c3944c279ea721d7254a	no	4
Warnings:					
Information:					
4	Power of Attorney	POA.pdf	755656 42bd3d67a86bf5408ae9712fb14f9dd0f20397fd	no	2
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Information:					
5	Application Data Sheet	ADS.pdf	1257006 a5ee1ad353249fec88dca9f5a8e41ed2e1b75dda	no	10
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6	Transmittal Letter	TransmittalLetter.pdf	97955 c0eebeb3cd3fb3ae1e0818aff2c692aed9f36498	no	2
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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.

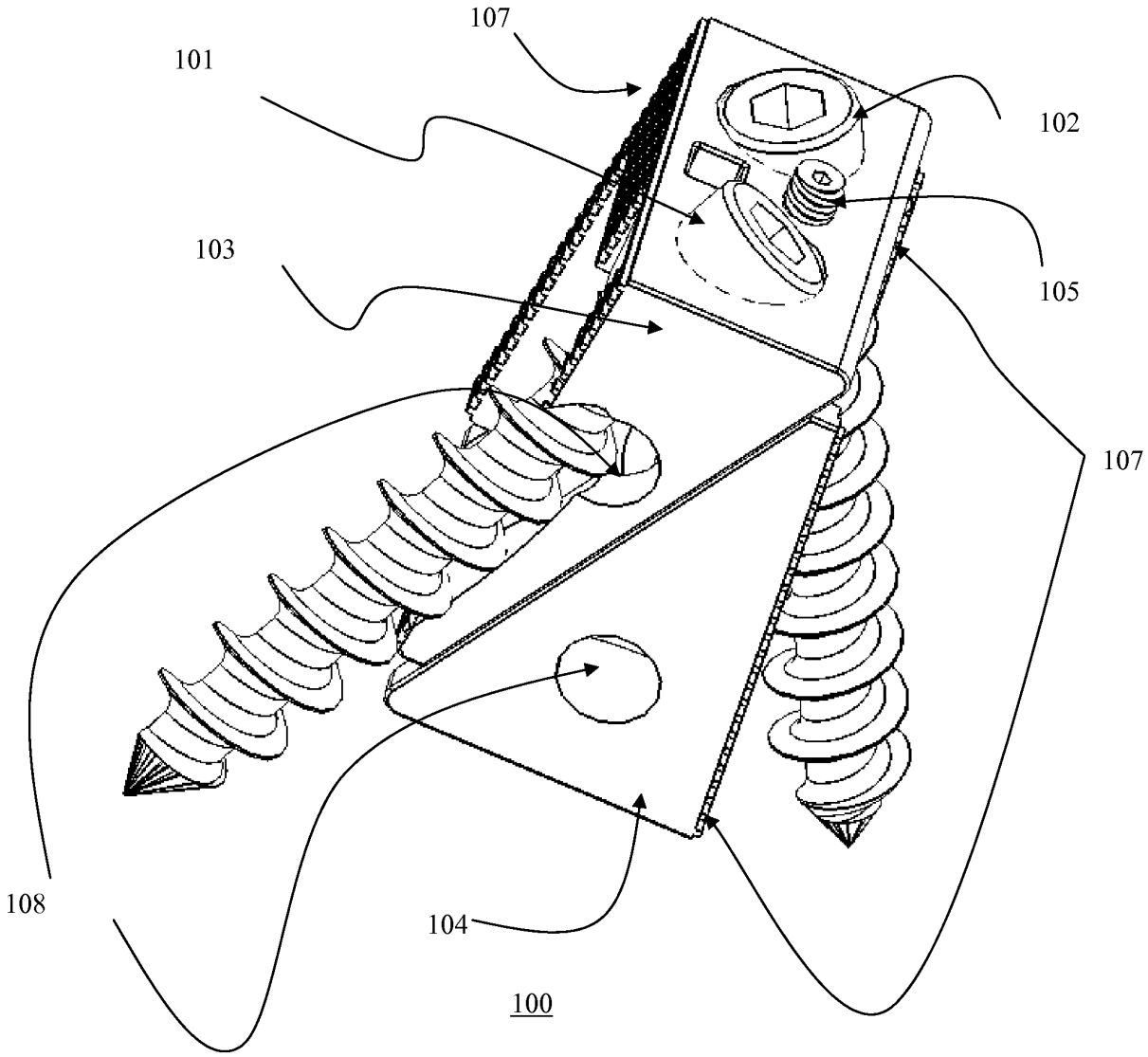


Fig. 1A

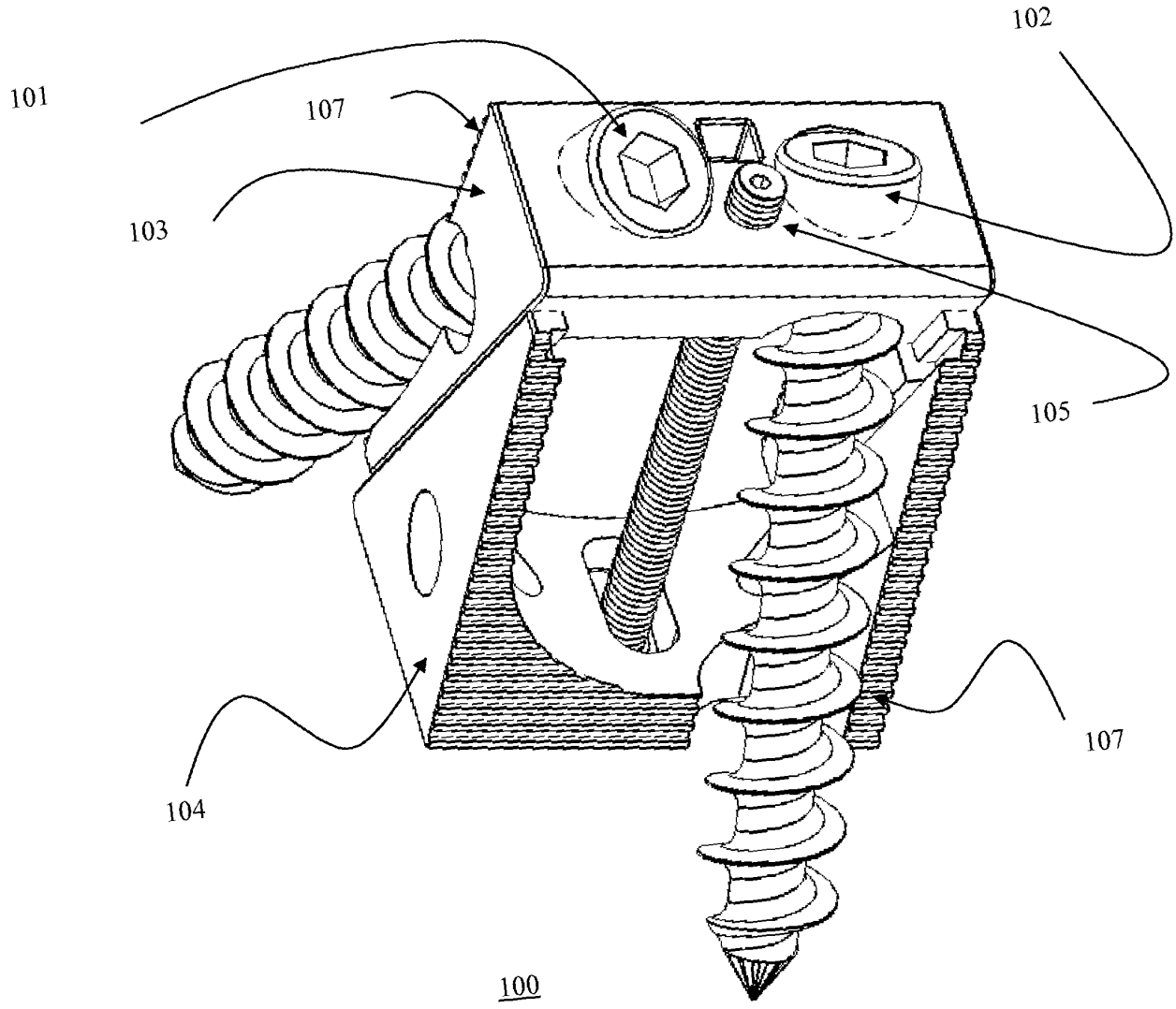


Fig. 1B

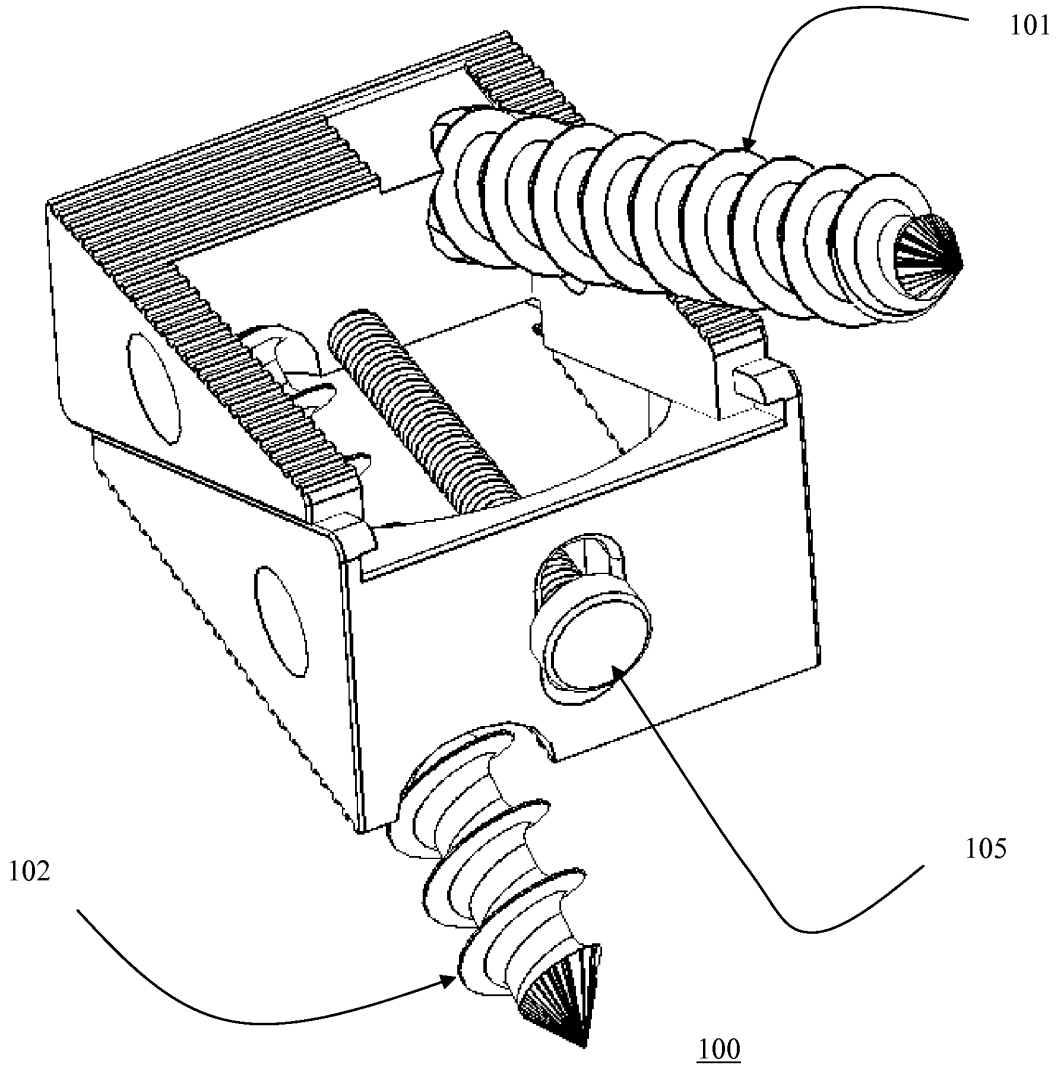


Fig. 1C

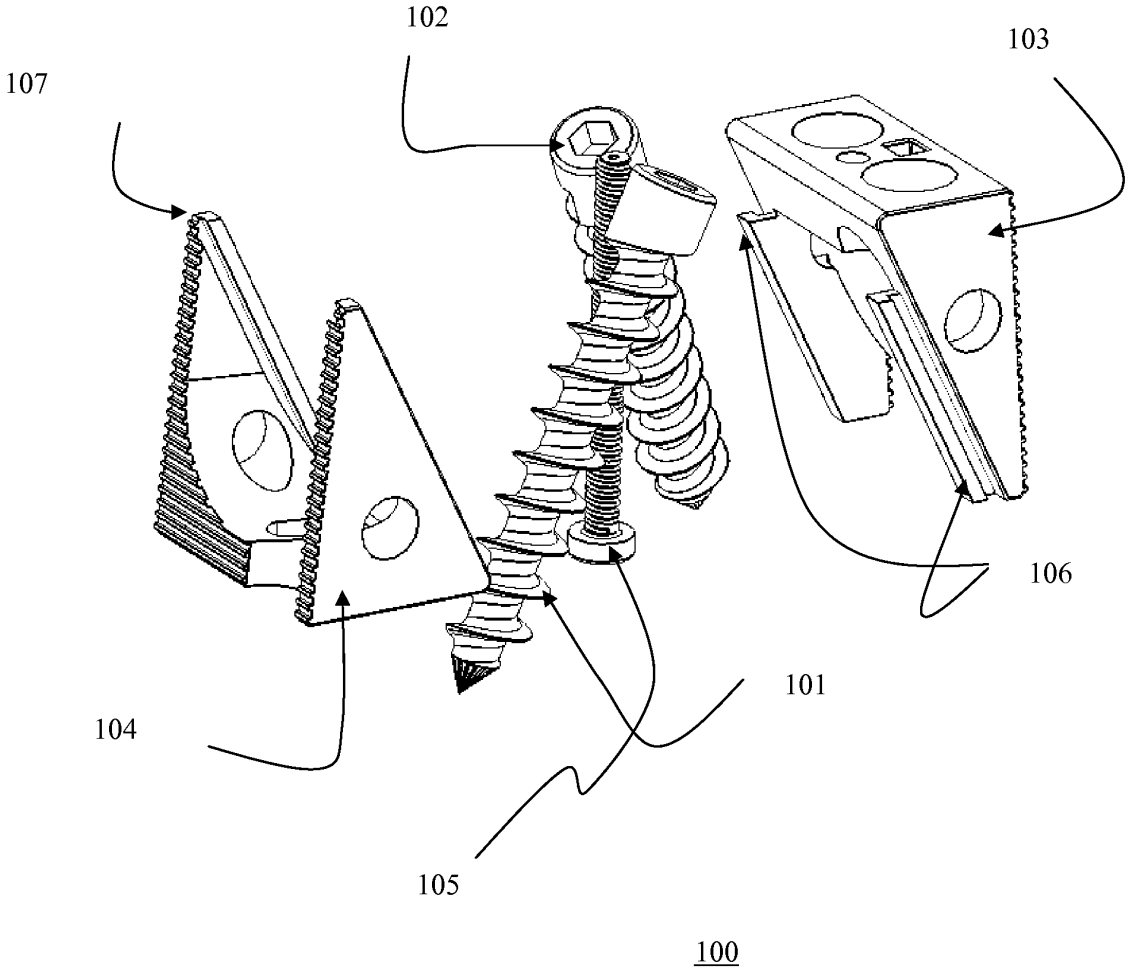


Fig. 1D

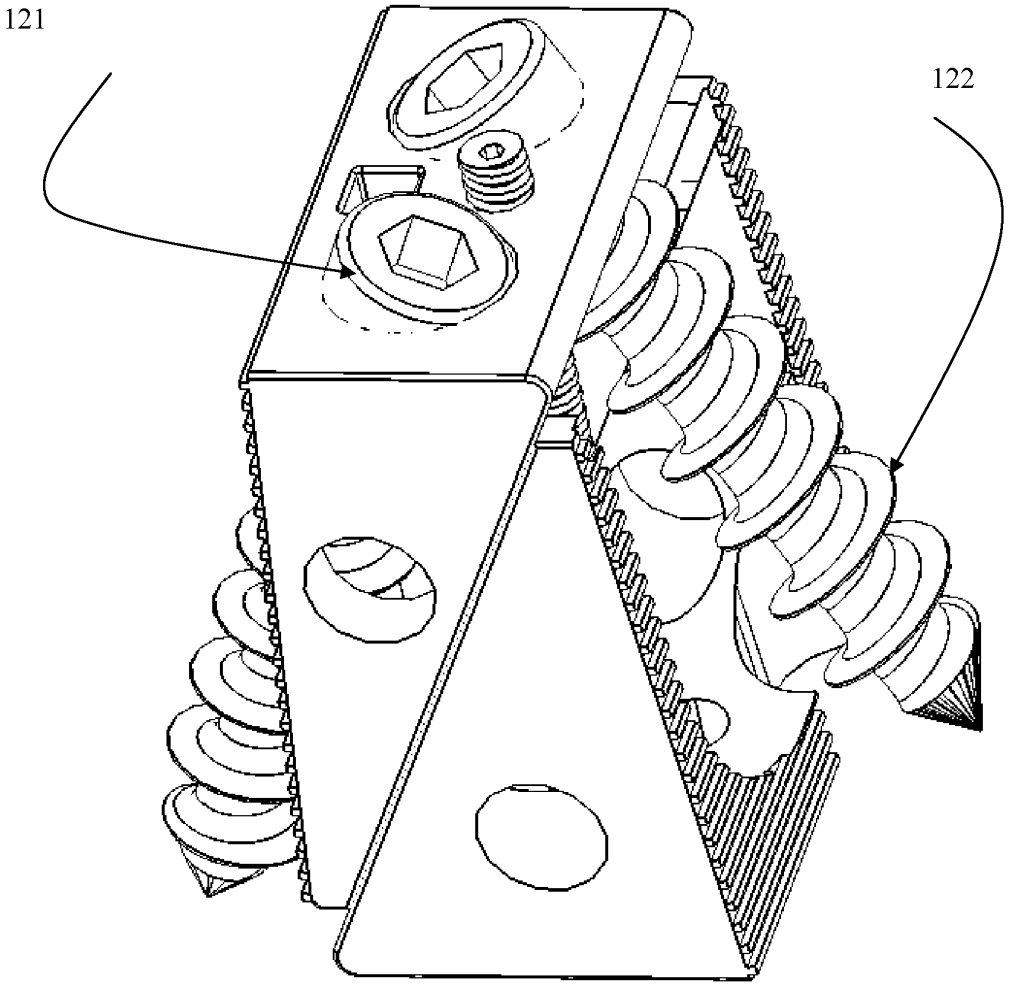


Fig. 1E

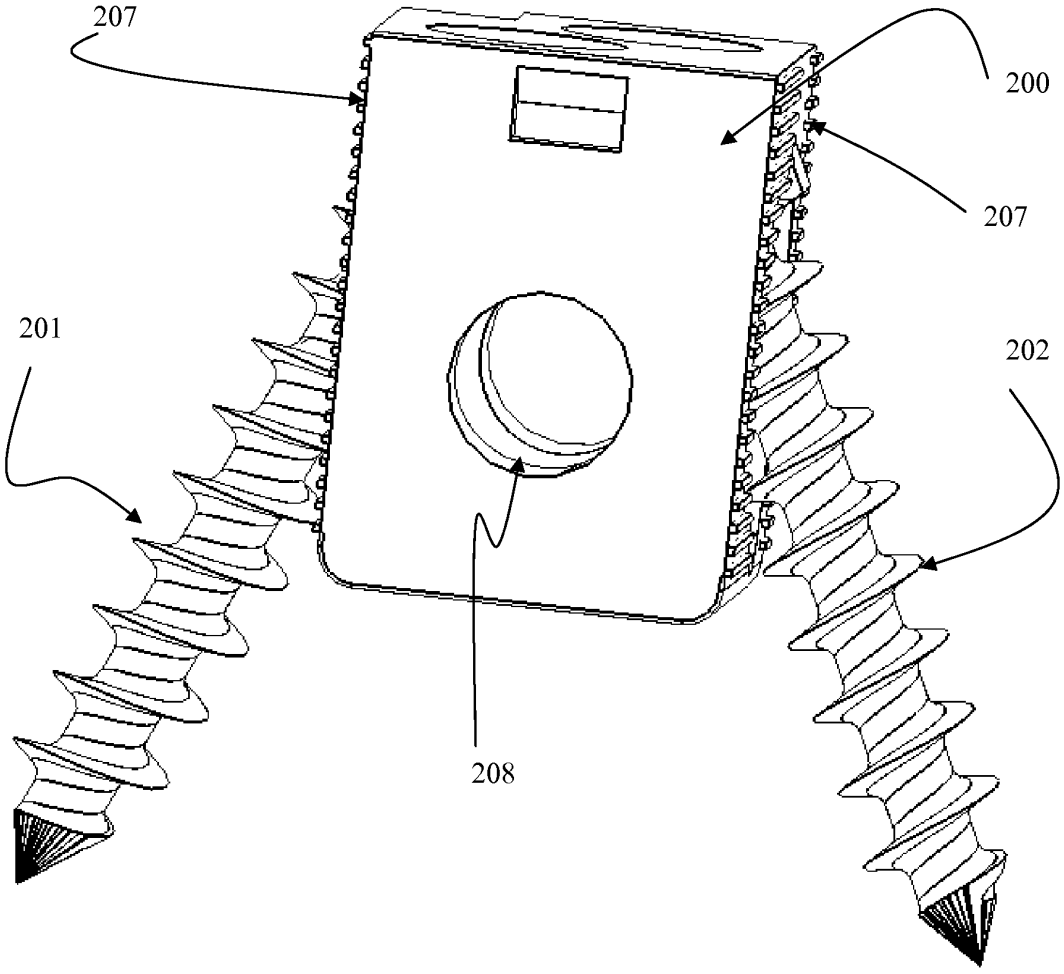


Fig. 2A

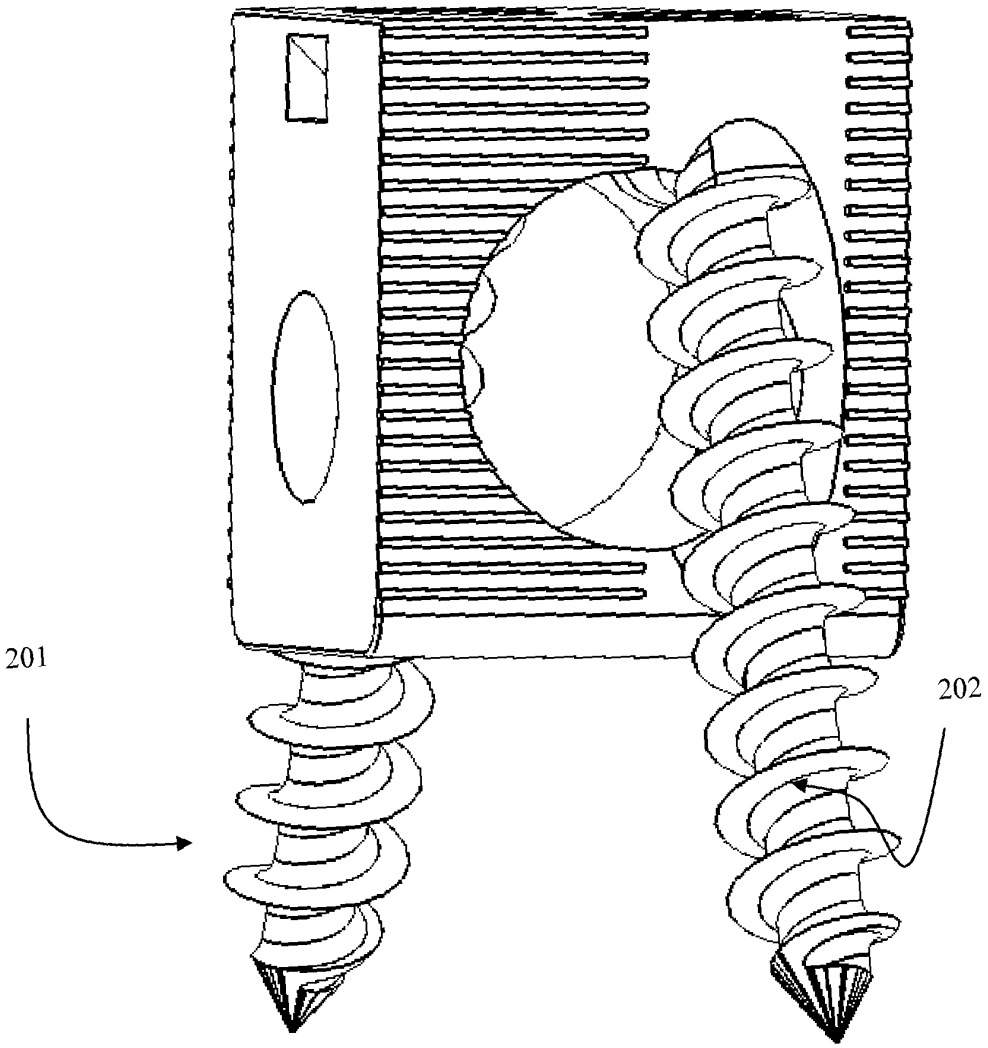


Fig. 2B

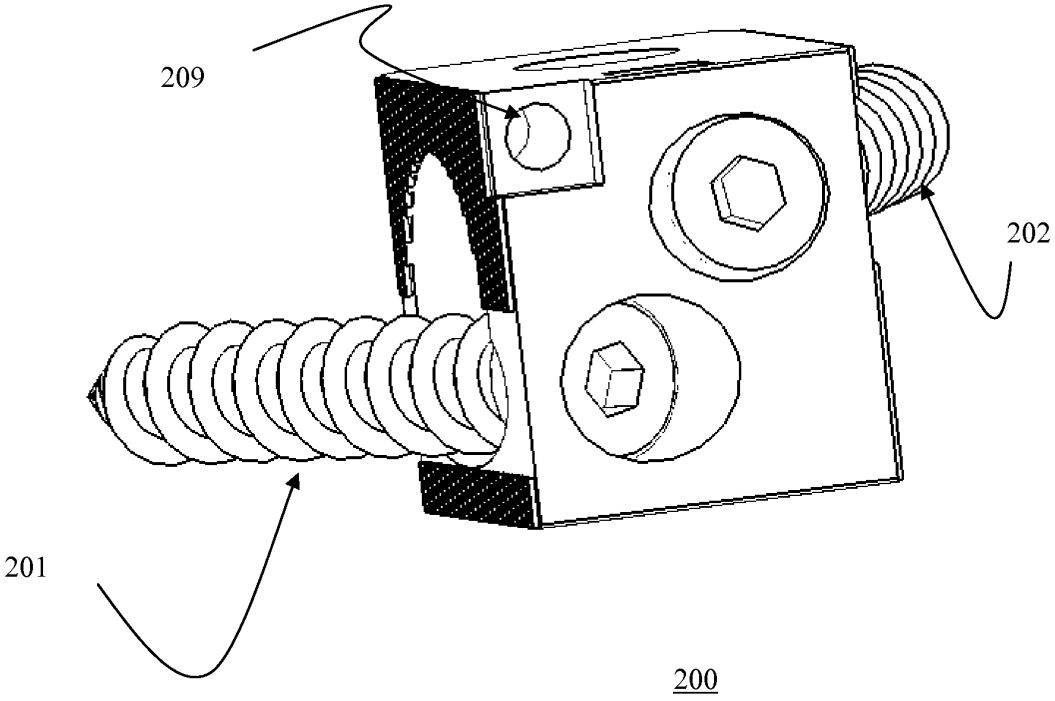


Fig. 2C

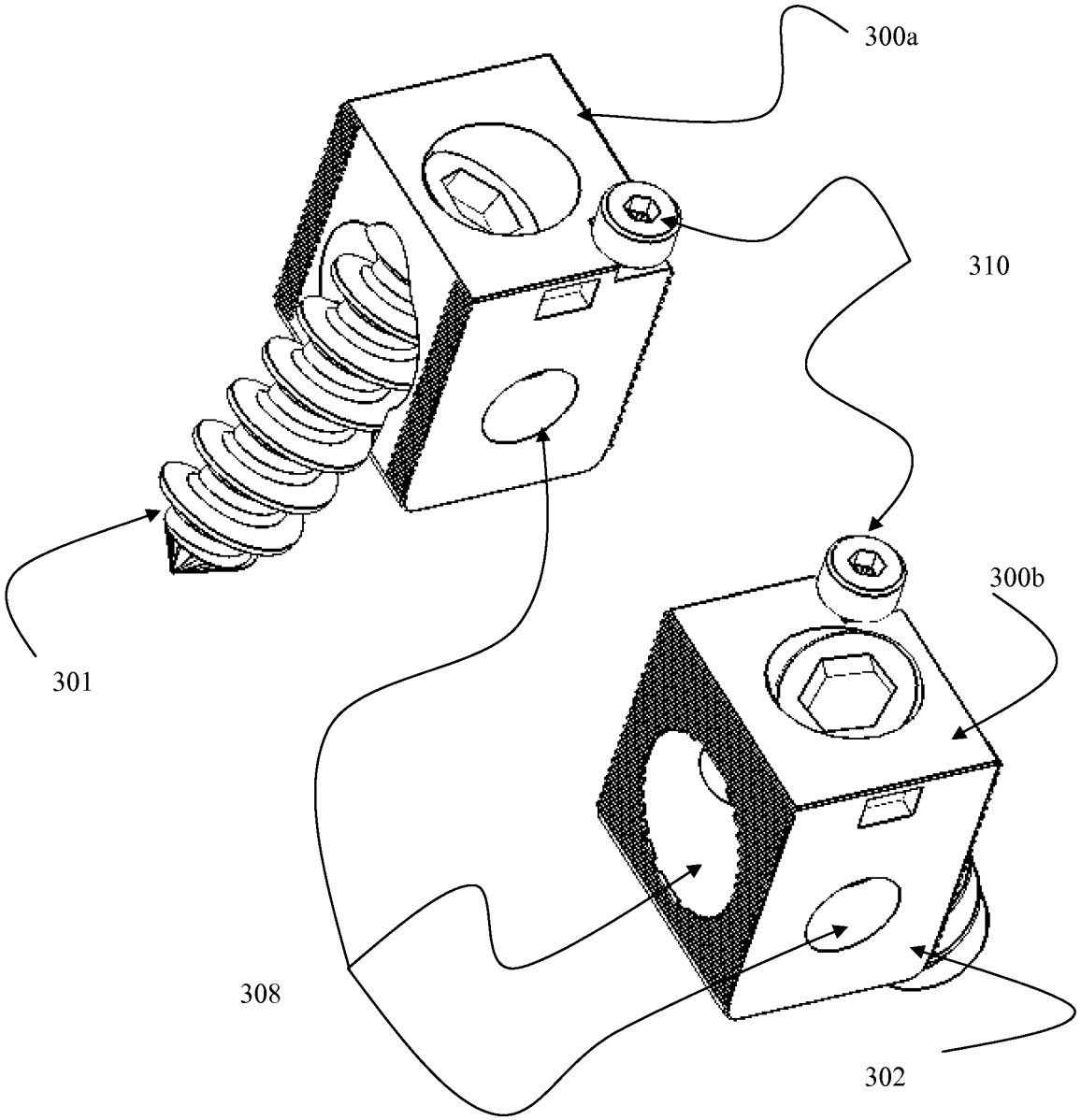


Fig. 3

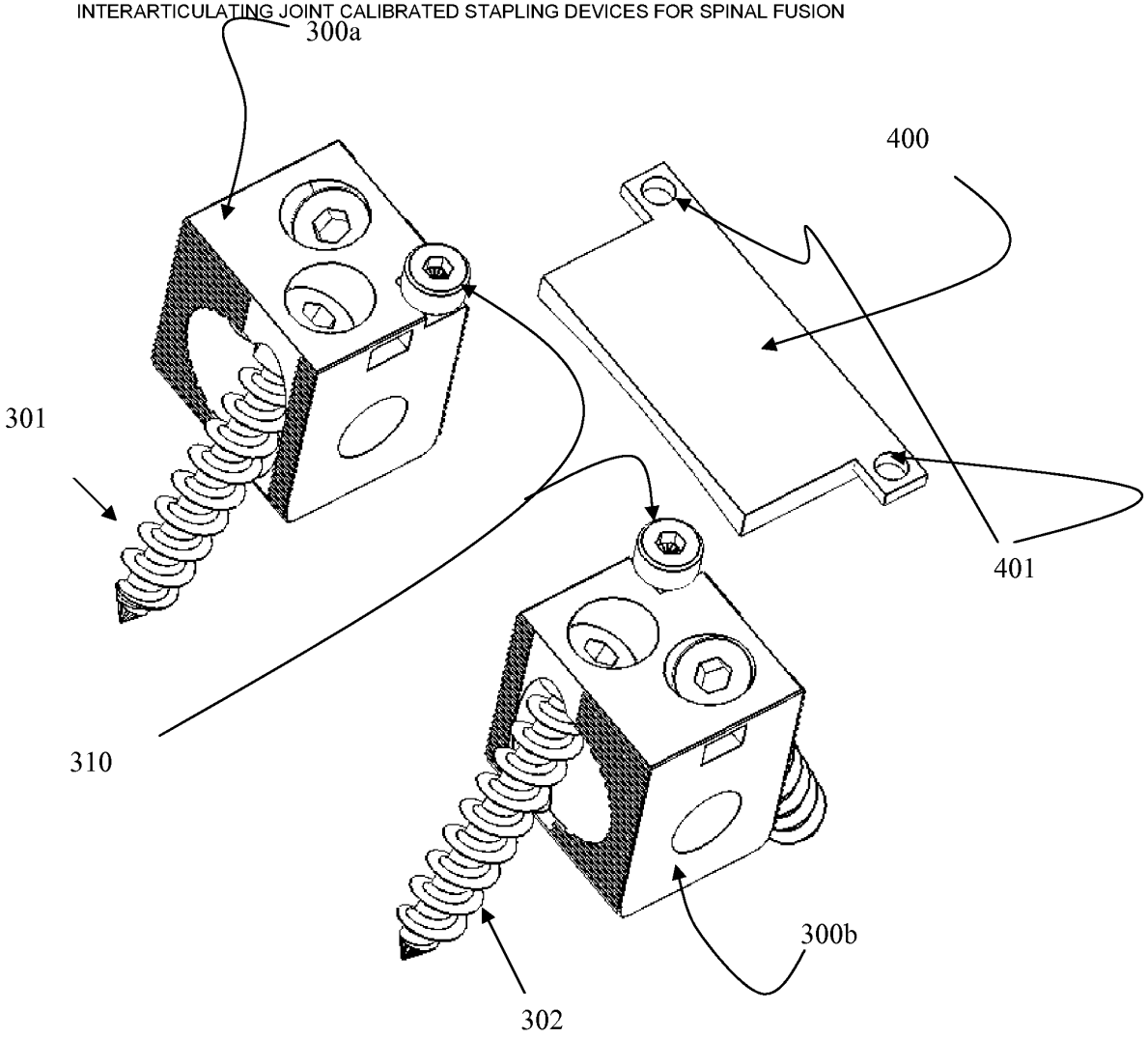


Fig. 4A

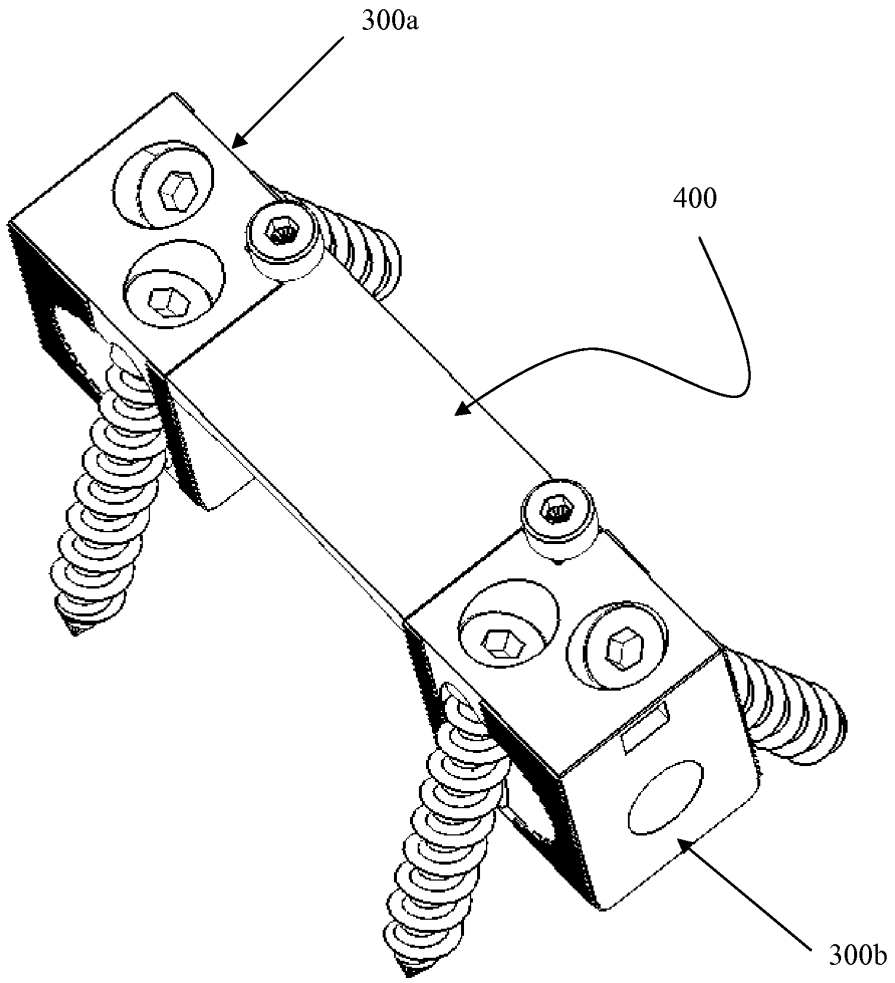


Fig. 4B

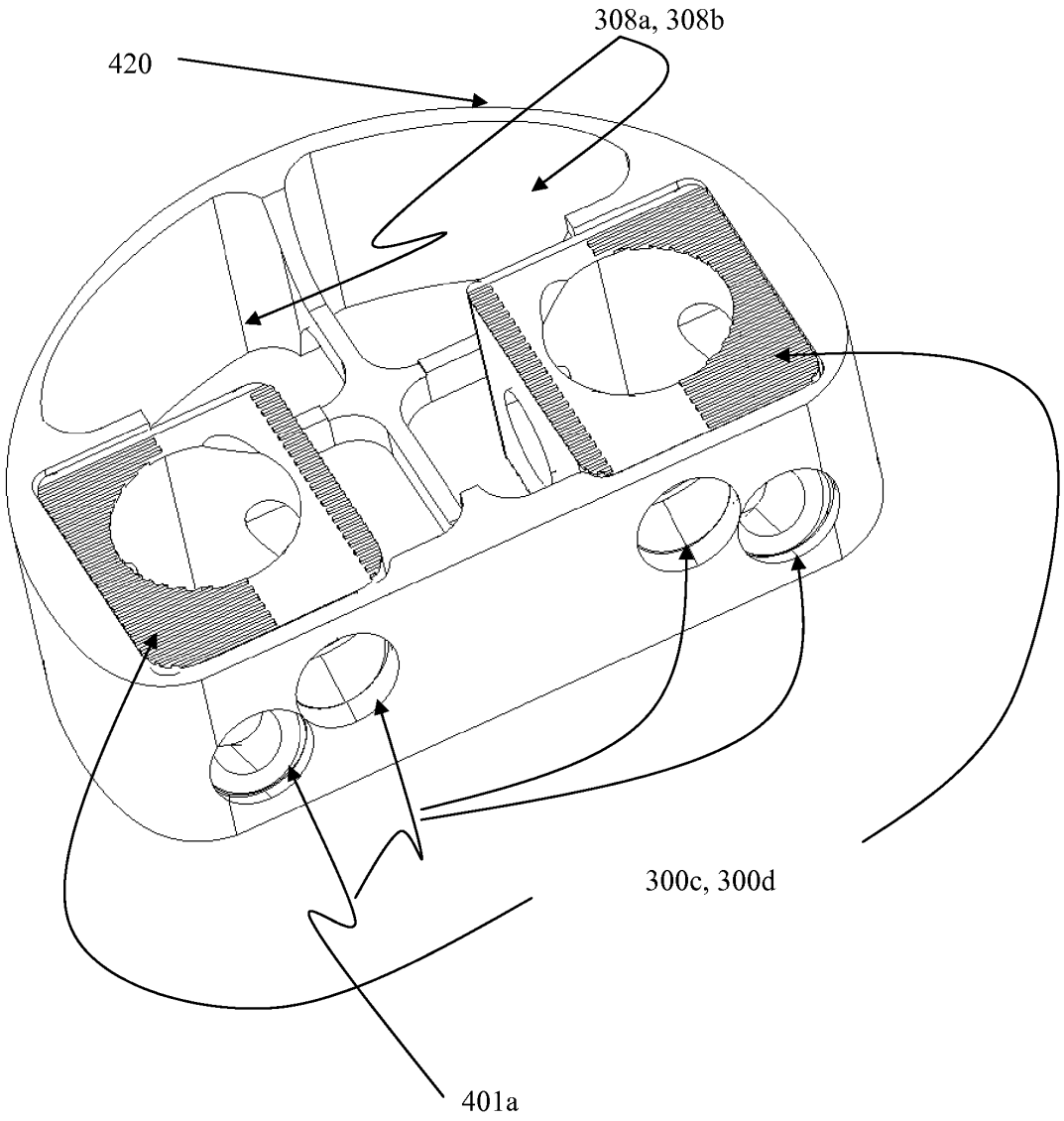


FIG. 4C

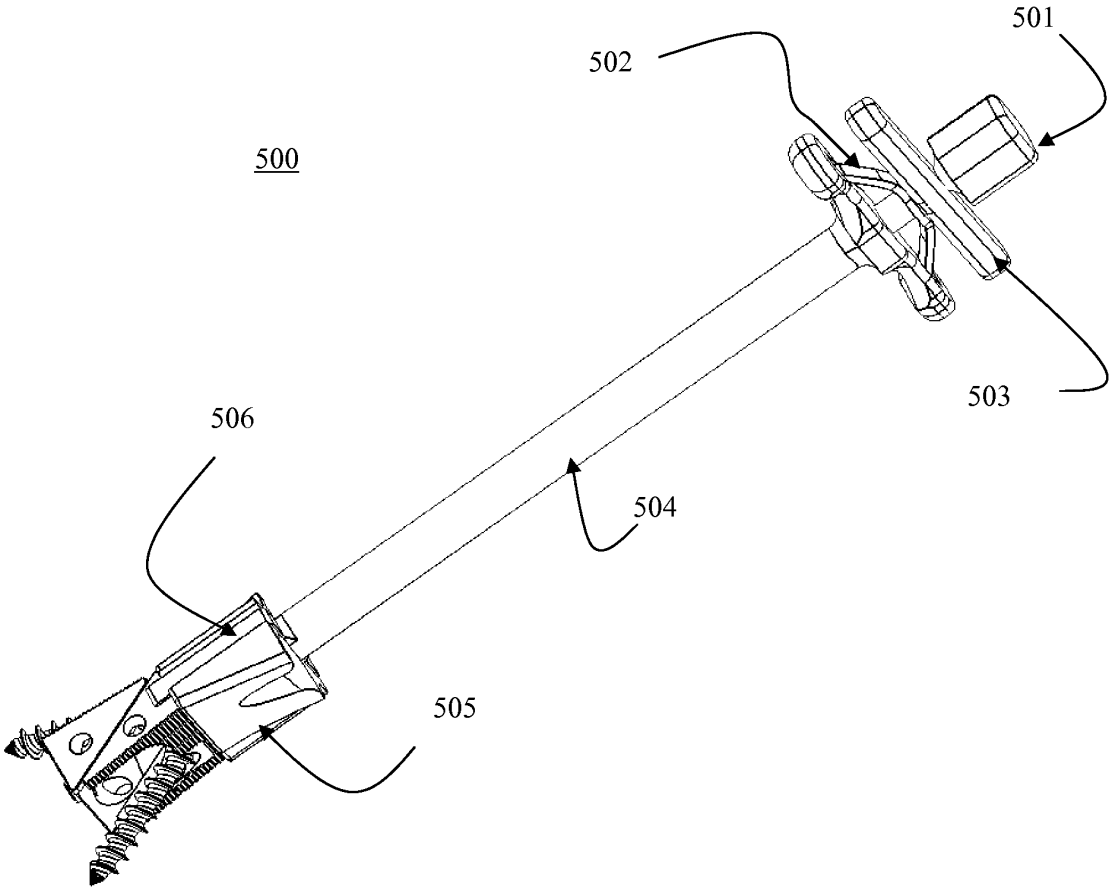


Fig. 5A

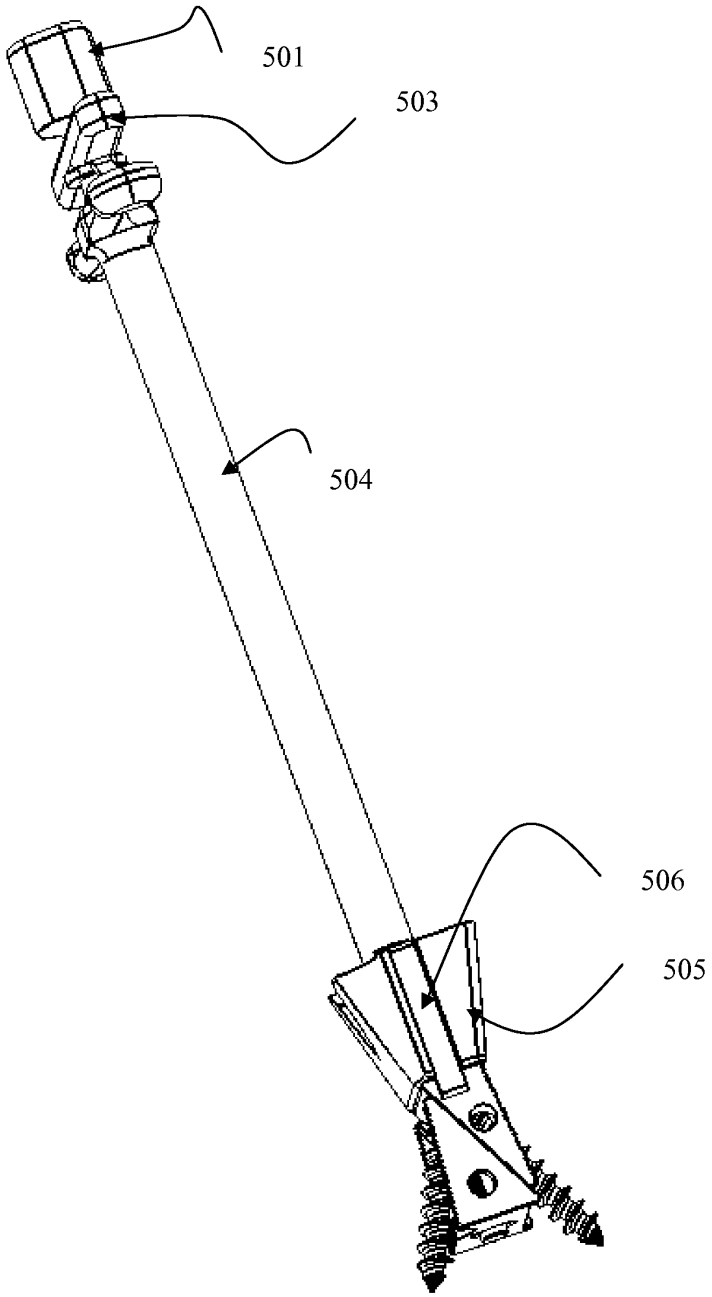


Fig. 5B

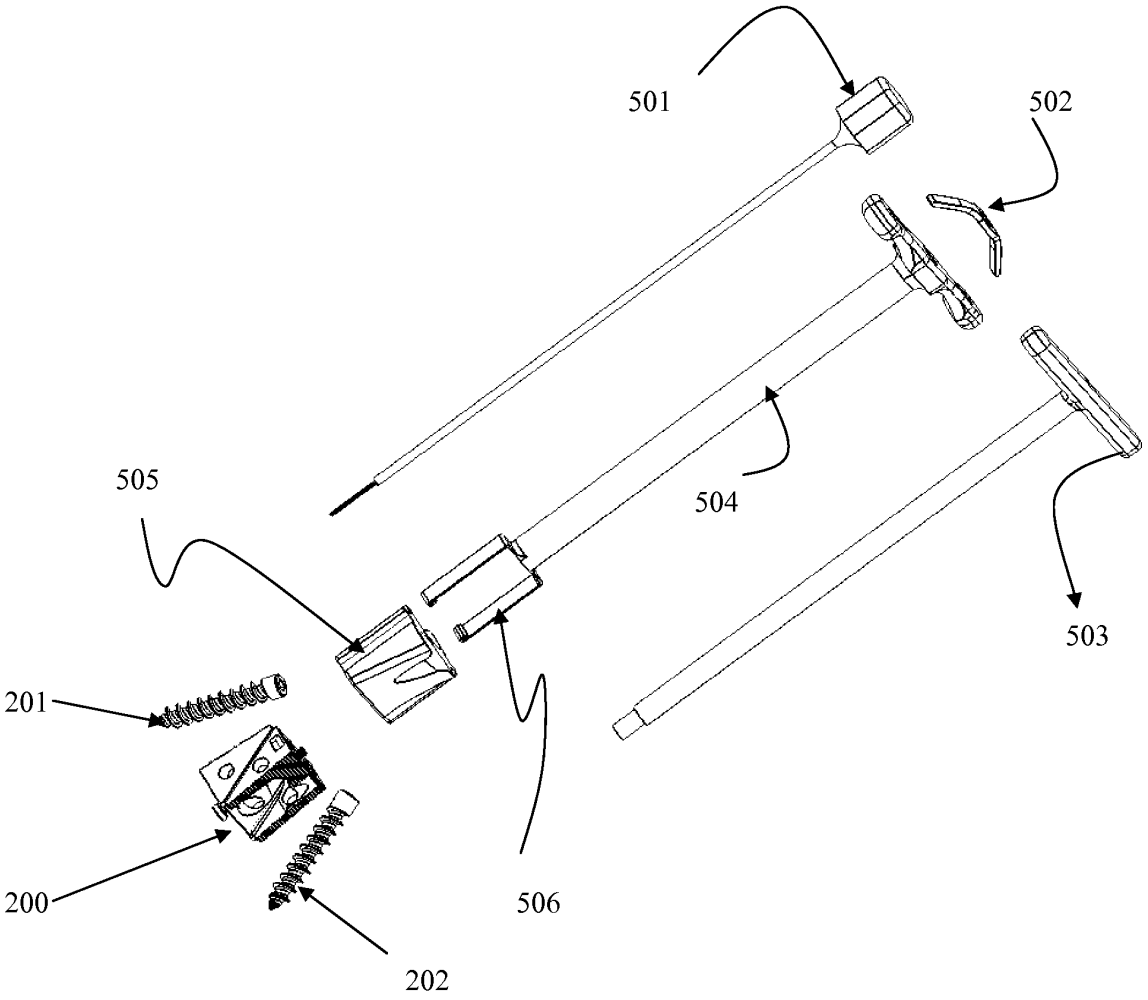


Fig. 5C

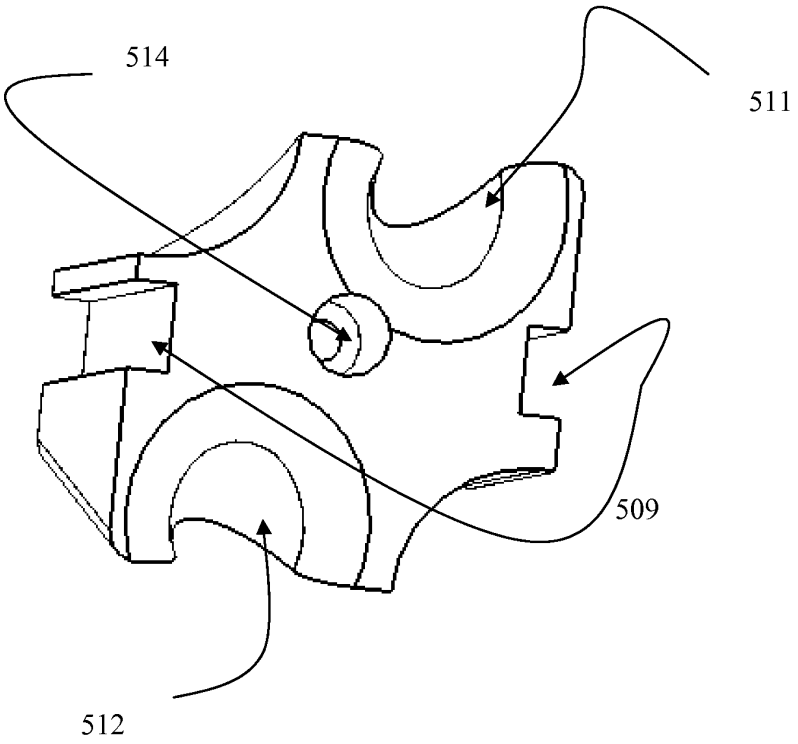


Fig. 5D

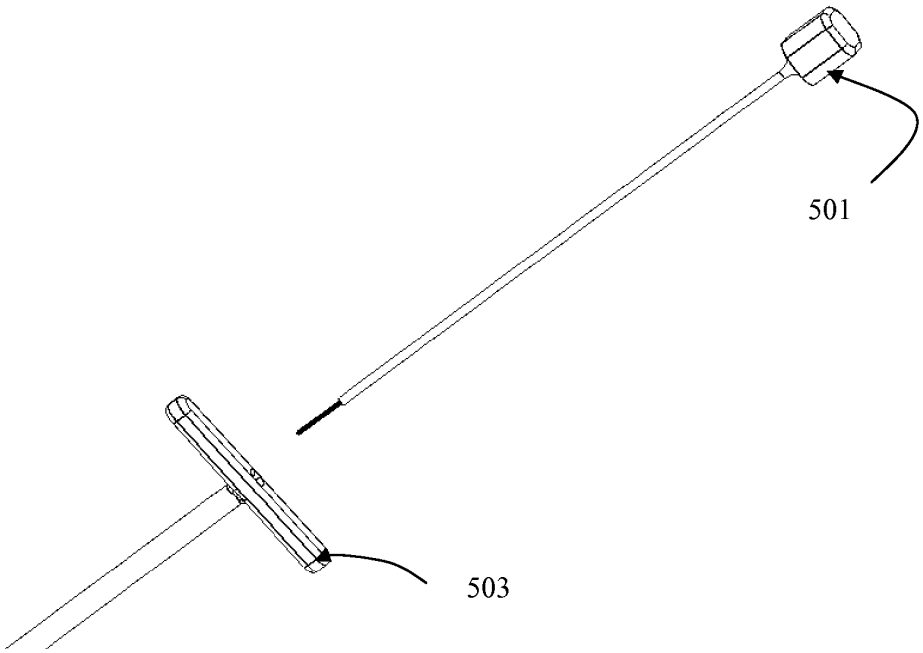


Fig. 5E

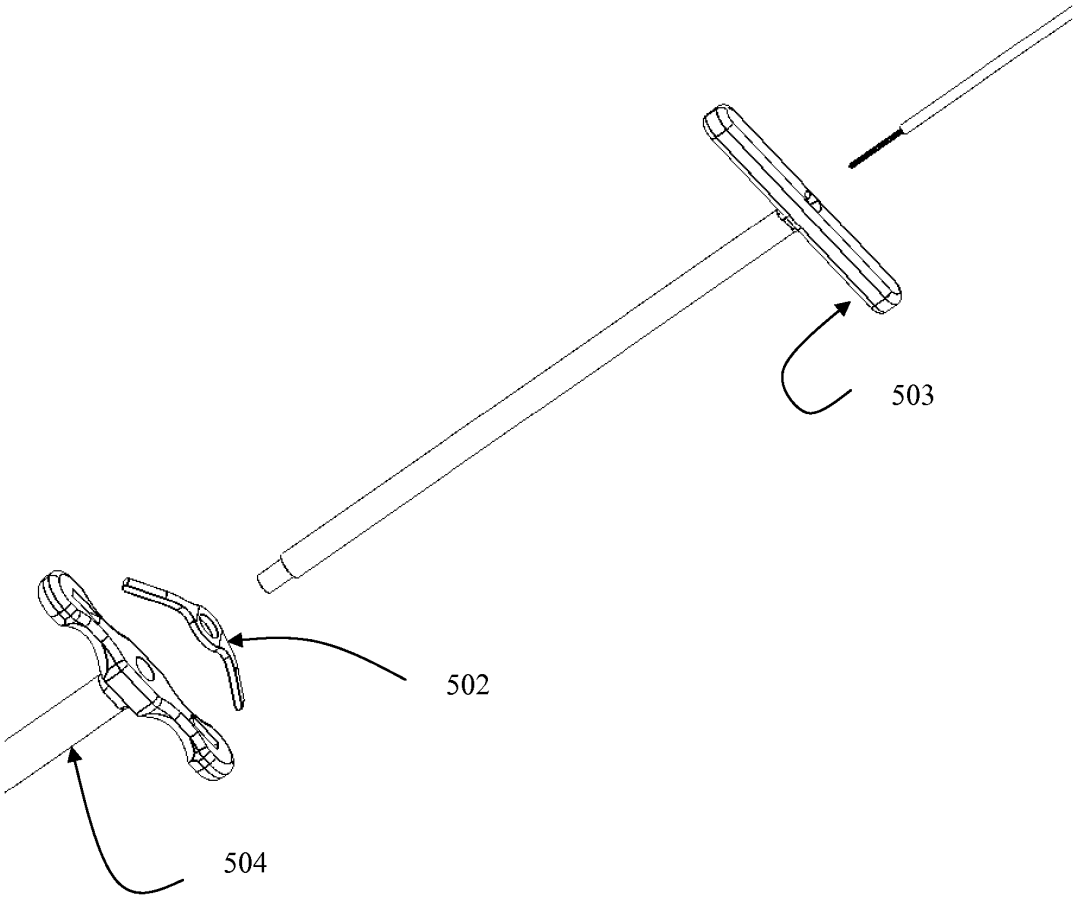


Fig. 5F

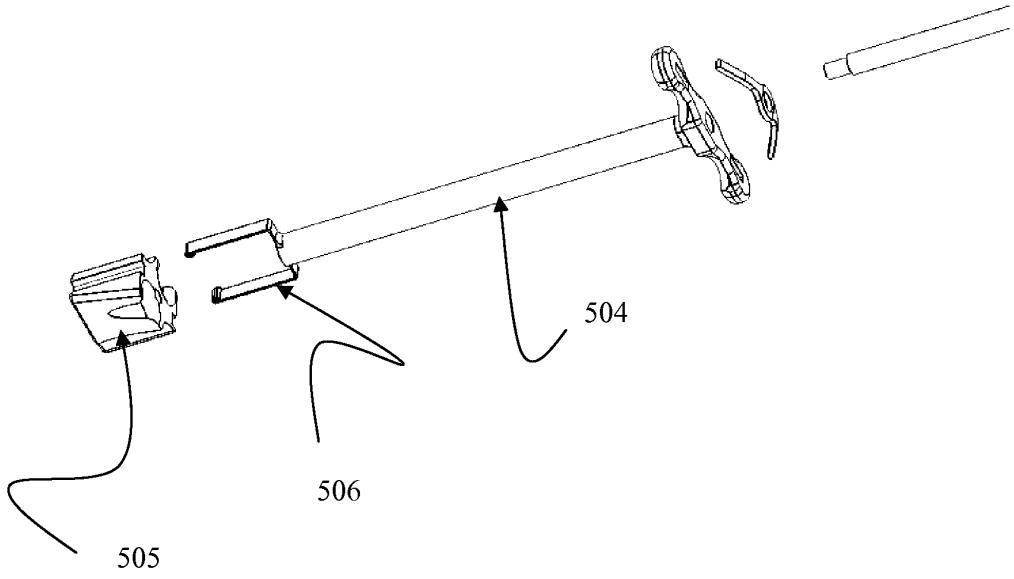


Fig. 5G

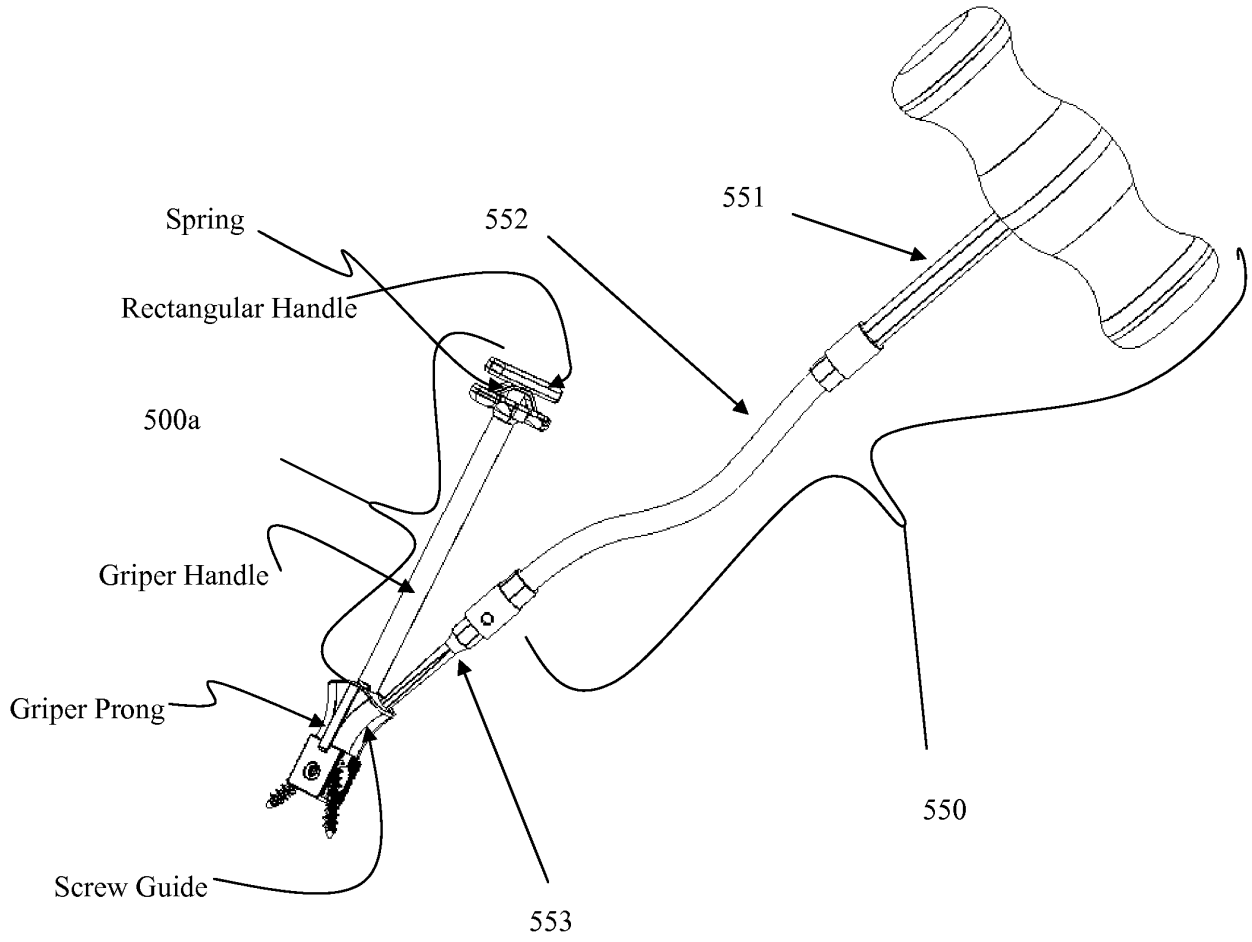

Spring
552
551
Rectangular Handle
500a
Griper Handle
Griper Prong
550
Screw Guide
553

FIG. 5H

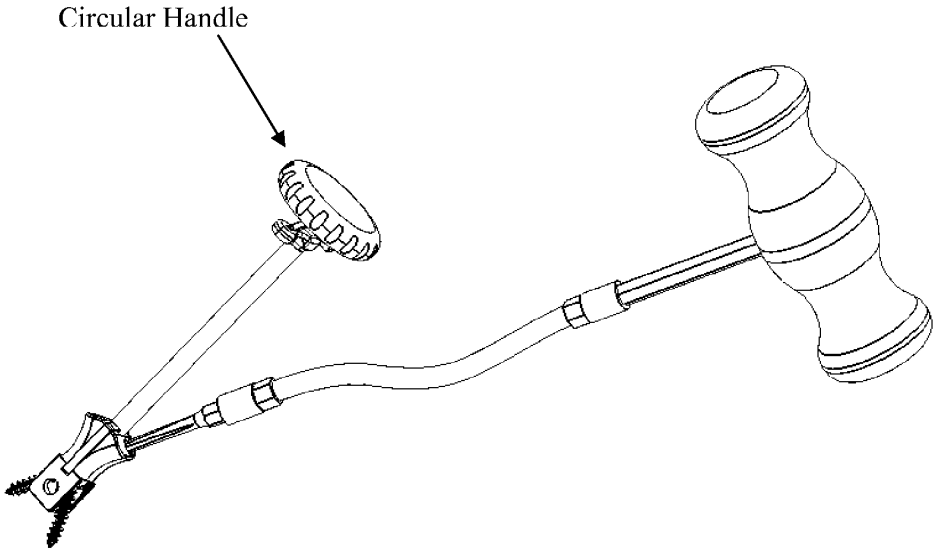


FIG. 5I

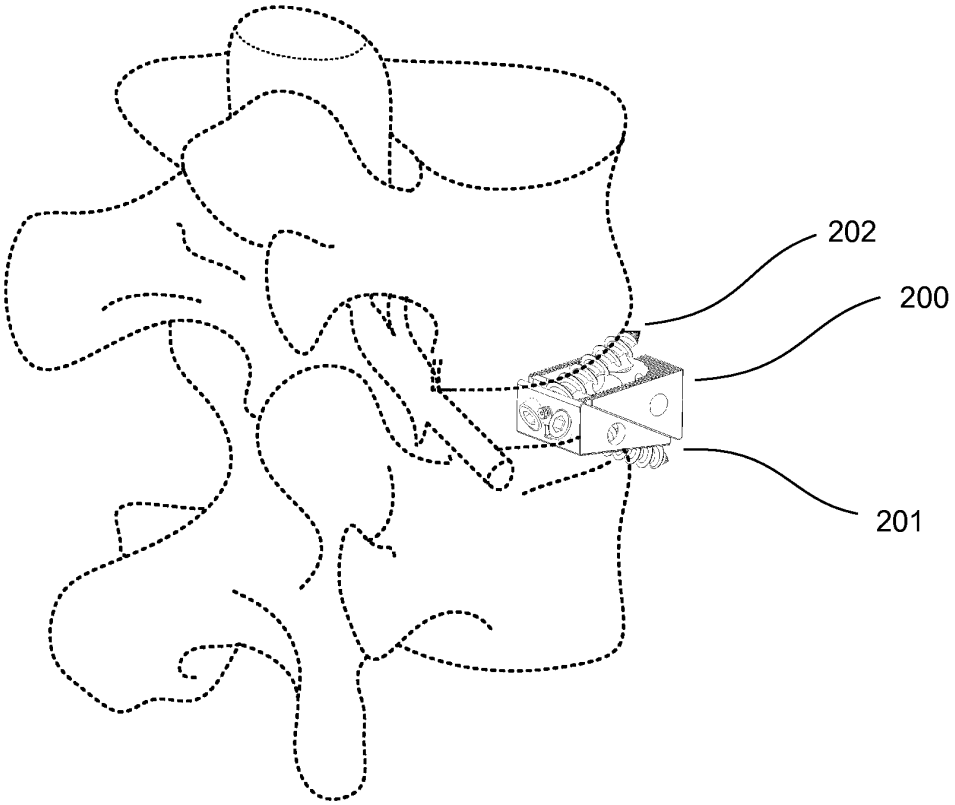


Fig. 6A

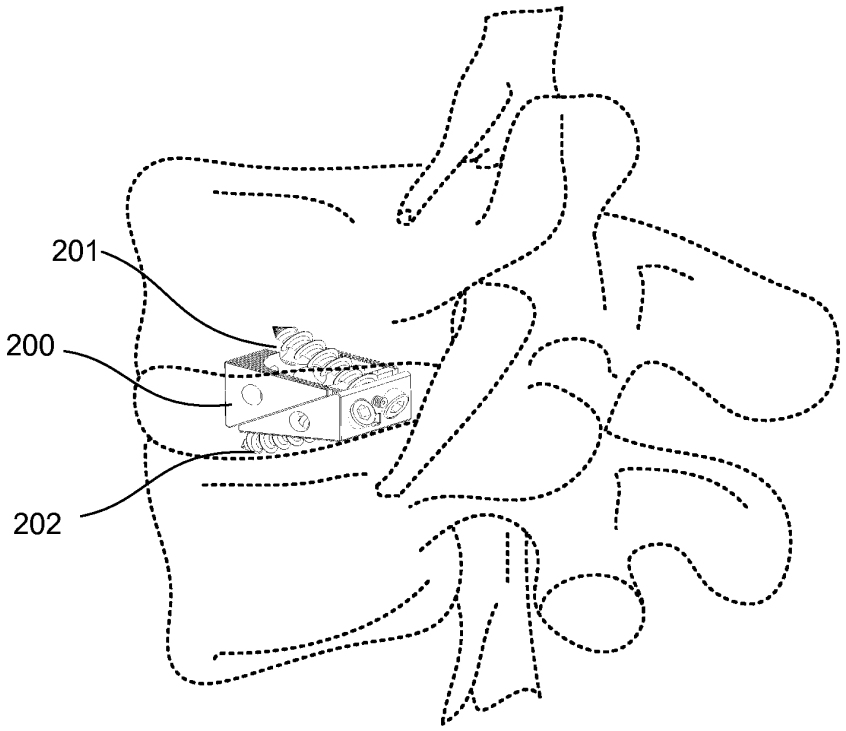


Fig. 6B

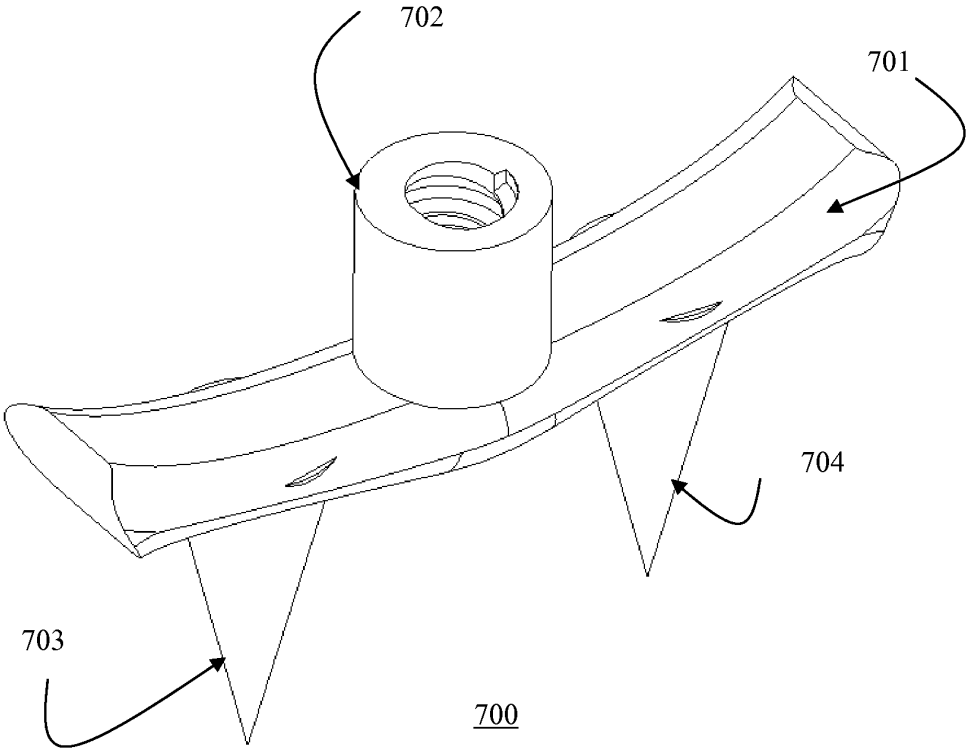
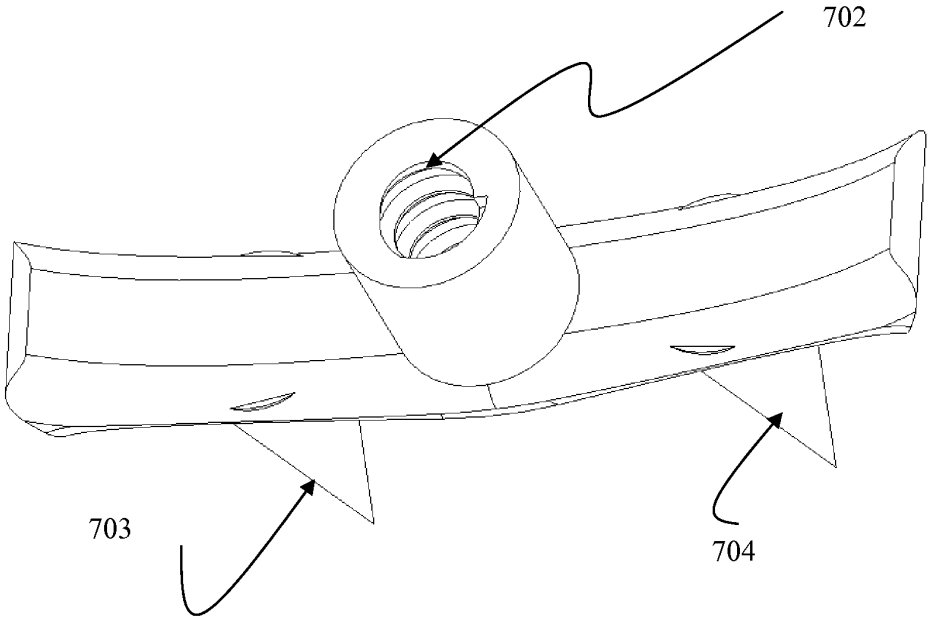
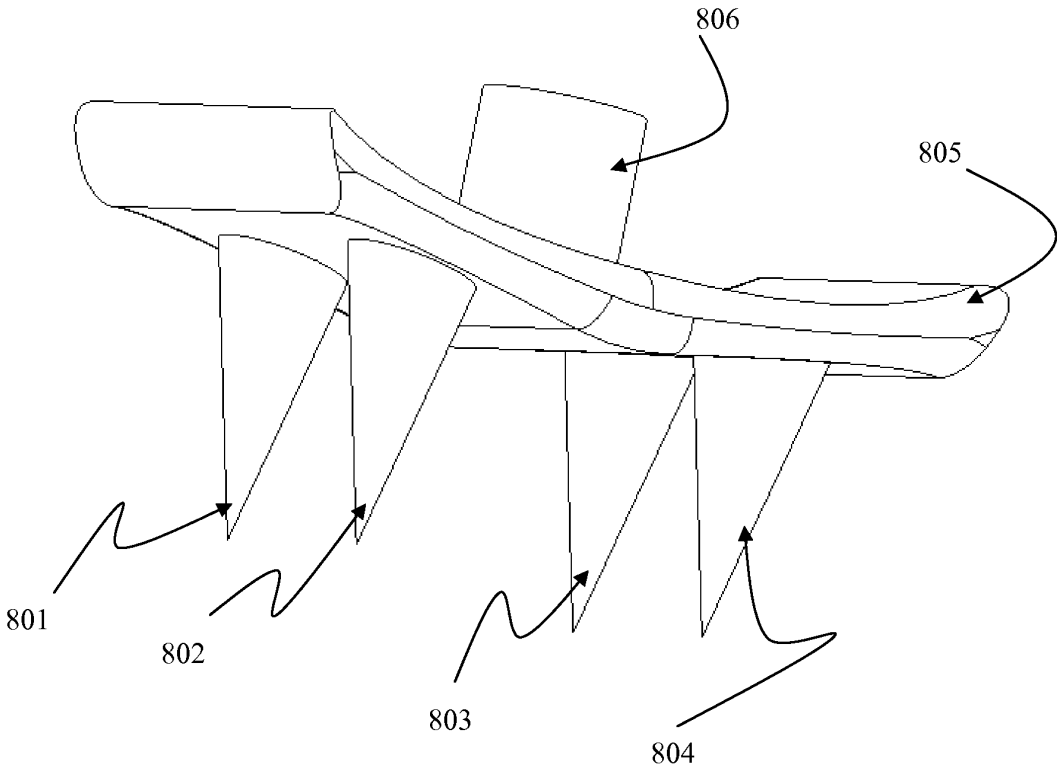


Fig. 7A



700

Fig. 7B



800

Fig. 8A

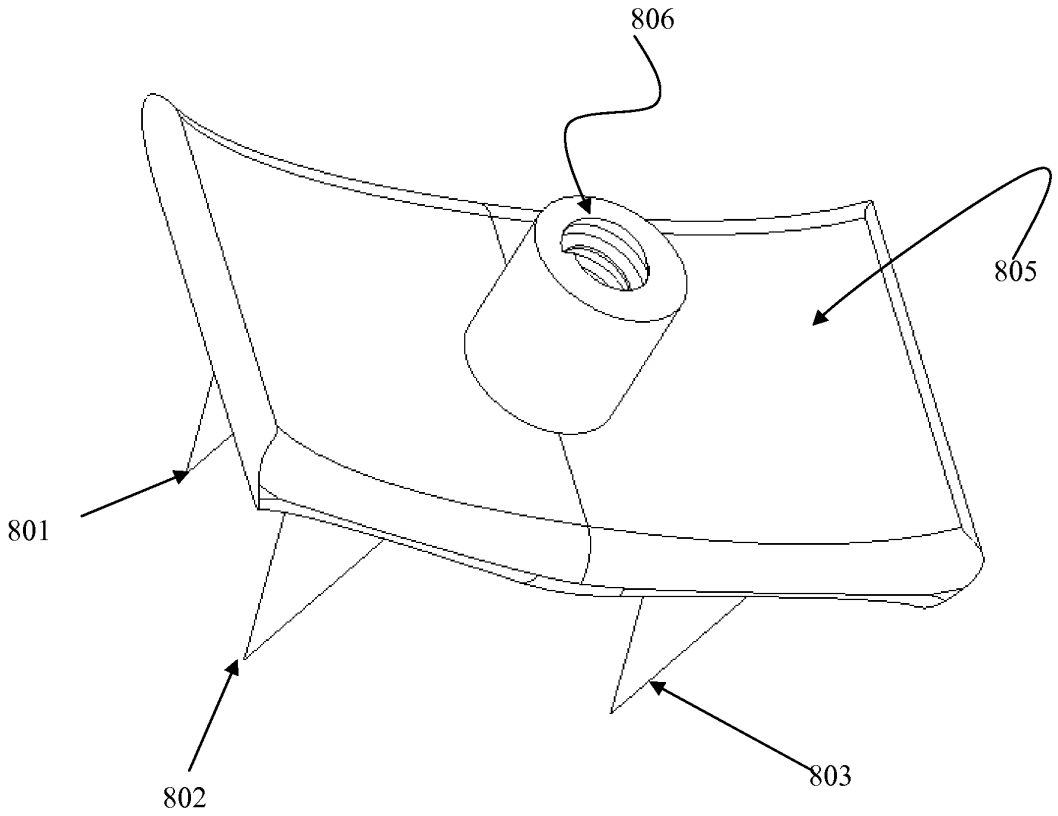
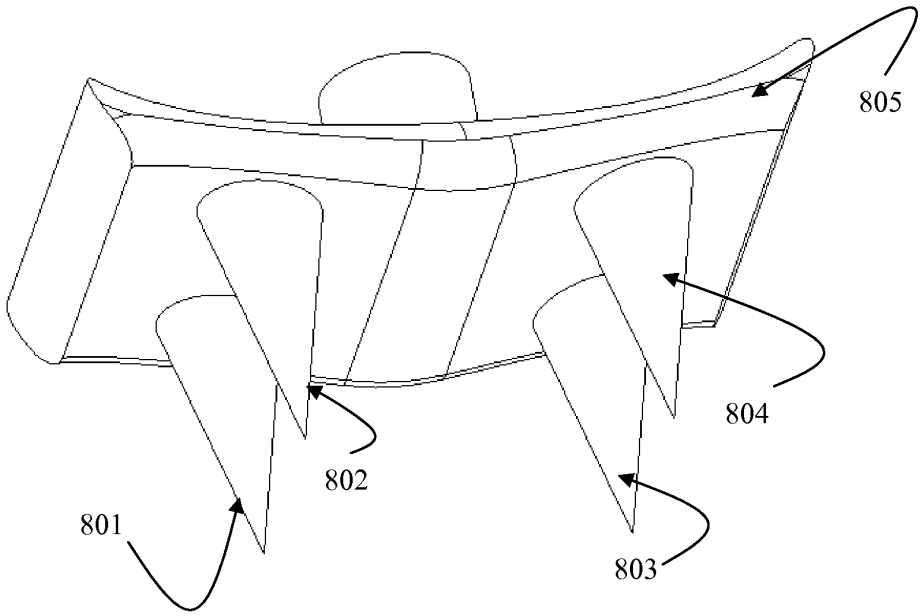


Fig. 8B



800

Fig. 8C

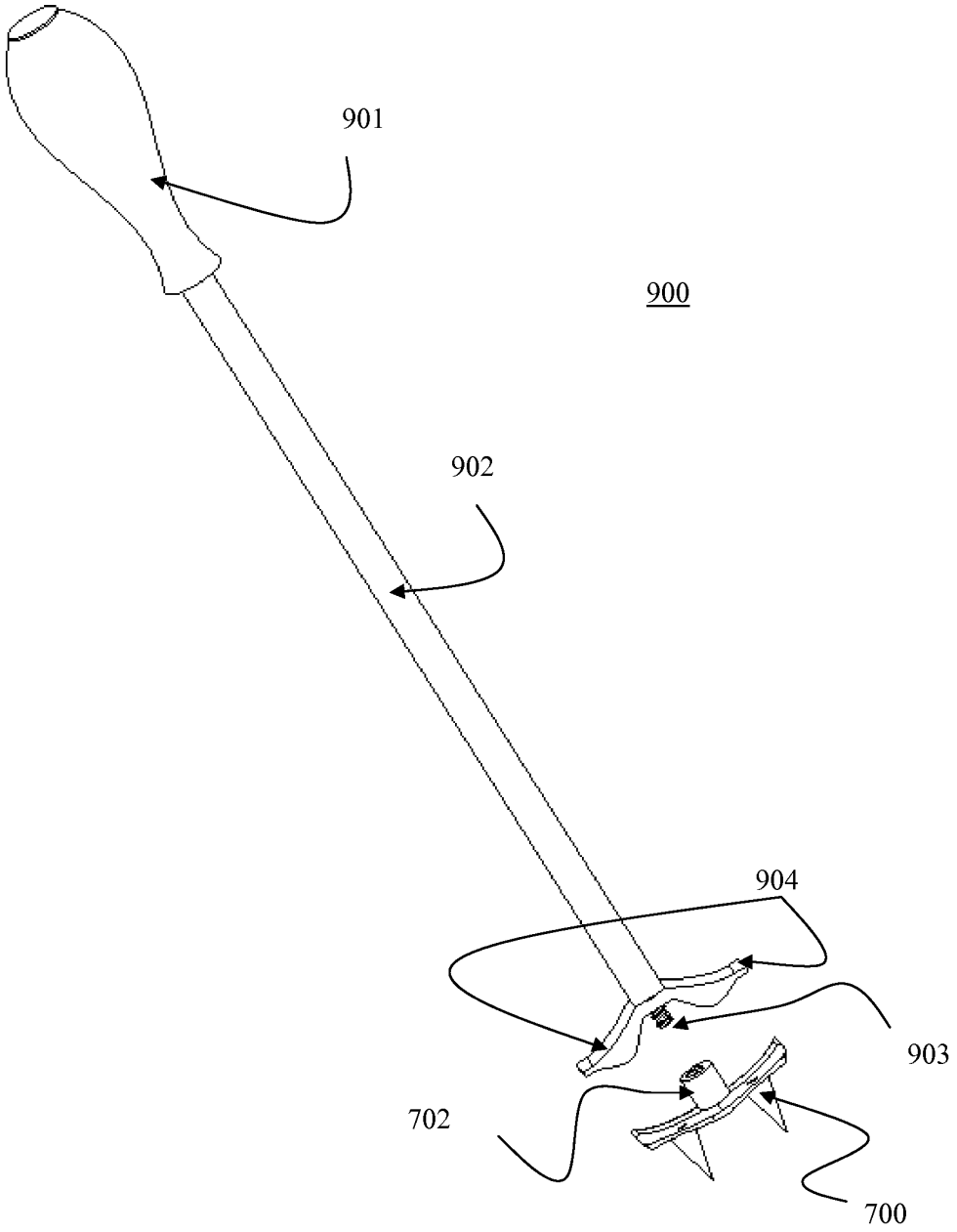


Fig. 9A

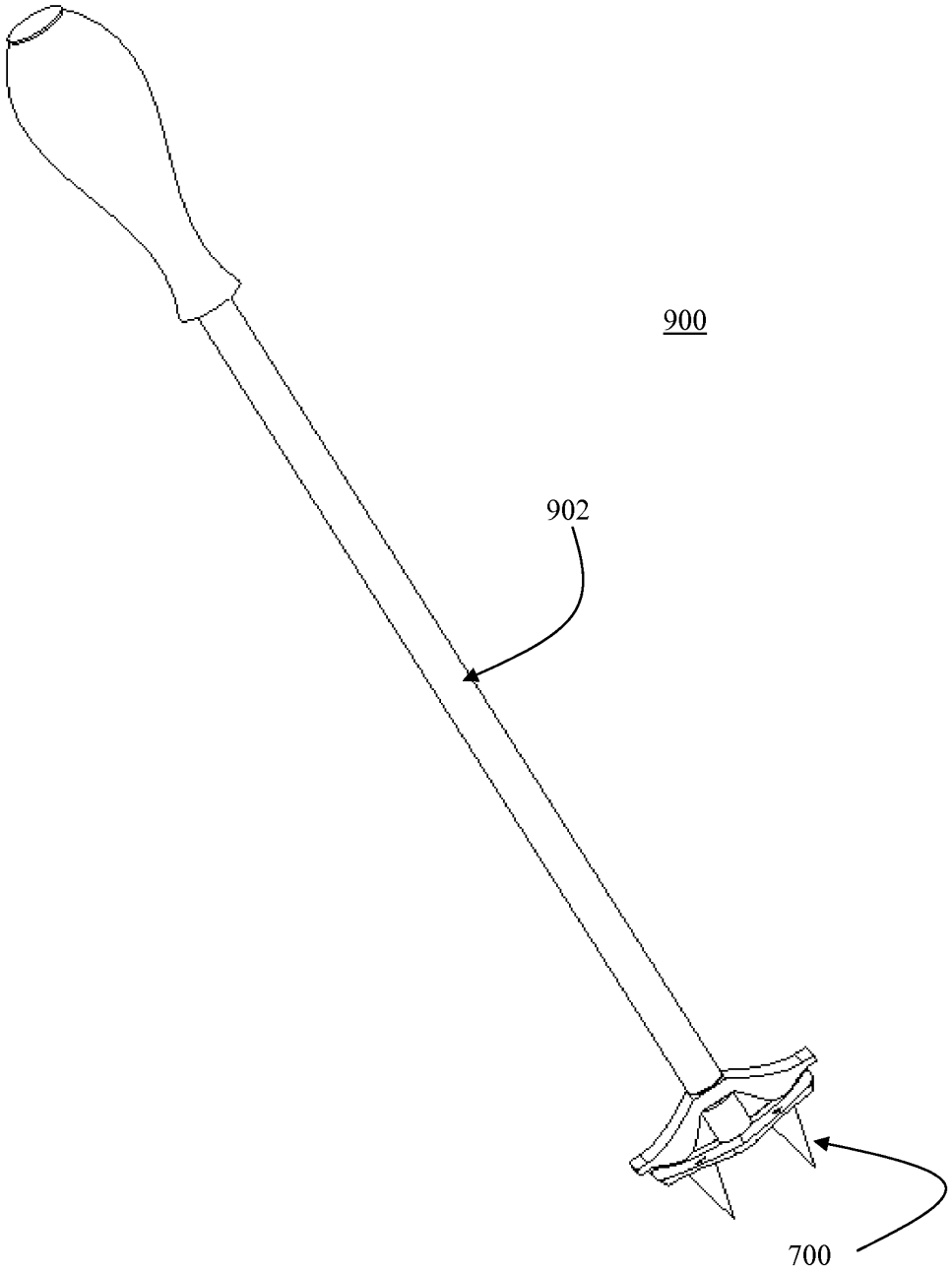


Fig. 9B

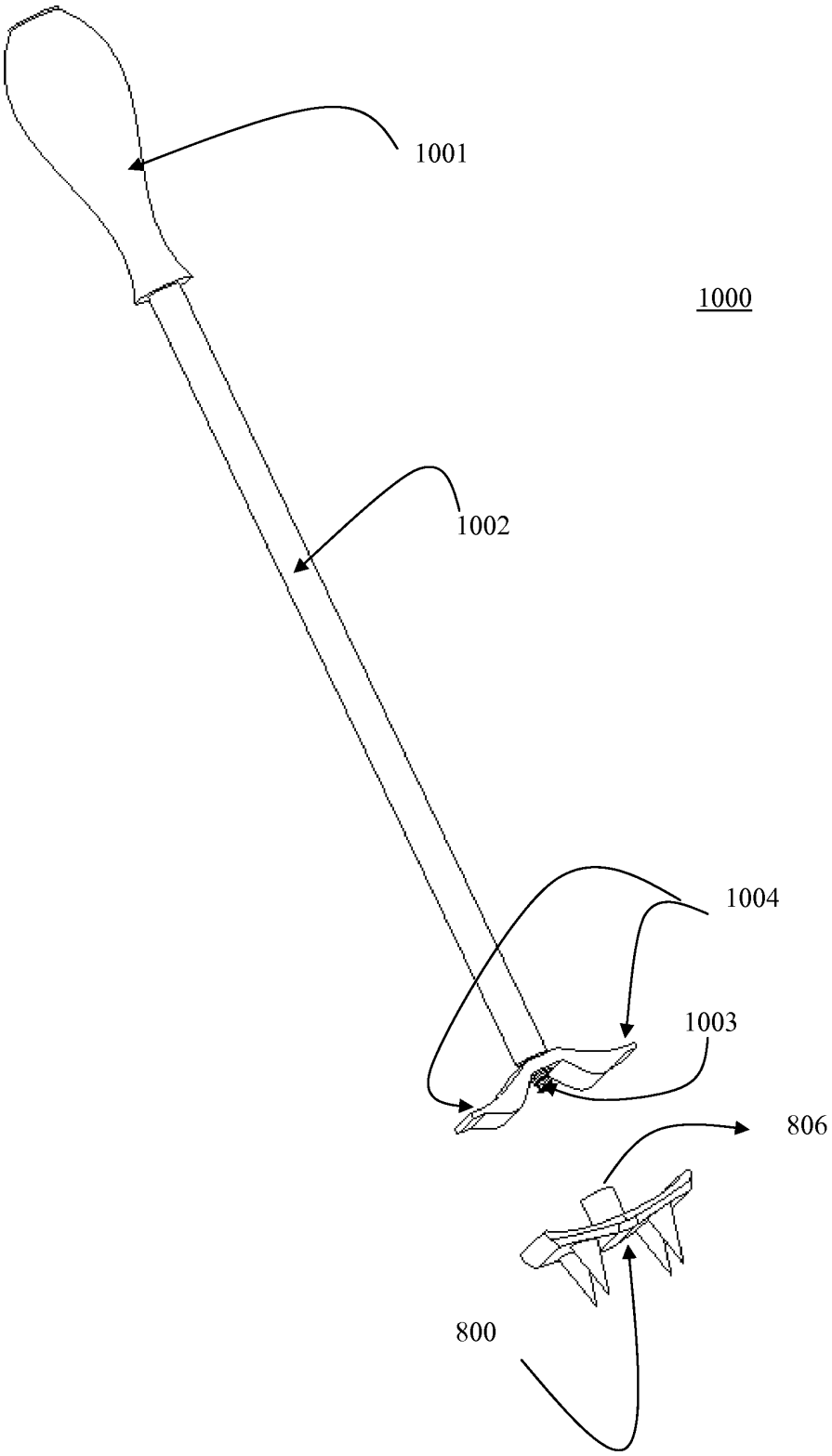


Fig. 10A

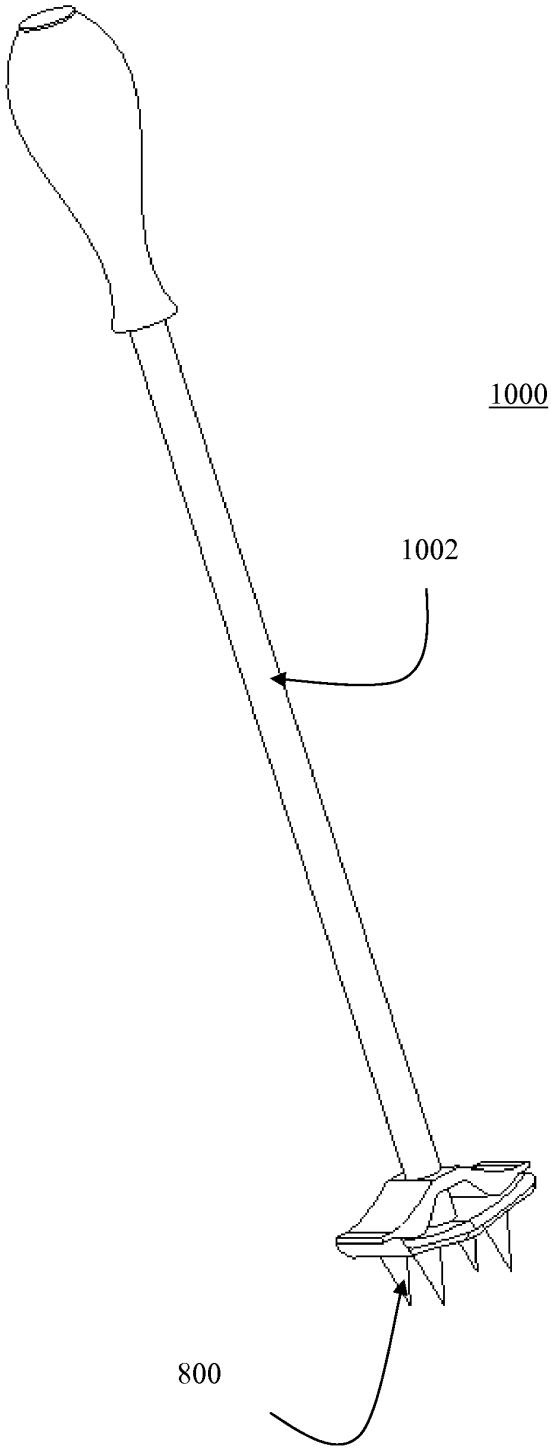


Fig. 10B

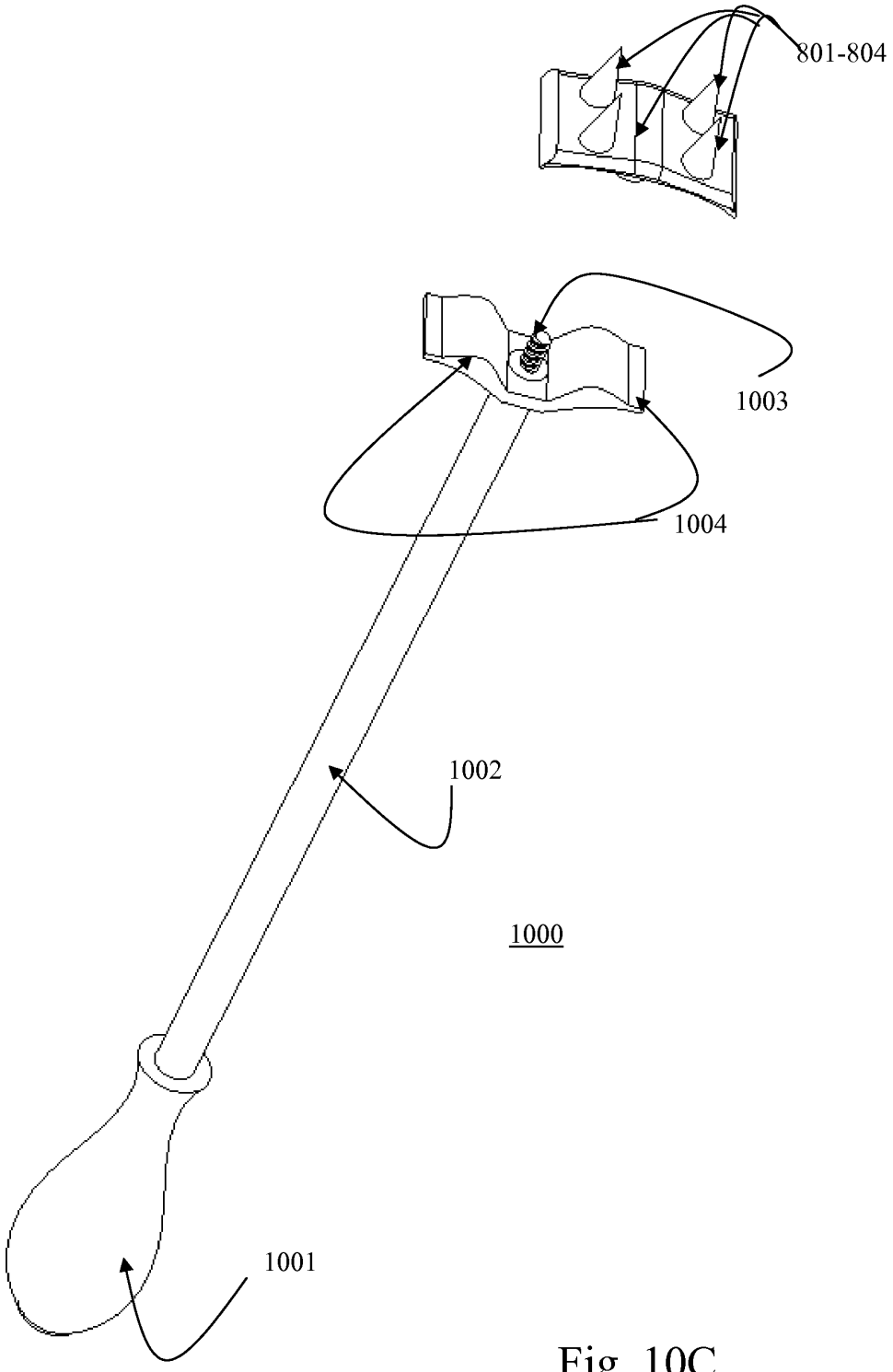


Fig. 10C

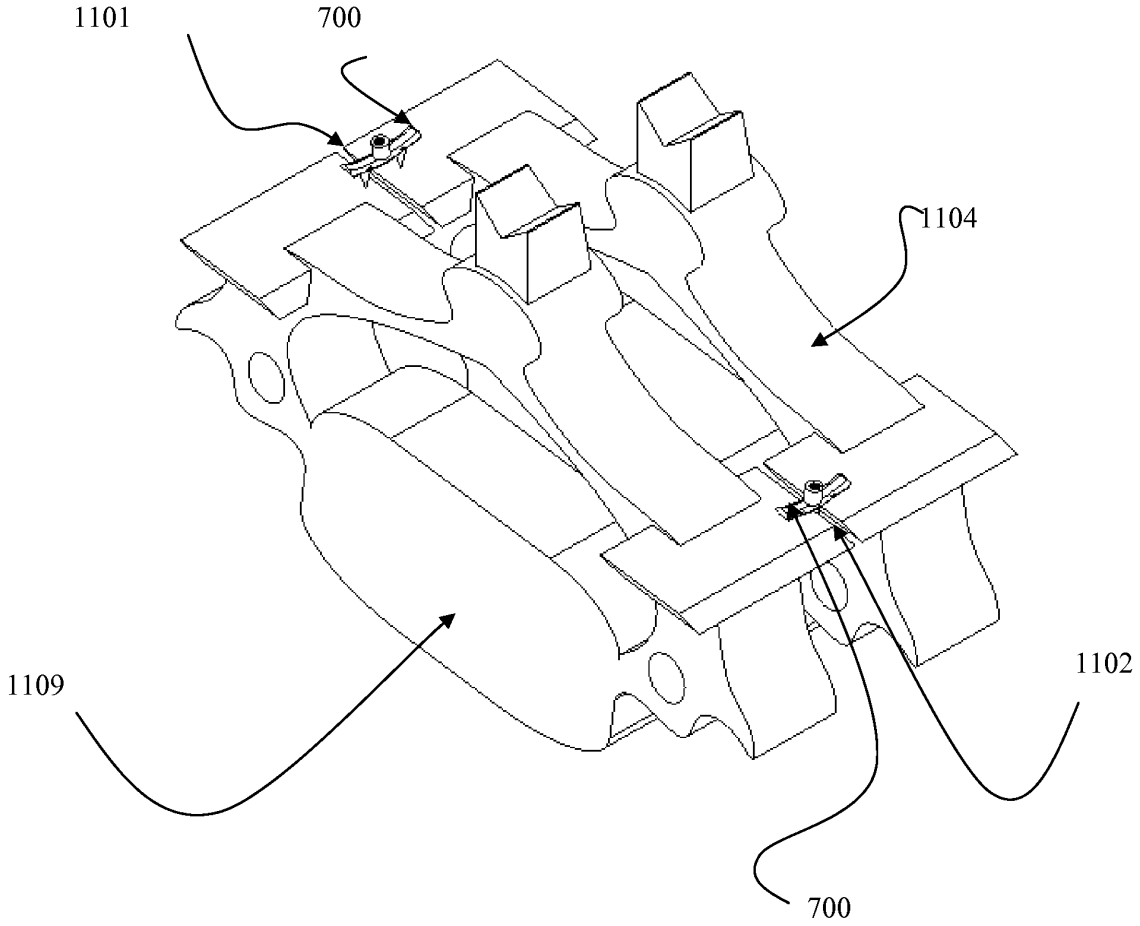


Fig. 11A

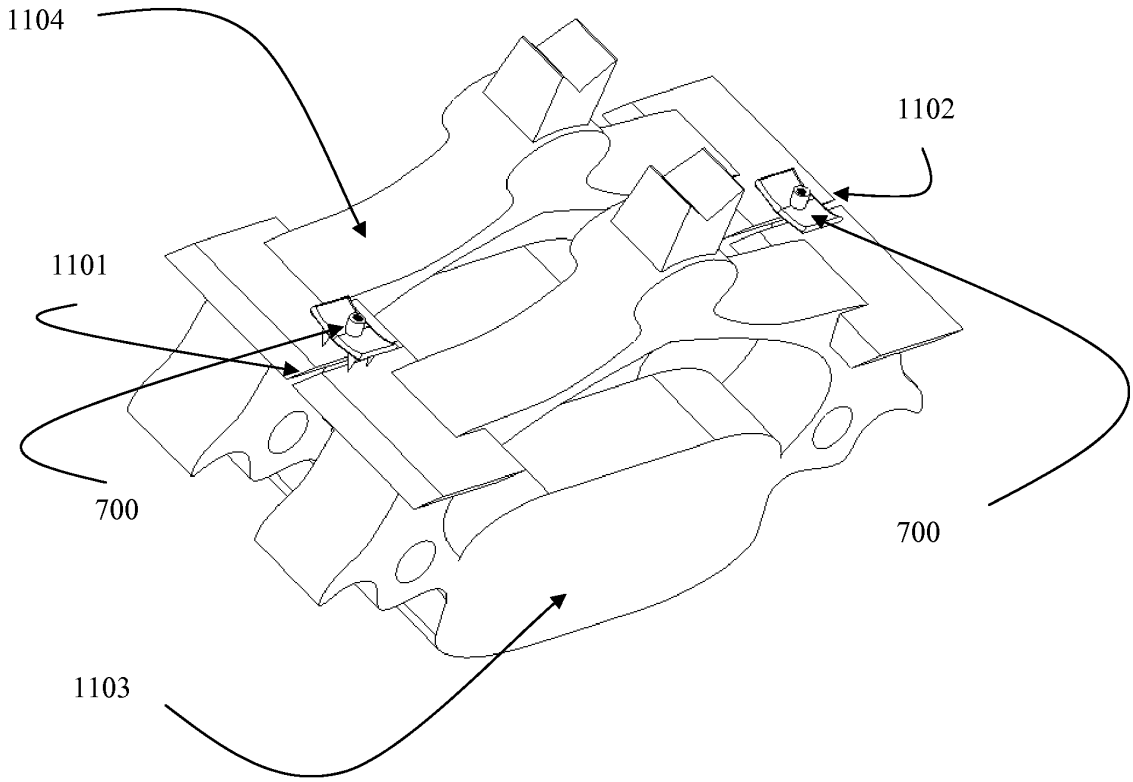


Fig. 11B

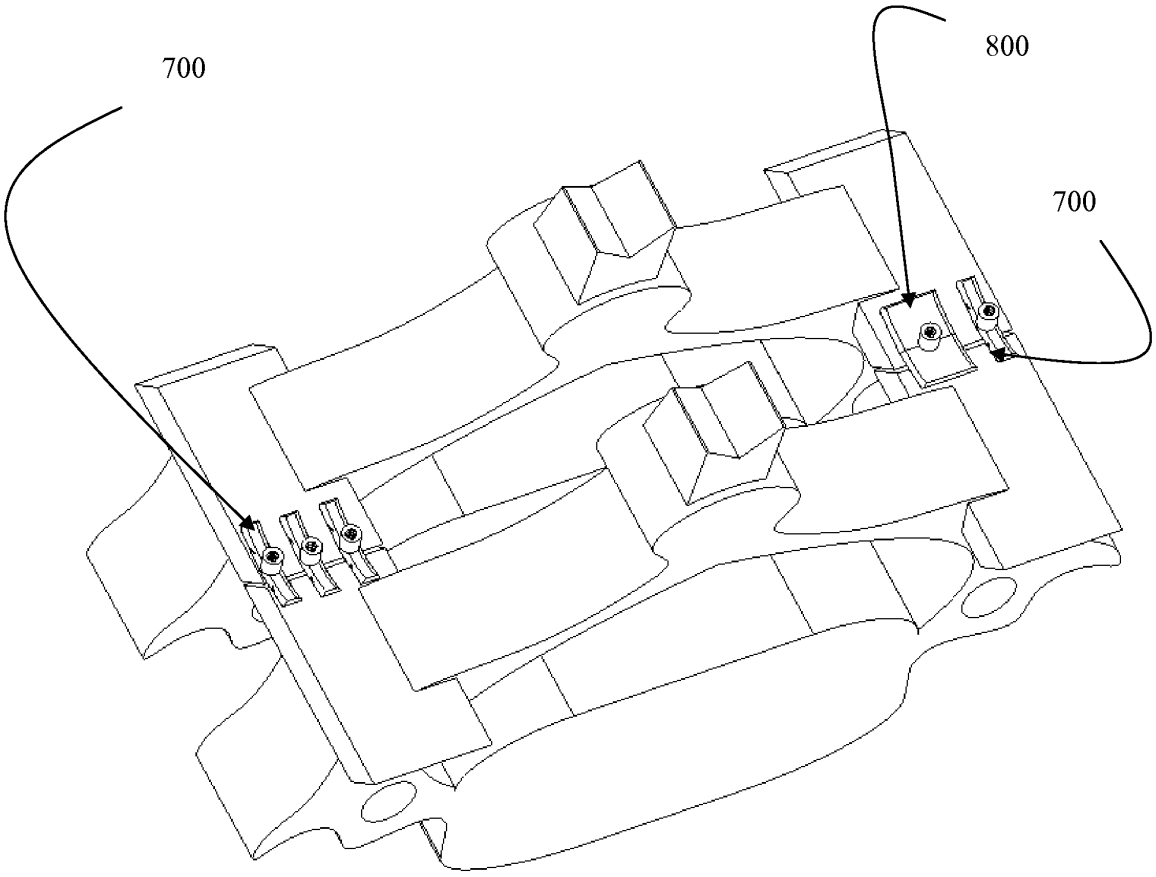


Fig. 11C

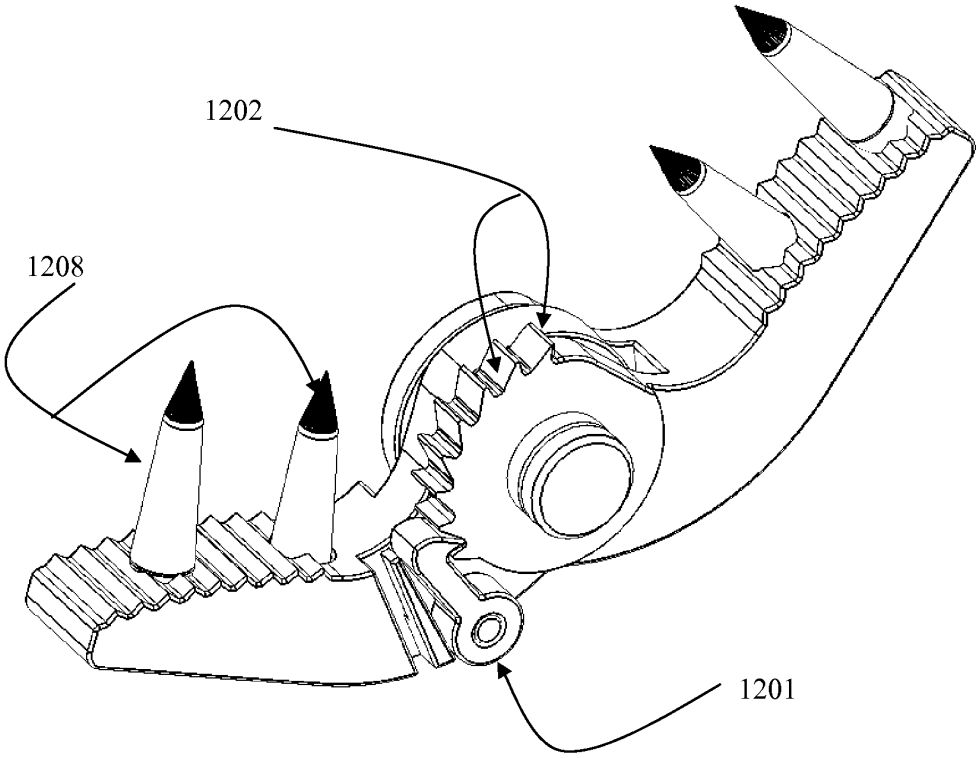


Fig. 12A

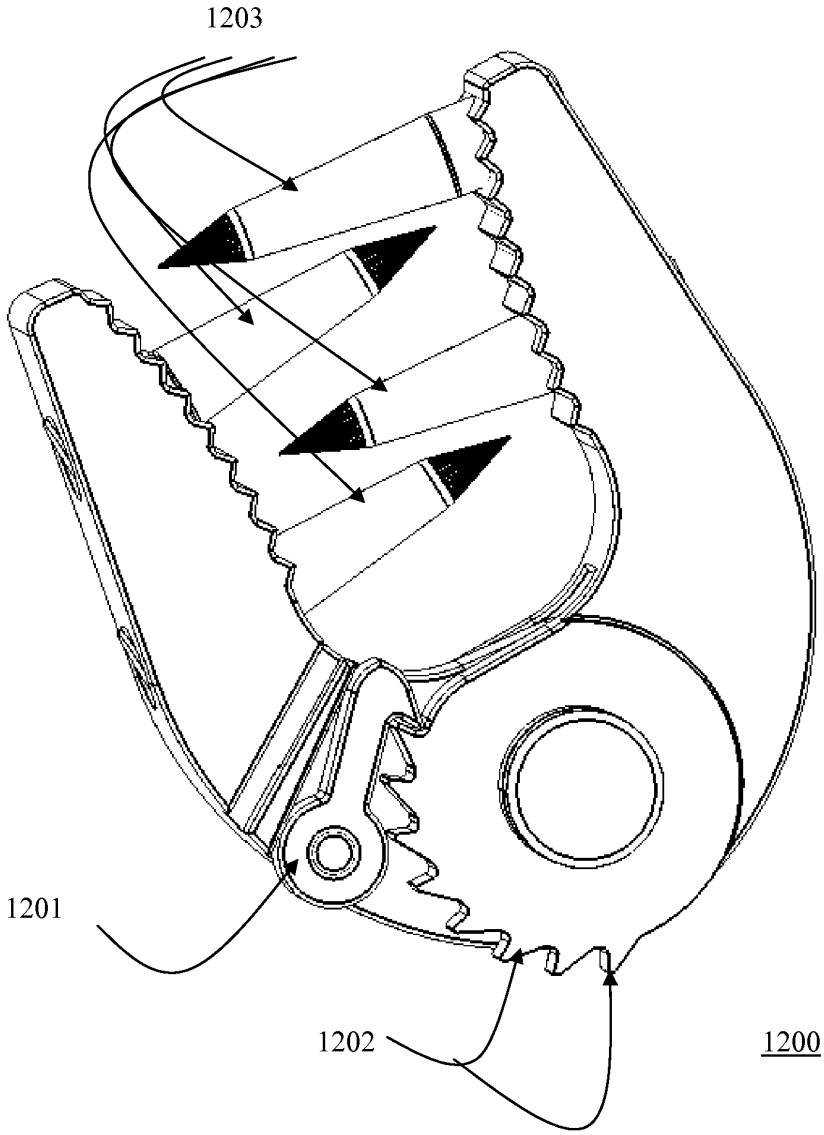


Fig. 12B

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. .

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 self-drilling bone fusion screw apparatus, which comprises:

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.

14. The self-drilling bone fusion screw apparatus according to claim 13 which further includes bone graft holes.

15. The self-drilling bone fusion screw apparatus according to claim 13 wherein the plate is joined to the first and second boxes by a plurality of screws.

16. 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.

17. The tool assembly for manipulating a self-drilling bone fusion screw apparatus, according to claim 16, which further includes a key for controlling an adjustment device which controls the height of the self-drilling bone fusion screw apparatus.

18. A cervical facet staple, comprising:

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.

19. The cervical facet staple, according to claim 18 further including at least four prongs attached to the bottom surface of the curved staple base.

20. The cervical facet staple, according to claim 19 wherein the insertion member includes a threaded insert.

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.

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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.

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

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LEGAL NAME OF INVENTOR

Inventor: Ahmnon D. Moskowitz Date (Optional) :

Signature:

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

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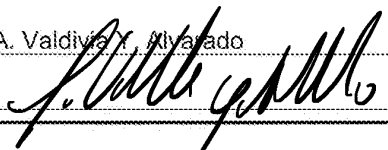
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LEGAL NAME OF INVENTOR

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

Signature:

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LEGAL NAME OF INVENTOR

Inventor: Nathan C. Moskowitz Date (Optional): 5/11/18

Signature:

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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 January 16, 2020	Group Art Unit

U.S. Patent Documents

Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Filing Date If Appropriate	Class	Subclass
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	52.	6613055	9/2/2003	Di Emidio			
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	113.	8328851	Dec-12	Curran			
	114.	8328872	12/11/2012	Duffield et al.			
	115.	8353913	Jan-13	Moskowitz et al.			
	116.	8403986	3/26/2013	Michelson			
	117.	8414651	4/9/2013	Tyber et al.			
	118.	8419797	4/6/2013	Biedermann et al.			
	119.	8425607	Apr-13	Waugh et al.			
	120.	8540774	9/24/2013	Kueenzi et al.			
	121.	8613761	12/24/2013	Lindermann et al.			
	122.	8728165	5/20/2014	Parry et al.			
	123.	8790405	7/29/2014	BIEDERMANN et al.			
	124.	8845731	9/30/2014	Weiman			
	125.	8882813	11/11/2014	Jones et al.			
	126.	9333095	5/10/2016	Beaurain et al			
	127.	9393130	7/19/2016	Suddaby & McClintock			
	128.	9895238	2/20/2018	Moskowitz et al.			
	129.	9907674	3/6/2018	Moskowitz			
	130.	10238505	3/26/2019	Moskowitz et al.			
	131.	20020068977	6/6/2002	Jackson			
	132.	20020143338	10/3/2002	Orbay et al.			
	133.	20030130737	7/10/2003	McGahan et al.			
	134.	20040015315	1/22/2004	Kreider			

Examiner Signature	Date Considered

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

Substitute Disclosure Form

Substitute Disclosure Form	U.S. Department of Commerce Patent and Trademark Office	Attorney Docket No. 46440-0009016	Application No. 16/744,755
Information Disclosure Statement by Applicant (Use several sheets if necessary) (37 CFR §1.98(b))		Applicant Moskowitz Family LLC	
		Filing Date January 16, 2020	Group Art Unit

U.S. Patent Documents

Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Filing Date If Appropriate	Class	Subclass
	135.	20040088054	5/6/2004	Berry			
	136.	20040162558	8/19/2004	Hegde			
	137.	20040177531	9/16/2004	DiBenedetto et al.			
	138.	20040186482	9/23/2004	Kolb et al.			
	139.	20040186569	9/23/2004	Berry			
	140.	20040193272	9/30/2004	Zubok et al.			
	141.	20040220571	11/4/2004	Assaker et al.			
	142.	20040254644	12/16/2004	Taylor			
	143.	20050027362	2/3/2005	Williams et al.			
	144.	20050049590	3/3/2005	Alleyne et al.			
	145.	20050177235	8/11/2005	Baynham et al.			
	146.	20050216084	9/29/2005	Fleischmann			
	147.	20050256576	11/17/2005	Moskowitz et al.			
	148.	20050261769	11/24/2005	Moskowitz et al.			
	149.	20050273170	12/8/2005	Navarro et al.			
	150.	20050278026	12/15/2005	Gordon, et al.			
	151.	20060058876	3/2006	Laurence			
	152.	20060155285	7/13/2006	Anderson et al.			
	153.	20060217713	9/28/2006	Serhan			
	154.	20060241621	10/26/2006	Moskowitz et al.			
	155.	20070049943	3/1/2007	Moskowitz et al.			
	156.	20070167678	7/19/2007	Moskowitz et al.			
	157.	20070191850	8/16/2007	Kim			
	158.	20070198089	8/23/2007	Moskowitz et al.			
	159.	20070213820	9/13/2007	Magerl et al			
	160.	20070250167	10/25/2007	Bray et al.			
	161.	20070250172	10/25/2007	Moskowitz et al.			

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		Filing Date January 16, 2020	Group Art Unit

U.S. Patent Documents

Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Filing Date If Appropriate	Class	Subclass
	162.	20070276498	11/29/2007	Aebi et al.			
	163.	20080033440	2/7/2008	Moskowitz et al.			
	164.	20080177307	7/24/2008	Moskowitz et al.			
	165.	20080183293	7/31/2008	Parry et al.			
	166.	20080249569	10/9/2008	Waugh et al.			
	167.	20080249575	10/9/2008	Waugh et al.			
	168.	20080249625	10/9/2008	Waugh et al.			
	169.	20080281424	11/13/2008	Parry et al.			
	170.	20080281425	11/13/2008	Thalgott et al.			
	171.	20090030520	1/29/2009	Biedermann et al.			
	172.	20090080997	3/26/2009	Johnson			
	173.	20090105830	4/23/2009	Jones et al.			
	174.	20090105831	4/23/2009	Jones et al.			
	175.	20090112271	4/30/2009	Moskowitz et al.			
	176.	20090182430	7/16/2009	Tyber et al.			
	177.	20090187218	7/23/2009	Schaffhausen et al.			
	178.	20090210062	8/20/2009	Thalgott et al.			
	179.	20090224023	9/10/2009	Moskowitz et al.			
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	181.	20100100138	4/22/2010	Reynolds			
	182.	20100145460	6/10/2010	McDonough et al.			
	183.	20100305704	12/2/2010	Messerli et al.			
	184.	20100324606	12/23/2010	Moskowitz et al.			
	185.	20110125269	5/26/2011	Moskowitz et al.			
	186.	20110137349	6/9/2011	Moskowitz et al.			
	187.	20110172774	7/14/2011	Varela			
	188.	20110178600	7/21/2011	Moskowitz et al.			

Examiner Signature	Date Considered

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

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Information Disclosure Statement by Applicant (Use several sheets if necessary) (37 CFR §1.98(b))		Applicant Moskowitz Family LLC	
		Filing Date January 16, 2020	Group Art Unit

U.S. Patent Documents

Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Filing Date If Appropriate	Class	Subclass
	189.	20110208312	8/25/2011	Moskowitz et al.			
	190.	20110288646	11/24/2011	Moskowitz et al.			
	191.	20110295327	12/1/2011	Moskowitz et al.			
	192.	20110295371	12/1/2011	Moskowitz et al.			
	193.	20110307011	12/15/2011	Moskowitz et al.			
	194.	20110319935	12/29/2011	Moskowitz et al.			
	195.	20120010714	1/12/2012	Moskowitz et al.			
	196.	20120271423	10/25/2012	Wallenstein et al.			
	197.	20120277870	11/1/2012	Wolters et al.			
	198.	20120323330	12/20/2012	Kueenzi et al.			
	199.	20120330419	12/27/2012	Moskowitz et al.			
	200.	20130018468	1/17/2013	Moskowitz et al.			
	201.	20130018469	1/17/2013	Moskowitz et al.			
	202.	20130018470	1/17/2013	Moskowitz et al.			
	203.	20130023991	1/24/2013	Moskowitz et al.			
	204.	20130023992	1/24/2013	Moskowitz et al.			
	205.	20130053962	2/28/2013	Moskowitz et al.			
	206.	20130060339	3/7/2013	Duffield et al.			
	207.	20130073044	3/21/2013	Gamache			
	208.	20130173002	7/4/2013	Moskowitz et al.			
	209.	20130211526	8/15/2013	Alheidt et al			
	210.	20130282017	10/24/2013	Moskowitz et al.			
	211.	20140249629	9/4/2014	Moskowitz et al.			
	212.	20150025637	1/22/2015	Moskowitz et al.			
	213.	20150105824	4/16/2015	Moskowitz et al.			
	214.	20150148847	5/28/2015	Moskowitz et al.			
	215.	20160374830	12/29/2016	Moskowitz et al.			

Examiner Signature	Date Considered

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Substitute Disclosure Form

Substitute Disclosure Form	U.S. Department of Commerce Patent and Trademark Office	Attorney Docket No. 46440-0009016	Application No. 16/744,755
Information Disclosure Statement by Applicant (Use several sheets if necessary) (37 CFR §1.98(b))		Applicant Moskowitz Family LLC	
		Filing Date January 16, 2020	Group Art Unit

U.S. Patent Documents

Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Filing Date If Appropriate	Class	Subclass
	216.	20170252178	9/7/2017	Moskowitz et al.			
	217.	20180311052	11/1/2018	Moskowitz			

Foreign Patent Documents or Published Foreign Patent Applications

Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Translation	Class	Subclass
	218.	2727003	5/24/1996	FR			
	219.	2004093749	11/4/2004	WO			
	220.	2006091503	8/31/2006	WO			

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

Examiner Initial	Desig. ID	Document
	221.	DIETER GROB et al., "Clinical Experience With the Dynesys Semirigid Fixation System for the Lumbar Spine," SPINE, Vol. 30, No. 3, 2005, pp. 324-331
	222.	E.K. WAI et al., "Disk Replacement Arthroplasties: Can The Success of Hip and Knee Replacements be Repeated in the Spine?," Seminars in Spine Surgery, Vol. 15, No. 4 (December) 2003, pp 473-482.
	223.	International Search Report (ISR) and Written Opinion of the International Searching Authority, 03 December 2007, International Application No. PCT/US 07/05005
	224.	International Search Report (ISR) and Written Opinion of the International Searching Authority, 09 July 2008, International Application No. PCT/US2007021013
	225.	International Search Report (ISR) and Written Opinion of the International Searching Authority, 21 May 2008, International Application No. PCT/US2007/021015
	226.	Richard D. GUYER et al., "lntervertebral Disc Prostheses," SPINE JOURNAL, Volume 28, Number 15S, Supp. To 8/1/03, pages S15-S23
	227.	Vincent C. TRAYNELIS, "Prosthetics and Biologics: The Wave of the Future," CLINICAL NEUROSURGERY, Volume 50, Proceedings of the Congress of Neurological Surgeons, Philadelphia, PA 2002, Chapter 9, pages 207-219

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

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor	:	Ahmnon D. Moskowitz	Art Unit	:	Unknown
Application No.	:	16/744,755	Examiner	:	Unknown
Filed	:	January 16, 2020	Conf. No.	:	5369
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).

Under 35 U.S.C. § 120, this application relies on the earlier filing date of application number 15/944,117, filed on April 3, 2018. The documents corresponding to Desig. ID Nos. 3, 14, 21, 37, 55, 63, 136, 153, 157, 181, and 217 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 within three months of the filing date of the application or before the receipt of a first action on the merits.

Apply any necessary charges or credits 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: 1/24/2020

/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

62231778.doc

Electronic Acknowledgement Receipt	
EFS ID:	38387595
Application Number:	16744755
International Application Number:	
Confirmation Number:	5369
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/Emma Johnson
Filer Authorized By:	Stuart A. Nelson
Attorney Docket Number:	46440-0009016
Receipt Date:	24-JAN-2020
Filing Date:	
Time Stamp:	10:26:37
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	IDS.pdf	2147303 097aa482a5ed6275d745e12875ee271537450f1f	no	11

Warnings:

Information:	
This is not an USPTO supplied IDS fillable form	
Total Files Size (in bytes):	2147303

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

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

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number: 16/744,755

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY FEE($)
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	75		N/A	
SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	330		N/A	
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	380		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	20 minus 20 =	*	x 50 =	0.00	OR		
INDEPENDENT CLAIMS (37 CFR 1.16(h))	5 minus 3 =	* 2	x 230 =	460			
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	1245		TOTAL	

APPLICATION AS AMENDED - PART II

		(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($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE($)
AMENDMENT A	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	

		(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($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE($)
AMENDMENT B	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
United States Patent and Trademark Office
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www.uspto.gov

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
16/744,755	01/16/2020	Ahmnon D. Moskowitz	46440-0009016

CONFIRMATION NO. 5369

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

FORMALITIES LETTER

OC000000114451905

Date Mailed: 02/05/2020

NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION

FILED UNDER 37 CFR 1.53(b)

Filing Date Granted

Items Required To Avoid Abandonment:

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

- The statutory basic filing fee is missing.
- The application search fee must be submitted.
- The application examination fee must be submitted.
- Additional claim fees of $ **460** as a small entity, including any required multiple dependent claim fee, are required. Applicant must submit the additional claim fees or cancel the additional claims for which fees are due.
- Surcharge as set forth in 37 CFR 1.16(f) must be submitted.
  The surcharge is due for any one of:
  - late submission of the basic filing fee, search fee, or examination fee,
  - late submission of inventor's oath or declaration,
  - filing an application that does not contain at least one claim on filing, or
  - submission of an application filed by reference to a previously filed application.

SUMMARY OF FEES DUE:

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

- $ **75** basic filing fee.
- $ **80** surcharge.
- $ **330** search fee.
- $ **380** examination fee.
- $ **460** for **2** independent claims over 3.

- $(**0**) previous unapplied payment amount.
- $ **1325** TOTAL FEE BALANCE DUE.

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

Replies should be mailed to:

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

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

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

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

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

/mhaile/

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UNITED STATES DEPARTMENT OF COMMERCE
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Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
16/744,755	01/16/2020		0.00	46440-0009016	20	5

CONFIRMATION NO. 5369

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

FILING RECEIPT



Date Mailed: 02/05/2020

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 15/944,117 04/03/2018 PAT 10537442
which 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 13/084,543 04/11/2011 PAT 8353913
and is a CON of 13/108,982 05/16/2011 PAT 9005293
and said 13/084,543 04/11/2011
is a CON of 11/842,855 08/21/2007 PAT 7942903
and said 13/108,982 05/16/2011
is a CON of 11/842,855 08/21/2007 PAT 7942903
which is a CIP of 11/536,815 09/29/2006 PAT 7846188 *
which is a CIP of 11/208,644 08/23/2005 PAT 7704279
which claims benefit of 60/670,231 04/12/2005
(*)Data provided by applicant is not consistent with PTO records.

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: 02/04/2020

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 16/744,755**

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

Non-Publication Request: No

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

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

Preliminary Class

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.

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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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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor	:	Ahmnon D. Moskowitz	Art Unit	:	Unknown
Application No.	:	16/744,755	Examiner	:	Unknown
Filed	:	January 16, 2020	Conf. No.	:	5369

Title : BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR

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

PRELIMINARY AMENDMENT

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

Amendments to the Specification:

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

This application is a Continuation Application of U.S. Application Serial No. 15/944,117, filed April 3, 2018 (now U.S. Patent 10,537,442), which is a Continuation Application of U.S. Application Serial No. 15/894,471, filed February 12, 2018 (now U.S. Patent 10,390,969), which is a Continuation of U.S. Application Serial No. 13/210,157, filed August 15, 2011 (now U.S. Patent No. 9,889,022), which is a Continuation of U.S. Application Serial Nos. 13/084,543, filed April 11, 2011 (now U.S. Patent No. 8,353,913) and 13/108,982, filed May 16, 2011 (now U.S. Patent No. 9,005,293).

U.S. Application Serial No. 13/084,543 is a Continuation of 11/842,855, filed August 21, 2007 (now U.S. Patent No. 7,942,903). U.S. Application Serial No. 13/108,982 is a Continuation of 11/842,855, filed August 21, 2007 (now U.S. Patent No. 7,942,903), which is a Continuation-in-Part of U.S. Application Serial No. 11/536,815, filed September 29, 2006 (now U.S. Patent No. 7,846,188), which is a Continuation-in-Part of U.S. Application Serial No. 11/208,644, filed August 23, 2005 (now U.S. Patent No. 7,704,279), which claims priority of U.S. Provisional Application Serial No. 60/670,231, filed April 12, 2005; the entire contents of all the above identified patent applications are hereby incorporated by reference.

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 the Claims:

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

Listing of Claims:

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

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

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

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

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

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

12. (Original) 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. (Cancelled)

14. (Cancelled)

15. (Cancelled)

16. (Cancelled)

17. (Cancelled)

18. (Original) A cervical facet staple,

comprising: 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.

19. (Original) The cervical facet staple, according to claim 18 further including at least four prongs attached to the bottom surface of the curved staple base.

20. (Original) The cervical facet staple, according to claim 19 wherein the insertion member includes a threaded insert.

REMARKS

With this amendment, claims 13-17 are cancelled without prejudice. The specification has been amended in a manner consistent with the parent application. No new matter is added.

Applicant asks that all claims be examined in view of the amendments.

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

Respectfully submitted,

Date: 5/5/2020

/Stuart A. Nelson/
Stuart A. Nelson
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62227286.doc

Electronic Patent Application Fee Transmittal

Application Number:	16744755
Filing Date:	16-Jan-2020
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/Christine Rogers
Attorney Docket Number:	46440-0009016

Filed as Small Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
UTILITY FILING FEE (ELECTRONIC FILING)	4011	1	75	75
UTILITY SEARCH FEE	2111	1	330	330
UTILITY EXAMINATION FEE	2311	1	380	380
Pages:				
Claims:				
Miscellaneous-Filing:				
LATE FILING FEE FOR OATH OR DECLARATION	2051	1	80	80
Petition:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Extension - 2 months with $0 paid	2252	1	300	300
Miscellaneous:				
		Total in USD ($)		**1165**

Electronic Acknowledgement Receipt	
EFS ID:	39365485
Application Number:	16744755
International Application Number:	
Confirmation Number:	5369
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/Christine Rogers
Filer Authorized By:	Stuart A. Nelson
Attorney Docket Number:	46440-0009016
Receipt Date:	06-MAY-2020
Filing Date:	16-JAN-2020
Time Stamp:	12:58:17
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	$1165
RAM confirmation Number	E202056C58591827
Deposit Account	061050
Authorized User	Christine Rogers
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: 37 CFR 1.16 (National application filing, search, and examination fees) 37 CFR 1.17 (Patent application and reexamination processing fees)	

37 CFR 1.19 (Document supply fees)

37 CFR 1.20 (Post Issuance fees)

37 CFR 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Applicant Response to Pre-Exam Formalities Notice	46440_0009016_Response.pdf	150738 2e6190d7f595feb6909868af03158e4ce45dc153	no	4
Warnings:					
Information:					
2		46440_0009016_Prelim_Amendment.pdf	99847 75ba482a7489984d3b9fb3ec438209fca96e214b	yes	8

Multipart Description/PDF files in .zip description

Document Description	Start	End
Preliminary Amendment	1	1
Specification	2	3
Claims	4	7
Applicant Arguments/Remarks Made in an Amendment	8	8

Warnings:					
Information:					
3	Fee Worksheet (SB06)	fee-info.pdf	39445 465750f57293a141dcf1b254364385b7f6a272cc	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	290030		

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	:	Unknown
Application No.	:	16/744,755	Examiner	:	Unknown
Filed	:	January 16, 2020	Conf. No.	:	5369

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

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

REPLY TO NOTICE TO FILE MISSING PARTS OF APPLICATION

In response to the Notice to File Missing Parts of Application under 37 CFR §1.53(b) dated February 5, 2020, applicant claims small entity status (see 37 CFR §1.27) and submits herewith the following:

- ☒ Payment of the basic filing fee of $75;
- ☒ Payment of the search fee of $330;
- ☒ Payment of the examination fee of $380;
- ☒ Payment of the surcharge of $80 for late filing of the basic filing fee and/or declaration.

The fees in the amount of $865 are being paid with this reply on the Electronic Filing System. Apply any necessary charges or credits to Deposit Account 06-1050, referencing the above attorney docket number.

Respectfully submitted,

Date: 5/5/2020

/Stuart A. Nelson/
Stuart A. Nelson
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Customer Number 26191
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UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
16/744,755	01/16/2020	Ahmnon D. Moskowitz	46440-0009016

CONFIRMATION NO. 5369

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

FORMALITIES LETTER

OC000000114451905

Date Mailed: 02/05/2020

NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION

FILED UNDER 37 CFR 1.53(b)

Filing Date Granted

Items Required To Avoid Abandonment:

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

- The statutory basic filing fee is missing.
- The application search fee must be submitted.
- The application examination fee must be submitted.
- Additional claim fees of $ **460** as a small entity, including any required multiple dependent claim fee, are required. Applicant must submit the additional claim fees or cancel the additional claims for which fees are due.
- Surcharge as set forth in 37 CFR 1.16(f) must be submitted.
  The surcharge is due for any one of:
  - late submission of the basic filing fee, search fee, or examination fee,
  - late submission of inventor's oath or declaration,
  - filing an application that does not contain at least one claim on filing, or
  - submission of an application filed by reference to a previously filed application.

SUMMARY OF FEES DUE:

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

- $ **75** basic filing fee.
- $ **80** surcharge.
- $ **330** search fee.
- $ **380** examination fee.
- $ **460** for **2** independent claims over 3.

- $(**0**) previous unapplied payment amount.
- $ **1325** TOTAL FEE BALANCE DUE.

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

Replies should be mailed to:

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

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

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

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

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

/mhaile/

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number: 16/744,755

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))	15 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

		(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($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE($)
AMENDMENT A	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	

		(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($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE($)
AMENDMENT B	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

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Alexandria, Virginia 22313-1450
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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
16/744,755	01/16/2020		865	46440-0009016	15	3

CONFIRMATION NO. 5369

UPDATED FILING RECEIPT

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



Date Mailed: 05/08/2020

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 15/944,117 04/03/2018 PAT 10537442
which 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 13/084,543 04/11/2011 PAT 8353913
and is a CON of 13/108,982 05/16/2011 PAT 9005293
and said 13/084,543 04/11/2011
is a CON of 11/842,855 08/21/2007 PAT 7942903
and said 13/108,982 05/16/2011
is a CON of 11/842,855 08/21/2007 PAT 7942903
which is a CIP of 11/536,815 09/29/2006 PAT 7846188 *
which is a CIP of 11/208,644 08/23/2005 PAT 7704279
which claims benefit of 60/670,231 04/12/2005
(*)Data provided by applicant is not consistent with PTO records.

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.

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Projected Publication Date: 08/13/2020

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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

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

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Substitute Disclosure Form	U.S. Department of Commerce Patent and Trademark Office	Attorney Docket No. 46440-0009016	Application No. 16/744,755
Information Disclosure Statement by Applicant (Use several sheets if necessary)		Applicant Moskowitz Family LLC	
(37 CFR §1.98(b))		Filing Date January 16, 2020	Group Art Unit Unknown

U.S. Patent Documents

Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Filing Date If Appropriate	Class	Subclass
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	27.	20020161443	10/31/2002	Michelson			

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(37 CFR §1.98(b))		Filing Date January 16, 2020	Group Art Unit Unknown

U.S. Patent Documents

Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Filing Date If Appropriate	Class	Subclass
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Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Translation	Class	Subclass
	35.	KR 20-0290058	9/26/2002	KR	Machine Translation		
	36.	WO 1999038463	8/5/1999	WO			

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

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor	:	Ahmnon D. Moskowitz	Art Unit	:	Unknown
Application No.	:	16/744,755	Examiner	:	Unknown
Filed	:	January 16, 2020	Conf. No.	:	5369
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MAIL STOP AMENDMENT
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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: 5/21/2020

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Patents KR 20-0290058

Lumbar vertebra fixture

Abstract

The present invention relates to a lumbar spine fixture, the configuration is a through-hole is formed in the center portion and the guide surface is formed at both ends and the dovetail groove is formed along the guide surface, forming a symmetrical structure with the fixture body and spaced below the A corresponding wedge body disposed therein, a dovetail fitted to each dovetail groove of each of the two end portions of the fastener main body protrudingly formed, and a lead wedge having a threaded hole through the center of the body, and having a structure corresponding to the lead wedge; It includes a corresponding wedge coupled to each dovetail groove of the rear end of the fastener body, and a grooved screw for fastening between the corresponding wedge and the lead wedge to adjust the separation distance between the two fastener bodies by adjusting the distance therebetween. It features. According to the fixture, it is possible to freely adjust the height of the vertebrae so as not to protrude or deviate from the vertebrae and to maintain the proper intervals according to the patient's condition, and the procedure is very simple, after a long time Even if a deformation occurs, it can be easily calibrated by a simple operation of tightening or releasing the screw, and its lifespan is not only semi-permanent but also has the advantage of minimizing the burden of medical expenses.

KR200290058Y1

South Korea

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Other languages: Korean

Inventor: 정연룡, 박형권, 요시문

Worldwide applications

Application KR2020020014412U events

2002-05-11 Application filed by 정연룡

2002-09-26 Application granted

2002-09-26 Publication of KR200290058Y1

Info: Cited by (1), Similar documents

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Claims (4)

Hide Dependent

1. They are divided into mutually symmetrical planes along the central plane in the longitudinal direction, and are coupled to each other by fasteners. Through these combinations, through-holes through which vertebral implants can flow are formed in the central part. A pair of fastener bodies having a photographic guide surface and a dovetail groove formed along the guide surface;

   An integral corresponding fixture body symmetrical with the fixture body and spaced apart from each other to face the lower portion of the fixture body;

   Lead wedges having both sides close to each guide surface of the both ends of the fastener main body, and a dovetail to be fitted to the dovetail grooves of the two fastener main bodies respectively along the longitudinal direction of the contact surface thereof, and having a threaded hole through the center of the body. ;

   Corresponding wedges having a structure corresponding to the lead wedges, the wedges of which both sides are coupled to each other to closely contact the respective guide surfaces of the rear end portions of the two fastener bodies; And

   Lumbar vertebrae, comprising: a grooved screw fastened to the through hole of the corresponding wedge and the screw hole of the lead wedge to adjust the separation distance between the two fastener bodies by adjusting the distance between the corresponding wedge and the lead wedge. Fixture.

2. The method of claim 1,

   Lumbar fasteners, characterized in that the outer surface of the two fastener body adjacent to the vertebrae is formed with a one-way teeth inclined toward the corresponding wedge to prevent the fastener body from escaping in the opposite direction to the entrance.

3. The method of claim 1,

   The through-hole of the corresponding wedge forms a double rounded jaw structure that extends outward, and a spiral is formed on the inner side of the large diameter side of the through-hole in the direction of the left screw to allow the operator to engage a cylindrical tubular gripper that can grip the lumbar fixture. Lumbar support characterized in that it is possible.

4. The method of claim 1,

   Between the dovetail groove of the fastener body and the corresponding fastener body, and the dovetail of the lead wedge and the corresponding wedge, a predetermined play is formed to differentially adjust and correct the front and rear position spacing of the vertebrae of the patient. Lumbar fixture.

Description

Lumbar vertebra fixture

The present invention relates to a medical device for chiropractic, more specifically, it is inserted between the vertebrae forming the lumbar vertebrae to fix the vertebrae firmly and to adjust the height freely to maintain the proper interval according to the patient's condition. Lumbar fixture.

In the human body, the spine supports the head upwards and the lower part connects with the pelvis to transfer weight to the lower extremities, consisting of 33 vertebrae and fibrocartilage intervertebral discs between them, reinforced with strong ligaments and muscles from the skull to the pelvis. It supports the body, maintains equilibrium, protects the spinal cord in the spinal canal, and branches each spinal nerve root, maintaining the posture of the human body, protecting important nerves in it, and absorbing shocks. Do this.

Typically in adults, the vertebral column has a length of 70-75 cm, about 60 cm from the cervical spine to just before the sacrum, of which 1/4 is composed of intervertebral discs. At the site, only the front, respectively, at the thoracic and sacral areas, respectively, only after. The muscles, ligaments, nerves, and blood vessels are arranged symmetrically about the vertebrae.

That is, 33 vertebrae are formed from the cervical spine, the thoracic spine, 12 thoracic, lumbar spine, five, sacral and five lumbar spine, in the case of adults, the sacral and cilia are fused to form sacrum and coccyx. Typical vertebrae, except for vertebrae, vertebrae, and sacrum, vary in size and shape depending on the site, but have a common structure. There is a vertebrae in the front and a vertebral arch consisting of the pedicle and the plaque and a protrusion for muscle attachment and joint connection. The vertebral body bears the load, and the upper and lower marginal densities are thicker and rounder than other parts and separated from the adjacent vertebrae by the intervertebral discs.

When an external stimulus is applied to a human body having such a vertebral structure, changes in the total curvature of the cervical spine and lumbar spine and the posterior curvature of the thoracic spine come first. This results in a change in the center of gravity of each part of the body and a change in the body's posture, which in turn can lead to an imbalance of the spinal muscles which can cause injury. External stimuli mentioned above include adolescents' incorrect study posture, chronic fatigue, injuries from various sports activities, car accidents and nutritional imbalances.

In particular, the patient is injured in the lumbar spine due to the narrowing of the interval between each vertebrae that make up the lumbar spine causes nerves to be pressed by these vertebrae, causing the behavior can not be freely. As a procedure for such a patient, a method of relieving nerve compression is mainly applied by inserting a lumbar fixture (prosthesis) between the vertebrae forming the lumbar spine and maintaining a proper spacing between the vertebrae.

Conventional lumbar spine fixtures that have been used until recently are those of the structure shown in FIG. The lumbar spine fixture is provided with a cuboid-shaped fastener body 100, and has an open portion 101 is open from the inside to the outside, the side of the opening is used during the insertion between the vertebrae (1) The screw hole 102 for coupling a separate surgical instrument (grip) is formed.

The fixture body 100 is made of a metal such as titanium, after the procedure is to be able to maintain the distance between the vertebrae (1) by the fixture body 100.

The opening 101 is provided for communication of nutrients, etc. in the body, and the vertebral bone graft material is filled to facilitate body fusion through the opening 101.

However, the conventional lumbar spine fixture as described above is protruded or deviated from the vertebrae (1) as the patient resumes activity after the procedure and as time passes, the patient still feels pain by stimulating the nerve of the patient. In order to prevent the need for regular checkups and reoperation was a hassle.

In addition, in order to prevent the separation of the lumbar lumbar fixture, a separate fixation procedure must be performed in parallel, thereby increasing the burden of medical expenses.

The present invention was devised to solve the above problems, the purpose of which is to firmly fix the vertebrae and to freely adjust the height to maintain the appropriate interval according to the condition of the patient, and after a long time Even if deformation occurs from the initial state of the procedure, it is easy to correct by simply manipulating or unscrewing the screw, and its life is not only semi-permanent but also to provide a lumbar spine fixture that can minimize the medical cost burden.

Lumbar lumbar fixture according to the present invention for achieving the above object is divided into mutually symmetrical along the center plane in the longitudinal direction is coupled to correspond to each other by the fastener and the vertebral implant material in the center by the combination between them A through-hole is formed which can flow and a guide surface inclined in both directions is formed at both ends, and a pair of fastener bodies having a dovetail groove formed along the guide surface, and formed in a symmetrical structure with the fastener body facing each other below The integral fastener main body is disposed and the dovetails, which are both sides close to each guide surface of the front end portions of the two fastener main bodies, and are respectively fitted with the dovetail grooves of the two fastener main bodies along the longitudinal direction of the respective contact surfaces. Lead wedge formed through the threaded hole in the center of the body, and a sphere corresponding to the lead wedge And a corresponding wedge coupled to each of the two guide surfaces of the rear end of the two fastener main bodies so as to be in close contact with each other, and a through hole of the corresponding wedge and a screw hole of the lead wedge are connected to each other to adjust the distance between the corresponding wedge and the lead wedge. Characterized in that it comprises a grooved screw to adjust the separation distance of the fixture body.

Here, it is preferable that one side teeth inclined toward the corresponding wedge are formed on the outer surfaces of the two fastener bodies adjacent to the vertebrae to prevent the fastener body from escaping in the opposite direction of entry.

In addition, the through-hole of the corresponding wedge forms a double rounded jaw structure that extends outwards and a spiral is formed on the inner side of the large diameter side of the through-hole in the direction of the left screw to allow the operator to grip the lumbar fixture by the operator. It is desirable to be able to bond.

In addition, between the dovetail groove of the fastener body and the corresponding fastener body and the dovetail of the lead wedge and the corresponding wedge, a predetermined play is formed to differentially adjust and correct the distance between the front and rear positions of the vertebrae of the patient. desirable.

1 is a perspective view of the lumbar lumbar fastener according to the present invention.

Figure 2 is an exploded perspective view of the lumbar spine fixture according to the present invention.

Figure 3 is a cross-sectional view of the state inserted between the lumbar spine fixture between the vertebrae.

Figure 4 is a cross-sectional view showing an example of correcting by adjusting the interval between the vertebrae evenly to fit the state of the patient after inserting the lumbar anchor between the vertebrae according to the present invention.

Figure 5 is a cross-sectional view showing an example of correcting by differentially adjusting the front and rear position interval between the vertebrae to fit the state of the patient after insertion of the lumbar spine fixture according to the present invention.

Figure 6 is a schematic perspective view showing the structure of the lumbar spine fixture according to the prior art and its application state.

<Description of Symbols for Major Parts of Drawings>

One ; Vertebra 2; wrench

3; Grip region 10; Fixture body

10a, 10b; Split fixture body 11, 21; Penetration

12, 22; One-way teeth 13, 23; Guide

14, 24; Dovetail groove 15; Fastener

16; Fastener 20; Correspondence fixture body

30; Lead wedges 31; Screwman

32, 42; Dovetail 40; Wedge

41; Through hole 50; Slotted Screw

100; Fixture body 101; Opening

102; Screwman

Hereinafter, the lumbar lumbar fixture according to a preferred embodiment of the present invention will be described in detail with reference to the accompanying drawings.

1 to 5 show the structure and application state of the lumbar lumbar fixture according to the present invention, Figure 1 is a perspective view of the lumbar lumbar fixture, Figure 2 is an exploded perspective view of the lumbar lumbar fixture, Figure 3 is the lumbar lumbar fixture Cross-sectional view of the state inserted between the vertebra 1, Figure 4 is inserted into the lumbar spine fixture according to the present invention between the vertebra (1) and then adjusted by adjusting the interval between the vertebrae (1) evenly to fit the patient's condition 5 is a cross-sectional view showing an example, and the lumbar fixture according to the present invention is inserted between the vertebrae 1 and then shows an example of correcting by differentially adjusting the front and rear position intervals between the vertebrae 1 to fit the condition of the patient. One cross section.

As shown in FIGS. 1 and 2 of the drawings, the lumbar spine fixture according to the present invention includes a fixture body 10 and a corresponding fixture body 20 in contact with adjacent vertebrae 1 into which the lumbar spine fixture is inserted. And, the lead wedge 30 and the corresponding wedge that is a wedge-shaped separation means for narrowing or widening the distance between the two fastener main body 10, 20 while sliding between both ends of the fastener body (10, 20) (40, and the grooved screw 50 for adjusting the gap between the lead wedge 30 and the corresponding wedge 40 is tightened or loosened.

The two fastener bodies 10 and 20 have a pair of arched structures spaced apart to face each other in symmetry with each other, and through holes 11 and 21 through which vertebral bone graft materials can flow in the center, respectively. Guide surfaces 13 and 23 inclined diagonally at both ends are formed, and dovetail grooves 14 and 24 are formed along the guide surfaces 13 and 23, respectively.

And, the outer surface of the both fixture body 10, 20 adjacent to the vertebra 1, the both fixture body 10 (in the opposite direction to the entry direction of the both fixture body 10, 20 during the procedure) The one-way teeth 12 and 22 which are inclined toward the corresponding wedge 40 at the rear end side thereof are formed to prevent the 20 from being separated.

Here, the two fastener main body 10, 20 and both wedges 30, 40 is the coupling surface is symmetrically spread out toward each other, so it is not easy to combine the last one of these members, to solve this in order to achieve a structure in which any one of the two fixture body (10, 20) is divided in the longitudinal direction is ideal.

That is, as one example, the fastener body 10 is divided into a plane symmetrical along the center plane in the longitudinal direction is divided into a pair of split fastener body (10a) coupled to correspond to each other by a plurality of fasteners (15) It is preferable to form by (10b). Each of the split fastener bodies 10a and 10b is provided with a plurality of fastening holes 16 which can be matched when they are brought into close contact with each other, and each of the fastening holes 16 has a rivet or bolt inserted therethrough. It can be fixed in close contact with each other by a riveting or fastening method by a nut. Of course, the corresponding fixture body 20 at this time may be of an integral structure.

The lumbar spine fixture of the present invention constituting such a structure pushes each dovetail 32 and 42 of both wedges 30 and 40 into both dovetail grooves 24 of the corresponding fixture body 20, respectively. Thereafter, the two parts of each of the wedge 30, 40, the upper side of the dovetail (32, 42) on both sides of the split fastener main body 10a (10b) in close contact with each other by fixing the fastener 15 It is possible to maintain the connection state between them.

On the other hand, the lead wedge 30 and the corresponding wedge 40 is a pair of separation means for adjusting the distance between the two fixture body (10, 20), forming a structure corresponding to each other, the both fixture body The dovetail grooves 14 of the two fixture bodies 10 and 20 are in close contact with each of the guide surfaces 13 and 23 at the line and the rear end of the line 10 and 20, respectively. The dovetails 32 and 42, which are fitted with the 24, respectively, protrude from each other.

However, the lead wedge 30 is the front end portion of the surface so that the smooth surface when inserting the lumbar fixture according to the present invention between the vertebra 1, the corresponding wedge 40 is the rear end thereof The lead wedge 30 has a flat surface and a threaded hole 31 having a predetermined diameter is formed in the center of the body so that the threaded portion of the grooved screw 50 can be fastened. The wedge 40 has a through hole 41 having a stepped structure so that the head portion of the grooved screw 50 can be caught.

To describe this in more detail, the through hole 41 of the corresponding wedge 40 forms a double rounded jaw structure that extends outward, and a spiral is formed on the inner circumferential surface of the large through hole 41 in a left-handed thread direction. Is to be able to combine the cylindrical tubular gripper 3 that can hold the lumbar fixture.

The gripping tool 3 is capable of being separated from the through hole 41 by reverse rotation after the procedure. As shown in FIG. 3, the gripping tool 3 is a means for the operator to grip the outside of the torso of the patient. The wrench (2) is inserted through the slotted screw (50). Since the lumbar fixture of the present invention should not rotate together when the grooved screw 50 is removed, the grooved screw 50 is formed to be fastened in the form of a right hand screw and the gripper 3 is left screwed, respectively.

The grooved screw 50 is fastened to the through hole 41 of the corresponding wedge 40 and the threaded hole 31 of the lead wedge 30 to adjust the distance between the corresponding wedge 40 and the lead wedge 30. By adjusting it to be able to adjust the separation distance of both the fixture body (10, 20).

The lumbar spine fixture of the present invention having such a configuration, as shown in FIG. 3, grasps the gripper 3 and is inserted between two adjacent vertebrae 1, and then the wrench 2 in the gripper 3.) By fastening the grooved screw 50 so that the outer surfaces of the two fastener main bodies 10 and 20 are brought into close contact with the surfaces of the vertebrae 1, respectively.

As mentioned above, FIG. 4 illustrates a change state of relative movement between the two fastener bodies 10 and 20 and the lead wedge 30 and the corresponding wedge 40 according to the loosening or fastening of the grooved screw 50. It shows well.

As an example, FIG. 4 shows a time when the grooved screw 50 is tightened so that both ends of the lumbar fixture according to the present invention can maintain an even interval. In this case, the grooved screw 50 and Combined both wedges 30 and 40 slide along the guide surfaces 13 and 23 of both fixture bodies 10 and 20 to gradually approach each of the two fixture bodies 10 and 20, respectively. Will be pushed out. Therefore, lumbar spine fixture can be firmly fixed in close contact with the vertebra (1). At this time, the one-way teeth 12, 22 exert a strong friction force against the contact surface of the vertebra 1, it is possible to prevent the departure in the reverse direction to the entry direction of the lumbar fixture.

On the contrary, when the grooved screw 50 is loosened, both wedges 30 and 40 coupled to the grooved screw 50 are guide surfaces 13 of the both fixture bodies 10 and 20 (Sliding outward along the 23 and gradually away from each other to pull the two fixture body (10, 20) inward. Thus, the lumbar spine fixture is separated from the vertebra 1.

That is, when it is necessary to separate and remove the lumbar fixture from between the adjacent vertebrae 1, the gripper 3 and the wrench 2 are used until a sufficient gap is formed from the vertebrae 1. After loosening and separating the grooved screw 50, the lumbar fixture is to be lifted by the surgical instrument.

On the other hand, Figure 5 shows the state corrected by differentially adjusting the front and rear position interval between the vertebrae (1) to fit the state of the patient after insertion of the lumbar spine fixture according to the present invention. In the usual case, the interval between the vertebrae 1 of the lesion to be treated is most often in a state where the front and rear intervals are not kept constant.

Lumbar fastener of the present invention, the dovetail grooves (14) and (24) of the fixture body (10) and the corresponding fixture body (20), and the dovetail (32) of the lead wedge (30) and the corresponding wedge (40). By providing a predetermined clearance between the 42, the position of the lead wedge 30 and the corresponding wedge 40 by the clearance is differentially adjusted to be equal to the front and rear position interval between the vertebrae 1 of the patient and corrected. As it can, its utilization value will be higher.

As described above, the lumbar spine fixture of the present invention is inserted between the vertebrae, so that the height of the vertebrae is fixed so as to continuously fix the vertebrae firmly and to maintain an appropriate interval according to the patient's condition without protruding or deviating from the vertebrae. It can be adjusted freely, so the procedure is very simple.Even if deformation occurs from the initial state of the procedure after a long time, it can be easily corrected with a simple operation of tightening or loosening the screw, and its life is semi-permanent, and it can minimize the medical cost burden. There is an advantage.

The present invention has been described with reference to the embodiments shown in the accompanying drawings, which can be referred to as exemplary, and those skilled in the art can devise various modifications and equivalent embodiments therefrom. Such equivalent embodiments are also to be seen as included within the utility model registration claims of the present invention is quite natural. Therefore, the true scope of protection of the present invention should be determined only by the appended claims.

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요약

본 고안은 요추 고정구에 관한 것으로, 그 구성은 중앙부에 관통장공이 형성되고 양단부에 안내면이 형성되며 상기 안내면을 따라 더브테일홈이 형성된 고정구 본체와, 상기 고정구 본체와 대칭 구조를 이루며 그 하부에 이격 배치되는 대응 고정구 본체와, 상기 양 고정구 본체 선단부의 각 더브테일홈과 각각 끼워 맞춰지는 더브테일이 돌출 형성되고 몸체 중심부에 나사공이 관통 형성된 리드웨지와, 상기 리드웨지와 대응되는 구조를 이루며 상기 양 고정구 본체 후단부의 각 더브테일홈에 결합되는 대응웨지와, 상기 대응웨지와 리드웨지간에 체결되어 이들간의 거리를 조절함으로써 상기 양 고정구 본체의 이격거리를 조절할 수 있도록 하는 홈붙이나사를 포함하여 이루어짐을 특징으로 한다. 상기 고정구에 의하면, 척추골들로부터 돌출되거나 이탈되지 않고 상기 척추골들을 연속적으로 견고히 고정시켜줌과 아울러 환자의 상태에 맞게 적정간격을 유지할 수 있도록 그 높낮이를 자유롭게 조절할 수 있어 시술이 매우 간편하며, 장시간 경과 후 변형이 발생된 경우에도 나사를 죄거나 푸는 간단한 조작만으로 쉽게 교정 가능하고, 그 수명이 반영구적일 뿐만 아니라 의료비 부담을 최소화할 수 있는 이점이 있는 것이다.

대표도
도 1

색인어
고정구 본체, 웨지, 안내면, 더브테일, 일방향 톱니

명세서

도면의 간단한 설명

도 1은 본 고안에 따른 요추 고정구의 결합 사시도.

도 2는 본 고안에 따른 요추 고정구의 분해 사시도.

도 3은 본 고안에 따른 요추 고정구를 척추골 사이에 삽입한 상태의 단면도.

도 4는 본 고안에 따른 요추 고정구를 척추골 사이에 삽입한 후 환자의 상태에 맞도록 척추골간의 간격을 균등하게 조절하여 교정하는 일례를 도시한 단면도.

도 5는 본 고안에 따른 요추 고정구를 척추골 사이에 삽입한 후 환자의 상태에 맞도록 척추골간의 전후위치 간격을 차등적으로 조절하여 교정하는 일례를 도시한 단면도.

도 6은 종래 기술에 따른 요추 고정구의 구조 및 그 적용 상태를 도시한 개략 사시도.

< 도면의 주요부분에 대한 부호의 설명

1 ; 척추골 2 ; 렌치

3 ; 파지구 10 ; 고정구 본체

10a, 10b ; 분할 고정구 본체 11, 21 ; 관통장공

12, 22 ; 일방향 톱니 13, 23 ; 안내면

14, 24 ; 더브테일홈 15 ; 체결구

16 ; 체결공 20 ; 대응 고정구 본체

30 ; 리드웨지 31 ; 나사공

32, 42 ; 더브테일 40 ; 대응웨지

41 ; 관통공 50 ; 홈붙이 나사

100 ; 고정구 본체 101 ; 개방부

102 ; 나사공

고안의 상세한 설명

고안의 목적

고안이 속하는 기술 및 그 분야의 종래기술

본 고안은 척추 교정용 의료기기에 관한 것으로, 더욱 상세하게는 요추를 이루는 척추골들 사이에 삽입되어 그 척추골들을 견고히 고정시켜줌과 아울러 환자의 상태에 맞게 적정간격을 유지할 수 있도록 그 높낮이를 자유롭게 조절할 수 있는 요추 고정구에 관한 것이다.

인체에 있어서 척추는 위쪽으로 머리를 받치고 아래쪽은 골반과 연결되어 체중을 하지로 전달하며, 33개의 척추골과 그 사이의 섬유연골성 추간판으로 이루어져 있고, 두개골로부터 골반골까지 강한 인대와 근육으로 강화되어 신체를 지지하고 평형을 유지하며, 척주관내의 척수를 보호하고 각 척추 신경근이 분기되는 구조를 이루고 있는 것으로서, 인체의 자세를 유지시켜주고 그 속에 있는 중요한 신경을 보호하며 충격을 흡수하는 등의 역할을 수행한다.

통상적으로 성인의 경우, 척주(; Vertebral column)는 그 길이가 70~75cm인데 경추부터 천골 직전까지의 길이가 약 60cm이며, 이중 1/4이 추간판으로 이루어져 있고, 측면에서 볼 때 경추와 요추 부위에서는 각각 전만을, 흉추 및 천골 부위에서는 각각 후만을 이루게 된다. 그리고, 근육, 인대, 신경 및 혈관 등은 척추골을 중심으로 좌우 대칭적으로 배열된다.

즉, 척추골은 33개가 형성되어 상부로부터 경추 7개, 흉추 12개, 요추 5개, 천추 5개 및 미추 4개로 구성되며, 성인의 경우에는 천추와 미추가 융합되어 천골과 미골을 형성한다. 환추, 축추와 천골을 제외한 전형적인 척추골은 부위에 따라 크기와 모양이 다르나 공통적인 구조를 갖는다. 앞쪽에는 추체가 있고 뒤쪽에는 척추경과 추궁판으로 구성된 척추궁(Vertebral arch) 및 근육 부착과 관절 연결을 위한 돌기로 이루어져 있다. 추체는 하중을 지탱하는 부분으로 상, 하 변연부의 치밀골은 다른 부위보다 두껍고 둥근 모양이며 인접한 추체와는 추간판에 의해 분리되어 있다.

이러한 척추 구조를 갖는 인체에 외부 자극이 가해지면 우선적으로 경추 및 요추의 전만곡도와 흉추의 후만곡도에 변화가 온다. 이는 신체의 각 부분이 받는 무게중심의 변화를 초래하고 신체의 자세까지 변화를 야기해 결국에는 척추 근육의 불균형을 초래하여 상해를 입을 수 있다. 앞에서 말한 외부의 자극이란 청소년들의 바르지 못한 공부자세, 만성피로, 각종 스포츠 활동으로 인한 부상, 자동차 사고 및 영양의 불균형 등이 있다.

특히, 요추에 손상을 입은 환자는 요추를 이루는 각 척추골 사이의 간격이 좁아짐으로 인하여 이들 척추골에 의해 신경이 압박되면서 통증을 유발하게 되고, 이로 인해 거동을 마음대로 할 수 없게 된다. 이러한 환자에 대한 시술로는 요추를 이루는 척추골들 사이에 요추 고정구(보형물)를 삽입하여 그 척추골들 사이의 간격을 적정하게 유지시켜줌으로써 신경 압박을 해소하는 방법이 주로 적용되고 있다.

최근까지 사용되고 있는 기존의 요추 고정구로는 도 5와 같은 구조의 것이 있다. 상기 요추 고정구는 직육면체 형상의 고정구 본체(100)가 마련되고, 그 내부로부터 외측으로 육면이 개방된 개방부(101)를 갖는 것으로서, 상기 개방부의 일측면에는 척추골(1) 사이에 삽입 시술시 사용하게 되는 별도의 수술용 기구(파지구)를 결합하기 위한 나사공(102)이 형성되어 있다.

상기 고정구 본체(100)는 티타늄 등의 금속으로 이루어져 있으며, 시술 후에는 상기 고정구 본체(100)에 의해 그 척추골(1)들 간의 간격을 유지할 수 있게 되는 것이다.

상기 개방부(101)는 신체 내 영양분 등의 소통을 위하여 마련된 것으로, 상기 개방부(101)를 통해서 신체 융합을 촉진하는 척추골 이식물질이 채워지게 된다.

그러나, 상기한 바와 같은 종래의 요추 고정구는 시술 후 환자가 활동을 재개하여 그 시간이 경과됨에 따라 상기 척추골(1)들 사이로부터 점차 돌출되거나 이탈되어 환자의 신경을 자극함으로써 여전히 고통을 느끼게 되므로 이를 예방하기 위해서는 정기적인 검진 후 재수술을 하여야 하는 번거로움이 있었다.

또한, 이와 같은 요추 고정구의 이탈 방지를 위해서는 별도의 고정 시술을 병행하여야 하므로 의료비 부담이 가중되는 문제점이 있었다.

고안이 이루고자 하는 기술적 과제

본 고안은 상기한 바와 같은 제반 문제점을 해결하기 위하여 안출된 것으로, 그 목적은, 척추골들을 견고히 고정시켜줌과 아울러 환자의 상태에 맞게 적정간격을 유지할 수 있도록 그 높낮이를 자유롭게 조절할 수 있으며, 장시간 경과 후 시술 초기상태로부터 변형이 발생된 경우에도 나사를 죄거나 푸는 간단한 조작만으로 쉽게 교정 가능하고, 그 수명이 반영구적일 뿐만 아니라 의료비 부담을 최소화할 수 있는 요추 고정구를 제공함에 있다.

상기의 목적을 달성하기 위한 본 고안에 따른 요추 고정구는, 길이방향으로의 중심면을 따라 상호 면대칭을 이루며 분할되어 체결구에 의해 상호 대응되도록 결합되고 이들간의 결합에 의해 그 중앙부에 척추골 이식물질이 유동할 수 있는 관통장공이 형성되며 양단부에 사선방향으로 경사진 안내면이 형성되고 상기 안내면을 따라 더브테일홈이 형성된 한 쌍의 고정구 본체와, 상기 고정구 본체와 대칭 구조를 이루며 그 하부에 마주보도록 이격 배치되는 일체형의 대응 고정구 본체와, 상기 양 고정구 본체 선단부의 각 안내면에 양면이 각각 밀접하고 그 각 접촉면의 길이방향을 따라 상기 양 고정구 본체의 더브테일홈과 각각 끼워 맞춰지는 더브테일이 돌출 형성되며 몸체 중심부에 나사공이 관통 형성된 리드웨지와, 상기 리드웨지와 대응되는 구조를 이루며 상기 양 고정구 본체 후단부의 각 안내면에 양면이 각각 밀접하도록 결합 배치된 대응웨지와, 상기 대응웨지의 관통공과 리드웨지의 나사공에 체결되어 상기 대응웨지와 리드웨지간의 거리를 조절함으로써 상기 양 고정구 본체의 이격거리를 조절할 수 있도록 하는 홈붙이나사를 포함하여 구성됨을 특징으로 한다.

여기서, 척추골과 인접하는 상기 양 고정구 본체의 외측면에는 상기 고정구 본체의 진입 역방향으로의 이탈을 방지할 수 있도록 상기 대응웨지쪽으로 기울어진 일방향 톱니가 형성된 것이 바람직하다.

또한, 상기 대응웨지의 관통공은 외측으로 확장된 이중 환턱 구조를 이루고 상기 관통공의 큰 직경쪽 내주면상에는 왼나사방향으로 나선이 형성되어 시술자가 상기 요추 고정구를 파지할 수 있는 원통 관형의 파지구를 결합시킬 수 있도록 함이 바람직하다.

또한, 상기 고정구 본체 및 대응 고정구 본체의 더브테일홈과, 상기 리드웨지 및 대응웨지의 더브테일 간에는, 환자의 척추골간 전후위치 간격을 차등적으로 조절하여 교정할 수 있도록 소정의 유격을 형성함이 바람직하다.

고안의 구성 및 작용

이하, 본 고안의 바람직한 실시예에 따른 요추 고정구를 첨부된 도면에 의거하여 상세히 설명하면 다음과 같다.

도 1 내지 도 5는 본 고안에 따른 요추 고정구의 구조 및 그 적용상태를 도시한 것으로, 도 1은 상기 요추 고정구의 결합 사시도, 도 2는 상기 요추 고정구의 분해 사시도, 도 3은 상기 요추 고정구를 척추골(1) 사이에 삽입한 상태의 단면도, 도 4는 본 고안에 따른 요추 고정구를 척추골(1) 사이에 삽입한 후 환자의 상태에 맞도록 척추골(1)간의 간격을 균등하게 조절하여 교정하는 일례를 도시한 단면도, 도 5는 본 고안에 따른 요추 고정구를 척추골(1) 사이에 삽입한 후 환자의 상태에 맞도록 척추골(1)간의 전후위치 간격을 차등적으로 조절하여 교정하는 일례를 도시한 단면도이다.

상기 도면중 도 1 및 도 2에 도시된 바와 같이, 본 고안에 따른 요추 고정구는, 상기 요추 고정구가 삽입될 인접 척추골(1)들과 접촉하게 되는 고정구 본체(10) 및 대응 고정구 본체(20)와, 상기 양 고정구 본체(10)(20)들의 양단부 사이에서 슬라이딩되면서 상기 양 고정구 본체(10)(20)들의 간격을 좁히거나 넓혀주는 쐐기 형상의 이격수단인 리드웨지(30) 및 대응웨지(40)와, 상기 리드웨지(30) 및 대응웨지(40)간에 관통 체결되어 죄어지거나 풀리면서 이들의 간격

을 조절하여주는 홈붙이나사(50)로 이루어져 있다.

상기 양 고정구 본체(10)(20)는 상호 대칭을 이루며 마주보도록 이격 배치된 한 쌍의 아치형상을 이루는 구조로서, 중앙부에 척추골 이식물질이 유동할 수 있는 관통장공(11)(21)이 각각 형성되고, 양단부에 사선방향으로 경사진 안내면(13)(23)이 각각 형성되며, 상기 안내면(13)(23)들을 따라 더브테일홈(14)(24)이 각각 형성되어 있다.

그리고, 척추골(1)과 인접하는 상기 양 고정구 본체(10)(20)의 외측면에는 시술시 상기 양 고정구 본체(10)(20)의 진입방향에 대한 역방향으로 상기 양 고정구 본체(10)(20)가 이탈되는 것을 방지할 수 있도록 그 후단부쪽인 상기 대응웨지(40)를 향하여 기울어진 일방향 톱니(12)(22)가 각각 형성되어 있다.

여기서, 상기 양 고정구 본체(10)(20)와 양 웨지(30)(40)는 그 결합면이 외측을 향해 상호 대칭적으로 벌어져 있어 이들 부재중 마지막 하나의 결합이 용이하지 못하므로, 이를 해소하기 위해서는 상기 양 고정구 본체(10)(20)중 어느 하나가 길이방향으로 분할된 구조를 이루는 것이 이상적이다.

즉, 그 일례로서, 상기 고정구 본체(10)는 길이방향으로의 중심면을 따라 상호 면대칭을 이루며 분할되어 다수의 체결구(15)에 의해 상호 대응되도록 결합되는 한 쌍의 분할 고정구 본체(10a)(10b)로 형성함이 바람직하다. 상기 각 분할 고정구 본체(10a)(10b)에는 이들을 상호 대응되도록 밀착시켰을 때 일치할 수 있는 다수의 체결공(16)이 형성되어 있고, 상기 각 체결공(16)에는 리벳 또는 보울트 등이 관통 삽입되어 리벳팅 또는 너트에 의한 체결 방식에 의해 상호 밀착된 상태로 고정될 수 있다. 물론, 이때의 상기 대응 고정구 본체(20)는 일체형의 구조를 이루는 것이어도 무방하다.

이러한 구조를 이루는 본 고안의 요추 고정구는 상기 대응 고정구 본체(20)의 양쪽 더브테일홈(24)에 상기 양 웨지(30)(40)의 각 더브테일(32)(42)을 각각 밀어 넣어 결합한 후, 상기 양 웨지(30)(40)의 각 상부쪽 더브테일(32)(42)의 양측에서 상기 분할 고정구 본체(10a)(10b)를 밀착시키고, 체결구(15)로 고정함으로써 각 부재간의 연결상태를 유지할 수 있게 된다.

한편, 상기 리드웨지(30) 및 대응웨지(40)는 상기 양 고정구 본체(10)(20)들의 간격을 조절하기 위한 한 쌍의 이격수단으로서, 상호 대응되는 구조를 이루고 있으며, 상기 양 고정구 본체(10)(20) 선, 후단부의 각 안내면(13)(23)에 양면이 각각 밀접하고 그 각 접촉면의 길이방향을 따라 상기 양 고정구 본체(10)(20)의 더브테일홈(14)(24)과 각각 끼워 맞춰지는 더브테일(32)(42)이 각각 돌출 형성되어 있다.

다만, 상기 리드웨지(30)는 본 고안에 따른 요추 고정구를 척추골(1)들 사이로 삽입할 때 작업이 원활하도록 그 선단부 표면이 원호면을 이루는데 비하여, 상기 대응웨지(40)는 그 후단부 표면이 평면을 이루고, 또한, 상기 리드웨지(30)는 상기 홈붙이나사(50)의 나사부가 체결될 수 있도록 그 몸체 중심부에 일정 직경의 나사공(31)이 관통 형성되어 있는데 비하여, 상기 대응웨지(40)는 상기 홈붙이나사(50)의 헤드부가 걸릴 수 있도록 단턱을 갖는 구조의 관통공(41)이 형성되어 있다.

이를 더욱 상세히 설명하면, 상기 대응웨지(40)의 관통공(41)은 외측으로 확장된 이중 환턱 구조를 이루는 것으로서, 상기 관통공(41)의 큰 직경쪽 내주면상에는 왼나사방향으로 나선이 형성되어 시술자가 상기 요추 고정구를 파지할 수 있는 원통 관형의 파지구(3)를 결합할 수 있도록 된 것이다.

상기 파지구(3)는 시술 후에는 역회전시켜 상기 관통공(41)으로부터 분리해낼 수 있게 된 것으로서, 도 3에서 보는 바와 같이 환자의 몸통 외부에서 시술자가 파지할 수 있는 수단이며, 그 중공부를 통해 렌치(2)를 삽입하여 홈붙이나사(50)를 죌 수 있도록 되어 있다. 상기 홈붙이나사(50)를 죌 때 본 고안의 요추 고정구가 함께 회전하여서는 안되므로 상기 홈붙이나사(50)는 오른나사, 상기 파지구(3)는 왼나사의 형태로 체결되도록 각각 형성한다.

상기 홈붙이나사(50)는 상기 대응웨지(40)의 관통공(41)과 리드웨지(30)의 나사공(31)에 체결되어 상기 대응웨지(40)와 리드웨지(30)간의 거리를 조절함으로써 상기 양 고정구 본체(10)(20)의 이격거리를 조절할 수 있도록 해주는 것이다.

이와 같은 구성을 갖는 본 고안의 요추 고정구는, 도 3에 도시된 바와 같이 파지구(3)를 잡고 인접하는 2개의 척추골(1) 사이에 삽입한 후, 상기 파지구(3)내에 렌치(2)를 삽입해서 상기 홈붙이나사(50)를 죄어 그 양 고정구 본체(10)(20)의 외측면이 상기 각 척추골(1)의 표면에 각각 밀착되도록 함으로써 견고히 고정할 수 있다.

앞서 언급한 도 4는 상기 홈붙이나사(50)를 풀거나 죔에 따른 상기 양 고정구 본체(10)(20)와, 상기 리드웨지(30) 및 대응웨지(40) 간의 상대적인 움직임에 대한 변화 상태를 잘 보여주고 있다.

그 일례로서, 상기한 도 4는 본 고안에 따른 요추 고정구의 양단부가 균등 간격을 유지할 수 있도록 상기 홈붙이나사(50)를 죄었을 때를 나타내고 있으며, 이 경우에는 상기 홈붙이나사(50)와 결합된 양 웨지(30)(40)가 상기 양 고정구 본체(10)(20)의 안내면(13)(23)을 따라 슬라이딩되어 점차 근접하게 되면서 상기 양 고정구 본체(10)(20)를 각각 외측으로 밀어내게 된다. 따라서, 요추 고정구는 척추골(1)과 밀착되어 견고하게 고정될 수 있는 것이다. 이때, 상기 일방향 톱니(12)(22)는 상기 척추골(1)의 접촉 표면에 대하여 강한 마찰력을 발휘하여 요추 고정구의 진입방향에 대한 역방향으로의 이탈을 방지할 수 있게 된다.

이와는 반대로, 상기 홈붙이나사(50)를 풀었을 경우에는 상기 홈붙이나사(50)와 결합된 양 웨지(30)(40)가 상기 양 고정구 본체(10)(20)의 안내면(13)(23)을 따라 외측으로 슬라이딩되어 점차 멀어지게 되면서 상기 양 고정구 본체(10)(20)를 각각 내측으로 당겨주게 된다. 따라서, 요추 고정구는 척추골(1)과 이격되어 분리 가능하게 된다.

즉, 상기 요추 고정구를 인접한 척추골(1) 사이로부터 분리하여 제거할 필요가 있을 때에는, 파지구(3)와 렌치(2)를 사용하여 상기 척추골(1)들로부터 충분한 간극이 형성될 때까지 상기 홈붙이나사(50)를 풀어 분리시킨 후, 상기 요추 고정구를 수술용 기구로 들어내면 되는 것이다.

한편, 도 5는 본 고안에 따른 요추 고정구를 척추골(1) 사이에 삽입한 후 환자의 상태에 맞도록 척추골(1)간의 전후위치 간격을 차등적으로 조절하여 교정한 상태를 도시하고 있다. 통상의 경우에 있어서, 시술하고자 하는 환부의 척추골(1) 간격은 전후 간격이 일정하게 유지되지 않는 상태일 때가 대부분이다.

본 고안의 요추 고정구는, 상기 고정구 본체(10) 및 대응 고정구 본체(20)의 더브테일홈(14)(24)과, 상기 리드웨지(30) 및 대응웨지(40)의 더브테일(32)(42) 간에, 소정의 유격을 둠으로써, 그 유격만큼 상기 리드웨지(30) 및 대응웨지(40)의 위치를 환자의 척추골(1)간 전후위치 간격과 동일하게 차등적으로 조절하여 교정할 수 있으므로 그 활용 가치가 더욱 높다 할 것이다.

고안의 효과

이상에서 살펴본 바와 같이 본 고안의 요추 고정구는, 척추골들 사이에 삽입되어 척추골들로부터 돌출되거나 이탈되지 않고 상기 척추골들을 연속적으로 견고히 고정시켜줌과 아울러 환자의 상태에 맞게 적정간격을 유지할 수 있도록 그 높낮이를 자유롭게 조절할 수 있어 시술이 매우 간편하며, 장시간 경과 후 시술 초기상태로부터 변형이 발생된 경우에도 나사를 죄거나 푸는 간단한 조작만으로 쉽게 교정 가능하고, 그 수명이 반영구적일 뿐만 아니라 의료비 부담을 최소화 할 수 있는 이점이 있다.

본 고안은 첨부된 도면에 도시된 실시예를 기준하여 설명되어 있으나 이는 예시적인 것이라 할 수 있고, 당해 기술분야에서 통상의 지식을 가진 자라면 이로부터 다양한 변형 및 균등한 실시예들을 생각해 낼 수 있으므로 이러한 균등한 실시예들 또한 본 고안의 실용신안등록청구범위 내에 포함되는 것으로 보아야 함은 극히 당연한 것이다. 따라서 본 고안의 진정한 보호범위는 첨부된 청구범위에 의해서만 결정되어야 할 것이다.

(57) 청구의 범위

청구항 1.

길이방향으로의 중심면을 따라 상호 면대칭을 이루며 분할되어 체결구에 의해 상호 대응되도록 결합되고 이들간의 결합에 의해 그 중앙부에 척추골 이식물질이 유동할 수 있는 관통장공이 형성되며 양단부에 사선방향으로 경사진 안내면이 형성되고 상기 안내면을 따라 더브테일홈이 형성된 한 쌍의 고정구 본체;

상기 고정구 본체와 대칭 구조를 이루며 그 하부에 마주보도록 이격 배치되는 일체형의 대응 고정구 본체;

상기 양 고정구 본체 선단부의 각 안내면에 양면이 각각 밀접하고 그 각 접촉면의 길이방향을 따라 상기 양 고정구 본체의 더브테일홈과 각각 끼워 맞춰지는 더브테일이 돌출 형성되며 몸체 중심부에 나사공이 관통 형성된 리드웨지;

상기 리드웨지와 대응되는 구조를 이루며 상기 양 고정구 본체 후단부의 각 안내면에 양면이 각각 밀접하도록 결합 배치된 대응웨지; 및

상기 대응웨지의 관통공과 리드웨지의 나사공에 체결되어 상기 대응웨지와 리드웨지간의 거리를 조절함으로써 상기 양 고정구 본체의 이격거리를 조절할 수 있도록 하는 홈붙이나사;를 포함하여 구성됨을 특징으로 하는 요추 고정구.

청구항 2.

제 1 항에 있어서,

척추골과 인접하는 상기 양 고정구 본체의 외측면에는 상기 고정구 본체의 진입 역방향으로의 이탈을 방지할 수 있도록 상기 대응웨지쪽으로 기울어진 일방향 톱니가 형성된 것을 특징으로 하는 요추 고정구.

청구항 3.

제 1 항에 있어서,

상기 대응웨지의 관통공은 외측으로 확장된 이중 환턱 구조를 이루고 상기 관통공의 큰 직경쪽 내주면상에는 왼나사방향으로 나선이 형성되어 시술자가 상기 요추 고정구를 파지할 수 있는 원통 관형의 파지구를 결합할 수 있도록 된 것을 특징으로 하는 요추 고정구.

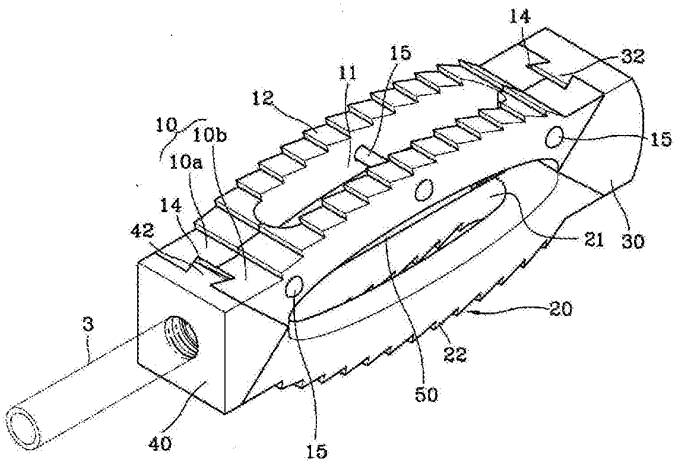
청구항 4.

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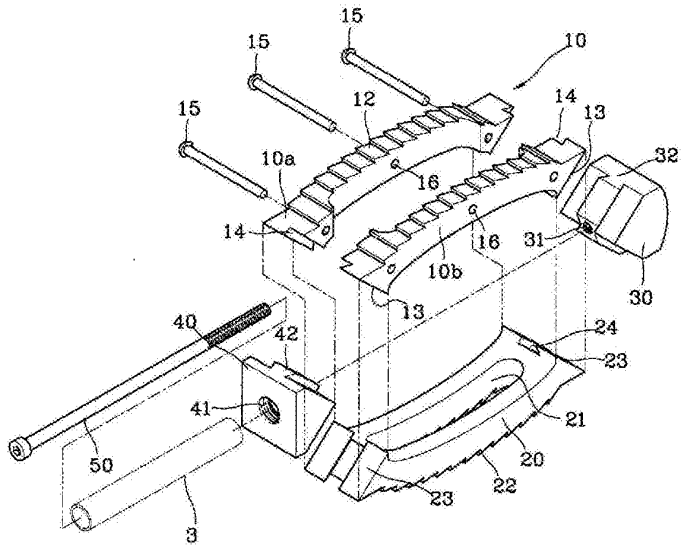
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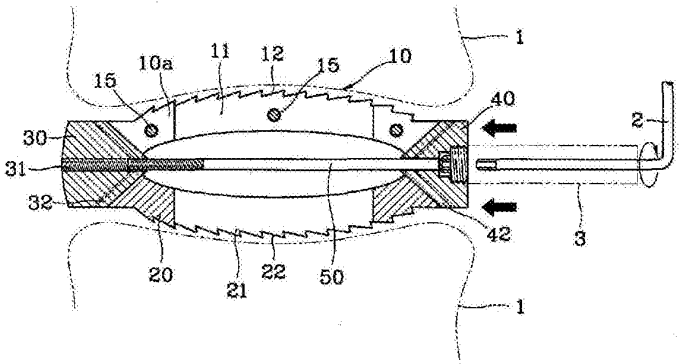
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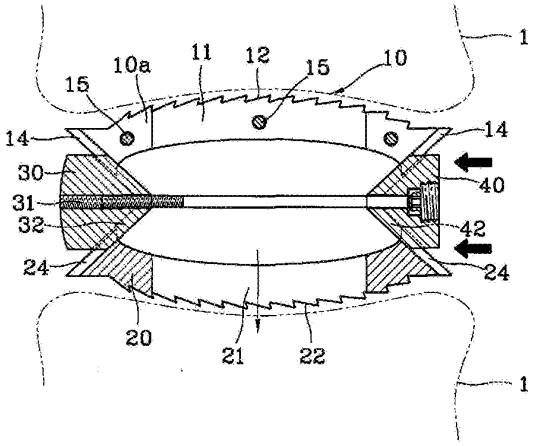
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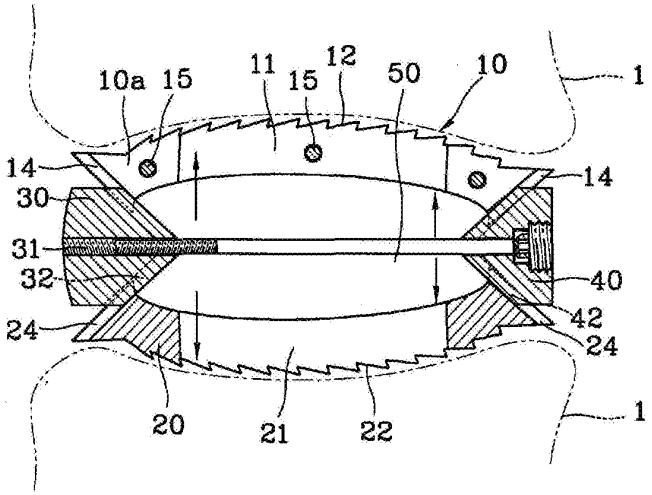
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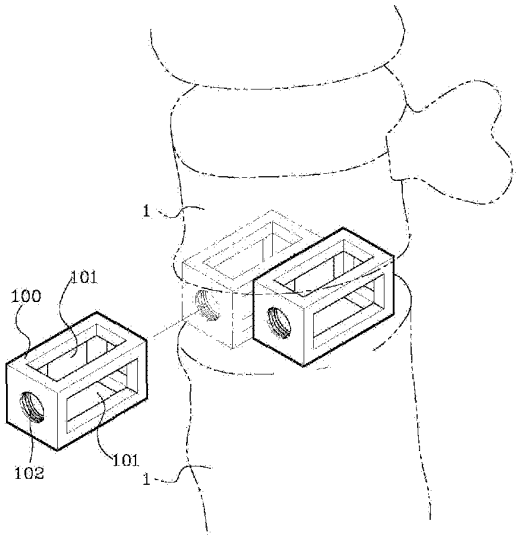
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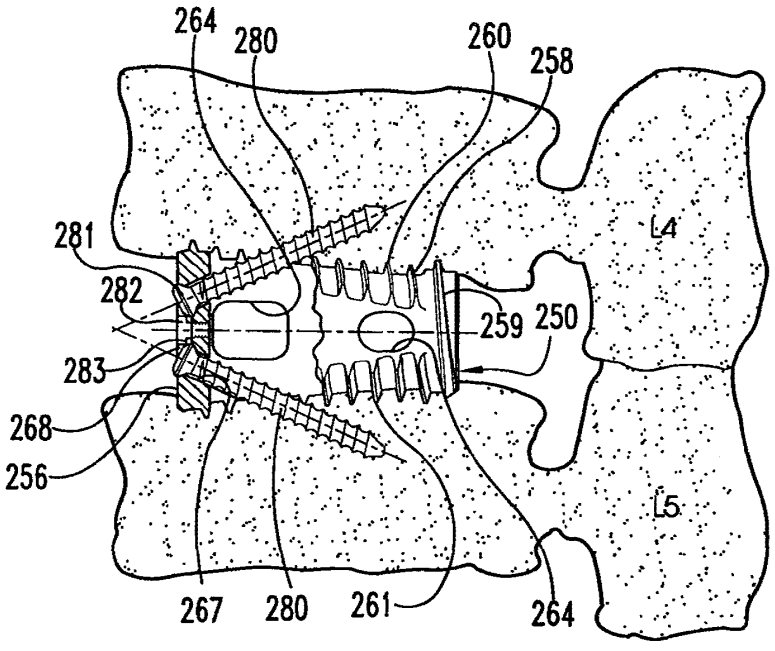
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(54) Title: METHODS AND INSTRUMENTS FOR INTERBODY FUSION

(57) Abstract

A laparoscopic surgical technique is provided for preparing a site for implantation of a novel fusion device or implant. In accordance with one embodiment of the technique, laparoscope (170) is provided having an outer sleeve (171) with distraction fingers (173) at one end to distract the disc space. The laparoscope (170) provides a sealed working channel to the disc space, through which the disc space is distracted, the vertebral endplates and surrounding disc is reamed, and the fusion device (250) inserted. A distraction plug (290) is provided for centering the outer sleeve (171) and for providing midline distraction of the disc space. In one embodiment, a fusion device (250) includes diverging bone screws (280) passing through an end wall (256) and upper and lower walls (260, 261) of the device to engage the adjacent vertebrae. In another embodiment, a connector plate (365, 375) is engaged to bilaterally position fusion devices (350) to prevent rotation and resist expulsion of the devices from the disc space.



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METHODS AND INSTRUMENTS FOR INTERBODY FUSION

BACKGROUND OF THE INVENTION

This application is a continuation-in-part of application serial number 08/604,874, filed on February 22, 1996, which is a continuation-in-part of application serial number 08/411, 017, filed on March 27, 1995, all owned by the assignee of the present application.

The present invention relates to methods and instruments for performing an interbody fusion of a disc space between two adjacent vertebrae. Specifically, the invention concerns laparoscopic techniques and instruments to prepare a fusion site and to insert fusion devices and implants.

The number of spinal surgeries to correct the causes of low back pain has steadily increased over the last several years. Most often, low back pain originates from damage or defects in the spinal disc between adjacent vertebrae. The disc can be herniated or can be suffering from a variety of degenerative conditions, so that in either case the anatomical function of the spinal disc is disrupted. The most prevalent surgical treatment for these types of conditions has been to fuse the two vertebrae surrounding the affected disc. In most cases, the entire disc will be removed, except for the annulus, by way of a discectomy procedure. Since the damaged disc material has been removed, something must be positioned within the intradiscal space, otherwise the space may collapse resulting in damage to the nerves extending along the spinal column.

The intradiscal space is often filled with bone or a bone substitute in order to prevent disc space collapse and to promote fusion of the two adjacent vertebrae. In early techniques, bone material was simply disposed between the adjacent vertebrae, typically at the posterior aspect of the vertebrae, and the spine column was stabilized by way of a plate or a rod spanning the affected vertebrae. Once fusion occurred the hardware used to maintain the stability of the segment became superfluous. Moreover, the surgical procedures necessary to implant a rod or plate to stabilize the level during fusion were frequently lengthy and involved.

It was therefore determined that a more optimal solution to the stabilization of an excised disc space is to fuse the vertebrae between their respective end plates, preferably with the need for anterior or posterior plating. There have been an extensive number of attempts to develop an acceptable intradiscal implant that could be used to replace a damaged disc and maintain the stability of the disc interspace between the adjacent vertebrae, at least until complete arthrodesis is achieved. These "interbody fusion devices" have taken many forms. For example, one of the more prevalent designs takes the form of a cylindrical implant. These types of implants are represented by the patents to Bagby, No. 4,501,269; Brantigan, No. 4,878,915; Ray, Nos. 4,961,740 and 5,055,104; and Michelson, No. 5,015,247. In these cylindrical implants, the exterior portion of the cylinder can be threaded to facilitate insertion of the interbody fusion device, as represented by the Ray, Brantigan and Michelson patents. In the alternative, some of the fusion implants are designed to be pounded into the intradiscal space and the vertebral end plates. These types of devices are represented by the patents to Brantigan, Nos. 4,743,256; 4,834,757 and 5,192,327.

Interbody fusion devices can be generally divided into two basic categories, namely solid implants and implants that are designed to permit bone ingrowth. Solid implants are represented by U.S. Patent Nos. 4,878,915; 4,743,256; 4,349,921 and 4,714,469. The remaining patents discussed above include some aspect that permits bone to grow across the implant. It has been found that devices that promote natural bone ingrowth achieve a more rapid and stable arthrodesis. The device depicted in the Michelson patent is representative of this type of hollow implant which is typically filled with autologous bone prior to insertion into the intradiscal space. This implant includes a plurality of circular apertures which communicate with the hollow interior of the implant, thereby providing a path for tissue growth between the vertebral end plates and the bone or bone substitute within the implant. In preparing the intradiscal space, the end plates are preferably reduced to bleeding bone to facilitate this tissue ingrowth. During fusion, the metal structure provided by the Michelson implant helps maintain the patency and stability of the motion segment to be fused. In addition, once arthrodesis occurs, the implant itself serves as a sort of anchor for the solid bony mass.

Another interbody fusion device that is designed to permit bone ingrowth is shown in

FIG. 1. This device is described and claimed in co-pending parent application serial no. 08/411, 017, filed on March 27, 1995, which disclosure is incorporated herein by reference. In one embodiment, this invention contemplates a hollow threaded interbody fusion device 10 configured to restore the normal angular relation between adjacent vertebrae. In particular, the device 10 as shown in FIG. 1 includes an elongated body 11, tapered along substantially its entire length, defining a hollow interior 15 and having a largest outer diameter at the anterior end 12 of the device to receive the bone growth material. The body 11 includes an outer surface 16 with opposite tapered cylindrical portions and a pair of opposite flat tapered side surfaces 22 between the cylindrical portions. Thus, at an end view, the fusion device gives the appearance of a cylindrical body in which the sides of the body have been truncated along a chord of the body's diameter.

The cylindrical portions include threads 18 for controlled insertion and engagement into the end plates of the adjacent vertebrae. A started thread 19 is provided at the posterior end 13 of the device 10 to facilitate engagement within a prepared bore. The outer surface of this fusion device is tapered along its length at an angle corresponding, in one embodiment, to the normal lordotic angle of the lower lumbar vertebrae. The outer surface is also provided with a number of vascularization openings 24, 25 defined in the flat side surfaces, and a pair of opposite elongated bone ingrowth slots 27 defined in the cylindrical portions.

Various surgical methods have been devised for the implantation of fusion devices into a subject disc space. A patent to Dr. Gary Michelson, U. S. No. 5,484,437, discloses one such technique and the associated instruments. As described in more detail in that patent, the surgical technique involved the use of a hollow sleeve having teeth at one end that are driven into the adjacent vertebrae. These teeth and the sleeve maintain the disc space height during the subsequent steps of the procedure. In accordance with one aspect of the invention in the '437 Patent, a drill is passed through the hollow sleeve to remove the disc and bone material to produce a prepared bore for the fusion device. The drill is then removed from the sleeve and the fusion device is positioned within the disc space using an insertion tool.

In another aspect of the procedure and instruments disclosed in the '437 Patent, a long distractor is provided having penetrating portions that urge the vertebral bodies apart to

facilitate the introduction of the necessary instruments. The long distractor can act as a guide for drilling and reaming tools concentrically advanced over the outside of the distractor to prepare the site for the fusion device.

While the Michelson technique represents a significant advance over prior surgical procedures for the preparation and insertion of fusion devices, the need for improvement remains. In particular, procedures and instruments that preserve the integrity of the surgical site are desirable. The present invention is directed to this need in the field.

SUMMARY OF THE INVENTION

In accordance with one aspect of the invention, a novel fusion device is provided that integrates a pair of bone screws. The fusion device can be a hollow substantially cylindrical body, such as the device shown in FIG. 1. In this aspect, the device includes a pair of screw bores formed in an end face of the body. The bores are arranged so that bone screws extending through the bores will be driven into the endplates of the adjacent vertebrae. In certain features, the heads of the bone screws are recessed within the body and held in place by a common locking screw. The screws help prevent retrograde expulsion or rotation of the fusion device, or a spacer, from the disc space.

The present invention also contemplates another approach to preventing rotation and/or dislodgment of fusion devices placed bilaterally in the disc space. In one embodiment, a transverse connector plate is engaged by locking screws to the end walls of the bilateral fusion devices. In one feature, the end walls define central recesses and transverse grooves to receive the connector plate. In another embodiment, the connector plate can include screw bores to receive bone screws driven into the vertebrae at a location in between the fusion devices.

In another aspect of the invention, a method is provided for preparing a subject disc space for implantation of a fusion device or implant between adjacent vertebrae. In this technique, a laparoscope is provided that includes an outer sleeve with opposite extensions at one end of the outer sleeve and a laparoscopic port engaged at the outer end of the outer sleeve, the laparoscopic port having a number of seals, with the opposite extensions configured to maintain distraction of the adjacent vertebrae.

The preferred technique comprises the steps of making an incision in the skin of the patient aligned with the subject disc space, retracting tissue beneath the incision to expose the disc annulus; and piercing the disc annulus to create an opening. The outer sleeve of the laparoscope is advanced through the incision, leaving the port outside the skin of the patient while inserting the opposite extensions into the disc space with the outer sleeve contacting the disc annulus. The laparoscope, and particularly, the outer sleeve, creates a protected working channel between the disc space and the laparoscopic port outside the patient.

In a further step of the preferred inventive technique, a reamer is operated through the number of seals and the outer sleeve of the laparoscope to create a prepared bore in the disc material and the adjacent vertebrae for implantation of a device into the bore.

In a most preferred embodiment of the surgical technique, the technique comprises the steps of percutaneously exposing the annulus of the disc in the subject disc space through an incision in the skin of the patient and piercing the disc annulus to create an opening. A distractor can then be inserted through the incision and through the opening into the disc space to distract the vertebrae adjacent the subject disc space. The laparoscope outer sleeve is then introduced through the incision and over the distractor, leaving the port outside the skin of the patient while inserting the opposite extensions through the opening into the disc space to create the protected working channel between the port and the distractor tip.

In subsequent steps, the distractor is removed and a reamer is advanced through the number of seals of the laparoscope and through the outer sleeve into the disc space to ream the disc space and adjacent vertebrae to create a prepared bore for the fusion implant. After the reamer is removed from the laparoscope, the fusion implant can be advanced through the number of seals and through the outer sleeve into the prepared bore. With the fusion implant in position, the laparoscope can be withdrawn from the patient.

In one aspect of the invention, a switching sleeve is placed within the outer sleeve of the laparoscope with an end of the switching sleeve projecting beyond the opposite fingers of the outer sleeve, the end of the switching sleeve being tapered to minimize trauma to tissue adjacent the subject disc space as the outer sleeve adjacent into the patient with the switching sleeve projecting beyond the opposite extensions of the outer sleeve.

In a further embodiment, the laparoscopic method is used for bilateral placement of two fusion devices into a subject disc space. In addition to the steps previously described, this embodiment of the surgical technique includes unseating the outer sleeve of the laparoscope from the first opening in the disc annulus by withdrawing the laparoscope until the opposite extensions of the outer sleeve are outside the disc annulus. With the switching sleeve in position within the outer sleeve, the laparoscope is moved to the second opening in the disc space without removing the laparoscope from the patient. The steps for preparing the bore to receive a fusion implant can be repeated. In one specific embodiment, these steps

are conducted at the second opening with the distractor remaining within the first opening. After a fusion implant is advanced through the number of seals and through the outer sleeve into the second prepared bores the laparoscope can then be returned to the first opening for insertion of another fusion implant. During this step, the fusion implant contained within the second prepared bore maintains distraction of the disc space.

As an adjunct to this inventive technique, a distraction device is provided in one aspect of the invention. The distraction device can include an elongated stem sized for insertion along the A-P midline of the intervertebral disc space. Preferably, opposite surfaces of the device include a number of ridges that operate as bone engaging surfaces to resist expulsion of the device. In one important feature, the stem of the distraction device includes a bore to receive a spike projecting from a tubular body, such as the outer sleeve discussed above. With this feature, the distraction device acts not only as a midline distractor, but also as a centering guide to locate the tubular body through which subsequent surgical procedures can be performed.

In a further feature, the distraction device can include a flange projecting from the stem. The flange has a bone contacting that transmits to the vertebra a force applied to the distraction device (preferably by a manual tool). This flange can be used to reduce a high grade spondylolisthesis condition as the distraction device is driven into the disc space.

One object of the present invention is to provide surgical technique and instruments that permit the preparation of a disc space for insertion of a fusion implant under a sealed condition. A further object of the invention is to implement laparoscopic techniques to implant fusion devices.

With respect to fusion devices, one object is to enhance the stability of the device *in situ* while reducing the risk of expulsion of the device. Yet another object is to provide means for readily reducing a spondylolisthesis condition from a laparoscopic approach .

One benefit of the present invention is that all of the steps necessary to prepare a disc space and to implant a fusion device can be conducted in a protected environment. In

addition, the inventive techniques and instruments allow minimal intrusion into the patient, which minimized the risks normally associated with spinal surgery.

Other objects and benefits can be discerned from the following written description and accompanying figures.

DESCRIPTION OF THE FIGURES

FIG. 1 is a side perspective view of a threaded fusion device having a tapered configuration to restore the normal angle of a spinal motion segment.

FIG. 2 is a top elevational view of an implant driver for use in engaging and driving a fusion device such as the device shown in FIG. 1.

FIG. 3 is an enlarged perspective view of the end of the implant driver shown in FIG. 2 engaged to a fusion device such as shown in FIG. 1.

FIG. 4 is an enlarged side cross-sectional view of the implant driver and fusion device shown in FIG. 3.

FIG. 5 is an enlarged side cross-sectional view of an alternative embodiment of an implant driver for engaging and driving a fusion device such as the device shown in FIG. 1.

FIG. 6 is a driving tool attachment according to one aspect of the present invention.

FIG. 7 is an enlarged side cross-sectional view similar to the view in FIG. 5 with the driving tool attachment of FIG. 6 engaged between the implant driver and the fusion device.

FIG. 8 is an end perspective view of a threaded fusion device according to a further embodiment of the invention.

FIG. 9 is a side perspective view of a driving tool attachment according to a further aspect of the present invention in which the driving tool attachment is configured to engage the fusion device depicted in FIG. 8.

FIG. 10 is a side partial cross-sectional view of a fusion device according to the embodiment of FIG. 8 disposed between adjacent vertebrae and engaged in position by a pair of bone screws in accordance with one aspect of the present invention.

FIGS. 11(a)-(d) are lateral representations of the spine showing four steps of a surgical method for implanting a fusion device such as the device in FIG. 1 according to an anterior approach in one aspect of the present invention.

FIGS. 12(a)-(d) are lateral representations of the spine showing four steps of a surgical method for implanting a fusion device such as the device in FIG. 1 according to a posterior approach in a further aspect of the present invention.

FIG. 13 is a frontal view of a patient with locations identified for surgical incisions

according to a preferred embodiment of the present inventive laparoscopic surgical technique.

FIG. 14 is an A-P representation of a spinal segment at the laparoscopic surgical site depicting one step of the inventive surgical technique in which bilateral locations are marked on the disc annulus for insertion of a pair of fusion devices, such as the device shown in FIG. 1.

FIG. 15 is an enlarged A-P view of the disc at the spinal segment showing the use of the template represented in FIG. 14 of the invention.

FIG. 16 is an A-P representation of the laparoscopic surgical site depicting a further step of the inventive surgical technique of creating a pilot hole at each of the bilateral locations marked in the step shown in FIG. 14.

FIG. 17 is an A-P representation of the laparoscopic surgical site depicting a further step of the inventive surgical technique of using a trephine to create a bore at each of the bilateral locations marked in the step shown in FIG. 14.

FIG. 18 is an A-P representation of the laparoscopic surgical site depicting a further step of the inventive surgical technique for inserting a distractor into the prepared site at each of the bilateral locations marked in the step shown in FIG. 11.

FIG. 19 is a perspective representation of the laparoscope according to the present invention in which the outer sleeve of the laparoscope is engaged within the subject disc space.

FIG. 20(a) is a perspective representation of the laparoscope of FIG. 19 with a switching sleeve according to one aspect of the invention disposed within the laparoscope.

FIG. 20(b) is an enlarged A-P representation of the laparoscope and switching sleeve of FIG. 20(a) showing the positioning of the distractor tip as depicted in FIG. 18.

FIG. 21 is a perspective representation of the laparoscope of FIG. 19 with a reamer extending through the laparoscope to prepare the site for receiving a fusion device.

FIG. 22 is a perspective view of an implant driver of the type shown in FIG. 2 engaged to a fusion device and including a T-handle assembly engaged to the driver.

FIG. 23 is a perspective view of an implant holder according to one aspect of the present invention.

FIG. 24 is a perspective representation of the laparoscope used to implant a bone dowel within the prepared site and including a bone dowel impactor in accordance with one aspect of the present invention.

FIG. 25 is a top perspective view of a distraction plug in accordance with one embodiment of the present invention.

FIG. 26 is a side cross-sectional view of the distraction plug shown in FIG. 25.

FIG. 27 is an end elevational view of the distraction plug shown in FIGS. 25 and 26.

FIG. 28 is a side view of the distraction plug shown in FIG. 25 as it is inserted between adjacent vertebrae using a plug driver in accordance with one aspect of the present invention.

FIG. 29 is a side perspective view of a distraction plug in accordance with a further embodiment of the present invention.

FIG. 30 is a side perspective view of a plug driver in accordance with a further embodiment of the invention configured for engaging a distractor plug as shown in FIG. 29.

FIG. 31 is a rear perspective view of a percutaneous surgical sleeve in engagement with a distractor plug in accordance with the embodiment shown in FIG. 25.

FIG. 32 is a superior A-P view of a vertebra of the spine with the distractor plug and percutaneous surgical sleeve shown in FIG. 31 disposed within the disc space, with an alternative position of the sleeve shown in phantom.

FIG. 33 is a side perspective view of a percutaneous surgical sleeve in accordance with a further embodiment of the invention with an outrigger spike engaged thereto for attachment to a distractor plug according to FIGS. 25 or 29.

FIG. 34 is an end perspective view of a double barrel percutaneous surgical sleeve configured for engaging a distractor plug, such as the distractor plug shown in FIG. 29.

FIG. 35 is a side perspective view of an assembly in accordance with a further embodiment of the present invention utilizing a pair of fusion devices connected by a connector plate.

FIG. 36 is a side perspective view of an alternative embodiment of the assembly with a pair of fusion devices interconnected by an alternative connector plate.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

For the purposes of promoting an understanding of the principles of the invention, reference will now be made to the embodiments illustrated in the drawings and specific language will be used to describe the same. It will nevertheless be understood that no limitation of the scope of the invention is thereby intended, such alterations and further modifications in the illustrated device, and such further applications of the principles of the invention as illustrated therein being contemplated as would normally occur to one skilled in the art to which the invention relates.

As described above, one interbody fusion device, as shown in FIG. 1, can be implanted within the intradiscal space. This interbody fusion device 10 can be implanted using the implant driver 50 shown in FIG. 2. The implant driver 50 is comprised of a shaft 51 and sleeve 52 concentrically disposed about the shaft. Tongs 54 are formed at one end of the shaft for gripping the interbody fusion device 10 for implantation. Preferably the tongs include a tapered outer surface 55 and an opposite flat inner surface 56 adapted to engage the truncated side walls 22 of the interbody fusion device as shown in FIGS. 3, 4. Most preferably the tapered outer surface 55 conforms to the root diameter of the interrupted threads 18 of the device 10 so that the tongs 54 essentially complete the full cylindrical shape of the body wall 16. The adaptation of the tongs' tapered outer surface 55 facilitates screw insertion of the interbody fusion device 10 since the outer surface 55 will ride within the tapped bore in the vertebral end plates.

Each of the tongs 54 can be provided with interlocking fingers 58 and a driving projection 59 extending from the inner surface 56, most clearly shown in FIG. 4. Referring again to FIG. 2, the shaft 51 defines a hinge slot 62 supporting each of the pair of tongs 54. The hinge slot 62 is configured so that the tongs will have a naturally biased position spread sufficiently apart to accept the fusion device 10 therebetween. The shaft 51 defines a conical taper 63 between the hinged slot 62 and each of the tongs 54. This conical taper mates with a conical chamfer 67 defined on the inner wall of the sleeve 52. Thus, as the sleeve 52 is advanced toward the tongs 54, the conical chamfer 67 rides against the conical taper 63 to close or compress the hinge slot 62. In this manner, the tongs 54 are pushed toward each

other and pressed into gripping engagement with the interbody fusion device situated between the tongs.

The shaft 51 and sleeve 52 are provided with a threaded interface 65 which permits the sleeve 52 to be threaded up and down the length of the shaft. Specifically, the threaded interface 65 includes external threads on the shaft 51 and internal threads on the sleeve 52 having the same pitch so that the sleeve can be readily moved up and down the implant driver 50. The shaft 51 is also provided with a pair of stops 69 which restrict the backward movement of the sleeve 52 to only the extent necessary to allow the tongs 54 to separate a sufficient distance to accept the interbody fusion device 10.

The use of the implant driver 50 is shown with reference to FIGS. 3, 4. As can be seen in FIG. 3, the outer surface 55 of the tongs 54 reside generally flush with the root diameter of the interrupted threads 18. As seen in FIG. 4, the interlocking fingers 58 can be arranged to fit within the vascularization opening 24 on each of the truncated side walls 22. In a similar fashion, the driving projections 59 engage the driving tool slots 29 at the anterior end 12 of the conical body 11. The combination of the interlocking fingers 58 and driving projections 59 firmly engage the interbody fusion device 10 so that the device can be screw threaded into a tapped or untapped opening in the vertebral bone. The tongs 54 in this embodiment are configured to engage the fusion device 10 and to impart a threading or rotational force to the device. It is understood that the tongs can adopt other configurations depending upon the structure of the fusion device to be implanted.

An alternative embodiment of the implant driver is shown in FIG. 5. The driver 90 includes a shaft 91, having a length sufficient to reach into the intradiscal space from outside the patient. Connected to the end of shaft 91 is a head which defines a pair of opposite tongs 93, each of which are configured for flush contact with the flat truncated side walls 22 of the fusion device 10. Like the tongs 54 of the previously described implant driver 50, the outer surface of the tongs is cylindrical to correspond to the cylindrical threaded portion of the device.

Unlike the implant driver 50, the driver 90 of the embodiment in FIG. 5 uses an expanding collet assembly to firmly grip the fusion device 10 for insertion into the body. Specifically, the head 92 defines a collet 94 having a central collet bore 95 formed

therethrough. The collet 94 terminates in an annular flange 96 that at least initially has a diameter slightly smaller than the inner diameter of the fusion device 10 at its end 12. An expander shaft 97 slidably extends through the collet bore and includes a flared tip 98 situated adjacent and extending just beyond the annular flange 96. The flared tip 98 of the expander shaft 97 starts at a diameter sized to slide within the collet bore 95 and gradually flares to a diameter larger than the bore.

The implant driver 90 further includes a puller shaft 99 slidably disposed within a bore 100 defined in the shaft 91. The puller shaft 99 has a locking chamber 101 at its end which engages a locking hub 102 formed at the end of the expander shaft 97. The puller shaft 99 projects beyond the end of the shaft 91 for access by the surgeon. When the puller shaft 99 is pulled, it pulls the expander shaft 97 away from the annular flange 96 of the collet 94 so that the flared tip 98 becomes progressively engaged within the collet bore 95. As the tip 98 advances further into the bore 95, the annular flange 96 expands from its initial diameter to a larger second diameter sufficient for firm gripping contact with the interior of the fusion device 10. With the fusion device so engaged, the implant driver can be used to insert the device 10 into the surgical site, after which the expander shaft can be advanced beyond the collet bore to release the flat tip and, consequently, the fusion device.

In certain circumstances, it may be necessary to drive the fusion device 10 deeper into the disc space. When either of the implant drivers 50 or 90 is engaged to the fusion device, the device can be readily advanced farther into the disc space. However, once the implant driver is removed and it is then discovered that the fusion device needs to be repositioned, the flexible nature of the tongs 54 and 93 of the two implant drivers makes reacquisition of the now implanted fusion device difficult. To alleviate this difficulty, a driving tool attachment 120 is provided, as shown in FIG. 6. The driving tool attachment 120 includes a body 121 having a first end 122 and an opposite second end 123. Like the fusion implant, the body 121 of the driving tool attachment 120 includes a cylindrical portion 125 and opposite flat side portions 126. The opposite side portions 126 are configured to be engaged by the tongs of the above driving tools 50 or 90.

The driving tool attachment 120 includes a pair of opposing flanges 130 at end 123. The flanges 130 are configured to engage the opposite flat surface 122 on the fusion

implant 10, in a manner similar to that accomplished by the tongs of the implant driver 50 and 90. The end 123 also includes a boss 131 which is configured to be inserted into the opening at the end of the implant 10 (see FIG. 7).

In use, the driving tool attachment 120 can be engaged with one of the driving tools 50 or 90, with the tongs firmly grasping the flat surfaces 126, as shown in FIG. 7. The driving tool attachment can then be advanced into the disc space with the flanges 130 oriented across the space so that they can readily interface with the flat surfaces 22 of the fusion device 10. When the driving tool attachment 120 is properly aligned, the boss 131 projects into the hollow opening 15 at the anterior end 12 of the fusion device and the flanges 130 engage the opposite flat surfaces 22 of the device. The driving tool can then be rotated as if the fusion implant were directly engaged to the main driving tool. The attachment readily transmits the rotational driving force to the implant 10 to thread it deeper into the disc space or to retract it back within the disc space. One particular advantage provided by the driving tool attachment 120 is that the relatively flexible tongs of the two driving tools 50 and 90 can be already engaged to the attachment 120 before insertion into the surgical site. This eliminates a great deal of fiddle factor and avoids the risk that the tongs would be unable to firmly grasp the implant 10 when it is already in position within the disc space.

In a further embodiment of the present invention, an interbody fusion device is provided that permits supplemental fastening to the adjacent vertebrae. In particular, an interbody fusion device 250, as depicted in FIG. 8, includes a hollow body 251 having a first end 252 and a second end 253. The hollow body 251 defines a hollow interior 255 and includes an end wall 256 at the first end 252. Like the fusion device 10 shown in FIG. 1, the interbody fusion device 250 includes external threads 258 spanning a substantial portion of the length of the hollow body 251, and a continuous thread 259 adjacent the second end 253 of the body. Also like the fusion device 10, the interbody fusion device 250 includes opposite flat sidewalls 262 that interrupt the external threads 258, as well as opposing slots 263 offset from the flat sidewalls 262 which also interrupts a portion of the external threads 258. Thus far, the interbody fusion device 250 is substantially similar to the device 10 shown in FIG. 1. For example, the device can be tapered so that it has a

larger diameter at the first end 252 than at the second end 253. In addition, side windows 264 (see FIG. 10) can be provided in the flat sidewalls 262. The side walls 262 essentially divide the body 251 into upper and lower threaded portions that are configured to be threadedly driven into adjacent vertebrae.

In accordance with this embodiment, the interbody fusion device 250 includes a pair of driver openings 265 defined in the end wall 256 at the first end 252. Intermediate between the driver openings 265 are a pair of offset screw bores 267. In this preferred embodiment, the screw bores 267 are formed so that their respective longitudinal axes intersect and project out from the top and bottom portions 260, 261. Preferably the axes are arranged to intersect the slots 263 in the top and bottom of the fusion device. In this configuration, the longitudinal axes of the two screw bores intersect outside the hollow body 251 and the end wall 256, as seen in FIG. 10. A threaded bore 270 is formed between the two screw bores 267. The screw bores 267 also define a recessed portion 268, while the threaded bore defines a recessed portion 271 that intersects each of the recessed portions 268 of the screw bores 267 at an overlap 272.

In using the interbody fusion device 250, a driving tool attachment 275 is provided that permits insertion of the device within a properly prepared intervertebral space. As depicted in FIG. 9, the driving tool attachment 275 is similar to the implant driver shown in FIG. 6. In this instance, the driving tool attachment 275 includes a body 276 having opposite flat sidewalls 277, so that the body is adapted to be engaged by the implant driver 90 in the manner depicted in FIG. 7. In accordance with the present embodiment, the driving tool attachment 275 includes a pair of spaced-apart driving bosses 278 projecting from a mating face 279. The bosses 278 are sized and shaped to fit within the driver openings 265 when the mating face 279 is in direct contact with the end wall 256 of the fusion device 250. The driving tool attachment 275 can be engaged to a fusion device, such as device 250, to permit threading of the device into the intervertebral disc space, such as the space between lumbar vertebrae L4 and L5, as shown in FIG. 10.

With the fusion device 250 appropriate positioned within the intervertebral disc space, a pair of bone screws 280 can be extended through respective screw bores 267 in the hollow body 251. The screws are passed through the bores 267 until the bone

engaging threads of the screws 280 contact the vertebral bone. As the bone screws 280 are threaded into the vertebral bone, the head 281 of each of the bone screws 280 seats within the respective recessed portions 268 of each of the screw bores 267. In this orientation, the heads 281 of the bone screws 280 are flush with or below the surface of the end wall 256 of the fusion device 250. At this point, a locking screw 282 can be threaded into the threaded bore 270. As the locking screw is tightened into the bore 270, the head 283 of the locking screw contacts the heads 281 of both bone screws 280. Further tightening of the locking screw 282 causes the head 283 to seat within the recessed portion 271 to trap the heads 281 of the bone screws 280 within their respective screw bores 267. Thus, the set screw 282 prevents backout of the bone screws 280 when they are engaged within the adjacent vertebrae.

The diverging bone screws 280 provide greater stability to the fusion device 250 than can be achieved with prior threaded devices. The bone screws enhance the resistance to retrograde expulsion of the device and prevents counter-rotation or unthreading. The bone screws 280 can be of a wide range of sized provided that the screws are long enough to achieve an effective purchase in the adjacent vertebrae.

In accordance with additional aspects of the present invention, two methods for implanting an interbody fusion device, such as the devices 10 or 250, are contemplated. First, with reference to FIGS. 11(a) – 11(d), an anterior approach is shown. As a preliminary step, it is necessary to locate appropriate starting points for implanting the fusion device, preferably bilaterally. In the first step of the anterior approach, a distractor 75 is disposed between the vertebral end plates E to dilate the L4-L5 or L5-S1 disc space. (It is understood, of course, that this procedure can be applied at other vertebral levels). In the second step, shown in FIG. 11(b), an outer sleeve 76 is disposed about the disc space. The outer sleeve 76 can be configured to positively engage the anterior aspect of the vertebral bodies to firmly, but temporarily, anchor the outer sleeve 76 in position. In essence, this outer sleeve 76 operates as a working channel for this approach. In the step of FIG. 11(b), a drill 77 of know design is extended through the outer sleeve and used to drill out circular openings in the adjacent vertebral bodies. The openings can be tapped to facilitate screw insertion of the fusion device 10, although this step is not necessary.

In the next step shown in FIG. 11(c), the fusion device 10 is engaged by the implant driver 50 and extended through the outer sleeve 76 until the starter thread 19 contacts the bone opening. The implant driver 50 can then be used to screw thread the fusion device into the tapped or untapped opening formed in the vertebral end plate E. It is understood that in this step, other suitable driving tools could be used, such as a screw driver configured to engage the driving tool slots 29 at the anterior end 12 of the device 10. The degree of insertion of the fusion device 10 determines the amount of lordosis added or restored to the vertebral level. In the final step, the implant driver is removed leaving the fusion device 10 in position. It can be seen that once implanted, the closed posterior end 13 is directed toward the posterior aspect of the vertebrae. The hollow interior 15 is open at its anterior end 12, but can be closed by a plastic or metal material, if necessary.

In a second inventive method, as depicted in FIGS. 12(a)-12(d), a posterior approach is implemented. The first two steps of the posterior approach are similar to that of the prior anterior approach, except that the distractor 75, outer sleeve 76 and drill 77 are introduced posteriorly at the instrumented motion segment. This approach may require decortication and removal of vertebral bone to accept the outer sleeve 76. In the third step of this method, the fusion device 10 is inserted through the outer sleeve 76 into the dilated disc space. It is understood that the disc space is preferably dilated only to the extent necessary to receive the implant with the truncated side walls 22 directly facing the vertebral end plates E. Thus, as shown in FIG. 12(c), the bone ingrowth slot 27 is facing laterally, rather than coronally, as expected for its final implanted position. A suitable driving tool 80 can be provided to project the fusion device 10 through the outer sleeve 76 and into the intradiscal space. In one embodiment, the driving tool 80 includes a projection 81 which is configured to engage a slot opening formed in the end wall at the posterior end 13 of the fusion device 10. An internal thread (not shown) can be used to fix the device 10 to the driver 80.

Once the fusion device 10 has been advanced into the intradiscal space to the appropriate depth relative to the pivot axis P of the vertebrae, the driving tool 80 is used to rotate the implant in the direction of the rotational arrow R in FIG. 12(c). As the driving tool 80 is rotated, the device itself rotates so that the interrupted threads 18 start cutting

into the vertebral bone at the end plates E. In this manner, the implant operates as a cam to separate the adjacent vertebrae in the direction of the spreading direction arrows S in FIG. 12(c). This camming approach provides a somewhat easier insertion procedure than for the anterior approach of FIGS. 11(a)-(d) in that a single rotation is required to lock the implant into the vertebral bone. In contrast, the formerly discussed screw insertion technique of the anterior approach requires continuous threading of the device into position.

With either the anterior (FIGS. 11(a)-(d)) or the posterior approach (FIGS. 12(a)-(d)), the position of the fusion device 10 with respect to the adjacent vertebrae can be verified by radiograph or other suitable techniques for establishing the angular relationship between the vertebrae. Alternatively, the preferred depth of insertion of the implant can be determined in advance and measured from outside the patient as the implant is positioned between the vertebrae. The depth of insertion of the fusion device can be ascertained using depth markings (not shown) on the implant drivers 50, 90 or 80.

In another embodiment of the inventive surgical technique, laparoscopic technology is used to provide a sealed and protected channel for instruments and implants directed to the subject disc space. In accordance with one aspect of this inventive method, an anterior approach to the L5-S1 motion segment is illustrated. It is of course understood that these same techniques and instruments to be described below could be used at different vertebral levels or in a posterior approach under appropriate conditions.

As depicted in FIG. 13, the present inventive technique includes making a small incision 140 and preferably inserting an insufflator needle into the abdominal cavity. Fluid is introduced into the abdominal cavity through the insufflator needle to a pressure of preferably approximately 15mm of mercury to assist in visualization of the surgical site. An initial port 141 for the laparoscope is placed five to ten centimeters cephalad of the umbilicus in the midline ten millimeters in length. The abdomen is visually explored and the patient is placed in steep Trandelenburg. The abdominal wall is visualized endoscopically as two working ports 142, 143 are placed just lateral to the epigastric vessels, opposite the level or levels to be fused. It is believed to be advantageous to stagger the ports slightly from direct opposition to each other.

The preferred method continues with insertion of retractors through the ports 142, 143. The retractors can be used to sweep the small bowel superiorly out of the pelvis. The sigmoid colon is also pulled out of the pelvis and held laterally with the left fan retractor. For fusion at the L5-S1 junction, the sacral promontory and drop-off can be easily seen at this point. The posterior peritoneum overlying the L5-S1 disc space is then incised longitudinally with endoshears for the desired exposure. Using opposing fan retractors as blunt dissectors, the soft tissue underlying the parietal peritoneum can be swept laterally to bilaterally expose the anterior L5-S2 disc annulus. The sacral artery and vein coursing the disc are individually ligated with hemoclips and transected. A dissector can be used to remove residual soft tissue over the disc. Exposure is maintained with the left fan retractor in place holding the colon out of the way. It has been found that usually the right side does not require retraction, so a suction irrigation catheter can be used through this port.

In one specific procedure for the L4-L5 disc, the posterior peritoneum is incised more proximally about 3 centimeters. Again, the left fan is used to retract the colon laterally and with careful blunt dissection the aorta is exposed anteriorly at the bifurcation. The L4-L5 disc is usually right below this point. Left lateral dissection is carried out over the left common iliac vein and artery, gently retracting these vessels to the right. In order to retract these vessels enough to the right for adequate disc exposure the ascending segmental vein branch must be identified and transected. Once this vessel is cut, the artery and vein can then be bluntly retracted to the right with a fan or loop retractor to expose a significant amount of the L4-L5 disc for fusion.

Once the subject disc is exposed, it can be important to align the abdominal entry operating trocar port site 145 with the disc to be fused so that the operating trocar is parallel with the endplates of the disc in the sagittal plane. The entry point is estimated and a small Steinmann pin can be placed either in the interspace or along the patient and checked with lateral C-arm and adjusted accordingly. A 1.5 to 2.5 centimeter incision can be made for placement of the operating trocar. A blunt introducer is placed in the abdomen and an 18mm working trocar 147 (FIG. 14) can be placed over it under endoscopic visualization.

In accordance with a further aspect of the present embodiment of the surgical

technique, the annular of the subject disc D is marked for bilateral placement of a pair of fusion devices. For example, as shown in FIG. 14, a working trocar 147 is situated within the working port 145 (see FIG. 13). The bilateral marks can be made with a template 150, as shown in general in FIG. 14 and in more detail in FIG. 15. Greater detail concerning this template and its method of use can be found in U. S. Patent No. 5,645,549, issued on July 8, 1997. The description of this template in this co-pending application is incorporated herein by reference.

For convenience, a brief description of the template will be made with specific reference to FIG. 15. In particular, the template 150 includes tubular body 151 and an elongated guide foot 152 that is pivotable connected to the end 153 of the tubular body. A guide wire or stylet 155 extends through the tubular body to pivot the foot 152 to the side. The sharp tip 156 of the stylet can then be used to pierce the disc annulus D. Using a mallet, the template can be secured to the center of the disc space by driving the stylet 156 into the disc tangential to the curvature of the annulus and parallel to the endplates. The template can then be slide down the guide wire or stylet until the foot 152 contacts the disc annulus.

The foot includes an opening 157 through which an electrocautery device 160 can extend. The tip 161 of the electrocautery device is guided through the opening 157 in the foot 152 to contact the disc annulus D. When the tip 161 is energized, it leaves a mark MR that is lateral to the center of the subject disc. The template 150 can then be rotated in the direction of the arrow T so that the foot is situated laterally opposite the first mark MR. At that point, the electrocautery device can be used to make a second mark ML providing the bilateral positions for the two fusion devices.

Once the bilateral marks MR, ML have been made on the disc annulus, the surgeon has a visual indication as to the proper location for placement of the fusion device. Under direct visualization of the insufflated abdominal region by way of a laparoscope through port 141 (FIG. 13), the surgeon can then direct a T-handle probe 160 through the working port 147 to the either of the cauterization marks MR and ML (FIG. 16). The T-handle probe 160 includes a sharp tip 161 that is used to break through the disc annulus. The T-handle allows the surgeon to rotate the probe 160 as necessary to facilitate penetration into

the annulus. Once an initial opening has been made in the disc annulus by way of the T-handle probe 160, a T-handle trephine 165 can be used to create pilot holes for subsequent instrumentation. The T-handle trephine 165 can include a series of marking 166 at 5mm increments to control the depth of insertion of the trephine into the disc space, as shown in FIG. 17. The markings 166 are compared to the working trocar 147 to gauge the depth of the cutting edge of the trephine, and therefore the depth of the prepared bore in the disc space and vertebral endplates. Again, the T-handle of the trephine allows the surgeon to rotate the trephine 165. This procedure is repeated at both of the electrocautery marks ML and MR. At this point, the surgeon has two bilateral holes to use for orientation during the remainder of the procedure. The trephine 165 is also preferably used to core into the disc space to form bilateral bores. A rongeur may be used to clear disc material from each of the bilateral bores in the disc.

In accordance with further steps of the present inventive method, a distractor 167 is advanced through the working trocar 147 as shown in FIG. 18. The distractor has a distractor tip 169 that is selected according to the vertebral level being instrumented. For instance, distractors for a 16mm size implant can be either 12mm or 14mm in width to maintain the disc space at its proper anatomical height. The tip 169 is removably attached to a distractor shaft 168. Preferably, progressively larger distractor tips are sequentially inserted in alternating fashion into each of the bilateral holes in the disc space and annulus until the annulus is taut and the adjacent vertebrae are adequately distracted for restoration of a proper disc space height. In one aspect of the invention, the distractor tips 169, once they are disposed in their bilateral positions, will acts as a centering point or alignment guide for use of the instruments throughout the remainder of the procedure. It is therefore important that the distractor tips 169 be properly located, which can be accurately confirmed with fluoroscopy.

Once the bilateral distractor tips have been properly seated, a shaft extension (not shown) can be engaged to distractor shaft 168. At this point, in accordance with the preferred embodiment, the disposable trocar 147 is removed and a laparoscope 170 is introduced through the port 145 in the skin and into the disc space, using the distractor shaft and distractor tip as a positioning guide. In accordance with one embodiment of the

present invention, the laparoscope 170 includes an outer sleeve 171 having a first end 172 and a second end 173, as shown in FIG. 19. The second end 173 is engaged to a laparoscopic port 180 which can be of conventional design. In particular, the laparoscopic port 180 can include a bore 184 (FIG. 20(a)) extending therethrough and in communication with the interior of the hollow outer sleeve 171. This bore 184 in the laparoscopic port allows introduction of instruments through the port and into the outer sleeve 171. The bore is preferably closed by a number of seals 182, which are configured to accept cylindrical tools and instruments therethrough while maintaining tight sealed engagement about the instrument.

The laparoscopic port 180 also preferably includes a trumpet valve 183, which can be of conventional design. Specifically, the trumpet valve 183 maintains the laparoscopic port 180 in a normally closed position in which its internal bore is closed from communication with the outer sleeve 171. However, once a instrument is introduced into the port 180 through the seals 182, the trumpet valve 183 moves aside to allow passage of the instrument or tool into the sleeve 171.

In a further unique aspect of the invention, the end 172 of the outer sleeve 171 includes a pair of opposite distraction extensions or fingers 173. These distraction fingers 173 are sized according to the height of the particular disc space. Specifically, the fingers 173 are intended to maintain the spacing between the adjacent vertebrae during subsequent steps of the procedure after the distractor tip 169 has been removed. Thus, the width of the fingers 173 can be varied depending upon the particular vertebral level being instrumented. In addition, the distraction fingers 173 can be tapered to conform to a normal angle between adjacent vertebrae at the instrumented level. The position of the fingers 713 is correlated with the position of the distractor tips within the bilateral bores in the disc space by aligning the fingers 173 with the trumpet valve 183 when the port 180 is engaged to the outer sleeve 171. When the laparoscope 170 is inserted, the trumpet valves provide a visual indication of the alignment of the fingers. In other words, when the trumpet valve 183 is lateral to the midline, the fingers 173 are properly oriented between the vertebral endplates.

In one specific embodiment, the outer sleeve 171 can include opposite spikes 174

disposed between the distraction fingers 173. These spikes are preferably configured to penetrate at least partially into the adjacent vertebral bodies, to help maintain the position of the outer sleeve 171 at the surgical site. In some instances, the outer sleeve 171 does not include the teeth 174. For example, where the procedure is to implant a tapered fusion device, the teeth 174 are preferably eliminated and where the device is a uniform cylinder, the teeth can be retained.

In one embodiment of the present surgical method, the laparoscope 170 can be directly inserted over the distractor shaft extension (not shown). However, it is believed that the distraction fingers 173 and the spikes 172 can cause trauma to the skin during entry and to the soft tissue surrounding the surgical site during introduction of the laparoscope 170. Thus, a further feature of the preferred embodiment includes a switching sleeve 190, as shown in FIGS. 20(a), (b). The switching sleeve 190 has a length sufficient to span the entire length of the laparoscope 170 from the port seals 182 to the end 172 of the outer sleeve 171. In particular, the switching sleeve 190 has a tapered tip 191 configured to extend beyond the end 172 of the outer sleeve 171, and more particularly beyond the ends of the fingers 173. The switching sleeve 190 also includes a flared tip 192 at its opposite end that is enlarged to prevent its passage through the laparoscopic port 180 and particularly the seals 182.

In accordance with a preferred embodiment of the inventive surgical procedure, the switching sleeve 190 is placed inside the laparoscope 170 prior to insertion into the patient. The switching sleeve 190 has an outer diameter nearly equal to the inner diameter of the outer sleeve 171 to slide in close running fit within the laparoscope 170. The laparoscope 170 and switching sleeve 190 can then be slide over the distractor shaft and with a twisting motion pass through the skin and fascia until the outer sleeve contacts the disc annulus. It is important to consider that the opposite fingers 173 on the outer sleeve 171 of the laparoscope must pass through the opening in the disc space and be aligned between the adjacent vertebrae. As the fingers 173 are pushed into the disc space, the switching sleeve 190 will remain outside the disc annulus as its tapered tip 191 contacts the annulus in the region between the distraction fingers 173 (see FIG. 20(b)). The outer sleeve 171 of the laparoscope 170 is properly oriented when the fingers 173 are correctly

oriented between and contacting the adjacent vertebra endplates. The outer sleeve 171 is then seated by striking a driving cap (not shown) mounted on the laparoscopic port, to thereby drive the fingers 173 fully into the disc space between the vertebral endplates and to drive the spikes 174 into the adjacent vertebrae.

With the laparoscope 170 in place, all of the remaining steps of this inventive technique occur under a relatively protected or sealed environment. Specifically, the outer sleeve 171 of the laparoscope provides a sealed passageway from the bilateral bores at locations MR and ML on the disc to the laparoscopic port 180 outside the patient. The laparoscope 170 can be used as a passageway to provide irrigation and aspiration where necessary, without the risk of fluids leaking into the space adjacent the operative site. Moreover, the sealed working channel to the prepared sites in the disc space prevent leakage of abdominal distension fluids into the working channel and disc space. This latter aspect allows direct vision of the surgical site outside the working channel created by the laparoscope.

With the laparoscope 170 in position, the distractor shaft 168 is removed as well as the distractor tip 169 that is disposed between the adjacent vertebrae. Since the fingers 173 of the laparoscope outer sleeve 171 will maintain the spacing between the adjacent vertebrae, the distractor tip is being removed from the disc space to prevent dislodgment of the outer sleeve. In a bilateral procedure, the bilateral bores in the disc each contain a distractor tip. In the preferred method, the right left bore remains in place. Thus, the fingers 173 of the laparoscope engaged within one of the bilateral locations share the distraction load with a distractor tip 169 disposed within the other bilateral location. When the right side is instrumented with a fusion device, as described below, the fingers 173 will be within the left bore in the disc and will share the distraction load with the fusion device.

With the distraction tip removed and the disc space supported by the fingers 173, the next step in the inventive method is the preparation of the vertebral end plates and disc to provide a site for insertion of a fusion device. The switching sleeve 190 is first removed and, in accordance with one aspect of the invention, a

reaming sleeve 195 is advanced through the laparoscope 170. As shown in FIG. 21, the reaming sleeve 195 includes spikes 196 that are adapted to penetrate the adjacent vertebral bodies to hold the reaming sleeve in place. One object of the reaming sleeve in this embodiment is to help maintain the position of the laparoscope while the disc material and vertebral end plates are being reamed. This object is of particular importance when the laparoscope outer sleeve 171 does not include the teeth 174. In addition, the spikes 195 on the reaming sleeve 195 will prevent the vertebral bodies from being pushed away or distracted while reaming, since the force generated by the reamer can have a tendency to drive the vertebral bodies apart. This force is particularly present when a tapered fusion device is to be implanted, necessitating cutting conical threads into the vertebra.

In accordance with the invention, an adjustable reamer 197 is extended through the reaming sleeve 195. The reamer 197 can be of conventional design with a cutting surface configured to evacuate the disc space and prepare the adjacent vertebral bodies to receive a threaded implant. The reamer 197 includes an adjustable depth stop 198 disposed adjacent the laparoscopic port 180. The depth stop 198 contacts the seals 182 of the port to prevent introduction of the reamer 197 to deeply into the disc space. The depth of reaming necessary, and consequently the position of the depth stop 198, can be determined prior to this reaming step by review of fluoroscopic images.

The reamer 197 is manually operated by way of a T-handle 199 to successively remove disc tissue and bone from the adjacent vertebral bodies to provide a prepared bore for the fusion implant. Preferably, several passes will be made with the reamer, after which the outer sleeve will be examined visually and fluoroscopically to verify that it remains fully seated within the disc space. In addition, the reaming should be observed under C-arm imaging to prevent reaming into the spinal canal. Preferably, the depth stop 198 will be set at an initial drilling depth less than the anticipated full depth for implant insertion. For example, for an L5-S1 fusion, a 20mm deep reamed bore may be prepared for a 26mm long implant.

After the disc material and vertebral bodies have been reamed by the reamer 197, one prepared site is available for insertion of the fusion implant at the right location MR. It is then necessary to prepare the other bilateral location previously marked using the template 150 (location ML in FIG. 15). In the next steps of the inventive method, the reamer 197 is withdrawn as well as the reaming sleeve 195. The laparoscope 170 is then unseated in a controlled manner so that the fingers 174 are disengaged from between the vertebrae and withdrawn through the opening of the disc annulus. However, the laparoscope 170, and particularly the outer sleeve 171, is not removed from the skin after unseating from the disc space. Instead, the outer sleeve is reoriented over the second bilateral location ML (see FIG. 15). Preferably, immediately after the outer sleeve 171 is disengaged from the disc annulus, the switching sleeve 190 is extended back through the outer sleeve 171 so that the tapered end 191 of the sleeve extends beyond the fingers 173. The switching sleeve will then protect the soft tissue surrounding the instrumented disc space as the outer sleeve 171 is repositioned over the second bilateral location ML.

With the laparoscope 170 oriented over the second location ML and with the switching sleeve 190 contacting the disc annulus, a distractor tip 169 attached to a distractor shaft 168 is extended through the outer sleeve 171. In the preferred technique, the laparoscope is not yet fully seated at this location ML. The distractor tip 169 is advanced through the bore within the disc and anchored between the adjacent vertebral end plates. The laparoscope 170, and particularly the outer sleeve 171, is reseated within the disc space in the manner described above, namely with the distraction fingers 173 disposed between the vertebral end plates. Once the position of the outer sleeve and fingers 173 is confirmed using fluoroscopy, the remaining steps for preparing the vertebral bodies to receive the fusion implant are repeated at the left location ML.

Once the second bore in the disc space has been prepared, the following steps of the technique involve insertion of the implant. In accordance with the present invention, the implant can be a fusion cage of the type shown in FIG. 1

which is tapered to restore the normal curvature at the particular vertebral level. In the case of a fusion cage of the type shown in FIG. 1, the implant driver 50 can be used to implant the device 10. The implant drive 50 can be substantially as depicted in FIG. 2 and can engage the implant 10 as shown in FIG. 3. In accordance with the present technique, the implant drive 50 can be engaged by a T-handle assembly 200, as shown in FIG. 22. The T-handle assembly 200 includes a collet 201 which engages the end of the implant drive 50 opposite the gripping tongs 54. The assembly 200 also includes T-handle 202 which is aligned with the gripping tongs 54 so that the surgeon has a visual indication of the orientation of the tongs 54 when the implant driver 560 is extended through the laparoscope 170.

In accordance with the preferred technique, the implant drive 50 carrying the fusion device 10 is inserted through the laparoscopic port 180 and through the outer sleeve 171 until the implant 10 contacts the prepared bore within the disc space. At that point, the implant drive 50 can be rotated using the T-handle 202 to thread the implant into the prepared bore. The implant driver 50 can preferably include a plurality of depth markings on the driver shaft 51 beneath the collet 201 to give the surgeon the visual indication of the depth of insertion of the implant 10 into the prepared bore. Once the implant has been screwed in to its predetermined depth, as indicated by the depth markings on the implant drive shaft 51, insertion of the implant should be halted with the T-handle 202 parallel to the vertebral end plates. With this orientation of the T-handle 202, the tongs 54 of the implant drive 50 will be exposed to the disc space, rather than in contact with the vertebral bone. Consequently, then the long slots 27 (see FIG. 1) of the fusion device 10 will be directly exposed to and in contact with the vertebral bodies.

With a fusion device 10 implanted within the left location ML, the implant driver is removed from the implant and the laparoscope 170 is unseated from the left bilateral location. Again, the laparoscope 170 is not removed from the skin after unseating, but is simply moved to the next bilateral location MR, preferably with the switching sleeve 190 protecting the surrounding tissue from the distraction

fingers 173 of the laparoscope. At this location, the same steps are repeated to implant a second fusion device 10 at this right location.

When each of the implant devices 10 is bilaterally implanted within the disc space, the position of the implants should be confirmed. In some instances, it may be necessary to reposition an implant within the disc space, such as by driving it further into the disc space. In this instance, the driving attachment 120 can be engaged to the implant drive 50 and the attachment 120 engaged with the implanted device 10 to permit additional manipulation of the device.

In switching between the left location RL and the right location MR, it is preferred that the implant drive 50 be fully removed from the laparoscope 170 and the switching sleeve 190 extended through the outer sleeve 171. Also, the distractor tip 169 attached to the distractor shaft 168 should then be extended through the switching sleeve 170 and the distractor tip can be used to locate the previous bore at the right location MR. Once the distractor tip 169 is situated within the bore, the outer sleeve 171 can be seated at the right most location in the disc space. With the outer sleeve 171 properly seated, the distractor shaft can be removed to make way for the implant drive 50 carrying a new implant fusion device 10. Of course, the switching sleeve is removed prior to extending the implant and implant drive through the outer sleeve 171.

Once both fusion devices are disposed in their bilateral positions at location ML and MR, an A-P radiograph can be taken to assure proper placement. In addition, where possible, it is preferred that additional bone graft material is packed around the implants *in situ* to further facilitate fusion.

As discussed above, the fusion device 10 includes a hollow opening 15 to receive bone growth material. In one specific embodiment, this bone growth material can include autogenous bone harvested from the patient's anterior iliac crest. Autograft bone from other locations, autologous bone, allograft, bone growth substitutes or other bone material capable of promoting or inducing bone ingrowth can be loaded into the implant. In the preferred technique, the interior 15

of each fusion implant 10 is filled prior to insertion of the implant into the disc space.

The facilitate this "pre-loading" of the fusion material, an implant holder 210 is provided in accordance with the invention (FIG. 23). This holder 210 includes a base 211 that includes a fixed clamp section 212 and a movable clamp section 215. The fixed clamp section 212 includes a flange 213 projecting from the base 211. The movable clamp section includes an impactor plate 216 that slides within a groove 217 formed in the base 211. The impactor plate 216 is connected by a threaded shaft 218 to a knob 219. The threaded shaft is rotationally supported by an upstanding flange 221 attached to base 211. The upstanding flange 221 includes a threaded bore (not shown) through which the threaded shaft 218 extends. As the knob 219 is rotated, the shaft rotates within the threaded bore of the flange 221 to move the impactor plate 216 forward toward the fixed clamp half 212.

In accordance with the present embodiment, a pair of blocks 225 and 226 are provided which are disposed adjacent a corresponding one of clamp sections 212 and 215. The blocks 225 and 227 include implant engagement surfaces 226 and 228 which are configured to match the outer shape of the implant at its large slots 27. These blocks, therefore, serve to close off the slots 27 as bone growth material is packed into the opening 15 of the implant 10. In one specific embodiment, the blocks 225 and 227 are formed of plastic to effectively seal the large openings 27 in the sides of the implant 10. Once the bone growth material has been tightly compacted within the implant device 10, the knob 219 can be rotated in the opposite direction to release the movable clamp 216 from the device 10.

In accordance with another aspect of the present invention, the laparoscope 170 can be used to implant a bone dowel 240, as depicted in FIG. 24. The bone dowel 240 can be of a variety of configurations, such as an allograft Crock dowel, autograft tricortical or button dowels, manufactured composite dowels or hybrid dowels (e.g., an autogeneous button combined with allograft Crock dowel). While

it is preferable that the bone dowel 240 be cylindrical, this configuration is not essential to the invention, provided the dowel is configured to pass easily through the outer sleeve 171 of the laparoscope.

In accordance with this embodiments, the disc space and adjacent vertebral bodies are prepared as described above (see, FIGS. 13-21 and accompanying text). In the preferred technique for implanting a bone dowel, the reamer 197 is used to create a partially cylindrical cut in the vertebral endplates to receive a cylindrical dowel. Alternatively, if a non-cylindrical dowel is used, the endplates can be prepared accordingly. It is understood that the dowel will typically have a uniform outer diameter or width corresponding to the disc space height. Unlike the fusion device 10 discussed above the bone dowel is not tapered; however, preparation of the vertebral bodies with the tapered distraction fingers 173 of the outer sleeve 171 providing an appropriate angle will allow the implanted bone dowel to retain this angle.

Once the disc space and vertebral endplates have been prepared to receive the dowel, the bone dowel 240 is dropped into the laparoscope through outer sleeve 171. Due to the precise fit between the bone dowel and the vertebral endplates, resistance will be experienced during insertion of the dowel. An impactor 245 is provided to drive the dowel into its prepared site. The impactor includes an impactor head 246 that is preferably threaded engaged to an impactor shaft 247. The head and shaft are sized for a close running fit through the outer sleeve 171. Preferably, the impactor head 246 can be provided to be implanted. Also preferably, the impactor shaft 247 will have a smaller diameter so that it can be used with impactor heads and outer sleeves of several diameters.

The impactor shaft 247 includes a driving cap 248 that can be stricken by a hammer or similar tool to drive the bone dowel into the prepared site in a controlled manner. Preferably, the impactor shaft also includes a series of depth markings 249 corresponding to the depth of insertion of the bone dowel 240 into the disc space. The final position of the dowel can be verified later by A-P radiograph. The second bone dowel can be inserted in a similar manner and

additional bone graft placed between the bilateral bone dowels.

The present invention involves instruments and surgical techniques usable at any level of the spine. For simplicity, the above discussion has focused on fusion of the L5-S1 disc space. The dimensions of each of the components of the instruments would be sized appropriately for the specific vertebral level being instrumented. For example, the fusion devices 10 may be offered in several sizes, including 12mm, 14mm, and 16mm. Based upon the size of the fusion implant, the trephine 165 can be provided in several sizes, such as trephines to form bores having a diameter of 6mm, 8mm or 10mm.

The distractor tips 169 are also sized according to the size of the fusion device to be implanted. Preferably, the distractors are smaller than the fusion device. For example, for a 16mm fusion device, the distractor tips 169 can be either 12mm or 14mm. For a 16mm fusion device, a 16mm reaming sleeve is provided to accept a 16mm reamer to prepare a hole of the same diameter within the disc space and vertebral bodies. Smaller reamers and reaming sleeves would be provided for smaller fusion devices. As previously described, the outer sleeve 171 of the laparoscope 170 is preferably a 2mm in diameter to readily accept all of the instruments and sleeves passing therethrough during the several steps of the inventive procedure.

In the surgical techniques described above in relation to FIGS. 13-21, an outer sleeve 171 is utilized which incorporated fingers 173 that served to maintain distraction of the intervertebral space. In addition, the prior illustrated technique utilizes a series of distractor tips 169 that are used to maintain distraction at one side of the disc space while a fusion device is implanted in the other bilateral location. A further embodiment of the present invention provides an improvement to this technique. Specifically, this improvement resides in a distraction mechanism that is centrally disposed between the bilateral fusion device locations. This centralized distraction provides a more uniform distraction across the entire disc space than can be provided by a distractor tip, such as tip 169, situated at one side or the other of the intervertebral space.

In accordance with the embodiment of the invention shown in FIGS. 25-27, a distractor plug 290 is provided that includes an elongated stem 291 terminating at one end in a fan-shaped flange 292. The stem is sized to be maintained within the disc space. In one specific embodiment, the stem 291 has a length of about 22mm. The flange 292 includes a forward facing bone contacting face 293 that is adapted to contact the vertebral bone in a manner disclosed herein. The elongated stem 191 includes opposite inwardly curved or concave walls 194. The curved walls 194 of the stem 191 merge into or are contiguous with opposite curved or concave edges 195 of the flange 192. In accordance with the present invention, these curved walls 294 and curved edges 295 are preferably sized to provide clearance for the outer diameter of various tools and instruments that might be advanced into the intervertebral disc space through an outer sleeve, such as the sleeve 171 described above. In a specific embodiment, these contiguous curved walls 194 and edges 195 are defined at a diameter of between 20mm-29mm.

The distractor plug 290 further includes a locking surface 297 at the top and bottom portions of the elongated stem 291 and intermediate between the opposite curved walls 294. These locking surfaces 297 can have a variety of configurations; however, in one specific embodiment, these locking surfaces 297 includes a series of ridges 298 that are adapted to provide a modest grip on the endplates of the adjacent vertebrae that will contact the elongated stem 291 of the distractor plug 290. In accordance with the invention, the elongated stem 291 has a height between the two locking surfaces 297 that approximates the distracted height of the disc space to be instrumented. In the case of a threaded fusion device, such as the device 250, this height of the elongated stem 291 will be less than the outer crest diameter of the threads of the fusion device 250. In a specific embodiment, the top and bottom locking surfaces 297 define an outer diameter of between 10mm-14mm.

The distractor sleeve 290 further includes a lower stop face 296 that is integral with the flange 292 but that is on the opposite side of the elongated stem 291 from the bone contacting face 293. The elongated stem 291 is hollow with a

bore extending along its length, as shown in FIG. 26. The stem 291 defines a threaded bore 302 at the end adjacent the flange 292. The threaded bore merges into and communicates with a keyed bore 301 that is at the opposite end of the distractor plug 290. The opposite end of the stem 291 of the plug 290 forms a blunt nose 299 through which the keyed bore 301 exits. In the illustrated embodiment, the keyed bore 301 is square in configuration. Alternatively, the keyed bore can have a variety of shapes that permit a keyed interface with a similarly shaped spike extending through the bore 301.

In its use, the distractor plug 290 is configured to be pushed into the intervertebral disc space between adjacent vertebrae. The distractor plug 290 is particularly well suited to providing distraction in a disc space spanning a spondylolisthesis condition. In this condition, one of the vertebrae is anteriorly offset from an adjacent vertebrae. In the condition specifically illustrated in FIG. 28, the superior lower lumbar vertebrae L5 is offset from the inferior sacral vertebra S1. Thus, the distractor plug 290 is advanced anteriorly into the disc space between the lumbar vertebra L5 and sacrum S1.

The blunt nose 299 first contacts the adjacent vertebrae and provides a smooth and steady distraction as the remainder of the plug, namely the elongated stem 291, comes in contact with the endplates of the adjacent vertebrae. In order to drive the distractor plug 290 into this disc space, the present invention contemplates a plug driver 305. While the plug driver 305 can have a variety of configurations, in its simplest form the driver 305 includes a threaded stem 306 projecting from an elongated bar 307. A handle 308 is formed at an opposite end of the bar 307 to provide a gripping surface to push the plug driver 305 toward the instrumented disc space. The threaded stem 306 of the plug driver 305 is configured to engage the threaded bore 302 of the distractor plug 290. Thus, the distractor plug 290 is first threaded onto the end of the plug driver 305 and then subsequently advanced anteriorly into the disc space between the adjacent vertebrae.

As a force F is applied to the distractor plug 290 through the plug driver

305, the flange 292 is advanced toward the lumbar vertebra L5 until the bone contacting face 293 is in contact with the vertebra. At this point, further force F applied to the distractor plug 290 not only pushes the elongated stem 291 into the intervertebral space, but also pushes the lumbar vertebra L5 into its proper alignment with the sacrum S1.

As the distractor plug 290 is advanced further into the intervertebral space, the upper and lower locking surfaces 297, and particularly the ridges 298, grip the adjacent vertebral endplates to prevent retrograde expulsion of the distractor plug 290. The locking surfaces 297 of the distractor plug 290 provide a sufficiently strong engagement between the vertebral endplates to also prevent restoration of the original spondylolisthesis condition. The distractor plug 290 is pushed further into the intervertebral space until the stop face 296 of the flange 292 contacts the inferior vertebra, in this case the sacrum S1. It is understood that this stop face 296 can have a variety of configurations depending upon the desired final orientation of the two vertebrae relative to each other. For instance, the flange 292 can be wider at the stop face 296 than at the bone contacting face 292 so that the anterior portion of the displaced vertebra still retains some anterior offset from the anterior portion of the properly positioned vertebra.

It is known that some threaded cages can permit a reduction of a spondylolisthesis condition, provided the condition is only a grade one. The distractor plug 290, and particularly the locking surface 297 of the stem 291 and the flange 292, permit reduction of higher grade spondylolisthesis conditions. The flange and locking surfaces reduce the risk of slippage between the inferior and superior vertebrae as the superior vertebra is reduced.

In an alternative embodiment, a distractor plug 310 is provided that does not include a flange, as in the case of the distractor plug 290 shown in FIG. 25. Specifically, the distractor plug 310 shown in FIG. 20 includes an opposite curved or concave sidewall 311, a blunt nose 312 and opposite locking surface 313. Each of these features is substantially similar to the features of the distractor plug 290. Likewise, the distractor plug 310 includes a stop face 314 that is adapted to contact

the inferior vertebra during the reduction process. Finally, the distractor plug 310 is hollow and includes a threaded bore (not shown) and an integral keyed bore 315.

With this embodiment, the primary reduction force is provided by the driver 316, depicted in FIG. 30. This driver includes a threaded stem 317 that is adapted to engage the threaded bore (not shown) in the distractor plug 310 of FIG. 29. A driving flange 318 is formed so that the threaded stem projects outward from the driving flange 318. The driving flange 318 includes a bone contacting surface 319 that at least initially contacts only the end of the distractor plug 310 when the stem 317 is threaded into the plug. Once the driver 316 is used to push the distractor plug 310 in place, the bone contacting face 319 abuts the displaced vertebra and is used to transmit a force to reduce that vertebra.

As described above, the distractor plugs 290 and 310 first provide a means for reducing a spondylolisthesis condition. Once the vertebral offset has been reduced, the driving tools can be removed and the distractor plugs 290, 310 left in position in the intervertebral disc space. At this point, a further feature of the distractor plugs comes into play. Specifically looking, for example, at the distractor plug 290, the hollow stem 291, and particularly the keyed bore 301 provides an interface for a percutaneous surgical sleeve. In one embodiment, such a sleeve 320 includes a tubular body 321 as shown in FIG. 31. A distraction extension 322 is formed at one end of the tubular body 321. This distraction extension preferably has a height that is comparable to the height of the elongated stem 291 so that the extension can assist in maintaining the distracted height of the intervertebral space.

Substantially 180 degrees opposite from the distraction extension 322 is a locating spike 323. In the specific embodiment, the locating spike 323 integrally extends from the end of the tubular body 321 contiguous with the outer wall of the body. This locating spike 323 is configured to extend first through the threaded bore 302 and finally through the keyed bore 301 of the distractor plug 290. The locating spike 323 preferably has a shape that conforms to the shape of the keyed bore 301. In the specific embodiment, that shape is a square, although other

configurations can be utilized that prevent relative rotation between the distractor plug 290 and the locating spike 323. The locating spike is preferably long enough to extend through the entire stem 291 without projecting beyond the blunt end 299 of the distraction device.

The manner of use of the distractor plug and sleeve combination is shown in FIG. 32. In particular, it can be seen that a distractor plug 290 is centrally located within the intervertebral disc space. The distractor plug 290 then serves as a locator or an anchor for the sleeve 320. Specifically, the locating spike 323 projects into the distractor plug 290 into keyed engagement with the keyed bore 301. As shown in FIG. 32, the sleeve 320 is oriented to the right of the centrally disposed distractor plug 290 so that the distraction extension 322 provides outboard support for the distracted disc space. In this position, the sleeve 320 can then be used to perform the drilling and reaming operations previously described particularly in connection with FIG. 21, as well as the step of inserting the fusion device as also described above. The curved wall 294 and curved edge 295 of the flange 292 provide clearance for insertion of the various cylindrical tools and cylindrical fusion device into the intervertebral space.

Once a fusion site has been prepared at the right side of the disc space, the sleeve 320 can be retracted, so that the locating spike 323 is pulled out of the keyed bore 301 of the distractor plug 290. The sleeve 320 can then be rotated to the position shown in phantom in FIG. 32 with the tubular body 321 directed to the left of the intervertebral disc space. The same operations can be performed at this location in the intervertebral space. Using the distractor plug 290 and the sleeve 320, the present invention provides a means to maintain midline distraction through the center line of the intervertebral disc space. Moreover, the distractor plug provides a constant fixed pivot point for the various operations involved in implanting an interbody fusion device.

In accordance with another embodiment of the invention, a sleeve 325 is provided as shown in FIG. 33. In this embodiment, the sleeve 25 includes a tubular body 326 that has a distraction extension 327 projecting from one side of

one end of the sleeve. Unlike the sleeve 320, the sleeve 325 includes a separate outrigger spike 328 that is fixed to the tubular body by way of an engagement flange 329. It is understood that the outrigger spike 328 could be integrally formed with the tubular body 326 or connected to the body in some other fashion. Nevertheless, a primary feature of the sleeve 325 is that the spike 328 is disposed outside the diameter or outer wall of the tubular body 326. In this manner, the sleeve 325 and its hollow cannula opening can be offset further from the midline of the intervertebral disc space. Thus, interbody fusion devices, such as device 350, can be disposed farther outboard within that space using the sleeve 320.

In a further embodiment, a double-barrel sleeve 330 is provided. In this embodiment, two tubular bodies 331 and 332 are affixed at a joint 333. Each tubular body 331, 332 includes a respective distractor extension 334, 335. As with the other sleeve embodiments, the distractor extensions 334, 335 have a width that approximates the width of the distractor plug.

In this embodiment, a bore 336 is formed at the joint 333 between the two tubular bodies 331, 332. A spike, in the form of an elongated rod 337, is configured to extend through the bore 336. This spike can then engage a distractor plug, such as the distractor plug 310 shown in FIG. 34. With this double-barrel sleeve 330, there is no need to retract the sleeve, rotated to the bilateral position and re-dispose it within a distractor plug, as in the embodiment of FIG. 32. This double-barrel sleeve 330 provides an additional distractor extension, so that distraction is achieved not only at the midline location of the distractor plug 310, but also at the outboard positions of the distractor extensions 334, 335. Again, the distractor extensions are arranged together with the distractor plug so that various percutaneous operations can be occurring through the double-barrel sleeve of and in the intervertebral disc space.

One problem that faces many interbody fusion devices is the risk of backing out or retrograde expulsion of the device. In the case of push-in implants, the natural compressive forces achieved by the disc annulus in a distracted space can have a tendency to squeeze the fusion devices in a retrograde direction. These

same forces, coupled with relative movement between the instrumented vertebrae, can also cause threaded fusion devices to slowly unthread. In accordance with the present invention, one embodiment of a fusion cage is provided that is designed to prevent this counter rotation of the fusion device. The fusion device 250 shown in FIG. 8 includes a pair of bone screws that are threaded into the adjacent vertebrae. These bone screws prevent the fusion device 250 from rotating within their prepared bores.

Another approach is presented in FIGS. 35-36. In this approach, bilaterally placed fusion devices are connected laterally across the disc space, thereby preventing each device from rotating. In a first embodiment shown in FIG. 35, a pair of fusion devices 350 are provided that include a hollow body 351 having a first end 352 and a second end 353. As with the fusion devices previously discussed, the devices 350 each include a hollow interior 355 and an end wall 356. The devices also include external threads 358 that are adapted to be threaded into a prepared bore in adjacent vertebrae.

In a deviation from the previously discussed fusion devices, the fusion device 350 includes a recess 360 formed in the end wall 356. A lateral groove 361 traverses the recess 360 and opens at the flat side walls 357 of the device 350. Each device also includes a threaded bore 363 centrally formed at the base of the recess 360. When each fusion device 350 is placed bilaterally within an instrumented disc space, the devices are separated by some distance, as depicted in FIG. 35. This distance is spanned by a connector plate 365. The connector plate includes an elongate arm 366 having mating ends 367 formed at the ends of the arm. Each of the mating ends 367 defines an outer wall 368 that is generally configured to conform to the recesses 360 in each of the fusion devices 350. The elongate arm 366 is configured to rest within the groove 361 so that the connector plate 365 can span between and interconnect the two fusion devices 350.

The connector plate 365 is provided with a slot 369 at each of the mating ends 367. This slot is oriented directly above the threaded bore 363 in the end wall 356 of the fusion device 350. A locking screw 370 having a threaded stem 371 is

provided that extends through each slot 369 and into the threaded bore 363. The locking screw 370 is then tightened into the bore to clamp the connector plate 365 to each of the interbody fusion devices 350. Thus, the presence of the connector plate 365 when disposed within the grooves 361 of the adjacent fusion devices, prevents each fusion device 350 from rotating when within the patient. The length of the connector plate 365 is dictated by the spacing of the fusion devices 350 within the disc space.

In an additional embodiment, a connector plate 375 is shown in FIG. 36. The connector plate includes an elongate arm 376 with mating ends 377, each element of which is similar to the like named elements of the connector plate 365. However, in an alternative configuration, the connector plate 375 includes an intermediate plate 379 that preferably projects perpendicularly outward from the elongate arm 376. The intermediate plate 379 is generally in the middle of the connector plate 375 and sized to sit between each of the fusion devices 350. In one specific embodiment, the intermediate plate 379 has a width that is sufficient so that the plate 379 is in contact with one side wall 357 of the adjacent devices 350.

In the illustrated embodiments, the focus has been on threaded fusion devices. However, it is understood that the present invention has utility in implanting non-threaded fusion devices, threaded and non-threaded spacers, and cylindrical or non-cylindrical devices or plugs.

In a further aspect of this embodiment, the intermediate plate 379 is provided with angled screw bores 380. In particular, these screw bores are angled so that a bone screw inserted through the bores can be driven upward into the vertebral endplates of the adjacent vertebrae. Preferably, the screw bores are oriented at an angle similar to the angle of the screw bores 268 of the fusion device 250. Thus, the connector plate 375 provides an additional degree of security to prevent retrograde expulsion of the interbody fusion device 350.

While the invention has been illustrated and described in detail in the drawings and foregoing description, the same is to be considered as illustrative and not restrictive in character, it being understood that only the preferred embodiment

has been shown and described and that all changes and modifications that come within the spirit of the invention are desired to be protected.

WHAT IS CLAIMED IS:

1. An interbody fusion apparatus for implantation in the disc space between adjacent vertebrae to be fused, comprising:

a hollow body having at least two substantially cylindrical portions defining an outer diameter greater than the height of the disc space between the adjacent vertebrae, said at least two substantially cylindrical portions each configured to contact a portion of one of the adjacent vertebrae, said body having a first end and an opposite second end and including an end wall at said first end;

at least one screw bore defined through said end wall, said screw bore defining a longitudinal axis oriented such that said longitudinal axis intersects one of said substantially cylindrical portions; and

a bone screw sized to extend through said at least one screw bore and project outward from one of said substantially cylindrical portions of said hollow body, said bone screw configured to threadedly engage one of the adjacent vertebrae to retain said hollow body within the disc space.

2. The interbody fusion apparatus according to claim 1, wherein:

said at least one screw bore includes an enlarged recess at said end wall; and

said bone screw includes an enlarged head sized to be received within said enlarged recess.

3. The interbody fusion apparatus according to claim 1, wherein:

said hollow body includes two screw bores defined in said end wall, each screw bore defining a longitudinal axis arranged to intersect opposite ones of said at least two substantially cylindrical portions of said hollow body, the longitudinal axes of said two screw bores diverging from each other toward said second end; and

said apparatus includes two bone screws, each sized to extend through a

respective one of said two screw bores to threadedly engage a respective one of the adjacent vertebrae to retain said hollow body within the disc space.

4. The interbody fusion apparatus according to claim 3, wherein each of said two screw bores includes an enlarged recess at said end wall; and

each of said two bone screws includes an enlarged head sized to be received within said enlarged recess.

5. The interbody fusion apparatus according to claim 3, wherein:

said end wall of said hollow body defines a threaded bore between said two screw bores; and

said apparatus includes a locking screw configured for engagement within said threaded bore, said locking screw having a head sized to contact each of said two bone screws when said bone screws are extending through a respective one of said two screw bores and when said locking screw is engaged in said threaded bore.

6. The interbody fusion apparatus according to claim 5, wherein each of said two screw bores includes an enlarged recess at said end wall;

each of said two bone screws includes an enlarged head sized to be received within said enlarged recess; and

said threaded bore includes an enlarged recess sized to receive said enlarged head of said locking screw therein, said enlarged recess of said threaded bore overlapping said enlarged recess of each of said bone screw bores.

7. The interbody fusion apparatus according to claim 1, wherein said at least two substantially cylindrical portions of said hollow body include external threads configured for threaded engagement with said adjacent vertebrae.

8. The interbody fusion apparatus according to claim 1, wherein said hollow body is tapered from said first end to said second end.

9. The interbody fusion apparatus according to claim 1, wherein said hollow body defines two opposite substantially flat walls between said at least two substantially cylindrical portions.

10. The interbody fusion apparatus according to claim 1, wherein said hollow body defines at least one slot extending through said hollow body and intersecting at least one of said substantially cylindrical portions.

11. The interbody fusion apparatus according to claim 10, wherein said at least one screw bore intersects said at least one slot.

12. The interbody fusion apparatus according to claim 1, wherein:

said end wall defines a midline and said at least one screw bore is disposed along said midline; and

further wherein said end wall defines a pair of elongated slots offset from and substantially parallel to said midline of said end wall.

13. A driving tool assembly for use with the interbody fusion apparatus of claim 12, comprising:

a driving tool attachment including a body having a mating face and a pair of elongated driving bosses extending from said mating face, said mating face configured to contact said end face of said interbody fusion apparatus and said driving bosses configured to be slidably received within corresponding ones of said elongated slots; and

a driving tool including an elongated shaft for applying a driving force and means at one end of said shaft for engaging said driving tool attachment.

14. A distraction device for distracting the disc space between adjacent vertebrae, comprising:

an elongated stem having a height corresponding to a desired height of distraction for the disc space, said stem having a first end and a second end defining a longitudinal axis therebetween and a length along said axis that is sized to be maintained within the disc space when said elongated stem is driven into the disc space; and

a flange at said first end projecting outward from said longitudinal axis of said stem, said flange having a bone contacting face for contacting at least one of the vertebrae when said stem is driven into the disc space and for transmitting a reduction force to the vertebra upon application of an external force to the distraction device.

15. The distraction device according to claim 14, wherein said elongated stem defines a bore extending between said first and second end.

16. The distraction device according to claim 15, wherein said bore includes a keyed bore adjacent said second end, said keyed bore having a non-circular configuration for receiving a complementary-shaped portion of a tool therethrough.

17. The distraction device according to claim 15, wherein said bore includes a threaded bore adjacent said first end for receiving a threaded portion of a tool therein.

18. The distraction device according to claim 14, wherein said elongated stem has opposite top and bottom portions, said top and bottom portions having a bone engaging surface configured to resist expulsion of said elongated stem from the disc space.

19. The distraction device according to claim 18, wherein said bone engaging surface of said top and bottom portions include a plurality of ridges defined thereon.

20. The distraction device according to claim 18, wherein said elongated stem includes side portions between said top and bottom portions, said side portions each defining an inwardly curved surface.

21. The distraction device according to claim 18, wherein said flange includes inwardly curved side edges contiguous with said inwardly curved surface of a corresponding one of said side portions.

22. The distraction device according to claim 14, wherein said flange is fan shaped and is substantially perpendicular to said longitudinal axis of said elongated stem.

23. The distraction device according to claim 14, wherein:

said elongated stem includes opposite top and bottom surfaces configured to contact a superior and an inferior vertebra, respectively;

said flange projects from said stem in a direction toward the superior vertebra; and

the device includes a stop face at said first end of said stem projecting in a direction toward the inferior vertebra.

24. An apparatus for reducing a spondylolisthesis condition between an offset vertebra and an adjacent vertebra, comprising:

an elongated stem sized for introduction into the disc space between the offset and adjacent vertebrae;

an enlarged flange at one end of said stem, said flange having a bone contacting face configured to apply a force to the offset vertebra; and

a tool engagable to said elongated stem, said tool sized for manipulation outside the disc space to apply a pushing force communicated through said distraction device to the offset vertebra to reduce the offset vertebra relative to the adjacent vertebra.

25. The apparatus for reducing a spondylolisthesis condition according to claim 24, wherein said enlarged flange is integral with said elongated stem.

26. The apparatus for reducing a spondylolisthesis condition according to claim 24, wherein said enlarged flange is integral with said tool.

27. The apparatus for reducing a spondylolisthesis condition according to claim 24, wherein said elongated stem includes bone engaging surfaces to engage the offset and adjacent vertebrae to prevent slip between the vertebrae after the spondylolisthesis condition has been reduced.

28. The apparatus for reducing a spondylolisthesis condition according to claim 24, wherein said elongated stem includes opposite top and bottom surfaces and further includes a stop face projecting from said stem away from said bottom surface and configured for contacting the adjacent vertebra to prevent further reduction of the offset vertebra.

29. Laparoscopic instrumentation for performing surgical procedures between adjacent vertebrae, said instrumentation comprising:

a tubular sleeve having a longitudinal axis and a hollow interior along said axis sized for advancement of surgical tools from outside the patient's body to the adjacent vertebrae, said sleeve including a spike projecting from said sleeve substantially parallel to said longitudinal axis; and

a centering device including an elongated stem sized for introduction into the disc space between the adjacent vertebrae, said stem defining a bore sized to

receive said spike of said tubular sleeve therethrough.

30. The laparoscopic instrumentation according to claim 29, wherein said bore is a keyed bore having a non-circular shape and said stem has a shape complementary to said keyed bore to prevent relative rotation between said sleeve and said centering device.

31. The laparoscopic instrumentation according to claim 29, wherein:

said elongated stem of said centering device has a height sufficient to distract the disc space between the adjacent vertebrae; and

said sleeve includes an extension projecting therefrom substantially parallel to said spike, said extension having a height substantially equal to the height of said elongated stem.

32. The laparoscopic instrumentation according to claim 29, wherein said sleeve includes a tubular wall and said spike extends contiguously from said wall.

33. The laparoscopic instrumentation according to claim 29, wherein said sleeve includes a tubular wall and said spike is attached to the outside of said wall.

34. The laparoscopic instrumentation according to claim 28, wherein:said sleeve includes a bore extending along the length of said sleeve; andsaid spike is sized for slidable passage through said bore in said sleeve.

35. An apparatus for implantation in the disc space between adjacent vertebrae, comprising:

at least two devices having elongated bodies sized for introduction adjacent each other in the disc space and including surfaces for engaging the adjacent

vertebrae and defining a width less than a transverse dimension of the disc space, each of said devices having an end wall defining a threaded bore therethrough;

an elongated plate sized to be fully contained within the disc space, said plate having at least two bores defined therethrough and spaced apart a distance at least equal to said width of said devices; and

at least two set screws having a threaded stem sized to extend through each of said at least two bores and configured for threaded engagement with said threaded bore of a corresponding one of said devices.

36. The apparatus for implantation in the disc space between adjacent vertebrae according to claim 35, wherein:

said end wall of each of said devices defines a recess surrounding said threaded bore and a groove communicating with said recess; and

said elongated plate includes an enlarged portion surrounding each of said at least two bores and sized to be retained within said recess of each of said devices with said plate passing through said groove in each of said devices.

37. The apparatus for implantation in the disc space between adjacent vertebrae according to claim 35, wherein:

said elongated plate includes an intermediate plate extending outward from said elongated plate between said at least tow bores, said intermediate plate defining at least one screw bore therethrough; and

the apparatus further includes a bone screw sized for passage through said screw bore in said intermediate plate.

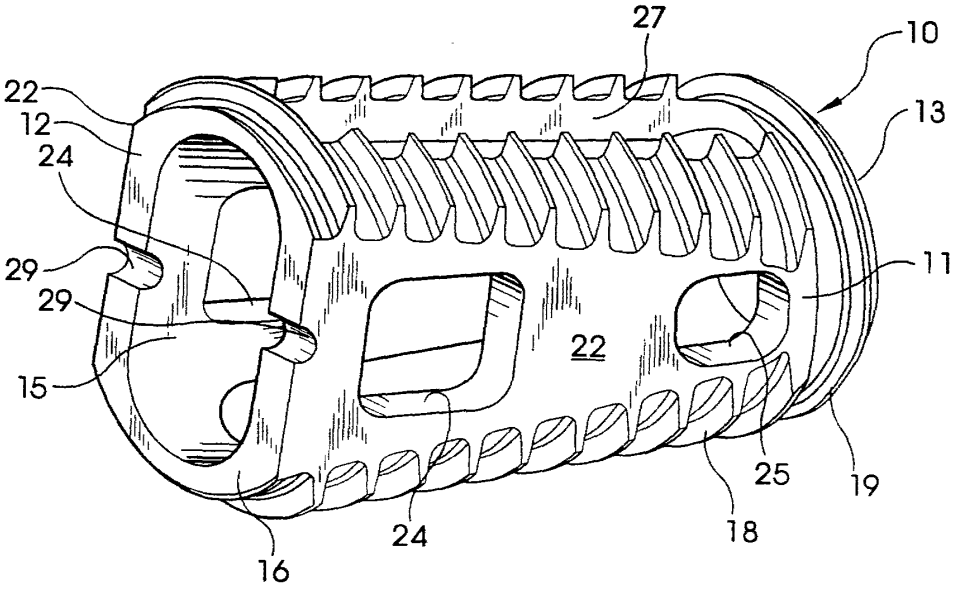

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Fig. 1

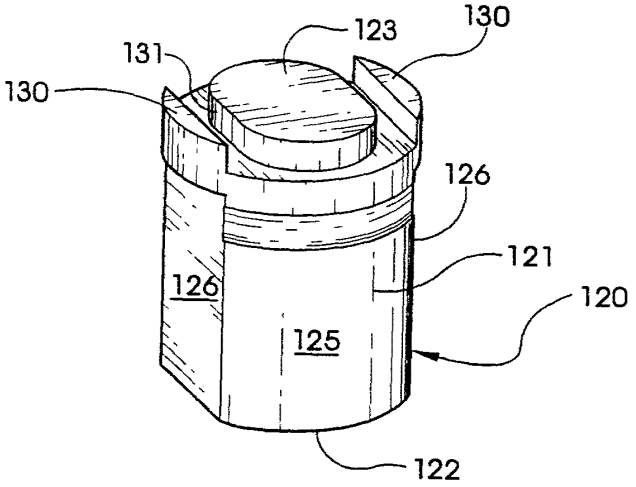

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Fig. 6

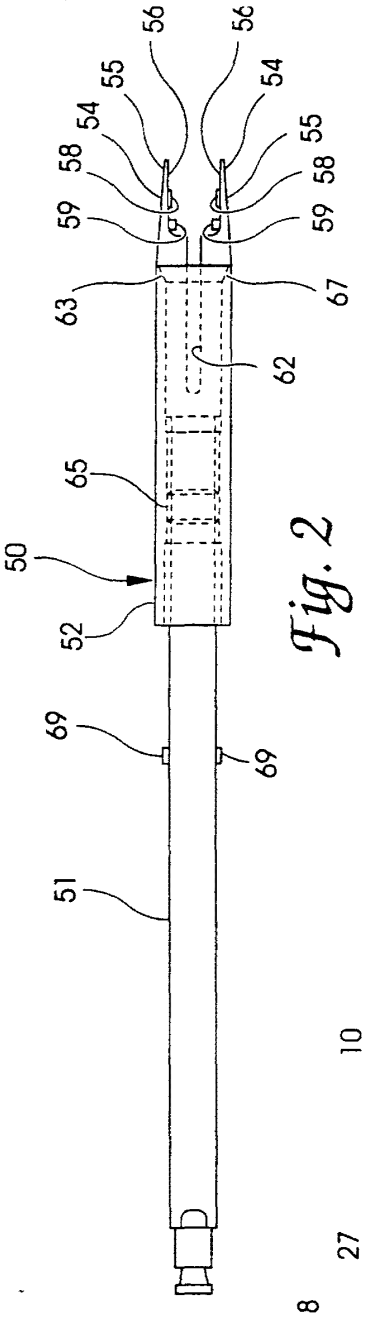


Fig. 2

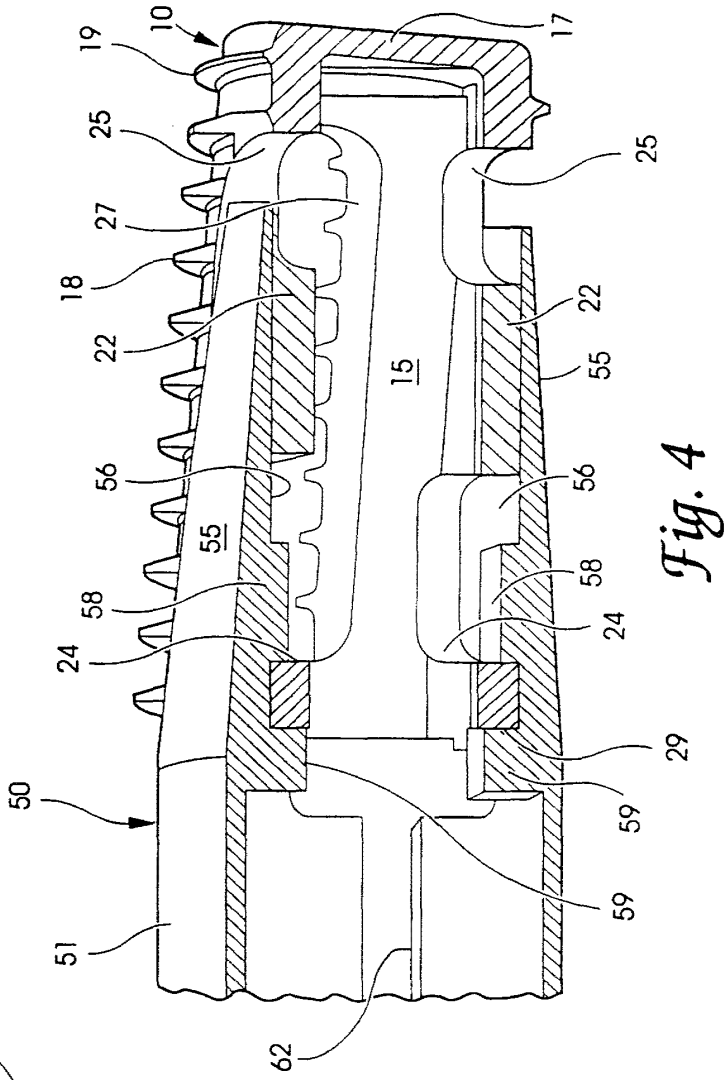


Fig. 4

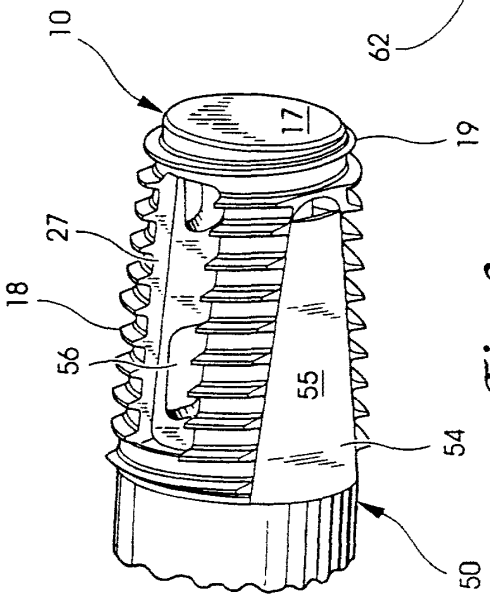


Fig. 3

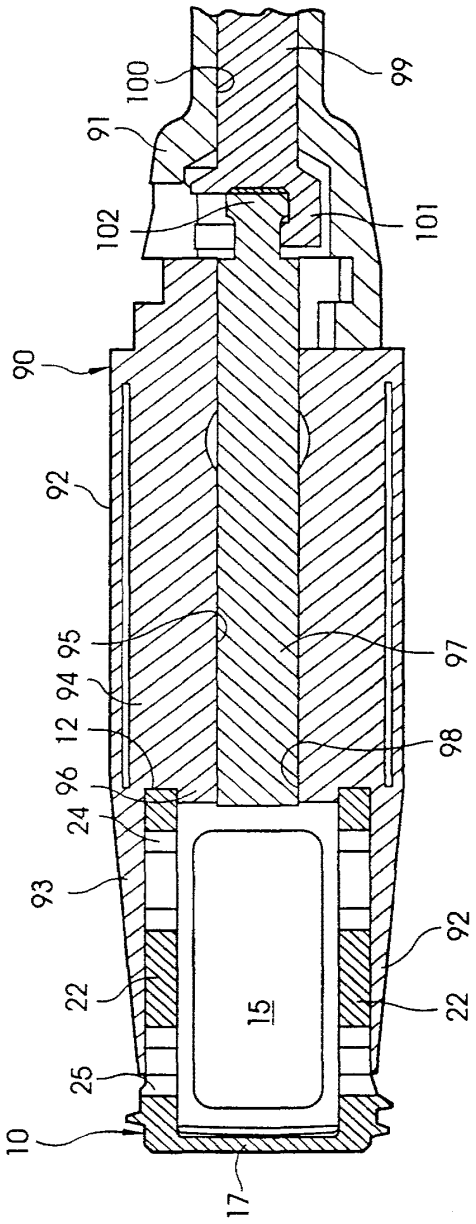

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Fig. 5

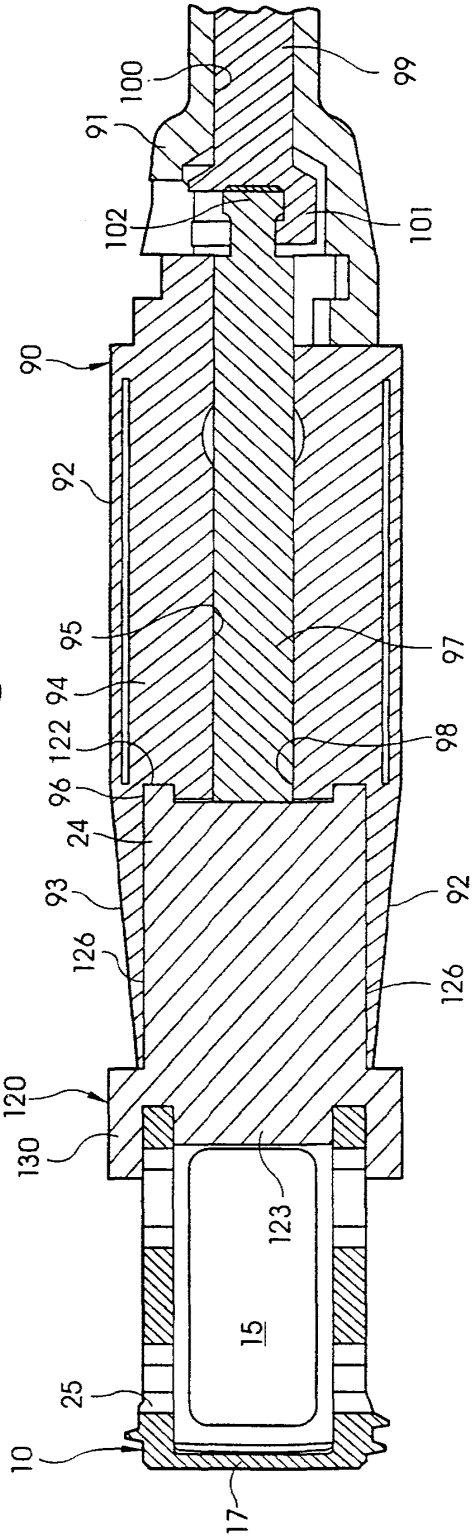

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Fig. 7

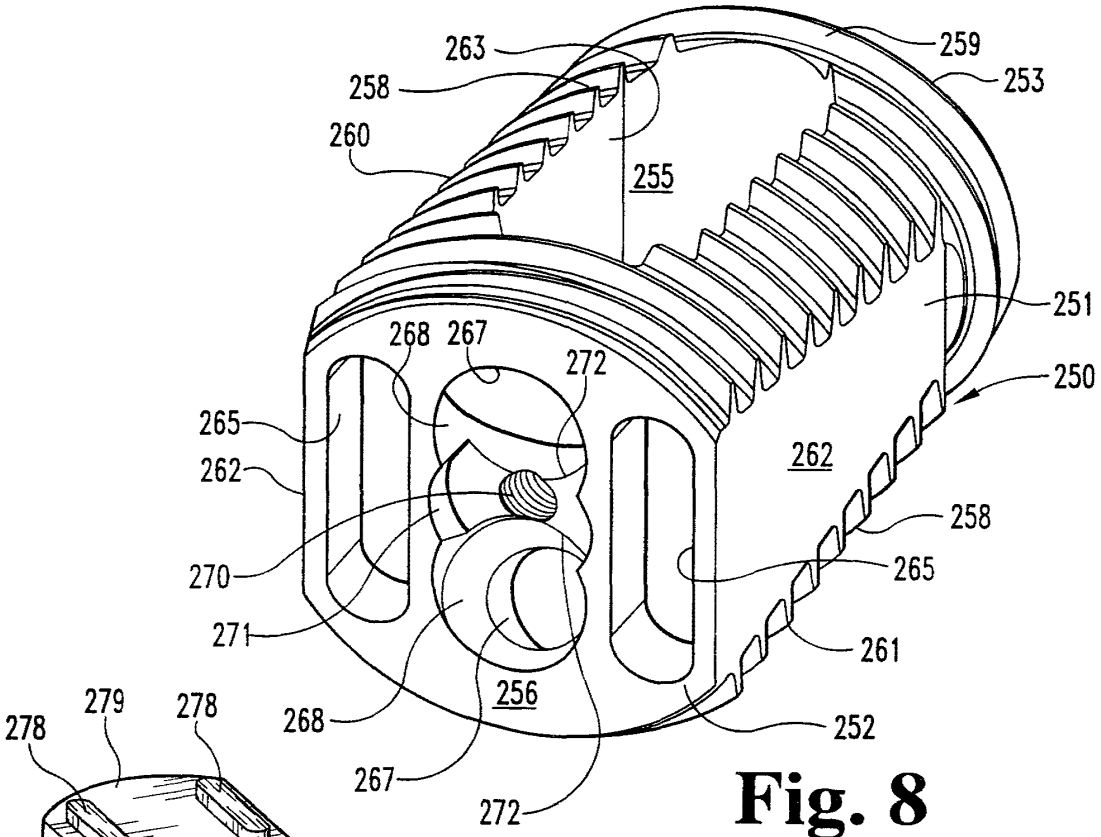


Fig. 8

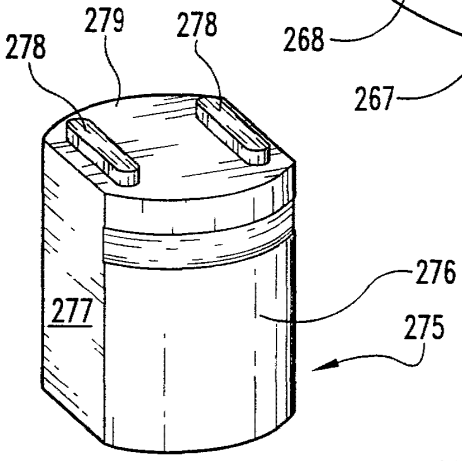


Fig. 9

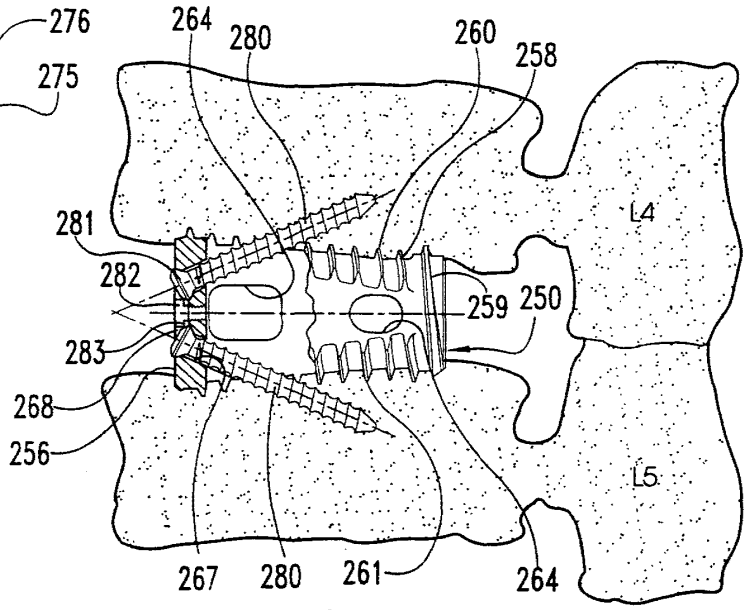


Fig. 10

1. Dilate the disc space (slight lordosis):

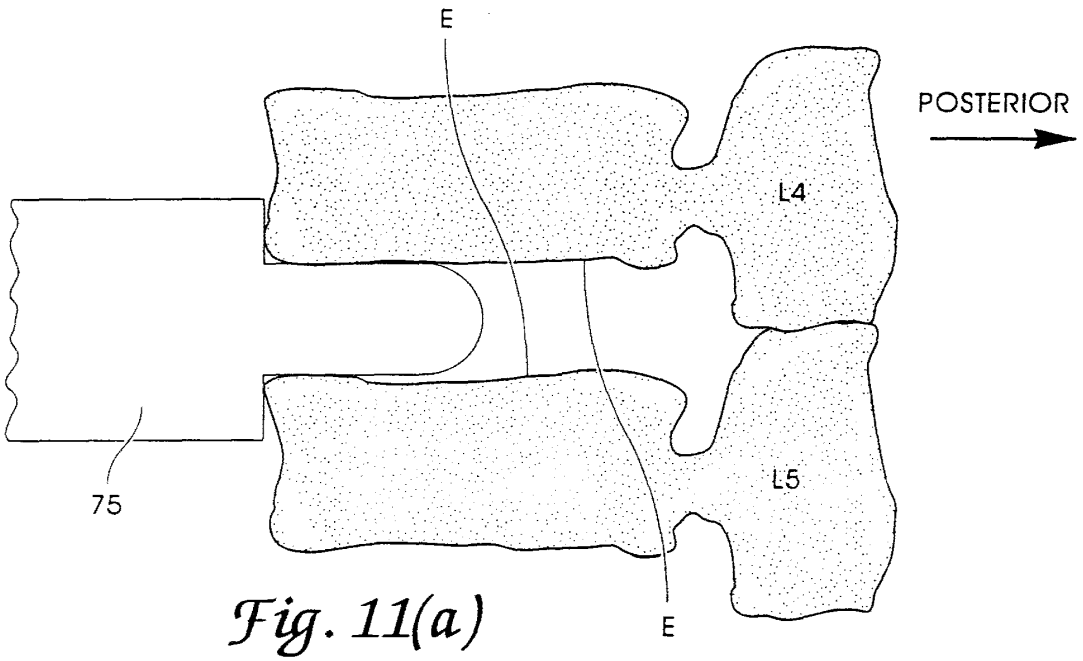


Fig. 11(a)

2. Place outer sleeve & drill minor diameter hole:

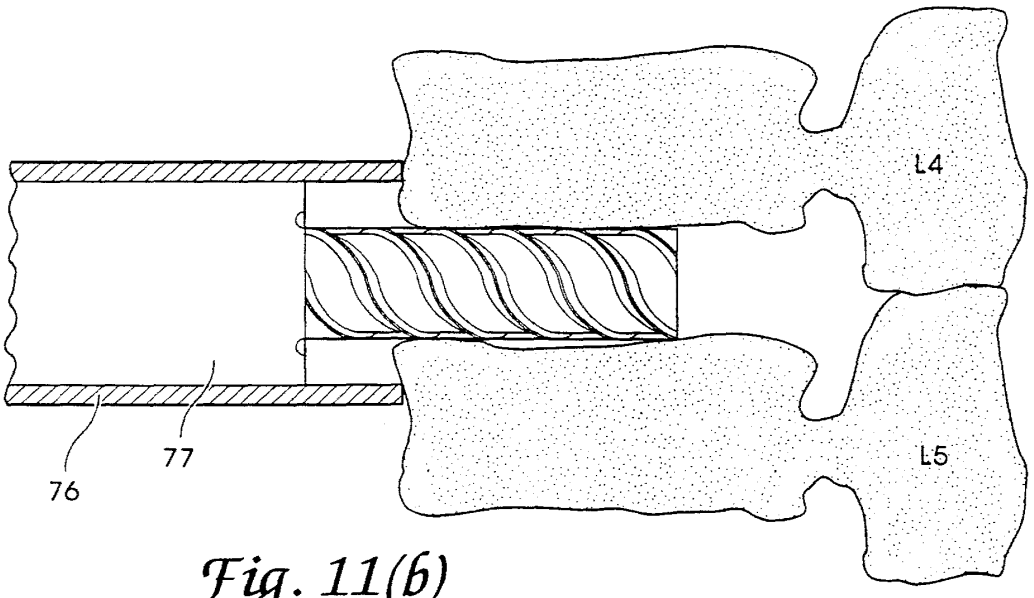


Fig. 11(b)

3. Insert implant to secure lordosis required

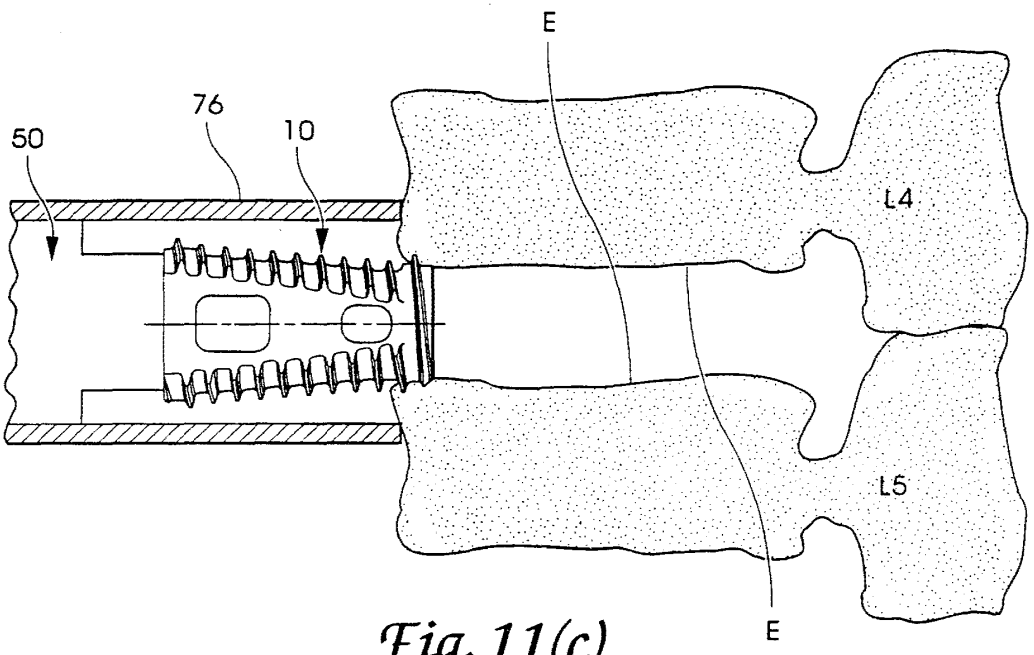


Fig. 11(c)

4. Remove implant driver

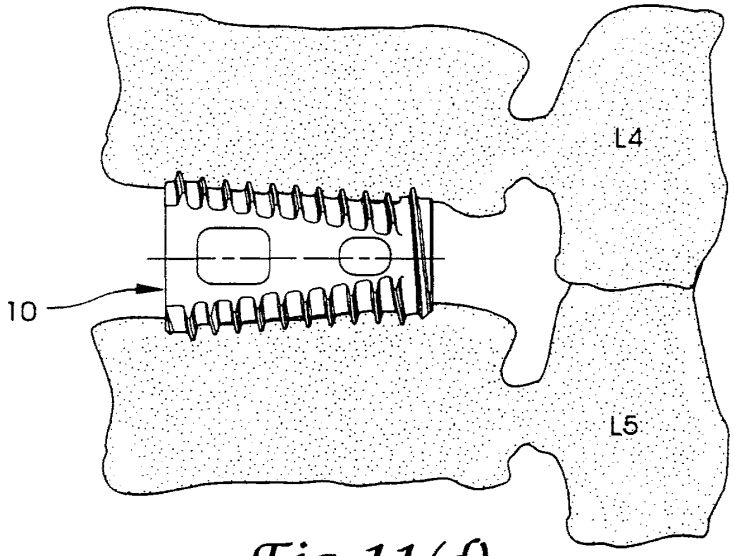


Fig. 11(d)

1. **Dilate the disc space:**

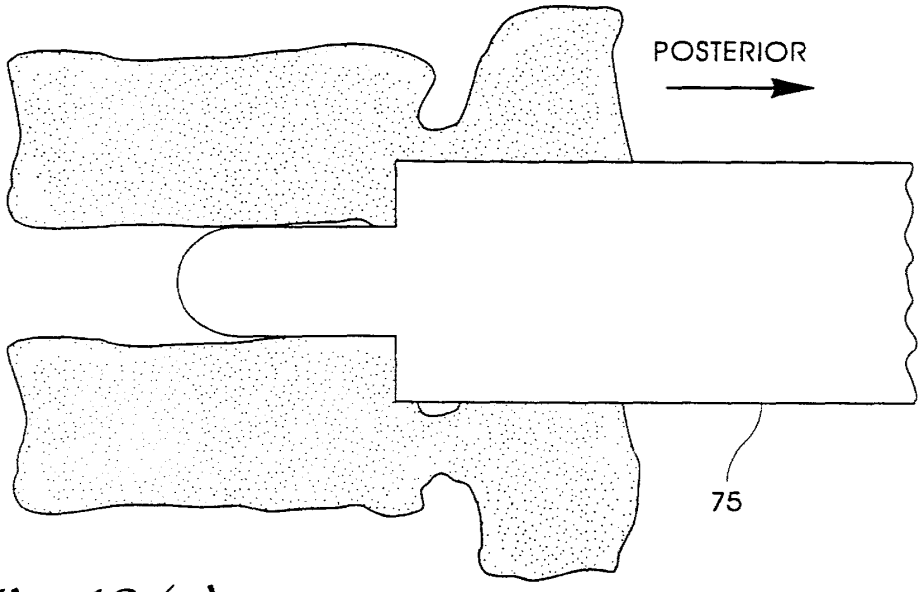


Fig. 12 (a)

2. **Place outer sleeve & drill minor diameter hole:**

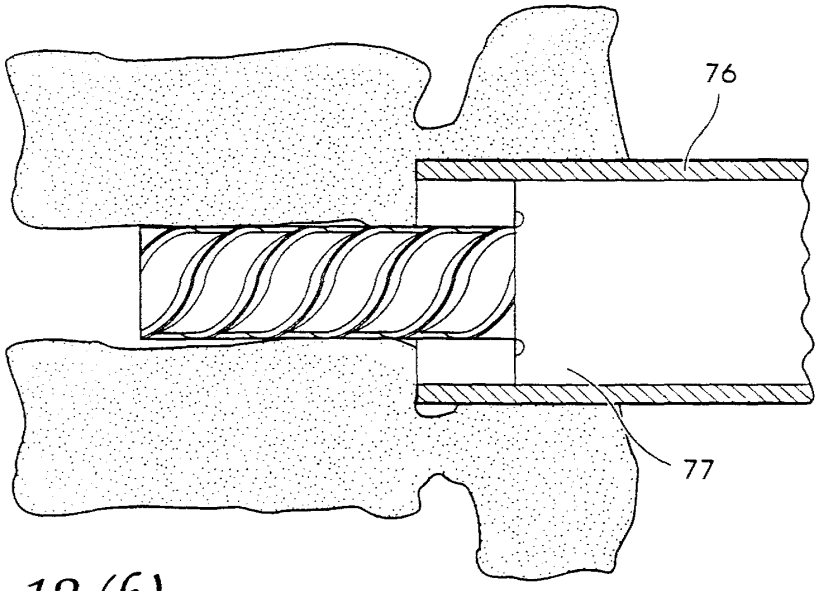


Fig. 12 (b)

3. Insert implant to appropriate depth

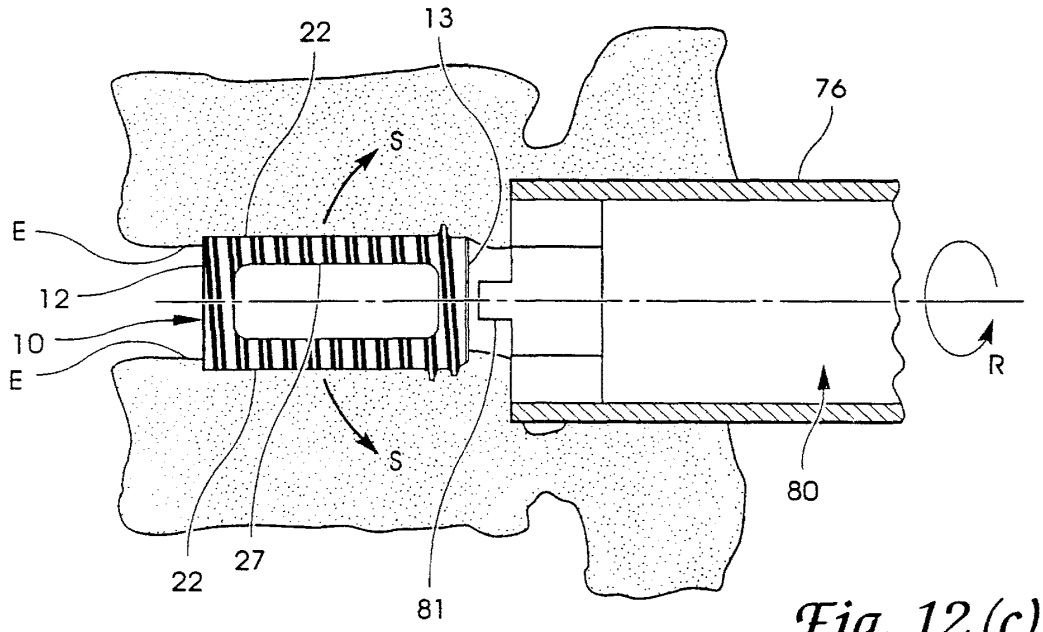


Fig. 12(c)

4. Rotate to restore lordosis, remove implant driver

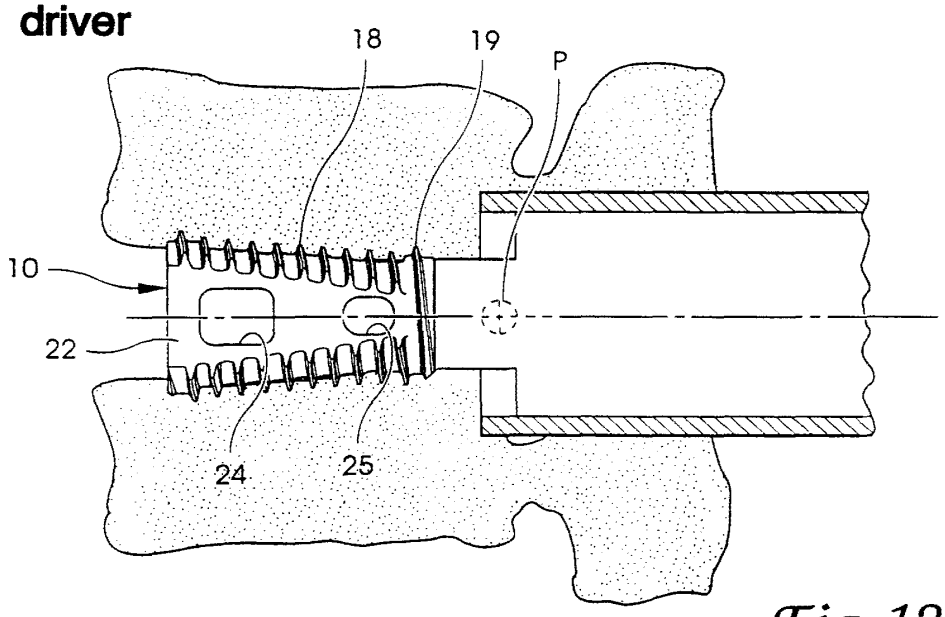


Fig. 12(d)

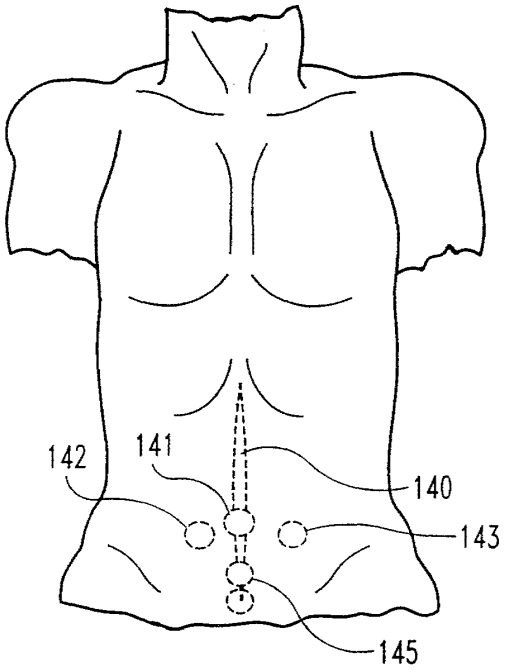


Fig. 13

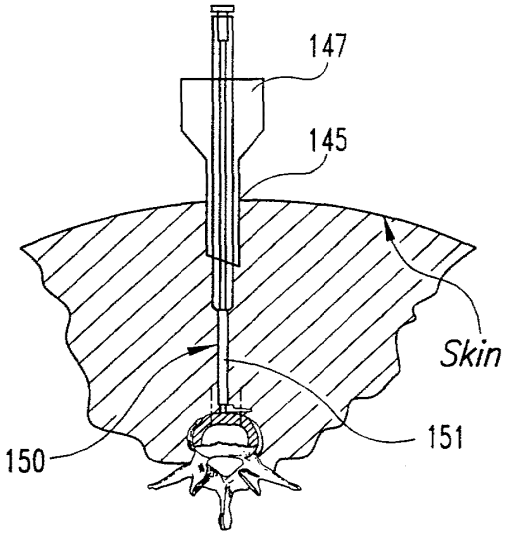


Fig. 14

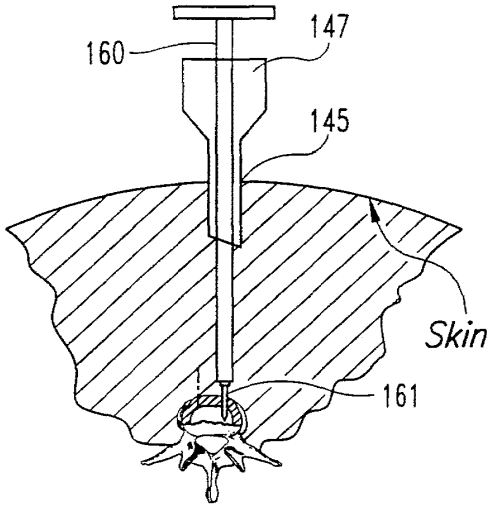


Fig. 16

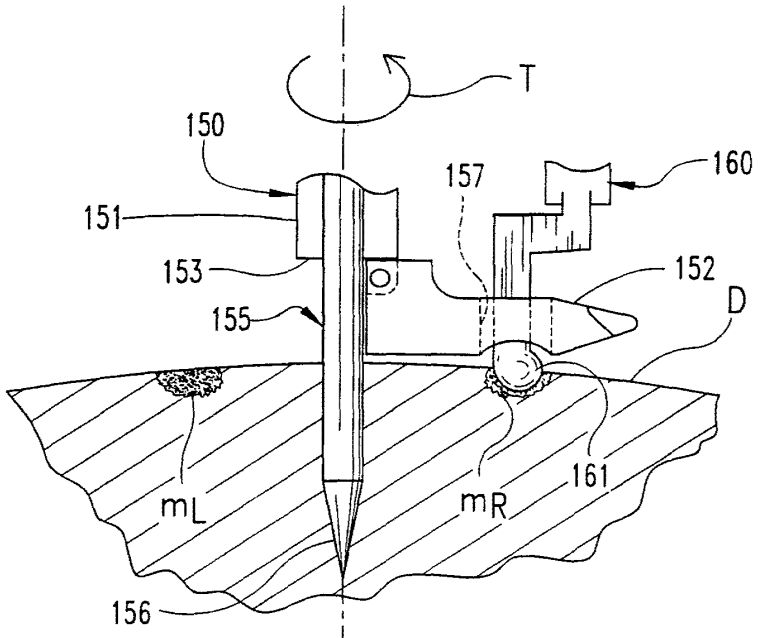


Fig. 15

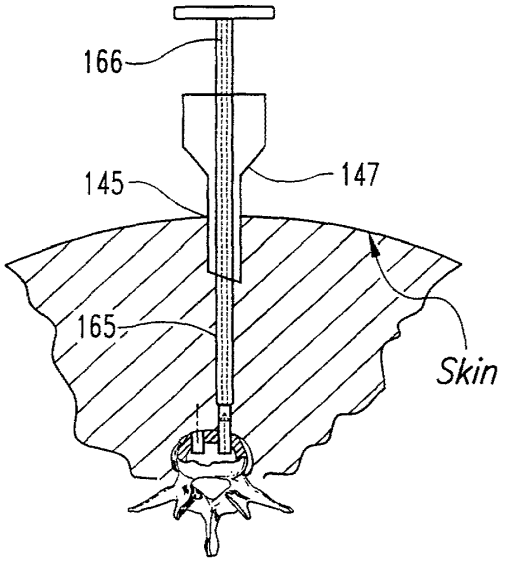


Fig. 17

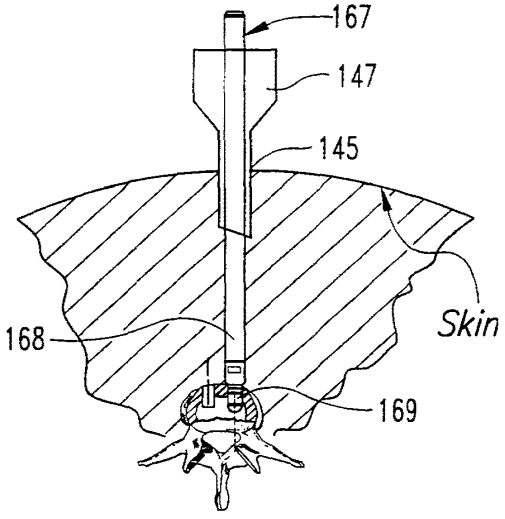


Fig. 18

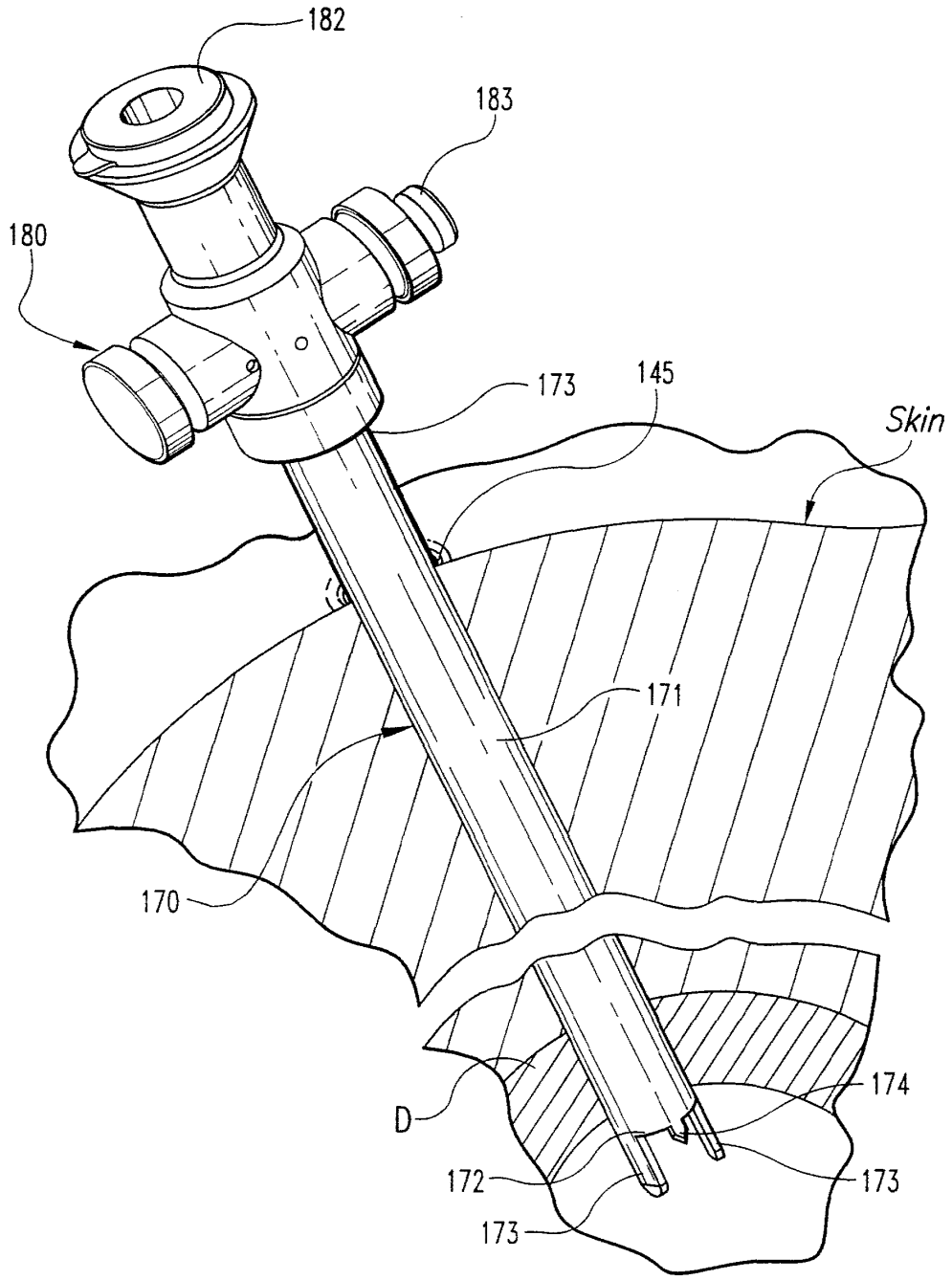


Fig. 19

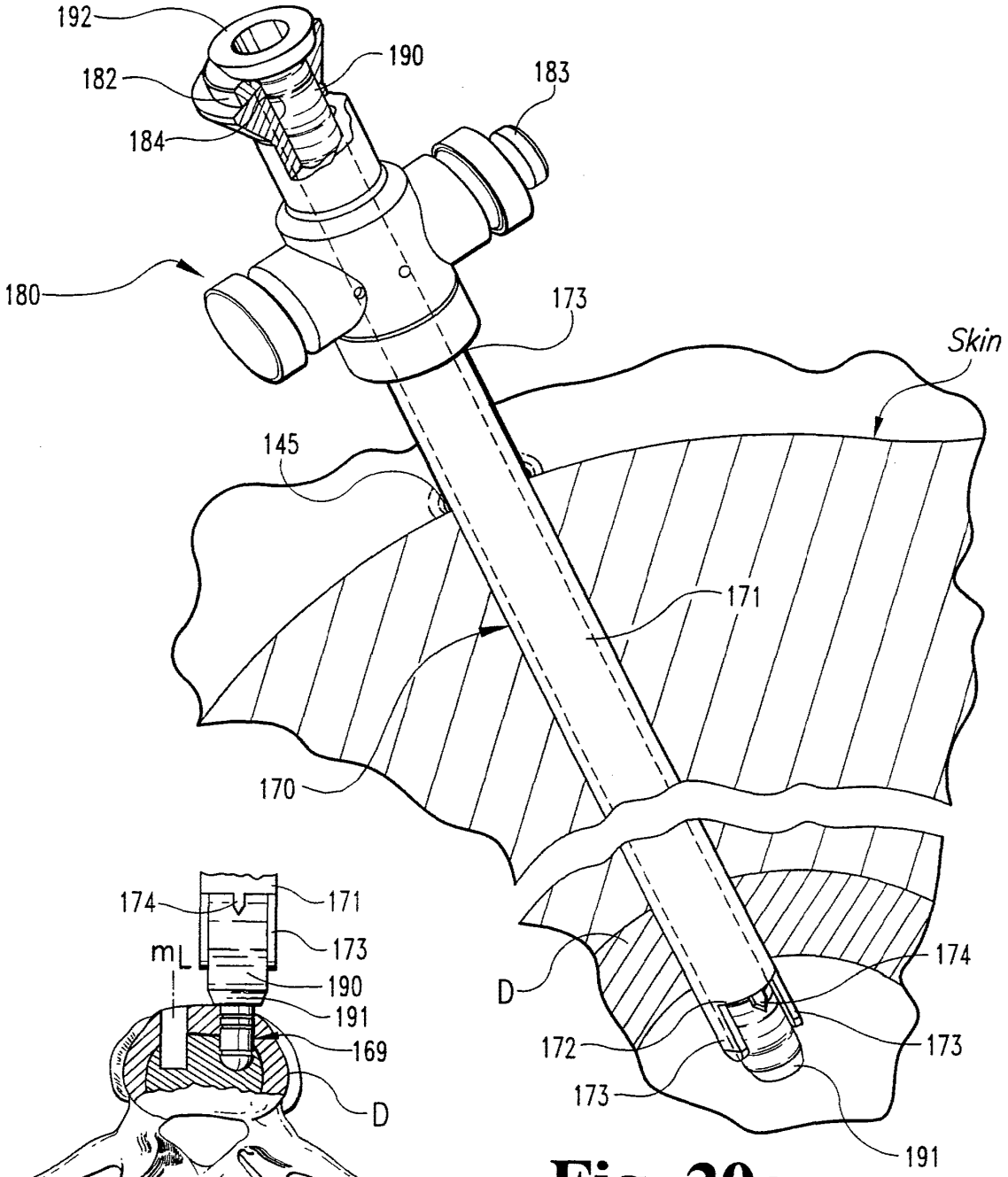


Fig. 20a

Fig. 20b

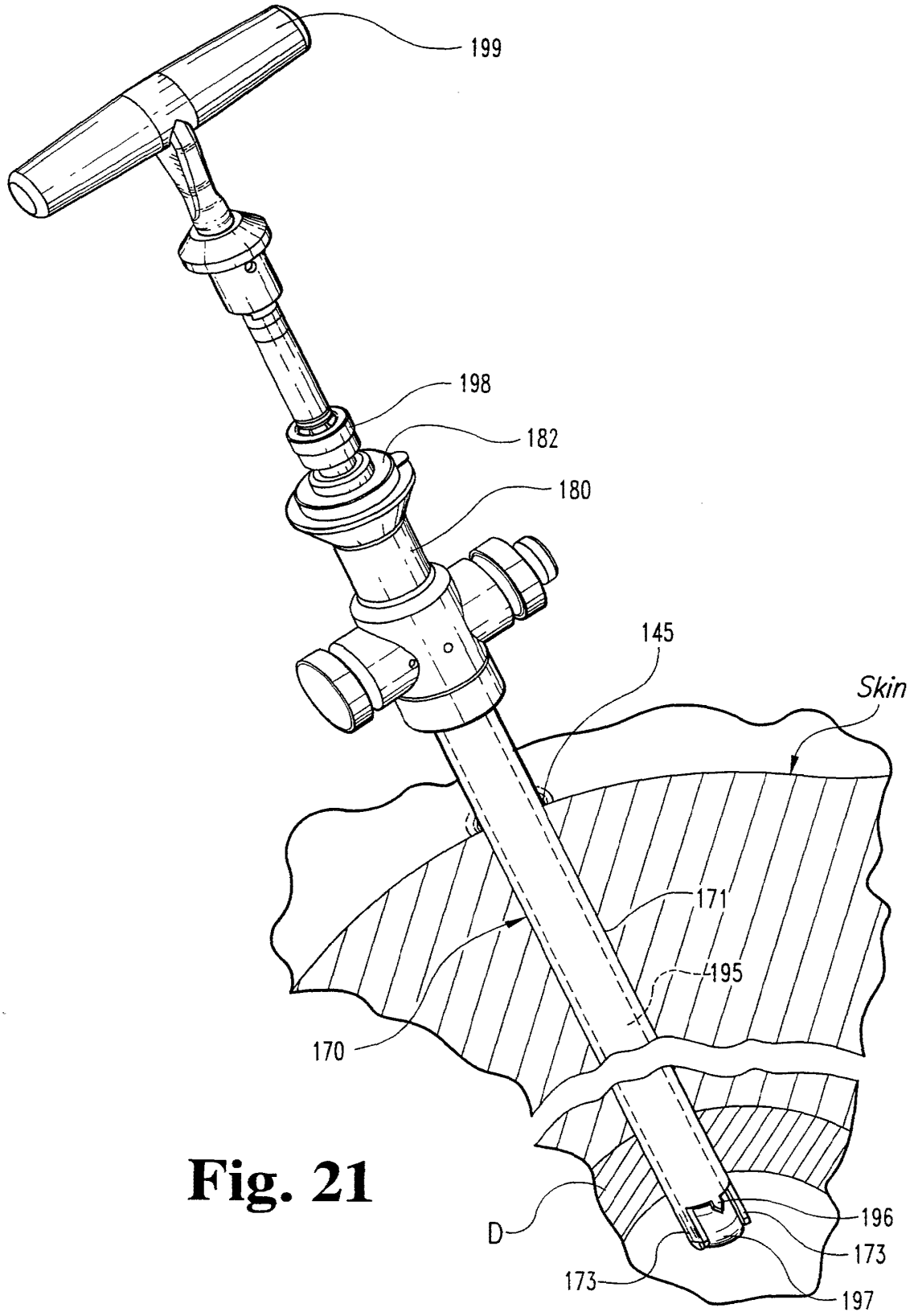


Fig. 21

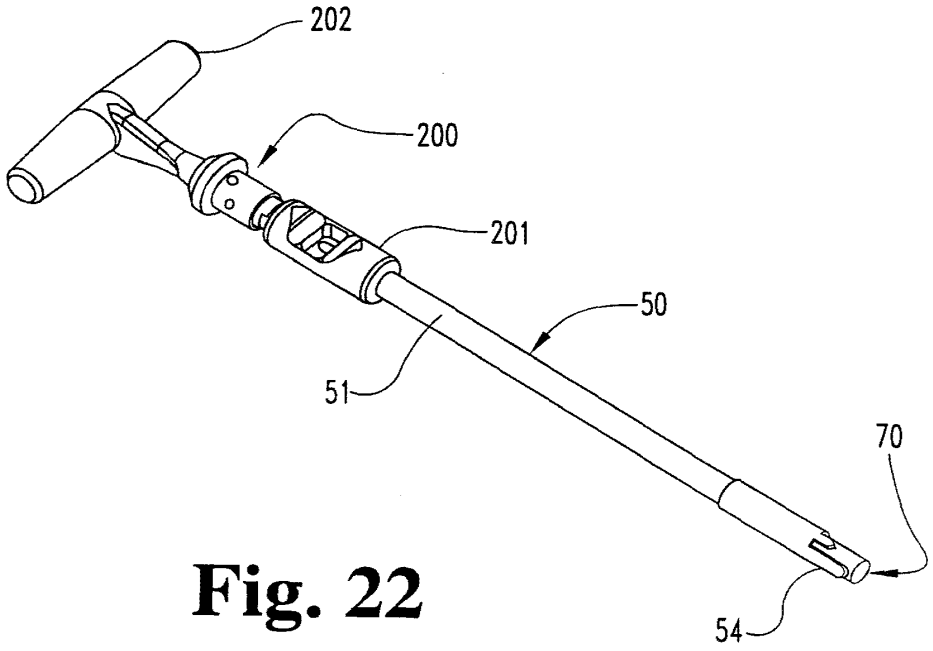

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Fig. 22

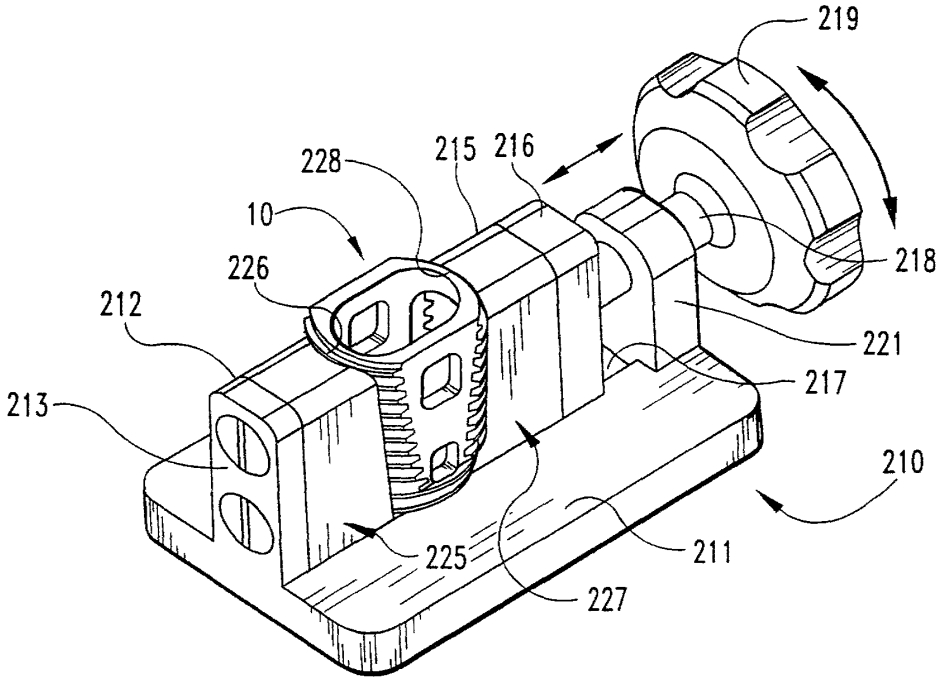

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Fig. 23

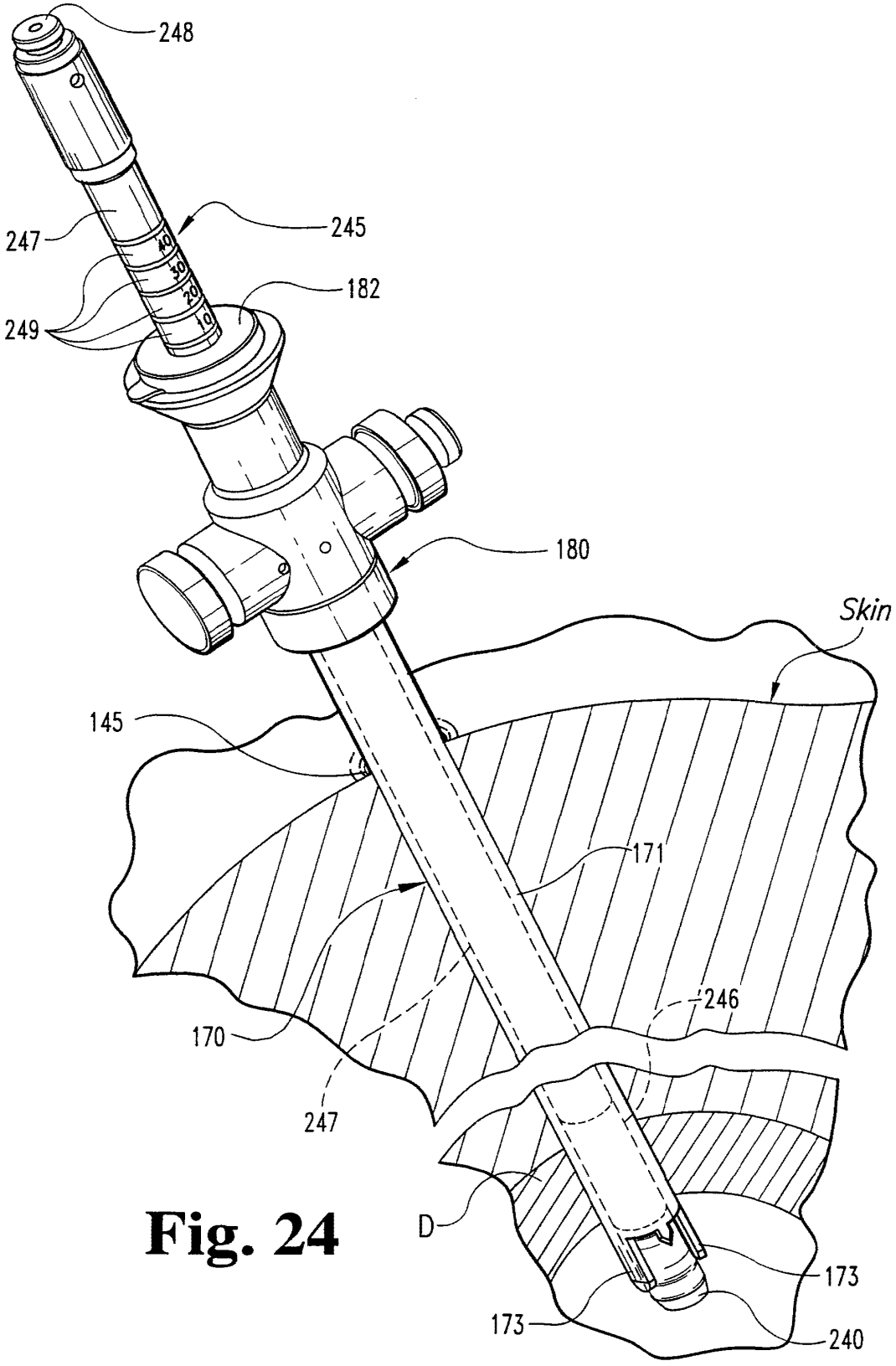


Fig. 24

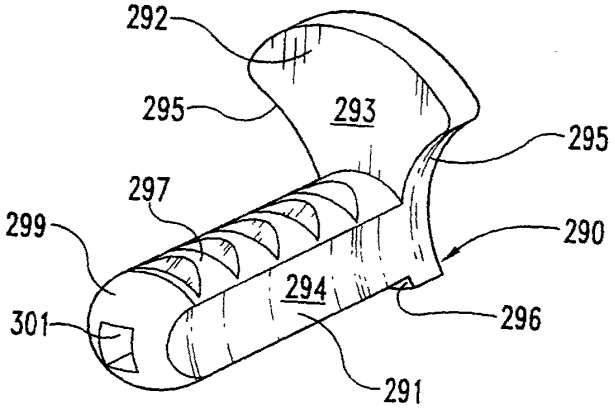


Fig. 25

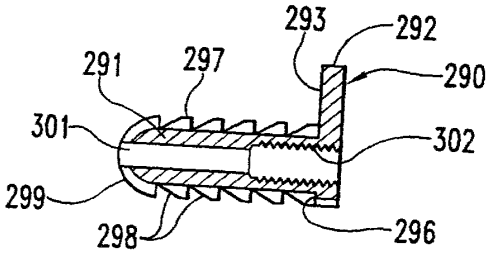


Fig. 26

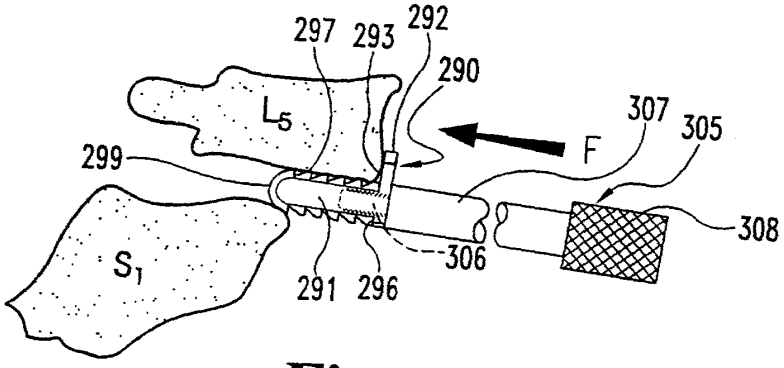


Fig. 28

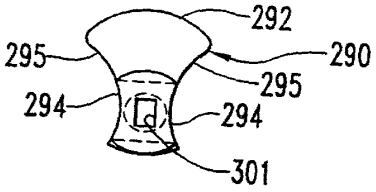


Fig. 27

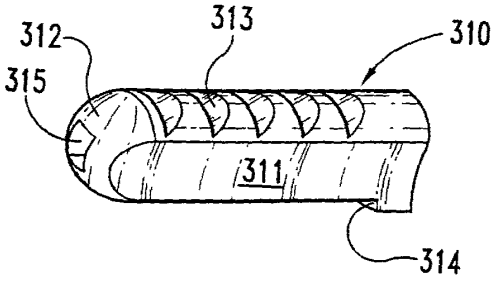


Fig. 29

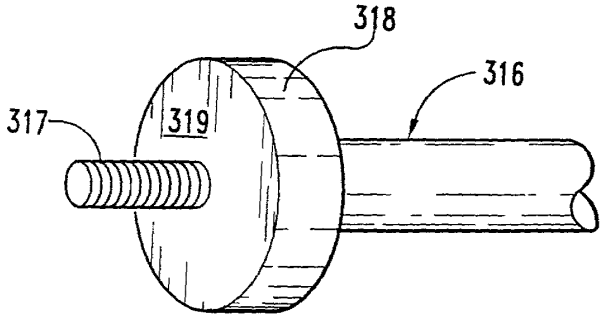


Fig. 30

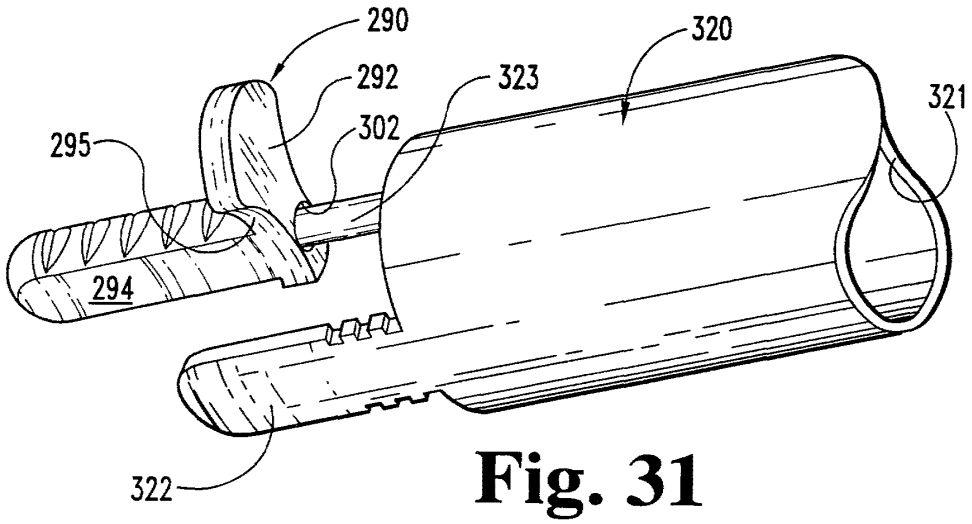

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Fig. 31

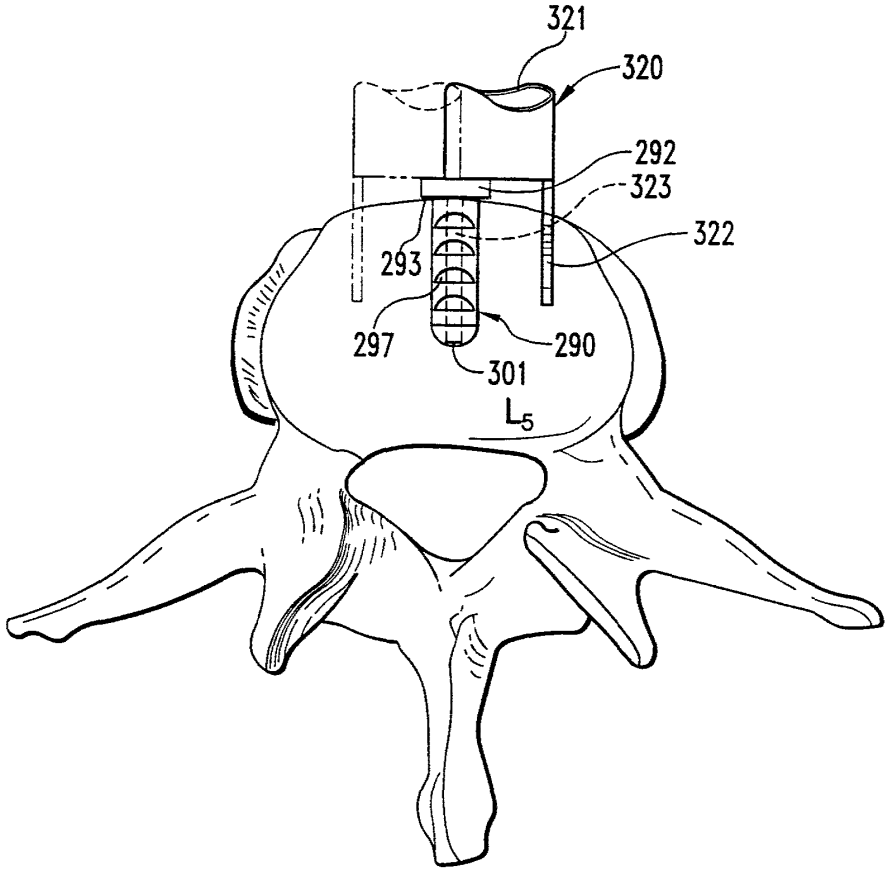

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Fig. 32

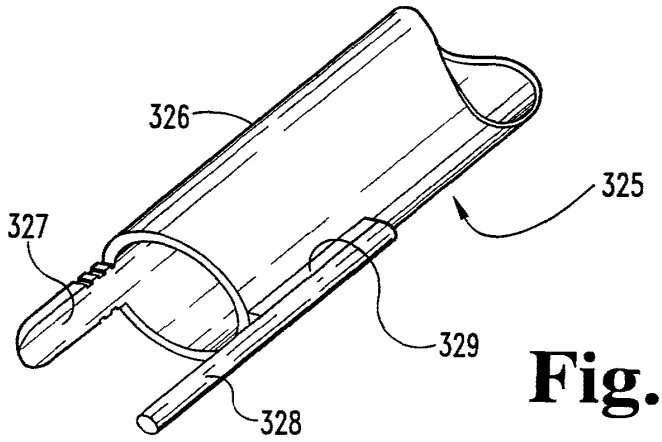


Fig. 33

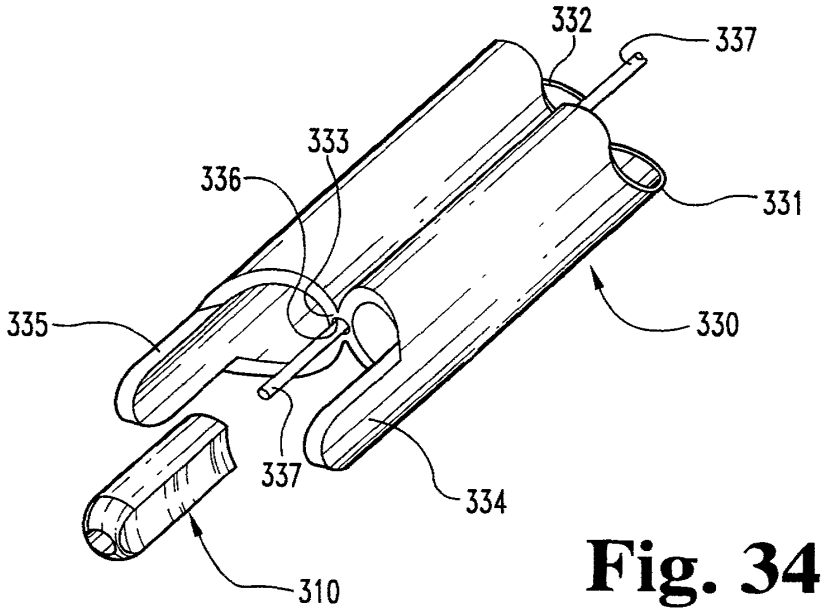


Fig. 34

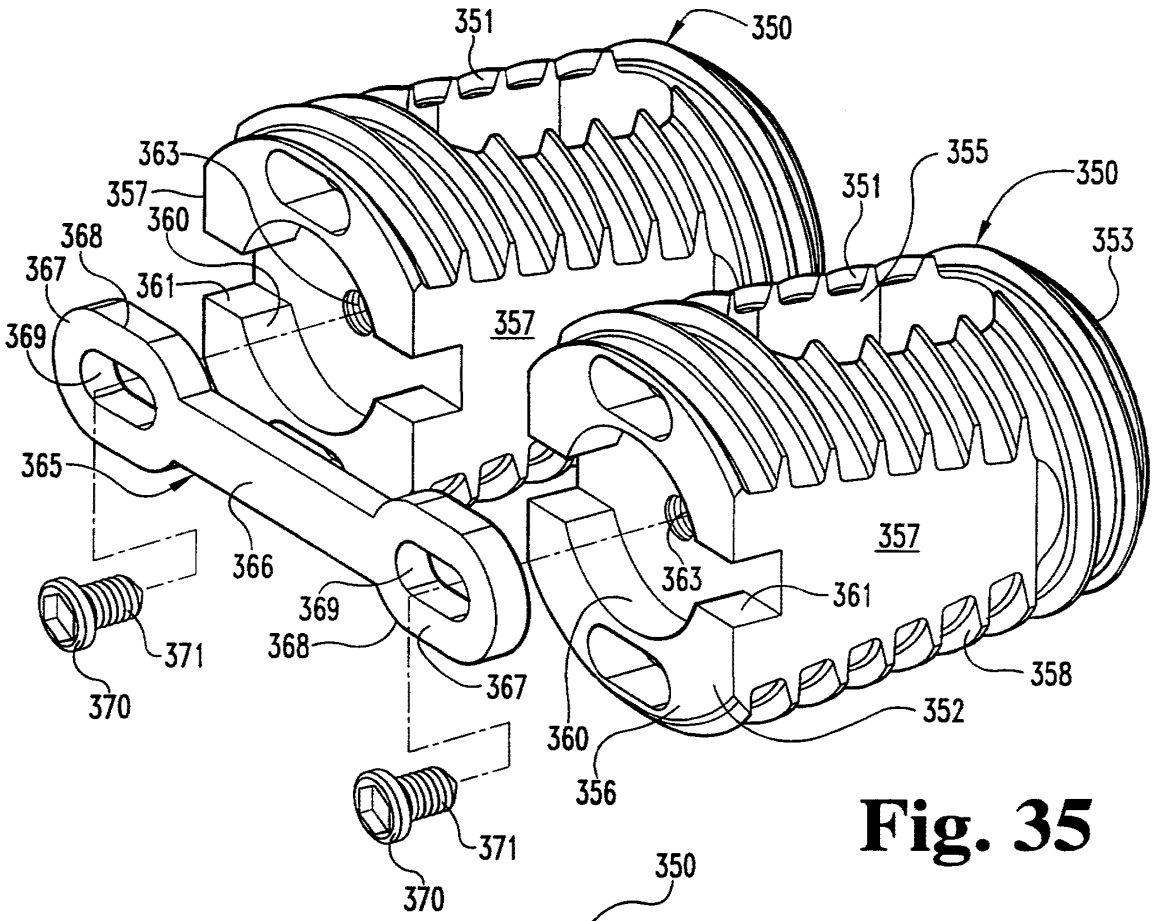

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Fig. 35

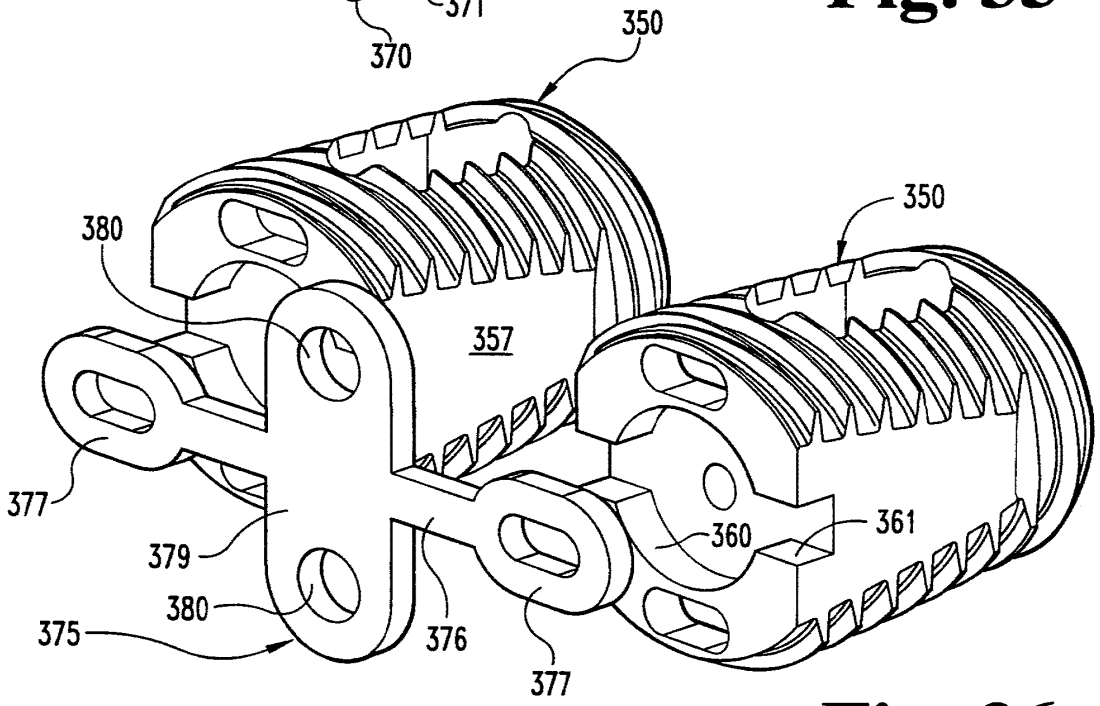

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Fig. 36

Electronic Acknowledgement Receipt

EFS ID:	39504105
Application Number:	16744755
International Application Number:	
Confirmation Number:	5369
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/Kerstin Kinzer
Filer Authorized By:	Stuart A. Nelson
Attorney Docket Number:	46440-0009016
Receipt Date:	21-MAY-2020
Filing Date:	16-JAN-2020
Time Stamp:	12:16:14
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	1449.pdf	215646 8ce811252477de4f05e1108e7a3f2cdb97873127	no	3

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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

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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
16/744,755	01/16/2020	Ahmnon D. Moskowitz	46440-0009016

CONFIRMATION NO. 5369

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

PUBLICATION NOTICE

OC000000119225543

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

Publication No.US-2020-0253747-A1
Publication Date:08/13/2020

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First Named Inventor	:	Ahmnon D. Moskowitz	Art Unit	:	Unknown
Application No.	:	16/744,755	Examiner	:	Unknown
Filed	:	January 16, 2020	Conf. No.	:	5369
Title	:	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION			

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INFORMATION DISCLOSURE STATEMENT

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

This statement is being filed 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: 9/9/2020

/Stuart A. Nelson/
Stuart A. Nelson
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Telephone: (612) 337-2538
Facsimile: (877) 769-7945

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Substitute Disclosure Form	U.S. Department of Commerce Patent and Trademark Office	Attorney Docket No. 46440-0009016	Application No. 16/744,755
Information Disclosure Statement by Applicant (Use several sheets if necessary) (37 CFR §1.98(b))		Applicant Moskowitz Family LLC	
		Filing Date January 16, 2020	Group Art Unit

U.S. Patent Documents

Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Filing Date If Appropriate	Class	Subclass
	1.	5192327	3/9/1993	Brantigan			
	2.	7001385	2/21/2006	Bonutti			
	3.	9889022	2/13/2018	Moskowitz et al.			
	4.	10307268	6/4/2019	Moskowitz et al.			
	5.	10478319	11/19/2019	Moskowitz et al.			
	6.	20020143399	10/3/2002	Sutcliffe			
	7.	20040204717	10/14/2004	Fanger et al.			
	8.	20050177236	8/11/2005	Mathieu et al.			
	9.	20070270968	11/22/2007	Baynham			

Foreign Patent Documents or Published Foreign Patent Applications

Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Translation	Class	Subclass

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

Examiner Initial	Desig. ID	Document
	10.	Auguste et al., "Expandable cylindrical cages in the cervical spine: a review of 22 cases," J. Neurosurg. Spine, 4:285–291, 2006, Exhibit No. 1006 in Case IPR2020-01303, U.S. Patent 10,307,268
	11.	Auguste et al., "Expandable cylindrical cages in the cervical spine: a review of 22 cases," J. Neurosurg. Spine, 4:285–291, 2006, Exhibit No. 1006 in Case IPR2020-01304, U.S. Patent 10,307,268
	12.	Auguste et al., "Expandable cylindrical cages in the cervical spine: a review of 22 cases," J. Neurosurg. Spine, 4:285–291, 2006, Exhibit No. 1006 in Case IPR2020-01305, U.S. Patent 10,478,319
	13.	Auguste et al., "Expandable cylindrical cages in the cervical spine: a review of 22 cases," J. Neurosurg. Spine, 4:285–291, 2006, Exhibit No. 1006 in Case IPR2020-01306, U.S. Patent 10,478,319
	14.	Auguste et al., "Expandable cylindrical cages in the cervical spine: a review of 22 cases," J. Neurosurg. Spine, 4:285–291, 2006, Exhibit No. 1006 in Case IPR2020-01307, U.S. Patent 8,353,913
	15.	Auguste et al., "Expandable cylindrical cages in the cervical spine: a review of 22 cases," J. Neurosurg. Spine, 4:285–291, 2006, Exhibit No. 1006 in Case IPR2020-01308, U.S. Patent 9,889,022
	16.	Boakye et al., "The Poly-ether-ether-ketone (PEEK) Spacer," Thieme Medical Publishers, Inc., 333 Seventh Ave., New York, NY 10001, 6 pages, Exhibit No. 1007 in Case IPR2020-01303, U.S. Patent 10,307,268

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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 January 16, 2020	Group Art Unit

Other Documents (include Author, Title, Date, and Place of Publication)		
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	17.	Boakye et al., "The Poly-ether-ether-ketone (PEEK) Spacer," Thieme Medical Publishers, Inc., 333 Seventh Ave., New York, NY 10001, 6 pages, Exhibit No. 1007 in Case IPR2020-01304, U.S. Patent 10,307,268
	18.	Boakye et al., "The Poly-ether-ether-ketone (PEEK) Spacer," Thieme Medical Publishers, Inc., 333 Seventh Ave., New York, NY 10001, 6 pages, Exhibit No. 1007 in Case IPR2020-01305, U.S. Patent 10,478,319
	19.	Boakye et al., "The Poly-ether-ether-ketone (PEEK) Spacer," Thieme Medical Publishers, Inc., 333 Seventh Ave., New York, NY 10001, 6 pages, Exhibit No. 1007 in Case IPR2020-01306, U.S. Patent 10,478,319
	20.	Boakye et al., "The Poly-ether-ether-ketone (PEEK) Spacer," Thieme Medical Publishers, Inc., 333 Seventh Ave., New York, NY 10001, 6 pages, Exhibit No. 1007 in Case IPR2020-01307, U.S. Patent 8,353,913
	21.	Boakye et al., "The Poly-ether-ether-ketone (PEEK) Spacer," Thieme Medical Publishers, Inc., 333 Seventh Ave., New York, NY 10001, 6 pages, Exhibit No. 1007 in Case IPR2020-01308, U.S. Patent 9,889,022
	22.	Centinel Spine, [https://www.centinelspine.com/corp_producthistory.php, Retrieved on 6/4/2020 11:48:58 PM], 7 pages, Exhibit No. 1009 in Case IPR2020-01303, U.S. Patent 10,307,268
	23.	Centinel Spine, [https://www.centinelspine.com/corp_producthistory.php, Retrieved on 6/4/2020 11:48:58 PM], 7 pages, Exhibit No. 1009 in Case IPR2020-01304, U.S. Patent 10,307,268
	24.	Centinel Spine, [https://www.centinelspine.com/corp_producthistory.php, Retrieved on 6/4/2020 11:48:58 PM], 7 pages, Exhibit No. 1009 in Case IPR2020-01305, U.S. Patent 10,478,319
	25.	Centinel Spine, [https://www.centinelspine.com/corp_producthistory.php, Retrieved on 6/4/2020 11:48:58 PM], 7 pages, Exhibit No. 1009 in Case IPR2020-01306, U.S. Patent 10,478,319
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	28.	Cheung and Leong, "Spinal Instrumentation Overview in Lumbar Degenerative Disorders: Cages," Spinal Instrumentation Overview, Ch. 26, 8 pages, Exhibit No. 1008 in Case IPR2020-01303, U.S. Patent 10,307,268
	29.	Cheung and Leong, "Spinal Instrumentation Overview in Lumbar Degenerative Disorders: Cages," Spinal Instrumentation Overview, Ch. 26, 8 pages, Exhibit No. 1008 in Case IPR2020-01304, U.S. Patent 10,307,268
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	31.	Cheung and Leong, "Spinal Instrumentation Overview in Lumbar Degenerative Disorders: Cages," Spinal Instrumentation Overview, Ch. 26, 8 pages, Exhibit No. 1008 in Case IPR2020-01306, U.S. Patent 10,478,319
	32.	Cheung and Leong, "Spinal Instrumentation Overview in Lumbar Degenerative Disorders: Cages," Spinal Instrumentation Overview, Ch. 26, 8 pages, Exhibit No. 1008 in Case IPR2020-01307, U.S. Patent 8,353,913

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		Filing Date January 16, 2020	Group Art Unit

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	34.	Dickman, "Internal Fixation and Fusion of the Lumbar Spine Using Threaded Interbody Cages," [https://www.barrowneuro.org/education/grand-rounds-publications-and-media/barrow-quarterly/, Retrieved on 6/20/2020], 41 pages, Exhibit No. 1010 in Case IPR2020-01303, U.S. Patent 10,307,268
	35.	Dickman, "Internal Fixation and Fusion of the Lumbar Spine Using Threaded Interbody Cages," [https://www.barrowneuro.org/education/grand-rounds-publications-and-media/barrow-quarterly/, Retrieved on 6/20/2020], 41 pages, Exhibit No. 1010 in Case IPR2020-01304, U.S. Patent 10,307,268
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	38.	Dickman, "Internal Fixation and Fusion of the Lumbar Spine Using Threaded Interbody Cages," [https://www.barrowneuro.org/education/grand-rounds-publications-and-media/barrow-quarterly/, Retrieved on 6/20/2020], 41 pages, Exhibit No. 1010 in Case IPR2020-01307, U.S. Patent 8,353,913
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	40.	Dryer, "Affinity Anterior Cervical Cage System," Thieme Medical Publisher, Inc., New York, New York, 2005, 9 pages, Exhibit No. 1011 in Case IPR2020-01303, U.S. Patent 10,307,268
	41.	Dryer, "Affinity Anterior Cervical Cage System," Thieme Medical Publisher, Inc., New York, New York, 2005, 9 pages, Exhibit No. 1011 in Case IPR2020-01304, U.S. Patent 10,307,268
	42.	Dryer, "Affinity Anterior Cervical Cage System," Thieme Medical Publisher, Inc., New York, New York, 2005, 9 pages, Exhibit No. 1011 in Case IPR2020-01305, U.S. Patent 10,478,319
	43.	Dryer, "Affinity Anterior Cervical Cage System," Thieme Medical Publisher, Inc., New York, New York, 2005, 9 pages, Exhibit No. 1011 in Case IPR2020-01306, U.S. Patent 10,478,319
	44.	Dryer, "Affinity Anterior Cervical Cage System," Thieme Medical Publisher, Inc., New York, New York, 2005, 9 pages, Exhibit No. 1011 in Case IPR2020-01307, U.S. Patent 8,353,913
	45.	Dryer, "Affinity Anterior Cervical Cage System," Thieme Medical Publisher, Inc., New York, New York, 2005, 9 pages, Exhibit No. 1011 in Case IPR2020-01308, U.S. Patent 9,889,022
	46.	Folman et al., "Posterior Lumbar Interbody Fusion for Degenerative Disc Disease Using a Minimally Invasive B-Twin Expandable Spinal Spacer," Journal of Spinal Disorders & Techniques, October 2003, 16(5):455-60, Exhibit No. 1012 in Case IPR2020-01303, U.S. Patent 10,307,268

Examiner Signature	Date Considered

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		Filing Date January 16, 2020	Group Art Unit

Other Documents (include Author, Title, Date, and Place of Publication)		
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	47.	Folman et al., "Posterior Lumbar Interbody Fusion for Degenerative Disc Disease Using a Minimally Invasive B-Twin Expandable Spinal Spacer," Journal of Spinal Disorders & Techniques, October 2003, 16(5):455-60, Exhibit No. 1012 in Case IPR2020-01304, U.S. Patent 10,307,268
	48.	Folman et al., "Posterior Lumbar Interbody Fusion for Degenerative Disc Disease Using a Minimally Invasive B-Twin Expandable Spinal Spacer," Journal of Spinal Disorders & Techniques, October 2003, 16(5):455-60, Exhibit No. 1012 in Case IPR2020-01305, U.S. Patent 10,478,319
	49.	Folman et al., "Posterior Lumbar Interbody Fusion for Degenerative Disc Disease Using a Minimally Invasive B-Twin Expandable Spinal Spacer," Journal of Spinal Disorders & Techniques, October 2003, 16(5):455-60, Exhibit No. 1012 in Case IPR2020-01306, U.S. Patent 10,478,319
	50.	Folman et al., "Posterior Lumbar Interbody Fusion for Degenerative Disc Disease Using a Minimally Invasive B-Twin Expandable Spinal Spacer," Journal of Spinal Disorders & Techniques, October 2003, 16(5):455-60, Exhibit No. 1012 in Case IPR2020-01307, U.S. Patent 8,353,913
	51.	Folman et al., "Posterior Lumbar Interbody Fusion for Degenerative Disc Disease Using a Minimally Invasive B-Twin Expandable Spinal Spacer," Journal of Spinal Disorders & Techniques, October 2003, 16(5):455-60, Exhibit No. 1012 in Case IPR2020-01308, U.S. Patent 9,889,022
	52.	GLOBUS MEDICAL, INC., Petitioner v. MOSKOWITZ FAMILY LLC, Patent Owner PETITION FOR INTER PARTES REVIEW OF U.S. PATENT NO. 10,307,268 PURSUANT TO 35 U.S.C. §§ 311–319 AND 37 C.F.R. § 42, dated July 21, 2020, 75 pages
	53.	GLOBUS MEDICAL, INC., Petitioner v. MOSKOWITZ FAMILY LLC, Patent Owner PETITION FOR INTER PARTES REVIEW OF U.S. PATENT NO. 10,307,268 PURSUANT TO 35 U.S.C. §§ 311–319 AND 37 C.F.R. § 42, dated July 21, 2020, 79 pages
	54.	GLOBUS MEDICAL, INC., Petitioner v. MOSKOWITZ FAMILY LLC, Patent Owner PETITION FOR INTER PARTES REVIEW OF U.S. PATENT NO. 10,478,319 PURSUANT TO 35 U.S.C. §§ 311–319 AND 37 C.F.R. § 42, dated July 21, 2020, 78 pages
	55.	GLOBUS MEDICAL, INC., Petitioner v. MOSKOWITZ FAMILY LLC, Patent Owner PETITION FOR INTER PARTES REVIEW OF U.S. PATENT NO. 10,478,319 PURSUANT TO 35 U.S.C. §§ 311–319 AND 37 C.F.R. § 42, dated July 21, 2020, 83 pages
	56.	GLOBUS MEDICAL, INC., Petitioner v. MOSKOWITZ FAMILY LLC, Patent Owner PETITION FOR INTER PARTES REVIEW OF U.S. PATENT NO. 8,353,913 PURSUANT TO 35 U.S.C. §§ 311–319 AND 37 C.F.R. § 42, dated July 21, 2020, 69 pages
	57.	GLOBUS MEDICAL, INC., Petitioner v. MOSKOWITZ FAMILY LLC, Patent Owner PETITION FOR INTER PARTES REVIEW OF U.S. PATENT NO. 9,889,022 PURSUANT TO 35 U.S.C. §§ 311–319 AND 37 C.F.R. § 42, dated July 21, 2020, 68 pages
	58.	GLOBUS MEDICAL, INC., v. MOSKOWITZ FAMILY LLC, "DECLARATION OF JORGE A. OCHOA, PH.D., P.E.," Case IPR2020-01303 & 01304, U.S. Patent 10,307,268, dated July 21, 2020, 127 pages (Exhibit No. 1003)
	59.	GLOBUS MEDICAL, INC., v. MOSKOWITZ FAMILY LLC, "DECLARATION OF JORGE A. OCHOA, PH.D., P.E.," Case IPR2020-01303 & 01304, U.S. Patent 10,307,268, dated July 21, 2020, 127 pages (Exhibit No. 1003)
	60.	GLOBUS MEDICAL, INC., v. MOSKOWITZ FAMILY LLC, "DECLARATION OF JORGE A. OCHOA, PH.D., P.E.," Case IPR2020-01305 & 01306, U.S. Patent 10,478,319, dated July 21, 2020, 141 pages (Exhibit No. 1003)

Examiner Signature	Date Considered

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Substitute Disclosure Form

Substitute Disclosure Form	U.S. Department of Commerce Patent and Trademark Office	Attorney Docket No. 46440-0009016	Application No. 16/744,755
Information Disclosure Statement by Applicant (Use several sheets if necessary) (37 CFR §1.98(b))		Applicant Moskowitz Family LLC	
		Filing Date January 16, 2020	Group Art Unit

Other Documents (include Author, Title, Date, and Place of Publication)		
Examiner Initial	Desig. ID	Document
	61.	GLOBUS MEDICAL, INC., v. MOSKOWITZ FAMILY LLC, "DECLARATION OF JORGE A. OCHOA, PH.D., P.E.," Case IPR2020-01305 & 01306, U.S. Patent 10,478,319, dated July 21, 2020, 141 pages (Exhibit No. 1003)
	62.	GLOBUS MEDICAL, INC., v. MOSKOWITZ FAMILY LLC, "DECLARATION OF JORGE A. OCHOA, PH.D., P.E.," Case IPR2020-01307, U.S. Patent 8,353,913, dated July 21, 2020, 67 pages (Exhibit No. 1003)
	63.	GLOBUS MEDICAL, INC., v. MOSKOWITZ FAMILY LLC, "DECLARATION OF JORGE A. OCHOA, PH.D., P.E.," Case IPR2020-01308, U.S. Patent 9,889,022, dated July 21, 2020, 65 pages (Exhibit No. 1003)
	64.	Guyer and Ohnmeiss, "Degenerative Disc Disease: Fusion Cages and Dowels," Lippincott Williams & Wilkins, Philadelphia, PA, 2004, Ch. 35, 12 pages, Exhibit No. 1013 in Case IPR2020-01303, U.S. Patent 10,307,268
	65.	Guyer and Ohnmeiss, "Degenerative Disc Disease: Fusion Cages and Dowels," Lippincott Williams & Wilkins, Philadelphia, PA, 2004, Ch. 35, 12 pages, Exhibit No. 1013 in Case IPR2020-01304, U.S. Patent 10,307,268
	66.	Guyer and Ohnmeiss, "Degenerative Disc Disease: Fusion Cages and Dowels," Lippincott Williams & Wilkins, Philadelphia, PA, 2004, Ch. 35, 12 pages, Exhibit No. 1013 in Case IPR2020-01305, U.S. Patent 10,478,319
	67.	Guyer and Ohnmeiss, "Degenerative Disc Disease: Fusion Cages and Dowels," Lippincott Williams & Wilkins, Philadelphia, PA, 2004, Ch. 35, 12 pages, Exhibit No. 1013 in Case IPR2020-01306, U.S. Patent 10,478,319
	68.	Guyer and Ohnmeiss, "Degenerative Disc Disease: Fusion Cages and Dowels," Lippincott Williams & Wilkins, Philadelphia, PA, 2004, Ch. 35, 12 pages, Exhibit No. 1013 in Case IPR2020-01307, U.S. Patent 8,353,913
	69.	Guyer and Ohnmeiss, "Degenerative Disc Disease: Fusion Cages and Dowels," Lippincott Williams & Wilkins, Philadelphia, PA, 2004, Ch. 35, 12 pages, Exhibit No. 1013 in Case IPR2020-01308, U.S. Patent 9,889,022
	70.	Holte et al., "Anterior lumbar fusion using a hybrid interbody graft," Eur. Spine J., 3:32-38, 1994, Exhibit No. 1014 in Case IPR2020-01303, U.S. Patent 10,307,268
	71.	Holte et al., "Anterior lumbar fusion using a hybrid interbody graft," Eur. Spine J., 3:32-38, 1994, Exhibit No. 1014 in Case IPR2020-01304, U.S. Patent 10,307,268
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	73.	Holte et al., "Anterior lumbar fusion using a hybrid interbody graft," Eur. Spine J., 3:32-38, 1994, Exhibit No. 1014 in Case IPR2020-01306, U.S. Patent 10,478,319
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	76.	Lane et al., "Transperitoneal Approach to the Intervertebral Disc in the Lumbar Area," Annals of Surgery, March 1948, 127(3):537, Exhibit No. 1015 in Case IPR2020-01303, U.S. Patent 10,307,268

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Information Disclosure Statement by Applicant (Use several sheets if necessary) (37 CFR §1.98(b))		Applicant Moskowitz Family LLC	
		Filing Date January 16, 2020	Group Art Unit

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	78.	Lane et al., "Transperitoneal Approach to the Intervertebral Disc in the Lumbar Area," Annals of Surgery, March 1948, 127(3):537, Exhibit No. 1015 in Case IPR2020-01305, U.S. Patent 10,478,319
	79.	Lane et al., "Transperitoneal Approach to the Intervertebral Disc in the Lumbar Area," Annals of Surgery, March 1948, 127(3):537, Exhibit No. 1015 in Case IPR2020-01306, U.S. Patent 10,478,319
	80.	Lane et al., "Transperitoneal Approach to the Intervertebral Disc in the Lumbar Area," Annals of Surgery, March 1948, 127(3):537, Exhibit No. 1015 in Case IPR2020-01307, U.S. Patent 8,353,913
	81.	Lane et al., "Transperitoneal Approach to the Intervertebral Disc in the Lumbar Area," Annals of Surgery, March 1948, 127(3):537, Exhibit No. 1015 in Case IPR2020-01308, U.S. Patent 9,889,022
	82.	Michelson et al., "BAK/C Interbody Fusion System: A Threaded Cylindrical Cage for Cervical Fusion," Thieme Medical Publisher, Inc., New York, New York, 2005, 10 pages, Exhibit No. 1016 in Case IPR2020-01303, U.S. Patent 10,307,268
	83.	Michelson et al., "BAK/C Interbody Fusion System: A Threaded Cylindrical Cage for Cervical Fusion," Thieme Medical Publisher, Inc., New York, New York, 2005, 10 pages, Exhibit No. 1016 in Case IPR2020-01304, U.S. Patent 10,307,268
	84.	Michelson et al., "BAK/C Interbody Fusion System: A Threaded Cylindrical Cage for Cervical Fusion," Thieme Medical Publisher, Inc., New York, New York, 2005, 10 pages, Exhibit No. 1016 in Case IPR2020-01305, U.S. Patent 10,478,319
	85.	Michelson et al., "BAK/C Interbody Fusion System: A Threaded Cylindrical Cage for Cervical Fusion," Thieme Medical Publisher, Inc., New York, New York, 2005, 10 pages, Exhibit No. 1016 in Case IPR2020-01306, U.S. Patent 10,478,319
	86.	Michelson et al., "BAK/C Interbody Fusion System: A Threaded Cylindrical Cage for Cervical Fusion," Thieme Medical Publisher, Inc., New York, New York, 2005, 10 pages, Exhibit No. 1016 in Case IPR2020-01307, U.S. Patent 8,353,913
	87.	Michelson et al., "BAK/C Interbody Fusion System: A Threaded Cylindrical Cage for Cervical Fusion," Thieme Medical Publisher, Inc., New York, New York, 2005, 10 pages, Exhibit No. 1016 in Case IPR2020-01308, U.S. Patent 9,889,022
	88.	Prpa et al., "Lumbar Interbody Cages," Sug. Pro., Ch. 41, pp. 489-502, 2005, Exhibit No. 1017 in Case IPR2020-01303, U.S. Patent 10,307,268
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	94.	Ryu and Kim, "Cervical Carbon Fiber Interbody Fusion Cage: Bengal System," Thieme Medical Publisher, Inc., New York, New York, 2005, 8 pages, Exhibit No. 1018 in Case IPR2020-01303, U.S. Patent 10,307,268
	95.	Ryu and Kim, "Cervical Carbon Fiber Interbody Fusion Cage: Bengal System," Thieme Medical Publisher, Inc., New York, New York, 2005, 8 pages, Exhibit No. 1018 in Case IPR2020-01304, U.S. Patent 10,307,268
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	97.	Ryu and Kim, "Cervical Carbon Fiber Interbody Fusion Cage: Bengal System," Thieme Medical Publisher, Inc., New York, New York, 2005, 8 pages, Exhibit No. 1018 in Case IPR2020-01306, U.S. Patent 10,478,319
	98.	Ryu and Kim, "Cervical Carbon Fiber Interbody Fusion Cage: Bengal System," Thieme Medical Publisher, Inc., New York, New York, 2005, 8 pages, Exhibit No. 1018 in Case IPR2020-01307, U.S. Patent 8,353,913
	99.	Ryu and Kim, "Cervical Carbon Fiber Interbody Fusion Cage: Bengal System," Thieme Medical Publisher, Inc., New York, New York, 2005, 8 pages, Exhibit No. 1018 in Case IPR2020-01308, U.S. Patent 9,889,022
	100.	Schimmel et al., "PEEK Cages in Lumbar Fusion," Clin. Spine Surg., 29(5):E252-E258, June 2016, Exhibit No. 1019 in Case IPR2020-01303, U.S. Patent 10,307,268
	101.	Schimmel et al., "PEEK Cages in Lumbar Fusion," Clin. Spine Surg., 29(5):E252-E258, June 2016, Exhibit No. 1019 in Case IPR2020-01304, U.S. Patent 10,307,268
	102.	Schimmel et al., "PEEK Cages in Lumbar Fusion," Clin. Spine Surg., 29(5):E252-E258, June 2016, Exhibit No. 1019 in Case IPR2020-01305, U.S. Patent 10,478,319
	103.	Schimmel et al., "PEEK Cages in Lumbar Fusion," Clin. Spine Surg., 29(5):E252-E258, June 2016, Exhibit No. 1019 in Case IPR2020-01306, U.S. Patent 10,478,319
	104.	Schimmel et al., "PEEK Cages in Lumbar Fusion," Clin. Spine Surg., 29(5):E252-E258, June 2016, Exhibit No. 1019 in Case IPR2020-01307, U.S. Patent 8,353,913
	105.	Schimmel et al., "PEEK Cages in Lumbar Fusion," Clin. Spine Surg., 29(5):E252-E258, June 2016, Exhibit No. 1019 in Case IPR2020-01308, U.S. Patent 9,889,022
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	108.	Synfix, "EVOLUTION System," Online Product, DATE, 1 page, Exhibit No. 1021 in Case IPR2020-01305, U.S. Patent 10,478,319
	109.	Synfix, "EVOLUTION System," Online Product, DATE, 1 page, Exhibit No. 1021 in Case IPR2020-01306, U.S. Patent 10,478,319
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		Filing Date January 16, 2020	Group Art Unit

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	112.	Synthes "SynFix-LR. Implant and instrumentation for stand alone anterior lumbar interbody fusion (ALIF)," 2006, 26 pages, Exhibit No. 1020 in Case IPR2020-01303, U.S. Patent 10,307,268
	113.	Synthes "SynFix-LR. Implant and instrumentation for stand alone anterior lumbar interbody fusion (ALIF)," 2006, 26 pages, Exhibit No. 1020 in Case IPR2020-01304, U.S. Patent 10,307,268
	114.	Synthes "SynFix-LR. Implant and instrumentation for stand alone anterior lumbar interbody fusion (ALIF)," 2006, 26 pages, Exhibit No. 1020 in Case IPR2020-01305, U.S. Patent 10,478,319
	115.	Synthes "SynFix-LR. Implant and instrumentation for stand alone anterior lumbar interbody fusion (ALIF)," 2006, 26 pages, Exhibit No. 1020 in Case IPR2020-01306, U.S. Patent 10,478,319
	116.	Synthes "SynFix-LR. Implant and instrumentation for stand alone anterior lumbar interbody fusion (ALIF)," 2006, 26 pages, Exhibit No. 1020 in Case IPR2020-01307, U.S. Patent 8,353,913
	117.	Synthes "SynFix-LR. Implant and instrumentation for stand alone anterior lumbar interbody fusion (ALIF)," 2006, 26 pages, Exhibit No. 1020 in Case IPR2020-01308, U.S. Patent 9,889,022
	118.	Wagner et al., "Surgical Stabilization of the Equine Cervical Spine," Veterinary Surg., 8:1-6, January-March 1979, Exhibit No. 1023 in Case IPR2020-01303, U.S. Patent 10,307,268
	119.	Wagner et al., "Surgical Stabilization of the Equine Cervical Spine," Veterinary Surg., 8:1-6, January-March 1979, Exhibit No. 1023 in Case IPR2020-01304, U.S. Patent 10,307,268
	120.	Wagner et al., "Surgical Stabilization of the Equine Cervical Spine," Veterinary Surg., 8:1-6, January-March 1979, Exhibit No. 1023 in Case IPR2020-01305, U.S. Patent 10,478,319
	121.	Wagner et al., "Surgical Stabilization of the Equine Cervical Spine," Veterinary Surg., 8:1-6, January-March 1979, Exhibit No. 1023 in Case IPR2020-01306, U.S. Patent 10,478,319
	122.	Wagner et al., "Surgical Stabilization of the Equine Cervical Spine," Veterinary Surg., 8:1-6, January-March 1979, Exhibit No. 1023 in Case IPR2020-01307, U.S. Patent 8,353,913
	123.	Wagner et al., "Surgical Stabilization of the Equine Cervical Spine," Veterinary Surg., 8:1-6, January-March 1979, Exhibit No. 1023 in Case IPR2020-01308, U.S. Patent 9,889,022
	124.	Weiner and Fraser, "Spine Update Lumbar Interbody Cages," Spine, 23(5):634-640, 1998, Exhibit No. 1024 in Case IPR2020-01303, U.S. Patent 10,307,268
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	128.	Weiner and Fraser, "Spine Update Lumbar Interbody Cages," Spine, 23(5):634-640, 1998, Exhibit No. 1024 in Case IPR2020-01307, U.S. Patent 8,353,913
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	130.	Wilke et al., "Primary stabilizing effect of interbody fusion devices for the cervical spine: an in vitro comparison between three different cage types and bone cement," Eur. Spine J., 2000, 9:410-416, Exhibit No. 1025 in Case IPR2020-01303, U.S. Patent 10,307,268

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Substitute Disclosure Form / U.S. Department of Commerce Patent and Trademark Office	Attorney Docket No.	Application No.
Information Disclosure Statement by Applicant (Use several sheets if necessary) (37 CFR §1.98(b))	46440-0009016	16/744,755
	Applicant: Moskowitz Family LLC	
	Filing Date: January 16, 2020	Group Art Unit

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	131.	Wilke et al., "Primary stabilizing effect of interbody fusion devices for the cervical spine: an in vitro comparison between three different cage types and bone cement," Eur. Spine J., 2000, 9:410-416, Exhibit No. 1025 in Case IPR2020-01304, U.S. Patent 10,307,268
	132.	Wilke et al., "Primary stabilizing effect of interbody fusion devices for the cervical spine: an in vitro comparison between three different cage types and bone cement," Eur. Spine J., 2000, 9:410-416, Exhibit No. 1025 in Case IPR2020-01305, U.S. Patent 10,478,319
	133.	Wilke et al., "Primary stabilizing effect of interbody fusion devices for the cervical spine: an in vitro comparison between three different cage types and bone cement," Eur. Spine J., 2000, 9:410-416, Exhibit No. 1025 in Case IPR2020-01306, U.S. Patent 10,478,319
	134.	Wilke et al., "Primary stabilizing effect of interbody fusion devices for the cervical spine: an in vitro comparison between three different cage types and bone cement," Eur. Spine J., 2000, 9:410-416, Exhibit No. 1025 in Case IPR2020-01307, U.S. Patent 8,353,913
	135.	Wilke et al., "Primary stabilizing effect of interbody fusion devices for the cervical spine: an in vitro comparison between three different cage types and bone cement," Eur. Spine J., 2000, 9:410-416, Exhibit No. 1025 in Case IPR2020-01308, U.S. Patent 9,889,022
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	137.	Wiseman et al., "Posterior Lumbar Interbody Fusion," Surgical Procedures, Ch. 39, 24 pages, Exhibit No. 1026 in Case IPR2020-01304, U.S. Patent 10,307,268
	138.	Wiseman et al., "Posterior Lumbar Interbody Fusion," Surgical Procedures, Ch. 39, 24 pages, Exhibit No. 1026 in Case IPR2020-01305, U.S. Patent 10,478,319
	139.	Wiseman et al., "Posterior Lumbar Interbody Fusion," Surgical Procedures, Ch. 39, 24 pages, Exhibit No. 1026 in Case IPR2020-01306, U.S. Patent 10,478,319
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Electronic Acknowledgement Receipt	
EFS ID:	40511338
Application Number:	16744755
International Application Number:	
Confirmation Number:	5369
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/Kirsten Neuman
Filer Authorized By:	Stuart A. Nelson
Attorney Docket Number:	46440-0009016
Receipt Date:	09-SEP-2020
Filing Date:	16-JAN-2020
Time Stamp:	18:04:17
Application Type:	Utility under 35 USC 111(a)

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Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Non Patent Literature	ExpertDeclaration_01305X_Part1.pdf	25150738 b1a1a87ec1b653c900569b2740bca49f6399c023	no	105

Warnings:

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2	Non Patent Literature	ExpertDeclaration_01305X_Part2.pdf	8739709 081d6b302ac08b70cc2bc1c97f9adeb39564d18d	no	36
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Information:					
3	Non Patent Literature	Michelson_2005_01305X.pdf	5025297 4514ae975055f32091d765722b22b26742377004	no	10
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Information:					

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Information:					
13	Non Patent Literature	EX1003ExpertDeclaration_1306X_Part2.pdf	8739719 88fd9b01d5ece7475063eff38d55f0ab34b01ed7	no	36
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15	Non Patent Literature	EX1007Boakye2005_1306X.pdf	3077385 cd2f06cb71ec50728cdd02d8f4c2f18941aaf829	no	6
Warnings:					
Information:					

16	Non Patent Literature	EX1008Cheung2004Chapter26_1306.pdf	1059197 ac76b4f7c023075a0f33f2c7cbc162f1d89baecd	no	8
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17	Non Patent Literature	EX1009CentinelSpine_1306X.pdf	2048370 59b532aff65b5eaf4c70b008bb40005a41724d24	no	7
Warnings:					
Information:					
18	Non Patent Literature	EX1010Dickman1997_1306.pdf	4001174 c6e00ebc87aa428e55f524617034d666662d6724	no	41
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19	Non Patent Literature	EX1011Dryer2005_1306X.pdf	4037261 07a81a9501e4bd0ded1849b65d7e50afdc6bf02a	no	9
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20	Non Patent Literature	EX1012Folman2003_1306.pdf	1048699 c3377fa9c39c9876a154ba4b7339a90cb5a175fe	no	6
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Information:					
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57	Non Patent Literature	EX1003ExpertDeclaration_1308X.pdf	16999937 25f436ea7e127306f5a14a62af74da47c8a92b17	no	65
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58	Non Patent Literature	EX1006Auguste2006_1308.pdf	927005 2627081c22dcaa79ef9c06b38acdbb67eeba62f8	no	8
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<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.

Electronic Acknowledgement Receipt

EFS ID:	40511463
Application Number:	16744755
International Application Number:	
Confirmation Number:	5369
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/Kirsten Neuman
Filer Authorized By:	Stuart A. Nelson
Attorney Docket Number:	46440-0009016
Receipt Date:	09-SEP-2020
Filing Date:	16-JAN-2020
Time Stamp:	18:11:50
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	Non Patent Literature	EX1008Cheung2004Chapter26_1308.pdf	1059197 ac76b4f7c023075a0f33f2c7cbc162f1d89baecd	no	8

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7	Non Patent Literature	EX1014Holte1994_1308.pdf	2359893 467960e1ec020f637713a9c772334fe0515bf510	no	7
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11	Non Patent Literature	EX1018Ryu2005_1308X.pdf	3680404 9e76581ef0c28e8ba6fe2df604e6237c6f2adf6c	no	8
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13	Non Patent Literature	EX1020TechniqueGuideSynFixLR_1308.pdf	1066801 f3becf8523faf46171449f3d04f210f29cc4aca9	no	26
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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	:	Unknown
Application No.	:	16/744,755	Examiner	:	Unknown
Filed	:	January 16, 2020	Conf. No.	:	5369
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). A copy of a communication from a foreign patent office in a counterpart application is also being submitted.

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: 9/9/2020

/Stuart A. Nelson/
Stuart A. Nelson
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Facsimile: (877) 769-7945

62414099.doc

Electronic Acknowledgement Receipt

EFS ID:	40507458
Application Number:	16744755
International Application Number:	
Confirmation Number:	5369
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/Kirsten Neuman
Filer Authorized By:	Stuart A. Nelson
Attorney Docket Number:	46440-0009016
Receipt Date:	09-SEP-2020
Filing Date:	16-JAN-2020
Time Stamp:	15:09:30
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

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32	Non Patent Literature	IPR2020-01304.pdf	1314788 4b3a3af4a030136f73ce3aae89a41d5b34c0ec62	no	75
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37	Non Patent Literature	Wilke_2000_1304.pdf	758723 460343d240fdf7e26541c614ae797eb4a899b3f6	no	8
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38	Non Patent Literature	Boakye_2005_1304X.pdf	3077375 9961ae695438f8cecd84f9ebdd1bc3d5b3789e34	no	6
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45	Non Patent Literature	Wagner_1979_1304X.pdf	1144158 023cd51815be312c7638277f56f5fbf3bc183ec3	no	6
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Information:					
46	Non Patent Literature	Wiseman_2005Chapter39_1304X.pdf	3141714 846f07a1e98b9292e904eae7715f21ac20b85197	no	24
Warnings:					
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47	Non Patent Literature	Expert_Declaration_1304X_Part1.pdf	25151524 b01f0feeb2d5ee125803fad416d3086d3f5842fe	no	107
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48	Non Patent Literature	Expert_Declaration_1304X_Part2.pdf	4592048 43606df1dc4f86d21eee23ecc528aff52323a836	no	20
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49	Non Patent Literature	Auguste_2006_01305.pdf	927005 2627081c22dcaa79ef9c06b38acdbb67eeba62f8	no	8
Warnings:					
Information:					
50	Non Patent Literature	Cheung_2004Chapter26_01305.pdf	1059197 ac76b4f7c023075a0f33f2c7cbc162f1d89baecd	no	8
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51	Non Patent Literature	Dickman_1997_01305.pdf	4001174 c6e00ebc87aa428e55f524617034d666662d6724	no	41
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52	Non Patent Literature	Folman_2003_01305.pdf	1048699 c3377fa9c39c9876a154ba4b7339a90cb5a175fe	no	6
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53	Non Patent Literature	Guyer_2004_01305.pdf	1918918 c3503675588badf547efe197fc0a5dd64640377d	no	12
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54	Non Patent Literature	Holte_1994_01305.pdf	2359893 467960e1ec020f637713a9c772334fe0515bf510	no	7
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55	Non Patent Literature	IPR2020-01305.pdf	4493688 04686b9f3b2186cf4a287fee1b1b83938b664226	no	83
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56	Non Patent Literature	Lane_1948_01305.pdf	4656899 34e65bbb4e2ff849081b85d1dcd870468ebb470e	no	15
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57	Non Patent Literature	Boakye_2005_01305X.pdf	3077377 633fd0a5e74e041b8cfddc0b5a153bcbaa0b7a55	no	6
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Information:					

58	Non Patent Literature	CentinelSpine_01305X.pdf	2048360 79402c2a1e02f657d8374ea4f464b1c14af918d1	no	7
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59	Non Patent Literature	Dryer_2005_01305X.pdf	4037253 e4699a631b126cd3488877e39a3a72f71ca5f11b	no	9
Warnings:					
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60	Non Patent Literature	Schimmel_2016_01305.pdf	788049 2df60c43e668fa968b0b2f2c50eddf96abcc5c8e	no	7
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		Total Files Size (in bytes):	216905202		

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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

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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 16/744,755	Filing Date 01/16/2020	☐ To be Mailed

ENTITY: ☐ LARGE ☑ SMALL ☐ MICRO

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA		RATE ($)	FEE ($)
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☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A		N/A	
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor	:	Ahmnon D. Moskowitz	Art Unit	:	Unknown
Application No.	:	16/744,755	Examiner	:	Unknown
Filed	:	January 16, 2020	Conf. No.	:	5369

Title : BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR

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

PRELIMINARY AMENDMENT

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

Amendments to the Title:

Please amend the title as follows:

EXPANDABLE SPINAL IMPLANT AND TOOL SYSTEM ~~BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR~~

Amendments to the Claims:

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

Listing of Claims:

1-20. (Cancelled)

21. (New) 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 first tool engagement indentation is intended into a first side surface of the expandable spinal implant and the second tool engagement indentation is indented into a second side surface of the expandable spinal implant, 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.

22. (New) The system of claim 21, wherein the first expandable spinal implant structure is a first single integral structure and the second expandable spinal implant structure is a second single integral structure.

23. (New) The system of claim 21, 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.

24. (New) The system of claim 21, 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.

25. (New) The system of claim 21, 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.

26. (New) The system of claim 25, 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.

27. (New) A method of using the system of claim 21, 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.

28. (New) The system of claim 21, and further comprising bone graft material configured to be placed inside and outside of the expandable spinal implant.

29. (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; 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 first tool engagement indentation is intended into a first side surface of the expandable spinal implant and the second tool engagement indentation is indented into a second side surface of the expandable spinal implant, 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.

30. (New) The system of claim 29, wherein the expandable spinal implant comprises an implant proximal end and an implant distal end, wherein the first and second tool engagement indentations are positioned at or near the implant proximal end, and wherein the screw head of the adjusting screw extends at least partially out of the implant proximal end in a proximal direction.

31. (New) The system of claim 29, 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.

32. (New) The system of claim 29, wherein the first expandable spinal implant structure defines an end gap between the first and second side surfaces at a proximal 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 some of the ridges are positioned on the first vertebral body engagement surface on a first side of the end gap and some of the ridges are positioned on the first vertebral body engagement surface on a second side of the end gap.

33. (New) The system of claim 32, wherein the end gap causes the first vertebral body

engagement surface to appear to be substantially U-shaped when viewed from an angle perpendicular to the first vertebral body engagement surface.

34. (New) The system of claim 29, wherein the first and second expandable spinal implant structures each include a through-hole sized to allow for placement of bone material into the expandable spinal implant for fusion.

35. (New) The system of claim 34, wherein the first expandable spinal implant structure includes an end gap at a longitudinal end of the first expandable spinal implant structure such that first engagement surface is open at the proximal end of the first expandable spinal implant structure.

36. (New) The system of claim 29, wherein the first expandable spinal implant structure is a first single integral structure and the second expandable spinal implant structure is a second single integral structure.

37. (New) The system of claim 29, wherein outer sides of the first and second engagement prongs are substantially straight when viewed from an angle perpendicular to the perpendicular to the first vertebral body engagement surface when the first and second engagement prongs are engaged with the first and second tool engagement indentations on the first and second side surfaces of the expandable spinal implant.

38. (New) A method of using the system of claim 29, 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.

39. (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 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 tool engagement indentations of the expandable

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

40. (New) The system of claim 39, wherein the expandable spinal implant comprises one or more substantially cylindrical side holes extending through one or more sides 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 one or more substantially cylindrical side holes 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, wherein the expandable spinal implant comprises an implant proximal end and an implant distal end, and wherein the screw head of the adjusting screw extends at least partially out of the implant proximal end in a proximal direction.

REMARKS

With this amendment, claims 1-12 and 18-20 are cancelled without prejudice and claims 21-40 are added. No new matter is added.

Applicant asks that all claims be examined in view of the amendments.

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

Respectfully submitted,

Date: 1/4/2021

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

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

62227286.doc

Electronic Acknowledgement Receipt

EFS ID:	41547422
Application Number:	16744755
International Application Number:	
Confirmation Number:	5369
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/Emily Whitcomb
Filer Authorized By:	Stuart A. Nelson
Attorney Docket Number:	46440-0009016
Receipt Date:	04-JAN-2021
Filing Date:	16-JAN-2020
Time Stamp:	16:50:32
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		PrelimAmend.PDF	113888 b3795bbc0fb79f7fdc32c683bc3f590125f7143b	yes	14

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Preliminary Amendment	1	1
	Specification	2	2
	Claims	3	13
	Applicant Arguments/Remarks Made in an Amendment	14	14
Warnings:			
Information:			
	Total Files Size (in bytes):	113888	

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	:	Unknown
Application No.	:	16/744,755	Examiner	:	Unknown
Filed	:	January 16, 2020	Conf. No.	:	5369
Title	:	EXPANDABLE SPINAL IMPLANT AND TOOL SYSTEM			

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: 2/26/2021

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62509910.doc

Substitute Disclosure Form / U.S. Department of Commerce Patent and Trademark Office	Attorney Docket No.	Application No.
Information Disclosure Statement by Applicant (Use several sheets if necessary) (37 CFR §1.98(b))	46440-0009016	16/744,755
	Applicant: Moskowitz Family LLC	
	Filing Date: January 16, 2020	Group Art Unit

U.S. Patent Documents							
Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Filing Date If Appropriate	Class	Subclass

Foreign Patent Documents or Published Foreign Patent Applications							
Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Translation	Class	Subclass

Other Documents (include Author, Title, Date, and Place of Publication)		
Examiner Initial	Desig. ID	Document
	1.	GLOBUS MEDICAL, INC., v. MOSKOWITZ FAMILY LLC, "Decision Denying Institution of Inter Partes Review 35 U.S.C. § 314", IPR2020-01303, U.S. Patent 10,307,268, Paper 7, dated January 26, 2021, 38 pages
	2.	GLOBUS MEDICAL, INC., v. MOSKOWITZ FAMILY LLC, "Decision Denying Institution of Inter Partes Review 35 U.S.C. § 314", IPR2020-01304, U.S. Patent 10,307,268, Paper 7, dated January 27, 2021, 34 pages
	3.	GLOBUS MEDICAL, INC., v. MOSKOWITZ FAMILY LLC, "Decision Denying Institution of Inter Partes Review 35 U.S.C. § 314", IPR2020-01305, U.S. Patent 10,478,319, Paper 7, dated January 8, 2021, 31 pages
	4.	GLOBUS MEDICAL, INC., v. MOSKOWITZ FAMILY LLC, "Decision Denying Institution of Inter Partes Review 35 U.S.C. § 314", IPR2020-01306, U.S. Patent 10,478,319, Paper 7, dated January 8, 2021, 34 pages
	5.	GLOBUS MEDICAL, INC., v. MOSKOWITZ FAMILY LLC, "Decision Denying Institution of Inter Partes Review 35 U.S.C. § 314", IPR2020-01307, U.S. Patent 8,353,913, Paper 7, dated December 21, 2020, 18 pages
	6.	GLOBUS MEDICAL, INC., v. MOSKOWITZ FAMILY LLC, "Decision Denying Institution of Inter Partes Review 35 U.S.C. § 314", IPR2020-01308, U.S. Patent 9,889,022, Paper 8, dated January 25, 2021, 24 pages

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:	42042087
Application Number:	16744755
International Application Number:	
Confirmation Number:	5369
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/Kirsten Neuman
Filer Authorized By:	Stuart A. Nelson
Attorney Docket Number:	46440-0009016
Receipt Date:	26-FEB-2021
Filing Date:	16-JAN-2020
Time Stamp:	18:04:36
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	Transmittal.pdf	72525 dc6ed3adbf1f6e410d560f086dd551fc5235a2be	no	1

Warnings:

Information:					
This is not an USPTO supplied IDS fillable form					
2	Information Disclosure Statement (IDS) Form (SB08)	PTO.pdf	127479 42e5524c3734859fa7b541dd477f637b17eb1938	no	1
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
3	Non Patent Literature	DecisionDenyingInstitutionOfInterPartesReview35_IPR2020013 03_Jan26_2021.pdf	10353466 cef8c7a502d1f21be9058d2d9e1f60cdbd7a729d	no	38
Warnings:					
Information:					
4	Non Patent Literature	DecisionDenyingInstitutionOfInterPartesReview35_IPR2020013 04_Jan27_2021.pdf	9625669 e7d5893508b71a0e652a4d814e4a05804f76687a	no	34
Warnings:					
Information:					
5	Non Patent Literature	DecisionDenyingInstitutionOfInterPartesReview35_IPR2020013 05_Jan8_2021.pdf	8176698 6be01ebae28405963e003de23331290bfd071a2a	no	31
Warnings:					
Information:					
6	Non Patent Literature	DecisionDenyingInstitutionOfInterPartesReview35_IPR2020013 06_Jan8_2021.pdf	9738791 d27a9c13929abe74560c054e268fa962ed4066a1	no	34
Warnings:					
Information:					
7	Non Patent Literature	DecisionDenyingInstitutionOfInterPartesReview35_IPR2020013 07_Dec21_2020.pdf	4972763 36a6dafa272b00a40514e08f403da261c188a71b	no	18
Warnings:					
Information:					
8	Non Patent Literature	DecisionDenyingInstitutionOfInterPartesReview35_IPR2020013 08_Jan25_2021.pdf	6905713 482b639cd60ce26a9500de7b0c624bda5e880a70	no	24
Warnings:					

Information:	
Total Files Size (in bytes):	49973104

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New Applications Under 35 U.S.C. 111
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National Stage of an International Application under 35 U.S.C. 371
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UNITED STATES PATENT AND TRADEMARK OFFICE

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

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/744,755	01/16/2020	Ahmnon D. Moskowitz	46440-0009016	5369

26191 7590 10/25/2021

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

EXAMINER	
PHILOGENE, PEDRO	

ART UNIT	PAPER NUMBER
3773	

NOTIFICATION DATE	DELIVERY MODE
10/25/2021	ELECTRONIC

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

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

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

PATDOCTC@fr.com

Office Action Summary	Application No. 16/744,755	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 1/4/21.

☐ 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) 21-40 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) 21-40 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 1/16/20 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.

Claim Objections

Claims 21 and 29 are objected to because of the following informalities: in claim 21, line 25 and claim 29, line 29, the word "intended" should be –indented--. Appropriate correction is required.

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 § 2146 *et seq.* 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 21-40 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-21 of U.S. Patent No. 10,478,319. Although the claims at issue are not identical, they are not patentably distinct from each other because applicant is claiming the same invention as that of the patent. Specifically claims 21-40 of the application recite the same inventive system as claimed in claims 1-21 of the patent. All the claims in both the patent and the application call for a tool assembly which comprises a first tool having … a handle and a gripper… gripper having first and second engagement prongs…the tool defines an adjusting tool passage… a second adjusting tool having … a second handle.. a screw engagement portion…the second adjusting tool can extend through the adjusting tool passage of the first tool… and expandable spinal implant comprising … first expandable implant structure and second expandable implant structure, and an adjusting screw.. the expandable is configured to expand the first and second expandable spinal implant structures in response to turning the adjusting screw… the expandable spinal implant defines first and second tool engagement indentations… on first and second side surfaces of the expandable spinal implant…the adjusting screw is positioned within the expandable spinal implant in a screw location.

The remaining specific structural limitations can either be said to have been obviously implied by equivalent language in the claims of the patent. The examiner finds that claims of the application merely recite an obvious variant of claims of the patent.

Claims 21-40 are 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 applicant is claiming the same invention as that of the patent. Specifically claims 21-40 of the application recite the same inventive system as claimed in claims 1-21 of the patent. All the claims in both the patent and the application call for a tool assembly which comprises a first tool having … a handle and a gripper… gripper having first and second engagement prongs…the tool defines an adjusting tool passage… a second adjusting tool having … a second handle.. a screw engagement portion…the second adjusting tool can extend through the adjusting tool passage of the first tool… and expandable spinal implant comprising … first expandable implant structure and second expandable implant structure, and an adjusting screw.. the expandable is configured to expand the first and second expandable spinal implant structures in response to turning the adjusting screw… the expandable spinal implant defines first and second tool engagement indentations… on first and second side surfaces of the expandable spinal implant…the adjusting screw is positioned within the expandable spinal implant in a screw location.

The remaining specific structural limitations can either be said to have been obviously implied by equivalent language in the claims of the patent. The examiner finds that claims of the application merely recite an obvious variant of claims of the patent.

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.
2006/0058876	3-2006	McKinley
5,658,335	8-1997	Allen

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 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.

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/PEDRO PHILOGENE/
Primary Examiner, Art Unit 3773
October 20, 2021

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	Examiner PEDRO PHILOGENE	Art Unit 3773	Page 1 of 1

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*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
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*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.

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	Examiner	Art Unit
	PEDRO PHILOGENE	3773

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Symbol	Date	Examiner
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A61F2220/0025,005; A61F2230/0015; A61F2250/0007		

CPC Combination Sets - Searched*		
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US Classification - Searched*			
Class	Subclass	Date	Examiner
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Search Notes		
Search Notes	Date	Examiner
EAST search enclosed	10/20/2021	/P.P./

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

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✓	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								
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	50.	Folman et al., "Posterior Lumbar Interbody Fusion for Degenerative Disc Disease Using a Minimally Invasive B-Twin Expandable Spinal Spacer," Journal of Spinal Disorders & Techniques, October 2003, 16(5):455-60, Exhibit No. 1012 in Case IPR2020-01307, U.S. Patent 8,353,913
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Substitute Disclosure Form	U.S. Department of Commerce Patent and Trademark Office	Attorney Docket No. 46440-0009016	Application No. 16/744,755
Information Disclosure Statement by Applicant (Use several sheets if necessary) (37 CFR §1.98(b))		Applicant Moskowitz Family LLC	
		Filing Date January 16, 2020	Group Art Unit

Other Documents (include Author, Title, Date, and Place of Publication)		
Examiner Initial	Desig. ID	Document
	77.	Lane et al., "Transperitoneal Approach to the Intervertebral Disc in the Lumbar Area," Annals of Surgery, March 1948, 127(3):537, Exhibit No. 1015 in Case IPR2020-01304, U.S. Patent 10,307,268
	78.	Lane et al., "Transperitoneal Approach to the Intervertebral Disc in the Lumbar Area," Annals of Surgery, March 1948, 127(3):537, Exhibit No. 1015 in Case IPR2020-01305, U.S. Patent 10,478,319
	79.	Lane et al., "Transperitoneal Approach to the Intervertebral Disc in the Lumbar Area," Annals of Surgery, March 1948, 127(3):537, Exhibit No. 1015 in Case IPR2020-01306, U.S. Patent 10,478,319
	80.	Lane et al., "Transperitoneal Approach to the Intervertebral Disc in the Lumbar Area," Annals of Surgery, March 1948, 127(3):537, Exhibit No. 1015 in Case IPR2020-01307, U.S. Patent 8,353,913
	81.	Lane et al., "Transperitoneal Approach to the Intervertebral Disc in the Lumbar Area," Annals of Surgery, March 1948, 127(3):537, Exhibit No. 1015 in Case IPR2020-01308, U.S. Patent 9,889,022
	82.	Michelson et al., "BAK/C Interbody Fusion System: A Threaded Cylindrical Cage for Cervical Fusion," Thieme Medical Publisher, Inc., New York, New York, 2005, 10 pages, Exhibit No. 1016 in Case IPR2020-01303, U.S. Patent 10,307,268
	83.	Michelson et al., "BAK/C Interbody Fusion System: A Threaded Cylindrical Cage for Cervical Fusion," Thieme Medical Publisher, Inc., New York, New York, 2005, 10 pages, Exhibit No. 1016 in Case IPR2020-01304, U.S. Patent 10,307,268
	84.	Michelson et al., "BAK/C Interbody Fusion System: A Threaded Cylindrical Cage for Cervical Fusion," Thieme Medical Publisher, Inc., New York, New York, 2005, 10 pages, Exhibit No. 1016 in Case IPR2020-01305, U.S. Patent 10,478,319
	85.	Michelson et al., "BAK/C Interbody Fusion System: A Threaded Cylindrical Cage for Cervical Fusion," Thieme Medical Publisher, Inc., New York, New York, 2005, 10 pages, Exhibit No. 1016 in Case IPR2020-01306, U.S. Patent 10,478,319
	86.	Michelson et al., "BAK/C Interbody Fusion System: A Threaded Cylindrical Cage for Cervical Fusion," Thieme Medical Publisher, Inc., New York, New York, 2005, 10 pages, Exhibit No. 1016 in Case IPR2020-01307, U.S. Patent 8,353,913
	87.	Michelson et al., "BAK/C Interbody Fusion System: A Threaded Cylindrical Cage for Cervical Fusion," Thieme Medical Publisher, Inc., New York, New York, 2005, 10 pages, Exhibit No. 1016 in Case IPR2020-01308, U.S. Patent 9,889,022
	88.	Prpa et al., "Lumbar Interbody Cages," Sug. Pro., Ch. 41, pp. 489-502, 2005, Exhibit No. 1017 in Case IPR2020-01303, U.S. Patent 10,307,268
	89.	Prpa et al., "Lumbar Interbody Cages," Sug. Pro., Ch. 41, pp. 489-502, 2005, Exhibit No. 1017 in Case IPR2020-01304, U.S. Patent 10,307,268
	90.	Prpa et al., "Lumbar Interbody Cages," Sug. Pro., Ch. 41, pp. 489-502, 2005, Exhibit No. 1017 in Case IPR2020-01305, U.S. Patent 10,478,319
	91.	Prpa et al., "Lumbar Interbody Cages," Sug. Pro., Ch. 41, pp. 489-502, 2005, Exhibit No. 1017 in Case IPR2020-01306, U.S. Patent 10,478,319
	92.	Prpa et al., "Lumbar Interbody Cages," Sug. Pro., Ch. 41, pp. 489-502, 2005, Exhibit No. 1017 in Case IPR2020-01307, U.S. Patent 8,353,913

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	93.	Prpa et al., "Lumbar Interbody Cages," Sug. Pro., Ch. 41, pp. 489-502, 2005, Exhibit No. 1017 in Case IPR2020-01308, U.S. Patent 9,889,022
	94.	Ryu and Kim, "Cervical Carbon Fiber Interbody Fusion Cage: Bengal System," Thieme Medical Publisher, Inc., New York, New York, 2005, 8 pages, Exhibit No. 1018 in Case IPR2020-01303, U.S. Patent 10,307,268
	95.	Ryu and Kim, "Cervical Carbon Fiber Interbody Fusion Cage: Bengal System," Thieme Medical Publisher, Inc., New York, New York, 2005, 8 pages, Exhibit No. 1018 in Case IPR2020-01304, U.S. Patent 10,307,268
	96.	Ryu and Kim, "Cervical Carbon Fiber Interbody Fusion Cage: Bengal System," Thieme Medical Publisher, Inc., New York, New York, 2005, 8 pages, Exhibit No. 1018 in Case IPR2020-01305, U.S. Patent 10,478,319
	97.	Ryu and Kim, "Cervical Carbon Fiber Interbody Fusion Cage: Bengal System," Thieme Medical Publisher, Inc., New York, New York, 2005, 8 pages, Exhibit No. 1018 in Case IPR2020-01306, U.S. Patent 10,478,319
	98.	Ryu and Kim, "Cervical Carbon Fiber Interbody Fusion Cage: Bengal System," Thieme Medical Publisher, Inc., New York, New York, 2005, 8 pages, Exhibit No. 1018 in Case IPR2020-01307, U.S. Patent 8,353,913
	99.	Ryu and Kim, "Cervical Carbon Fiber Interbody Fusion Cage: Bengal System," Thieme Medical Publisher, Inc., New York, New York, 2005, 8 pages, Exhibit No. 1018 in Case IPR2020-01308, U.S. Patent 9,889,022
	100.	Schimmel et al., "PEEK Cages in Lumbar Fusion," Clin. Spine Surg., 29(5):E252-E258, June 2016, Exhibit No. 1019 in Case IPR2020-01303, U.S. Patent 10,307,268
	101.	Schimmel et al., "PEEK Cages in Lumbar Fusion," Clin. Spine Surg., 29(5):E252-E258, June 2016, Exhibit No. 1019 in Case IPR2020-01304, U.S. Patent 10,307,268
	102.	Schimmel et al., "PEEK Cages in Lumbar Fusion," Clin. Spine Surg., 29(5):E252-E258, June 2016, Exhibit No. 1019 in Case IPR2020-01305, U.S. Patent 10,478,319
	103.	Schimmel et al., "PEEK Cages in Lumbar Fusion," Clin. Spine Surg., 29(5):E252-E258, June 2016, Exhibit No. 1019 in Case IPR2020-01306, U.S. Patent 10,478,319
	104.	Schimmel et al., "PEEK Cages in Lumbar Fusion," Clin. Spine Surg., 29(5):E252-E258, June 2016, Exhibit No. 1019 in Case IPR2020-01307, U.S. Patent 8,353,913
	105.	Schimmel et al., "PEEK Cages in Lumbar Fusion," Clin. Spine Surg., 29(5):E252-E258, June 2016, Exhibit No. 1019 in Case IPR2020-01308, U.S. Patent 9,889,022
	106.	Synfix, "EVOLUTION System," Online Product, DATE, 1 page, Exhibit No. 1021 in Case IPR2020-01303, U.S. Patent 10,307,268
	107.	Synfix, "EVOLUTION System," Online Product, DATE, 1 page, Exhibit No. 1021 in Case IPR2020-01304, U.S. Patent 10,307,268
	108.	Synfix, "EVOLUTION System," Online Product, DATE, 1 page, Exhibit No. 1021 in Case IPR2020-01305, U.S. Patent 10,478,319
	109.	Synfix, "EVOLUTION System," Online Product, DATE, 1 page, Exhibit No. 1021 in Case IPR2020-01306, U.S. Patent 10,478,319
	110.	Synfix, "EVOLUTION System," Online Product, DATE, 1 page, Exhibit No. 1021 in Case IPR2020-01307, U.S. Patent 8,353,913

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	111.	Synfix, "EVOLUTION System," Online Product, DATE, 1 page, Exhibit No. 1021 in Case IPR2020-01308, U.S. Patent 9,889,022
	112.	Synthes "SynFix-LR. Implant and instrumentation for stand alone anterior lumbar interbody fusion (ALIF)," 2006, 26 pages, Exhibit No. 1020 in Case IPR2020-01303, U.S. Patent 10,307,268
	113.	Synthes "SynFix-LR. Implant and instrumentation for stand alone anterior lumbar interbody fusion (ALIF)," 2006, 26 pages, Exhibit No. 1020 in Case IPR2020-01304, U.S. Patent 10,307,268
	114.	Synthes "SynFix-LR. Implant and instrumentation for stand alone anterior lumbar interbody fusion (ALIF)," 2006, 26 pages, Exhibit No. 1020 in Case IPR2020-01305, U.S. Patent 10,478,319
	115.	Synthes "SynFix-LR. Implant and instrumentation for stand alone anterior lumbar interbody fusion (ALIF)," 2006, 26 pages, Exhibit No. 1020 in Case IPR2020-01306, U.S. Patent 10,478,319
	116.	Synthes "SynFix-LR. Implant and instrumentation for stand alone anterior lumbar interbody fusion (ALIF)," 2006, 26 pages, Exhibit No. 1020 in Case IPR2020-01307, U.S. Patent 8,353,913
	117.	Synthes "SynFix-LR. Implant and instrumentation for stand alone anterior lumbar interbody fusion (ALIF)," 2006, 26 pages, Exhibit No. 1020 in Case IPR2020-01308, U.S. Patent 9,889,022
	118.	Wagner et al., "Surgical Stabilization of the Equine Cervical Spine," Veterinary Surg., 8:1-6, January-March 1979, Exhibit No. 1023 in Case IPR2020-01303, U.S. Patent 10,307,268
	119.	Wagner et al., "Surgical Stabilization of the Equine Cervical Spine," Veterinary Surg., 8:1-6, January-March 1979, Exhibit No. 1023 in Case IPR2020-01304, U.S. Patent 10,307,268
	120.	Wagner et al., "Surgical Stabilization of the Equine Cervical Spine," Veterinary Surg., 8:1-6, January-March 1979, Exhibit No. 1023 in Case IPR2020-01305, U.S. Patent 10,478,319
	121.	Wagner et al., "Surgical Stabilization of the Equine Cervical Spine," Veterinary Surg., 8:1-6, January-March 1979, Exhibit No. 1023 in Case IPR2020-01306, U.S. Patent 10,478,319
	122.	Wagner et al., "Surgical Stabilization of the Equine Cervical Spine," Veterinary Surg., 8:1-6, January-March 1979, Exhibit No. 1023 in Case IPR2020-01307, U.S. Patent 8,353,913
	123.	Wagner et al., "Surgical Stabilization of the Equine Cervical Spine," Veterinary Surg., 8:1-6, January-March 1979, Exhibit No. 1023 in Case IPR2020-01308, U.S. Patent 9,889,022
	124.	Weiner and Fraser, "Spine Update Lumbar Interbody Cages," Spine, 23(5):634-640, 1998, Exhibit No. 1024 in Case IPR2020-01303, U.S. Patent 10,307,268
	125.	Weiner and Fraser, "Spine Update Lumbar Interbody Cages," Spine, 23(5):634-640, 1998, Exhibit No. 1024 in Case IPR2020-01304, U.S. Patent 10,307,268
	126.	Weiner and Fraser, "Spine Update Lumbar Interbody Cages," Spine, 23(5):634-640, 1998, Exhibit No. 1024 in Case IPR2020-01305, U.S. Patent 10,478,319
	127.	Weiner and Fraser, "Spine Update Lumbar Interbody Cages," Spine, 23(5):634-640, 1998, Exhibit No. 1024 in Case IPR2020-01306, U.S. Patent 10,478,319
	128.	Weiner and Fraser, "Spine Update Lumbar Interbody Cages," Spine, 23(5):634-640, 1998, Exhibit No. 1024 in Case IPR2020-01307, U.S. Patent 8,353,913
	129.	Weiner and Fraser, "Spine Update Lumbar Interbody Cages," Spine, 23(5):634-640, 1998, Exhibit No. 1024 in Case IPR2020-01308, U.S. Patent 9,889,022
	130.	Wilke et al., "Primary stabilizing effect of interbody fusion devices for the cervical spine: an in vitro comparison between three different cage types and bone cement," Eur. Spine J., 2000, 9:410-416, Exhibit No. 1025 in Case IPR2020-01303, U.S. Patent 10,307,268

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(37 CFR §1.98(b))		Filing Date January 16, 2020	Group Art Unit

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	131.	Wilke et al., "Primary stabilizing effect of interbody fusion devices for the cervical spine: an in vitro comparison between three different cage types and bone cement," Eur. Spine J., 2000, 9:410-416, Exhibit No. 1025 in Case IPR2020-01304, U.S. Patent 10,307,268
	132.	Wilke et al., "Primary stabilizing effect of interbody fusion devices for the cervical spine: an in vitro comparison between three different cage types and bone cement," Eur. Spine J., 2000, 9:410-416, Exhibit No. 1025 in Case IPR2020-01305, U.S. Patent 10,478,319
	133.	Wilke et al., "Primary stabilizing effect of interbody fusion devices for the cervical spine: an in vitro comparison between three different cage types and bone cement," Eur. Spine J., 2000, 9:410-416, Exhibit No. 1025 in Case IPR2020-01306, U.S. Patent 10,478,319
	134.	Wilke et al., "Primary stabilizing effect of interbody fusion devices for the cervical spine: an in vitro comparison between three different cage types and bone cement," Eur. Spine J., 2000, 9:410-416, Exhibit No. 1025 in Case IPR2020-01307, U.S. Patent 8,353,913
	135.	Wilke et al., "Primary stabilizing effect of interbody fusion devices for the cervical spine: an in vitro comparison between three different cage types and bone cement," Eur. Spine J., 2000, 9:410-416, Exhibit No. 1025 in Case IPR2020-01308, U.S. Patent 9,889,022
	136.	Wiseman et al., "Posterior Lumbar Interbody Fusion," Surgical Procedures, Ch. 39, 24 pages, Exhibit No. 1026 in Case IPR2020-01303, U.S. Patent 10,307,268
	137.	Wiseman et al., "Posterior Lumbar Interbody Fusion," Surgical Procedures, Ch. 39, 24 pages, Exhibit No. 1026 in Case IPR2020-01304, U.S. Patent 10,307,268
	138.	Wiseman et al., "Posterior Lumbar Interbody Fusion," Surgical Procedures, Ch. 39, 24 pages, Exhibit No. 1026 in Case IPR2020-01305, U.S. Patent 10,478,319
	139.	Wiseman et al., "Posterior Lumbar Interbody Fusion," Surgical Procedures, Ch. 39, 24 pages, Exhibit No. 1026 in Case IPR2020-01306, U.S. Patent 10,478,319
	140.	Wiseman et al., "Posterior Lumbar Interbody Fusion," Surgical Procedures, Ch. 39, 24 pages, Exhibit No. 1026 in Case IPR2020-01307, U.S. Patent 8,353,913
	141.	Wiseman et al., "Posterior Lumbar Interbody Fusion," Surgical Procedures, Ch. 39, 24 pages, Exhibit No. 1026 in Case IPR2020-01308, U.S. Patent 9,889,022

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		Filing Date January 16, 2020	Group Art Unit Unknown

U.S. Patent Documents

Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Filing Date If Appropriate	Class	Subclass
	1.	5236460	8/17/1993	Barber			
	2.	5390683	2/21/1995	Pisharodi			
	3.	5425490	6/20/1995	Goble et al.			
	4.	5522899	6/4/1996	Michelson			
	5.	5658335	8/19/1997	Allen			
	6.	5800550	9/1/1998	Sertich			
	7.	6066175	5/23/2000	Henderson et al.			
	8.	6102950	8/15/2000	Vaccaro			
	9.	6120503	9/19/2000	Michelson			
	10.	6176882	1/23/2001	Biedermann et al.			
	11.	6179873	1/30/2011	Zientek			
	12.	6336928	1/8/2002	Guerin et al.			
	13.	6443989	9/3/2002	Jackson			
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	15.	6730127	5/4/2004	Michelson			
	16.	6752832	6/22/2004	Neumann			
	17.	6773437	8/10/2004	Ogilvie			
	18.	6849093	2/1/2005	Michelson			
	19.	6905512	6/14/2005	Paes et al.			
	20.	7172627	2/6/2007	Fiere et al.			
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	22.	7763078	7/27/2010	Peterman et al.			
	23.	7828849	11/9/2010	Lim			
	24.	8172854	5/8/2012	Blain et al.			
	25.	8388686	3/5/2013	Aebi et al.			
	26.	8696681	4/15/2014	Harris et al.			
	27.	20020161443	10/31/2002	Michelson			

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	28.	20030149438	8/7/2003	Nichols et al.			
	29.	20060022180	2/2/2006	Selness			
	30.	20060129244	6/15/2006	Ensign			
	31.	20060253201	11/9/2006	McLuen			
	32.	20080045968	2/21/2008	Yu et al.			
	33.	20180344477	12/6/2018	Lechmann et al.			
	34.	60/869,088		Olmos et al.	12/7/2006		

Foreign Patent Documents or Published Foreign Patent Applications

Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Translation	Class	Subclass
	35.	KR 20-0290058	9/26/2002	KR	Machine Translation		
	36.	WO 1999038463	8/5/1999	WO			

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor	:	Ahmnon D. Moskowitz	Art Unit	:	Unknown
Application No.	:	16/744,755	Examiner	:	Unknown
Filed	:	January 16, 2020	Conf. No.	:	5369
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: 5/21/2020

/Stuart A. Nelson/
Stuart A. Nelson
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	1.	GLOBUS MEDICAL, INC., v. MOSKOWITZ FAMILY LLC, "Decision Denying Institution of Inter Partes Review 35 U.S.C. § 314", IPR2020-01303, U.S. Patent 10,307,268, Paper 7, dated January 26, 2021, 38 pages
	2.	GLOBUS MEDICAL, INC., v. MOSKOWITZ FAMILY LLC, "Decision Denying Institution of Inter Partes Review 35 U.S.C. § 314", IPR2020-01304, U.S. Patent 10,307,268, Paper 7, dated January 27, 2021, 34 pages
	3.	GLOBUS MEDICAL, INC., v. MOSKOWITZ FAMILY LLC, "Decision Denying Institution of Inter Partes Review 35 U.S.C. § 314", IPR2020-01305, U.S. Patent 10,478,319, Paper 7, dated January 8, 2021, 31 pages
	4.	GLOBUS MEDICAL, INC., v. MOSKOWITZ FAMILY LLC, "Decision Denying Institution of Inter Partes Review 35 U.S.C. § 314", IPR2020-01306, U.S. Patent 10,478,319, Paper 7, dated January 8, 2021, 34 pages
	5.	GLOBUS MEDICAL, INC., v. MOSKOWITZ FAMILY LLC, "Decision Denying Institution of Inter Partes Review 35 U.S.C. § 314", IPR2020-01307, U.S. Patent 8,353,913, Paper 7, dated December 21, 2020, 18 pages
	6.	GLOBUS MEDICAL, INC., v. MOSKOWITZ FAMILY LLC, "Decision Denying Institution of Inter Partes Review 35 U.S.C. § 314", IPR2020-01308, U.S. Patent 9,889,022, Paper 8, dated January 25, 2021, 24 pages

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	1.	5192327	3/9/1993	Brantigan			
	2.	7001385	2/21/2006	Bonutti			
	3.	9889022	2/13/2018	Moskowitz et al.			
	4.	10307268	6/4/2019	Moskowitz et al.			
	5.	10478319	11/19/2019	Moskowitz et al.			
	6.	20020143399	10/3/2002	Sutcliffe			
	7.	20040204717	10/14/2004	Fanger et al.			
	8.	20050177236	8/11/2005	Mathieu et al.			
	9.	20070270968	11/22/2007	Baynham			

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	10.	Auguste et al., "Expandable cylindrical cages in the cervical spine: a review of 22 cases," J. Neurosurg. Spine, 4:285–291, 2006, Exhibit No. 1006 in Case IPR2020-01303, U.S. Patent 10,307,268
	11.	Auguste et al., "Expandable cylindrical cages in the cervical spine: a review of 22 cases," J. Neurosurg. Spine, 4:285–291, 2006, Exhibit No. 1006 in Case IPR2020-01304, U.S. Patent 10,307,268
	12.	Auguste et al., "Expandable cylindrical cages in the cervical spine: a review of 22 cases," J. Neurosurg. Spine, 4:285–291, 2006, Exhibit No. 1006 in Case IPR2020-01305, U.S. Patent 10,478,319
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	20.	Boakye et al., "The Poly-ether-ether-ketone (PEEK) Spacer," Thieme Medical Publishers, Inc., 333 Seventh Ave., New York, NY 10001, 6 pages, Exhibit No. 1007 in Case IPR2020-01307, U.S. Patent 8,353,913
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	34.	Dickman, "Internal Fixation and Fusion of the Lumbar Spine Using Threaded Interbody Cages," [https://www.barrowneuro.org/education/grand-rounds-publications-and-media/barrow-quarterly/, Retrieved on 6/20/2020], 41 pages, Exhibit No. 1010 in Case IPR2020-01303, U.S. Patent 10,307,268
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	50.	Folman et al., "Posterior Lumbar Interbody Fusion for Degenerative Disc Disease Using a Minimally Invasive B-Twin Expandable Spinal Spacer," Journal of Spinal Disorders & Techniques, October 2003, 16(5):455-60, Exhibit No. 1012 in Case IPR2020-01307, U.S. Patent 8,353,913
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	52.	GLOBUS MEDICAL, INC., Petitioner v. MOSKOWITZ FAMILY LLC, Patent Owner PETITION FOR INTER PARTES REVIEW OF U.S. PATENT NO. 10,307,268 PURSUANT TO 35 U.S.C. §§ 311–319 AND 37 C.F.R. § 42, dated July 21, 2020, 75 pages
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	54.	GLOBUS MEDICAL, INC., Petitioner v. MOSKOWITZ FAMILY LLC, Patent Owner PETITION FOR INTER PARTES REVIEW OF U.S. PATENT NO. 10,478,319 PURSUANT TO 35 U.S.C. §§ 311–319 AND 37 C.F.R. § 42, dated July 21, 2020, 78 pages
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	63.	GLOBUS MEDICAL, INC., v. MOSKOWITZ FAMILY LLC, "DECLARATION OF JORGE A. OCHOA, PH.D., P.E.," Case IPR2020-01308, U.S. Patent 9,889,022, dated July 21, 2020, 65 pages (Exhibit No. 1003)
	64.	Guyer and Ohnmeiss, "Degenerative Disc Disease: Fusion Cages and Dowels," Lippincott Williams & Wilkins, Philadelphia, PA, 2004, Ch. 35, 12 pages, Exhibit No. 1013 in Case IPR2020-01303, U.S. Patent 10,307,268
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	101.	Schimmel et al., "PEEK Cages in Lumbar Fusion," Clin. Spine Surg., 29(5):E252-E258, June 2016, Exhibit No. 1019 in Case IPR2020-01304, U.S. Patent 10,307,268
	102.	Schimmel et al., "PEEK Cages in Lumbar Fusion," Clin. Spine Surg., 29(5):E252-E258, June 2016, Exhibit No. 1019 in Case IPR2020-01305, U.S. Patent 10,478,319
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	105.	Schimmel et al., "PEEK Cages in Lumbar Fusion," Clin. Spine Surg., 29(5):E252-E258, June 2016, Exhibit No. 1019 in Case IPR2020-01308, U.S. Patent 9,889,022
	106.	Synfix, "EVOLUTION System," Online Product, DATE, 1 page, Exhibit No. 1021 in Case IPR2020-01303, U.S. Patent 10,307,268
	107.	Synfix, "EVOLUTION System," Online Product, DATE, 1 page, Exhibit No. 1021 in Case IPR2020-01304, U.S. Patent 10,307,268
	108.	Synfix, "EVOLUTION System," Online Product, DATE, 1 page, Exhibit No. 1021 in Case IPR2020-01305, U.S. Patent 10,478,319
	109.	Synfix, "EVOLUTION System," Online Product, DATE, 1 page, Exhibit No. 1021 in Case IPR2020-01306, U.S. Patent 10,478,319
	110.	Synfix, "EVOLUTION System," Online Product, DATE, 1 page, Exhibit No. 1021 in Case IPR2020-01307, U.S. Patent 8,353,913

Examiner Signature	Date Considered
/PEDRO PHILOGENE/	10/20/2021

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

Substitute Disclosure Form

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

Substitute Disclosure Form	U.S. Department of Commerce Patent and Trademark Office	Attorney Docket No. 46440-0009016	Application No. 16/744,755
Information Disclosure Statement by Applicant (Use several sheets if necessary) (37 CFR §1.98(b))		Applicant Moskowitz Family LLC	
		Filing Date January 16, 2020	Group Art Unit

Other Documents (include Author, Title, Date, and Place of Publication)		
Examiner Initial	Desig. ID	Document
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	112.	Synthes "SynFix-LR. Implant and instrumentation for stand alone anterior lumbar interbody fusion (ALIF)," 2006, 26 pages, Exhibit No. 1020 in Case IPR2020-01303, U.S. Patent 10,307,268
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	118.	Wagner et al., "Surgical Stabilization of the Equine Cervical Spine," Veterinary Surg., 8:1-6, January-March 1979, Exhibit No. 1023 in Case IPR2020-01303, U.S. Patent 10,307,268
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	130.	Wilke et al., "Primary stabilizing effect of interbody fusion devices for the cervical spine: an in vitro comparison between three different cage types and bone cement," Eur. Spine J., 2000, 9:410-416, Exhibit No. 1025 in Case IPR2020-01303, U.S. Patent 10,307,268

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/PEDRO PHILOGENE/	10/20/2021

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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 January 16, 2020	Group Art Unit

Other Documents (include Author, Title, Date, and Place of Publication)		
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	131.	Wilke et al., "Primary stabilizing effect of interbody fusion devices for the cervical spine: an in vitro comparison between three different cage types and bone cement," Eur. Spine J., 2000, 9:410-416, Exhibit No. 1025 in Case IPR2020-01304, U.S. Patent 10,307,268
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	136.	Wiseman et al., "Posterior Lumbar Interbody Fusion," Surgical Procedures, Ch. 39, 24 pages, Exhibit No. 1026 in Case IPR2020-01303, U.S. Patent 10,307,268
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Bibliographic Data

Application No: 16/744,755

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.
01/16/2020	623	3773	46440-0009016
RULE			

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Nathan C. Moskowitz, Rockville, MD, UNITED STATES

CONTINUING DATA

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(*) Data provided by applicant is not consistent with PTO record

FOREIGN APPLICATIONS

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Circled Ref#'s reviewed

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
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			EPO; JPO; DERWENT; IBM_TDB			
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Substitute Disclosure Form	U.S. Department of Commerce Patent and Trademark Office	Attorney Docket No. 46440-0009016	Application No. 16/744,755
Information Disclosure Statement by Applicant (Use several sheets if necessary)		Applicant Moskowitz Family LLC	
(37 CFR §1.98(b))		Filing Date January 16, 2020	Group Art Unit

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Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Filing Date If Appropriate	Class	Subclass
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Examiner Signature	Date Considered
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		Filing Date January 16, 2020	Group Art Unit

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Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Filing Date If Appropriate	Class	Subclass
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	29.	5951574	9/14/1999	Stefanchik et al.			
	30.	5960522	10/5/1999	Boe			
	31.	5968054	10/19/1999	Yeatts et al.			
	32.	5976136	11/2/1999	Bailey et al.			
	33.	6126689	10/3/2000	Brett			
	34.	6224602	5/1/2001	Hayes			
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	38.	6342074	1/29/2002	Simpson			
	39.	6368350	4/9/2002	Erickson et al.			
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	42.	6432106	8/13/2002	Fraser			
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	44.	6458159	10/1/2002	Thalgott			
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	46.	6533818	3/18/2003	Weber et al.			
	47.	6558423	5/6/2003	Michelson			
	48.	6562074	5/13/2003	Gerbec et al.			
	49.	6572653	6/3/2003	Simonson			
	50.	6579318	6/17/2003	Varga et al.			
	51.	6582468	6/24/2003	Gauchet			
	52.	6613055	9/2/2003	Di Emidio			
	53.	6629998	10/7/2003	Lin			
	54.	6641614	11/4/2003	Wagner et al.			

Examiner Signature	Date Considered
/PEDRO PHILOGENE/	10/20/2021

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

Substitute Disclosure Form

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

Substitute Disclosure Form	U.S. Department of Commerce Patent and Trademark Office	Attorney Docket No. 46440-0009016	Application No. 16/744,755
Information Disclosure Statement by Applicant (Use several sheets if necessary) (37 CFR §1.98(b))		Applicant Moskowitz Family LLC	
		Filing Date January 16, 2020	Group Art Unit

U.S. Patent Documents

Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Filing Date If Appropriate	Class	Subclass
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	56.	6655243	12/2/2003	Anderson et al.			
	57.	6706070	3/16/2004	Wagner et al.			
	58.	6716247	4/6/2004	Michelson			
	59.	6719794	4/13/2004	Gerber			
	60.	6723126	4/20/2004	Berry			
	61.	6733532	5/11/2004	Gauchet et al.			
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	63.	6746450	6/8/2004	Wall			
	64.	6764491	7/20/2004	Frey et al.			
	65.	6770094	8/3/2004	Fehling et al.			
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	68.	6890355	5/10/2005	Michelson			
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	70.	6953477	10/11/2005	Berry			
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	73.	6972019	12/6/2005	Michelson			
	74.	6974480	12/13/2005	Messerli et al.			
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	81.	7211112	5/1/2007	Baynham et al.			

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(37 CFR §1.98(b))		Filing Date January 16, 2020	Group Art Unit

U.S. Patent Documents

Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Filing Date If Appropriate	Class	Subclass
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	86.	7442299	10/28/2008	Lee et al.			
	87.	7588573	9/15/2009	Berry			
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		Filing Date January 16, 2020	Group Art Unit

U.S. Patent Documents

Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Filing Date If Appropriate	Class	Subclass
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	116.	8403986	3/26/2013	Michelson			
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	133.	20030130737	7/10/2003	McGahan et al.			
	134.	20040015315	1/22/2004	Kreider			

Examiner Signature	Date Considered
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		Filing Date January 16, 2020	Group Art Unit

U.S. Patent Documents

Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Filing Date If Appropriate	Class	Subclass
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	137.	20040177531	9/16/2004	DiBenedetto et al.			
	138.	20040186482	9/23/2004	Kolb et al.			
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	147.	20050256576	11/17/2005	Moskowitz et al.			
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	149.	20050273170	12/8/2005	Navarro et al.			
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		Filing Date January 16, 2020	Group Art Unit

U.S. Patent Documents

Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Filing Date If Appropriate	Class	Subclass
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	171.	20090030520	1/29/2009	Biedermann et al.			
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	182.	20100145460	6/10/2010	McDonough et al.			
	183.	20100305704	12/2/2010	Messerli et al.			
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Examiner Signature	Date Considered
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		Filing Date January 16, 2020	Group Art Unit

U.S. Patent Documents

Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Filing Date If Appropriate	Class	Subclass
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	193.	20110307011	12/15/2011	Moskowitz et al.			
	194.	20110319935	12/29/2011	Moskowitz et al.			
	195.	20120010714	1/12/2012	Moskowitz et al.			
	196.	20120271423	10/25/2012	Wallenstein et al.			
	197.	20120277870	11/1/2012	Wolters et al.			
	198.	20120323330	12/20/2012	Kueenzi et al.			
	199.	20120330419	12/27/2012	Moskowitz et al.			
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	205.	20130053962	2/28/2013	Moskowitz et al.			
	206.	20130060339	3/7/2013	Duffield et al.			
	207.	20130073044	3/21/2013	Gamache			
	208.	20130173002	7/4/2013	Moskowitz et al.			
	209.	20130211526	8/15/2013	Alheidt et al			
	210.	20130282017	10/24/2013	Moskowitz et al.			
	211.	20140249629	9/4/2014	Moskowitz et al.			
	212.	20150025637	1/22/2015	Moskowitz et al.			
	213.	20150105824	4/16/2015	Moskowitz et al.			
	214.	20150148847	5/28/2015	Moskowitz et al.			
	215.	20160374830	12/29/2016	Moskowitz et al.			

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		Filing Date January 16, 2020	Group Art Unit

U.S. Patent Documents

Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Filing Date If Appropriate	Class	Subclass
	216.	20170252178	9/7/2017	Moskowitz et al.			
	217.	20180311052	11/1/2018	Moskowitz			

Foreign Patent Documents or Published Foreign Patent Applications

Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Translation	Class	Subclass
	218.	2727003	5/24/1996	FR			
	219.	2004093749	11/4/2004	WO			
	220.	2006091503	8/31/2006	WO			

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

Examiner Initial	Desig. ID	Document
	221.	DIETER GROB et al., "Clinical Experience With the Dynesys Semirigid Fixation System for the Lumbar Spine," SPINE, Vol. 30, No. 3, 2005, pp. 324-331
	222.	E.K. WAI et al., "Disk Replacement Arthroplasties: Can The Success of Hip and Knee Replacements be Repeated in the Spine?," Seminars in Spine Surgery, Vol. 15, No. 4 (December) 2003, pp 473-482.
	223.	International Search Report (ISR) and Written Opinion of the International Searching Authority, 03 December 2007, International Application No. PCT/US 07/05005
	224.	International Search Report (ISR) and Written Opinion of the International Searching Authority, 09 July 2008, International Application No. PCT/US2007021013
	225.	International Search Report (ISR) and Written Opinion of the International Searching Authority, 21 May 2008, International Application No. PCT/US2007/021015
	226.	Richard D. GUYER et al., "lntervertebral Disc Prostheses," SPINE JOURNAL, Volume 28, Number 15S, Supp. To 8/1/03, pages S15-S23
	227.	Vincent C. TRAYNELIS, "Prosthetics and Biologics: The Wave of the Future," CLINICAL NEUROSURGERY, Volume 50, Proceedings of the Congress of Neurological Surgeons, Philadelphia, PA 2002, Chapter 9, pages 207-219

Examiner Signature	Date Considered
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor	:	Ahmnon D. Moskowitz	Art Unit	:	Unknown
Application No.	:	16/744,755	Examiner	:	Unknown
Filed	:	January 16, 2020	Conf. No.	:	5369
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).

Under 35 U.S.C. § 120, this application relies on the earlier filing date of application number 15/944,117, filed on April 3, 2018. The documents corresponding to Desig. ID Nos. 3, 14, 21, 37, 55, 63, 136, 153, 157, 181, and 217 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 within three months of the filing date of the application or before the receipt of a first action on the merits.

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

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: 1/24/2020

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

Customer Number 26191
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62231778.doc

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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	16744755
Filing Date	16-Jan-2020
First Named Inventor	Ahmnon Moskowitz
Attorney Docket Number	46440-0009016
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)

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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 75476 ( ) 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	/Kiersten M. Batzli/
Name	Kiersten M. Batzli

*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:	16744755
Filing Date:	16-Jan-2020
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:	Kiersten M. Batzli/Emily Whitcomb
Attorney Docket Number:	46440-0009016
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	170	170
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**170**

Doc Code: DISQ.E.FILE
Document Description: Electronic Terminal Disclaimer – Approved

Application No.: 16744755

Filing Date: 16-Jan-2020

Applicant/Patent under Reexamination: Moskowitz

Electronic Terminal Disclaimer filed on January 20, 2022

☒ 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:	44787749
Application Number:	16744755
International Application Number:	
Confirmation Number:	5369
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:	Kiersten M. Batzli/Emily Whitcomb
Filer Authorized By:	Kiersten M. Batzli
Attorney Docket Number:	46440-0009016
Receipt Date:	20-JAN-2022
Filing Date:	16-JAN-2020
Time Stamp:	10:58:34
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	$170
RAM confirmation Number	E20221JA58290968
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	41485 c7e0b07b6c179df70d713ddcc81911135a5a959d	no	2
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	38377 93f953d0749816a57748345b0c0e50ab236e8111	no	2
Warnings:					
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor	:	Ahmnon D. Moskowitz	Art Unit	:	3773
Application No.	:	16/744,755	Examiner	:	Pedro Philogene
Filed	:	January 16, 2020	Conf. No.	:	5369
Title	:	EXPANDABLE SPINAL IMPLANT AND TOOL SYSTEM			

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

REPLY TO ACTION OF OCTOBER 25, 2021

Please consider the following reply.

Amendments to Claims:

Listing of Claims.

1-20. (Cancelled)

21. (Currently Amended) 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 holder portion ~~gripper~~, the ~~gripper~~ holder portion being positioned at the first distal end[[,]] opposite of ~~cooperating with~~ the first handle which is positioned at the first proximal end, and the holder portion 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 portions each defining a space that is ~~indentations~~ sized, shaped, and configured for receiving the first and second engagement prongs of the first tool, wherein the first tool engagement portion ~~indentation~~ is formed at a proximal end of ~~intended into~~ a first side surface of the expandable spinal implant and the second tool engagement portion ~~indentation~~ is formed at a proximal end of ~~indented into~~ a second side surface of the expandable spinal implant, 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 portions ~~indentations~~ of the expandable spinal implant

22. (Previously Presented) The system of claim 21, wherein the first expandable spinal implant structure is a first single integral structure and the second expandable spinal implant structure is a second single integral structure.

23. (Previously Presented) The system of claim 21, 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.

24. (Previously Presented) The system of claim 21, 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.

25. (Currently Amended) The system of claim 21, 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;

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 portions so as to guide the first and second anchors through the third and fourth anchor guides into the first and second anchor guides.

26. (Cancelled).

27. (Currently Amended) A method of using the system of claim 21, 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 portions ~~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.

28. (Previously Presented) The system of claim 21, and further comprising bone graft material configured to be placed inside and outside of the expandable spinal implant.

29. (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 vertebral body engagement surface sized and configured to engage a first vertebral

body, a second expandable spinal implant structure defining a second vertebral body 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 portions ~~indentations~~ sized, shaped, and configured for receiving the first and second engagement prongs of the first tool, wherein the first tool engagement portion ~~indentation~~ is formed in ~~intended into~~ a first side surface of the expandable spinal implant and the second tool engagement portion ~~indentation~~ is formed in ~~indented into~~ a second side surface of the expandable spinal implant, 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 portions ~~indentations~~ of the expandable spinal implant.

30. (Currently Amended) The system of claim 29, wherein the expandable spinal implant comprises an implant proximal end and an implant distal end, wherein the first and second tool engagement portions ~~indentations~~ are formed as recessed surfaces and positioned at or near the implant proximal end, and wherein the screw head of the adjusting screw is accessible at the implant proximal end from ~~extends at least partially out of the implant proximal end in~~ a proximal direction.

31. (Previously Presented) The system of claim 29, 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.

32. (Currently Amended) The system of claim 29, wherein ~~the first expandable spinal implant structure defines an end gap between the first and second side surfaces at a proximal 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 some of the ridges are positioned on the first vertebral body engagement surface at a distal end of the first vertebral body engagement surface ~~on a first side of the end gap and some of the ridges are positioned on the first vertebral body engagement surface on a second side of the end gap~~.

33. (Currently Amended) The system of claim [[32]] 29, wherein the first expandable spinal implant structure defines an end gap between the first and second side surfaces at a proximal end of the first vertebral body engagement surface and of the first expandable spinal implant structure such that first vertebral body engagement surface is open at a proximal end of the first expandable spinal implant structure, wherein the first vertebral body engagement surface comprises a plurality of ridges extending from the first vertebral body engagement surface, wherein some of the ridges are positioned on the first vertebral body engagement surface on

a first side of the end gap and some of the ridges are positioned on the first vertebral body engagement surface on a second side of the end gap; and wherein the end gap causes the first vertebral body engagement surface to appear to be substantially U-shaped when viewed from an angle perpendicular to the first vertebral body engagement surface.

34. (Previously Presented) The system of claim 29, wherein the first and second expandable spinal implant structures each include a through-hole sized to allow for placement of bone material into the expandable spinal implant for fusion.

35. (Cancelled).

36. (Previously Presented) The system of claim 29, wherein the first expandable spinal implant structure is a first single integral structure and the second expandable spinal implant structure is a second single integral structure.

37. (Currently Amended) The system of claim 29, wherein outer sides of the first and second engagement prongs are substantially straight when viewed from an angle perpendicular to ~~the perpendicular to~~ the first vertebral body engagement surface when the first and second engagement prongs are engaged with the first and second tool engagement portions ~~indentations~~ on the first and second side surfaces of the expandable spinal implant.

38. (Currently Amended) A method of using the system of claim 29, 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 portions ~~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.

39. (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~~ extensions 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~~ tool engagement feature ~~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 portions ~~indentations~~ sized, shaped, 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~~ tool engagement feature ~~portion~~ of the adjusting screw while one or more engagement ~~prongs~~ extensions of the first tool are engaged with the one or more tool engagement portions ~~indentations~~ of the expandable spinal implant, wherein at least one of the one or more tool engagement portions ~~indentations~~ of the expandable spinal implant is indented into one or more side surfaces of the expandable spinal implant such that the one or more engagement ~~prongs~~ extensions of the gripper is positioned in the one or more tool engagement portions ~~indentations~~ on the one or more side surfaces of the expandable spinal implant when the first tool is engaged with the expandable spinal implant.

40. (Currently Amended) The system of claim 39, wherein the expandable spinal implant comprises one or more substantially cylindrical side holes extending through one or more sides 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 one or more substantially cylindrical side holes 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, wherein the expandable spinal implant comprises an implant proximal end and an implant distal end, and wherein the ~~screw~~ tool engagement feature ~~head~~ of the adjusting screw extends at least partially out of the implant proximal end in a proximal direction.

41. (New) The system of claim 39, the expandable spinal implant further comprising:

an implant proximal end and an implant distal end, the first and second tool engagement portions positioned at or near the implant proximal end, and the tool engaging portion of the adjusting screw is accessible at the implant proximal end from a proximal direction, such that the second engaging tool screw engagement portion engages with the tool engaging portion of the adjusting screw at the implant proximal end;

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 at or near the implant distal end, said ridges configured to contact the first vertebral body;

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; and

first and second openings extending through the first and second vertebral body engagement surfaces to a cavity within the expandable spinal implant, the cavity sized to receive bone material;

wherein the first expandable spinal implant structure is a first single integral structure and the second expandable spinal implant structure is a second single integral structure; and

wherein outer sides of the first and second engagement extensions are substantially straight when viewed from an angle perpendicular to the first vertebral body engagement surface when the first and second engagement extensions are engaged with the first and second tool engagement portions on the first and second side surfaces of the expandable spinal implant, and the second adjusting tool is engaged with the tool engagement feature of the adjusting screw.

42. (New) The system of claim 21, the expandable spinal implant further comprising:

an implant proximal end and an implant distal end, the first and second tool engagement portions positioned at or near the implant proximal end, and the screw head of the adjusting screw is accessible at the implant proximal end from a proximal direction;

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 at or near the implant distal end;

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; and

first and second openings extending through the first and second vertebral body engagement surfaces to a cavity within the expandable spinal implant, the cavity sized to receive bone material; and

wherein outer sides of the first and second engagement prongs are substantially straight when viewed from an angle perpendicular to the first vertebral body engagement surface when the first and second engagement prongs are engaged with the first and second tool engagement portions on the first and second side surfaces of the expandable spinal implant, and the second adjusting tool is engaged with the screw head of the adjusting screw.

REMARKS

Claims 21-25, 27-34, and 36-42 are pending, with claims 21, 29, and 39 being independent. Claims 21, 25, 27, 29, 30, 32, 33, and 37-40 have been amended, and new claims 41 and 42 are added. Claims 26 and 35 are cancelled without prejudice or disclaimer. The amendments are supported throughout the specification and no new matter is added.

Claim Objections

Claims 21 and 29 are objected to for containing informalities. Applicant believes that the amendments to claims 21 and 29 render the objection moot. Applicant requests withdrawal of the rejections in view of the amendments to claims 21 and 29.

Double Patenting

Claims 21-40 were rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-21 of U.S. Patent No. 10,478,319. Claims 21-40 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 the rejection. In view of the terminal disclaimer, the Applicant respectfully requests that this rejection be withdrawn.

New Claims

New claims 41 and 42 depend from independent claims 39 and 21, respectively, and are patentable over the prior art of record for at least the same reasons as claims 39 and 21. New claims 41 and 42 also recite novel and inventive features and are patentable over the prior art for this additional reason.

CONCLUSION

In view of the foregoing, Applicant believes that the application is in condition for allowance, and respectfully requests prompt consideration and a Notice of Allowance. In the even that no Notice of Allowance will be provided in the next communication, Applicant requests that the Examiner telephone the undersigned attorney (617-766-2015) 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.

Applicant believes no fees other than those indicated on the Fee Transmittal are due with this amendment. Apply those fees and any other necessary charges or credits to Deposit Account 06-1050, referencing the above attorney docket number.

Respectfully submitted,

Date: January 20, 2022

/Kiersten M. Batzli/
Kiersten M. Batzli, Reg. No. 75,476

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Electronic Acknowledgement Receipt	
EFS ID:	44787935
Application Number:	16744755
International Application Number:	
Confirmation Number:	5369
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:	Kiersten M. Batzli/Emily Whitcomb
Filer Authorized By:	Kiersten M. Batzli
Attorney Docket Number:	46440-0009016
Receipt Date:	20-JAN-2022
Filing Date:	16-JAN-2020
Time Stamp:	11:10:09
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		ReplytoOA.PDF	149839 2178255569943 0abb3d667ead198a759be1530ed	yes	17

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Amendment/Req. Reconsideration-After Non-Final Reject	1	1
	Claims	2	14
	Applicant Arguments/Remarks Made in an Amendment	15	17
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<u>National Stage of an International Application under 35 U.S.C. 371</u>
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<u>New International Application Filed with the USPTO as a Receiving Office</u>
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EXAMINER
HAMMOND, ELLEN CHRISTINA

ART UNIT	PAPER NUMBER
3773	

DATE MAILED: 04/05/2022

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/744,755	01/16/2020	Ahmnon D. Moskowitz	46440-0009016	5369

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	$600	$0.00	$0.00	$600	07/05/2022

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. 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 04/05/2022
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.
16/744,755	01/16/2020	Ahmnon D. Moskowitz	46440-0009016	5369

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	$600	$0.00	$0.00	$600	07/05/2022

EXAMINER	ART UNIT	CLASS-SUBCLASS
HAMMOND, ELLEN CHRISTINA	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/AIA/122 or PTO/SB/122) attached.

❑ "Fee Address" indication (or "Fee Address" Indication form PTO/AIA/47 or PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

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

1 _____
2 _____
3 _____

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

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

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

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

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

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

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

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

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

❑ Applicant certifying micro entity status. See 37 CFR 1.29

❑ Applicant asserting small entity status. See 37 CFR 1.27

❑ Applicant changing to regular undiscounted fee status.

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

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

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

UNITED STATES PATENT AND TRADEMARK OFFICE

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

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/744,755	01/16/2020	Ahmnon D. Moskowitz	46440-0009016	5369

26191 7590 04/05/2022

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

EXAMINER	
HAMMOND, ELLEN CHRISTINA	
ART UNIT	PAPER NUMBER
3773	

DATE MAILED: 04/05/2022

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. 16/744,755	Applicant(s) Moskowitz et al.	
	Examiner ELLEN C HAMMOND	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 the amendment filed 1/20/2022.
   ☐ 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 See Continuation Sheet . 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 _____.

/ELLEN C HAMMOND/
Primary Examiner, Art Unit 3773

Continuation of 3. The allowed claim(s) is/are: 21-25,27-34 and 36-42

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/744,755	Moskowitz et al.
	Examiner	Art Unit
	ELLEN C HAMMOND	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	10/20/2021	03/18/2022							
	1	-	-							
	2	-	-							
	3	-	-							
	4	-	-							
	5	-	-							
	6	-	-							
	7	-	-							
	8	-	-							
	9	-	-							
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	15	-	-							
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	17	-	-							
	18	-	-							
	19	-	-							
	20	-	-							
1	21	✓	=							
2	22	✓	=							
3	23	✓	=							
4	24	✓	=							
5	25	✓	=							
	26	✓	-							
6	27	✓	=							
7	28	✓	=							
9	29	✓	=							
10	30	✓	=							
11	31	✓	=							
12	32	✓	=							
13	33	✓	=							
14	34	✓	=							
	35	✓	-							
15	36	✓	=							
16	37	✓	=							
17	38	✓	=							
18	39	✓	=							
19	40	✓	=							
20	41		=							
8	42		=							

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/744,755	Moskowitz et al.
	Examiner	**Art Unit**
	ELLEN C HAMMOND	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	/	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
A61F	/	2220	/	005		A	2013-01-01

NONE		**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	20	
/ELLEN C HAMMOND/ Primary Examiner, Art Unit 3773	18 March 2022	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	5C

U.S. Patent and Trademark Office — Part of Paper No.: 20220318

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/744,755	Moskowitz et al.
	Examiner	**Art Unit**
	ELLEN C HAMMOND	3773

CPC						
Symbol					**Type**	**Version**
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	/	30593	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		**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	20	
/ELLEN C HAMMOND/ Primary Examiner, Art Unit 3773	18 March 2022	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	5C

U.S. Patent and Trademark Office — Part of Paper No.: 20220318

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/744,755	Moskowitz et al.
	Examiner	**Art Unit**
	ELLEN C HAMMOND	3773

INTERNATIONAL CLASSIFICATION				
CLAIMED				
A61F2/46	/	2	/	46
A61F2/44	/	2	/	44

NON-CLAIMED				
	/		/	

US ORIGINAL CLASSIFICATION	
CLASS	**SUBCLASS**

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

NONE		**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	20	
/ELLEN C HAMMOND/ Primary Examiner, Art Unit 3773	18 March 2022	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	5C

U.S. Patent and Trademark Office — Part of Paper No.: 20220318

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/744,755	Moskowitz et al.
	Examiner	**Art Unit**
	ELLEN C HAMMOND	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		19	7	28	16	37						
	2		11		20	9	29	17	38						
	3		12	1	21	10	30	18	39						
	4		13	2	22	11	31	19	40						
	5		14	3	23	12	32	20	41						
	6		15	4	24	13	33	8	42						
	7		16	5	25	14	34								
	8		17		26		35								
	9		18	6	27	15	36								

NONE		**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	20	
/ELLEN C HAMMOND/ Primary Examiner, Art Unit 3773	18 March 2022	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	5C

U.S. Patent and Trademark Office Part of Paper No.: 20220318

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/744,755	Moskowitz et al.
	Examiner	Art Unit
	ELLEN C HAMMOND	3773

CPC - Searched*		
Symbol	**Date**	**Examiner**
A61F2/4611,4465,447; A61B17/0642,7064,809,8635,8875,8894,92,0644,1757,86	10/20/2021	/P.P./
A61B2017/00407,0641,0648,922		
A61F2002/2835,30133,30387,30448,30507,30579,30593,30604,30772,30878,30879,30904,448,4627,4681,4687		
A61F2220/0025,005; A61F2230/0015; A61F2250/0007		
Above - UPDATED	03/18/2022	ECH

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

US Classification - Searched*			
Class	**Subclass**	**Date**	**Examiner**
1	1	10/20/2021	/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	10/20/2021	/P.P./
Reviewed PLUS claims and text search.	03/18/2022	ECH

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/744,755	Moskowitz et al.
	Examiner	Art Unit
	ELLEN C HAMMOND	3773

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner
	See Interference Search History printout.	03/18/2022	ECH

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	645	a61f2/4611,4465,447.cpc. and @pd>="20211020"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2022/03/18 10:00
L2	1,043	a61f2002/2835,30133,30387,30448,30507,30579,30593,30604,30772,30878,30879,30904,448,4627,4681,4687.cpc. and @pd>="20211020"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2022/03/18 10:03
L3	376	a61b2017/00407,0641,0648,922.cpc. and @pd>="20211020"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2022/03/18 10:08

L4	40	l2 and (tool and prongs and (expand or increase or separate) and thread$3)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2022/03/18 10:11
L5	928	a61b17/0642,7064,809,8635,8875,8894,92,0644,1757,86.cpc. and @pd>="20211020"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2022/03/18 10:12
L6	307	a61f2220/0025,005.cpc. and @pd>="20211020"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2022/03/18 10:16
L7	27	a61f2230/0015.cpc. and @pd>="20211020"	US-PGPUB; USPAT; USOCR; FPRS; EPO;	OR	ON	2022/03/18 10:17

			JPO; DERWENT; IBM_TDB			
L9	49	(("9937054") or ("9913725") or ("9907670") or ("9814602") or ("9713536") or ("9655744") or ("9433444") or ("9387088") or ("9198765") or ("9173747") or ("8454695") or ("8231656") or ("7985256") or ("7985256") or ("20180296360") or ("20180200070") or ("20180193739") or ("20180116818") or ("20180078385") or ("20170246006") or ("20170216051") or ("20170216045") or ("20170042695") or ("20170007417") or ("20160354126") or ("20160331542") or ("20160206440") or ("20150282797") or ("20150201976") or ("20150094811") or ("20150066145") or ("20140135934") or ("20120158061") or ("20110270398") or ("20080140207") or ("20070043361") or ("20060079898") or ("11185421") or ("11135071") or ("11071633") or ("10864087") or ("10850193") or ("10478319") or ("10322010") or ("10195524") or ("10188527") or ("10159584") or ("10105232") or ("10076421") or ("10004608")).PN.	US-PGPUB; USPAT	OR	OFF	2022/03/18 11:20
L10	49	(("10307268") or ("10376386") or ("10390969") or ("10478319") or ("10537442") or ("20080033440") or ("20110277598") or ("20110295327") or ("20110295371") or ("20130018468") or ("20130018469") or ("20130023991") or ("20130053962") or ("20130282017") or ("20150103537") or ("20160374830") or ("20180168824") or ("20180221173") or ("20180311052") or ("20180325697") or ("20190175361") or ("20200253747") or ("4388099") or ("4444179") or ("5470333") or ("5531746") or ("5558674") or ("5667507") or ("5707372") or ("5709684") or ("5752955") or ("5755796") or ("5941880") or ("5989291") or ("6090143") or ("6139548") or ("6159245") or ("6267737") or ("6923096") or ("7942903") or ("7942903") or ("8353913") or ("9005293") or ("9261247") or ("9301854") or ("9848998") or ("9867719") or ("9889022") or ("9895238") or ("9907674")).PN.	US-PGPUB; USPAT	OR	OFF	2022/03/18 11:21

3/18/2022 11:23:07 AM
C:\Users\erust\Documents\EAST\Workspaces\16744755.wsp

EAST Search History

EAST Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L8	2	(system and tool and screw and handle and implant and expand$4 and prongs).clm.	USPAT	OR	ON	2022/03/18 11:06

3/18/2022 11:14:15 AM
C:\Users\erust\Documents\EAST\Workspaces\16744755.wsp

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor	:	Ahmnon D. Moskowitz	Art Unit	:	3773
			Examiner	:	Ellen Christina Hammond
Application No.	:	16/744,755			
Filed	:	January 16, 2020	Confirmation No.	:	5369
			Notice of Allowance Date: 4/5/2022		
Title	:	EXPANDABLE SPINAL IMPLANT AND TOOL SYSTEM			

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 Title:

Please amend the title as follows:

EXPANDABLE SPINAL IMPLANT AND TOOL SYSTEM ~~BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR~~

Amendments to the Claims:

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

Listing of Claims:

1-20. (Cancelled)

21. (Currently Amended) 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 holder portion, the holder portion being positioned at the first distal end opposite of the first handle which is positioned at the first proximal end, and the holder portion 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 portions each defining a space that ~~issized~~ is sized, shaped, and configured for receiving the first and second engagement prongs of the first tool, wherein the first tool engagement portion is formed at a proximal end of a first side surface of the expandable spinal implant and the second tool engagement portion is formed at a proximal end of a second side surface of the expandable spinal implant, 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 portions of the expandable spinal implant

22. (Previously Presented) The system of claim 21, wherein the first expandable spinal implant structure is a first single integral structure and the second expandable spinal implant structure is a second single integral structure.

23. (Previously Presented) The system of claim 21, 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.

24. (Previously Presented) The system of claim 21, 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.

25. (Previously Presented) The system of claim 21, 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;

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 portions so as to guide the first and second anchors through the third and fourth anchor guides into the first and second anchor guides.

26. (Cancelled).

27. (Previously Presented) A method of using the system of claim 21, 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 portions;

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 adjusting screw of the

expandable spinal implant.

28. (Previously Presented) The system of claim 21, and further comprising bone graft material configured to be placed inside and outside of the expandable spinal implant.

29. (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 vertebral body engagement surface sized and configured to engage a first vertebral body, a second expandable spinal implant structure defining a second vertebral body

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 portions sized, shaped, and configured for receiving the first and second engagement prongs of the first tool, wherein the first tool engagement portion is formed in a first side surface of the expandable spinal implant and the second tool engagement portion is formed in a second side surface of the expandable spinal implant, 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 portions of the expandable spinal implant.

30. (Previously Presented) The system of claim 29, wherein the expandable spinal implant comprises an implant proximal end and an implant distal end, wherein the first and second tool engagement portions are formed as recessed surfaces and positioned at or near the implant proximal end, and wherein the screw head of the adjusting screw is accessible at the implant proximal end from a proximal direction.

31. (Currently Amended) The system of claim 29, wherein the expandable spinal implant comprises first and second angled wedge surfaces, wherein rotation of the adjusting ~~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.

32. (Previously Presented) The system of claim 29, wherein the first vertebral body engagement surface comprises a plurality of ridges extending from the first vertebral body engagement surface, wherein some of the ridges are positioned on the first vertebral body engagement surface at a distal end of the first vertebral body engagement surface.

33. (Previously Presented) The system of claim 29, wherein the first expandable spinal implant structure defines an end gap between the first and second side surfaces at a proximal end of the first vertebral body engagement surface and of the first expandable spinal implant structure such that first vertebral body engagement surface is open at a proximal end of the first expandable spinal implant structure, wherein the first vertebral body engagement surface comprises a plurality of ridges extending from the first vertebral body engagement surface, wherein some of the ridges are positioned on the first vertebral body engagement surface on a first side of the end gap and some of the ridges are positioned on the first vertebral body engagement surface on a second side of the end gap; and wherein the end gap causes the first vertebral body engagement surface to appear to be substantially U-shaped when viewed from an angle perpendicular to the first vertebral body engagement surface.

34. (Previously Presented) The system of claim 29, wherein the first and second expandable spinal implant structures each include a through-hole sized to allow for placement of bone material into the expandable spinal implant for fusion.

35. (Cancelled).

36. (Previously Presented) The system of claim 29, wherein the first expandable spinal implant structure is a first single integral structure and the second expandable spinal implant structure is a second single integral structure.

37. (Previously Presented) The system of claim 29, wherein outer sides of the first and second engagement prongs are substantially straight when viewed from an angle perpendicular to the first vertebral body engagement surface when the first and second engagement prongs are engaged with the first and second tool engagement portions on the first and second side surfaces of the expandable spinal implant.

38. (Previously Presented) A method of using the system of claim 29, 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 portions;

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 adjusting screw of the expandable spinal implant.

39. (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 extensions 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 tool engagement feature 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 portions sized, shaped, 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 tool engagement feature of the adjusting screw while one or more engagement extensions of the first tool are engaged with the one or more tool engagement portions of the expandable spinal implant, wherein at least one of the one or more tool engagement portions of the expandable spinal implant is indented into one or more side surfaces of the expandable spinal implant such that the one or more engagement extensions of the gripper is positioned in the one or more tool engagement portions on the one or more side surfaces of the expandable spinal implant when the first tool is engaged with the expandable spinal implant.

40. (Previously Presented) The system of claim 39, wherein the expandable spinal implant comprises one or more substantially cylindrical side holes extending through one or more sides 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 one or more substantially cylindrical side holes 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, wherein the expandable spinal implant comprises an implant proximal end and an implant distal end, and wherein the tool engagement feature of the adjusting screw extends at least partially out of the implant proximal end in a proximal direction.

41. (Currently Amended) The system of claim 39, the expandable spinal implant further comprising:

an implant proximal end and an implant distal end, the one or more ~~first and second~~ tool engagement portions positioned at or near the implant proximal end, and the tool engagement feature ~~engaging portion~~ of the adjusting screw is accessible at the implant proximal end from a proximal direction, such that the second adjusting tool ~~engaging tool screw engagement portion~~ engages with the tool engagement feature ~~engaging portion~~ of the adjusting screw at the implant proximal end;

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 at or near the implant distal end, said ridges configured to contact the first vertebral body;

first and second angled wedge surfaces, wherein rotation of the adjusting ~~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; and

first and second openings extending through the first and second ~~vertebral body~~ engagement surfaces to a cavity within the expandable spinal implant, the cavity sized to receive bone material;

wherein the first expandable spinal implant structure is a first single integral structure and the second expandable spinal implant structure is a second single integral structure; and

wherein outer sides of the one or more ~~first and second~~ engagement extensions

are substantially straight when viewed from an angle perpendicular to the first ~~vertebral body~~ engagement surface when the one or more ~~first and second~~ engagement extensions are engaged with the one or more ~~first and second~~ tool engagement portions on the one or more ~~first and second~~ side surfaces of the expandable spinal implant, and the second adjusting tool is engaged with the tool engagement feature of the adjusting screw.

42. (Currently Amended) The system of claim 21, the expandable spinal implant further comprising:

an implant proximal end and an implant distal end, the first and second tool engagement portions positioned at or near the implant proximal end, and the screw head of the adjusting screw is accessible at the implant proximal end from a proximal direction;

a plurality of ridges extending from a [[the]] first vertebral body engagement surface, wherein at least some of the ridges are positioned on the first vertebral body engagement surface at or near the implant distal end;

first and second angled wedge surfaces, wherein rotation of the adjusting ~~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; and

first and second openings extending through the first vertebral body engagement surface and a second vertebral body engagement surface ~~surfaces~~ to a cavity within the expandable spinal implant, the cavity sized to receive bone material; and

wherein outer sides of the first and second engagement prongs are substantially straight when viewed from an angle perpendicular to the first vertebral body engagement

surface when the first and second engagement prongs are engaged with the first and second tool engagement portions on the first and second side surfaces of the expandable spinal implant, and the second adjusting tool is engaged with the screw head of the adjusting screw.

REMARKS

Applicant respectfully requests entry of the amendment to the title. The title has been amended to more closely reflect the subject matter of the allowed claims, and no new matter has been added by these amendments. Applicant notes that the amendment to the tile was previously presented in the preliminary amendment filed on January 4, 2021.

Applicant respectfully requests entry of the amendments to claims 21, 31, 41 and 42. Claims 21, 31, 41, and 42 are amended to correct minor informalities including antecedent basis. The amendments are fully supported by the specification and drawings, and no new matter is added.

These amendments address formal matters in the claims and title without altering the claim scope. Accordingly, no additional search is required by the amendments.

Applicant believes no fees are due with this submission. However, if Applicant is incorrect, please apply any necessary charges or credits to Deposit Account 06-1050, referencing the above attorney docket number.

Respectfully submitted,

Date: April 7, 2022 /Kiersten M. Batzli/
Kiersten M. Batzli, Reg. No. 75,476

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100636199.doc

Electronic Patent Application Fee Transmittal

Application Number:	16744755
Filing Date:	16-Jan-2020
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:	Kiersten M. Batzli/Emily Whitcomb
Attorney Docket Number:	46440-0009016

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	600	600

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**600**

Electronic Acknowledgement Receipt	
EFS ID:	45419960
Application Number:	16744755
International Application Number:	
Confirmation Number:	5369
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:	Kiersten M. Batzli/Emily Whitcomb
Filer Authorized By:	Kiersten M. Batzli
Attorney Docket Number:	46440-0009016
Receipt Date:	07-APR-2022
Filing Date:	16-JAN-2020
Time Stamp:	15:12:57
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	$600
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Issue Fee Payment (PTO-85B)	IssueFee.PDF	130325 77b3cae23744d3621d65bd56bd4ee5baea1ea1f5	no	1
Warnings:					
Information:					
2	Issue Fee Payment (PTO-85B)	ResponsetoNOA.PDF	57981 f381adc7a840f444e26c4cc363204ed334203519	no	2
Warnings:					
Information:					
3		Amend312.PDF	137134 fd23924c60acadb3862efaa47a5883b03940613c	yes	16

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	15
Applicant Arguments/Remarks Made in an Amendment	16	16

Warnings:					
Information:					
4	Fee Worksheet (SB06)	fee-info.pdf	38307 f42fa7dfb917ad3998d74df0cf0c78558ebc2578	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	363747		

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.

PART B - FEE(S) TRANSMITTAL

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Alexandria, Virginia 22314-1450

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

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/744,755	01/16/2020	Ahmnon D. Moskowitz	46440-0009016	5369

TITLE OF INVENTION: EXPANDABLE SPINAL IMPLANT AND TOOL SYSTEM

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$600	$0	$0	$600	07/05/2022

EXAMINER	ART UNIT	CLASS-SUBCLASS
HAMMOND, ELLEN CHRISTINA	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*):

[X] 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 /Kiersten M. Batzli/ Date April 7, 2022

Typed or printed name Kiersten M. Batzli Registration No. 75,476

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor	:	Ahmnon D. Moskowitz	Art Unit	:	3773
			Examiner	:	Ellen Christina Hammond
Application No.	:	16/744,755			
Filed	:	January 16, 2020	Confirmation No.	:	5369
			Notice of Allowance Date: April 5, 2022		
Title	:	EXPANDABLE SPINAL IMPLANT AND TOOL SYSTEM			

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 April 5, 2022, enclosed is a completed Part B - Fee(s) Transmittal.

The issue fee is being paid with this reply on the Electronic Filing System. Apply that fee and any other necessary charges or credits to Deposit Account 06-1050, referencing the above attorney docket number.

COMMENTS ON EXAMINER'S REASONS FOR ALLOWANCE

It is recognized that, in accordance with M.P.E.P. § 1302.14, the Examiner's reasons for allowance need not set forth all of the details as to why the claims are allowed. In the above-referenced application, it is not conceded that the Examiner's stated reasons for allowance are the only reasons for which the claims are allowable. The Examiner's reasons for allowance indicate that particular claim elements are not disclosed or suggested by the prior art of record, yet the claims may be patentable for other reasons as well, including the inventive combination of all of the recited claim elements. It is not conceded that the specific limitations identified by the Examiner are necessary to distinguish the art of record or to satisfy the requirements of 35 U.S.C. § 112. Moreover, the Examiner does not assert, and it would not be conceded, that the Examiner's reasons have any bearing on the patentability of claims in any other applications directed to the disclosed subject matter.

In addition, each dependent claim stands on its own and may be allowable on its own merits. In particular, each dependent claim may be allowable on the basis of a combination of some of the features recited in the dependent claim and its base claim(s), which combination of features may not include all of the limitations identified in the Examiner's reasons for allowance.

Respectfully submitted,

Date: April 7, 2022

/Kiersten M. Batzli/
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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
16/744,755	01/16/2020	3773	865	46440-0009016	15	3

CONFIRMATION NO. 5369

CORRECTED FILING RECEIPT

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

OC000000133057235

Date Mailed: 04/11/2022

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 15/944,117 04/03/2018 PAT 10537442
which 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 13/084,543 04/11/2011 PAT 8353913
and is a CON of 13/108,982 05/16/2011 PAT 9005293
and said 13/084,543 04/11/2011
is a CON of 11/842,855 08/21/2007 PAT 7942903
and said 13/108,982 05/16/2011
is a CON of 11/842,855 08/21/2007 PAT 7942903
which is a CIP of 11/536,815 09/29/2006 PAT 7846188 *
which is a CIP of 11/208,644 08/23/2005 PAT 7704279
which claims benefit of 60/670,231 04/12/2005
(*)Data provided by applicant is not consistent with PTO records.

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: 02/04/2020

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 16/744,755**

Projected Publication Date: Not Applicable

Non-Publication Request: No

Early Publication Request: No

**** SMALL ENTITY ****

Title

EXPANDABLE SPINAL IMPLANT AND TOOL SYSTEM

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

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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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NOT GRANTED

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/744,755	01/16/2020	Ahmnon D. Moskowitz	46440-0009016	5369

26191 7590 04/15/2022
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MINNEAPOLIS, MN 55440-1022

EXAMINER	
HAMMOND, ELLEN CHRISTINA	

ART UNIT	PAPER NUMBER
3773	

NOTIFICATION DATE	DELIVERY MODE
04/15/2022	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

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
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Application No. : 16744755
Applicant : Moskowitz
Filing Date : 01/16/2020
Date Mailed : 04/15/2022

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. 16744755 **Drawings filed: 01/16/2020**

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)
- [X] An ink stamp or the image thereof obscures part of the illustration. FIG(s) 4A
- [ ] 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)
- [ ] Data, a reference number, or part of the drawing is truncated or missing, or a lead line has no reference number. FIG(s)
- [ ] 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. 16744755

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 01/16/2020 include FIG. 5E-5G, 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:
there is a typo on page 14 of the specification where "5" is missing before the "E-G"

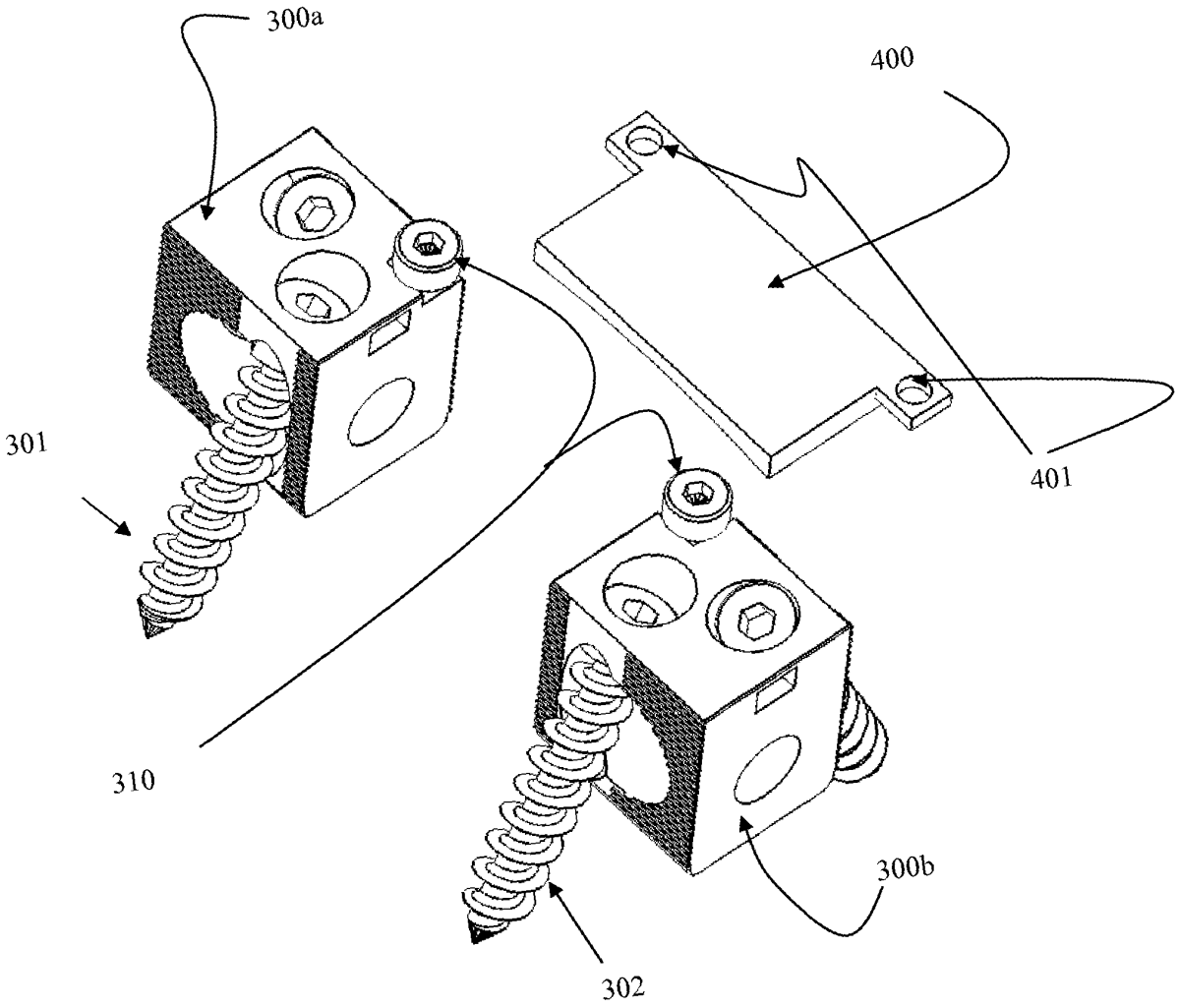


Fig. 4A

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.

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.

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Customer Number:	26191
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Filer Authorized By:	Kiersten M. Batzli
Attorney Docket Number:	46440-0009016
Receipt Date:	19-APR-2022
Filing Date:	16-JAN-2020
Time Stamp:	13:34:40
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	Post Allowance Communication - Incoming	ResponsetoNoticetoFileCorrectedApplnPapers.PDF	101750 f8b4a8f6bfde9d26c71040dedcd2918af90a8233	no	5

Warnings:

Information:					
2	Drawings-only black and white line drawings	ReplacementFigure4A.pdf	1184798 d241dfc0c92f2eb33784f70a0aeb51829bea3ebf	no	1
Warnings:					
Information:					
3	Specification	MARKEDUPSPEC.pdf	183077 e920f67c4fe15e197cc813d4e31b9f6f130c647b	no	27
Warnings:					
Information:					
4	Specification	SUBSPEC.pdf	183511 6ab6dd0d79615a8ce01670e76afd1fc18fe208e7	no	27
Warnings:					
Information:					
		Total Files Size (in bytes):	1653136		

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.	:	16/744,755	Examiner	:	Ellen Christina Hammond
Filed	:	January 16, 2020	Conf. No.	:	5369
Title	:	EXPANDABLE SPINAL IMPLANT AND TOOL SYSTEM			

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

REPLY TO NOTICE TO FILE CORRECTED APPLICATION PAPERS

DATED APRIL 15, 2022

The applicant as a small entity submits:

☒ Substitute drawings (1 sheet) correcting Figure 4A in compliance with 37 C.F.R. §1.84.

☒ A substitute specification in compliance with 37 C.F.R. §1.52. The number "5" was added to the phrase "Figures 5E-G" in paragraph 0046. No new matter has been added.

Please replace Figure 4A as originally filed with the substitute drawing of corrected Figures 4A. Please replace the specification with the amended substitute specification. 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: April 19, 2022

/Kiersten M. Batzli/
Kiersten M. Batzli, Reg. No. 75,476

Customer Number 26191
Fish & Richardson P.C.
Telephone: +1 (612) 766-2015
Facsimile: (877) 769-7945

100643669.doc

UNITED STATES PATENT AND TRADEMARK OFFICE

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

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/744,755	01/16/2020	Ahmnon D. Moskowitz	46440-0009016	5369

26191 7590 04/15/2022
FISH & RICHARDSON P.C. (TC)
PO BOX 1022
MINNEAPOLIS, MN 55440-1022

EXAMINER	
HAMMOND, ELLEN CHRISTINA	

ART UNIT	PAPER NUMBER
3773	

NOTIFICATION DATE	DELIVERY MODE
04/15/2022	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

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

Application No. : 16744755
Applicant : Moskowitz
Filing Date : 01/16/2020
Date Mailed : 04/15/2022

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. 16744755 **Drawings filed: 01/16/2020**

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)
- [X] An ink stamp or the image thereof obscures part of the illustration. FIG(s) 4A
- [ ] 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)
- [ ] Data, a reference number, or part of the drawing is truncated or missing, or a lead line has no reference number. FIG(s)
- [ ] 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. 16744755

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 01/16/2020 include FIG. 5E-5G, 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:
there is a typo on page 14 of the specification where "5" is missing before the "E-G"

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/744,755	01/16/2020	Ahmnon D. Moskowitz	46440-0009016	5369

26191 7590 04/22/2022

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

EXAMINER	
HAMMOND, ELLEN CHRISTINA	

ART UNIT	PAPER NUMBER
3773	

NOTIFICATION DATE	DELIVERY MODE
04/22/2022	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.** 16/744,755	**Applicant(s)** Moskowitz et al.	
	Examiner ELLEN C HAMMOND	**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 the amendment filed 04/07/2022.
   ☐ 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 See Continuation Sheet . 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 _____.

/ELLEN C HAMMOND/
Primary Examiner, Art Unit 3773

Continuation of 3. The allowed claim(s) is/are: 21-25,27-34 and 36-42

Notice of Pre-AIA or AIA Status

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

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

The application has been amended as follows:

In claim 21 insert a period at the end thereof.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELLEN HAMMOND whose telephone number is (571)270-3819. The examiner can normally be reached Monday-Friday 8 - 4 PM .

If attempts to reach the examiner by telephone are unsuccessful, ***please contact*** **the examiner's supervisor, Eduardo C. Robert, *at* 571 272-4719**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ELLEN C HAMMOND/
Primary Examiner, Art Unit 3773

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/744,755	Moskowitz et al.
	Examiner	Art Unit
	ELLEN C HAMMOND	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	10/20/2021	03/18/2022	04/18/2022						
	1	-	-	-						
	2	-	-	-						
	3	-	-	-						
	4	-	-	-						
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	6	-	-	-						
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	9	-	-	-						
	10	-	-	-						
	11	-	-	-						
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	18	-	-	-						
	19	-	-	-						
	20	-	-	-						
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5	25	✓	=	=						
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6	27	✓	=	=						
7	28	✓	=	=						
9	29	✓	=	=						
10	30	✓	=	=						
11	31	✓	=	=						
12	32	✓	=	=						
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15	36	✓	=	=						
16	37	✓	=	=						
17	38	✓	=	=						
18	39	✓	=	=						
19	40	✓	=	=						
20	41		=	=						
8	42		=	=						

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/744,755	Moskowitz et al.
	Examiner	**Art Unit**
	ELLEN C HAMMOND	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	/	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
A61F	/	2220	/	005			A	2013-01-01

NONE		**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	20	
/ELLEN C HAMMOND/ Primary Examiner, Art Unit 3773	18 April 2022	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	5C

U.S. Patent and Trademark Office — Part of Paper No.: 20220418

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/744,755	Moskowitz et al.
	Examiner	**Art Unit**
	ELLEN C HAMMOND	3773

CPC						
Symbol					**Type**	**Version**
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	/	30593	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		**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	20	
/ELLEN C HAMMOND/ Primary Examiner, Art Unit 3773	18 April 2022	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	5C

U.S. Patent and Trademark Office — Part of Paper No.: 20220418

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
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	Examiner	Art Unit
	ELLEN C HAMMOND	3773

INTERNATIONAL CLASSIFICATION					
CLAIMED					
A61F2/46	/	2	/	46	
A61F2/44	/	2	/	44	

NON-CLAIMED				
	/		/	

US ORIGINAL CLASSIFICATION	
CLASS	SUBCLASS

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

NONE		Total Claims Allowed:	
(Assistant Examiner)	(Date)	20	
/ELLEN C HAMMOND/ Primary Examiner, Art Unit 3773	18 April 2022	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	5C

U.S. Patent and Trademark Office

Part of Paper No.: 20220418

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
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	Examiner	**Art Unit**
	ELLEN C HAMMOND	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		19	7	28	16	37						
	2		11		20	9	29	17	38						
	3		12	1	21	10	30	18	39						
	4		13	2	22	11	31	19	40						
	5		14	3	23	12	32	20	41						
	6		15	4	24	13	33	8	42						
	7		16	5	25	14	34								
	8		17		26		35								
	9		18	6	27	15	36								

NONE		**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	20	
/ELLEN C HAMMOND/ Primary Examiner, Art Unit 3773	18 April 2022	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	5C

U.S. Patent and Trademark Office Part of Paper No.: 20220418

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/744,755	Moskowitz et al.
	Examiner	Art Unit
	ELLEN C HAMMOND	3773

CPC - Searched*		
Symbol	**Date**	**Examiner**
A61F2/4611,4465,447; A61B17/0642,7064,809,8635,8875,8894,92,0644,1757,86	10/20/2021	/P.P./
A61B2017/00407,0641,0648,922		
A61F2002/2835,30133,30387,30448,30507,30579,30593,30604,30772,30878,30879,30904,448,4627,4681,4687		
A61F2220/0025,005; A61F2230/0015; A61F2250/0007		
Above - UPDATED	03/18/2022	ECH
Above - UPDATED	04/18/2022	ECH

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

US Classification - Searched*			
Class	**Subclass**	**Date**	**Examiner**
1	1	10/20/2021	/P.P./

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

/ELLEN C HAMMOND/ Primary Examiner, Art Unit 3773	

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/744,755	Moskowitz et al.
	Examiner	Art Unit
	ELLEN C HAMMOND	3773

Search Notes		
Search Notes	**Date**	**Examiner**
EAST search enclosed	10/20/2021	/P.P./
Reviewed PLUS claims and text search.	03/18/2022	ECH
IPR2020-01307 Reviewed Petition for Inter Partes Review of U.S. Patent No. 8,353,913 on 04/18/2022.	04/18/2022	ECH
IPR2020-01308 Reviewed Inter Partes Review of U.S. Patent No. 9,889,022 on 04/18/2022.	04/18/2022	ECH

Interference Search			
US Class/CPC Symbol	**US Subclass/CPC Group**	**Date**	**Examiner**
	See Interference Search History printout.	03/18/2022	ECH
	Above - UPDATED	04/18/2022	ECH

/ELLEN C HAMMOND/ Primary Examiner, Art Unit 3773	

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor	:	Ahmnon D. Moskowitz	Art Unit	:	3773
			Examiner	:	Ellen Christina Hammond
Application No.	:	16/744,755			
Filed	:	January 16, 2020	Confirmation No.	:	5369
			Notice of Allowance Date: 4/5/2022		
Title	:	EXPANDABLE SPINAL IMPLANT AND TOOL SYSTEM			

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.

OK TO ENTER: /E.C.H/

PE2E SEARCH - Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
L1	645	a61f2/4611,4465,447.cpc. and @pd>="20211020"	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/03/18 10:00 AM
L2	1043	a61f2002/2835,30133,30387,30448,30507,30579,30593,30604,30772,30878,30879,30904,448,4627,4681,4687.cpc. and @pd>="20211020"	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/03/18 10:03 AM
L3	376	a61b2017/00407,0641,0648,922.cpc. and @pd>="20211020"	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/03/18 10:08 AM
L4	40	L2 and (tool and prongs and (expand or increase or separate) and thread$3)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/03/18 10:11 AM
L5	928	a61b17/0642,7064,809,8635,8875,8894,92,0644,1757,86.cpc. and @pd>="20211020"	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/03/18 10:12 AM
L6	307	a61f2220/0025,005.cpc. and @pd>="20211020"	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/03/18 10:16 AM
L7	27	a61f2230/0015.cpc. and @pd>="20211020"	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/03/18 10:17 AM
L8	49	(("9937054") or ("9913725") or ("9907670") or ("9814602") or ("9713536") or ("9655744") or ("9433444") or ("9387088") or ("9198765") or ("9173747") or ("8454695") or ("8231656") or ("7985256") or ("7985256") or ("20180296360") or ("20180200070") or ("20180193739") or ("20180116818") or ("20180078385") or ("20170246006") or	(US-PGPUB; USPAT)	OR	ON	ON	2022/03/18 11:20 AM

		("20170216051") or ("20170216045") or ("20170042695") or ("20170007417") or ("20160354126") or ("20160331542") or ("20160206440") or ("20150282797") or ("20150201976") or ("20150094811") or ("20150066145") or ("20140135934") or ("20120158061") or ("20110270398") or ("20080140207") or ("20070043361") or ("20060079898") or ("11185421") or ("11135071") or ("11071633") or ("10864087") or ("10850193") or ("10478319") or ("10322010") or ("10195524") or ("10188527") or ("10159584") or ("10105232") or ("10076421") or ("10004608")).PN.					
L9	49	(("10307268") or ("10376386") or ("10390969") or ("10478319") or ("10537442") or ("20080033440") or ("20110277598") or ("20110295327") or ("20110295371") or ("20130018468") or ("20130018469") or ("20130023991") or ("20130053962") or ("20130282017") or ("20150103537") or ("20160374830") or ("20180168824") or ("20180221173") or ("20180311052") or ("20180325697") or ("20190175361") or ("20200253747") or ("4388099") or ("4444179") or ("5470333") or ("5531746") or ("5558674") or	(US-PGPUB; USPAT)	OR	ON	ON	2022/03/18 11:21 AM

		("5667507") or ("5707372") or ("5709684") or ("5752955") or ("5755796") or ("5941880") or ("5989291") or ("6090143") or ("6139548") or ("6159245") or ("6267737") or ("6923096") or ("7942903") or ("7942903") or ("8353913") or ("9005293") or ("9261247") or ("9301854") or ("9848998") or ("9867719") or ("9889022") or ("9895238") or ("9907674")).PN.					
L10	3	"8353913".pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/04/18 11:59 AM
L11	3	"8425607".pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/04/18 12:02 PM
L12	3	"20040204717"	(US-PGPUB; USPAT; USOCR; FIT (AU, AP,	OR	ON	ON	2022/04/18 12:02 PM

			AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)				
L13	3	"9889022".pn.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/04/18 12:19 PM
L14	3	a61f2230/0015.cpc. AND @pd>="20220318"	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/04/18 12:49 PM
L15	47	a61f2220/0025,005.cpc. AND @pd>="20220318"	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/04/18 12:49 PM
L16	110	a61b17/0642,7064,809,8635,8875,8894,92,0644,1757,86.cpc. AND @pd>="20220318"	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/04/18 12:50 PM
L17	44	a61b2017/00407,0641,0648,922.cpc. AND @pd>="20220318"	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/04/18 12:52 PM
L18	290	a61f2002/2835,30133,30387,30448,30507,30579,30593,30604,30772,30878,30879,30904,448,4627,4681,4687.cpc. AND @pd>="202203"	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/04/18 12:52 PM
L19	85	a61f2/4611,4465,447.cpc. AND @pd>="20220318"	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT;	OR	ON	ON	2022/04/18 12:53 PM

			IBM_TDB)				

PE2E SEARCH - Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
N10	2	(system and tool and screw and handle and implant and expand$4 and prongs).clm.	(USPAT)	OR	ON	ON	2022/03/18 11:06 AM

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/744,755	01/16/2020	Ahmnon D. Moskowitz	46440-0009016	5369

26191 7590 05/13/2022

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

EXAMINER	
HAMMOND, ELLEN CHRISTINA	

ART UNIT	PAPER NUMBER
3773	

NOTIFICATION DATE	DELIVERY MODE
05/13/2022	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

Response to Rule 312 Communication	Application No.	Applicant(s)	
	16/744,755	Moskowitz et al.	
	Examiner	Art Unit	AIA (FITF) Status
	ELLEN C HAMMOND	3773	No

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

1. ☑ The amendment filed on 19 April 2022 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.

f) ☐ not entered because the supplemental or corrected Application Data sheet (ADS)

☐ was not accompanied by a petition to accept an unintentionally delayed claim under 37 CFR 1.55 or 27 CFR 1.78;

☐ did not identify the information being changed in accordance with 37 CFR 1.76(c)(2);

☐ was not properly signed in accordance with 37 CFR 1.76(e) (or 37 CFR 1.33(b) for applications filed prior to September 16, 2012).

/ELLEN C HAMMOND/
Primary Examiner, Art Unit 3773

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/744,755	01/16/2020	Ahmnon D. Moskowitz	46440-0009016	5369

26191 7590 04/15/2022
FISH & RICHARDSON P.C. (TC)
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EXAMINER	
HAMMOND, ELLEN CHRISTINA	

ART UNIT	PAPER NUMBER
3773	

NOTIFICATION DATE	DELIVERY MODE
04/15/2022	ELECTRONIC

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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):

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OK TO ENTER: /E.C.H/

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Commissioner for Patents
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P.O. Box 1450
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Application No. : 16744755
Applicant : Moskowitz
Filing Date : 01/16/2020
Date Mailed : 04/15/2022

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. 16744755 **Drawings filed: 01/16/2020**

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)
- [X] An ink stamp or the image thereof obscures part of the illustration. FIG(s) 4A
- [ ] 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)
- [ ] Data, a reference number, or part of the drawing is truncated or missing, or a lead line has no reference number. FIG(s)
- [ ] 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. 16744755

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 01/16/2020 include FIG. 5E-5G, 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:
there is a typo on page 14 of the specification where "5" is missing before the "E-G"

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APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/744,755	07/05/2022	11376136	46440-0009016	5369

26191 7590 06/15/2022

FISH & RICHARDSON P.C. (TC)
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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 206 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 Patents Stakeholder Experience (OPSE), Stakeholder Support Division (SSD) at (571)-272-4200.

INVENTOR(s) (Please see PAIR WEB site http://pair.uspto.gov for additional inventors):

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

APPLICANT(s) (Please see PAIR WEB site http://pair.uspto.gov for additional applicants):

Moskowitz Family LLC, Rockville, MD;

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IR103 (Rev. 10/09)