EXHIBIT 1002

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APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/063,613	06/01/2021	11020129	13438.008-12	3498

141269 7590 05/12/2021

Hill Ward Henderson, P.A.
101 East Kennedy Blvd., Suite 3700
Tampa, FL 33602

ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

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

The Patent Term Adjustment is 0 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Application Assistance Unit (AAU) of the Office of Data Management (ODM) at (571)-272-4200.

APPLICANT(s) (Please see PAIR WEB site http://pair.uspto.gov for additional applicants):

Sean LaNeve, Tampa, FL;
Pain TEQ, LLC, Tampa, FL;
Charles Girsch, Tampa, FL;
Chris Girsch, Tampa, FL;

The United States represents the largest, most dynamic marketplace in the world and is an unparalleled location for business investment, innovation, and commercialization of new technologies. The USA offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to encourage and facilitate business investment. To learn more about why the USA is the best country in the world to develop technology, manufacture products, and grow your business, visit SelectUSA.gov.

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)

141269 7590 02/03/2021

Hill Ward Henderson, P.A.
101 East Kennedy Blvd., Suite 3700
Tampa, FL 33602

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.

Stephen E. Kelly	(Typed or printed name)
/Steve Kelly/	(Signature)
04/29/2021	(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/063,613	10/05/2020	Sean LaNeve	13438.008-12	3498

TITLE OF INVENTION: DRILL-LESS METHOD OF FUSING A SACROILIAC JOINT

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	05/03/2021

EXAMINER	ART UNIT	CLASS-SUBCLASS
SEVILLA, CHRISTIAN ANTHONY	3775	606-084000

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 Stephen E. Kelly
2 Thomas J. Banks
3 Hill Ward Henderson, P.A.

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: Pain TEQ, LLC

(B) RESIDENCE: (CITY and STATE OR COUNTRY): Tampa, Florida

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. 600193

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 /Steve Kelly/ Date 04/29/2021

Typed or printed name Stephen E. Kelly Registration No. 59,973

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P.O. Box 1450
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Stephen E. Kelly	(Typed or printed name)
/Steve Kelly/	(Signature)
04/29/2021	(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/063,613	10/05/2020	Sean LaNeve	13438.008-12	3498

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APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
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EXAMINER	ART UNIT	CLASS-SUBCLASS
SEVILLA, CHRISTIAN ANTHONY	3775	606-084000

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2 Thomas J. Banks
3 Hill Ward Henderson, P.A.

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(B) RESIDENCE: (CITY and STATE OR COUNTRY): Tampa, Florida

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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)

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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 /Steve Kelly/ Date 04/29/2021

Typed or printed name Stephen E. Kelly Registration No. 59,973

Electronic Patent Application Fee Transmittal

Application Number:	17063613
Filing Date:	05-Oct-2020
Title of Invention:	DRILL-LESS METHOD OF FUSING A SACROILIAC JOINT
First Named Inventor/Applicant Name:	Sean LaNeve
Filer:	Stephen E. Kelly/Lauren Forsythe
Attorney Docket Number:	13438.008-12

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:	42596135
Application Number:	17063613
International Application Number:	
Confirmation Number:	3498
Title of Invention:	DRILL-LESS METHOD OF FUSING A SACROILIAC JOINT
First Named Inventor/Applicant Name:	Sean LaNeve
Customer Number:	141269
Filer:	Stephen E. Kelly/Lauren Forsythe
Filer Authorized By:	Stephen E. Kelly
Attorney Docket Number:	13438.008-12
Receipt Date:	29-APR-2021
Filing Date:	05-OCT-2020
Time Stamp:	18:03:17
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	$600
RAM confirmation Number	E20214SI03470192
Deposit Account	600193
Authorized User	Lauren Forsythe

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

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	Issue Fee Payment (PTO-85B)	13438_008_12_Issue_Fee_04292021.pdf	286111 764383db1f6d8cd5a6a0aeac74adef30cb562e9a	no	1
Warnings:					
Information:					
2	Issue Fee Payment (PTO-85B)	13438_008_12_Issue_Fee2_04292021.pdf	286185 b5be83854e6ac9361da117ef89d81b9c3772c848	no	1
Warnings:					
Information:					
3	Fee Worksheet (SB06)	fee-info.pdf	30386 10fd7ac0b3c23b8553951811f721405bb3a12214	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	602682		

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

New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

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

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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www.uspto.gov

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
17/063,613	10/05/2020	Sean LaNeve	13438.008-12

CONFIRMATION NO. 3498

141269
Hill Ward Henderson, P.A.
101 East Kennedy Blvd., Suite 3700
Tampa, FL 33602

PUBLICATION NOTICE

OC000000124727239

Title:DRILL-LESS METHOD OF FUSING A SACROILIAC JOINT

Publication No.US-2021-0100662-A1
Publication Date:04/08/2021

NOTICE OF PUBLICATION OF APPLICATION

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

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

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

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

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

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

PTO/SB/08 Equivalent

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application No.	17/063,613
	Filing Date	10/05/2020
	First Named Inventor	LaNeve, Sean
	Art Unit	3775
(Multiple sheets used when necessary)	Examiner	Sevilla, Christian Anthony
SHEET 1 OF 2	Attorney Docket No.	13438.008-12

U.S. PATENT DOCUMENTS

Examiner Initials	Cite No.	Document Number *Number - Kind Code (if known)* Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	1	6371988	04-16-2002	Pafford, John et al.	
	2	6652533	11-25-2003	O'Neil, Michael	
	3	6846327	01-25-2005	Khandkar, Ashok C., et al.	
	4	7125425	10-24-2006	Foley, Kevin T. et al.	
	5	8221503	07-17-2012	Garcia, Javier et al.	
	6	8945224	02-03-2015	Trieu, Hai H.	
	7	9247943	02-02-2016	Kleiner, Jeffrey B.	
	8	9451986	09-27-2016	Stoffman, Michael R.	
	9	9668781	06-06-2017	Stark, John G.	
	10	9700356	07-11-2017	Donner, Edward Jeffrey et al.	
	11	9757154	09-12-2017	Donner, Edward Jeffrey et al.	
	12	10492802	12-03-2019	Donner, Edward Jeffrey et al.	
	13	10646258	05-12-2020	Donner, Edward Jeffrey et al.	
	14	10682150	06-16-2020	Stark, John G.	
	15	20050080422	04-14-2005	Otte, John F. et al.	
	16	20110238181	09-29-2011	Trieu, Hai H.	

FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No.	Foreign Patent Document *Country Code-Number-Kind Code* Example: JP 1234567 AI	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear	T[1]
				.		

NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[1]
	17	United Stated Patent and Trademark Office, Office Action for U.S. Appl. No. 17/063609, dated February 2, 2021	

T[1] - Place a check mark in this area when an English language Translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /C.A.S/

PTO/SB/08 Equivalent

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application No.	17/063,613
	Filing Date	10/05/2020
	First Named Inventor	LaNeve, Sean
	Art Unit	3775
(Multiple sheets used when necessary)	Examiner	Sevilla, Christian Anthony
SHEET 2 OF 2	Attorney Docket No.	13438.008-12

CO-PENDING U.S. PATENT APPLICATIONS COMMONLY OWNED WITH THE PRESENT APPLICATION

EXAMINER NOTE: Applicant respectfully requests the Examiner to consider whether the claims of any one or more of the following co-pending U.S. patent applications (which are commonly owned with the present application) create any issues of double patenting with respect to any of the claims of the present application; and, where relevant, to consider whether the disclosure of any one or more of the following co-pending applications creates any issues of patentability with respect to any of the claims of the present application. In addition, Applicant respectfully requests the Examiner to consider whether any office actions issued in the following co-pending applications create any issues of patentability with respect to any of the claims of the present application.

SPECIFICATION, DRAWINGS and CLAIMS: Except where indicated, each of the co-pending applications listed below is stored in the USPTO's IFW system. As provided in M.P.E.P. § 609.04(a), copies of the specifications, drawings and claims of these co-pending applications are not enclosed herewith.

Examiner Initials	Cite No.	Serial No.	Filing Date MM-DD-YYYY	Inventor(s)	Pub. No.	Atty. Docket No.	Date(s) of Office Action(s) MM-DD-YYYY

Examiner Signature	/CHRISTIAN A SEVILLA/	Date Considered	04/02/2021

***Examiner:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

T[1] - Place a check mark in this area when an English language Translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /C.A.S/

PTO/SB/08 Equivalent

SUPPLMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application No.	17/063,613
	Filing Date	10/05/2020
	First Named Inventor	LaNeve, Sean
	Art Unit	3775
	Examiner Name	Sevilla, Christian Anthony
	Attorney Docket No.	13438.008-12

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☒ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☒ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Steve Kelly/	Date (YYYY-MM-DD)	2021-03-26
Name/Print	Stephen E. Kelly	Registration Number	59,973

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450**.

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EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	2	"20080249569"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2021/04/02 14:23
L2	10	(US-1234567-$ | US-10219912-$ | US-20080249569-$ | US-8128700-$ | US-8403991-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2021/04/02 14:25
L3	33	(US-1234567-$ | US-10492802-$ | US-10646258-$ | US-10682150-$ | US-20050080422-$ | US-20110238181-$ | US-6371988-$ | US-6652533-$ | US-6846327-$ | US-7125425-$ | US-8221503-$ | US-8945224-$ | US-9247943-$ | US-9451986-$ | US-9668781-$ | US-9700356-$ | US-9757154-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2021/04/02 14:29
L4	5	"20050080422"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2021/04/02 14:38
L5	2	"20110238181"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2021/04/02 14:39
S1	22,458	(A61F2/4611).cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2021/01/25 11:02

S2	645	(A61F2002/30995).cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2021/01/25 11:03
S4	10,537	(A61B17/1671).cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2021/01/25 15:08
S5	0	(LaNeve near2 Sean).in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2021/01/25 16:18
S6	17	(Girsch near2 Charles).in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2021/01/25 16:18
S7	0	(Girsch near2 Chris).in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2021/01/25 16:19
S8	0	"17063613"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2021/01/26 09:00
S9	0	"17063613"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2021/01/28 13:56

S10	27	(US-20200390566-$ or US-20200315811-$ or US-20210015502-$ or US-20200253619-$ or US-20180303624-$ or US-20160030191-$ or US-20200179135-$ or US-20140277204-$ or US-20190343640-$ or US-20200093612-$ or US-20190021868-$ or US-20150328012-$ or US-20150073552-$ or US-20150230937-$ or US-20150012097-$ or US-20080009861-$ or US-20090216238-$ or US-20140088711-$ or US-20140081279-$ or US-20110184518-$ or US-20140031935-$ or US-20190083271-$ or US-20090312763-$).did. or (US-9101371-$).did. or (WO-2012015976-$ or WO-2013043584-$ or US-20140031935-$).did.	US-PGPUB; USPAT; DERWENT	OR	OFF	2021/01/28 14:08
S11	0	(2019/0083271).CCLS.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2021/01/28 14:44
S12	4	"20190083271"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2021/01/28 14:45
S13	2	"20060178673"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2021/01/28 14:46
S14	187	(US-1234567-$ | US-10004547-$ | US-10070970-$ | US-10136932-$ | US-10149764-$ | US-10166033-$ | US-10194962-$ | US-10201427-$ | US-10206739-$ | US-10219841-$ | US-10245044-$ | US-10245158-$ | US-10265176-$ | US-10292720-$ | US-10314710-$ | US-10321945-$ | US-10357368-$ | US-10363140-$ | US-10426539-$ | US-10555818-$ | US-10736752-$ | US-10744003-$ | US-	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2021/01/28 14:59

		10751196-$ | US-10765532-$ | US-10779958-$ | US-10820917-$ | US-20010031967-$ | US-20020143400-$ | US-20050240195-$ | US-20060054171-$ | US-20060178673-$ | US-20070156241-$ | US-20080009861-$ | US-20080154374-$ | US-20090024174-$ | US-20090076551-$ | US-20090099610-$ | US-20090259261-$ | US-20110098817-$ | US-20110184518-$ | US-20110264229-$ | US-20120083883-$ | US-20120259365-$ | US-20130006368-$ | US-20130173004-$ | US-20130218215-$ | US-20140207191-$ | US-20150025534-$ | US-20150112444-$ | US-20150250611-$ | US-20150250612-$ | US-20160175113-$ | US-20160310197-$ | US-20170245999-$ | US-20180036017-$ | US-20180092748-$ | US-20190083271-$ | US-20190090888-$ | US-20190133613-$ | US-20190262010-$ | US-20190336292-$ | US-20200029979-$ | US-20200138452-$ | US-20200138589-$ | US-4569338-$ | US-5334205-$ | US-5722978-$ | US-6080155-$ | US-6436098-$ | US-6648917-$ | US-6770074-$ | US-7018416-$ | US-7229477-$ | US-7648509-$ | US-8021392-$ | US-8025684-$ | US-8157865-$ | US-8162981-$ | US-8197513-$ | US-8348950-$ | US-8551171-$ | US-8579912-$ | US-8623053-$ | US-8740912-$ | US-8882818-$ | US-8961571-$ | US-8979928-$ | US-9017407-$ | US-9101371-$ | US-9119732-$ | US-9186155-$ | US-9241798-$ | US-9375243-$ | US-9421109-$ | US-9492284-$ | US-9662128-$ | US-9795396-$ | US-9801732-$ | US-9808346-$ | US-9833321-$ | US-9883874-$ | US-9895176-$ | US-9949843-$ | US-D905232-$).DID.				
S15	31	(US-20200390566-$ or US-20200315811-$ or US-20210015502-$ or US-20200253619-$ or US-20180303624-$ or US-20160030191-$ or US-20200179135-$ or US-20140277204-$ or US-20190343640-$ or US-20200093612-$ or US-	US-PGPUB; USPAT; DERWENT	OR	OFF	2021/01/28 20:06

		20190021868-$ or US-20150328012-$ or US-20150073552-$ or US-20150230937-$ or US-20150012097-$ or US-20080009861-$ or US-20090216238-$ or US-20140088711-$ or US-20140081279-$ or US-20110184518-$ or US-20140031935-$ or US-20190083271-$ or US-20090312763-$ or US-20120277801-$ or US-20060178673-$ or US-20060089633-$).did. or (US-9101371-$).did. or (WO-2012015976-$ or WO-2013043584-$ or US-20140031935-$ or WO-2010108166-$).did.				
S16	64	("20010049527" | "20030191474" | "20040267269" | "20050137600" | "20050159746" | "20050267482" | "20060111780" | "20060155289" | "20070123889" | "20070198020" | "20070260270" | "20080009861" | "20080009875" | "20080091199" | "20080114364" | "20080269754" | "20080294167" | "20090138053" | "20090216238" | "20090259261" | "20090319043" | "20100030216" | "20100131011" | "20100241123" | "20110028978" | "20110087294" | "20110098709" | "20110118796" | "20110264229" | "20110295272" | "20120323285" | "20130030456" | "5242444" | "5334205" | "5928239" | "6358251" | "6440138" | "6635059" | "6679886" | "6726690" | "6740090" | "6746451" | "6821276" | "6923813" | "6939351" | "7699849" | "7867233" | "7879038" | "7909827" | "7914545" | "8109957" | "8114084" | "8348950" | "D601711").PN. OR ("9101371").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/01/28 20:08
S17	6,689	(A61B17/1604).cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2021/01/28 20:11

EAST Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp

S18	0	(method and implant and void and sacroiliac and arms and abrading and slide adj hammer).clm.	US-PGPUB; USPAT	OR	OFF	2021/01/28 19:49
S19	0	(method and implant adj void and abrading adj device and slide adj hammer).clm.	US-PGPUB; USPAT	OR	OFF	2021/01/29 09:07

4/2/2021 2:40:48 PM
C:\Users\csevilla\Desktop\17063613.wsp

PTO/SB/08 Equivalent

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application No.	17/063,613
	Filing Date	10/05/2020
	First Named Inventor	LaNeve, Sean
	Art Unit	3775
(Multiple sheets used when necessary)	Examiner	Sevilla, Christian Anthony
SHEET 1 OF 1	Attorney Docket No.	13438.008-12

U.S. PATENT DOCUMENTS

Examiner Initials	Cite No.	Document Number *Number - Kind Code (if known)* Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	1	8128700	03-06-2012	Delurio, Robert J. et al.	
	2	8403991	03-26-2013	Ullrich Jr., Peter F. et al.	
	3	10219912	03-05-2019	Suh, Jon et al.	
	4	20080249569	10-09-2008	Waugh, Lindsey G. et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No.	Foreign Patent Document *Country Code-Number-Kind Code* Example: JP 1234567 AI	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear	T[1]

NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[1]
	11	International Search Report and Written Opinion for International. Appl. No. PCT/US20/54312, dated February 8, 2021.	

CO-PENDING U.S. PATENT APPLICATIONS COMMONLY OWNED WITH THE PRESENT APPLICATION

EXAMINER NOTE: Applicant respectfully requests the Examiner to consider whether the claims of any one or more of the following co-pending U.S. patent applications (which are commonly owned with the present application) create any issues of double patenting with respect to any of the claims of the present application; and, where relevant, to consider whether the disclosure of any one or more of the following co-pending applications creates any issues of patentability with respect to any of the claims of the present application. In addition, Applicant respectfully requests the Examiner to consider whether any office actions issued in the following co-pending applications create any issues of patentability with respect to any of the claims of the present application.

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Examiner Initials	Cite No.	Serial No.	Filing Date MM-DD-YYYY	Inventor(s)	Pub. No.	Atty. Docket No.	Date(s) of Office Action(s) MM-DD-YYYY

Examiner Signature	/CHRISTIAN A SEVILLA/	Date Considered	04/02/2021

***Examiner:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

T[1] - Place a check mark in this area when an English language Translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /C.A.S/

SUPPLMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application No.	17/063,613
	Filing Date	10/05/2020
	First Named Inventor	LaNeve, Sean
	Art Unit	3775
	Examiner Name	Sevilla, Christian Anthony
	Attorney Docket No.	13438.008-12

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☒ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☒ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Steve Kelly/	Date (YYYY-MM-DD)	2021-03-26
Name/Print	Stephen E. Kelly	Registration Number	59,973

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450**.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /C.A.S/

PTO/SB/08 Equivalent

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	Filing Date	10/05/2020
	First Named Inventor	LaNeve, Sean
	Art Unit	3775
(Multiple sheets used when necessary)	Examiner	Sevilla, Christian Anthony
SHEET 1 OF 2	Attorney Docket No.	13438.008-12

U.S. PATENT DOCUMENTS

Examiner Initials	Cite No.	Document Number *Number - Kind Code (if known)* Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	1	6371988	04-16-2002	Pafford, John et al.	
	2	6652533	11-25-2003	O'Neil, Michael	
	3	6846327	01-25-2005	Khandkar, Ashok C., et al.	
	4	7125425	10-24-2006	Foley, Kevin T. et al.	
	5	8221503	07-17-2012	Garcia, Javier et al.	
	6	8945224	02-03-2015	Trieu, Hai H.	
	7	9247943	02-02-2016	Kleiner, Jeffrey B.	
	8	9451986	09-27-2016	Stoffman, Michael R.	
	9	9668781	06-06-2017	Stark, John G.	
	10	9700356	07-11-2017	Donner, Edward Jeffrey et al.	
	11	9757154	09-12-2017	Donner, Edward Jeffrey et al.	
	12	10492802	12-03-2019	Donner, Edward Jeffrey et al.	
	13	10646258	05-12-2020	Donner, Edward Jeffrey et al.	
	14	10682150	06-16-2020	Stark, John G.	
	15	20050080422	04-14-2005	Otte, John F. et al.	
	16	20110238181	09-29-2011	Trieu, Hai H.	

FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No.	Foreign Patent Document *Country Code-Number-Kind Code* Example: JP 1234567 AI	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear	T[1]
				.		

NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[1]
	17	United Stated Patent and Trademark Office, Office Action for U.S. Appl. No. 17/063609, dated February 2, 2021	

T[1] - Place a check mark in this area when an English language Translation is attached.

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application No.	17/063,613
	Filing Date	10/05/2020
	First Named Inventor	LaNeve, Sean
	Art Unit	3775
(Multiple sheets used when necessary)	Examiner	Sevilla, Christian Anthony
SHEET 2 OF 2	Attorney Docket No.	13438.008-12

CO-PENDING U.S. PATENT APPLICATIONS COMMONLY OWNED WITH THE PRESENT APPLICATION

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Examiner Initials	Cite No.	Serial No.	Filing Date MM-DD-YYYY	Inventor(s)	Pub. No.	Atty. Docket No.	Date(s) of Office Action(s) MM-DD-YYYY

Examiner Signature	Date Considered

***Examiner:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

T[1] - Place a check mark in this area when an English language Translation is attached.

SUPPLMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application No.	17/063,613
	Filing Date	10/05/2020
	First Named Inventor	LaNeve, Sean
	Art Unit	3775
	Examiner Name	Sevilla, Christian Anthony
	Attorney Docket No.	13438.008-12

CERTIFICATION STATEMENT

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OR

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☐ See attached certification statement.

☒ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Steve Kelly/	Date (YYYY-MM-DD)	2021-03-26
Name/Print	Stephen E. Kelly	Registration Number	59,973

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T[1] - Place a check mark in this area when an English language Translation is attached.

Electronic Patent Application Fee Transmittal

Application Number:	17063613
Filing Date:	05-Oct-2020
Title of Invention:	DRILL-LESS METHOD OF FUSING A SACROILIAC JOINT
First Named Inventor/Applicant Name:	Sean LaNeve
Filer:	Stephen E. Kelly/Lauren Forsythe
Attorney Docket Number:	13438.008-12

Filed as Small Entity

Filing Fees for Utility under 35 USC 111(a)

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

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
SUBMISSION- INFORMATION DISCLOSURE STMT	2806	1	130	130
		Total in USD ($)		**130**

Electronic Acknowledgement Receipt

EFS ID:	42290034
Application Number:	17063613
International Application Number:	
Confirmation Number:	3498
Title of Invention:	DRILL-LESS METHOD OF FUSING A SACROILIAC JOINT
First Named Inventor/Applicant Name:	Sean LaNeve
Customer Number:	141269
Filer:	Stephen E. Kelly/Lauren Forsythe
Filer Authorized By:	Stephen E. Kelly
Attorney Docket Number:	13438.008-12
Receipt Date:	26-MAR-2021
Filing Date:	05-OCT-2020
Time Stamp:	11:52:04
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	$130
RAM confirmation Number	E20213PB52210849
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	Information Disclosure Statement (IDS) Form (SB08)	13838_008_12_DomesticSuppl IDS_03262021.pdf	277248 b29ab611f8c54ae1cc064472a8ddc53b54e bd9aa	no	3
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
2	Non Patent Literature	13438_008_NonFinalOfficeActi on_dated_02022021.pdf	1131792 7112893c9c069717f53e0ce4e97459ef9c3f b90e	no	26
Warnings:					
Information:					
3	Fee Worksheet (SB06)	fee-info.pdf	30257 73b0b2f62a42b7f32e7776b662be6c0ecd7 8a152	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	1439297		

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

New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

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

PTO/SB/08 Equivalent

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT		
	Application No.	17/063,613
	Filing Date	10/05/2020
	First Named Inventor	LaNeve, Sean
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(Multiple sheets used when necessary)	Examiner	Sevilla, Christian Anthony
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U.S. PATENT DOCUMENTS

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	11	International Search Report and Written Opinion for International. Appl. No. PCT/US20/54312, dated February 8, 2021.	

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EXAMINER NOTE: Applicant respectfully requests the Examiner to consider whether the claims of any one or more of the following co-pending U.S. patent applications (which are commonly owned with the present application) create any issues of double patenting with respect to any of the claims of the present application; and, where relevant, to consider whether the disclosure of any one or more of the following co-pending applications creates any issues of patentability with respect to any of the claims of the present application. In addition, Applicant respectfully requests the Examiner to consider whether any office actions issued in the following co-pending applications create any issues of patentability with respect to any of the claims of the present application.

SPECIFICATION, DRAWINGS and CLAIMS: Except where indicated, each of the co-pending applications listed below is stored in the USPTO's IFW system. As provided in M.P.E.P. § 609.04(a), copies of the specifications, drawings and claims of these co-pending applications are not enclosed herewith.

Examiner Initials	Cite No.	Serial No.	Filing Date MM-DD-YYYY	Inventor(s)	Pub. No.	Atty. Docket No.	Date(s) of Office Action(s) MM-DD-YYYY

Examiner Signature	Date Considered

***Examiner:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

T[1] - Place a check mark in this area when an English language Translation is attached.

SUPPLMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application No.	17/063,613
	Filing Date	10/05/2020
	First Named Inventor	LaNeve, Sean
	Art Unit	3775
	Examiner Name	Sevilla, Christian Anthony
	Attorney Docket No.	13438.008-12

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☒ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☒ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Steve Kelly/	Date (YYYY-MM-DD)	2021-03-26
Name/Print	Stephen E. Kelly	Registration Number	59,973

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450**.

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference		FOR FURTHER ACTION
13438-008.17		see Form PCT/ISA/220 as well as, where applicable, item 5 below.
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/US2020/054312	05 October 2020	04 October 2019
Applicant		
PAIN TEQ, LLC		

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

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

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

1. **Basis of the report**

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

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

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

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

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

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

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

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

☒ the text is approved as submitted by the applicant.

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

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

☒ the text is approved as submitted by the applicant.

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

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

a. the figure of the **drawings** to be published with the abstract is Figure No. 2

☒ as suggested by the applicant.

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

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

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

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2020/054312

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61F 2/44; A61B 17/70; A61F 2/30; A61F 2/46 (2021.01)
CPC - A61F 2/447; A61F 2/442; A61F 2/4465; A61F 2/4611 (2021.01)

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
see Search History document

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
see Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2008/0249569 A1 (WAUGH et al) 09 October 2008 (09.10.2008) entire document	1-8
A	US 10,219,912 B2 (CTL MEDICAL CORPORATION) 05 March 2019 (05.03.2019) entire document	1-8
A	US 8,128,700 B2 (DELURIO et al) 06 March 2012 (06.03.2012) entire document	1-8
A	US 8,403,991 B2 (ULLRICH, JR. et al) 26 March 2013 (26.03.2013) entire document	1-8

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

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

Date of the actual completion of the international search	Date of mailing of the international search report
07 January 2021	08 FEB 2021
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, VA 22313-1450 Facsimile No. 571-273-8300	Authorized officer Blaine R. Copenheaver Telephone No. PCT Helpdesk: 571-272-4300

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To: STEPHEN E. KELLY
HILL WARD HENDERSON, P.A.
101 EAST KENNEDY BOULEVARD, SUITE 3700
TAMPA, FL 33602

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)*	08 FEB 2021
Applicant's or agent's file reference 13438-008.17	**FOR FURTHER ACTION** See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US2020/054312	05 October 2020	04 October 2019

International Patent Classification (IPC) or both national classification and IPC
IPC(8) - A61F 2/44; A61B 17/70; A61F 2/30; A61F 2/46 (2021.01)
CPC - A61F 2/447; A61F 2/442; A61F 2/4465; A61F 2/4611 (2021.01)

Applicant PAIN TEQ, LLC

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

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

2. **FURTHER ACTION**

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

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

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

Name and mailing address of the ISA/US	Date of completion of this opinion	Authorized officer
Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, VA 22313-1450 Facsimile No. 571-273-8300	07 January 2021	Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 Telephone No. 571-272-4300

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2020/054312

Box No. I Basis of this opinion

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

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

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

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

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

   a. ☐ forming part of the international application as filed:

      ☐ in the form of an Annex C/ST.25 text file.

      ☐ on paper or in the form of an image file.

   b. ☐ furnished together with the international application under PCT Rule 13*ter*.1(a) for the purposes of international search only in the form of an Annex C/ST.25 text file.

   c. ☐ furnished subsequent to the international filing date for the purposes of international search only:

      ☐ in the form of an Annex C/ST.25 text file (Rule 13*ter*.1(a)).

      ☐ on paper or in the form of an image file (Rule 13*ter*.1(b) and Administrative Instructions, Section 713).

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

5. Additional comments:

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2020/054312

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

1. Statement

Novelty (N)	Claims	1-8	YES
	Claims	None	NO
Inventive step (IS)	Claims	None	YES
	Claims	1-8	NO
Industrial applicability (IA)	Claims	1-8	YES
	Claims	None	NO

2. Citations and explanations:

Claims 1-8 lack an inventive step under PCT Article 33(3) as being obvious over Waugh et al. (hereinafter Waugh).

Regarding Claim 1, Waugh discloses an allograft implant for fusing a sacroiliac joint (Title; Abstract; Para. [0005] Another example would be a sacrum and one vertebra), the allograft implant comprising: a body having a proximal end (Fig. 4 at the end where clip 104 attaches), a distal end (Fig. 4 near element 114), and a length disposed therebetween (Fig. 4 shows a length between 114 and where clip 104 attaches), the distal end having a rounded nose (Fig. 4 shows the distal end 114 being a rounded nose); two sides (Fig. 4 shows the device having 2 sides 112a and 112b), each side comprising a groove beginning at the proximal end of the body and continuing along each of the two sides for at least part of the length (Fig. 4 at groove 122), the distance between the two sides defining a width (W) of the body (Fig. 4 shows the distance between 112a and 112b having a width); two opposing faces (Fig. 4 shows two opposing faces at 108 and 110), each face having one or more anti-migration features (Fig. 4 shows anti-migration features on the face), and each face configured for abutting contact with a sacrum or an ilium of the sacroiliac joint (Para. [0005] Another example would be a sacrum and one vertebra); a graft window disposed between each face (Fig. 4 shows a graft window at 118), the graft window providing passage through the body between the two opposing faces (Fig. 4 shows the window as an open passage between the two faces), wherein a portion of the body located between the graft window and each of the sides defines a wall (Fig. 4 shows an inner wall of the window), and wherein the graft window has a cross-sectional area (Fig. 4 shows the graft window having a cross-sectional area); and each opposing face that makes contact with the sacrum or the ilium of the sacroiliac joint (Para. [0005] Another example would be a sacrum and one vertebra), but fails to explicitly disclose the allograft implant including herein the graft window has a cross-sectional area that is: about 35% to about 40% of a first cross-sectional area of the body; and about 60% of an area of each opposing face that makes contact with the sacrum or the ilium of the sacroiliac joint.
It would have been obvious to one of ordinary skill in the art at the time the invention was made to an allograft implant including herein the graft window has a cross-sectional area that is: about 35% to about 40% of a first cross-sectional area of the body; and about 60% of an area of each opposing face that makes contact with the sacrum or the ilium of the sacroiliac joint, since where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. The motivation for doing so would have been to design an implant to have a higher volume of allograft to improve tissue growth.

Regarding Claim 2, Waugh discloses the allograft implant of claim 1, wherein the graft window is unobstructed by internal or intermediate supports (Fig. 4 shows the window open and unobstructed).

Regarding Claim 3, Waugh discloses the allograft implant of claim 1, wherein the graft window has a proximal portion located in proximity to the grooves (Fig. 4 shows the graft window shown in proximity to the grooves), and a distal portion (Fig. 4 shows the distal portion of the device near 114), the proximal portion having a width (W1) that is less than a width (W2) of the distal portion (Fig. 4 shows the proximal end having a width less than the distal end), but fails to explicitly disclose the allograft implant including the proximal portion having a width (W1) that is less than a width (W2) of the distal portion such that the wall maintains a minimum thickness in a range of about 17% to about 20% of the width (W) of the body.
It would have been obvious to one of ordinary skill in the art at the time the invention was made to an allograft implant including the proximal portion having a width (W1) that is less than a width (W2) of the distal portion such that the wall maintains a minimum thickness in a range of about 17% to about 20% of the width (W) of the body, since where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. The motivation for doing so would have been to design an implant to have a higher volume of allograft to improve tissue growth.

Regarding Claim 4, Waugh discloses the allograft implant of claim 2, wherein the graft window has a proximal portion located in proximity to the grooves (Fig. 4 shows the graft window shown in proximity to the grooves), and a distal portion (Fig. 4 shows the distal portion of the device near 114), but fails to explicitly disclose the allograft implant including the proximal portion having a width (W1) that is less than a width (W2) of the distal portion such that the wall maintains a minimum thickness in the range of about 17% to about 20% of the width (W) of the body.
It would have been obvious to one of ordinary skill in the art at the time the invention was made to an allograft implant including the proximal portion having a width (W1) that is less than a width (W2) of the distal portion such that the wall maintains a minimum thickness in a range of about 17% to about 20% of the width (W) of the body, since where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. The motivation for doing so would have been to design an implant to have a higher volume of allograft to improve tissue growth.

Regarding Claim 5, Waugh discloses the allograft implant of claim 1, wherein the proximal end of the body comprises a taper that reduces a second cross-sectional area of the body (Fig. 4 shows the proximal end having a taper that results in a different cross sectional area).

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2020/054312

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of:

Regarding Claim 6, Waugh discloses the allograft implant of claim 5, wherein the graft window is unobstructed by internal or intermediate supports (Fig. 4 shows the window open and unobstructed).

Regarding Claim 7, Waugh discloses the allograft implant of claim 5, wherein the graft window has a proximal portion located in proximity to the grooves (Fig. 4 shows the graft window shown in proximity to the grooves), and a distal portion (Fig. 4 shows the distal portion of the device near 114), the proximal portion having a width (W1) that is less than a width (W2) of the distal portion (Fig. 4 shows the proximal end having a width less than the distal end), but fails to explicitly disclose the allograft implant including the proximal portion having a width (W1) that is less than a width (W2) of the distal portion such that the wall maintains a minimum thickness in a range of about 17% to about 20% of the width (W) of the body.
It would have been obvious to one of ordinary skill in the art at the time the invention was made to an allograft implant including the proximal portion having a width (W1) that is less than a width (W2) of the distal portion such that the wall maintains a minimum thickness in a range of about 17% to about 20% of the width (W) of the body, since where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. The motivation for doing so would have been to design an implant to have a higher volume of allograft to improve tissue growth.

Regarding Claim 8, Waugh discloses the allograft implant of claim 7, wherein the graft window has a proximal portion located in proximity to the grooves (Fig. 4 shows the graft window shown in proximity to the grooves), and a distal portion (Fig. 4 shows the distal portion of the device near 114), the proximal portion having a width (W1) that is less than a width (W2) of the distal portion (Fig. 4 shows the proximal end having a width less than the distal end), but fails to explicitly disclose the allograft implant including the proximal portion having a width (W1) that is less than a width (W2) of the distal portion such that the wall maintains a minimum thickness in a range of about 17% to about 20% of the width (W) of the body.
It would have been obvious to one of ordinary skill in the art at the time the invention was made to an allograft implant including the proximal portion having a width (W1) that is less than a width (W2) of the distal portion such that the wall maintains a minimum thickness in a range of about 17% to about 20% of the width (W) of the body, since where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. The motivation for doing so would have been to design an implant to have a higher volume of allograft to improve tissue growth.

Claims 1-8 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

Search History:

Limited Classification Search

The Patent Analyst performed a limited classification search within the following US, IPC, CPC, ECLA, or F-Term classification areas:

CPC Class/Subclass(es): A61F 2/447; A61F 2/442; A61F 2/4465; A61F 2/4611 (2021.01)

IPC (8) Class/Subclass(es): A61F 2/44; A61B 17/70; A61F 2/30; A61F 2/46 (2021.01)

U.S. Class/Subclass(es): 606/249; 623/17.15; 623/17.16

See Global Search Results.

Global Patent Literature Text Search

The Patent Analyst performed the following global text search, which was not limited by classification but may or may not have been limited by other criteria:

Questel Orbit: https://www.orbit.com

#	Search query	Results
1	((ALLOGRAFT IMPLANT)/TI/AB/CLMS/DESC/ODES/OBJ/ICLM/KEYW/TX AND (SACROILIAC)/TI/AB/CLMS/DESC/ODES/OBJ/KEYW/TX AND (GRAFT 4W WINDOW)/TI/AB/OBJ/ADB/ICLM)	0
2	((ALLOGRAFT)/TI/AB/CLMS/DESC/ODES/OBJ/ICLM/KEYW/TX AND (SACROILIAC)/TI/AB/CLMS/DESC/ODES/OBJ/KEYW/TX AND (GRAFT 4W WINDOW)/TI/AB/OBJ/ADB/ICLM)	3
3	((ALLOGRAFT)/TI/AB/CLMS/DESC/ODES/OBJ/ICLM/KEYW/TX AND (SACRUM OR ILIUM)/TI/AB/CLMS/DESC/ODES/OBJ/KEYW/TX AND (WINDOW)/TI/AB/OBJ/ADB/ICLM)	20
4	((ALLOGRAFT 4W IMPLANT)/TI/AB/CLMS/DESC/ODES/OBJ/ICLM/KEYW/TX AND (WINDOW)/TI/AB/CLMS/DESC/ODES/OBJ/KEYW/TX)	75
5	..SIMILARITY SS 4 RANKED 1	31798
6	5 AND (ALLOGRAFT)/TI/AB/CLMS/DESC/ODES/OBJ/KEYW/TX	3982
7	6 AND (WINDOW)/TI/AB/CLMS/DESC/ODES/OBJ/KEYW/TX	614
8	7 AND (GROOVE?)/TI/AB/CLMS/DESC/ODES/OBJ/KEYW/TX	377
9	8 AND (SACRUM)/TI/AB/CLMS/DESC/ODES/OBJ/KEYW/TX	67
10	((PAIN 1D TEQ)/PA/OPA)	0
11	((HILL 1D WARD 1D HENDERSON)/IN/OIN/INH/INV)	0
12	((HILL 1D WARD 1D HENDERSON)/RP/ORP/RPH/REP)	12

13	(US8128700 OR US8403991 OR US9198772 OR US10219912 OR US20080249569)/PN	5
14	..CITB NOSOURCE SS 13 RANKED	432
15	..CITF NOSOURCE SS 13 RANKED	297
16	(623017160 OR 623017150 OR 606249000)/PCL	2565
17	(A61F-002/44 OR A61F-002/30 OR A61B-017/70 OR A61F-002/46)/IPC	37124
18	(A61F-002/44/7 OR A61F-002/44/65 OR A61F-002/46/11 OR A61F-002/44/2)/CPC	5343
19	(16 OR 17 OR 18) AND (ALLOGRAFT)/TI/AB/CLMS/DESC/ODES/OBJ/KEYW/TX	3463
20	19 AND (WINDOW?)/TI/AB/CLMS/DESC/ODES/OBJ/KEYW/TX	643
21	20 AND (GROOVE?)/TI/AB/CLMS/DESC/ODES/OBJ/KEYW/TX	417
22	21 AND (SACRUM)/TI/AB/CLMS/DESC/ODES/OBJ/KEYW/TX	71

Google Patents: https://patents.google.com

#	Search query	Results
1	sacrum allograft implant with a window	2,080
2	sacroiliac allograft implant with a window	7,244
3	sacrum allograft implant with a window and anti-slip	348
4	sacrum allograft implant with a window and grooves	1,016

Computer Accessed Text Databases Searched

The Patent Analyst searched the following computer accessed text databases:

PubMed.gov (NCBI): http://www.ncbi.nlm.nih.gov/pubmed

#	Search query	Results
1	(((allograft) AND (window)) AND (groove)) AND (sacrum)	0
2	(((allograft) AND (window)) AND (sacrum)	0
3	(((allograft) AND (sacrum)	71

Google Scholar: https://scholar.google.com/

#	Search query	Results
1	sacrum allograft implant with a window	5,380
2	sacroiliac allograft implant with a window	1,580
3	sacrum allograft implant with a window and anti-slip	9
4	sacrum allograft implant with a window and grooves	1,100

Date search was completed: 07 January 2021

MP/DD

Electronic Patent Application Fee Transmittal

Application Number:	17063613
Filing Date:	05-Oct-2020
Title of Invention:	DRILL-LESS METHOD OF FUSING A SACROILIAC JOINT
First Named Inventor/Applicant Name:	Sean LaNeve
Filer:	Stephen E. Kelly/Lauren Forsythe
Attorney Docket Number:	13438.008-12

Filed as Small Entity

Filing Fees for Utility under 35 USC 111(a)

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

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
SUBMISSION- INFORMATION DISCLOSURE STMT	2806	1	130	130
		Total in USD ($)		**130**

Electronic Acknowledgement Receipt

EFS ID:	42290069
Application Number:	17063613
International Application Number:	
Confirmation Number:	3498
Title of Invention:	DRILL-LESS METHOD OF FUSING A SACROILIAC JOINT
First Named Inventor/Applicant Name:	Sean LaNeve
Customer Number:	141269
Filer:	Stephen E. Kelly/Lauren Forsythe
Filer Authorized By:	Stephen E. Kelly
Attorney Docket Number:	13438.008-12
Receipt Date:	26-MAR-2021
Filing Date:	05-OCT-2020
Time Stamp:	11:53:13
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	$130
RAM confirmation Number	E20213PB53400899
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	Information Disclosure Statement (IDS) Form (SB08)	13838_008_12_ForeignSupplIDS_03262021.pdf	205027 c0f87e4681a71ccaa605549f6380ad8aaa97aecd	no	2
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
2	Non Patent Literature	13438_008__ISRandWO_54312_dated_02082021.pdf	617821 d85a36d03353b4e76b950b2d2ba719bd0701b86d	no	8
Warnings:					
Information:					
3	Fee Worksheet (SB06)	fee-info.pdf	30256 2c089fc617651714e3ee44e8592e524980754811	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	853104		

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

New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

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

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
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NOTICE OF ALLOWANCE AND FEE(S) DUE

141269 7590 02/03/2021

Hill Ward Henderson, P.A.
101 East Kennedy Blvd., Suite 3700
Tampa, FL 33602

EXAMINER
SEVILLA, CHRISTIAN ANTHONY

ART UNIT	PAPER NUMBER
3775	

DATE MAILED: 02/03/2021

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/063,613	10/05/2020	Sean LaNeve	13438.008-12	3498

TITLE OF INVENTION: DRILL-LESS METHOD OF FUSING A SACROILIAC JOINT

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	05/03/2021

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

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

HOW TO REPLY TO THIS NOTICE:

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

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

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Maintenance fees are due in utility patents issuing on applications filed on or after Dec. 12, 1980. It is patentee's responsibility to ensure timely payment of maintenance fees when due. More information is available at www.uspto.gov/PatentMaintenanceFees.

PART B - FEE(S) TRANSMITTAL

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

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

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

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

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

141269 7590 02/03/2021

Hill Ward Henderson, P.A.
101 East Kennedy Blvd., Suite 3700
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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.
17/063,613	10/05/2020	Sean LaNeve	13438.008-12	3498

TITLE OF INVENTION: DRILL-LESS METHOD OF FUSING A SACROILIAC JOINT

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	05/03/2021

EXAMINER	ART UNIT	CLASS-SUBCLASS
SEVILLA, CHRISTIAN ANTHONY	3775	606-084000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

❑ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

❑ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-09 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

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

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

1 _____

2 _____

3 _____

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

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

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

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

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

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

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

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

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

❑ Applicant certifying micro entity status. See 37 CFR 1.29

❑ Applicant asserting small entity status. See 37 CFR 1.27

❑ Applicant changing to regular undiscounted fee status.

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

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

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/063,613	10/05/2020	Sean LaNeve	13438.008-12	3498

141269 7590 02/03/2021

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Tampa, FL 33602

EXAMINER	
SEVILLA, CHRISTIAN ANTHONY	
ART UNIT	PAPER NUMBER
3775	

DATE MAILED: 02/03/2021

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. 17/063,613	Applicant(s) LaNeve et al.	
	Examiner CHRISTIAN A SEVILLA	Art Unit 3775	AIA (FITF) Status Yes

-- 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 claims of 10/5/2020.
   ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

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

3. ☑ The allowed claim(s) is/are 1-16 . 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 _____.

/CHRISTIAN A SEVILLA/
Primary Examiner, Art Unit 3775

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. Authorization for this examiner's amendment was given in an interview with Stephen Kelly on 1/28/2021.

The application has been amended as follows:

In claim 1, line 6: deleted "connected by a working channel"

In claim 1, line 10: replaced "sacral contour seated" with ---sacral contour is seated---

In claim 1, line 10: replaced "iliac contour seated" with ---iliac contour is seated---

In claim 1, line 11: replaced "the ilium" with ---an ilium---

The following is an examiner's statement of reasons for allowance: The claims distinguish over closest prior art cited in the 892. The claims in the instant application have not been rejected using prior art because no references, or reasonable combination thereof, could be found which disclose, or suggest, a method of forming an implant void in a sacroiliac joint comprising at least the steps of inserting working channel including arms and iliac/sacral contours and introducing abrading device including open tip and slap hammer. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTIAN A. SEVILLA whose telephone number is (571)270-5621. The examiner can normally be reached on Monday through Thursday, 8:00 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, ***please contact*** **the examiner's supervisor, KEVIN T. TRUONG,** ***at*** 571-272-4705. 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.

/CHRISTIAN A SEVILLA/
Primary Examiner, Art Unit 3775

Notice of References Cited	Application/Control No. 17/063,613	Applicant(s)/Patent Under Reexamination LaNeve et al.	
	Examiner CHRISTIAN A SEVILLA	Art Unit 3775	Page 1 of 3

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
*	A	US-20200390566-A1	12-2020	Murray; James	A61F2/4657	1/1
*	B	US-20200315811-A1	10-2020	Cryder; Joel	A61F2/4455	1/1
*	C	US-9101371-B2	08-2015	Assell; Robert L.	A61B17/320016	1/1
*	D	US-20210015502-A1	01-2021	Sharifi-Mehr; Amir Ali	A61B90/50	1/1
*	E	US-20200253619-A1	08-2020	Gregory; Zachary	A61B17/1757	1/1
*	F	US-20180303624-A1	10-2018	Shoshtaev; Eugene	A61F2/4611	1/1
*	G	US-20160030191-A1	02-2016	McLuen; Gary R.	A61F2/447	623/17.16
*	H	US-20200179135-A1	06-2020	Castro; Frank	A61F2/4455	1/1
*	I	US-20140277204-A1	09-2014	Sandhu; Faheem A.	A61F2/447	606/86A
*	J	US-20190343640-A1	11-2019	Donner; Edward Jeffrey	A61F2/447	1/1
*	K	US-20200093612-A1	03-2020	Blain; Jason	A61F2/4601	1/1
*	L	US-20190021868-A1	01-2019	Ludwig; Stephen	A61F2/447	1/1
*	M	US-20150328012-A1	11-2015	Hansell; Noah	A61F2/4425	623/17.16

FOREIGN PATENT DOCUMENTS

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

NON-PATENT DOCUMENTS

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

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

Notice of References Cited	Application/Control No. 17/063,613	Applicant(s)/Patent Under Reexamination LaNeve et al.	
	Examiner CHRISTIAN A SEVILLA	Art Unit 3775	Page 2 of 3

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
*	A	US-20150073552-A1	03-2015	TO; JOHN	A61F2/4684	623/17.15
*	B	US-20150230937-A1	08-2015	Voellmicke; John C.	A61F2/4455	623/17.16
*	C	US-20150012097-A1	01-2015	IBARRA; Matthew	A61F2/442	623/17.15
*	D	US-20080009861-A1	01-2008	Stark; John G.	A61F2/4601	606/914
*	E	US-20090216238-A1	08-2009	Stark; John G.	A61F2/30988	606/96
*	F	US-20140088711-A1	03-2014	CHIN; KINGSLEY R.	A61F2/447	623/17.16
*	G	US-20140081279-A1	03-2014	Kleiner; Jeffrey B.	A61F2/4611	606/94
*	H	US-20110184518-A1	07-2011	Trieu; Hai H.	A61B17/562	623/17.11
*	I	US-20140031935-A1	01-2014	Donner; Edward Jeffrey	A61B17/7055	623/17.11
*	J	US-20190083271-A1	03-2019	Donner; Edward Jeffrey	A61B17/1757	1/1
*	K	US-20090312763-A1	12-2009	McCormack; Bruce M.	A61B17/8822	606/83
*	L	US-20120277801-A1	11-2012	Marik; Greg C.	A61B17/1671	606/279
*	M	US-20060178673-A1	08-2006	Curran; Peter	A61B17/92	606/100

FOREIGN PATENT DOCUMENTS

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

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	U	
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	W	
	X	

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

Notice of References Cited	Application/Control No. 17/063,613	Applicant(s)/Patent Under Reexamination LaNeve et al.	
	Examiner CHRISTIAN A SEVILLA	Art Unit 3775	Page 3 of 3

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
*	A	US-20060089633-A1	04-2006	L. Bleich; Jeffery	A61B90/04	606/32
	B					
	C					
	D					
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	L					
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FOREIGN PATENT DOCUMENTS

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

NON-PATENT DOCUMENTS

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

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/063,613	LaNeve et al.
	Examiner	Art Unit
	CHRISTIAN A SEVILLA	3775

CPC - Searched*		
Symbol	**Date**	**Examiner**
A61F2/4611	01/28/2021	cs
A61F2002/30995	01/28/2021	cs
A61B17/1671	01/28/2021	cs
A61B17/1604	01/29/2021	cs

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

US Classification - Searched*			
Class	**Subclass**	**Date**	**Examiner**

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	**Date**	**Examiner**
inventor search	01/28/2021	cs

Interference Search			
US Class/CPC Symbol	**US Subclass/CPC Group**	**Date**	**Examiner**
	(method and implant and void and sacroiliac and arms and abrading and slide adj hammer).clm.	01/28/2021	cs

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/063,613	LaNeve et al.
	Examiner	**Art Unit**
	CHRISTIAN A SEVILLA	3775

CPC								
Symbol							**Type**	**Version**
A61B	/	17	/	1671			F	2013-01-01
A61F	/	2	/	4611			I	2013-01-01
A61B	/	17	/	025			I	2013-01-01
A61B	/	2017	/	0256			A	2013-01-01
A61F	/	2002	/	4681			A	2013-01-01
A61B	/	17	/	1604			A	2013-01-01

CPC Combination Sets								
Symbol					**Type**	**Set**	**Ranking**	**Version**
	/		/					

NONE		Total Claims Allowed:	
(Assistant Examiner)	(Date)	16	
/CHRISTIAN A SEVILLA/ Primary Examiner, Art Unit 3775	28 January 2021	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	13 & 15

U.S. Patent and Trademark Office — Part of Paper No.: 20210128

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/063,613	LaNeve et al.
	Examiner	**Art Unit**
	CHRISTIAN A SEVILLA	3775

INTERNATIONAL CLASSIFICATION				
CLAIMED				
A61F	/	2	/	46
A61B	/	17	/	16

NON-CLAIMED				
	/		/	

US ORIGINAL CLASSIFICATION	
CLASS	**SUBCLASS**

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

NONE		**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	16	
/CHRISTIAN A SEVILLA/ Primary Examiner, Art Unit 3775	28 January 2021	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	13 & 15

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/063,613	LaNeve et al.
	Examiner	**Art Unit**
	CHRISTIAN A SEVILLA	3775

☑ 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

NONE		**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	16	
/CHRISTIAN A SEVILLA/ Primary Examiner, Art Unit 3775	28 January 2021	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	13 & 15

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S1	22,458	(A61F2/4611).cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2021/01/25 11:02
S2	645	(A61F2002/30995).cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2021/01/25 11:03
S4	10,537	(A61B17/1671).cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2021/01/25 15:08
S5	0	(LaNeve near2 Sean).in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2021/01/25 16:18
S6	17	(Girsch near2 Charles).in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2021/01/25 16:18
S7	0	(Girsch near2 Chris).in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2021/01/25 16:19

S8	0	"17063613"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2021/01/26 09:00
S9	0	"17063613"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2021/01/28 13:56
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S11	0	(2019/0083271).CCLS.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2021/01/28 14:44
S12	4	"20190083271"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2021/01/28 14:45
S13	2	"20060178673"	US-PGPUB; USPAT; USOCR; FPRS; EPO;	OR	OFF	2021/01/28 14:46

			JPO; DERWENT; IBM_TDB			
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		9241798-$ | US-9375243-$ | US-9421109-$ | US-9492284-$ | US-9662128-$ | US-9795396-$ | US-9801732-$ | US-9808346-$ | US-9833321-$ | US-9883874-$ | US-9895176-$ | US-9949843-$ | US-D905232-$).DID.				
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S16	64	("20010049527" | "20030191474" | "20040267269" | "20050137600" | "20050159746" | "20050267482" | "20060111780" | "20060155289" | "20070123889" | "20070198020" | "20070260270" | "20080009861" | "20080009875" | "20080091199" | "20080114364" | "20080269754" | "20080294167" | "20090138053" | "20090216238" | "20090259261" | "20090319043" | "20100030216" | "20100131011" | "20100241123" | "20110028978" | "20110087294" | "20110098709" | "20110118796" | "20110264229" | "20110295272" | "20120323285" | "20130030456" | "5242444" | "5334205" | "5928239" | "6358251" | "6440138" | "6635059" | "6679886" | "6726690" | "6740090" | "6746451" | "6821276" | "6923813" | "6939351" | "7699849" | "7867233" | "7879038" | "7909827" | "7914545" | "8109957" | "8114084" | "8348950" | "D601711").PN. OR ("9101371").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/01/28 20:08

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EAST Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	0	(method and implant adj void and abrading adj device and slide adj hammer).clm.	US-PGPUB; USPAT	OR	OFF	2021/01/29 09:07
S18	0	(method and implant and void and sacroiliac and arms and abrading and slide adj hammer).clm.	US-PGPUB; USPAT	OR	OFF	2021/01/28 19:49

1/29/2021 9:33:06 AM
C:\Users\csevilla\Desktop\17063613.wsp

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BIB DATA SHEET

CONFIRMATION NO. 3498

SERIAL NUMBER	FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
17/063,613	10/05/2020 RULE	606	3775	13438.008-12

APPLICANTS
Pain TEQ, LLC, Tampa, FL;

INVENTORS
Sean LaNeve, Tampa, FL;
Charles Girsch, Tampa, FL;
Chris Girsch, Tampa, FL;

** **CONTINUING DATA** *************************
This application is a CIP of 16/851,840 04/17/2020
which claims benefit of 62/910,913 10/04/2019
This application 17/063,613 10/05/2020
claims benefit of 62/910,913 10/04/2019

** **FOREIGN APPLICATIONS** *************************

** **IF REQUIRED, FOREIGN FILING LICENSE GRANTED** ** ** SMALL ENTITY **
10/22/2020

Foreign Priority claimed ☐ Yes ☑ No 35 USC 119(a-d) conditions met ☐ Yes ☐ No Verified and Acknowledged /CHRISTIAN ANTHONY SEVILLA/ Examiner's Signature	☐ Met after Allowance Initials	STATE OR COUNTRY	SHEETS DRAWINGS	TOTAL CLAIMS	INDEPENDENT CLAIMS
		FL	23	16	1

ADDRESS

Hill Ward Henderson, P.A.
101 East Kennedy Blvd., Suite 3700
Tampa, FL 33602
UNITED STATES

TITLE

DRILL-LESS METHOD OF FUSING A SACROILIAC JOINT

FILING FEE RECEIVED		
830	FEES: Authority has been given in Paper No.____________ to charge/credit DEPOSIT ACCOUNT No.____________ for following:	☐ All Fees ☐ 1.16 Fees (Filing) ☐ 1.17 Fees (Processing Ext. of time) ☐ 1.18 Fees (Issue) ☐ Other ________________ ☐ Credit

PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application No.	17/063,613
	Filing Date	10/05/2020
	First Named Inventor	LaNeve, Sean
	Art Unit	3775
(Multiple sheets used when necessary)	Examiner	Sevilla, Christian Anthony
SHEET 1 OF 5	Attorney Docket No.	13438.008-12

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Examiner Initials	Cite No.	Document Number *Number - Kind Code (if known)* Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
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T[1] - Place a check mark in this area when an English language Translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /C.A.S/

PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application No.	17/063,613
	Filing Date	10/05/2020
	First Named Inventor	LaNeve, Sean
	Art Unit	3775
(Multiple sheets used when necessary)	Examiner	Sevilla, Christian Anthony
SHEET 2 OF 5	Attorney Docket No.	13438.008-12

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T[1] - Place a check mark in this area when an English language Translation is attached.

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PTO/SB/08 Equivalent

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(Multiple sheets used when necessary)	Examiner	Sevilla, Christian Anthony
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	66	10820917	11-03-2020	Sharifi-Mehr et al.	
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T[1] - Place a check mark in this area when an English language Translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /C.A.S/

PTO/SB/08 Equivalent

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	Art Unit	3775
(Multiple sheets used when necessary)	Examiner	Sevilla, Christian Anthony
SHEET 4 OF 5	Attorney Docket No.	13438.008-12

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Examiner Initials	Cite No.	Foreign Patent Document *Country Code-Number-Kind Code* Example: JP 1234567 AI	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear	T[1]
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Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[1]
	112	STEVEN P. COHEN, MD, Sacroiliac Joint Pain: A Comprehensive Review of anatomy, Diagnosis, and Treatment, Review Article, April 27, 2005, 1440-1453, volume 101, International Anesthesia Research Society, United States	
	113	K. A. GIANNIKAS, A. M. KHAN, M.T. KARSKI, H. A. MAXWELL, Sacroiliac joint fusion for chronic pain: a simple technique avoiding the use of metalwork, Journal, November 28, 2003, 253-256, Volume 13, Springer-Verlag, Greece	
	114	Captiva Spine, TransFasten Posterior Sacroiliac (SI) Joint Fusion System, available at, https://transfasten.captivaspine.com/si-joint-surgeon-providers/, last visited on January 5, 2021	
	115	United Stated Patent and Trademark Office, Office Action for U.S. Appl. No. 17/063,616, dated January 04, 2021.	

T[1] - Place a check mark in this area when an English language Translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /C.A.S/

PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT		
	Application No.	17/063,613
	Filing Date	10/05/2020
	First Named Inventor	LaNeve, Sean
	Art Unit	3775
(Multiple sheets used when necessary)	Examiner	Sevilla, Christian Anthony
SHEET 5 OF 5	Attorney Docket No.	13438.008-12

	116	International Search Report and Written Opinion for International. Appl. No. PCT/US20/54299, dated January 08, 2021.	
	117	International Search Report and Written Opinion for International. Appl. No. PCT/US20/54308, dated January 08, 2021	
	118	International Search Report and Written Opinion for International. Appl. No. PCT/US20/54290, dated January 21, 2021	

CO-PENDING U.S. PATENT APPLICATIONS COMMONLY OWNED WITH THE PRESENT APPLICATION

EXAMINER NOTE: Applicant respectfully requests the Examiner to consider whether the claims of any one or more of the following co-pending U.S. patent applications (which are commonly owned with the present application) create any issues of double patenting with respect to any of the claims of the present application; and, where relevant, to consider whether the disclosure of any one or more of the following co-pending applications creates any issues of patentability with respect to any of the claims of the present application. In addition, Applicant respectfully requests the Examiner to consider whether any office actions issued in the following co-pending applications create any issues of patentability with respect to any of the claims of the present application.

SPECIFICATION, DRAWINGS and CLAIMS: Except where indicated, each of the co-pending applications listed below is stored in the USPTO's IFW system. As provided in M.P.E.P. § 609.04(a), copies of the specifications, drawings and claims of these co-pending applications are not enclosed herewith.

Examiner Initials	Cite No.	Serial No.	Filing Date MM-DD-YYYY	Inventor(s)	Pub. No.	Atty. Docket No.	Date(s) of Office Action(s) MM-DD-YYYY
	119	16/851,840	04-/17-2020	Sean LaNeve Charles Girsch Chris Girsch	N/A	13438.008-10	N/A
	120	17/063,609	10-05-2020	Sean LaNeve Charles Girsch Chris Girsch	N/A	13438.008-11	N/A
	121	17/063,616	10-05-2020	Sean LaNeve Charles Girsch Chris Girsch	N/A	13438.008-13	01-04-2021 – Non-Final Office Action

Examiner Signature	/CHRISTIAN A SEVILLA/	Date Considered	01/28/2021

***Examiner:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

T[1] - Place a check mark in this area when an English language Translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /C.A.S/

PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application No.	17/063,613
	Filing Date	10/05/2020
	First Named Inventor	LaNeve, Sean
	Art Unit	3775
(Multiple sheets used when necessary)	Examiner	Sevilla, Christian Anthony
SHEET 1 OF 5	Attorney Docket No.	13438.008-12

U.S. PATENT DOCUMENTS

Examiner Initials	Cite No.	Document Number *Number - Kind Code (if known)* Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	1	D905,232	12-15-2020	Schifano, Troy et al.	
	2	4569338	02-11-1986	Edwards, Charles C.	
	3	5334205	08-02-1994	Cain, James E.	
	4	5722978	03-03-1998	Jenkins, Jr., Joseph Robert	
	5	6080155	06-27-2000	Michelson, Gary Karlin	
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	7	6648917	11-18-2003	Gerbec, Daniel E., et al.	
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	10	7229477	06-12-2007	Biscup, Robert S.	
	11	7648509	01-19-2010	Stark, John G.	
	12	8021392	09-20-2011	Petersen, David A.	
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	14	8157865	04-17-2012	Hochschuler, Stephen et al.	
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	22	8882818	11-11-2014	Vestgaarden, Tov Inge	
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T[1] - Place a check mark in this area when an English language Translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT					
				Application No.	17/063,613
				Filing Date	10/05/2020
				First Named Inventor	LaNeve, Sean
				Art Unit	3775
(Multiple sheets used when necessary)				Examiner	Sevilla, Christian Anthony
SHEET 2 OF 5				Attorney Docket No.	13438.008-12

	32	9492284	11-15-2016	Ginn, Richard S. et al.	
	33	9662128	05-30-2017	Reiley, Mark A.	
	34	9795396	10-24-2017	Donner, Edward Jeffrey	
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	38	9883874	02-06-2018	Vestgaarden, Tov Inge	
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	44	10149764	12-11-2018	Stark, John G.	
	45	10166033	01-01-2019	Reiley, Mark A. et al.	
	46	10194962	02-05-2019	Schneider, Brett W et al.	
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	48	10206739	02-19-2019	Godara, Neil et al.	
	49	10219841	03-05-2019	Compton, Robert A.	
	50	10245158	04-02-2019	Song Kwang Yong	
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	54	10314710	06-11-2019	Donner, Edward Jeffrey et al.	
	55	10321945	06-18-2019	Schifano, Troy et al.	
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	59	10555818	02-11-2020	McConnell, Jeffrey R. et al.	
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	61	10744003	08-18-2020	Ryan Robert et al.	
	62	10751196	08-25-2020	Schifano, Troy et al.	
	63	10765532	09-08-2020	Ashleigh, Michael et al.	
	64	10765532	09-08-2020	Ashleigh, Michael et al.	

T[1] - Place a check mark in this area when an English language Translation is attached.

PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT		
	Application No.	17/063,613
	Filing Date	10/05/2020
	First Named Inventor	LaNeve, Sean
	Art Unit	3775
(Multiple sheets used when necessary)	Examiner	Sevilla, Christian Anthony
SHEET 3 OF 5	Attorney Docket No.	13438.008-12

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	71	20060178673	08-10-2006	Curran, Peter et al.	
	72	20070156241	07-05-2007	Reiley, Mark A. et al.	
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	79	20110098817	4/28/2011	Eckhardt, Jason J.	
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	82	20120083883	04-05-2012	Ginn, Richard S.	
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	86	20130218215	08-22-2013	Ginn, Richard S. et al.	
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	91	20150250612	09-10-2015	Schifano, Troy et al.	
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	94	20170245999	08-31-2017	Ginn, Richard S. et al.	
	95	20180036017	02-08-2018	Donner, Edward Jeffery et al.	
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T[1] - Place a check mark in this area when an English language Translation is attached.

PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT		
	Application No.	17/063,613
	Filing Date	10/05/2020
	First Named Inventor	LaNeve, Sean
	Art Unit	3775
(Multiple sheets used when necessary)	Examiner	Sevilla, Christian Anthony
SHEET 4 OF 5	Attorney Docket No.	13438.008-12

	99	20190133613	05-09-2019	Reiley, Mark A. et al.	
	100	20190262010	08-29-2019	Cerundolo, Daniel et al.	
	101	20190336292	11-07-2019	AKSU, Kenan	
	102	20200029979	01-30-2020	Donner, Edward Jeffrey et al.	
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	104	20200138589	05-07-2020	Abbasi, Hamid R.	

FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No.	Foreign Patent Document *Country Code-Number-Kind Code* Example: JP 1234567 AI	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear	T[1]
	105	AU 756550	05-23-2002	Karlin Technology, Inc.		
	106	CN110123436	8-16-2019	Li Yong et al.		
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	109	WO/2019137626	7-18-2019	Bake, Nina et al.		
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	111	AU 726979	10-01-1998	Michelson, Gary Karlin		

NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[1]
	112	STEVEN P. COHEN, MD, Sacroiliac Joint Pain: A Comprehensive Review of anatomy, Diagnosis, and Treatment, Review Article, April 27, 2005, 1440-1453, volume 101, International Anesthesia Research Society, United States	
	113	K. A. GIANNIKAS, A. M. KHAN, M.T. KARSKI, H. A. MAXWELL, Sacroiliac joint fusion for chronic pain: a simple technique avoiding the use of metalwork, Journal, November 28, 2003, 253-256, Volume 13, Springer-Verlag, Greece	
	114	Captiva Spine, TransFasten Posterior Sacroiliac (SI) Joint Fusion System, available at, https://transfasten.captivaspine.com/si-joint-surgeon-providers/, last visited on January 5, 2021	
	115	United Stated Patent and Trademark Office, Office Action for U.S. Appl. No. 17/063,616, dated January 04, 2021.	

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	First Named Inventor	LaNeve, Sean
	Art Unit	3775
(Multiple sheets used when necessary)	Examiner	Sevilla, Christian Anthony
SHEET 5 OF 5	Attorney Docket No.	13438.008-12

	116	International Search Report and Written Opinion for International. Appl. No. PCT/US20/54299, dated January 08, 2021.	
	117	International Search Report and Written Opinion for International. Appl. No. PCT/US20/54308, dated January 08, 2021	
	118	International Search Report and Written Opinion for International. Appl. No. PCT/US20/54290, dated January 21, 2021	

CO-PENDING U.S. PATENT APPLICATIONS COMMONLY OWNED WITH THE PRESENT APPLICATION

EXAMINER NOTE: Applicant respectfully requests the Examiner to consider whether the claims of any one or more of the following co-pending U.S. patent applications (which are commonly owned with the present application) create any issues of double patenting with respect to any of the claims of the present application; and, where relevant, to consider whether the disclosure of any one or more of the following co-pending applications creates any issues of patentability with respect to any of the claims of the present application. In addition, Applicant respectfully requests the Examiner to consider whether any office actions issued in the following co-pending applications create any issues of patentability with respect to any of the claims of the present application.

SPECIFICATION, DRAWINGS and CLAIMS: Except where indicated, each of the co-pending applications listed below is stored in the USPTO's IFW system. As provided in M.P.E.P. § 609.04(a), copies of the specifications, drawings and claims of these co-pending applications are not enclosed herewith.

Examiner Initials	Cite No.	Serial No.	Filing Date MM-DD-YYYY	Inventor(s)	Pub. No.	Atty. Docket No.	Date(s) of Office Action(s) MM-DD-YYYY
	119	16/851,840	04-/17-2020	Sean LaNeve Charles Girsch Chris Girsch	N/A	13438.008-10	N/A
	120	17/063,609	10-05-2020	Sean LaNeve Charles Girsch Chris Girsch	N/A	13438.008-11	N/A
	121	17/063,616	10-05-2020	Sean LaNeve Charles Girsch Chris Girsch	N/A	13438.008-13	01-04-2021 – Non-Final Office Action

Examiner Signature	Date Considered

***Examiner:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

T[1] - Place a check mark in this area when an English language Translation is attached.

Electronic Acknowledgement Receipt

EFS ID:	41748771
Application Number:	17063613
International Application Number:	
Confirmation Number:	3498
Title of Invention:	DRILL-LESS METHOD OF FUSING A SACROILIAC JOINT
First Named Inventor/Applicant Name:	Sean LaNeve
Customer Number:	141269
Filer:	Stephen E. Kelly/Lauren Forsythe
Filer Authorized By:	Stephen E. Kelly
Attorney Docket Number:	13438.008-12
Receipt Date:	26-JAN-2021
Filing Date:	05-OCT-2020
Time Stamp:	17:31:46
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Foreign Reference	AU756550B2_with_abstract.pdf	5423008 a6dd26d611c444f339bae88d39cea920bd80c5bb	no	100

Warnings:

Information:					
2	Foreign Reference	CN110123436A_with_english_abstract.pdf	642489 7e3ab07e1eb50c879481d25f8b682fb892cdfbc4	no	12
Warnings:					
Information:					
3	Foreign Reference	FR_2727004_A1_with_english_abstract.pdf	346917 1320178226b1f240b28022c887e3b65d4b8bce46	no	12
Warnings:					
Information:					
4	Foreign Reference	WO2017066443A1.pdf	1612950 942ecc478c8eeea2966d825f96841d9edb907269	no	38
Warnings:					
Information:					
5	Foreign Reference	WO2019137626.pdf	4151664 b5b5a465eb911417238471e168c593f0fffc57d2	no	80
Warnings:					
Information:					
6	Foreign Reference	WO2018195406_A1.pdf	2642403 7be9ae91d8cb7ee72f45a55b9b6d88e73e765da0	no	70
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Information:					
7	Foreign Reference	AU726979B2_with_abstract.pdf	1969702 e039edfb9d70576ae9308595553307feb9f9e5d3	no	103
Warnings:					
Information:					
8	Non Patent Literature	Cohen_2005_Sacroiliac_Joint_Pain_A_Comprehensive_Review_of_Anatomy.pdf	426106 b2e2165e3cdb29a30c6ddb0837038bdc51a0b434	no	14
Warnings:					
Information:					

9	Non Patent Literature	SI_Joint_fusion_for_chronic_pain_2003.pdf	688298 5fa058f917ce84923ffd67e5ee95dbe07669e49f	no	4
Warnings:					
Information:					
10	Non Patent Literature	Captiva_Spine_Video_Screen_Shot.pdf	4331555 d60103c22dbbfbebc4b95f7adbd256973a96651d	no	17
Warnings:					
Information:					
11	Non Patent Literature	13438_008_13_NonFinalOfficeAction_01042021.pdf	815753 87c859e95994b9a177aaaf677fcc712bcd123af1	no	21
Warnings:					
Information:					
12	Non Patent Literature	13438_008_14_ISR_and_WO_MailDate_01082021.pdf	1401266 446a0cc2ebe2e40c1b2bd7e42fd5941e32d74718	no	19
Warnings:					
Information:					
13	Non Patent Literature	13438_008_15_ISR_and_WO_MailDate_01212021.pdf	3487421 5bd38ff447505adea5fd7e6788f2db5efedcc704	no	12
Warnings:					
Information:					
14	Non Patent Literature	13438_008_16_ISR_and_WO_MailDate_01082021.pdf	960158 4ef630476394156b9124f86a0e4c4294c6840e18	no	12
Warnings:					
Information:					
15	Transmittal Letter	13438_008_12_IDS_TRANSMITTAL_01262021.pdf	142086 4807c79c2c7cbbbcde1fe7eecdb1d5a55323f68f	no	2
Warnings:					
Information:					

16	Information Disclosure Statement (IDS) Form (SB08)	13438_008_12_IDS_01262021.pdf	274323 bd2b2967235ca77ac8957637a6822fdded93c237	no	5

Warnings:

Information:

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Total Files Size (in bytes):	29316099

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.

(12) PATENT
(19) AUSTRALIAN PATENT OFFICE

(11) Application No. **AU 200229321 B2**
(10) Patent No. **756550**

(54) Title
Method of inserting spinal implants

(51)[7] International Patent Classification(s)
A61B 017/88

(21) Application No: **200229321**

(22) Application Date: **2002.03.28**

(43) Publication Date : **2002.05.23**
(43) Publication Journal Date : **2002.05.23**
(44) Accepted Journal Date : **2003.01.16**

(62) Divisional of:
200116742

(71) Applicant(s)
Karlin Technology, Inc.

(72) Inventor(s)
Gary Karlin Michelson

(74) Agent/Attorney
PHILLIPS ORMONDE and FITZPATRICK,367 Collins Street,MELBOURNE VIC 3000

(56) Related Art
US 4142517

ABSTRACT

The application discloses a method for inserting a spinal implant between two adjacent vertebrae, the method including the steps of inserting a spinal distractor into a disc space between the two adjacent vertebrae, positioning a guard over said spinal distractor and into contact with the two adjacent vertebrae, forming, through said guard, an opening across the disc space and inserting said implant into the opening.

AUSTRALIA

Patents Act

COMPLETE SPECIFICATION
(ORIGINAL)

Class Int. Class

Application Number:
Lodged:

Complete Specification Lodged:
Accepted:
Published:

Priority

Related Art:

Name of Applicant:

Karlin Technology, Inc.

Actual Inventor(s):

Gary Karlin Michelson

Address for Service:

PHILLIPS ORMONDE & FITZPATRICK
Patent and Trade Mark Attorneys
367 Collins Street
Melbourne 3000 AUSTRALIA

Invention Title:

METHOD OF INSERTING SPINAL IMPLANTS

Our Ref : 665997
POF Code: 459955/459955

The following statement is a full description of this invention, including the best method of performing it known to applicant(s):

Method of Inserting Spinal Implants
Background of the Invention

This application is a divisional application of Australian patent application 16742/01, which in turn is a divisional application of Australian patent 726979. Australian patent 726979 is a divisional of Australian patent application 71399/94. The entire contents of Australian patent application 16742/01, Australian patent 726979 and Australian patent application 71399/94 are herein incorporated by reference.

1. Field of the Invention

The present invention relates to a method of inserting artificial fusion implants between the intervertebral space left remaining after the removal of a damaged spinal disc,

2. Description of the Prior Art

For the purpose of achieving long term stability to a segment of injured spine, a fusion (the joining together of two or more bones via a continuous bridge of incorporated bone) may be performed. Well-known to those skilled in such art is the interbody fusion wherein the disc is partially excised and bone placed within that space previously occupied by that disc material (between adjacent vertebrae) for the purpose of restoring a more normal spatial relationship, and to provide for stability; short term by mechanical support, and long term by the permanent cross bonding of bone from vertebra to vertebra.

For fusion to occur within the disc space, it is necessary to prepare the vertebrae to be fused by breaking through, or cutting into, the hardened outside plates of bone (the endplates) to allow the interposed bone graft to come into direct contact with the more vascular cancellous (spongy) bone, and to thereby trick the body into attempting to heal this induced, but controlled, "fracturing" by both bone production and the healing of the grafts to both opposed vertebral surfaces such that they become one continuous segment of bone.

The purpose of the present invention, is to provide a method of inserting an implant within the intervertebral space left after the removal of the disc material and permanently eliminate all motion at that location. The implant inserted by the method of the present invention can be space occupying within the disc interspace, rigid, self-stabilizing to resist dislodgement, stabilizing to the adjacent spinal vertebrae to eliminate local motion, and able to intrinsically participate in a vertebra to vertebra bony fusion so as to assure the permanency of the result.

At present, following the removal of a damaged disc, either bone or nothing is placed into the remaining space. Placing nothing into this space allows the space to collapse which may result in damage to the nerves; or the space may fill with scar tissue and eventually lead to a reherniation. The use of bone to fill the space is less than optimal in that bone obtained from the patient requires additional surgery and is of limited availability in its most useful form, and if obtained elsewhere, lacks living bone cells, carries a significant risk of infection, and is also limited in supply as it is usually obtained from accident victims. Furthermore, regardless of the source of the bone, it is only marginal structurally and lacks a means to either stabilize itself against dislodgement, or to stabilize the adjacent vertebrae.

An area of related prior art to be considered is that of devices designed to be placed within the vertebral interspace following the removal of a damaged disc, and seeking to eliminate further motion at that location.

Such a device is contained in Patent No. 4,501,269 issued to BAGBY which describes an implantable device and limited instrumentation. The method employed is as follows: a hole is bored transversely across the joint and a hollow metal basket of larger diameter than the hole is then pounded into the hole and then the hollow metal basket is filled with the bone debris generated by the drilling.

The differences between the BAGBY invention and the present invention are many fold and highly significant. These differences include the following:

1. Safety - The present invention utilises a system of completely guarded instrumentation so that all contiguous vital structures (e.g. large blood vessels, neural structures) are absolutely protected. The instrumentation used

in the method of the present invention also makes overpenetration by the drill impossible. Such overpenetration in the cervical spine, for example, would result in the total paralysis or death of the patient. In the thoracic spine, the result would be complete paraplegia. In the lumbar spine, the result would be paraplegia or a life-threatening perforation of the aorta, vena cava, or iliac vessels.

The method of the present invention can be utilized to atraumatically screw an implant into place while the BAGBY device, in contradistinction, is pounded into position. BAGBY describes that its implant is significantly larger in size than the hole drilled and must be pounded in. This is extremely dangerous and the pounding occurs directly over the spinal cord which is precariously vulnerable to percussive injury. Furthermore, while the method of the present invention can be utilized to insert an implant, for example in the lumbar spine, and away from the spinal cord and nerves. The BAGBY device must always be pounded directly towards the spinal cord.

Furthermore, since the BAGBY device is pounded into a smooth hole under great resistance, and lacking any specific design features to secure it, the device is highly susceptible to forceful ejection which would result in great danger to the patient and clinical failure. The method of the present invention, in contradistinction, can be carried out to securely screw an implant into place. Further, the implant can possess highly specialized locking threads to make accidental dislodgement impossible. Because of the proximity of the spinal cord, spinal nerves, and blood vessels, any implant dislodgement as might occur with the BAGBY device might have catastrophic consequences.

2. Broad applicability - The BAGBY device can only be inserted from the front of the vertebral column, however, in contrast, the method of the present invention can be utilized in the cervical, thoracic, and lumbar spine, and can be carried out to insert an implant from behind (posteriorly) in the lumbar spine. This is of great importance in that the purpose of these devices is in the treatment of disc disease and probably greater than 99 percent of all lumbar operations for the treatment of disc disease are performed from behind where the present invention can easily be utilized, but the BAGBY device, as per BAGBY'S description, cannot.

3. Disc removal - The BAGBY invention requires the complete removal of the disc prior to the drilling step, whereas the present invention eliminates the laborious separate process of disc removal and efficiently removes the disc and prepares the vertebral end plates in a single step.

4. Time required - The present invention saves time over the BAGBY invention since time is not wasted laboring to remove the disc prior to initiating the fusion. Also, with the present invention the procedure is performed through a system of guarded instrumentation, time is not wasted constantly placing and replacing various soft tissue retractors throughout the procedure.

5. Implant stability - Dislodgement of the implant would be a major source of device failure (an unsuccessful clinical result), and might result in patient paralysis or even death. As discussed, the BAGBY device lacks any specific means of achieving stability and since it is pounded in against resistance to achieve vertebral distraction, and is susceptible to forceful dislodgement by the tendency of the two distracted vertebrae, to return to their original positions squeezing out the device. The method of the present invention can be carried out to screw an implant into place. As there is no unscrewing force present between the vertebrae, compression alone cannot dislodge the implant.

b. Prior Art Instrumentations And Methods

The following is a history of the prior art apparatus and methods of inserting spinal implants:

In 1956, Ralph Cloward developed a method and instruments which he later described for preparing the anterior aspect (front) of the cervical spine, and then fusing it. Cloward surgically removed the disc to be fused across and then placed a rigid drill quide with a large foot plate and prongs down over an aligner rod and embedded said prongs into the adjacent vertebrae to maintain the alignment so as to facilitate the reaming out of the bone adjacent the disc spaces. As the large foot plate sat against the front of the spine, it also served as a fixed reference point to control the depth of drilling. The reaming left two

opposed resected arcs, one each, from the opposed vertebral surfaces, The tubular drill guide, which was placed only preliminary to the drilling, was thereafter completely removed. A cylindrical bony, dowel, significantly larger in diameter than the hole formed, was then pounded into the hole already drilled. Cloward's method of instrumentation was designed for, and limited to, use on the anterior aspect and in the region of the cervical spine only. The hole was midline, which would preclude its use posteriorly where the spinal cord would be in the way.

As the bone graft to be inserted in Cloward's method was necessarily larger in diameter than the hole drilled, the graft could not be inserted through the drill guide. This mandated the removal of the drill guide and left the graft insertion phase completely unprotected. Thus Cloward's method and instrumentation was inappropriate for posterior application. In addition, the failure to provide continuous protection to the delicate neural structures from the instruments, as well as the bony and cartilaginous debris generated during the procedure, made Cloward's method inappropriate for posterior application. Also, the drill guide described by Cloward could not be placed posteriorly within the spinal canal, as the foot plate would crush the nerves. Modifying Cloward's drill guide by removing the foot plate completely, would still leave the instrument unworkable as it would then lack stability, and would not be controllable for depth of seating. Nevertheless, Wilterberger, (Wilterberger, B,R., Abbott, K.H., "Dowel Intervertebral Fusion as Used in Lumbar Disc Surgery," The Journal of Bone and Joint Surgery, Volume 39A, pg. 234—292, 1957) described the unprotected drilling of a hole from the posterior into the lumbar spine between the nerve roots and across the disc space, and then inserting a stack of button-like dowels into that space. While Wilterberger had taken the Cloward concept of circular drilling and dowel fusion and applied it to the lumbar spine from a posterior, approach, he had not provided for an improved method, nor had he advanced the instrumentation so as to make that procedure sufficiently safe, and it rapidly fell into disrepute.

Crock (Crock, H,V., "Anterior Lumbar Interbody Fusion - Indications for its Use and notes on Surgical Technique," Clinical Orthopedics, Volume 165, pg. 157-l63, 1981) described his technique and instrumentation for Anterior Interbody Fusion of the lumbar spine, wherein he drilled two large holes side by

side across the disc space from anterior to posterior essentially unprotected and then pounded in two at least partially cylindrical grafts larger than the holes prepared.

A review of the prior art is instructive as to a number of significant deficiencies in regard to the method and instrumentation for the performance of Interbody Spinal Fusion utilizing drilling to prepare the endplates.

As the great majority of spinal surgery is performed in the lumbar spine and from posteriorly, a review of the prior art reveals a number of deficiencies in regard to the spine in general, and to the posterior approach to the lumbar spine specfically. These deficiencies include the:

1. Failure to protect the surrounding tissues throughout the procedure, specifically, prior to drilling and until after the insertion of the graft;

2. Failure to contain the debris, bony and cartilaginous, generated during the procedure;

3. Failure to optimize the contact of the cylindrical drill hole and bone graft, the mismatch in their diameters resulting in incongruence of fit;

4. Failure to determine the optimal drill size prior to drilling;

5. Failure to determine the optimal amount of distraction prior to drilling;

6. Inability to optimise the amount of distraction so as to restore the normal spatial relationships between adjacent vertebrae;

7. Inability to create sufficient working space within the spinal canal (between the nerve roots and the dural sac) to make the procedure safe;

8. Absent a foot plate on the drill guide, as necessitated by the close tolerances posteriorly, the inability to reliably insure that the drilling is parallel to the vertebral endplates;

9. The inability to insure equal bone removal from the opposed vertebral surfaces; and

10. The inability to determine within the spinal canal, the proper side by side positioning for dual drill holes.

The discussion of the background to the invention herein is included to explain the context of the invention. This is not to be taken as an admission that any of the material referred to was published, known or part of the common general knowledge in Australia as at the priority date of any of the claims.

BRIEF SUMMARY OF THE INVENTION

In one aspect the present invention is directed to a method for inserting a spinal implant between two adjacent vertebrae, the method including the steps of:

inserting a spinal distractor into a disc space between the two adjacent vertebrae;

positioning a guard over said spinal distractor and into contact with the two adjacent vertebrae;

forming, through said guard, an opening across the disc space; and

inserting said implant into the opening.

In another aspect the present invention is directed to a method for securing a hollow tubular sleeve to two adjacent vertebrae including:

inserting a spinal distractor in the disc space on one side of the vertebrae, said distractor having a flat shoulder portion abutting the vertebrae;

placing said hollow tubular sleeve having on one end engagement means for engaging two adjacent vertebrae and a circumferentially enlarged tubular back end, said back end having a raised crown portion, said sleeve being placed over said distractor, said distractor serving as a centering post and as an

alignment rod for said outer sleeve;

engaging a driver cap to said back end, said driver cap having a closed rear surface on one end and a circular front opening at the other end, said driver cap defining a first large recess within said circular opening for engaging the tubular back end of said outer sleeve and a second smaller recess for engaging said crown portion forming an internal shoulder between said first and second recesses;

applying an impaction force with an impacting means to said driver cap whereby said force is transmitted via said internal shoulder to said outer sleeve until said crown is seated within said second recess;

removing said driver cap from said back end; and

removing said distractor with a distractor pulling means leaving said outer sleeve in place.

In another aspect the present invention is directed to a method for securing a guard to two adjacent vertebrae of a spine, the method including the steps of:

inserting at least one spinal distractor into a disc space intermediate the two adjacent vertebrae;

placing said guard over said distractor;

positioning one end of said guard in contact with the spine; and

removing said distractor from said guard

In another aspect the present invention is directed to a method for securing a guard to two adjacent vertebrae of a spine, the method including the steps of:

inserting at least one alignment rod into a disc space intermediate the two adjacent vertebrae;

placing said guard over said rod, said rod serving to centre and align said guard;

positioning one end of said guard in contact with the spine; and

removing said rod from said guard.

In another aspect the present invention is directed to a method for inserting a spinal implant between two adjacent vertebra including:

inserting a spinal distractor in the disc on one side of the spinal column to provide for proper spacing of the disc space between the vertebra;

inserting over the spinal distractor a hollow tubular member having engagement means for engaging two adjacent vertebrae into the vertebrae;

passing a trephine through the tubular member and over the spinal distractor to drill a hole in the disc and a portion of the two adjacent vertebrae;

removing the trephine; inserting an implant in the vertebrae through the tubular member; and

removing said tubular member.

Other aspects of the present invention include the implantation of a series of artificial implants, the purpose of which is to participate in, and directly cause bone fusion across an intervertebral space following the excision of a damaged disc. Such implants are structurally load bearing devices, stronger than bone, capable of withstanding the substantial forces generated within the spinal

interspace. The devices of the present invention have a plurality of macro sized cells and openings, which can be loaded with fusion promoting materials, such as autogenous bone, for the purpose of materially influencing the adjacent vertebrae to perform a bony bond to the implants and to each other. The implant casing may be surface textured or otherwise treated by any of a number of known technologies to achieve a " bone ingrowth surface" to further enhance the stability of the implant and to expedite the fusion.

The devices of the present invention configured and designed so as to promote stability within the vertebral interspace and to resist being dislodged, and furthermore, to stabilise the adjacent spinal segments.

Another aspect of the present invention provides a method for Interbody Spinal Fusion utilising novel instrumentation, whereby a protective tubular member is placed prior to the drilling part of the procedure and is left in place until the graft is fully seated.

The apparatus and method of the present invention for preparing the vertebrae for insertion of the implant allows for the rapid and safe removal of the disc, preparation of the vertebrae, performance of the fusion, and internal stabilisation of the spinal segment.

In summary then, the various aspects of the present invention, provides for a single surgery providing for an integrated discectomy, fusion, and interbody internal spinal fixation.

DISCUSSION OF THE INSTRUMENTATION

The apparatus and method of the various aspects of the present invention may provide the following advantages:

1. The present invention is safer by providing protection of the surrounding tissues. An Outer Sleeve or guard places all of the delicate soft tissue structures, nerves, blood vessels, and organs outside of the path of the various sharp surgical instruments and the implant. Further, it is an improvement upon hand held retractors in that it occupies the least possible amount of area, avoids the stretching associated with manual retraction, provides for the retraction and shielding of the surrounding tissues in all directions circumferentially and simultaneously, and it does so exclusively with

smooth, curved surfaces.

2. The present invention is safer by providing protection against the danger of instrument or implant overpenetration.

3. The present invention is safer as the surgical site and wound are protected from the debris generated during the procedure.

4. The present invention is safer because the method provides for absolute protection to the soft tissues directly and from indirect injury by overpenetration. It makes safe the use of power instrumentation which is both more effective and efficient.

5. The present invention can maintain the vertebrae to be fused rigid throughout the procedure.

6. The present invention can hold the vertebrae to be fused aligned throughout the procedure.

7. The present invention can hold the vertebrae to be fused distracted throughout the procedure.

8. The present invention assures that all instruments introduced through the Outer Sleeve or guard are coaxial and equally centered through the disc space and parallel the endplates.

9. The present invention facilitates the implant insertion by countering the high compressive forces tending to collapse the interspace, which if left unchecked would resist the introduction and advancement of the implant and make stripping more likely.

10. The present invention extends the range and use of the procedure and similarly the interbody spinal implant itself by making the procedure safe throughout the spine.

11. The present invention increases the ability to use a specifically sized implant.

12. In the present invention the end of all the penetrating instrumentation may be blunt faced.

13. In the present invention all of the instruments may be stopped at a predetermined depth to avoid overpenetration.

14. The design of the Outer Sleeve or guard in the present invention may conform to the spacial limitations of the specific surgical site.

15. The design and use of a second or Inner Sleeve in the present invention allows for the difference in size between the inside diameter of the Outer Sleeve, and the outside diameter of the drill itself. This difference being necessary to accommodate the sum of the distraction to be produced, and the depth of the circumferential threading present of the implant.

16. In the present invention there can be provided a specially designed drill bit with a central shaft recess allows for the safe collection of the drilling products, which can then be removed without disturbing the Outer Sleeve or guard by removing the drill bit and Inner Sleeve as a single unit.

17. In the present invention there can be provided a specially designed trephine for re-moving a core of bone slightly smaller in diameter than the internal diameter of the implant cavity itself, however of a greater length.

18. In the present invention there can be provided a specially designed press for forcefully compressing and injecting the long core of autogenous bone into the implant, such that it extrudes through the implant itself.

19. In the present invention there can be provided a specially

designed driver extractor, which attaches to the implant and allows the implant to be either inserted or removed without itself dissociating from the implant, except by the deliberate disengagement of the operator.

Where predistraction is carried out as a step of the method of this invention, this provides a number of advantages.

20. The Distractor in the present invention is self-orienting acting as a directional finder.

21. The Distractor in the present invention is self-centralizing between the opposed vertebral surfaces acting as a centering post for the subsequent bone removal.

22. In the present invention predistraction increases the working space.

23. In the present invention predistraction assures the equal removal of bone from the adjacent vertebral surfaces.

24. In the present invention predistraction assures the exact congruence between the hole drilled and the device.

25. In the present invention predistraction assures that the drilling is parallel to the vertebral endplates.

26. In the present invention predistraction allows for the determination of the optimal distraction prior to drilling.

27. In the present invention predistraction allows for the verification of the correct prosthesis size prior to drilling.

28. In the present invention predistraction facilitates device insertion by relieving the compressive loads across the interspace which would resist implantation.

29. In the present invention predistraction decreases the likelihood of stripping the bone during insertion.

30. In the present invention predistraction provides for the side by side positioning, spacing, and parallelism required prior to the irrevocable event of drilling.

31. In the present invention predistraction provides for the rigid stabilization of the vertebrae opposed to the disc space throughout the surgical procedure.

32. In the present invention predistraction provides for an implant easier to insert as the compressive loads of the opposed vertebrae are held in check so that the device itself need not drive the vertebrae apart to be inserted.

33. In the present invention predistraction allows for the insertion of a more effective implant as more of the implant can be dedicated to its intended purpose and be full diameter, whereas without the benefit of predistraction and the ability to maintain the same, a significant portion of the forward end of the implant would need to be dedicated to the purpose of separating the opposing vertebrae.

34. The present invention allows for the use of an implant with a sharper thread or surface projections as there is no danger to the surrounding tissues.

35. The present invention allows for the implant to be fully preloaded as provided to the surgeon, or for the surgeon to load it with the material of his choice at the time of surgery.

36. The present invention allows for the loading of a spinal implant outside of the spinal canal and prior to implantation.

OBJECTS OF THE PRESENT INVENTION

It is an object of the present invention to provide an improved method of performing a discectomy, a fusion, and an internal stabilization of the spine, and specifically, all three of the above simultaneously and as a single procedure.

It is another object of the present invention to provide an improved method of performing a discectomy, a fusion, and an internal stabilization of the spine, which is both quicker and safer than is possible by previous methods.

It is another object of the present invention to provide an improved method of performing a discectomy, a fusion and an internal stabilization of the spine, to provide for improved surgical spinal implants.

It is another object of the present invention to provide an improved method of performing a discectomy, a fusion, and an internal stabilization of the spine, which provides for an improved system of surgical instrumentation

to facilitate the performance of the combined discectomy, fusion, and internal spinal stabilization.

It is another object of the present invention to provide an improved method of performing a discectomy, a fusion, and an internal stabilization of the spine procedures.

It is an object of the present invention to provide instrumentation and a method of spinal interbody arthrodesis that is faster, safer, and more efficacious than prior methods, and can effectively be performed in the cervical, thoracic, and lumbar spine anteriorly, as well as in the lower lumbar spine posteriorly.

It is a further object of the present invention to provide a means for inserting a spinal implant between adjacent vertebrae while maintaining their optimal spacing, positioning, and alignment.

These and other objects of the present invention will be apparent from review of the following specification and the accompanying drawings which illustrate and describe preferred embodiments of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a side view of the Long Distractor, of the present invention inserted into the intervertebral space.

Figure 2 is a side view of a Convertible Distractor assembly in relation to the spine.

Figure 3 is a perspective view of a high

retention Short Distractor of Figure 2.

Figure 3A is a side view of the high retention Short Distractor of Figure 2.

Figure 3B is a side view of an alternative Short Distractor with circumferential forward facing ratcheting.

Figure 3C is a top view of the alternative Short Distractor of Figure 3B.

Figure 3D is a perspective view of an alternative embodiment of a Short Distractor.

Figure 3E is a top view of the alternative distractor of Figure 3D.

Figure 3F is a side view of a further alternative rectangularized Short Distractor with knurled surfaces.

Figure 4 is a perspective view of a spinal segment (two vertebrae and an interposed disc) with a Short Distractor in place, with a portion of the upper vertebrae and disc cut away to show the Short Distractor on one side of the spine and the Long Distractor about to be placed contralaterally.

Figure 5 shows a side view of the Outer Sleeve in place over the Long Distractor, and about to receive the Driver Cap in preparation for being seated.

Figure 6 shows the Long Distractor, Outer Sleeve, and Driver Cap following the proper seating of the Outer Sleeve into the two adjacent vertebrae.

Figure 7A is a side view of the cervical Outer Sleeve being placed over a Long Distractor which is in place within the disc space anteriorly.

Figure 7B is a bottom view of the single Outer Sleeve of Figure 7A.

Figure 7C is a bottom view of a Dual Outer Sleeve.

Figure 7D is an enlarged side view of the proximal portion of Figure 7C.

Figure 7E is a bottom view of a Dual Driver Cap for driving two distractors.

Figure 7F is a side sectional view showing the Dual Outer Sleeve of Figures 7C and 7D, Distractors and Dual Cap of Figure 7E seated.

Figure 8 is a side view of the Outer Sleeve of Figure 7A centered on the Long Distractor and fully seated on the anterior aspect of the cervical spine.

Figure 9 is a perspective view of the Distractor Puller.

Figure 10 is a cutaway partial side view of the Proximal Puller engaging the extraction ring of the Long Distractor over the end of the Outer Sleeve.

Figure 10A is a side view of the Puller coupled to the Long Distractor just prior to its extraction.

Figure 10B is a posterior view of the proximal Outer Sleeve and a Short Distractor in place in regard to the vertebrae, disc and nerves.

Figure 11A is a side sectional view of the Drill and Inner Sleeve within the Outer Sleeve and drilling across the intervertebral space and cutting partially cylindrical arcs from the adjacent vertebrae.

Figure 11B is a sectional side view of preparation of the intervertebral space by the alternative "Trephine Method" showing the Distractor, Trephine, Inner Sleeve, and Outer Sleeve in place.

Figure 11C is a sectional side view as in Figure 11A, but showing the use of an alternative drilling conformation wherein the extended proximal portion is both distracting and self-centering.

Figure 11D is a side view of an instrument for removing arcs of bone from vertebrae following drilling.

Figure 12 is a perspective view of the surgical Tap.

Figure 13 is a side view of the Outer Sleeve and the surgical Tap fully threaded within the interspace.

Figure 14A is a side view of the bone harvesting Trephine and motor adapter.

Figure 14B is a perspective view of the implant Bone Loading Device.

Figure 14C is a perspective view of the Corkscrew bone freeing and extracting instrument.

Figure 15 is a partial perspective view of the Bone Loading Device in operation.

Figure 16 is a perspective view of the Implant Driver about to engage the spinal implant.

Figure 17 is a side view of the spinal implant being fully seated within the intervertebral space by means of the Driver apparatus in place within the Outer Sleeve.

Figure 18 is a side view of the lumbar spine

showing the end result of the device implantation via the posterior route.

Detailed Description of the Drawings And

Detailed Description of Method of Insertion

The following discussion will be in regard to application in the lumbar spine via the posterior approach. In its simplest form, the method of the present invention involves the following steps. The patient is placed on a spinal surgery frame, which allows for the distraction and alignment of the disc space to be fused. A bilateral posterior exposure of the interspace, with or without partial discectomy is then performed. Utilizing distractors the disc space is distracted, and a hollow Outer Sleeve is fitted over one of the distractors. The end of the Outer Sleeve has teeth for engaging the two adjacent vertebrae. The Outer Sleeve is driven into the vertebrae and the distractor is then removed. A hollow Inner Sleeve is then inserted into the Outer Sleeve and a stopped Drill is utilized to prepare the opposed vertebral surfaces. The Drill and the Inner Sleeve are removed as a single unit. The space is tapped if so required. The prepared spinal implant is then inserted via the Outer Sleeve utilizing a stopped inserter. The instruments are then removed and the procedure repeated on the contralateral side of the spine.

Detailed Description of the Preferred Embodiment

Step 1a. Prior to surgery, translucent implant templates appropriately adjusted for scale are superimposed on AP, lateral, and axial images of the interspace to be fused, for the purpose of selecting the optimal implant size and to determine the desired distraction.

Step 1b. The patient is preferably placed onto a spinal surgery frame capable of inducing both distraction and vertebral alignment.

Step 2. In the preferred embodiment, a standard bilateral (partial) discectomy is performed and any posterior lipping of the vertebral bodies adjacent the interspace is removed. Alternatively, no disc material need be removed. In the preferred embodiment, the interspace is exposed by performing bilateral paired semihemilaminotomies and resecting the inner aspects of the facet joints adjacent the spinal canal while preserving the supra and interspinous ligaments.

Step 3. Beginning on the first side, the dural sac and traversing nerve root at that level are retracted medially and a Long Distractor then inserted and impacted flush to the posterior vertebral bodies adjacent that interspace. Long Distractors with working ends of increasing diameter are then sequentially inserted until the optimal distraction is obtained. This optimal distraction not only restores the normal height of the interspace, but further achieves a balance wherein the tendency for the space to collapse is resisted, which in

urging the vertebral bodies apart is being equally resisted by the powerful soft tissue structures about the spinal segment including the outer casing of the disc (the annulus fibrosus), various ligaments, capsular structures, as well as the muscles and other soft tissue structures. This balanced distraction not only provides for the spatial restoration of the height of the interspace, but for considerable stability as the space now resists further distraction or collapse.

In the preferred embodiment, as the desired distraction is approached, the use of the solid bodied Long Distractors is terminated and a disassemblable Convertible Distractor is placed with tactile and/or radiographic confirmation of ideal distraction. The Convertible Distractor is then disassembled such that the Short Distractor portion is left in place and the ultra-low profile head portion being positioned adjacent to the canal floor and safely away from the neural structures. To insure that the Short Distractor remains in place until its removal is desired, various embodiments of the Short Distractor are available with varying degrees of resistance to dislodgment. In the preferred embodiment of the procedure, attention is then directed to the contralateral side of the spine.

Step 4. On the contralateral side of the same interspace the Long Distractor having at its working end the diameter matching the Short Distractor already in place, is then inserted. If however, due to an

asymmetrical collapse of the interspace it is then determined that greater distraction is required on the second side to achieve the optimal stability, then the appropriate Short Distractor would be placed on the second side. Then the Short Distractor would be removed from the first side and replaced with a larger Long Distractor so as to bring the interspace into balance.

In an alternative embodiment, the entire procedure is performed on the one side of the spine utilizing only the Long Distractor prior to repeating the procedure on the contralateral side of the spine. While this method can be performed in accordance with the remaining steps as described in the preferred embodiment, when utilized it is best performed using a Trephine which allows the Long Distractor to remain in place, thereby allowing for interspace distraction otherwise provided in the first method by the Short Distractor. This alternative method then requires the use of a Trephine over the Long Distractor in lieu of a reamer and is therefore called the "Trephine Method", which will be discussed in detail later.

Step 5. With the Short Distractor in place on the first side of the spine, and the matching Long Distractor in place on the second side of the spine, and with the dural sac and traversing nerve root safely retracted, the Outer Sleeve is placed over the Long Distractor and firmly impacted to its optimal depth using the Impaction Cap and a mallet. The Long Distractor is then removed.

Step 6. An Inner Sleeve is then placed within the Outer Sleeve, and the interspace is then prepared on that side by utilizing a Drill, Endmill, Reamer, or Trephine to drill, ream, or cut out the bone to be removed to either side, as well as any remaining interposed discal material. In the preferred method, utilizing a specially designed Endmill-Drill, it and the Inner Sleeve are removed as a unit, safely carrying away the bone and disc debris trapped within them from the spinal canal.

Step 7. If required, a thread forming Tap with penetration limiting means to control the depth of insertion, is then inserted through the Outer Sleeve.

Step 8. The prepared implant is then inserted utilizing the specialized Driver unit. It should be noted that the implant may be coated with, made of, and/or loaded with substances consistent with bony fusion. However, in the preferred embodiment, the implant is treated with bone promoting and inducing substances, but is loaded with materials suitable for participating in a fusion.

While substances both natural and artificial are covered by the present invention, the preferred embodiment is in regard to the use of the patient's own bone by the following method. A hollow Trephine is utilized to harvest a core of bone from the posterior superior aspect of the iliac crest adjacent the sacroiliac joint. This core of bone is at its outside diameter, slightly smaller than the inside diameter of the spinal implant to be loaded, but longer than the spinal implant. Utilizing an instrument

designed for that purpose, the core of bone is then injected from within the Trephine into the central cavity of the implant causing a superabundance of the bone material within the implant such that the bone material tends to press out through the openings communicating with the outside surface of the implant.

Step 9. Using the Driver Extractor instrument, the prepared implant is threaded into the prepared interspace. The instrumentation is removed from that side of the spine and attention is then redirected to the first side of the spine. A small retractor is utilized to move the dural sac and traversing nerve root medially and to protect them and allowing the direct visualization of the retained Short Distractor unit. Without removing the Short Distractor, it is reassembled to its shaft portion, essentially reconstituting itself into a Long Distractor. With the inserted implant now acting as the distractor on the opposite side, the Long Distractor is utilized to guide the Outer Sleeve down where it is impacted as described in Step 5.

Steps 6 & 7 are then repeated, completing the procedure at that level. The wound is then irrigated and closed in the routine manner.

Representative Example of The Preferred Method

Through preoperative templating of the patient's anterior posterior, lateral, and axially imaged MRI scan in conjunction with translucent overlays of the various sized

implants, the correct implant diameter and length are accurately assessed, as well as the correct amount of distraction needed to restore the interspace to its premorbid height. The patient is then properly positioned and a bilateral partial discectomy performed via paired semihemilaminotomies.

For the purpose of this example, it will be assumed that by preoperative assessment it was determined that the correct implant would have an external diameter of 18mm and be 26mm long. Further, the distraction necessary to restore the height of the interspace would be approximately 10mm. The dural sac and traversing nerve root would then be retracted medially and protected, while a Long Distractor having an outside diameter to the barrel portion corresponding to the implant to be inserted, that is 18mm, and having a diameter at the working end of perhaps 8mm, would be inserted. This then being found to be slightly smaller than optimal by direct observation, a Convertible Distractor having in its barrel portion an 18mm outside diameter, but having in its working portion a 10mm diameter would then be inserted. Direct observation and/or x-ray then confirming the ideal distraction, the Convertible Distractor would then be disassembled, the barrel and head portion removed, and the Short Distractor portion left deeply embedded and with its flanged head flat against the canal floor and deep to the neural structures. It would then be safe to allow the dural sac and nerve root to return to their normal positions, which would be

superficial to the flanged portion of the Short Distractor.

Attention would then be directed to the contralateral side. The dural sac and nerve root would then be retracted medially on this second side, and a Long Distractor with an 18mm diameter barrel portion and a 10mm working portion would then be inserted into the interspace and driven flush to the bone if necessary, such impaction imploding any osteophytes not already removed, and assuring that the shoulder portion of the barrel comes to lie flat against the posterior aspects of the adjacent bodies. With the dural sac and nerve root still safely retracted, the Outer Sleeve would then be placed over the Long Distractor and utilizing the Driver Cap and a mallet, seated to the optimal depth.

In the preferred embodiment, the Long Distractor is then removed and the Inner Sleeve is inserted into the Outer Sleeve. Since the purpose of the Inner Sleeve is to support the drill and allow for the increased size of the implant over the size of the drill, thus making it possible for the insertion of the implant to occur through the Outer Sleeve, the Inner Sleeve therefore measures 18mm in its outside diameter, and 16.6mm in its inside diameter. This allows it to fit within the Outer Sleeve, the diameter of which is 18.1 mm and to admit the drill bit which is 16.5mm in diameter.

Following the drilling procedure, the Drill and Inner Sleeve are removed as a single unit with the trapped

interposed cartilaginous and bony debris. The depth of drill penetration is preset and limited by the fixed rigid column of the Outer Sleeve. In this example, the space will be prepared to a depth of 28mm in anticipation of countersinking a 26mm long implant at least 2mm. If a Tap were to be utilized, it would be inserted at this time and be appropriate to the minor and major diameters of the implant to be inserted and as with the Drill, controlled for its depth of penetration. The spinal implant would then be prepared for implantation by utilizing a Trephine to harvest a core of posterior iliac bone greater than 30mm long and approximately 14.5mm in diameter.

Using the Bone Loading Device, this core of bone would be forcefully injected into the internal chamber of the spinal implant which would then be capped. Cap end forward, the fully loaded implant would then be attached to the Insertion Driver, down the Outer Sleeve and screwed into place with the depth of penetration limited by the Insertion instrument. The Insertion Driver is then unscrewed from the implant and removed from the Outer Sleeve. With the dural sac and nerve root retracted and protected, the Outer Sleeve would then be removed. This would complete the fusion procedure on that side, and then as described, the procedure would be repeated on the other (first) side of the same interspace.

Alternative Methods

An alternative and extremely useful method is the

"Trephine Method". Its advantages include that it may be used in conjunction with the preferred embodiment substituting the use of a hollow, tubular cutter, called a Trephine for the use of the Drill in Step 5 of the preferred embodiment. Additionally, it may be utilized so as to obviate the need for the placement of the Short Distractor and to allow the procedure to be effectively performed from start to finish on one side prior to initiating the procedure on the opposite side, and while nevertheless maintaining distraction at the site of the bone removal.

The following is a description of the "Trephine Method".

Having completed the exposure of the interspace on at least one side, the dural sac and nerve root are retracted. A Long Distractor differing from the Long Solid Bodied Distractor of the preferred embodiment only in that the barrel portion is of a precisely lesser diameter than the spinal implant. As in the preferred embodiment, the Outer Sleeve has an inner diameter only slightly greater than the implant to be inserted. Therefore, at this time, a first Inner Sleeve is inserted into the Outer Sleeve to make up the difference between the outside diameter of the Long Distractor and the inside diameter of the Outer Sleeve. With the Outer Sleeve and first Inner Sleeve thus assembled, they are placed over the Long Distractor and the Outer Sleeve is optimally seated using the Impaction Cap. The Cap and first Inner Sleeve are removed, but the Long

Distractor and Outer Sleeve are left in place.

With the Long Distractor maintaining optimal distraction and with the Outer Sleeve locking the vertebrae together so as to resist any movement of the vertebrae, a hollow, tubular cutter known as a Trephine is then inserted over the Long Distractor and its barrel portion and within the Outer Sleeve. The Trephine, which is stopped out to the appropriate depth, can then be utilized to cut equal arcs of bone from the opposed vertebral endplates.

Alternatively, a second Inner Sleeve may be placed within the Outer Sleeve prior to placing the Trephine over the Long Distractor and within that second sleeve. This second Inner Sleeve would be just greater in its internal diameter than the Long Distractor and just smaller in its outside diameter than the inner diameter of the Outer Sleeve. While it would provide enhanced stability to the Trephine, provision would then need to be made in the way of large flutes passing longitudinally or obliquely along the outer surface of the Distractor to its barrel portion to accommodate the bony and cartilaginous debris generated during the cutting procedure.

Following the use of the Trephine to the appropriate depth by either of these methods, the Trephine, the Long Distractor, and the second Inner Sleeve, if utilized, are all removed. Since the Trephine cuts two arcs of bone but does not ream them out, a shafted instrument with a perpendicular cutting portion at its working end is then inserted parallel to the disc space and

then rotated through an arc of motion cutting the bases of the two longitudinally cut arcs, thus freeing them for removal through the Outer Sleeve. The space may then be tapped if required, and the implant is inserted as per the preferred method. As already mentioned, the "Trephine Method" can be used with or without the use of the Short Distractor on the contralateral side.

Applications of Method in Other Areas of the Spine

The following method is the preferred embodiment for performing anterior interbody fusion in the thoracic and lumbar spines. It is also appropriate in the cervical spine when the width of the spine anteriorly is sufficient so that it is possible to place two implants side by side and such that each intrudes at least several millimeters into the substance of the opposed vertebrae and for the length of the implants.

The interspace to be fused is adequately exposed and the soft tissues and vital structures retracted and protected to either side. Visualization of the broad width of the interspace anteriorly is made possible by the absence of the neurological structures in relation to this aspect of the spine. The center line of the anterior aspect of the interspace is noted and marked. The disc is removed using first a knife and then curettes and rongeurs as needed. Alternatively, the disc may be left intact to be removed during the drilling stage of the procedure. However, as per the preferred embodiment of the procedure,

having removed the great mass of the nucleus and the greater portion of the annulus anteriorly, Long Distractors with progressively increasing diameters to their working ends are inserted into the interspace at a point midway between the central marking line and the lateral extent of the anterior aspect of the spine as visualized.

The Dual Outer Sleeve with its common Foot Plate and Retention Prongs is then inserted over either a singly placed Long Distractor and then the second Distractor placed, or is placed over both Distractors if already placed. The Dual Outer Sleeve is then seated firmly against the anterior aspect of the spine. Any spurs which would interfere with the flush seating of the Foot Plate to the anterior aspect of the spine should be removed prior to inserting the Long Distractors. Once the Outer Sleeve has been optimally seated, one of the Long Distractors is removed and in its place is inserted an Inner Sleeve and drill bit. The drill bit has as its outside diameter the minor diameter of the implant to be inserted. The Inner Sleeve is essentially equal in thickness to the difference between the minor and major diameters of the threaded implant.

A Stopped Drill is then utilized to prepare the opposed vertebral surfaces and to remove any remaining disc material interposed. If required, a Stopped Tap may be inserted through the Outer Sleeve and into the interspace to create a thread form. The properly prepared implant is then affixed to the Insertion Driver and passed through the

Outer Sleeve down into the interspace and inserted until its depth of penetration is limited by the stop on the Insertion Driver. With the implant itself now in a position to act as a distractor, the Long Distractor is then removed from the contralateral side and the procedure repeated. When both implants are firmly in place, the outer sleeve may then be removed. The amount of countersinking of the implants may then be adjusted under direct vision.

Detailed Description of the Preferred Embodiment

Method and Instrumentation

In the preferred embodiment, the disc (D) between adjacent vertebrae (V) is approached via bilateral paired semihemilaminotomies of the adjacent vertebrae. In the preferred embodiment the supraspinous ligament, the interspinous ligament, the spinous process, portions of the lamina, and most of the facet joints are preserved. However, while less desirable, these structures may be removed.

In the preferred method, a bilateral partial nuclear discectomy is then performed through bilateral openings created through the posterior aspect of the annulus fibrosus. While considered less desirable, disc excision can be delayed and performed simultaneously with the vertebral bone resection during the drilling procedure. Starting on the first side a dural nerve root retractor is placed such that the dural sac and lower nerve root are

retracted medially allowing exposure to one side of a portion of two adjacent vertebral bodies and the interposed disc posteriorly.

Referring now to Figure 1, preferably after removing some portion of nuclear disc material, a Long Distractor 100 is inserted under direct vision into the intervertebral space. The disc penetrating portion 102 is essentially cylindrical with a bullet-shaped front end 103 and a shoulder portion 104 where the penetrating portion 102 extends from barrel 106. The penetrating portion 102 urges the vertebral bodies apart, facilitating the introduction of the instruments. Long Distractors with sequentially increasing diameter penetrating portions 102 are then introduced. As the optimal diameter of penetrating portion 102 is achieved, the vertebral bodies to either side are forced into full congruence and thus become parallel, not only to the penetrating portion 102, but to each other. At this time, any remaining excrescences of bone of the posterior vertebral bodies adjacent the posterior disc which have not already been removed are flattened flush to the vertebral body by the forced impaction, such as by hitting with a hammer flat surface 109 of crown 110, driving the shoulder 104 against the lipped portions of vertebrae V. Because of the forced opposition of the vertebral endplates to portion 102 with optimal distraction, unit 100 will then come to lie absolutely perpendicular to the plane of the posterior bodies and absolutely parallel to the vertebral endplates,

allowing optimal alignment for the procedure to be performed.

Penetrating portion 102 is available in various diameters, but all are of a constant length, which is less than the known depth of the interspace. This combined with the circumferential shoulder 104, which is too large to fit within the interspace, protects against the danger of overpenetration. Barrel 106 is of the same diameter as the external diameter of the device to be implanted. A recessed portion 108 below the crown 110 allows for the Long Distractor 100 to be engaged by an extractor unit shown in Figure 9.

In the preferred embodiment, a Convertible Long Distractor 113 is used on the first side of the spine. As shown in Figures 2, the Convertible Long Distractor 113 has a barrel portion 152 separable from the Short Distractor portion 120. While the initial distraction may be performed with a solid Long Distractor, as the optimal distraction is approached the appropriate Convertible Long Distractor is utilized. The Convertible Long Distractor 113 consists of a Short Distractor portion 120 and a barrel 152 having a rectangular projection 134 at one end. The Short Distractor 120 has an increased diameter head 128, a rectangular slot 118 and an internal threaded opening 114. The barrel 152 is hollow and has an internal shaft 111 terminating in a large diameter hexagonal crown 115 at one end and a reduced diameter portion 112. The crown has a detent portion 117 in its flat surface. The other end of

the shaft 111 has a threaded small member 116 that corresponds to threaded opening 114. The shaft 111 is prevented from removal from the barrel 152 by set pin 119 passing through the wall of barrel 152 in a convenient manner. The Short Distractor portion 120 is removably attached to the barrel portion 152 via the mating of female rectangular slot 118 and the male mating member 134. The mating held together by utilizing knob 136 to drive the crown 110 connected to interior shaft 111 having a threaded working end screw 116 that threads into the female aperture 118 of the Short Distractor portion 120.

Cap 136 has an open socket 138 for fitting around crown 115 and engages the reduced diameter hexagonal portion 112 so as to permit the rotation of shaft 111 and threaded male member 116. A detent ball 150 in the inside of the socket 138 engages detent 117 in the crown 115, holding them together.

The Short Distractor portion 120 of Figures 2, 3, and 3A-3F are designed to provide for high stability when temporarily situated so as to resist inadvertent migration while the surgeon is working on the second side. To that end, the embodiment of the Short Distractor 120 shown in Figures 3 and 3A has a pair of sharp pegs 126, to embed into the opposing vertebral bodies and forward facing ratchetings 124, that further resist backward movement. Figures 3B and 3C, which show the preferred embodiment, are side and top views of an alternative embodiment of the distractor portion such that the distractor portion to be

interposed between the vertebrae is essentially cylindrical, but with circumferential forward facing ratchetings 124.

A further alternative embodiment is shown in Figures 3D and 3E. This is a more rectangularized design, with forward facing ratchetings, without the sharp prongs 126 of Figure 3. Figure 3F is a side view of a further embodiment of the Short Distractor 120 shown with knurling, to increase the interference with the bone surface so as to add stability to the unit and to resist dislodgment. To this end, it is apparent that the working ends of both the Long and Short Distractors can have a variety of configurations consistent with their purpose, and that surface irregularities as well as the shape of the ends themselves, with or without prongs 126, may be utilized to make the Short Distractor 120 more resistant to migration.

Once the ideal distraction has been achieved on the first side of the spine, the Convertible Distractor is dissociated, leaving Short Distractor 120 in place with its rounded external end 128, safely on the canal floor and deep to the dural sac and nerve root.

As shown in Figure 4, the surgeon then moves to the other side of the spine at the same disc (D) level, and retracts the dural sac and nerve root medially, exposing the disc on that side. Long Distractors 100 are then sequentially inserted into the disc space until the diameter of the distractor on the second side is at least as big as that on the first side. If because of some

asymmetry of the interspace a larger diameter distractor is required on the second side to achieve the ideal distraction as compared to the first side, then the second side is fitted with a Short Distractor of the larger diameter, and the surgeon would then return back to the first side. In that event, the first side Short Distractor would then be removed and the Long Distractor 100 corresponding to the increased diameter of the already placed Short Distractor 120 would then be inserted. In either event, the operation is continued by working on the one side where the Long Distractor is in place. In this regard, it should be noted, that by the use of such a device as the Michelson Spinal Surgery Frame, it may be possible to obtain adequate distraction preoperatively such that the surgeon is either disinclined to use a distractor, or to simply place the correct Long Distractor on the first side and then proceed with the surgical procedure on that side before moving to the opposite side. These variations are within the scope of the present invention.

The Long Distractor now serves as both a centering post and an alignment rod for the hollow Outer Sleeve 140 shown in Figure 5 which is fitted over the Long Distractor 100, shown by phantom lines 101 in Figure 5. The Outer Sleeve 140 is metal and has a sharp toothed front end 142 that is capable of penetrating into and holding fast the two adjacent vertebrae (V). Interrupting the circumferential sharp teeth of 142 are flat, planar areas 152 which serve to resist the further insertion of the

sharp teeth into the vertebral bodies. The toothed front end 142 of the Outer Sleeve 140 is a continuation of the tubular shaft 144, which in turn is connected to circumferentially enlarged tubular back end 146 having a knurled outer surface 148 for easier manipulation. An alternative embodiment of an Outer Sleeve incorporates an expansile key hole and slot configuration 154 to either side of shaft 144 along the mid-plane of the interspace and parallel to it such that the end 142 resists the collapse of the vertebrae (V) to either side of the disc (D), but may nevertheless allow for their further distraction, in the event the only diameter or the root diameter of the implant is larger than the hole drilled.

A Driver Cap 160 in the form of an impaction cap has at its far end a flat, closed-back surface 162 and at its other end a broad, circular opening. The Driver Cap 160 fits over both the Outer Sleeve 140 and the Long Distractor 100. As the Driver Cap 160 is seated, interior surface 170 circumferentially engages portion 146 of the Outer Sleeve until the back end 172 engages the internal shoulder 164. As mallet blows are applied to surface 162, that force is transmitted via the internal shoulder 164 to the Outer Sleeve 140 via its far end 172, seating teeth 142 into the vertebral bodies adjacent the disc space D and to the depth of the teeth 142 to the flat portions 152. As the Outer Sleeve 140 is advanced forward, crown portion 110 of the Long Distractor is allowed to protrude within the Driver Cap 160 unobstructed until it contacts the interior

flat surface 168. Once crown 110 comes into contact with the flat interior surface 168, then further taps of the mallet will not advance the Outer Sleeve, any further motion being resisted by the flat shoulder portion 104 of the Long Distractor abutting the hard surfaces of the posterior vertebral bodies. In this way, the Outer Sleeve 140 is safely and assuredly inserted to its optimal depth and rigidly securing the two opposed vertebrae as shown in Figure 6.

The Cap 160 is then removed and the Distractor Puller 200 of Figure 9 utilized to remove the Long Distractor 100 from the spine leaving the Outer Sleeve 140 in place. The Distractor Puller 200 has front portion 202, a mid portion 204, and a back handle portion 206. At the front portion 202 of the Distractor Puller 200, a socket 208 is connected to one end of shaft 210 which at its far end is connected to back handle portion 206. The socket 208 has defined within it a cavity 212 that is open at its front end and funnelized on the interior aspect of its sides. The cavity 212 is constructed so that the head of the Distractor Puller 200 and the partially circumferential flange 218 engages the circumferential recess 108 of the Distractor 100. The entrance to cavity 212 is slightly funnelized, and the leading edges of flange 218 slightly rounded to facilitate the engagement of recess 108 and head 110 of Distractor 100, which is further facilitated in that the Driver Cap 160 leaves portion 108 of Distractor 100 precisely flush with the back surface 172 of the Outer

Sleeve 140. This provides a large, flat surface 172 to precisely guide surface 230 of socket 208, and open portion 212 around head 110 while flange 218 engages recess 108. The springloaded detent ball 228 engages hemispherical depression 112 in the crown 110, shown in Figure 2. This springloaded detent 228 in engagement with complimentary indent 218 protects against the inadvertent dissociation of the Long Distractor from the Puller 200 after the Distractor has been removed from within the Outer Sleeve 140 and prior to its removal from the wound. Once out of the body, the two instruments are easily disassociated by freeing the crown portion 110 from cavity 212 by a manual force applied perpendicular to their relative long axes at this location.

A cylindrical and free removable weight 216 is fitted around shaft 210 between the front portion 202 and the rear handle portion 206. Gently, but repeatedly sliding the weight 216 along shaft 210 and driven rearwardly against flat surface 228, transmits a rearward vector to proximal end 202 and thereby to the Long Distractor 100 to which it is engaged.

Paired extended handle 224 and 226, allow the surgeon to resist any excessive rearward motion as the instrument is used to liberate the Long Distractor 100. Paired handles 224 and 226 are also useful in that they allow a rotational directing of portion 208, via the shaft 210. This allows the surgeon to control and manipulate rotationally the orientation of the opening of cavity 212

to facilitate its application, to the head 110 of the distractor 100.

The Distractor Puller 200 is a significant improvement over the alternatives of striking a remover instrument with an independent hammer over the exposed surgical wound, or manually extracting the distractor by forcefully pulling. The use of a free hammer over the open wound is dangerous because the neural structures can be impacted on the back swing which is made even more likely by the effects of gravity on the mallet head. Manual extraction by pulling is dangerous because of the significant interference fit of portion 102 within the spine such that significant force would be required to remove the Distractor 100, and if force were not coaxial then the Outer Sleeve might be dislodged or misaligned. Further, once the flat portion 102 became free of the interspace, all resistance to withdrawal would be lost and in the face of the considerable force necessary to free it, the Distractor 100 might easily become projectile imparting injury to the patient and/or the surgeon.

Once the Long Distractor 100 has been fully removed from the Outer Sleeve 140, the toothed end 142 of the Outer Sleeve 140, working in conjunction with the Short Distractor 120 on the contralateral side rigidly maintains the relative position of the adjacent vertebrae V. Further, since the remainder of the procedure on that side of the spine occurs entirely through the protective Outer Sleeve 140, and as the nerves and dural sac are external to

that Outer Sleeve and superficial to the toothed end 142 of the Outer Sleeve 140, which is firmly embedded into the adjacent vertebrae V, the Outer Sleeve 140 serves to insure the safety of these delicate neural structures. Further, since the Outer Sleeve 140 is of a fixed length and rigid, its flat rearward surface 172 may be used as a stop to the advancement of all instruments placed through the Outer Sleeve 140, thus protecting against accidental overpenetration. Further, the Outer Sleeve 140 assures that the further procedure to be performed will occur coaxial to the disc space D and further, be symmetrical in regard to each of the opposed vertebral surfaces.

Figure 10B is a posterior view of the spine at this stage of the procedure, showing a Short Distractor 120 in place on one side of the spine and the bottom portion of Outer Sleeve 140 in place on the opposite side of the spine.

Referring to Figure 11A, an Inner Sleeve 242 is inserted from the rear within the Outer Sleeve 140. This Inner Sleeve has a collar portion 244 of a known thickness which seats against the top edge surface 172 of Outer Sleeve 140. The cylindrical barrel portion of Inner Sleeve 242 comes to approximate the posterior aspect of the vertebral bodies interior the Outer Sleeve when fully seated. A Drill 240, having a known selected length is then introduced through the rearward aperture of the Inner Sleeve 242 and utilized to ream out the arcs of bone which it engages from the opposed vertebral endplates as well as

any discal material within its path down to its predetermined and limited depth. The Drill 240, has a narrow engagement portion 246, which allows it to be affixed to a drill mechanism which may be either a manual or a power unit. A circumferential collar 248 of an increased diameter serves to limit the depth of penetration of the drill 240 and may be fixed, or lockably adjustable.

Not shown here, but well known to those skilled in the art, are various mechanisms to lockably adjust such instruments as drills. Such mechanisms include, but are not limited to, the use of collets, threaded shafts with lock nuts, and flanges engaging grooves forced therein by either a cap pulled over the flanges or screwed down upon them.

In the preferred embodiment, the forward cutting edge 252 of Drill 240 is a modification of a large fluted drill design such that the end resembles an end cutting mill which may contain any workable number of cutting surfaces, but preferably four or more, and such cutting surfaces being relatively shallow such that the advancement of the instrument occurs more slowly. The outside diameter of the Drill 240 corresponds to the minor diameter of the threaded spinal implant. The Inner Sleeve 242 has an inner diameter slightly greater than that dimension and its outer diameter is slightly smaller than the inside diameter of the Outer Sleeve 140 which has the same outer diameter as the major diameter of the threaded implant.

The drill shaft of drill 240 comprises an upper portion 243, a central recessed portion 256 of a smaller diameter and a lower cutting drill portion 250. The upper portion 243 and lower portion 256 of the drill 240 have the same outside diameter.

The Inner Sleeve 242 serves many functions. First, it provides a more intimate drill guide for drill 240 in the event a smaller diameter hole is to be drilled than that of the inside diameter of the Outer Sleeve 140. Second, since it now guides the Drill, it allows for the Outer Sleeve 140 to have an internal diameter large enough to admit the threaded spinal implant, which is indeed considerably larger in diameter than the Drill 240 itself.

If a larger Outer Sleeve 140 were utilized absent the Inner Sleeve 242, then the Drill 240 would be free to wander within the confines of that greater space and would not reliably make parallel cuts removing equal portions of bone from the adjacent vertebrae V. Further, the bone removal not only needs to be equal, but must be correctly oriented in three dimensions. That is, the path of the Drill 240 must be equally centered within the disc space, parallel the endplates, and parallel to the sagittal axis dissecting the interspace.

A further purpose of the Inner Sleeve 242 is that it may be removed simultaneously with the Drill 240, thereby trapping the debris, both cartilaginous and bony generated during the drilling procedure, which are guided rearward by the large flutes 251 of Drill portion 250,

where they are collected around recessed portion 256 between the recessed portion 256 and the inner wall of the Inner Sleeve 242 are there contained therein. Thus, by removing the Drill 240 in conjunction with the Inner Sleeve 242, all of the debris generated by the reaming procedure is safely removed from the spinal canal and wound area.

Further, if the disc tissue in the area to be reamed has been removed previously, as per the preferred method, then the patient's own bone of good quality and useful within the operation will then be contained between the Inner Sleeve 242 and the shaft portion 256. Once away from the surgical wound, this material may be used to load the spinal implant or placed deep within the interspace to participate in the fusion.

The method of actually producing the surgical hole within the spine is variable. As shown in Figure 11C, in an alternative embodiment Drill end 250 has a forward projecting nipple 260, which itself is bullet-shaped in its leading aspect so as to ease its entrance into the disc space and to urge the vertebrae apart. Nipple 260 is distracting, stabilizing as it resists any tendency of the vertebrae to move together, is self-centering to the Drill portion 250 when working in conjunction with Sleeves 140 and 242, and virtually assures the symmetrical resection of bone from the opposed vertebral surfaces.

The alternative "Trephine Method" referred to earlier in this application, is shown in Figure 11B. In this alternative, a Long Distractor 100 is left in place

after the Outer Sleeve 140 is seated. The Long Distractor 100 in this case differs from the Long Distractor of the preferred embodiment in that its outside diameter of the barrel 106 is of a smaller diameter than in the prior version. This is made necessary because regardless of the method, the hole to be formed corresponds to the minor diameter of the spinal implant. Trephine 270, a hollow, tubular member with sharp cutting teeth 251 at its proximal end, has a wall thickness and since the outside diameter of that trephine 270 must correspond to the root diameter of the implant, then the wall thickness of the trephine 270 must be allowed for by a corresponding reduction in the diameter of the Long Distractor 100.

A further modification of the Long Distractor 100 to the "Trephine Method" would use longitudinal grooves (not shown) along the barrel surface 106 for the purpose of transmitting any debris generated during the cutting procedure, rearward. Since the cutting element is both centered and aligned by the Long Distractor, the use of the Inner Sleeve 242 is not mandatory, but may once again be useful in controlling the path of the debris. To that end, little debris is generated in the "Trephine Method" as the bony arcs are not so much being reamed out and removed as they are simply being cut into the bone where these arcs of bone are left connected at their far ends. Thus, when the Trephining Method has been completed and the Trephine 270 and Inner Sleeve 242 removed, unlike in the preferred embodiment where the hole is drilled out, it remains

necessary to remove both the two arcs of bone, and any interposed material. Nevertheless, this is very easily performed by various means, one of which is depicted in Figure 11D.

Instrument 272 consisting of a shaft 276 attached off center to the lower surface 273 handle 274. The shaft 274 terminates in a cutting arm 278. The instrument 272 is inserted through Outer Sleeve 140 where the lower surface 273 of handle 274 abuts the top 172 of the Outer Sleeve 140, both stopping downward motion of instrument 272 and precisely placing the perpendicularly cutting arm 278 of instrument 272 so that as handle portion 274 is rotated, the cutting arm 278 is also rotated, cutting the arcs of bone and liberating them from their last attachments. These portions of bone are then removed utilizing this instrument or a long forceps, and then placed within the implants or otherwise used to participate in the fusion.

While in the preferred embodiment of the present invention the spinal implant I, is essentially self-tapping, if the bone is unusually hard it may be desirable to form the thread pattern within the interspace prior to the insertion of the implant I. To that end, as shown in Figure 12, Tap 280 has a threadcutting portion 282 connected by a shaft 286 to a handle portion 292, which has been designed to give mechanical advantage to the rotation of the instrument for the purpose of cutting threads. The lower portion of handle 290 has a forward facing flat surface 288 too large to fit through the opening of Outer

Sleeve 140 which thus safely limits the depth of penetration of the cutting element 282. This tap 280 is further made safe by blunt end 294 which will engage the uncut portions of the vertebral bone just prior to the engagement of shoulder 288 against surface 172. This feature allows the surgeon to appreciate a less harsh resistance as the blunt nose 294 encounters the remaining unresected bone for the drill hole and prior to the sudden increase in resistance caused by the seating of shoulder 288 against top edge 172, which first resistance serves as a warning to the surgeon to discontinue the tapping procedure. Thus, the surgeon has both visual (as shoulder 288 approaches top edge 172) and tactile warnings to avoid stripping the thread form. Tap end 282 is highly specialized for its specific purpose. Rearward to the specialized blunt tip 294 is a truncated bullet-shaped area 298 which ramps up to the constant diameter intermediate the cutting ridges 296. Ramp portion 298 urges the opposed vertebral bodies apart, which motion is resisted by Outer Sleeve 140, thus progressively driving the sharp leading edges of thread forms 296 into the vertebral bodies. The periodic longitudinal grooves 284 interrupting the thread forms, which may number 1 to 8, but preferably 4, function to accumulate the bony material which is removed during the thread cutting process. In that regard, in the ideal embodiment, the thread cutting form is designed to compress the bone to be formed rather than to trough through it. Further, while both the major and minor diameters of the

Tap 280 may be varied, in the preferred embodiment, the minor diameter corresponds to the minor diameter of the implant I, but the major diameter is slightly less than the major diameter of the implant.

With Tap 280 now removed, and Sleeve 140 still in place, the surgical site is now fully prepared to receive the spinal implant I. In the preferred embodiment of the spinal implant, the implant has been enhanced by the use of, application to, and filling with fusion promoting, enhancing, and participating substances and factors. Thus, the implant may be fully prepared for insertion as provided to the operating surgeon. However, at the present time, human bone is most commonly used as the graft material of choice, with the patient's own bone being considered the best source.

Figure 14a shows a trephine 300 with an exceedingly sharp front cutting edge 302 for quickly and cleanly coring into the patient's posterior iliac crest, or any other bony tissue, and for the purpose of producing a core of bone then contained within the hollow 304 of the trephine 300. Trephine 300 has a rear portion 306 with a pair of diametrically opposed slots 310, and disposed clockwise from their longitudinally oriented rearward facing openings so as to engage diametrically and opposing members 312 of Drive unit 308, by which trephine 300 may be attached to either a hand or power drill. It can be appreciated that engagement mechanism 312 is stable during the clockwise cutting procedure, and yet allows for the

rapid disconnection of the two components once the cutting is completed.

Because of the high interference between the graft and the inner wall of hollow portion 304, and the relative weakness of the cancellous bone being harvested, it is possible to remove the Trephine 300 while still drilling, and to have it extract the core of bone with it. However, in the highly unlikely event that the core of bone would remain fixed at its base, then with the drive mechanism 308 removed, a corkscrew 408 shown in Figure 14C is introduced though the central opening of rear portion 306 and threaded down and through the core of bone within 304 and to the depth of teeth 302. The tip 318 of the corkscrew 408, which extends substantially on line with the outer envelope of the corkscrew, then cuts radially through the base of the bone core. As the handle portion 314 of the corkscrew 408 abuts the flat, rearward surface of portion 306 and it can no longer advance. As corkscrew 408 is continued to be turned further, it will cause the core of bone to be pulled rearward, as in removing a cork from a wine bottle. Trephine 300 has a barrel portion 304 continuous with sharp toothed portion 302 having an inner diameter just less than the inner diameter of the spinal implant I to be loaded.

The Trephine 300 with its core of harvested bone is then placed as shown in Figure 14B, through opening 340 of Implant Bone Loading device 320, where the barrel portion 304 then passes through and is stopped by circular

flange 344. The plunger shaft 326 of instrument 320 is then prepared for attachment by rotating knob 332 counterclockwise such that the plunger 372 is pulled via the long threaded shaft portion 328 back to the base of collar 330 at its proximal end. In this position, knob 332 is considerably extended rearward from collar 330. With plunger shaft 326 in this position, the plunger head 372 is inserted into the central hollow of portion 306 of Trephine 300 as the proximal cylindrical portion of collar 330 then follows it, such that the plunger 372 then occupies the rearward portion of barrel 304 and the proximal cylindrical portion of collar 330 occupies the central hollow of portion 306. A pair of diametrically opposed radially projecting arms 346 on collar 330 are then advanced longitudinally into diametrically opposed paired L slots 340 and then rotated clockwise to complete this assembly.

At the other end of instrument 320, a spinal implant I is engaged through its female rectangular slot 364 by a rectangular protruding bar extending from rearward facing surface of end plug 324, (not shown) and secured there by knob 334 which extends as a rod through a central aperture within end plug 324 to extend at the far end as a small bolt which threads to a female aperture centered within the female slot 364 of the spinal implant. With the spinal implant I secured to end plug 324 and the opposite end of the implant I presenting as a hollow, tubular opening, end plug 324 is advanced into device 320 where it

is secured by rotationally engaging diametrically opposed L-shaped slots 321. With device 320 fully assembled, end 302 of trephine 300 lies coaxial and opposed to the open end of implant I.

As shown in Figure 15, as knob 332 is then rotated clockwise, the plunger 372 proximal the threaded shaft 328 is then forcibly, but controllably driven forward down the barrel 304 ejecting the bone graft directly into the spinal implant I. As the bone graft is greater in length than the interior of the spinal implant, with further compression the bone is forced into the radially disposed apertures through the wall of the device communicating from the central cavity to the exterior.

End plug 324 is then removed from apparatus 320. Using end plug 324 as a handle, end cap 374 shown in Figure 16 is secured to the open end of the spinal implant I. The implant is then disassociated from end plug 324 by rotating knob 334 counterclockwise.

Figure 16 shows an Implant Driver instrument which may be used to either insert or to remove said implant I. Driver 350 has at its far end 362, a rectangular protrusion 398, which protrusion intimately engages the complimentary rectangular slot 364 of implant I. Protruding from slot 398 of end 362 is threaded portion 353, which extends as a rod through hollow shaft 358 and hollow hand barrel 360 to knob 354 where it can be rotationally controlled. Threaded portion 353 screws into a female aperture central slot 364, urging 353 into 364,

and binding them together such that instrument 350 can be rotated via paired and diametrically opposed extending arms 366 and in either direction while maintaining contact with the implant.

Affixed to the Driver 350, the implant is then introduced through the Outer Sleeve 140 and screwed into the interspace opposed between the two prepared vertebrae V until such time as the leading edge of the Implant Cap 374 reaches the depth of the prepared hole at which time its forward motion is impeded by the bone lying before it which had not been drilled out. This allows for a progressive feel to the surgeon as the implant is screwed home.

As described previously, with the use of the Tap 280, this terminal resistance to further seating provides significant tactile feedback to the surgeon. Again, as with the Tap 280, visual monitoring of the depth of insertion of the implant is provided to the surgeon by observing the progressive approximation of the forward surface 370, of barrel portion 360, as it approaches the rearward facing surface 172 of Outer Sleeve 140. Nevertheless, a final safety mechanism, when the full depth of insertion has been achieved, surface 370 of instrument 350 will abut surface 172 of the Outer Sleeve 140, prohibiting any further installation of the spinal implant.

Once the implant has been fully installed, the Driver 350 is dissociated from the implant by turning knob 354 in a counterclockwise direction. The Driver 350 is

then withdrawn from the outer sheath, then the Outer Sleeve 140 is removed. This leaves the implant fully installed and inset to the determined depth as shown in Figure 18.

Attention is then redirected to the other, or first, side of the spine. A dural nerve root retractor is used to retract the neural structures medially, bringing into full view the head 128 of the Short Distractor 120, lying flush on the canal floor. Utilizing apparatus 152, extended screw portion 116 is inserted into the female threaded portion 114 of the Short Distractor 120 as the extended rectangular portion 134 of apparatus 152 is engaged to the female rectangular portion 118 of the Short Distractor 120. Then turning rearward facing portions 108 and 110, utilizing the knob 136 of Figure 2, the Long Distractor configuration is restored.

With the dural sac and nerve roots still retracted and protected, the Outer Sleeve 140 is slipped over the reconstituted Long Distractor and seated using the Driver Cap 162. The entire sequence of events as described for the implantation of the spinal implant I as already placed, is then repeated such that both spinal implants come to lie side by side within the interspace. Though not necessary, circlage or other internal fixation of the levels to be fused may additionally be performed, and then the wound is closed in the routine manner.

Brief Discussion With Reference To The Drawings of The Preferred Method And Instrumentation For Anterior Interbody Fusion

Incorporating Intercorporeal Predistraction And Utilizing A Guarded Sleeve System Is Disclosed

Because of the absence of the spinal cord and nerve roots, it is generally possible to visualize in one instance the entire width of the disc space from side to side throughout the cervical, thoracic, or lumbar spine. In the preferred embodiment of the anterior interbody fusion, implants are placed side by side from anterior to posterior parallel to the interspace and extending through into the adjacent vertebral bodies. Where the transverse width of the disc space is insufficient to allow for the use of two implants, each of which would be large enough to protrude to the required depth into the adjacent vertebrae, then a singular and significantly larger implant may be placed centrally. With this in mind, and in light of the very detailed description of the technique and instrumentation already provided in regard to the method of posterior lumbar interbody fusion, a brief discussion of anterior spinal interbody fusion with dual implant installation will suffice, and the method for installation of a large, singular midline graft will become obvious.

The interspace to be fused is exposed anteriorly. The soft tissues are withdrawn and protected to either side, and if necessary, above and below as well. It is then possible to visualize the entire width of the vertebrae anteriorly adjacent that interspace. As discussed above, the surgeon has already templated the

appropriate patient radiographs to determine the requisite distraction and optimal implant size. In the preferred method, the surgeon then broadly excises the great bulk of the nuclear disc portion. (Alternatively, the disc can be left to be removed via the drill later.) The surgeon then notes and marks a point midway from side to side anteriorly. He then inserts Long Distractor 100 centering it on a point midway between the point just noted and the lateral extent of the intervertebral space visualized anteriorly. The outer barrel portion 106 of the Distractor 100 utilized, will correspond to the outside diameter of the implants to be installed. The Distractor tips 102 inserted are sequentially larger in diameter until the optimal distraction is achieved. This optimal distraction, although suggested by the initial templating, may be visually and tactilely confirmed as performed. When the optimal distraction is achieved, the vertebral endplates will come into full congruence and parallel to the forward shaft portion 102 of the Distractor 100, causing an alteration in the alignment of the vertebrae and a significant increase in the interference fit and pressurization at the tip, such that the instrument becomes exceedingly stable.

There is a sensation imparted to the surgeon of the tissues having moved through their elastic range to the point where the two adjacent vertebrae V begin to feel and move as if a single solid. These changes are easily appreciated visually as the vertebrae realign to become

congruent to tip 102, and can also easily be appreciated via lateral Roentgenography. However, should the surgeon fail to appreciate that optimal distraction has been achieved and attempt to further distract the interspace, he would find that extremely difficult to do because of the increased resistance as the tissues are moved beyond their range of elastic deformation. Further, there would be no elasticity left to allow the vertebrae to move further apart and the sensation to the surgeon should he attempt to gently tap the oversized Distractor forward with a mallet, would be one of great brittleness.

Returning now to the procedure, when the correct intercorporeal Distractor 100 producing the ideal interspace distraction having its barrel portion 106 corresponding to the implant to be installed has been inserted, then its exact duplicate is inserted anteriorly equidistant to the other side of the spine. As the barrel portion 106 of Long Distractor 100 is exactly of the same major diameter as the spinal implant I looking coaxially on end, the surgeon can then asses the anticipated side by side relationship of the dual implants when implanted.

As shown in Figures 7C and 7D, a Dual Outer Sleeve 340 consisting of a pair of hollow tubes is then introduced over the side by side Long Distractors protruding anteriorly from the spine. The Dual Outer Sleeve 340 is comprised of two hollow tubular members identical in size displaced from each other ideally the sum of the difference between the minor and major diameters of

both implants combined, but not less than that difference for one implant, as it is possible to have the threads of one implant nest interposed to the threads of the other, such that they both occupy a common area between them. However, while the preferred embodiment is slightly greater than two times the difference between the major and minor diameters of the implant (the sum of both) the distance may be considerably greater. Whereas in the preferred embodiment extending-tubular portions 348 of instrument 340 are parallel, when the area between them 350, is sufficiently great, these elements may be inclined or declined relative to each other such that they either converge or diverge at their proximal ends. Paired tubular structures 348, may be bridged in part or wholly throughout their length, but are rigidly fixed by Foot Plate 344. In its preferred embodiment, a top view shows the Foot Plate to be essentially rectangular, but without sharp corners.

Other shapes can be utilized. In side view 7D it can be appreciated, that Foot Plate 344 is contoured so as to approximate the shape of the vertebrae anteriorly. Extending forward from Foot Plate 344 are multiple sharp prongs 342 sufficiently long to affix them to the vertebrae. The prongs 342 are limited in length so as to not penetrate too far posteriorly and number from 2 to 10, but preferably 6. As the Dual Outer Sleeve 340 is driven forward utilizing Dual Driver Cap 420, of Figure 7E, engaging the rearward end 352, the prongs 342 extending

from Foot Plate 344 are embedded into the opposed vertebral bodies until their forward motion is inhibited by the curved Foot Plate 344 becoming congruent to and being stopped by, the anterior aspect of the vertebral bodies.

As already taught in Figure 5, the Dual Driver Cap 420 is of the same design as Single Driver Cap 160, in that there is a recess 354 as per 168, allowing the Outer Sleeve to be fully seated without impeding the rearward projection of the Long Distractor unit. However, unlike in Cap 160, area 354 is more relieved as it is unnecessary for the Dual Cap 420 to contact the Long Distractor through portion 110 to inhibit its forward motion, as the Foot Plate 344 functions to that effect. Further, the Dual Cap 420 for the Dual Outer Sleeve 340 is correspondingly dual itself and engages the rearward facing dual tubular portion 352. Once the Dual Outer Sleeve has been fully seated, the vertebrae adjacent the interspace to be fused are rigidly held via Foot Plate 344 and the prongs 342. Thus, it is possible to remove either one, or if desired, both of the Long Distractor rods utilizing Long Distractor puller 200, as per the method already described. It is then the surgeon's choice to work on one or both sides of the spine. As per previous discussion, the surgeon may drill the interspace utilizing the Inner Sleeve 242 or leave the Long Distractors in place as per the "Trephine Method".

Tapping, if necessary, and the insertion of the implants then occurs through the protective Outer Sleeve 340. Once the implants have been fully inserted, the Outer

Sleeve is removed.

Having utilized the Drill method, or "Trephine Method", with or without an Inner Sleeve to prepare the fusion site, it is the preferred embodiment to leave the Outer Sleeve 340 in place as it provides for the ideal placement and alignment of the Tap 280 and implant I.

It is anticipated that the surgeon wishing to work deep within the interspace, or preferring the ability to directly visualize the tap being used, or the implant being inserted, may choose to remove the Outer Sleeve after the insertion of the first prosthesis to maintain stability, or prior to that, which while not the preferred embodiments, are nevertheless within the scope of the present invention.

Alternative Methods To The Preferred Embodiment For Method Of Anterior Interbody Fusion

As previously described for the posterior lumbar spine, alternatively, one can employ the "Trephine Method" as has been described in detail.

As a further alternative, it should be noted that the key element in the anterior method is the use of the predistraction principle, where such distraction is maintained by the Outer Sleeve with or without the Long Distractor. Therefore, once the preparation of the interspace has been completed, while not the preferred embodiment, it is nevertheless within the scope of this invention that one could remove the Outer Sleeve as there

are no neural structures requiring protection, and insert the implants directly rather than through the Outer Sleeve.

As yet a further alternative of this method, where the height of the distracted interspace is such that the diameter of the implant required to span that height and to embed with sufficient depth into the opposed vertebral bodies is such that it is not possible to place two such implants side by side, then only a single implant which may be of significantly increased diameter, is used and placed centrally within the interspace rather than to either side. The placement of a singular central graft via the present invention method and instrumentation is in keeping with the methods already described and can be performed using either a drill or the "Trephine Method".

Referring to Figures 16-18, a cylindrical embodiment of the spinal implant I of the present invention is shown. In Figure 16 the implant I is shown attached to the insertion device 350. In Figures 17 and 18 the implant I is shown installed in the disc space D, between the adjacent vertebrae.

The cylindrical implant I comprises a hollow tubular member which in the preferred embodiment is made of an ASTM surgically implantable material, preferably Titanium. The cylindrical implant I is closed at one end and open at the other end covered by a cap 394. The cylindrical implant I has a series of macro-sized openings 390 through the side walls of the cylindrical implant I. A series of external threads 392 are formed on the

circumference of the cylindrical implant I. Any variety of threads may be used on the implant. The cap 374 has a hexagonal opening 394 for tightening the cap 374.

While the present invention has been described in association with the implant of a threaded spinal implant, it is recognized that other forms of implants may be used with the present method. For example, dowels, made from bone or artificial materials, knurled or irregularly shaped cylinders or spheres, or any other shaped implants that can be introduced through the outer sleeve may be used. Being able to perform the procedure through the outer sleeve permits the procedure to be performed safely and quickly, and more accurately.

The claims defining the invention are as follows:

1. A method for inserting a spinal implant between two adjacent vertebrae, the method including the steps of:

inserting a spinal distractor into a disc space between the two adjacent vertebrae;

positioning a guard over said spinal distractor and into contact with the two adjacent vertebrae;

forming, through said guard, an opening across the disc space; and

inserting said implant into the opening.

2. The method of claim 1, further including the step of removing said spinal distractor prior to the step of forming.

3. The method of either claim 1 or 2, wherein the positioning step includes the step of positioning a tubular member into contact with the two adjacent vertebrae.

4. The method of either claim 1 or 2, wherein the positioning step includes the step of positioning a guard at least in part being generally tubular.

5. The method of any one of the above claims, wherein the step of inserting said spinal distractor includes the sub-step of spacing the two adjacent vertebrae apart.

6. The method of any one of the above claims, further including the step of engaging said guard into the two adjacent vertebrae.

7. The method of any one of claims 1-5, further including the step of embedding said guard into the two adjacent vertebrae.

8. The method of any one of claims 1-5, wherein the step of positioning includes the step of driving said guard against the two adjacent vertebrae.

9. The method of any one of the above claims, further including the step of removing said guard after the step of inserting.

10. The method of any one of the above claims, wherein the forming step includes the sub-step of using one of a mill and a reamer in forming the opening.

11. The method of any one of claims 1-9, wherein the forming step includes the sub-step of drilling the opening.

12. The method of claim 11, wherein the forming step further includes the sub-step of placing a drill having a diameter greater than the height of the disc space through said guard prior to the sub-step of drilling.

13. The method of claim 11, wherein the forming step further includes the sub-step of placing a drill through said guard prior to the sub-step of drilling.

14. The method of claim 13, further including the sub-step of removing said drill after the sub-step of drilling.

15. The method of any one of claims 1-9, wherein the forming step includes the sub-step of using a trephine to form the opening.

16. The method of claim 15, wherein the sub-step of using a trephine includes the sub-step of placing said trephine over said spinal distractor.

17. The method of claim 15, wherein the sub-step of using a trephine includes the sub-steps of inserting through said guard a rotary cutter for amputating the base of a portion of the two adjacent vertebrae partially cut through by use of said trephine and removing the rotary cutter.

18. The method of claim 17, wherein the sub-step of using a trephine includes the sub-step of removing from the opening the portion of the two adjacent vertebrae cut by use of said trephine.

19. The method of any one of claims 1-9, wherein the forming step includes the step of forming the opening across the disc space and into a portion of each of the two adjacent vertebrae.

20. The method of any one of the above claims, further including the step of tapping the opening to provide threads over at least a portion of the two adjacent vertebrae prior to the step of inserting said implant.

21. The method of any one of the above claims, wherein the step of inserting said implant includes the sub-step of screwing said implant into the opening.

22. The method of any one of claims 1-20, wherein the step of inserting said implant includes the sub-step of inserting said implant through said guard and into the opening.

23. The method of claim 22, wherein the sub-step of inserting said implant includes the sub-step of screwing said implant into the opening.

24. The method of any one of the above claims, further including the step of attaching a driving member to said implant prior to the step of inserting said implant.

25. The method of claim 24, wherein the step of inserting said implant includes the sub-step of using said driving member to insert said implant into the opening through said guard.

26. The method of claim 25, further including the step of removing said driving member from said implant after the step of inserting said implant.

27. The method of claim 26, further including the step of removing said driving member from said guard after the step of inserting said implant.

28. The method of claim 26, further including the step of removing said driving member and said guard together after the step of inserting said implant.

29. The method of any one of the above claims, further including the step of loading said implant with fusion promoting material prior to the step of inserting said implant.

30. The method of any one of claims 1-28, further including the step of loading said implant with osteogenic material prior to the step of inserting said implant.

31. The method of any one of claims 1-28, wherein the step of inserting said implant includes inserting an implant containing a fusion promoting substance.

32. The method of any one of claims 1-28, wherein the step of inserting said implant includes inserting an implant including a fusion promoting substance.

33. The method of any one of claims 1-28, wherein the step of inserting said implant includes inserting an implant including a bone ingrowth surface.

34. The method of claim 29, further including the step of retaining the fusion promoting material within said implant after the step of loading.

35. The method of claim 34, wherein the step of retaining includes the sub-step of attaching a cap to said implant to retain the fusion material.

36. The method of any one of claims 1-9, further including the step of placing an inner sleeve within said guard prior to the step of forming the opening.

37. The method of claim 36, wherein the forming step includes the sub-step of drilling the opening.

38. The method of claim 37, further including the step of removing said inner sleeve prior to the step of inserting said implant.

39. The method of claim 38, wherein the forming step further includes the sub-step of placing a drill through said inner sleeve prior to the sub-step of drilling.

40. The method of claim 39, further including the step of removing said inner sleeve and said drill together prior to the inserting step.

41. The method of any one of the above claims, further including the step of using a radiographic imaging device during at least a portion of said method.

42. A method for securing a hollow tubular sleeve to two adjacent vertebrae including:

inserting a spinal distractor in the disc space on one side of the vertebrae, said distractor having a flat shoulder portion abutting the vertebrae;

placing said hollow tubular sleeve having on one end engagement means for engaging two adjacent vertebrae and a circumferentially enlarged tubular back end, said back end having a raised crown portion, said sleeve being placed over said distractor, said distractor serving as a centering post and as an alignment rod for said outer sleeve;

engaging a driver cap to said tubular back end, said driver cap having a closed rear surface on one end and a circular front opening at the other end, said driver cap defining a first large recess within said circular opening for engaging the tubular back end of said outer sleeve, and a second smaller recess for engaging said crown portion forming an internal shoulder between said first and second recesses;

applying an impaction force with an impacting means to said driver cap whereby said force is transmitted via said internal shoulder to said outer sleeve until said crown is seated within said second recess;

removing said driver cap from said back end; and

removing said distractor with a distractor pulling means leaving said outer sleeve in place.

43. The method of claim 42, wherein said engaging means include teeth and said outer sleeve includes penetration preventing means for preventing penetration of said teeth.

44. The method of claim 43, wherein said penetration preventing means is lockably adjustable.

45. The method of claim 43, wherein said penetration preventing means includes flat portions between at least some of said teeth.

46. A method for securing a guard to two adjacent vertebrae of a spine, the method including the steps of:

inserting at least one spinal distractor into a disc space intermediate the two adjacent vertebrae;

placing said guard over said distractor;

positioning one end of said guard in contact with the spine; and

removing said distractor from said guard.

47. The method of claim 46, wherein the positioning step includes the sub-step of preventing over penetration of said guard into the spine.

48. The method of claim 47, wherein the sub-step of preventing over penetration includes the sub-step of utilizing lockably adjusting means for preventing over penetration of said guard.

49. The method of claim 46, wherein the positioning step includes the sub-step of impacting said one end of said guard into the spine.

50. The method of claim 46, wherein the positioning step includes the sub-step of driving said one end of said guard against the spine.

51. The method of claim 46, wherein the positioning step includes the sub-step of abutting one end of said guard against the spine.

52. The method of any one of claims 46-51, further including the step of embedding said one end of said guard into the spine after the step of positioning.

53. A method for securing a guard to two adjacent vertebrae of a spine, the method including the steps of:

inserting at least one alignment rod into a disc space intermediate the two adjacent vertebrae;

placing said guard over said rod, said rod serving to center and align said guard;

positioning one end of said guard in contact with the spine; and

removing said rod from said guard.

54. The method of claim 53, wherein the positioning step includes the sub-step of preventing over penetration of said guard into the spine.

55. The method of claim 54, wherein the sub-step of preventing over penetration includes the sub-step of utilizing lockably adjusting means for preventing over penetration of said guard.

56. The method of claim 53, wherein the positioning step includes the sub-step of impacting said one end of said guard into the spine.

57. The method of claim 53, wherein the positioning step includes the sub-step of driving said one end of said guard against the spine.

58. The method of claim 53, wherein the positioning step includes the sub-step of abutting one end of said guard against the spine.

59. The method of any one of claims 53-58, further including the step of embedding said one end of said guard into the spine after the step of positioning.

60. A method for inserting a spinal implant between two adjacent vertebra including:

inserting a spinal distractor in the disc on one side of the spinal column to provide for proper spacing of the disc space between the vertebra;

inserting over the spinal distractor a hollow tubular member having engagement means for engaging two adjacent vertebrae into the vertebrae;

passing a trephine through the tubular member and over the spinal distractor to drill a hole in the disc and a portion of the two adjacent vertebrae;

removing the trephine; inserting an implant in the vertebrae through the tubular member; and

removing said tubular member.

61. The method of claim 60, wherein said implant is cylindrical.

62. The method of claim 60, wherein said step of inserting an implant includes inserting one or more partially cylindrical implants.

63. The method of claim 60, wherein said implant has a diameter corresponding to the diameter of the opening formed by the trephine.

64. The method of any one of claims 60-63, wherein said trephine has means associated therewith for limiting the depth of the drilling.

65. The method of claim 64, wherein said depth limiting means is lockably adjustable.

66. The method of claim 64, wherein said depth limiting means includes a shoulder within said trephine.

67. The method of any one of claims 60-66, wherein the tubular member has a removable hollow inner sleeve.

68. The method of claim 60, wherein said hollow tubular member has means for limiting the penetration of the engagement means into the vertebrae.

69. The method of claim 68, wherein said penetration limiting means is lockably adjustable.

70. The method of any one of claims 60-69, wherein said implant is made of bone.

71. The method of any one of claims 60-69, wherein said implant is made of a material that promotes bone ingrowth.

72. The method of claim 61, including tapping a thread into the hole and said cylindrical implant has a thread.

73. The method of claim 60, wherein said spinal distractor remains in place in the disc space while the implant is being inserted.

74. The method of claim 73, wherein said spinal distractor remaining in place includes a barrel portion that is separable from a front portion of the spinal implant in the disc space.

75. The method of claim 60, further including the steps of freeing and removing any remaining bone cut by the trephine from within the trephine.

76. The method of claim 75, wherein the remaining cut bone is removed from the trephine by an apparatus including a handle and a shaft, said shaft being connected to said handle at one end and having a cutting blade at an angle to said shaft, said shaft connected off center to a central axis of said handle.

77. A method for inserting a spinal implant between two adjacent vertebrae substantially as hereinbefore described as illustrated in any one of the figures.

78. A method for securing a hollow tubular sleeve to two adjacent vertebrae substantially as hereinbefore described as illustrated in any one of the figures.

79. A method for securing a guard to two adjacent vertebrae substantially as hereinbefore described as illustrated in any one of the figures.

80. The method of claim 29, wherein the step of loading said implant includes loading said implant with bone.

81. The method of claim 60, further including the step of loading said implant with fusion promoting material prior to the step of inserting said implant.

82. The method of claim 81, wherein the step of loading said implant includes loading said implant with bone.

DATED: 27 March 2002

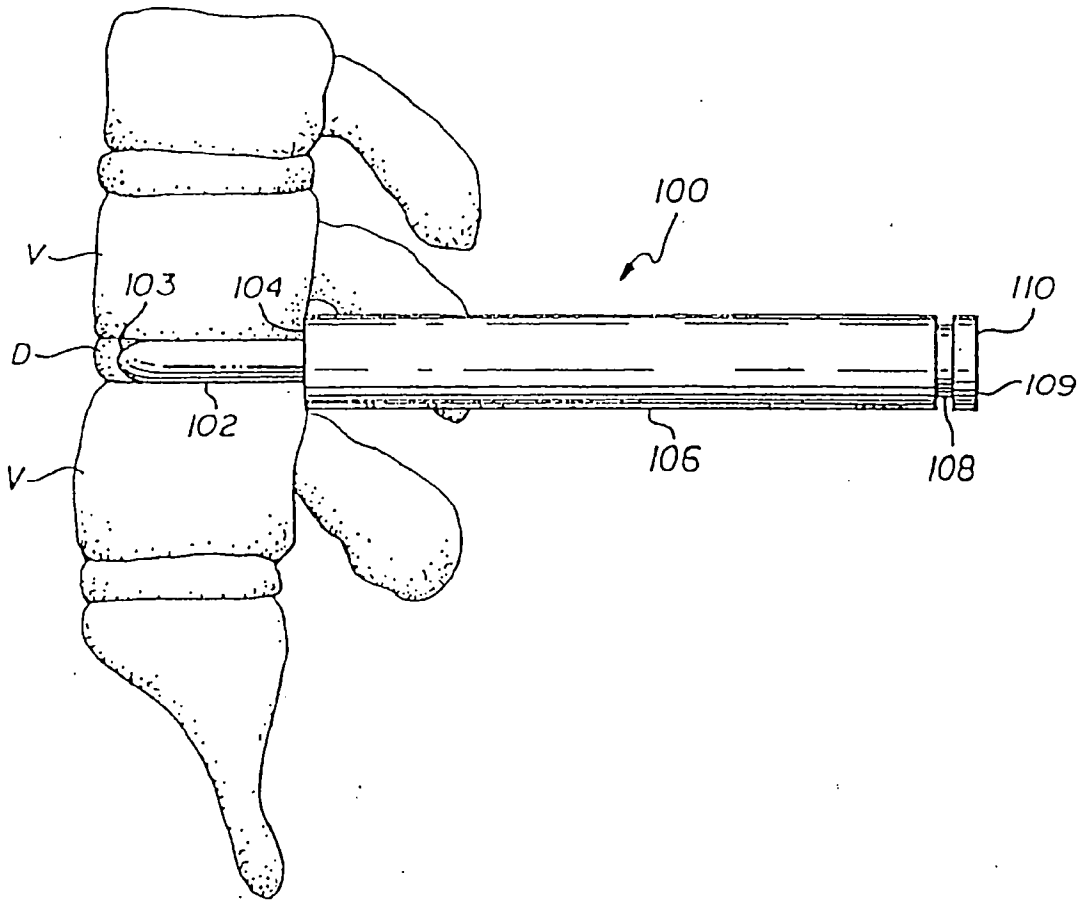
PHILLIPS ORMONDE & FITZPATRICK

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KARLIN TECHNOLOGY INC

David B Fitzpatrick

FIG. 1



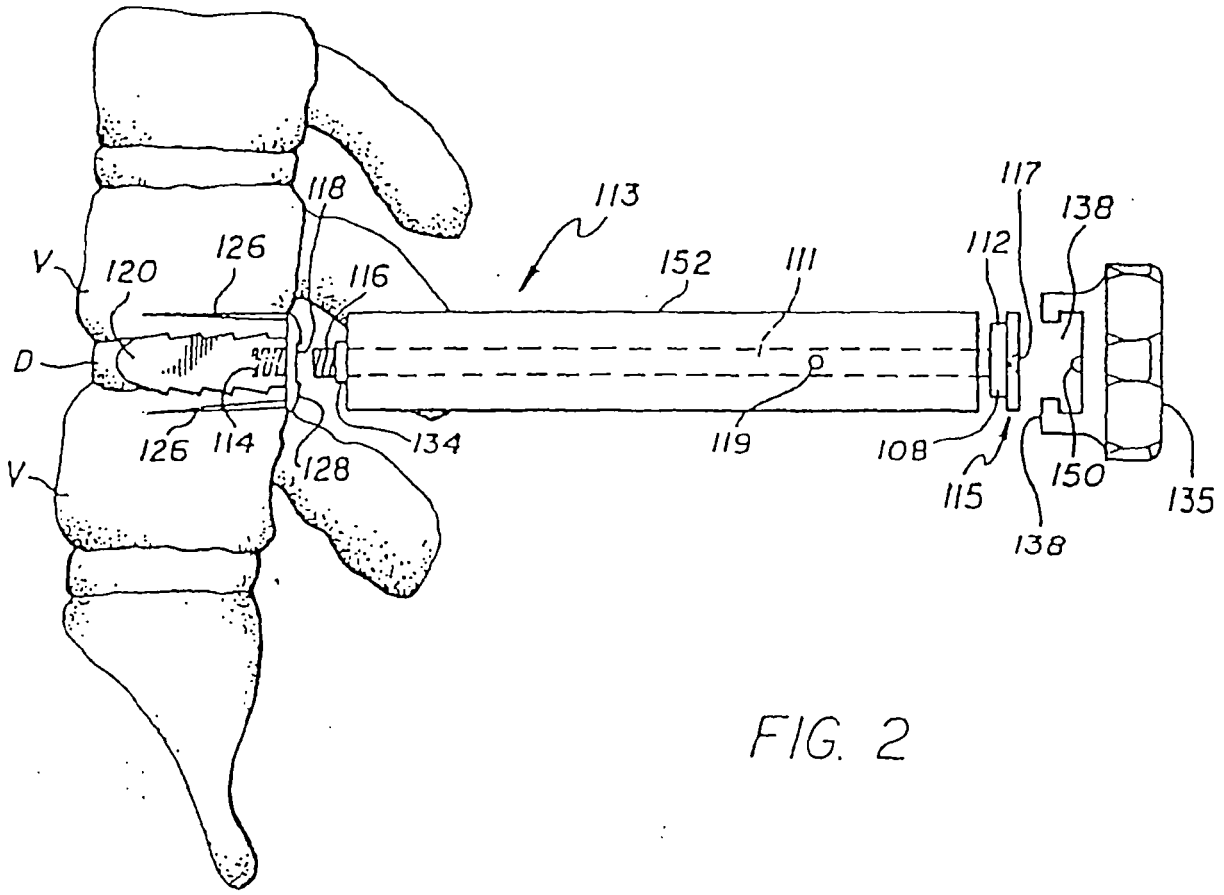

V
120
126
118
116
113
152
111
117
138
112
D
126
114
128
134
119
108
115
150
135
138
V

FIG. 2

FIG. 3

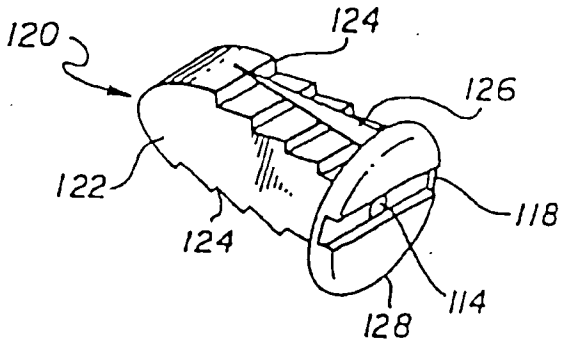


FIG. 3A

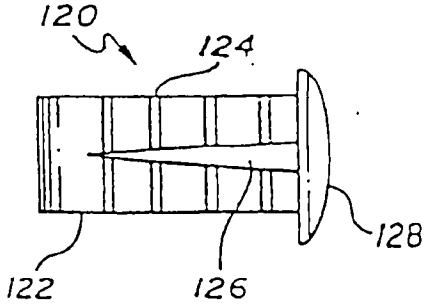


FIG. 3B

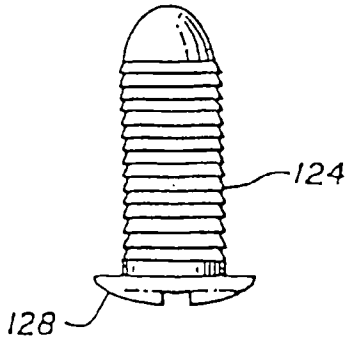


FIG. 3C

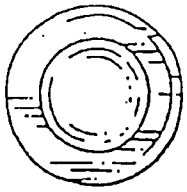


FIG. 3D

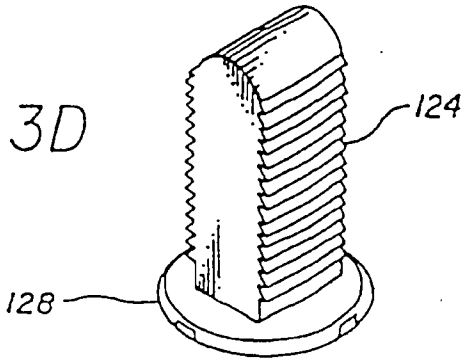
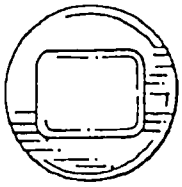


FIG. 3E



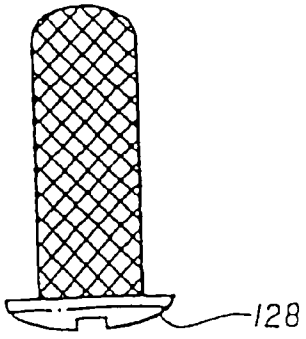
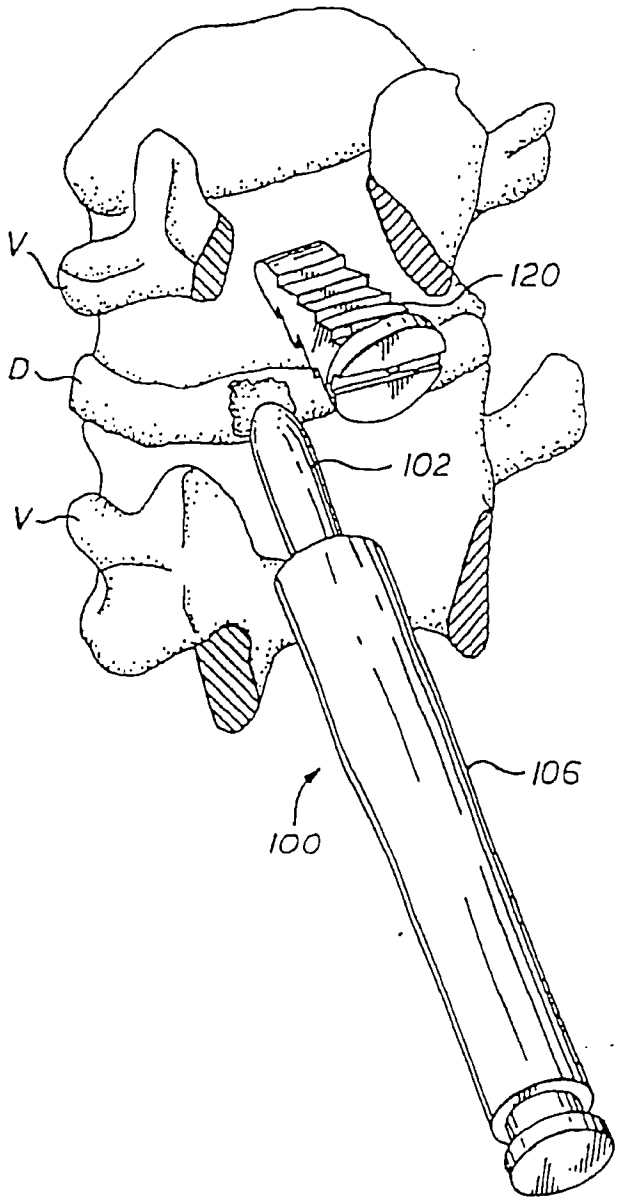


FIG. 3F

FIG. 4



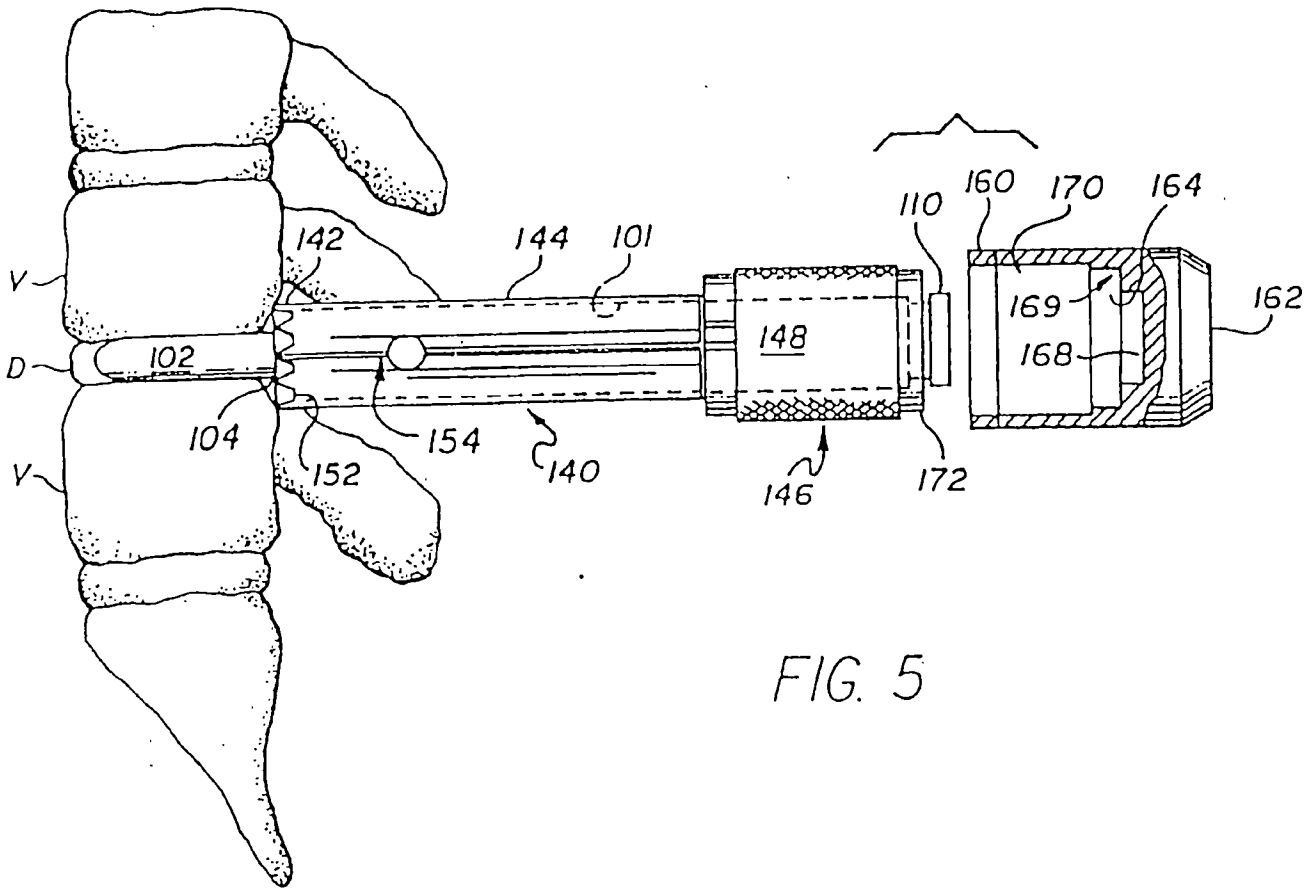

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FIG. 5

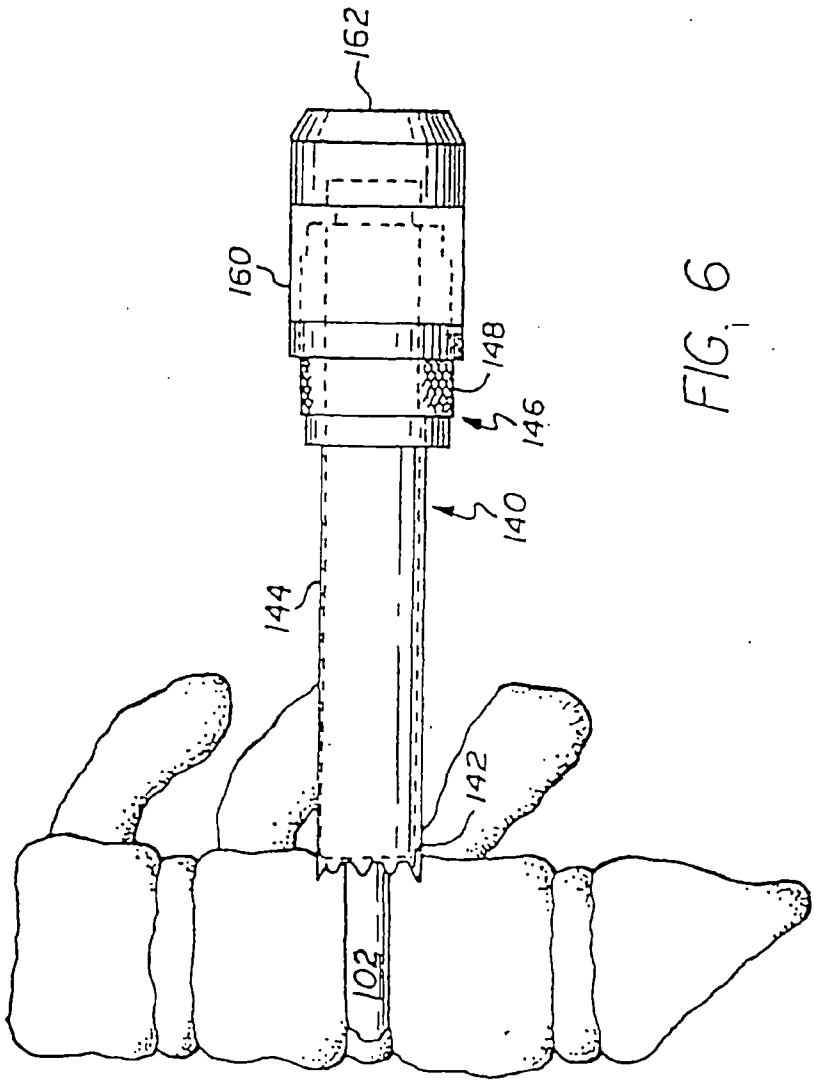
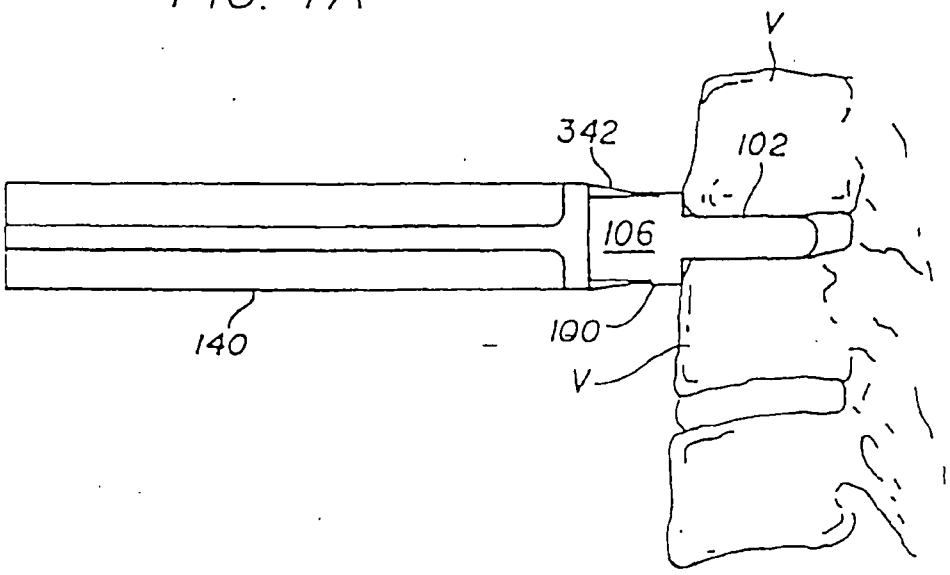


FIG. 6

FIG. 7A



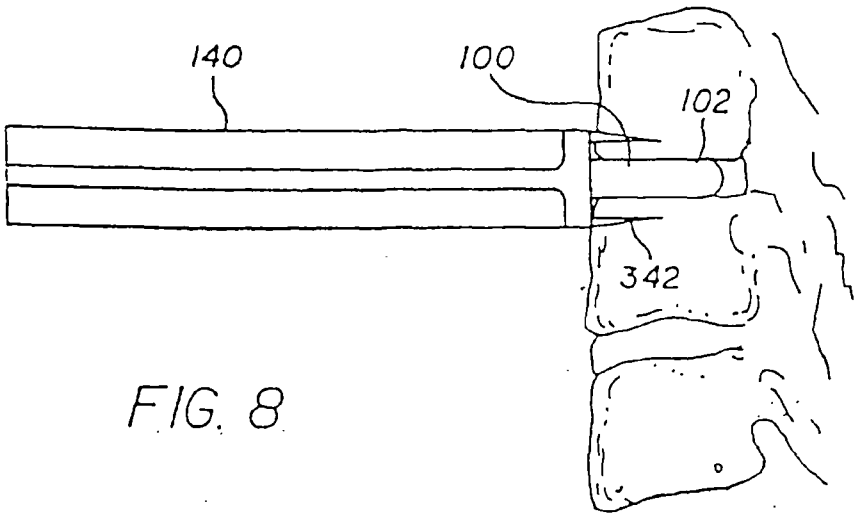


FIG. 8

FIG. 7B

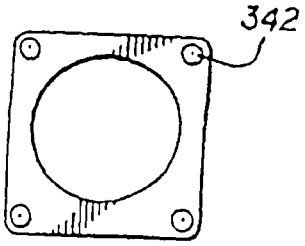


FIG. 7C

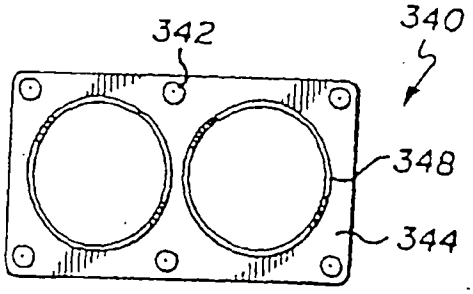


FIG. 7D

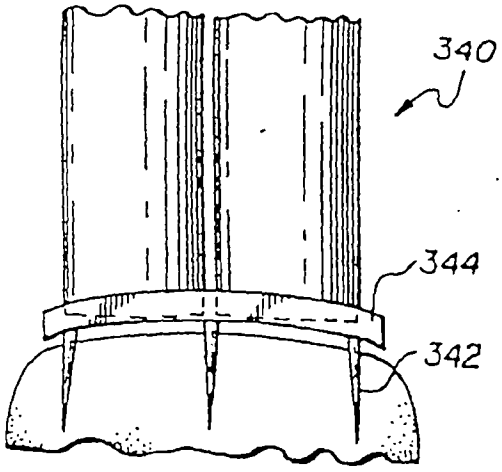
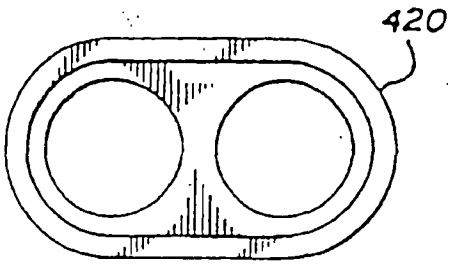


FIG. 7E



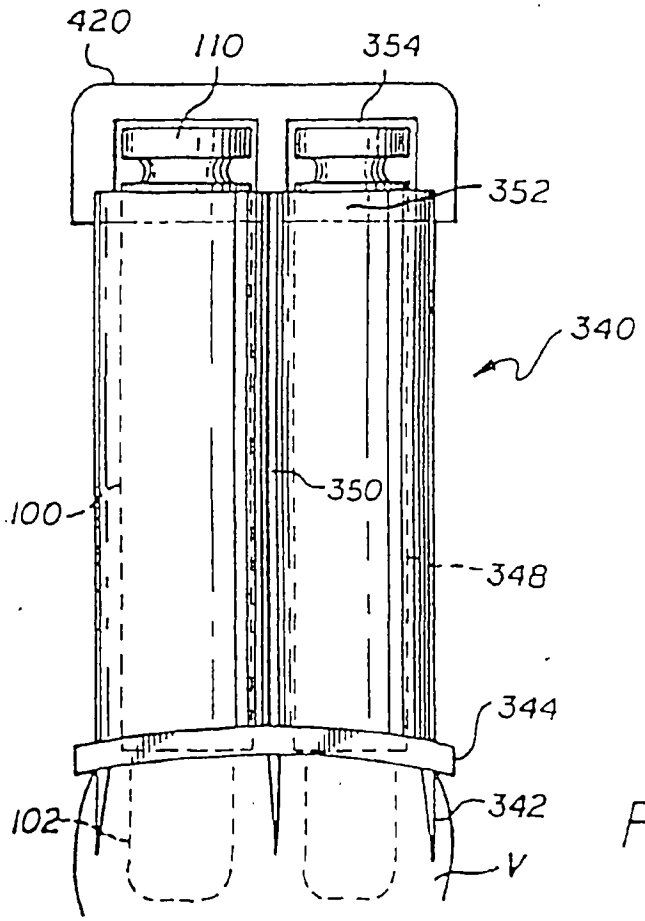
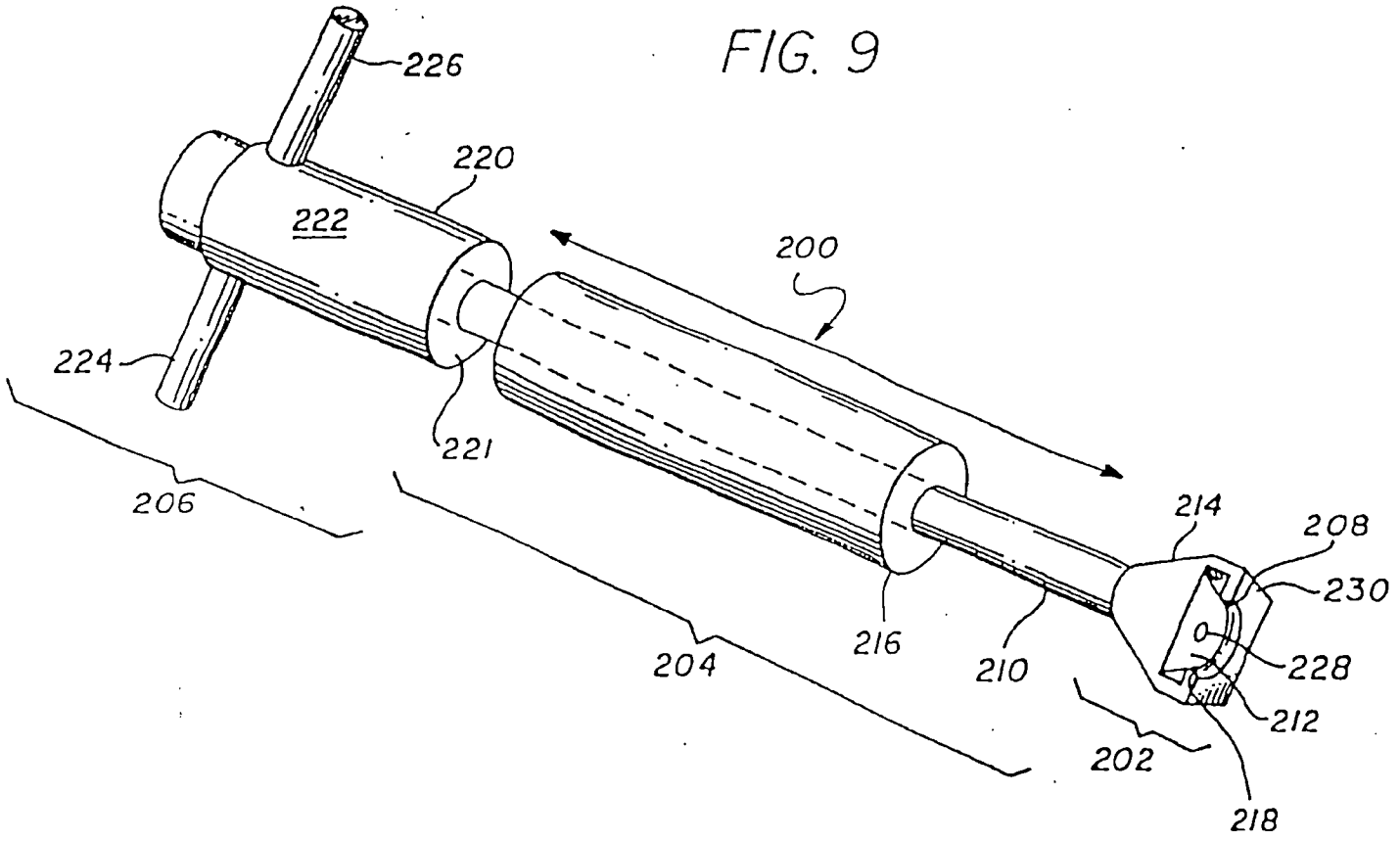


FIG. 7F

FIG. 9


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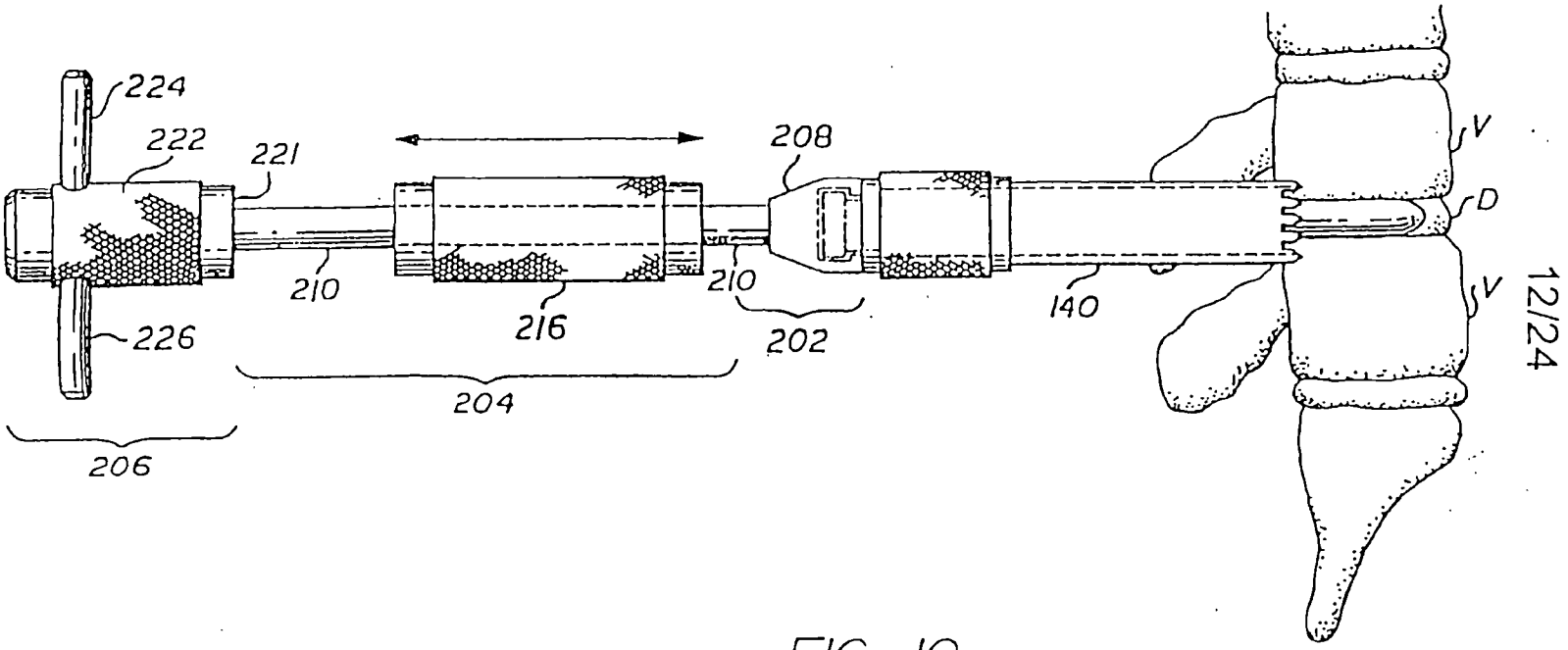


FIG. 10

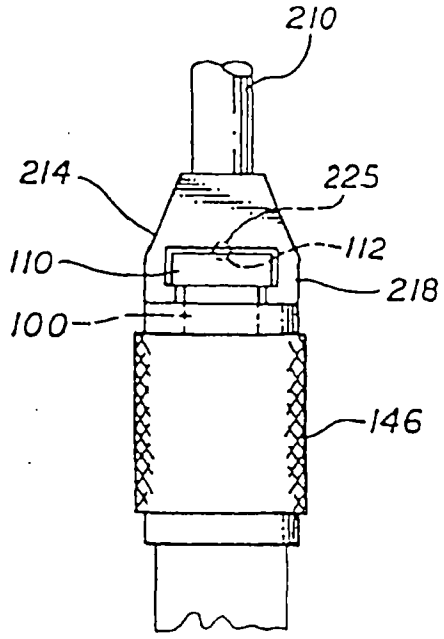


FIG. 10A

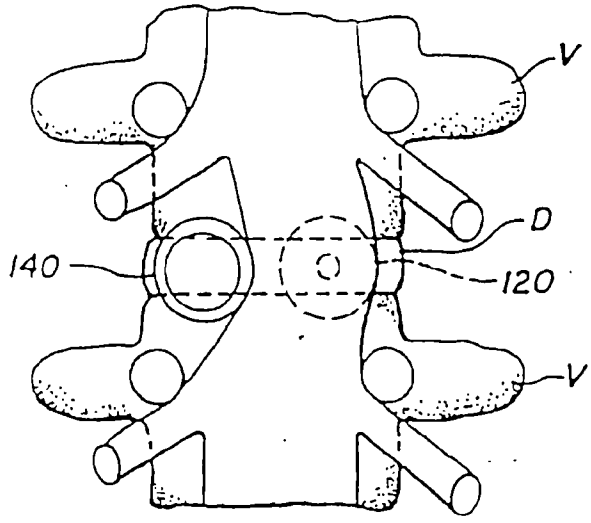


FIG. 10B

FIG. 11A

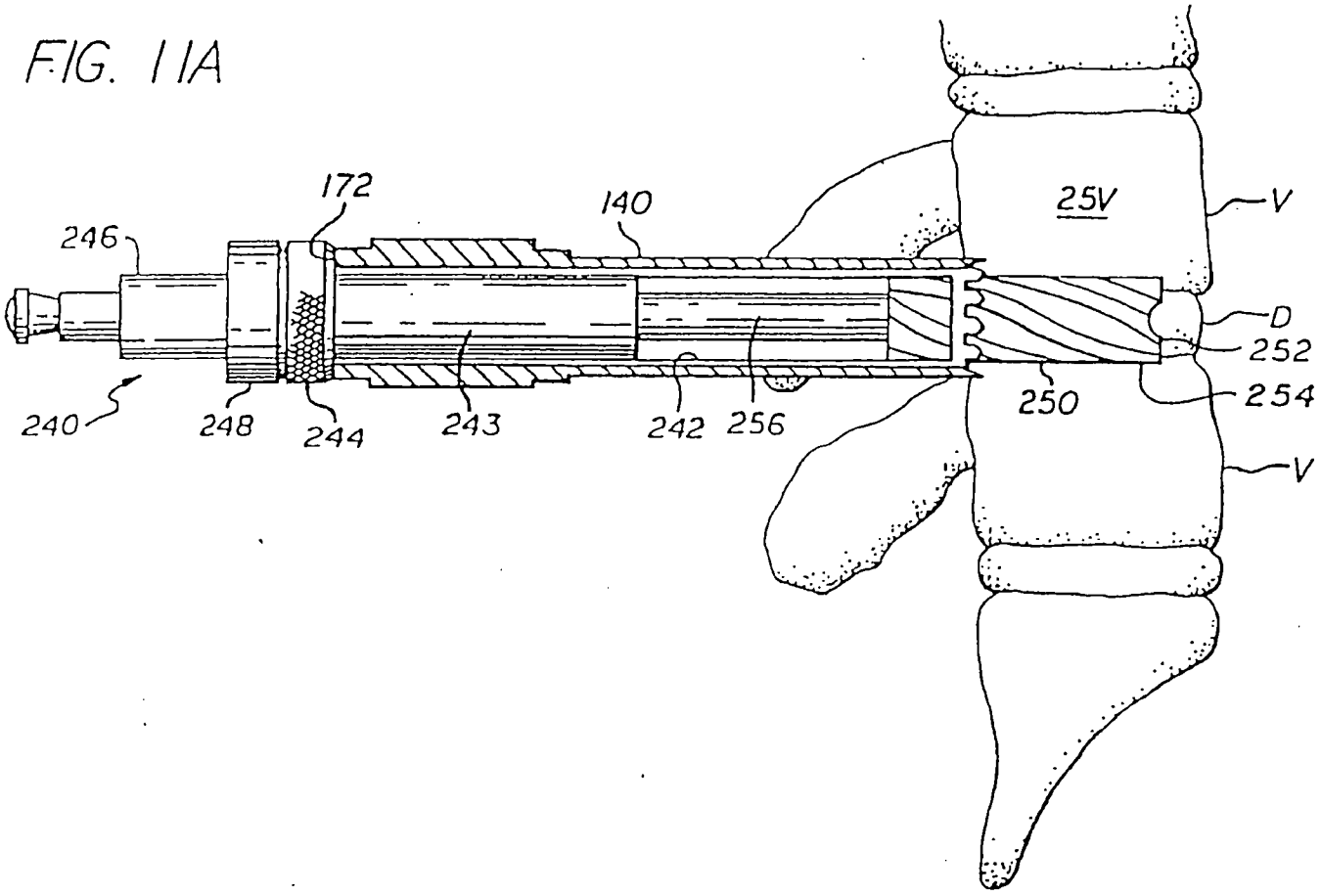
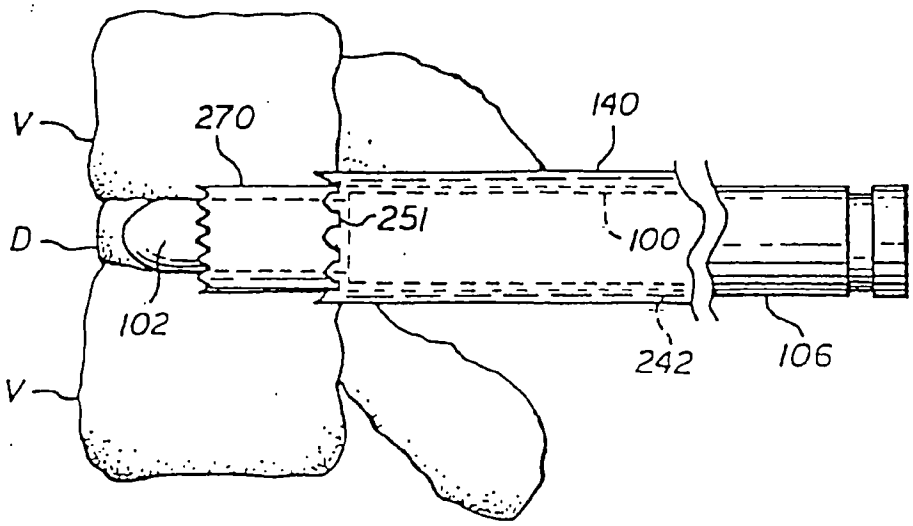


FIG. 11B



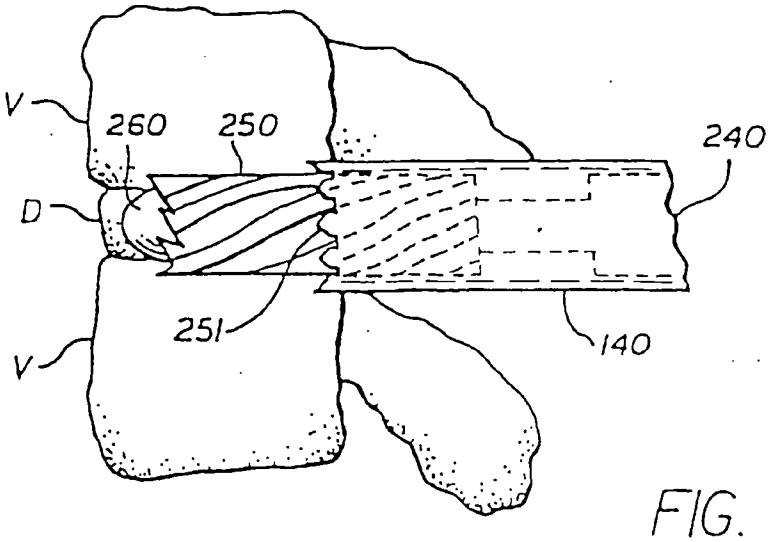


FIG. 11C

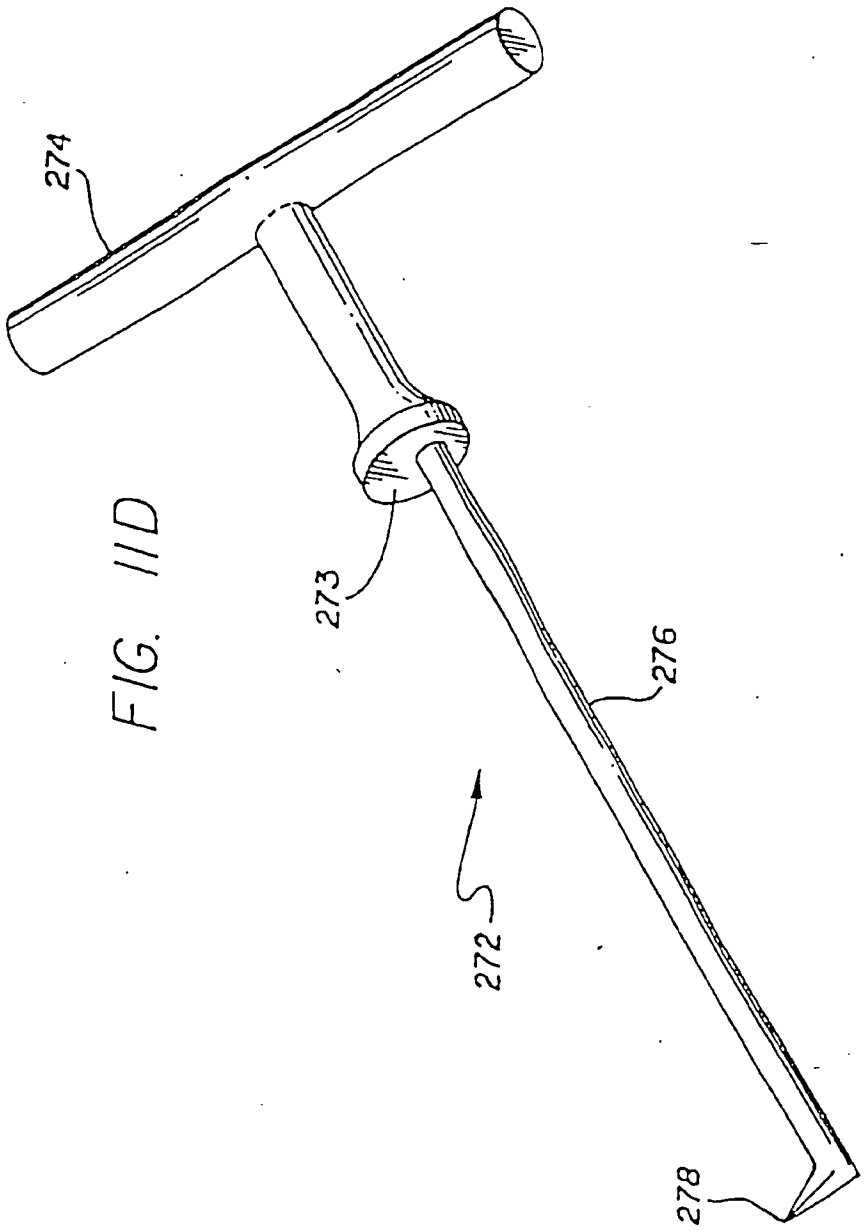


FIG. 11D

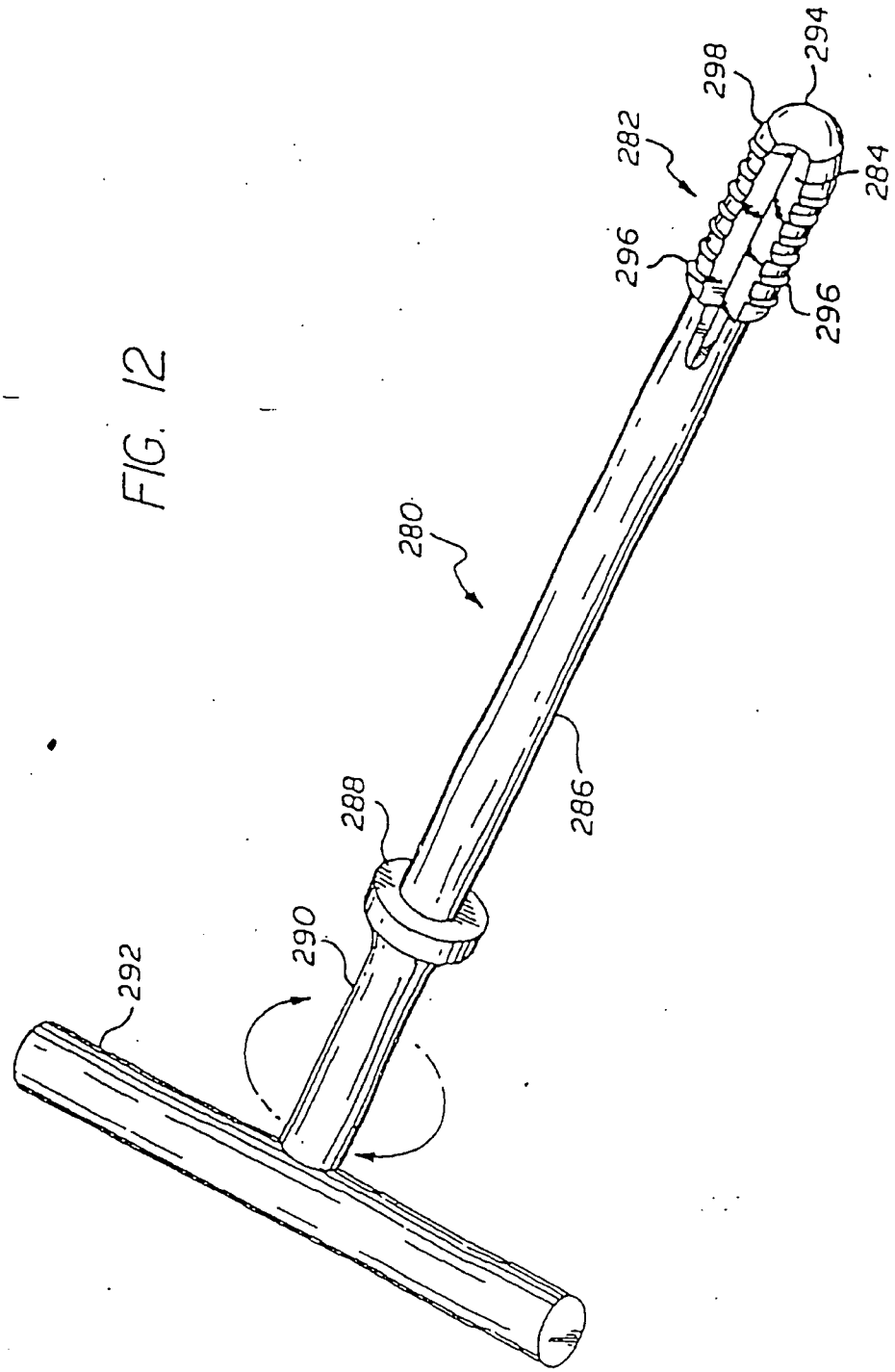


FIG. 12

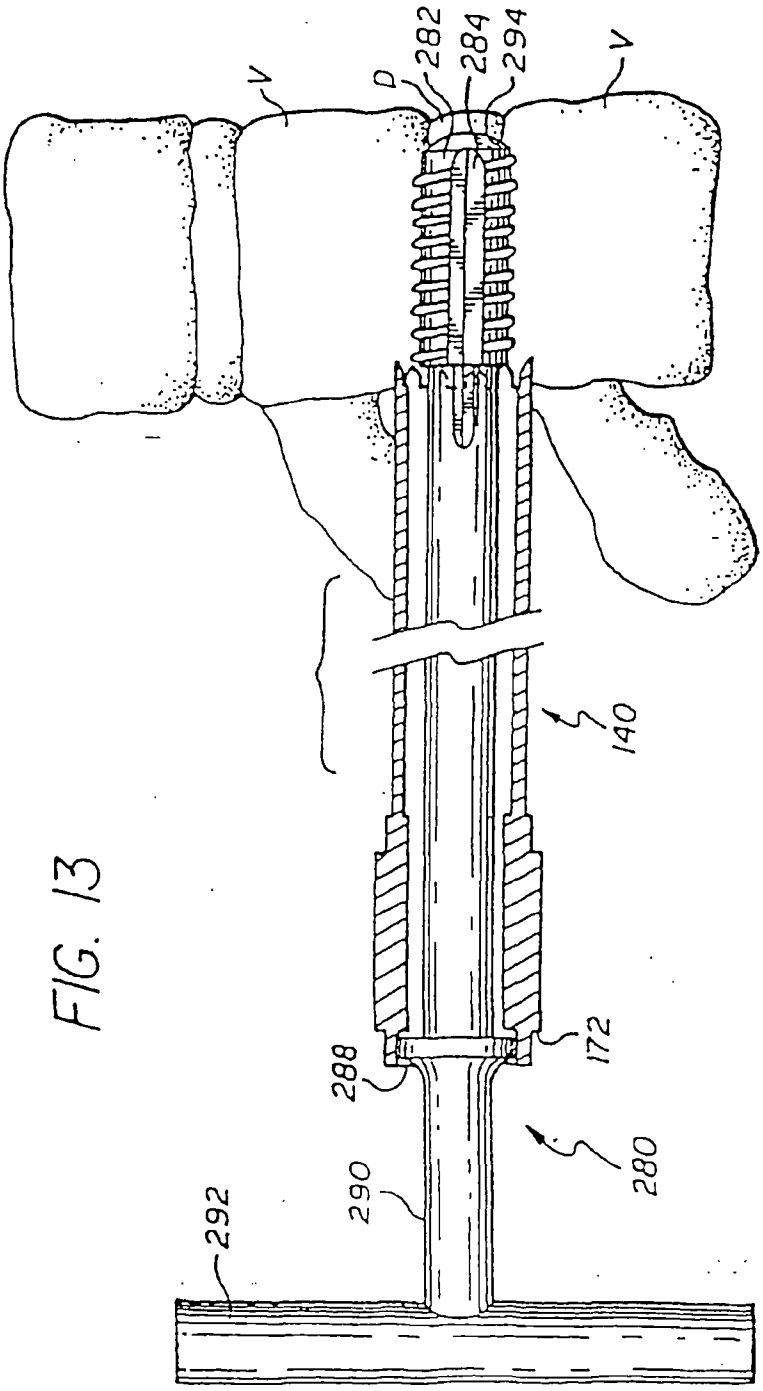


FIG. 13

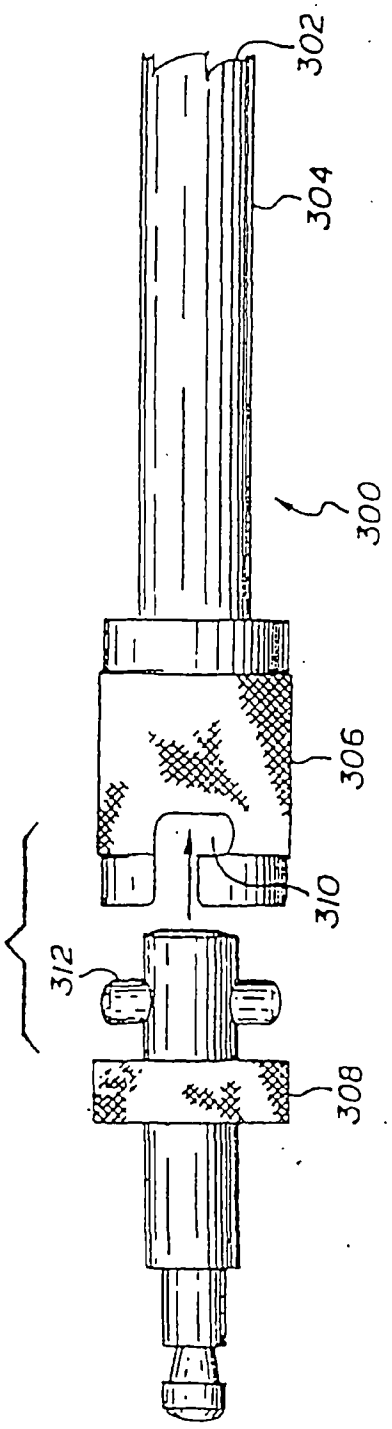


FIG. 14A

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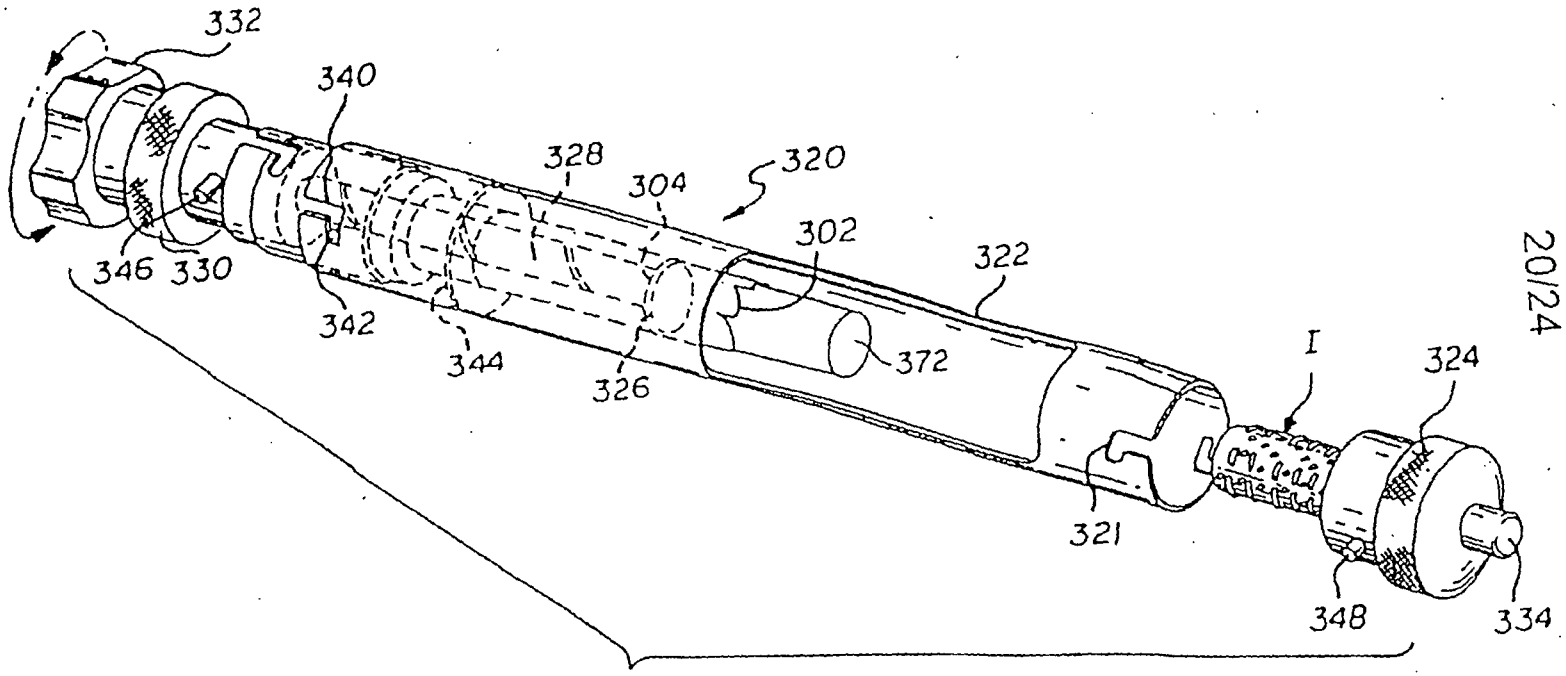


FIG. 14B

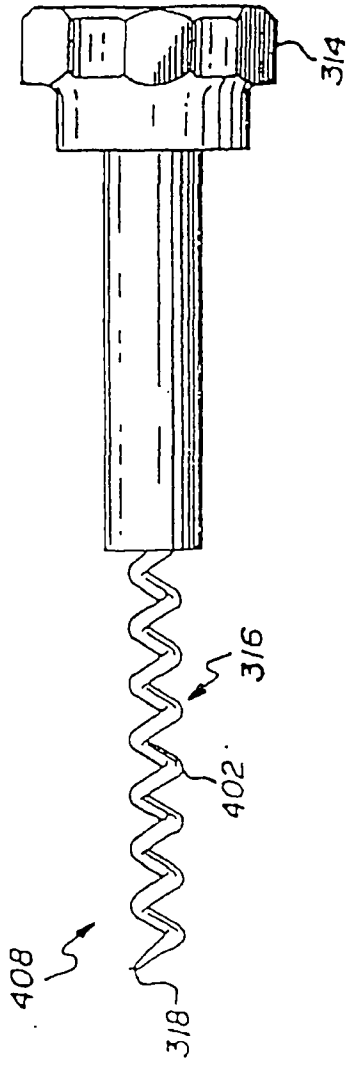


FIG. 14C

FIG. 15

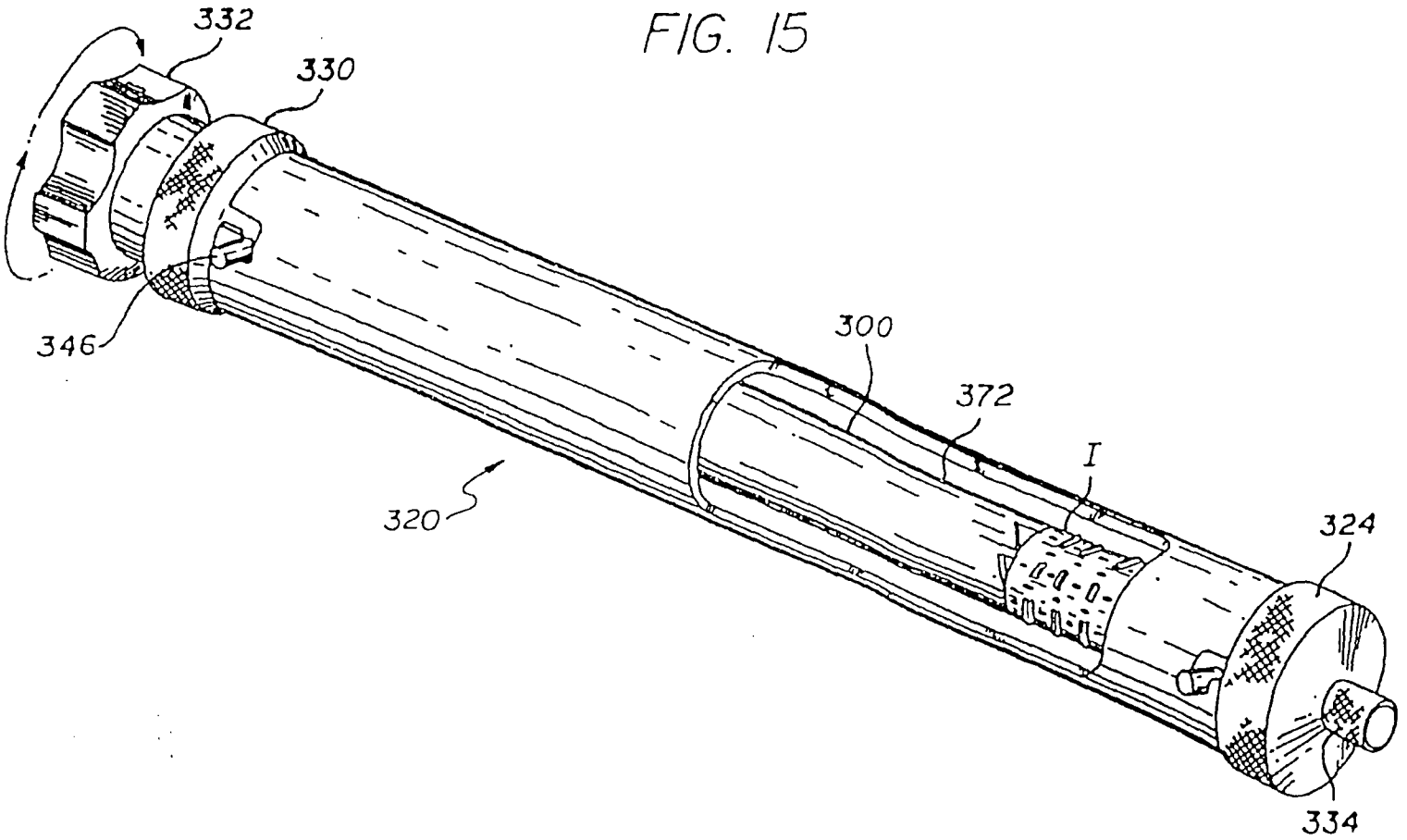


FIG. 16

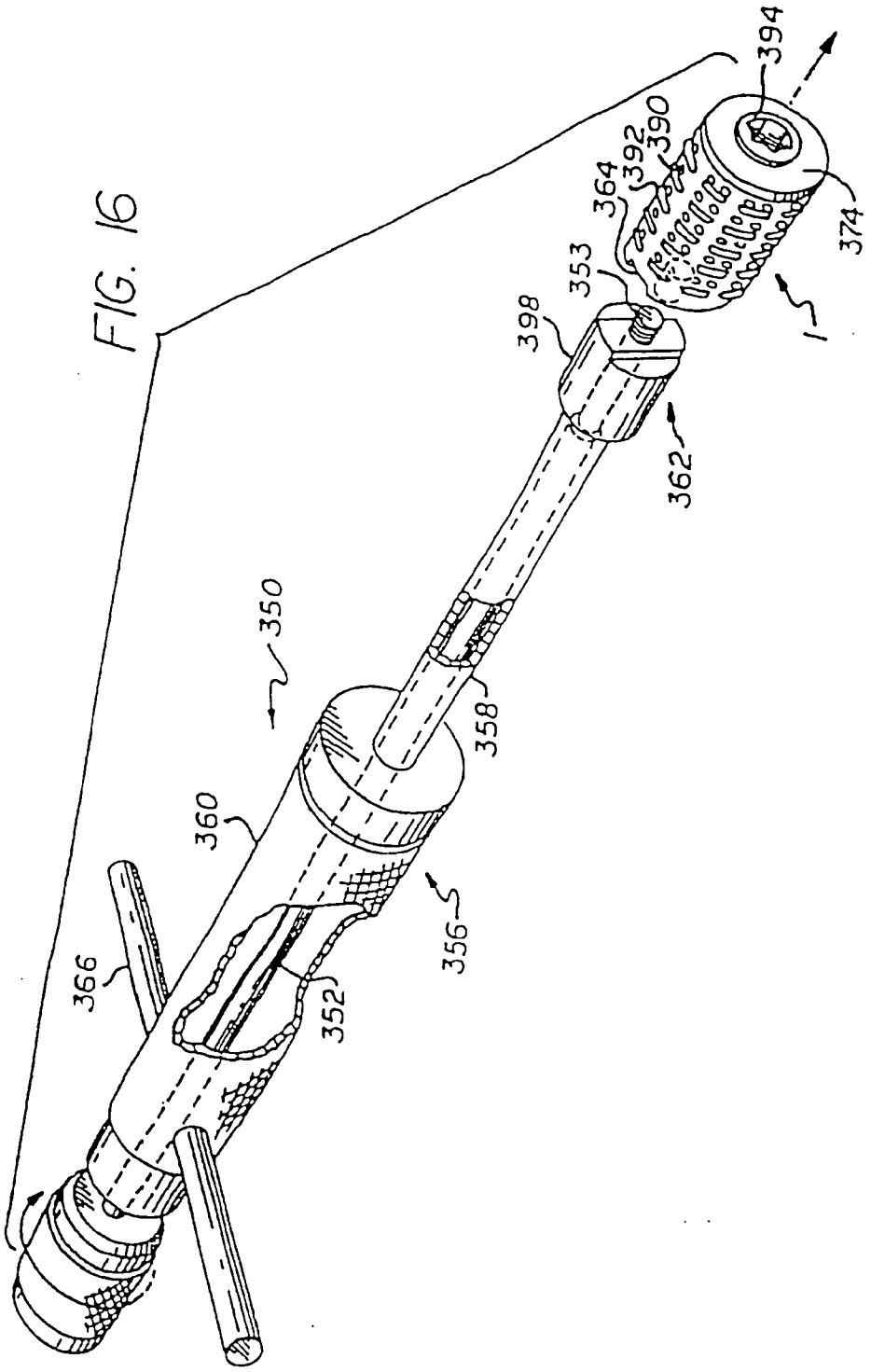


FIG. 17

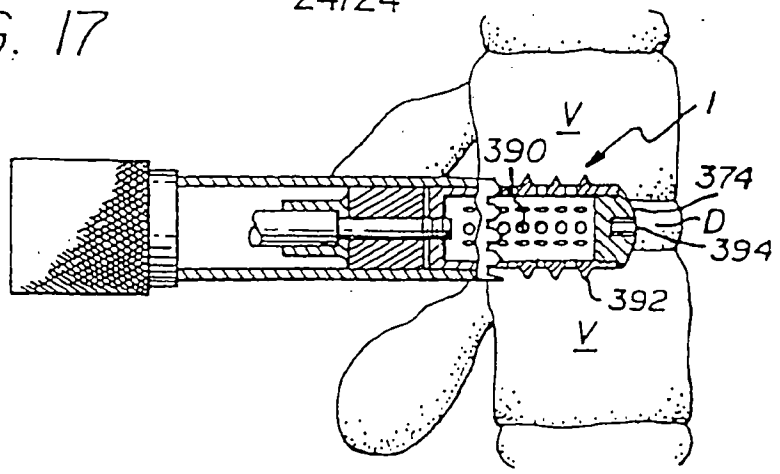
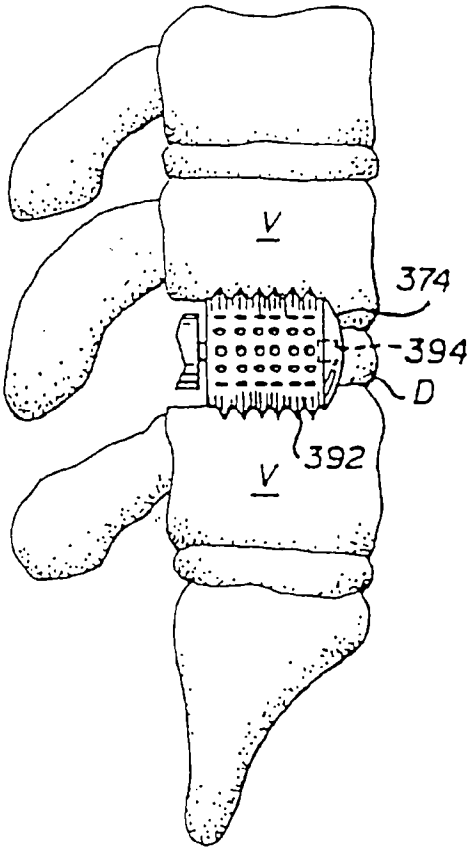


FIG. 18



(19)中华人民共和国国家知识产权局

(12)发明专利申请

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A61F 2/44(2006.01)

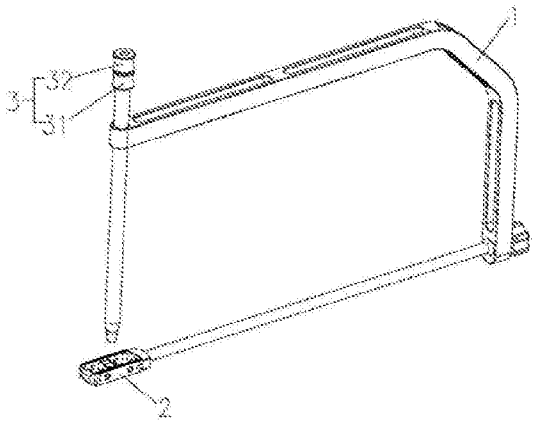
权利要求书1页 说明书5页 附图4页

(54)发明名称

一种骶髂融合系统及使用方法

(57)摘要

本发明涉及医疗器械领域，具体涉及一种骶髂融合系统及使用方法。一种骶髂融合系统，包括：植入装置，所述植入装置的一端用于夹持融合器，所述植入装置的另一端设置有导向组件；融合器，所述融合器上开有螺钉孔；导向组件，所述导向组件包括钻孔导向件和固定导向件，钻头在所述钻孔导向件的作用下穿过所述螺钉孔钻孔，固定件在固定导向件的作用下植入所述融合器的所述螺钉孔内。解决了现有技术中的骶髂融合系统使用时存在的关节骨面上的软骨未被去除、融合效果差；如去除软骨又会出现间隙的技术问题。



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1.一种骶髂融合系统,其特征在于,包括:

植入装置(1),所述植入装置(1)的一端用于夹持融合器(2),所述植入装置(1)的另一端设置有导向组件(3);

融合器(2),所述融合器(2)上开有螺钉孔(21);

导向组件(3),所述导向组件(3)包括固定导向件(31)和钻孔导向件(32),钻头在所述钻孔导向件(32)的导向作用下穿过所述螺钉孔(21)钻孔,固定件(4)在固定导向件(31)的导向作用下被植入所述融合器(2)的所述螺钉孔(21)内。

2.根据权利要求1所述的一种骶髂融合系统,其特征在于,所述植入装置(1)的一端设置有夹持头(13),所述夹持头(13)用于夹持融合器(2),所述植入装置(1)的另一端开有供导向组件(3)穿过的导向孔(111),所述导向孔(111)的轴线与夹持在所述植入装置(1)上的融合器(2)的螺钉孔(21)的轴线共线。

3.根据权利要求2所述的一种骶髂融合系统,其特征在于,所述植入装置(1)包括固定连接的植入臂(11)和端臂(12),所述端臂(12)呈直线延伸且两端开口的中空管状,所述端臂(12)的远离植入臂(11)的一端连接有夹持头(13),螺纹杆(14)穿过所述端臂(12)与所述融合器(2)螺纹连接。

4.根据权利要求2所述的一种骶髂融合系统,其特征在于,所述固定导向件(31)呈中空管状,所述固定导向件(31)可置于所述导向孔(111)内并可沿所述导向孔(111)轴向运动。

5.根据权利要求4所述的一种骶髂融合系统,其特征在于,所述固定导向件(31)包括固定导向管(311),所述固定导向管(311)靠近所述融合器(2)的一端为第一锥形头部(312),所述固定导向管(311)的另一端设置有第一手持部(313)。

6.根据权利要求5所述的一种骶髂融合系统,其特征在于,所述钻孔导向件(32)呈中空管状,所述钻孔导向件(32)可置于所述固定导向件(31)内,所述固定导向件(31)的轴线、钻孔导向件(32)的轴线和导向孔(111)的轴线共线。

7.根据权利要求6所述的一种骶髂融合系统,其特征在于,所述钻孔导向件(32)包括钻孔导向管(321),所述钻孔导向管(321)靠近所述融合器(2)的一端为第二锥形头部(322),所述钻孔导向管(321)的另一端设置有第二手持部(323)。

8.如权利要求1所述的一种骶髂融合系统,其特征在于,还包括扩展件(5),所述扩展件(5)与所述植入装置(1)连接,所述扩展件(5)上开有扩展导向孔(51),所述固定导向件(31)被置于所述扩展导向孔(51)内,辅助固定件(6)在固定导向件(31)的导向作用下被植入在所述融合器(2)的四周。

9.一种骶髂融合系统的使用方法,其特征在于,采用上述权利要求1-8任一项所述的骶髂融合系统,包括如下步骤:

S1、去除骶髂关节的关节面上的软骨;

S2、采用植入装置(1)将融合器(2)填充到去除了软骨的间隙中;

S3、钻头在钻孔导向件(32)的作用下穿过螺钉孔(21)在骶骨和髂骨上进行钻孔;

S4、通过固定导向件(31)沿钻得的孔向螺钉孔(21)内植入固定件(4)。

10.根据权利要求9所述的一种骶髂融合系统的使用方法,其特征在于,还包括步骤S5、固定导向件(31)被置于扩展件(5)上的扩展导向孔(51)内,在融合器(2)的四周植入辅助固定件(6)。

一种骶髂融合系统及使用方法

技术领域

[0001] 本发明涉及医疗器械领域，具体涉及一种骶髂融合系统及使用方法。

背景技术

[0002] 研究表明，高达25％的腰痛源自骶髂关节，骶髂关节的融合可有效治疗上述问题。申请号为201180058533.X的申请文件公开了一种利用压缩性植入物固定或融合骨的系统，该系统主要包括一个截面为三角形的空心锚固体、一个螺帽、一个垫片、一个螺纹锚固体和一个将上述各部件串接在一起的螺杆。螺纹锚固件植入骶骨中，空心锚固体植入骶骨和髂骨中承受载荷，螺杆穿入螺纹锚固件及空心锚固体中，螺帽和垫片旋在螺杆上并处在髂骨外，旋紧螺帽即可对骶髂关节实施加压，促进融合。上述装置仅仅是对骶髂关节进行了加压，关节骨面上的软骨未被去除，因此融合效果不佳。

发明内容

[0003] 为了解决现有技术中的骶髂融合系统使用时存在的关节骨面上的软骨未被去除、融合效果差；如去除软骨又会出现间隙的技术问题，本发明提出一种骶髂融合系统及使用方法，解决了上述技术问题。本发明的技术方案如下：

[0004] 一种骶髂融合系统，包括：植入装置，所述植入装置的一端用于夹持融合器，所述植入装置的另一端设置有导向组件；融合器，所述融合器上开有螺钉孔；导向组件，所述导向组件包括钻孔导向件和固定导向件，钻头在所述钻孔导向件的导向作用下穿过所述螺钉孔钻孔，固定件在固定导向件的导向作用下被植入所述融合器的所述螺钉孔内。

[0005] 通过设置骶髂融合系统包括融合器，可在软骨被去除出现间隙的情况下，采用融合器去填充间隙，保证融合效果；进一步通过植入装置一端夹持融合器，融合器上开有螺钉孔，另一端设置导向组件，可使得钻头在钻孔导向件的作用下穿过螺钉孔在骶骨和髂骨上钻孔，固定件在固定导向件的作用下植入融合器螺钉孔，对骶髂关节进行了加压。

[0006] 进一步地，所述植入装置的一端设置有夹持头，所述夹持头用于夹持融合器，所述植入装置的另一端开有供导向组件穿过的导向孔，所述导向孔的轴线与夹持在所述植入装置上的融合器的螺钉孔的轴线共线。

[0007] 进一步地，所述植入装置包括固定连接的植入臂和端臂，所述端臂呈直线延伸且两端开口的中空管状，所述端臂的远离植入臂的一端连接有夹持头，螺纹杆穿过所述端臂与所述融合器螺纹连接。

[0008] 进一步地，所述固定导向件呈中空管状，所述固定导向件可置于所述导向孔内并可沿所述导向孔轴向运动。

[0009] 进一步地，所述固定导向件包括固定导向管，所述固定导向管靠近所述融合器的一端为第一锥形头部，所述固定导向管的另一端设置有第一手持部。

[0010] 进一步地，所述钻孔导向件呈中空管状，所述钻孔导向件可置于所述固定导向件内，所述固定导向件的轴线、钻孔导向件(32)的轴线和导向孔的轴线共线。

[0011] 进一步地，所述钻孔导向件包括钻孔导向管，所述钻孔导向管靠近所述融合器的一端为第二锥形头部，所述固定导向管的另一端设置有第二手持部。

[0012] 进一步地，还包括扩展件，所述扩展件与所述植入装置连接，所述扩展件上开有扩展导向孔，所述固定导向件被置于所述扩展导向孔内，辅助固定件在固定导向件的导向作用下被植入在所述融合器的四周。

[0013] 一种骶髂融合系统的使用方法，采用上述权利要求1-8任一项所述的骶髂融合系统，包括如下步骤：S1、去除骶髂关节的关节面上的软骨；S2、采用植入装置将融合器填充到去除了软骨的间隙中；S3、钻头在钻孔导向件的作用下穿过螺钉孔在骶骨和髂骨上进行钻孔；S4、通过固定导向件沿钻得的孔向螺钉孔内植入固定件。

[0014] 进一步地，还包括步骤S5、固定导向件被置于扩展件上的扩展导向孔内，在融合器的四周植入辅助固定件。

[0015] 基于上述技术方案，本发明所能实现的技术效果为：

[0016] 1.本发明的骶髂融合系统及使用方法，包括融合器，可在软骨被去除出现间隙的情况下，采用融合器去填充间隙，保证融合效果；进一步通过植入装置一端夹持融合器，融合器上开有螺钉孔，另一端设置导向组件，可使得钻头在钻孔导向件的作用下穿过螺钉孔在骶骨和髂骨上钻孔，固定件在固定导向件的作用下植入融合器螺钉孔，对骶髂关节进行了加压；进一步地，融合器上设有植骨窗，用于填充植骨，促进融合；

[0017] 2.本发明的骶髂融合系统及使用方法，通过设置植入装置上的导向孔与夹持头夹持的融合器的螺钉孔的轴线共线，可实现导向组件沿导向孔运动即可将固定件植入融合器的螺钉孔内，方便操作，且准确性高；

[0018] 3.本发明的骶髂融合系统及使用方法，通过设置螺纹杆与穿过端臂与融合器螺纹连接，可实现与融合器的稳定连接，在融合器植入到位后，可转动螺纹杆，使螺纹杆脱离融合器，方便拆卸；

[0019] 4.本发明的骶髂融合系统及使用方法，通过设置固定导向件位于导向孔内，钻孔导向件位于固定导向件内部，使钻孔导向件的轴线、固定导向件轴线和导向孔的轴线共线，可实现钻头自钻孔导向件伸出即可穿过融合器的螺钉孔进行打孔，通过固定导向件植入的固定件可沿上述打孔固定到融合器的螺钉孔中，方便对准；

[0020] 5.本发明的骶髂融合系统及使用方法，通过设置扩展件，扩展件上开有的扩展导向孔偏离螺钉孔，即扩展导向孔与螺钉孔的轴线不共线，可使得固定导向件被置于扩展导向孔内，在融合器的四周植入辅助固定件，加强固定；

[0021] 6.本发明的骶髂融合系统的使用方法，采用去除软骨→植入融合器→钻孔→植入固定件→植入辅助固定件的步骤，实现了对骶髂关节的去除软骨并消除间隙，同时采用固定件和辅助固定件对融合器及骶髂关节进行固定为融合提供生物及力学环境，保证了融合效果。

附图说明

[0022] 图1为本发明的骶髂融合系统的结构示意图；

[0023] 图2为植入装置的爆炸图；

[0024] 图3为融合器的结构示意图；

[0025] 图4为固定导向件的结构示意图；

[0026] 图5为钻孔导向件的结构示意图；

[0027] 图6为本发明的骶髂融合系统在钻孔时的工作状态图；

[0028] 图7为带有扩展件的骶髂融合系统的结构示意图；

[0029] 图8为带有扩展件的骶髂融合系统的爆炸图；

[0030] 图9为扩展件的结构示意图；

[0031] 图中：1-植入装置；11-植入臂；111-导向孔；12-端臂；13-夹持头；14-螺纹杆；141-杆头；142-旋钮；2-融合器；21-螺钉孔；22-螺纹孔；23-植骨窗；3-导向组件；31-固定导向件；311-固定导向管；312-第一锥形头部；313-第一手持部；32-钻孔导向件；321-钻孔导向管；322-第二锥形头部；323-第二手持部；4-固定件；5-扩展件；51-辅助导向孔；52-导向柱；6-辅助固定件。

具体实施方式

[0032] 下面结合说明书附图对本发明的内容作进一步地描述。在本发明的描述中，需要理解的是，术语“径向”、“轴向”、“上”、“下”、“顶”、“底”、“内”、“外”等指示的方位或位置关系为基于附图所示的方位或位置关系，仅是为了便于描述本发明和简化描述，而不是指示或暗示所指的装置或元件必须具有特定的方位、以特定的方位构造和操作，因此不能理解为对本发明的限制。在本发明的描述中，除非另有说明，“多个”的含义是两个或两个以上。

[0033] 在本发明的描述中，需要说明的是，除非另有明确的规定和限定，术语“安装”、“设置”、“连接”应做广义理解，例如，可以是固定连接，也可以是可拆卸连接，或一体地连接；可以是直接相连，也可以通过中间媒介间接相连。对于本领域的普通技术人员而言，可以根据具体情况理解上述术语在本发明中的具体含义。

[0034] 如图1-9所示，本实施例提出一种骶髂融合系统，包括植入装置1、融合器2和导向组件3，植入装置1的一端用于夹持融合器2，将融合器2植入人体的骶髂关节中；植入装置1的另一端设置导向组件3，钻头经过导向组件3穿过融合器2在骶骨和髂骨上钻孔，固定件4在导向组件3的作用下植入融合器2中，对融合器2及骶髂关节进行固定为融合提供生物及力学环境。

[0035] 植入装置1包括植入臂11和端臂12，植入臂11呈弯折状，端臂12呈直线延伸且两端开口的中空管状，植入臂11的一端与端臂12的一端固定连接，植入臂11的另一端设置导向孔111，端臂12的另一端设置有夹持头13。夹持头13的两侧延伸有夹持端可分别压紧融合器2的两侧相对的侧面，起到对融合器2的夹持作用。

[0036] 进一步地，为了实现对融合器2的稳定植入，植入装置1还包括螺纹杆14，螺纹杆14可穿过端臂12与融合器2螺纹连接。具体地，螺纹杆14的与融合器2连接的杆头141上设置有外螺纹，融合器2上设置有螺纹孔22与杆头141螺纹配合，螺纹杆14的另一端伸出端臂12并设置有旋钮142，当融合器2植入到位，通过旋转旋钮142可使螺纹杆14直线运动，脱离融合器2。

[0037] 融合器2呈方形框体结构，融合器2上设置有螺钉孔21，螺钉孔21贯穿融合器2的上表面和下表面，当融合器2被植入装置1夹持时，螺钉孔21的轴线与导向孔111的轴线共线，如此方便钻头穿过螺钉孔21进行钻孔，也方便固定件4植入螺钉孔21内。融合器2上还设置

有与杆头141配合的螺纹孔22，本实施例中螺纹孔22设置在融合器2的较短的侧面上。融合器2内还设置有植骨窗23，用于容纳自体骨、异体骨或人工骨，本实施例中植骨窗23的个数为两个。进一步地，融合器的上表面和下表面上设置有防滑结构，优选地，防滑结构为防滑齿，融合器的上表面和下表面上分布有防滑齿，使融合器固定稳定，达到融合的目的。融合器的侧壁上设置有侧方融合孔，优选地，侧方融合孔为多个，多个侧方融合孔分布在融合器的长边的侧壁上，方便实现多方向融合。

[0038] 导向组件3包括固定导向件31和钻孔导向件32，固定导向件31和钻孔导向件32均为中空管状，固定导向件31位于导向孔111内并可沿导向孔111轴向运动，钻孔导向件32可伸入到固定导向件31的内部。具体地，固定导向件31包括固定导向管311，固定导向管311的靠近被夹持的融合器2的一端为第一锥形头部312，固定导向管311的另一端设置有第一手持部313，第一手持部313的外径大于固定导向管311的外径，方便抓握。钻孔导向件32包括钻孔导向管321，钻孔导向管321的靠近被夹持的融合器2的一端为第二锥形头部322，钻孔导向管321的另一端设置有第二手持部323，第二手持部323的外径大于钻孔导向管321的外径，方便操作。当钻孔导向件32被置于固定导向件31内时，第二锥形头部322至少部分伸出第一锥形头部312，第二手持部323可压紧在第一手持部313上，如图1所示。当固定导向件31位于导向孔111内，钻孔导向件32伸入到固定导向件31内时，固定导向件31的轴线、钻孔导向件32的轴线和导向孔111的轴线共线，如此，在需要穿过融合器2上的螺钉孔21钻孔时，钻头伸入钻孔导向件32内并沿钻孔导向件32伸入人体，可直接穿过螺钉孔21在骶骨和髂骨上钻孔；钻孔后，通过外部工具(例如上钉扳手等)连接固定件4，在固定导向件31导向作用下，外部工具带动固定件4沿钻头钻得的孔植入螺钉孔21内。

[0039] 为了加强固定，骶髂融合系统还包括扩展件5，方便在融合器2的附近植入辅助固定件6，加强对融合器2和骶髂关节的固定。扩展件5的一端与植入装置1的设有导向孔111的一端连接，扩展件5的另一端设置有扩展导向孔51，固定导向件31可脱离导向孔111，被放置到扩展导向孔51内，外部工具(例如上钉扳手等)连接辅助固定件6，在固定导向件31导向作用下，外部工具带动辅助固定件6植入到人体内。通过设置扩展件5，使得扩展导向孔51的轴线偏离导向孔111的轴线，进一步合理设置扩展件5的尺寸，可将辅助固定件6植入在融合器2的附近。优选地，扩展件5与植入装置1可拆卸连接，扩展件5与植入装置1连接的一端的下端面凸出设有导向柱52，导向柱52可与导向孔111间隙配合，即如需进行辅助固定件6的植入，则将导向组件3自导向孔111中取出，将扩展件5上的导向柱52插入导向孔111中，再将导向组件3插入扩展导向孔51中，即可进行辅助固定件6的植入。

[0040] 进一步地，固定件4和辅助固定件6均可选但不限于螺钉。固定件4和辅助固定件6与外部工具连接的一端设置有连接接口，例如梅花形接口等。

[0041] 本实施例还提供了一种骶髂融合系统的使用方法，采用上述骶髂融合系统，包括如下步骤：

[0042] S1、去除骶髂关节的关节面上的软骨；

[0043] S2、采用植入装置1将融合器2填充到去除了软骨的间隙中；

[0044] S3、钻头在钻孔导向件32的作用下穿过螺钉孔111在骶骨和髂骨上进行钻孔；

[0045] S4、通过固定导向件31沿钻得的孔向螺钉孔21内植入固定件4。

[0046] 步骤S2中，融合器2的植骨窗23内可填充自体骨、异体骨或人工骨等帮助融合的物

质，融合器2位于夹持件13的两个夹持端上，融合器2上的螺纹孔22与螺纹杆14的杆头141螺纹连接，从后位将融合器植入到人体内。

[0047] 步骤S3中，固定导向件31需插入导向孔111内，钻孔导向件32插入固定导向件31内，且钻孔导向件32的第二手持部323压紧在第一手持部313上，钻头经过钻孔导向件32从侧方进行钻孔。

[0048] 步骤S4中，取出钻孔导向件32，只保留固定导向件31在导向孔111内，在固定导向件31导向作用下，外部工具(例如上钉扳手)可带动固定件4穿过固定导向件31，沿钻得的孔从侧方植入融合器2的螺钉孔21内。

[0049] 进一步地，还可包括步骤S5、固定导向件31穿过扩展件5上的扩展导向孔51，在融合器2的四周植入辅助固定件6。具体地，将导向孔111内的导向组件3取出，将扩展件5上的导向柱52插入导向孔111内，实现扩展件5与植入装置1的连接；然后将固定导向件31置于扩展导向孔51内，在固定导向件31导向作用下，外部工具(例如上钉扳手)可带动辅助固定件6穿过固定导向件31，将辅助固定件6植入在融合器2的附近。

[0050] 上面结合附图对本发明的实施方式作了详细说明，但是本发明并不限于上述实施方式，在本领域普通技术人员所具备的知识范围内，还可以在不脱离本发明的宗旨的前提下做出各种变化。

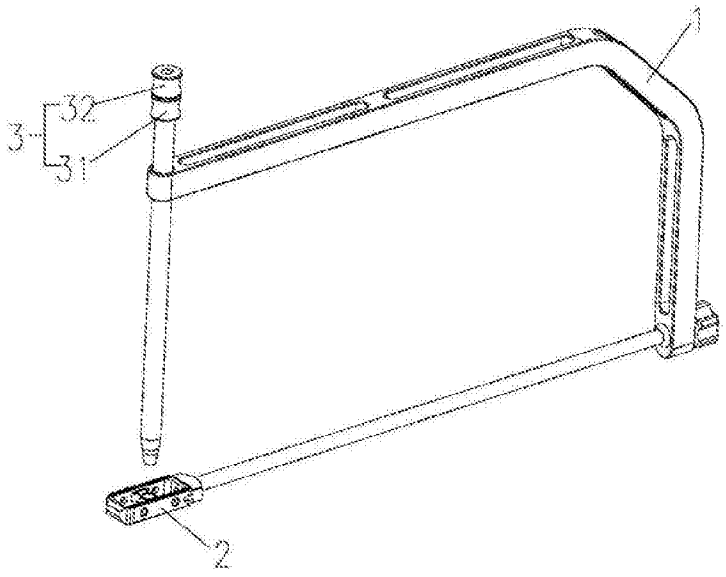


图1

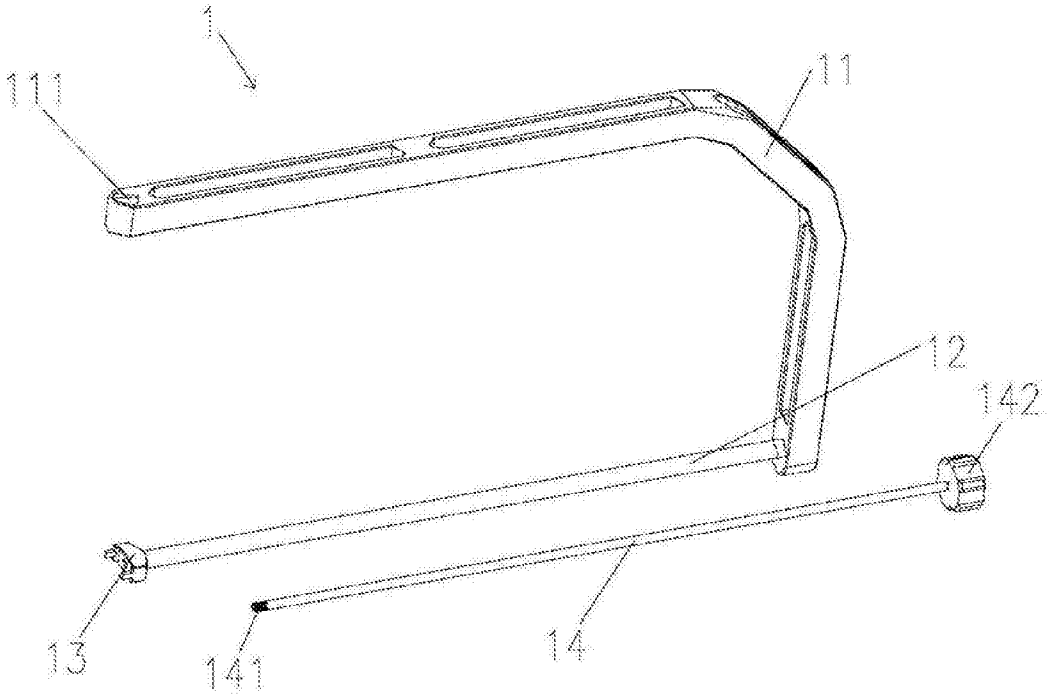


图2

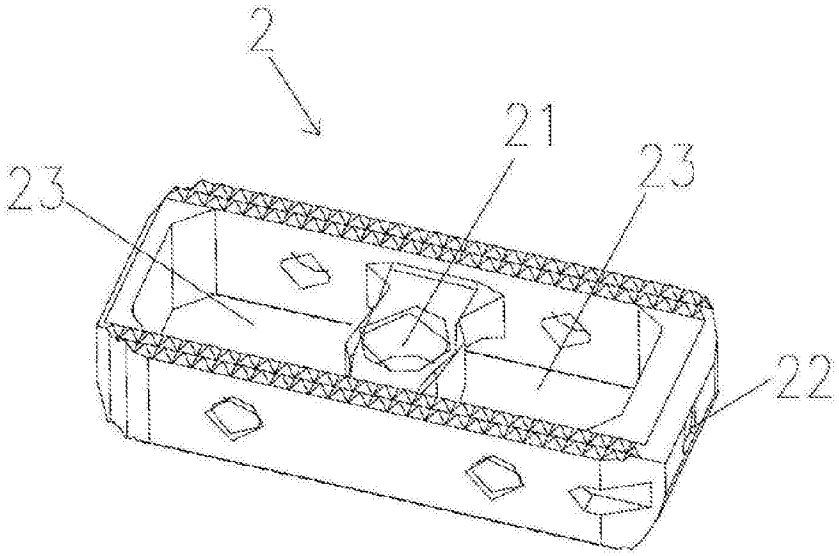


图3

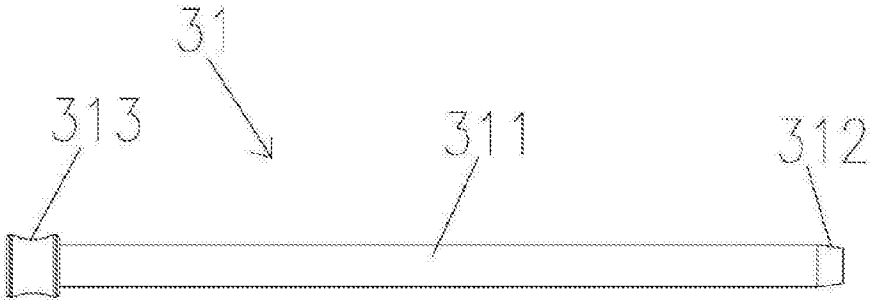


图4

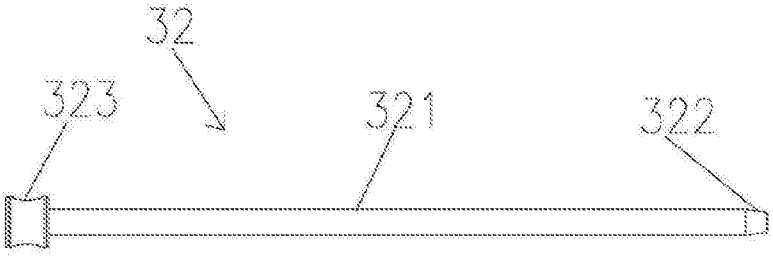


图5

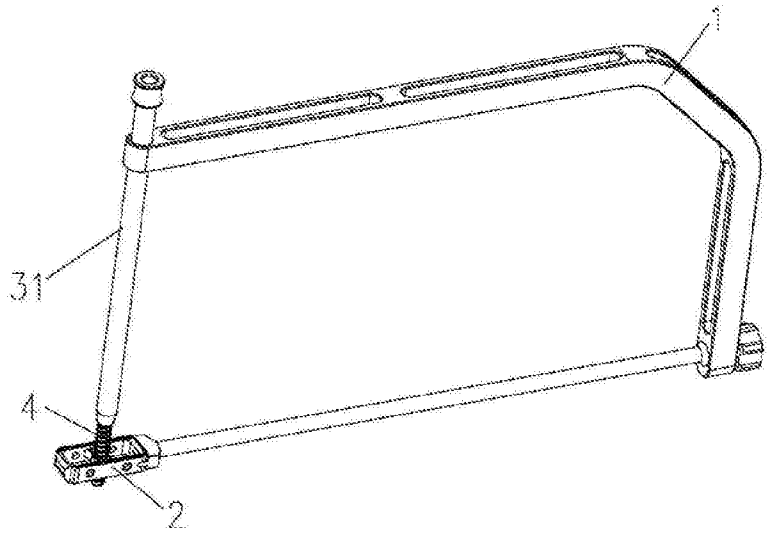


图6

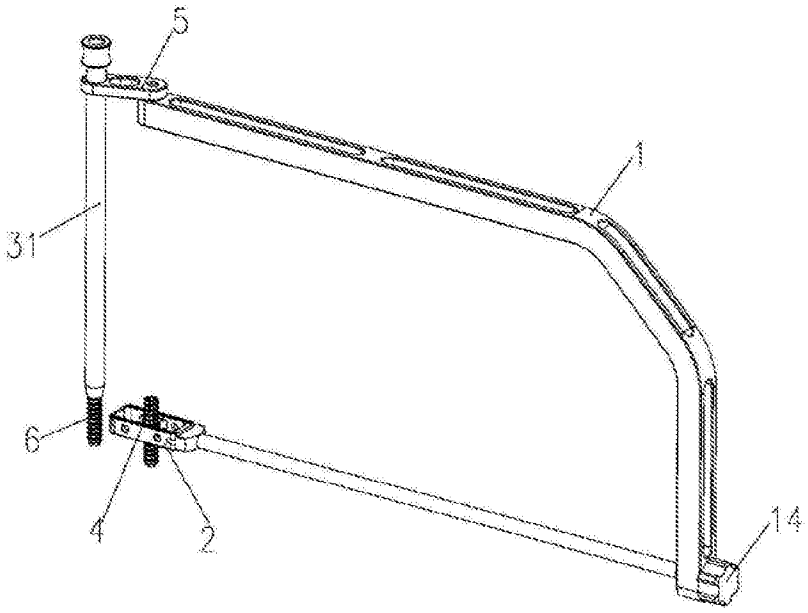


图7

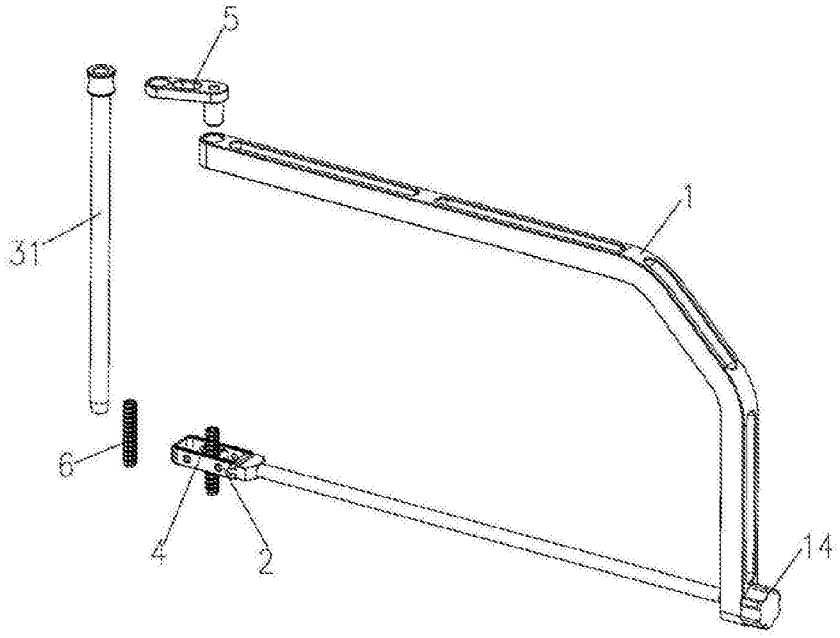


图8

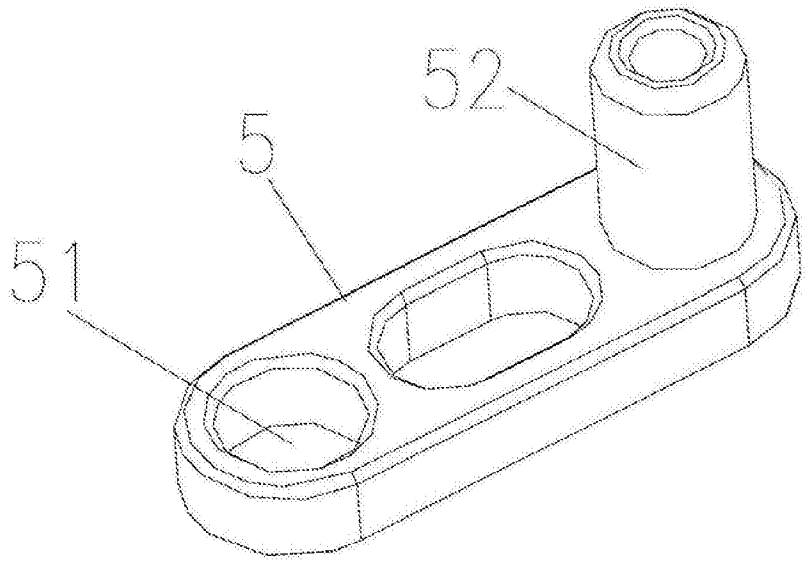


图9

Espacenet

Bibliographic data: CN110123436 (A) — 2019-08-16

Sacroiliac fusion system and use method thereof

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Classification: - international: ***A61B17/16; A61B17/17; A61B17/70; A61B17/86; A61B17/90; A61F2/44***
- cooperative: **A61B17/1615 (CN)**; **A61B17/1659 (CN)**; **A61B17/1671 (CN)**; **A61B17/1757 (CN)**; **A61B17/86 (CN)**; **A61B17/863 (CN)**; **A61B17/8897 (CN)**; **A61F2/4455 (CN)**; A61F2/30749 (CN)

Application number: CN201910541943 20190621 Global Dossier

Priority number(s): CN201910541943 20190621

Abstract of CN110123436 (A)

The invention relates to the field of medical instrument, and concretely relates to a sacroiliac fusion system and use method thereof. The system comprises an implant device, wherein one end of the implant device is used for clamping a fusion cage, and the other end of the implant device is provided with a guide assembly; the fusion cage having a screw hole; the guide assembly comprising a drill guide and a fixed guide, wherein a drill bit passes through the screw hole for drilling under the action of the drill guide, and a fixed part is implanted within the screw hole of the fusion cage underthe action of a fixed guide. The sacroiliac fusion system solves the problems that according to the sacroiliac fusion system in the prior art, cartilage on the joint bone surface is not removed, andthe fusion effect is poor, and a gap is generated by removing the cartilage.

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(12) DEMANDE DE BREVET D'INVENTION A1

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

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

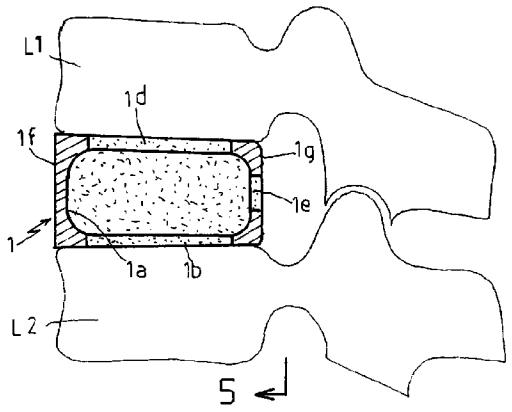
(72) **Inventeur(s) :** TISSERAND PHILIPPE.

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

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

(54) DISPOSITIF DE STABILISATION POSTERIEURE DU RACHIS LOMBAIRE ET LOMBO-SACRE.

(57) Le dispositif présente deux éléments (1) disposés de part et d'autre de l'apophyse épineuse en étant aptes à maintenir l'écartement entre les corps vertébraux concernés (L1) (L2), chacun desdits éléments (1) étant agencé pour recevoir des greffons spongieux et permettre une fusion intersomatique.



FR 2 727 004 - A1

Dispositif de stabilisation postérieure du rachis lombaire et lombo-sacré.

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

Le problème que se propose de résoudre l'invention, est de stabiliser les vertèbres lombaires et lombo-sacrées, par voie postérieure.

Dans certains cas de figures, il n'est plus possible d'intervenir au niveau du rachis, en utilisant la voie antérieure. Ce peut être le cas, par exemple, pour un sujet qui a été opéré plusieurs fois. Or, il est souvent intéressant de pouvoir aborder le sujet dans une zone saine, en évitant les inconvénients d'une reprise.

Toutefois, une intervention par la voie postérieure, est beaucoup plus délicate à réaliser que par la voie antérieure, compte-tenu notamment, de la présence du système nerveux.

Dans ces conditions, il existe peu d'implants aptes à assurer, par la voie postérieure, une stabilité intersomatique, pour le rétablissement de la lordose lombaire et un recalibrage des foramens intervertébraux.

Pour résoudre un tel problème, il a été conçu et mis au point, un dispositif de stabilisation postérieure du rachis lombaire et lombo-sacré, qui présente deux éléments disposés de part et d'autre de l'apophyse épineuse en étant aptes à maintenir l'écartement entre les corps vertébraux concernés, chacun desdits éléments étant agencé pour recevoir des greffons spongieux et permettre une fusion intersomatique.

Pour résoudre le problème posé d'éviter tout écrasement, tout en ayant pour objectif de permettre la fusion intersomatique des greffons spongieux, chaque élément est constitué par une structure volumétrique creuse sous forme d'une cage dont les parois présentent des ouvertures de mise en communication.

Pour résoudre le problème posé de respecter la lordose lombaire, chaque élément est de forme générale parallèlépipédique dont la hauteur de la face antérieure est supérieure à celle de la face postérieure.

Pour résoudre le problème posé de faciliter la stabilité primaire, les faces supérieure et inférieure de chaque élément présentent des aspérités pour faciliter la stabilité primaire.

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

La figure 1 est une vue en perspective de l'un des éléments.

La figure 2 est une vue de dessus de l'élément.

La figure 3 est une vue de face de l'élément.

La figure 4 est une vue en coupe montrant la mise en place de l'élément au niveau lombaire.

La figure 5 est une vue en coupe transversale, considérée selon la ligne 5.5 de la figure 4.

Selon l'invention, le dispositif présente deux éléments identiques (1), disposés de part et d'autre de l'apophyse épineuse (A), en

étant aptes à maintenir l'écartement entre les corps vertébraux concernés (L1) et (L2). Comme indiqué, les éléments (1) sont introduits par voie postérieure. Chacun des éléments (1) est agencé pour recevoir des greffons spongieux et permettre leur fusion intersomatique. Les greffons sont avantageusement prélevés sur la crête iliaque ou dans l'extrémité supérieure du tibia.

Chaque élément (1) est constitué par une structure volumétrique creuse, sous forme d'une cage sensiblement parallèlépipédique et dont les parois présentent des ouvertures (1a) (1b) (1c) (1d) de mise en communication. La face postérieure peut également présenter une ouverture (1e). La hauteur de la face antérieure (1f) est supérieure à la hauteur de la face postérieure (1g). Chaque élément (1) est donc oblique d'avant en arrière pour respecter la lordose lombaire.

A titre indicatif, chaque élément peut avoir une longueur d'environ 25mm et une largeur de 10mm, tandis que la hauteur peut présenter trois tailles possibles, à savoir pour la face antérieure 9mm, 11mm et 13mm, et pour la face postérieure, 8mm, 10mm et 12mm. On n'exclut pas de réaliser un élément de hauteurs inférieures, à savoir par exemple 6mm pour la face antérieure et 5mm pour la face postérieure.

Chaque élément (1) est réalisé en titane ou en polymère renforcé en fibres de carbone. Les faces supérieure et inférieure de l'élément (1) peuvent présenter des aspérités aptes à faciliter la stabilité primaire.

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

Après abord postérieur et repérage précis du segment mobile

à arthrodéser, le canal vertébral est ouvert par résection du ligament jaune. on procède alors à la résection partielle des lames sus et sous-jacentes et à la résection partielle des massifs articulaires. Les racines sont soigneusement libérées, permettant ainsi d'aborder facilement la face postéro-latérale du disque intervertébral de chaque côté de l'apophyse épineuse. Le disque intervertébral est incisé, cureté, tandis que les plateaux vertébraux sus et sous-jacents sont avivés sans entamer le cortex. Une distraction vertébrale est réalisée par l'intermédiaire d'espaceurs, de taille croissante, introduits progressivement de chaque côté et permettant de distracter l'espace intervertébral de manière progressive.

Cette distraction intervertébrale peut être également réalisée au moyen d'un dispositif complémentaire d'ostéosynthèse postérieure, quatre vis pédiculaires ayant été préalablement mises en place dans les vertèbres considérées. Ces vis sont reliées transversalement par des plaques, la distraction pouvant s'effectuer soit entre chaque vis, soit entre les deux plaques supérieures et inférieures. Dans ce cas, la distraction est essentiellement postérieure et permet de faciliter le premier temps de préparation discale et de distraction intervertébrale.

Lorsque la hauteur intervertévrale souhaitée est obtenue, les deux éléments (1) remplis de greffons spongieux, sont mis en place alternativement d'un côté de l'apophyse épineuse, puis de l'autre. La hauteur de la face antérieure (1f) étant légèrement supérieure à la hauteur de la face postérieure (1g), une distraction légèrement supérieure à la taille de l'élément (1) est nécessaire pour pouvoir disposer correctement celui-ci dans l'espace intersomatique.

Une radioscopie de contrôle permet de s'assurer de la bonne position de l'élément. La distraction étant supprimée, un dispositif de compression postérieure est alors nécessaire pour récupérer la lordose physiologique et mettre en charge la partie postérieure de l'élément.

Les avantages ressortent bien de la description, en particulier on souligne et on rappelle :

- la stabilité vertébrale par l'intermédiaire d'une fusion intersomatique par voie postérieure,
- la mise en place de façon bi-latérale des éléments du dispositif,
- la hauteur de chaque élément permet de recalibrer les foramens intervertébraux, de remettre en tension les fibres annulaires périphériques du disque intervertébral,
- de stabiliser et d'immobiliser d'une manière satisfaisante, un ou plusieurs segments mobiles rachidiens, lombaires et lombo-sacrés,
- l'obliquité d'avant en arrière de l'élément, malgré le fait qu'il soit mis en place par voie postérieure.

REVENDICATIONS

-1- Dispositif de stabilisation postérieure du rachis lombaire et lombo-sacré, caractérisé en ce qu'il présente deux éléments (1) disposés de part et d'autre de l'apophyse épineuse en étant aptes à maintenir l'écartement entre les corps vertébraux concernés (L1) (L2), chacun desdits éléments (1) étant agencé pour recevoir des greffons spongieux et permettre une fusion intersomatique.

-2- Dispositif selon la revendication 1, caractérisé en ce que chaque élément (1) est constitué par une structure volumétrique creuse sous forme d'une cage dont les parois présentent des ouvertures de mise en communication (1a) (1b) (1c) (1d) (1e).

-3- Dispositif selon la revendication 1, caractérisé en ce que chaque élément (1) est de forme générale parallèlépipédique dont la hauteur de la face antérieure (1f) est supérieure à celle de la face postérieure (1g).

-4- Dispositif selon la revendication 1, caractérisé en ce que les faces supérieure et inférieure de chaque élément (1) présentent des aspérités pour faciliter la stabilité primaire.

-5- Dispositif selon la revendication 1, caractérisé en ce que chaque élément (1) est réalisé en titane ou polymère renforcé en fibre de carbone

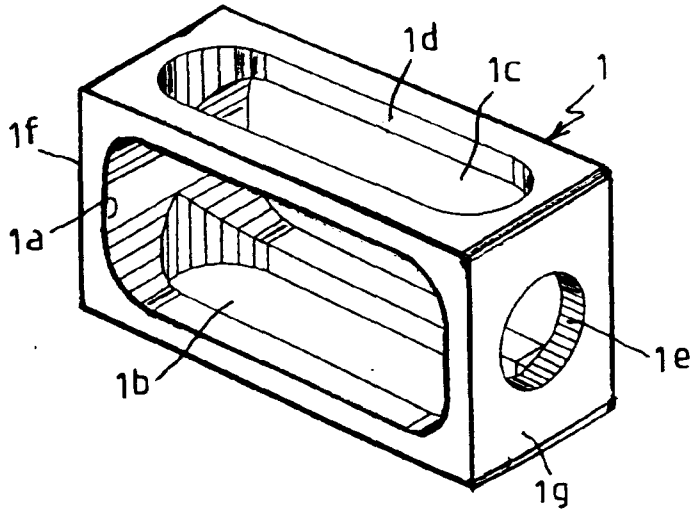


FIG.1

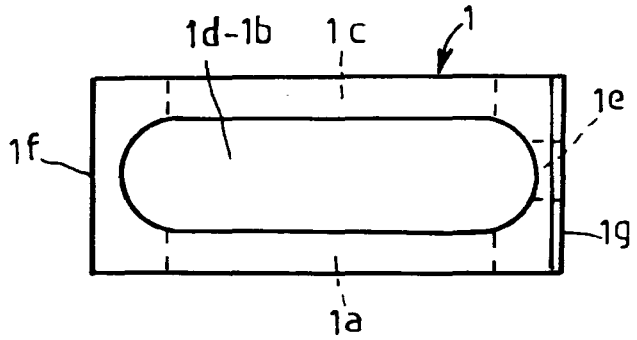


FIG.2

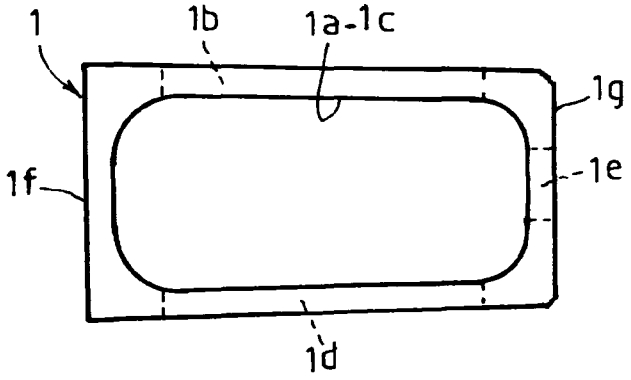


FIG.3

FIG.4

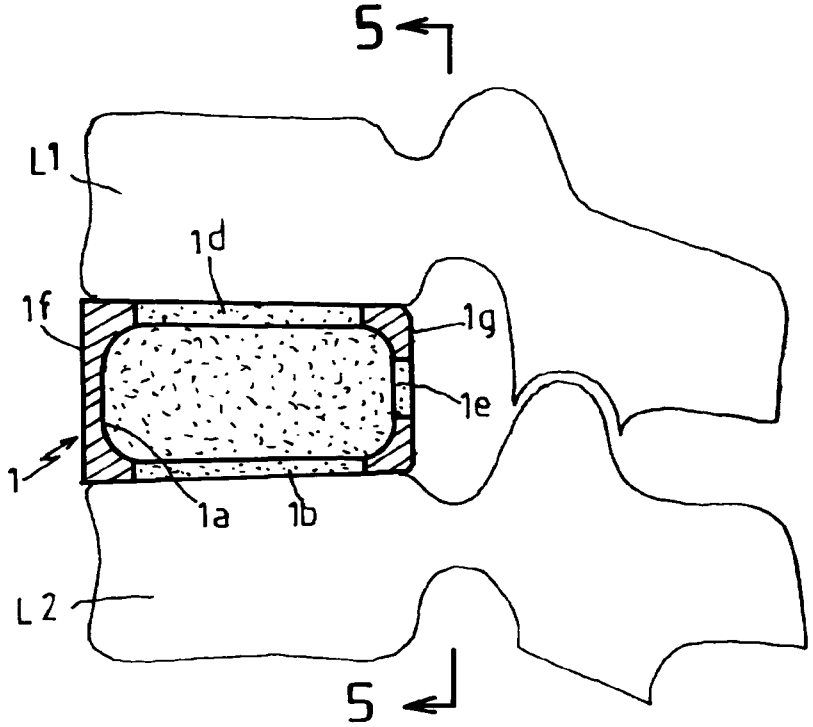
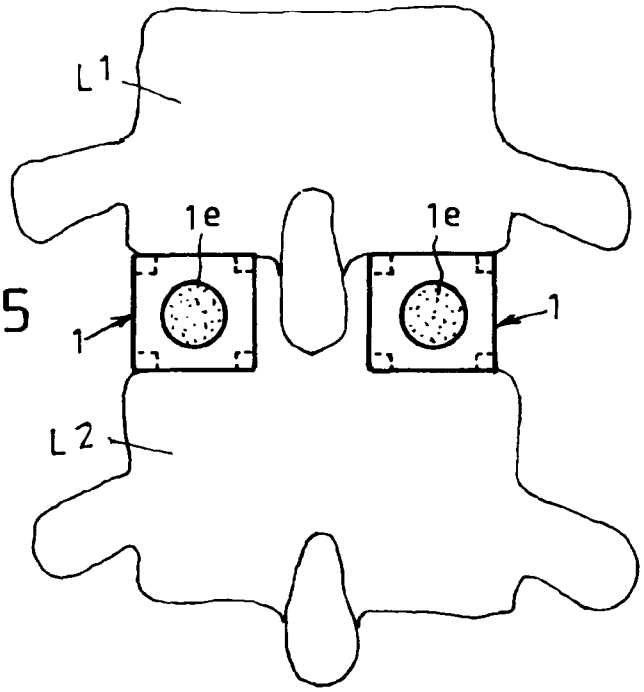


FIG.5



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RAPPORT DE RECHERCHE PRELIMINAIRE

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

2727004
N° d'enregistrement national

FA 507770
FR 9414068

DOCUMENTS CONSIDERES COMME PERTINENTS

Catégorie	Citation du document avec indication, en cas de besoin, des parties pertinentes	Revendications concernées de la demande examinée
X	EP-A-0 307 241 (BRANTIGAN JOHN W) 15 Mars 1989 * colonne 7, ligne 16 - ligne 21; figures * * colonne 11, ligne 16 - colonne 12, ligne 9 *	1,2,4,5
A	---	3
X	US-A-5 294 391 (MCMILLIN CARL R) 15 Mars 1994 * colonne 5, ligne 48 - ligne 68; revendication 2; figure 4 *	1,2,4,5
A	---	3
E	FR-A-2 710 519 (ROBINE DOMINIQUE ;HERMAN SERGE) 7 Avril 1995 * page 2, ligne 5 - page 3, ligne 10; figures *	1,2,5

A	FR-A-2 703 580 (ROBERT GILLES) 14 Octobre 1994 * abrégé; figure 1 *	1-5

DOMAINES TECHNIQUES RECHERCHES (Int.Cl.6)

A61F

Date d'achèvement de la recherche: 17 Juillet 1995

Examinateur: Neumann, E

CATEGORIE DES DOCUMENTS CITES

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

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

& : membre de la même famille, document correspondant

EPO FORM 1503 03.82 (P04C13)

Espacenet

Bibliographic data: FR2727004 (A1) — 1996-05-24

Lumbar and lumbar-sacral posterior stabiliser

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

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

Classification: - **international:** ***A61F2/44;*** *A61F2/00; A61F2/28; A61F2/30;* (IPC1-7): A61B17/70; A61F2/44

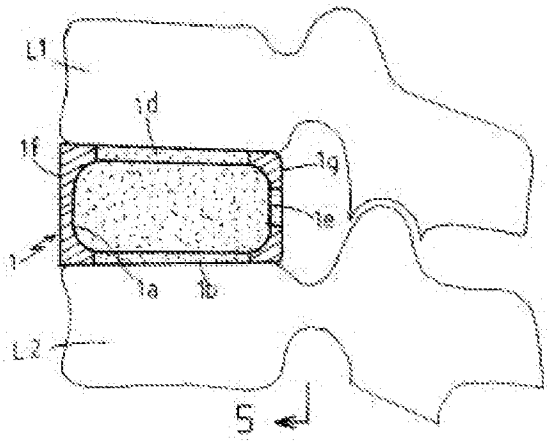
- **cooperative:** **A61F2/447 (EP);** A61F2/30767 (EP); A61F2/30965 (EP); A61F2/442 (EP); A61F2002/2835 (EP); A61F2002/30158 (EP); A61F2002/30261 (EP); A61F2002/30266 (EP); A61F2002/3028 (EP); A61F2002/30329 (EP); A61F2002/30593 (EP); A61F2002/30616 (EP); A61F2002/30772 (EP); A61F2002/30777 (EP); A61F2002/30789 (EP); A61F2002/448 (EP); A61F2220/0025 (EP); A61F2230/0026 (EP); A61F2230/0063 (EP); A61F2230/0082 (EP); A61F2310/00023 (EP)

Application number: FR19940014068 19941118

Priority number(s): FR19940014068 19941118

Abstract of FR2727004 (A1)

The stabiliser comprises two components (1) located on either side of the spinal apophysis and designed to maintain the spacing between two adjacent vertebrae (L<1>, L<2>). They are made hollow so they can receive spongy grafts which permit inter-somatic fusion.Each of the components is parallelepiped in shape, with a hollow three-dimensional cage structure and apertures (1a, 1b, 1d, 1e) in its walls. The upper and lower surfaces of each component are striated to facilitate primary stability, and they are made from titanium or carbon fibre reinforced polymer.



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PCT/US2016/056834

(22) International Filing Date:
13 October 2016 (13.10.2016)

(25) Filing Language: English

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(30) Priority Data:
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(74) Agents: **BRUSSEL, Dana A.** et al.; Carter, Deluca, Farrell & Schmidt LLP, 445 Broad Hollow Road, Suite 420, Melville, New York 11747 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM,

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(54) Title: INTERBODY SPACER

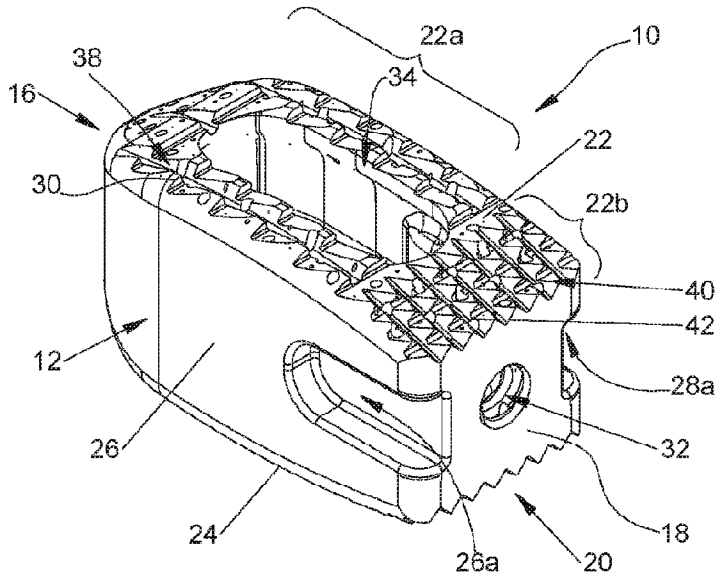


FIG. 1

(57) Abstract: An interbody spacer is provided including a body portion defining a longitudinal axis. The body portion includes a distal end portion, a proximal end portion, opposed side surfaces that extend between the distal and proximal end portions, and top and bottom surfaces configured and adapted to engage vertebral bodies. The interbody spacer includes first orifices defined through the top surface. The first orifices include orifices having first and second cross-sectional configurations and the first orifices are arranged in rows extending along the longitudinal axis.

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TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

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Published:

— *with international search report (Art. 21(3))*

INTERBODY SPACER

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority to, and the benefit of U.S. Provisional Patent Application Serial No. 62/240,662, filed on October 13, 2015, the entire content of which is hereby incorporated by reference herein.

BACKGROUND

Technical Field

[0002] The present disclosure relates to an apparatus for treating spinal conditions, and more particularly, to an interbody spacer and a method of use therefor.

Background of Related Art

[0003] The human spinal column is a highly complex structure. It includes twenty-four discrete bones, known as vertebrae, coupled sequentially to one another to house and protect critical elements of the nervous system. The vertebrae interlock with one another to form a spinal column. Each vertebra has a cylindrical bony body (vertebral body), two pedicles extending from the vertebral body, a lamina extending from the pedicles, two wing-like projections extending from the pedicles, a spinous process extending from the lamina, a pars interarticularis, two superior facets extending from the pedicles, and two inferior facets extending from the lamina.

[0004] The vertebrae are separated and cushioned by thin pads of tough, resilient fiber known as inter-vertebral discs. Inter-vertebral discs provide flexibility to the spine and act as shock absorbers during activity. A small opening (foramen) located between each vertebra allows passage of nerves. When the vertebrae are properly aligned, the nerves pass through without a

problem. However, when the vertebrae are misaligned or a constriction is formed in the spinal canal, the nerves get compressed and may cause back pain, leg pain, or other neurological disorders.

[0005] For many reasons, such as aging and trauma, the intervertebral discs can begin to deteriorate and weaken, potentially resulting in chronic pain, degenerative disc disease, or even tearing of the disc. Ultimately, the disc may deteriorate or weaken to the point of tearing and herniation, in which the inner portions of the disc protrude through the tear. A herniated disc may press against, or pinch, the spinal nerves, thereby causing radiating pain, numbness, tingling, and/or diminished strength or range of motion.

[0006] Many treatments are available to remedy these conditions, including surgical procedures in which one or more damaged intervertebral discs are removed and replaced with a prosthetic. After a partial or complete discectomy, the normally occupied space between adjacent vertebral bodies is subject to collapse and/or misalignment due to the absence of all or part of the intervertebral disc. In such situations, the physician may insert one or more prosthetic spacers between the affected vertebrae to maintain normal disc spacing and/or the normal amount of lordosis in the affected region.

[0007] Typically, a prosthetic implant is inserted between the adjacent vertebrae and may include pathways that permit bone growth between the adjacent vertebrae until they are fused together. However, there exists a possibility that conventional prosthetic implants may be dislodged and moved from their desired implantation location due to movement by the patient before sufficient bone growth has occurred.

[0008] Bone growth is a key factor in ensuring adequate retention of the implant to the vertebra. Specifically, bone ingrowth within and around the prosthetic implant promotes fusion between the adjacent vertebra, thereby strengthening the joint therebetween. However, conventional

implants do not allow optimal space for bone ingrowth. In these instances, as the prosthetic implants do not mimic bone density of the adjacent vertebra, the body may reject the implant, and non-union (i.e., no fusion) may occur.

[0009] Conventional prosthetic implants are typically constructed in a manner that inhibits bone ingrowth, particularly those that include no spaces or avenues for such bone growth to occur within and around the prosthetic implant. The lack of fusion may allow the implant to become dislodged or moved from its desired location. Additionally, in the instances where the prosthetic implant includes a lumen for the packing of ingrowth material, the material is often able to dislodge from the lumen, and in some instances, from the implant, thereby reducing the chances that adequate bone ingrowth occurs.

[0010] Therefore, a need exists for a prosthetic implant that can mimic the density of bone or adequately retain ingrowth material therein to allow for optimal bone ingrowth and provide a solid fusion of the vertebral segments.

SUMMARY

[0011] In accordance with an embodiment of the present disclosure, there is provided an interbody spacer including a body portion defining a longitudinal axis. The body portion includes a distal end portion, a proximal end portion, opposed side surfaces that extend between the distal and proximal end portions, and top and bottom surfaces configured and adapted to engage vertebral bodies. The interbody spacer includes first orifices defined through the top surface. The first orifices include orifices having first and second cross-sectional configurations and are arranged in rows extending along the longitudinal axis.

[0012] In embodiments, the second cross-sectional configuration may be larger than the first cross-sectional configuration. The first orifices may be arranged in each row of the

longitudinal rows in an alternating pattern of orifices having first and second cross-sectional configurations.

[0013] In embodiments, the first orifices may include orifices with a third cross-sectional configuration, wherein the third cross-sectional configuration is larger than the second cross-sectional configuration. The first orifices may be arranged in each row of the longitudinal rows in a pattern, such that the cross-sectional configuration of each orifice of the first orifices increases from the first cross-sectional configuration to the third cross-sectional configuration. Alternatively, the first orifices may be arranged in a random pattern.

[0014] In embodiments, each orifice of the first orifices may include a cross-sectional configuration selected from the group consisting of arcuate, more than four sides, quadrilateral, triangle, and sinusoidal.

[0015] In embodiments, each orifice of the first orifices may include a cross-sectional configuration selected from the group consisting of oval, kidney, elliptical, circular, teardrop, semicircle, and ovoid.

[0016] In embodiments, each orifice of the first orifices may include a cross-sectional configuration selected form the group consisting of squircle, square, rhombus, trapezoid, and rectangle.

[0017] In embodiments, each orifice of the first orifices may include a cross-sectional configuration selected from the group consisting of hexagon, octagon, heptagon, and pentagon.

[0018] In embodiments, each orifice of the first orifices may include a cross-sectional configuration selected from the group consisting of isosceles, equilateral, scalene, arrowhead with arcuate base, and right.

[0019] In embodiments, each orifice of the first orifices may include a cross-sectional configuration selected from the group consisting of greek cross and clover.

[0020] In embodiments, second orifices may be defined through the bottom surface. One of the first orifices may include a cross-sectional configuration different than that of one of the second orifices. One of the first orifices may be offset from one of the second orifices.

[0021] In embodiments, a respective orifice of the first and second orifices may be in open communication, thereby defining a respective channel through the body portion. Each channel includes a cross-sectional configuration that varies in a direction from the top surface to the bottom surface.

[0022] In embodiments, each channel may include a sinusoidal cross-sectional configuration. Alternatively, each channel may include a cross-sectional configuration including spherical, cylindrical, frusto conical, ellipsoidal, hyperboloid, or any combination thereof. Alternatively, each channel may include a cross-sectional configuration including helical grooves disposed on an inner wall surface thereof.

[0023] In embodiments, a respective orifice of the first orifices may be in open communication with an orifice defined through one of the opposed side surfaces, thereby defining a respective channel through the body portion.

BRIEF DESCRIPTION OF THE DRAWINGS

[0024] Various embodiments of the present disclosure are described hereinbelow with reference to the drawings, wherein:

[0025] FIG. 1 is a rear, perspective view of an interbody spacer provided in accordance with the present disclosure;

[0026] FIG. 2, is a side view of the interbody spacer of FIG. 1;

[0027] FIG. 3 is a top view of the interbody spacer of FIG. 1;

[0028] FIG. 4 is a top view of another embodiment of an interbody spacer similar to the interbody spacer of FIG. 1;

[0029] FIG. 5 is a top view of yet another embodiment of an interbody spacer similar to the interbody spacer of FIG. 1;

[0030] FIG. 6 is a top view of still another embodiment of an interbody spacer similar to the interbody spacer of FIG. 1;

[0031] FIG. 7 is a top view of another embodiment of an interbody spacer similar to the interbody spacer of FIG. 1, without a cavity extending therethrough;

[0032] FIG. 8 is a side, cross-sectional, view of the interbody spacer of FIG. 7, taken along section-line 8-8 of FIG. 7;

[0033] FIG. 8A is a side, cross-sectional, view of an alternate embodiment of the interbody spacer of FIG. 7, taken along section-line 8-8 of FIG. 7;

[0034] FIG. 8B is a side, cross-sectional, view of an alternate embodiment of the interbody spacer of FIG. 8, taken along section-line 8-8 of FIG. 7;

[0035] FIG. 9 is an illustration of a family of cross-sectional shapes for an orifice defined through an interbody spacer in accordance with the present disclosure;

[0036] FIG. 10 is an illustration of another family of cross-sectional shapes for an orifice defined through an interbody spacer in accordance with the present disclosure;

[0037] FIG. 11 is an illustration of yet another family of cross-sectional shapes for an orifice defined through an interbody spacer in accordance with the present disclosure;

[0038] FIG. 12 is an illustration of still another family of cross-sectional shapes for an orifice defined through an interbody spacer in accordance with the present disclosure;

[0039] FIG. 13 is an illustration of another family of cross-sectional shapes for an orifice defined through an interbody spacer in accordance with the present disclosure;

[0040] FIG. 14 is an illustration still another family of cross-sectional shapes for an orifice defined through an interbody spacer in accordance with the present disclosure;

[0041] FIG. 15 is an illustration of yet another family of cross-sectional shapes for an orifice defined through an interbody spacer in accordance with the present disclosure;

[0042] FIG. 16 is a side, cross-sectional view, of a family shapes for a channel defined through an interbody spacer in accordance with the present disclosure;

[0043] FIG. 17 is a side, cross-sectional view, of another family of shapes for a channel defined through an interbody spacer in accordance with the present disclosure;

[0044] FIG. 18 is a side, cross-sectional view, of yet another family of shapes for a channel defined through an interbody spacer in accordance with the present disclosure;

[0045] FIG. 19 is a side, cross-sectional view, of still another family of shapes for a channel defined through an interbody spacer in accordance with the present disclosure;

[0046] FIG. 20 is a side, cross-sectional view, of another family of shapes for a channel defined through an interbody spacer in accordance with the present disclosure;

[0047] FIG. 21 is a side, cross-sectional view, of still another family of shapes for a channel defined through an interbody spacer in accordance with the present disclosure;

[0048] FIG. 22 is a side, cross-sectional view, of yet another family of shapes for a channel defined through an interbody spacer in accordance with the present disclosure; and

[0049] FIG. 23 is a side, cross-sectional view, of still another family of shapes for a channel defined through an interbody spacer in accordance with the present disclosure.

DETAILED DESCRIPTION OF EMBODIMENTS

[0050] Embodiments of the present disclosure are now described in detail with reference to the drawings in which like reference numerals designate identical or corresponding elements in each of the several views. As commonly known, the term "clinician" refers to a doctor, a nurse, or any other care provider and may include support personnel. Additionally, the term "proximal" refers to the portion of the device or component thereof that is closer to the clinician and the term "distal" refers to the portion of the device or component thereof that is farther from the clinician. In addition, the term "cephalad" is known to indicate a direction toward a patient's head, whereas the term "caudal" indicates a direction toward the patient's feet. Further still, for the purposes of this application, the term "lateral" indicates a direction toward a side of the body of the patient, i.e., away from the middle of the body of the patient. The term "posterior" indicates a direction toward the patient's back, and the term "anterior" indicates a direction toward the patient's front. Additionally, in the drawings and in the description that follows, terms such as front, rear, upper, lower, top, bottom, and similar directional terms are used simply for convenience of description and are not intended to limit the disclosure. In the following description, well-known functions or constructions are not described in detail to avoid obscuring the present disclosure in unnecessary detail.

[0051] Referring now to the drawings, FIGS. 1-3 illustrate an interbody spacer provided in accordance with the present disclosure and generally identified by reference numeral 10. Interbody spacer 10 includes a body portion 12 having a substantially contoured first end surface 14 (FIG. 2) at a distal or leading end 16 and a second end surface 18 opposite thereto at a proximal or trailing end 20, having a substantially planar configuration. Axis A-A (FIG. 3) is defined through a midpoint of first and second end surfaces 14, 18, respectively. Body portion

12 extends between first and second end surfaces 14, 18 to define respective top and bottom surfaces 22 and 24 (FIG. 2), respectively, as well as opposed side surfaces 26, 28 (FIG. 3). As best illustrated in FIG. 2, top and bottom surfaces 22, 24 include a generally convex or arcuate profile, each extending in a cephalad and caudal direction (or vice-versa), respectively. Although shown and described as the top surface 22 being oriented in a cephalad direction and the bottom surface 24 being oriented in a caudal direction, the interbody spacer 10 may be positioned such that the top surface 22 is in a caudal orientation and the bottom surface 24 is in a cephalad orientation. As can be appreciated, top and bottom surfaces 22 and 24 may include a concave profile, a planar profile, or any combination thereof. In embodiments, top surface 22 may include a different profile than that of bottom surface 24. Additionally, it is contemplated that top and bottom surfaces 22, 24 may approximate in a direction along axis A-A (or vice-versa), or may approximate in a direction from side surface 26 towards side surface 28 (or vice-versa), or any combination thereof.

[0052] As best illustrated in FIG. 3, opposed side surfaces 26, 28 are substantially planar, although other configurations are also contemplated such as convex, concave, or the like. Opposed side surfaces 26, 28 approximate towards each other at distal end 16 along longitudinal axis A-A in order to facilitate insertion within the intervertebral space and enhance the atraumatic character of body portion 12. In this manner, the intersection of top and bottom surfaces 22, 24 with each of first and second end surfaces 14, 18 and opposed side surfaces 26, 28 may include a fillet or rounded configuration 30 to inhibit sharp edges from causing trauma to the surrounding tissue and/or vertebral bodies.

[0053] Referring again to FIG. 1, second end surface 18 includes an aperture 32 defined therethrough and extending along longitudinal axis A-A. Aperture 32 is configured for selective

engagement with a suitable insertion tool (not shown), such as that described in U.S. Patent Application No. 2012/0158062, filed October 11, 2011, the entire contents of which are hereby incorporated by reference herein. In embodiments, aperture 32 may be threaded or otherwise include various features capable of selectively retaining a suitable insertion tool (not shown) therein, such as a keyhole configuration, quarter-turn configuration, or the like.

[0054] Each of opposed side surfaces 26, 28 includes a corresponding depression or recess 26a, 28a defined therein adjacent second end surface 18. Recesses 26a, 28a extend along longitudinal axis A-A and are symmetrically disposed on each of opposed side surfaces 26, 28 to define a substantially I-shaped configuration to second end surface 18 at proximal end 20. In cooperation with aperture 32, the recesses 26a, 28a are further configured to enable engagement with stabilizing jaws of a suitable insertion instrument (not shown) to facilitate the insertion of interbody spacer 10. As can be appreciated, interbody spacer 10 may not include recesses 26a, 28a, and rather, include planar side surfaces 26, 28 that extend between first and second end surfaces 14, 18.

[0055] Body portion 12 includes a through-bore or cavity 34 defined through top and bottom surfaces 22, 24, respectively. Although shown as having a generally oval configuration, it is contemplated that through-bore 34 may include any suitable shape such as square, rectangular, circular, or the like, or may include a configuration similar to that of the outer perimeter of body portion 12. It is contemplated that through-bore 34 may receive allograft material, autograft material, calcium phosphate/bone marrow aspirate (BMA), autogenous material, synthetic materials comprised of a biocompatible osteoconductive, osteoinductive, or osteogeneic material such as VITOSS® Synthetic Cancellous Bone Void Filler material, or any other suitable biological material known in the art. Through-bore 34 includes a cross-sectional

area or surface area that is greater than any orifice of the plurality of orifices or enlarged orifices detailed hereinbelow. In embodiments, through-bore 34 includes a surface area that is equal to or greater than 25% of the surface area of top surface 22 or bottom surface 24.

[0056] Top and bottom surfaces 22, 24 of body portion 12 are configured to engage respective endplates of adjacent vertebral bodies. In this manner, each of top and bottom surfaces 22, 24 includes at least first and second surface regions 22a, 22b and 24a, 24b, respectively, which have distinct surface characteristics. As best illustrated in FIG. 2, first surface regions 22a, 24a are disposed distal to second surface regions 22b, 24b and include a surface characteristic that is different than that of second surfaces 22b, 24b. In embodiments, first surface regions 22a, 24a may include a same or similar surface characteristic to that of second surface regions 22b, 24b, or each of first and second surface regions 22a, 24a and 22b, 24b may include the same or different surface characteristics, or any combination thereof.

[0057] First surface regions 22a, 24a each have a plurality of protrusions (i.e., teeth) or ridges 36 disposed thereof to aid in securing interbody spacer 10 to each respective adjacent vertebral body and stability against fore and aft, oblique or side to side movement of interbody spacer 10 within the intervertebral space. Specifically, protrusions 36 frictionally engage endplates of adjacent vertebral bodies and inhibit movement of the interbody spacer 10 with respect to the adjacent vertebral bodies. In embodiments, a plurality of longitudinal grooves 38 (FIGS. 1 and 3) may be defined within protrusions 36, each of which extends along longitudinal axis A-A. Each of second surface regions 22b, 24b includes substantially pyramidal protrusions 40, where each pyramidal protrusion 40 includes a plurality of protrusions or ridges disposed thereon to similarly aid in securing interbody spacer 10 to each respective adjacent vertebral body. In particular, each pyramidal protrusion 40 includes opposed first and second faces that

face, respectively, distally and proximally. Further, each pyramidal protrusion 40 has third and fourth faces that face, respectively, medially and laterally. For a detailed description of an interbody spacer having exemplary surface characteristics, reference can be made to U.S. Patent No. 8,801,791 to Soo et al., filed September 27, 2007, the entire contents of which are hereby incorporated by reference herein.

[0058] Interbody spacer 10 is constructed of a biocompatible material, such as commercially pure titanium or titanium alloy and includes a porosity capable of promoting bone ingrowth and fusion with interbody spacer 10. In this manner, top and bottom surfaces 22, 24 and opposed side surfaces 26, 28 have a surface roughness that can promote bone growth and fusion with interbody spacer 10. The surface roughness may be in a range of about 0.10-50 μm, and preferably in a range of about 3-4 μm. As can be appreciated, top and bottom surfaces 22, 24 and opposed side surfaces 26, 28 may include the same or different surface roughness's (i.e., the surface roughness of top surface 22 may be different than the surface roughness of bottom surface 24), or top and bottom surfaces 22, 24 and opposed side surfaces 26, 28 may not include a surface roughness; rather, top and bottom surfaces 22, 24 and opposed side surfaces 26, 28 may be smooth. In embodiments top and bottom surfaces 22, 24 and opposed side surfaces 26, 28 may include any combination of surface roughness or smooth surface. Additionally, body portion 12 includes a plurality of orifices 44 and 46 defined through top and bottom surfaces 22, 24 and opposed side surfaces 26, 28, respectively, configured to promote bone ingrowth. Although illustrated as having a generally circular cross-section, orifices 44 may include any suitable cross-section, as will be described in further detail hereinbelow. Orifices 46 are illustrated as having a generally diamond shaped cross-section, however, it is contemplated that orifices 46 may include any suitable cross-section, as will be described in further detail

hereinbelow. The cross-sectional shapes of orifices 44, 46 mimic bone growth along Haversian canals and lamellar structures of bone. The plurality of orifices 44, 46 reduces the density and stiffness of interbody spacer 10 to enable the application of bone putty or the like (e.g., bone-morphogenetic proteins, etc.) to interbody spacer 10 to promote bone ingrowth within interbody spacer 10 and fusion to adjacent vertebral bodies. Bone ingrowth and fusion strengthens interbody spacer 10. In this manner, the likelihood that micromotion would occur would be reduced.

[0059] As best illustrated in FIG. 3, the plurality of orifices 44 are arranged in evenly spaced longitudinal rows along longitudinal axis A-A. The plurality of orifices 44 includes orifices with a first diameter 44a, orifices with a second diameter 44b, and orifices with a third diameter 44c. In one non-limiting embodiment, the first diameter 44a is 30 μm, the second diameter 44b is 150 μm, and the third diameter 44c is 500 μm, although other suitable diameters are also contemplated. As can be appreciated, each of the orifices 44 may include a cross-section corresponding to any cross-sectional shape detailed herein. As such, the cross-sectional area of each of orifice 44a, 44b, and 44c may be 0.000707 μm^2, 0.0177 μm^2, and 0.196 μm^2, respectively. In this manner, the plurality of orifices 44 is defined through top and bottoms surfaces 22, 24 and arranged in groups of three orifices, 44a, 44b, 44c, that define a respective pattern along axis A-A of body portion 12.

[0060] Referring to FIG. 4, another embodiment of an interbody spacer provided in accordance with the preset disclosure is illustrated and generally identified by reference numeral 110. Interbody spacer 110 is substantially similar to interbody spacer 10, and therefore only the differences therebetween will be described in detail in the interest of brevity. The orifices of the plurality of orifices 144 include orifices with a first diameter 144a and orifices with a second,

larger, diameter 144b. In one non-limiting embodiment, the diameter of the first diameter 144a is 150 μm and the diameter of the second diameter 144b is 500 μm, although other diameters are also contemplated. As can be appreciated, each of the orifices 144 may include a cross-section corresponding to any cross-sectional shape detailed herein. As such, the cross-sectional area of each of orifice 144a and 144b may be 0.0177 μm^2 and 0.196 μm^2, respectively. In this manner, a pair of rows of orifices 144 having the second, larger diameter 144b is defined through the distal end 116 of top surface 122 and the bottom surfaces (not shown) and extending in a direction transverse to longitudinal axis A-A. A pair of rows of orifices 144 having the first diameter 144a is disposed proximal to the pair of rows of orifices 144 having the second, larger diameter 144b and extends in a direction transverse to longitudinal axis A-A. This pattern is repeated in a proximal (or distal) direction along axis A-A.

[0061] With reference to FIG. 5, yet another embodiment of an interbody spacer provided in accordance with the present disclosure is illustrated and generally identified by reference numeral 210. Interbody spacer 210 is substantially similar to interbody spacer 10, and therefore only the differences therebetween will be described in detail in the interest of brevity. The plurality of orifices 244 includes orifices having a first diameter 244a and orifices having a second, larger, diameter 244b. In one non-limiting embodiment, the first diameter 244a is 150 μm and the second diameter 244b is 500 μm, although other diameters are also contemplated. As can be appreciated, each of the orifices 244 may include a cross-section corresponding to any cross-sectional shape detailed herein. As such, the cross-sectional area of each of orifice 244a and 244b may be 0.0177 μm^2 and 0.196 μm^2, respectively. In this manner, the plurality of orifices 244 is defined through top and bottom surfaces 222, 224 such that the diameter of the plurality of orifices 244 alternates between orifices having the first diameter 244a and orifices

having the second, larger, diameter 244b in a direction along longitudinal axis A-A. This pattern is offset in a direction transverse to longitudinal axis A-A such that an orifice of the plurality of orifices 244 having a first diameter 244a is only adjacent an orifice of the plurality of orifices 244 having a second, larger, diameter 244b.

[0062] With reference to FIG. 6, still another embodiment of an interbody spacer provided in accordance with the present disclosure is illustrated and generally identified by reference numeral 310. Interbody spacer 310 is substantially similar to interbody spacer 10, and therefore only the differences therebetween will be described in detail in the interest of brevity. The plurality of orifices 344 includes orifices of various diameters. In one non-limiting embodiment, the diameter of each orifice of the plurality of orifices 344 may vary between 50 μm and 1000 μm. As can be appreciated, each of the orifices 344 may include a cross-section corresponding to any cross-sectional shape detailed herein. As such, the cross-sectional area of each of orifice 344 may be 0.0707 μm^2 and 0.385 μm^2. The plurality of orifices 344 is defined through top surface 322 and the bottom surfaces (not shown) in a random manner such that there are no defined rows, and the diameters of each orifice of the plurality of orifices 344 vary.

[0063] Referring now to FIGS. 7 and 8, an alternate embodiment of an interbody spacer provided in accordance with the present disclosure is illustrated and generally identified by reference numeral 410. Interbody spacer 410 is substantially similar to interbody spacer 10, and therefore, only the differences therebetween will be described in detail in the interest of brevity. Interbody spacer 410 does not include a through-bore defined through top surface 422 and the bottom surfaces (not shown). Rather, as best illustrated in FIG. 8, interbody spacer 410 includes a void 448 defined within an interior portion of body 412. In this manner, void 448 does not breach leading or trailing surface 414, 418, top or bottom surface 422, 424, or the opposed side

surfaces 426, 428 (FIG. 7). In one non-limiting embodiment, aperture 432 extends through a proximal end of void 448 such that aperture 432 is in open communication therewith. Although illustrated as having a generally circular cross-section, it is contemplated that void 448 may include any suitable shape and/or volume, such as spheroid, ovoid, cuboid, rectanguloid, ellipsoid, or the like. In certain embodiments, void 448 may include an amorphous shape. Additionally, as best illustrated in FIG. 8A, it is contemplated that void 448 may be isolated from the plurality of orifices defined through top surface 422 and the plurality of orifices 446 defined through the opposed side surfaces 426, 428 (FIG. 7), or only one or the other. It is further contemplated that void 448 may include one or more protrusions (not shown) extending towards an interior portion of void 448. As can be appreciated, the one or more protrusions may include any suitable shape, such as frusto conical, spheroid, ovoid, cuboid, rectanguloid, conical, ellipsoid, or the like. By varying the shape and or volume of void 448, the density and stiffness of interbody spacer 410 may be likewise varied, thereby allowing a clinician to select an implant more closely tailored to the density of adjacent vertebral bodies. In embodiments, interbody spacer 448 may include a plurality of smaller voids 448 defined in an interior portion of body 412.

[0064] Alternatively, as best illustrated in FIG. 8B, interbody spacer 410 may include no through-bore or void. In this manner, aperture 432 is blind (i.e., terminates in a distal face in an interior portion of interbody spacer 410). Additionally, the plurality of orifices 446 defined through the opposed side surfaces includes a diamond shaped cross-section 446a on distal and proximal ends 416, 420 and a random array of orifices having a circular cross-section 446b and varying diameters defined through the opposed side surfaces (not shown) at a medial portion of body 412. As can be appreciated, the plurality of orifices 446 having a diamond-shaped cross-

section 446a may be defined through the medial portion of the opposed side surfaces and the random array of circular orifices 446b may be defined through distal and proximal ends 416, 420 of the opposed side surfaces, or any combination thereof.

[0065] Referring now to FIGS. 9-15, the plurality of orifices 44, 46 may include various cross-sectional shapes of differing families. As illustrated in FIG. 9, orifices 44, 46 may include a cross-sectional shape having varying curvature, designated as a first family 50. Cross-sectional shapes included in first family 50 include oval 50a, kidney 50b, elliptical 50c, circular 50d, teardrop 50e, semicircle 50f, and ovoid 50g. As can be appreciated, orifices 44, 46 from first family 50 may include any cross-sectional shape having an arcuate, curvate, or otherwise amorphous shape not otherwise illustrated in FIG. 9.

[0066] A second family 52 of cross-sectional shapes having more than four sides is illustrated in FIG. 10. In this manner, the plurality of orifices 44, 46 may include a cross-sectional shape of a hexagon 52a, an octagon 52b, a heptagon 52c, and a pentagon 52d. As can be appreciated, any polygon having more than four sides may be included in second family 52, such as nonagon, decagon, dodecagon, etc.

[0067] With reference to FIG. 11, a third family 54 of cross-sectional shapes from which the plurality of orifices 44, 46 may be defined is illustrated. Third family 54 includes quadrilaterals, such as a square with rounded edges 54a (such as a squircle), square 54b, rhombus 54c, trapezoid 54d, and rectangle 54e. As can be appreciated, third family 54 may include any quadrilateral, such as parallelogram, kite, isosceles trapezoid, trapezium, etc.

[0068] A fourth family 56 of cross-sectional shapes from which the plurality of orifices 44, 46 may be defined is illustrated in FIG. 12. Fourth family 56 includes triangles, such as

isosceles 56a, equilateral 56b, scalene 56c, arrowhead with arcuate base 56d, and right 56e. As can be appreciated, fourth family 56 may include any type of triangle known in the art.

[0069] FIG. 13 illustrates a fifth family 58 of cross-sectional shapes from which the plurality of orifices 44, 46 may be defined. Fifth family 58 includes a greek cross 58a and clover 58b, although other similar cross-sectional shapes are contemplated, like, cross, star, or the like.

[0070] As illustrated in FIG. 14, a sixth family 60 of cross-sectional shapes from which the plurality of orifices 44, 46 may be defined includes sinusoidal shapes having various lengths, widths, and number of sides. A first sinusoidal shape 60a includes a width that is larger than that of a second sinusoidal shape 60b. A third sinusoidal shape 60c includes pointed opposed ends. As can be appreciated, any suitable sinusoidal shape may be included in sixth family 60.

[0071] FIG. 15 illustrates a seventh family 62 of cross-sectional shapes from which the plurality of orifices 44, 46 may be defined. The cross-sectional shapes included in the seventh family 62 include ornate designs having various circular designs as illustrated in first design 62a or rectangular designs as illustrated in second design 62b. First design 62a includes upper and lower apertures 62aa and 62ab defining a generally oval shape. First design 62a includes a plurality of additional bores 62ac defined in an interior portion thereof. In this manner, a plurality of circular features resembling wheels and spokes and/or pinwheels are defined. The plurality of bores 62ac define a corresponding plurality of bridges or spokes 62ad that separate each of each of the upper and lower apertures 62aa, 62ab, and plurality of bores 62ac.

[0072] Similarly, second design 62b includes upper and lower apertures 62ba and 62bb defining a generally rectangular shape. A plurality of elongate, arcuate, bores 62bc are defined in an interior portion of second design 62b, the plurality of elongate, arcuate, bores 62bc defining cooperating to define a generally triangular shape. The plurality of elongate, arcuate, bores 62bc

define a corresponding plurality of bridges 62bd that separate each of the upper and lower apertures 62ba, 62bb and plurality of bores 62bc.

[0073] As can be appreciated, any of the above described families may be interchanged or randomly selected as the cross-sectional shape of orifices 44, 46 defined through upper and lower surfaces 22, 24 or opposed side surfaces 26, 28, respectively, of body portion 12. In embodiments, the plurality of orifices 44 defined through top surface 22 may utilize a different cross-sectional shape than that of the plurality of orifices 44 defined through bottom surface 24. Similarly, the plurality of orifices 46 defined through side surface 26 may include a different cross-sectional shape than the plurality of orifices 46 defined through opposite side surface 28. It is contemplated that any number of combinations of cross-sectional shapes may be employed.

[0074] Referring now to FIGS 16-23, the plurality of orifices 44, 46 defined through top and bottom surfaces 22, 24 and opposed side surfaces 26, 28 define a respective channel through body portion 12. FIGS. 16-23 illustrate a variety of families of channels that may be defined through body portion 12. As best illustrated in FIG. 16, a first family of channels 64 having a generally arcuate profile is illustrated. The first family of channels 64 includes a first channel 64a having a generally arcuate profile. First channel 64a includes a pair of bowed or bulging sidewalls and includes a constant width. A second channel 64b includes a generally sinusoidal profile. A third channel 64c includes a pair of channels 64ca, 64cb defining a generally X-shaped configuration. In this manner, channel 64ca of the pair of channels is bowed in a first direction and channel 64cb of the pair of channels bows in an opposite direction, such that channels 64ca, 64cb intersect (i.e., channels 64ca and 64cb are in open communication). A fourth channel 64d includes a generally hourglass profile. A fifth channel 64e includes an

elliptical profile. As can be appreciated, first family of channels 64 may include any suitable profile having arcuate sidewalls.

[0075] FIG. 17 illustrates a second family of channels 66 having generally planar sidewalls. First channel 66a includes planar sidewalls extending in a diagonal direction such that the openings of an orifice of the plurality of orifices 44, 46 on the top and bottom surfaces 22, 24, respectively, are offset in relation to one another. A second channel 66b includes a generally arrowhead or rotated chevron type profile (i.e., upper and lower portions extending diagonally toward one another in a medial portion of body portion 12 to define a point). A third channel 66c includes a generally hourglass profile having planar sidewalls. A fourth channel 66d includes a generally inverted hourglass profile (i.e., the width of fourth channel 66d increases at a middle portion thereof).

[0076] A third family of channels 68 is illustrated in FIG. 18. Each channel of the third family of channels 68 is mirrored about axis B-B defined at a medial portion of body 12. A first channel 68a is defined through top surface 22 and includes a first cylinder 68aa having a first diameter extending towards bottom surface 24. First cylinder 68aa transitions to a second cylinder 68ab and includes a second, larger, diameter than the diameter of first cylinder 68aa. A second channel 68b is essentially an inverse of first channel 68a. In particular, a first cylinder 68ba having a first diameter intersects top surface 22 and extends towards bottom surface 24. First cylinder 68ba transitions to a second cylinder 68bb and includes a second, smaller, diameter than the diameter of first cylinder 68ba.

[0077] Referring now to FIG. 19, a fourth family of channels 70 is illustrated. A first channel 70a is defined through top surface 22 of body portion 12 and includes a generally arcuate shape such that first channel 70a curves towards, and extends through, one of opposed

side surfaces 26, 28. A second channel 70b is defined through bottom surface 24 of body portion 12 and includes a generally arcuate shape such that second channel 70b curves towards, and extends through, an opposite one of opposed side surfaces 26, 28 than that of first channel 70a.

[0078] FIG. 20 illustrates a fifth family of channels 72 including similar profile to that of the fourth family of channels 70. In this manner, a first channel 72a includes a tighter radius of curvature than that of a second, opposed channel 72b. As can be appreciated, second channel 72b may have a tighter radius than that of first channel 72a.

[0079] A sixth family of channels is illustrated in FIG. 21 and is generally identified by reference numeral 74. Each channel of the third family of channels 74 is mirrored about axis B-B defined at a medial portion of body 12. A first channel 74a includes a frusto conical profile 74aa defined through top surface 22 of body portion 12 extending towards bottom surface 24. Frusto conical profile 74aa includes a generally inverted orientation (i.e., the diameter decreases in a direction from top surface 22 towards bottom surface 24). Frusto conical profile 74aa transitions to a cylindrical profile 74ab at a medial portion of body portion 12 having a larger diameter than that of the portion of frusto conical profile 74aa that intersect cylindrical profile 74ab.

[0080] A second channel 74b includes a substantially similar profile to that of first channel 74a except that the frusto conical profile 74ba is inverted with respect to frusto conical profiles 74aa of first channel 74a.

[0081] Third channel 74c includes first portion 74ca having a generally hourglass configuration that intersects top surface 22 of body portion 12 and extends towards bottom surface 24. First portion 74ca transitions to a second portion 74cb having a generally cylindrical configuration at a medial portion of body portion 12.

[0082] A fourth channel 74d includes a first portion 74da having a generally spherical configuration. First portion 74da is defined through top surface 22 of body portion 12 and extends towards bottom surface 24. First portion 74da transitions to a second portion 74db having a generally cylindrical configuration at a medial portion of body portion 12. Second portion 74db includes a diameter less than the diameter of first portion 74da.

[0083] FIG. 22 illustrates a seventh family of channels generally identified by reference numeral 76. Each channel of the third family of channels 76 is mirrored about axis B-B defined at a medial portion of body 12. A first channel 76a includes a first and second spherical portion 76aa and 76ab respectively, disposed in a generally stacked configuration such that first spherical portion extends through upper surface 22 of body 12. Each of first and second spherical portions 76aa and 76ab include a generally similar diameter, although other configurations are also contemplated.

[0084] A second channel 76b includes a first portion 76ba defined through top surface 22 of body portion 12 and extending towards bottom surface 24. First portion 76ba includes a generally cylindrical configuration and transitions to a second portion 76bb having a generally spherical configuration at a medial portion of body portion 12.

[0085] Third channel 76c includes a first portion 76ca having a generally inverted frusto conical configuration (i.e., the diameter of first portion decreases in a direction from top surface 22 towards bottom surface 24). First portion 76ca is defined through top surface 22 of body portion 12 and extends towards bottom surface 24. First portion 76ca transitions to a second portion 76cb having a generally ellipsoid configuration at a medial portion of body portion 12, although it is contemplated that second portion 76cb may include a generally spherical configuration similar to that of second portion 76bb of second channel 76b.

[0086] Fourth channel 76d is similar to that of third channel 76c except that the first portions 76da includes a frusto conical configuration that is inverted relative to first portion 76ca of third channel 76c. Second portion 76db includes a generally spherical configuration.

[0087] A fifth channel 76e includes a first portion 76ea having a generally hourglass configuration. First portion 76ea is defined through top surface 22 of body portion 12 and extends towards bottom surface 24. First portion 76ea transitions to a second portion 76eb having a generally spherical configuration at a medial portion of body portion 12.

[0088] FIG. 23 illustrates an eighth channel 78 defined through top and bottom surfaces 22, 24 of body portion 12. Eighth channel 78 includes a generally cylindrical profile including helical grooves 78b defined on an inner sidewall 78a thereof.

[0089] Although each orifice and channel has been hereinabove described as being defined through top and bottom surfaces 22, 24 of body 12, as can be appreciated, the orifices and channels may be defined through opposed side surfaces 26, 28.

[0090] As can be appreciated, manufacturing interbody spacers 10, 110, 210, 310, and 410 using standard machining methods (e.g., lathe, mill, EDM, etc.) could be difficult. In view of this, it is contemplated that in addition to manufacturing interbody spacers 10, 110, 210, 310, and 410 using the aforementioned conventional means, interbody spacers 10, 110, 210, 310, and 410 may be manufactured by means of additive manufacturing methods (e.g., SDM, SLPP, DMLS (i.e., EOS), SLS, SLM, SHS, EBM, VAT photopolymerisation, material jetting, binder jetting, or the like). In one non-limiting embodiment, interbody spacers 10, 110, 210, 310, and 410 may be manufactured using Selective Laser Powder Processing (SLPP). SLPP utilizes powdered metal and a laser which sinters or cures the metal in a selective fashion according to the design intent in thin layers. In embodiments, the layers have a thickness of about 250 μm.

Interbody spacers 10, 110, 210, 310, and 410 are built layer by layer to allow for more design options and features that would be difficult to be machined using conventional methods. Specifically, a first layer of powder is applied to a specialized build plate, at which point the laser cures portions of the powder according to the design intent. At this point, a second layer is applied to the build plate and the laser is again used to cure selective portions of this second layer. This process is repeated until interbody spacers 10, 110, 210, 310, and 410 are fully formed. Once interbody spacers 10, 110, 210, 310, and 410 are fully formed, uncured powder is removed using compressed air or other similar means. Next, post machining is performed on interbody spacers 10, 110, 210, 310, and 410 to remove any burrs or similar imperfections embedded within interbody spacers 10, 110, 210, 310, and 410 during the additive manufacturing process. In embodiments, the burrs are removed by means of buffer wheels, clippers, files, or the like. Once de-burred, interbody spacers 10, 110, 210, 310, and 410 are heat treated, and thereafter, media blasted using aluminum oxide. Thereafter, interbody spacers 10, 110, 210, 310, and 410 are immersed in a hydrofluoric bath to strip the aluminum oxide therefrom. Finally, interbody spacers 10, 110, 210, 310, and 410 are inspected by quality control personnel (or using automated means), cleaned via ultrasonic cleaning, dried, and packaged. It is contemplated that the design of interbody spacers 10, 110, 210, 310, and 410 may be customized for each specific patient using SLPP. For a detailed description of exemplary manufacturing methods, reference may be made to U.S. Patent No. 8,590,157, issued on November 26, 2013 to Kruth et al., the entire contents of which are hereby incorporated by reference herein.

[0091] Interbody spacers 10, 110, 210, 310, and 410 may be constructed from commercially pure titanium, titanium alloy, cobalt-chrome, ceramic, Polyetheretherketone

(PEEK), or any other suitable biocompatible material. In embodiments, interbody spacers 10, 110, 210, 310, and 410 may be manufactured using a three-dimensional printer utilizing a biocompatible polymer.

[0092] With reference to FIGS. 1-8B, in use, an intervertebral space is first prepared, e.g., damaged or diseased tissue is removed. As the construction of interbody spacer 10 is similar to that of interbody spacers 110, 210, 310, and 410, only the method of use of interbody spacer 10 will be described in detail for purposes of brevity. An appropriately sized interbody spacer 10 is selected based on the patient's spinal characteristics and the desired amount of lordosis. Next, the interior space of through-bore 34 of body portion 12 may be packed with bone in-growth material, drugs, or other suitable materials or compounds. Examples of such materials are allograft material, or synthetic materials comprised of a biocompatible, osteoconductive, osteoinductive, or osteogeneic material such as VITOSS® Synthetic Cancellous Bone Void Filler material. Next, a suitable insertion instrument (not shown) is threaded into aperture 32 of body portion 12 until interbody spacer 10 is securely affixed to the insertion instrument. At this point, interbody spacer 10 is advanced within an incision within the patient, and thereafter, the previously prepared inverterterbal space of the patient's spine. Once interbody spacer 10 is placed within the intervertebral space such that interbody spacer 10 rests on the distal apophyseal ring of the vertebral body, the tool (not shown) is released from aperture 32, and thereafter, the incision within the patient. By residing on the apophyseal ring, interbody spacer 10 is less likely to experience subsidence into the end plates which will facilitate fusion between the intervertebral plates.

[0093] This process may be repeated as many times as the procedure requires, whether it be for the same interbody spacer 10 or for a plurality of interbody spacers 10 as required by the procedure being performed.

[0094] It is envisioned that the manufacturing processes and orifice designs detailed above may be utilized to form various other medical devices known in the art. In this manner, the additive manufacturing process detailed above may be employed to form corpectomy devices, fixed spinal implants, expandable spinal implants, bone screws, cervical implants, and the like. Similarly, the orifice designs detailed above may be formed in any of the beforementioned medical devices that would benefit from an increased ability to fuse with bone. Examples of such devices may be found in the following commonly owned references: U.S. Patent No. 8,585,761 to Theofilos, U.S. Patent No. 8,673,011 to Theofilos et al., U.S. Application Serial No. 14/936,911 to Sutterlin et al., U.S. Patent No. 8,801,791 to Soo et al., U.S. Patent No. 8,439,977 to Kostuik et al., U.S. Patent Application Publication No. 2010/0100131 to Wallenstein, U.S. Patent Application Publication No. 2012/0179261 to Soo, U.S. Patent No. 8,449,585 to Wallenstein et al., U.S. Patent No. 8,814,919 to Barrus et al., U.S. Patent No. 5,733,286 to Errico et al., and U.S. Patent Application Publication No. 2013/0046345 to Jones et al.

[0095] It will be understood that various modifications may be made to the embodiments of the presently disclosed interbody spacer. Therefore, the above description should not be construed as limiting, but merely as exemplifications of embodiments. Those skilled in the art will envision other modifications within the scope and spirit of the present disclosure.

What is claimed is:

1. An interbody spacer comprising:

a body portion defining a longitudinal axis, the body portion including a distal end portion, a proximal end portion, opposed side surfaces that extend between the distal and proximal end portions, and top and bottom surfaces configured and adapted to engage vertebral bodies; and

first orifices defined through the top surface, the first orifices including orifices having first and second cross-sectional configurations,

wherein the first orifices are arranged in rows extending along the longitudinal axis.

2. The interbody spacer of claim 1, wherein the second cross-sectional configuration is larger than the first cross-sectional configuration.

3. The interbody spacer of claim 2, wherein the first orifices are arranged in each row of the longitudinal rows in an alternating pattern of orifices having first and second cross-sectional configurations.

4. The interbody spacer of claim 1, wherein the first orifices include orifices with a third cross-sectional configuration, wherein the third cross-sectional configuration is larger than the second cross-sectional configuration.

5. The interbody spacer of claim 4, wherein the first orifices are arranged in each row of the longitudinal rows in a pattern, such that the cross-sectional configuration of each orifice of the

first orifices increases from the first cross-sectional configuration to the third cross-sectional configuration.

6. The interbody spacer of claim 4, wherein the first orifices are arranged in a random pattern.

7. The interbody spacer of claim 1, wherein each orifice of the first orifices includes a cross-sectional configuration selected from the group consisting of arcuate, more than four sides, quadrilateral, triangle, and sinusoidal.

8. The interbody spacer of claim 1, wherein each orifice of the first orifices includes a cross-sectional configuration selected from the group consisting of oval, kidney, elliptical, circular, teardrop, semicircle, and ovoid.

9. The interbody spacer of claim 1, wherein each orifice of the first orifices includes a cross-sectional configuration selected from the group consisting of squircle, square, rhombus, trapezoid, and rectangle.

10. The interbody spacer of claim 1, wherein each orifice of the first orifices includes a cross-sectional configuration selected from the group consisting of hexagon, octagon, heptagon, and pentagon.

11. The interbody spacer of claim 1, wherein each orifice of the first orifices includes a cross-sectional configuration selected from the group consisting of isosceles, equilateral, scalene, arrowhead with arcuate base, and right.

12. The interbody spacer of claim 1, wherein each orifice of the first orifices includes a cross-sectional configuration selected from the group consisting of greek cross and clover.

13. The interbody spacer of claim 1, further including second orifices defined through the bottom surface.

14. The interbody spacer of claim 13, wherein one of the first orifices includes a cross-sectional configuration different than that of one of the second orifices.

15. The interbody spacer of claim 13, wherein one of the first orifices is offset from one of the second orifices.

16. The interbody spacer of claim 13, wherein a respective orifice of the first and second orifices are in open communication, thereby defining a respective channel through the body portion, each channel including a cross-sectional configuration that varies in a direction from the top surface to the bottom surface.

17. The interbody spacer of claim 16, wherein each channel includes a sinusoidal cross-sectional configuration.

18. The interbody spacer of claim 16, wherein each channel includes a cross-sectional configuration including spherical, cylindrical, frusto conical, ellipsoidal, hyperboloid, or any combination thereof.

19. The interbody spacer of claim 16, wherein each channel includes a cross-sectional configuration including helical grooves disposed on an inner wall surface thereof.

20. The interbody spacer of claim 1, wherein a respective orifice of the first orifices is in open communication with an orifice defined through one of the opposed side surfaces, thereby defining a respective channel through the body portion.

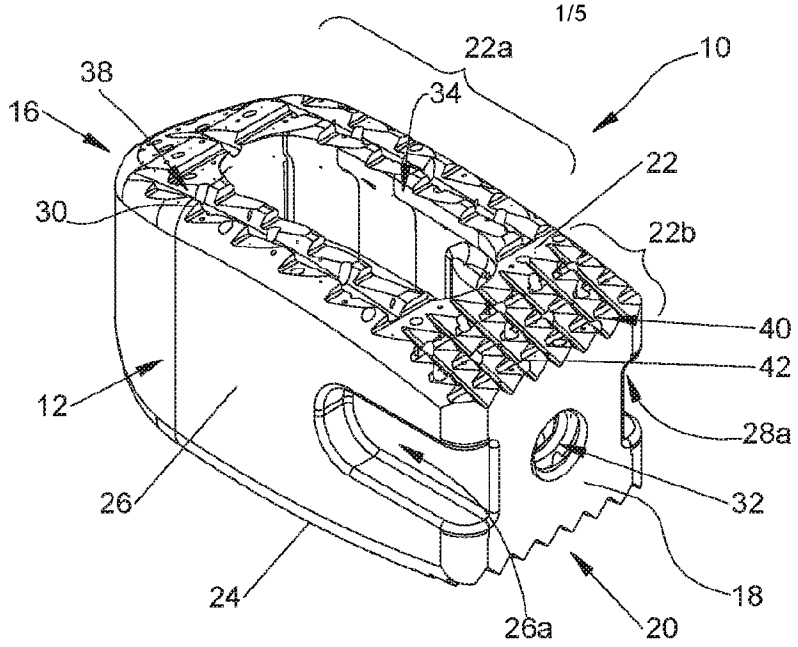


FIG. 1

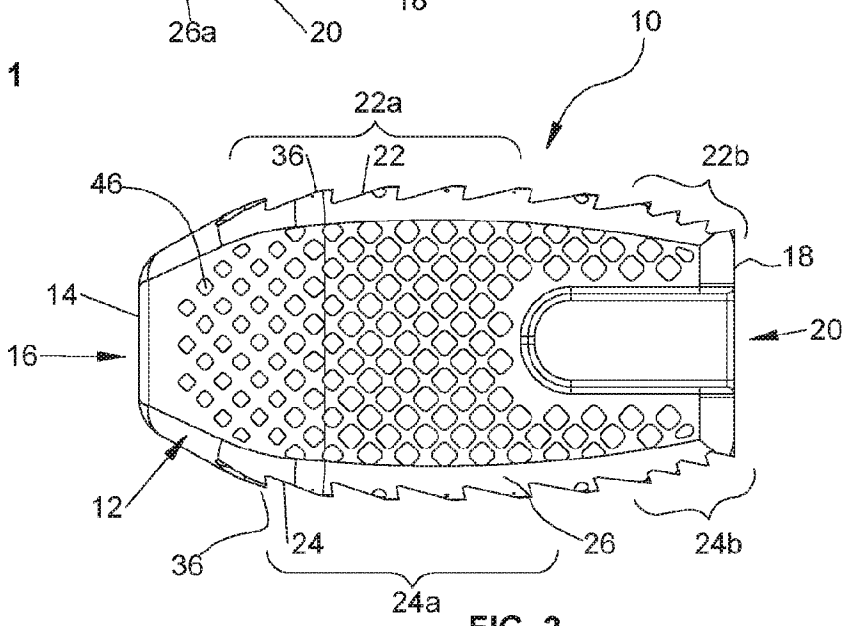


FIG. 2

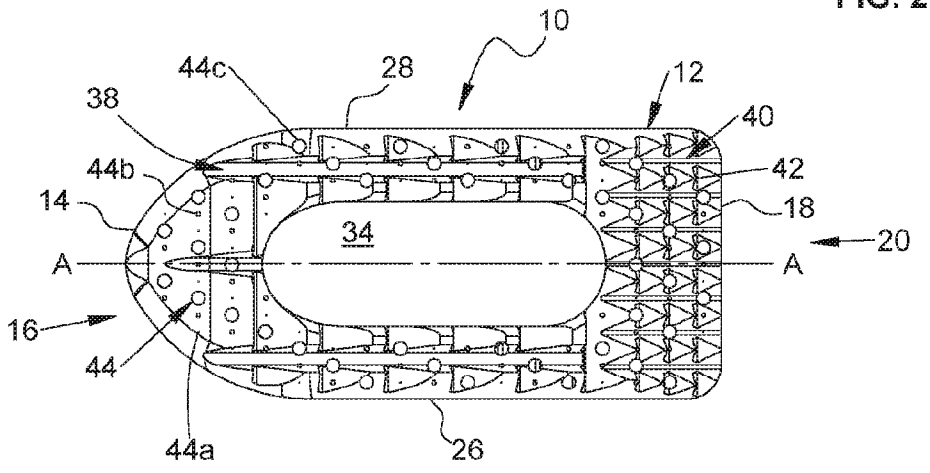


FIG. 3

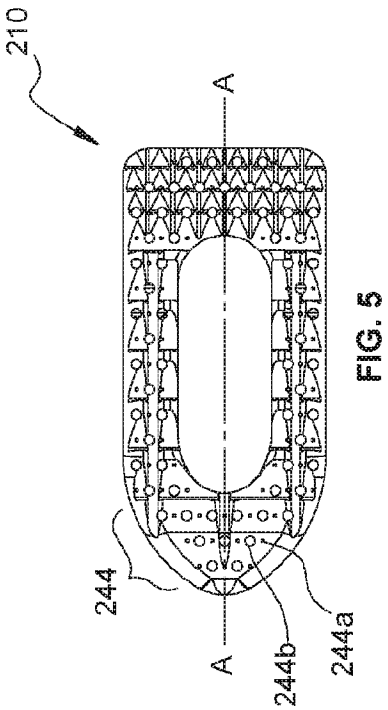


FIG. 5

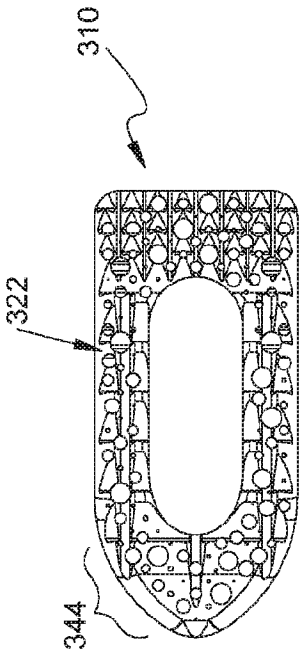


FIG. 6

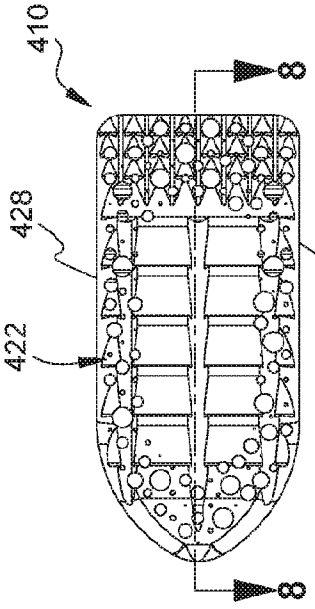


FIG. 7

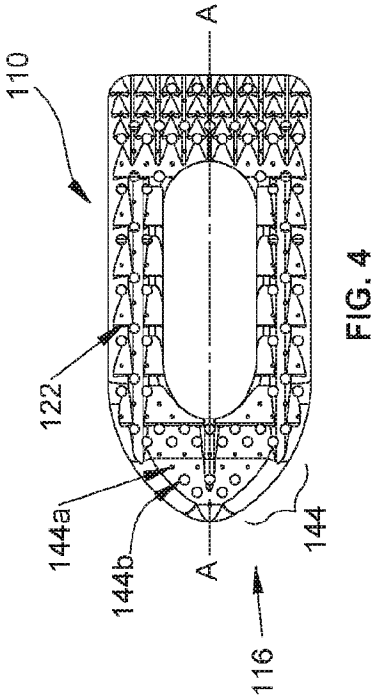


FIG. 4

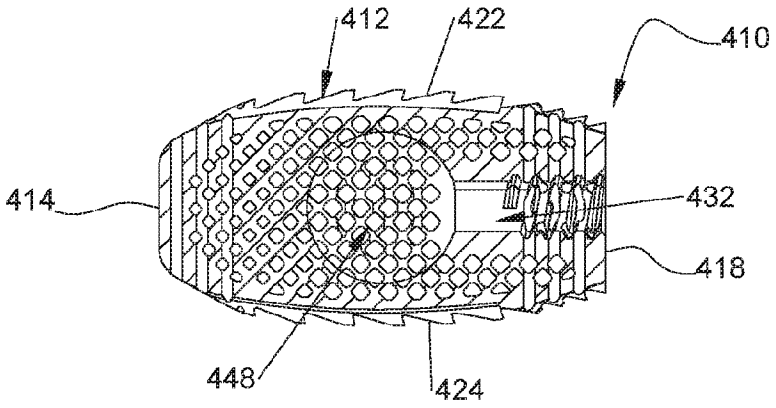


FIG. 8

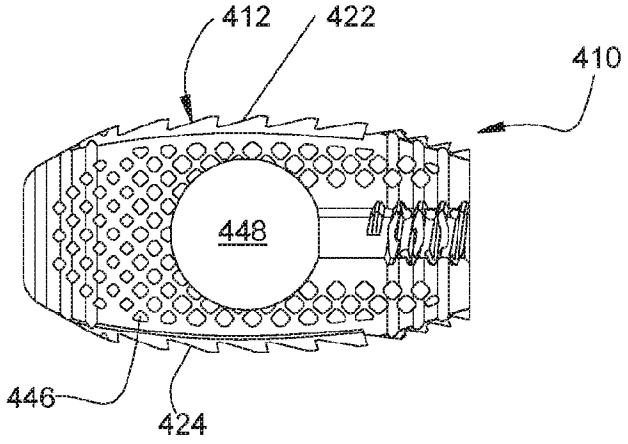


FIG. 8A

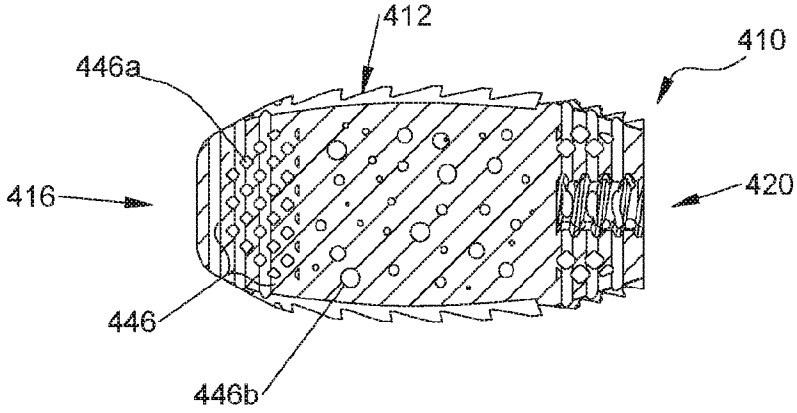


FIG. 8B

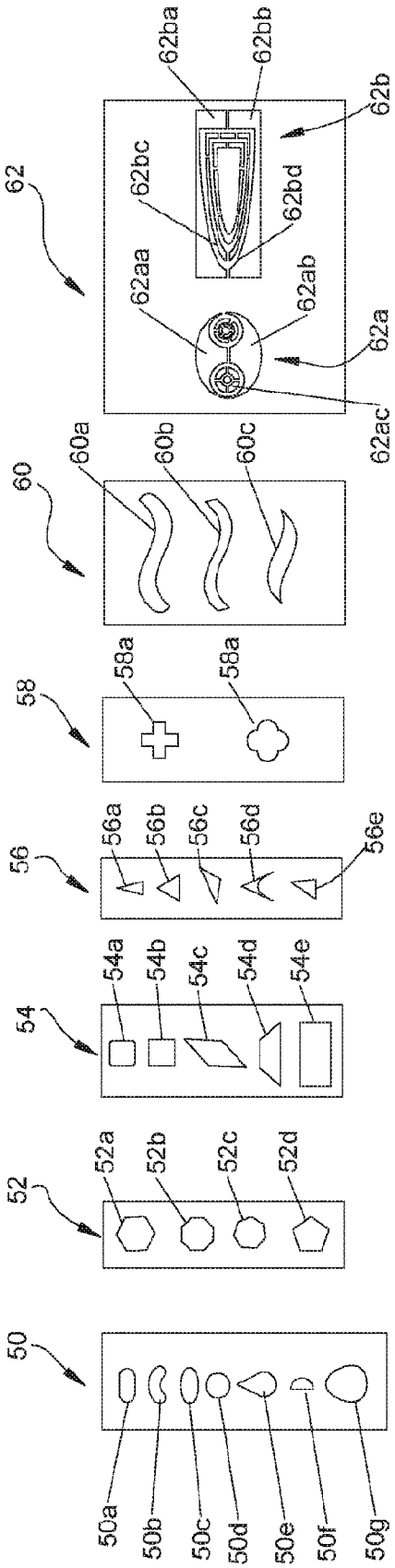


FIG. 9 FIG. 10 FIG. 11 FIG. 12 FIG. 13 FIG. 14 FIG. 15

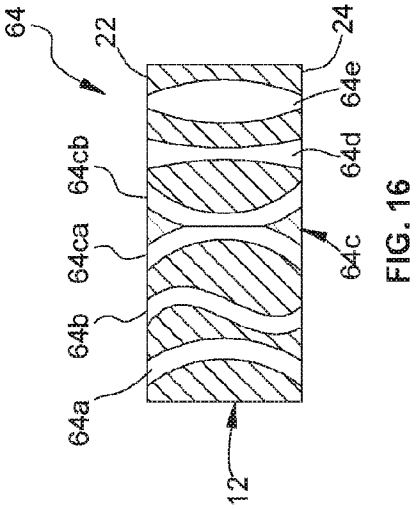


FIG. 16

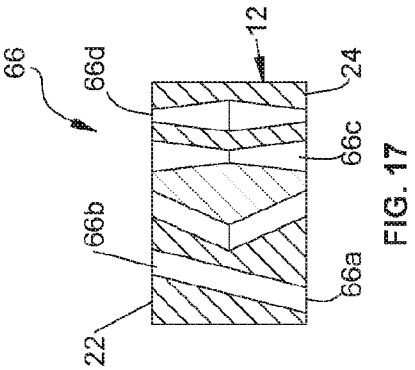


FIG. 17

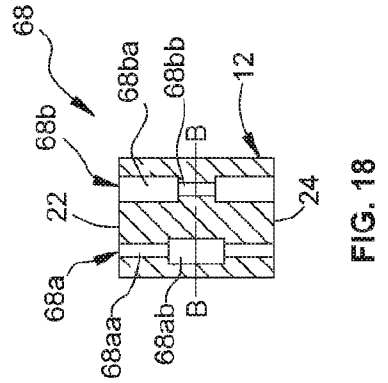


FIG. 18

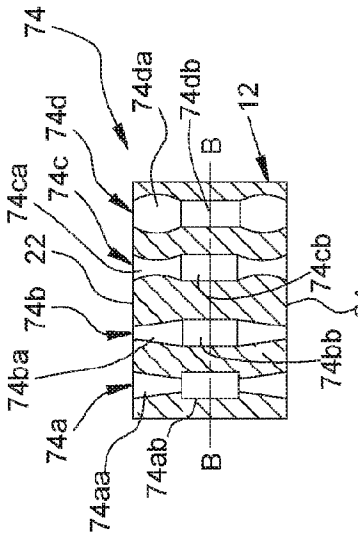


FIG. 21

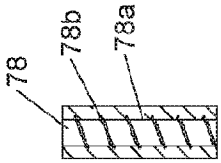
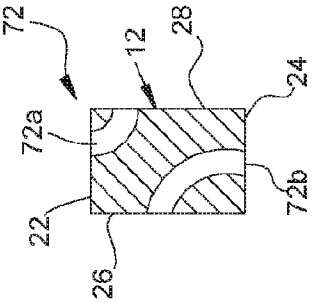


FIG. 23



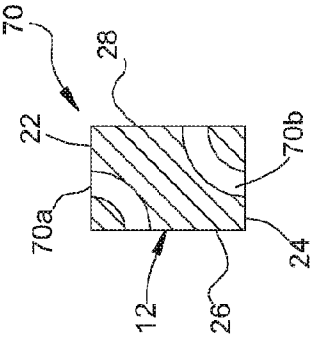


FIG. 19

FIG. 20

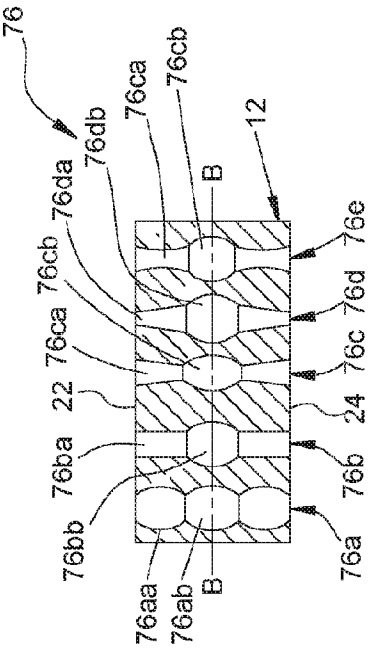


FIG. 22

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US16/56834

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61F 2/44; A61B 17/70 (2016.01)
CPC - A61B 17/70, 17/562; A61F 2/44, 2/442
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC(8) - A61F 2/44; A61B 17/70 (2016.01)
CPC - A61B 17/70, 17/562, 17/564, 17/7062; A61F 2/44, 2/442, 2/4425, 2/4455, 2/446, 2/4465, 2/447

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PatSeer (US, EP, WO, JP, DE, GB, CN, FR, KR, ES, AU, IN, CA, INPADOC Data); Google/Google Scholar; IEEE; EBSCO
Keywords used: vertebral, spinal, spacer, disc, implant, orifice, via, sinusoidal, channel

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,192,327 A (BRANTIGAN, J) March 9, 1993; figures 1, 4, 5; column 4, lines 1-19; column 6, lines 23-35	1, 7, 8, 11, 13-15 and 20
Y		2-3, 9-10, 12
A		4-6 and 16-19
Y	US 6,454,811 B1 (SHERWOOD, J et al.) September 24, 2002; column 6, lines 23-35	2-3, 9-10, 12
A	US 2013/0150893 A1 (KIRSCHMAN, D) June 13, 2013; entire document	1-20
A	US 2005/055099 A1 (KU, D) March 10, 2005; entire document	1-20
A	US 7,645,301 B2 (HUDGINS, R et al.) January 12, 2010; entire document	1-20
P, X	US 2016/0213485 A1 (K2M, INC) July 28, 2016; claims 1-16	1

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

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

Date of the actual completion of the international search	Date of mailing of the international search report
13 December 2016 (13.12.2016)	12 JAN 2017
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Authorized officer Shane Thomas PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

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(54) Title: TOOLS FOR ASSISTING IN OSTEOTOMY PROCEDURES, AND METHODS FOR DESIGNING AND MANUFACTURING OSTEOTOMY TOOLS

(57) Abstract: The present invention relates to a surgical kit, a saw guide and other related tools used in the osteotomy for temporary removal of a piece of a first bone structure to gain temporary access treatment of defects of a second bone structure, as well as methods for designing and manufacturing said tools.

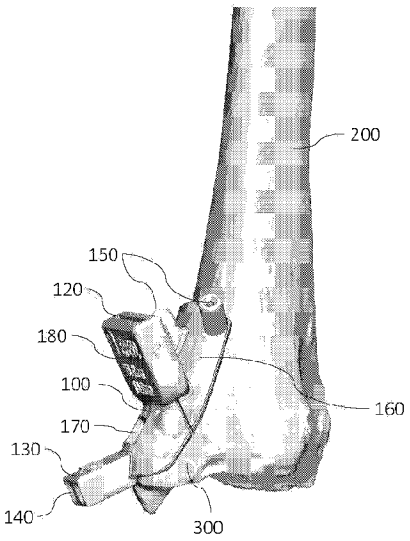


Fig. 1

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TITLE

TOOLS FOR ASSISTING IN OSTEOTOMY PROCEDURES, AND METHODS FOR DESIGNING AND MANUFACTURING OSTEOTOMY TOOLS

TECHNICAL FIELD

The present invention relates to a surgical kit, a saw guide and other related tools used in osteotomy for temporary removal of a piece of the bone of a first bone structure to gain temporary access for treatment of defects of the cartilage and/or bone of a second bone structure, as well as methods for designing and manufacturing said tools.

BACKGROUND

Generally, the technology disclosed relates to surgical tools used in the temporary removal of a piece of a first bone structure to gain temporary access for surgical treatment of defects of a second bone structure. The defects of the second bone structure may e.g. be damage in the bone, cartilage or cartilage and underlying bone of the second bone structure.

In certain aspects, the technology disclosed relates to joint defects, such as osteochondral defects, of the talar dome which may e.g. be caused by a traumatic event. They may lead to deep ankle pain on weight bearing, prolonged swelling, diminished range of motion, and synovitis. The mean cartilage thickness of the talar dome is in the range 1.2 to 1.4 mm. Cartilage defects are strongly linked to damage in the subchondral bone. Treatment options for talar osteochondral defects (OCDs) are numerous. High success rates have been reported for bone marrow stimulation techniques and osteochondral autograft transfer. Because osteochondral autograft transfer can cause knee morbidity at the donor site, debridement and bone marrow stimulation often remains the treatment of choice for primary OCDs, i.e., those without previous surgery, up to 15 mm in diameter. During debridement and bone marrow stimulation, the OCD is preferably approached by anterior ankle arthroscopy with the ankle in full plantar flexion for adequate exposure of the defect. However, the ankle is a congruent joint with limited surgical access. Some defects are located so far posteriorly that they may not be accessible by anterior ankle arthroscopy.

If the lesion is located on the medial side of the talar dome (ca 60% of cases), most of these treatment options require an osteotomy, e.g. a medial malleolar osteotomy, to obtain sufficient access to the talar dome. There are different varieties of osteotomy to get access to the talar dome, but a medial malleolar osteotomy is an established approach for the operative treatment of medial osteochondral defects of the talar dome and fractures of the talar body.

Lesions after failed previous surgery or large lesions can be treated by various alternative surgical methods, including autologous cancellous bone grafting, osteochondral autograft transfer, osteochondral allograft transfer and autologous chondrocyte implantation (ACI) or treatment with resurfacing implants. These techniques are generally more complicated and require more bulky tools compared to debridement and bone marrow stimulation, thus requiring better access to the talar dome, especially for larger lesions. The methods mentioned above are therefore sometimes combined with osteotomy for better access to the talar dome.

PROBLEMS WITH THE PRIOR ART

An osteotomy, which includes cutting out and temporarily removing a bone fragment of a first bone structure to gain access to a second bone structure for medical treatment of damage to the cartilage and/or bone of that second bone structure, can be a crucial step for any kind of treatment of various second bone structures. e.g. for the treatment with bone marrow stimulation, osteochondral grafting or the surgical implantation of resurfacing inlay implants into the second bone structure.

A commonly used osteotomy for the treatment of defects of the talar dome of the ankle joint is the oblique osteotomy, such as the medial malleolar osteotomy, which is a crucial step for obtaining access to the talar dome for treatment of the talus, e.g. the treatment with bone marrow stimulation, treatment through osteochondral grafting or the surgical implantation of resurfacing inlay implants. To obtain a congruent joint surface after refixation of the temporarily removed bone fragment, the osteotomy in state of the art solutions is often directed essentially perpendicularly to the articular surface of the tibia at the intersection between the tibial plafond and the medial malleolus. Failure to direct the osteotomy properly may lead to limited exposure of the defect site (too medial), or violate the weight-bearing cartilage on the tibial plafond (too lateral).

The anatomy of the talocrural area differs from that of e.g. the knee joint in that it is very difficult for the surgeon to access the dome of the talus. It is covered by the lower condylar surface of the distal tibia, as well as being encased by different muscles, tendons and ligaments extending

between the tibia and the calcaneus, the navicular and the talus, particularly the medial (deltoid) ligaments and flexor digitorum longus and the tibialis posterior muscles. Any severing of these muscles and tendons when performing osteotomy to gain access to the talus dome will create exceptional and sometimes permanent problems regarding repair and rehabilitation.

In this osteotomy procedure aimed at gaining access to the treatment area, e.g. the dome of the talus, a drilling, or predrilling, through the saw cutting plane of the piece of the tibia to be removed to create fixation holes in the inner portions of the tibia may be performed. The drilling, or pre-drilling, of the fixation holes is preferably performed before the saw cutting and the created fixation holes through the malleolus and into the inner portions of the tibia are later used for refixation of the temporarily removed bone fragment. Any significant improvement to the osteotomy procedure, including a faster and more precise and reliable pre-drilling and refixation, would be almost impossible to achieve with the currently used methods and tools for free-hand drilling of the fixation holes, or with an osteotomy where the saw cutting procedure and the pre-drilling and refixation procedure are essentially separate procedures which are not strongly linked to each other.

If a bone fragment in the form of a piece of the lower tibia, or malleolus, is sawn out to gain access to the talus dome, it is necessary that the bone be sawn precisely on the first try, so that the bone fragment, or bone segment, will fit precisely in place when put back and screwed in place. For better healing and alignment, the single saw cut is preferably a partial cut, not a through cut. The last part of the bone fragment is generally loosened with the aid of a surgical tool referred to as osteotome, tapped down to create breakage of the last part of bone.

It is thus necessary to expose the talus dome by cutting out a portion of the lower medial tibia, under a number of difficult constrictions:

- avoiding all important tendons, muscles and ligaments and leaving them attached and intact,
- avoiding the anterior tibial artery,
- providing enough exposed space to correctly perform a treatment of at least one of a bone and a cartilage damage of the talus dome,
- making the drilling of the fixation holes and the sawing of the bone cut precise and correct on the first try,

- facilitating a correct refixation of the temporarily removed bone fragment in form of a piece of the lower tibia, e.g. a piece of the malleolus, in its correct position for healing and for creating a congruent joint surface,
- avoiding cutting through the bone fragment and into the cartilage of the talar dome, damaging the articular surface.

SUMMARY

The entire complex of problems listed above finds its solution in the invention as defined in the appended patent claims.

The technology disclosed can generally be applied for any osteotomy followed by fixation of an anatomical part or a device. In some embodiments, the technology can be applied for temporary osteotomy of a part of the distal tibia for access to the medial talar dome of the ankle joint. In other embodiments, the technology can be applied for access to the lateral part of the talus through osteotomy of the lateral part of the distal tibia, or osteotomy of the fibula. In example embodiments, the joint can be a wrist where osteotomy of radius is performed. In yet other embodiments, the joint can be an elbow where an olecranon osteotomy is performed for access to humerus.

The inventors have identified a need for an improved osteotomy procedure including a faster and more precise and reliable pre-drilling and refixation procedure which would first of all increase the likelihood of a congruent joint surface after refixation but also increase the likelihood of preserving the deltoid ligament that originates more distally, yet reducing the risk for a drilling that can cause severing of any muscles, tendons and ligaments, or a screw placement causing disruption of the deltoid ligament. Thus, it is important that the drilling, or predrilling, of the fixation holes is performed in a precise and reliable manner.

Generally, the technology disclosed proposes a surgical saw guide, and a method for designing a surgical saw guide suitable for use in osteotomy and the temporary osteotomic removal of a bone fragment of a first bone structure of a patient for exposing a second bone structure for surgical treatment. The saw guide may comprise a slit, or opening, configured to receive a saw cutting tool and to guide the saw cutting tool to form a single saw cut in a straight direction at an angle to an inner engagement surface of the saw guide. The inner engagement surface of the saw guide may be adapted to at least partly conform to the surface of the first bone structure of a patient. The saw guide may further comprise, as an integral part, a drill guide having at least one hole with a certain

diameter, thickness or depth, orientation and position on the saw guide to thereby be configured to guide the drilling, or pre-drilling, of a hole in a straight direction at an angle relative to the saw cutting direction provided by the guidance of the slit, or opening.

The slit, or opening, and the portion of the saw guide comprising said slit, may be configured to be used to form a single saw cut in the removal of a bone fragment of a first bone structure to gain access to a second bone structure for medical treatment of damage to the cartilage and/or bone of that second bone structure. The portion of the saw guide comprising said slit, or opening, may be designed and configured with a height that matches, or corresponds to, the length of the sawblade to be used during sawing to thereby make the powertool used during sawing stop against the top surface of the portion of the saw guide, thereby minimizing the risk of unintentionally sawing too far. In certain example embodiment of and method for designing the saw guide, the dimensions, e.g. the height, of the portion of the saw guide may be customized, e.g. via imagery of the patient´s bone structure through e.g. MRI, CT or X-ray and/or based on the sawblade selected. As an example, the length of the sawblade and/or the thickness of the malleolus of a specific patient may be used to determine the height of the portion of the saw guide.

The at least one hole of the drill guide of the above saw guide may be configured to guide the drilling, or pre-drilling, of at least one hole past the single saw cutting plane provided by the guidance of said slit and into the inner portions of the first bone structure therebehind, thereby being adapted to provide for the pre-drilling of at least one fixation hole through the bone fragment to be removed, past the saw cutting plane and into the inner portions of the first bone structure that can be used for facilitating correct refixation of the removed bone fragment in its original, or substantially original, position after performed treatment, e.g. surgical treatment, by the use of fixation means, e.g. in the form of at least one screw. The use of the word substantially in substantially original position relates to that a small portion of the first bone structure is pulverized in the saw cutting procedure which, in turn, implies that the bone fragment, when remounted, is fixed to the inner portions of the first bone structure in a position which deviates slightly from its original position. The fixation means are inserted into the first bone structure through the pre-drilled at least one fixation hole, thereby fixing the temporarily removed bone fragment to the first bone structure.

In non-limiting embodiments of the technology disclosed, a plurality of screws are used as fixation means for the refixation of the removed bone fragment in its original, or substantially original, position after performed treatment. The plurality of screws are screwed into the first bone

structure through a plurality of fixation holes created by the pre-drilling, thereby fixing the temporarily removed bone fragment to the first bone structure. In alternative embodiments, the fixation means used for the refixation of the removed bone fragment may be a plurality of nails, which are driven into the first bone structure through a plurality of fixation holes, thereby fixing the temporarily removed bone fragment to the first bone structure. In yet other alternative embodiments, the fixation means used for the refixation of the removed bone fragment may be a plurality of fixation pins, e.g. self-tapping threaded pins, which are driven into the first bone structure through a plurality of fixation holes, thereby fixing the temporarily removed bone fragment to the first bone structure.

According to certain aspects of the technology disclosed, the surgical saw guide is suitable for use in oblique osteotomy and the temporary osteotomic removal of a bone fragment of a tibia for exposing the talus dome for surgical treatment. The saw guide may comprise at least one first opening, or pin hole, adapted to receive a fixation means, such as a pin, where the at least one hole has an orientation adapted to guide the temporary fixation of the saw guide to the tibia. The saw guide may comprise a slit, or opening, configured to receive a saw cutting tool and to guide the saw cutting tool to form a single saw cut in a straight direction at an angle to an inner engagement surface of the saw guide. The inner engagement surface of the saw guide may be adapted to at least partly conform to the distal or lower portion of the tibia of a patient. The saw guide may further comprise, as an integral part, a drill guide having at least one hole having a certain diameter, thickness/depth, orientation and position on the saw guide to thereby be configured to guide the drilling of a hole in a straight direction and at a certain angle relative to the saw cutting direction provided by the guidance of the slit, or opening. The at least one hole of the drill guide may also be designed to have a certain diameter adapted to be suitable for a certain type of drill having certain dimensions, including a certain diameter, so as to achieve a fit upon insertion of the drill into the at least one hole for optimal drilling, or pre-drilling, of the fixation holes into the tibia.

The slit, or opening, and the portion of the saw guide comprising said slit, may be configured to be used to form a single saw cut in the removal of a bone fragment of the tibia to gain access to the medial talar dome of the ankle joint for a specific treatment of damage to the cartilage and/or bone of the talus. The at least one hole of the drill guide of the above saw guide may be configured to guide the drilling, or pre-drilling, of at least one hole through the bone fragment, or piece of the tibia, to be removed, past the single saw cutting plane provided by the guidance of said slit and into the inner portions of the tibia therebehind, thereby being adapted to provide for the pre-drilling of

at least one fixation hole which can be used for facilitating correct refixation of the removed bone fragment in its original position, or substantially original, after performed treatment, e.g. surgical treatment, by the use of fixation means, e.g. in the form of at least one screw. The fixation means are inserted through the bone fragment to be removed and into the inner portions of the tibia through the pre-drilled of at least one fixation hole fixation, thereby fixing the temporarily removed bone fragment to the inner portions of the tibia. The use of the word substantially in substantially original position relates to that a small portion of the tibia is pulverized in the saw cutting procedure which, in turn, implies that the bone fragment, when remounted, is fixed to the inner portions of the tibia in a position which deviates slightly from its original position. In example embodiments, the portion of the saw guide comprising said slit, or opening, may be designed and configured with a height that matches, or corresponds to, the length of the sawblade to be used during sawing to thereby make the powertool used during sawing stop against the top surface of the portion of the saw guide, thereby minimizing the risk of unintentionally sawing too far, e.g. into the articular surface of the talus. In certain example embodiment of a method for designing the saw guide, the dimensions, e.g. the height, of the portion of the saw guide may be customized, e.g. via imagery of the patient´s bone structure through e.g. MRI, CT or X-ray and/or based on the sawblade selected. As an example, the length of the sawblade to be used and/or the thickness of the malleolus of a specific patient may be used to determine the height of the portion of the saw guide.

In non-limiting embodiments of the technology disclosed, a plurality of screws are used as fixation means for the refixation of the removed bone fragment in its original, or substantially original, position after performed treatment. The plurality of screws are then screwed into the tibia through a plurality of fixation holes created by the pre-drilling, thereby fixing the temporarily removed bone fragment to the tibia. In alternative embodiments, the fixation means used for the refixation of the removed bone fragment to the inner portions of the tibia may be a plurality of nails, which are driven through the bone fragment into a plurality of fixation holes created in the inner portions of the tibia, where the fixation holes are created by the pre-drilling, thereby fixing the temporarily removed bone fragment to the tibia. In alternative embodiments, the fixation means used for the refixation of the removed bone fragment may be a plurality of fixation pins, e.g. self-tapping threaded pins, which are driven into the tibia through a plurality of fixation holes, thereby fixing the temporarily removed bone fragment to the tibia.

In certain embodiments of the technology disclosed, the at least one hole of the drill guide has a certain orientation and position on the saw guide to thereby be configured to guide the drilling, or

pre-drilling, of at least one hole past the single saw cutting plane provided by the guidance of said slit and into the inner portions of the tibia bone therebehind, thereby being adapted to provide for the pre-drilling of at least one fixation hole in the inner portions of the tibia bone that can be used for facilitating correct refixation of the removed bone fragment in its original, or substantially original, position after performed surgical treatment, e.g. by the use of fixation means in the form of at least one screw.

In certain embodiments, the at least one hole of the drill guide is configured to guide the drilling along a straight line at a specific angle direction with respect to at least one of:

- at least a portion of the inner engagement surface adapted to conform to the distal or lower portion of the tibia of a patient,
- the longitudinal axis of the patient, and
- the direction for forming said single saw cut.

According to certain embodiments, the at least one hole of said drill guide is configured to guide the drilling in a direction at an angle or within an angle range to the longitudinal tibial axis of a patient, wherein said angle or angle range is within the angle range of 50-70 degrees to the longitudinal tibial axis of a patient.

According to certain embodiments, the at least one hole of said drill guide is configured to guide the drilling in a direction along a straight line at an angle β at 60 degrees, or close to 60 degrees, to the longitudinal tibial axis of a patient.

According to certain embodiments, the at least one hole of the drill guide is configured to guide drilling in a direction at an angle or within an angle range to the direction for forming said single saw cut, wherein said angle or angle range is within the angle range of 80-100 degrees to the direction for forming said single saw cut.

According to certain embodiments, the at least one hole of the drill guide is configured to guide drilling in a perpendicular direction, or close to 90 degrees, with respect to the direction for forming said single saw cut.

According to certain embodiments, the slit, or opening, for guiding a saw cutting tool is configured to guide a saw cutting tool to form a single saw cut at an angle or within an angle range to the longitudinal tibial axis of a patient, wherein said angle or angle range is within the angle range of 15-50 degrees to the longitudinal tibial axis of a patient.

According to certain embodiments, the slit, or opening, for guiding a saw cutting tool is configured to guide a saw cutting tool to form a single saw cut in a direction at a 30 degrees angle, or close to 30 degrees, to the longitudinal tibial axis of a patient.

In certain example embodiments, the saw guide further comprises an opening forming an inspection window adapted to allow visual inspection of how well the saw guide conforms to the distal or lower portion of the tibia of a patient, thereby facilitating adjustment of the positioning of the saw guide to provide for a correct positioning of the saw guide to the distal or lower portion of the tibia of the patient, to provide for both a more precise saw cutting procedure and a more precise drilling procedure.

The technology disclosed further provides a surgical kit including the saw guide according to any of the embodiments described above. In certain aspects, the surgical kit includes fixation means in form of e.g. screws such as e.g. titanium screws, which have dimensions and a certain length configured to allow for a correct refixation of the temporarily removed bone fragment, e.g. the fixation means have a length corresponding to, or adapted to, the depth of the holes pre-drilled through the bone fragment and beyond the saw cutting plane into the inner portions of the tibia.

In other example embodiments, the surgical kit of the present invention may include a verification tool, or depth meter tool, having a depth stop designed to be engaging a powertool, used for the saw cutting procedure, at a specific depth, to prevent insertion of saw cutting blades into the slit of the saw guide that cut beyond a certain length. In the verification process, the saw attachment and sawblade are first attached to the powertool and the depth meter is used for verifying that the selected sawblade has the correct dimension for a designed saw guide.

In other embodiments related to the example use of the technology disclosed in the surgical treatment by the implantation of an implant into a second bone structure, e.g. by resurfacing of an implant into the dome of the talus, the surgical kit of the present invention may include a hollow tubular shell suitable for guiding correct preparations such as implant pre-drilling at the surgical site of the talus dome. In these embodiments, the surgical kit of the present invention may also include different sockets adapted to be positioned in the hollow tubular shell. One such socket is a pin socket configured with a steering hole in the form of a through hole. The pin socket, when positioned in said hollow tubular shell, provides mechanical support and directional guidance for vertical drilling through said steering hole and into the articular surface of the second bone structure, creating a steering hole for further drilling to remove cartilage and bone to prepare the

site for implantation of an implant. In some embodiments, the pin socket, when positioned in said hollow tubular shell, may provide mechanical support and the directional guidance for vertical drilling through the steering hole of the pin socket and into the articular surface of a joint to form a steering hole in the articular surface of a joint for further drilling to remove cartilage and bone to prepare the site for implantation of an implant. In example embodiments, the pin socket, when positioned in said hollow tubular shell, provides mechanical support and directional guidance for vertical drilling through said steering hole and into the dome of the talus, creating a steering hole for further drilling to remove cartilage and bone to prepare the site for implantation of an implant into the dome of the talus. Two other sockets; a drilling socket and an adjustment socket, may further be used in the process of removing a portion of the talus bone for creating a recess for the implant, preceding hammering of the surgical implant into place in the talus dome. When the pre-drilling through the steering hole of the pin socket has been performed, the drilling socket is mounted into the hollow tubular shell and the drilling operation continues until the drill stops at the top of the drilling socket. The drilling guide is removed and the adjustment socket is instead inserted into the hollow tubular shell. When inserting the drill into the adjustment socket, the drill is inserted into the pre-drilled hole. Preferably, the drill body should not be in contact with the cartilage surface when the drilling starts. The drilling into the talar dome continues until the drill stops at the top of the adjustment socket. A flushing device and suction may be used to cleanse the drilled hole. For the final placement of the implant into the drilled hole, a mandrel and/or a hammer may be used to gently tap down the surgical implant into the bone until bottomed.

In certain example embodiments, the surgical kit may, in addition to the various embodiment of a saw guide described in this disclosure, also include at least one of a surgical implant, a dummy implant, a drill, a mandrel and a hollow tubular shell used for drilling of the damaged area on the articular surface of a second bone structure in the surgical procedure of implantation of resurfacing inlay implants.

The technology disclosed further proposes a method for designing a saw guide comprising the above-mentioned technical features. The method for designing the saw guide includes the designing of a saw guide which comprises as integral parts both a slit configured to guide the saw cutting in a first direction and a drill guide having at least one hole configured to guide the pre-drilling in a second direction different from the first direction.

In certain embodiments, the technology disclosed proposes a method for designing any of the above-mentioned embodiments of a saw guide which includes a step for designing the at least

portion of the surface of the inner engagement surface adapted to conform to the distal or lower portion of the tibia of a patient to be individually patient customized on the basis of radiologically obtained patient data, such as MR, CT or X-ray imaging.

In certain embodiments, the technology disclosed proposes a method for designing any of the above-mentioned embodiments of a saw guide which includes a step for designing the placement and orientation of the at least one hole of the drill guide to be individually patient customized on the basis of radiologically obtained patient data, such as MR, CT or X-ray imaging.

In certain embodiments, the technology disclosed proposes a method for designing any of the above-mentioned embodiments of a saw guide which includes a step for designing the placement and orientation of the slit, or opening, to be individually patient customized on the basis of radiologically obtained patient data, such as MR, CT or X-ray imaging.

In other embodiments, the technology disclosed proposes a method for designing any of the above-mentioned embodiments of a saw guide which includes a step for designing the at least one hole of the drill guide, said at least one hole having a certain orientation and position on the saw guide, to be individually patient customized on the basis of radiologically obtained patient data, such as MR, CT or X-ray imaging, in that the drilling direction provided by the position and orientation of the at least one hole is designed to have a patient customized angle relationship to at least one of the distal or lower portion of the tibia of a patient and the longitudinal axis of the patient.

In yet other embodiments, the technology disclosed proposes a method for designing any of the above-mentioned embodiments of a saw guide which includes a step for designing the slit, or opening, to be individually patient customized on the basis of radiologically obtained patient data, such as MR, CT or X-ray imaging, in that the saw cutting direction, and thereby also the saw cutting plane, provided by the position and orientation of said slit is designed to have a patient customized angle relationship to at least one of the distal or lower portion of the tibia of a patient and the longitudinal axis of the patient.

In yet other embodiments, the technology disclosed proposes a method for designing any of the above-mentioned embodiments of a saw guide which includes at least one step for designing both the saw cutting direction provided by the position and orientation of said slit, or opening, and the drilling direction provided by position and orientation of the at least one hole of the drill guide to have a patient customized angular relationship to at least one of the distal or lower portion of the tibia of a patient and the longitudinal axis of the patient.

Thus, the above-mentioned saw guide comprises as integral parts both a slit configured to guide the saw cutting in a first direction and a drill guide having at least one hole configured to guide the predrilling in a second direction different from the first direction. The technology disclosed enables the design of a saw guide comprising at least one hole of a drill guide having a fixed physical relationship to a slit suitable to be used for saw cutting, i.e. both a positional and angular relationship between the at least one holes of the drill guide and the saw cutting slit, thereby enabling the design of a saw guide having a fixed angular relationship between the angle direction of the saw cutting provided by the guidance direction of the slit and the angle direction for predrilling of the at least one fixation hole provided by the guidance direction of the at least one hole of the drill guide. In certain embodiments of the technology disclosed, this fixed angular relationship (between the guidance direction for the saw cutting direction provided by the orientation of the slit and the guidance direction of the predrilling of the at least one fixation hole provided by the at least one hole of the drill guide of the at least one fixation hole) is individually patient customized on the basis of radiologically obtained patient data, such as MR, CT or X-ray imaging. The thickness, or depth, of the slit and the dimensions and/or shape of the slit area of the slit, i.e. the longitudinal length and width of the slit area, may also be designed to be adapted and optimized to the length, width, and/or shape of a certain type of sawblade selected for the saw cutting procedure. The dimensions and/or depth/height of the portion of the saw guide which comprises the slit may be customized based on the sawblade selected.

In certain embodiments, the osteotomy and the surgical tools used, e.g. the design of the saw guide, can be adapted to the selected treatment of the damage, e.g. the damaged portions of a talus. The design of the saw guide may be based on both radiologically obtained patient data, such as MR, CT or X-ray imaging, and at least one of the selected type of treatment of the damaged area and, optionally, the size and location of the osteotomy. As an example, a drill guide, e.g. in form of a hollow tubular shell used for the implantation of a surgical implant, which has larger dimensions or a larger diameter, may require more space which in turn may require a larger osteotomy and the use of a saw guide that is designed for a larger osteotomy. A hollow tubular shell is designed to cover with its hollow part the damaged area of the talus to be repaired and is used for supporting the drilling on the talus dome, providing for a bore which is used for insertion of a surgical implant into the talus.

In certain embodiments, the technology disclosed may generally provide for patient-specific surgical kits including patient-specific saw guides and associated tools and components for use in

osteotomy, low tibial or medial malleolar osteotomy, for example. The patient-specific saw guides can be used either with conventional or patient-specific implant components prepared with computer-assisted image methods. Computer modeling for obtaining three dimensional images of the patient's anatomy using MRI or CT scans of the patient's anatomy, and the patient-specific guides and templates can be provided by various CAD programs and/or software available.

In example embodiments, the patient-specific saw guides and associated patient-specific openings, holes and/or slits disclosed herein can be generally formed using computer modelling based on the patient's three-dimensional anatomic image generated from image scans. In specific embodiments, the design of the patient-specific saw guide and associated patient-specific openings, holes and/or slits disclosed herein may also be determined partly based on the patient's three-dimensional anatomic image generated from image scans and partly on other requests, e.g. concerning the size and location of the osteotomy, which may be requested by the surgeon performing the osteotomy. The patient-specific saw guides can have a three-dimensional inner engagement surface that is made to at least partly conformingly contact and match a three-dimensional image of the patient's bone surface, by the computer methods discussed above. In certain aspects of the technology disclosed, the patient-specific saw guide may also include customized guiding formations, such as a patient-customized drill guide and/or a patient-customized slit, or opening.

In various embodiments, the patient-specific saw guide comprises a slit, e.g. a patient-specific slit, for receiving and guiding a cutting blade at certain cutting plane orientations, e.g. relative to a selected anatomic axis for the specific patient. The patient-specific saw guide can also include drill guide formations and at least one hole for guiding the drilling, or predrilling, associated with the osteotomy procedure, at specific drilling orientations, e.g. relative to a selected anatomic axis of a specific patient. The geometry, shape and orientation of the various features of the patient-specific saw guide, as well as various patient-specific implants and other patient-specific tools that optionally may be used together with the saw guide according to certain example embodiments of the technology disclosed, can be determined during the pre-operative planning stage of the procedure in connection with the computer-assisted modelling of the patient's anatomy.

In example embodiments of the technology disclosed, the saw guide may be individually made specific to the patient´s specific anatomy and to the specific damage to the second bone structure, possibly through the following saw guide design steps:

a. identifying a damage of a second bone structure through radiological images such as MR, CT or X-ray images or through arthroscopy;

b. planning the size and the location of an osteotomy needed to get access to the second bone structure to perform a specific treatment of the damage;

c. creating a virtual 3D model of at least one of a first and the second bone structure from radiological images such as MR, CT or X-ray images; and

d. virtually designing a patient specific osteotomy guide based on the 3D model of at least one of the first and second bone structure and the size and location of the osteotomy needed.

In various embodiments, the surgical saw guide may be manufactured by a 3D printing process in which material is joined or solidified under computer control to create the surgical saw guide. The method of manufacturing by a 3D printing process may include building the surgical saw guide from computer-aided design (CAD) data by successively adding material layer by layer. The CAD data may further be based on a virtually designed patient specific osteotomy saw guide based on the 3D model of the at least portion of the first bone structure and the size and location of the osteotomy needed.

According to example embodiment, the above method of manufacturing the saw guide in a 3D printing process may be preceded by the following steps of virtually designing a patient specific osteotomy saw guide:

a. identifying at least one of a bone and a cartilage damage of the second bone structure through radiological images such as MR, CT or X-ray images;

b. planning the size and the location of an osteotomy needed to get access to the second bone structure in the surgical treatment of said at least one of a bone and cartilage damage of the second bone structure;

c. creating a 3D model of at least portions of at least one of a first bone structure and the second bone structure from radiological images such as MR, CT or X-ray images; and

d. virtually designing a patient specific osteotomy saw guide based on the 3D model and the size and location of the osteotomy needed.

In various embodiments, a surgical saw guide configured to be used for an osteotomy of a part of distal tibia for access to the medial talar dome of the ankle joint is manufactured by a 3D printing process in which material is joined or solidified under computer control to create the surgical saw

guide. The method of manufacturing of the saw guide for an osteotomy of a part of distal tibia by a 3D printing process may include building the surgical saw guide from computer-aided design (CAD) data by successively adding material layer by layer. The CAD data may further be based on a virtually designed patient specific osteotomy saw guide based on the 3D model of the at least portion of the first bone structure and the size and location of the osteotomy needed.

According to example embodiment, the above method of manufacturing a saw guide suitable for an osteotomy of a part of distal tibia in a 3D printing process may be preceded by the following steps of virtually designing a patient specific osteotomy saw guide:

a. identifying at least one of a bone and a cartilage damage of the talus through radiological images such as MR, CT or X-ray images;
b. planning the size and the location of an osteotomy needed to get access to the dome of the talus in the treatment, e.g. surgical treatment, of said at least one of a bone and cartilage damage of the talus;
c. creating a 3D model of at least portions of at least one of the tibia and talus from radiological images such as MR, CT or X-ray images; and
d. virtually designing a patient specific osteotomy saw guide based on the 3D model and/or the size and location of the osteotomy needed.

In example embodiments, the technology disclosed may be used with a surgical method comprising at least some of the following steps:

a. attaching a three-dimensional engagement surface of a patient-specific saw guide to a corresponding surface of a tibia of a patient for whom the saw guide is customized by computer imaging during a pre-operative planning stage, the three-dimensional engagement surface conforming as a negative surface to the corresponding surface of the patient's tibia;
b. drilling, or predrilling, at least one fixation hole through the tibia bone;
c. making a partial bone cut in the tibia through an opening of the saw guide, the slot oriented at a patient-specific angle relative to an anatomic axis of the patient, the angle custom-selected during the pre-operative planning stage for correcting the patient's anatomy;
d. loosening, by use of an osteotome, a bone segment defined by the partial bone cut;

e. removing the bone segment, or cut out piece of the tibia, to obtain access to the dome of the talus;
f. drilling a hole in the dome of the talus for the peg and the shallow hole for the cap of an implant;
g. inserting an implant into the dome of the talus; and
h. refixating the bone fragment in its original position with the aid of surgical screws inserted into the pre-drilled holes.

The patient-specific osteotomy kit of the technology disclosed may also include patient-specific fixation means in form of e.g. screws such as titanium screws, which have a certain diameter and a certain length configured to allow for a correct, or predetermined, refixation of the temporarily removed bone fragment, e.g. a length corresponding or adapted to the depth of the holes predrilled through the bone fragment and beyond the saw cutting plane into the inner portions of the tibia.

The osteotomy surgical kit can also include saw blades configured to allow for a predetermined cutting length corresponding to a cutting depth, in order to avoid unintentionally sawing too deep and thereby damaging the articular surface of the talar dome. The cutting depth can be determined at the pre-operative planning stage. In various other embodiments, the cutting depth of the selected sawblade can be verified using a separate verification tool, e.g. a depth meter tool, which may e.g. have a depth stop. The cutting depth can also be verified by a separate depth meter verification tool having a depth stop with a certain depth adapted to be engaging a powertool at a specific depth and preventing insertion of sawblades that cut beyond a certain depth. Thus, the depth meter verification tool can be used for verifying that the sawblade is restricted to saw cutting to a pre-determined cutting depth which may be patient-specific and determined on the basis of radiologically obtained patient data, such as MR, CT or X-ray imaging.

In the verification process, the saw attachment and sawblade are first attached to the powertool and a verification tool, or depth meter tool, is used to verify that the selected sawblade has the correct dimension for the saw guide. The verification tool is configured with a depth stop designed to be engaging the powertool at a specific depth to prevent insertion of sawblades into the slit of the saw guide that cut beyond a certain length. In example embodiments, the verification process using the depth meter verification tool includes at least some of the following steps:

- The surgeon selects a sawblade that is either commonly used for a specific osteotomy procedure, and/or the surgeon believes have the desired dimensions,

- The dimensions of the sawblade selected by the surgeon are uploaded together with radiologically obtained patient data to the system used for designing the saw guide,
- The saw guide is designed based on the uploaded dimensions of the sawblade and the radiologically obtained patient data,
- Prior to performing surgery, the surgeon uses a verification tool in form of an osteotomy depth meter to verify that the selected sawblade has the correct or desired dimensions for the designed saw guide.

The size and dimension of the portion of the saw guide which comprises the saw cutting slit, and which may correspond to or define the depth of the slit, may be designed to be adapted to the length of the sawblade as the powertool, to which the sawblade is attached, engages and stops at the upper surface of the portion of the saw guide. In certain example embodiment of the method for designing the saw guide, the dimensions, e.g. the depth/height, of the portion of the saw guide comprising the slit may be customized based on the sawblade selected.

BRIEF DESCRIPTION OF DRAWINGS

Embodiments of the invention will now be described in more detail with reference to the appended drawings, wherein:

Fig. 1 shows a visualization of a saw guide placed on the distal tibia of a patient, according to one or more embodiments.

Fig. 2 shows the same example saw guide placed on the distal end of the tibia as Fig. 1, but from a different angle, according to one or more embodiments.

Fig. 3 shows the same example saw guide placed on the distal end of the tibia as Fig. 1, but from a different angle, according to one or more embodiments.

Fig. 4a illustrates an example embodiment of the technology disclosed where the osteotomy saw cut is made at a 30 degrees angle to the longitudinal tibial axis and the drilling of fixation holes is made at a 60 degrees angle to the longitudinal tibial axis.

Fig. 4b illustrate the example embodiment of an osteotomy of Fig. 4a and the refixation of the temporarily removed bone fragment at approximately a 60 degrees angle to the longitudinal tibial axis, by the use of fixation means such as e.g. at least one screw.

Fig. 5a shows a saw guide attached and secured to its position on the tibia, according to one or more embodiments of the technology disclosed.

Fig. 5b shows the saw guide where the chuck and designated drill are attached to the power tool, for drilling of the drill holes, according to one or more embodiments.

Fig. 5c shows the saw guide where a sagittal saw attachment and sawblade are attached to the powertool and the sawblade is inserted into the saw guide, according to one or more embodiments.

Fig. 5d illustrates a later stage in the osteotomic procedure when both the surgical pins and the saw guide have been removed, and an osteotome is applied for final loosening of the bone segment, according to one or more embodiments.

Fig. 6 shows a pin socket positioned in said hollow tubular shell, according to one or more embodiments of the technology disclosed.

Fig. 7 shows a verification tool, or depth meter tool, for verifying that the correct sawblade has been selected, according to one or more embodiments.

Fig. 8 is a process flow diagram showing the steps of an osteotomic procedure used, according to one or more embodiments of the technology disclosed.

DETAILED DESCRIPTION

The inventors have identified a need for an improved procedure and improved tools aimed at addressing problems related to the technical difficulties of performing a successful oblique osteotomy, such as an oblique medial malleolar osteotomy. These difficulties include sawing at a precise angle that allowed refixation of the distal fragment without creating an articular incongruence, and, for the example embodiment of a medial malleolar osteotomy, identifying the intersection between the tibial plafond and medial malleolus. The technical difficulties that the inventors have identified need to be addressed also include the difficulty of reduction and potential for malunion because apposition may not be collinear with respect to the osteotomy cut. In the example embodiment of a medial malleolar osteotomy, an incongruent joint fixation after refixation of the removed piece of the tibia could lead to secondary osteoarthritis of the ankle joint. The longitudinal, or long, tibial axis can serve as an intraoperative reference to direct the osteotomy.

This axis is commonly used for several orthopedic procedures, including total knee arthroplasty and high tibial osteotomy.

The technology disclosed is aimed at providing a more reliable osteotomy procedure by providing the surgical tools enabling a more precise and reliable alignment and identification of desired, or optimal, angles for saw cutting and refixation of the bone fragment, which would be helpful for use during surgery. In this connection, the inventors of the technology disclosed have identified a need for improved surgical tools designed for aiding the surgeon in properly performing the saw cutting and refixation of the removed bone fragment at the desired angles relative certain anatomic landmarks, e.g. the long tibial axis A, including improved tools for aiding the surgeon to perform these tasks in a precise and reliable manner, for optimized resulting osteotomy and to minimize the risks for complications.

Fig. 1 shows a saw guide 100 placed on an example area of use of the technology disclosed in form of the lower tibia of a patient to receive surgical treatment to repair the condylar dome surface of the talus. The bones and ligaments of the area of the foot where the kit and saw guide according to the invention is to be used constitute, of course, no part of the present invention and are therefore labelled with letters. The lower medial end of the tibia 200 is shown as well as the malleolus 300.

Figs. 2 and 3 show the same example saw guide 100 placed on the distal end of the tibia as Fig. 1, but from a different angle.

Figs. 4a and 4b illustrate an example embodiment of the technology disclosed aiming at avoiding an articular step off after refixation through predrilled fixation holes 410, screw holes. Fig. 4a illustrates that, after predrilling the fixation holes 410, or screw holes, at 60 degrees angle β in relation to the long tibial axis A, the osteotomy is made at 30 degrees angle in relation to the long tibial axis A. In Fig. 4a, the single saw cut is made in a direction B, or axis B, at an angle φ relative to the reference axis A in form of the longitudinal tibial axis, and the drilling is made in a direction C, at an angle β relative to the longitudinal tibial axis. Fig. 4b illustrates that the introduction of the compression screws through the predrilled holes, which are illustrated in Fig.4a, will result in a smooth joint surface.

The single saw cut may be selected at an angle φ relative to a selected reference axis A, another angle direction defined by the saw guide or at least a portion of surface of the saw guide or the patient. In the example embodiment of the technology disclosed illustrated in Figs. 4a and 4b, the reference axis A is in form of the longitudinal tibial axis of a patient and, in this example, the single

saw cut is made in a first direction B at an angle φ which is 30 degrees in relation to the longitudinal tibial axis A. In this example, the drilling, or pre-drilling, of the at least one fixation hole is made in a second direction C at a second angle β which is 60 degrees in relation to the long tibial axis A. In this example of the technology disclosed, the first angle φ and the second angle β to the longitudinal axis A have a sum of 90 degrees. The saw guide according to example embodiments of the technology disclosed is provided with a drill guide comprising at least one hole which is configured with an orientation adapted to guide drilling in a perpendicular direction, or close to 90 degrees, with respect to the direction for forming said single saw cut. The first reference axis A can also be another selected anatomic axis. Other anatomic axes, such as axes having significantly different orientations than the orientation of axis A illustrated in Figs. 4a and 4b, can be used as reference axes.

The saw guide 100 according to embodiments of the technology disclosed comprises, as an integral part, a drill guide 130 having at least one hole 140 with a certain diameter, depth, orientation and position on the saw guide to thereby be adapted for guiding the drilling in a direction at a precise and desired or optimal angle, e.g. relative the long tibial axis A , and which thereby has the additional advantage of preserving the deltoid ligament that originates more distally yet avoiding screw placement that can cause disruption of the deltoid ligament. A surgical kit including a saw guide comprising a drill guide 130 according to the technology disclosed makes this possible in a precise and reliable manner, providing for a precise and reliable predrilling operation which would be almost impossible to achieve with a free-hand predrilling procedure, or when the saw cutting procedure and the predrilling and refixation procedure are essentially two separate procedures which are not strongly linked to each other. The surgical kit according to the invention may, in addition to the saw guide 100, be comprised of fixation screws 420 with dimensions, a diameter and a length configured to be used for screwing through the at least one hole 140 of the drill guide 130 and sawblades 190 with dimensions, a diameter and a length suitable for saw cutting through the slit 120. In certain example embodiments, the surgical kit may, in addition to the saw guide 100 for assisting the surgeon in osteotomy procedure of a first bone structure, also include at least one of a surgical implant, a dummy implant, a drill, a mandrel and a second drill guide in form of a hollow tubular shell 620 used for drilling of the damaged area on the articular surface of a second bone structure in the surgical procedure of implantation of resurfacing inlay implants. The mandrel may be used to gently tap down the surgical implant into the bone until bottomed.

The at least one hole 140 of the drill guide 130 may be used to guide the predrilling of at least one fixation hole to be used for refixation of the removed bone fragment after surgical treatment of e.g. a bone fracture, a damaged cartilage and/or a tissue. The predrilling of the at least one fixation hole has the purpose of facilitating the correct refixation of the bone fragment to the first bone structure. The saw guide may further comprise at least one pin hole 150, or first opening, adapted to receive a fixation means 510, such as a pin, where the at least one pin hole 150 have an orientation adapted to guide the temporary fixation of the saw guide to the first bone structure of a patient. The at least one pin hole 150, or first opening, is provided for securing the saw guide in place on the first bone structure during both the predrilling and the saw cutting. The at least one hole 140 of the drill guide 130 may be used to guide the pre-drilling of at least one fixation hole 410 to be used for refixation of the removed bone fragment after surgical treatment. The pre-drilling of the at least one fixation hole 410 has the purpose of facilitating the correct refixation of the bone fragment. The at least one pin hole 150, or first opening 150, is provided for securing the saw guide 100 in place on the tibia during both the pre-drilling and the saw cutting.

In example embodiments of a method for designing the saw guide 100 suitable for use in osteotomy and the temporary osteotomic removal of a bone fragment of a first bone structure of a patient for exposing a second bone structure for surgical treatment, the portion 180 of the saw guide comprising said slit 120, or opening may be designed with a height that matches, or corresponds to, the length of the sawblade 190 to be used during sawing to thereby make the powertool 520 used during sawing stop against the top surface of the portion 180, thereby minimizing the risk of unintentionally sawing too far, e.g. into the articular surface of the second bone structure. In certain example embodiments, the dimensions of the portion 180 of the saw guide, e.g. the height, may be customized, e.g. via imagery of at least one of a first and second bone structure of the patient through e.g. MRI, CT or X-ray and/or based on the sawblade selected. As an example, the length of the sawblade and/or the thickness of the malleolus of a specific patient may be used to determine the height of the portion of the saw guide.

In accordance with certain aspects and in a preferred osteotomy procedure aimed at gaining access to the dome of the talus, a predrilling to create fixation holes to be used for refixation of the removed bone fragment is preferably performed before the saw cutting. The pre-drilling is performed through and past the saw cutting plane B defining the bone fragment to be cut out and removed and into the bone therebehind, thereby creating predrilled fixation holes in the inner portions of the tibia bone which will remain in the inner portion of the tibia bone when the bone

fragment is temporarily removed. As of today, the saw cutting procedure and the predrilling procedure are essentially two separate procedures which are not strongly linked or interrelated to each other.

The slit, or opening, and the portion 180 of the saw guide comprising said slit, may be configured to be used to form a single saw cut in the removal of a bone fragment of the tibia to gain access to the medial talar dome of the ankle joint for a specific treatment of damage to the cartilage and/or bone of the talus. In example embodiments of the technology disclosed, the portion 180 of the saw guide comprising said slit 120, or opening is designed with a height that matches, or corresponds to, the length of the sawblade 190 to be used during sawing to thereby make the powertool 520 used during sawing stop against said portion 180, thereby minimizing the risk of unintentionally sawing too far, e.g. sawing into the articular surface of the talus. The at least one hole of the drill guide of the above saw guide may be configured to guide the drilling, or pre-drilling, of at least one hole through the bone fragment, or piece of the tibia, to be removed, past the single saw cutting plane provided by the guidance of said slit 120 and into the inner portions of the tibia therebehind, thereby being adapted to provide for the pre-drilling of at least one fixation hole 410 which can be used for facilitating correct refixation of the removed bone fragment in its original, or substantially original, position after performed treatment, e.g. surgical treatment, by the use of fixation means 420, e.g. in the form of at least one screw. The fixation means 420 are inserted through the bone fragment to be removed and into the inner portions of the tibia through the pre-drilled at least one fixation hole 410, thereby fixing the temporarily removed bone fragment to the inner portions of the tibia.

The size and dimension of the portion 180 of the saw guide 100 which comprises the saw cutting slit, and which may correspond to or define the depth of the slit 120, may be designed to be adapted to length of the sawblade 190 as the powertool 520, to which the sawblade 190 is attached, engages and stops at the top surface of the portion 180 of the saw guide. In certain example embodiment of the method for designing the saw guide, the dimensions of the portion 180 of the saw guide 100 may be customized based on the sawblade selected.

The saw guide 100 is designed to improve the procedure for refixation of the bone fragment by providing improved surgical tools for a more precise and reliable procedure for the predrilling of at least one fixation holes past the bone fragment to be removed and into the bone therebehind. The drilling, or predrilling, of the at least one fixation hole 410 has the purpose of facilitating the correct refixation of the temporarily removed bone fragment, thereby increasing the likelihood of

preserving the deltoid ligament that originates more distally, yet reducing the risk for a drilling that can cause severing of any muscles, tendons and ligaments. If the at least one fixation hole 410 is predrilled at a less desirable angle relative certain anatomic landmarks in a direction so that the at least one screw 420 is inserted either more horizontally or more vertically than optimal, an intra-articular step off might result. A screw placement which is too vertical may also cause disruption of the deltoid ligament. In this connection, an important aspect of the technology disclosed is that the predrilling of the at least one fixation hole 410 enables a correct positioning of the removed bone fragment in its correct original, or substantially original, position to create a congruent joint surface for better healing. According to the technology disclosed, the predrilling at a desired position and angle direction relative an anatomy landmark of a patient is determined by the position for the placement of the saw guide 100 on the surface of a first bone structure, e.g. the distal end of the tibia, and the fixed angular and positional relationship between the position and orientation of the slit 120 on the saw guide 100 and the position and orientation of the at least one hole 140 of the drill guide 130 on the saw guide 100. The saw guide 100 according to the technology disclosed, having a drill guide 130 with its at least one hole 140 as an integral part, thereby enables a precise and reliable positioning of the removed bone fragment in its original, or substantially original, position to create a congruent joint surface for better healing. In certain embodiments of the technology disclosed, the inner engagement surface 160 and/or the fixed angular and positional relationship between the position and orientation of the slit 120 and the at least one hole 140 of the drill guide 130 of the saw guide 100 is patient-customized on the basis of radiologically obtained patient data, such as MR, CT or X-ray imaging.

The improved saw guide according to the technology disclosed comprises, as an integral part, a drill guide 130 having at least one hole 140 with a certain diameter, orientation and a position configured for guiding the drilling in a direction at a precise and optimum angle, e.g. relative the long tibial axis A. The introduction of a saw guide which comprises a drill guide as an integral part and thereby provides a fixed angular relationship between the orientation and position of the at least one hole of the drill guide and the engagement surface 160 of the saw guide and the orientation of the slit 120, or opening, for guiding the saw cutting enables a fast osteotomy procedure including a more precise and reliable predrilling operation. A more precise and reliable predrilling operation gives the advantage of increasing the likelihood of preserving the deltoid ligament that originates more distally, yet avoiding screw placement that may cause disruption of the deltoid ligament. The present disclosure further provides different method for designing a saw guide 100 having a drill guide 130 as an integral part and with a fixed angular and positional

relationship between orientation and position of the at least one hole 140 of the drill guide 130 for guiding the direction of the drilling, or predrilling, and the orientation of the slot 120, or opening, for guiding the direction of the saw cutting.

Certain embodiments provide for a saw guide which comprises as integral parts both a slit configured to guide the saw cutting in a first direction and a drill guide having at least one hole configured to guide the predrilling in a second direction different from the first direction, where at least some of the features of the saw guide is individually patient customized on the basis of radiologically obtained patient data, such as MR, CT or X-ray imaging.

In certain embodiments, a method for designing a saw guide 100 is provided which comprises as integral parts both a slit 120 configured to guide the saw cutting in a first direction and a drill guide 130 having at least one hole 140 configured to guide the pre-drilling in a second direction different from the first direction, where at least some of the features of the saw guide are individually patient customized on the basis of radiologically obtained patient data, such as MR, CT or X-ray imaging. In example embodiments, the method for designing the saw guide comprises designing the inner engagement surface 160 and/or the fixed angular and positional relationship between the position and orientation of the slit 120 and the at least one hole 140 of the drill guide 130 of the saw guide 100 to be patient-customized on the basis of radiologically obtained patient data, such as MR, CT or X-ray imaging. According to certain example embodiments, the method includes designing the at least one hole 140 of the drill guide 130 to have a position and orientation on the saw guide 100 that guide the drilling, or pre-drilling, to be performed at a desired position and angle relative to other features of the saw guide and/or an anatomy landmark of a patient. The method for designing a patient customized saw guide 100 based on radiologically obtained patient data, such as MR, CT or X-ray imaging may be used for at least one of determining a patient-unique inner engagement surface of the saw guide, the position for the placement of the saw guide 100 on the surface of a first bone structure, e.g. the distal end of the tibia, and/or the fixed angular and positional relationship between the position and orientation on the saw guide 100 for the slit 120 and the position and orientation on the saw guide 100 for the at least one hole 140 of the drill guide 130. The patient-customized design of the saw guide 100 according of the technology disclosed, having a drill guide 130 with its at least one hole 140 as an integral part, thereby enables a precise and reliable positioning of the removed bone fragment in its original, or substantially original, position to create a congruent joint surface for better healing. In certain embodiments of the technology disclosed, the inner engagement surface 160 and/or the fixed angular and positional relationship

between the position and orientation of the slit 120 and the at least one hole 140 of the drill guide 130 of the saw guide 100 are patient-customized.

In certain embodiments, the present invention provides a surgical kit including a saw guide designed to improve the precision and reliability of the combined predrilling, saw cutting and refixation procedures of osteotomy used in surgical treatment.

In order to obtain a congruent joint surface after refixation, the osteotomy is preferably directed at an essentially perpendicular angle relation, or at least within an angle range of 60 to 90 degrees, to the articular surface of the tibia at the intersection between the tibial plafond and medial malleolus so that the saw cutting avoids all important tendons, muscles and ligaments as well as the anterior tibial artery. According to certain aspects of the technology disclosed, the saw guide 100 is designed so that the osteotomy is aimed at 30 degrees relative to the long tibial axis, or at least within an angle range of 15-50 degrees relative to the long tibial axis A. The saw cutting direction is then preferably essentially perpendicular, or at least within an angle range of 60 to 90 degrees, to the articular surface of the tibia and directed at the intersection of between tibial plafond and articular facet of the medial malleolus. Applying this osteotomy direction minimizes the occurrence of a step off at the articular surface after reduction. A medial malleolar osteotomy directed at 30 degrees relative to the tibial axis A enters the joint perpendicular to the tibial cartilage, and will likely result in a congruent joint surface after reduction.

The inventors of the technology disclosed have identified shortcomings associated with the currently used procedure of free-hand drilling and sawing cutting in that these two operations are not strongly linked to each other. The osteotomy procedure used today therefore does not allow for sufficiently precise and reliable drilling and sawing cutting operations at desired positions and angles that allow for a sufficiently accurate refixation of the temporarily removed distal fragment without creating an articular incongruence.

An improved accuracy in the angle of the osteotomy and the direction of drilling relative to an anatomic landmark, e.g. to the longitudinal tibial axis A or the articular surface of the tibia, would be helpful for use during surgery. Currently used surgical tools for osteotomy do not provide for sufficiently precise and reproducible accuracy in the saw cutting and direction of drilling for fixating the saw guide 100, which can lead to severing of muscles and tendons creating exceptional and sometimes permanent problems. Specifically, damage to muscles and tendons caused by the currently used surgical tools and inaccurate osteotomic procedure of free-hand drilling, i.e. where

the drilling direction for fixating the saw guide is not directly linked to the saw cutting plane B and/or the anatomy of the patient, may lead to severe problems as regard to repair and rehabilitation.

A saw guide 100 according to the technology disclosed, which in addition to a saw cut opening 120 adapted for providing saw cutting also comprises a drill guide that is an integral part of the saw guide, is configured to enable a precise and reproducible accuracy in the angle direction of drilling of the at least one fixation screw 420 along a straight line which would be almost impossible to achieve with prior art solutions where the drilling of the fixation screws is made by free-hand, or with an osteotomy where the saw cutting procedure and the predrilling and refixation procedure are essentially separate procedures which are not strongly linked to each other.

The inventive concept of the present invention, where the drill guide 130 with its at least one hole 140 is made an integral part of the saw guide 100 and thereby provides for a fixation of the saw guide at a fixed angle direction with respect to the saw cutting plane B provided by the saw cutting opening of said same saw guide, mitigates the risk for the osteomtomic procedure causing disruption of the deltoid ligament, or result in an incongruent joint surface after reduction.

According to certain embodiments, the saw guide 100 is patient customized via imagery of the patient´s tibia through at least one radiological image, e.g. an MRI, CT or X-ray image, thereby providing for a patient customized saw guide that have a surface conforming to a certain patient's tibia. This patient customized saw guide may then preferably comprise both a saw cut opening adapted to guide the saw cutting in one saw cutting plane B only and a drill guide with at least one hole configured to provide for drilling in a direction, or along an axis C, at an angle to the one saw cutting plane B. Because the surface of the saw guide is designed based on radiological images of the patient's tibia and both the saw cutting plane B and the direction for drilling provided by the saw guide may be set to be in a fixed angle relation to the patient customized saw guide surface, both the saw cutting plane B and the drilling direction may therefore be determined based on said at least one radiological image of the individual patient's tibia when said saw guide is placed in position and conforms to the articular surface.

In certain other aspects of the technology disclosed, at least one of the saw cutting opening providing for the saw cutting plane B and the at least one drilling hole 410 of the drilling guide providing for the direction for drilling at least one fixation means 420, or screw, for refixation of the saw guide to the tibia 200, may be determined based on at least one radiological image of the

patient's tibia, e.g. an MRI, CT or X-ray image. In certain configurations of a patient customized saw guide and methods for designing such a saw guide, the saw cutting opening and the at least one drilling hole are both designed based on at least one radiological image of the patient's tibia in that a patient customized angle relationship between at least one of the one saw cutting plane B and the drilling direction along a straight line, or axis C, for fixating the saw guide to the tibia 200, is determined based on said at least one radiological image. In yet another example of a saw guide and method for designing the saw guide according to the technology disclosed, at least one of the angle relation between the saw cutting plane B provided by the saw cutting opening to the longitudinal axis of the patient's tibia and the angle relation of the drilling direction to the longitudinal axis of the patient is determined based on said at least one radiological image of the patient.

Any severing of muscles and tendons to gain access to a second bone structure through an osteotomic procedure of a first bone structure will create exceptional and sometimes permanent problems as regards repair and rehabilitation.

It is thus necessary to expose the second bone structure by drilling the fixation holes and cutting out a portion of the first bone structure, under a number of difficult constrictions:

- avoiding all important tendons, muscles and ligaments and leaving them attached and intact,
- avoiding any arteries of the first bone structure,
- providing enough exposed space to correctly perform a surgical treatment of at least one of a bone and a cartilage damage of the second bone structure,
- making the drilling of the fixation holes and the sawing of the bone cut precise and correct on the first try,
- facilitating a correct refixation of the temporarily removed bone fragment in its original position for healing.

The anatomy of the talocrural area differs from that of e.g. the knee in that it is very difficult for the surgeon to access the dome of the talus. It is covered by the lower condylar surface of the tibia, as well as being encased by a many different muscles, tendons and ligaments. Any severing of these muscles and tendons to gain access to the talus dome will create exceptional and sometimes permanent problems as regards repair and rehabilitation.

The longitudinal tibial axis A can serve as an intraoperative reference to direct the medial malleolar osteotomy. This axis is commonly used for several orthopedic procedures, including total knee

arthroplasty and high tibial osteotomy. If a bone fragment in form of a piece of a first bone structure is sawn out to gain access for surgical treatment of a second bone structure, it is necessary that the bone be sawn precisely on the first try, so that the bone fragment, or bone segment, will fit precisely in place when put back and screwed in place. For better healing and alignment, the single saw cut is preferably a partial cut, not a through cut. It is also important that the drilling, or predrilling, of the fixation holes 410 is performed in a precise and reliable manner.

If a bone fragment in form of a piece of the lower tibia, or malleolus 300, is sawn out to gain access to the talus dome, it is necessary that the bone be sawn precisely on the first try, so that the bone fragment, or bone segment, will fit precisely in place when put back and screwed in place. For better healing and alignment, the single saw cut is preferably a partial cut, not a through cut. It is also important that the drilling, or predrilling, of the fixation holes is performed in a precise and reliable manner.

It is thus necessary to expose the talus dome by cutting out a portion of the lower medial tibia, under a number of difficult constrictions:

- avoiding all important tendons, muscles and ligaments and leaving them attached and intact,
- avoiding the anterior tibial artery,
- providing enough exposed space to correctly perform a surgical treatment of at least one of a bone and a cartilage damage of the talus dome,
- making the drilling of the fixation holes and the sawing of the bone cut precise and correct on the first try,
- facilitating a correct refixation of the temporarily removed bone fragment in form of a piece of the lower tibia, e.g. a piece of the malleolus, in its correct position for healing.

As regards to the above-mentioned aspect of facilitating the replacement and fixation of the bone fragment, the inventors have identified that it is increasingly important to provide for a more precise and reliable procedure for the predrilling past the bone fragment to be removed and into the bone therebehind to thereby create fixation holes having the purpose of facilitating the correct refixation of the bone fragment after surgical treatment. If the at least one fixation hole is predrilled at a less desirable angle relative certain anatomic landmarks in a direction so that the at least one screw 420 is inserted either more horizontally or more vertically than optimal, an intra-articular step off might result. Vertical crew placement may also cause disruption of the deltoid ligament.

In order to obtain a congruent joint surface after fixation, the osteotomy cut is best directed perpendicular, or at least within an angle range of 60 to 90 degrees, to the articular surface of the tibia. An osteotomy which is too vertical or horizontal may result in an incongruent joint surface or shortening of the malleolus 300 after fixation. Furthermore, the fixation screws 420 should be directed essentially perpendicular, or within an angle range of 80-100 degrees, to the osteotomy plane.

The saw guide according to example embodiments is designed to achieve optimal compression and a congruent joint surface after surgical treatment of a damaged talus dome, i.e. when the removed bone fragment of a tibia is remounted, the at least one screw 420 needs to be inserted at a precise angle relative to e.g. the long tibial axis. As mentioned above, the osteotomy may then preferably be directed essentially perpendicularly, or at least within an angle range of 60 to 90 degrees, to the articular surface of the tibia at the intersection between the tibial plafond and medial malleolus. Furthermore, the fixation screws 420 should be directed essentially perpendicular, or within an angle range of 80-100 degrees, to the osteotomy plane.

According to a preferred method using the surgical kit and saw guide of the technology disclosed, the at least one screw hole 410, or fixation hole 410, is pre-drilled through the piece of the tibia and into the inner portions of the tibia, before the saw cuts are made to make sure that the tibia bone fragment will be remounted to its original, or substantially original, position. Certain aspects of the technology disclosed is aimed at providing the guiding tools facilitating a more precise saw cutting and a predrilling which are both performed in directions at desired, or optimal, angles relative certain anatomic landmarks of a patient, e.g. the long tibial axis.

In order to achieve optimal compression and a congruent joint surface after surgical treatment of the damaged talus dome, i.e. when the removed bone fragment of the tibia is remounted, the at least one screw 420 needs to be inserted at a precise angle relative to e.g. the long tibial axis. According to a preferred method using the surgical kit and saw guide of the technology disclosed, the at least one screw hole 410, or fixation hole 410, is pre-drilled through the piece of the tibia and into the inner portions of the tibia, before the saw cuts are made to make sure that the tibia bone fragment will be remounted to its original, or substantially original, position.

An example surgical kit according to the technology disclosed, which is suitable for repair of articular surfaces in the talocrural joint, comprises:

a. A surgical implant having a cap with an outer surface conforming to a talus dome surface and an inner surface having a central implant anchoring peg extending perpendicularly from said inner surface,
b. A drilling guide, conforming to a talus dome surface, comprising a hollow tubular shell 620 suitable for supporting vertical drilling into the dome,
c. A saw guide 100 configured to conform to the lower portion of a tibia and comprising an opening 120 suitable for insertion of a cutting saw and directed at an angle providing for only one single saw cut and a single saw guide surface in one plane, wherein said saw guide, when conforming to the lower portion of the tibia, is configured to provide for saw cutting at an angle direction to the longitudinal axis of the tibia suitable for osteotomy of a lower portion of a tibia to expose the dome of the talus, thereby providing access for a surgeon implanting said surgical implant into the talar dome, and wherein said saw guide further comprises, as integral part, a drill guide 130 having at least one hole(s) 140 configured to guide and provide for drilling by a drilling tool at an angle direction which is within a range of 80-100 degrees to the saw cutting direction provided by said opening.

The above surgical kit may further comprise at least one screw(s) 420 which is adapted to be used for drilling through said drill hole(s) 410, said screw hole(s) having a shape, dimensions and a length adapted for drilling through and past the at least portion of the malleolus 300 to be removed and into the inner portions of the tibia before the single saw cut is made so that at least one hole remains in the inner portions of the tibia after removal of both the at least portion of the malleolus 300 and the saw guide 100, wherein a portion of the at least one hole 410 remaining in the inner portions of the tibia made by the drilling operation can be used for remounting the temporarily removed at least portion of the malleolus 300 in its original, or substantially original, position.

The above surgical kit may further be designed so that said saw guide is individually patient customized to conform to the lower portion of the tibia of a patient and is further configured so that the orthogonal direction to the plane of said opening for inserting a cutting saw is at an angle direction which is less than 45 degrees to the longitudinal tibial axis of the patient, thereby providing for said one saw cut through said at least portion of the malleolus 300 used for osteotomy of a lower portion of a tibia to expose the dome of the talus.

The above surgical kit may further be designed so that said saw guide is individually patient customized to conform to the lower portion of the tibia of a patient and further configured so that

the saw cutting direction provided by said opening is at an angle direction within a range between 15 and 45 degrees to the longitudinal tibial axis of the patient, thereby providing for said one saw cut through said at least a portion of the malleolus used for osteotomy of a lower portion of a tibia to expose the dome of the talus.

The above surgical kit may further be designed so that said saw guide is individually patient customized to conform to the lower portion of the tibia of a patient and further configured so that the saw cutting direction provided by said opening is at an angle direction of 30 degrees to the longitudinal tibial axis of the patient, thereby providing for said one saw cut through said at least a portion of the malleolus used for osteotomy of a lower portion of a tibia to expose the dome of the talus.

The above surgical kit may further be designed so that at least a portion of the inner engagement surface 160 of said saw guide conforms to the lower medial anterior portion of the tibia. In certain aspects, the at least a portion of the inner engagement surface 160 of the saw guide is patient uniquely customized with a surface and dimensions designed to conform to the lower medial anterior portion of the tibia.

The surgical implant of the above surgical kit may be customized to an undamaged talus dome of a specific patient to be treated.

Figs. 1 to 3 show the saw guide 100 of the kit according to the invention. In this example embodiment related to defects of the talar dome, each saw guide may be customized via imagery of the patient's tibia through e.g. MRI, CT or X-ray. The saw guide has a slit 120, or first opening 120, providing for a single saw cutting plane B. This example saw guide also has two pin holes 150 provided for securing the saw guide in place on the tibia. The portion 180 of the saw guide in Fig. 1 to 130 which comprises the saw cutting slit 120, and which may have dimensions corresponding to or defining the depth of the slit, may be designed with a depth or height which is adapted to a specific length of the sawblade 190 as the powertool 520, to which the sawblade is attached, engages and stops at the upper surface of this portion 180 of the saw guide 100. The portion 180 of the saw guide comprising said slit 120, or opening may be designed with a height that matches, or corresponds to, the length of the sawblade 190 to be used during sawing to thereby make the powertool 520 used during sawing stop against the top surface of the portion 180, thereby minimizing the risk of unintentionally sawing too far. In certain example embodiment of the method for designing the saw guide 100, the dimensions of the portion 180 of the saw guide may be

customized, e.g. via imagery of the patient's bone structure through e.g. MRI, CT or X-ray and/or based on the sawblade selected.

According to certain aspects of this example embodiment illustrated in Figs. 1 to 3, the saw guide may be individually made specific to the patient's specific anatomy and to the specific damage to the talus, possibly through the following saw guide design steps:

a. identifying a subchondral damage of the talus dome through radiological images such as MR, CT or X-ray images or through arthroscopy;

b. planning the size and the location of an osteotomy needed to get access to the talar dome to treat the damage;

c. creating a virtual 3D model of at least portions of at least one of the tibial bone and the talus bone from radiological images such as MR, CT or X-ray images; and

d. virtually designing a patient specific osteotomy guide based on the 3D model and the size and location of the osteotomy needed.

According to certain of the example embodiment illustrated in Figs. 1 to 3, the surgical saw guide 100 may be manufactured by a 3D printing process in which material is joined or solidified under computer control to create the surgical saw guide. The method of manufacturing by a 3D printing process may include building the surgical saw guide from computer-aided design (CAD) data by successively adding material layer by layer. The CAD data may further be based on a virtually designed patient specific osteotomy saw guide based on the 3D model of the at least portion of the first bone structure and the size and location of the osteotomy needed.

According to example embodiment, the above method of manufacturing the saw guide in a 3D printing process may preceded by the following steps of virtually designing a patient specific osteotomy saw guide:

a. identifying at least one of a bone and a cartilage damage of the second bone structure through radiological images such as MR, CT or X-ray images;

b. planning the size and the location of an osteotomy needed to get access to the second bone structure in the surgical treatment of said at least one of a bone and cartilage damage of the second bone structure;

c. creating a 3D model of at least a portion of at least one of the first and the second bone structure from radiological images such as MR, CT or X-ray images; and

d. virtually designing a patient specific osteotomy saw guide based on the 3D model and the size and location of the osteotomy needed.

According to example embodiments, the technology disclosed proposes a method for designing a saw guide and a surgical method for use in osteotomy and the temporary osteotomic removal of a bone fragment of a first bone structure for exposing a portion of a second bone structure for treatment, comprising the steps of:

a. identifying at least one of a bone and a cartilage damage of the second bone structure through radiological images such as MR, CT or X-ray images;
b. planning the size and the location of an osteotomy of the first bone structure needed to get access to the second bone structure in the treatment, e.g. surgical treatment, of the at least one of a bone and cartilage damage of the second bone structure;
c. creating a virtual 3D model of at least a portion of at least one of the first and second bone structure from radiological images such as MR, CT or X-ray images;
d. designing a patient specific osteotomy saw guide based on the 3D model and the size and location of the osteotomy needed;
e. positioning and fixing the designed patient customized saw guide 100 so that the saw guide is conforming and fixable to the surface of the first bone structure;
f. making a saw cut along the saw guide surface excising a bone fragment in form of a piece of the first bone structure;
g. removing said bone fragment, or folding said bone fragment forward and outward preserving the attachment, and exposing the damaged area of the second bone structure;
h. performing treatment of said at least one of a bone and cartilage damage of the second bone structure; and
i. replacing said excised bone fragment into its original, or substantially original, position and fixing it in place.

With reference to the angle relationships and angles φ and β illustrated in Figs. 4a and 4b and in example embodiments, the saw guide 100 of the technology disclosed can be designed with at least one hole 140 of an integrated drill guide 130 where the at least one hole 140 is configured to have an orientation adapted to guide the drilling at an angle β, or within an angle range, to the longitudinal tibial axis A of a patient, where the angle β, or angle range, is within the angle range of

50-70 degrees to the longitudinal tibial axis A of a patient. At least one the angles φ and β can be determined during the pre-operative planning stage of the osteotomy and may be determined in relation to other features, angle direction and surfaces of the saw guide or a patient. In certain aspects of the technology disclosed, the determination of at least one of the angles φ and β is individually patient customized on the basis of radiologically obtained patient data, such as MR, CT or X-ray imaging.

Fig. 5a shows a saw guide 100, e.g. a talus osteotomy guide, in its unique position on the tibia. The saw guide 100 is attached and secured to the bone by inserting two pins 510 in the pin holes 150 on the proximal side of the saw guide.

Fig. 5b shows the saw guide 100 where the chuck and designated drill are attached to the power tool. The distal guiding holes 140 of the drilling guide 130 on the saw guide 100 are used for pre-drilling the fixation holes 410, or channels, which are used to refixate the temporarily removed bone fragment of the tibia after performing the surgical treatment of the talus.

Fig. 5c shows the saw guide 100 where the sagittal saw attachment and sawblade 190 are attached to the powertool 520. The saw guide will guide the sawing and controls the depth of the cut. In certain aspects of the technology disclosed, the sawing will continue until the saw bottoms on the top of the saw guide.

Fig. 5d illustrates a later stage in the osteotomic procedure when both the surgical pins 510 and the saw guide 100 have been removed. In this example, the osteotomy is continued by using an osteotome 530 to make sure to keep surrounding tissues away. In this example of procedure, a slight amount of bone is left intact to allow a final break-off by hand to reduce the risk of damaging the talus surface. This slight amount of bone left intact is then preferably broken off by hand and, as illustrated in Fig. 5d, a scalpel or chisel 530 is used to free the bone fragment of the last tibia adjoining tissue to remove the bone fragment in one piece, thereby providing temporary access to the dome of the talus for the surgeon to perform treatment such as e.g. surgical treatment.

Fig. 6 illustrates the pin socket 610 positioned in a hollow tubular shell 620. The pin socket 610 comprises a through hole in form of a steering hole 630. The pin socket, when positioned in said hollow tubular shell 620, provides mechanical support and the directional guidance for vertical drilling through said steering hole 630 and into the articular surface of a joint to form a steering hole in the articular surface of a joint for further drilling to remove cartilage and bone to prepare the site for implantation of an implant.

Fig. 7 shows the depth meter verification tool 710. The verification tool 710, or depth meter tool, comprises a depth stop which is designed to be engaging a powertool used for the saw cutting procedure, at a specific depth to prevent insertion of saw cutting blades into the slit 120 of the saw guide that cut beyond a certain length. In the verification process, the saw attachment and sawblade 190 are first attached to the powertool 520 and the depth meter 710 is used to verify that the selected sawblade has the correct dimension for the designed saw guide. The verification process selected sawblade 190 has the correct dimensions and length for the designed saw guide 100 using the depth meter verification tool 710 in Fig. 7 includes verifying that the tip of the sawblade 190 is visible within the MIN/MAX markings 720 of the depth meter verification tool.

Fig. 8 is a process flow diagram showing the steps of an osteotomic procedure used according to example embodiments of the technology disclosed, the example osteotomic procedure comprises at least a plurality of the following steps:

810: inserting at least one pin 510 in the at least one pin hole 5 on the proximal side of the saw guide 100 to secure the saw guide to the bone;

820: drilling the at least one fixation holes 410 by use of the directional guidance of the at least one hole 140 of the drill guide 130 of the saw guide 100;

830: attaching the saw attachment and sawblade 190 to a powertool 520 and inserting the sawblade 190 into the saw guide 100 to start sawing the saw cut;

840: removing the pins 510 and the saw guide 100 from the surgical field;

850: removing a bone fragment, or piece of the tibia, defined by the saw cut by breaking-off the bone fragment by the aid of an osteotome 530, e.g. a scalpel or chisel 530, to free the bone fragment of the last tibia adjoining tissue;

860: performing surgical treatment of the talar dome; and

870: refixating the removed bone fragment by use of fixation means 420 in form of e.g. screws which are screwed into the at least one fixation hole 410.

In certain embodiments of the above procedure and the technology disclosed, the cut out piece of the tibia bone, or malleolus, is not completely removed but is removed by still being attached to the tibia bone via the last tibia adjoining tissue and is only folded out when performing surgery treatment of the talar dome. After performed surgery, the cut out piece of the tibia is then folded

back into its original, or substantially original, position and screwed into place preferably by the use of fixation means, e.g. by the use of two titanium screws.

According to example embodiments, the technology disclosed proposes a surgical method for use in osteotomy and the temporary osteotomic removal of a bone fragment of a tibia for exposing the talus dome for treatment, comprising the steps of:

1) identifying at least one of a bone and a cartilage damage of the talus dome through radiological images such as MR, CT or X-ray images;
2) planning the size and the location of an osteotomy needed to get access to the talus dome in the treatment of said at least one of a bone and a cartilage damage of the talus;
3) creating a virtual 3D model of at least a portion of at least one of the tibial bone and the talus bone from radiological images such as MR, CT or X-ray images;
4) designing a patient specific osteotomy saw guide based on the 3D model and the size and location of the osteotomy needed;
5) positioning and fixing the patient customized saw guide 100 so that the saw guide is conforming and fixable to the lower medial anterior portion of the tibia;
6) making a saw cut along the saw guide surface excising a lower medial anterior piece of the tibia;
7) removing said lower medial anterior piece, or folding said lower medial anterior piece forward and outward preserving the attachment of medial deltoid ligaments, and exposing the damaged condylar area of the talus dome;
8) performing treatment of said at least one of a bone and cartilage damage of the at least one of a bone and a cartilage damage of the talus; and
9) replacing said excised lower medial anterior piece of the tibia into its original, or substantially original, position and fixing it in place.

Exemplary surgical procedures for use together with the technology disclosed

In the following one exemplary procedure is described for the use of the kit and the saw guide 100 according to the invention. This description is of course not at all limiting of the invention. Rather other procedures may be used, for example with a piece of the tibia removed with surfaces at other angles than the orthogonal angles described below. According to the technology disclosed, the patient customized saw guide only provides for a cut in one plane, e.g. for severing a portion of the

malleolus, straight off, if, thereby only the medial portion of the talus dome need be exposed. The surgical saw guide can further be used for other treatments than the surgical implantation of implants according to certain embodiments of the present invention. The saw guide can for example be used for access to the talus dome for osteochondral treatment through biological procedures or for implantation of artificial plugs.

The osteotomy procedure may comprise at least a plurality of the following actions of a surgical treatment comprising the implantation of an implant into the dome of the talus:

1. The patient customized saw guide is placed on the tibia after the bone has been exposed. Two pins 510 are inserted through pin holes 150 on the saw guide 100 and are driven into the tibia 200, holding the saw guide securely in place for the single saw cut to follow.

2. Two bore holes 410 are first drilled through the intended osteotomic tibial piece and past the saw cutting plane B into the bone therebehind. These holes 410 are drilled at this time to assure exact replacement and fixation of the removed bone fragment in its original, or substantially original, position.

3. A single saw cut, preferably not a through cut but a partial cut, is made in a saw cutting plane B.

4. An osteotome 530, e.g. in form of a flat and broad surgical chisel or scalpel, is used to remove any remaining bone holding the bone fragment to the rest of the tibia 200.

5. The saw guide is removed.

6. The bone fragment is pulled out and folded forward and downward all the while preserving the vital attachment of the medial (deltoid) ligaments to the removed tibia fragment and to the calcaneus and the navicular.

7. The patient customized saw guide has assured that a bone fragment has been sawn and removed in one try, which is large enough to provide access to the damaged area of the talus dome, to allow for surgical treatment of the talus, e.g. the vertical mounting and anchoring of a second drill guide, to allow for vertical drilling into the talus through the drill guide to prepare for an implant.

8. Perform surgical treatment of at least one medial osteochondral defect of the talar dome. A drill sleeve may be used and inserted into the second drill guide. A drill, e.g. a double drill,

may be used to drill the deeper hole for an implant peg and the shallow hole for the implant cap, which may have a slight peripheral rim on its underside.

9. A drill sleeve which is adjustable to the correct depth is inserted and fine-tuning of the drilling depth is performed.

10. A dummy implant is inserted into the drilled hole to check for correct depth and postion of the hole. The dummy is then pulled out.

11. The drill guide is then removed.

12. The patient customized implant is then pushed into place.

13. After performed surgical treatment, the excised tibia fragment is then fixated, or folded up, into its original, or substantially original, position and two screws 420 are used for screwing the removed piece of the tibia, or malleolus, precisely into its original, or substantially original, position by virtue of the fact that the deep screw holes 410 were drilled into the intact tibia before the sawing operation.

In step 13 above, the patient customized implant may be pushed into place and then tapped finally into place using a mandrel. The cut out tibia piece which has been removed or folded out exposes enough space within the tibia and above the talus dome to enable drilling for and insertion of the implant peg in the proper direction so that downward forces exerted by the tibia, when walking for example will be exerted largely in the direction of the peg so that no lateral forces will be exerted tending to dislodge the implant over time.

The surgical kit according to the invention makes it possible to perform the above described surgical implant procedure which will make it possible to:

- avoid all important tendons, muscles and ligaments and leaving them attached and intact,
- provide enough exposed space for medical treatment, e.g. a surgical treatment which includes correctly drill for and drive in the implant at the correct angle,
- make the bone cuts precise and correct on the first try,
- make possible precise reattachment of the tibia piece to its original, or substantially original, position for healing and correct alignment of the joint.

Certain aspects and embodiments of the technology disclosed the surgical procedure in which the kit and the saw guide of the invention are used could be defined in the following definitional points:

Method of joint implant surgery for repair of articular surfaces in the talocrural joint, comprising:

a) Positioning and fixing a patient customized saw guide 100 so that the saw guide is conforming and fixable to the lower medial anterior portion of the tibia and is further providing a saw guide surface in one plane, thereby being suitable for osteotomy of a lower medial anterior piece of a tibia to expose the dome of the talus,

b) Making a saw cut along the saw guide surface excising a lower medial anterior piece of the tibia,

c) Removing said lower medial anterior piece, or folding said lower medial anterior piece forward and outward preserving the attachment of medial deltoid ligaments, and exposing the damaged condylar area of the talus dome,

d) Mounting a patient customized form fitting hollow drill guide comprising a tubular shell in place on the talus dome, covering with its hollow part the damaged area of the talus to be repaired,

e) Drilling in said drill guide with a double drill having a narrow diameter deeper drill and a larger diameter shallower drill providing a bore for a talus implant,

f) Removing said drill guide,

g) Inserting into said bore a surgical implant having a cap with an outer surface conforming to a talus dome surface and an inner surface having a central implant anchoring peg extending perpendicularly from said inner surface,

h) Replacing said excised lower medial piece into its original, or substantially original, position and fixing it in place.

Certain embodiments related to surgical treatment and the implantation of metal implants

Implants having a top cap surface customized to each patient to replicate the surface of the talus dome before it was injured, must be implanted so that the forces, applied during standing and walking via the lower condylar surfaces of the tibia against the new implant will act axially in relation to the implantation peg, for optimum force absorption and length of life.

Because of the disadvantages of current secondary treatment methods for OCDs, metal resurfacing inlay implants have been developed and started to reach the market. A precise surgical technique is required in terms of implantation depth, position, and orientation because of the biomechanical properties of the ankle joint. A protruding implant may damage the opposite cartilage by causing excessive contact pressures during loading, which is thought to be due to "plowing" of the cartilage.

On the other hand, a deep implant might result in collapse of the adjacent cartilage due to insufficient support.

The advantages of implants over complete replacement of the joint, see e.g. patent applications WO2014/020562 and US2010/0262150, have stimulated a further development of smaller implants that can be implanted with less invasive surgery. In this development, there has also been an effort to achieve small joint implants, suitable for repair of a small bone and/or cartilage injury that have a minimal influence on the surrounding parts of the joint. In the current development, such small implants are designed with an implant body that may be formed as a mushroom cap with a hard surface to face the articulating side of the joint and a bone contacting surface engaging the bone below the damaged part of cartilage. The shape and the curvature of the articulating surface of the implant may be designed to be a reconstitution of the shape and the curvature of the part of the joint when it was undamaged. Such implants are usually designed as mushrooms with an implant body or head and with a peg or a rod projecting from the bone contacting side of the implant body for anchoring the implant into the bone. The cap of the mushroom for repair of the talus dome is often slanted or irregular to conform to the shape of the original undamaged ridge or dome of the talus. The talar metal resurfacing implants preferably have an exact match to the undamaged talar anatomy.

CLAIMS

1. A surgical saw guide (100) suitable for use in osteotomy and the temporary osteotomic removal of a bone fragment of a tibia for exposing the talus dome for treatment, said saw guide comprises a slit (120), or opening, configured to receive a saw cutting tool and to guide the saw cutting tool to form a single cut in a straight direction at an angle to at least a portion of an inner engagement surface (160) of said saw guide, wherein said saw guide further comprises, as an integral part, a drill guide (130) having at least one hole (140) configured to guide the drilling of a hole in a straight direction at an angle relative to the saw cutting direction provided by the guidance of said slit (120), or opening.

2. The surgical saw guide of claim 1, wherein said surgical saw guide further comprises at least one pin hole (150), or opening, adapted to receive a fixation means (510), e.g. a pin, to guide the temporary fixation of the saw guide to the tibia of a patient and said at least a portion of an inner engagement surface (160) is adapted to at least partly conform the lower portion of the tibia of a patient.

3. The surgical saw guide of any of claims 1-2, wherein said at least one hole (140) of the drill guide (130) is configured to guide the predrilling of at least one hole past the single saw cutting plane B provided by the guidance of said slit (120) and into the inner portions of the tibia bone therebehind, thereby being adapted to provide for the predrilling of at least one fixation hole in the inner portions of the tibia bone to be used for facilitating correct refixation, e.g. by the use of fixation means (420) in the form of at least one screw, of the removed bone fragment in its original, or substantially original, position after performed surgical treatment.

4. The surgical saw guide of any of claims 1-3, wherein said at least one hole (140) of the drill guide (130) is configured to guide the drilling along a straight line at a specific angle direction with respect to at least one of:
    - at least a portion of the inner engagement surface adapted to conform to the lower portion of the tibia of a patient,
    - the longitudinal axis A of the patient, and

- the direction for forming said single saw cut.

5. The surgical saw guide of claim 4, wherein the at least one hole (140) of said drill guide (130) is configured to guide the drilling in a direction at an angle β or within an angle range to the longitudinal tibial axis of a patient, and wherein said angle β or angle range is within the angle range of 50-70 degrees to the longitudinal tibial axis A of a patient.

6. The surgical saw guide of claim 4, wherein the at least one hole (140) of said drill guide (130) is configured to guide the drilling in a direction along a straight line at an angle β at 60 degrees, or close to 60 degrees, to the longitudinal tibial axis of a patient.

7. The surgical saw guide according to any of the preceding claims, wherein the at least one hole (140) of the drill guide (130) is configured to guide drilling in a direction at an angle β or within an angle range to the direction for forming said single saw cut, and wherein said angle β or angle range is within the angle range of 80-100 degrees to the direction for forming said single saw cut.

8. The surgical saw guide according to any of the preceding claims, wherein the at least one hole (140) is configured to guide drilling in a perpendicular direction, or close to 90 degrees, with respect to the direction for forming said single saw cut.

9. The surgical saw guide according to any of the preceding claims, wherein said slit (120), or opening, for guiding a saw cutting tool is configured to guide a saw cutting tool to form a single saw cut in a direction at an angle with respect to at least a portion of said inner engagement surface (160) adapted to conform to the lower portion of the tibia of a patient.

10. The surgical saw guide according to any of the preceding claims, wherein said slit, or opening, for guiding a saw cutting tool is configured to guide a saw cutting tool to form a single saw cut in a direction along a straight line having an angle relationship to at least a portion of said inner engagement surface (160) adapted to conform to the lower portion of the tibia of a patient.

11. The surgical saw guide according to any of the preceding claims, wherein said slit, or opening, for guiding a saw cutting tool is configured to guide a saw cutting tool to form a

single saw cut at an angle or within an angle range to the longitudinal tibial axis of a patient, and wherein said angle φ or angle range is within the angle range of 15-50 degrees to the longitudinal tibial axis A of a patient.

12. The surgical saw guide according to any of the preceding claims, wherein said slit, or opening, for guiding a saw cutting tool is configured to guide a saw cutting tool to form a single saw cut in a direction at a 30 degrees angle, or close to 30 degrees, to the longitudinal tibial axis A of a patient.

13. The surgical saw guide according to any of the preceding claims, wherein said saw guide further comprises an opening which forms an inspection window (170) adapted to allow visual inspection of how well the saw guide conforms to the to the lower portion of the tibia of a patient to facilitate adjustment of the positioning of the saw guide to provide for a correct positioning of the saw guide to the lower portion of the tibia of the patient, thereby providing for both a correct saw cutting procedure and a correct drilling procedure.

14. The surgical saw guide according to any of the preceding claims, wherein a portion (180) of the saw guide comprising said slit (120), or opening is configured to have a height that matches, or corresponds to, the length of a sawblade (190) to be used during saw cutting to make a powertool (520) used during saw cutting stop against the top surface of the portion (180), thereby minimizing the risk of unintentionally sawing too far.

15. A method for designing a surgical saw guide according to any of claims 1-14, wherein the method includes the designing of a saw guide (100) having as integral parts both a slit (120) designed for guiding the saw cutting in a first direction and a drill guide (130) having at least one hole (140) designed for guiding the drilling in a second direction different from the first direction.

16. A method for designing a surgical saw guide according to any of claims 1-14, wherein the at least portion of the inner engagement surface (160) adapted to conform to the lower portion of the tibia of a patient is individually patient customized on the basis of radiologically obtained patient data, such as MR, CT or X-ray imaging.

17. A method for designing a surgical saw guide according to any of claims 1-14, wherein the at least one hole (140) of the drill guide (130) is individually patient customized on the basis of radiologically obtained patient data, such as MR, CT or X-ray imaging, in that the drilling direction provided by said at least one hole is designed to have a patient customized angle relationship to at least one of the lower portion of the tibia of a patient and the longitudinal axis A of the patient.

18. A method for designing a surgical saw guide according to any of claims 1-14, wherein the slit (120), or opening, is individually patient customized on the basis of radiologically obtained patient data, such as MR, CT or X-ray imaging, in that the saw cutting direction provided by said slit is designed to have a patient customized angle relationship to at least one of the lower portion of the tibia of a patient and the longitudinal axis A of the patient.

19. A method for designing a surgical saw guide according to any of claims 1-14, wherein both the slit (120), or opening, and the at least one hole (140) of the drill guide (130) are individually patient customized on the basis of radiologically obtained patient data, such as MR, CT or X-ray imaging, in that both the saw cutting direction provided by said slit (120) and the drilling direction provided by the at least one hole (140) of the drill guide (130) are each designed to have a patient customized angle relationship to at least one of the lower portion of the tibia of a patient and the longitudinal axis A of the patient.

20. The method of designing a surgical saw guide according to any of claims 15 to 19, comprising the steps of:

a. identifying at least one of a bone and a cartilage damage of the talus dome through radiological images such as MR, CT or X-ray images;

b. planning the size and the location of an osteotomy needed to get access to the talus dome in the treatment of said at least one of a bone and a cartilage damage of the talus;

c. creating a virtual 3D model of at least a portion of at least one of the tibial bone and the talus bone from radiological images such as MR, CT or X-ray images; and

d. designing a patient specific osteotomy saw guide based on the 3D model and the size and location of the osteotomy needed.

21. A surgical kit comprising a saw guide according to any of claims 1-14, wherein the surgical kit further comprises fixation means (420) with dimensions to adapted for insertion through the at least one hole (140) of the drill guide (130), said fixation means (420) further has a certain length for providing fixation of the saw guide to the tibia by use of the at least one fixation hole in the inner portions of the tibia, said surgical kit is thereby designed to provide for the remounting of the temporarily removed bone fragment in its original, or substantially original, position by using the pre-drilled at least one hole in the inner portions of the tibia.

22. The surgical kit according to claim 21, wherein said fixation means (420) is at least one a screw designed to be screwed through and past the at least portion of the bone fragment of the tibia to be removed and into a pre-drilled fixation hole in the inner portion of the tibia bone, thereby being configured to provide for the remounting of the temporarily removed bone fragment in its original, or substantially original, position by using the pre-drilled at least one fixation hole in the inner portions of the tibia.

23. The surgical kit according to claim 21 or 22, further comprising a surgical implant having a cap with an outer surface conforming to a talus dome surface and a hollow tubular shell (620) suitable for vertical drilling to prepare the talus dome for implantation of an implant.

24. The surgical kit according to any of claims 21-23, further comprising a pin socket (610) adapted to be positioned in said hollow tubular shell (620) and which is configured with a steering hole (630) in the form of a through hole, wherein said pin socket (610), when positioned in said hollow tubular shell, provides mechanical support and the directional guidance for vertical drilling through said steering hole (630) and into the dome of the talus to form a steering hole in the dome of the talus for further drilling to remove cartilage and bone to prepare the site for implantation of an implant of the talus dome.

25. A pin socket (610) adapted to be positioned in a hollow tubular shell (620), said pin socket is configured with a steering hole (630) in the form of a through hole, wherein said pin socket, when positioned in said hollow tubular shell, provides mechanical support and the directional guidance for vertical drilling through said steering hole and

into the articular surface of a joint to form a steering hole in the articular surface of a joint for further drilling to remove cartilage and bone to prepare the site for implantation of an implant.

26. A surgical kit comprising a saw guide according to any of claims 1-14, further comprising a surgical implant having a cap with an outer surface conforming to a talus dome surface and a hollow tubular shell (620) suitable for providing support to the vertical drilling to prepare the talus dome for implantation of an implant.

27. The surgical kit according to claim 26, further comprising a pin socket (610) adapted to be positioned in said hollow tubular shell (620) and which is configured with a steering hole (630) in the form of a through hole, wherein said pin socket, when positioned in said hollow tubular shell, provides mechanical support and the directional guidance for vertical drilling through said steering hole and into the dome of the talus to form a steering hole in the dome of the talus for further drilling to remove cartilage and bone to prepare the site for implantation of an implant of the talus dome.

28. The surgical kit according to any of claims 26 and 27, further comprising at least one fixation means (420) designed with dimensions and a length adapted for insertion of said fixation means through the at least one hole (140) of the drill guide (130) and to provide fixation of the saw guide to the tibia,, said fixation means (420) having a certain length adapted to enable insertion into the at least one fixation hole into the inner portions of the tibia, said surgical kit is thereby designed to provide for the remounting of the temporarily removed bone fragment in its original, or substantially original, position by using the pre-drilled at least one hole in the inner portions of the tibia.

29. A surgical saw guide (100) suitable for use in osteotomy and the temporary osteotomic removal of a bone fragment of a first bone structure for exposing a portion of a second bone structure for surgical treatment, said saw guide comprises a slit, or opening, configured to receive a saw cutting tool and to guide the saw cutting tool to form a single cut in a straight direction at an angle to an inner engagement surface of said saw guide, wherein said saw guide further comprises, as an integral part, a drill guide having at least one hole configured to guide the drilling, or predrilling, of a hole in a straight

direction at an angle relative to the saw cutting direction provided by the guidance of said slit.

30. The surgical saw guide (100) of claim 29, wherein said surgical saw guide further comprises at least one pin hole (150), or first opening, adapted to receive a fixation means (510), e.g. a pin, to guide the temporary fixation of the saw guide to the tibia of a patient and said at least a portion of an inner engagement surface (6) is adapted to at least partly conform to the lower portion of the tibia of a patient.

31. The surgical saw guide (100) of claims 29 or 30, wherein said at least one hole of the drill guide is configured to guide the drilling, or pre-drilling, of at least one hole past the single saw cutting plane B provided by the guidance of said slit and into the inner portions of the tibia bone therebehind, thereby being adapted to provide for the pre-drilling of at least one fixation hole in the inner portions of the tibia bone that can be used for facilitating correct refixation, by the use of fixation means (420), of the removed bone fragment in its original, or substantially original, position after performed surgical treatment.

32. The surgical saw guide (100) of any of claims 29 to 31, wherein said at least one hole of the drill guide is configured to guide the drilling along a straight line at a specific angle direction C with respect to at least one of:

- at least a portion of the inner engagement surface adapted to conform to the lower portion of the tibia of a patient,
- the longitudinal axis A of the patient, and
- the direction B for forming said single saw cut.

33. A method for designing a surgical saw guide (100) according to any of claims 29-32, wherein the method includes the designing of a saw guide having as integral parts both a slit designed for guiding the saw cutting in a first direction and a drill guide having at least one hole designed for guiding the drilling in a second direction different from the first direction.

34. The method for designing a surgical saw guide (100) according to claims 33, wherein the at least one hole of the drill guide is individually patient customized on the basis of

radiologically obtained patient data, such as MR, CT or X-ray imaging, in that the drilling direction provided by said at least one hole is designed to have a patient customized angle relationship to at least one of the surface of the first bone structure of a patient and the longitudinal axis of the patient.

35. The method for designing a surgical saw guide (100) according to any of claims 33 and 34, wherein the slit, or opening, is individually patient customized on the basis of radiologically obtained patient data, such as MR, CT or X-ray imaging, in that the saw cutting direction provided by said slit is designed to have a patient customized angle relationship to at least one of the surface of the first bone structure of a patient and the longitudinal axis of the patient.

36. A surgical kit comprising a saw guide (100) according to any of claims 29-32, herein the surgical kit further comprises at least one fixation means (420) designed with dimensions and a length to enter through the at least one hole of the drill guide and provide fixation of the saw guide to the tibia by use of the at least one fixation hole in the inner portions of the tibia , said surgical kit is thereby designed to provide for the remounting of the temporarily removed bone fragment in its original, or substantially original, position by using the pre-drilled at least one hole in the inner portions of the tibia.

37. The method of designing a surgical saw guide (100) according to any of claims 33 to 35, comprising the steps of:

a. identifying at least one of a bone and a cartilage damage of the second bone structure through radiological images such as MR, CT or X-ray images;

b. planning the size and the location of an osteotomy of a first bone structure needed to get access to the second bone structure in the treatment, e.g. surgical treatment, of said at least one of a bone and cartilage damage of the second bone structure;

c. creating a virtual 3D model of at least a portion of at least one of the first and second bone structure from radiological images such as MR, CT or X-ray images; and

d. designing a patient specific osteotomy saw guide based on the 3D model and the size and location of the osteotomy needed.

38. A method of manufacturing the surgical saw guide (100) according to any of claims 1-14 and 29-32, wherein said method of manufacturing the surgical saw guide is a 3D printing process in which material is joined or solidified under computer control to create the surgical saw guide.

39. The method of manufacturing of claim 38, wherein said 3D printing process includes building the surgical saw guide from computer-aided design (CAD) data by successively adding material layer by layer.

40. The method of manufacturing of any of claims 38 and 39, wherein the CAD data is based on a virtually designed patient specific osteotomy saw guide based on the 3D model of the at least portion of the first bone structure and the size and location of the osteotomy needed.

41. The method of manufacturing of claim 40, wherein the 3D printing process is preceded by the following steps of virtually designing a patient specific osteotomy saw guide:
a. identifying at least one of a bone and a cartilage damage of the second bone structure through radiological images such as MR, CT or X-ray images;
b. planning the size and the location of an osteotomy of a first bone structure needed to get access to the second bone structure in the treatment, e.g. surgical treatment, of said at least one of a bone and cartilage damage of the second bone structure;
c. creating a virtual 3D model of at least a portion of at least one of the first and second bone structure from radiological images such as MR, CT or X-ray images; and
d. designing a patient specific osteotomy saw guide based on the 3D model and the size and location of the osteotomy needed.

42. A surgical method for use in osteotomy and the temporary osteotomic removal of a bone fragment of a first bone structure for exposing a portion of a second bone structure for treatment, comprising the steps of:

a. identifying at least one of a bone and a cartilage damage of the second bone structure through radiological images such as MR, CT or X-ray images;
b. planning the size and the location of an osteotomy of the first bone structure needed to get access to the second bone structure in the treatment, e.g. surgical

treatment, of said at least one of a bone and cartilage damage of the second bone structure;

c. creating a virtual 3D model of at least a portion of at least one of the first and second bone structure from radiological images such as MR, CT or X-ray images;

d. designing a patient specific osteotomy saw guide based on the 3D model and the size and location of the osteotomy needed;

e. positioning and fixing the designed patient customized saw guide 100 so that the saw guide is conforming and fixable to the surface of the first bone structure;

f. making a saw cut along the saw guide surface excising a bone fragment in form of a piece of the first bone structure;

g. removing said lower medial anterior piece, or folding said bone fragment forward and outward preserving the attachment, and exposing the damaged area of the second bone structure;

h. performing treatment of said at least one of a bone and cartilage damage of the second bone structure; and

i. replacing said excised bone fragment into its original, or substantially original, position and fixing it in place.

43. A surgical method for use in osteotomy and the temporary osteotomic removal of a bone fragment of a tibia for exposing the talus dome for treatment, comprising the steps of:

a. identifying at least one of a bone and a cartilage damage of the talus dome through radiological images such as MR, CT or X-ray images;

b. planning the size and the location of an osteotomy needed to get access to the talus dome in the treatment of said at least one of a bone and a cartilage damage of the talus;

c. creating a virtual 3D model of at least a portion of at least one of the tibial bone and the talus bone from radiological images such as MR, CT or X-ray images;

d. designing a patient specific osteotomy saw guide based on the 3D model and the size and location of the osteotomy needed;

e. positioning and fixing the patient customized saw guide 100 so that the saw guide is conforming and fixable to the lower medial anterior portion of the tibia;

f. making a saw cut along the saw guide surface excising a lower medial anterior piece of the tibia;

g. removing said lower medial anterior piece, or folding said lower medial anterior piece forward and outward preserving the attachment of medial deltoid ligaments, and exposing the damaged condylar area of the talus dome;

h. performing treatment of said at least one of a bone and cartilage damage of the at least one of a bone and a cartilage damage of the talus; and

i. replacing said excised lower medial anterior piece of the tibia into its original, or substantially original, position and fixing it in place.

AMENDED CLAIMS
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1. A surgical saw guide (100) suitable for use in osteotomy and the temporary osteotomic removal of a bone fragment of a tibia for exposing the talus dome for treatment, said saw guide comprises a slit (120), or opening, configured to receive a saw cutting tool and to guide the saw cutting tool to form a single cut in a straight direction at an angle to at least a portion of an inner engagement surface (160) of said saw guide, wherein said saw guide further comprises, as an integral part, a drill guide (130) having at least one hole (140) configured to guide the drilling of a hole in a straight direction at an angle relative to the saw cutting direction provided by the guidance of said slit (120), or opening, wherein said at least one hole (140) of the drill guide (130) is configured to guide the predrilling of at least one hole past the single saw cutting plane (B) provided by the guidance of said slit (120) and into the inner portions of the tibia bone there behind, thereby being adapted to provide for the predrilling of at least one fixation hole in the inner portions of the tibia bone to be used for facilitating correct refixation of the removed bone fragment in its original position after performed surgical treatment.

2. The surgical saw guide of claim 1, wherein said surgical saw guide further comprises at least one pin hole (150), or opening, adapted to receive a fixation means (510), e.g. a pin, to guide the temporary fixation of the saw guide to the tibia of a patient and said at least a portion of an inner engagement surface (160) is adapted to at least partly conform the lower portion of the tibia of a patient.

3. The surgical saw guide of any of claims 1-2, wherein said at least one hole (140) of the drill guide (130) is configured to guide the drilling along a straight line at a specific angle direction with respect to at least one of:
at least a portion of the inner engagement surface adapted to conform to the lower portion of the tibia of a patient,
the longitudinal axis A of the patient, and
the direction for forming said single saw cut.

4. The surgical saw guide according to any of the preceding claims, wherein the at least one hole (140) of said drill guide (130) is configured to guide the drilling in a direction at an angle (β) or within an angle range to the longitudinal tibial axis of a patient, and wherein said angle (β) or angle range is within the angle range of 50-70 degrees to the longitudinal tibial axis (A) of a patient.

5. The surgical saw guide according to any of the preceding claims, wherein the at least one hole (140) of said drill guide (130) is configured to guide the drilling in a direction along a straight line at an angle (β) at 60 degrees, or close to 60 degrees, to the longitudinal tibial axis of a patient.

6. The surgical saw guide according to any of the preceding claims, wherein the at least one hole (140) of the drill guide (130) is configured to guide drilling in a direction at an angle (β) or within an angle range to the direction for forming said single saw cut, and wherein said angle (β) or angle range is within the angle range of 80-100 degrees to the direction for forming said single saw cut.

7. The surgical saw guide according to any of the preceding claims, wherein the at least one hole (140) is configured to guide drilling in a perpendicular direction, or close to 90 degrees, with respect to the direction for forming said single saw cut.

8. The surgical saw guide according to any of the preceding claims, wherein said slit (120), or opening, for guiding a saw cutting tool is configured to guide a saw cutting tool to form a single saw cut in a direction at an angle with respect to at least a portion of said inner engagement surface (160) adapted to conform to the lower portion of the tibia of a patient.

9. The surgical saw guide according to any of the preceding claims, wherein said slit, or opening, for guiding a saw cutting tool is configured to guide a saw cutting tool to form a single saw cut in a direction along a straight line having an angle relationship to at least a portion of said inner engagement surface (160) adapted to conform to the lower portion of the tibia of a patient.

10. The surgical saw guide according to any of the preceding claims, wherein said slit, or opening, for guiding a saw cutting tool is configured to guide a saw cutting tool to form a single saw cut at an angle or within an angle range to the longitudinal tibial axis of a

patient, and wherein said angle (ϕ) or angle range is within the angle range of 15-50 degrees to the longitudinal tibial axis (A) of a patient.

11. The surgical saw guide according to any of the preceding claims, wherein said slit, or opening, for guiding a saw cutting tool is configured to guide a saw cutting tool to form a single saw cut in a direction at a 30 degrees angle, or close to 30 degrees, to the longitudinal tibial axis (A) of a patient.

12. The surgical saw guide according to any of the preceding claims, wherein said saw guide further comprises an opening which forms an inspection window (170) adapted to allow visual inspection of how well the saw guide conforms to the to the lower portion of the tibia of a patient to facilitate adjustment of the positioning of the saw guide to provide for a correct positioning of the saw guide to the lower portion of the tibia of the patient, thereby providing for both a correct saw cutting procedure and a correct drilling procedure.

13. The surgical saw guide according to any of the preceding claims, wherein a portion (180) of the saw guide comprising said slit (120), or opening is configured to have a height that matches, or corresponds to, the length of a sawblade (190) to be used during saw cutting to make a power tool (520) used during saw cutting stop against the top surface of the portion (180), thereby minimizing the risk of unintentionally sawing too far.

14. A method for designing a surgical saw guide according to any of claims 1-13, wherein the method includes the designing of a saw guide (100) having as integral parts both a slit (120) designed for guiding the saw cutting in a first direction and a drill guide (130) having at least one hole (140) designed for guiding the drilling in a second direction different from the first direction, and wherein said slit (120) is designed to provide a single saw cutting plane B, and wherein said at least one hole (140) of the drill guide (130) is designed to guide the predrilling of at least one hole past the single saw cutting plane (B) provided by the design of said slit (120) and into the inner portions of the tibia bone there behind, the design of the surgical saw guide is thereby adapted to provide for the predrilling of at least one fixation hole in the inner portions of the tibia bone to be used for facilitating correct refixation of the removed bone fragment in its original position after performed surgical treatment.

15. A method for designing a surgical saw guide according to any of claims 1-13, wherein the at least portion of the inner engagement surface (160) is designed to conform to the lower portion of the tibia of a patient is individually patient customized on the basis of radiologically obtained patient data, such as MR, CT or X-ray imaging.

16. A method for designing a surgical saw guide according to any of claims 1-13, wherein the at least one hole (140) of the drill guide (130) is designed to be individually patient customized on the basis of radiologically obtained patient data, such as MR, CT or X-ray imaging, in that the drilling direction provided by said at least one hole is designed to have a patient customized angle relationship to at least one of the lower portion of the tibia of a patient and the longitudinal axis (A) of the patient.

17. A method for designing a surgical saw guide according to any of claims 1-13, wherein the slit (120), or opening, is designed to be individually patient customized on the basis of radiologically obtained patient data, such as MR, CT or X-ray imaging, in that the saw cutting direction provided by said slit is designed to have a patient customized angle relationship to at least one of the lower portion of the tibia of a patient and the longitudinal axis (A) of the patient.

18. A method for designing a surgical saw guide according to any of claims 1-13, wherein both the slit (120), or opening, and the at least one hole (140) of the drill guide (130) are designed to be individually patient customized on the basis of radiologically obtained patient data, such as MR, CT or X-ray imaging, in that both the saw cutting direction provided by said slit (120) and the drilling direction provided by the at least one hole (140) of the drill guide (130) are each designed to have a patient customized angle relationship to at least one of the lower portion of the tibia of a patient and the longitudinal axis (A) of the patient.

19. The method of designing a surgical saw guide according to any of claims 14 to 18, comprising the steps of:
a. identifying at least one of a bone and a cartilage damage of the talus dome through radiological images such as MR, CT or X-ray images;
b. planning the size and the location of an osteotomy needed to get access to the talus dome in the treatment of said at least one of a bone and a cartilage damage of the talus;

c. creating a virtual 3D model of at least a portion of at least one of the tibial bone and the talus bone from radiological images such as MR, CT or X-ray images; and
d. designing a patient specific osteotomy saw guide based on the 3D model and the size and location of the osteotomy needed.

20. A surgical kit comprising a saw guide according to any of claims 1-13, wherein the surgical kit further comprises fixation means (420) with dimensions to adapted for insertion through the at least one hole (140) of the drill guide (130), said fixation means (420) further has a certain length for providing fixation of the saw guide to the tibia by use of the at least one fixation hole in the inner portions of the tibia, said surgical kit is thereby designed to provide for the remounting of the temporarily removed bone fragment in its original, or substantially original, position by using the pre-drilled at least one hole in the inner portions of the tibia.

21. The surgical kit according to claim 20, wherein said fixation means (420) is at least one a screw designed to be screwed through and past the at least portion of the bone fragment of the tibia to be removed and into a pre-drilled fixation hole in the inner portion of the tibia bone, thereby being configured to provide for the remounting of the temporarily removed bone fragment in its original, or substantially original, position by using the pre-drilled at least one fixation hole in the inner portions of the tibia.

22. The surgical kit according to claim 20 or 21, further comprising a surgical implant having a cap with an outer surface conforming to a talus dome surface and a hollow tubular shell (620) suitable for vertical drilling to prepare the talus dome for implantation of an implant.

23. The surgical kit according to any of claims 20-22, further comprising a pin socket (610) adapted to be positioned in said hollow tubular shell (620) and which is configured with a steering hole (630) in the form of a through hole, wherein said pin socket (610), when positioned in said hollow tubular shell, provides mechanical support and the directional guidance for vertical drilling through said steering hole (630) and into the dome of the talus to form a steering hole in the dome of the talus for further drilling to remove cartilage and bone to prepare the site for implantation of an implant of the talus dome.

24. A pin socket (610) adapted to be positioned in a hollow tubular shell (620), said pin socket is configured with a steering hole (630) in the form of a through hole, wherein said pin socket, when positioned in said hollow tubular shell, provides mechanical support and the directional guidance for vertical drilling through said steering hole and into the articular surface of a joint to form a steering hole in the articular surface of a joint for further drilling to remove cartilage and bone to prepare the site for implantation of an implant.

25. A surgical kit comprising a saw guide according to any of claims 1-13, further comprising a surgical implant having a cap with an outer surface conforming to a talus dome surface and a hollow tubular shell (620) suitable for providing support to the vertical drilling to prepare the talus dome for implantation of an implant.

26. The surgical kit according to claim 25, further comprising a pin socket (610) adapted to be positioned in said hollow tubular shell (620) and which is configured with a steering hole (630) in the form of a through hole, wherein said pin socket, when positioned in said hollow tubular shell, provides mechanical support and the directional guidance for vertical drilling through said steering hole and into the dome of the talus to form a steering hole in the dome of the talus for further drilling to remove cartilage and bone to prepare the site for implantation of an implant of the talus dome.

27. The surgical kit according to any of claims 25 and 26, further comprising at least one fixation means (420) designed with dimensions and a length adapted for insertion of said fixation means through the at least one hole (140) of the drill guide (130) and to provide fixation of the saw guide to the tibia,, said fixation means (420) having a certain length adapted to enable insertion into the at least one fixation hole into the inner portions of the tibia, said surgical kit is thereby designed to provide for the remounting of the temporarily removed bone fragment in its original, or substantially original, position by using the pre-drilled at least one hole in the inner portions of the tibia.

28. A surgical saw guide (100) suitable for use in osteotomy and the temporary osteotomic removal of a bone fragment of a first bone structure for exposing a portion of a second bone structure for surgical treatment, said saw guide comprises a slit, or opening, configured to receive a saw cutting tool and to guide the saw cutting tool to form a single cut in a straight direction at an angle to an inner engagement surface of said saw guide, wherein said saw guide further comprises, as an integral part, a drill guide having at least one hole configured to guide the drilling, or predrilling, of a hole in a straight direction at

an angle relative to the saw cutting direction provided by the guidance of said slit, , wherein said at least one hole (140) of the drill guide (130) is configured to guide the predrilling of at least one hole past the single saw cutting plane (B) provided by the guidance of said slit (120) and into the inner portions of the bone there behind, thereby being adapted to provide for the predrilling of at least one fixation hole in the inner portions of the tibia bone that can be used for facilitating correct refixation, by the use of fixation means (42), of the removed bone fragment in its original, or substantially original, position after performed surgical treatment.

29. The surgical saw guide (100) of claim 28, wherein said surgical saw guide further comprises at least one pin hole (150), or first opening, adapted to receive a fixation means (510), e.g. a pin, to guide the temporary fixation of the saw guide to the tibia of a patient and said at least a portion of an inner engagement surface (6) is adapted to at least partly conform to the lower portion of the tibia of a patient.

30. The surgical saw guide (100) of any of claims 28 and 29, wherein said at least one hole of the drill guide is configured to guide the drilling along a straight line at a specific angle direction C with respect to at least one of:
    - at least a portion of the inner engagement surface adapted to conform to the lower portion of the tibia of a patient,
    - the longitudinal axis A of the patient, and
    - the direction B for forming said single saw cut.

31. A method for designing a surgical saw guide (100) according to any of claims 28-30, wherein the method includes the designing of a saw guide having as integral parts both a slit designed for guiding the saw cutting in a first direction and a drill guide having at least one hole designed for guiding the drilling in a second direction different from the first direction.

32. The method for designing a surgical saw guide (100) according to claims 31, wherein the at least one hole of the drill guide is designed to be individually patient customized on the basis of radiologically obtained patient data, such as MR, CT or X-ray imaging, in that the drilling direction provided by said at least one hole is designed to have a patient

customized angle relationship to at least one of the surface of the first bone structure of a patient and the longitudinal axis of the patient.

33. The method for designing a surgical saw guide (100) according to any of claims 31 and 32, wherein the slit, or opening, is designed to be individually patient customized on the basis of radiologically obtained patient data, such as MR, CT or X-ray imaging, in that the saw cutting direction provided by said slit is designed to have a patient customized angle relationship to at least one of the surface of the first bone structure of a patient and the longitudinal axis of the patient.

34. A surgical kit comprising a saw guide (100) according to any of claims 28-30, herein the surgical kit further comprises at least one fixation means (420) designed with dimensions and a length to enter through the at least one hole of the drill guide and provide fixation of the saw guide to the tibia by use of the at least one fixation hole in the inner portions of the tibia , said surgical kit is thereby designed to provide for the remounting of the temporarily removed bone fragment in its original, or substantially original, position by using the pre-drilled at least one hole in the inner portions of the tibia.

35. The method of designing a surgical saw guide (100) according to any of claims 31 to 33, comprising the steps of:
a. identifying at least one of a bone and a cartilage damage of the second bone structure through radiological images such as MR, CT or X-ray images;
b. planning the size and the location of an osteotomy of a first bone structure needed to get access to the second bone structure in the treatment, e.g. surgical treatment, of said at least one of a bone and cartilage damage of the second bone structure;
c. creating a virtual 3D model of at least a portion of at least one of the first and second bone structure from radiological images such as MR, CT or X-ray images; and
d. designing a patient specific osteotomy saw guide based on the 3D model and the size and location of the osteotomy needed.

36. A method of manufacturing the surgical saw guide (100) according to any of claims 1-13 and 31-33, wherein said method of manufacturing the surgical saw guide is a 3D printing process in which material is joined or solidified under computer control to create the surgical saw guide.

37. The method of manufacturing of claim 36, wherein said 3D printing process includes building the surgical saw guide from computer-aided design (CAD) data by successively adding material layer by layer.

38. The method of manufacturing of any of claims 36 and 37, wherein the CAD data is based on a virtually designed patient specific osteotomy saw guide based on the 3D model of the at least portion of the first bone structure and the size and location of the osteotomy needed.

39. The method of manufacturing of claim 38, wherein the 3D printing process is preceded by the following steps of virtually designing a patient specific osteotomy saw guide:
a. identifying at least one of a bone and a cartilage damage of the second bone structure through radiological images such as MR, CT or X-ray images;
b. planning the size and the location of an osteotomy of a first bone structure needed to get access to the second bone structure in the treatment, e.g. surgical treatment, of said at least one of a bone and cartilage damage of the second bone structure;
c. creating a virtual 3D model of at least a portion of at least one of the first and second bone structure from radiological images such as MR, CT or X-ray images; and
d. designing a patient specific osteotomy saw guide based on the 3D model and the size and location of the osteotomy needed.

40. A surgical method for use in osteotomy and the temporary osteotomic removal of a bone fragment of a first bone structure for exposing a portion of a second bone structure for treatment, comprising the steps of:

    a. identifying at least one of a bone and a cartilage damage of the second bone structure through radiological images such as MR, CT or X-ray images;
    b. planning the size and the location of an osteotomy of the first bone structure needed to get access to the second bone structure in the treatment, e.g. surgical treatment, of said at least one of a bone and cartilage damage of the second bone structure;
    c. creating a virtual 3D model of at least a portion of at least one of the first and second bone structure from radiological images such as MR, CT or X-ray images;
    d. designing a patient specific osteotomy saw guide based on the 3D model and the size and location of the osteotomy needed;

e. positioning and fixing the designed patient customized saw guide 100 so that the saw guide is conforming and fixable to the surface of the first bone structure;
f. making a saw cut along the saw guide surface excising a bone fragment in form of a piece of the first bone structure;
g. removing said lower medial anterior piece, or folding said bone fragment forward and outward preserving the attachment, and exposing the damaged area of the second bone structure;
h. performing treatment of said at least one of a bone and cartilage damage of the second bone structure; and
i. replacing said excised bone fragment into its original, or substantially original, position and fixing it in place.

41. A surgical method for use in osteotomy and the temporary osteotomic removal of a bone fragment of a tibia for exposing the talus dome for treatment, comprising the steps of:

a. identifying at least one of a bone and a cartilage damage of the talus dome through radiological images such as MR, CT or X-ray images;
b. planning the size and the location of an osteotomy needed to get access to the talus dome in the treatment of said at least one of a bone and a cartilage damage of the talus;
c. creating a virtual 3D model of at least a portion of at least one of the tibial bone and the talus bone from radiological images such as MR, CT or X-ray images;
d. designing a patient specific osteotomy saw guide based on the 3D model and the size and location of the osteotomy needed;
e. positioning and fixing the patient customized saw guide 100 so that the saw guide is conforming and fixable to the lower medial anterior portion of the tibia;
f. making a saw cut along the saw guide surface excising a lower medial anterior piece of the tibia;
g. removing said lower medial anterior piece, or folding said lower medial anterior piece forward and outward preserving the attachment of medial deltoid ligaments, and exposing the damaged condylar area of the talus dome;
h. performing treatment of said at least one of a bone and cartilage damage of the at least one of a bone and a cartilage damage of the talus; and
i. replacing said excised lower medial anterior piece of the tibia into its original, or substantially original, position and fixing it in place.

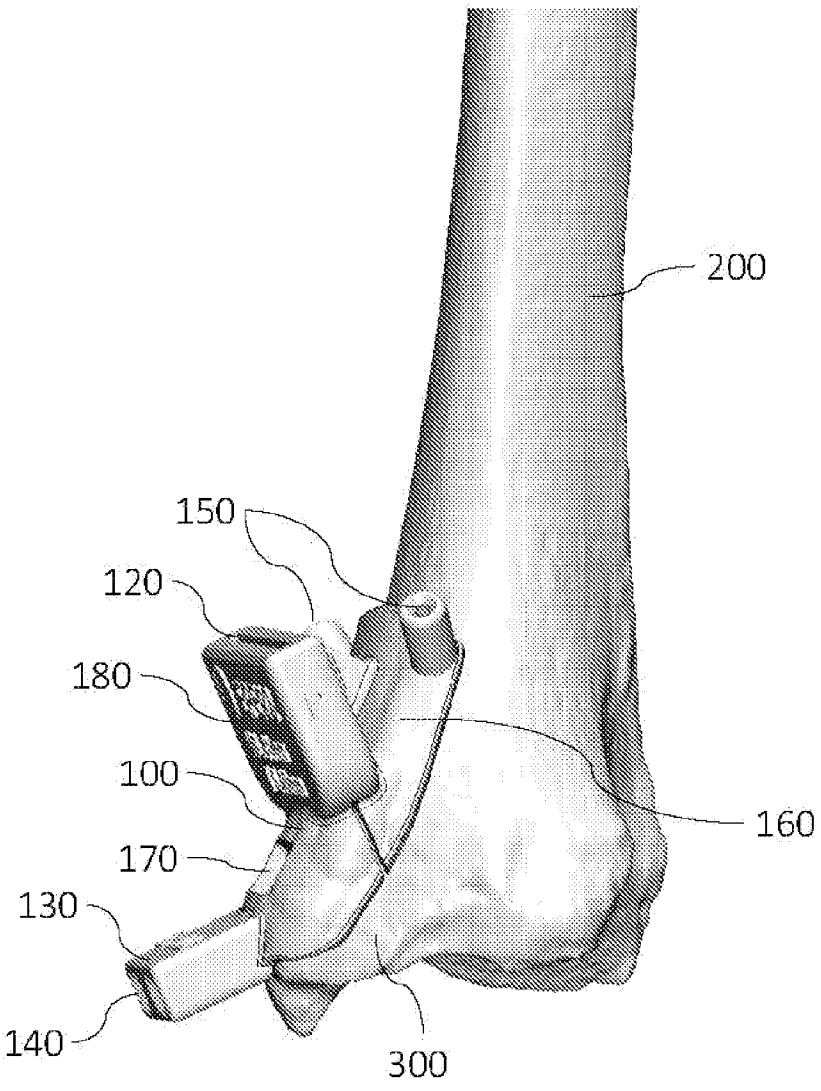


Fig. 1

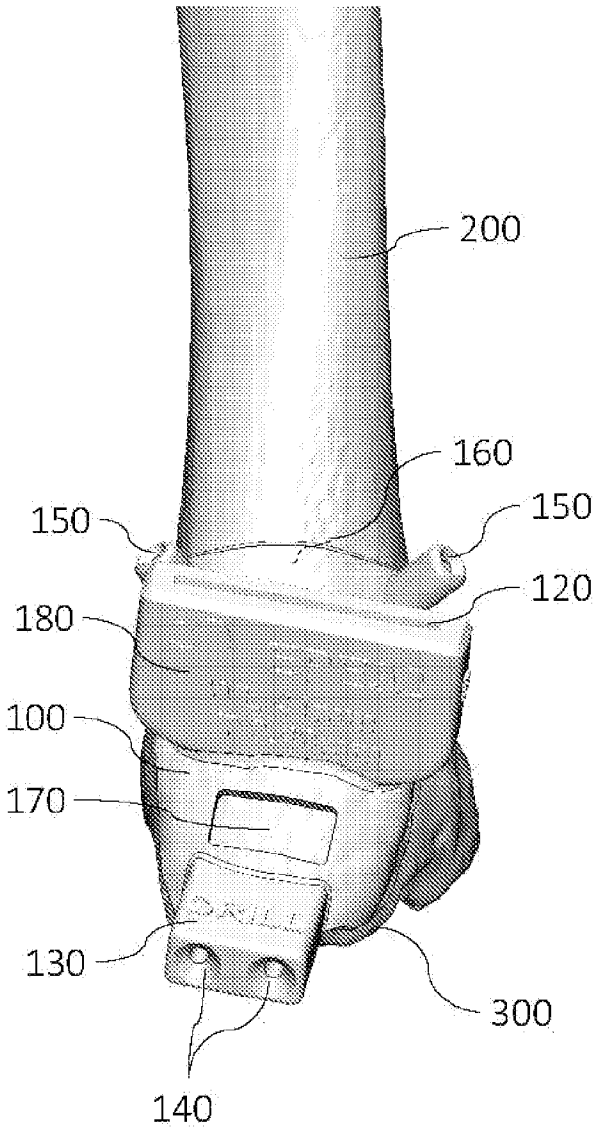


Fig. 2

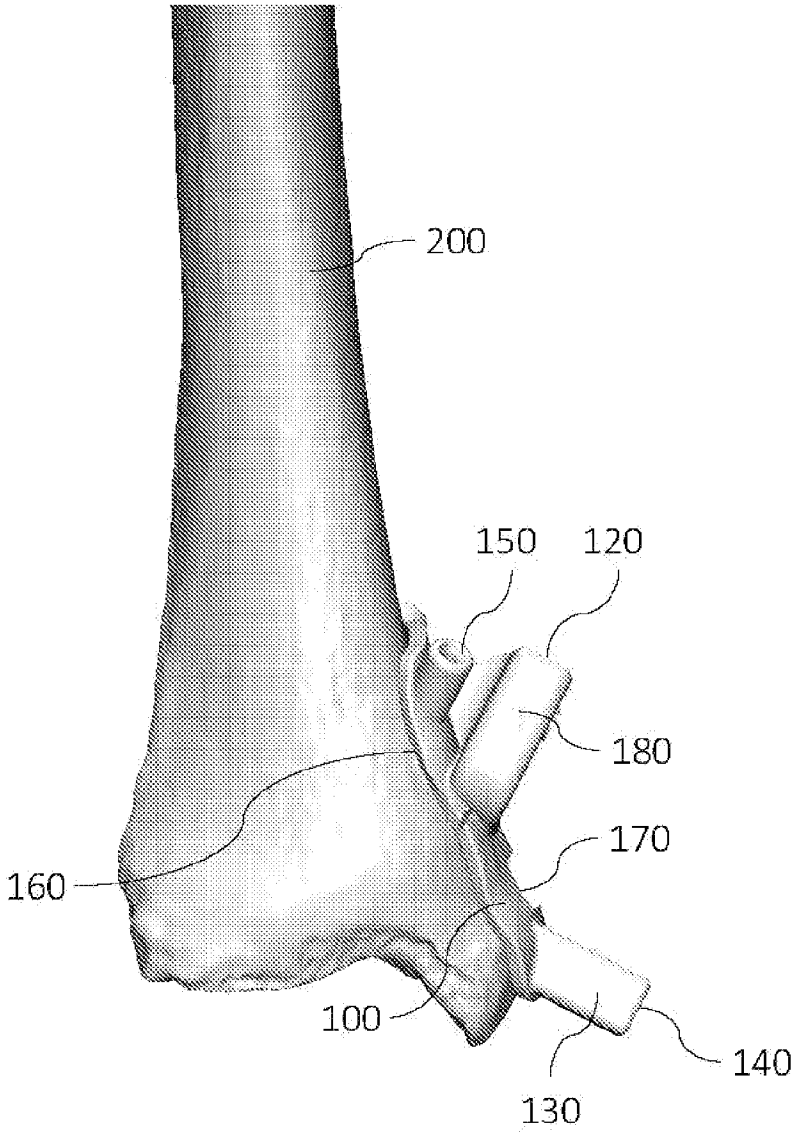


Fig. 3

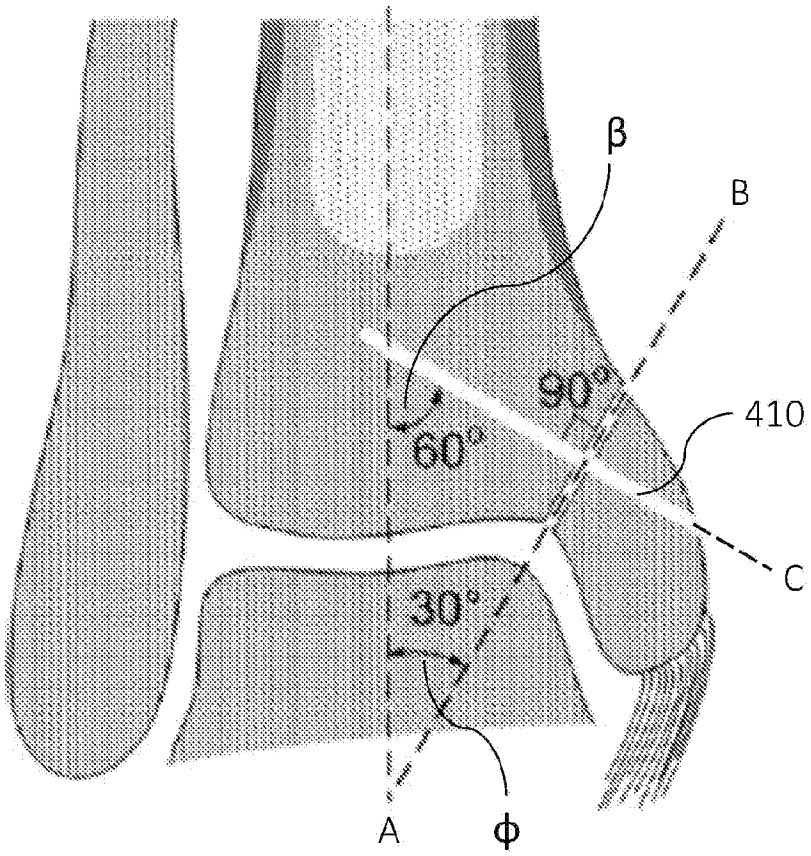


Fig. 4a

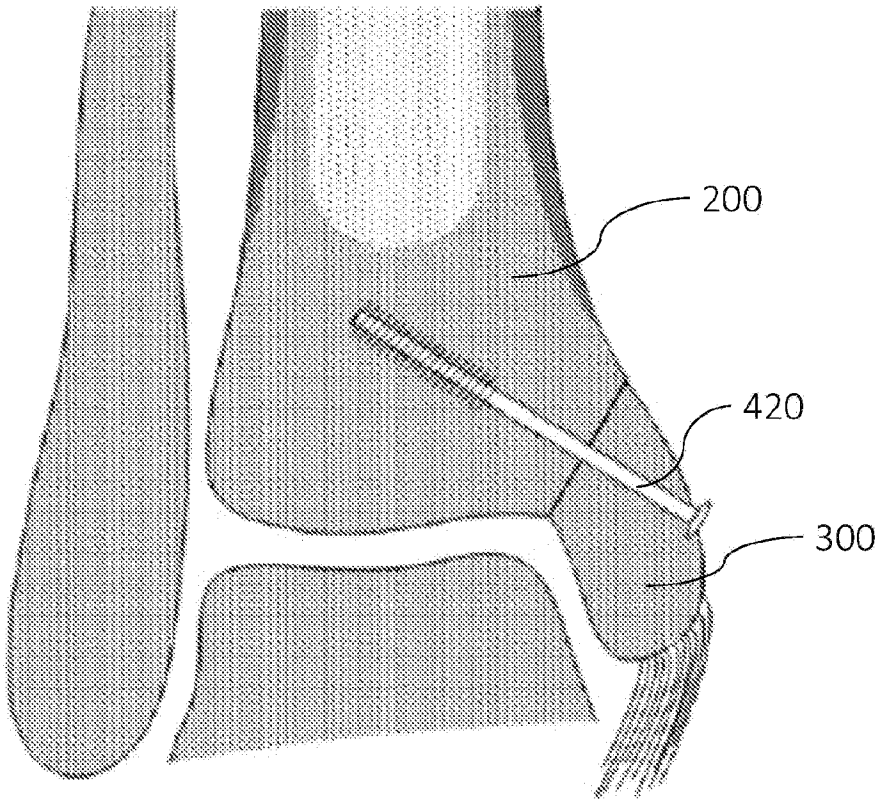


Fig. 4b

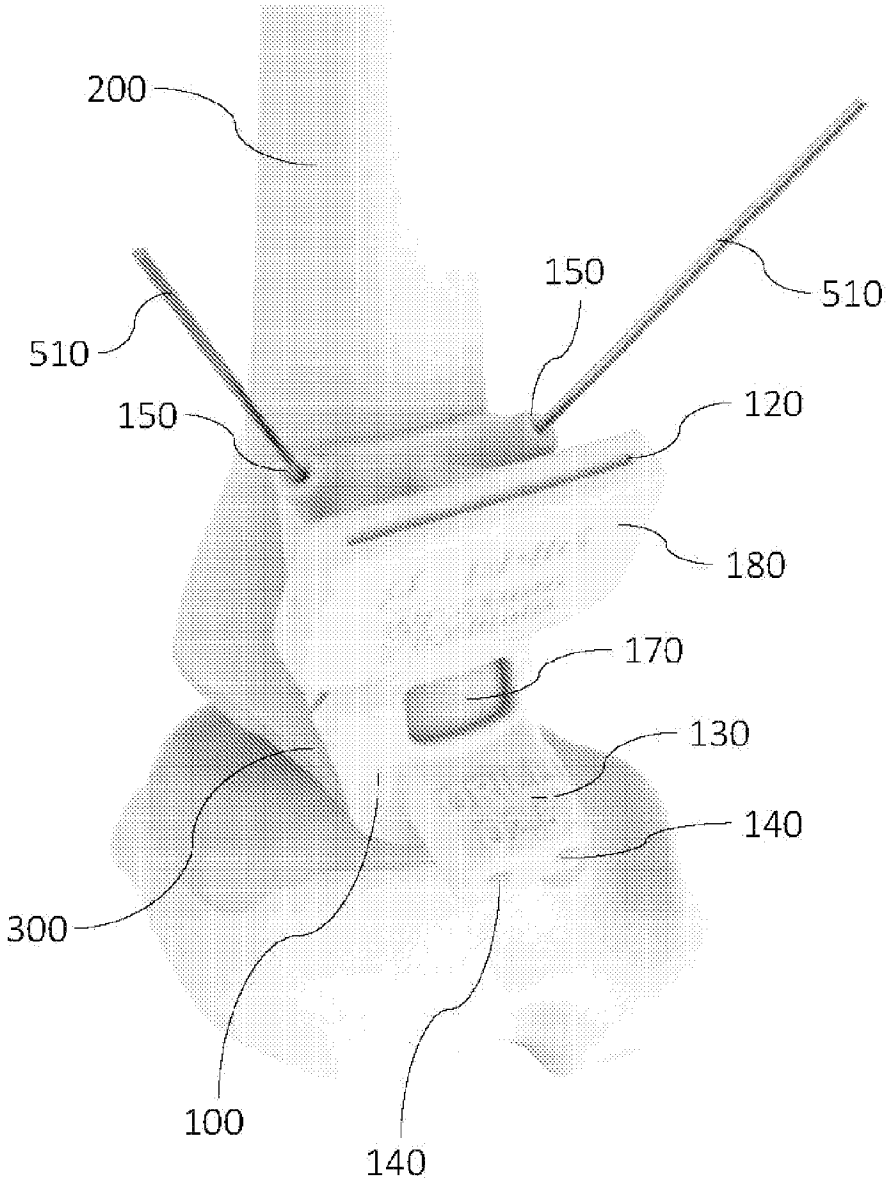


Fig. 5a

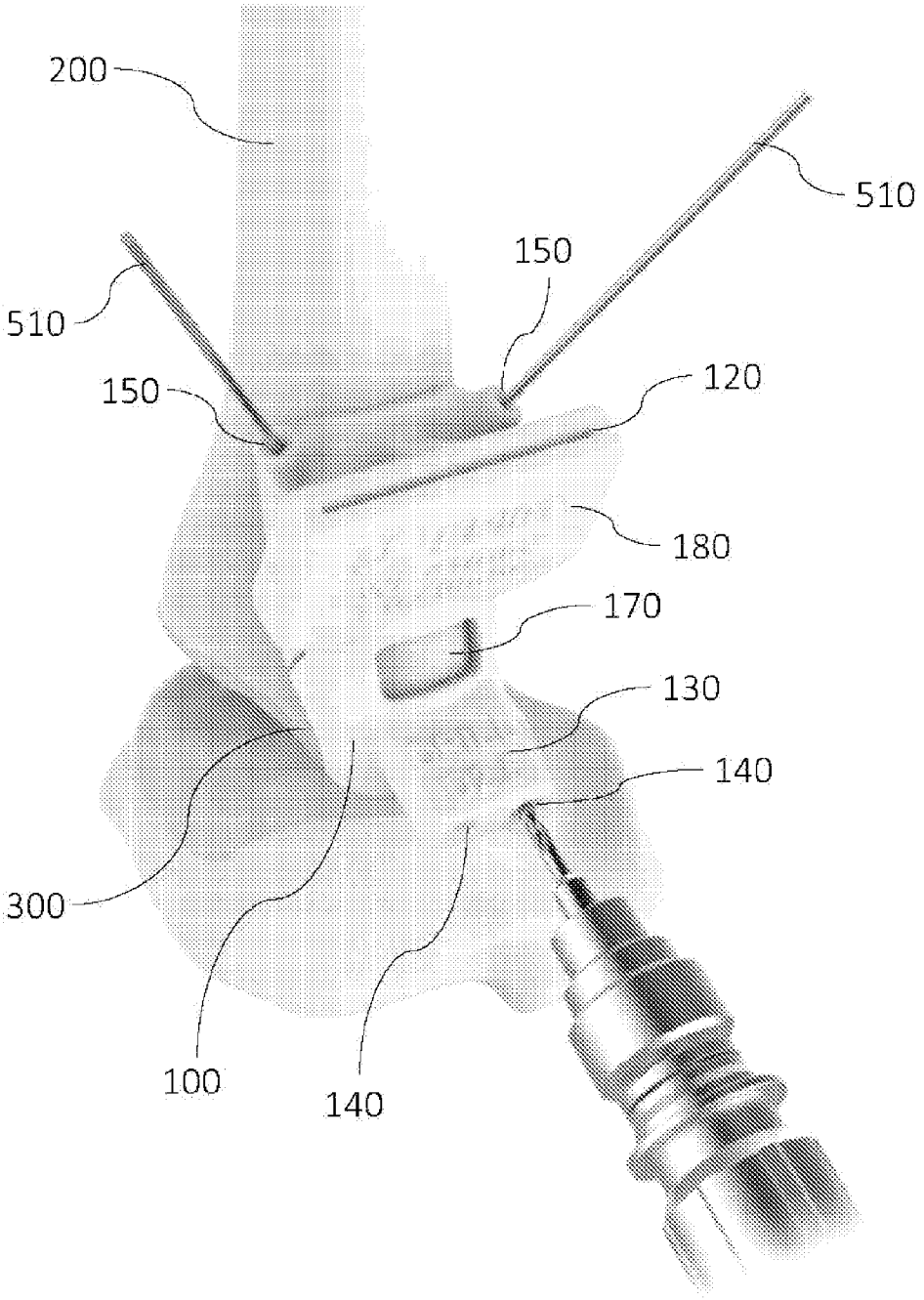


Fig. 5b

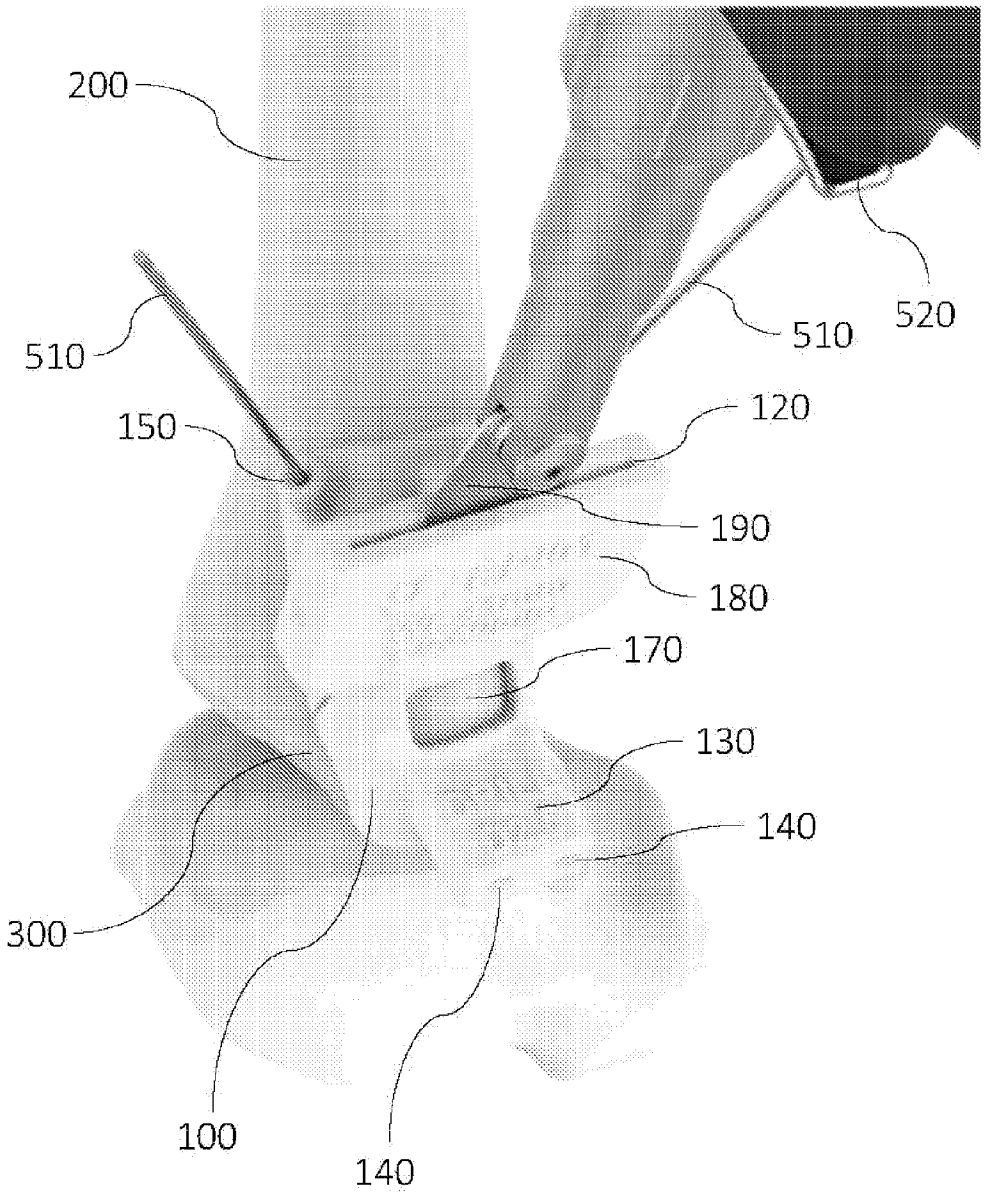


Fig. 5c

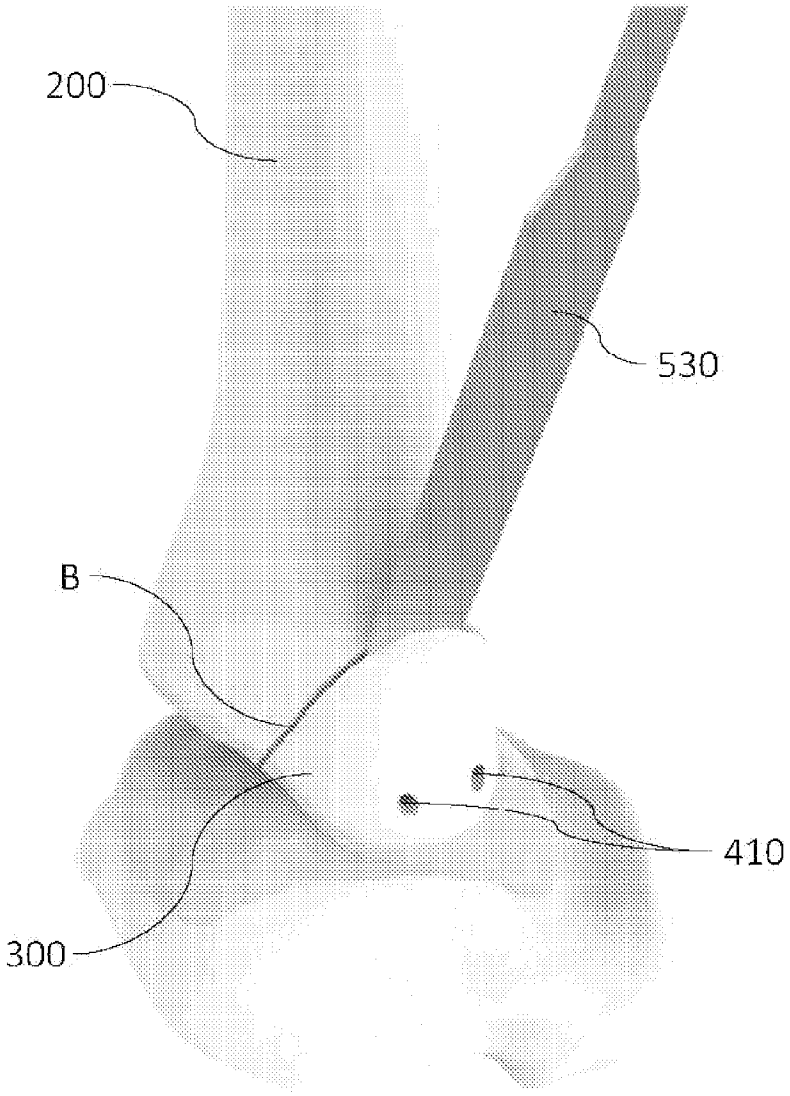


Fig. 5d

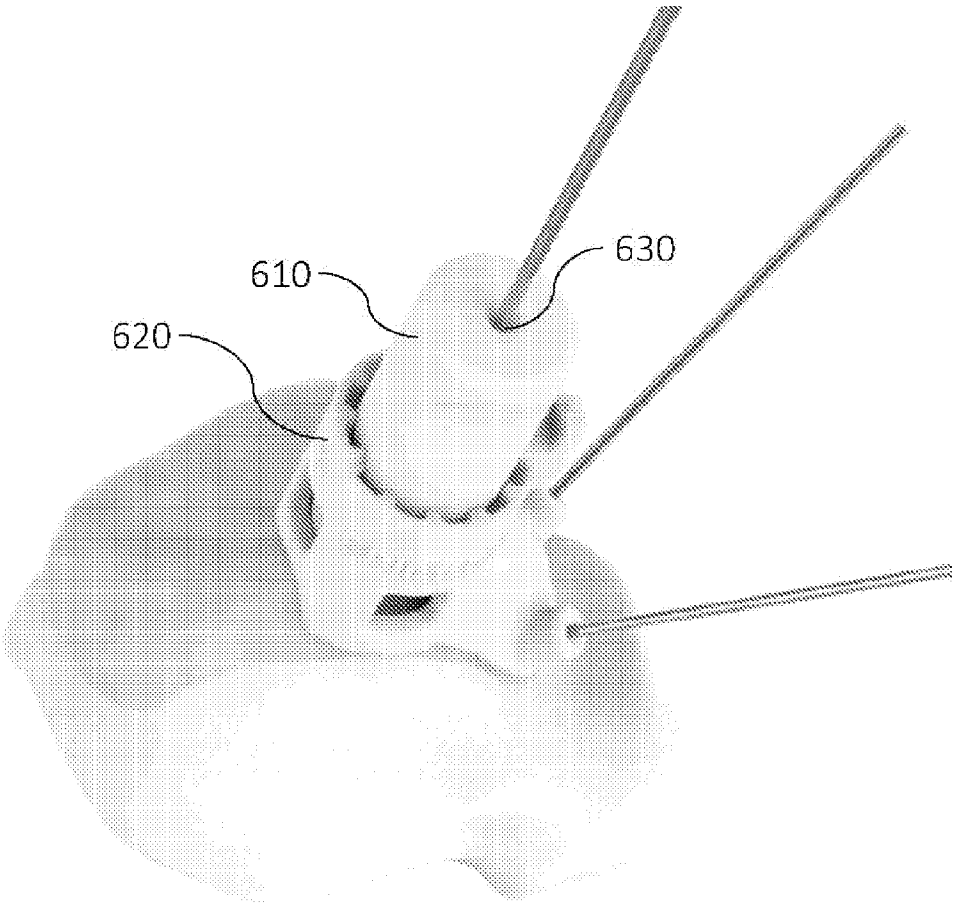


Fig. 6

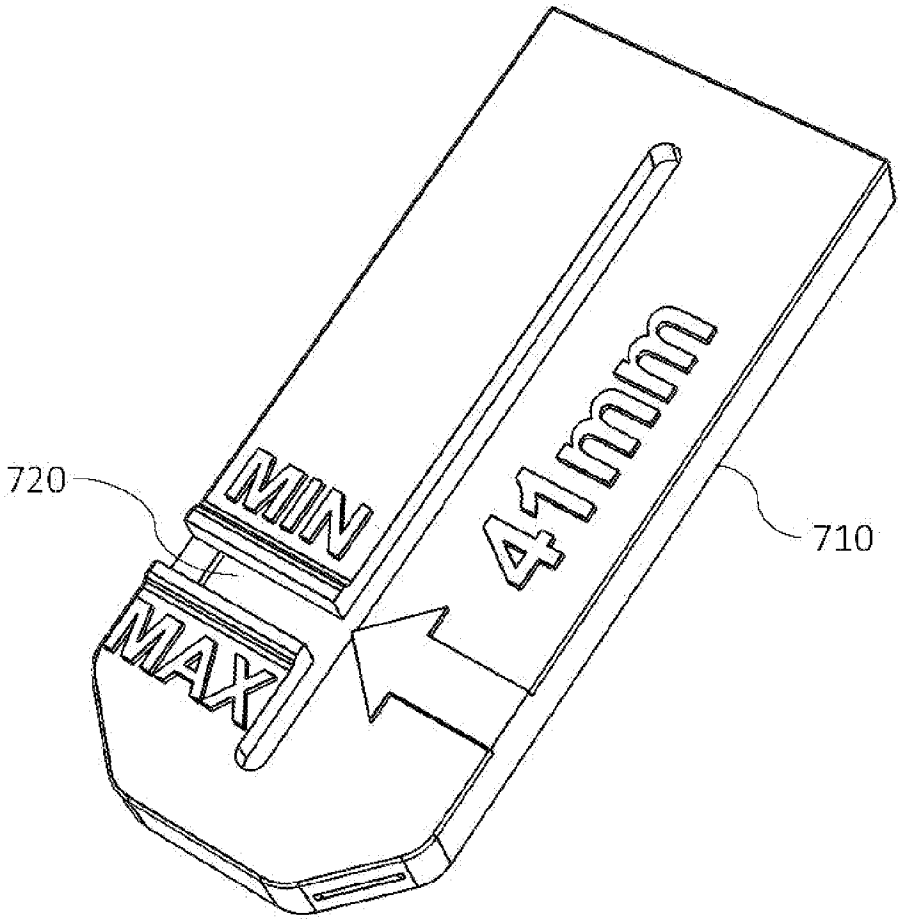


Fig. 7

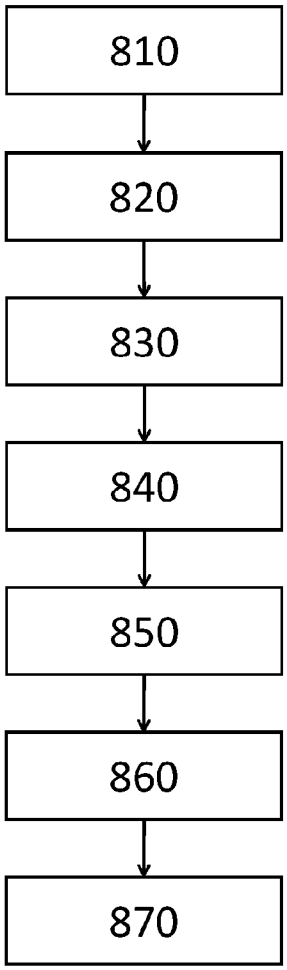


Fig.8

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2018/050889

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/15 A61F2/30 A61B17/86 A61B17/17
ADD.

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

B. FIELDS SEARCHED

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

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2010/262150 A1 (LIAN GEORGE JOHN [US]) 14 October 2010 (2010-10-14) cited in the application figure 19	1-11, 14-20, 29-35,37
X	WO 2014/020562 A1 (CUSTOM MED ORTHOPAEDICS PROPRIETARY LTD [ZA]) 6 February 2014 (2014-02-06) cited in the application figure 6	1,29
X	WO 2017/070318 A1 (MAT N V [BE]; MAT USA LLC [US]) 27 April 2017 (2017-04-27) figure 2	1,12
X	US 2010/087824 A1 (COLLAZO CARLOS E [US]) 8 April 2010 (2010-04-08) figures 7, 8	1,12

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

☒ See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
21 September 2018	10/12/2018

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Fernández Arillo, J

1

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP2018/050889

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 42, 43
because they relate to subject matter not required to be searched by this Authority, namely:

Pursuant to Rule 39.1(iv) PCT, the subject-matter of claims 42 and 43 has not been searched, since it is directed to a method for treatment of the human body by surgery.

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [X] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1-12, 14-20, 29-35, 37, 42, 43

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-12, 14-20, 29-35, 37, 42, 43

The surgical saw guide of claim 1, wherein the slit, or opening, is configured to guide a saw cutting tool to form a single saw cut in a direction at a 30 degrees angle to the longitudinal tibial axis A of a patient (claim 12), thereby solving the problem of efficiently allowing the talar dome to be temporarily exposed.

---

2. claim: 13

The surgical saw guide of claim 1, wherein said saw guide further comprises an opening which forms an inspection window, thereby solving the problem of allowing visual inspection of how well the saw guide conforms to the to the tibia.

---

3. claims: 21-24, 36

A surgical kit comprising the surgical saw guide of claim 1 or claim 29, wherein the surgical kit further comprises fixation means with dimensions adapted for insertion through the at least one hole of the drill guide (claims 21, 36), thereby solving the problem of effectively remounting the temporarily removed tibial fragment in its original position.

---

4. claim: 25

A pin socket having a steering hole in the form of a through hole, thereby solving the problem of providing mechanical support and directional guidance for vertical drilling through said steering hole and into the articular surface of a joint to form a steering hole in the articular surface of a joint for further drilling to remove cartilage and bone to prepare the site for implantation of an implant.

---

5. claims: 26-28

A surgical kit comprising the surgical saw guide of claim 1, further comprising a surgical implant having a cap with an outer surface conforming to a talus dome surface, thereby solving the problem of repairing a cartilage damage of the talus.

---

6. claims: 38-41

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

A method of manufacturing the surgical saw guide of claim 1 or claim 29, wherein said method of manufacturing the surgical saw guide is a 3D printing process, thereby solving the problem of easily manufacturing a surgical saw guide.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/EP2018/050889

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2010262150 A1	14-10-2010	US 2010262150 A1	14-10-2010
		US 2013085499 A1	04-04-2013
		US 2017296208 A1	19-10-2017
		WO 2010120346 A1	21-10-2010
WO 2014020562 A1	06-02-2014	NONE	
WO 2017070318 A1	27-04-2017	EP 3364887 A1	29-08-2018
		US 2018303491 A1	25-10-2018
		WO 2017070318 A1	27-04-2017
US 2010087824 A1	08-04-2010	NONE	

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WIPO | PCT

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A61B 17/84 (2006.01) *A61B 17/86* (2006.01)
A61B 17/88 (2006.01) *A61B 17/72* (2006.01)

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20 April 2018 (20.04.2018)

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(30) Priority Data:
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(71) Applicant: **STRYKER CORPORATION** [US/US]; 2825 Airview Boulevard, Kalamazoo, MI 49002 (US).

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(74) Agent: **WOOLBRIGHT, Jacob, P.** et al.; Howard & Howard Attorneys PLLC, 450 West 4th St., Royal Oak, MI 48067 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JO, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ,

(54) Title: STABILIZATION SYSTEM AND IMPLANT FOR PREVENTING RELATIVE MOTION BETWEEN SECTIONS OF TISSUE

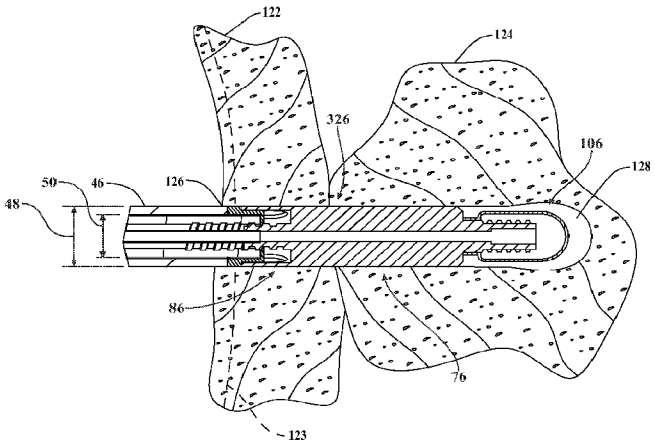


FIG. 7

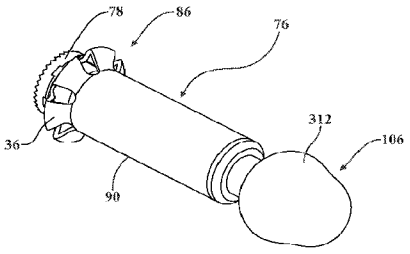


FIG. 8

(57) Abstract: A stabilization system and implant for preventing relative motion between tissue sections of a patient, for example, an ilium and a sacrum defining a sacroiliac joint. The stabilization system comprises an implant comprising an elongate trunk, a proximal anchor configured to be positioned within the ilium, and a distal anchor configured to be positioned within the sacrum. The proximal anchor comprises a deformable feature configured to engage the ilium and the distal anchor comprises an expandable member configured to engage the sacrum. The stabilization system further comprises a tool removably coupled to the anchor to insert the implant in the patient and selectively engage the anchors with the respective bones. The implant is configured to be implanted through a minimally invasive incision.

[Continued on next page]

WO 2018/195406 A1

UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:

— *of inventorship (Rule 4.17(iv))*

Published:

— *with international search report (Art. 21(3))*

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*

STABILIZATION SYSTEM AND IMPLANT FOR PREVENTING RELATIVE MOTION BETWEEN SECTIONS OF TISSUE

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] The present patent application claims priority to and all the benefits of U.S. Provisional Patent Application No. 62/488,417, filed on April 21, 2017, the disclosure of which is hereby incorporated by reference in its entirety.

TECHNICAL FIELD

[0002] The present disclosure is related generally to an implant for a stabilization system for securing two sections of tissue. More particularly, but not exclusively, the present disclosure is directed to stabilization system, an implant, and methods for preventing relative motion between a first bone and a second bone, for example, an ilium and a sacrum defining a sacroiliac (SI) joint during minimally invasive surgery.

BACKGROUND

[0003] A number of different medical procedures involve securing sections of tissue. For example, for an individual to receive relief from pain in the pelvic region or lower back, a recognized treatment is to perform SI joint fusion in which the sacrum is fixed to the ilium. Another situation when it is indicated to secure two sections of tissue is fixation of a fractured bone. Still further, spinal fusion including fixation of adjacent vertebrae is also a procedure of particular interest.

[0004] Securing adjacent sections of bone (or two adjacent bones) may include drilling a bore that at least partially extends through each of the adjacent sections of the bone. An elongated implant is seated and secured within the bore. A portion of the implant is positioned in one of the

sections of the bone (*e.g.*, a first bone), and another portion of the implant is positioned within another section of the bone (*e.g.*, a second bone). The implant, and sometimes plural implants, prevents movement of the sections of the bone. The adjacent surfaces of the sections of the bone may fuse together to form a single bone. The fusion increases the strength of the bond between the two sections of bone.

[0005] Known systems and methods of securing sections of tissue are associated with several disadvantages. For example, eliminating relative movement between the sections of the bone often requires the implant to be relatively large in size to ensure adequate contact area between the implant and the sections of the bone. It readily follows that a relatively larger implant requires a commensurately larger incision. The invasiveness of the larger incision may lead to increased healing time and risk of infection.

[0006] Therefore, there is a need in the art for a stabilization system and an implant for the stabilization system designed to overcome one or more of the aforementioned disadvantages

SUMMARY

[0007] One aspect of the present disclosure is directed toward an implant for a minimally invasive bone stabilization system for preventing relative motion between an ilium and a sacrum. The implant comprises an elongate trunk defined between a proximal end configured to be positioned within the ilium, a distal end configured to be positioned within the sacrum. The elongate trunk extends between the ilium and the sacrum. A bore extends through the elongate trunk. A longitudinal axis may be defined between the proximal and distal ends, and a periphery may be defined by an outer surface of the elongate trunk. The implant further comprises a proximal anchor comprising at least one deformable feature. The deformable feature is adapted to move between an initial configuration in which the deformable feature is within the periphery of the

elongate trunk, and a deployed configuration in which at least a portion of the deformable feature extends outwardly beyond the periphery of the elongate trunk relative to the longitudinal axis to engage the ilium. Additionally, the implant comprises a distal anchor coupled to the elongate trunk. The distal anchor comprising an expandable member defining an interior in fluid communication with the bore of the elongate trunk. The expandable member is adapted to receive curable material to move between a collapsed state in which the expandable member is within the periphery of the elongate trunk, and an expanded state in which at least a portion of the expandable member extends outwardly beyond the periphery of the elongate trunk relative to the longitudinal axis to engage the sacrum.

[0008] According to certain aspects of the present disclosure, the implant comprises a stem extending proximally from the proximal end of the elongate trunk. The stem comprises driven features configured to engage complimentary drive features of an insertion tool. The proximal anchor comprises engagement features coupled to the elongate trunk and configured to engage complimentary engagement features of the insertion tool. The deformable features may be circumferentially arranged about the outer surface of the elongate trunk. The deformable features are adapted to buckle in response to compressive loads applied to the proximal anchor such that at least a portion of the deformable features extend beyond the periphery of the elongate trunk relative to the longitudinal axis to engage the ilium.

[0009] According to certain aspects of the present disclosure, the minimally invasive bone stabilization system includes the insertion tool comprising a driver configured to receive a rotational input, a first shaft comprising a distal end and engagement features at the distal end, a second shaft coaxially arranged within the first shaft. The second shaft includes a proximal end

coupled to the driver, a distal end opposite the proximal end, drive features near the distal end, and a lumen extending through the second shaft.

[0010] A method for preventing relative motion between the ilium and the sacrum with the implant is also disclosed. The method comprises the steps of creating a minimally invasive incision within skin. An access cannula is positioned through the minimally invasive incision. A borehole is resected through the ilium and into the sacrum through the access cannula. The implant is positioned within the borehole such that the proximal anchor is disposed in the ilium and the distal anchor is disposed in the sacrum. The insertion tool removably coupled to the implant is operated to apply a compressive force to the proximal anchor along the longitudinal axis. The proximal anchor moves from the initial configuration in which the proximal anchor is within the periphery of the elongate trunk, to the deployed configuration in which at least a portion of the deformable feature of the proximal anchor extends outwardly beyond the periphery of the elongate trunk relative to the longitudinal axis to engage the ilium. Curable material is injected through the bore and into the expandable member to move the expandable member between the collapsed state in which the expandable member is within the periphery of the elongate trunk, and the expanded state in which at least a portion of the expandable member extends outwardly beyond the periphery of the elongate trunk relative to the longitudinal axis to engage the sacrum

BRIEF DESCRIPTION OF THE DRAWINGS

[0011] The disclosure is pointed out with particularity in the claims. The above and further features and benefits of the disclosure are understood by the following Detailed Description taken in conjunction with the accompanying drawings.

[0012] Figure 1 is a perspective view of an implant and an insertion tool.

[0013] Figure 2 is a cross sectional view of the implant of Figure 1.

[0014] Figure 3A is a perspective view of the implant of Figure 1 with an expandable member forming a portion of a distal anchor removed.

[0015] Figure 3B is a partial perspective view of the implant of Figure 1 showing a proximal anchor.

[0016] Figure 4 is an exploded view of the insertion tool of Figure 1 with a delivery cannula configured to be positioned within a lumen of the insertion tool.

[0017] Figure 5 is a cross sectional view of the implant and the insertion tool of Figure 1.

[0018] Figure 6 is an enlarged cross sectional view showing the implant secured to a distal end of the insertion tool.

[0019] Figure 7 is a cross sectional view of the implant and the insertion tool of Figure 6 with the implant positioned within first and second tissue sections. The proximal anchor is in the initial configuration and the distal anchor is in the collapsed state.

[0020] Figure 8 is a perspective view of the implant of Figure 1 with the proximal anchor in the deployed configuration and the distal anchor in the expanded state.

[0021] Figure 9 is a cross sectional view of the implant of Figure 8 with the proximal anchor in the deployed configuration within the first tissue section and the distal anchor in the expanded state within the second tissue section.

[0022] Figure 10 is a perspective view of an implant in accordance with another exemplary embodiment of the present disclosure.

[0023] Figure 11 is a perspective view of an implant in accordance with another exemplary embodiment of the present disclosure.

[0024] Figure 12 is a cross section view of an implant in accordance with another exemplary embodiment of the present disclosure.

[0025] Figures 13A, 13B and 13C is a cross sectional view of the implant within the first and second tissue sections, as shown in Figure 9, and further illustrating directing of material(s) into or between the first and second tissue sections at various points along a length of the implant.

[0026] Figure 14 is an elevation view of an access cannula and access needle positioned through an incision within skin.

[0027] Figure 15 is an elevation view of an access cannula of Figure 14 with a drill used to resect a borehole in the first and second tissue sections.

[0028] Figures 16 and 17 illustrate steps of positioning the implant through the access cannula and into the borehole using the insertion tool.

[0029] Figure 18 is a schematic view of a sacroiliac joint of a patient with a plurality of implants positioned within the SI joint and each of the implants depicting a different step of an exemplary method for fixing the ilium and sacrum.

DETAILED DESCRIPTION

[0030] Figure 1 depicts an insertion tool 30 and an implant 76 for a minimally invasive stabilization system. The implant 76 is configured to be inserted into a patient to hold two sections of tissue together. Figures 7, 9 and 13A-13C, for example, show a first tissue section 122 and a second tissue section 124 separated by an interface 326 or joint space. The first and second tissue sections 122, 124 may be a first and second bone, respectively. In one example to be described throughout the present disclosure, the first tissue section 122 is an ilium, the second tissue section 124 is a sacrum, and the interface 326 may generally define the SI joint. It is to be understood that

the implant 76 may be used with other surgical procedures to prevent relative motion of patient anatomy, for example, spinal fusion, ankle fusion, foot fusion, wrist fusion, hand fusion, fracture fixation, dislocation reduction, and the like. In a manner to be described in more detail, the implant 76 is removably coupled to the tool 30. The tool 30 is operated by a user to position and deploy the implant 76 to prevent relative motion between the sacrum and the ilium.

[0031] The implant 76, best shown in Figures 2, 3A, 3B and 8, includes an elongate trunk 90. The trunk 90 is defined between a proximal end 302 configured to be positioned within the first tissue section 122 and a distal end 304 configured to be positioned within the second tissue section 124. The trunk 90 extends between the first tissue section 122 and the second tissue section 124. A proximal anchor 86 is located proximally from the proximal end 302 of trunk 90, and a distal anchor 106 is located distally to the distal end 304 of the trunk 90. ("Proximal" is understood to mean towards the practitioner, away from the site in which the implant 76 is to be seated; and "distal" is understood to mean away from the practitioner holding the tool 30, towards the site in which the implant 76 is to be seated.) In a manner to be described, the tool 30 is used to deploy the proximal anchor 86, and in certain embodiments the distal anchor 106. Once the proximal and distal anchors 86, 106 are deployed, the implant 76 secures the first and second tissue sections 122, 124.

[0032] The implant 76 is shaped so that trunk 90 is elongate in shape. The trunk 90 includes a periphery 306 defined by an outer surface 308 of the trunk 90. In the illustrated embodiment, the trunk 90 is cylindrical and has a length defined between the proximal and distal ends 302, 304 and a diameter defined by the periphery 306. In other words, Figure 3A shows the outer surface 308 extending circumferentially to define the periphery 306. The proximal anchor 86 may be a tubular shaped structure that extends proximally from the proximal end 302 of trunk 90.

In the illustrated embodiment, at least a portion of the proximal anchor 86 is formed integrally with the trunk 90. The proximal anchor 86 comprises at least one deformable feature 310 that is, at least initially, within the periphery 306 of the trunk 90. In certain embodiments, the implant 76 is shaped so that the outer diameter of proximal anchor 86 and the periphery 306 of the trunk 90 are initially equal. The deformable feature 310 of the proximal anchor 86 is adapted to move between an initial configuration (shown in Figures 2 and 3) in which the deformable feature 310 is within the periphery 306 of the trunk 90, and a deployed configuration (shown in Figures 8 and 9) in which at least a portion of the deformable feature 310 extends outwardly beyond the periphery 306 relative to the longitudinal axis 300 to engage the first tissue section 122, *e.g.*, the ilium. The distal anchor 106 is coupled to the trunk 90 and comprises an expandable member 312. The expandable member 312 is adapted to receive injectable material to move between a collapsed state (shown in Figures 6 and 7) in which the expandable member 312 is within the periphery 306 of the trunk 90, and an expanded state (shown in Figures 8 and 9) in which at least a portion of the expandable member 312 extends outwardly beyond the periphery 306 of the trunk 90 relative to the longitudinal axis 300 to engage the second tissue section 124; *e.g.*, the sacrum. Thus, prior to positioning the implant 76 within the patient, the proximal and distal anchors 86, 106 are within the periphery 306 to minimize the axial profile of the implant 76 and facilitate surgery that is less or minimally invasive. Relative to known system with diameters of 10, 12 or greater millimeters (mm) (and/or requiring the use of a tissue dilator), the implant 76 of the present disclosure advantageously has smaller diameters that provides for percutaneous placement through a minimally invasive incision. Exemplary diameters of the implant 76 include less than 10 mm, and more particularly less than 7 mm, and even more particularly less than 4 mm. Further, the component of tool 30 used to position the implant 76 need not require a diameter larger than that

of the implant 76 itself. Consequently, the relatively smaller incision and borehole exposes the patient to less trauma.

[0033] As used herein, injectable material may include any material suitable for injection into the patient for use with the stabilization system and/or as part of the methods disclosed herein. The injectable material may include a curable material, for example, a biocompatible curable material (bone cement). Exemplary curable materials include non-resorbable curable materials such as polymethylmethacrylate (PMMA) or glass ionomer cements, or resorbable material such as calcium phosphate. The injectable material may include a bone growth material (*e.g.*, autograft bone, allograph bone, and/or synthetic material that fosters bone growth). The injectable material may include therapeutic agents, for example, a pharmacologic that reduces infection or tissue inflammation). Other injectable materials suitable with the present system and methods are contemplated, and it is also understood that combinations of the aforementioned injectable materials may be utilized (*e.g.*, calcium phosphate with demineralized bone matrix and bioglass). In alternative embodiments, the material received within the interior 314 of the expandable member 312 is not injected, but rather packed with a tamp or otherwise provided in a suitable manner.

[0034] With reference to Figures 3A and 3B, the proximal anchor 86 includes a plurality of apertures 104. The apertures 104 extend through the anchor 86, and may be circumferentially arranged and arcuately spaced apart from each other on an outer surface 309 of the proximal anchor 86 integrally formed with the outer surface 308 of the trunk 90. In other words, the outer surfaces 308, 309 may be a singular, continuous structure, as shown, but are separately identified to delineate the portion of the outer surface defining the proximal anchor 86. The apertures 104 define a deformable feature 310 interposed between each adjacent pair of

apertures 104. Each of the apertures 104 may be oval in shape and comprise a major axis 316 and a minor axis 318. The implant 76 is formed so that the major axes 316 of apertures 104 are parallel to the longitudinal axis 300 through the implant 76, as shown in Figure 3B. In a manner to be described, the apertures 104 are configured to localize stresses to the deformable feature 310 from compressive loads applied to the proximal anchor 86 to induce deformation of the deformable feature 310 and move the deformable feature 310 from the initial configuration to the deployed configuration. Each of the deformable features define a width, where the width is smallest at a position between the minor axes 318 of adjacent pairs of apertures 104 such that the localized stresses induce buckling to the deformable features 310 at the widths. In another exemplary embodiment, a plurality of slots (not shown) may be circumferentially arranged and spaced apart from each other on the outer surface 309 of the proximal anchor 86. The slots define the deformable feature 310 interposed between each adjacent pair of the slots with the deformable feature 310 being strut-like in shape. The localized stresses induce bowing of the struts with each of the bowed struts including an apex in the deployed configuration with the apex extending beyond the periphery 306 of the trunk 90 relative to the longitudinal axis 300. In still another exemplary embodiment, the proximal anchor 86 may take the appearance of an annular cage in at least some respects similar to a cardiovascular stent. The annular cage include a grid-like pattern of structural members (*i.e.*, the deformable features 310) with interstitial spaces (*i.e.*, the apertures 104). The cage is configured to deform, deflect, buckle, bow, and/or otherwise deform in response to the compressive loads applied to the proximal anchor 86 such that at least a portion of the cage extends beyond the periphery 306 of the trunk 90 relative to the longitudinal axis 300.

[0035] For still another example, the proximal anchor 86 may include opposing wings configured to deflect outwardly in response to the screw-like member being axially advanced on

contact with the opposing wings. It is to be understood that deformation may include deflection of at least a portion of the proximal anchor 86. For still yet another example, the proximal anchor 86 may include a scissor-like jack having two opposing surfaces configured to move in opposite directions in response to the screw-like member being axially advanced.

[0036] The proximal end of proximal anchor 86 may be castellated. Specifically plural arcuately spaced apart tabs 87, as shown in Figure 3A and 3B, extend proximally from the proximal end of the proximal anchor 86. A cap 78 is disposed over the proximal end of proximal anchor 86. The cap 78 is formed to have a base 79. The base 79 is formed with slots 80 that extend inwardly from a distally directed face of the base 79. The slots 80 are dimensioned to receive the tabs 87 defining the castellated proximal end of the proximal anchor 86. The seating of the tabs 87 in the slots 80 prevents relative rotation of cap 78 and the trunk 90. The cap 78 may include cylindrically shaped skirt 82. The skirt 82 extends distally forward from an inner perimeter of the base 79. The skirt 82 defines a circular void space or cavity 320 for purposes to be described. The cap 78 is further formed so the proximal end of the base 79 is formed to have an engagement feature, such as teeth 81 identified in Figures 3A and 3B, adapted to receive a complimentary engagement feature, such as complimentary teeth of the tool 30 (see Figure 6). The cap 78 includes a lid 83, identified only in Figure 2, extending over the top of skirt 82 to define an aperture (not identified).

[0037] With reference to Figure 2, the implant 76 also includes a stem 88. The stem 88, like the proximal anchor 86, extends proximally from the proximal end 302 of the trunk 90. A diameter of the stem 88 is less than the diameter of the trunk 90 such that the stem 88 may be disposed in the void space 320 internal to the proximal anchor 86 and within the skirt 82 of the cap 78. The stem 88 may extend through the aperture of the lid 83 of the cap 78. The stem 88

may be centered on a longitudinal axis 300 of the trunk 90. In the illustrated embodiment, a proximal end of the stem 88 is located distally forward of the proximal end of proximal anchor 86. The stem 88 is formed so that a driven feature, such as threads 89, extends around the outer surface of the stem 88. The driven feature is configure to engage a drive feature, such as complimentary threading 64, of the tool 30.

[0038] Turning to the distal anchor 106 of the implant 76, a neck 92 extends distally forward from the distal end 304 of the trunk 90. Referring to Figures 2, 3A and 3B, the neck 92 may be cylindrical in shape and comprises a diameter less than the diameter of the trunk 90 and separated by a distally directed step surface defining the distal end 304 of the trunk 90. The implant 76 may include a head 94 distal to the neck 92. The head 94 may be cylindrical in shape and centered on the longitudinal axis 300. A gripping feature is coupled to the neck 92 in order to facilitate axial retention of the implant 76 in the sacrum 124. One example of the gripping feature is ribs 96, one each identified in Figures 2 and 3, which are coupled to and extend radially outwardly from the neck 92. The ribs 96 extend arcuately around the outer surface of the neck 92. In the illustrated embodiment, implant 76 is formed to have plural ribs 96 longitudinally spaced apart from each other along the head 94. In the illustrated embodiment, the implant 76 may be formed so that multiple ribs 96 may be spaced axially from each other such that the ribs 96 form multiple rows. The ends of these ribs 96 are angularly spaced apart from each other. The ribs 96 may have an outer diameter approximately equal to the outer diameter of the neck 92. Alternative gripping features may be used instead of or in combination with the rib 96. For example, the gripping feature may include a porous surface, a coating, a knurled surface, a circumferential groove, threads, a roughened surface of neck 92 and the head 94, and an anchor similar to the

proximal anchor. The gripping features provide enhanced axial retention between the implant 76 and the curable material to be cured about the head 94 in a manner to be described.

[0039] With reference to Figures 2 and 6, the implant 76 is also formed to have a bore 102 that extends proximally to distally along the longitudinal axis 300 of the implant 76. The bore 102 may be in communication with a coaxial counterbore 98 extending distally forward from a proximal end of stem 88 to a distal end of the stem 88 (*e.g.*, the proximal end 302 of the trunk 90). The counterbore 98 is understood to be larger in diameter than bore 102. The bore 102 extends from through the trunk 90, through the neck 92 and head to an opening in the head 94.

[0040] The distal anchor 106 is coupled to the trunk 90 and comprises an expandable member 312 that defines an interior 314 in fluid communication with the bore 102 of the trunk 90. The expandable member 312 is coupled to the neck 92 such that the head 94 and each rib 96 is located within the interior 314 of the expandable member 312. For example, the expandable member 312 may be a flexible, inflatable balloon. In some versions of the disclosure, the expandable member 312 is formed from a thermoplastic polyurethane or other elastomeric material. The expandable member 312 is shaped to have a narrowed portion 108, identified only in Figure 9. The narrowed portion 108 is shaped to tightly fit around neck 92. An adhesive, clamp, or other joining means may be used to hold the narrowed portion 108 fast to the neck 92. Distal to the narrowed portion 108, the expandable member 312 is shaped to have an expanding portion 110, identified in Figures 2, 10 and 11. The expanding portion 110 of the expandable member 312 extends over and around head 94 such that the head 94 of the implant 76 (and the ribs 96) are disposed within the interior 314 of the expandable member 312. The distal end of bore 102 opens into the interior 314 defined by the distal anchor 106 to receive the injectable material in a manner to be described.

[0041] Returning to Figure 1 and with concurrent reference to Figures 4-6, the tool 30 includes a handle 32, sometimes called a housing. The handle 32 is shaped to have a barrel 34. In the illustrated embodiment, barrel 34 is cylindrically shaped. A handgrip 36, also part of the handle 32, extends outward from the barrel 34 adjacent the distal end of the barrel 34 to form a "pistol grip." In the illustrated embodiment, the handgrip 36 is cylindrical in shape. Plural longitudinally spaced apart grooves 38 extend circumferentially around the outer curved surface of the handle. The grooves 38 facilitate the grasping of the handle 32.

[0042] The barrel 34 is formed so that immediately forward of the proximal end there is a slot 40. The slot 40 extends inwardly from and circumferentially around the outer surface of the barrel 34. The handle 32 is further formed so two coaxial bores extend between the opposed proximal and distal end of the barrel 34. A first bore, bore 42, extends distally forward from the proximal end of the barrel 34. The bore 42 extends a length that is between 40% and 80% of the overall length of the barrel 34. A second bore, bore 44, extends forward from the distal end of bore 42 to the distal end of the barrel 34. The bore 44 has a diameter that is less than the diameter of bore 42. The bores 42 and 44 are centered on the proximal to distal longitudinal axis 300 through the barrel 34.

[0043] A first shaft 46 extends distally forward of the distal front end of the barrel 34 and is defined by an outer diameter 48. The bore 44 extends through the shaft 46 and is defined by an inner diameter 50. The inner diameter 50 and outer diameter 48 may be approximately equal to, if not identical to the inner and outer diameters of the base 79 of the cap 78. The distal end of the shaft 46 is formed to have a complementary engagement feature, such as teeth 47, identified in Figures 1 and 6. The teeth 47 are shaped to engage cap teeth 81. The shaft 46 may be integrally formed with the barrel 34, or a separate component that is secured to the barrel 34.

[0044] A driver 52 is rotatably mounted to the handle 32. The driver 52 includes a knob 54. The knob 54 is rotatably mounted around the proximal end of the barrel 34. Shown in Figure 5, the driver 52 includes an inwardly-directed lip 56. The handle 32 is assembled so that the lip 56 seats in, and is able to rotate in, the slot 40 formed in the barrel 34. The driver 52 is able to rotate within, but not move longitudinally relative to, the barrel 34. The driver 52 comprises a drive shaft 60 (also referred to herein as a second shaft) integral with and extending distally forward from the knob 54 along the longitudinal axis 300. The drive shaft 60 has an outer diameter 330 that is less than an inner diameter 50 of the shaft 46. The drive shaft 60 includes a shoulder portion 58 that extends distally forward from the distally directed face of the knob 54. The shoulder portion 58 is shaped to closely slip fit and rotate in the bore 42 and has a diameter 334 larger than the outer diameter 330. The drive shaft 60, which is smaller in outer diameter than the shoulder portion 58, is shaped to closely slip fit and rotate in both the barrel 34 and the shaft 46. The components forming the handle 32 are further constructed so that the distal end of the drive shaft 60 is located forward of a distal end of the first shaft 46. A lumen 62, identified in Figure 6, extends longitudinally through the driver 52 and has a diameter 332. The lumen 62 extends from the proximally directed face of the knob 54, through the drive shaft 60 to the distal end of the drive shaft 60.

[0045] The driver 52 is further formed so immediately rearward of the open distal end of the drive shaft 60, there is a drive feature, such as threading 64, around the inner wall of the driver 52 that defines the lumen 62. The driver 52 is dimensioned so the distal end of the drive shaft 60 can seat in the annular space within the cap skirt 82, the lumen 62 can seat over the stem 88 and threading 64 can engage the threading 89. The driver 52 is further formed so a delivery cannula 68, seen in Figures 4 and 5, can be slidably disposed in the lumen 62. The system

is further dimensioned so a distal end of the delivery cannula 68 is sized to be seated in the counterbore 98 internal to the implant 76, for example, through an interference fit. In some embodiments, such as shown in Figure 18, the delivery cannula 68 has a length defined between opposing ends with the length being such that when the implant 76 is positioned within the borehole 126 the delivery cannula 68 extends above the skin 352 of the patient. The delivery cannula 68 may be used to verify the placement of the implant 76, and/or to inject the injectable material, discussed in further detail below.

[0046] To prepare tissue for receiving implant 76 of this disclosure, the first and second tissue sections 122, 124 are aligned. A dashed line 123 marks the approximate boundary between the outer relatively hard outer layer of cortical bone and softer internal layer of cancellous bone of the tissue or bone section 122 (it is also understood the second tissue section may also include cortical and cancellous bone). Once the first and second tissue sections 122, 124 are aligned, an incision may be provided within the overlying tissue (*e.g.*, skin, fascia and muscle), and the overlying tissue may be dilated with a suitable instrument to provide a working channel to the first tissue section 122. A borehole 126 is formed through at least a portion of the first and second tissue sections 122, 124. The borehole 126 may be formed so as to have an overall length that is greater than the length of the implant. More particularly, the borehole 126 may be formed so as to have a length such that when the proximal anchor 86 is deployed, the proximal anchor 86 may be deployed within the portion of the cancellous bone adjacent the cortical bone. A closed distal end of the borehole 126 may be cored so as to create a cavity 128, for example, slightly larger than the diameter of the borehole 126. A cavity creator such as an expandable balloon tamp or a blade type cavity creator such as disclosed in PCT Pub. No. WO 2010/017377/US Pat. Pub. No.

US 2010/0036381, the contents of which are explicitly incorporated herein may be used to form the borehole 126.

[0047] In certain embodiments, a guidewire (not shown) may be provided to facilitate creation of the borehole 126. An access cannula 354 with an access needle 356 (see Figure 14) disposed within the access cannula 354 are directed through the incision 350 and the overlying tissue to dilate the overlying tissue. The access needle 356 prevents coring of the overlying tissue within the access cannula 354 as the access cannula 354 and the access needle 356 are directed through the overlying tissue. The access needle 356 (*e.g.*, a trocar) is removed to provide the working channel through the overlying tissue to the first tissue section 122. The guidewire is directed through the working channel and into engagement with the first tissue section 122. The access cannula 354 may be removed with the guidewire remaining in engagement with the first tissue section 122 and extending above the skin 352 of the patient.

[0048] The borehole 126 is then formed through at least a portion of the first and second tissue sections 122, 124. In particular, a drill 358 (see Figure 15) is cannulated so as to slidably receive the guidewire. The drill 358 is directed through the incision 352 and the overlying tissue while constrained by the guidewire. The drill 358 is actuated (*e.g.*, rotated under manual or powered input) to create the borehole 126. The drill 358 is removed with the guidewire remaining in engagement with the first tissue section 122 and extending above the skin 352 of the patient.

[0049] The implant 76 is removably coupled to the tool 30. In particular, the distal end of the drive shaft 60 of the tool 30 is positioned within the skirt 82 integral of the implant 76. The knob 54 is rotated to cause the like rotation of drive shaft 60. The rotation of the drive shaft 60 causes the threading 64 to engage the threading 89 coupled to the stem 88. The implant 76 is threaded onto drive shaft 60 until the teeth 81 of the cap 78 engage the complementary teeth 47

integral with tool 30, as seen in Figures 5 and 6. The engagement of teeth 47 with the teeth 81 prevent the implant 76 from rotating relative to tool shaft 46.

[0050] The delivery cannula 68 may be inserted into the lumen 62. The delivery cannula 68 is optionally preloaded loaded with the injectable material. The cannula 68 is fitted in the lumen 62 so the distal end of the cannula 68 seats in counterbore 98 internal to the implant 76.

[0051] The tool 30 is used to position the implant 76 within the borehole 126. In certain embodiments, the tool 30 directs the implant 76 through the access cannula 352 and into the borehole 126. The implant 76 may be positioned such that the proximal anchor 86 is located inward of the boundary 123 between the cortical and cancellous layers of the first tissue section 122, and distal anchor 106 is located in the second tissue section 124, for example, within the cavity 128. In embodiments utilizing the guidewire (with the access cannula 352 removed), the tool 30 and the implant 76 are cannulated so as to slidably receive the guidewire. The tool 30 and the implant 76 are directed through the incision 352 and the overlying tissue while constrained by the guidewire.

[0052] The proximal anchor 86 is deployed by actuating the driver 52. The driver 52 is actuated by rotating knob 54, and the rotation of knob 54 results in a like rotation of drive shaft 60. It is understood that, at this time, implant 76 is blocked from rotation relative to tool 30, and the stem 88 is threadably engaging the drive shaft 60. Accordingly, the rotation of drive shaft 60 draws the stem 88 proximally and, by extension, an entirety of the implant 76 moves proximally relative to the tool 30. With movement of the cap 78 blocked by the abutment of the cap 78 against the distal end of shaft 46, the proximal anchor 86 is compressed between cap 78 and trunk 90 of the implant 76. Owing to the presence of apertures 104 localizing compressive stresses, the deformable features 310 of the proximal anchor 86 is relatively mechanically weak. In other

words, in response to longitudinally compressive forces, the deformable features 310 of the proximal anchor 86, in comparison to other sections of the implant 76, are less able to resist buckling. Accordingly, in response to the longitudinally compressive force placed on anchor 86, the deformable features 310 buckle outwardly. The deformable features 310 are adapted to buckle into two buckled sections separated by an elbow that projects radially outwardly beyond the periphery 306 of trunk 90, as seen in Figures 8 and 9. As a result of this buckling, the buckled sections and the elbow of the anchor 86 penetrate into the first tissue section 122 surrounding borehole 126. The penetration of the deployed anchor 86 into the surrounding tissue prevents movement of the implant 76 relative to the first tissue section 122.

[0053] The distal anchor 106 is deployed. It is understood the deploying of the distal anchor 106 may occur before or after deploying of the proximal anchor 86. The deploying of the distal anchor 106 may include expanding the expandable member 312 with the injectable material. In one example, a stylet (not shown) is inserted into the lumen 62 to urge the injectable material preloaded into the delivery cannula 68 to flow through bore 102 internal to the implant 76 and into the expandable member 312. The injectable material is discharged from the open end of bore 102 in into the interior 314 of the expandable member 312. The injectable material expands the expandable member 312 from the collapsed state from which the expandable member 312 is within the periphery 306 of the trunk 90, the expanded state in which at least a portion of the expandable member 312 extend outwardly beyond the periphery 306 of the trunk 90 relative to the longitudinal axis 300. The expandable member 312 contacts and engages the second tissue section 124. The expandable member 312 may compress the surrounding tissue against which the expandable member 312. In embodiments utilizing the guidewire (with the access cannula 352 removed), the distal anchor 106 cannulated so as to slidably receive the guidewire. For example, the expandable

member 312 of the distal anchor 106 may be, for example, a torus or toroid defining an inner passageway through the expandable member 312. A suitable structure may be coupled to the implant 76 to axially support the toroidal expandable member at its distal end. For example, the neck 92 (or an additional neck) may extend through substantially an entirely of a length of the toroidal expandable member. In such an example, the inner passageway is sized to slidably receive the guidewire such that, as the tool 30 and the implant 76 are directed through the incision 352, the guidewire is disposed within the inner passageway of the expandable member 312 prior to injecting the injectable material into the interior 314 of the expandable member 312.

[0054] In embodiments where the injectable material is curable material, the curable material may be permitted to cure or harden, resulting in a mass 130 of cured material, shown in Figure 9, extending outwardly from and around the head 94 of the implant 76. Further, the curable material hardens around the ribs 96 integral with head 94 and neck 92. The hardening of the curable material around the ribs 96 reduces the likelihood that, should the implant 76 and tissue section 124 be subjected to axial loads, the implant 76 will work free from the hardened mass 130 (*e.g.*, "pull out"). The mass 130 and the expandable member 312 prevent movement of the implant 76 relative to the second tissue section 124. When the proximal and distal anchors 86 and 106 engaging the first and second tissue sections 122, 124, respectively, relative movement between the tissue sections 122, 124 is prevented.

[0055] Once the implant 76 is deployed, driver 52 is actuated to disconnect the tool 30 from the implant 76. The knob 54 is rotated in the direction opposite the direction in which the knob 54 is rotated to deploy the proximal anchor 86. At this time, the proximal and distal anchors 86, 106 constrain the implant 76 from movement relative to the tissue sections 122, 124. Accordingly, as a result of the rotation of drive shaft 60, the drive shaft 60 rotates proximally away

from the stem 88. Since the drive shaft 60 does not move longitudinally relative to the rest of the tool 30, the proximal movement of the tool 30 separates the tool from the implant 76. Subsequent steps of exemplary procedures will be described in further detail.

[0056] Referring now to Figure 10, an implant 142 in accordance with another exemplary embodiment is shown. In at least many respects the implant 142 of the present embodiment is the same as that previously described. The implant 142 of Figure 10 includes an elongate trunk 144 formed with one or more recesses 146 that extend inwardly through a portion of the outer surface 308. The recesses 146 are sized to receive the injectable material(s). The recesses 146 are positioned between the proximal end 302 and the distal end 304 of the trunk 144. The implant 142 may be positioned within the patient such that the recess 146 is positioned near or adjacent the interface 326 between the first and second tissue sections 122, 124.

[0057] Figure 11 shows an implant 152 in accordance with another exemplary embodiment of the present disclosure. In at least many respects the implant 152 of the present embodiment is the same as that previously described. The implant 152 of Figure 11 includes the trunk 154 formed with one or more orifices 156 (one shown). The orifices 156 extend inwardly from the outer surface of the trunk 154 and in fluid communication with bore 102. The implant 152 may be positioned within the patient such that the orifices 156 are positioned near or adjacent the interface 326 between the first and second tissue sections 122, 124. In one example, when injectable material is injected into the bore 102, at least a fraction of the injectable material flows out of the orifices 156. In another example to be described (see Figure 13B), a cannula 190 may be selectively positioned to cause the injectable material to be directed through the orifices 156. It is contemplated that the orifices 156 of Figure 11 may be provided in addition to the recesses 146 of Figure 10.

[0058] Referring now to Figure 12, another exemplary implant 162 includes the trunk 164 defining the bore 102. A valve 172 may be in communication with the distal end 160 of the bore 102, for example, coupled within the head 168 of the implant 162. In the illustrated embodiment, the valve 172 is a duck-billed valve. To facilitate the fitting of valve 172, internal to the head 94 of the trunk 164 there is a counterbore 160 with the bore 102 opening into the counterbore 160. The counterbore 160 is shaped to receive the valve 172. The valve 172 is configured to allow fluid flow from bore 102 into the interior 314 within expandable member 312 while blocking fluid flow in the reverse direction.

[0059] In certain embodiments, the injectable material may be introduced at different locations along the length of the implant 76. This would allow the injectable material to selectively be introduced into the distal anchor 106, through the orifices 156 in the trunk 90, and/or through the apertures 104 of the proximal anchor 86. Figures 13A, 13B and 13C illustrate an implant 180 with which this type of cannula may be used. For clarity, the figures show the first and second tissue sections 124, 124 spaced apart from one another. In at least many respects the implant 180 of the present embodiment is the same as that previously described. The implant 180 of the present embodiment includes an elongate trunk 182 with the orifice(s) 156 previously described. The implant 180 may further include additional pathways 184 defined between the apertures 104 of the proximal anchor 86 prior to or after buckling of the deformable features 310.

[0060] A cannula 190 is slidably disposed in the bore 102 formed in trunk 182. It is to be understood that the delivery cannula 68 of Figure 4 may alternatively be used. The cannula 190 includes a proximal inlet port configured to be in fluid communication with a source of injectable material, and an outlet port 192. The cannula 190 may be formed so the distal end of the cannula

190 is closed, and the outlet port 192 is a side port. For example, Figures 13A to 13C show the closed distal end and the outlet port immediately proximal to the closed distal end.

[0061] The implant 180 may be suitably positioned within the first and second tissue sections 122, 124. As seen in Figure 13A, the cannula 190 is directed through the bore 102 to position the outlet port 192 distal to the head 94 and within the interior 314 of the expandable member 312a. The curable material is flowed through the cannula 190 and outlet port 192 into the expandable member 312a. The injectable material first expands the expanding portion 110a of the expandable member 312a. Since expandable member 312a is formed with pores 178 (and/or fenestrations), the continued flow of curable material into the expandable member 312a causes the curable material to flow out of the pores 178 and into the borehole 126 and the surrounding surface of the second tissue section 124. Subsequent to the curable material curing external to the expandable member 314, within the interior 314, and through the pores 178 (and/or fenestrations), the interaction (*e.g.*, retention) of the distal anchor 106 and the second tissue section 124 is improved.

[0062] Referring now to Figure 13B, the cannula 190 is axially positioned so the outlet port 192 is in fluid communication with the orifice 156. Material(s) to be introduced into the interface 326 or joint space between the sections of first and second tissue sections 122, 124. For example, the injectable material may be the curable material, the bone growth material, and/or the therapeutic agent. It is understood that the interface 326 or joint space is comprised of cartilaginous material with synovial space not particularly conductive to receiving injected material. In certain exemplary methods, anatomy from the interface 326 or joint space may be removed prior to injecting the material(s). For example, the joint space may be decorticated (*i.e.*, removing outer layers of cartilage to expose the surfaces of the first and second tissue sections

122, 124). The decortication may be performed with a mechanical instrument such as a curette. The instrument may be directed through a portion of the borehole 126 and into the interface 326 prior to positioning the implant 76 within the borehole 126 (*e.g.*, during or subsequent to creation of the borehole 126). In another example, a working end of instrument may be sized to be extend through the orifice(s) 156 of the implant 76. With the implant 76 suitably positioned within the borehole 126, the working end of the instrument is directed through the orifice(s) 156 to decorticate the interface 326. The implant 76 may be rotated within the borehole 126 (with the proximal and distal anchors 86, 106 in the initial configuration and collapsed state, respectively) with the working end of the instrument extend through the orifice(s) 156 to decorticate the interface 326. With the surfaces of the first and second tissue sections 122, 124 exposed, the injected material(s), for example the bone growth material, directly contacts the bone surfaces to promote bone growth and fusion.

[0063] The cannula 190 may be positioned so that outlet port 192 is placed in fluid communication with the orifice 184, as shown in Figure 13C. The injectable material may be introduced to the additional pathways 184 defined between the apertures 104 of the proximal anchor 86 prior to or after buckling of the deformable features 310. In one example, the additional curable material introduced through the pathways 184, upon hardening, strengthens the fixation of the proximal anchor 86 to the first tissue section 122. Further, it is contemplated that the cannula 190 may be replaced with another cannula to inject different types of materials to different locations along the length of the implant 180.

[0064] Figures 14-18 show several steps of an exemplary method for preventing relative motion between the first and second tissue sections 122, 124. The first tissue section 122 is hereinafter referred to as the ilium 122, and the second tissue section 124 is hereinafter referred

to as the sacrum 124 of the patient. The implant 76 is implanted using a minimally invasive procedure. First, a minimally invasive incision 350 (see Figure 18) is created in the skin 352 of the patient. The incision 350 may be formed with a scalpel, the access needle 356 disposed inside the access cannula 354, or by other methods. The access cannula 354 with the access needle 356 is directed through the overlying soft tissue towards the ilium 122. The overlying soft tissue is dilated, and a distal end of the access cannula 354 is positioned near or adjacent the ilium 122 as shown in Figure 14. The access needle 356 may be removed to provide a working channel through the access cannula 354 to the ilium 122.

[0065] As previously described, the guidewire (not shown) may be provided to facilitate creation of the borehole 126. The guidewire is directed through the working channel and into engagement with the ilium 122. The access cannula 354 may be removed with the guidewire remaining in engagement with the ilium 122 and extending above the skin 352 of the patient. The drill 358, the tool 30, and the implant 76 being cannulated to receive the guidewire with the subsequent steps performed with the access cannula 354 removed.

[0066] Referring to Figure 15, the drill 358 is inserted through the access cannula 354 to engage the ilium 122. The drill 358 is operated to resect the borehole 126 through the ilium 122 and into the sacrum 124, after which the drill 358 is removed from the access cannula 354. Figure 15 shows the drill with a handle configured to be hand-operated, but it is understood that powered drills, burs, shavers, and the like, may be used to resect the borehole 126.

[0067] Figure 16 shows the tool 30 is provided with the implant 76 removably coupled to the distal end of the shaft 46. In some embodiments, a single tool 30 is used throughout the procedure and the method may include a step of removably coupling the implant 76 to the tool 30. In this embodiment, the tool 30 is operated by applying a torque to the driver 52 in a first direction

to engage drive features (*e.g.*, the threads 64), of the drive shaft 60 of the tool 30 with complimentary driven features (*e.g.*, the threads 89) coupled to the stem 88. The tool 30 is further operated to engage engagement features, such as teeth 47, coupled to the shaft 46 of the tool 30 with complimentary engagement features (*e.g.*, the teeth 81) coupled to the trunk 90 to prevent rotation of the proximal anchor 86 relative to the shaft 46 and prevent an axial movement of the proximal end of the proximal anchor 86 relative to the shaft 46. Further, the delivery cannula 68, which is coaxially disposed within the lumen 62 is placed in fluid communication with the bore 102.

[0068] Figures 16 and 17 illustrate the steps of positioning the implant 76 within the borehole 126 such that the proximal anchor 86 is disposed in the ilium 122 and the distal anchor 106 is disposed in the sacrum 124, and operating an insertion tool 30 to apply a compressive force to the proximal anchor 86 along the longitudinal axis 300 to move the proximal anchor 86 from the initial configuration to the deployed configuration. The implant 76 may be positioned within the borehole 126 such that the expandable member 312 is disposed within the cancellous bone of the sacrum 124. Prior to applying the compressive force to the proximal anchor 86, the deformable feature 310 is within the periphery 306 of the trunk 90. The compressive force is applied by rotating the knob 54 in a first direction (represented by the arrow shown in Figure 17). The rotation of the knob 54 in turn rotates the drive shaft 60, which due to the engagement of the threads 64 on the drive shaft 60 and the threads 89 on the stem 88, the stem 88 is drawn into the lumen 62. Because rotation of the proximal anchor 86 relative to the shaft 46 and axial movement of the proximal end of the proximal anchor 86 relative to the shaft 46 is prevented, the compressive force is applied to the deformable feature 310. The compressive force deforms the deformable feature

310 such that at least a portion of the deformable feature 310 extends outwardly beyond the periphery 306 of the trunk 90 relative to the longitudinal axis 300 to engage the ilium 122.

[0069] Once the proximal anchor 86 is engaged and maintaining the position of the implant 76 relative to the ilium 122, the tool 30 may be decoupled from the implant 76. A torque is applied to the driver 52 of the tool 30 in a second direction opposite to the first direction (represented by the arcuate arrow shown in Figure 18) to rotate the drive shaft 60. The proximal anchor 86 is in the deployed configuration and engaging the ilium 122, and rotation of the drive shaft 60 decouples the threads 64 from the complimentary threads 89 of the implant 76. When the distal end of the shaft 46 of the tool 30 is decoupled from the implant 76, the delivery cannula 190 (or the delivery cannula 68) remains coupled to the implant 76 positioned within the borehole 126, as shown in Figure 18. The presence of the delivery cannula 190 extending above the incision 350 in the skin 352 provides visual indication to the surgeon of the presence, location, and orientation of the implant 72 within the patient.

[0070] After the proximal anchor 86 is engaged and maintaining the position of the implant 76 relative to the ilium 122, the distal anchor 106 is engaged with the sacrum 124. The injectable material is injected from the source of injectable material. In order to inject the injectable material, an injectable material delivery system 360 includes or is coupled to the source of injectable material. One such injectable material delivery system 360 is shown in Figure 18. The injectable material delivery system 360 is coupled to the cannula 190 such that injectable material injected into the cannula 190 flows through the bore 102 and into the interior 314 of the expandable member 312. The injectable material moves the expandable member 312 between the collapsed state in which the expandable member 312 is within the periphery 306 of the trunk 90, and the expanded state in which at least a portion of the expandable member 312 extends outwardly

beyond the periphery 306 of the trunk 90 relative to the longitudinal axis 300. Owing to the porosity of the cancellous bone, the expandable member 312 (and in certain embodiments the injectable material directed through porous features or fenestrations 178 of the expandable member 312), displace blood and marrow forming the cancellous bone. In embodiments where the injectable material is curable material, the curable material is permitted to cure within the interior 314 of the expandable member 312 with the expandable member 312 engaging the sacrum 124. Additionally, the curable material injected into the interior 314 of the expandable member 312 surrounds the neck 92 and is in contact with the rib 96. The curable material is permitted to cure in contact with the rib 96 to facilitate axial retention of the implant 76 within the cured curable material.

[0071] In some embodiments of the method, the expandable member 312 comprises fenestrations 178. In this embodiment the method further comprises a step of injecting additional curable material into the interior 314 of the expandable member 312 such that a portion of the curable material is urged through the fenestrations 178 and into contact with the sacrum 124. In another embodiment of the method, the expandable member 312 is formed from a permeable material. In this embodiment the method further comprises a step of injecting additional curable material into the interior 314 of the expandable member 312 such that a portion of the curable material is urged through the permeable material and into contact with the sacrum 124.

[0072] In some embodiments of the method, multiple implants 76 may be implanted into a patient. As mentioned above, each implant 76 may have as dedicated tool 30, or a single tool 30 may be used to insert multiple implants 76. The method further comprises the step of decoupling the tool 30 from a first implant, and removably coupling the tool 30 to a second implant. With continued reference to Figure 18, the second implant is then inserted through a

second minimally invasive incision and within a second borehole with a proximal anchor of the second implant engaging the ilium 122 and a distal anchor of the second implant disposed in the sacrum 124. The proximal anchor of the second implant is then deployed in a manner substantially the same as the first implant. Prior to both the first implant and second implant receiving the injectable material, the second implant is decoupled from the distal end of the shaft 46 of the installation tool 30 with a second delivery cannula remaining coupled to the second implant positioned within the second borehole. The delivery cannulas coupled to the first and second implants extend through the first and second minimally invasive incisions, respectively. The injectable material is then injected into each delivery cannula to expand the expandable member of the first implant and the second implant.

[0073] After expanding the expandable member 312 of the one or more implants 76 outwardly to engage the sacrum 124, the delivery cannula 68 and the access cannula 354 are each removed through the minimally invasive incision 350. Finally, the minimally invasive incision 350 is closed with the expandable member 312 and cured curable material remaining within the patient.

[0074] The foregoing is directed to specific versions of the disclosure. Other features of the stabilization system and/or the implant are contemplated. For example, the shapes of the components of the implant 76 may vary from what has been described. In alternative versions of the disclosure the trunk 90 may be non-circular in cross section. In some of these versions of the disclosure the trunk 90 may be formed so as to have straight edges that meet at corners. A benefit of providing the trunk 90 with non-circular cross-sectional shapes is that it can serve to limit the rotation of the implant 76 in the tissue in which the implant 76 is seated. In certain embodiments, certain structures of the implant 76 may be formed of unitary construction (*e.g.*, the trunk 90 and

the cap 78). Likewise, for ease of manufacture, it may be desirable to form the trunk 90 out of coaxial inner and outer tubes. Further, in certain embodiments, the trunk 90 may be curved or angled along a curved longitudinal axis 300. This feature may be useful to facilitate placement of the implant 76 or the mechanical properties of the implant 76. In certain embodiments, one or both of the proximal and distal anchors 86, 106, may be configured to deploy asymmetrically. This would be particularly suitable for applications where space considerations are present in the intended area of the implant. Additionally or alternatively, the implant 76 may be configured to withstand asymmetric mechanical loading. In certain embodiments, the proximal and distal anchors 86, 106 of the implant 76 of may be configured to be deployed either simultaneously or sequentially.

[0075] In certain embodiments, the proximal anchor 86 may not extend beyond the periphery 306 in the deployed configuration, and/or the distal anchor 106 may not extend beyond the periphery 306 in the expanded state. The deployed configuration and the expanded state may be alternatively defined as the proximal anchor 86 and the distal anchor 106, respectively, simply moving radially outwardly from the longitudinal axis 300 of the trunk 90 (even if not beyond the periphery 306).

[0076] The proximal anchor 86 may be of any suitable construction. For example, a screw-like member may be provided with a threaded shaft having a pointed tip. The screw-type member is deployed by rotating the anchor so the shaft threads into the bone. The shaft threading engages the bone to secure the anchor and, by extension, the implant to the bone. For another example, one or more rigid pins may be provided to deploy by being forced outwardly from the trunk. Another alternative includes a spring that is under tension with the anchor deployed by releasing a member restraining the spring.

[0077] Likewise, the distal anchor 106 may be of any suitable construction. In certain embodiments, the expandable member 312 is formed from a non-compliant material that inflates to a defined shape. An example of a non-compliant material is a synthetic textile such as woven polyester fabric. An outer surface of the expandable member 312 may be impregnated with materials. One such material may be a material to encourage bone growth, and another material may include the therapeutic agent (*e.g.*, a material that reduces the likelihood of infection). It should be understood that that the distal anchor may take the form of an outwardly buckling assembly and the proximal anchor take the form of an inflatable expandable member.

[0078] The tool 30 may include the additional and/or alternative components for deploying the implant 76. These components may include solid shafts that are moved longitudinally relative to the tool handle 32. Each shaft is advanced or retracted to deploy the anchor that the shaft engages. Likewise, other means than threading may be used to releasably hold the implant 76 to the tool 30. For example, for some versions of the disclosure, the tool 30 may be formed with fingers that retract or contract. The implant 76 is formed with complementary openings for receiving the distally located tips of these fingers. Once the implant 76 is set the fingers are retracted or contracted away from the openings in which they are seated so as to disconnect the tool 30 from the implant 76.

[0079] The cannula (*e.g.*, the delivery cannula 86 or the cannula 190) itself may be comprised of a flexible material to allow the cannula to exit the opening and deliver injectable material distally of the implant 76 through that opening. For example, cannula may be comprised of a superelastic metallic material, such as nitinol, that possesses a preset curved shape that allows it to exit the opening in the implant 76 and deliver injectable material to a tissue location a certain distance away from the implant 76. It is further contemplated that another instrument may be

deployed through the bore 102, for example, a curette that is used to form a cavity around the implant 76.

[0080] Variations in the above described exemplary methods are also contemplated. The borehole 126 in which the implant is fitted may have a diameter equal to or less than the diameter of the trunk 90 of the implant 76. For example, the diameter of the borehole 126 is less than the diameter of the trunk 90, by 1 mm or less. In such an example, there is a compression or interference fit between the trunk 90 and the tissue surrounding the trunk 90. In certain methods, the tool 30 are arranged to hold the trunk 90 of the implant 76 static while the tool 30 is advanced distally (as opposed to retracted proximally) to provide the compressive force to induce buckling of the proximal anchor 86. Further, it is also contemplated that the adjacent sections of soft tissue may be secured together. For example, the implant 76 may include one or more barbs.

[0081] The foregoing is directed to specific versions of the disclosure. Other versions of the disclosure may have different features. It should likewise be understood that not all versions of the disclosure may have each of the above described features. Likewise, the features of the different versions of the disclosure may be combined. Accordingly, it is an object of the appended claims to cover all such variations and modifications that come within the scope of this disclosure.

CLAIMS

What is claimed is:

1. An implant for a minimally invasive bone stabilization system for preventing relative motion between an ilium and a sacrum, said implant comprising:

an elongate trunk defined between a proximal end configured to be positioned within the ilium, a distal end configured to be positioned within the sacrum such that said elongate trunk extends between the ilium and the sacrum, a bore extending through said elongate trunk, a longitudinal axis defined between said proximal and distal ends, and a periphery defined by an outer surface of said elongate trunk;

a proximal anchor comprising at least one deformable feature adapted to move between an initial configuration in which said deformable feature is within said periphery of said elongate trunk, and a deployed configuration in which at least a portion of said deformable feature extends outwardly beyond said periphery of said elongate trunk relative to said longitudinal axis to engage the ilium; and

a distal anchor coupled to said elongate trunk and comprising an expandable member defining an interior in fluid communication with said bore of said elongate trunk with said expandable member adapted to receive injectable material to move between a collapsed state in which said expandable member is within said periphery of said elongate trunk, and an expanded state in which at least a portion of said expandable member extends outwardly beyond said periphery of said elongate trunk relative to said longitudinal axis to engage the sacrum.

2. The implant of claim 1, wherein said elongate trunk is substantially cylindrical and comprising a diameter, wherein said implant further comprises a neck extending distally from said

distal end of said elongate trunk with said expandable member coupled to said neck, wherein said neck comprises a diameter less than said diameter of said elongate trunk to provide space to accommodate said expandable member within said periphery in said collapsed state.

3. The implant of claim 2, further comprising and at least one rib coupled to and extending radially outwardly from said neck such that, with said expandable member coupled to said neck, said rib is located within said interior of said expandable member.

4. The implant of any of claims 1-3, wherein said expandable member is formed from permeable material configured to permit the received injectable material to permeate through the expandable member into the sacrum.

5. The implant of any of claims 1-3, wherein said expandable member further comprises fenestrations configured to permit the received injectable material to pass through said fenestrations into the sacrum.

6. The implant of any of claims 1-5, wherein said at least one deformable feature is adapted to buckle into two portions separated by an elbow.

7. The implant of any of claims 1-6, wherein said proximal anchor further comprises a plurality of apertures defining said at least one deformable feature interposed between each adjacent pair of said apertures, wherein said apertures are configured to localized stresses to said deformable feature from compressive loads applied to said proximal anchor to induce deformation

of said deformable feature and move said deformable feature from said initial configuration to said deployed configuration.

8. The implant of claim 7, wherein said plurality of apertures extend through and are circumferentially arranged about said proximal anchor.

9. The implant of claims 7 or 8, wherein said plurality of apertures are oval-shaped and each comprising a major axis and a minor axis with said major axes oriented parallel to said longitudinal axis.

10. The implant of any of claims 1-6, wherein said proximal anchor further comprises further comprises a plurality of slots extending through and circumferentially arranged about an outer surface of said proximal anchor with each adjacent pair of said slots defining said deformable feature therebetween comprising a strut, wherein said slots are configured to localized stresses to said struts from the compressive loads applied and induce bowing of said struts.

11. The implant of any of claims 7-10, further comprising a stem extending proximally from said proximal end of said elongate trunk and comprising a diameter less than said diameter of said elongate trunk, and driven features configured to engage complimentary drive features of an insertion tool.

12. The implant of claim 11, further comprising a cap coupled to and rotatably fixed relative to said elongate trunk with said cap defining a cavity adapted to receive an inner shaft of

the insertion tool and comprising engagement features configured to engage complimentary engagement features of the insertion tool.

13. The implant of any of claims 1-12, further comprising an orifice extending through said outer surface of said elongate trunk and in fluid communication with said bore with said orifice configured to deliver material between the ilium and sacrum.

14. The implant of any of claims 1-12, further comprising an recess extending inwardly through a portion of said outer surface of said elongate trunk and sized to receive tissue growth-promoting material with said recess between said proximal and distal ends such that, with said proximal end positioned in the ilium and said distal end positioned within the sacrum, said recess configured to provide the tissue growth-promoting material between the ilium and the sacrum.

15. An implant for a minimally invasive bone stabilization system for preventing relative motion between an ilium and a sacrum, said implant comprising:

an elongate trunk defined between a proximal end configured to be positioned within the ilium, a distal end configured to be positioned within the sacrum such that said elongate trunk extends between the ilium and the sacrum, a longitudinal axis defined between said proximal and distal ends, and a periphery defined by an outer surface of said elongate trunk;

a stem extending proximally from said proximal end of said elongate trunk and comprising driven features configured to engage complimentary drive features of an insertion tool;

a proximal anchor comprising:

engagement features coupled to said elongate trunk and configured to engage complimentary engagement features of the insertion tool;

deformable features arranged about said outer surface of said proximal anchor with said deformable features adapted to deform in response to compressive loads applied to said proximal anchor such that at least a portion of said deformable features extend beyond said periphery of said elongate trunk relative to said longitudinal axis to engage the ilium; and

a distal anchor coupled to said elongate trunk configured to engage the sacrum.

16. The implant of claim 15, further comprising a plurality of apertures extending through and circumferentially arranged about an outer surface of said proximal anchor with each adjacent pair of said apertures defining said deformable feature therebetween, wherein said apertures are configured to localized stresses to said deformable features from the compressive loads applied and induce the deformation of said deformable features.

17. The implant of claim 16, wherein said plurality of apertures are oval-shaped and each comprising a major axis and a minor axis with said major axes oriented parallel to said longitudinal axis.

18. The implant of claims 16 or 17, wherein a width of each said deformable features is smallest between said minor axes of said adjacent pairs of said apertures such that the localized stresses induce buckling of said deformable features at said widths.

19. The implant of claim 15, further comprising a plurality of slots extending through and circumferentially arranged about an outer surface of said proximal anchor with each adjacent pair of said slots defining said deformable feature therebetween comprising a strut, wherein said slots are configured to localized stresses to said struts from the compressive loads applied and induce bowing of said struts.

20. An implant for a stabilization system for preventing relative motion between an ilium and a sacrum, said implant comprising:

an elongate trunk defined between a proximal end configured to be positioned within the ilium, a distal end configured to be positioned within the sacrum such that said elongate trunk extends between the ilium and the sacrum, a bore extending through said elongate trunk, a longitudinal axis defined between said proximal and distal ends, and a periphery defined by an outer surface of said elongate trunk;

a proximal anchor configured to engage the ilium;

a neck extending distally from said distal end of said elongate trunk;

an expandable member coupled to said neck and defining an interior in fluid communication with said bore of said elongate trunk, wherein said interior of said expandable member is adapted to receive injectable material to expand outwardly beyond said periphery of said elongate trunk relative to said longitudinal axis to engage the sacrum.

21. The implant of claim 20, wherein said elongate trunk is cylindrical and further comprises a diameter with said neck further comprising a diameter less than said diameter of said elongate trunk to provide space to accommodate said expandable member within said periphery

prior to said interior receiving the injectable material and expanding outwardly beyond said periphery.

22. The implant of claims 20 or 21, wherein the injectable material comprises a curable material further comprising a gripping feature coupled to said neck and disposed within said interior of said expandable member such that the curable material injected into the expandable member contacts said gripping feature to, once cured, fixedly engage said neck.

23. The implant of any of claims 19-21, wherein at least a portion of said expandable member is formed from permeable material configured to permit the injectable material received from an injectable material delivery system to permeate through the expandable member into the sacrum.

24. A minimally invasive bone stabilization system for preventing relative motion between an ilium and a sacrum, said system comprising:

an insertion tool comprising:

a driver configured to receive a rotational input;

a first shaft comprising a distal end and engagement features near said distal end;

a second shaft disposed within said first shaft with said second shaft comprising a proximal end coupled to said driver, and a distal end opposite said proximal end, and drive features near said distal end;

an implant adapted to be removably coupled to said insertion tool and comprising:

an elongate trunk defined between a distal end and a proximal end, a longitudinal axis defined between said proximal and distal ends, a periphery defined by an outer surface of said elongate trunk;

driven features coupled to said elongate trunk and configured to engage said drive features of said insertion tool;

an engagement feature coupled to said elongate trunk and configured to engage said engagement features of the insertion tool to prevent rotation of said elongate trunk relative to said insertion tool such that, in response to said driver receiving the rotational input and with said complimentary engagement features and said complimentary drive features engaged, a compressive load is provided to said implant along said longitudinal axis; and

a proximal anchor configured to engage the ilium and comprising a deformable feature adapted to deform in response to the compressive load, thereby extending at least a portion of said deformable feature beyond said periphery of said elongate trunk relative to said longitudinal axis to engage the ilium.

25. The stabilization system of claim 24, wherein said implant further comprises a plurality of apertures with each adjacent pair of said apertures defining said deformable feature therebetween, wherein said apertures are configured to localize stresses to said deformable features from the compressive load to induce buckling of said deformable features.

26. The stabilization system of claim 24 or 25, wherein said implant further comprises a bore extending through said elongate trunk and adapted to be in fluid communication with a lumen extending through said second shaft of said insertion tool when said implant is coupled to said insertion tool, and an expandable member coupled to said elongate trunk configured to engage

the sacrum with said expandable member defining an interior in fluid communication with said bore of said elongate trunk, wherein said expandable member is adapted to receive injectable material from the insertion tool to expand outwardly beyond said periphery of said elongate trunk relative to said longitudinal axis to engage the sacrum.

27. The stabilization system of claim 26, further comprising a delivery cannula insertable within said bore of said implant with said delivery cannula comprising an inlet port configured to be in fluid communication with a source of injectable material and an outlet port configured to be positioned in fluid communication with said interior of said expandable member.

28. The stabilization system of claim 27, wherein said implant further comprises an orifice extending from said bore through said outer surface of said elongate trunk with said delivery cannula slidable within said bore to position said outlet port in fluid communication with said orifice to deliver material between the ilium and sacrum.

29. The stabilization system of claim 27, wherein said proximal anchor further comprises a passageway extending through said proximal anchor and in fluid communication with said bore with said with said delivery cannula slidable within said bore to position said outlet port in fluid communication with said passageway of said proximal anchor to deliver material to the ilium.

30. The stabilization system of any of claims 27-30, wherein said delivery cannula further comprise a closed distal end and an opening within a sidewall proximal to said closed distal end to define said outlet port.

31. A method for preventing relative motion between an ilium and a sacrum with an implant including an elongate trunk having opposed proximal and distal ends defining a longitudinal axis, a periphery defined by an outer surface, and a bore extending through the elongate trunk, the implant further including a proximal anchor, and a distal anchor including an expandable member defining an interior in fluid communication with the bore, said method comprising the steps of:

creating a minimally invasive incision within skin;

positioning an access cannula through the minimally invasive incision;

resecting a borehole through the ilium and into the sacrum through the access cannula;

positioning the implant within the borehole such that the proximal anchor is disposed in the ilium and the distal anchor is disposed in the sacrum;

operating an insertion tool removably coupled to the implant to apply a compressive force to the proximal anchor along the longitudinal axis to move the proximal anchor from an initial configuration in which the proximal anchor is within said periphery of the elongate trunk to a deployed configuration in which at least a portion of a deformable feature of the proximal anchor extends outwardly beyond the periphery of said elongate trunk relative to the longitudinal axis to engage the ilium; and

injecting injectable material through the bore and into the expandable member to move the expandable member between a collapsed state in which said expandable member is within the

periphery of the elongate trunk, and an expanded state in which at least a portion of said expandable member extends outwardly beyond the periphery of the elongate trunk relative to said longitudinal axis to engage the sacrum.

32. The method of claim 31, wherein said step of operating the tool to apply the compressive force to the proximal anchor further comprises the steps of:

operating the tool to engage drive features of a first shaft of the tool with complimentary driven features coupled to the elongate trunk;

operating the insertion tool to engage engagement features coupled to a second shaft of the tool with complimentary engagement features coupled to the elongate trunk to prevent rotation of the proximal anchor relative to the second shaft and prevent an axial movement of a proximal end of the proximal anchor relative to the second shaft;

applying a torque to the insertion tool in a first direction to rotate the first shaft and draw the driven features proximally such that, with rotation of the proximal anchor and axial movement of the proximal end of the proximal anchor prevented, the compressive force is applied to the proximal anchor along the longitudinal axis.

33. The method of claim 31 or 32, wherein said step of moving the proximal anchor from the initial configuration the deployed configuration is performed prior to the step of injecting the injectable material into the expandable member.

34. The method of any of claims 31-33, wherein the implant further comprises an orifice extending through the outer surface of the elongate trunk and in fluid communication with the bore, wherein the method further comprises the steps of:

positioning the implant within the borehole with the orifice approximately positioned at an interface between the ilium and the sacrum; and

injecting additional injectable material through the orifice.

35. The method of any of claims 31-34, further comprising the step of decoupling the insertion tool from the implant by applying a torque to the insertion tool in a second direction opposite to the first direction to rotate the first shaft such that, with the proximal anchor in the deployed configuration and engaging the ilium, rotation of the first shaft decouples the drive features from the complimentary driven features of the implant.

36. The method of any of claims 31-35, wherein the injectable material is curable material, said method further comprising the step of allowing the curable material to cure with the expandable member engaging the sacrum in the expanded state.

37. The method of claim 36, wherein the expandable member is formed from permeable material, said method further comprising the step of injecting additional curable material into the expandable member such that a portion of the curable material is urged through the permeable material into the sacrum.

38. The method of any of claims 31-37, wherein the sacrum includes an exterior cortical bone wall and interior cancellous bone region, said method further comprising the steps of:

positioning the implant within the borehole with the expandable member disposed within the interior cancellous bone region; and

performing the step of injecting the injectable material into the expandable member with the expandable member disposed within the interior cancellous bone region.

39. An implant for a stabilization system for preventing relative motion between a first bone and a second bone, said implant comprising:

an elongate trunk defined between a proximal end configured to be positioned within the first bone, a distal end configured to be positioned within the second bone such that said elongate trunk extends between the first and second bones, a bore extending through said elongate trunk, a longitudinal axis defined between said proximal and distal ends, and a periphery defined by an outer surface of said elongate trunk;

a proximal anchor comprising at least one deformable feature adapted to move between an initial configuration in which said deformable feature is within said periphery of said elongate trunk, and a deployed configuration in which at least a portion of said deformable feature extends outwardly beyond said periphery of said elongate trunk relative to said longitudinal axis to engage the first bone; and

a distal anchor coupled to said elongate trunk and comprising an expandable member defining an interior in fluid communication with said bore of said elongate trunk with said expandable member adapted to receive injectable material to move between a collapsed state in

which said expandable member is within said periphery of said elongate trunk, and an expanded state in which at least a portion of said expandable member extends outwardly beyond said periphery of said elongate trunk relative to said longitudinal axis to engage the second bone.

40. A method for preventing relative motion between an ilium and a sacrum of a patient with an implant including an elongate trunk having opposed proximal and distal ends, a bore extending through the elongate trunk, a proximal anchor, and a distal anchor including an expandable member defining an interior in fluid communication with the bore, said method comprising the steps of:

creating a minimally invasive incision within skin;

positioning an access cannula through the minimally invasive incision;

resecting a borehole through the ilium and into the sacrum through the access cannula;

positioning the implant within the borehole;

deploying the proximal anchor to engage the ilium;

injecting an injectable material comprising a curable material through the bore and into the interior of the expandable member to expand the expandable member outwardly to engage the sacrum;

permitting the curable material to cure within the interior of the expandable member with the expandable member engaging the sacrum;

removing the access cannula through the minimally invasive incision; and

closing the minimally invasive incision with the expandable member and curable material remaining within the patient.

41. The method of claim 40, further comprising the step of withdrawing the access cannula after the implant is positioned within the borehole.

42. The method of claim 40, wherein the implant is cannulated, said further comprising the steps of:

positioning a guidewire through the access cannula to engage the sacrum;

withdrawing the access cannula; and

directing the cannulated implant along the guidewire to positioning the implant within the borehole.

43. The method of any of claims 40-42, further comprising the steps of:

providing an insertion tool comprising a shaft extending from a handpiece; and

removably coupling the implant to a distal end of the shaft prior to positioning the implant within the borehole.

44. The method of claim 43, further comprising the steps of:

inserting a delivery cannula within the bore of the implant; and

positioning an outlet port of the delivery cannula in fluid communication with the interior of the expandable member.

45. The method of claim 44, wherein the implant further comprises an orifice extending through the elongate trunk and in fluid communication with the bore, said method further comprising the steps of:

positioning the outlet port of the delivery cannula in fluid communication with the orifice of the implant and not in fluid communication with the interior of the expandable member; and

injecting additional injectable material into the delivery cannula and through the orifice.

46. The method of claims 45, wherein the proximal anchor comprises a passageway extending through the proximal anchor, said method further comprising the step of:

positioning the outlet port of the delivery cannula in fluid communication with the passageway of the proximal anchor and not in fluid communication with the interior of the expandable member and the orifice; and

injecting additional injectable material into the delivery cannula and through the passageway.

47. The method of claim 46, further comprising the step of decoupling the implant from the distal end of the shaft of the installation tool with the delivery cannula remaining coupled to the implant positioned within the borehole.

48. The method of claim 47, wherein the delivery cannula has a length defined between opposing ends such that, with the delivery cannula remaining coupled to the implant positioned within the borehole, the delivery cannula extends through the minimally invasive incision and one of the opposing ends is above the skin of the patient

49. The method of any of claims 44-48, further comprising the steps of:

coupling a curable material delivery system in communication with a source of curable material to the delivery cannula; and

operating the curable material delivery system to perform the step of injecting the curable material through the bore.

50. The method of any of claims 40-49, wherein the expandable member is formed from permeable material with said method further comprising the step of injecting additional curable material into the interior of the expandable member such that a portion of the curable material is urged through the permeable material and into contact with the sacrum.

51. The method of any of claims 40-50, wherein the expandable member comprises fenestrations with said method further comprising the step of injecting additional curable material into the interior of the expandable member such that a portion of the curable material is urged through the fenestrations and into contact with the sacrum.

52. The method of any of claims 40-51, wherein the implant includes a neck extending distally from the elongate trunk and a gripping feature coupled to the neck and positioned within the interior of the expandable member, said method further comprising the steps of:

injecting the curable material through the bore and into the interior of the expandable member such that the curable material surrounds the neck and is in contact with the gripping feature; and

permitting the curable material in contact with the gripping feature to cure to facilitate axial retention of the implant within the cured curable material.

53. The method of any of claims 40-52, wherein the implant is a first implant, said method further comprising the step of prior to the step of injecting curable material through the bore of the first implant, positioning a second implant through a second minimally invasive incision and within a second borehole with a proximal anchor of the second implant engaging the ilium and a distal anchor of the second implant disposed in the sacrum.

54. The method of claim 53, further comprising the steps of:

removably coupling the second implant to the distal end of the shaft of the installation tool prior to positioning the second implant within the second borehole; and

decoupling the second implant from the distal end of the shaft of the installation tool with a second delivery cannula remaining coupled to the second implant positioned within the second borehole such that the delivery cannulas of the first and second implants extend through the first and second minimally invasive incisions, respectively, prior to both the first implant and second implants receiving the curable material.

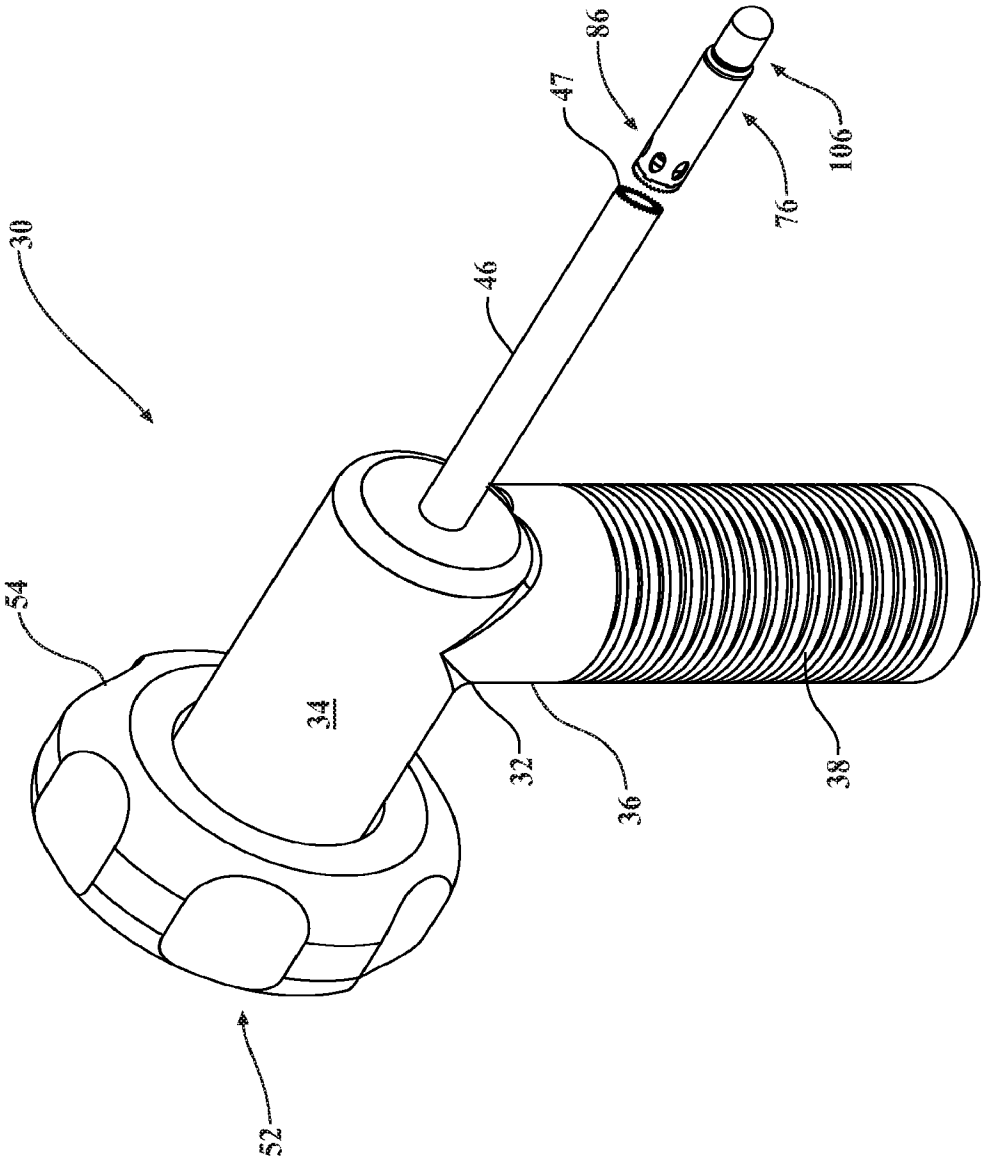


FIG. 1

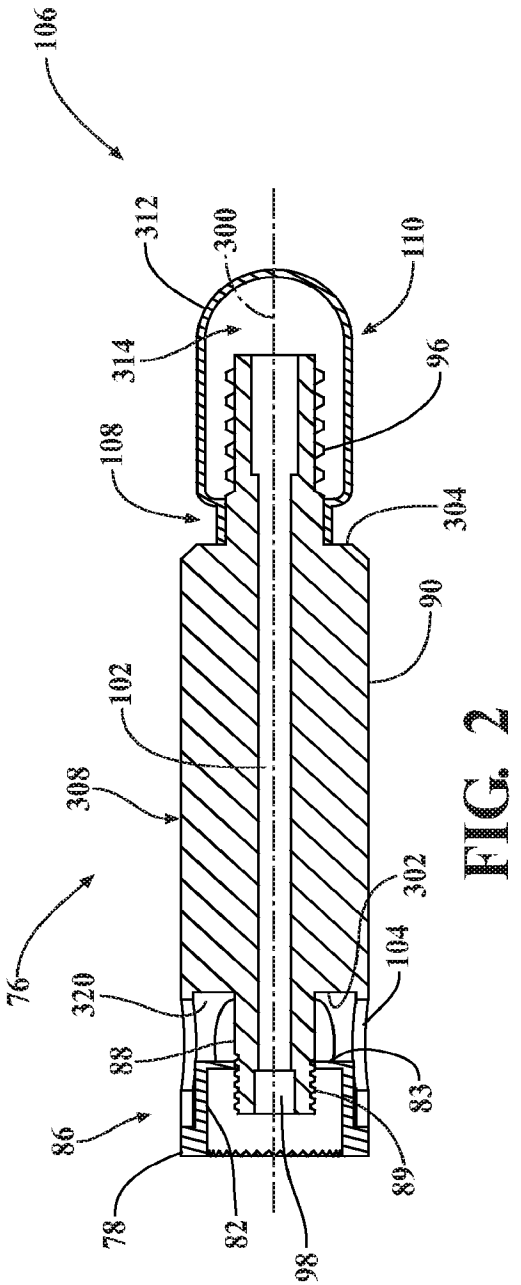

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FIG. 2

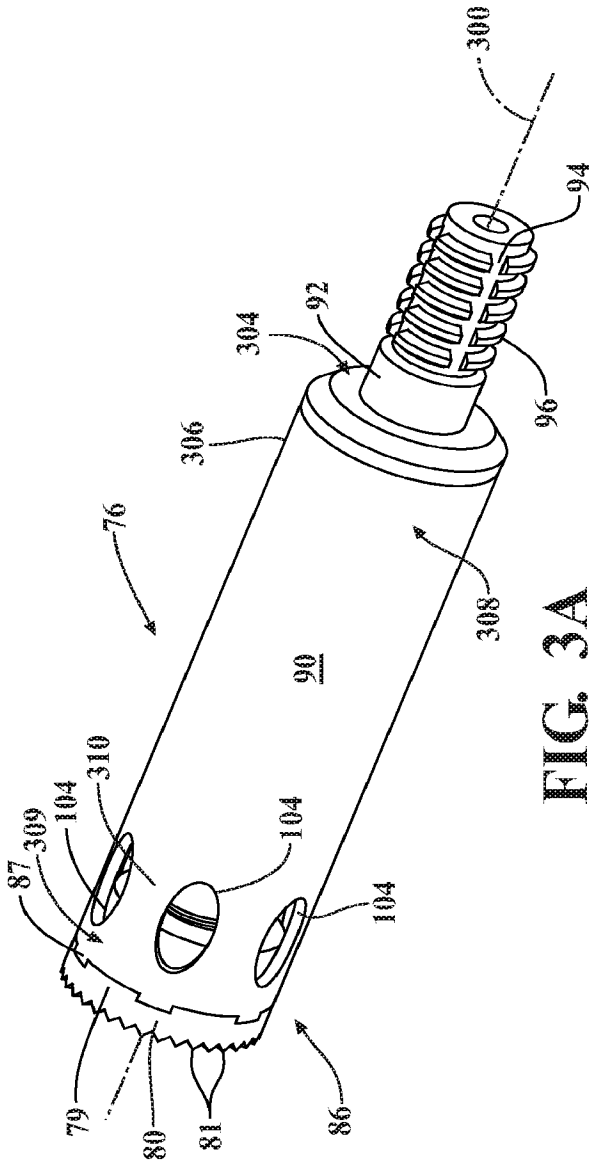

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FIG. 3A

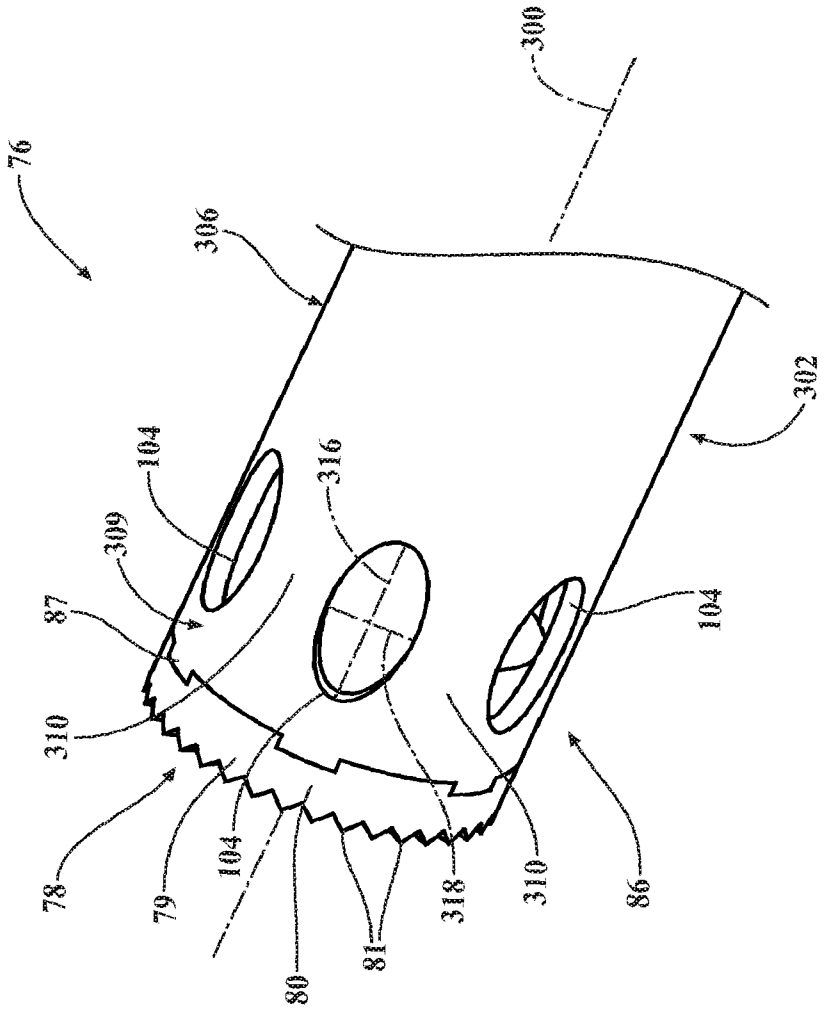


FIG. 3B

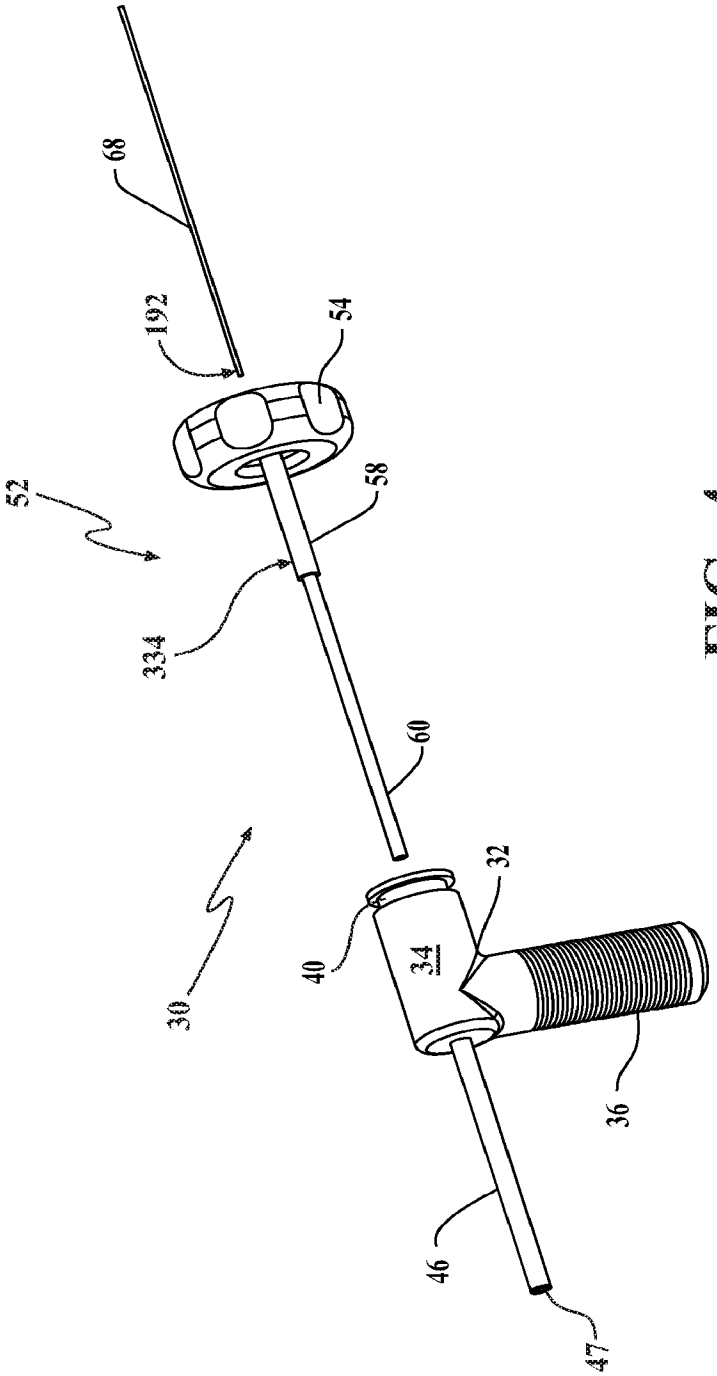


FIG. 4

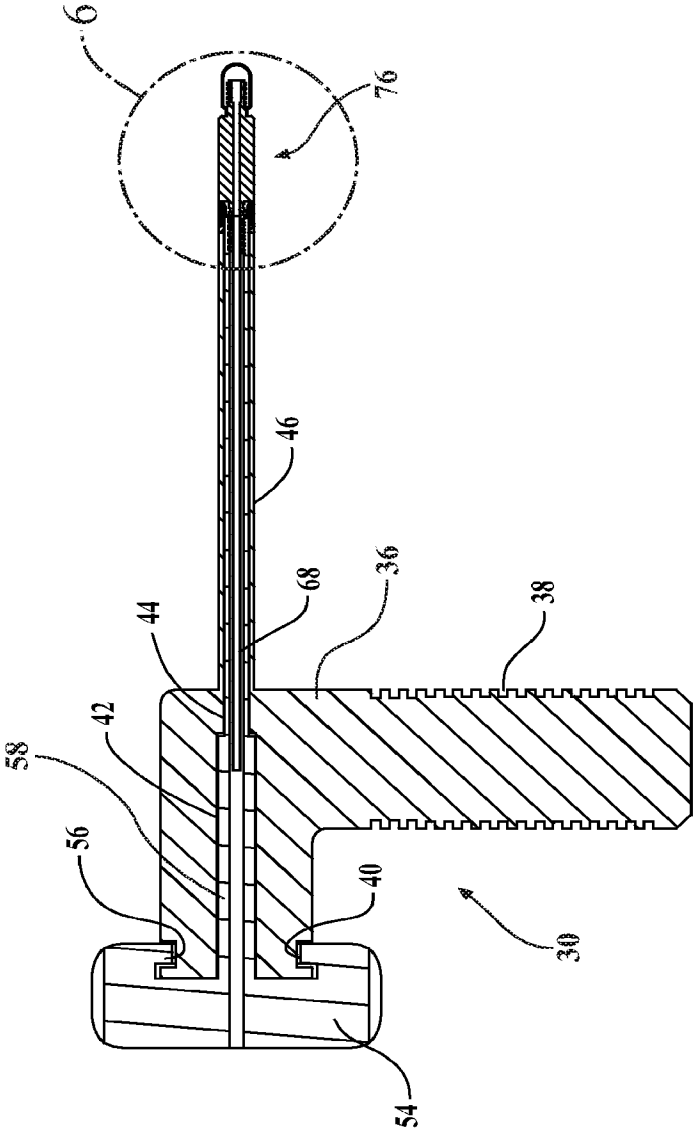

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FIG. 5

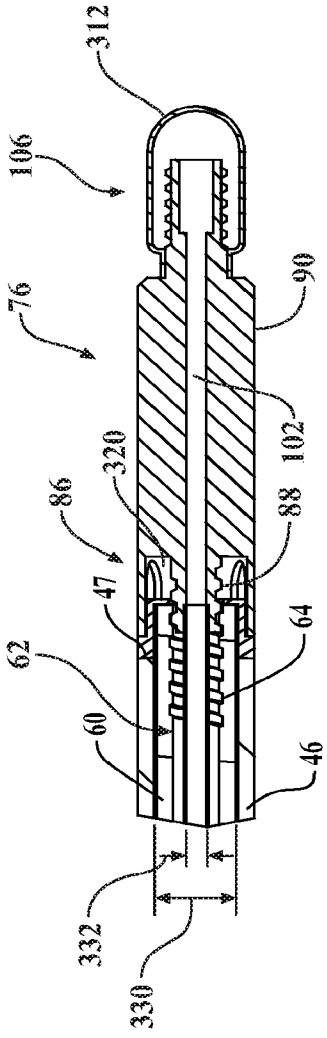

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FIG. 6

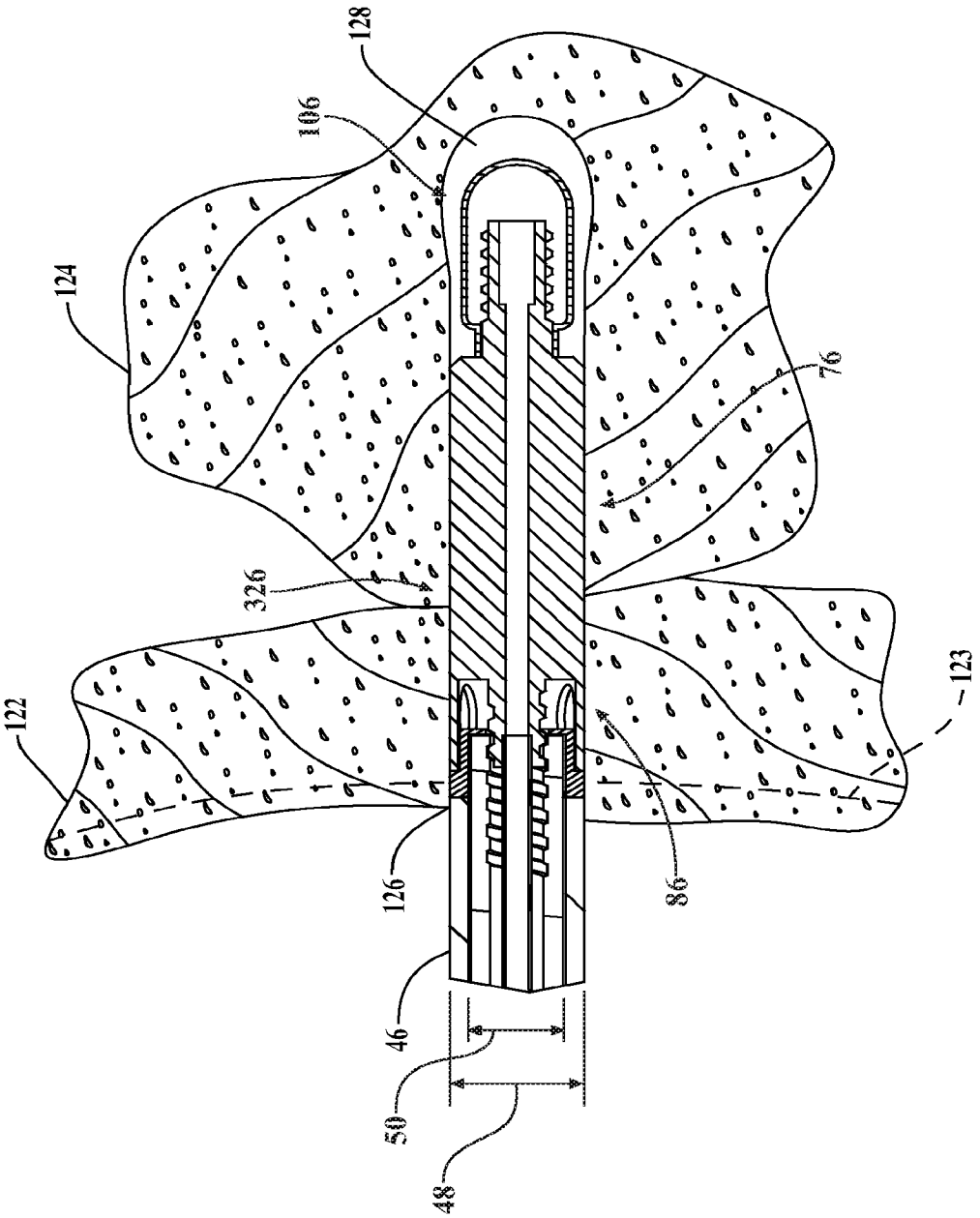


FIG. 7

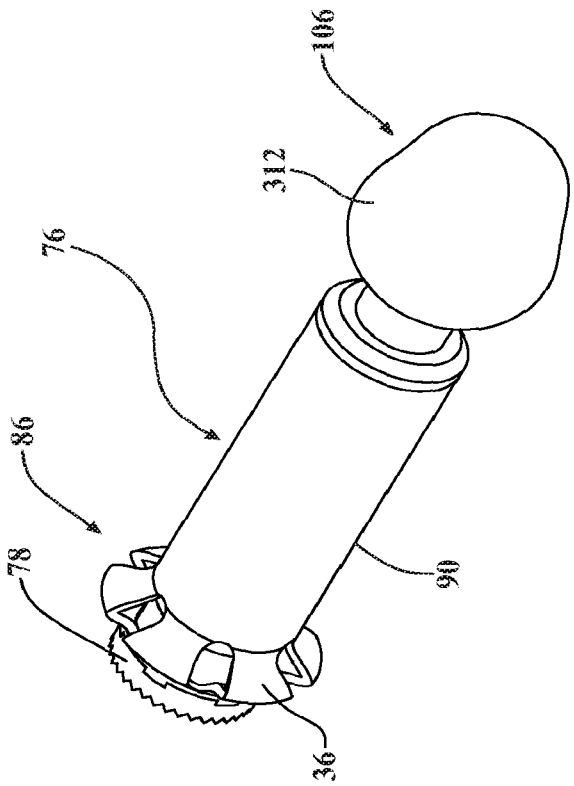


FIG. 8

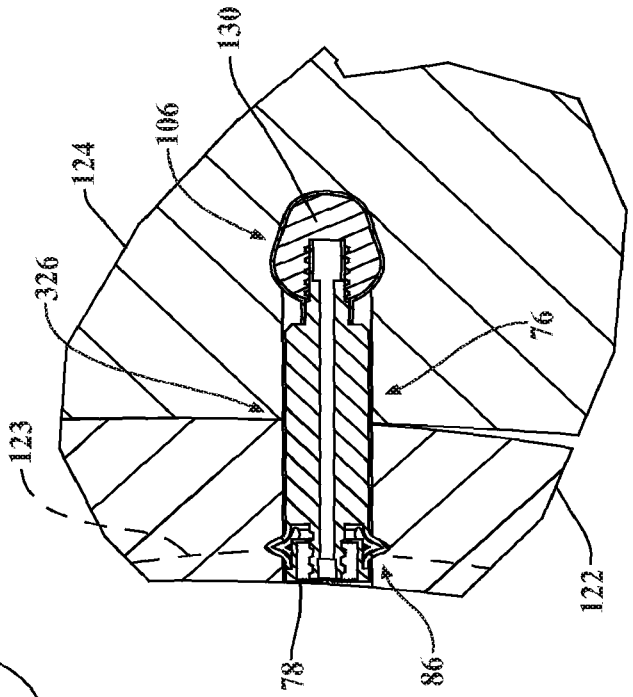


FIG. 9

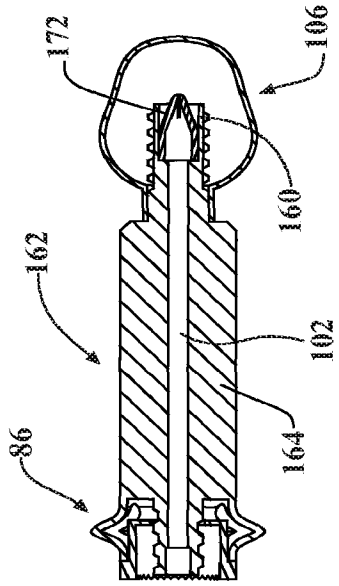


FIG. 12

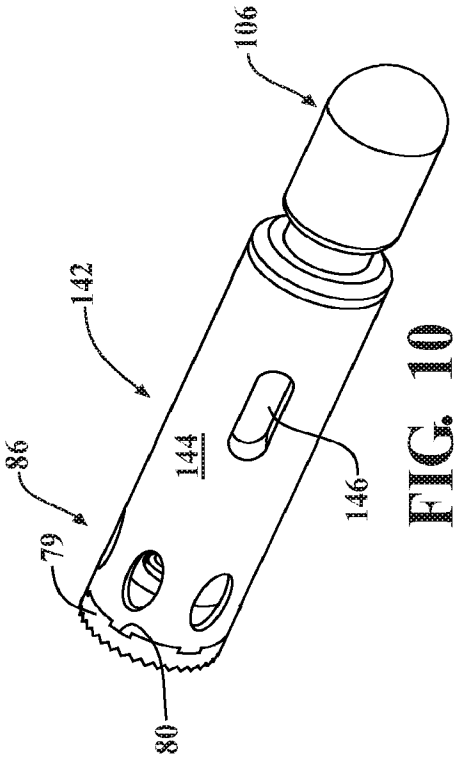


FIG. 10

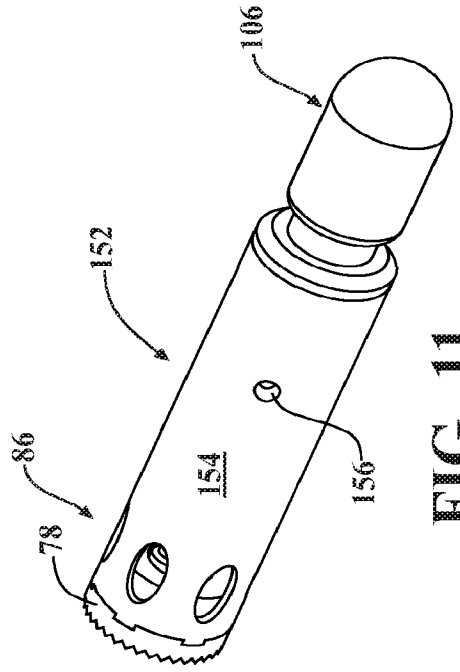


FIG. 11

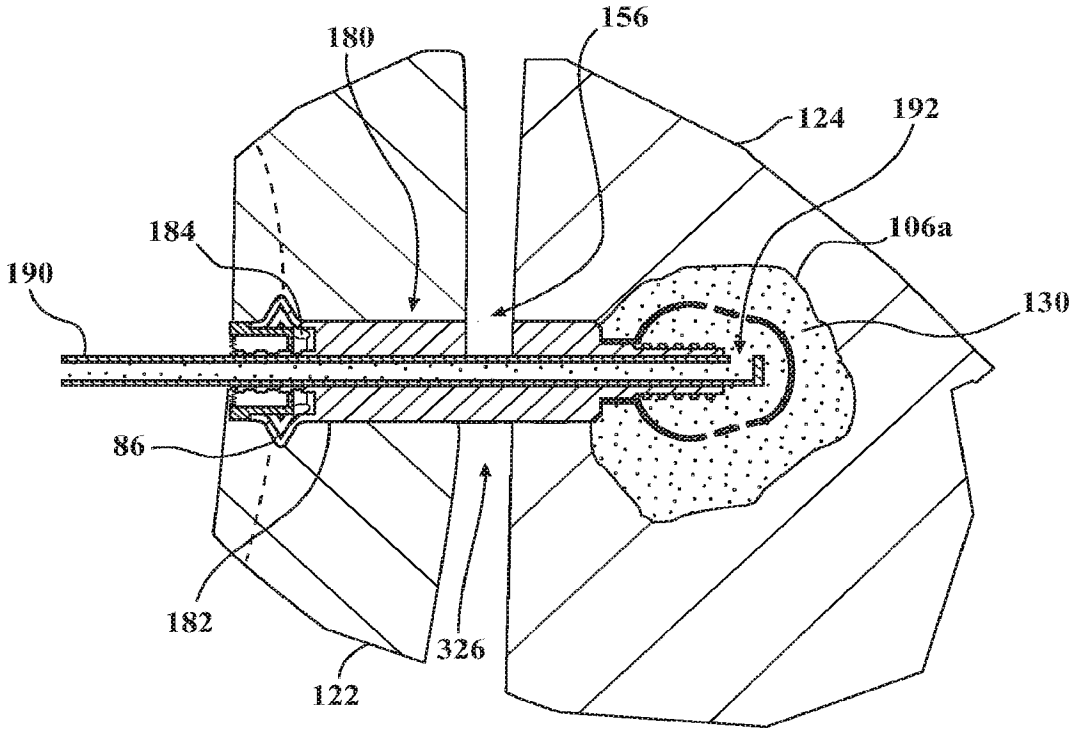


FIG. 13A

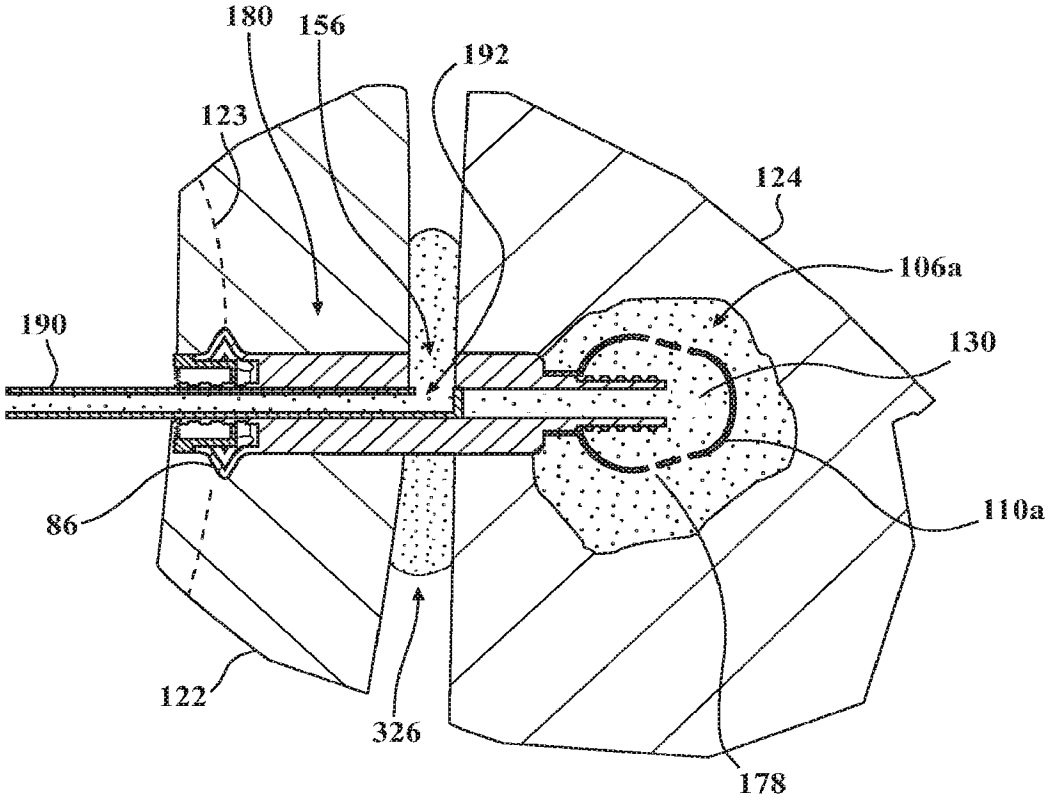


FIG. 13B

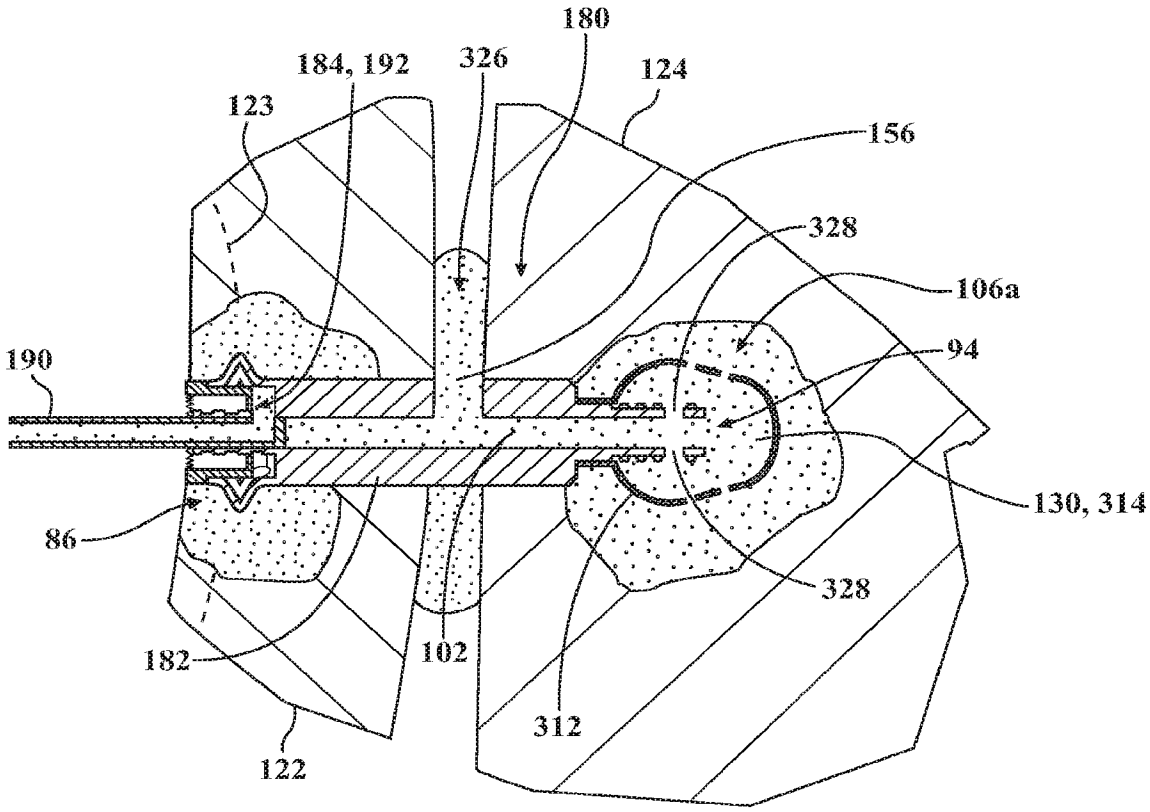

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FIG. 13C

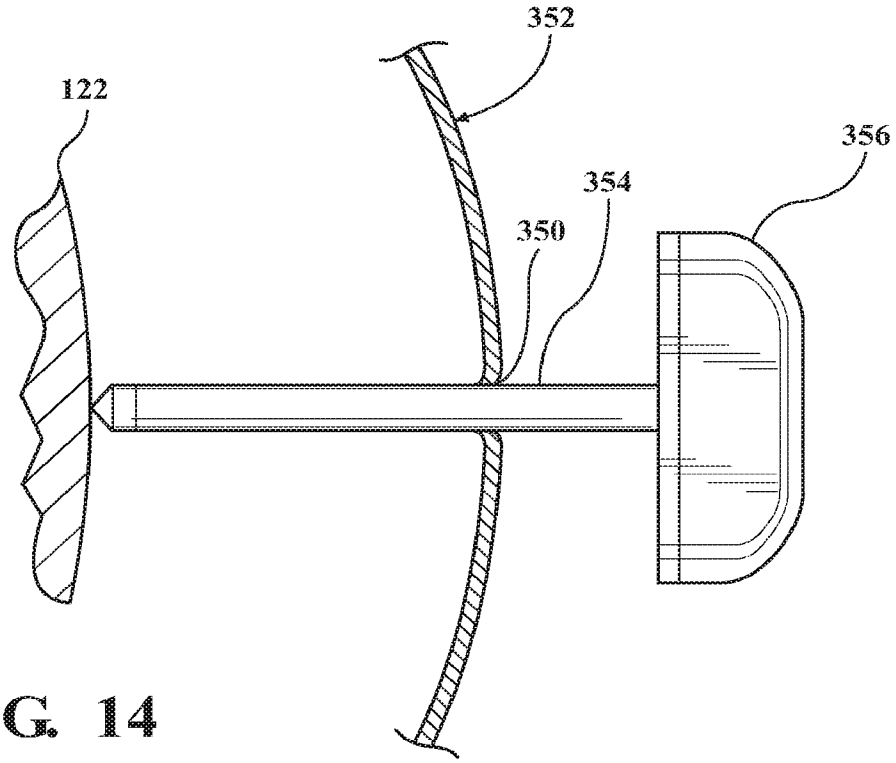


FIG. 14

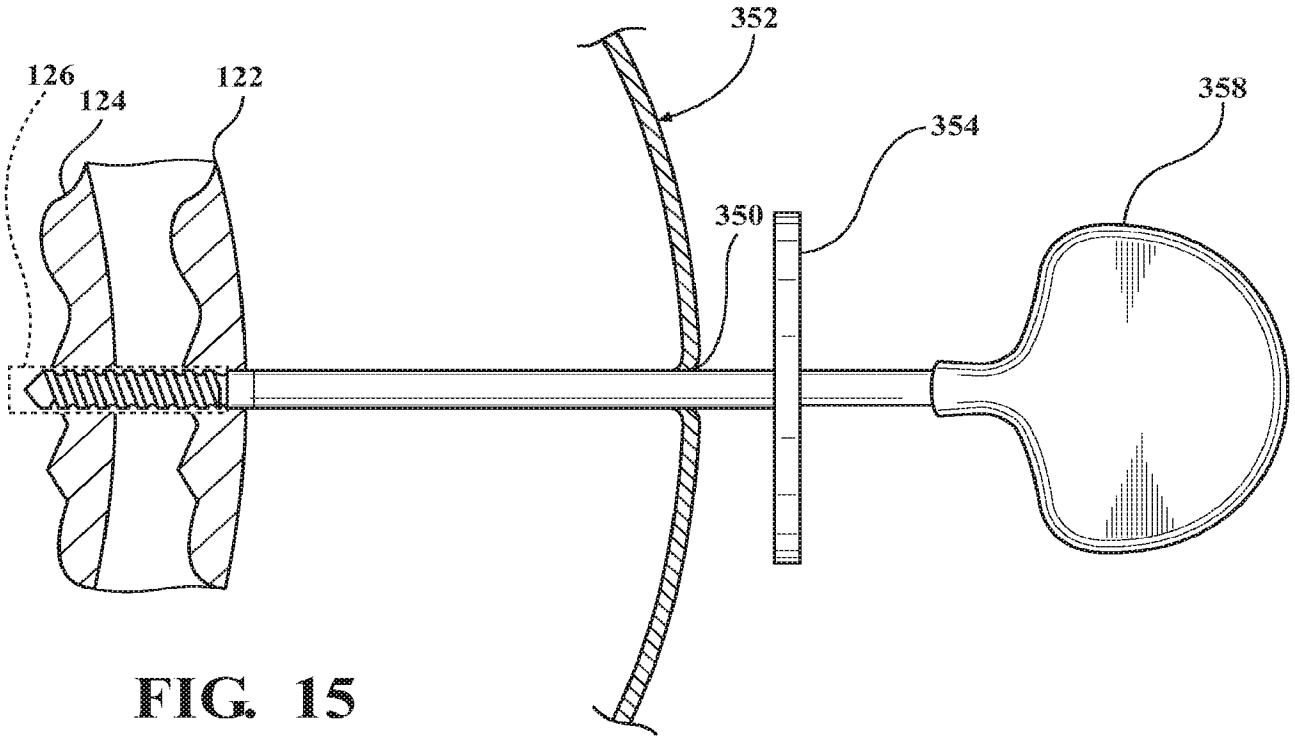


FIG. 15

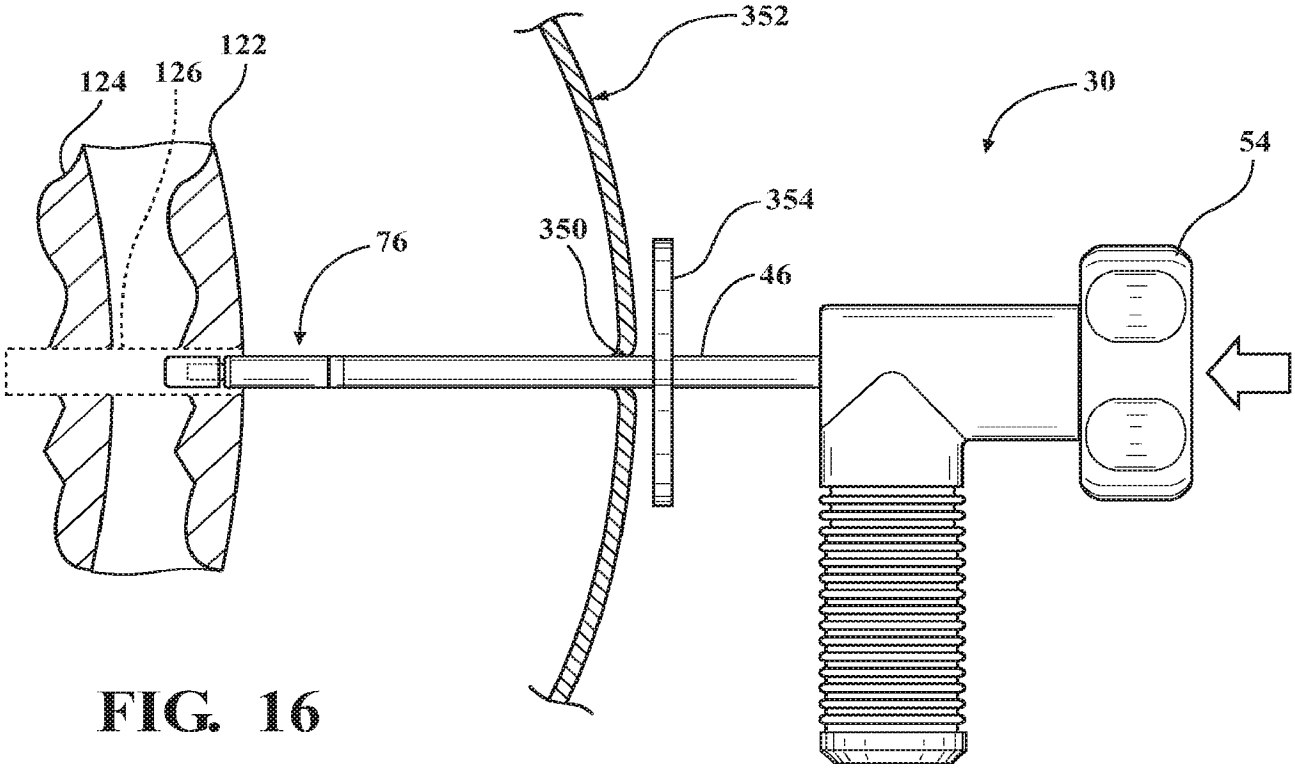

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FIG. 16

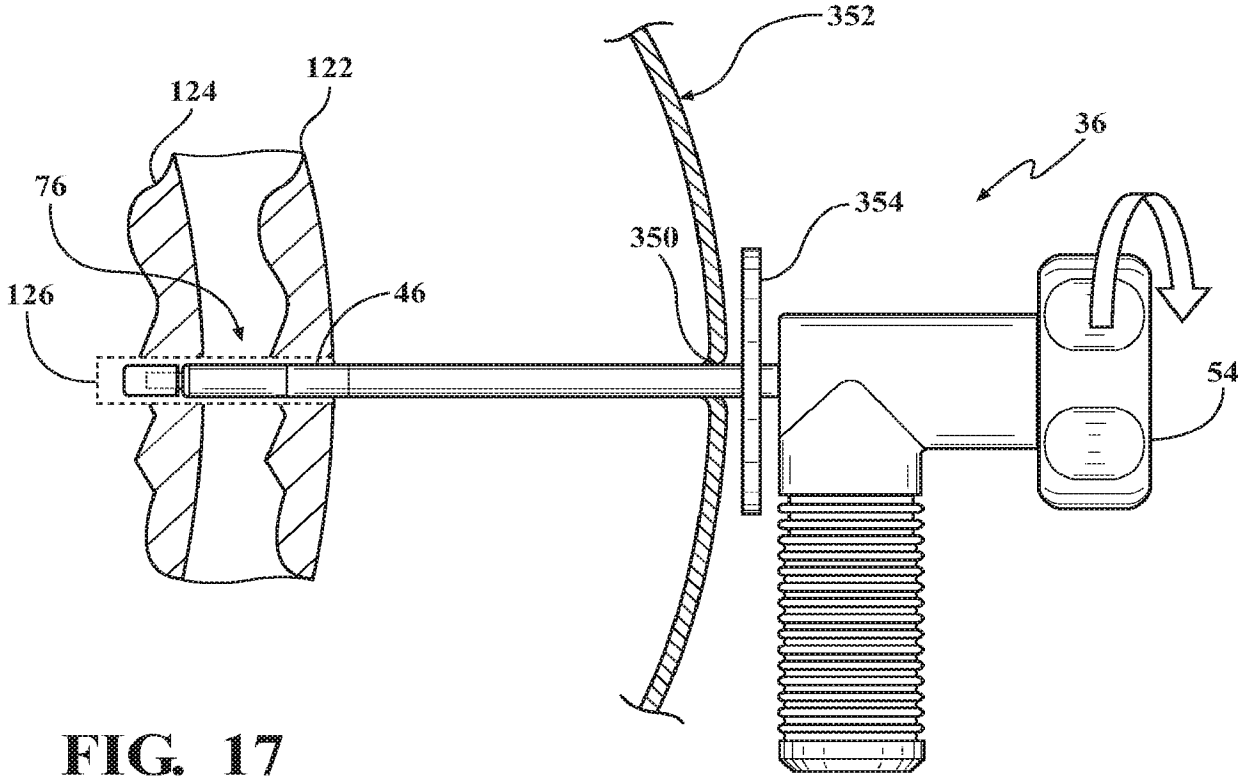
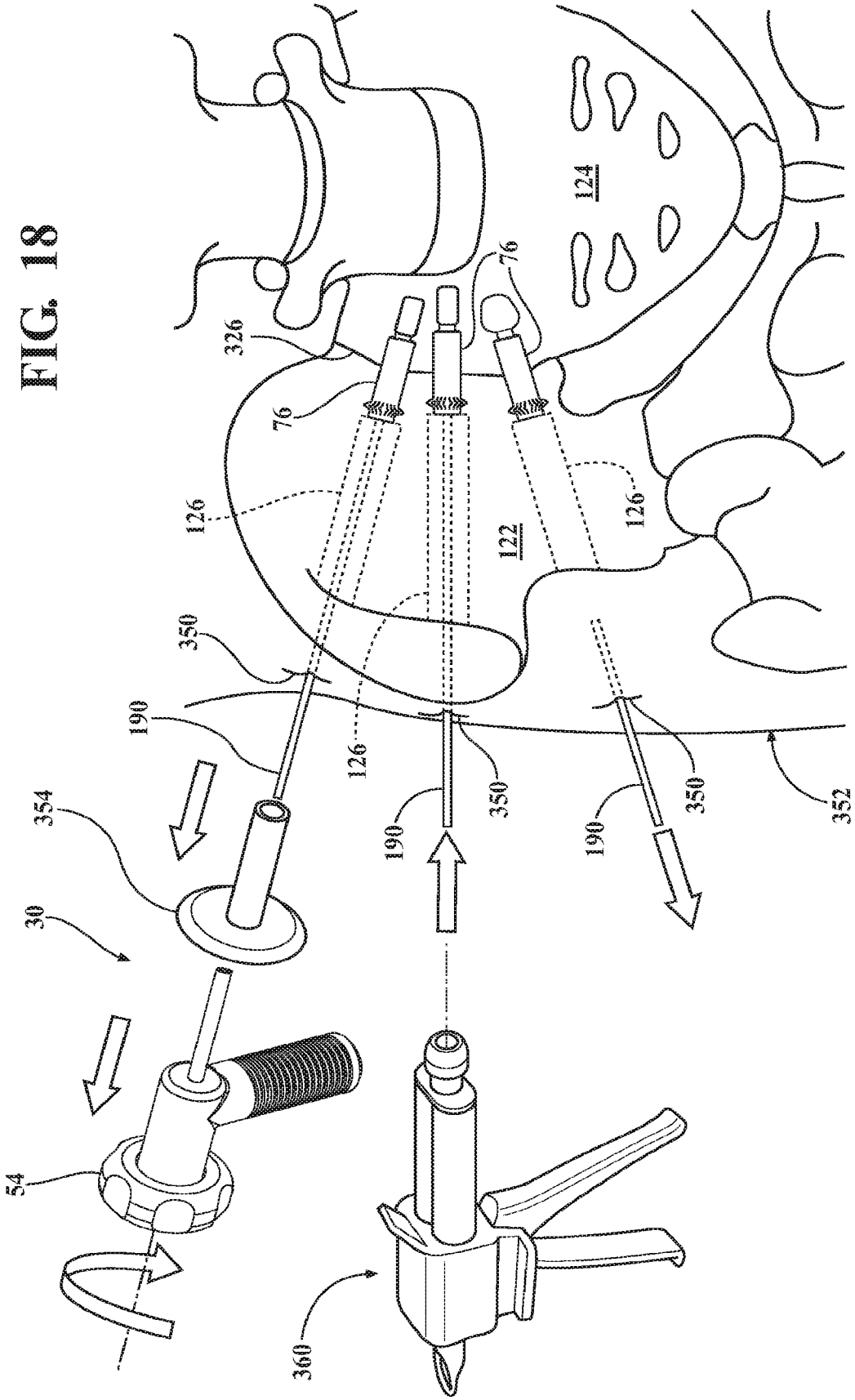

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FIG. 17

FIG. 18


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INTERNATIONAL SEARCH REPORT

International application No
PCT/US2018/028546

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/68 A61B17/70 A61B17/84 A61B17/88
ADD. A61F2/46 A61F2/30 A61B17/86 A61B17/72

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

B. FIELDS SEARCHED

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

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2012/015976 A1 (GINN RICHARD S [US]) 2 February 2012 (2012-02-02) page 9, line 19 - page 10, line 2; figures 4A-4G page 10, line 15 - page 11, line 10; figures 5B, 5C	1-14,39
X	US 2005/113919 A1 (CRAGG ANDREW H [US] ET AL) 26 May 2005 (2005-05-26) paragraph [0161] - paragraph [0164]; figures 11-13	1,39

-/--

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

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
27 June 2018	29/08/2018

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

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

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2018/028546

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2008/112308 A1 (STOUT MEDICAL GROUP LP [US]; GREENHALGH E SKOTT [US]; ROMANO JOHN PAUL) 18 September 2008 (2008-09-18) paragraph [0263] - paragraph [0266]; figures 165-168 paragraph [0198] - paragraph [0201]; figures 72-75 paragraph [0159] - paragraph [0161]; figures 25-27	1,39
X	WO 2010/105196 A1 (UNIV TOLEDO [US]; GOEL VIJAY K [US]; MATYAS AARON [US]) 16 September 2010 (2010-09-16) paragraph [0039] - paragraph [0041]; figures 7A-7C	1,2,5-8, 13,14
A	US 2013/053902 A1 (TRUDEAU JEFFREY L [US]) 28 February 2013 (2013-02-28) paragraph [0086] - paragraph [0087]; figures 11, 23,29	1,39

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2018/028546

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2012015976 A1	02-02-2012	AU 2011282746 A1	21-02-2013
		BR 112013002081 A2	30-01-2018
		CA 2806755 A1	02-02-2012
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		EP 3372179 A1	12-09-2018
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		WO 2010105196 A1	16-09-2010
US 2013053902 A1	28-02-2013	US 2013053902 A1	28-02-2013
		US 2015359578 A1	17-12-2015

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2018/028546

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 31-38, 40-54
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [X] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1-14, 39

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-14, 39

   Deployable Implant with further expandable distal anchor actuated by injectable material.

   ---

2. claims: 15-19

   Implant with a deployable proximal anchor deformed in response to compressive loads.

   ---

3. claims: 20-23

   Fix implant with an balloon attached distally.

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4. claims: 24-30

   Insertion tool and implant with a single deployable proximal anchor deformed in response to compressive loads provided the rotational input of said tool.

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(12) PATENT
(19) AUSTRALIAN PATENT OFFICE

(11) Application No. AU 199877415 B2
(10) Patent No. 726979

(54) Title
Apparatus and method of inserting spinal implants

(51)[6] International Patent Classification(s)
A61B 017/88

(21) Application No: 199877415

(22) Application Date: 1998.07.21

(43) Publication Date : 1998.10.01
(43) Publication Journal Date : 1998.10.01
(44) Accepted Journal Date : 2000.11.30

(62) Divisional of:
199471399

(71) Applicant(s)
Karlin Technology, Inc.

(72) Inventor(s)
Gary Karlin Michelson

(74) Agent/Attorney
SPRUSON and FERGUSON,GPO Box 3898,SYDNEY NSW 2001

(56) Related Art
SU 1063397
WO 94/17759
US 5484437

Apparatus and Method of Inserting Spinal Implants

Abstract

A spinal distractor (100) for use in spinal surgery for positioning two adjacent vertebrae in selected relationship to each other, said spinal distractor comprising:

a body (106); and

a disc penetrating extension (102) extending from said body for insertion into the disc space between the two adjacent vertebrae and for bearing against adjacent endplates of the two adjacent vertebrae, said disc penetrating extension having a first portion for bearing against one of the adjacent endplates and a second portion for bearing against the other of the adjacent endplates.

S & F Ref: 322547D1

AUSTRALIA

PATENTS ACT 1990

COMPLETE SPECIFICATION

FOR A STANDARD PATENT

ORIGINAL

Name and Address of Applicant: Karlin Technology, Inc.
4929 Premier Avenue
Lakewood California 90712
UNITED STATES OF AMERICA

Actual Inventor(s): Gary Karlin Michelson

Address for Service: Spruson & Ferguson, Patent Attorneys
Level 33 St Martins Tower, 31 Market Street
Sydney, New South Wales, 2000, Australia

Invention Title: Apparatus and Method of Inserting Spinal Implants

The following statement is a full description of this invention, including the best method of performing it known to me/us:-

Apparatus and Method of Inserting Spinal Implants

Background of the Invention

1. Field of the Invention

The present invention relates to artificial fusion implants to be placed into the intervertebral space left remaining after the removal of a damaged spinal disc and specifically to the apparatus for and method of, inserting the implants.

2. Description of the Prior Art

For the purpose of achieving long term stability to a segment of injured spine, a fusion (the joining together of two or more bones via a continuous bridge of incorporated bone) may be performed. Well-known to those skilled in such art is the interbody fusion wherein the disc is partially excised and bone placed within that space previously occupied by that disc material (between adjacent vertebrae) for the purpose of restoring a more normal spatial relationship, and to provide for stability; short term by mechanical support, and long term by the permanent cross bonding of bone from vertebra to vertebra. For fusion to occur within the disc space, it is necessary to

prepare the vertebrae to be fused by breaking through, or cutting into, the hardened outside plates of bone (the endplates) to allow the interposed bone graft to come into direct contact with the more vascular cancellous (spongy) bone, and to thereby trick the body into attempting to heal this induced, but controlled, "fracturing" by both bone production and the healing of the grafts to both opposed vertebral surfaces such that they become one continuous segment of bone.

The purpose of the present invention is to provide an implant, and the apparatus and method of inserting the implant within the intervertebral space left after the removal of the disc material and permanently eliminate all motion at that location. To do so, the device of the present invention is space occupying within the disc interspace, rigid, self-stabilizing to resist dislodgement, stabilizing to the adjacent spinal vertebrae to eliminate local motion, and able to intrinsically participate in a vertebra to vertebra bony fusion so as to assure the permanency of the result.

At present, following the removal of a damaged disc, either bone or nothing is placed into the remaining space. Placing nothing into this space allows the space to collapse which may result in damage to the nerves; or the space may fill with scar tissue and eventually lead to a reherniation. The use of bone to fill the space is less than optimal in that bone obtained from the patient requires additional surgery and is of limited availability

in its most useful form, and if obtained elsewhere, lacks living bone cells, carries a significant risk of infection, and is also limited in supply as it is usually obtained from accident victims. Furthermore, regardless of the source of the bone, it is only marginal structurally and lacks a means to either stabilize itself against dislodgement, or to stabilize the adjacent vertebrae.

a. Prior Art Implants

There have been an extensive number of attempts to develop an acceptable disc prosthesis (an artificial disc). Such devices by design would be used to replace a damaged disc and seek to restore the height of the interspace and to restore the normal motion of that spinal joint. No such device has been found that is medically acceptable. This group of prosthetic or artificial disc replacements, seeking to preserve spinal motion and so are different from the present invention, would include:

U.S. Patent No. 3,867,728 to STUBSTAD - describing a flexible disc implant.

U.S. Patent No. 4,349,921 to KUNTZ - describing a flexible disc replacement with file-like surface projections to discourage device dislocation.

U.S. Patent No. 4,309,777 to PATIL - describing a motion preserving implant with spiked outer surfaces to resist dislocation and containing a series of springs to urge the vertebrae away from each other.

U.S. Patent No. 3,875,595 to FRONING - describing

a motion preserving bladder-like disc replacement with two opposed stud-like projections to resist dislocation.

Patent No. 2,372,622 to FASSIO (France) - describing a motion preserving implant comprising complimentary opposed convex and concave surfaces.

In summary, these devices resemble the present invention only in that they are placed within the intervertebral space following the removal of a damaged disc. In that they seek to preserve spinal motion, they are diametrically different from the present invention which seeks to permanently eliminate all motion at that spinal segment.

A second related area of prior art includes those devices utilized to replace essentially wholly removed vertebrae. Such removal is generally necessitated by extensive vertebral fractures, or tumors, and is not associated with the treatment of disc disease. While the present invention is to be placed within the disc space, these other vertebral devices cannot be placed within the disc space as at least one vertebra has already been removed such that there no longer remains a "disc space". Furthermore, these devices are limited in that they seek to perform as temporary structural members mechanically replacing the removed vertebrae (not a removed disc), and do not intrinsically participate in supplying osteogenic material to achieve cross vertebrae bony fusion. Therefore, unlike the present invention which provides for a source of osteogenesis, use of this group of devices must

be accompanied by a further surgery consisting of a bone fusion procedure utilizing conventional technique. This group consisting of vertebral struts rather than disc replacements would include the following:

U.S. Patent No. 4,553,273 to WU - describing a turnbuckle-like vertebral strut.

U.S. Patent No. 4,401,112 to REZAIAN - describing a turnbuckle- like vertebral strut with the addition of a long stabilizing staple that spans the missing vertebral body.

U.S. Patent No. 4,554,914 to KAPP - describing a large distractible spike that elongates with a screw mechanism to span the gap left by the removal of an entire vertebra and to serve as an anchor for acrylic cement which is then used to replace the missing bone (vertebrae).

U.S. Patent No. 4,636,217 to OGILVIE - describing a vertebral strut mechanism that can be implanted after at least one vertebrae has been removed and consists of a mechanism for causing the engagement of screws into the vertebrae above and the vertebrae below the one removed.

In summary, this second group of devices differs from the present invention in that they are vertebral replacements struts, do not intrinsically participate in the bony fusion, can only be inserted in the limited circumstances where an entire vertebra has been removed from the anterior approach, and are not designed for, or intended to be used for the treatment of disc disease.

A third area of prior art related to the present

invention includes all devices designed to be applied to one of the surfaces of the spine. Such devices include all types of plates, struts, and rods which are attached by hooks, wires and screws. These devices differ significantly from the present invention in that they are not inserted within the disc space and furthermore do not intrinsically participate in supplying osteogenic material for the fusion.

Therefore, where permanent spinal immobilization is desired, an additional surgery, consisting of a spinal fusion performed by conventional means or the use of supplemental methylmethacrylate cement is required. Such devices applied to the spine, but not within the disc space, would include the following:

U.S. Patent No. 4,604,995 to STEPHENS - describing a "U" shaped metal rod attached to the posterior elements of the spine with wires to stabilize the spine over a large number of segments.

U.S. Patent No. 2,677,369 to KNOWLES - describing a metal column device to be placed posteriorly along the lumbar spine to be held in position by its shape alone and to block pressure across the posterior portions of the spinal column by locking the spine in full flexion thereby shifting the maximum weight back onto the patient's own disc.

Other devices are simply variations on the use of rods (e.g. Harrington, Luque, Cotrel-Dubosset, Zielke), wires or cables (Dwyer), plates and screws (Steffee), or

struts (Dunn, Knowles)

In summary, none of these devices are designed to be nor can be used within the disc space. Moreover, these devices do not replace a damaged disc, and do not intrinsically participate in the generation of a bony fusion.

Another area of related prior art to be considered is that of devices designed to be placed within the vertebral interspace following the removal of a damaged disc, and seeking to eliminate further motion at that location.

Such a device is contained in Patent No. 4,501,269 issued to BAGBY which describes an implantable device and limited instrumentation. The method employed is as follows: a hole is bored transversely across the joint and a hollow metal basket of larger diameter than the hole is then pounded into the hole and then the hollow metal basket is filled with the bone debris generated by the drilling.

While the present invention (device, instrumentation, and method) may appear to bear some superficial resemblance to the BAGBY invention, it is minimal, while the differences are many fold and highly significant. These differences include the following:

1. Safety - The present invention provides for a system of completely guarded instrumentation so that all contiguous vital structures (e.g. large blood vessels, neural structures) are absolutely protected. The

instrumentation of the present invention also makes overpenetration by the drill impossible. Such overpenetration in the cervical spine, for example, would result in the total paralysis or death of the patient. In the thoracic spine, the result would be complete paraplegia. In the lumbar spine, the result would be paraplegia or a life-threatening perforation of the aorta, vena cava, or iliac vessels.

The present invention is atraumatically screwed into place while the BAGBY device, in contradistinction, is pounded into position. BAGBY describes that its implant is significantly larger in size than the hole drilled and must be pounded in. This is extremely dangerous and the pounding occurs directly over the spinal cord which is precariously vulnerable to percussive injury. Furthermore, while it is possible, for example in the lumbar spine, to insert the present invention away from the spinal cord and nerves, the BAGBY device must always be pounded directly towards the spinal cord.

Furthermore, since the BAGBY device is pounded into a smooth hole under great resistance, and lacking any specific design features to secure it, the device is highly susceptible to forceful ejection which would result in great danger to the patient and clinical failure. The present invention, in contradistinction, is securely screwed into place, and possesses highly specialized locking threads to make accidental dislodgement impossible. Because of the proximity of the spinal cord, spinal nerves,

and blood vessels, any implant dislodgement as might occur with the BAGBY device might have catastrophic consequences.

2. Broad applicability - The BAGBY device can only be inserted from the front of the vertebral column, however, in contrast, the present invention can be utilized in the cervical, thoracic, and lumbar spine, and can be inserted from behind (posteriorly) in the lumbar spine. This is of great importance in that the purpose of these devices is in the treatment of disc disease and probably greater than 99 percent of all lumbar operations for the treatment of disc disease are performed from behind where the present invention can easily be utilized, but the BAGBY device, as per BAGBY'S description, cannot.

3. Disc removal - The BAGBY invention requires the complete removal of the disc prior to the drilling step, whereas the present invention eliminates the laborious separate process of disc removal and efficiently removes the disc and prepares the vertebral end plates in a single step.

4. Time required - The present invention saves time over the BAGBY invention since time is not wasted laboring to remove the disc prior to initiating the fusion. Also, with the present invention the procedure is performed through a system of guarded instrumentation, time is not wasted constantly placing and replacing various soft tissue retractors throughout the procedure.

5. Implant stability - Dislodgement of the implant would be a major source of device failure (an

unsuccessful clinical result), and might result in patient paralysis or even death. As discussed, the BAGBY device lacks any specific means of achieving stability and since it is pounded in against resistance to achieve vertebral distraction, and is susceptible to forceful dislodgement by the tendency of the two distracted vertebrae, to return to their original positions squeezing out the device. The present invention, however, is screwed into place. As there is no unscrewing force present between the vertebrae, compression alone cannot dislodge the implant. The implant is inherently stable by its design. Furthermore, the threads of the present invention are highly specialized in that they are periodically interrupted so that the tail ends of each of the tabs so formed are blunted and twisted so as to resist accidental unscrewing. The removal of an implant with such "locking threads" requires the use of a special extractor included within the instrumentation. The stability of the present invention is still further enhanced, again in contradistinction to the BAGBY device, by the presence of a "bone ingrowth" surface texturing, which both increases the friction of the fit and allows for the direct growth of the vertebral bone into the casing of the implant itself.

6. Spinal stability - The present invention is not only self-stabilizing, it also provides stability to the adjacent vertebrae in at least three ways that the BAGBY device cannot. First, the BAGBY device is placed transversely across the joint in the center, leaving both

vertebrae free to rock back and forth over this round barrel shaped axis, much like a board over a barrel, being used for a seesaw.

Secondly, as the BAGBY device lacks any specific design features to resist sliding, it may actually behave as a third body allowing the translation of the vertebrae relative to the device and to each other.

Thirdly, any device can only provide stability if it remains properly, seated. The present invention is inherently stable, and therefore assures that it will stabilize the adjacent vertebrae, rather than, as with the BAGBY, the instability of the spine to be treated may cause a dislocation of the BAGBY implant, with further loss of spinal stability.

7. The collapse of the interspace - While both the present invention and the BAGBY device can be fabricated to withstand the compression forces within the interspace, the interspace may nevertheless collapse under the superincumbent body weight as the implant settles into the vertebral bone. This is related to the load per unit area. Again the present invention is superior to the BAGBY device in at least four ways.

First, the present invention offers considerably greater surface area to distribute the load. Secondly, while the BAGBY device is placed centrally, the present device is placed bilaterally where the bone tends to be more cortical and much stronger out towards the rim. Thirdly, the present invention supports the load achieving

an "I" beam effect, whereas the BAGBY implant does not. Fourthly, it is not pressure alone that causes the collapse of the bone adjacent to the implant, but also bony erosion that is caused by the motion under pressure of the implant against the bone. As discussed in item 6 above, the present invention alone is highly resistant to such motion, again diminishing the likelihood of erosion and interspace collapse.

8. Bone ingrowth surface texturing - The present invention has a surface treatment of known and conventional technology to induce the growth of bone from the vertebrae directly into the casing material of the implant itself. The BAGBY device has no similar feature. {L.A. - we may want to list examples of these bone growth factors}.

9. Fusion mass - The BAGBY invention calls for removing the disc and then drilling a hole between the adjacent vertebrae. The bony debris so generated is then put into the device. The present invention takes a core of pure bone producing marrow from the iliac crest, and then by use of a special press, forcibly injects the implant device with an extremely dense compressed core of that osteogenic material until the material itself virtually extrudes from every cell of the implant.

10. The probability of achieving fusion - The fusion rate within the spine is known to be related directly to the amount of exposed vascular bone bed area, the quality and quantity of the fusion mass available, and

the extent of the stabilization obtained with all other factors being half constant. It would then be anticipated, that the fusion rate would be superior with the present invention as compared to the BAGBY device, because of optimal implant stability (#5), optimal spinal stability (#6), bone ingrowth surface treatment (#8), superior fusion mass (#9), and the greater exposed vertebral bony surface area (#7).

The last area of prior art possibly related to the present invention and therefore, to be considered related to "bony ingrowth", are patents that either describe methods of producing materials and or materials or devices to achieve the same. Such patents would include:

U.S. Patents No. 4,636,526 (DORMAN), No. 4,634,720 (DORMAN), No. 4,542,539 (ROWE), No. 4,405,319 (COSENTINO), No. 4,439,152 (SMALL), No. 4,168,326 (BROEMER), No. 4,535,485 (ASHMAN), No. 3,987,499 (SCHARBACH), No. 3,605,123 (HAHN), No. 4,655,777 (DUNN), No. 4,645,503 (LIN), No. 4,547,390 (ASHMAN), No. 4,608,052 (VAN KAMPEN), No. 4,698,375 (DORMAN), No. 4,661,536 (DORMAN), No. 3,952,334 (BOKROS), No. 3,905,047 (LONG), No. 4,693,721 (DUCHEYNE), No. 4,070,514 (ENTHERLY).

However, while the implant of the present invention would utilize bone ingrowth technology, it would do so with conventional technology.

b. Prior Art Instrumentations And Methods

The following is a history of the prior art

apparatus and methods of inserting spinal implants:

In 1956, Ralph Cloward developed a method and instruments which he later described for preparing the anterior aspect (front) of the cervical spine, and then fusing it. Cloward surgically removed the disc to be fused across and then placed a rigid drill guide with a large foot plate and prongs down over an aligner rod and embedded said prongs into the adjacent vertebrae to maintain the alignment so as to facilitate the reaming out of the bone adjacent the disc spaces. As the large foot plate sat against the front of the spine, it also served as a fixed reference point to control the depth of drilling. The reaming left two opposed resected arcs, one each, from the opposed vertebral surfaces. The tubular drill guide, which was placed only preliminary to the drilling, was thereafter completely removed. A cylindrical bony dowel, significantly larger in diameter than the hole formed, was then pounded into the hole already drilled. Cloward's method of instrumentation was designed for, and limited to, use on the anterior aspect and in the region of the cervical spine only. The hole was midline, which would preclude its use posteriorly where the spinal cord would be in the way.

As the bone graft to be inserted in Cloward's method was necessarily larger in diameter than the hole drilled, the graft could not be inserted through the drill guide. This mandated the removal of the drill guide and left the graft insertion phase completely unprotected.

Thus Cloward's method and instrumentation was inappropriate for posterior application.

In addition, the failure to provide continuous protection to the delicate neural structures from the instruments, as well as the bony and cartilaginous debris generated during the procedure, made Cloward's method inappropriate for posterior application. Also, the drill guide described by Cloward could not be placed posteriorly within the spinal canal, as the foot plate would crush the nerves. Modifying Cloward's drill guide by removing the foot plate completely, would still leave the instrument unworkable as it would then lack stability, and would not be controllable for depth of seating.

Nevertheless, Wilterberger, (Wilterberger, B.R., Abbott, K.H., "Dowel Intervertebral Fusion as Used in Lumbar Disc Surgery," The Journal of Bone and Joint Surgery, Volume 39A, pg. 234-292, 1957) described the unprotected drilling of a hole from the posterior into the lumbar spine between the nerve roots and across the disc space, and then inserting a stack of button-like dowels into that space. While Wilterberger had taken the Cloward concept of circular drilling and dowel fusion and applied it to the lumbar spine from a posterior approach, he had not provided for an improved method, nor had he advanced the instrumentation so as to make that procedure sufficiently safe, and it rapidly fell into disrepute.

Crock (Crock, H.V., "Anterior Lumbar Interbody Fusion - Indications for its Use and notes on Surgical

Technique," Clinical Orthopedics, Volume 165, pg. 157-163, 1981) described his technique and instrumentation for Anterior Interbody Fusion of the lumbar spine, wherein he drilled two large holes side by side across the disc space from anterior to posterior essentially unprotected and then pounded in two at least partially cylindrical grafts larger than the holes prepared.

A review of the prior art is instructive as to a number of significant deficiencies in regard to the method and instrumentation for the performance of Interbody Spinal Fusion utilizing drilling to prepare the endplates.

As the great majority of spinal surgery is performed in the lumbar spine and from posteriorly, a review of the prior art reveals a number of deficiencies in regard to the spine in general, and to the posterior approach to the lumbar spine specifically. These deficiencies include the:

1. Failure to protect the surrounding tissues throughout the procedure, specifically, prior to drilling and until after the insertion of the graft;

2. Failure to contain the debris, bony and cartilaginous, generated during the procedure;

3. Failure to optimize the contact of the cylindrical drill hole and bone graft, the mismatch in their diameters resulting in incongruence of fit;

4. Failure to determine the optimal drill size prior to drilling;

5. Failure to determine the optimal amount of

distraction prior to drilling;

6. Inability to optimize the amount of distraction so as to restore the normal spatial relationships between adjacent vertebrae;

7. Inability to create sufficient working space within the spinal canal (between the nerve roots and the dural sac) to make the procedure safe;

8. Absent a foot plate on the drill guide, as necessitated by the close tolerances posteriorly, the inability to reliably insure that the drilling is parallel to the vertebral endplates;

9. The inability to insure equal bone removal from the opposed vertebral surfaces; and

10. The inability to determine within the spinal canal, the proper side by side positioning for dual drill holes.

BRIEF SUMMARY OF THE INVENTION

The present invention comprises a series of artificial implants, the purpose of which is to participate in, and directly cause bone fusion across an intervertebral space following the excision of a damaged disc. Such implants are structurally load bearing devices, stronger than bone, capable of withstanding the substantial forces generated within the spinal interspace. The devices of the present invention have a plurality of macro sized cells and openings, which can be loaded with fusion promoting materials, such as autogenous bone, for the purpose of

materially influencing the adjacent vertebrae to perform a bony bond to the implants and to each other. The implant casing may be surface textured or otherwise treated by any of a number of known technologies to achieve a "bone ingrowth surface" to further enhance the stability of the implant and to expedite the fusion.

The devices of the present invention are configured and designed so as to promote their own stability within the vertebral interspace and to resist being dislodged, and furthermore, to stabilize the adjacent spinal segments.

The apparatus and method of the present invention for preparing the vertebrae for insertion of the implant allows for the rapid and safe removal of the disc, preparation of the vertebrae, performance of the fusion, and internal stabilization of the spinal segment.

The present invention is a method for Interbody Spinal Fusion utilizing novel instrumentation, whereby a protective tubular member is placed prior to the drilling part of the procedure and is left in place until the graft is fully seated.

Accordingly, a first aspect of the present invention provides a spinal distractor for use in spinal surgery for positioning two adjacent vertebral bodies in selected relationship to each other, said spinal distractor including:

a body; and

a disc penetrating extension extending from said body for insertion into the disc space between the two adjacent vertebral bodies and for bearing against adjacent endplates of the two adjacent vertebral bodies, said disc penetrating extension having a first portion for bearing against one of the adjacent endplates and a second portion for bearing against the other of the adjacent endplates, said first and second portions converging away from said body along at least a portion of their length.

A second aspect of the present invention provides a spinal distractor for use in spinal surgery for positioning two adjacent vertebral bodies in selected relationship to each other, said spinal distractor including:

a body; and

a disc penetrating extension extending from said body for insertion into the disc space between the two adjacent vertebral bodies and for bearing against adjacent endplates of the two adjacent vertebral bodies, said disc penetrating extension having a first portion for bearing against one of the adjacent endplates and a second portion for bearing against the other of the adjacent endplates, said first and second portions diverging away from said body along at least a portion of their length, said disc penetrating extension having a tapered leading end to facilitate placement of said disc penetrating extension into the disc space.

In the preferred embodiment two distractors are used to separate two adjacent vertebrae to a preferred distance. A hollow Outer Sleeve having teeth at one end is driven into the adjacent

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vertebrae on one side to hold the vertebrae in position when the distractor is removed, a diameter reducing hollow Inner Sleeve is introduced into the Outer Sleeve, a drill having a drill stop is passed

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through the hollow Inner Sleeve to drill a hole to a desired depth, and an implant is inserted in the hole. The method is repeated on the other side of the disc.

In summary then, the present invention, instrumentation, and method, provides for a single surgery providing for an integrated discectomy, fusion, and interbody internal spinal fixation.

Discussion of the Instrumentation

The apparatus and method of the present invention provide the following advantages:

1. The present invention is safer by providing protection of the surrounding tissues. An Outer Sleeve places all of the delicate soft tissue structures, nerves, blood vessels, and organs outside of the path of the various sharp surgical instruments and the implant. Further, it is an improvement upon hand held retractors in that it occupies the least possible amount of area, avoids the stretching associated with manual retraction, provides for the retraction and shielding of the surrounding tissues in all directions circumferentially and simultaneously, and it does so exclusively with smooth, curved surfaces.

2. The present invention is safer by providing protection against the danger of instrument or implant overpenetration.

3. The present invention is safer as the surgical site and wound are protected from the debris generated during the procedure.

4. The present invention is safer because the method provides for absolute protection to the soft tissues directly and from indirect injury by overpenetration. It makes safe the use of power instrumentation which is both more effective and efficient.

5. The present invention maintains the vertebrae to be fused rigid throughout the procedure.

6. The present invention holds the vertebrae to be fused aligned throughout the procedure.

7. The present invention holds the vertebrae to be fused distracted throughout the procedure.

8. The present invention assures that all instruments introduced through the Outer Sleeve are coaxial and equally centered through the disc space and parallel the endplates.

9. The present invention facilitates the implant insertion by countering the high compressive forces tending to collapse the interspace, which if left unchecked would resist the introduction and advancement of the implant and make stripping more likely.

10. The present invention extends the range and use of the procedure and similarly the interbody spinal implant itself by making the procedure safe throughout the spine.

11. The present invention increases the ability to use a specifically sized implant.

12. In the present invention the end of all the penetrating instrumentation is blunt faced.

13. In the present invention all of the instruments have been stopped at a predetermined depth to avoid overpenetration.

14. The design of the Outer Sleeve in the present invention conforms to the spacial limitations of the specific surgical site.

15. The design and use of a second or Inner Sleeve in the present invention allows for the difference in size between the inside diameter of the Outer Sleeve, and the outside diameter of the drill itself. This difference being necessary to accommodate the sum of the distraction to be produced, and the depth of the circumferential threading present of the implant.

16. In the present invention a specially designed drill bit with a central shaft recess allows for the safe collection of the drilling products, which can then be removed without disturbing the Outer Sleeve by removing the drill bit and Inner Sleeve as a single unit.

17. In the present invention a specially designed trephine for removing a core of bone slightly smaller in diameter than the internal diameter of the implant cavity itself, however of a greater length.

18. In the present invention a specially designed press for forcefully compressing and injecting the long core of autogenous bone into the implant, such that it extrudes through the implant itself.

19. In the present invention a specially designed driver extractor, which attaches to the implant

and allows the implant to be either inserted or removed without itself dissociating from the implant, except by the deliberate disengagement of the operator.

20. In the present invention predistraction increases the working space.

21. The Distractor in the present invention is self-orienting acting as a directional finder.

22. The Distractor in the present invention is self-centralizing between the opposed vertebral surfaces acting as a centering post for the subsequent bone removal.

23. In the present invention predistraction assures the equal removal of bone from the adjacent vertebral surfaces.

24. In the present invention predistraction assures the exact congruence between the hole drilled and the device.

25. In the present invention predistraction assures that the drilling is parallel to the vertebral endplates.

26. In the present invention predistraction allows for the determination of the optimal distraction prior to drilling.

27. In the present invention predistraction allows for the verification of the correct prosthesis size prior to drilling.

28. In the present invention predistraction facilitates device insertion by relieving the compressive loads across the interspace which would resist

implantation.

29. In the present invention predistraction decreases the likelihood of stripping the bone during insertion.

30. In the present invention predistraction provides for the side by side positioning, spacing, and parallelism required prior to the irrevocable event of drilling.

31. In the present invention predistraction provides for the rigid stabilization of the vertebrae opposed to the disc space throughout the surgical procedure.

32. In the present invention predistraction provides for an implant easier to insert as the compressive loads of the opposed vertebrae are held in check so that the device itself need not drive the vertebrae apart to be inserted.

33. In the present invention predistraction allows for the insertion of a more effective implant as more of the implant can be dedicated to its intended purpose and be full diameter, whereas without the benefit of predistraction and the ability to maintain the same, a significant portion of the forward end of the implant would need to be dedicated to the purpose of separating the opposing vertebrae.

34. The present invention allows for the use of an implant with a sharper thread or surface projections as there is no danger to the surrounding tissues.

35. The present invention allows for the implant to be fully preloaded as provided to the surgeon, or for the surgeon to load it with the material of his choice at the time of surgery.

36. The present invention allows for the loading of a spinal implant outside of the spinal canal and prior to implantation.

OBJECTS OF THE PRESENT INVENTION

It is an object of the present invention to provide an improved method of performing a discectomy, a fusion, and an internal stabilization of the spine, and specifically, all three of the above simultaneously and as a single procedure.

It is another object of the present invention to provide an improved method of performing a discectomy, a fusion, and an internal stabilization of the spine, which is both quicker and safer than is possible by previous methods.

It is another object of the present invention to provide an improved method of performing a discectomy, a fusion and an internal stabilization of the spine, to provide for improved surgical spinal implants.

It is another object of the present invention to provide an improved method of performing a discectomy, a fusion, and an internal stabilization of the spine, which provides for an improved system of surgical instrumentation

to facilitate the performance of the combined discectomy, fusion, and internal spinal stabilization.

It is another object of the present invention to provide an improved method of performing a discectomy, a fusion, and an internal stabilization of the spine procedures.

It is an object of the present invention to provide instrumentation and a method of spinal interbody arthrodesis that is faster, safer, and more efficacious than prior methods, and can effectively be performed in the cervical, thoracic, and lumbar spine anteriorly, as well as in the lower lumbar spine posteriorly.

It is a further object of the present invention to provide a means for inserting a spinal implant between adjacent vertebrae while maintaining their optimal spacing, positioning, and alignment.

These and other objects of the present invention will be apparent from review of the following specification and the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a side view of the Long Distractor, of the present invention inserted into the intervertebral space.

Figure 2 is a side view of a Convertible Distractor assembly in relation to the spine.

Figure 3 is a perspective view of a high

retention Short Distractor of Figure 2.

Figure 3A is a side view of the high retention Short Distractor of Figure 2.

Figure 3B is a side view of an alternative Short Distractor with circumferential forward facing ratcheting.

Figure 3C is a top view of the alternative Short Distractor of Figure 3B.

Figure 3D is a perspective view of an alternative embodiment of a Short Distractor.

Figure 3E is a top view of the alternative distractor of Figure 3D.

Figure 3F is a side view of a further alternative rectangularized Short Distractor with knurled surfaces.

Figure 4 is a perspective view of a spinal segment (two vertebrae and an interposed disc) with a Short Distractor in place, with a portion of the upper vertebrae and disc cut away to show the Short Distractor on one side of the spine and the Long Distractor about to be placed contralaterally.

Figure 5 shows a side view of the Outer Sleeve in place over the Long Distractor, and about to receive the Driver Cap in preparation for being seated.

Figure 6 shows the Long Distractor, Outer Sleeve, and Driver Cap following the proper seating of the Outer Sleeve into the two adjacent vertebrae.

Figure 7A is a side view of the cervical Outer Sleeve being placed over a Long Distractor which is in place within the disc space anteriorly.

Figure 7B is a bottom view of the single Outer Sleeve of Figure 7A.

Figure 7C is a bottom view of a Dual Outer Sleeve.

Figure 7D is an enlarged side view of the proximal portion of Figure 7C.

Figure 7E is a bottom view of a Dual Driver Cap for driving two distractors.

Figure 7F is a side sectional view showing the Dual Outer Sleeve of Figures 7C and 7D, Distractors and Dual Cap of Figure 7E seated.

Figure 8 is a side view of the Outer Sleeve of Figure 7A centered on the Long Distractor and fully seated on the anterior aspect of the cervical spine.

Figure 9 is a perspective view of the Distractor Puller.

Figure 10 is a cutaway partial side view of the Proximal Puller engaging the extraction ring of the Long Distractor over the end of the Outer Sleeve.

Figure 10A is a side view of the Puller coupled to the Long Distractor just prior to its extraction.

Figure 10B is a posterior view of the proximal Outer Sleeve and a Short Distractor in place in regard to the vertebrae, disc and nerves.

Figure 11A is a side sectional view of the Drill and Inner Sleeve within the Outer Sleeve and drilling across the intervertebral space and cutting partially cylindrical arcs from the adjacent vertebrae.

Figure 11B is a sectional side view of preparation of the intervertebral space by the alternative "Trephine Method" showing the Distractor, Trephine, Inner Sleeve, and Outer Sleeve in place.

Figure 11C is a sectional side view as in Figure 11A, but showing the use of an alternative drilling conformation wherein the extended proximal portion is both distracting and self-centering.

Figure 11D is a side view of an instrument for removing arcs of bone from vertebrae following drilling.

Figure 12 is a perspective view of the surgical Tap.

Figure 13 is a side view of the Outer Sleeve and the surgical Tap fully threaded within the interspace.

Figure 14A is a side view of the bone harvesting Trephine and motor adapter.

Figure 14B is a perspective view of the implant Bone Loading Device.

Figure 14C is a perspective view of the Corkscrew bone freeing and extracting instrument.

Figure 15 is a partial perspective view of the Bone Loading Device in operation.

Figure 16 is a perspective view of the Implant Driver about to engage the spinal implant.

Figure 17 is a side view of the spinal implant being fully seated within the intervertebral space by means of the Driver apparatus in place within the Outer Sleeve.

Figure 18 is a side view of the lumbar spine

showing the end result of the device implantation via the posterior route.

Detailed Description of the Drawings And

Detailed Description of Method of Insertion

The following discussion will be in regard to application in the lumbar spine via the posterior approach. In its simplest form, the method of the present invention involves the following steps. The patient is placed on a spinal surgery frame, which allows for the distraction and alignment of the disc space to be fused. A bilateral posterior exposure of the interspace, with or without partial discectomy is then performed. Utilizing distractors the disc space is distracted, and a hollow Outer Sleeve is fitted over one of the distractors. The end of the Outer Sleeve has teeth for engaging the two adjacent vertebrae. The Outer Sleeve is driven into the vertebrae and the distractor is then removed. A hollow Inner Sleeve is then inserted into the Outer Sleeve and a stopped Drill is utilized to prepare the opposed vertebral surfaces. The Drill and the Inner Sleeve are removed as a single unit. The space is tapped if so required. The prepared spinal implant is then inserted via the Outer Sleeve utilizing a stopped inserter. The instruments are then removed and the procedure repeated on the contralateral side of the spine.

Detailed Description of the Preferred Embodiment

Step 1a. Prior to surgery, translucent implant templates appropriately adjusted for scale are superimposed on AP, lateral, and axial images of the interspace to be fused, for the purpose of selecting the optimal implant size and to determine the desired distraction.

Step 1b. The patient is preferably placed onto a spinal surgery frame capable of inducing both distraction and vertebral alignment.

Step 2. In the preferred embodiment, a standard bilateral (partial) discectomy is performed and any posterior lipping of the vertebral bodies adjacent the interspace is removed. Alternatively, no disc material need be removed. In the preferred embodiment, the interspace is exposed by performing bilateral paired semihemilaminotomies and resecting the inner aspects of the facet joints adjacent the spinal canal while preserving the supra and interspinous ligaments.

Step 3. Beginning on the first side, the dural sac and traversing nerve root at that level are retracted medially and a Long Distractor then inserted and impacted flush to the posterior vertebral bodies adjacent that interspace. Long Distractors with working ends of increasing diameter are then sequentially inserted until the optimal distraction is obtained. This optimal distraction not only restores the normal height of the interspace, but further achieves a balance wherein the tendency for the space to collapse is resisted, which in

urging the vertebral bodies apart is being equally resisted by the powerful soft tissue structures about the spinal segment including the outer casing of the disc (the annulus fibrosus), various ligaments, capsular structures, as well as the muscles and other soft tissue structures. This balanced distraction not only provides for the spatial restoration of the height of the interspace, but for considerable stability as the space now resists further distraction or collapse.

In the preferred embodiment, as the desired distraction is approached, the use of the solid bodied Long Distractors is terminated and a disassemblable Convertible Distractor is placed with tactile and/or radiographic confirmation of ideal distraction. The Convertible Distractor is then disassembled such that the Short Distractor portion is left in place and the ultra-low profile head portion being positioned adjacent to the canal floor and safely away from the neural structures. To insure that the Short Distractor remains in place until its removal is desired, various embodiments of the Short Distractor are available with varying degrees of resistance to dislodgment. In the preferred embodiment of the procedure, attention is then directed to the contralateral side of the spine.

Step 4. On the contralateral side of the same interspace the Long Distractor having at its working end the diameter matching the Short Distractor already in place, is then inserted. If however, due to an

asymmetrical collapse of the interspace it is then determined that greater distraction is required on the second side to achieve the optimal stability, then the appropriate Short Distractor would be placed on the second side. Then the Short Distractor would be removed from the first side and replaced with a larger Long Distractor so as to bring the interspace into balance.

In an alternative embodiment, the entire procedure is performed on the one side of the spine utilizing only the Long Distractor prior to repeating the procedure on the contralateral side of the spine. While this method can be performed in accordance with the remaining steps as described in the preferred embodiment, when utilized it is best performed using a Trephine which allows the Long Distractor to remain in place, thereby allowing for interspace distraction otherwise provided in the first method by the Short Distractor. This alternative method then requires the use of a Trephine over the Long Distractor in lieu of a reamer and is therefore called the "Trephine Method", which will be discussed in detail later.

Step 5. With the Short Distractor in place on the first side of the spine, and the matching Long Distractor in place on the second side of the spine, and with the dural sac and traversing nerve root safely retracted, the Outer Sleeve is placed over the Long Distractor and firmly impacted to its optimal depth using the Impaction Cap and a mallet. The Long Distractor is then removed.

Step 6. An Inner Sleeve is then placed within the Outer Sleeve, and the interspace is then prepared on that side by utilizing a Drill, Endmill, Reamer, or Trephine to drill, ream, or cut out the bone to be removed to either side, as well as any remaining interposed discal material. In the preferred method, utilizing a specially designed Endmill-Drill, it and the Inner Sleeve are removed as a unit, safely carrying away the bone and disc debris trapped within them from the spinal canal.

Step 7. If required, a thread forming Tap with penetration limiting means to control the depth of insertion, is then inserted through the Outer Sleeve.

Step 8. The prepared implant is then inserted utilizing the specialized Driver unit. It should be noted that the implant may be coated with, made of, and/or loaded with substances consistent with bony fusion. However, in the preferred embodiment, the implant is treated with bone promoting and inducing substances, but is loaded with materials suitable for participating in a fusion.

While substances both natural and artificial are covered by the present invention, the preferred embodiment is in regard to the use of the patient's own bone by the following method. A hollow Trephine is utilized to harvest a core of bone from the posterior superior aspect of the iliac crest adjacent the sacroiliac joint. This core of bone is at its outside diameter, slightly smaller than the inside diameter of the spinal implant to be loaded, but longer than the spinal implant. Utilizing an instrument

designed for that purpose, the core of bone is then injected from within the Trephine into the central cavity of the implant causing a superabundance of the bone material within the implant such that the bone material tends to press out through the openings communicating with the outside surface of the implant.

Step 9. Using the Driver Extractor instrument, the prepared implant is threaded into the prepared interspace. The instrumentation is removed from that side of the spine and attention is then redirected to the first side of the spine. A small retractor is utilized to move the dural sac and traversing nerve root medially and to protect them and allowing the direct visualization of the retained Short Distractor unit. Without removing the Short Distractor, it is reassembled to its shaft portion, essentially reconstituting itself into a Long Distractor. With the inserted implant now acting as the distractor on the opposite side, the Long Distractor is utilized to guide the Outer Sleeve down where it is impacted as described in Step 5.

Steps 6 & 7 are then repeated, completing the procedure at that level. The wound is then irrigated and closed in the routine manner.

Representative Example of The Preferred Method

Through preoperative templating of the patient's anterior posterior, lateral, and axially imaged MRI scan in conjunction with translucent overlays of the various sized

implants, the correct implant diameter and length are accurately assessed, as well as the correct amount of distraction needed to restore the interspace to its premorbid height. The patient is then properly positioned and a bilateral partial discectomy performed via paired semihemilaminotomies.

For the purpose of this example, it will be assumed that by preoperative assessment it was determined that the correct implant would have an external diameter of 18mm and be 26mm long. Further, the distraction necessary to restore the height of the interspace would be approximately 10mm. The dural sac and traversing nerve root would then be retracted medially and protected, while a Long Distractor having an outside diameter to the barrel portion corresponding to the implant to be inserted, that is 18mm, and having a diameter at the working end of perhaps 8mm, would be inserted. This then being found to be slightly smaller than optimal by direct observation, a Convertible Distractor having in its barrel portion an 18mm outside diameter, but having in its working portion a 10mm diameter would then be inserted. Direct observation and/or x-ray then confirming the ideal distraction, the Convertible Distractor would then be disassembled, the barrel and head portion removed, and the Short Distractor portion left deeply embedded and with its flanged head flat against the canal floor and deep to the neural structures. It would then be safe to allow the dural sac and nerve root to return to their normal positions, which would be

superficial to the flanged portion of the Short Distractor.

Attention would then be directed to the contralateral side. The dural sac and nerve root would then be retracted medially on this second side, and a Long Distractor with an 18mm diameter barrel portion and a 10mm working portion would then be inserted into the interspace and driven flush to the bone if necessary, such impaction imploding any osteophytes not already removed, and assuring that the shoulder portion of the barrel comes to lie flat against the posterior aspects of the adjacent bodies. With the dural sac and nerve root still safely retracted, the Outer Sleeve would then be placed over the Long Distractor and utilizing the Driver Cap and a mallet, seated to the optimal depth.

In the preferred embodiment, the Long Distractor is then removed and the Inner Sleeve is inserted into the Outer Sleeve. Since the purpose of the Inner Sleeve is to support the drill and allow for the increased size of the implant over the size of the drill, thus making it possible for the insertion of the implant to occur through the Outer Sleeve, the Inner Sleeve therefore measures 18mm in its outside diameter, and 16.6mm in its inside diameter. This allows it to fit within the Outer Sleeve, the diameter of which is 18.1 mm and to admit the drill bit which is 16.5mm in diameter.

Following the drilling procedure, the Drill and Inner Sleeve are removed as a single unit with the trapped

interposed cartilaginous and bony debris. The depth of drill penetration is preset and limited by the fixed rigid column of the Outer Sleeve. In this example, the space will be prepared to a depth of 28mm in anticipation of countersinking a 26mm long implant at least 2mm. If a Tap were to be utilized, it would be inserted at this time and be appropriate to the minor and major diameters of the implant to be inserted and as with the Drill, controlled for its depth of penetration. The spinal implant would then be prepared for implantation by utilizing a Trephine to harvest a core of posterior iliac bone greater than 30mm long and approximately 14.5mm in diameter.

Using the Bone Loading Device, this core of bone would be forcefully injected into the internal chamber of the spinal implant which would then be capped. Cap end forward, the fully loaded implant would then be attached to the Insertion Driver, down the Outer Sleeve and screwed into place with the depth of penetration limited by the Insertion instrument. The Insertion Driver is then unscrewed from the implant and removed from the Outer Sleeve. With the dural sac and nerve root retracted and protected, the Outer Sleeve would then be removed. This would complete the fusion procedure on that side, and then as described, the procedure would be repeated on the other (first) side of the same interspace.

Alternative Methods

An alternative and extremely useful method is the

"Trephine Method". Its advantages include that it may be used in conjunction with the preferred embodiment substituting the use of a hollow, tubular cutter, called a Trephine for the use of the Drill in Step 5 of the preferred embodiment. Additionally, it may be utilized so as to obviate the need for the placement of the Short Distractor and to allow the procedure to be effectively performed from start to finish on one side prior to initiating the procedure on the opposite side, and while nevertheless maintaining distraction at the site of the bone removal.

The following is a description of the "Trephine Method".

Having completed the exposure of the interspace on at least one side, the dural sac and nerve root are retracted. A Long Distractor differing from the Long Solid Bodied Distractor of the preferred embodiment only in that the barrel portion is of a precisely lesser diameter than the spinal implant. As in the preferred embodiment, the Outer Sleeve has an inner diameter only slightly greater than the implant to be inserted. Therefore, at this time, a first Inner Sleeve is inserted into the Outer Sleeve to make up the difference between the outside diameter of the Long Distractor and the inside diameter of the Outer Sleeve. With the Outer Sleeve and first Inner Sleeve thus assembled, they are placed over the Long Distractor and the Outer Sleeve is optimally seated using the Impaction Cap. The Cap and first Inner Sleeve are removed, but the Long

Distractor and Outer Sleeve are left in place.

With the Long Distractor maintaining optimal distraction and with the Outer Sleeve locking the vertebrae together so as to resist any movement of the vertebrae, a hollow, tubular cutter known as a Trephine is then inserted over the Long Distractor and its barrel portion and within the Outer Sleeve. The Trephine, which is stopped out to the appropriate depth, can then be utilized to cut equal arcs of bone from the opposed vertebral endplates.

Alternatively, a second Inner Sleeve may be placed within the Outer Sleeve prior to placing the Trephine over the Long Distractor and within that second sleeve. This second Inner Sleeve would be just greater in its internal diameter than the Long Distractor and just smaller in its outside diameter than the inner diameter of the Outer Sleeve. While it would provide enhanced stability to the Trephine, provision would then need to be made in the way of large flutes passing longitudinally or obliquely along the outer surface of the Distractor to its barrel portion to accommodate the bony and cartilaginous debris generated during the cutting procedure.

Following the use of the Trephine to the appropriate depth by either of these methods, the Trephine, the Long Distractor, and the second Inner Sleeve, if utilized, are all removed. Since the Trephine cuts two arcs of bone but does not ream them out, a shafted instrument with a perpendicular cutting portion at its working end is then inserted parallel to the disc space and

then rotated through an arc of motion cutting the bases of the two longitudinally cut arcs, thus freeing them for removal through the Outer Sleeve. The space may then be tapped if required, and the implant is inserted as per the preferred method. As already mentioned, the "Trephine Method" can be used with or without the use of the Short Distractor on the contralateral side.

Applications of Method in Other Areas of the Spine

The following method is the preferred embodiment for performing anterior interbody fusion in the thoracic and lumbar spines. It is also appropriate in the cervical spine when the width of the spine anteriorly is sufficient so that it is possible to place two implants side by side and such that each intrudes at least several millimeters into the substance of the opposed vertebrae and for the length of the implants.

The interspace to be fused is adequately exposed and the soft tissues and vital structures retracted and protected to either side. Visualization of the broad width of the interspace anteriorly is made possible by the absence of the neurological structures in relation to this aspect of the spine. The center line of the anterior aspect of the interspace is noted and marked. The disc is removed using first a knife and then curettes and rongeurs as needed. Alternatively, the disc may be left intact to be removed during the drilling stage of the procedure. However, as per the preferred embodiment of the procedure,

having removed the great mass of the nucleus and the greater portion of the annulus anteriorly, Long Distractors with progressively increasing diameters to their working ends are inserted into the interspace at a point midway between the central marking line and the lateral extent of the anterior aspect of the spine as visualized.

The Dual Outer Sleeve with its common Foot Plate and Retention Prongs is then inserted over either a singly placed Long Distractor and then the second Distractor placed, or is placed over both Distractors if already placed. The Dual Outer Sleeve is then seated firmly against the anterior aspect of the spine. Any spurs which would interfere with the flush seating of the Foot Plate to the anterior aspect of the spine should be removed prior to inserting the Long Distractors. Once the Outer Sleeve has been optimally seated, one of the Long Distractors is removed and in its place is inserted an Inner Sleeve and drill bit. The drill bit has as its outside diameter the minor diameter of the implant to be inserted. The Inner Sleeve is essentially equal in thickness to the difference between the minor and major diameters of the threaded implant.

A Stopped Drill is then utilized to prepare the opposed vertebral surfaces and to remove any remaining disc material interposed. If required, a Stopped Tap may be inserted through the Outer Sleeve and into the interspace to create a thread form. The properly prepared implant is then affixed to the Insertion Driver and passed through the

Outer Sleeve down into the interspace and inserted until its depth of penetration is limited by the stop on the Insertion Driver. With the implant itself now in a position to act as a distractor, the Long Distractor is then removed from the contralateral side and the procedure repeated. When both implants are firmly in place, the outer sleeve may then be removed. The amount of countersinking of the implants may then be adjusted under direct vision.

Detailed Description of the Preferred Embodiment

Method and Instrumentation

In the preferred embodiment, the disc (D) between adjacent vertebrae (V) is approached via bilateral paired semihemilaminotomies of the adjacent vertebrae. In the preferred embodiment the supraspinous ligament, the interspinous ligament, the spinous process, portions of the lamina, and most of the facet joints are preserved. However, while less desirable, these structures may be removed.

In the preferred method, a bilateral partial nuclear discectomy is then performed through bilateral openings created through the posterior aspect of the annulus fibrosus. While considered less desirable, disc excision can be delayed and performed simultaneously with the vertebral bone resection during the drilling procedure. Starting on the first side a dural nerve root retractor is placed such that the dural sac and lower nerve root are

retracted medially allowing exposure to one side of a portion of two adjacent vertebral bodies and the interposed disc posteriorly.

Referring now to Figure 1, preferably after removing some portion of nuclear disc material, a Long Distractor 100 is inserted under direct vision into the intervertebral space. The disc penetrating portion 102 is essentially cylindrical with a bullet-shaped front end 103 and a shoulder portion 104 where the penetrating portion 102 extends from barrel 106. The penetrating portion 102 urges the vertebral bodies apart, facilitating the introduction of the instruments. Long Distractors with sequentially increasing diameter penetrating portions 102 are then introduced. As the optimal diameter of penetrating portion 102 is achieved, the vertebral bodies to either side are forced into full congruence and thus become parallel, not only to the penetrating portion 102, but to each other. At this time, any remaining excrescences of bone of the posterior vertebral bodies adjacent the posterior disc which have not already been removed are flattened flush to the vertebral body by the forced impaction, such as by hitting with a hammer flat surface 109 of crown 110, driving the shoulder 104 against the lipped portions of vertebrae V. Because of the forced opposition of the vertebral endplates to portion 102 with optimal distraction, unit 100 will then come to lie absolutely perpendicular to the plane of the posterior bodies and absolutely parallel to the vertebral endplates,

allowing optimal alignment for the procedure to be performed.

Penetrating portion 102 is available in various diameters, but all are of a constant length, which is less than the known depth of the interspace. This combined with the circumferential shoulder 104, which is too large to fit within the interspace, protects against the danger of overpenetration. Barrel 106 is of the same diameter as the external diameter of the device to be implanted. A recessed portion 108 below the crown 110 allows for the Long Distractor 100 to be engaged by an extractor unit shown in Figure 9.

In the preferred embodiment, a Convertible Long Distractor 113 is used on the first side of the spine. As shown in Figures 2, the Convertible Long Distractor 113 has a barrel portion 152 separable from the Short Distractor portion 120. While the initial distraction may be performed with a solid Long Distractor, as the optimal distraction is approached the appropriate Convertible Long Distractor is utilized. The Convertible Long Distractor 113 consists of a Short Distractor portion 120 and a barrel 152 having a rectangular projection 134 at one end. The Short Distractor 120 has an increased diameter head 128, a rectangular slot 118 and an internal threaded opening 114. The barrel 152 is hollow and has an internal shaft 111 terminating in a large diameter hexagonal crown 115 at one end and a reduced diameter portion 112. The crown has a detent portion 117 in its flat surface. The other end of

the shaft 111 has a threaded small member 116 that corresponds to threaded opening 114. The shaft 111 is prevented from removal from the barrel 152 by set pin 119 passing through the wall of barrel 152 in a convenient manner. The Short Distractor portion 120 is removably attached to the barrel portion 152 via the mating of female rectangular slot 118 and the male mating member 134. The mating held together by utilizing knob 136 to drive the crown 110 connected to interior shaft 111 having a threaded working end screw 116 that threads into the female aperture 118 of the Short Distractor portion 120.

Cap 136 has an open socket 138 for fitting around crown 115 and engages the reduced diameter hexagonal portion 112 so as to permit the rotation of shaft 111 and threaded male member 116. A detent ball 150 in the inside of the socket 138 engages detent 117 in the crown 115, holding them together.

The Short Distractor portion 120 of Figures 2, 3, and 3A-3F are designed to provide for high stability when temporarily situated so as to resist inadvertent migration while the surgeon is working on the second side. To that end, the embodiment of the Short Distractor 120 shown in Figures 3 and 3A has a pair of sharp pegs 126, to embed into the opposing vertebral bodies and forward facing ratchetings 124, that further resist backward movement. Figures 3B and 3C, which show the preferred embodiment, are side and top views of an alternative embodiment of the distractor portion such that the distractor portion to be

interposed between the vertebrae is essentially cylindrical, but with circumferential forward facing ratchetings 124.

A further alternative embodiment is shown in Figures 3D and 3E. This is a more rectangularized design, with forward facing ratchetings, without the sharp prongs 126 of Figure 3. Figure 3F is a side view of a further embodiment of the Short Distractor 120 shown with knurling, to increase the interference with the bone surface so as to add stability to the unit and to resist dislodgment. To this end, it is apparent that the working ends of both the Long and Short Distractors can have a variety of configurations consistent with their purpose, and that surface irregularities as well as the shape of the ends themselves, with or without prongs 126, may be utilized to make the Short Distractor 120 more resistant to migration.

Once the ideal distraction has been achieved on the first side of the spine, the Convertible Distractor is dissociated, leaving Short Distractor 120 in place with its rounded external end 128, safely on the canal floor and deep to the dural sac and nerve root.

As shown in Figure 4, the surgeon then moves to the other side of the spine at the same disc (D) level, and retracts the dural sac and nerve root medially, exposing the disc on that side. Long Distractors 100 are then sequentially inserted into the disc space until the diameter of the distractor on the second side is at least as big as that on the first side. If because of some

asymmetry of the interspace a larger diameter distractor is required on the second side to achieve the ideal distraction as compared to the first side, then the second side is fitted with a Short Distractor of the larger diameter, and the surgeon would then return back to the first side. In that event, the first side Short Distractor would then be removed and the Long Distractor 100 corresponding to the increased diameter of the already placed Short Distractor 120 would then be inserted. In either event, the operation is continued by working on the one side where the Long Distractor is in place. In this regard, it should be noted, that by the use of such a device as the Michelson Spinal Surgery Frame, it may be possible to obtain adequate distraction preoperatively such that the surgeon is either disinclined to use a distractor, or to simply place the correct Long Distractor on the first side and then proceed with the surgical procedure on that side before moving to the opposite side. These variations are within the scope of the present invention.

The Long Distractor now serves as both a centering post and an alignment rod for the hollow Outer Sleeve 140 shown in Figure 5 which is fitted over the Long Distractor 100, shown by phantom lines 101 in Figure 5. The Outer Sleeve 140 is metal and has a sharp toothed front end 142 that is capable of penetrating into and holding fast the two adjacent vertebrae (V). Interrupting the circumferential sharp teeth of 142 are flat, planar areas 152 which serve to resist the further insertion of the

sharp teeth into the vertebral bodies. The toothed front end 142 of the Outer Sleeve 140 is a continuation of the tubular shaft 144, which in turn is connected to circumferentially enlarged tubular back end 146 having a knurled outer surface 148 for easier manipulation. An alternative embodiment of an Outer Sleeve incorporates an expansile key hole and slot configuration 154 to either side of shaft 144 along the mid-plane of the interspace and parallel to it such that the end 142 resists the collapse of the vertebrae (V) to either side of the disc (D), but may nevertheless allow for their further distraction, in the event the only diameter or the root diameter of the implant is larger than the hole drilled.

A Driver Cap 160 in the form of an impaction cap has at its far end a flat, closed-back surface 162 and at its other end a broad, circular opening. The Driver Cap 160 fits over both the Outer Sleeve 140 and the Long Distractor 100. As the Driver Cap 160 is seated, interior surface 170 circumferentially engages portion 146 of the Outer Sleeve until the back end 172 engages the internal shoulder 164. As mallet blows are applied to surface 162, that force is transmitted via the internal shoulder 164 to the Outer Sleeve 140 via its far end 172, seating teeth 142 into the vertebral bodies adjacent the disc space D and to the depth of the teeth 142 to the flat portions 152. As the Outer Sleeve 140 is advanced forward, crown portion 110 of the Long Distractor is allowed to protrude within the Driver Cap 160 unobstructed until it contacts the interior

flat surface 168. Once crown 110 comes into contact with the flat interior surface 168, then further taps of the mallet will not advance the Outer Sleeve, any further motion being resisted by the flat shoulder portion 104 of the Long Distractor abutting the hard surfaces of the posterior vertebral bodies. In this way, the Outer Sleeve 140 is safely and assuredly inserted to its optimal depth and rigidly securing the two opposed vertebrae as shown in Figure 6.

The Cap 160 is then removed and the Distractor Puller 200 of Figure 9 utilized to remove the Long Distractor 100 from the spine leaving the Outer Sleeve 140 in place. The Distractor Puller 200 has front portion 202, a mid portion 204, and a back handle portion 206. At the front portion 202 of the Distractor Puller 200, a socket 208 is connected to one end of shaft 210 which at its far end is connected to back handle portion 206. The socket 208 has defined within it a cavity 212 that is open at its front end and funnelized on the interior aspect of its sides. The cavity 212 is constructed so that the head of the Distractor Puller 200 and the partially circumferential flange 218 engages the circumferential recess 108 of the Distractor 100. The entrance to cavity 212 is slightly funnelized, and the leading edges of flange 218 slightly rounded to facilitate the engagement of recess 108 and head 110 of Distractor 100, which is further facilitated in that the Driver Cap 160 leaves portion 108 of Distractor 100 precisely flush with the back surface 172 of the Outer

Sleeve 140. This provides a large, flat surface 172 to precisely guide surface 230 of socket 208, and open portion 212 around head 110 while flange 218 engages recess 108. The springloaded detent ball 228 engages hemispherical depression 112 in the crown 110, shown in Figure 2. This springloaded detent 228 in engagement with complimentary indent 218 protects against the inadvertent dissociation of the Long Distractor from the Puller 200 after the Distractor has been removed from within the Outer Sleeve 140 and prior to its removal from the wound. Once out of the body, the two instruments are easily disassociated by freeing the crown portion 110 from cavity 212 by a manual force applied perpendicular to their relative long axes at this location.

A cylindrical and free removable weight 216 is fitted around shaft 210 between the front portion 202 and the rear handle portion 206. Gently, but repeatedly sliding the weight 216 along shaft 210 and driven rearwardly against flat surface 228, transmits a rearward vector to proximal end 202 and thereby to the Long Distractor 100 to which it is engaged.

Paired extended handle 224 and 226, allow the surgeon to resist any excessive rearward motion as the instrument is used to liberate the Long Distractor 100. Paired handles 224 and 226 are also useful in that they allow a rotational directing of portion 208, via the shaft 210. This allows the surgeon to control and manipulate rotationally the orientation of the opening of cavity 212

to facilitate its application, to the head 110 of the distractor 100.

The Distractor Puller 200 is a significant improvement over the alternatives of striking a remover instrument with an independent hammer over the exposed surgical wound, or manually extracting the distractor by forcefully pulling. The use of a free hammer over the open wound is dangerous because the neural structures can be impacted on the back swing which is made even more likely by the effects of gravity on the mallet head. Manual extraction by pulling is dangerous because of the significant interference fit of portion 102 within the spine such that significant force would be required to remove the Distractor 100, and if force were not coaxial then the Outer Sleeve might be dislodged or misaligned. Further, once the flat portion 102 became free of the interspace, all resistance to withdrawal would be lost and in the face of the considerable force necessary to free it, the Distractor 100 might easily become projectile imparting injury to the patient and/or the surgeon.

Once the Long Distractor 100 has been fully removed from the Outer Sleeve 140, the toothed end 142 of the Outer Sleeve 140, working in conjunction with the Short Distractor 120 on the contralateral side rigidly maintains the relative position of the adjacent vertebrae V. Further, since the remainder of the procedure on that side of the spine occurs entirely through the protective Outer Sleeve 140, and as the nerves and dural sac are external to

that Outer Sleeve and superficial to the toothed end 142 of the Outer Sleeve 140, which is firmly embedded into the adjacent vertebrae V, the Outer Sleeve 140 serves to insure the safety of these delicate neural structures. Further, since the Outer Sleeve 140 is of a fixed length and rigid, its flat rearward surface 172 may be used as a stop to the advancement of all instruments placed through the Outer Sleeve 140, thus protecting against accidental overpenetration. Further, the Outer Sleeve 140 assures that the further procedure to be performed will occur coaxial to the disc space D and further, be symmetrical in regard to each of the opposed vertebral surfaces.

Figure 10B is a posterior view of the spine at this stage of the procedure, showing a Short Distractor 120 in place on one side of the spine and the bottom portion of Outer Sleeve 140 in place on the opposite side of the spine.

Referring to Figure 11A, an Inner Sleeve 242 is inserted from the rear within the Outer Sleeve 140. This Inner Sleeve has a collar portion 244 of a known thickness which seats against the top edge surface 172 of Outer Sleeve 140. The cylindrical barrel portion of Inner Sleeve 242 comes to approximate the posterior aspect of the vertebral bodies interior the Outer Sleeve when fully seated. A Drill 240, having a known selected length is then introduced through the rearward aperture of the Inner Sleeve 242 and utilized to ream out the arcs of bone which it engages from the opposed vertebral endplates as well as

any discal material within its path down to its predetermined and limited depth. The Drill 240, has a narrow engagement portion 246, which allows it to be affixed to a drill mechanism which may be either a manual or a power unit. A circumferential collar 248 of an increased diameter serves to limit the depth of penetration of the drill 240 and may be fixed, or lockably adjustable.

Not shown here, but well known to those skilled in the art, are various mechanisms to lockably adjust such instruments as drills. Such mechanisms include, but are not limited to, the use of collets, threaded shafts with lock nuts, and flanges engaging grooves forced therein by either a cap pulled over the flanges or screwed down upon them.

In the preferred embodiment, the forward cutting edge 252 of Drill 240 is a modification of a large fluted drill design such that the end resembles an end cutting mill which may contain any workable number of cutting surfaces, but preferably four or more, and such cutting surfaces being relatively shallow such that the advancement of the instrument occurs more slowly. The outside diameter of the Drill 240 corresponds to the minor diameter of the threaded spinal implant. The Inner Sleeve 242 has an inner diameter slightly greater than that dimension and its outer diameter is slightly smaller than the inside diameter of the Outer Sleeve 140 which has the same outer diameter as the major diameter of the threaded implant.

The drill shaft of drill 240 comprises an upper portion 243, a central recessed portion 256 of a smaller diameter and a lower cutting drill portion 250. The upper portion 243 and lower portion 256 of the drill 240 have the same outside diameter.

The Inner Sleeve 242 serves many functions. First, it provides a more intimate drill guide for drill 240 in the event a smaller diameter hole is to be drilled than that of the inside diameter of the Outer Sleeve 140. Second, since it now guides the Drill, it allows for the Outer Sleeve 140 to have an internal diameter large enough to admit the threaded spinal implant, which is indeed considerably larger in diameter than the Drill 240 itself.

If a larger Outer Sleeve 140 were utilized absent the Inner Sleeve 242, then the Drill 240 would be free to wander within the confines of that greater space and would not reliably make parallel cuts removing equal portions of bone from the adjacent vertebrae V. Further, the bone removal not only needs to be equal, but must be correctly oriented in three dimensions. That is, the path of the Drill 240 must be equally centered within the disc space, parallel the endplates, and parallel to the sagittal axis dissecting the interspace.

A further purpose of the Inner Sleeve 242 is that it may be removed simultaneously with the Drill 240, thereby trapping the debris, both cartilaginous and bony generated during the drilling procedure, which are guided rearward by the large flutes 251 of Drill portion 250,

where they are collected around recessed portion 256 between the recessed portion 256 and the inner wall of the Inner Sleeve 242 are there contained therein. Thus, by removing the Drill 240 in conjunction with the Inner Sleeve 242, all of the debris generated by the reaming procedure is safely removed from the spinal canal and wound area.

Further, if the disc tissue in the area to be reamed has been removed previously, as per the preferred method, then the patient's own bone of good quality and useful within the operation will then be contained between the Inner Sleeve 242 and the shaft portion 256. Once away from the surgical wound, this material may be used to load the spinal implant or placed deep within the interspace to participate in the fusion.

The method of actually producing the surgical hole within the spine is variable. As shown in Figure 11C, in an alternative embodiment Drill end 250 has a forward projecting nipple 260, which itself is bullet-shaped in its leading aspect so as to ease its entrance into the disc space and to urge the vertebrae apart. Nipple 260 is distracting, stabilizing as it resists any tendency of the vertebrae to move together, is self-centering to the Drill portion 250 when working in conjunction with Sleeves 140 and 242, and virtually assures the symmetrical resection of bone from the opposed vertebral surfaces.

The alternative "Trephine Method" referred to earlier in this application, is shown in Figure 11B. In this alternative, a Long Distractor 100 is left in place

after the Outer Sleeve 140 is seated. The Long Distractor 100 in this case differs from the Long Distractor of the preferred embodiment in that its outside diameter of the barrel 106 is of a smaller diameter than in the prior version. This is made necessary because regardless of the method, the hole to be formed corresponds to the minor diameter of the spinal implant. Trephine 270, a hollow, tubular member with sharp cutting teeth 251 at its proximal end, has a wall thickness and since the outside diameter of that trephine 270 must correspond to the root diameter of the implant, then the wall thickness of the trephine 270 must be allowed for by a corresponding reduction in the diameter of the Long Distractor 100.

A further modification of the Long Distractor 100 to the "Trephine Method" would use longitudinal grooves (not shown) along the barrel surface 106 for the purpose of transmitting any debris generated during the cutting procedure, rearward. Since the cutting element is both centered and aligned by the Long Distractor, the use of the Inner Sleeve 242 is not mandatory, but may once again be useful in controlling the path of the debris. To that end, little debris is generated in the "Trephine Method" as the bony arcs are not so much being reamed out and removed as they are simply being cut into the bone where these arcs of bone are left connected at their far ends. Thus, when the Trephining Method has been completed and the Trephine 270 and Inner Sleeve 242 removed, unlike in the preferred embodiment where the hole is drilled out, it remains

necessary to remove both the two arcs of bone, and any interposed material. Nevertheless, this is very easily performed by various means, one of which is depicted in Figure 11D.

Instrument 272 consisting of a shaft 276 attached off center to the lower surface 273 handle 274. The shaft 274 terminates in a cutting arm 278. The instrument 272 is inserted through Outer Sleeve 140 where the lower surface 273 of handle 274 abuts the top 172 of the Outer Sleeve 140, both stopping downward motion of instrument 272 and precisely placing the perpendicularly cutting arm 278 of instrument 272 so that as handle portion 274 is rotated, the cutting arm 278 is also rotated, cutting the arcs of bone and liberating them from their last attachments. These portions of bone are then removed utilizing this instrument or a long forceps, and then placed within the implants or otherwise used to participate in the fusion.

While in the preferred embodiment of the present invention the spinal implant I, is essentially self-tapping, if the bone is unusually hard it may be desirable to form the thread pattern within the interspace prior to the insertion of the implant I. To that end, as shown in Figure 12, Tap 280 has a threadcutting portion 282 connected by a shaft 286 to a handle portion 292, which has been designed to give mechanical advantage to the rotation of the instrument for the purpose of cutting threads. The lower portion of handle 290 has a forward facing flat surface 288 too large to fit through the opening of Outer

Sleeve 140 which thus safely limits the depth of penetration of the cutting element 282. This tap 280 is further made safe by blunt end 294 which will engage the uncut portions of the vertebral bone just prior to the engagement of shoulder 288 against surface 172. This feature allows the surgeon to appreciate a less harsh resistance as the blunt nose 294 encounters the remaining unresected bone for the drill hole and prior to the sudden increase in resistance caused by the seating of shoulder 288 against top edge 172, which first resistance serves as a warning to the surgeon to discontinue the tapping procedure. Thus, the surgeon has both visual (as shoulder 288 approaches top edge 172) and tactile warnings to avoid stripping the thread form. Tap end 282 is highly specialized for its specific purpose. Rearward to the specialized blunt tip 294 is a truncated bullet-shaped area 298 which ramps up to the constant diameter intermediate the cutting ridges 296. Ramp portion 298 urges the opposed vertebral bodies apart, which motion is resisted by Outer Sleeve 140, thus progressively driving the sharp leading edges of thread forms 296 into the vertebral bodies. The periodic longitudinal grooves 284 interrupting the thread forms, which may number 1 to 8, but preferably 4, function to accumulate the bony material which is removed during the thread cutting process. In that regard, in the ideal embodiment, the thread cutting form is designed to compress the bone to be formed rather than to trough through it. Further, while both the major and minor diameters of the

Tap 280 may be varied, in the preferred embodiment, the minor diameter corresponds to the minor diameter of the implant I, but the major diameter is slightly less than the major diameter of the implant.

With Tap 280 now removed, and Sleeve 140 still in place, the surgical site is now fully prepared to receive the spinal implant I. In the preferred embodiment of the spinal implant, the implant has been enhanced by the use of, application to, and filling with fusion promoting, enhancing, and participating substances and factors. Thus, the implant may be fully prepared for insertion as provided to the operating surgeon. However, at the present time, human bone is most commonly used as the graft material of choice, with the patient's own bone being considered the best source.

Figure 14a shows a trephine 300 with an exceedingly sharp front cutting edge 302 for quickly and cleanly coring into the patient's posterior iliac crest, or any other bony tissue, and for the purpose of producing a core of bone then contained within the hollow 304 of the trephine 300. Trephine 300 has a rear portion 306 with a pair of diametrically opposed slots 310, and disposed clockwise from their longitudinally oriented rearward facing openings so as to engage diametrically and opposing members 312 of Drive unit 308, by which trephine 300 may be attached to either a hand or power drill. It can be appreciated that engagement mechanism 312 is stable during the clockwise cutting procedure, and yet allows for the

rapid disconnection of the two components once the cutting is completed.

Because of the high interference between the graft and the inner wall of hollow portion 304, and the relative weakness of the cancellous bone being harvested, it is possible to remove the Trephine 300 while still drilling, and to have it extract the core of bone with it. However, in the highly unlikely event that the core of bone would remain fixed at its base, then with the drive mechanism 308 removed, a corkscrew 408 shown in Figure 14C is introduced though the central opening of rear portion 306 and threaded down and through the core of bone within 304 and to the depth of teeth 302. The tip 318 of the corkscrew 408, which extends substantially on line with the outer envelope of the corkscrew, then cuts radially through the base of the bone core. As the handle portion 314 of the corkscrew 408 abuts the flat, rearward surface of portion 306 and it can no longer advance. As corkscrew 408 is continued to be turned further, it will cause the core of bone to be pulled rearward, as in removing a cork from a wine bottle. Trephine 300 has a barrel portion 304 continuous with sharp toothed portion 302 having an inner diameter just less than the inner diameter of the spinal implant I to be loaded.

The Trephine 300 with its core of harvested bone is then placed as shown in Figure 14B, through opening 340 of Implant Bone Loading device 320, where the barrel portion 304 then passes through and is stopped by circular

flange 344. The plunger shaft 326 of instrument 320 is then prepared for attachment by rotating knob 332 counterclockwise such that the plunger 372 is pulled via the long threaded shaft portion 328 back to the base of collar 330 at its proximal end. In this position, knob 332 is considerably extended rearward from collar 330. With plunger shaft 326 in this position, the plunger head 372 is inserted into the central hollow of portion 306 of Trephine 300 as the proximal cylindrical portion of collar 330 then follows it, such that the plunger 372 then occupies the rearward portion of barrel 304 and the proximal cylindrical portion of collar 330 occupies the central hollow of portion 306. A pair of diametrically opposed radially projecting arms 346 on collar 330 are then advanced longitudinally into diametrically opposed paired L slots 340 and then rotated clockwise to complete this assembly.

At the other end of instrument 320, a spinal implant I is engaged through its female rectangular slot 364 by a rectangular protruding bar extending from rearward facing surface of end plug 324, (not shown) and secured there by knob 334 which extends as a rod through a central aperture within end plug 324 to extend at the far end as a small bolt which threads to a female aperture centered within the female slot 364 of the spinal implant. With the spinal implant I secured to end plug 324 and the opposite end of the implant I presenting as a hollow, tubular opening, end plug 324 is advanced into device 320 where it

is secured by rotationally engaging diametrically opposed L-shaped slots 321. With device 320 fully assembled, end 302 of trephine 300 lies coaxial and opposed to the open end of implant I.

As shown in Figure 15, as knob 332 is then rotated clockwise, the plunger 372 proximal the threaded shaft 328 is then forcibly, but controllably driven forward down the barrel 304 ejecting the bone graft directly into the spinal implant I. As the bone graft is greater in length than the interior of the spinal implant, with further compression the bone is forced into the radially disposed apertures through the wall of the device communicating from the central cavity to the exterior.

End plug 324 is then removed from apparatus 320. Using end plug 324 as a handle, end cap 374 shown in Figure 16 is secured to the open end of the spinal implant I. The implant is then disassociated from end plug 324 by rotating knob 334 counterclockwise.

Figure 16 shows an Implant Driver instrument which may be used to either insert or to remove said implant I. Driver 350 has at its far end 362, a rectangular protrusion 398, which protrusion intimately engages the complimentary rectangular slot 364 of implant I. Protruding from slot 398 of end 362 is threaded portion 353, which extends as a rod through hollow shaft 358 and hollow hand barrel 360 to knob 354 where it can be rotationally controlled. Threaded portion 353 screws into a female aperture central slot 364, urging 353 into 364,

and binding them together such that instrument 350 can be rotated via paired and diametrically opposed extending arms 366 and in either direction while maintaining contact with the implant.

Affixed to the Driver 350, the implant is then introduced through the Outer Sleeve 140 and screwed into the interspace opposed between the two prepared vertebrae V until such time as the leading edge of the Implant Cap 374 reaches the depth of the prepared hole at which time its forward motion is impeded by the bone lying before it which had not been drilled out. This allows for a progressive feel to the surgeon as the implant is screwed home.

As described previously, with the use of the Tap 280, this terminal resistance to further seating provides significant tactile feedback to the surgeon. Again, as with the Tap 280, visual monitoring of the depth of insertion of the implant is provided to the surgeon by observing the progressive approximation of the forward surface 370, of barrel portion 360, as it approaches the rearward facing surface 172 of Outer Sleeve 140. Nevertheless, a final safety mechanism, when the full depth of insertion has been achieved, surface 370 of instrument 350 will abut surface 172 of the Outer Sleeve 140, prohibiting any further installation of the spinal implant.

Once the implant has been fully installed, the Driver 350 is dissociated from the implant by turning knob 354 in a counterclockwise direction. The Driver 350 is

then withdrawn from the outer sheath, then the Outer Sleeve 140 is removed. This leaves the implant fully installed and inset to the determined depth as shown in Figure 18.

Attention is then redirected to the other, or first, side of the spine. A dural nerve root retractor is used to retract the neural structures medially, bringing into full view the head 128 of the Short Distractor 120, lying flush on the canal floor. Utilizing apparatus 152, extended screw portion 116 is inserted into the female threaded portion 114 of the Short Distractor 120 as the extended rectangular portion 134 of apparatus 152 is engaged to the female rectangular portion 118 of the Short Distractor 120. Then turning rearward facing portions 108 and 110, utilizing the knob 136 of Figure 2, the Long Distractor configuration is restored.

With the dural sac and nerve roots still retracted and protected, the Outer Sleeve 140 is slipped over the reconstituted Long Distractor and seated using the Driver Cap 162. The entire sequence of events as described for the implantation of the spinal implant I as already placed, is then repeated such that both spinal implants come to lie side by side within the interspace. Though not necessary, circlage or other internal fixation of the levels to be fused may additionally be performed, and then the wound is closed in the routine manner.

Brief Discussion With Reference To The Drawings of The Preferred Method And Instrumentation For Anterior Interbody Fusion

Incorporating Intercorporeal Predistraction And Utilizing A Guarded Sleeve System Is Disclosed

Because of the absence of the spinal cord and nerve roots, it is generally possible to visualize in one instance the entire width of the disc space from side to side throughout the cervical, thoracic, or lumbar spine. In the preferred embodiment of the anterior interbody fusion, implants are placed side by side from anterior to posterior parallel to the interspace and extending through into the adjacent vertebral bodies. Where the transverse width of the disc space is insufficient to allow for the use of two implants, each of which would be large enough to protrude to the required depth into the adjacent vertebrae, then a singular and significantly larger implant may be placed centrally. With this in mind, and in light of the very detailed description of the technique and instrumentation already provided in regard to the method of posterior lumbar interbody fusion, a brief discussion of anterior spinal interbody fusion with dual implant installation will suffice, and the method for installation of a large, singular midline graft will become obvious.

The interspace to be fused is exposed anteriorly. The soft tissues are withdrawn and protected to either side, and if necessary, above and below as well. It is then possible to visualize the entire width of the vertebrae anteriorly adjacent that interspace. As discussed above, the surgeon has already templated the

appropriate patient radiographs to determine the requisite distraction and optimal implant size. In the preferred method, the surgeon then broadly excises the great bulk of the nuclear disc portion. (Alternatively, the disc can be left to be removed via the drill later.) The surgeon then notes and marks a point midway from side to side anteriorly. He then inserts Long Distractor 100 centering it on a point midway between the point just noted and the lateral extent of the intervertebral space visualized anteriorly. The outer barrel portion 106 of the Distractor 100 utilized, will correspond to the outside diameter of the implants to be installed. The Distractor tips 102 inserted are sequentially larger in diameter until the optimal distraction is achieved. This optimal distraction, although suggested by the initial templating, may be visually and tactilely confirmed as performed. When the optimal distraction is achieved, the vertebral endplates will come into full congruence and parallel to the forward shaft portion 102 of the Distractor 100, causing an alteration in the alignment of the vertebrae and a significant increase in the interference fit and pressurization at the tip, such that the instrument becomes exceedingly stable.

There is a sensation imparted to the surgeon of the tissues having moved through their elastic range to the point where the two adjacent vertebrae V begin to feel and move as if a single solid. These changes are easily appreciated visually as the vertebrae realign to become

congruent to tip 102, and can also easily be appreciated via lateral Roentgenography. However, should the surgeon fail to appreciate that optimal distraction has been achieved and attempt to further distract the interspace, he would find that extremely difficult to do because of the increased resistance as the tissues are moved beyond their range of elastic deformation. Further, there would be no elasticity left to allow the vertebrae to move further apart and the sensation to the surgeon should he attempt to gently tap the oversized Distractor forward with a mallet, would be one of great brittleness.

Returning now to the procedure, when the correct intercorporeal Distractor 100 producing the ideal interspace distraction having its barrel portion 106 corresponding to the implant to be installed has been inserted, then its exact duplicate is inserted anteriorly equidistant to the other side of the spine. As the barrel portion 106 of Long Distractor 100 is exactly of the same major diameter as the spinal implant I looking coaxially on end, the surgeon can then asses the anticipated side by side relationship of the dual implants when implanted.

As shown in Figures 7C and 7D, a Dual Outer Sleeve 340 consisting of a pair of hollow tubes is then introduced over the side by side Long Distractors protruding anteriorly from the spine. The Dual Outer Sleeve 340 is comprised of two hollow tubular members identical in size displaced from each other ideally the sum of the difference between the minor and major diameters of

both implants combined, but not less than that difference for one implant, as it is possible to have the threads of one implant nest interposed to the threads of the other, such that they both occupy a common area between them. However, while the preferred embodiment is slightly greater than two times the difference between the major and minor diameters of the implant (the sum of both) the distance may be considerably greater. Whereas in the preferred embodiment extending tubular portions 348 of instrument 340 are parallel, when the area between them 350, is sufficiently great, these elements may be inclined or declined relative to each other such that they either converge or diverge at their proximal ends. Paired tubular structures 348, may be bridged in part or wholly throughout their length, but are rigidly fixed by Foot Plate 344. In its preferred embodiment, a top view shows the Foot Plate to be essentially rectangular, but without sharp corners.

Other shapes can be utilized. In side view 7D it can be appreciated, that Foot Plate 344 is contoured so as to approximate the shape of the vertebrae anteriorly. Extending forward from Foot Plate 344 are multiple sharp prongs 342 sufficiently long to affix them to the vertebrae. The prongs 342 are limited in length so as to not penetrate too far posteriorly and number from 2 to 10, but preferably 6. As the Dual Outer Sleeve 340 is driven forward utilizing Dual Driver Cap 420, of Figure 7E, engaging the rearward end 352, the prongs 342 extending

from Foot Plate 344 are embedded into the opposed vertebral bodies until their forward motion is inhibited by the curved Foot Plate 344 becoming congruent to and being stopped by, the anterior aspect of the vertebral bodies.

As already taught in Figure 5, the Dual Driver Cap 420 is of the same design as Single Driver Cap 160, in that there is a recess 354 as per 168, allowing the Outer Sleeve to be fully seated without impeding the rearward projection of the Long Distractor unit. However, unlike in Cap 160, area 354 is more relieved as it is unnecessary for the Dual Cap 420 to contact the Long Distractor through portion 110 to inhibit its forward motion, as the Foot Plate 344 functions to that effect. Further, the Dual Cap 420 for the Dual Outer Sleeve 340 is correspondingly dual itself and engages the rearward facing dual tubular portion 352. Once the Dual Outer Sleeve has been fully seated, the vertebrae adjacent the interspace to be fused are rigidly held via Foot Plate 344 and the prongs 342. Thus, it is possible to remove either one, or if desired, both of the Long Distractor rods utilizing Long Distractor puller 200, as per the method already described. It is then the surgeon's choice to work on one or both sides of the spine. As per previous discussion, the surgeon may drill the interspace utilizing the Inner Sleeve 242 or leave the Long Distractors in place as per the "Trephine Method".

Tapping, if necessary, and the insertion of the implants then occurs through the protective Outer Sleeve 340. Once the implants have been fully inserted, the Outer

Sleeve is removed.

Having utilized the Drill method, or "Trephine Method", with or without an Inner Sleeve to prepare the fusion site, it is the preferred embodiment to leave the Outer Sleeve 340 in place as it provides for the ideal placement and alignment of the Tap 280 and implant I.

It is anticipated that the surgeon wishing to work deep within the interspace, or preferring the ability to directly visualize the tap being used, or the implant being inserted, may choose to remove the Outer Sleeve after the insertion of the first prosthesis to maintain stability, or prior to that, which while not the preferred embodiments, are nevertheless within the scope of the present invention.

Alternative Methods To The Preferred Embodiment For Method Of Anterior Interbody Fusion

As previously described for the posterior lumbar spine, alternatively, one can employ the "Trephine Method" as has been described in detail.

As a further alternative, it should be noted that the key element in the anterior method is the use of the predistraction principle, where such distraction is maintained by the Outer Sleeve with or without the Long Distractor. Therefore, once the preparation of the interspace has been completed, while not the preferred embodiment, it is nevertheless within the scope of this invention that one could remove the Outer Sleeve as there

are no neural structures requiring protection, and insert the implants directly rather than through the Outer Sleeve.

As yet a further alternative of this method, where the height of the distracted interspace is such that the diameter of the implant required to span that height and to embed with sufficient depth into the opposed vertebral bodies is such that it is not possible to place two such implants side by side, then only a single implant which may be of significantly increased diameter, is used and placed centrally within the interspace rather than to either side. The placement of a singular central graft via the present invention method and instrumentation is in keeping with the methods already described and can be performed using either a drill or the "Trephine Method".

Referring to Figures 16-18, a cylindrical embodiment of the spinal implant I of the present invention is shown. In Figure 16 the implant I is shown attached to the insertion device 350. In Figures 17 and 18 the implant I is shown installed in the disc space D, between the adjacent vertebrae.

The cylindrical implant I comprises a hollow tubular member which in the preferred embodiment is made of an ASTM surgically implantable material, preferably Titanium. The cylindrical implant I is closed at one end and open at the other end covered by a cap 394. The cylindrical implant I has a series of macro-sized openings 390 through the side walls of the cylindrical implant I. A series of external threads 392 are formed on the

circumference of the cylindrical implant I. Any variety of threads may be used on the implant. The cap 374 has a hexagonal opening 394 for tightening the cap 374.

While the present invention has been described in association with the implant of a threaded spinal implant, it is recognized that other forms of implants may be used with the present method. For example, dowels, made from bone or artificial materials, knurled or irregularly shaped cylinders or spheres, or any other shaped implants that can be introduced through the outer sleeve may be used. Being able to perform the procedure through the outer sleeve permits the procedure to be performed safely and quickly, and more accurately.

The claims defining the invention are as follows:

1. A spinal distractor for use in spinal surgery for positioning two adjacent vertebral bodies in selected relationship to each other, said spinal distractor including:

a body; and

a disc penetrating extension extending from said body for insertion into the disc space between the two adjacent vertebral bodies and for bearing against adjacent endplates of the two adjacent vertebral bodies, said disc penetrating extension having a first portion for bearing against one of the adjacent endplates and a second portion for bearing against the other of the adjacent endplates, said first and second portions converging away from said body along at least a portion of their length.

2. A spinal distractor for use in spinal surgery for positioning two adjacent vertebral bodies in selected relationship to each other, said spinal distractor including:

a body; and

a disc penetrating extension extending from said body for insertion into the disc space between the two adjacent vertebral bodies and for bearing against adjacent endplates of the two adjacent vertebral bodies, said disc penetrating extension having a first portion for bearing against one of the adjacent endplates and a second portion for bearing against the other of the adjacent endplates, said first and second portions diverging away from said body along at least a portion of their length, said disc penetrating extension having a tapered leading end to facilitate placement of said disc penetrating extension into the disc space.

3. The spinal distractor of claim 1 or claim 2, further including means for limiting the penetration of said disc penetrating extension into the disc space.

4. The spinal distractor of claim 3, wherein said limiting means includes a shoulder on said body at the juncture of said disc penetrating extension and said body for preventing said body from entering the disc space.

5. The spinal distractor of claim 1 or claim 2, wherein said body is removably attached to said disc penetrating extension.

6. The spinal distractor of claim 5, wherein said disc penetrating extension includes a head proximate the juncture of said disc penetrating extension and said body.

7. The spinal distractor of claim 5, further including means for limiting the depth of insertion of said disc penetrating extension into the disc space.

8. The spinal distractor of claim 7, wherein said limiting means includes a head associated with said disc penetrating extension, said head being dimensioned to prevent entry into the disc space.

9. The spinal distractor of claim 8, wherein said head has a low profile so as to minimize protrusion of said head from the two adjacent vertebrae.

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10. The spinal distractor of claim 5, further including means for engaging at least one of the two adjacent vertebral bodies.

11. The spinal distractor of claim 10, wherein said engaging means is a prong.

12. The spinal distractor of claim 1 or claim 2, wherein said disc penetrating extension has surface irregularities.

13. The spinal distractor of claim 12, wherein said surface irregularities include ratchetings.

14. The spinal distractor of claim 12, wherein said surface irregularities include knurling.

15. The spinal distractor of claim 12, wherein said body has means for engaging an extraction device for extracting said disc penetrating extension from the disc space.

16. The spinal distractor of claim 15, wherein said engaging means includes a mating member for mating with an extraction device.

17. The spinal distractor of claim 5, wherein said disc penetrating extension includes means for engaging said body, said body having means for engaging an extraction device for extracting said disc penetrating extension from the disc space.

18. The spinal distractor of claim 1 or claim 2, further including an impacting surface proximate the juncture of said body and said disc penetrating extension for flattening portions of the exterior surface of the two adjacent vertebral bodies.

19. The spinal distractor of claim 1 or claim 2, in combination with a guard having an opening for providing protected access to the disc space and the adjacent vertebrae, said spinal distractor capable of passing through said opening.

20. The spinal distractor and guard combination of claim 19, wherein said guard is a hollow tubular sleeve.

21. The spinal distractor and guard combination of claim 19, wherein said guard is a solid sheath.

22. The spinal distractor and guard combination of claim 19, wherein said guard is a solid piece.

23. The spinal distractor and guard combination of any one of claims 19 to 22, wherein said guard further includes at least one extension for penetrating the spine.

24. The spinal distractor and guard combination of claim 19, further including a removable inner sleeve disposed within said opening of said guard for positioning and aligning a drill.

25. The spinal distractor of claim 1, wherein said disc penetrating extension has a tapered front end to facilitate insertion of said disc penetrating extension into the disc space.

26. The spinal distractor of claim 1 or claim 2, wherein said body includes flutes along the outer surface of said body.

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27. The spinal distractor of claim 1 or claim 2, in combination with a trephine configured for passage over said spinal distractor.

28. A spinal distractor, substantially as hereinbefore described with reference to the accompanying drawings.

29. A spinal distractor for use in spinal surgery for positioning two adjacent vertebrae in selected relationship to each other, substantially as hereinbefore described with reference to the accompanying drawings.

Dated 17 August, 2000
Karlin Technology, Inc.

Patent Attorneys for the Applicant/Nominated Person
SPRUSON & FERGUSON

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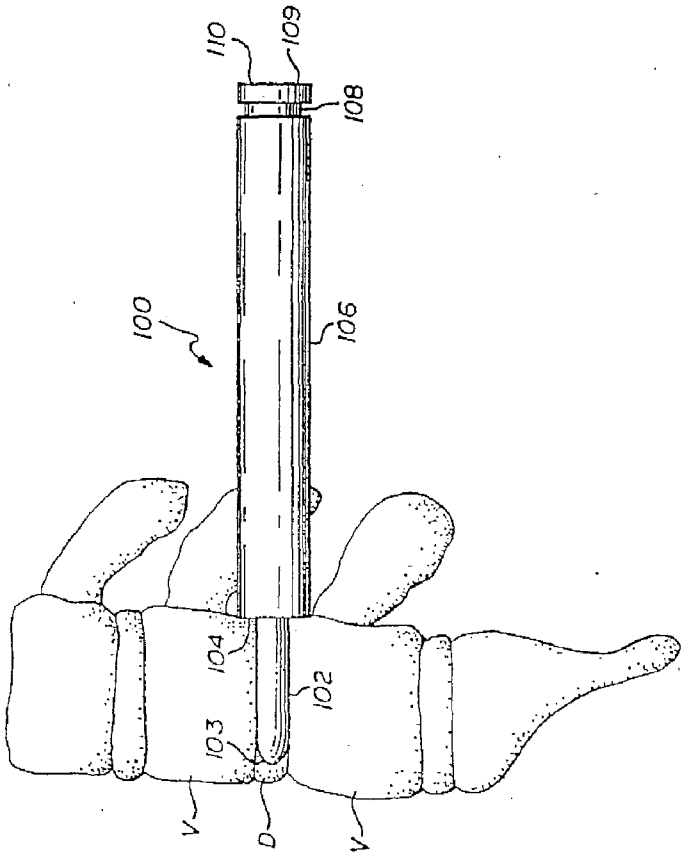


FIG. 1

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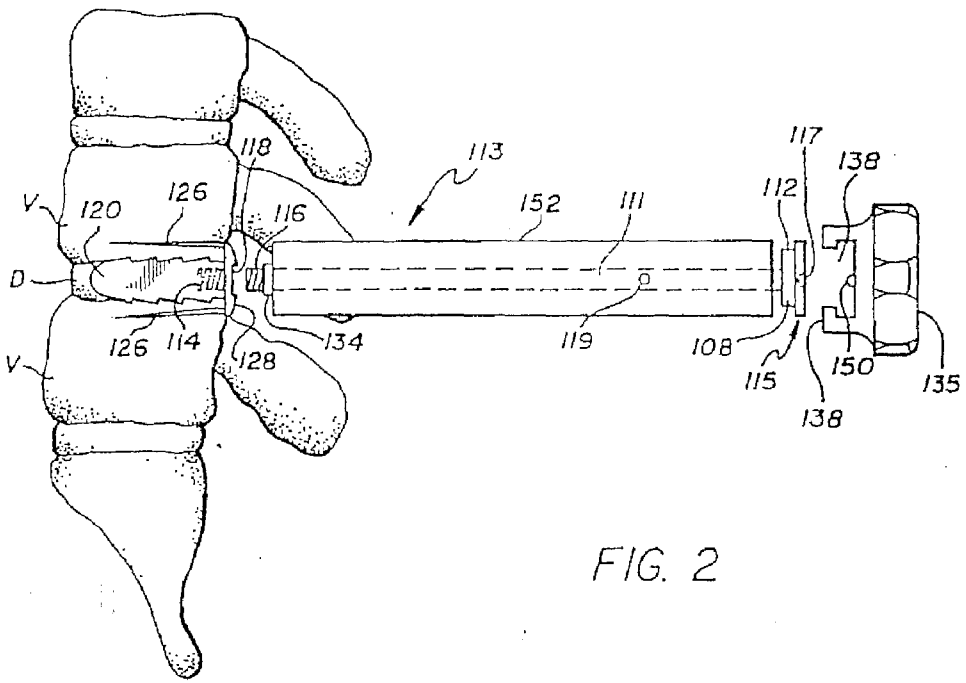

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FIG. 2

FIG. 3

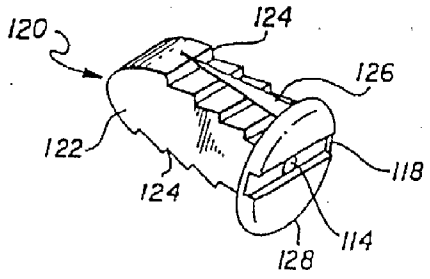


FIG. 3A

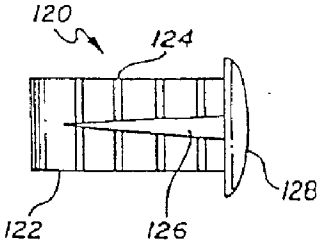


FIG. 3B

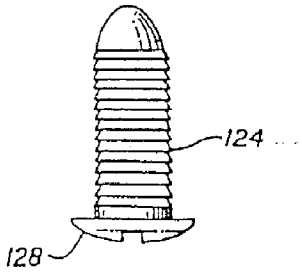


FIG. 3C

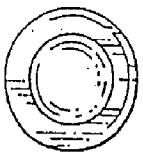


FIG. 3D

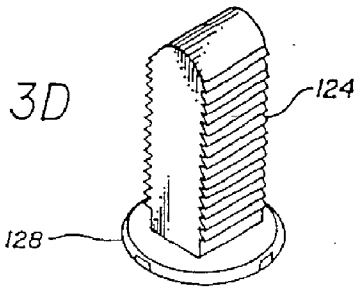


FIG. 3E

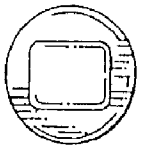
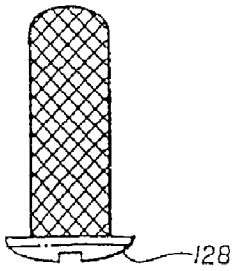
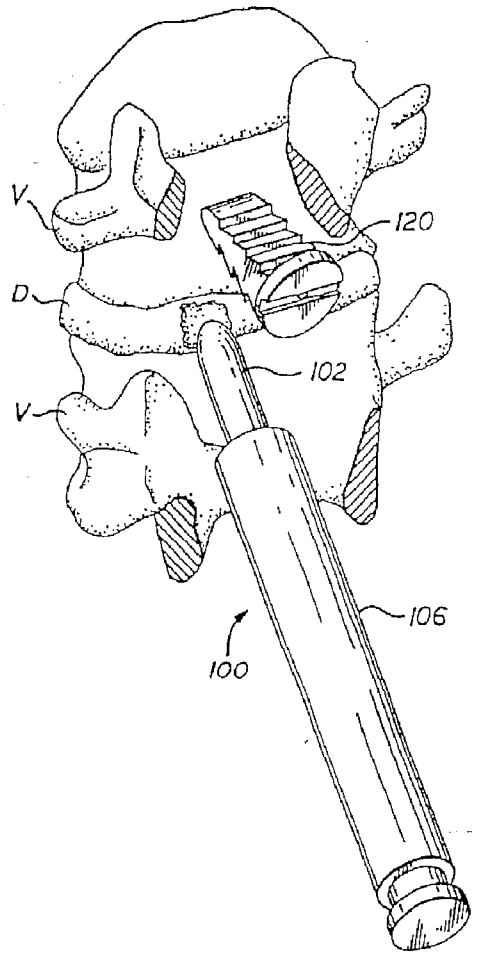


FIG. 3F



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FIG. 4



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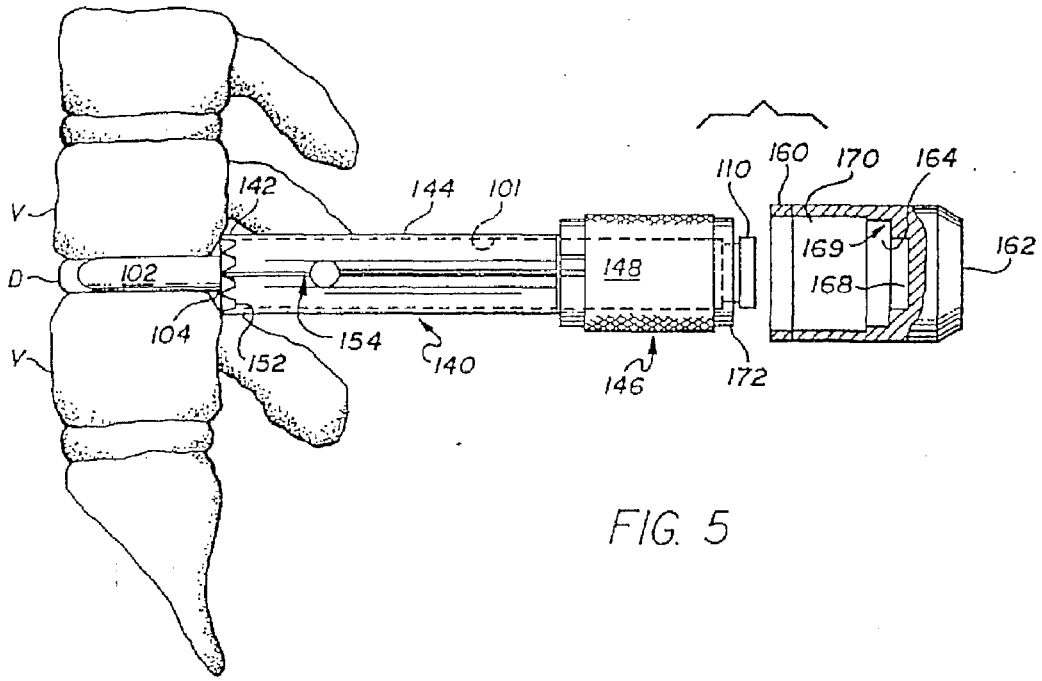

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FIG. 5

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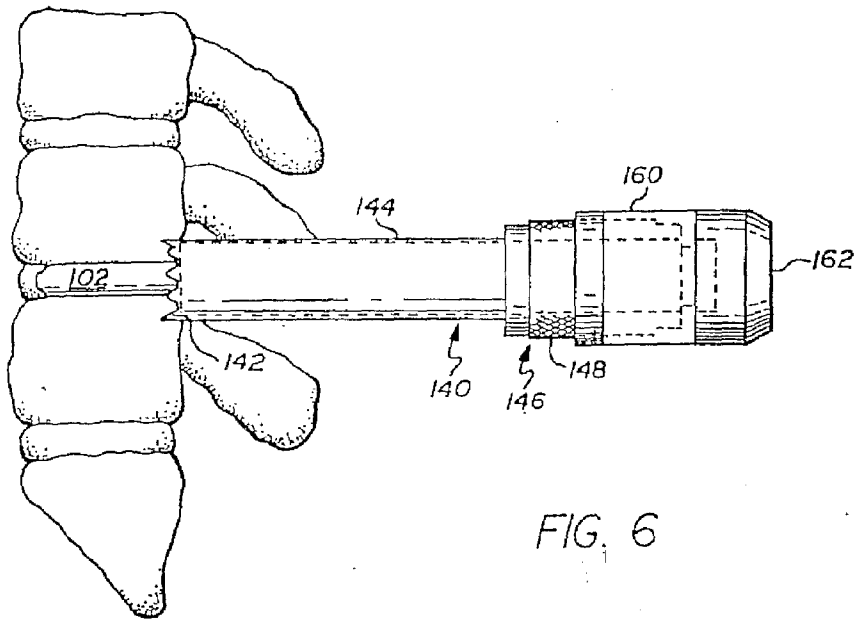
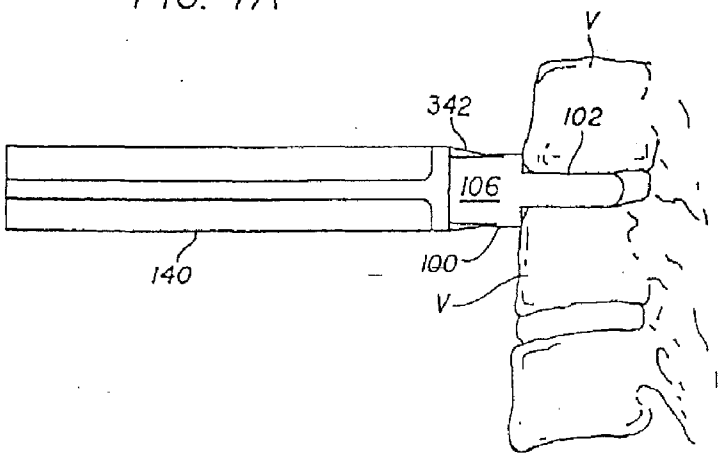


FIG. 6

FIG. 7A



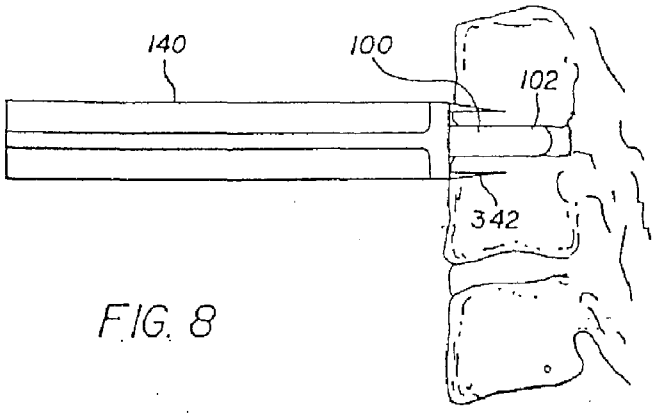


FIG. 8

FIG. 7B

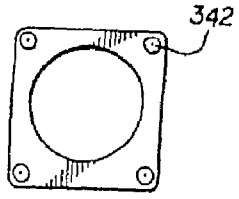


FIG. 7C

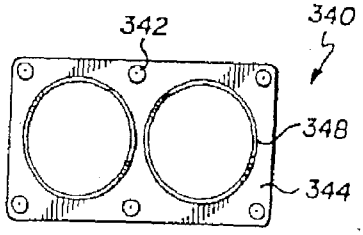


FIG. 7D

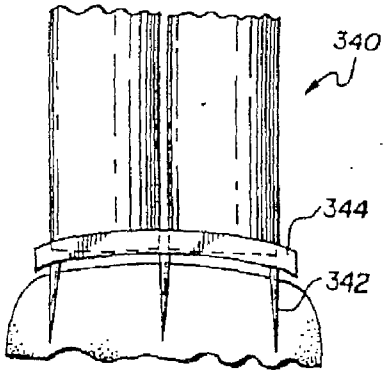
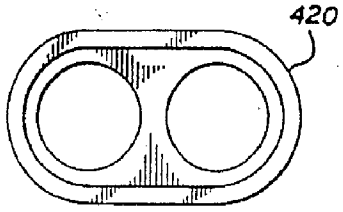


FIG. 7E



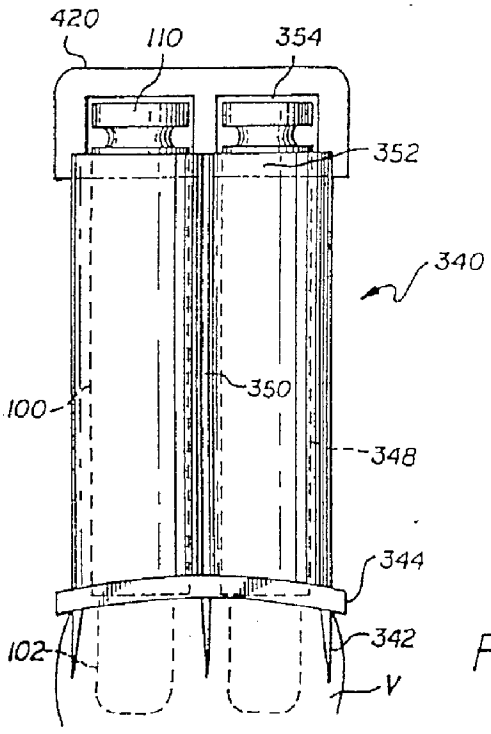


FIG. 7F

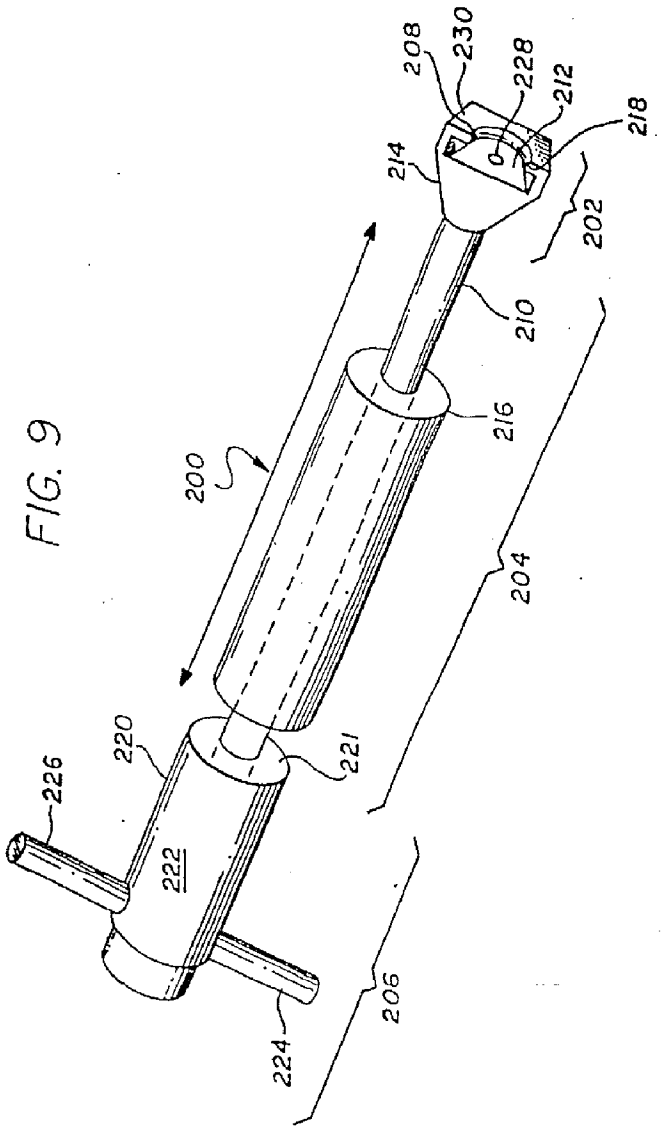

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FIG. 9

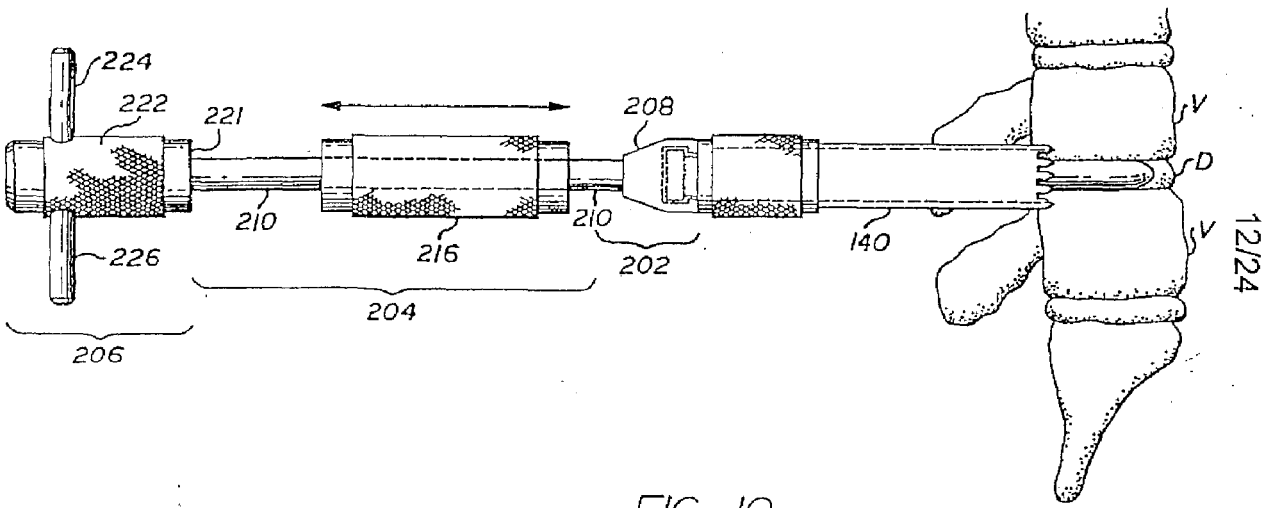


FIG. 10

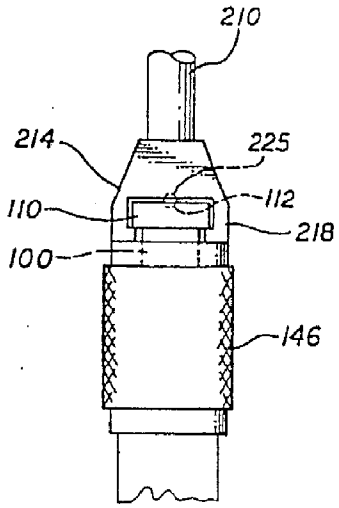


FIG. 10A

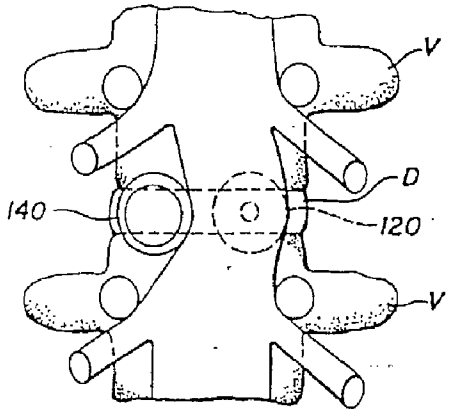


FIG. 10B

FIG. 11A

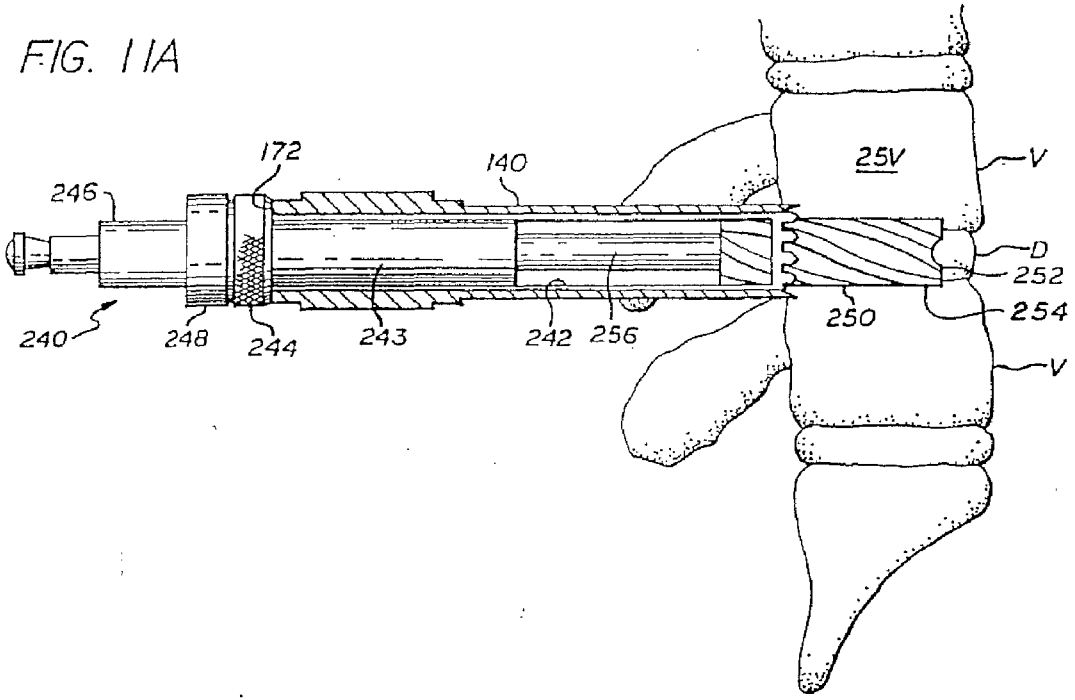
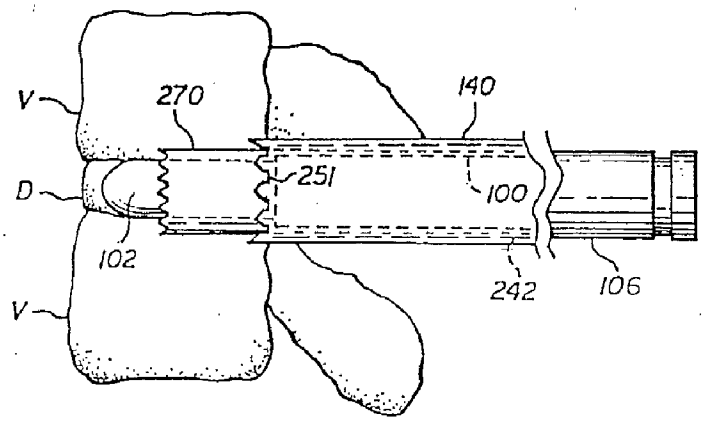


FIG. 11B



SUBSTITUTE SHEET (RULE 26)

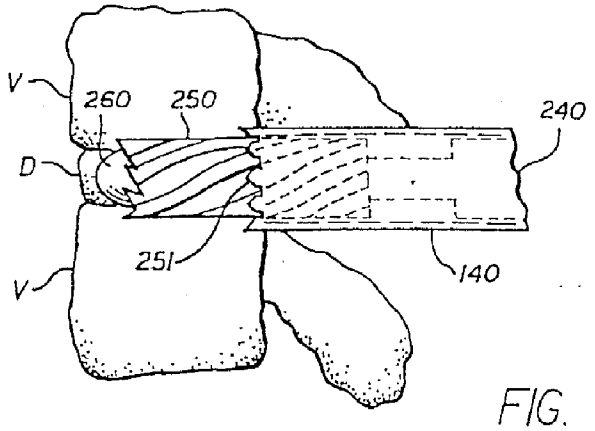
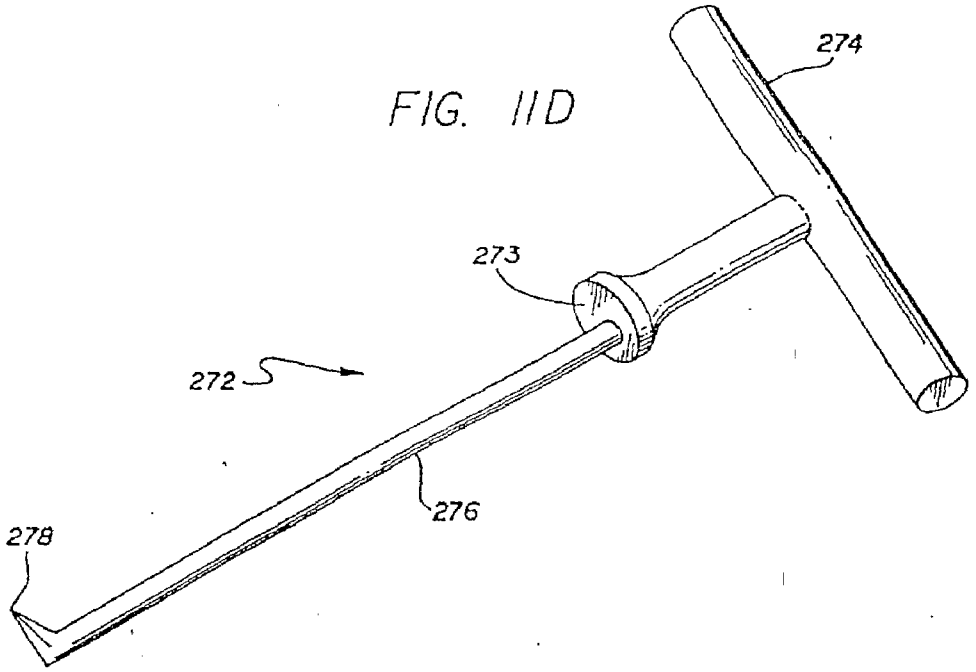


FIG. 11C

FIG. 11D



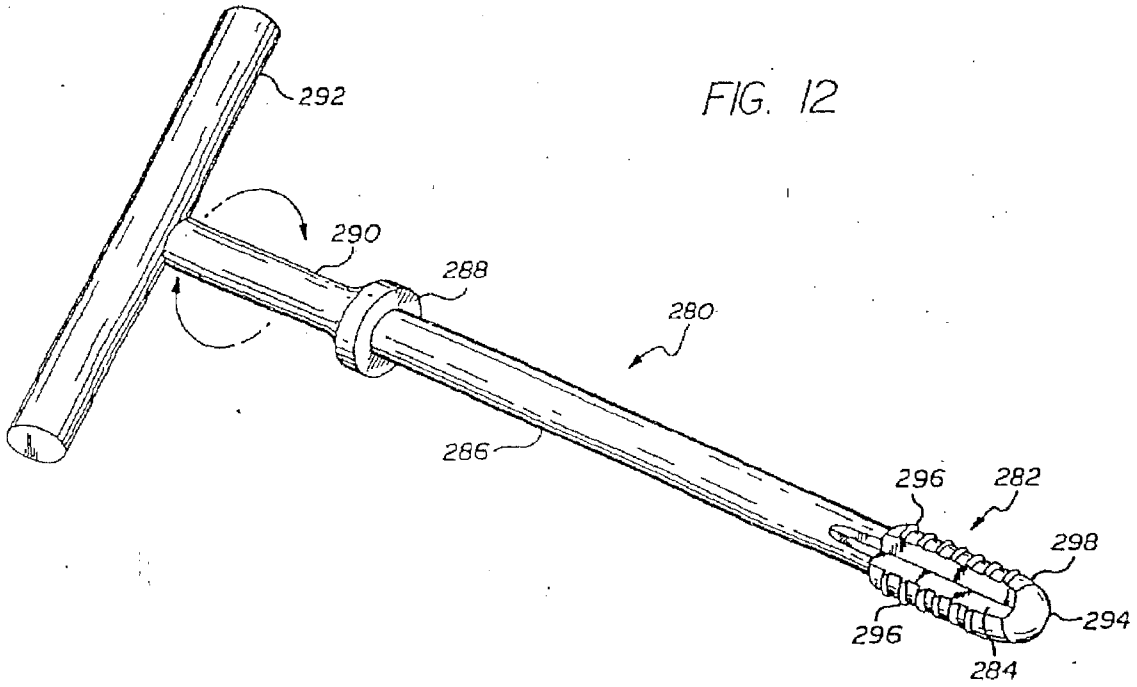
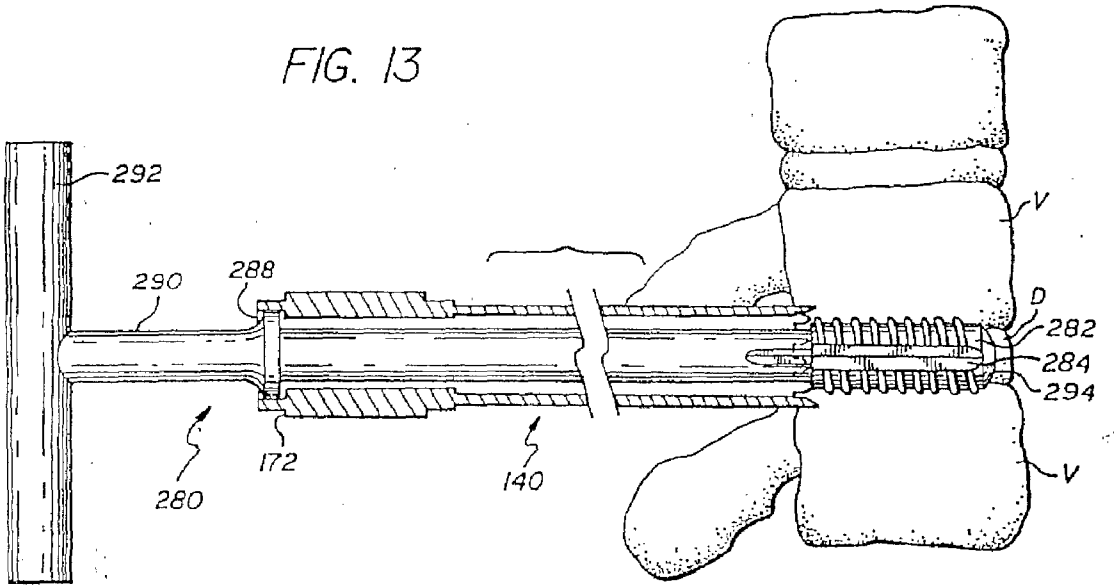


FIG. 12

FIG. 13



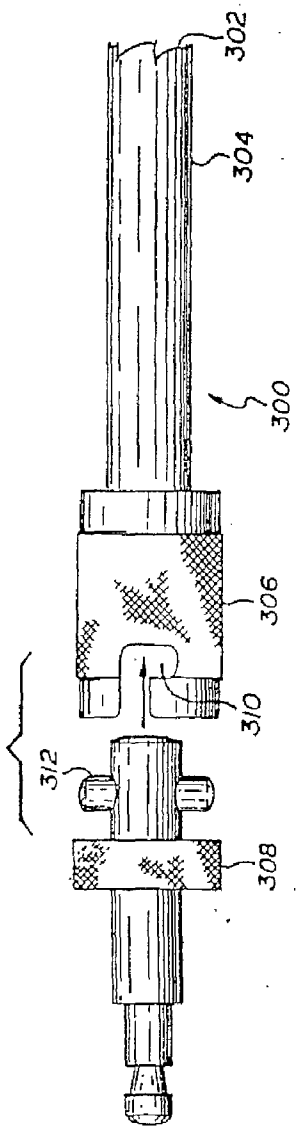


FIG. 14A

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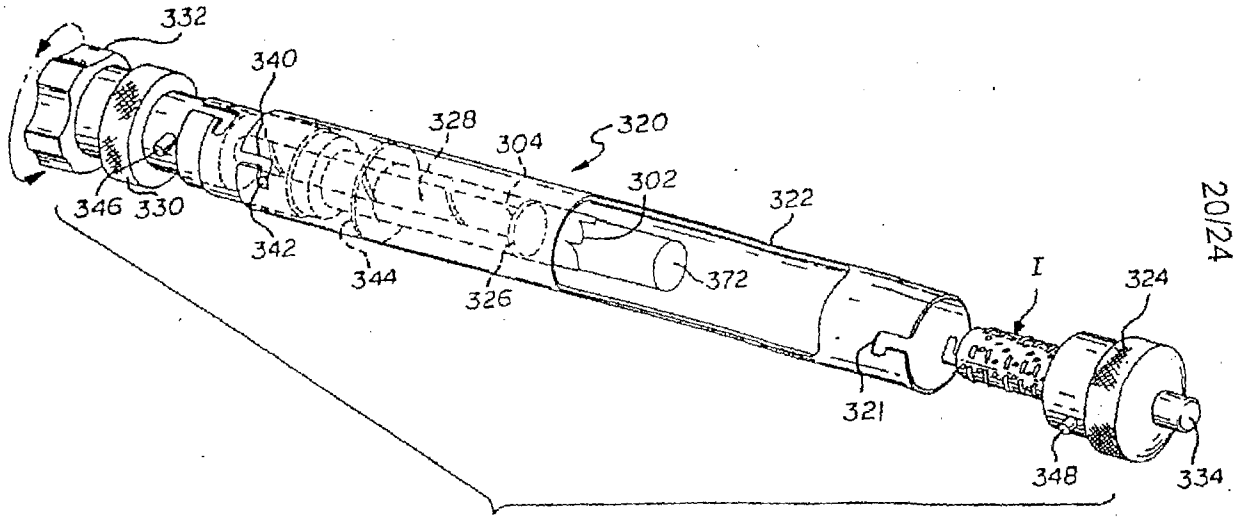


FIG. 14B

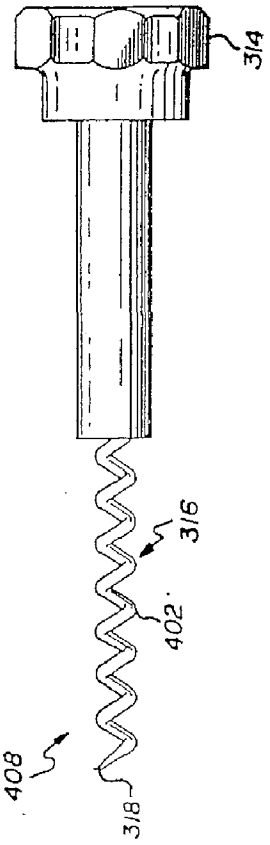
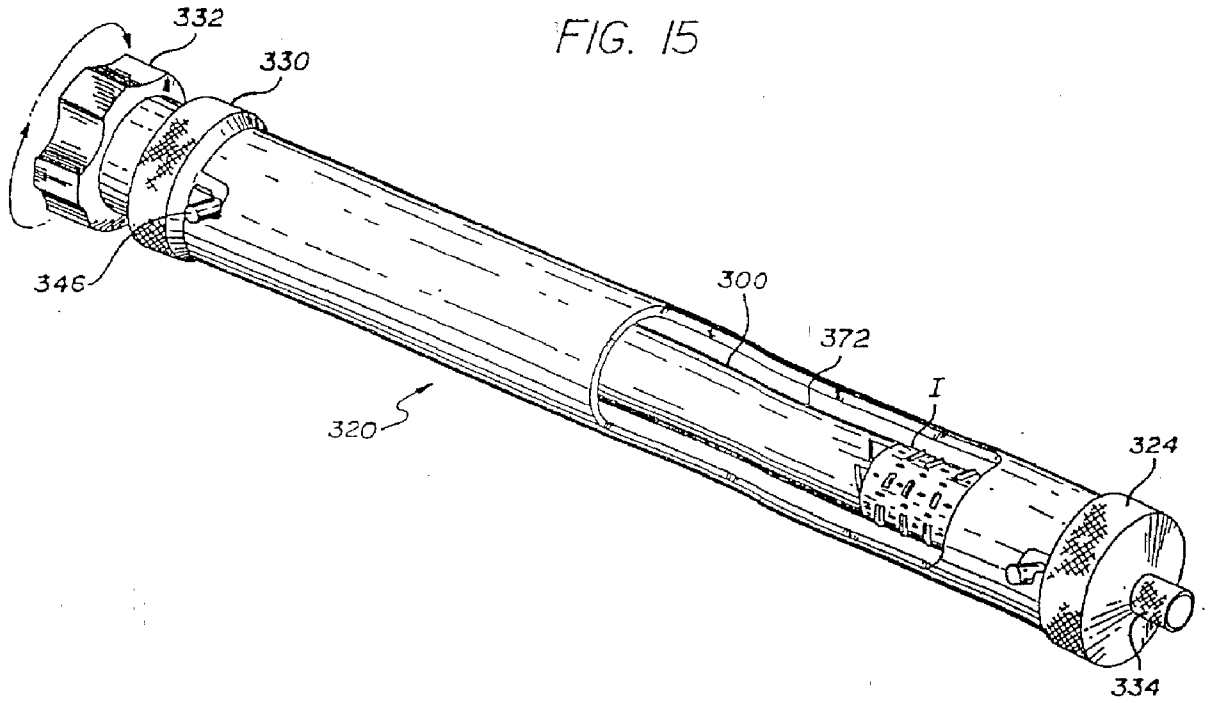


FIG. 14C

FIG. 15



21 07 98 TH15

FIG. 16

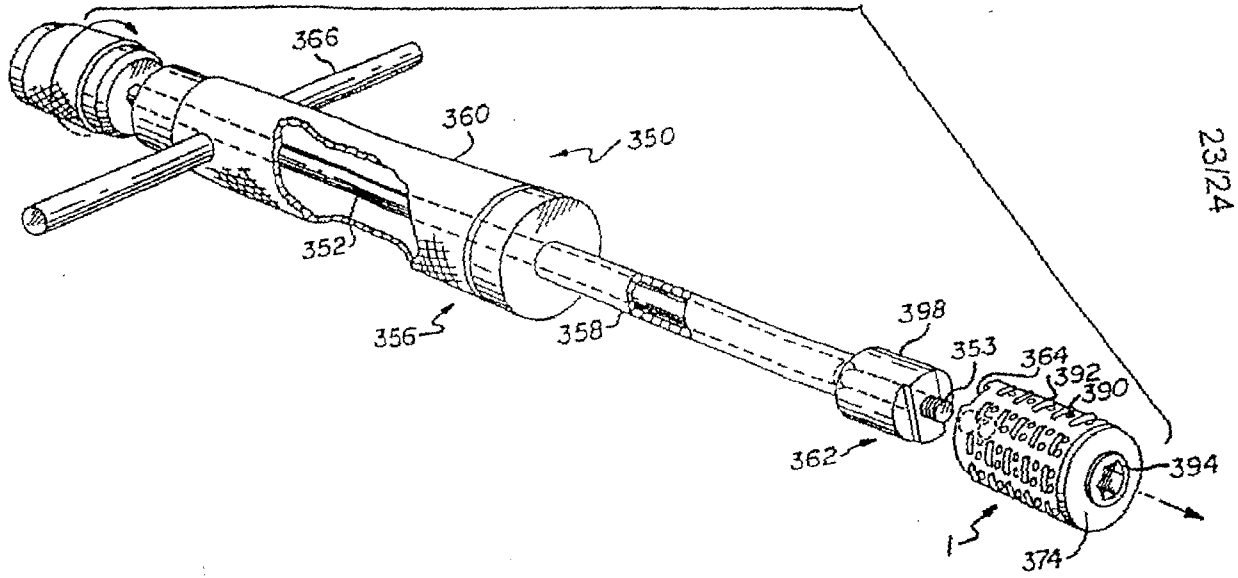


FIG. 17

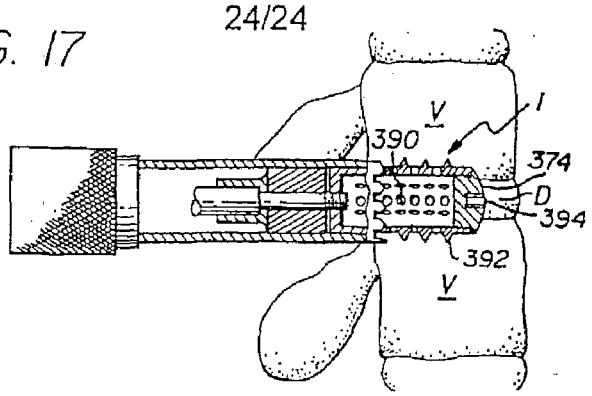
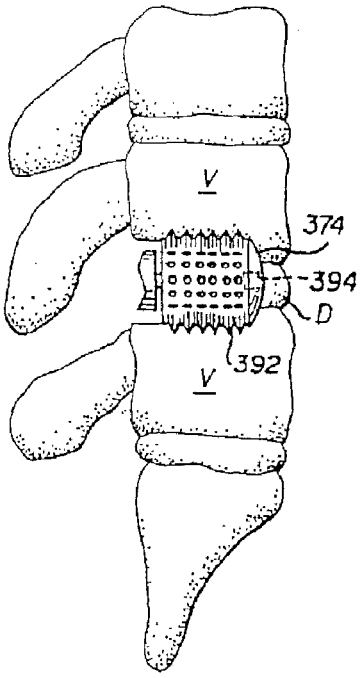


FIG. 18



PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference		FOR FURTHER ACTION
13438-008.14		see Form PCT/ISA/220 as well as, where applicable, item 5 below.
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/US20/54299	05 October 2020 (05.10.2020)	04 October 2019 (04.10.2019)
Applicant Pain TEQ, LLC		

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

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

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

1. **Basis of the report**

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

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

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

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

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

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

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

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

   ☒ the text is approved as submitted by the applicant.

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

5. With regard to the **abstract**

   ☒ the text is approved as submitted by the applicant.

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

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

   a. the figure of the drawings to be published with the abstract is Figure No. 4

   ☒ as suggested by the applicant.

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

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

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

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US20/54299

A. CLASSIFICATION OF SUBJECT MATTER

IPC - A61F 2/46 (2020.01)

CPC - A61F 2/4603; A61F 2002/30622; A61F 2002/30995; A61F 2002/4615; A61F 2002/4687

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
See Search History document

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
See Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2014/0277460 A1 (ORTHOCISION, INC.) 18 September 2014; figures 8, 25, 32 76; paragraphs [0126], [0132], [0134], [0142], [0158]	1-20
A	US 2019/0083271 A1 (JCBD, LLC) 21 March 2019; figures 28A, 28C, 37A, 37D, 117A, 118A; paragraphs [0282], [0310], [0375], [0377]	1-20
A	US 2017/0209155 A1 (PETERESEN, D) 27 July 2017; figures 7B, 7E, 10B, 11B; paragraphs [0162], [0163], [0179], [0193]	1-20
A	US 2011/0106261 A1 (CHIN, K et. al) 05 May 2011; figures 7-8; paragraphs [0037]-[0038]	1-20

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

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

Date of the actual completion of the international search	Date of mailing of the international search report
11 December 2020 (11.12.2020)	08 JAN 2021
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Authorized officer Shane Thomas Telephone No. PCT Helpdesk: 571-272-4300

Form PCT/ISA/210 (second sheet) (July 2019)

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To: Stephen E. Kelly
Hill Ward Henderson, P.A.
101 East Kennedy Boulevard, Suite 3700
Tampa, FL 33602
United States Of America

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)*	08 JAN 2021
Applicant's or agent's file reference 13438-008.14	FOR FURTHER ACTION See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US20/54299	05 October 2020 (05.10.2020)	04 October 2019 (04.10.2019)

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

IPC - A61F 2/46 (2020.01)

CPC - A61F 2/4603; A61F 2002/30622; A61F 2002/30995; A61F 2002/4615; A61F 2002/4687

Applicant Pain TEQ, LLC

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

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

2. **FURTHER ACTION**

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

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

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

Name and mailing address of the ISA/US	Date of completion of this opinion	Authorized officer
Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	11 December 2020 (11.12.2020)	Shane Thomas PCT Help Desk Telephone No. 571-272-4300

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US20/54299

Box No. I Basis of this opinion

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

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

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

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

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

   a. ☐ forming part of the international application as filed:

      ☐ in the form of an Annex C/ST.25 text file.

      ☐ on paper or in the form of an image file.

   b. ☐ furnished together with the international application under PCT Rule 13*ter*.1(a) for the purposes of international search only in the form of an Annex C/ST.25 text file.

   c. ☐ furnished subsequent to the international filing date for the purposes of international search only:

      ☐ in the form of an Annex C/ST.25 text file (Rule 13*ter*.1(a)).

      ☐ on paper or in the form of an image file (Rule 13*ter*.1(b) and Administrative Instructions, Section 713).

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

5. Additional comments:

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US20/54299

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

1. Statement

Novelty (N)	Claims	1-20	YES
	Claims	NONE	NO
Inventive step (IS)	Claims	1-20	YES
	Claims	NONE	NO
Industrial applicability (IA)	Claims	1-20	YES
	Claims	NONE	NO

2. Citations and explanations:

Claim 1 meets the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest, in combination with the other claimed elements, a system of instruments for installing a fusion implant into a sacroiliac joint, the system of instruments comprising: a working channel having an insertion end and a working end connected by a working channel, the working channel further comprising an alignment means; a joint locator having a penetration tip at an insertion end, a handle at a proximal end, and a first keying means for mating engagement with the alignment means; an abrading device having an abrading head at a distal end and a slide hammer assembly at a proximal end, the abrading device further comprising a second keying means for mating engagement with the alignment means; and an implant inserter having an insertion end with a pair of tines for releasably receiving a joint fusion implant, the implant inserter further comprising a third keying means for mating engagement with the alignment means.

As per claim 1, US 2014/0277460 A1 to ORTHOCISION, INC. (hereinafter 'ORTHOCISION') discloses a system of instruments for installing a fusion implant into a sacroiliac joint (tools for implanting a graft to fuse the sacroiliac joint; abstract), the system of instruments comprising: a working channel having an insertion end and a working end connected by a working channel (working channel 290 is shown comprising an insertion end and an opposite working end with a working channel 290 extending between them; figure 76; paragraph [0158]), the working channel further comprising an alignment means (a female timing feature 146 (alignment means) on the inside of a working channel 290 to keep the instrument from traveling too far into the surgical site and to further keep the instrument in the proper orientation for desired implant site preparation; paragraph [0134]); a joint locator having a penetration tip at an insertion end (using a joint probe 112 the insertion area on the posterior side of the SI joint may be determined, wherein joint probe 112 comprises a tip 111 (penetration tip) for locating the insertion point; figure 8; paragraphs [0126], [0142]), a handle at a proximal end (handle 110; figure 8; paragraph [0126]); an abrading device having an abrading head at a distal end (rasp 132 comprising a distal tip 135 with teeth for scraping bone; figure 25; paragraph [0132]), the abrading device further comprising a second keying means for mating engagement with the alignment means (the rasp 132 may have a timing feature 133 (second keying means) that mates with a female timing feature 146 (alignment means) on the inside of a working channel 290 to keep the instrument from traveling too far into the surgical site and to further keep the instrument in the proper orientation for desired implant site preparation; figure 25; paragraph [0132]); and an implant inserter having an insertion end with a pair of tines for releasably receiving a joint fusion implant (a fusion inserter 147 with fork arms 149 (a pair of tines) that enter the implant at recesses 152 to keep the implant from losing its desired orientation during insertion; figure 32; paragraph [0134]), the implant inserter further comprising a third keying means for mating engagement with the alignment means (the inserter may have a timing feature 150 (third keying means) that mates with a female timing feature 146 on the inside of a working channel 290 to keep the instrument from traveling too far into the surgical site and to further keep the instrument in the proper orientation for desired implant site preparation; figure 32; paragraph [0134]). ORTHOCISION does not disclose a joint locator having a first keying means for mating engagement with the alignment means; an abrading device having a slide hammer assembly at a proximal end.

US 2019/0083271 A1 to JCBD, LLC (hereinafter 'JCBD') discloses a system of instruments for installing a fusion implant into a sacroiliac joint (a system for performing a fusion procedure on a sacroiliac joint defined between a sacrum and an ilium; abstract), the system of instruments comprising: a working channel having an insertion end and a working end connected by a working channel (working cannula 506 having a distal end (insertion end) and a proximal end 520 (working end) connected by a passageway 556; figures 28A, C; paragraph [0282]), the working channel further comprising an alignment means (an inner surface 558 of the passageway 556 is keyed (alignment means) in the shape of an I-beam or H-beam; figure 28C; paragraph [0282]); a joint locator having a penetration tip at an insertion end (joint finder 532 comprising a spatulate tip 536 (penetration tip) at a distal end 538 (insertion end); figure 177A; paragraph [0375]), a handle at a proximal end (handle 542 at a proximal end 544; figure 117A; paragraph [0375]), and a first keying means for mating engagement with the alignment means (the joint finder 532 may include an I-beam or H-beam shaped handle 542 that is integral with the body 534, and thus is capable of engaging with the alignment means; figure 117A; paragraph [0374]); an abrading device having an abrading head at a distal end (dual saw blade broach 638 (abrading device) having saw distal body 922 (abrading head) at a distal end 648 and a proximal end 652; figure 118A; paragraph [0377]; and an implant inserter having an insertion end with a pair of tines for releasably receiving a joint fusion implant (implant arm 504 (implant inserter) comprising a distal body 696 (insertion end) comprising a pair of protrusions 698 that fit within corresponding recesses in a proximal face of the joint fusion implant 502; figures 37A, 37D; paragraph [0310]) JCBD does not disclose an abrading device having a slide hammer assembly at a proximal end; the abrading device further comprising a second keying means for mating engagement with the alignment means; the implant inserter further comprising a third keying means for mating engagement with the alignment means.

-***-Continued in Supplemental Box-***-

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US20/54299

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

Claim 1 is objected to under PCT Rule 66.2(a)(iii) as containing the following defect in the form or contents thereof: in claim 1, line 9, "having a an abrading" comprises a typographical error, and for the purposes of this opinion, will be changed to "having an abrading".

Claim 12 is objected to under PCT Rule 66.2(a)(iii) as containing the following defect in the form or contents thereof: in claim 12, line 8, "having a an abrading" comprises a typographical error, and for the purposes of this opinion, will be changed to "having an abrading".

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US20/54299

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of:
-***-Continued From Box V. 2: Citations and Explanations-***-

US 2017/0209155 A1 (PETERSEN) discloses a system of instruments for installing a fusion implant into a sacroiliac joint (tools useful for treating an SI joint and inserting a graft to fuse the patient's ilium to the patient's sacrum; abstract), the system of instruments comprising: a working channel having an insertion end and a working end connected by a working channel (guide 90 (working channel) comprising end 340 (insertion end) and end 330 (working end) connected by channel 380; figures 7B, 7E; paragraph [0163]); a joint locator (pin 80 provides a tactile feedback to the surgeon that the surgeon's location of the SI joint; paragraph [0193]) having a penetration tip at an insertion end (end 290 is a tip sharp enough to penetrate human flesh and tissue; paragraph [0162]), a handle at a proximal end (opposite end 280 (proximal end) is capable of being gripped by hand; figure 6A; paragraph [0162]); an abrading device having an abrading head at a distal end (broach 120 comprising impaction area 680 (abrading head at a distal end) for displacing bone; figure 10B; paragraph [0174]); and an implant inserter having an insertion end with a pair of tines for releasably receiving a joint fusion implant (inserter 130 comprising an end 750 (insertion end) with a pair of fins or extensions 790 (tines) for holding graft 40 (joint fusion implant); figure 11B; abstract; paragraph [0179]). PETERSEN does not disclose the working channel further comprising an alignment means; a joint locator having a first keying means for mating engagement with the alignment means; an abrading device having a slide hammer assembly at a proximal end; the abrading device further comprising a second keying means for mating engagement with the alignment means; the implant inserter further comprising a third keying means for mating engagement with the alignment means.

US 2011/0106261 A1 to CHIN et al. (hereinafter 'CHIN') discloses a system of instruments for installing a fusion implant into a sacroiliac joint (an inserter tool for inserting an intervertebral fusion implant into the spine, and so is capable of installing a fusion implant into a sacroiliac joint; abstract; figures 7-8), the system of instruments comprising: a working channel having an insertion end and a working end connected by a working channel (outer sleeve 140 (working channel) having a chamfered cut 144 at the inner edge of the distal end of the sleeve (insertion end) and a handle 141 at a proximal end (working end), wherein the insertion end and working end inherently have a working channel for insertion of the middle sleeve 130 and inner shaft 121; figures 7-8; paragraph [0037]); and an implant inserter having an insertion end with a pair of tines for releasably receiving a joint fusion implant (middle sleeve 130 (implant inserter) comprises attachment jaws 135 (pair of tines) at the distal end (insertion end) for receiving the fusion implant 100; figures 7-8; paragraph [0038]). CHIN does not disclose the working channel further comprising an alignment means; a joint locator having a penetration tip at an insertion end, a handle at a proximal end, and a first keying means for mating engagement with the alignment means; an abrading device having a an abrading head at a distal end and a slide hammer assembly at a proximal end, the abrading device further comprising a second keying means for mating engagement with the alignment means; the implant inserter further comprising a third keying means for mating engagement with the alignment means.

Thus, it would not have been obvious to one of ordinary skill in the art at the time of the invention to have modified ORTHOCISION, JCBD, PETERSEN, and CHIN, with a system of instruments for installing a fusion implant into a sacroiliac joint, the system of instruments comprising: a working channel having an insertion end and a working end connected by a working channel, the working channel further comprising an alignment means; a joint locator having a penetration tip at an insertion end, a handle at a proximal end, and a first keying means for mating engagement with the alignment means; an abrading device having an abrading head at a distal end and a slide hammer assembly at a proximal end, the abrading device further comprising a second keying means for mating engagement with the alignment means; and an implant inserter having an insertion end with a pair of tines for releasably receiving a joint fusion implant, the implant inserter further comprising a third keying means for mating engagement with the alignment means, as described, because the references of record fail to disclose all of the elements of the inventive system. Furthermore, it would not have been obvious to have modified the joint probe 112 of ORTHOCISION such that it comprises a first keying means for mating engagement with the alignment means of the working channel since the joint probe 112 of ORTHOCISION is removed from the sacroiliac joint before the working channel is even inserted into the patient. Since the joint probe is removed after insertion of a guide pin and then insertion of dilator for preparation of the surgical site for the working channel, the joint probe and working channel do not interact with one another and thus there would be no need for the joint probe to comprise a first keying means for interacting with the alignment means of the working channel. Additionally, it would not have been obvious to have modified JCBD such that the abrading device further comprises a second keying means for mating engagement with the alignment means of the working channel, since JCBD discloses wherein the flanged base 650 is sized and shaped to prevent the broach 638 from extending beyond the standoff 578 when distally advanced relative to the working cannula 506 (JCBD; paragraph [0379]), and thus there would be no need for a second keying means. Moreover, although the device of JCBD comprises a slide hammer, JCBD discloses wherein the slide hammer is used with the cannulated joint finder 800 to remove the joint finder 800 from the working cannula 506, and thus it is not used or needed for the broach 638 (JCBD; paragraphs [0346] [0347]).

Claims 2-11 meet the criteria set out in PCT Article 33(2)-(3), because they depend on claim 1.

Claim 12 meets the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a system of instruments for installing a fusion implant into a sacroiliac joint, the system of instruments comprising: a working channel having an insertion end and a working end connected by a channel, the working channel further comprising an alignment means; a joint locator having a penetration tip, a handle, and a first keying means for mating engagement with the alignment means; an abrading device having an abrading head at a distal end and a slide hammer assembly at a proximal end, the abrading device further comprising a second keying means for mating engagement with the alignment means, and the slide hammer assembly comprising: a collar on the abrading device, the collar having internal threads and external threads; a slide hammer shaft having a threaded end for mating with the internal threads of the collar on the abrading device, and having a slide stop end; a hammer sleeve having a hollow, cylindrical bore comprising an internal diaphragm and a threaded connector configured for mating with the external threads of the collar, the diaphragm having a diaphragm opening sized to permit sliding passage of the slide hammer shaft and block passage of the slide stop end; and an implant inserter having an insertion end with a pair of tines for releasably receiving a joint fusion implant, the implant inserter further comprising a third keying means for mating engagement with the alignment means.

As per claim 12, ORTHOCISION discloses a system of instruments for installing a fusion implant into a sacroiliac joint (tools for implanting

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Supplemental Box

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a graft to fuse the sacroiliac joint; abstract), the system of instruments comprising: a working channel having an insertion end and a working end connected by a channel (working channel 290 is shown comprising an insertion end and an opposite working end with a working channel 290 extending between them; figure 76; paragraph [0158]), the working channel further comprising an alignment means (a female timing feature 146 (alignment means) on the inside of a working channel 290 to keep the instrument from traveling too far into the surgical site and to further keep the instrument in the proper orientation for desired implant site preparation; paragraph [0134]); a joint locator having a penetration tip (using a joint probe 112 the insertion area on the posterior side of the SI joint may be determined, wherein joint probe 112 comprises a tip 111 (penetration tip) for locating the insertion point; figure 8; paragraphs [0126], [0142]), a handle (handle 110; figure 8; paragraph [0126]); an abrading device having an abrading head at a distal end (rasp 132 comprising a distal tip 135 with teeth for scraping bone; figure 25; paragraph [0132]), the abrading device further comprising a second keying means for mating engagement with the alignment means (the rasp may have a timing feature 133 (second keying means) that mates with a female timing feature 146 (alignment means) on the inside of a working channel 290 to keep the instrument from traveling too far into the surgical site and to further keep the instrument in the proper orientation for desired implant site preparation; figure 25; paragraph [0132]); and an implant inserter having an insertion end with a pair of tines for releasably receiving a joint fusion implant (a fusion inserter 147 with fork arms 149 (pair of tines) that enter the implant at recesses 152 to keep the implant from losing its desired orientation during insertion; figure 32; paragraph [0134]), the implant inserter further comprising a third keying means for mating engagement with the alignment means (the inserter may have a timing feature 150 (third keying means) that mates with a female timing feature 146 (alignment means) on the inside of a working channel 290 to keep the instrument from traveling too far into the surgical site and to further keep the instrument in the proper orientation for desired implant site preparation; figure 32; paragraph [0134]). ORTHOCISION does not disclose a joint locator having a first keying means for mating engagement with the alignment means; an abrading device having a slide hammer assembly at a proximal end, and the slide hammer assembly comprising: a collar on the abrading device, the collar having internal threads and external threads; a slide hammer shaft having a threaded end for mating with the internal threads of the collar on the abrading device, and having a slide stop end; a hammer sleeve having a hollow, cylindrical bore comprising an internal diaphragm and a threaded connector configured for mating with the external threads of the collar, the diaphragm having a diaphragm opening sized to permit sliding passage of the slide hammer shaft and block passage of the slide stop end.

JCBD discloses a system of instruments for installing a fusion implant into a sacroiliac joint (a system for performing a fusion procedure on a sacroiliac joint defined between a sacrum and an ilium; abstract), the system of instruments comprising: a working channel having an insertion end and a working end connected by a channel (working cannula 506 having a distal end (insertion end) and a proximal end 520 (working end) connected by a passageway 556; figures 28A, C; paragraph [0282]), the working channel further comprising an alignment means (an inner surface 558 of the passageway 556 is keyed (alignment means) in the shape of an I-beam or H-beam; figure 28C; paragraph [0282]); a joint locator having a penetration tip (joint finder 532 comprising a spatulate tip 536 (penetration tip) at a distal end 538; figure 177A; paragraph [0375]), a handle (handle 542 at a proximal end 544; figure 117A; paragraph [0375]), and a first keying means for mating engagement with the alignment means (the joint finder 532 may include an I-beam or H-beam shaped handle 542 that is integral with the body 534; figure 117A; paragraph [0374]); an abrading device having an abrading head at a distal end (dual saw blade broach 638 (abrading device) having saw distal body 922 (abrading head) at a distal end 648 and a proximal end 652; figure 118A; paragraph [0377]; and an implant inserter having an insertion end with a pair of tines for releasably receiving a joint fusion implant (implant arm 504 (implant inserter) comprising a distal body 696 (insertion end) comprising a pair of protrusions 698 that fit within corresponding recesses in a proximal face of the joint fusion implant 502; figures 37A, 37D; paragraph [0310]). JCBD does not disclose an abrading device having a slide hammer assembly at a proximal end; the abrading device further comprising a second keying means for mating engagement with the alignment means, and the slide hammer assembly comprising: a collar on the abrading device, the collar having internal threads and external threads; a slide hammer shaft having a threaded end for mating with the internal threads of the collar on the abrading device, and having a slide stop end; a hammer sleeve having a hollow, cylindrical bore comprising an internal diaphragm and a threaded connector configured for mating with the external threads of the collar, the diaphragm having a diaphragm opening sized to permit sliding passage of the slide hammer shaft and block passage of the slide stop end; the implant inserter further comprising a third keying means for mating engagement with the alignment means.

PETERSEN discloses a system of instruments for installing a fusion implant into a sacroiliac joint (tools useful for treating an SI joint and inserting a graft to fuse the patient's ilium to the patient's sacrum; abstract), the system of instruments comprising: a working channel having an insertion end and a working end connected by a channel (guide 90 (working channel) comprising end 340 (insertion end) and end 330 (working end) connected by channel 380; figure 7B, 7E; paragraph [0163]); a joint locator (pin 80 provides a tactile feedback to the surgeon that the surgeon's location of the SI joint; paragraph [0193]) having a penetration tip (end 290 is a tip sharp enough to penetrate human flesh and tissue; paragraph [0162]), a handle (opposite end 280 is capable of being gripped by hand; figure 6A; paragraph [0162]); an abrading device having an abrading head at a distal end (broach 120 comprising impaction area 680 (abrading head at a distal end) for displacing bone; figure 10B; paragraph [0174]); and an implant inserter having an insertion end with a pair of tines for releasably receiving a joint fusion implant (inserter 130 comprising an end 750 (insertion end) with a pair of fins or extensions 790 (tines) for holding graft 40 (joint fusion implant); figure 11B; abstract; paragraph [0179]). PETERSEN does not disclose the working channel further comprising an alignment means; a joint locator having a first keying means for mating engagement with the alignment means; an abrading device having a slide hammer assembly at a proximal end; the abrading device further comprising a second keying means for mating engagement with the alignment means, and the slide hammer assembly comprising: a collar on the abrading device, the collar having internal threads and external threads; a slide hammer shaft having a threaded end for mating with the internal threads of the collar on the abrading device, and having a slide stop end; a hammer sleeve having a hollow, cylindrical bore comprising an internal diaphragm and a threaded connector configured for mating with the external threads of the collar, the diaphragm having a diaphragm opening sized to permit sliding passage of the slide hammer shaft and block passage of the slide stop end; the implant inserter further comprising a third keying means for mating engagement with the alignment means.

CHIN discloses a system of instruments for installing a fusion implant into a sacroiliac joint (an inserter tool for inserting an intervertebral fusion implant into the spine, and so is capable of installing a fusion implant into a sacroiliac joint; abstract; figures 7-8), the system of

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Supplemental Box

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instruments comprising: a working channel having an insertion end and a working end connected by a channel (outer sleeve 140 (working channel) having a chamfered cut 144 at the inner edge of the distal end of the sleeve (insertion end) and a handle 141 at a proximal end (working end), wherein the insertion end and working end inherently have a working channel for insertion of the middle sleeve 130 and inner shaft 121; figures 7-8; paragraph [0037]); and an implant inserter having an insertion end with a pair of tines for releasably receiving a joint fusion implant (middle sleeve 130 (implant inserter) comprises attachment jaws 135 (pair of tines) at the distal end (insertion end) for receiving the fusion implant 100; figures 7-8; paragraph [0038]). CHIN does not disclose the working channel further comprising an alignment means; a joint locator having a penetration tip, a handle, and a first keying means for mating engagement with the alignment means; an abrading device having a an abrading head at a distal end and a slide hammer assembly at a proximal end, the abrading device further comprising a second keying means for mating engagement with the alignment means, and the slide hammer assembly comprising: a collar on the abrading device, the collar having internal threads and external threads; a slide hammer shaft having a threaded end for mating with the internal threads of the collar on the abrading device, and having a slide stop end; a hammer sleeve having a hollow, cylindrical bore comprising an internal diaphragm and a threaded connector configured for mating with the external threads of the collar, the diaphragm having a diaphragm opening sized to permit sliding passage of the slide hammer shaft and block passage of the slide stop end; the implant inserter further comprising a third keying means for mating engagement with the alignment means.

Thus, it would not have been obvious to one of ordinary skill in the art at the time of the invention to have modified ORTHOCISION, JCBD, PETERSEN, and CHIN, with a system of instruments for installing a fusion implant into a sacroiliac joint, the system of instruments comprising: a working channel having an insertion end and a working end connected by a channel, the working channel further comprising an alignment means; a joint locator having a penetration tip, a handle, and a first keying means for mating engagement with the alignment means; an abrading device having an abrading head at a distal end and a slide hammer assembly at a proximal end, the abrading device further comprising a second keying means for mating engagement with the alignment means, and the slide hammer assembly comprising: a collar on the abrading device, the collar having internal threads and external threads; a slide hammer shaft having a threaded end for mating with the internal threads of the collar on the abrading device, and having a slide stop end; a hammer sleeve having a hollow, cylindrical bore comprising an internal diaphragm and a threaded connector configured for mating with the external threads of the collar, the diaphragm having a diaphragm opening sized to permit sliding passage of the slide hammer shaft and block passage of the slide stop end; and an implant inserter having an insertion end with a pair of tines for releasably receiving a joint fusion implant, the implant inserter further comprising a third keying means for mating engagement with the alignment means, as described, because the references of record fail to disclose all of the elements of the inventive system. Furthermore, it would not have been obvious to have modified the joint probe 112 of ORTHOCISION such that it comprises a first keying means for mating engagement with the alignment means of the working channel since the joint probe 112 of ORTHOCISION is removed from the sacroiliac joint before the working channel is even inserted into the patient. Since the joint probe is removed after insertion of a guide pin and then insertion of dilator for preparation of the surgical site for the working channel, the joint probe and working channel do not interact with one another and thus there would be no need for the joint probe to comprise a first keying means for interacting with the alignment means of the working channel. Additionally, it would not have been obvious to have modified JCBD such that the abrading device further comprises a second keying means for mating engagement with the alignment means of the working channel, since JCBD discloses wherein the flanged base 650 is sized and shaped to prevent the broach 638 from extending beyond the standoff 578 when distally advanced relative to the working cannula 506 (JCBD; paragraph [0379]), and thus there would be no need for a second keying means. Moreover, although the device of JCBD comprises a slide hammer, JCBD discloses wherein the slide hammer is used with the cannulated joint finder 800 to remove the joint finder 800 from the working cannula 506, and thus it is not used or needed for the broach 638 (JCBD; paragraphs [0346]-[0347]).

Claims 13-20 meet the criteria set out in PCT Article 33(2)-(3), because they depend on claim 12.

Claims 1-20 have industrial applicability as defined by PCT Article 33(4) because the subject matter can be made or used in industry.

PCT Recordation of Search History

PCT Recordation of Search History

Case/PCT Application Number: PCT/US20/54299

CLIN Number/Technical Field of PCT Application: 0002 Life Sciences

Date(s) during which the search was conducted: 09 December 2020 to 11 December 2020

Date of Completion of Recordation of Search History Form: 11 December 2020

Research Analyst Initials: KMB

Search Approval Official (SAO) Initials: AWB

Field of Search/Classification Information:

CPC Classification(s): A61B17/1757; A61F2002/30622; A61F2002/30995; A61F2/4455; A61F2/46; A61F2/4603; A61F2/4611; A61F2002/4615; A61F2002/4625; A61F2002/4627; A61F2/4675; A61F2002/4687

IPC(8) Classification(s): A61F2/44; A61F2/46 (2020.01)

Database(s) Searched (patent and Non-Patent Literature (NPL), Including Sub-Databases and Files Searched) and Search Terms Used:

Orbit; PatSeer (US, EP, WO, JP, CN, KR, CA, DE, FR, GB, ES, AU, IN, CH, AT, BR, TH, RU, PH, SE, NO, DK, FI, BE, NL, LU, INPADOC Data); EBSCO; Google Scholar; Pubmed/Medline

Search Terms Used: sacroiliac, ilium, sacrum, joint, intervertebral, interbody, vertebrae, fusion, implant, prosthetic, working, cannula, trocar, channel, align, key, abrading, broach, rasp, scraping

Database Search String Recordation (Including Dates of Searches):

Patent Database Search Strategy/Results

Orbit

ID	Search String	Deduped	Records	Created Date
1	**Search String:** A61F2002/4687		412	10 December 2020
2	**Search String:** A61F2002/30995		108	10 December 2020
3	**Search String:** A61F2/4611 AND TACD: (slide OR sliding OR slap+) AND (hammer+)		402	10 December 2020

4	**Search String:** A61F2/4603 AND TACD: (slide OR sliding OR slap+) AND (hammer+)	263	11 December 2020
5	**Search String:** A61F2/46 AND TACD: (slide OR sliding OR slap+) AND (hammer+)	861	11 December 2020

PatSeer (US, EP, WO, JP, CN, KR, CA, DE, FR, GB, ES, AU, IN, CH, AT, BR, TH, RU, PH, SE, NO, DK, FI, BE, NL, LU, INPADOC Data)

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L26	**Search String:** L11 AND TACD: (cannula OR trocar OR working OR introduc*) AND (channel OR lumen OR conduit OR passage) AND (align* OR key* OR track* OR rail*) AND (cannula OR trocar OR working OR introduc* OR channel) AND (broach* OR abrad* OR abras* OR scrap* OR erod* OR rough* OR rasp) AND (insert* OR introduc* OR install* OR carry*) AND (hammer*) W10 (slid* OR slap*) AND (prong* OR tine* OR fork* OR fin OR projection OR arm OR finger)	SFAM	132	11 December 2020

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L23	**Search String:** CPC: (A61F2002/30995)	SFAM	105	11 December 2020
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L11	**Search String:** AC: (A61B17/1757 OR A61F2002/30622 OR A61F2002/30995 OR A61F2/4455 OR A61F2/46 OR A61F2/4603 OR A61F2/4611 OR A61F2002/4615 OR A61F2002/4625 OR A61F2002/4627 OR A61F2/4675 OR A61F2002/4687)	ALL	70437	09 December 2020
L10	**Search String:** L9 NOT L8	SFAM	8	09 December 2020
L9	**Search String:** TA: (sacroiliac OR sacrum OR ilium OR pelvis OR pelvic) AND (fusing OR fusion OR implant*) AND TACD: (cannula OR trocar OR (working W5 channel) OR introduc*) AND (align* OR key* OR track*) AND (penetrat* OR sharp OR point*) AND (end OR tip OR distal*) AND (abrad* OR abras* OR scrap* OR erod* OR rough*) AND (implant OR fusion) AND (insert* OR introduc* OR install* OR carry*)	SFAM	132	09 December 2020

L8	**Search String:** TA: (sacroiliac OR sacrum OR ilium OR pelvis OR pelvic) AND (fusing OR fusion OR implant*) AND TACD: (cannula OR trocar OR (working W5 channel) OR introduc*) AND (align* OR key* OR track*) AND (penetrat* OR sharp OR point*) AND (end OR tip OR distal*) AND (abrad* OR scrap* OR erod* OR rough*) AND (implant OR fusion) AND (insert* OR introduc* OR install* OR carry*)	SFAM	124	09 December 2020
L7	**Search String:** TA: (sacroiliac OR sacrum OR ilium OR pelvis OR pelvic) AND (fusing OR fusion OR implant*) AND TACD: (cannula OR trocar OR (working W5 channel) OR introduc*) AND (align* OR key* OR track*) AND (penetrat* OR sharp OR point*) AND (end OR tip OR distal*) AND (abrad* OR scrap* OR erod* OR rough*) AND (slid* W5 hammer*) AND (implant OR fusion) AND (insert* OR introduc* OR install* OR carry*)	SFAM	9	09 December 2020
L6	**Search String:** TAC: (sacroiliac OR sacrum OR ilium OR pelvis OR pelvic) AND (fusing OR fusion OR implant*) AND (cannula OR trocar OR (working W5 channel) OR introduc*) AND (align* OR key* OR track*) AND (penetrat* OR sharp OR point*) AND (end OR tip OR distal*) AND (abrad* OR scrap* OR erod* OR rough*) AND (slid* W5 hammer*) AND (implant OR fusion) AND (insert* OR introduc* OR install* OR carry*)	SFAM	0	09 December 2020
L5	**Search String:** TAC: (sacroiliac OR sacrum OR ilium OR pelvis OR pelvic) AND (fusing OR fusion OR implant*) AND (cannula OR trocar OR (working W5 channel) OR introduc*) AND (align* OR key* OR track*) AND (penetrat* OR sharp OR point*) AND (end OR tip OR distal*) AND (abrad* OR scrap* OR erod* OR rough*) AND (implant OR fusion) AND (insert* OR introduc* OR install* OR carry*)	SFAM	16	09 December 2020

L4	**Search String:** TAC: (sacroiliac OR sacrum OR ilium OR pelvis OR pelvic) AND (fusing OR fusion OR implant*) AND (cannula OR trocar OR (working W5 channel)) AND (align* OR key* OR track*) AND (penetrat* OR sharp OR point*) AND (end OR tip OR distal*) AND (abrad* OR scrap* OR erod* OR rough*) AND (implant OR fusion) AND (insert* OR introduc* OR install* OR carry*)	SFAM	4	09 December 2020
L3	**Search String:** TAC: (sacroiliac OR sacrum OR ilium OR pelvis OR pelvic) AND (fusing OR fusion OR implant) AND (cannula OR trocar OR (working W5 channel)) AND (align* OR key* OR track*) AND (penetrat* OR sharp OR point*) AND (end OR tip OR distal*) AND (abrad* OR scrap* OR erod*) AND (implant OR fusion) AND (insert OR introduc* OR install OR carry*)	SFAM	2	09 December 2020
L2	**Search String:** TA: (sacroiliac OR sacrum OR ilium OR pelvis OR pelvic) AND (fusing OR fusion OR implant) AND (cannula OR trocar OR (working W5 channel)) AND (align* OR key* OR track*) AND (penetrat* OR sharp OR point*) AND (end OR tip OR distal*) AND (abrad* OR scrap* OR erod*) AND (implant OR fusion) AND (insert OR introduc* OR install OR carry*)	SFAM	0	09 December 2020
L1	**Search String:** AASN: Pain W2 TEQ	SFAM	0	09 December 2020

Non-Patent Literature (NPL) Search Strategy/Results

EBSCO

11 December 2020

sacroiliac fusion working channel alignment key abrading slide hammer
fusion implant installation cannula channel alignment broach inserter tines
fusion inserter channel key slide hammer prongs

Google Scholar

11 December 2020

sacroiliac joint fusion cannula alignment joint finder key abrading slide hammer inserter tines
joint fusion working channel alignment key broach prongs
bone implant channel alignment broach slap hammer

Pubmed/Medline

11 December 2020

sacroiliac joint trocar alignment slot abrading slide hammer inserter prongs
joint fusion working channel alignment key rasp slide hammer tines
bone implant channel key joint probing broach hammer inserter fork

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	FOR FURTHER ACTION
13436-008.18	see Form PCT/ISA/220 as well as, where applicable, item 5 below.

International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/US20/54290	05 October 2020 (05.10.2020)	04 October 2019 (04.10.2019)

Applicant
Pain TEQ, LLC

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

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

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

1. **Basis of the report**

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

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

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

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

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

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

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

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

   ☒ the text is approved as submitted by the applicant.

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

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

   ☒ the text is approved as submitted by the applicant.

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

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

   a. the figure of the **drawings** to be published with the abstract is Figure No. 18

   ☒ as suggested by the applicant.

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

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

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

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US20/54290

A. CLASSIFICATION OF SUBJECT MATTER

IPC - A61B 17/68; A61B 17/70; A61B 17/56; A61B 17/16 (2020.01)

CPC - A61B 17/16; A61B 17/1659; A61B 17/1662; A61B 17/1671; A61B 17/70; A61B 17/7055; A61B 17/86; A61B 17/88

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
See Search History document

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
See Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2018/0036017 A1 (JCBD, LLC) 08 February 2018; figure 22A, 22C & 22D, paragraphs [0019], [0020] & [0025] & [0190]	1-20
A	US 2016/0310197 A1 (CAMBER SPINE TECHNOLOGIES, LLC) 27 October 2016; figure 8, paragraphs [0011], [0012], [0076], [0077] & [0098]	1-20
A	US 2019/0083271 A1 (JCBD, LLC) 21 March 2019; figure 74, paragraphs [0036], [0037] & [0346]	1-20
A	US 8,348,960 B2 (ASSELL, R ET AL.) 08 January 2013; see entire document	1-20

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

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

Date of the actual completion of the international search	Date of mailing of the international search report
16 December 2020 (16.12.2020)	11 JAN 2021
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Authorized officer Shane Thomas Telephone No. PCT Helpdesk: 571-272-4300

Form PCT/ISA/210 (second sheet) (July 2019)

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:
Stephen E. Kelly
Hill Ward Henderson, P.A.
101 East Kennedy Boulevard, Suite 3700
Tampa, FL 33602

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)*	21 JAN 2021
Applicant's or agent's file reference 13438-008.15	FOR FURTHER ACTION See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US20/54290	05 October 2020 (05.10.2020)	04 October 2019 (04.10.2019)

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

IPC - A61B 17/68; A61B 17/70; A61B 17/56; A61B 17/16 (2020.01)

CPC - A61B 17/16; A61B 17/1659; A61B 17/1662; A61B 17/1671; A61B 17/70; A61B 17/7055; A61B 17/56; A61B 17/68

Applicant Pain TEQ, LLC

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

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

2. **FURTHER ACTION**

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

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

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

Name and mailing address of the ISA/US	Date of completion of this opinion	Authorized officer
Mail Stop PCT, Attn. ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	16 December 2020 (16.12.2020)	Shane Thomas PCT Help Desk Telephone No. 571-272-4300

Form PCT/ISA/237 (cover sheet) (revised January 2019)

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US20/54290

Box No. I Basis of this opinion

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

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

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

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

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

   a. ☐ forming part of the international application as filed:

      ☐ in the form of an Annex C/ST.25 text file.

      ☐ on paper or in the form of an image file.

   b. ☐ furnished together with the international application under PCT Rule 13*ter*.1(a) for the purposes of international search only in the form of an Annex C/ST.25 text file.

   c. ☐ furnished subsequent to the international filing date for the purposes of international search only:

      ☐ in the form of an Annex C/ST.25 text file (Rule 13*ter*.1(a)).

      ☐ on paper or in the form of an image file (Rule 13*ter*.1(b) and Administrative Instructions, Section 713).

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

5. Additional comments:

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US20/54290

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

1. Statement

Novelty (N)	Claims	1-20	YES
	Claims	NONE	NO
Inventive step (IS)	Claims	1-20	YES
	Claims	NONE	NO
Industrial applicability (IA)	Claims	1-20	YES
	Claims	NONE	NO

2. Citations and explanations:

Claims 1 & 9 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest an abrading device comprising a slide hammer assembly having a released position that enables operation and a locked position that prohibits operation.

In the closest prior art US 2018/0036017 A1 to JCBD, LLC (hereinafter 'JCBD') discloses a multimodal abrading device for forming a fusion implant insertion location in a sacroiliac joint (a cutting tool with multiple uses (multimodal) for a surgical implant fusion procedure in a sacroiliac joint; paragraphs [0019], [0020] & [0025]), the abrading device comprising: an abrading head at a distal end of the abrading device (the cutting tool comprising a planar rasping head 190 at a distal end of the cutting tool; figure 22A, paragraph [0190]), the abrading head having: abrading surfaces on each of a first pair of opposing sides (the planar rasping head 190 having a planar top surface 196 and a planar bottom surface 198 opposing each other and each with a rasping surface 216; figures 22C & 22D, paragraph [0190]), the abrading surfaces comprising one or more teeth, barbs, blades, ridges, slots, broaches, or other members capable of abrading a cortical bone of the sacroiliac joint (the rasping surfaces 216 comprising a series of ridges 220 for rasping boney surfaces of the sacroiliac joint; paragraph [0190]).

In the second closest prior art, US 2016/0310187 A1 to Camber Spine Technologies, LLC (hereinafter 'Camber') discloses a abrading device for forming a fusion implant insertion location in a sacroiliac joint (an abrasive tool for a sacroiliac joint implant fusion; paragraphs [0011], [0012], [0077] & [0096]), the abrading device comprising: an abrading head at a distal end of the abrading device (the abrasive tool comprising a proximal end 1020; figure 8, paragraphs [0076] & [0077]), the abrading head having: abrading surfaces on each of a first pair of opposing sides (the abrasive tool having abrasive surfaces on each of two generally flat sides 1024 and 1026 opposing each other; figure 8, paragraph [0077]), the abrading surfaces comprising one or more teeth, barbs, blades, ridges, slots, broaches, or other members capable of abrading a cortical bone of the sacroiliac joint (the abrasive surfaces comprising a pattern of sharp diamond shaped structures 1022 protruding therefrom for rasping a bone surface of the sacroiliac joint; figure 8, paragraphs [0077] & [0096]).

In the third closest prior art, US 2019/0083271 A1 to JCBD, LLC (hereinafter 'JCBD'271') discloses a multimodal abrading device for forming a fusion implant insertion location in a sacroiliac joint (a surgical preparation tool with multiple uses, including cutting (abrading), for performing an implant fusion procedure on a sacroiliac joint; paragraphs [0036] & [0037]); and a slide hammer assembly at a proximal end of the abrading device (a slide hammer 820 at an end of the surgical preparation tool; figure 74, paragraph [0346]).

Specifically, while JCBD, Camber, and JCBD'271, in combination, cover most of the claimed limitations, they fail to show or fairly suggest key aspects of the instant application. In particular, the uncovered references failed to discuss, suggest, or provide motivations or advantages for an abrading device comprising a slide hammer assembly having a released position that enables operation and a locked position that prohibits operation. Both JCBD and Camber do discuss an abrading device largely similar in structure and purpose to the instant application, however the abrading device of JCBD lacks a distinct open tip with cutting edge as well as proper slide hammer assembly as described by the instant application. JCBD'271 does discuss a slide hammer assembly more in line with that of the instant application, however still lacking all the described features such as separate operational positions. Since none of the references of record provided sufficient discussion of or benefits for the missing claimed limitations, it would not have been obvious to one of ordinary skill in the art at the time of the invention to have discussed an abrading device comprising a slide hammer assembly having a released position that enables operation and a locked position that prohibits operation.

Claims 2-8 and 10-20 meet the criteria set out in PCT Article 33(2)-(3), because of their dependence from claims 1 and 9, respectively.

Claims 1-20 have industrial applicability as defined by PCT Article 33(4) because the subject matter can be made or used in industry.

PCT Recordation of Search History

PCT Recordation of Search History

Case/PCT Application Number: PCT/US20/54290

CLIN Number/Technical Field of PCT Application: 0002 Life Sciences

Date(s) during which the search was conducted: 15 December 2020 to 16 December 2020

Date of Completion of Recordation of Search History Form: 16 December 2020

Research Analyst Initials: J1C

Search Approval Official (SAO) Initials: MWS

Field of Search/Classification Information:

CPC Classification(s): A61B17/16; A61B17/1659; A61B17/1662; A61B17/1671; A61B17/56; A61B17/68; A61B17/70; A61B17/7055

IPC(8) Classification(s): A61B17/16; A61B17/56; A61B17/68; A61B17/70 (2020.01)

Database(s) Searched (patent and Non-Patent Literature (NPL), Including Sub-Databases and Files Searched) and Search Terms Used:

PatSeer (US, EP, WO, JP, CN, KR, CA, DE, FR, GB, ES, AU, IN, CH, AT, BR, TH, RU, PH, SE, NO, DK, FI, BE, NL, LU, INPADOC Data); Google Patent; Google Scholar; EBSCO; IEEE

Search Terms Used: sacroiliac, 'SI joint', SIJ, sacrum, ilium, pelvis, cortical, osteotomy, abrade, rasp, barbs, teeth, ridges, tip, distal, end, cut, blade, pierce, penetrate

Database Search String Recordation (Including Dates of Searches):

Patent Database Search Strategy/Results

PatSeer (US, EP, WO, JP, CN, KR, CA, DE, FR, GB, ES, AU, IN, CH, AT, BR, TH, RU, PH, SE, NO, DK, FI, BE, NL, LU, INPADOC Data)

ID	Search String	Deduped	Records	Created Date
L34	**Search String:** BCT:(US20180036017A1 or US20160310197A1 or US20190083271A1 or US8348950B2)	SFAM (C)	47	16 December 2020
L33	**Search String:** FCT:(US20180036017A1 or US20160310197A1 or US20190083271A1 or US8348950B2)	SFAM (C)	48	16 December 2020

L32	**Search String:** TACD:((sacroiliac or SI_joint or SIJ or sacrum or ilium or pelvis or cortical or osteotomy) and (abrad* or abras* or rasp* or barbs or teeth or ridges) ws (tip or distal or end) ws (cut* or blade or pierc* or penetrat*)) and AC:(A61B17/7055)	SFAM (C)	20	16 December 2020
L31	**Search String:** TACD:((sacroiliac or SI_joint or SIJ or sacrum or ilium or pelvis or cortical or osteotomy) and (abrad* or abras* or rasp* or barbs or teeth or ridges) ws (tip or distal or end) ws (cut* or blade or pierc* or penetrat*)) and AC:(A61B17/70)	SFAM (C)	144	16 December 2020
L30	**Search String:** TACD:((sacroiliac or SI_joint or SIJ or sacrum or ilium or pelvis or cortical or osteotomy) and (abrad* or abras* or rasp* or barbs or teeth or ridges) ws (tip or distal or end) ws (cut* or blade or pierc* or penetrat*)) and AC:(A61B17/68)	SFAM (C)	77	16 December 2020
L29	**Search String:** TACD:((sacroiliac or SI_joint or SIJ or sacrum or ilium or pelvis or cortical or osteotomy) and (abrad* or abras* or rasp* or barbs or teeth or ridges) ws (tip or distal or end) ws (cut* or blade or pierc* or penetrat*) and (hammer)) and AC:(A61B17/56)	SFAM (C)	47	16 December 2020
L28	**Search String:** TACD:((sacroiliac or SI_joint or SIJ or sacrum or ilium or pelvis or cortical or osteotomy) and (abrad* or abras* or rasp* or barbs or teeth or ridges) ws (tip or distal or end) ws (cut* or blade or pierc* or penetrat*)) and AC:(A61B17/56)	SFAM (C)	314	16 December 2020
L27	**Search String:** TACD:((sacroiliac or SI_joint or SIJ or sacrum or ilium or pelvis or cortical or osteotomy) and (abrad* or abras* or rasp* or barbs or teeth or ridges) ws (tip or distal or end) ws (cut* or blade or pierc* or penetrat*)) and AC:(A61B17/1671)	SFAM (C)	147	16 December 2020

L26	**Search String:** TACD:((sacroiliac or SI_joint or SIJ or sacrum or ilium or pelvis or cortical or osteotomy) and (abrad* or abras* or rasp* or barbs or teeth or ridges) ws (tip or distal or end) ws (cut* or blade or pierc* or penetrat*)) and AC:(A61B17/1662)	SFAM (C)	18	16 December 2020
L25	**Search String:** TACD:((sacroiliac or SI_joint or SIJ or sacrum or ilium or pelvis or cortical or osteotomy) and (abrad* or abras* or rasp* or barbs or teeth or ridges) ws (tip or distal or end) ws (cut* or blade or pierc* or penetrat*)) and AC:(A61B17/1659)	SFAM (C)	133	16 December 2020
L24	**Search String:** TACD:((sacroiliac or SI_joint or SIJ or sacrum or ilium or pelvis or cortical or osteotomy) and (abrad* or abras* or rasp* or barbs or teeth or ridges) ws (tip or distal or end) ws (cut* or blade or pierc* or penetrat*) and (hammer)) and AC:(A61B17/16)	SFAM (C)	99	16 December 2020
L23	**Search String:** TACD:((sacroiliac or SI_joint or SIJ or sacrum or ilium or pelvis or cortical or osteotomy) and (abrad* or abras* or rasp* or barbs or teeth or ridges) ws (tip or distal or end) ws (cut* or blade or pierc* or penetrat*)) and AC:(A61B17/16)	SFAM (C)	492	16 December 2020
L22	**Search String:** TACD:((sacroiliac or SI_joint or SIJ or sacrum or ilium or pelvis or cortical or osteotomy) and (abrad* or abras* or rasp* or barbs or teeth or ridges) ws (tip or distal or end) ws (cut* or blade or pierc* or penetrat*))	SFAM (C)	2042	16 December 2020

L21	**Search String:** TAC:((sacroiliac or SI_joint or SIJ or sacrum or ilium or pelvis or cortical) and (abrad* or abras* or rasp* or barbs or teeth or ridges) and (tip or distal or end) and (cut* or blade or pierc* or penetrat*)) and AC: (A61B17/16 or A61B17/1659 or A61B17/1662 or A61B17/1671 or A61B17/56 or A61B17/68 or A61B17/70 or A61B17/7055)	SFAM (C)	194	16 December 2020
L20	**Search String:** TAC:((sacroiliac or SI_joint or SIJ or sacrum or ilium or pelvis or cortical) and (abrad* or abras* or rasp* or barbs or teeth or ridges) and (tip or distal or end) and (cut* or blade or pierc* or penetrat*))	SFAM (C)	610	16 December 2020
L19	**Search String:** TA:((sacroiliac or SI_joint or SIJ or sacrum or ilium or pelvis or cortical) and (abrad* or abras* or rasp* or barbs or teeth or ridges) and (tip or distal or end) and (cut* or blade or pierc* or penetrat*))	SFAM (C)	35	16 December 2020
L18	**Search String:** TACD:((sacroiliac or SI_joint or SIJ or sacrum or ilium or pelvis) and (abrad* or abras* or rasp* or scrap*) and (slid* or slap* or hammer)) and AC:(A61B17/7055)	SFAM (C)	56	15 December 2020
L17	**Search String:** TACD:((sacroiliac or SI_joint or SIJ or sacrum or ilium or pelvis) and (abrad* or abras* or rasp* or scrap*) and (slid* or slap* or hammer)) and AC:(A61B17/70)	SFAM (C)	191	15 December 2020
L16	**Search String:** TACD:((sacroiliac or SI_joint or SIJ or sacrum or ilium or pelvis) and (abrad* or abras* or rasp* or scrap*) and (slid* or slap* or hammer)) and AC:(A61B17/68)	SFAM (C)	67	15 December 2020
L15	**Search String:** TACD:((sacroiliac or SI_joint or SIJ or sacrum or ilium or pelvis) and (abrad* or abras* or rasp* or scrap*) and (slid* or slap* or hammer)) and AC:(A61B17/56)	SFAM (C)	201	15 December 2020

L14	**Search String:** TACD:((sacroiliac or SI_joint or SIJ or sacrum or ilium or pelvis) and (abrad* or abras* or rasp* or scrap*) and (slid* or slap* or hammer)) and AC:(A61B17/1671)	SFAM (C)	131	15 December 2020
L13	**Search String:** TACD:((sacroiliac or SI_joint or SIJ or sacrum or ilium or pelvis) and (abrad* or abras* or rasp* or scrap*) and (slid* or slap* or hammer)) and AC:(A61B17/1662)	SFAM (C)	14	15 December 2020
L12	**Search String:** TACD:((sacroiliac or SI_joint or SIJ or sacrum or ilium or pelvis) and (abrad* or abras* or rasp* or scrap*) and (slid* or slap* or hammer)) and AC:(A61B17/1659)	SFAM (C)	105	15 December 2020
L11	**Search String:** TACD:((sacroiliac or SI_joint or SIJ or sacrum or ilium or pelvis) and (abrad* or abras* or rasp* or scrap*) and (slid* or slap* or hammer)) and AC:(A61B17/16)	SFAM (C)	265	15 December 2020
L10	**Search String:** TACD:((sacroiliac or SI_joint or SIJ or sacrum or ilium or pelvis) and (abrad* or abras* or rasp* or scrap*) and (slid* or slap* or hammer))	SFAM (C)	4315	15 December 2020
L9	**Search String:** TAC:((sacroiliac or SI_joint or SIJ or sacrum or ilium or pelvis) and (abrad* or abras* or rasp* or scrap*) and (slid* or slap* or hammer))	SFAM (C)	79	15 December 2020
L8	**Search String:** TA:((sacroiliac or SI_joint or SIJ or sacrum or ilium or pelvis) and (abrad* or abras* or rasp* or scrap*) and (slid* or slap* or hammer))	SFAM (C)	4	15 December 2020
L7	**Search String:** TACD:((sacroiliac_joint or SI_joint or SIJ) and (abrad* or abras* or rasp* or scrap*) and (hammer w4 (slid* or slap*)))	SFAM (C)	11	15 December 2020

L6	**Search String:** TAC:((sacroiliac_joint or SI_joint or SIJ) and (abrad* or abras* or rasp* or scrap*) and (hammer w4 (slid* or slap*)))	SFAM (C)	0	15 December 2020
L5	**Search String:** TA:((sacroiliac_joint or SI_joint or SIJ) and (abrad* or abras* or rasp* or scrap*) and (hammer w4 (slid* or slap*)))	SFAM (C)	0	15 December 2020
L4	**Search String:** TACD:((sacroiliac_joint or SI_joint or SIJ) and (abrad*))	SFAM (C)	66	15 December 2020
L3	**Search String:** TAC:((sacroiliac_joint or SI_joint or SIJ) and (abrad*))	SFAM (C)	4	15 December 2020
L2	**Search String:** TA:((sacroiliac_joint or SI_joint or SIJ) and (abrad*))	SFAM (C)	0	15 December 2020
L1	**Search String:** AASN:(Pain_TEQ)	SFAM (C)	0	15 December 2020

Google Patent

ID	Search String	Deduped	Records	Created Date
	Search String: multimodal abrading device fusion implant insertion sacroiliac joint			15 December 2020
	Search String: sacroiliac joint implant fusion abrasion tool			15 December 2020
	Search String: surgical slide hammer assembly locked position			15 December 2020
	Search String: joint fusion implant rasping tool			15 December 2020

Search String: 16 December 2020
osteotomy abrasion cutting tool heads

Search String: 16 December 2020
osteotome cutting tool head with abrading surfaces

Search String: 16 December 2020
bone cutting tool with slide hammer assembly

Non-Patent Literature (NPL) Search Strategy/Results

Google Scholar

15 December 2020

Pain TEQ, LLC
multimodal abrading device for fusing a sacroiliac joint
sacroiliac joint implant fusion abrasion tool
SI joint implant fusion abrasion tool slide hammer

EBSCO

15 December 2020

multimodal abrading device fusing sacroiliac joint
sacroiliac joint fusion abrading device
SI joint implant fusion abrasion tool
SI joint abrasion device slide hammer assembly

IEEE

15 December 2020

multimodal abrasion device fusing sacroiliac joint
sacroiliac joint fusion abrasion tool
SI joint implant fusion abrasion tool
SI joint abrasion tool slide hammer assembly

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference		FOR FURTHER ACTION
13438-008.16		see Form PCT/ISA/220 as well as, where applicable, item 5 below.
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/US 20/54308	05 October 2020 (05.10.2020)	04 October 2019 (04.10.2019)
Applicant PAIN TEQ, LLC		

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

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

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

1. **Basis of the report**

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

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

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

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

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

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

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

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

☒ the text is approved as submitted by the applicant.

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

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

☒ the text is approved as submitted by the applicant.

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

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

a. the figure of the **drawings** to be published with the abstract is Figure No. 4

☒ as suggested by the applicant.

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

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

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

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 20/54308

A. CLASSIFICATION OF SUBJECT MATTER
IPC - A61F 2/32 (2020.01)
CPC - A61F 2/32

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
See Search History document

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
See Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2019/0083271 A1 (JCBD, LLC); 21 March 2019 (21.03.2019); entire document, especially Fig. 28a-28d, 33a-33d, 64-114, para. [0002], [0282], [0295]-[0296], [0338], [0343]-[0346], [0353].	1-16
Y	US 2006/0178673 A1 (CURRAN); 10 August 2006 (10.08.2006); entire document, especially Fig. 3, para. [0009], [0018], [0023]-[0026].	1-16
A	US 2019/0090888 A1 (SI-BONE INC); 28 March 2019 (28.03.2019); entire document.	1-16
A	US 9,808,346 B2 (ILION MEDICAL, LLC); 7 November 2017 (07.11.2017); entire document.	1-16
A	US 2009/0216238 A1 (STARK); 27 August 2009 (27.08.2009); entire document.	1-16

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

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

Date of the actual completion of the international search	Date of mailing of the international search report
30 November 2020 (30.11.2020)	08 JAN 2021
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Authorized officer Lee Young Telephone No. PCT Helpdesk: 571-272-4300

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To: STEPHEN E. KELLY
HILL WARD HENDERSON, P.A.
101 EAST KENNEDY BOULEVARD, SUITE 3700
TAMPA, FL 33602

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)*	08 JAN 2021
Applicant's or agent's file reference 13438-008.16	FOR FURTHER ACTION See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US 20/54308	05 October 2020 (05.10.2020)	04 October 2019 (04.10.2019)

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

IPC - A61F 2/32 (2020.01)

CPC - A61F 2/32

Applicant PAIN TEQ, LLC

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

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

2. **FURTHER ACTION**

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

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

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

Name and mailing address of the ISA/US	Date of completion of this opinion	Authorized officer
Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	30 November 2020 (30.11.2020)	Lee Young PCT Help Desk Telephone No. 571-272-4300

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 20/54308

Box No. I Basis of this opinion

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

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

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

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

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

   a. ☐ forming part of the international application as filed:

      ☐ in the form of an Annex C/ST.25 text file.

      ☐ on paper or in the form of an image file.

   b. ☐ furnished together with the international application under PCT Rule 13*ter*.1(a) for the purposes of international search only in the form of an Annex C/ST.25 text file.

   c. ☐ furnished subsequent to the international filing date for the purposes of international search only:

      ☐ in the form of an Annex C/ST.25 text file (Rule 13*ter*.1(a)).

      ☐ on paper or in the form of an image file (Rule 13*ter*.1(b) and Administrative Instructions, Section 713).

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

5. Additional comments:

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 20/54308

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

1. Statement

Novelty (N)	Claims	1-16	YES
	Claims	None	NO
Inventive step (IS)	Claims	None	YES
	Claims	1-16	NO
Industrial applicability (IA)	Claims	1-16	YES
	Claims	None	NO

2. Citations and explanations:

Claims 1-16 lack an inventive step under PCT Article 33(3) as being obvious over US 2019/0083271 A1 to JCBD, LLC (hereinafter 'JCBD') in view of US 2006/0178673 A1 to Curran (hereinafter 'Curran').

Regarding claim 1, JCBD teaches a method of forming an implant void in a sacroiliac joint (methods for preparing and fusing a sacroiliac joint for fusion, para. [0002]) without the use of a rotary cutting instrument (box osteotome 618 positioned through the working cannula 506 such that the cutting structure 620 extends into the articular region 1044 of the joint so as to remove a rectangular portion of the joint space formed by the sacrum 1004 and ilium 1005, para. [0353]; thus osteotome 618 forms the rectangular void and is not a rotary cutting instrument), the method comprising the steps of:

locating an insertion point in the sacroiliac joint (posterior access into the joint 1000, para. [0339]), the insertion point defining an intended location for the implant void (this provides the surgeon with the location of the sacroiliac joint 1000 and general angular orientation of it, para. [0339]);

introducing a working channel into the insertion point (the working cannula 506 may be positioned in the sacroiliac joint 1000, Fig. 69, para. [0343]), the working channel having an insertion end (working channel 506 having distal end 550, Fig. 28A-28D) and a working end (working channel 506 having proximal end 520, Fig. 28A-28D, para. [0278]) connected by a working channel (passageway 556, Fig. 28A-28D, para. [0278]), the insertion end of the working channel further comprising a first iliac contour (surface facing ilium 1005, Fig. 69), a first sacral contour (surface facing sacrum 1004, Fig. 29), and insertion arms (prongs, spikes, or projections 548 at a distal end 550, Fig. 28A-28D, para. [0282]);

inserting the insertion arms into the sacroiliac joint at the insertion point such that the first sacral contour seated against a sacrum bone and the first iliac contour seated against the ilium (working channel 506 positioned in the sacroiliac joint 1000, Fig. 72, para. [0345]; joint 1000 is the SI joint between the sacrum 1004 and ilium 1005, channel 506 positions first surface against sacrum and second surface against ilium, Fig. 72);

introducing an abrading device into the working channel (box osteotome 618 positioned through the working cannula 506, Fig. 87, para. [0353]), the abrading device comprising:

an abrading head at a distal end of the abrading device (four sided cutting structure 620, Fig. 33A-33D, para. [0295]), the abrading head having:

abrading surfaces on each of a first pair of opposing sides, the abrading surfaces comprising one or more teeth, barbs, blades, ridges, slots, broaches, or other members capable of abrading a cortical bone of the sacroiliac joint (linear cutting surfaces on the narrow surfaces 634, Fig. 33a-33D, para. [0295]); and

an open tip (distal end is open, Fig. 33B) comprising a cutting edge disposed at a leading edge of the open tip (distal tip 636 of the tubular cutting structure 620 may include rounded cutting surfaces defined on the wide surfaces 630, para. [0296]), the cutting edge configured to cut bone tissue in the sacroiliac joint (distal advancement may cut the surfaces of the sacrum and ilium, para. [0297]); and

advancing the abrading device into the sacroiliac joint such that the open tip cuts bone tissue away from the sacrum or the ilium and the abrading surfaces decorticate the cortical bone inside the sacroiliac joint, thereby forming a decorticated implant void at the insertion point without using a rotary cutting instrument (box osteotome 618 positioned through the working cannula 506 such that the cutting structure 620 extends into the articular region 1044 of the joint so as to remove a rectangular portion of the joint space formed by the sacrum 1004 and ilium 1005, para. [0353]; thus Osteotome 618 forms the rectangular void and is not a rotary cutting instrument);

While JCBD teaches other tools comprising a slide hammer assembly (slide hammer 820, Fig. 74, para. [0346]), JCBD fails to teach a slide hammer assembly at a proximal end of the abrading device, the slide hammer assembly having a released position that enables operation of the slide hammer assembly, a locked position that prohibits operation of the slide hammer assembly, and a releasing means for transitioning the slide hammer assembly between the locked position and the released position.

Curran teaches a device for extracting a surgical instrument stuck in a bone (para. [0023]) comprising a slide hammer assembly at a proximal end of the surgical instrument (attaching at least one surgical instrument to gripping member (10), Fig. 3, para. [0026]), the slide hammer assembly having a released position that enables operation of the slide hammer assembly (when said handle element (16) is in an unlocked configuration, provides a hammer element (16) that allows the surgeon to hit a surface of the apparatus, para. [0009]), a locked position that prohibits operation of the slide hammer assembly (said handle member (18), when in a locked configuration, provides a secure surface for a surgeon to manually manipulate the apparatus (30), para. [0009]; immobilizing hammer member (16) on shaft member (14), para. [0018]), and a releasing means for transitioning the slide hammer assembly between the locked position and the released position (lock member 18, Fig. 3, para. [0009], [0018], [0025]). It would have been obvious to one of ordinary skill in the art that the method of JCBD could have been modified as claimed in view of Curran to extract an osteotome stuck in the bone.

-*-Continued in Supplemental Box-*-

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 20/54308

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of:
-*-Box No. V.2 - Citations and explanations-*-

Regarding claim 2, JCBD in view of Curran teach the method of claim 1. Curran further teaches wherein, upon the abrading head becoming lodged inside the sacroiliac joint (surgical instrument stuck in a bone, para. [0023]; surgical instrument selected from group of a reamer, drill, dilator, broach and cannula, para. [0027]), unlocking the slide hammer assembly via the releasing means (when said handle element (16) is in an unlocked configuration, provides a hammer element (16) that allows the surgeon to hit a surface of the apparatus, para. [0009]), and using the slide hammer assembly to dislodge the abrading head from the sacroiliac joint (proximally urging the hammer member (16) against an opposing surface to retract the surgical instrument the target location, para. [0027]). It would have been obvious to one of ordinary skill in the art that the method of JCBD could have been modified as claimed in view of Curran to extract an osteotome stuck in the bone.

Regarding claim 3, JCBD in view of Curran teach the method of claim 1. JCBD further teaches wherein introducing the working channel into the insertion point further comprises:
introducing a joint locator [into the working channel] (cannulated joint finder 800 positioned over the pin 796 and in the sacroiliac joint 1000, para. [0342], Fig. 68), the joint locator having a penetration tip at an insertion end (with dual spatulate tips 804 at a distal end 806...cannulated joint finder 800 may exert a pressure against the joint surfaces, para. [0342]), the penetration tip comprising a second iliac contour and a second sacral contour (cannulated joint finder 800 may exert a pressure against the joint surfaces of the sacrum 1004 and ilium 1005 with sufficient force to hold the joint distractor in position in the joint 1000, para. [0342; first and second surfaces facing ilium 1005 and sacrum 1004, respectively, Fig. 68); and
placing the first and second iliac contours and the first and second sacral contours in mating alignment (the pair of prongs 548 extends into the articular region 1044 of the joint 1000, and are positioned superior and inferior to the dual spatulate tips 804 of the joint distractor 800, para. [0343]) [by fully inserting the joint locator into the working channel], thereby defining a combined joint locator and working channel device (Fig. 69).
While JCBD fails to specifically teach introducing the joint locator into the working channel and the contours in mating alignment by fully inserting the joint locator into the working channel, JCBD teaches the working cannula 506, cannulated joint finder 800, and pin 796 positioned in the sacroiliac joint 1000 (para. [0344]) and the pairs of prongs in alignment (para. [0343], Fig. 69). It would have been obvious to one of ordinary skill in the art that the method of JCBD could have been modified as claimed to simplify insertion of the joint locator and the working channel.

Regarding claim 4, JCBD in view of Curran teach the method of claim 3. JCBD further teaches wherein inserting the insertion arms into the sacroiliac joint further comprises inserting the combined joint locator and working channel device into the sacroiliac joint at the insertion point such that the first and second sacral contours are seated against the sacrum bone and the first and second iliac contours are seated against the ilium (the working cannula 506, cannulated joint finder 800, and pin 796 positioned in the sacroiliac joint 1000, Fig. 70, para. [0344]; surfaces facing ilium 1005 and sacrum 1004, respectively, Fig. 70).

Regarding claim 5, JCBD in view of Curran teach the method of claim 4. JCBD further teaches the method further comprising the first and second iliac contours abut the ilium and the first and second sacral contours abut the sacrum (Fig. 70). While JCBD fails to specifically teach the method further comprising tearing through soft tissue above and inside the sacroiliac joint via the penetration tip, JCBD teaches in an alternative embodiment dilating soft tissue adjacent the sacroiliac joint and for introducing the working cannula, para. [0227]). It would have been obvious to one of ordinary skill in the art that the method of JCBD could have been modified as claimed to simplify insertion of the joint locator and the working channel.

Regarding claim 6, JCBD in view of Curran teach the method of claim 2. JCBD further teaches wherein introducing the working channel into the insertion point further comprises:
introducing a joint locator [into the working channel] (cannulated joint finder 800 positioned over the pin 796 and in the sacroiliac joint 1000, para. [0342], Fig. 68), the joint locator having a penetration tip at an insertion end (with dual spatulate tips 804 at a distal end 806...cannulated joint finder 800 may exert a pressure against the joint surfaces, para. [0342]), the penetration tip comprising a second iliac contour and a second sacral contour (cannulated joint finder 800 may exert a pressure against the joint surfaces of the sacrum 1004 and ilium 1005 with sufficient force to hold the joint distractor in position in the joint 1000, para. [0342; first and second surfaces facing ilium 1005 and sacrum 1004, respectively, Fig. 68); and
placing the first and second iliac contours and the first and second sacral contours in mating alignment (the pair of prongs 548 extends into the articular region 1044 of the joint 1000, and are positioned superior and inferior to the dual spatulate tips 804 of the joint distractor 800, para. [0343]) [by fully inserting the joint locator into the working channel], thereby defining a combined joint locator and working channel device (Fig. 69).
While JCBD fails to specifically teach introducing the joint locator into the working channel and the contours in mating alignment by fully inserting the joint locator into the working channel, JCBD teaches the working cannula 506, cannulated joint finder 800, and pin 796 positioned in the sacroiliac joint 1000 (para. [0344]) and the pairs of prongs in alignment (para. [0343], Fig. 69). It would have been obvious to one of ordinary skill in the art that the method of JCBD could have been modified as claimed to simplify insertion of the joint locator and the working channel.

Regarding claim 7, JCBD in view of Curran teach the method of claim 6. JCBD further teaches wherein inserting the insertion arms into the sacroiliac joint further comprises inserting the combined joint locator and working channel device into the sacroiliac joint at the insertion point such that the first and second sacral contours are seated against the sacrum bone and the first and second iliac contours are seated against the ilium (the working cannula 506, cannulated joint finder 800, and pin 796 positioned in the sacroiliac joint 1000, Fig. 70, para. [0344]; surfaces facing ilium 1005 and sacrum 1004, respectively, Fig. 70).

-*-Continued in next Supplemental Box-*-

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 20/54308

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of:
-*-Supplemental Box - Box No. V.2 - Citations and explanations-*-

Regarding claim 8, JCBD in view of Curran teach the method of claim 7. JCBD further teaches the method further comprising the first and second iliac contours abut the ilium and the first and second sacral contours abut the sacrum (Fig. 70). While JCBD fails to specifically teach the method further comprising tearing through soft tissue above and inside the sacroiliac joint via the penetration tip, JCBD teaches in an alternative embodiment dilating soft tissue adjacent the sacroiliac joint and for introducing the working cannula, para. [0227]). It would have been obvious to one of ordinary skill in the art that the method of JCBD could have been modified as claimed to simplify insertion of the joint locator and the working channel.

Regarding claim 9, JCBD in view of Curran teach the method of claim 1. JCBD further teaches wherein forming the decorticated implant void at the insertion point further comprises forming a generally rectangular cross sectional shape for the decorticated implant void (the cutting structure 620 extends into the articular region 1044 of the joint so as to remove a rectangular portion of the joint space formed by the sacrum 1004 and ilium 1005, para. [0353]) such that the decorticated implant void is adapted for receiving a fusion implant having a generally rectangular cross sectional shape (receive joint implant 502, para. [0354]; 502 having a generally rectangular cross section, fig. 23).

Regarding claim 10, JCBD in view of Curran teach the method of claim 9. Curran further teaches wherein, upon the abrading head becoming lodged inside the sacroiliac joint (surgical instrument stuck in a bone, para. [0023]; surgical instrument selected from group of a reamer, drill, dilator, broach and cannula, para. [0027], unlocking the slide hammer assembly via the releasing means (when said handle element (16) is in an unlocked configuration, provides a hammer element (16) that allows the surgeon to hit a surface of the apparatus, para. [0009]), and using the slide hammer assembly to dislodge the abrading head from the sacroiliac joint (proximally urging the hammer member (16) against an opposing surface to retract the surgical instrument the target location, para. [0027]). It would have been obvious to one of ordinary skill in the art that the method of JCBD could have been modified as claimed in view of Curran to extract an osteotome stuck in the bone.

Regarding claim 11, JCBD in view of Curran teach the method of claim 9. JCBD further teaches wherein introducing the working channel into the insertion point further comprises:
introducing a joint locator [into the working channel] (cannulated joint finder 800 positioned over the pin 796 and in the sacroiliac joint 1000, para. [0342], Fig. 68), the joint locator having a penetration tip at an insertion end (with dual spatulate tips 804 at a distal end 806...cannulated joint finder 800 may exert a pressure against the joint surfaces, para. [0342]), the penetration tip comprising a second iliac contour and a second sacral contour (cannulated joint finder 800 may exert a pressure against the joint surfaces of the sacrum 1004 and ilium 1005 with sufficient force to hold the joint distractor in position in the joint 1000, para. [0342; first and second surfaces facing ilium 1005 and sacrum 1004, respectively, Fig. 68); and
placing the first and second iliac contours and the first and second sacral contours in mating alignment (the pair of prongs 548 extends into the articular region 1044 of the joint 1000, and are positioned superior and inferior to the dual spatulate tips 804 of the joint distractor 800, para. [0343]) [by fully inserting the joint locator into the working channel], thereby defining a combined joint locator and working channel device (Fig. 69).
While JCBD fails to specifically teach introducing the joint locator into the working channel and the contours in mating alignment by fully inserting the joint locator into the working channel, JCBD teaches the working cannula 506, cannulated joint finder 800, and pin 796 positioned in the sacroiliac joint 1000 (para. [0344]) and the pairs of prongs in alignment (para. [0343], Fig. 69). It would have been obvious to one of ordinary skill in the art that the method of JCBD could have been modified as claimed to simplify insertion of the joint locator and the working channel.

Regarding claim 12, JCBD in view of Curran teach the method of claim 11. JCBD further teaches wherein inserting the insertion arms into the sacroiliac joint further comprises inserting the combined joint locator and working channel device into the sacroiliac joint at the insertion point such that the first and second sacral contours are seated against the sacrum bone and the first and second iliac contours are seated against the ilium (the working cannula 506, cannulated joint finder 800, and pin 796 positioned in the sacroiliac joint 1000, Fig. 70, para. [0344]; surfaces facing ilium 1005 and sacrum 1004, respectively, Fig. 70).

Regarding claim 13, JCBD in view of Curran teach the method of claim 12. JCBD further teaches the method further comprising the first and second iliac contours abut the ilium and the first and second sacral contours abut the sacrum (Fig. 70). While JCBD fails to specifically teach the method further comprising tearing through soft tissue above and inside the sacroiliac joint via the penetration tip, JCBD teaches in an alternative embodiment dilating soft tissue adjacent the sacroiliac joint and for introducing the working cannula, para. [0227]). It would have been obvious to one of ordinary skill in the art that the method of JCBD could have been modified as claimed to simplify insertion of the joint locator and the working channel.

-*-Continued in next Supplemental Box-*-

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 20/54308

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of:
-*-Supplemental Box - Box No. V.2 - Citations and explanations-*-

Regarding claim 14, JCBD in view of Curran teach the method of claim 10. JCBD further teaches wherein introducing the working channel into the insertion point further comprises:
introducing a joint locator [into the working channel] (cannulated joint finder 800 positioned over the pin 796 and in the sacroiliac joint 1000, para. [0342], Fig. 68), the joint locator having a penetration tip at an insertion end (with dual spatulate tips 804 at a distal end 806...cannulated joint finder 800 may exert a pressure against the joint surfaces, para. [0342]), the penetration tip comprising a second iliac contour and a second sacral contour (cannulated joint finder 800 may exert a pressure against the joint surfaces of the sacrum 1004 and ilium 1005 with sufficient force to hold the joint distractor in position in the joint 1000, para. [0342; first and second surfaces facing ilium 1005 and sacrum 1004, respectively, Fig. 68); and
placing the first and second iliac contours and the first and second sacral contours in mating alignment (the pair of prongs 548 extends into the articular region 1044 of the joint 1000, and are positioned superior and inferior to the dual spatulate tips 804 of the joint distractor 800, para. [0343]) [by fully inserting the joint locator into the working channel], thereby defining a combined joint locator and working channel device (Fig. 69).
While JCBD fails to specifically teach introducing the joint locator into the working channel and the contours in mating alignment by fully inserting the joint locator into the working channel, JCBD teaches the working cannula 506, cannulated joint finder 800, and pin 796 positioned in the sacroiliac joint 1000 (para. [0344]) and the pairs of prongs in alignment (para. [0343], Fig. 69). It would have been obvious to one of ordinary skill in the art that the method of JCBD could have been modified as claimed to simplify insertion of the joint locator and the working channel.

Regarding claim 15, JCBD in view of Curran teach the method of claim 14. JCBD further teaches wherein inserting the insertion arms into the sacroiliac joint further comprises inserting the combined joint locator and working channel device into the sacroiliac joint at the insertion point such that the first and second sacral contours are seated against the sacrum bone and the first and second iliac contours are seated against the ilium (the working cannula 506, cannulated joint finder 800, and pin 796 positioned in the sacroiliac joint 1000, Fig. 70, para. [0344]; surfaces facing ilium 1005 and sacrum 1004, respectively, Fig. 70).

Regarding claim 16, JCBD in view of Curran teach the method of claim 15. JCBD further teaches the method further comprising the first and second iliac contours abut the ilium and the first and second sacral contours abut the sacrum (Fig. 70). While JCBD fails to specifically teach the method further comprising tearing through soft tissue above and inside the sacroiliac joint via the penetration tip, JCBD teaches in an alternative embodiment dilating soft tissue adjacent the sacroiliac joint and for introducing the working cannula, para. [0227]). It would have been obvious to one of ordinary skill in the art that the method of JCBD could have been modified as claimed to simplify insertion of the joint locator and the working channel.

Claims 1-16 have industrial applicability as defined by PCT Article 33(4) because the subject matter can be made or used by industry.

SEARCH HISTORY

Application Number	PCT/US 20/54308
Search Conducted By	AAY
Search Approved By	SCL

CPC/IPC Classifications Searched	IPC (8) A61F 2/32 (2020.01) CPC: A61F 2/32
Date Conducted	30 November 2020 (30.11.2020)

Documentation Searched	IPC (8) A61B 17/16 (2020.01) CPC: A61B 17/1659, A61B 17/1757
Search Terms Used	sacroiliac joint preparation method prepare implant SI abrading device working channel abrasion tool decorticating introducing forming opening passageway form chisel fused fusion reamer osteotome slide hammer scraper void create passage sacro iliac sacrum ilium generate produce establish abrasive rough file surface tool instrument exterior side plane
Date Conducted	30 November 2020 (30.11.2020)

Electronic Database Searched	PatBase
Files Searched	Full-text: AU BE BR CA CH CN DE DK EP ES FI FR GB IN JP KR SE TH TW US WO Bibliographic: (European) AT BA BE BG CH CS CY CZ DD DK EE ES FI GE GR HR HU IE IS IT LT LU LV MC MD MT NL NO PL PT RO RS SE SI SK SM TR UA YU (Asia) EA GC HK ID IL IN KZ MN MY PH RU SG SU TH TJ TW UZ VN (North America) CA CR CU DO GT HN MX NI PA SV TT (South America) AR BR CL CO EC PE UY (Australasia) AU NZ (Africa) AP DZ EG KE MA MW OA ZA ZM ZW
Date Conducted	30 November 2020 (30.11.2020)
Search Logic:	

Search 1:	FT=((sacroiliac# OR sacro%iliac# OR (sacro iliac#) OR (SI joint)) NEAR (passage# OR passageway# OR channel# OR decortica*)) (Results 34)
Search 2:	1 AND FT=((form# OR create# OR generate# OR produce# OR establish#) NEAR (passage# OR passageway# OR channel# OR decortica*)) (Results 19)
Search 3:	RF=(54308) (Results 2)
Search 4:	ctf 3 or ctb 3 (Results 207)
Search 5:	4 AND FT=(sacroiliac# OR sacro%iliac# OR (sacro iliac#) OR (SI joint)) (Results 67)
Search 6:	5 AND FT=((abrade## OR abrasive# OR rough# OR file#) NEAR (surface# OR face# OR tool OR instrument OR exterior OR side# OR plane#)) (Results 21)
Search 7:	CPC=(A61B17/1659) (Results 1118)
Search 8:	7 AND FT=(sacroiliac# OR sacro%iliac# OR (sacro iliac#) OR (SI joint)) (Results 15)
Search 9:	IC=(A61F2/32) (Results 5243)
Search 10:	9 OR CPC=(A61F2/32) (Results 5536)
Search 11:	10 AND FT=((sacroiliac# OR sacro%iliac# OR (sacro iliac#) OR SI) NEAR joint#) (Results 36)
Search 12:	9 AND FT=(fuse# NEAR (sacrum AND ilium)) (Results 2)
Search 13:	9 AND FT=(sacrum# NEAR ilium#) (Results 48)
Search 14:	CPC=(A61B17/1757) (Results 1123)
Search 15:	14 AND FT=(((sacroiliac# OR sacro%iliac# OR (sacro iliac#) OR SI) NEAR joint#) OR (sacrum# NEAR ilium#)) (Results 66)
Search 16:	15 AND FT=(scrape# OR chisel# OR tap# OR file# OR abrade#) (Results 62)
Search 17:	16 AND FT=(cannula OR (working channel#)) (Results 31)
Search 18:	IC=(A61B17/16) (Results 13219)
Search 19:	18 AND FT=(((sacroiliac# OR sacro%iliac# OR (sacro iliac#) OR SI) NEAR joint#) OR (sacrum# NEAR ilium#)) (Results 101)

Electronic Database Searched	Google
Files Searched	Google Web
Date Conducted	30 November 2020 (30.11.2020)
Search Logic:	

sacroiliac joint preparation method
About 1,030,000 results (0.56 seconds)

prepare sacroiliac joint for implant
About 1,870,000 results (0.47 seconds)

SI joint implant preparation abrading device
About 134,000 results (0.84 seconds)

working channel and abrasion tool for SI joint implant
About 1,780,000 results (0.81 seconds)

tools and method for decorticating si joint
About 218,000 results (0.74 seconds)

tools for decorticating si joint introducing channel for abrading tool
About 23,400 results (0.67 seconds)

tool for forming opening in si joint
About 32,800,000 results (0.66 seconds)

abrading device form passageway in si joint
About 328,000 results (0.69 seconds)

Electronic Database Searched	Google
Files Searched	Google Scholar
Date Conducted	30 November 2020 (30.11.2020)
Search Logic:	

form working channel to fused sacroiliac joint
About 18,200 results (0.08 sec)

SI joint fusion guide working channel for bone cutting reamer
About 328 results (0.06 sec)

SI joint fusion guide working channel for bone cutting chisel
About 1,170 results (0.07 sec)

Electronic Database Searched	Google
Files Searched	Google Patents
Date Conducted	30 November 2020 (30.11.2020)
Search Logic:	

sacroiliac joint working channel
About 4,000 results (0.37 seconds)

sacroiliac joint working channel for chisel
About 2,130 results (0.42 seconds)

form void in sacroiliac joint working channel for chisel
About 603 results (0.44 seconds)

form working channel to fused sacroiliac joint
About 39,900 results (0.52 seconds)

SI joint fusion guide working channel for bone cutting reamer
About 1,720 results (0.49 seconds)

SI joint fusion guide working channel for bone cutting chisel
About 7,410 results (0.63 seconds)

method for forming passage into SI joint
About 50,700 results (0.45 seconds)

prepare passageway in SI joint chisel
About 204 results (0.32 seconds)

create void between sacrum and ilium
About 3,290 results (0.45 seconds)

create void between sacrum and ilium without a drill
About 517 results (0.47 seconds)

chisel or scraper create void between sacrum and ilium -drill
3 results (0.65 seconds)

osteotome slide hammer
About 362 results (0.31 seconds)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Pain TEQ, LLC	**Art Unit:**	3498
Serial No.:	17/063,613		
Filed:	October 5, 2020	**Docket No.:**	13438.008-12
For:	DRILL-LESS METHOD OF FUSING A SACROILIAC JOINT		

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. 1.97

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

Dear Examiner:

Under 37 C.F.R. § 1.97, a list of documents is disclosed on the attached form PTO/SB/08a Equivalent in connection with the above-referenced application. Pursuant to 37 C.F.R. § 1.97(b), the enclosed disclosure statement is submitted before the first office action on the merits in the above-referenced application. It is respectfully requested that these documents be considered by the examiner.

Applicant makes no admission as to the prior art status of the documents identified or enclosed herewith. Instead, Applicant identifies these documents in the interest of full disclosure and to comply with the Applicant's duty of candor. This disclosure statement should not be construed as a representation that a search has been made or that no other material information as defined in 37 C.F.R. § 1.56(a) exists. Nor should any inference be drawn that any or all submissions are pertinent to the invention, that the apparatus therein is analogous to the invention, or that any apparatus disclosed is the equivalent of the subject invention.

Applicant believes that there are no required fees beyond any provided for in documents accompanying this paper. However, in the event any additional fees are due for consideration of this

paper, such fees are hereby authorized to be charged to Deposit Account No. 60-0193, and credit of any overpayments to the same.

Hill Ward Henderson, P.A.
3700 Bank of America Plaza
101 East Kennedy Blvd.
Tampa, FL 33602
813-221-3900
813-221-2900 (fax)

Respectfully submitted,

/Steve Kelly/

Stephen E. Kelly, Reg. No.59,973
Attorney for Applicant

ELECTRONICALLY FILED IN THE UNITED STATES PATENT AND TRADEMARK OFFICE VIA THE EFS-WEB ELECTRONIC FACILITY FILING ON SYSTEM ON JANUARY 26, 2021.

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.
17/063,613	10/05/2020	Sean LaNeve	13438.008-12	3498

141269 7590 01/12/2021

Hill Ward Henderson, P.A.
101 East Kennedy Blvd., Suite 3700
Tampa, FL 33602

EXAMINER	

ART UNIT	PAPER NUMBER
3775	

MAIL DATE	DELIVERY MODE
01/12/2021	PAPER

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.

Decision Granting Request for Prioritized Examination (Track I)	**Application No.** 17/063,613	**Applicant(s)** LaNeve et al.	
	Examiner DIANE C GOODWYN	**Art Unit** OPET	**AIA (FITF) Status** Yes

1. THE REQUEST FILED 05 October 2020 IS **GRANTED** .

   The above-identified application has met the requirements for prioritized examination
   - A. ☑ for an original nonprovisional application (Track I).
   - B. ☐ for an application undergoing continued examination (RCE).

2. **The above-identified application will undergo prioritized examination**. The application will be accorded special status throughout its entire course of prosecution until one of the following occurs:
   - A. filing a **petition for extension of time** to extend the time period for filing a reply;
   - B. filing an **amendment to amend the application to contain more than four independent claims, more than thirty total claims** , or a multiple dependent claim;
   - C. filing a **request for continued examination** ;
   - D. filing a notice of appeal;
   - E. filing a request for suspension of action;
   - F. mailing of a notice of allowance;
   - G. mailing of a final Office action;
   - H. completion of examination as defined in 37 CFR 41.102; or
   - I. abandonment of the application.

Telephone inquiries with regard to this decision should be directed to DIANE GOODWYN at (571) 272-6735. In his/her absence, calls may be directed to Petition Help Desk at (571) 272-3282.

/DIANE C GOODWYN/ Paralegal Specialist, OPET	

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number: 17/063,613

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	80		N/A	
SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	350		N/A	
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	400		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	16 minus 20 =	*	x 50 =	0.00	OR		
INDEPENDENT CLAIMS (37 CFR 1.16(h))	1 minus 3 =	*	x 240 =	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	830		TOTAL	

APPLICATION AS AMENDED - PART II

AMENDMENT A

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

AMENDMENT B

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

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest found in the appropriate box in column 1.

UNITED STATES PATENT AND TRADEMARK OFFICE

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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
17/063,613	10/05/2020		830	13438.008-12	16	1

CONFIRMATION NO. 3498

UPDATED FILING RECEIPT

141269
Hill Ward Henderson, P.A.
101 East Kennedy Blvd., Suite 3700
Tampa, FL 33602

OC000000122004328

Date Mailed: 12/14/2020

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)

Sean LaNeve, Tampa, FL;
Charles Girsch, Tampa, FL;
Chris Girsch, Tampa, FL;

Applicant(s)

Pain TEQ, LLC, Tampa, FL;

Power of Attorney: The patent practitioners associated with Customer Number 141269

Domestic Priority data as claimed by applicant

This application is a CIP of 16/851,840 04/17/2020
which claims benefit of 62/910,913 10/04/2019
This application 17/063,613
claims benefit of 62/910,913 10/04/2019

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: 10/22/2020

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 17/063,613**

Projected Publication Date: 04/08/2021

Non-Publication Request: No

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

DRILL-LESS METHOD OF FUSING A SACROILIAC JOINT

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

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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.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign AssetsControl, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

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

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The United States represents the largest, most dynamic marketplace in the world and is an unparalleled location for business investment, innovation, and commercialization of new technologies. The U.S. offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to promote and facilitate business investment. SelectUSA provides information assistance to the international investor community; serves as an ombudsman for existing and potential investors; advocates on behalf of U.S. cities, states, and regions competing for global investment; and counsels U.S. economic development organizations on investment attraction best practices. To learn more about why the United States is the best country in the world to develop

technology, manufacture products, deliver services, and grow your business, visit http://www.SelectUSA.gov or call +1-202-482-6800.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Pain TEQ, LLC	**Examiner:**	Not Assigned
Serial No.:	17/063,613	**Art Unit:**	Not Assigned
Filing Date:	October 5, 2020	**Docket No.:**	13438-008.12
Title:	Drill-less Method of Fusing a Sacroiliac Joint		

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

RESPONSE TO NOTICE TO FILE CORRECTED APPLICATION PAPERS

Dear Commissioner:

This correspondence is in response to the Notice to File Corrected Application Papers having a mailing date of October 23, 2020 ("Notice") and a two month response period set to expire on December 23, 2020.

Enclosed herewith are (i) seven (7) sheets of replacement drawings for Figures 14-16 and 27-36, and (ii) a copy of the Notice. These replacement sheets have been corrected by adding reference numerals to Figures 14-16 and by replacing the informal drawings of Figures 27-36 with formal drawings. Figures 27-36 now have numbers, letters, and reference characters that measure at least 0.32 cm in height, and the drawings are electronically reproducible. Therefore, these replacement sheets are now in compliance with 37 C.F.R. § 1.84 and 37 C.F.R. § 1.121(d), as required by the Notice. The replacement sheets correct typographical errors, stray markings,

CERTIFICATE OF TRANSMISSION

I hereby certify that this document is being transmitted electronically to the United States Patent and Trademark Office via the EFS Web e-Filing system on December 11, 2020.

/ Steve Kelly /
Stephen E. Kelly, Reg. No. 59,973

and photocopying degradation, and the Applicant submits that these replacement sheets do not add new matter to the application.

Applicant believes that this paper and the enclosed documents provide a complete response to the Notice, and that no other action or response is necessary at this time. Applicant further believes that there are no required fees associated with this response. However, in the event that any fees are due for consideration of this paper, whether for extensions of time or otherwise, the Commissioner is hereby authorized to charge such fees to Deposit Account No. 60-0193, and to credit any overpayments to the same.

HILL WARD HENDERSON
CUSTOMER NUMBER: 141269
101 East Kennedy Boulevard
Suite 3700
Tampa, Florida 33602
Tel: 813-506-5180
Fax: 513-221-2900

Respectfully submitted,

/Steve Kelly/
Stephen E. Kelly, Reg. No. 59,973
Attorney for Applicant

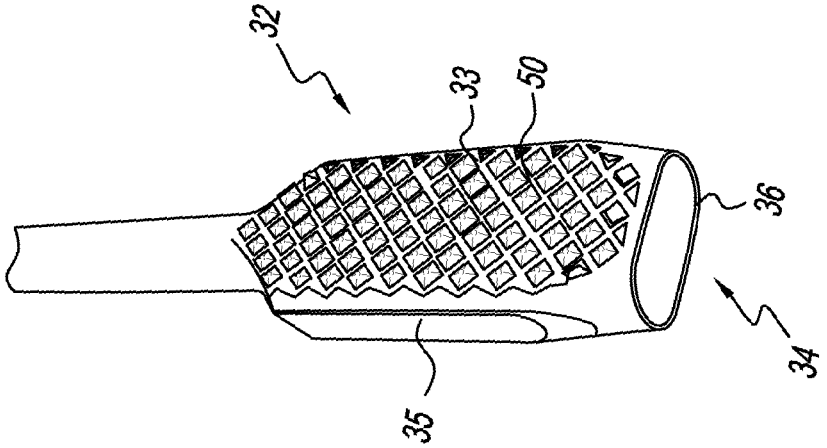


FIG. 15

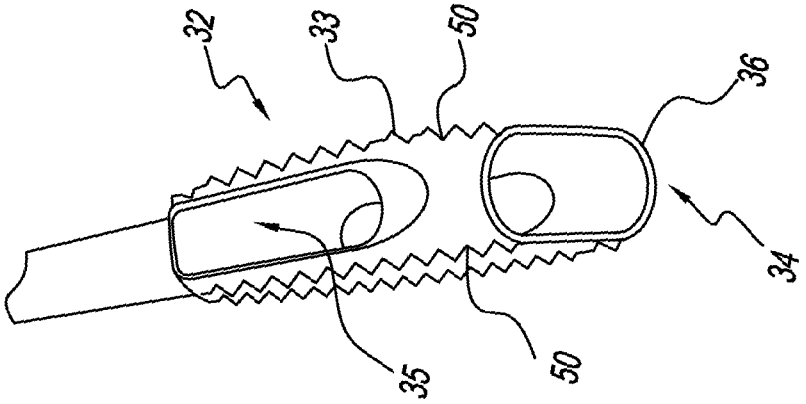


FIG. 14

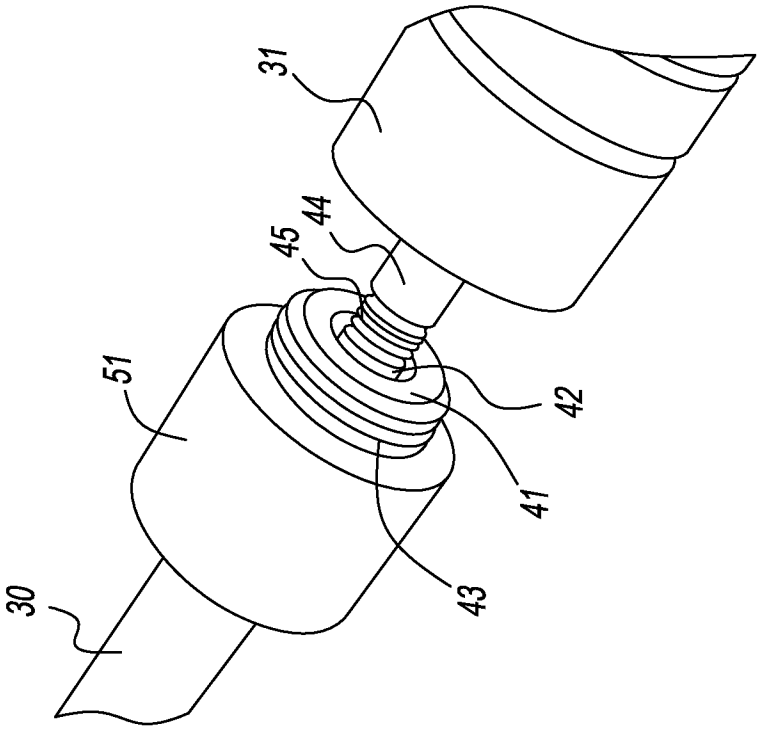


FIG. 17

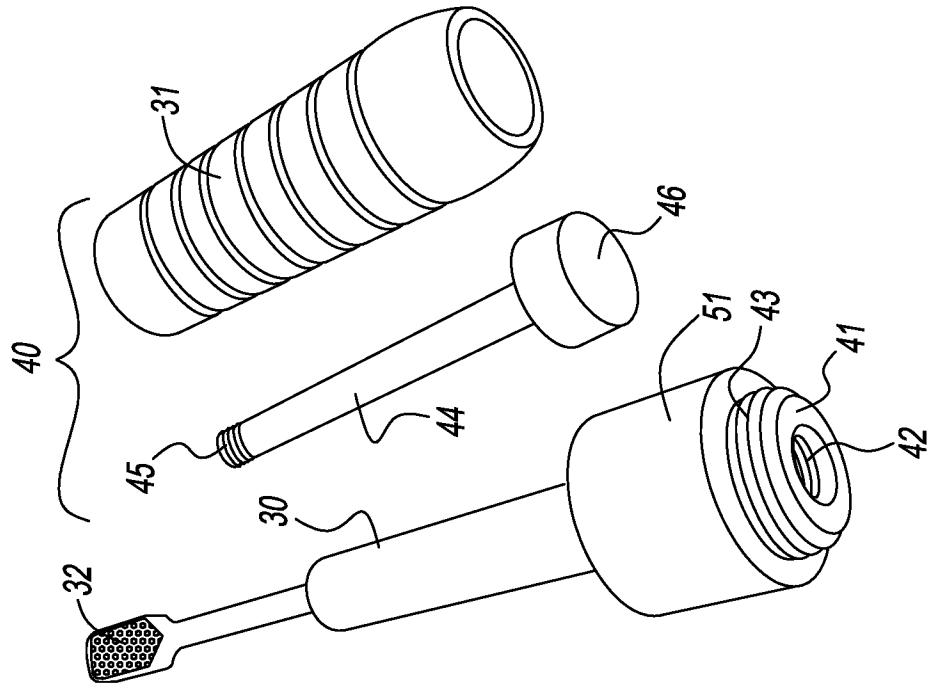


FIG. 16

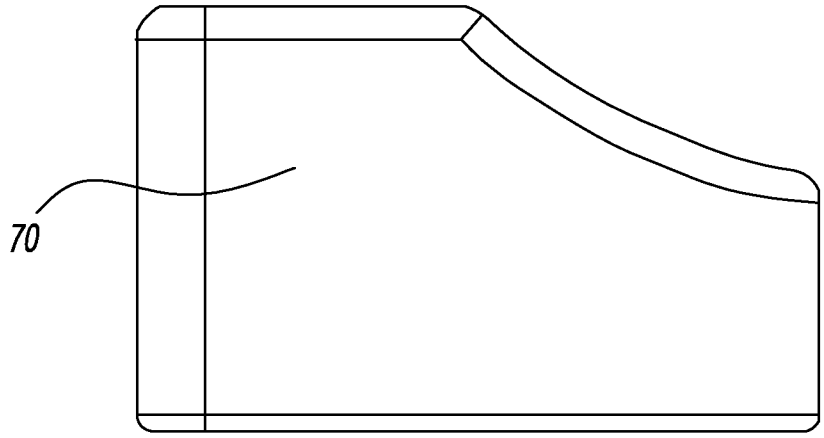


FIG. 27

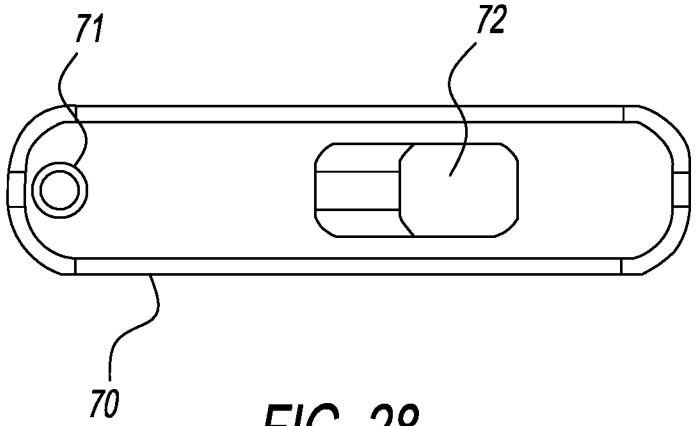


FIG. 28

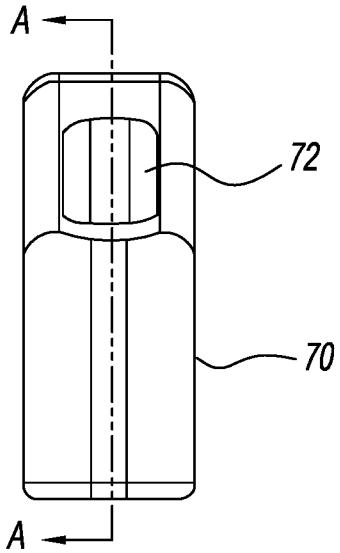


FIG. 29

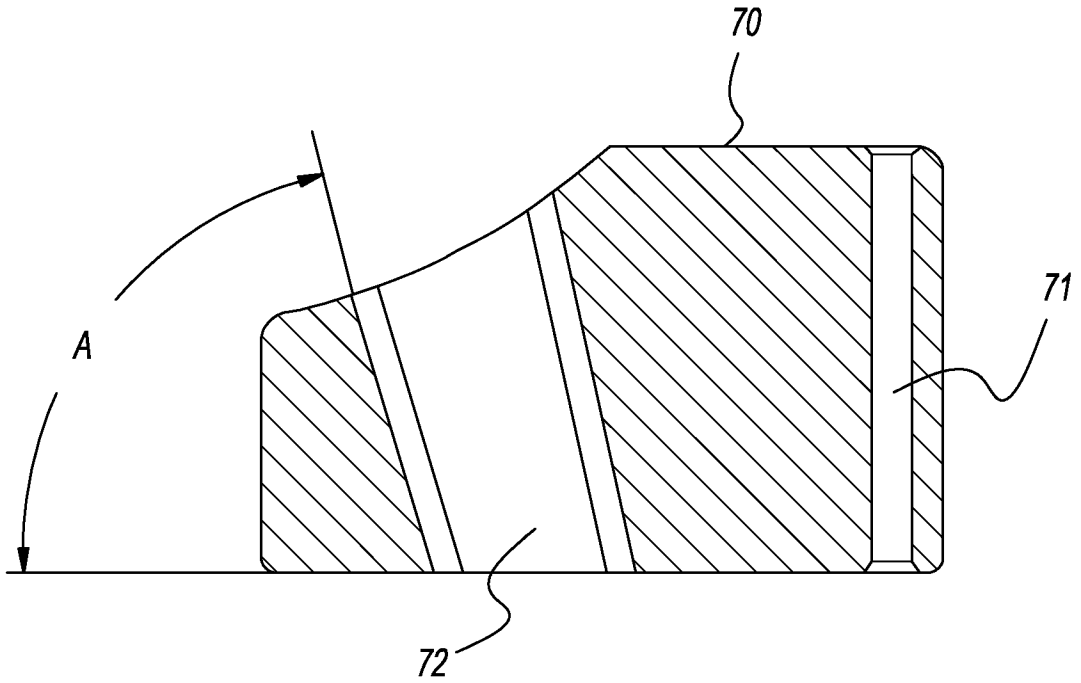


FIG. 30

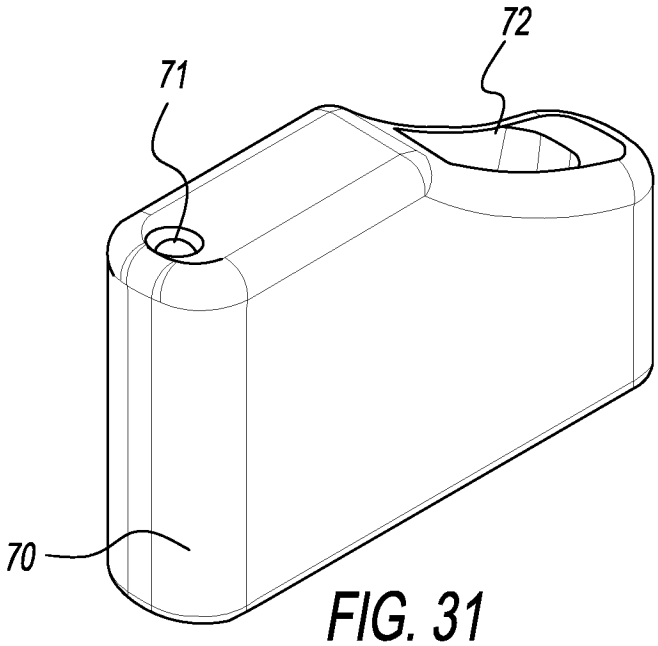


FIG. 31

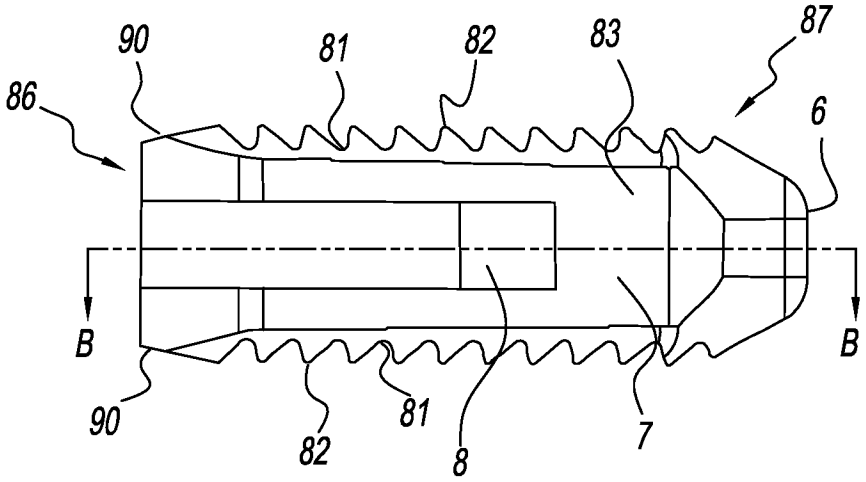


FIG. 32

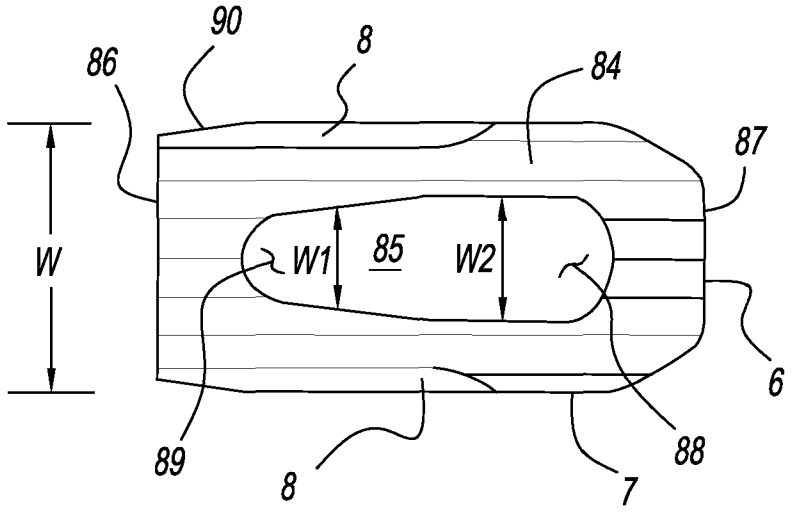


FIG. 33

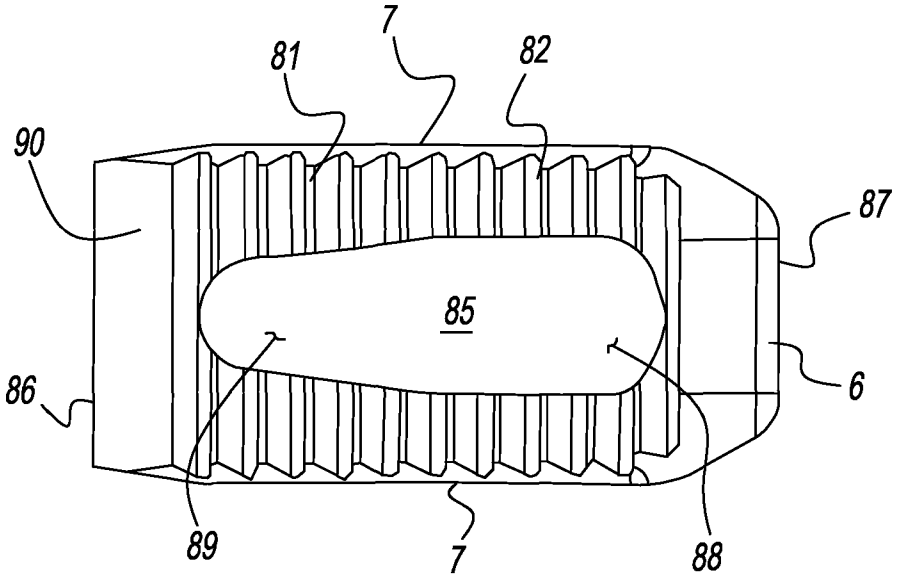


FIG. 34

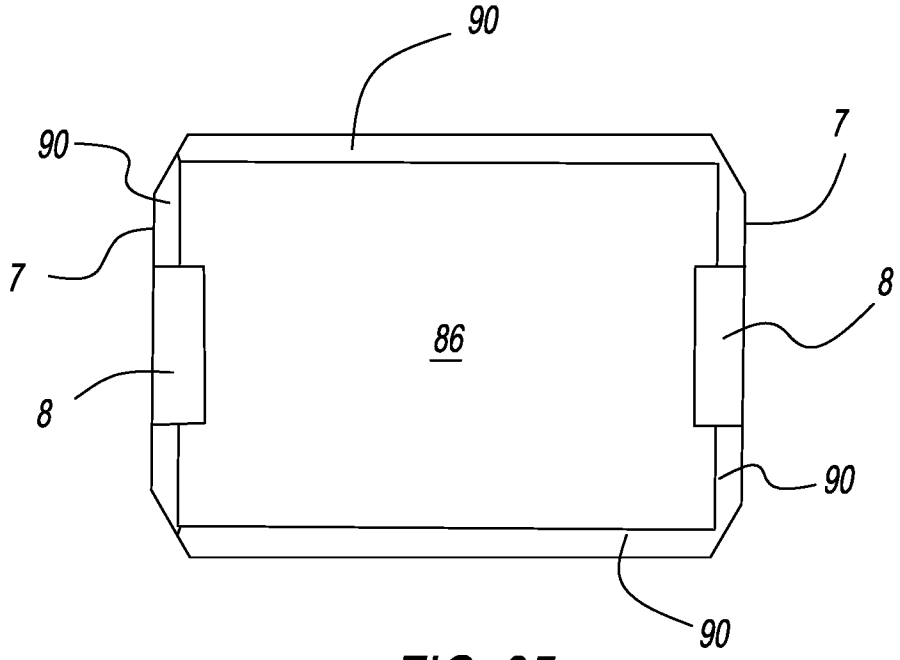


FIG. 35

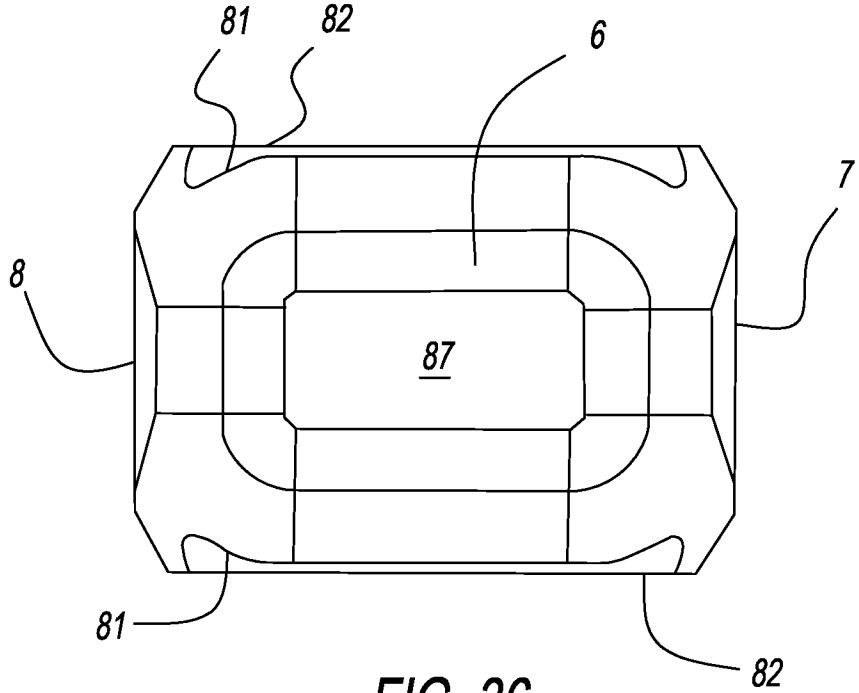


FIG. 36

UNITED STATES PATENT AND TRADEMARK OFFICE

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

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
17/063,613	10/05/2020	Sean LaNeve	13438.008-12

CONFIRMATION NO. 3498

141269
Hill Ward Henderson, P.A.
101 East Kennedy Blvd., Suite 3700
Tampa, FL 33602

FORMALITIES LETTER

OC000000120867186

Date Mailed: 10/23/2020

NOTICE TO FILE CORRECTED APPLICATION PAPERS

Filing Date Granted

An application number and filing date have been accorded to this application. The application is informal since it does not comply with the regulations for the reason(s) indicated below. Applicant is given **TWO MONTHS** from the date of this Notice within which to correct the informalities indicated below. 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 required item(s) identified below must be timely submitted to avoid abandonment:

- Replacement drawings in compliance with 37 CFR 1.84 and 37 CFR 1.121(d) are required. The drawings submitted are not acceptable because:
  - The drawings submitted to the Office are not electronically reproducible because portions of figures 27-31 are missing and/or blurry.

Applicant is cautioned that correction of the above items may cause the specification and drawings page count to exceed 100 pages. If the specification and drawings exceed 100 pages, applicant will need to submit the required application size fee.

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**.

/hngo/

Electronic Acknowledgement Receipt

EFS ID:	41367068
Application Number:	17063613
International Application Number:	
Confirmation Number:	3498
Title of Invention:	DRILL-LESS METHOD OF FUSING A SACROILIAC JOINT
First Named Inventor/Applicant Name:	Sean LaNeve
Customer Number:	141269
Filer:	Stephen E. Kelly/Lauren Forsythe
Filer Authorized By:	Stephen E. Kelly
Attorney Docket Number:	13438.008-12
Receipt Date:	11-DEC-2020
Filing Date:	05-OCT-2020
Time Stamp:	18:32:56
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Transmittal Letter	13438_008_12_Reponse_To_File_Corrected_Application_Papers.pdf	143868 128e66eda1887049c795324ed4f94747433d9df9	no	2

Warnings:

Information:					
2	Drawings-only black and white line drawings	13438_008_12_Replacement_Drawings.pdf	142650 b5bcd846d532eefa33d4f612e660f25ae653b64f	no	7
Warnings:					
Information:					
3	Transmittal Letter	13438_008_12_Copy_of_Notice_To_File_Corrected_Application_Papers.pdf	176001 3d253bfe5bbfbc375b0309dc8d0b47b652e36042	no	2
Warnings:					
Information:					
			Total Files Size (in bytes):	462519	

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: 17/063,613

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	80		N/A	
SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	350		N/A	
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	400		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	16 minus 20 =	*	x 50 =	0.00	OR		
INDEPENDENT CLAIMS (37 CFR 1.16(h))	1 minus 3 =	*	x 240 =	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	830		TOTAL	

APPLICATION AS AMENDED - PART II

AMENDMENT A

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

AMENDMENT B

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

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest found in the appropriate box in column 1.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
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
17/063,613	10/05/2020		830	13438.008-12	16	1

CONFIRMATION NO. 3498

FILING RECEIPT

141269
Hill Ward Henderson, P.A.
101 East Kennedy Blvd., Suite 3700
Tampa, FL 33602

OC000000120867185

Date Mailed: 10/23/2020

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)

Sean LaNeve, Tampa, FL;
Charles Girsch, Tampa, FL;
Chris Girsch, Tampa, FL;

Applicant(s)

Pain TEQ, LLC, Tampa, FL;

Power of Attorney: The patent practitioners associated with Customer Number 141269

Domestic Priority data as claimed by applicant

This application is a CIP of 16/851,840 04/17/2020
which claims benefit of 62/910,913 10/04/2019
This application 17/063,613
claims benefit of 62/910,913 10/04/2019

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: 10/22/2020

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 17/063,613**

Projected Publication Date: To Be Determined - pending completion of Corrected Papers

Non-Publication Request: No

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

DRILL-LESS METHOD OF FUSING A SACROILIAC JOINT

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).

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Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

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This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign AssetsControl, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

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

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technology, manufacture products, deliver services, and grow your business, visit http://www.SelectUSA.gov or call +1-202-482-6800.

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Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
17/063,613	10/05/2020	Sean LaNeve	13438.008-12

CONFIRMATION NO. 3498

141269
Hill Ward Henderson, P.A.
101 East Kennedy Blvd., Suite 3700
Tampa, FL 33602

FORMALITIES LETTER

OC000000120867186

Date Mailed: 10/23/2020

NOTICE TO FILE CORRECTED APPLICATION PAPERS

Filing Date Granted

An application number and filing date have been accorded to this application. The application is informal since it does not comply with the regulations for the reason(s) indicated below. Applicant is given **TWO MONTHS** from the date of this Notice within which to correct the informalities indicated below. 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 required item(s) identified below must be timely submitted to avoid abandonment:

- Replacement drawings in compliance with 37 CFR 1.84 and 37 CFR 1.121(d) are required. The drawings submitted are not acceptable because:
  - The drawings submitted to the Office are not electronically reproducible because portions of figures 27-31 are missing and/or blurry.

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Mail Stop Missing Parts
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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.

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/hngo/

PTO/AIA/15 (10-17)
Approved for use through 11/30/2020. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995 no persons are required to respond to a collection of information unless it displays a valid OMB control number.

UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new nonprovisional applications under 37 CFR 1.53(b))

Attorney Docket No.	13438-008.12
First Named Inventor	Sean LaNeve
Title	DRILL-LESS METHOD OF FUSING A SACROILIAC JOINT
Priority Mail Express® Label No.	Filed EFS Web

APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents.

1. [✔] **Fee Transmittal Form** (PTO/SB/17 or equivalent)
2. [✔] **Applicant asserts small entity status.** See 37 CFR 1.27
3. [ ] **Applicant certifies micro entity status.** See 37 CFR 1.29. Applicant must attach form PTO/SB/15A or B or equivalent.
4. [✔] **Specification** [*Total Pages* 31] Both the claims and abstract must start on a new page. *(See MPEP § 608.01(a) for information on the preferred arrangement)*
5. [✔] **Drawing(s)** (35 U.S.C. 113) [*Total Sheets* 23]
6. **Inventor's Oath or Declaration** [*Total Pages* 3] *(including substitute statements under 37 CFR 1.64 and assignments serving as an oath or declaration under 37 CFR 1.63(e))*
   a. [✔] Newly executed (original or copy)
   b. [ ] A copy from a prior application (37 CFR 1.63(d))
7. [✔] **Application Data Sheet** ** See note below.* See 37 CFR 1.76 (PTO/AIA/14 or equivalent)
8. **CD-ROM or CD-R** in duplicate, large table, or Computer Program (*Appendix*)
   [ ] Landscape Table on CD
9. **Nucleotide and/or Amino Acid Sequence Submission** (*if applicable, items a. – c. are required*)
   a. [ ] Computer Readable Form (CRF)
   b. [ ] Specification Sequence Listing on:
      i. [ ] CD-ROM or CD-R (2 copies); or
      ii. [ ] Paper
   c. [ ] Statements verifying identity of above copies

ADDRESS TO:

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

ACCOMPANYING APPLICATION PAPERS

10. [ ] **Assignment Papers** (cover sheet & document(s))
    Name of Assignee _____
11. [ ] **37 CFR 3.73(c) Statement** (*when there is an assignee*) [✔] **Power of Attorney**
12. [ ] **English Translation Document** (*if applicable*)
13. [ ] **Information Disclosure Statement** (PTO/SB/08 or PTO-1449)
    [ ] Copies of citations attached
14. [ ] **Preliminary Amendment**
15. [ ] **Return Receipt Postcard** (*MPEP § 503*) (*Should be specifically itemized*)
16. [ ] **Certified Copy of Priority Document(s)** (*if foreign priority is claimed*)
17. [ ] **Nonpublication Request** Under 35 U.S.C. 122(b)(2)(B)(i). Applicant must attach form PTO/SB/35 or equivalent.
18. [✔] **Other:** Certification and Request for Prioritized Examination

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

19. CORRESPONDENCE ADDRESS

[✔] The address associated with Customer Number: 141269 **OR** [ ] Correspondence address below

Name					
Address					
City		State		Zip Code	
Country		Telephone		Email	

Signature	/Steve Kelly/	Date	10/05/2020
Name (Print/Type)	Stephen E. Kelly	Registration No. (Attorney/Agent)	59973

This collection of information is required by 37 CFR 1.53(b). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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

Privacy Act Statement

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

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

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
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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.

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

Title of Invention: **DRILL-LESS METHOD OF FUSING A SACROILIAC JOINT**

As the below named inventor, I hereby declare that:

This declaration is directed to: ☒ The attached application, or
☐ United States application or PCT international application number _____ filed on _____

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.

I have reviewed and understand the subject matter of the above-identified application, including the claims.

I am aware of and acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

WARNING:

Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore not publicly available.

LEGAL NAME OF INVENTOR:

Inventor: **Sean LaNeve** Date (optional): _____

Signature: _____

Note: An application data sheet (PTO/SB/14 or equivalent), including the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/A1A/01 form for each additional inventor.

THIS IS A MODIFIED VERSION OF USPTO FORM PTO/A1A/01

v

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

Title of Invention: **DRILL-LESS METHOD OF FUSING A SACROILIAC JOINT**

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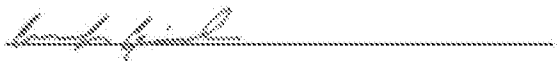
I am aware of and acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

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LEGAL NAME OF INVENTOR:

Inventor: **Charles Girsch** Date (optional): October 5, 2020

Signature: 

Note: An application data sheet (PTO/SB/14 or equivalent), including the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/A1A/01 form for each additional inventor.

THIS IS A MODIFIED VERSION OF USPTO FORM PTO/A1A/01

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

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

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

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WARNING:

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LEGAL NAME OF INVENTOR:

Inventor: **Chris Gleschen** Date (optional): 10-1-20

Signature: _____

Note: An application data sheet (PTO/SB/14 or equivalent), including the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/A1A/01 form for each additional inventor.

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v

Electronic Patent Application Fee Transmittal

Application Number:	
Filing Date:	
Title of Invention:	DRILL-LESS METHOD OF FUSING A SACROILIAC JOINT
First Named Inventor/Applicant Name:	Sean LaNeve
Filer:	Stephen E. Kelly/Lauren Forsythe
Attorney Docket Number:	13438.008-12

Filed as Small Entity

Filing Fees for Track I Prioritized Examination - Nonprovisional Application under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
UTILITY FILING FEE (ELECTRONIC FILING)	4011	1	80	80
UTILITY SEARCH FEE	2111	1	350	350
UTILITY EXAMINATION FEE	2311	1	400	400
REQUEST FOR PRIORITIZED EXAMINATION	2817	1	2100	2100
Pages:				
Claims:				
Miscellaneous-Filing:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
PUBL. FEE- EARLY, VOLUNTARY, OR NORMAL	1504	1	0	0
PROCESSING FEE, EXCEPT PROV. APPLS.	2830	1	70	70

Petition:	
Patent-Appeals-and-Interference:	
Post-Allowance-and-Post-Issuance:	
Extension-of-Time:	
Miscellaneous:	
Total in USD ($)	**3000**

Electronic Acknowledgement Receipt

EFS ID:	40763823
Application Number:	17063613
International Application Number:	
Confirmation Number:	3498
Title of Invention:	DRILL-LESS METHOD OF FUSING A SACROILIAC JOINT
First Named Inventor/Applicant Name:	Sean LaNeve
Customer Number:	141269
Filer:	Stephen E. Kelly/Lauren Forsythe
Filer Authorized By:	Stephen E. Kelly
Attorney Docket Number:	13438.008-12
Receipt Date:	05-OCT-2020
Filing Date:	
Time Stamp:	20:36:39
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$3000
RAM confirmation Number	E202005K37531606
Deposit Account	600193
Authorized User	Lauren Forsythe

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

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	TrackOne Request	13438_008_12_Certification_And_Request_for_Prioritized_Examination_10052020.pdf	1030841 fcd84d24b447d9d09f454686c961737ac9ccd6f9	no	2
Warnings:					
Information:					
2		13438_008_12_Specification_10052020.pdf	216814 76a87f3bd15b2960628cb612cf7d2c878770687c	yes	31

Multipart Description/PDF files in .zip description

Document Description	Start	End
Specification	1	24
Claims	25	30
Abstract	31	31

Warnings:					
Information:					
3	Drawings-only black and white line drawings	13438_008_NewFinalDrawings_10052020.pdf	769089 d62463892331ae9d2505092c16184149723e2da9	no	23
Warnings:					
Information:					
4	Power of Attorney	13438_008_Executed_POA_Chris_Girsch_10052020.pdf	184363 e18d9bdf10c855b2f42d51ea674bbd180c4367d1	no	1
Warnings:					
Information:					
5	Application Data Sheet	13438_008_12_ADS_10052020.pdf	543209 559267476c7f1031c950e367c310d9a326099d71	no	10

Warnings:					
Information:					
This is not an USPTO supplied ADS fillable form					
6	Transmittal of New Application	13438_008_12_UtilityTransmittal_10052020.pdf	117278 ea8a8888dc14bcbce75ea6a5f9b37a2f0bc706b5	no	2
Warnings:					
Information:					
7	Oath or Declaration filed	13438_008_12_ExecutedDeclarations_10052020.pdf	407939 9af114c407a3b752b372993a387285ed308f3eab	no	3
Warnings:					
Information:					
8	Fee Worksheet (SB06)	fee-info.pdf	39932 2b34b2da9fc58a6d0ef166e51f3f417bb7b9316b	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	3309465		

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

New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

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

Doc Code: TRACK1.REQ
Document Description: TrackOne Request

PTO/AIA/424 (04-14)

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

First Named Inventor:	Sean LaNeve	Nonprovisional Application Number (if known):	62910913
Title of Invention:	DRILL-LESS METHOD OF FUSING A SACROILIAC JOINT		

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

1. The processing fee set forth in 37 CFR 1.17(i)(1) and the prioritized examination fee set forth in 37 CFR 1.17(c) have been filed with the request. The publication fee requirement is met because that fee, set forth in 37 CFR 1.18(d), is currently $0. The basic filing fee, search fee, and examination fee are filed with the request or have been already been paid. I understand that any required excess claims fees or application size fee must be paid for the application.

2. I understand that the application may not contain, or be amended to contain, more than four independent claims, more than thirty total claims, or any multiple dependent claims, and that any request for an extension of time will cause an outstanding Track I request to be dismissed.

3. The applicable box is checked below:

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

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

---OR---

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

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

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

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

Signature /Steve Kelly/	Date 10/05/2020
Name (Print/Typed) Stephen E. Kelly	Practitioner Registration Number 59973

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

☐ *Total of _____ forms are submitted.

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.

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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.
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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)).
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DRILL-LESS METHOD OF FUSING A SACROILIAC JOINT

CROSS-REFERENCE TO RELATED APPLICATION

[0001] Pursuant to 35 U.S.C. §§ 119(e) and 120, this application:

(i) is a continuation-in-part of United States Patent Application Serial No. 16/851,840, filed on April 17, 2020, which claims the benefit of United States Provisional Patent Application Serial No. 62/910,913, filed on October 4, 2019; and

(ii) claims the benefit of United States Provisional Patent Application Serial No. 62/910,913, filed on October 4, 2019,

the entire contents of each of which are incorporated herein by this reference.

BACKGROUND

[0002] (1) Field of Endeavor.

[0003] The present invention relates generally to the field of sacroiliac joint fusion procedures, and more particularly, to a unique method for fusing a sacroiliac joint without the use of a rotary cutting instrument.

[0004] (2) Description of Related Art.

[0005] The sacroiliac joint ("SI Joint") is located at the interface between the sacrum and ilium bones in a human's pelvic area. The SI Joint includes strong ligaments that permit only slight movement between the sacrum and the ilium. The sacrum is connected to the base of the spine, and each ilium is connected to the top of the leg and hip area. Thus, the SI Joint is the interface between a human's upper body and lower body.

[0006] Dysfunction in the SI Joint is a common problem of back pain. In fact, over 25% of back pain is caused by SI Joint dysfunction. Even a properly functioning SI Joint can become painful after certain types of spinal procedures. For example, over 75% of lumbar fusion surgeries lead to SI Joint pain. Often, SI Joint pain or dysfunction is addressed by fusing the SI Joint, and many past procedures exist for doing so. Past SI Joint fusion procedures involve installation of complex implant devices, such as bone anchors, fusion devices, and multi-component implants. These procedures involve complex devices, such as drills and drill bits, and multi-component dilators, braces, and anchor installation devices. As a result, fusion procedures using these devices are complex and time consuming, often leading to suboptimal results.

[0007] The present set of instruments seeks to overcome these problems by providing a streamlined system and procedure for installing an allograft implant in the SI Joint, without using a drill, drill bits, or other rotary cutting instruments.

[0008] Another complication of SI Joint fusion is that promoting bone fusion often involves decorticating the cortical bone inside the SI Joint. This decortication is accomplished with a broach, a rasp, or a similar abrading device. These abrading devices often become lodged inside the SI Joint during the decortication process. When the abrading device becomes lodged, counter pressure cannot be applied to the patient to counteract the pull-out force needed to dislodge the abrading device. Any such counter pressure applied to the patient could result in injury to the patient or damage to the tissue surrounding the surgical site. A past solution is to attach a separate slap hammer, or slide hammer, to the abrading device such that pull-out forces can be applied to the abrading device without the need for applying any counter pressure to the patient or to any other object. However, past slide hammer assemblies are cumbersome to

operate, difficult to attach to the abrading device, and difficult to operate. They also complicate the instrumentation needed to perform the SI Joint fusion procedure.

[0009] The present set of instruments seeks to overcome these problems by providing a slide hammer integrated into the abrading device in a single tool, which eliminates the need for using a rotary cutting instrument in the bone of the SI Joint to form a pilot hole for the implant.

SUMMARY OF THE PREFERRED EMBODIMENTS

[0010] In the preferred embodiment, the system and instrumentation described herein comprises a working channel, a joint locator, an abrading device, and an implant inserter. The working channel has an insertion end and a working end, and a channel extending therebetween. The working channel provides a working passage for insertion of the other instruments of the system, and for delivery of the implant to the SI Joint. The insertion end has a pair of arms for providing engagement of the SI Joint and distraction of tissue surrounding the insertion end. The insertion end further comprises a first iliac contour and a first sacral contour, both of which are defined by the contour between the insertion arms and the body of the working channel. The inside surface of the working channel has an alignment means comprising a groove, recess, channel, indent, or the like for receiving and engaging a ridge, rib, detent, or other protrusion on the mating instrument that is keyed to the alignment means. In one embodiment, the working channel further comprises a channel collar for receiving mating components of the joint locator, abrading device, or implant inserter in an abutting engagement.

[0011] The joint locator has an insertion end and a handle. The insertion end comprises a penetration tip for penetrating the soft tissue in proximity to the SI Joint. A leading edge of the penetration tip may comprise, in whole or in part, a blade or chisel component to promote this penetration. Alternately, the penetration tip may be rounded or dull so that it does not inadvertently penetrate the sacrum or ilium in the event that the joint locator is misaligned during insertion. The joint locator insertion end comprises a second iliac contour and a second sacral contour. The outside surface of the joint locator has a keying means for engagement with the alignment means of the working channel, the keying means comprising a ridge, rib, detent, or

other protrusion on the outside surface of the joint locator capable of engaging the alignment means.

[0012] The abrading device comprises a hammer sleeve at a proximate end, an abrading head at a distal end, and a keying means that is similar to the joint locator keying means of the joint locator. In the preferred embodiment, the abrading device further comprises a slap hammer assembly, or slide hammer assembly. In one embodiment, the slide hammer assembly comprises a base connected to a shaft, and a releasing means that releasably connects a hammer sleeve to the base. The released hammer sleeve is configured for sliding engagement along the shaft. To operate the slide hammer assembly, the hammer sleeve is disengaged from the base, placing the slide hammer assembly in its released position. This released position enables the hammer sleeve to slide freely along the shaft. The hammer sleeve is pulled until a diaphragm inside the hammer sleeve engages a stop end of the shaft, thereby causing an impact that delivers the slide hammer force.

[0013] The implant inserter comprises a handle and an implant insertion end. The implant insertion end has a pair of tines for holding the implant during the process of inserting the implant into the SI Joint. The implant inserter further comprises an inserter keying means, which is similar to the keying means of the joint locator.

BRIEF DESCRIPTION OF THE DRAWINGS

[0014] **FIG. 1** shows the posterior view of a typical human pelvis.

[0015] **FIG. 2** is a perspective view of an embodiment of an allograft implant for insertion into the SI Joint.

[0016] **FIG. 3** shows an alternate view of one embodiment of an allograft implant.

[0017] **FIG. 4** shows an embodiment of the instruments in the joint fusion apparatus.

[0018] **FIG. 5** shows an embodiment of the working channel and an embodiment of the joint locator.

[0019] **FIG. 6** shows a close up of the insertion end of one embodiment of a working channel.

[0020] **FIG. 7** shows an alternate view of the embodiment shown in Fig. 6.

[0021] **FIG. 8** is an enlarged view of the insertion end of an embodiment of the joint locator fully inserted into the working channel of Fig. 4.

[0022] **FIG. 9** is an enlarged view showing the device of Fig. 8 with the orientation reversed.

[0023] **FIG. 10** shows a close up of the working end of one embodiment of a working channel.

[0024] **FIG. 11** shows the joint locator of Fig. 4 partially inserted into the working channel.

[0025] **FIG. 12** shows the joint locator of Fig. 4 fully inserted into the working channel.

[0026] **FIG. 13** shows the working channel of Fig. 4 and an embodiment of the abrading device.

[0027] **FIG. 14** is an enlarged view of an embodiment of the abrading head.

[0028] **FIG. 15** shows an enlarged view of one embodiment of an abrading head.

[0029] **FIG. 16** shows the abrading device of Fig. 13 with an embodiment of a slide hammer disassembled.

[0030] **FIG. 17** is an enlarged view of an embodiment of the connection interface of a slide hammer.

[0031] **FIG. 18** shows a close up of one embodiment of the diaphragm and threaded connector of a slide hammer assembly.

[0032] **FIG. 19** shows the abrading device of Fig. 13 partially inserted into the working channel of Figs. 4.

[0033] **FIG. 20** shows the abrading device of Fig. 13 fully inserted into the working channel of Fig. 4 with the slide hammer in its locked position.

[0034] **FIG. 21** shows the abrading device of Fig. 13 fully inserted into the working channel of Fig. 4 with the slide hammer in its extended position.

[0035] **FIG. 22** shows the working channel of Fig. 4 and an embodiment of the insertion device.

[0036] **FIG. 23** is an enlarged view of the insertion end of the insertion device of Fig. 22.

[0037] **FIG. 24** shows the insertion device of Fig. 22 with an embodiment of an allograft implant loaded into the tines of the insertion end.

[0038] **FIG. 25** shows the insertion device of Fig. 22 and the allograft implant partially inserted into the working channel of Fig. 4.

[0039] **FIG. 26** shows the insertion device of Fig. 22 and the allograft implant fully inserted into the working channel of Fig. 4.

[0040] **FIG. 27** is a front view of one embodiment of the incision guide.

[0041] **FIG. 28** is a top view of one embodiment of the incision guide

[0042] **FIG. 29** is a right side view of one embodiment of the incision guide.

[0043] **FIG. 30** is a cross-sectional view A-A of the incision guide of Fig. 29.

[0044] **FIG. 31** is an isometric view of one embodiment of the incision guide.

[0045] **FIG. 32** is a side view of one embodiment of an allograft implant.

[0046] **FIG. 33** is a cross-sectional view B-B of the allograft implant of Fig. 32.

[0047] **FIG. 34** is a top view of one embodiment of an allograft implant.

[0048] **FIG. 35** is a rear view of one embodiment of an allograft implant.

[0049] **FIG. 36** is a front view of one embodiment of an allograft implant.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0050] With reference to the drawings, the method for fusing a sacroiliac joint ("SI Joint") now will be described with regard for the best mode and the preferred embodiment. The embodiments disclosed herein are meant for illustration and not limitation of the invention. An ordinary practitioner will appreciate that it is possible to create many variations of the following embodiments without undue experimentation.

[0051] The method and corresponding system and instrumentation described herein are used primarily for fusing an SI Joint 3 in the pelvis of a human. Referring to Figs. 1-3, an allograft implant 5 is placed in the soft tissue of the SI Joint 3 between the sacrum 1 and the ilium 2 of the pelvis. For the purpose of reference, the SI Joint plane as used herein means the general plane of the SI Joint 3 as defined by the abutting surfaces of the sacrum 1 and ilium 2. The implant 5 provides a matrix for bone healing across the SI Joint, thereby fusing the sacrum 1 and ilium 2 together. In one embodiment, the implant 5 generally comprises a nose 6 and at least one pair of opposing lateral sides 7, each comprising a groove 8 that is disposed at least partially along the length of each such lateral side 7.

[0052] Referring to Fig. 4, in one embodiment, the system comprises a working channel 10, a joint locator 20, an abrading device 30, and an implant inserter 60. Each of these instruments has a longitudinal axis along the centerline of its length. Referring to Fig. 5, the working channel 10 is a tube-like member that provides a working passage for insertion of the other instruments of the system, and for delivery of the implant 5 to the SI Joint 3. The working channel 10 is a cannula, a lumen, a sleeve, or another device suitable for providing working access of the other instruments to the SI Joint 3, as described below. The working channel 10 has an insertion end

11 and a working end 12, and a channel 13 extending therebetween. The channel 13 is a tube or bore having a cross section that is rectilinear or curvilinear. The insertion end 11 has a pair of arms 14 for providing engagement of the SI Joint 3 and distraction of tissue surrounding the insertion end 11. The arms 14 are probes, prongs, or other members protruding from the insertion end 11 of the working channel 10. Insertion of the arms 14 into the SI Joint 3, as described below, resists or prevents the working channel 10 from rotating about its longitudinal axis in relation to the SI Joint 3. The longitudinal axis generally extends along the length of the working channel 10 in proximity to the centerline of the channel 13.

[0053] The insertion end 11 of the working channel 10 is configured for seating in and against the SI Joint 3, and against the sacrum 1 and ilium 2 in particular. The insertion end 11 comprises a first iliac contour 15 and a first sacral contour 16, both of which are defined by the contour between the insertion arms 14 and the body of the working channel 10. For example, referring to Figs. 6-9, one side of the insertion end 11 comprises the arms 14 connected to the working channel 10 via the first iliac contour 15, which is configured for abutment against the ilium 2 when the arms 14 are inserted into, and seated within, the SI Joint 3 as described below. The opposite side of the insertion end 11 comprises the arms 14 connected to the working channel 10 via the first sacral contour 16, which is configured for abutment against the sacrum 1 when the arms 14 are inserted into, and seated within, the SI Joint 3.

[0054] Referring to Figs. 5 and 10, the inside surface of the working channel 10 has a means for aligning instruments, the alignment means 17 comprising a groove, recess, channel, indent, or the like for receiving and engaging a ridge, rib, detent, or other protrusion on the mating instrument that is keyed to the alignment means 17. In one embodiment, the working channel 10 further comprises a channel collar 18 for receiving mating components of the joint locator 20,

abrading device 30, or implant inserter 60 in an abutting engagement, as described below. In an embodiment of the channel collar 18, the collar further comprises an alignment means 17.

[0055] Referring to Fig. 5, the joint locator 20 has an insertion end 21 and a handle 22, or working end. The insertion end 21 comprises a penetration tip 23 for penetrating the soft tissue in proximity to the SI Joint 3. This soft tissue is the soft tissue between the surface of the patient's skin the SI Joint 3, such as muscle tissue, and the soft tissue inside the SI Joint 3, such as cartilage and ligaments. The penetration tip 23 is configured for penetrating these types of soft tissue. For example, one embodiment of the penetration tip 23 comprises a blade or chisel component for cutting the soft tissue. A leading edge of the penetration tip 23 may comprise, in whole or in part, such a blade or chisel component. In another embodiment of the penetration tip 23, the penetration tip 23 is rounded or dull so that it does not inadvertently penetrate the sacrum 1, the ilium 2, or any other bone structure in the pelvic area in the event that the joint locator 20 is misaligned during insertion and penetration. In this embodiment, the penetration tip 23 tends to tear or rip through the soft tissue rather than slicing or cutting through it.

[0056] Referring again to Figs. 8 and 9, the joint locator 20 insertion end 21 comprises a second iliac contour 24 and a second sacral contour 25. For example, one side of the joint locator 20 insertion end 21 comprises the second iliac contour 24, which is configured for abutment against the ilium 2 when the penetration tip 23 is inserted into the SI Joint 3, as described below. The other side of the joint locator 20 insertion end 21 comprises the second sacral contour 25, which is configured for abutment against the sacrum 1 when the penetration tip 23 is inserted into the SI Joint 3.

[0057] The outside surface of the joint locator 20 has a means for keying with the alignment means 17 of the working channel 10, the keying means 27 comprising a ridge, rib, detent, or

other protrusion on the outside surface of the joint locator 20 capable of engaging the alignment means 17 to resist or prevent relative rotation between the joint locator 20 and the working channel 10.

[0058] In one embodiment, referring to Figs. 5, 11, and 12, the joint locator 20 has a channel 26 for receiving the K-wire 4. This channel 26 is a cannula, lumen, or other bore-like feature capable of receiving the K-wire 4 in a pass-through manner, preferably along a longitudinal axis, or centerline, of the joint locator 20. In one embodiment of the joint locator 20, the handle 22 further comprises a stop 28 for abutting against the channel collar 18 of the working channel 10.

[0059] Referring to Fig. 13, the abrading device 30 comprises a hammer sleeve 31 at a proximate end and an abrading head 32 at a distal end. The abrading head 32 is a rasp, broach, or other abrading tool that is used to grate, abrade, or otherwise decorticate the cortical bone inside the SI Joint 3. In one embodiment, shown in Fig. 14 and 15, the abrading head 32 is a generally rectangular member comprising abrading surfaces 33 on a first pair of opposing sides of the head 32, an open tip 34 for insertion into the SI Joint 3, and a second pair of opposing sides 35 between the abrading surfaces 33, the second pair of opposing lateral sides 35 having one or more lateral openings. Each abrading surface 33 comprises one or more teeth, barbs, blades, ridges, slots, broaches, or other members or features capable of abrading the cortical bone in the SI Joint 3. The open tip 34 comprises a cutting edge 36 around all or part of the leading edge of the open tip 34, the cutting edge 36 configured for cutting bone tissue inside the SI Joint 3, such as the sacrum 1 or ilium 2. The abrading surfaces 33 and lateral sides 35 form a box-like abrading head 32 having a void therein. The openings in the lateral sides 35 enable lateral ingress into and egress from the void. For example, as the cutting edge 36 cuts bone tissue inside the SI Joint 3, the dislodged bone tissue falls into the void and may exit the abrading head 32 via

the openings in the lateral sides 35.

[0060] In one embodiment, each side of the first pair of opposing sides is a substantially planar member having a distal edge terminating at the open tip 34, the interface between the open tip 34 and the distal edge comprising a substantially straight cutting edge 36. Each side of the second pair of opposing sides may comprise a curved distal portion terminating at the open tip 34, the interface between the open tip 34 and the curved distal portion comprising a curved cutting edge 36. The curved distal portion of each side of the second pair of opposing sides 35 may further comprise a taper toward its opposite side of the second pair of opposing sides 35.

[0061] Referring to Fig. 19, the abrading device 30 further comprises a keying means 37, which is similar to the joint locator 20 keying means 27 described above. The keying means 37 mates with the alignment means 17 in the working channel 10 to resist or to prevent relative rotation between the abrading device 30 and the working channel 10 about each member's respective longitudinal axis. The abrading device 30 further comprises an abrading stop 38 for abutting against the channel collar 18 of the working channel 10. In one embodiment, the abrading device 30 further comprises a K-wire channel for receiving the K-wire 4. This K-wire channel is a cannula, lumen, or other bore-like feature capable of receiving the K-wire 4 in a pass-through manner, preferably along a longitudinal axis of the abrading device 30.

[0062] Referring to Figs. 16, 17, and 18, the abrading device 30 further comprises a slap hammer assembly, or slide hammer assembly 40. In one embodiment, the slide hammer assembly 40 comprises a base 51 connected to a shaft 44, and a releasing means that releasably connects a hammer sleeve 31 to the base 51. The released hammer sleeve 31 is configured for sliding engagement along the shaft 44. The releasing means is any means for releasably connecting the hammer sleeve 31 to the base 51, thereby transitioning the slide hammer

assembly between its released position and its locked position. The releasing means could be a mating threaded connection, a quick disconnect attachment, a depressible tab, a latch, a clasp, a clip, a clamp, or other equivalent connection structure.

[0063] In one embodiment, shown in Figs. 16, 17, and 18, the releasing means is a mating threaded connection. This embodiment includes a collar 41 on the abrading device 30, a slide hammer shaft 44, and the hammer sleeve 31. The collar 41 comprises internal threads 42 and external threads 43. The shaft 44 comprises a threaded end 45 and a stop end 46. The hammer sleeve 31 has a threaded connector 48 and a hollow, cylindrical bore comprising an internal diaphragm 47 having a diaphragm opening 49 (see Fig. 18). The diaphragm opening 49 is sized to permit sliding passage of all parts of the shaft 44 except the stop end 46. The stop end 46 is sized too large to fit through the diaphragm opening 49.

[0064] To assemble the slide hammer assembly 40 of this embodiment, the threaded end 45 of the shaft 44 is inserted into the bore of the hammer sleeve 31, through the diaphragm 47 inside the hammer sleeve 31, and the threaded end 45 is threaded into, and mated with, the internal threads 42 of the collar 41. The threaded connector 48 in the hammer sleeve 31 is then mated to the external threads 43 on the collar 41 to promote a secure connection. The stop end 46 is disposed inside the bore of the hammer sleeve 31 on a side of the diaphragm 47 opposite that of the location of the threaded connector 48. In this configuration, shown in Fig. 20, the slide hammer assembly 40 is in its locked position.

[0065] To operate the slide hammer assembly 40, the threaded connector 48 is disengaged from the external threads 43 of the collar 41, placing the slide hammer assembly 40 in its released position, which is shown in Fig. 21. This released position enables the hammer sleeve 31 to slide freely along the shaft 44. The hammer sleeve 31 is pulled until the diaphragm 47

inside the hammer sleeve 31 engages the stop end 46 of the shaft 44, thereby causing an impact that delivers the slide hammer force. Thus, the slide hammer assembly has a released position that enables operation of the slide hammer assembly, and a locked position that prohibits operation of the slide hammer assembly.

[0066] Referring to Figs. 22-26, the implant inserter 60 comprises a handle 61 and an implant insertion end 62. The implant insertion end 62 has a pair of tines 63 for holding the implant 5 during the process of inserting the implant 5 into the SI Joint 3. Each tine 63 is supported by a tine shaft 66, which terminates at a shoulder 67. The tine shafts 66 provide flexibility such that the implant 5 is removably retained between the tines 63 with the shoulder 67 abutting against the implant 5 (see Fig. 24). For example, in one embodiment the width of the implant 5 between the opposing grooves 8 is slightly larger than the space between the respective tines 63 such that when the implant 5 is seated in the implant insertion end 62, the respective tines 63 are pushed slightly apart by the grooves 8. This causes a slight amount of friction between the tines 63 and the grooves 8, thereby releasably retaining the implant 5 in the implant insertion end 62.

[0067] The implant inserter 60 further comprises an inserter keying means 65, which is similar to the keying means 27 of the joint locator 20. The inserter keying means 65 mates with the alignment means 17 in the working channel 10 to resist or to prevent relative rotation between the implant inserter 60 and the working channel 10 about each member's longitudinal axis. In one embodiment, the implant inserter 60 further comprises a channel 64 for receiving the K-wire 4 (see Fig. 23). This channel 64 is a cannula, lumen, or other bore-like feature capable of receiving the K-wire 4 in a pass-through manner. In one embodiment of the implant inserter 60, the handle 61 further comprises an inserter stop 68 for abutting against the channel collar 18 of the working channel 10.

[0068] In one embodiment of a method of installing the implant 5, the procedure for installing the implant 5 in the SI Joint 3 is started by locating an insertion point in the SI Joint 3, which is the location where the implant 5 is to be installed. For example, the free end of the K-wire 4 in inserted into the SI Joint 3 at the insertion point where the implant 5 is to be installed, thereby defining an intended location for the implant void. The implant void is a seat or groove between the sacrum 1 and ilium 2 for seating the implant 5, as described below. The K-wire 4 is preferably inserted from a posterior approach. It is preferable, but not required, that the implant 5 is installed under the portion of the posterior superior iliac spine that overhangs the SI Joint 3. One or more alternate location are also suitable for fusion of the SI Joint 3. A K-wire 4 is inserted into the SI Joint 3 at each location where an implant 5 is to be inserted.

[0069] In one embodiment, referring to Figs. 27-31, the initial incision is made using an incision guide 70 that comprises a channel 71 for removably receiving a K-wire 4. The incision guide 10 further comprises a guide slot 72 for receiving a blade, scalpel, or similar cutting instrument (not shown). The guide slot 72 is disposed at an angle in relation to the channel 71 such that when the scalpel is extended through the guide slot 72, the tip of the scalpel is disposed above the patient's skin at the proper location for making the initial incision into the patient. This location is above the SI Joint 3 where the allograft implant 5 will be introduced into the soft tissue above the SI Joint 3, and eventually into the SI Joint 3 itself. In one embodiment, the guide slot 72 is oriented at an angle A of about 70^{o} to about 75^{o} in relation to horizontal H (see Fig. 30). In this orientation, the channel 71 is perpendicular to horizontal.

[0070] In this embodiment, the K-wire 4 is inserted into the SI Joint 3 as described above. The incision guide 70 is placed over the K-wire 4 such that the K-wire 4 is slidably received into the channel 71. In one embodiment, the scalpel is inserted into the guide slot 72 and retained in

fixed relation to the channel 71 such that the cutting tip of the scalpel is located in close proximity to the K-wire 4. The incision guide 70 is then advanced toward the SI Joint 3, and the cutting tip of the scalpel makes the incision as the incision guide 70 advances. Once the initial incision is adequately formed, the incision guide 70 is lifted to remove it from the K-wire 4, and the surgery proceeds with other instruments for inserting the implant 5 into the SI Joint 3.

[0071] The joint locator 20 is then fully inserted into the working channel 10 (see Fig. 12). In mating the joint locator 20 inside the working channel 10, the keying means 27 of the joint locator 20 is oriented to engage the alignment means 17 of the working channel 10. This engagement enables the first iliac contour 15 of the working channel to be disposed in mating alignment with the second iliac contour 24 of the joint locator 20, and the first sacral contour 16 of the working channel 10 to be disposed in mating alignment with the second sacral contour 25 of the joint locator 20 (see Figs. 8 and 9). The respective first and second iliac contours 15, 24 are configured to be seated in mating placement against the ilium 2 when the insertion end 11 is disposed inside the SI Joint 3, and the respective first and second sacral contours 16, 25 are configured to be seated in corresponding mating placement against the sacrum 1 when the insertion end 11 is disposed inside the SI Joint 3. The stop 28 abuts against the channel collar 18 of the working channel 10 to prevent over penetration of the penetration tip 23 into the SI Joint 3, thereby avoiding damage to the soft tissue and nerves on the anterior side of the SI Joint 3.

[0072] The free end of the K-wire is inserted into the K-wire channel 26 of the combined joint locator 20 / working channel 10, and this combined device is advanced toward the SI Joint 3, guided by the K-wire 4. As the joint locator 20 / working channel 10 combination is advanced, the penetration tip 23 cuts or tears though the soft tissue above and inside the SI Joint 3. If necessary, the combined joint locator 20 / working channel 10 is advanced via blows from a

mallet against the proximal end of the handle 22 to deliver an appropriate axial force. The impact from the mallet causes an axial force that is transmitted though the handle 22 to the stop 28, where the axial force is imparted to the channel collar 18 and into the working channel 10. As such, the impact force from a mallet is shared between the working channel insertion end 11 and the joint locator insertion end 21.

[0073] The combined joint locator 20 / working channel 10 is advanced until the respective first and second iliac contours 15, 24 abut the ilium 2 and the respective first and second sacral contours 16, 25 abut the sacrum 1. In this position, the arms 14 of the working channel 10 are disposed inside the SI Joint 3 to retain the proper alignment of the working channel 10, and therefore the alignment means 17, thereby ensuring a proper alignment of the abrading device 30 and the implant inserter 60 later in the procedure. In some embodiments, insertion of the arms 14 into the SI joint 3 will distract the joint, thus separating the sacrum 1 and the ilium 2. This distraction establishes a uniform width of the spacing in the SI joint 3 prior to use of the other instrumentation. Thus, the instrumentation described herein will work with a patient of any size because the arms 14 set the width of the SI joint 3 to a uniform distance regardless of the size or scale of the sacrum 1 or ilium 2.

[0074] In an alternate embodiment of the installation method, a K-wire 4 is omitted from the procedure. Instead, the combined joint locator 20 / working channel 10 is advanced through an incision in the patient, and this advancement continues as described above until the insertion ends 11, 21 are inserted into the SI Joint 3 as described above.

[0075] Once the combined joint locator 20 / working channel 10 device is properly seated in the SI Joint 3, the joint locator 20 is removed from the working channel 10. The surrounding soft tissue remains distracted or dilated by the working channel 10 and the respective arms 14,

thereby enabling direct access to the SI Joint 3 area. The abrading device 30 is then inserted into the working channel 10, with the keying means 37 engaging the alignment means 17 to promote proper alignment of the abrading head 32 with respect to the SI Joint 3. The abrading head 32 is advanced through the working channel 10 until the abrading head 32 makes contact with the SI Joint 3. The abrading head 32 is forced into the SI Joint 3 (using a mallet if necessary), and the cutting edge 36 cuts the bone tissue and any soft tissue, such as ligaments or cartilage. The abrading stop 38 abuts against the channel collar 18 of the working channel 10 to prevent over penetration of the abrading head 32 into the SI Joint 3, thereby avoiding damage to the soft tissue and nerves on the anterior side of the SI Joint 3. During this process, the cutting edge 36 cuts through the relevant bone portions of the sacrum 1 and ilium 2, and the abrading surfaces 33 work simultaneously in connection with the cutting edge 36 to decorticate the cortical bone inside the SI Joint 3, thereby forming a decorticated implant void at the insertion point of the SI Joint 3. The decorticated implant void has a generally rectangular cross sectional shape such that the decorticated implant void is adapted for receiving the fusion implant 5, which has a generally rectangular cross sectional shape for mating with the decorticated implant void. Thus, use of the abrading head 32 enables installation of the implant 5 without the need for using a drill or other rotary cutting instrument to form a pilot hole for the implant 5. As used herein, a rotary cutting instrument is any device capable of cutting material by turning, rotating, or other angular motion about an axis of the device, whether power-driven or hand-driven. This is a significant improvement of the present set of instruments over prior art methods and instrument sets for SI Joint 3 fusion.

[0076] The abrading device 30 is then worked in and out of the working channel 10 such that the abrading surfaces 33 abrade, or decorticate, the respective surfaces of the sacrum 1 and the

ilium 2 inside the SI Joint 3. Again, the abrading stop 38 abuts against the channel collar 18 to prevent over penetration of the abrading head 32. During this process, the abrading head 32 may become lodged in the SI Joint 3, becoming difficult to remove. In these instances, the slide hammer assembly 40 is enabled so that the abrading head 32 may be removed by the impact force of the slide hammer assembly 40, as described above. Operation of the slide hammer assembly 40 provides a significant advantage over prior systems because when the abrading head 32 becomes lodged in the SI joint 3, counter pressure cannot be applied to the patient to counter the pull-out force needed to dislodge the abrading head 32 from the SI joint 3. The slide hammer assembly 40 enables removal of a lodged abrading head 32 in a safe manner without applying any counter pressure to the patient.

[0077] As the abrading head 32 is worked in and out of the SI Joint 3, the abrading surfaces 33 abrade the cortical bone of the sacrum 1 and the ilium 2 inside the SI Joint 3. The cortical bone is abraded until bleeding begins, thereby promoting the patient's healing process of the cortical bone. This degree of abrasion and corresponding healing promotes fusion of the SI Joint 3.

[0078] Once the SI Joint 3 is adequately abraded, the abrading device 30 is removed from the working channel 10. Thus, this method of fusing the SI Joint 3 comprises steps for forming a void for a fusion implant 5 in the SI Joint 3 without using a rotary cutting instrument. At this point in the procedure, the K-wire 4 may be removed from the working channel 10 to enable proper advancement of the implant 5 through the working channel 10 and proper installation of the implant 5 into the SI Joint 5. Alternately, the K-wire 4 can be removed from the working channel 10 at any time after the working channel 10 is properly seated in the SI Joint 3, as described above.

[0079] The allograft implant 5 is placed into the tines 63 of the implant inserter 60 such that each tine 63 is seated into a mating groove 8 on the lateral side 7 of the implant 5, and the shoulder 67 abuts the implant 5 (see Fig. 24). The implant inserter 60 is then inserted into the working channel 10 such that the keying means 65 engages the alignment means 17 to ensure proper orientation of the implant inserter 60, and thus, the implant 5. The implant inserter 60 is used to deliver the implant 5 to the abraded area of the SI Joint 3 through the working channel 10. If necessary, the implant inserter 60 is struck by a mallet to force the implant 5 into the abraded area of the SI Joint 3, the shoulder 67 transferring the impact force to the implant 5. In these instances, the inserter stop 68 abuts against the channel collar 18 of the working channel 10 to prevent over penetration of the implant 5 into the SI Joint 3, thereby ensuring that the implant 5 is properly placed inside the SI Joint 3.

[0080] Once the implant 5 is fully inserted into the SI Joint 3, the implant inserter 60 is removed from the working channel 10, leaving the implant 5 installed in the abraded area of the SI Joint 3. In most instances, the friction force between the implant 5 and the inside of the SI Joint 3 is greater than the friction force between the respective tines 63 and grooves 8. In these instances, removal of the implant inserter 60 is accomplished by applying a removal force to the implant inserter 60 greater than the friction force between the tines 63 and the grooves 8. The tines 63 slice out of the grooves 8 as the implant inserter 60 is retracted from the working channel 10. In other instances, the friction force between the implant 5 and the inside of the SI Joint 3 is less than the friction force between the respective tines 63 and grooves 8. In these instances, removal of the implant inserter 60 is accomplished by inserting a K-wire 4 or similar device into the K-wire channel 64 and advancing the K-wire 4 until the distal end of the K-wire abuts against the implant 5 between the tines 63. The K-wire 4 is used to hold the implant 5 in

place inside the SI Joint 3 as the removal force is applied to the implant inserter 60. The tines 63 are thereby removed from the grooves 8 as the K-wire 4 holds the implant 5 in its installed location. Once the tines 63 are pulled free from the grooves 8, the implant inserter 60 is disengaged from the implant 5, and the implant inserter 60 and the K-wire 4 are removed from the working channel 10. The working channel 10 is then removed from the surgical site, causing the SI Joint 3 to contract, thereby exerting a compressive force on the implant 5. This compressive force is caused by the ligaments of the SI Joint 3 that compress the joint, thereby holding it together. The surgical site is then sterilized and closed for healing.

[0081] As the abraded cortical bone heals, the bone fuses with the allograft implant 5, eventually causing the sacrum 1 and the ilium 2 to grow together at the location of the implant 5, thereby fusing the SI Joint 3.

[0082] In any of the foregoing embodiments, one or more instruments may comprise disposable material, such as medical grade plastics, certain metals, or other disposable material.

[0083] Referring to Figs. 32-36, the implant 5 generally has two opposing faces 81. When the implant 5 is inserted into the SI Joint 3, one opposing face 81 is disposed against the sacrum 2, and the other opposing face 81 is disposed against the ilium 3. Each of the opposing faces 81 comprises one or more anti-migration features 82, such as teeth or ridges, that resist movement of the implant inside the SI Joint 3.

[0084] In one embodiment, the implant 5 comprises a body 83 having a proximal end 86, a distal end 87, and a length disposed therebetween, the distal end having a rounded nose 6. The body 83 further comprises two sides 7, each side 7 comprising a groove 8 beginning at the proximal end 86 of the body 83 and continuing along each of the two sides 7 for at least part of the length, the distance between the two sides 7 defining a width W of the body.

[0085] The implant 5 further comprises a central graft window 85 that enables fusion of the SI Joint 3 to occur through the implant 5. The graft window 85 is disposed between each of the opposing faces 81, the graft window 85 providing passage through the body 83 between the two opposing faces 81. The portion of the body 83 located between the graft window 85 and each of the sides 7 defines a wall 84.

[0086] When viewed in cross section (see Fig. 33), the area of the graft window 85 is about 35% to about 40% of a first cross-sectional area of the body, which is the area of the total implant 5 as shown by the hatched area in Fig. 33. The area of the window 85 is about 60% of the total area of each opposing face 81 that makes contact with the bone, whether the sacrum 1 or the ilium 2. These ratios provide a strength-to-contact area relationship that optimizes performance of the implant 5 as a promoter of SI Joint 3 fusion. In these ratios, the implant 5 provides enough strength so that it is not crushed inside the SI Joint 3, and it provides a large enough graft window 85 to expedite fusion of the SI Joint 3 across and through the implant 5.

[0087] In one embodiment, the graft window 85 has a proximal portion 88 located in proximity to the grooves 8, and a distal portion 89, the proximal portion 88 having a width W1 that is less than a width W2 of the distal portion 89 such that the wall 84 maintains a minimum thickness in a range of about 17% to about 20% of the width W of the body 83.

[0088] In the foregoing embodiments, it is preferable, but not required, that the graft window 85 is unobstructed by internal or intermediate supports. Such internal or intermediate supports are sometimes used in allograft implants to provide structural support to the implant. However, these internal or intermediate supports obstruct bone fusion from occurring through the window. As such, the graft window 85 may provide an open passage through the body 83 between the opposing faces 81. The open passage may be rectilinear or curvilinear. The proximal end 86 of

the body 83 may further comprise a taper 90 that reduces a second cross-sectional area of the body 83.

[0089] The foregoing embodiments are merely representative of the SI Joint fusion method and not meant for limitation of the invention. For example, persons skilled in the art would readily appreciate that there are several embodiments and configurations of abrading devices, slide hammer devices, and other devices and instruments described herein that will not substantially alter the nature of the SI Joint fusion method. Some steps of the method can be performed in a sequence other than that described above. Consequently, it is understood that equivalents and substitutions for certain elements and components set forth above are part of the invention described herein, and the true scope of the invention is set forth in the claims below.

CLAIMS

What is claimed is:

1. A method of forming an implant void in a sacroiliac joint without the use of a rotary cutting instrument, the method comprising the steps of:

locating an insertion point in the sacroiliac joint, the insertion point defining an intended location for the implant void;

introducing a working channel into the insertion point, the working channel having an insertion end and a working end connected by a working channel, the insertion end of the working channel further comprising a first iliac contour, a first sacral contour, and insertion arms;

inserting the insertion arms into the sacroiliac joint at the insertion point such that the first sacral contour seated against a sacrum bone and the first iliac contour seated against the ilium;

introducing an abrading device into the working channel, the abrading device comprising:

an abrading head at a distal end of the abrading device, the abrading head having:

abrading surfaces on each of a first pair of opposing sides, the abrading surfaces comprising one or more teeth, barbs, blades, ridges, slots, broaches, or other members capable of abrading a cortical bone of the sacroiliac joint; and

an open tip comprising a cutting edge disposed at a leading edge of the open tip, the cutting edge configured to cut bone tissue in the sacroiliac joint; and

a slide hammer assembly at a proximal end of the abrading device, the slide hammer assembly having a released position that enables operation of the slide hammer assembly, a locked position that prohibits operation of the slide hammer assembly, and a releasing means for transitioning the slide hammer assembly between the locked position and the released position; and

advancing the abrading device into the sacroiliac joint such that the open tip cuts bone tissue away from the sacrum or the ilium and the abrading surfaces decorticate the cortical bone inside the sacroiliac joint, thereby forming a decorticated implant void at the insertion point without using a rotary cutting instrument.

2. The method of claim 1, wherein, upon the abrading head becoming lodged inside the sacroiliac joint, unlocking the slide hammer assembly via the releasing means, and using the slide hammer assembly to dislodge the abrading head from the sacroiliac joint.

3. The method of claim 1, wherein introducing the working channel into the insertion point further comprises:

introducing a joint locator into the working channel, the joint locator having a penetration tip at an insertion end, the penetration tip comprising a second iliac contour and a second sacral contour; and

placing the first and second iliac contours and the first and second sacral contours in mating alignment by fully inserting the joint locator into the working channel, thereby defining a combined joint locator and working channel device.

4. The method of claim 3, wherein inserting the insertion arms into the sacroiliac joint further comprises inserting the combined joint locator and working channel device into the sacroiliac joint at the insertion point such that the first and second sacral contours are seated against the sacrum bone and the first and second iliac contours are seated against the ilium.

5. The method of claim 4, further comprising tearing through soft tissue above and inside the sacroiliac joint via the penetration tip until the first and second iliac contours abut the ilium and the first and second sacral contours abut the sacrum.

6. The method of claim 2, wherein introducing the working channel into the insertion point further comprises:

introducing a joint locator into the working channel, the joint locator having a penetration tip at an insertion end, the penetration tip comprising a second iliac contour and a second sacral contour; and

placing the first and second iliac contours and the first and second sacral contours in mating alignment by fully inserting the joint locator into the working channel, thereby defining a combined joint locator and working channel device.

7. The method of claim 6, wherein inserting the insertion arms into the sacroiliac joint further comprises inserting the combined joint locator and working channel device into the sacroiliac joint at the insertion point such that the first and second sacral contours are seated against the sacrum bone and the first and second iliac contours are seated against the ilium.

8. The method of claim 7, further comprising tearing through soft tissue above and inside the sacroiliac joint via the penetration tip until the first and second iliac contours abut the ilium and the first and second sacral contours abut the sacrum.

9. The method of claim 1, wherein forming the decorticated implant void at the insertion point further comprises forming a generally rectangular cross sectional shape for the decorticated implant void such that the decorticated implant void is adapted for receiving a fusion implant having a generally rectangular cross sectional shape.

10. The method of claim 9, wherein, upon the abrading head becoming lodged inside the sacroiliac joint, unlocking the slide hammer assembly via the releasing means, and using the slide hammer assembly to dislodge the abrading head from the sacroiliac joint.

11. The method of claim 9, wherein introducing the working channel into the insertion point further comprises:

introducing a joint locator into the working channel, the joint locator having a penetration tip at an insertion end, the penetration tip comprising a second iliac contour and a second sacral contour; and

placing the first and second iliac contours and the first and second sacral contours in mating alignment by fully inserting the joint locator into the working channel, thereby defining a combined joint locator and working channel device.

12. The method of claim 11, wherein inserting the insertion arms into the sacroiliac joint further comprises inserting the combined joint locator and working channel device into the sacroiliac joint at the insertion point such that the first and second sacral contours are seated against the sacrum bone and the first and second iliac contours are seated against the ilium.

13. The method of claim 12, further comprising tearing through soft tissue above and inside the sacroiliac joint via the penetration tip until the first and second iliac contours abut the ilium and the first and second sacral contours abut the sacrum.

14. The method of claim 10, wherein introducing the working channel into the insertion point further comprises:

introducing a joint locator into the working channel, the joint locator having a penetration tip at an insertion end, the penetration tip comprising a second iliac contour and a second sacral contour; and

placing the first and second iliac contours and the first and second sacral contours in mating alignment by fully inserting the joint locator into the working channel, thereby defining a combined joint locator and working channel device.

15. The method of claim 14, wherein inserting the insertion arms into the sacroiliac joint further comprises inserting the combined joint locator and working channel device into the sacroiliac joint at the insertion point such that the first and second sacral contours are seated against the sacrum bone and the first and second iliac contours are seated against the ilium.

16. The method of claim 15, further comprising tearing through soft tissue above and inside the sacroiliac joint via the penetration tip until the first and second iliac contours abut the ilium and the first and second sacral contours abut the sacrum.

ABSTRACT

An method for installing a fusion implant into a sacroiliac joint ("SI Joint") without the use of a rotary cutting instrument. The method incorporates a multimodal abrading device having abrading surfaces on opposing sides and an open tip comprising a cutting edge. The method includes the step of using the abrading head to cut bone tissue from the SI Joint at an insertion point while simultaneously using the abrading surfaces to decorticate the cortical bone at the insertion point.

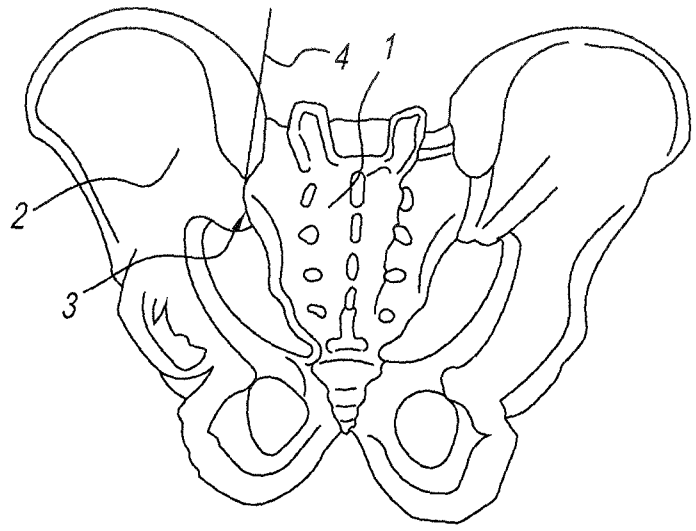


FIG. 1

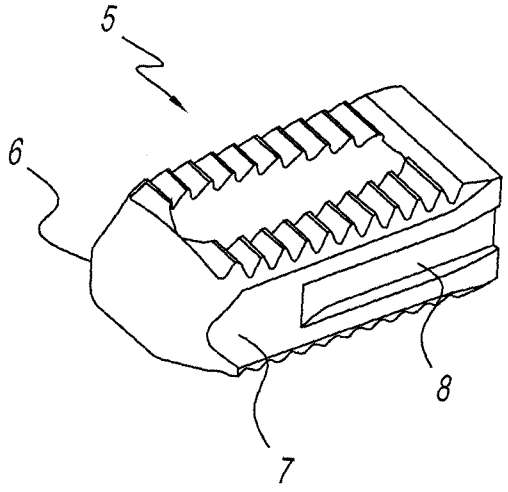


FIG. 2

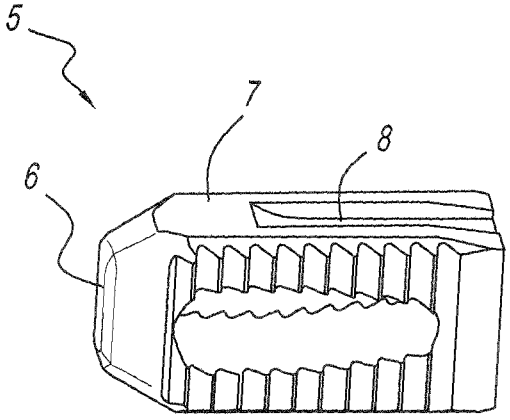


FIG. 3

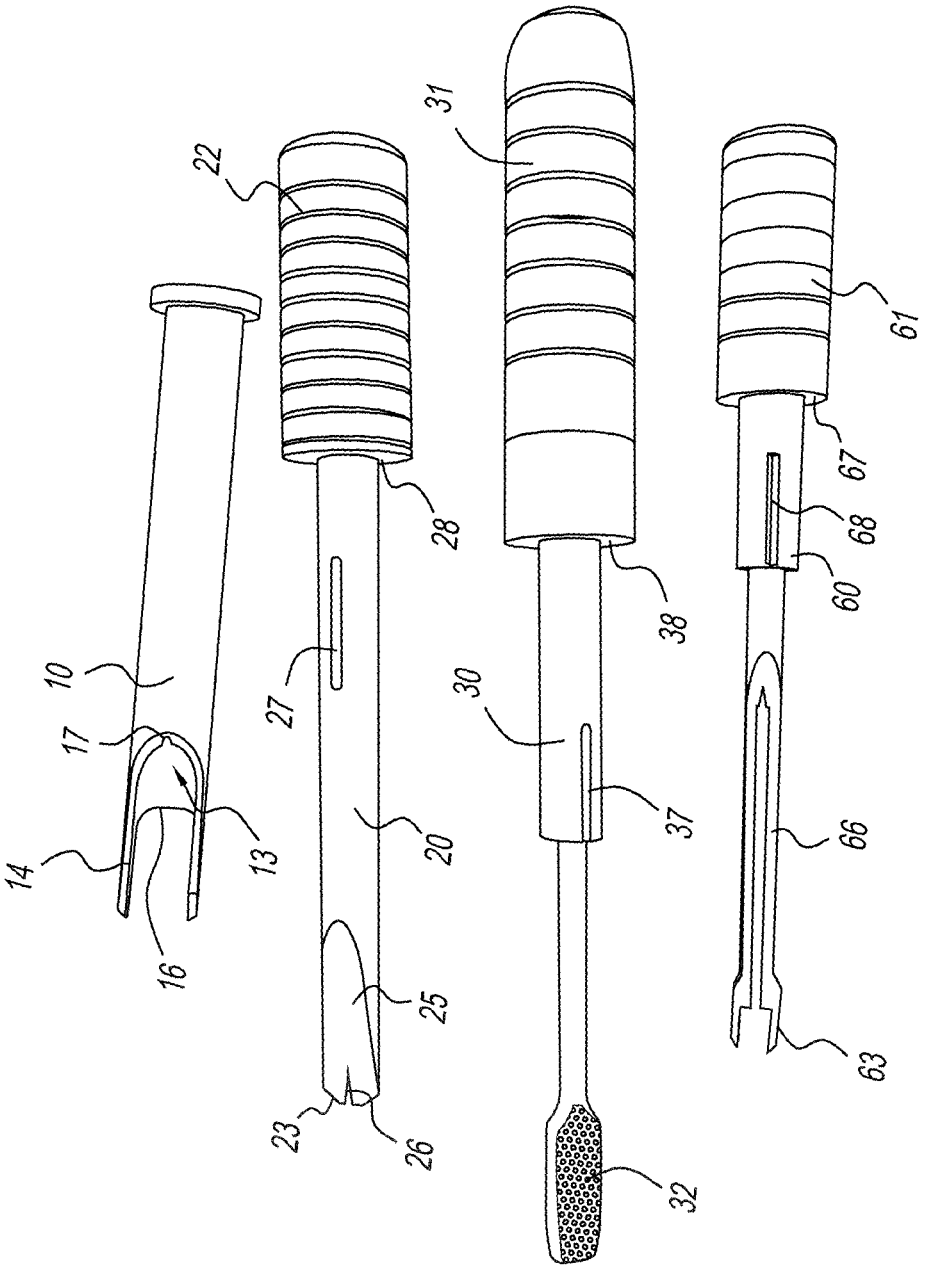


FIG. 4

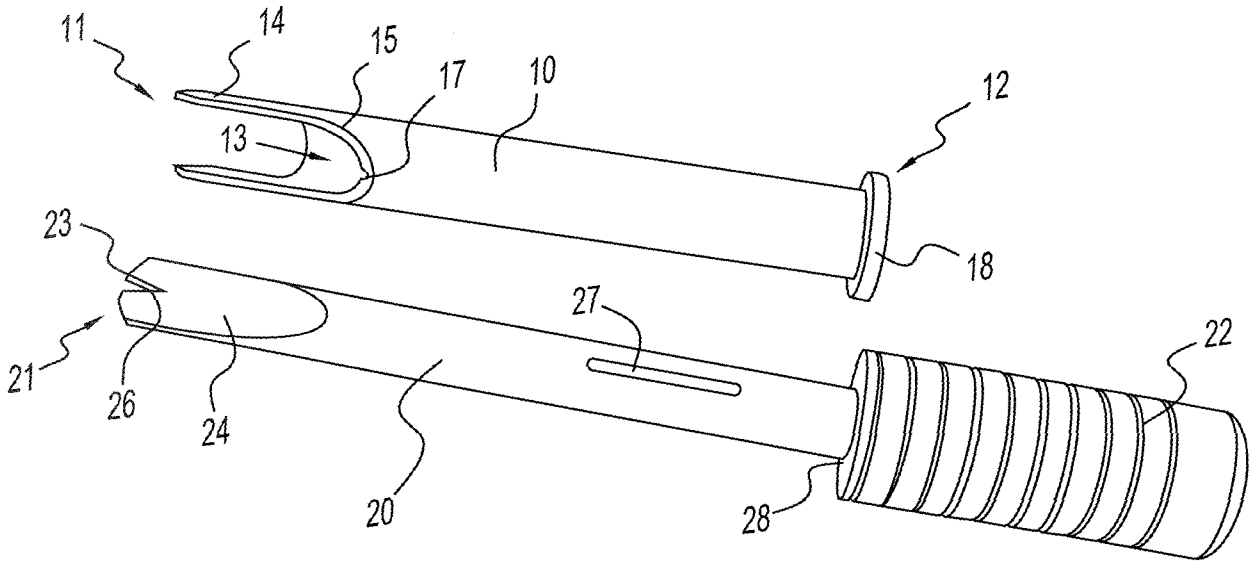


FIG. 5

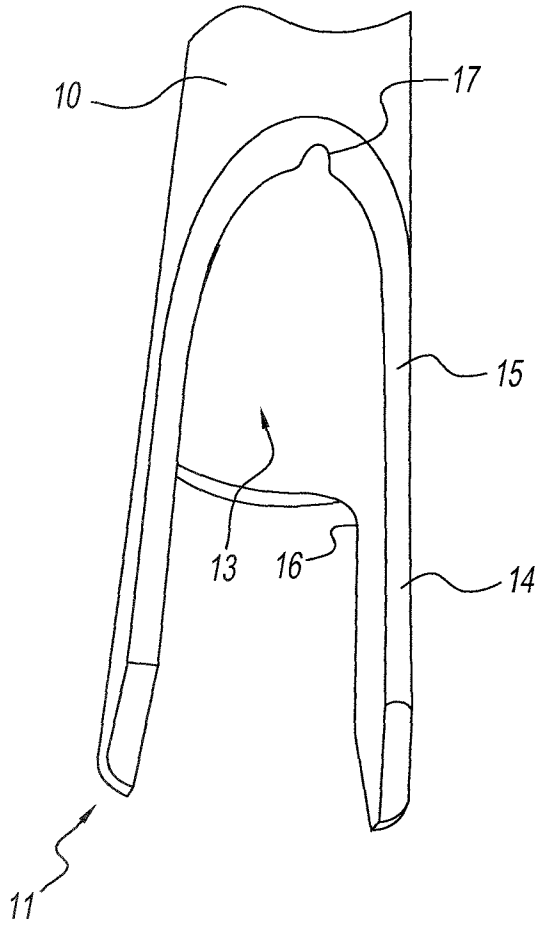


FIG. 6

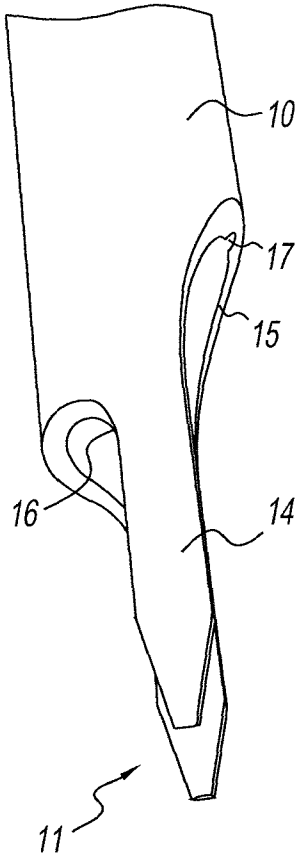


FIG. 7

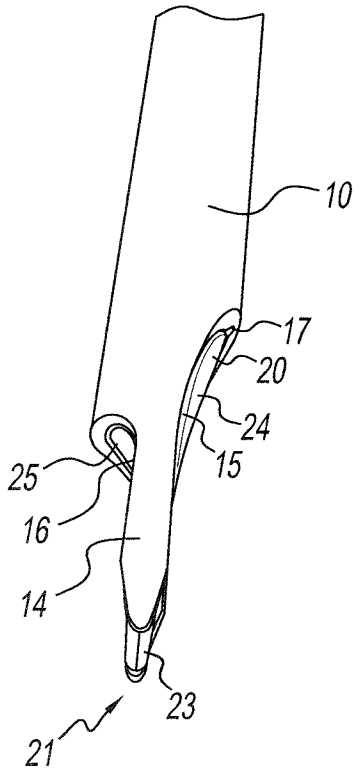


FIG. 8

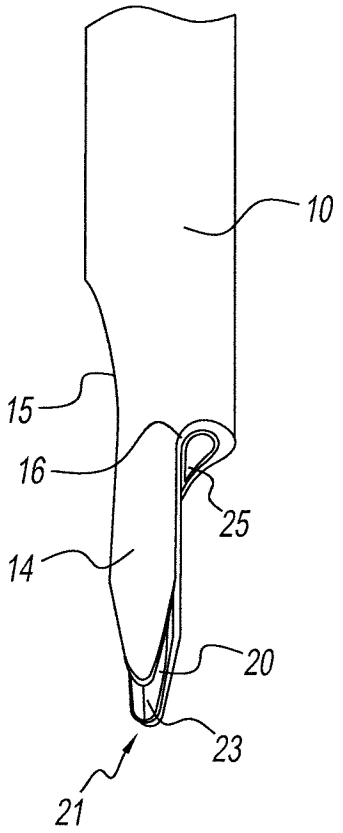


FIG. 9

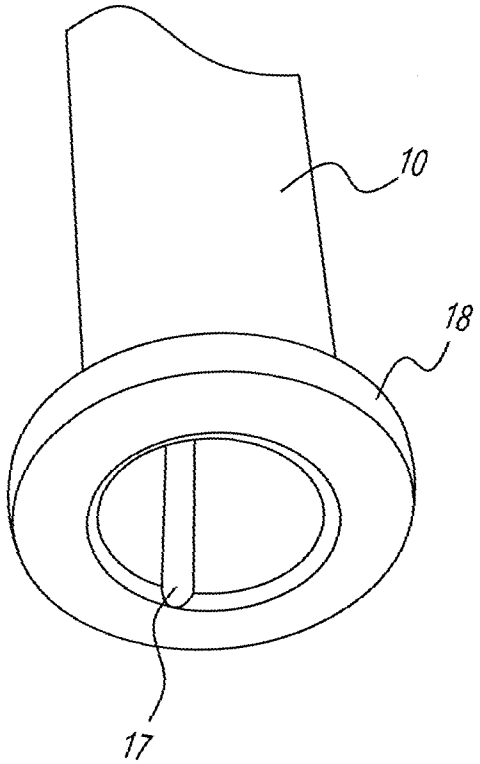


FIG. 10

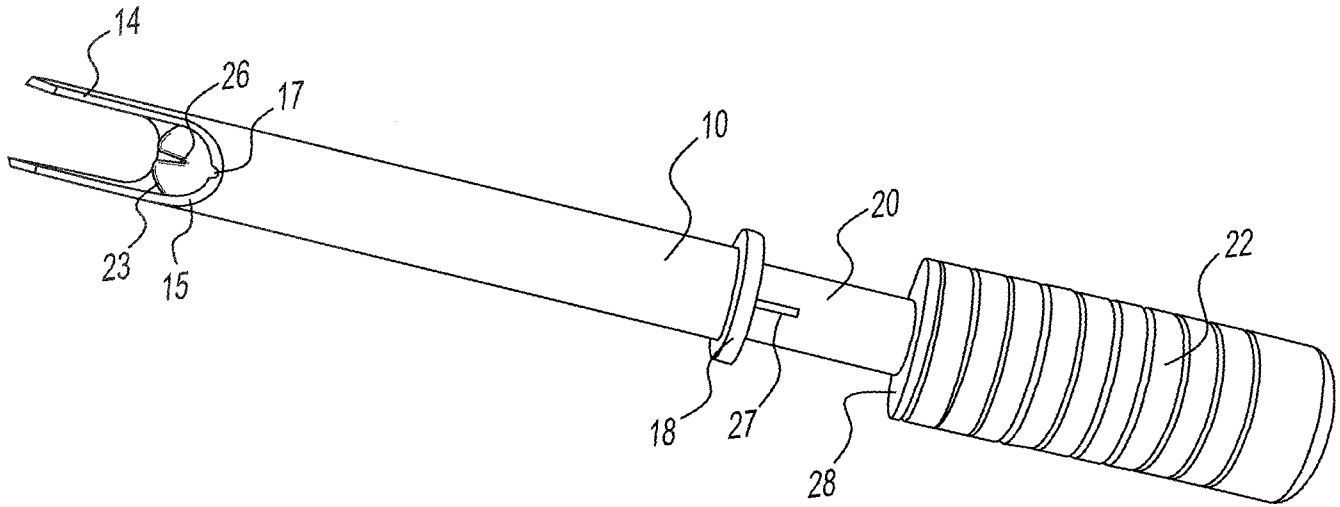


FIG. 11

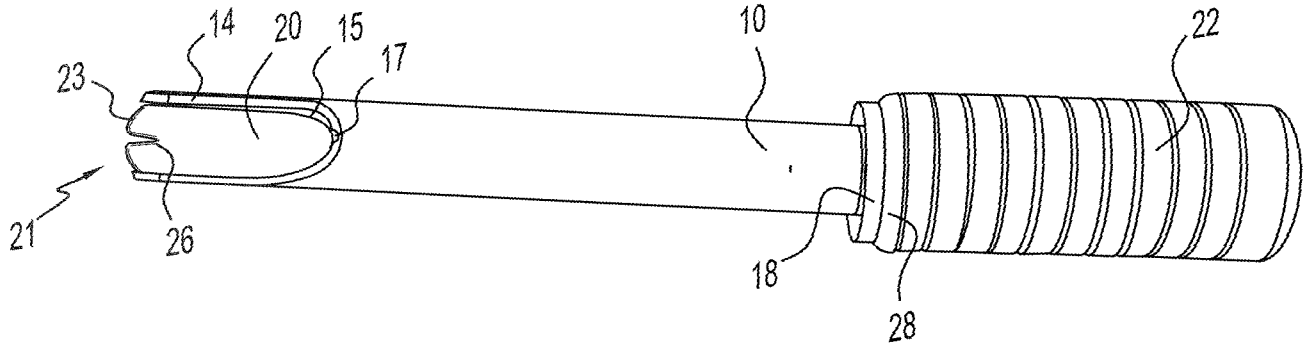


FIG. 12

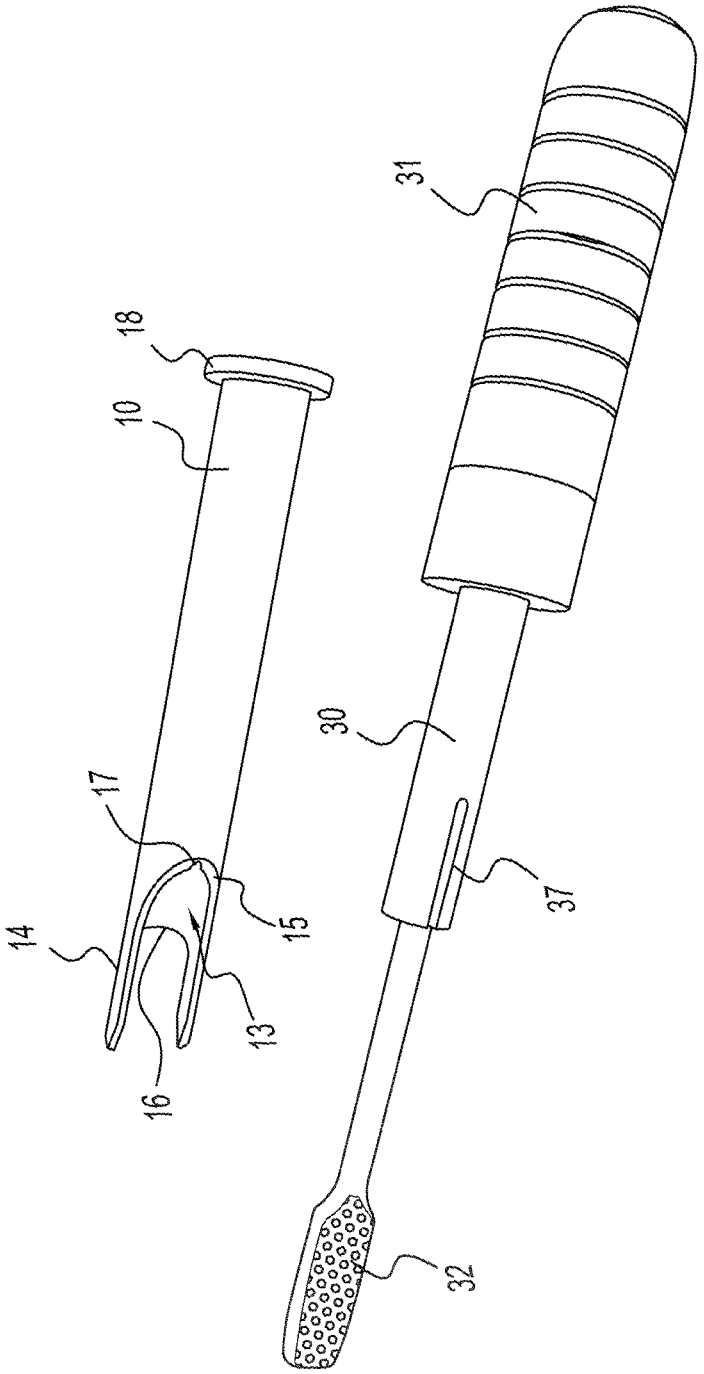


FIG. 13

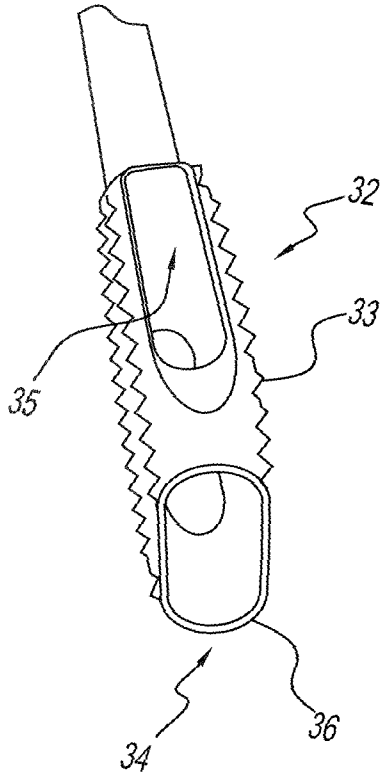


FIG. 14

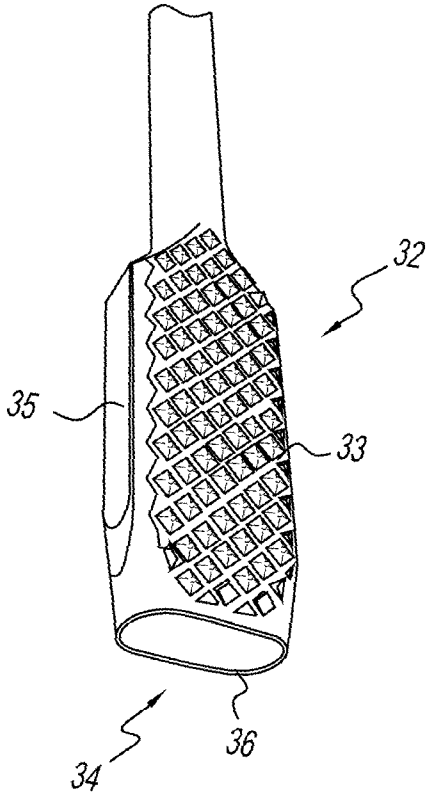


FIG. 15

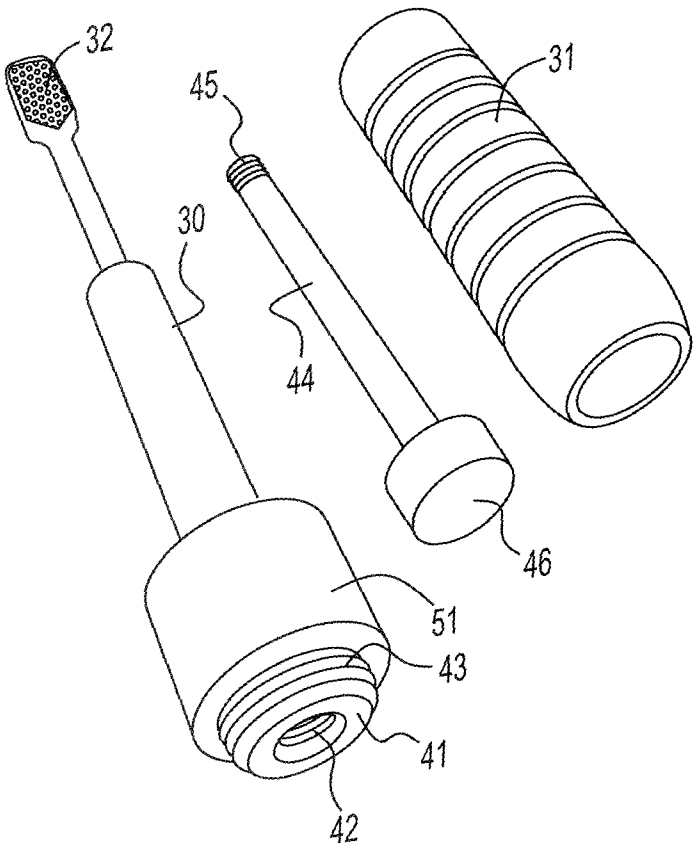


FIG. 16

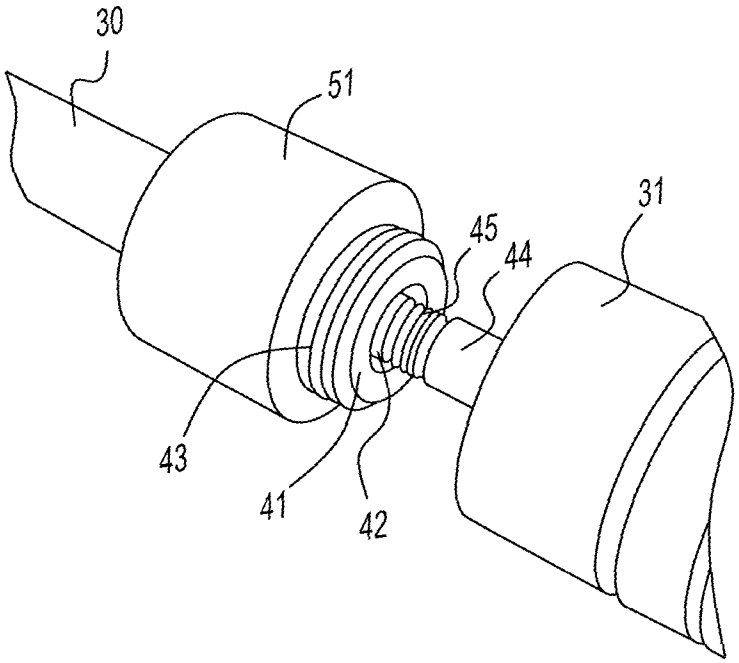


FIG. 17

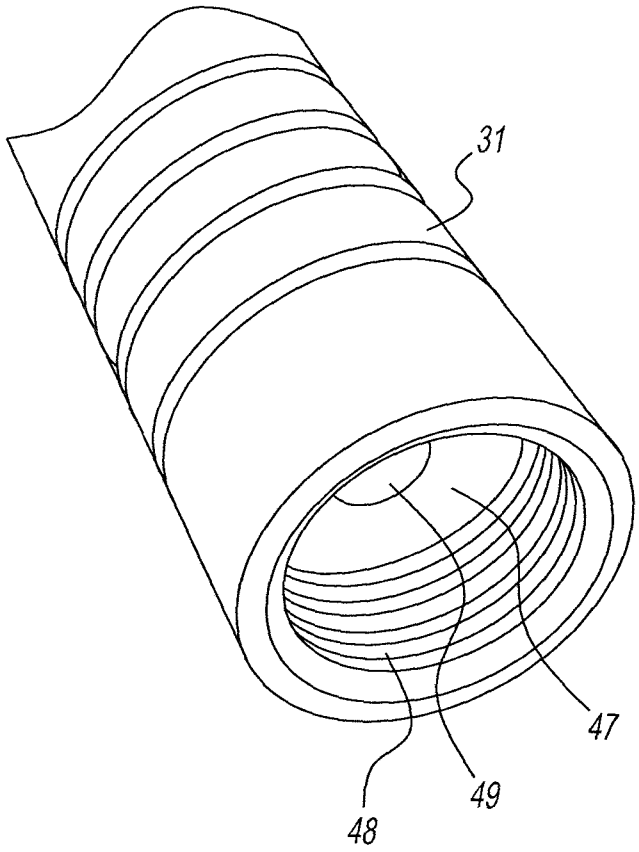


FIG. 18

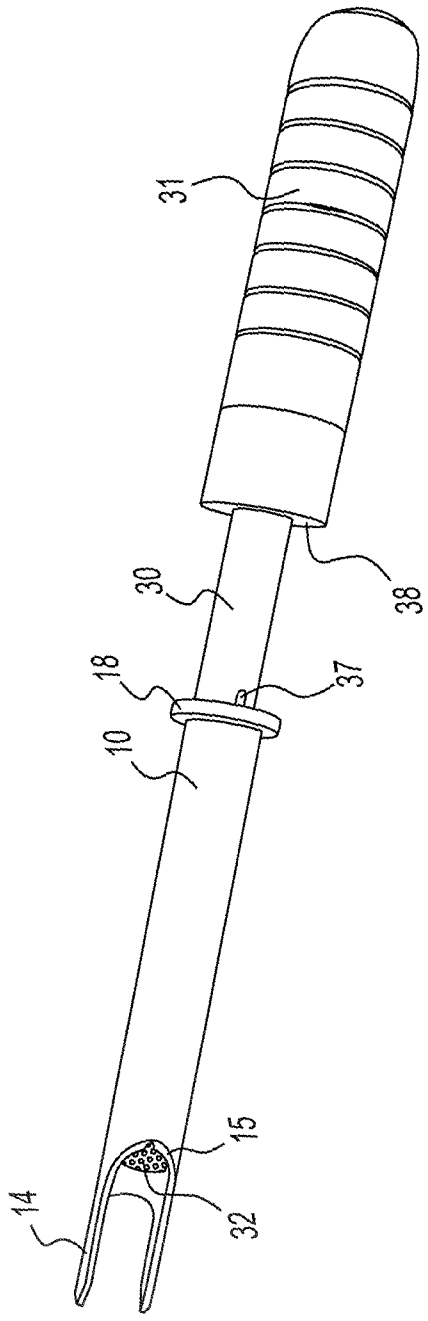


FIG. 19

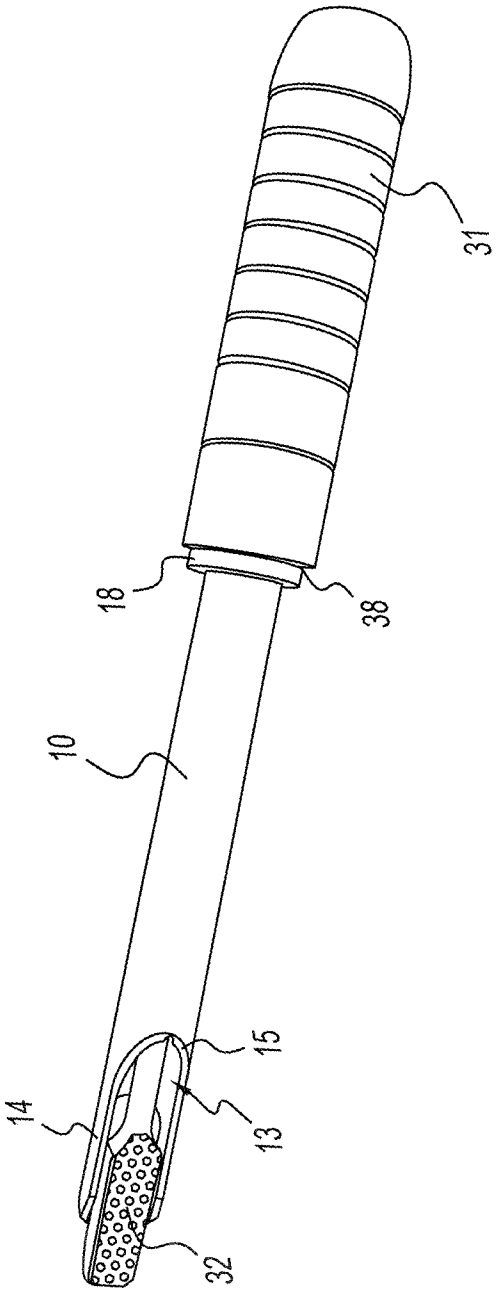


FIG. 20

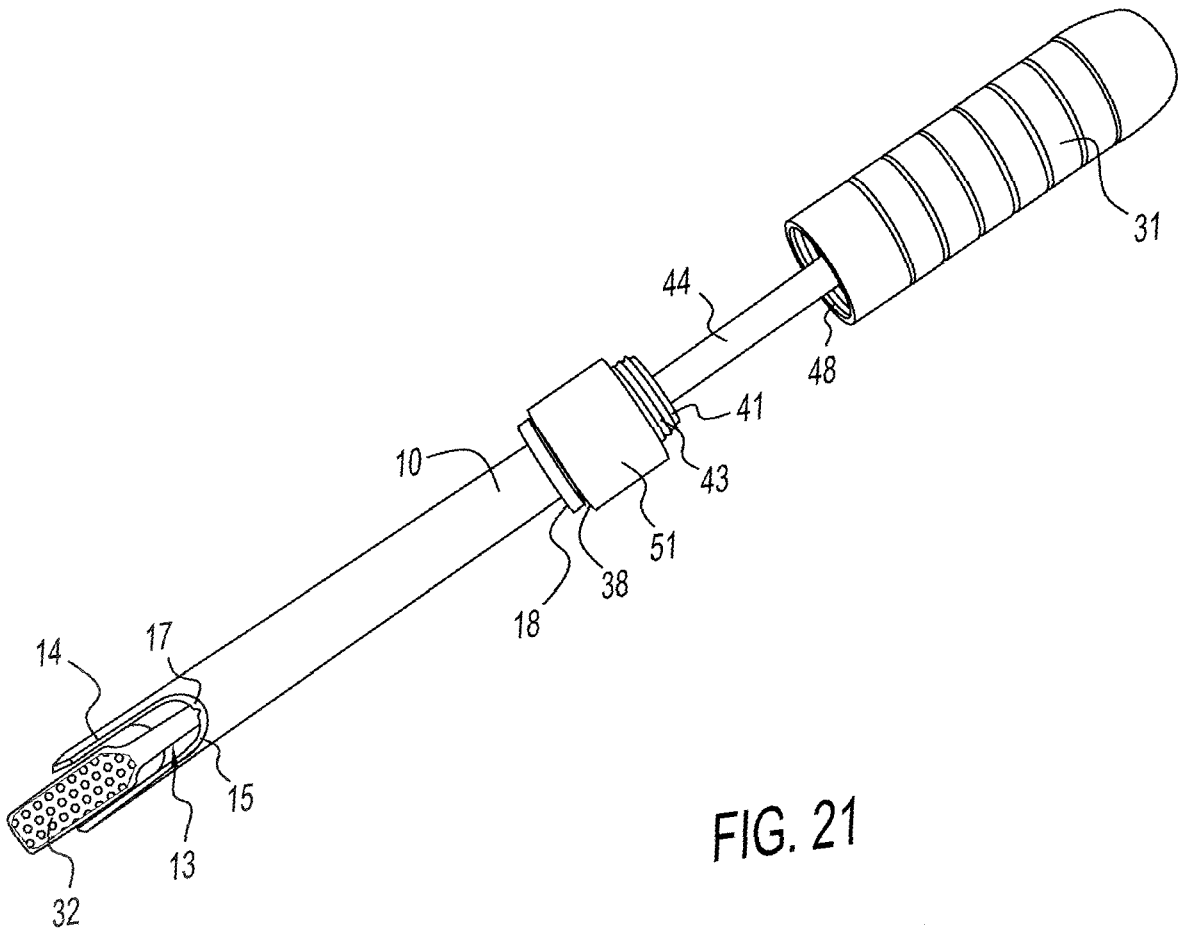


FIG. 21

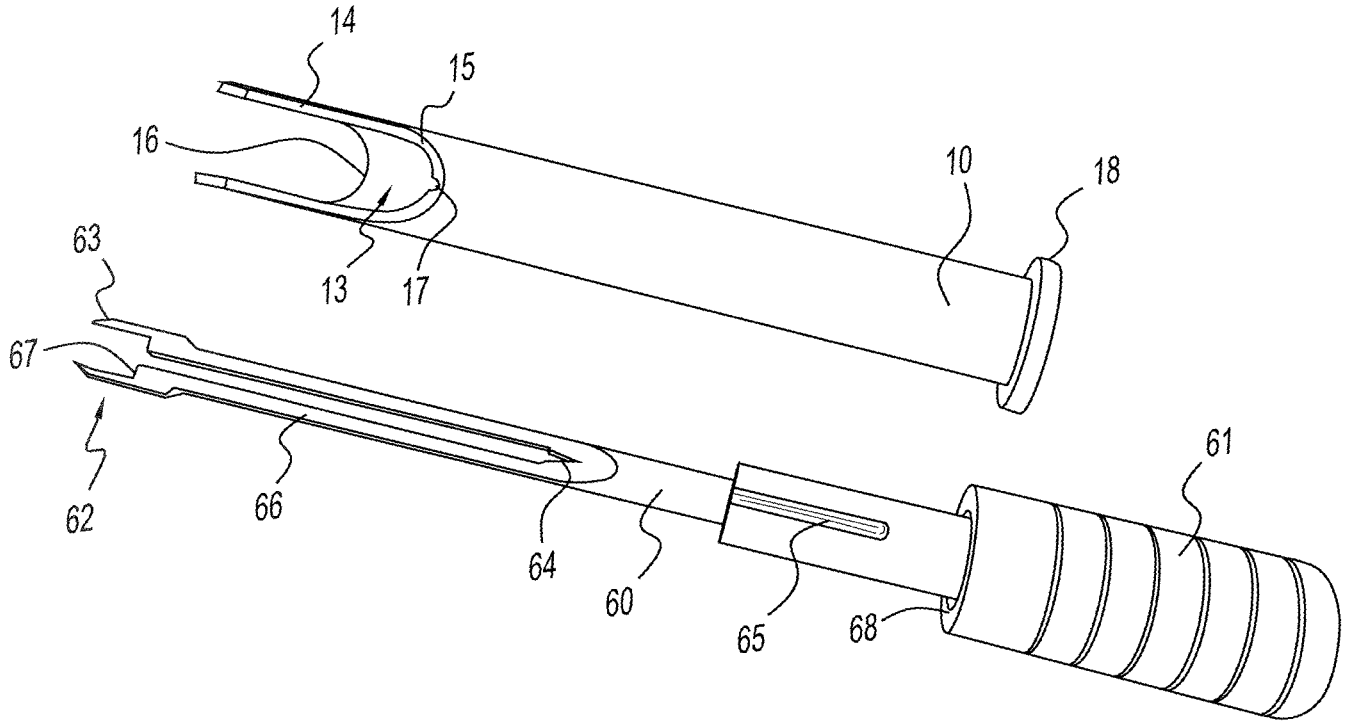


FIG. 22

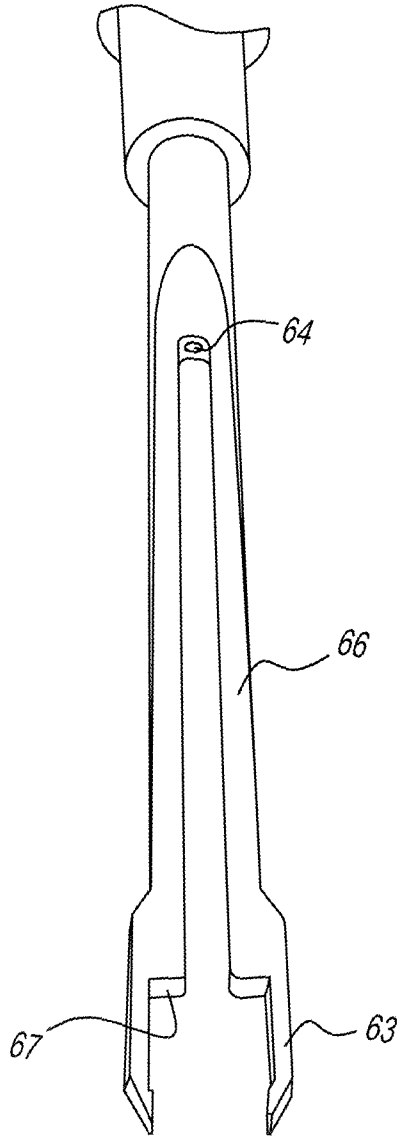


FIG. 23

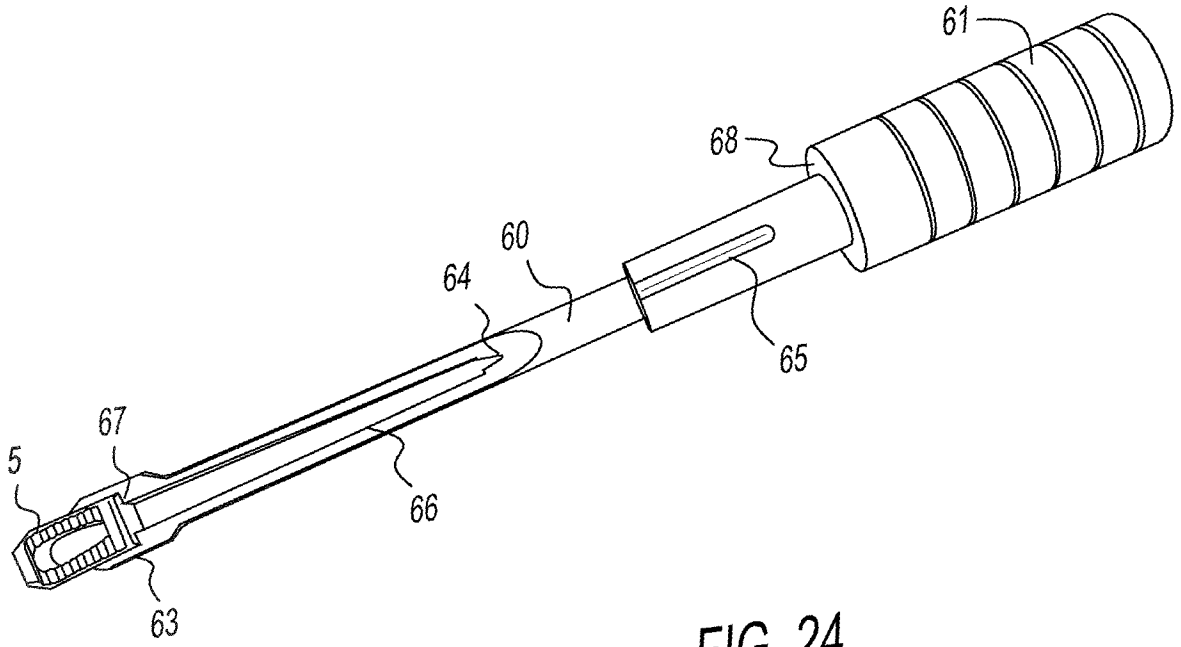


FIG. 24

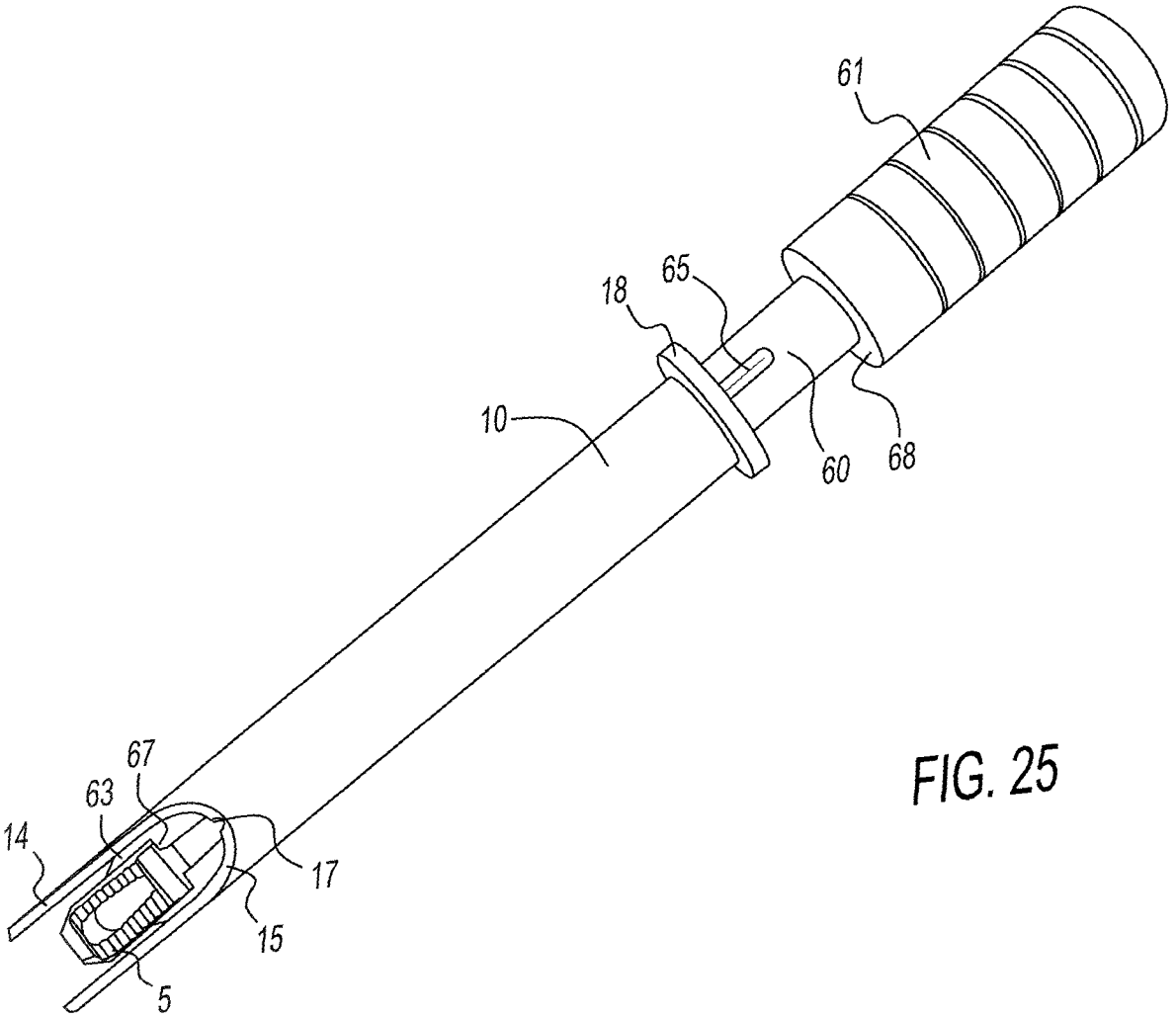


FIG. 25

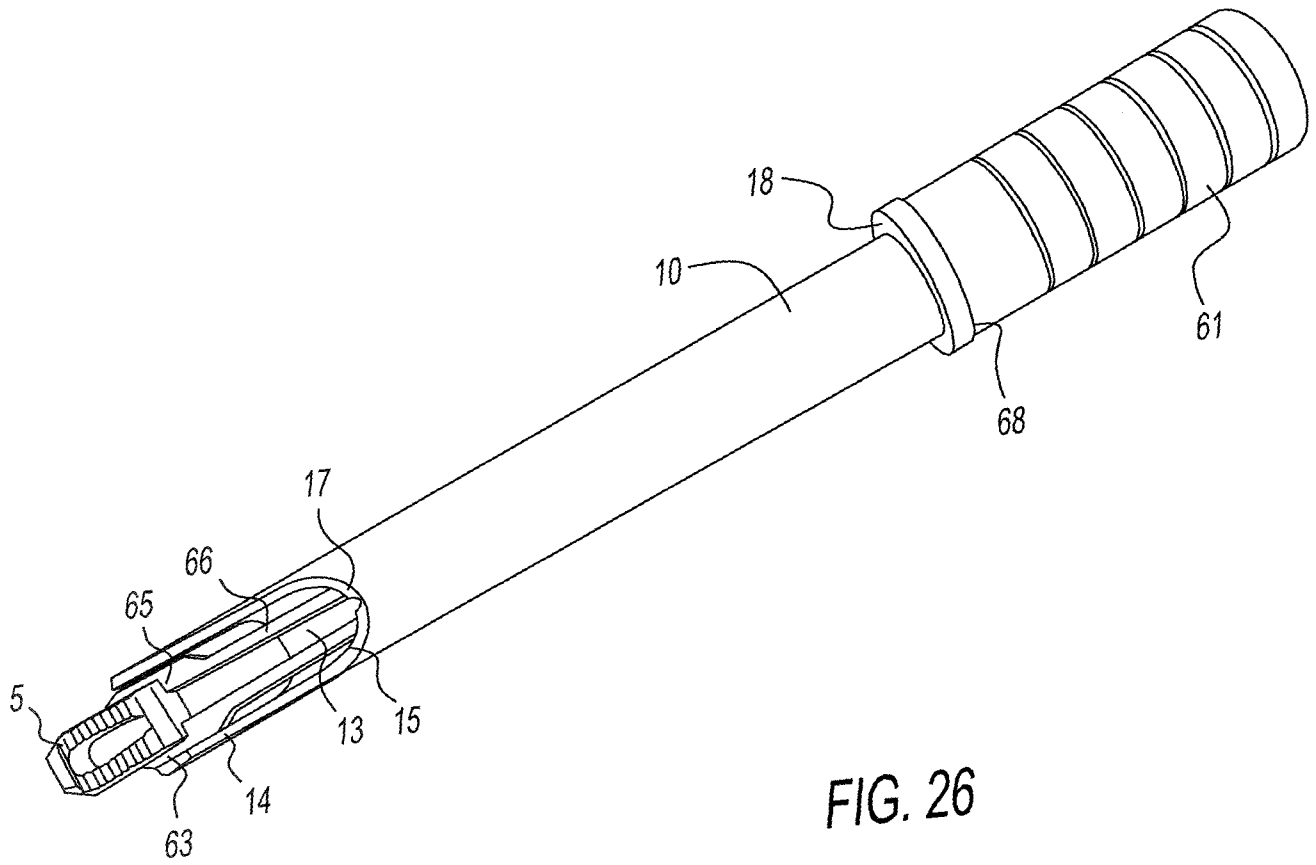


FIG. 26

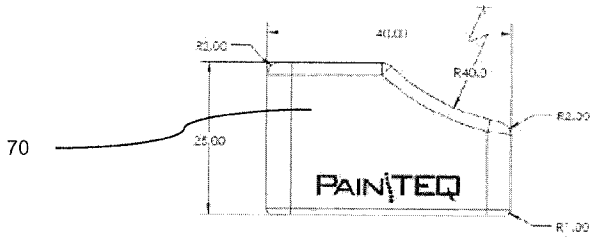


FIG. 27

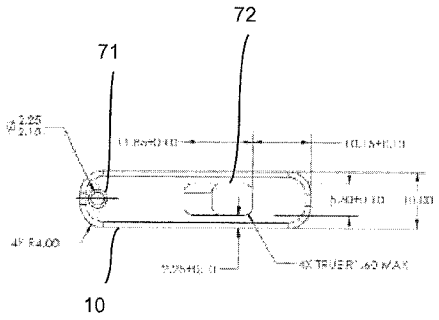


FIG. 28

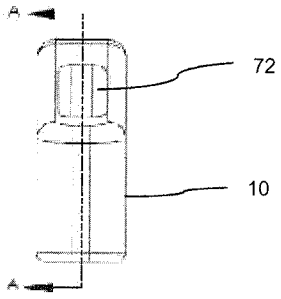


FIG. 29

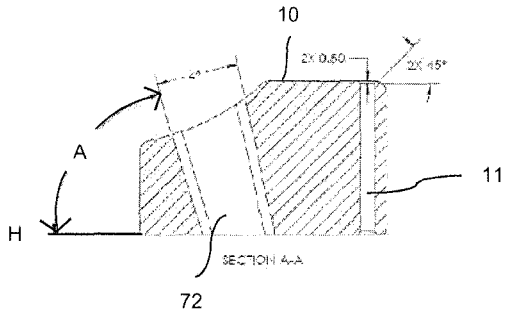


FIG. 30

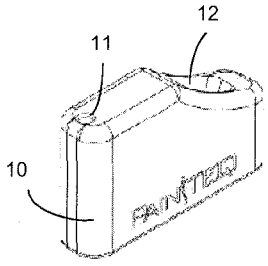


FIG. 31

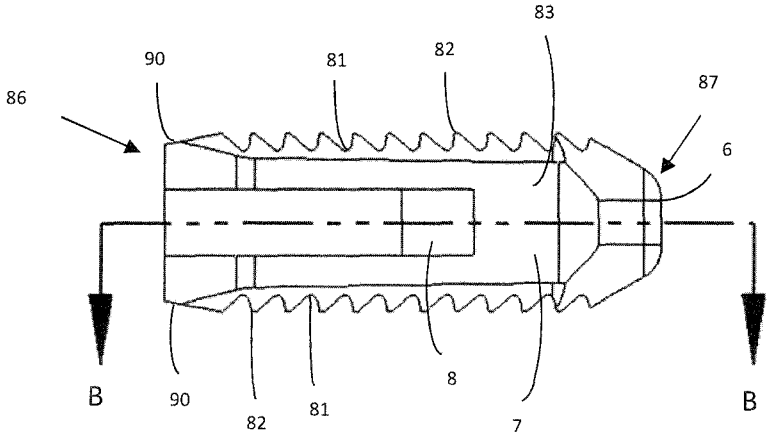


FIG. 32

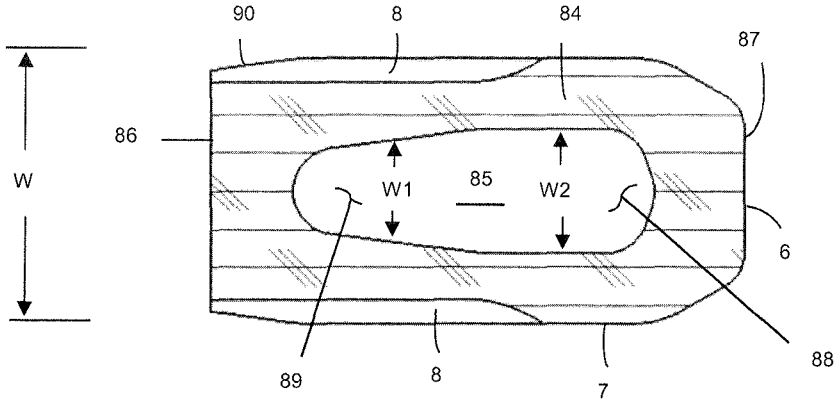


FIG. 33

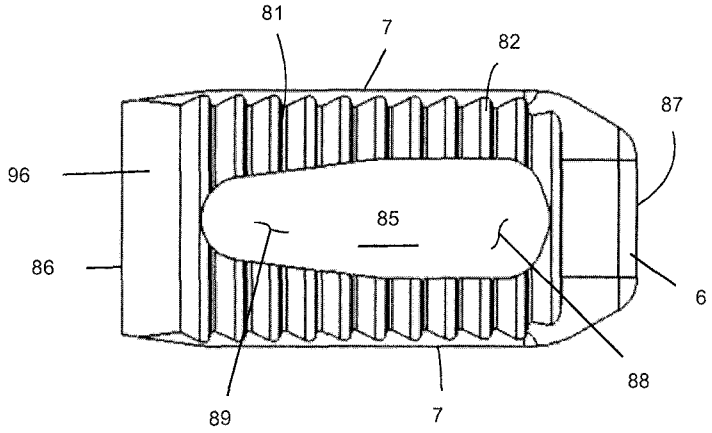


FIG. 34

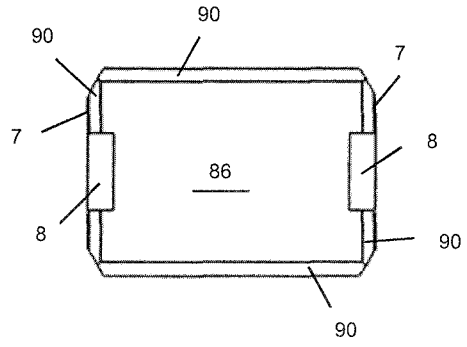


FIG. 35

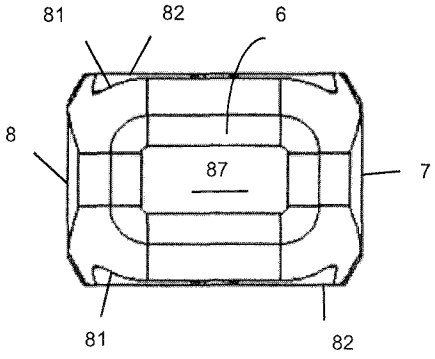


FIG. 36

Doc Code: PA..
Document Description: Power of Attorney

PTO/AIA/82B (07-13)
Approved for use through 03/31/2021. OMB 0651-0035
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POWER OF ATTORNEY BY APPLICANT

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

Application Number	Filing Date
Submitted Herewith	10/05/2020

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☑ 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 (form PTO/AIA/82A) or identified above: 141269

OR

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City		State		Zip	
Country					
Telephone		Email			

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

Pain TEQ, 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		Date (Optional)	October 5, 2020
Name	Chris Girsch		
Title	President, Pain TEQ, 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 1 forms are submitted.

This collection of information is required by 37 CFR 1.131, 1.32, and 1.33. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	13438-008.12
	Application Number	
Title of Invention	DRILL-LESS METHOD OF FUSING A SACROILIAC JOINT	

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
	Sean		LaNeve	

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

City	Tampa	State/Province	FL	Country of Residence	US

City		Country of Residence	

Mailing Address of Inventor:

Address 1	1511 N Westshore Blvd		
Address 2			
City	Tampa	State/Province	FL
Postal Code	33607	Country	US

Inventor 2 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Charles		Girsch	

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

City	Tampa	State/Province	FL	Country of Residence	US

City		Country of Residence	

Mailing Address of Inventor:

Address 1	1511 N Westshore Blvd		
Address 2			
City	Tampa	State/Province	FL
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	13438-008.12
	Application Number	
Title of Invention	DRILL-LESS METHOD OF FUSING A SACROILIAC JOINT	

Inventor 3 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Chris		Girsch	

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

City	Tampa	State/Province	FL	Country of Residence	US

City		Country of Residence	

Mailing Address of Inventor:

Address 1	1511 N Westshore Blvd		
Address 2			
City	Tampa	State/Province	FL
Postal Code	33607	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	141269		
Name 1		Name 2	
Address 1			
Address 2			
City		State/Province	
Country		Postal Code	
Phone Number		Fax Number	
Email Address	ipdocket@hwhlaw.com	Add Email	Remove Email

Application Information:

Title of the Invention	DRILL-LESS METHOD OF FUSING A SACROILIAC JOINT		
Attorney Docket Number	13438-008.12	Small Entity Status Claimed	☒
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)	23	Suggested Figure for Publication (if any)	4

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	13438-008.12
	Application Number	
Title of Invention	DRILL-LESS METHOD OF FUSING A SACROILIAC JOINT	

Plant Submissions Only:			
Latin Name		**Variety Denomination Name**	

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	141269		

Prefix	**Given Name**	Middle Name	**Family Name**	Suffix	
					Remove
Registration Number					
Prefix	**Given Name**	Middle Name	**Family Name**	Suffix	
					Remove
Registration Number					

Additional Representative Information blocks may be generated within this form by selecting the **Add** button.

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	13438-008.12
	Application Number	
Title of Invention	DRILL-LESS METHOD OF FUSING A SACROILIAC JOINT	

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 in part of	16851840	2020-04-17

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

Prior Application Status	Pending		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
16851840	Claims benefit of provisional	62910913	2019-10-04

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

Prior Application Status	Pending		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
	Claims benefit of provisional	62910913	2019-10-04

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

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

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)

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	13438-008.12
	Application Number	
Title of Invention	DRILL-LESS METHOD OF FUSING A SACROILIAC JOINT	

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

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	13438-008.12
	Application Number	
Title of Invention	DRILL-LESS METHOD OF FUSING A SACROILIAC JOINT	

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	13438-008.12
	Application Number	
Title of Invention	DRILL-LESS METHOD OF FUSING A SACROILIAC JOINT	

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

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	Pain TEQ, LLC

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

Mailing Address Information For Applicant:

Address 1	1511 N Westshore Blvd		
Address 2			
City	Tampa	**State/Province**	FL
Country	US	Postal Code	33607
Phone Number		Fax Number	
Email Address			

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

Assignee Information including Non-Applicant Assignee Information:

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

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	13438-008.12
	Application Number	
Title of Invention	DRILL-LESS METHOD OF FUSING A SACROILIAC JOINT	

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.

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

Organization Name	

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		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.

Signature:

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	/Steve Kelly/			Date (YYYY-MM-DD)	2020-10-05
First Name	Stephen	Last Name	Kelly	Registration Number	59,973

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

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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.