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UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
14/480,309	09/08/2014	Neal Blitz	24004350-304505

27683
HAYNES AND BOONE, LLP
IP Section
2323 Victory Avenue
Suite 700
Dallas, TX 75219

CONFIRMATION NO. 9464
POA ACCEPTANCE LETTER



Date Mailed: 10/02/2019

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 09/26/2019.

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

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

/hteffer/

Paragon 28 v. Treace Medical Concepts
PGR2026-00020
Paragon Ex. 1020

Under the Paperwork Reduction Act of 1995, no person is required to respond to a collection of information unless it displays a valid OMB control number

POWER OF ATTORNEY TO PROSECUTE APPLICATIONS BEFORE THE USPTO

I hereby revoke all previous powers of attorney given in the application identified in the attached statement under 37 CFR 3.73(c).

I hereby appoint:

☒ Practitioners associated with Customer Number: 27683

OR

☐ Practitioner(s) named below (if more than ten patent practitioners are to be named, then a customer number must be used):

Name	Registration Number

Name	Registration Number

As attorney(s) or agent(s) to represent the undersigned before the United States Patent and Trademark Office (USPTO) in connection with any and all patent applications assigned only to the undersigned according to the USPTO assignment records or assignment documents attached to this form in accordance with 37 CFR 3.73(c).

Please change the correspondence address for the application identified in the attached statement under 37 CFR 3.73(c) to:

☒ The address associated with Customer Number: 27683

OR

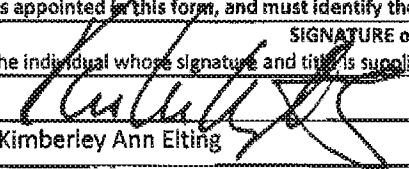
☐ Firm or individual name		
Address		
City	State	Zip
Country		
Telephone		Email

Assignee name and address: Orthofix S.R.L.
Via Delle Nazioni, 9
Bussolengo (Verona), Italy I-37012

A copy of this form, together with a statement under 37 CFR 3.73(c) (Form PTO/AIA/96 or equivalent) is required to be filed in each application in which this form is used. The statement under 37 CFR 3.73(c) may be completed by one of the practitioners appointed in this form, and must identify the application in which this Power of Attorney is to be filed.

SIGNATURE of Assignee of Record

The individual whose signature and title is supplied below is authorized to act on behalf of the assignee.

Signature		Date	July 24, 2019
Name	Kimberley Ann Elting	Telephone	214-937-2000
Title Chief Legal and Administrative Officer			

This collection of information is required by 37 CFR 1.31, 1.32, and 1.33. The information is required to obtain or retain a benefit by the public, which is to update (and by the USPTO to process) the file of a patent or reexamination proceeding. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 18 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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

Electronic Acknowledgement Receipt

EFS ID:	37289064
Application Number:	14480309
International Application Number:	
Confirmation Number:	9464
Title of Invention:	FIXATION PLATE FOR USE IN THE LAPIDUS APPROACH
First Named Inventor/Applicant Name:	Neal Blitz
Customer Number:	23562
Filer:	J. Andrew Lowes/Sidney Buchanan
Filer Authorized By:	J. Andrew Lowes
Attorney Docket Number:	24004350-304505
Receipt Date:	26-SEP-2019
Filing Date:	08-SEP-2014
Time Stamp:	15:47:03
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		164US02_POA_STATEMENT.pdf	411402	yes	3
			a9edf0fe509cb7b967ba8304558a1a938727eaba		

	Multipart Description/PDF files in .zip description		
	Document Description	Start	End
	Assignee showing of ownership per 37 CFR 3.73	2	3
	Power of Attorney	1	1
Warnings:			
Information:			
Total Files Size (in bytes):		411402	
This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503. <u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application. <u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course. <u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.			

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

STATEMENT UNDER 37 CFR 3.73(c)

Applicant/Patent Owner: Neal Blitz; Michael George

Application No./Patent No.: 9,107,715

Filed/Issue Date: 08-18-2015

Titled: FIXATION PLATE FOR USE IN THE LAPIDUS APPROACH

Orthofix S.R.L., a Corporation

(Name of Assignee)

(Type of Assignee, e.g., corporation, partnership, university, government agency, etc.)

states that, for the patent application/patent identified above, it is (choose one of options 1, 2, 3 or 4 below):

1. ☒ The assignee of the entire right, title, and interest.
2. ☐ An assignee of less than the entire right, title, and interest (check applicable box):
- ☐ The extent (by percentage) of its ownership interest is ____%. Additional Statement(s) by the owners holding the balance of the interest must be submitted to account for 100% of the ownership interest.
- ☐ There are unspecified percentages of ownership. The other parties, including inventors, who together own the entire right, title and interest are:

Additional Statement(s) by the owner(s) holding the balance of the interest must be submitted to account for the entire right, title, and interest.

3. ☐ The assignee of an undivided interest in the entirety (a complete assignment from one of the joint inventors was made). The other parties, including inventors, who together own the entire right, title, and interest are:

Additional Statement(s) by the owner(s) holding the balance of the interest must be submitted to account for the entire right, title, and interest.

4. ☐ The recipient, via a court proceeding or the like (e.g., bankruptcy, probate), of an undivided interest in the entirety (a complete transfer of ownership interest was made). The certified document(s) showing the transfer is attached.

The interest identified in option 1, 2 or 3 above (not option 4) is evidenced by either (choose one of options A or B below):

- A. ☐ An assignment from the inventor(s) of the patent application/patent identified above. The assignment was recorded in the United States Patent and Trademark Office at Reel _____, Frame _____, or for which a copy thereof is attached.
- B. ☒ A chain of title from the inventor(s), of the patent application/patent identified above, to the current assignee as follows:

1. From: Neal Blitz, Michael George To: AMEI Technologies, Inc.

The document was recorded in the United States Patent and Trademark Office at
Reel 021871, Frame 0996, or for which a copy thereof is attached.

2. From: AMEI Technologies, Inc. To: Orthofix S.R.L.

The document was recorded in the United States Patent and Trademark Office at
Reel 047502, Frame 0769, or for which a copy thereof is attached.

[Page 1 of 2]

This collection of information is required by 37 CFR 3.73(b). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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

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

STATEMENT UNDER 37 CFR 3.73(c)

3. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at
Reel _____, Frame _____, or for which a copy thereof is attached.

4. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at
Reel _____, Frame _____, or for which a copy thereof is attached.

5. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at
Reel _____, Frame _____, or for which a copy thereof is attached.

6. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at
Reel _____, Frame _____, or for which a copy thereof is attached.☐ Additional documents in the chain of title are listed on a supplemental sheet(s).☒ As required by 37 CFR 3.73(c)(1)(i), the documentary evidence of the chain of title from the original owner to the assignee was, or concurrently is being, submitted for recordation pursuant to 37 CFR 3.11.

[NOTE: A separate copy (i.e., a true copy of the original assignment document(s)) must be submitted to Assignment Division in accordance with 37 CFR Part 3, to record the assignment in the records of the USPTO. See MPEP 302.08]

The undersigned (whose title is supplied below) is authorized to act on behalf of the assignee.

/J. Andrew Lowes/

09-26-2019

Signature

Date

J. Andrew Lowes

40,706

Printed or Typed Name

Title or Registration Number

[Page 2 of 2]



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/480,309	08/18/2015	9107715	24004350-304505	9464

23562 7590 07/29/2015
BAKER & MCKENZIE LLP
PATENT DEPARTMENT
2001 ROSS AVENUE
SUITE 2300
DALLAS, TX 75201

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):

Neal Blitz, New York, NY;
AMEI TECHNOLOGIES, INC., Wilmington, DE;
Michael George, McKinney, TX;

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), to: Mail Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885**

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

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

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.

23562 7590 04/14/2015
BAKER & MCKENZIE LLP
PATENT DEPARTMENT
2001 ROSS AVENUE
SUITE 2300
DALLAS, TX 75201

Certificate of Mailing or Transmission

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

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

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/480,309	09/08/2014	Neal Blitz	24004350-304505	9464

TITLE OF INVENTION: FIXATION PLATE FOR USE IN THE LAPIDUS APPROACH

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	\$960	\$0	\$0	\$960	07/14/2015

EXAMINER	ART UNIT	CLASS-SUBCLASS
JONES, DIANA S	3775	606-283000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363). ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached. ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer Number is required.	2. For printing on the patent front page, list (1) The names of up to 3 registered patent attorneys or agents OR, alternatively, (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 Baker & McKenzie LLP 2 3
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3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

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

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

AMEI TECHNOLOGIES, INC.

Wilmington, Delaware

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

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

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

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

- ☐ A check is enclosed.
☐ Payment by credit card. Form PTO-2038 is attached.
☒ The director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number 13-0480 (enclose an extra copy of this form).

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

- ☐ Applicant certifying micro entity status. See 37 CFR 1.29
☐ Applicant asserting small entity status. See 37 CFR 1.27
☐ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

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

Authorized Signature /William D. McSpadden/

Date July 13, 2015

Typed or printed name William D. McSpadden

Registration No. 44,234

Electronic Patent Application Fee Transmittal				
Application Number:		14480309		
Filing Date:		08-Sep-2014		
Title of Invention:		FIXATION PLATE FOR USE IN THE LAPIDUS APPROACH		
First Named Inventor/Applicant Name:		Neal Blitz		
Filer:		William Desmond McSpadden		
Attorney Docket Number:		24004350-304505		
Filed as Large 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:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Utility Appl Issue Fee	1501	1	960	960
Publ. Fee- Early, Voluntary, or Normal	1504	1	0	0
Extension-of-Time:				
Miscellaneous:				
Total in USD (\$)				960

Electronic Acknowledgement Receipt

EFS ID:	22902313
Application Number:	14480309
International Application Number:	
Confirmation Number:	9464
Title of Invention:	FIXATION PLATE FOR USE IN THE LAPIDUS APPROACH
First Named Inventor/Applicant Name:	Neal Blitz
Customer Number:	23562
Filer:	William Desmond McSpadden
Filer Authorized By:	
Attorney Docket Number:	24004350-304505
Receipt Date:	13-JUL-2015
Filing Date:	08-SEP-2014
Time Stamp:	20:21:06
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	\$960
RAM confirmation Number	7406
Deposit Account	130480
Authorized User	MCSPADDEN, WILLIAM D

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

Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.19 (Document supply fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.20 (Post Issuance fees)

Charge any Additional Fees required under 37 C.F.R. Section 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	Transmittal Letter	24004350_304505_Response_Notice_Requiring_Declaration_Sub_Statement.pdf	18914	no	1
			b6aa213d252da1bd3798c8cf6f93faa68cbf5b80		
Warnings:					
Information:					
2	Oath or Declaration filed	24004350_304505_Signed_Substitute_Statement.pdf	709450	no	3
			663110fb3c0d1e6400cb0d6934c959da7e6d5e8a		
Warnings:					
Information:					
3	Oath or Declaration filed	24004350_304505_Signed_Declaration_Blitz.pdf	787898	no	1
			72f0f0ec5bde6d9015b540a9ec9c88fd8352bd3		
Warnings:					
Information:					
4	Issue Fee Payment (PTO-85B)	24004350_304505_IssueFeePayment.pdf	190925	no	1
			8e763b7736697b1eba84c97acfa136d8c616cfe8		
Warnings:					
Information:					
5	Fee Worksheet (SB06)	fee-info.pdf	32423	no	2
			5b85738c75abe71c089a361824a3061a66997b9d		
Warnings:					
Information:					
Total Files Size (in bytes):			1739610		

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

New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

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

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Neal Blitz, et al. Docket No.: 24004350-304505
Serial No.: 14/480,309 Art Unit: 3775
Filed: September 8, 2014 Examiner: Diana S. Jones
For: FIXATION PLATE FOR USE IN THE LAPIDUS APPROACH

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

RESPONSE TO NOTICE REQUIRING INVENTOR'S OATH OR DECLARATION

Dear Sir:

In response to the Notice dated May 22, 2015, please find attached the signed declaration from Inventor Blitz for the above-referenced application filed on September 8, 2014 with serial number 14/480,309. Also attached is a Substitute Statement signed by the Assignee on behalf of Inventor George.

The Commissioner has already charged the required late oath surcharge of \$140 to Deposit Account No. 13-0480 (fee code 1051) on September 15, 2014. If necessary, please charge any additional fees and credit any overpayments to the same.

Please contact Applicant's attorney with any questions regarding this matter.

Respectfully submitted,
BAKER & McKENZIE LLP
Attorney for Applicant

Date: July 13, 2015

/William D. McSpadden/
William D. McSpadden
Registration No. 44,234
CUSTOMER ACCOUNT NO. **23562**
BAKER & McKENZIE LLP
2300 Trammell Crow Center
2001 Ross Avenue
Dallas, TX 75201
Phone: 214-978-3040

801019-v1\DALDMS

**SUBSTITUTE STATEMENT IN LIEU OF AN OATH OR DECLARATION FOR UTILITY
OR DESIGN PATENT APPLICATION (35 U.S.C. 115(d) AND 37 CFR 1.64)**

Title of Invention	FIXATION PLATE FOR USE IN THE LAPIDUS APPROACH		
This statement is directed to:			
☐ The attached application,			
OR			
☒ United States application or PCT international application number <u>14/480,309</u> filed on <u>September 8, 2014</u>			
LEGAL NAME of inventor to whom this substitute statement applies:			
(E.g., Given Name (first and middle (if any)) and Family Name or Surname)			
Michael George			
Residence (except for a deceased or legally incapacitated inventor):			
City	McKinney	State	TX
		Country	US
Mailing Address (except for a deceased or legally incapacitated inventor):			
1105 North Market Street, Suite 1300			
City	Wilmington	State	DE
		Zip	19899
		Country	US
I believe the above-named inventor or joint inventor to be the original inventor or an original joint inventor of a claimed invention in the application.			
The above-identified application was made or authorized to be made by me.			
I hereby acknowledge that any willful false statement made in this statement is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.			
Relationship to the inventor to whom this substitute statement applies:			
☐ Legal Representative (for deceased or legally incapacitated inventor only),			
☒ Assignee,			
☐ Person to whom the inventor is under an obligation to assign,			
☐ Person who otherwise shows a sufficient proprietary interest in the matter (petition under 37 CFR 1.46 is required), or			
☐ Joint Inventor.			

[Page 1 of 2]

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

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

SUBSTITUTE STATEMENT

Circumstances permitting execution of this substitute statement:

- ☐ Inventor is deceased,
☐ Inventor is under legal incapacity,
☒ Inventor cannot be found or reached after diligent effort, or
☐ Inventor has refused to execute the oath or declaration under 37 CFR 1.63.

If there are joint inventors, please check the appropriate box below:

- ☒ An application data sheet under 37 CFR 1.76 (PTO/AIA/14 or equivalent) naming the entire inventive entity has been or is currently submitted.

OR

- ☐ An application data sheet under 37 CFR 1.76 (PTO/AIA/14 or equivalent) has not been submitted. Thus, a Substitute Statement Supplemental Sheet (PTO/AIA/11 or equivalent) naming the entire inventive entity and providing inventor information is attached. See 37 CFR 1.64(b).

WARNING:

Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.

PERSON EXECUTING THIS SUBSTITUTE STATEMENT:

Name: **Charles J. Dlabik**

Date (Optional):

Signature: *Charles J. Dlabik*

APPLICANT NAME AND TITLE OF PERSON EXECUTING THIS SUBSTITUTE STATEMENT:

If the applicant is a juristic entity, list the applicant name and the title of the signer:

AMEI TECHNOLOGIES, INC.

Applicant Name:

Title of Person Executing
This Substitute Statement: **Assistant General Counsel**

The signer, whose title is supplied above, is authorized to act on behalf of the applicant.

Residence of the signer (unless provided in an application data sheet, PTO/AIA/14 or equivalent):

City **Prosper**

State **TX**

Country **US**

Mailing Address of the signer (unless provided in an application data sheet, PTO/AIA/14 or equivalent)
3451 Plano Parkway

City **Lewisville**

State **TX**

Zip **75056**

Country **US**

Note: Use an additional PTO/AIA/02 form for each inventor who is deceased, legally incapacitated, cannot be found or reached after diligent effort, or has refused to execute the oath or declaration under 37 CFR 1.63.

Privacy Act Statement

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

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

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

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

**DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN
APPLICATION DATA SHEET (37 CFR 1.76)****Title of
Invention****FIXATION PLATE FOR USE IN THE LAPIDUS APPROACH**

As the below named inventor, I hereby declare that:

This declaration
is directed to:☐

The attached application, or

☒United States application or PCT international application number 14/480,309filed on September 8, 2014

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

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

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

Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.

LEGAL NAME OF INVENTORInventor: Neal Blitz

Date (Optional) : _____

Signature: _____

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

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

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



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/480,309	09/08/2014	Neal Blitz	24004350-304505	9464
7590 05/22/2015 BAKER & MCKENZIE LLP PATENT DEPARTMENT 2001 ROSS AVENUE SUITE 2300 DALLAS, TX 75201			EXAMINER JONES, DIANA S	
			ART UNIT	PAPER NUMBER
			3775	
			NOTIFICATION DATE	DELIVERY MODE
			05/22/2015	ELECTRONIC

NOTICE REQUIRING INVENTOR'S OATH OR DECLARATION

An inventor's oath or declaration in compliance with 37 CFR 1.63 or 1.64 executed by or with respect to each inventor has not yet been submitted.

An oath or declaration in compliance with 37 CFR 1.63, or a substitute statement in compliance with 37 CFR 1.64, executed by or with respect to each inventor **MUST** be filed **no later than the date on which the issue fee is paid**. See 35 U.S.C. 115(f). Failure to timely comply will result in ABANDONMENT of this application. This period for reply is not extendable under 37 CFR 1.136(a).

Questions relating to this Notice should be directed to the Application Assistance Unit at 571-272-4200.

(571)-272-4200 or 1(888)-786-0101

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/480,309	09/08/2014	Neal Blitz	24004350-304505	9464

23562 7590 04/29/2015

BAKER & MCKENZIE LLP
PATENT DEPARTMENT
2001 ROSS AVENUE
SUITE 2300
DALLAS, TX 75201

EXAMINER

JONES, DIANA S

ART UNIT	PAPER NUMBER
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3775

NOTIFICATION DATE	DELIVERY MODE
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04/29/2015

ELECTRONIC

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

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

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

docket@bakermckenzie.com

Supplemental Notice of Allowability	Application No. 14/480,309	Applicant(s) BLITZ ET AL.	
	Examiner DIANA S. JONES	Art Unit 3775	AIA (First Inventor to File) Status No

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

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

1. ☒ This communication is responsive to 3/20/2015.
☐ 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 15-21. 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 <u>9/8/2014</u> 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 _____.
--	---

/DIANA S JONES/ Examiner, Art Unit 3775	/CHRISTOPHER BECCIA/ Primary Examiner, Art Unit 3775
--	---

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

The application has been amended as follows:

This application is in condition for allowance except for the presence of claims 1-14 directed to a non-elected invention without traverse. Accordingly, claims 1-14 have been cancelled.

Reasons for Allowance

The following is an examiner's statement of reasons for allowance:

Claims 15-21 are allowable over the prior art of record because none of the prior art of record teaches nor fairly suggests all the limitations recited in the claims. Specifically, none of the prior art of record teaches or suggests, "The method steps of laterally and inferiorly translating and rotating a metatarsal such that an end of the metatarsal abuts the cuneiform".

These limitations, taken in context of the entire claims are allowable over the prior art of record.

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

Art Unit: 3775

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 DIANA S. JONES whose telephone number is (571)270-5963. The examiner can normally be reached on Flexible schedule M-F 7:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Truong can be reached on 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.

/DIANA S JONES/
Examiner, Art Unit 3775

/CHRISTOPHER BECCIA/
Primary Examiner, Art Unit 3775

Receipt date: 09/08/2014

14480309 - GAU: 3775

Doc code: IDS

PTO/SB/08a (01-10)

Doc description: Information Disclosure Statement (IDS) Filed

Approved for use through 07/31/2012. OMB 0651-0031

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

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number

Filing Date

First Named Inventor

Neal Blitz, et al.

Art Unit

Examiner Name

Attorney Docket Number

24004350-304505

U.S.PATENTS

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Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	6206882	B1	2001-03-27	Cohen	
	2	7052499	B2	2006-05-30	Steger, et al.	
	3	6344042	B1	2002-02-05	Curtis, et al.	
	4	7344538	B2	2008-03-18	Myerson, et al.	
	5	4159716		1979-07-03	Borchers	

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Examiner Initial*	Cite No	Publication Number	Kind Code ¹	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20050234458	A1	2005-10-20	Huebner	

Receipt date: 09/08/2014 INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		14480309 - GAU: 3775	
	Filing Date			
	First Named Inventor	Neal Blitz, et al.		
	Art Unit			
	Examiner Name			
	Attorney Docket Number	24004350-304505		

	2	20070265629	A1	2007-11-15	Martin, et al.	
	3	20060241607	A1	2006-10-26	Myerson, et al.	
	4	20060241608	A1	2006-10-26	Myerson, et al.	
	5	20070239163	A1	2007-10-11	Strnad, et al.	
	6	20060173459	A1	2006-08-03	Kay, et al.	
	7	20070239163	A1	2007-10-11	Strnad, et al.	
	8	20020128654	A1	2002-09-12	Steger, et al.	
	9	20050065521	A1	2005-03-24	Steger, et al.	
	10	20060241592	A1	2006-10-26	Myerson, et al.	

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Examiner Initial*	Cite No	Foreign Document Number ³	Country Code ²	Kind Code ⁴	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear	T ⁵

Receipt date: 09/08/2014 INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		14480309 - GAU: 3775	
	Filing Date			
	First Named Inventor	Neal Blitz, et al.		
	Art Unit			
	Examiner Name			
	Attorney Docket Number	24004350-304505		

1	2006-280949	JP	A	2006-10-19	Depuy Products Inc.	☒
2	2006-280951	JP	A	2006-10-19	Depuy Products Inc.	☒
3	2905590	FR	A1	2008-03-14	Surge Foot	☒

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NON-PATENT LITERATURE DOCUMENTS

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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, pages(s), volume-issue number(s), publisher, city and/or country where published.	T ⁵
	1	Australian Examination Report, AU Application No. 2009316867, dated March 20, 2014, 3 pages.	☐
	2	Japanese Office Action, dated October 1, 2013, JP Application No. 2011-537509, 6 pages.	☒
	3	Communication pursuant to Article 94(3) EPC, EP Application No. 09828045.6, dated June 11, 2013, 5 pages.	☐
	4	Communication pursuant to Article 94(3) EPC, EP Application No. 09828045.6, dated October 5, 2012, 5 pages.	☐
	5	MORTON, D.J., "The Human Foot: Its Evolution, Physiology and Functional Disorders," Columbia University Press, Morningside Heights, N.Y., 1935, Abstract provided.	☐
	6	Extended European Search report, EP Application No. 09828045.6, dated February 24, 2012, 10 pages.	☐

Receipt date: 09/08/2014 INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		14480309 - GAU: 3775	
	Filing Date			
	First Named Inventor	Neal Blitz, et al.		
	Art Unit			
	Examiner Name			
	Attorney Docket Number	24004350-304505		

	7	International Search Report, PCT/US2009/064150, date of mailing January 6, 2010, 2 pages.	☐
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EXAMINER SIGNATURE

Examiner Signature	/Diana Jones/	Date Considered	04/24/2015
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***EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. ² Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). ³ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ Applicant is to place a check mark here if English language translation is attached.

Receipt date: 09/08/2014 INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		14480309 - GAU: 3775
	Filing Date		
	First Named Inventor	Neal Blitz, et al.	
	Art Unit		
	Examiner Name		
	Attorney Docket Number	24004350-304505	

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	/Matthew S. Dushek/	Date (YYYY-MM-DD)	2014-09-08
Name/Print	Matthew S. Dushek	Registration Number	61921

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.**

Privacy Act Statement

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

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

Issue Classification 	Application/Control No. 14480309	Applicant(s)/Patent Under Reexamination BLITZ ET AL.	
	Examiner DIANA S JONES	Art Unit 3775	

CPC						
Symbol					Type	Version
A61B		17	/	8061	F	2013-01-01
A61B		17	/	8085	I	2013-01-01
Y10S		606	/	906	A	2013-01-01
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CPC Combination Sets				
Symbol	Type	Set	Ranking	Version
				
				

/DIANA S JONES/ Examiner.Art Unit 3775 (Assistant Examiner)	04/01/2015 (Date)	Total Claims Allowed: 7	
/CHRISTOPHER BECCIA/ Primary Examiner.Art Unit 3775 (Primary Examiner)	04/24/2015 (Date)	O.G. Print Claim(s) 15	O.G. Print Figure 5B

Issue Classification 	Application/Control No. 14480309	Applicant(s)/Patent Under Reexamination BLITZ ET AL.
	Examiner DIANA S JONES	Art Unit 3775

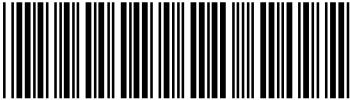
US ORIGINAL CLASSIFICATION						INTERNATIONAL CLASSIFICATION														
CLASS		SUBCLASS				CLAIMED					NON-CLAIMED									
						A	6	1	B	17 / 80 (2006.01.01)										
CROSS REFERENCE(S)																				
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)																			

/DIANA S JONES/ Examiner.Art Unit 3775 (Assistant Examiner)	04/01/2015 (Date)	Total Claims Allowed: 7	
/CHRISTOPHER BECCIA/ Primary Examiner.Art Unit 3775 (Primary Examiner)	04/24/2015 (Date)	O.G. Print Claim(s) 15	O.G. Print Figure 5B

Issue Classification 	Application/Control No. 14480309	Applicant(s)/Patent Under Reexamination BLITZ ET AL.
	Examiner DIANA S JONES	Art Unit 3775

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47															
Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
	1	3	17												
	2	4	18												
	3	5	19												
	4	6	20												
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	13														
	14														
1	15														
2	16														

/DIANA S JONES/ Examiner.Art Unit 3775 (Assistant Examiner)	04/01/2015 (Date)	Total Claims Allowed: 7	
/CHRISTOPHER BECCIA/ Primary Examiner.Art Unit 3775 (Primary Examiner)	04/24/2015 (Date)	O.G. Print Claim(s) 15	O.G. Print Figure 5B

Search Notes 	Application/Control No. 14480309	Applicant(s)/Patent Under Reexamination BLITZ ET AL.
	Examiner DIANA S JONES	Art Unit 3775

CPC- SEARCHED		
Symbol	Date	Examiner
A61B 17/8061	4/1/2015	D.J.
A61B 17/8085	4/1/2015	D.J.
Y10S 606/906	4/1/2015	D.J.
Y10S 606/902	4/1/2015	D.J.

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner

SEARCH NOTES		
Search Notes	Date	Examiner
Inventors' Name Search	4/1/2015	D.J.
Performed Text Search	4/1/2015	D.J.
Performed CPC Search	4/1/2015	D.J.
Assignee Search	4/1/2015	D.J.

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner
See EAST Search		4/1/2015	D.J.

/DIANA S JONES/ Examiner.Art Unit 3775	/CHRISTOPHER BECCIA/ Primary Examiner, Art Unit 3775
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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

NOTICE OF ALLOWANCE AND FEE(S) DUE

23562 7590 04/14/2015
BAKER & MCKENZIE LLP
PATENT DEPARTMENT
2001 ROSS AVENUE
SUITE 2300
DALLAS, TX 75201

EXAMINER

JONES, DIANA S

ART UNIT

PAPER NUMBER

3775

DATE MAILED: 04/14/2015

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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14/480,309

09/08/2014

Neal Blitz

24004350-304505

9464

TITLE OF INVENTION: FIXATION PLATE FOR USE IN THE LAPIDUS APPROACH

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	\$960	\$0	\$0	\$960	07/14/2015

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: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: **Mail** **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax **(571)-273-2885**

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

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

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.

23562 7590 04/14/2015
BAKER & MCKENZIE LLP
PATENT DEPARTMENT
2001 ROSS AVENUE
SUITE 2300
DALLAS, TX 75201

Certificate of Mailing or Transmission

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

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

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/480,309	09/08/2014	Neal Blitz	24004350-304505	9464

TITLE OF INVENTION: FIXATION PLATE FOR USE IN THE LAPIDUS APPROACH

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	\$960	\$0	\$0	\$960	07/14/2015

EXAMINER	ART UNIT	CLASS-SUBCLASS
JONES, DIANA S	3775	606-283000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363). ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached. ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer Number is required.	2. For printing on the patent front page, list (1) The names of up to 3 registered patent attorneys or agents OR, alternatively, 1 _____ (2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed. 2 _____ 3 _____
---	---

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

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

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

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

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

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

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

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

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

- ☐ Applicant certifying micro entity status. See 37 CFR 1.29
☐ Applicant asserting small entity status. See 37 CFR 1.27
☐ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

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

Authorized Signature _____ Date _____
Typed or printed name _____ Registration No. _____



UNITED STATES PATENT AND TRADEMARK OFFICE

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

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/480,309	09/08/2014	Neal Blitz	24004350-304505	9464

23562 7590 04/14/2015
BAKER & MCKENZIE LLP
PATENT DEPARTMENT
2001 ROSS AVENUE
SUITE 2300
DALLAS, TX 75201

EXAMINER

JONES, DIANA S

ART UNIT	PAPER NUMBER
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3775

DATE MAILED: 04/14/2015

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

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

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

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

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

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

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

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

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

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

Notice of Allowability	Application No. 14/480,309	Applicant(s) BLITZ ET AL.	
	Examiner DIANA S. JONES	Art Unit 3775	AIA (First Inventor to File) Status No

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

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

1. ☒ This communication is responsive to 3/20/2015.
☐ 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 15-21. 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 <u>9/8/2014</u> 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 _____.
--	---

/DIANA S JONES/ Examiner, Art Unit 3775	/Andrew Yang/ Primary Examiner, Art Unit 3775
--	--

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

The application has been amended as follows:

This application is in condition for allowance except for the presence of claims 1-14 directed to a non-elected invention without traverse. Accordingly, claims 15-21 have been cancelled.

Reasons for Allowance

The following is an examiner's statement of reasons for allowance:

Claims 15-21 are allowable over the prior art of record because none of the prior art of record teaches nor fairly suggests all the limitations recited in the claims. Specifically, none of the prior art of record teaches or suggests, "The method steps of laterally and inferiorly translating and rotating a metatarsal such that an end of the metatarsal abuts the cuneiform".

These limitations, taken in context of the entire claims are allowable over the prior art of record.

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

Art Unit: 3775

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 DIANA S. JONES whose telephone number is (571)270-5963. The examiner can normally be reached on Flexible schedule M-F 7:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Truong can be reached on 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.

/DIANA S JONES/
Examiner, Art Unit 3775

Doc code: IDS

PTO/SB/08a (01-10)

Doc description: Information Disclosure Statement (IDS) Filed

Approved for use through 07/31/2012. OMB 0651-0031

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

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

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		
	Filing Date		
	First Named Inventor	Neal Blitz, et al.	
	Art Unit		
	Examiner Name		
	Attorney Docket Number	24004350-304505	

U.S.PATENTS						Remove
Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	6206882	B1	2001-03-27	Cohen	
	2	7052499	B2	2006-05-30	Steger, et al.	
	3	6344042	B1	2002-02-05	Curtis, et al.	
	4	7344538	B2	2008-03-18	Myerson, et al.	
	5	4159716		1979-07-03	Borchers	
If you wish to add additional U.S. Patent citation information please click the Add button.						Add
U.S.PATENT APPLICATION PUBLICATIONS						Remove
Examiner Initial*	Cite No	Publication Number	Kind Code ¹	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20050234458	A1	2005-10-20	Huebner	

Receipt date: 09/08/2014 INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		14480309 - GAU: 3775	
	Filing Date			
	First Named Inventor	Neal Blitz, et al.		
	Art Unit			
	Examiner Name			
	Attorney Docket Number	24004350-304505		

	2	20070265629	A1	2007-11-15	Martin, et al.	
	3	20060241607	A1	2006-10-26	Myerson, et al.	
	4	20060241608	A1	2006-10-26	Myerson, et al.	
	5	20070239163	A1	2007-10-11	Strnad, et al.	
	6	20060173459	A1	2006-08-03	Kay, et al.	
	7	20070239163	A1	2007-10-11	Strnad, et al.	
	8	20020128654	A1	2002-09-12	Steger, et al.	
	9	20050065521	A1	2005-03-24	Steger, et al.	
	10	20060241592	A1	2006-10-26	Myerson, et al.	

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Receipt date: 09/08/2014 INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		14480309 - GAU: 3775	
	Filing Date			
	First Named Inventor	Neal Blitz, et al.		
	Art Unit			
	Examiner Name			
	Attorney Docket Number	24004350-304505		

1	2006-280949	JP	A	2006-10-19	Depuy Products Inc.	☒
2	2006-280951	JP	A	2006-10-19	Depuy Products Inc.	☒
3	2905590	FR	A1	2008-03-14	Surge Foot	☒

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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, pages(s), volume-issue number(s), publisher, city and/or country where published.	T ⁵
	1	Australian Examination Report, AU Application No. 2009316867, dated March 20, 2014, 3 pages.	☐
	2	Japanese Office Action, dated October 1, 2013, JP Application No. 2011-537509, 6 pages.	☒
	3	Communication pursuant to Article 94(3) EPC, EP Application No. 09828045.6, dated June 11, 2013, 5 pages.	☐
	4	Communication pursuant to Article 94(3) EPC, EP Application No. 09828045.6, dated October 5, 2012, 5 pages.	☐
	5	MORTON, D.J., "The Human Foot: Its Evolution, Physiology and Functional Disorders," Columbia University Press, Morningside Heights, N.Y., 1935, Abstract provided.	☐
	6	Extended European Search report, EP Application No. 09828045.6, dated February 24, 2012, 10 pages.	☐

Receipt date: 09/08/2014 INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		14480309 - GAU: 3775
	Filing Date		
	First Named Inventor	Neal Blitz, et al.	
	Art Unit		
	Examiner Name		
	Attorney Docket Number	24004350-304505	

	7	International Search Report, PCT/US2009/064150, date of mailing January 6, 2010, 2 pages.	☐
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Examiner Signature	/Diana Jones/	Date Considered	03/31/2015
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¹ See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. ² Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). ³ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ Applicant is to place a check mark here if English language translation is attached.

Receipt date: 09/08/2014 INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		14480309 - GAU: 3775
	Filing Date		
	First Named Inventor	Neal Blitz, et al.	
	Art Unit		
	Examiner Name		
	Attorney Docket Number	24004350-304505	

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	/Matthew S. Dushek/	Date (YYYY-MM-DD)	2014-09-08
Name/Print	Matthew S. Dushek	Registration Number	61921

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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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.
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9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Search Notes 	Application/Control No. 14480309	Applicant(s)/Patent Under Reexamination BLITZ ET AL.
	Examiner DIANA S JONES	Art Unit 3775

CPC- SEARCHED		
Symbol	Date	Examiner
A61B 17/8061	4/1/2015	D.J.
A61B 17/8085	4/1/2015	D.J.
Y10S 606/906	4/1/2015	D.J.
Y10S 606/902	4/1/2015	D.J.

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner

SEARCH NOTES		
Search Notes	Date	Examiner
Inventors' Name Search	4/1/2015	D.J.
Performed Text Search	4/1/2015	D.J.
Performed CPC Search	4/1/2015	D.J.
Assignee Search	4/1/2015	D.J.

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner
See EAST Search		4/1/2015	D.J.

/DIANA S JONES/ Examiner.Art Unit 3775	
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EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
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S2	420	george adj michael.in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/03/29 14:02
S3	140	amei adj technologies.as.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/03/29 14:13
S4	290	606/280-299.ccls. and (\$metatars\$ or \$foot\$)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/03/29 14:17
S5	80	S4 and \$twist\$	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/03/29 14:53
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S7	7	S5 and S6	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT;	OR	OFF	2012/03/29 14:54

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S31	301	606/280-299.ccls. and S24	US-PGPUB; USPAT	OR	ON	2012/10/17 12:52
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S34	18	S26 and threaded	US-PGPUB; USPAT	OR	ON	2012/10/17 13:14
S35	7	S22 and threaded	US-PGPUB; USPAT	OR	ON	2012/10/17 13:17
S37	1	"20060241607"	US-PGPUB; USPAT	OR	ON	2012/10/17 13:40
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S42	12	("20060241607" "20060241607" "20060173459" "4159716" "20060241592" "6206882" "20070239163" "20050234458" "20060241608" "7344538" "20050065521" "6206882" "6344042" "20020128654" "20070239163").PN.	US-PGPUB; USPAT	OR	ON	2013/06/30 22:54
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S48	835	plate and bone and metatarsal and (radius radial adj bone)	US-PGPUB; USPAT	OR	ON	2014/04/21 15:21
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S55	5	S53 and cuneiform	US-PGPUB; USPAT	OR	ON	2015/03/31 12:09
S56	24	metatarsocuneiform	US-PGPUB; USPAT	OR	ON	2015/03/31 12:29
S57	1820	(A61B17/8061 OR A61B17/8085 OR Y10S606/902 OR Y10S606/906).CPC.	US-PGPUB; USPAT	OR	ON	2015/03/31 12:37

EAST Search History (I nterference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
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S52	0	(plate) and (bone) and (metatarsocuneiform) and (trapezoidal)	USPAT; UPAD	OR	ON	2014/04/29 17:50

4/ 1/ 2015 12:49:49 PM

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CONFIRMATION NO. 9464

SERIAL NUMBER 14/480,309	FILING or 371(c) DATE 09/08/2014 RULE	CLASS 606	GROUP ART UNIT 3775	ATTORNEY DOCKET NO. 24004350-304505		
APPLICANTS AMEI TECHNOLOGIES, INC., Wilmington, DE, Assignee (with 37 CFR 1.172 Interest); INVENTORS Neal Blitz, New York, NY; Michael George, McKinney, TX; ** CONTINUING DATA ***** This application is a CON of 12/274,199 11/19/2008 PAT 8828063 ** FOREIGN APPLICATIONS ***** ** IF REQUIRED, FOREIGN FILING LICENSE GRANTED ** 09/15/2014						
Foreign Priority claimed ☐ Yes ☒ No 35 USC 119(a-d) conditions met ☐ Yes ☒ No Verified and Acknowledged <u>/DIANA S JONES/</u> Examiner's Signature		☐ Met after Allowance Initials	STATE OR COUNTRY NY	SHEETS DRAWINGS 8	TOTAL CLAIMS 21	INDEPENDENT CLAIMS 2
ADDRESS BAKER & MCKENZIE LLP PATENT DEPARTMENT 2001 ROSS AVENUE SUITE 2300 DALLAS, TX 75201 UNITED STATES						
TITLE FIXATION PLATE FOR USE IN THE LAPIDUS APPROACH						
FILING FEE RECEIVED 1820	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			

Issue Classification 	Application/Control No. 14480309	Applicant(s)/Patent Under Reexamination BLITZ ET AL.	
	Examiner DIANA S JONES	Art Unit 3775	

CPC					
Symbol				Type	Version
A61B	17	8061		F	2013-01-01
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Y10S	606	906		A	2013-01-01

CPC Combination Sets				
Symbol	Type	Set	Ranking	Version

/DIANA S JONES/ Examiner.Art Unit 3775 (Assistant Examiner)	04/01/2015 (Date)	Total Claims Allowed: 7	
/ANDREW YANG/ Primary Examiner.Art Unit 3775 (Primary Examiner)	04/06/2015 (Date)	O.G. Print Claim(s) 15	O.G. Print Figure 5B

Issue Classification 	Application/Control No. 14480309	Applicant(s)/Patent Under Reexamination BLITZ ET AL.
	Examiner DIANA S JONES	Art Unit 3775

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47															
Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
	1	3	17												
	2	4	18												
	3	5	19												
	4	6	20												
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	10														
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	12														
	13														
	14														
1	15														
2	16														

/DIANA S JONES/ Examiner.Art Unit 3775 (Assistant Examiner)	04/01/2015 (Date)	Total Claims Allowed: 7	
/ANDREW YANG/ Primary Examiner.Art Unit 3775 (Primary Examiner)	04/06/2015 (Date)	O.G. Print Claim(s) 15	O.G. Print Figure 5B

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of:	Neal BLITZ, et al.	Examiner: Diana S. Jones
Application No.:	14/480,309	Group Art Unit: 3775
Filing Date:	September 8, 2014	Confirmation No. 9464
For:	FIXATION PLATE FOR USE IN THE LAPIDUS APPROACH	

Via EFS Web

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

RESPONSE TO RESTRICTION REQUIREMENT

In response to the Restriction Requirement dated January 26, 2015, Applicant elects, without traverse, Group II, Claims 15-21 for examination on the merits.

Applicant reserves the right to file one or more divisional applications, which shall be subject to the third sentence of 35 U.S.C. 121.¹

No fees are believed to be necessitated by this response. If any other fees are determined to be due with this filing, the Director is authorized to charge any such fees, or credit any overpayment, to our Deposit Account No. 13-0480, referencing the Docket No. stated herein.

Respectfully Submitted,

Date: March 20, 2015

/Matt Dushek, Reg. No. 61921/

Matt Dushek, Reg. No. 61,921
Baker & McKenzie LLP
815 Connecticut Ave NW
Washington, DC 20006
Ph: (202) 835-6165
Fax: (202) 416-7165

¹ “A patent issuing on an application with respect to which a requirement for restriction under this section has been made, or on an application filed as a result of such a requirement, *shall not be used as a reference* either in the Patent and Trademark Office or in the courts against a divisional application or against the original application or any patent issued on either of them[.]”

Electronic Acknowledgement Receipt

EFS ID:	21829911
Application Number:	14480309
International Application Number:	
Confirmation Number:	9464
Title of Invention:	FIXATION PLATE FOR USE IN THE LAPIDUS APPROACH
First Named Inventor/Applicant Name:	Neal Blitz
Customer Number:	23562
Filer:	Matthew S. Dushek
Filer Authorized By:	
Attorney Docket Number:	24004350-304505
Receipt Date:	20-MAR-2015
Filing Date:	08-SEP-2014
Time Stamp:	12:11:00
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no
------------------------	----

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Response to Election / Restriction Filed	24004350_304505_Election.pdf	21403 7bf67796c117e8dc8934b76ef50eefd37d025818	no	1

Warnings:

Information:

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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Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/480,309	09/08/2014	Neal Blitz	24004350-304505	9464

23562 7590 01/26/2015

BAKER & MCKENZIE LLP
PATENT DEPARTMENT
2001 ROSS AVENUE
SUITE 2300
DALLAS, TX 75201

EXAMINER

JONES, DIANA S

ART UNIT	PAPER NUMBER
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3775

NOTIFICATION DATE	DELIVERY MODE
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01/26/2015

ELECTRONIC

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

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

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

docket@bakermckenzie.com

Office Action Summary	Application No. 14/480,309	Applicant(s) BLITZ ET AL.	
	Examiner DIANA S. JONES	Art Unit 3775	AIA (First Inventor to File) Status No

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

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 2 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

- 5) ☒ Claim(s) 1-21 is/are pending in the application.
5a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) _____ is/are allowed.
- 7) ☐ Claim(s) _____ is/are rejected.
- 8) ☐ Claim(s) _____ is/are objected to.
- 9) ☒ Claim(s) 1-21 are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

- a) ☐ All b) ☐ Some** c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) ☐ Notice of References Cited (PTO-892) | 3) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) ☐ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)
Paper No(s)/Mail Date _____ | 4) ☐ Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-14 drawn to a plate adapted for fixation across a metatarsocuneiform joint, classified in A61B 17/6425.

II. Claims 15-21, drawn to a method for fusing a metatarsocuneiform joint, classified in A61B 17/8061.

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the product as claimed can be used in a materially different process of using that product, such as being used in spinal fixation.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and/or examination burden if restriction were not required because one or more of the following reasons apply:

The inventions require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search strategies or search queries).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of an invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

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

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

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be corrected in compliance with 37 CFR 1.48(a) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. A request to correct inventorship under 37 CFR 1.48(a)

must be accompanied by an application data sheet in accordance with 37 CFR 1.76 that identifies each inventor by his or her legal name and by the processing fee required under 37 CFR 1.17(i).

The examiner has required restriction between product or apparatus claims and process claims. Where applicant elects claims directed to the product/apparatus, and all product/apparatus claims are subsequently found allowable, withdrawn process claims that include all the limitations of the allowable product/apparatus claims should be considered for rejoinder. All claims directed to a nonelected process invention must include all the limitations of an allowable product/apparatus claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product/apparatus claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product/apparatus are found allowable, an otherwise proper restriction requirement between product/apparatus claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product/apparatus claim will not be rejoined. See MPEP § 821.04. Additionally, in order for rejoinder to occur, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product/apparatus claims. **Failure to do so may result in no rejoinder.** Further, note

Art Unit: 3775

that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANA S. JONES whose telephone number is (571)270-5963. The examiner can normally be reached on Flexible schedule M-F 7:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Truong can be reached on 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.

/DIANA S JONES/
Examiner, Art Unit 3775

Application/Control Number: 14/480,309
Art Unit: 3775

Page 6

<i>Index of Claims</i> 	Application/Control No. 14480309	Applicant(s)/Patent Under Reexamination BLITZ ET AL.
	Examiner DIANA S JONES	Art Unit 3775

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

☐ Claims renumbered in the same order as presented by applicant		☐ CPA		☐ T.D.		☐ R.1.47			
CLAIM		DATE							
Final	Original	01/21/2015							
	1	÷							
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	3	÷							
	4	÷							
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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
14/480,309	09/08/2014	Neal Blitz	24004350-304505

CONFIRMATION NO. 9464

PUBLICATION NOTICE



OC000000072576649

23562
BAKER & MCKENZIE LLP
PATENT DEPARTMENT
2001 ROSS AVENUE
SUITE 2300
DALLAS, TX 75201

Title:FIXATION PLATE FOR USE IN THE LAPIDUS APPROACH

Publication No.US-2014-0379036-A1

Publication Date:12/25/2014

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 Office of Public Records. The Office of Public Records can be reached by telephone at (703) 308-9726 or (800) 972-6382, by facsimile at (703) 305-8759, by mail addressed to the United States Patent and Trademark Office, Office of Public Records, 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 <http://pair.uspto.gov/>. 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 Management, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Neal Blitz, et al.
Application No.: 14/480,309
Group Art Unit: 3775
Filing Date: September 8, 2014
Examiner: TBD
For: FIXATION PLATE FOR USE IN THE
LAPIDUS APPROACH

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

RESPONSE TO NON-COMPLIANT AMENDMENT

In response to the non-compliant amendment notice mailed on September 23, 2014, please amend the above-identified application as indicated below.

Amendments to the Specification begin on page **2** of this paper.

Remarks/Arguments begin on page **3** of this paper.

Amendments to the Specification

Please add the following paragraph to the specification on page 1, before TECHNICAL FIELD, and after the title, as follows:

CROSS-REFERENCE TO RELATED APPLICATION(S)

This application is a continuation of U.S. Application Serial No. 12/274,199, filed on November 19, 2008, which application is incorporated herein by reference in its entirety.

REMARKS

In response to the notice that indicated that the new paragraph should not be underlined, Applicant respectfully requests entry of this amendment prior to examination. In this amendment, a continuity paragraph incorporating the previously filed parent application by reference has been added without underlining. No new matter is added by this amendment. Applicants do not believe any fees are deemed to be due in connection with this filing, however the Commissioner is hereby authorized to charge any additional fees and/or credit any overpayment to Deposit Account Number 13-0480 referencing Attorney Docket Number 24004350-304505.

Respectfully submitted,
BAKER & McKENZIE LLP

Date: September 24, 2014

/Matthew S. Dushek/

Matthew S. Dushek
Attorney of Record
Registration No.61,921

815 Connecticut Ave NW
Washington, DC 20006
Phone: 202-835-6165
Fax: 202-416-7165

Electronic Acknowledgement Receipt

EFS ID:	20233798
Application Number:	14480309
International Application Number:	
Confirmation Number:	9464
Title of Invention:	FIXATION PLATE FOR USE IN THE LAPIDUS APPROACH
First Named Inventor/Applicant Name:	Neal Blitz
Customer Number:	23562
Filer:	Matthew S. Dushek
Filer Authorized By:	
Attorney Docket Number:	24004350-304505
Receipt Date:	24-SEP-2014
Filing Date:	08-SEP-2014
Time Stamp:	17:05:35
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		24004350_304505_Response_Non_Compliant.pdf	21776 3d45392591a5fbacd91fd72832eac01078657552	yes	3

	Multipart Description/PDF files in .zip description		
	Document Description	Start	End
	Applicant Response to Pre-Exam Formalities Notice	1	1
	Specification	2	2
	Applicant Arguments/Remarks Made in an Amendment	3	3
Warnings:			
Information:			
Total Files Size (in bytes):		21776	
This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503. <u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application. <u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course. <u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.			



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23562 e 2014-09-23

BAKER & MCKENZIE LLP
PATENT DEPARTMENT
2001 ROSS AVENUE
SUITE 2300
DALLAS, TX 75201

Paper No.

Application No.:	14/480,309 	Date Mailed:	2014-09-23
First Named Inventor:	Blitz, Neal,	Examiner:	,
Attorney Docket No.:	24004350-304505	Art Unit:	3775
Confirmation No.:	9464	Filing Date:	2014-09-08

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

Commissioner for Patents

Notice of Non-Compliant Amendment (37 CFR 1.121)	Application No. 14/480,309	Applicant(s) BLITZ ET AL.
		Art Unit 3998

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

The amendment document filed on 08 September, 2014 is considered non-compliant because it has failed to meet the requirements of 37 CFR 1.121 or 1.4. In order for the amendment document to be compliant, correction of the following item(s) is required.

THE FOLLOWING MARKED (X) ITEM(S) CAUSE THE AMENDMENT DOCUMENT TO BE NON-COMPLIANT:

- ☒ 1. Amendments to the specification:
 - ☐ A. Amended paragraph(s) do not include markings.
 - ☒ B. New paragraph(s) should not be underlined.
 - ☐ C. Other _____.
- ☐ 2. Abstract:
 - ☐ A. Not presented on a separate sheet. 37 CFR 1.72.
 - ☐ B. Other _____.
- ☐ 3. Amendments to the drawings:
 - ☐ A. The drawings are not properly identified in the top margin as "Replacement Sheet," "New Sheet," or "Annotated Sheet" as required by 37 CFR 1.121(d).
 - ☐ B. The practice of submitting proposed drawing correction has been eliminated. Replacement drawings showing amended figures, without markings, in compliance with 37 CFR 1.84 are required.
 - ☐ C. Other _____.
- ☐ 4. Amendments to the claims:
 - ☐ A. A complete listing of all of the claims is not present.
 - ☐ B. The listing of claims does not include the text of all pending claims (including withdrawn claims)
 - ☐ C. Each claim has not been provided with the proper status identifier, and as such, the individual status of each claim cannot be identified. Note: the status of every claim must be indicated after its claim number by using one of the following status identifiers: (Original), (Currently amended), (Canceled), (Previously presented), (New), (Not entered), (Withdrawn) and (Withdrawn-currently amended).
 - ☐ D. The claims of this amendment paper have not been presented in ascending numerical order.
 - ☐ E. Other: _____.
- ☐ 5. Other (e.g., the amendment is unsigned or not signed in accordance with 37 CFR 1.4): For further explanation of the amendment format required by 37 CFR 1.121, see MPEP § 714.

TIME PERIODS FOR FILING A REPLY TO THIS NOTICE:

1. Applicant is given **no new time period if the non-compliant amendment is an** after-final amendment or an amendment filed after allowance, or a drawing submission (only) If applicant wishes to resubmit the non-compliant after-final amendment with corrections, the **entire corrected amendment** must be resubmitted.
2. Applicant is given **two months** from the mail date of this notice to supply the correction, if the non-compliant amendment is one of the following: a preliminary amendment, a non-final amendment (including a submission for a request for continued examination (RCE) under 37 CFR 1.114), a supplemental amendment filed within a suspension period under 37 CFR 1.103(a) or (c), and an amendment filed in response to a Quayle action. If any of above boxes 1 to 4 are checked, the correction required is only the corrected section of the non-compliant amendment in compliance with 37 CFR 1.121.

Extensions of time are available under 37 CFR 1.136(a) only if the non-compliant amendment is a non-final amendment or an amendment filed in response to a *Quayle* action.

Failure to timely respond to this notice will result in:

Abandonment of the application if the non-compliant amendment is a non-final amendment or an amendment filed in response to a *Quayle* action; or

Non-entry of the amendment if the non-compliant amendment is a preliminary amendment or supplemental amendment.

Legal Instruments Examiner (LIE), if applicable /BRENDA TURNER/

Telephone No: (571)272-3614



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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
14/480,309	09/08/2014	3775	1820	24004350-304505	21	2

CONFIRMATION NO. 9464

23562
BAKER & MCKENZIE LLP
PATENT DEPARTMENT
2001 ROSS AVENUE
SUITE 2300
DALLAS, TX 75201

FILING RECEIPT



Date Mailed: 09/17/2014

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

Inventor(s)

Neal Blitz, New York, NY;
Michael George, McKinney, TX;

Applicant(s)

AMEI TECHNOLOGIES, INC., Wilmington, DE

Assignment For Published Patent Application

AMEI TECHNOLOGIES, INC., Wilmington, DE

Power of Attorney: None

Domestic Priority data as claimed by applicant

This application is a CON of 12/274,199 11/19/2008 PAT 8828063

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 - A proper **Authorization to Permit Access to Application by Participating Offices** (PTO/SB/39 or its equivalent) has been received by the USPTO.

If Required, Foreign Filing License Granted: 09/15/2014

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 14/480,309**

Projected Publication Date: 12/25/2014

Non-Publication Request: No

Early Publication Request: No
Title

FIXATION PLATE FOR USE IN THE LAPIDUS APPROACH

Preliminary Class

606

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

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

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

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

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

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at <http://www.uspto.gov/web/offices/pac/doc/general/index.html>.

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

LICENSE FOR FOREIGN FILING UNDER
Title 35, United States Code, Section 184
Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

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

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign Assets Control, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

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

SelectUSA

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

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875						Application or Docket Number 14/480,309			
APPLICATION AS FILED - PART I									
(Column 1)		(Column 2)		SMALL ENTITY		OR OTHER THAN SMALL ENTITY			
FOR	NUMBER FILED	NUMBER EXTRA	RATE(\$)	FEE(\$)		RATE(\$)	FEE(\$)		
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	280		
SEARCH FEE (37 CFR 1.16(k), (l), or (m))	N/A	N/A	N/A			N/A	600		
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	720		
TOTAL CLAIMS (37 CFR 1.16(j))	21	minus 20 = *				x 80 =	80		
INDEPENDENT CLAIMS (37 CFR 1.16(h))	2	minus 3 = *				x 420 =	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		TOTAL	1680		
APPLICATION AS AMENDED - PART II									
(Column 1)		(Column 2)		(Column 3)		SMALL ENTITY		OR OTHER THAN SMALL ENTITY	
AMENDMENT A	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE(\$)	ADDITIONAL FEE(\$)		RATE(\$)	ADDITIONAL FEE(\$)	
	Total (37 CFR 1.16(i))	*	Minus **	=			x	=	
	Independent (37 CFR 1.16(h))	*	Minus ***	=			x	=	
	Application Size Fee (37 CFR 1.16(s))								
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))								
				TOTAL ADD'L FEE		TOTAL ADD'L FEE			
AMENDMENT B	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE(\$)	ADDITIONAL FEE(\$)		RATE(\$)	ADDITIONAL FEE(\$)	
	Total (37 CFR 1.16(i))	*	Minus **	=			x	=	
	Independent (37 CFR 1.16(h))	*	Minus ***	=			x	=	
	Application Size Fee (37 CFR 1.16(s))								
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))								
				TOTAL ADD'L FEE		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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United States Patent and Trademark Office
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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
14/480,309	09/08/2014	Neal Blitz	24004350-304505

CONFIRMATION NO. 9464

23562
BAKER & MCKENZIE LLP
PATENT DEPARTMENT
2001 ROSS AVENUE
SUITE 2300
DALLAS, TX 75201

NOTICE



Date Mailed: 09/17/2014

INFORMATIONAL NOTICE TO APPLICANT

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

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

- A properly executed inventor's oath or declaration has not been received for the following inventor(s):
Neal Blitz
Michael George

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Neal Blitz, et al.
Application No.: TBD
Group Art Unit: TBD
Filing Date: Herewith
Examiner: TBD
For: FIXATION PLATE FOR USE IN THE
LAPIDUS APPROACH

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

PRELIMINARY AMENDMENT

Prior to examination, please amend the above-identified application as indicated below.

Amendments to the Specification begin on page **2** of this paper.

Remarks begin on page **3** of this paper.

Amendments to the Specification

Please add the following paragraph to the specification on page 1, before TECHNICAL FIELD, and after the title, as follows:

CROSS-REFERENCE TO RELATED APPLICATION(S)

This application is a continuation of U.S. Application Serial No. 12/274,199, filed on November 19, 2008, which application is incorporated herein by reference in its entirety.

REMARKS

Entry of this amendment prior to examination is respectfully requested. In this amendment, a continuity paragraph incorporating the previously filed parent application by reference has been added. No new matter is added by this amendment. Applicants do not believe any fees are deemed to be due in connection with this filing, however the Commissioner is hereby authorized to charge any additional fees and/or credit any overpayment to Deposit Account Number 13-0480 referencing Attorney Docket Number 24004350-304505.

Respectfully submitted,
BAKER & McKENZIE LLP

Date: September 8, 2014

/Matthew S. Dushek/

Matthew S. Dushek
Attorney of Record
Registration No. 61,921

815 Connecticut Ave NW
Washington, DC 20006
Phone: 202-835-6165
Fax: 202-416-7165

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		
	Filing Date		
	First Named Inventor	Neal Blitz, et al.	
	Art Unit		
	Examiner Name		
	Attorney Docket Number	24004350-304505	

U.S.PATENTS						Remove
Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	6206882	B1	2001-03-27	Cohen	
	2	7052499	B2	2006-05-30	Steger, et al.	
	3	6344042	B1	2002-02-05	Curtis, et al.	
	4	7344538	B2	2008-03-18	Myerson, et al.	
	5	4159716		1979-07-03	Borchers	
If you wish to add additional U.S. Patent citation information please click the Add button.						Add
U.S.PATENT APPLICATION PUBLICATIONS						Remove
Examiner Initial*	Cite No	Publication Number	Kind Code ¹	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20050234458	A1	2005-10-20	Huebner	

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number		
Filing Date		
First Named Inventor	Neal Blitz, et al.	
Art Unit		
Examiner Name		
Attorney Docket Number	24004350-304505	

2	20070265629	A1	2007-11-15	Martin, et al.	
3	20060241607	A1	2006-10-26	Myerson, et al.	
4	20060241608	A1	2006-10-26	Myerson, et al.	
5	20070239163	A1	2007-10-11	Strnad, et al.	
6	20060173459	A1	2006-08-03	Kay, et al.	
7	20070239163	A1	2007-10-11	Strnad, et al.	
8	20020128654	A1	2002-09-12	Steger, et al.	
9	20050065521	A1	2005-03-24	Steger, et al.	
10	20060241592	A1	2006-10-26	Myerson, et al.	

If you wish to add additional U.S. Published Application citation information please click the Add button. [Add](#)

FOREIGN PATENT DOCUMENTS								Remove
Examiner Initial*	Cite No	Foreign Document Number ³	Country Code ² ;	Kind Code ⁴	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T ⁵

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number		
Filing Date		
First Named Inventor	Neal Blitz, et al.	
Art Unit		
Examiner Name		
Attorney Docket Number	24004350-304505	

1	2006-280949	JP	A	2006-10-19	Depuy Products Inc.		☒
2	2006-280951	JP	A	2006-10-19	Depuy Products Inc.		☒
3	2905590	FR	A1	2008-03-14	Surge Foot		☒

If you wish to add additional Foreign Patent Document citation information please click the Add button **Add**

NON-PATENT LITERATURE DOCUMENTS

Remove

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, pages(s), volume-issue number(s), publisher, city and/or country where published.	T ⁵
	1	Australian Examination Report, AU Application No. 2009316867, dated March 20, 2014, 3 pages.	☐
	2	Japanese Office Action, dated October 1, 2013, JP Application No. 2011-537509, 6 pages.	☒
	3	Communication pursuant to Article 94(3) EPC, EP Application No. 09828045.6, dated June 11, 2013, 5 pages.	☐
	4	Communication pursuant to Article 94(3) EPC, EP Application No. 09828045.6, dated October 5, 2012, 5 pages.	☐
	5	MORTON, D.J., "The Human Foot: Its Evolution, Physiology and Functional Disorders," Columbia University Press, Morningside Heights, N.Y., 1935, Abstract provided.	☐
	6	Extended European Search report, EP Application No. 09828045.6, dated February 24, 2012, 10 pages.	☐

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		
	Filing Date		
	First Named Inventor	Neal Blitz, et al.	
	Art Unit		
	Examiner Name		
	Attorney Docket Number	24004350-304505	

	7	International Search Report, PCT/US2009/064150, date of mailing January 6, 2010, 2 pages.	☐
--	---	---	--------------------------

If you wish to add additional non-patent literature document citation information please click the Add button **Add**

EXAMINER SIGNATURE

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

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

¹ See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. ² Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). ³ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ Applicant is to place a check mark here if English language translation is attached.

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number	
Filing Date	
First Named Inventor	Neal Blitz, et al.
Art Unit	
Examiner Name	
Attorney Docket Number	24004350-304505

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	/Matthew S. Dushek/	Date (YYYY-MM-DD)	2014-09-08
Name/Print	Matthew S. Dushek	Registration Number	61921

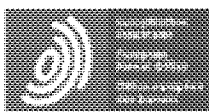
This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 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.**

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 Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.



Espacenet

Bibliographic data: FR2905590 (A1) — 2008-03-14

Arthrodesis plate for a metatarsal-phalanges joint

Inventor(s): ARNOULD HERVE CHARLES MARIE ± (ARNOULD HERVE CHARLES MARIE)

Applicant(s): SURGE FOOT [FR] ± (SURGE FOOT)

Classification: - **international:** A61B17/80
- **cooperative:** A61B17/8061; A61B17/80

Application number: FR20060007921 20060911

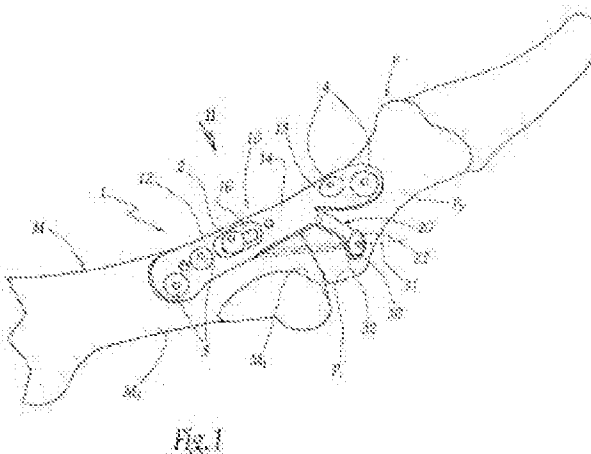
Priority number (s): FR20060007921 20060911

Also published as: FR2905590 (B1) EP1897509 (A1) EP1897509 (B1)
DK1897509 (T3) AT435620 (T)

Abstract not available for FR2905590 (A1)

Abstract of corresponding document: EP1897509 (A1)

The plate has an elongated plate body (10) fixed on respective upper faces of the metatarsal (M) and the phalange (P) and including an elongated lower lug (20) provided at a lateral side of an epiphysis (P1) of the phalange. The lug extends in length from a longitudinal side of the plate body and is provided, at its longitudinal end (22) opposite to the plate body, with a traversing hole adapted for receiving an elongated bone anchoring unit e.g. long screw, to be inserted into the phalange and the metatarsal.



①9 RÉPUBLIQUE FRANÇAISE
INSTITUT NATIONAL
DE LA PROPRIÉTÉ INDUSTRIELLE
PARIS

①1 N° de publication : **2 905 590**
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commandes de reproduction)

②1 N° d'enregistrement national : **06 07921**

⑤1 Int Cl⁸ : A 61 B 17/80 (2006.01)

⑫ **DEMANDE DE BREVET D'INVENTION** **A1**

②2 Date de dépôt : 11.09.06.

③0 Priorité :

④3 Date de mise à la disposition du public de la
demande : 14.03.08 Bulletin 08/11.

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

⑥0 Références à d'autres documents nationaux
apparentés :

⑦1 Demandeur(s) : *SURGE FOOT — FR.*

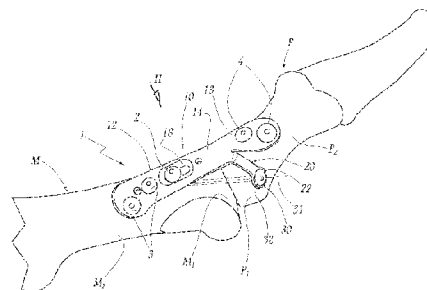
⑦2 Inventeur(s) : *ARNOULD HERVE CHARLES MARIE.*

⑦3 Titulaire(s) :

⑦4 Mandataire(s) : *LAVOIX.*

⑤4 **PLAQUE D'ARTHRODESE D'UNE ARTICULATION METATARSO- PHALANGIENNE.**

⑤7 Cette plaque d'arthrodèse (1) comporte un corps de plaque allongé (10) adapté pour être mis en place et fixé sur la face supérieure du métatarsien (M) et de la phalange (P) reliés par l'articulation à bloquer par arthrodèse, de manière à s'étendre à cheval sur l'articulation. Pour faciliter et pérenniser la fixation de la plaque, le corps de plaque est muni d'une patte allongée (20) de fixation à une face latérale de l'épiphyse (P₁) de la phalange (P), laquelle patte s'étend en longueur depuis un côté longitudinal du corps de plaque et est pourvue, à son extrémité longitudinale (22) opposée au corps de plaque, d'un trou traversant adapté pour recevoir une vis longue (30) d'ancrage osseux dans, à la fois, la phalange et le métatarsien.



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La présente invention concerne une plaque d'arthrodèse d'une articulation métatarso-phalangienne, notamment pour l'articulation entre le premier métatarsien et la première phalange du gros orteil. L'invention concerne également une
5 méthode chirurgicale de pose d'une telle plaque d'arthrodèse.

Lorsqu'une articulation métatarso-phalangienne souffre d'arthrose ou de déformations, dans certains cas iatrogènes, il est fréquent de fusionner le métatarsien et
10 la phalange reliés par cette articulation, c'est-à-dire de bloquer définitivement cette articulation. A cet effet, on utilise généralement une plaque d'arthrodèse, se présentant sous la forme d'un corps allongé globalement plan, mis en place contre les faces supérieures du métatarsien et de la
15 phalange, à cheval sur l'articulation à bloquer. La partie métatarsienne et la partie phalangienne de ce corps comportent respectivement un ou plusieurs trous traversants, dans chacun desquels on introduit, selon une direction globalement verticale, une vis d'ancrage osseux
20 dans, respectivement, le métatarsien et la phalange. Un exemple de ce genre de plaque est donné dans EP-A-1 297 793.

Ce genre de plaque présente plusieurs inconvénients. En particulier, juste avant d'immobiliser définitivement la
25 plaque contre le métatarsien et la phalange, il est généralement nécessaire de rapprocher ces deux os l'un de l'autre, de manière à les rendre sensiblement jointifs au niveau de leur extrémité en regard, préalablement réséquée. Les gestes chirurgicaux correspondants sont délicats, dans
30 le sens où, tout en maintenant jointifs le métatarsien et la phalange, le chirurgien doit visser fermement à la fois une vis dans la partie métatarsienne du corps de plaque et une autre vis dans la partie phalangienne. Les risques d'un positionnement non optimal des deux os à fusionner sont

réels, impliquant une éventuelle gêne ultérieure pour le patient. Par ailleurs, la fixation de la plaque tend, à la longue, à s'altérer : lorsque le patient marche, ses articulations métatarso-phalangiennes sont soumises à un mouvement de flexion lié à l'appui progressif de sa voûte plantaire, depuis le talon jusqu'aux orteils. Pour l'articulation bloquée par la plaque, la contrainte de flexion est essentiellement encaissée par cette plaque, ce qui, par répétition cyclique de cette contrainte, fragilise l'ancrage osseux des vis retenant la plaque contre les os fusionnés.

Le but de la présente invention vise à remédier à ces inconvénients, en proposant une plaque d'arthrodèse dont la fixation est simple et pérenne.

A cet effet, l'invention a pour objet une plaque d'arthrodèse d'une articulation métatarso-phalangienne, comportant un corps de plaque allongé adapté pour être mis en place et fixé sur les faces supérieures respectives du métatarsien et de la phalange reliés par l'articulation à bloquer par arthrodèse, de manière à s'étendre en longueur à cheval sur l'articulation, caractérisée en ce que le corps de plaque est muni d'une patte allongée de fixation à une face latérale de l'épiphyse de la phalange, laquelle patte s'étend en longueur depuis un côté longitudinal du corps de plaque et est pourvue, à son extrémité longitudinale opposée au corps de plaque, d'un trou traversant adapté pour recevoir un moyen allongé d'ancrage osseux dans, à la fois, la phalange et le métatarsien, tel qu'une vis longue.

La patte de la plaque selon l'invention permet de fixer la plaque sur une face latérale de l'épiphyse de la phalange, c'est-à-dire, anatomiquement parlant, sur la face médiale de la base phalangienne. Cette zone épiphysaire de l'os est généralement solide, permettant la mise en place

d'un moyen d'ancrage s'enfonçant profondément dans la matière osseuse. En pratique, lorsque la plaque selon l'invention est implantée au niveau de l'articulation reliant le premier métatarsien et la première phalange du gros orteil, cette patte est fixée à la face interne de l'épiphyse phalangienne, c'est-à-dire la face osseuse dirigée vers le plan sagittal médian du patient, notamment car cette face présente un abord chirurgical aisé. De plus, cette patte est conformée pour que son trou d'extrémité puisse recevoir une vis longue, ou plus généralement un moyen allongé d'ancrage osseux, qui va s'étendre à la fois à travers la matière osseuse de la phalange et dans la matière osseuse du métatarsien, en particulier dans les épiphyses en regard de ces os. On comprend que cette vis longue s'étend en longueur dans une direction présentant une composante antéro-postérieure, de sorte que cette vis encaisse essentiellement, voire exclusivement les contraintes de flexion générées lors de la marche du patient, étant remarqué que, en raison de sa position, la vis travaille principalement en traction. Comme cette vis présente, de par sa structure et sa zone d'implantation, une capacité à s'opposer aux contraintes de flexion nettement plus élevée que celle du corps de la plaque, l'implantation de la plaque est stable dans le temps. Par ailleurs, lors de l'introduction de la vis longue dans le trou d'extrémité de la patte, cette vis tend à générer d'elle-même un effet de rappel du métatarsien vers la phalange lorsque la pointe de la vis atteint et progresse dans la matière osseuse du métatarsien. D'un seul geste, consistant à visser intégralement cette vis longue, le chirurgien rapproche ainsi automatiquement les deux os à fusionner l'un de l'autre, puis il immobilise totalement le corps de plaque sur le métatarsien pour bloquer l'articulation. On comprend que les deux os rendus ainsi

jointifs sont fixés l'un par rapport à l'autre de manière prédéterminée, en fonction de la direction dans laquelle le chirurgien introduit la vis longue dans le trou d'extrémité de la patte conforme à l'invention. Ce trou aide donc le
5 chirurgien, dans le sens où il lui fixe le point d'application de la vis, tout en limitant le risque que la pointe de cette vis s'en écarte, notamment par ripement contre la face latérale de la phalange.

Suivant d'autres caractéristiques avantageuses de
10 cette plaque d'arthrodèse, prises isolément ou suivant toutes les combinaisons techniquement possibles :

- selon une direction d'observation sensiblement verticale lorsque la plaque est implantée, la patte s'étend suivant une direction longitudinale qui forme avec la
15 direction longitudinale du corps de plaque un angle compris entre 20 et 60°, de préférence égal à 40° +/- 1° ;

- le trou traversant de la patte est adapté pour recevoir le moyen d'ancrage osseux dans une position dans laquelle, selon une direction d'observation sensiblement
20 verticale lorsque la plaque est implantée, la direction longitudinale de ce moyen d'ancrage, tel que l'axe central d'une vis longue, forme avec la direction longitudinale du corps de plaque un angle inférieur à 45° ;

- la patte est pliée selon au moins une ligne de
25 pliage sensiblement perpendiculaire à la direction longitudinale de la patte ;

- le corps de plaque comprend, suivant sa longueur, une partie métatarsienne et une partie phalangienne, respectivement adaptées pour être mises en
30 place et fixées sur les faces supérieures du métatarsien et de la phalange, et la patte s'étend depuis la partie phalangienne, en étant de préférence monobloc avec cette dernière ;

- la partie métatarsienne est pourvue d'un orifice traversant oblong dont la direction longitudinale est sensiblement parallèle à la direction longitudinale du corps de plaque ;

5 - la partie métatarsienne inclut, d'une part, du même côté longitudinal du corps de plaque que la patte, une section cintrée, dont la face concave est adaptée pour venir au contact et pour envelopper la face supérieure bombée de la diaphyse métatarsienne, et, d'autre part, une
10 section sensiblement plane reliant la section cintrée à la partie phalangienne ;

- la section cintrée et la section sensiblement plane de la partie métatarsienne sont pliées l'une par rapport à l'autre selon une ligne de pliage qui, selon une direction
15 d'observation sensiblement verticale lorsque la plaque est implantée, forme avec la direction longitudinale du corps de plaque un angle compris entre 10 et 20°, des valeurs homothétiques de cet angle étant de préférence prévues entre les bornes 12° et 18° pour un jeu de plaques
20 d'arthrodèse présentant des tailles respectives différentes ;

- la partie phalangienne inclut, d'une part, du même côté longitudinal du corps de plaque que la patte, une section cintrée, dont la face concave est adaptée pour
25 venir au contact et pour envelopper la face supérieure bombée de la diaphyse phalangienne, et, d'autre part, une section sensiblement plane reliant la section cintrée à la partie métatarsienne ;

- la section cintrée et la section sensiblement
30 plane de la partie phalangienne sont pliées l'une par rapport à l'autre selon une ligne de pliage qui, selon une direction d'observation sensiblement verticale lorsque la plaque est implantée, forme avec la direction longitudinale

du corps de plaque un angle compris entre 15 et 25°, de préférence égal à 20° +/- 1°.

L'invention a également pour objet une méthode de pose d'une plaque d'arthrodèse d'une articulation métatarso-phalangienne, laquelle plaque comporte un corps de plaque allongé muni d'une patte allongée qui s'étend en longueur depuis un côté longitudinal du corps de plaque et qui est pourvue, à son extrémité longitudinale opposée au corps de plaque, d'un trou traversant, ladite méthode comprenant les
10 gestes chirurgicaux successifs consistant à :

- inciser et dégager des parties molles entourant l'articulation à bloquer par arthrodèse,

- mettre en place le corps de plaque sur les faces supérieures du métatarsien et de la phalange reliés par l'articulation, de manière que le trou de la patte débouche
15 sur une face latérale de l'épiphyse de la phalange,

- immobiliser partiellement le corps de plaque sur le métatarsien, en autorisant une liberté de mouvements relatifs suivant globalement la direction longitudinale du
20 corps de plaque,

- introduire un moyen allongé d'ancrage osseux dans le trou de la patte, tel qu'une vis longue, et ancrer ce moyen dans successivement l'épiphyse de la phalange et le métatarsien, jusqu'à ce qu'une tête d'extrémité du moyen
25 d'ancrage vienne buter contre la patte, au niveau du bord de son trou,

- poursuivre l'ancrage du moyen d'ancrage de manière à provoquer le rapprochement du métatarsien de la phalange, par un déplacement du métatarsien par rapport au corps de plaque suivant globalement la direction longitudinale de ce
30 corps de plaque,

- immobiliser définitivement le corps de plaque sur le métatarsien et la phalange, et

- fermer l'incision.

Suivant une caractéristique avantageuse de cette méthode, on fixe le corps de plaque sur la face supérieure de la phalange soit avant, soit après avoir immobilisé partiellement le corps de plaque sur le métatarsien.

5 L'invention sera mieux comprise à la lecture de la description qui va suivre, donnée uniquement à titre d'exemple et faite en se référant aux dessins sur lesquels :

- la figure 1 est une vue en perspective d'une plaque d'arthrodèse selon l'invention, mise en place et
10 fixée sur une articulation métatarso-phalangienne bloquée par la plaque ;

- la figure 2 est une vue de la plaque de la figure 1, observée selon la flèche II de la figure 1, qui
15 correspond à une direction d'observation sensiblement verticale ;

- les figures 3 à 6 sont des vues en élévation, prises respectivement selon les flèches III à VI de la figure 2 ; et

20 - la figure 7 est une coupe partielle de la plaque, selon la ligne VII-VII de la figure 2.

Sur la figure 1 est représentée une plaque 1 d'arthrodèse d'une articulation entre le premier métatarsien M et la première phalange P du gros orteil d'un
25 pied gauche. Par commodité, la suite de la description est orientée par rapport au patient dont les os du gros orteil sont représentés à la figure 1, ce patient se tenant debout sur un sol horizontal. Ainsi, les termes « inférieur » et « bas » désignent une direction sensiblement verticale
30 dirigée vers le sol, tandis que les termes « supérieur » et « haut » désignent une direction de sens opposé. De même, le terme « intérieur » désigne une direction sensiblement horizontale dirigée vers le plan sagittal médian du patient, tandis que le terme « extérieur » désigne une

direction de sens opposé. Les termes « avant », « arrière » et analogues s'entendent également par rapport au patient.

En pratique, la plaque 1 considérée aux figures appartient avantageusement à un jeu de plusieurs plaques
5 d'arthrodèse, ayant des tailles respectives sensiblement homothétiques. La plaque 1 représentée est la plus appropriée au patient, notamment à la taille de son métatarsien M et de sa phalange P.

La plaque 1 comporte essentiellement, d'une part, un
10 corps de plaque 10 présentant une forme allongée suivant une direction globalement antéro-postérieure et, d'autre part, une patte allongée intérieure 20.

Comme représenté plus en détail sur les figures 2 à 7, dans la configuration d'implantation de la plaque 1, le
15 corps de plaque 10 inclut successivement, suivant sa direction longitudinale 11, une partie métatarsienne 12 et une partie phalangienne 13, qui sont respectivement adaptées pour être mises en place et fixées sur le métatarsien M et la phalange P, avec leur face inférieure
20 plaquée contre, respectivement, les surfaces supérieures du métatarsien et de la phalange. La zone 14 de jonction entre les parties 12 et 13 est prévue pour surplomber la zone de jointement entre les extrémités épiphysaires en regard M_1 et P_1 du métatarsien M et de la phalange P, de sorte que le
25 corps de plaque 10 s'étend à cheval sur l'articulation métatarso-phalangienne selon la direction 11.

Sur le côté longitudinal intérieur 10A du corps de plaque 10, la partie métatarsienne 12 comprend une section cintrée 12₁ reliée à la zone de jonction 14 par une section
30 sensiblement plane 12₂ de cette partie 12. Ces sections 12₁ et 12₂ sont pliées l'une par rapport à l'autre le long d'une ligne de pliage 12₃ s'étendant dans le prolongement rectiligne de la flèche III. La surface inférieure concave 12_{1A} de la section cintrée 12₁, bien visible à la figure 3,

est conformée pour épouser la face supérieure de la partie diaphysaire M_2 du métatarsien M , c'est-à-dire pour venir au contact de cette diaphyse, tout en la recouvrant partiellement de manière ajustée, comme représenté sur la figure 1. La surface inférieure sensiblement plate 12_{2A} de la section plane 12_2 est prévue pour recouvrir la zone dorsale de la diaphyse métatarsienne M_2 et, surtout, l'épiphyse métatarsienne M_1 qui a été réséquée préalablement à la mise en place de la plaque. Autrement dit, on comprend que la surface 12_{2A} est prévue pour être mise en place contre une zone surfacique globalement plate de la face supérieure du métatarsien M , tandis que la surface 12_{1A} recouvre une zone métatarsienne bombée.

Eu égard à la forme anatomique du métatarsien M , la ligne de pliage 12_3 forme, selon la direction d'observation de la flèche II, un angle γ_M non nul avec la direction longitudinale 11 du corps de plaque 10. Avantageusement, pour permettre un bon ajustement des surfaces inférieures 12_{1A} et 12_{2A} avec la face supérieure du métatarsien, cet angle γ_M est compris entre 10° et 20° , étant remarqué que des valeurs homothétiques de γ_M sont avantageusement prévues entre les bornes 12° et 18° pour le jeu des plaques de tailles respectives différentes.

Également sur le côté longitudinal intérieur 10A du corps de plaque 10, la partie phalangienne 13 comprend une section cintrée 13_1 reliée à la zone de jonction 14 par une section sensiblement plane 13_2 de cette partie 13. Ces sections 13_1 et 13_2 sont pliées l'une par rapport à l'autre selon une ligne de pliage 13_3 qui s'étend dans le prolongement rectiligne de la flèche IV. Par analogie avec les explications précédentes concernant les sections 12_1 et 12_2 de la partie métatarsienne 12, on comprend que la surface inférieure concave 13_{1A} de la section cintrée 13_1 ,

bien visible à la figure 4, est dimensionnée pour venir épouser la face médiale bombée de la diaphyse phalangienne P_2 , tandis que la surface inférieure 13_{2A} de la section 13_2 recouvre la face dorsale de cette diaphyse et, surtout,
 5 l'épiphyse phalangienne P_1 , comme représenté à la figure 1.

Pour des raisons anatomiques, la ligne de pliage 13_3 est, selon la direction d'observation correspondant à la flèche II, inclinée par rapport à la direction 11, en formant avantageusement avec cette dernière un angle non
 10 nul γ_p compris entre 15 et 25°. De préférence, l'angle γ_p est égal à 20° +/- 1°.

Selon la direction d'observation correspondant à la flèche II, les lignes de pliage 12_3 et 13_3 forment globalement un V dont la pointe est dirigée vers
 15 l'intérieur.

Selon une direction d'observation médio-latérale, comme celle correspondant à la flèche V, on note que les sections planes métatarsienne 12_2 et phalangienne 13_2 ne s'étendent pas dans le prolongement rectiligne l'une de
 20 l'autre, mais forment au contraire un angle non nul, noté α à la figure 5. A cet effet, les parties métatarsienne 12 et phalangienne 13 sont pliées l'une par rapport à l'autre au niveau de leur zone de jonction 14 , selon une ligne de pliage 14_1 sensiblement perpendiculaire à la direction
 25 longitudinale 11. Grâce à cette disposition, la partie phalangienne 13 est inclinée vers le haut dans un plan vertical par rapport à la partie métatarsienne 12, ce qui garantit une meilleure adaptation du corps de plaque 10 à l'anatomie de l'articulation métatarso-phalangienne
 30 lorsqu'elle est bloquée. En effet, la phalange P est alors immobilisée par rapport au métatarsien M avec un angle de dorsi-flexion non nul, correspondant à l'angle α .

Pour permettre la fixation du corps de plaque 10 au métatarsien M et à la phalange P, ce corps est pourvu d'une

série de trous traversants, adaptés chacun pour recevoir de manière complémentaire une vis d'ancrage osseux ou un moyen mécanique analogue. Avantageusement, chacune des sections 12₁, 12₂, 13₁ et 13₂ est munie d'au moins un de ces trous, 5 respectivement référencés 15₁, 15₂, 15₃ et 15₄. De la sorte, lors du vissage de vis dans ces trous, les surfaces inférieures respectives 12_{1A}, 12_{2A}, 13_{1A} et 13_{2A} de ces sections sont fermement appliquées contre les os.

La partie métatarsienne 12 est en outre munie d'un 10 orifice traversant 16 de forme oblongue, dont la direction longitudinale est sensiblement parallèle à la direction longitudinale 11 du corps de plaque 10. L'intérêt de cet orifice oblong sera mis en évidence plus loin, lors de la description de la pose de la plaque d'arthrodèse 1.

15 La patte 20, également située du côté longitudinal intérieur 10A du corps de plaque 10, s'étend en longueur depuis la partie phalangienne 13. Comme représenté à la figure 1, cette patte est conformée pour envelopper l'épiphyse phalangienne P₁, au plus proche de la matière 20 osseuse, incluant son extrémité libre 22, c'est-à-dire son extrémité longitudinale opposée au corps de plaque 10. La patte 20 donne ainsi l'impression de plonger vers le bas par rapport au corps de plaque 10, de manière que son extrémité 22, située verticalement au-dessous de ce corps 25 de plaque dans la configuration d'implantation de la plaque 1, soit plaquée contre la face latérale intérieure de l'épiphyse phalangienne P₁.

A cet effet, la patte 20 est pliée vers le bas par rapport au corps de plaque 10 le long d'une ligne de pliage 30 23 sensiblement perpendiculaire à la direction longitudinale 21 et située au niveau de la jonction entre la patte et la partie phalangienne 13. La patte 20 est également pliée sur elle-même selon une autre ligne de pliage 24 sensiblement perpendiculaire à la direction 21 et

située à la jonction entre son extrémité 22 et le reste de la plaque. La forme pliée de la patte 20 est bien visible à la figure 6, dont la direction d'observation, qui correspond à la flèche VI de la figure 2, est alignée avec la ligne de pliage 23.

Selon la direction d'observation correspondant à la flèche II, la patte 20 est inclinée par rapport au corps de plaque 10 : sa direction longitudinale 21 forme un angle non nul β avec la direction longitudinale 11 du corps de plaque, comme indiqué à la figure 2. Pour des raisons anatomiques, cet angle β est compris entre 20 et 60°. De préférence, l'angle β est égal à 40° +/- 1°, ce qui permet de disposer de la patte 20 sans que cette dernière ne limite trop l'étendue transversale de la partie phalangienne 13, tout en enveloppant au plus près l'épiphyse phalangienne P₁.

A son extrémité 22, la patte 20 est pourvue d'un trou traversant 25 adapté pour recevoir une vis 30 ou, plus généralement, un moyen allongé d'ancrage osseux analogue. Cette vis 30 est une vis longue dans le sens où, comme représenté en pointillés à la figure 1, elle présente une longueur suffisante pour s'étendre depuis le trou 25 à la fois dans l'épiphyse phalangienne P₁ et dans l'épiphyse métatarsienne M₁, voire également dans la diaphyse métatarsienne M₂.

Le trou 25 est prévu pour recevoir la vis 30 de sorte que, selon la direction d'observation correspondant à la flèche II, l'axe longitudinal 31 de cette vis puisse être incliné par rapport à la direction longitudinale 11 du corps de plaque 10, en formant avec cette direction 11 un angle non nul δ . On comprend que plus cet angle δ est petit, plus l'axe 31 de la vis 30 tend à s'aligner avec une direction antéro-postérieure, garantissant une profondeur de pénétration de la vis dans le métatarsien plus

importante, à longueur de vis donnée. En pratique, pour permettre de visser et de bloquer la vis 30 avec son axe 31 incliné par rapport à l'axe central 25₁ du trou 25, le bord 25₂ de ce trou présente, du côté tourné vers la tête 32 de la vis, une surface concave, sensiblement complémentaire d'une surface associée délimitée par cette tête de vis. De la sorte, lorsque la vis 31 est totalement introduite dans le trou 25, sa tête 32 vient prendre appui et se coincer contre au moins une portion du bord 25₂, même si son axe 31 est incliné par rapport à l'axe 25₁ du trou.

Pour des raisons anatomiques, l'angle δ est avantageusement choisi inférieur à 45°. Dans l'exemple considéré aux figures, cet angle vaut environ 20°.

Sur son côté longitudinal extérieur 10B, le corps de plaque 10 est chanfreiné, comme représenté à la figure 7. Le chanfrein correspondant 17, globalement plat, est tourné vers le haut dans la configuration d'implantation de la plaque 1. De la sorte, lorsque la plaque est implantée, les risques que cette dernière gêne, voire ne presse significativement le tendon extenseur de l'articulation métatarso-phalangienne sont limités.

Une méthode de pose de la plaque d'arthrodèse 1 est la suivante. Après avoir incisé et dégagé les parties molles entourant l'articulation à bloquer, le chirurgien résèque en partie les épiphyses métatarsienne M₁ et phalangienne P₁, afin de supprimer des irrégularités osseuses telles que des renflements d'arthrose présents dans l'articulation.

Après avoir choisi, parmi le jeu de plusieurs plaques d'arthrodèse homothétiques, la plaque 1 dont la taille est la plus appropriée au patient opéré, le chirurgien met ensuite en place la plaque sur les os M et P : le corps de plaque 10 est placé sur les faces supérieures de ces os, tandis que l'extrémité 22 de la patte 20 est placée contre la face latérale intérieure de l'épiphyse phalangienne P₁,

c'est-à-dire, anatomiquement, sa face médiale. Le corps de plaque 10 est ensuite partiellement immobilisé en utilisant l'orifice oblong 16 : le chirurgien introduit une vis 2 (figure 1) dans l'orifice 16, du côté du fond arrière 16₂ de cet orifice, sans serrer la tête de vis contre le bord de l'orifice. De la sorte, le corps de plaque 10 reste déplaçable selon la direction 11 par rapport au métatarsien M.

La vis 30 est ensuite introduite dans le trou 25, suivant une direction d'introduction inclinée par rapport au corps de plaque 10 sous l'angle δ dont la valeur est choisie par le chirurgien pour que cette vis, lors de son vissage, traverse successivement l'épiphyse phalangienne P₁ et l'épiphyse métatarsienne M₁, comme expliqué plus haut. Le vissage de la vis 30 est poursuivi jusqu'à ce que la tête 32 de cette vis vienne buter, selon son axe 31, contre le bord 25₂ du trou 25. En poursuivant le vissage, la vis 30 provoque le rapprochement du métatarsien M par rapport à la phalange P, ce mouvement de rapprochement étant guidé le long de la direction 11 par la coopération de l'orifice oblong 16 et de la vis non serrée 2. Le fond avant 16₁ de l'orifice 16 progresse alors vers l'arrière vis-à-vis de la vis 2, qui se retrouve alors progressivement du côté de ce fond avant 16₁. Le chirurgien poursuit ainsi le vissage de la vis 30 jusqu'à rendre sensiblement jointifs les extrémités épiphysaires M₁ et P₁ des os. On comprend que la direction d'introduction de la vis 30 dans le trou 25 conditionne le positionnement relatif du métatarsien et de la phalange à leur fusion.

La vis 2 est ensuite totalement vissée et serrée dans l'orifice 16, de manière à immobiliser complètement le corps de plaque 10 sur le métatarsien M. Cette fixation est renforcée en vissant des vis 3 dans les trous 15₁ et 15₂.

Avant ou après avoir ainsi immobilisé le corps de plaque 10 vis-à-vis du métatarsien M, d'autres vis 4 sont introduites dans les trous 15₃ et 15₄, de manière à fixer la partie phalangienne 13 sur la phalange P.

5 Le chirurgien ferme enfin l'incision.

En pratique, le chirurgien dispose bien entendu de plaques d'arthrodèse pour articulation métatarso-phalangienne du pied droit : ces plaques présentent une structure symétrique à celle de la plaque 1 par rapport à
10 un plan vertical médian à cette dernière.

Avantageusement, pour faciliter le choix de la taille de la plaque à implanter, le chirurgien dispose en outre d'un jeu de fantômes de plaque d'arthrodèse : chaque fantôme présente des contours extérieurs identiques à ceux
15 d'une des plaques d'arthrodèse disponibles dans le jeu à sa disposition, de sorte que, après avoir incisé le patient et effectué des premières résections osseuses, le chirurgien met en place l'un de ces fantômes, d'une part, pour sélectionner la taille d'implant la plus appropriée et,
20 d'autre part, pour s'assurer que les résections sont suffisantes, notamment au niveau de la zone de coaptation entre plaque d'une part et métatarsien et phalange d'autre part.

Par ailleurs, lors de la mise en place de la plaque 1,
25 le chirurgien a avantageusement la possibilité de modifier l'angle α pour ajuster au mieux cet angle avec l'angle anatomique de dorsi-flexion entre le métatarsien M et la phalange P du patient opéré, en tenant compte notamment des résections osseuses et de la morphologie générale des os du
30 patient, ainsi que des habitudes de chaussage et plus particulièrement la hauteur du talon de la chaussure.

La fabrication de la plaque 1 est réalisée à partir d'une plaque plane métallique. Cette plaque est, dans un premier temps, découpée suivant des contours prédéterminés

afin d'obtenir les parties métatarsienne 12 et phalangienne 13, ainsi que la patte 20. Dans un second temps, les différents trous 15₁ à 15₄ et l'orifice oblong 16 sont percés. Dans un troisième temps, les sections 12₁ et 13₁ sont cintrées, tandis que la plaque est pliée le long des lignes 12₃, 13₃, 23 et 24.

Divers aménagements et variantes à la plaque 1 décrite ci-dessus, ainsi qu'à sa méthode de pose sont envisageables. A titre d'exemples :

- 10 - la face inférieure de la plaque est grenailée ou, de manière plus générale, subit un traitement de surface, afin de favoriser une colonisation osseuse une fois que la plaque est implantée ; et/ou
- le nombre de trous 15₁ à 15₄ peut être modifié,
- 15 notamment en fonction de la taille longitudinale du corps de plaque 10.

REVENDICATIONS

1. Plaque (1) d'arthrodèse d'une articulation
5 métatarso-phalangienne, comportant un corps de plaque
allongé (10) adapté pour être mis en place et fixé sur les
faces supérieures respectives du métatarsien (M) et de la
phalange (P) reliés par l'articulation à bloquer par
arthrodèse, de manière à s'étendre en longueur à cheval sur
10 l'articulation,

caractérisée en ce que le corps de plaque (10) est muni
d'une patte allongée (20) de fixation à une face latérale
de l'épiphyse (P_1) de la phalange (P), laquelle patte
s'étend en longueur depuis un côté longitudinal (10A) du
15 corps de plaque et est pourvue, à son extrémité
longitudinale (22) opposée au corps de plaque, d'un trou
traversant (25) adapté pour recevoir un moyen allongé (30)
d'ancrage osseux dans, à la fois, la phalange (P) et le
métatarsien (M), tel qu'une vis longue.

20 2. Plaque selon la revendication 1, caractérisée en ce
que, selon une direction d'observation (flèche II)
sensiblement verticale lorsque la plaque (1) est implantée,
la patte (20) s'étend suivant une direction longitudinale
(21) qui forme avec la direction longitudinale (11) du
25 corps de plaque (10) un angle (β) compris entre 20 et 60°,
de préférence égal à 40° +/- 1°.

3. Plaque selon l'une des revendications 1 ou 2,
caractérisée en ce que le trou traversant (25) de la patte
(20) est adapté pour recevoir le moyen d'ancrage osseux
30 (30) dans une position dans laquelle, selon une direction
d'observation (flèche II) sensiblement verticale lorsque la
plaque (1) est implantée, la direction longitudinale (31)
de ce moyen d'ancrage, tel que l'axe central d'une vis

longue, forme avec la direction longitudinale (11) du corps de plaque (10) un angle (8) inférieur à 45°.

4. Plaque selon l'une quelconque des revendications précédentes, caractérisée en ce que la patte (20) est pliée
5 selon au moins une ligne de pliage (23, 24) sensiblement perpendiculaire à la direction longitudinale (21) de la patte.

5. Plaque selon l'une quelconque des revendications précédentes, caractérisée en ce que le corps de plaque (10)
10 comprend, suivant sa longueur, une partie métatarsienne (12) et une partie phalangienne (13), respectivement adaptées pour être mises en place et fixées sur les faces supérieures du métatarsien (M) et de la phalange (P), et en ce que la patte (20) s'étend depuis la partie phalangienne
15 (13), en étant de préférence monobloc avec cette dernière.

6. Plaque selon la revendication 5, caractérisée en ce que la partie métatarsienne (12) est pourvue d'un orifice traversant oblong (16) dont la direction longitudinale est sensiblement parallèle à la direction longitudinale (11) du
20 corps de plaque (10).

7. Plaque selon l'une des revendications 5 ou 6, caractérisée en ce que la partie métatarsienne (12) inclut, d'une part, du même côté longitudinal (10A) du corps de plaque (10) que la patte (20), une section cintrée (12₁),
25 dont la face concave (12_{1A}) est adaptée pour venir au contact et pour envelopper la face supérieure bombée de la diaphyse métatarsienne (M₂), et, d'autre part, une section sensiblement plane (12₂) reliant la section cintrée à la partie phalangienne (13).

30 8. Plaque selon la revendication 7, caractérisée en ce que la section cintrée (12₁) et la section sensiblement plane (12₂) de la partie métatarsienne (12) sont pliées l'une par rapport à l'autre selon une ligne de pliage (12₃) qui, selon une direction d'observation (flèche II)

sensiblement verticale lorsque la plaque (1) est implantée, forme avec la direction longitudinale (11) du corps de plaque (10) un angle (γ_M) compris entre 10 et 20°, des valeurs homothétiques de cet angle étant de préférence
5 prévues entre les bornes 12° et 18° pour un jeu de plaques d'arthrodèse présentant des tailles respectives différentes.

9. Plaque selon l'une quelconque des revendications 5 à 8, caractérisée en ce que la partie phalangienne (13) inclut, d'une part, du même côté longitudinal (10A) du
10 corps de plaque (10) que la patte (20), une section cintrée (13₁), dont la face concave (13_{1A}) est adaptée pour venir au contact et pour envelopper la face supérieure bombée de la diaphyse phalangienne (P₂), et, d'autre part, une section
15 sensiblement plane (13₂) reliant la section cintrée à la partie métatarsienne (12).

10. Plaque selon la revendication 9, caractérisée en ce que la section cintrée (13₁) et la section sensiblement plane (13₂) de la partie phalangienne (13) sont pliées l'une
20 par rapport à l'autre selon une ligne de pliage (13₃) qui, selon une direction d'observation (flèche II) sensiblement verticale lorsque la plaque (1) est implantée, forme avec la direction longitudinale (11) du corps de plaque (10) un angle (γ_P) compris entre 15 et 25°, de préférence égal à
25 20° +/- 1°.

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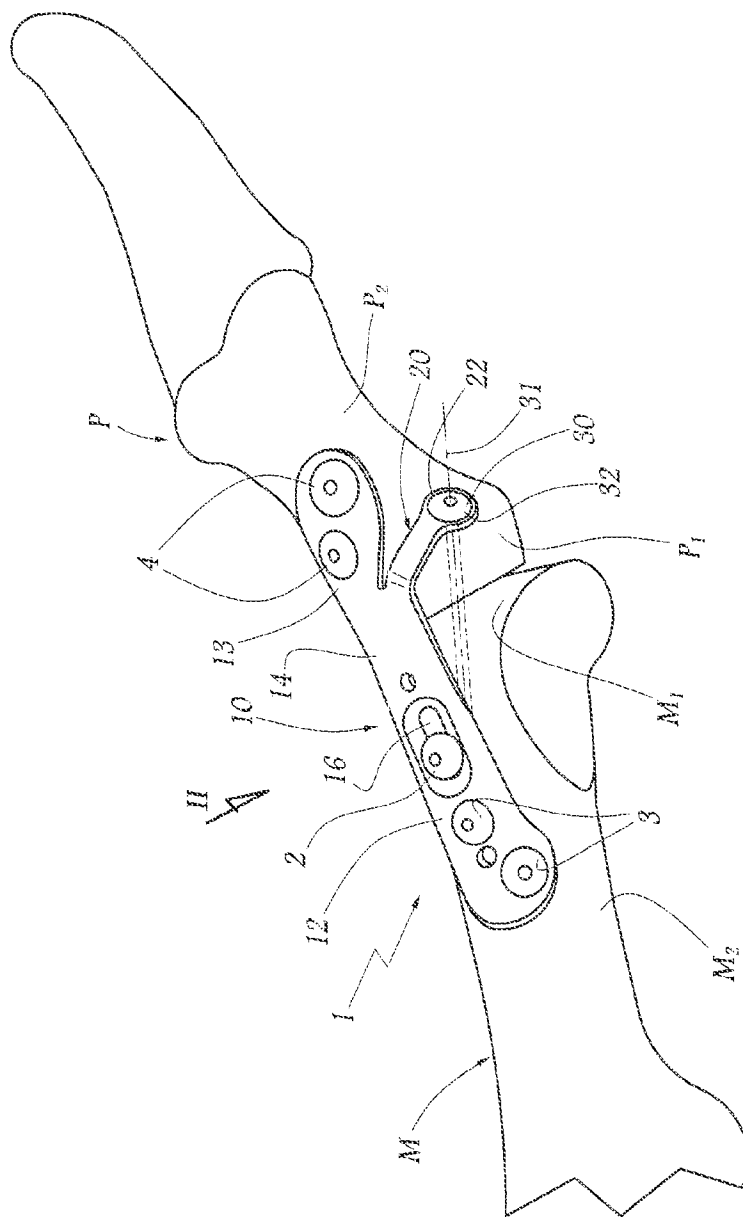


Fig. 1

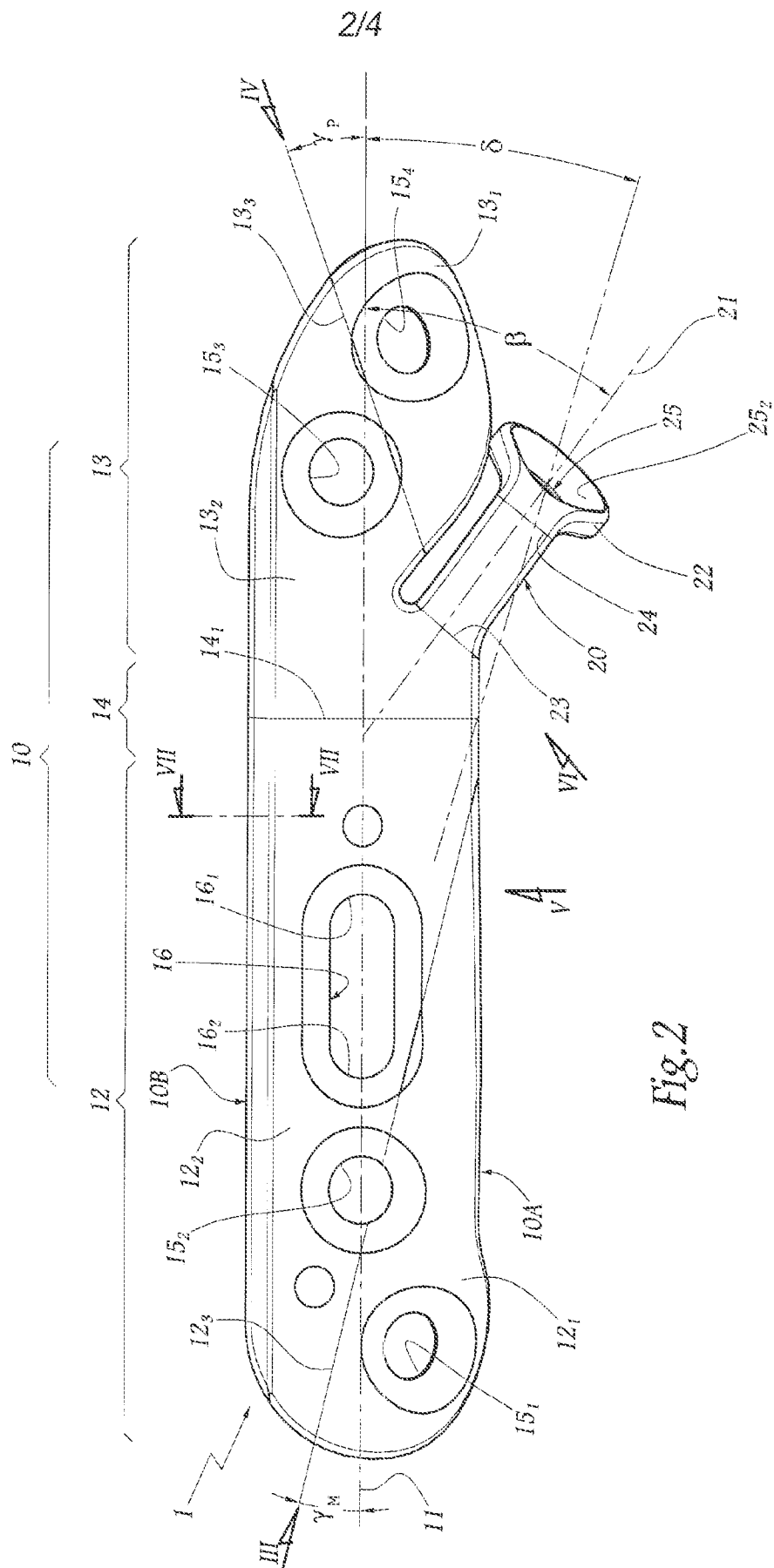
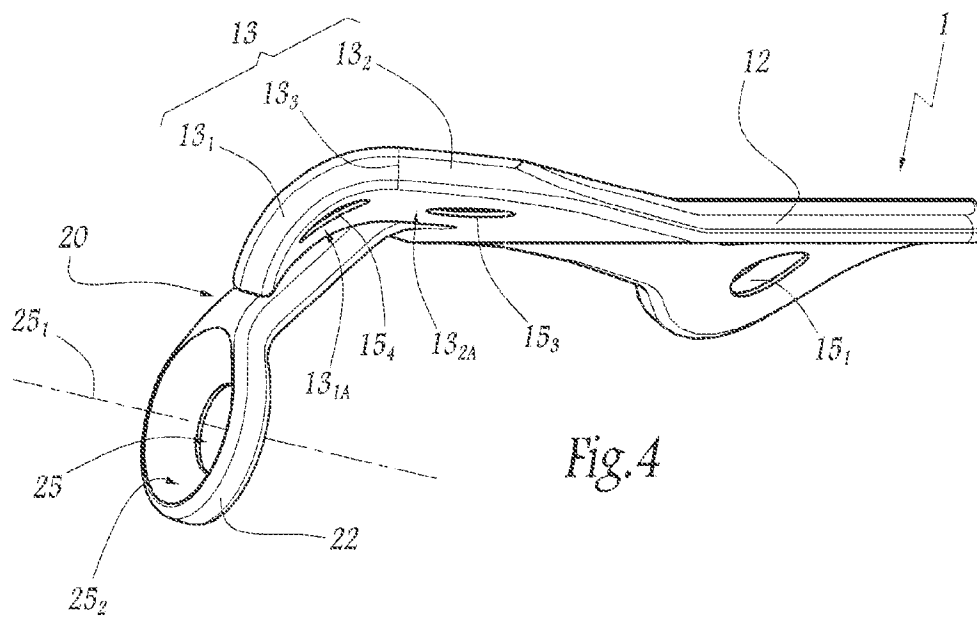
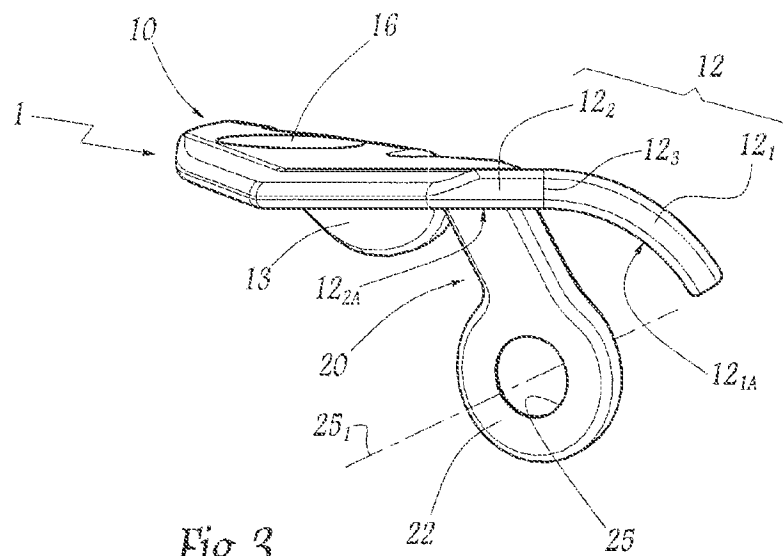
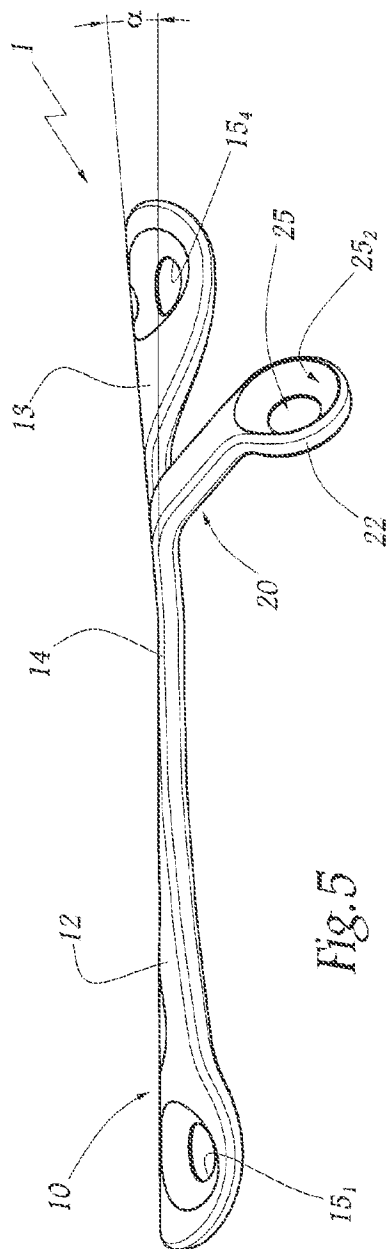


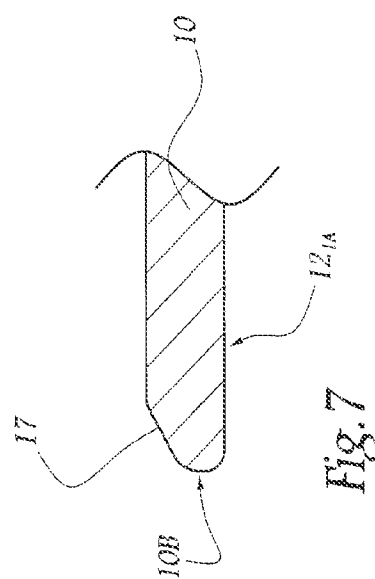
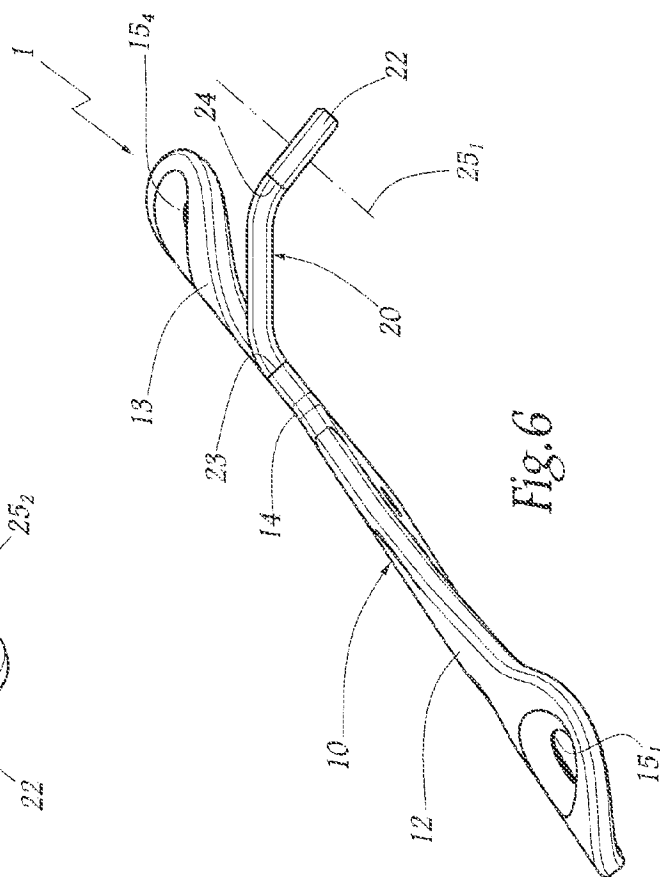
Fig. 2

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RAPPORT DE RECHERCHE PRÉLIMINAIRE

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

N° d'enregistrement
national

FA 684316
FR 0607921

DOCUMENTS CONSIDÉRÉS COMME PERTINENTS		Revendication(s) concernée(s)	Classement attribué à l'invention par l'INPI
Catégorie	Citation du document avec indication, en cas de besoin, des parties pertinentes		
A	EP 1 297 793 A1 (NEWDEAL S A [FR]) 2 avril 2003 (2003-04-02) * le document en entier *	1-10	A61B17/80
A	EP 1 452 145 A (CT PULSE ORTHOPEDICS LTD [CH]; ILE ASTRID SOC CIV [FR]) 1 septembre 2004 (2004-09-01) * le document en entier *	1-10	
A	EP 1 616 528 A (NEWDEAL S A [FR]) 18 janvier 2006 (2006-01-18) * alinéa [0036] - alinéa [0041]; figures 4,5 *	1-10	
			DOMAINES TECHNIQUES RECHERCHÉS (IPC)
			A61B
Date d'achèvement de la recherche		Examineur	
31 mai 2007		Filali, Salima	
CATÉGORIE DES DOCUMENTS CITÉS			
X : particulièrement pertinent à lui seul Y : particulièrement pertinent en combinaison avec un autre document de la même catégorie A : arrière-plan technologique 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 S : membre de la même famille, document correspondant	

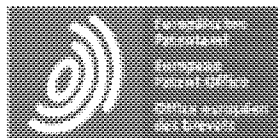
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**ANNEXE AU RAPPORT DE RECHERCHE PRÉLIMINAIRE
RELATIF A LA DEMANDE DE BREVET FRANÇAIS NO. FR 0607921 FA 684316**

La présente annexe indique les membres de la famille de brevets relatifs aux documents brevets cités dans le rapport de recherche préliminaire visé ci-dessus.
Les dits membres sont contenus au fichier informatique de l'Office européen des brevets à la date du **31-05-2007**
Les renseignements fournis sont donnés à titre indicatif et n'engagent pas la responsabilité de l'Office européen des brevets, ni de l'Administration française

Document brevet cité au rapport de recherche	Date de publication	Membre(s) de la famille de brevet(s)	Date de publication
EP 1297793 A1	02-04-2003	AT 282999 T	15-12-2004
		DE 60202037 D1	30-12-2004
		DE 60202037 T2	03-11-2005
		ES 2233788 T3	16-06-2005
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Pour tout renseignement concernant cette annexe : voir Journal Officiel de l'Office européen des brevets, No 12/92



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DESCRIPTION FR2905590

1 The present invention relates to a plate of a fusion

metatarsophalangeal joint, including the joint between the first metatarsal and the proximal phalanx of the great toe.

The invention also relates to a surgical method of installation of such a fusion plate.

When metatarsophalangeal joint has osteoarthritis or deformities in some iatrogenic cases, it is frequency: merging the metatarsal and the phalanx connected by this joint, that is to say definitively block this joint.

For this purpose, an arthrodesis plate, which is in the form of an elongated generally planar body, in place against the top faces of the metatarsal and the phalange, straddling the joint block is generally used.

The metatarsal portion and phalanx portion of the body comprise respectively one or more through holes, in each of which is introduced in a generally vertical direction, a bone anchor screw, respectively, the metatarsal and the phalange.

An example of this type of plate is shown in EP-A-1297793.

Such plate has several drawbacks.

In particular, just before permanently immobilize the plate against the metatarsal and the phalange, it is generally necessary to align these two bones from each other, so as to render them substantially contiguous at their opposite end, previously resected.

The corresponding surgical procedures are delicate, in the sense that, while maintaining the contiguous metatarsal and the phalanx, the surgeon must be screwed firmly to both a screw in the metatarsal area of the body to another plate and screws in the phalangeal part.

The risk of non-optimal positioning of the two bones are merging 2905590 2 real, implying a possible further discomfort to the patient.

Furthermore, the fixing of the plate is, in the long run, to alter: when the patient walks, the metatarsophalangeal joints are subjected to bending movement May 1 related to its gradual support arch, since the heel to toe.

For articulation blocked by plaque, the bending stress is mainly collected by the plate, which, by cyclic repetition of this constraint, 10 weakens the bone anchor screws holding the plate against the bone fused.

The purpose of the present invention seeks to overcome these disadvantages by providing a fusion plate, the fixing is simple and sustainable.

15 To this end, the invention provides a plate for arthrodesis of a metatarsophalangeal joint, comprising an elongated plate body adapted to be put in place and fixed on the respective top faces of the metatarsal and the phalange connected by the joint block 20 by arthrodesis so as to extend lengthwise straddling the joint, characterized in that the plate body is provided with an elongated fastening lug to a lateral face of the epiphysis phalanx, which leg extends lengthwise from a longitudinal side of the plate body 25 and is provided at its longitudinal end opposite the plate body, a through adapted to receive an elongated through hole in bone anchor , both, the

metatarsal and the phalange, such as a long screw.

The lug 30 of the plate according to the invention allows to fix the plate on a side face of the epiphysis of the phalange, that is to say, anatomically, on the medial aspect of the base joint.

This epiphyseal bone area is generally solid, allowing the implementation of a three 2905590 anchoring means sinking deeply into the bone tissue.

In practice, when the plate according to the invention is located at the joint connecting the first metatarsal and the proximal phalanx of the big toe 5, the tab is attached to the inner face of the epiphysis joint, that is to say bone side facing the median sagittal plane of the patient, such as this side has an easy surgical approach.

Furthermore, this tab is shaped so that its end hole 10 to receive a long screw, or more generally an elongated bone anchoring means, which will extend through both of the bone tissue in the phalanx and metatarsal bone material, in particular in the epiphyses of the bones facing.

It is understood that this long screw 15 extends lengthwise in a direction having a component anteroposterior, so that this screw cash primarily or exclusively bending stresses generated during walking of the patient, it being noted that, due of its position, the 20 screws works primarily in tension.

As this screw has, in its structure and its location area, the ability to resist bending stresses much higher than that of the body of the plate, the introduction of the plate is stable over time.

25 Furthermore, when the introduction of the long screw into the end of the leg hole, the screw tends to generate by itself an effect of the return towards the metatarsal phalanx when the screw reaches the peak and progresses in the bone tissue of the metatarsal.

In one motion, screw 30 of integrally this long screw, the surgeon automatically close and to fuse the two bones from each other, then it completely immobilized on the plate body to block the metatarsal joint.

It is understood that both bone and made contiguous 2905590 4 are fixed relative to each other in a predetermined manner, depending on the direction in which the surgeon introduces the long screw hole in the end of the tab according to the invention.

This hole is assisting the surgeon 5, in the sense that it sets him the point of application of the screw, while limiting the risk that the tip of the screw moves away, including ripement against the side of the phalanx .

According to other advantageous features of this 10 plate arthrodesis, in isolation or in any technically possible combinations - in a substantially vertical when the plate is implanted viewing direction, the leg extends along a longitudinal direction which together with 15 the longitudinal direction of the plate body at an angle between 20 and 60, preferably equal to 40 ± 1 ; - The through hole of the tab is adapted to receive the bone anchoring means in a position in which, in a viewing direction substantially vertical when the plate 20 is implanted, the longitudinal direction of the anchoring means, such as the central axis of a long screw, forms with the longitudinal direction of the plate body 45 in a lower corner; - The flap is folded along at least one folding line 25 substantially perpendicular to the longitudinal direction of the tab; - The plate body comprises along its length, a metatarsal part and a phalangeal part, adapted to be respectively put in place and 30 fixed on the top faces of the metatarsal and the phalange, and the leg extends from the phalangeal part , preferably being in one piece with the latter; 2905590 5 - the metatarsal part is provided with an oblong through hole whose longitudinal direction is substantially parallel to the longitudinal direction of the plate body; 5 - the metatarsal part includes on the one hand, of the same longitudinal side of the plate body as the leg, an arched section, the concave side of which is adapted to engage and to wrap the upper face of the curved metatarsal diaphysis and, on the other hand, a substantially planar section 10 connecting the arched section to the phalangeal part; - The curved section and the substantially planar section of the metatarsal part are folded in relation to each other along a fold line which, in a direction substantially vertical observation 15 when the plate is implanted, forms with the direction longitudinally of the plate body at an angle between 10 and 20, homothetic values of this angle preferably being provided between the terminals 12 and 18 for a set of arthrodesis plates 20 having respective different sizes; -the phalangeal part includes on the one hand, on the same longitudinal side of the plate body as the leg, an arched section, with the concave face 25 is adapted to engage and to wrap the upper face of the convex phalangeal diaphysis, and, secondly, a substantially planar section between the curved section to the metatarsal part -the curved section 30 and the substantially planar section of the phalangeal part are folded in relation to each other along a fold line , in a substantially vertical direction of observation when the plate is implanted, forms an angle between 15 and 25, preferably equal to 20 with 1 2.90559 million $\pm$ longitudinal direction of the plate body 6.

The invention also relates to a method of laying a fusion of a metatarsophalangeal phalangeal plate 5, which plate comprises an elongated body provided with an elongated plate which leg extends lengthwise from one side longitudinally of the plate body and is provided at its longitudinal end opposite the plate body, a through hole, said method comprising the 10 successive surgical procedures of: - generate and incise soft tissue surrounding the joint to block arthrodesis, implement the plate body on the upper surfaces of the metatarsal. and phalange 15 connected by the joint, so that the hole of the lug leads to a lateral face of the epiphysis of the phalanx, - partially immobilize the plate body on the metatarsal, allowing a relative freedom of movement generally along the longitudinal direction of the plate body 20, - introducing an elongate means of osseous anchorage in the hole of the tab, such as a long screw, the anchor means and successively in the epiphysis of the phalanx and the metatarsal, until an end of the anchor head means 25 abuts against the lug, at the edge of its hole, -Continue anchoring of the anchoring means so as to cause approximation of the metatarsal phalanx, by a relative movement of the metatarsal of the body plate 30 generally along the longitudinal direction of the plate body, - permanently immobilize the plate body on the metatarsal and the phalange and -close incision.

2905590 7 According to an advantageous feature of this method, the plate body fixed on the upper face of the phalange either before or after the partially immobilized on the plate body metatarsal.

5 The invention will be better understood on reading the description which will follow, given solely by way of example and with reference to the drawings in which: - Figure 1 is a perspective view of a plate 10 of fusion of the invention, establishment and fixed to a metatarsophalangeal joint blocked by the plate; - Figure 2 is a view of the plate of Figure 1, seen according to the arrow II of Figure 1, which corresponds to a 15 substantially vertical direction of observation; - Figures 3 to 6 are elevational views, respectively taken along arrows III-VI of Figure 2; and 20 - Figure 7 is a partial section of the plate, according to line VII-VII of Figure 2.

Figure 1 shows a plate 1 arthrodesis of a joint between the first metatarsal and the first phalanx M P of the big toe of his left foot 25.

For convenience, the following description is directed to the patient whose bones of the big toe are shown in Figure 1, the patient standing on horizontal ground.

Thus, the terms lower and below refer to a substantially vertical direction 30 towards the ground,

while the upper top and terms refer to a direction opposite direction.

Similarly, the term inside means a substantially horizontal direction toward the mid-sagittal plane of the patient, while the outer end 8 2905590 refers to a direction opposite direction.

The terms front, rear and the like also agree to the patient.

In practice, the plate 1 in the figures advantageously considered belongs to a set of arthrodesis plates 5 several, substantially homothetic with respective sizes.

The plate 1 shown is most appropriate to the patient, in particular its size and its M metatarsal phalanx P. The plate 1 comprises essentially of a hand, a body 10 of plate 10 having an elongated shape along a direction generally Anteroposterior and, secondly, an elongated inner leg 20.

As shown in more detail in Figures 2 to 7, in the configuration of implantation of the plate 1, the body 15 of plate 10 includes successively, in its longitudinal direction 11, a metatarsal portion 12 and a phalangeal part 13, which are respectively adapted to be put in place and attached to the metatarsal bone and phalanx P M, 20 with their underside flat against, respectively, the upper surfaces of the metatarsal bone and phalanx.

The junction area 14 between the portions 12 and 13 is provided to overlies the area of jointer between the epiphyseal ends facing M1 and P1 of the metatarsal and the phalanx M P, so that the body 25 of plate 10 extends Straddling the metatarsophalangeal joint in the direction 11.

10A on the inner longitudinal side of the plate body 10, the metatarsal portion 12 includes a curved section 121 connected to the junction area 30, 14 by a substantially planar section 122 of the part 12.

These sections 121 and 122 are bent relative to each other along a fold line 123 which extends in the rectilinear extension of the arrow III. The bottom 121A of the curved concave section 121, visible in Figure 3, 9 2.90559 million surface is shaped to conform to the upper face of the metatarsal diaphysis part M2 M, that is to say, to come into contact with this shaft while the overlapping snugly, as shown in Figure 1 5.

The bottom plate 122A of the substantially flat surface section 122 is provided to cover the dorsal region of the metatarsal diaphysis M2 and above the metatarsal epiphysis M1 was resected prior to the introduction of the plate.

In other words, it is understood that the 122A area 10 is intended to be placed against a generally flat upper face of the surface of the metatarsal M zone 121A while the surface covers a curved metatarsal area.

Given the anatomical shape of the metatarsal M, the 15 fold line 123 form, according to the viewing direction of the arrow II, a non-zero angle α_{M11} with the longitudinal direction of the plate body 10.

Advantageously, to allow a proper fit of lower surfaces 121A and 122A with the upper side of the metatarsal, the angle 20 is between 10 α_M and 20, it being noted that homothetic microM values are advantageously provided between the terminals 12 and 18 for game plates of different respective sizes.

10A also on the inner longitudinal side 25 of plate body 10, the phalangeal part 13 comprises a curved section 131 connected to the junction region 14 by a substantially planar section 132 of the part 13.

These sections 131 and 132 are bent relative to each other along a fold line 133 which extends in the rectilinear extension 30 of the arrow IV. By analogy with previous explanations of sections 121 and 122 of the metatarsal portion 12, it is understood that the concave bottom surface 131A of the curved section 131R 2,905,590 10 clearly visible in Figure 4, is sized to fit the medial domed phalangeal diaphysis P2, while the lower surface 132A of the section 132 covers the dorsal side of the shaft, and especially the 5 phalangeal epiphysis P1, as shown in FIG 1.

For anatomical reasons, the folding line 133 is, in the viewing direction corresponding to the arrow II, inclined relative to the direction 11, advantageously forming with the latter a non-zero angle γ_p 10 between 15 and 25.

Preferably, the angle α is 20 ± 1 .

According to the viewing direction corresponding to the arrow II, the fold lines 123 and 133 generally form a V whose point is directed towards the interior 15.

According to a medial-lateral direction of observation, such as the one corresponding to the arrow V, we note that the flat sections 122 and metatarsal phalangeal 132 do not extend into the straight prolongation of the other 20, but form the otherwise a non-zero angle is denoted in Figure 5.

For this purpose, the parts 12 and metatarsal phalangeal 13 are folded relative to each other at their junction region 14, according to a fold line 141 substantially perpendicular to the longitudinal direction 25 11.

With this arrangement, the phalangeal portion 13 is inclined upwardly in a vertical plane relative to the metatarsal portion 12, which guarantees a better adjustment of the plate body 10 to the anatomy of the metatarsophalangeal joint 30 when it is blocked.

Indeed, the P phalanx is then immobilized with respect to the metatarsal angle M with a nonzero dorsiflexion, corresponding to the angle α .

To allow attachment of the plate body 10 at the metatarsal phalanx and M P, is provided with a body 11 2.90559 million series of through holes, each adapted to receive a complementarily bone anchoring screw or the like mechanical means .

Advantageously, each of the 122 sections 121R, 131 and 132 is provided with at least one of these holes, 151R 5 respectively referenced 152, 153 and 154.

In this way, during the screwing of the screw holes in the respective bottom surfaces 131A and 132A 121Ar 122Ar these sections are firmly applied against the bone.

The metatarsal portion 12 is further provided with a hole 10 through 16 of oblong shape, whose longitudinal direction is substantially parallel to the longitudinal direction 11 of the plate body 10.

The advantage of this oblong hole will be highlighted below, in the description of the installation of the plate 1 arthrodesis.

15 The tab 20, also located on the inner longitudinal side 10A of the plate body 10, extends lengthwise from the phalangeal part 13.

As shown in Figure 1, this lug is formed to wrap the epiphysis phalangeal P1, to the nearest 20 of the bone material, including its free end 22, that is to say its longitudinal end opposite the plate body 10 .

The tab 20 and gives the impression to dive downwardly relative to the body plate 10, so that its end 22 located vertically below the plate body 25 in the implantation configuration to the plate 1, is pressed against the inner lateral face of the epiphysis phalangeal P1.

To this end, the tab 20 is bent downwardly relative to the plate body 10 along a fold line 30, 23 substantially perpendicular to the longitudinal direction 21 and located at the junction between the tab portion and the phalangeal 13.

Tab 20 is also folded over itself along a further fold line 24 substantially perpendicular to the direction 21 2.90559 million and 12 located at the junction between the tip 22 and the remainder of the plate.

The folded shape of the leg 20 is clearly visible in Figure 6, the viewing direction, which corresponds to the arrow VI in Figure 2, is aligned with 5 fold line 23.

According to the observation corresponding to the arrow II direction tab 20 is inclined relative to the plate body 10: a longitudinal direction 21 forms a non-zero angle (3 with the longitudinal direction of the body 11 of plate 10, as shown in FIG 2.

For anatomical reasons, the angle (3 is between 20 and 60.

Preferably, the angle θ is equal to $1 \pm 40^\circ$, allowing to have the tab 20 without the latter too the boundary section of the extended part 15 phalangeal 13, while wrapping the nearest phalangeal epiphysis P1.

At its end 22, the tab 20 is provided with a through hole 25 adapted to receive a screw 30 or, more generally, an elongated hole similar bone anchoring means.

This screw 20 is a long screw 30 in the sense that, as shown in dotted lines in Figure 1, it has a length sufficient to extend from the hole 25 in both the P1 and phalangeal epiphysis in the epiphysis metatarsal M1, or also in the metatarsal shaft 25 M2.

The hole 25 is provided for receiving the screw 30 so that, depending on the viewing direction corresponding to the arrow II, the longitudinal axis 31 of the screw can be tilted relative to the longitudinal direction 11 of the body 30 of plate 10, forming with this Dir 11 a nonzero angle α .

It is understood that the smaller the angle α is small, the axis 31 of the screw 30 tends to align with an anterior-posterior direction, ensuring a depth of penetration of the screw in the metatarsal 2905590 13 more important to length screws provided.

In practice, to enable the screw and the screw block 30 with its axis 31 inclined with respect to the central axis 251 of the hole 25, the edge of the hole 252 has, on the side facing the head 32 of the screw 5, a concave surface, substantially complementary to a surface defined by the associated screw head.

Thus, when the screw 31 is fully inserted into the hole 25, the head 32 abuts against and is caught at least a portion of edge 252, even if the axis 31 10 is inclined relative to the axis 251 of the hole.

For anatomical reasons, the angle α is advantageously chosen less than 45° .

In the example shown in the figures, this angle is about 20° .

On its outer longitudinal side 10B, the body 15 of plate 10 is chamfered, as shown in Figure 7.

The corresponding chamfer 17, generally flat, turned up in the implantation of the plate 1 configuration.

Thus, when the plate is implanted, the risks that it interferes or not Release 20 significantly the extensor tendon of the metatarsophalangeal joint is limited.

A method of laying of the arthrodesis plate 1 is as follows.

Having identified and incised soft tissue surrounding the joint to block the surgeon resected 25 partially metatarsal phalangeal epiphyses M1 P1r to remove bone defects such as bulges osteoarthritis present in the joint.

After choosing from the set of several plates arthrodesis homothetic plate 1 whose size is the most appropriate surgical patient 30, the surgeon then places the plate on the bone M and P: the plate body 10 is placed on the upper faces of the bone, while the end 22 of the tab 20 is placed against the inner lateral face of the epiphysis 14 phalangeal P1r 2.90559 million that is to say, anatomically, its medial side.

The plate body 10 is then partially locked using the elongate hole 16: the surgeon inserts a screw 2 (Figure 1) in the orifice 16, the side 162 of the rear base of 5×10 this orifice, the orifice. Mr. movable screw next to a body chosen parsans tighten the screw head against the edge 30 is then inserted into the hole 25, direction of inclined plate 10 from the point 8 introduction whose value is the surgeon for this screw during his this way, the plate body 10 remains in the direction 11 relative to the metatarsal screwing passes successively through P1 and phalangeal epiphysis epiphysis metatarsal M1r as explained above.

The screw 15 of the screw 30 is continued until the head of the screw 32 abuts along its axis 31, against the edge 252 of the hole 25.

Continuing screwing the screw 30 causes the approximation of the metatarsal million from the

phalanx P, movement toward being guided along the direction of 20 11 with the cooperation of the oblong hole 16 and unclamped screw 2 .

Bottom before 161 port 16 then progresses backward vis-à-vis the screw 2, which gradually finds himself on the side of the forward bulkhead 161.

The surgeon and continues to screw the screw 30 to 25 make substantially contiguous epiphyseal ends M1 and P1 bones.

It is understood that the direction of insertion of the screw 30 into the hole 25 determines the relative position of the metatarsal and the phalanx to their merger.

The screw 30 is then totally 2 screwed and clamped into the hole 16, so as to completely immobilize the plate body 10 of the metatarsal M. This is reinforced by screwing fixing screws into the holes 3 and 151 152.

2905590 15 before or after the thus immobilized plate body 10 vis-à-vis the metatarsal M, other screws 4 are inserted into the holes 153 and 154, so as to fix the part 13 of the phalangeal phalanx P. 5 The surgeon finally closes the incision.

In practice, the surgeon naturally plate for arthrodesis metatarsophalangeal joint of the right foot, these plates have a symmetric structure to that of the plate 1 relative to 10 to the latter a median vertical plane.

Advantageously, to facilitate the choice of the size of the implant plate, the surgeon also has a set of ghosts arthrodesis plate: each phantom has external contours 15 identical to those of one of arthrodesis plates game available at its disposal, so that, after incising the patient and the first bone resections performed, the surgeon places one of these ghosts, first, to select the size of the implant over appropriate, and 20 on the other hand, to ensure that the resections are sufficient, particularly at the coaptation area between plate and a metatarsal portion and phalanx other.

Moreover, during the development of the plate 1, 25 the surgeon the ability to conveniently change the angle to adjust the best angle to the anatomical angle of dorsiflexion between the

metatarsal and the phalanx M P patient operated ,, considering including bone resections and the general morphology of the bones of 30 patients, as well as habits of footwear and specifically the height of the heel of the shoe.

The manufacture of the plate 1 is made of a planar metal plate.

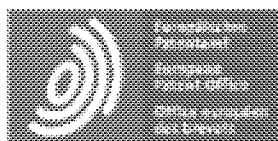
This plate is, at first, cut along predetermined contours 16 2905590 to obtain the parts 12 and metatarsal phalangeal joint 13, and the tab 20.

In a second step, the various holes 151-154 and oblong hole 16 are drilled.

Thirdly, sections 121 and 131 are bent 5, while the plate is folded along lines 123, 133, 23 and 24.

Various arrangements and variants of the plate 1 described above, as well as its installation method are possible.

Examples 10 - the lower face of the peened plaqueest or, more generally, undergoes a surface treatment to promote colonization after bone plate is implanted; and / or - the number of holes 151 to 154 can be changed, 15 in particular according to the longitudinal size of the plate body 10.



Notice

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CLAIMS FR2905590

CLAIMS

1.

Plate (1) a fusion of metatarsophalangeal joint, comprising an elongated plate body (10) adapted to be put in place and fixed on the respective top faces of the metatarsal (M) and phalange (P) connected the hinge block by arthrodesis so as to extend lengthwise straddling the joint, characterized in that the plate body (10) has an elongate tab (20) for attachment to one face side of the epiphysis (P 1) of the phalange (P), which leg extends lengthwise from a longitudinal side (10A) of the plate body and is provided at its longitudinal end (22) opposite to the plate body, a through hole (25) adapted to receive an elongate means (30) for bone anchoring in both the phalange (P) and metatarsal (M), such as a long screw.

2.

Plate according to claim 1, characterized in that, in a substantially vertical when the plate (1) is implanted direction of observation (arrow II), the tab (20) extends in a longitudinal direction (21) which forms with the longitudinal direction (11) of the plate body (10) an angle (P) between 20 and 60, preferably equal to 40 +/- 1.

3.

Plate according to one of claims 1 or 2, characterized in that the through hole (25) of the tab hole (20) is adapted to receive the bone anchoring means (30) in a position in which, in a direction of observation (arrow II) substantially vertical when the plate (1) is located, the longitudinal direction (31) of the anchoring means, such that the central axis of a screw 18 2905590 long forms with the longitudinal direction (11) of the plate body (10) an angle (8) of less than 45.

4.

Plate according to any one of the preceding claims, characterized in that the lug (20) is folded according to at least 5 fold line (23, 24) substantially perpendicular to the longitudinal direction (21) of the tab.

5.

Plate according to any one of the preceding claims, characterized in that the plate body (10) 10 comprises, along its length, a metatarsal portion (12) and a phalangeal part (13), respectively adapted to be set up and fixed on the top faces of the metatarsal (M) and phalange (P), and in that the tab (20) extends from the phalangeal part 15 (13), preferably being integral with the latter.

6.

Plate according to claim 5, characterized in that the metatarsal part (12) is provided with an oblong through hole (16) whose longitudinal direction is substantially parallel to the longitudinal direction (11) of the plate body 20 (10).

7.

Plate according to one of claims 5 or 6, characterized in that the metatarsal part (12) includes, on the one hand, of the same longitudinal side (10A) of the plate body (10) that the tab (20), a curved section (121), whose concave face 25 (12LA) is adapted to engage and to wrap the upper face of the curved metatarsal diaphysis (M 2), and, secondly, a substantially planar section (122) connecting the arched section to the phalangeal part (13).

30

8.

Plate according to claim 7, characterized in that the curved section (121) and the substantially flat section (122) of the metatarsal portion (12) are bent relative to each other along a fold line (123) which, according to a direction of observation (arrow II) 19 2.90559 million substantially vertical when the plate (1) is implanted, forms with the longitudinal direction (11) of the plate body (10) an angle (microM) of between 10 and 20 , homothetic values of this angle preferably being provided between five terminals 12 and 18 for a set of arthrodesis having respective different sizes plates.

9.

Plate according to any one of claims 5 to 8, characterized in that the phalangeal part (13) 10 includes, on the one hand, of the same longitudinal side (10A) of the plate body (10) that the tab (20) , a curved section (131), the concave face (131A) is adapted to engage and to wrap the upper face of the convex phalangeal diaphysis (P2), and, secondly, a substantially planar section 15 (132) connecting the arched section to the metatarsal part (12).

10.

Plate according to claim 9, characterized in that the curved section (131) and the substantially flat section (132) of the phalangeal part (13) are folded by 20 relative to one another along a fold line (133) which, when in a substantially vertical plate (1) is implanted, forms with the longitudinal direction (11) of the plate body (10) an angle (γ_p) between 15 and 25 viewing direction (arrow II), preferably equal to 25 ± 1 .

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 24179785.10045	FOR FURTHER ACTION see Form PCT/ISA/220 as well as, where applicable, item 5 below.	
International application No. PCT/US2009/064150	International filing date (<i>day/month/year</i>) 12 November 2009	(Earliest) Priority Date (<i>day/month/year</i>) 19 November 2008
Applicant AMEI TECHNOLOGIES, INC.		

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 43.6bis(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/US2009/064150

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61B 17/80 (2009.01)

USPC - 606/280

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) - A61B 17/80, 17/68, 17/58, 17/56, 17/88, 17/82, (2009.01)

USPC - 606/280, 60, 281, 283, 286, 290

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

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

PatBase

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 7,344,538 B2 (MYERSON et al) 18 March 2008 (18.03.2008) entire document	1, 5, 7-16, 18-20, 22-24
Y		2-4, 6, 17, 21, 25
Y	US 2006/0241607 A1 (MYERSON et al) 26 October 2006 (26.10.2006) entire document	2-4, 25
Y	US 6,206,882 B1 (COHEN) 27 March 2001 (27.03.2001) entire document	6, 17
Y	US 4,159,716 A (BORCHERS) 03 July 1979 (03.07.1979) entire document	21

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

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

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"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

22 December 2009

Date of mailing of the international search report

06 JAN 2010

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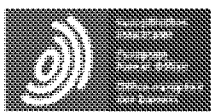
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PCT Helpdesk: 571-272-4300
PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (July 2009)



Espacenet

Bibliographic data: JP2006280949 (A) — 2006-10-19

PLATE FOR FIXING MID-FOOT

No documents available for this priority number.

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Applicant(s): DEPUY PRODUCTS INC $\pm$ (DEPUY PRODUCTS INC)

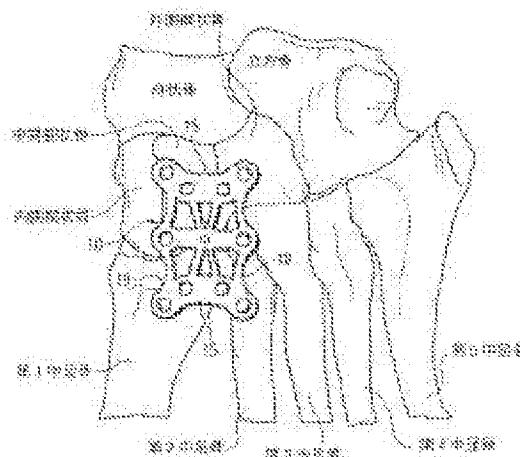
Classification: - international: **A61B17/58**
- cooperative: **A61B17/8061**; A61B17/8085; Y10S606/906

Application number: JP20060094526 20060330

Priority number (s): US20050094994 20050331

Also published as: JP5079251 (B2) EP1707139 (A1) EP1707139 (B1)
US2006241592 (A1) US7344538 (B2) more

Abstract of JP2006280949 (A)



PROBLEM TO BE SOLVED: To provide a fixing device by which a mid-foot can be reliably fixed. ; SOLUTION: The fixing device for fixing and/or fusion of bones and joints of the mid-foot has several screw holes for fitting a plate 10 on the periphery of the fusion part. Four screw holes can be arranged at the corners of the plate 10 and two screw holes can be arranged on both sides of the plate 10 at the midpoint of its length. Other four screw holes can be demarcated in the inside of the plate 10 for increasing the number of positions for fitting the plate 10 to the bones of the mid-foot and for more easily stabilizing several bone parts in the case of difficult bone fracture of the mid-foot. The plate 10 includes several cutouts demarcated between the screw holes or in its inside.; The cutouts are large enough to receive additional bone fasteners so that fitting of the plate 10 to the bones of the mid-foot may be easier or the bone part on the downside of the plate 10 may be reset by inserting fasteners. ; COPYRIGHT: (C) 2007,JPO&INPIT

Last updated: 11.12.2013 Worldwide Database 5 8 15; 92p

(19) 日本国特許庁(JP)

(12) 公開特許公報(A)

(11) 特許出願公開番号

特開2006-280949

(P2006-280949A)

(43) 公開日 平成18年10月19日(2006.10.19)

(51) Int. Cl.

A61B 17/58 (2006.01)

F 1

A61B 17/58 310

テーマコード(参考)

4C060

審査請求 未請求 請求項の数 10 O L 外国語出願 (全 11 頁)

(21) 出願番号 特願2006-94526 (P2006-94526)
(22) 出願日 平成18年3月30日(2006.3.30)
(31) 優先権主張番号 11/094,994
(32) 優先日 平成17年3月31日(2005.3.31)
(33) 優先権主張国 米国(US)

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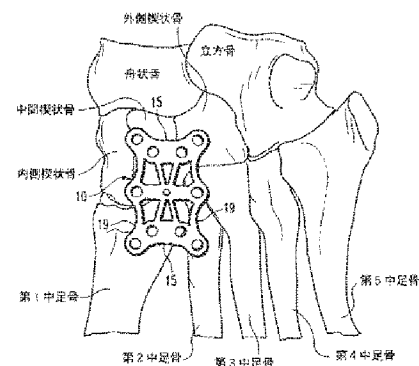
(54) 【発明の名称】 足中部固定プレート

(57) 【要約】 (修正有)

【課題】足中部を確実に固定できる固定装置を提供する。

【解決手段】足中部の骨および関節の固定および／または融合のための固定装置であって、融合部位の周辺にプレート10を取り付けるための複数のねじ孔を有する。4つのねじ孔を、プレート10の角に配置し、2つのねじ孔を、プレート10の長さの半分の所で両側に配置することができる。足中部の骨にプレート10を取り付けるための位置の数を増やすため、または困難な足中部の骨折の場合に複数の骨部分を安定させやすくするために、別の4つのねじ孔を、プレート10の内部に画定することができる。プレート10は、ねじ孔の間または内側に画定された複数のカットアウトを含む。カットアウトは、足中部の骨に対するプレート10の取付けを容易にするため、またはファスナーを挿入してプレート10の下側の骨部分を整復できるようにするために、追加の骨ファスナーを受容できる大きさである。

【選択図】図1



【特許請求の範囲】

【請求項1】

人間の足中部 (mid-foot) の骨または骨部分の融合のための固定装置において、
患者の足中部の中に植え込むための大きさのプレートを含み、
前記プレートが、複数の孔を画定しており、前記各孔が、足中部の骨または骨部分に前記プレートを取り付けるべく骨係合ファスナーを受容できる大きさの直径を有しており、
前記プレートが、複数のカットアウトをさらに画定しており、これらの各カットアウトの寸法が、前記複数の孔の直径よりも大きい、
固定装置。

【請求項2】

請求項1に記載の固定装置において、
前記プレートが、1.0mm未満の実質的に均一な厚みを有する、固定装置。

【請求項3】

請求項1に記載の固定装置において、
前記複数のねじ孔が、異なった大きさのファスナーを受容できるように外周面取り部を有する、固定装置。

【請求項4】

請求項1に記載の固定装置において、
前記複数のねじ孔が、前記プレートの周辺に配置されている、固定装置。

【請求項5】

請求項4に記載の固定装置において、
前記複数のカットアウトが、前記複数の孔のそれぞれの内側に配置されている、固定装置。

【請求項6】

請求項1に記載の固定装置において、
前記複数のカットアウトが、前記プレートの長軸に沿って配置された一対の三角形形状のカットアウトを含む、固定装置。

【請求項7】

請求項1に記載の固定装置において、
前記複数のカットアウトが、前記プレートの両側の近接した2つのカットアウトを含む、固定装置。

【請求項8】

請求項7に記載の固定装置において、
両側の近接した前記2つのカットアウトが、台形または実質的に長方形の形状である、固定装置。

【請求項9】

請求項1に記載の固定装置において、
前記プレートが、ガイドワイヤまたはKワイヤを受容する大きさのガイドワイヤ孔をさらに画定している、固定装置。

【請求項10】

請求項9に記載の固定装置において、
前記ガイドワイヤ孔が、前記プレートの中心に実質的に配置されている、固定装置。

【発明の詳細な説明】

【開示の内容】

【0001】

〔発明の背景〕

本発明は、骨および関節を固定するためのプレートに関する。詳細には、本発明は、足中部 (mid-foot) を固定するために構成された固定プレートに関する。

【0002】

足中部の外傷により、重度の骨折および／または脱臼が起こる場合が多い。このような

外傷の1つに、ナポレオン戦争中にフランス人医師が発表し、この医師によって命名された周知のリスフラン外傷(Lisfranc injury)がある。リスフラン(Lisfranc)医師によって明らかにされた外傷は、足がぶみに絡まって乗馬者が落馬したときに起こる。このようにして起こる外傷は、断片の脱臼を伴う足中部の複数の骨の骨折である。現代では、リスフラン外傷は、正常な立体的配置が損なわれる、楔状骨および中足骨関節の正常な配置に対する外傷を指す。このタイプの外傷は、足中部に重い物体が落下した場合、または小さな孔に足が入って転倒し、足を捻った場合に起こりうる。スポーツ外傷は、ウィンドサーフィンやスノーボードなどの足を固定するスポーツ、またはダンスやサッカーなどの衝撃の際に足が回転しているスポーツで一般的である。

【0003】

最も一般的なリスフラン外傷は、第1中足骨、第2中足骨、および中間楔状骨を伴う関節で起こる。これは主に、第1中足骨と第2中足骨を互いに保持する結合組織が存在しないためである。内側楔状骨と中間楔状骨との間の靭帯、または第1中足骨と第2中足骨と中間楔状骨との間の靭帯が断裂すると、これらの骨が分離し、関節の正常な整合が損なわれる。深刻なリスフラン外傷の治療に失敗すると、関節が変性し、近接する神経や血管さえも損傷を受けることがある。

【0004】

このタイプの外傷の治療は、特に骨が著しく分離している場合、通常は外科手術である。開放整備および内部固定として知られる外科治療では、通常は、ピン、ワイヤ、および/またはねじを挿入して骨および関節を安定させ、完全に治癒するまでこれらを所定の位置に保持する必要がある。この治療手順により、骨折した骨を修復するとともに、足中部の正常な解剖学的構造を再構築する。一般的なある処置では、ピンまたはねじを、内側楔状骨内に内側に挿入し、第2中足骨の基部を通す。

【0005】

場合によっては、第1中足骨、第2中足骨、中間楔状骨、および/または内側楔状骨の間の関節の融合が必要である。リスフラン外傷または同様の外傷を受けた患者に関節炎が発症した場合、または急性骨折/脱臼が足中部のどこかで起きた場合、関節固定術が必要である。

【0006】

ピン、ステープル、またはねじの使用は、若い患者、特に外傷が重症でない場合に容認できることが多い。しかしながら、この固定の形態は、融合しない足中部関節固定術になってしまう場合が多い。これは、骨の断片および/または関節が、ピン、ねじ、またはステープルだけでは十分に固定できないためであろう。したがって、足中部の外傷部位を確実に固定および安定させることができる固定装置が強く要望されている。様々な治療の可能性のためにも、足中部の骨および骨の断片に対して複数の位置で取り付けできる固定装置が必要である。

【0007】

〔発明の概要〕

このような要望に応えるべく、本発明は、足中部に植え込むように特別に構成された固定プレートを提供する。本発明の一実施形態では、固定装置は、融合部位の周辺にプレートを取り付けるための複数のねじ孔を有するプレートの形態である。好適な一実施形態では、4つのねじ孔が、プレートの角の突出部に配置されている。2つのねじ孔が、プレートの長さの半分の所で両側の突出部に配置されている。

【0008】

別の好適な態様では、別の4つのねじ孔が、足中部の骨にプレートを取り付けるための位置の数を増やすため、または困難な足中部の骨折の場合に複数の骨部分を安定させやすくするために、プレートの内部に画定されている。4つの追加のねじを、突出部に配置された6つのねじによって画定された領域内に配置することができる。

【0009】

本発明の好適な実施形態のさらに別の態様では、複数のカットアウトが、プレートのね

じ孔の間または内側に画定されている。最も好適な実施形態では、2つの概ね三角形のカットアウトが、内側のねじ孔の内側に位置するプレートの長軸に沿って設けられ、4つの大きいカットアウトが、三角形のカットアウトを取り囲むように、ねじ孔によって画定された領域内に設けられている。少なくとも大きいカットアウトは、ねじまたはピンなどの追加の骨ファスナーの通路となる大きさである。カットアウトは、取付けまたは固定のための追加の位置として用いることができる。加えて、カットアウトは、プレートの下側の骨の断片を修復するために固定ピンまたはねじを通す通路となりうる。

【0010】

カットアウトは、骨または骨の断片の安定化を助けるべく足中部の融合部位または骨の上に配置できるストラットによって結び付けられている。本プレートは、ねじ孔およびカットアウトが融合部位の上に配置されないように構成されている。

【0011】

突出部およびカットアウトにより、プレートの隆起が小さくなるだけでなく、必要な材料が低減される。プレートはまた、融合部位を安定させる能力を維持する最小の厚みで形成される。好適な実施形態では、プレートの厚みは、1.0mm未満である。局所構造により正確に一致するようにするために、プレートは、好ましくは固定された半径である球曲率で画定される。

【0012】

本発明の固定プレートの1つの利点は、足中部の融合において、従来の装置よりも大幅に利用範囲が広いことである。別の利点は、足中部の骨および関節を安定化させ、骨折の確実な修復を行い、そして最終的に確実に癒合および／または融合させるために骨ねじ配置の複数のオプションを提供できることである。

【0013】

本発明の別の利点および目的は、添付の図面を参照しながら以下の説明を読めば明らかになるであろう。

【0014】

〔好適な実施形態の説明〕

本発明の原理を容易に理解できるように、図面に例示し、以下に説明する実施形態を参照する。したがって、本発明の範囲を限定することを意図するものではないことを理解されたい。さらに、本発明が、例示する実施形態の変形態および改良形態、ならびに当分野に属する技術者が容易に想到するような本発明の原理の応用を含むことも理解されたい。

【0015】

図1に、本発明の好適な実施形態に従った固定プレート10が配置された、背側から示された足中部 (mid-foot) の骨が例示されている。図から分かるように、プレート10は、第1および第2の中足骨の間に跨り、内側および中間楔状骨に亘っている。図1に例示されている実施形態では、足中部のこの部分の各骨に取り付けることができる大きなプレート10が設けられている。

【0016】

プレート10の詳細は、図2 - 図4から明らかであろう。プレート10は、概ね均一の厚みおよび材料成分を有する本体11から全体的に形成されている。好適な実施形態では、本体11は、生体適合性材料、最も好ましくは金属から形成される。ある実施形態では、本体の材料は、チタン、またはTi-6Al-4Vなどのチタン合金である。足中部の骨の上のプレート10の隆起を小さくするために、プレートは、上面12と骨係合面13との間に、足中部の骨および関節の確実な固定に十分な強度を有する最小の厚みである有効厚みを有する。好適な実施形態では、プレートの厚みは、1.0mm未満、最も好ましくは約0.9mmである。この厚みにより、十分な強度を有するとともに、必要に応じて、植え込み部位の形状に一致するようにプレートを曲げることができる。具体的には、プレート10は、図1に示されている位置だけでなく、足中部に沿ったどの位置にも配置できるように構成されている。例えば、中間楔状骨の形状には、立方骨に亘って配置される

プレートとは異なった形状のプレートが必要であろう。

【0017】

しかしながら、足中部、特に中足骨関節に亘る構造に一致するように二次元で骨係合面13を湾曲させて、プレートを手術部位で整形する必要がないようにするのが好ましい。したがって、図3の側断面図に示されているように、骨係合面13、従ってプレート10は、プレートの長さに亘って湾曲している。プレートは、ある実施形態では、約75mmなどの均一の半径で湾曲しているのが好ましい。同様に、プレートは、図4の断面図に示されているように、その幅に亘って湾曲している。ある実施形態では、この曲率も約75mmである。最も好ましくは、プレート全体が球半径で形成され、ある実施形態では、この球半径は約75mmである。

【0018】

本体11は、さらに、端縁15および側縁18を含む。必要な材料を低減し、かつプレート10の隆起を最小にするために、各縁はそれぞれ、凹部16および19を画定している。図1に示されているように、端縁15は、プレートの両側の角の突出部17の間に1つの凹部16を画定している。これらの突出部17は、側縁18で凹部19と一体になっている。中心突出部20が、角の各突出部17から等距離となるように各側縁18に画定されるのが好ましい。好適な実施形態では、縁15および18は全て、植え込みプレートの周囲の軟組織に対する外傷を軽減するために丸められている。

【0019】

図2に示されているように、各突出部17および20により、ねじ孔25の位置が画定されている。各ねじ孔は、プレート10を足中部の骨に取り付けるように構成された骨係合ファスナーを受容するように構成されている。好適な実施形態では、骨係合ファスナーは、中足骨の基部、任意の楔状骨、または立方骨の中に植え込むのに適した大きさの骨ねじである。骨ねじの長さおよび直径は、固定する骨または骨の断片の大きさおよび位置によって概ね決まる。図2に示されているように、プレート10は、プレートの内部に別のねじ孔26を有する。これらのねじ孔26により、所定の骨に対する取付け位置が増え、重度の骨折の場合などで骨断片の固定のための通路が得られ、プレート10の利用範囲が広がる。

【0020】

本発明のプレート10は、足中部の植え込みおよび固定のために特別に構成されている。したがって、このプレートは、様々な足中部の外傷の修正および関節固定術のためにねじ孔25および26を最適に配置できる大きさである。ある実施形態では、プレートは、角の突出部17のねじ孔間および中間の突出部20のねじ孔間に約21.5mmの幅を有する。内部のねじ孔26間の幅は、約10.0mmであるのが好ましい。プレート10は、角の突出部のねじ孔25間に約36.8mmの長さを有する。

【0021】

ねじ孔25および26は、骨へのプレートの取付けに用いられる骨ねじの大きさに適した直径に形成される。好適な実施形態では、ねじ孔は、足の骨の固定に一般的に用いられる2.7mmまたは3.5mmのねじに適するように構成されている。本発明の一態様では、ねじ孔は、図5に示されているプレート50のねじ孔52の面取り部53などの外周面取り部を含むことができる。このねじ孔の構造により、プレートが、どのねじ孔の位置でも両方の大きさのねじを受容することができる。本発明は、さらに、骨ねじを非戻り止めねじまたは戻り止めねじとすることができ、ねじに合わせてねじ孔を形成することを企図する。ある実施形態では、止めねじが用いられ、ねじ孔25および26に、従来のデザインのテーパねじ（不図示）が設けられている。

【0022】

本発明のさらなる特徴が、図2に最も良く示されている。具体的には、プレートの本体11が、各側の2つのカットアウト32および2つの中心カットアウト30の合計6個のカットアウトを含む複数のカットアウトを画定している。カットアウト30および32により、プレート10の形成に必要な材料が減少する。加えて、カットアウトにより、スト

ストラット38および40によってつながっている、互いに反対側に位置する端部34および中心部36が形成されている。端部34および中心部36は、ねじ孔25および26を有する。ストラット38および40は、それらのストラットの下側の骨または骨の断片の安定に役立つ。端部34および中心部36とストラット38および40は、図1に反映されているように、融合を起こして足中部を安定させるべき部分にねじ孔が位置しないように構成されている。好適な実施形態では、カットアウト30の形状が、三角形であり、両側のカットアウト32の形状は、概ね台形または長方形である。カットアウト30および32は、ねじ孔25および26の直径よりも寸法が大きい。

【0023】

プレートの材料の低減に加えて、カットアウト30および32により、骨ねじを配置するための位置が増え、これらの位置を利用して固定を補強したり、骨部分をつないだりすることができる。固定を補強する場合は、骨ねじを、カットアウト30および32のいずれの角にも配置することができる。骨部分をつなぐ場合は、骨折部位をブリッジするように近接する骨部分に亘って、骨ねじをカットアウト内に通すことができる。カットアウト30は、足中部の骨の断片の固定のために標準的な骨ねじを受容する大きさに特別に形成されている。

【0024】

プレート10の適切な配置を容易にするために、小さい直径の孔28が、中心部36のプレート10の中心に画定されている。この孔28は、Kワイヤまたは他の同様のガイドワイヤを受容する大きさであるのが好ましい。リスフラン骨折／脱臼の修正のための模範的な処置では、Kワイヤを中間楔状骨内に挿入して、プレート10を中足骨と楔状骨の部分に亘るように案内する。発明の一態様では、プレート10により、融合すべき足中部部分の周辺部にねじを配置することができ、具体的には突出部17および20におけるねじ孔25にねじを配置することができる。ある場合は、最終的な融合のために外傷部位を十分に安定させるのに、これらの位置の取付けで十分である。別の場合は、追加のねじを、ねじ孔26に挿入し、そしてカットアウト30および32にも挿入することができる。骨の断片が存在する場合、整復ねじを1または複数のカットアウト30および32の中を通して整復することができる。

【0025】

足中部の構造または融合部分が小さい場合、プレート10を変更して、図5に示されているような小さいプレート50にすることができる。この小さいプレートは、大きいプレート10を用いて説明した、最小のプレートの厚みおよび球半径を維持している。加えて、プレート50は、ねじ孔52を有する角の突出部51を含む。プレートの利用範囲を広げるために、ねじ孔54をプレート50の内側に設けることができる。また、Kワイヤ孔56を、プレートの中心に設けることができる。小さいプレート50は、足中部の骨および関節の構造が小さい患者に適合するのが好ましい。

【0026】

本発明の好適な実施形態では、固定装置は、融合部位の周辺にプレートを取り付けるための複数のねじ孔を有するプレート10の形態である。最も好適な実施形態では、4つのねじ孔がプレートの角に配置され、2つのねじ孔がプレートの長さの半分の所で両側に配置されている。足中部の骨にプレートを取り付けるための位置の数を増やすため、または困難な足中部の骨折の場合に複数の骨部分を安定させやすくするために、別の4つのねじ孔を、プレートの内部に画定することができる。好適な実施形態の別の態様では、複数のカットアウトが、プレートのねじ孔の間または内側に画定されている。最も好適な実施形態では、2つの概ね三角形のカットアウトが、内側のねじ孔の内側に位置するプレートの長軸に沿って設けられ、4つの大きいカットアウトが、三角形のカットアウトを取り囲むように、ねじ孔によって画定された領域内に設けられている。

【0027】

図面および上記説明で本発明を詳細に例示および記載してきたが、これらの図面および説明は単に例示目的であり、本発明を限定するものではない。好適な実施形態のみを示し

たが、本発明の概念に含まれる全ての変更形態、改良形態、およびさらなる適用例が保護されることを望むことを理解されたい。

【0028】

〔実施の態様〕

(1) 人間の足中部の骨または骨部分の融合のための固定装置において、患者の足中部の中に植え込むための大きさのプレートを含み、前記プレートが、複数の孔を画定しており、前記各孔が、足中部の骨または骨部分に前記プレートを取り付けるべく骨係合ファスナーを受容できる大きさの直径を有しており、前記プレートが、複数のカットアウトをさらに画定しており、これらの各カットアウトの寸法が、前記複数の孔の直径よりも大きい、固定装置。

(2) 実施態様(1)に記載の固定装置において、前記プレートが、1.0mm未満の実質的に均一な厚みを有する、固定装置。

(3) 実施態様(1)に記載の固定装置において、前記複数のねじ孔が、異なった大きさのファスナーを受容できるように外周面取り部を有する、固定装置。

(4) 実施態様(1)に記載の固定装置において、前記複数のねじ孔が、前記プレートの周辺に配置されている、固定装置。

(5) 実施態様(4)に記載の固定装置において、前記複数のカットアウトが、前記複数の孔のそれぞれの内側に配置されている、固定装置。

【0029】

(6) 実施態様(1)に記載の固定装置において、前記複数のカットアウトが、前記プレートの長軸に沿って配置された一対の三角形状のカットアウトを含む、固定装置。

(7) 実施態様(1)に記載の固定装置において、前記複数のカットアウトが、前記プレートの両側の近接した2つのカットアウトを含む、固定装置。

(8) 実施態様(7)に記載の固定装置において、両側の近接した前記2つのカットアウトが、台形または実質的に長方形の形状である、固定装置。

(9) 実施態様(1)に記載の固定装置において、前記プレートが、ガイドワイヤまたはKワイヤを受容する大きさのガイドワイヤ孔をさらに画定している、固定装置。

(10) 実施態様(9)に記載の固定装置において、前記ガイドワイヤ孔が、前記プレートの中心に実質的に配置されている、固定装置。

【0030】

(11) 実施態様(1)に記載の固定装置において、前記プレートの縁が、複数の凹部および突出部を画定しており、前記複数の孔の少なくとも一部が、前記突出部の対応する1つの中に画定されている、固定装置。

(12) 実施態様(1)に記載の固定装置において、前記プレートが、実質的に均一の球半径で湾曲した骨係合面を含む、固定装置。

【図面の簡単な説明】

【0031】

【図1】本発明の一実施形態に従った、固定プレートが配置された足中部の背側部の拡大図である。

【図2】図1に示されている固定プレートの平面図である。

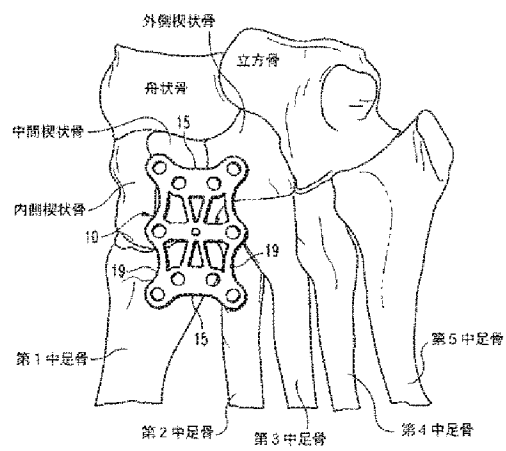
【図3】図2の線3-3に沿って矢印の方向に見たプレートの側断面図である。

【図4】図2の線4-4に沿って矢印の方向に見たプレートの端断面図である。

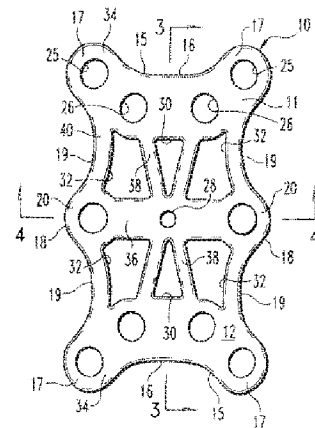
【図5】本発明の別の実施形態に従った、固定プレートが配置された足中部の背側部の拡大図である。

大図である。

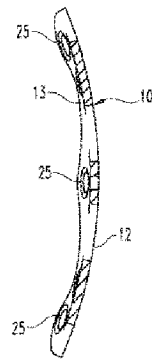
【図1】



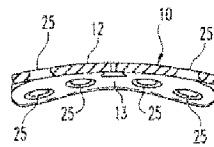
【図2】



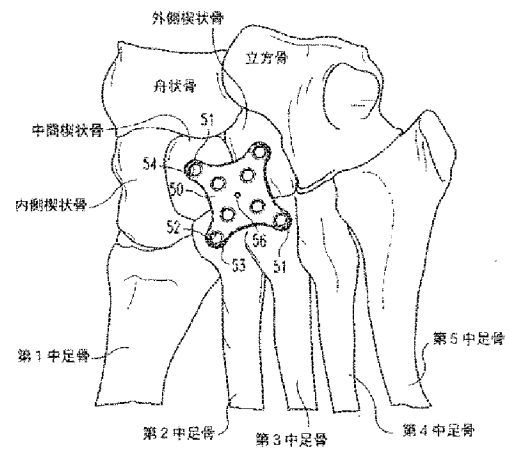
【図3】



【図4】



【図5】



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- Fターム(参考) 4C060 LL14 LL15 MM24

【外国語明細書】
2006280949000001.pdf

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DESCRIPTION JP2006280949

Background of the Invention

The present invention relates to a plate for fixing the bones and joints.

In particular, the present invention relates to a fixing plate configured to secure the mid-foot (mid-foot).

If the trauma of the mid-foot, dislocation and / or severe fracture occurs in many cases.

One of such trauma, French doctors announced during the Napoleonic Wars, there is a (Lisfranc injury) Lisfranc trauma of well-known, which is named by the doctor.

Trauma revealed by (Lisfranc) doctor Lisfranc occurs when the equestrian is unseated legs tangled in the stirrup.

Trauma that occurs in this way, a fracture of a bone of a plurality of mid-foot with dislocation of the fragments.

In modern times, a normal three-dimensional arrangement is impaired, and cuneiform Lisfranc injury refers to trauma to the normal placement of the metatarsal bone joint.

If something falls onto the mid-foot, and a fall or foot into the small pores, this type of injury can occur as a result of twisting the foot.

Sports injuries are common in sports that foot is rotating at the time of impact, such as soccer or dance or sports, to secure the foot and snowboarding and windsurfing.

First metatarsal, second metatarsal bone, and Lisfranc trauma most common, occurs at the joint with the intermediate cuneiform bone.

This is primarily due to connective tissue that held together the second metatarsal bone and the first metatarsal bone is not present.

Ligaments between the intermediate cuneiform and the second metatarsal bone and the first metatarsal bone or ligament, between the intermediate cuneiform bone and medial cuneiform bone is torn, these bones are separated, normal alignment of the joint There compromised.

If it fails in the treatment of severe Lisfranc injury, sometimes even blood vessels nerves and joints degenerate, close also be damaged.

If the bone is separated remarkably, treatment of trauma of this type is usually surgical.

In the surgical treatment, known as internal fixation and open reduction, usually, it is necessary to hold in place thereof to stabilize the bones and joints by inserting the screw and / or pin, wire, until completely healed .

This treatment procedure, it is possible to repair a fractured bone, and to reconstruct the normal anatomy of the mid-foot.

In the treatment of some common, and inserted inside the medial cuneiform bone in, a screw or pin, and passed through the base of the second metatarsal bone.

In some cases, the first metatarsal, second metatarsal bone, intermediate cuneiform, and is required fusion of the joint between the medial cuneiform bone and / or.

When arthritis developed in patients undergoing trauma or similar Lisfranc injury, or if the acute fracture / dislocation has occurred somewhere in the mid-foot arthrodesis is required.

The use of threaded pins, staples or young patients, it is acceptable if the injury is not particularly severe in many cases.

However, the form of the fixed, when it becomes the mid-foot arthrodesis that is not fused in many cases.

This is probably because the joint and / or bone segments can not secured enough to staples pins or screws.

Thus, fixation device which can be stably and reliably fixed to the trauma site of the mid-foot are strongly desired.

Also due to the possibility of various treatments, locking device which can be attached at multiple locations for fragments of bone and bone of the mid-foot is needed.

SUMMARY OF THE INVENTION

To meet this demand, the present invention provides a fixation plate that is configured specifically to be implanted in the mid-foot.

In one exemplary embodiment of the present invention, the fixation device is in the form of a plate having a plurality of screw holes for mounting the plate in the vicinity of the fusion site.

In one preferred embodiment, four screw holes are arranged on the projection of the corners of the plate.

Two screw holes are arranged on the protruding portion on both sides at the half of the length of the plate.

In another preferred embodiment, the four screw holes and another, increasing the number of positions for attaching the plate to the bone of the mid-foot, and tends to stabilize the bone portions of the plurality of in case of a broken leg or middle difficult to, and is defined within the plate.

Can be placed within the area defined by the six screws arranged in the protruding portion, the additional screws four.

In another embodiment, a plurality of cut-outs that are defined inside or between the screw holes of the plate further preferred embodiment of the present invention.

In a most preferred embodiment, the cut-out triangular, provided along the longitudinal axis of the plate is located inside the threaded hole of the inner two generally cut out large four, so as to surround the cut-out triangular I have provided in the region defined by the screw holes.

At least larger cutout is sized for passage of the bone fastener, such as an additional screw or a pin.

Cut-out, can be used as additional position for fixation or attachment.

In addition, cut-out, can be a passage through which a screw or pin fixed to reposition the bone fragments of the lower plate.

Cutouts are connected by struts that may be placed upon a bone or fusion site of the mid-foot in

order to help stabilize the bone fragments or bone.

This plate is formed of cut-out and screw hole so as not to be placed over the fusion site.

The protrusions and cut-outs, prominence of the plate not only is reduced, the required material is reduced.

The plate is formed with the minimum thickness to maintain the ability to stabilize the fusion site.

In a preferred embodiment, the thickness of the plate is less than 1.0mm.

In order to ensure that exactly the local structure, the plate is defined by the spherical curvature is the radius which is preferably fixed.

In the fusion of the mid-foot, one advantage of the fixation plate of the present invention is that the use range is significantly wider than conventional devices.

Another advantage is that it provides multiple options for bone screw placement to fuse and / or fusion surely eventually stabilize the bones and joints of the mid-foot, and then, performing an exact fracture reduction .

Advantages and objects of the present invention will become apparent upon reading the following description with reference to the accompanying drawings.

[DESCRIPTION OF PREFERRED EMBODIMENTS

It will be readily appreciated that the principles of the present invention, reference is made to the embodiment illustrated in the drawings and will be described below.

Therefore, it is to be understood that it is not intended to be limiting the scope of the present invention.

Further, the inclusion of the application of the principles of the present invention technicians belonging to the art and refinement, and modifications of the embodiments the present invention, illustrates such to occur easily to be understood.

Figure 1, the fixed plate 10 in accordance with a preferred embodiment of the present invention is disposed, mid-foot bone, shown from the back side of the (mid-foot) is illustrated.

As can be seen from FIG spans between the metatarsals of the first and second plate 10 extends over the intermediate cuneiform and inside.

In the embodiment illustrated in FIG 1, a large plate 10 can be attached to the bones of the mid-foot portion is provided.

Details of the plate 10, FIG 2 - will be apparent from FIG.

Plate 10 is formed entirely from the main body 11 having a material composition and thickness of the generally uniform.

In a preferred embodiment, a biocompatible material, the body 11 is formed of a metal, most preferably.

In some embodiments, the material of the body is a titanium alloy such as Ti-6Al-4V or titanium.

In order to reduce the prominence of the plate 10 above the bones of the mid-foot, between the bone engaging surface 13 and upper surface 12, the plate is minimum to have sufficient strength for reliable fixation of the bones and joints of the mid-foot have an effective thickness is the thickness of the.

In the preferred embodiment, 1.0mm less than the thickness of the plate is about 0.9mm, most preferably.

This thickness, it is possible as well with a sufficient strength, to bend the plate as desired, to match the shape of the implantation site.

Specifically, the plate 10 is configured to be located not only the position shown in FIG 1, in any position along the mid-foot.

For example, the shape of the intermediate cuneiform, plates of a different shape from the plate positioned across the cuboid bone may be required.

However, it is preferable to so it is not necessary to be curved bone engaging surface 13 in two dimensions to match the mid-foot, the structure across the metatarsal bone joint, especially for shaping at the surgical site plates.

Thus, as shown in the side sectional view of FIG 3, bone engaging surface 13, thus plate 10 is curved over the length of the plate.

Plate is preferred in certain embodiments, it's curved radius of uniform, such as about 75mm.

Similarly, the plate, as shown in the sectional view of FIG 4, and is curved across its width.

In an exemplary embodiment, the curvature is also about 75mm.

Most preferably, the entire plate is formed by a sphere radius, in certain embodiments, the sphere radius is about 75mm.

In addition, body 11 includes side edges 18 and end edges 15.

In order to minimize the prominence of the plate 10 and to reduce the required material, each edge defines a recess 19 and 16.

As shown in Figure 1, the edge 15 defines a recess 16 in one between the projecting portion 17 of the corners of each side of the plate.

Protruding portion 17 thereof is integral with the recess 19 in the side edge 18.

It is preferred that the central protrusion 20, it is defined on each side edge 18 so as to be equidistant from each protrusion 17 of the corner.

In a preferred embodiment, all 18 and edges 15 are rounded to reduce trauma to soft tissue surrounding the implant plate.

As shown in Figure 2, the 20 and the protrusions 17, the position of the screw hole 25 is defined.

Each screw hole is configured to receive a bone engaging fastener configured to attach to the bone of the mid-foot plate 10.

In a preferred embodiment, the bone engaging fastener is a bone screw having a size suitable for implantation into the cuboid base of the metatarsal or cuneiform, any.

The length and diameter of the bone screw is determined largely by the size and position of a fragment of bone or bone to fix.

As shown in Figure 2, plate 10 has a threaded bore 26 within another plate.

The screw holes 26 thereof, the mounting position relative to the bone a predetermined increases, the passage for the fixation of bone fragments obtained in a case of severe fracture, usage range of the plate 10 is increased.

Plate 10 of the present invention is specifically configured for implantation and fixation of the mid-foot.

Thus, the plate is sized to be positioned optimally 26 and screw holes 25 for arthrodesis and modifications trauma mid-foot variety.

In some embodiments, the screw holes between the protruding portion 17 of the corner and the plate has a width of about 21.5mm in the screw holes between the protruding portion 20 of the intermediate.

The width 26 between the screw holes inside, is about 10.0mm is preferred.

Plate 10 has a length of about 36.8mm to 25 between the screw hole of the protrusion of the corner.

26 and screw holes 25 are formed to a diameter suitable for the size of the bone screws used to attach the plate to the bone.

In a preferred embodiment, the screw holes are configured to suit the screws 3.5mm or 2.7mm commonly used for fixation of the bone of the foot.

In one aspect of the present invention, the screw holes may include a peripheral chamfered portion, such as the chamfered portion 53 of the screw hole 52 of the plate 50 shown in FIG.

I can be by the structure of the screw hole, plate, receiving a screw size both in the position of any screw hole.

Further, the present invention contemplates that it is possible to return a set screw or screws detent non bone screw to form a screw hole to fit the screw.

In an exemplary embodiment, a set screw is used, the screw holes 26 and 25, tapered threads of conventional design (not shown) is provided.

Further features of the present invention is shown best in FIG 2.

Specifically, the body 11 of the plate defines a plurality of cut-outs, including a cut-out of the total of six of the central cut-out 30 and two cut-out 32 of the two on each side.

The cut-outs 32 and 30, the material required for the formation of the plate 10 is reduced.

In addition, the cut-out, are connected by struts 40 and 38, central portion 36 and end portions 34 located opposite each other, are formed.

Center and 36 end 34 has a screw holes 25 and 26.

40 and the strut 38, help to stabilize the fragment of bone or bone of the lower side of the strut of those.

As is reflected in Figure 1, 40 and struts 38 and central portion 36 is formed a screw hole so as not positioned in a portion which should stabilize the mid-foot undergo fusion and end 34.

In a preferred embodiment, the shape of the cut-out 30 is triangular, the shape of the cutout 32 on both sides, is rectangular or generally trapezoidal.

32 and cutouts 30, the dimensions are larger than the diameter of the screw holes 26 and 25.

In addition to the reduction of the material of the plate, the 32 and the cut-out 30, it is possible positions for placing the bone screw is increased, or to reinforce the immobilized utilizing these positions, and Dari connect bone parts.

When reinforcing the fixation, it may be also disposed at the corners of one of 32 and cut-out 30, the bone screw.

When connecting the bone portions, it is possible over the bone portions to be close to bridge the fracture site, is passed through the cut-out in the bone screw.

Cut-out 30 is formed specially sized to receive a bone screw standard for fixation of bone fragments in the mid-foot.

To facilitate proper placement of the plate 10, holes 28 of small diameter, is defined in the center of the plate 10 of the central portion 36.

The holes 28, of a size to receive a guidewire or other similar K-wire is preferred.

In the exemplary treatment for correction of Lisfranc fracture / dislocation, can be inserted in the middle cuneiform bone in the K-wire, and guides so as to extend the part of the cuneiform bone and the metatarsal bone plate 10.

In one embodiment of the invention, it is possible that the plate 10, placing the screws in the peripheral portion of the mid-foot portion to be fused, to place the screws in holes 25 in 20 and the protrusions 17 in particular.

In some cases, though sufficiently stabilized the site of injury for the final fusion, it is sufficient in the mounting of these positions.

In other cases, it may be inserted to 32 and cut-out 30, and inserted into the screw hole 26, additional screws.

If bone fragments are present, it is possible to reduction are passed through the cut-outs 32 and 30 to one or more reduction screws.

If fusion moiety structure or mid-foot is small, it is possible to make small plate 50 by changing the plate 10, as shown in FIG.

This small plate is maintained as described with reference to a large plate 10, the ball radius and the thickness of the plates of the minimum.

In addition, the plate 50 includes a projecting portion 51 of the corner with a screw hole 52.

It is possible in order to extend the reach of the plate, is provided on the inside of the plate 50 and screw hole 54.

Further, it can be provided in the center of the plate, a K-wire hole 56.

It is preferred that the small plate 50, the structure of the bones and joints of the mid-foot is to conform to the small patient.

In a preferred embodiment of the present invention, the fixing device is in the form of a plate 10 having a plurality of screw holes for mounting the plate in the vicinity of the fusion site.

In a most preferred embodiment, four screw holes are positioned at the corners of the plate, two screw holes are located on both sides at the half of the length of the plate.

To increase the number of positions for attaching the plate to the bone of the mid-foot, to make it easier to stabilize the bone portions of the plurality of in case of a broken leg or middle difficult, the interior of the plate, and four screw holes in another can be defined.

In another aspect of the preferred embodiment, a plurality of cut-outs that are defined inside or between the screw holes of the plate.

In a most preferred embodiment, the cut-out triangular, provided along the longitudinal axis of the plate is located inside the threaded hole of the inner two generally cut out large four, so as to surround the cut-out triangular I have provided in the region defined by the screw holes.

Have been described and illustrated in detail the present invention in the drawings and foregoing

description, the drawings and description thereof are for illustrative purposes only and are not intended to limit the present invention.

Showed only the preferred embodiments, it will be understood that it is desired to cover all modifications which are within the scope of the present invention, refinement, and further applications are protected.

[Aspect of implementation]

In fixing device for fusion of bone or bone part of the mid-foot (1) human,

Includes a plate sized for implantation within the mid-foot of a patient,

The plate, which defines a plurality of holes, each hole has a diameter large enough to receive a bone engaging fastener so attaching the plate to the bone portions or bones of the mid-foot

The plate, which further define a plurality of cut-outs, the dimensions of each cut-out these larger than the diameter of the hole of the plurality,

Locking device.

In the fixing device (2) according to embodiment (1),

Has a uniform thickness substantially less than 1.0mm, the plate, the fixation device.

In the fixing device according to (3) embodiment (1),

Having an outer circumferential chamfered portion screw holes of the plurality, to be able to receive a fastener of different sizes, the fixed device.

In the fixation device (4) according to embodiment (1),

The threaded hole of the plurality are disposed on the periphery of the plate, the fixation device.

In the fixing device according to (5) in the embodiment (4),

Cut out of the plurality are disposed on the inner side of each hole of the plurality of fixing devices.

In the fixing device according to (6) embodiment (1),

Comprises a cut-out triangular pair of cutouts of said plurality are arranged along the longitudinal

axis of the plate, the fixation device.

In the fixing device according to (7) embodiment (1),

Comprises a cut-out of two adjacent sides of the plate, cut-out, wherein the plurality of fixing devices.

In fixing device (8) as claimed in embodiment (7),

In the form of substantially rectangular or trapezoidal cut-outs of the two in close proximity on both sides, the fixed device.

In the fixing device according to (9) embodiment (1),

The plate is further defines a guide wire hole sized to receive a K-wire or guide wire anchoring device.

In fixing device (10) according to embodiment (9),

Wherein said guide wire hole is disposed substantially in the center of the plate, the fixation device.

In the fixing device according to (11) embodiment (1),

Edge of the plate, which defines a projecting portion and a plurality of recesses, at least a portion of the plurality of holes are defined in a corresponding one of the protruding portion, the fixed device.

In the fixing device according to (12) embodiment (1),

Including a bone engaging surface curved in the sphere radius of substantially uniform, the plate, the fixation device.

Is an enlarged view of the dorsal mid-foot in accordance with an exemplary embodiment of the present invention, the fixed plate is disposed.

Is a plan view of the fixed plate shown in FIG 1.

Is a side sectional view of the plate as viewed in the direction of the arrows along the line 3-3 of FIG 2.

Is an end sectional view of the plate as viewed in the direction of the arrows along line 4-4 in FIG 2.

Is an enlarged view of the dorsal mid-foot in accordance with another embodiment of the present invention, the fixed plate is disposed.

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CLAIMS JP2006280949

(1).

In fixing device for fusion of bone or bone part of the (mid-foot) human mid-foot,

Includes a plate sized for implantation within the mid-foot of a patient,

The plate, which defines a plurality of holes, each hole has a diameter large enough to receive a bone engaging fastener so attaching the plate to the bone portions or bones of the mid-foot

The plate, which further define a plurality of cut-outs, the dimensions of each cut-out these larger than the diameter of the hole of the plurality,

Locking device.

(2).

In the fixation device of claim 1,

Has a uniform thickness substantially less than 1.0mm, the plate, the fixation device.

(3).

In the fixation device of claim 1,

Having an outer circumferential chamfered portion screw holes of the plurality, to be able to receive a fastener of different sizes, the fixed device.

(4).

In the fixation device of claim 1,

The threaded hole of the plurality are disposed on the periphery of the plate, the fixation device.

(5).

In the fixation device of claim 4,

Cut out of the plurality are disposed on the inner side of each hole of the plurality of fixing devices.

(6).

In the fixation device of claim 1,

Comprises a cut-out triangular pair of cutouts of said plurality are arranged along the longitudinal axis of the plate, the fixation device.

(7).

In the fixation device of claim 1,

Comprises a cut-out of two adjacent sides of the plate, cut-out, wherein the plurality of fixing devices.

(8).

In the fixation device of claim 7,

In the form of substantially rectangular or trapezoidal cut-outs of the two in close proximity on both sides, the fixed device.

(9).

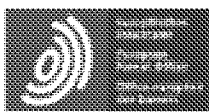
In the fixation device of claim 1,

The plate is further defines a guide wire hole sized to receive a K-wire or guide wire anchoring device.

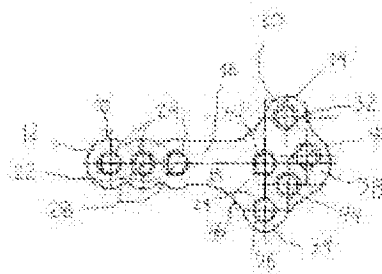
(10).

In the fixation device of claim 9,

Wherein said guide wire hole is disposed substantially in the center of the plate, the fixation device.

**Espacenet****Bibliographic data: JP2006280951 (A) — 2006-10-19****PLATE FOR UNITING METATARSOPHALANGEAL JOINT**

No documents available for this priority number.

Inventor(s): SANDERS ROY; BREMER CHRIS; PRASAD PRIYA ± (SANDERS ROY, ; BREMER CHRIS, ; PRASAD PRIYA)**Applicant(s):** DEPUY PRODUCTS INC ± (DEPUY PRODUCTS INC)**Classification:** - international: **A61B17/58**
- cooperative: **A61B17/8061****Application number:** JP20060094547 20060330**Priority number (s):** US20050094972 20050331**Also published as:** EP1707227 (A2) EP1707227 (A3) US2006241608 (A1)
AU2006201310 (A1)**Abstract of JP2006280951 (A)**

PROBLEM TO BE SOLVED: To provide a fixing plate which is used for uniting metatarsophalangeal (MTP) joints. ;

SOLUTION: The fixing plate (10) has a distant part (12) which is formed to be engaged in the metatarsal bone and a proximal part (14) which is formed to be engaged in the finger bone. The distant part (12) is elongate. Several screws are demarcated along the longitudinal axial line passing the distant part (12) and penetrate the distant part (12). The proximal part (14) has several screw holes (32, 36, 40, 42 and 44) which are arranged along axial lines parallel to the longitudinal axial line and axial lines perpendicular to it and are all deviated from one another. Only one (42) of the screw holes in the proximal part (14) is aligned with the longitudinal axial line. The fixing plate (10) is shaped like a cup to receive the bones of the MTP joint. The fixing plate (10) preferably has an intermediate part (16) which is bent at a predetermined angle of dorsiflexion. ; COPYRIGHT: (C)2007,JPO&INPIT

Last updated: 11.12.2013 Worldwide Database 5.8.15; 92p

(19) 日本国特許庁(JP)

(12) 公開特許公報(A)

(11) 特許出願公開番号

特開2006-280951

(P2006-280951A)

(43) 公開日 平成18年10月19日(2006.10.19)

(51) Int. Cl.

A61B 17/58 (2006.01)

F 1

A61B 17/58 310

テーマコード(参考)

4C060

審査請求 未請求 請求項の数 10 O L 外国語出願 (全 11 頁)

(21) 出願番号 特願2006-94547(P2006-94547)
(22) 出願日 平成18年3月30日(2006.3.30)
(31) 優先権主張番号 11/094,972
(32) 優先日 平成17年3月31日(2005.3.31)
(33) 優先権主張国 米国(US)

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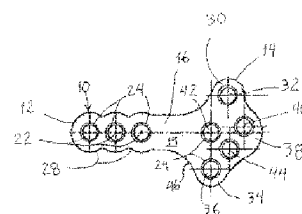
(54) 【発明の名称】 中足指節関節の癒合用板

(57) 【要約】

【課題】 中足指節(MTP)関節の癒合に用いられる固定板を提供する。

【解決手段】 固定板(10)は、中足骨に係合するよう形作られた遠位部分(12)と、指節骨に係合するよう形作られた近位部分(14)とを有する。遠位部分は、細長く、遠位部分を通る長手方向軸線に沿い、遠位部分を貫通して数本のねじが画定されている。近位部分は、長手方向軸線に平行な軸線と垂直な軸線に沿って全て互いに対してオフセットした複数のねじ穴(32, 36, 40, 42, 44)を有する。近位部分のねじ穴のうち、長手方向軸線と一致しているのは1つ(42)だけである。固定板は、MTP関節の骨をカップのようになって受けるよう形作られている。固定板は、所定の背屈角に曲げられた中間部分(16)を有するのがよい。

【選択図】 図2



【特許請求の範囲】

【請求項1】

中足骨との指節骨との間の中足指節（MTP）関節の癒合のための固定板において、
前記中足骨に取り付け可能に形作られた細長い遠位部分であって、該遠位部分は、この遠位部分を通る長手方向軸線に沿って少なくとも1つの遠位開口部を画定し、該少なくとも1つの遠位開口部は、骨係合締結具を挿通状態で受け入れるよう形作られている、遠位部分と、
前記遠位部分に連結されていて、骨係合締結具を挿通状態で受け入れるよう形作られた複数の近位開口部を画定する近位部分であって、前記複数の開口部の中で、前記長手方向軸線と整列しているのは1つだけである、近位部分と、
を有する固定板。

【請求項2】

請求項1記載の固定板において、
前記近位部分は、前記長手方向軸線から側方にオフセットした1対の互いに反対側のウイングを有し、該ウイングは各々、前記複数の近位開口部のうちの1つを有する、固定板。

【請求項3】

請求項2記載の固定板において、
前記近位部分は、前記ウイング相互間に位置する中央領域を更に有し、該中央領域は、前記複数の近位開口部のうち少なくとも1つを画定している、固定板。

【請求項4】

請求項3記載の固定板において、
前記中央領域は、前記複数の近位開口部のうち3つを画定する、固定板。

【請求項5】

請求項4記載の固定板において、
前記近位開口部は全て、前記長手方向軸線に平行な軸線に沿って互いに対してオフセットしている、固定板。

【請求項6】

請求項5記載の固定板において、
前記近位開口部は全て、前記長手方向軸線に垂直な軸線に沿って互いに対してオフセットしている、固定板。

【請求項7】

請求項1記載の固定板において、
少なくとも前記近位部分は、前記指節骨に接触する前記近位部分の表面に設けられていて、前記指節骨の表面にほぼ対応する曲率を備えている、固定板。

【請求項8】

請求項1記載の固定板において、
前記固定板は、前記長手方向軸線に沿って前記MTP関節から遠ざかる曲率を備えている、固定板。

【請求項9】

請求項1記載の固定板において、
前記遠位開口部および前記近位開口部のうち少なくとも幾つかは、前記MTP関節と反対側の前記固定板の表面に円周方向面取り部を有する、固定板。

【請求項10】

請求項1記載の固定板において、
前記近位部分を前記遠位部分に連結する中間部分を更に有し、該中間部分は、骨係合締結具を挿通状態で受け入れる開口部を備えていない、固定板。

【発明の詳細な説明】

【開示の内容】

【0001】

〔発明の概要〕

本発明は、関節固定を行うために、関節、特に中足指節関節の2つの骨部分を互いに固定したり互いに対して整列させたりする外科用器具の一般的な技術分野に関する。

【0002】

第一中足指節（MTP）関節の関節固定または癒合は、幾つかの適応、例えば外反母趾、ハラクスリミタス（hallux limitus）または強直母指、変形関節疾患、重症脱臼または亜脱臼、および変性変形のための選択治療である場合が多い。癒合は、これら適応と関連した変形を矯正するためまたはMTP関節の運動と関連した関節痛みを軽減するために利用できる。第一MTP関節の癒合により、患者は、不快感無く、通常は、足取りに対する衝撃を最小限に抑えた状態で歩行することができる。事実、処置の必要がある病理学的特徴が原因となって、患者の歩行能力に顕著な問題が生じた場合、癒合は事実上、患者の歩行パターンを改善することができる。

【0003】

一般に、関節固定は、この結果として関節位置が定められて元には戻せないために問題となる場合がある。かくして、MTP関節の関節固定は、2つの骨が互いに対して正確に位置決めされて後に生じる問題を無くすと共に患者ができるだけ普通に歩くことができる状況を保つようにするために注意深く行われることが非常に重要である。

【0004】

普及している1つの癒合手技では、中足骨および指節骨の関節面は、これらの骨を適当な背屈角および内外反角で位置決めできるよう必要に応じて前処理される。次に、1対の骨締結具、例えば4-0套管状ねじをMTP関節を横切って植え込んで関節位置を固定する。骨グラフトを骨分離領域に導入して関節の完全な癒合を促進するのがよい。

【0005】

一変形例では、固定板を関節を横切って植え込み、典型的には骨ねじにより対向した骨に固定する。固定板は、外科医により曲げられて患者に特有の背屈平面に角度を定め、それにより歩行中における患者にとっての問題を無くすと共に将来の合併症の恐れを最小限に抑える。多くの先行技術の固定板は、内外反角にわたり曲げるのに不適切であり、これが意味することは、これら固定板は、互いに癒合されるべき2つの骨の最適な解剖学的向きに十分に近い関節固定を行うことができないということである。

【0006】

最近、一定の内外反角および一定の背屈角をあらかじめ備えた固定板が提供された。この種の固定板の一例は、ニューディール・エス・エー（Newdeal SA）社により提供されたHALLU（登録商標）-C Plateである。この固定板は、互いに対して10°に固定された内外反角をなして整列した2つの直線状板部分で構成されている。この固定板も又、10°の背屈角を形成するようその中線のところで曲げられている。各直線状板部分は、この板部分の長手方向軸線に沿って配置された2つのねじ穴の間に設けられた細長いスロットを有する。この固定板の他の細部は、2003年3月27日に公開された米国特許出願第2003/0060827号明細書に見え、この米国特許を参照により引用し、その開示内容を本明細書の一部とする。

【0007】

この種の固定板は、外科医が外科手技中、固定板を背屈角に曲げることが必要であり、任意の内外反角を許容しない先行技術の固定板の改良となっている。しかしながら、MTP関節、特に第一MTP関節について固定板に依然として改良の余地が存在する。特に、固定板を関連の骨、特に指節骨に固定する骨締結具を位置決めする際に高い融通性をもたらす固定板が要望されている。また、軟組織に対する刺激を最小限に抑えるよう低いプロフィール（側面高さ）を持つ、即ち、薄型の固定板が要望されている。

【0008】

〔発明の概要〕

本発明は、中足指節関節の関節固定のための改良型固定板の要望を満足させる。本発明の一実施形態では、固定板は、中足骨の骨頭から遠位長さに沿って延びる全体として細長

い中足骨側部分を有する。一連の面取りねじ穴が、この中足骨部分の軸線に沿って延びている。

【0009】

固定板は、固定板の中間部分によって中足骨側部分に連結された指節骨側部分を更に有する。指節骨側部分は、細長い中足骨側部分に対して拡大されると共に非対称になっている。好ましい実施形態では、指節骨側部分は、内側ウイングおよび内側ウイングから軸方向にオフセットした反対側の外側ウイングを有する。各ウイングは、面取りねじ穴を支持している。2つのウイング相互間の中央領域も又、互いに側方にかつ軸方向にオフセットした3つのねじ穴を支持している。

【0010】

本発明の別の特徴では、固定板全体は、中足骨および指節骨の輪郭を全体として辿る湾曲した骨係合面を備えるよう湾曲している。本発明の固定板は、その中足骨側部分と指節骨側部分との間でオフセットした所定の内外反角を導入するのではなく、指節骨側部分が指節骨の近位端または骨底をカップのようになって受け、指節骨の骨底に固定された指節骨側部分の向きにより定められる角度が何度であれ、中足骨側部分が指節骨に固定されるべき中足骨の遠位部分を単に覆うように形作られている。好ましい実施形態では、固定板は、その中間部分が適当な背屈角に合わせて曲げられている。

【0011】

固定板のプロフィールを最小限に抑えるため、本発明は、厚さ約1 mmの板厚さを想定している。加うるに、固定板の周囲は、固定板の表面全体にわたり材料の量を減少させるようにねじ穴周りに輪郭付けられている。

【0012】

本発明の一利点は、MTP関節の関節固定用の板をこの関節の骨にしっかりと固定できるということにある。もう1つの利点は、板が特に指節骨の骨底を横切って種々のねじ固定箇所をもたらすということにある。

【0013】

本発明の固定板により得られる別の利点は、骨全体にわたって隆起部を減少させる最小限のプロフィールを示し、組織に対する刺激を最小限に抑えていることにある。本発明のこれら利点および他の利点は、添付の図面と共に以下の説明を読むと理解されよう。

【0014】

〔好ましい実施形態の説明〕

次に、本発明の原理の理解を促進する目的で、図面に示されていて以下の明細書において説明される実施形態を参照する。言うまでもないが、それにより本発明の範囲の限定を意図しているわけではない。さらに、本発明は、図示の実施形態の変形例および改造例を含み、また、当業者にとって通常思いつく本発明の原理の別の用途を含むものである。

【0015】

足第一指、即ち母指の遠位側の骨が図1に示されている。具体的に説明すると、足指は、第一中足骨、第一指節骨およびこれらの間に位置する中足指節（MTP）関節を有している。本発明の一実施形態の固定板10が、MTP関節を跨いでいて、この関節の両方の骨に固定されるよう構成されている。図2に詳細に示すように、固定板10は、遠位側部分または中足骨側部分12および近位側部分または指節骨側部分14を有している。一体の中間部分16が、遠位部分と近位部分を連結している。

【0016】

遠位部分12は全体として、細長く、少なくとも2つ、最もこのましくは3つの穴22が、実質的にこの遠位部分の長手方向軸線に沿って位置決めされている。穴22は、骨締結具、例えば骨ねじの軸部を受け入れるよう形作られている。本発明の一特徴では、穴22は、円周方向面取り部24を有している。この面取り部により、2つの互いに異なるサイズの骨ねじを使用することができる。特定の実施形態では、穴22は、3.8 mmの直径を有し、5.3 mmの近位側直径を生じさせるよう120°の面取り部24を備えている。この特定のねじ穴は、2.7 mm皮質性ねじか、3.5 mm皮質性ねじかのいずれか

を受け入れるよう形作られている。

【0017】

図示の実施形態では、ねじ穴22は、非弛み止めねじを受け入れるよう構成されている。変形実施形態では、ねじ穴は、例えばねじ穴内に弛み止めねじ山（図示せず）を設けることにより弛み止めねじを受け入れるよう設計されている。弛み止めねじ山は、特定の皮質性弛み止めねじにより定められる種々の公知の形態のものであってよい。特定の実施形態では、弛み止めねじ山は、ピッチが0.5mmであり、外径が4.0mmであり、内径が3.6mmであるのがよい。

【0018】

本発明の好ましい実施形態では、ねじ穴22は、6.0mm間隔で離隔している。本発明の一特徴では、遠位部分12の周囲28は、それほど大きな荷重を支持しない穴周りの領域における板材料を減少させるようねじ穴周りに輪郭付けられている。

【0019】

固定板の近位部分または指節骨側部分14は、図2で最もよく分かるように、非対称である。好ましい実施形態では、近位部分は、内側ウイング30およびこれと反対側の外側ウイング34を有している。これら2つのウイングは、互いに軸方向にオフセットしており、内側ウイングは、外側ウイングよりも近位側に位置決めされている。ウイング30、34の形状は全体として、指節骨が図1に示すように許容限度内の内外反角で位置決めされると、第一の指節骨の骨底の向きに一致する。許容限度内の内外反角は、5〜10°であるのがよく、5°が患者の大多数にとって最も好ましい。この角度では、指節骨の骨底の内側特徴部は、外側特徴部よりも近位側に位置する。このオフセットは、内側ウイングと外側ウイングとの間の軸方向オフセットにより固定板10に見込まれている。

【0020】

各ウイングは、これに対応したねじ穴32、36を支持している。ねじ穴は好ましくは、円周方向面取り部24を有するよう上述したねじ穴22と同様に形作られている。ねじ穴32、36は、上述したように皮質性弛み止めねじまたは非弛み止め皮質性ねじを受け入れることができる。遠位部分12のねじ穴の場合のように、各ウイング30、34の周囲は、骨よりも上の板プロフィール（側面高さ）または隆起を減少させて軟組織に対する刺激を最小限に抑えるよう対応のねじ穴32、36周りに輪郭付けられている。

【0021】

近位部分14は、2つのウイング相互間に中央領域38を有している。好ましい実施形態では、中央領域38は、3つのねじ穴40、42、44を有している。これらねじ穴の各々の中心は、互いに対してかつウイングのねじ穴32、36に対して軸方向かつ横方向にオフセットしている。ねじ穴42は、固定板10の遠位部分12のねじ穴22と軸方向に整列すると共に（あるいは）遠位部分の長手方向軸線に沿って軸方向に整列するのがよい。

【0022】

好ましい実施形態では、固定板の近位部分14は、5つのねじ穴32、36、40、42、44を有している。これらねじ穴は、ねじをかし合わせることなく各穴を通して指節骨にねじ込むことができるよう配置されている。外科医は、固定板10を指節骨に固定できるようねじ穴の全てまたは任意のサブセットを選択することができる。ねじ配置におけるこの融通性は、骨の一部が切除されている骨減少症の骨の患者または指節骨の骨底が骨折している場合に特に有利である。さらに、近位部分14全体にわたるねじ穴の配置により、外科医は、固定板10を骨に最適に固定する最低2つのねじ位置を選択することができる。換言すると、5つのねじ穴が近位部分に設けられている場合、外科医は、2本の骨ねじを十通りの互いに異なる向きで導入することができる（例えば、ねじを穴32、36または穴40、36または穴42、44内に配置できる。）

【0023】

理解できることとして、固定板10のねじ穴のかかる配置状態は、植え込み時においていかなる内外反角に適合する。固定板10の一植え込み方法では、外科医は、固定板を指

節骨に強固に取り付けるのに必要なねじの本数を判定する。固定板の近位部分14を指節骨上に位置決めし、骨ねじを骨内に打ち込んで固定板を骨に取り付ける（理解されることとして、骨は、採用されたやり方に従って例えば骨に穴をあらかじめ開けてタップ立てすることにより骨ねじを受け入れるよう前処理されている。）近位部分が指節骨に取り付けられた状態で、指節骨を許容可能な内外反角に位置決めするのがよい。このようにする際、固定板10の遠位部分12は、中足骨に対して位置がずれるが、この骨との十分な接触状態を常に保つ。

【0024】

許容可能な指節骨と中足骨の角度をいったん達成すると、次に、ねじ穴22内の骨ねじの任意の組み合わせを用いて遠位部分12を中足骨に取り付けるのがよい。したがって、理解できるように、本発明の固定板10は、許容可能な内外反角を達成またはこれに対応する際に先行技術の癒合板と関連した問題を無くす。固定板10は、外科医により所望される任意の角度を受け入れ、先行技術の板のように所定の内外反角を強要しない。本発明の固定板10のねじ穴配置では、外科医は、母指の固定のために約5°～約10°の外反角を生じさせることができる。

【0025】

また、固定板10のこの特徴は、この固定板の製造を容易にする。この固定板の一製造方法では、シート状材料を図2に示す平らなパターンの形状に打ち抜くのがよい。必要なエッジおよび表面処理（例えば、バリ取りや陽極処理）は、平らなパターン上で容易に実施される。次に、平らなパターンをマンドレル上で曲げて骨係合面18の曲率および上面19の曲率を生じさせるのがよく、これら両方については以下において説明する。

【0026】

固定板10の別の特徴では、固定板の骨係合面18は、図3および図5に示すように、骨の表面にほぼ等しい半径で輪郭付けられるのがよい。好ましい実施形態では、固定板10全体は、その長さに沿って約9.3mmの半径に輪郭付けられる。他の実施形態では、近位部分14のみを指節骨の骨底に合うように輪郭付けする。骨の上の固定板10の隆起を減少させることに加えて、輪郭付け面18は、骨、特に指節骨の骨底を「カップのようになって受ける」（以下、「カップ受け」という場合がある）よう働く。この「カップ受け」特徴は、骨の固定板の固定を促進し、指節骨の骨折部を整復するのを助け、骨ねじ軸線を位置合わせして骨内に最大係合状態を生じさせるのを助ける。

【0027】

表面18の輪郭に加えて、固定板は、図4に最もよく示されているように、固定板の長さに沿って上面19の曲率を更にもたらしのがよい。この漸次曲率は、固定板10と関節の2つの骨との間の堅固な接触を維持するのを助ける。特定の実施形態では、固定板は、固定板の長さ全体にわたり約130mmの半径で湾曲している。

【0028】

固定板10は好ましくは、図4に示すように所定の背屈角 α をもたらす。特に、固定板は、曲げを2つの骨の間のMTP関節のところで方向づけることができるよう中間部分16のところが曲げられている。最も好ましい実施形態では、固定板は、母指に関し約17°の背屈角であらかじめ曲げられており、これは、大抵の患者にとって解剖学的に最適であることが判明している。しかしながら、固定板10は、他の背屈角であらかじめ曲げられた状態で提供されてもよく、外科医がこの固定板を別の角度に曲げることができるようにしてもよい。

【0029】

固定板10は、癒合が達成されるまで足指を支持するのに十分強固な医用材料で作られている。好ましい実施形態では、固定板は、チタン合金、例えばTi-6Al-4Vで作られている。最小限度のプロフィールを維持するため、固定板の厚さは、約1mmである。

【0030】

図示の実施形態では、固定板10は、患者の右足用に構成されている。当然のことなが

ら、左足用の固定板は、図1～図3に示す固定板の鏡像となることはいうまでもない。

【0031】

本発明を図面に示すと共に上記説明において詳細に説明したが、本発明は、例示として解されるべきであって、本質において限定されるべきではない。好ましい実施形態だけが提供されており、本発明の精神に属する全ての変更、改造および別の用途は、保護が望まれている。

【0032】

〔実施の態様〕

本発明の具体的な実施態様は、次の通りである。

(1) 中足骨との指節骨との間の中足指節(MTP)関節の癒合のための固定板において、

前記中足骨に取り付け可能に形作られた細長い遠位部分であって、該遠位部分は、この遠位部分を通る長手方向軸線に沿って少なくとも1つの遠位開口部を画定し、該少なくとも1つの遠位開口部は、骨係合締結具を挿通状態で受け入れるよう形作られている、遠位部分と、

前記遠位部分に連結されていて、骨係合締結具を挿通状態で受け入れるよう形作られた複数の近位開口部を画定する近位部分であって、前記複数の開口部の中で、前記長手方向軸線と整列しているのは1つだけである、近位部分と、

を有する固定板。

(2) 実施態様(1)記載の固定板において、

前記近位部分は、前記長手方向軸線から側方にオフセットした1対の互いに反対側のウイングを有し、該ウイングは各々、前記複数の近位開口部のうちの1つを有する、固定板

。

(3) 実施態様(2)記載の固定板において、

前記近位部分は、前記ウイング相互間に位置する中央領域を更に有し、該中央領域は、前記複数の近位開口部のうち少なくとも1つを画定している、固定板。

(4) 実施態様(3)記載の固定板において、

前記中央領域は、前記複数の近位開口部のうち3つを画定する、固定板。

(5) 実施態様(4)記載の固定板において、

前記近位開口部は全て、前記長手方向軸線に平行な軸線に沿って互いに対してオフセットしている、固定板。

(6) 実施態様(5)記載の固定板において、

前記近位開口部は全て、前記長手方向軸線に垂直な軸線に沿って互いに対してオフセットしている、固定板。

【0033】

(7) 実施態様(1)記載の固定板において、

少なくとも前記近位部分は、前記指節骨に接触する前記近位部分の表面に設けられていて、前記指節骨の表面にほぼ対応する曲率を備えている、固定板。

(8) 実施態様(1)記載の固定板において、

前記固定板は、前記長手方向軸線に沿って前記MTP関節から遠ざかる曲率を備えている、固定板。

(9) 実施態様(1)記載の固定板において、

前記遠位開口部および前記近位開口部のうち少なくとも幾つかは、前記MTP関節と反対側の前記固定板の表面に円周方向面取り部を有する、固定板。

(10) 実施態様(1)記載の固定板において、

前記近位部分を前記遠位部分に連結する中間部分を更に有し、該中間部分は、骨係合締結具を挿通状態で受け入れる開口部を備えていない、固定板。

(11) 実施態様(10)記載の固定板において、

前記固定板は、所定の背屈角をなして前記中間部分のところで曲げられている、固定板

。

【図面の簡単な説明】

【0034】

【図1】 本発明の一実施形態としての固定板が装着された中足指節関節の平面図である。

【図2】 図1に示す固定板の平らなパターンにした平面図である。

【図3】 図1に示す固定板の底面図であり、特に固定板の骨係合面の曲率を示す図である。

【図4】 図3に示す固定板の4-4線に沿って矢印の方向に見た縦断面図である。

【図5】 図3に示す固定板の端面図である。

【符号の説明】

【0035】

10 固定板

12 遠位端部

14 近位端部

16 中間部分

18 骨係合面

19 上面

22 穴

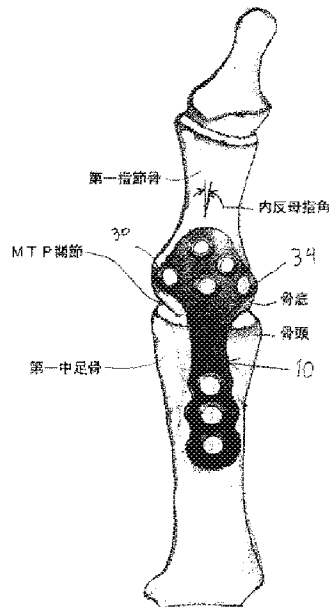
24 面取り部

30, 34 ウイング

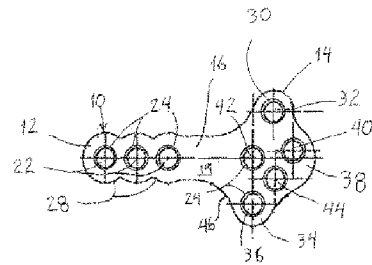
32, 36, 40, 42, 44 ねじ穴

38 中央領域

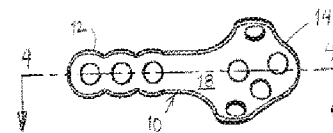
【図1】



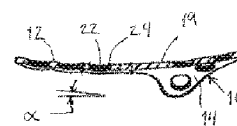
【図2】



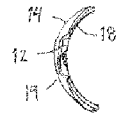
【図3】



【図4】



【図5】



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- Fターム(参考) 4C060 LL14 MM24

【外国語明細書】
2006280951000001.pdf

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DESCRIPTION JP2006280951

In order to perform arthrodesis, the present invention SUMMARY OF THE INVENTION Technical Field The general surgical instrument or aligned relative to each other joints, or mutually fixing bone parts of two metatarsophalangeal joint, especially about.

Adaptation of some, for example tonic thumb or (hallux limitus) hallux valgus, Ha Lux limiter vinegar, deformation joint disease, subluxation or dislocation severe, and fusion or arthrodesis (MTP) joint, modified variant first metatarsophalangeal If it is the treatment of choice for many cases.

For correcting deformation associated with adaptive These fusion can be used or to alleviate joint pain associated with movement of the MTP joint.

The fusion of the first MTP joint, without discomfort, usually, the patient is able to walk in a state of minimal impact on gait.

In fact, if the pathological features in need of treatment caused significant problems occurs in walking ability of the patients, healing can be effectively and to improve the walking pattern of the patient.

In general, arthrodesis, there can be a problem because it can not return to the original joint position is determined as a result.

Thus, the arthrodesis of the MTP joint to be performed carefully in order to keep the situation that a patient can walk normally as possible while eliminating the problem of two bones occurs later with accurately positioned relative to one another is very It is important to.

The fusion procedure of one widely used, the metatarsal bone and articular surface of the phalanx is pretreated as necessary so that it can be positioned in varus-valgus angle and dorsiflexion suitable to these bones.

Next, the bone fastener pair, for example, to fix the joint position to be implanted across the MTP joint 4-0 cannulated screws.

It is preferable to facilitate complete fusion of the joint can be introduced into bone separation region the bone graft.

In one variation, to be fixed to the bone it is implanted across the joint fixing plate, and opposed by the bone screws typically.

Define an angle to the back surface patient specific and bent by the surgeon, the fixed plate, to minimize the risk of future complications as well as trouble free for the patient in walking through it.

Fixed plate of many prior art is inappropriate to bend over the varus-valgus angle, the fixed plate these, What this means, enough to optimal anatomical orientation of the two bones to be fused to each other and that it is not possible to perform the close arthrodesis.

Recently, the fixed plate having pre dorsiflexion constant and varus-valgus angle of the constant is provided.

HALLU provided New Deal-er by S. (Newdeal SA)'s an example of a fixed plate of this kind is (R)-C Plate.

The fixing plate is formed of a straight plates two portions were aligned without a varus-valgus angle fixed to 10 ° relative to each other.

The fixing plate is also, and is bent at its mid-line to form a dorsiflexion of 10 °.

Each linear plate section includes an elongated slot provided on the side of the two screw holes disposed along the longitudinal axis of the plate portion.

It looks to U.S. Patent Application No. 2003/0060827 discloses published on March 27, 2003, and incorporated by reference to this U.S. patent, other details of the fixed plate, one of the disclosure of which is herein content Let me be part.

The surgical procedure in which the surgeon can bend dorsiflexion the fixing plate is necessary, the fixed plate of this type is a refinement of the fixed plate of the prior art does not allow for varus-valgus any corner.

However, MTP joint, room for improvement is still present in the fixed plate for the first MTP joint in particular.

In particular, the fixed plate providing high flexibility in the positioning of the relevant bones, the bone fastener that secures the phalanx particularly the fixing plate is desired.

Further, with a (high side) low profile to minimize the irritation to soft tissue, i.e., the fixed plate of thickness is desired.

SUMMARY OF THE INVENTION The present invention, to satisfy the needs of the improved fixing plate for arthrodesis of the metatarsophalangeal joint.

In one exemplary embodiment of the present invention, the fixed plate has a metatarsal portion in an elongated generally extending along the distal length from the condyles of the metatarsal.

Chamfered screw holes of the series extends along the axis of the metatarsal portion.

Fixed plate further includes a phalanx portion connected to the metatarsal portion by an intermediate portion of the fixed plate.

Phalanx portion is made asymmetric with respect to the enlarged metatarsal portion in the elongated.

In a preferred embodiment, the phalanx portion has an outer wing of the other side that is offset axially from the inner wing and inner wing.

Each wing supports a chamfered screw hole.

The central region of the wing between the two is also to support the three screw holes offset in the axial direction and laterally to each other.

In another aspect of the present invention, the metatarsus and the entire fixing plate is curved so as to comprise a bone engaging surface which is curved as a whole follows the contour of the phalanx.

Instead of introducing the varus-valgus angle of a predetermined offset between the phalanx portion and the metatarsal portion, the fixed plate of the present invention, the proximal end of phalangeal bone phalanx portion angle or receives it looks like a cup bone bottom, defined by the orientation of the phalanx portion fixed to the bone base of the phalanx is any number of times, the metatarsal portion is fixed to the finger bone and is shaped to cover just a distal portion of the metatarsus to be.

In a preferred embodiment, the fixed plate is bent to fit the appropriate dorsiflexion in its

intermediate portion.

To minimize the profile of the fixing plate, the present invention contemplates a plate thickness of about 1mm thick.

In addition, the periphery of the fixed plate is contoured to the screw holes around to reduce the amount of material across the surface of the fixed plate.

One advantage of the present invention is that you can securely fastened to the bone of the joint plate for arthrodesis of the MTP joint.

Another advantage is that the result that the screws fixing various places the plate across the bone base of the phalanx particular.

Another advantage obtained by the fixing plate of the present invention is that it shows minimal profile to reduce the raised portion over the entire bone, thereby minimizing irritation to the tissue.

It will be understood and other advantages these of the present invention includes a reading of the following description taken in conjunction with the accompanying drawings.

Next DESCRIPTION OF THE PREFERRED EMBODIMENTS For the purpose of promoting an understanding of the principles of the present invention, reference is made to the embodiments described in the following specification and have been shown in the drawings.

Needless to say, it is not necessarily intended to limit the scope of the present invention thereby.

In addition, also includes a variations and modifications of the illustrated embodiment, the present invention includes the use of another of the principles of the present invention that occur normally those skilled in the art.

Foot first finger, that the bone distal thumb is shown in Figure 1.

To be more specific, the first metatarsal bone, a first phalanx and the toe has a (MTP) joint metatarsophalangeal positioned therebetween.

And is configured such that the fixed plate 10 of one embodiment of the present invention, optionally across the MTP joint is fixed to the bone in both the joint.

As shown in detail in FIG 2, the fixing plate 10 includes a phalanx portion 14 or the proximal portion and the metatarsal portion 12 or distal portion.

Intermediate portion 16 of the integral, connects the proximal portion and a distal portion.

Overall, elongated, and at least two holes 22 3, the distal portion 12 is positioned along the longitudinal axis of the distal portion most preferably substantially.

Hole 22 is shaped to receive the shank of the bone screws such as bone fastener.

In one aspect of the present invention, hole 22 has a circumferential chamfer 24.

It allows the chamfered portion, using bone screws of different sizes from each other two.

In certain embodiments, the hole 22 is provided with a chamfered portion 24 of the 120 ° so as to have a diameter of 3.8mm, to produce a proximal diameter of 5.3mm.

Or 2.7mm cortical threads in this particular, is shaped to receive either a 3.5mm cortical Nejika.

In the illustrated embodiment, the screw hole 22 is configured to receive a non-loosening set screw.

In an alternative embodiment, the screw holes are designed to receive a loosening set screw, for example by providing loosening locking threads (not shown) into the threaded bore.

Loosening locking threads may be in the form of various known defined by cortical loosening set screw particular.

In certain embodiments, loosening locking threads are 0.5mm pitch, outer diameter of 4.0mm, and may have an inner diameter of a 3.6mm.

In a preferred embodiment of the present invention, the screw holes 22, are spaced at 6.0mm intervals.

In one aspect of the present invention, the periphery 28 of the distal portion 12 is contoured around the screw holes to reduce the plate material in the area surrounding the hole that do not support very large load.

As best seen in FIG 2, phalanx portion 14 or the proximal portion of the fixed plate is asymmetric.

In a preferred embodiment, the proximal portion has an outer wing 34 opposite thereto and the inner wing 30.

Wings, these two are axially offset from each other, the inner wing, is positioned proximal to the

outer wing.

Overall, it is positioned in the varus-valgus angle of within acceptable limits phalanx, as shown in FIG 1, the shape of the wings 30 and 34 coincides with the direction of the bone base of the phalanges of the first.

The varus-valgus angle of within acceptable limits, and is a $5 \sim 10^\circ$ is good, 5° is most preferred for the majority of patients.

In this angle, the inside features of the bone bottom of the phalanx is located on the proximal side of the exterior features.

This offset is allowed for the fixed plate 10 by the axial offset between the outer wing and an inner wing.

Each wing supports a threaded hole 32, 36 corresponding thereto.

Preferably, the screw holes are shaped similar to the screw holes 22 described above to have a circumferential chamfer 24.

Screw holes 32 and 36, can accept non-loosening locking cortical screws or cortical loosening the set screw, as described above.

As with the screw holes in the distal portion 12, the periphery of each wing 30 and 34, corresponding to minimize the irritation to soft tissue with a reduced or ridges (height side) plate profile above the bone It is contoured to 32 and 36 around the screw holes.

The proximal portion 14 has a central region 38 to the wing between the two.

In a preferred embodiment, the central region 38 has a three screw holes 40, 42, 44.

The center of each of these screw holes is offset laterally and axially with respect to the screw holes 32, 36 of the wing and to each other.

Good screw holes 42 and to align in the axial direction along the longitudinal axis of the distal portion (or) with axially aligned with the screw holes 22 of the distal portion 12 of the fixed plate 10.

In a preferred embodiment, the proximal portion 14 of the fixed plate has five screw holes 32,36,40,42,44.

Screw holes are arranged so that they can be screwed into the phalanx through each hole without

causing Kachiawa screws.

The surgeon can select a subset of all or any of the screw holes so as to be fixed to the finger bone fixation plate 10.

This flexibility in screw placement is particularly advantageous when the bone base of the phalanx or the patients bone osteopenia part of the bone has been cut is fractured.

Further, the arrangement of the screw holes across the proximal portion 14 as a whole, the surgeon can select the lowest two screws for fixing the position optimal to the bone fixation plate 10.

In other words, if the five screw holes are provided on the proximal portion (eg, the surgeon, the hole or holes 32 and 36 the screws can be introduced in different directions ten kinds bone two screws . that can be placed in the holes 42, 44 or in 40, 36)

As can be understanding, arrangement of such screw holes of the fixing plate 10 is adapted to any varus-valgus angle in when implanted.

The method of implanting one fixed plate 10, the surgeon determines the required number of screws to attach firmly to the finger bone fixation plate.

As it is positioned in phalanx on 14 proximal portion of the fixed plate, attached to the bone fixation plate are implanted into the bone and the bone screws to be (understood, in accordance manner to that employed such as bone and a hole in the bone . it is so pretreated receive a bone screw by a tapped by opening previously)

good in the state in which the proximal portion is attached to the phalanx, is to position at an acceptable varus-valgus angle the phalanx.

The In doing so, the distal portion 12 of the fixed plate 10, the position is shifted relative to the metatarsal bone, but always maintain sufficient contact with the bone.

When achieved once the angle of the metatarsal and acceptable phalanx, then, it is desirable to attach the metatarsal distal portion 12 using any combination of bone screws in the screw holes 22.

Thus, as can be seen, the fixed plate 10 of the present invention eliminates the problems associated with fusion plates of the prior art when responding to this or to achieve an acceptable varus-valgus angle.

Accepts any angle desired by the surgeon, the fixed plate 10 does not force the varus-valgus angle predetermined as a plate of the prior art.

The screw holes disposed on the fixed plate 10 of the present invention, the surgeon can produce valgus angle of about 10 ° to about 5 ° ~ for fixation of the thumb.

Further, the feature of the fixing plate 10, to facilitate the production of the fixing plate.

In one method of the fixed plate, it is preferable punched into the shape of a flat pattern shown in FIG 2 a sheet-like material.

Surface treatment and edge necessary (for example, anodized and deburring) is carried out easily in a flat pattern.

Next, may be described in the following description for both the curvature of 18 bone-engaging surface and produce the curvature of the upper surface 19 by bending mandrel on a flat pattern.

In another aspect of the fixing plate 10, as shown in Figures 3 and 5, bone-engaging surface 18 of the fixed plate, good to delineated in radius approximately equal to the surface of the bone.

In a preferred embodiment, the fixed plate 10 as a whole is contoured to a radius of about 9.3mm along its length.

In other embodiments, I contoured to fit the bottom of the bone phalanx only the proximal portion 14.

In addition to reducing the prominence of the fixation plate 10 above the bone, the bone, and "receive so the cup" the bone base of the phalanx (hereinafter, contoured surface 18 is referred to as "cup receiver" particularly I work as is the case) there.

This helps promote the fixing of the fixing plate of the bone, and to reduce the fracture portion of the phalanx, "cup receiver" this feature, produce maximum engagement within the bone in alignment bone screw axis I help.

In addition to the contour of the surface 18, as best shown in FIG 4, the fixed plate is good to further provide a curvature of the upper surface 19 along the length of the fixed plate.

This gradual curvature helps maintain a solid contact between the two bones of the joint between the fixed plate 10.

In certain embodiments, the fixed plate is curved at a radius of about 130mm over the entire length

of the fixing plate.

Preferably, the fixed plate 10 results in a dorsiflexion α predetermined as shown in FIG 4.

In particular, the fixed plate is bent at the intermediate portion 16 so that it can be oriented at the MTP joint between the two bones bending.

In a most preferred embodiment, the fixed plate is bent in advance in dorsiflexion of about 17 ° respect to the thumb, which will be optimal anatomically for most patients have been found.

However, may, fixing plate 10, may be that the surgeon can bend a different angle the fixing plate may be provided in pre-bent in dorsiflexion other.

Fixed plate 10 is made sufficiently strong biomaterial to support the toe until fusion is achieved.

In a preferred embodiment, the fixed plate, a titanium alloy, for example, are made of Ti-6AL-4V.

In order to maintain a minimal profile, the thickness of the fixing plate is about 1mm.

In the illustrated embodiment, the fixed plate 10 is formed on the right foot of the patient.

Of course, the fixed plate of the left foot, which is the mirror image of the fixed plate shown in Figures 1-3 of course.

Was described in detail in the foregoing description in conjunction with the drawings shown in the present invention, there should be construed as illustrative, the present invention should not be limited in nature.

Only a preferred embodiment there is provided, the use of different changes that belong to the spirit of the present invention, and modifications, protection is desired.

Specific embodiments of the present invention [aspect] embodiment is as follows. (

In the fixed plate for healing (MTP) joint in pediphalanx between the phalanx and 1) metatarsal, and an elongated distal portions shaped to be attached to the leg bone the middle, The distal portion, and defines a distal opening of at least one along the longitudinal axis passing through the distal portion, the distal one opening, to receive in inserted condition the bone engaging fastener and said at least A proximal portion defining a proximal opening of the plurality are shaped, and a distal portion, and optionally linked to the distal portion, shaped to receive in the inserted condition the bone engaging fastener, fixing plate having in the plurality of openings, and is aligned with the longitudinal axis is only one, and a proximal portion. (

In the fixed plate 2) embodiment described in (1), and a wing on the opposite sides of the pair was laterally offset from the longitudinal axis, each of said proximal portion, near the plurality of the wing has one of the opening position, the fixed plate. (

In the fixed plate 3) of embodiment (2), wherein the proximal portion further includes a central region located in the wings between, is the central region, at least one of the proximal opening of said plurality and defines a fixed plate. (

In the fixed plate 4) of embodiment (3) above, to define three of the proximal opening of said plurality, the central region, the fixed plate. (

In the fixed plate 5) of embodiment (4) above, all, are offset relative to each other along an axis parallel to the longitudinal axis of the proximal opening, the fixed plate. (

In the fixed plate 6) of embodiment (5) above, which are all offset relative to each other along an axis perpendicular to the longitudinal axis of the proximal opening, the fixed plate.

In the fixing plate (7) of embodiment (1) above, to be provided on a surface of said proximal portion contacting the phalanx bone, the proximal portion corresponds approximately to the surface of the phalanx least has a curvature, the fixed plate. (

In the fixing plate 8) of embodiment (1) above, has a curvature away from the MTP joint along the longitudinal axis, the fixed plate, the fixed plate. (

In the fixing plate 9) of embodiment (1) above, some, a circumferential chamfer on the surface of the fixing plate opposite the MTP joint, at least the distal opening and the proximal opening and a fixing plate. (

In the fixed plate 10) embodiment (1), wherein, further comprises an intermediate portion coupled to the distal portion of the proximal portion, the intermediate portion, an opening for receiving in inserted condition the bone engaging fastener is not provided, the fixed plate. (

In the fixed plate 11) embodiment (10) above, is bent at the intermediate portion to form a dorsiflexion predetermined, the fixed plate, the fixed plate.

Is a plan view of the metatarsophalangeal joint of the fixed plate according to an embodiment of the present invention is mounted.

Is a plan view and a flat pattern of the fixed plate shown in FIG.

Is a bottom view of the fixation plate shown in FIG 1, and shows the curvature of the bone engaging surface of the fixed plate in particular.

Is a longitudinal sectional view, as seen in the direction of the arrows along line 4-4 of the fixed plate shown in FIG 3.

Is an end view of the fixed plate shown in FIG 3.

14 proximal end 16 intermediate bone engaging surface portion 18 upper surface 19 22 24 hole chamfer 30, 34, 32,36,40,42,44 wing screw hole 38 central region 10 fixed plate 12 distal end

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CLAIMS JP2006280951

(1).

In the fixed plate for the healing (MTP) joints in the toe section between the phalanges and the metatarsals, and an elongate distal portion which is shaped to be attached to the metatarsal the middle, and distal Cry portion, and defines a distal opening of at least one along the longitudinal axis passing through the distal portion, the distal one opening is shaped to receive in the inserted condition the bone engaging fastener and said at least A proximal portion defining is, the proximal opening of the plurality of the distal portion, and optionally linked to the distal portion, shaped to receive in the inserted condition the bone engaging fastener, said plurality fixing plate having in the opening of, and aligned with the longitudinal axis is only one, and a proximal portion.

(2).

In the fixed plate according to claim 1, further comprising a wing on the opposite sides of a pair that is offset laterally from the longitudinal axis, respectively, the proximal portion of the proximal opening of said plurality of said wings with one of the options, fixed plate.

(3).

In the fixed plate according to claim 2, wherein the proximal portion further comprises a central region located in the wings between, the central region, define at least one of the proximal opening of said plurality are, fixed plate.

(4).

In the fixed plate according to claim 3, defining three of the proximal opening of said plurality, the central region, the fixed plate.

(5).

In the fixed plate according to claim 4, which are all offset relative to each other along an axis parallel to the longitudinal axis of the proximal opening, the fixed plate.

(6).

In the fixed plate according to claim 5, which are all offset relative to each other along an axis perpendicular to the longitudinal axis of the proximal opening, the fixed plate.

(7).

In the fixed plate according to claim 1, is provided on a surface of said proximal portion contacting the phalanx bone, the proximal portion includes a curvature substantially corresponding to the surface of the phalanx least , fixed plate.

(8).

In the fixed plate according to claim 1, which comprises a curvature away from the MTP joint along the longitudinal axis, the fixed plate, the fixed plate.

(9).

In the fixed plate according to claim 1, having a circumferential chamfer on the surface of the fixing plate opposite the MTP joint, some fixing plate, at least one of the distal opening and the proximal opening .

(10).

In the fixed plate according to claim 1, further comprising an intermediate portion connected to the distal portion of the proximal portion, the intermediate portion is not provided with an opening for receiving in inserted condition the bone engaging fastener, fixed plate.

Electronic Patent Application Fee Transmittal

Application Number:

Filing Date:

Title of Invention:

FIXATION PLATE FOR USE IN THE LAPIDUS APPROACH

First Named Inventor/Applicant Name:

Neal Blitz

Filer:

Matthew S. Dushek

Attorney Docket Number:

24004350-304505

Filed as Large Entity

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Utility application filing	1011	1	280	280
Utility Search Fee	1111	1	600	600
Utility Examination Fee	1311	1	720	720

Pages:

Claims:

Claims in Excess of 20	1202	1	80	80
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Miscellaneous-Filing:

Petition:

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
Total in USD (\$)				1680

Electronic Acknowledgement Receipt

EFS ID:	20077292
Application Number:	14480309
International Application Number:	
Confirmation Number:	9464
Title of Invention:	FIXATION PLATE FOR USE IN THE LAPIDUS APPROACH
First Named Inventor/Applicant Name:	Neal Blitz
Customer Number:	23562
Filer:	Matthew S. Dushek
Filer Authorized By:	
Attorney Docket Number:	24004350-304505
Receipt Date:	08-SEP-2014
Filing Date:	
Time Stamp:	18:13:21
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	\$ 1680
RAM confirmation Number	5285
Deposit Account	130480
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Application Data Sheet	24004350_304505_ADS.pdf	1561044 b26d281481612d884181e40993787ed5148dc7ff	no	7

Warnings:

Information:

2		24004350_304505_Specification.pdf	1731399 07834b0696f1807fa0472ed09a217a6695564214	yes	23
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Multipart Description/PDF files in .zip description

Document Description	Start	End
Specification	1	17
Claims	18	22
Abstract	23	23

Warnings:

Information:

3	Drawings-only black and white line drawings	24004350_304505_Drawings.pdf	808449 767cc7480d3ae8266d8551f6ebd40d18b67e6404	no	8
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Warnings:

Information:

4		24004350_304505_Preliminary_Amendment.pdf	19792 bacb41508d7131d7120b9569891c6dca9cc9bdf	yes	3
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Multipart Description/PDF files in .zip description

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

Warnings:

Information:

5	Information Disclosure Statement (IDS) Form (SB08)	24004350_304505_IDS.pdf	613077	no	6
			a654c4693164a5b8c7f9e718df90b8d73475dc5		
Warnings:					
Information:					
6	Other Reference-Patent/App/Search documents	AU_Examination_Report_20140321.pdf	220719	no	3
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Warnings:					
Information:					
7	Other Reference-Patent/App/Search documents	EESR_09828045_6_20120224.pdf	457757	no	10
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Warnings:					
Information:					
8	Other Reference-Patent/App/Search documents	EPO_Official_Action_110613.pdf	198111	no	5
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Warnings:					
Information:					
9	Foreign Reference	FR2905590A1_PTO.pdf	2450926	no	44
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Warnings:					
Information:					
10	Other Reference-Patent/App/Search documents	ISR_PCTUS2009064150.pdf	195504	no	2
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Warnings:					
Information:					
11	Other Reference-Patent/App/Search documents	JP2011_537509_OfficeAction.pdf	179769	no	6
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Warnings:					
Information:					
12	Foreign Reference	JP2006280949A.pdf	835121	no	28
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Warnings:					
Information:					
13	Foreign Reference	JP2006280951A.pdf	819100	no	26
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Warnings:					
Information:					
Page 195 of 236					

14	Non Patent Literature	NPL_MORTON_Human_Foot.pdf	543608 17cb5c4a44d2c066f2a5aef05cb4aa4d276b0f60	no	1
Warnings:					
Information:					
15	Other Reference-Patent/App/Search documents	OFFICIAL_ACTION_051012_PT O.pdf	318664 8f666a4f497be0b6a60eb32e3b762886432c34dc	no	5
Warnings:					
Information:					
16	Fee Worksheet (SB06)	fee-info.pdf	36807 2acc9a3537aa5c48b4a7b73533b14fcd9bfe68f	no	2
Warnings:					
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Total Files Size (in bytes):			10989847		
This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503. <u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application. <u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course. <u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.					

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Application Data Sheet 37 CFR 1.76		Attorney Docket Number	24004350-304505
		Application Number	
Title of Invention	FIXATION PLATE FOR USE IN THE LAPIDUS APPROACH		
The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76. This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application.			

Secrecy Order 37 CFR 5.2

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

Inventor 1					Remove	
Legal Name						
Prefix	Given Name	Middle Name	Family Name	Suffix		
	Neal		Blitz			
Residence Information (Select One) ☒ US Residency ☐ Non US Residency ☐ Active US Military Service						
City	New York	State/Province	NY	Country of Residence i	US	

Mailing Address of Inventor:

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Address 2	Suite 1300					
City	Wilmington	State/Province	DE			
Postal Code	19899	Country i	US			

Inventor 2					Remove	
Legal Name						
Prefix	Given Name	Middle Name	Family Name	Suffix		
	Michael		George			
Residence Information (Select One) ☒ US Residency ☐ Non US Residency ☐ Active US Military Service						
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Mailing Address of Inventor:

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Address 2	Suite 1300					
City	Wilmington	State/Province	DE			
Postal Code	19899	Country i	US			

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

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Correspondence Information:

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For further information see 37 CFR 1.33(a).

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	24004350-304505
		Application Number	
Title of Invention	FIXATION PLATE FOR USE IN THE LAPIDUS APPROACH		

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

Customer Number	23562		
Email Address	docket@bakermckenzie.com	Add Email	Remove Email

Application Information:

Title of the Invention	FIXATION PLATE FOR USE IN THE LAPIDUS APPROACH		
Attorney Docket Number	24004350-304505	Small Entity Status Claimed	☐
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)	8	Suggested Figure for Publication (if any)	

Filing By Reference :

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

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

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

Publication Information:

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

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

Representative Information:

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

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Customer Number	23562		

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	24004350-304505
		Application Number	
Title of Invention	FIXATION PLATE FOR USE IN THE LAPIDUS APPROACH		

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This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, or 365(c) or indicate National Stage entry from a PCT application. Providing this information in the application data sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78.

When referring to the current application, please leave the application number blank.

Prior Application Status	Pending	Remove	
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
	Continuation of	12274199	2008-11-19
Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the Add button.			Add

Foreign Priority Information:

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

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Application Number	Country ⁱ	Filing Date (YYYY-MM-DD)	Access Code ^j (if applicable)
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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.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	24004350-304505
		Application Number	
Title of Invention	FIXATION PLATE FOR USE IN THE LAPIDUS APPROACH		

Authorization to Permit Access:

☒ Authorization to Permit Access to the Instant Application by the Participating Offices

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In accordance with 37 CFR 1.14(h)(3), access will be provided to a copy of the instant patent application with respect to: 1) the instant patent application-as-filed; 2) any foreign application to which the instant patent application claims priority under 35 U.S.C. 119(a)-(d) if a copy of the foreign application that satisfies the certified copy requirement of 37 CFR 1.55 has been filed in the instant patent application; and 3) any U.S. application-as-filed from which benefit is sought in the instant patent application.

In accordance with 37 CFR 1.14(c), access may be provided to information concerning the date of filing this Authorization.

Applicant Information:

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

Applicant 1

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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 AMEI TECHNOLOGIES, INC.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	24004350-304505
		Application Number	
Title of Invention	FIXATION PLATE FOR USE IN THE LAPIDUS APPROACH		

Mailing Address Information:			
Address 1	1105 North Market Street		
Address 2	Suite 1300		
City	Wilmington	State/Province	DE
Country i	US	Postal Code	19899
Phone Number		Fax Number	
Email Address			
Additional Applicant Data may be generated within this form by selecting the Add button. Add			

Assignee Information including Non-Applicant Assignee Information:

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Assignee 1			
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Remove			
If the Assignee or Non-Applicant Assignee is an Organization check here. ☒			
Organization Name	AMEI TECHNOLOGIES, INC.		
Mailing Address Information For Assignee including Non-Applicant Assignee:			
Address 1	1105 North Market Street		
Address 2	Suite 1300		
City	Wilmington	State/Province	DE
Country i	US	Postal Code	19899
Phone Number		Fax Number	
Email Address			
Additional Assignee or Non-Applicant Assignee Data may be generated within this form by selecting the Add button. Add			

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NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications			
Signature	/Matthew S. Dushek/	Date (YYYY-MM-DD)	2014-09-08

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	24004350-304505		
		Application Number			
Title of Invention	FIXATION PLATE FOR USE IN THE LAPIDUS APPROACH				
First Name	Matthew S.	Last Name	Dushek	Registration Number	61921
Additional Signature may be generated within this form by selecting the Add button.					Add

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

TECHNICAL FIELD

[0001] The present disclosure generally relates to medical devices for use in correcting foot deformities, and methods for surgically installing such devices and correcting such deformities.

BACKGROUND

[0002] Bunions have long been one of the more common types of painful foot deformities. The technical name for this type of deformity is Hallux Abducto Valgus (HAV), which is generally described as a medial deviation of the first metatarsal accompanied by a lateral deviation and/or valgus rotation of the hallux (or “big toe”). The result effect is a subluxation of the big toe joint (or first metatarsophalangeal joint (MTPJ)) creating a boney prominence (or eminence) on the inside of the foot, near the base of the big toe. **Fig. 1A** illustrates the normal anatomical configuration of a left human foot, which includes the first metatarsal 10 that extends between the medial cuneiform 12 and the hallux 13. The first metatarsal 10 articulates with the medial cuneiform 12 at the first metatarsocuneiform joint 14 at its most proximal aspect; and is further connected to the hallux 13 at the metatarsophalangeal joint 15 at its most distal aspect. Located adjacent (lateral) to the first metatarsal 10 is the second metatarsal 16, which articulates with the intermediate cuneiform 17 at the second metatarsocuneiform joint 18. The joint between the medial cuneiform 12 and intermediate cuneiform 17 is

the intermetatarsocuneiform joint 18. The sesamoids 19 are located beneath (plantar to) the first metatarsal head at the first MTPJ, and articulates with the head of the first metatarsal.

[0003] **FIG. 1B** illustrates the resulting anatomical configuration of a human foot experiencing HAV. In particular, the first metatarsal 10 extends from the medial cuneiform 12 and deviates medially while the hallux 13 deviates laterally. As a result, the sesamoids 19 may rotate with the first metatarsal 10. This condition may lead to painful motion of the big toe joint and/or difficulty fitting footwear. Other conditions associated with HAV may include: hammer toe formation of the adjacent toes, forefoot pain on the ball of the foot (aka metatarsalgia), stress fractures of the adjacent metatarsals, flat feet (pes planus), and arthritis of the first MTPJ or midfoot.

[0004] Bunions may occur from a variety of causes, such as genetic factors, gender influences, biomechanical and structural causes, trauma (injury), and certain shoes. Some physicians believe genetics play a large role in the development of bunions. Dudley Morton suggested that bunions may be a result of evolutionary influence, and described a certain foot type that is associated with bunions – the so called Morton’s foot (a condition where the first metatarsal is shorter than the other metatarsals. *See Morton DJ. The Human Foot: Its evolution, Physiology and functional Disorders. Columbia University Press, Morningside Heights, NY, 1935.* Some people develop bunions when associated with a condition called hypermobility, where the midfoot (i.e., metatarsocuneiform joint or “MCJ,” illustrated in Fig. 1A as the joint defined at the meeting of the metatarsal 10 and the cuneiform 12) exhibits excessive

motion. Less commonly, malshaped bones (hallux and/or first metatarsal) may give the appearance of and/or cause bunions. Many physicians attribute the progressive development of bunions to high heel and pointy toe shoes more commonly worn by women. It is well known that women are more likely to develop bunions than men.

[0005] Surgeons use weightbearing radiographs to determine the severity of HAV in an attempt to quantify the deformity, and aid in surgical decision making. The most commonly utilized radiographic measurement is the intermetatarsal angle (IMA), which measures the angle between a longitudinal bisection of the first and second metatarsal shafts. The IMA essentially measures the extent with which the first metatarsal has deviated (medially) from the second metatarsal. The normal value for the IMA is less than 8 degrees. Another useful radiographic measurement is the hallux abductus angle (HAA), which measures the amount of lateral deviation of the big toe (hallux). The HAA essentially measures the extent with which the hallux has deviated (laterally) from its native position (nearly rectus with the more proximal metatarsal). The normal value for the HAA is less than 12 degrees. A patient with a mild HAV deformity may have an IMA of 10-12 degrees and an HAA of 21-30 degrees. A patient with a moderate HAV deformity may have an IMA of 12-16 degrees and an HAA of 31-40 degrees. A patient with a severe HAV deformity may have an IMA of greater than 16 degrees and an HAA of greater than 40 degrees.

[0006] Various techniques have been developed to surgically correct HAV. The most basic technique simply involves resecting any enlarged bone at the medial aspect of the first metatarsal head, but this approach is typically used in conjunction

with other more advanced techniques. A common technique involves an osteotomy (bone cut) procedure in which the first metatarsal is broken into two pieces and the distal portion of the bone is translated closer (medially) to the adjacent second metatarsal. The osteotomy may be performed at several locations on the first metatarsal, depending on the severity of the deformity. Less severe HAV deformities are typically corrected with an osteotomy near the head (10a in Fig. 1) of the first metatarsal, whereas moderate and larger deformities are corrected with an osteotomy near the base (10b in Fig. 1) of the first metatarsal. Whichever osteotomy technique is utilized, only the distal portion of the first metatarsal is relocated into a more lateral position while the proximal segment position remains unchanged. It should be understood that any osteotomy procedure reorients the first metatarsal by changing its shape from that of a straight bone to a more curved bone.

[0007] Alternative techniques have been developed that do not require breaking of the bone, or changing the natural shape of the first metatarsal. One such technique calls for fusion of the MCJ, wherein the entire first metatarsal is relocated into a corrected position. This approach was originally developed by Dr. Paul Lapidus, and hence this particular technique is often referred to as the Lapidus approach (or Lapidus Bunionectomy or Lapidus Arthrodesis or Modified Lapidus Bunionectomy/Arthrodesis). In some situations the procedure may involve an isolated fusion of the 1st MCJ, and in other situations surgeons may also incorporate a fusion of the intermediate cuneiform area and or 2nd metatarsal base. In general, the idea behind the Lapidus approach is to permanently fuse the base of the first metatarsal to the

medial cuneiform bone in a corrected new position. This permanent fixation is carried out by first reducing the IMA and then fusing the MCJ. Implementation of this approach often involves the use of a number of screws across the joint or a plate that can accommodate screws to attach the plate to the metatarsal and medial cuneiform. In some cases, a fusion of the 1st MCJ that incorporates lengthening of the entire segment by adding bone graft (i.e., a block of bone) into the fusion site is better termed a distraction Lapidus.

BRIEF SUMMARY

[0008] The present disclosure generally relates to an improved fixation or “Lapidus” plate for use in treating HAV deformities or other conditions that may call for a fusion of this joint and possibly concomitant fusion incorporating the 2nd metatarsal base and/or intermediate cuneiform. The term “Lapidus” as used herein is only meant to be descriptive in terms of a suggested use for the plate and does not confer any structural limitations on the plate described herein. In one exemplary embodiment, the Lapidus plate is used for joint arthrodesis at the first MCJ. The Lapidus plate according to the present disclosure provides mechanical stability of the first metatarsal while also accommodating and assisting reorientation of the first metatarsal to correct the HAV deformity. In one embodiment, the plate is generally elongated and comprises a thin and rigid stabilizing member of biocompatible material. The orientation of the fixation plate offers multiplanar stability including the plantar aspects of the joint to resist tensile forces transmitted across the fusion site. The screw configuration of the plate can be maintained for several different sizes of the plate

while still maintaining desired multiplanar stability. Also, the positioning of the screw holes are designed to avoid invasion of the fusion site by the screws that ultimately pass therethrough. Indeed, the screw angles are designed for the post-Lapidus position.

[0009] The Lapidus plate according to the present disclosure includes additional features that accommodate the desired reorientation of the first metatarsal during correction. For example, the Lapidus plate described herein includes a degree of twist along its longitudinal axis to follow the contour of the first metatarsal and medial cuneiform, thereby facilitating reorientation of the first metatarsal to its natural position. The Lapidus plate is further anatomically configured to include a recess, which accommodates the natural crests of the medial cuneiform and the first metatarsal. In this manner, the first metatarsal can be guided against the medial cuneiform and the plate such that the base of the first metatarsal fits within the recess. The recess thus facilitates a desired location and orientation of the first metatarsal that approximates its natural position. In this manner, the Lapidus plate according to the present disclosure accommodates the final position of the fusion of the MCJ. The fixation plate is anatomically configured to provide rigid support of the realigned MCJ fusion site while positioning screws to avoid invasion into the fusion site thus achieving desired stability. It is to be appreciated that the plate described herein can be adapted for use on both right and left feet with a right foot plate being a mirror-image of a left foot plate.

[0010] A surgical method for preparing the MCJ for receipt of the Lapidus plate and subsequently implanting the plate is further described. In patients with HAV, surgical procedures may be concomitantly performed near the first metatarsal head. A

capsular release of the first MTPJ and resection of the medial eminence, if present, is often performed in conjunction with release of the adductor tendon and lateral sesamoidal ligament. Next, all cartilage is removed from the first MCJ with either a reciprocal saw and/or manual resection. Removal of the cartilage is preferred to allow for bone on bone contact to allow for a fusion between the medial cuneiform and first metatarsal. The first metatarsal is then repositioned back to its native position (IMA as close to zero as possible). However, in order to compensate for the shortening that occurs with removal of the cartilage of the first MCJ, the first metatarsal must be translated inferiorly and/or angulated inferiorly (plantarflexed) to restore the weightbearing mechanics of the first metatarsal head at the ball of the foot. Lastly, the fusion site is stabilized with the fixation plate described herein. In some embodiments, the plate is placed on the dorsal medial surface of the segment to avoid contact with muscular attachments.

BRIEF DESCRIPTION OF THE DRAWINGS

[0011] Reference is now made to the following descriptions taken in conjunction with the accompanying drawings.

[0012] FIGURE 1A illustrates a top view of a human foot;

[0013] FIGURE 1B illustrates a top view of a human foot experiencing the condition of Hallux Valgus;

[0014] FIGURE 2 illustrates a top view of a fixation plate according to one embodiment of the present disclosure;

[0015] FIGURE 3A illustrates a side view of the fixation plate of Figure 2;

[0016] FIGURE 3B illustrates a side view of the fixation plate of Figure 2 positioned adjacent to the MCJ;

[0017] FIGURE 4 illustrates a schematic view depicting the gradual twist of the fixation plate of Figure 2;

[0018] FIGURE 5A illustrates a perspective view of the fixation plate of Figure 2 positioned against the medial cuneiform and first metatarsal;

[0019] FIGURE 5B illustrates another perspective view of the fixation plate of Figure 2 positioned against the medial cuneiform and first metatarsal;

[0020] FIGURE 6 illustrates a top view of the fixation plate of Figure 2 affixed to the medial cuneiform and first metatarsal;

[0021] FIGURE 7 is a bottom perspective view of the fixation plate of Figure 6 showing the orientation of the screws; and

[0022] FIGURE 8 is a perspective view of another embodiment of the fixation plate wherein the plate is a distraction plate.

DETAILED DESCRIPTION

[0023] Various aspects of a Lapidus plate and methods of using same according to the present disclosure are described. It is to be understood, however, that the following explanation is merely exemplary in describing the devices and methods of

the present disclosure. Accordingly, several modifications, changes and substitutions are contemplated.

[0024] A Lapidus plate 20 for a human left foot according to the present disclosure is illustrated in Fig. 2. It is to be appreciated that a Lapidus plate according to the present disclosure for a human right foot would be substantially similar to and have a mirror image configuration of the plate 20 illustrated in Fig. 2. The plate 20 generally comprises a distal portion 22 for attachment to a metatarsal and a proximal portion 24 for attachment to a cuneiform. For purposes of illustration only, the distal and proximal portions 22, 24 are divided along a joint axis (J) generally corresponding to the fusion site (i.e., the interface between the cuneiform and metatarsal) as will be described. In one exemplary embodiment, the metatarsal is the first metatarsal 10 (Fig. 1) and the cuneiform is the medial cuneiform (Fig. 1). The plate 20 is sized and shaped to conform to the anatomical contours of the first MCJ and as such the distal portion 22 includes a relatively narrow and rounded end portion 26. The distal portion gradually increases in width along a first side 28 of the plate towards the proximal portion 24. The proximal portion 24 includes a slight gradual increase in width along the first side 28 of the plate 20 culminating in a rounded end portion 30 that is larger in width than the end portion 26 of the proximal portion 22. The plate 20 further includes a substantially linear second side 32 opposite the first side 28.

[0025] The plate is configured and designed to avoid tendon and minimize soft tissue irritation, while also providing for optimal rigidity and stability. As such, in some embodiments, the end portion 26 of the distal portion 22 has an anatomically

optimal width W_1 in the range of 10.5 +/- 3mm, while the end portion 30 of the proximal portion 24 has an anatomically optimal width W_2 in the range of 16 +/- 4mm. In some embodiments, the plate has a varying thickness of between 0.75mm and 3.0mm, thus minimizing tissue irritation. Moreover, the edges of the plate may be tapered. In one embodiment, the Lapidus plate according to the present disclosure is sized and shaped for placement in a “safe zone” of the area to be treated; that is, the place on the dorsal medial surface of the first metatarsal and medial cuneiform that is devoid of tendon attachments. It is to be appreciated that the Lapidus plate according to the present disclosure may have a configuration different than that described herein so long as the plate accommodates the contours of the particular anatomical region being treated.

[0026] The distal and proximal portions 22, 24 of the plate 20 each include a plurality of screw holes formed therethrough to facilitate attachment of the plate to the respective metatarsal and cuneiform. In one embodiment, the distal portion 22 includes four screw holes formed through the plate 20 with two holes 40, 42 being positioned in proximity to the joint axis J and the remaining two holes 44, 46 being positioned distal of holes 40, 42. In some embodiments, the holes 40, 42 and 46 are countersunk and threaded to accommodate screws having threaded heads as will be described. Hole 40 is positioned adjacent to the second side 32 and the joint axis J while hole 42 is positioned distal of hole 40 and closer to side 28 of the plate 20. Hole 44 is positioned distally of holes 40, 42 and is generally elongated to accommodate movement of the plate 20 as will be described. The elongated nature of hole 44 defines a pair of

substantially parallel sides 47, 49, which are substantially parallel to second side 32 of the plate 20. Hole 46 is positioned distal of hole 44 and also accommodates a screw (not shown) to assist with fixation of the plate 20 to the metatarsal. The location of hole 46 assists with distributing weight away from the fusion site.

[0027] Similar to the distal portion 22 of the plate 20, the proximal portion 24 includes a plurality of screw holes to accommodate fixation. In one embodiment, the proximal portion 24 of the plate 20 includes three holes 48, 50 and 52 formed therethrough. In some embodiments, the holes 48, 50 and 52 are countersunk and threaded to accommodate screws having threaded heads as will be described. Hole 48 generally corresponds to hole 40 of the metatarsal portion, and as such, is positioned adjacent to the second side 32 and the joint axis J. Hole 50 generally corresponds to hole 42 of the metatarsal portion, and as such, is positioned proximal of hole 48 and closer to side 28 of the plate 20. Hole 52 is positioned proximal of holes 48, 50 and accommodates a screw (not shown) to assist with fixation of the plate 20 to the cuneiform bone. The location of hole 52 assists with distributing weight away from the fusion site.

[0028] In one embodiment, the holes 40, 42 of the distal portion 22 and the holes 48, 50 of the proximal portion are designed to assist with screw fixation into the widest part of both bone segments while maintaining a safe distance from the fusion site such that the screws that ultimately pass through such holes do not penetrate the fusion site. In this regard, the holes 40, 42, 48 and 50 form a substantially trapezoidal shape, which facilitates the even distribution of load across the MCJ. It is to be

appreciated that the arrangement of holes 40, 42, 48 and 50 may not form an exact trapezoid. For example, the line defined from the centerpoint of hole 40 to the centerpoint of hole 48 and the line defined from the centerpoint of hole 42 to the centerpoint of hole 50 may not be perfectly parallel. Rather, such lines may be only substantially parallel and thus the arrangement of holes 40, 42, 48 and 50 may form a substantially trapezoidal shape rather than a true trapezoidal shape. The substantially trapezoidal arrangement of the holes 40, 42, 48 and 50 define an angle θ measured between the non-parallel sides of the trapezoid (i.e., between the lines A_1 and A_2 shown for purposes of illustration in Fig. 2). Also, the distance between the dorsal screw holes 40, 48 is measured by the distance D. In some embodiments, the angle θ is optimally 57 ± 15 degrees and the distance between the dorsal screws 40, 48 is optimally 12 ± 4 mm.

[0029] Referring to **Figs. 3A and 3B**, the plate 20 according to the present disclosure further includes a recess 60 defined along a bone-contacting surface 62 of the plate. The recess 60 is generally defined at and adjacent to the joint axis J of the plate 20. In this manner, the plate 20 is designed to accommodate the crests of the first metatarsal 10 and medial cuneiform 12 upon placement of the plate against the MCJ as illustrated in Fig. 3B. In some embodiments, a channel 64 is formed laterally in the bone-contacting side of the plate 20 in a region generally corresponding to the recess 60 to facilitate additional flexibility at the fusion site along the joint axis J (Fig. 2). This flexibility assists the surgeon with bending of the plate 20 to achieve the desired final position of the plate at the fusion site.

[0030] In some HAV deformities, the first metatarsal experiences a lateral twist. As a result, the sesamoid bones are no longer in contact with the surface and are thus not able to carry most of the body load transferred through the forefoot during motion. This results in an extra load being placed on other adjacent metatarsals, thus increasing the possibility for metatarsalgia, or possibly stress fractures in those metatarsals. To correct this disorientation, in some embodiments, the plate 20 according to the present disclosure includes a degree of twist along its longitudinal axis (i.e., from end portion 30 to end portion 26 as shown in Fig. 2). Referring to **Fig. 4**, the plate 20 has a gradual twist γ from proximal portion 24 to distal portion 22. In some embodiments, the anatomically optimal twist is 12 +/- 6 degrees measured along the longitudinal axis of the plate 20 defined from end portion 30 to end portion 26.

[0031] In practice, the first MCJ is prepared for plate implantation by first performing a capsulotomy of the ligaments surrounding the first MCJ and then removing cartilage within this joint. Referring to **Figs. 5A, 5B and 6**, the proximal portion 24 of the plate 20 is placed against the medial cuneiform 12 and attached thereto using screws 70 having threaded heads and threaded shafts. The threaded heads of the screws 70 thread into the corresponding countersunk threaded holes 48, 50 and 52 (Fig. 2) such that the screws are fixed relative to the plate 20. It is to be appreciated that in some embodiments, the screws may have non-threaded heads such that the screws are not locked into place relative to the plate 20. Upon attachment of the plate 20 to the medial cuneiform 12, the first metatarsal 10 is translated inferiorly in the direction I as illustrated in Fig. 5B to maintain a natural distribution of ground force

over all the foot's sesamoid bones to avoid stress fracture or even breakage of the other four metatarsals. In some embodiments, the optimal amount of translation D_1 is 3 +/- 3mm to accommodate for the shortening that occurs when cartilage is removed from the joint. The first metatarsal 10 is also translated laterally and rotated in the direction R to return the metatarsal to its approximate natural anatomic orientation to reduce the intermetatarsal angle. The plate 20 according to the present disclosure is designed for placement against the medial cuneiform and first metatarsal in an area devoid of muscular and tendinous attachments.

[0032] Upon proper positioning of the first metatarsal 10, a screw (not shown) is placed through the elongated hole 44 and into the metatarsal with the elongation permitting movement of the bone. In some embodiments, the MCJ may be temporarily fixated in a corrected position using a k-wire. Also, the plate 20 may include k-wire holes such that k-wires can be used in conjunction with the plate to stabilize the first metatarsal for screw implantation. Upon stabilization, the first metatarsal 10 is then moved toward the medial cuneiform 12 whereupon the screw positioned through elongated hole 44 is tightened to compress the first MCJ. Once compression is achieved, the distal portion 22 of the plate 20 is further attached to the metatarsal using threaded screws 70 having threaded heads that are placed through screw holes 40, 42 and 46 (Fig. 2) and into the bone. The threaded heads of the screws 70 thread into the corresponding countersunk threaded holes 40, 42 and 46 such that the screws are fixed relative to the plate 20. It is to be appreciated that in some embodiments, the screws may have non-threaded heads such that the screws are not locked into place relative to

the plate 20. Once the plate is fixed to the medial cuneiform 12 and the first metatarsal 10, the screw passing through elongated hole 44 may be removed.

[0033] Referring to Fig. 7, the twist of the plate 20 along its longitudinal axis facilitates desired orientation of the screws into the metatarsal. More specifically, holes 40 and 42 are angled toward one another such that implantation of the screws 70 through these holes results in their axes crossing one another in a divergent manner. This, in turn, provides for optimal orientation of the screws 70 in the first metatarsal 10 to achieve desired stability.

[0034] A variation of the Lapidus plate according to the present disclosure involves providing for distraction (or lengthening) at the fusion site. As illustrated in Fig. 8, this allows for bone graft 80 to be interposed between the 1st metatarsal base 10b and the medial cuneiform 12, when the clinical situation arises. Providing for distraction at the fusion site maintains that the screw holes 40 and 42 purchase the 1st metatarsal base 10b, for which these holes are configured to provide maximal stability at the fusion site. The amount of distraction D' most commonly required is between 1mm – 25mm, with the distraction plate accommodating this length. It is to be appreciated, however, that other distraction lengths may be accommodated by the plate 20 of the present disclosure. In some embodiments, the plate 20 may add length by providing additional screw holes formed in distal portion 22 of the plate 20. In some embodiments, fixation of the plate may occur via a screw passing through the fusion site into the intermediate cuneiform and/or second metatarsal.

[0035] The Lapidus plate 20 described herein and associated method of implantation leads to fusion of the MCJ, which provides for mechanical stability of the first metatarsal and medial cuneiform and the reorientation to compensate for an HAV deformity. The orientation of the fixation achieved according to the principles of the present disclosure offers multiplanar stability including the plantar aspects of the MCJ to resist tensile forces across the fusion site. The screw configuration described herein can thus be maintained for several different sizes of distraction Lapidus arthrodesis. That is, the screw configuration provides multiplanar stability as distraction length is added to the plate 20.

[0036] While various embodiments of Lapidus plates and related methods of implanting such plates, have been described above, it should be understood that they have been presented by way of example only, and not limitation. Thus, the breadth and scope of the invention(s) should not be limited by any of the above-described exemplary embodiments, but should be defined only in accordance with the following claims and their equivalents. Moreover, the above advantages and features are provided in described embodiments, but shall not limit the application of the claims to processes and structures accomplishing any or all of the above advantages.

[0037] Additionally, the section headings herein are provided for consistency with the suggestions under 37 CFR 1.77 or otherwise to provide organizational cues. These headings shall not limit or characterize the invention(s) set out in any claims that may issue from this disclosure. Specifically and by way of example, although the headings refer to a "Technical Field," the claims should not be limited by the language

chosen under this heading to describe the so-called technical field. Further, a description of a technology in the “Background” is not to be construed as an admission that technology is prior art to any invention(s) in this disclosure. Neither is the “Brief Summary” to be considered as a characterization of the invention(s) set forth in the claims found herein. Furthermore, any reference in this disclosure to “invention” in the singular should not be used to argue that there is only a single point of novelty claimed in this disclosure. Multiple inventions may be set forth according to the limitations of the multiple claims associated with this disclosure, and the claims accordingly define the invention(s), and their equivalents, that are protected thereby. In all instances, the scope of the claims shall be considered on their own merits in light of the specification, but should not be constrained by the headings set forth herein.

What is claimed is:

1. A device, comprising:

a plate adapted for fixation across a metatarsocuneiform joint, the plate including
a joint axis defined to lie across the metatarsocuneiform joint,
an upper surface and a bone-contacting surface opposite to the upper surface, the
plate including a curvature directed towards the bone-contacting surface along a longitudinal
axis of the plate, and the plate including a bend about a second axis different from the
longitudinal axis and directed toward the bone-contacting surface,

a proximal portion adapted for fixation to a cuneiform, the proximal portion
including a first hole adjacent to the joint axis and a second hole proximal to the first hole, and

a distal portion adapted for fixation to a metatarsal, the distal portion including a
third hole adjacent to the joint axis and a fourth hole distal to the third hole, wherein

the proximal and distal portions are divided along the joint axis,

a first line segment is defined from a center of the first hole to a center of the second hole,

a second line segment is defined from the center of the second hole to a center of the third
hole,

a third line segment is defined from the center of the third hole to a center of the fourth
hole,

a fourth line segment is defined from the center of the fourth hole to the center of the first
hole, and

the first line segment, second line segment, third line segment and fourth line segment
define a substantially trapezoidal arrangement across the joint axis.

2. The device according to claim 1, wherein
the distal and proximal portions include end portions, and
the plate increases in width from the distal end portion to the proximal end portion.
3. The device according to claim 2, wherein the width of the distal end portion is 10.5 ± 3 millimeters.
4. The device according to claim 2, wherein the width of the proximal end portion is 16 ± 4 millimeters.
5. The device according to claim 1, further comprising a recess defined along the bone-contacting surface in a region corresponding to the joint axis of the plate.
6. The device according to claim 5, further comprising a channel formed in the recess to provide flexibility.
7. The device according to claim 1, wherein the plate has a gradual twist along a longitudinal axis defined from the proximal portion to the distal portion.
8. The device according to claim 7, wherein the plate twists approximately 12 ± 6 degrees along the longitudinal axis.

9. The device according to claim 1, wherein the holes are countersunk and threaded.
10. The device according to claim 1, further comprising another hole defined proximal of the first and second holes, the another hole being countersunk and threaded.
11. The device according to claim 10, further comprising two additional holes defined distal of the third and fourth holes, one of the two additional holes having an elongated configuration and the other of the two additional holes being countersunk and threaded.
12. The device according to claim 11, wherein the three countersunk holes in the proximal portion are oriented in a triangular arrangement and wherein the three countersunk holes in the distal portion are oriented in a triangular arrangement.
13. The device according to claim 1, wherein the plate accommodates a distraction length of 1 millimeter to 25 millimeters.
14. The device according to claim 1, wherein
 - the substantially trapezoidal arrangement defines substantially parallel sides and non-parallel sides,
 - the substantially non-parallel sides of the substantially trapezoidal arrangement define an angle θ between 42 degrees and 72 degrees, and
 - a distance D between the first hole of the proximal portion and the third hole of the distal portion is between 8 millimeters and 16 millimeters.

15. A method for fusing a metatarsocuneiform joint, comprising:
- positioning a fixation plate adjacent to a medial cuneiform, the plate having proximal and distal portions divided along a joint axis, the joint axis corresponding to the metatarsocuneiform joint and the plate further having a recess defined along a bone-contacting surface thereof,
- securing the plate to the cuneiform using three screws triangularly oriented through the plate;
- laterally and inferiorly translating and rotating a metatarsal such that an end of the metatarsal abuts the cuneiform and fits into the recess defined by the plate; and
- securing the plate to the metatarsal using three screws triangularly oriented through the plate.
16. A method according to claim 15, wherein the metatarsal is inferiorly translated a distance of $3+/-3$ mm.
17. A method according to claim 15, further comprising the step of compressing the metatarsocuneiform joint before securing the plate to the metatarsal.
18. A method according to claim 15, wherein the plate has a gradual twist from the proximal portion to the distal portion to match the contour of the metatarsal after rotation of the metatarsal.
19. A method according to claim 15, further comprising the step of securing the plate to a second metatarsal.

20. A method according to claim 15, further comprising the step of securing the plate to an intermediate cuneiform.

21. A method according to claim 15, wherein the fixation plate is designed for placement against an area of the medial cuneiform and first metatarsal that is devoid of muscular or tendinous attachments.

ABSTRACT OF THE DISCLOSURE

[0038] The present disclosure generally relates to fixation plates for use in correcting Hallux Valgus deformities under the Lapidus approach. The plate includes holes defined therethrough in such a way to facilitate multiplanar stability across the metatarsocuneiform joint. The plate is further sized and shaped to approximate the natural anatomic contour of the bone segments surrounding the metatarsocuneiform joint. Related methods for using the Lapidus approach to correct Hallux Valgus deformities are also described.

FIG. 1A

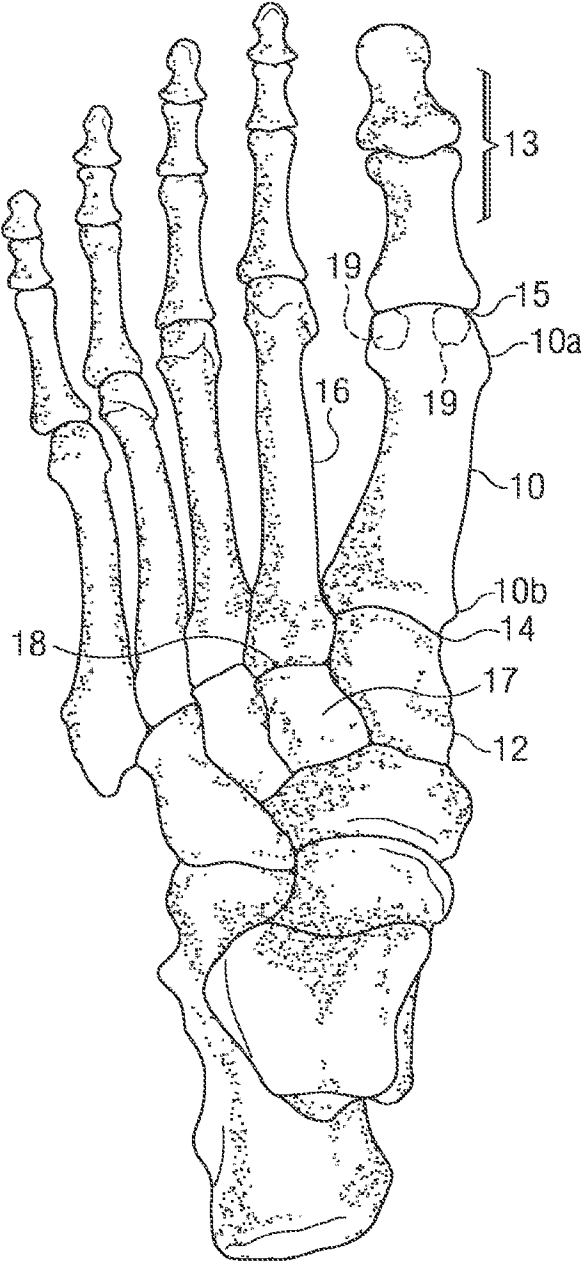
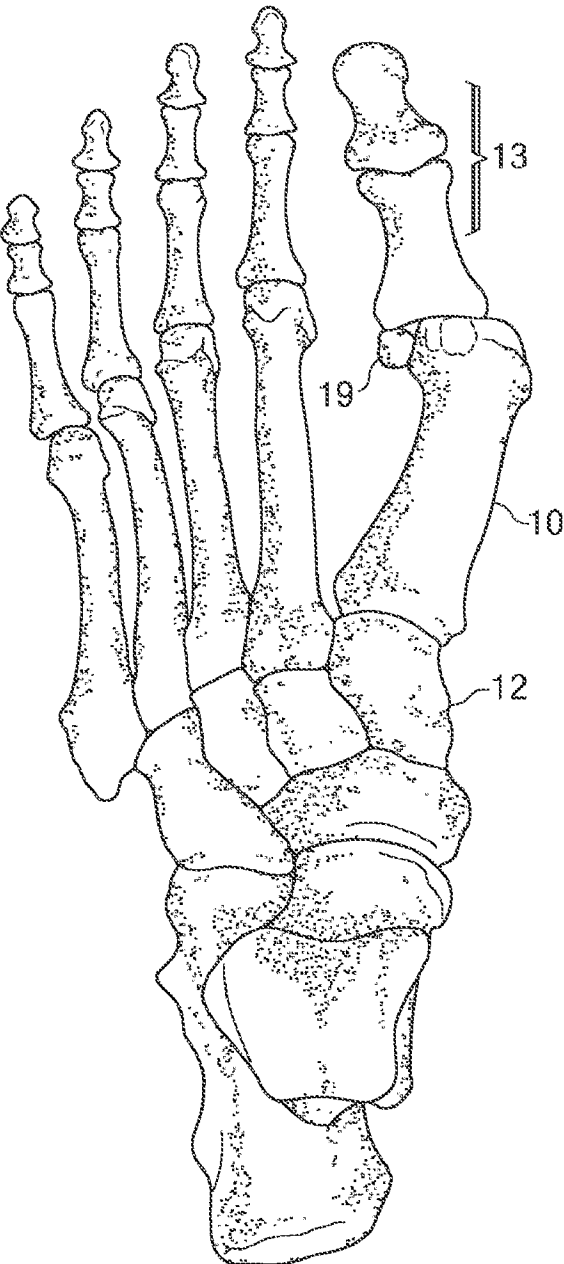


FIG. 1B



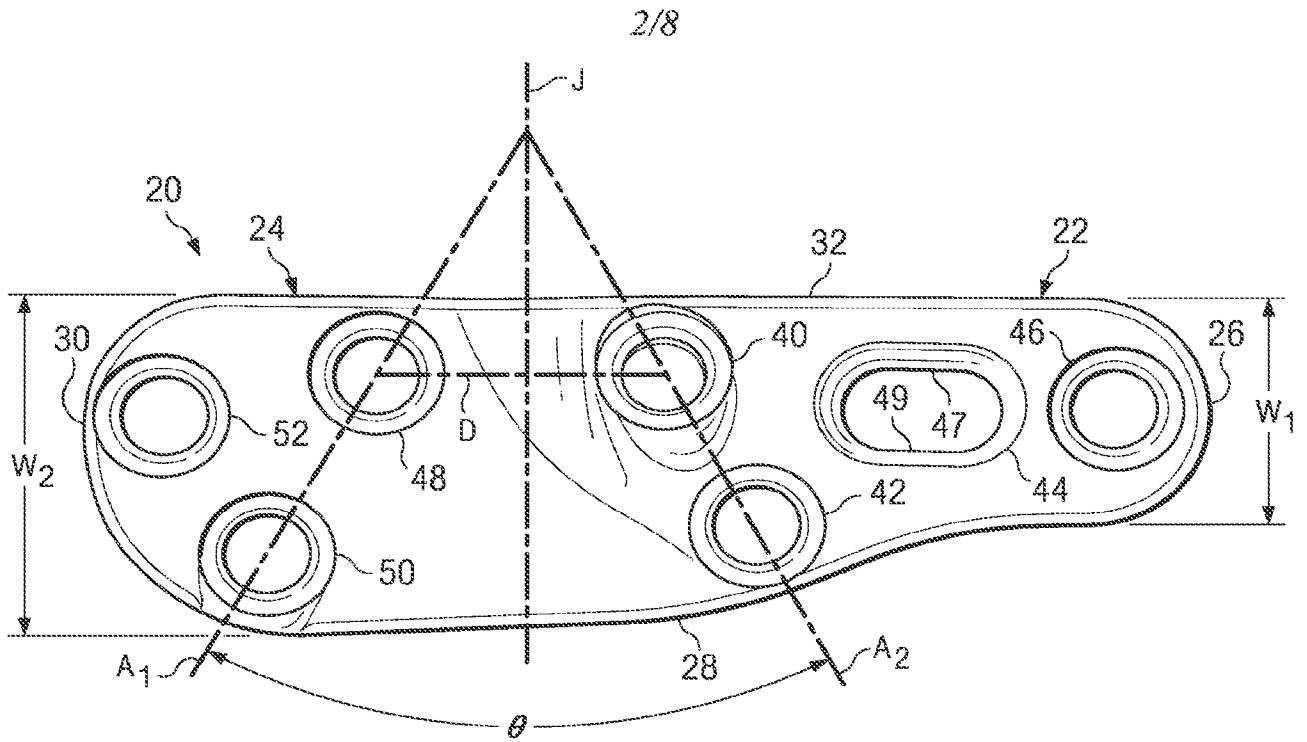


FIG. 2

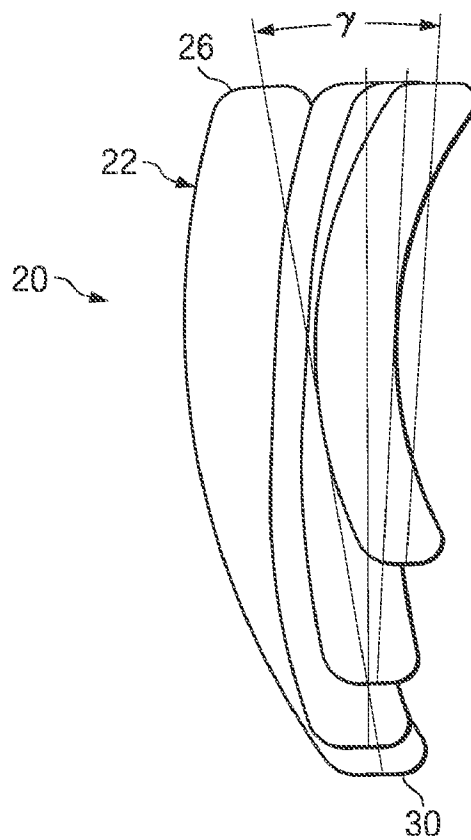
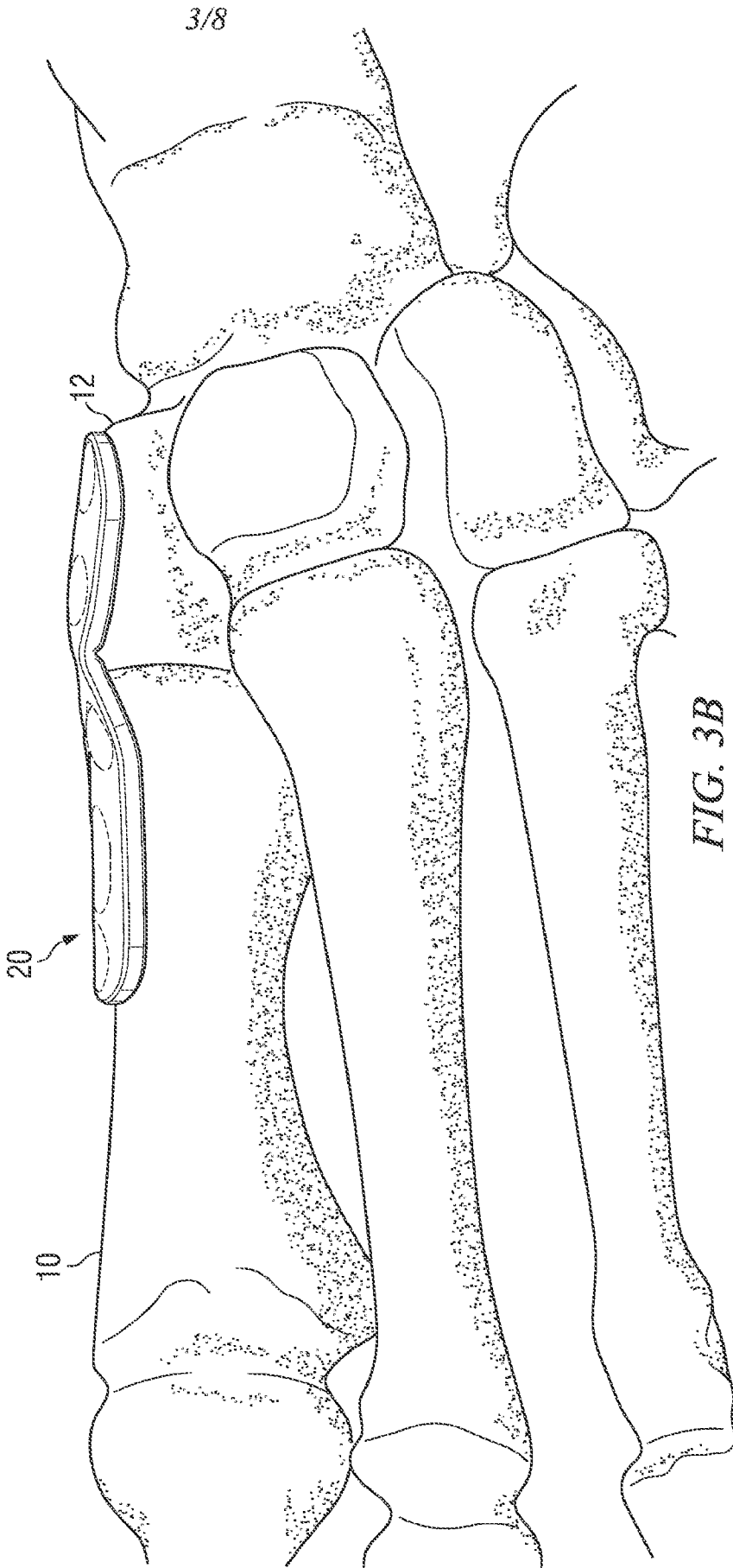
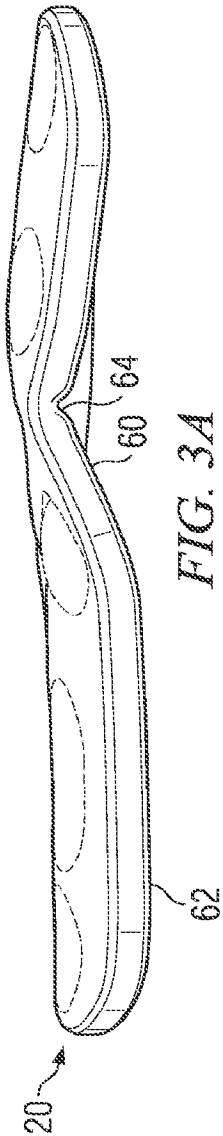


FIG. 4



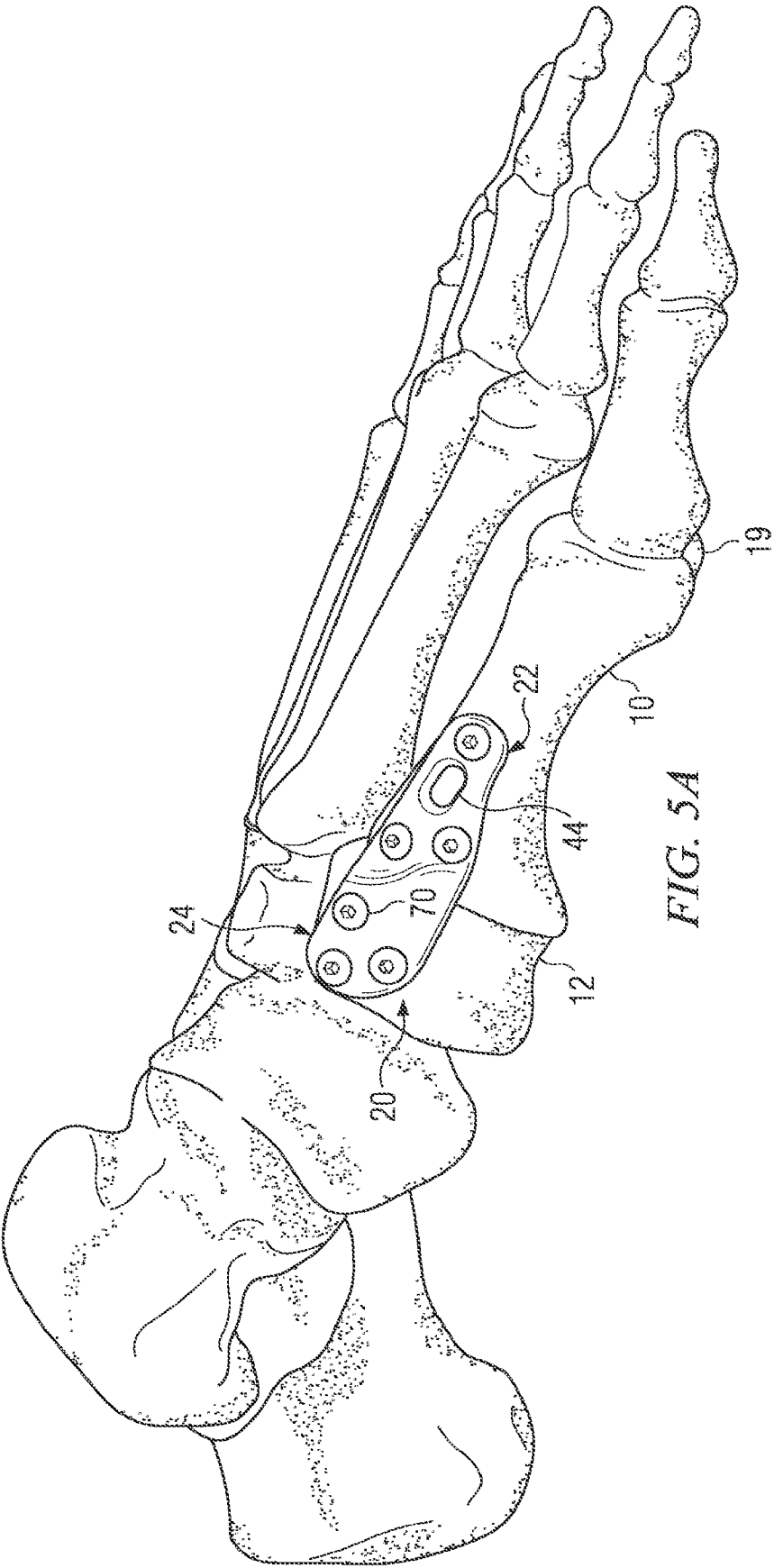
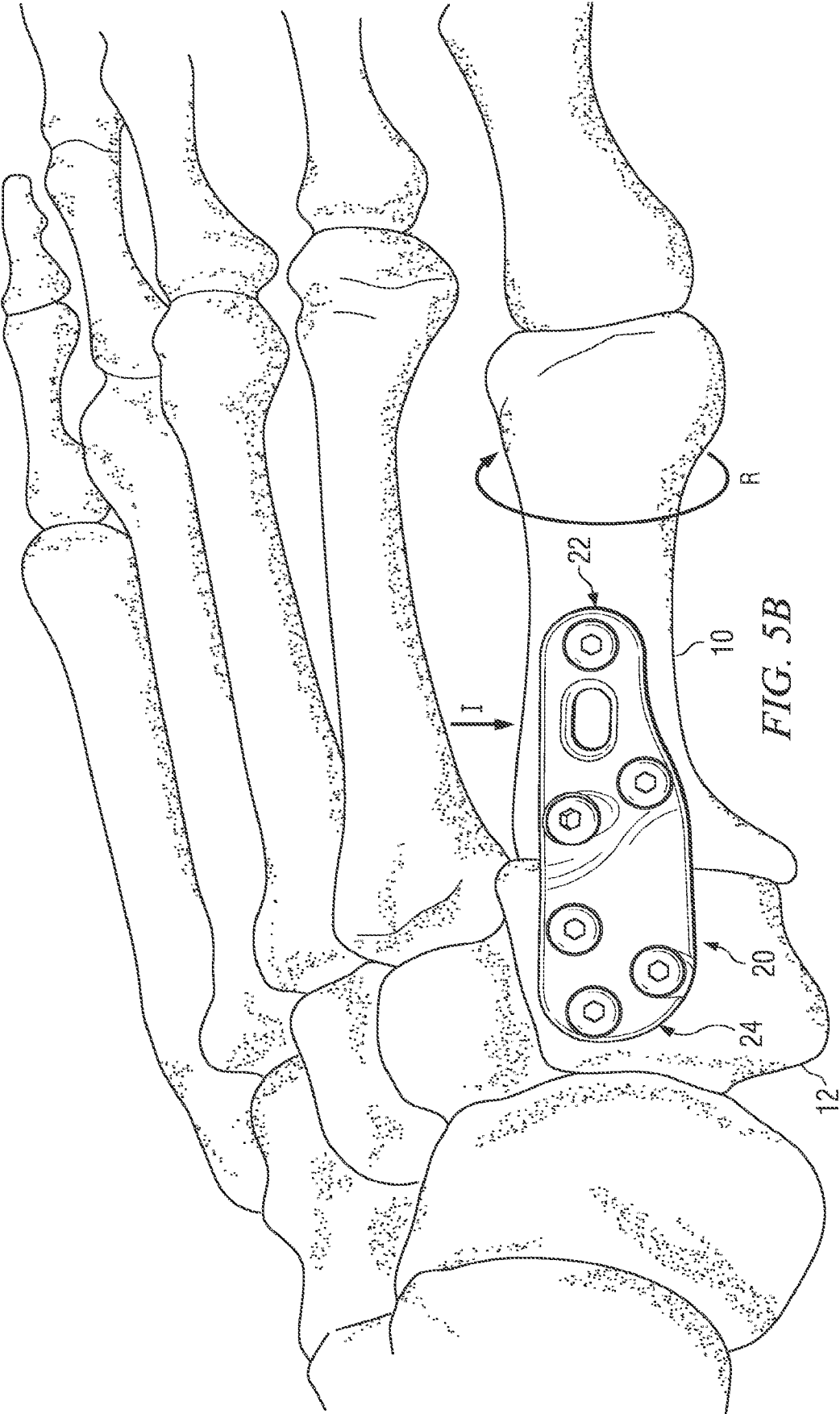
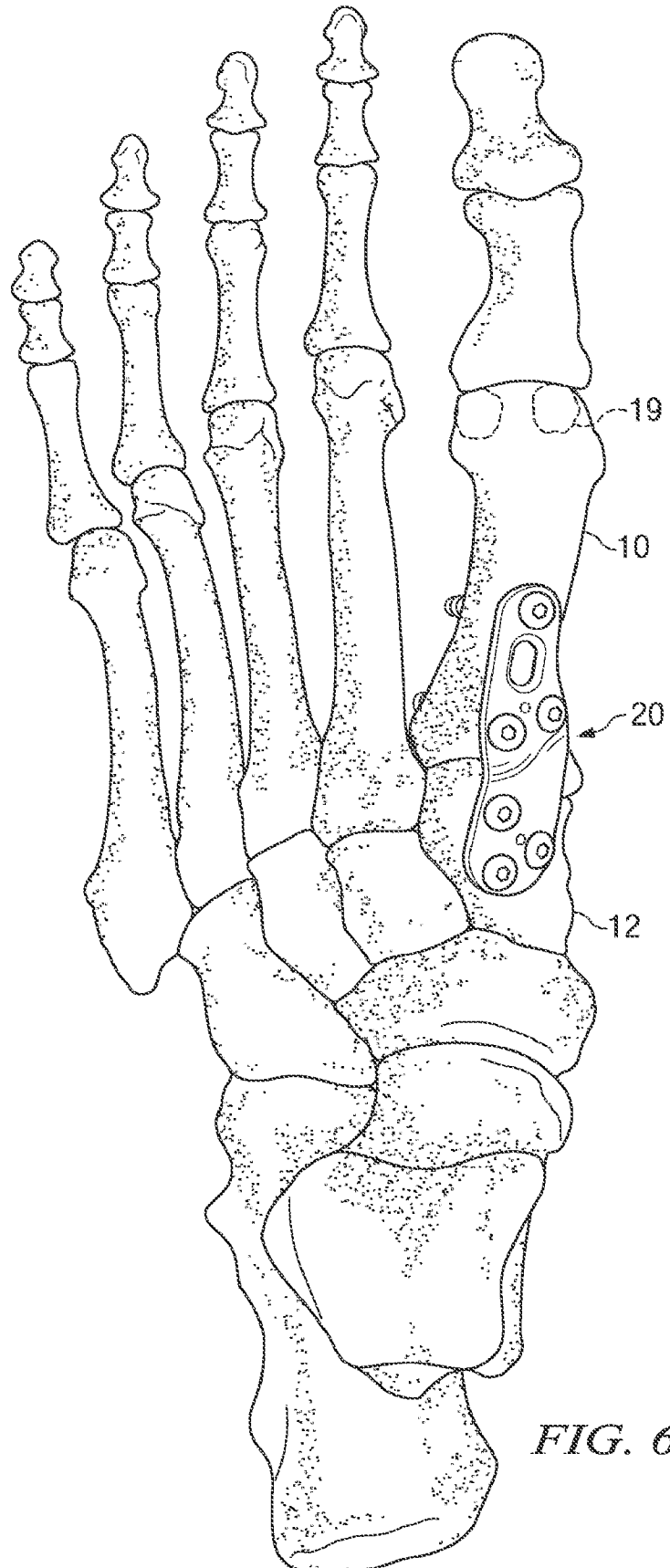


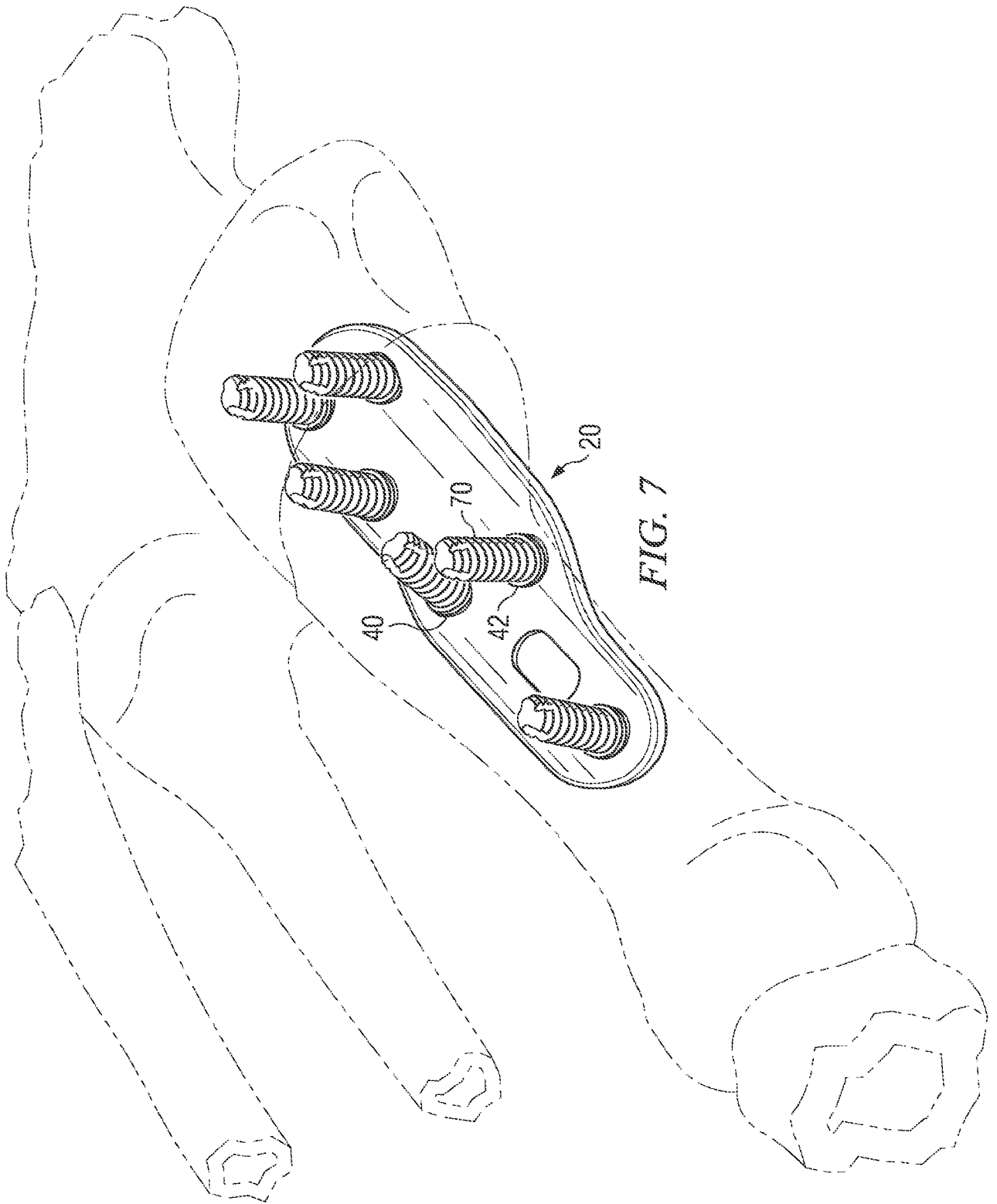
FIG. 5A



6/8



7/8



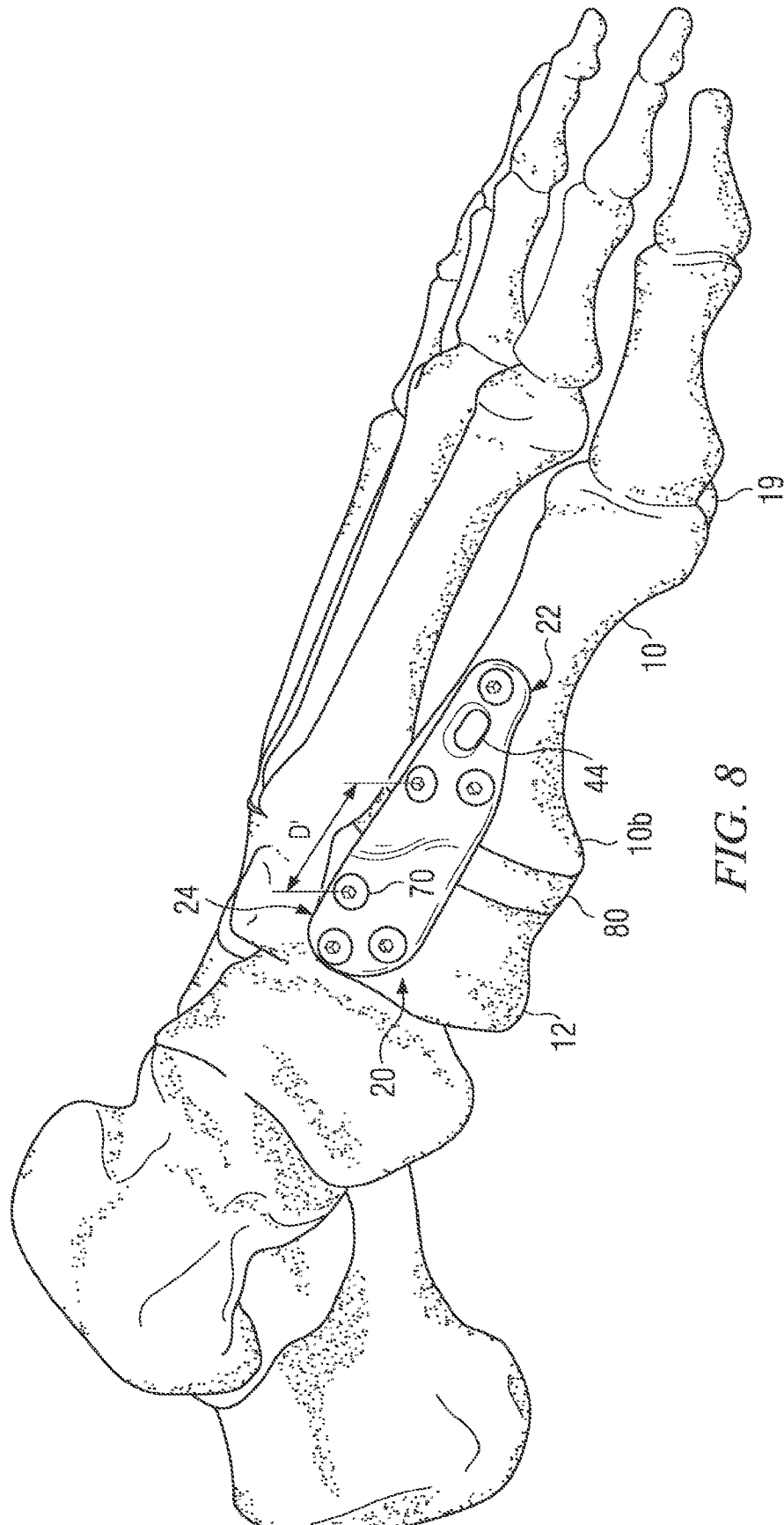


FIG. 8

Document code: WFEE

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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 14/480,309	Filing Date 09/08/2014	☐ To be Mailed
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 ENTITY: ☒ LARGE ☐ SMALL ☐ MICRO

APPLICATION AS FILED – PART I

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

APPLICATION AS AMENDED – PART II

AMENDMENT	(Column 1)	(Column 2)	(Column 3)	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)
	09/08/2014	CLAIMS REMAINING AFTER AMENDMENT					
	Total (37 CFR 1.16(i))	* 21	Minus	** 21	= 0	x \$80 =	0
	Independent (37 CFR 1.16(h))	* 2	Minus	***3	= 0	x \$420 =	0
	☐ Application Size Fee (37 CFR 1.16(s))						
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
TOTAL ADD'L FEE							0

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

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

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/BRENDA TURNER/

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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